Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tebentafusp (KIMMTRAK)

Immunocore Ireland Ltd.

Anhang 4 G: Ergänzende Unterlagen

(Kaplan-Meier-Kurven Subgruppenanalysen)

*Tebentafusp wird angewendet als Monotherapie bei der Behandlung von HLA (humanes Leukozyten-Antigen)-A*02:01-positiven erwachsenen Patienten mit inoperablem oder metastasiertem uvealem Melanom*

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Gefäßerkrankungen- Nicht-hispanisch 3382
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Erkrankungen der Atemwege, des Brustraums und Mediastinums- <65 3454
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ≥65 3455
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 0 3456
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 1 3457
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Erkrankungen der Atemwege, des Brustraums und Mediastinums- Keine Vorherige Therapie adjuvant/neoadjuvant 3463
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion ≤ 3cm .. 3464
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion 3,1-8,0 cm 3465
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Erkrankungen der Atemwege, des Brustraums und Mediastinums- Dacarbazin 3469
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Pembrolizumab 3470
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Ipilimumab 3471
Erkrankungen der Haut und des Unterhautgewebes- Gesamt 3472

Erkrankungen der Haut und des Unterhautgewebes- Hispanisch 3473
Erkrankungen der Haut und des Unterhautgewebes- Nicht-hispanisch 3474
Erkrankungen der Haut und des Unterhautgewebes- Männlich 3475
Erkrankungen der Haut und des Unterhautgewebes- Weiblich 3476
Erkrankungen der Haut und des Unterhautgewebes- <65 3477
Erkrankungen der Haut und des Unterhautgewebes- ≥65 3478
Erkrankungen der Haut und des Unterhautgewebes- ECOG 0 3479
Erkrankungen der Haut und des Unterhautgewebes- ECOG 1 3480
Erkrankungen der Haut und des Unterhautgewebes- ALP ≤ ULN 3481
Erkrankungen der Haut und des Unterhautgewebes- ALP > ULN 3482
Erkrankungen der Haut und des Unterhautgewebes- LDH =< ULN 3483
Erkrankungen der Haut und des Unterhautgewebes- LDH > ULN 3484
Erkrankungen der Haut und des Unterhautgewebes- Vorherige Therapie adjuvant/neoadjuvant 3485
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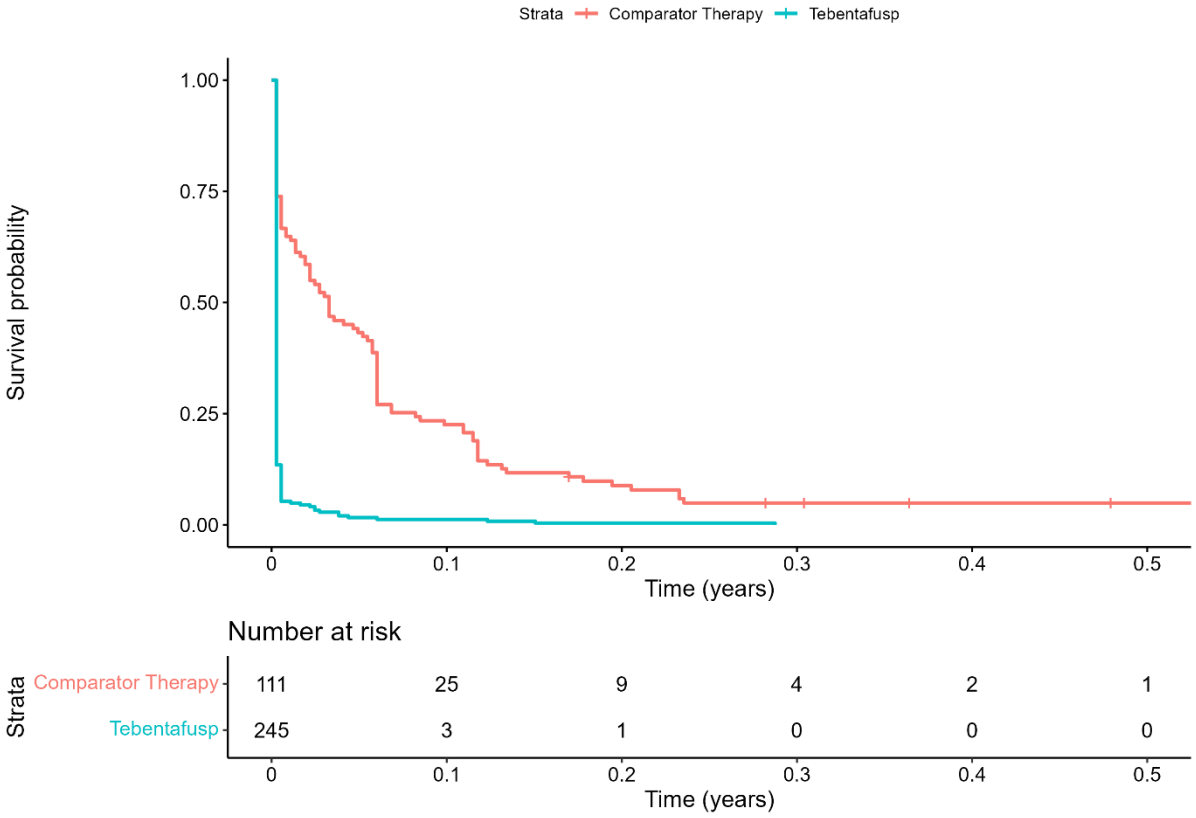
Erkrankungen der Haut und des Unterhautgewebes- Nicht-Nordamerika 3491
Erkrankungen der Haut und des Unterhautgewebes- Dacarbazin 3492
Erkrankungen der Haut und des Unterhautgewebes- Pembrolizumab 3493
Erkrankungen der Haut und des Unterhautgewebes- Ipilimumab 3494

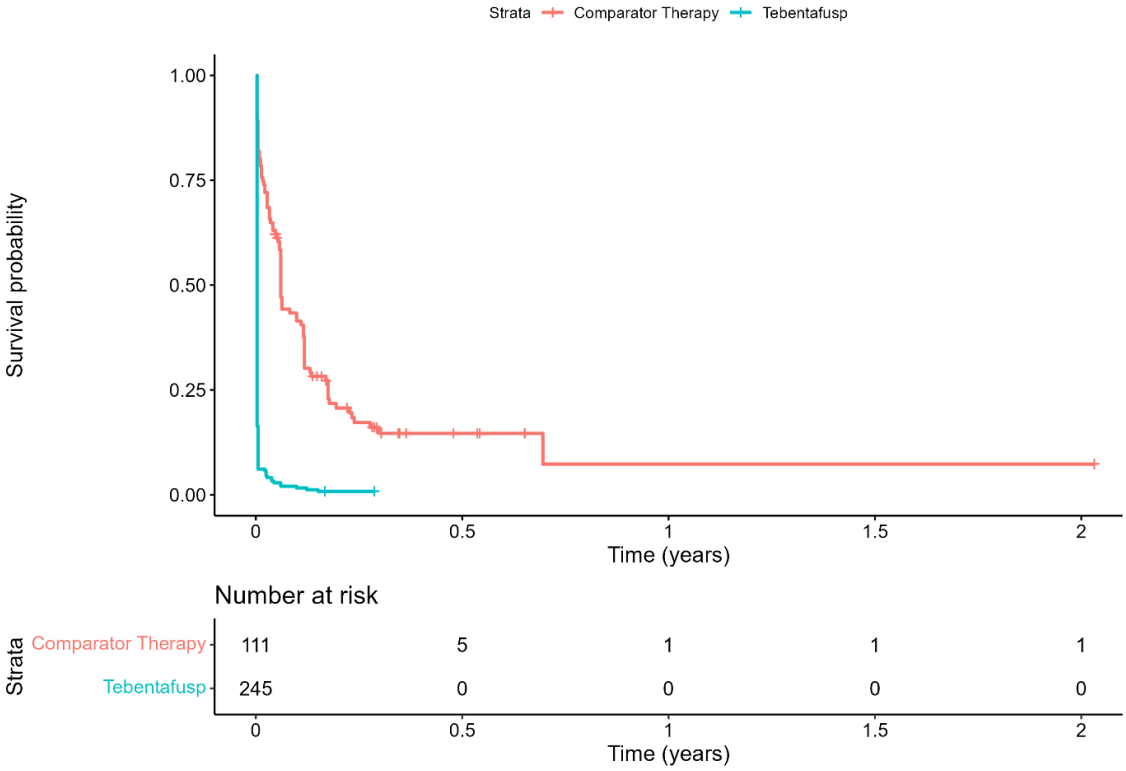
1 Ergänzende KM-Kurven zu 4.3.1.3.4 Endpunkt Sicherheit und Verträglichkeit – RCT

1.1 Primäranalyse (Oktober 2020) (Tabelle 4-51)

Jegliches UE

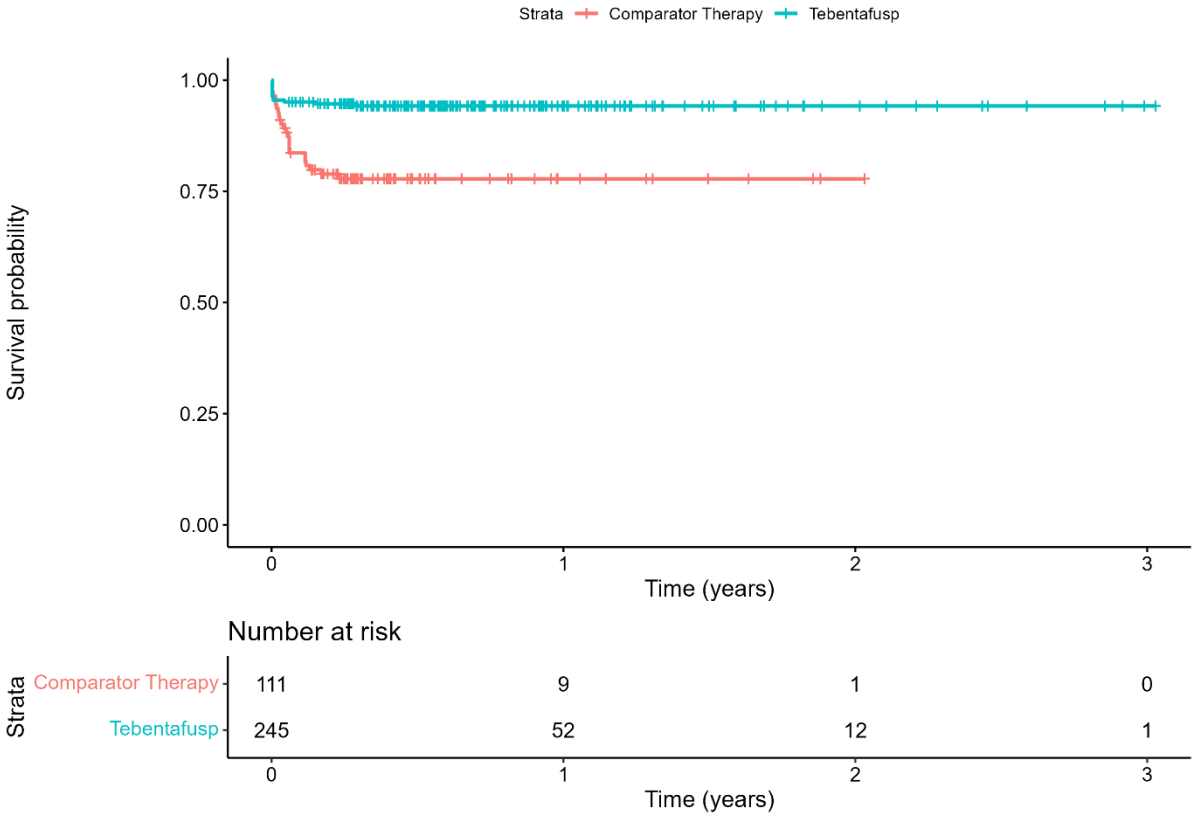


Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE



UE nach höchstem CTCAE-Grad

1



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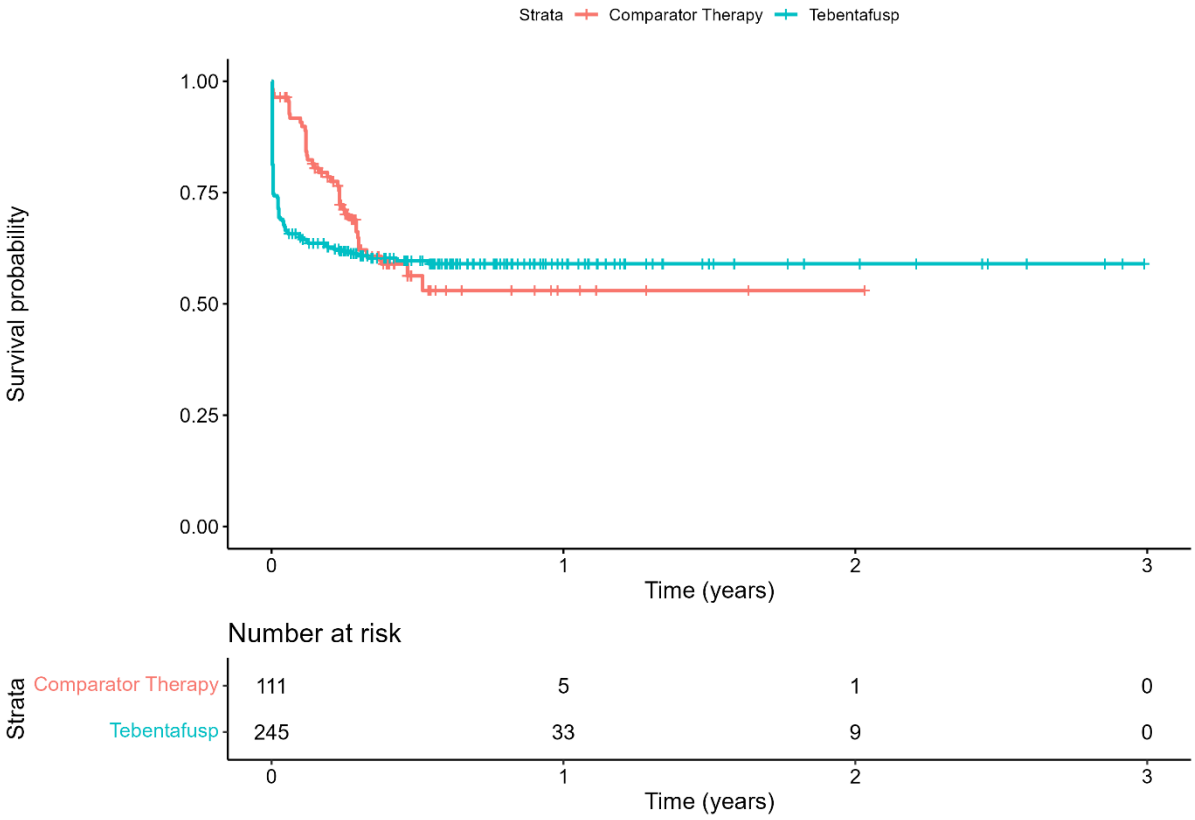
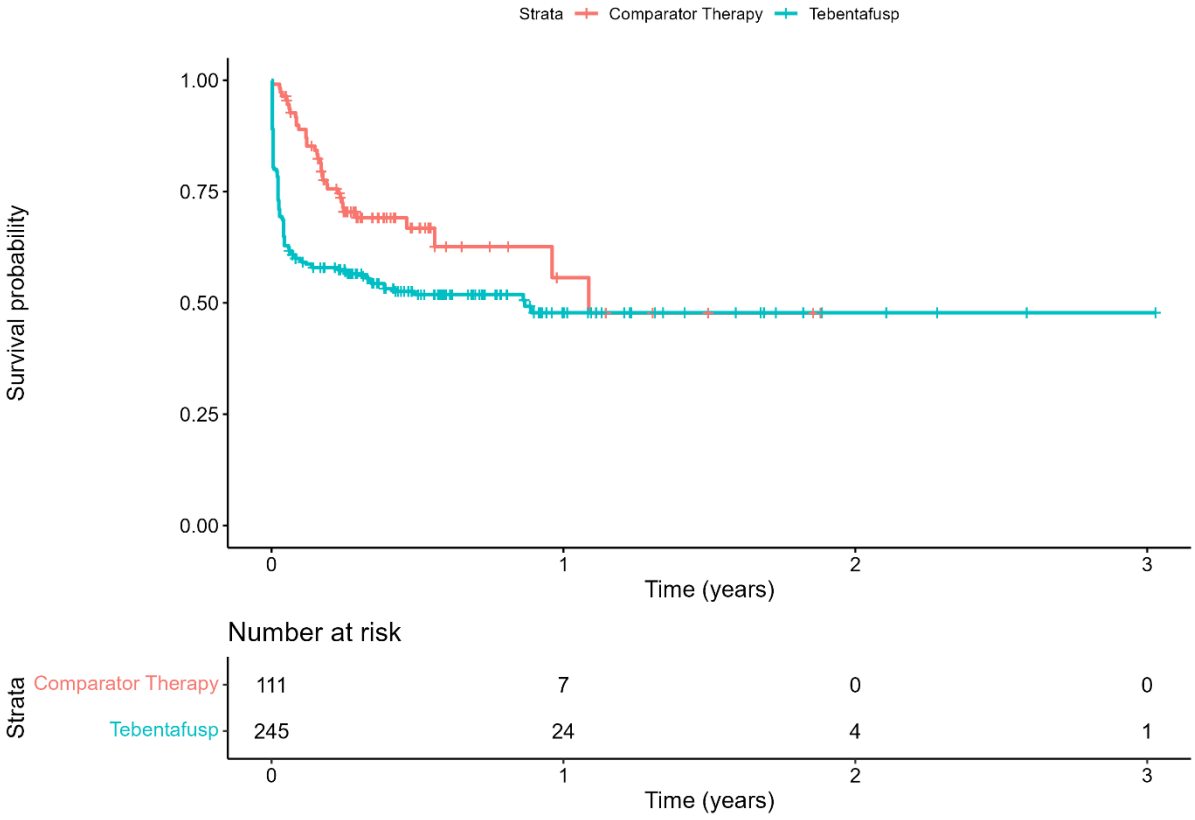
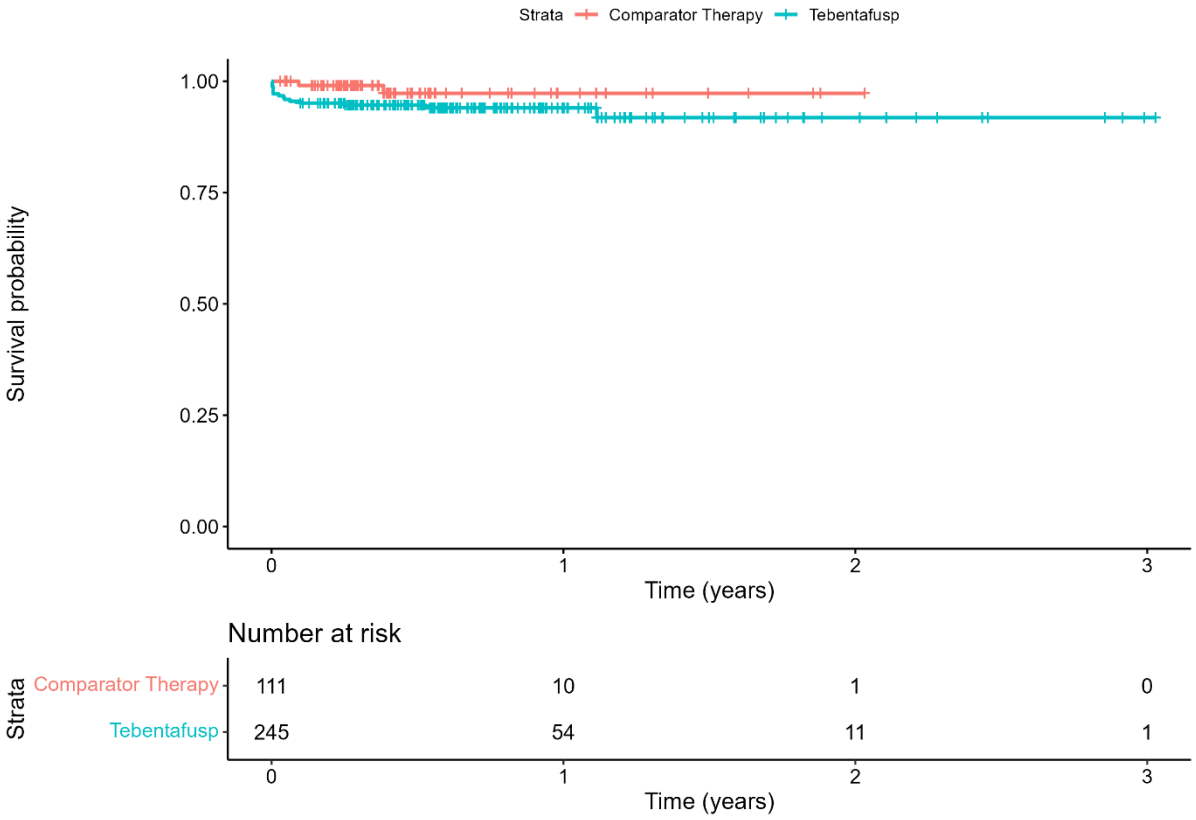

Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 5 1 0
Tebentafusp 245 33 9 0
0
1
2
3
Time (years)

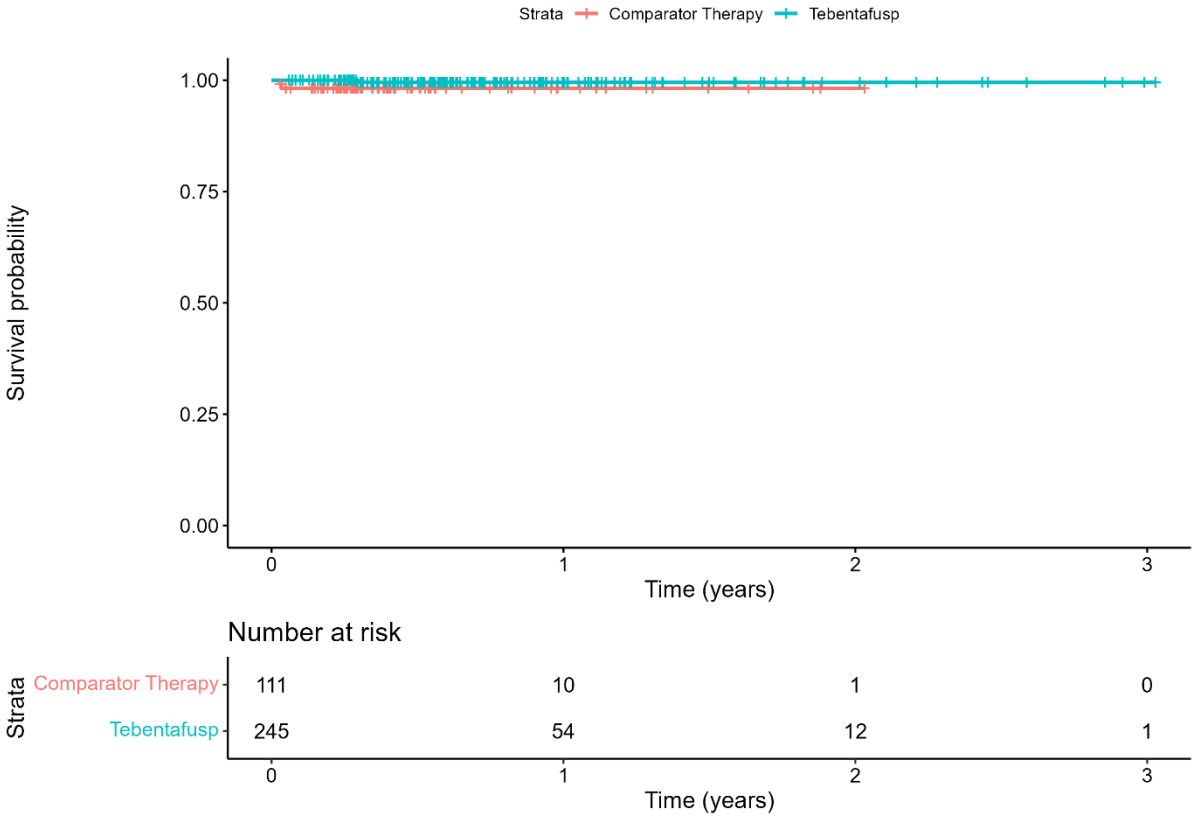
3


Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 7 0 0
Tebentafusp 245 24 4 1
0
1
2
3
Time (years)

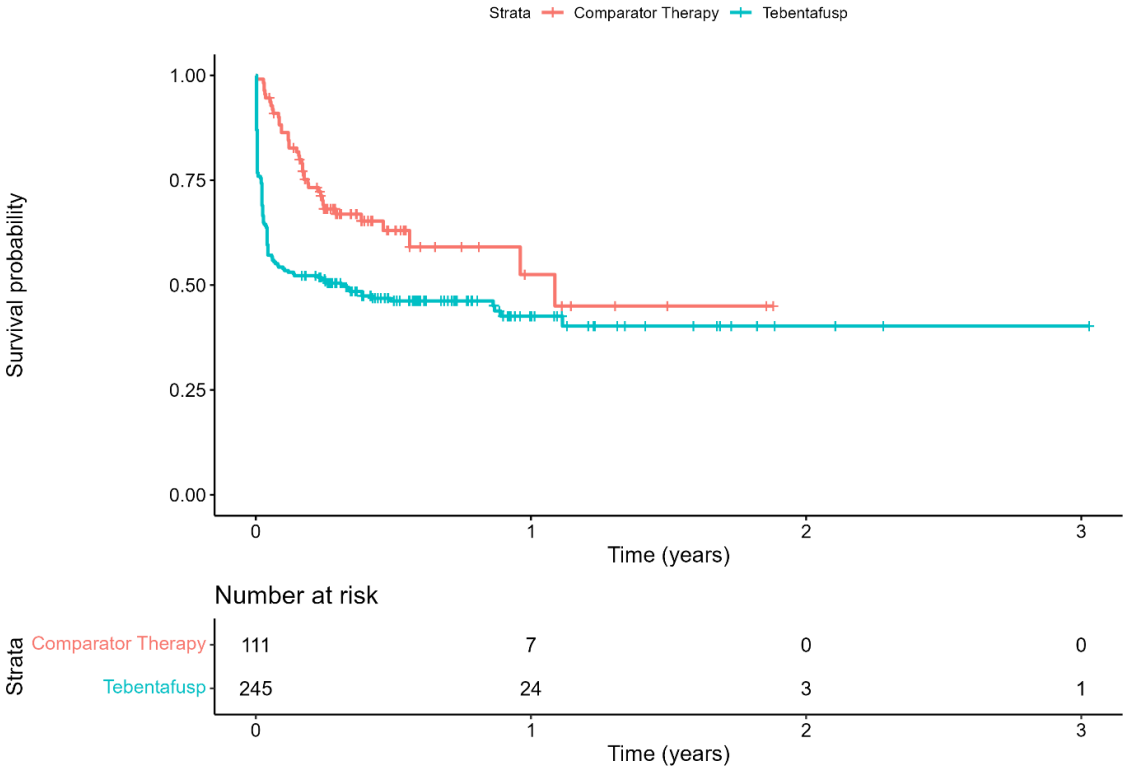
4


Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 10 1 0
Tebentafusp 245 54 11 1
0
1
2
3
Time (years)

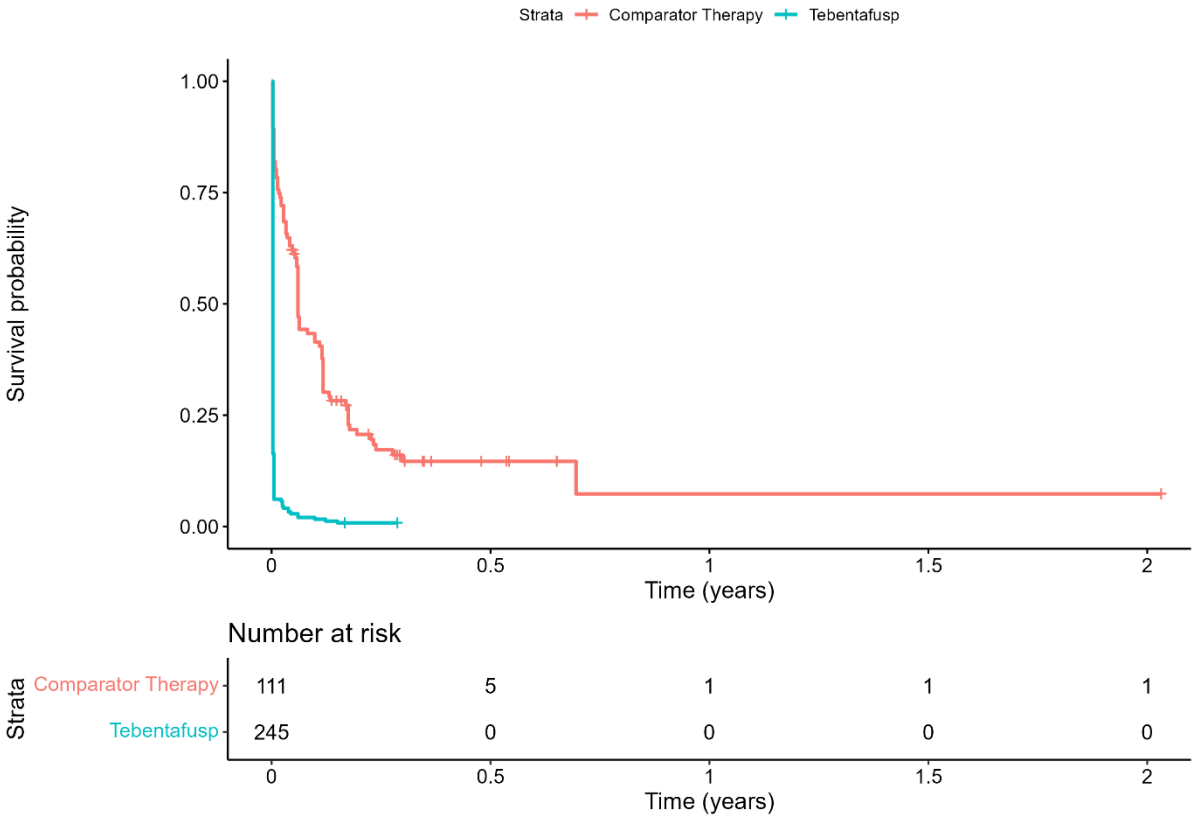
5


Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 10 1 0
Tebentafusp 245 54 12 1
0
1
2
3
Time (years)

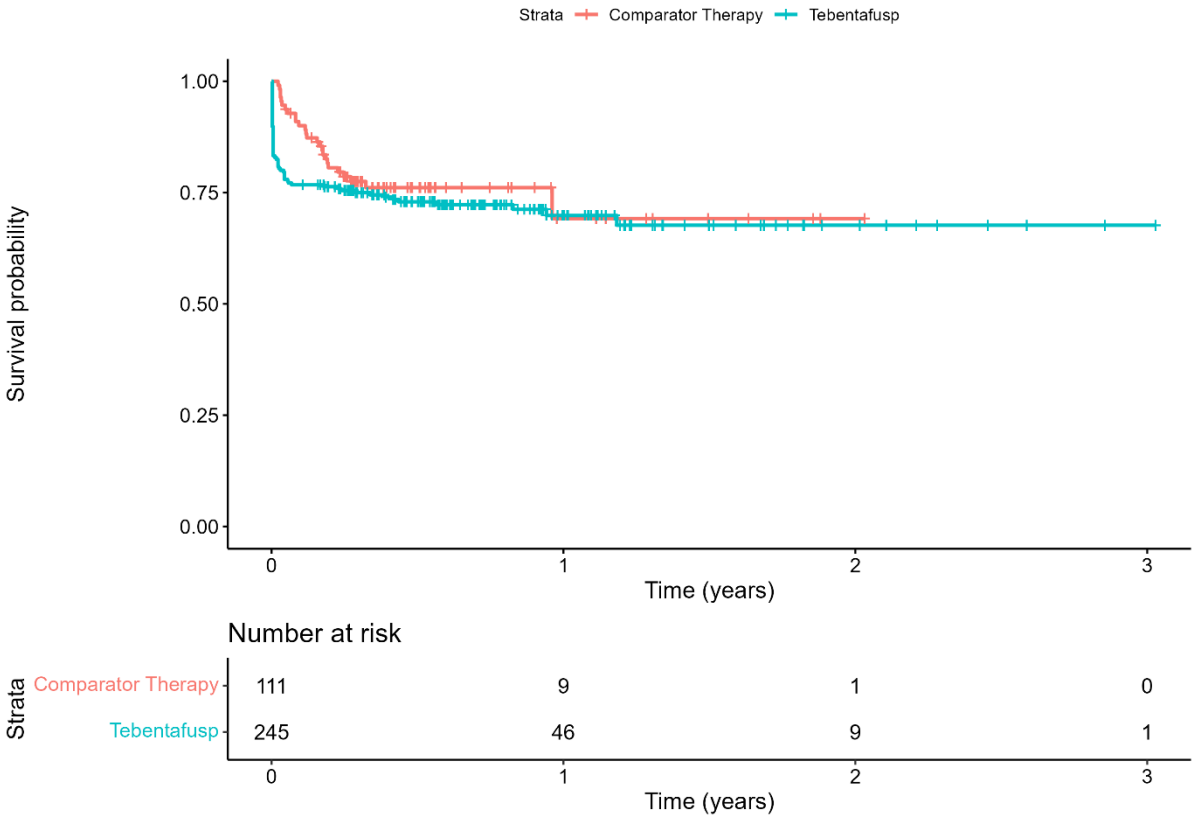
Jegliches UE mit CTCAE-Grad ≥ 3



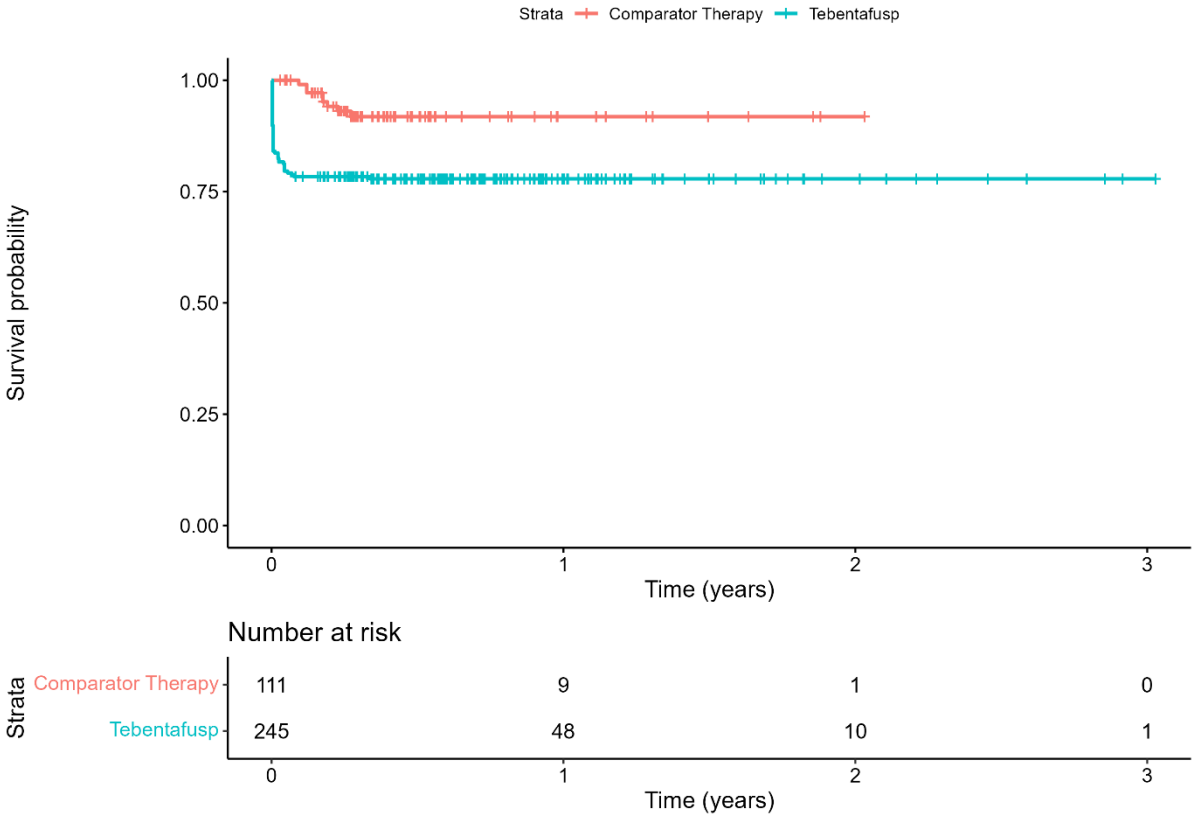
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE mit CTCAE-Grad ≥ 3



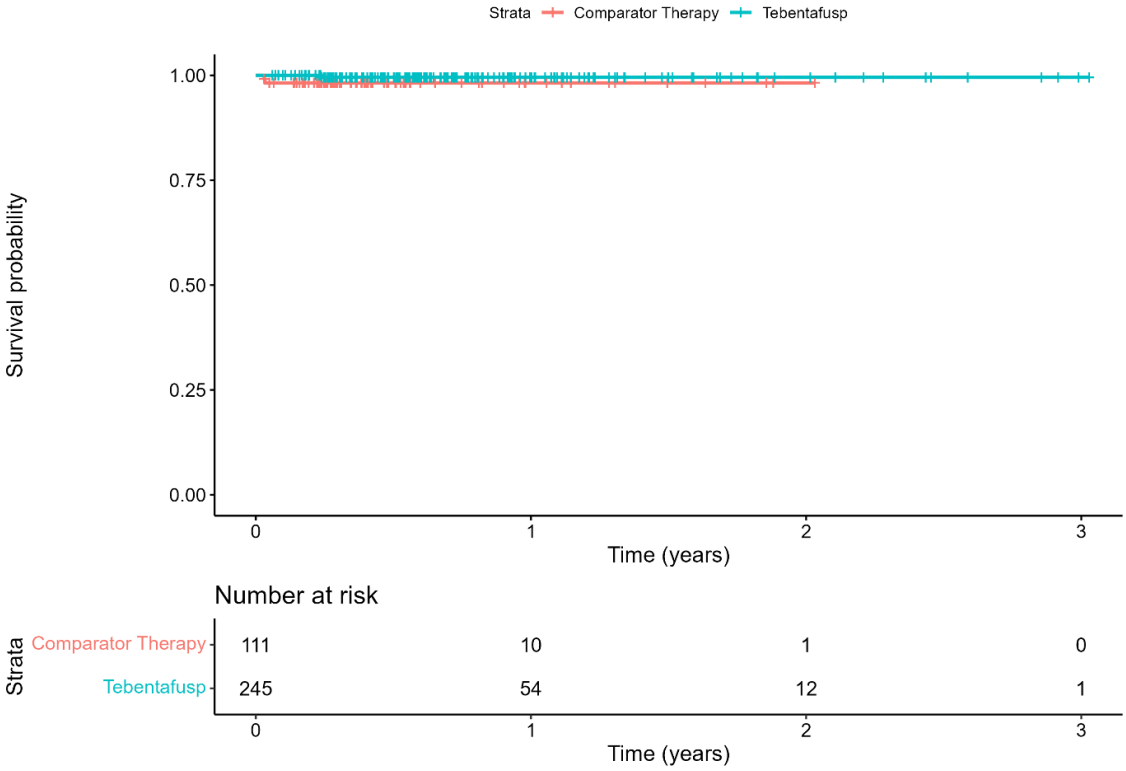
Jegliches SUE



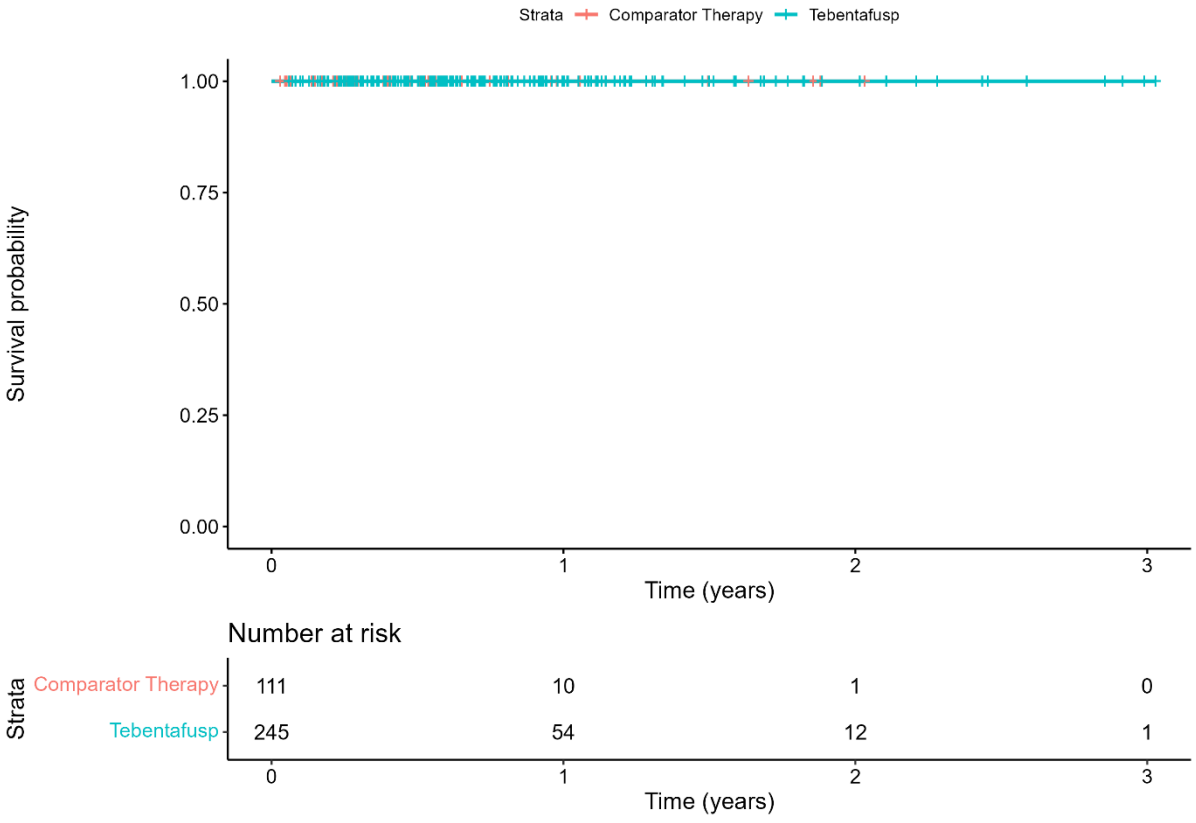
Jegliches mit dem Studienmedikament in Zusammenhang stehendes SUE



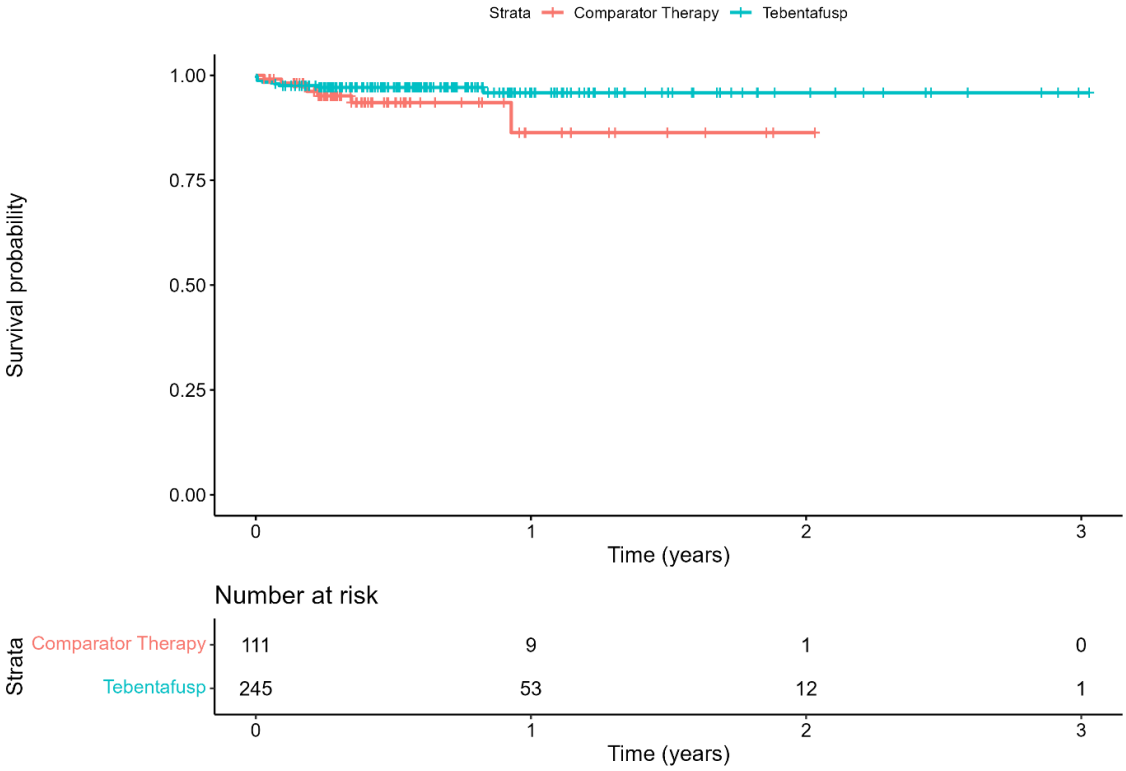
Jegliches UE, das zum Tod führte



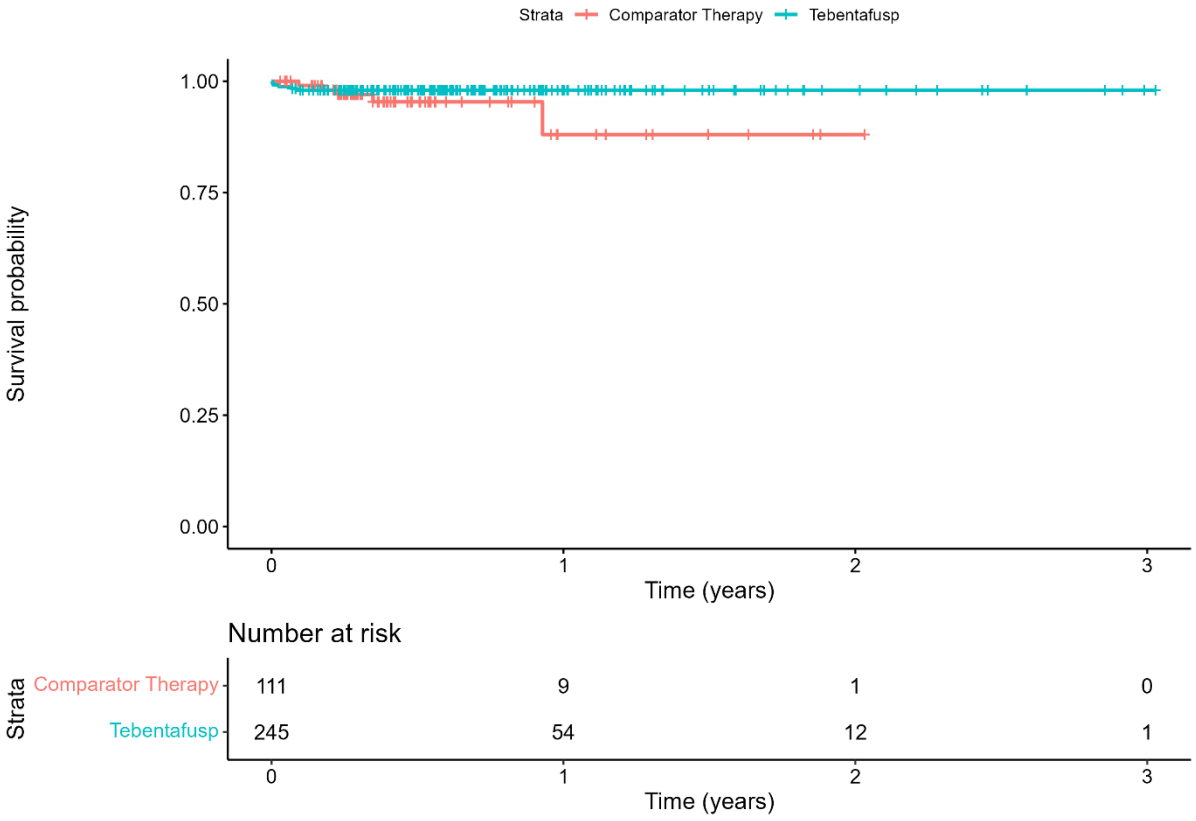
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zum Tod führte



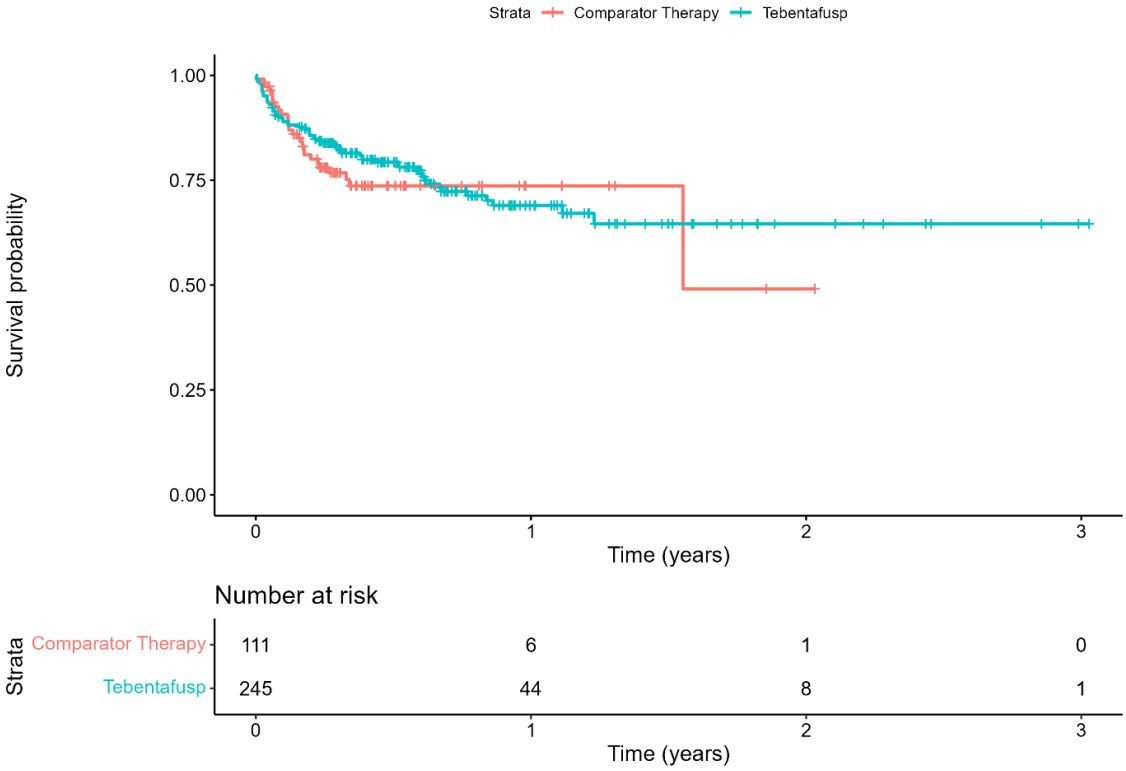
Jegliches UE, das zum Absetzen des Studienmedikaments führte



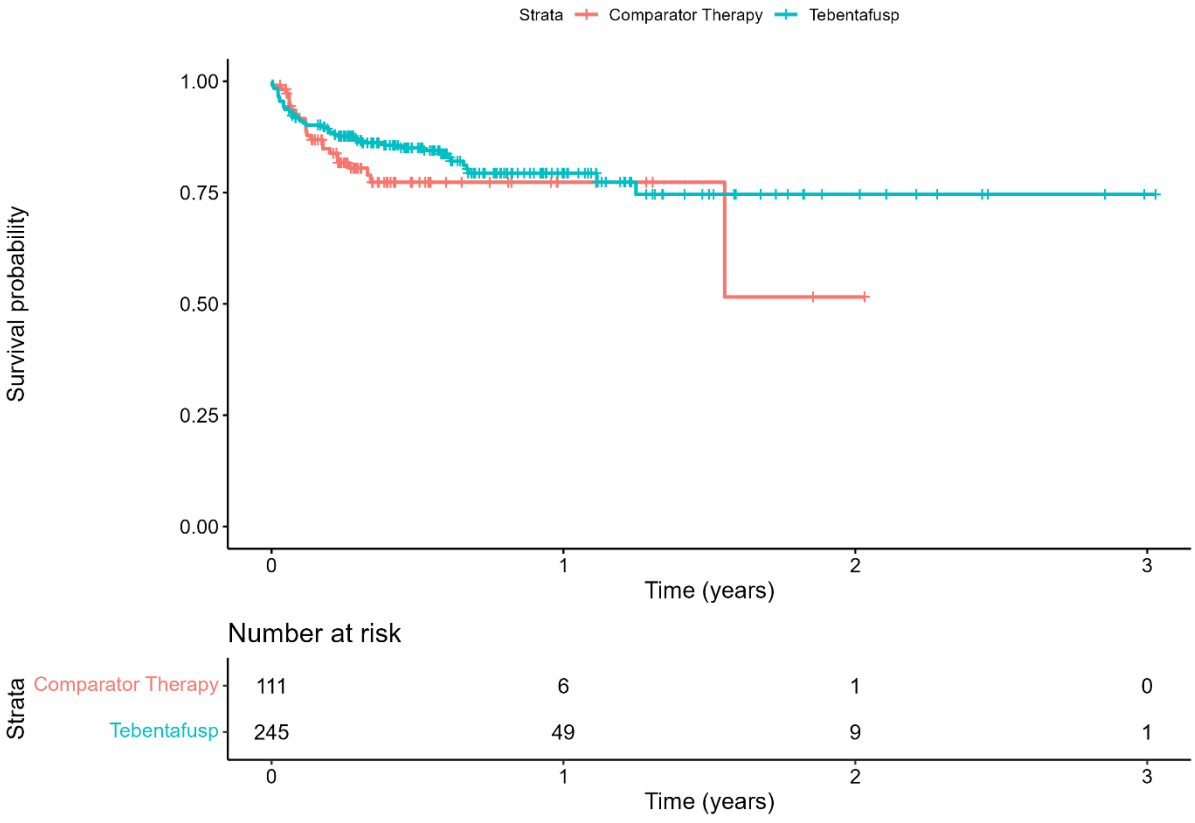
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zum Absetzen des Studienmedikaments führte



Jegliches UE, das zu einer Dosis- oder Infusionsunterbrechung führte

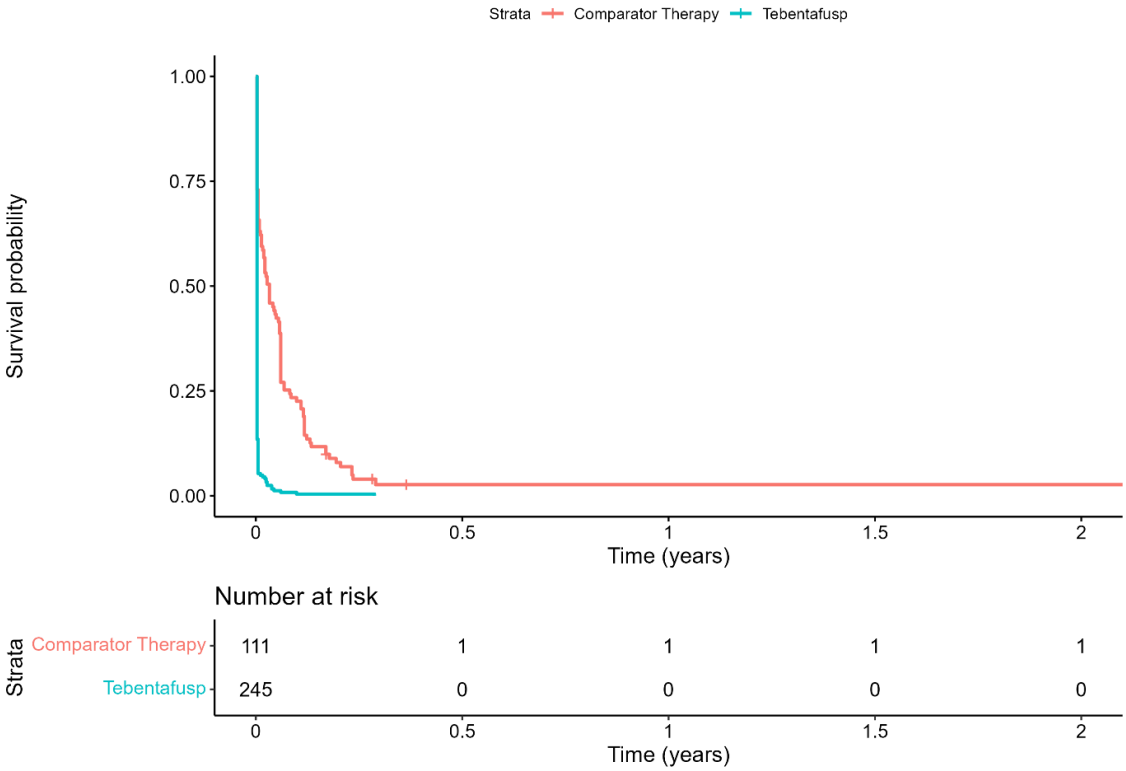


Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zu einer Dosis- oder Infusionsunterbrechung führte

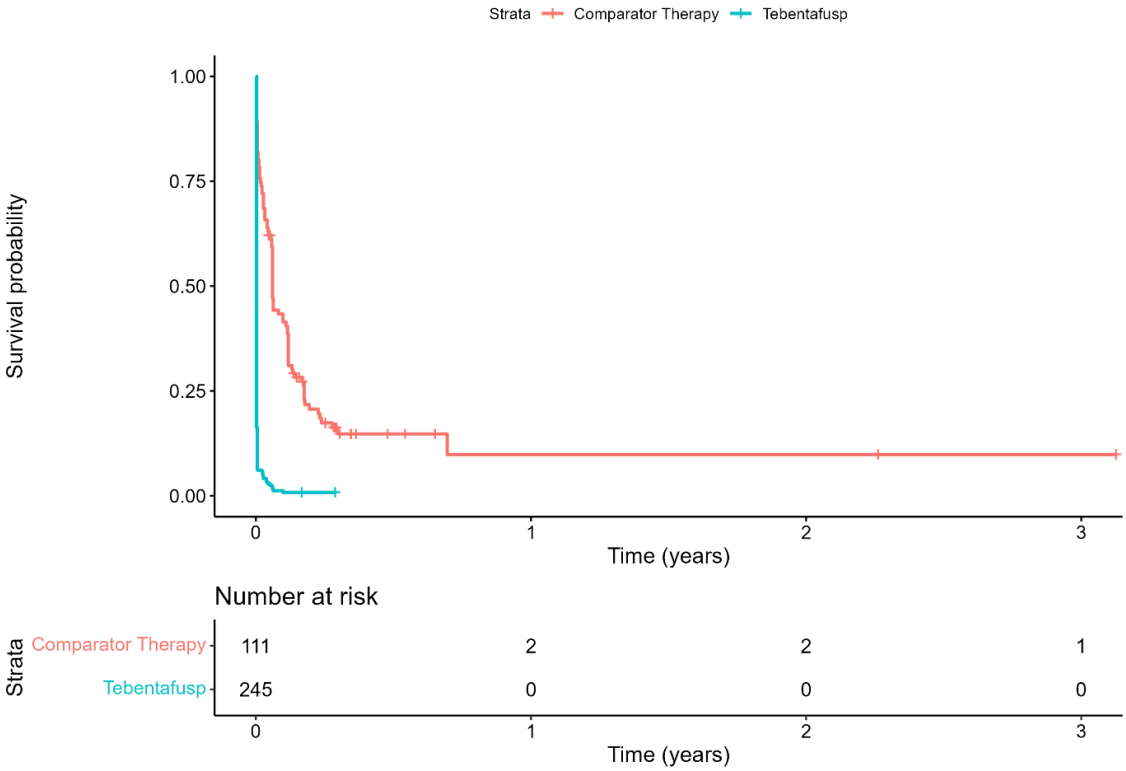


1.2 3-Jahres-Analyse (Juni 2023) (Tabelle 4-52)

Jegliches UE

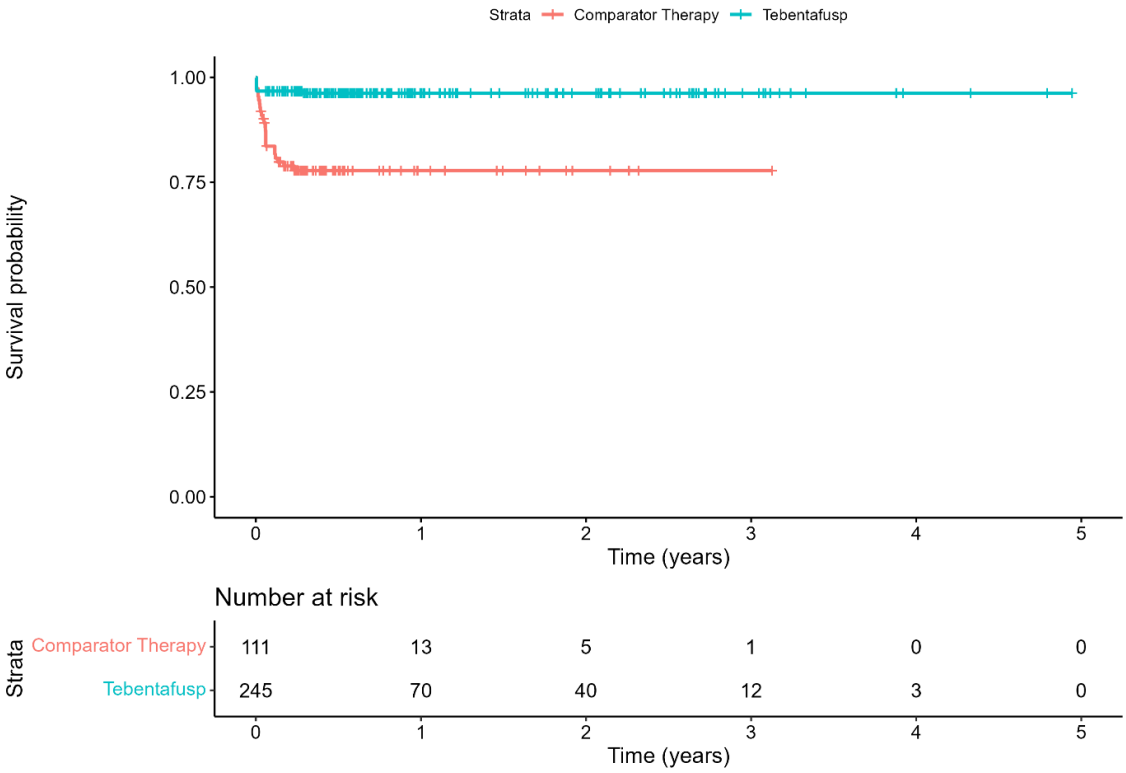


Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE



UE nach höchstem CTCAE-Grad

1



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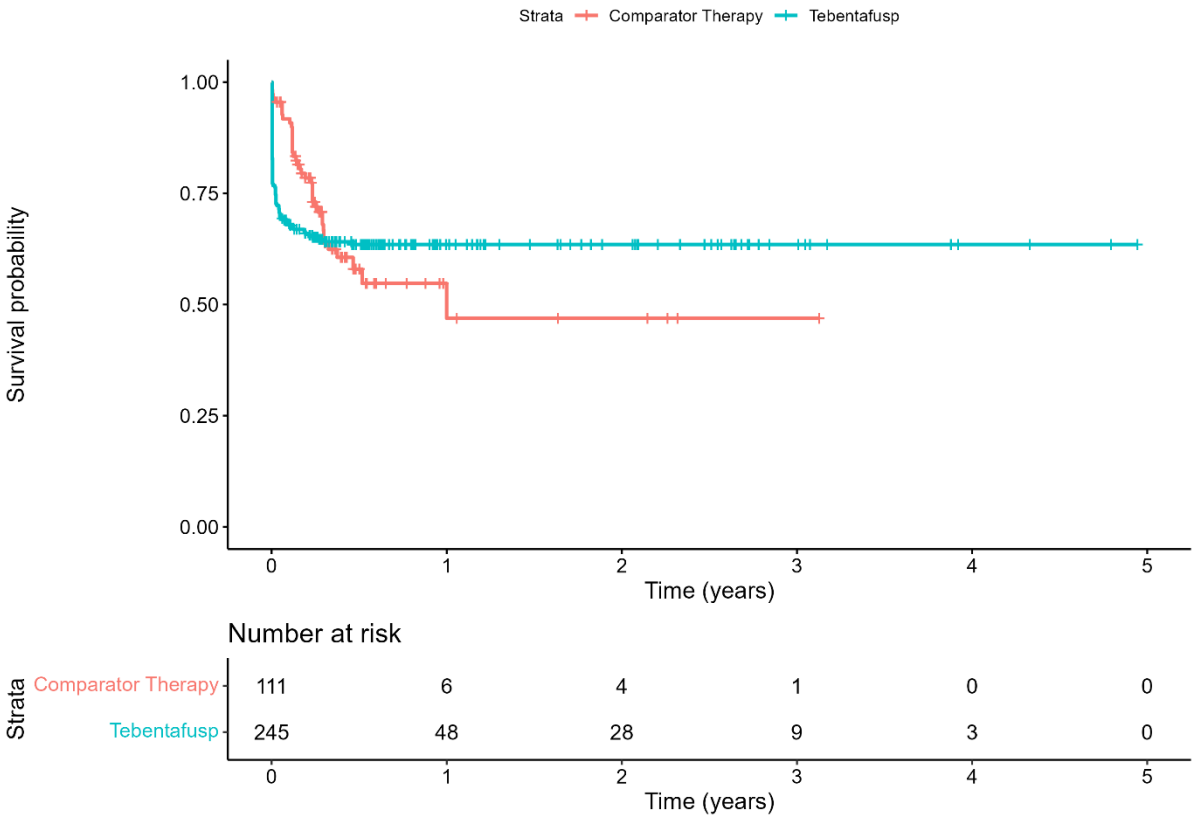

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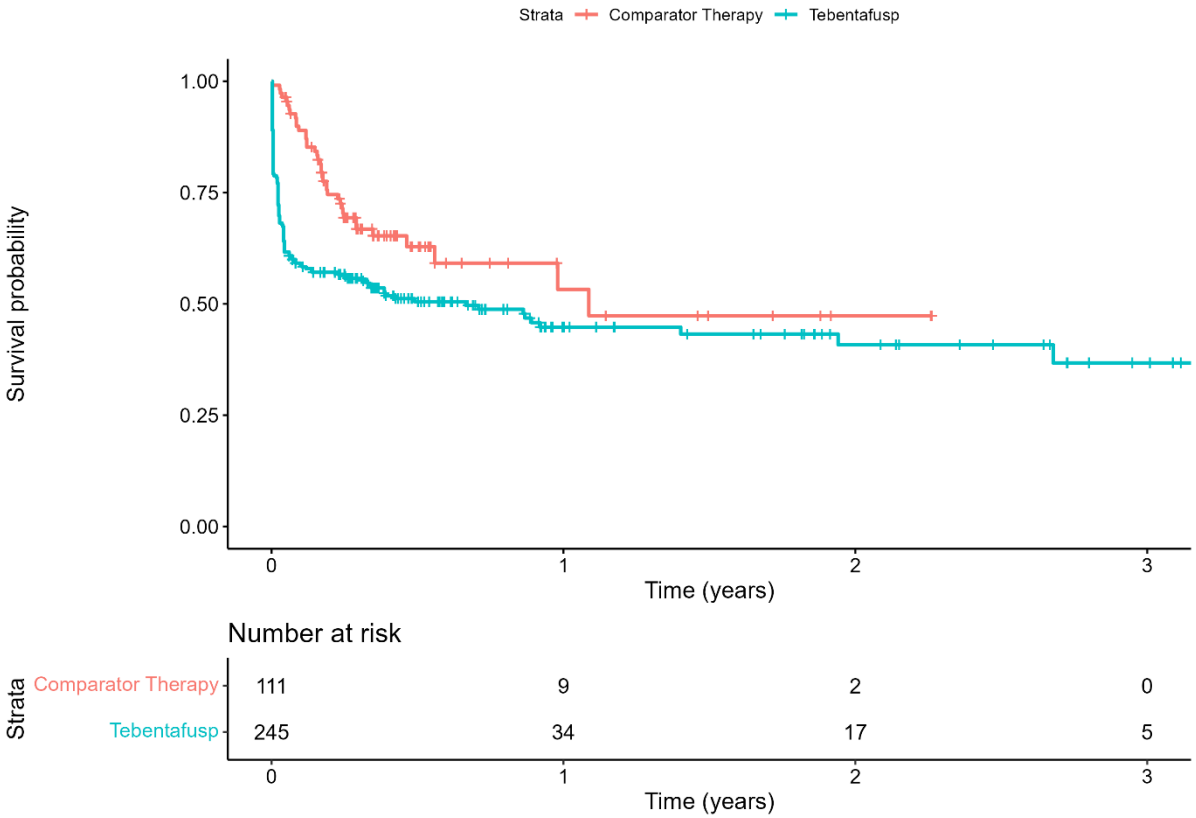
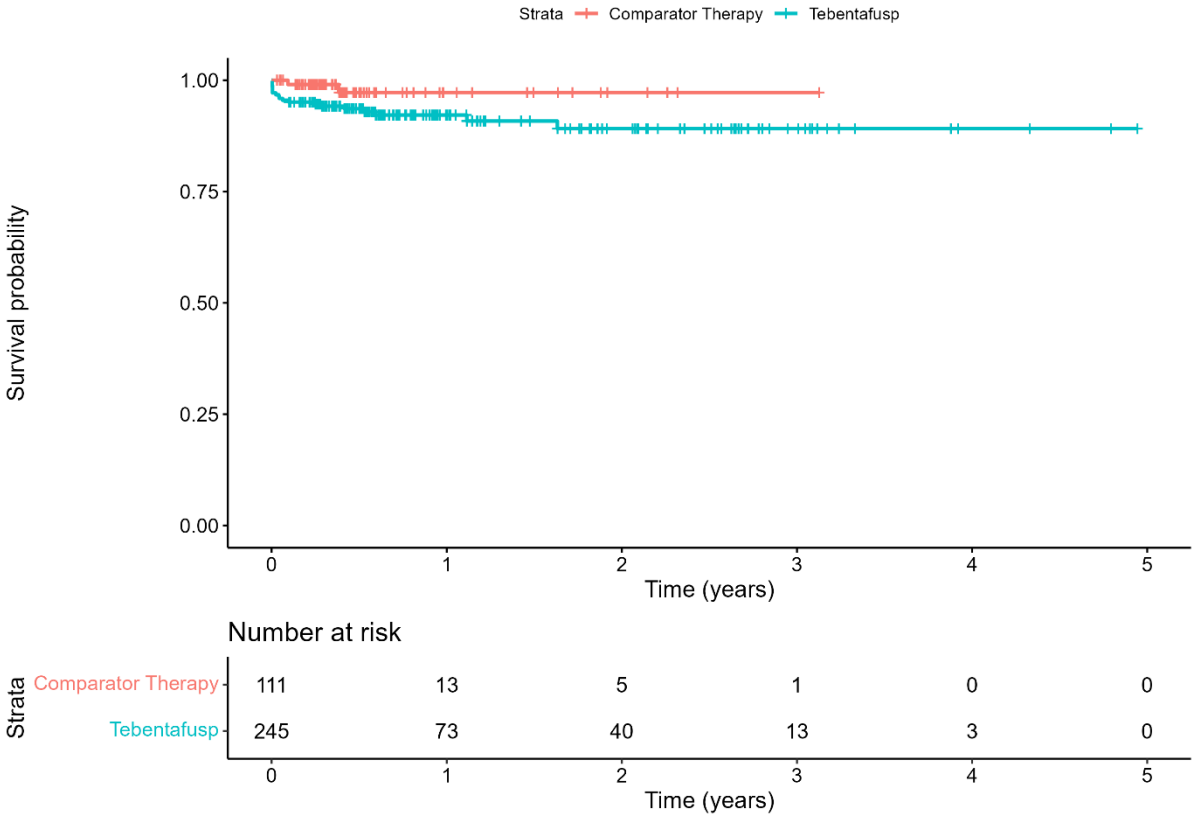
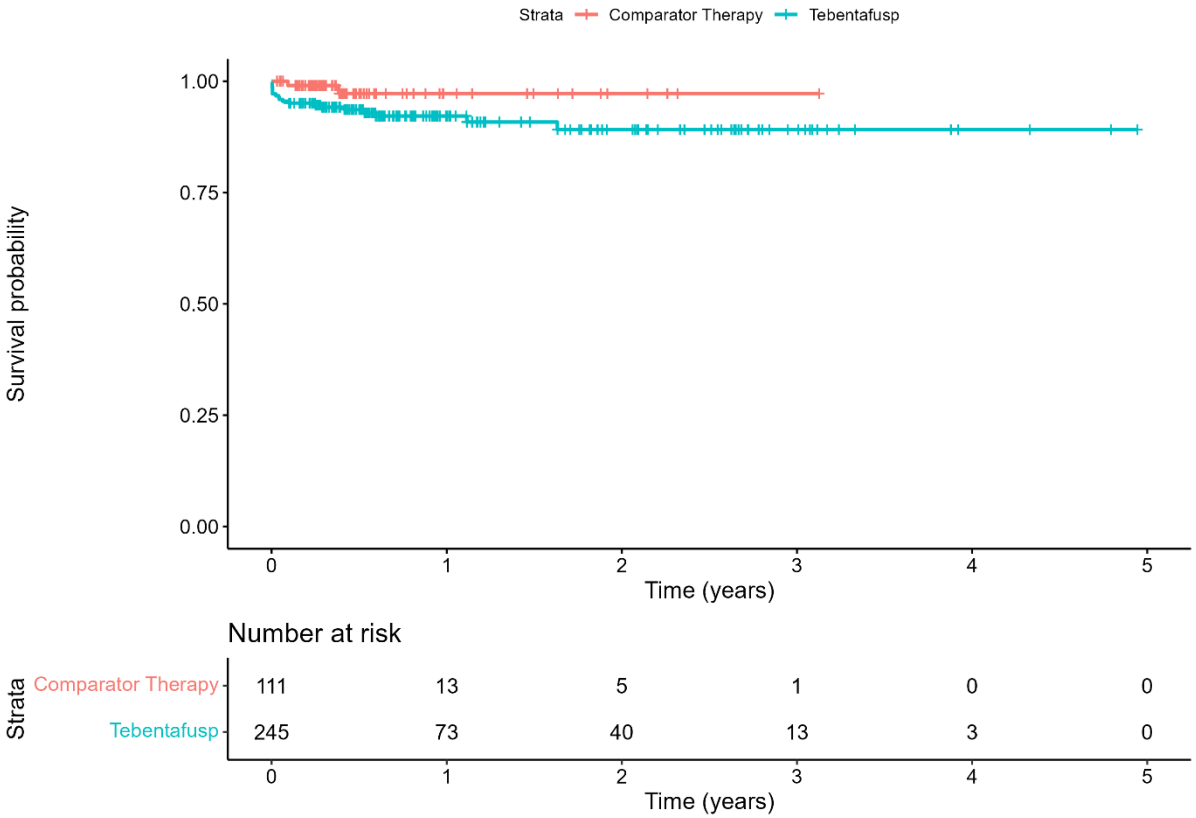

Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 9 2 0
Tebentafusp 245 34 17 5
0
1
2
3
Time (years)

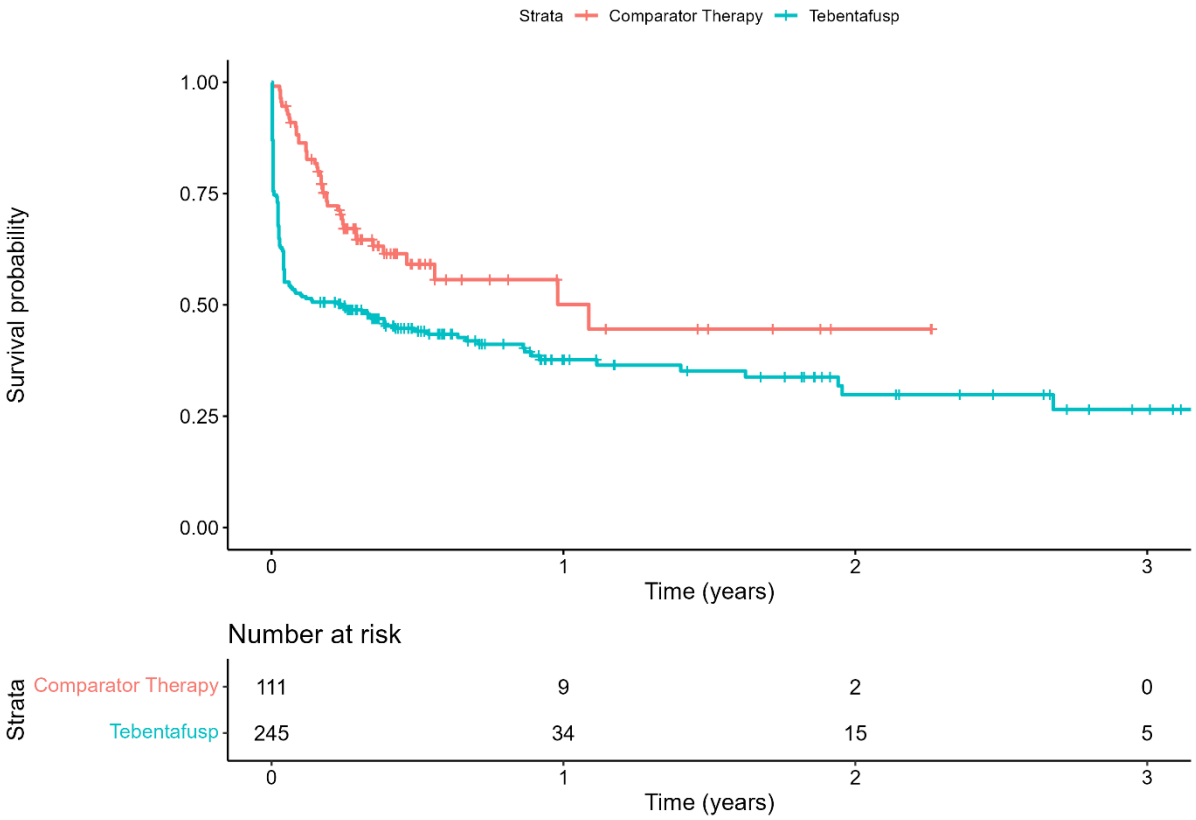
4


Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy 111 13 5 1 0 0
Tebentafusp 245 73 40 13 3 0
0
1
2
3
4
5
Time (years)

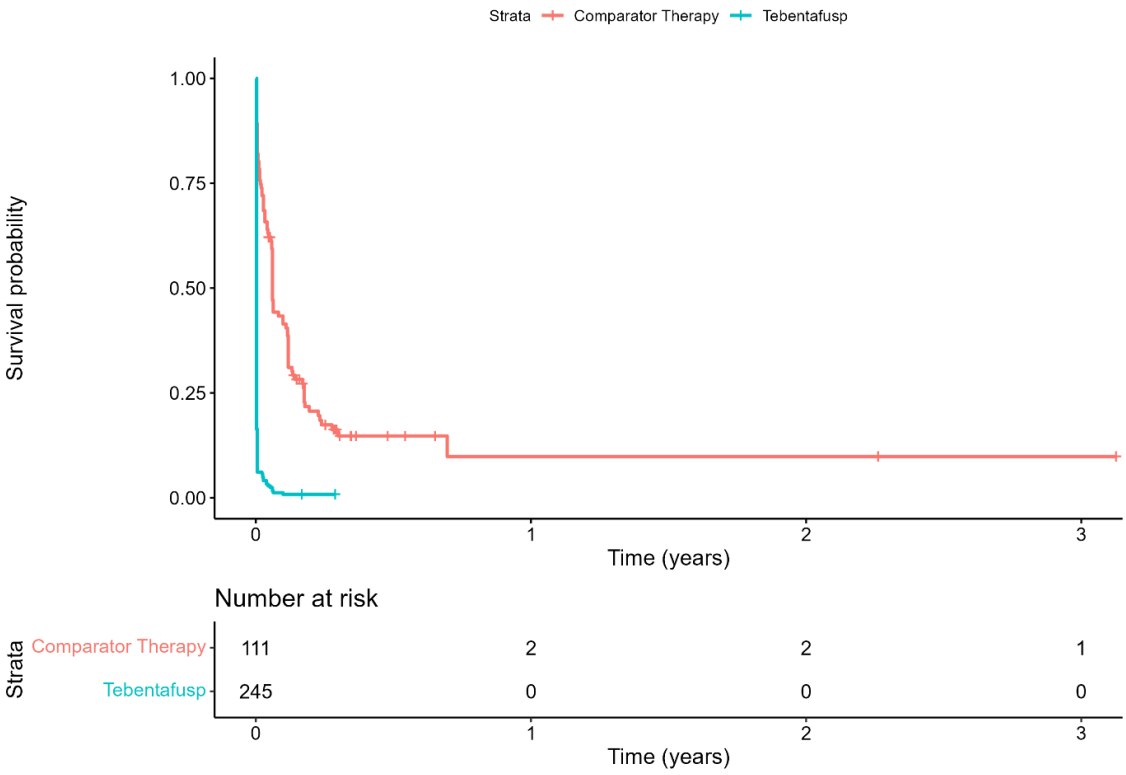
5



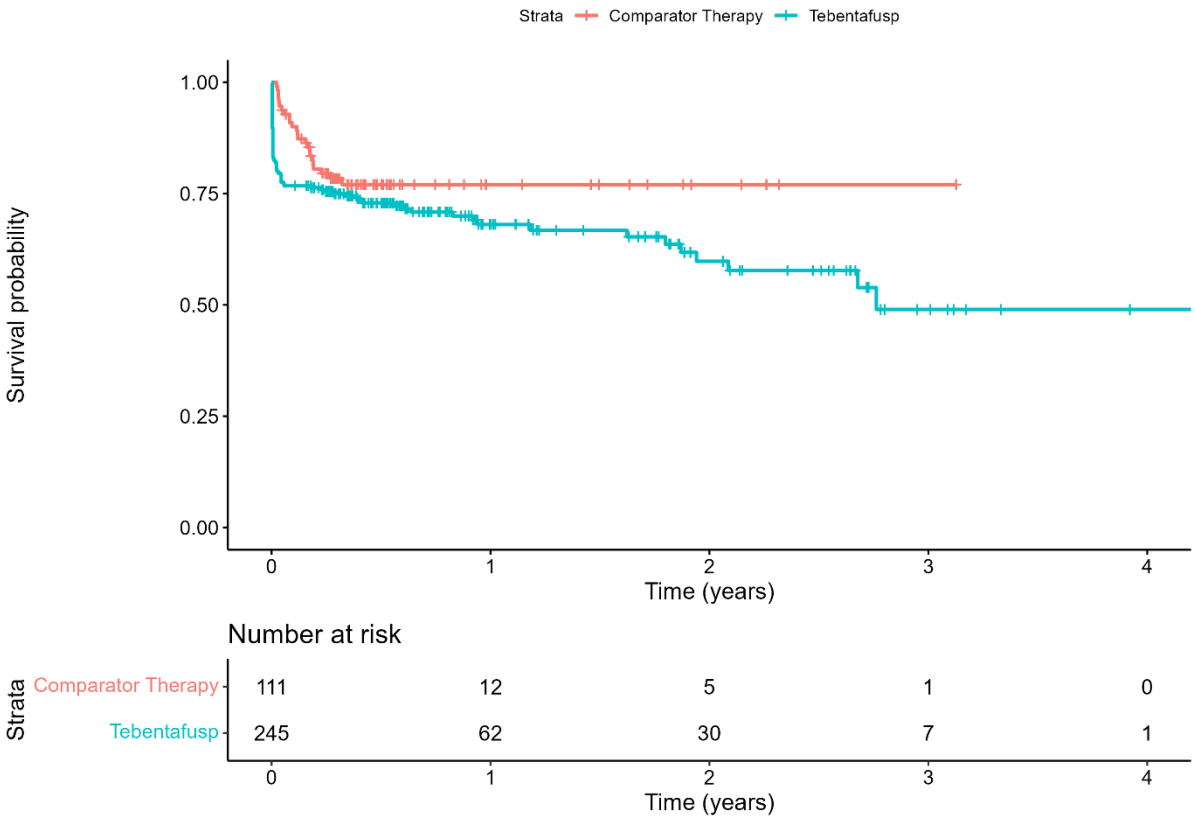
Jegliches UE mit CTCAE-Grad ≥ 3



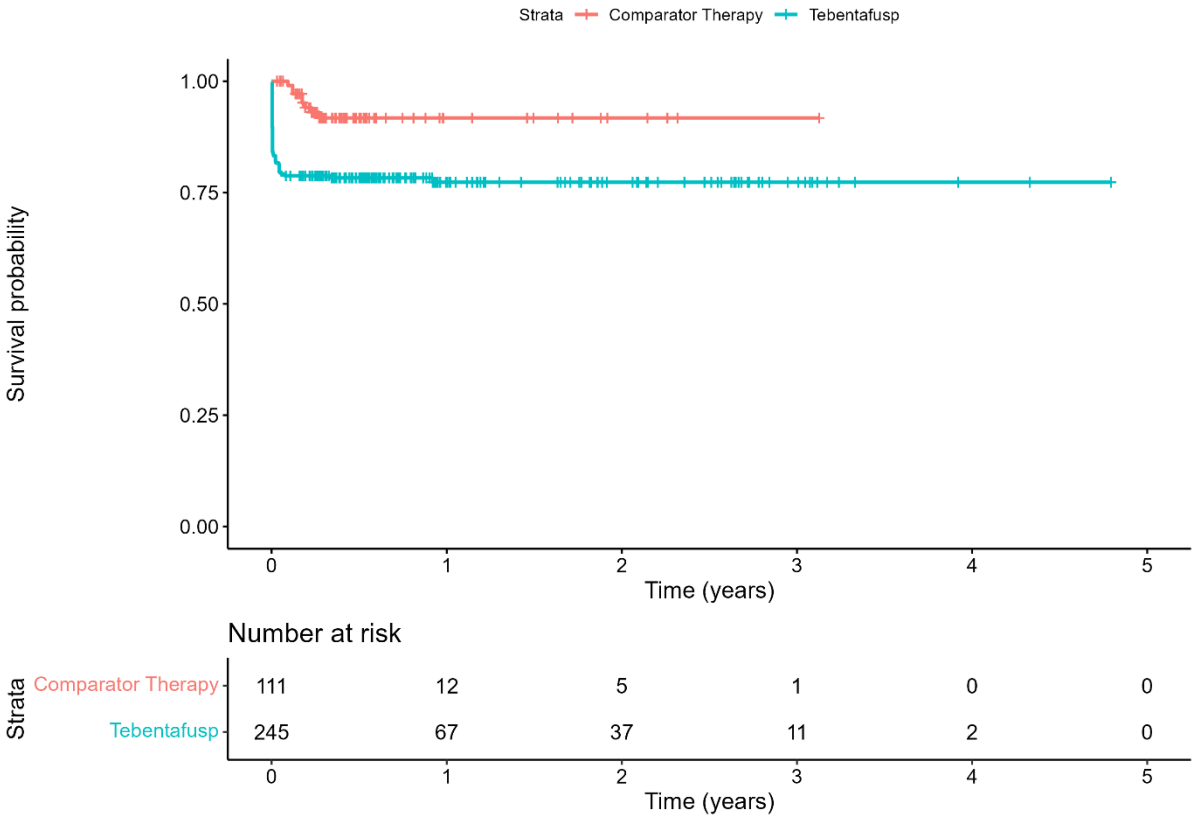
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE mit CTCAE-Grad ≥ 3



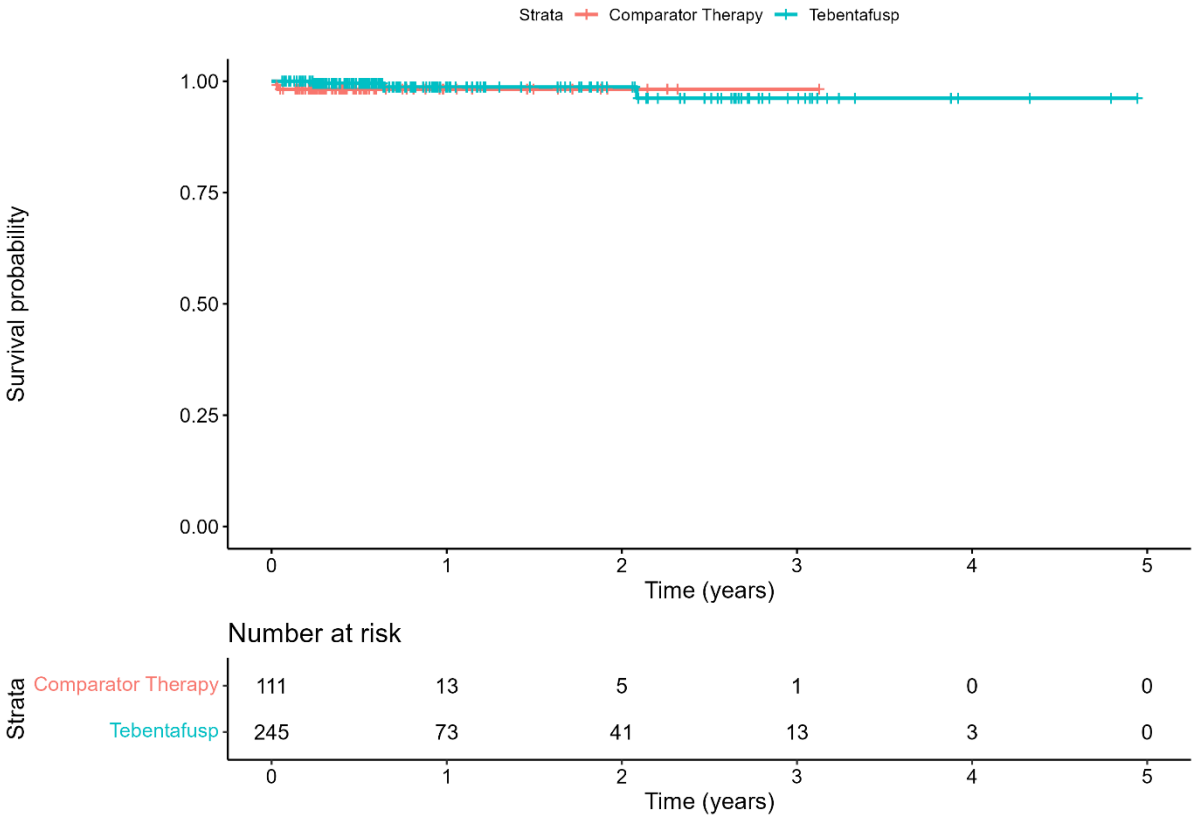
Jegliches SUE



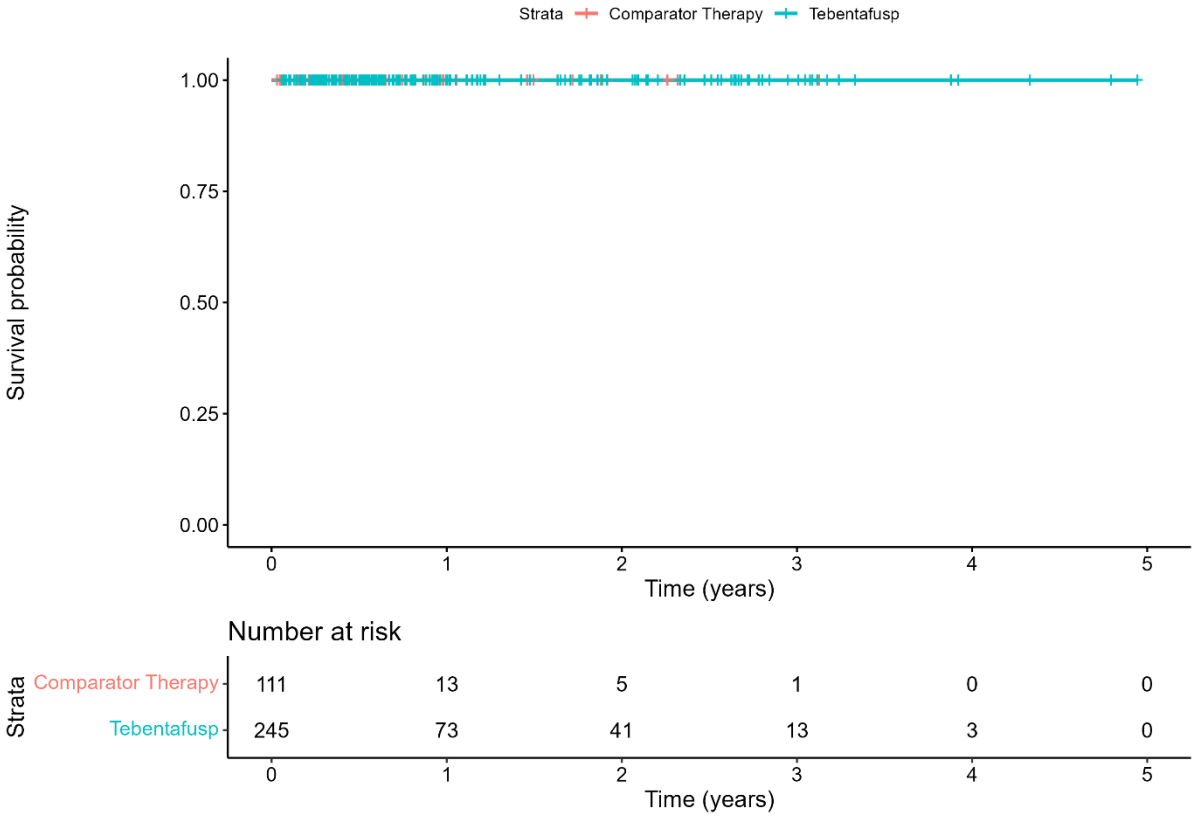
Jegliches mit dem Studienmedikament in Zusammenhang stehendes SUE



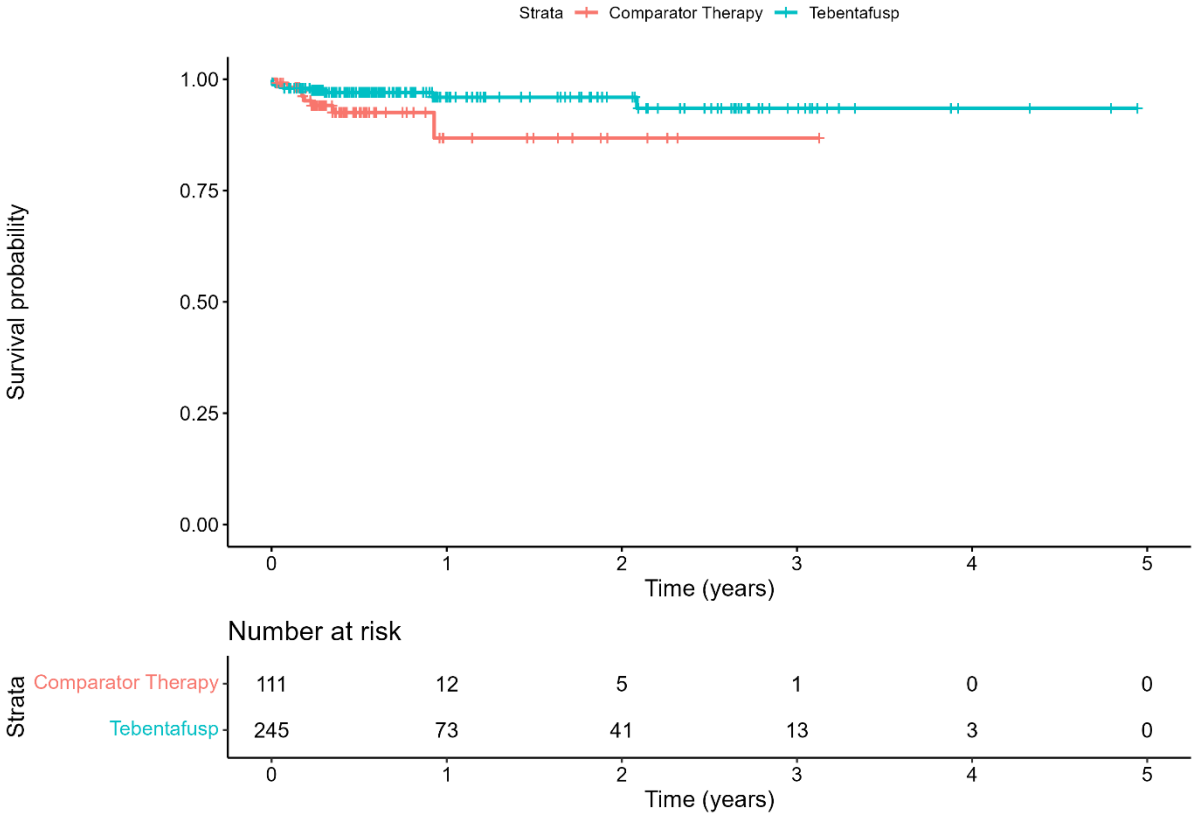
Jegliches UE, das zum Tod führte



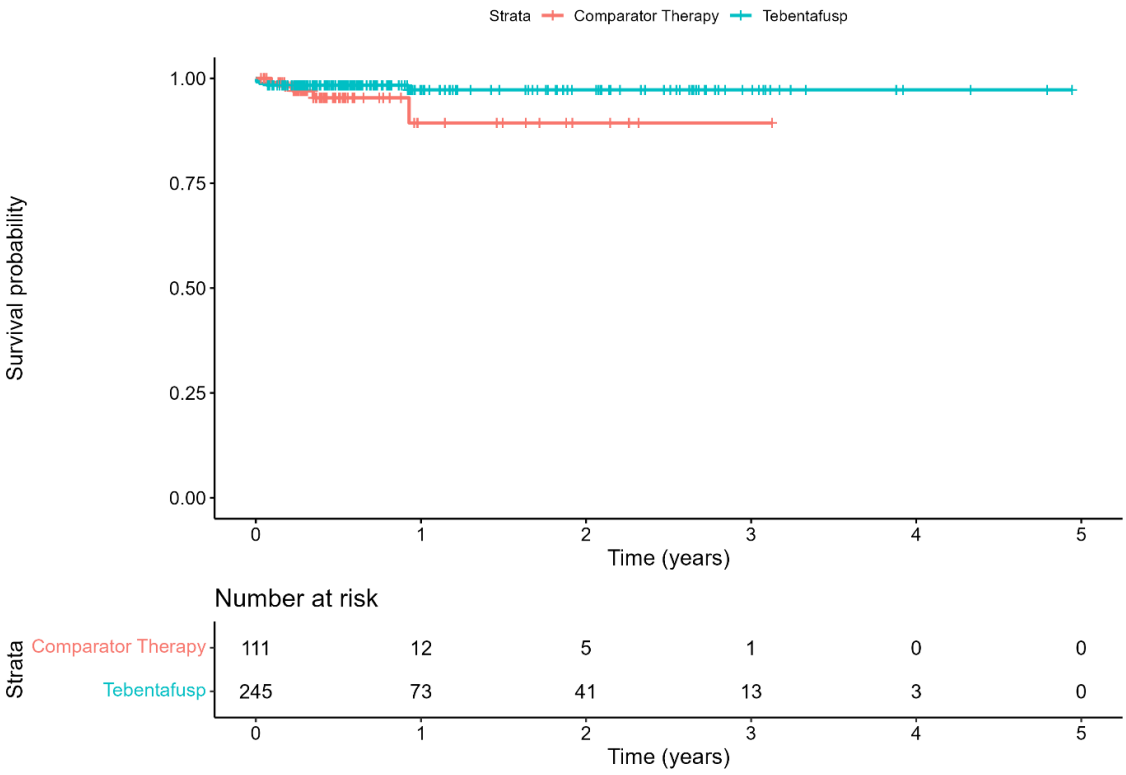
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zum Tod führte



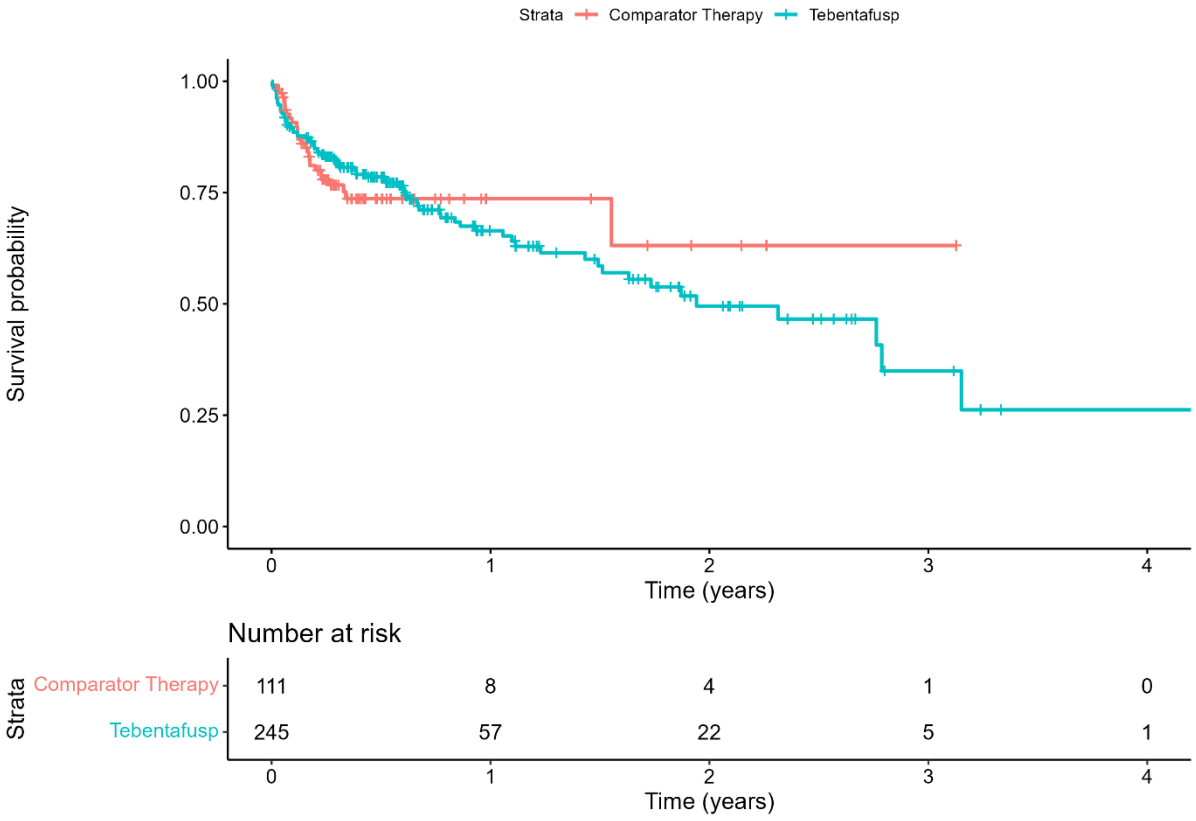
Jegliches UE, das zum Absetzen des Studienmedikaments führte



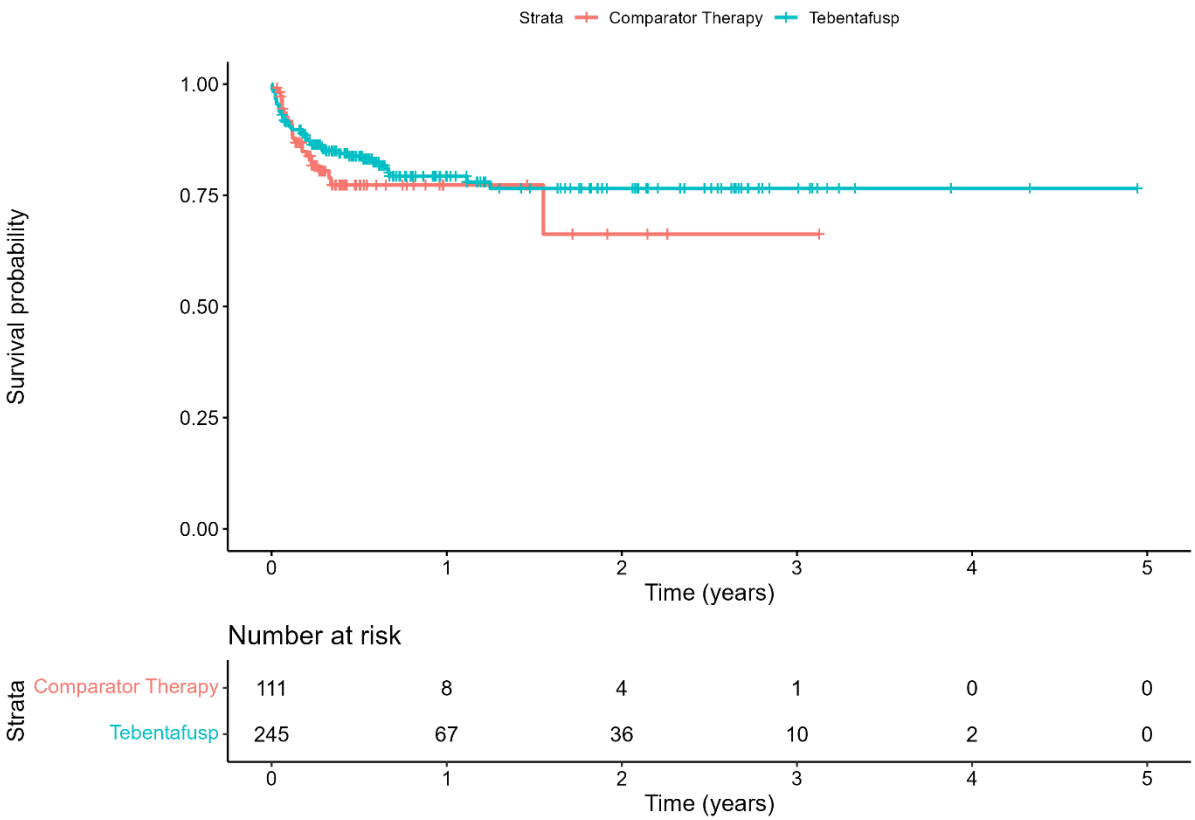
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zum Absetzen des Studienmedikaments führte



Jegliches UE, das zu einer Dosis- oder Infusionsunterbrechung führte



Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zu einer Dosis- oder Infusionsunterbrechung führte

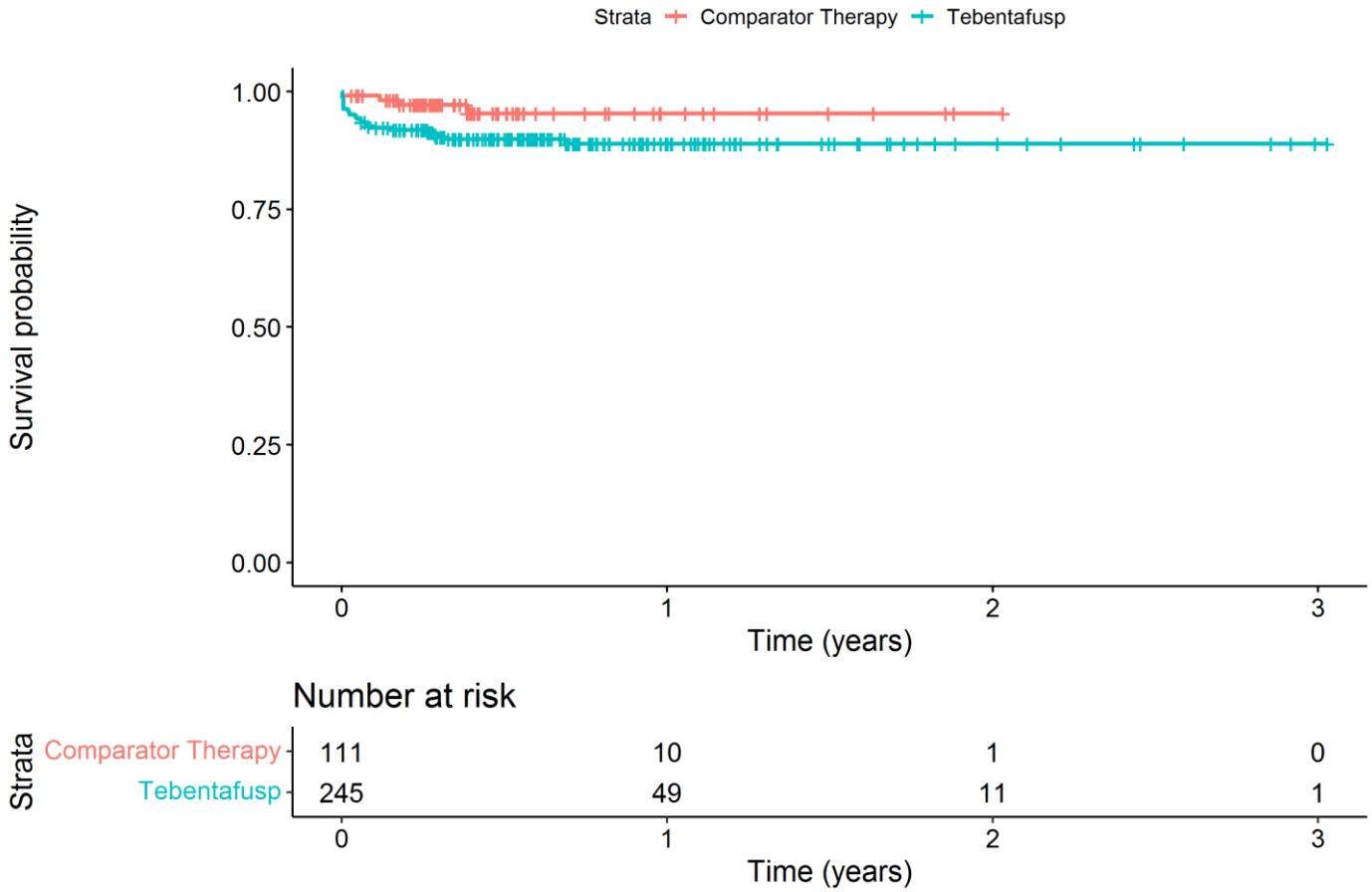


1.3 **Analyse der unerwünschten Ereignisse nach SOC und PT**

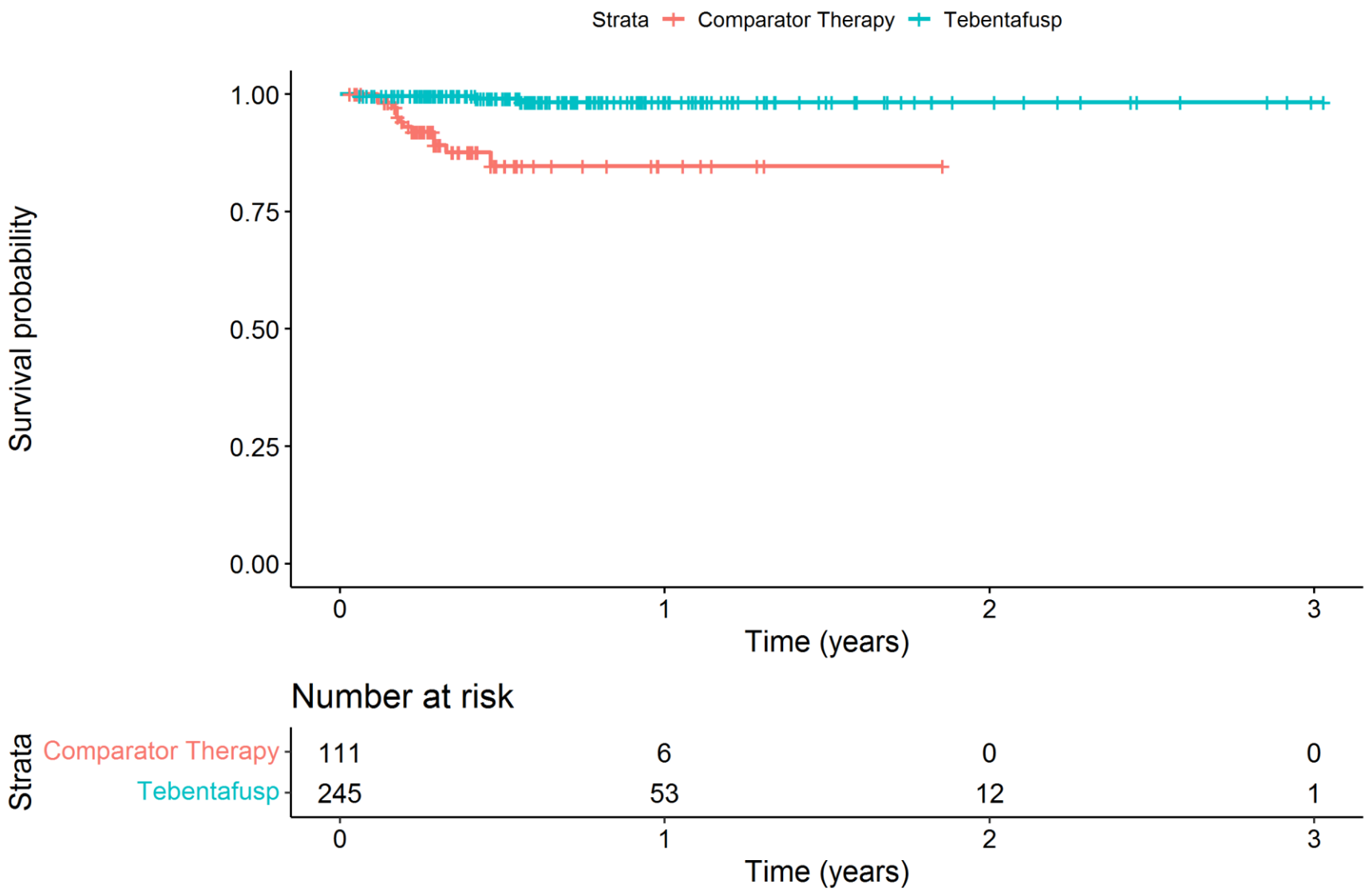
1.4 Alle unerwünschten Ereignisse – Primäranalyse (Oktober 2020) (Tabelle 4-53)

2 UEs (PT), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten

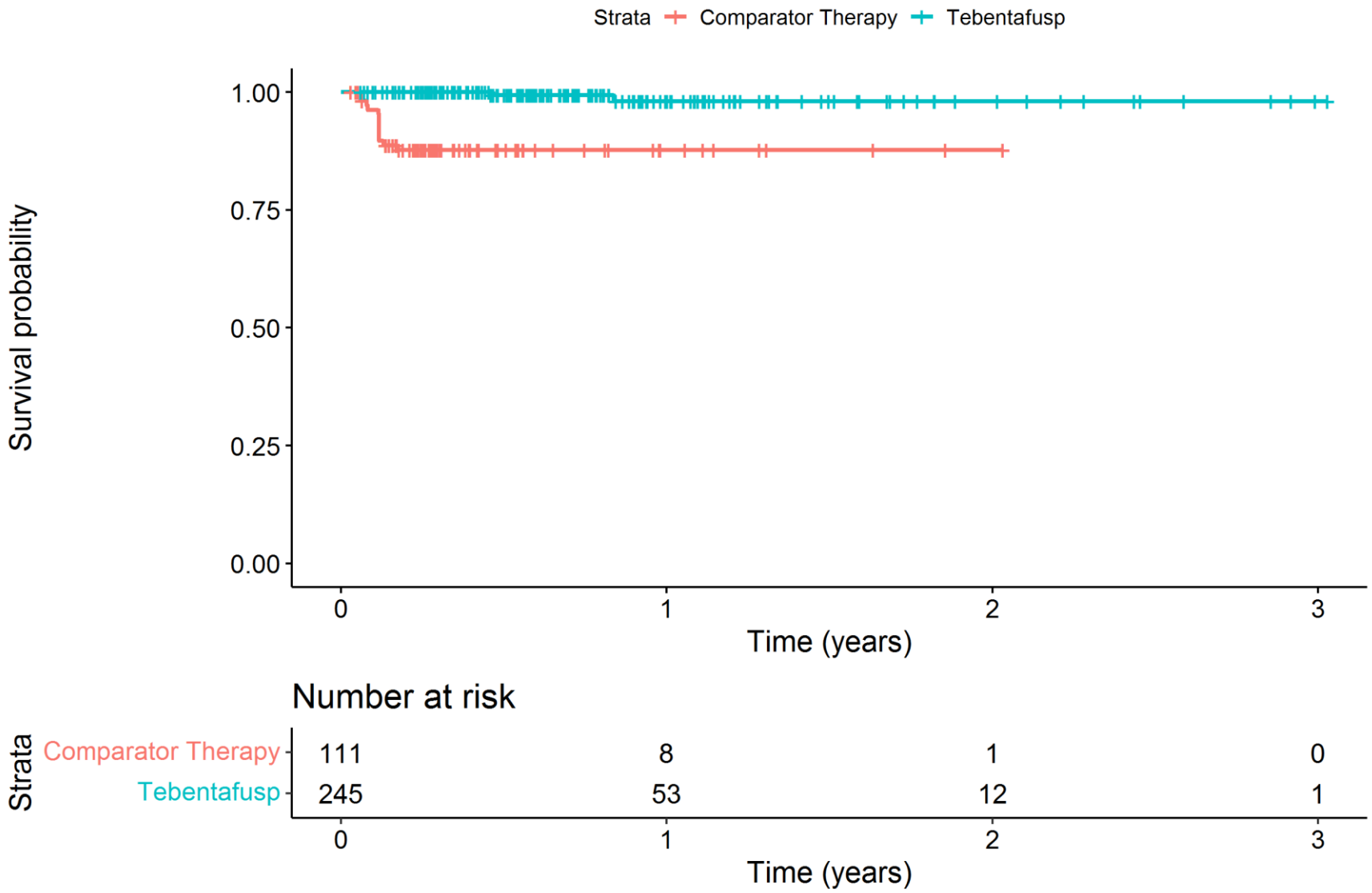
2.1 Anämie



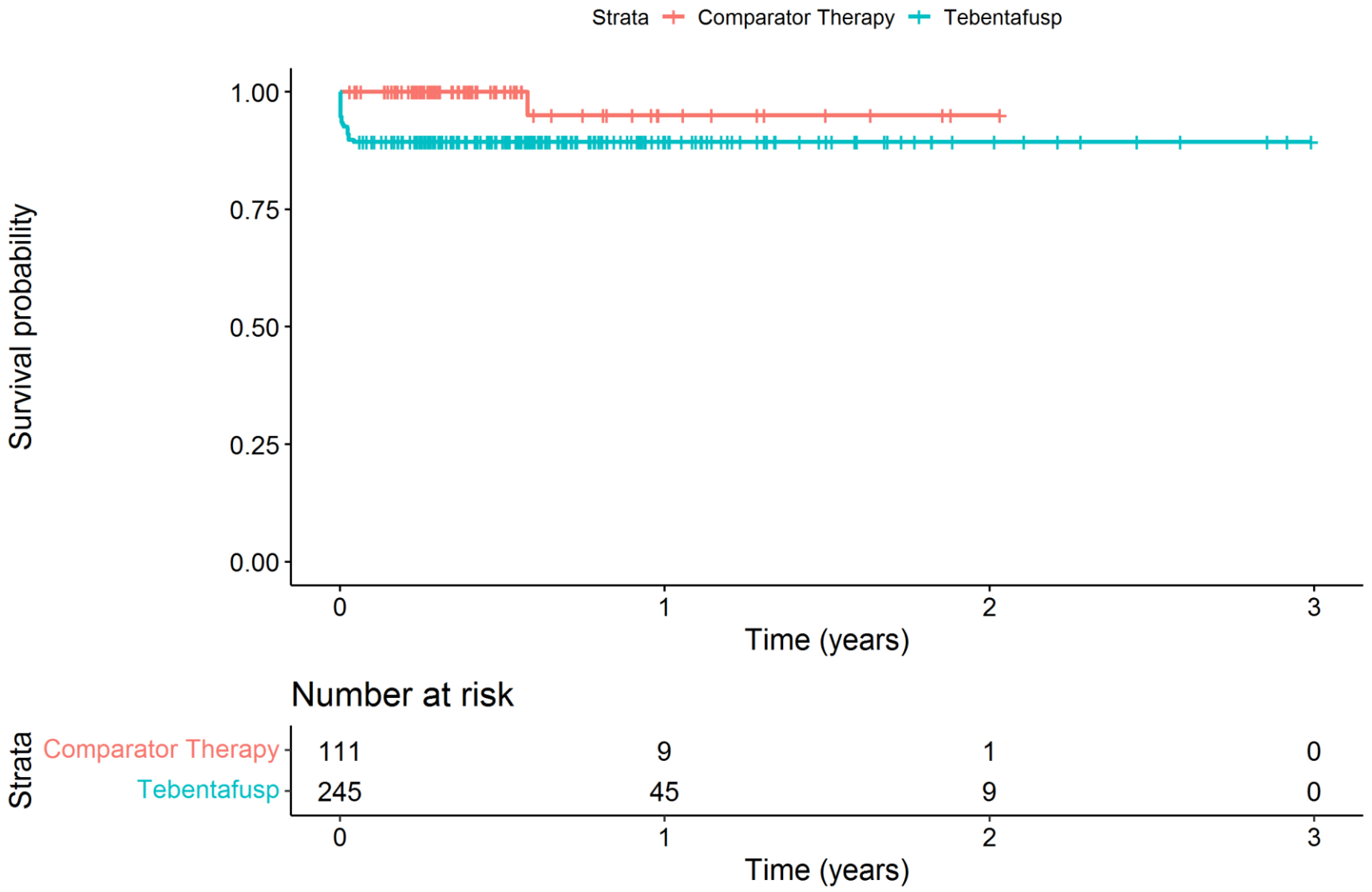
2.2 Hypothyreose



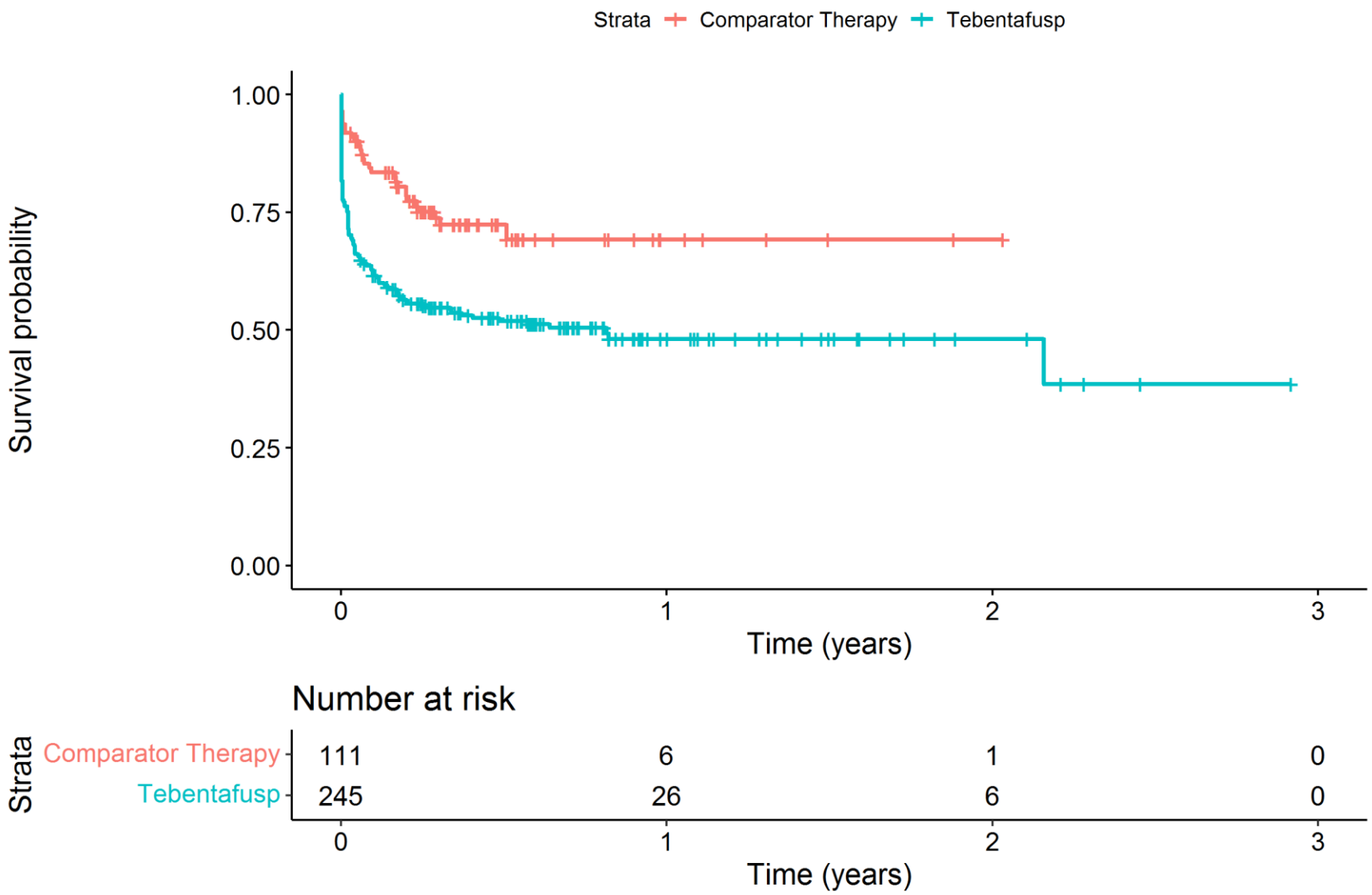
2.3 Hyperthyreose



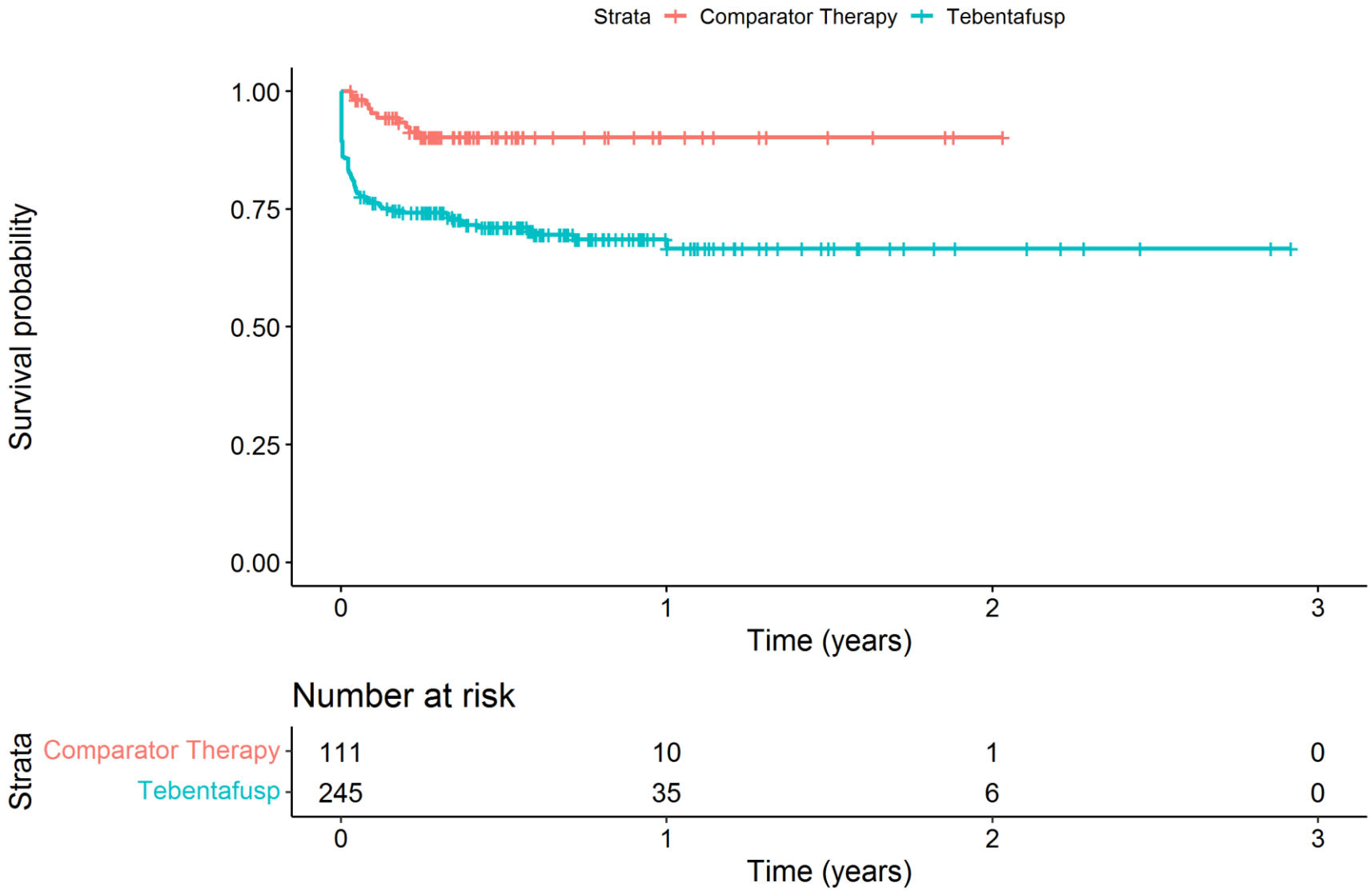
2.4 Periorbitales Ödem



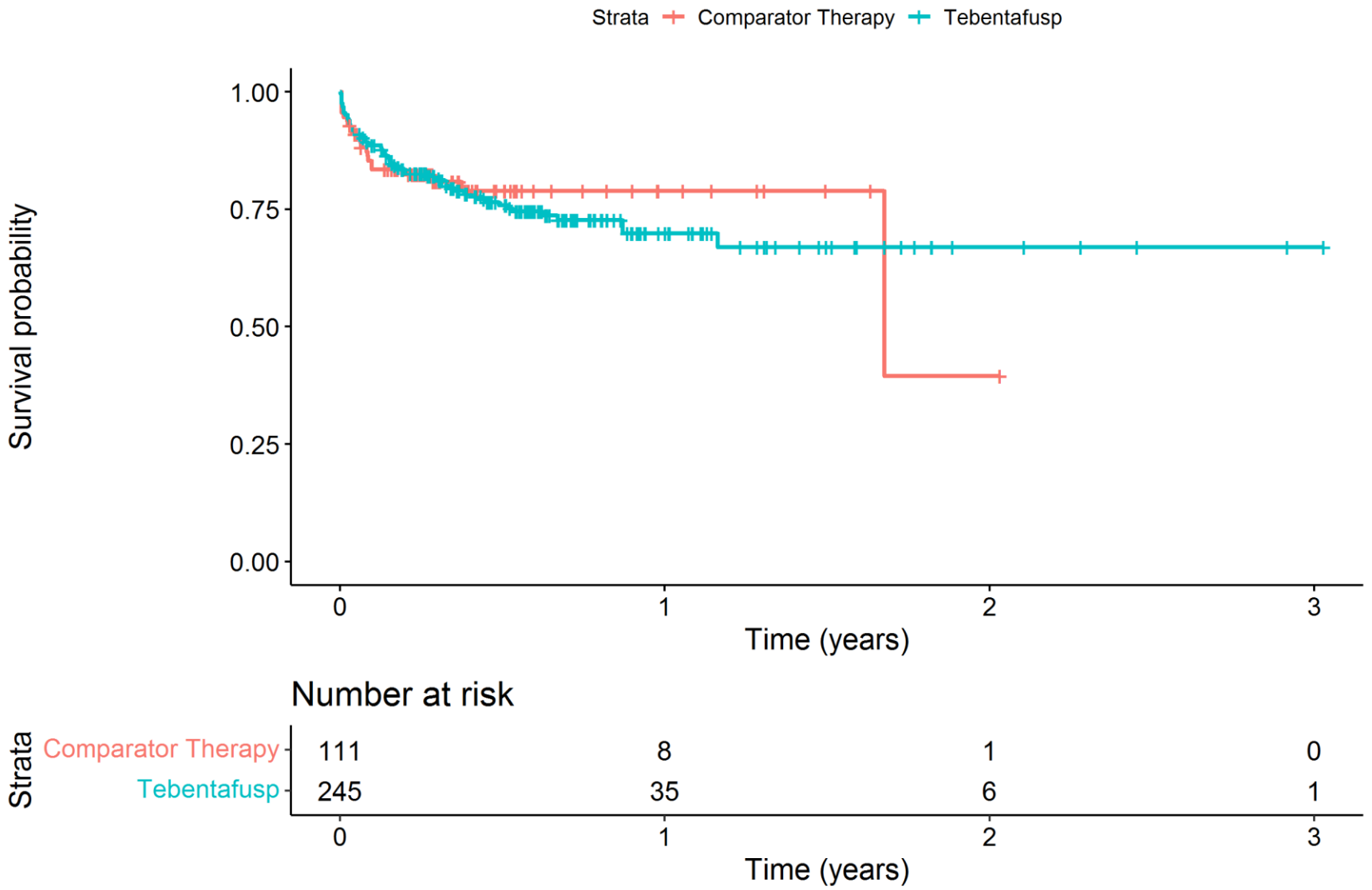
2.5 Übelkeit


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
6
1
0
245
26
6
0
0
1
2
3
Time (years)

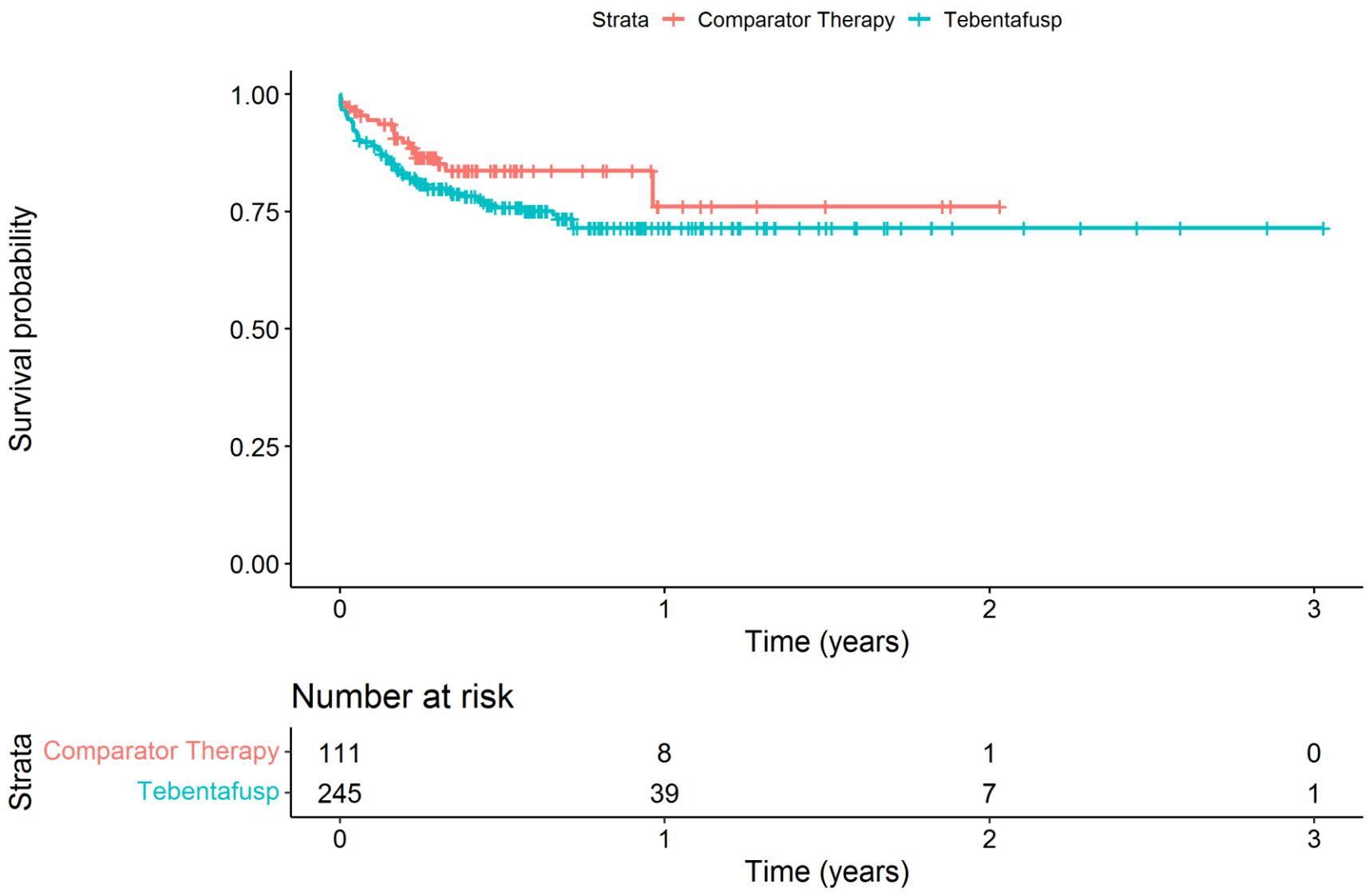
2.6 Erbrechen



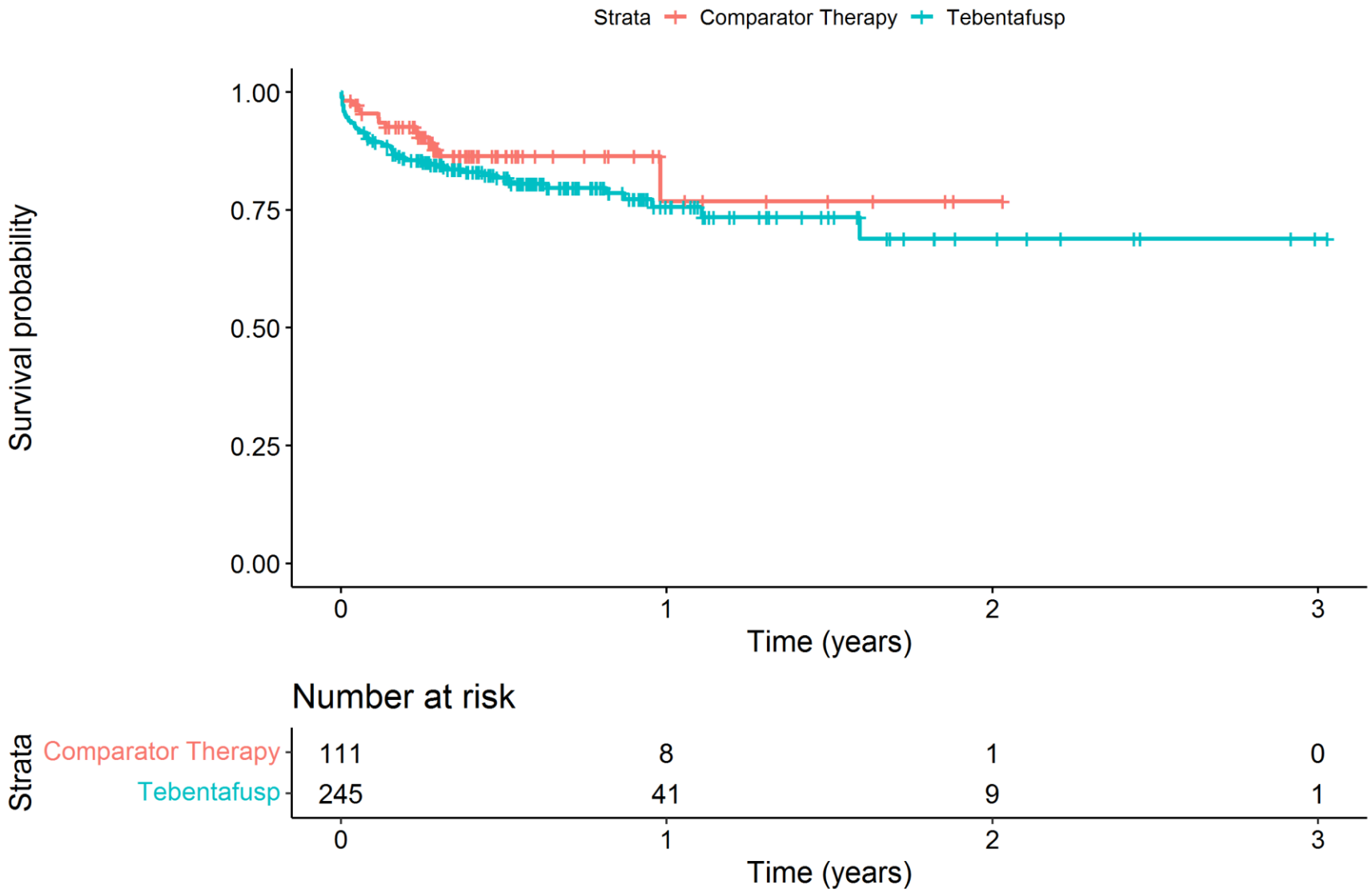
2.7 Diarrhoe


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
8
1
0
245
35
6
1
0
1
2
3
Time (years)

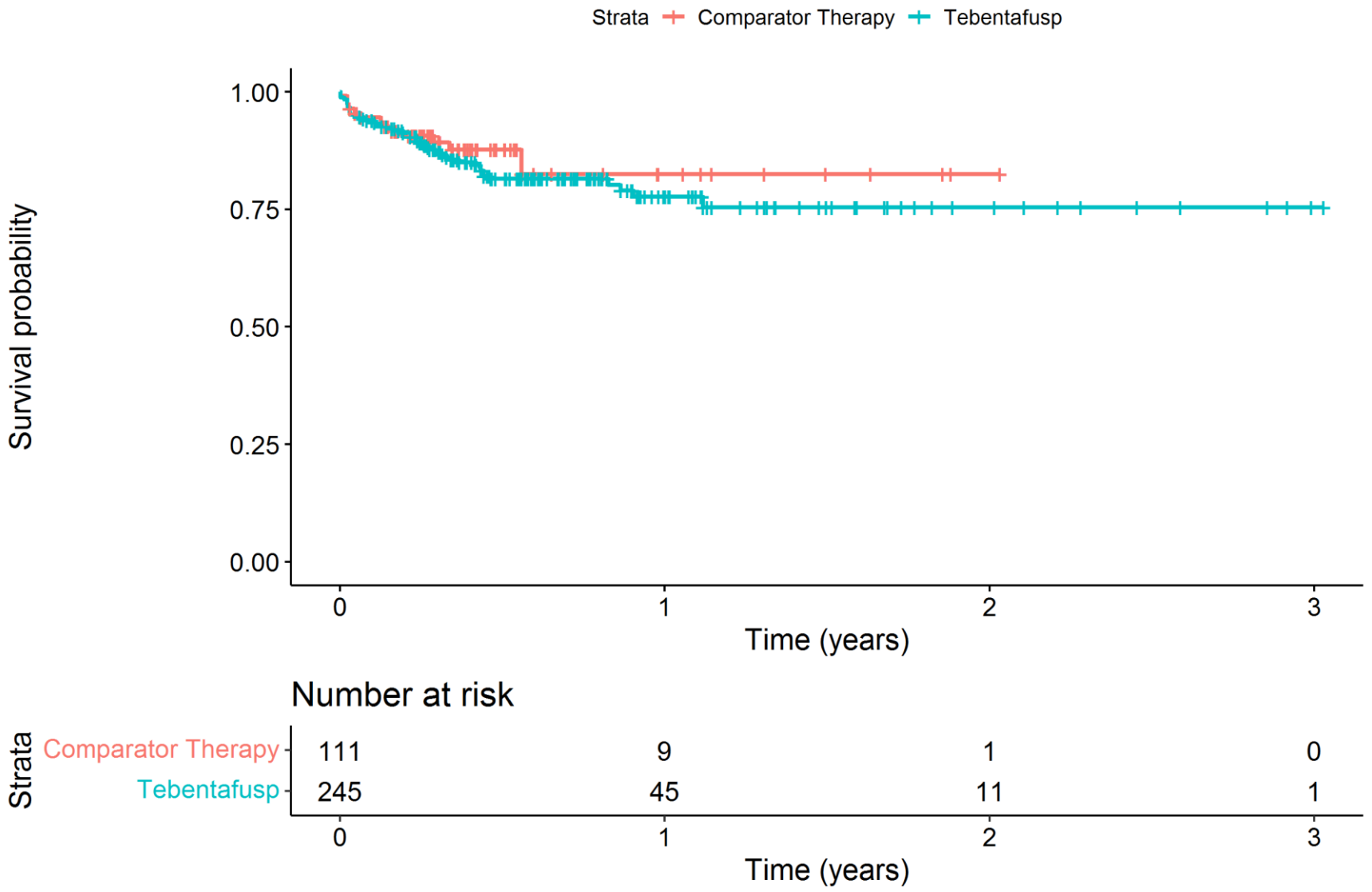
2.8 Unterleibschmerzen



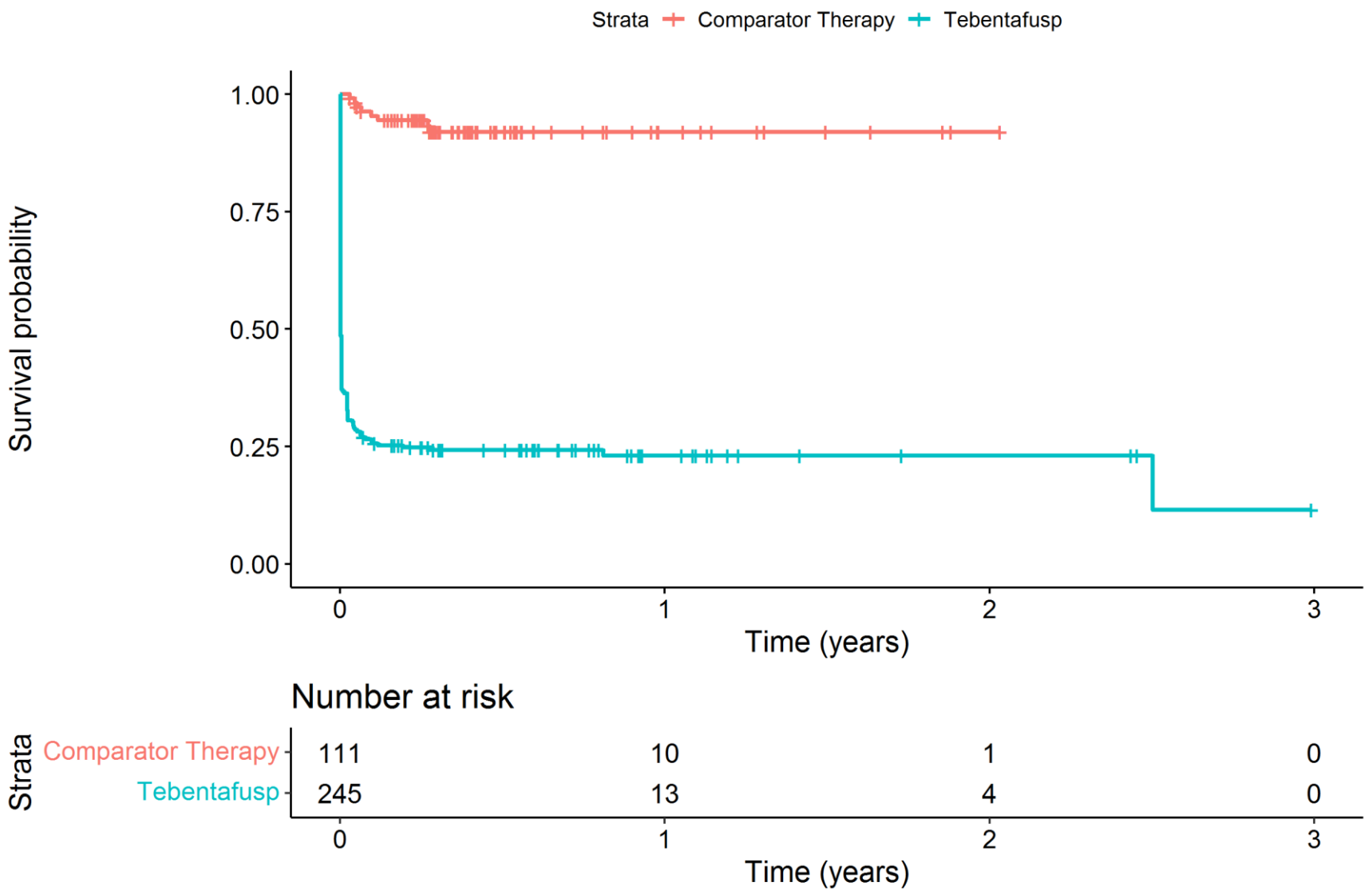
2.9 Oberbauchschmerzen



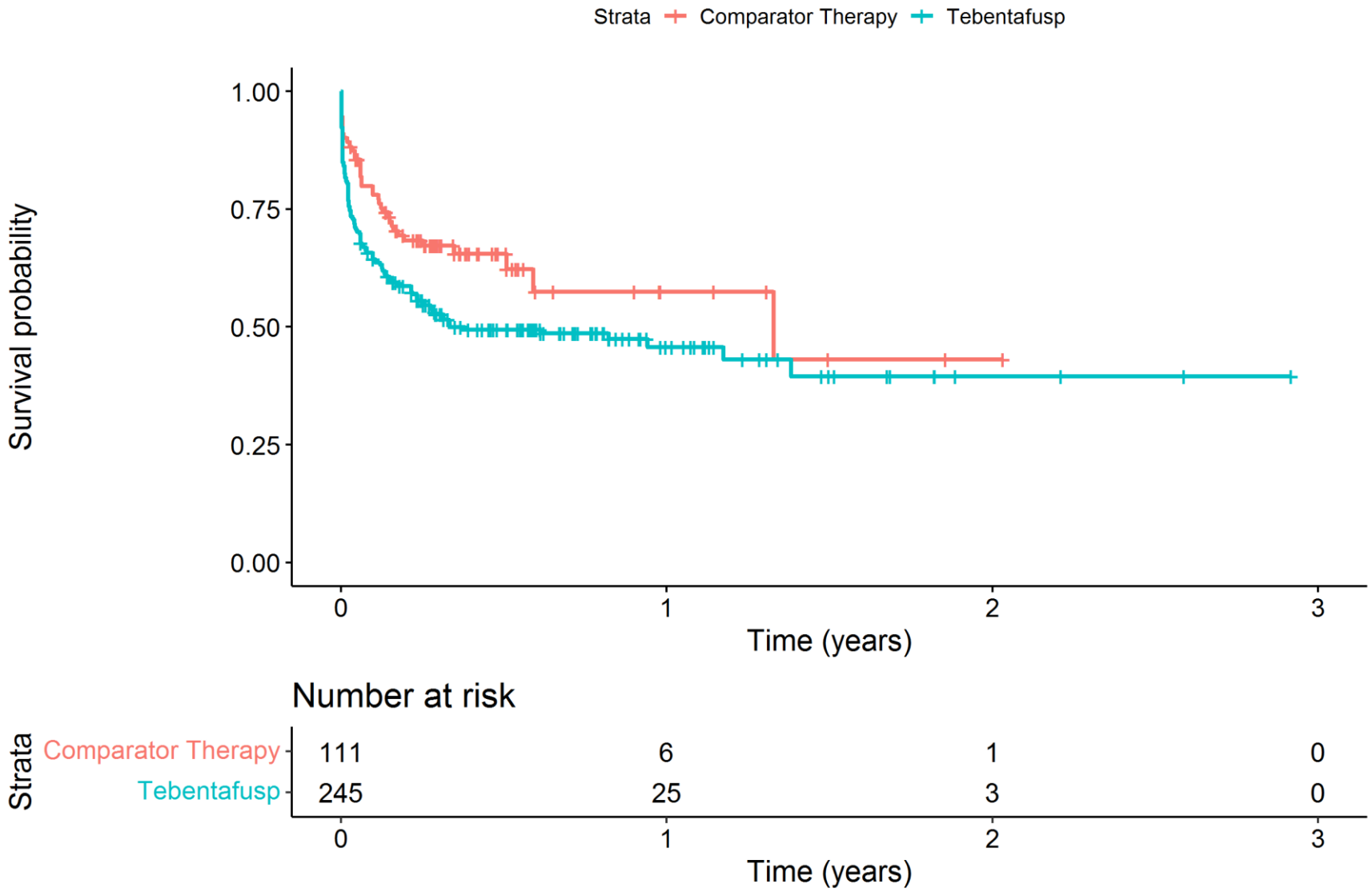
2.10 Verstopfung



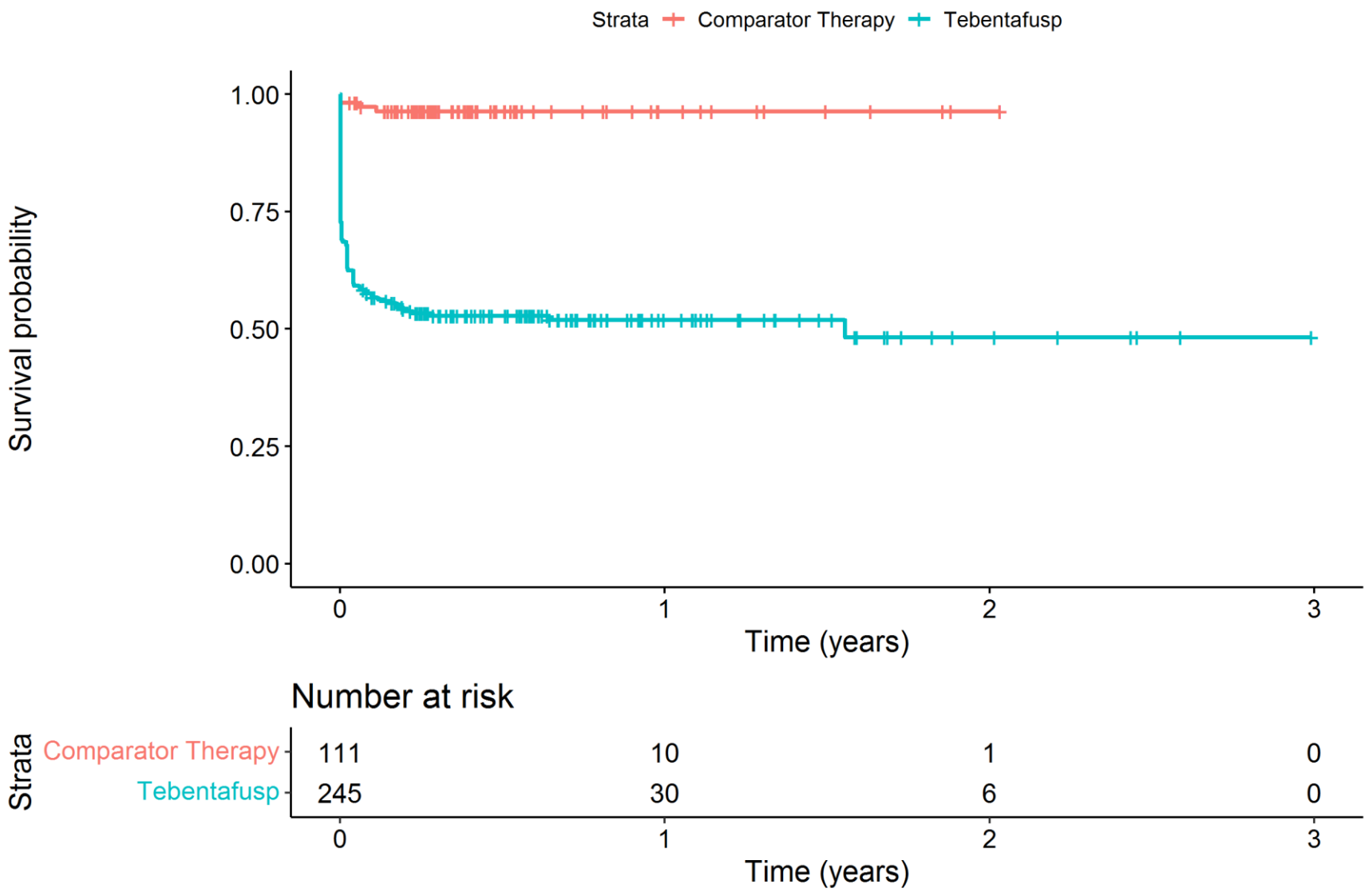
2.11 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
13
4
0
0
1
2
3
Time (years)

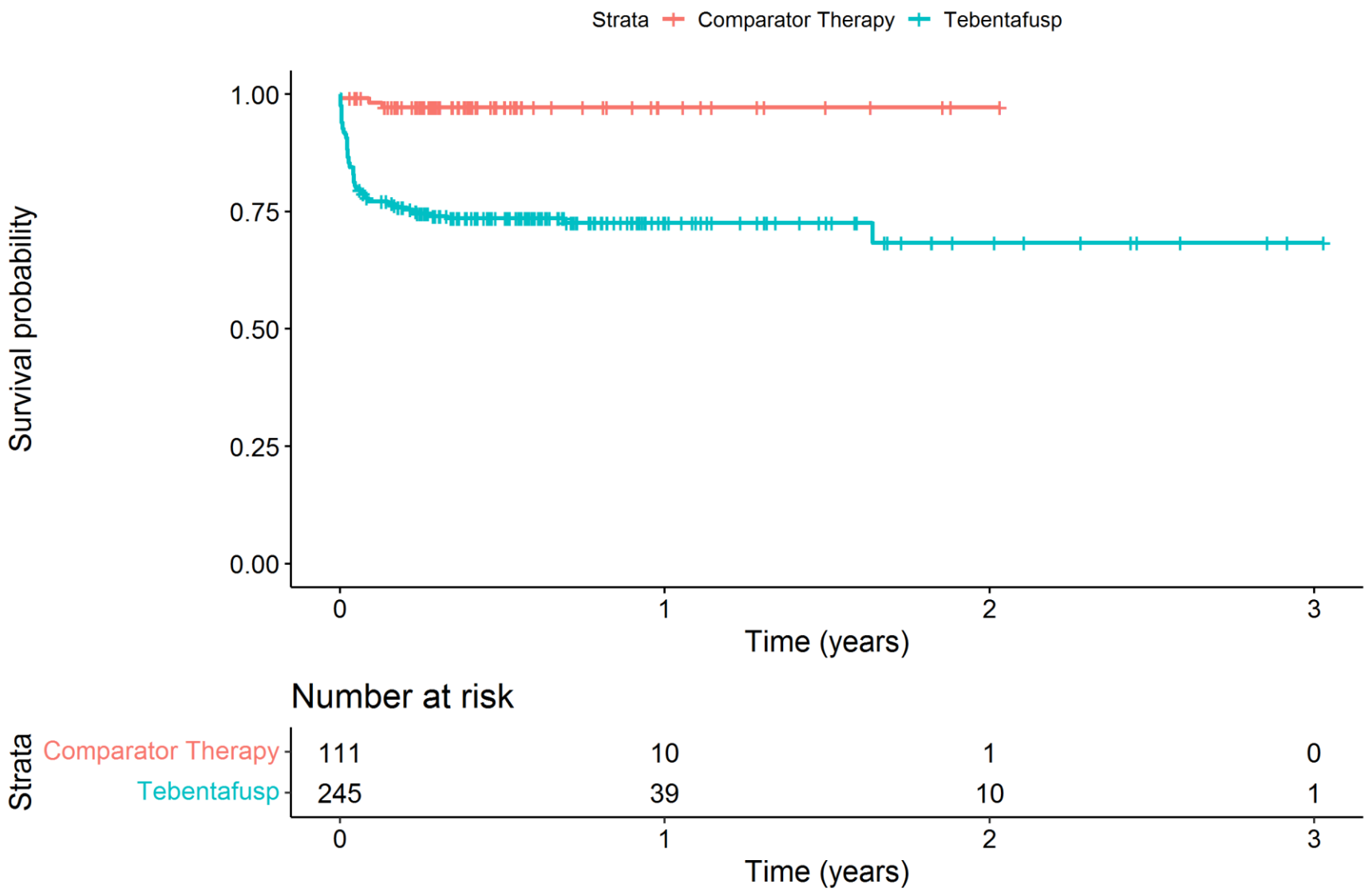
2.12 Müdigkeit



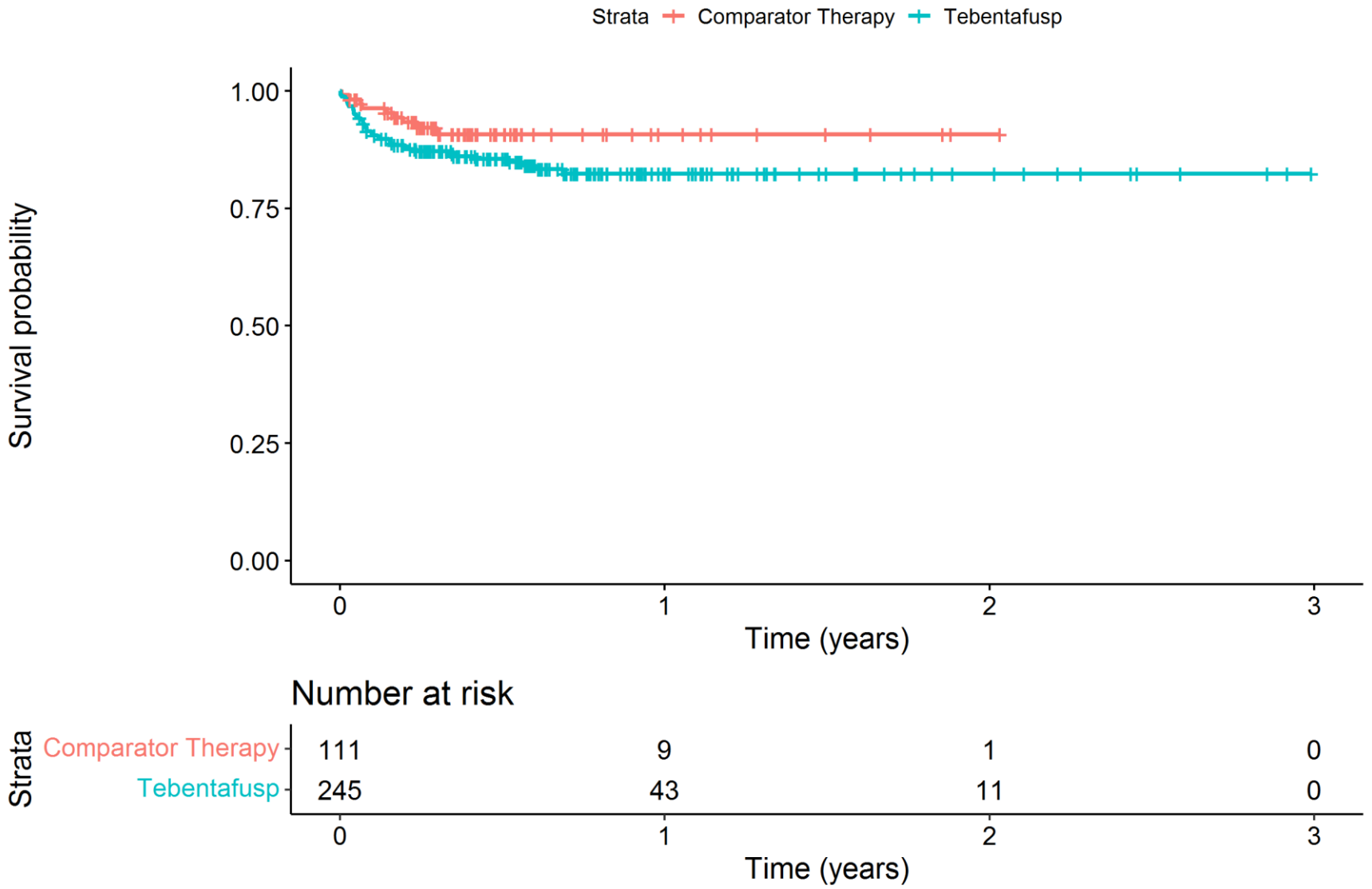
2.13 Schüttelfrost



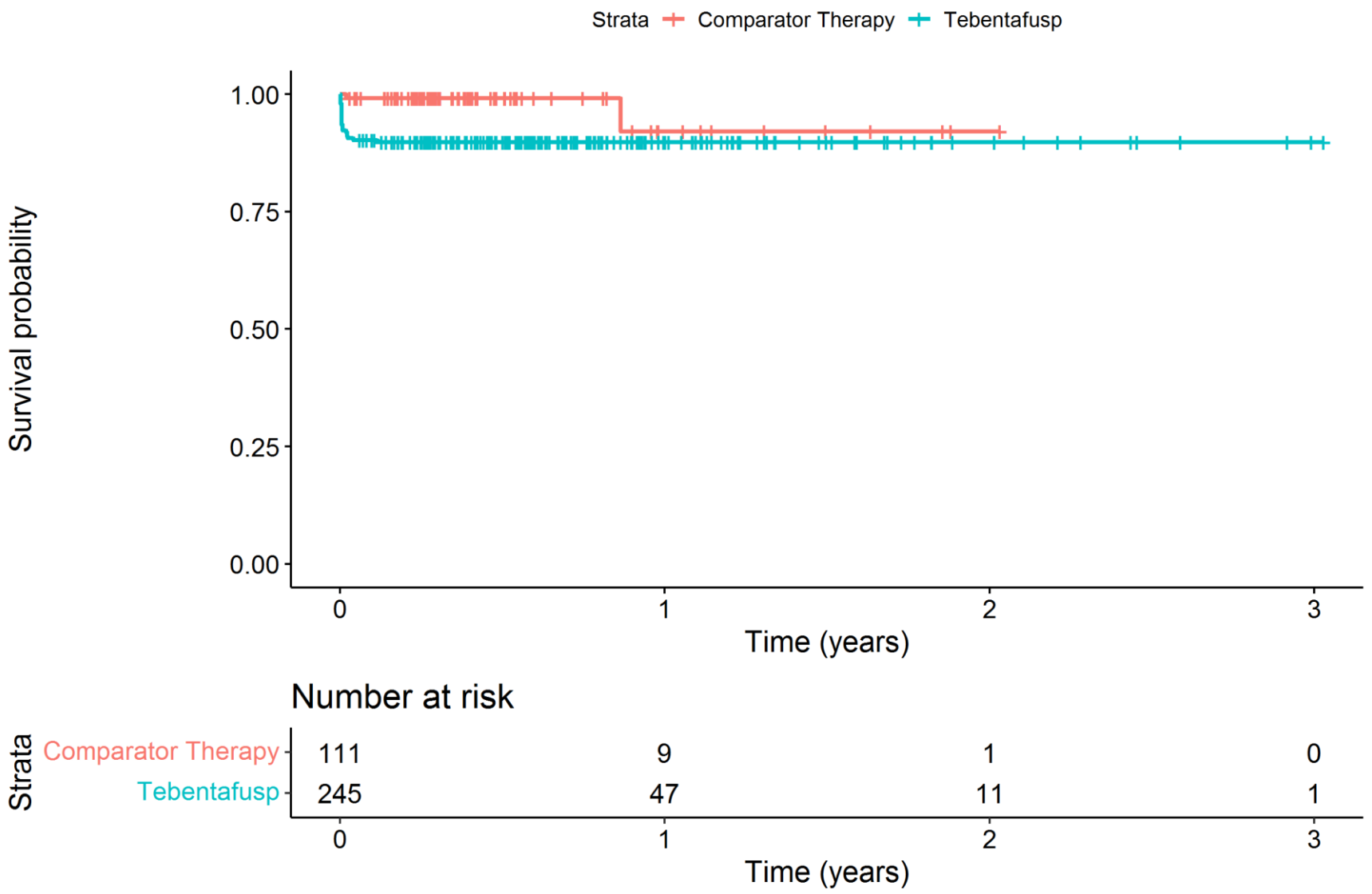
2.14 Periphere Öd eme



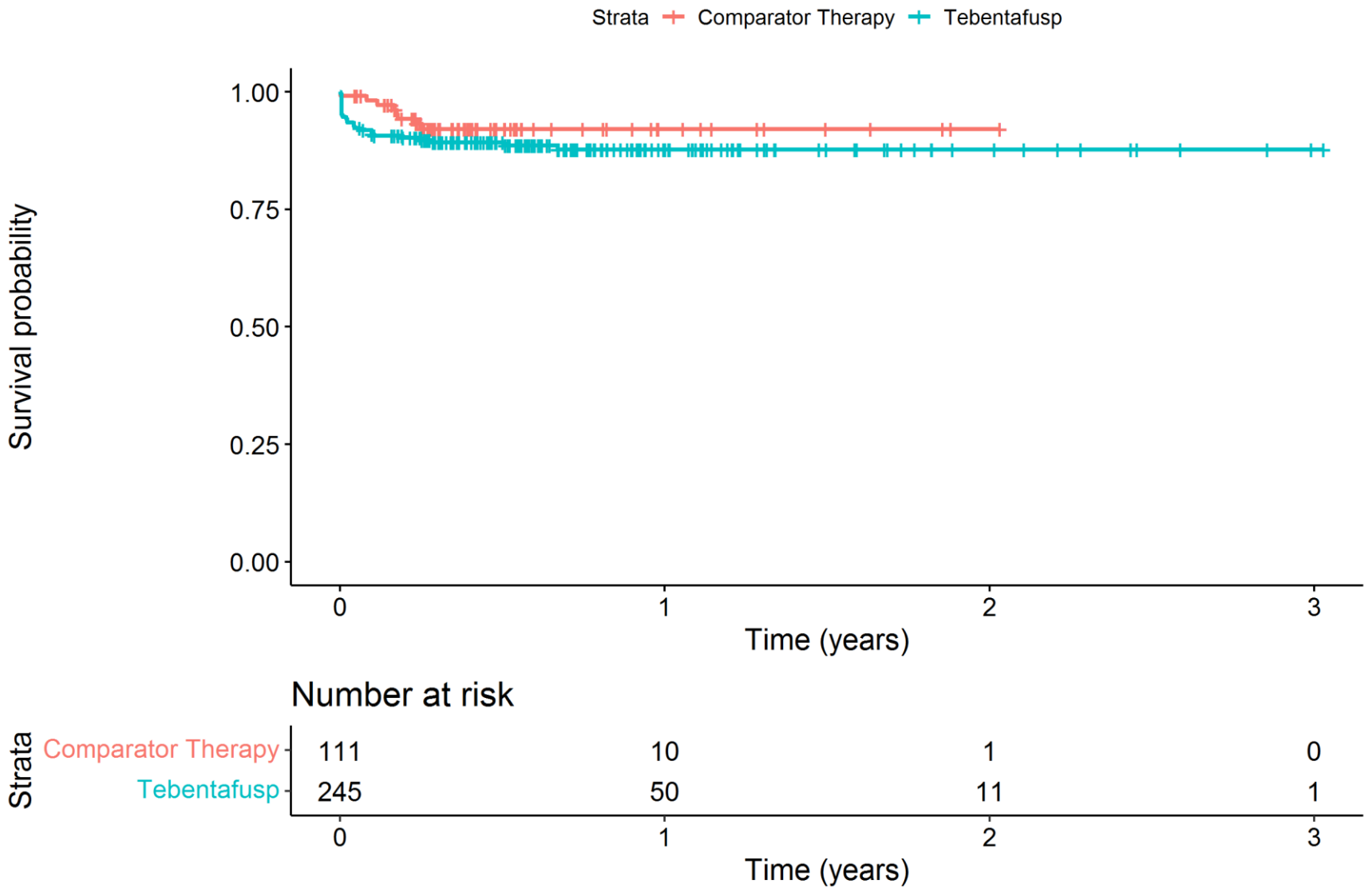
2.15 Asthenie



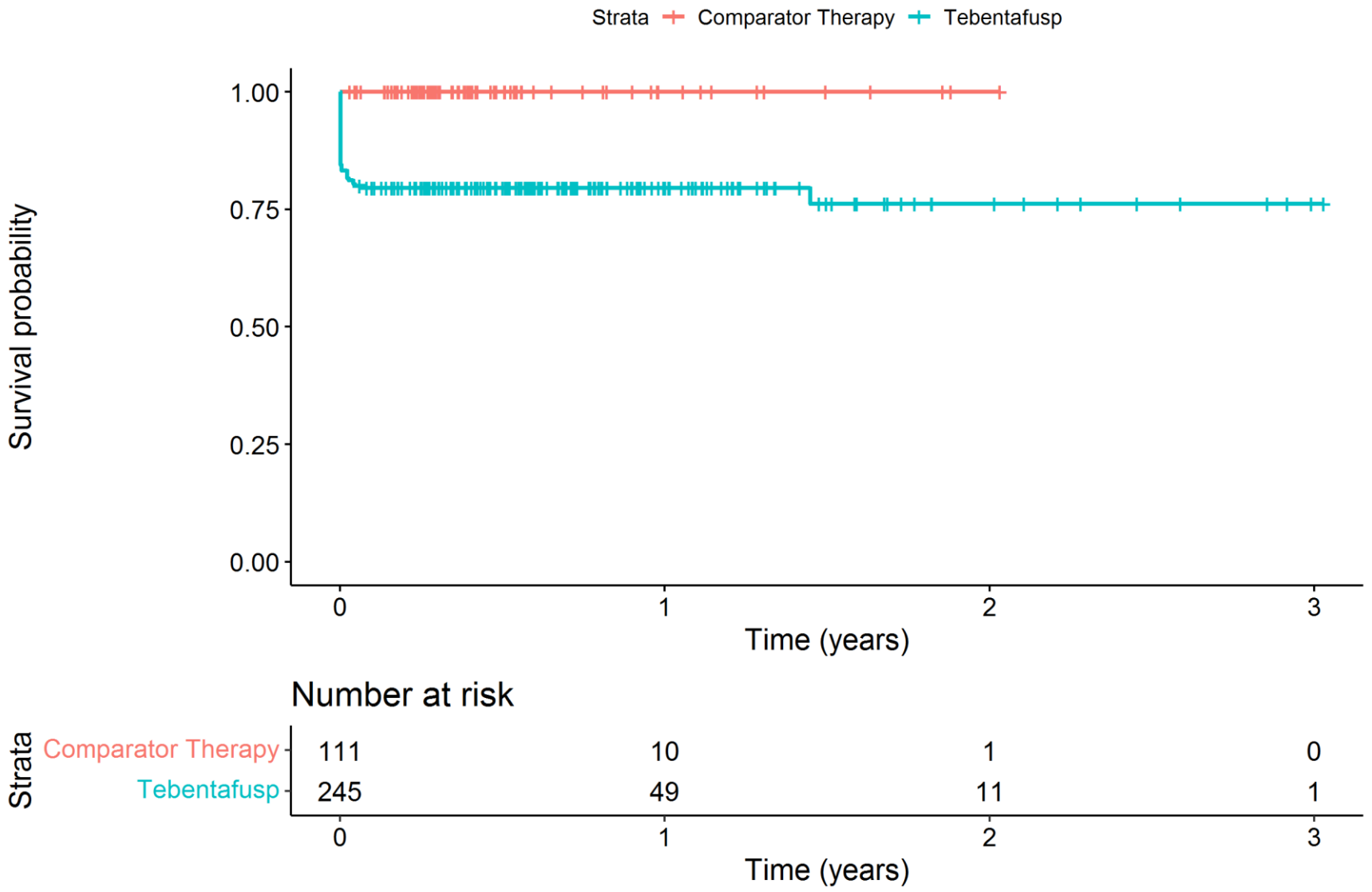
2.16 Gesichtsödeme



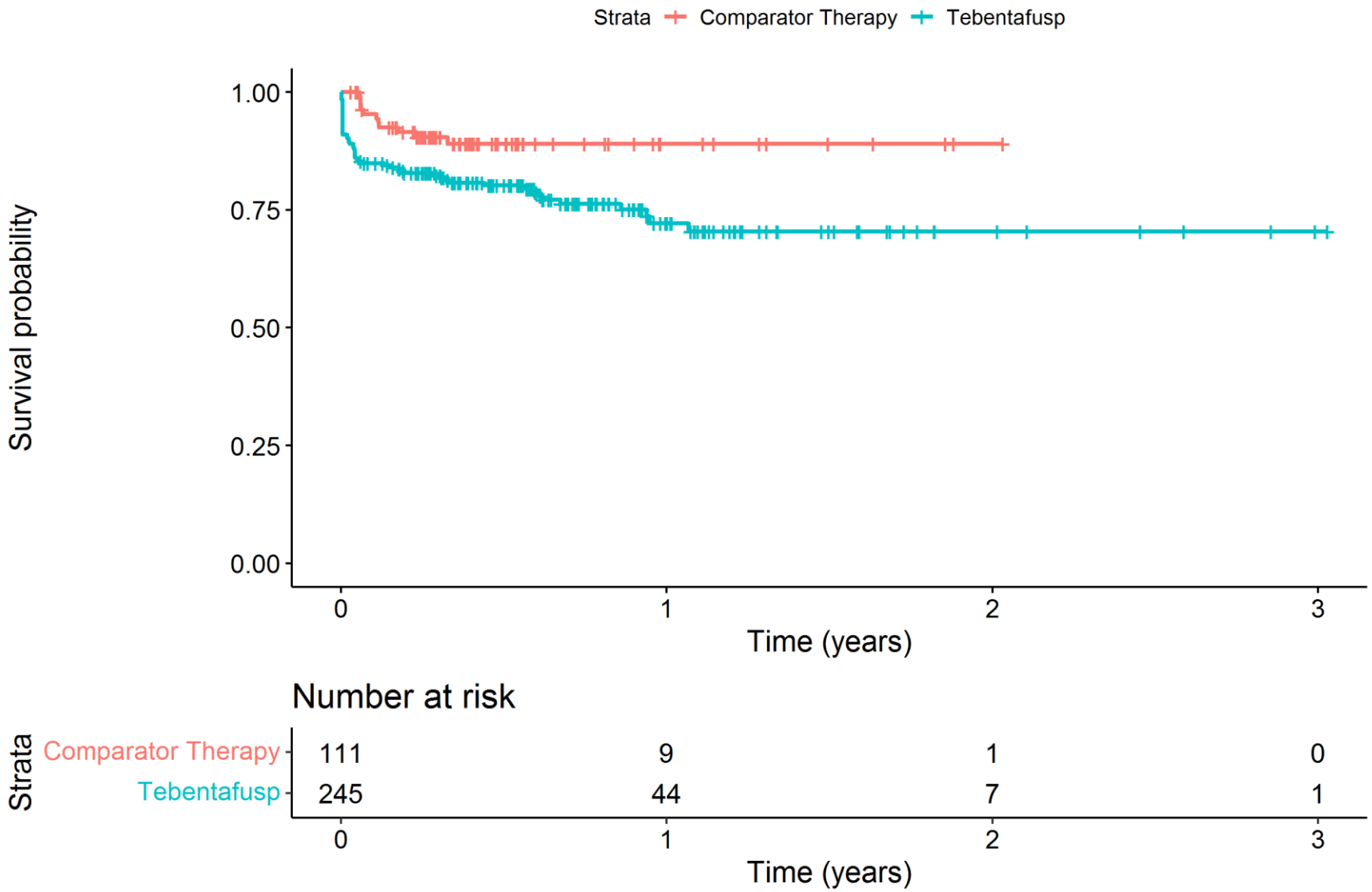
2.17 Hyperbilirubinämie



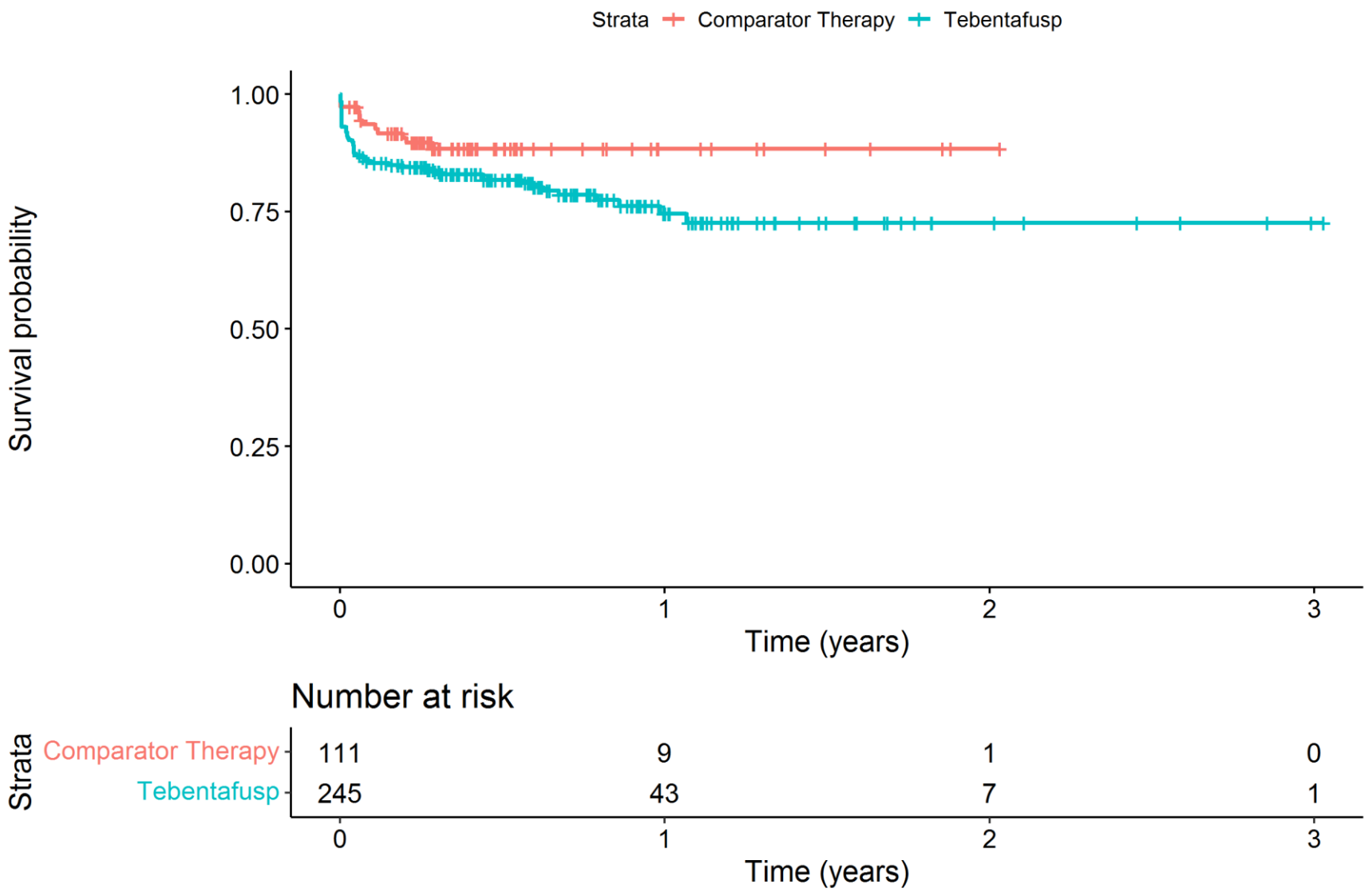
2.18 Zytokin-Freisetzungssyndrom



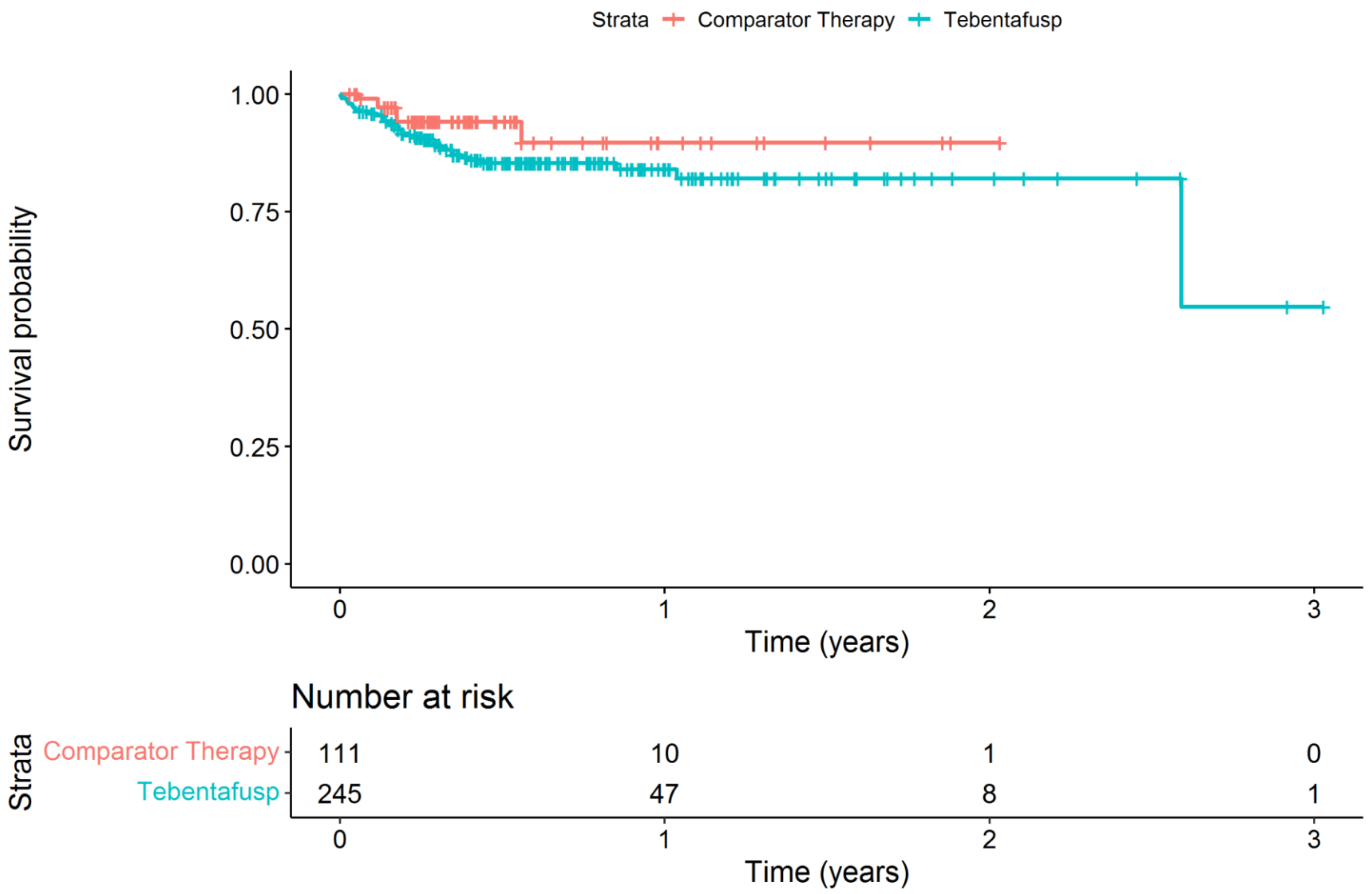
2.19 Erhöhte Aspartat-Aminotransferase



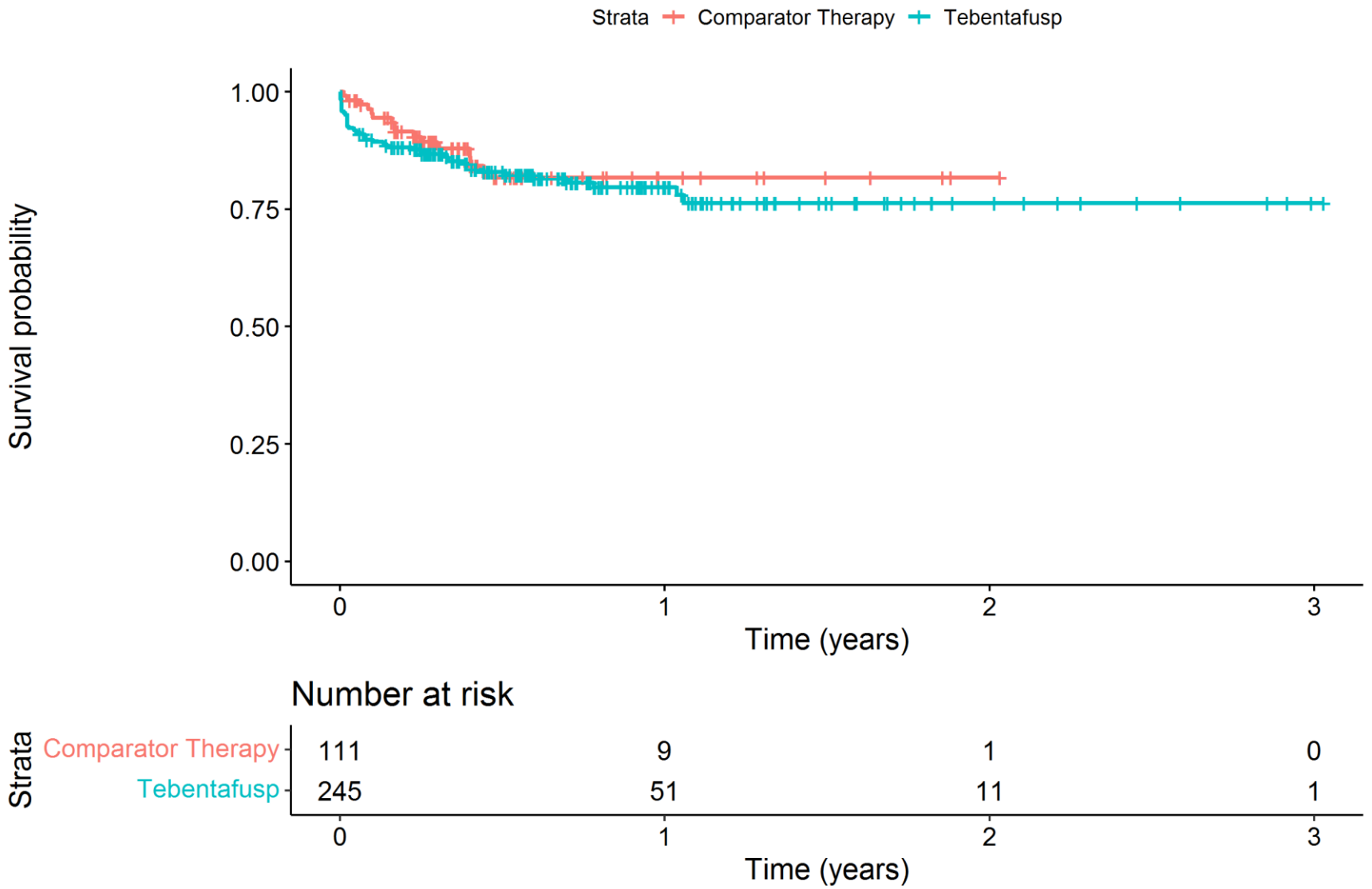
2.20 Erhöhte Alanin-Aminotransferase



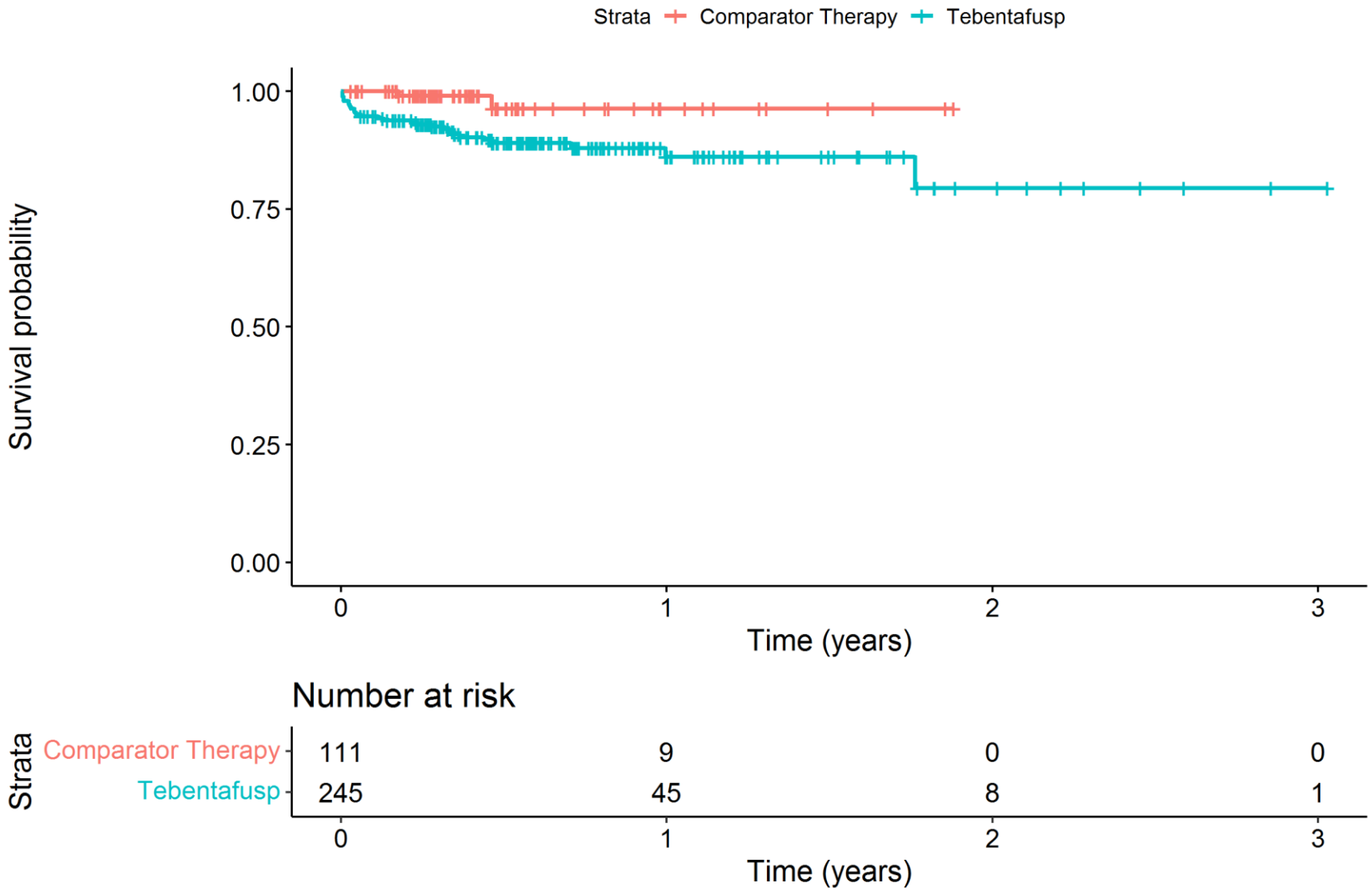
2.21 Erhöhte Lipase



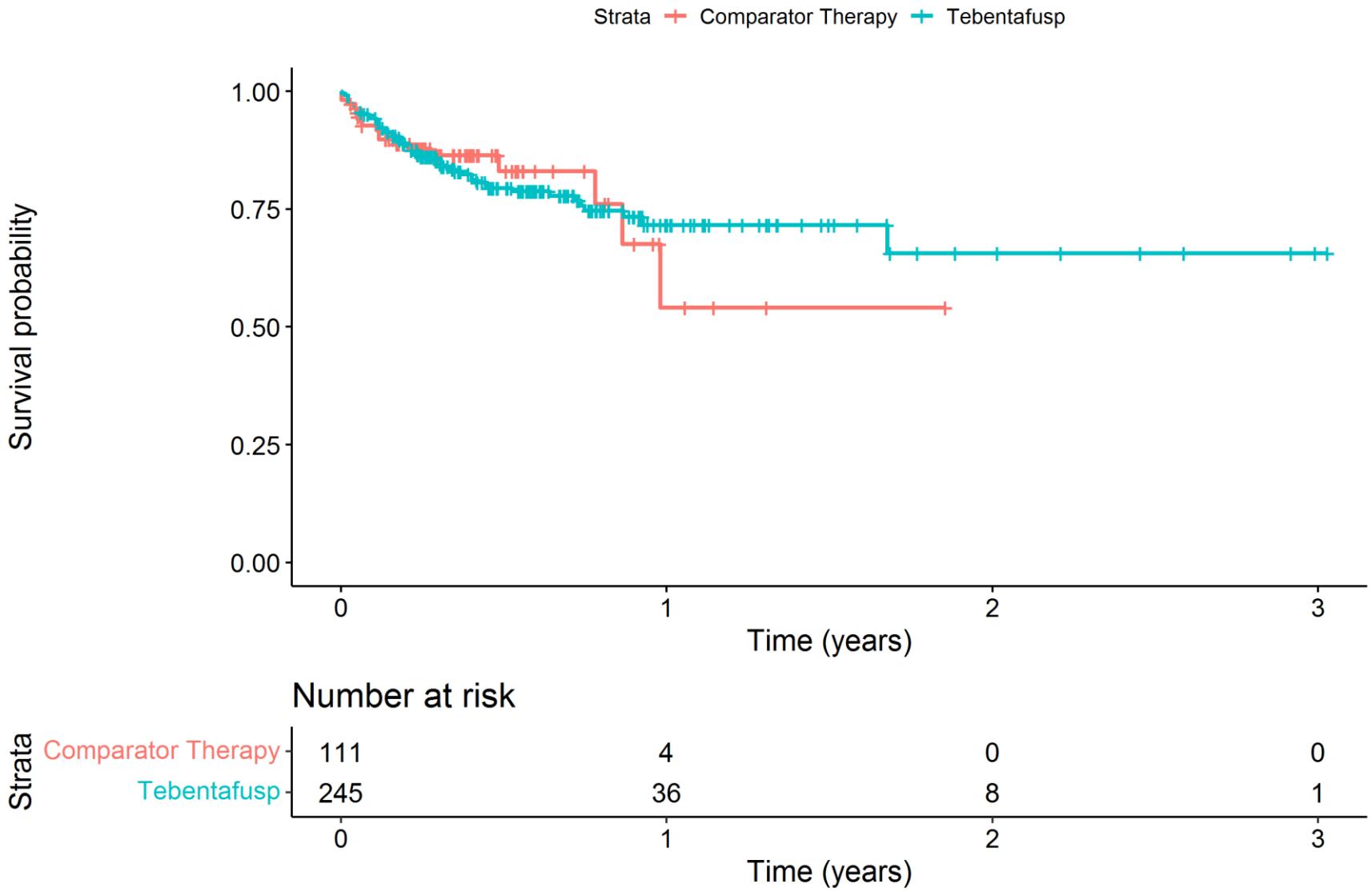
2.22 Verminderter Appetit



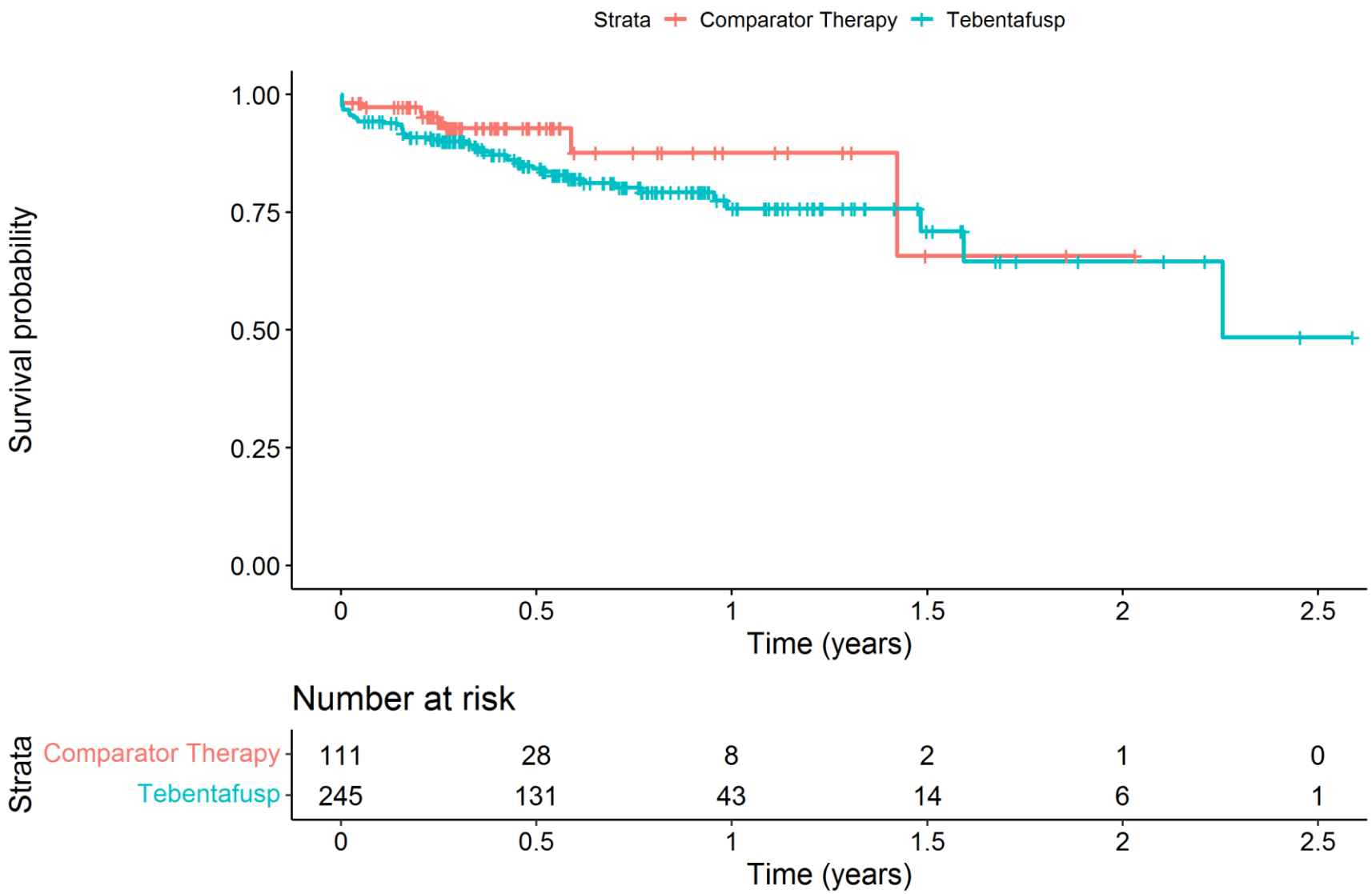
2.23 Hypophosphatämie



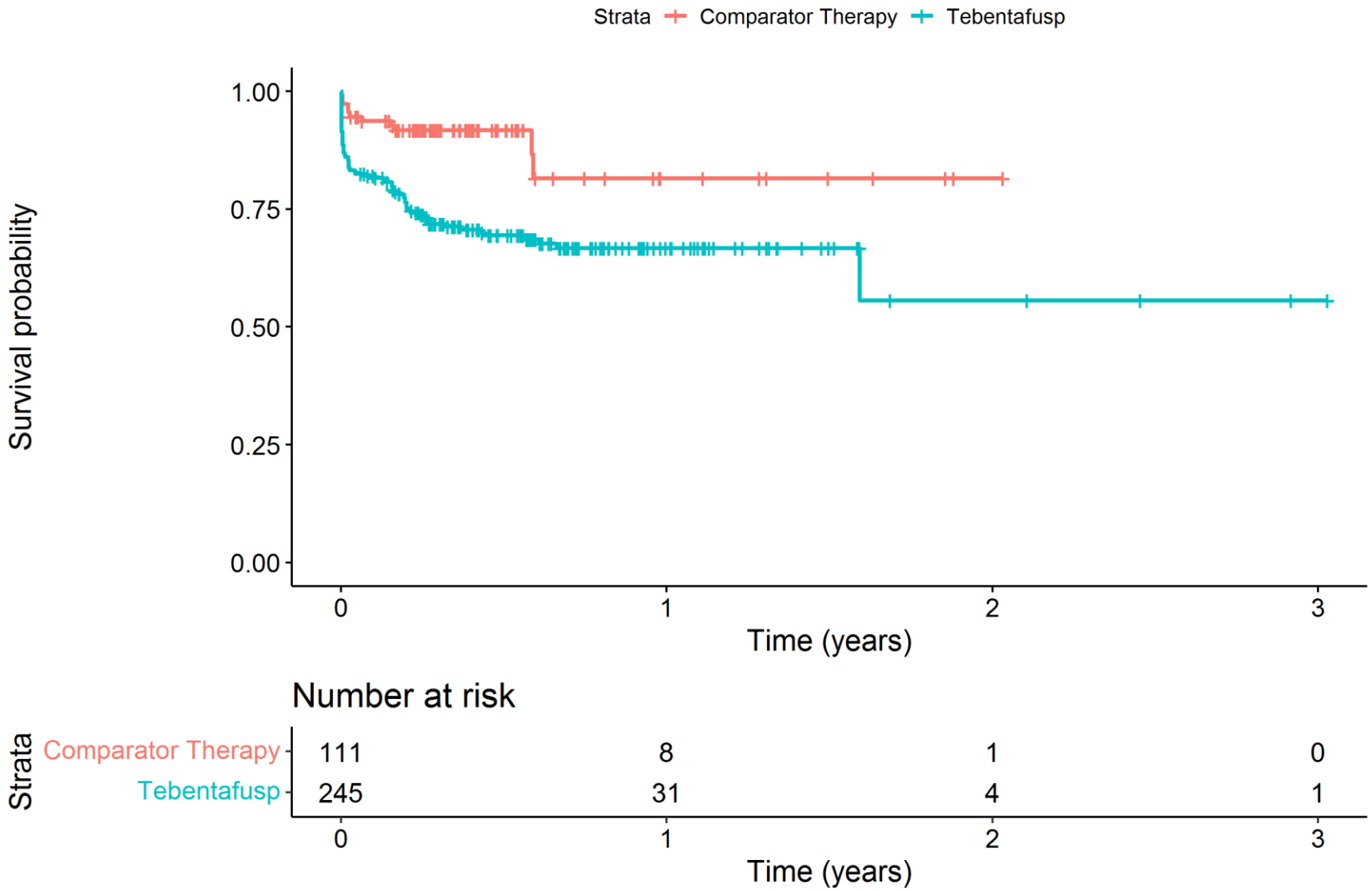
2.24 Arthralgie



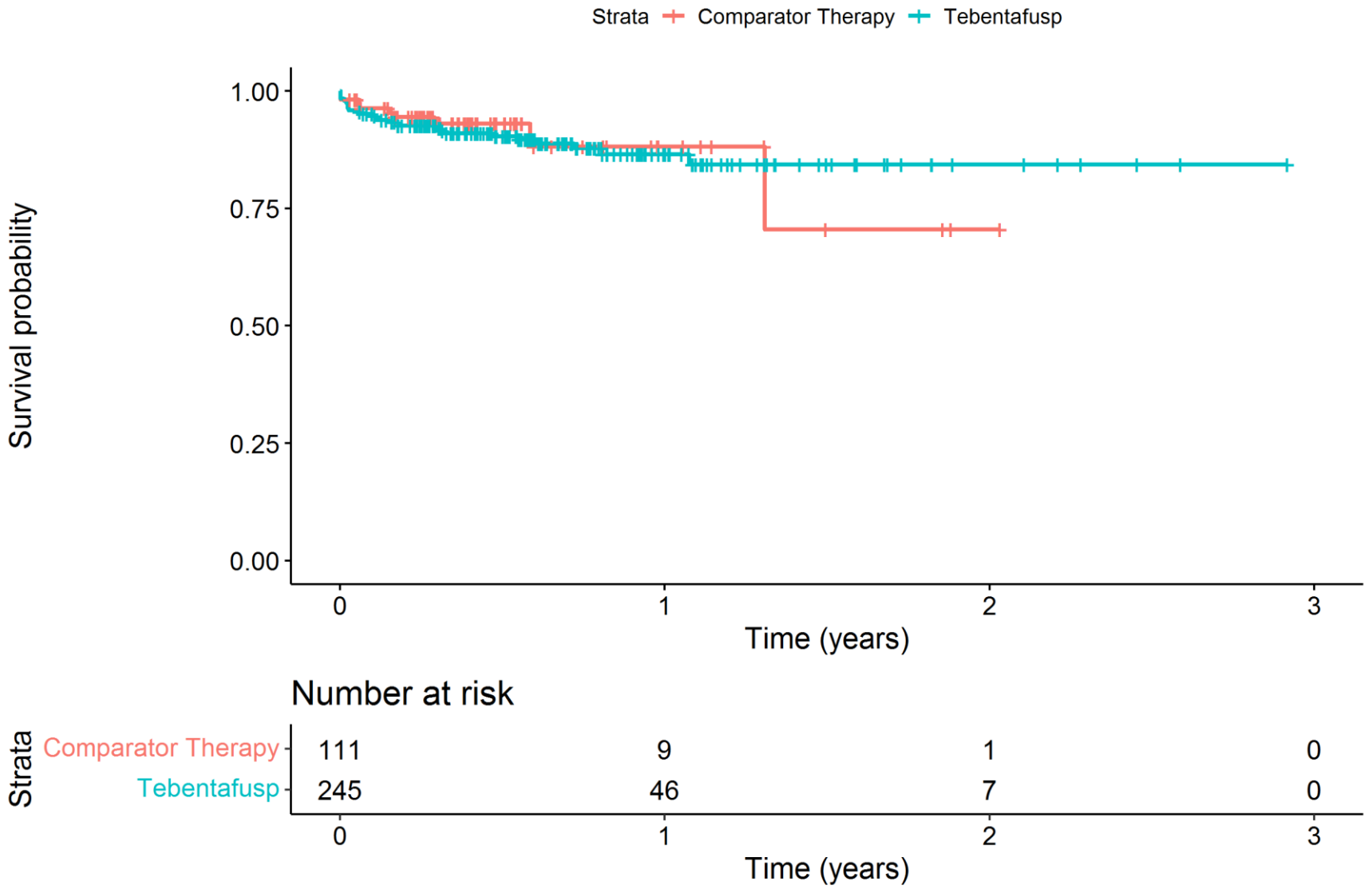
2.25 Rückenschmerzen



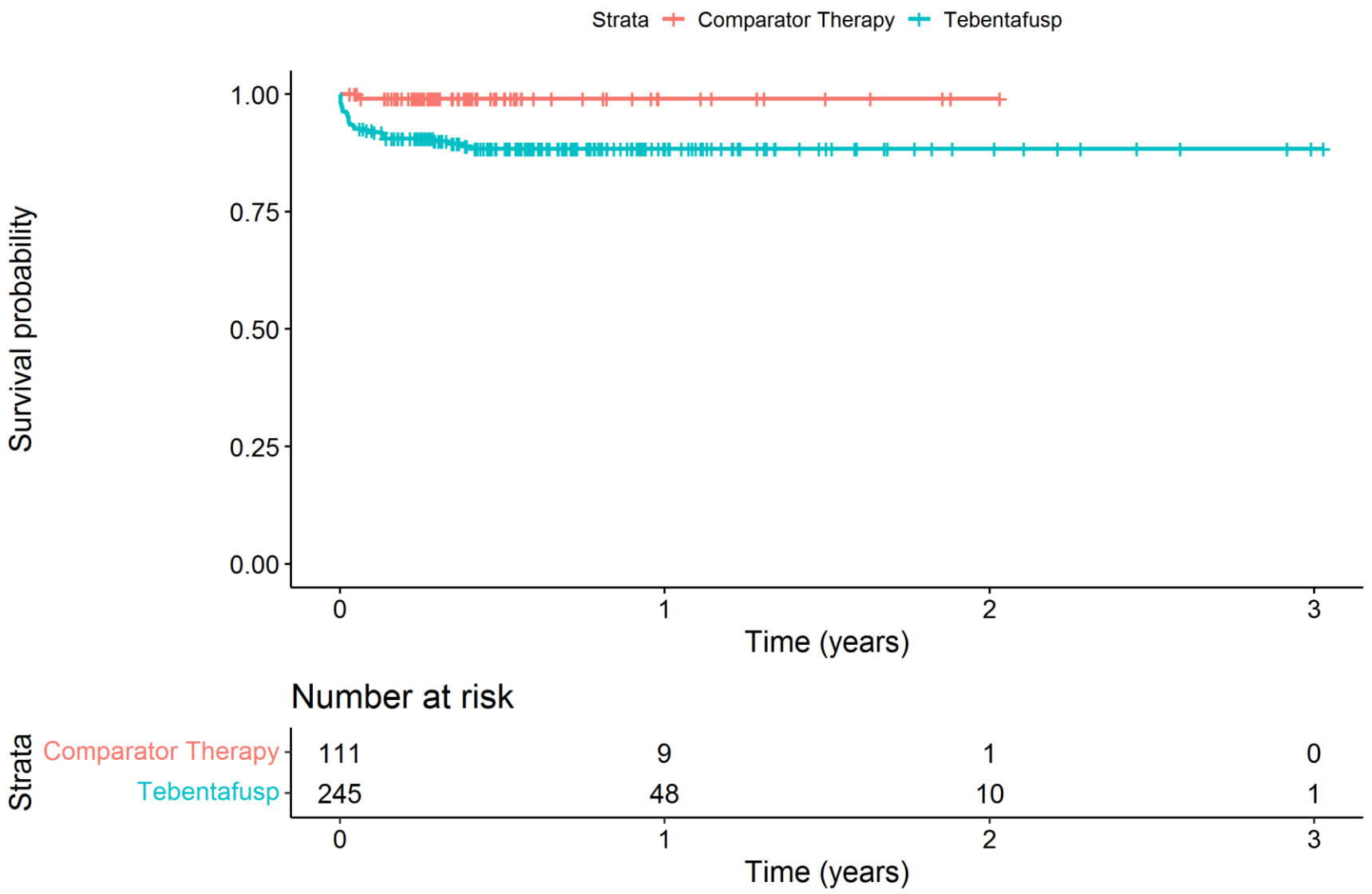
2.26 Kopfschmerzen



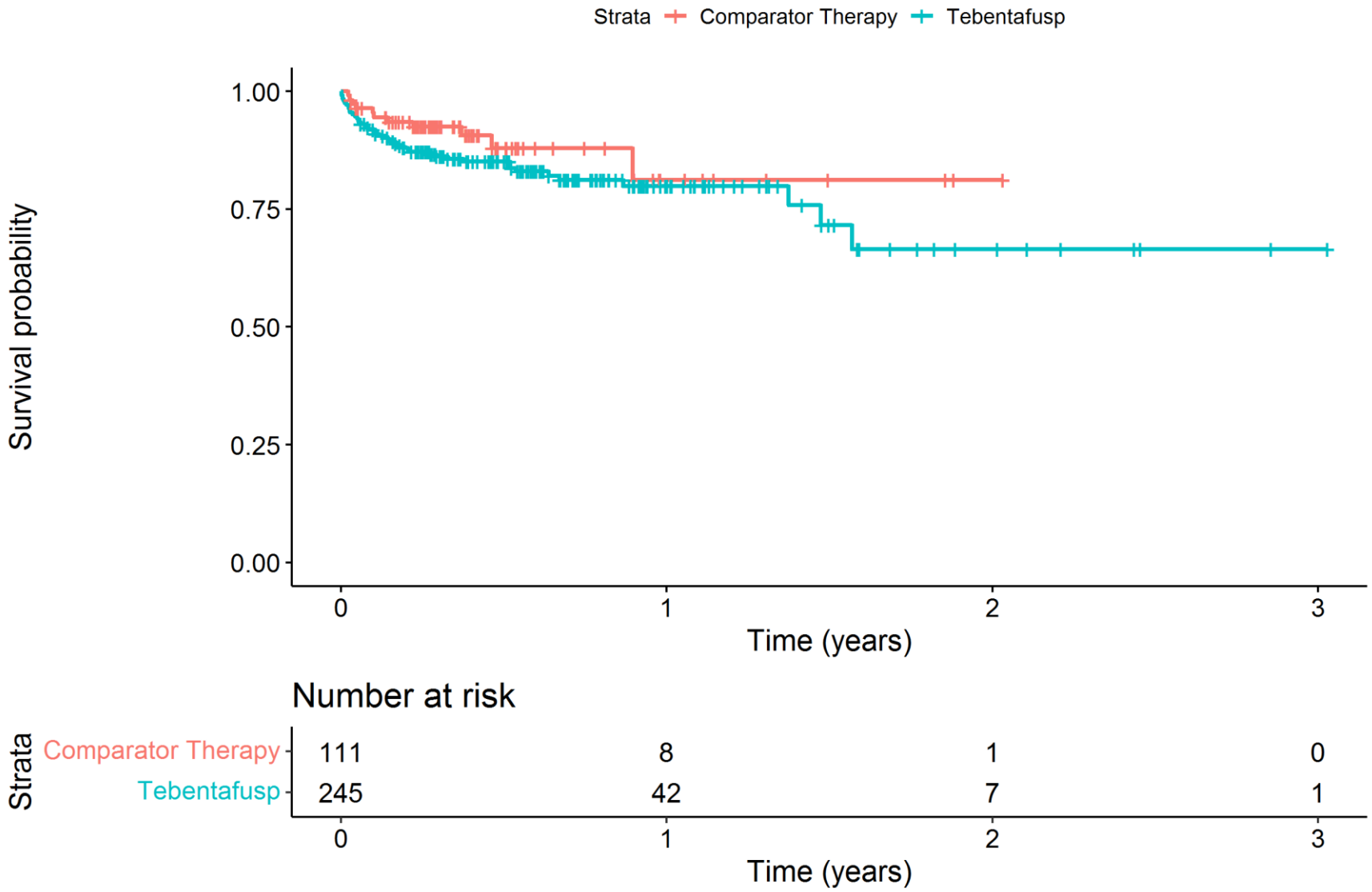
2.27 Schwindel



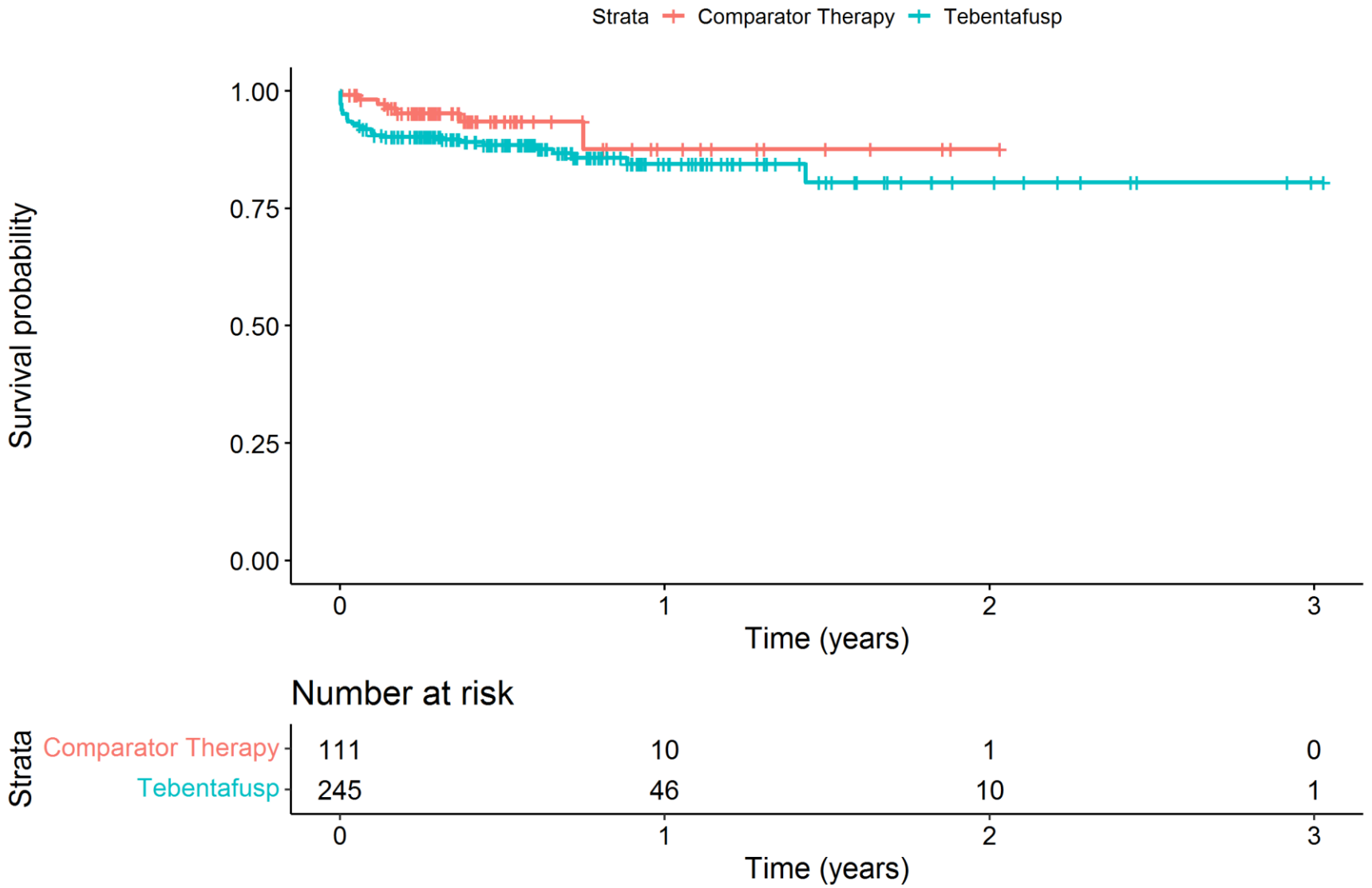
2.28 Parästhesie



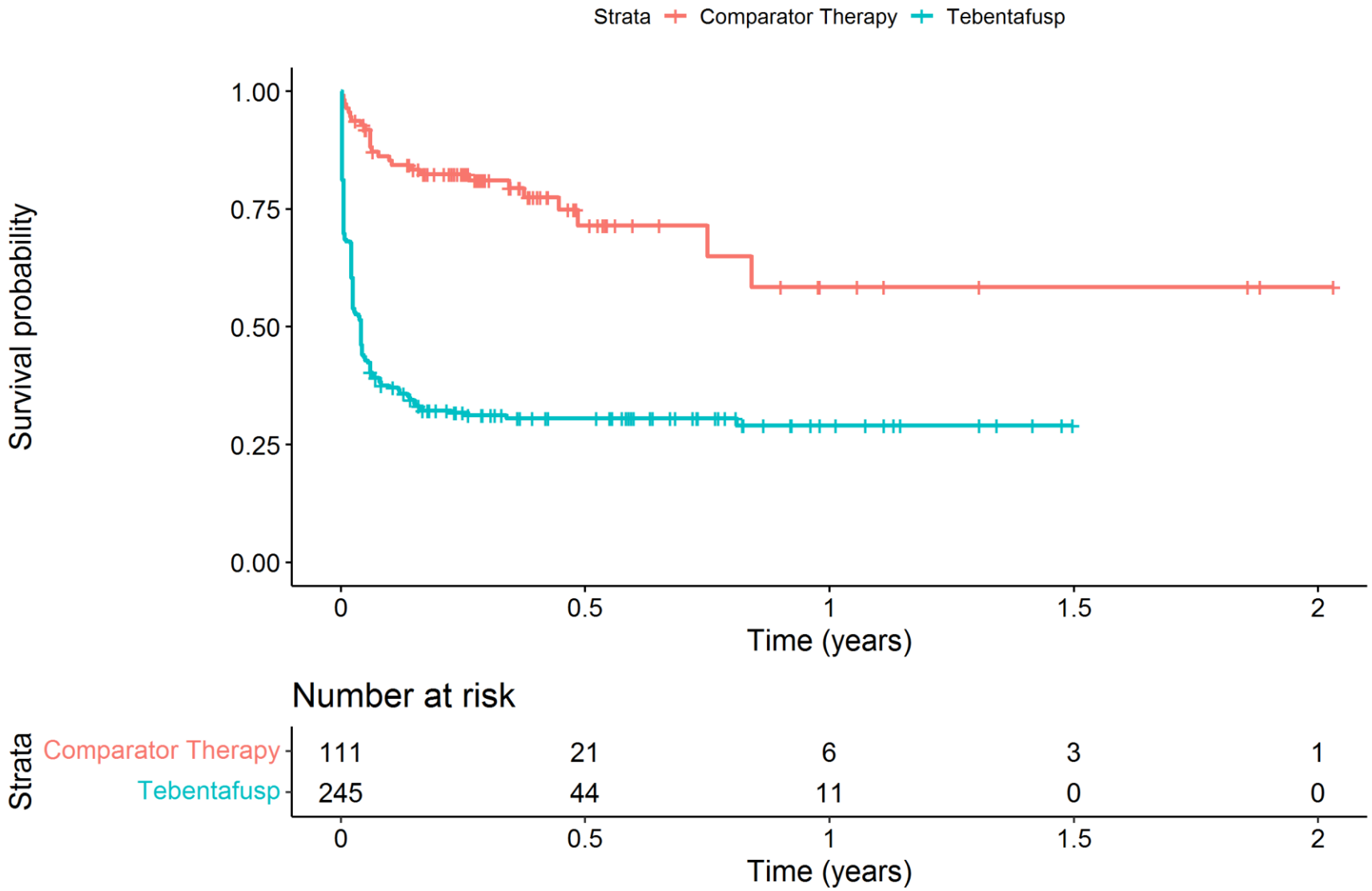
2.29 Husten


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
8
1
0
245
42
7
1
0
1
2
3
Time (years)

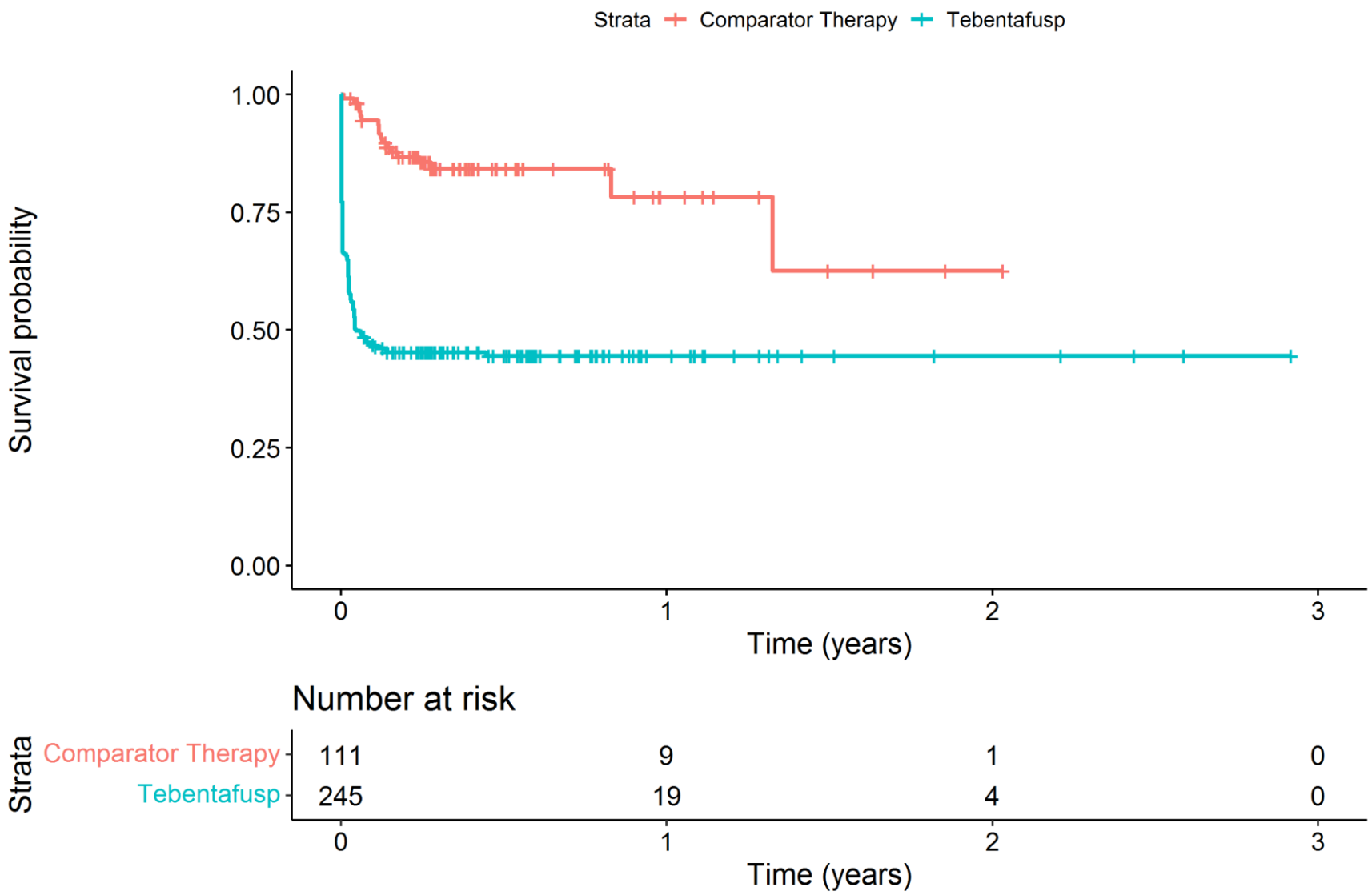
2.30 Dyspnoe


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
46
10
1
0
1
2
3
Time (years)

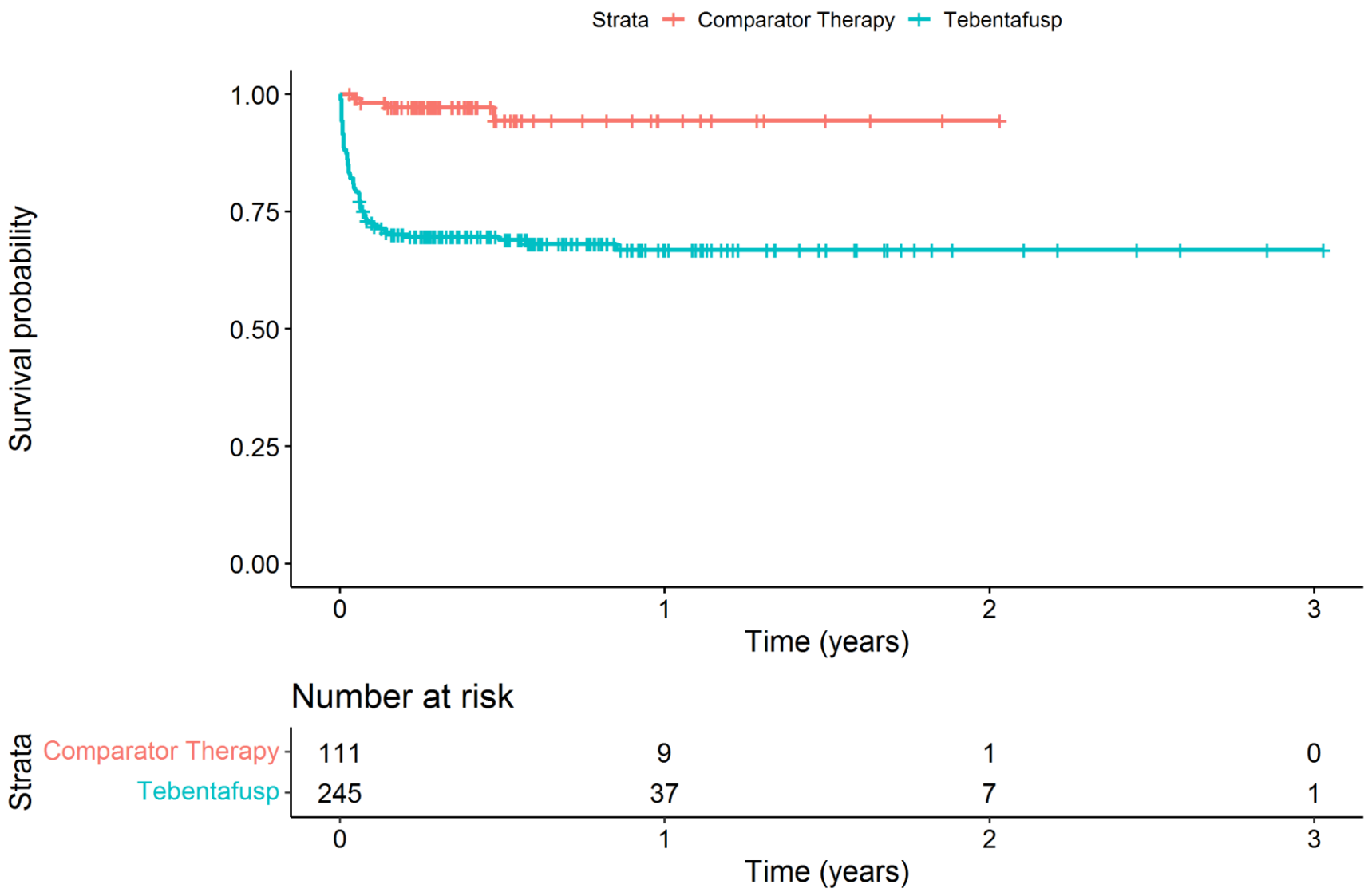
2.31 Pruritus



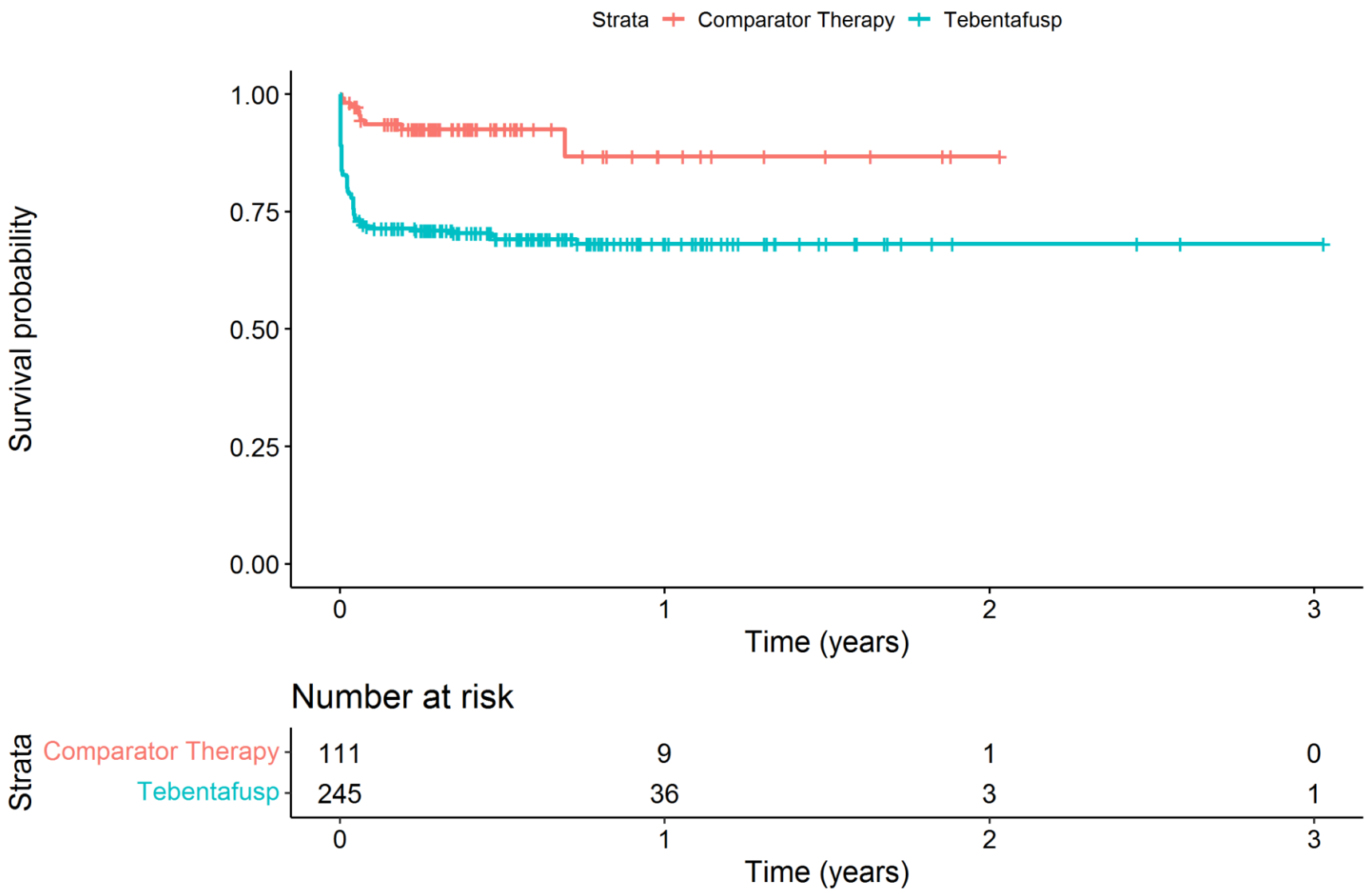
2.32 Hautausschlag



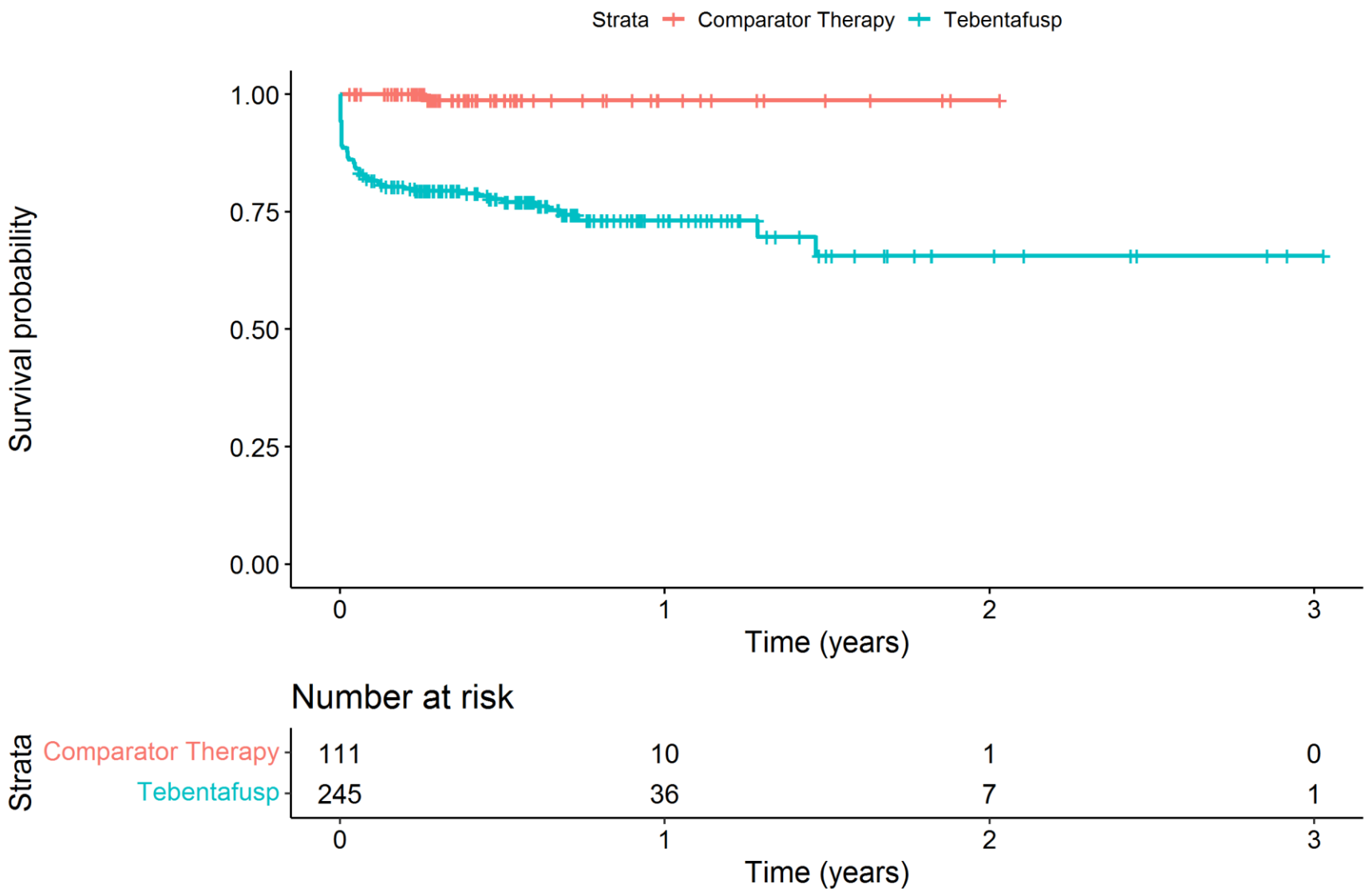
2.33 Trockene Haut



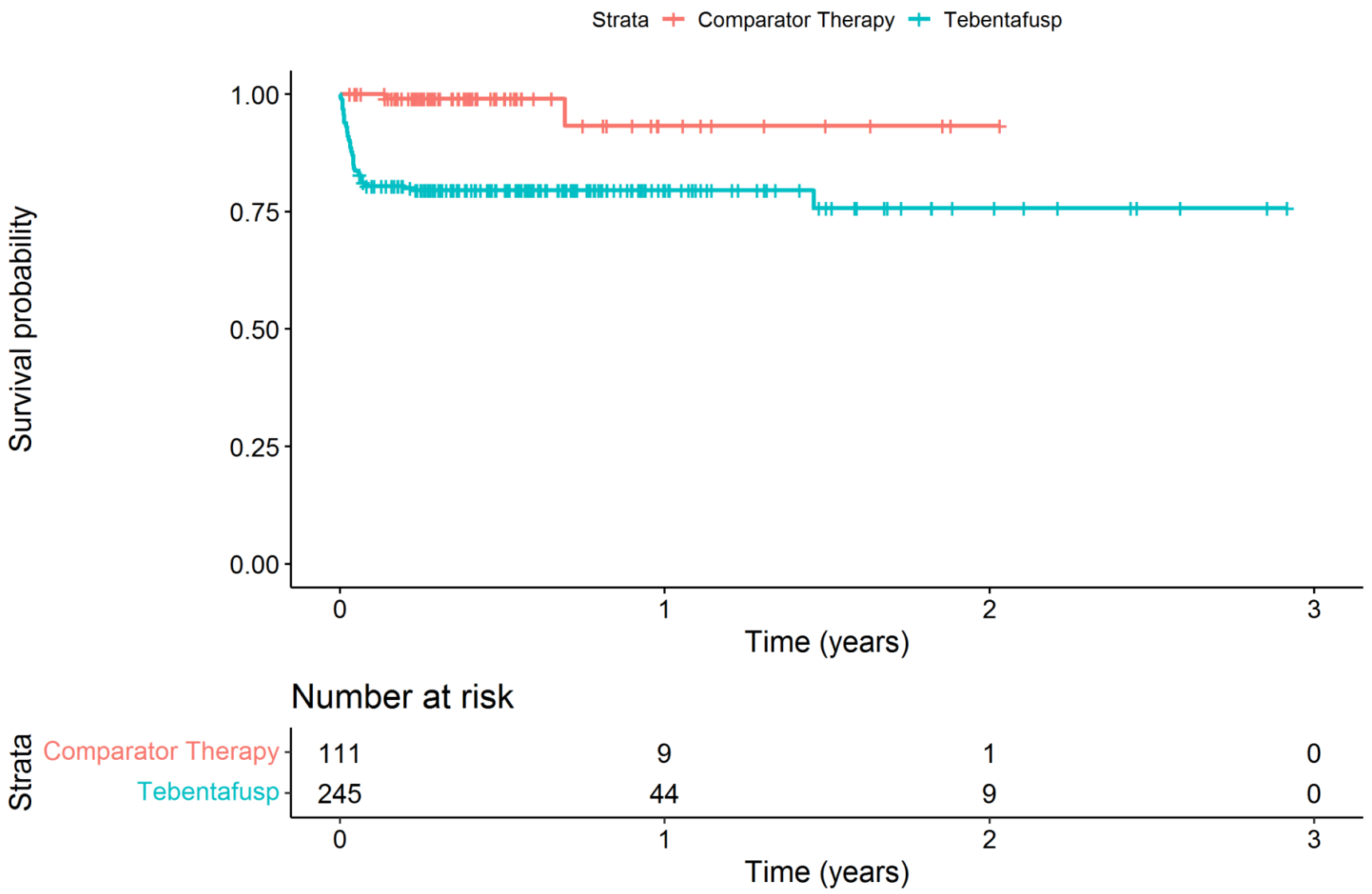
2.34 Makulo-papulöser Hautausschlag



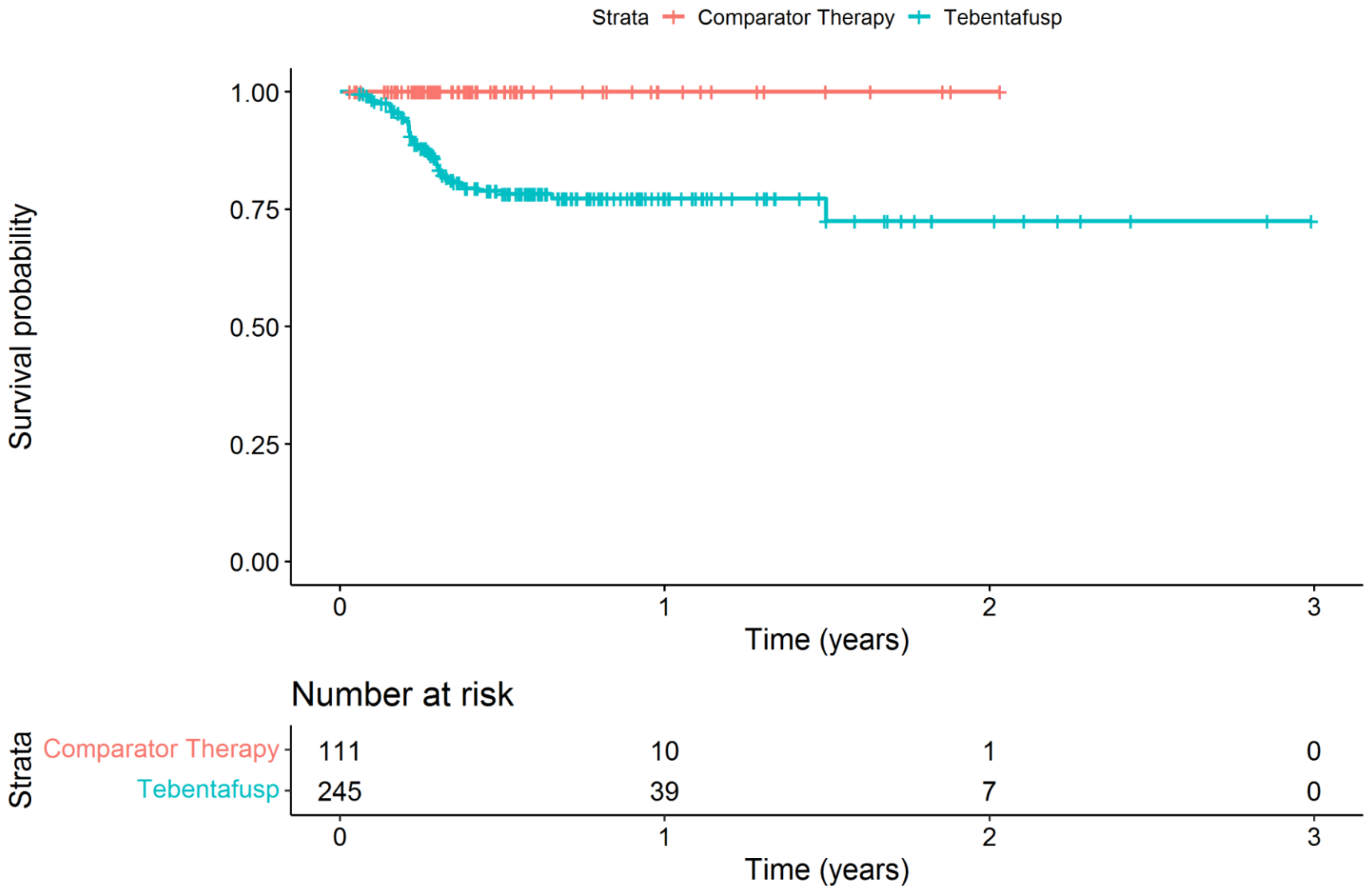
2.35 Erythem


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
36
7
1
0
1
2
3
Time (years)

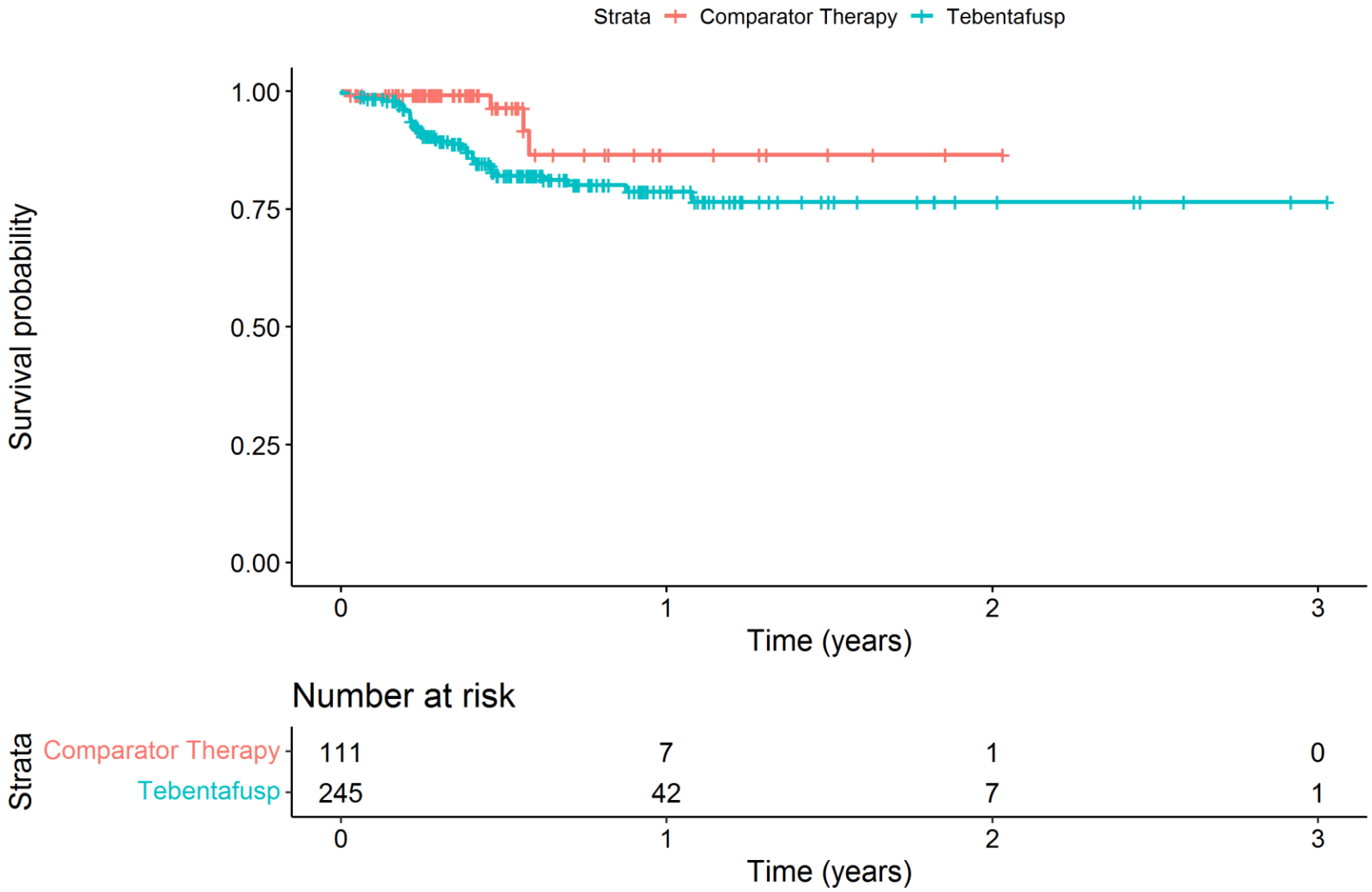
2.36 Hautabschälung



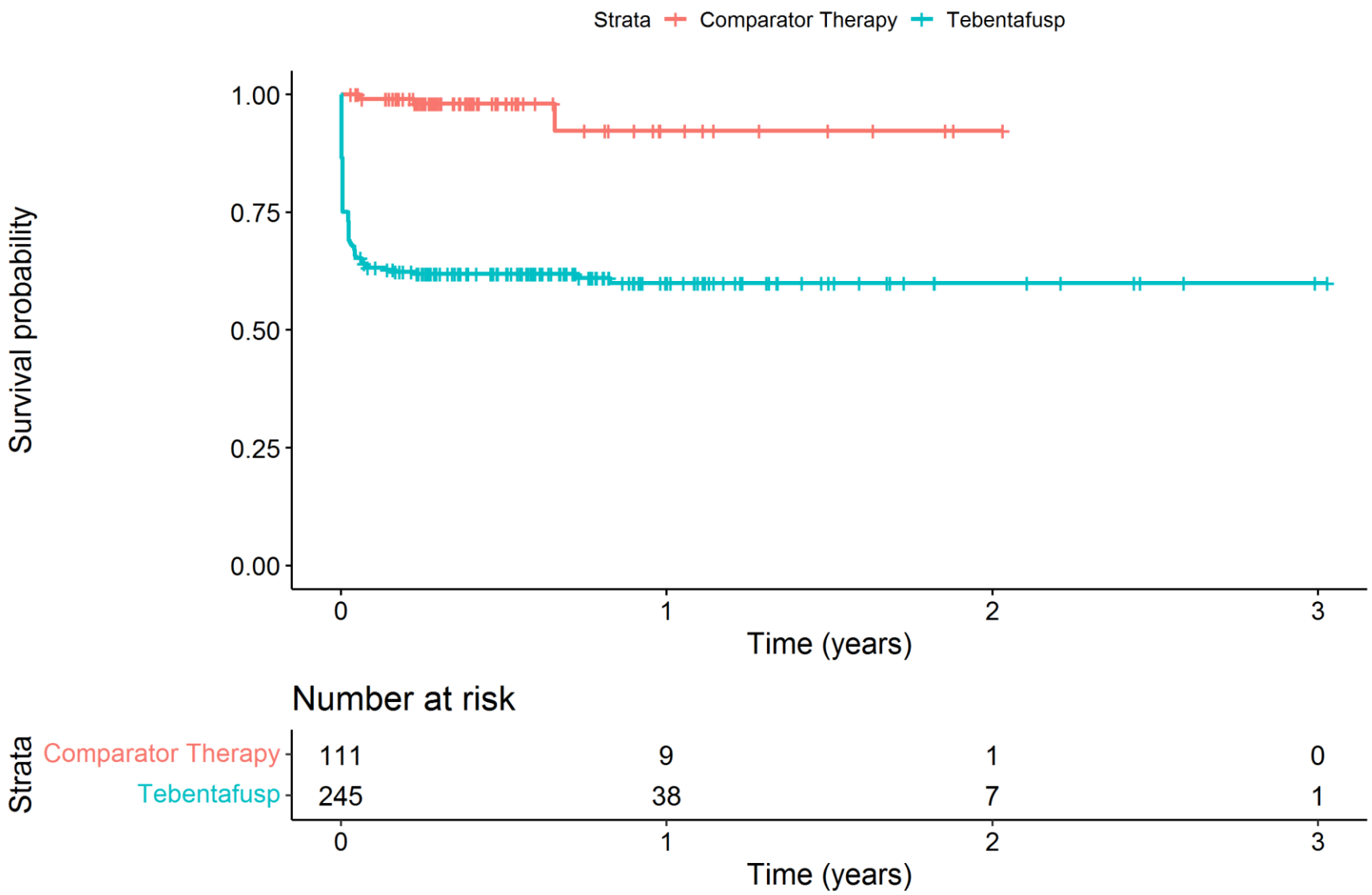
2.37 Veränderung der Haarfarbe



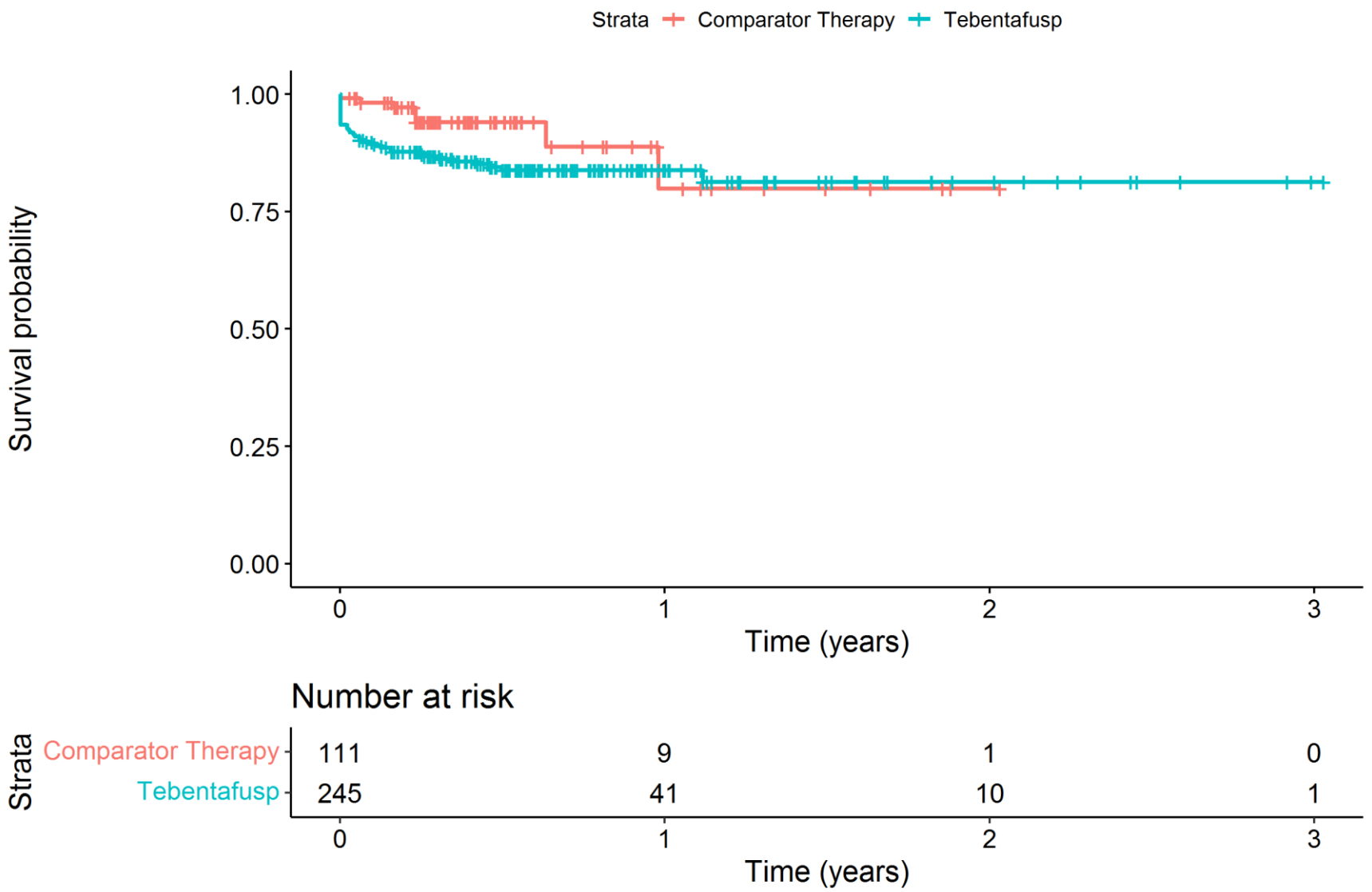
2.38 Vitiligo



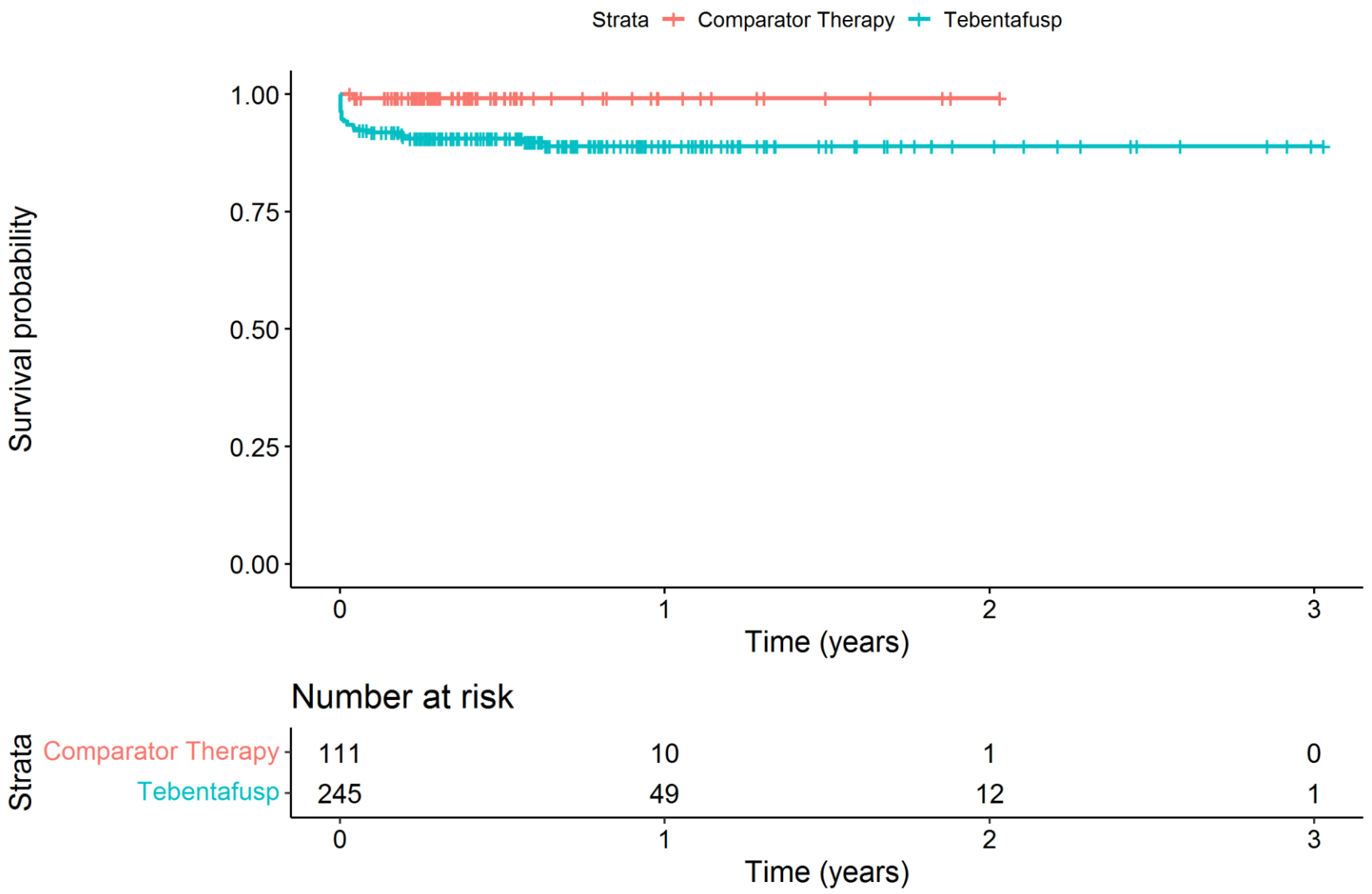
2.39 Hypotonie



2.40 Hypertonie

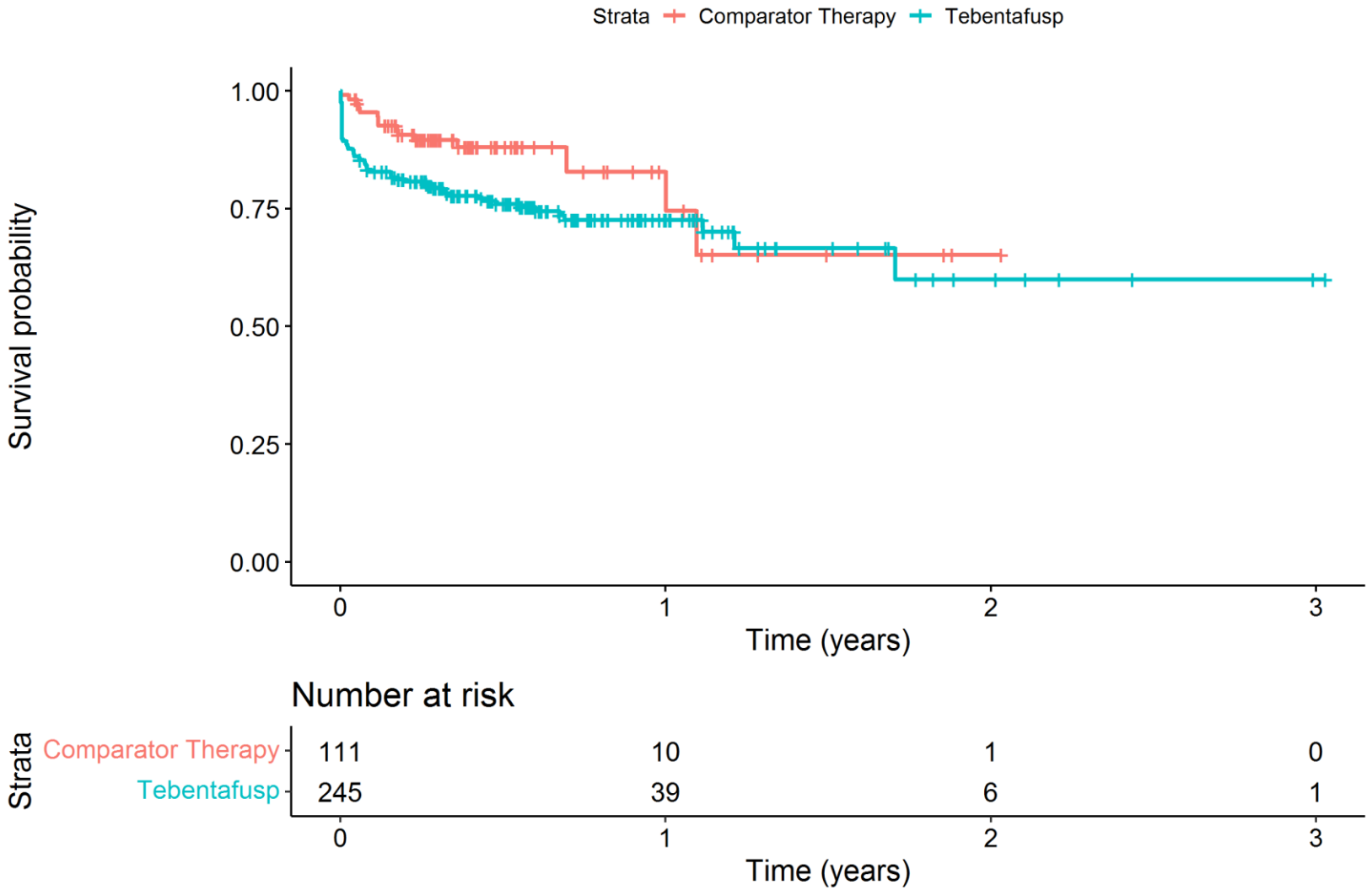


2.41 Hautrötung

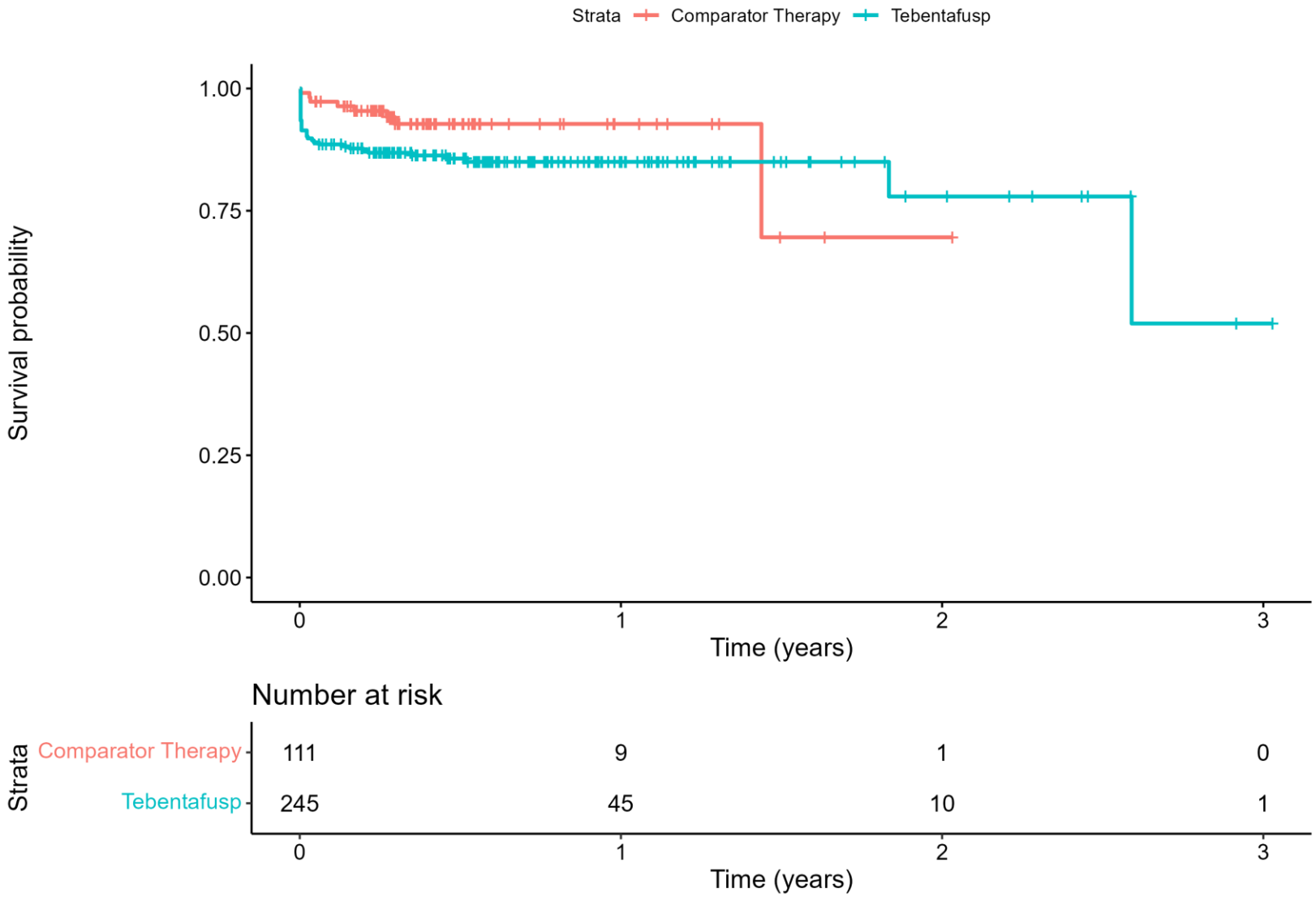


3 UEs (SOC), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten

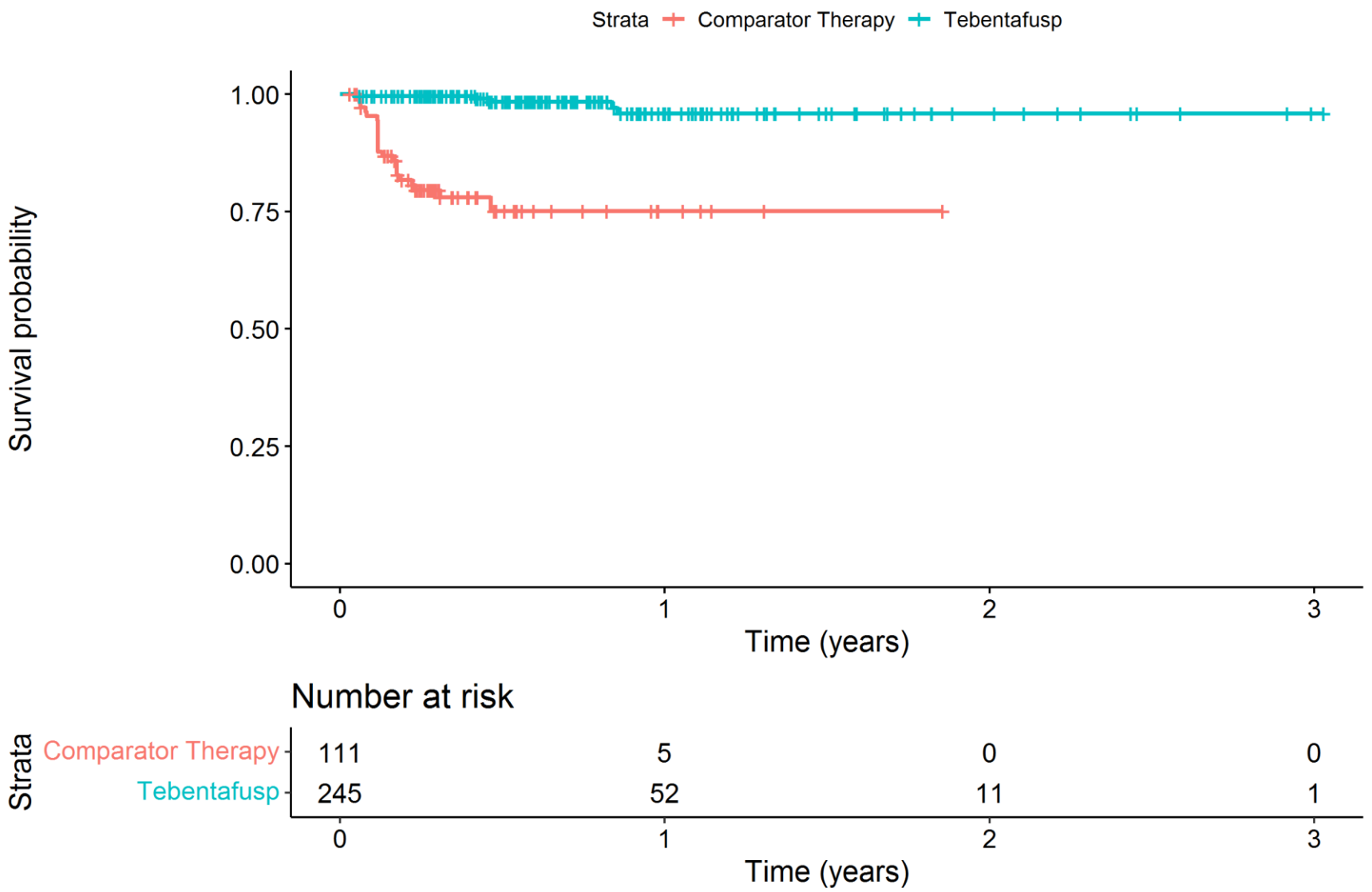
3.1 Erkrankungen des Blutes und des Lymphsystems


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
39
6
1
0
1
2
3
Time (years)

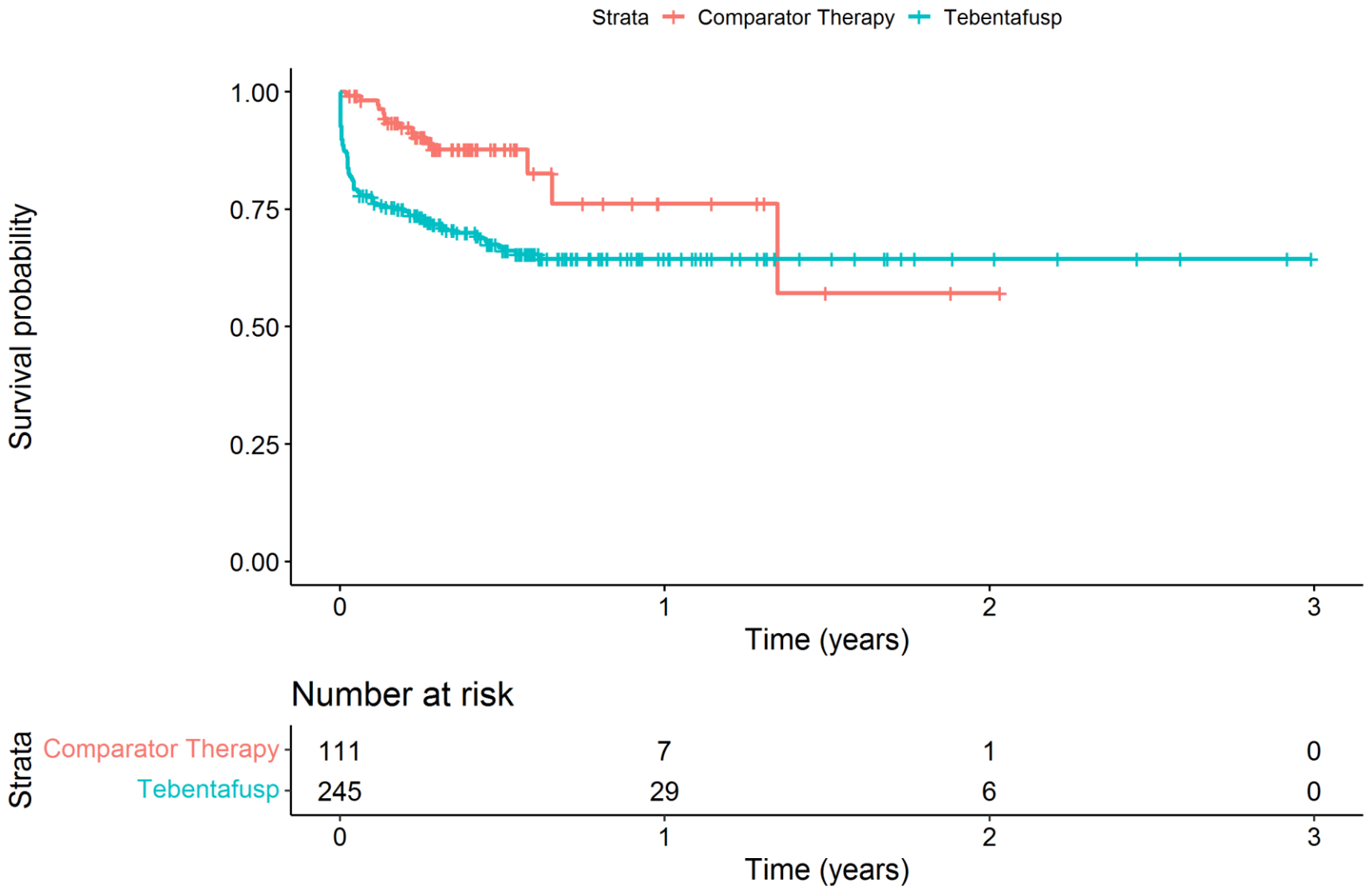
3.2 Herzerkrankungen



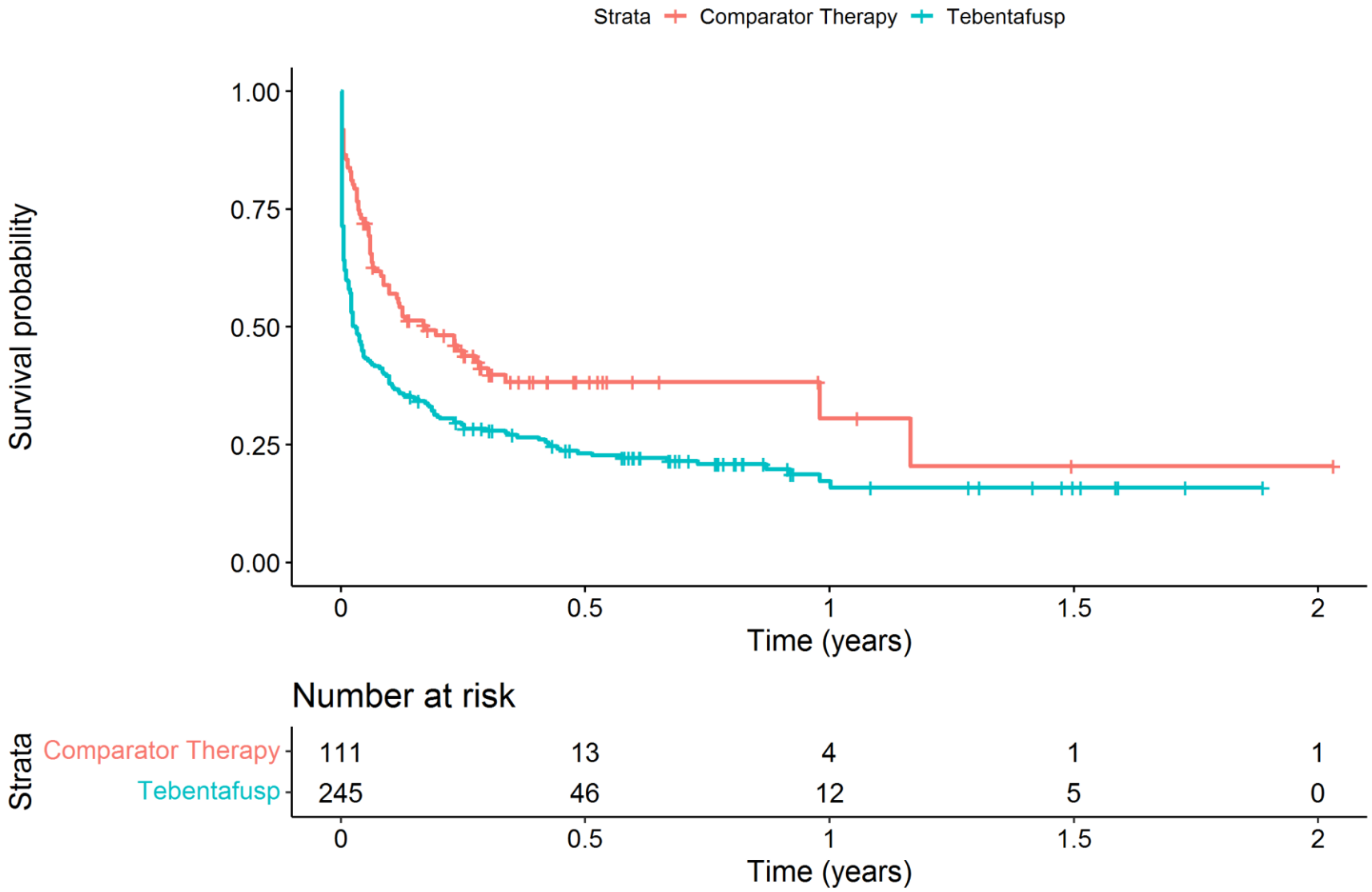
3.3 Endokrine Erkrankungen



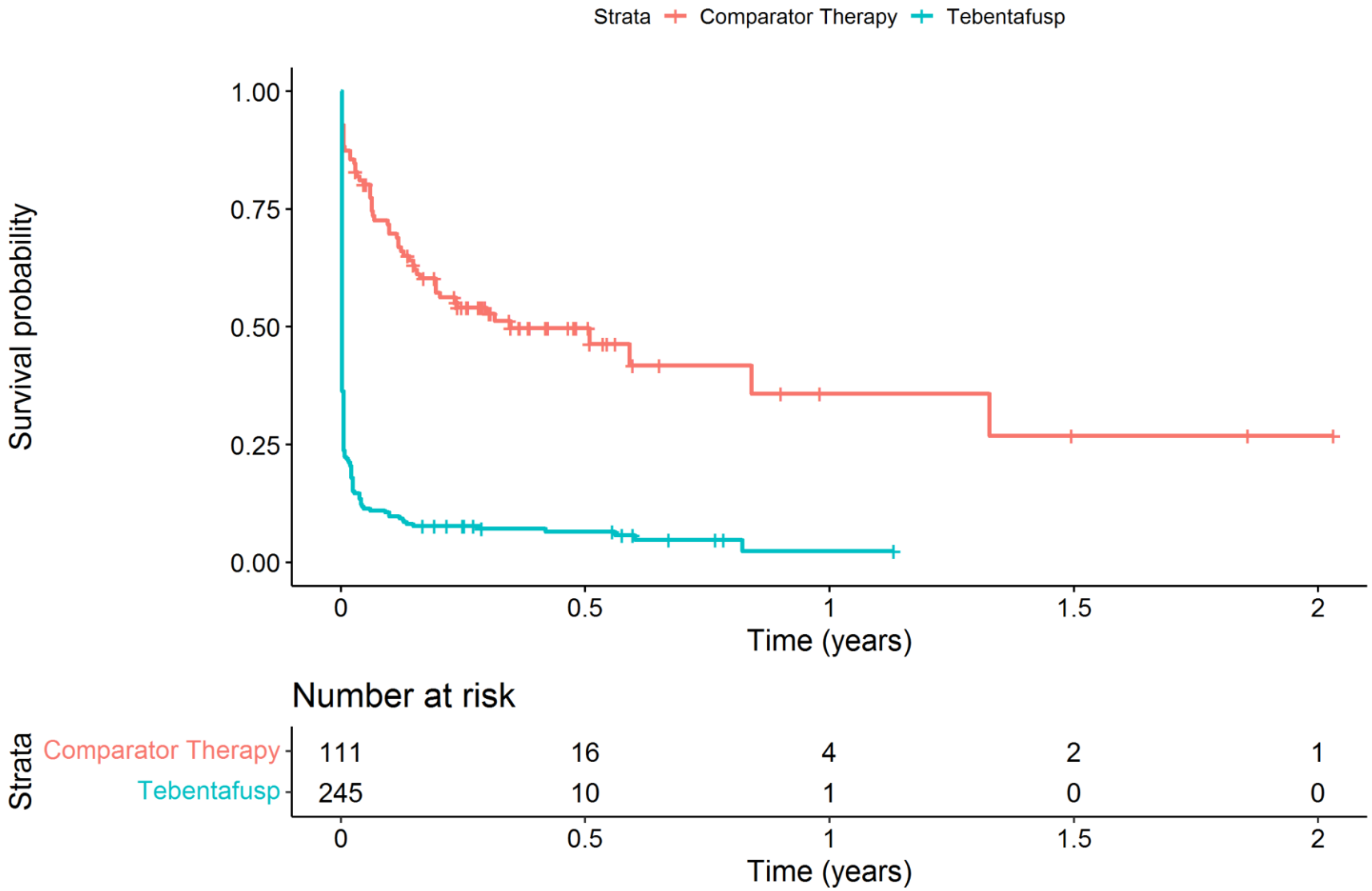
3.4 Augenerkrankungen



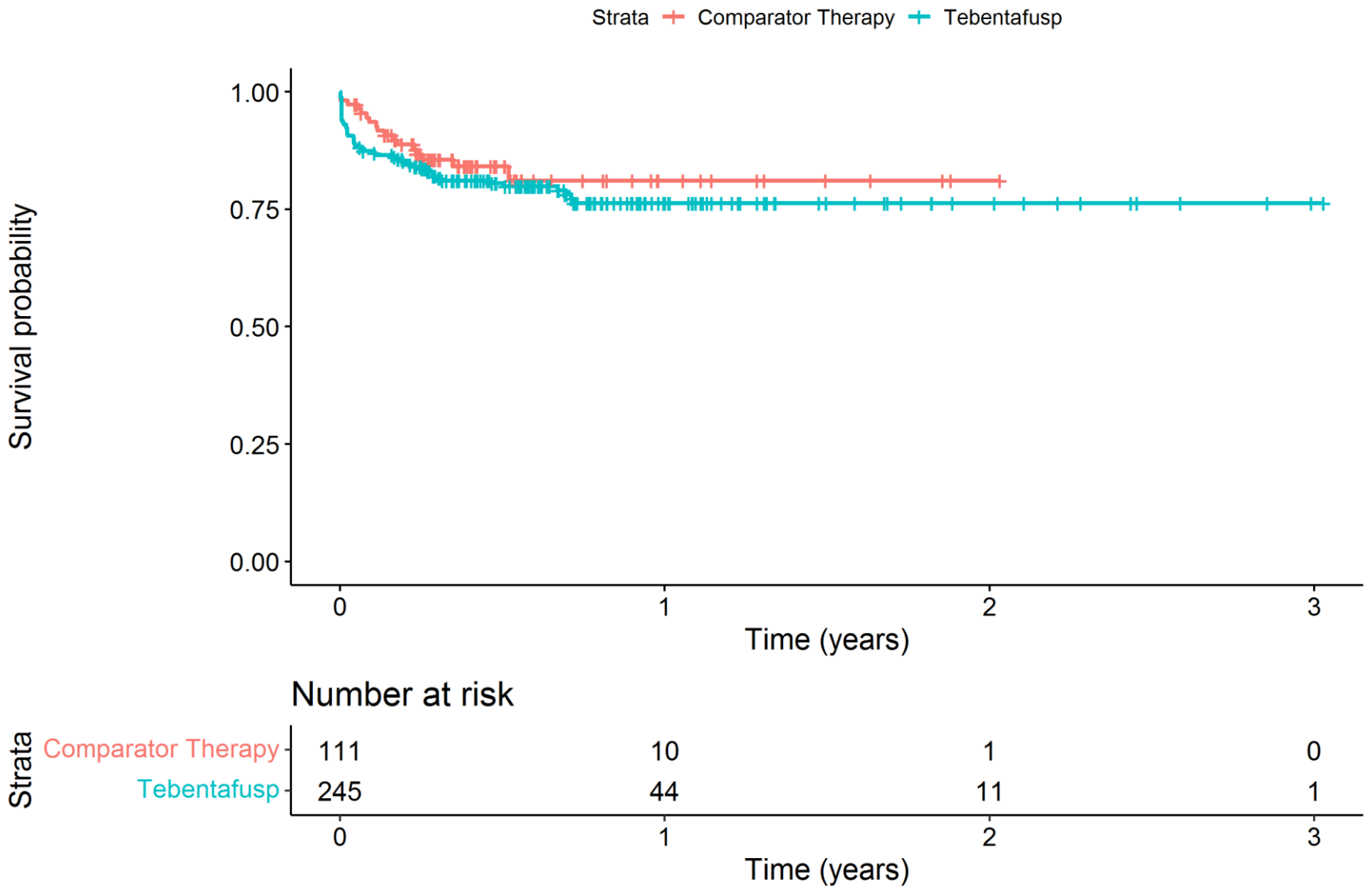
3.5 Erkrankungen des Gastrointestinaltrakts



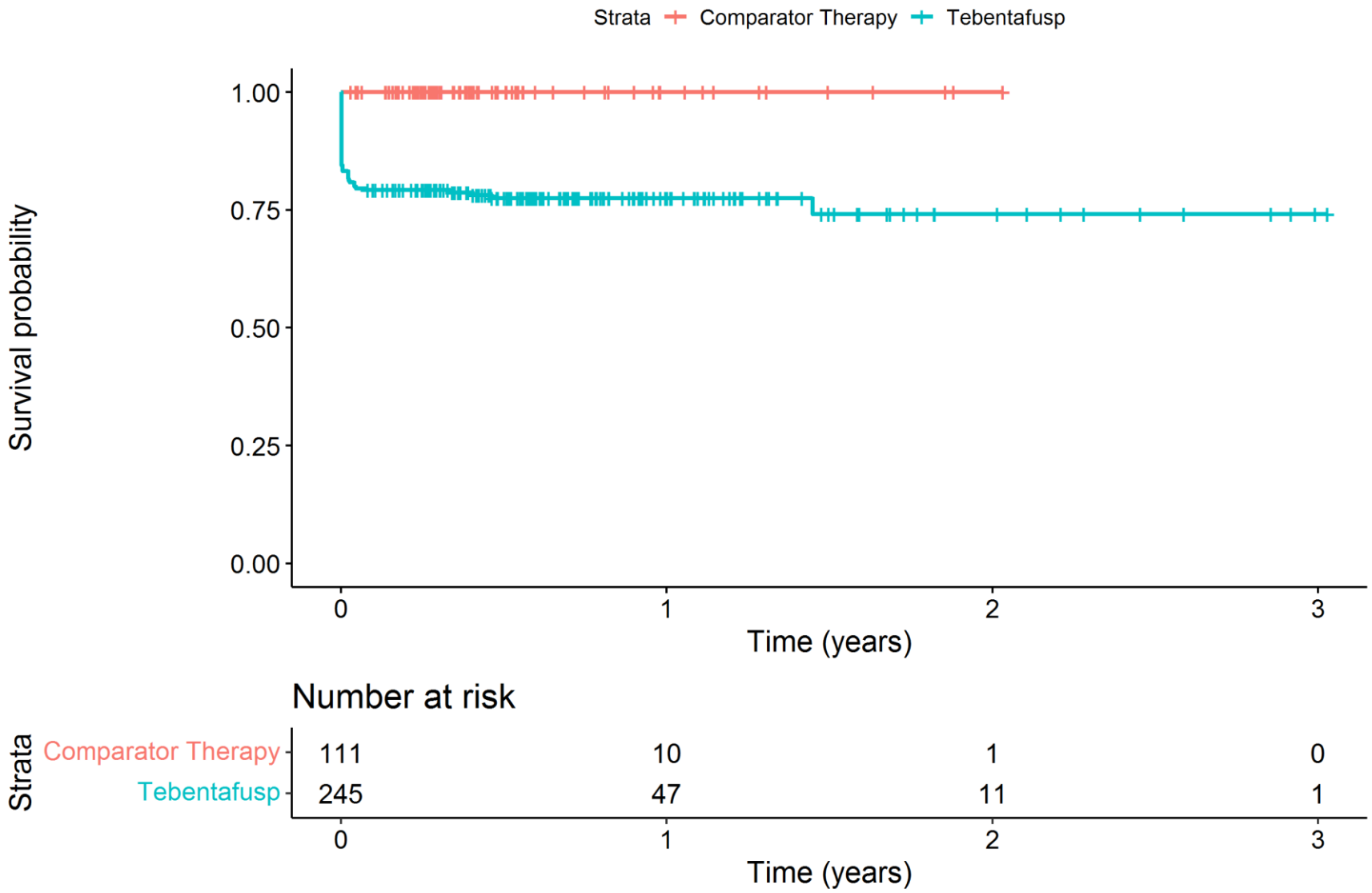
3.6 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



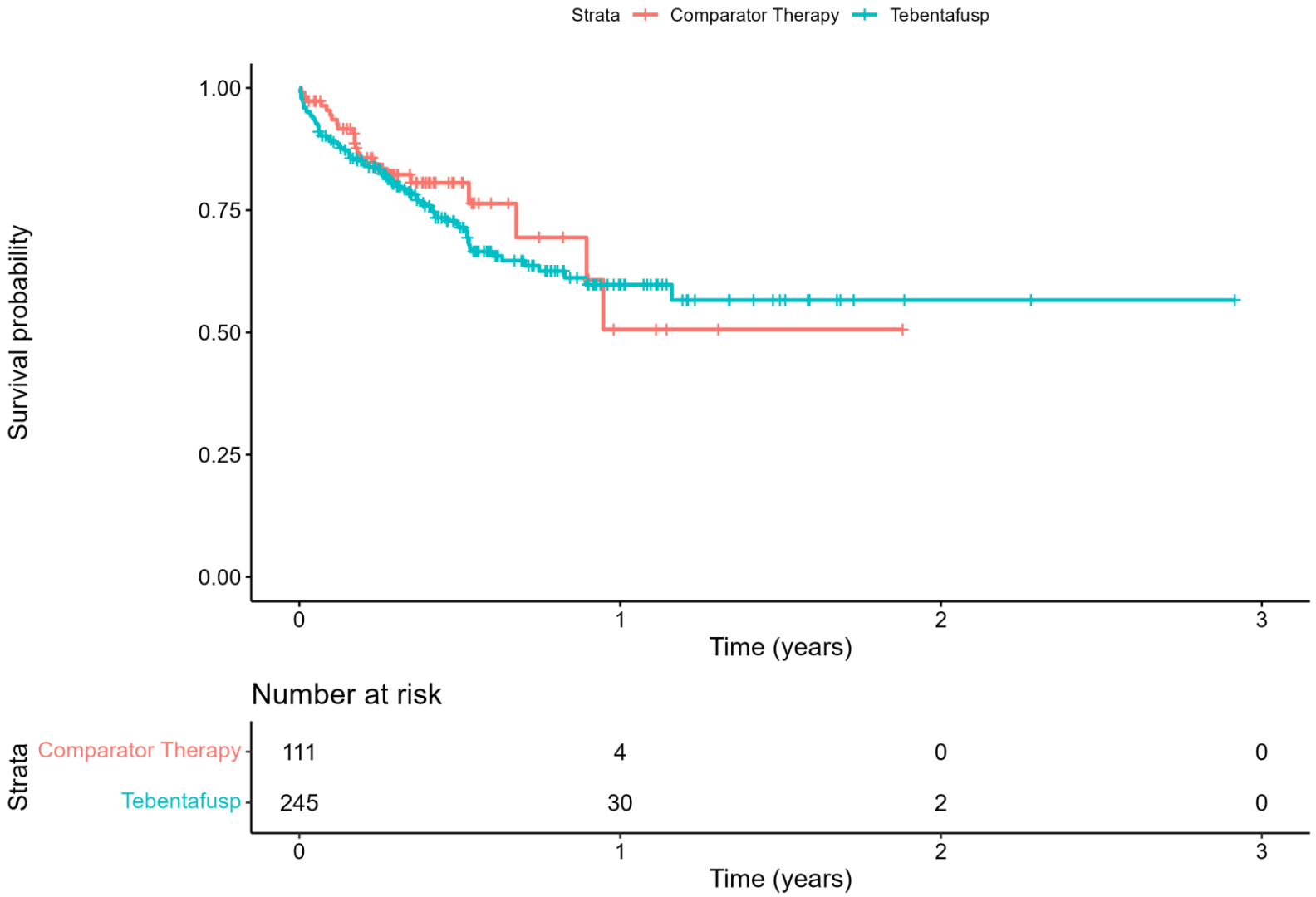
3.7 Leber- und Gallenerkrankungen



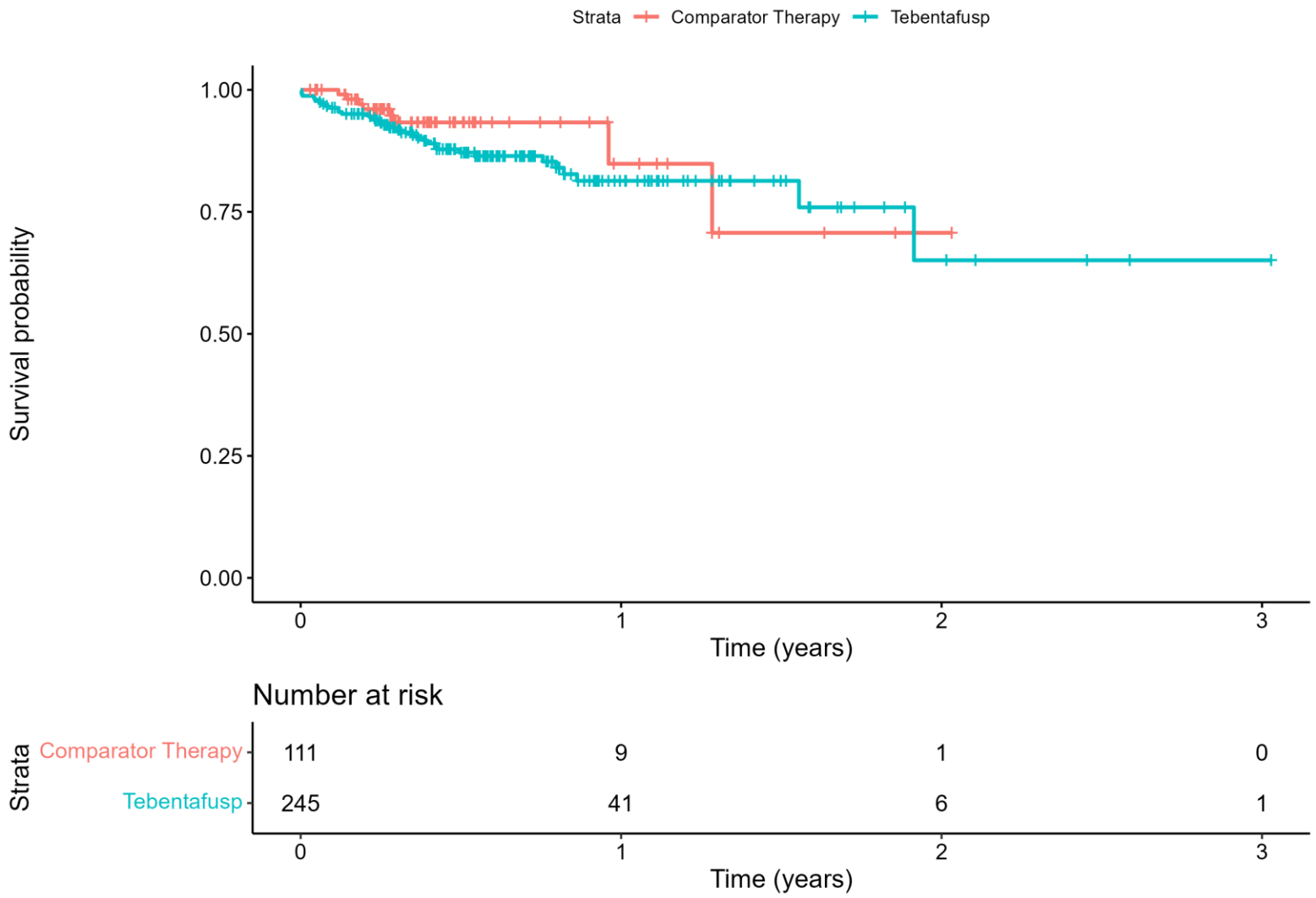
3.8 Erkrankungen des Immunsystems



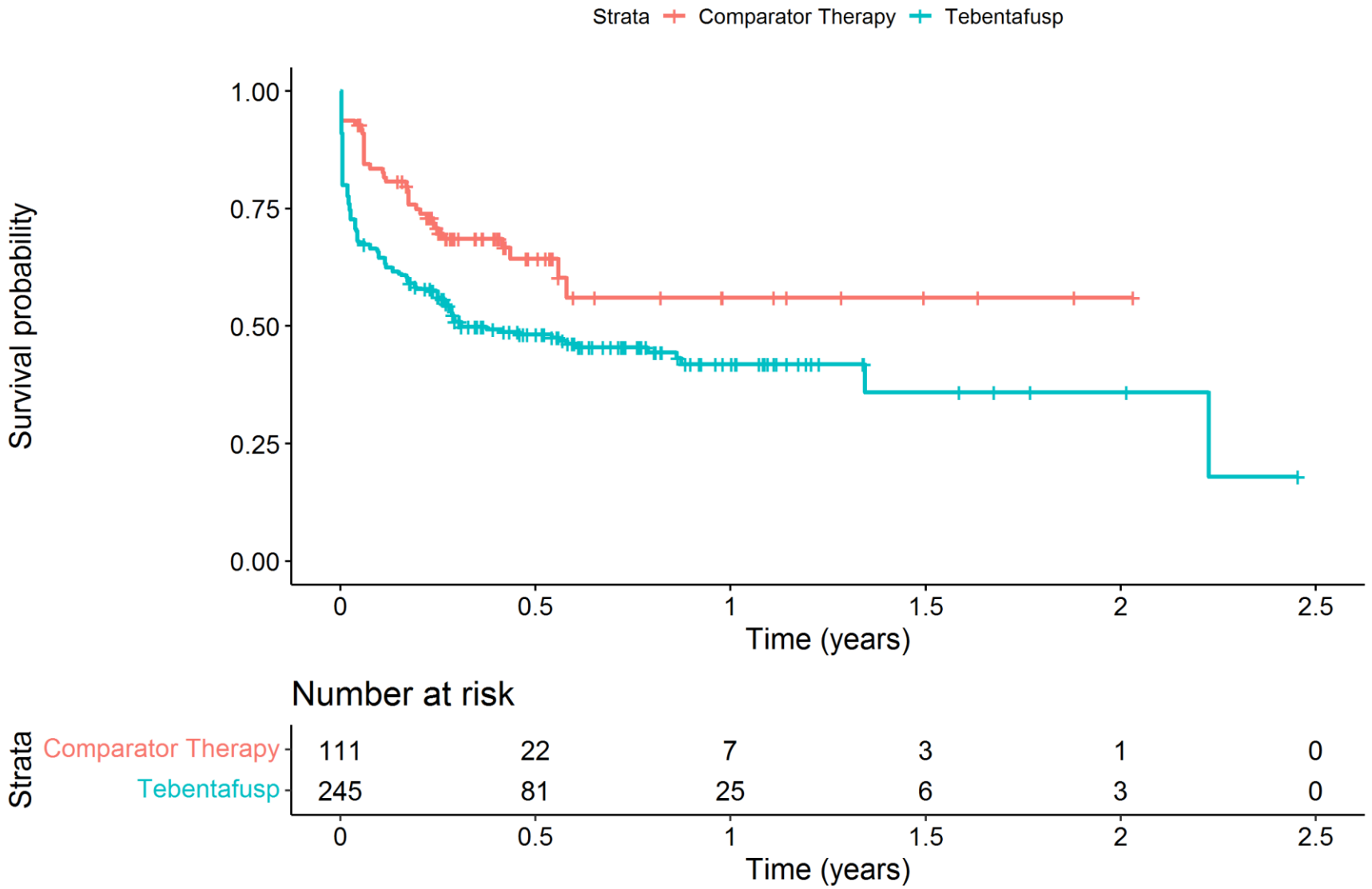
3.9 Infektionen und parasitäre Erkrankungen



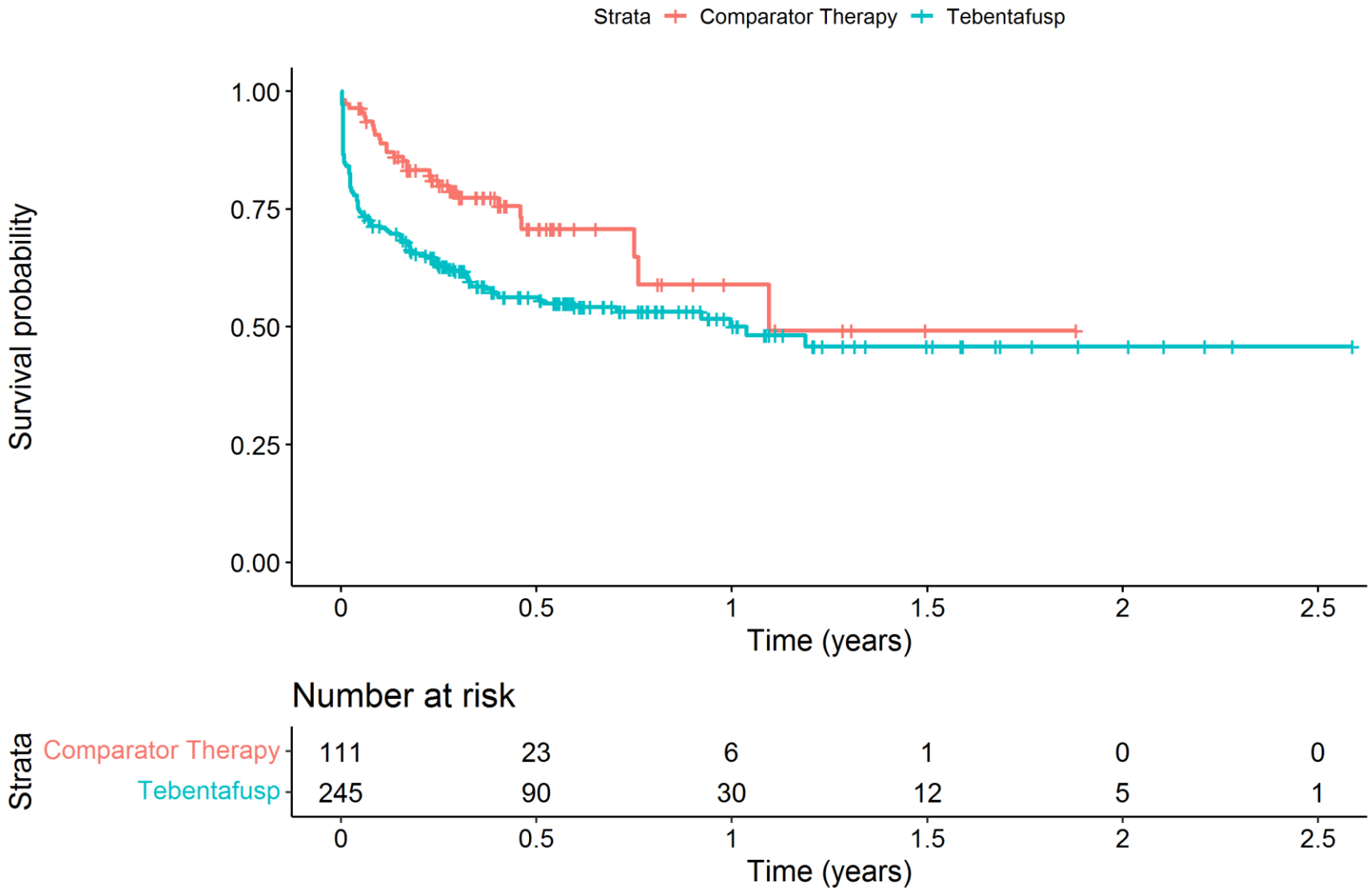
3.10 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



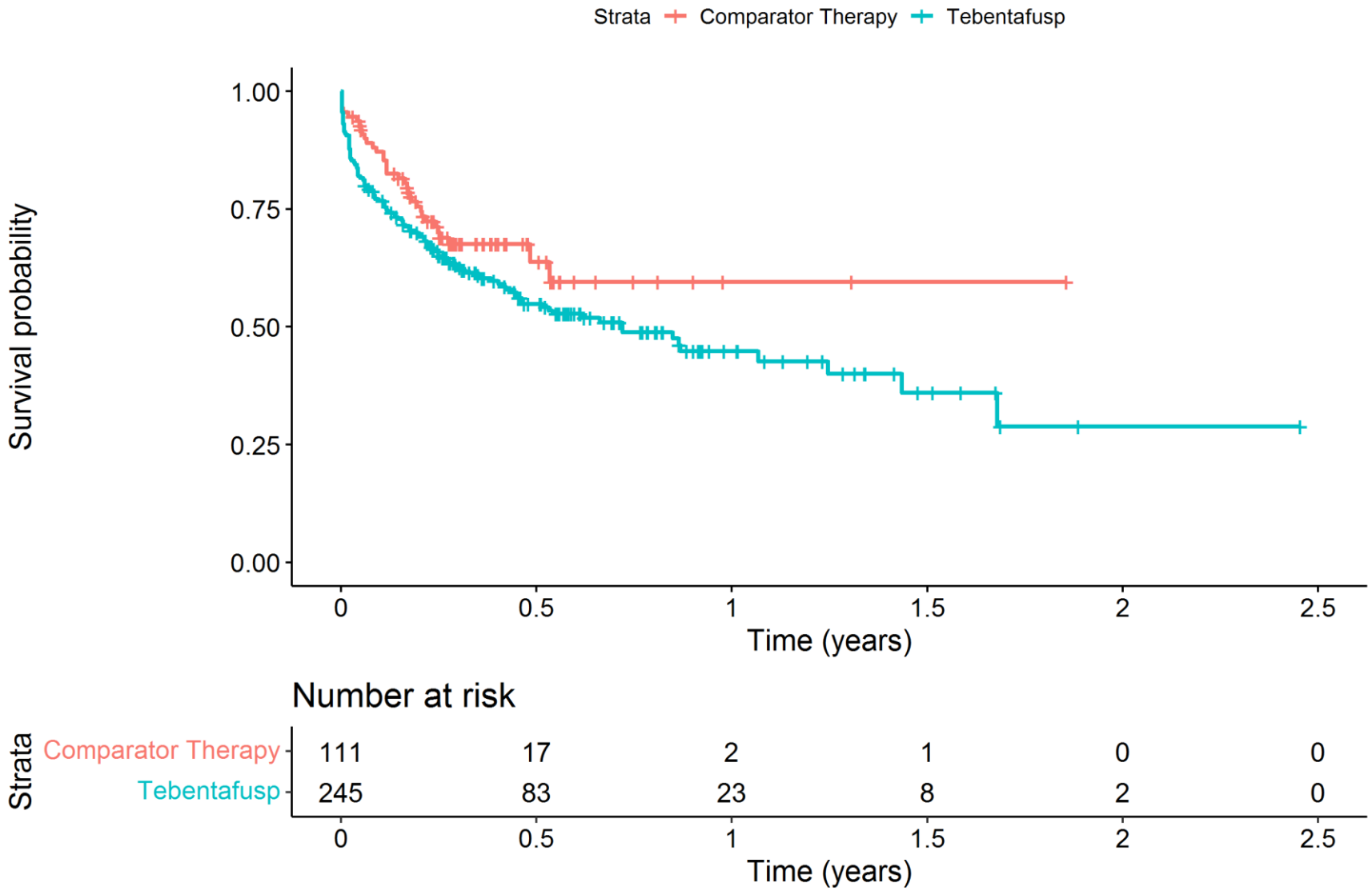
3.11 Untersuchungen



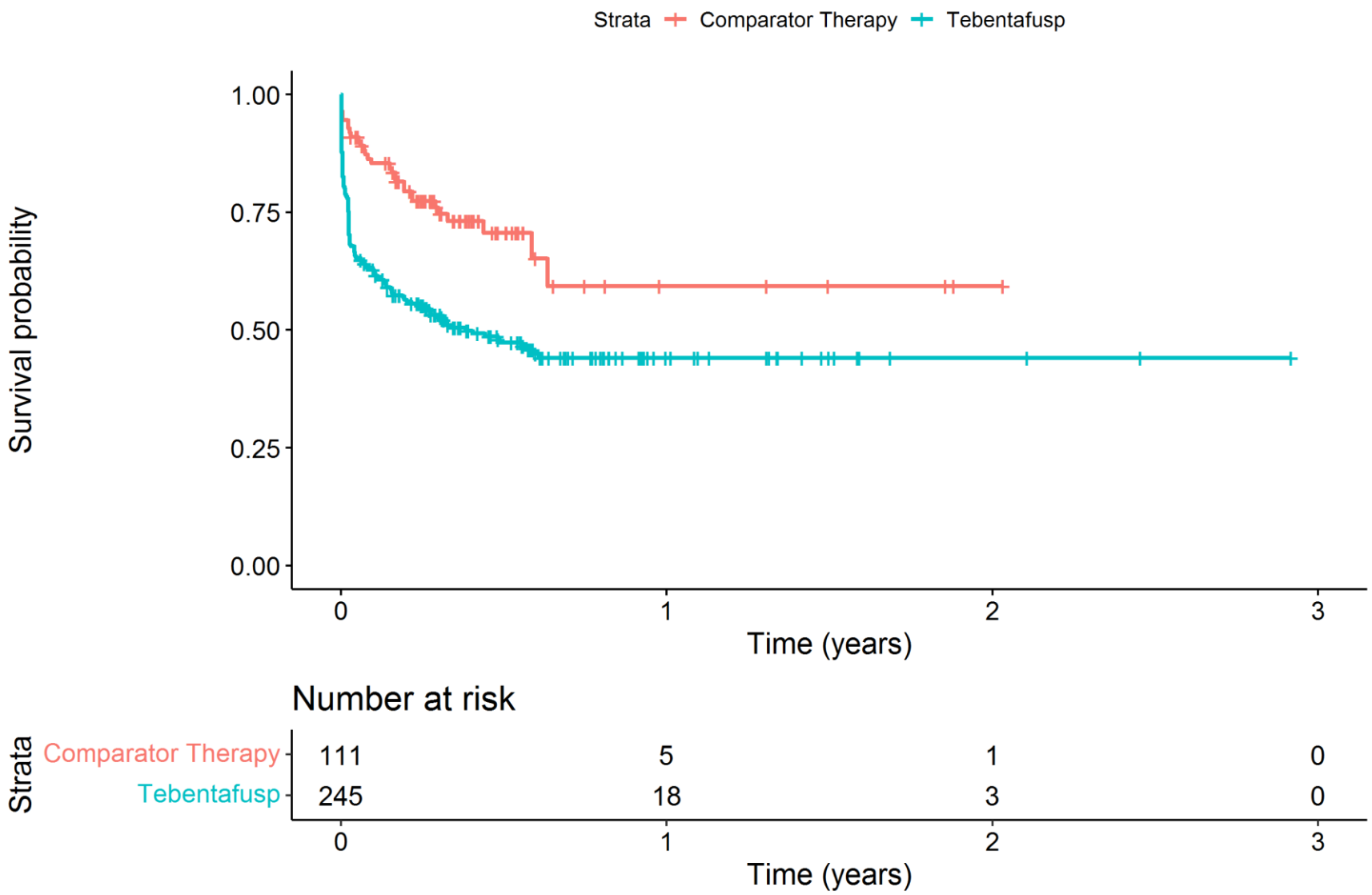
3.12 Stoffwechsel- und Ernährungsstörungen



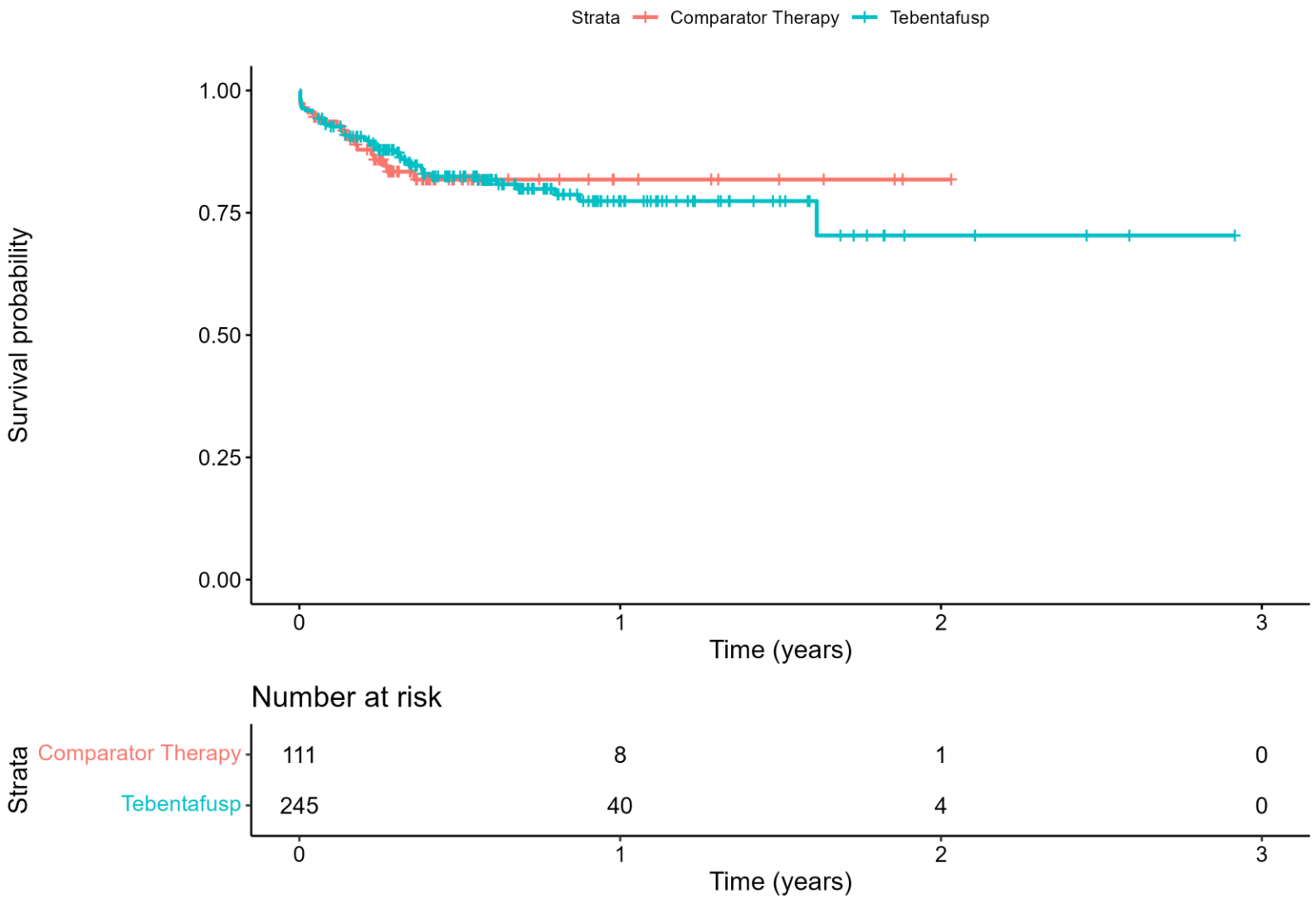
3.13 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



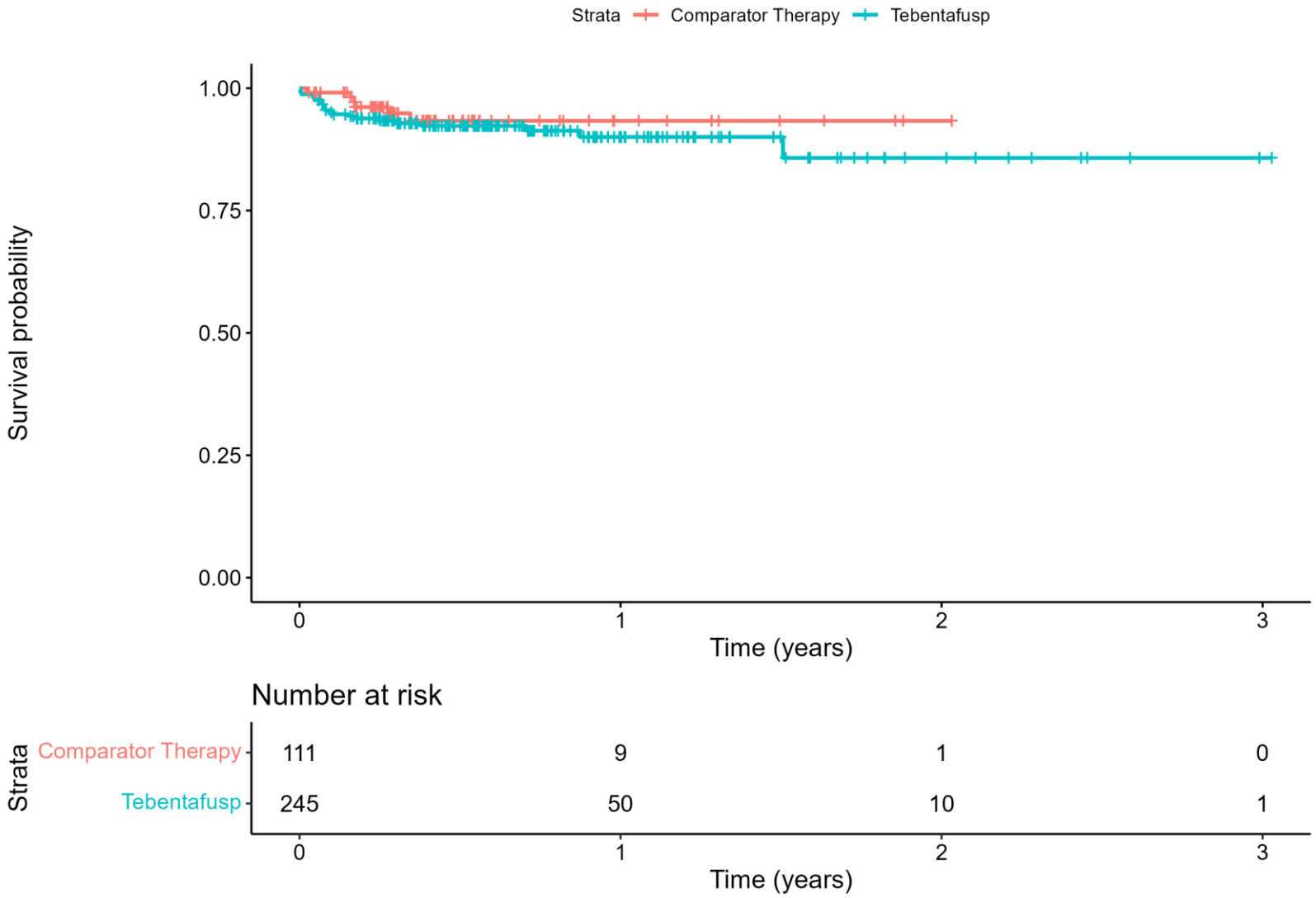
3.14 Erkrankungen des Nervensystems



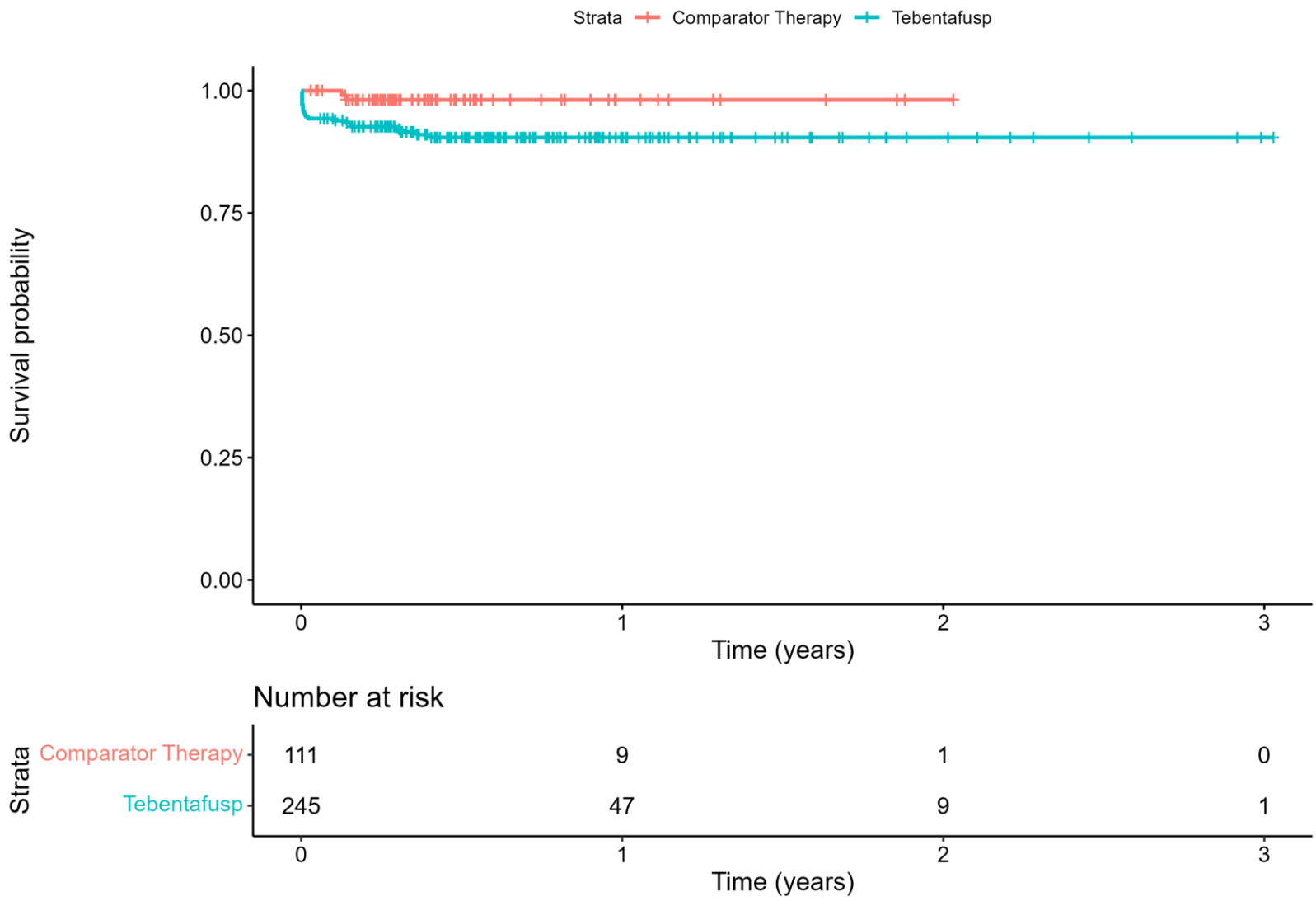
3.15 Psychiatrische Erkrankungen



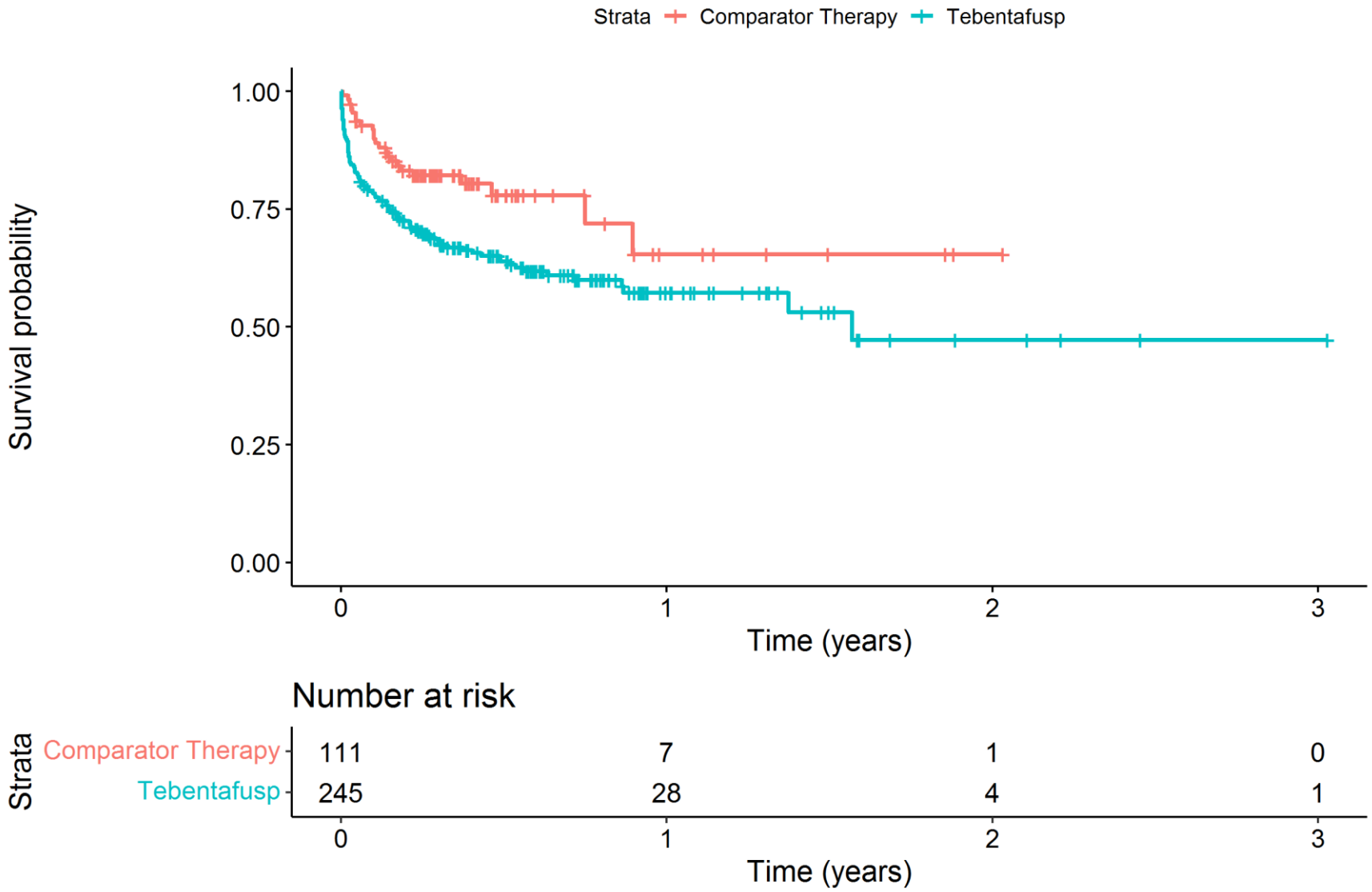
3.16 Erkrankungen der Nieren und Harnwege



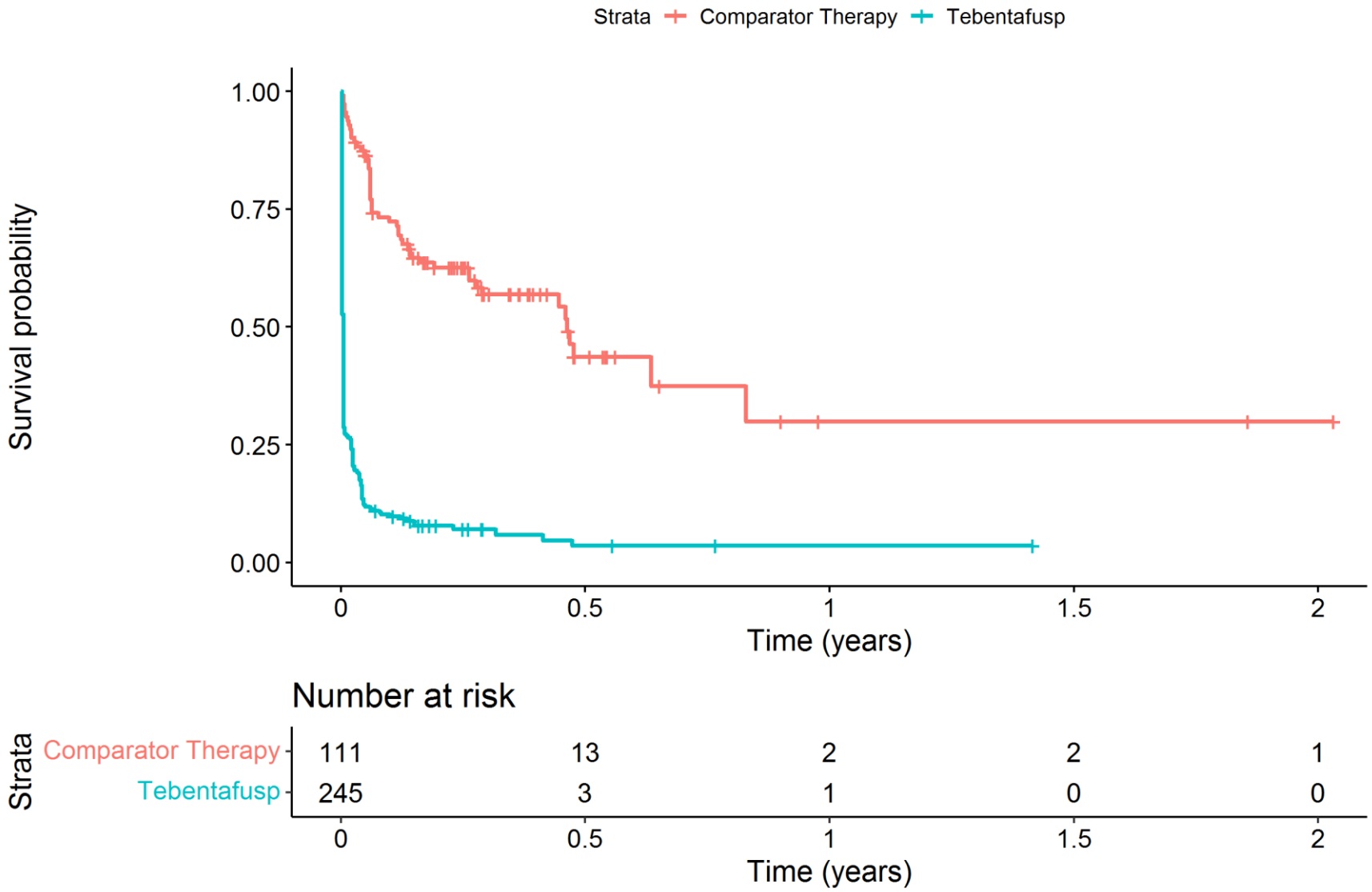
3.17 Erkrankungen der Geschlechtsorgane und der Brustdruese



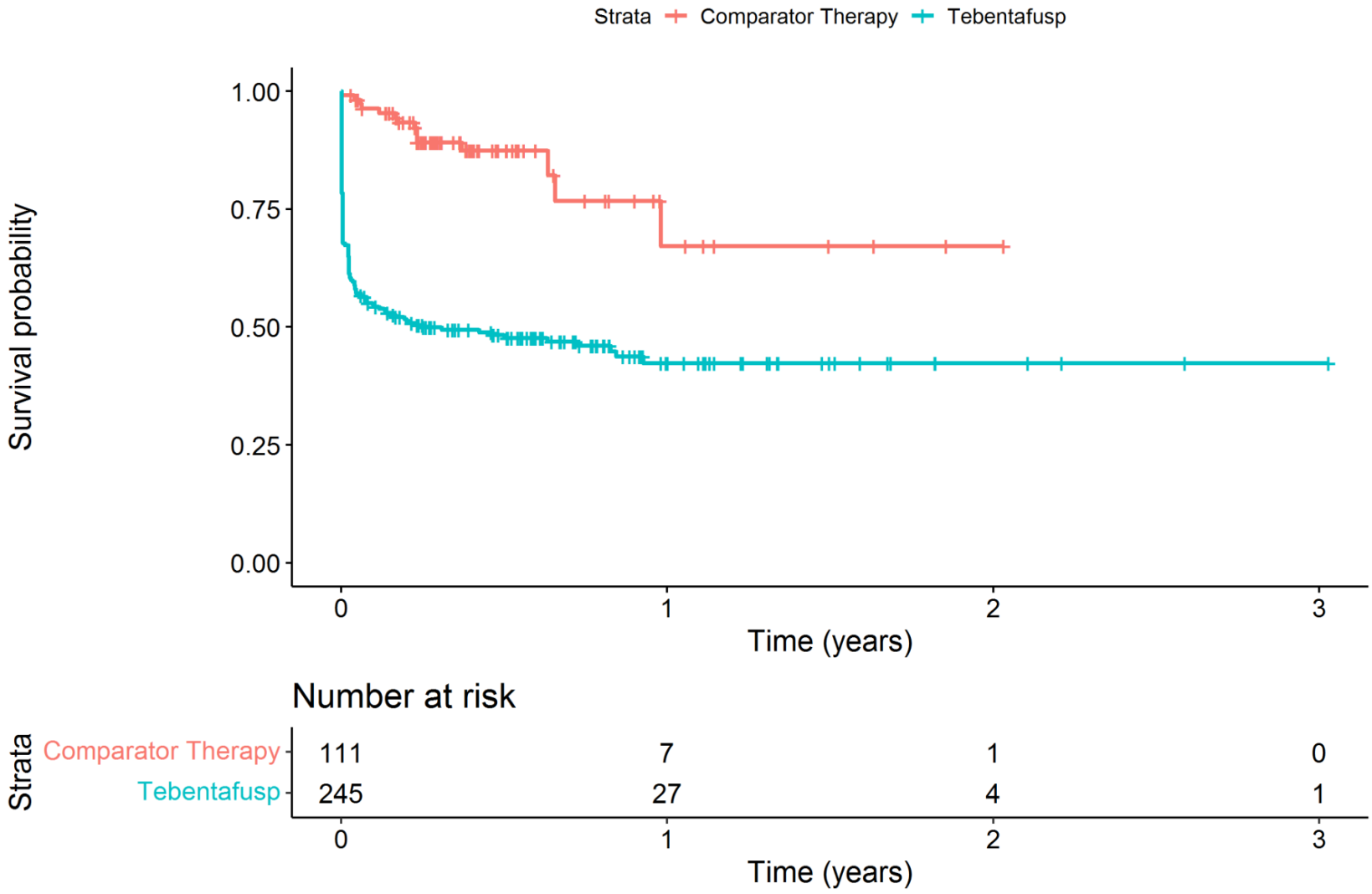
3.18 Erkrankungen der Atemwege, des Brustraums und Mediastinums



3.19 Erkrankungen der Haut und des Unterhautgewebes



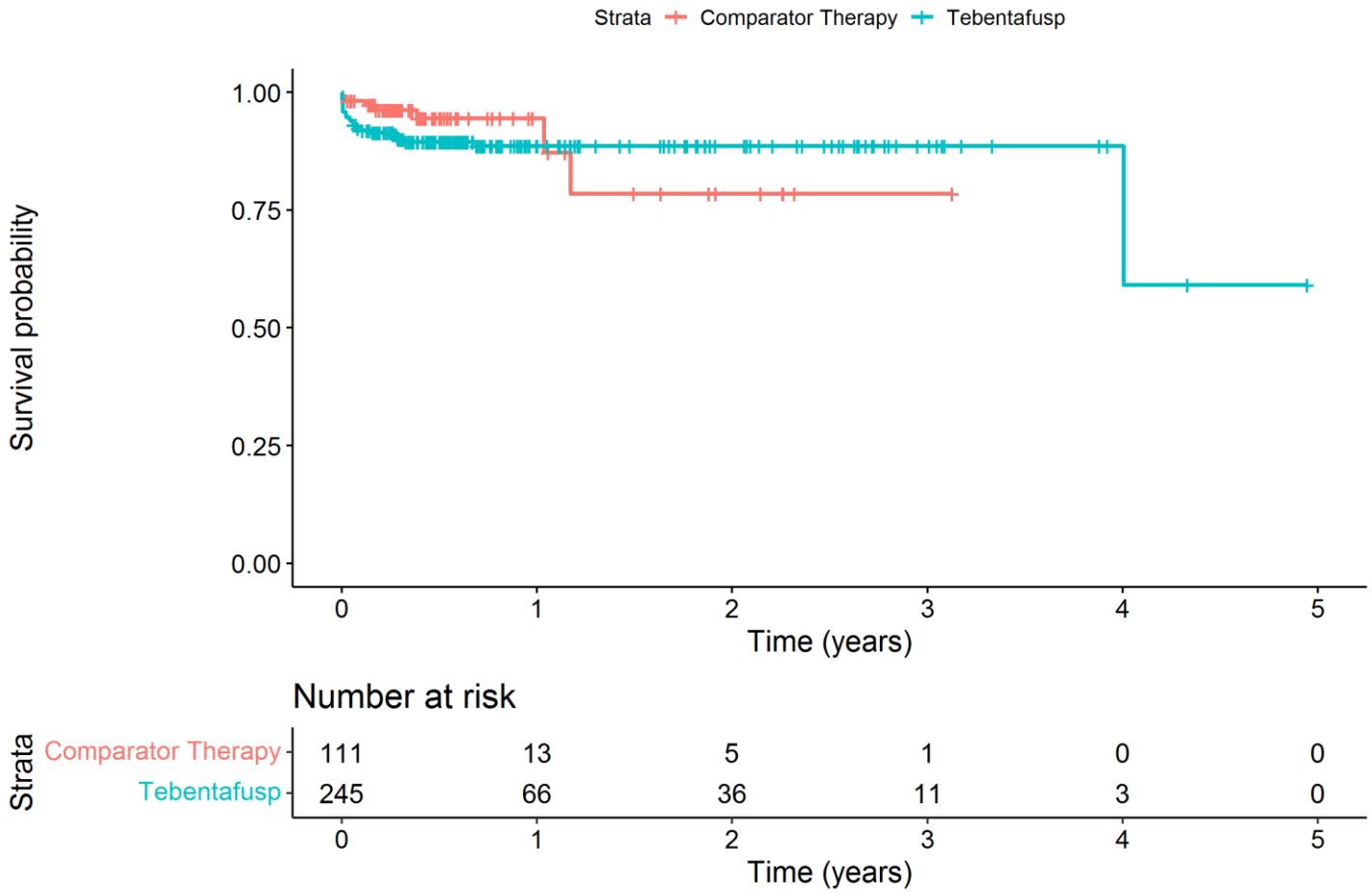
3.20 Gefäßerkrankungen



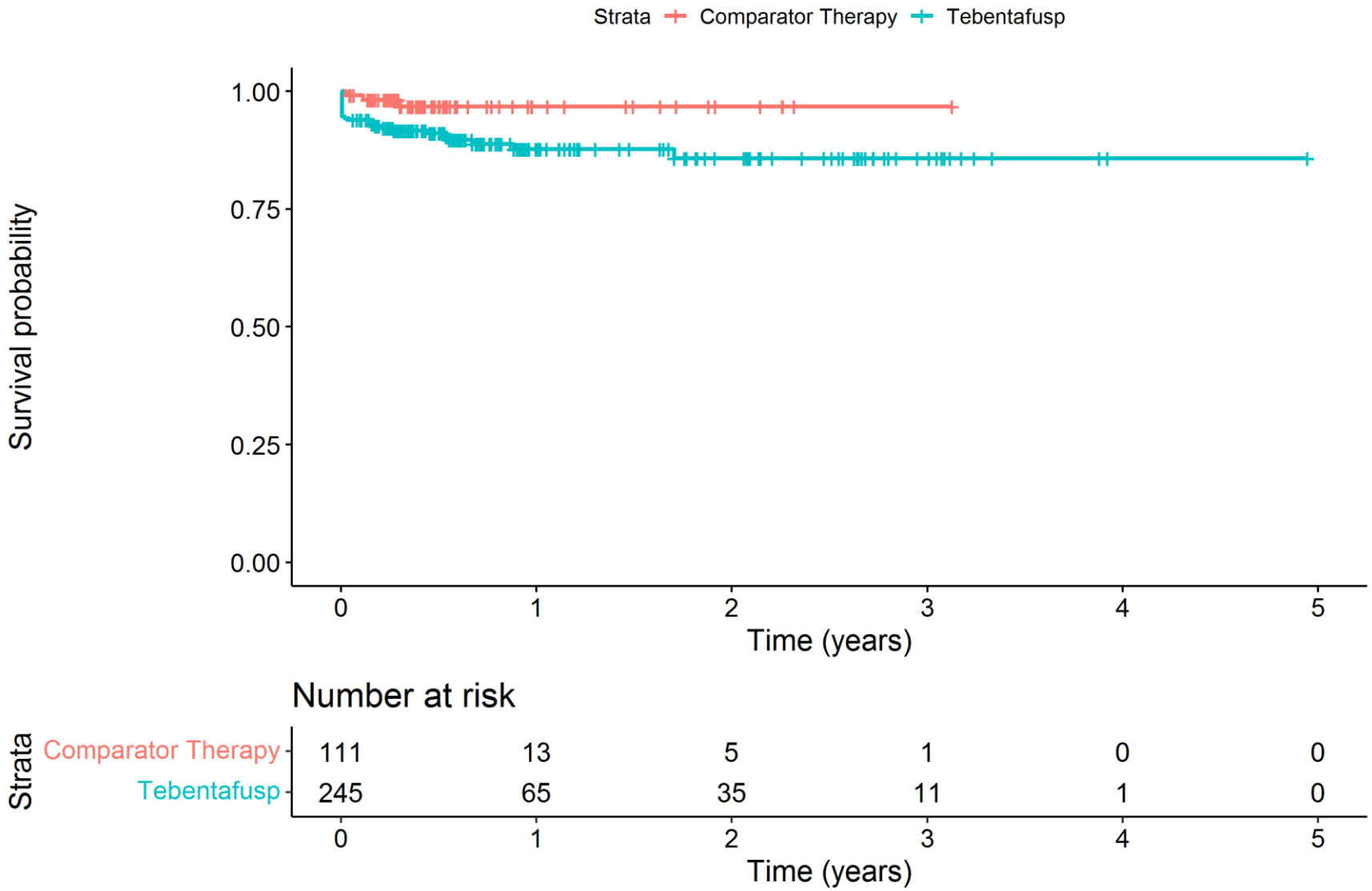
3.21 Alle unerwünschten Ereignisse – 3-Jahres-Analyse (Juni 2023) (Tabelle 4-54)

4 UEs (PT), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten

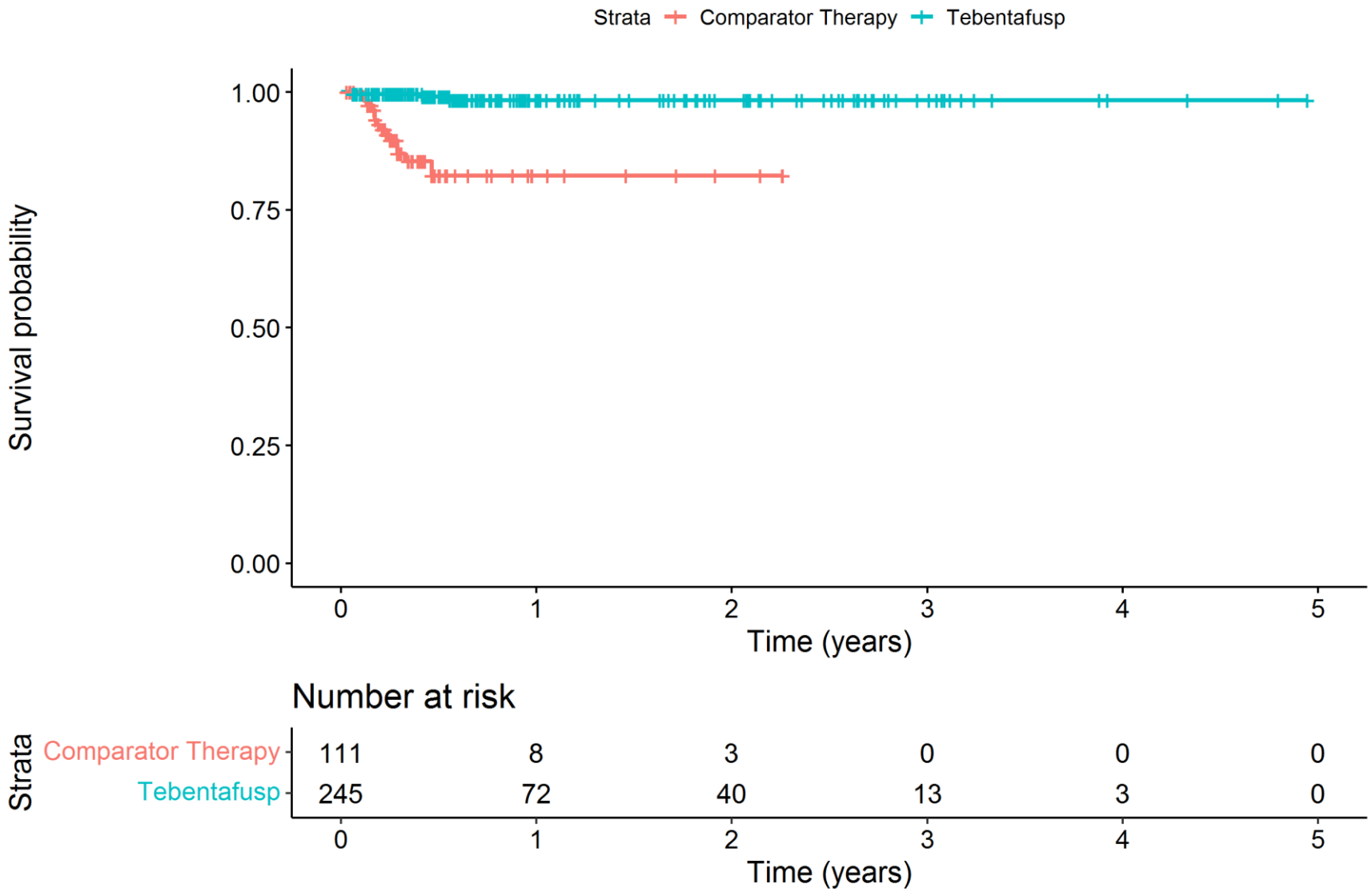
4.1 Anämie



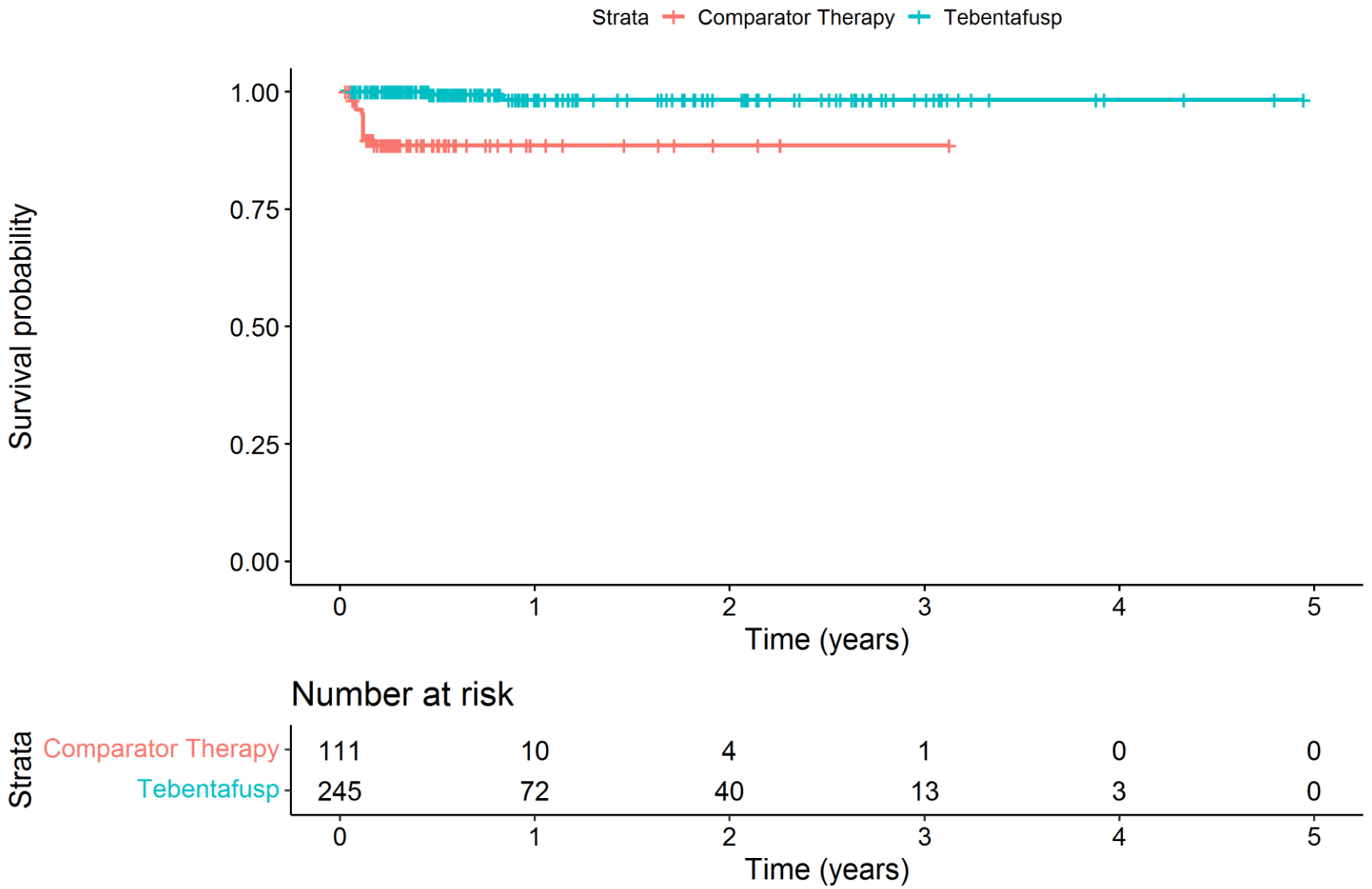
4.2 Lymphopenie



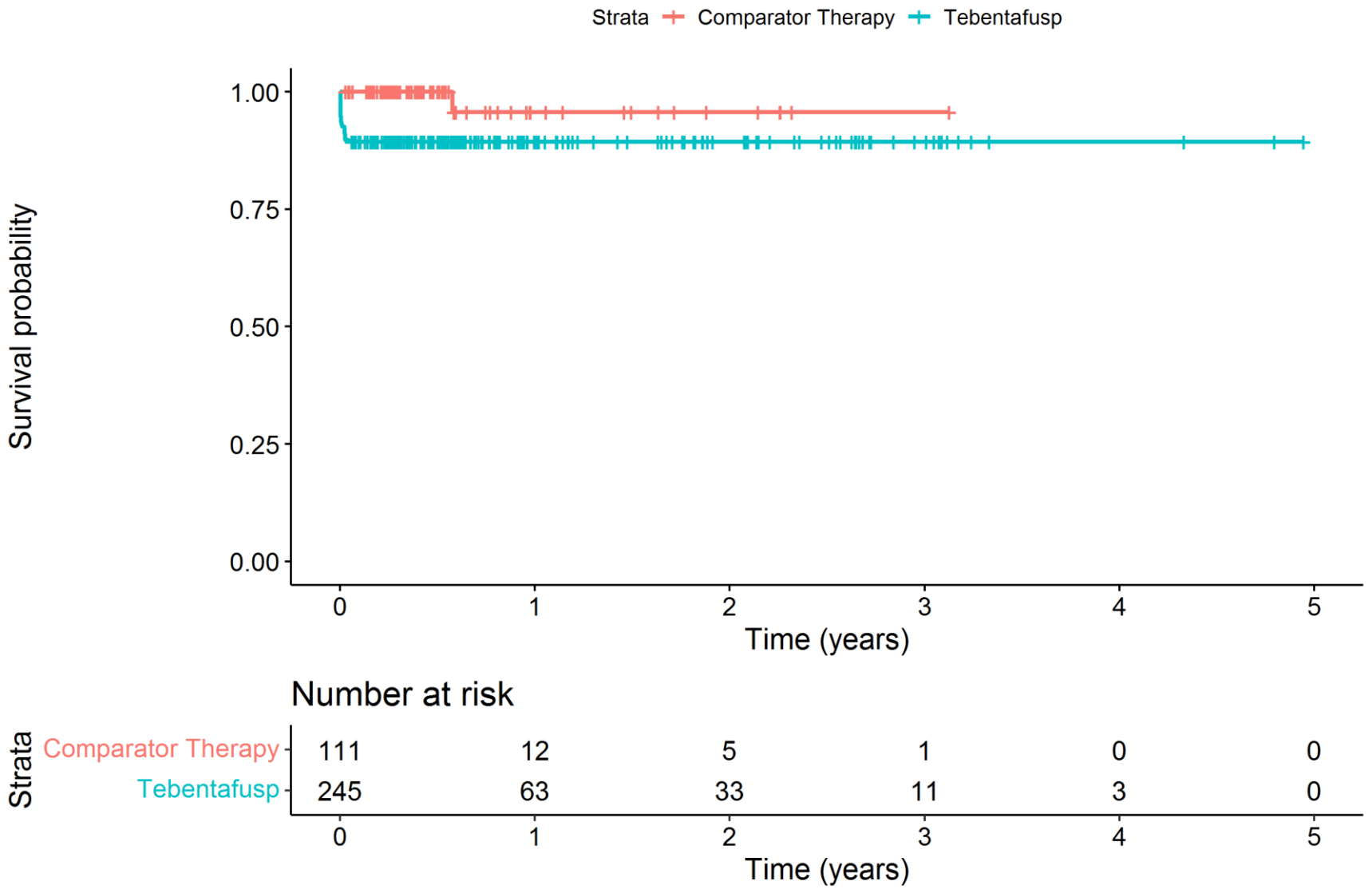
4.3 Hypothyreose



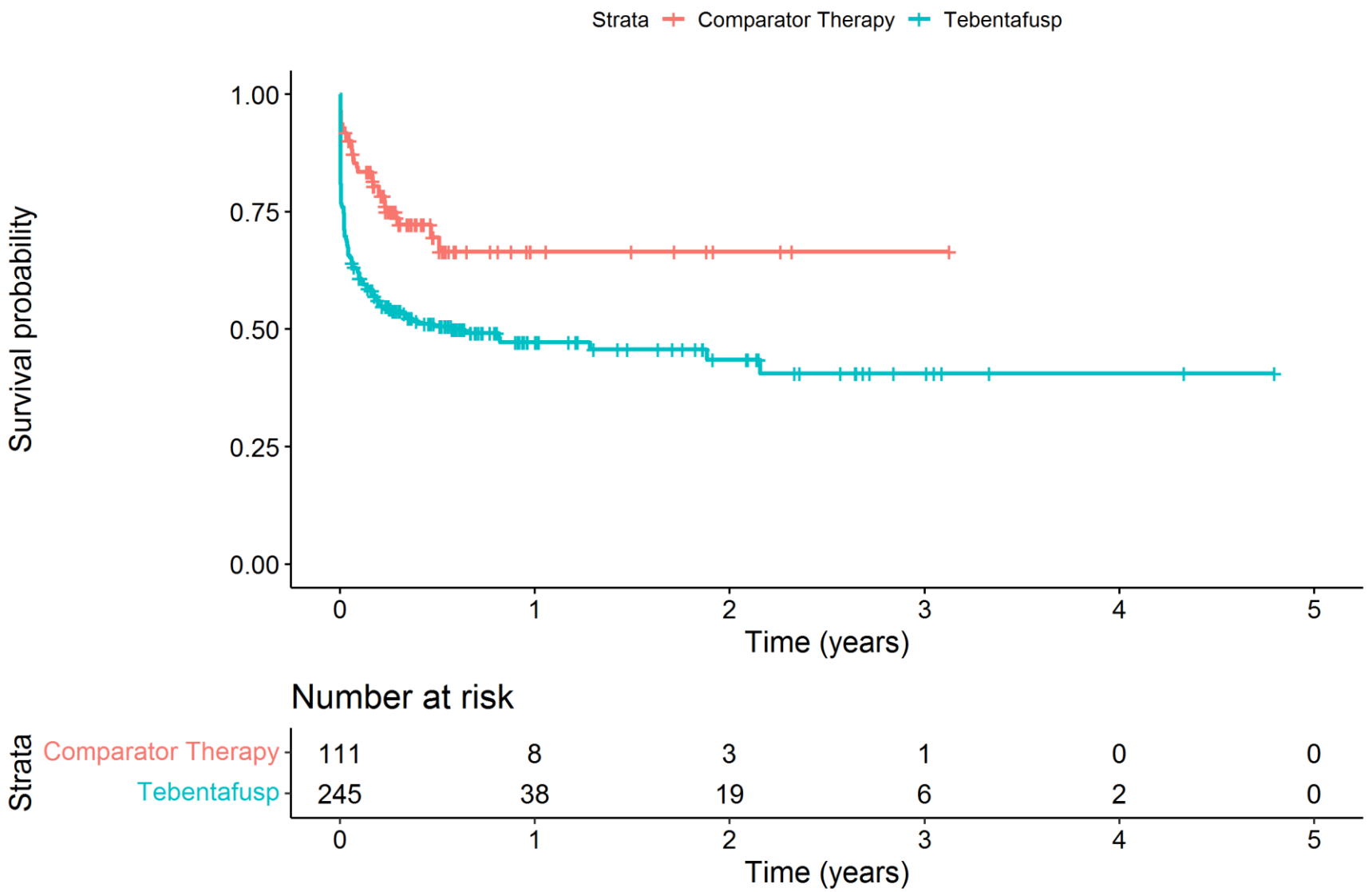
4.4 Hyperthyreose



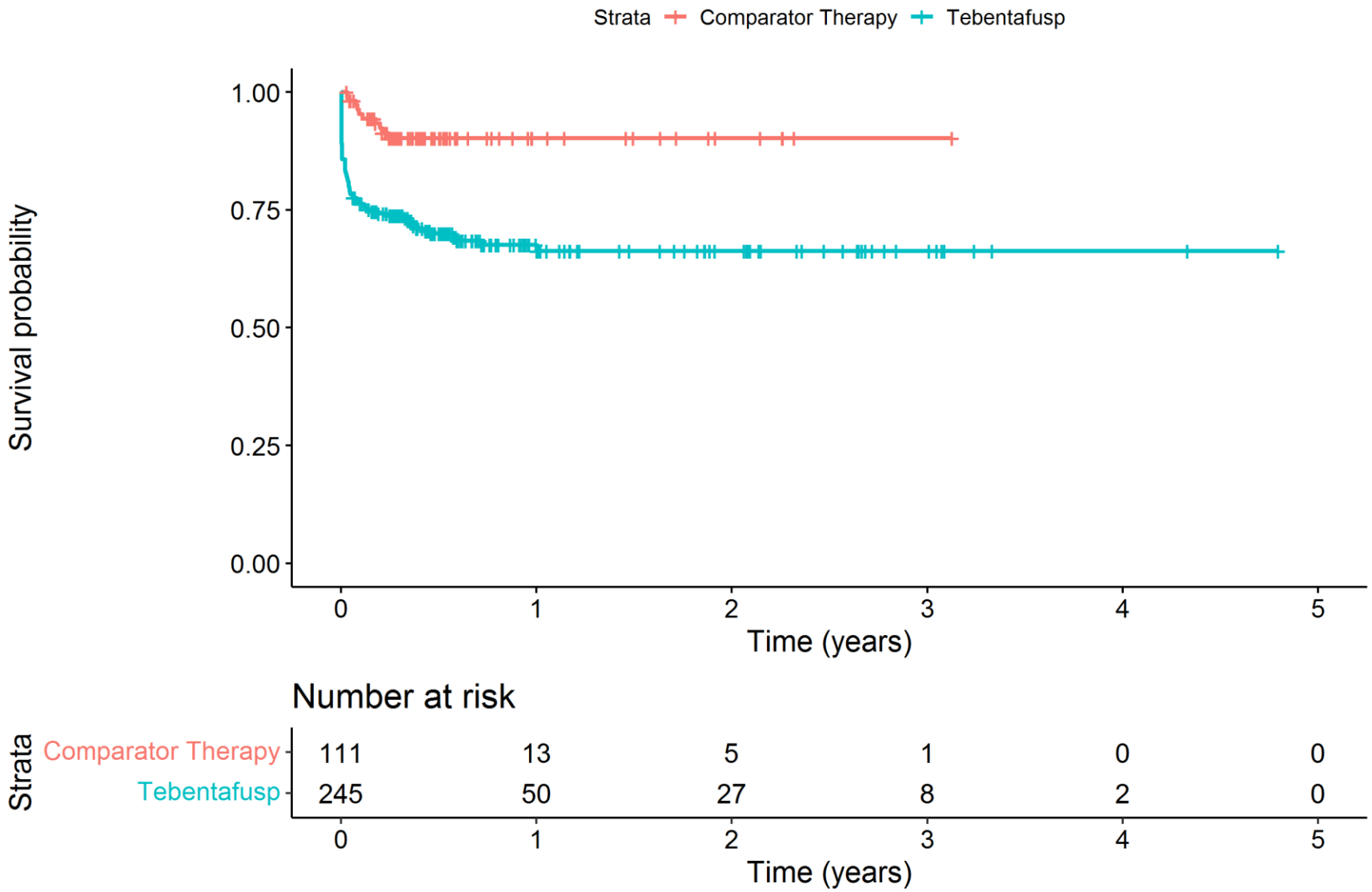
4.5 Periorbitales Ödem



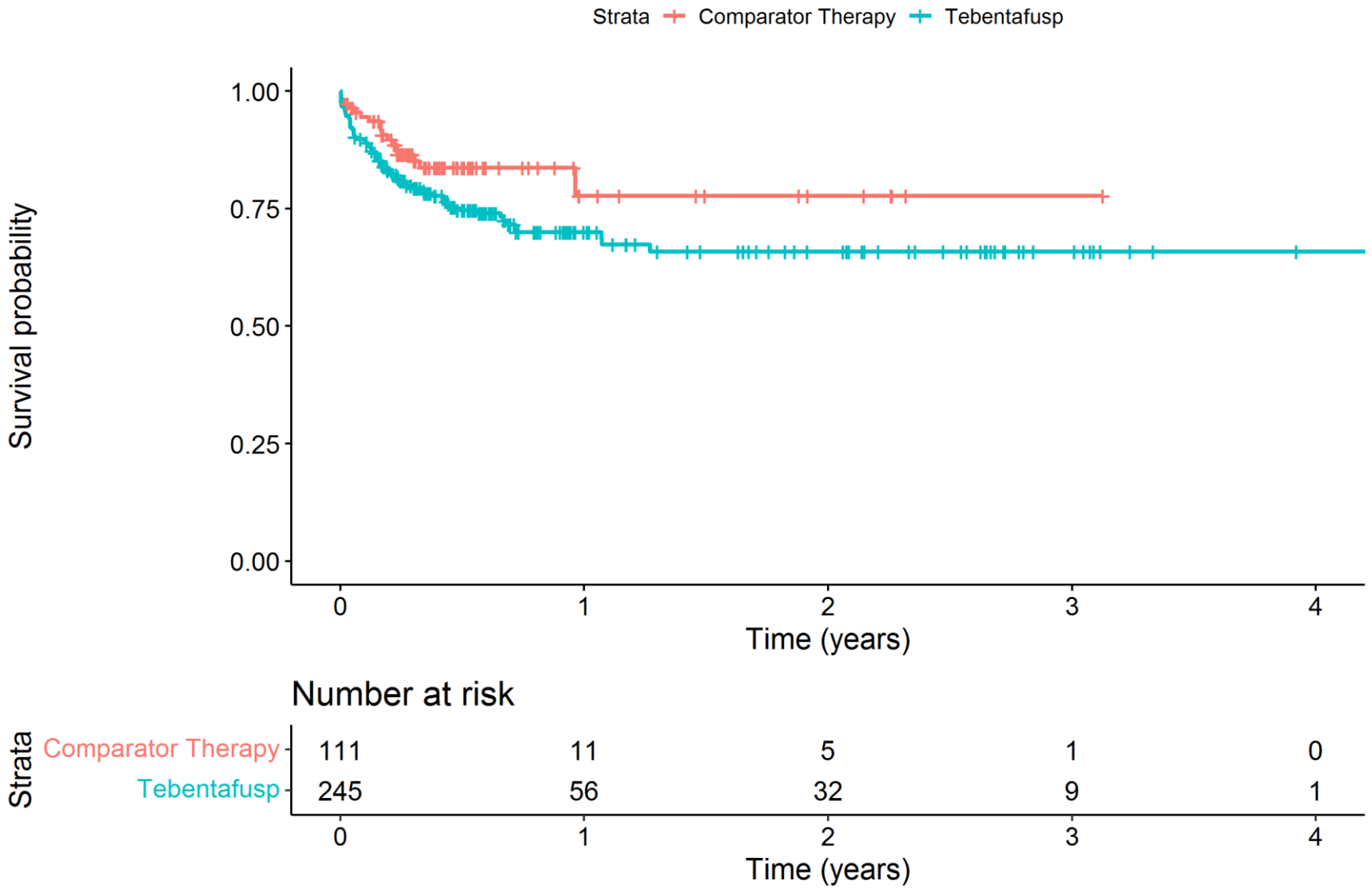
4.6 Übelkeit


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
8
3
1
0
0
245
38
19
6
2
0
0
1
2
3
4
5
Time (years)

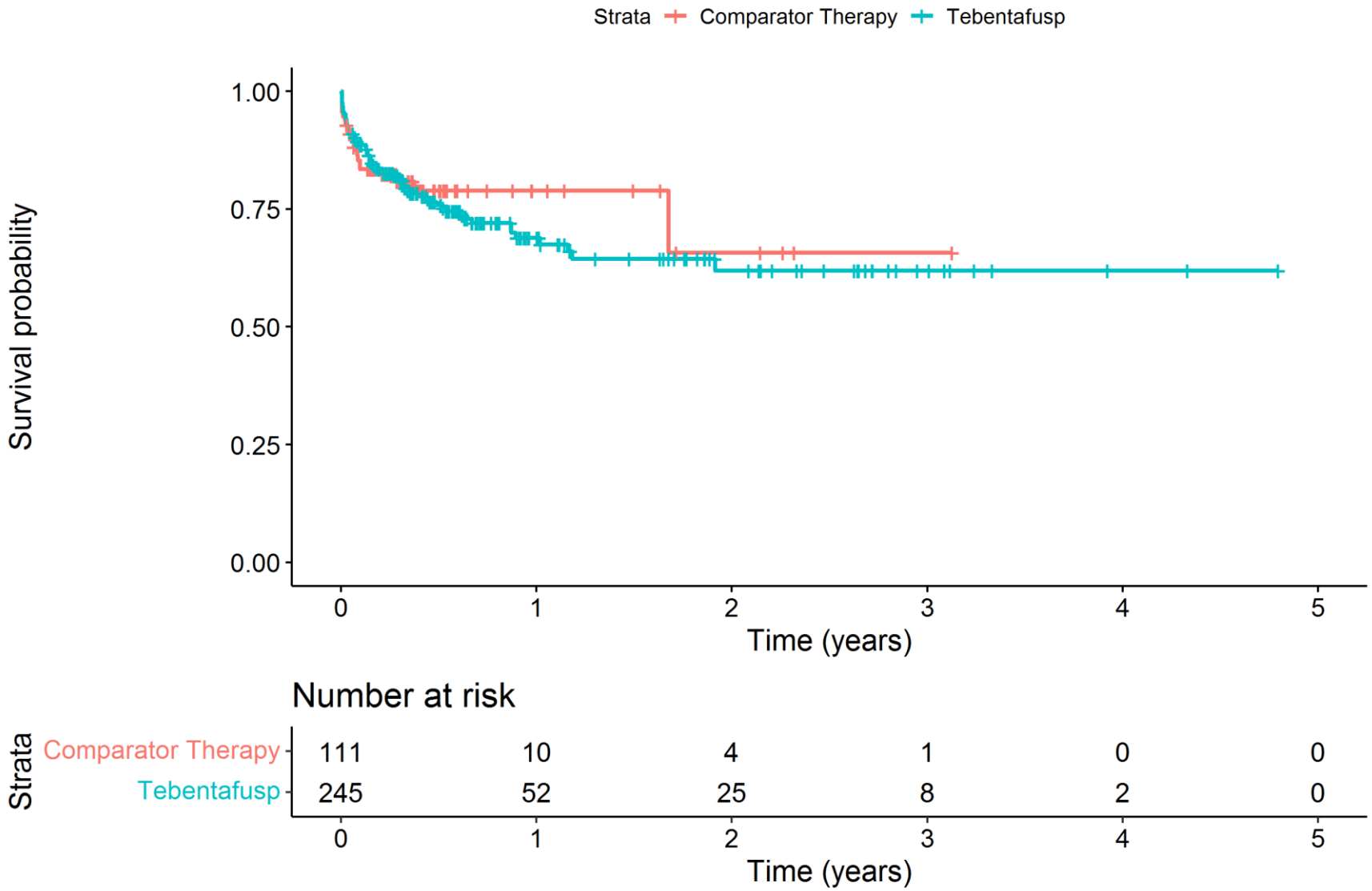
4.7 Erbrechen



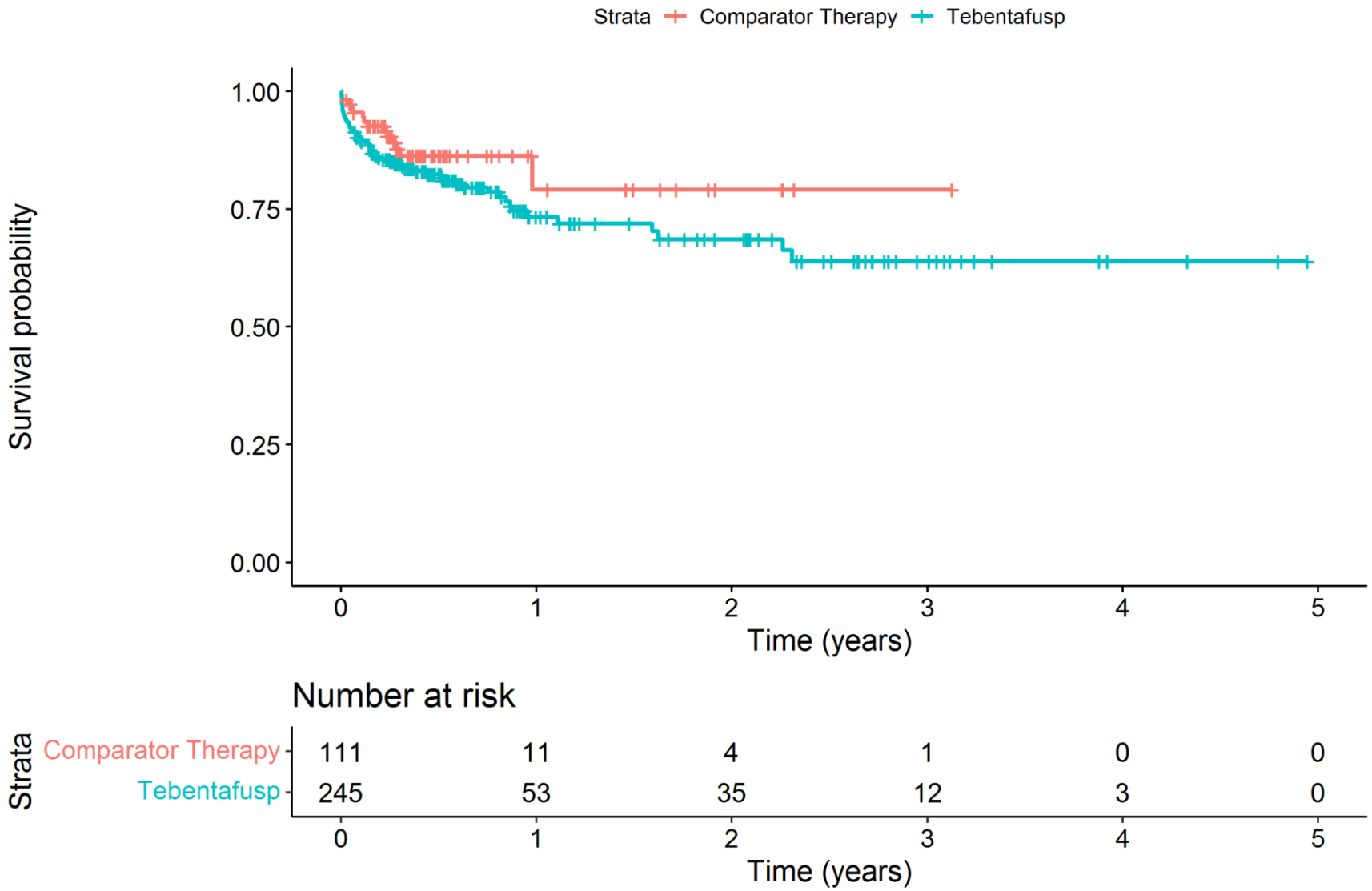
4.8 Unterleibsschmerzen



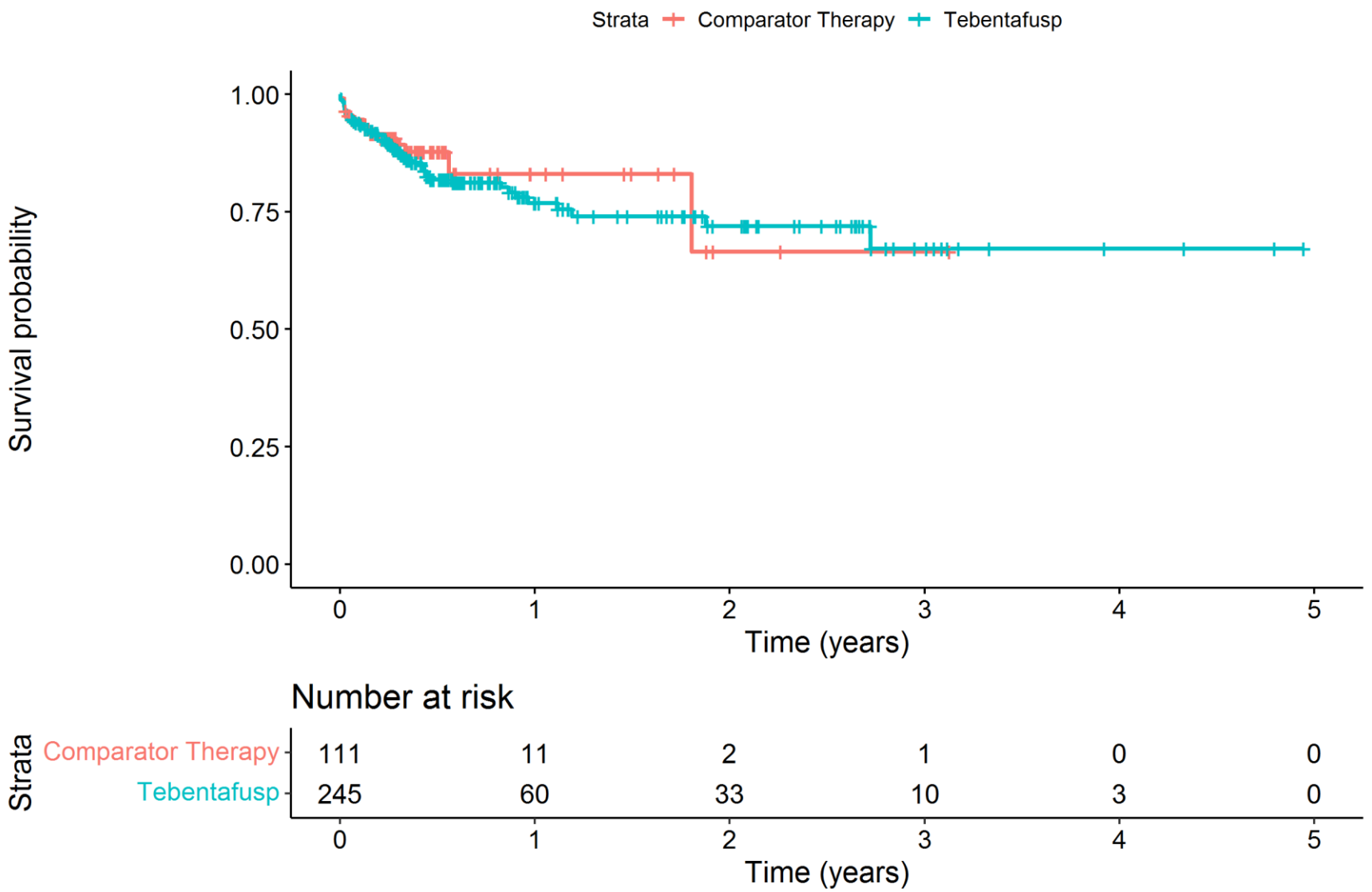
4.9 Diarrhoe


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
4
1
0
0
245
52
25
8
2
0
0
1
2
3
4
5
Time (years)

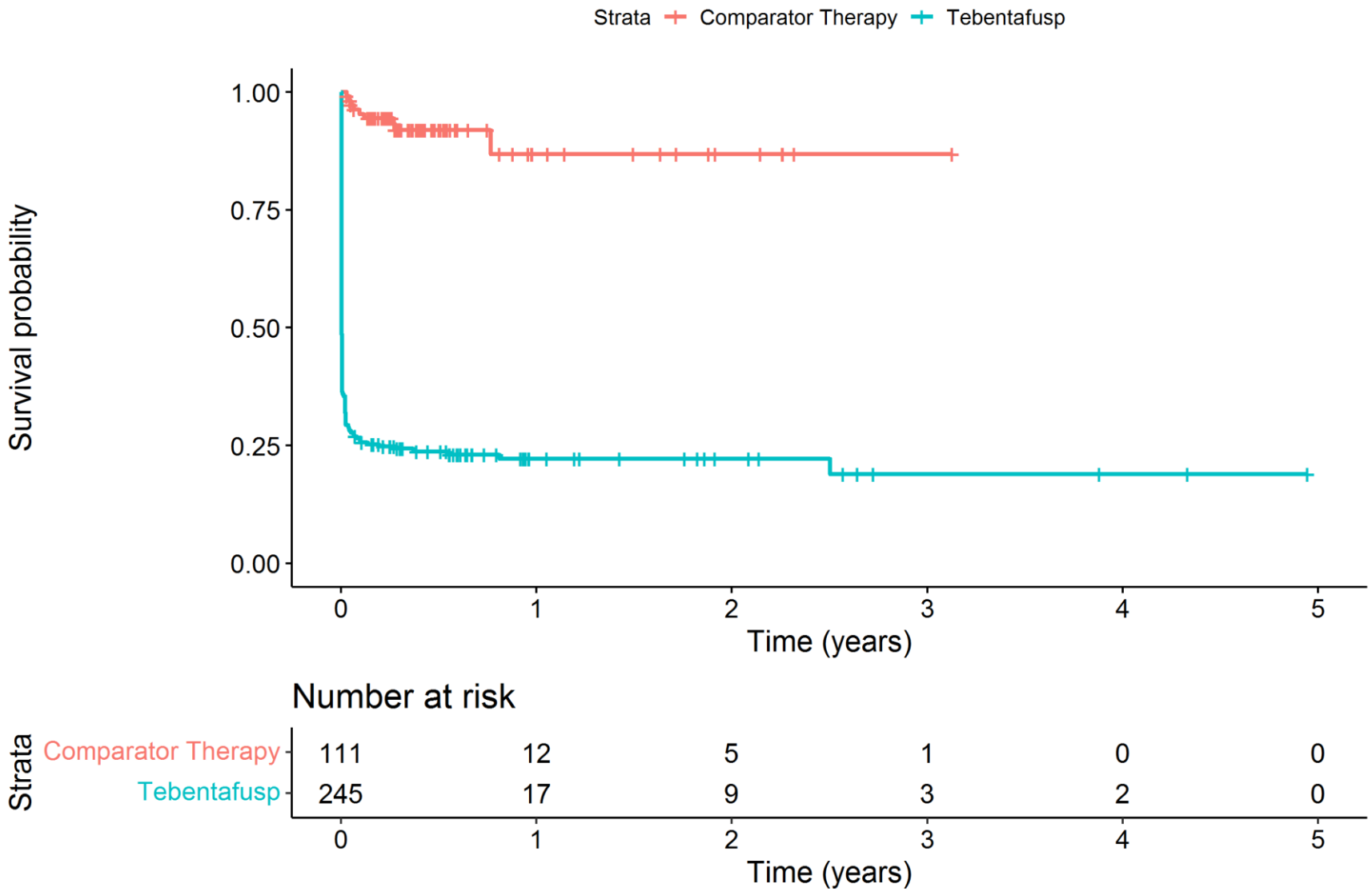
4.10 Oberbauchschmerzen



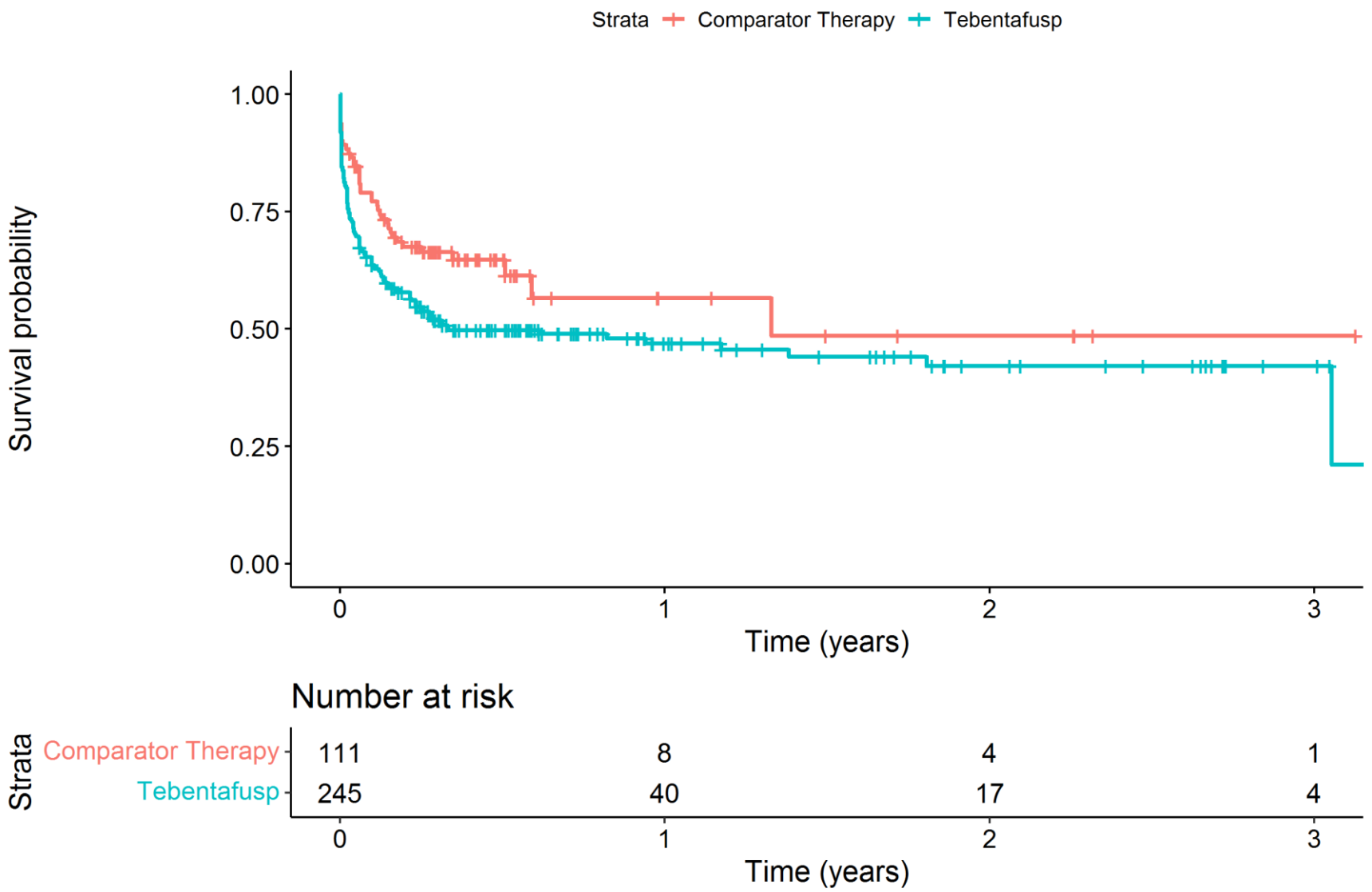
4.11 Verstopfung



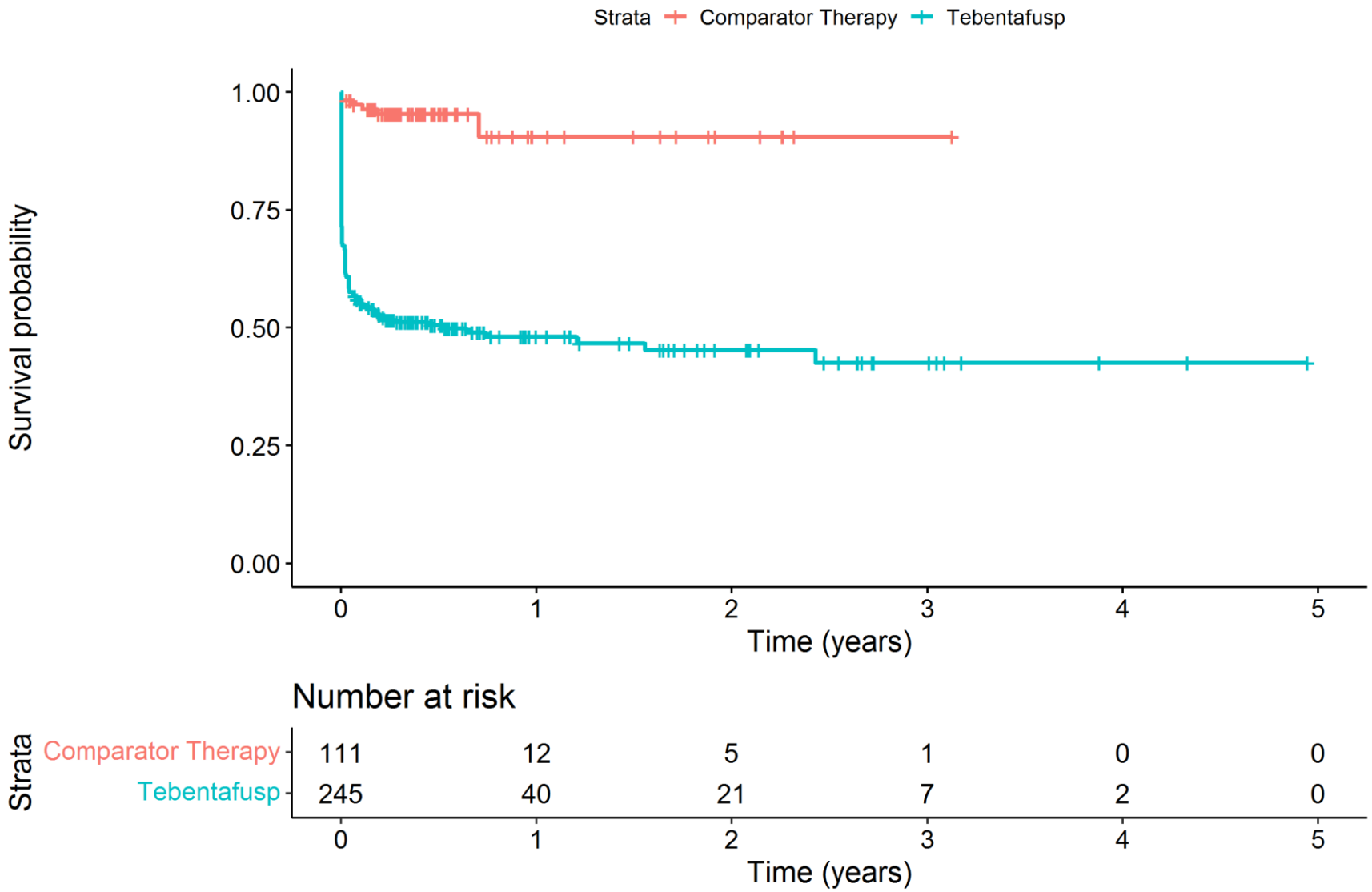
4.12 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
12
5
1
0
0
245
17
9
3
2
0
0
1
2
3
4
5
Time (years)

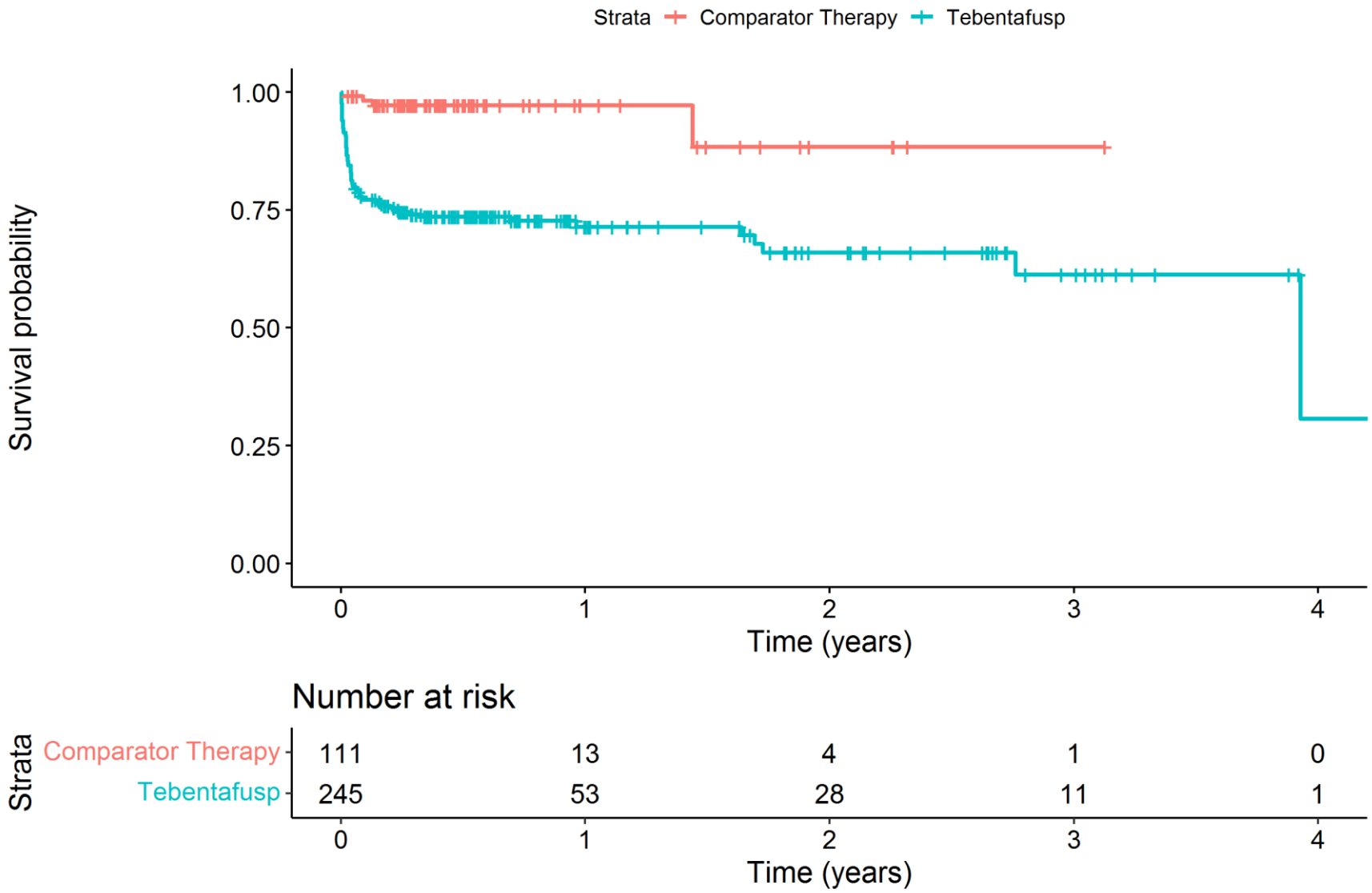
4.13 Müdigkeit



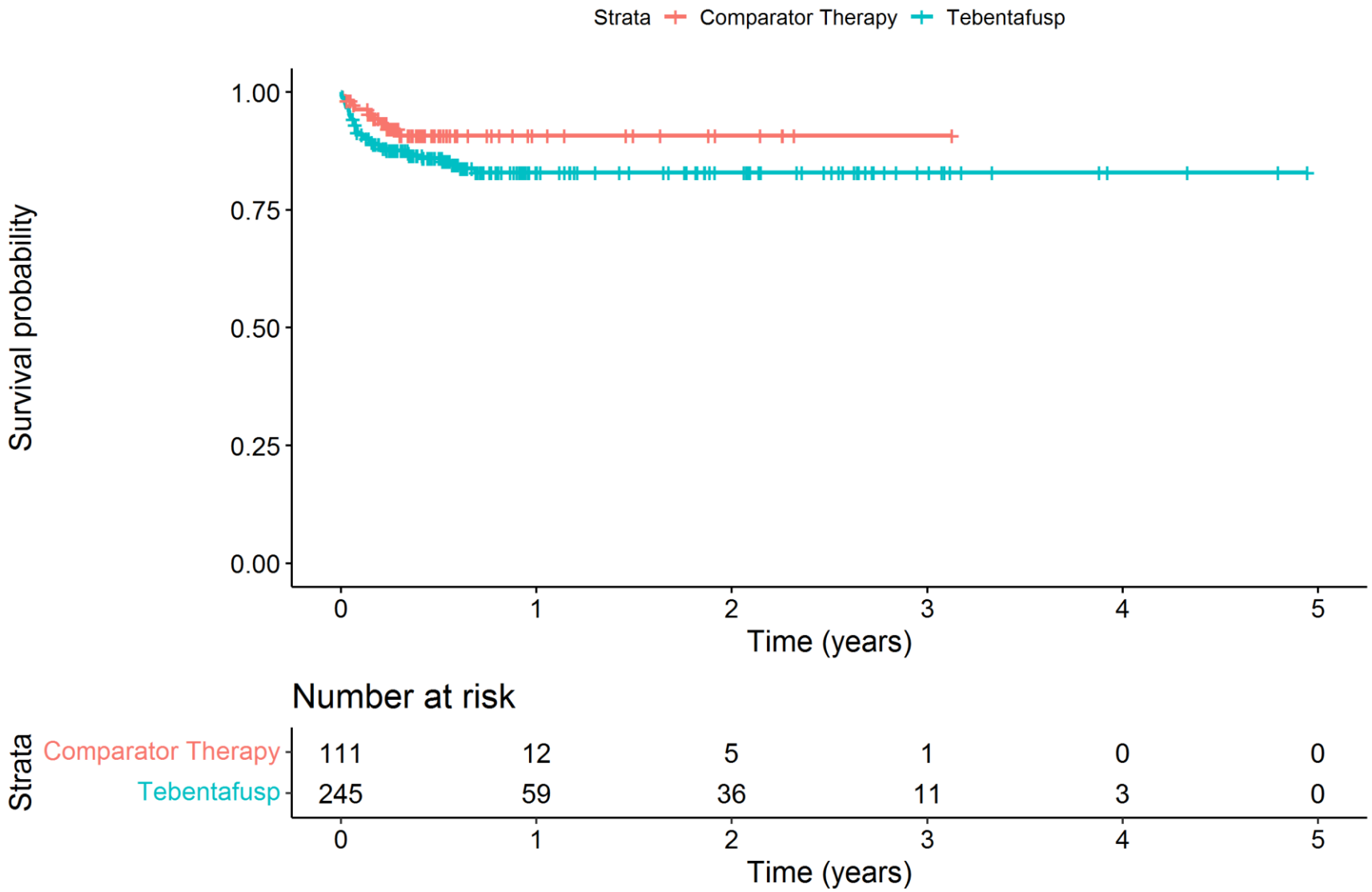
4.14 Schüttelfrost



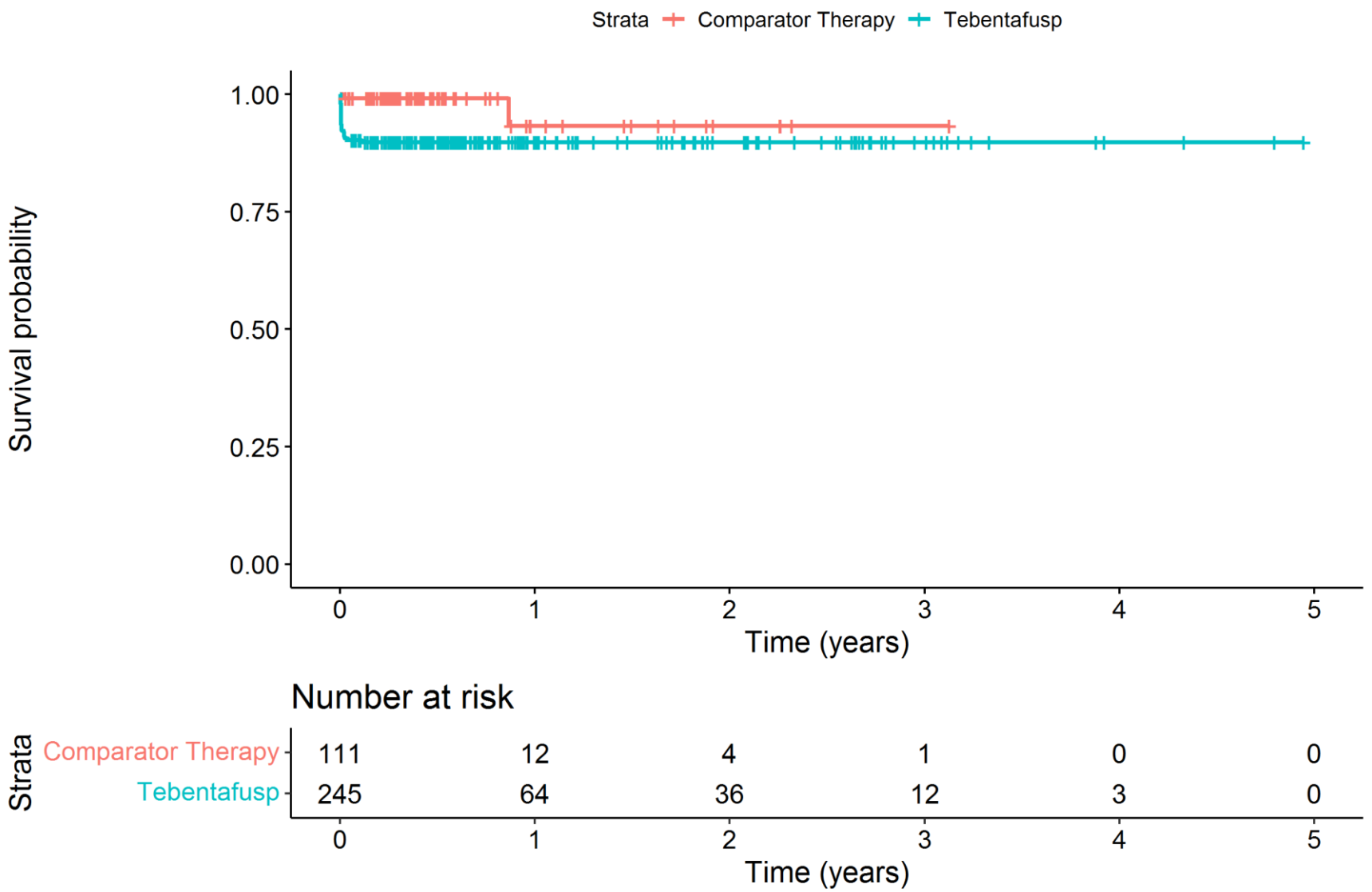
4.15 Periphere Ödeme



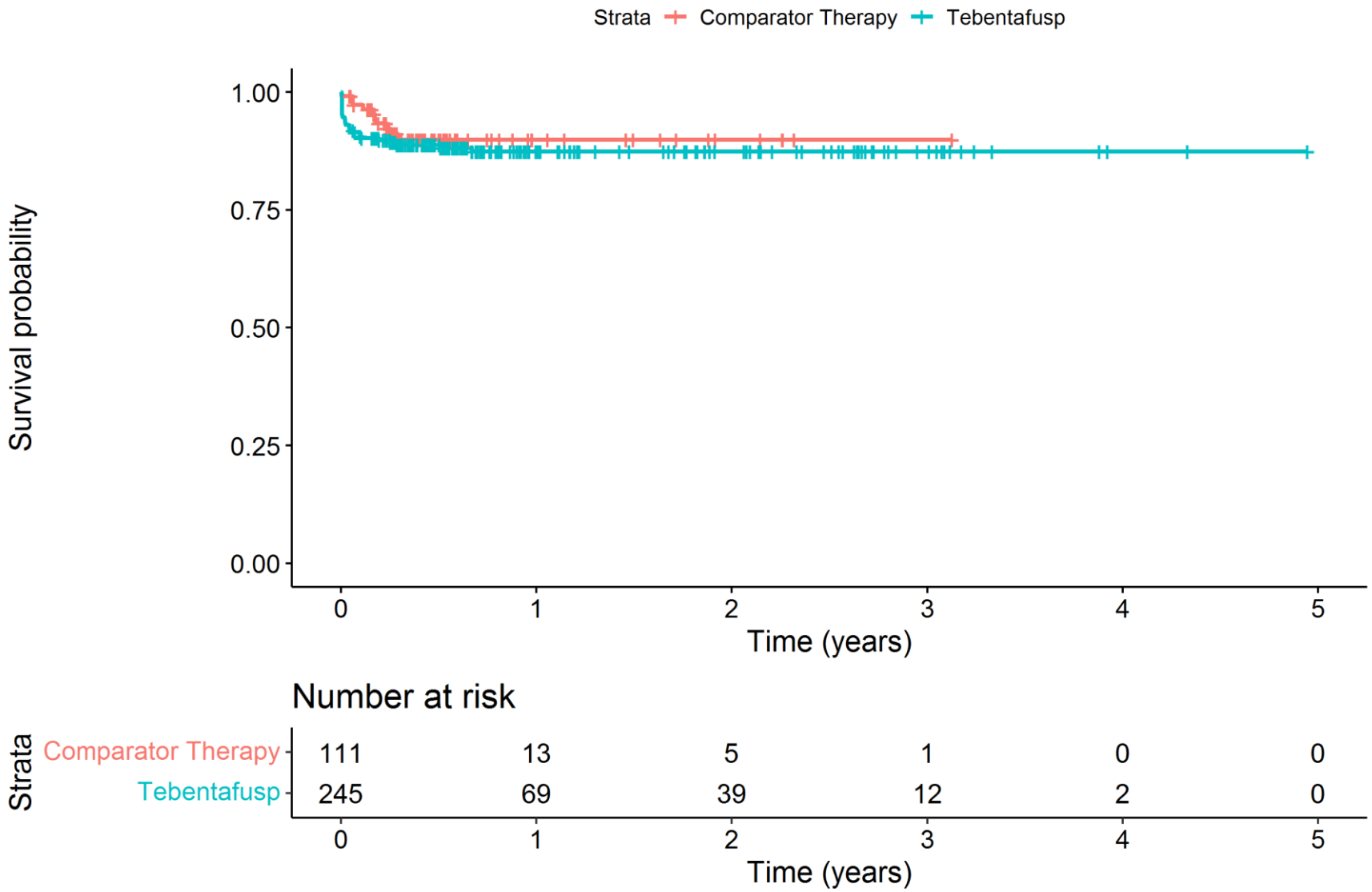
4.16 Asthenie



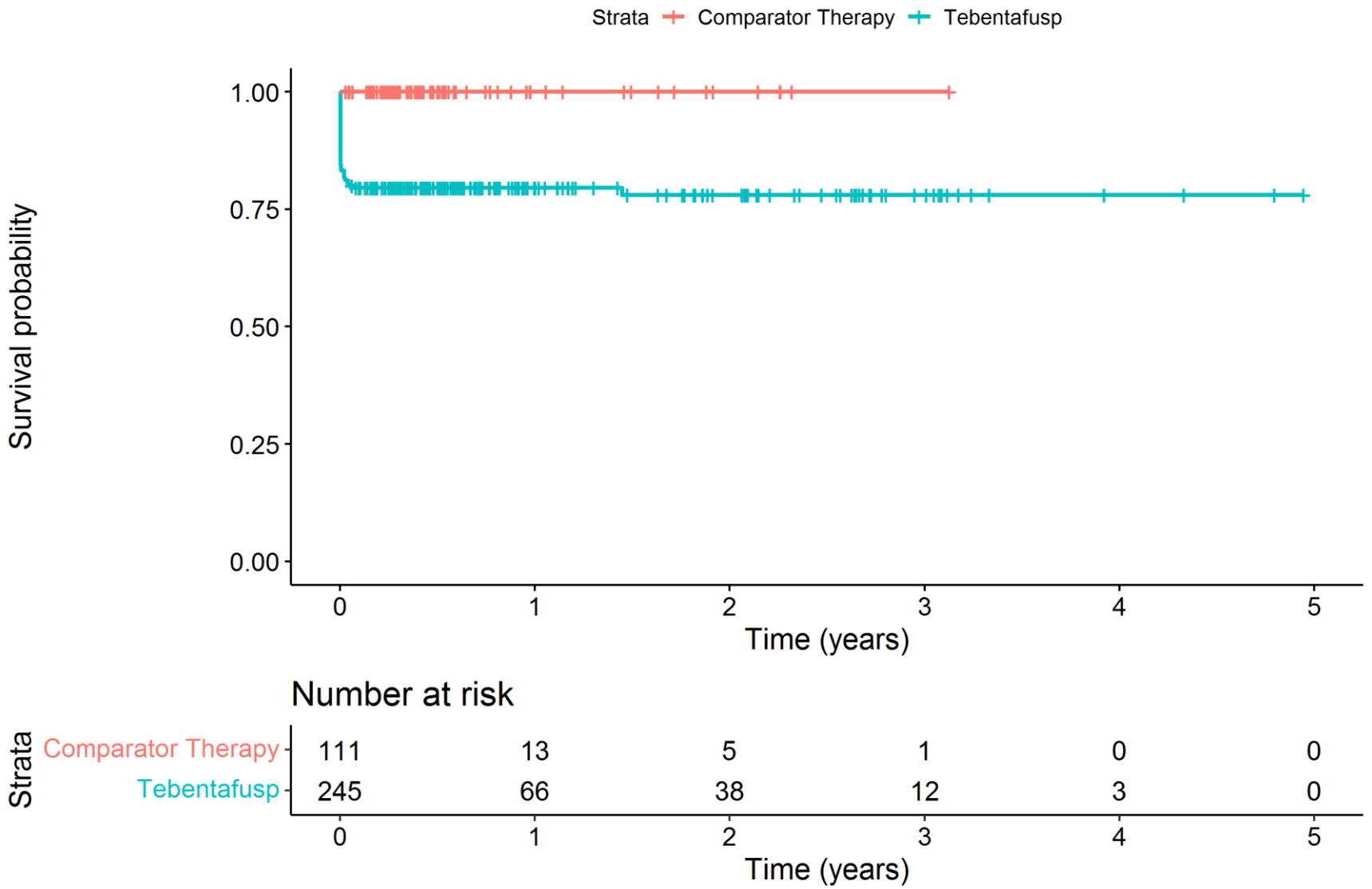
4.17 Gesichtsödeme



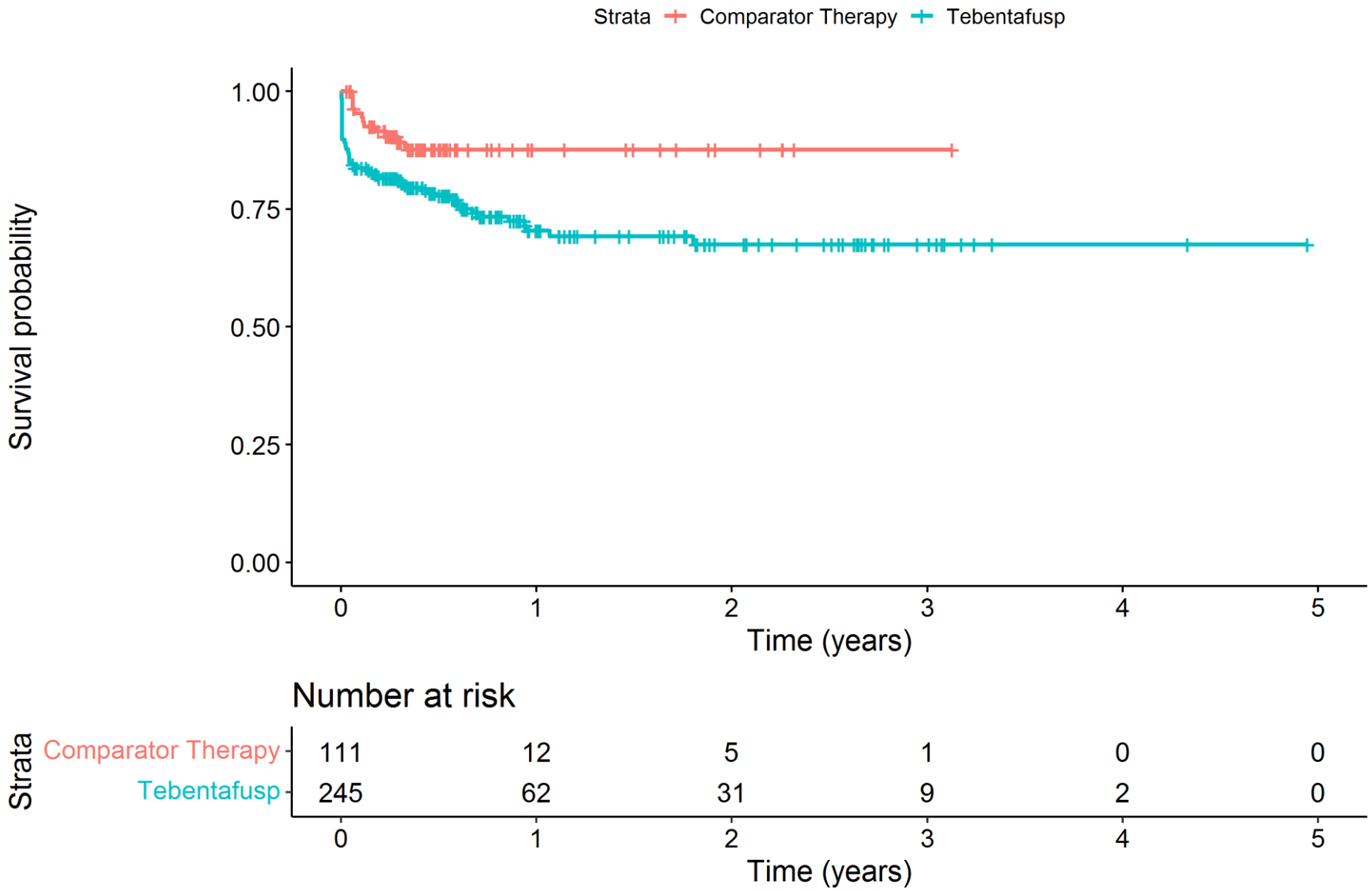
4.18 Hyperbilirubinämie



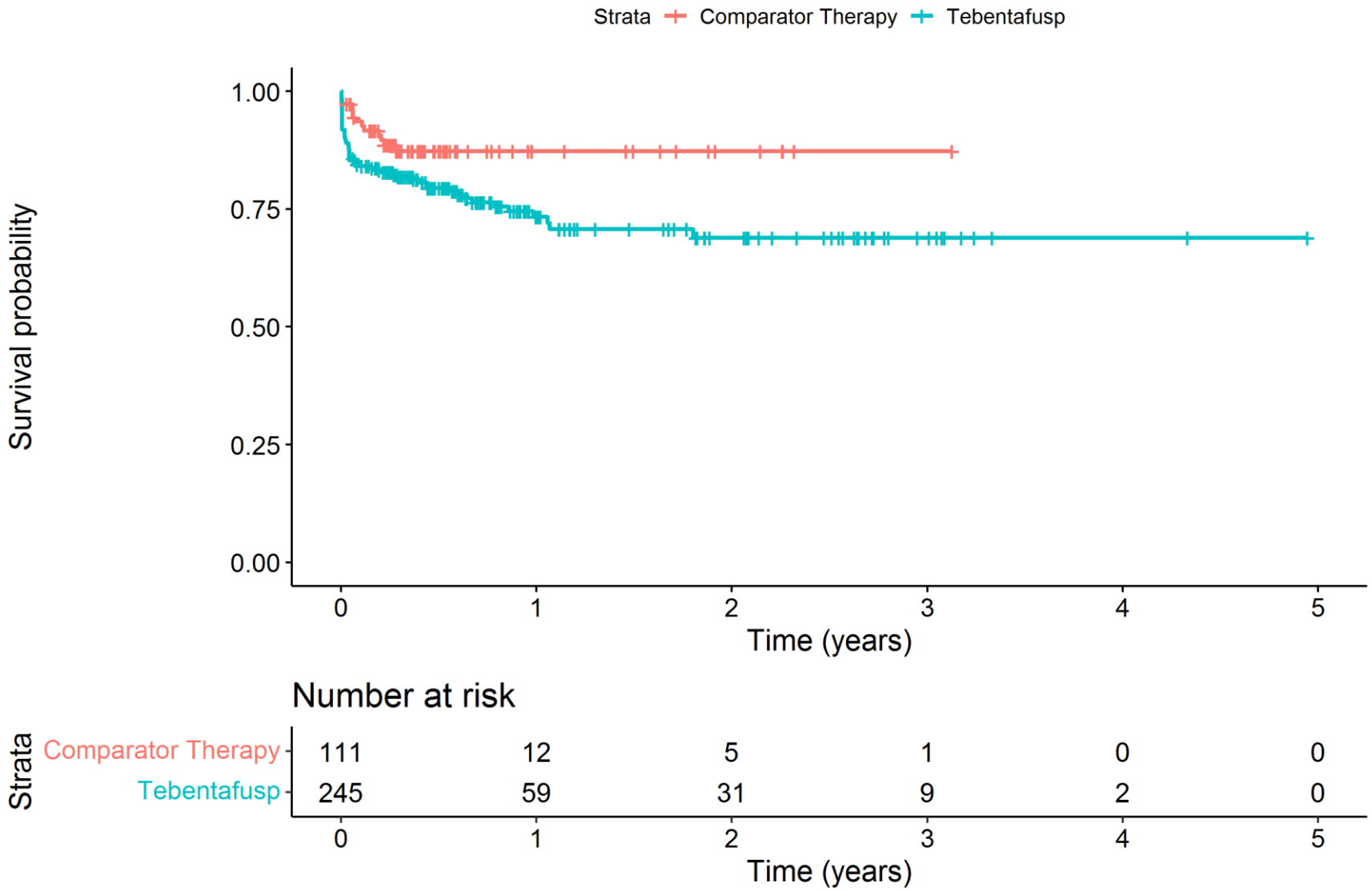
4.19 Zytokin-Freisetzungssyndrom



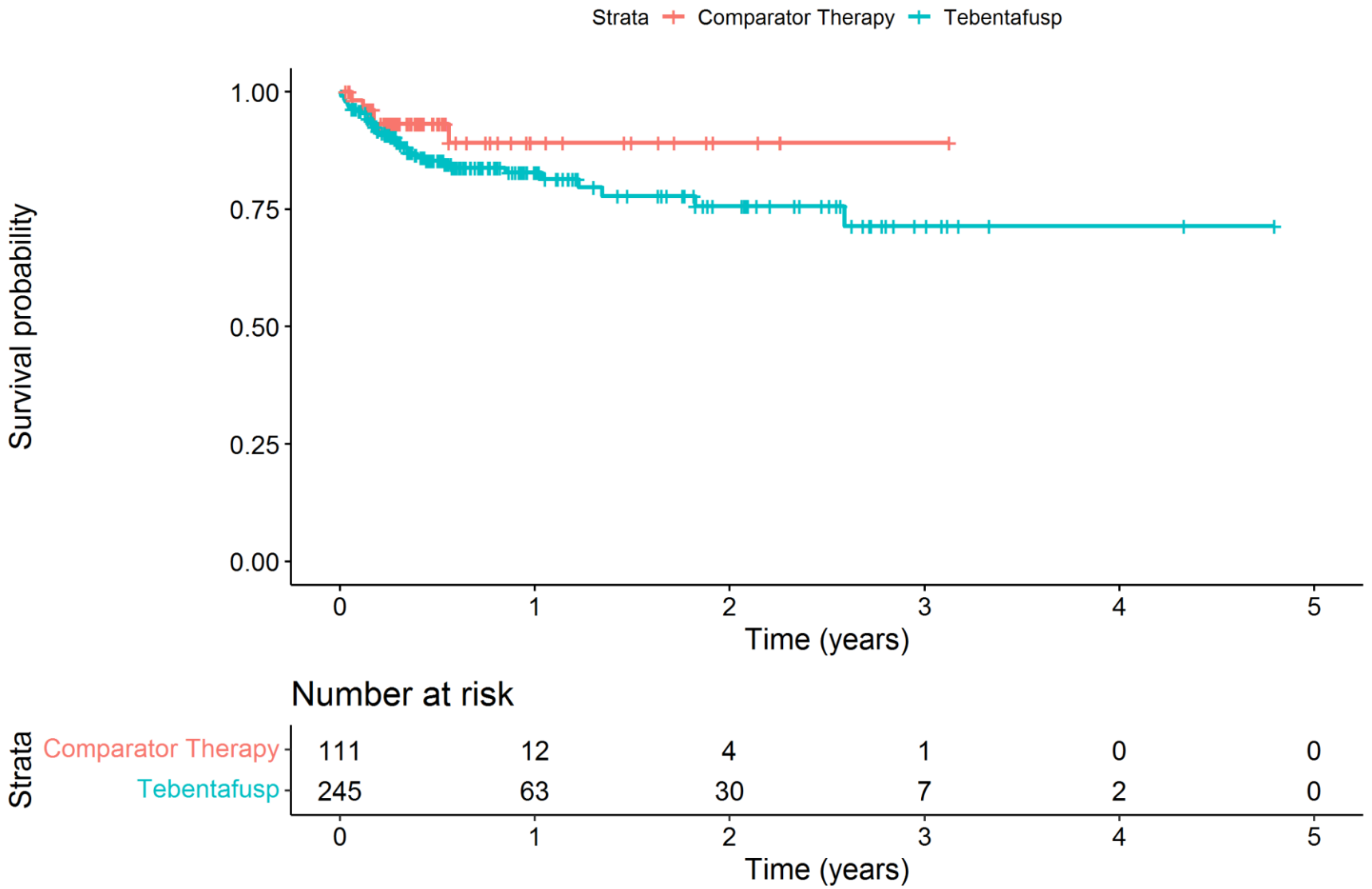
4.20 Erhöhte Aspartat-Aminotransferase



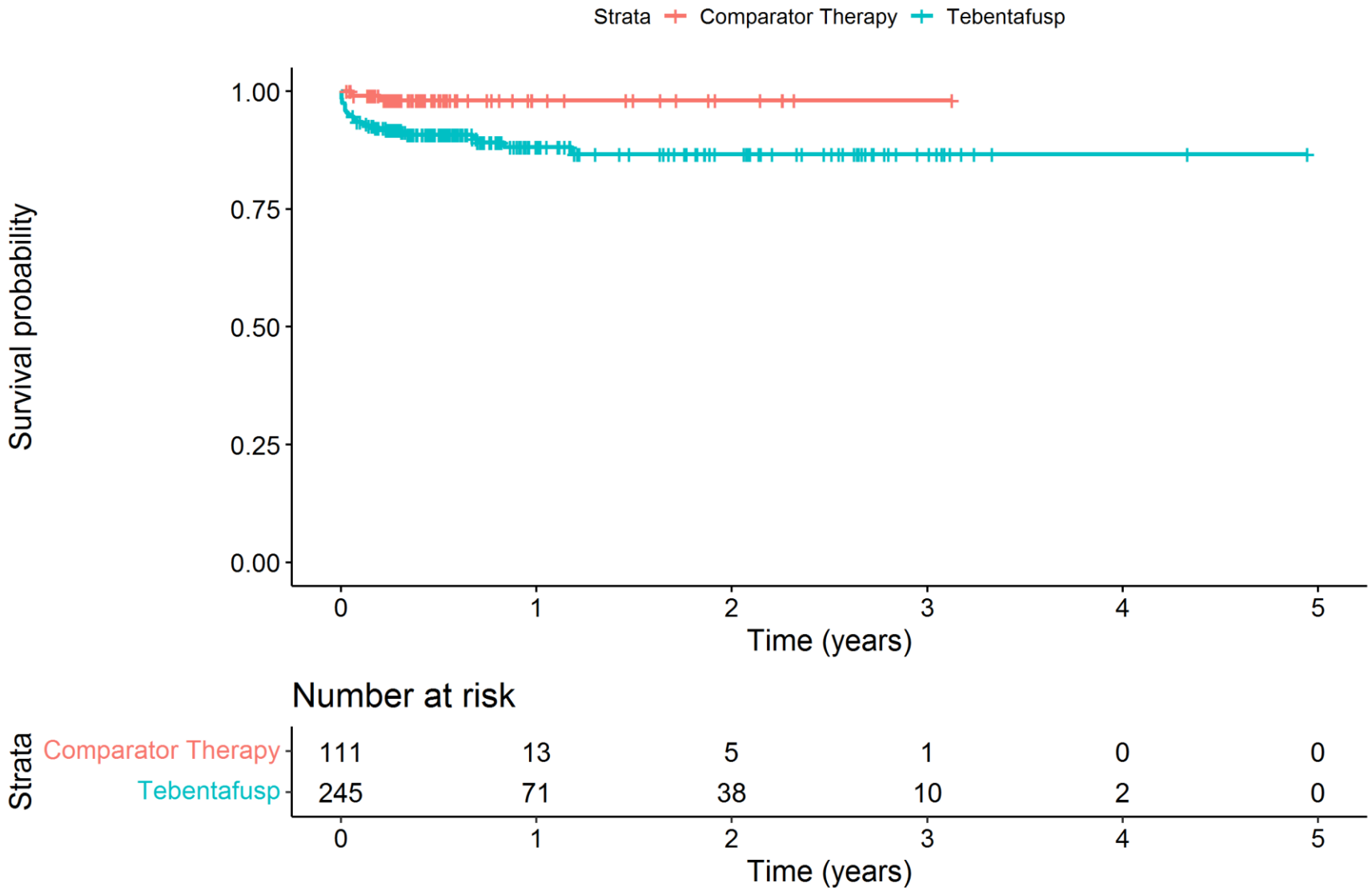
4.21 Erhöhte Alanin-Aminotransferase



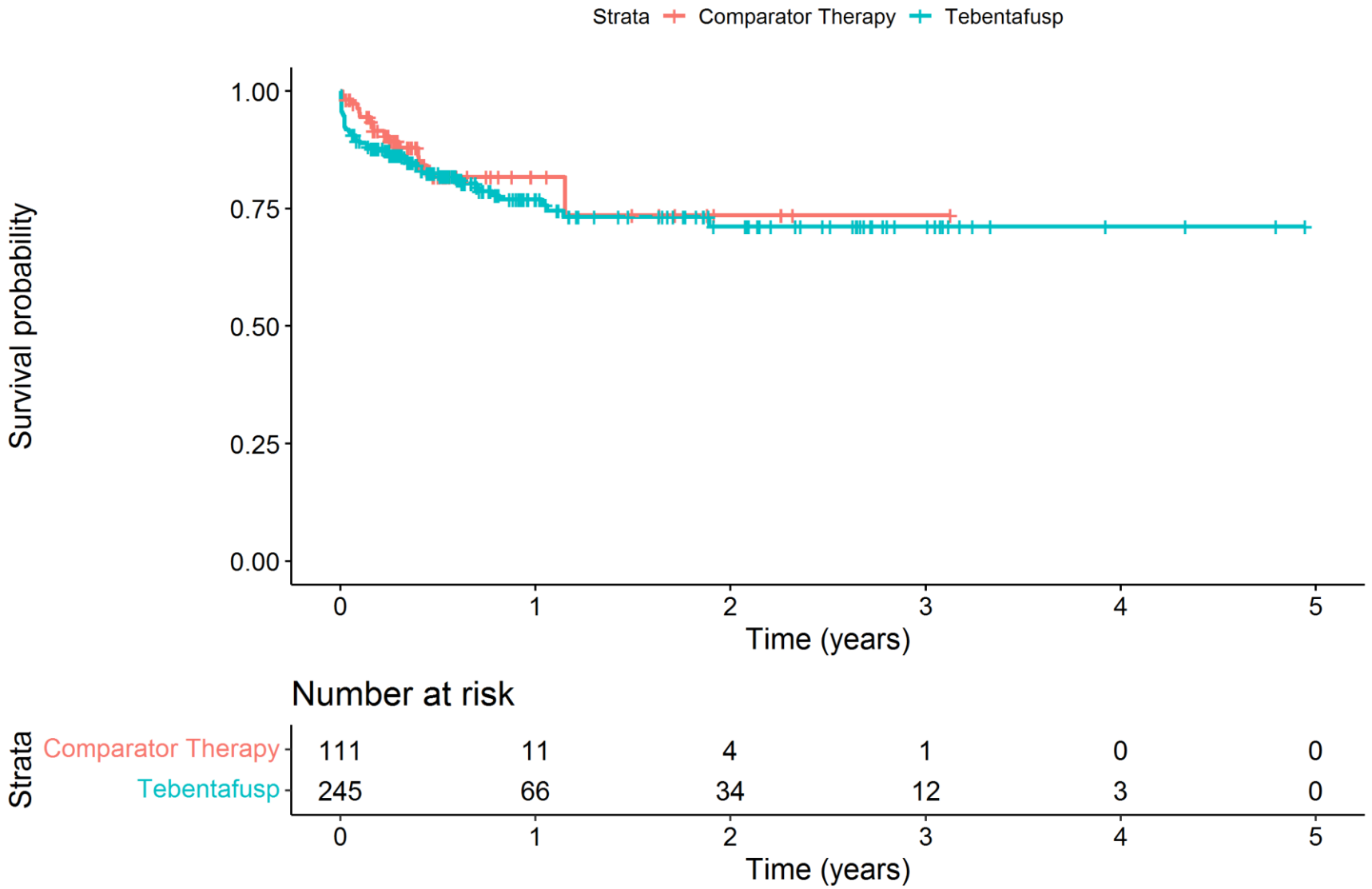
4.22 Erhöhte Lipase



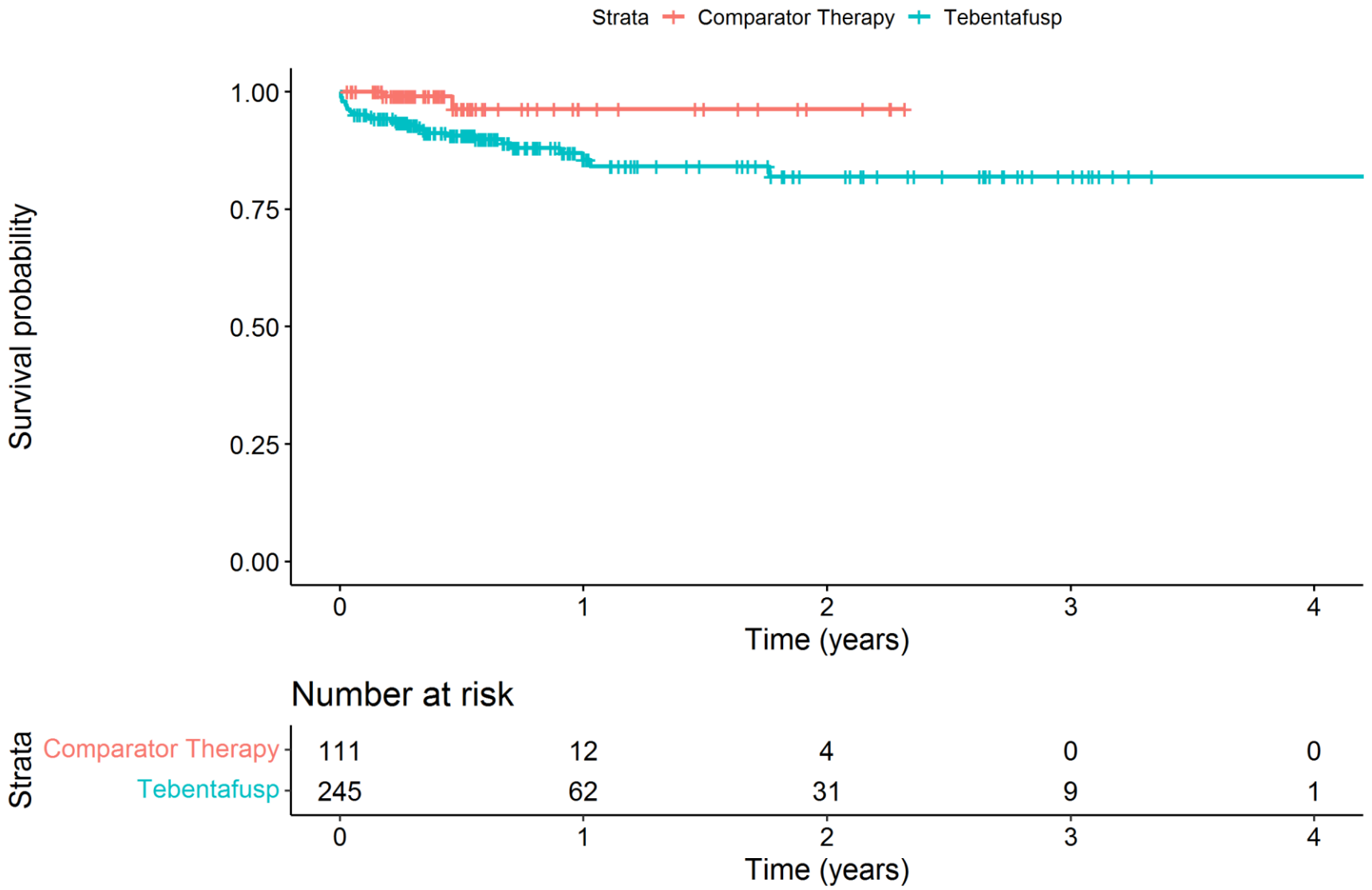
4.23 Erhöhte alkalische Phosphatase im Blut



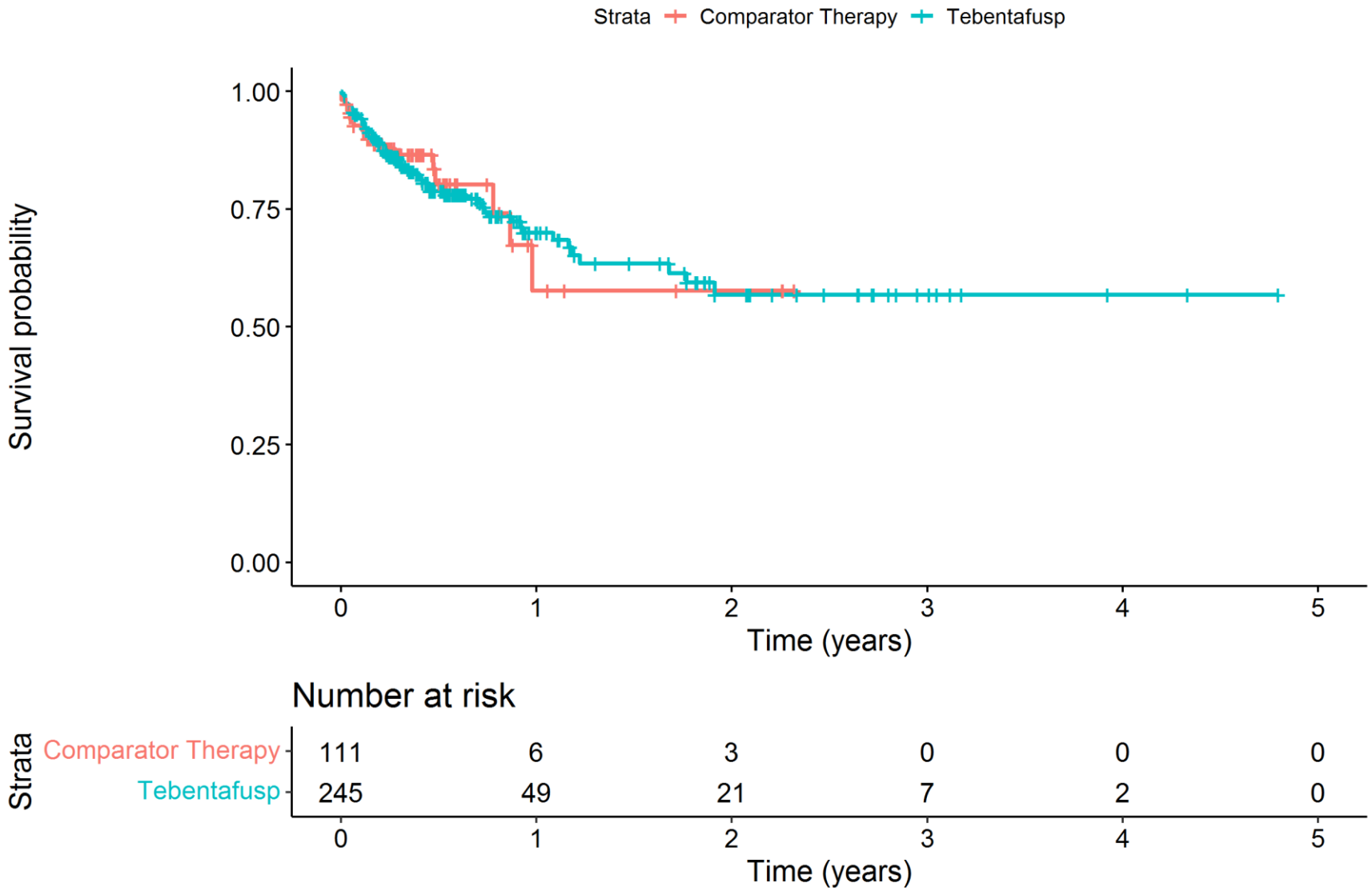
4.24 Verminderter Appetit



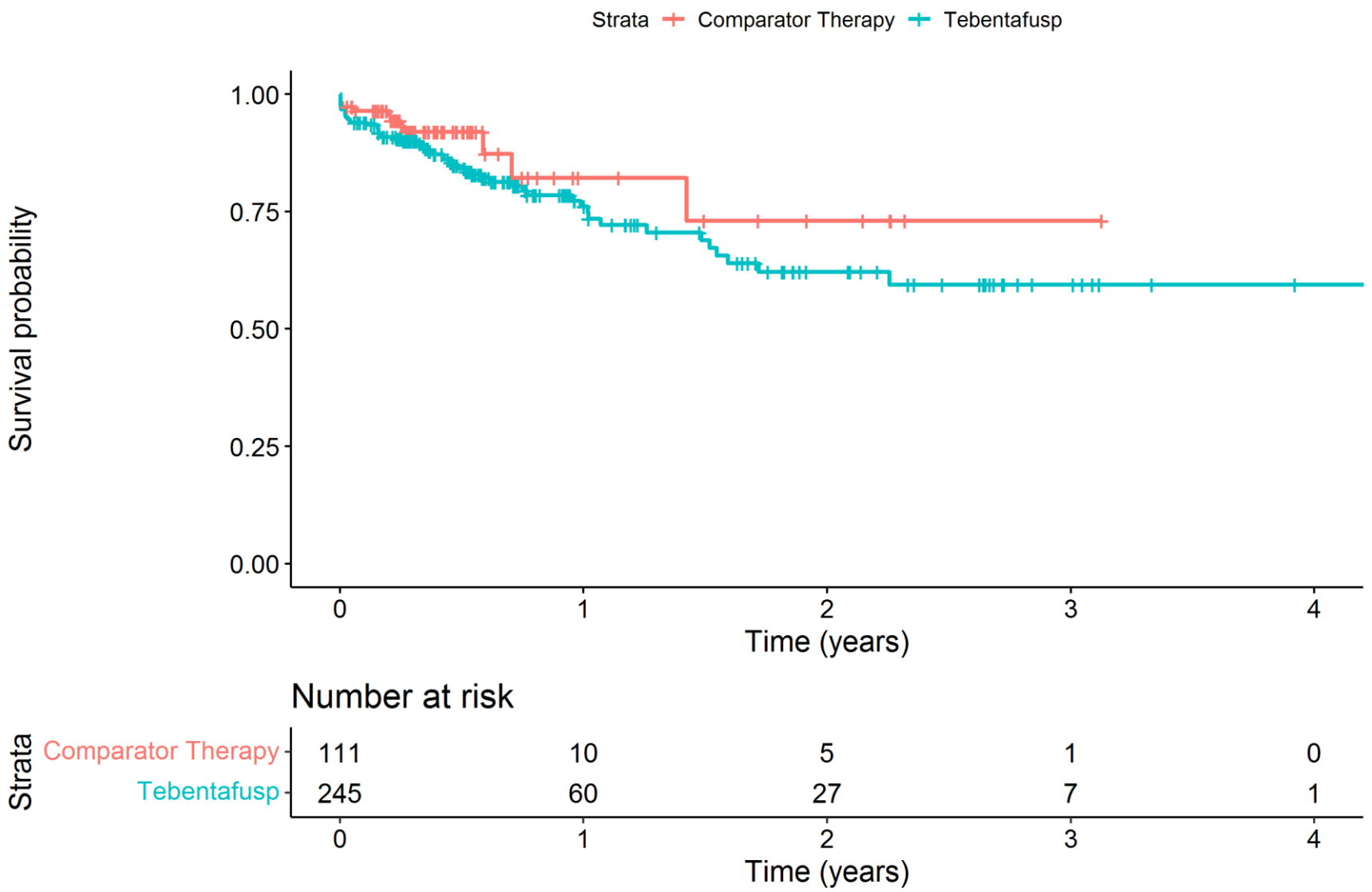
4.25 Hypophosphatämie



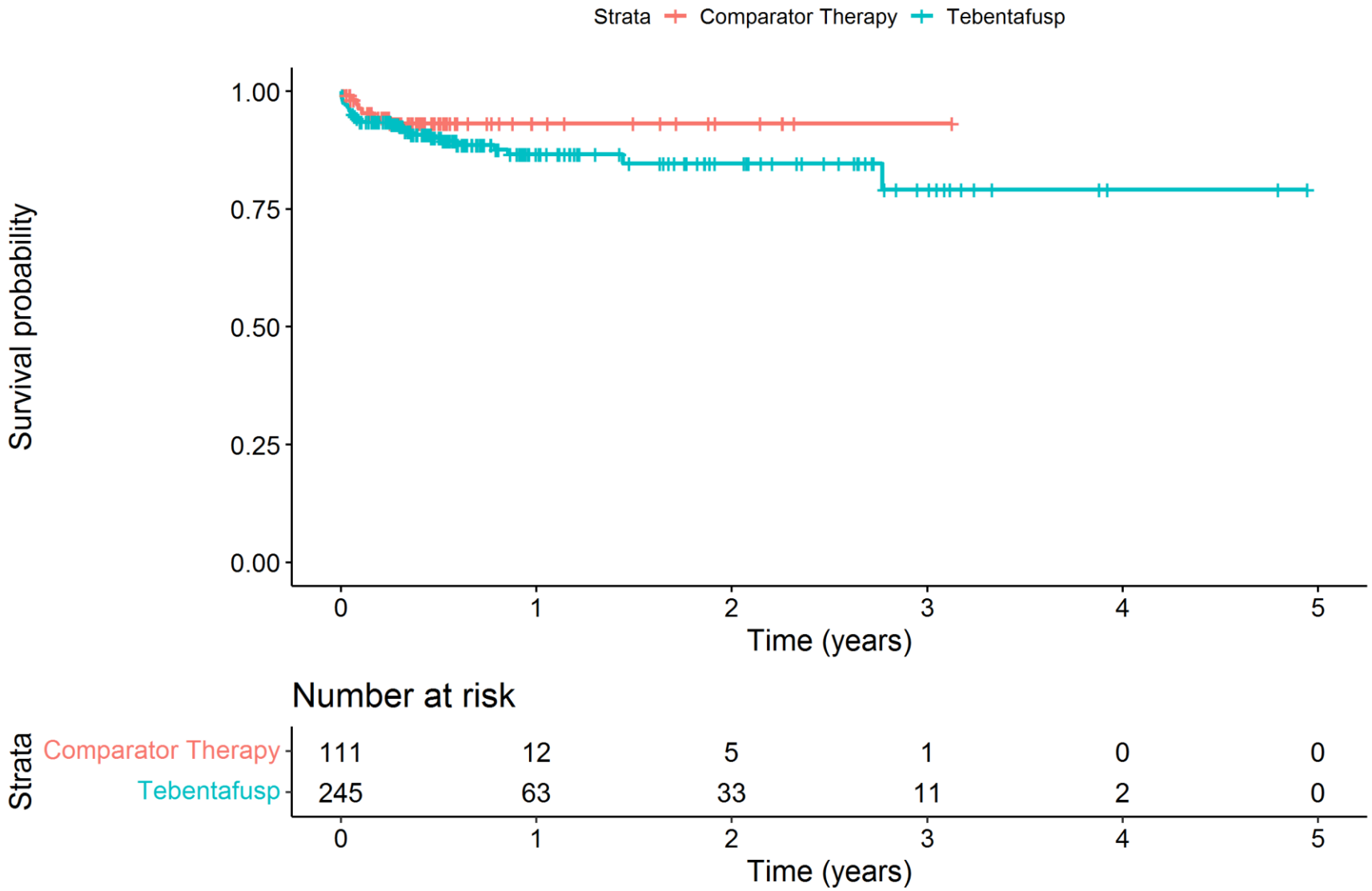
4.26 Arthralgie



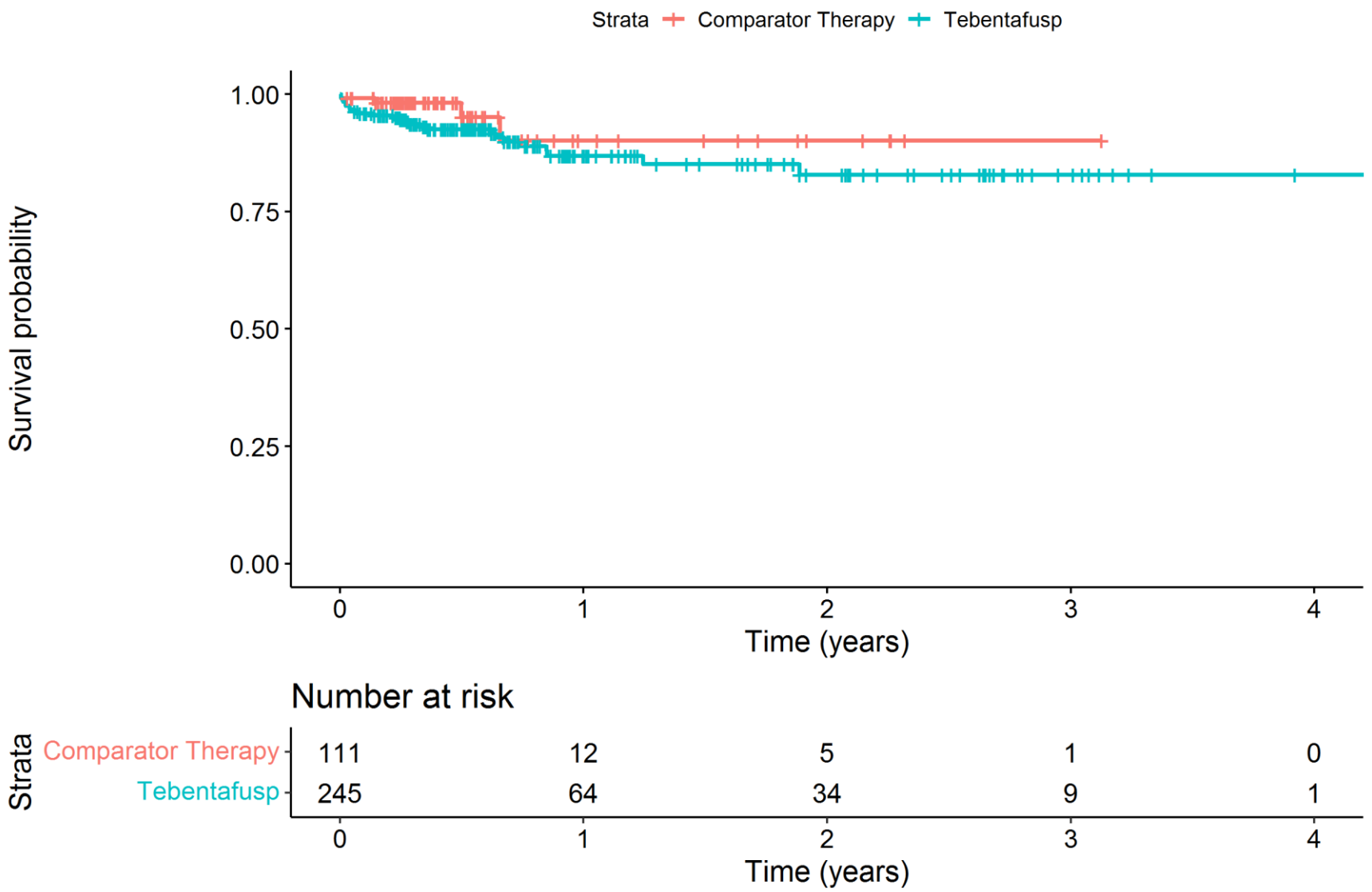
4.27 Rückenschmerzen



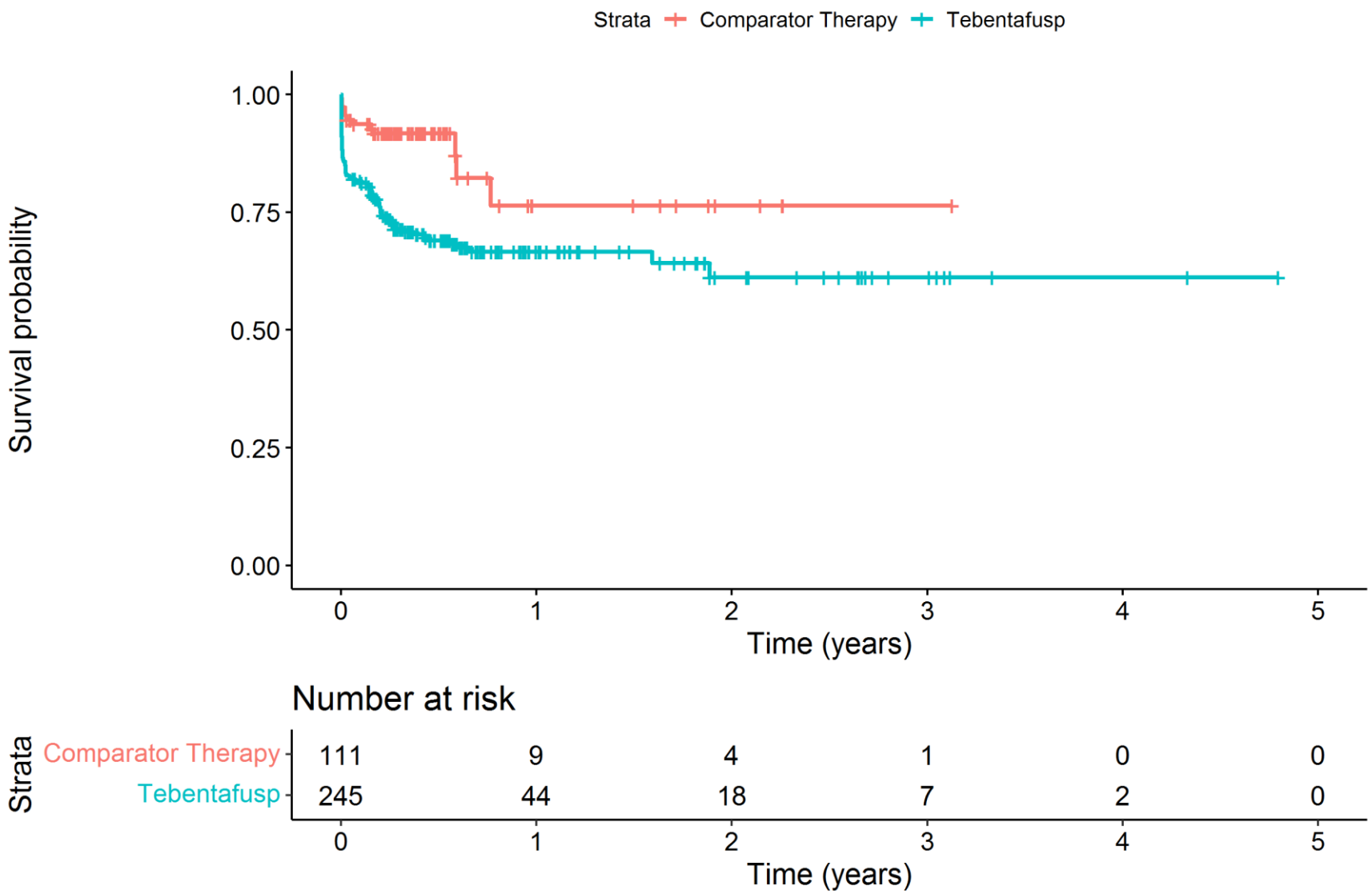
4.28 Myalgie


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
12
5
1
0
0
245
63
33
11
2
0
0
1
2
3
4
5
Time (years)

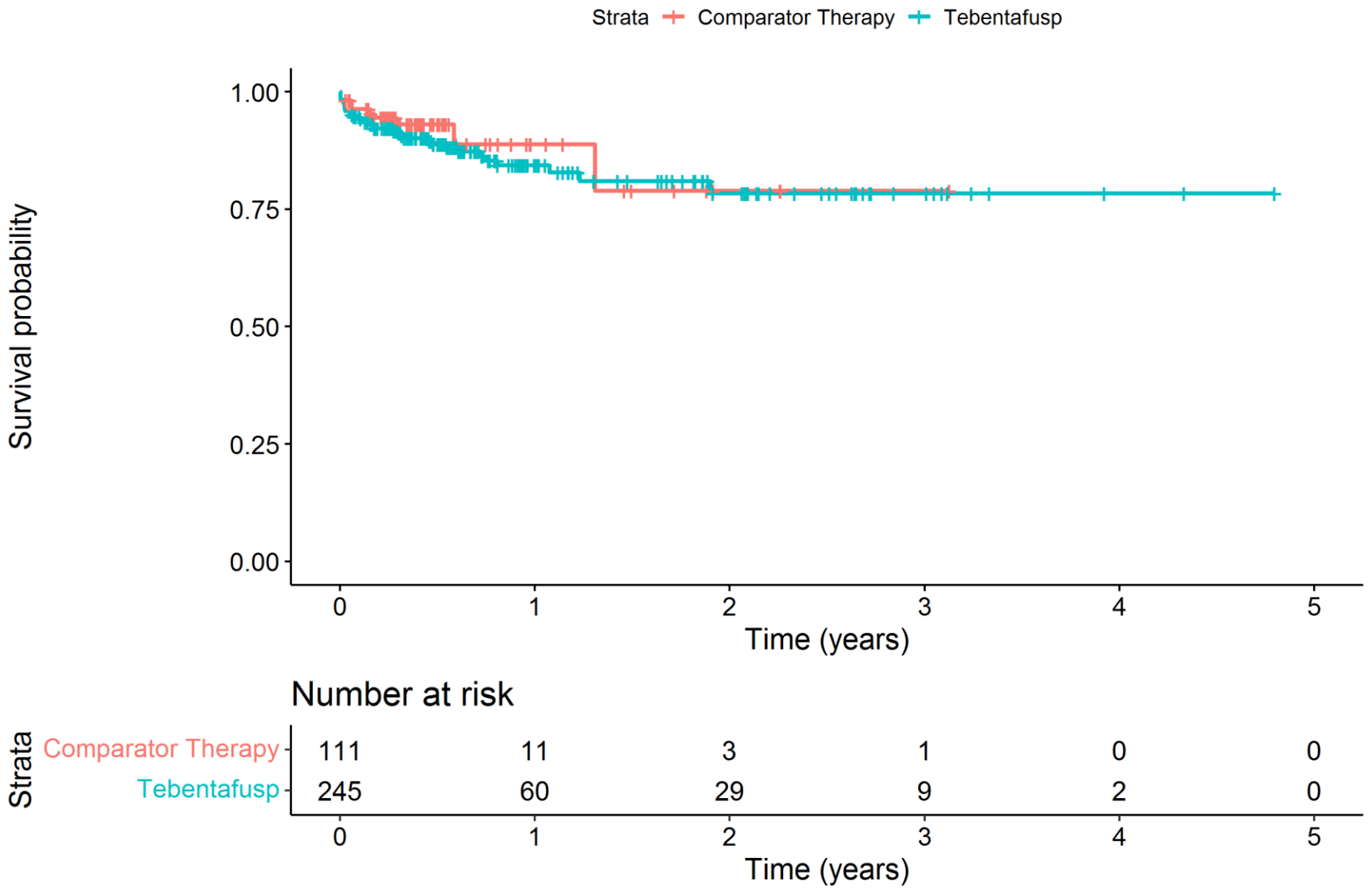
4.29 Schmerzen in den Extremitäten



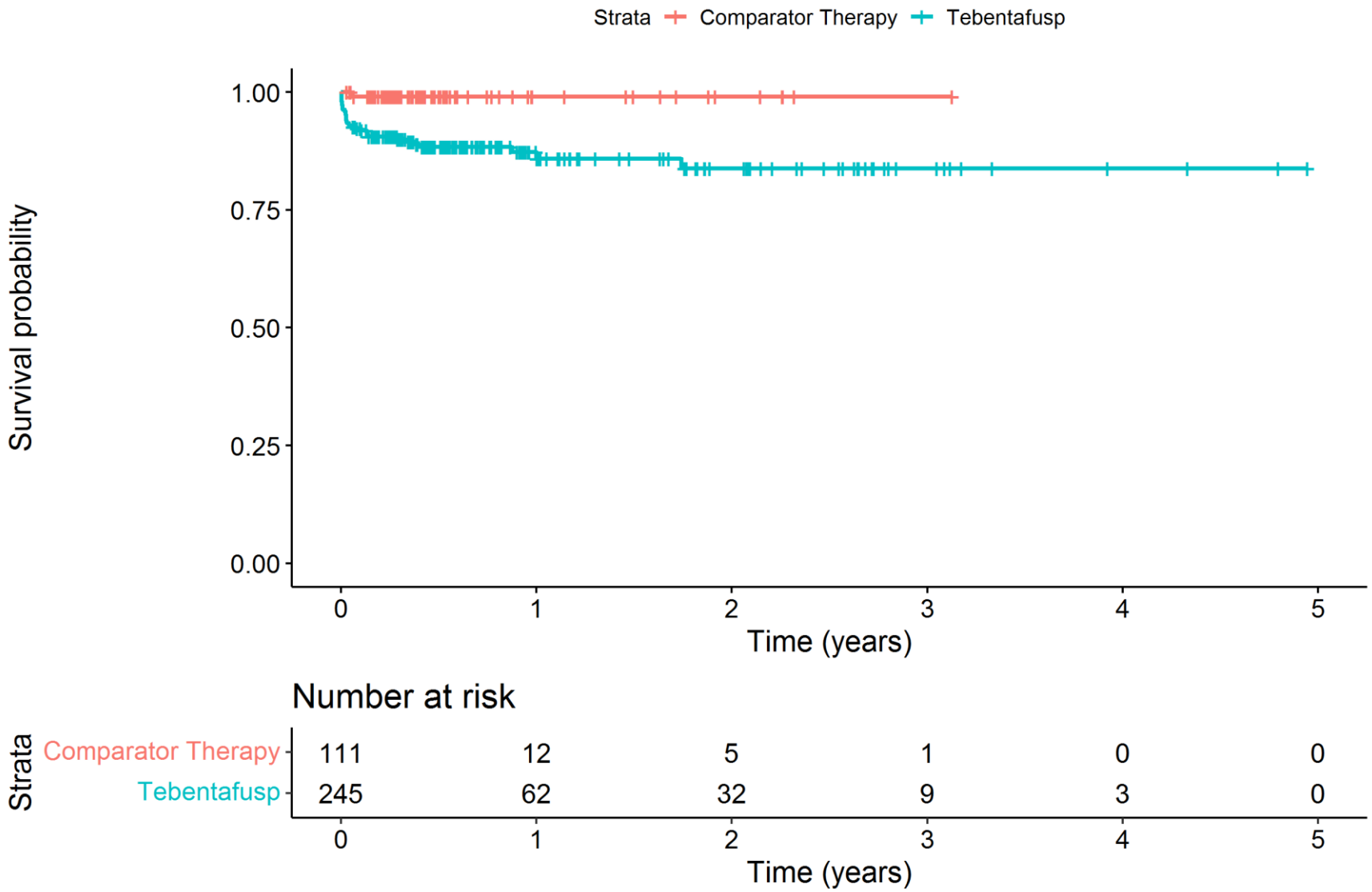
4.30 Kopfschmerzen



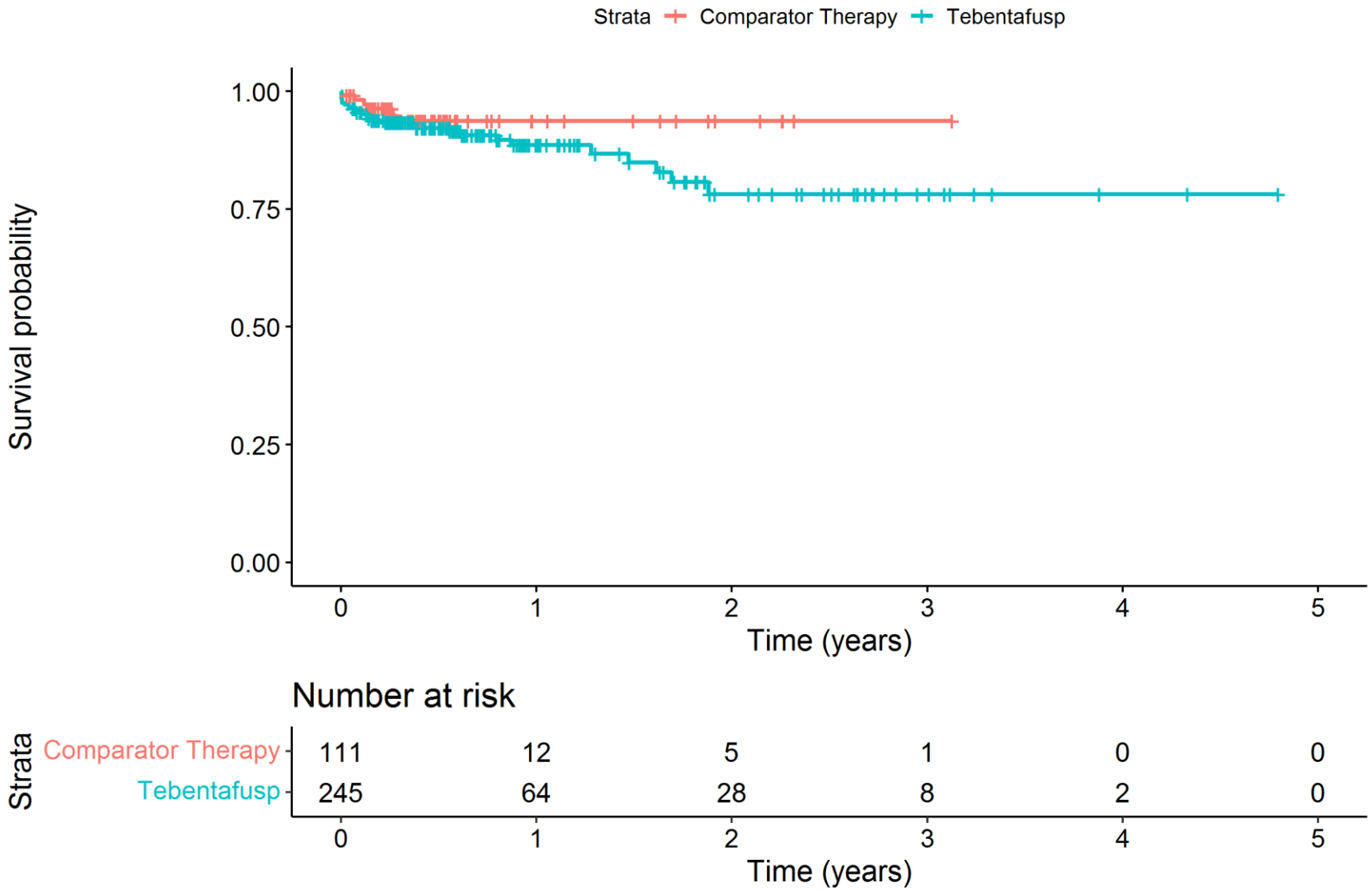
4.31 Schwindel



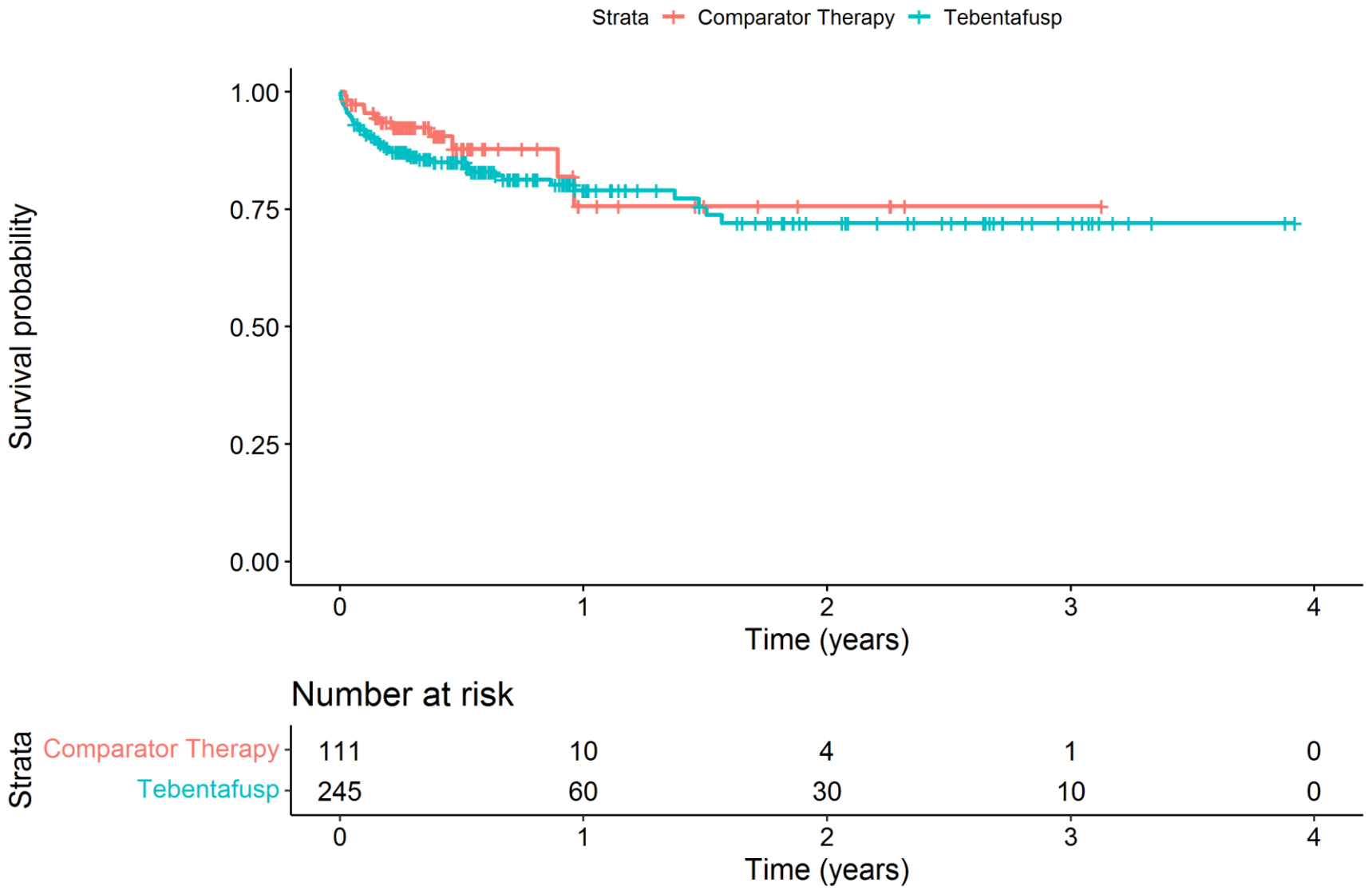
4.32 Parästhesie



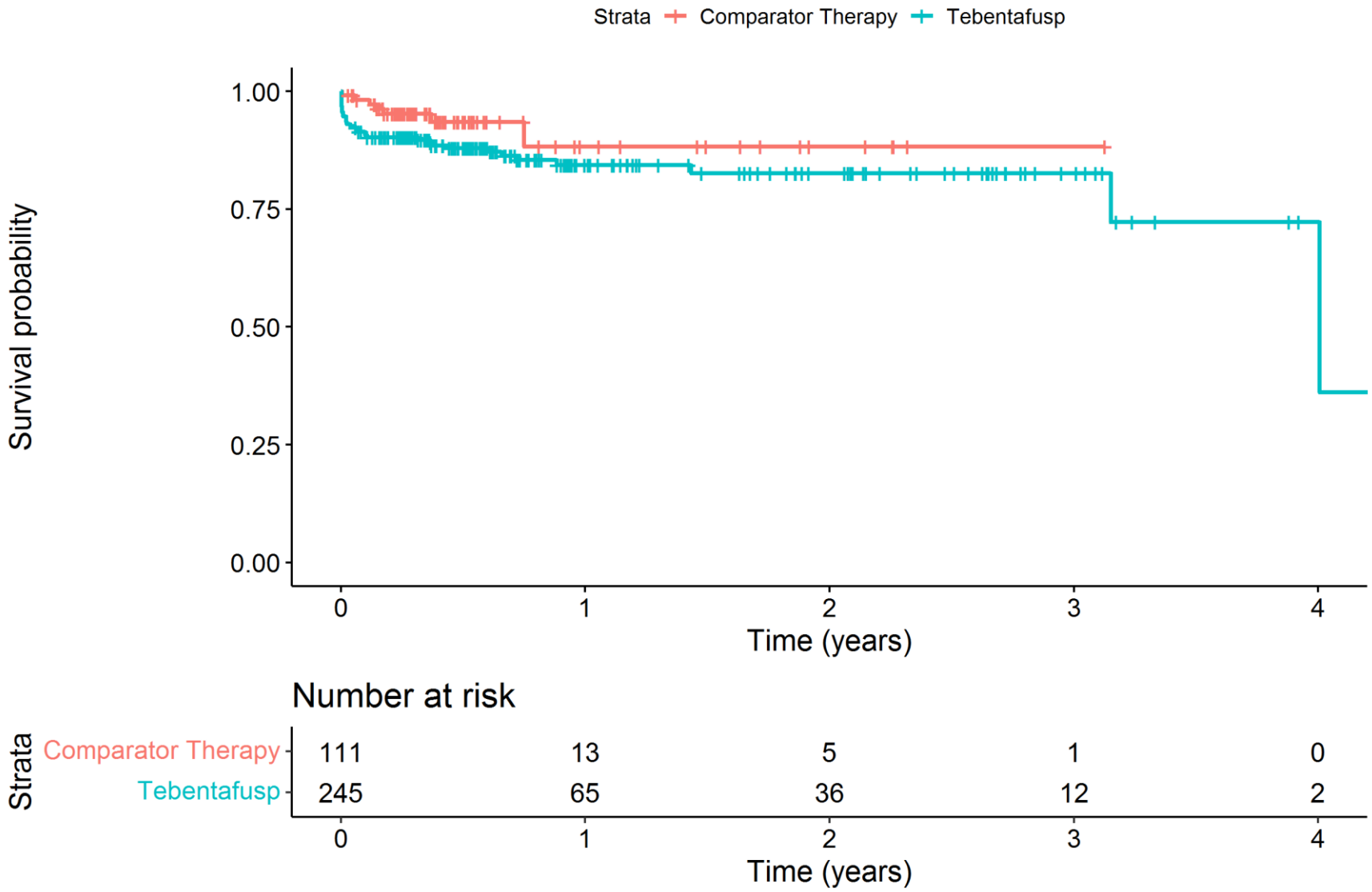
4.33 Schlaflosigkeit



4.34 Husten


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
4
1
0
245
60
30
10
0
0
1
2
3
4
Time (years)

4.35 Dyspnoe


Strata
Comparator Therapy
Tebentafusp
Survival probability
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0.75
0.50
0.25
0.00
0
1
2
3
4
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
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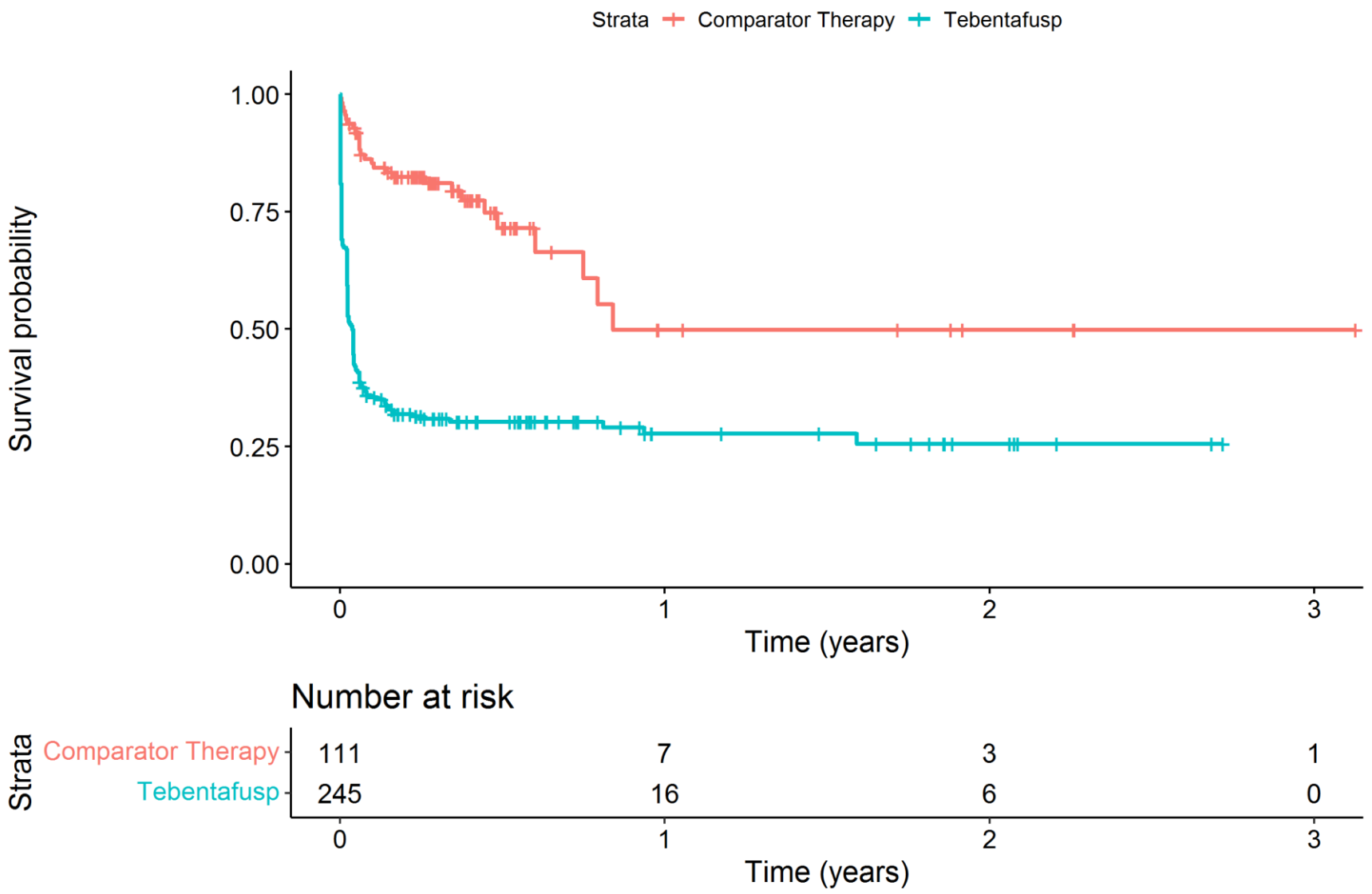
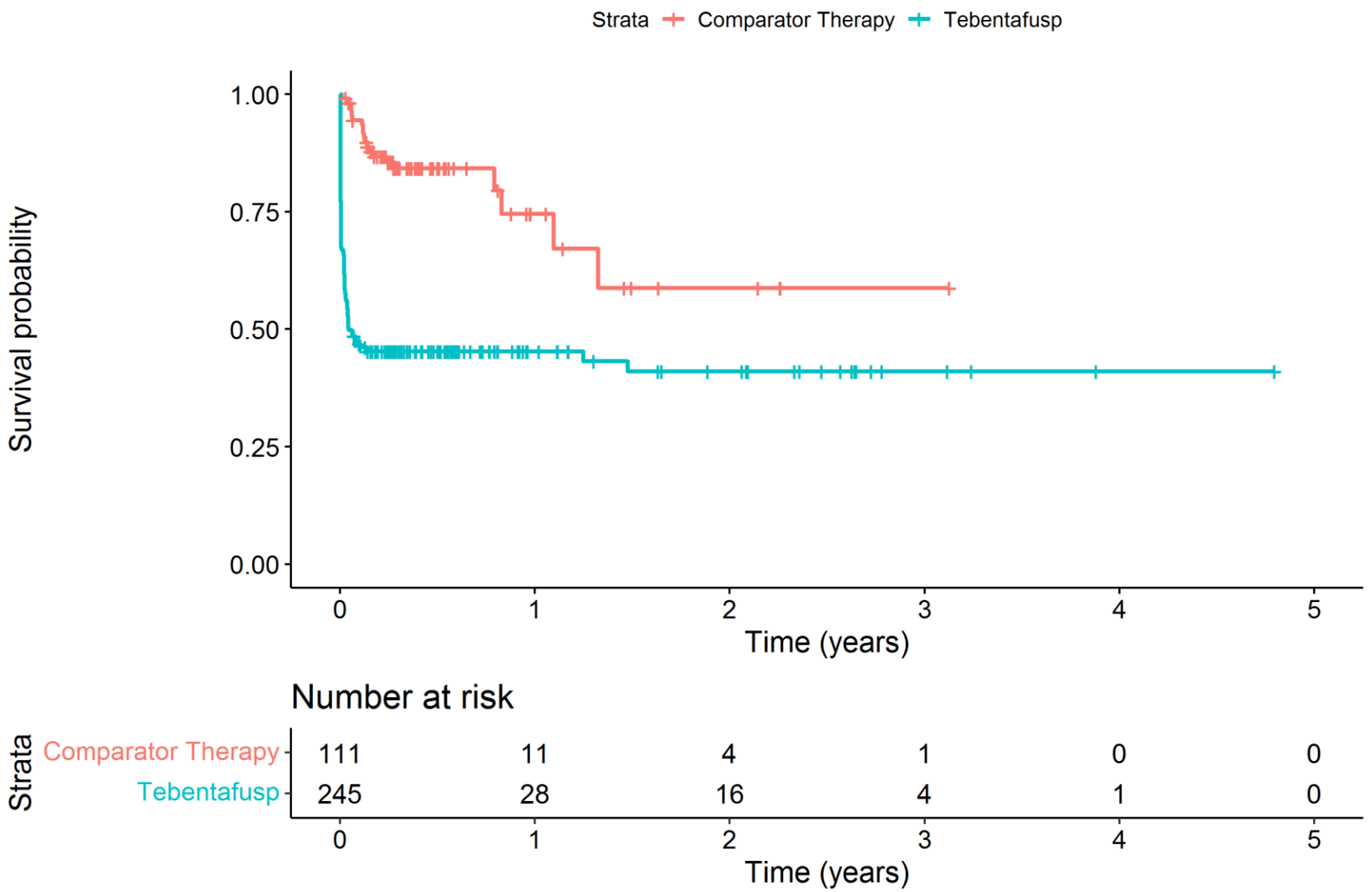
1
0
245
65
36
12
2
0
1
2
3
4
Time (years)

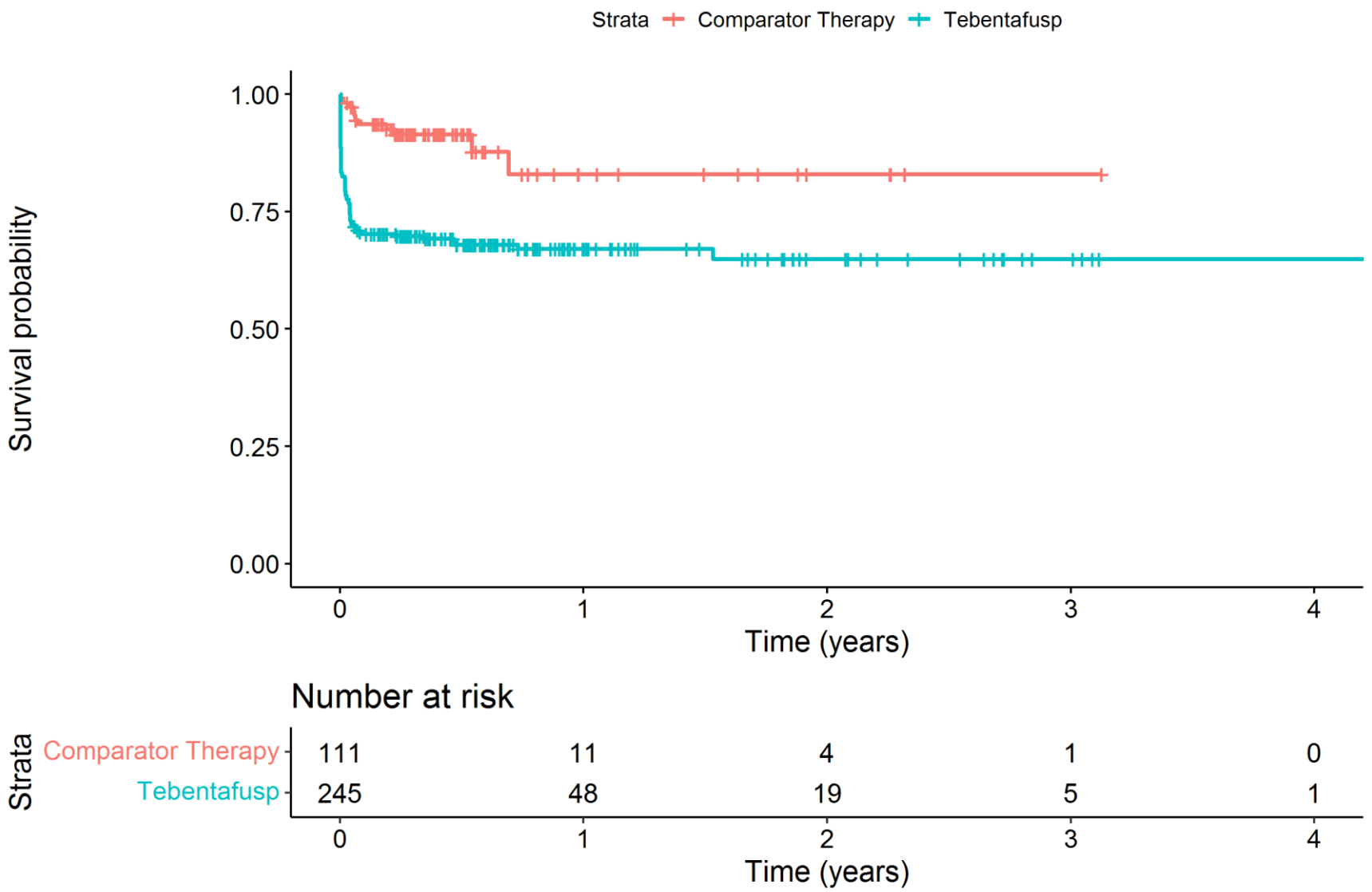
4.36 Pruritus



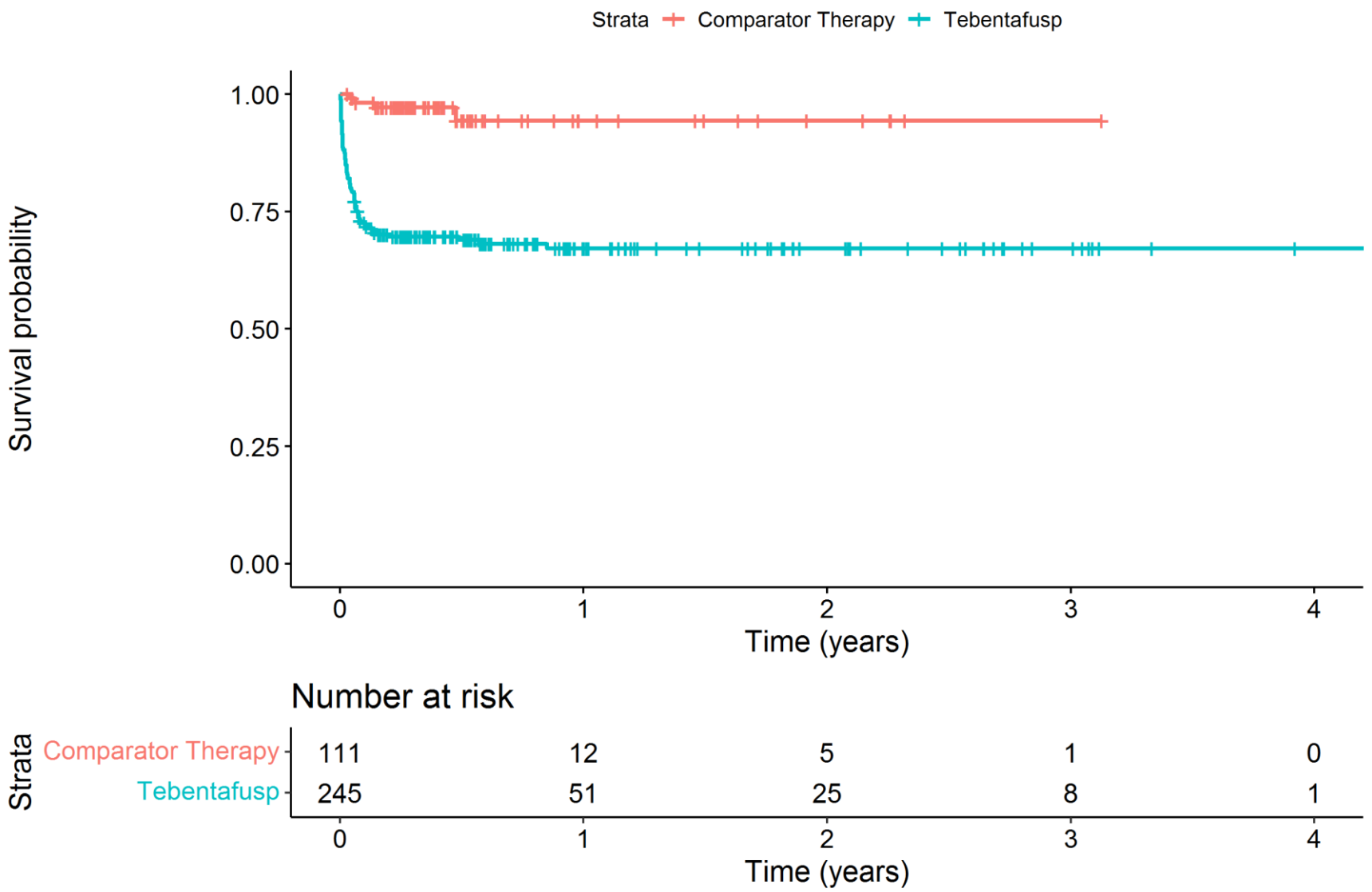
4.37 Hautausschlag



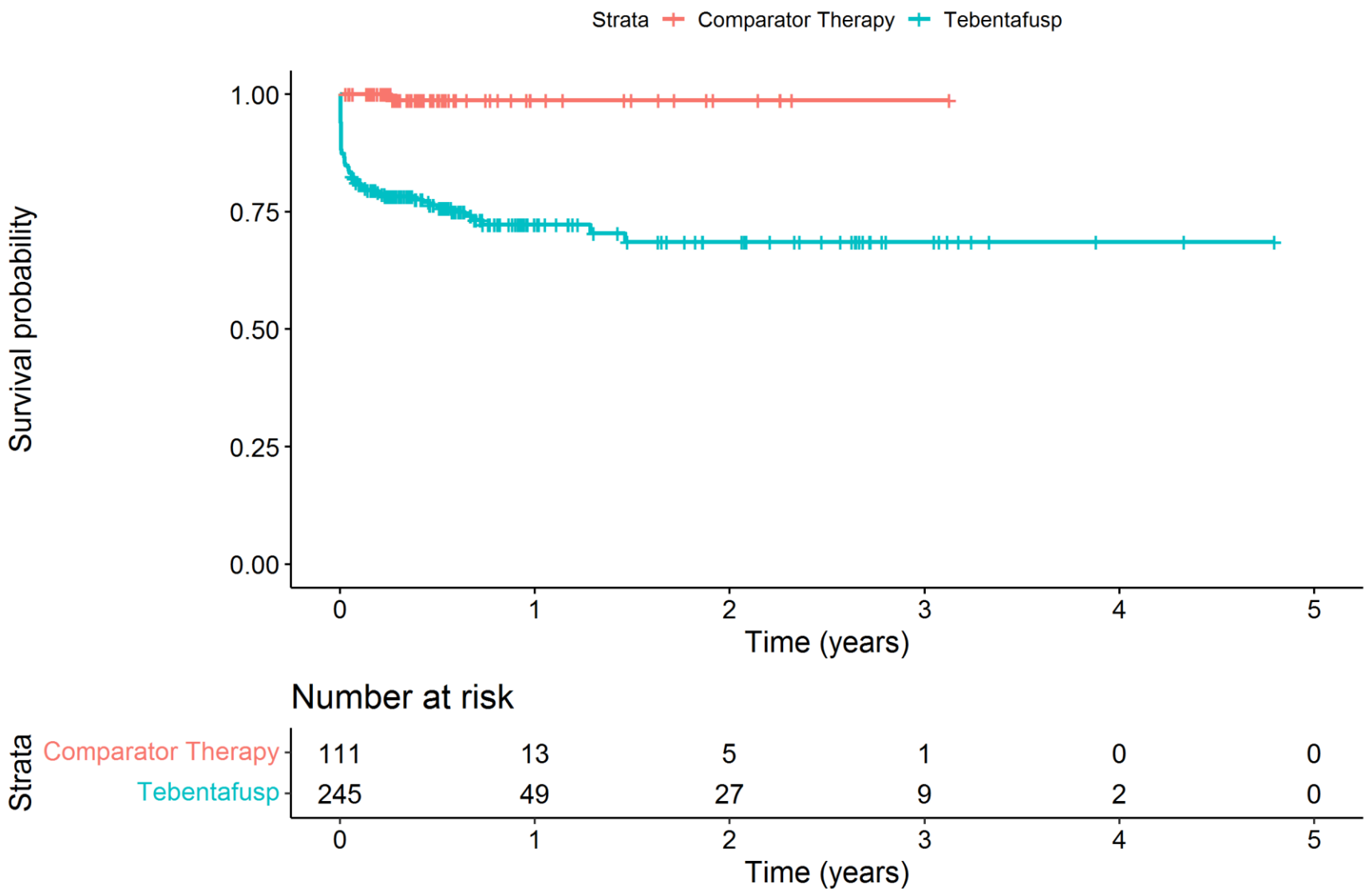
4.38 Makulo-papulöser Hautausschlag



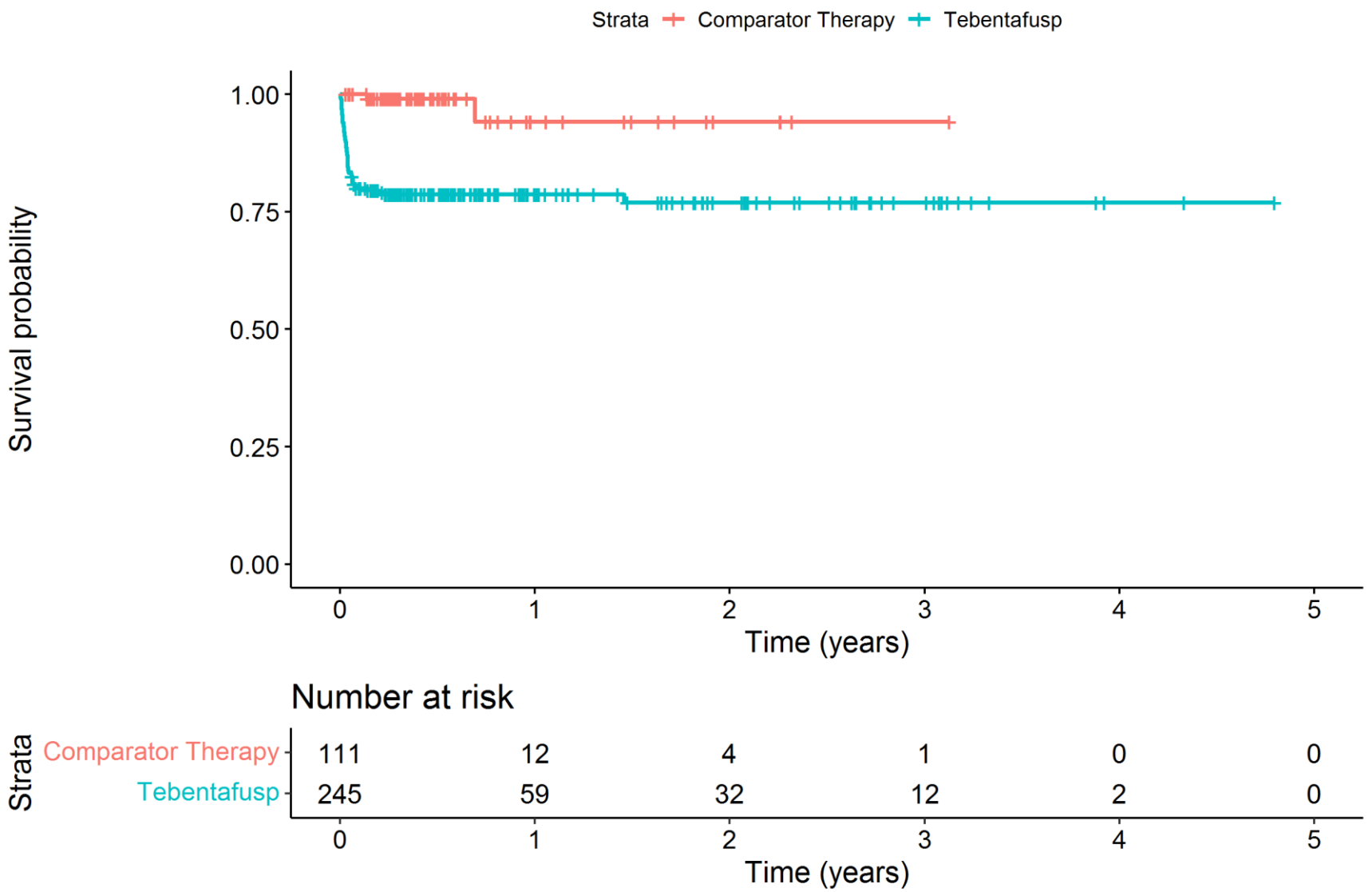
4.39 Trockene Haut



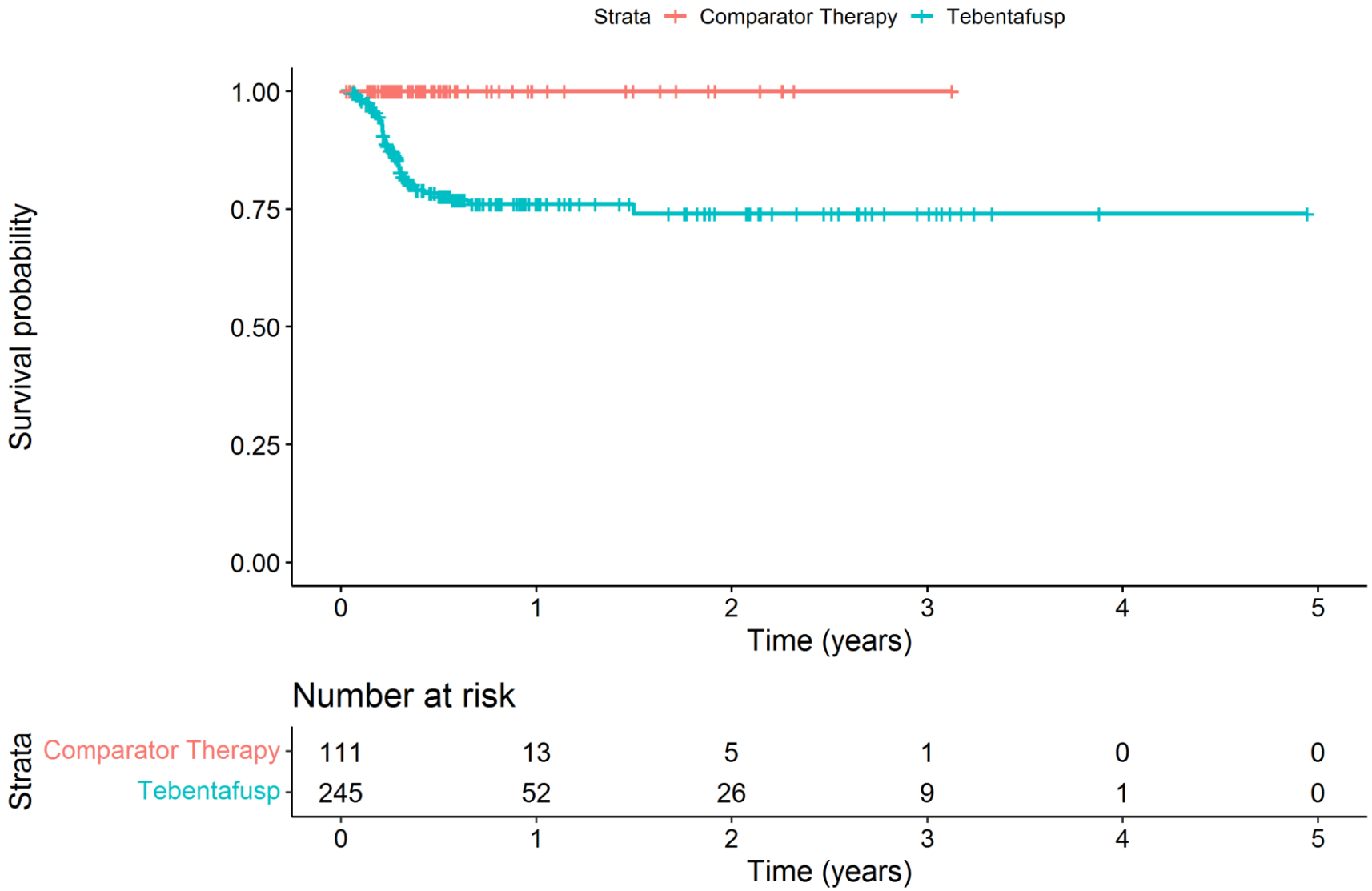
4.40 Erythem


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
49
27
9
2
0
0
1
2
3
4
5
Time (years)

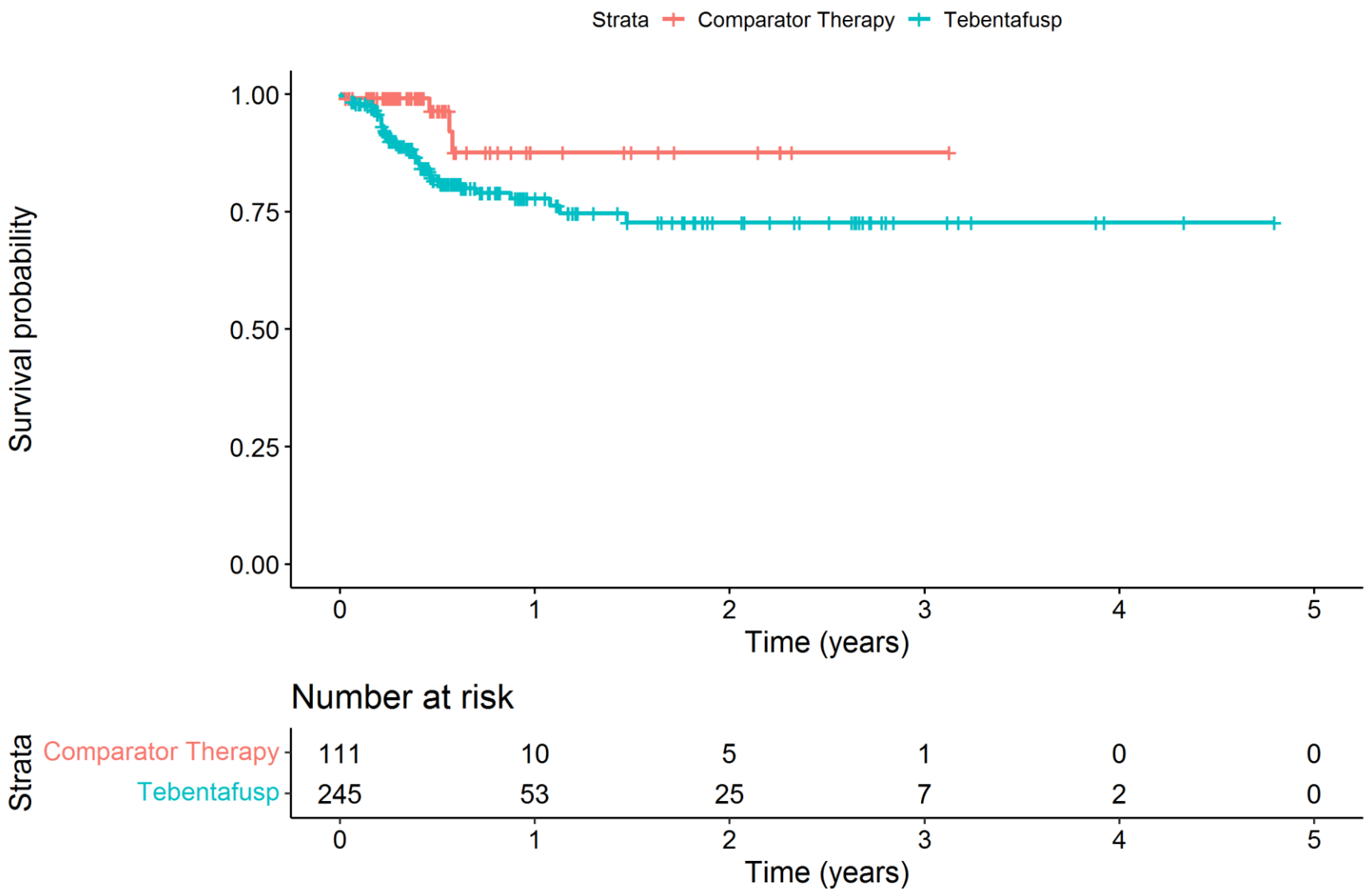
4.41 Hautabschälung



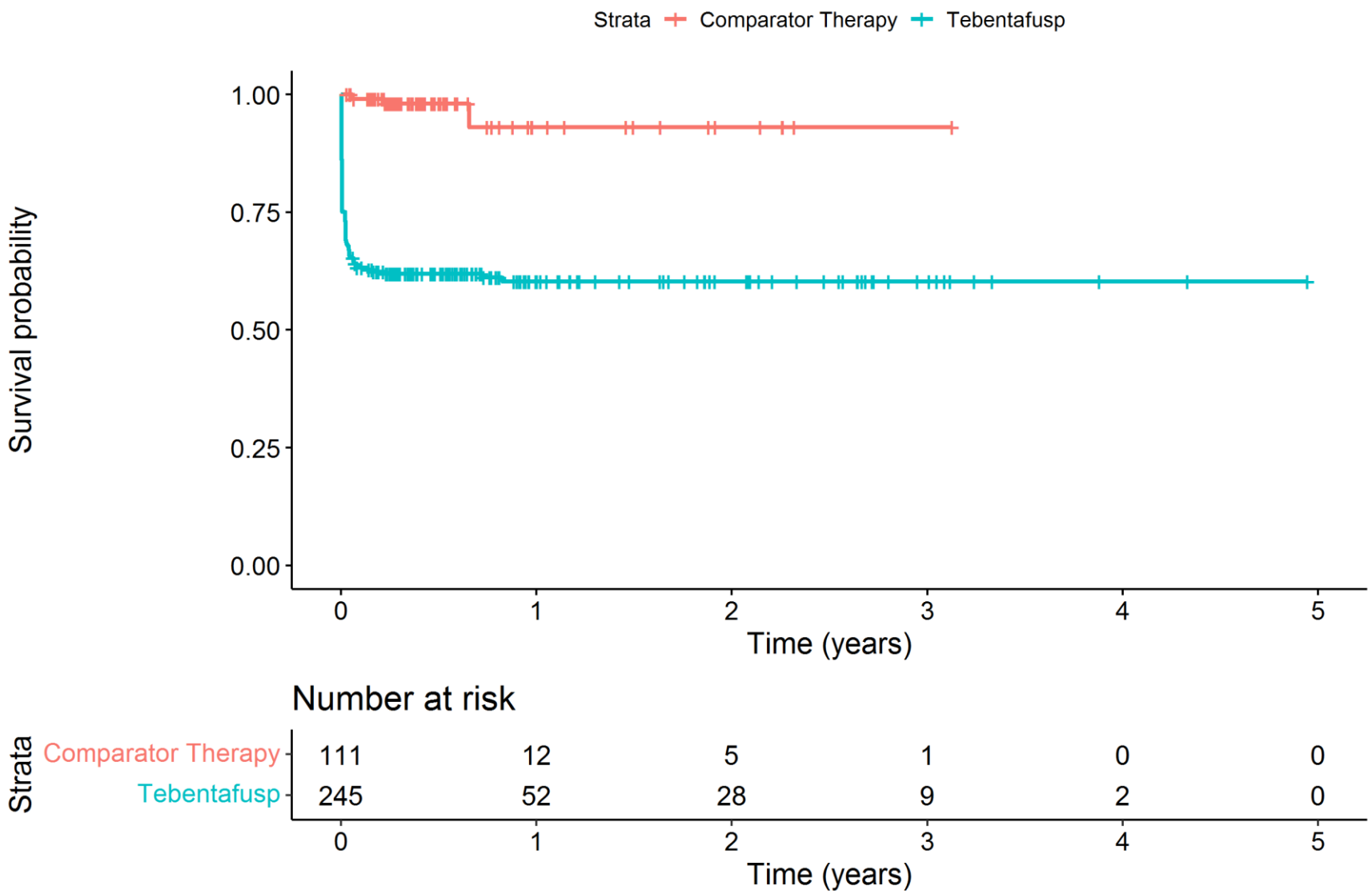
4.42 Veränderung der Haarfarbe



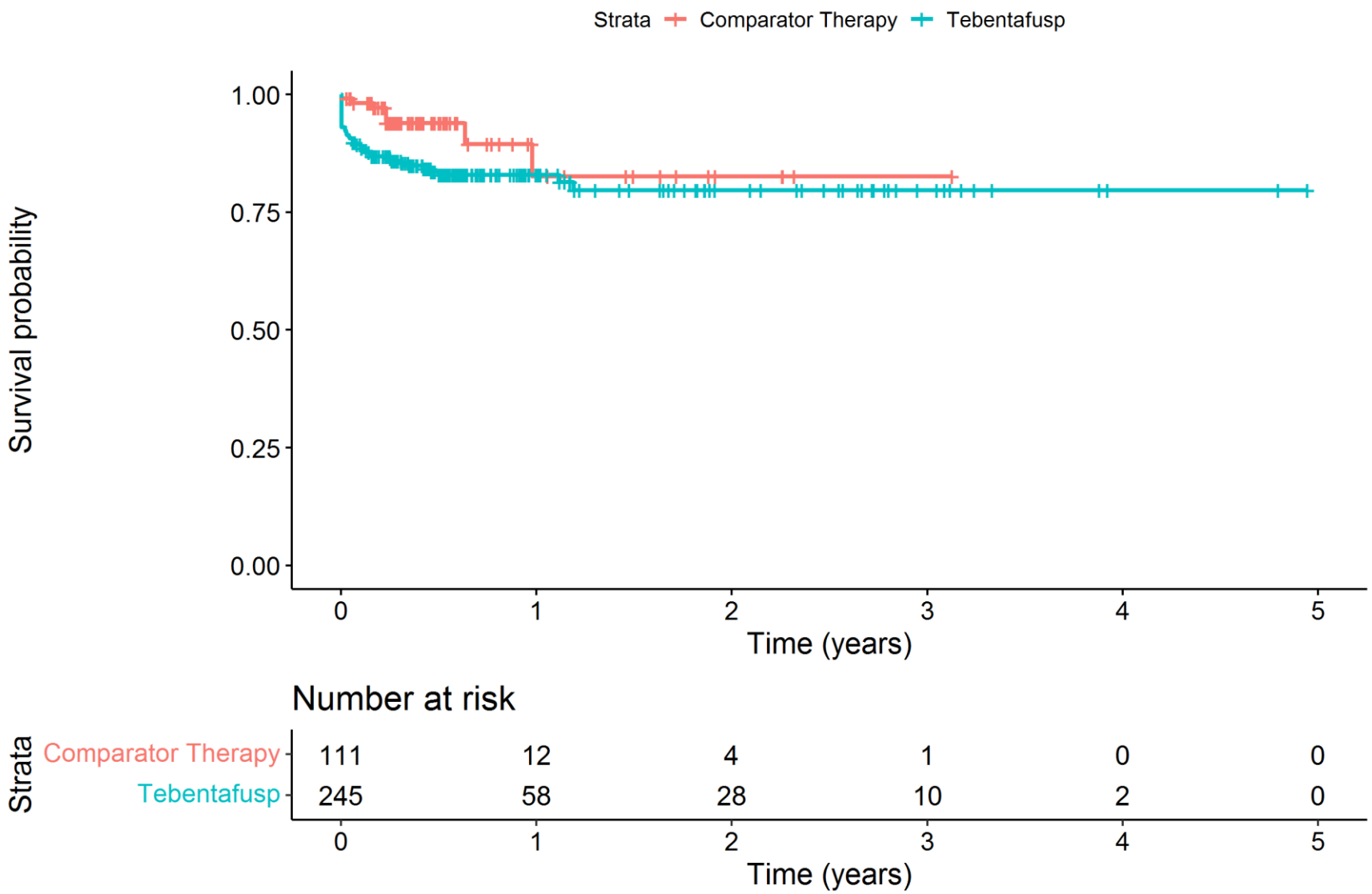
4.43 Vitiligo



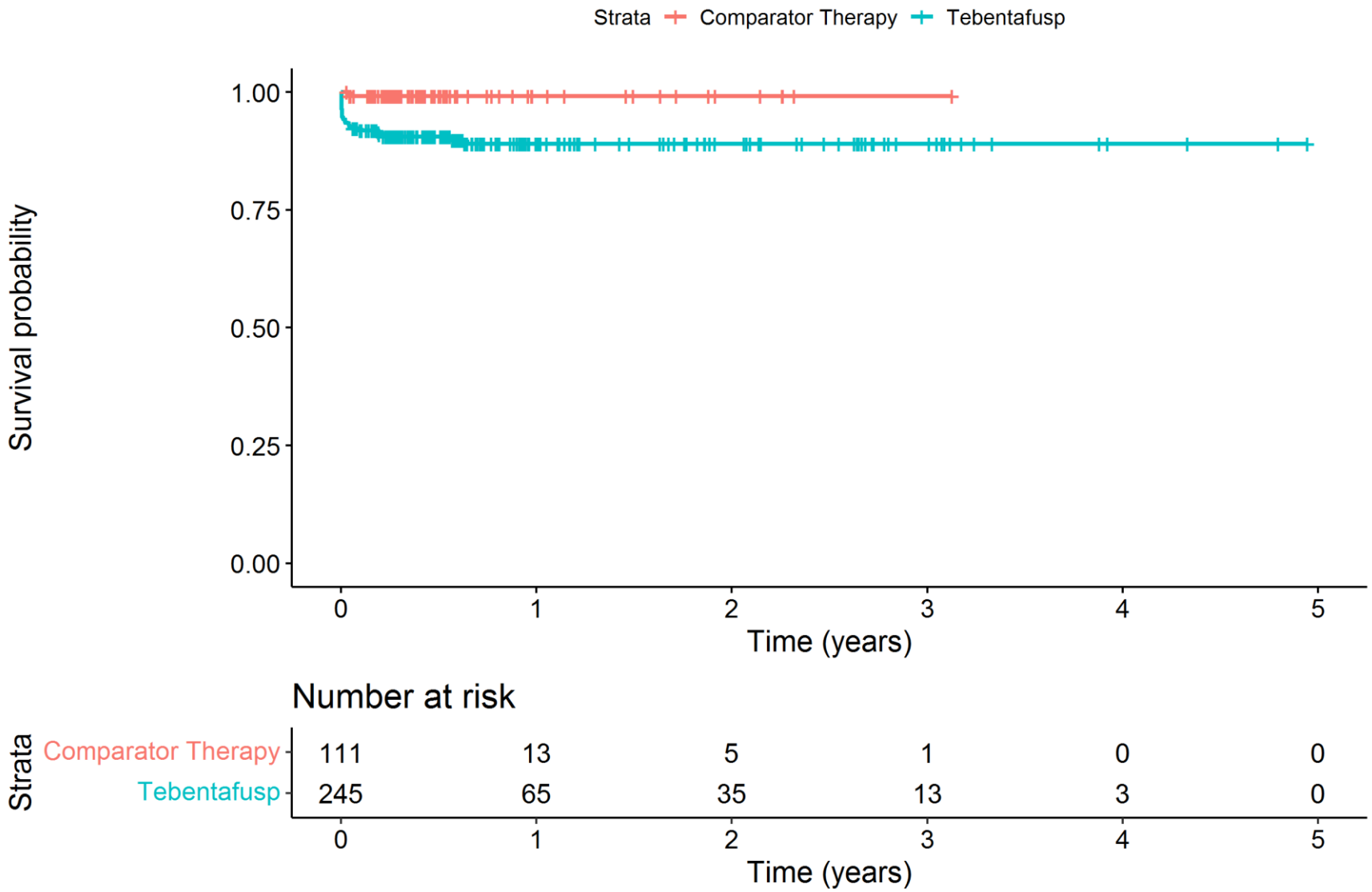
4.44 Hypotonie



4.45 Hypertonie

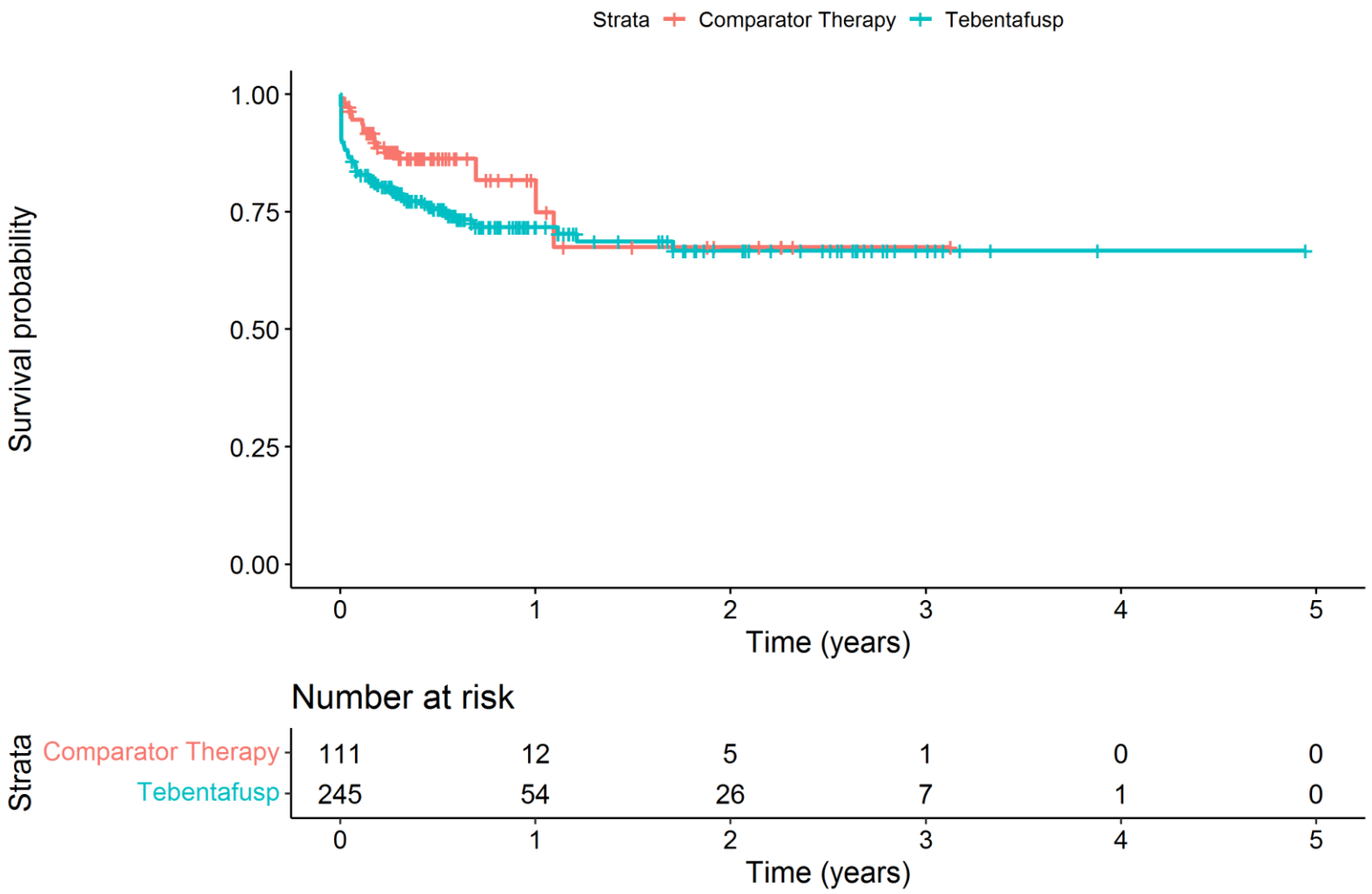


4.46 Hautrötung

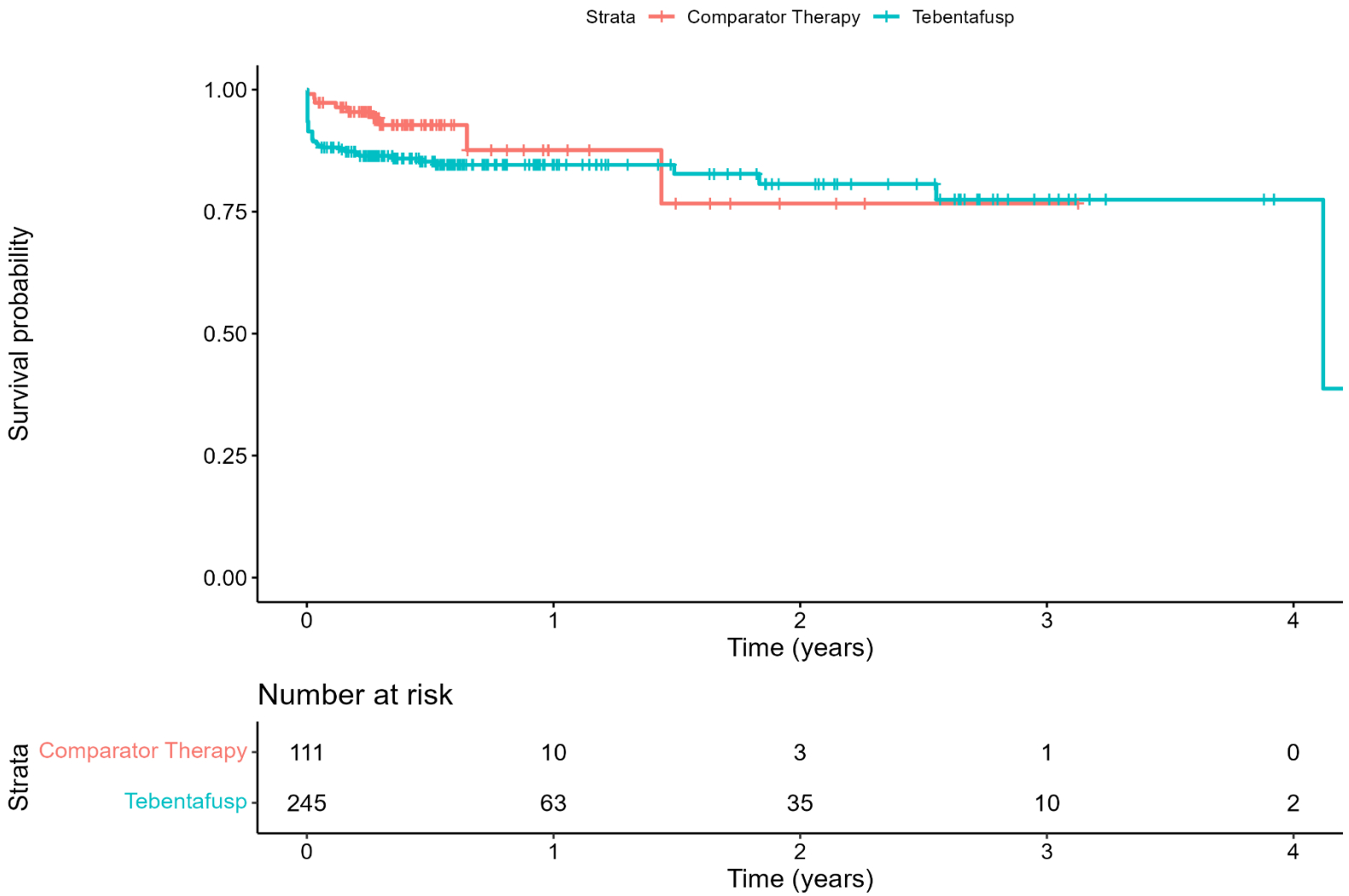


5 UEs (SOC), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten

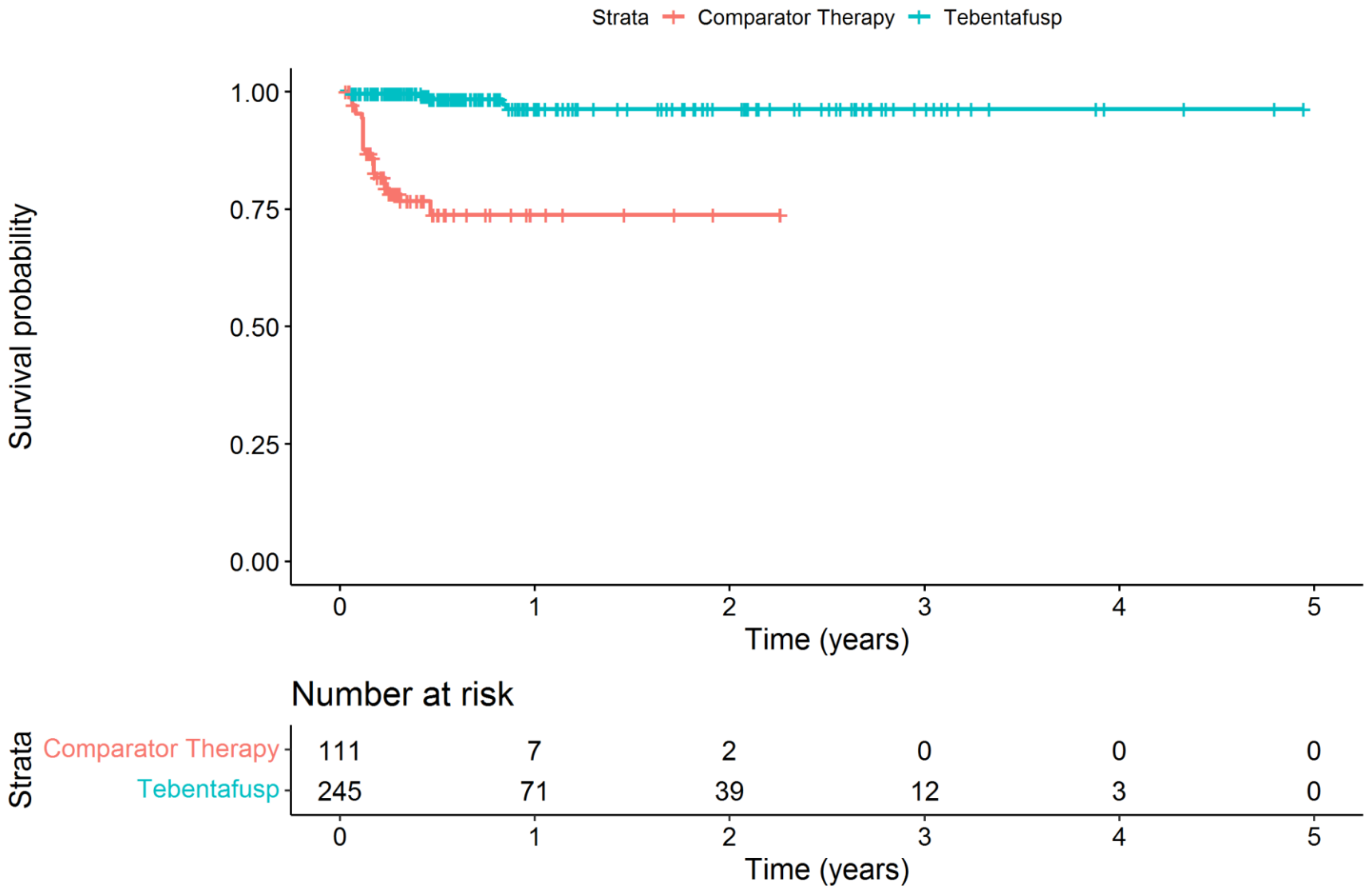
5.1 Erkrankungen des Blutes und des Lymphsystems



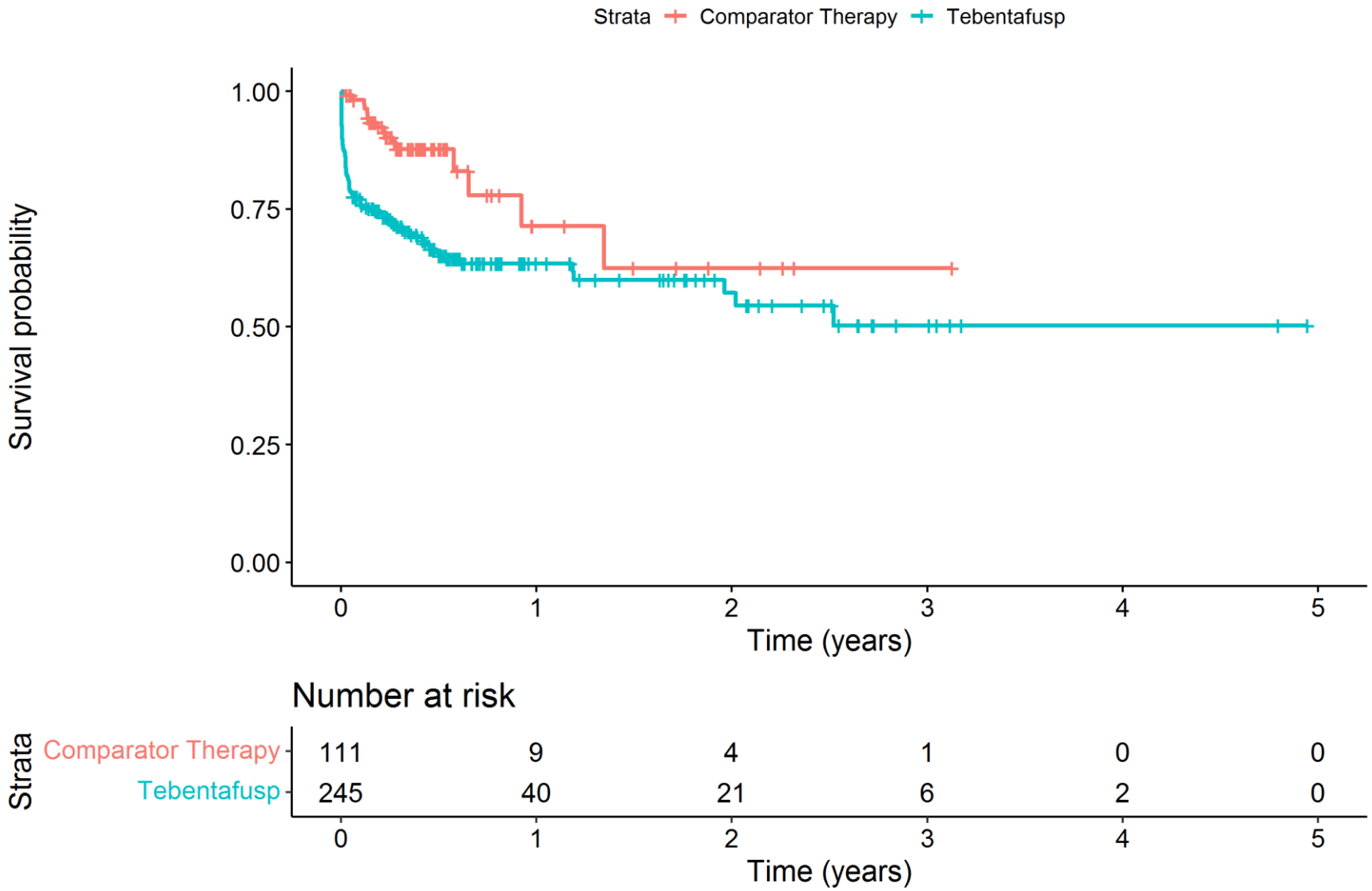
5.2 Herzerkrankungen



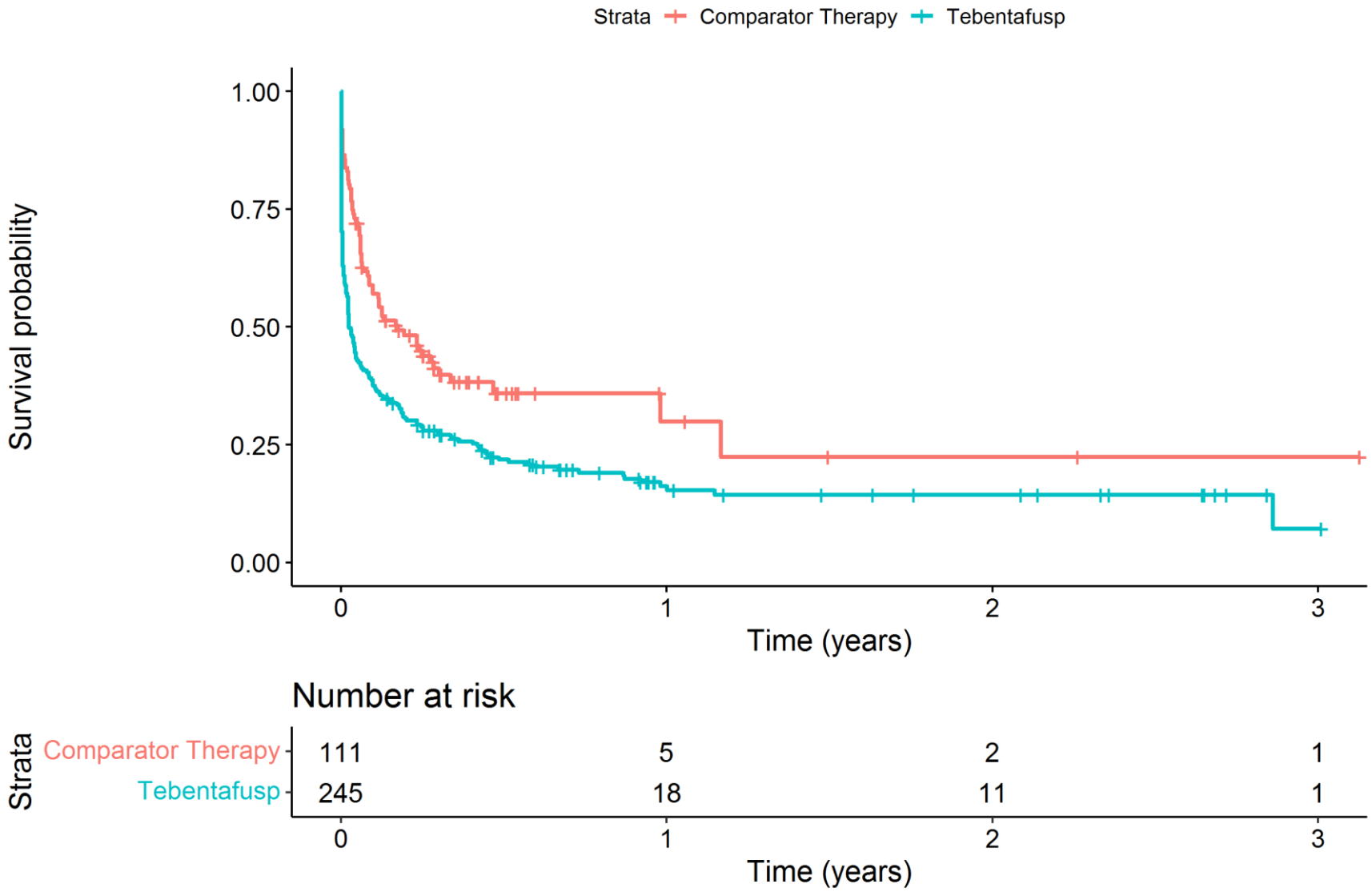
5.3 Endokrine Erkrankungen



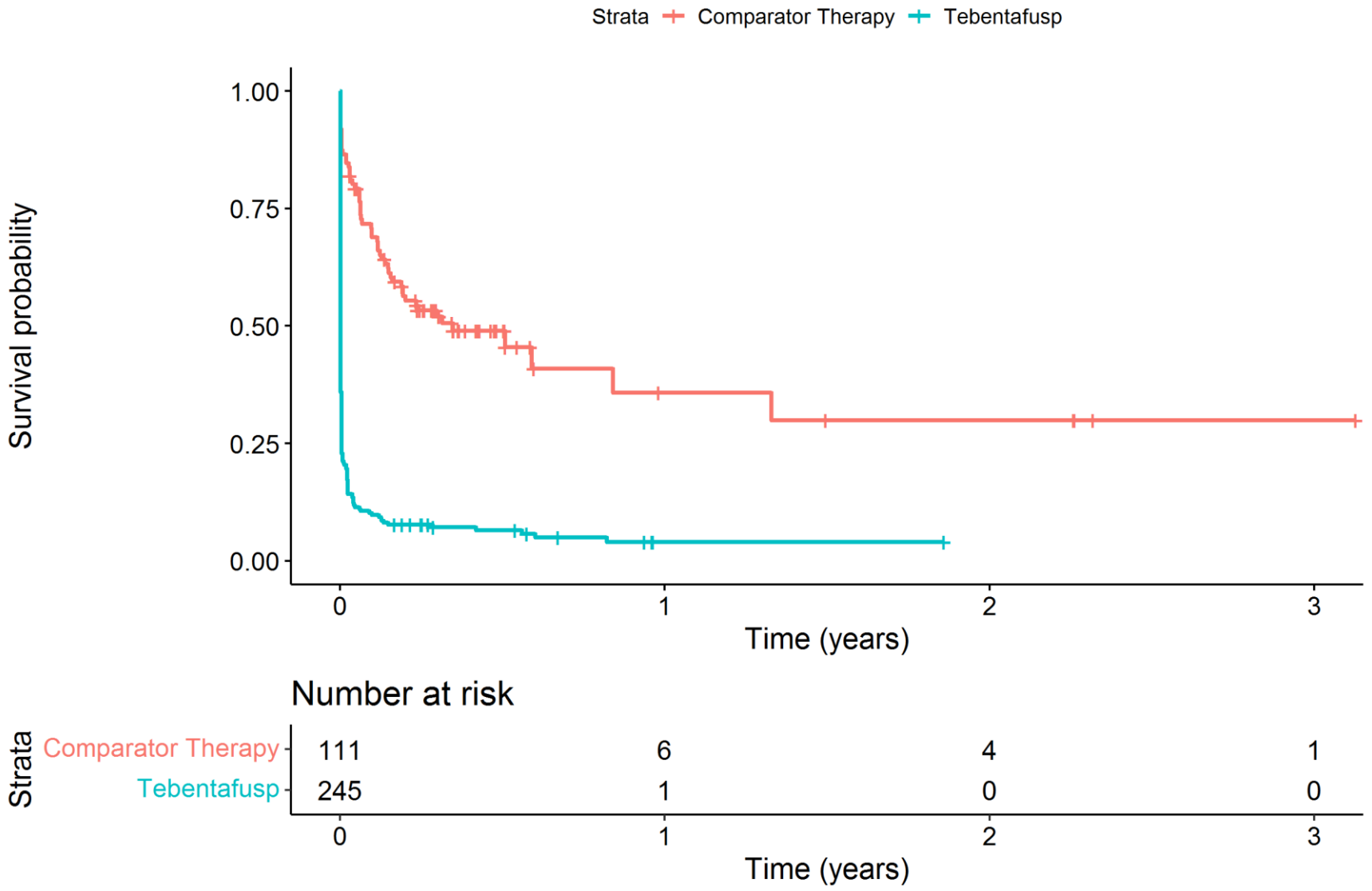
5.4 Augenerkrankungen



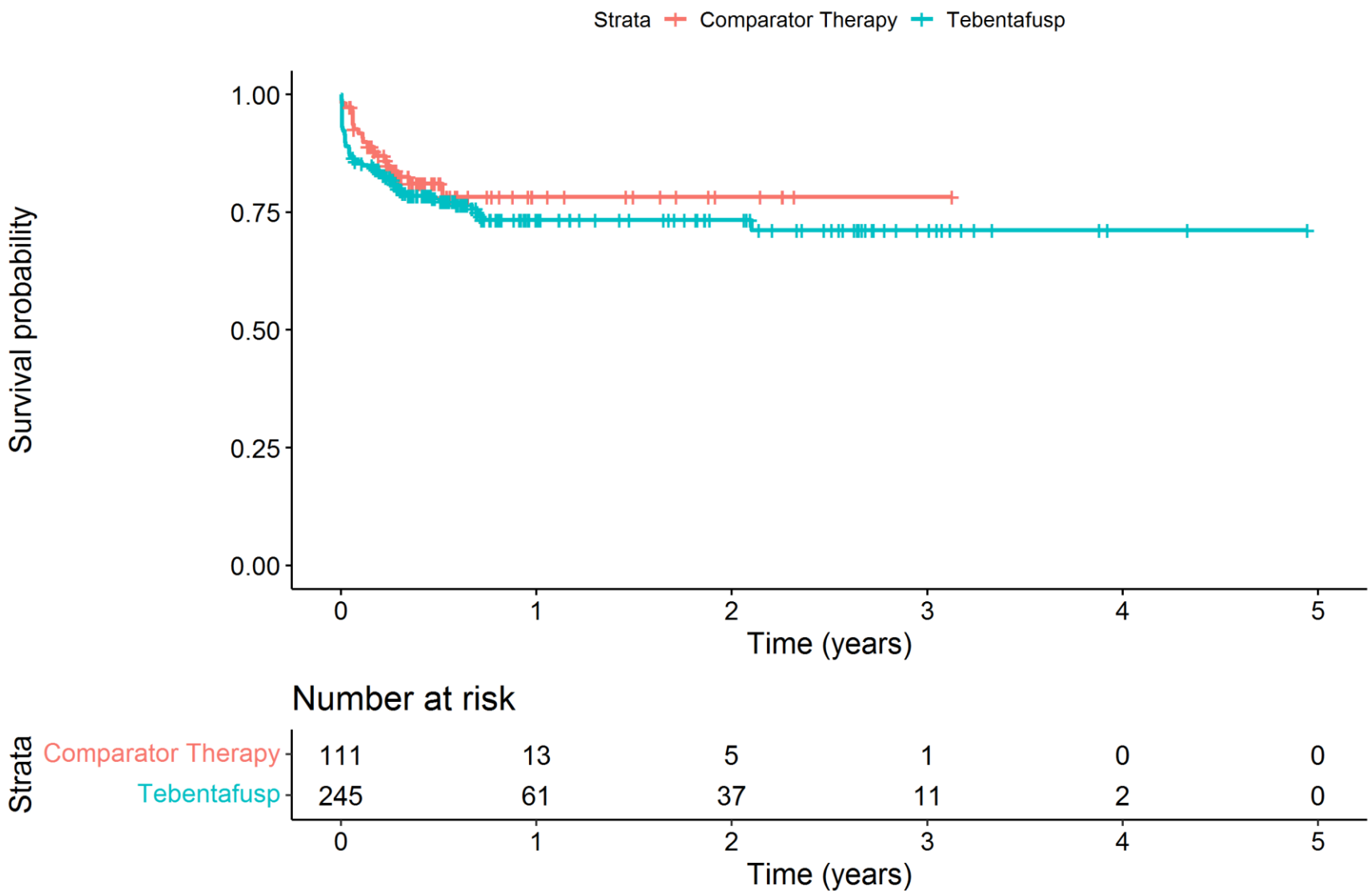
5.5 Erkrankungen des Gastrointestinaltrakts



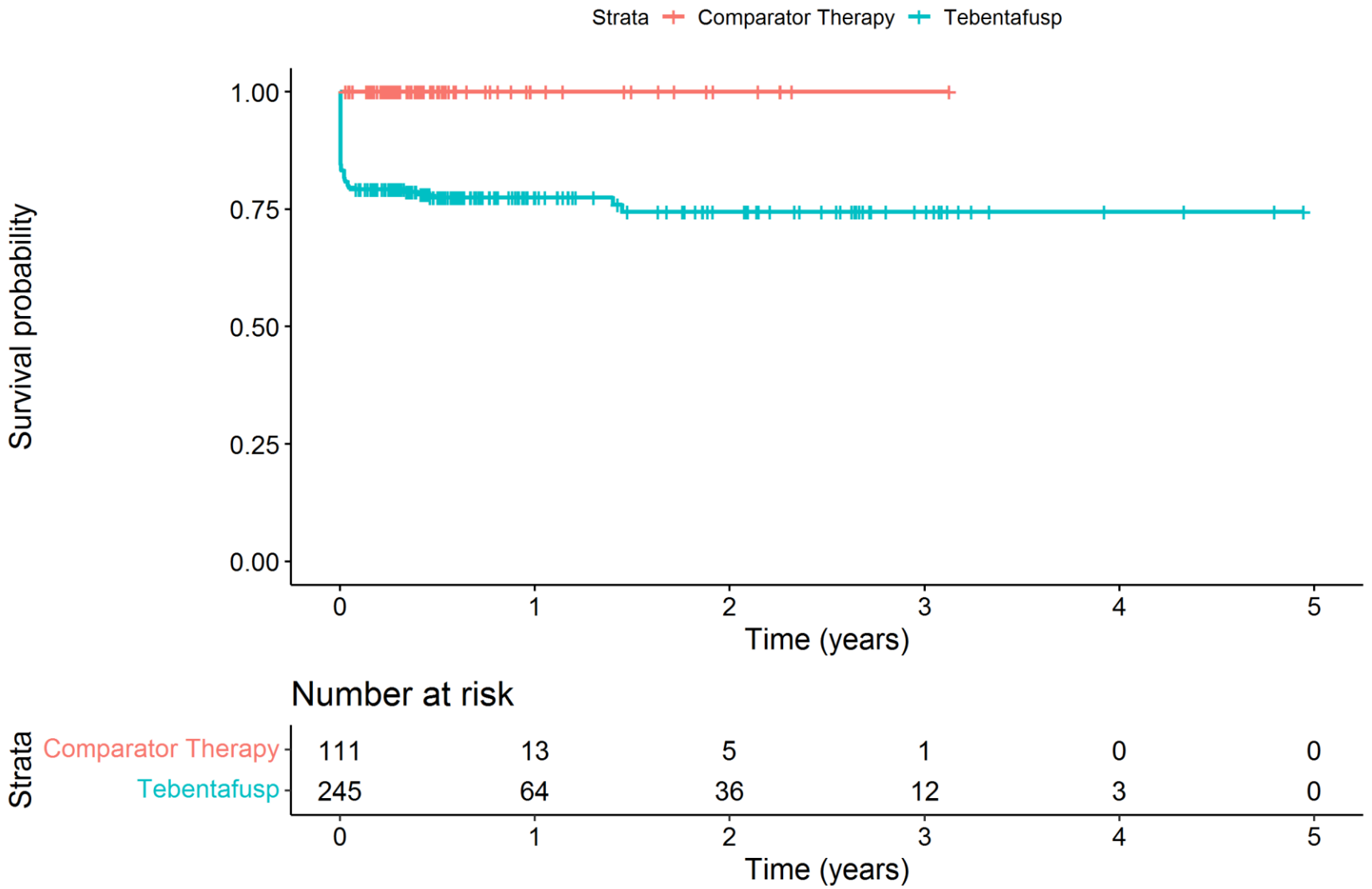
5.6 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



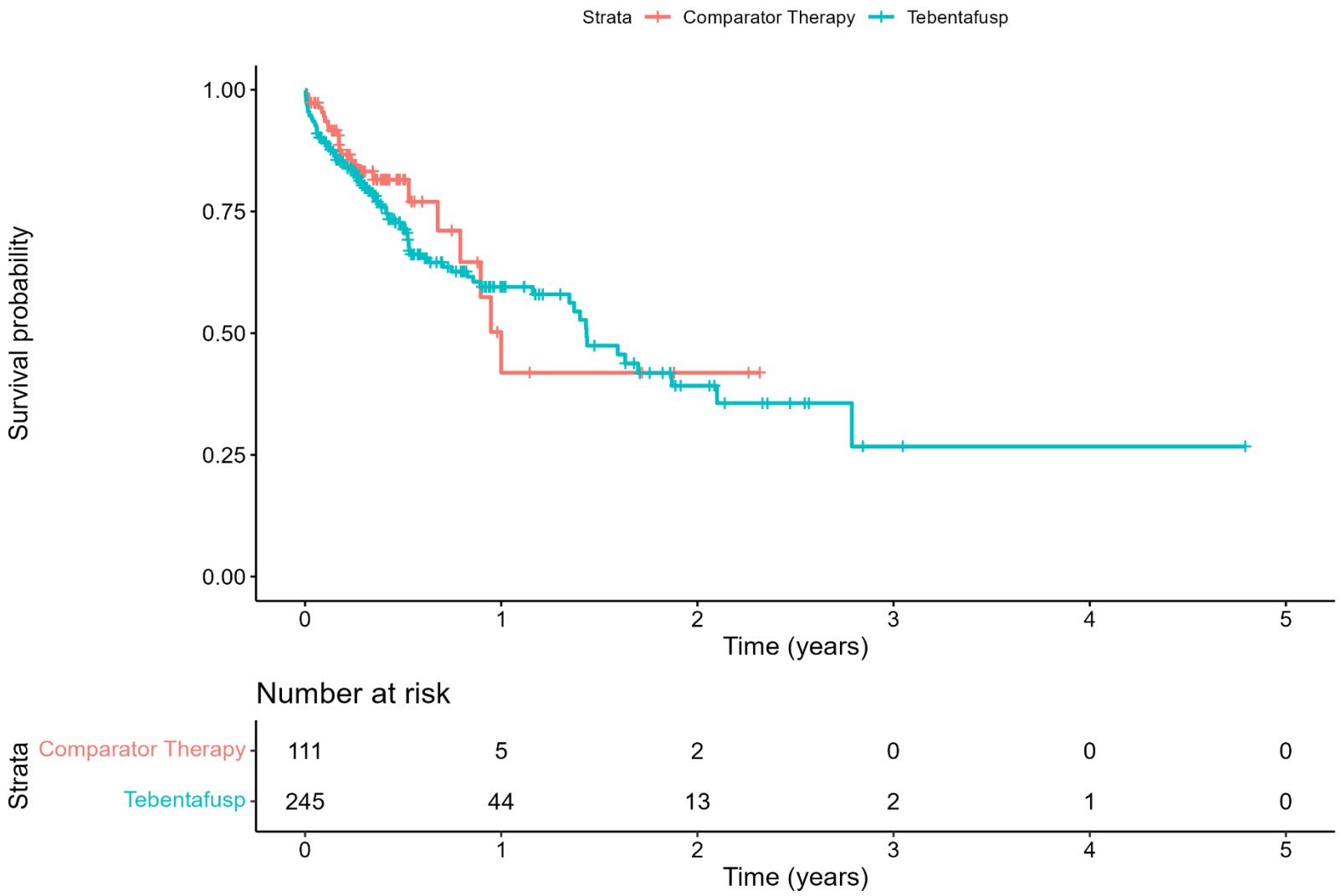
5.7 Leber- und Gallenerkrankungen



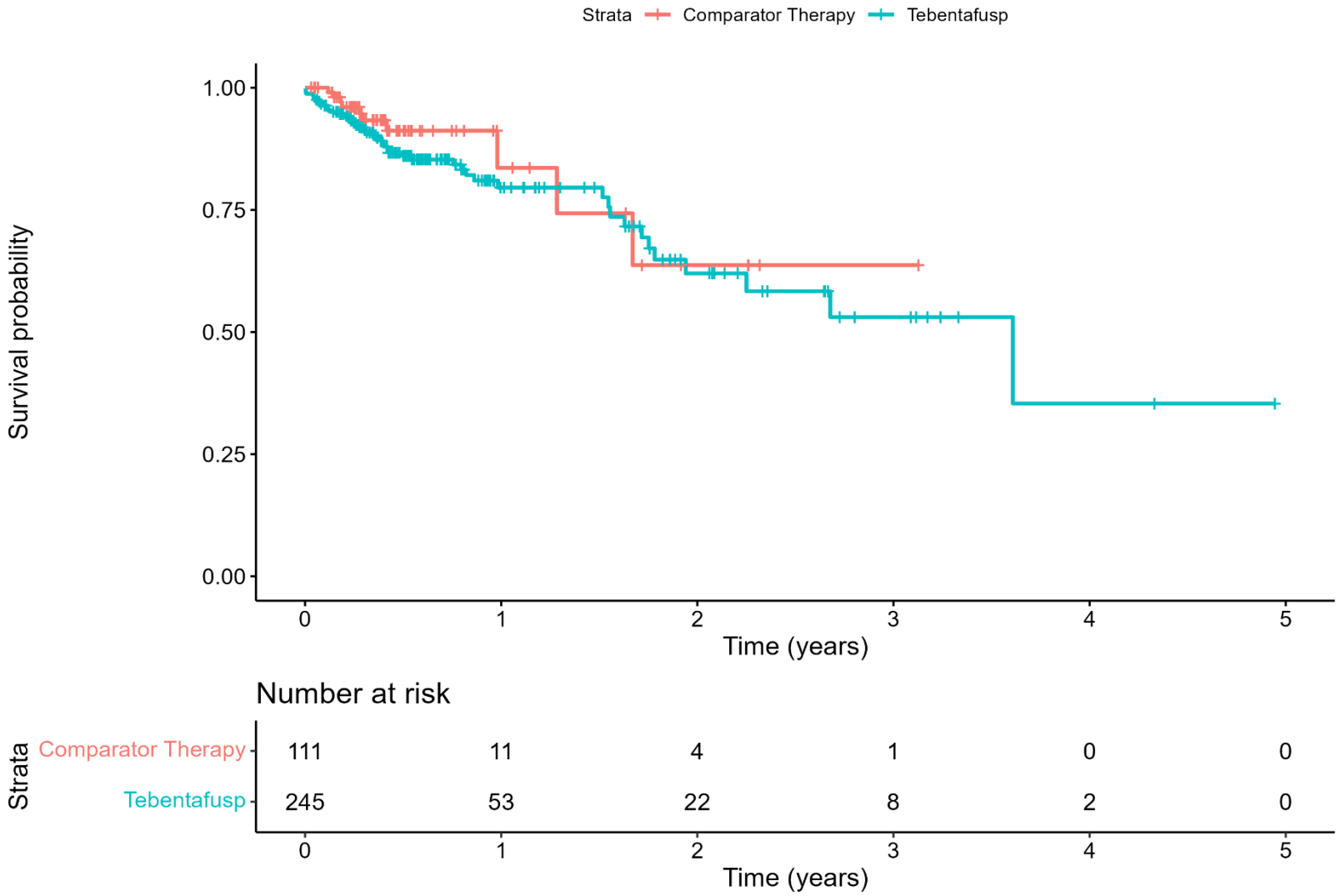
5.8 Erkrankungen des Immunsystems



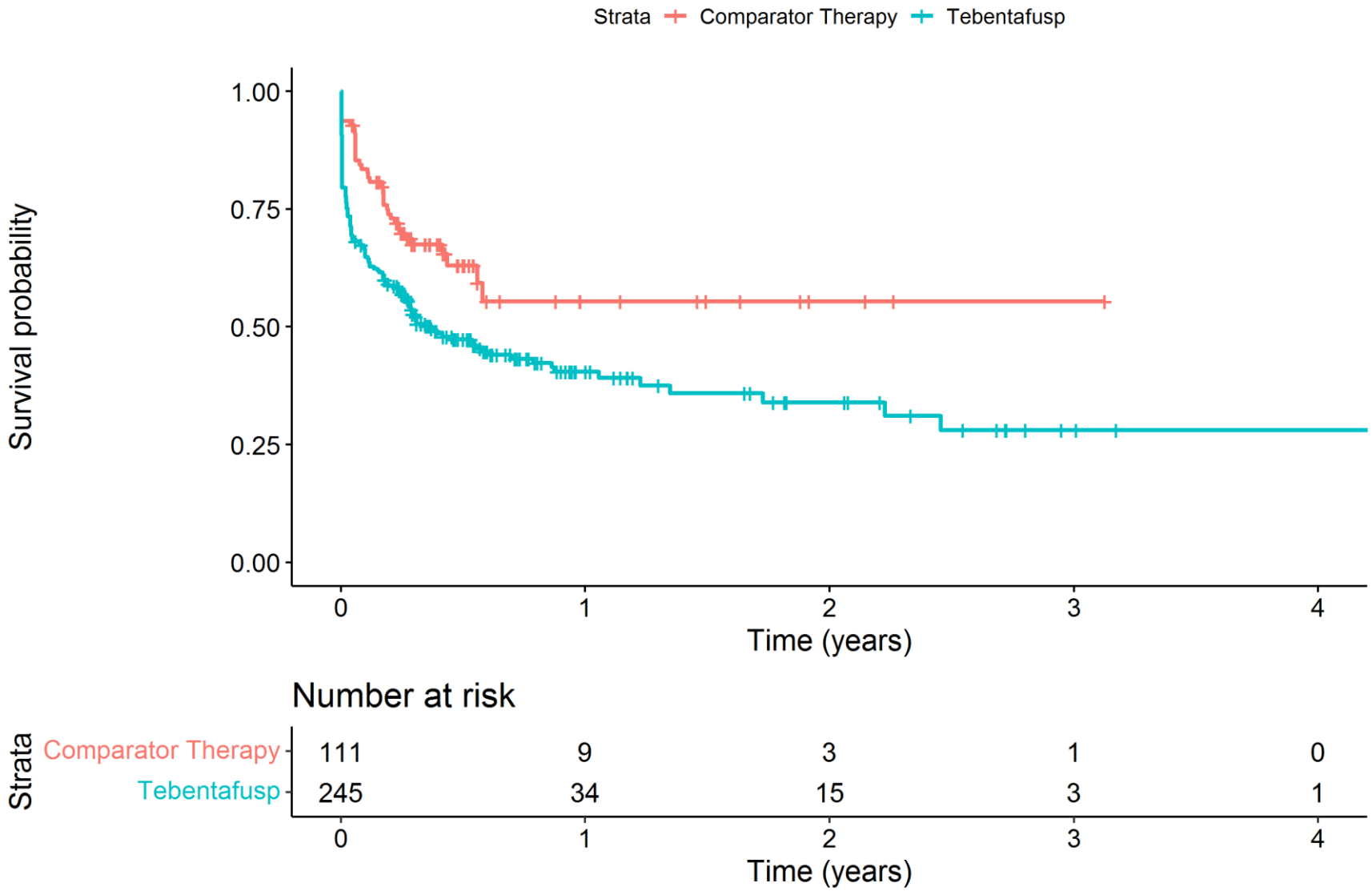
5.9 Infektionen und parasitäre Erkrankungen



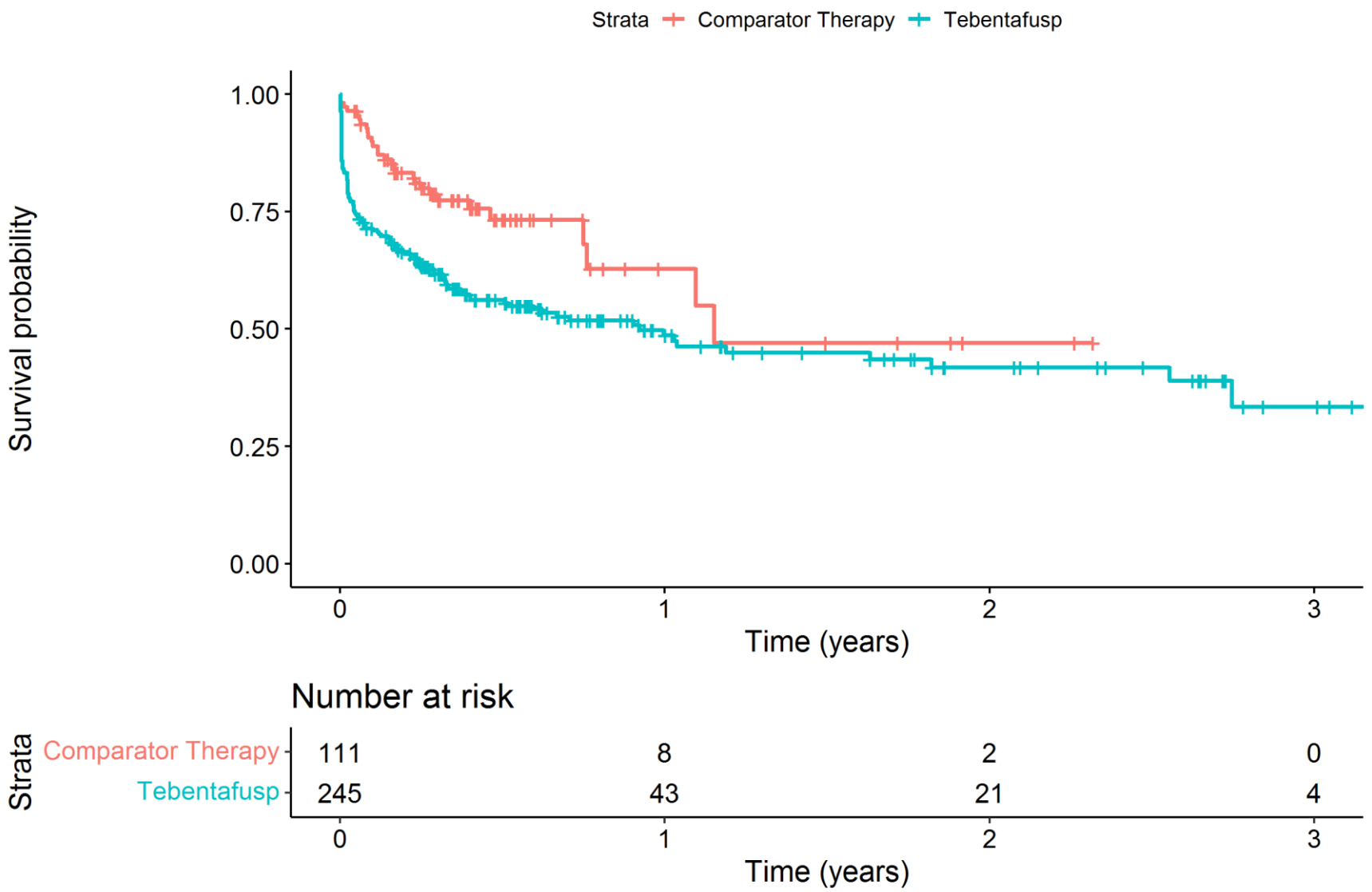
5.10 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



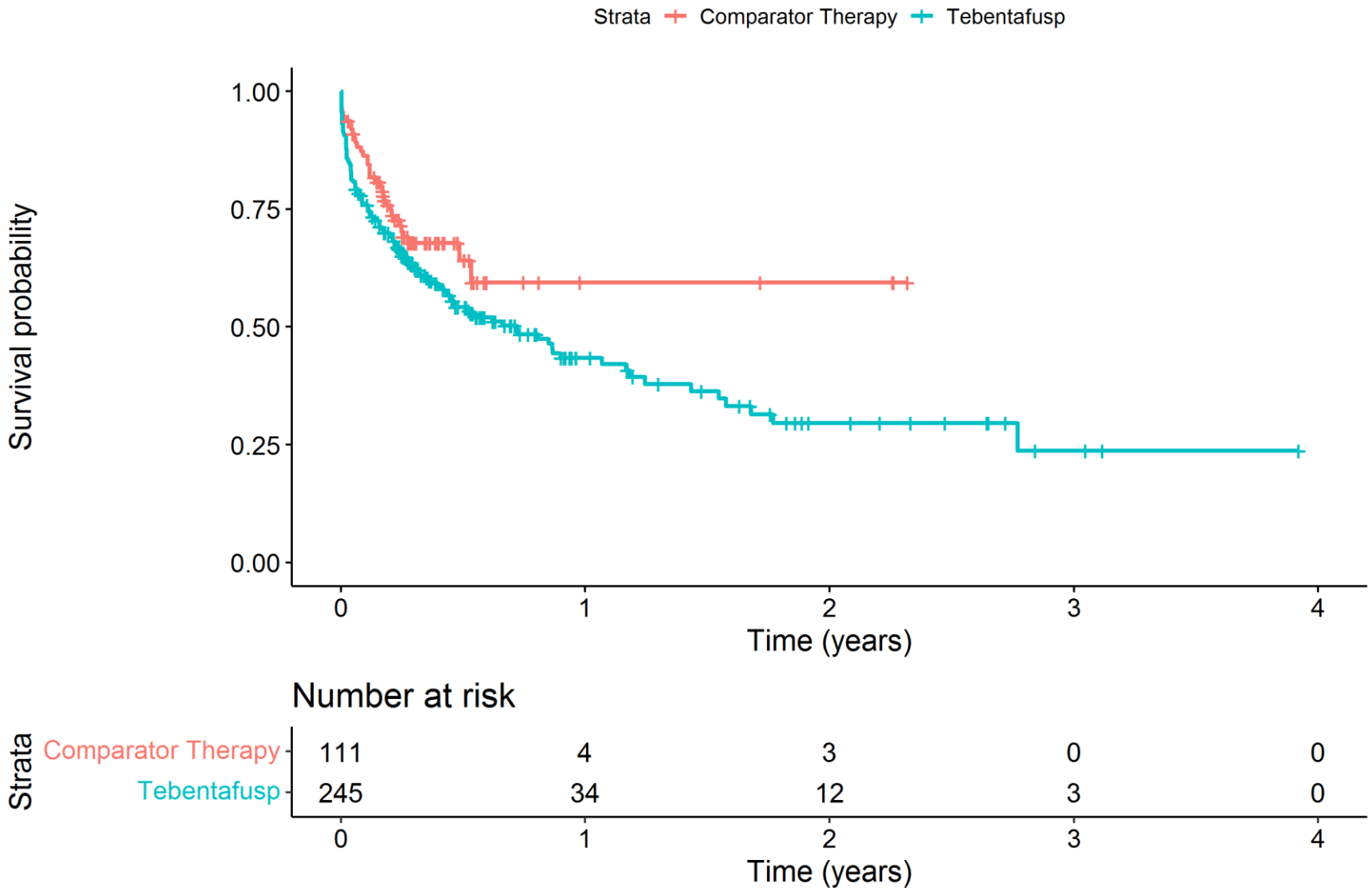
5.11 Untersuchungen



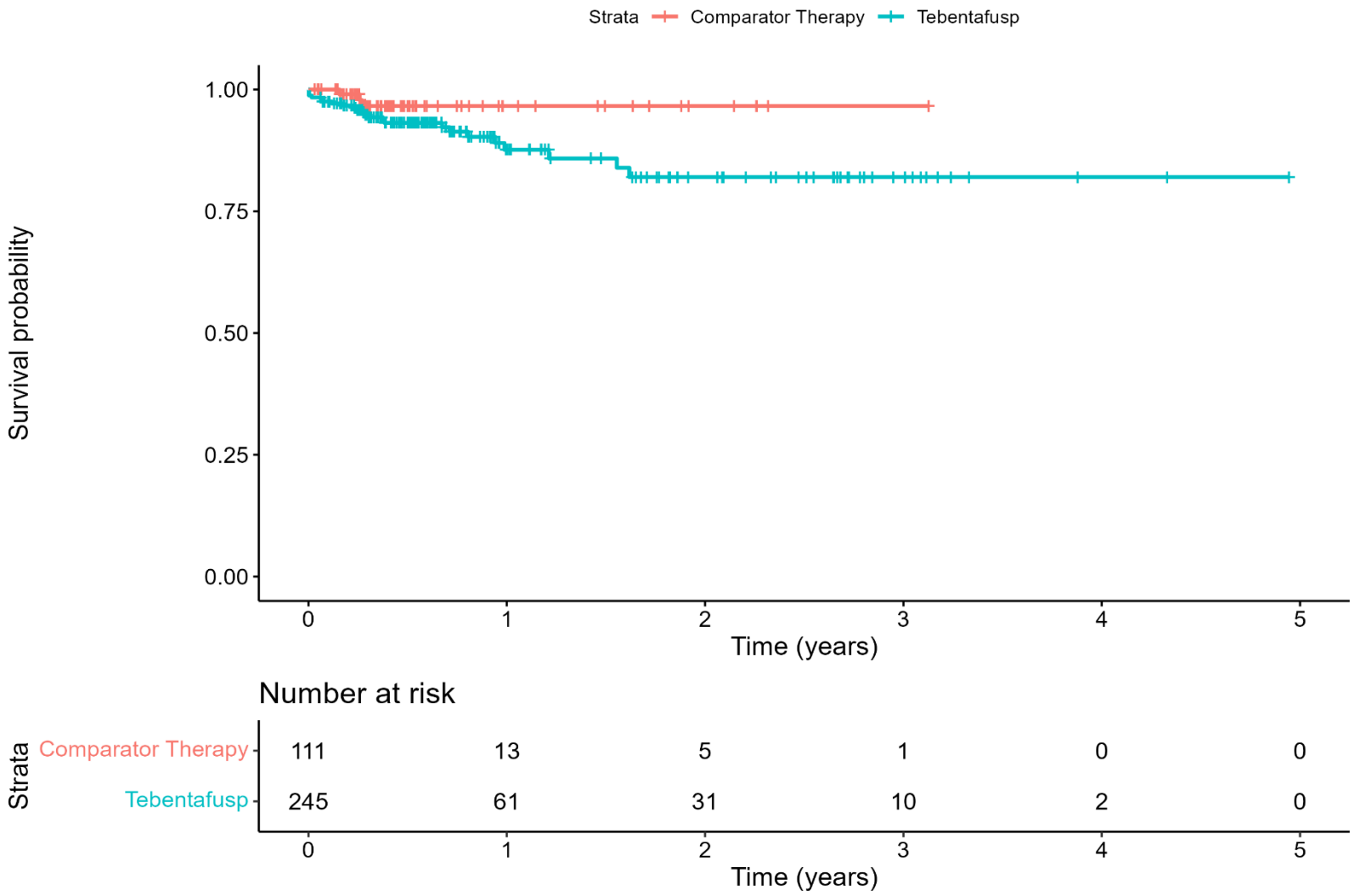
5.12 Stoffwechsel- und Ernährungsstörungen



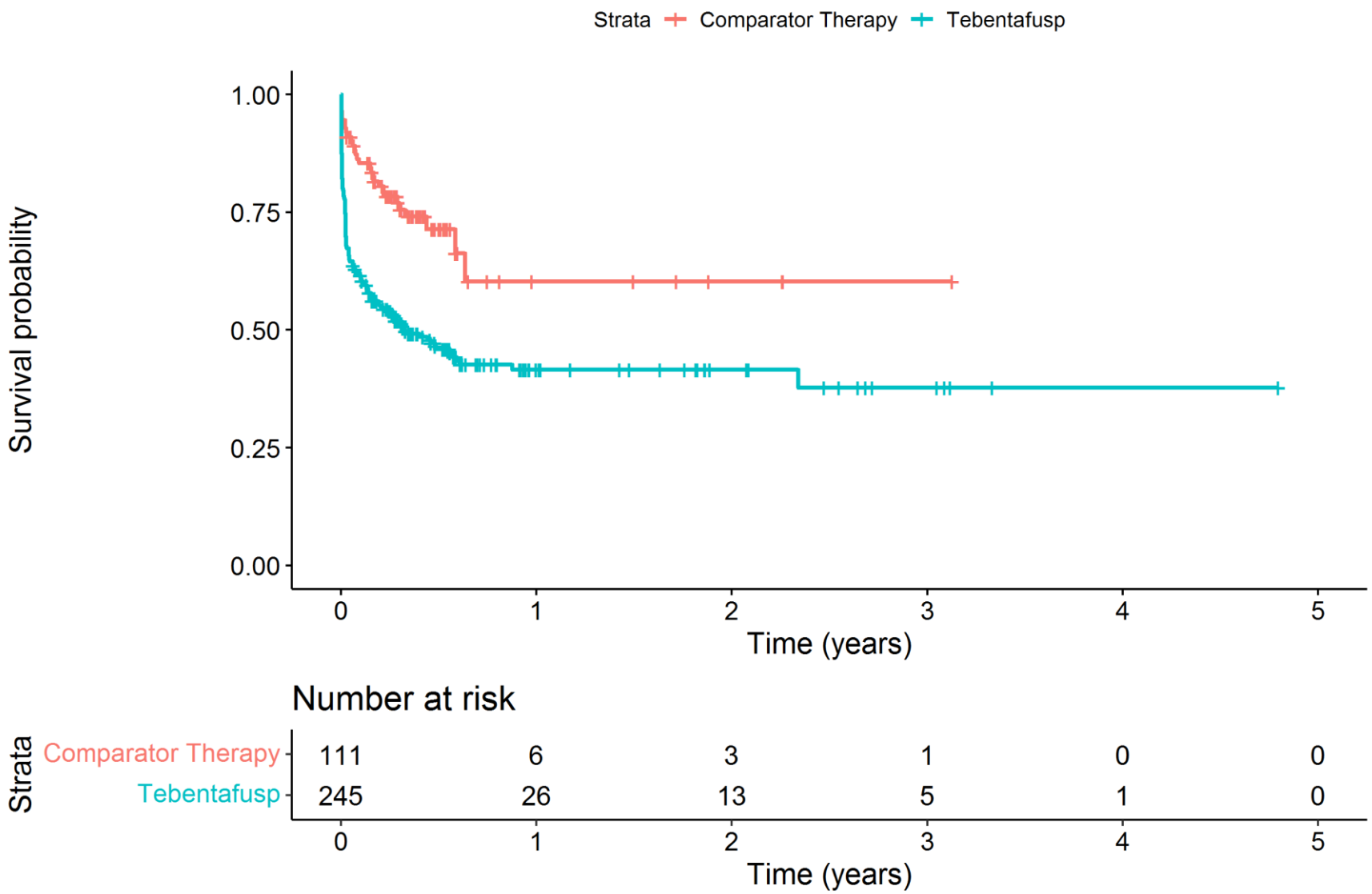
5.13 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



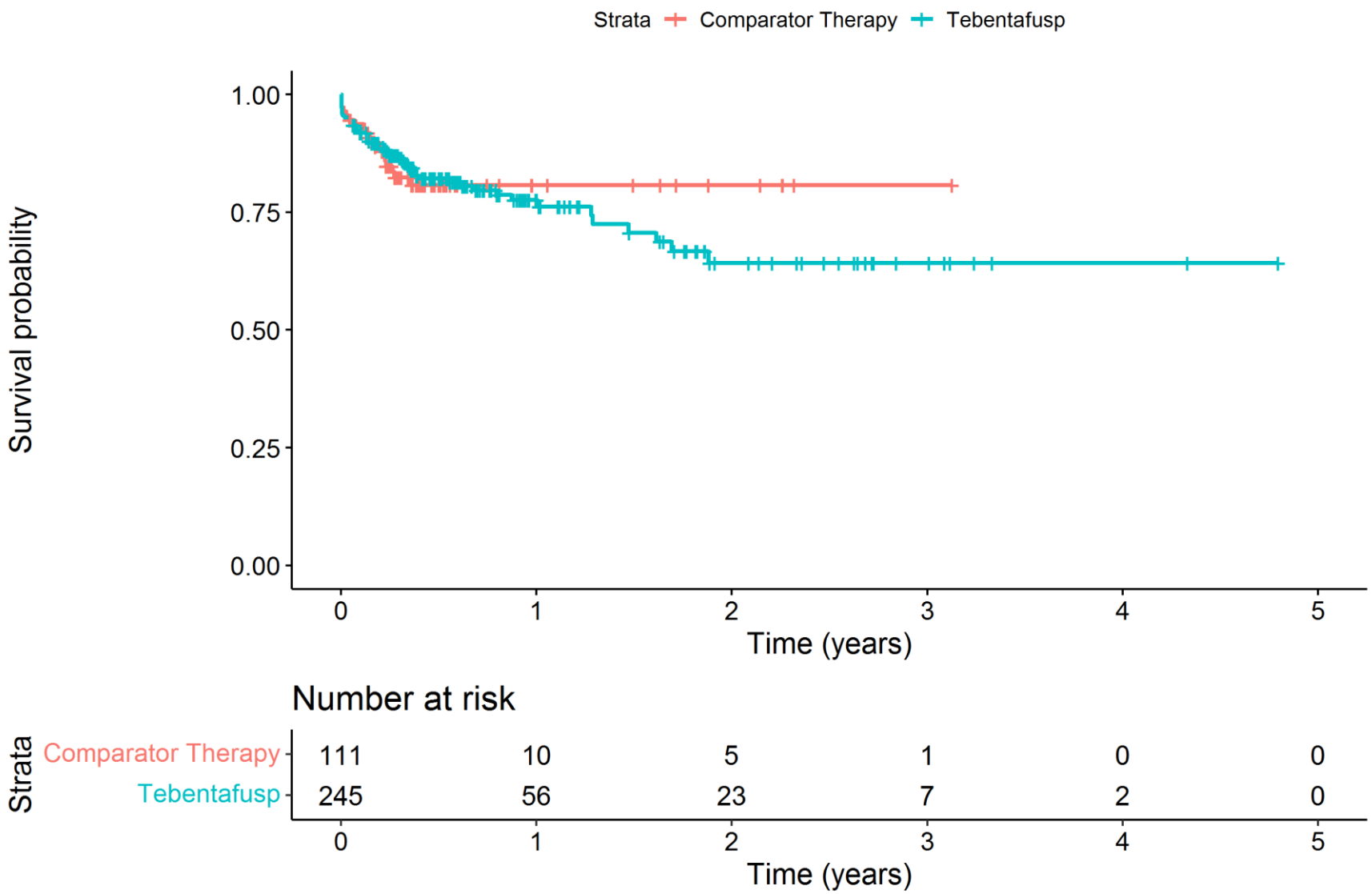
5.14 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



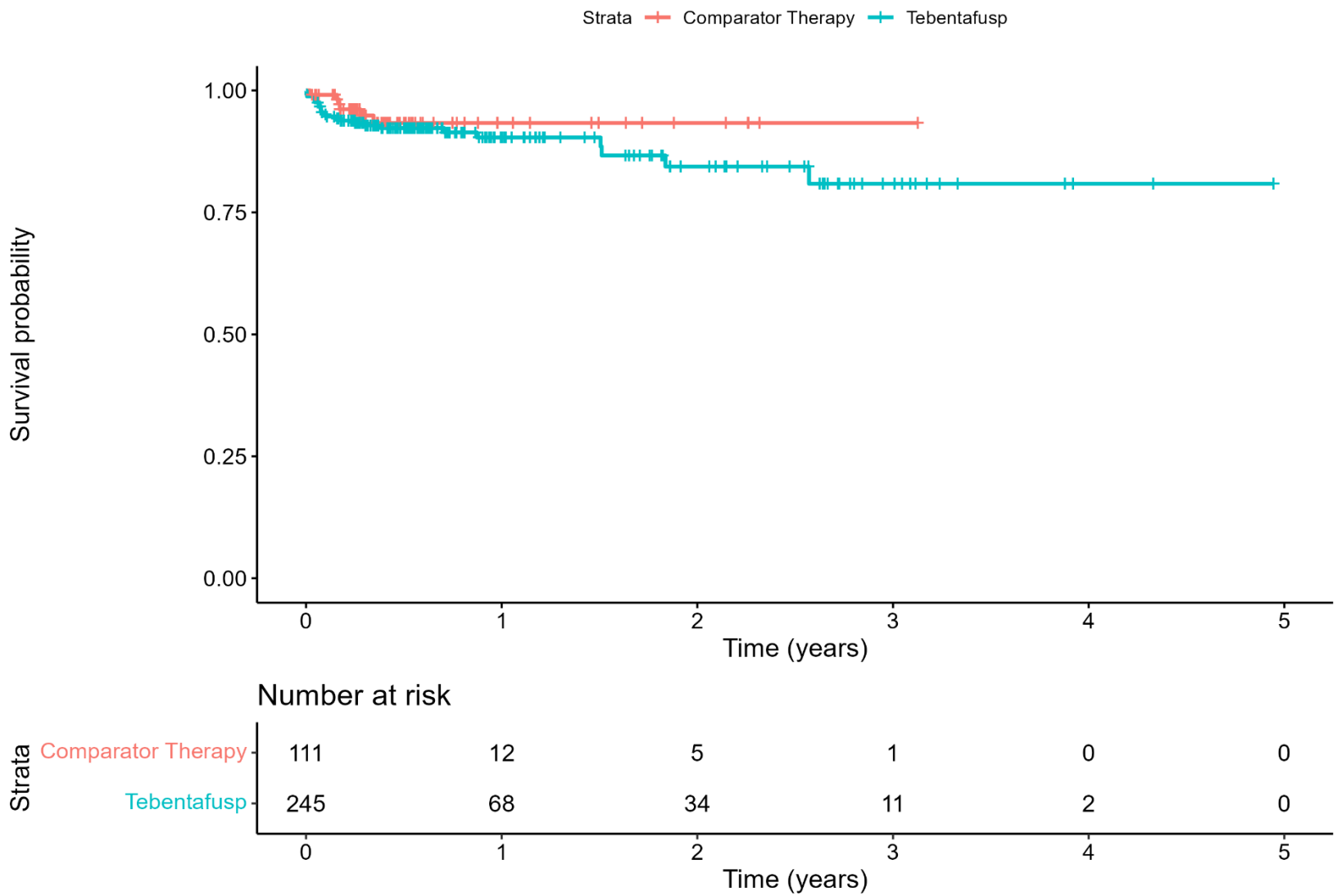
5.15 Erkrankungen des Nervensystems



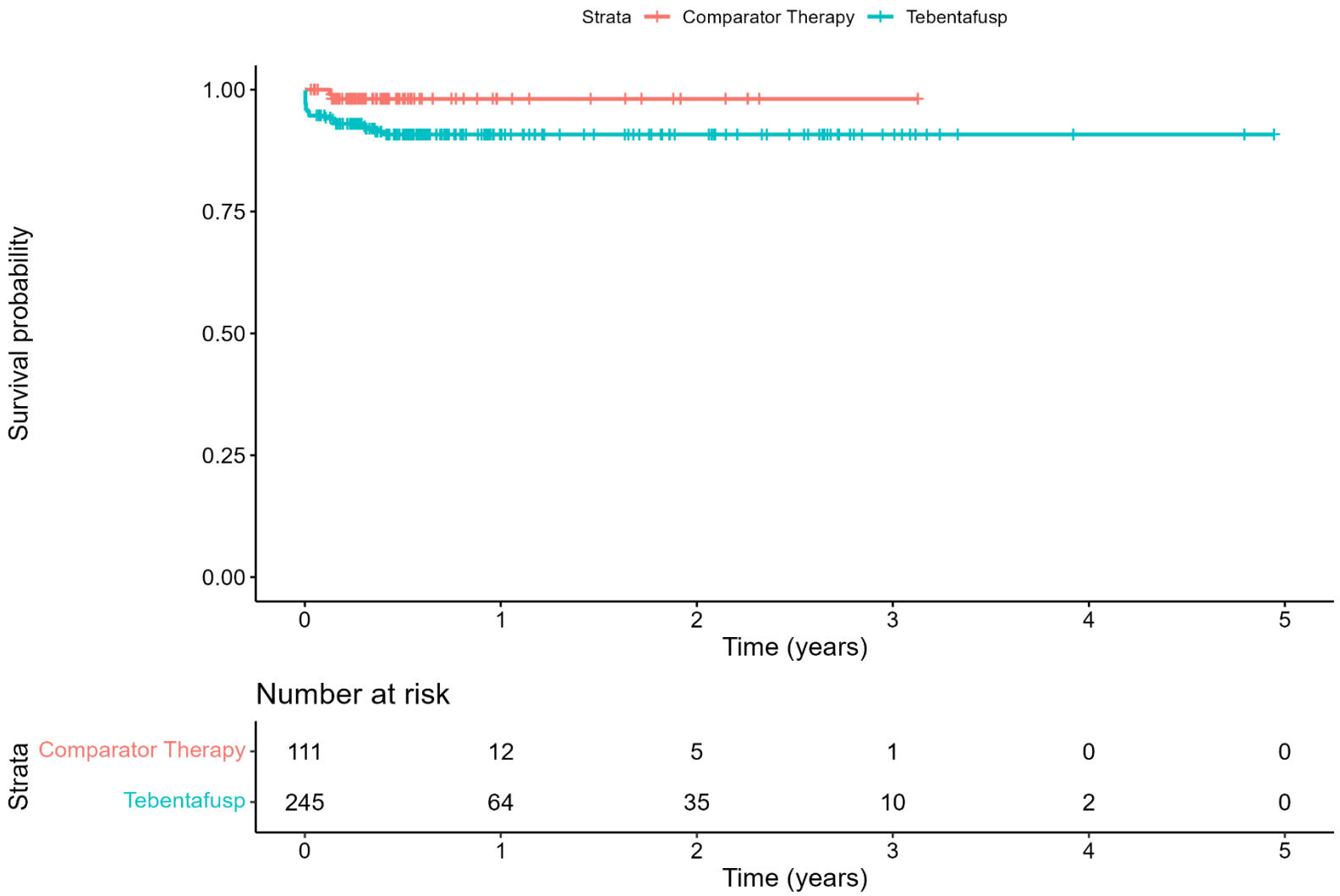
5.16 Psychiatrische Erkrankungen



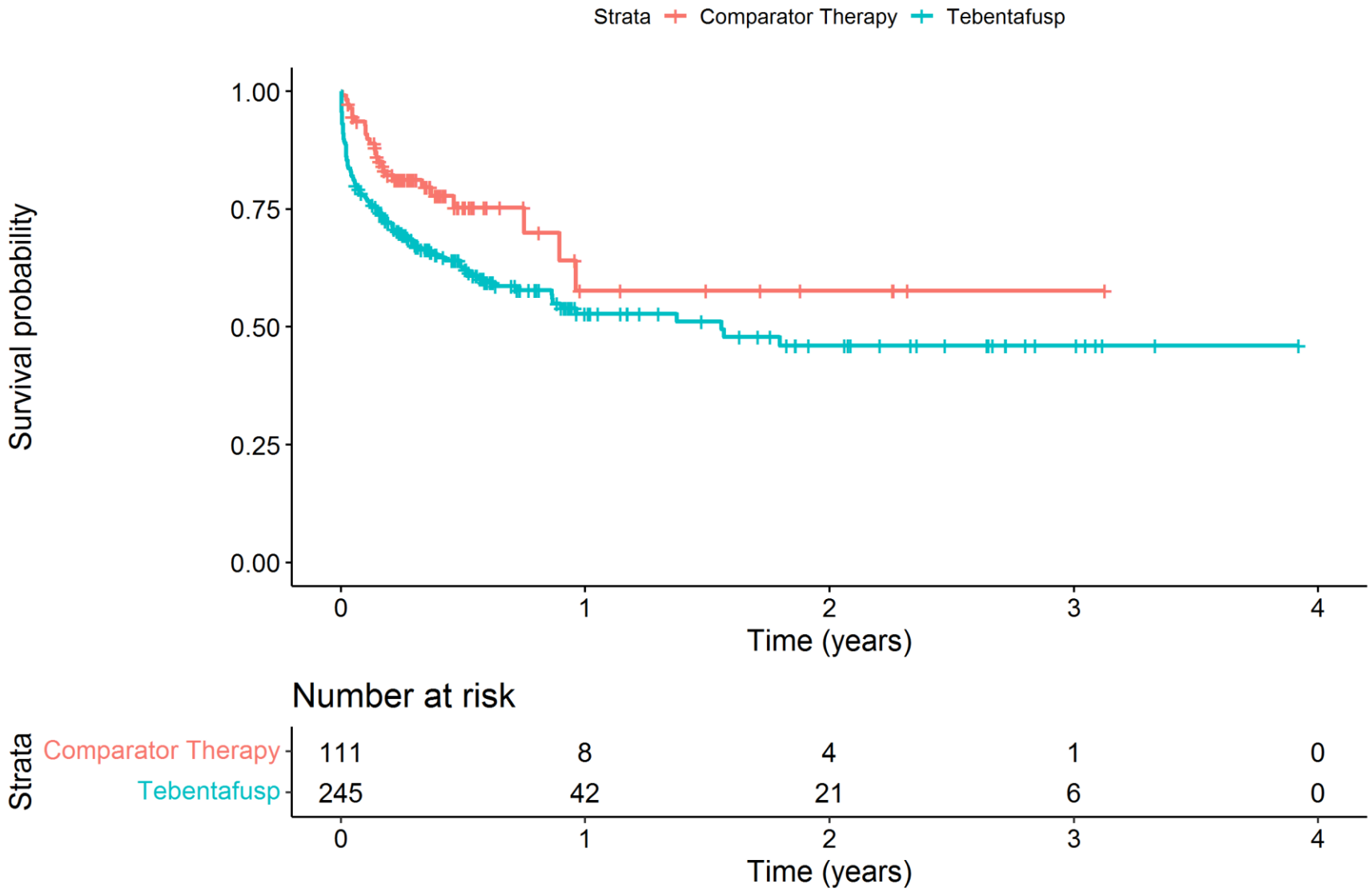
5.17 Erkrankungen der Nieren und Harnwege



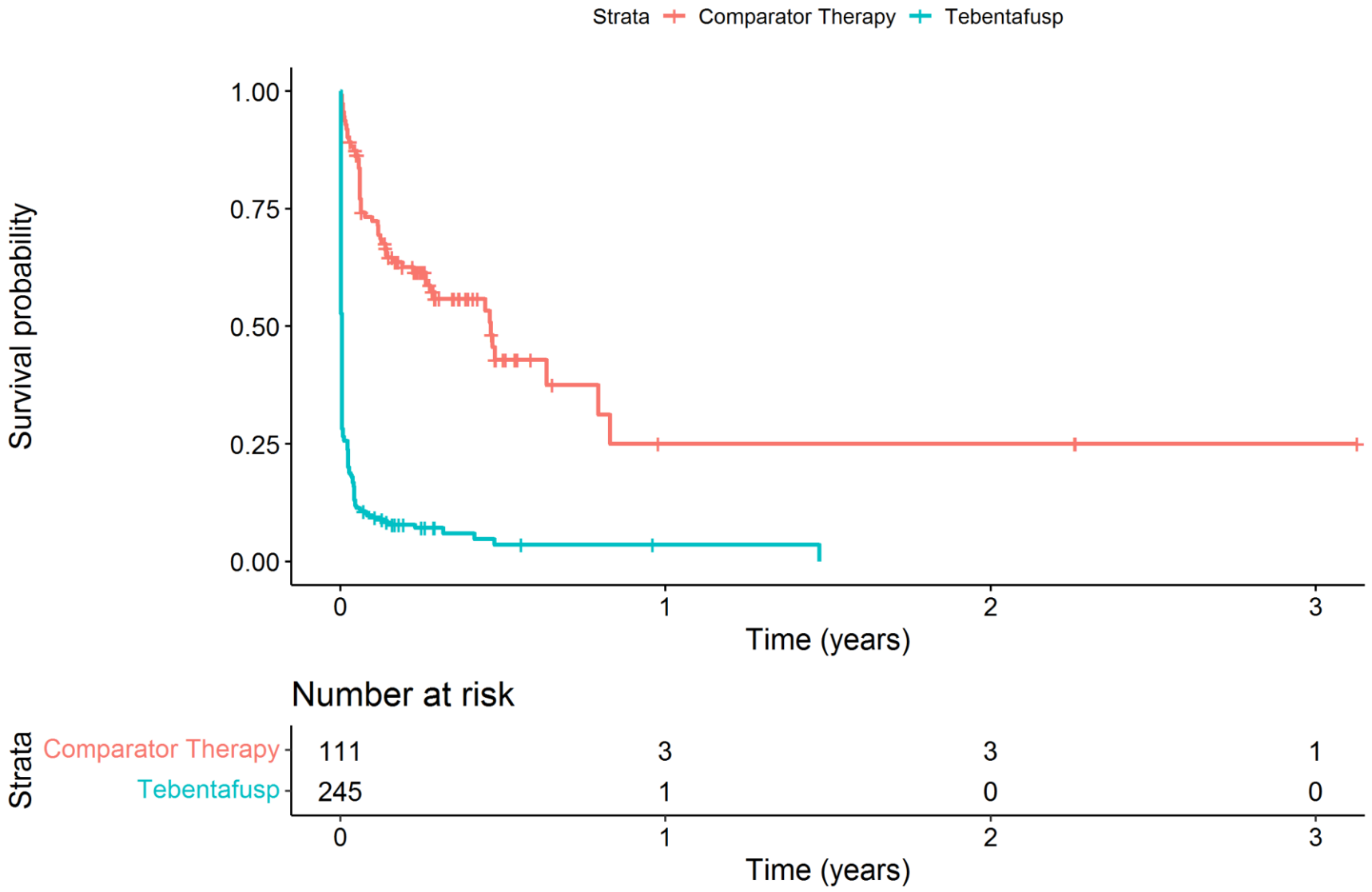
5.18 Erkrankungen der Geschlechtsorgane und der Brustdruese



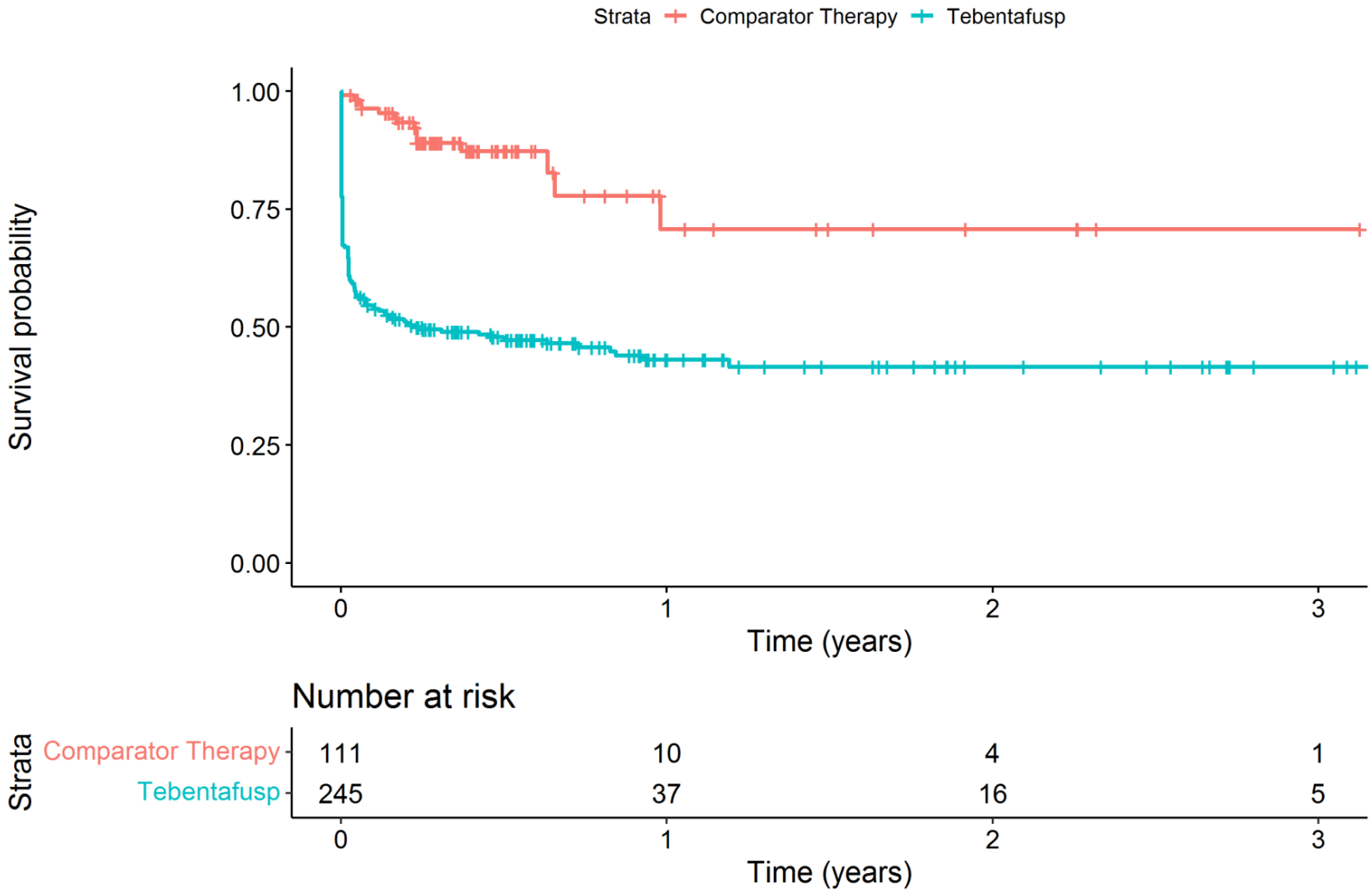
5.19 Erkrankungen der Atemwege, des Brustraums und Mediastinums



5.20 Erkrankungen der Haut und des Unterhautgewebes



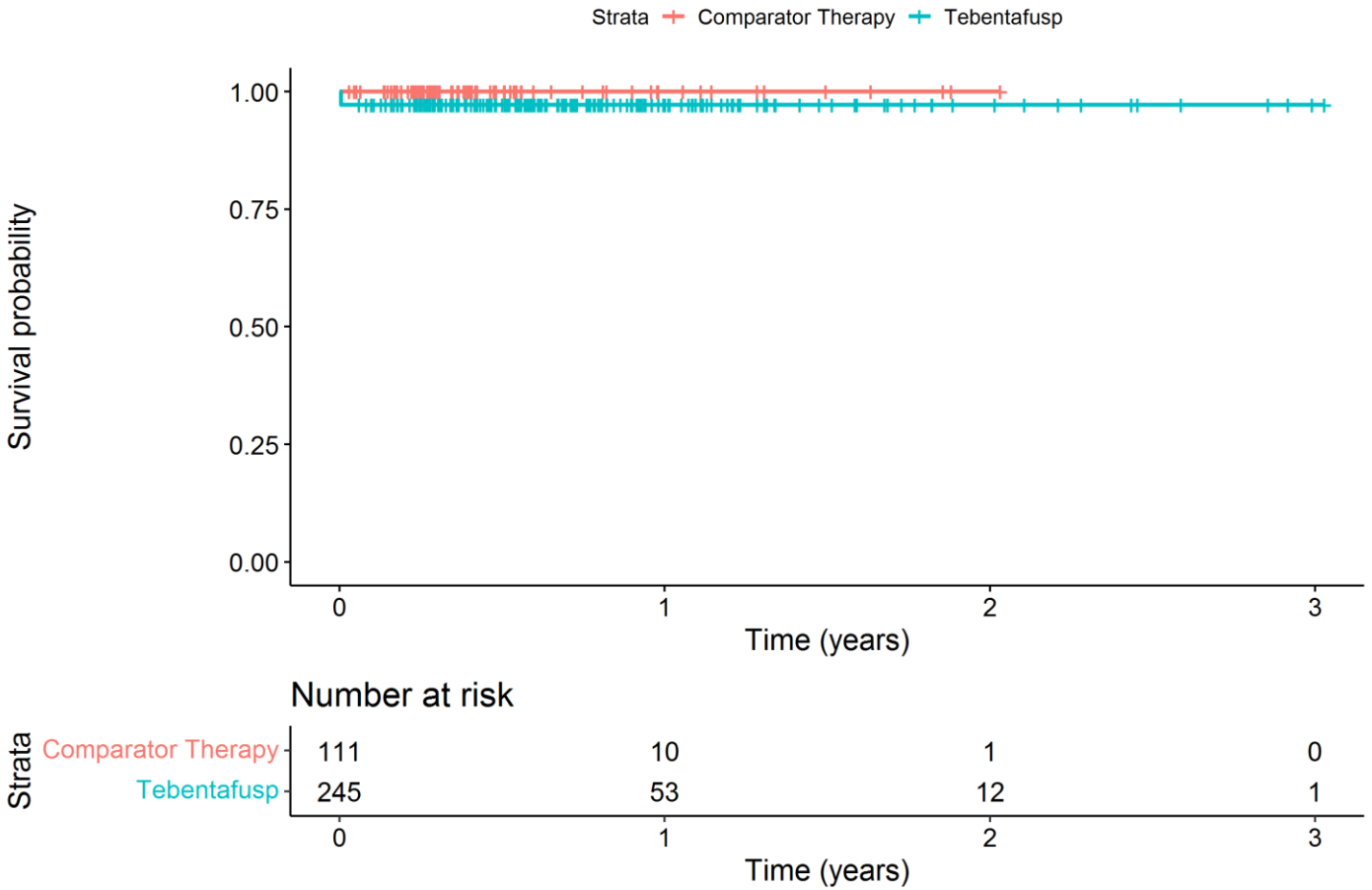
5.21 Gefäßerkrankungen



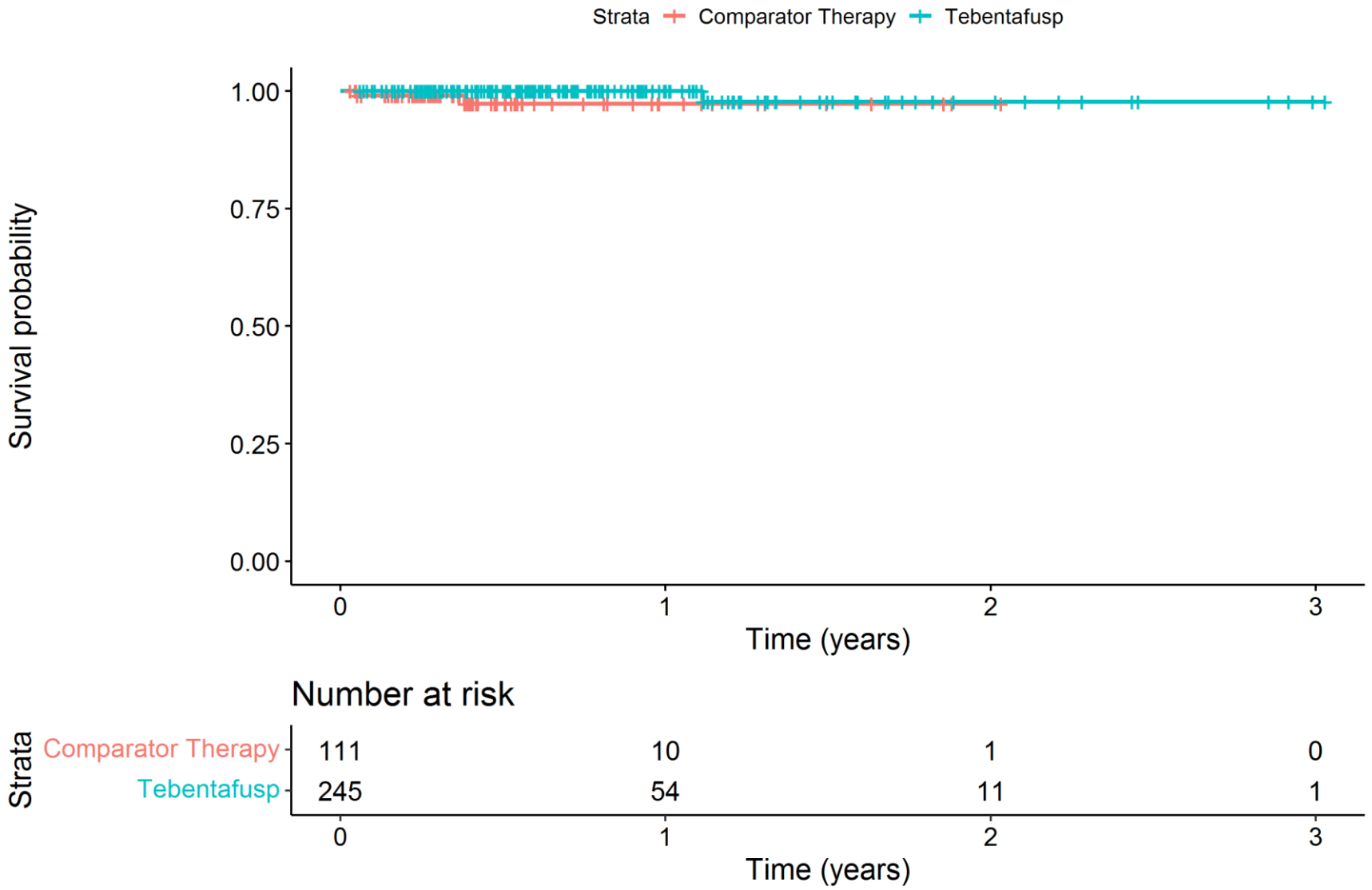
5.22 Unerwünschte Ereignisse nach Schweregrad – Primäranalyse (Oktober 2020) (Tabelle 4-55)

6 UEs (PT) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten

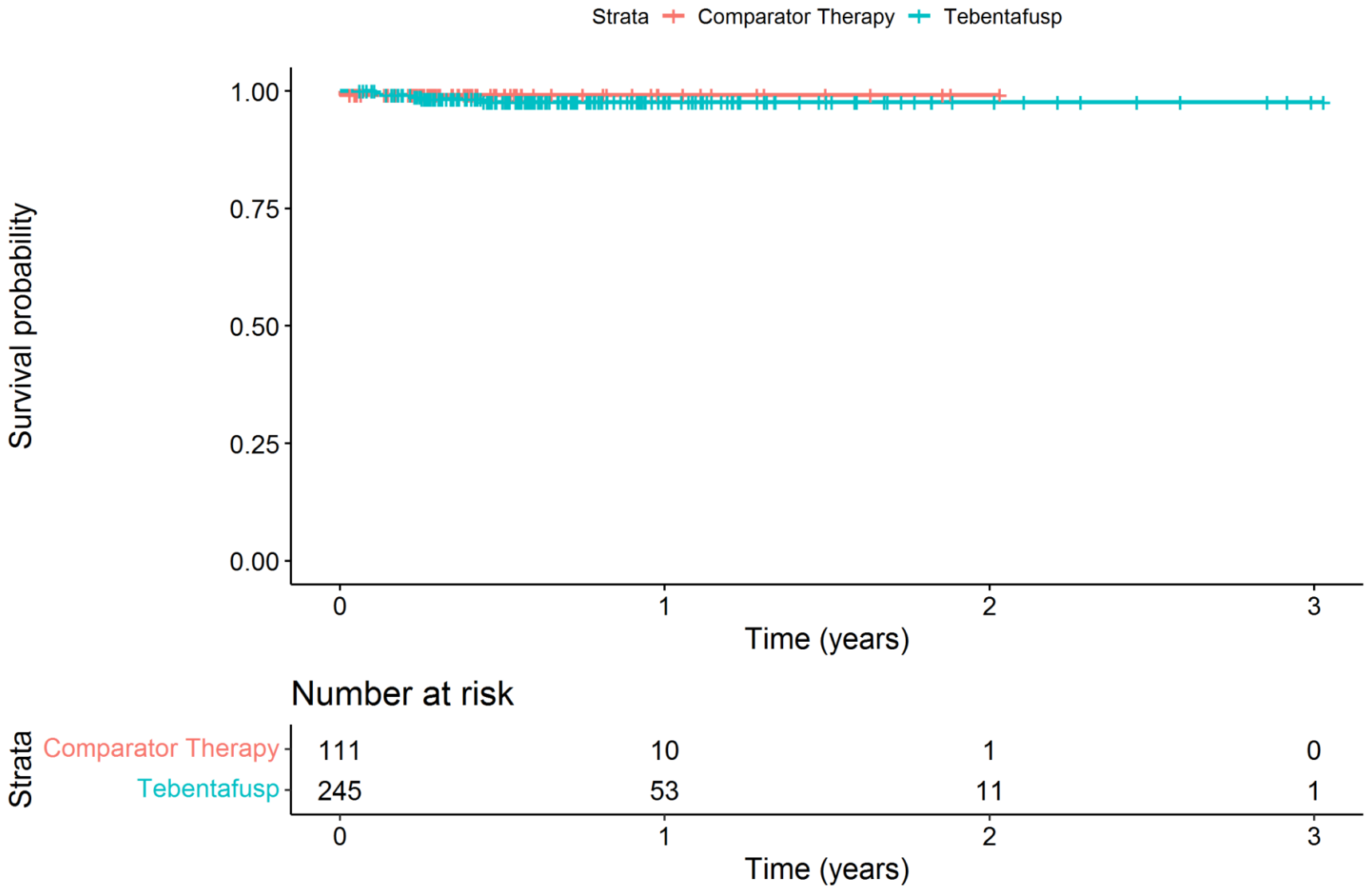
6.1 Lymphopenie



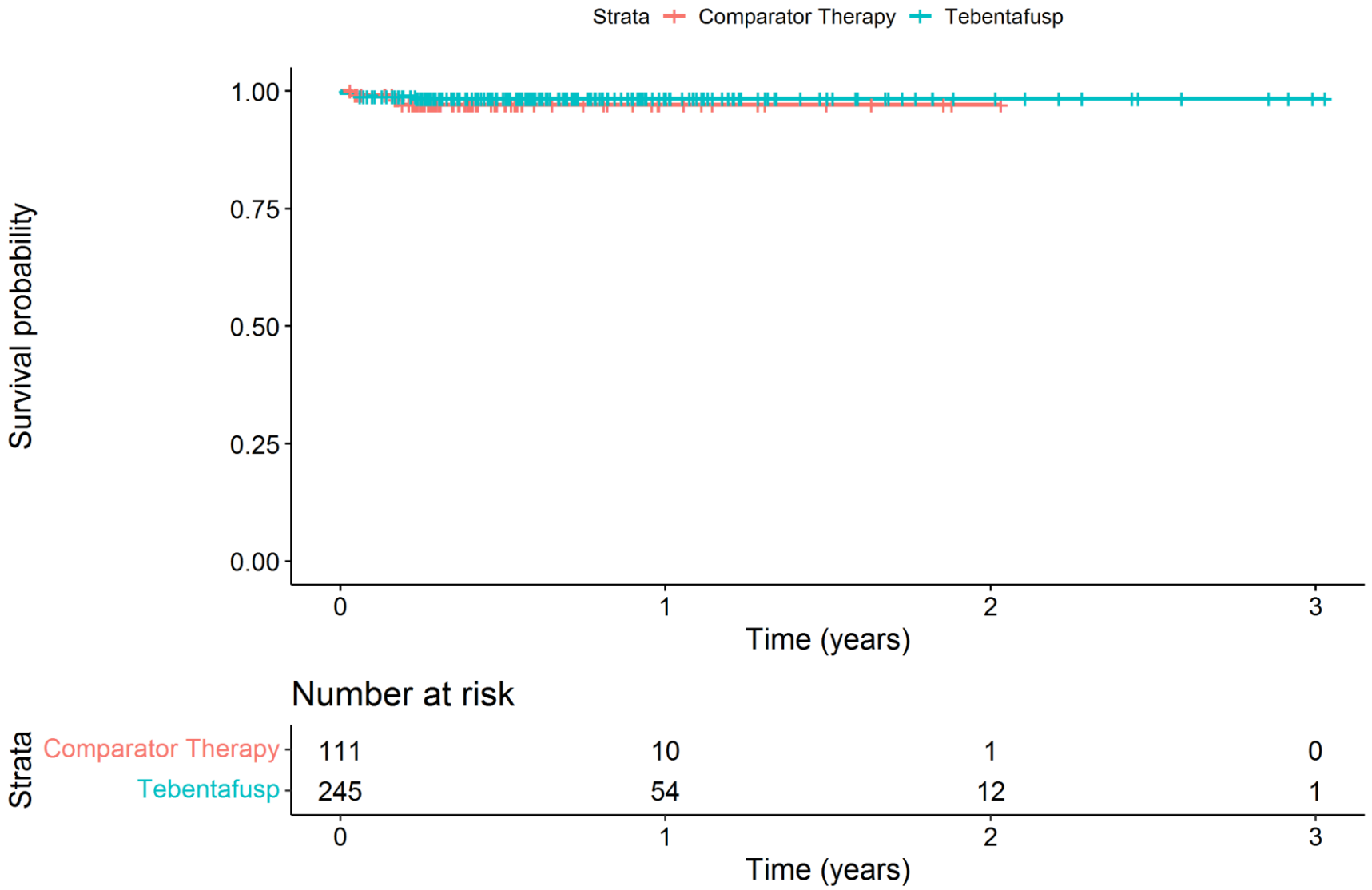
6.2 Neutropenie



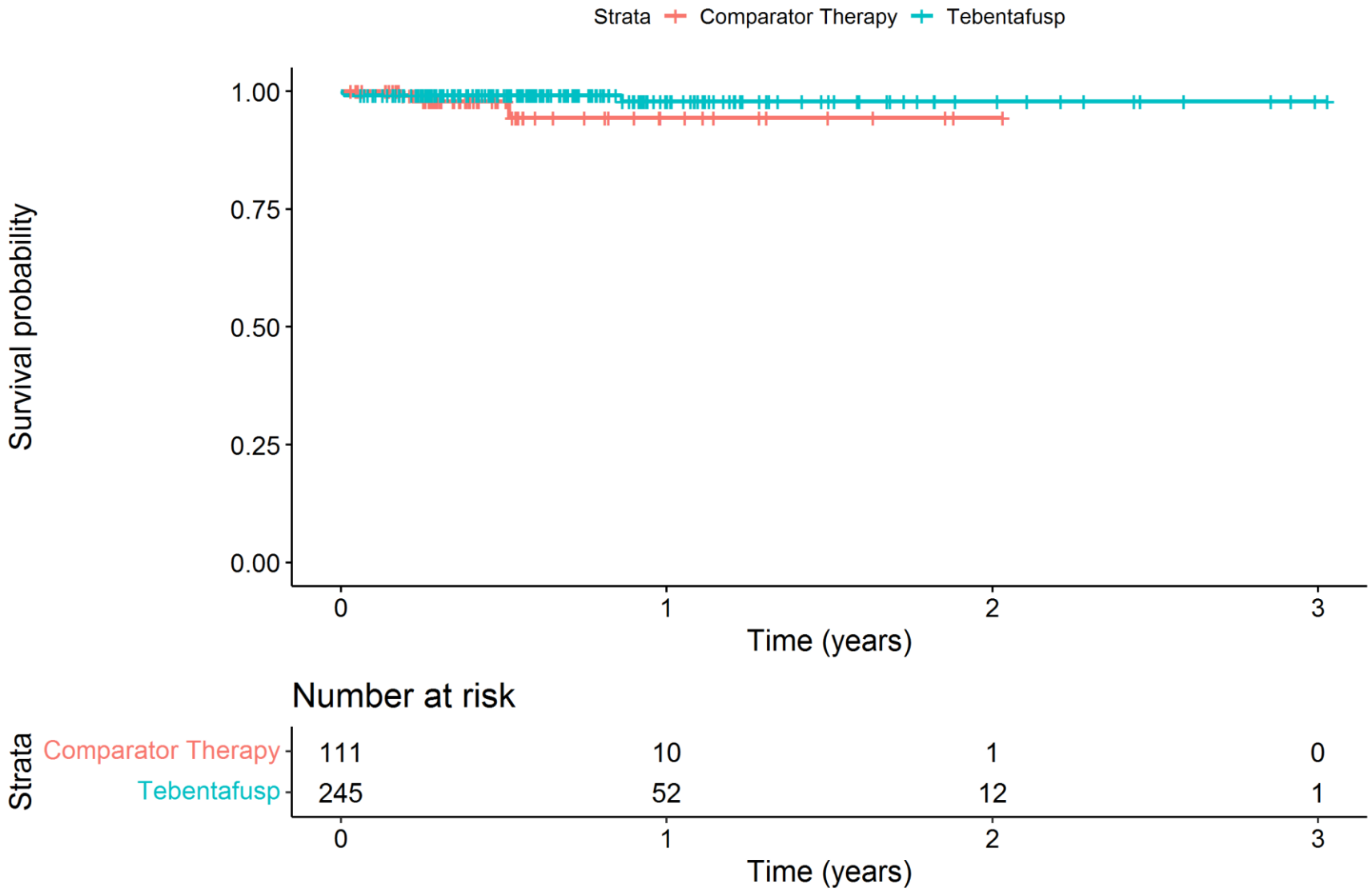
6.3 Übelkeit


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
53
11
1
0
1
2
3
Time (years)

6.4 Unterleibsschmerzen



6.5 Diarrhoe


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
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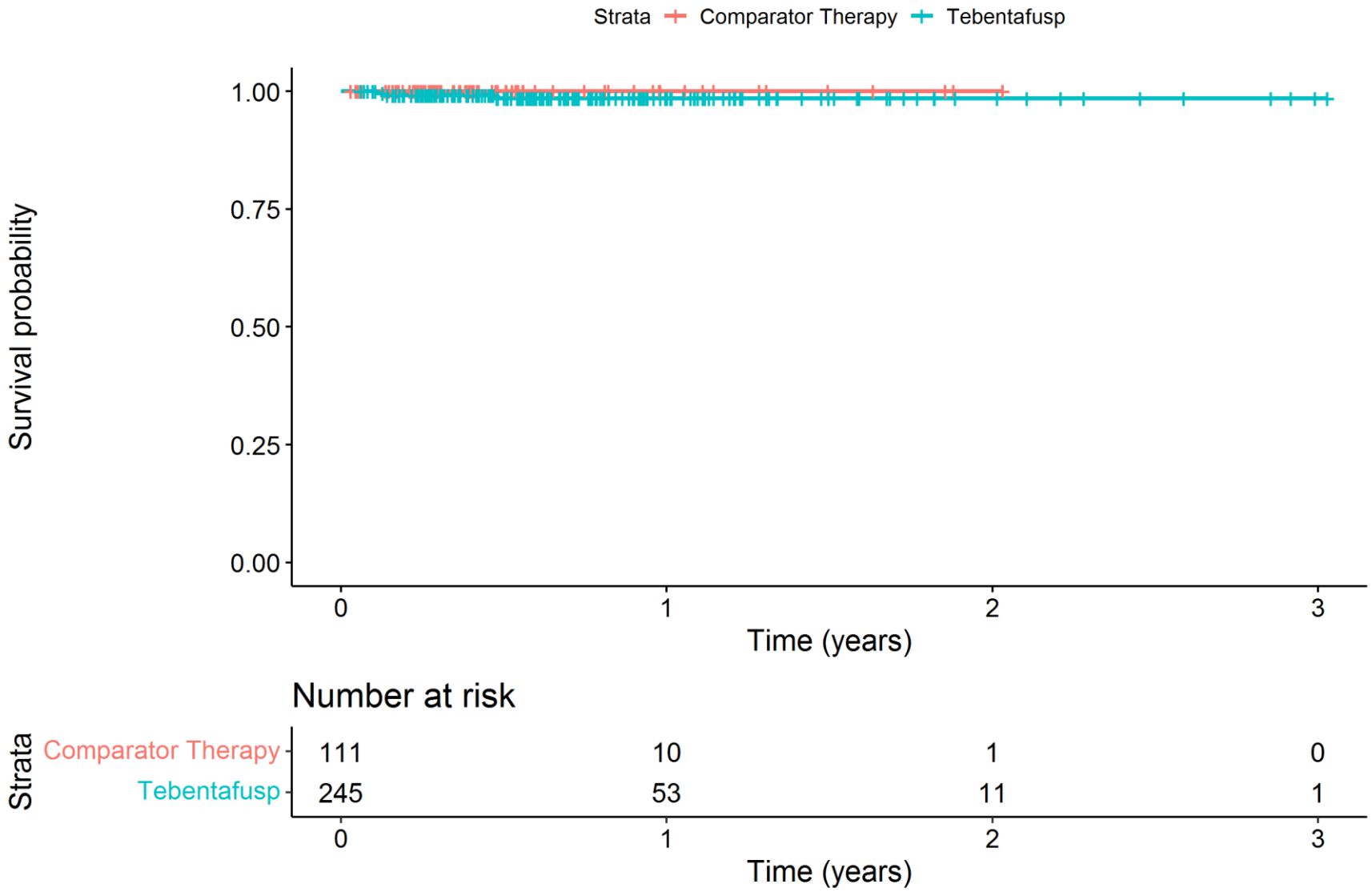
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
52
12
1
0
1
2
3
Time (years)

6.6 Erbrechen



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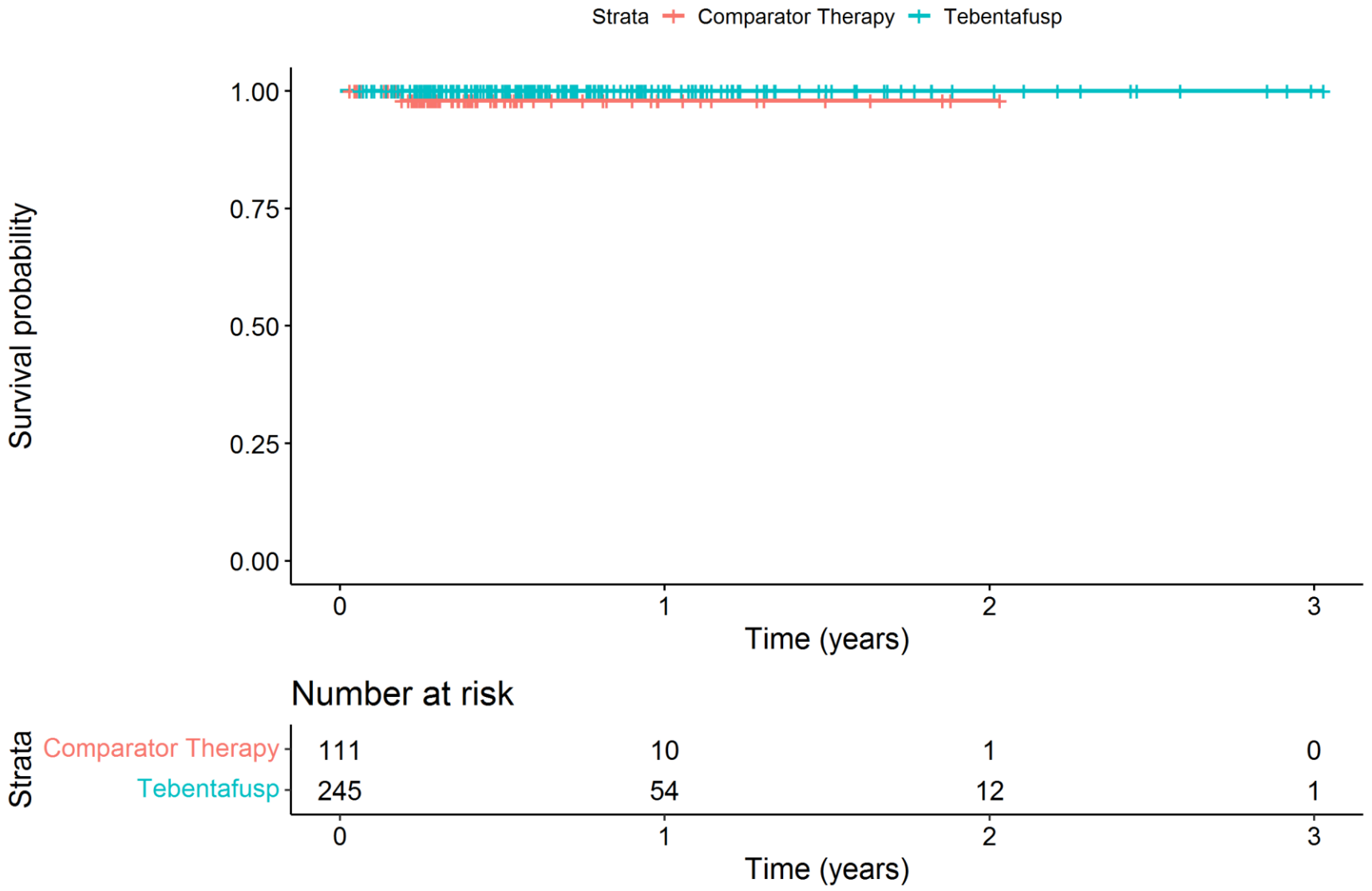
Strata
Comparator Therapy
Tebentafusp
Survival probability
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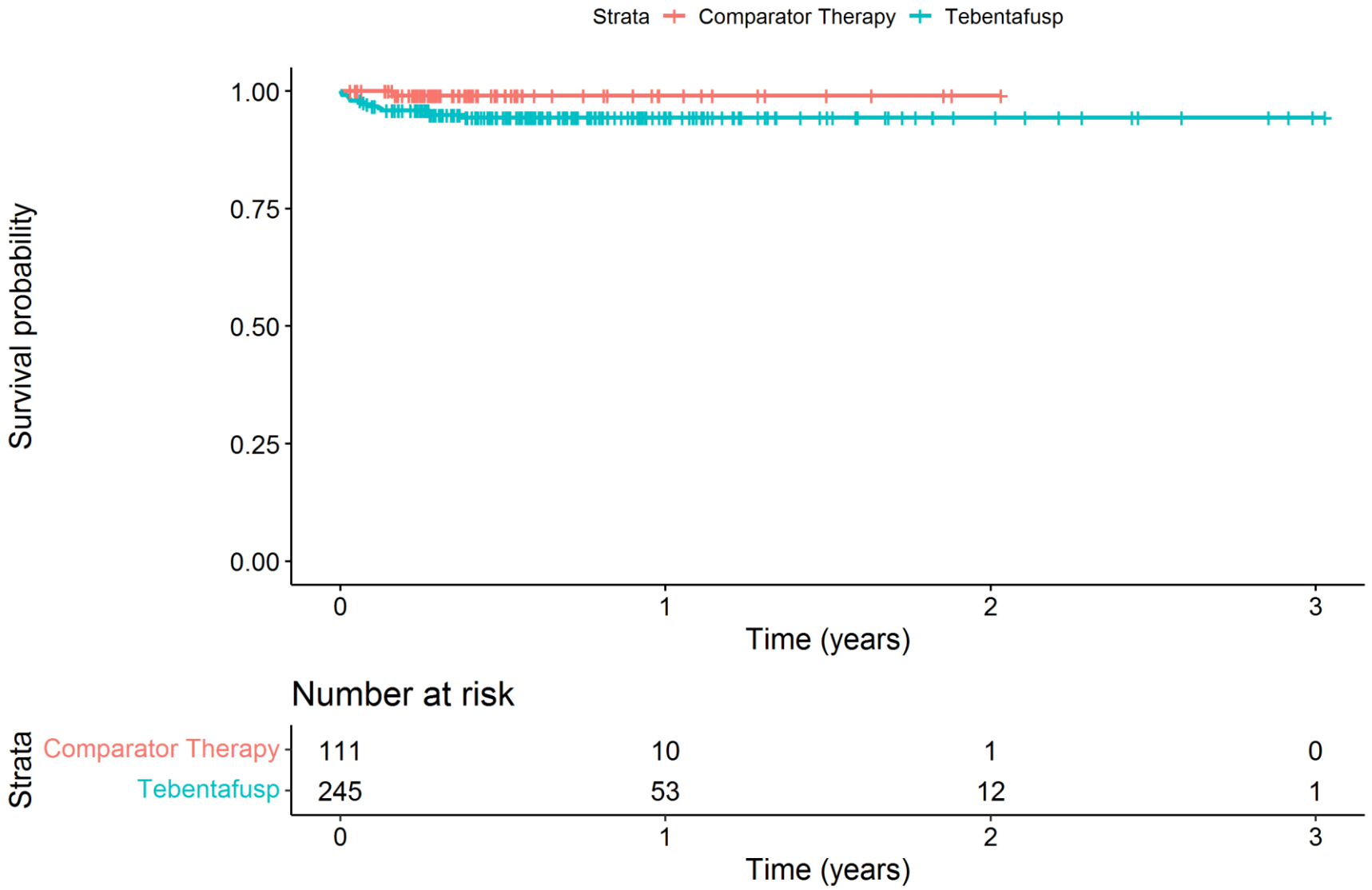
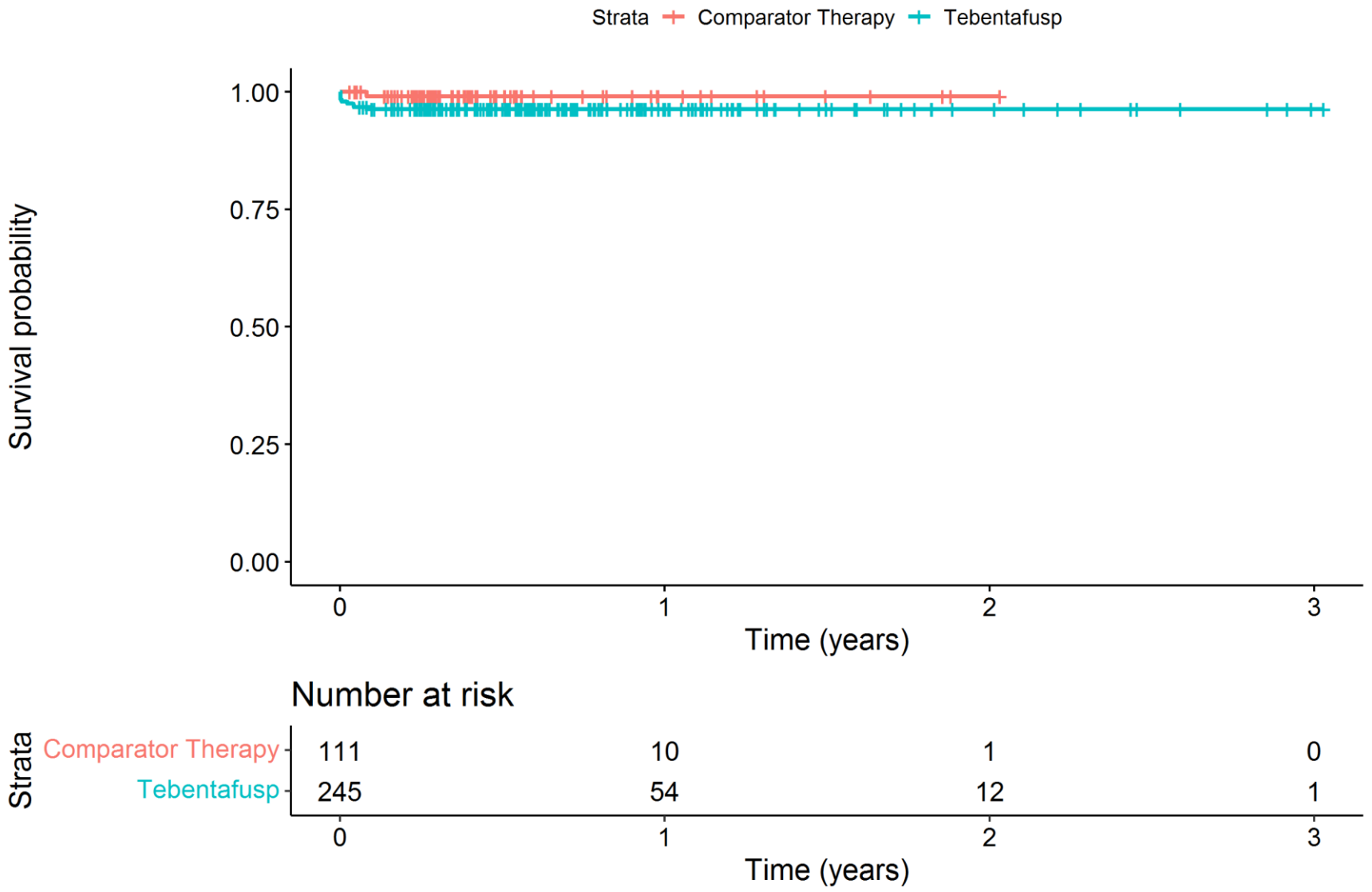
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
54
12
1
0
1
2
3
Time (years)

6.8 Müdigkeit



6.9 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
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0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
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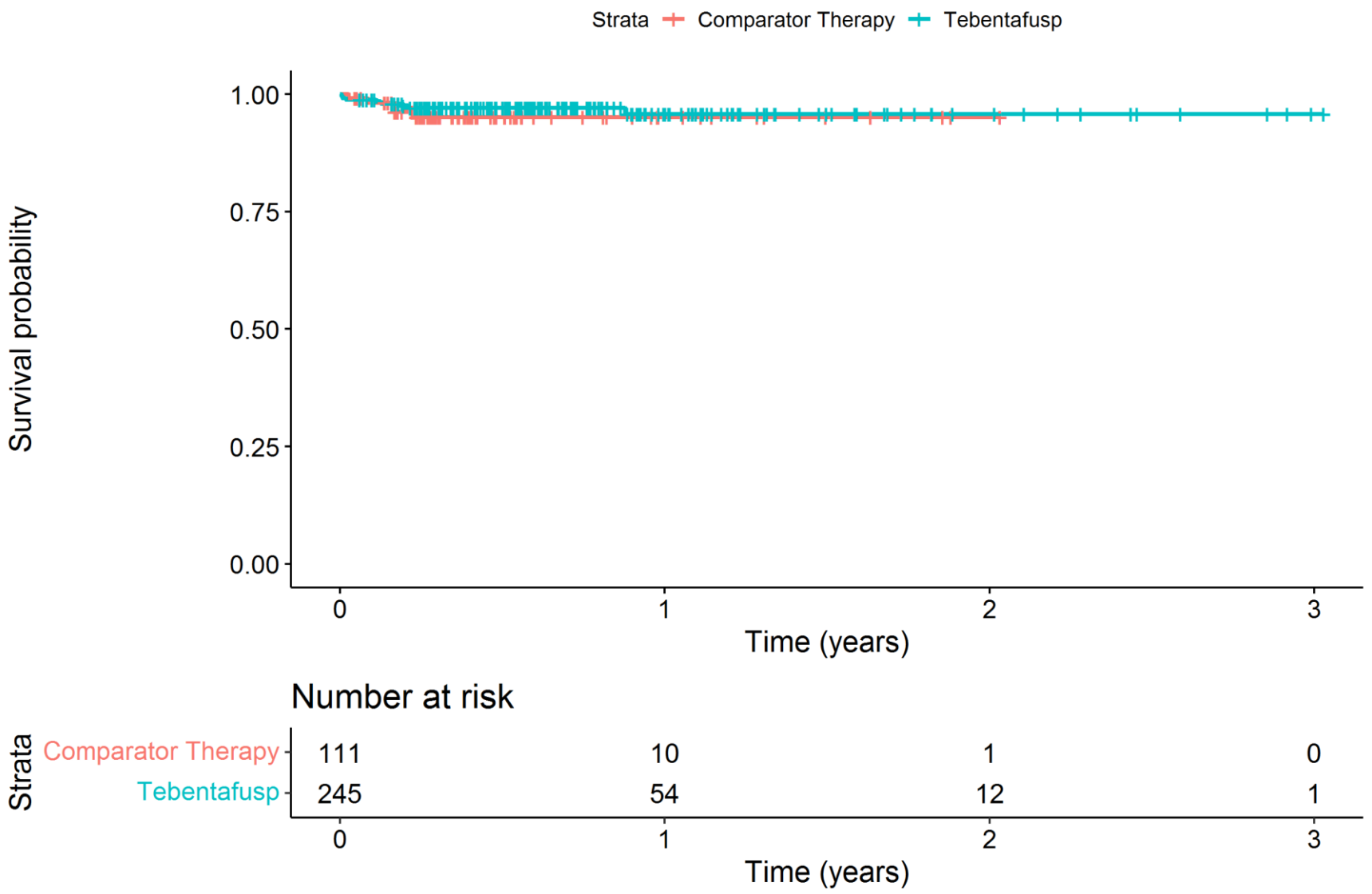
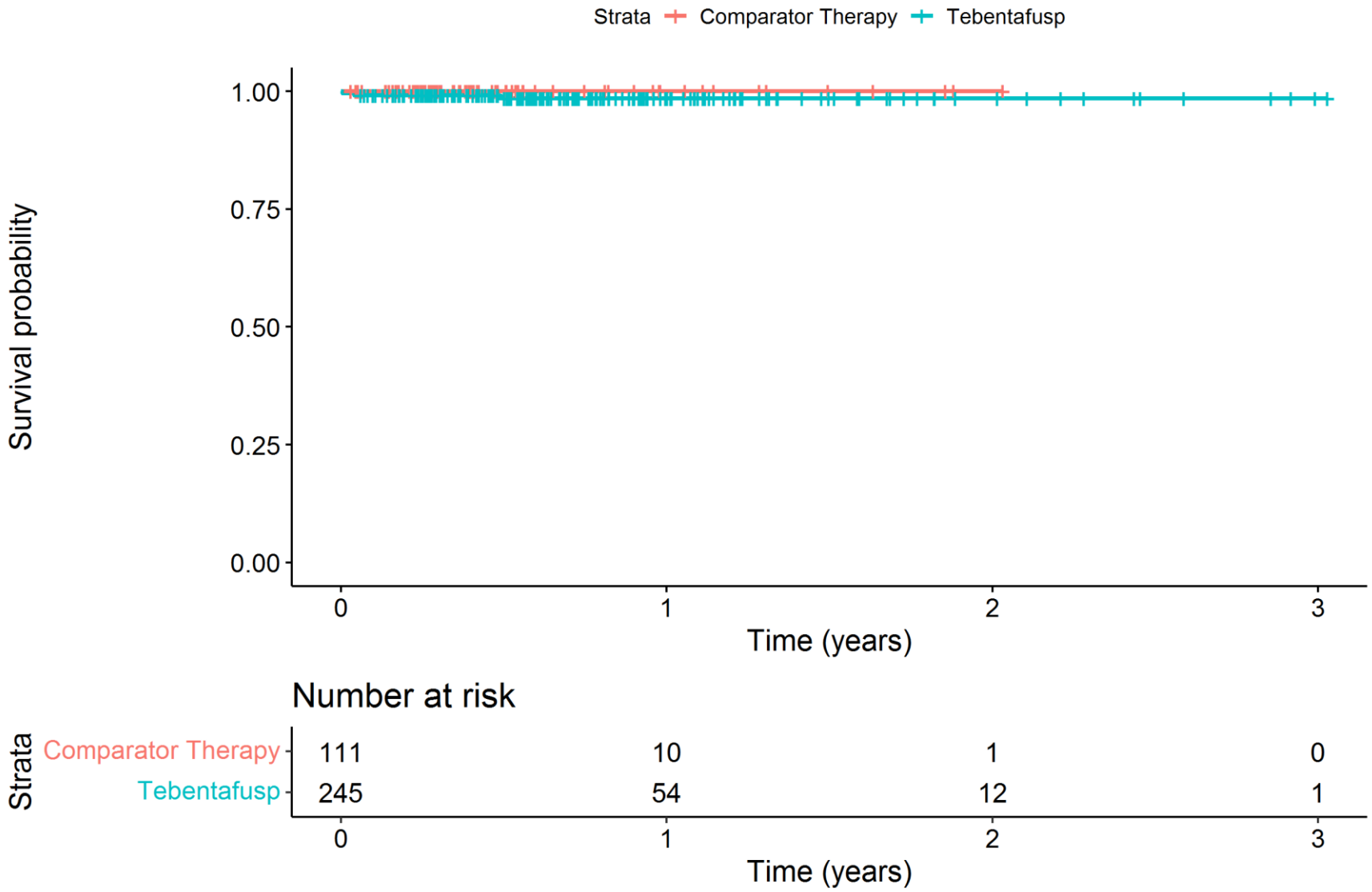
10
1
0
245
54
12
1
0
1
2
3
Time (years)

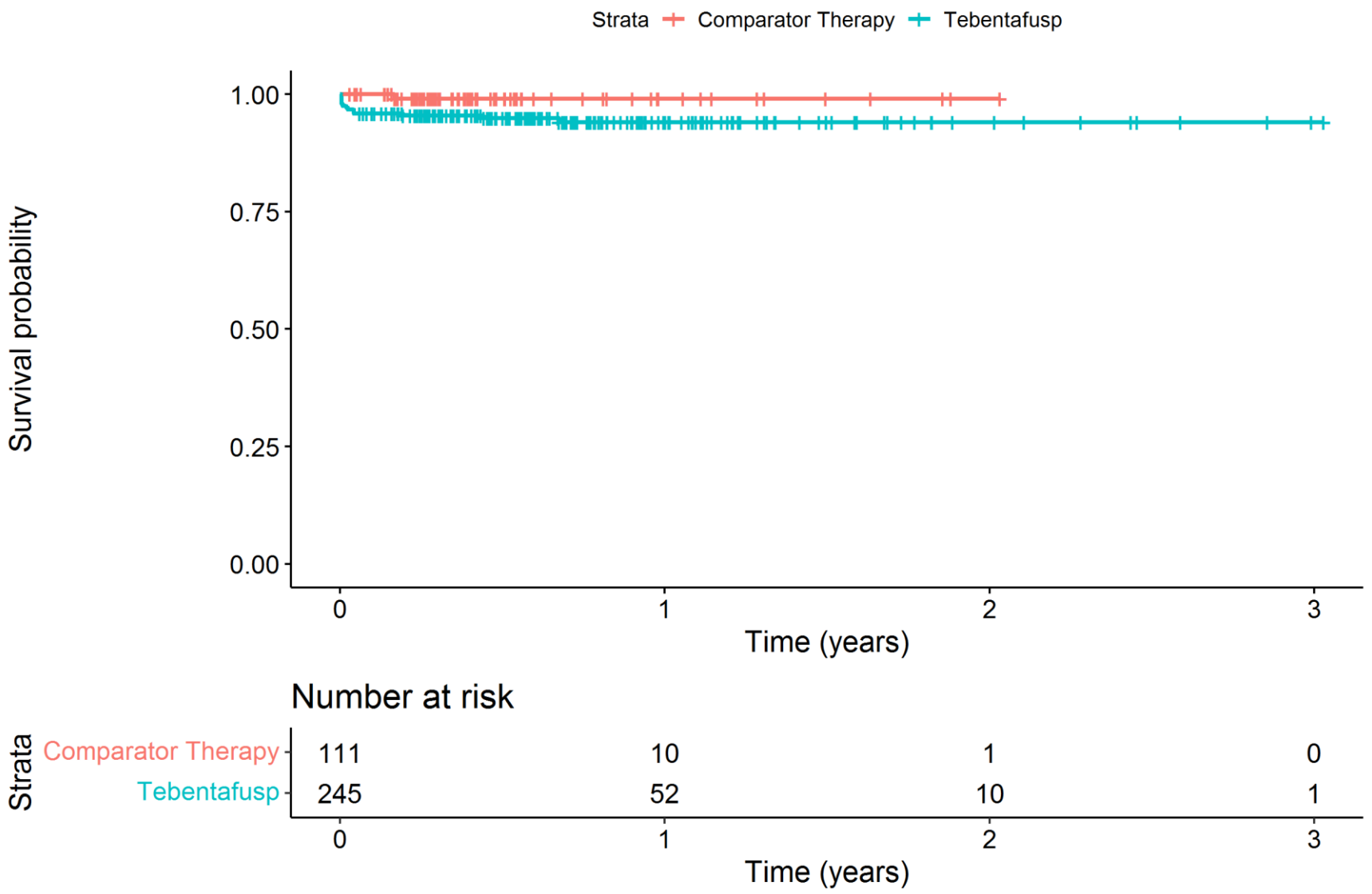
6.10 Hyperbilirubinämie



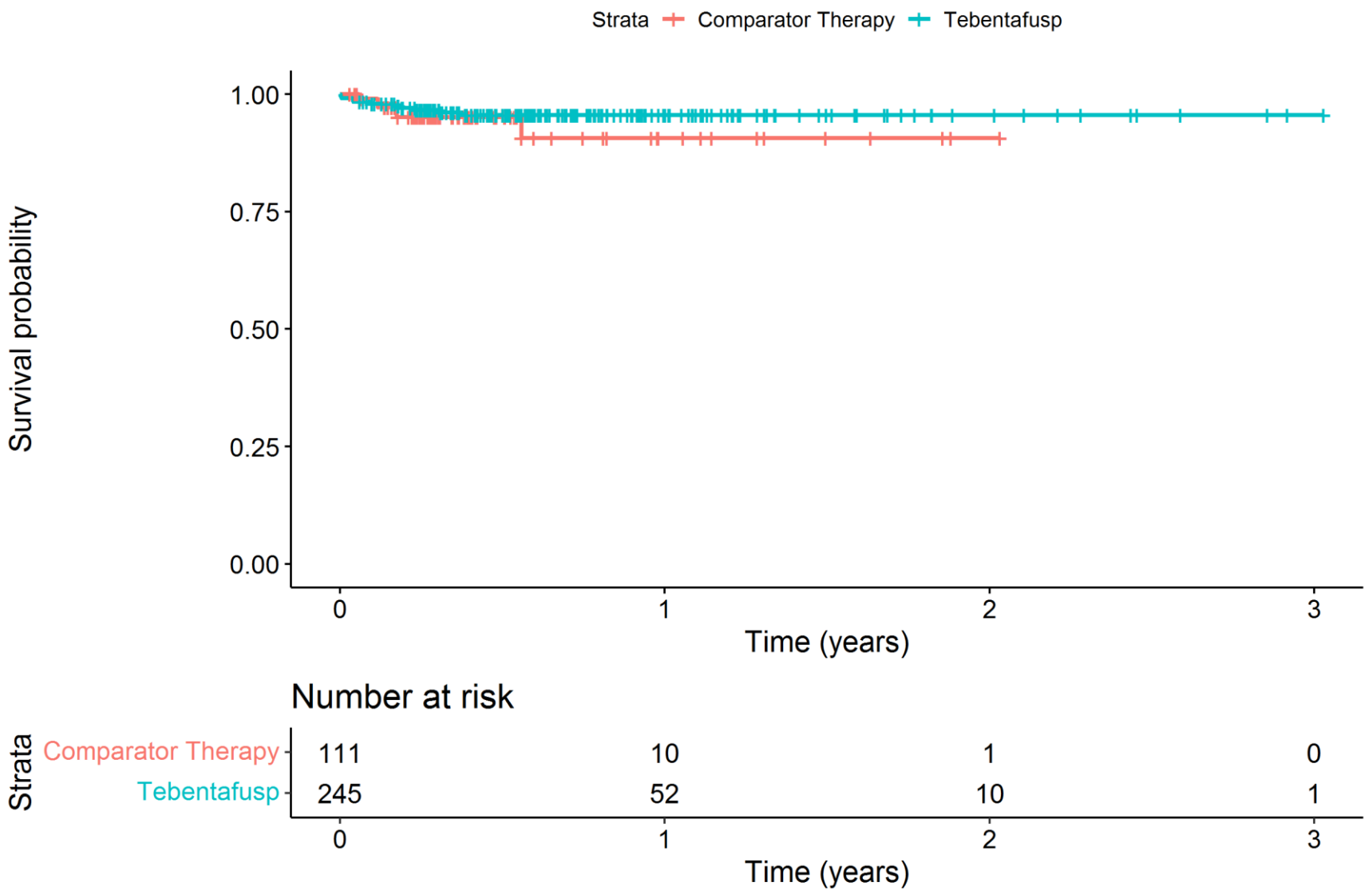
6.11 Harnwegsinfektion



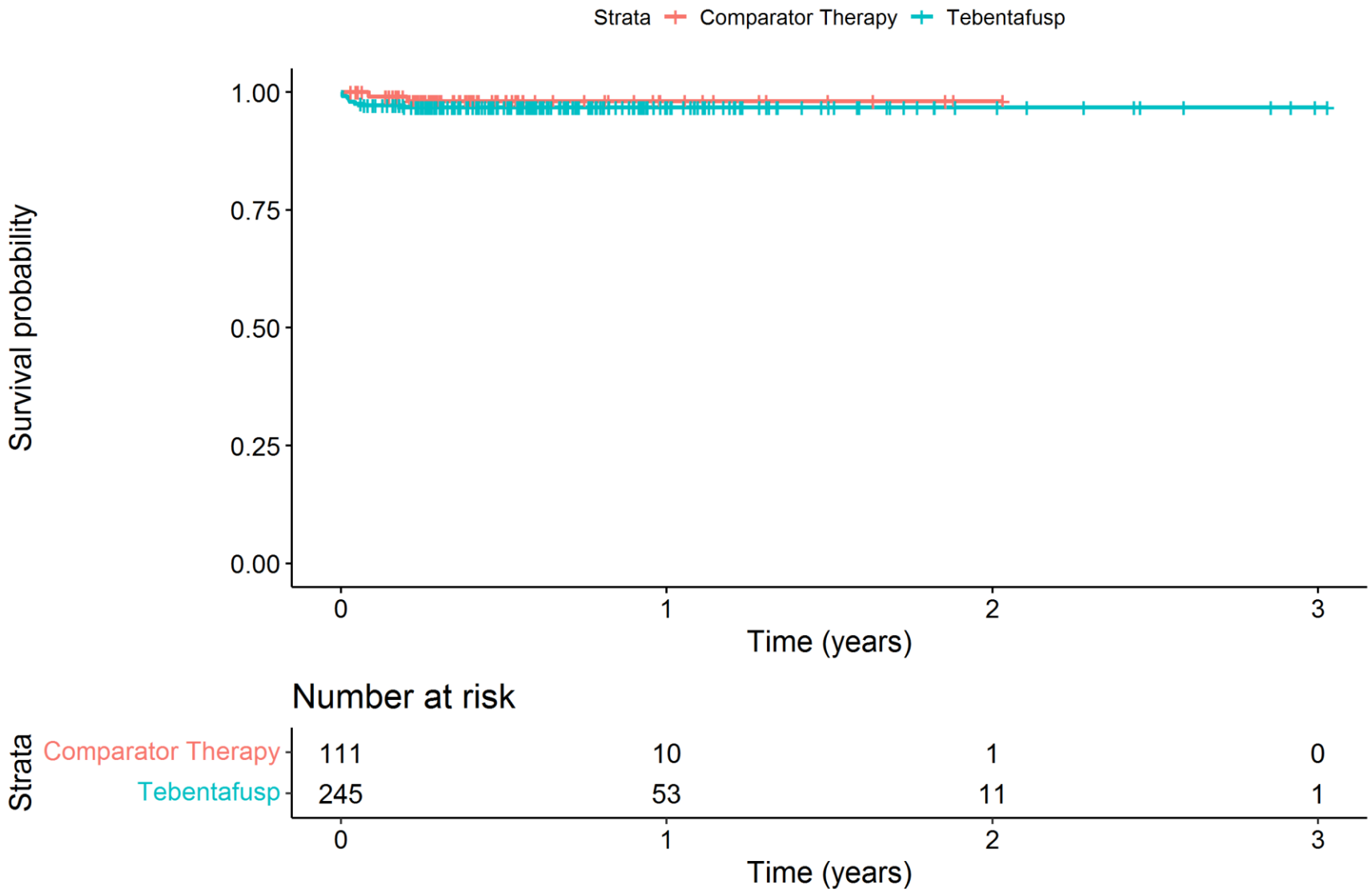
6.12 Erhöhte Aspartat-Aminotransferase



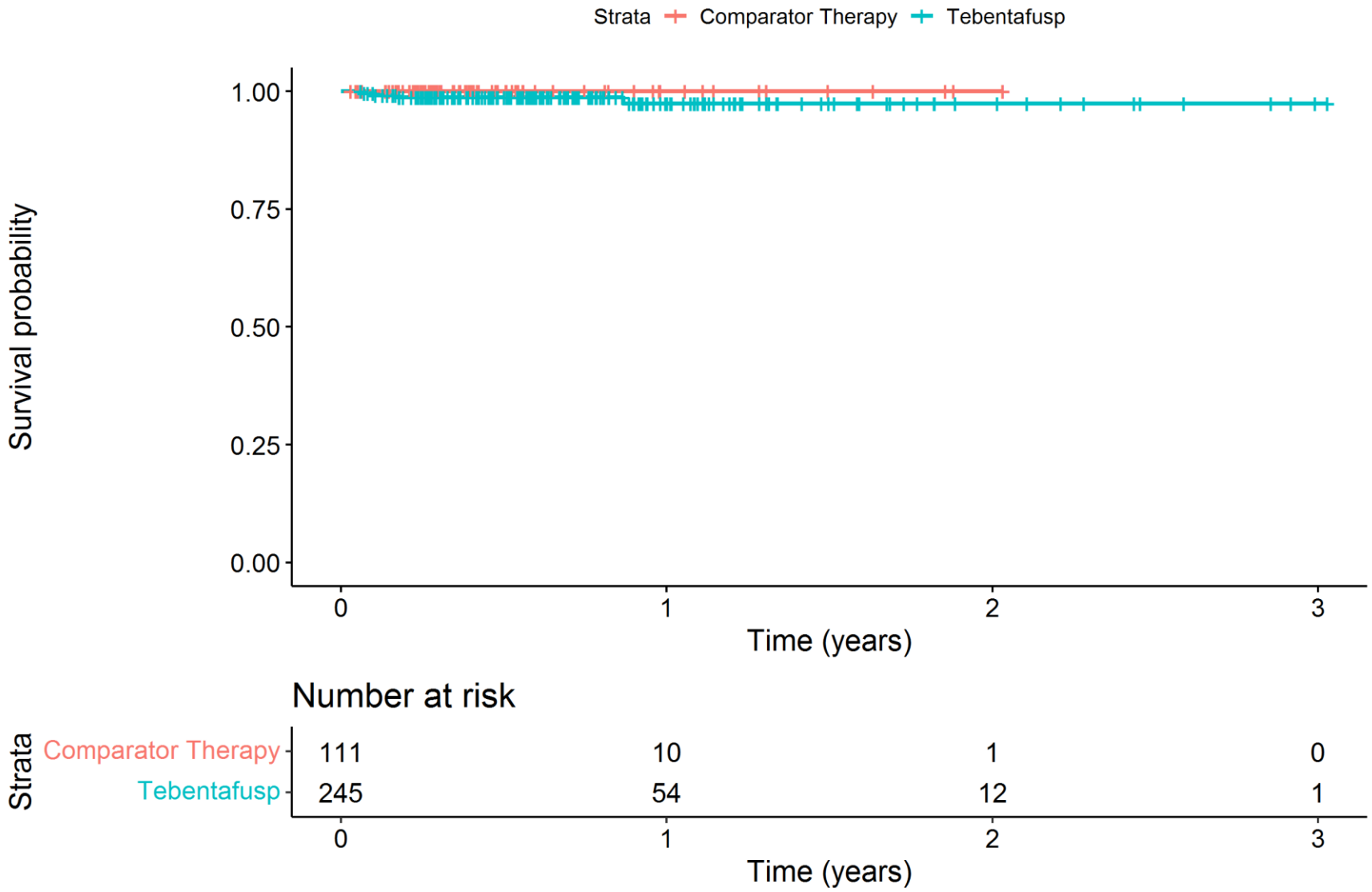
6.13 Erhöhte Lipase



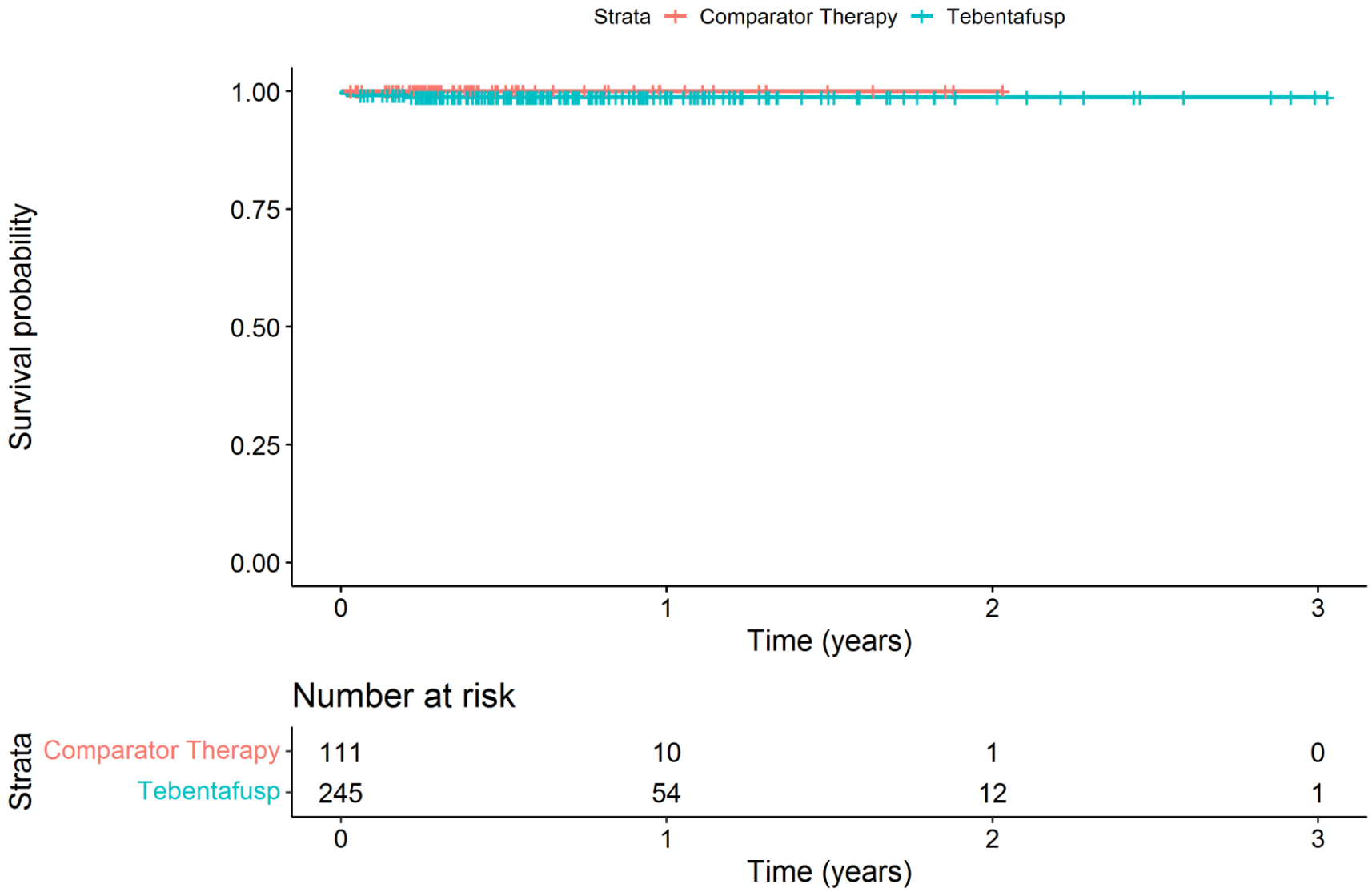
6.14 Erhöhte Alanin-Aminotransferase



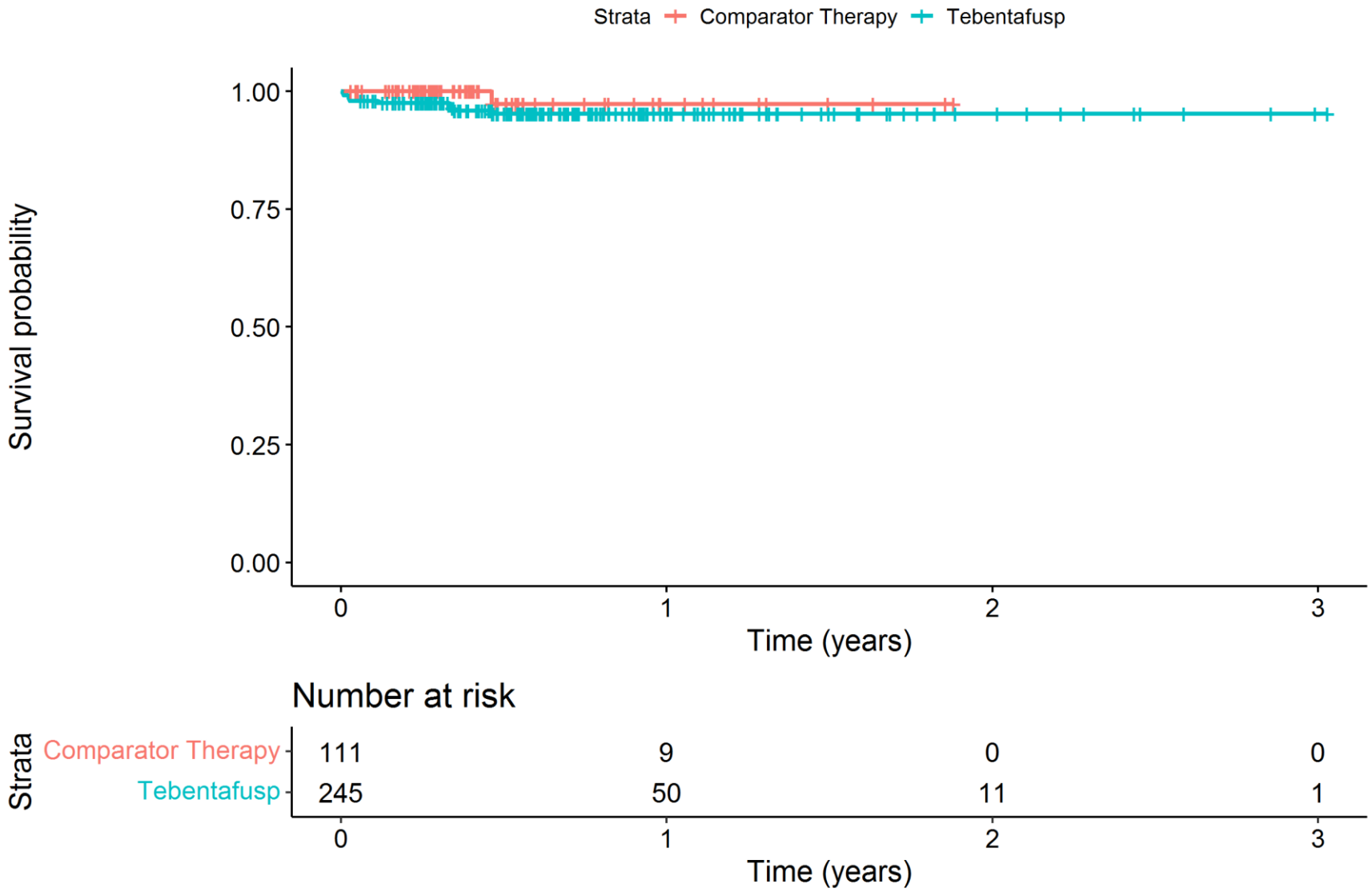
6.15 Erhöhte Gamma-Glutamyltransferase



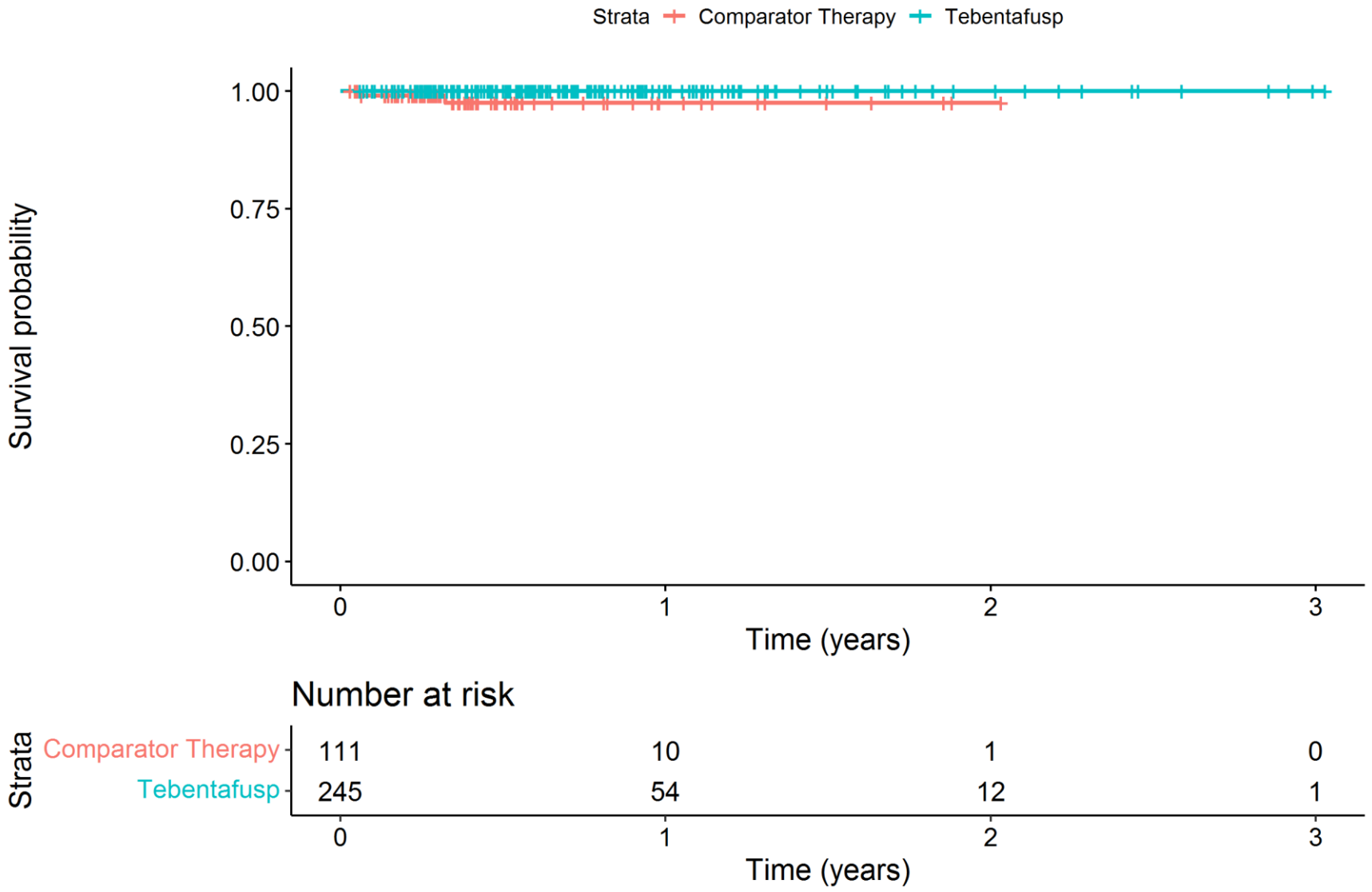
6.16 Erhöhte alkalische Phosphatase im Blut



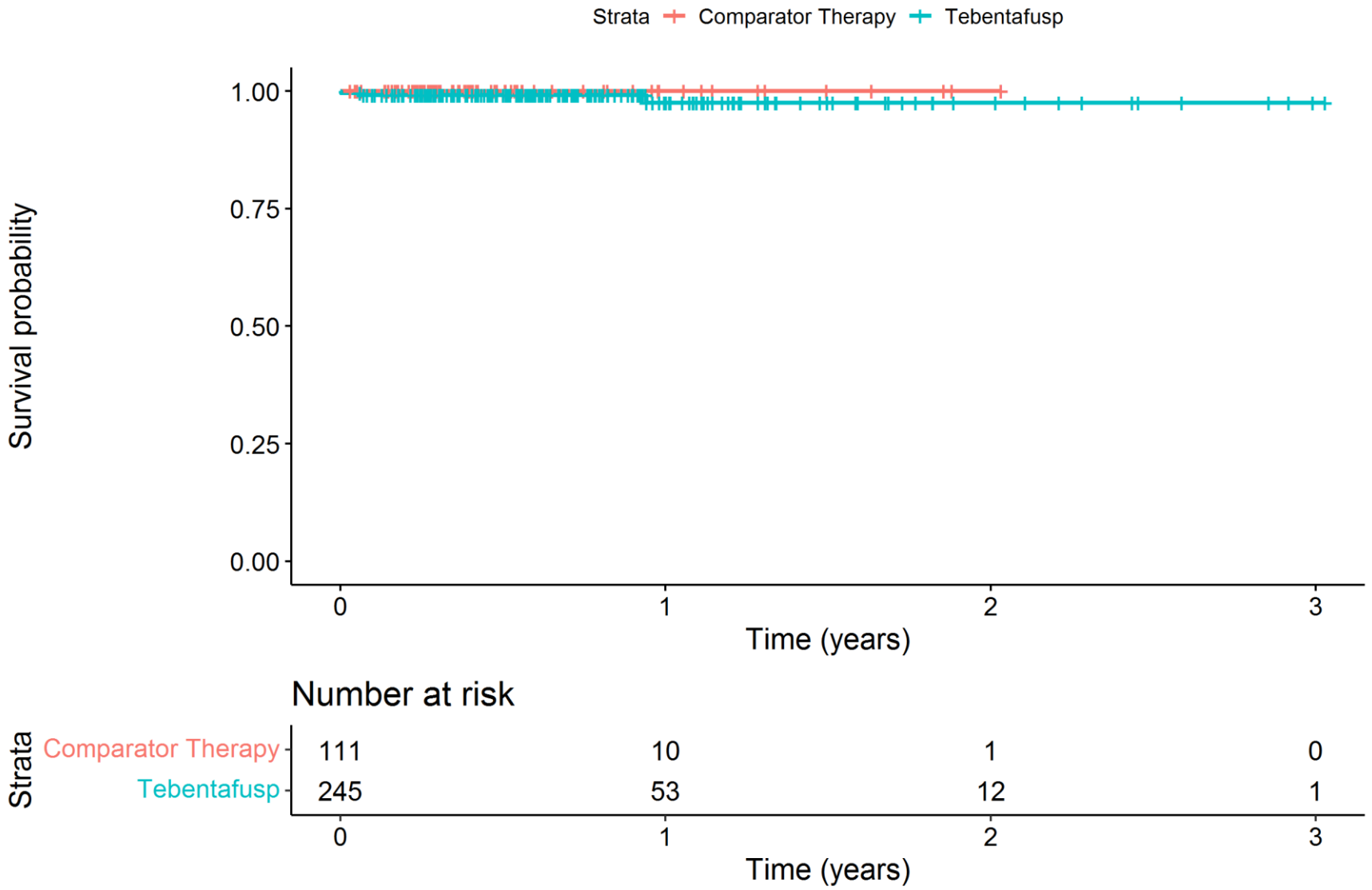
6.17 Hypophosphatämie



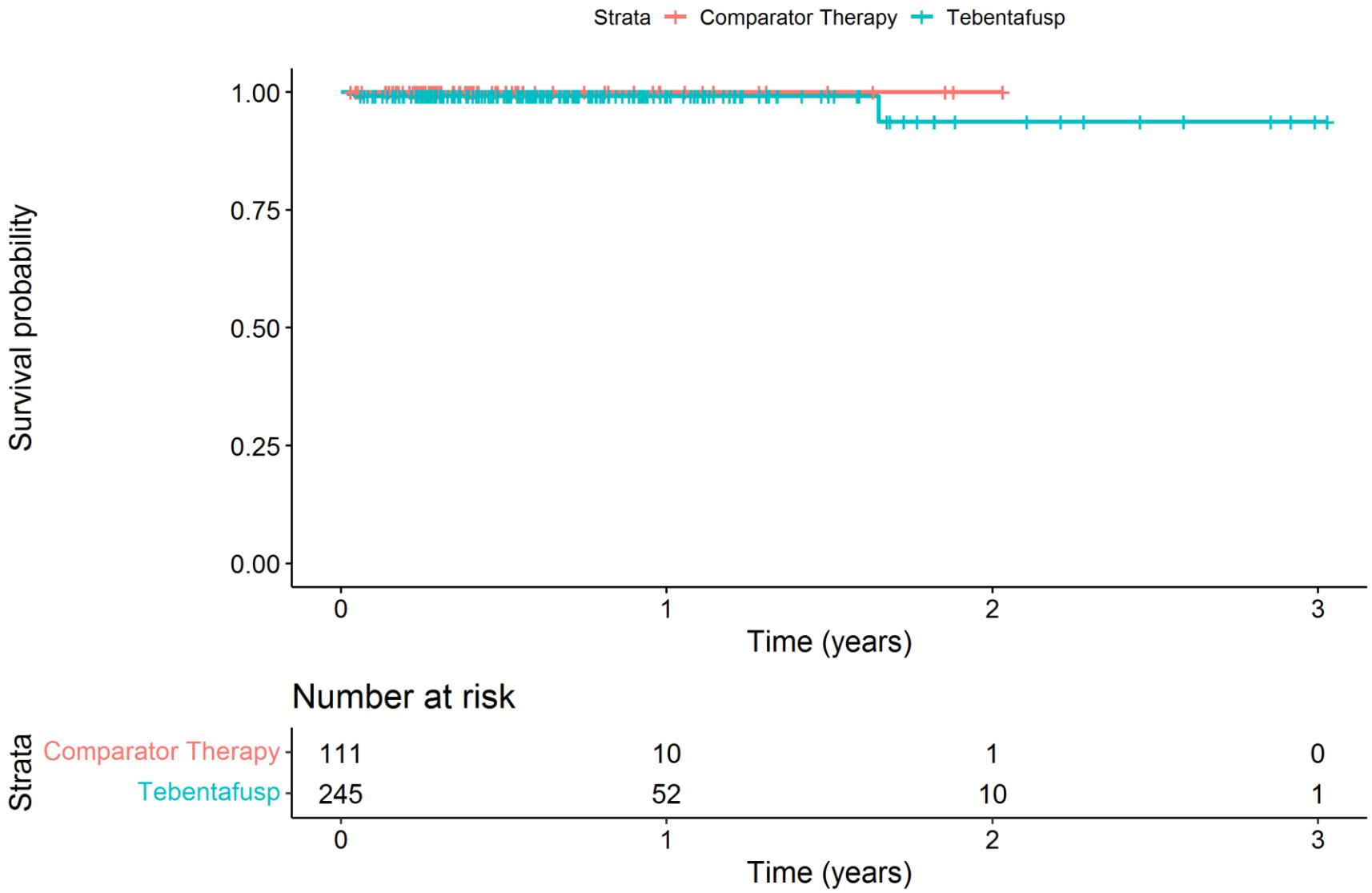
6.18 Dehydrierung



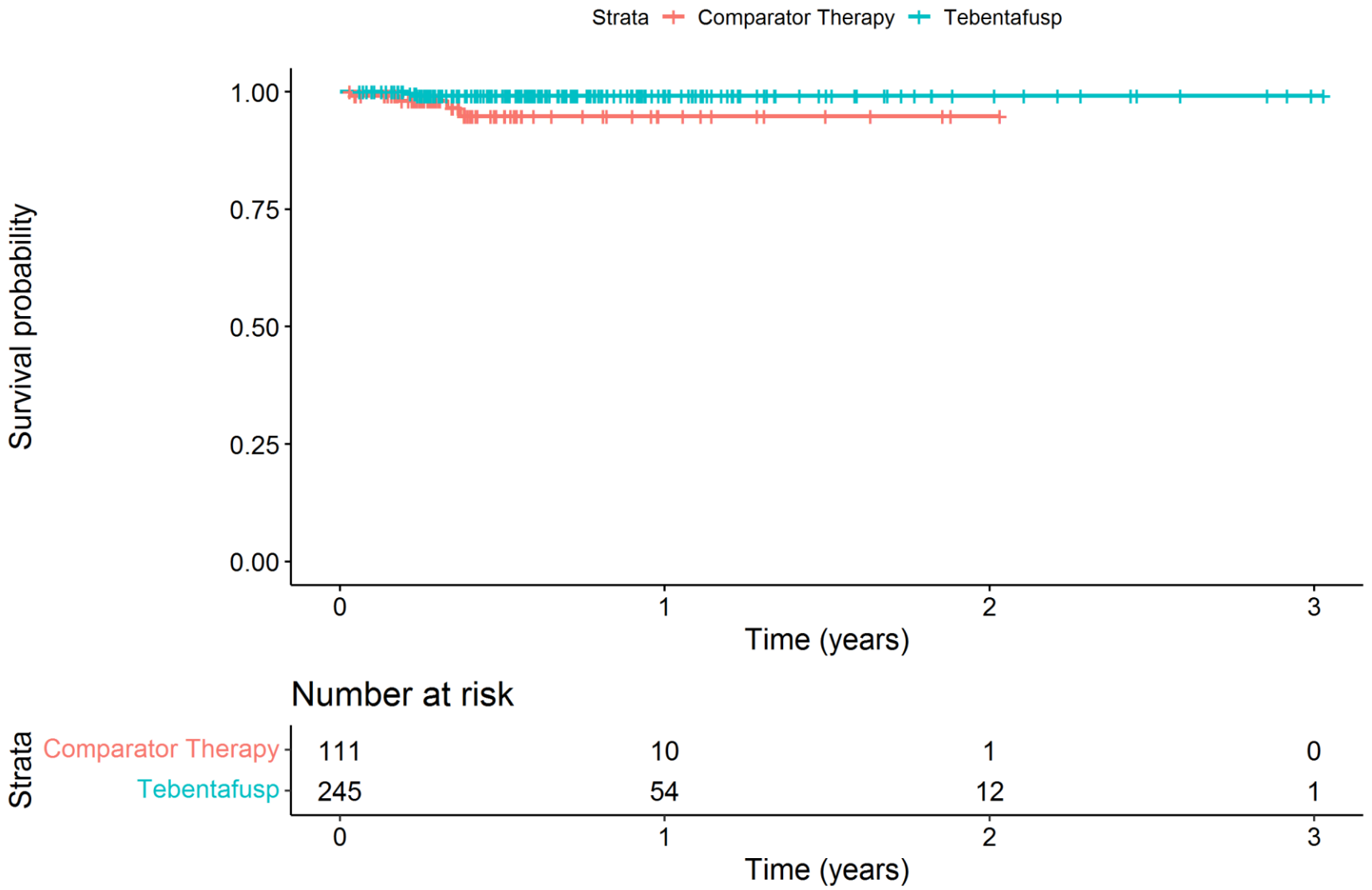
6.19 Tumorschmerzen



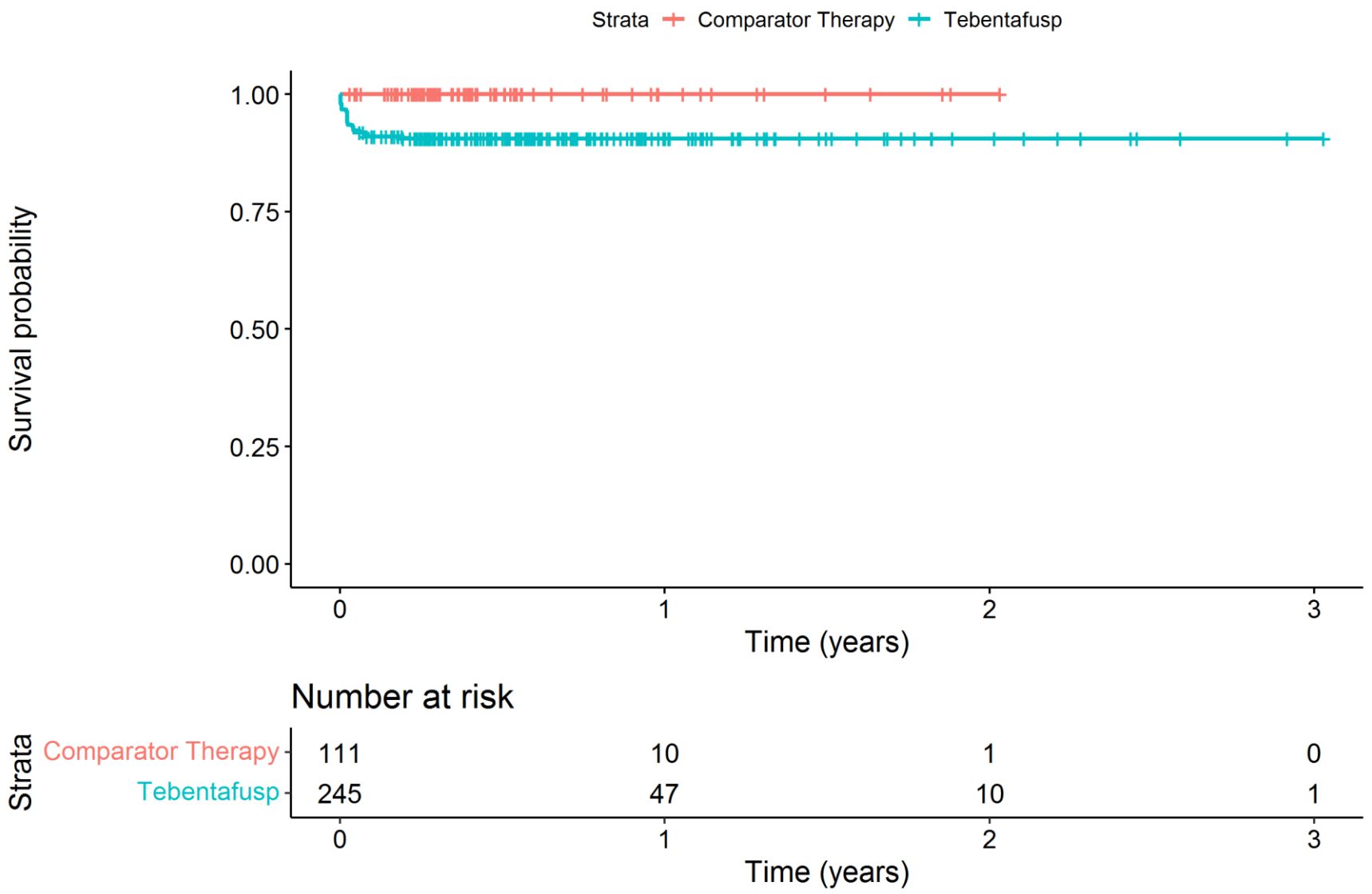
6.20 Synkope


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
52
10
1
0
1
2
3
Time (years)

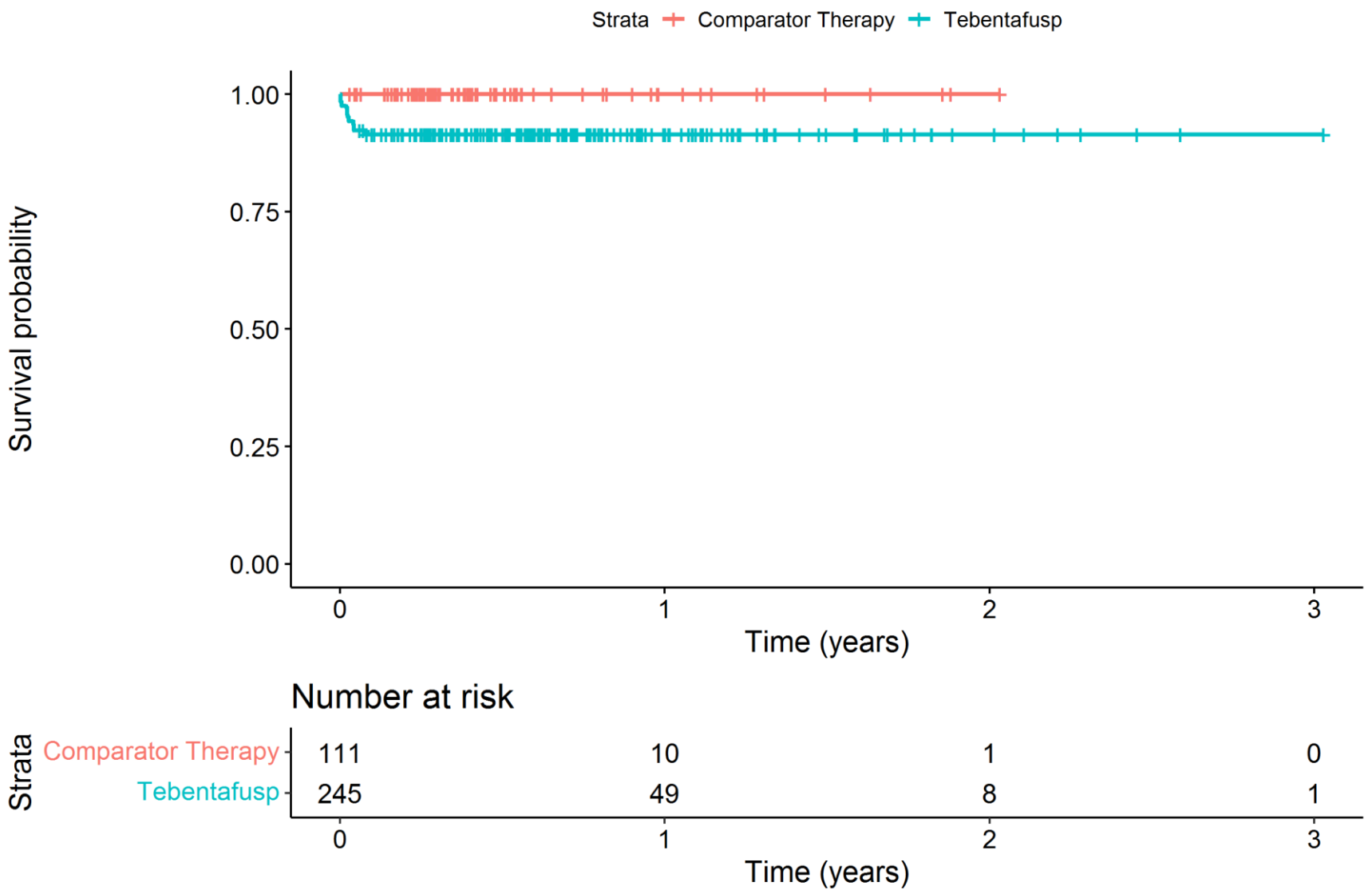
6.21 Lungenembolie



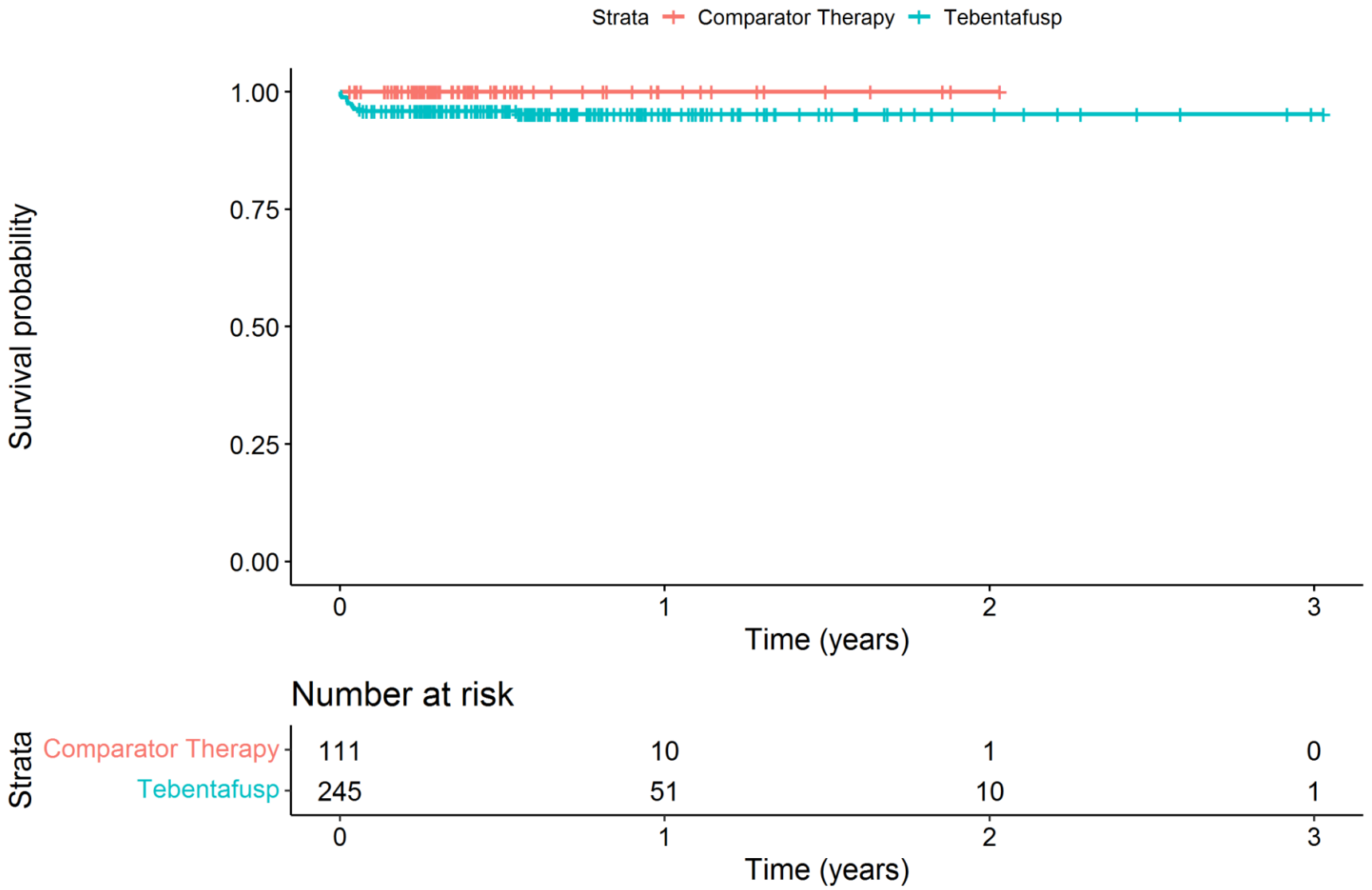
6.22 Hautausschlag



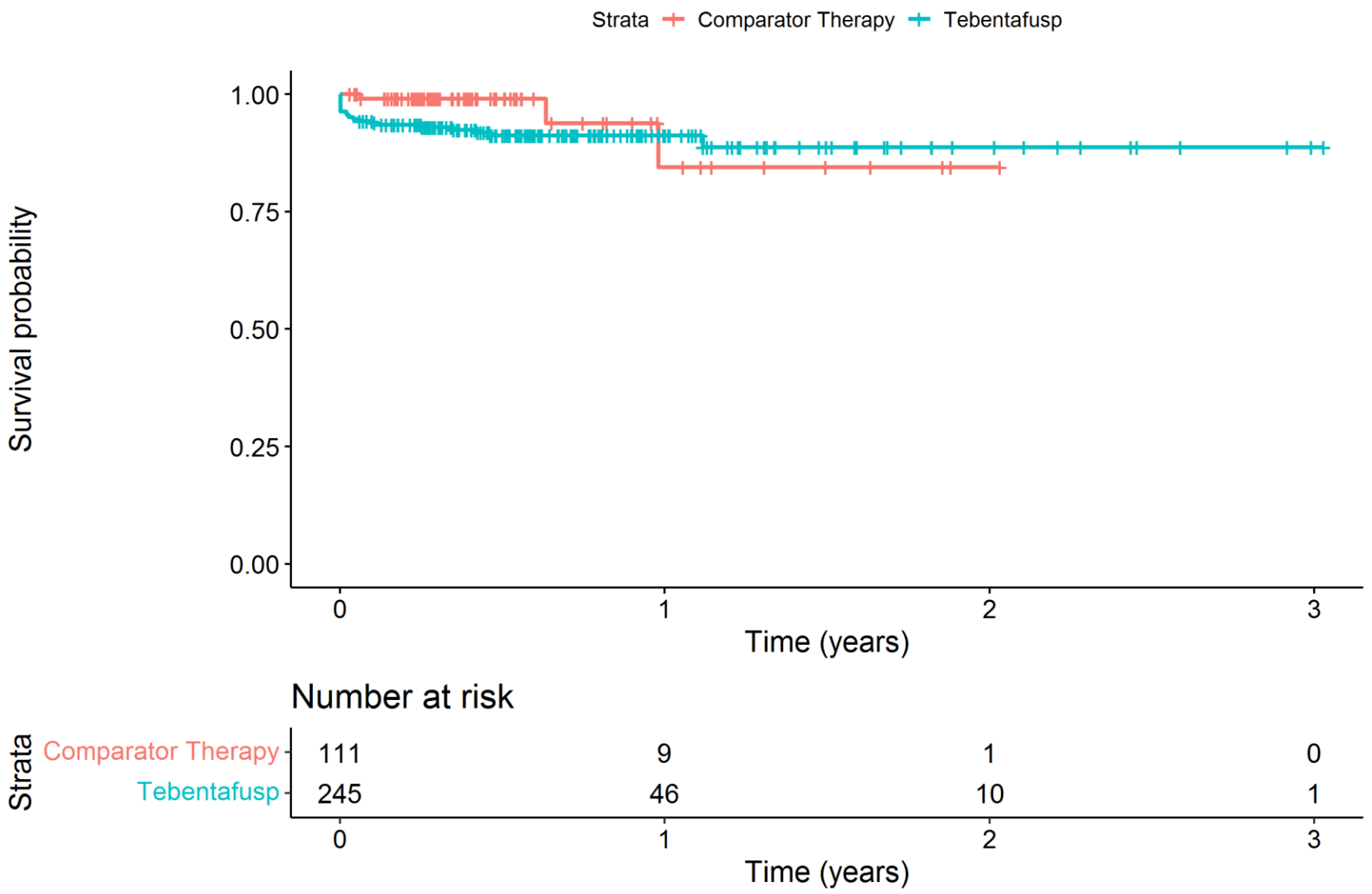
6.23 Makulo-papulöser Hautausschlag



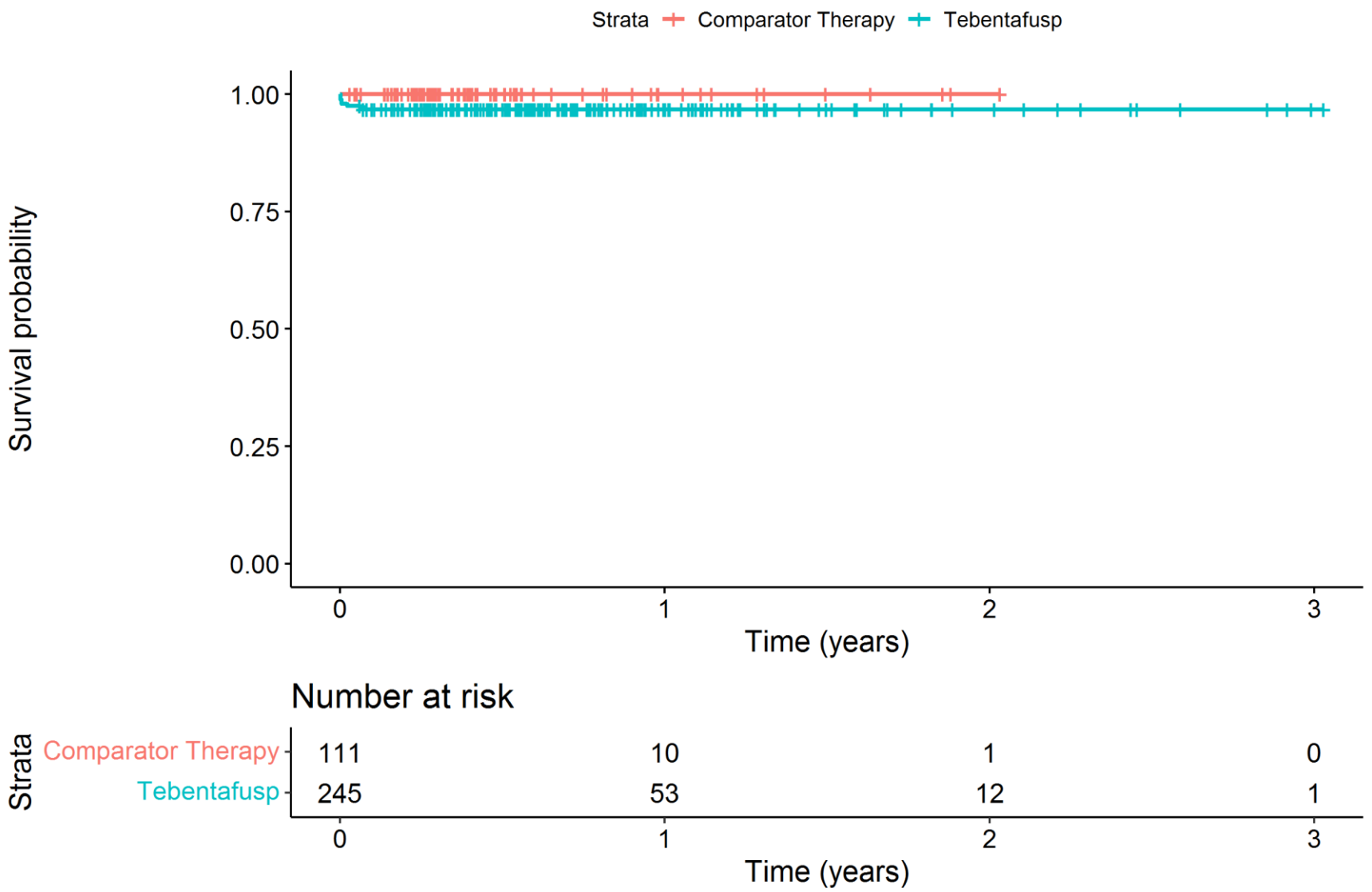
6.24 Pruritus



6.25 Hypertonie

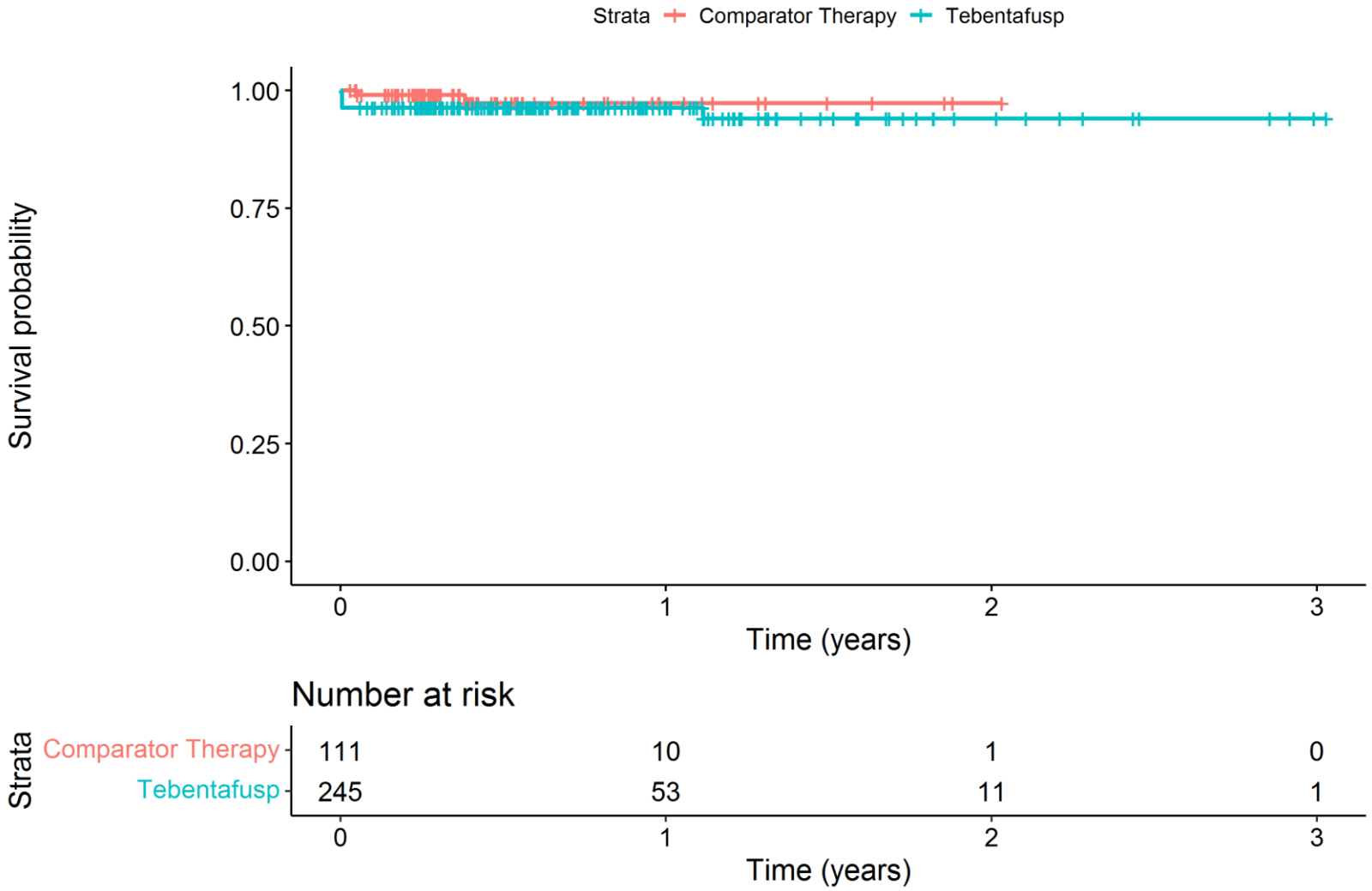


6.26 Hypotonie

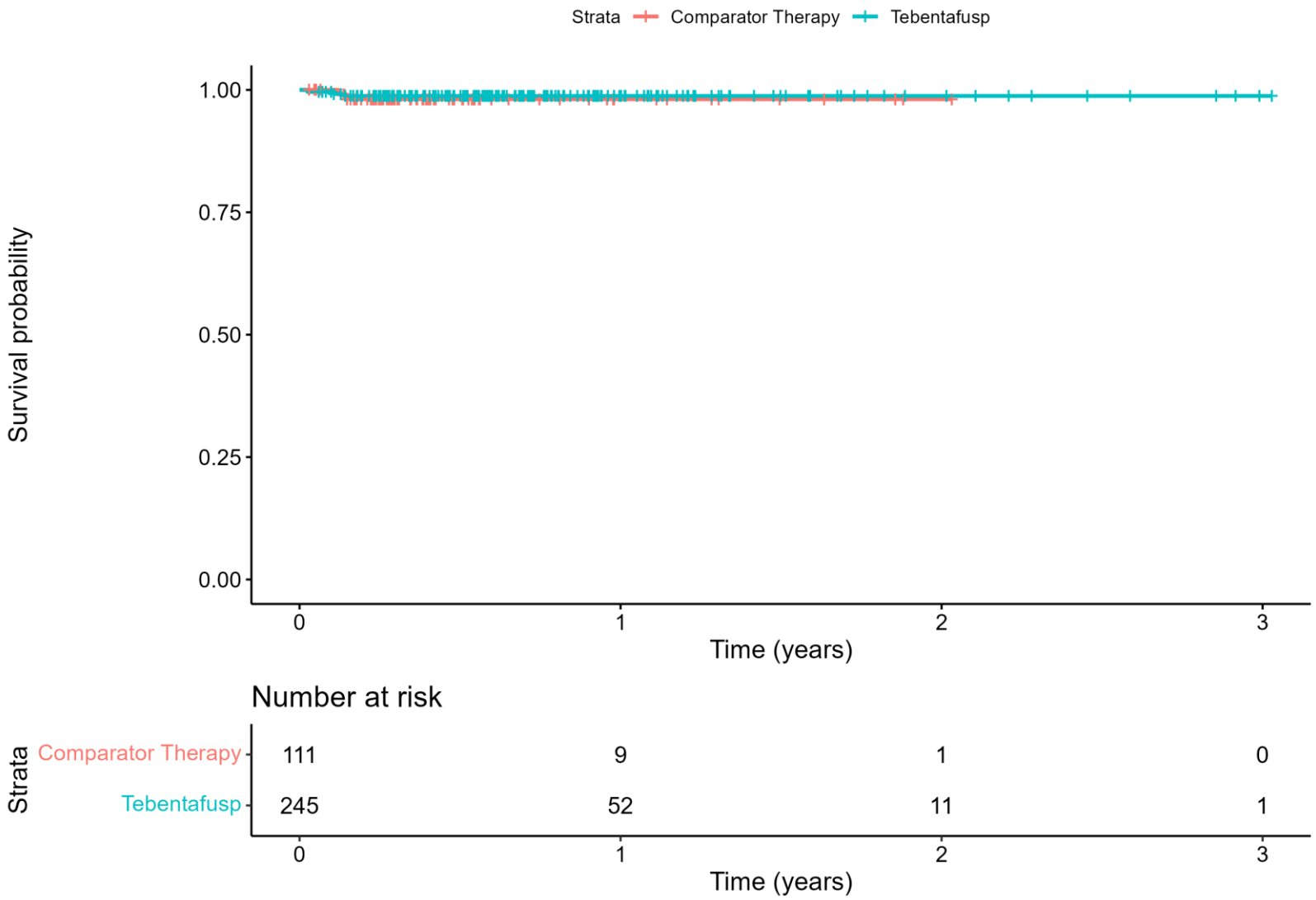


7 UEs (SOC) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten

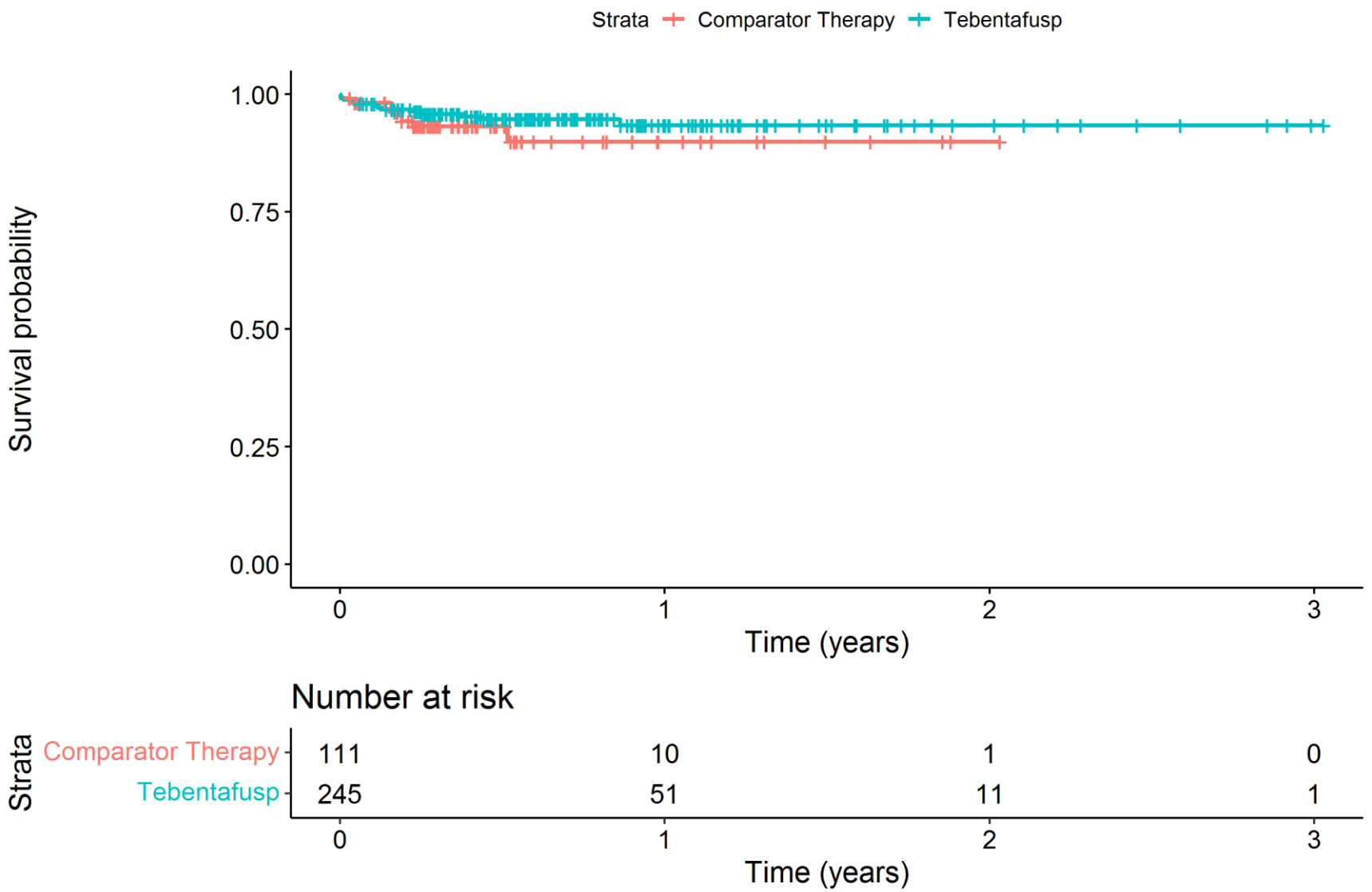
7.1 Erkrankungen des Blutes und des Lymphsystems



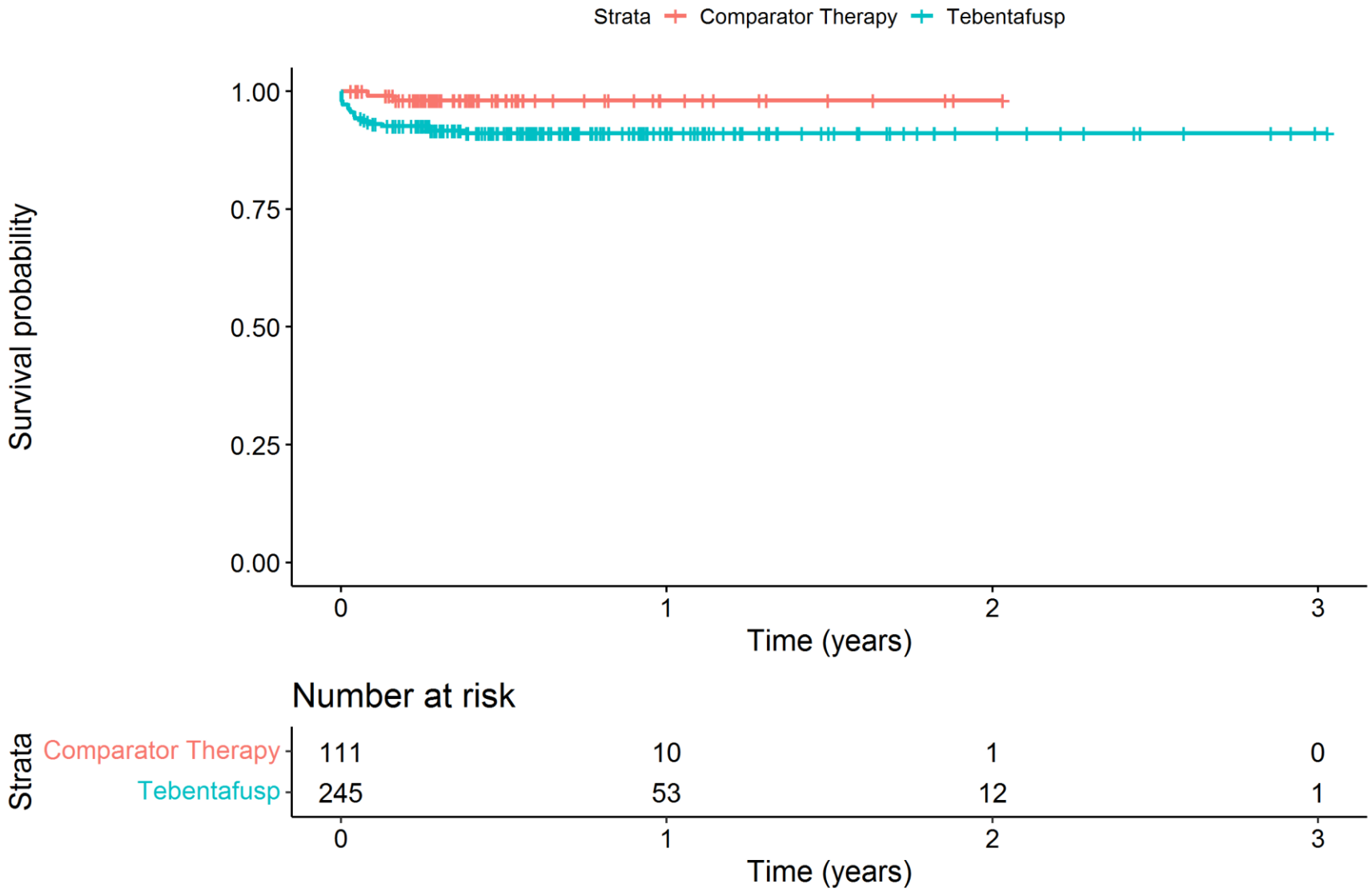
7.2 Augenerkrankungen



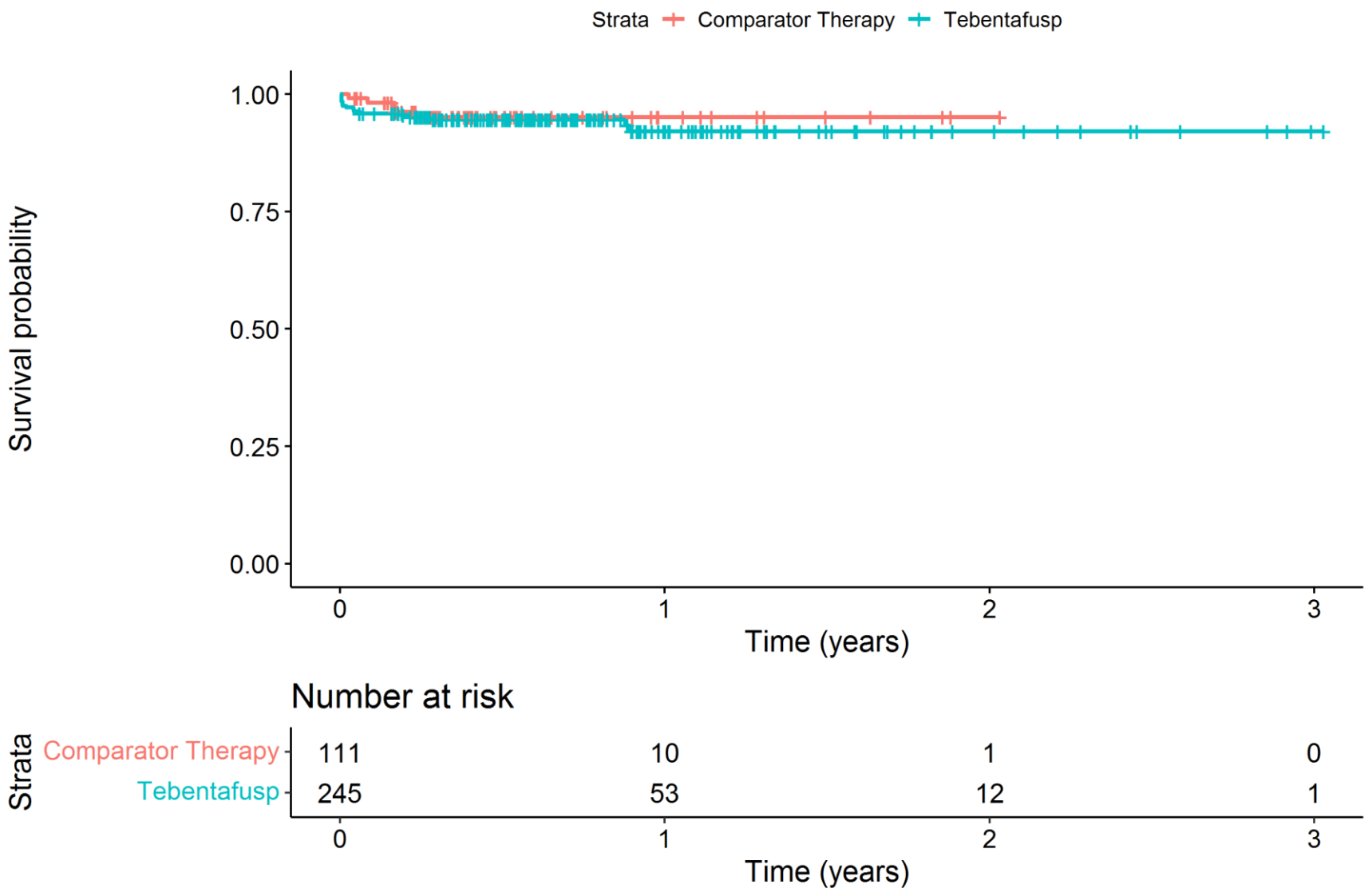
7.3 Erkrankungen des Gastrointestinaltrakts



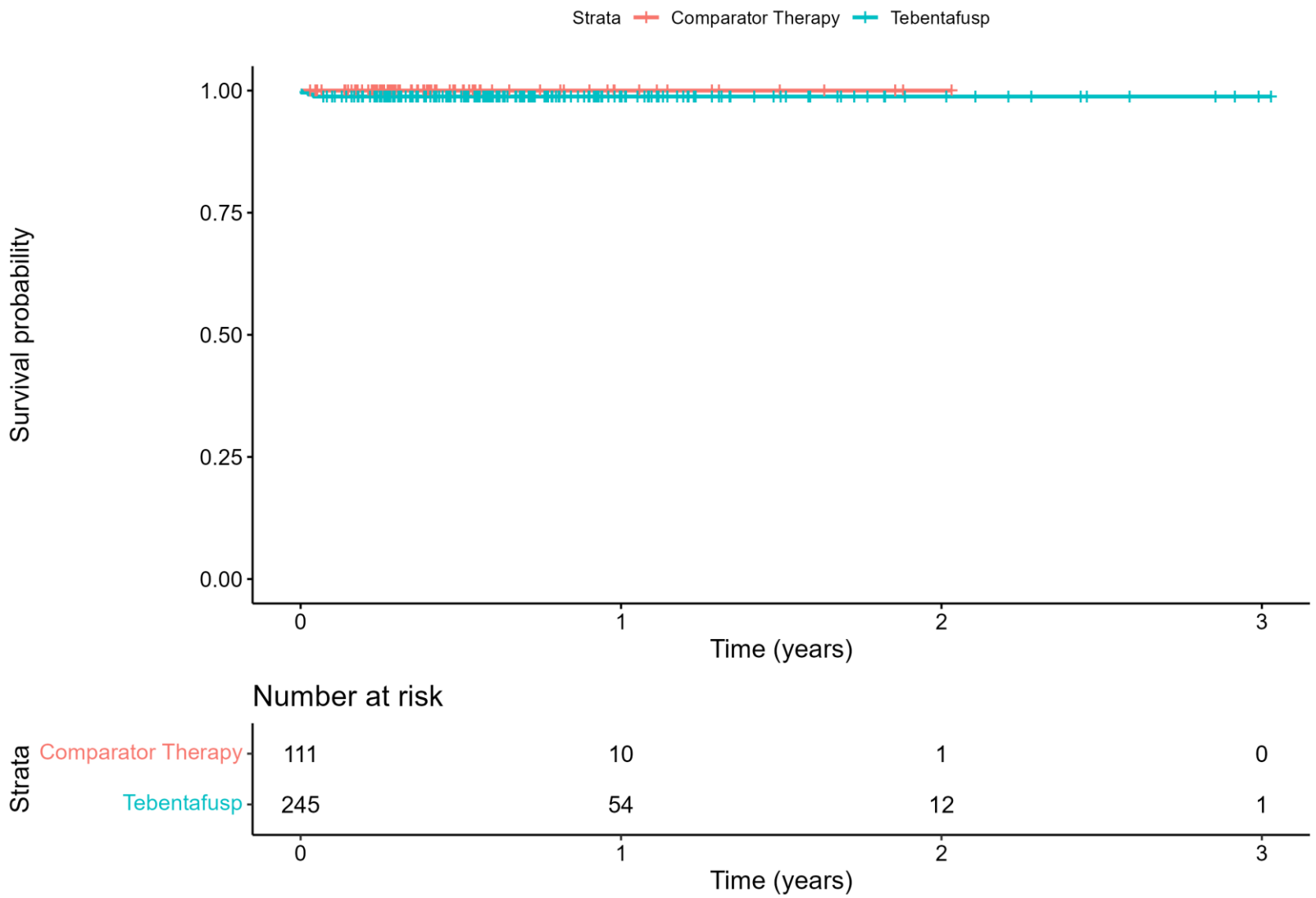
7.4 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



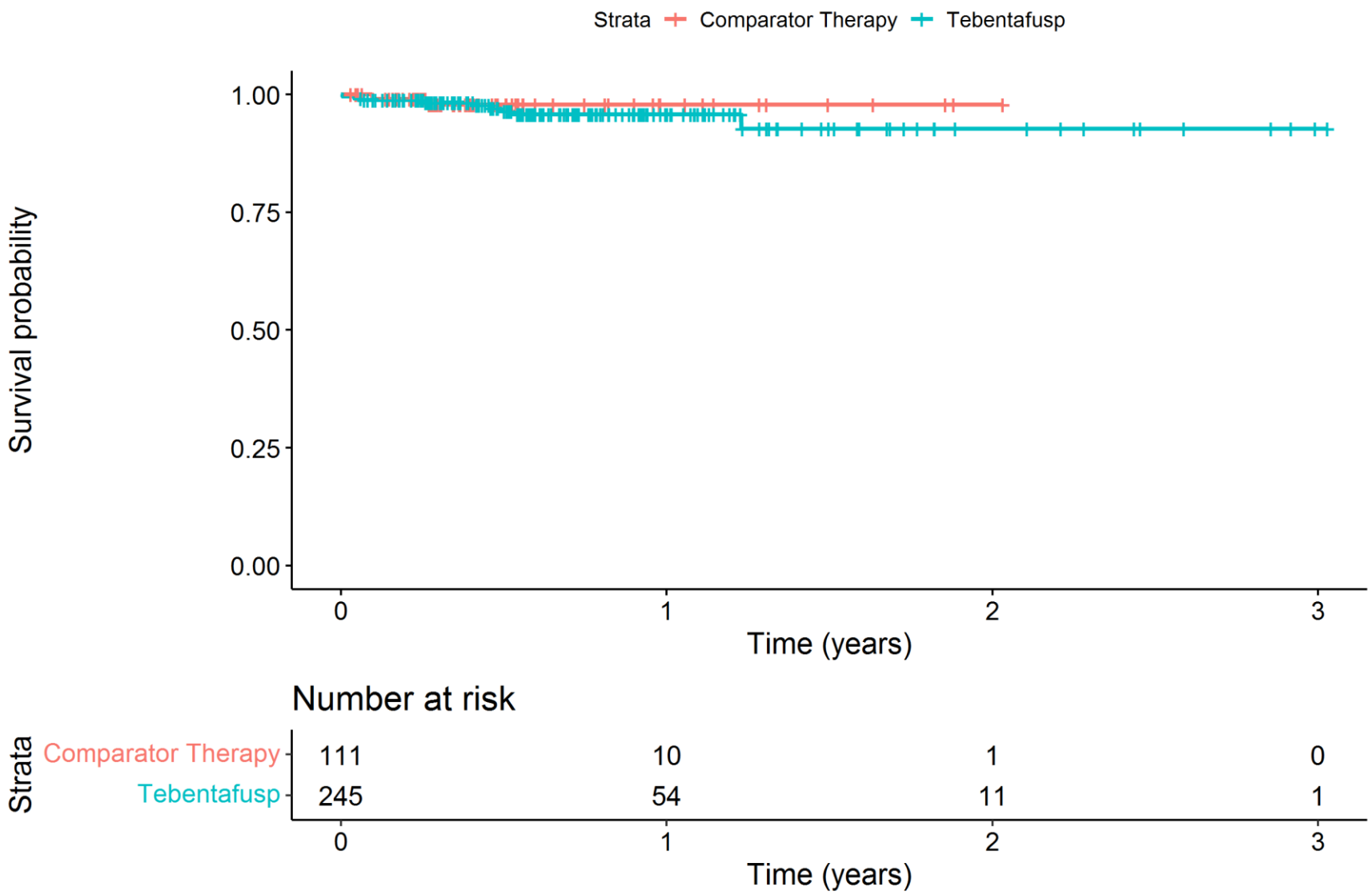
7.5 Leber- und Gallenerkrankungen



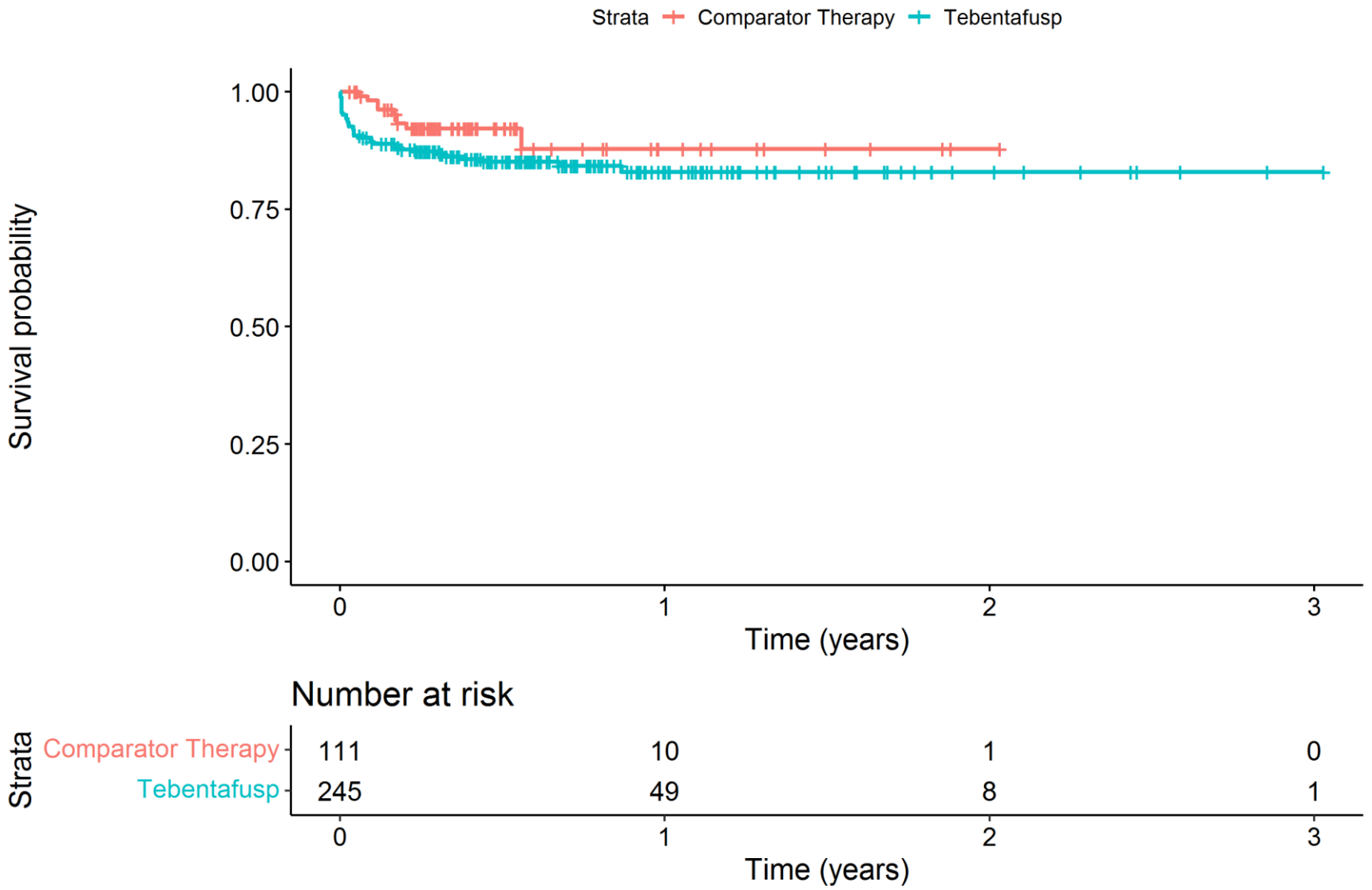
7.6 Erkrankungen des Immunsystems



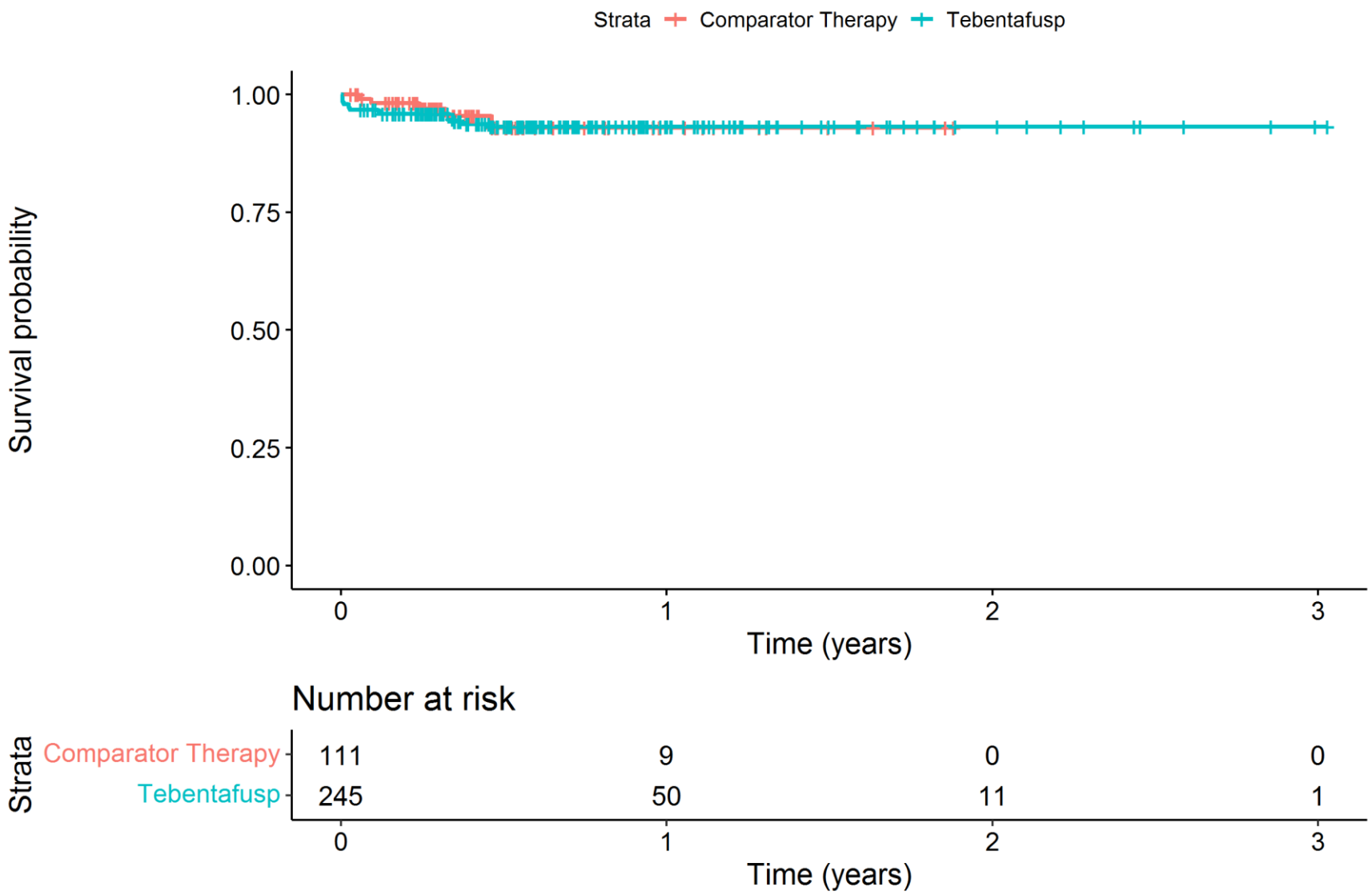
7.7 Infektionen und parasitäre Erkrankungen



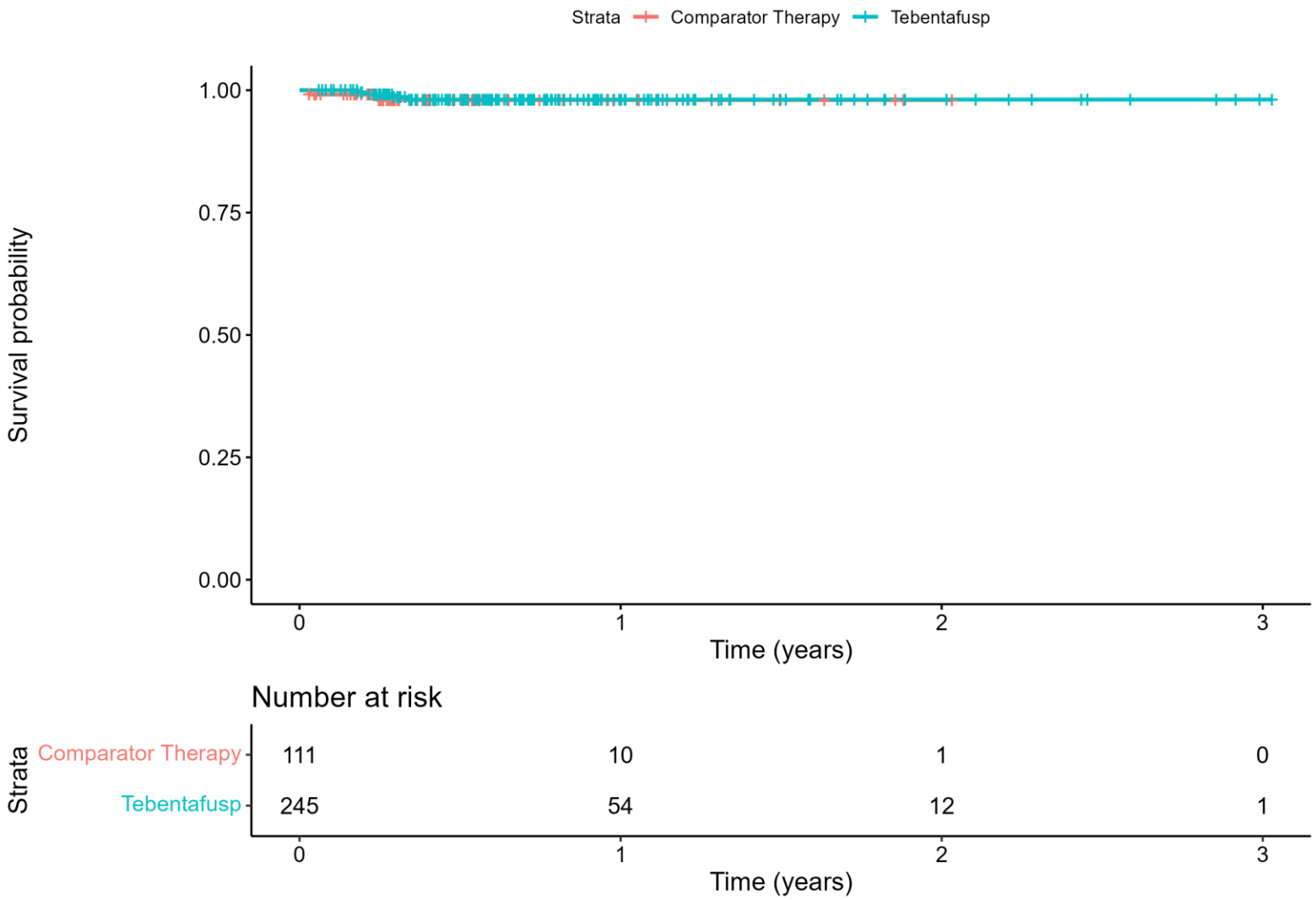
7.8 Untersuchungen



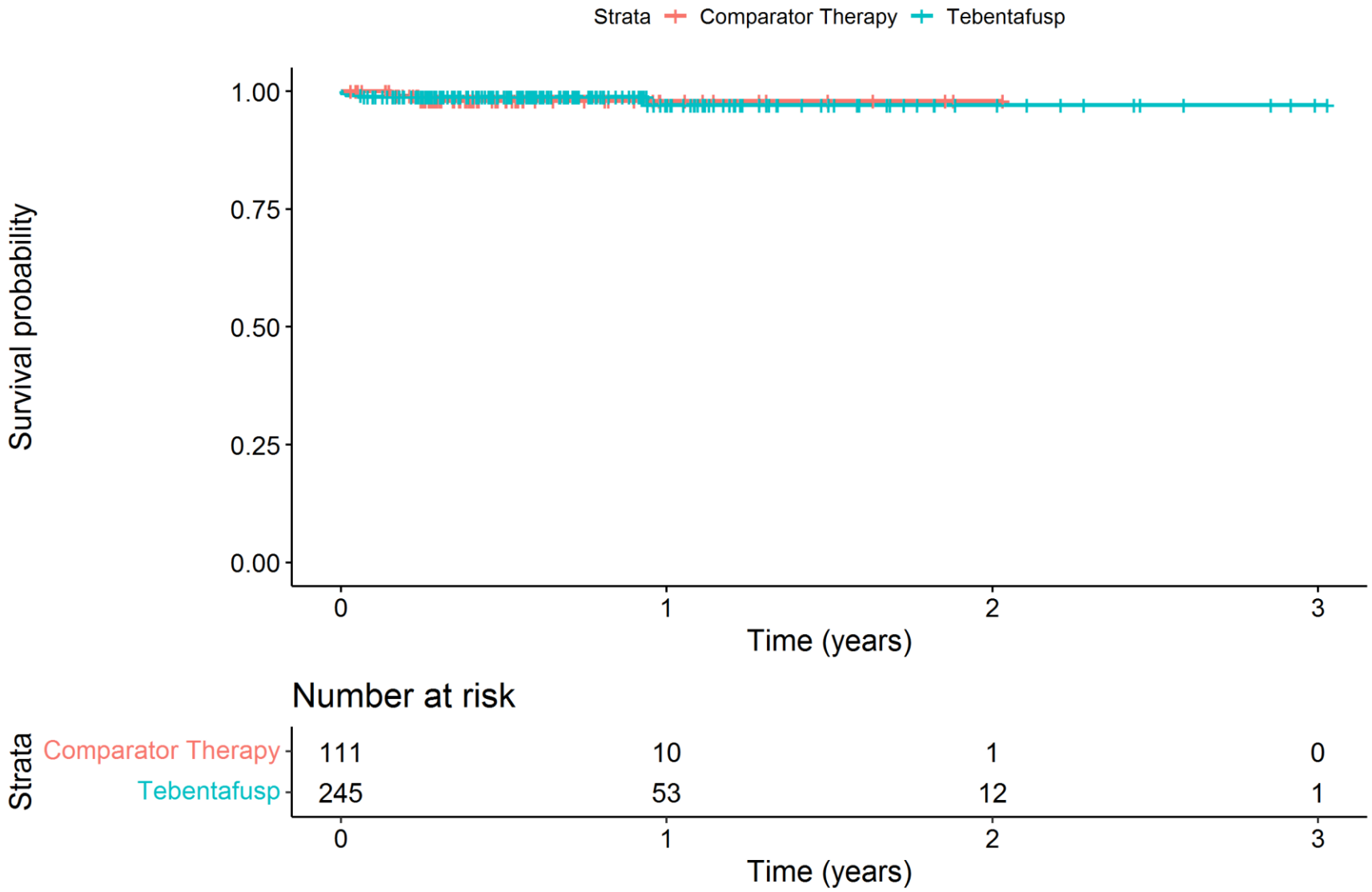
7.9 Stoffwechsel- und Ernährungsstörungen



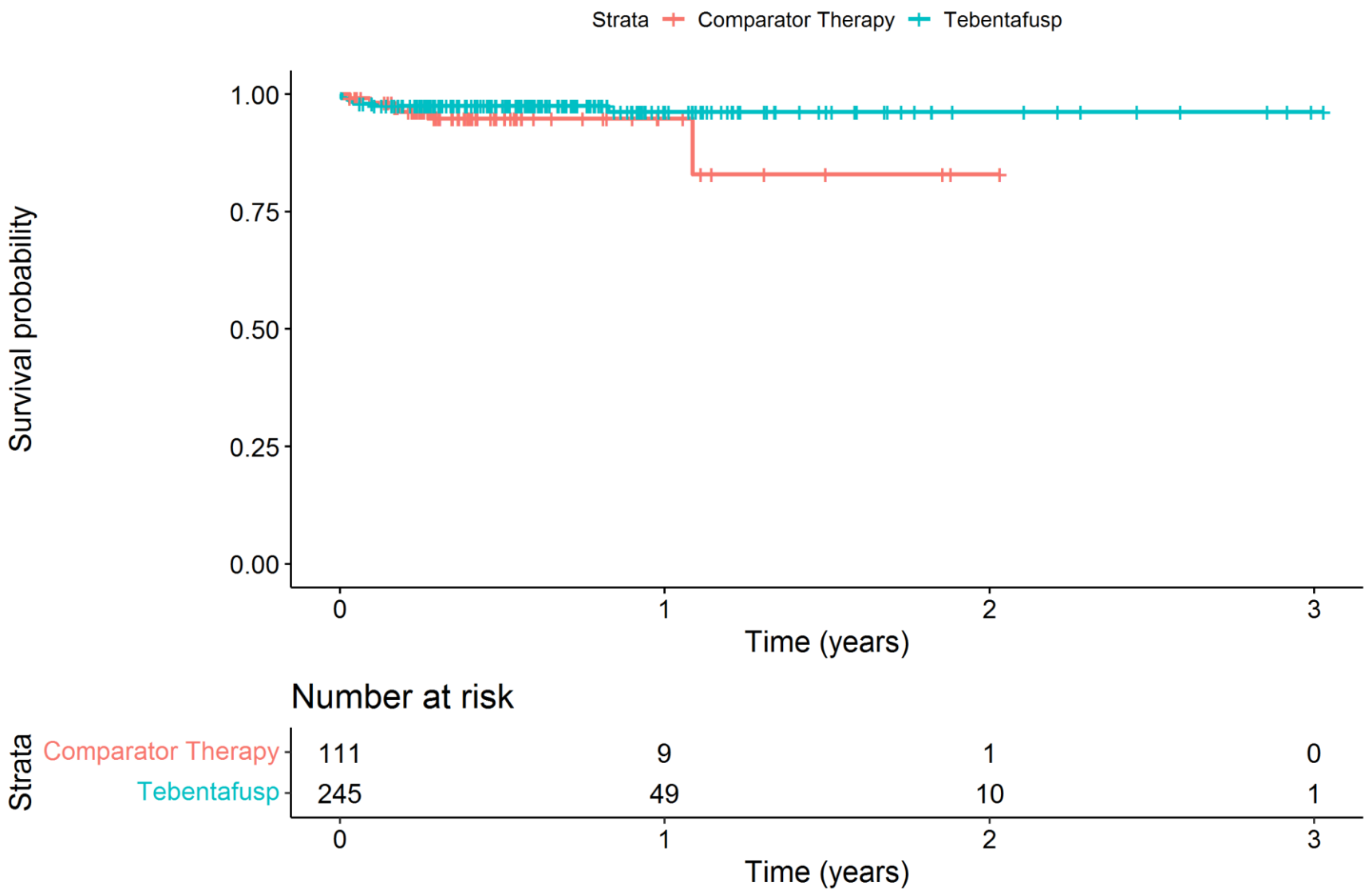
7.10 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



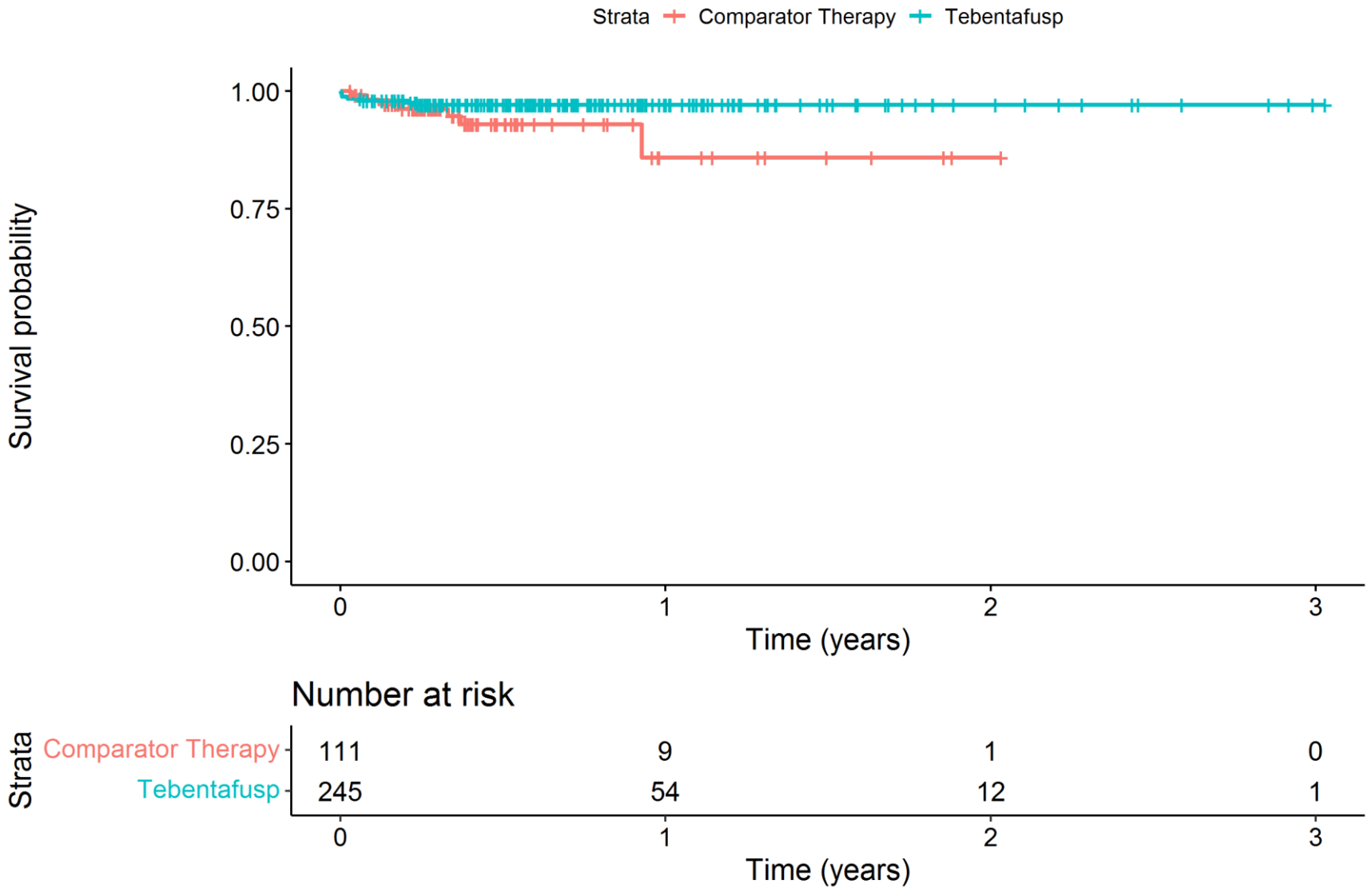
7.11 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



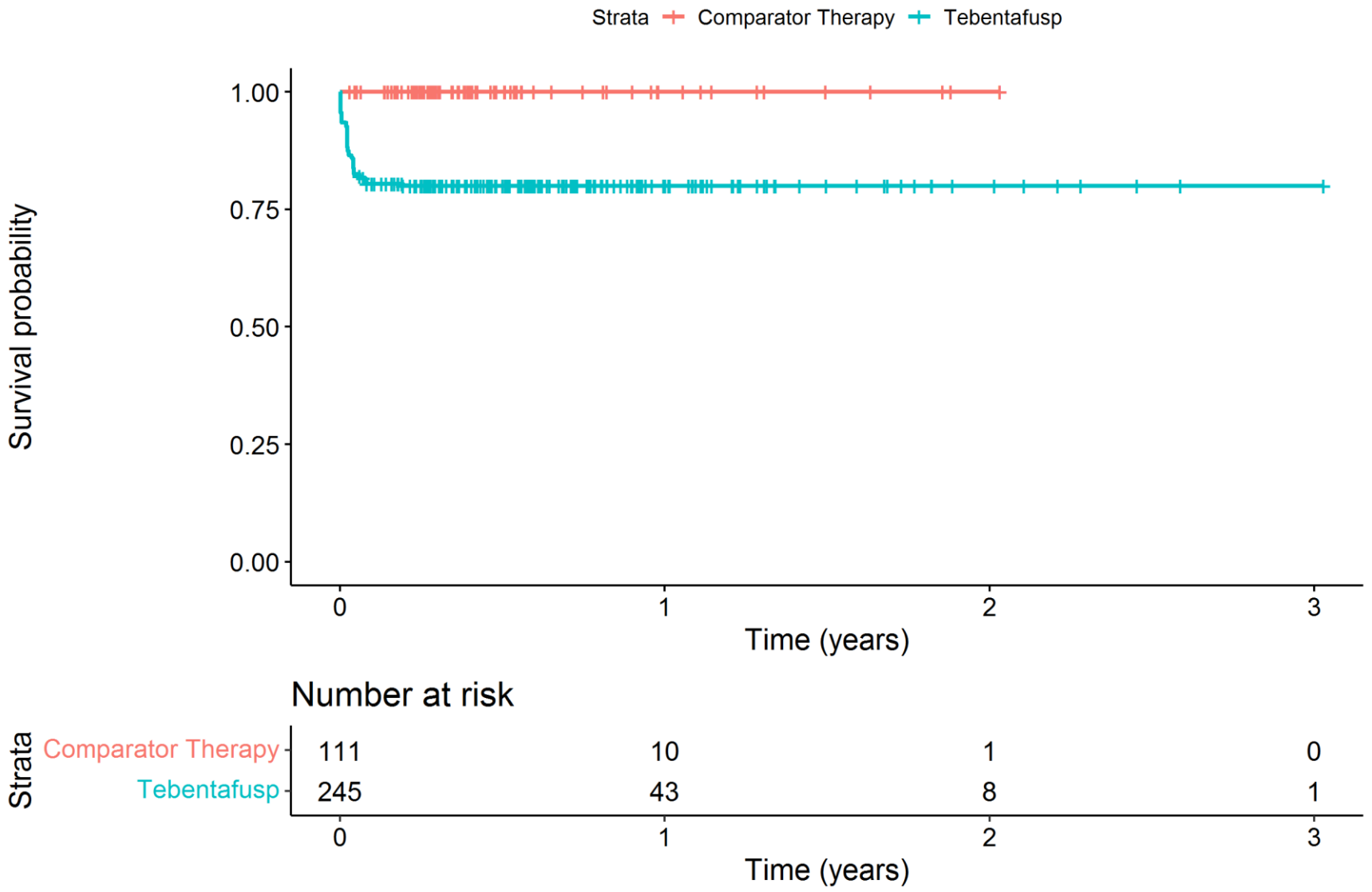
7.12 Erkrankungen des Nervensystems



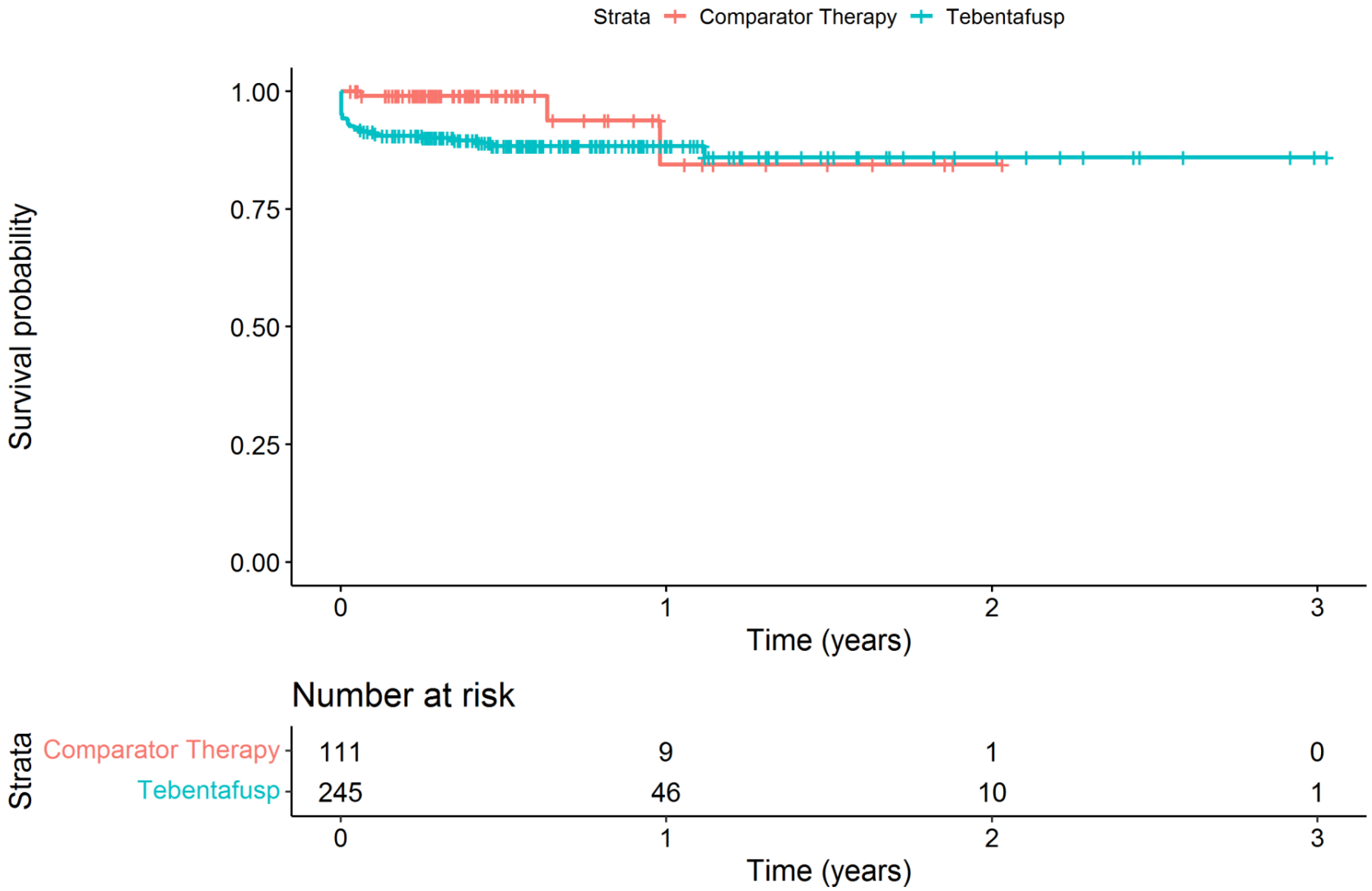
7.13 Erkrankungen der Atemwege, des Brustraums und Mediastinums



7.14 Erkrankungen der Haut und des Unterhautgewebes



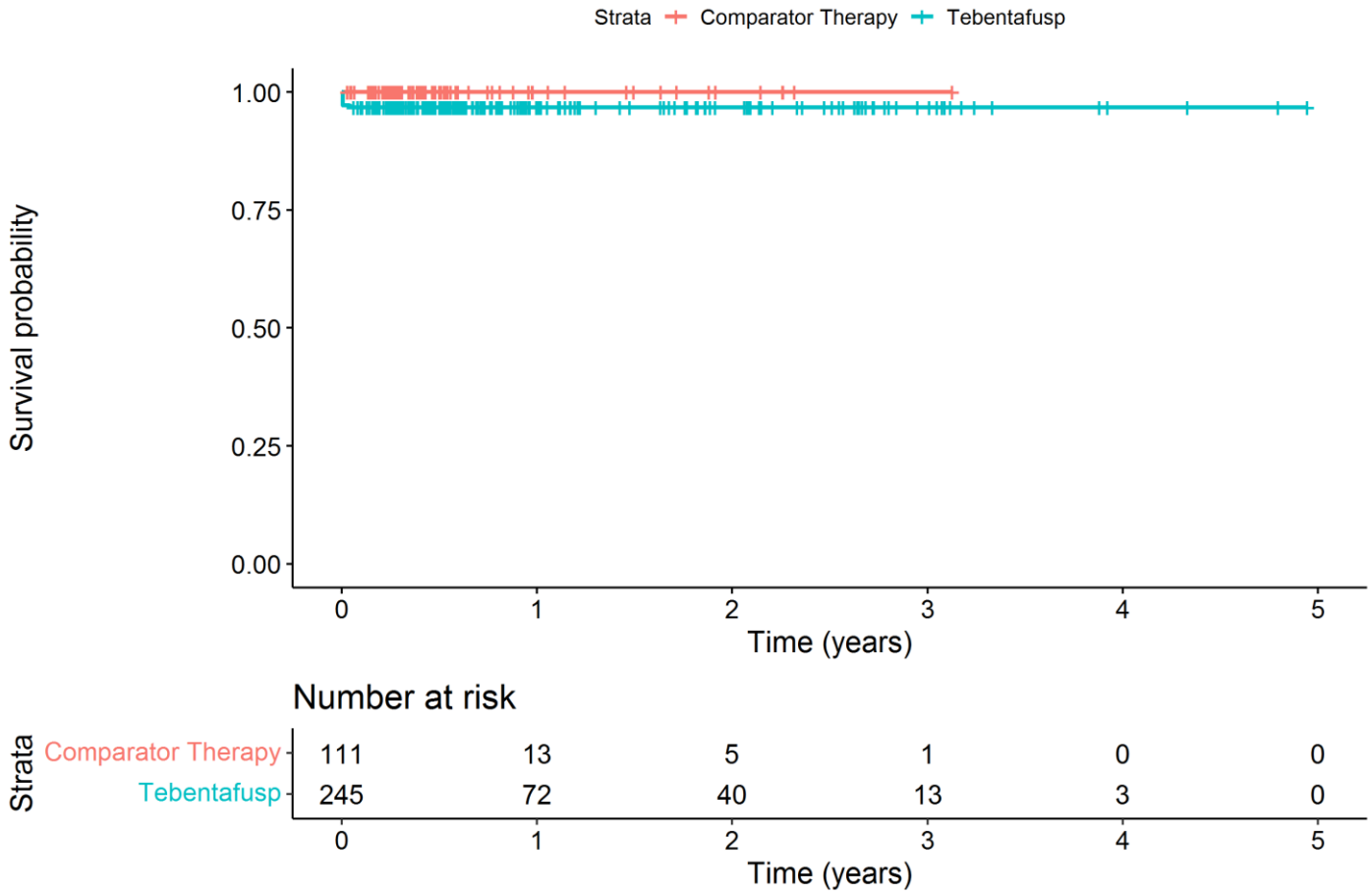
7.15 Gefäßerkrankungen



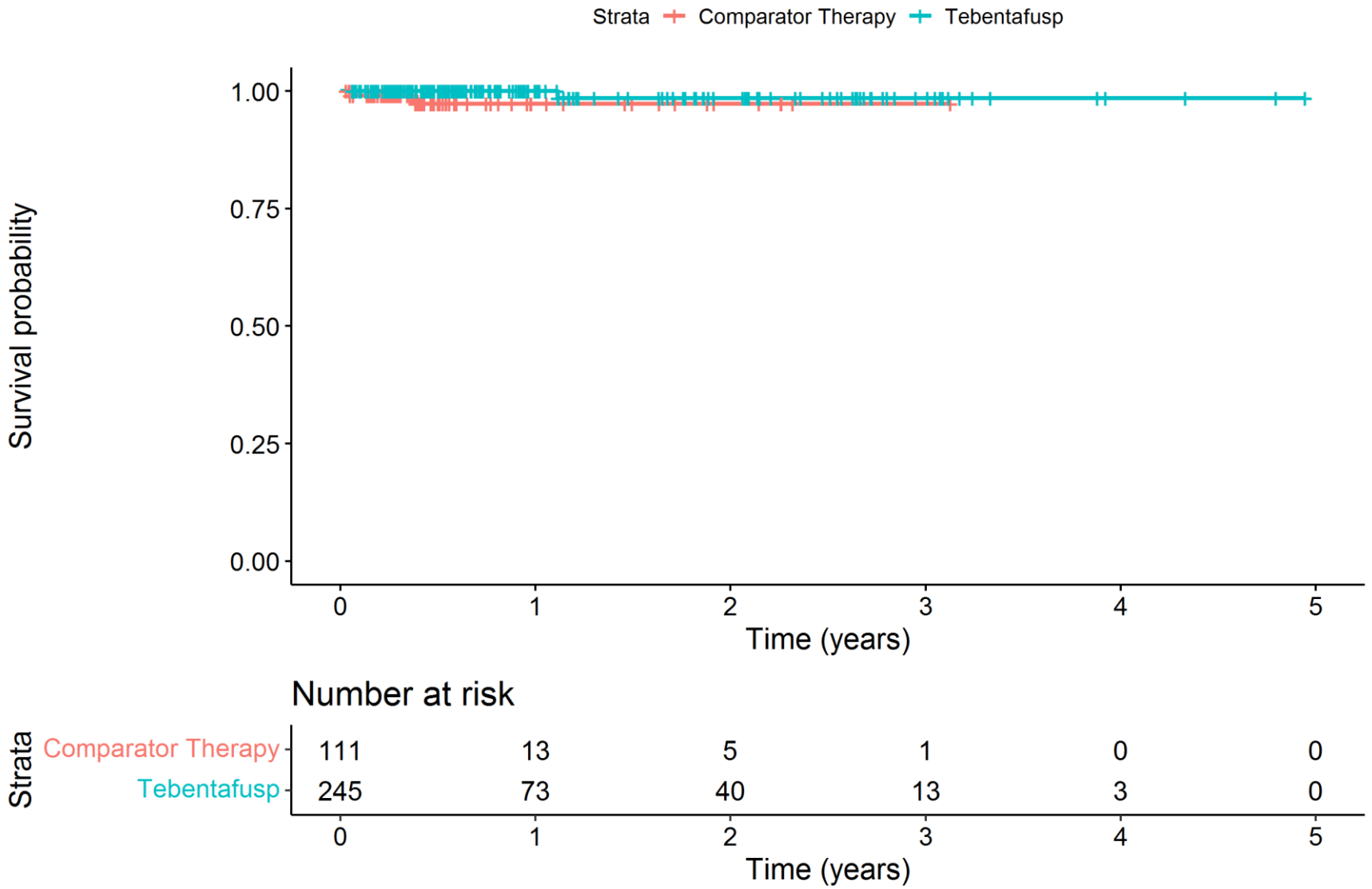
7.16 Unerwünschte Ereignisse nach Schweregrad – 3-Jahres-Analyse (Juni 2023) (Tabelle 4-56)

8 UEs (PT) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten

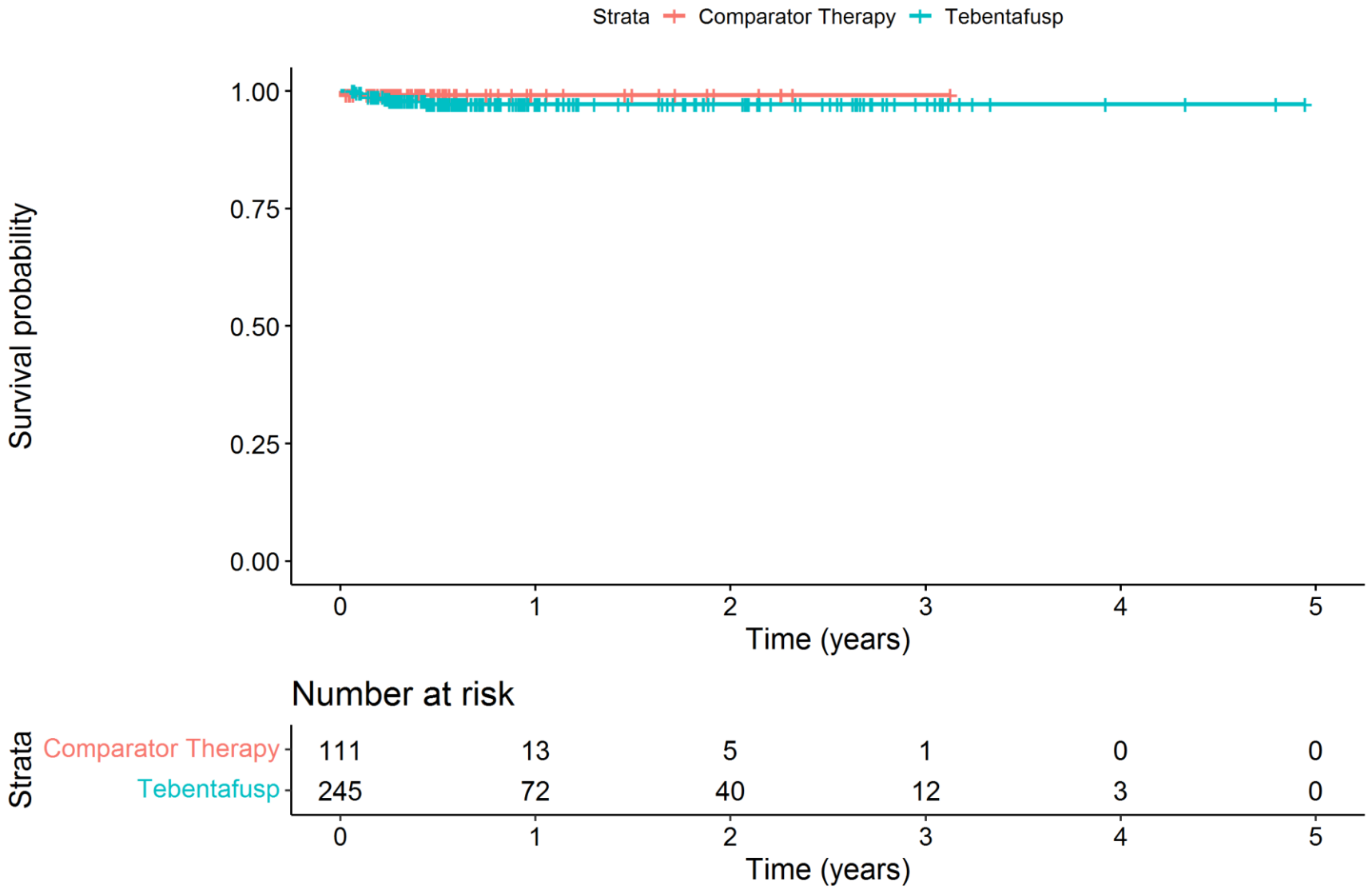
8.1 Lymphopenie



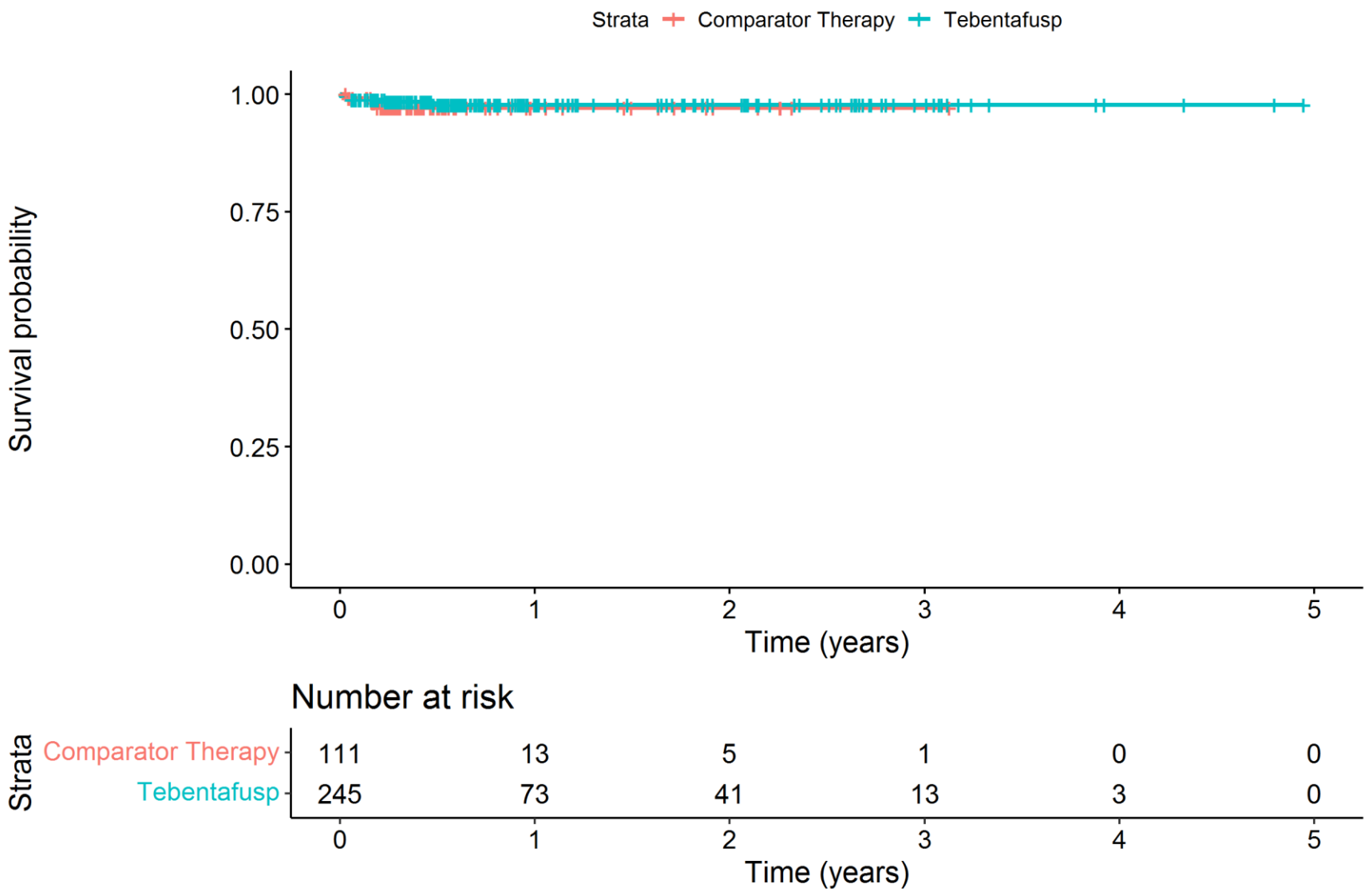
8.2 Neutropenie



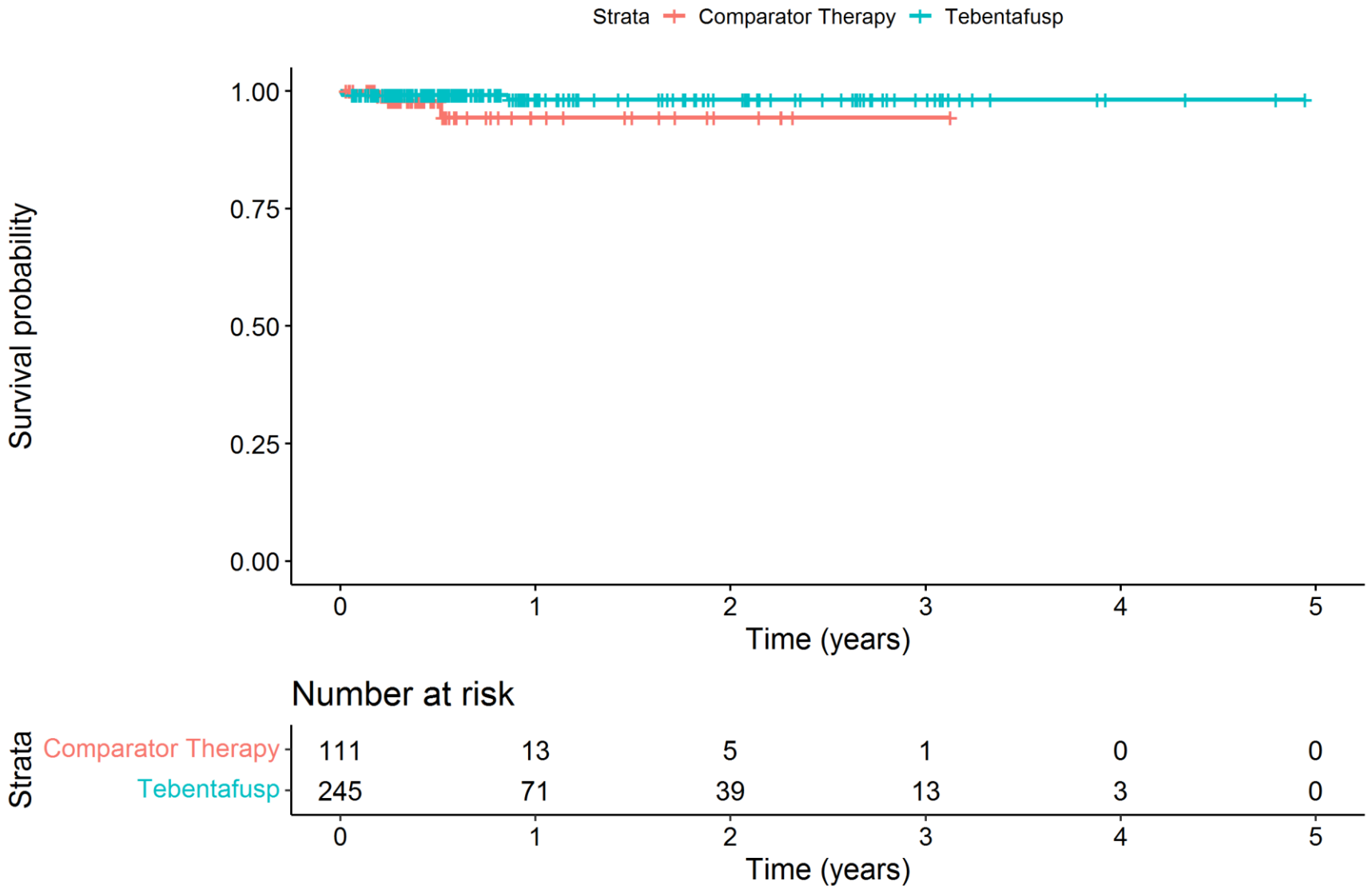
8.3 Übelkeit


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
72
40
12
3
0
0
1
2
3
4
5
Time (years)

8.4 Unterleibsschmerzen



8.5 Diarrhoe


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
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0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
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0
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71
39
13
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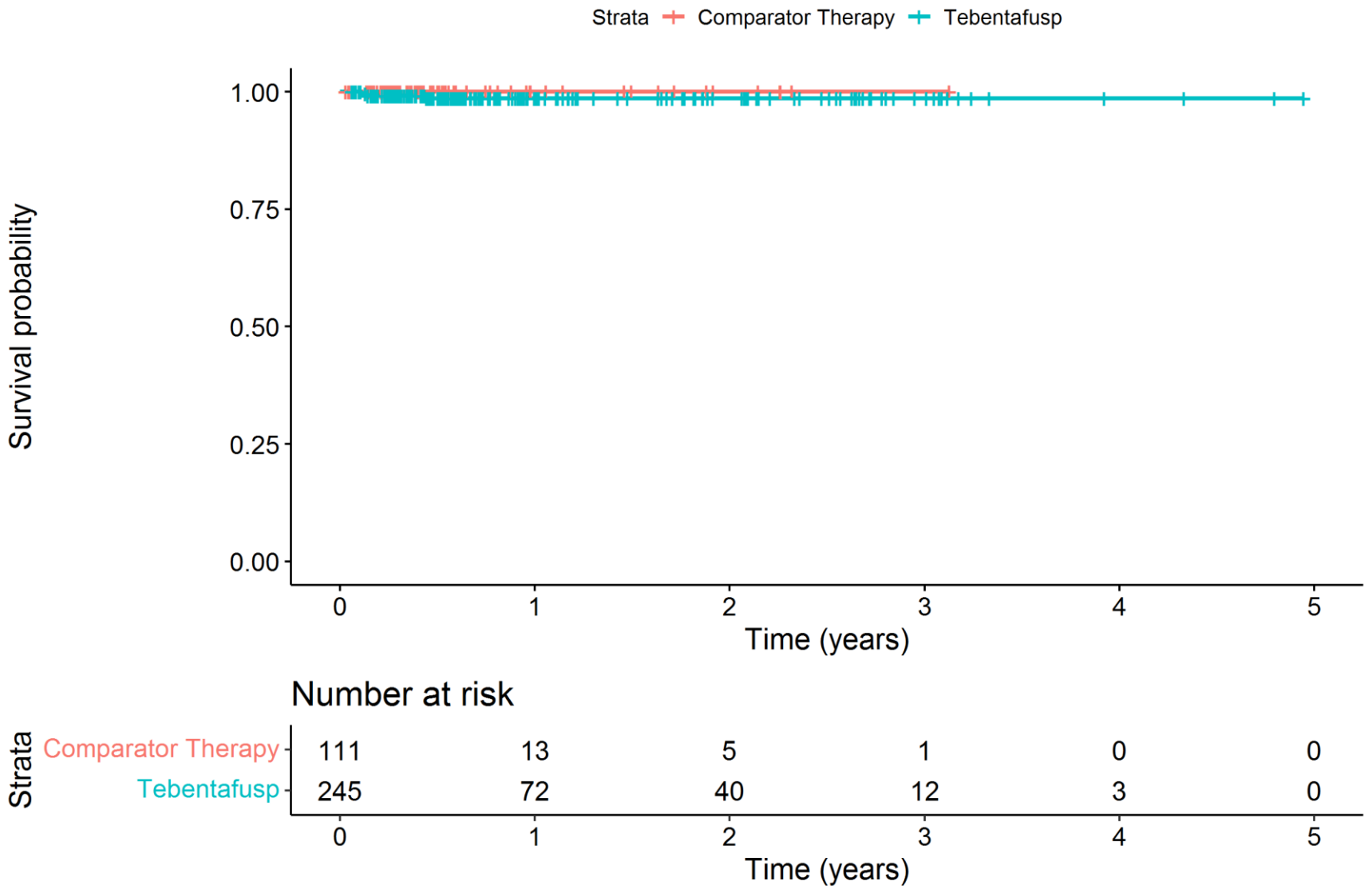
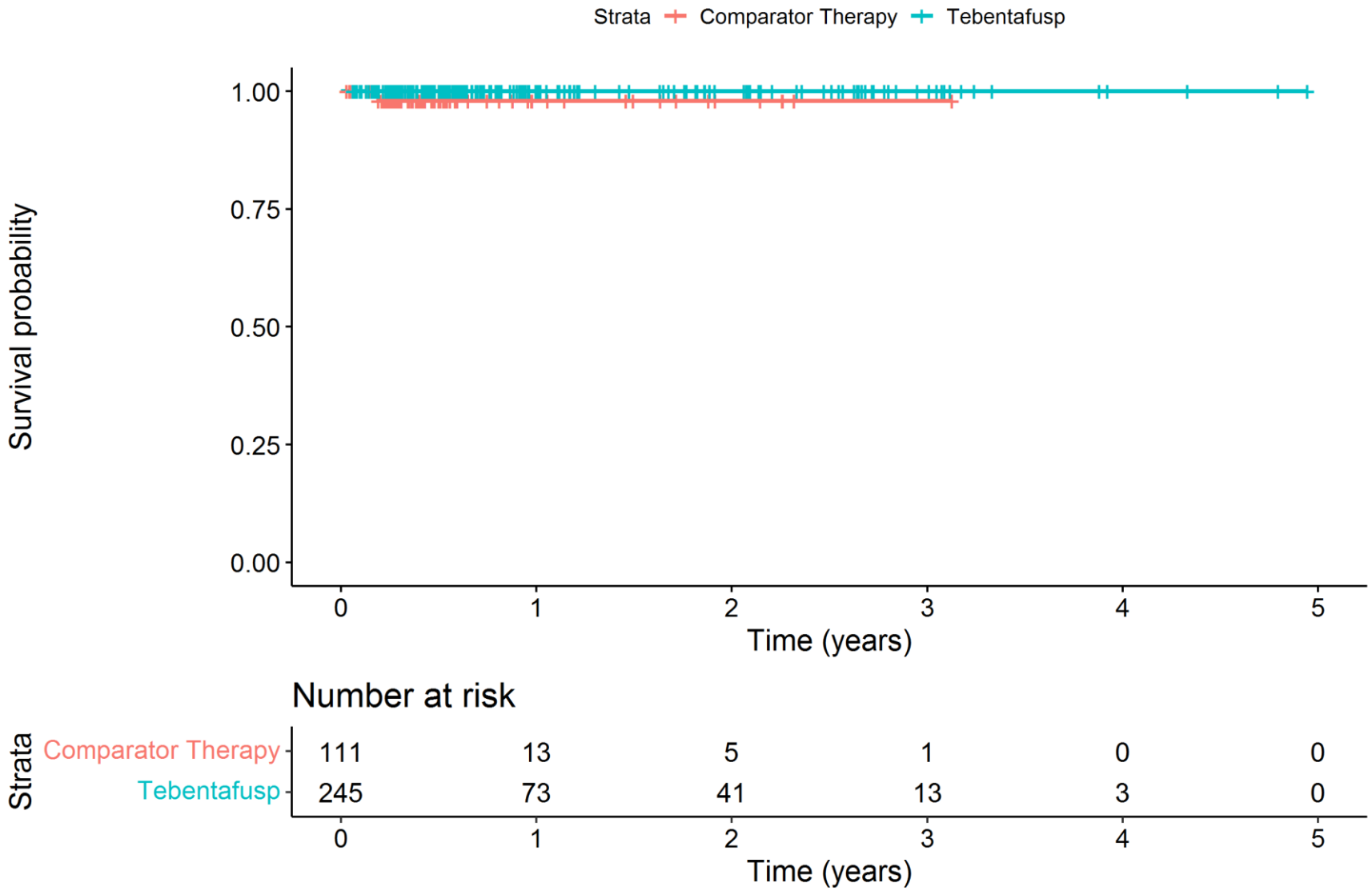
0
0
1
2
3
4
5
Time (years)

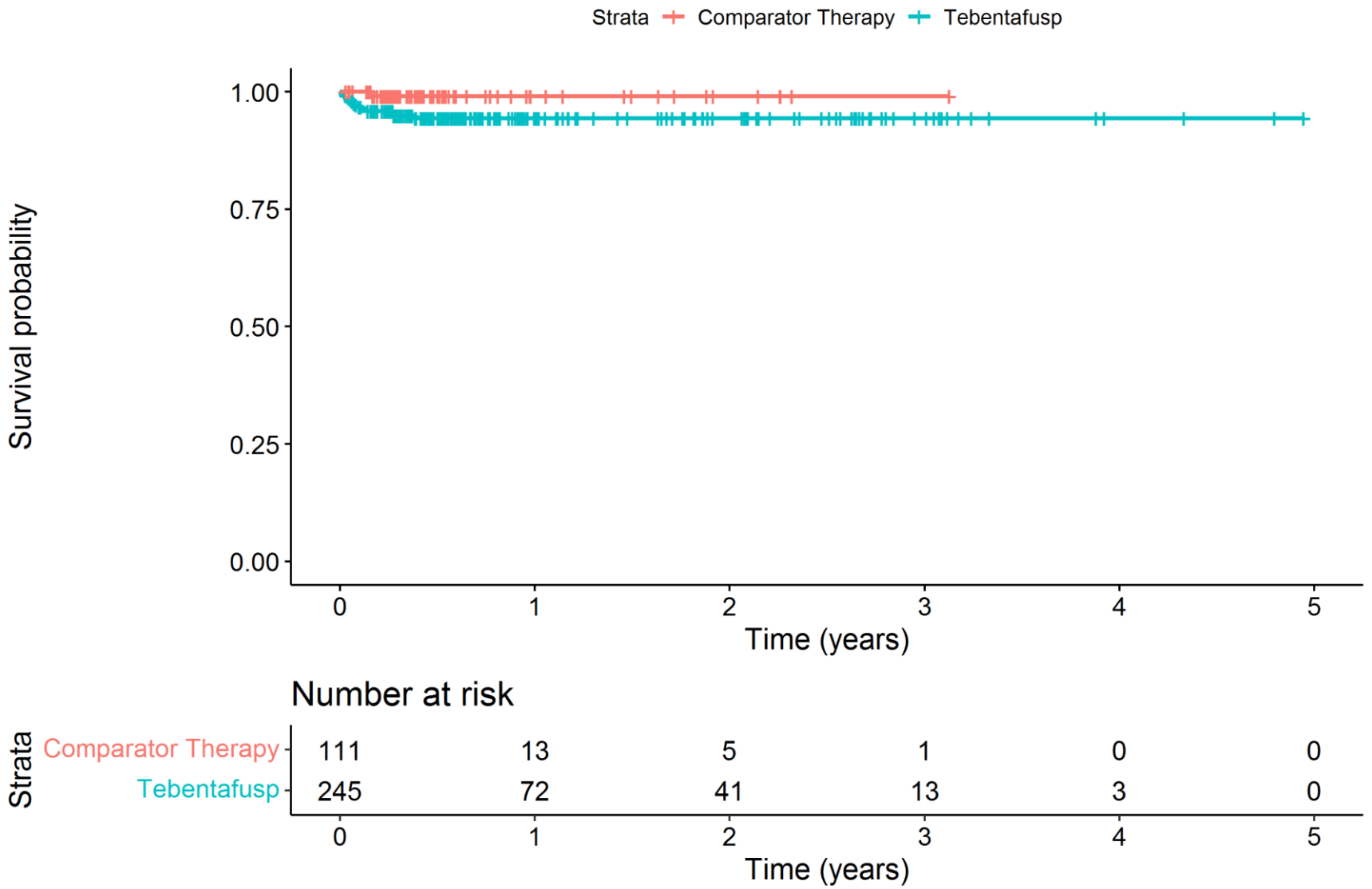
8.6 Erbrechen



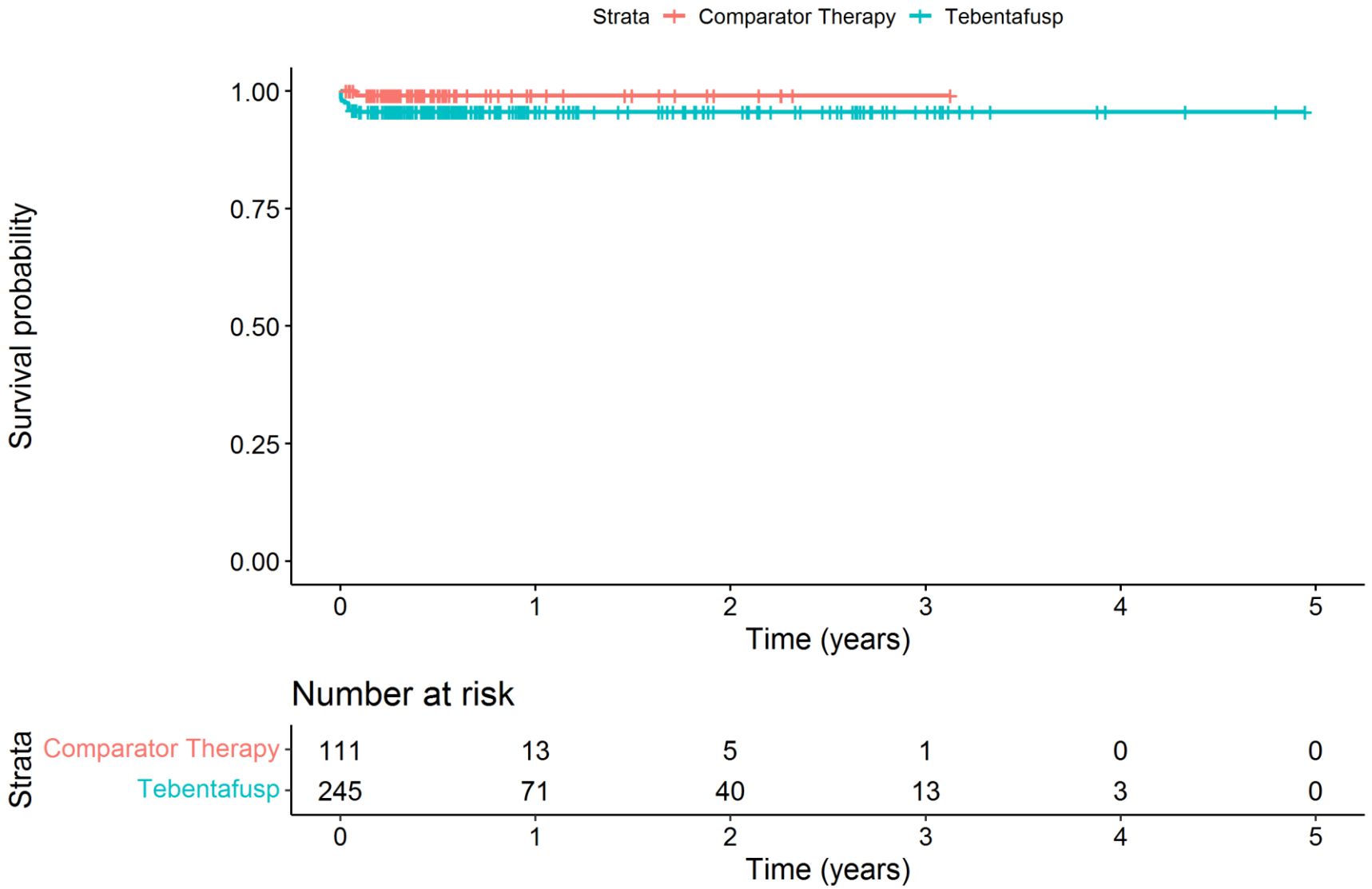
8.7 Colitis


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
73
41
13
3
0
0
1
2
3
4
5
Time (years)

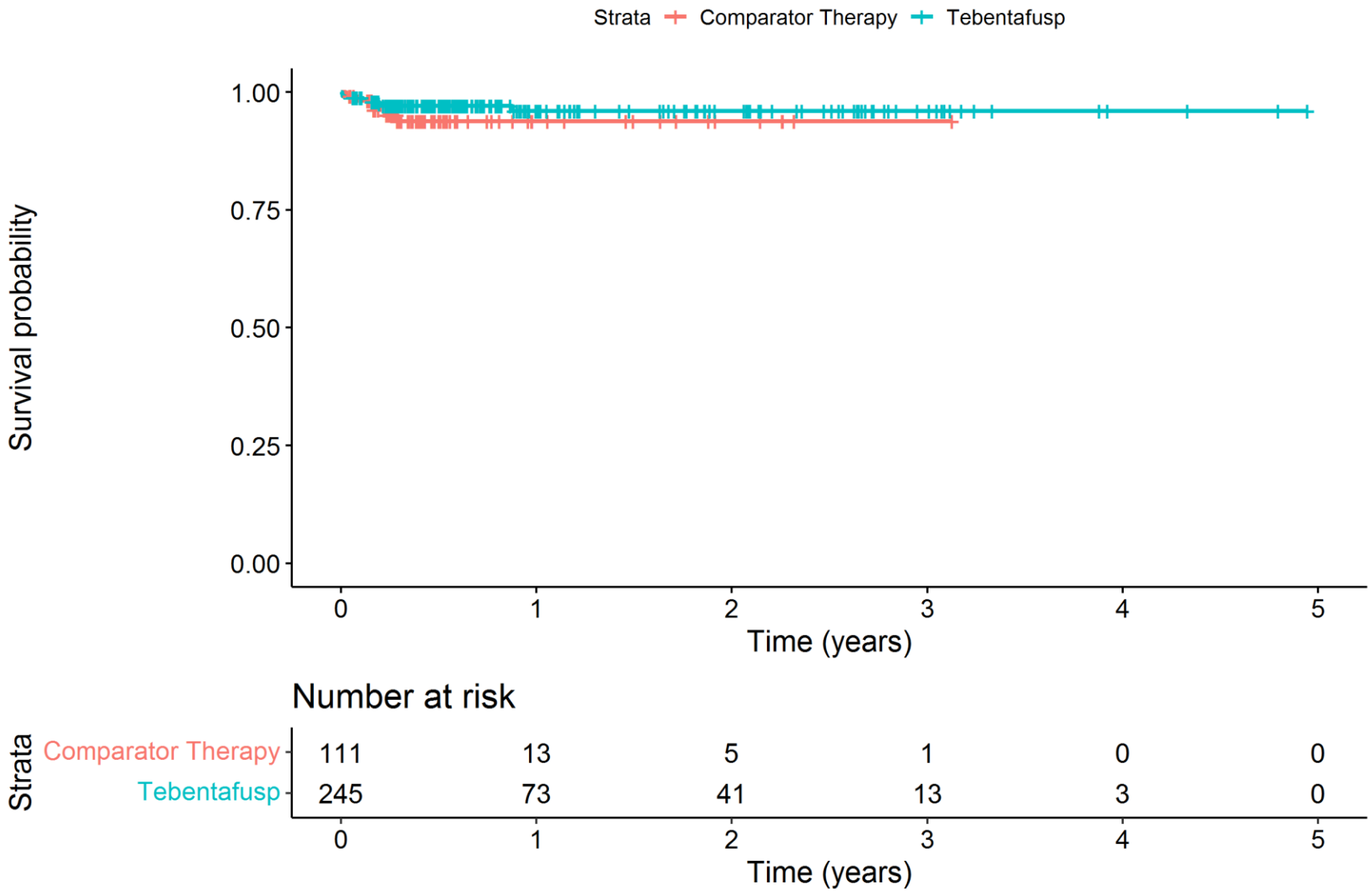
8.8 Müdigkeit



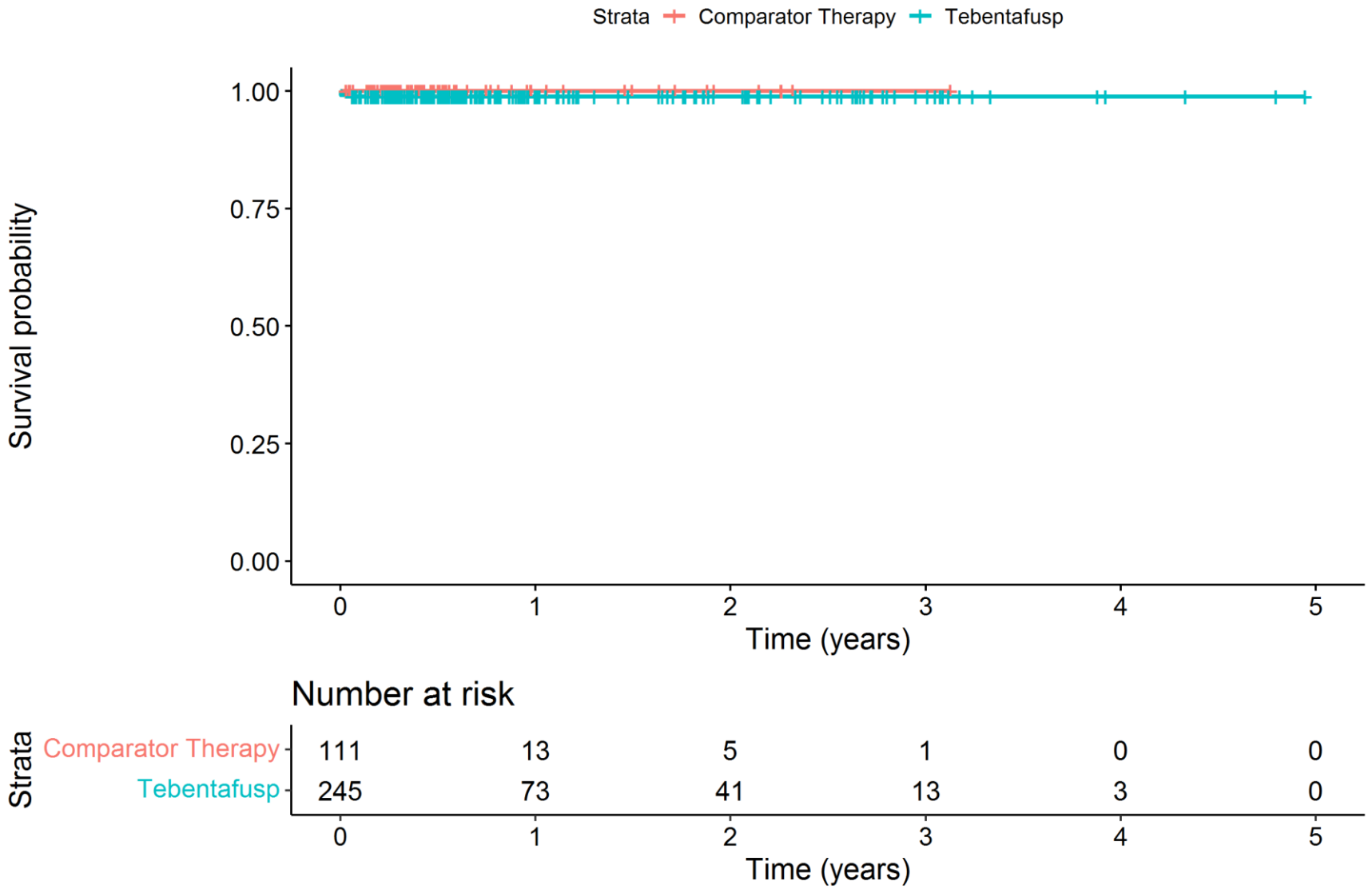
8.9 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
71
40
13
3
0
0
1
2
3
4
5
Time (years)

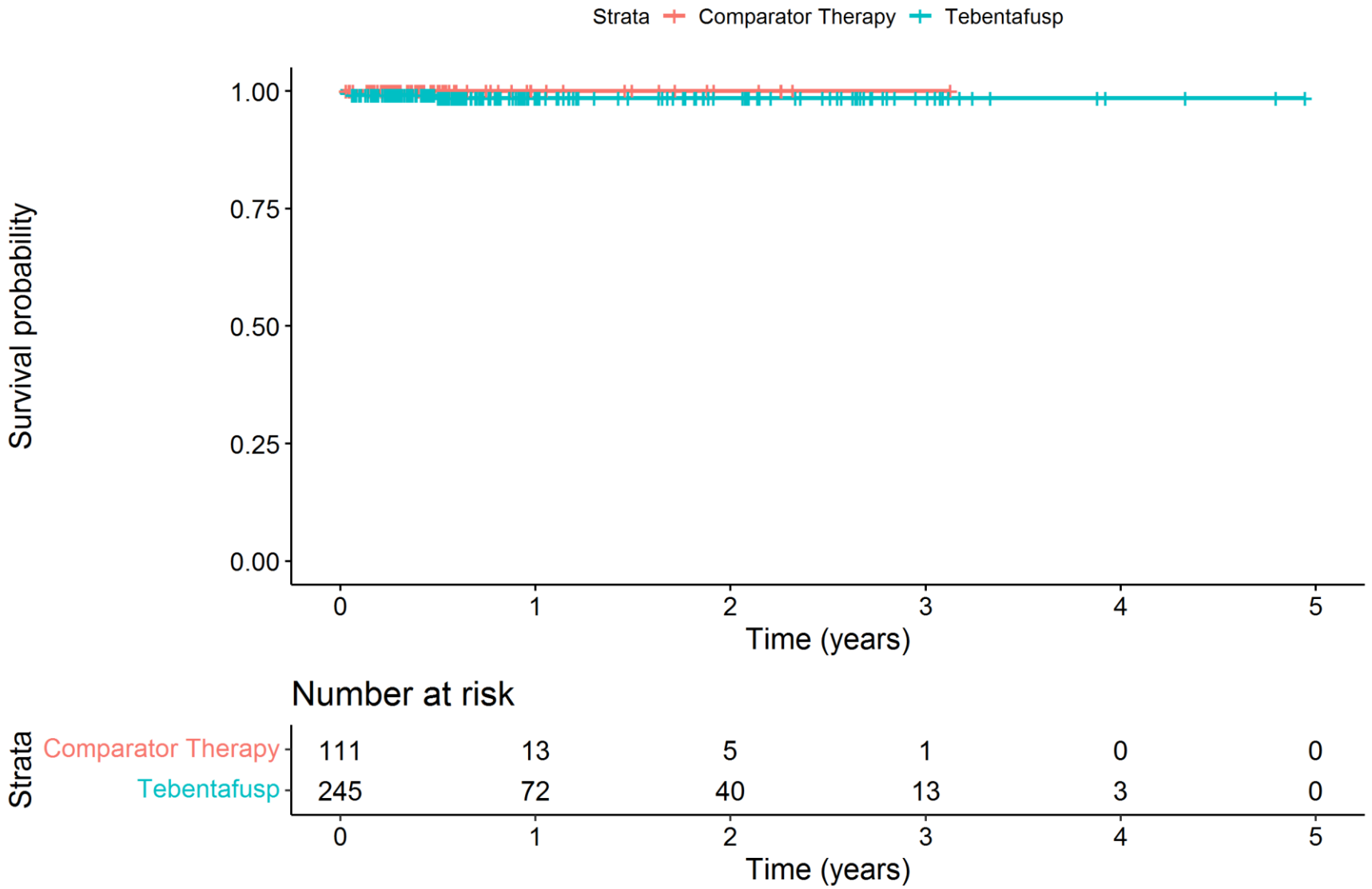
8.10 Hyperbilirubinämie



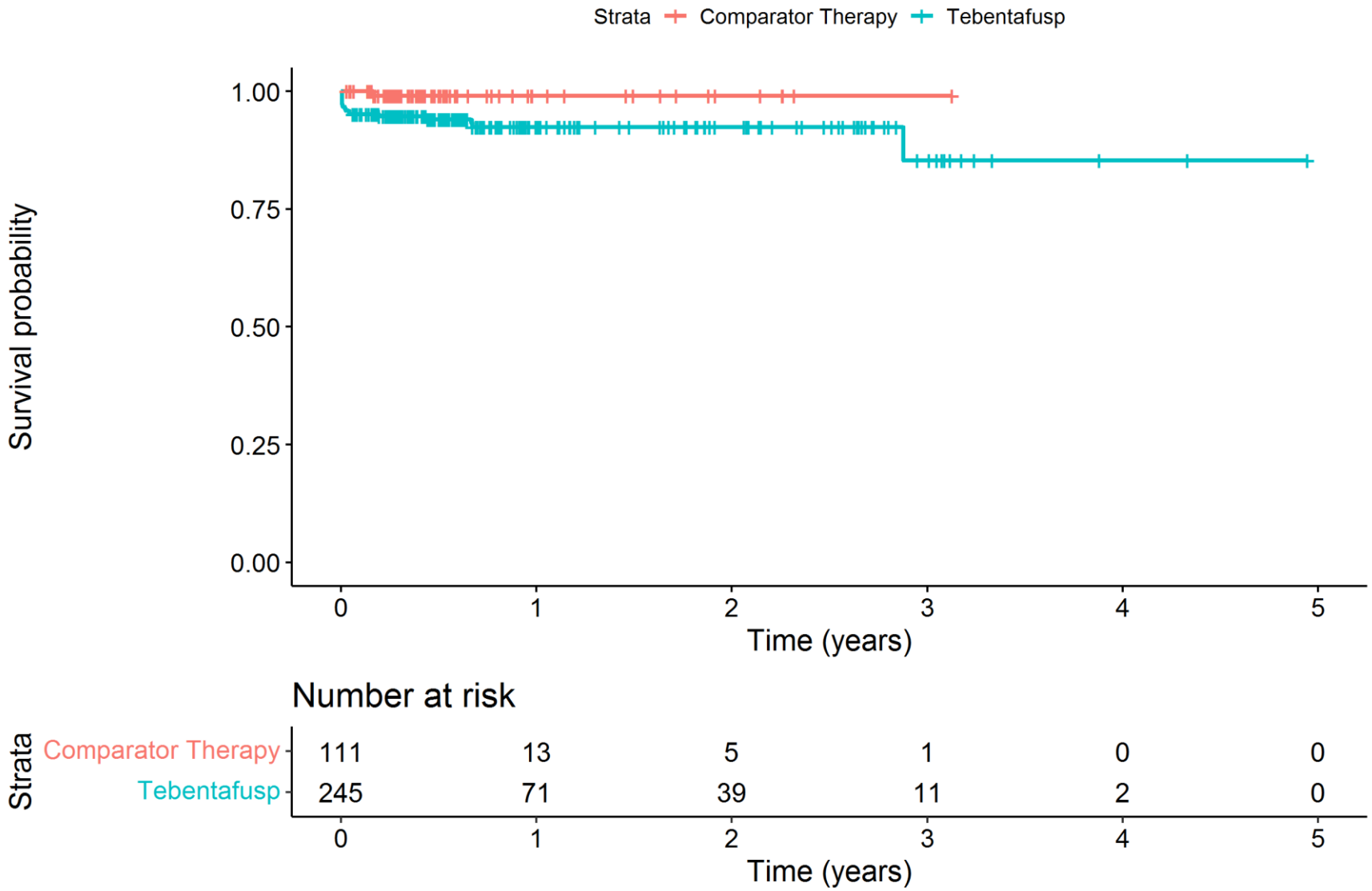
8.11 Zytokin-Freisetzungssyndrom



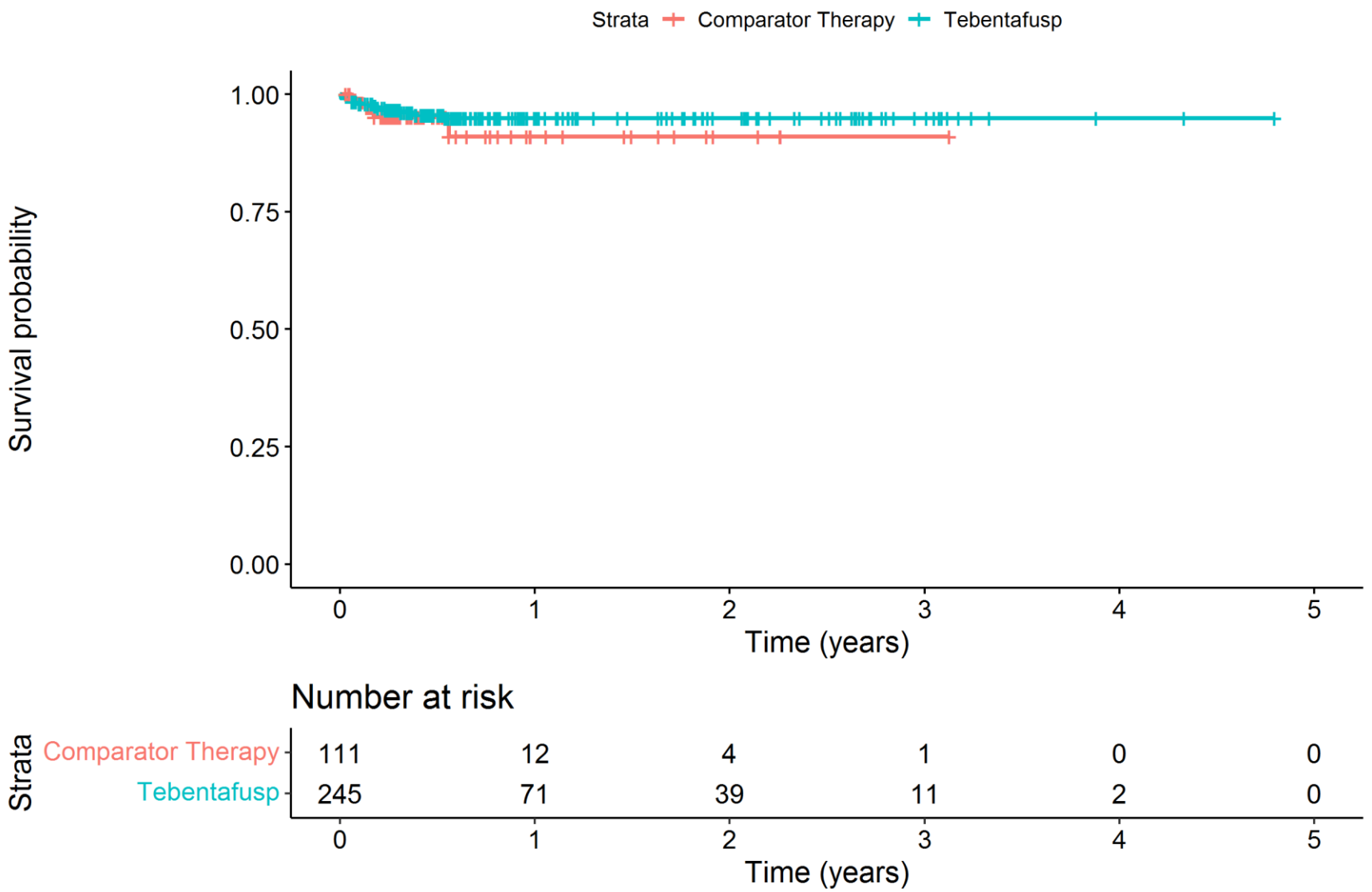
8.12 Harnwegsinfektion



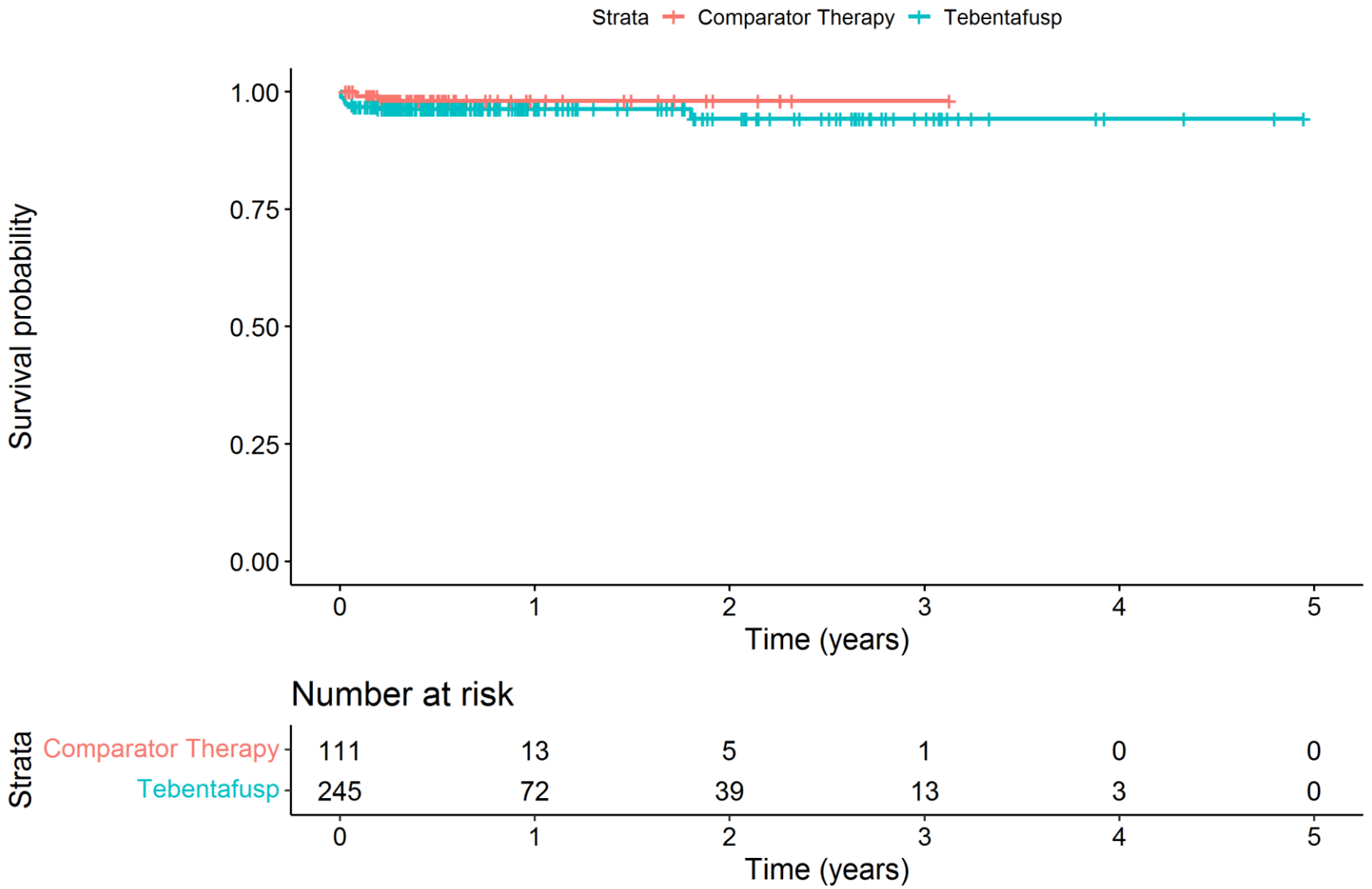
8.13 Erhöhte Aspartat-Aminotransferase



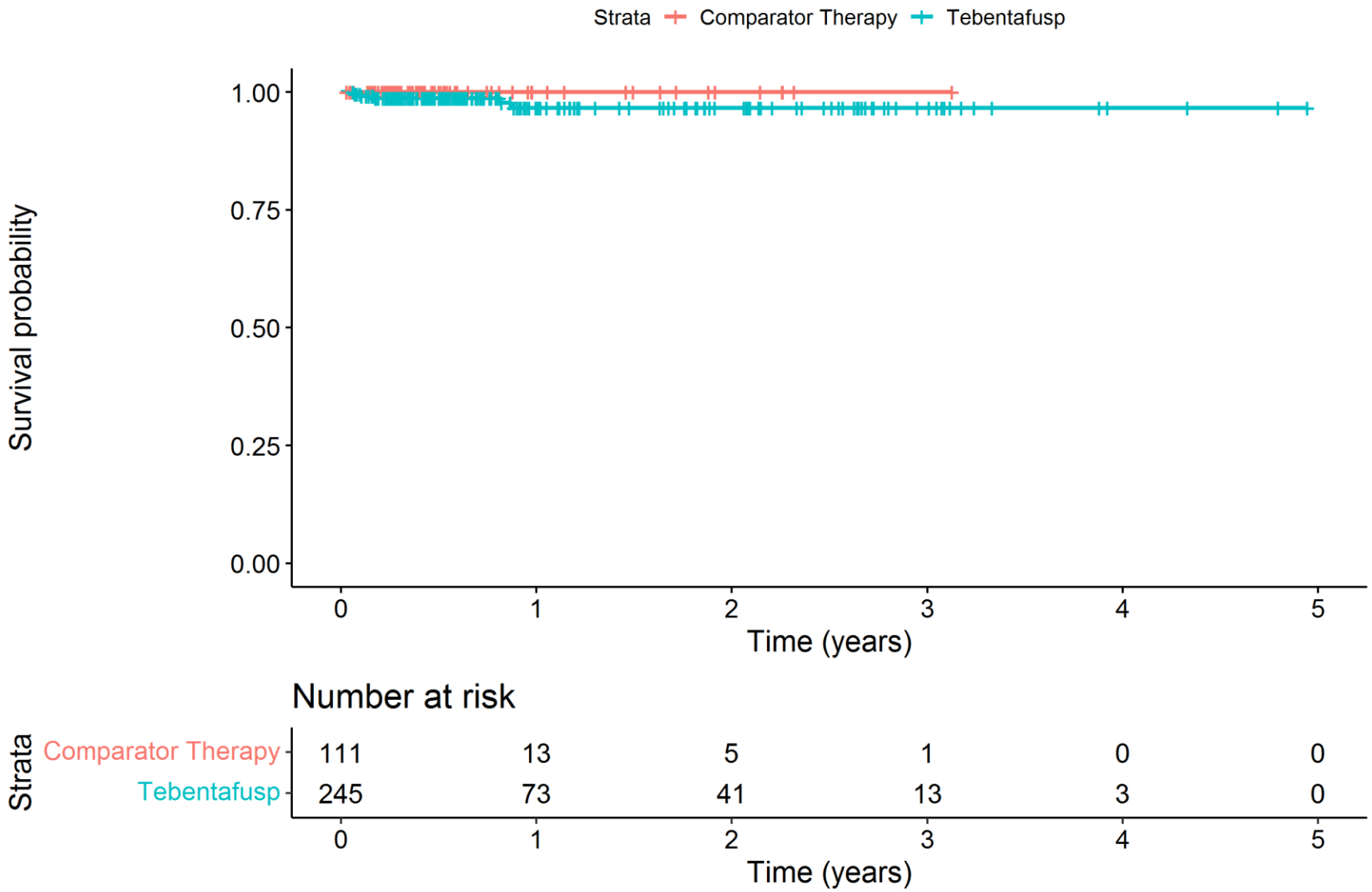
8.14 Erhöhte Lipase



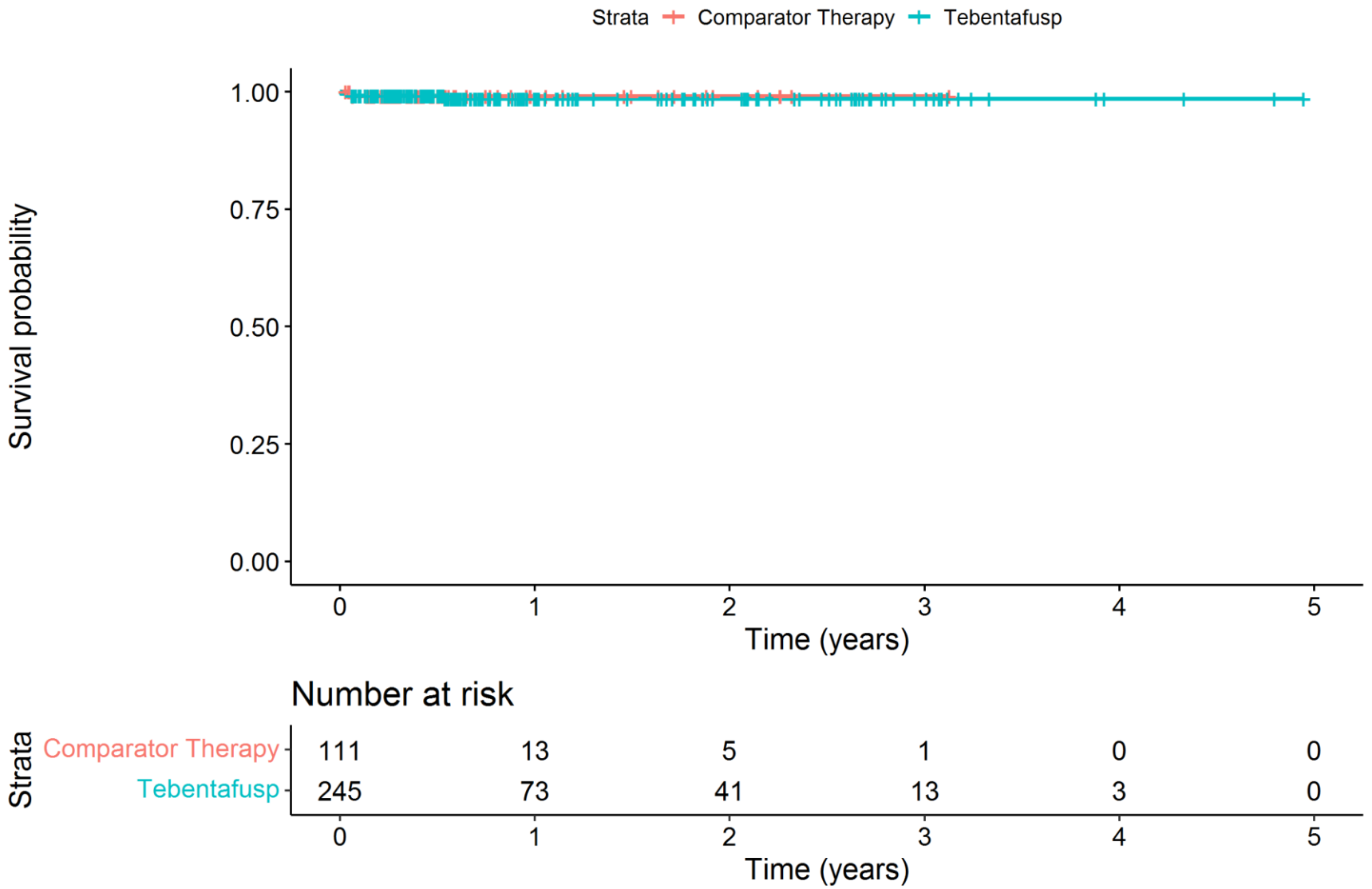
8.15 Erhöhte Alanin-Aminotransferase



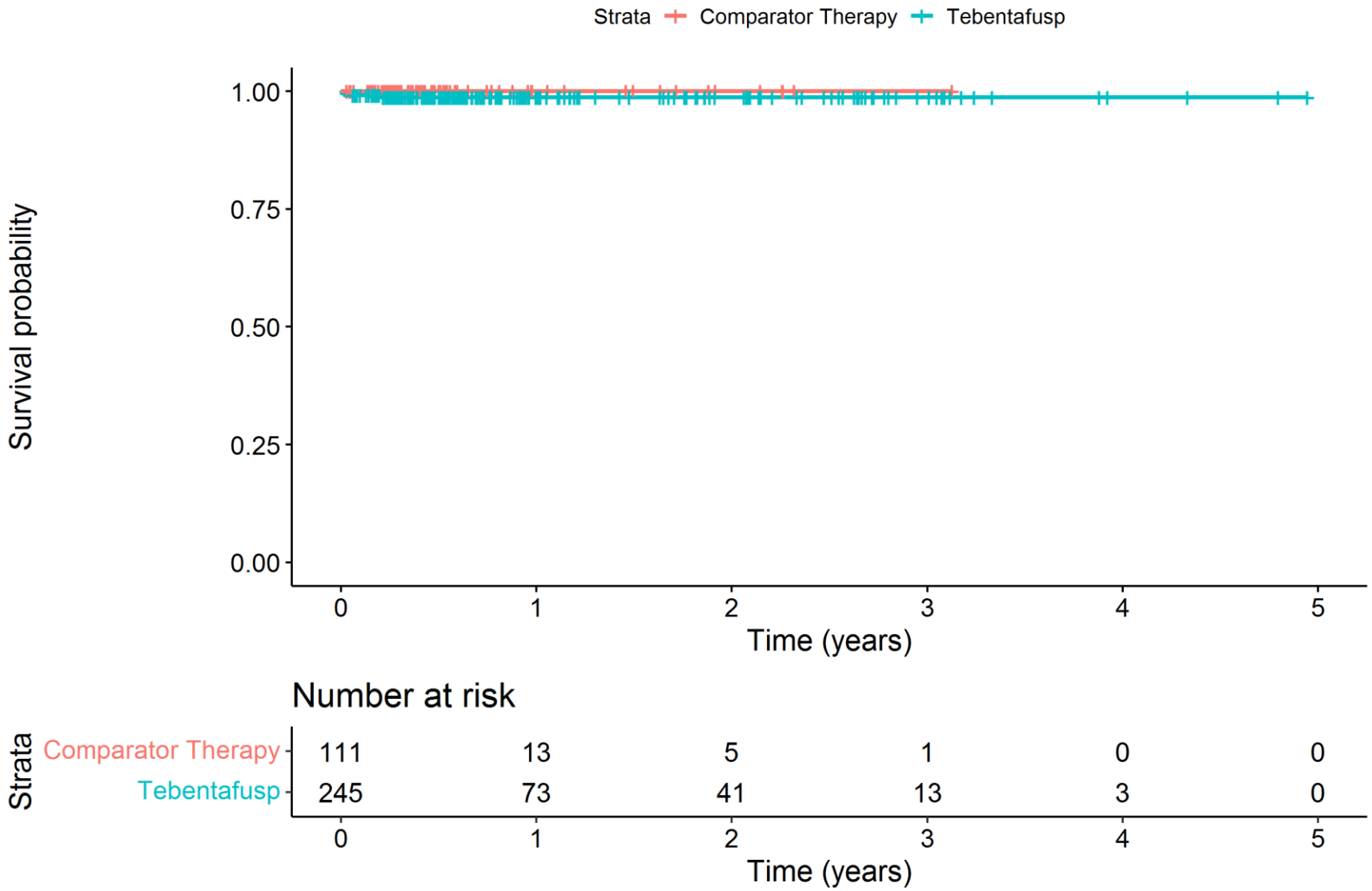
8.16 Erhöhte Gamma-Glutamyltransferase



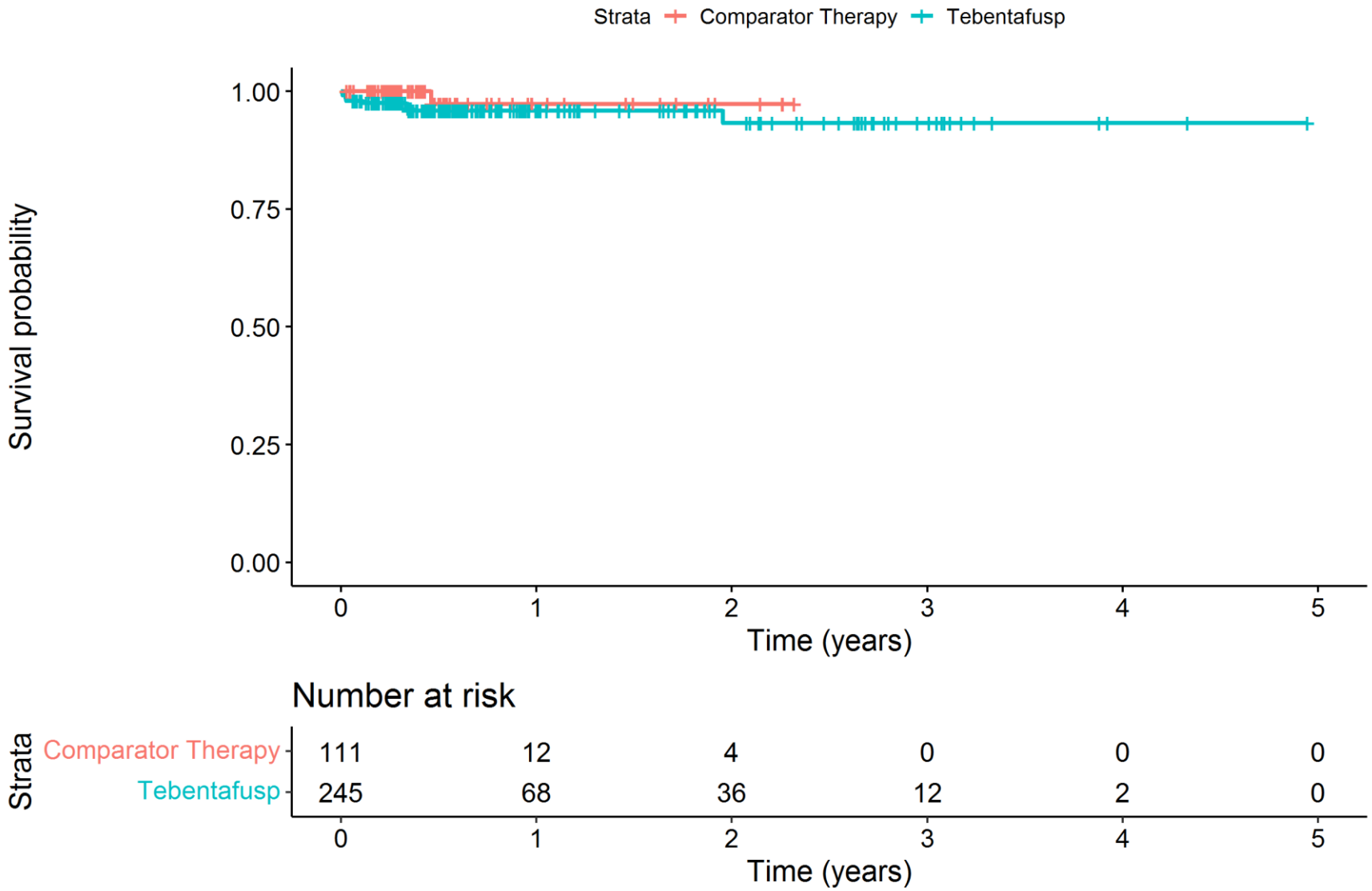
8.17 Erhöhte Amylase



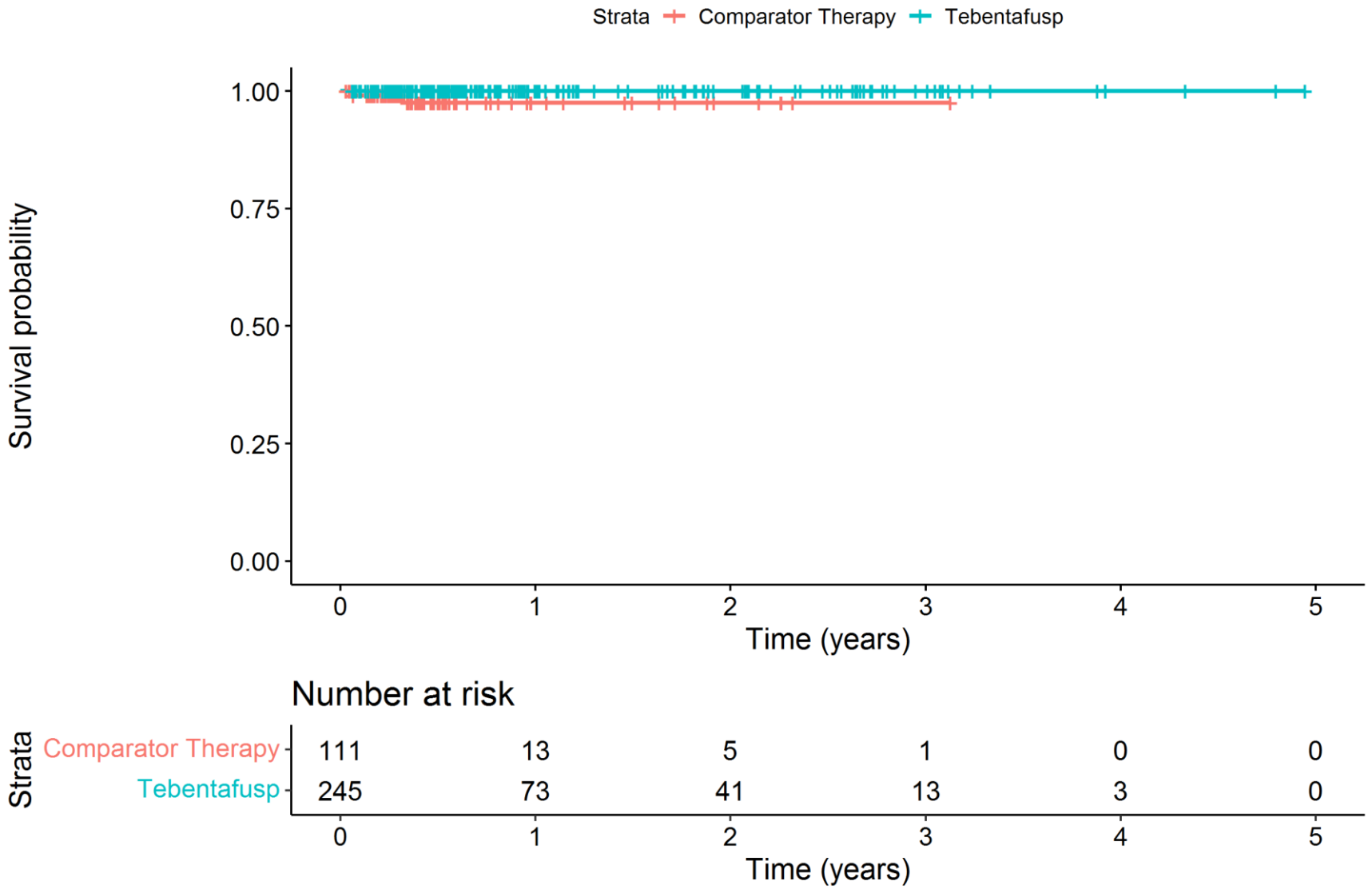
8.18 Erhöhte alkalische Phosphatase im Blut



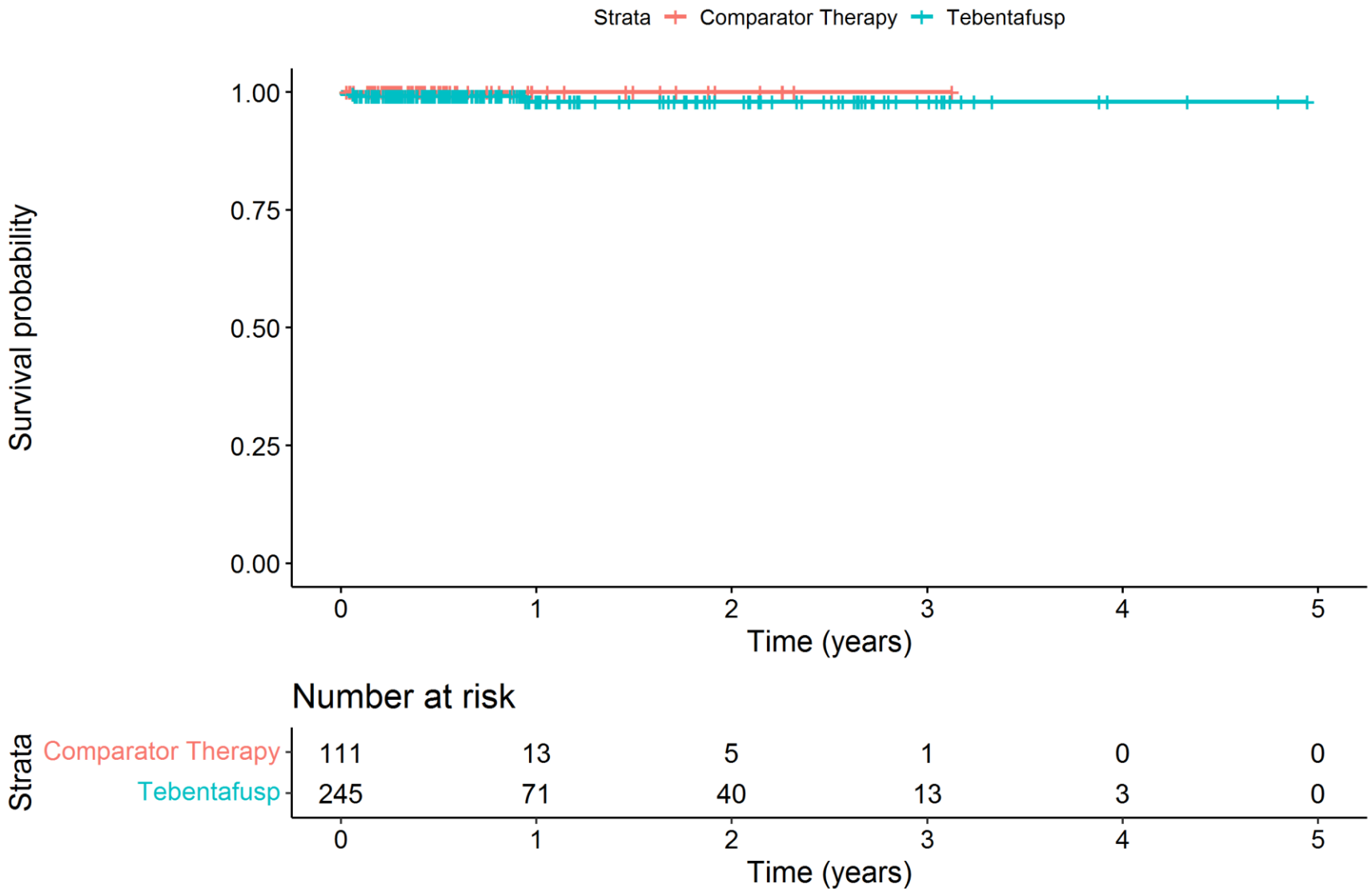
8.19 Hypophosphatämie



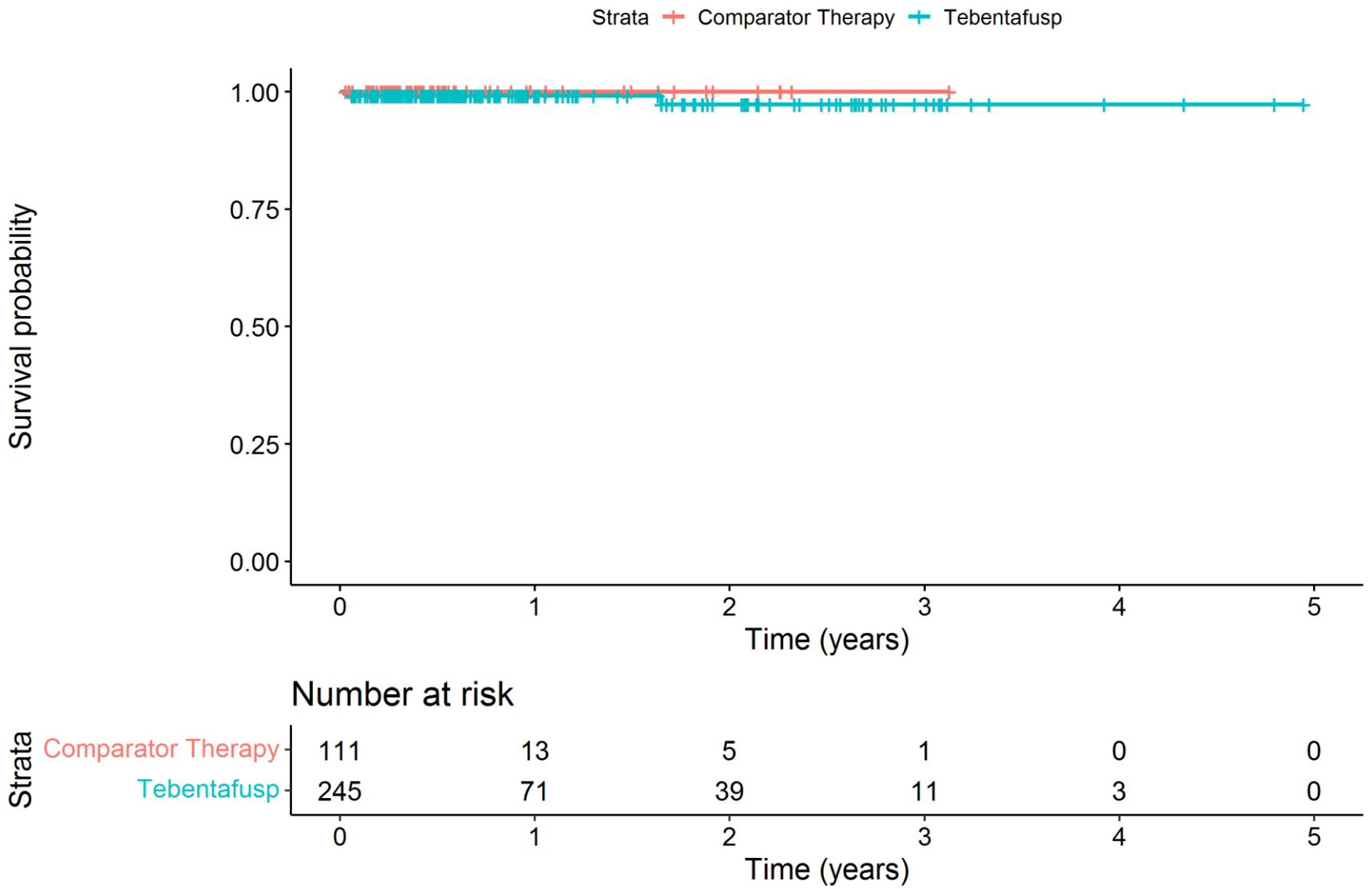
8.20 Dehydrierung



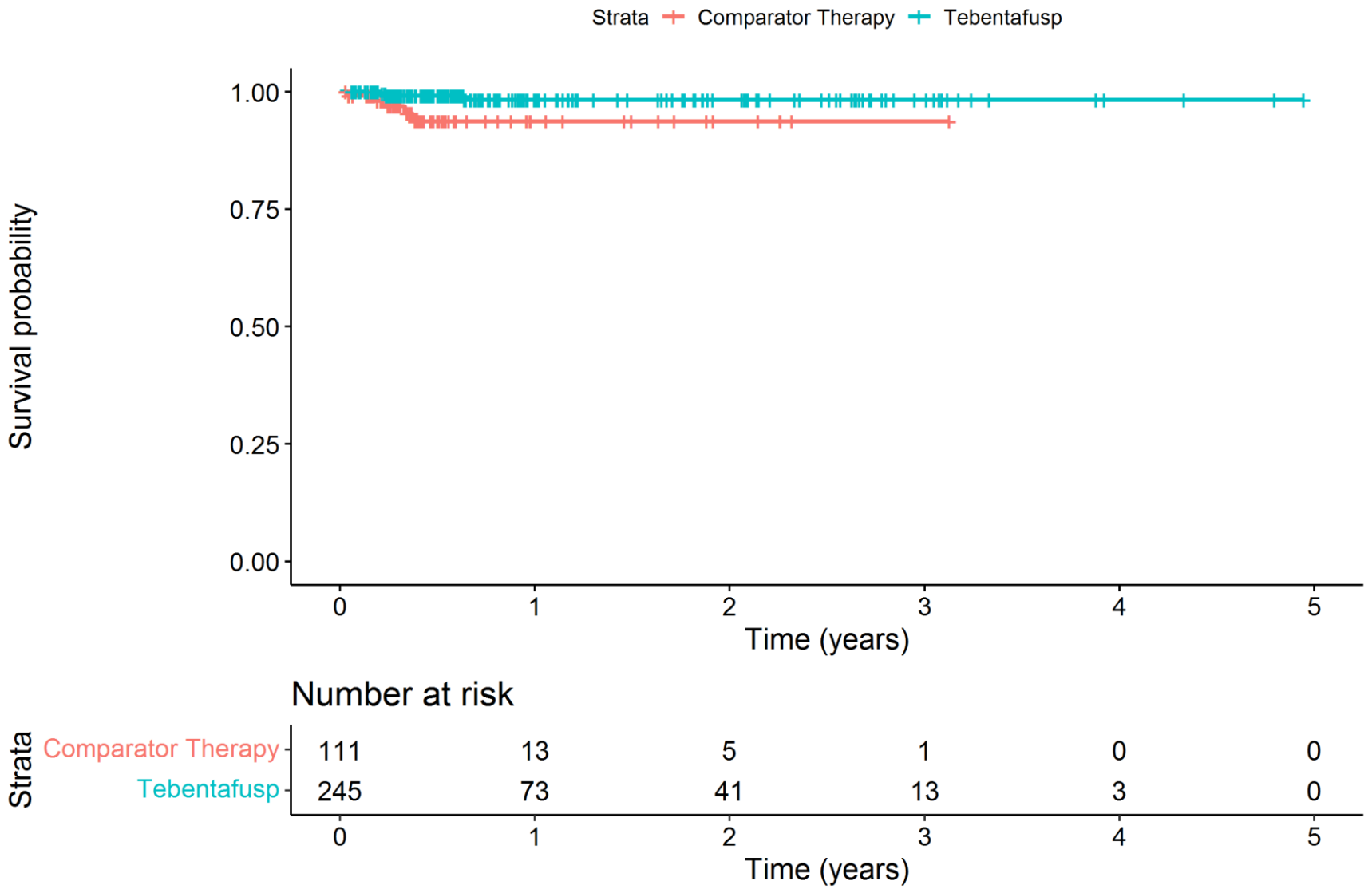
8.21 Tumorschmerzen



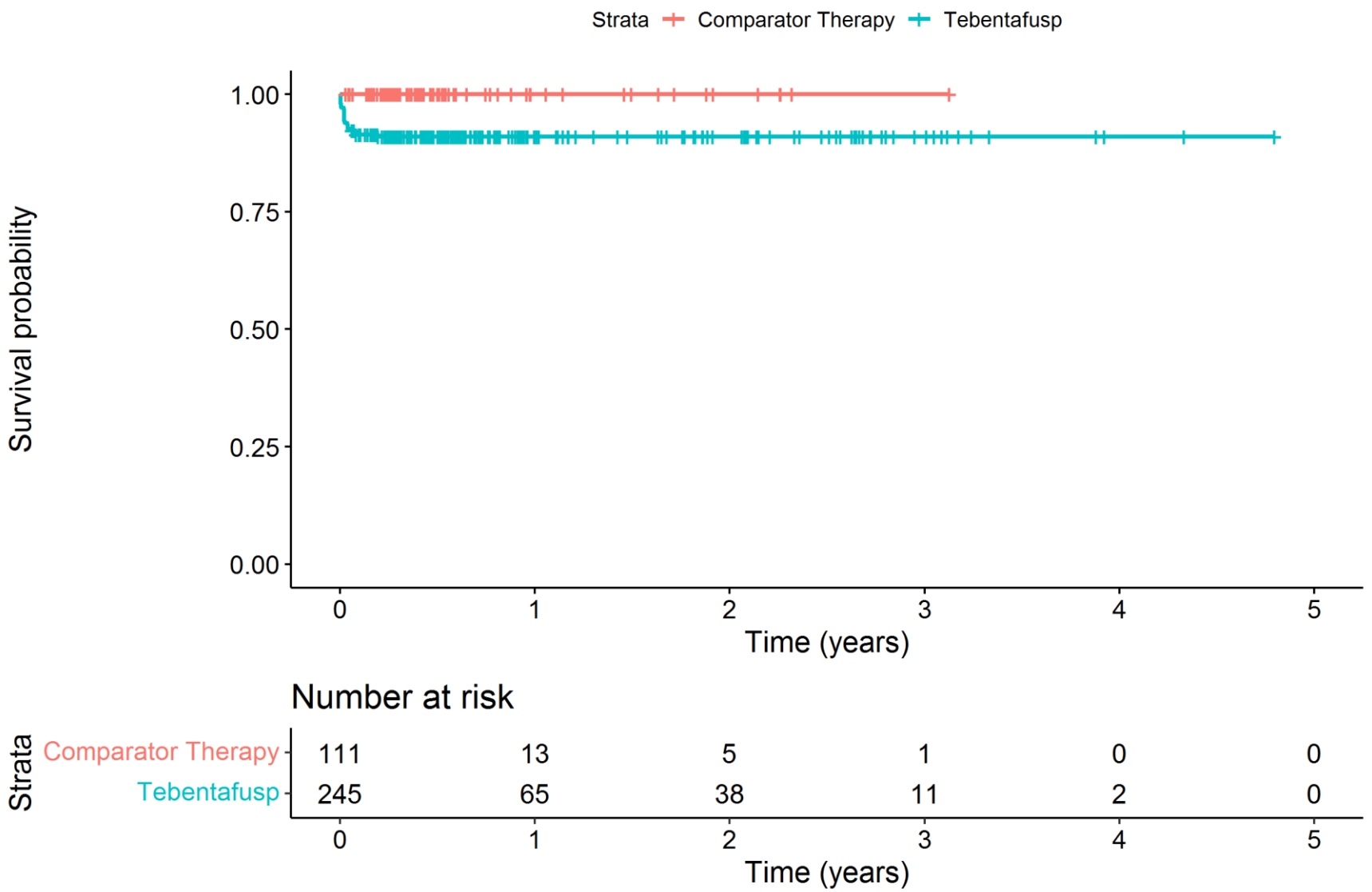
8.22 Synkope


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
71
39
11
3
0
0
1
2
3
4
5
Time (years)

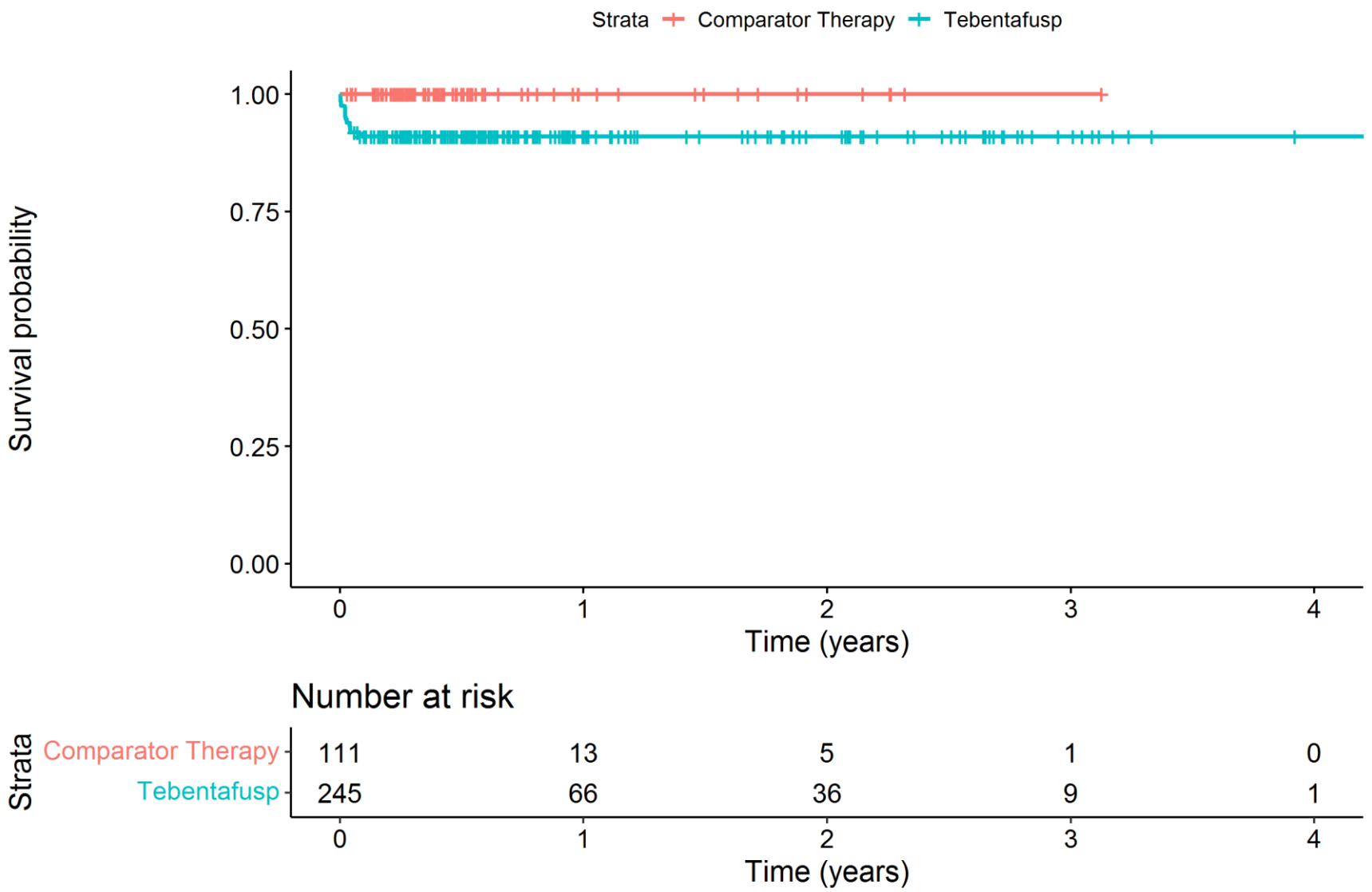
8.23 Lungenembolie



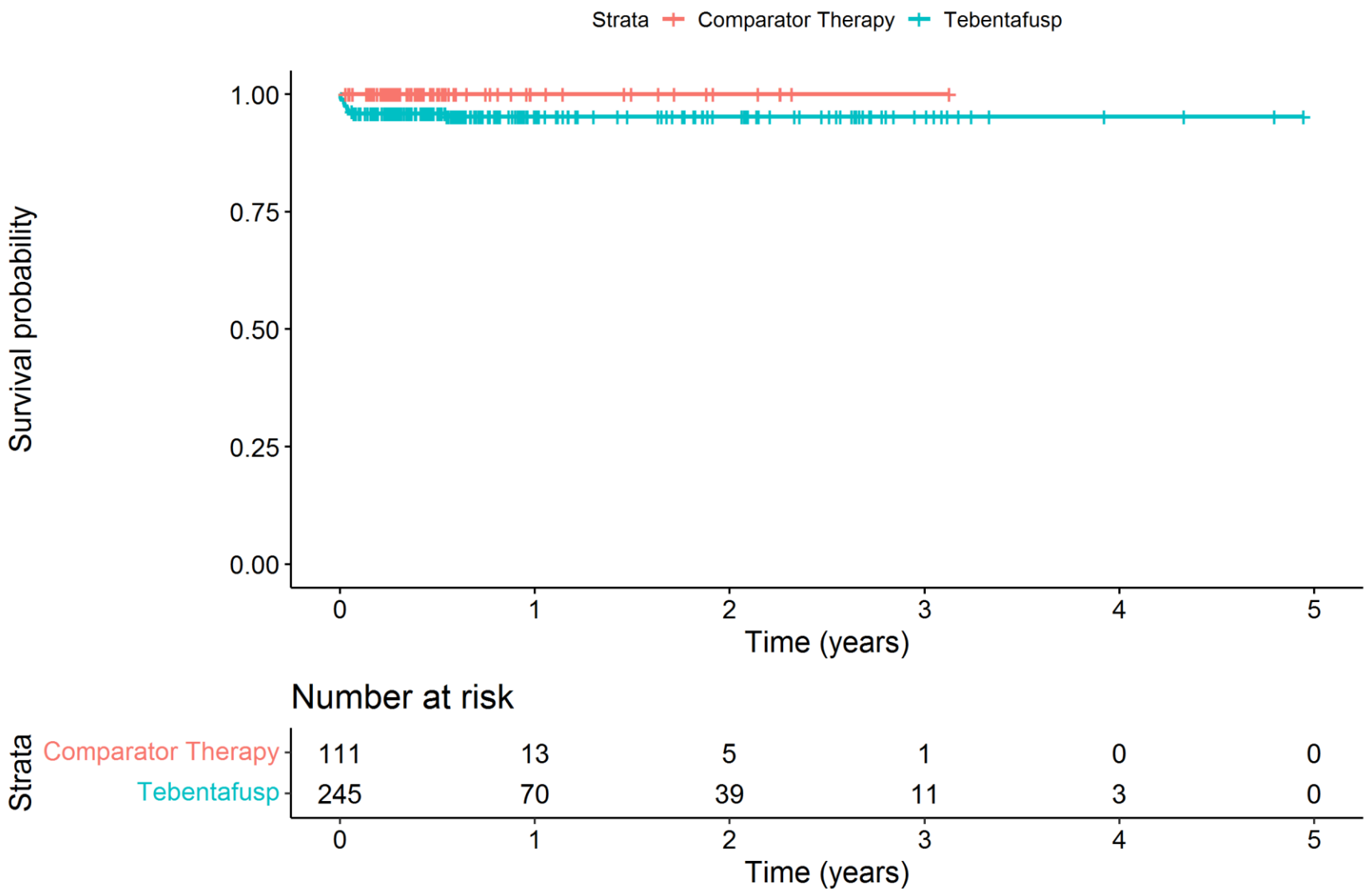
8.24 Hautausschlag



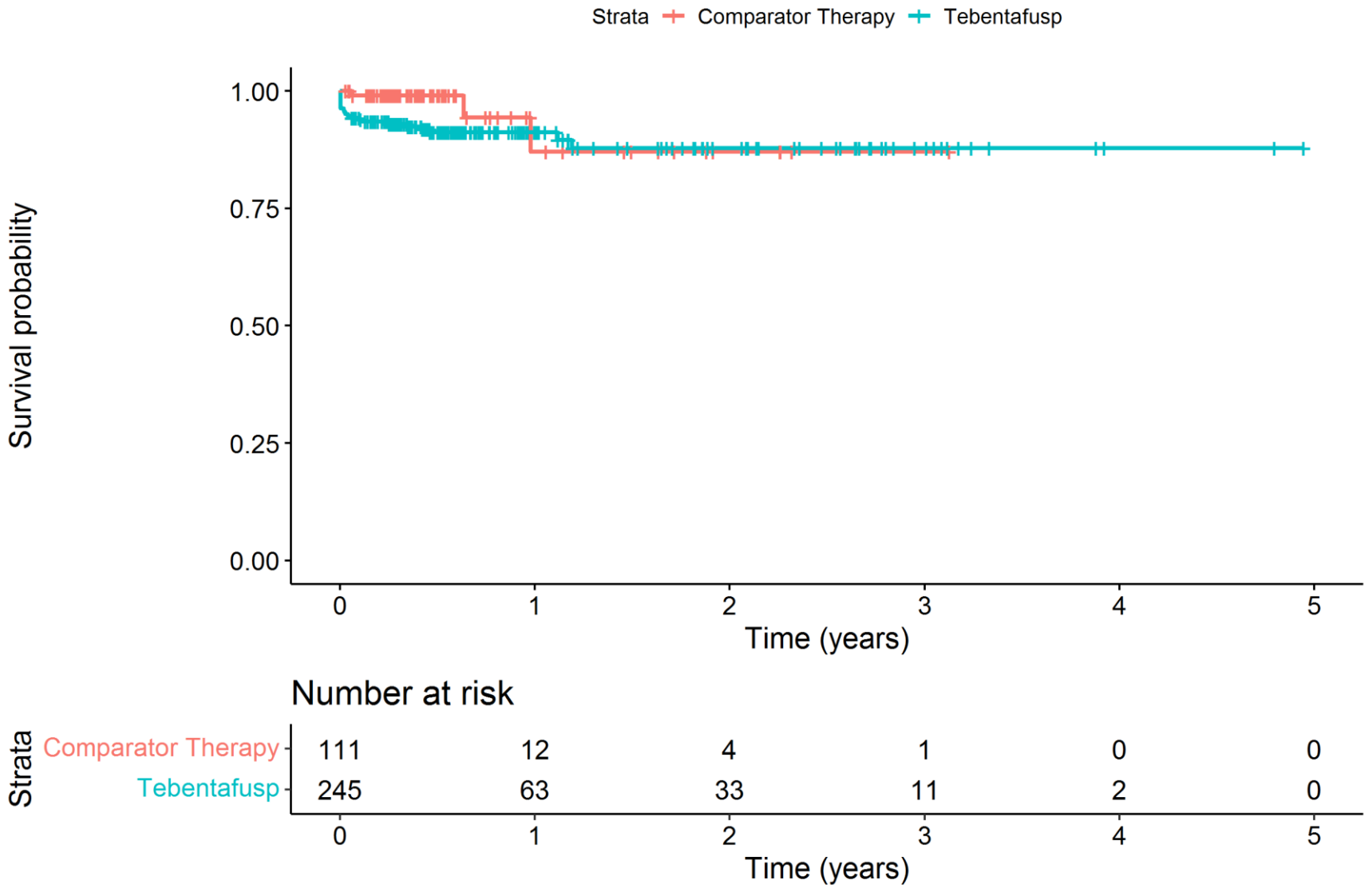
8.25 Makulo-papulöser Hautausschlag



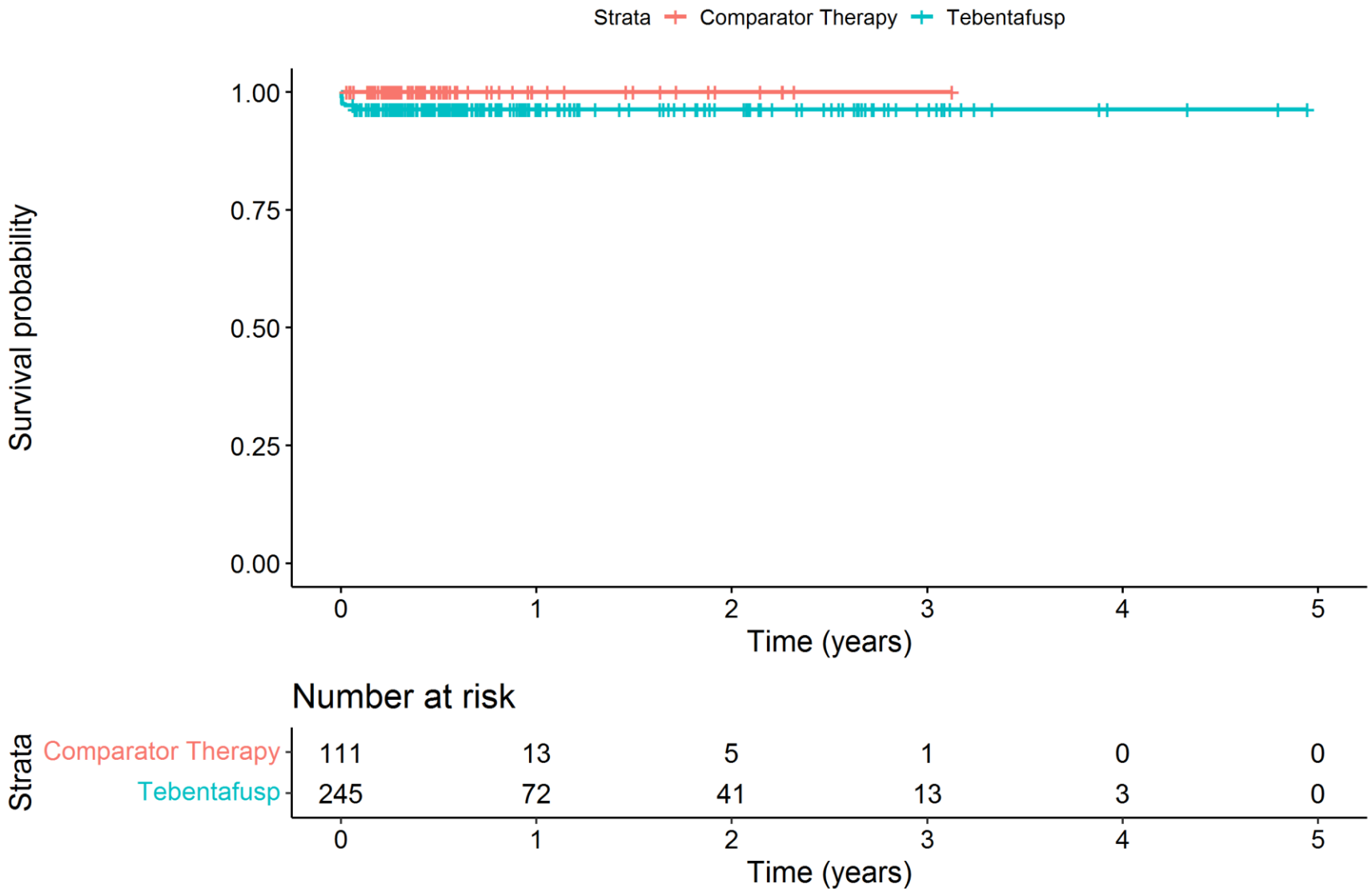
8.26 Pruritus



8.27 Hypertonie

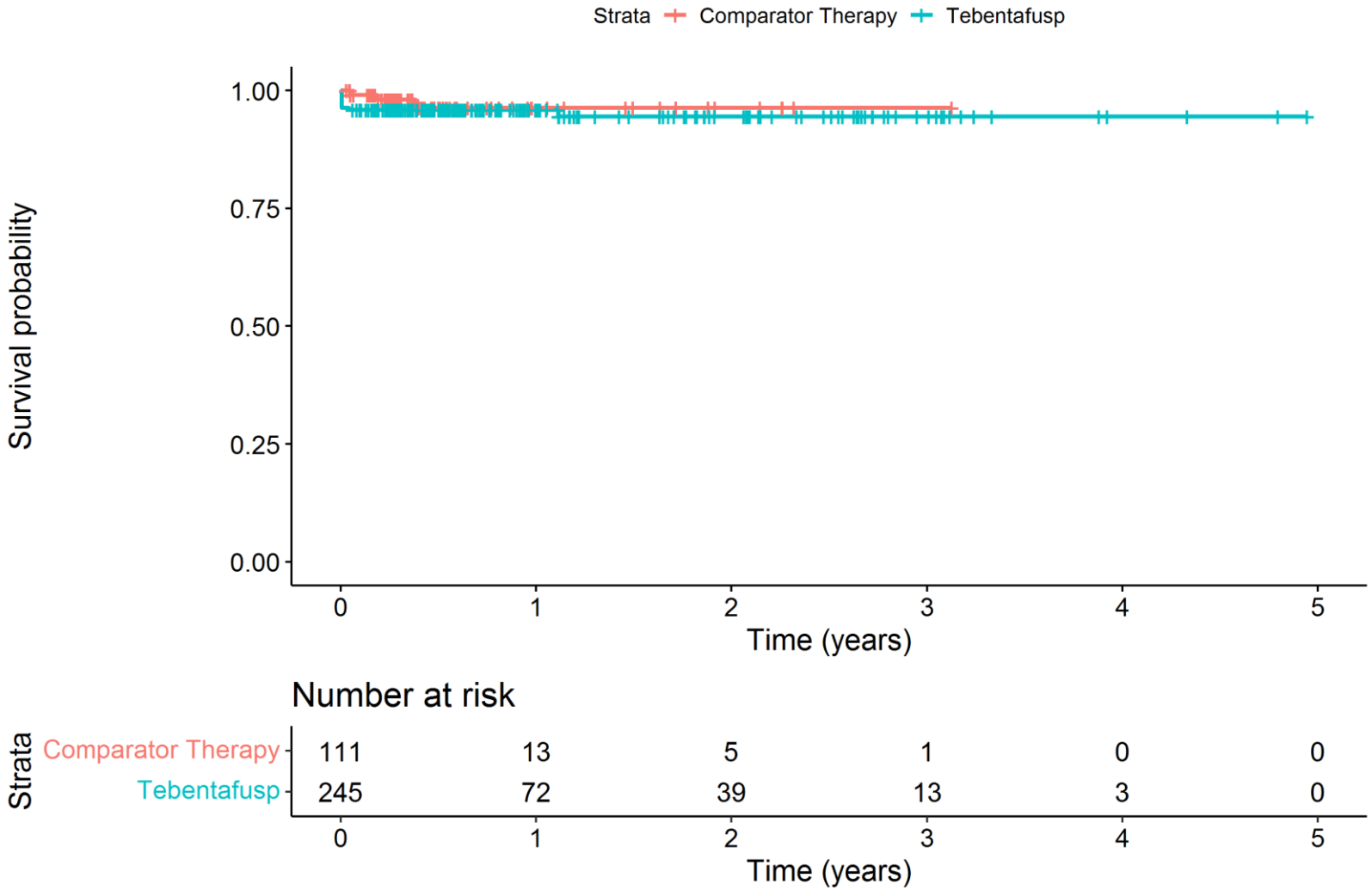


8.28 Hypotonie

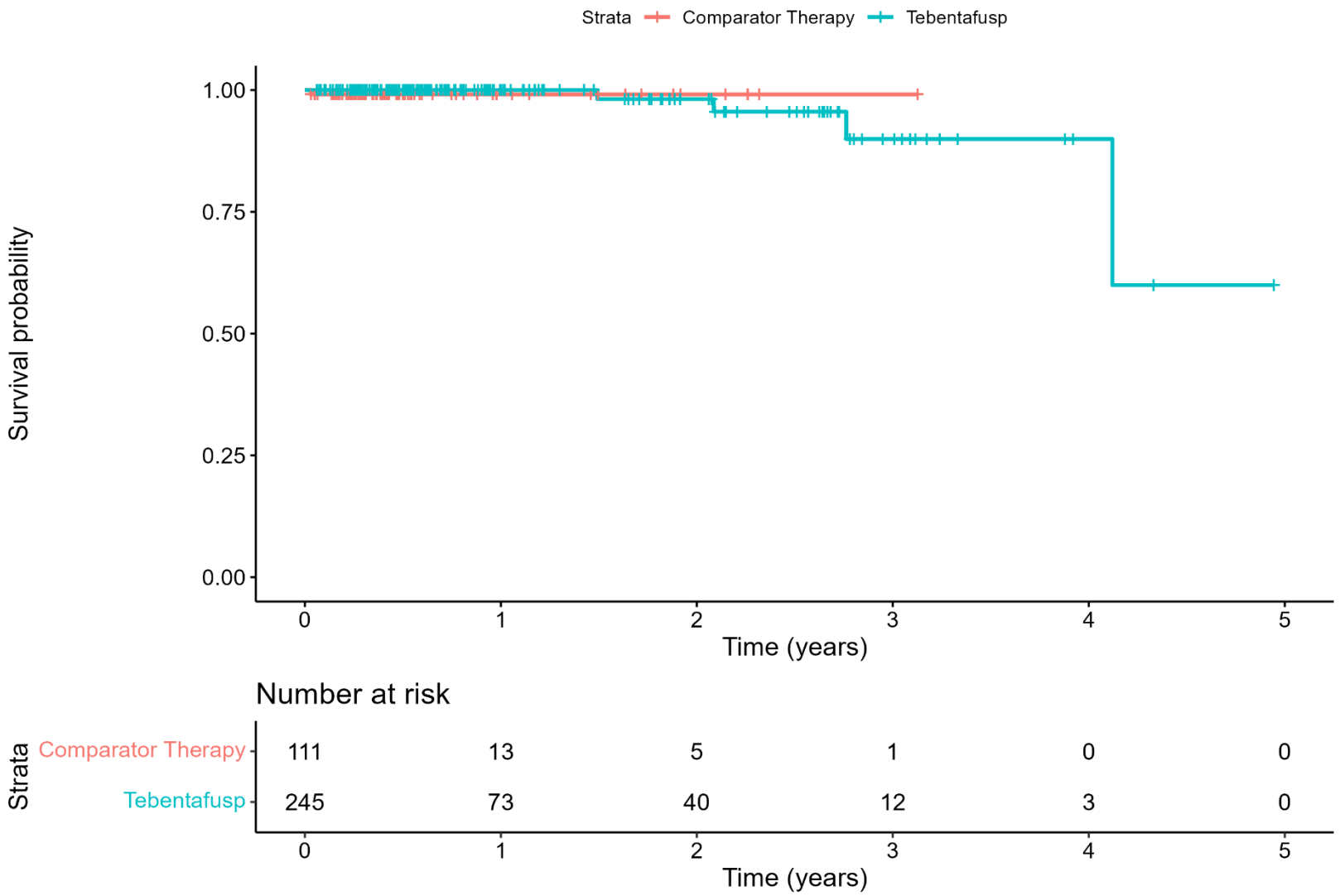


9 UEs (PT) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten

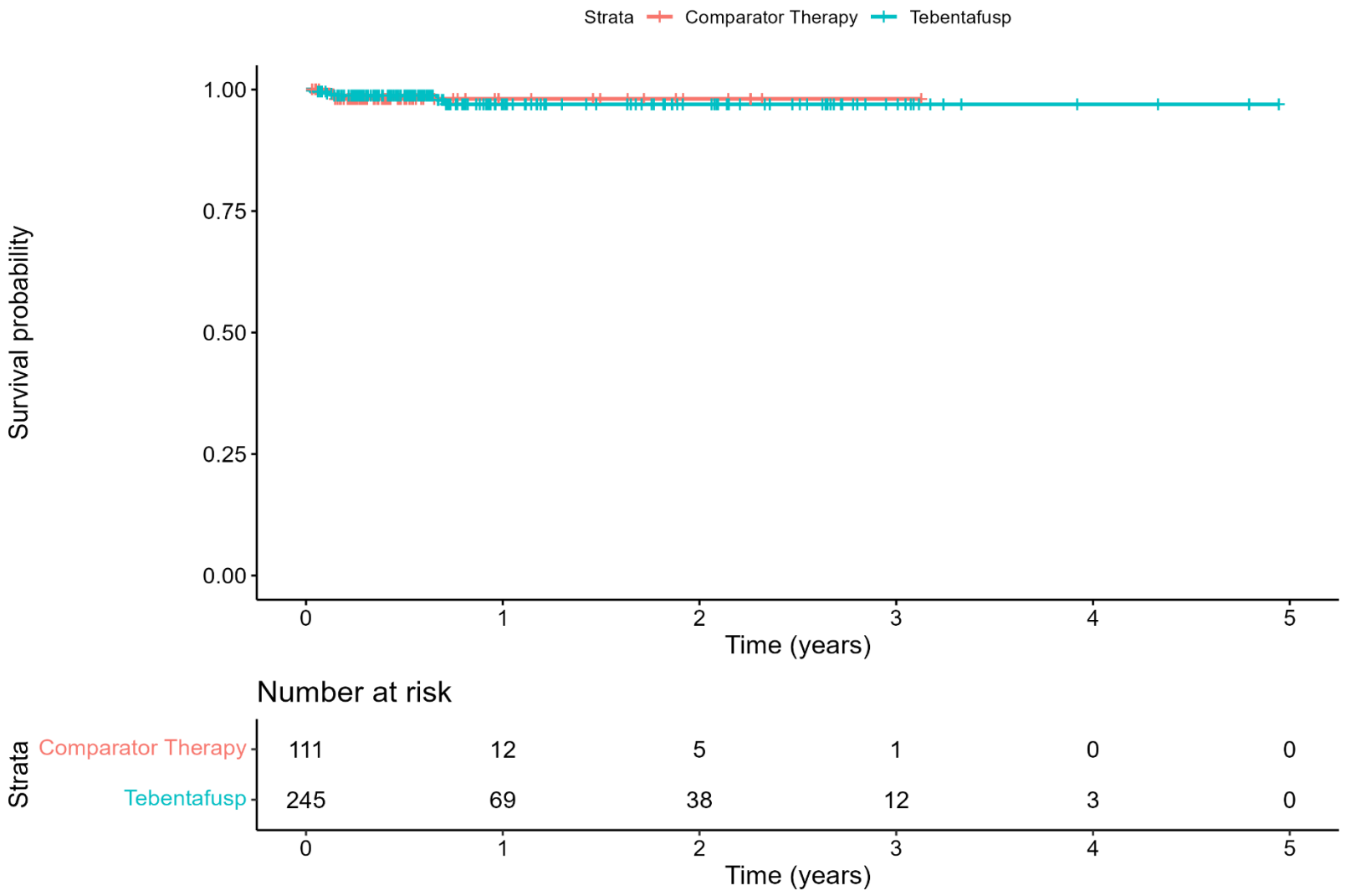
9.1 Erkrankungen des Blutes und des Lymphsystems



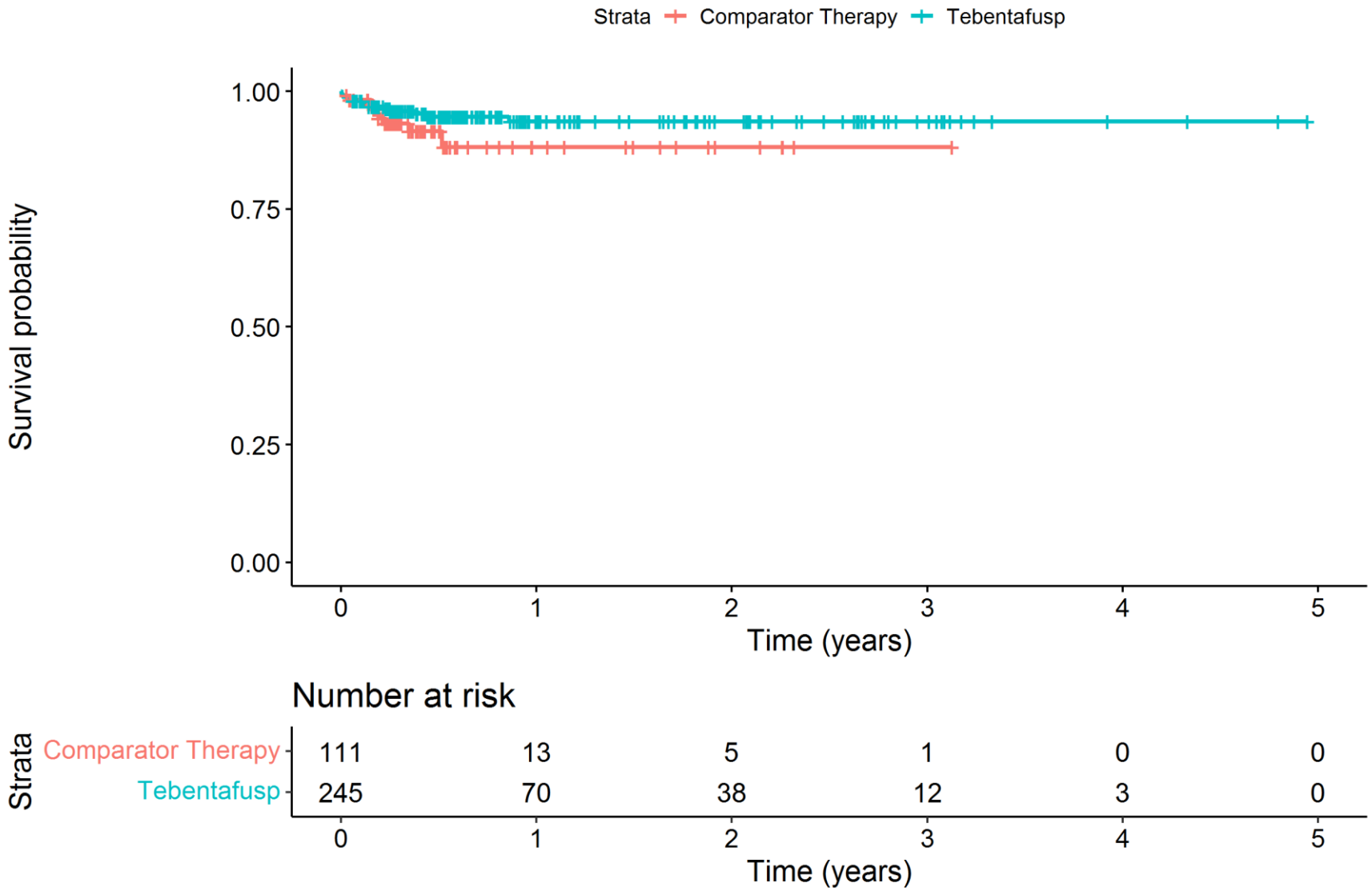
9.2 Herzerkrankungen



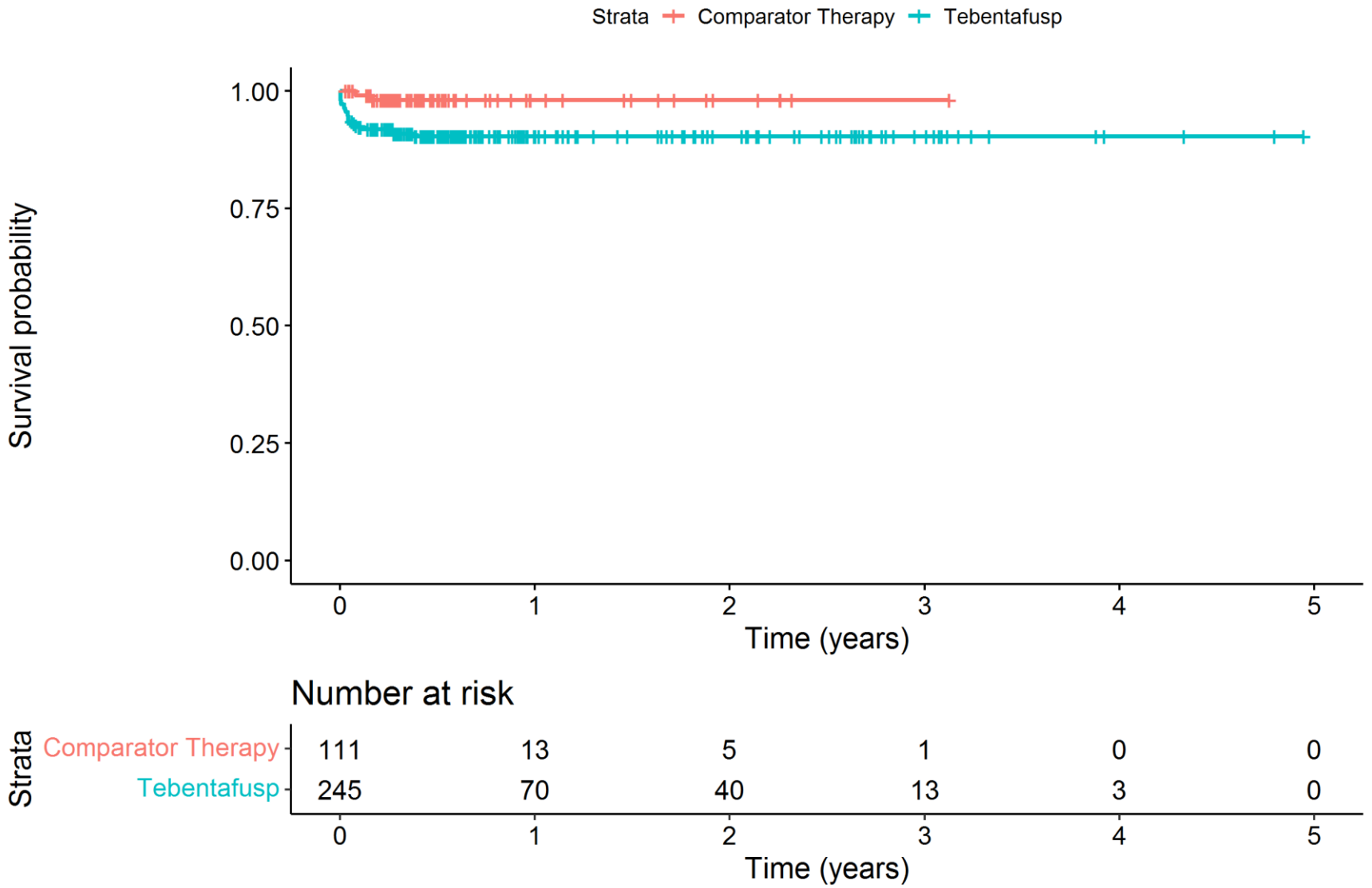
9.3 Augenerkrankungen



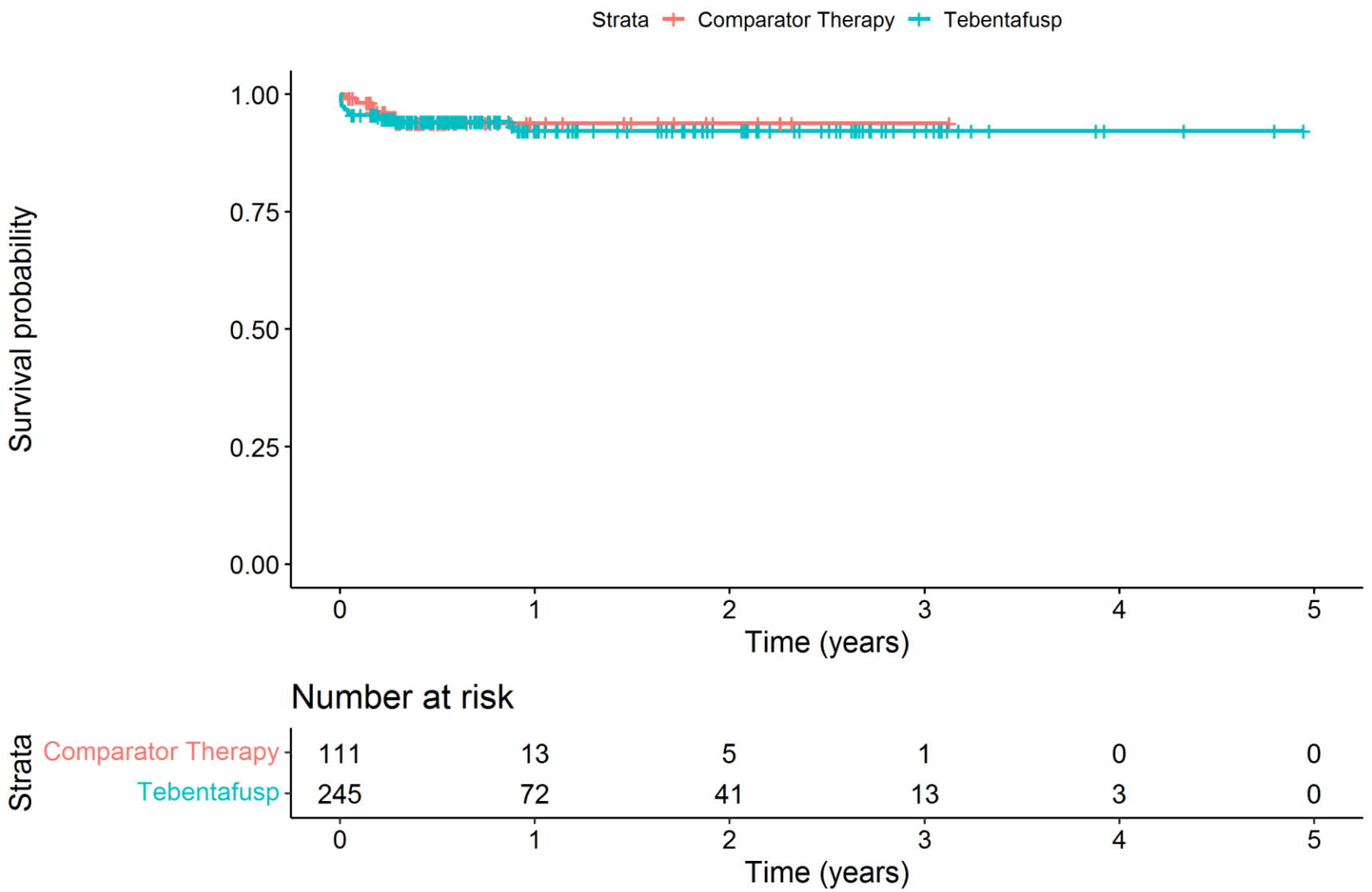
9.4 Erkrankungen des Gastrointestinaltrakts



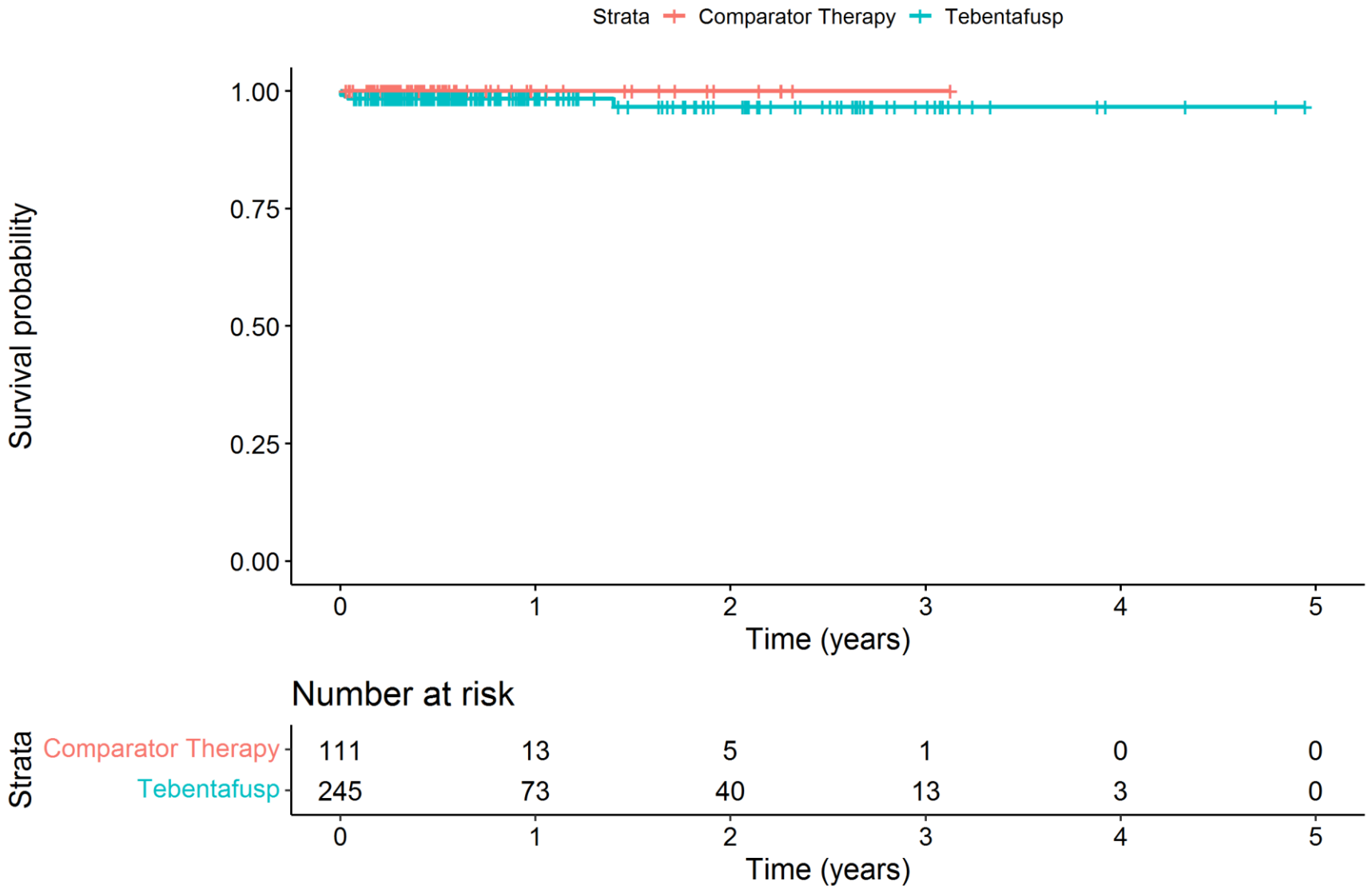
9.5 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



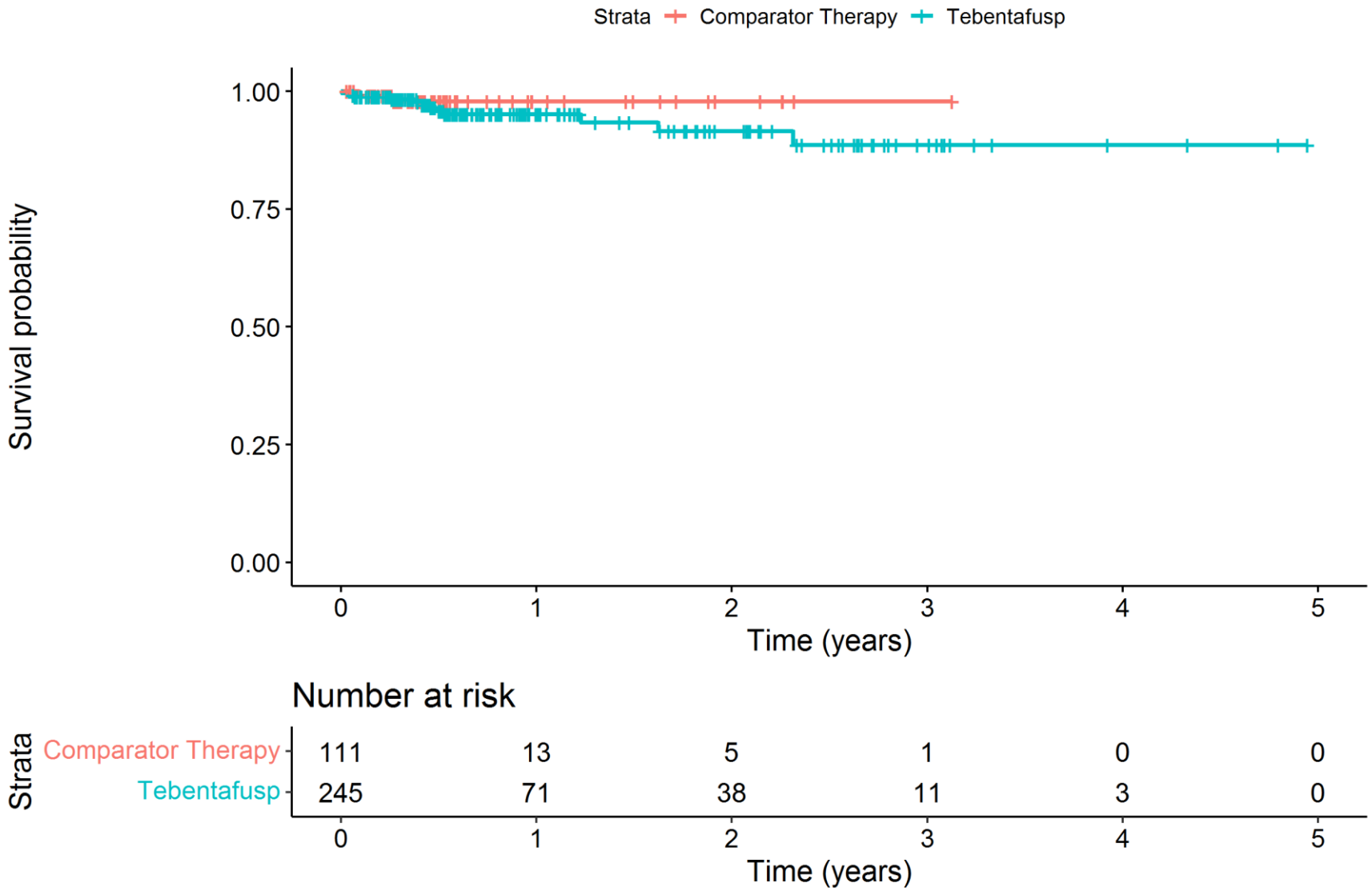
9.6 Leber- und Gallenerkrankungen



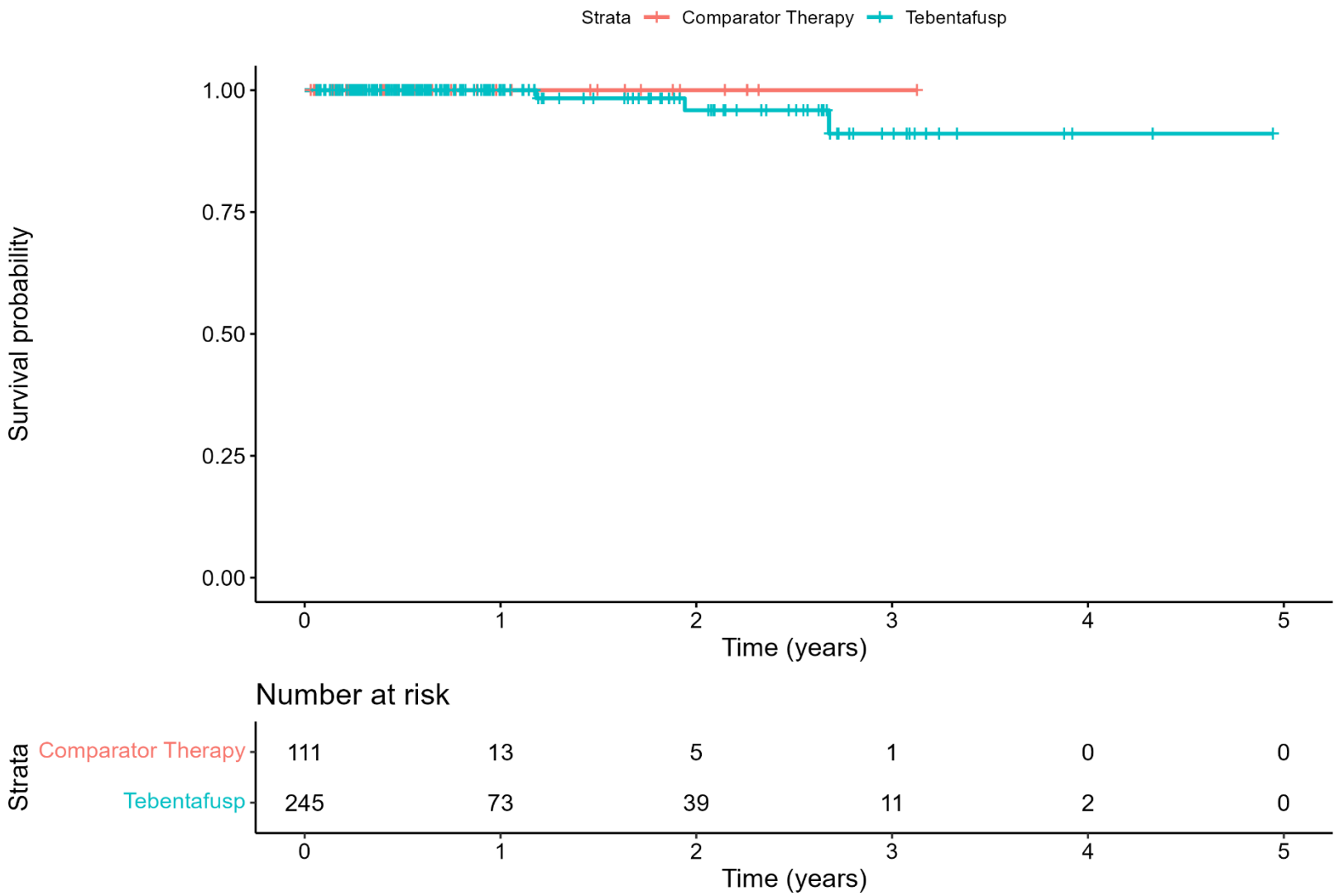
9.7 Erkrankungen des Immunsystems



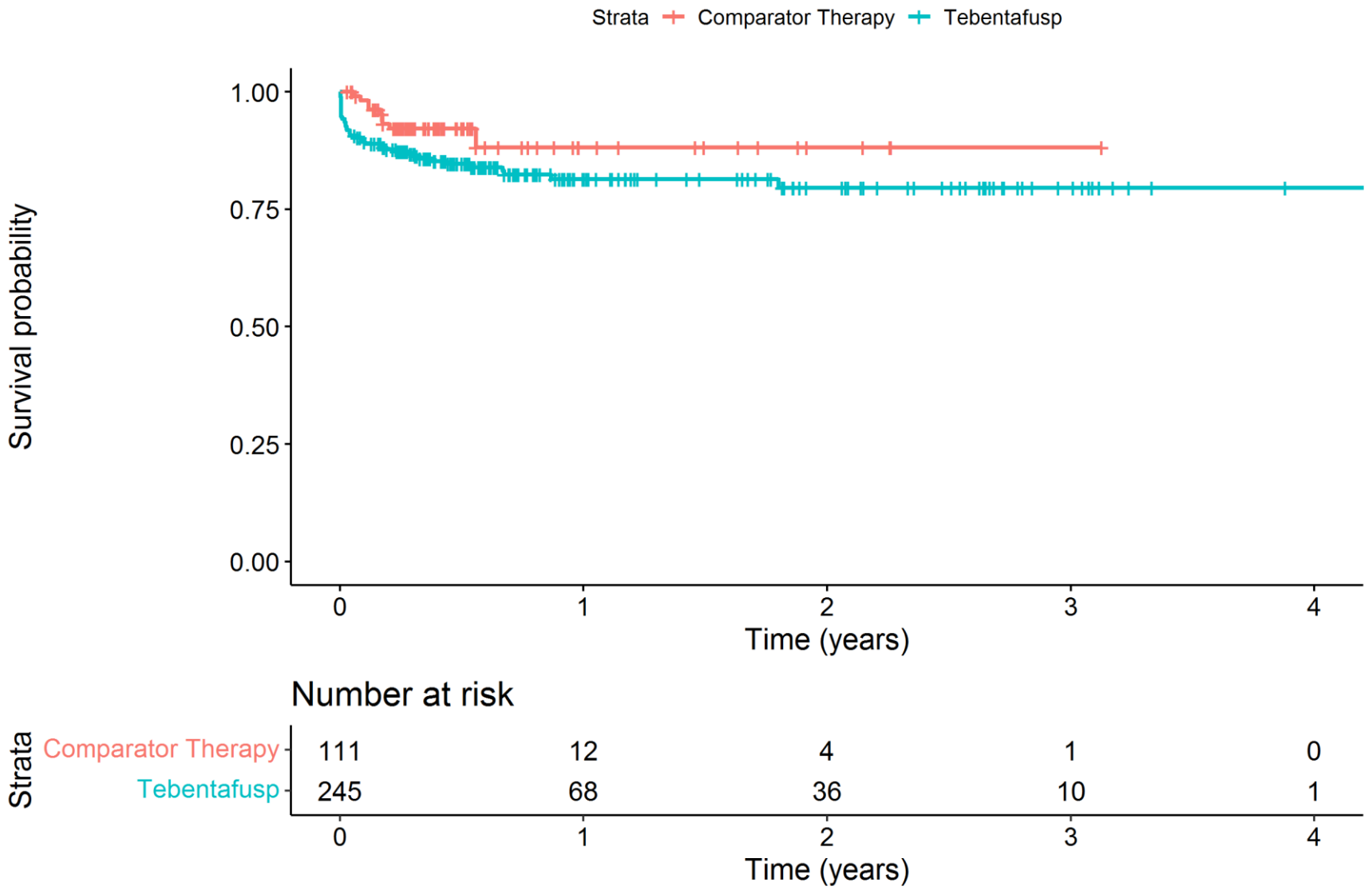
9.8 Infektionen und parasitäre Erkrankungen



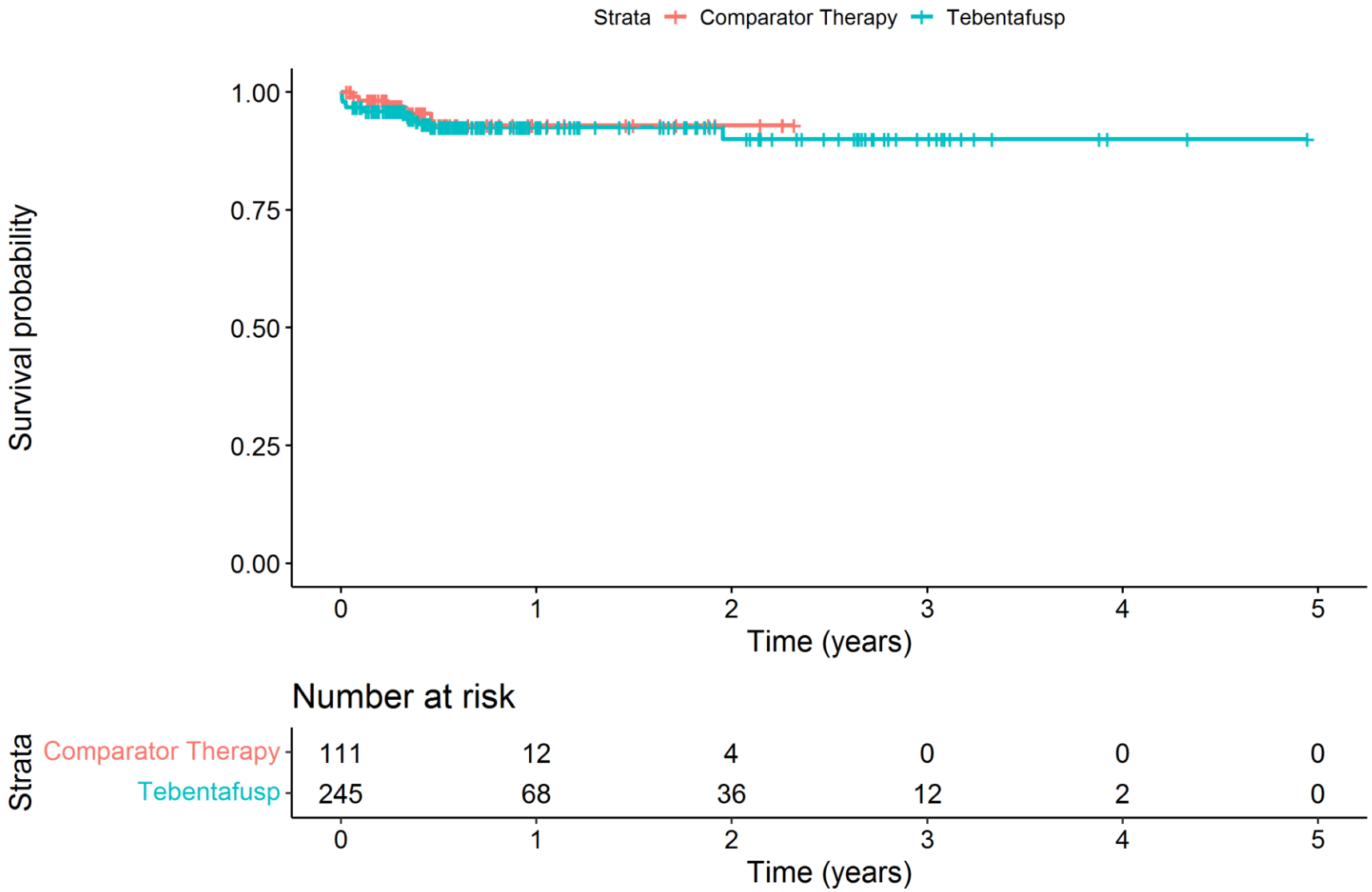
9.9 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



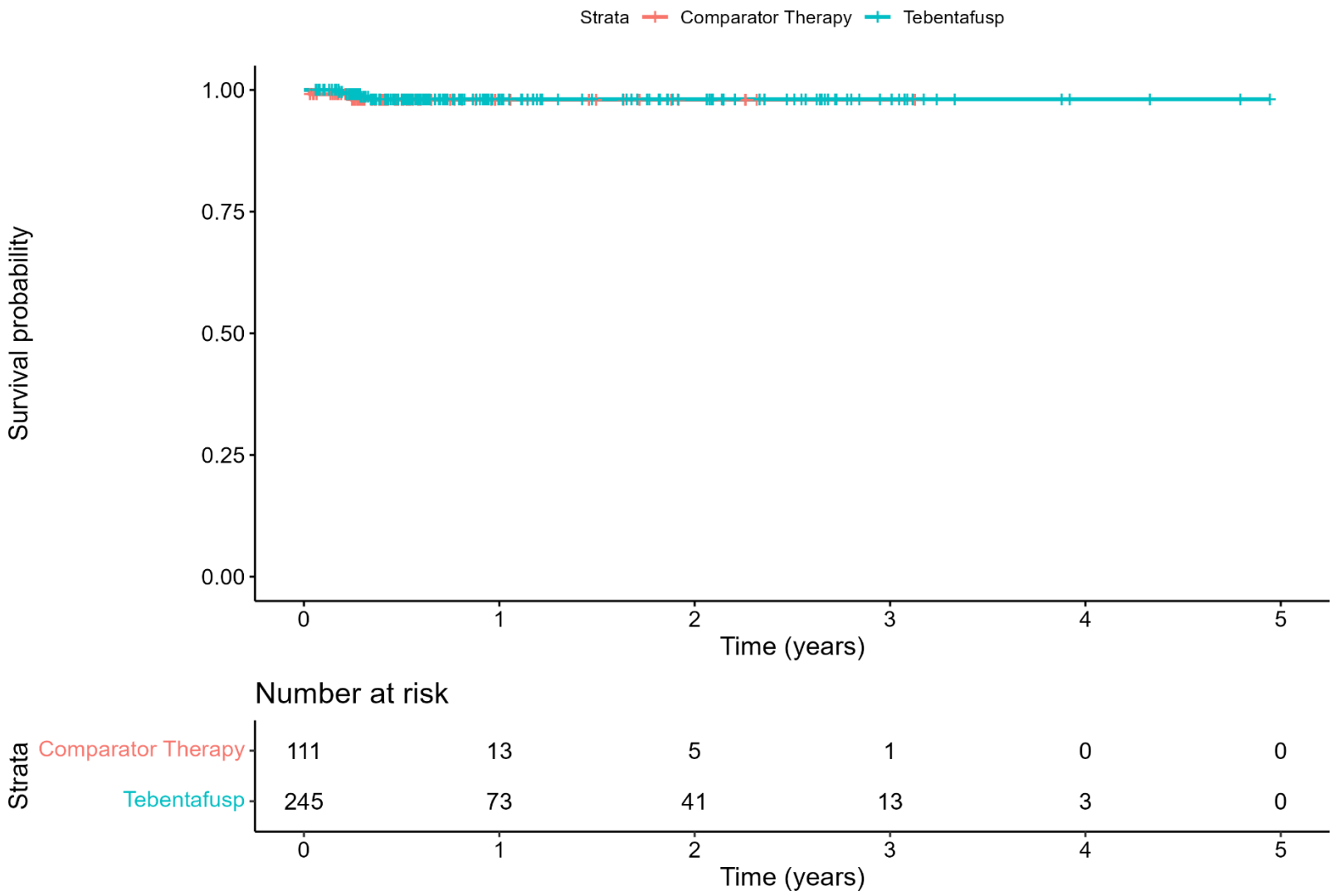
9.10 Untersuchungen



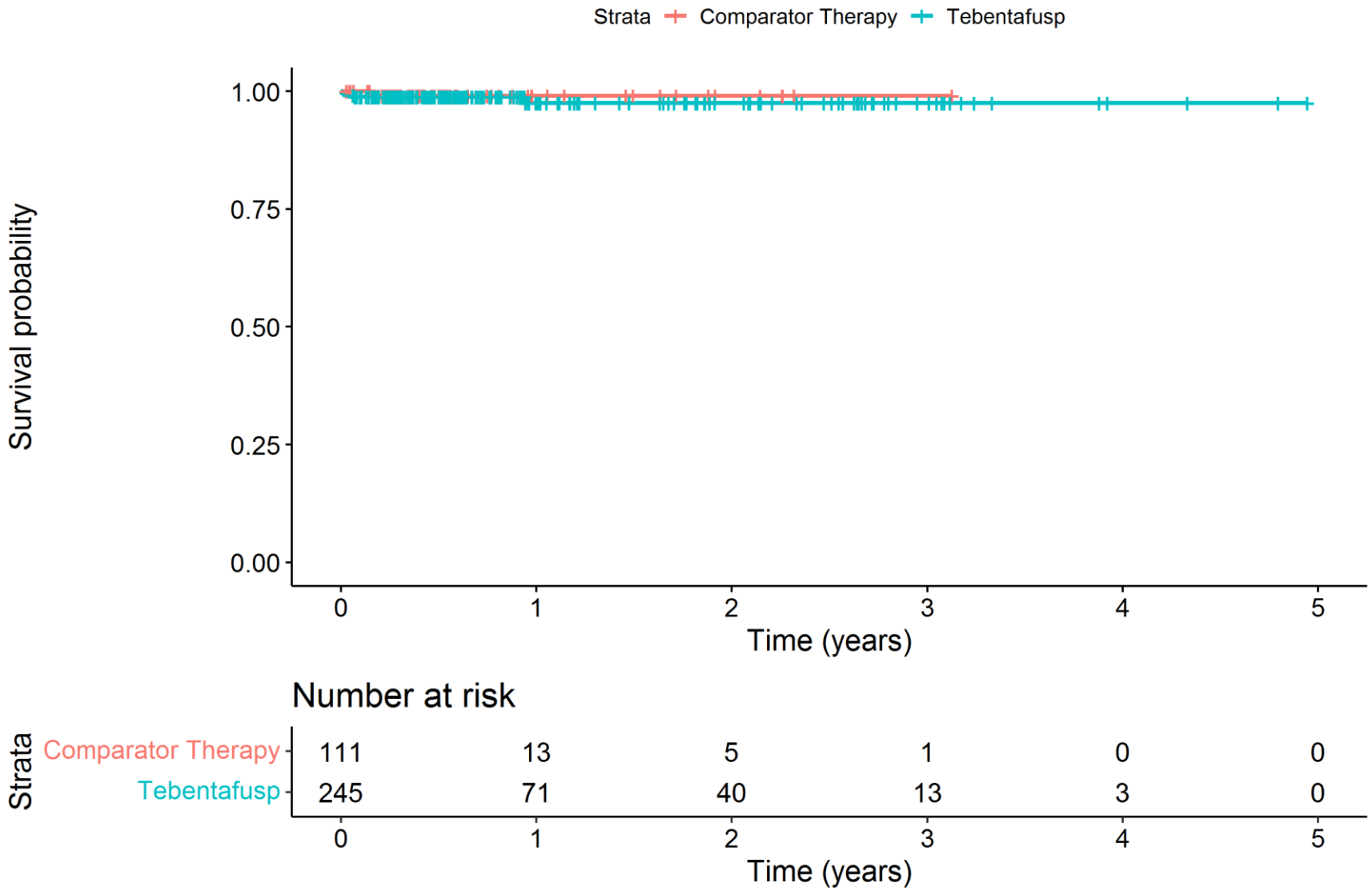
9.11 Stoffwechsel- und Ernährungsstörungen



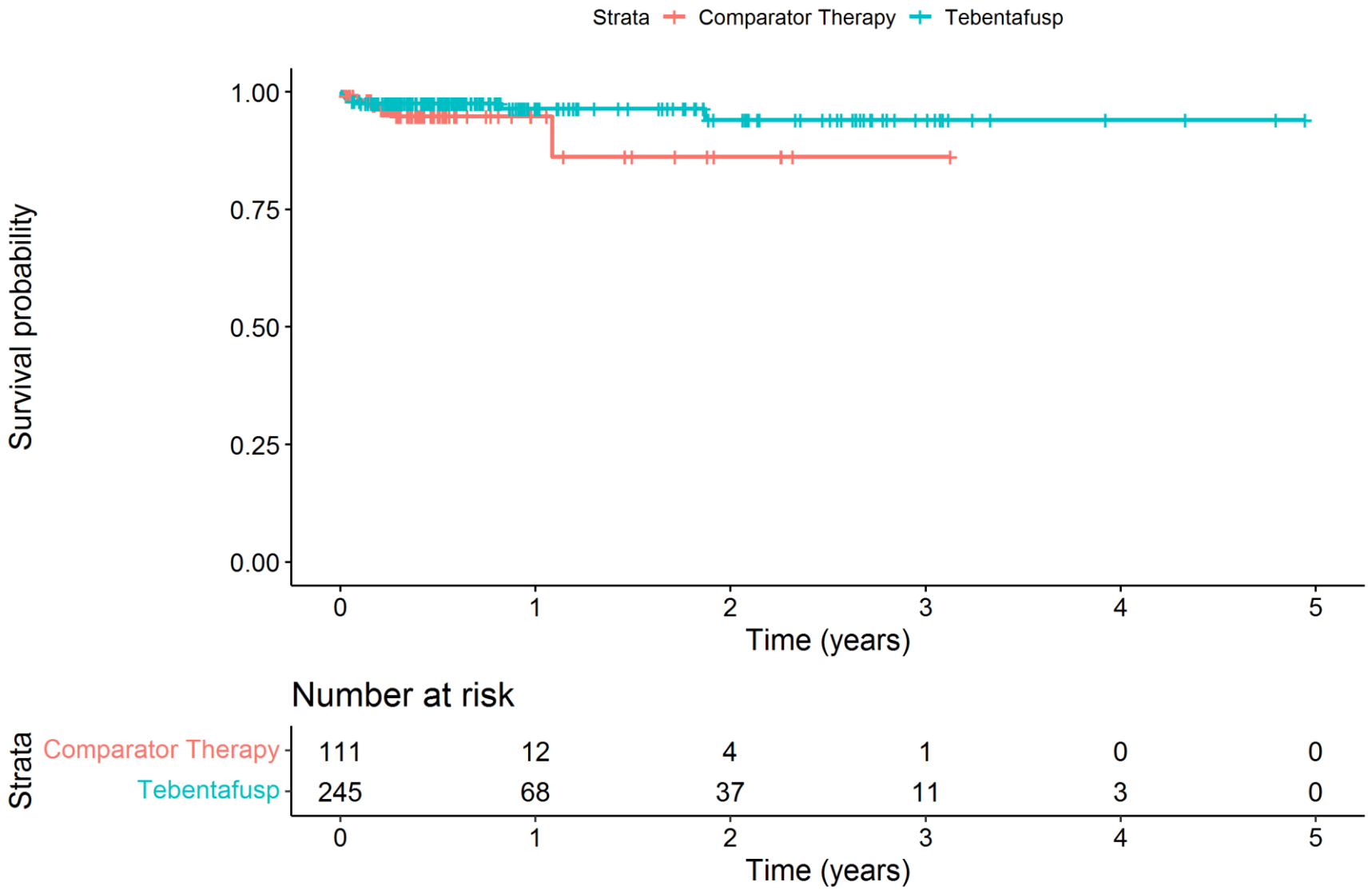
9.12 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



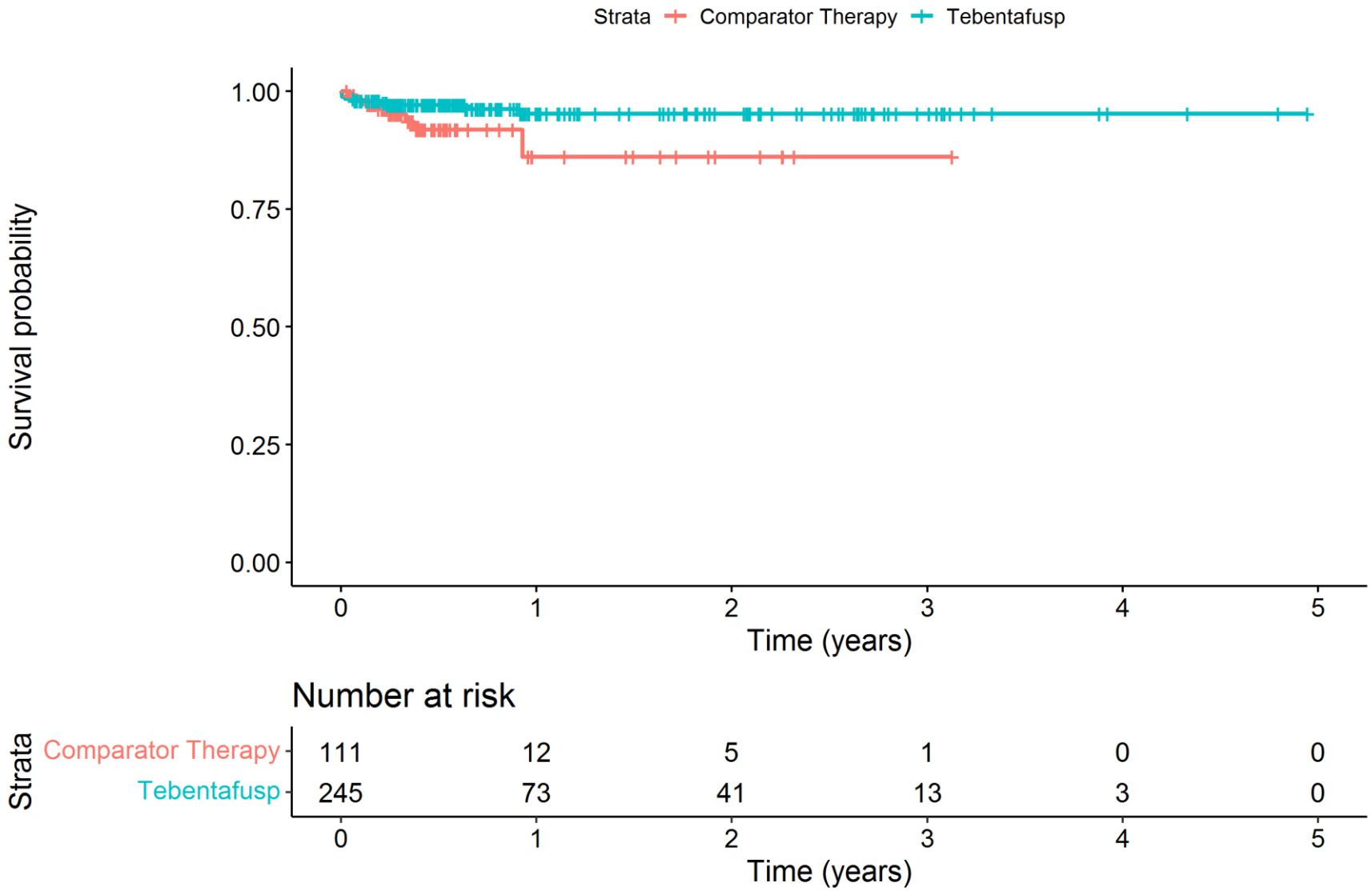
9.13 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



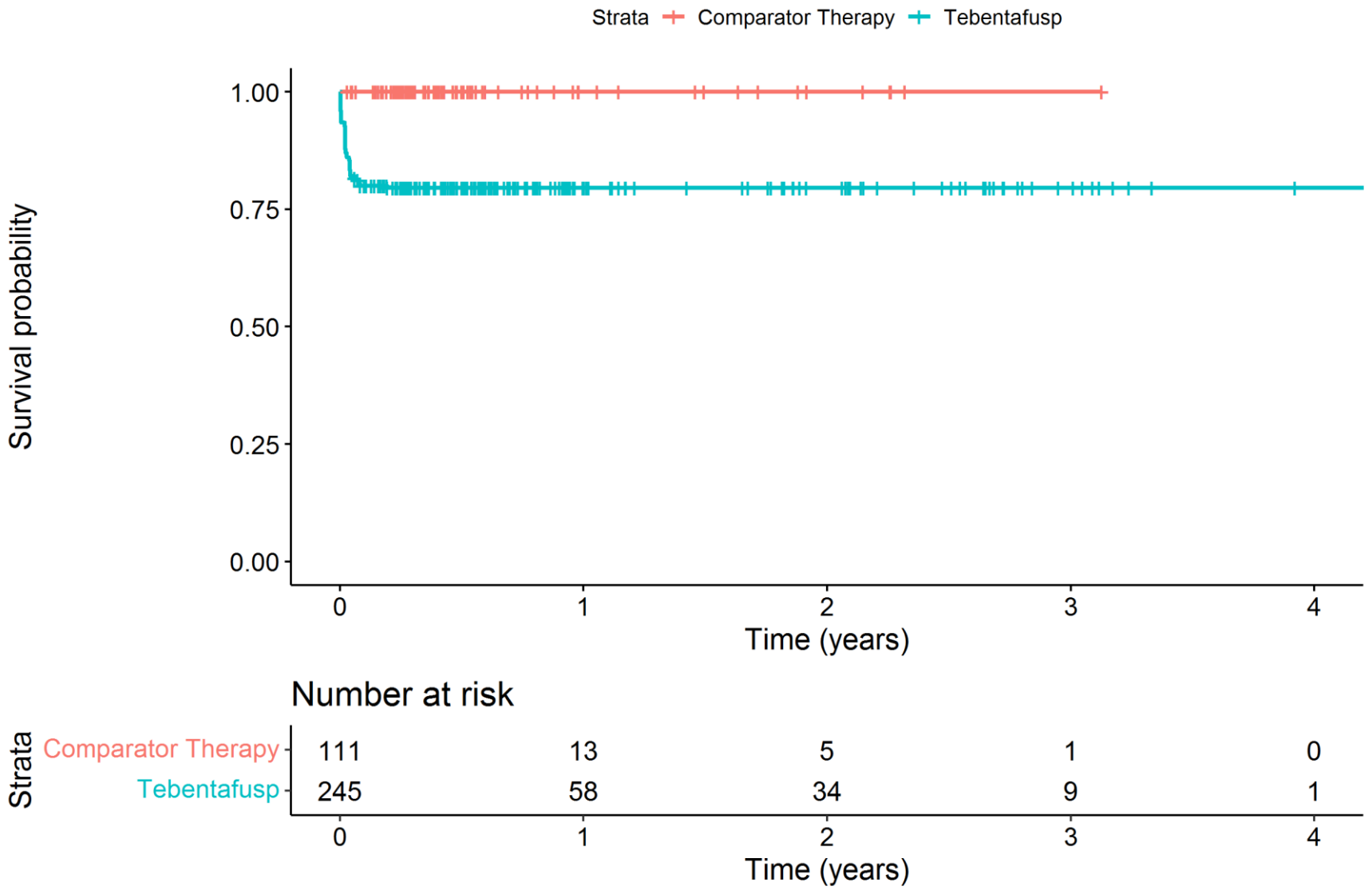
9.14 Erkrankungen des Nervensystems



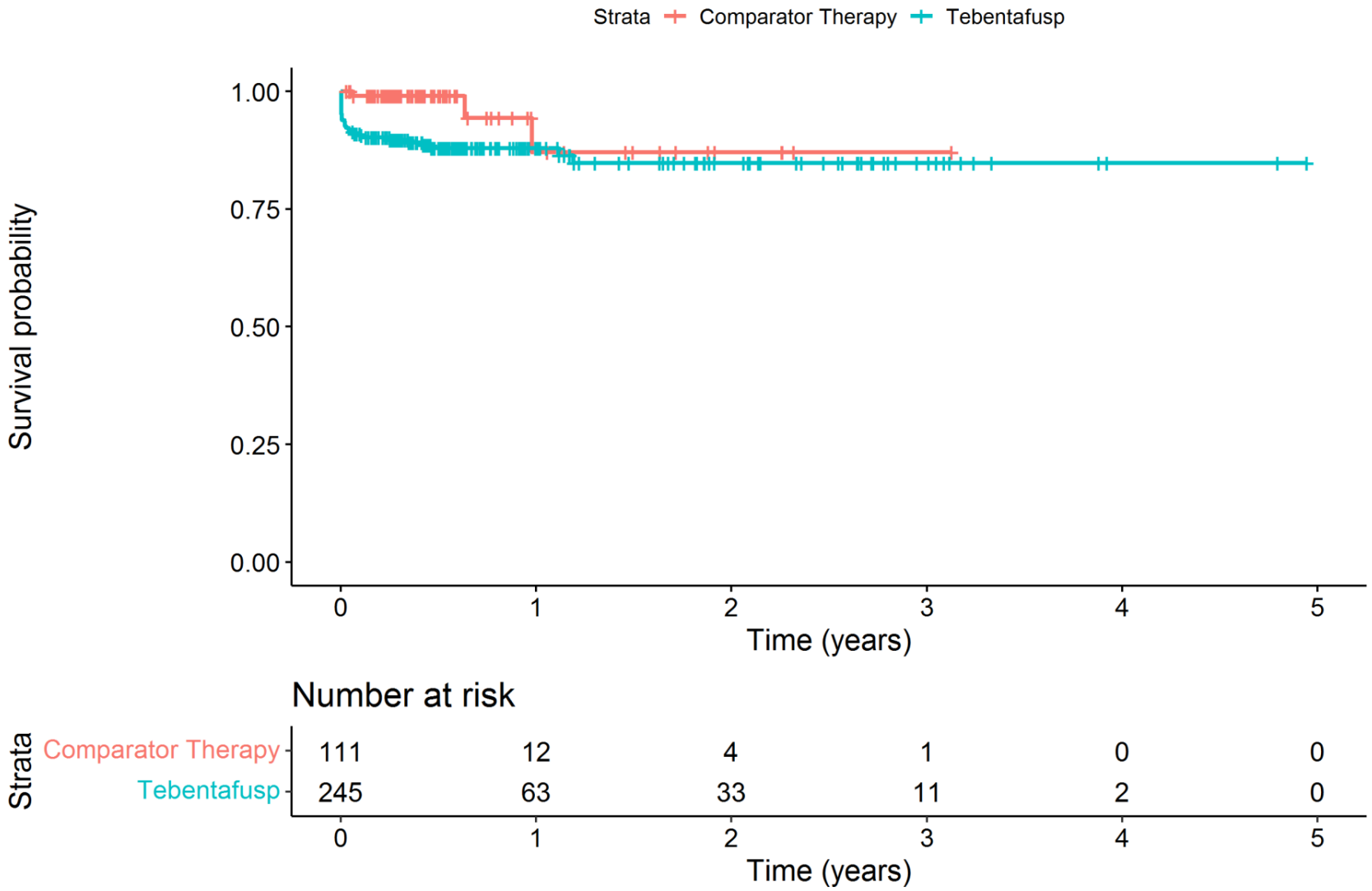
9.15 Erkrankungen der Atemwege, des Brustraums und Mediastinums



9.16 Erkrankungen der Haut und des Unterhautgewebes



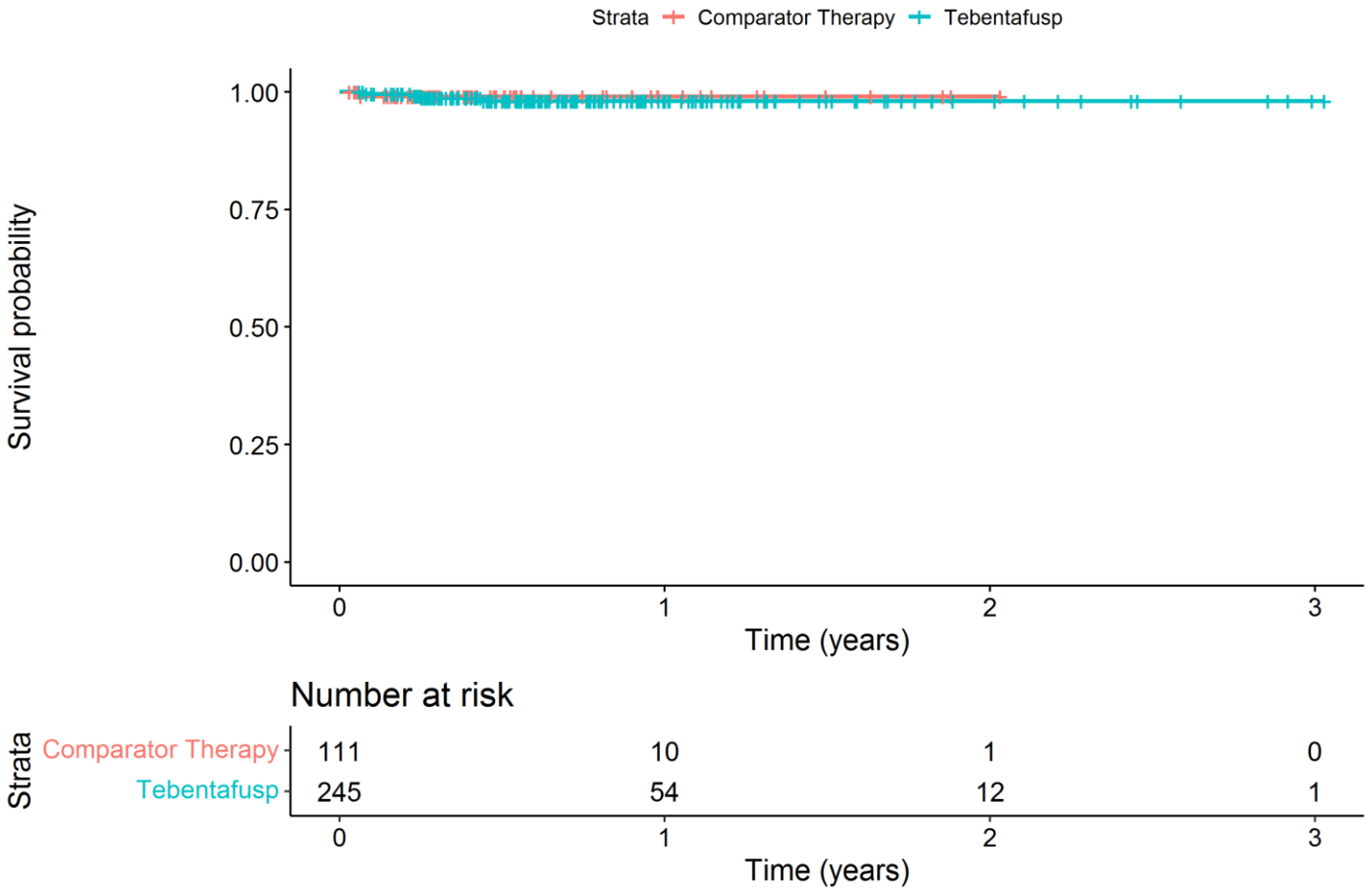
9.17 Gefäßerkrankungen



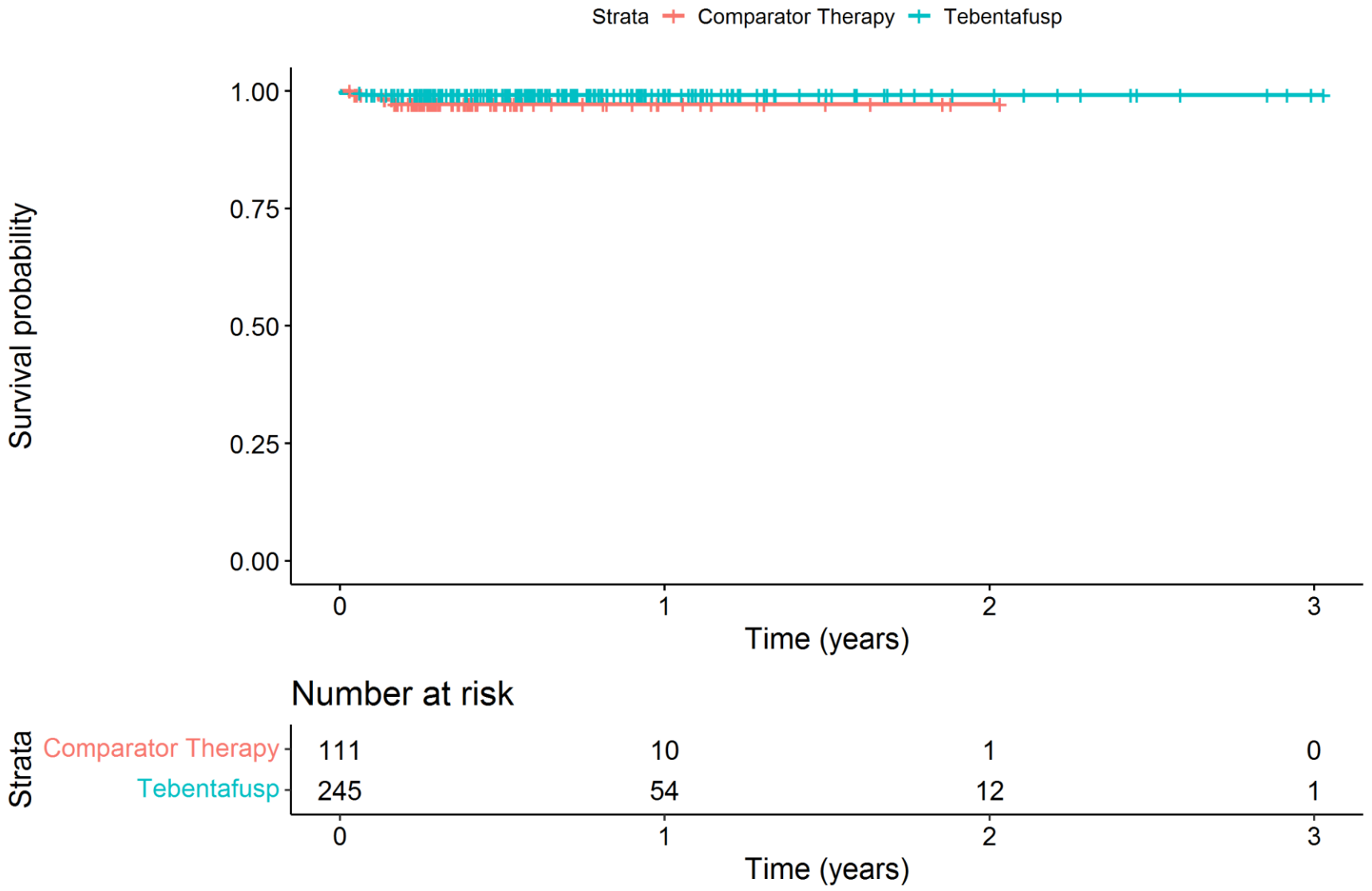
9.18 Schwerwiegende unerwünschte Ereignisse (SUEs) nach SOC und PT – Primäranalyse (Oktober 2020) (Tabelle 4-65)

10 SUEs (PT) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten

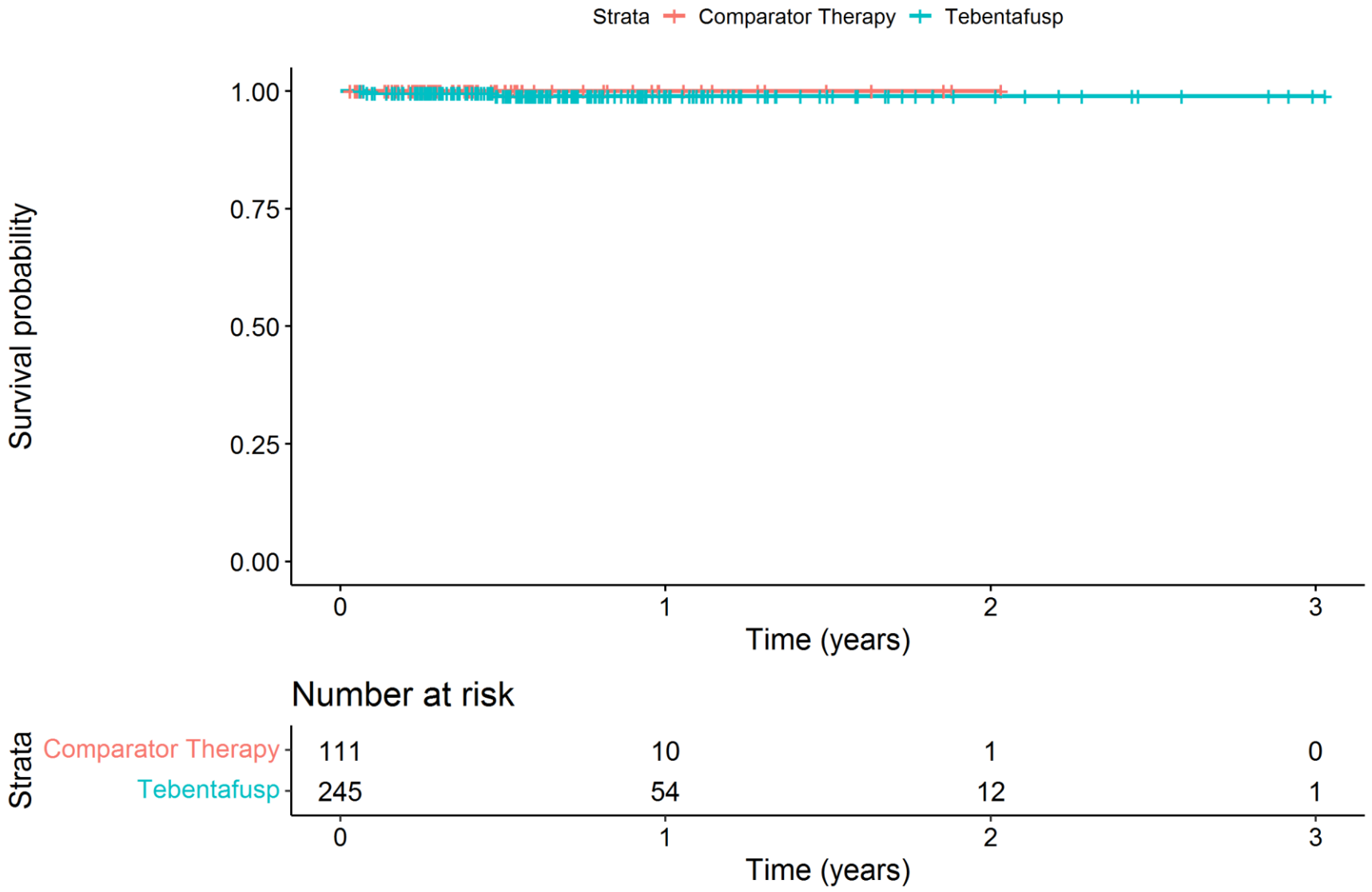
10.1 Übelkeit



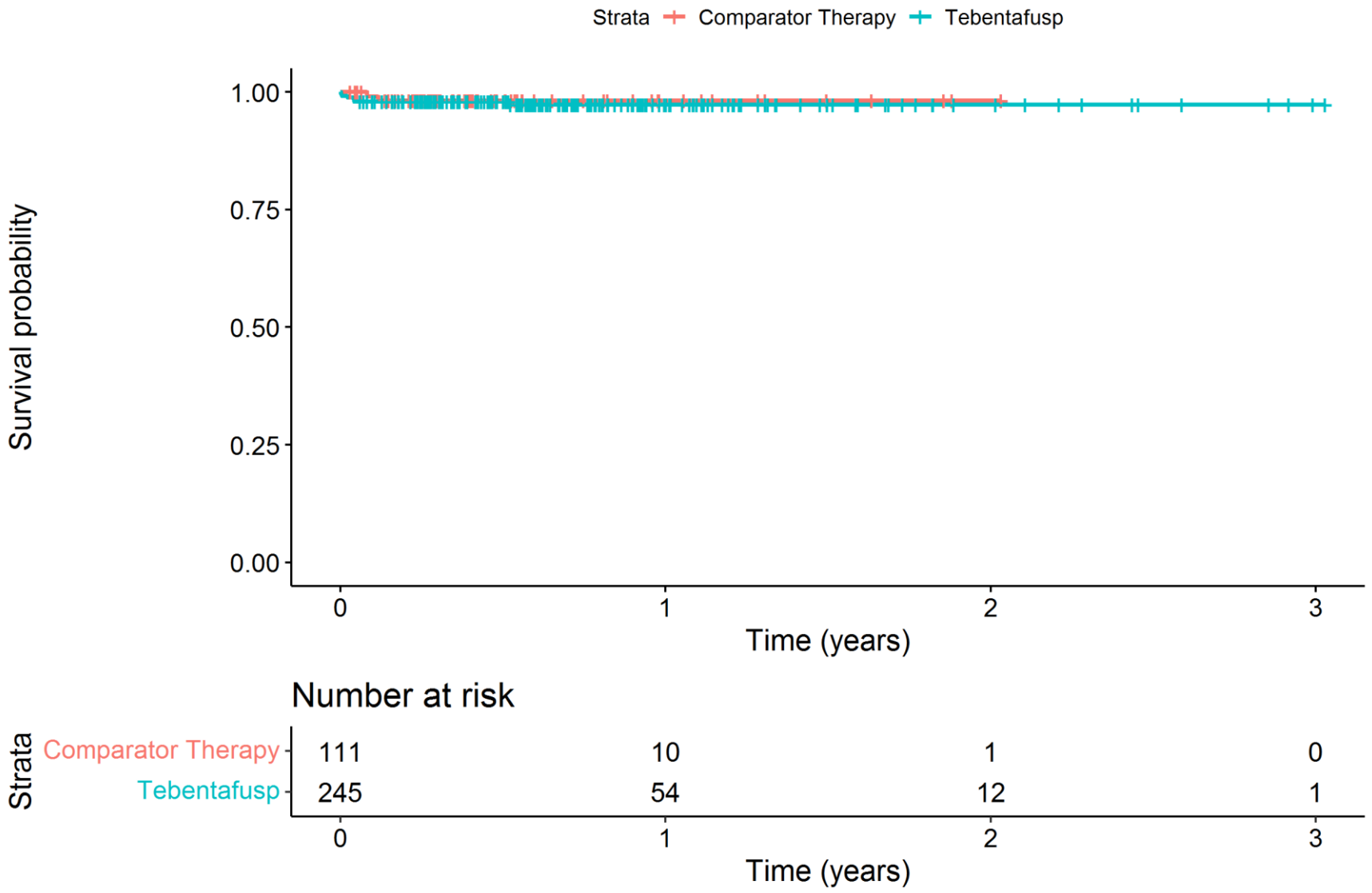
10.2 Unterleibsschmerzen



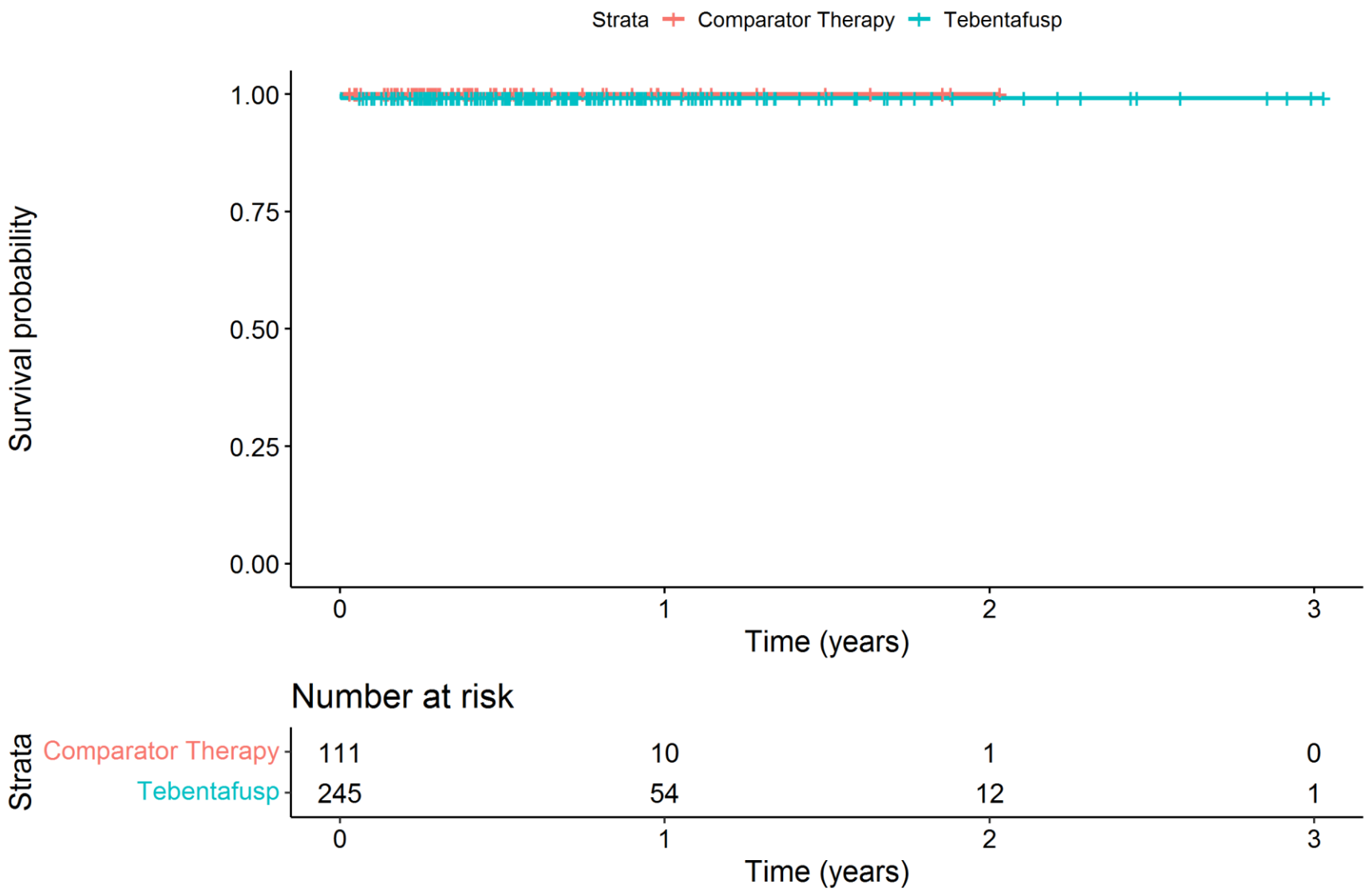
10.3 Erbrechen



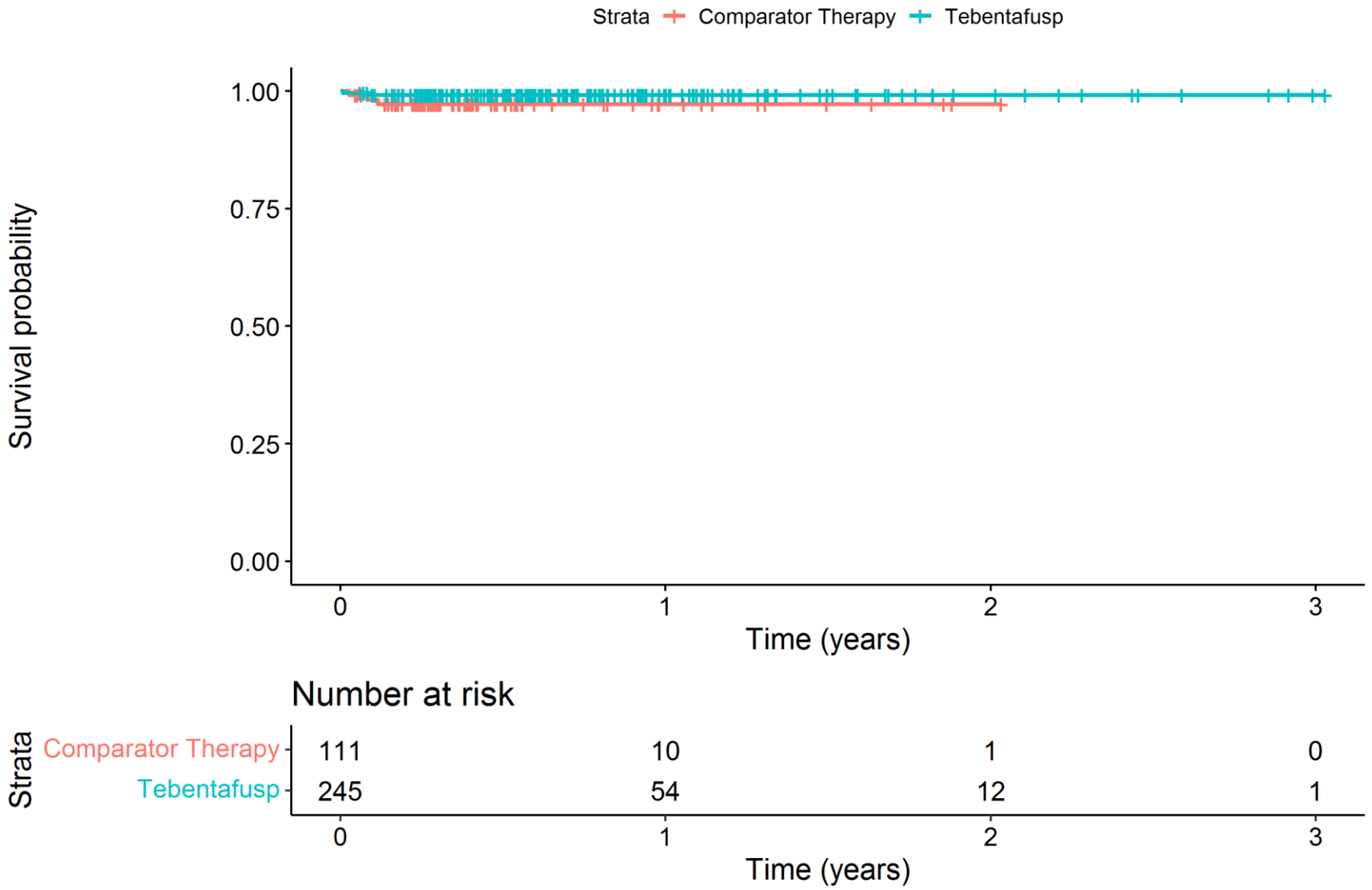
10.4 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
54
12
1
0
1
2
3
Time (years)

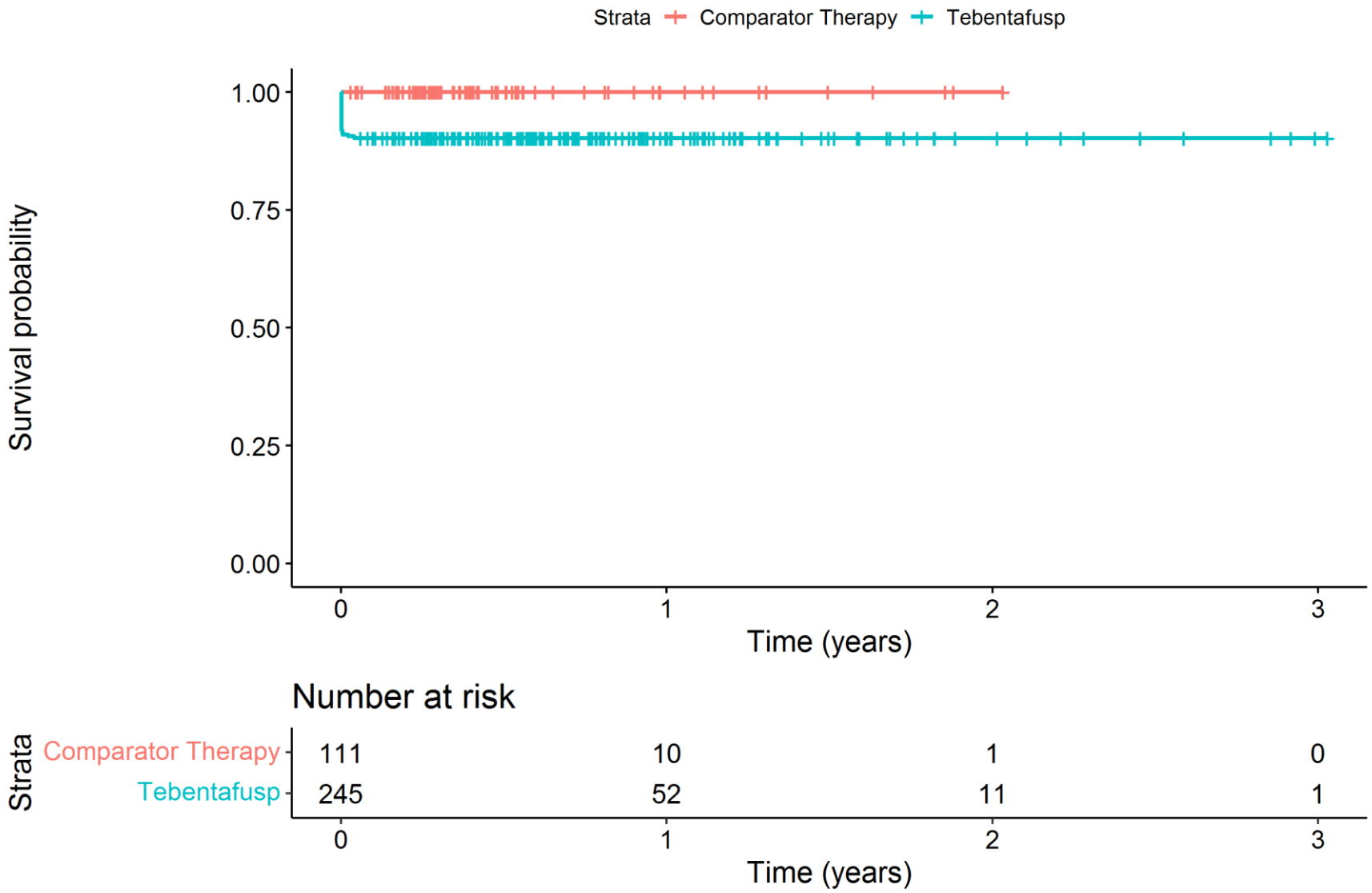
10.5 Hepatotoxizität



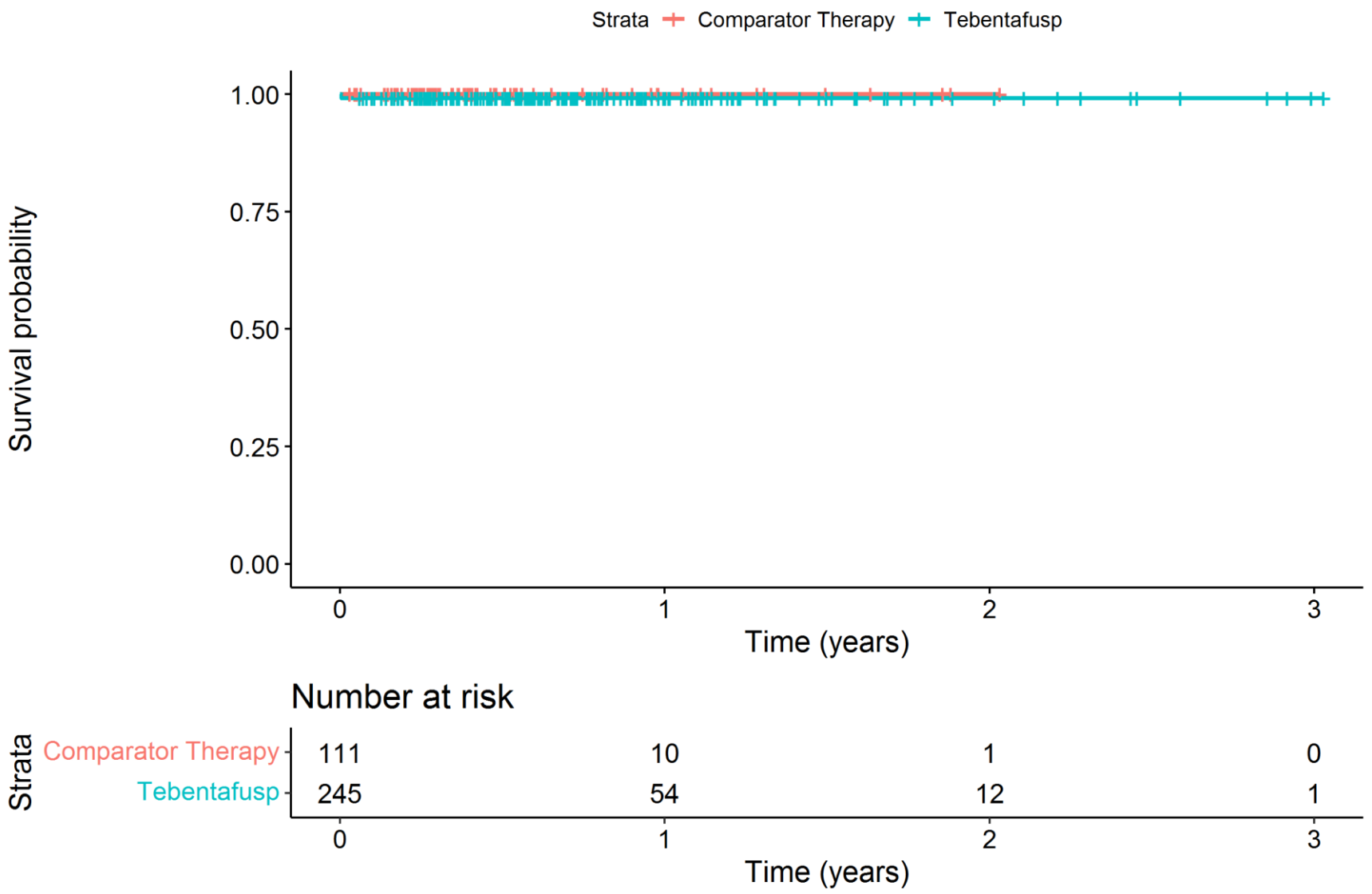
10.6 Hyperbilirubinämie



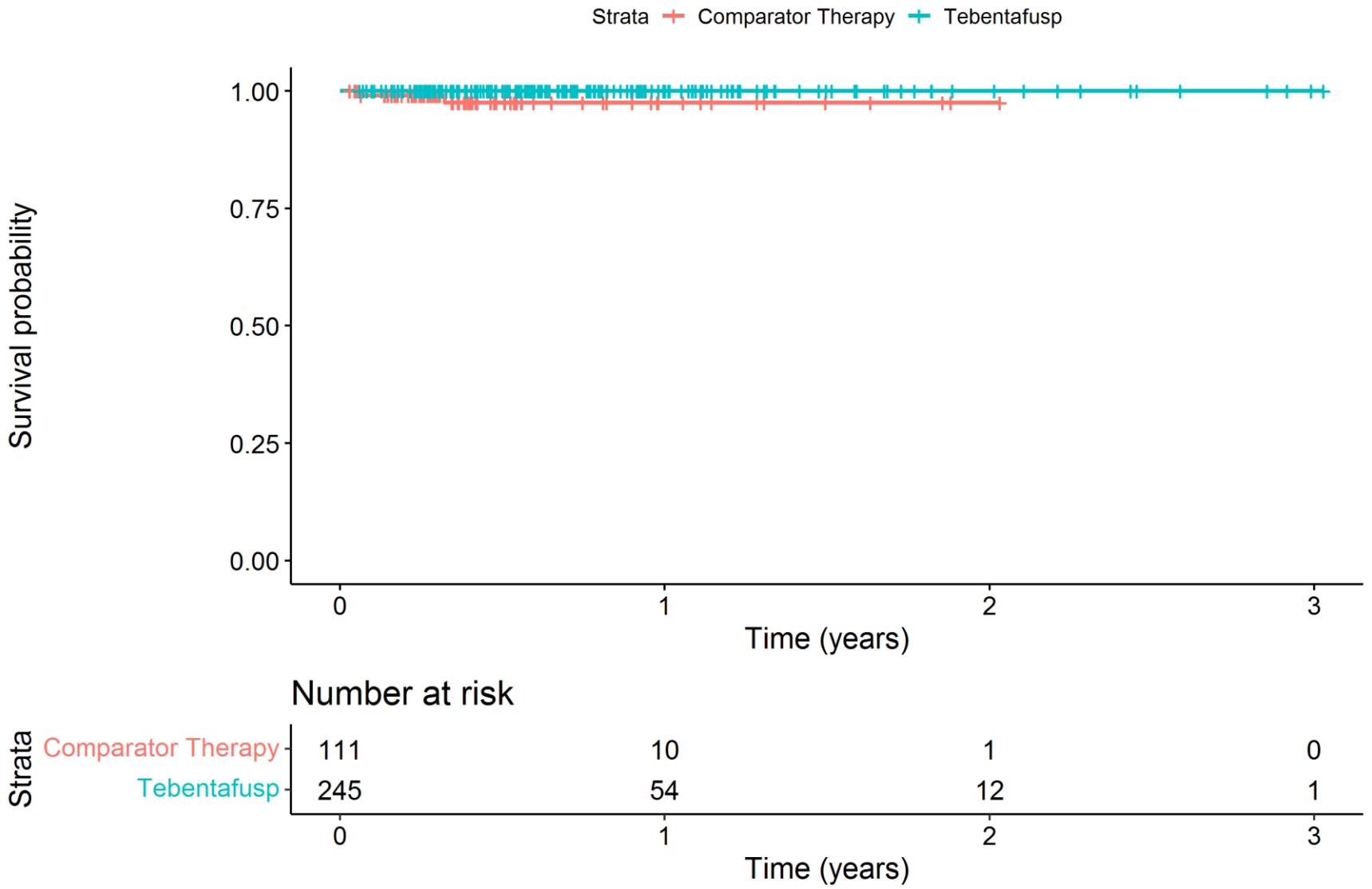
10.7 Zytokin-Freisetzungssyndrom



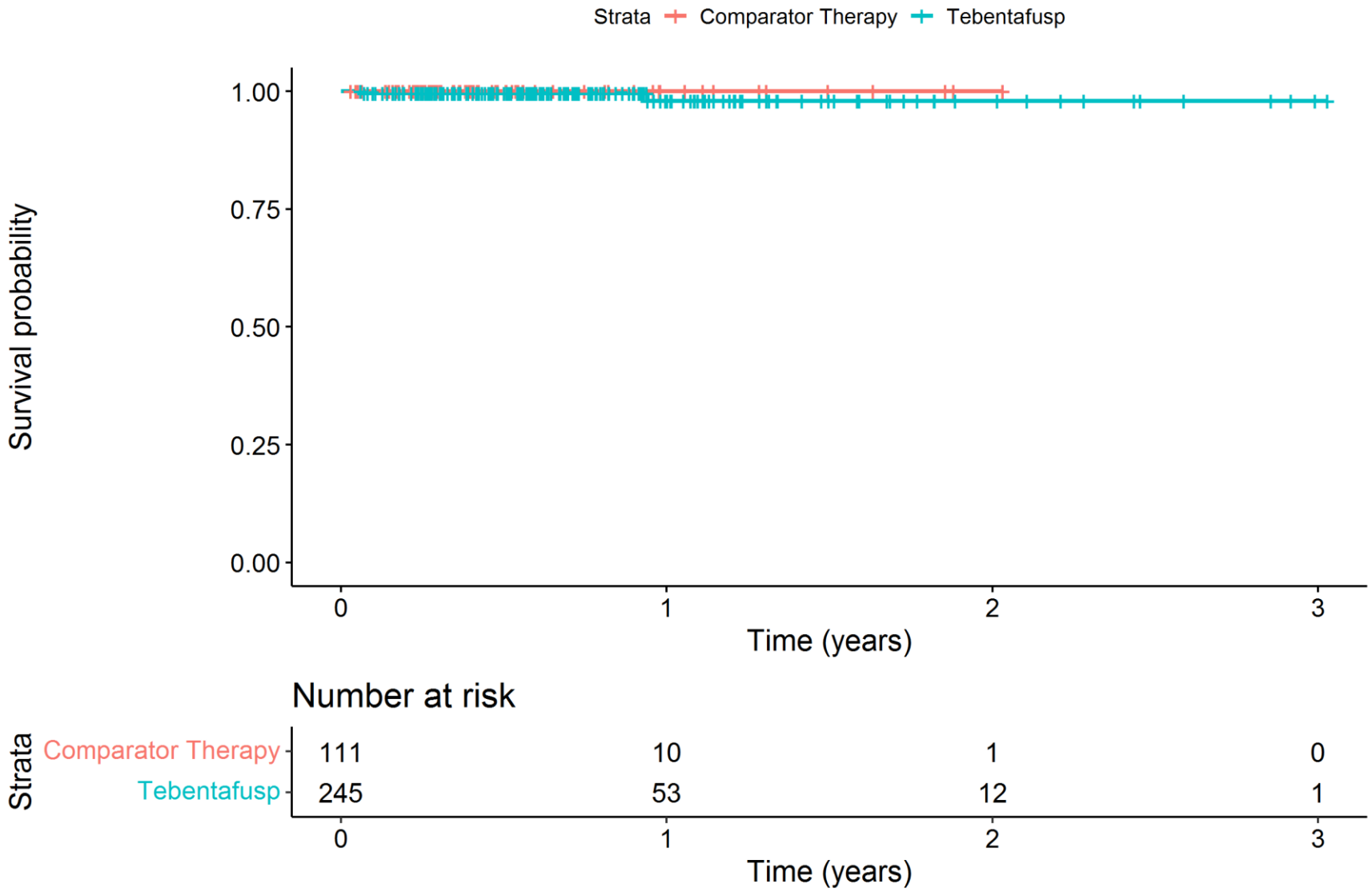
10.8 Kreatinin im Blut erhöht



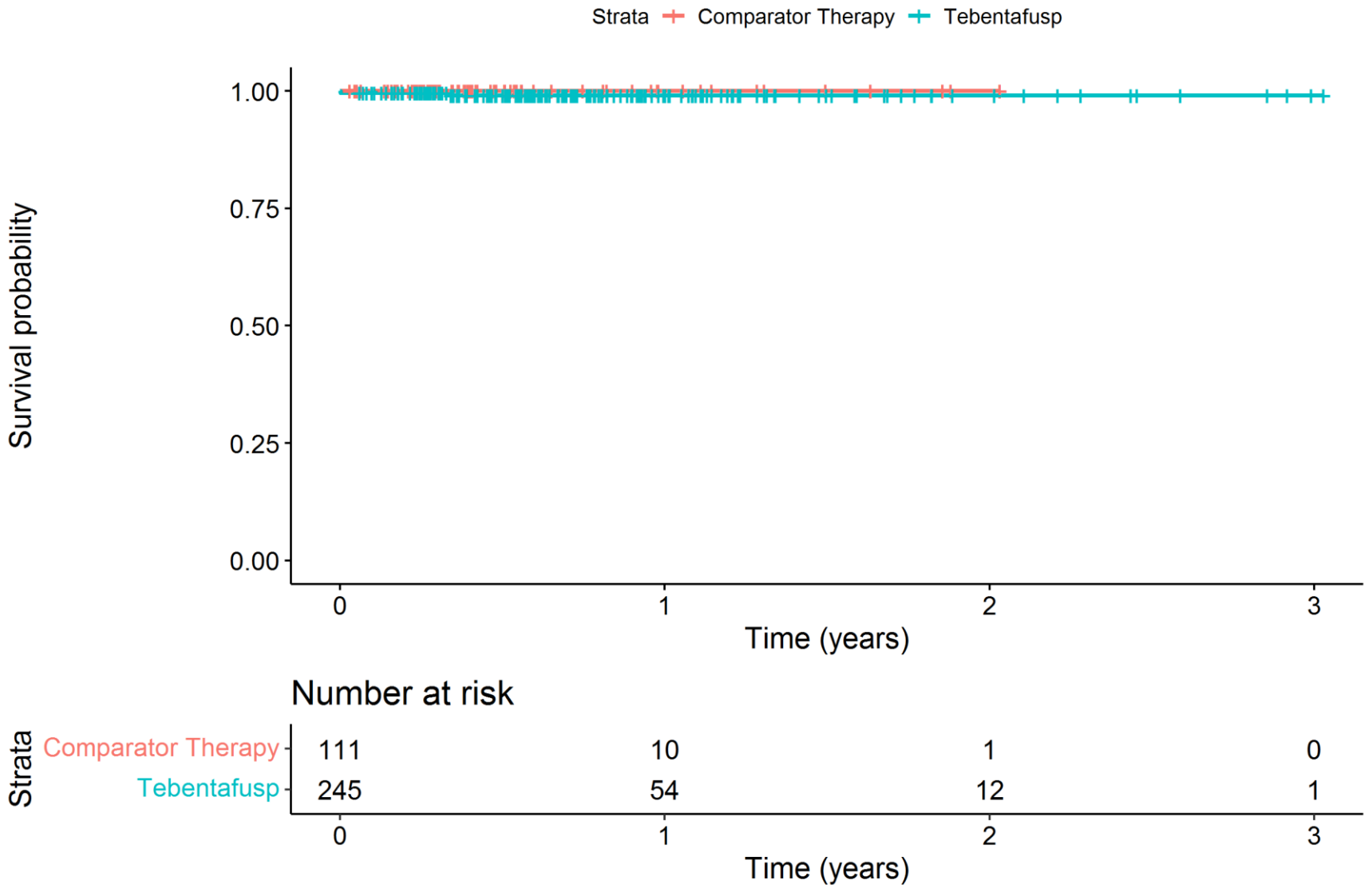
10.9 Dehydrierung



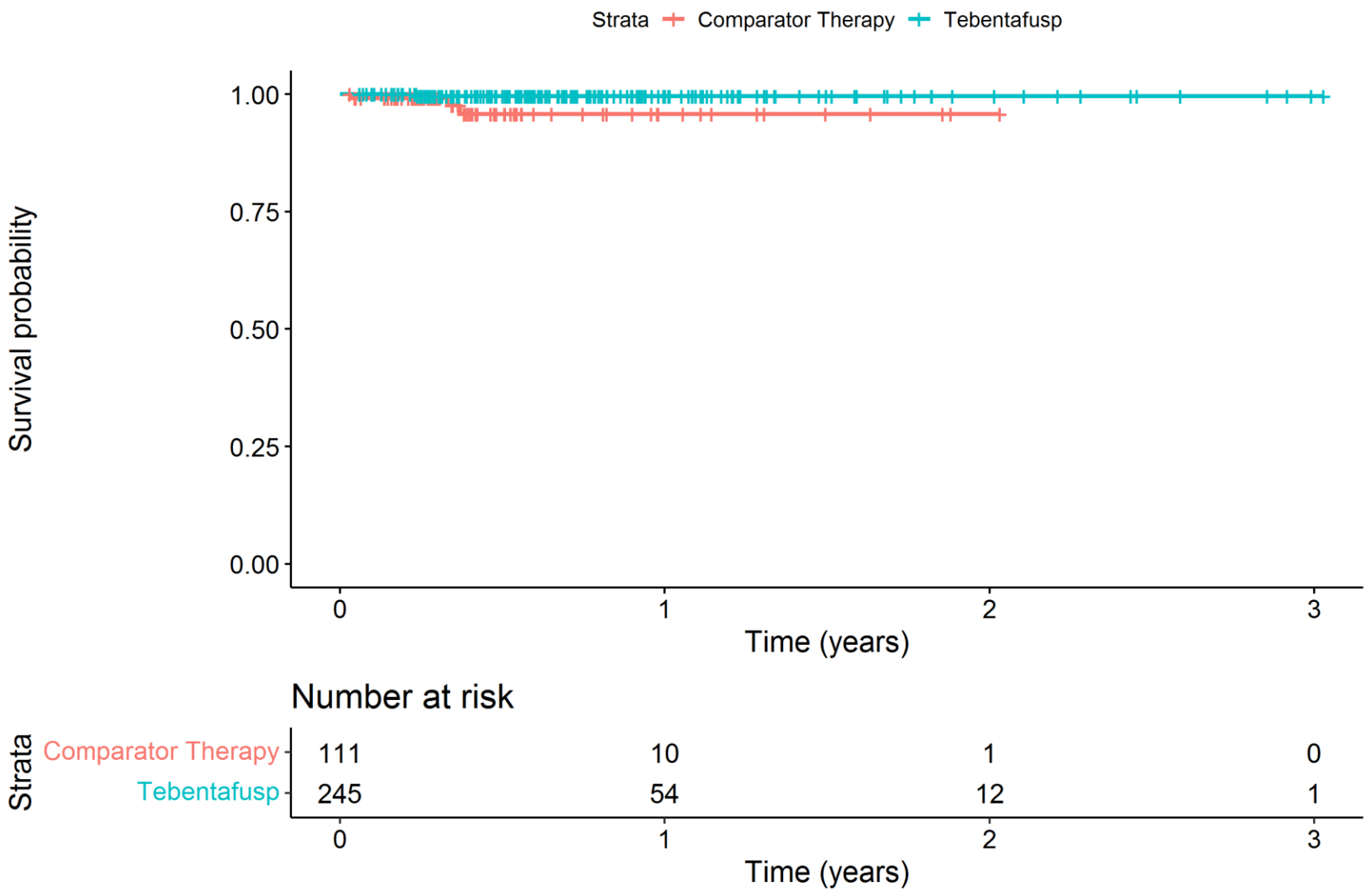
10.10 Tumorschmerzen



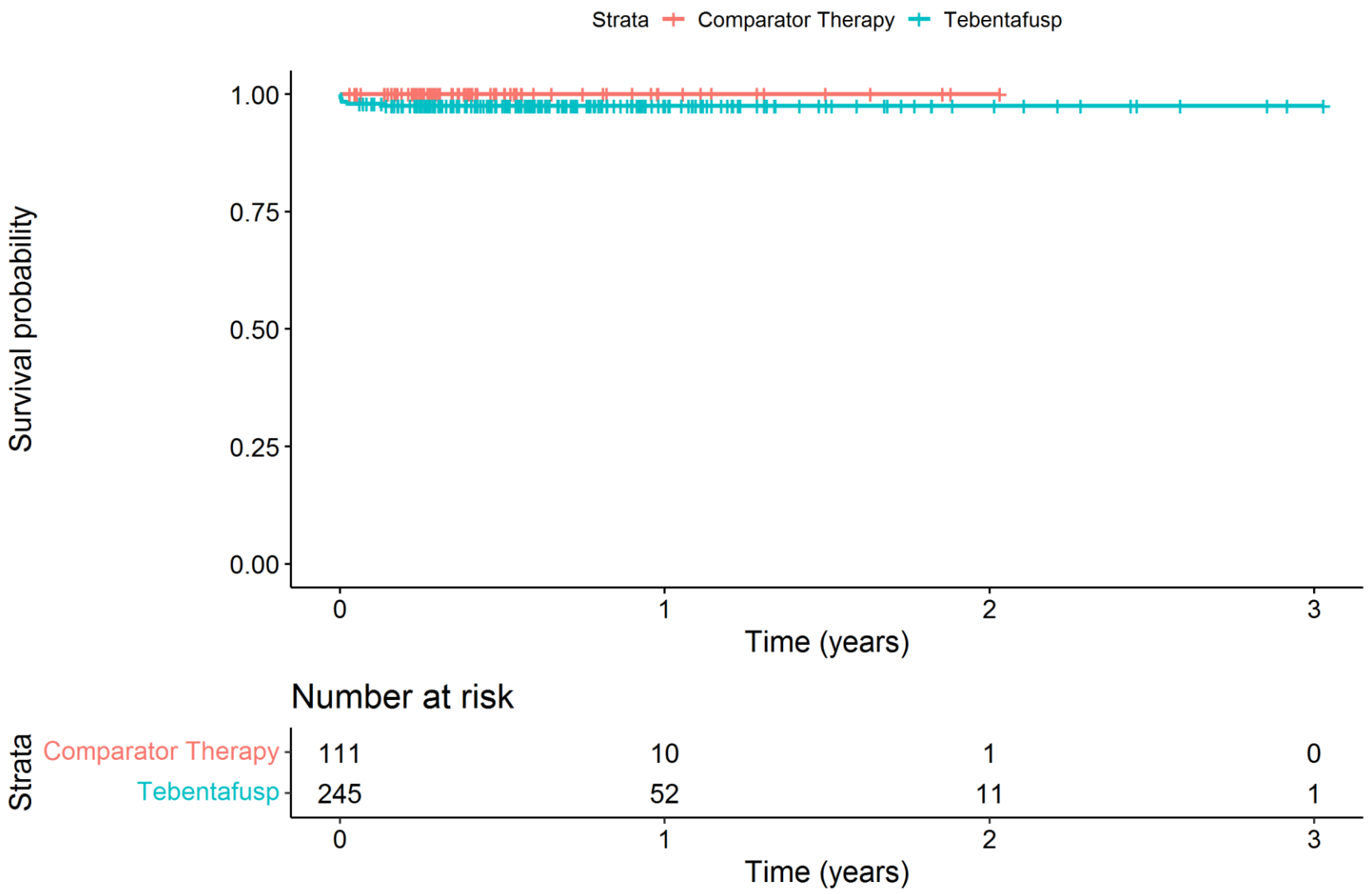
10.11 Dyspnoe



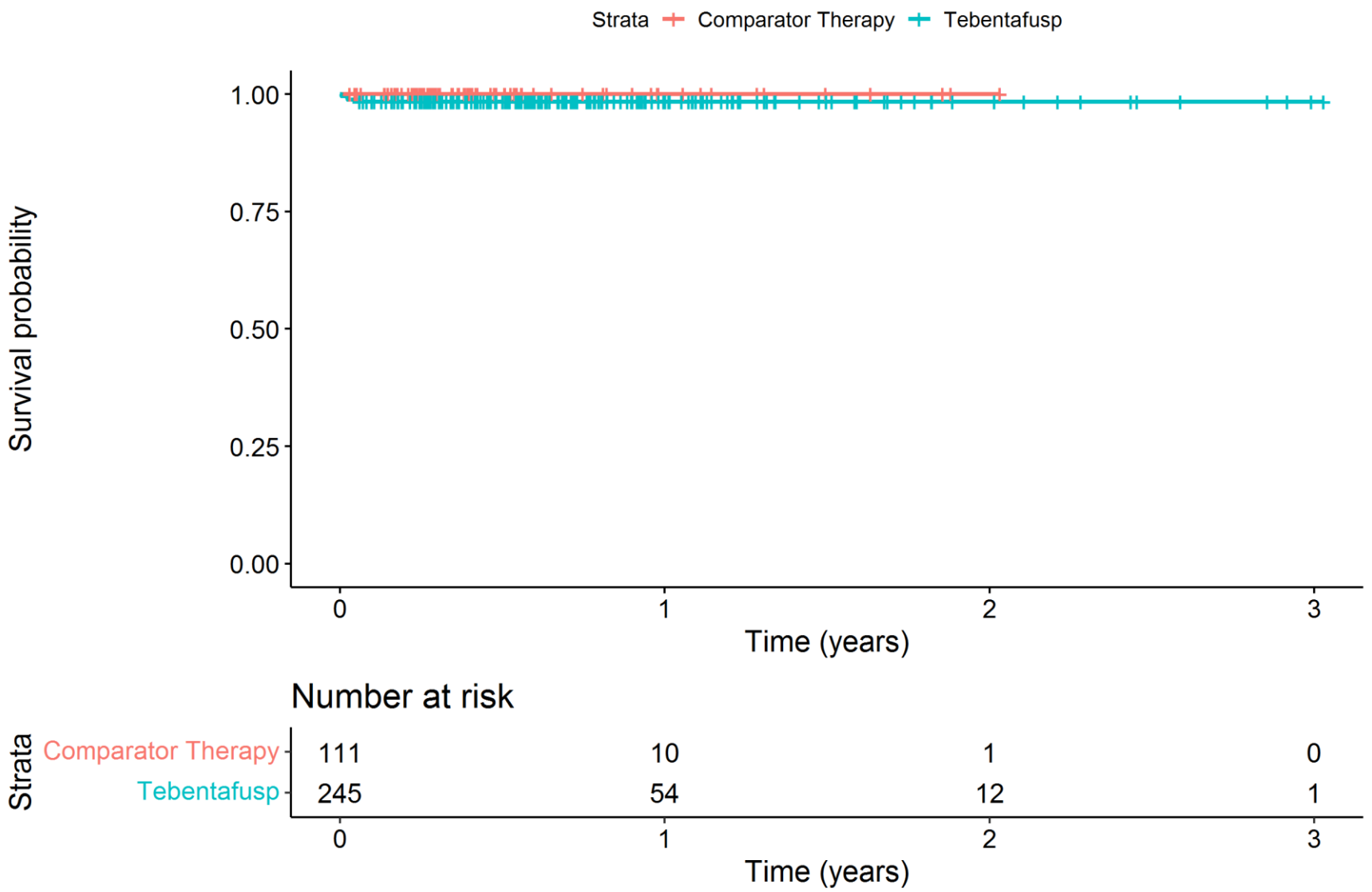
10.12 Lungenembolie



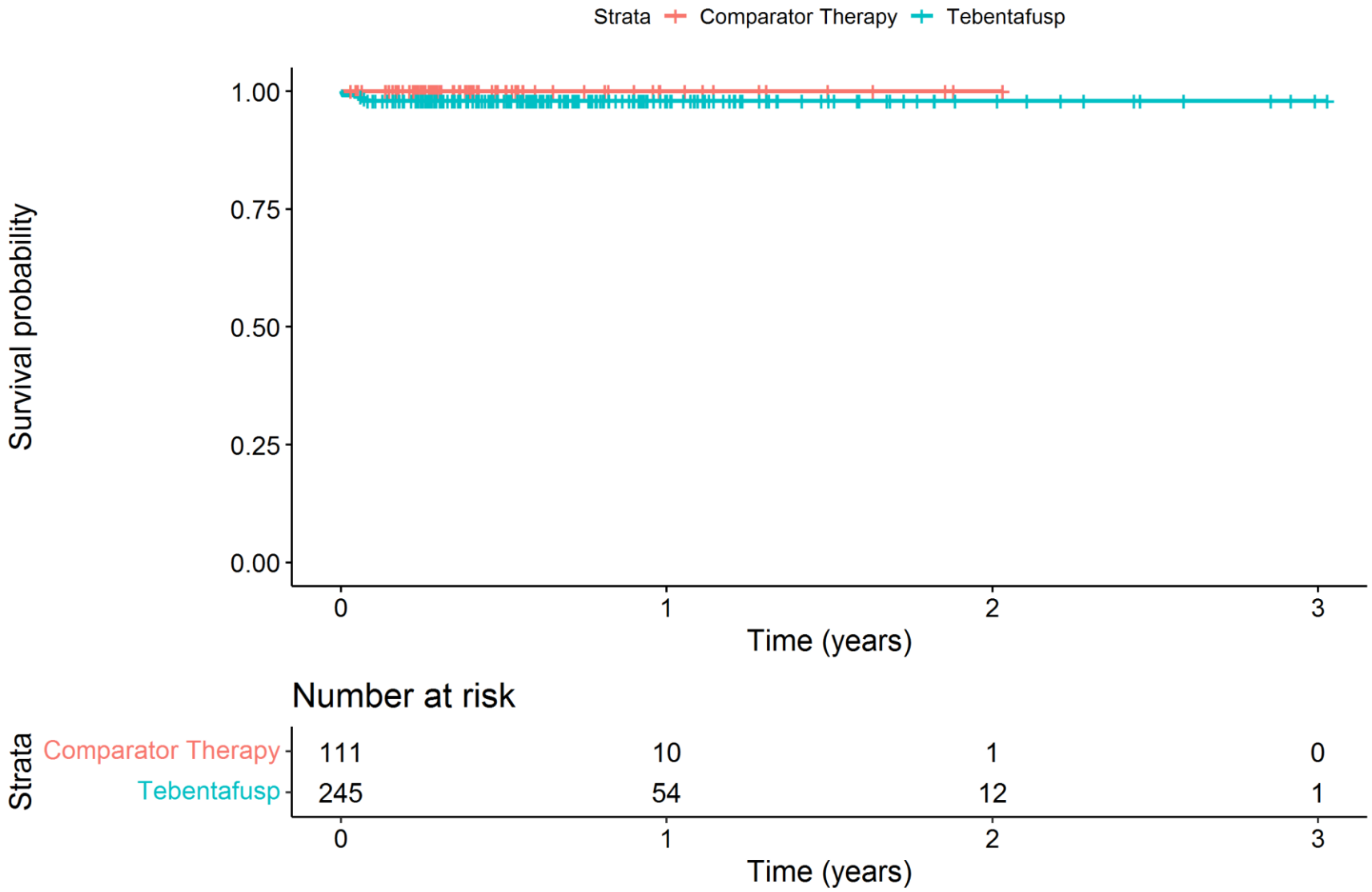
10.13 Hautausschlag



10.14 Makulo-papulöser Hautausschlag

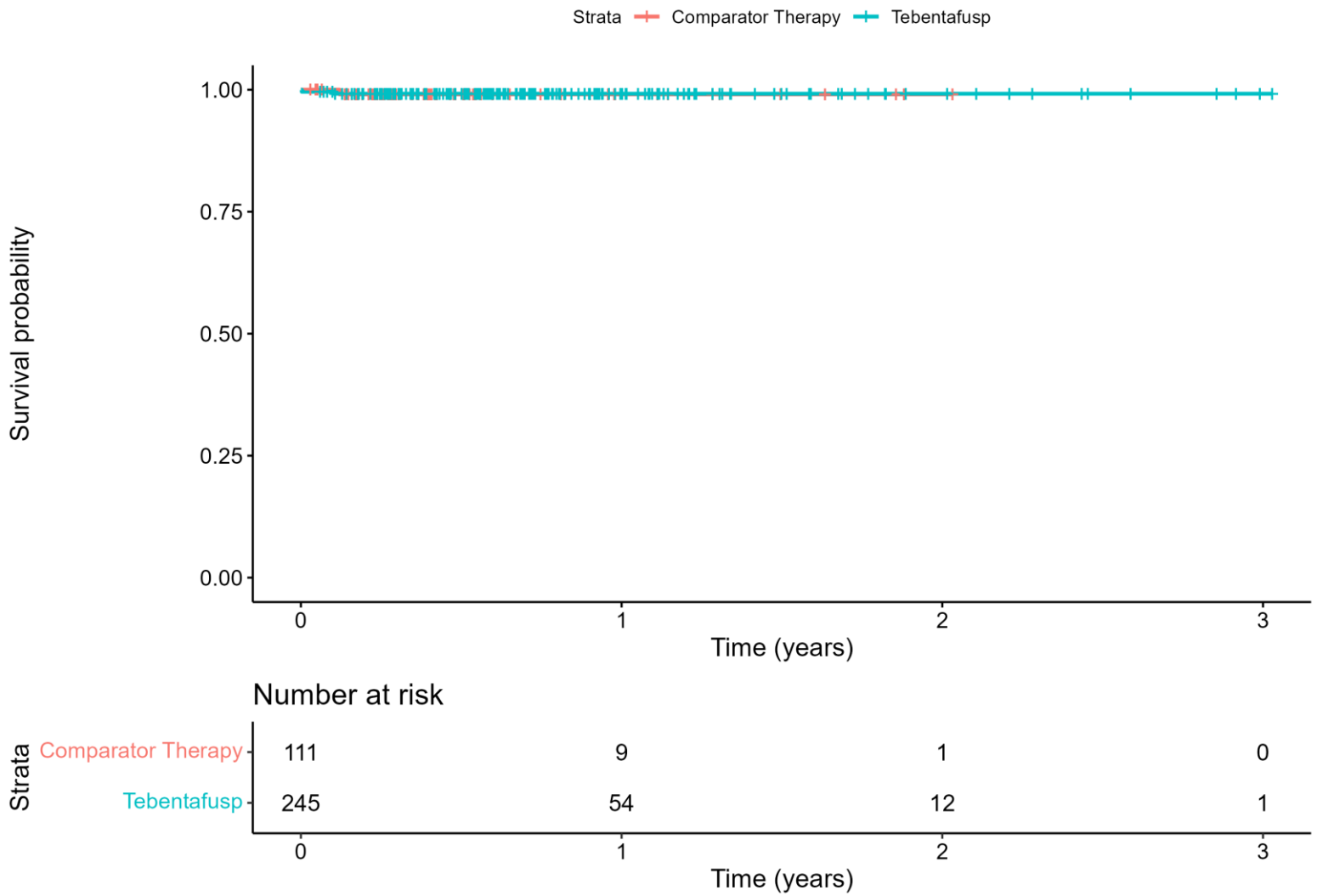


10.15 Hypotonie

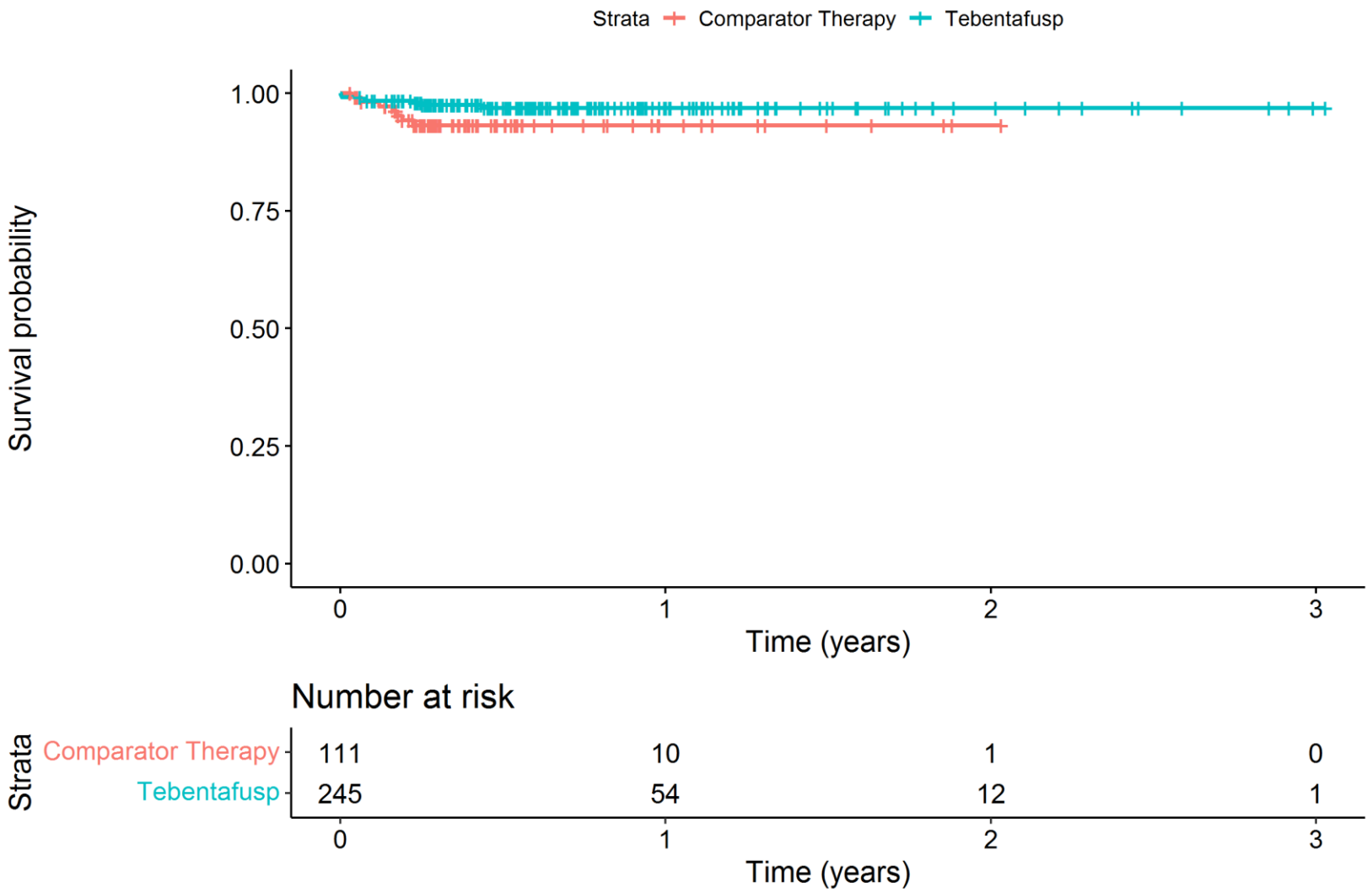


11 SUEs (SOC) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten

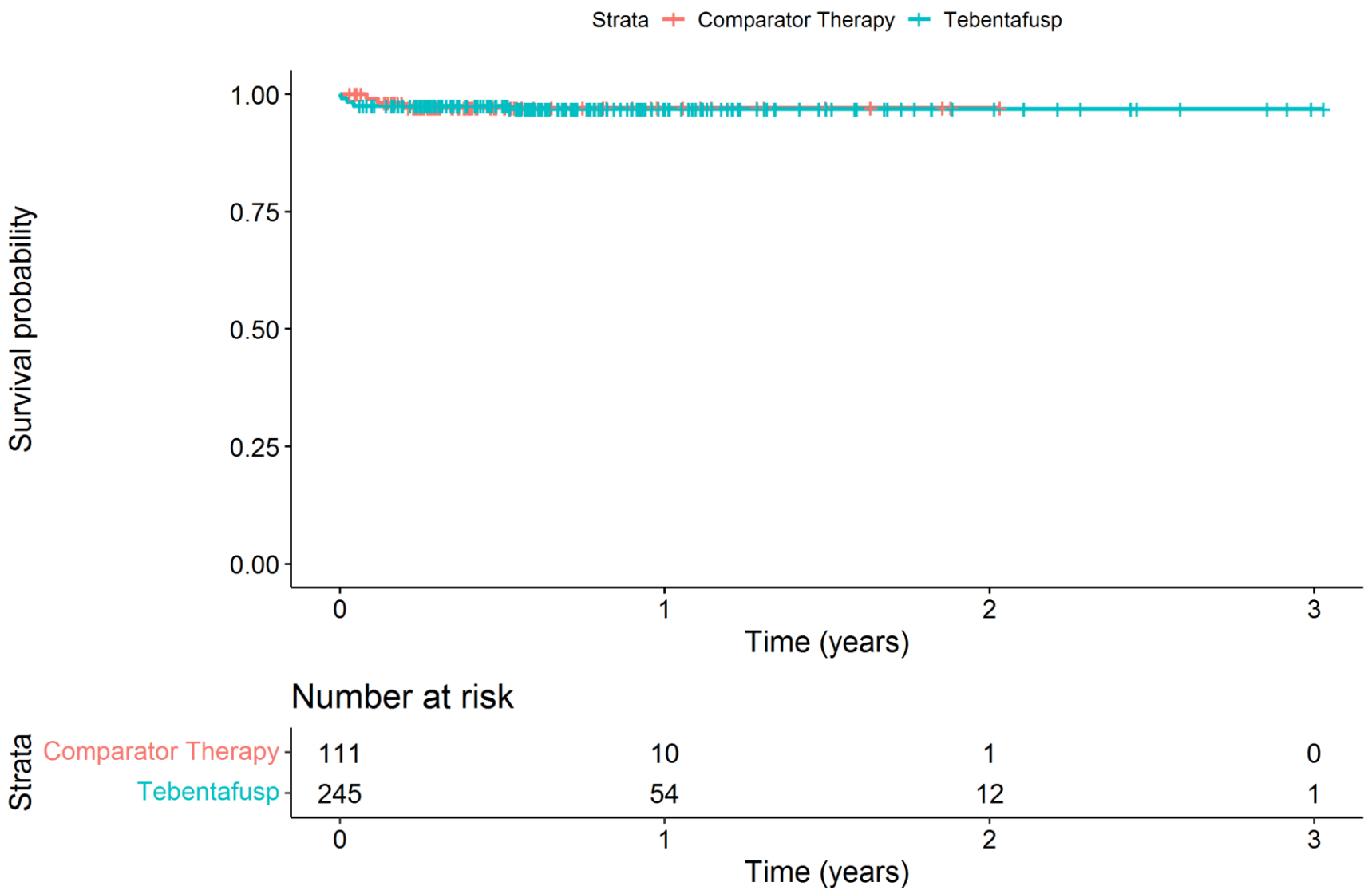
11.1 Augenerkrankungen


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
9
1
0
245
54
12
1
0
1
2
3
Time (years)

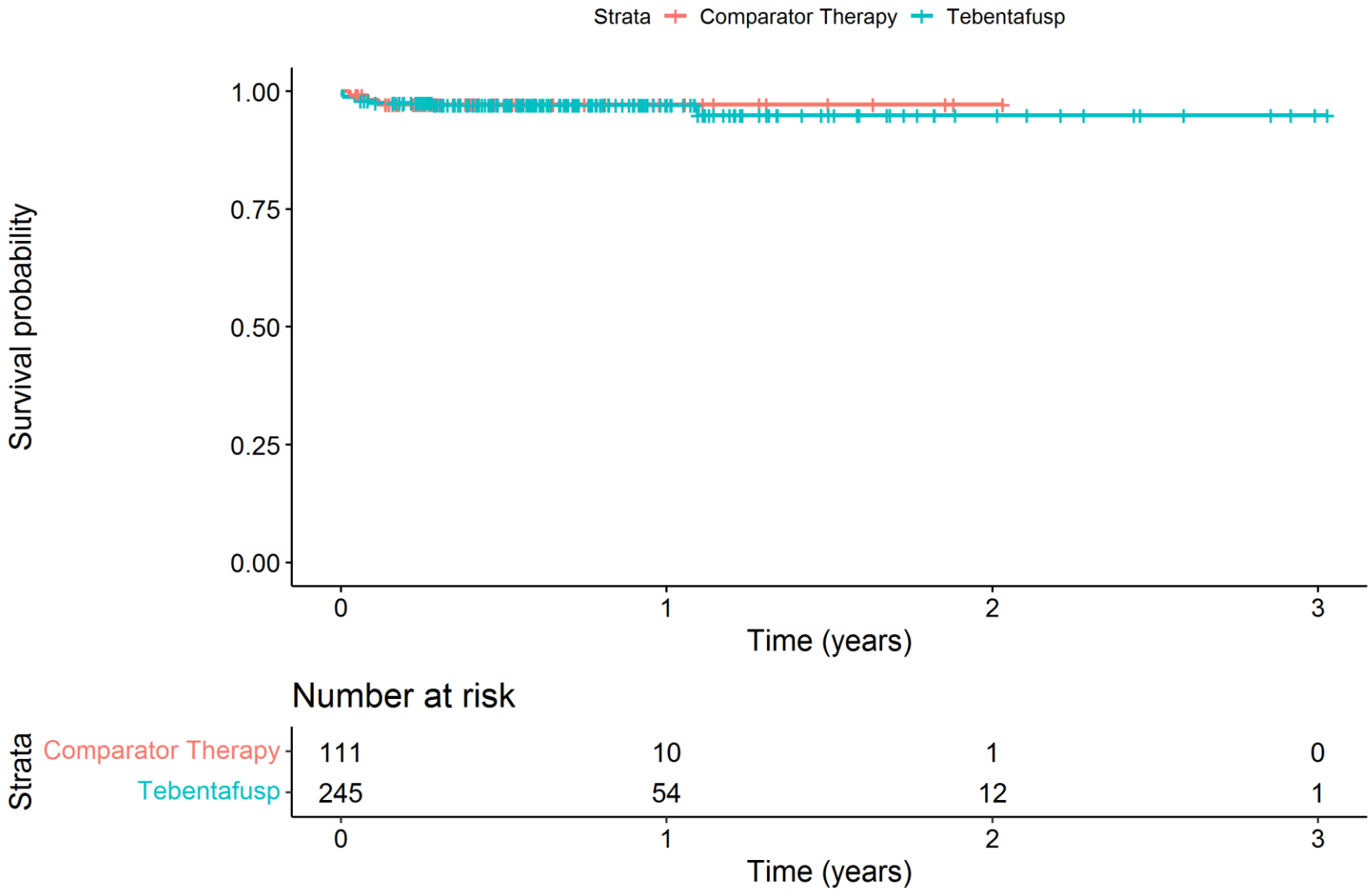
11.2 Erkrankungen des Gastrointestinaltrakts



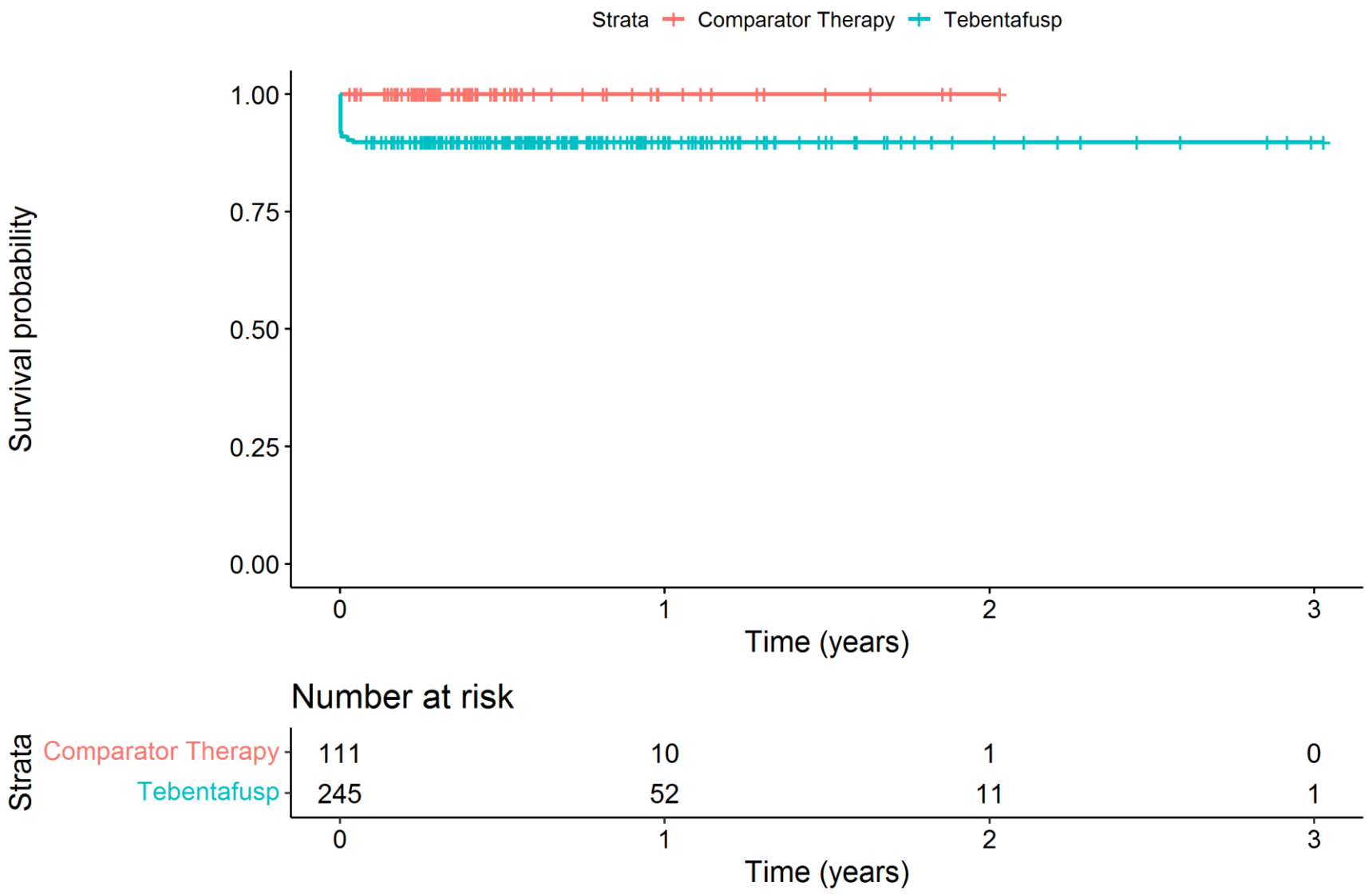
11.3 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



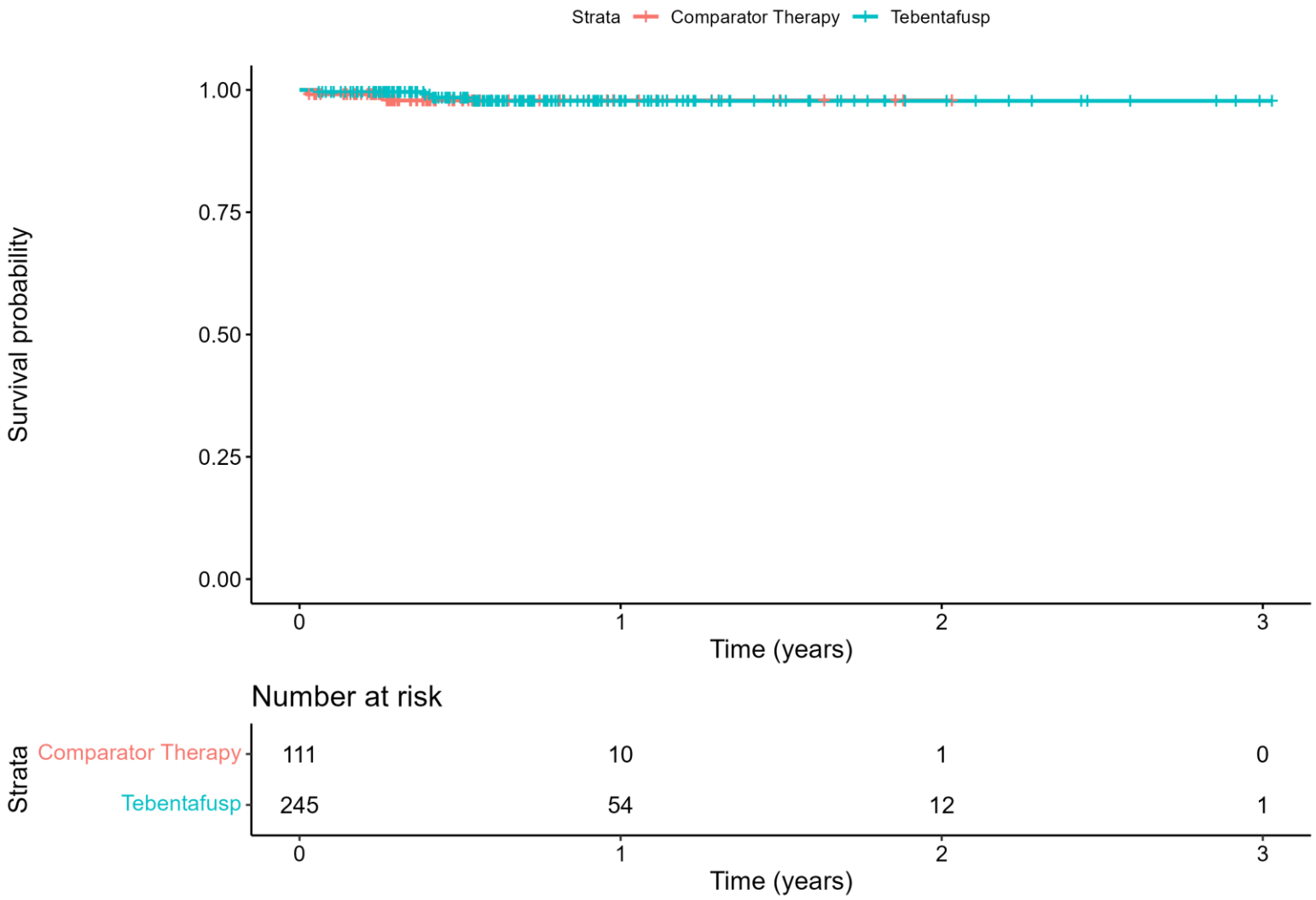
11.4 Leber- und Gallenerkrankungen



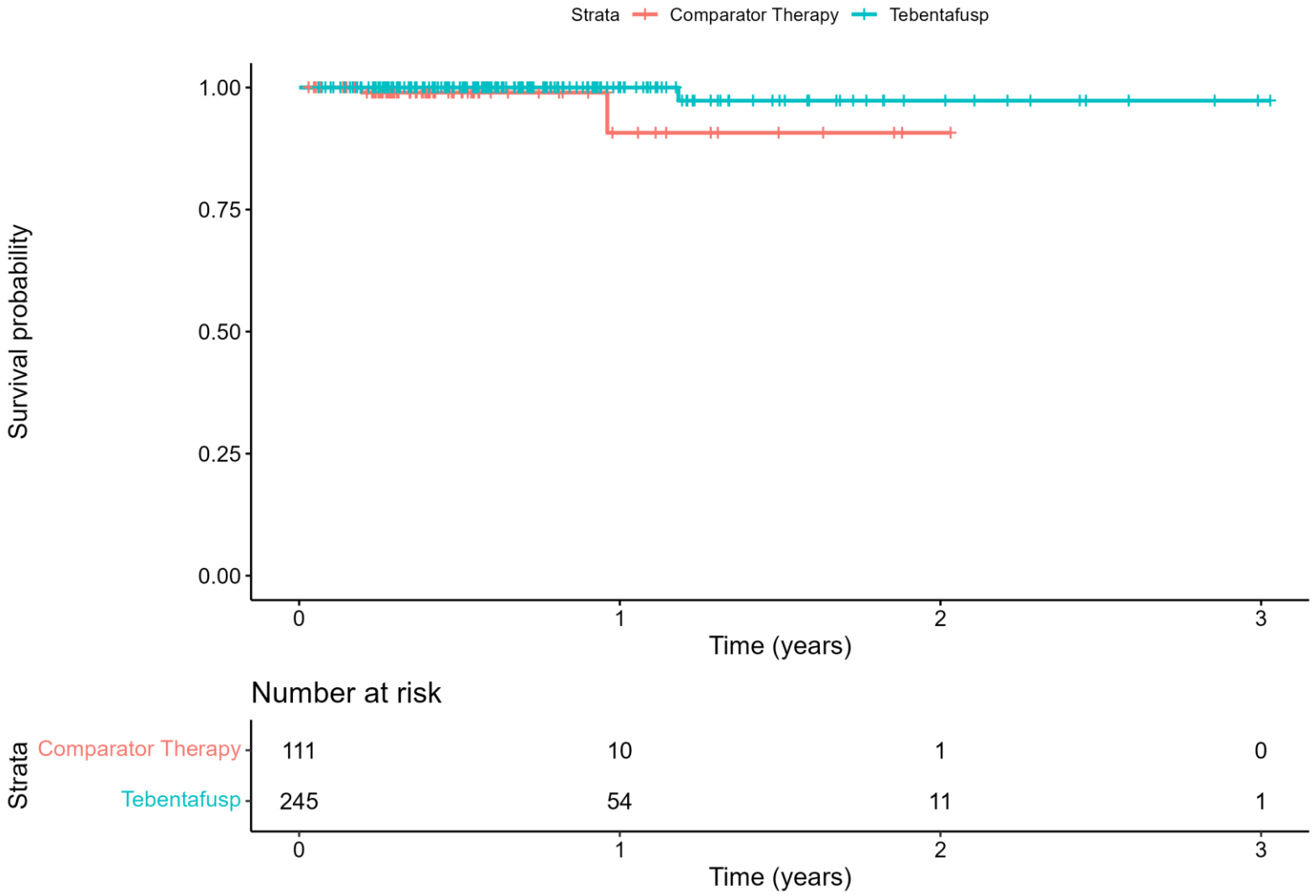
11.5 Erkrankungen des Immunsystems



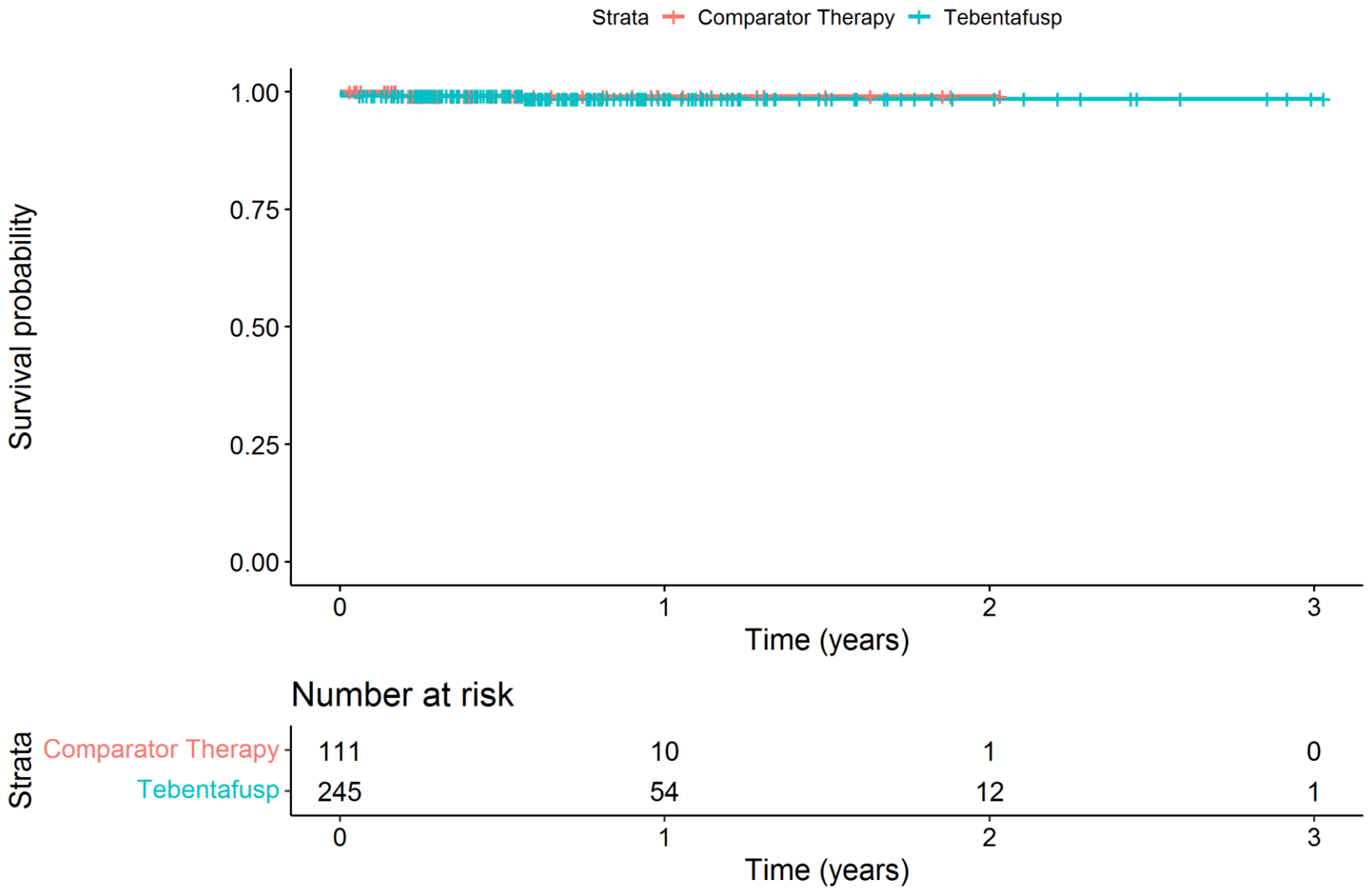
11.6 Infektionen und parasitäre Erkrankungen



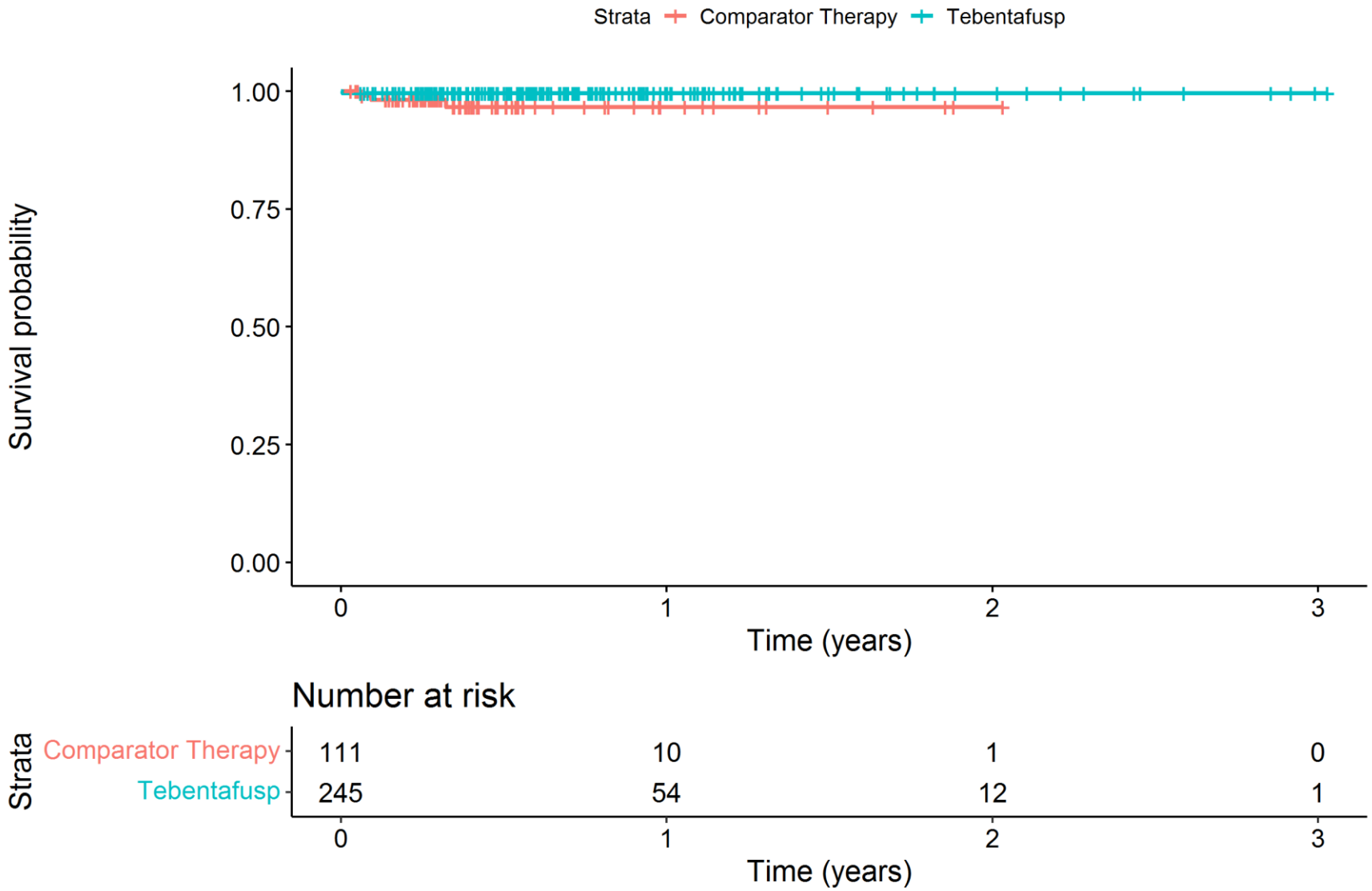
11.7 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



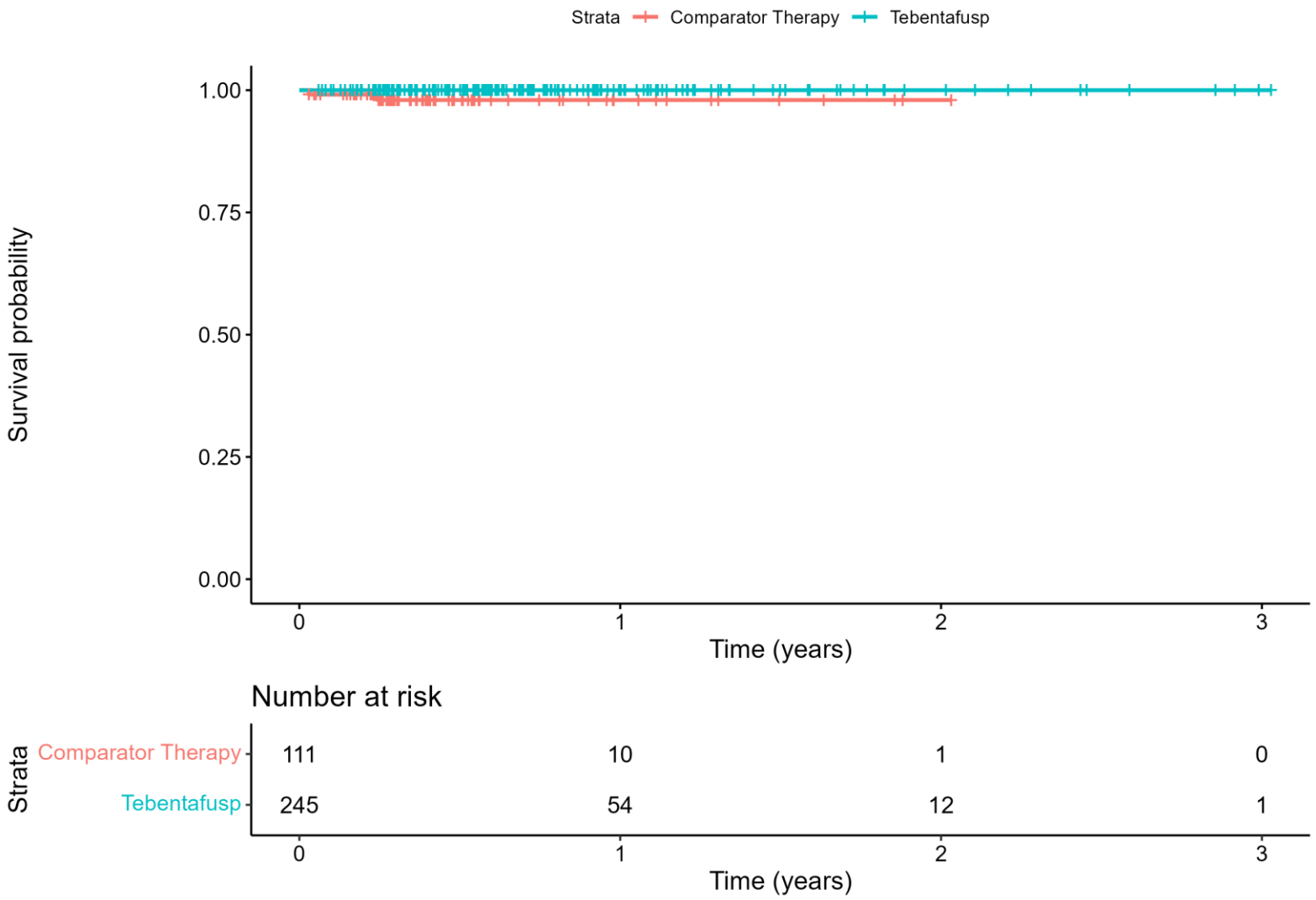
11.8 Untersuchungen



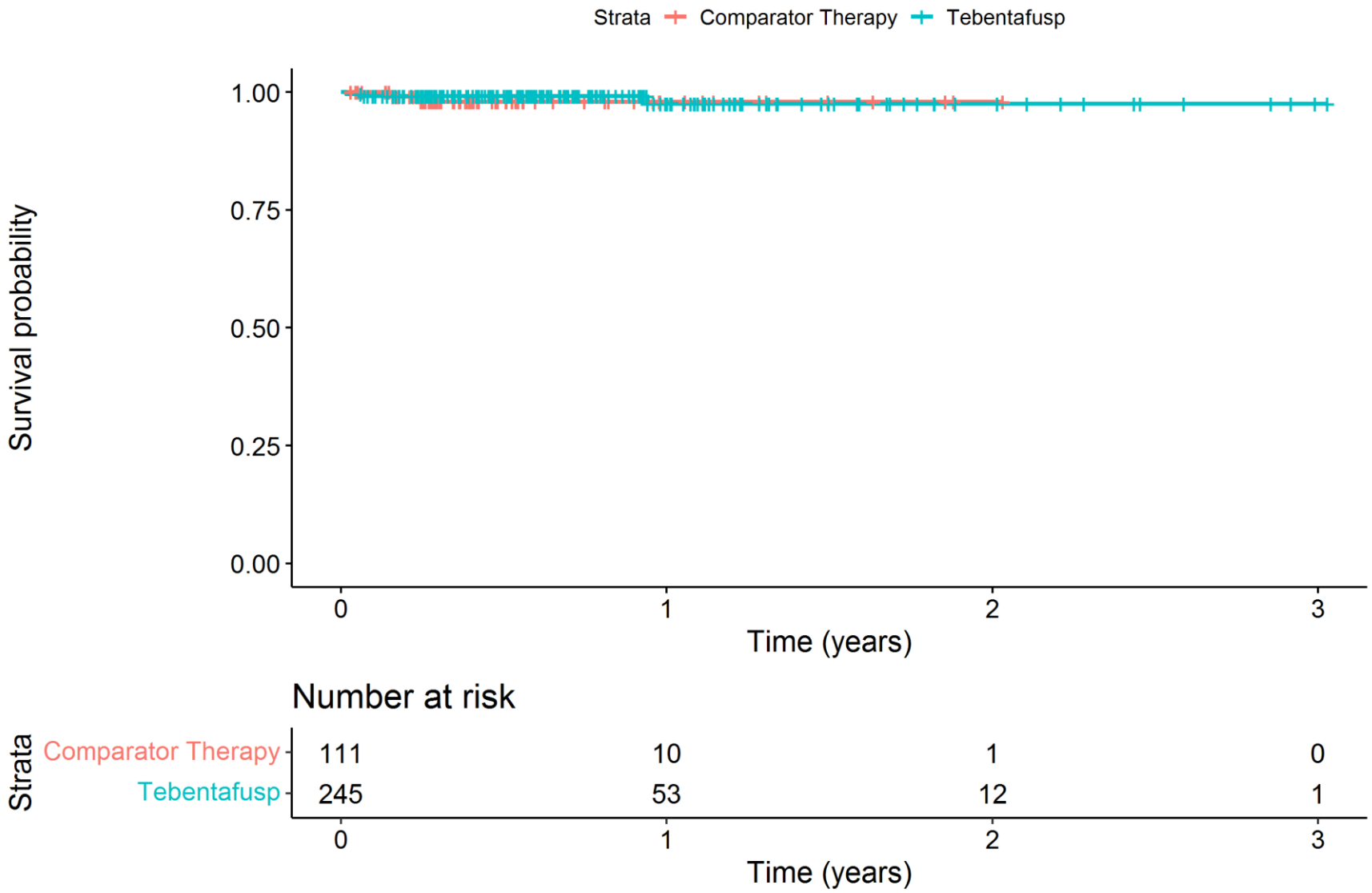
11.9 Stoffwechsel- und Ernährungsstörungen



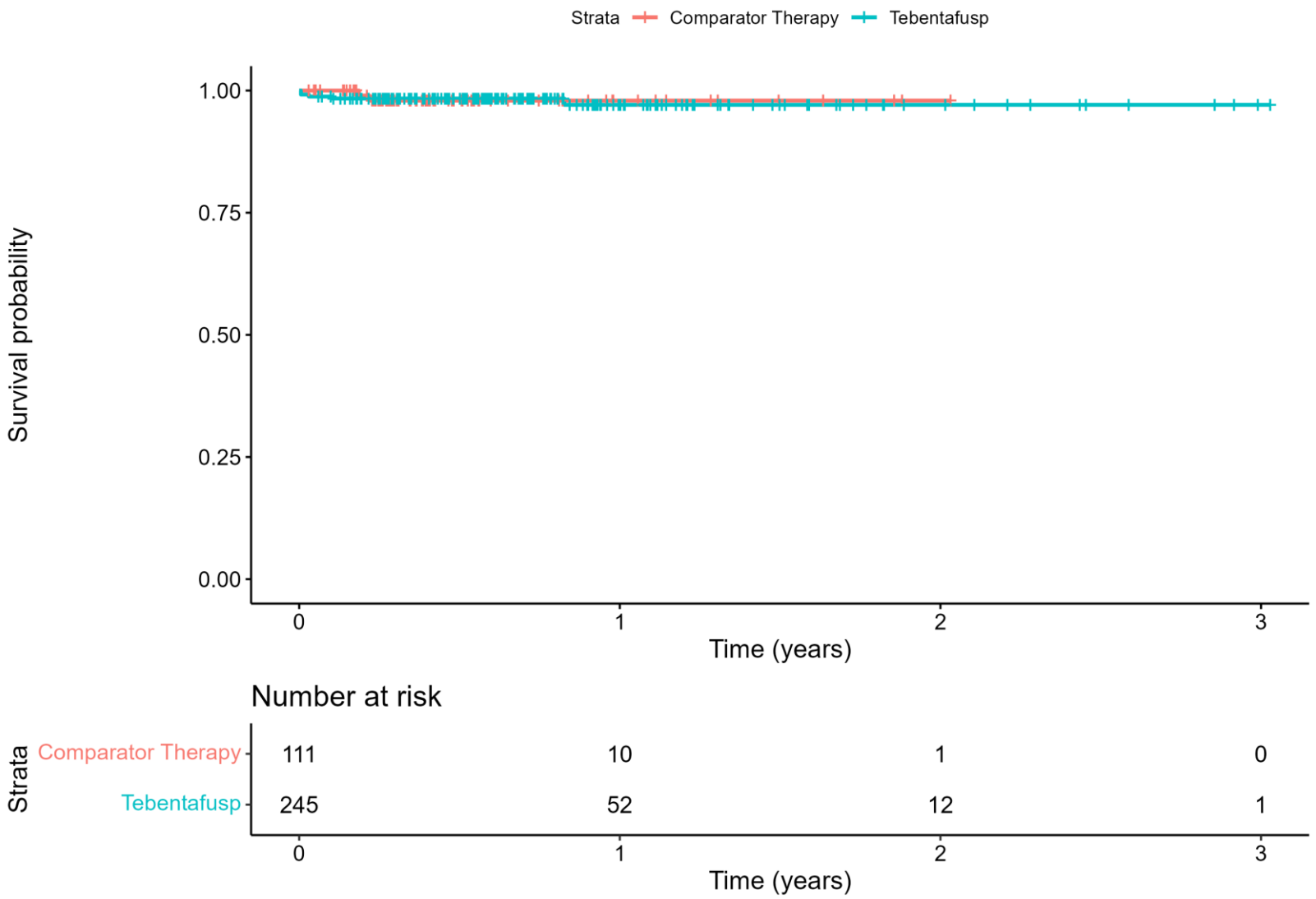
11.10 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



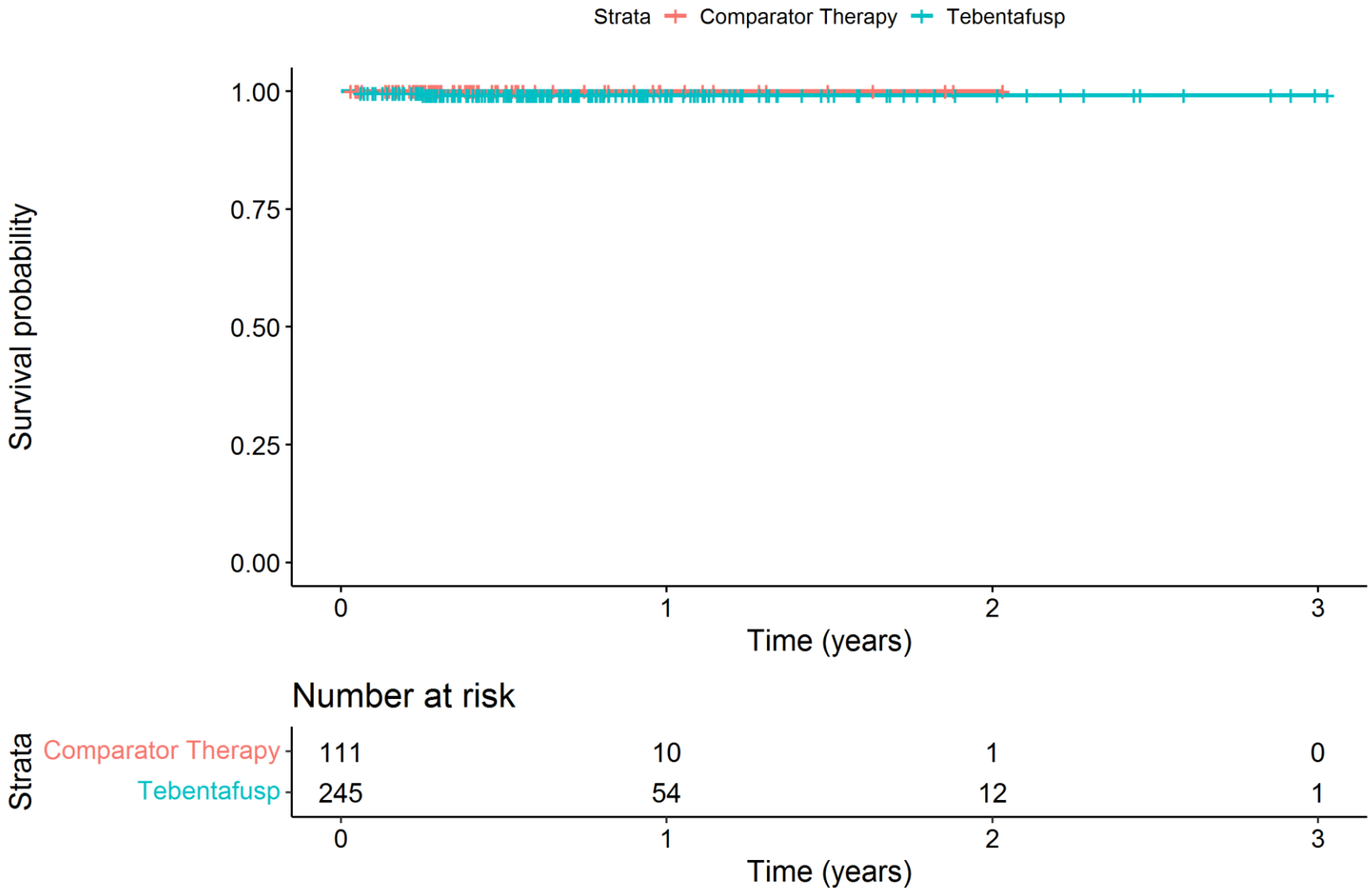
11.11 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



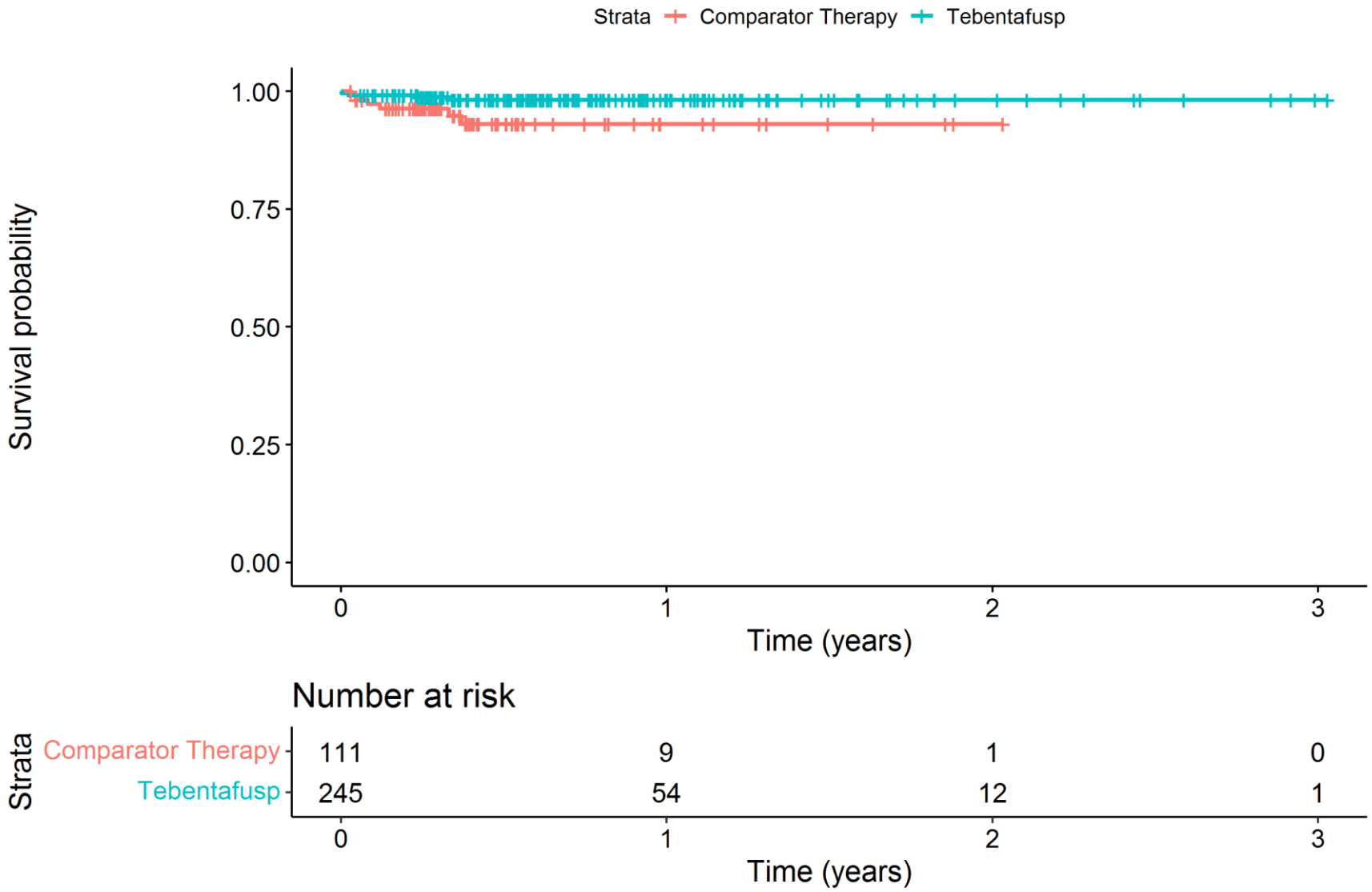
11.12 Erkrankungen des Nervensystems



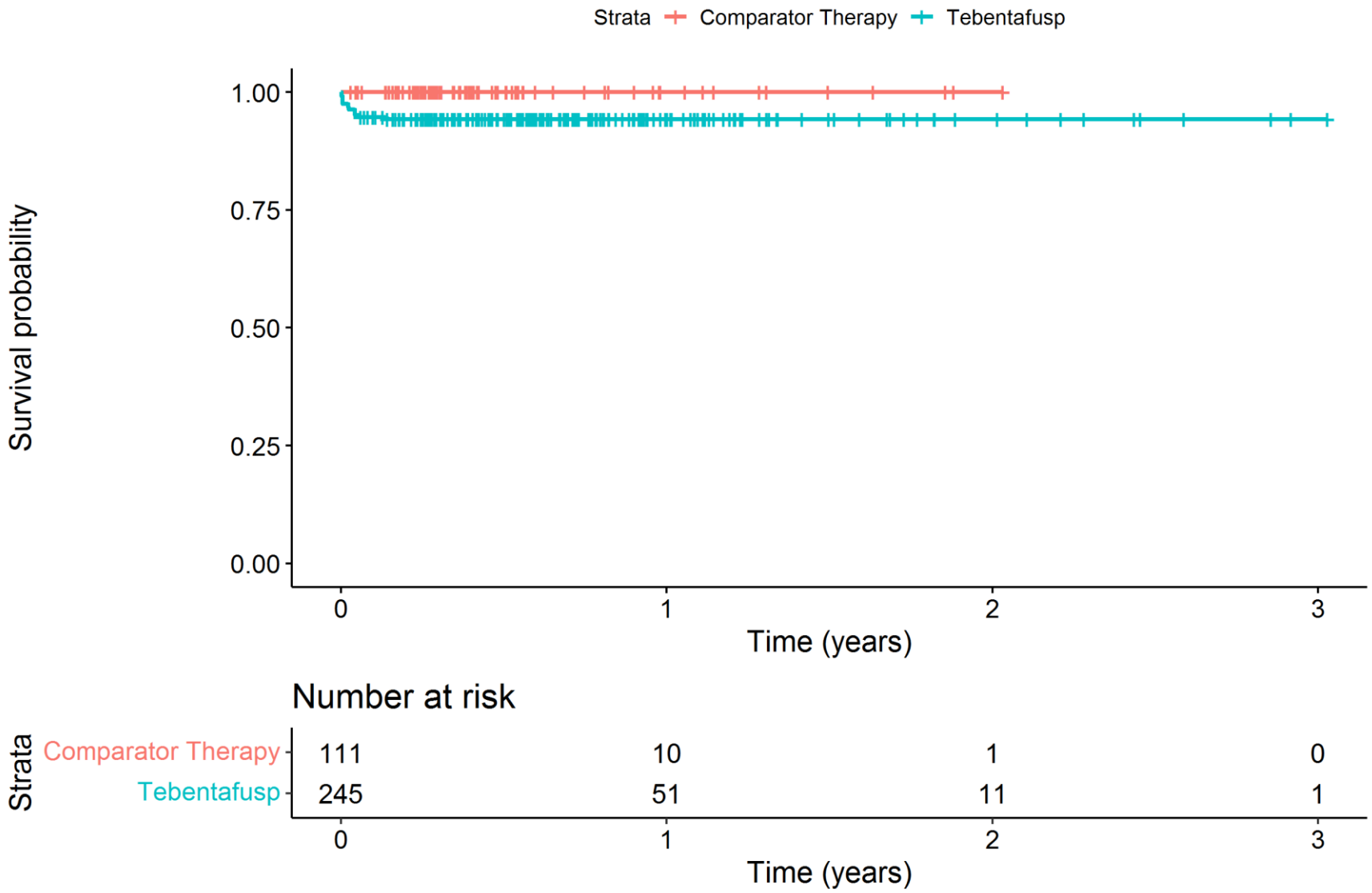
11.13 Erkrankungen der Nieren und Harnwege



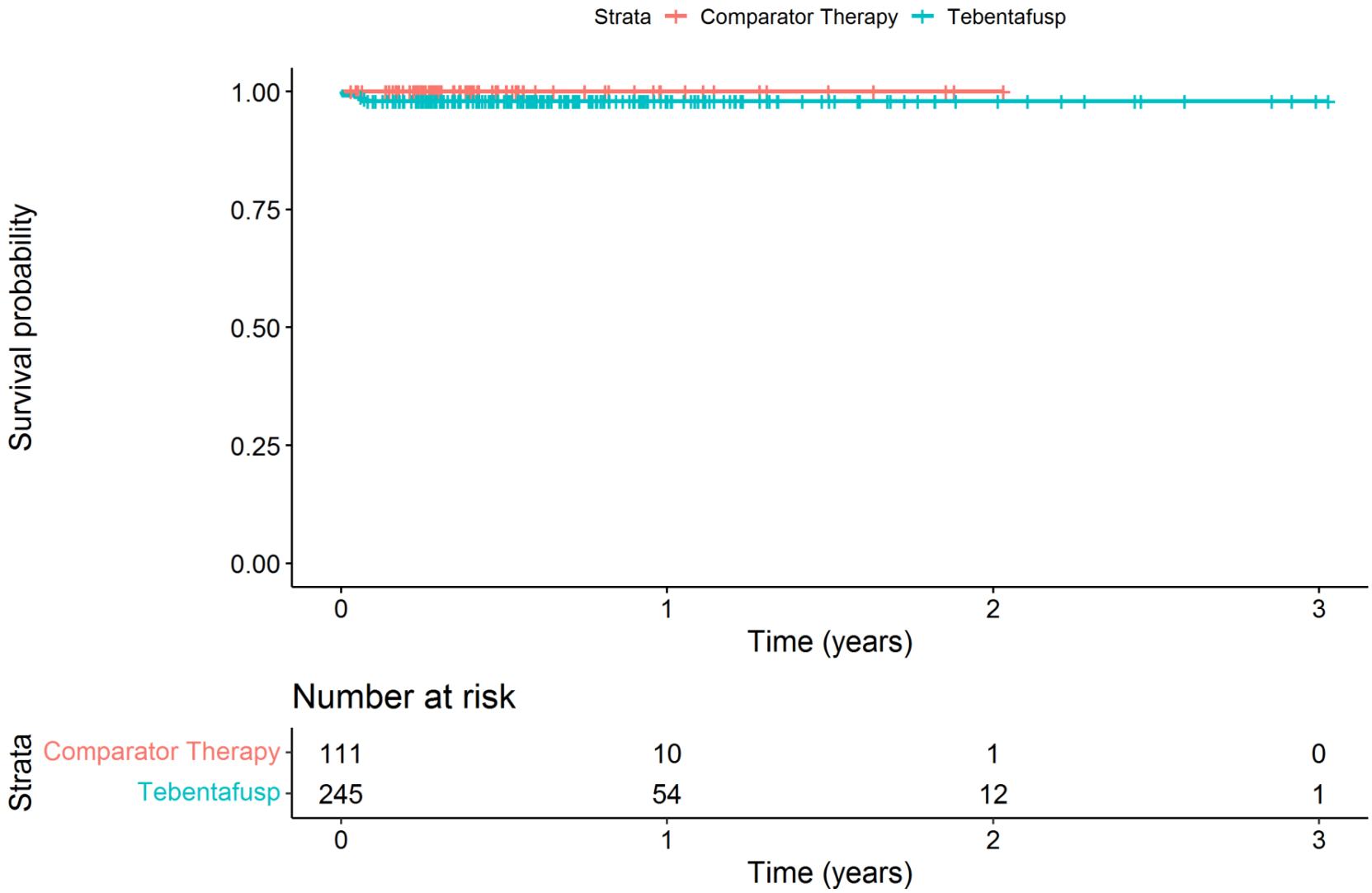
11.14 Erkrankungen der Atemwege, des Brustraums und Mediastinums



11.15 Erkrankungen der Haut und des Unterhautgewebes



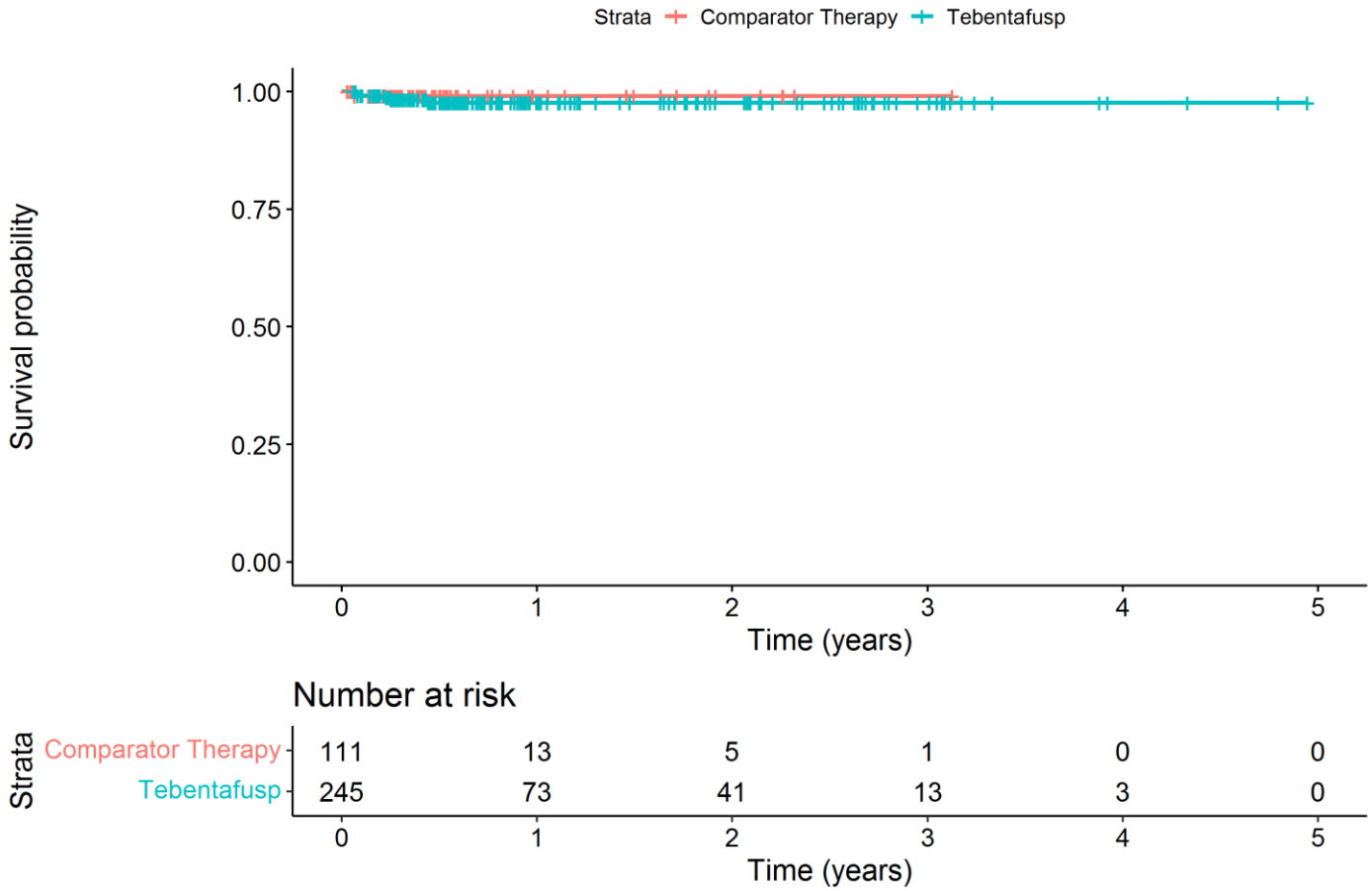
11.16 Gefäßerkrankungen



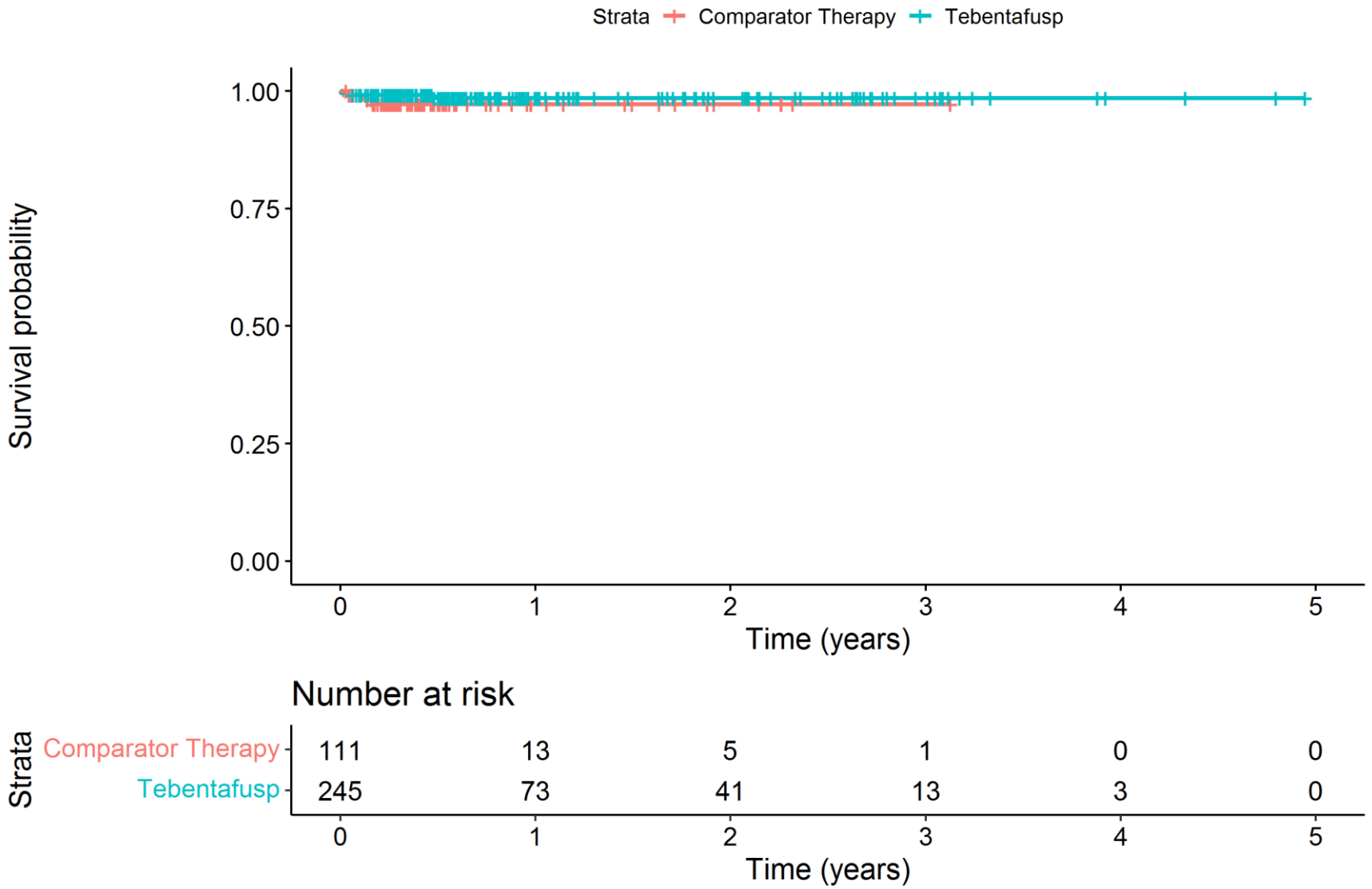
11.17 Schwerwiegende unerwünschte Ereignisse (SUEs) nach SOC und PT – 3-Jahres-Analyse (Juni 2023) (Tabelle 4-66)

12 SUEs (PT) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten

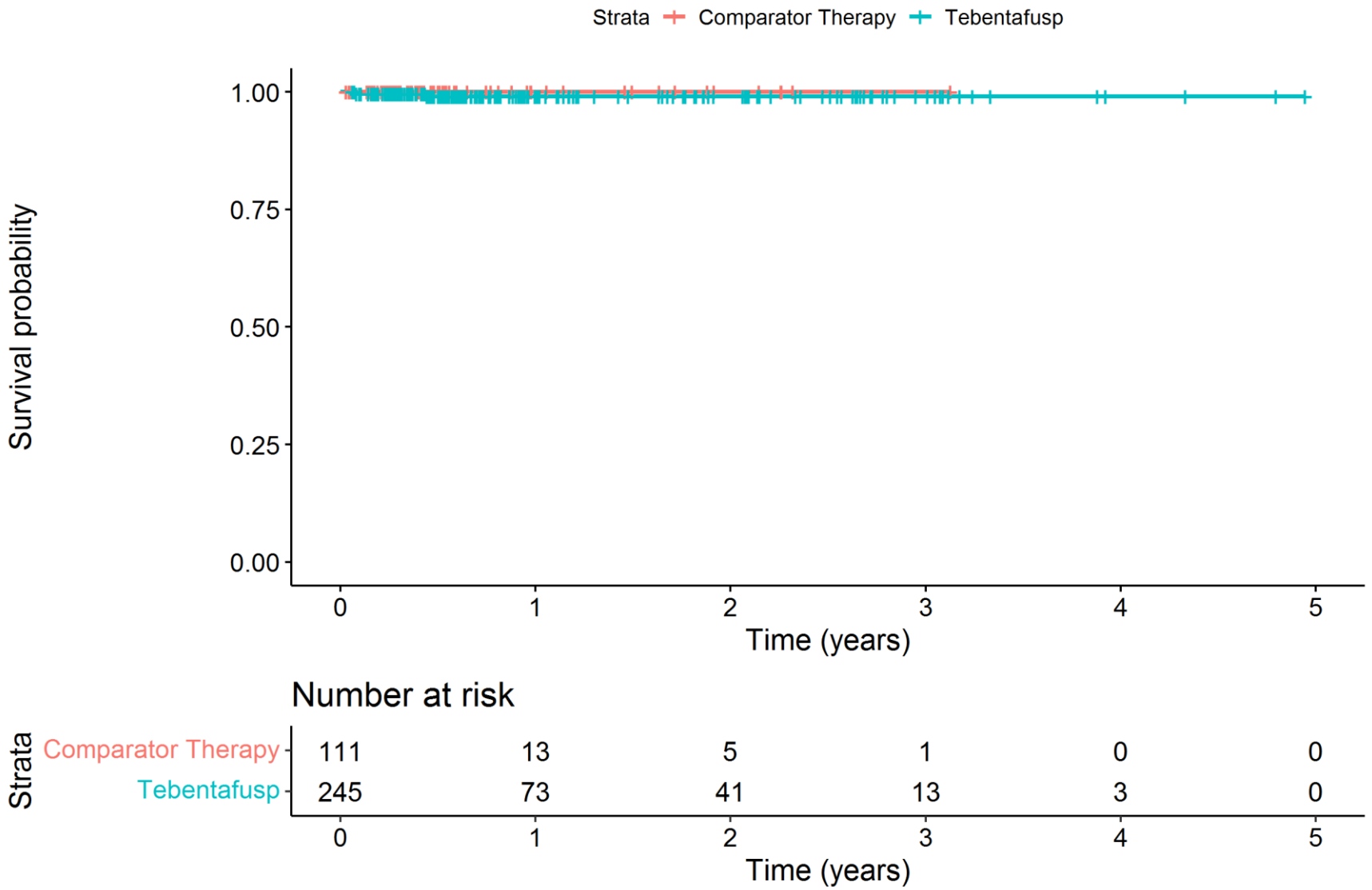
12.1 Übelkeit



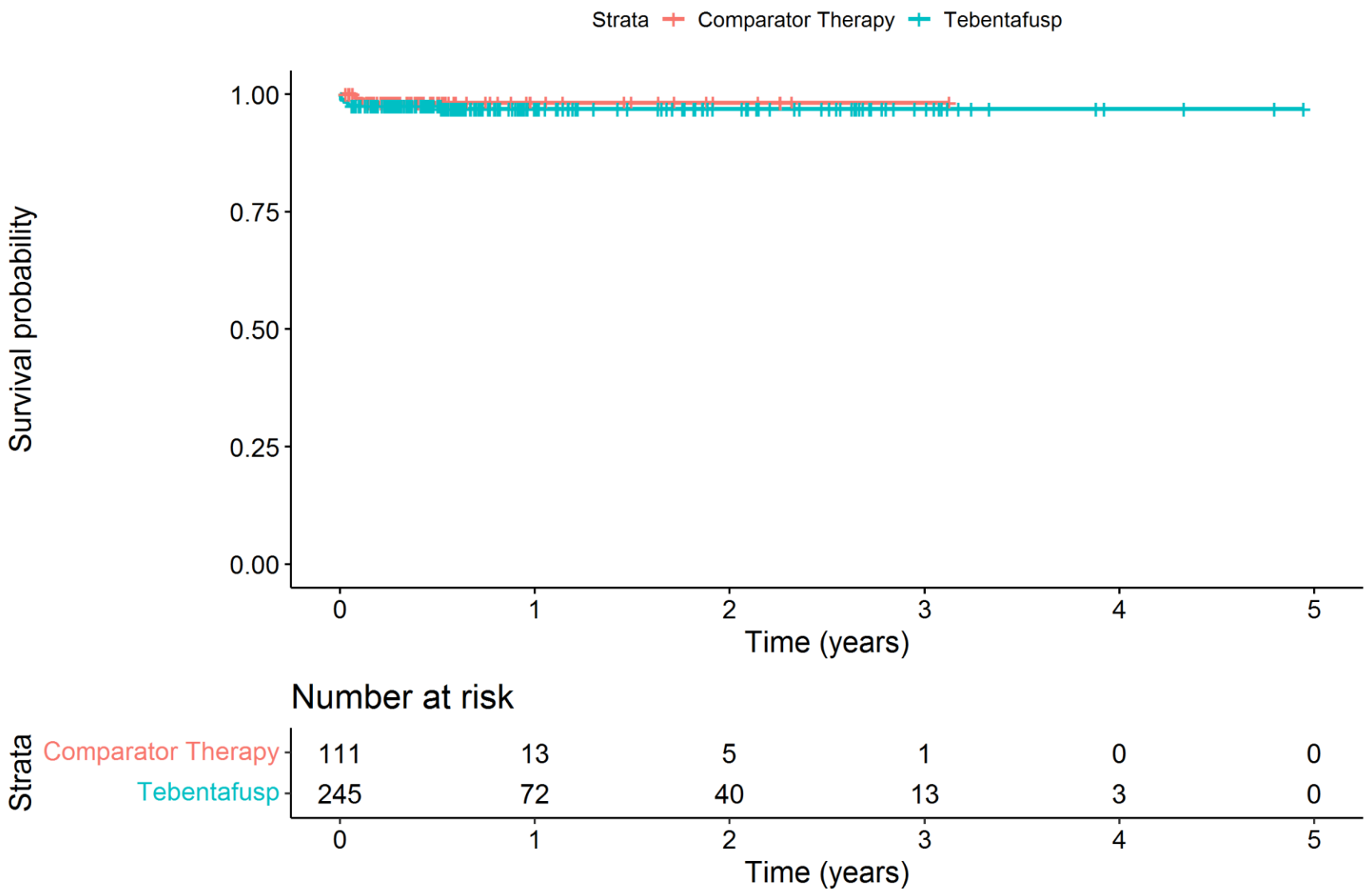
12.2 Unterleibsschmerzen



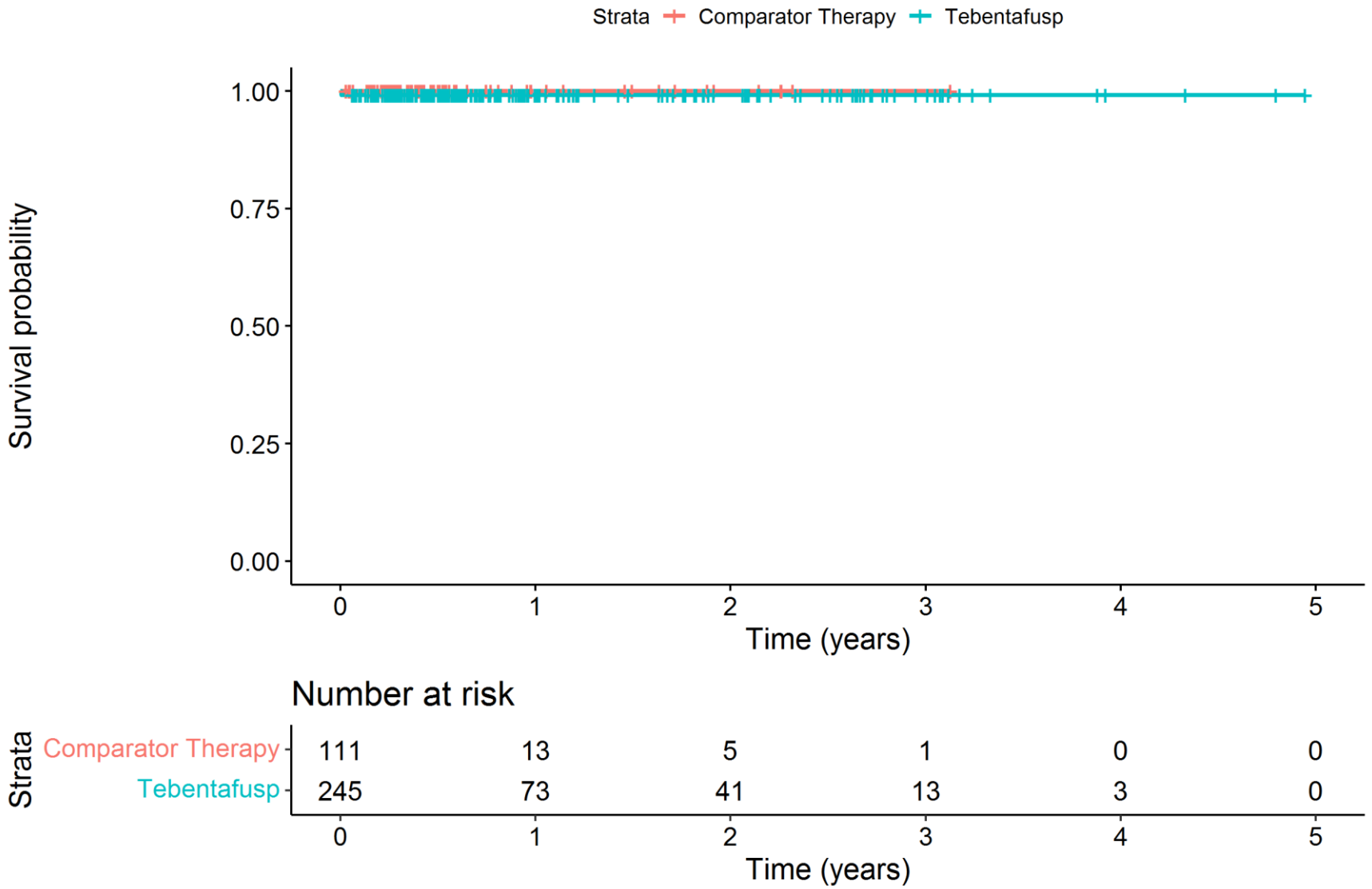
12.3 Erbrechen



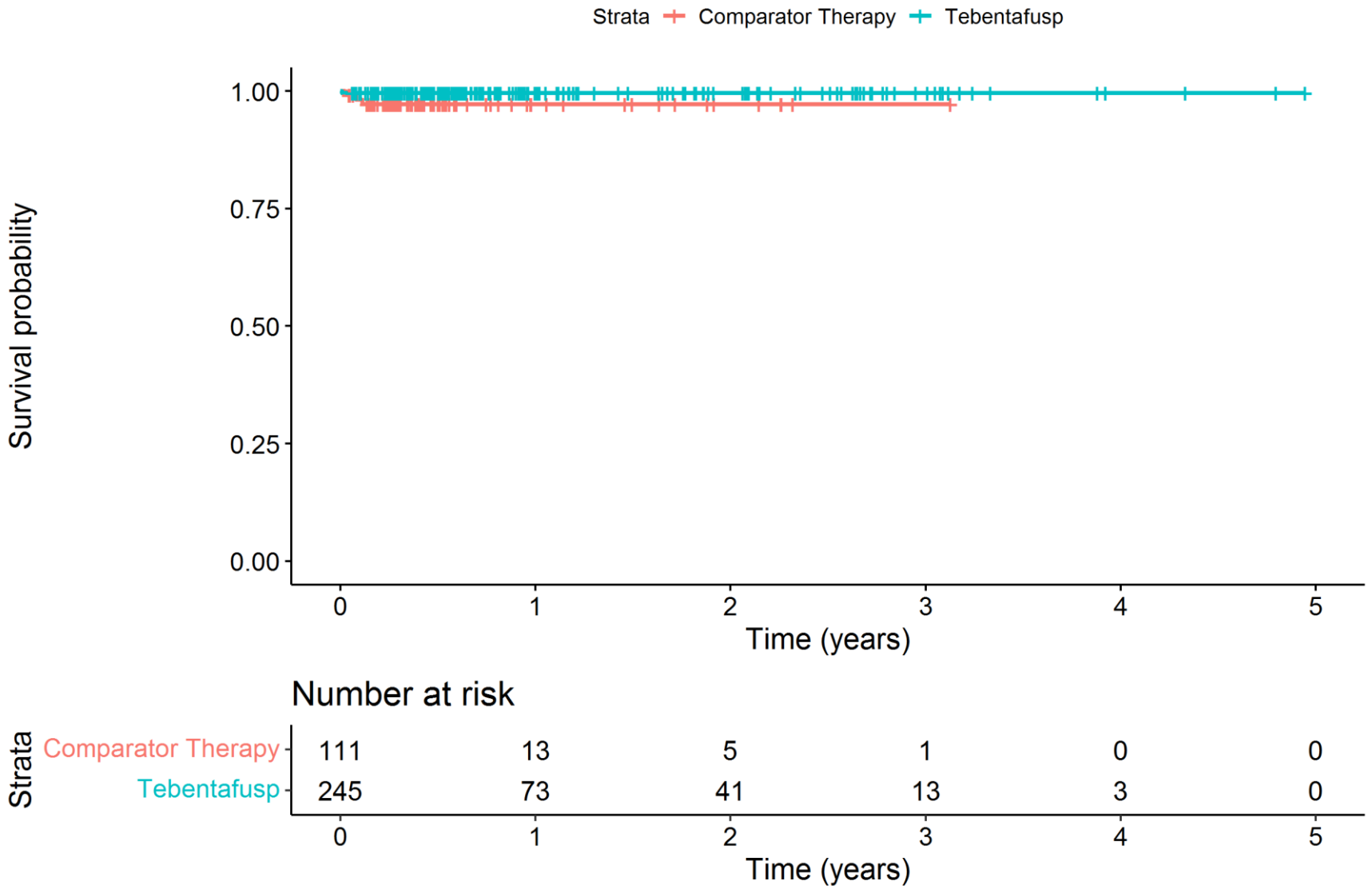
12.4 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
72
40
13
3
0
0
1
2
3
4
5
Time (years)

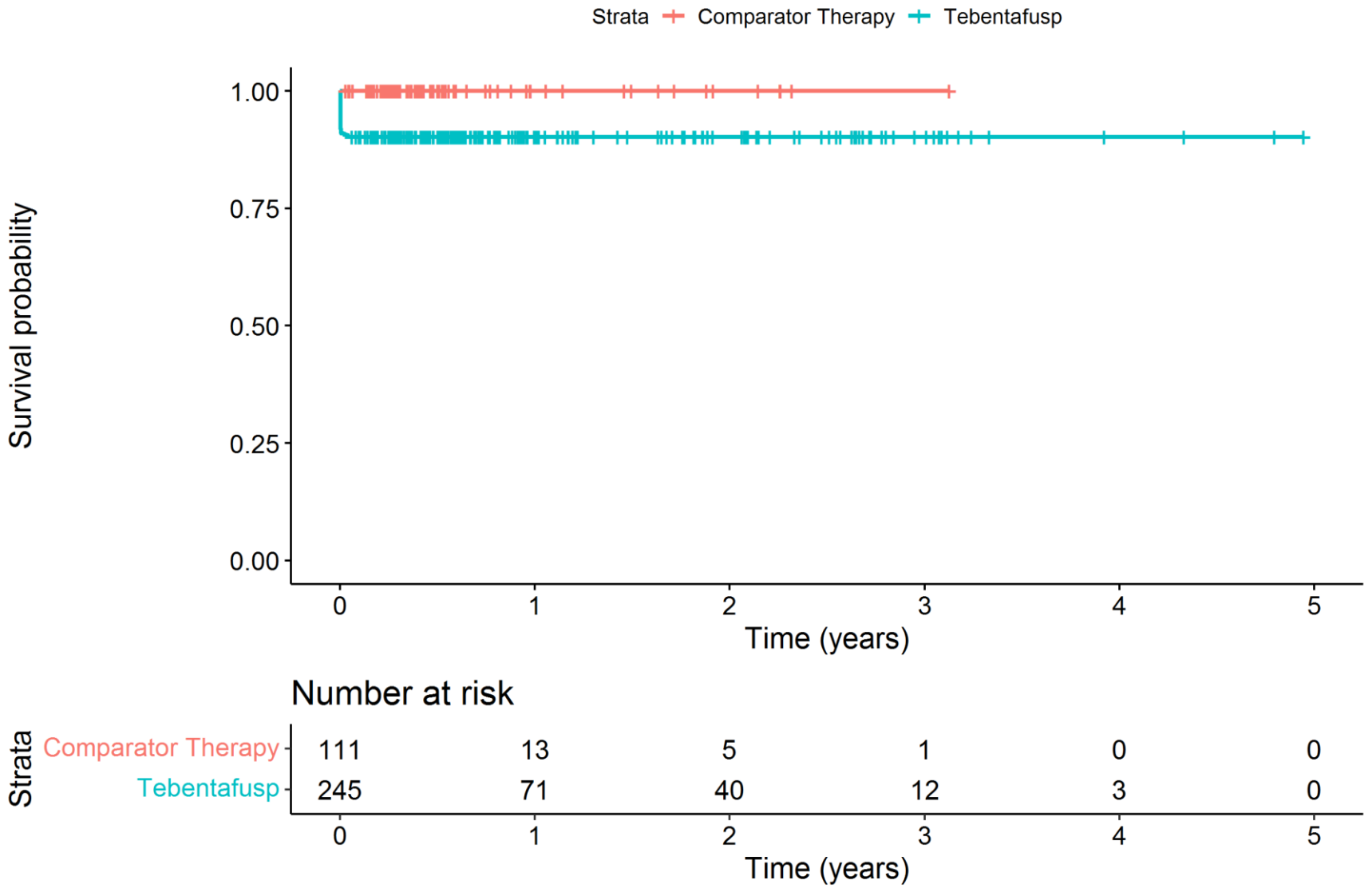
12.5 Hepatotoxizität



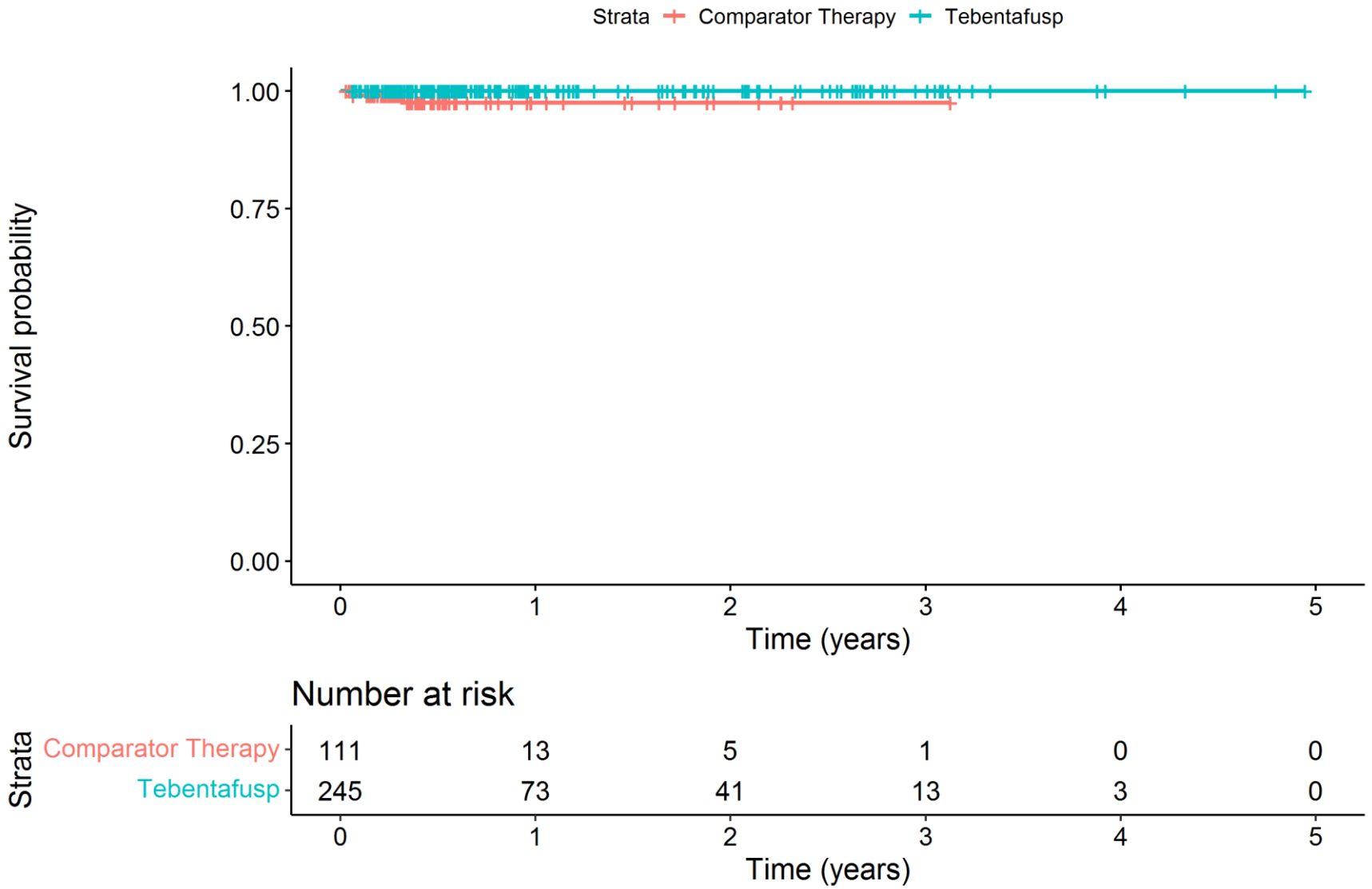
12.6 Hyperbilirubinämie



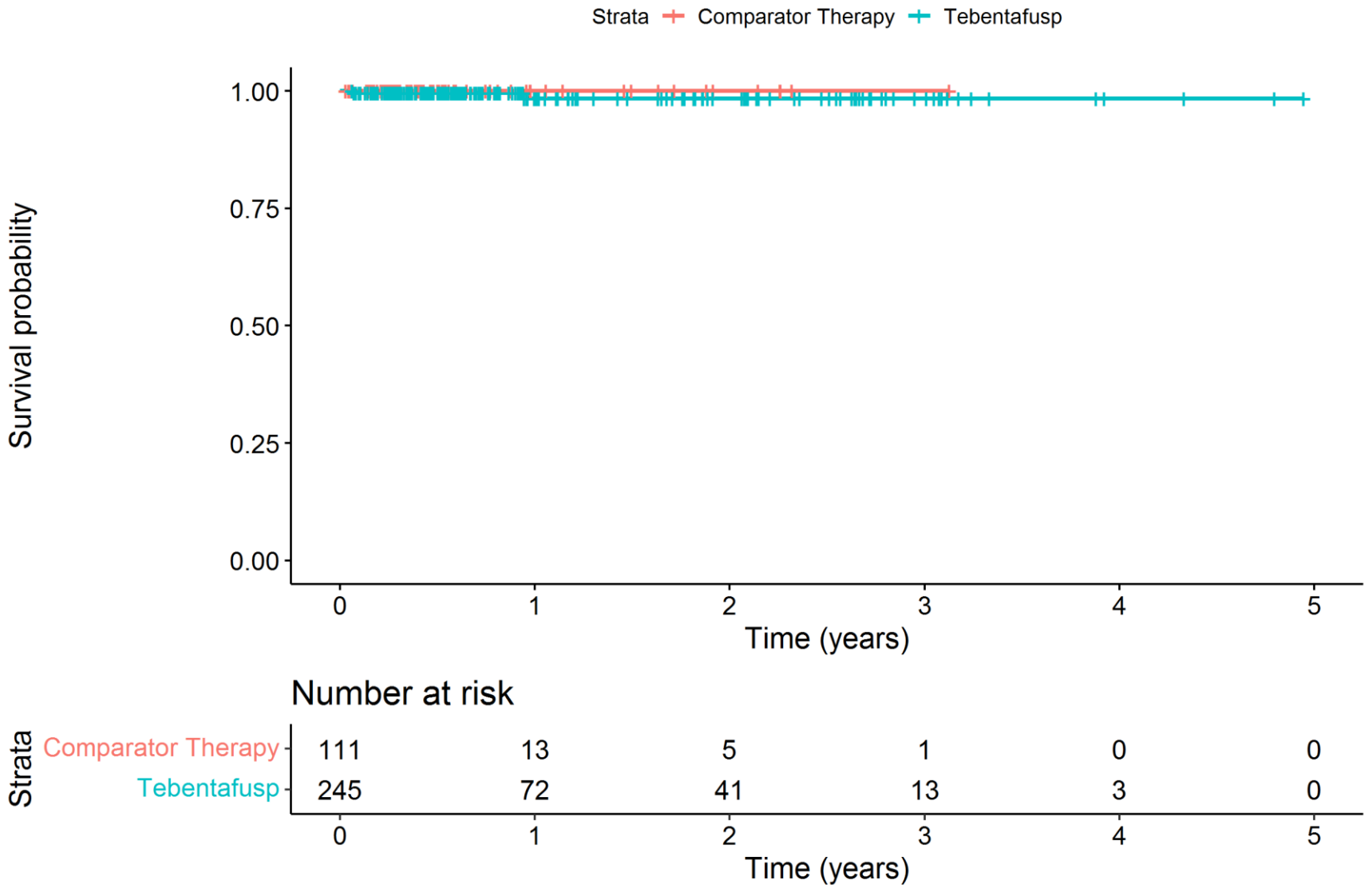
12.7 Zytokin-Freisetzungssyndrom



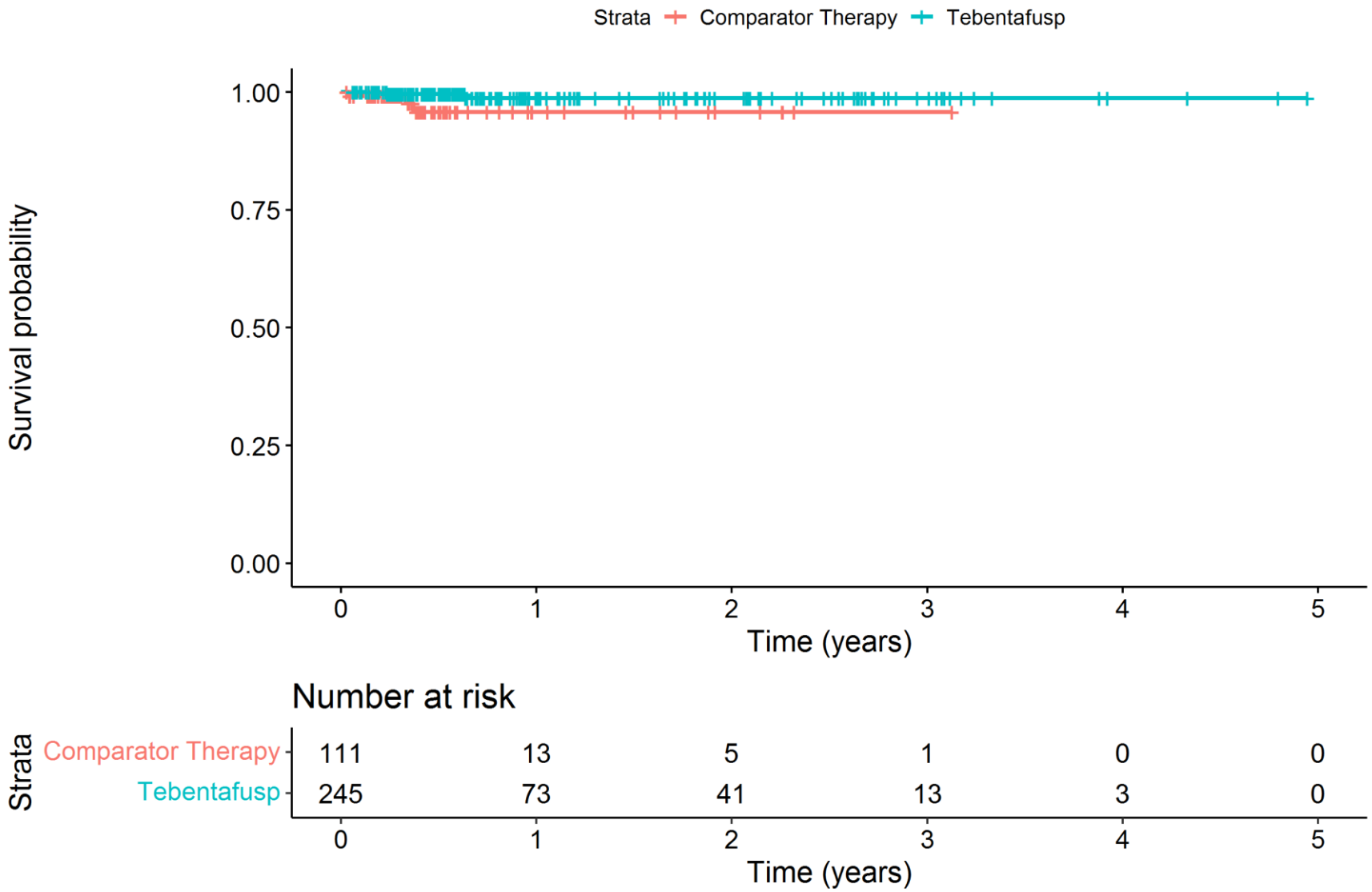
12.8 Dehydrierung



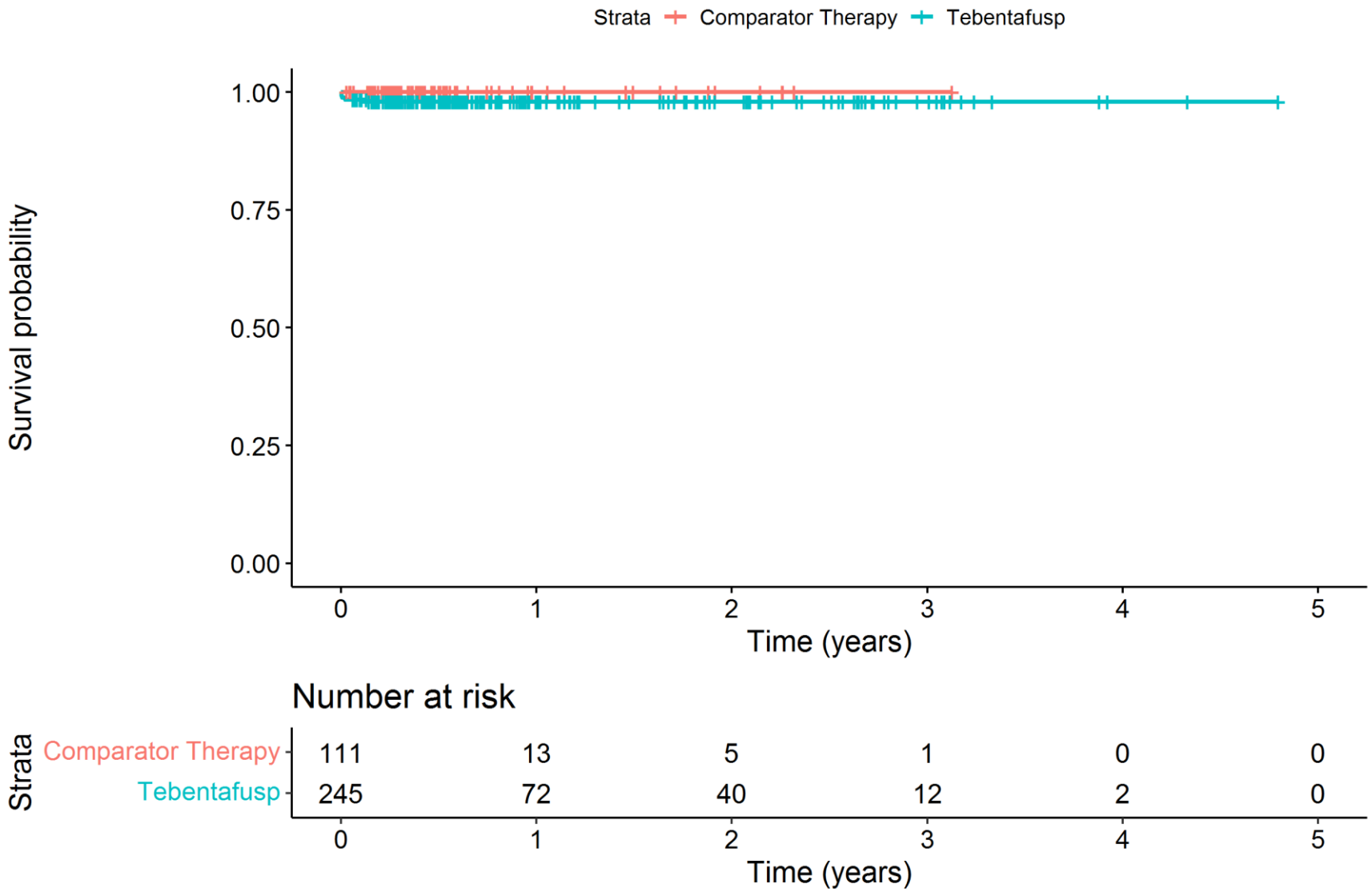
12.9 Tumorschmerzen



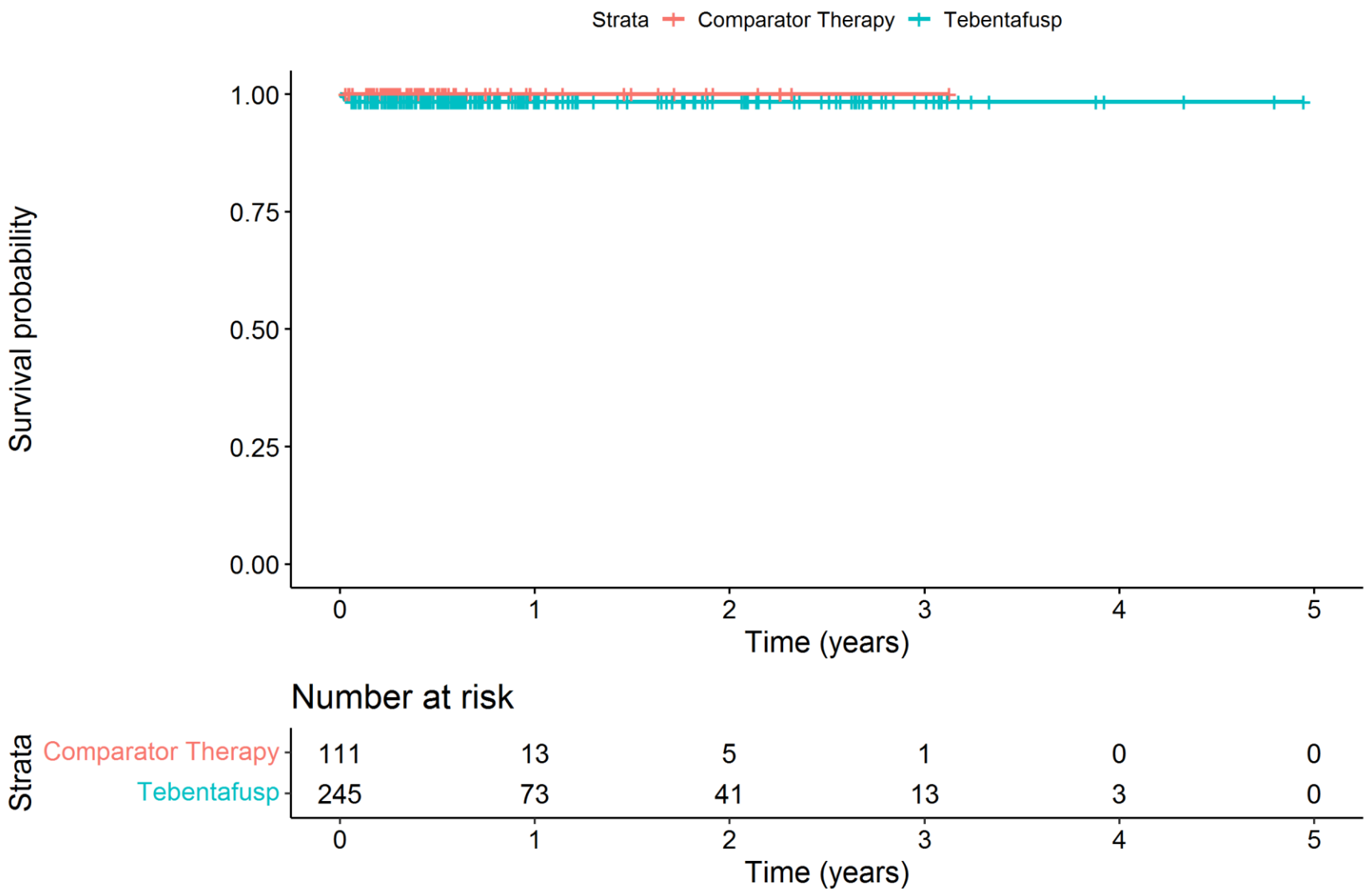
12.10 Lungenembolie



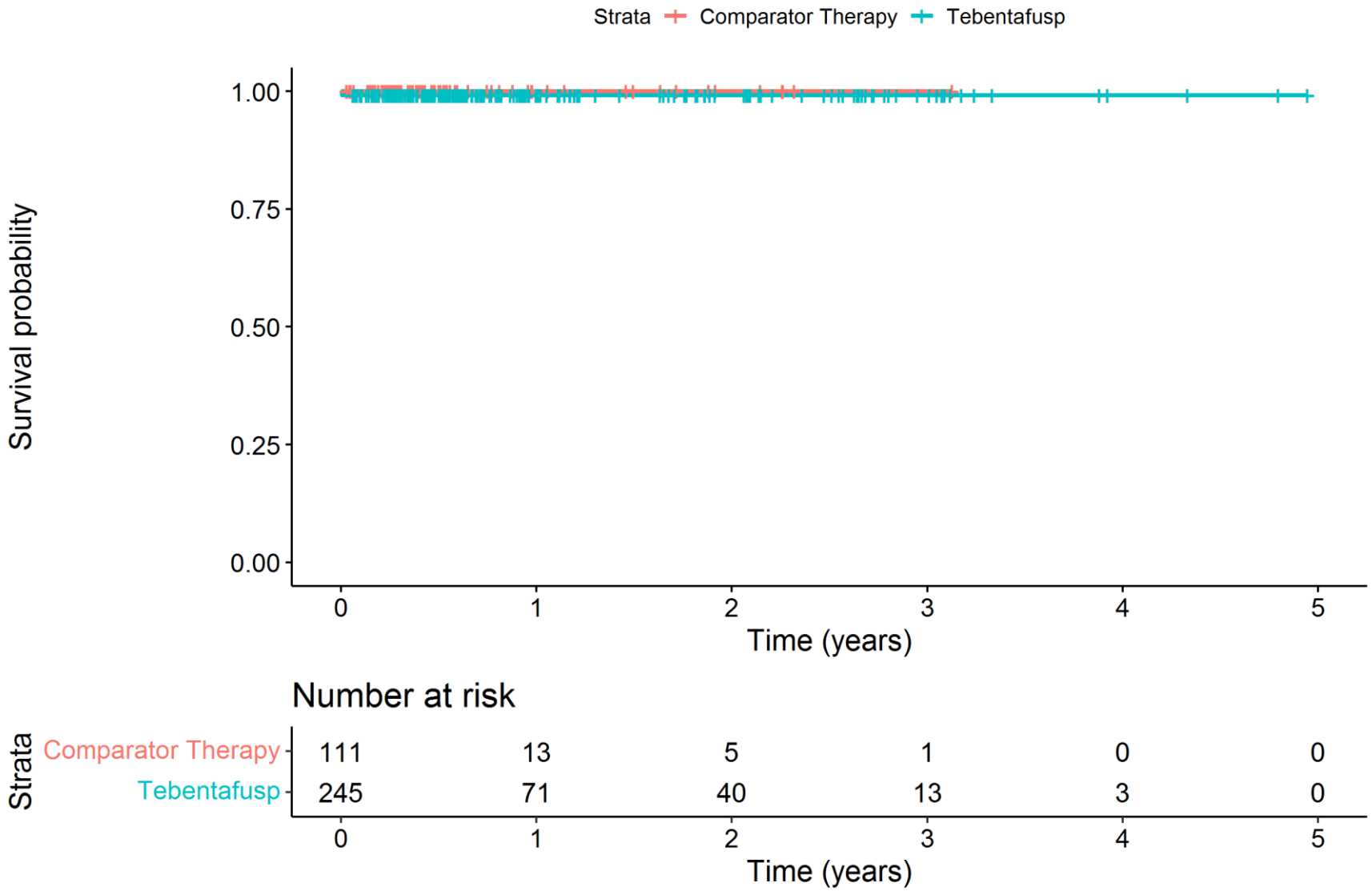
12.11 Hautausschlag



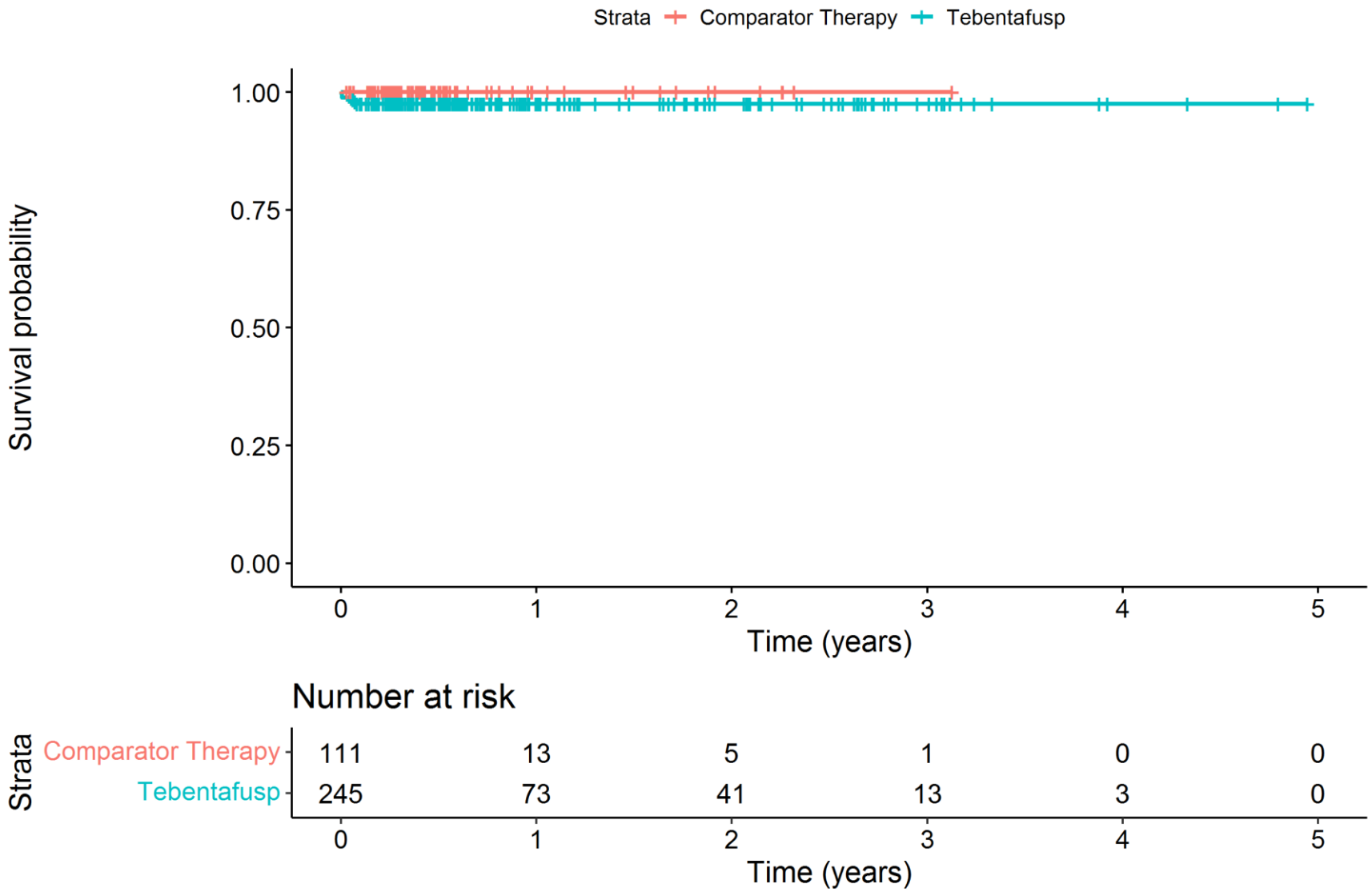
12.12 Makulo-papulöser Hautausschlag



12.13 Makulo-papulöser Hautausschlag

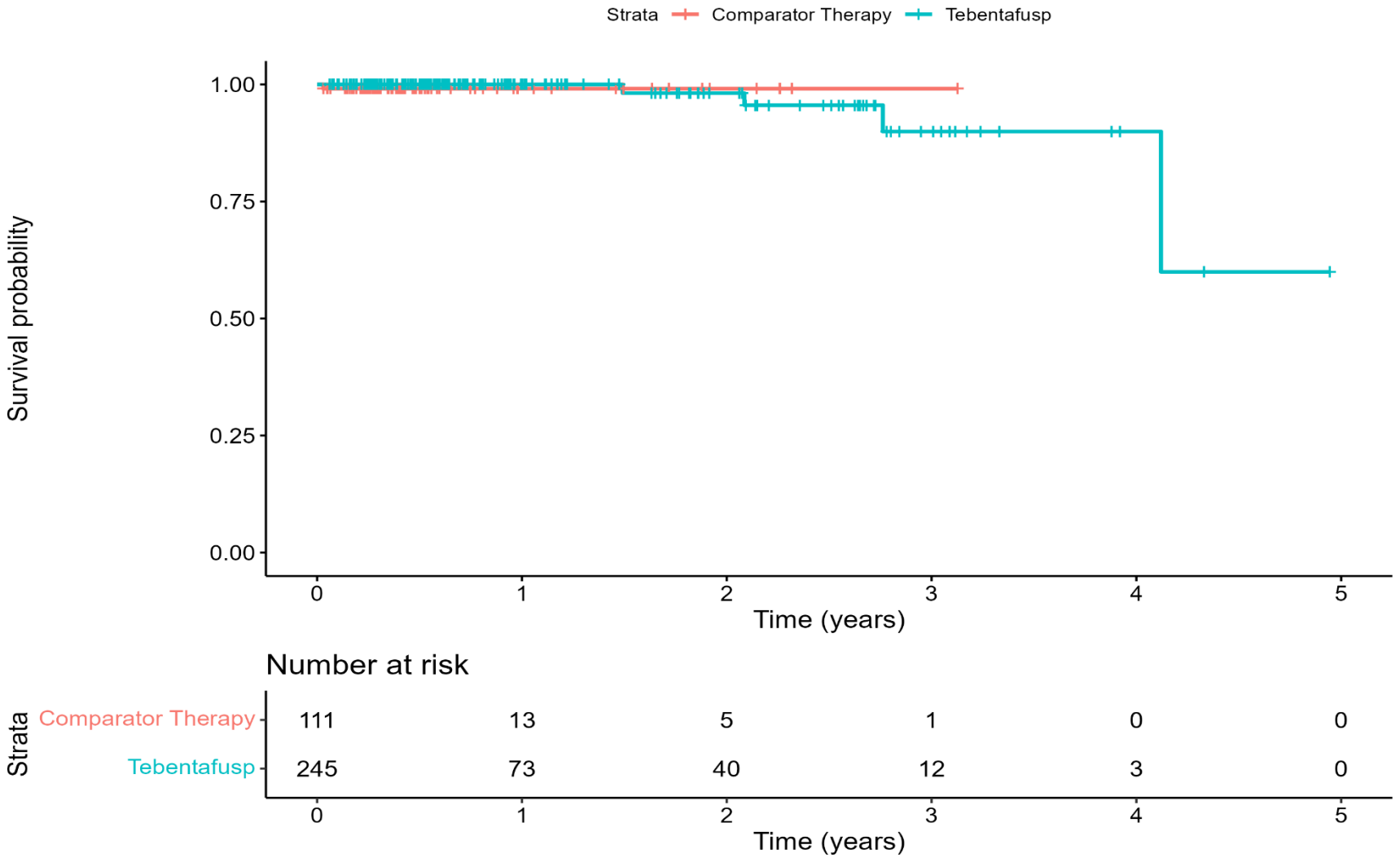


12.14 Hypotonie

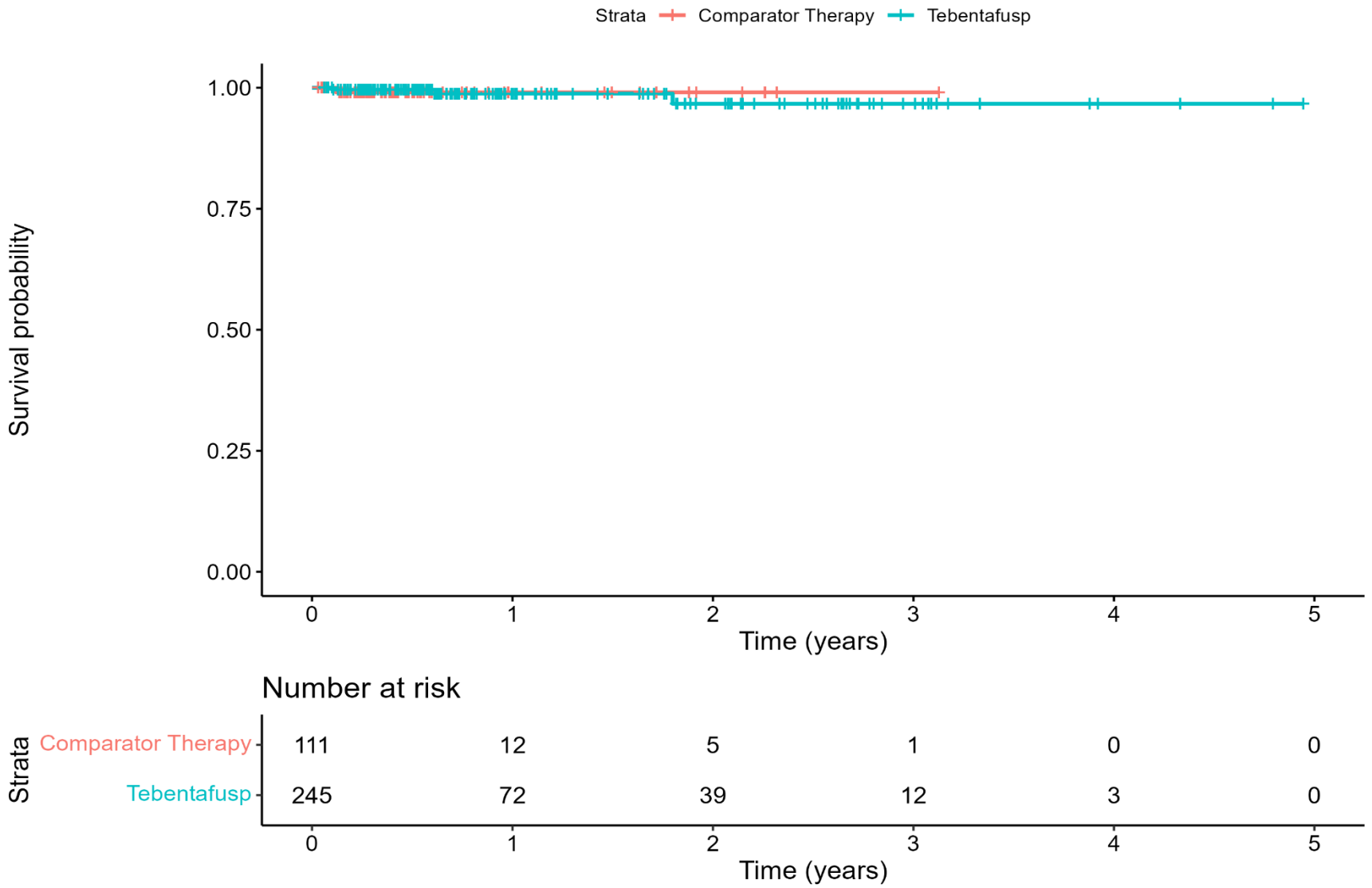


13 SUEs (SOC) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten

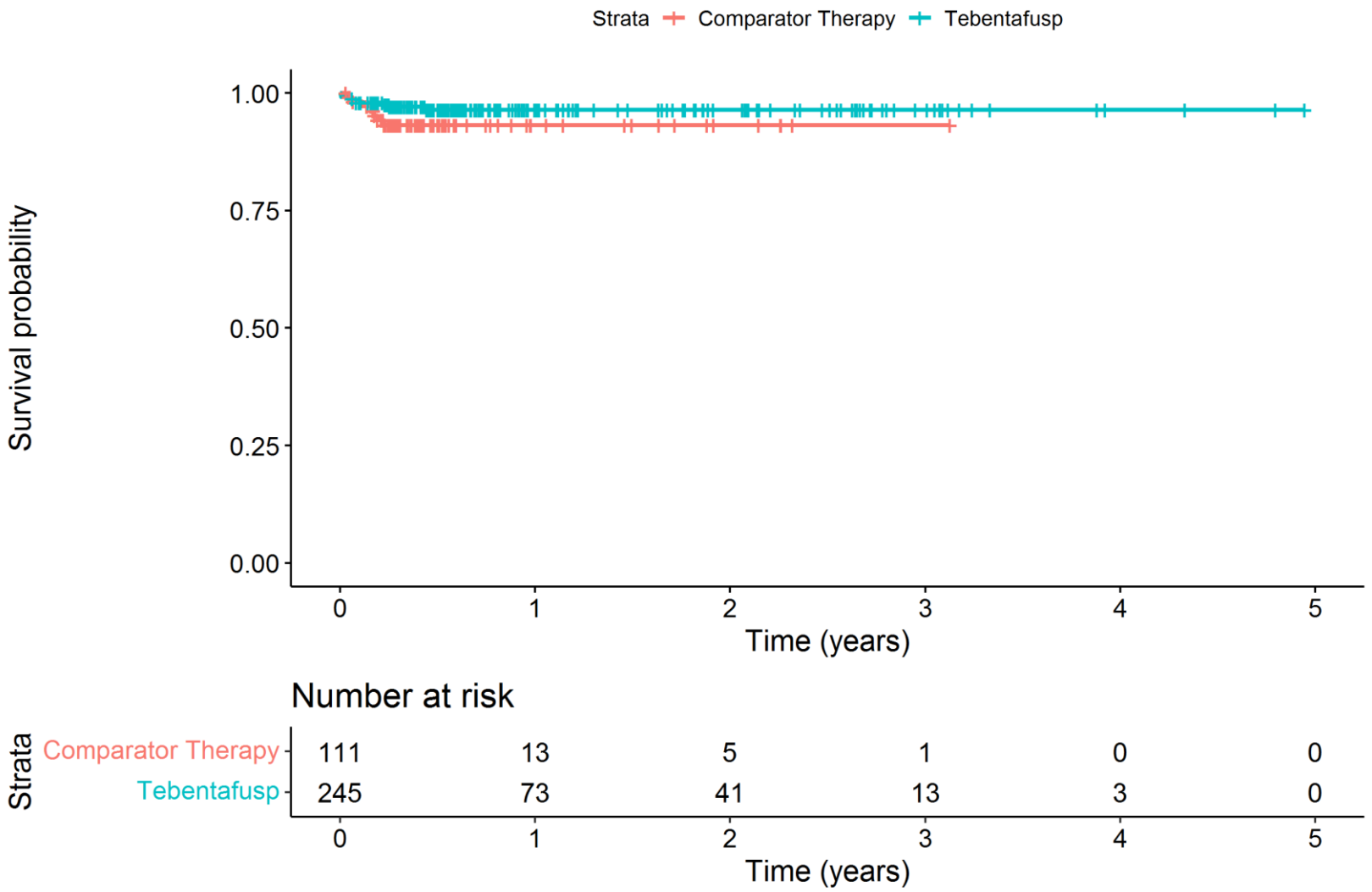
13.1 Herzerkrankungen


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
73
40
12
3
0
0
1
2
3
4
5
Time (years)

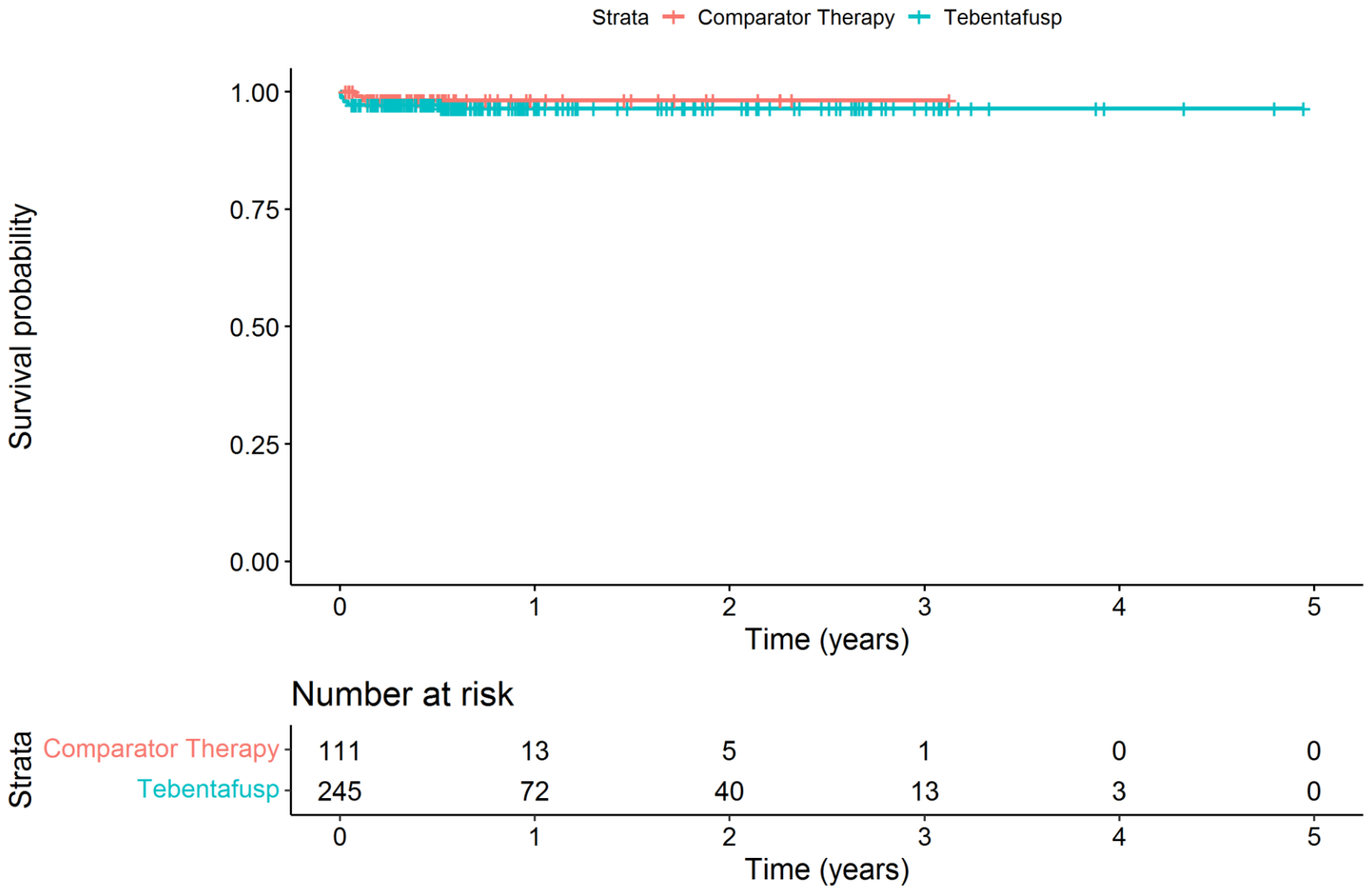
Augenerkrankungen



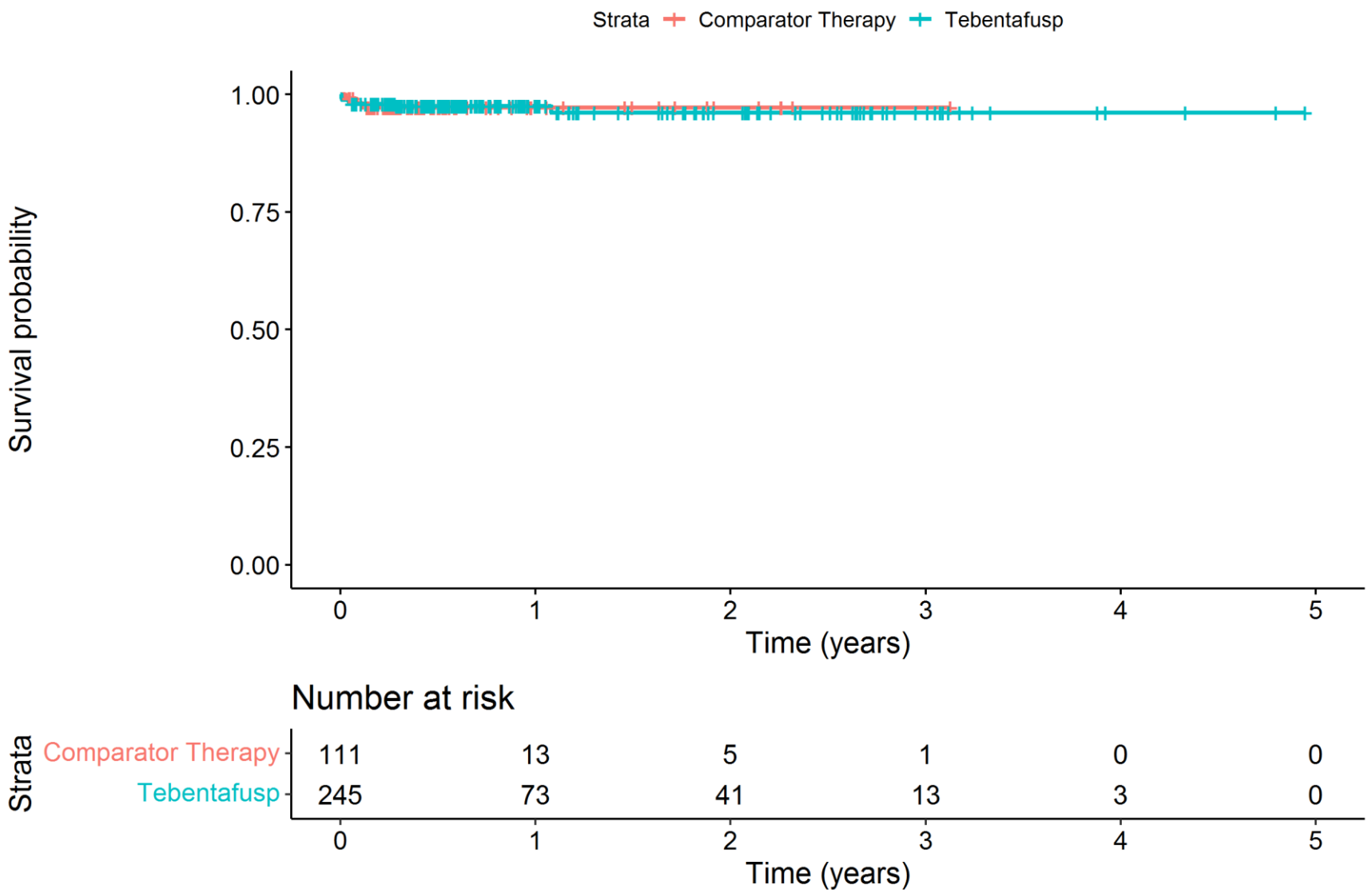
13.2 Erkrankungen des Gastrointestinaltrakts



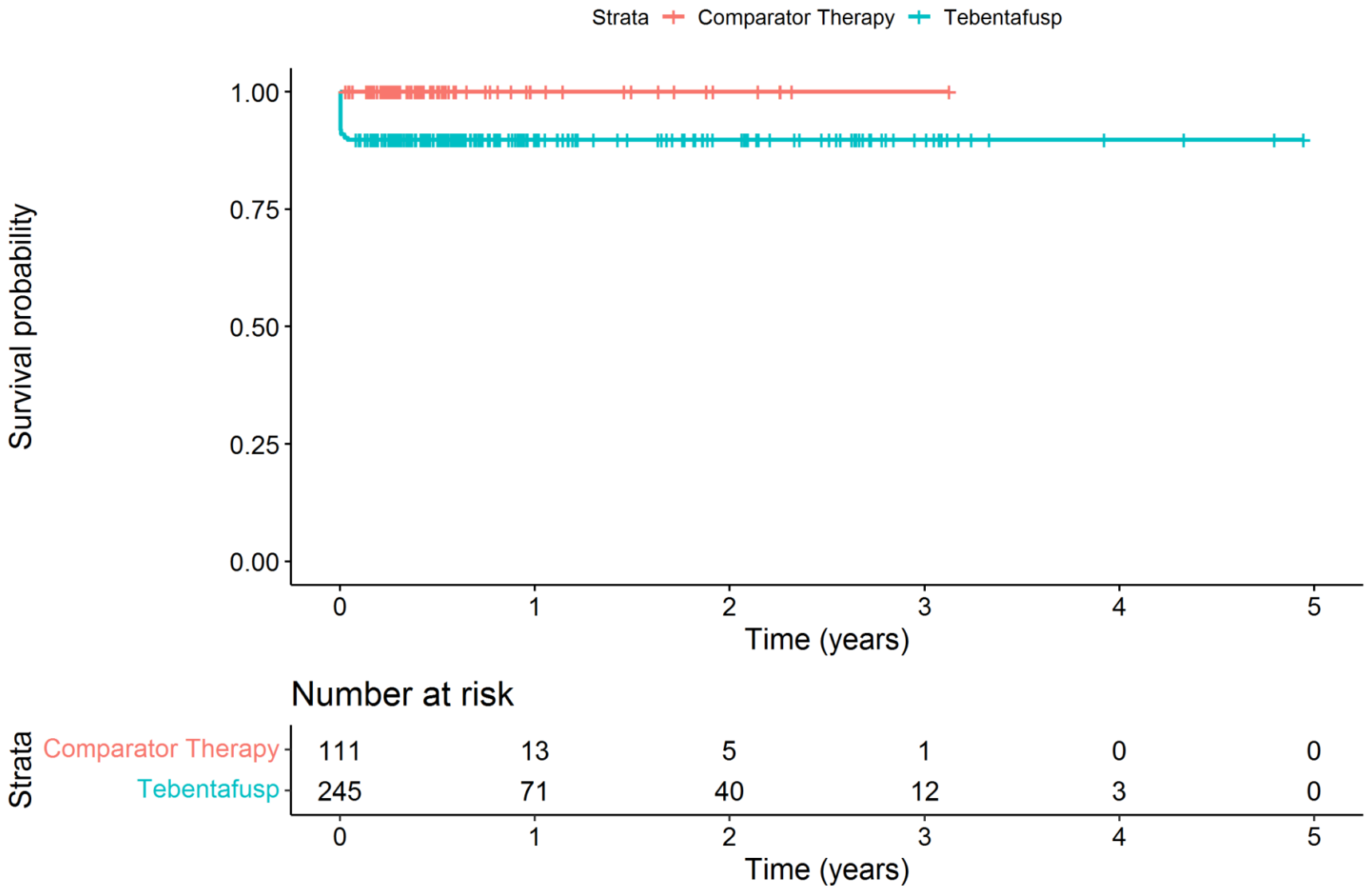
13.3 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



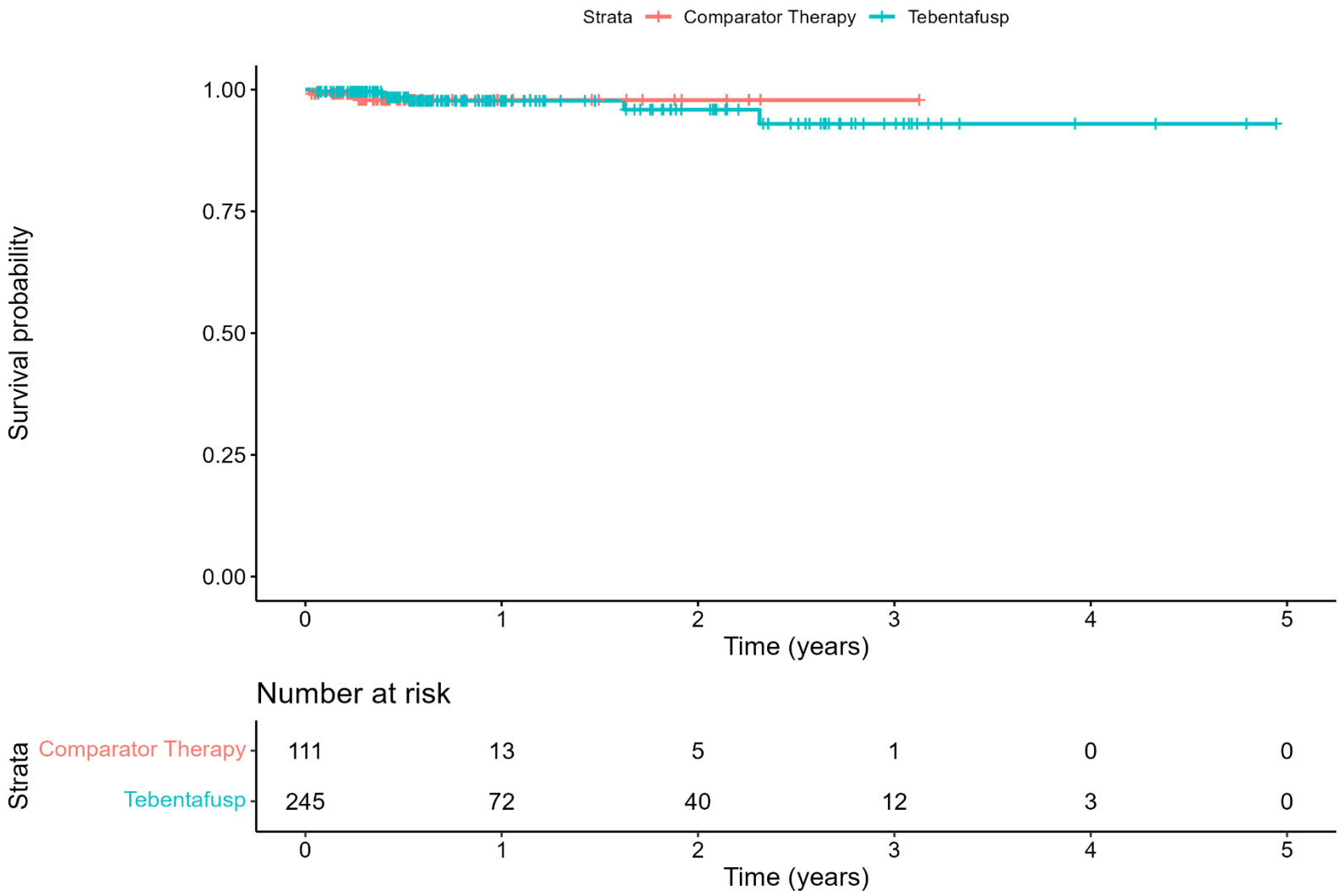
13.4 Leber- und Gallenerkrankungen



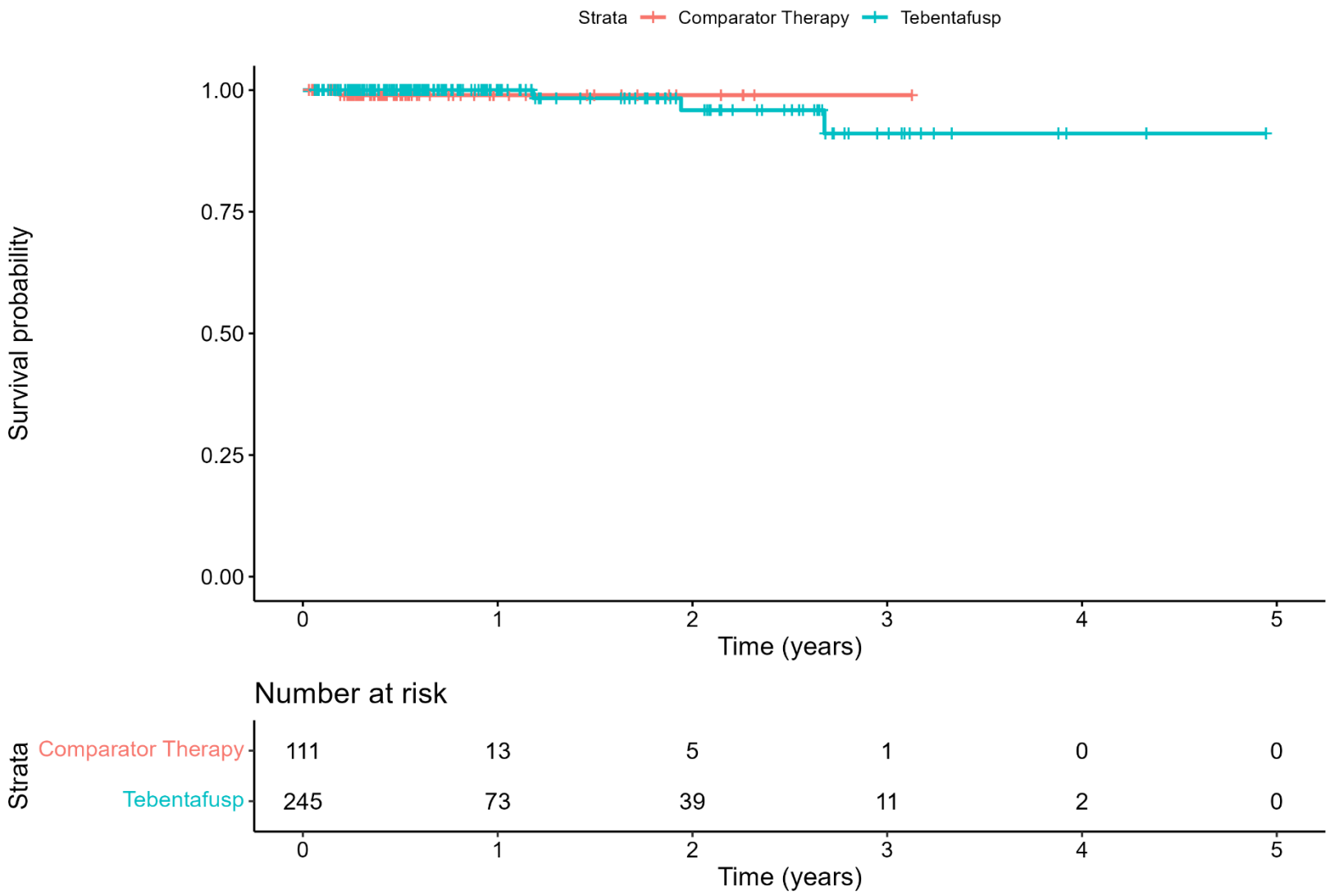
13.5 Erkrankungen des Immunsystems



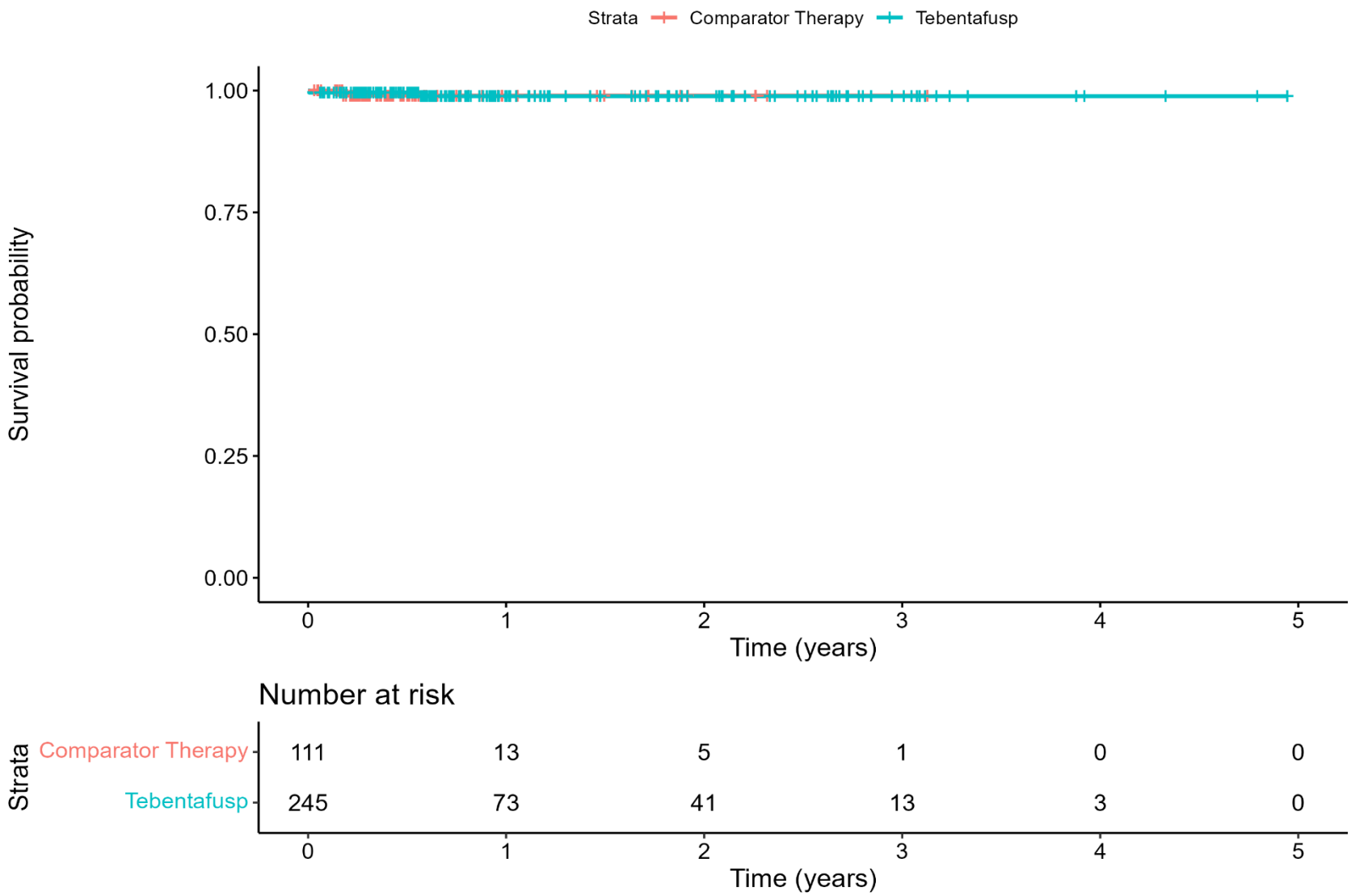
13.6 Infektionen und parasitäre Erkrankungen



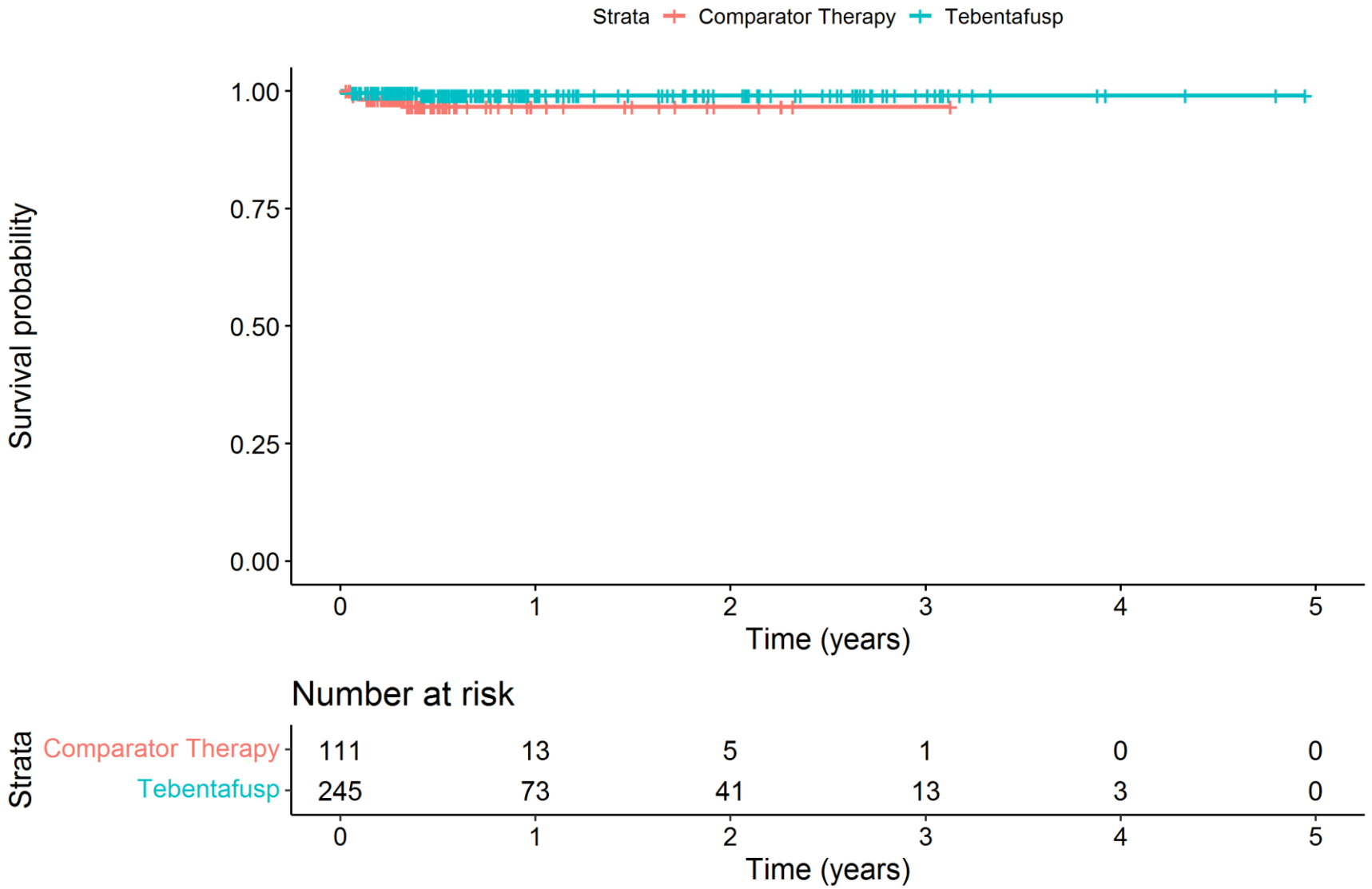
13.7 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



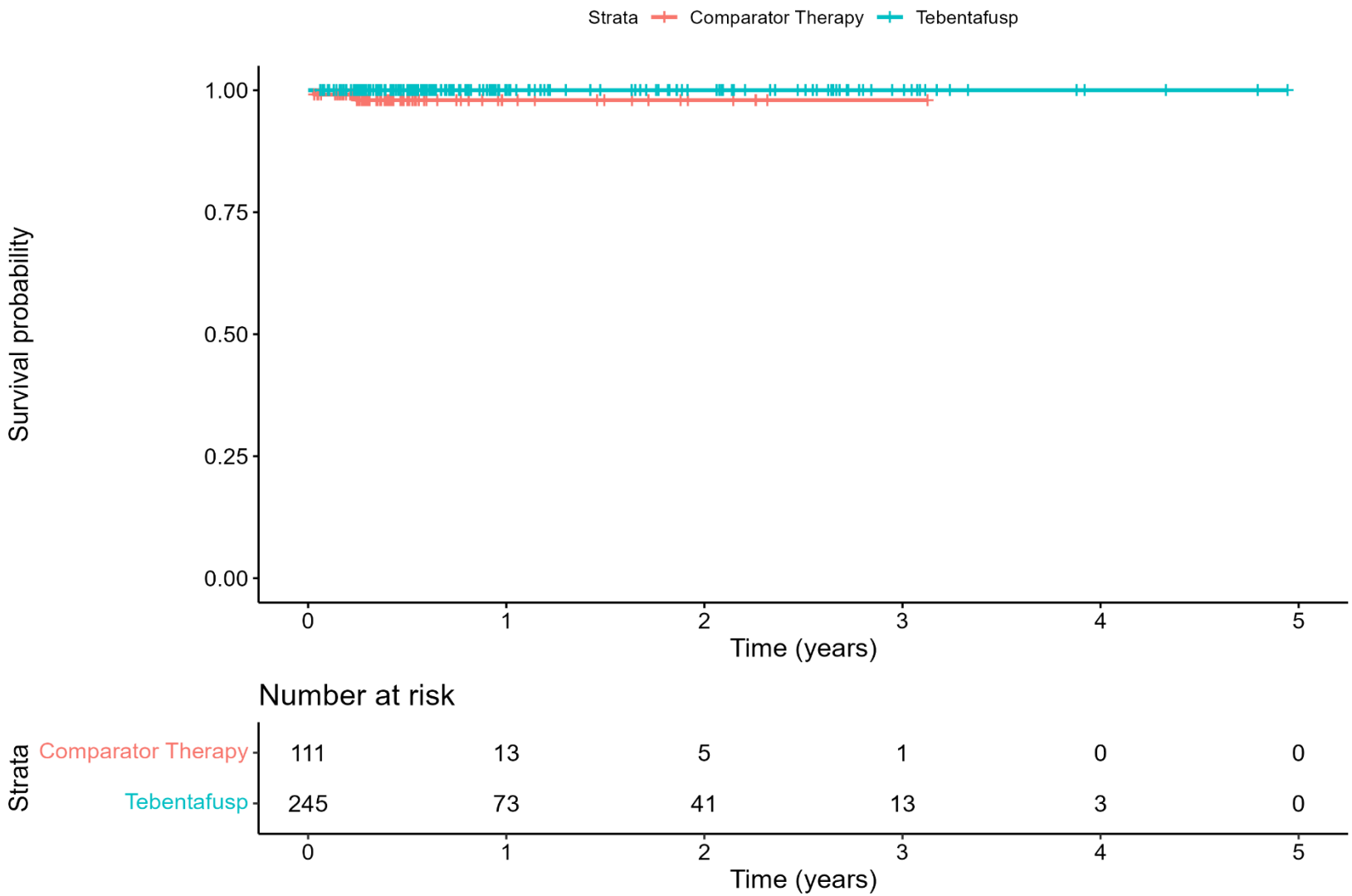
13.8 Untersuchungen



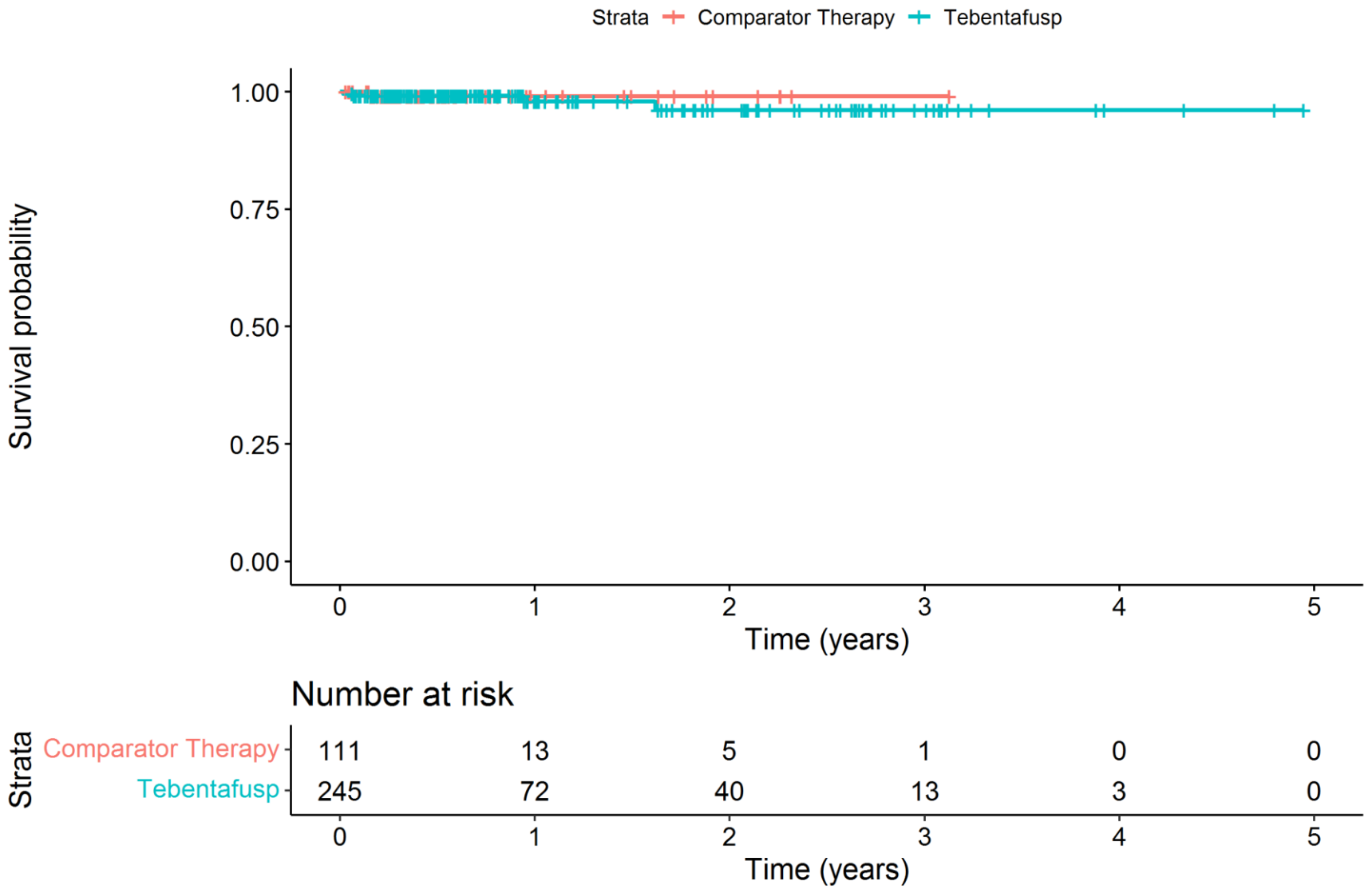
13.9 Stoffwechsel- und Ernährungsstörungen



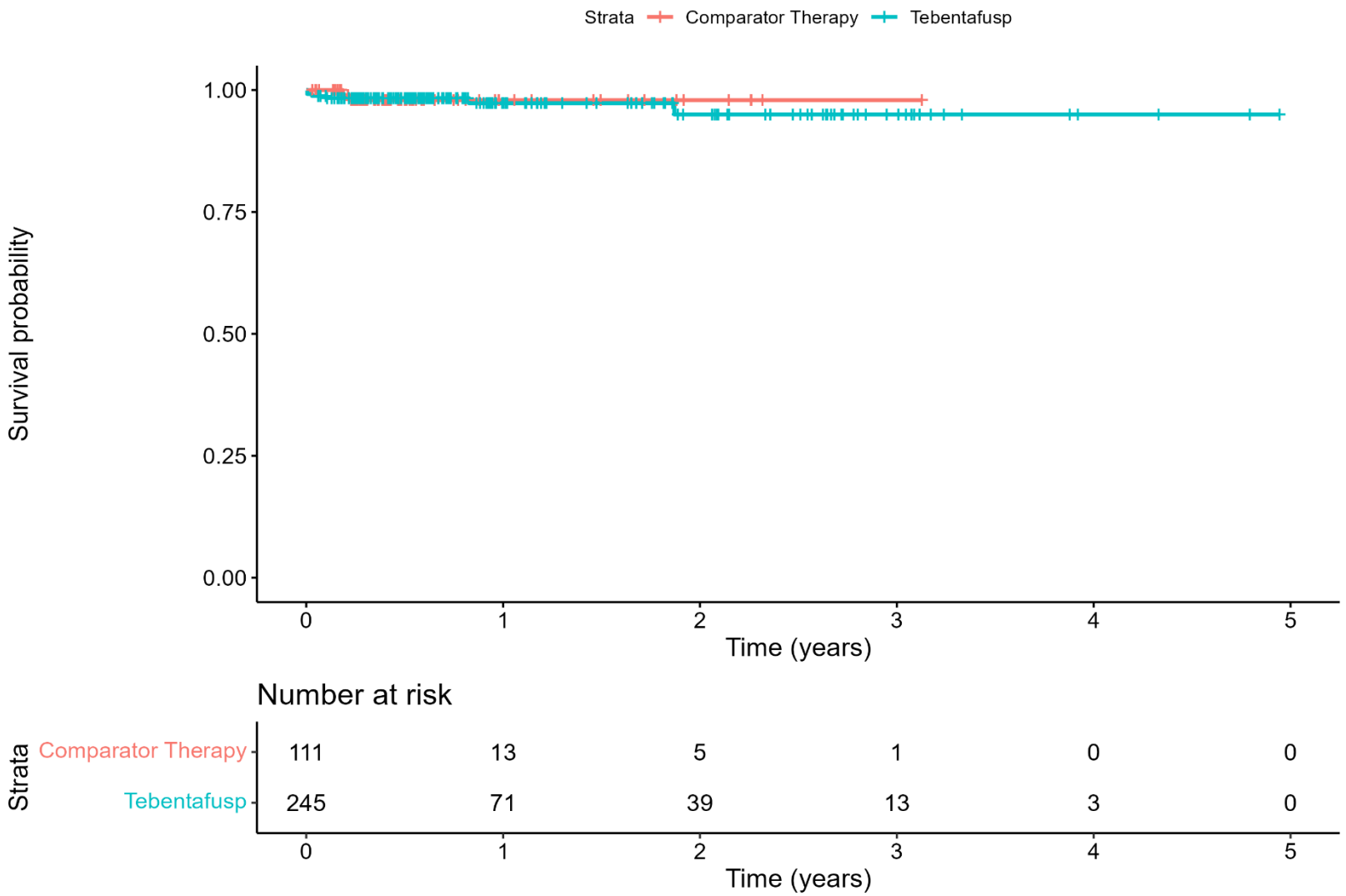
13.10 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



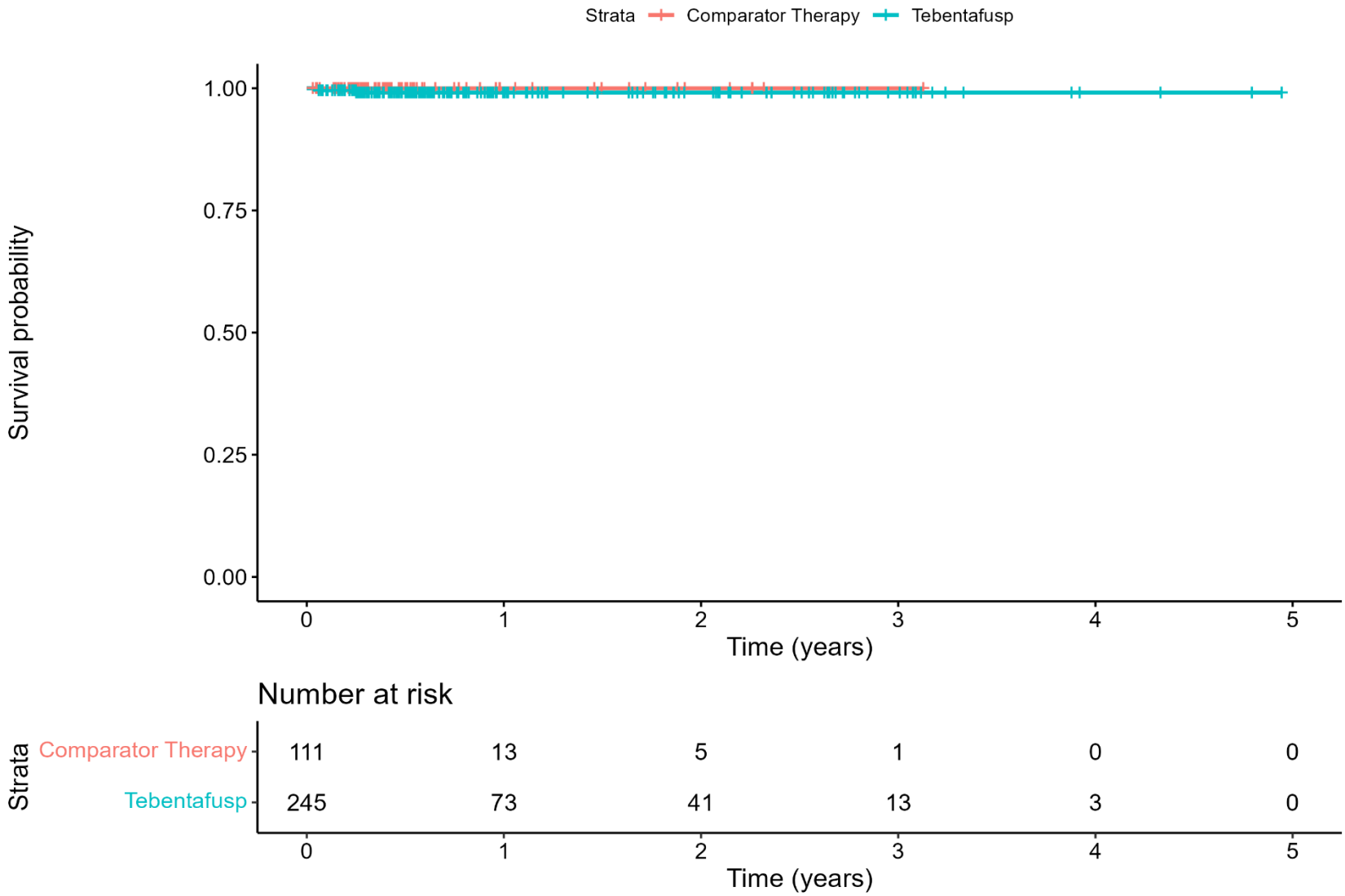
13.11 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



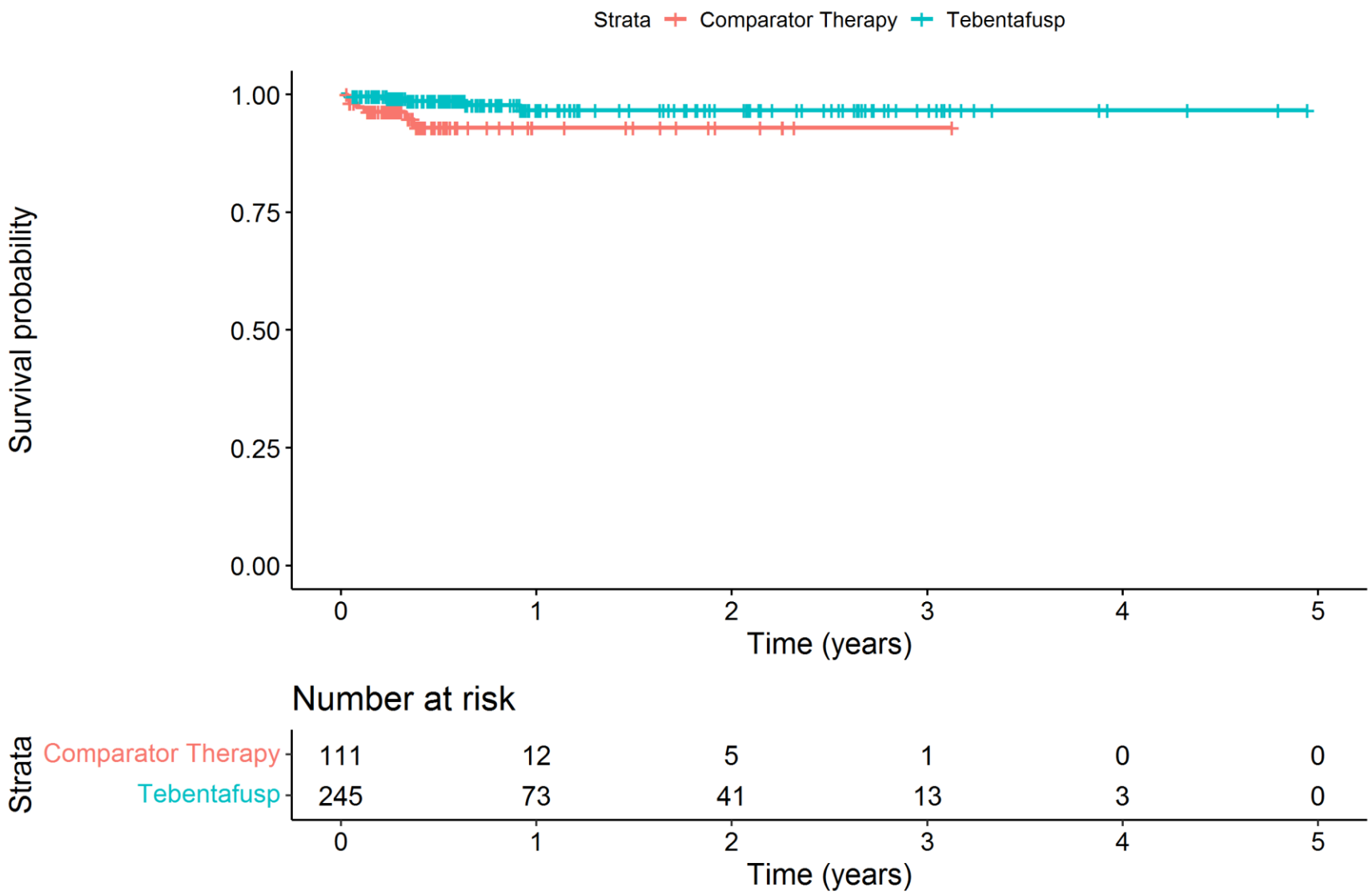
13.12 Erkrankungen des Nervensystems



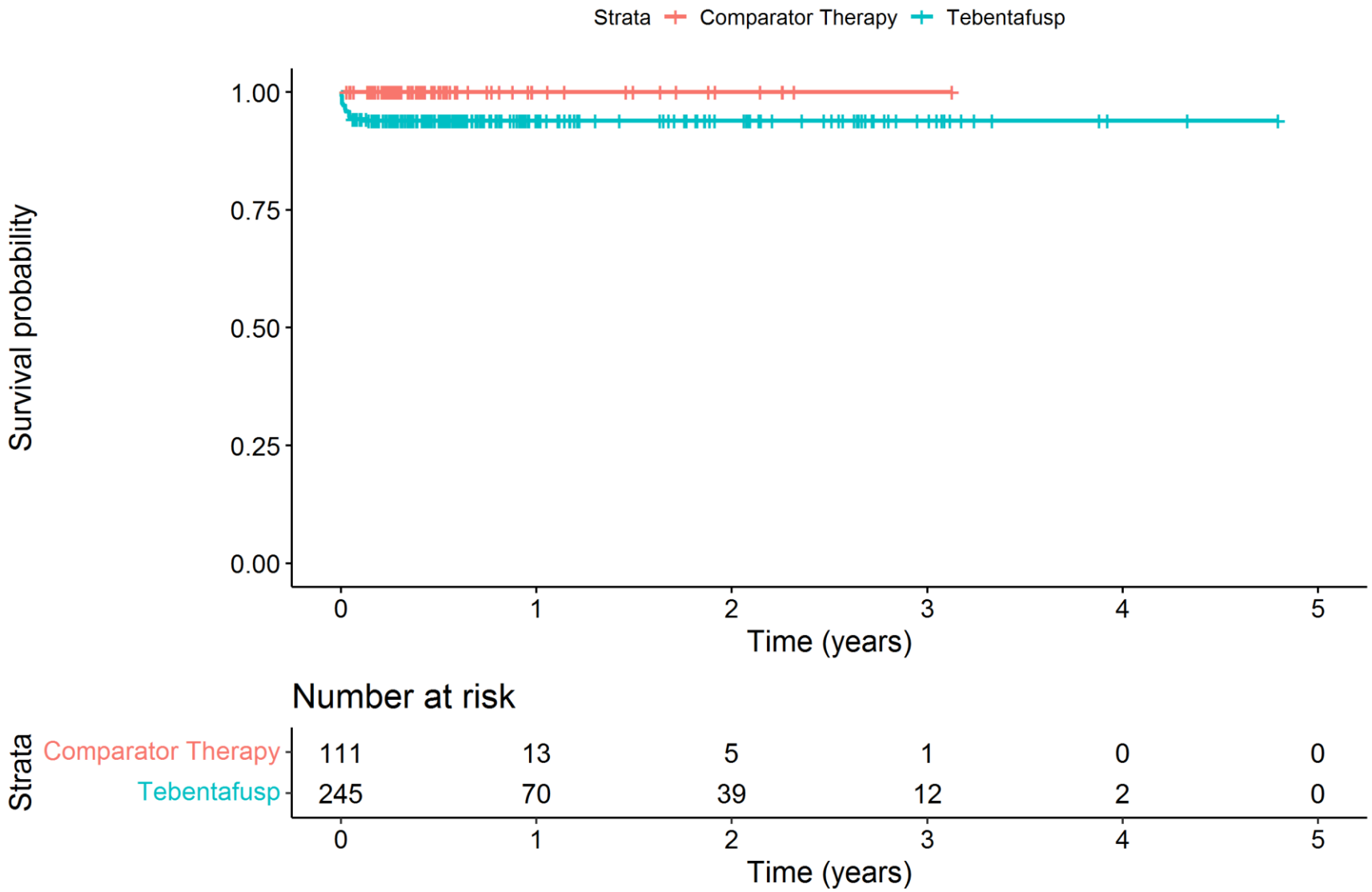
13.13 Erkrankungen der Nieren und Harnwege



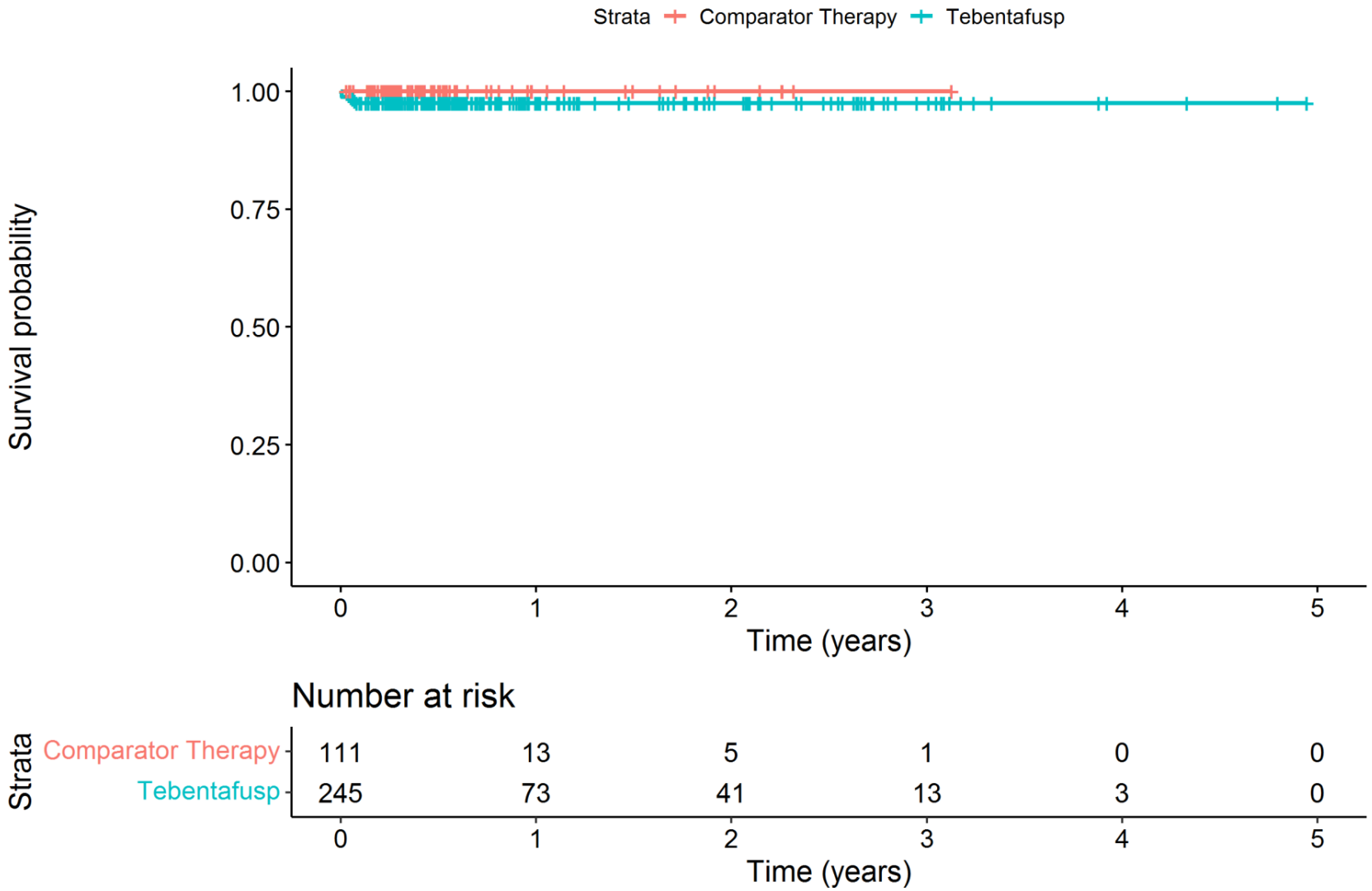
13.14 Erkrankungen der Atemwege, des Brustraums und Mediastinums



13.15 Erkrankungen der Haut und des Unterhautgewebes



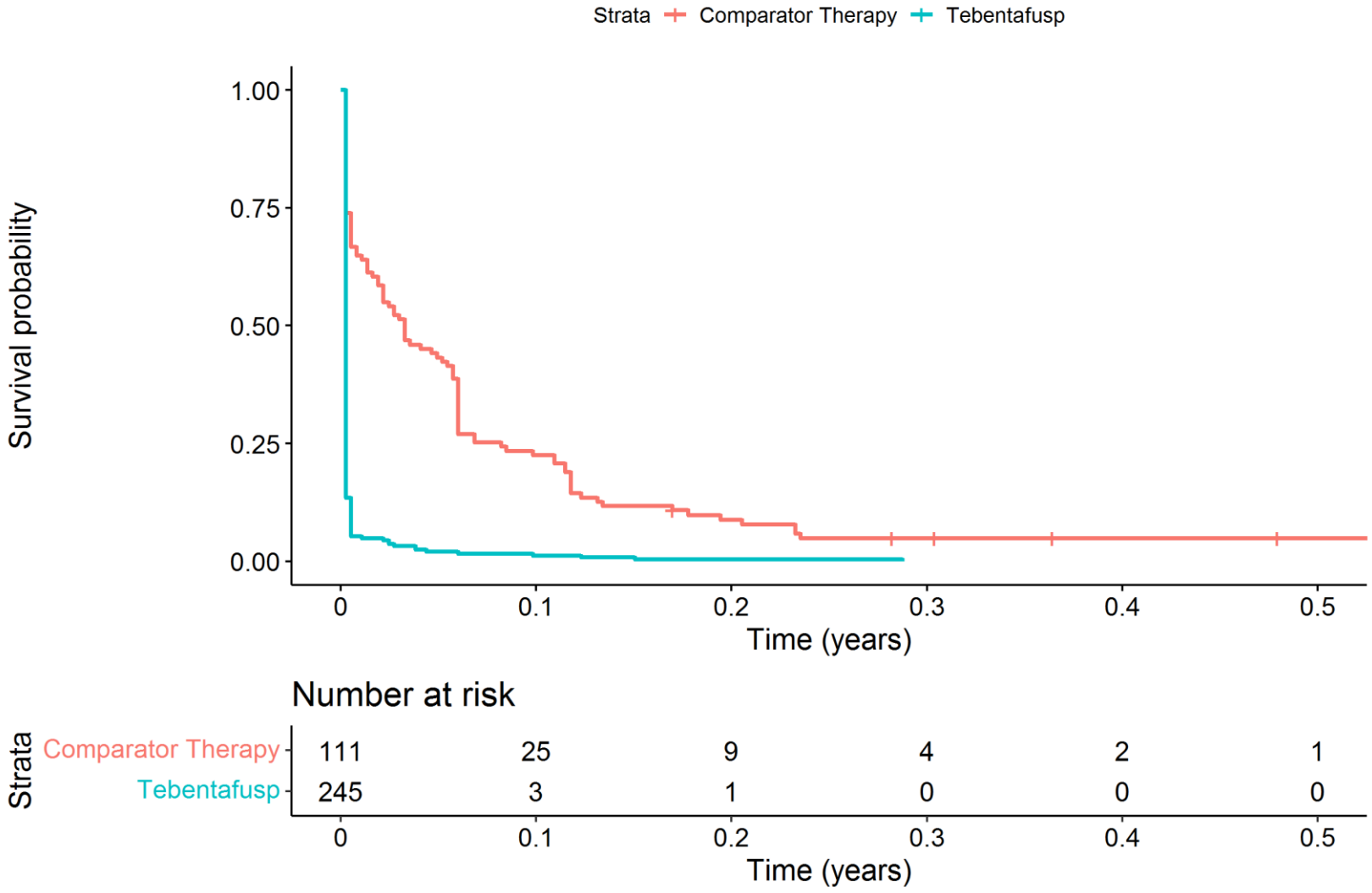
13.16 Gefäßerkrankungen



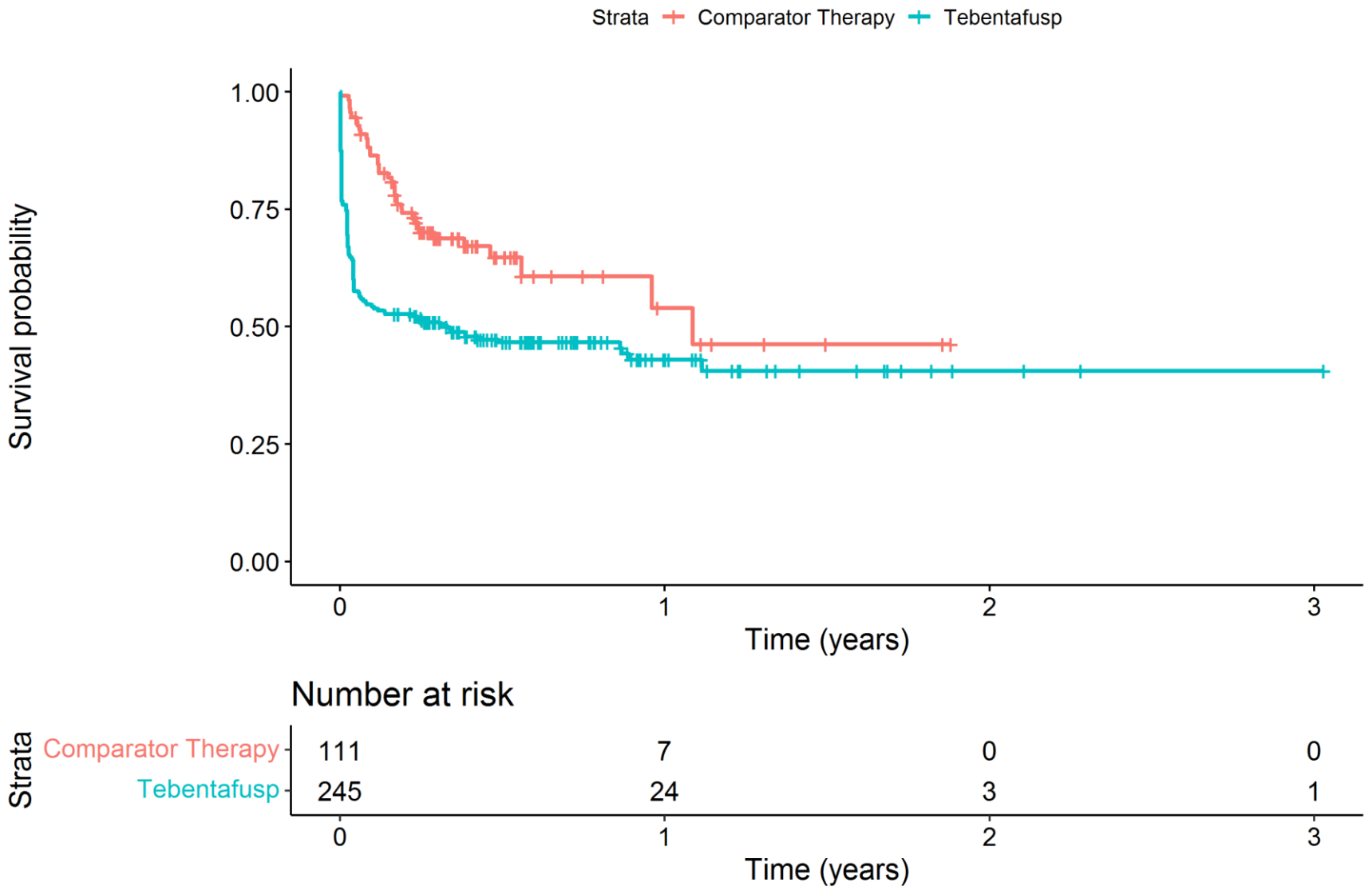
14 Unerwünschte Ereignisse ohne mit der Krankheitsprogression zusammenhängenden UEs

14.1 **Primäranalyse (Oktober 2020) (Tabelle 4-67)**

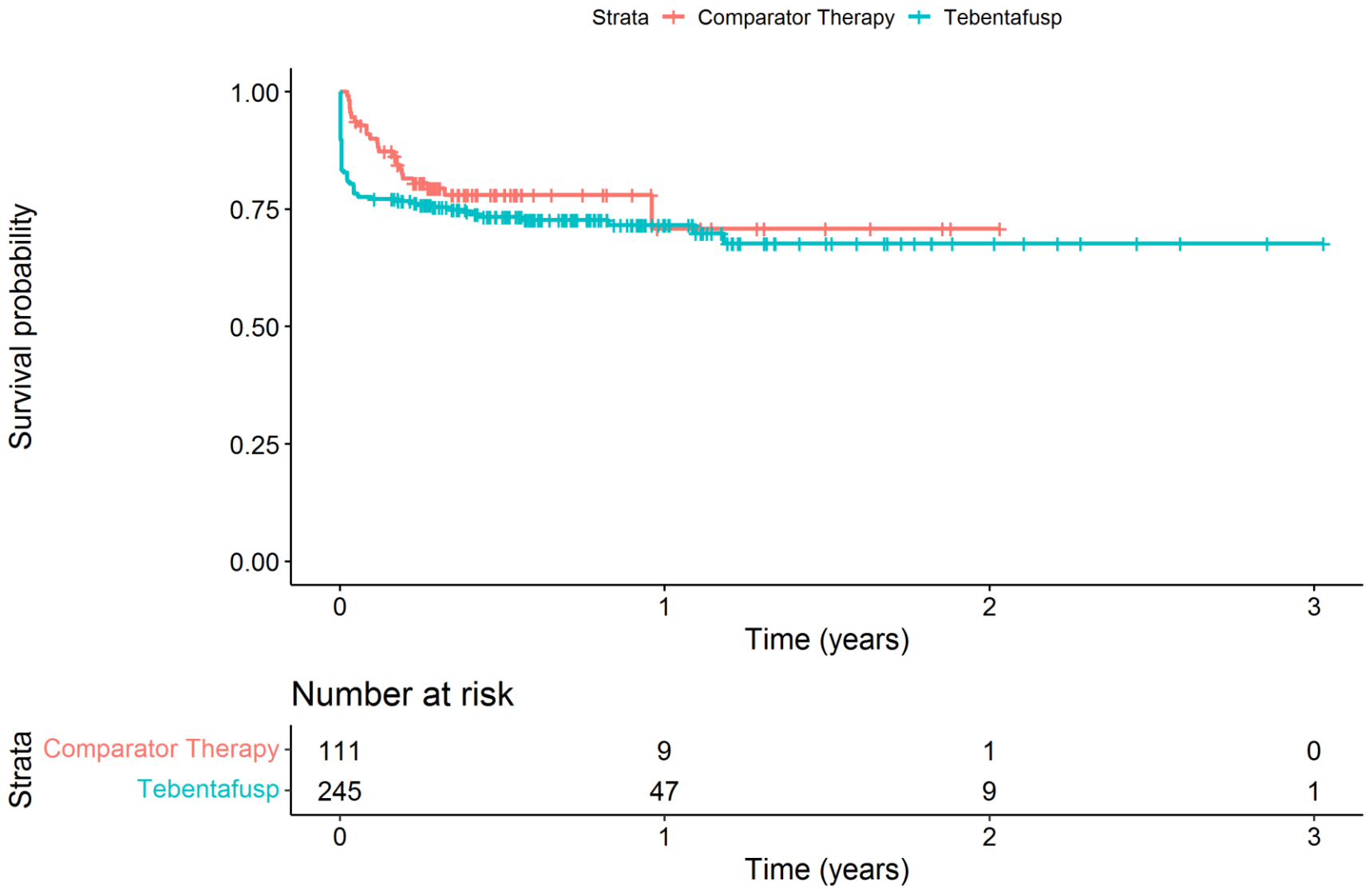
Unter der Behandlung aufgetretene UEs ohne krankheitsbedingte Ereignisse



Unter der Behandlung aufgetretene UEs des Grades ≥ 3 ohne krankheitsbedingte Ereignisse

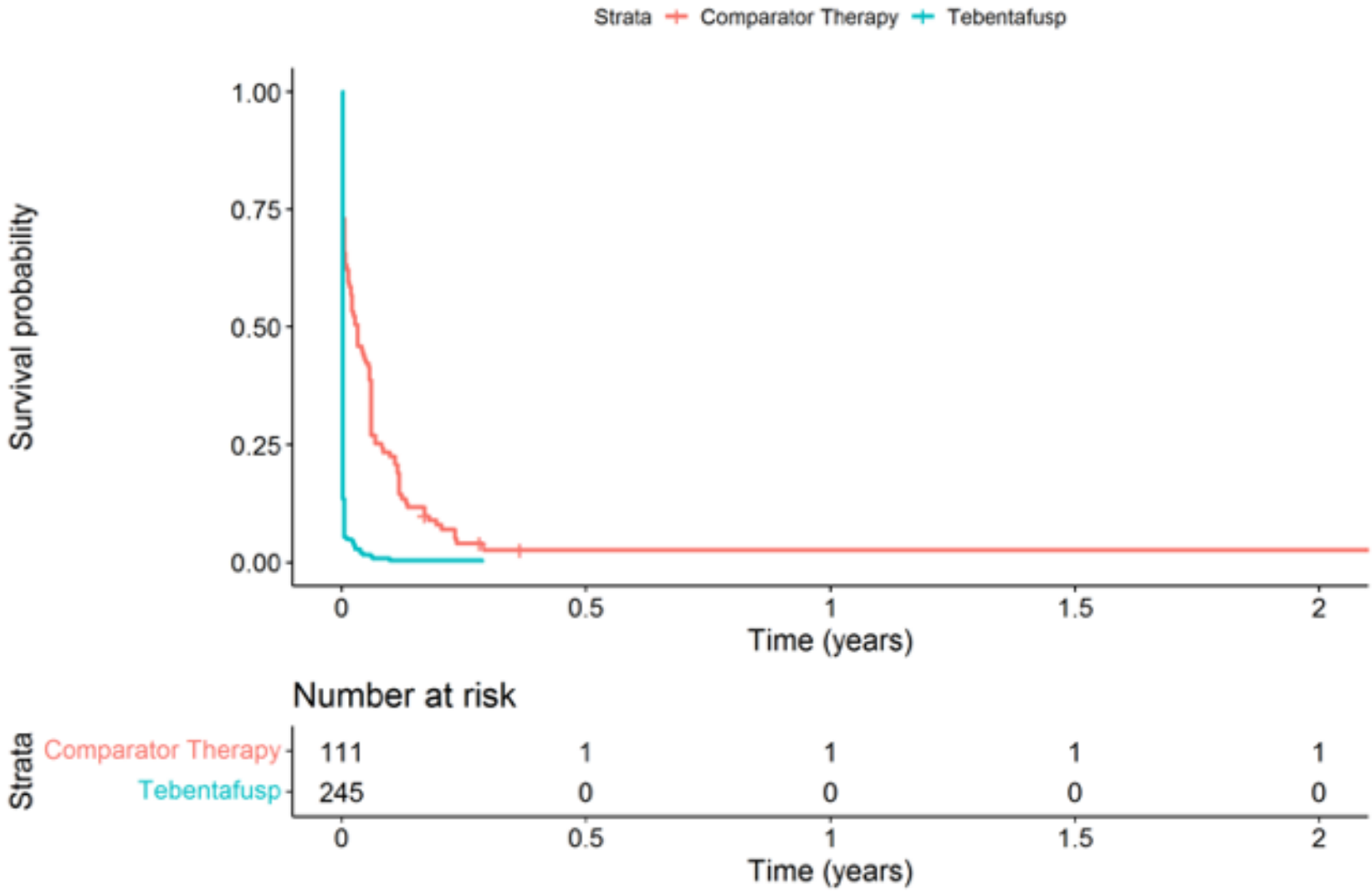


SUEs ohne krankheitsbedingte Ereignisse

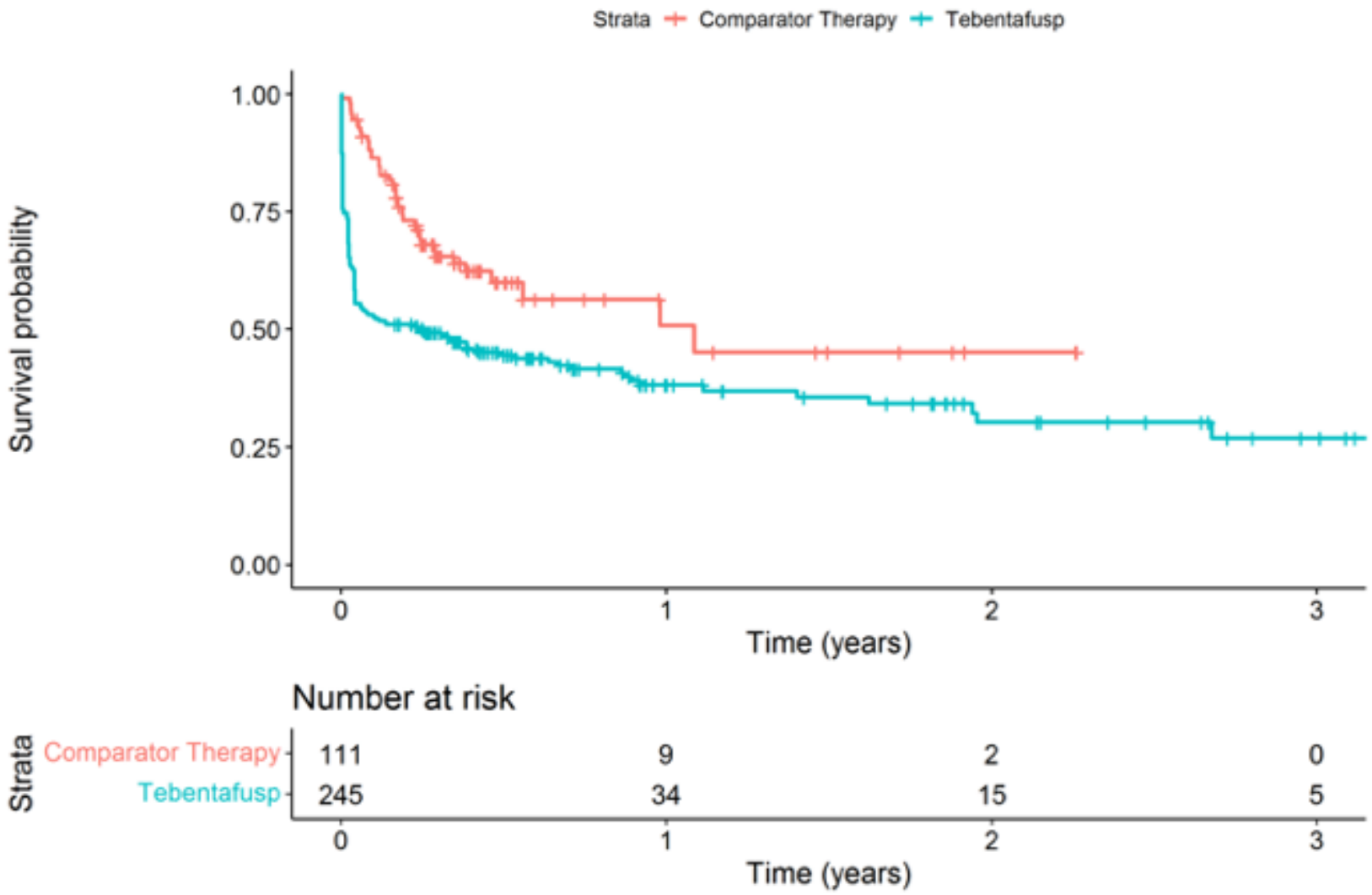


14.2 **3-Jahres-Analyse (Juni 2023) (Tabelle 4-68)**

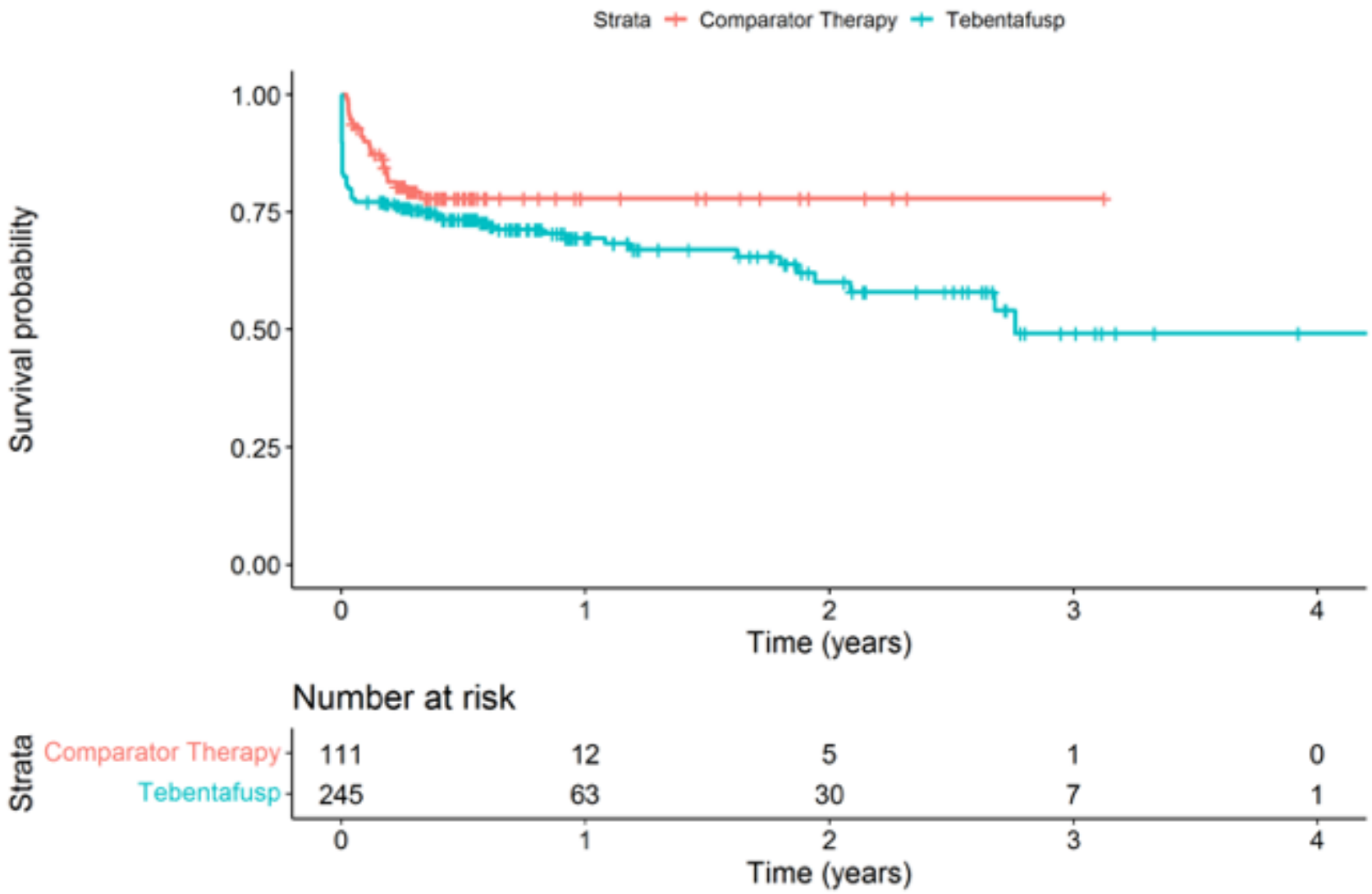
14.3 Unter der Behandlung aufgetretene UEs ohne krankheitsbedingte Ereignisse


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
0.5
1
1.5
2
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
1
1
1
1
245
0
0
0
0
0
0.5
1
1.5
2
Time (years)

14.4 Unter der Behandlung aufgetretene UEs des Grades ≥ 3 ohne krankheitsbedingte Ereignisse



14.5 SUEs ohne krankheitsbedingte Ereignisse

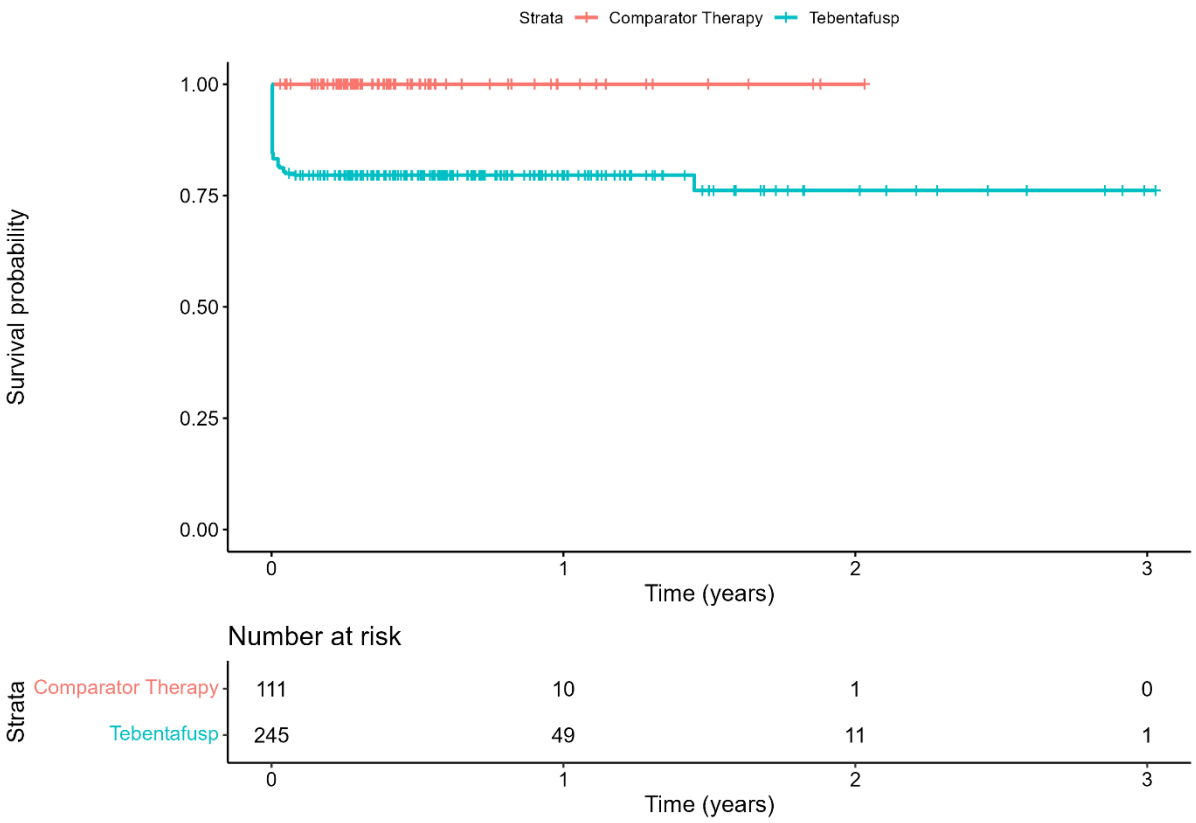


14.6 Unerwünschte Ereignisse von besonderem Interesse (AESIs)

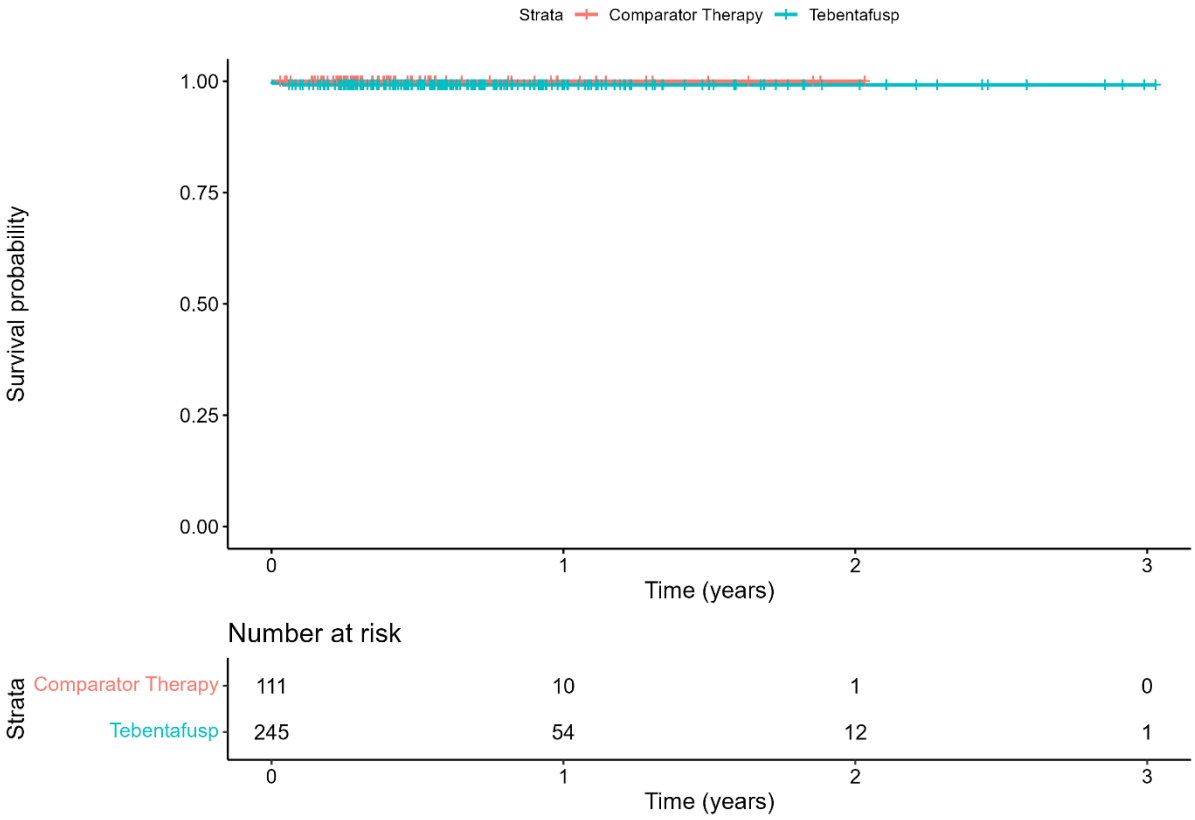
14.7 Zusammenfassung der AESIs

14.8 Primäranalyse (Oktober 2020) (Tabelle 4-58)

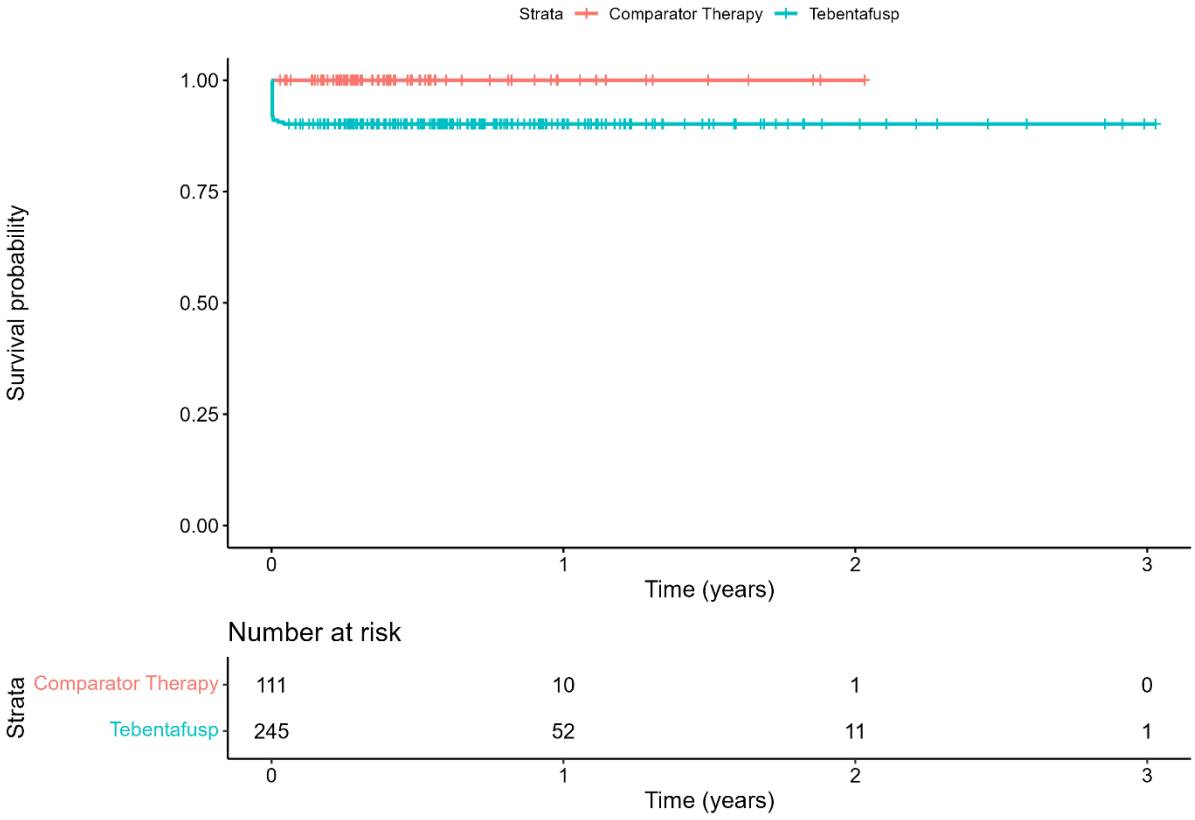
Zytokin-Freisetzungssyndrom



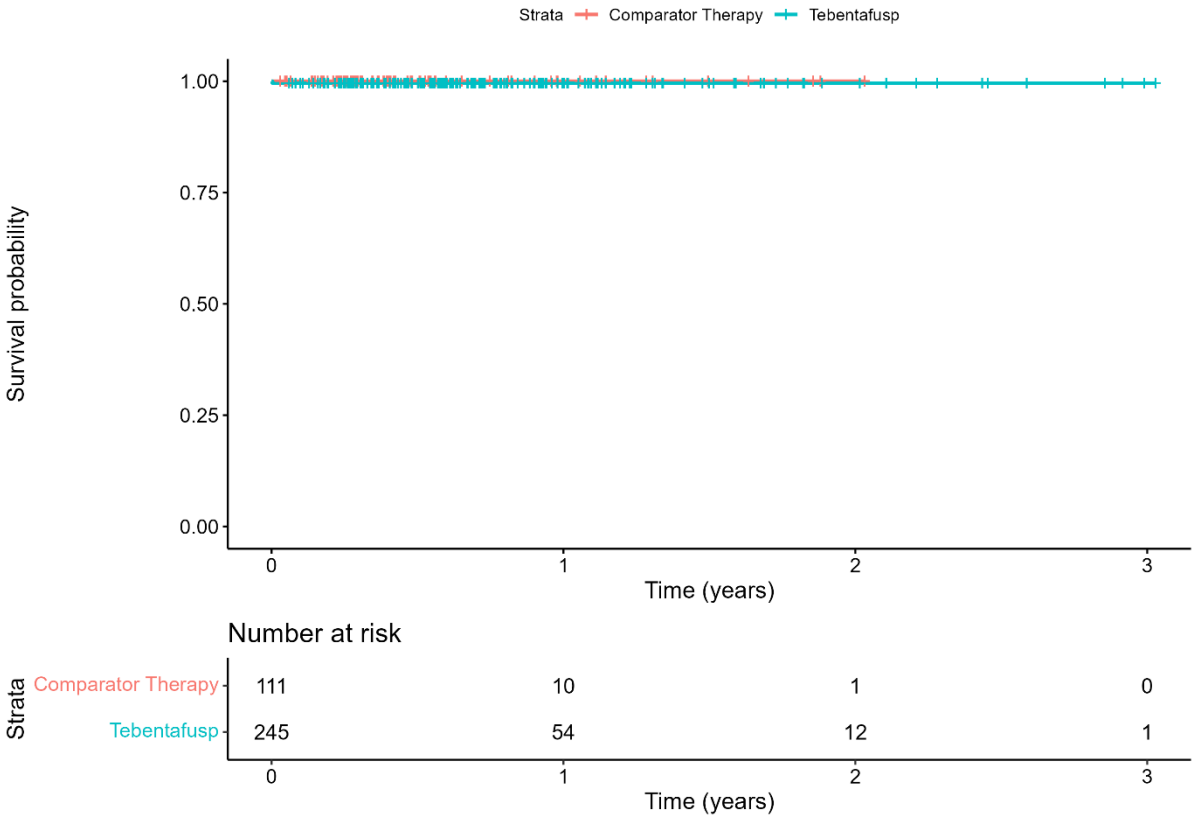
Zytokin-Freisetzungssyndrom mit CTCAE-Grad ≥ 3



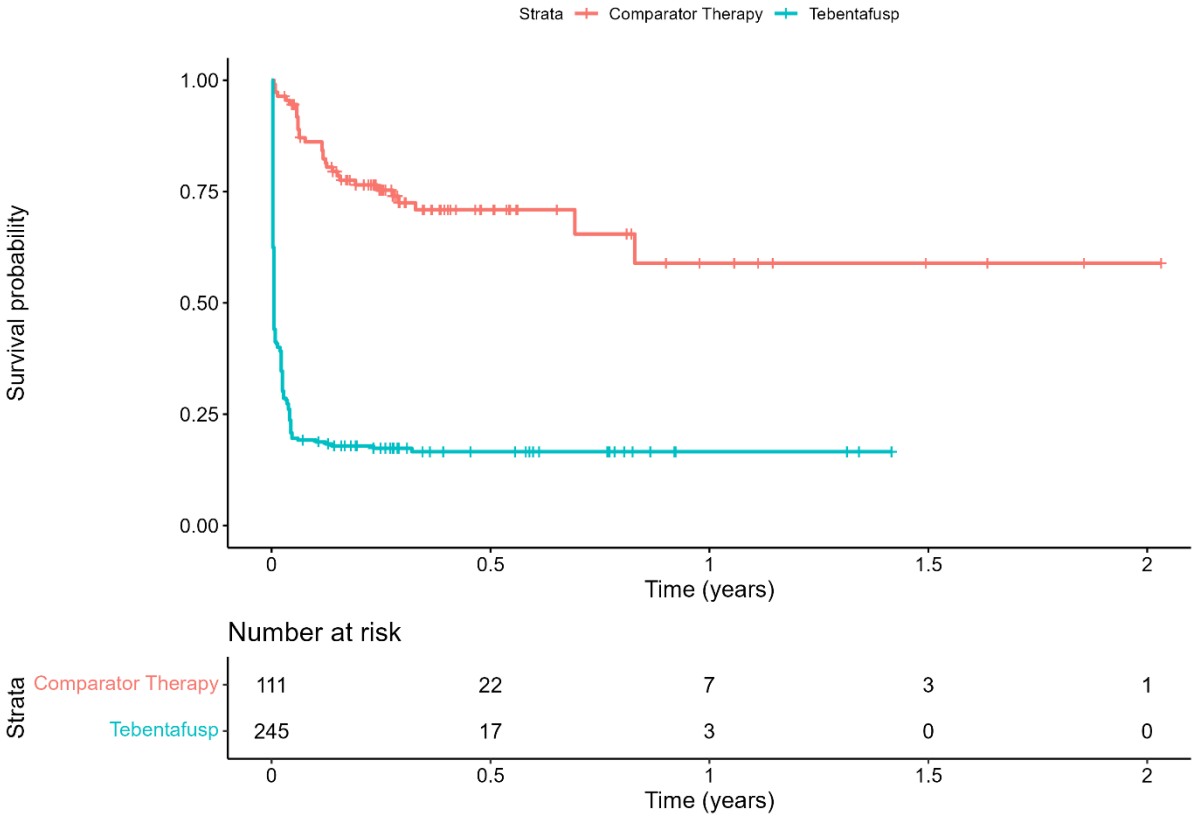
Schwerwiegendes Zytokin-Freisetzungssyndrom



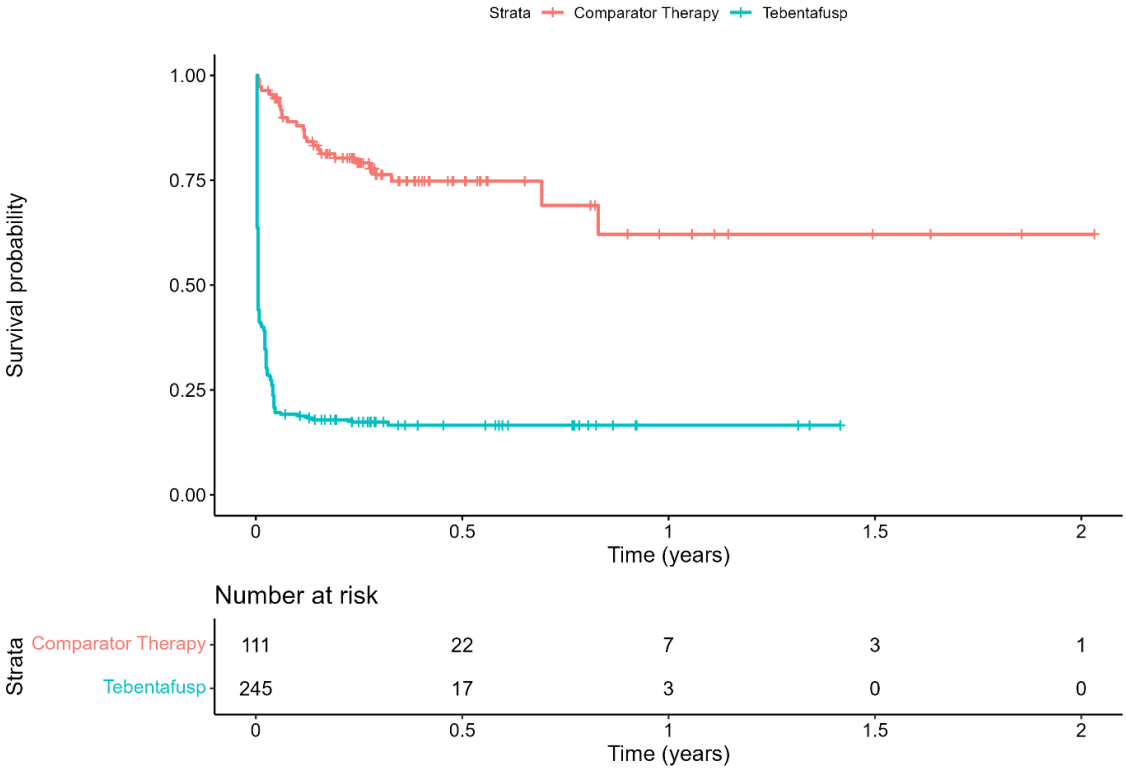
Zytokin-Freisetzungssyndrom, das zum Absetzen des Studienmedikaments führte



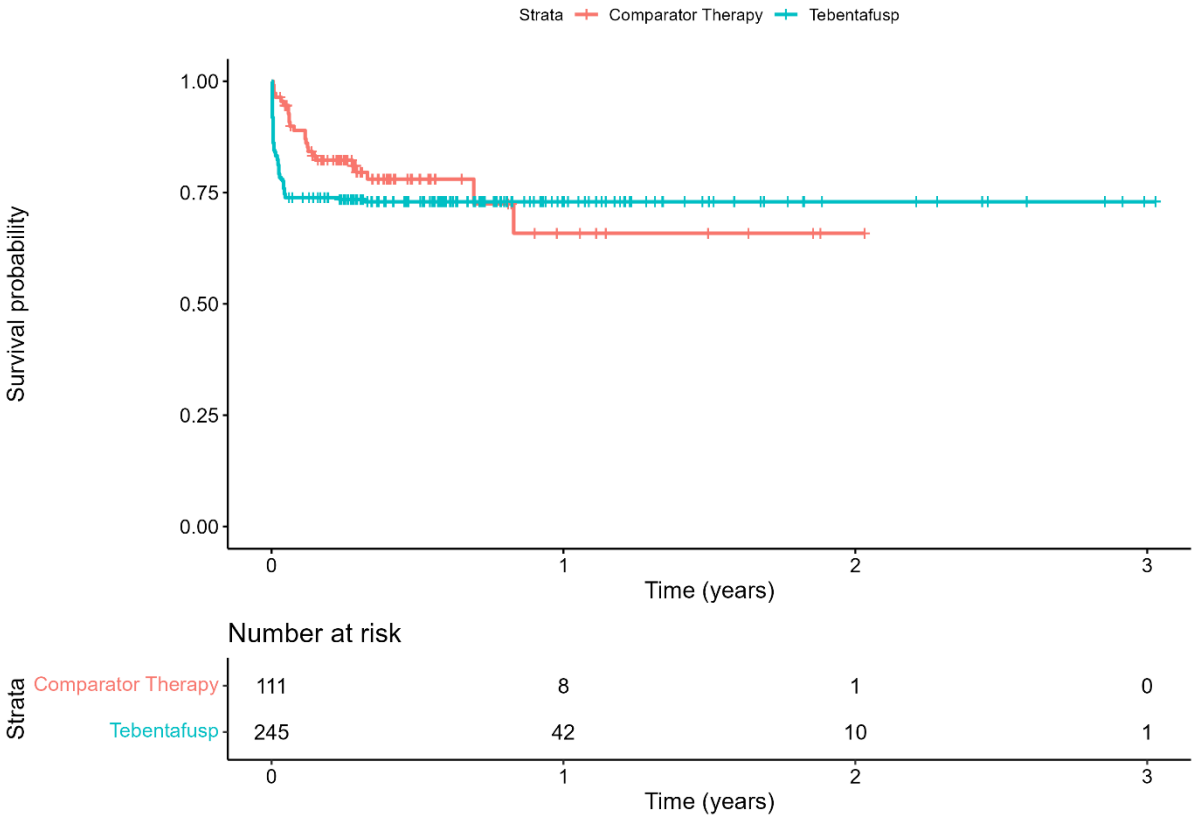
Hautausschlag



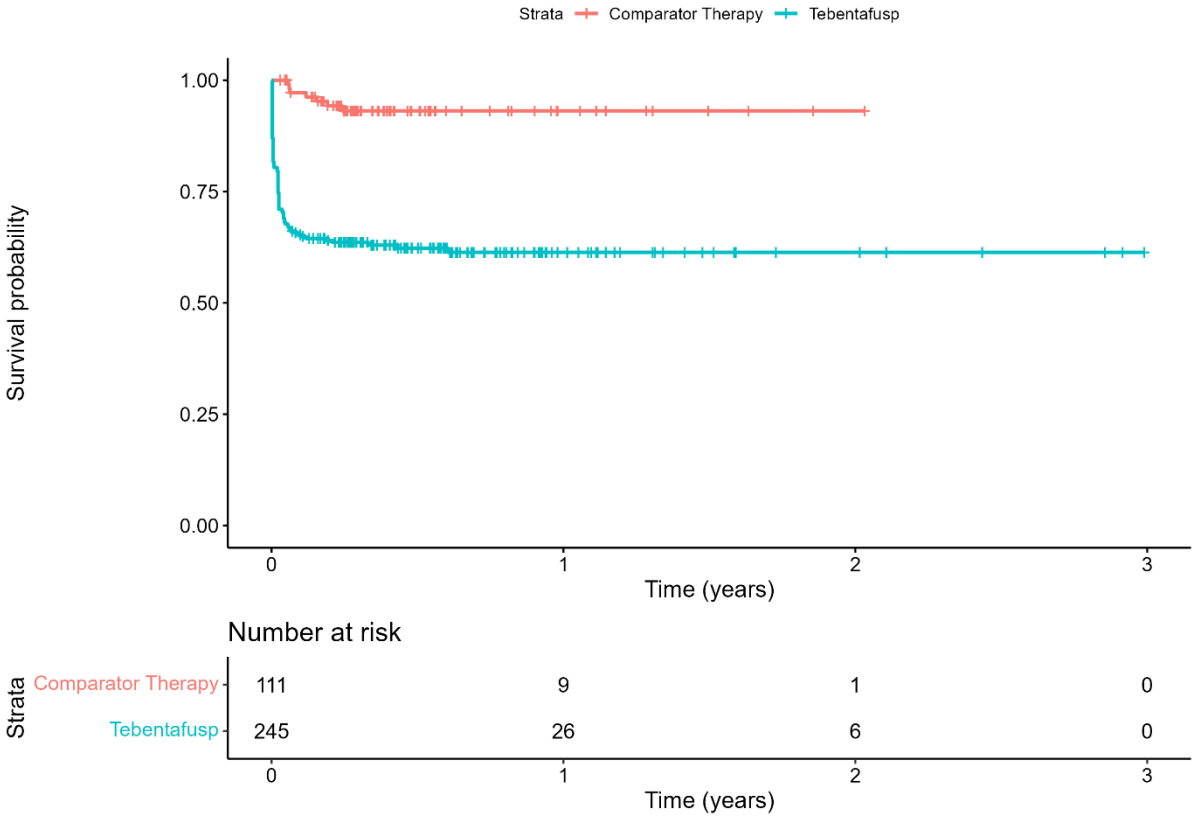
Hautausschlag in kausalem Zusammenhang mit der Behandlung



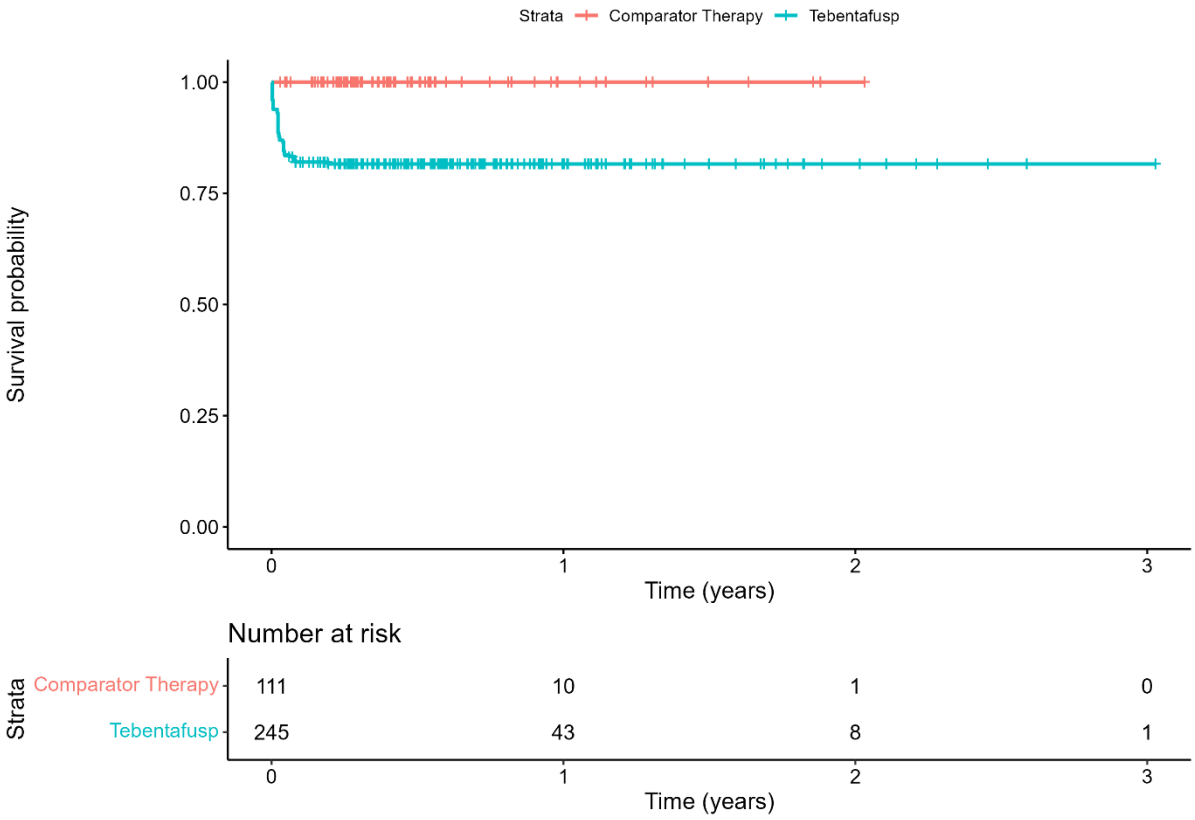
Hautausschlag nach höchstem CTCAE-Grad1



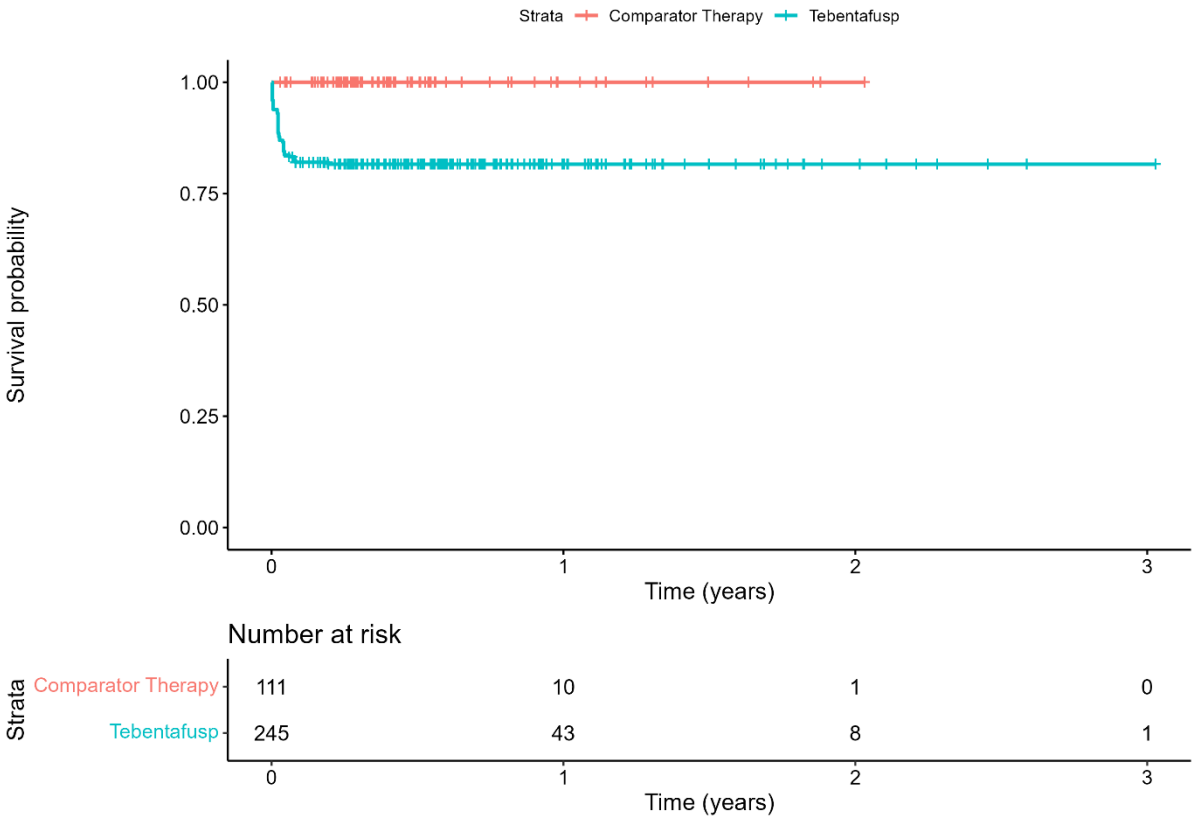
Hautausschlag nach höchstem CTCAE-Grad 2



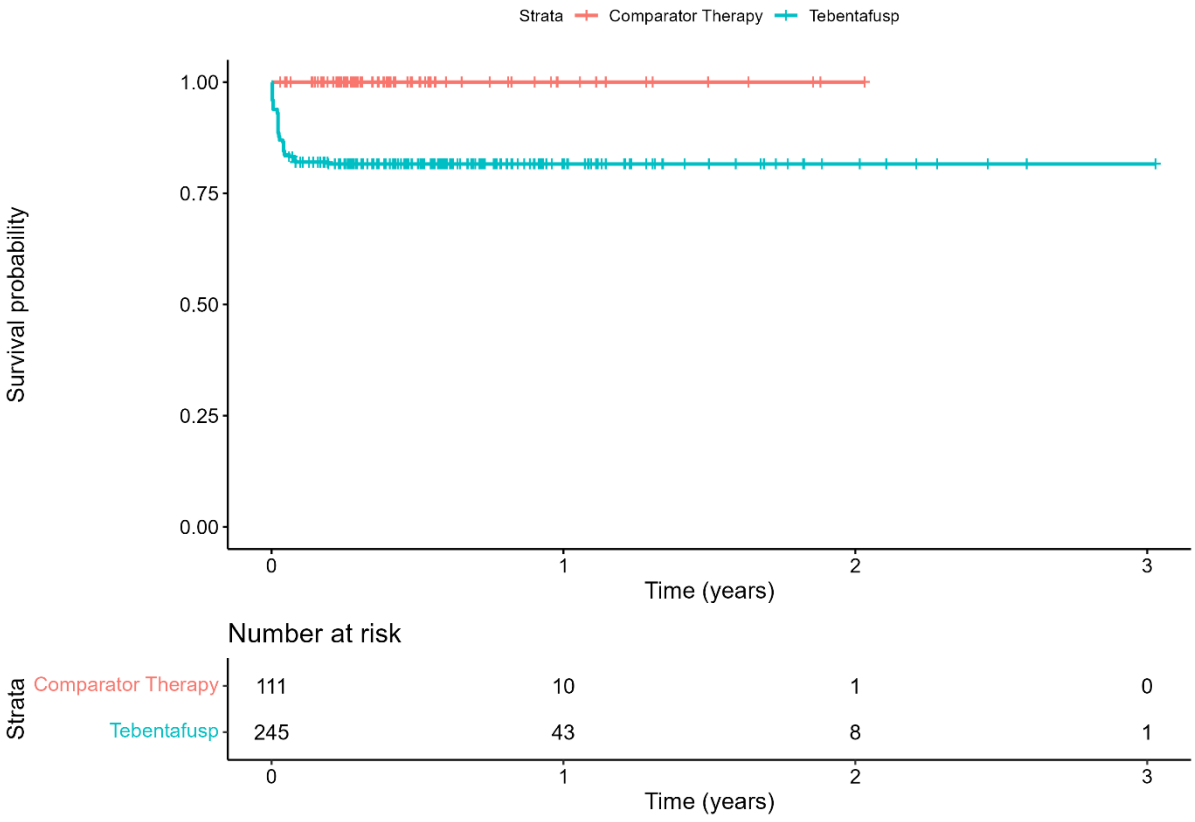
Hautausschlag nach höchstem CTCAE-Grad 3



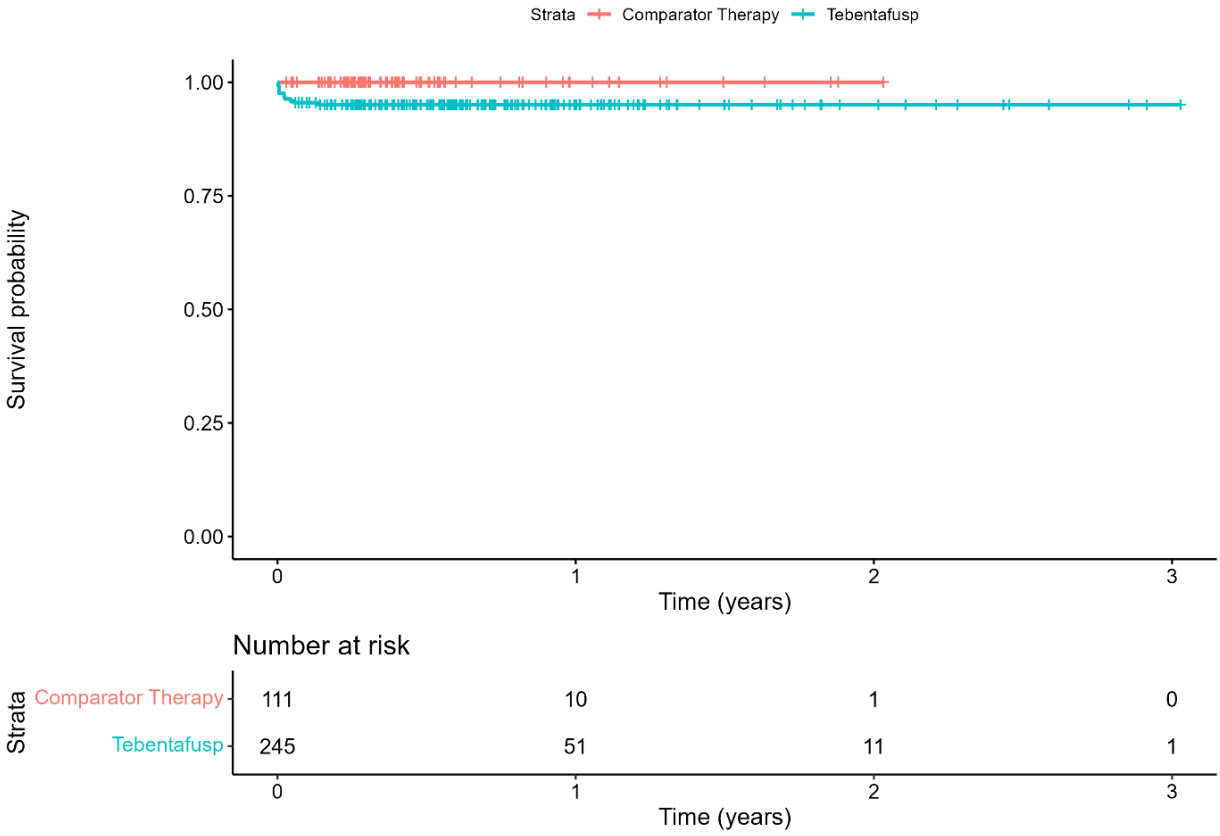
Hautausschlag mit CTCAE-Grad ≥ 3



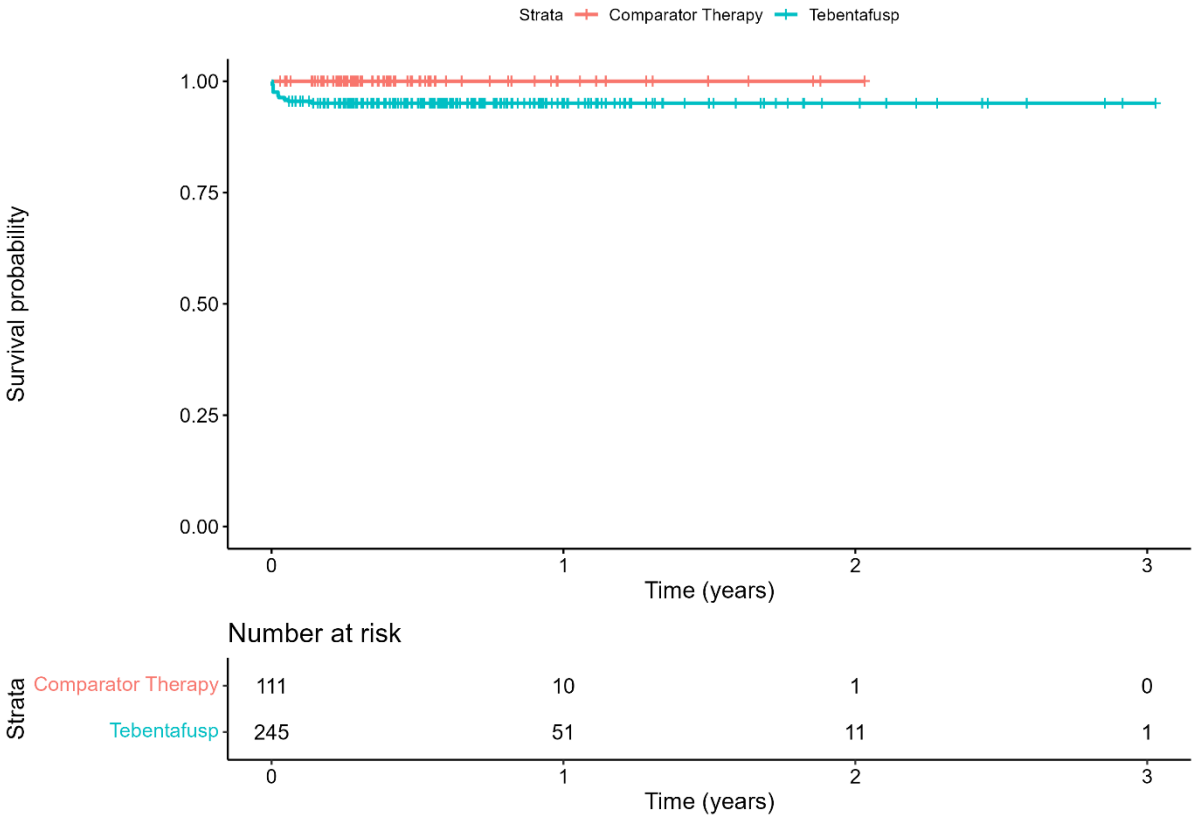
Hautausschlag mit CTCAE-Grad ≥ 3, in kausalem Zusammenhang mit der Behandlung



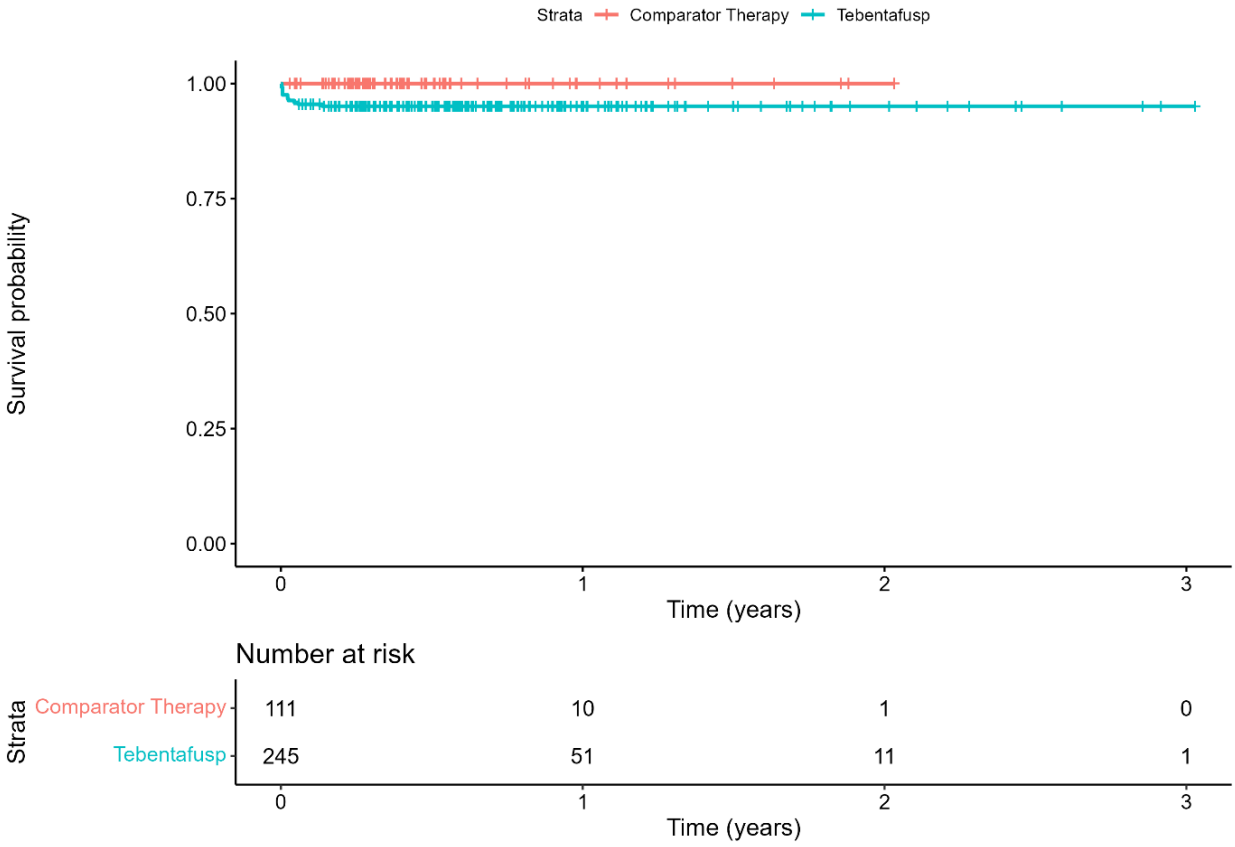
Schwerwiegender Hautausschlag



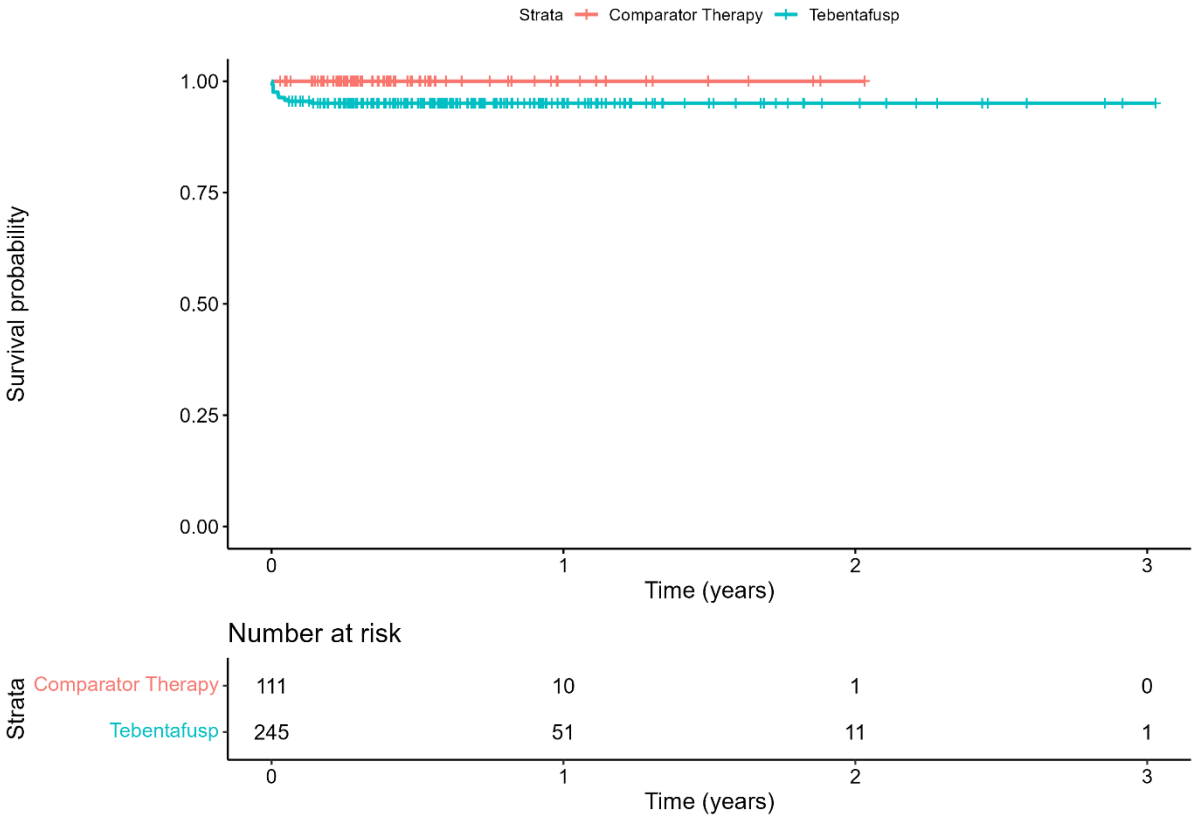
Schwerwiegender Hautausschlag, in kausalem Zusammenhang mit der Behandlung



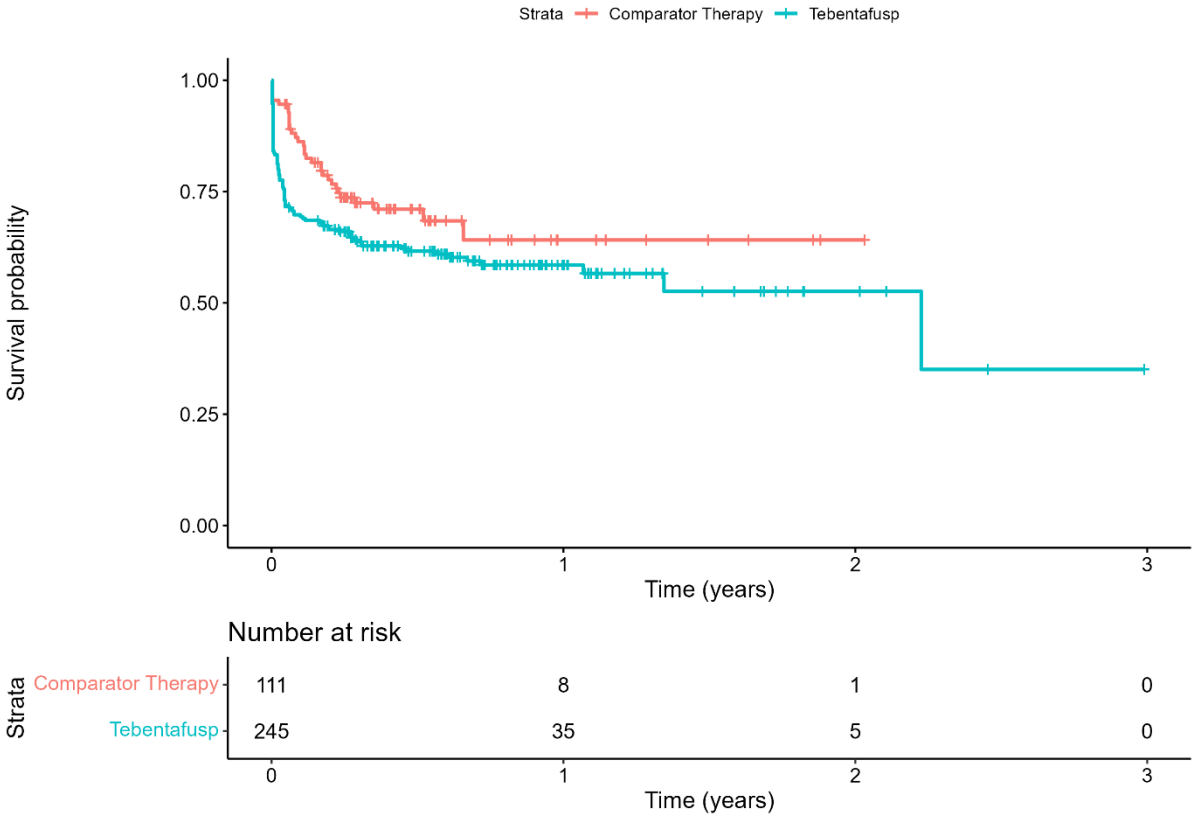
Hautausschlag, der zu einem Krankenhausaufenthalt führte



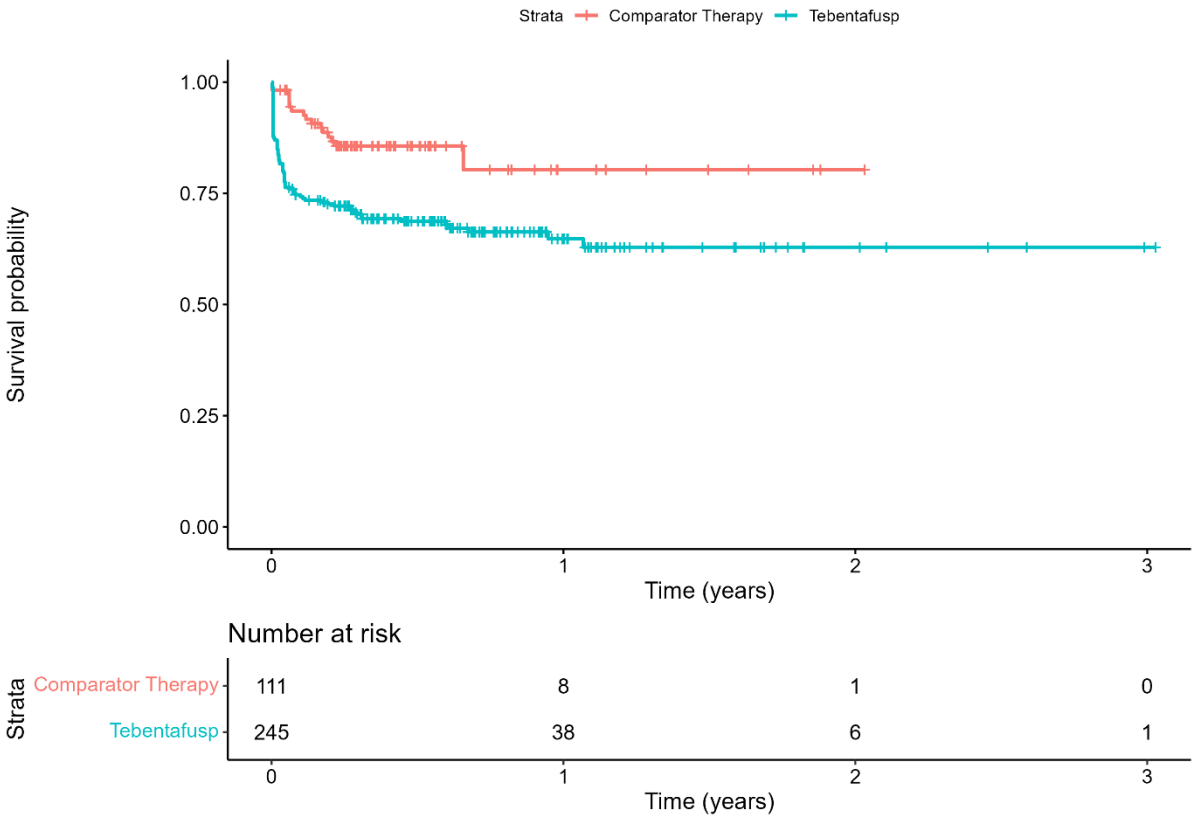
Hautausschlag, der zu einem Krankenhausaufenthalt führte, in kausalem Zusammenhang mit der Behandlung



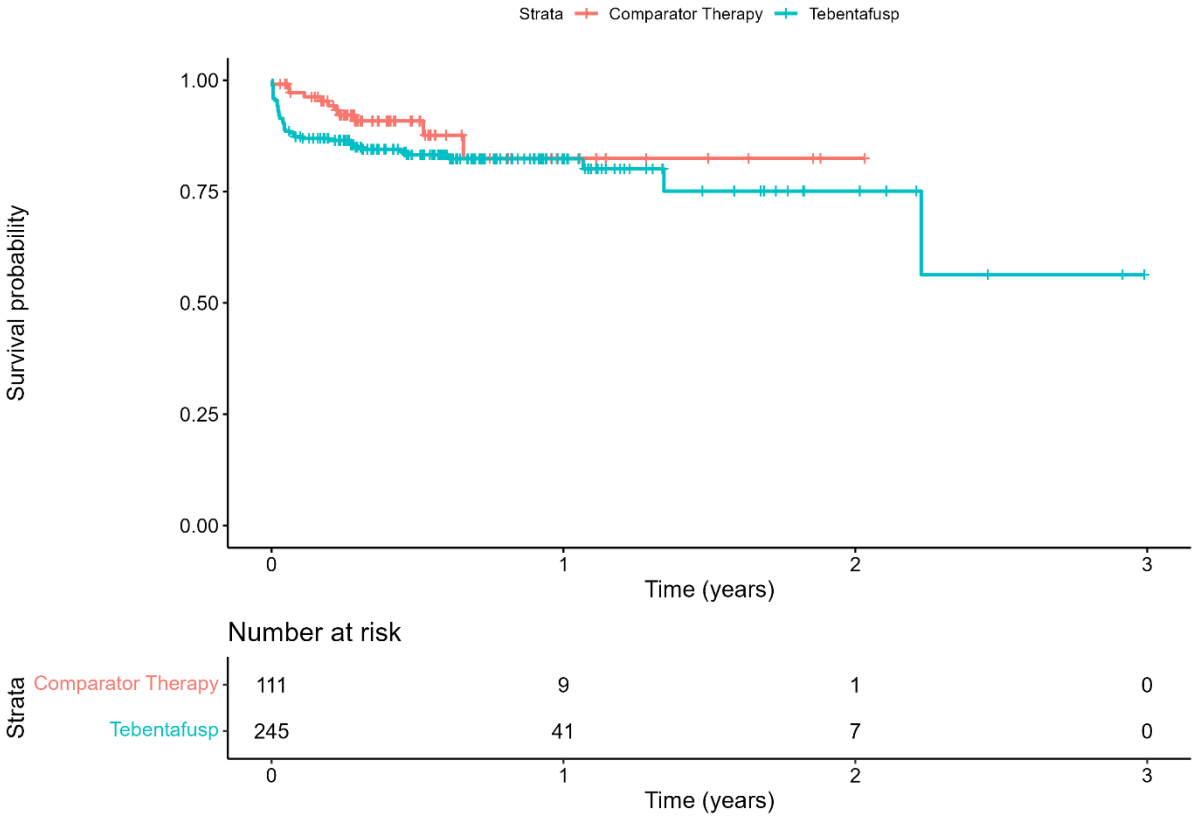
LFT-Erhöhung



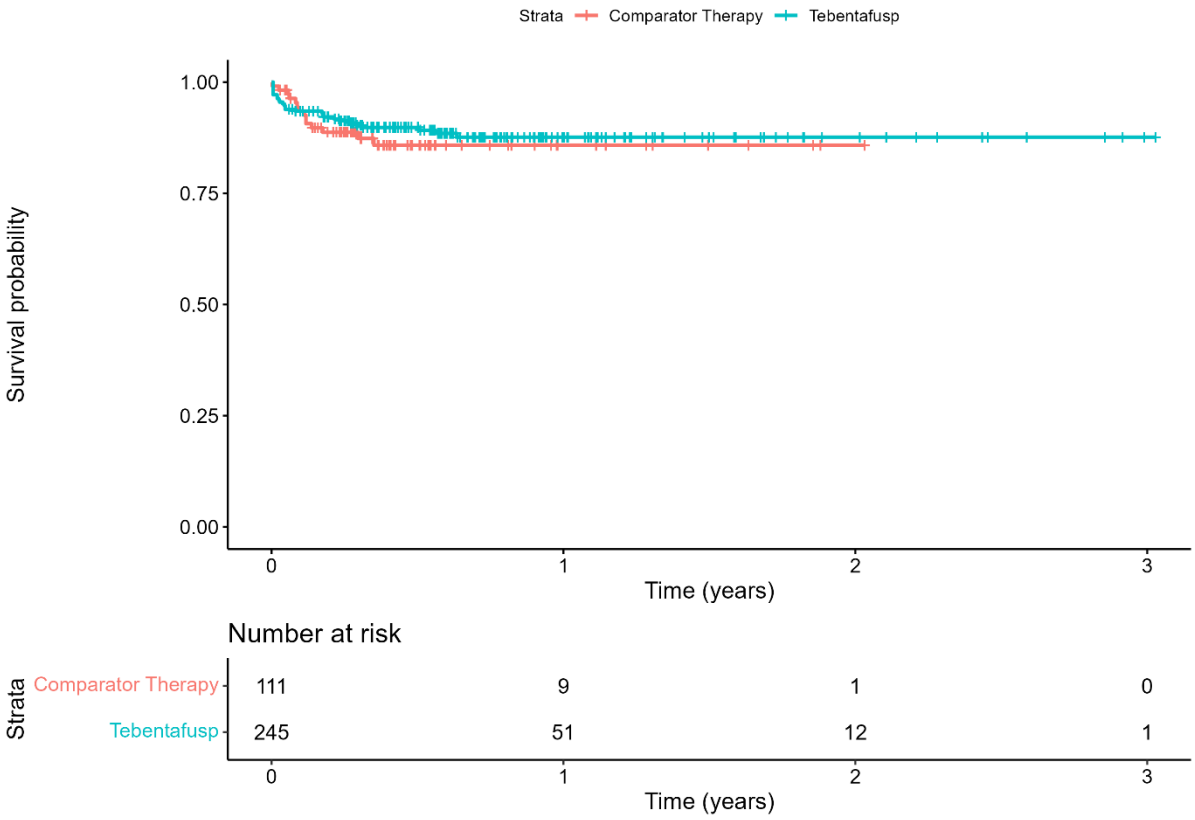
LFT-Erhöhung in kausalem Zusammenhang mit der Behandlung



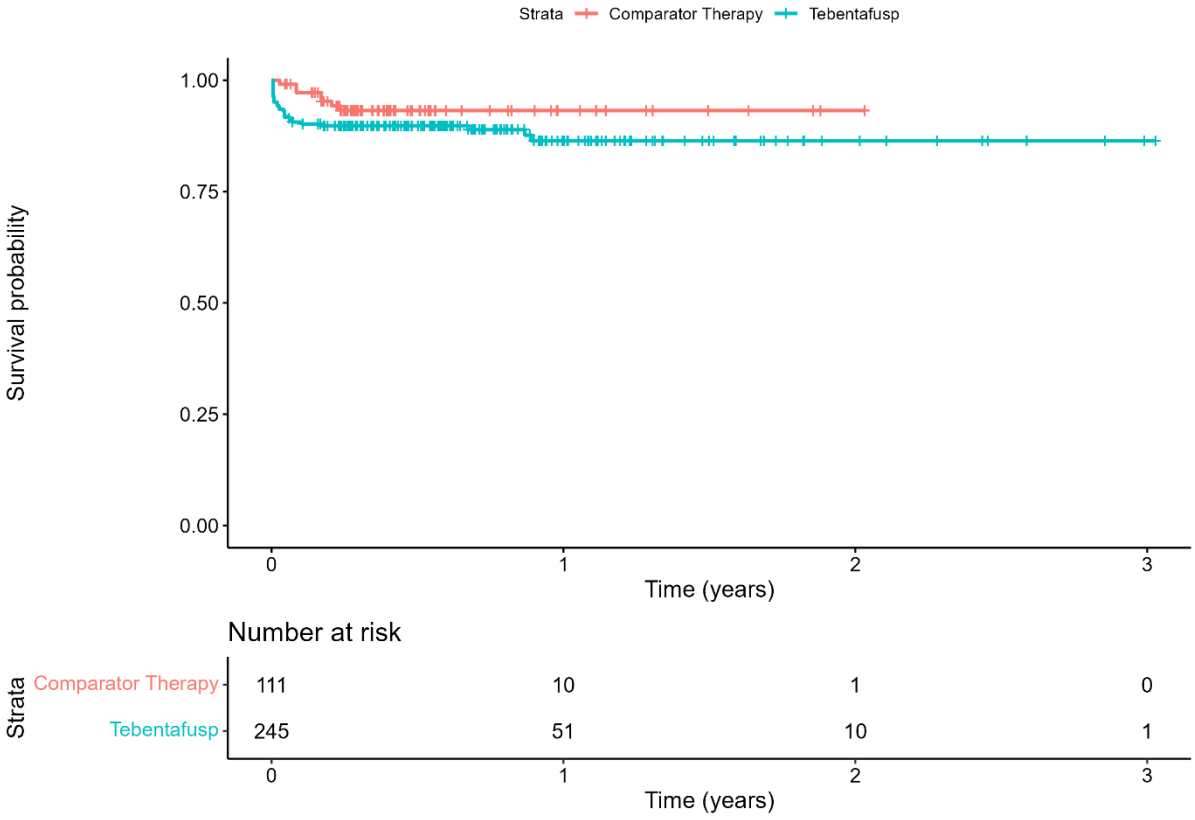
LFT-Erhöhung nach höchstem CTCAE-Grad1



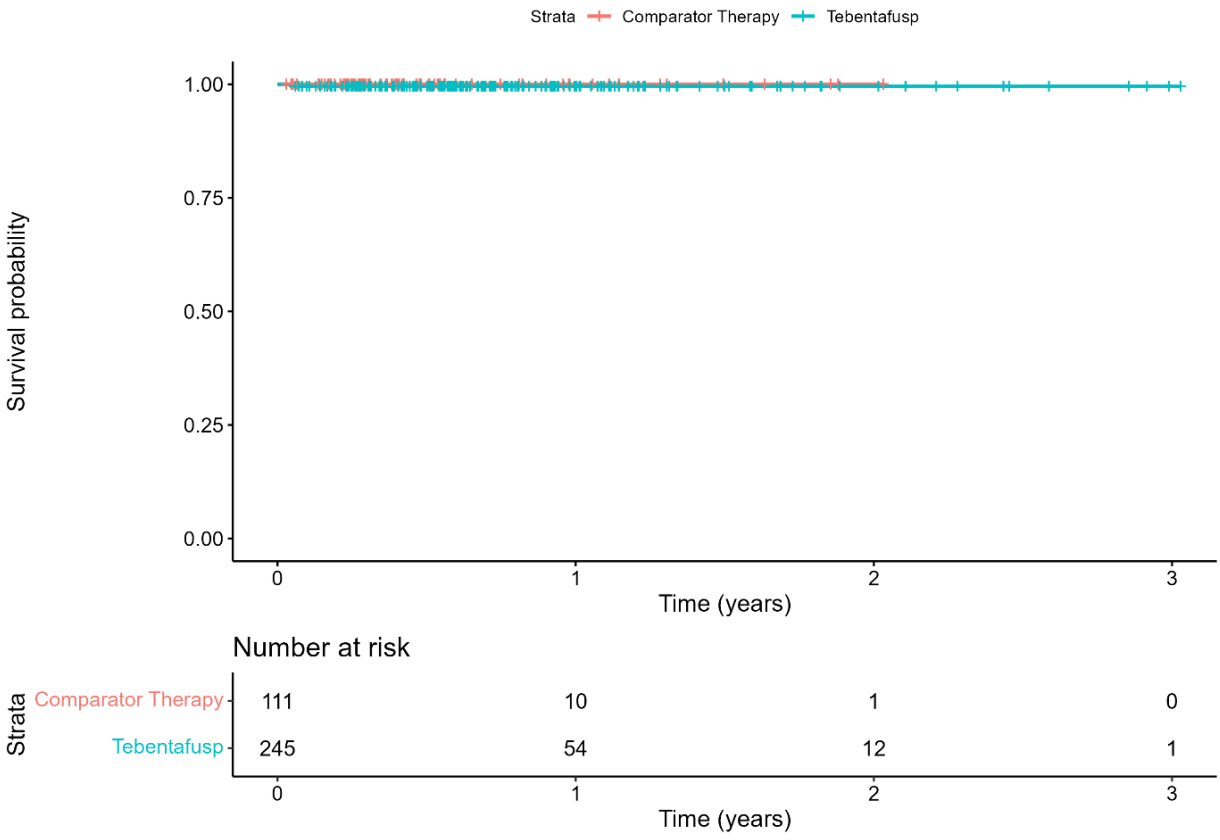
LFT-Erhöhung nach höchstem CTCAE-Grad 2



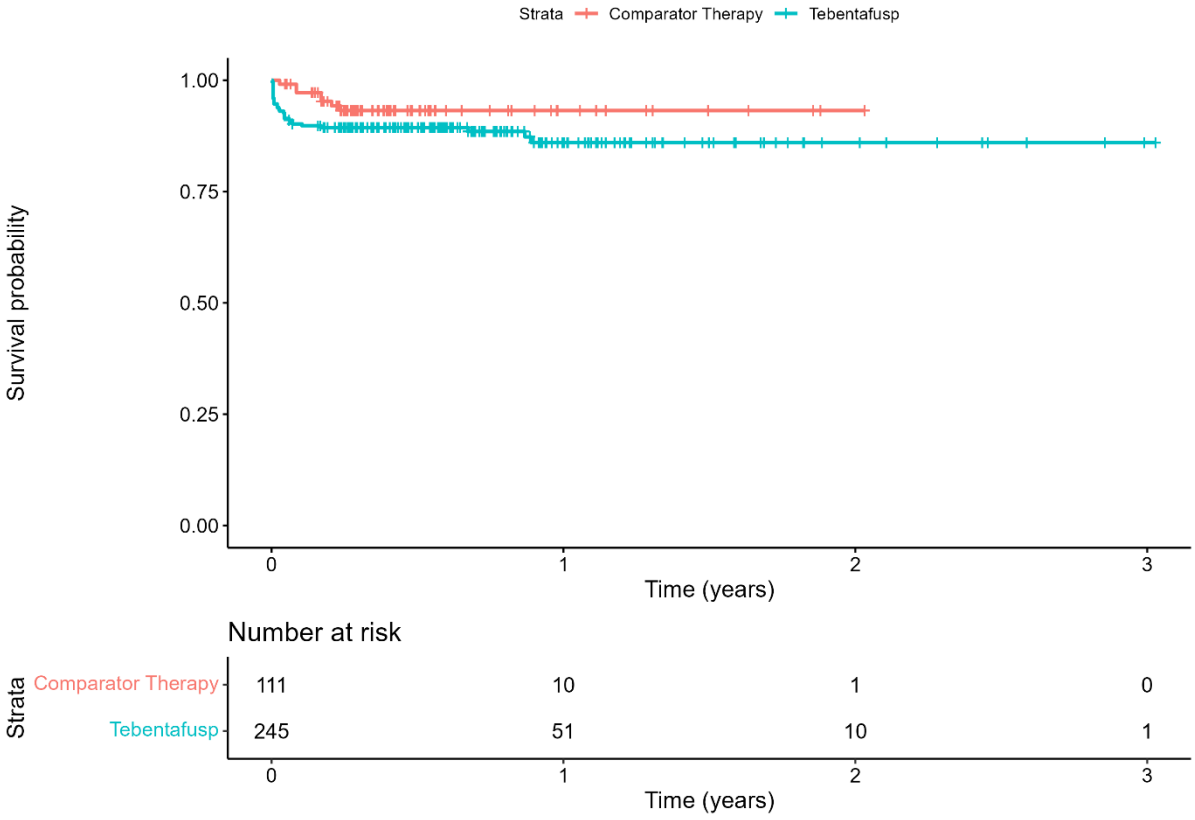
LFT-Erhöhung nach höchstem CTCAE-Grad 3



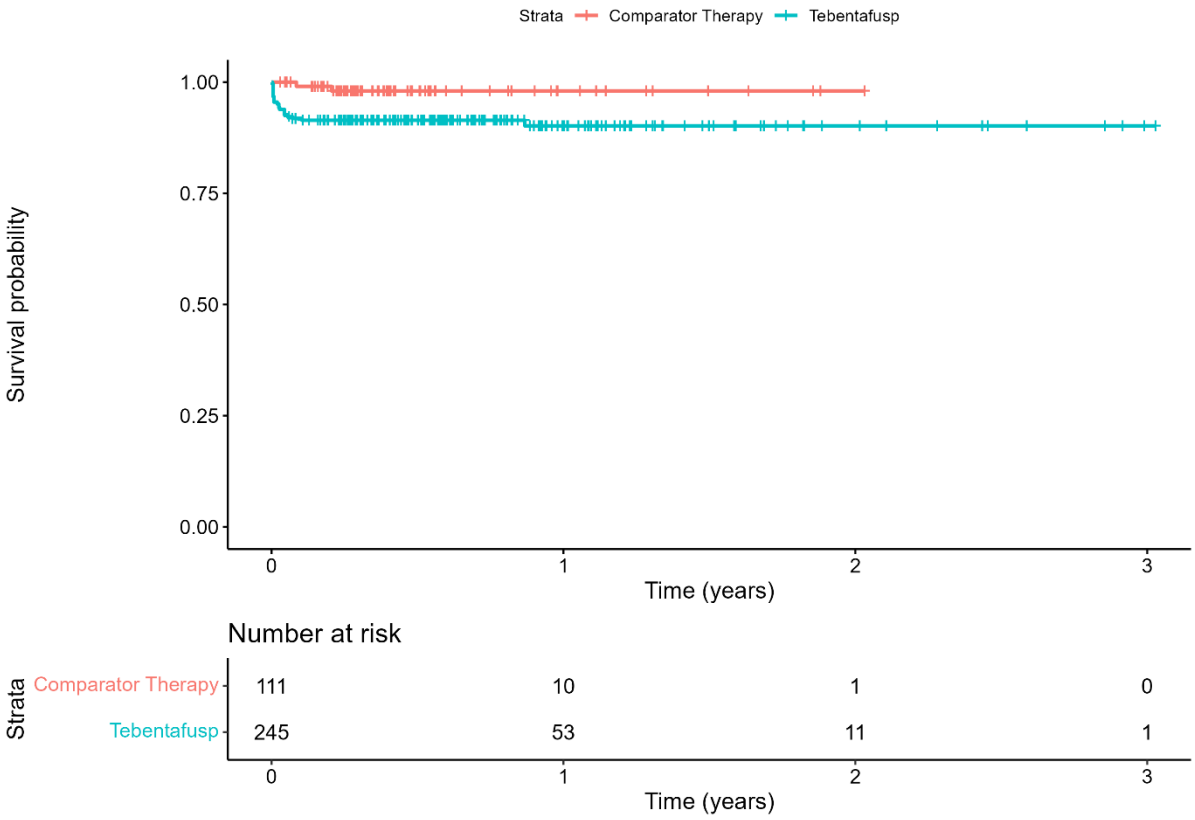
LFT-Erhöhung nach höchstem CTCAE-Grad 4



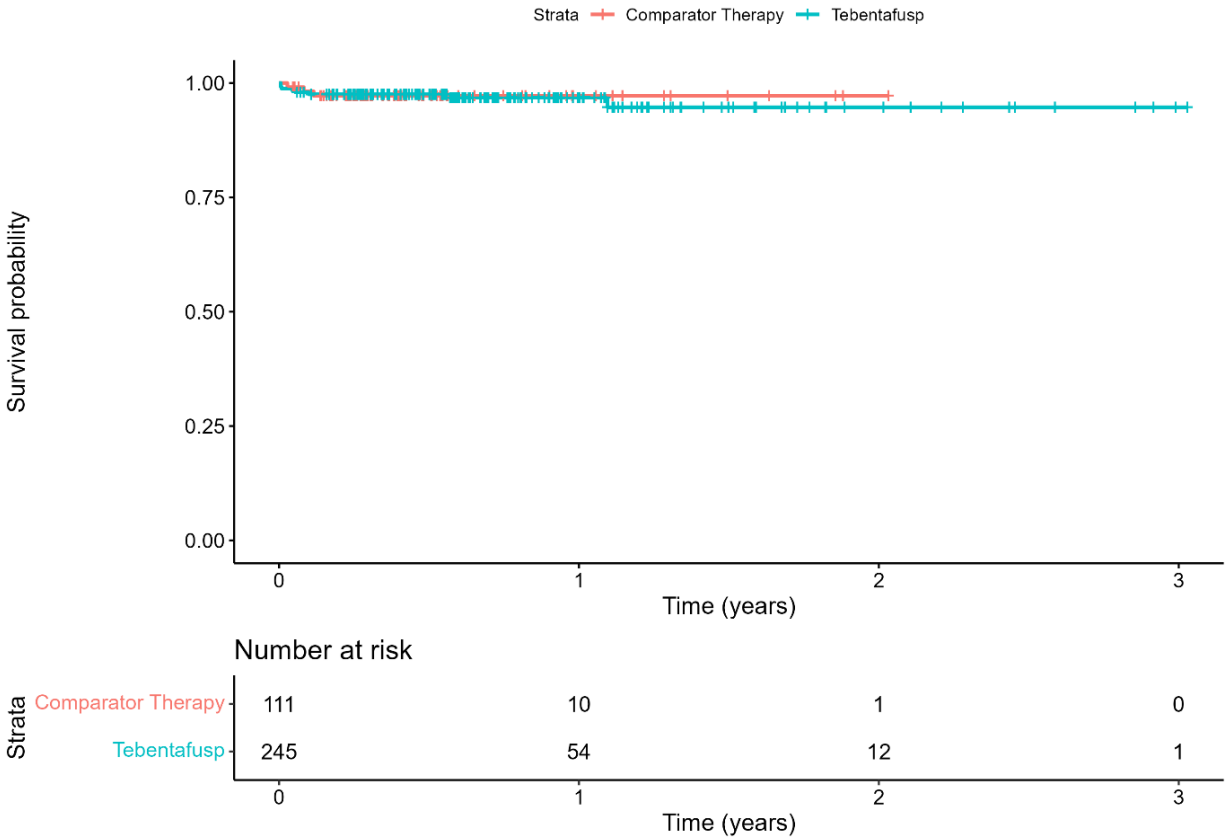
LFT-Erhöhung mit CTCAE-Grad ≥ 3



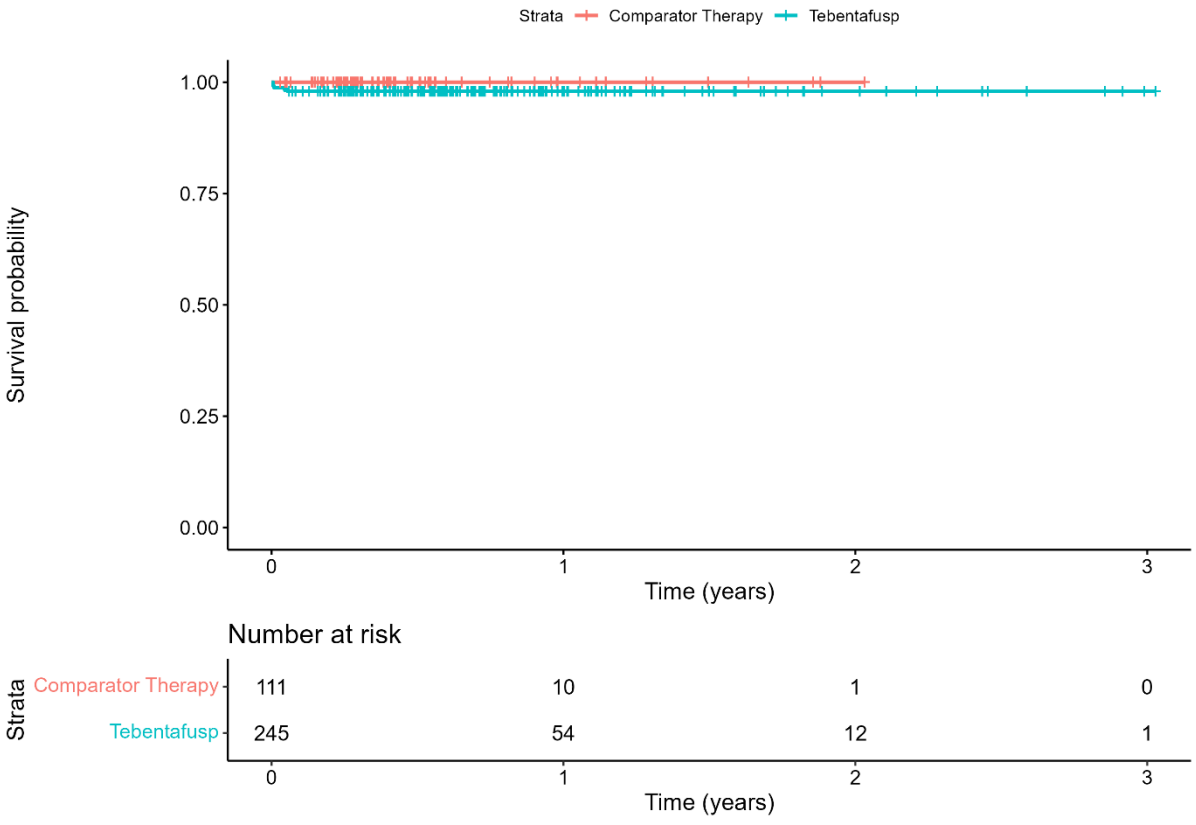
LFT-Erhöhung mit CTCAE-Grad ≥ 3, in kausalem Zusammenhang mit der Behandlung



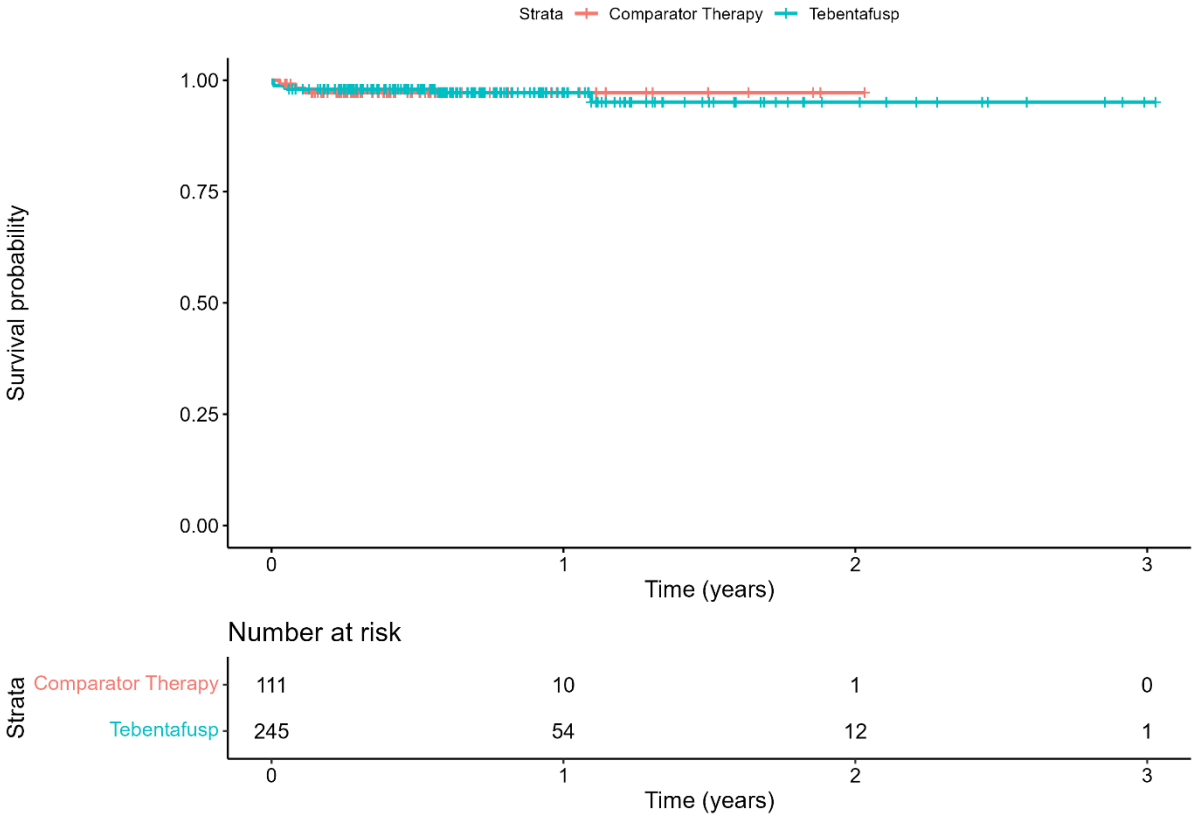
Schwerwiegende LFT-Erhöhung



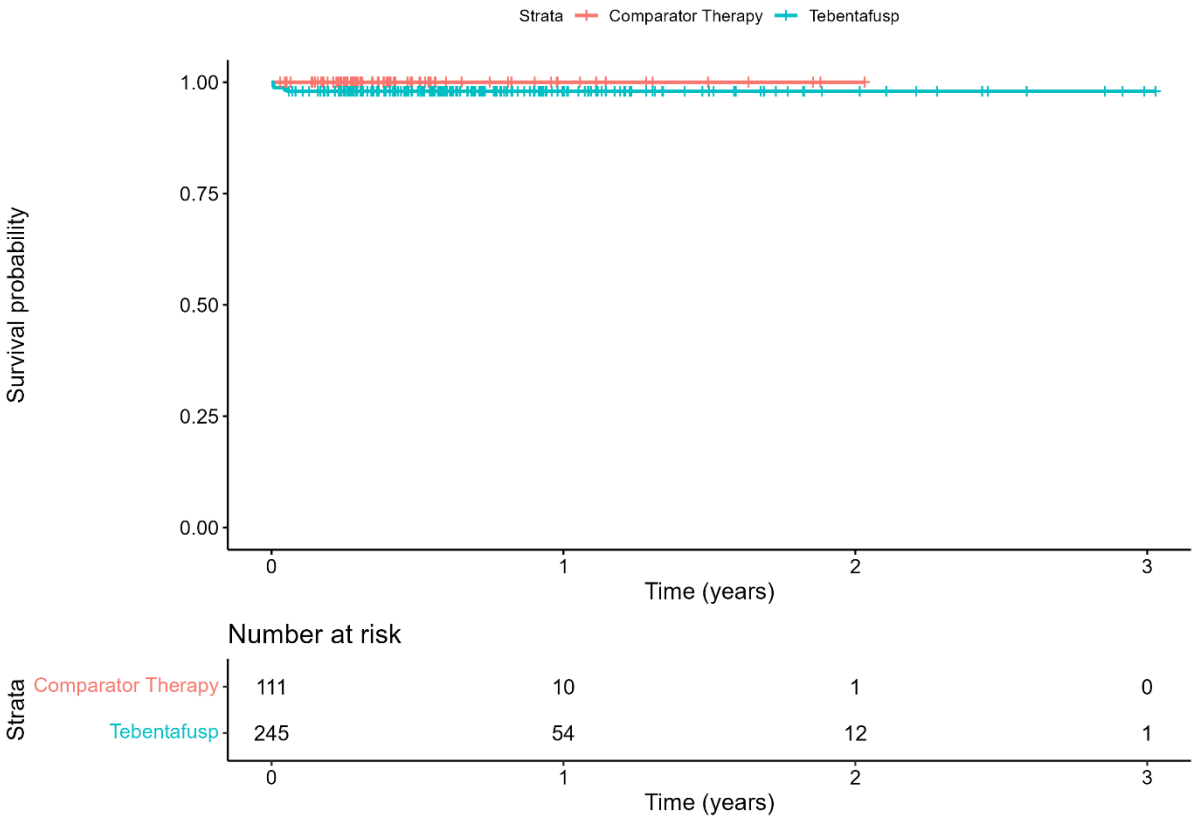
Schwerwiegende LFT-Erhöhung, in kausalem Zusammenhang mit der Behandlung



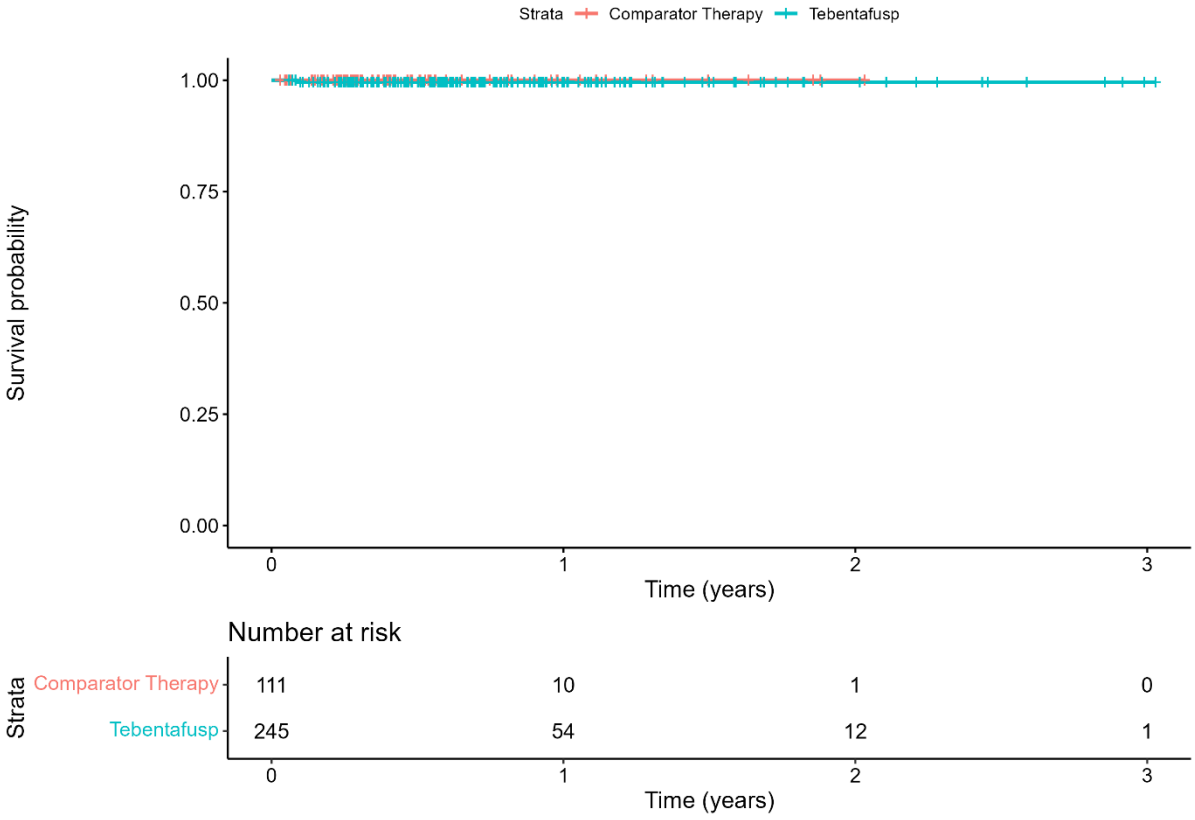
LFT-Erhöhung, die zu einem Krankenhausaufenthalt führte



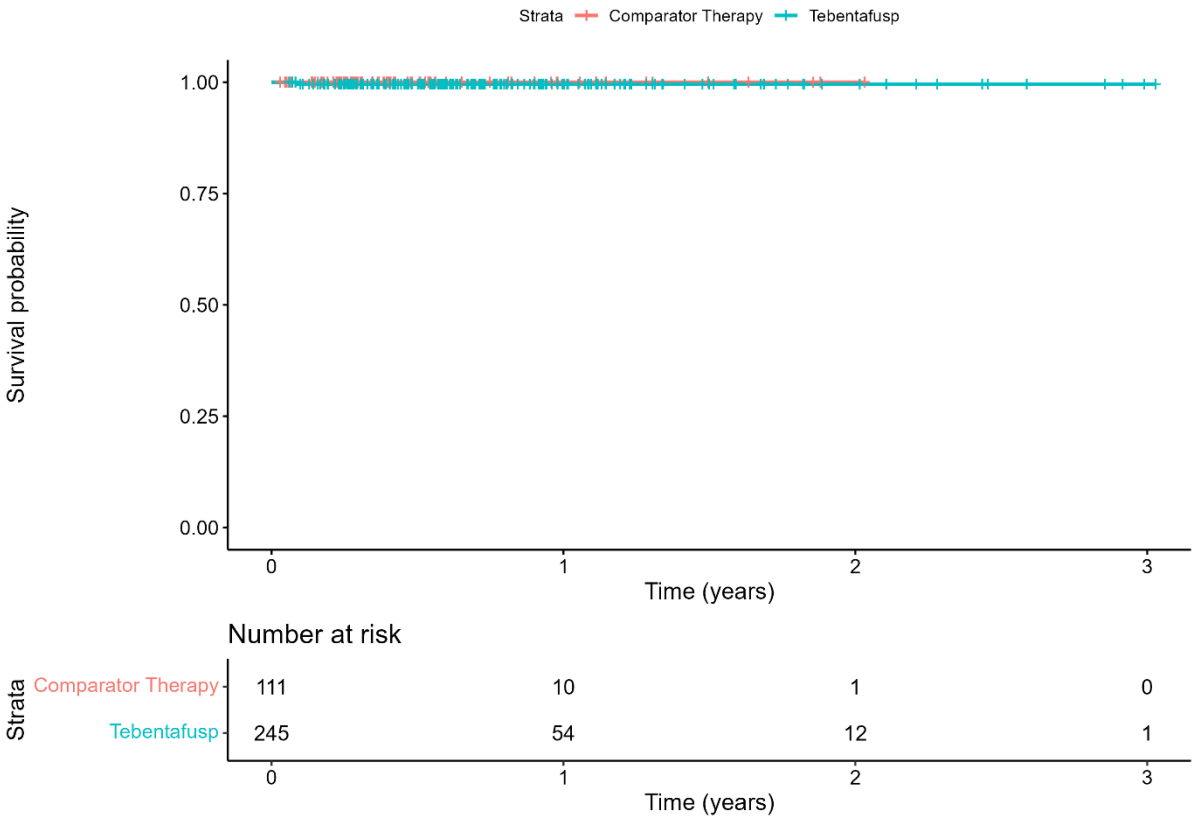
LFT-Erhöhung, die zu einem Krankenhausaufenthalt führte, in kausalem Zusammenhang mit der Behandlung



LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte

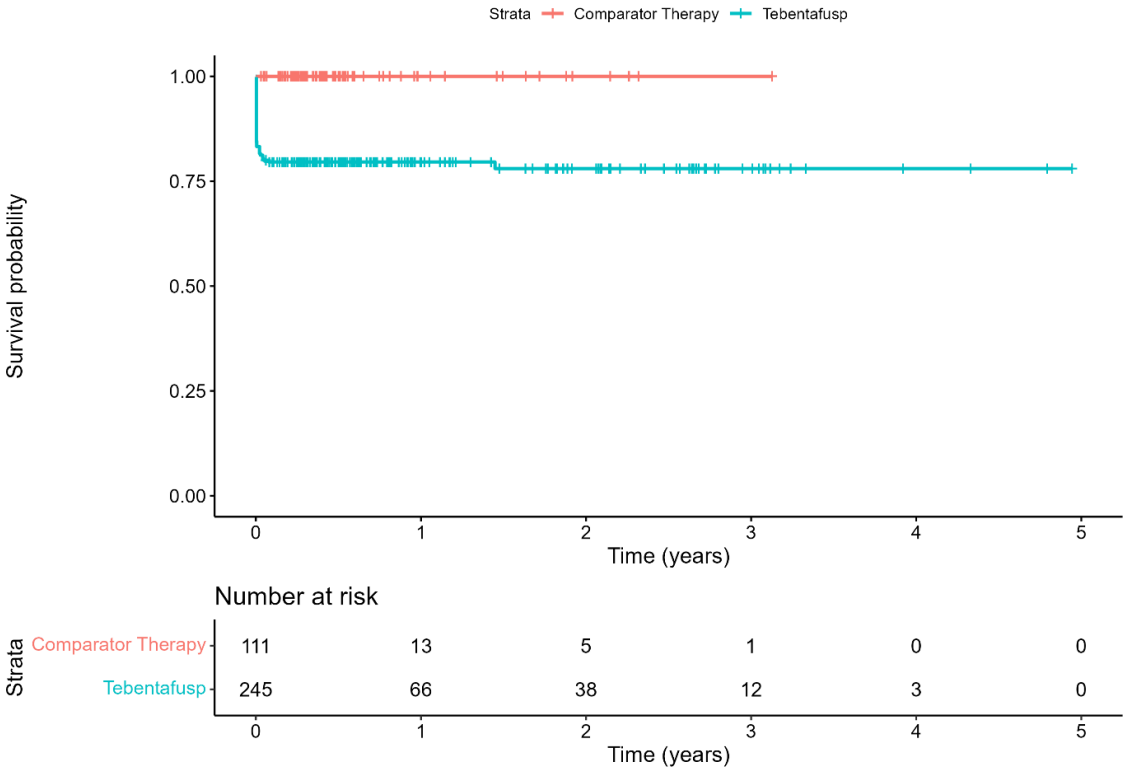


LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte, in kausalem Zusammenhang mit der Behandlung

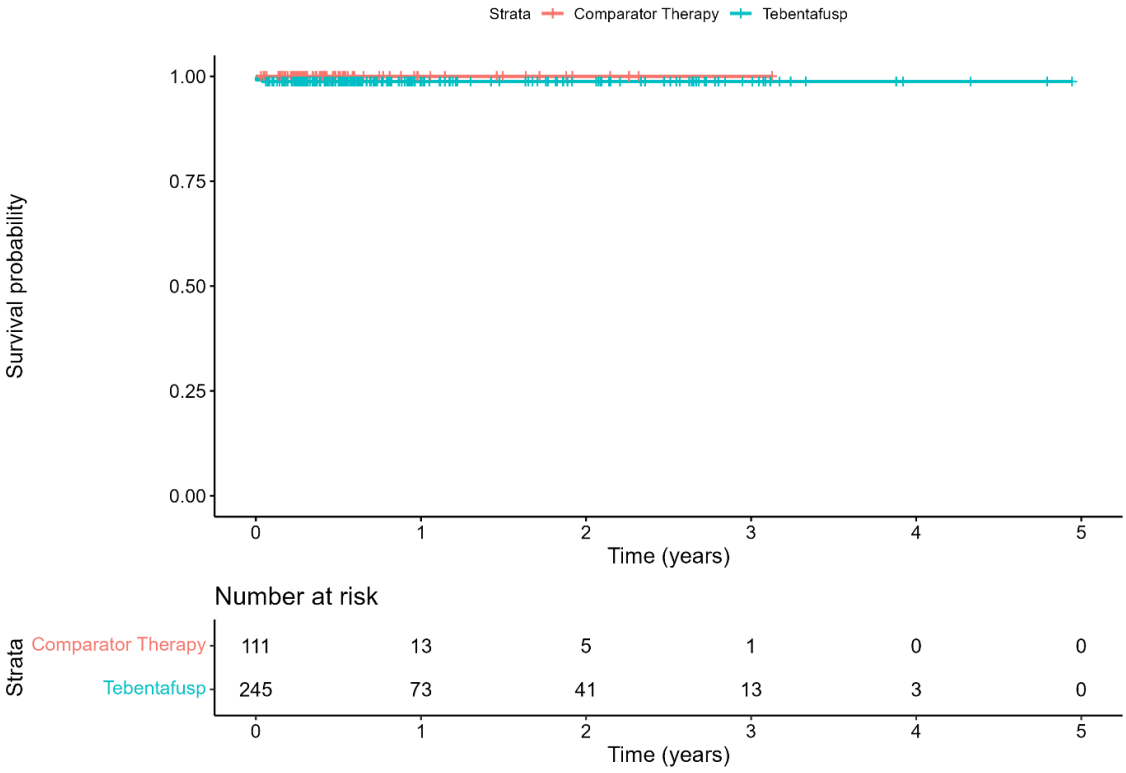


14.9 3-Jahres-Analyse (Juni 2023) (Tabelle 4-59)

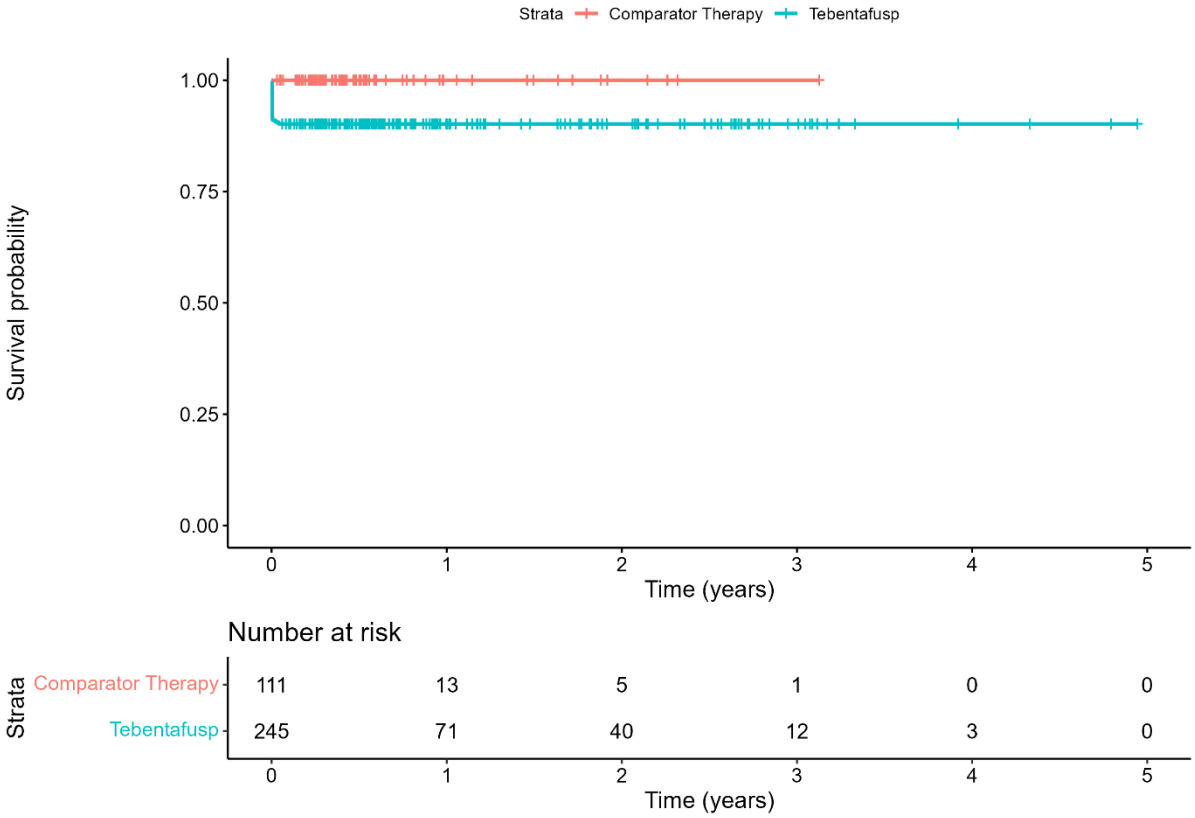
Zytokin-Freisetzungssyndrom



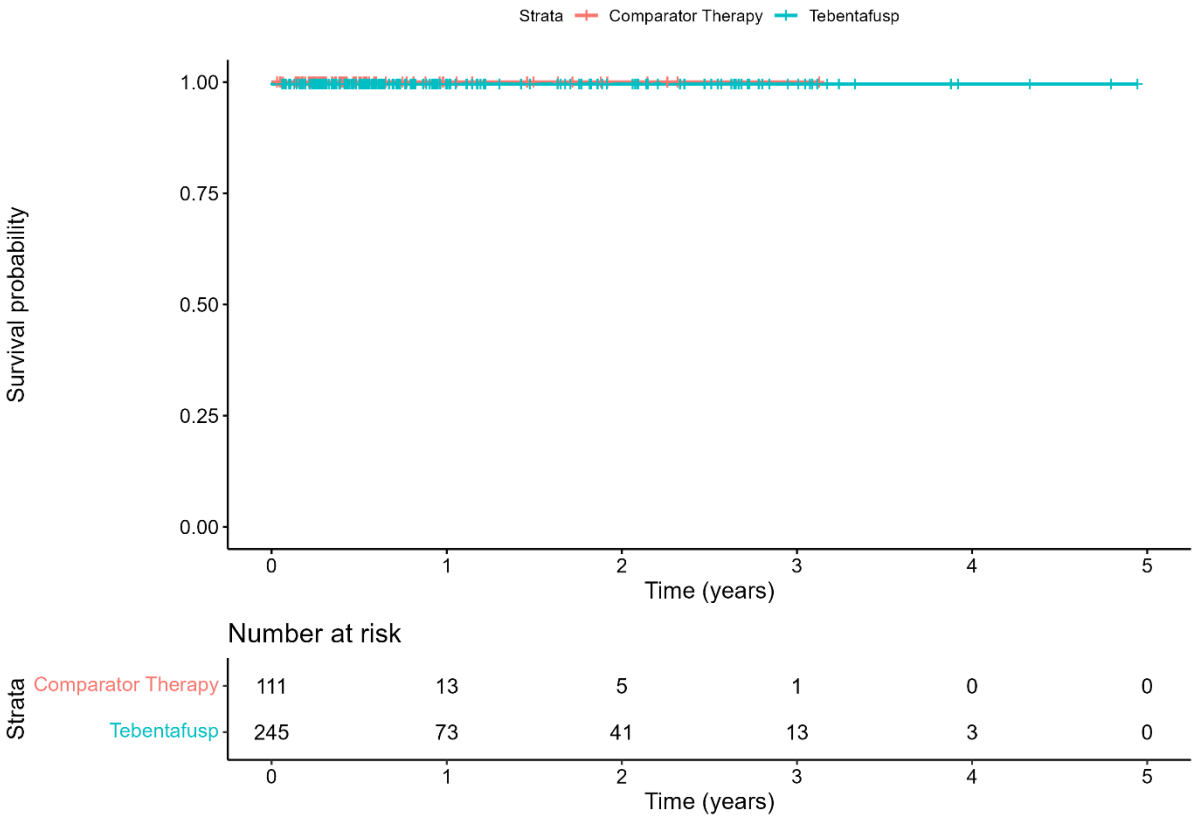
Zytokin-Freisetzungssyndrom mit CTCAE-Grad ≥ 3



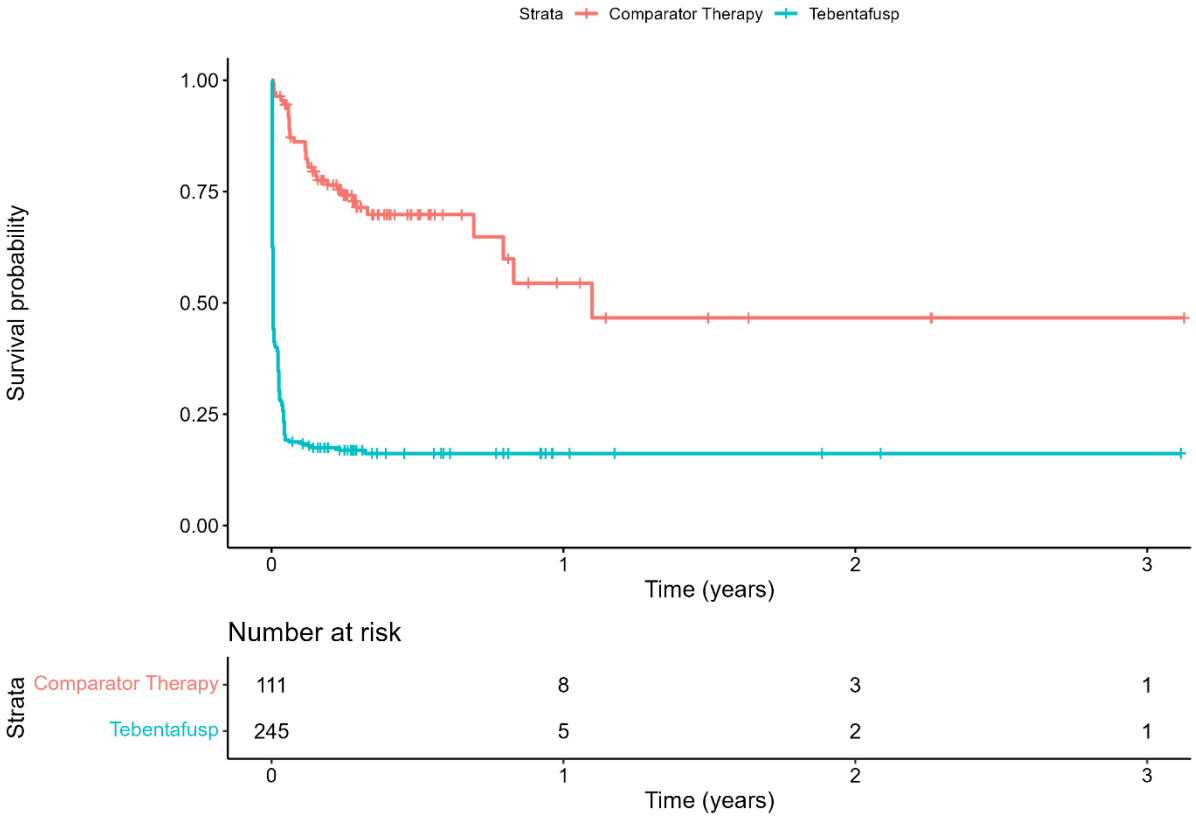
Schwerwiegendes Zytokin-Freisetzungssyndrom



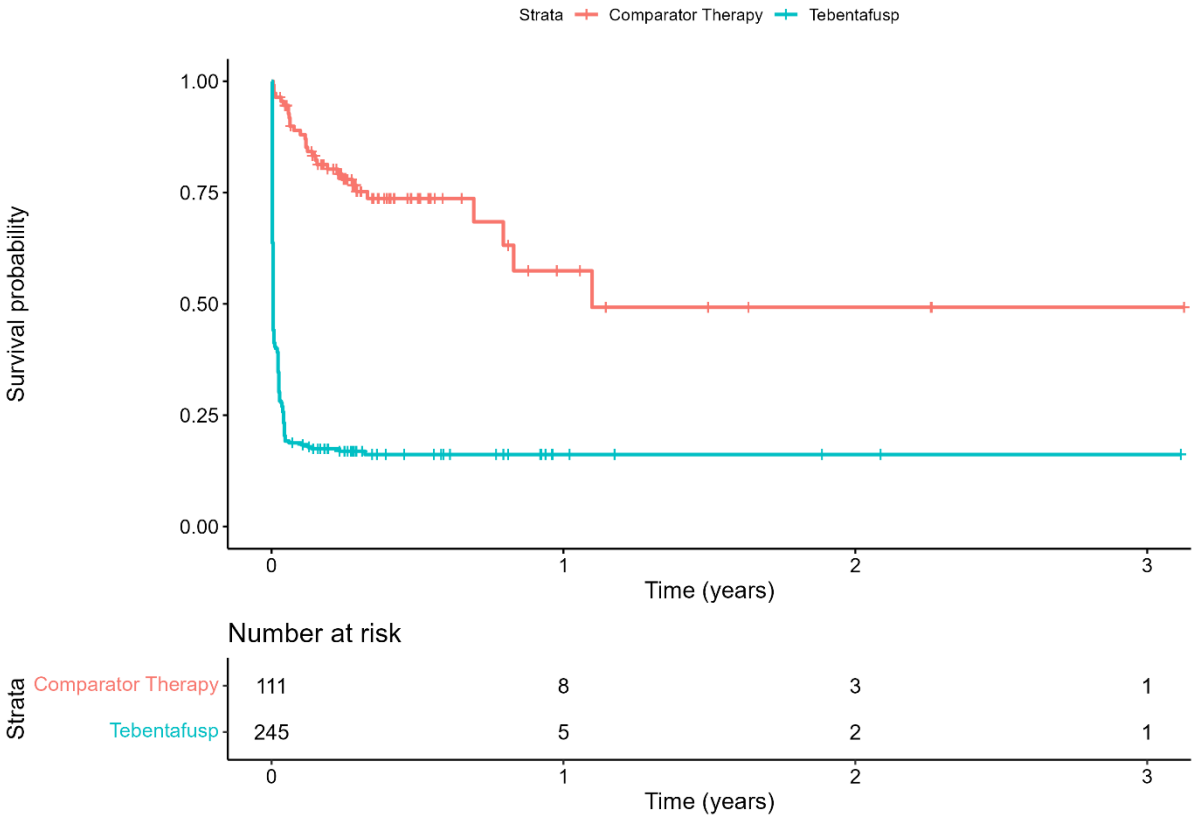
Zytokin-Freisetzungssyndrom, das zum Absetzen des Studienmedikaments führte



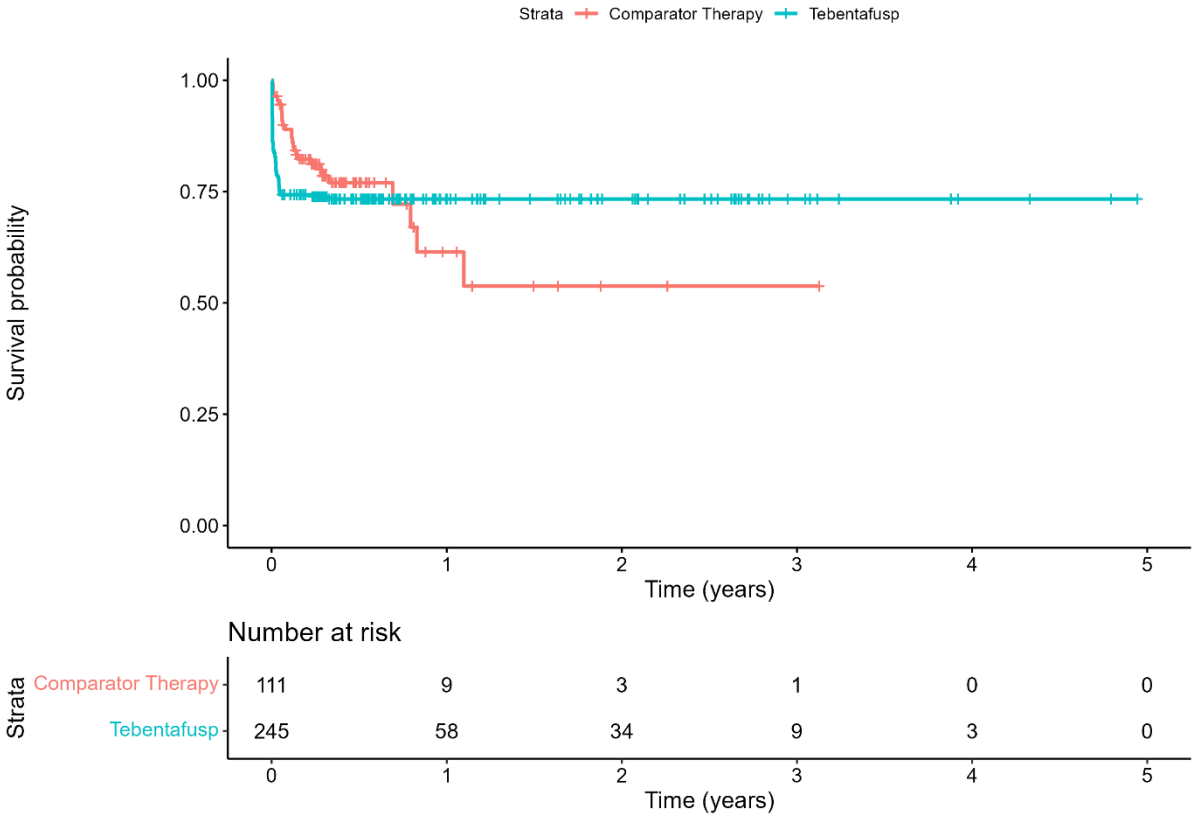
Hautausschlag



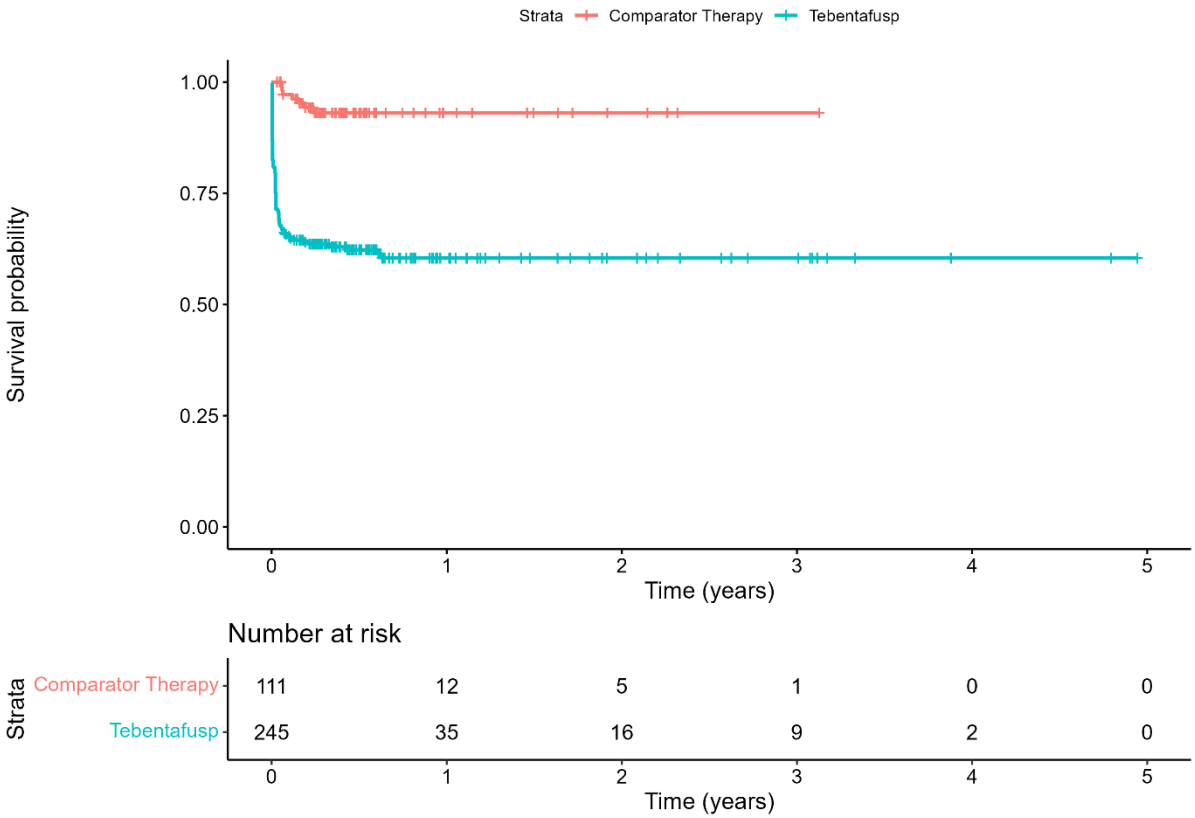
Hautausschlag in kausalem Zusammenhang mit der Behandlung



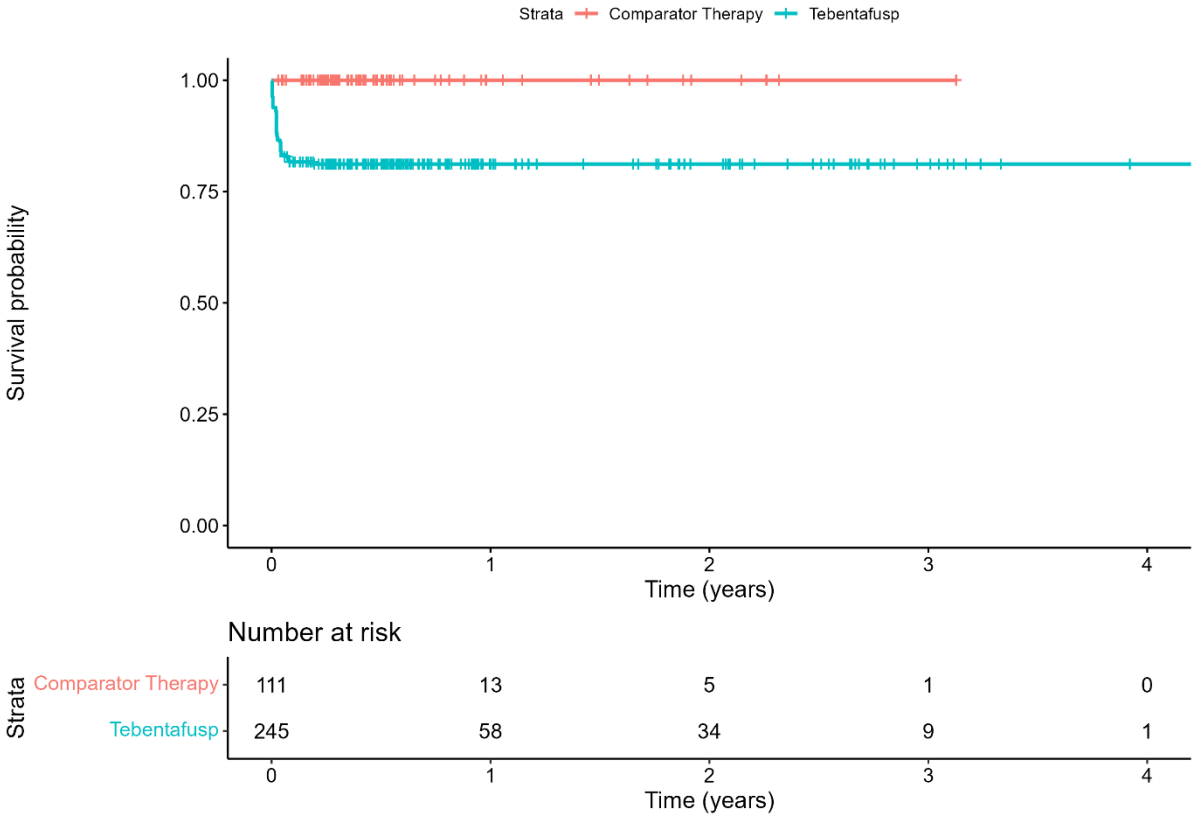
Hautausschlag nach höchstem CTCAE-Grad 1



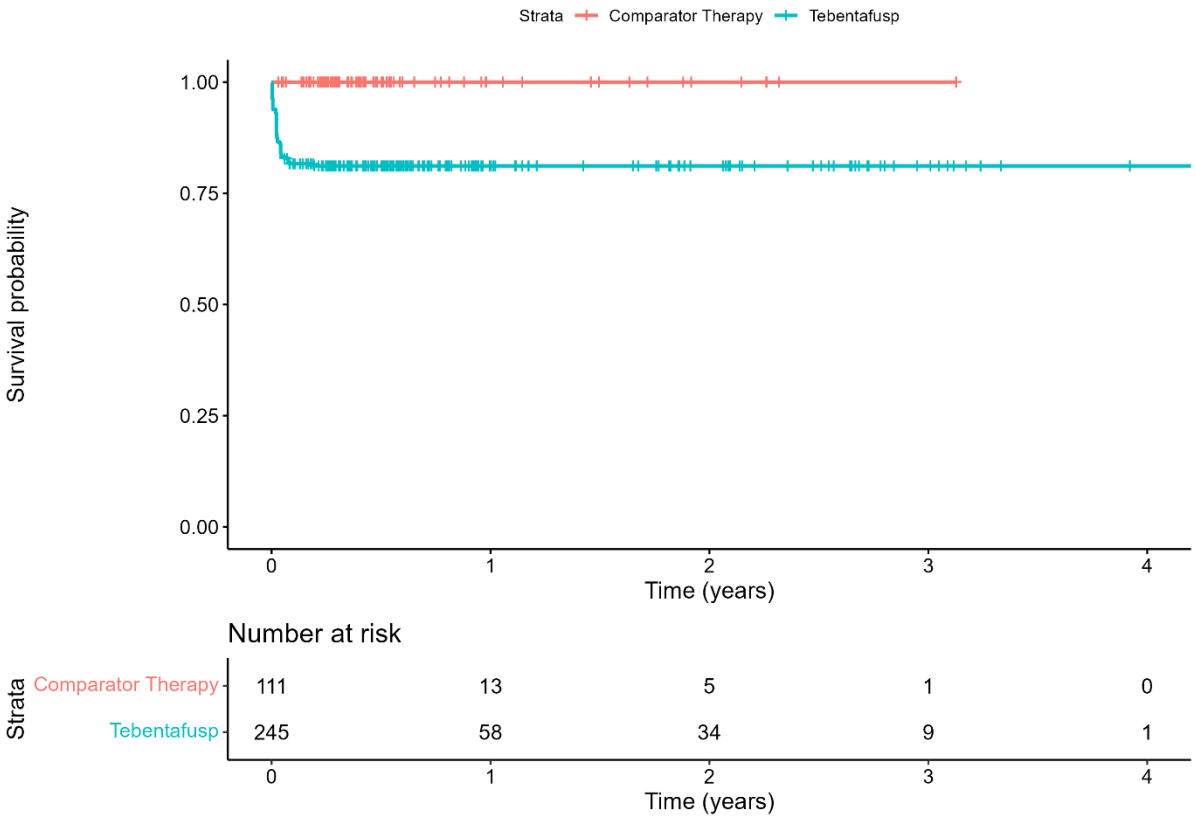
Hautausschlag nach höchstem CTCAE-Grad 2



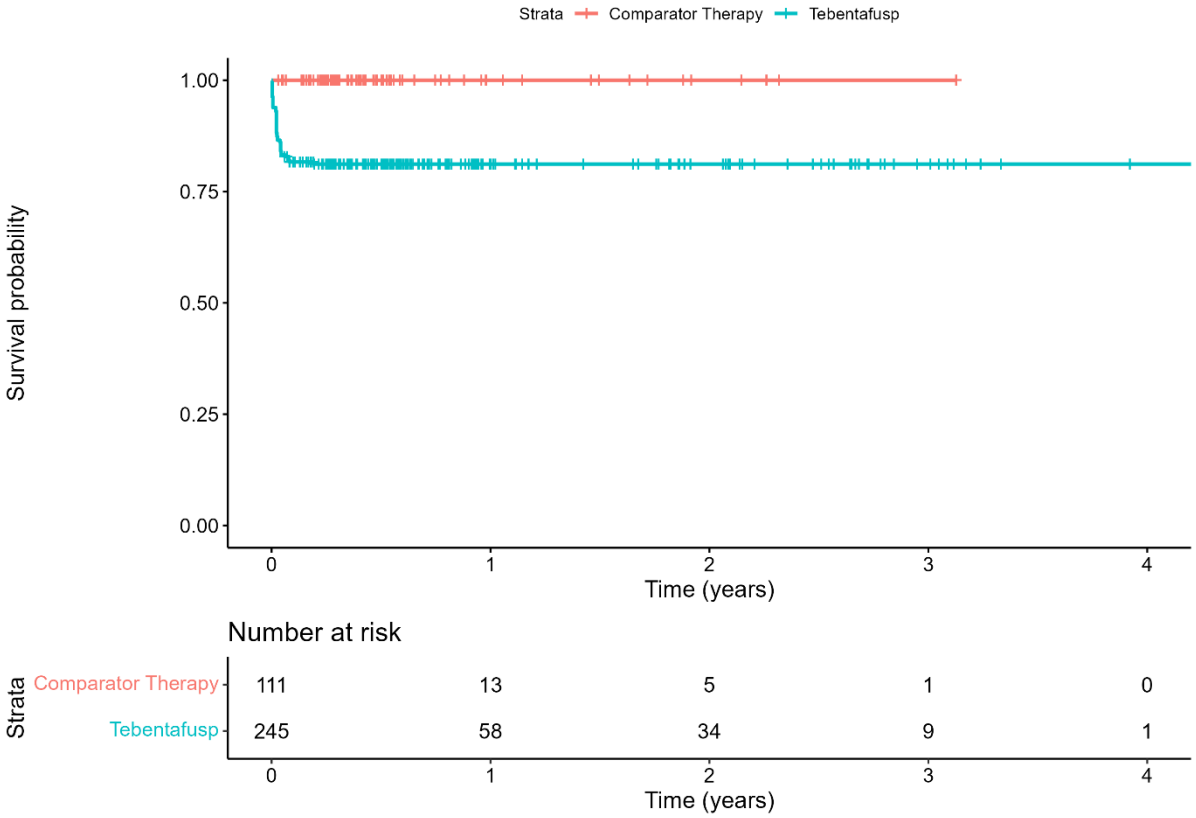
Hautausschlag nach höchstem CTCAE-Grad 3



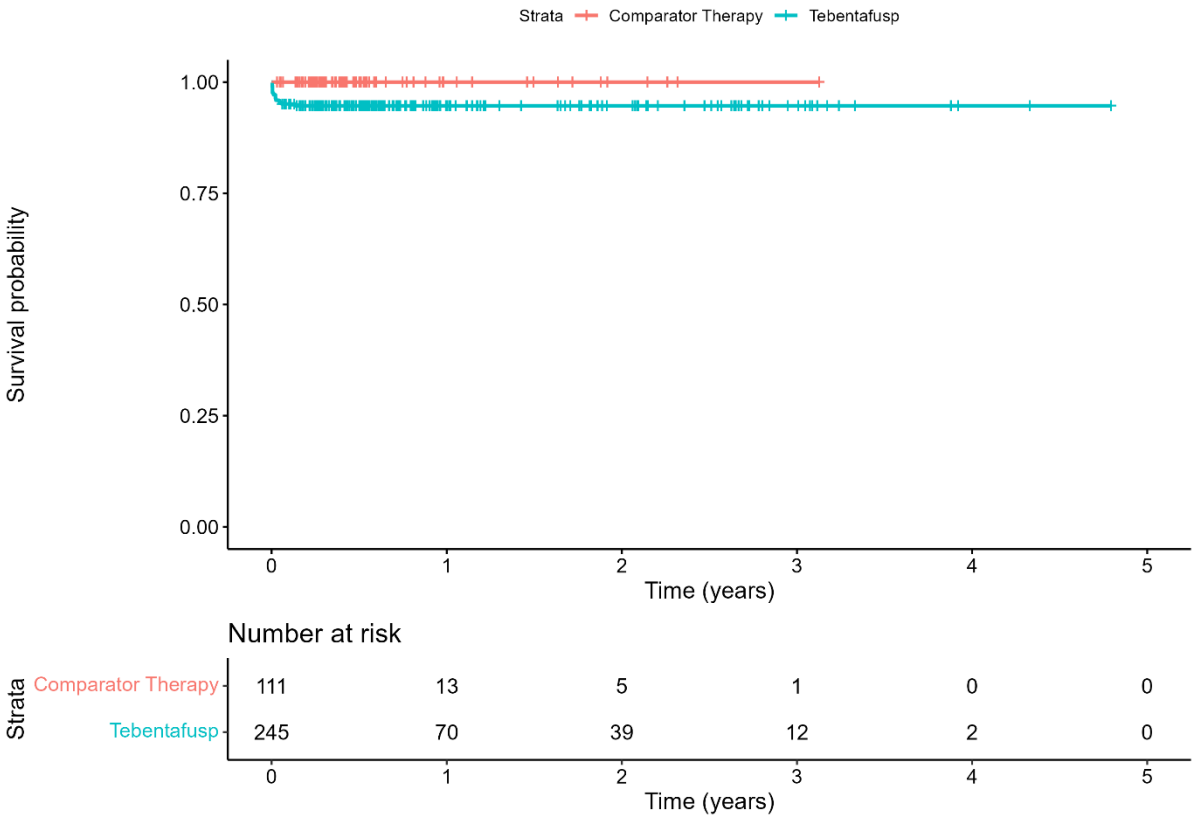
Hautausschlag mit CTCAE-Grad ≥ 3



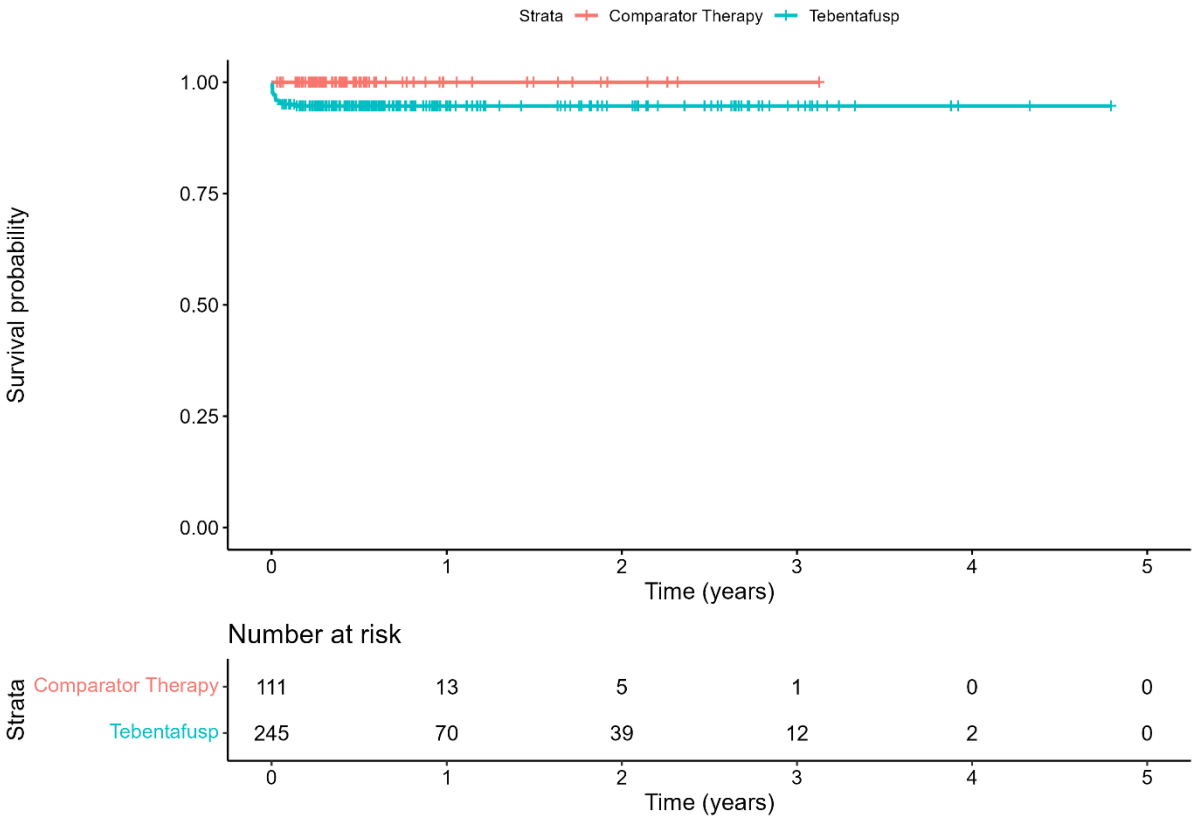
Hautausschlag mit CTCAE-Grad ≥ 3, in kausalem Zusammenhang mit der Behandlung



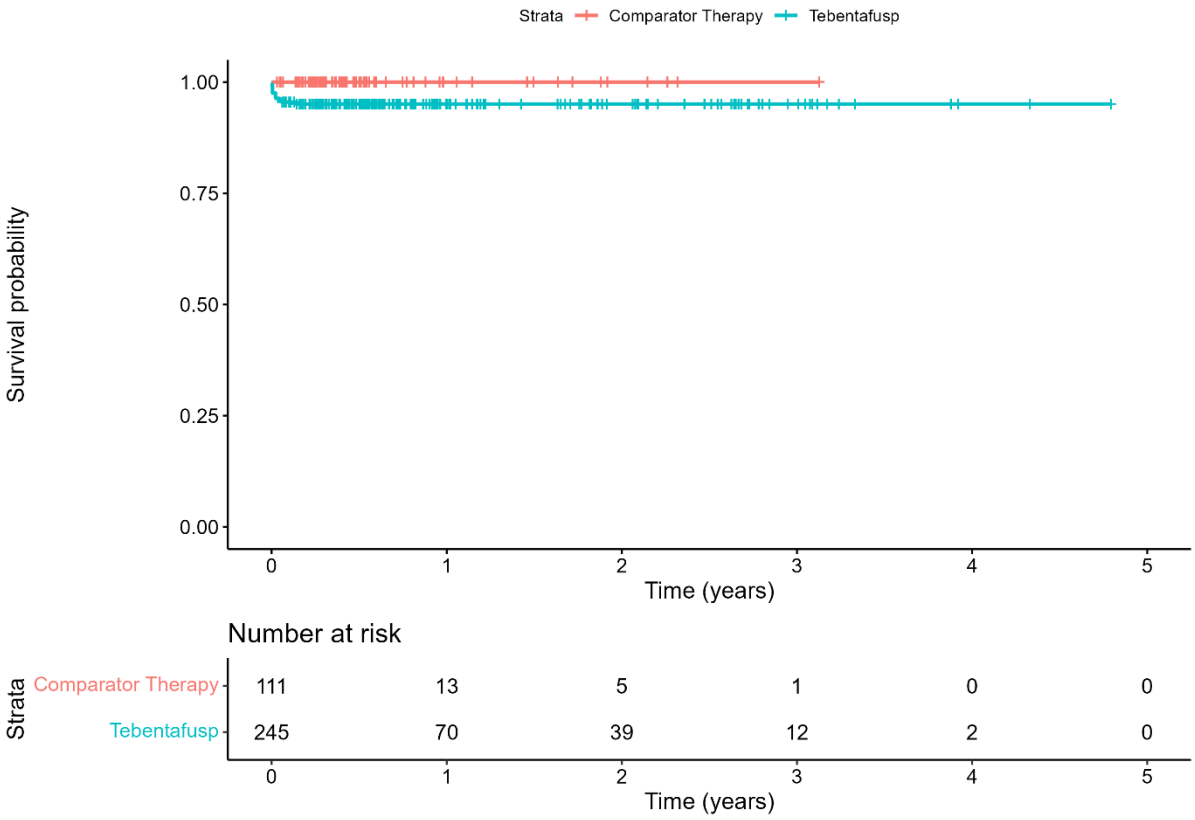
Schwerwiegender Hautausschlag



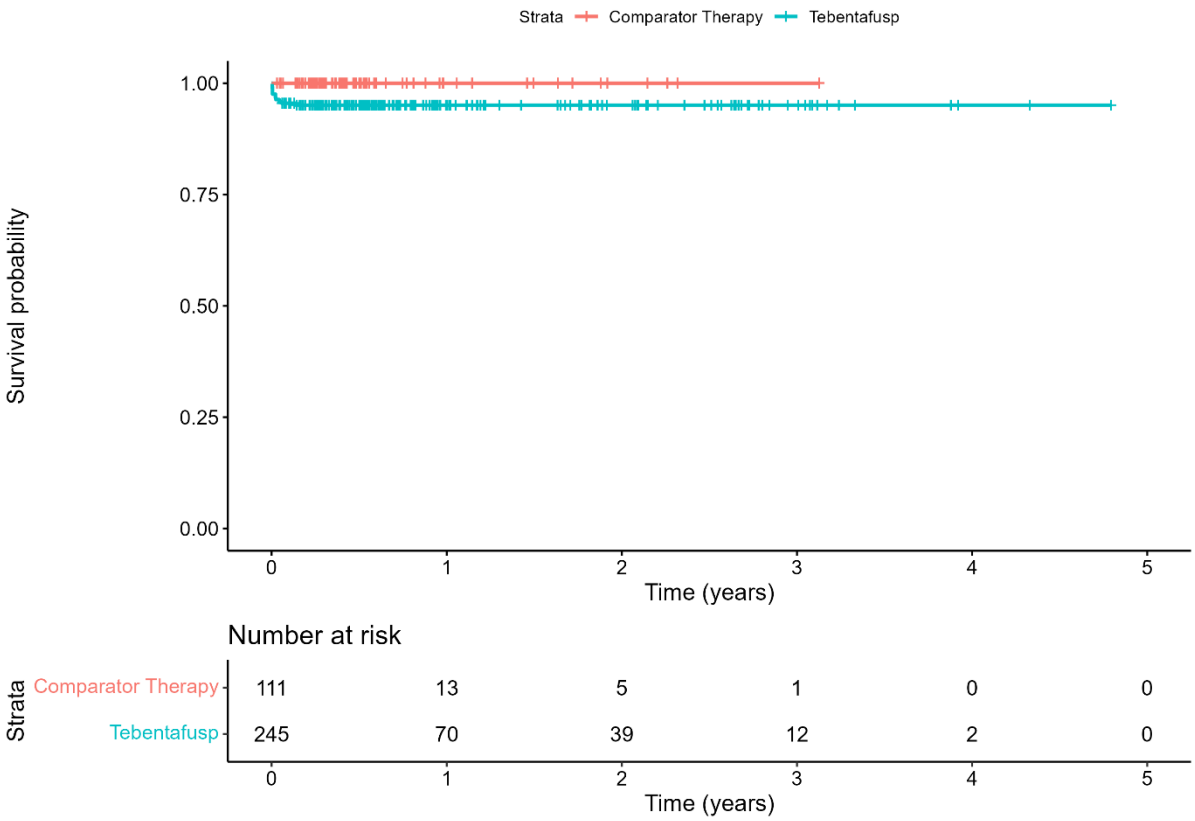
Schwerwiegender Hautausschlag, in kausalem Zusammenhang mit der Behandlung



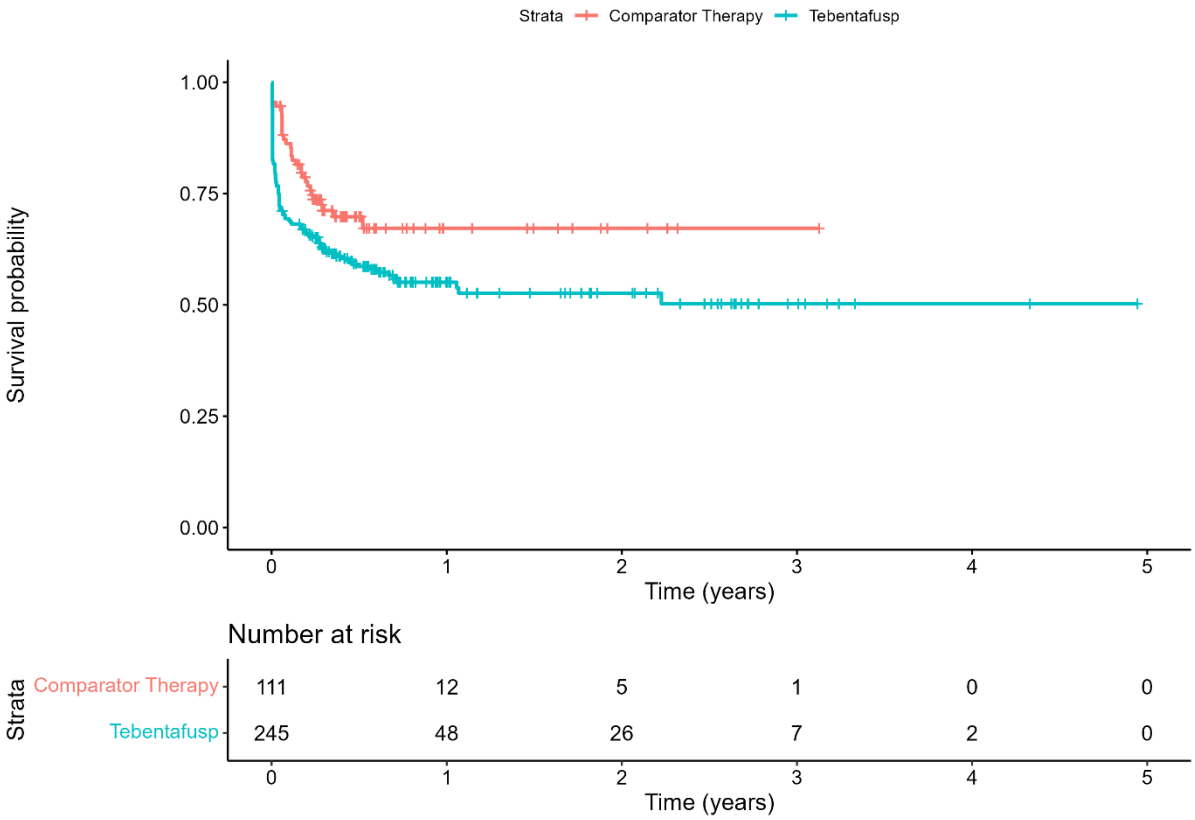
Hautausschlag, der zu einem Krankenhausaufenthalt führte



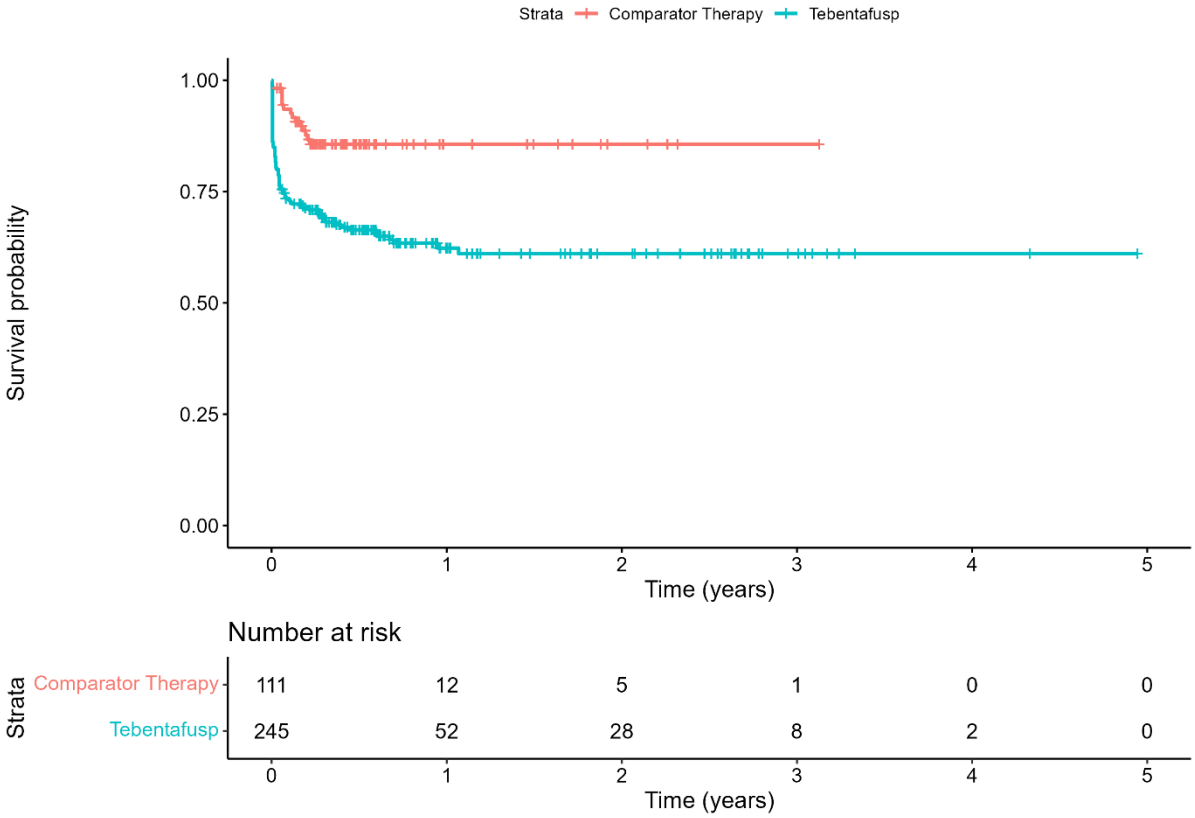
Hautausschlag, der zu einem Krankenhausaufenthalt führte, in kausalem Zusammenhang mit der Behandlung



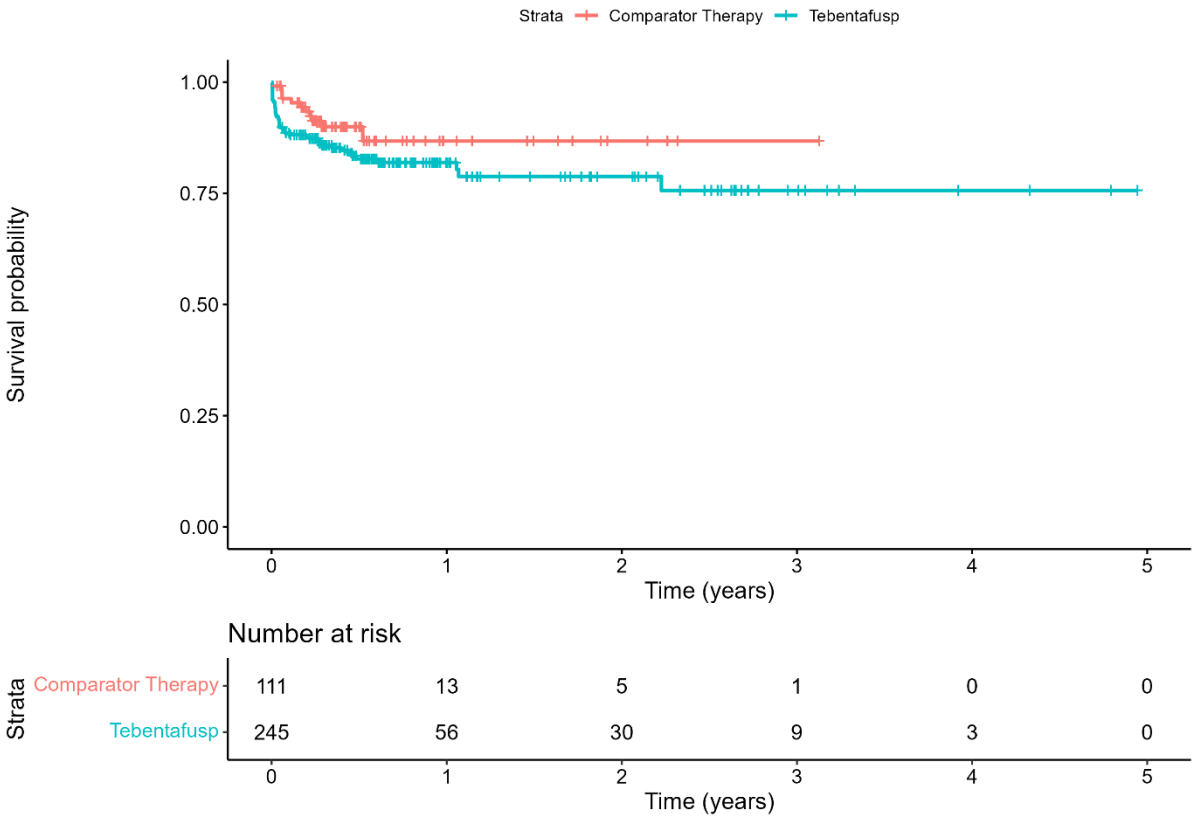
LFT-Erhöhung



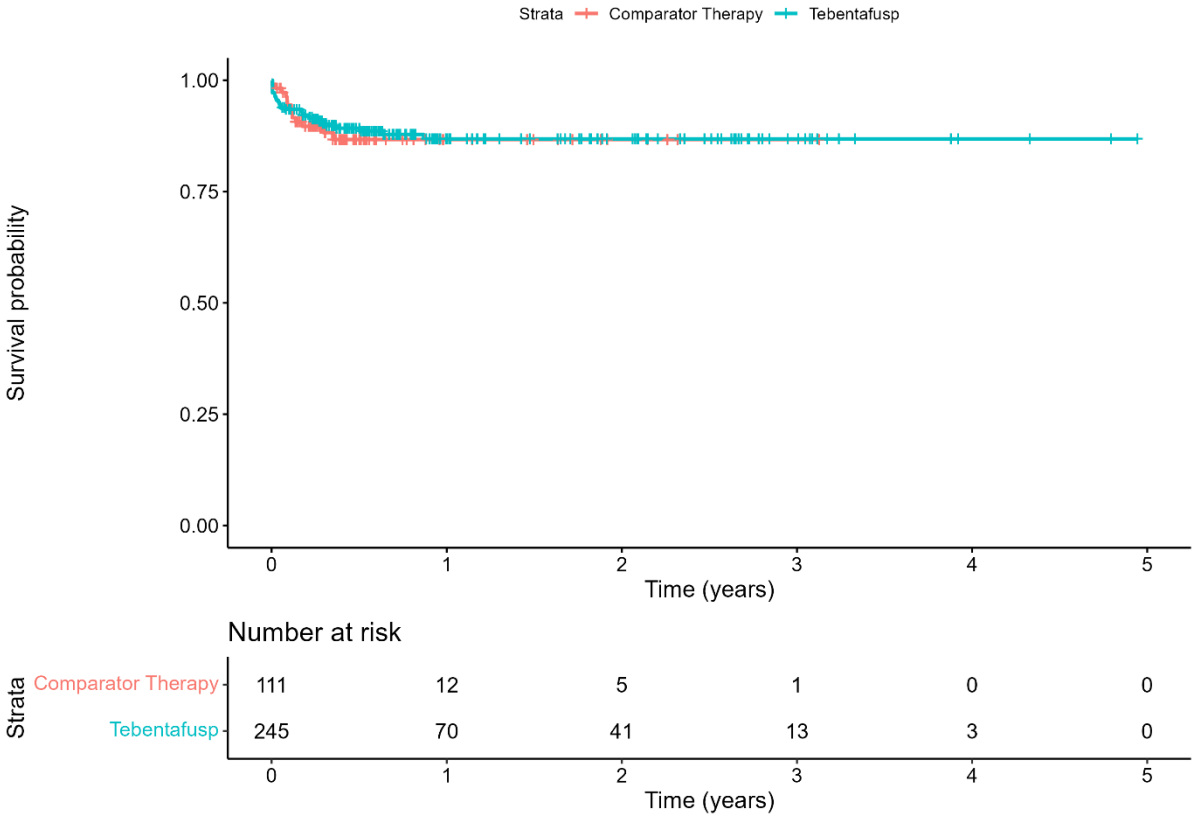
LFT-Erhöhung in kausalem Zusammenhang mit der Behandlung



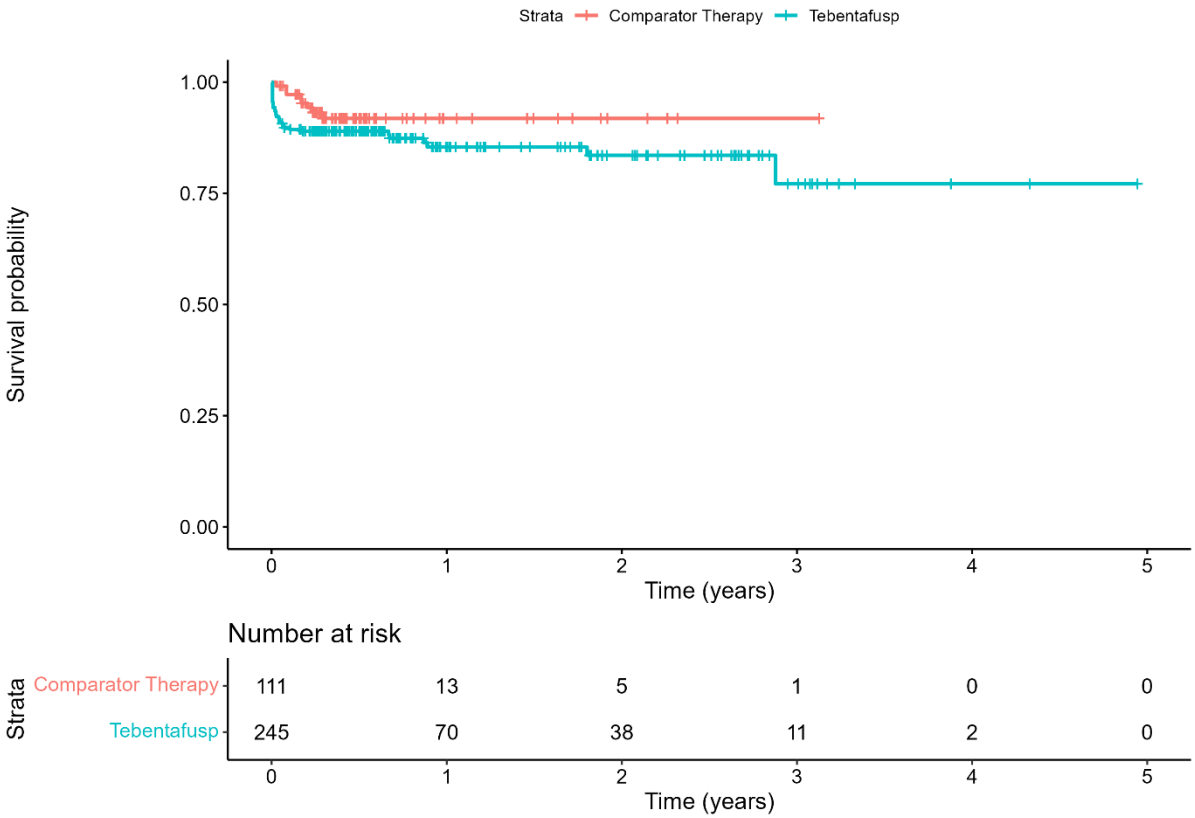
LFT-Erhöhung nach höchstem CTCAE-Grad 1



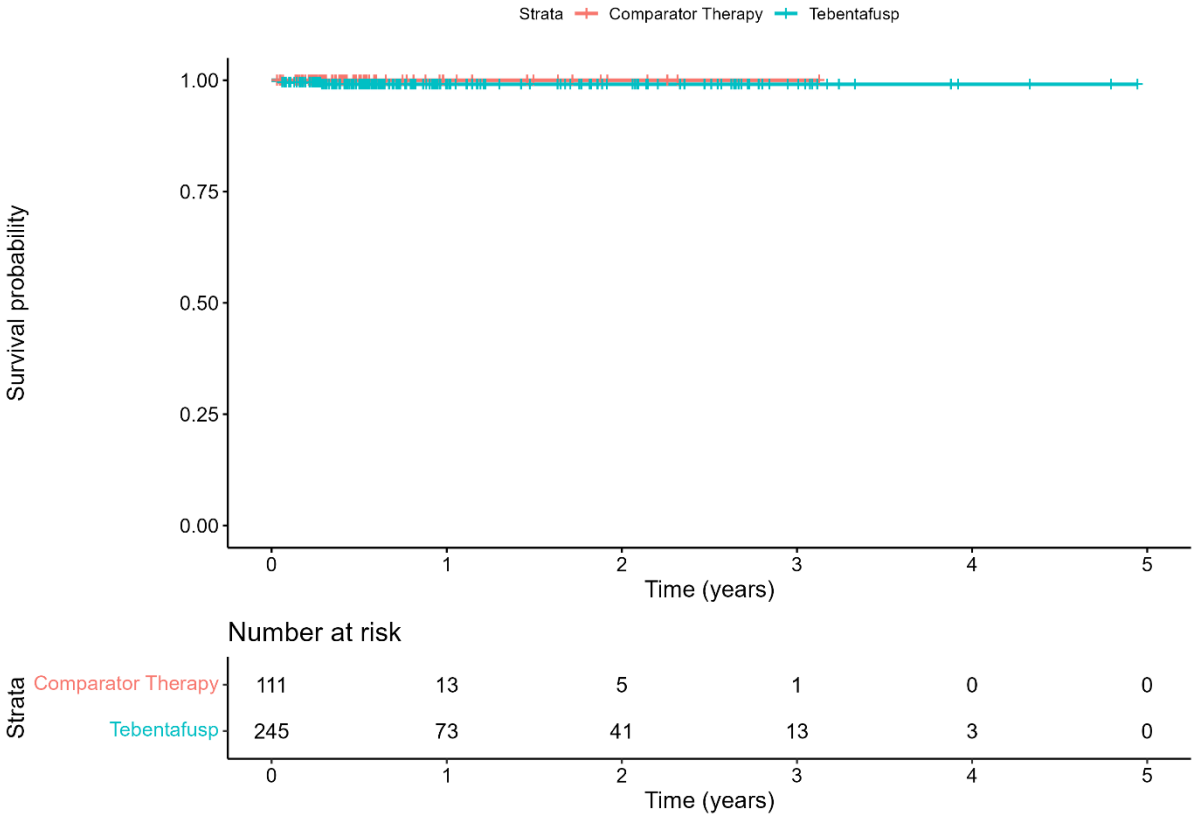
LFT-Erhöhung nach höchstem CTCAE-Grad 2



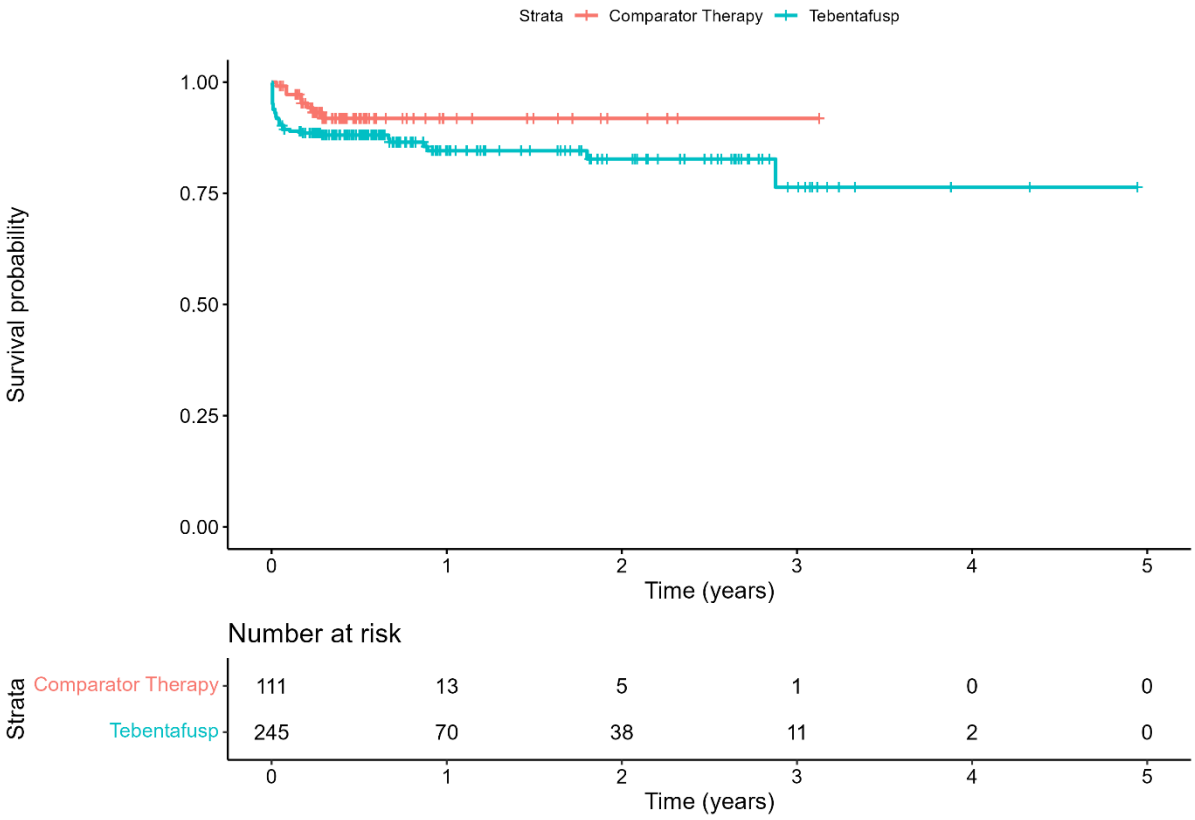
LFT-Erhöhung nach höchstem CTCAE-Grad 3



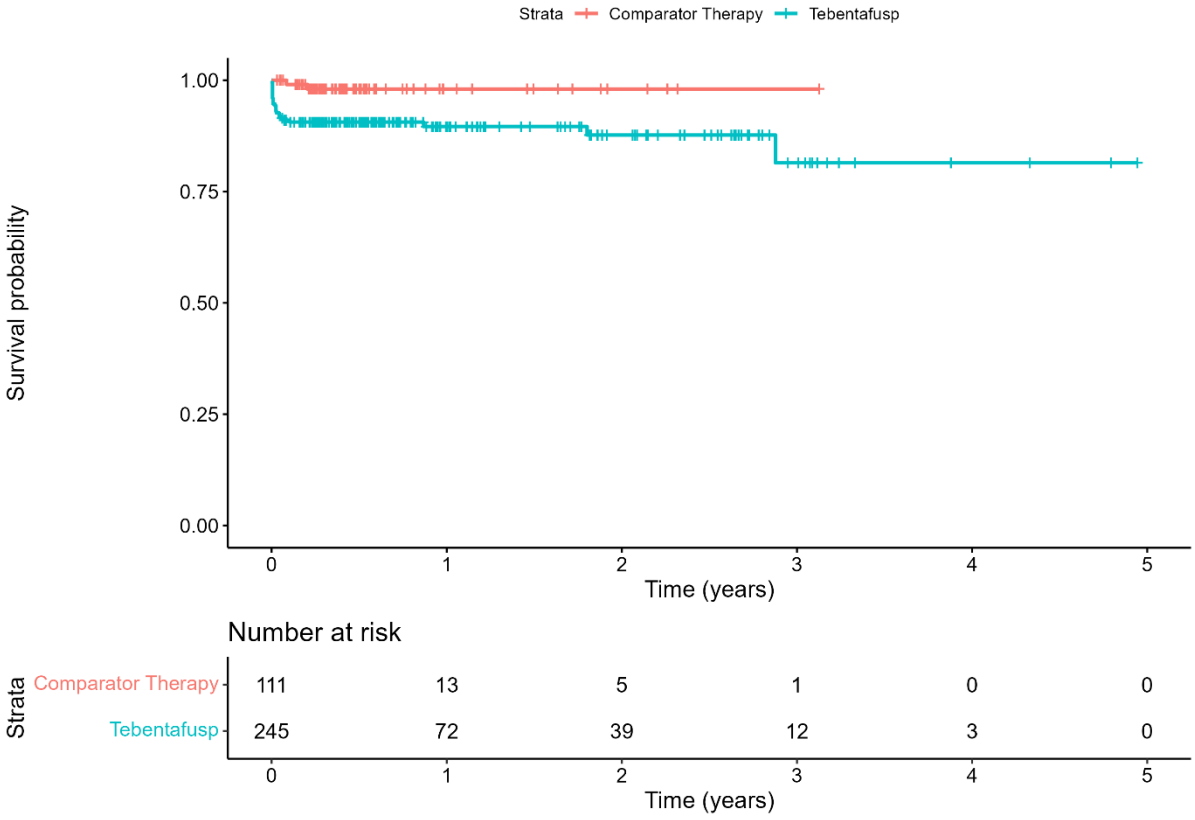
LFT-Erhöhung nach höchstem CTCAE-Grad 4



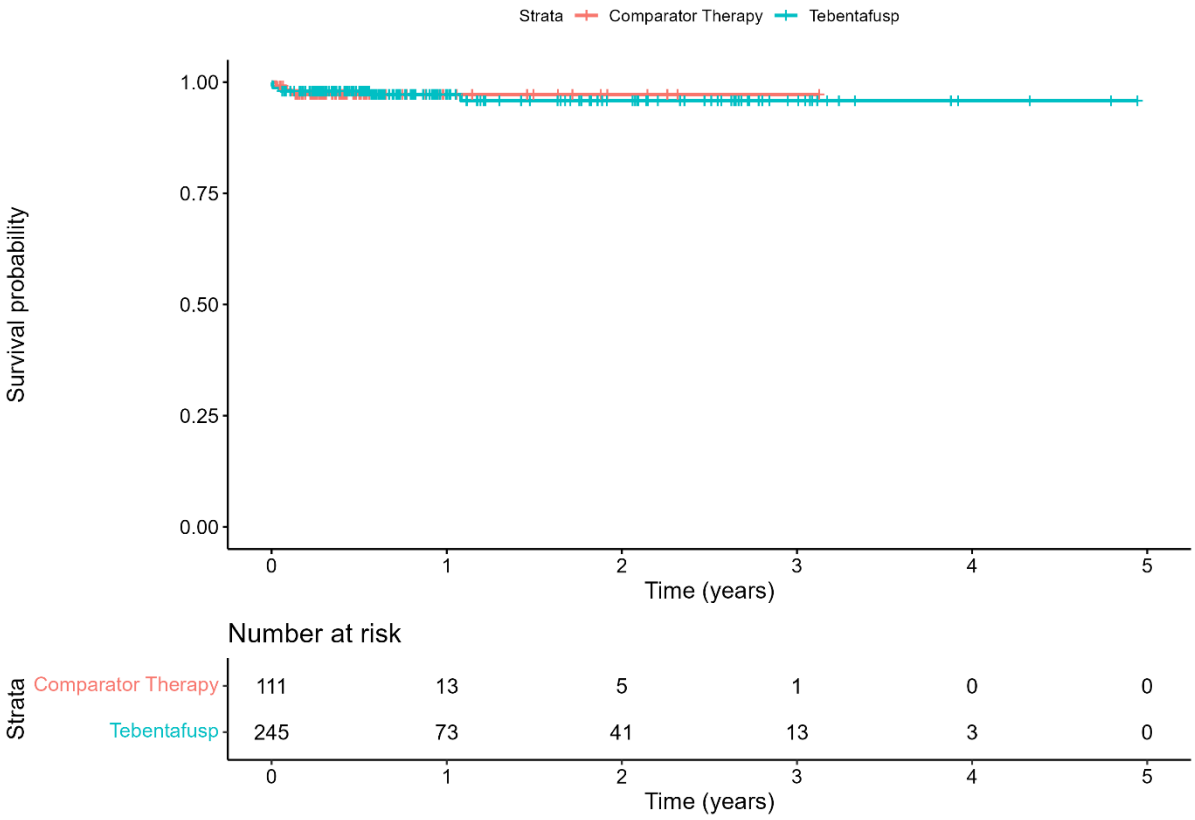
LFT-Erhöhung mit CTCAE-Grad ≥ 3



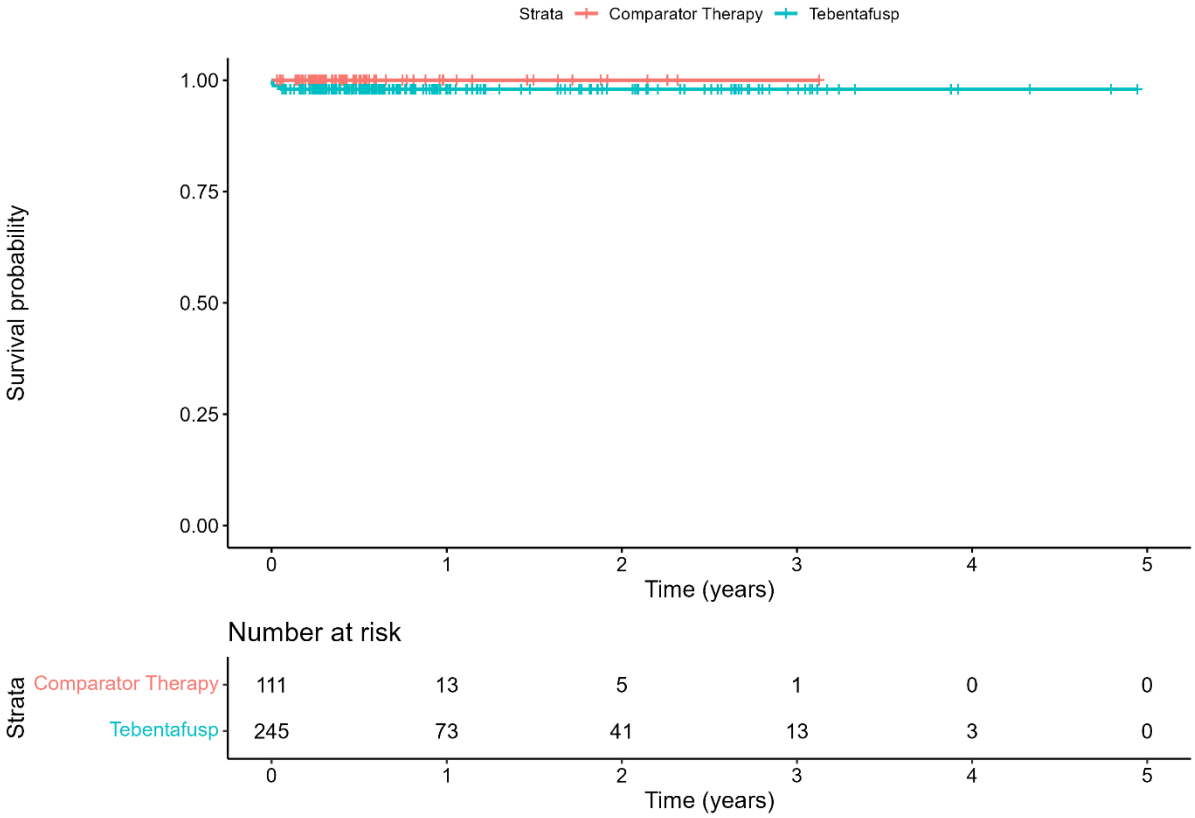
LFT-Erhöhung mit CTCAE-Grad ≥ 3, in kausalem Zusammenhang mit der Behandlung



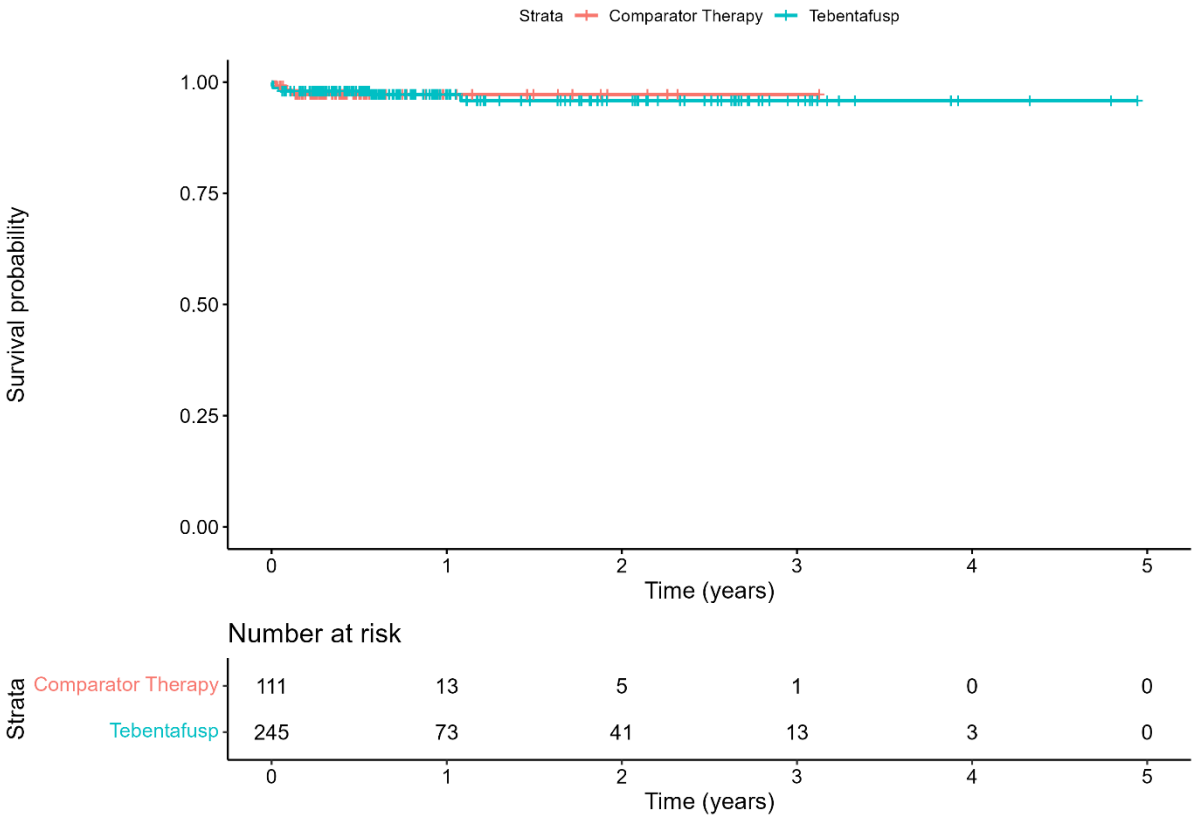
Schwerwiegende LFT-Erhöhung



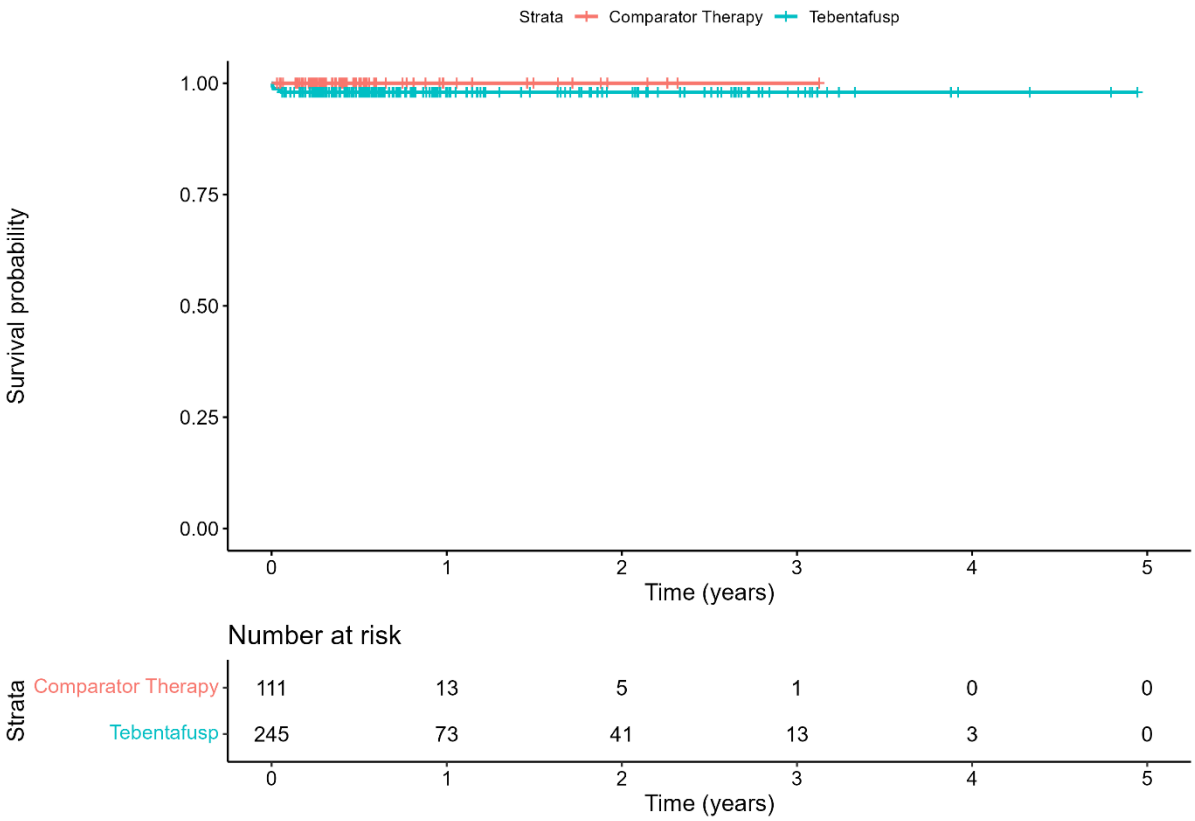
Schwerwiegende LFT-Erhöhung, in kausalem Zusammenhang mit der Behandlung



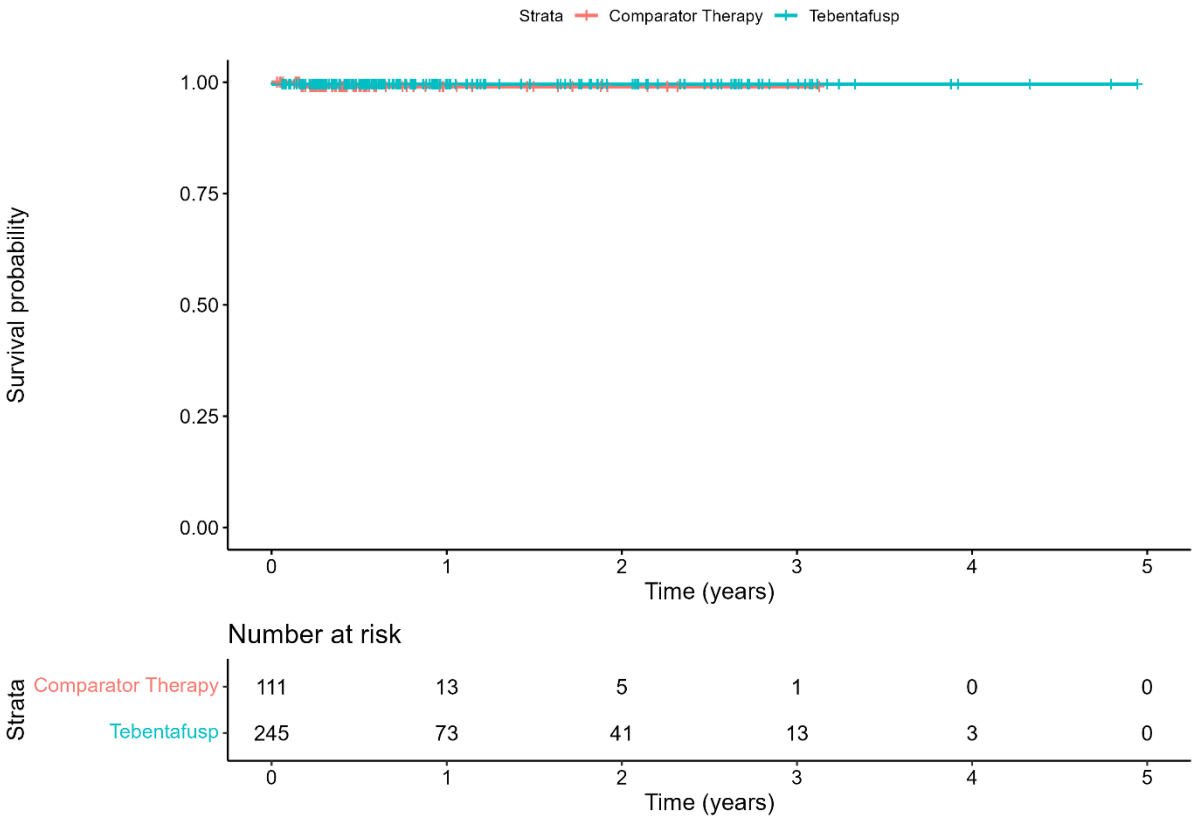
LFT-Erhöhung, die zu einem Krankenhausaufenthalt führte



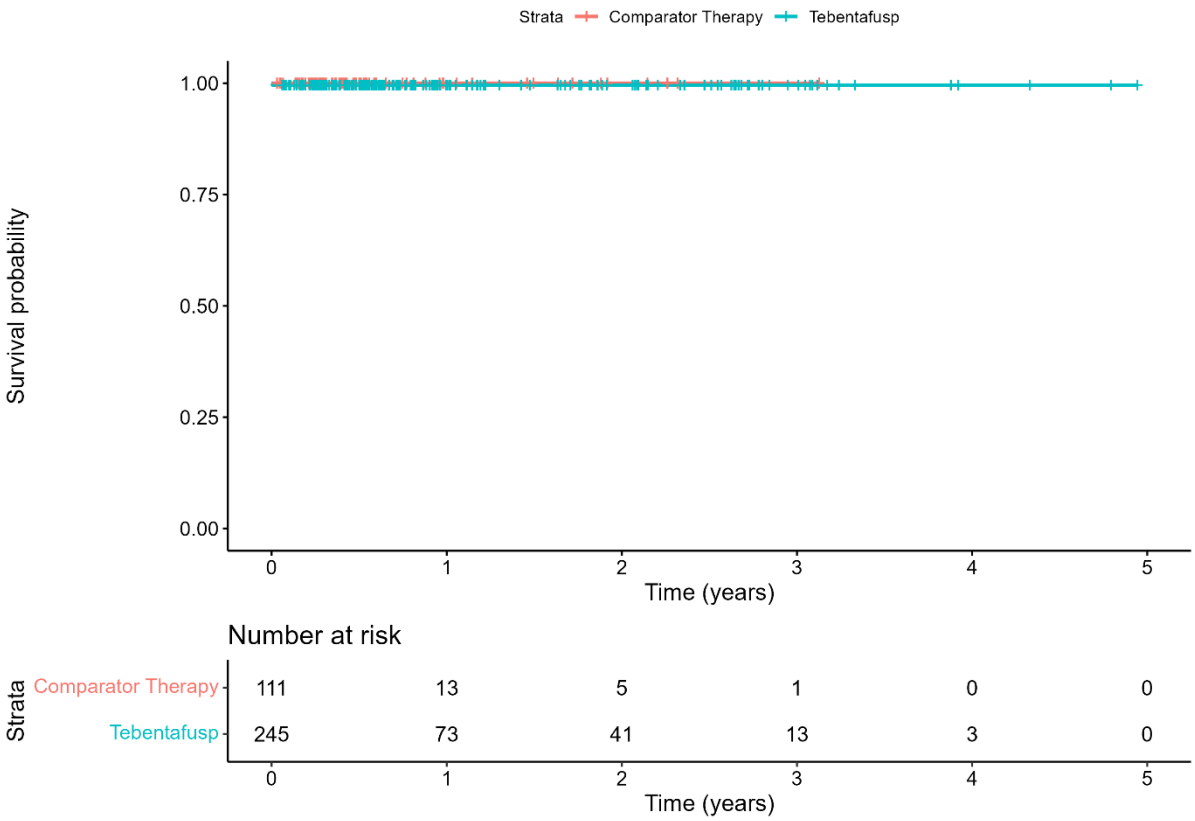
LFT-Erhöhung, die zu einem Krankenhausaufenthalt führte, in kausalem Zusammenhang mit der Behandlung



LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte



LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte, in kausalem Zusammenhang mit der Behandlung



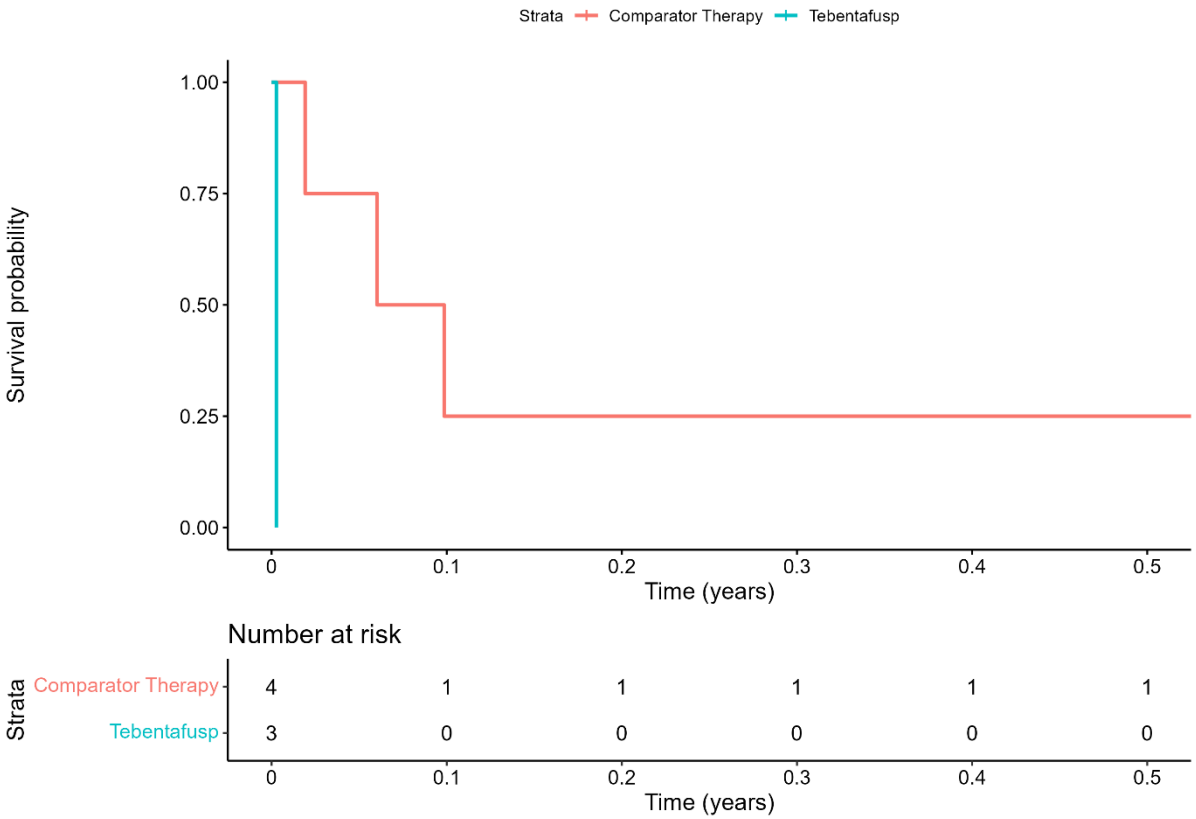
16 **4.3.1.3.5 Subgruppenanalysen – RCT**

16.1 **Endpunkt Sicherheit und Verträglichkeit**

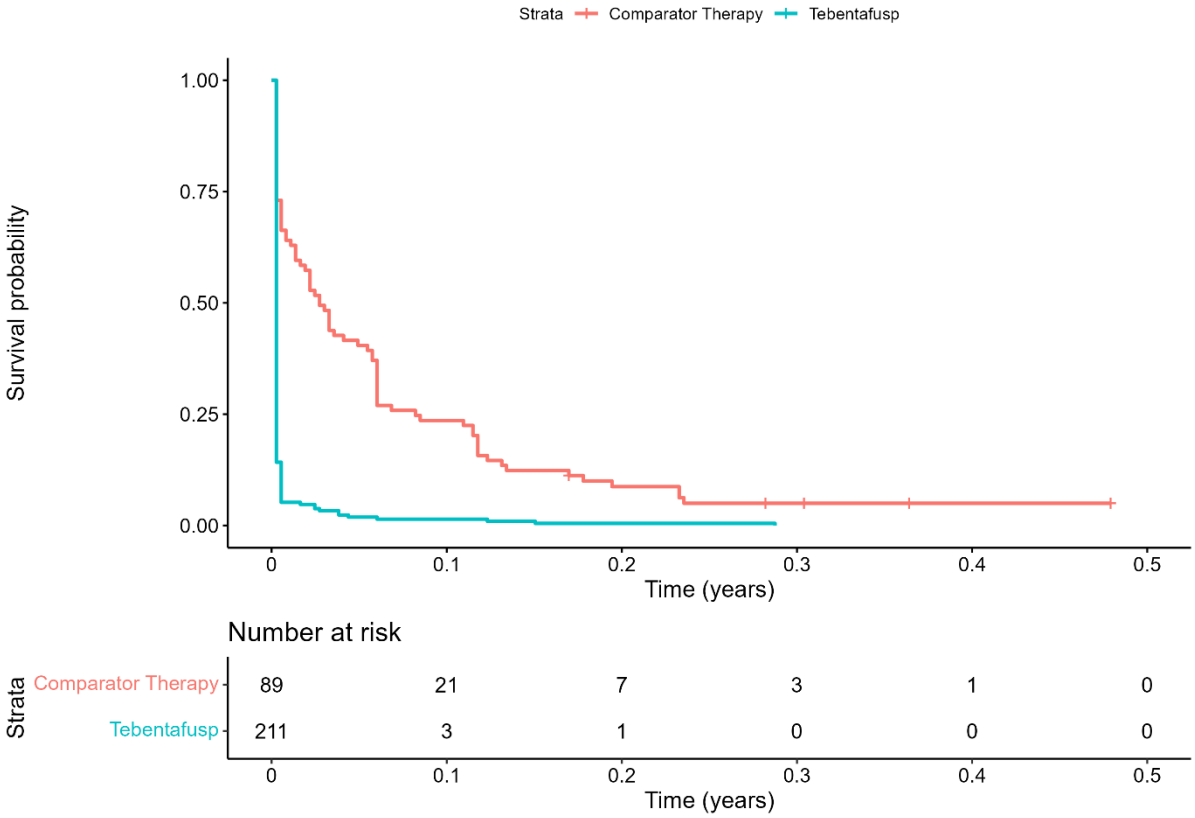
17 Primäranalyse (Oktober 2020)

17.1 Jegliches UE (Tabelle 4-87)

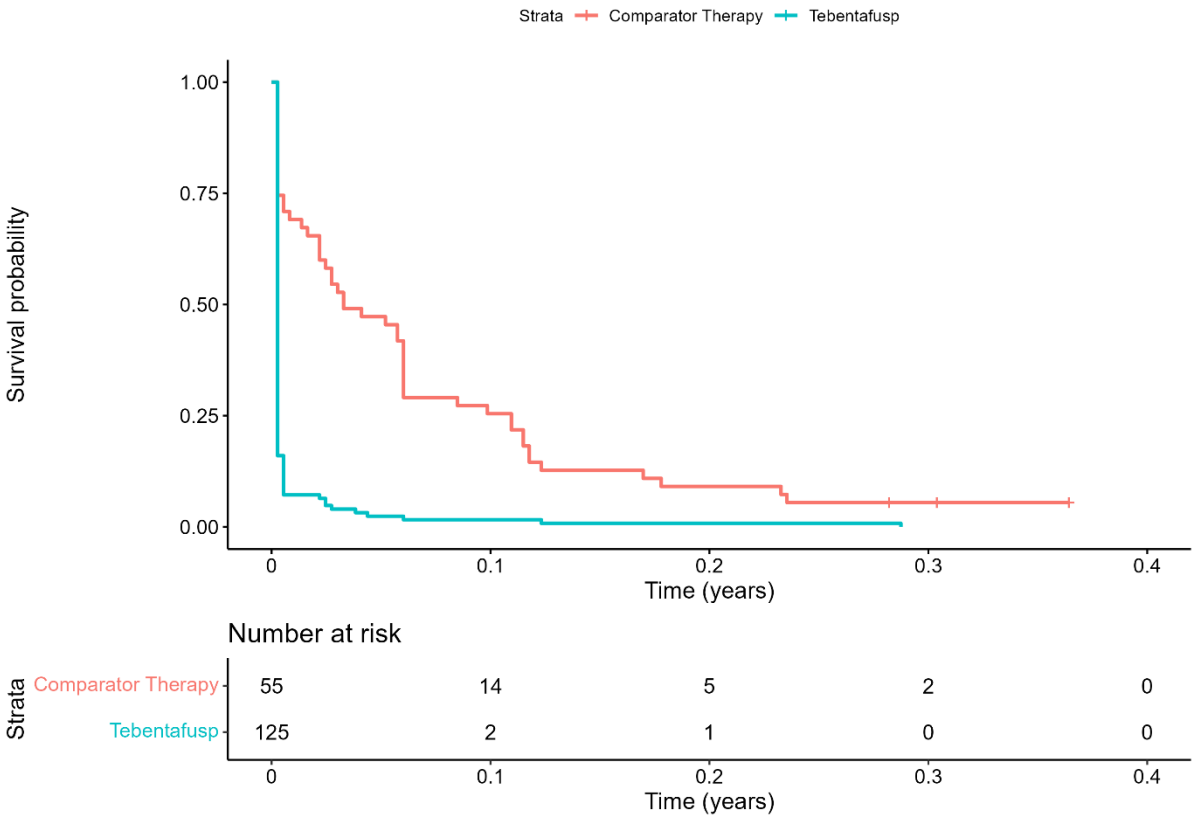
Herkunft: Hispanisch



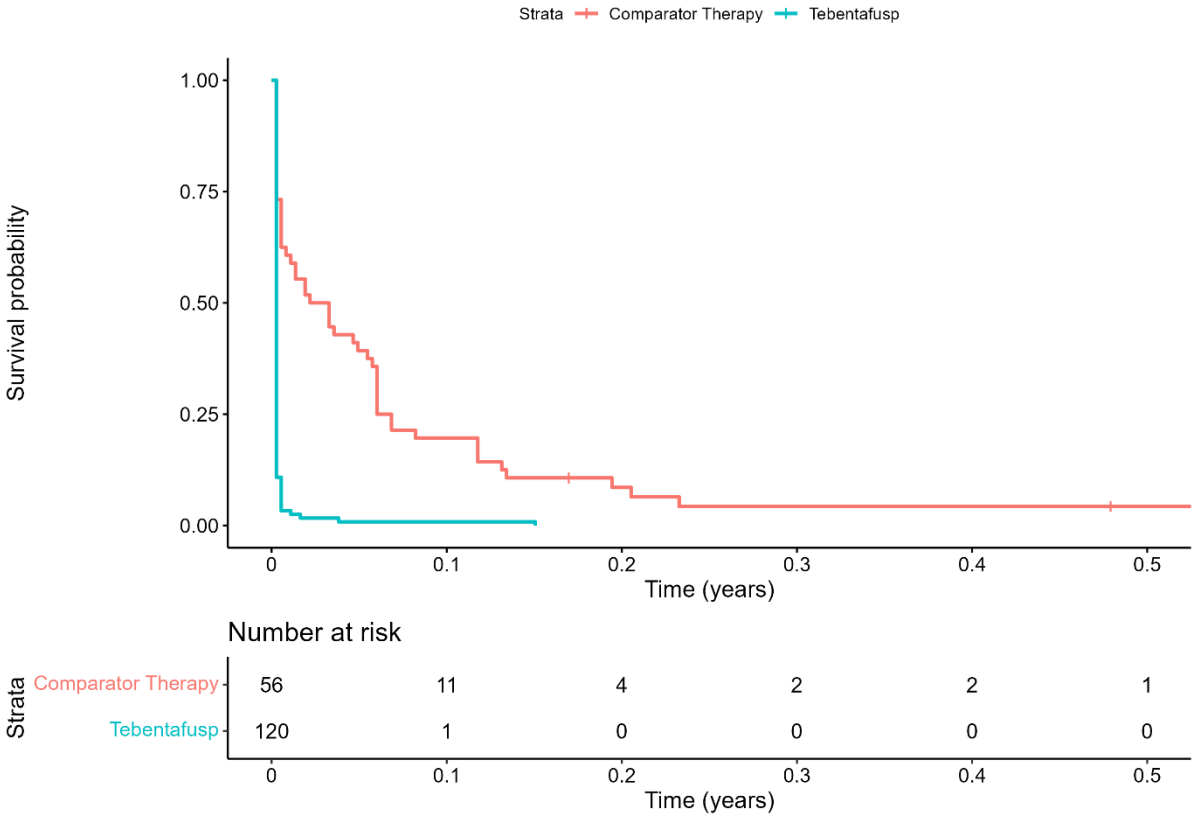
Herkunft: Nicht-hispanisch



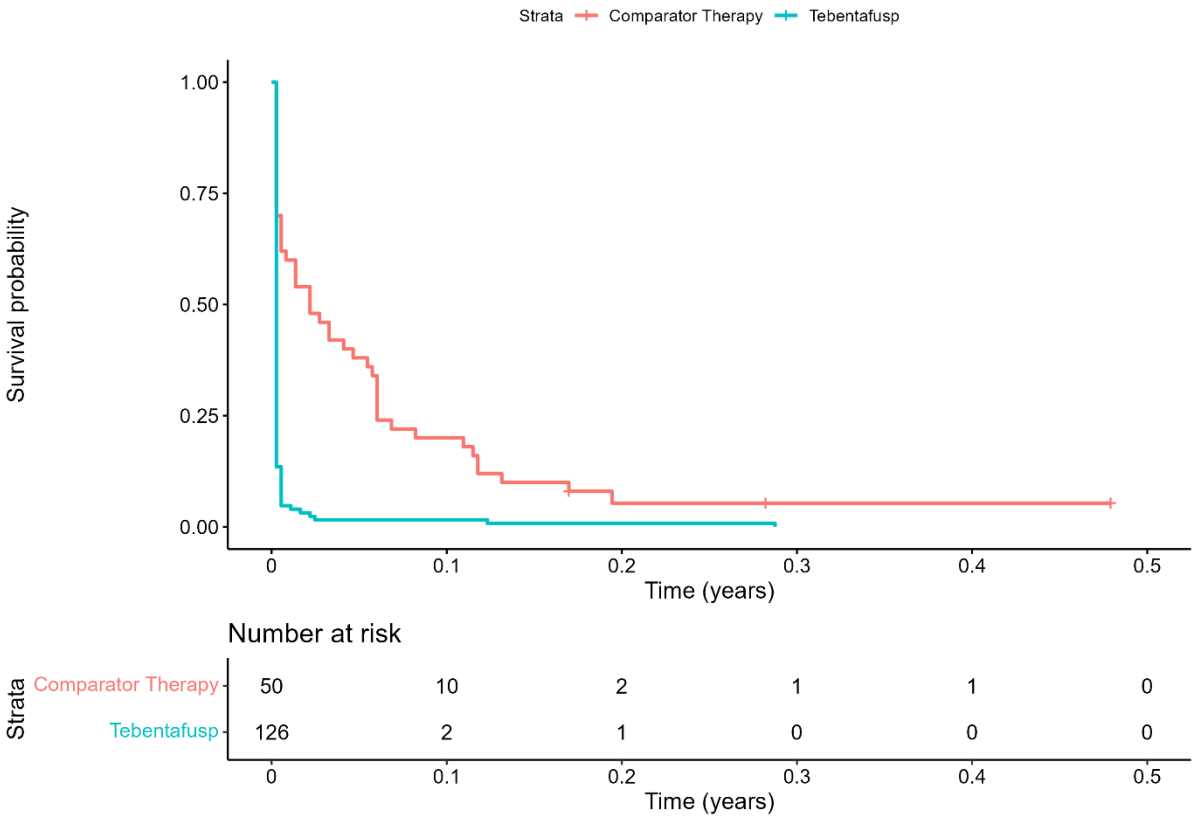
Geschlecht: Männlich



Geschlecht: Weiblich



Alter: <65 Jahre



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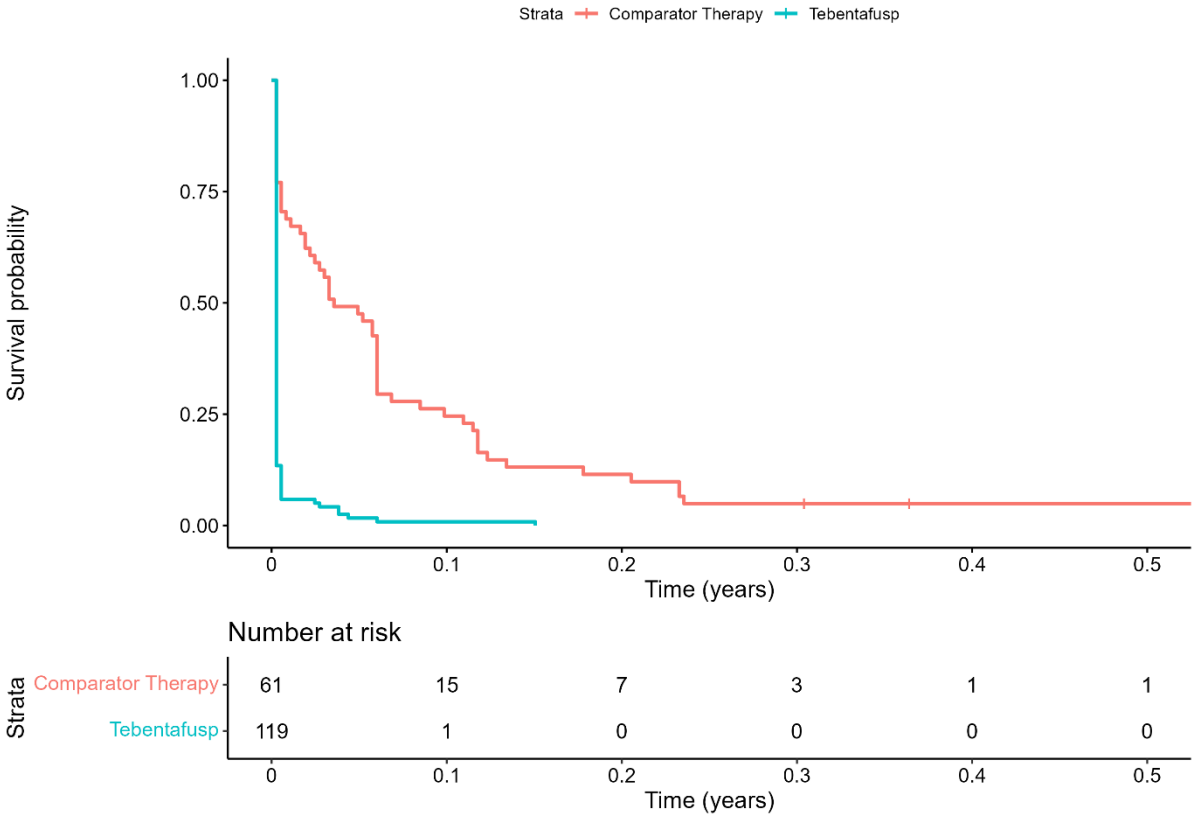
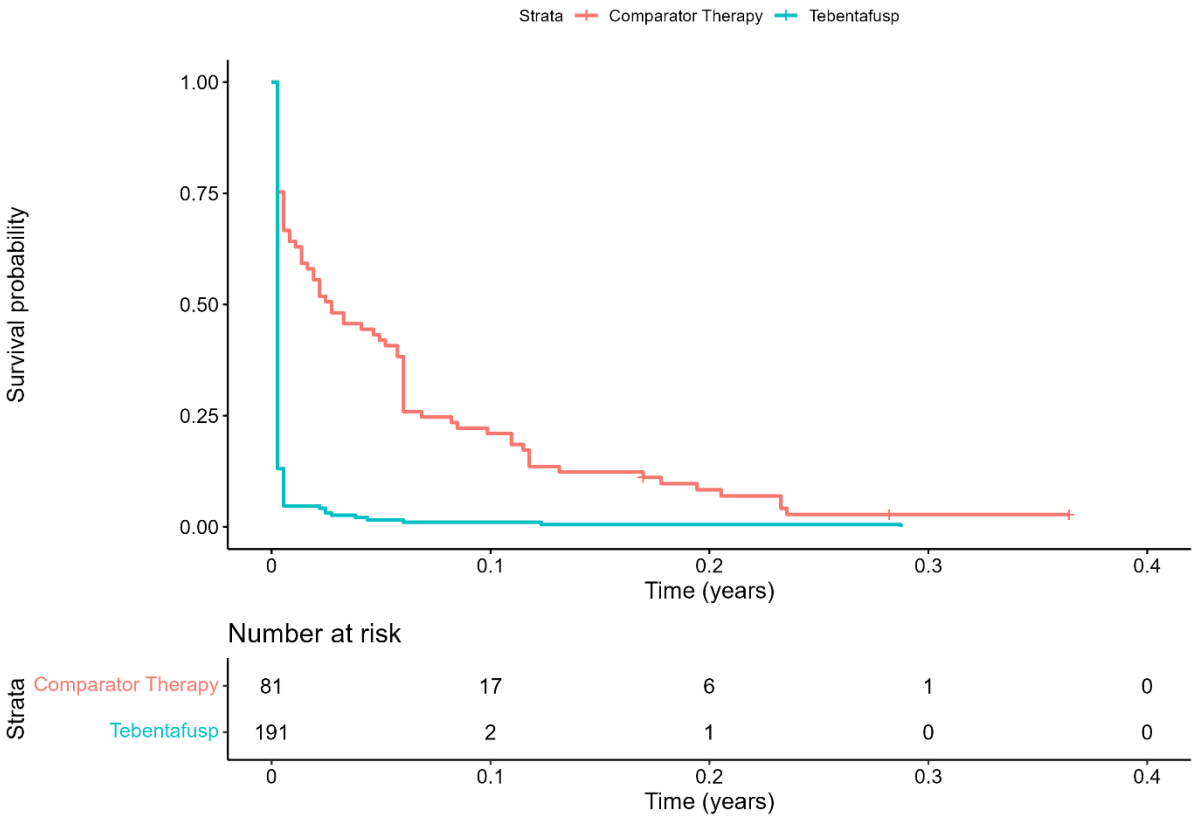
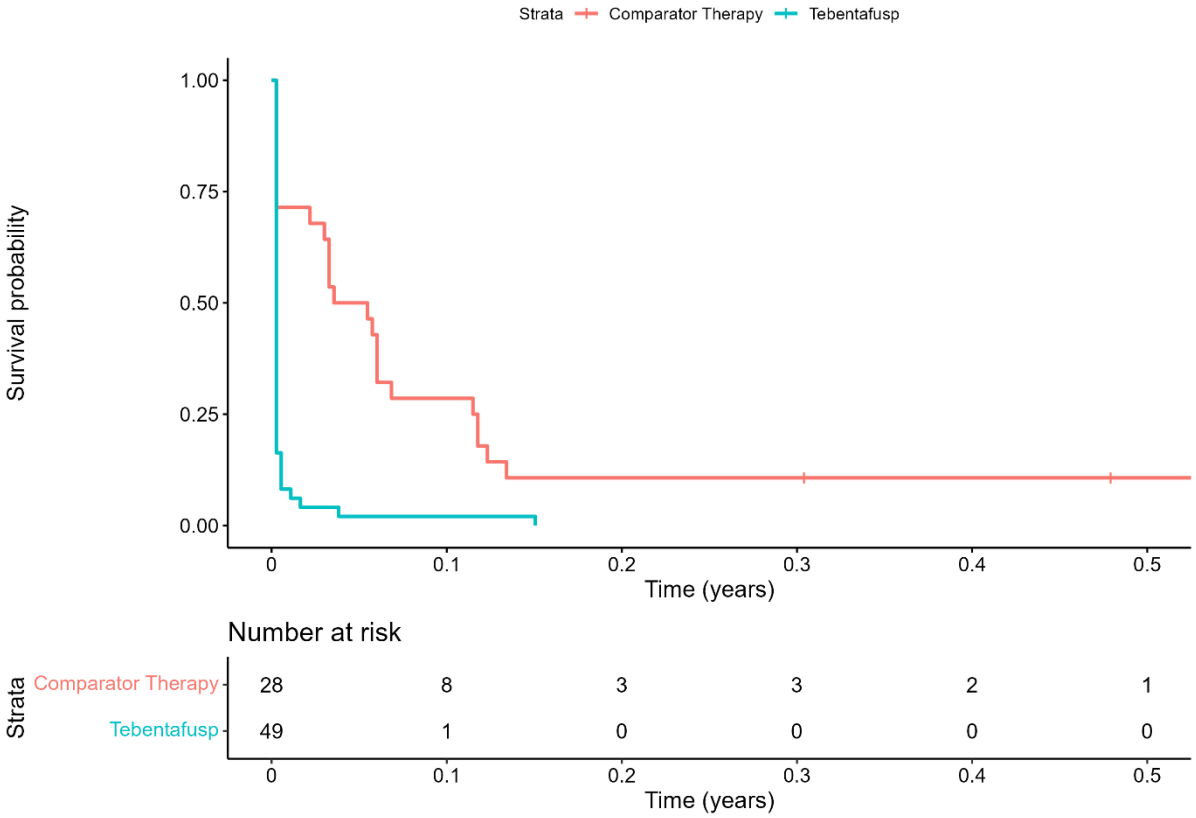


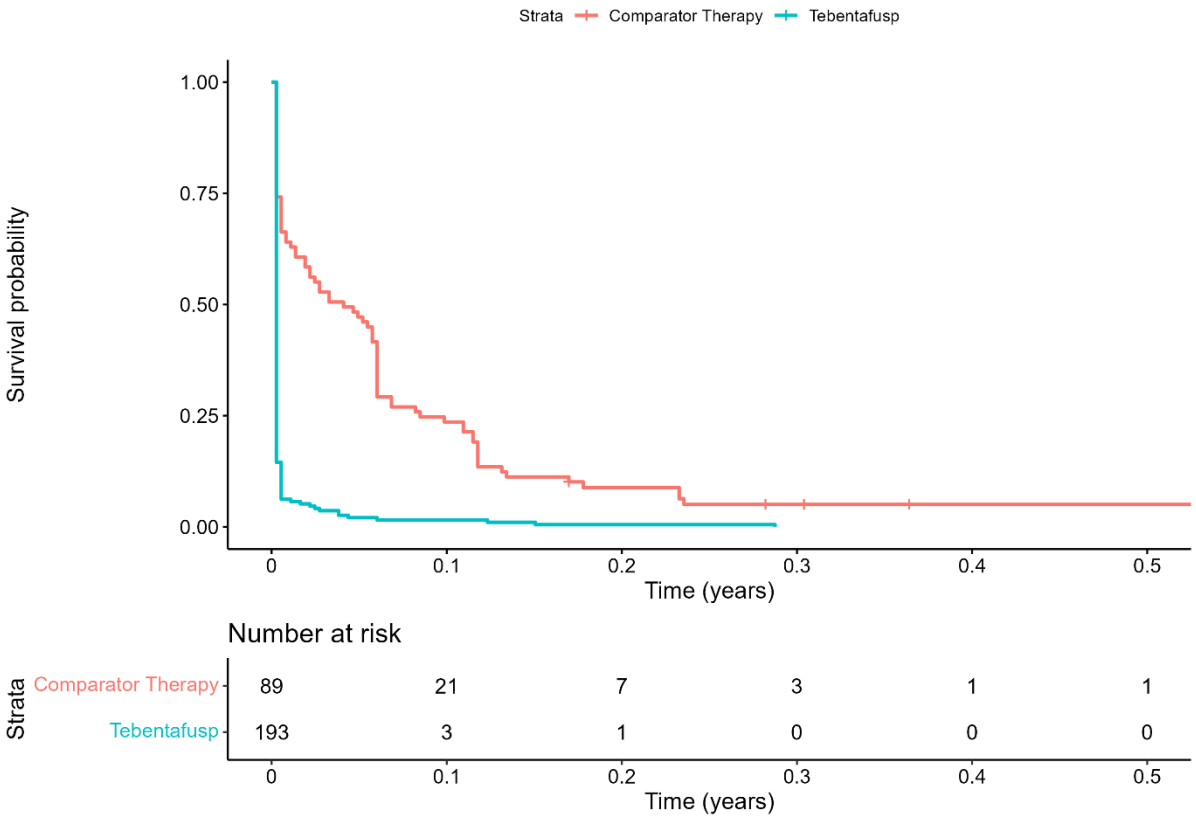
ECOG-Performance-Status: 0



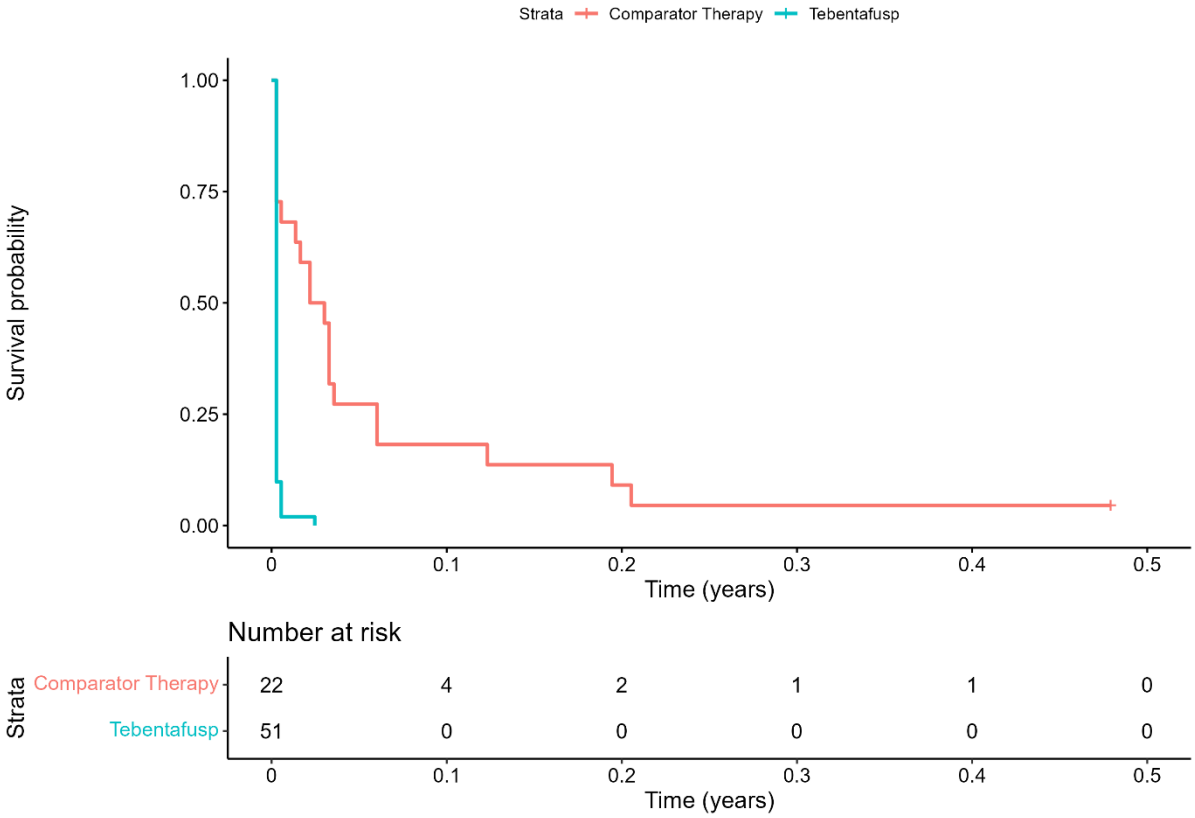
ECOG-Performance-Status: 1



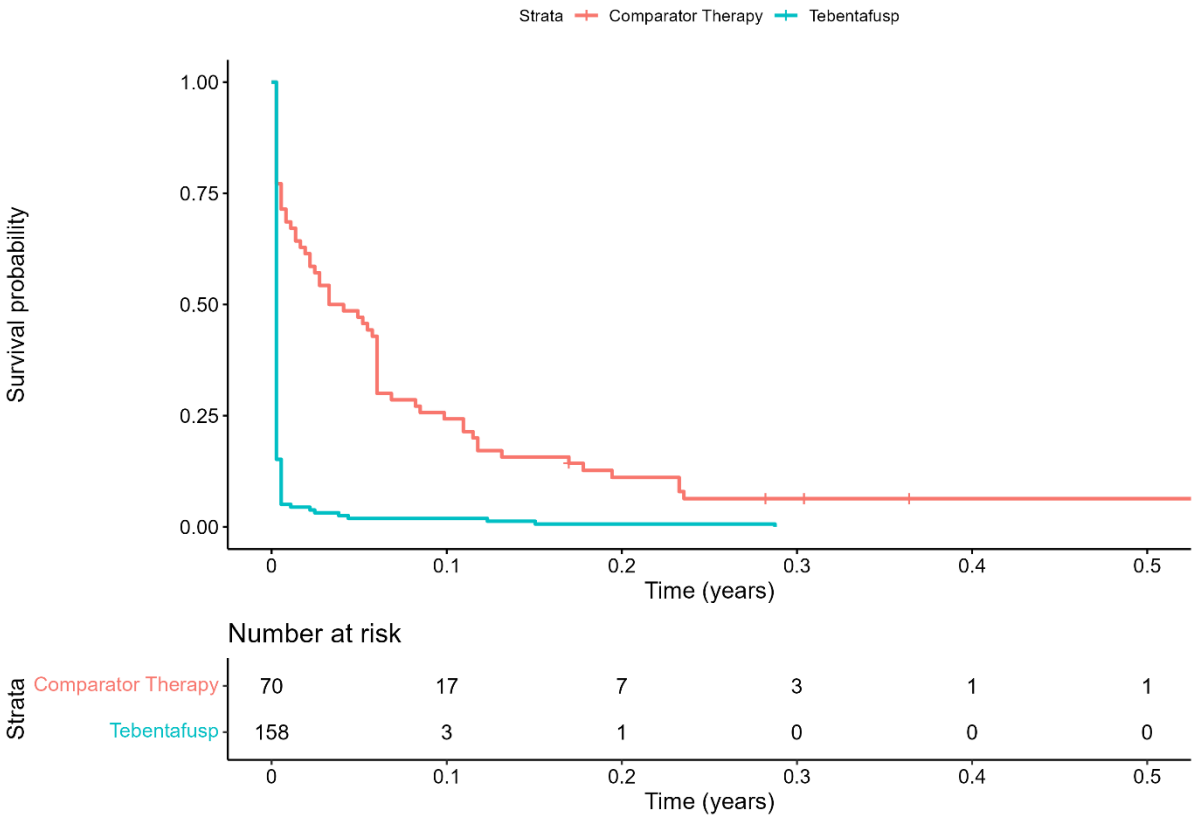
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



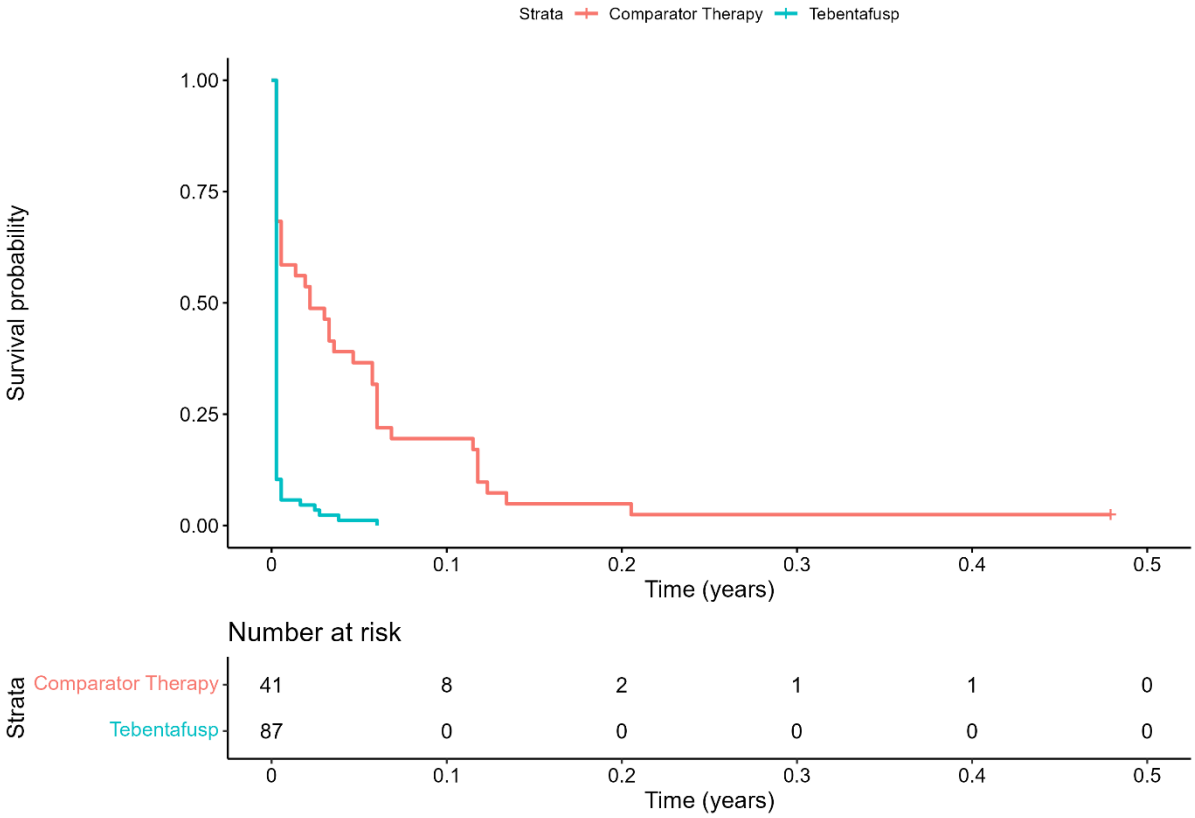
Alkalische Phosphatase (ALP) (Baseline): >ULN



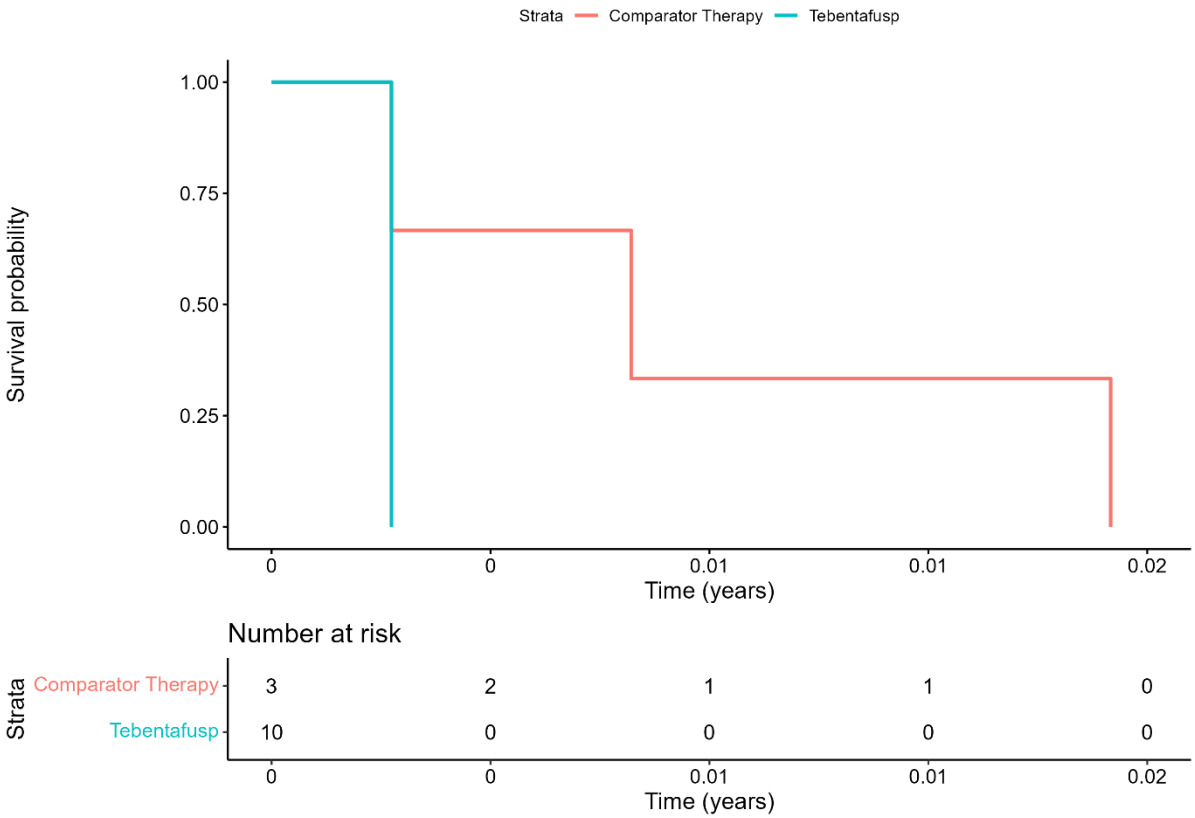
LDH: ≤ULN



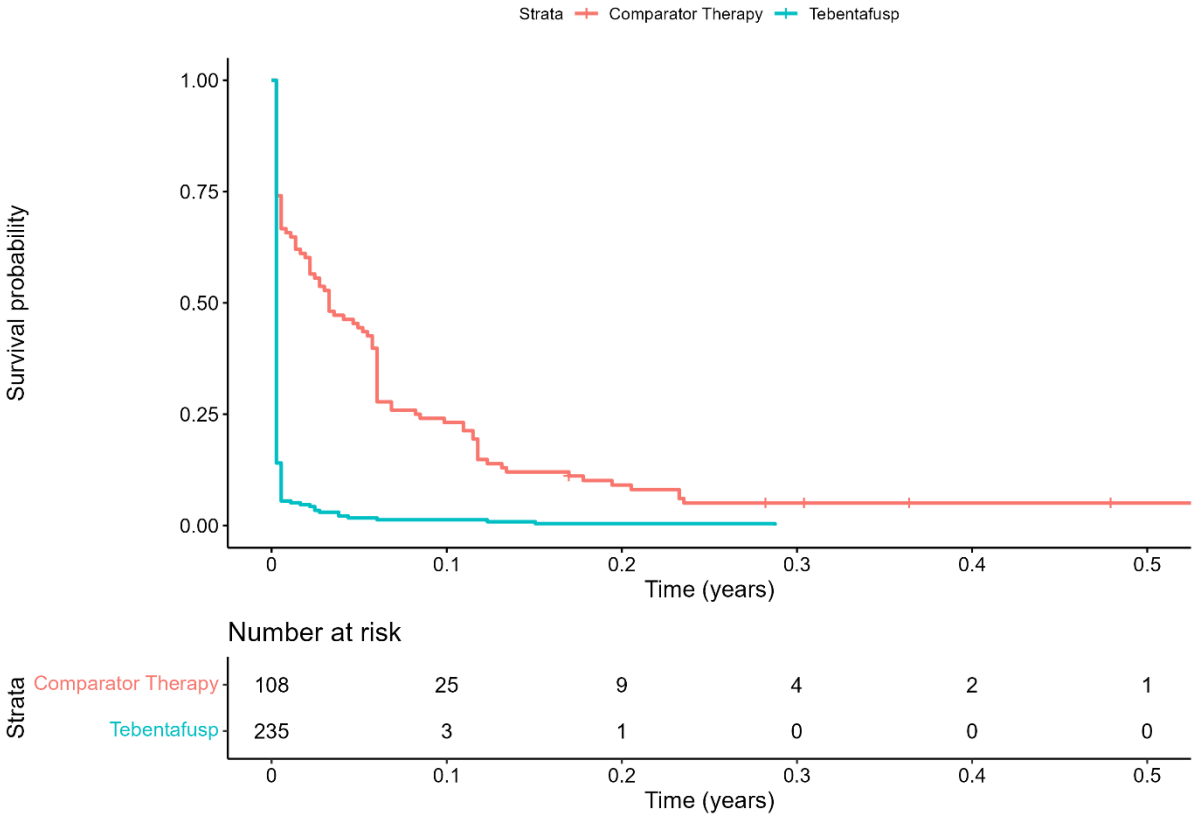
LDH: >ULN



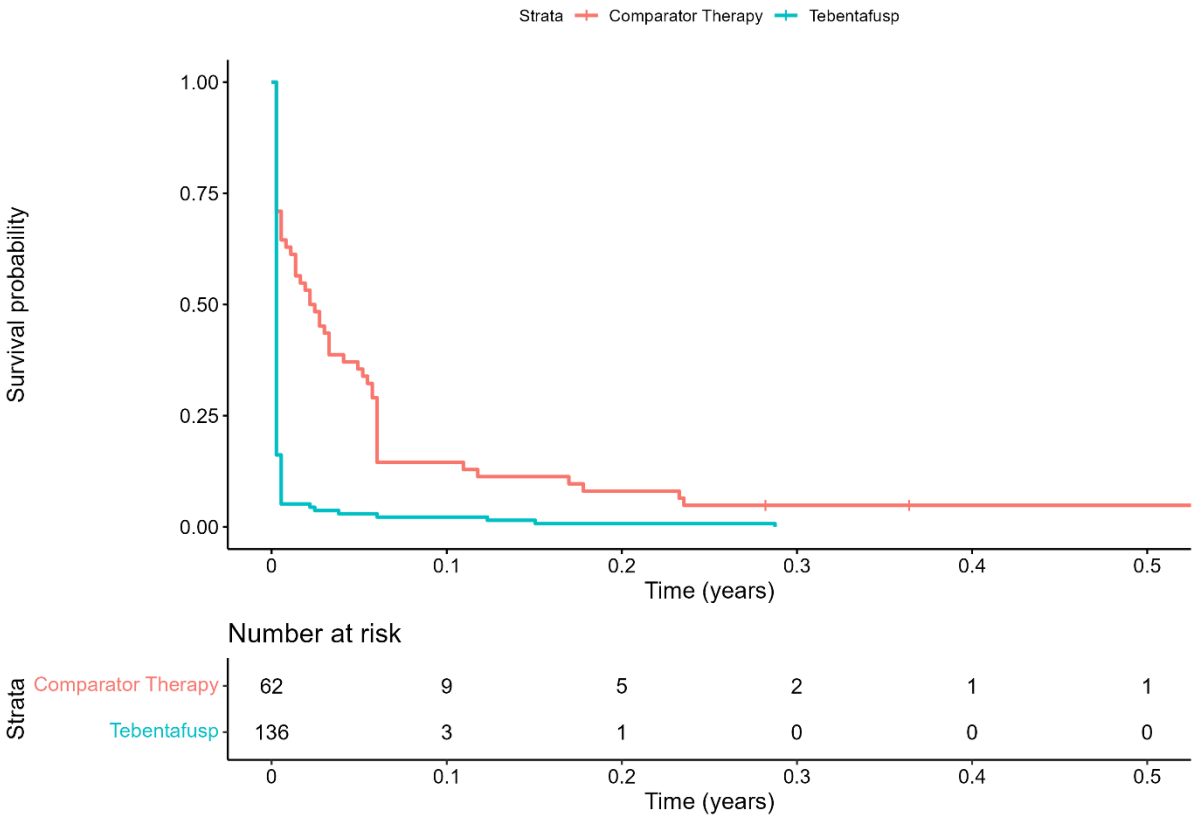
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



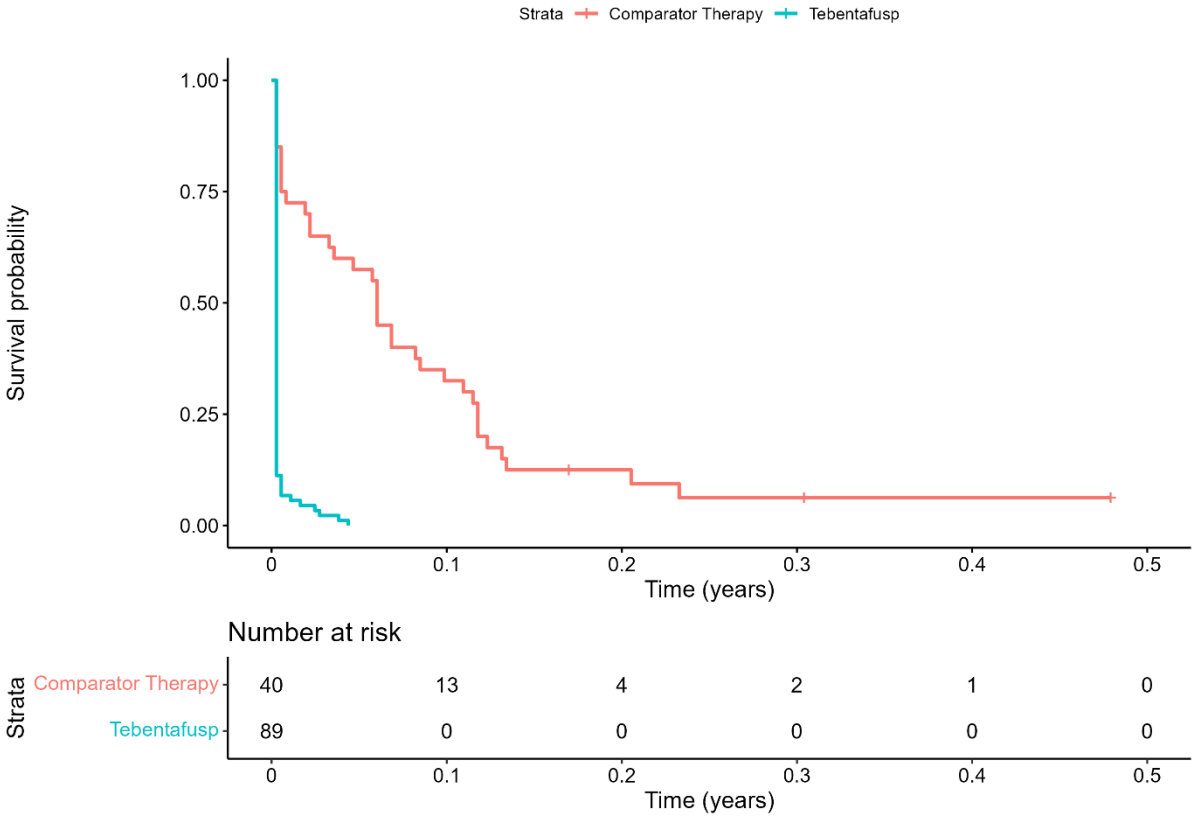
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



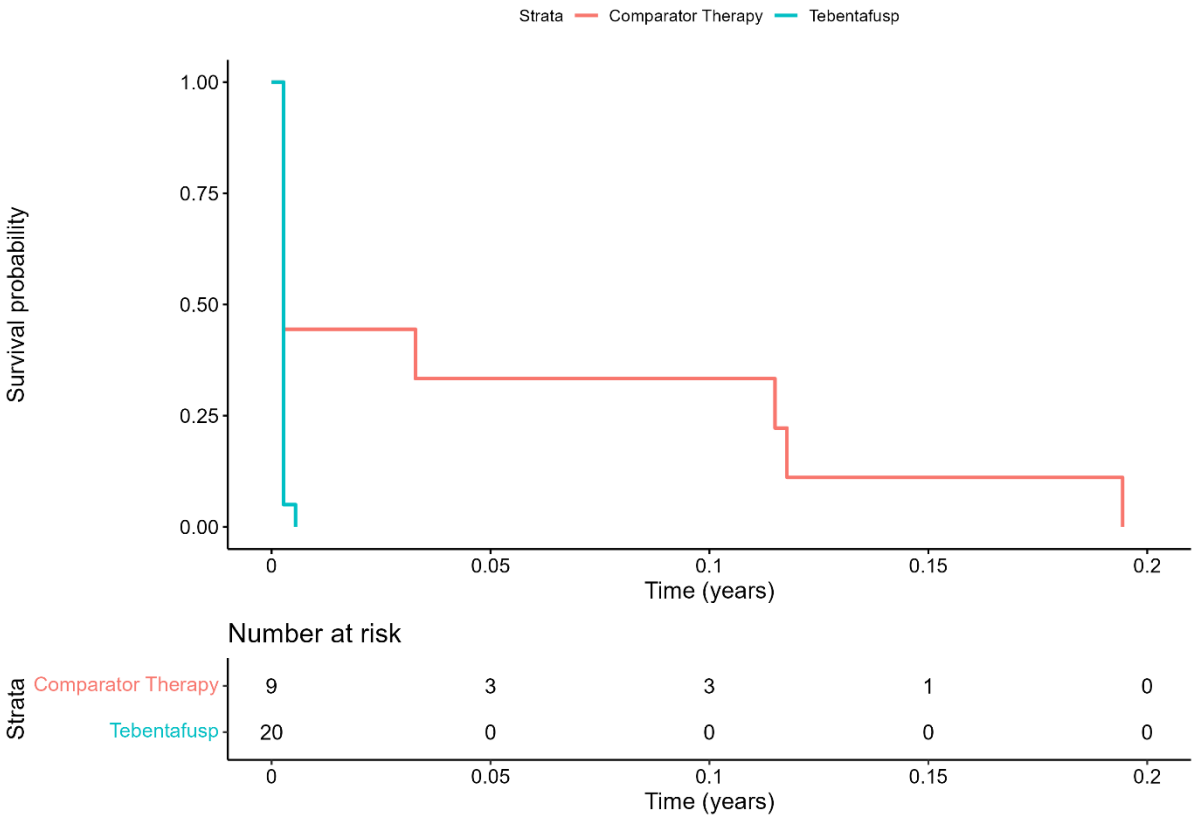
Größte metastatische Läsion (Baseline): ≤3,0 cm



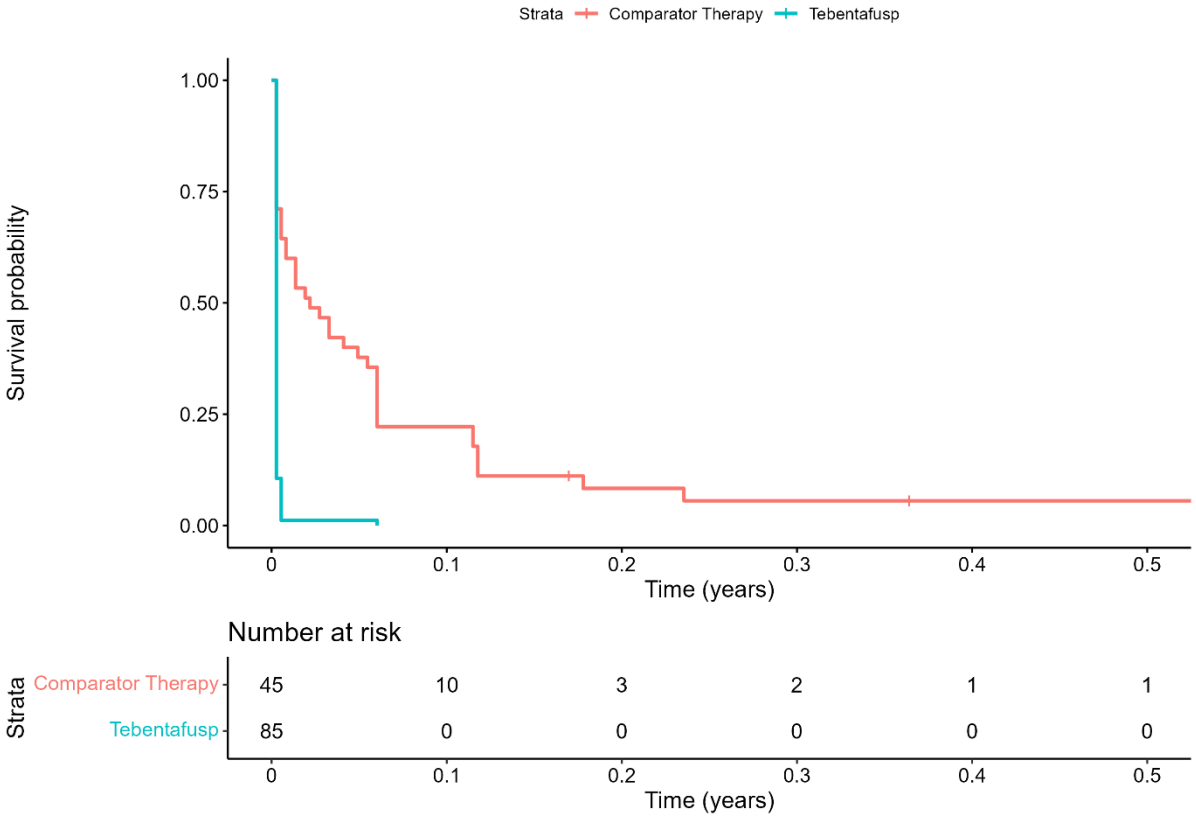
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



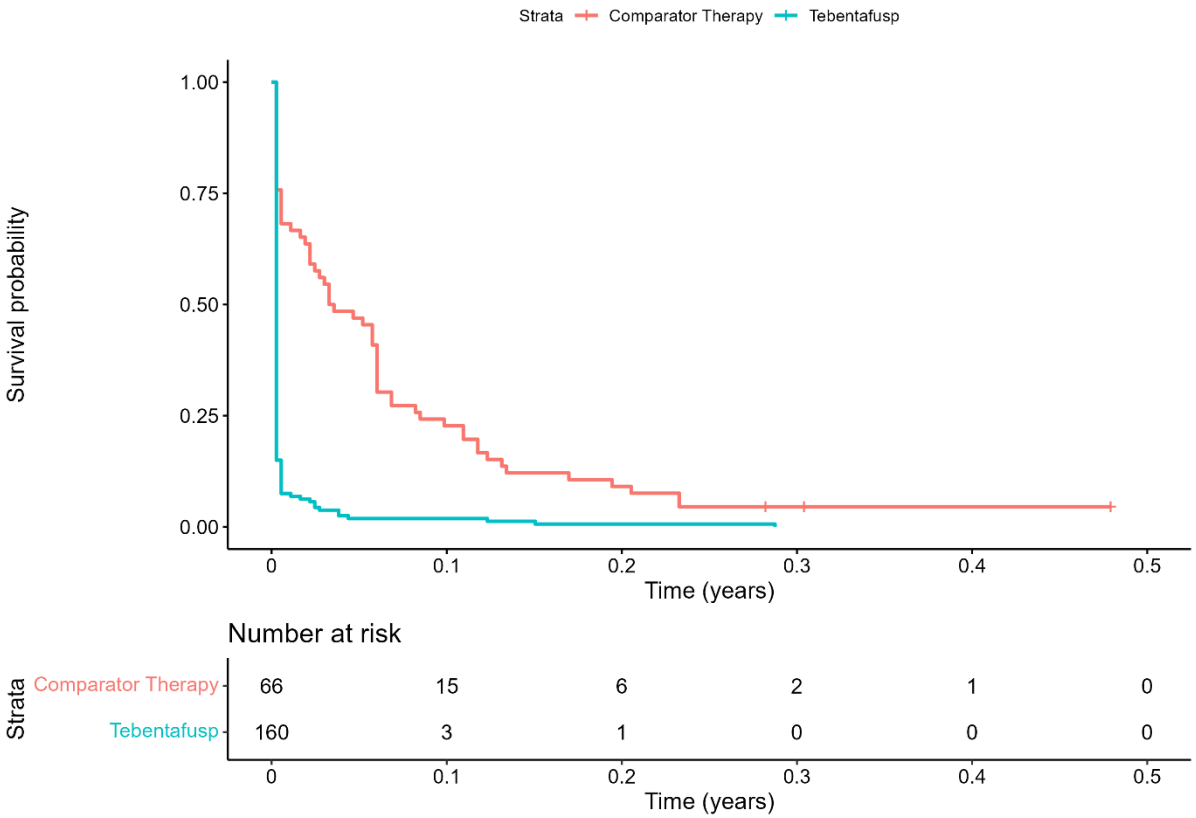
Größte metastatische Läsion (Baseline): ≥8,1 cm



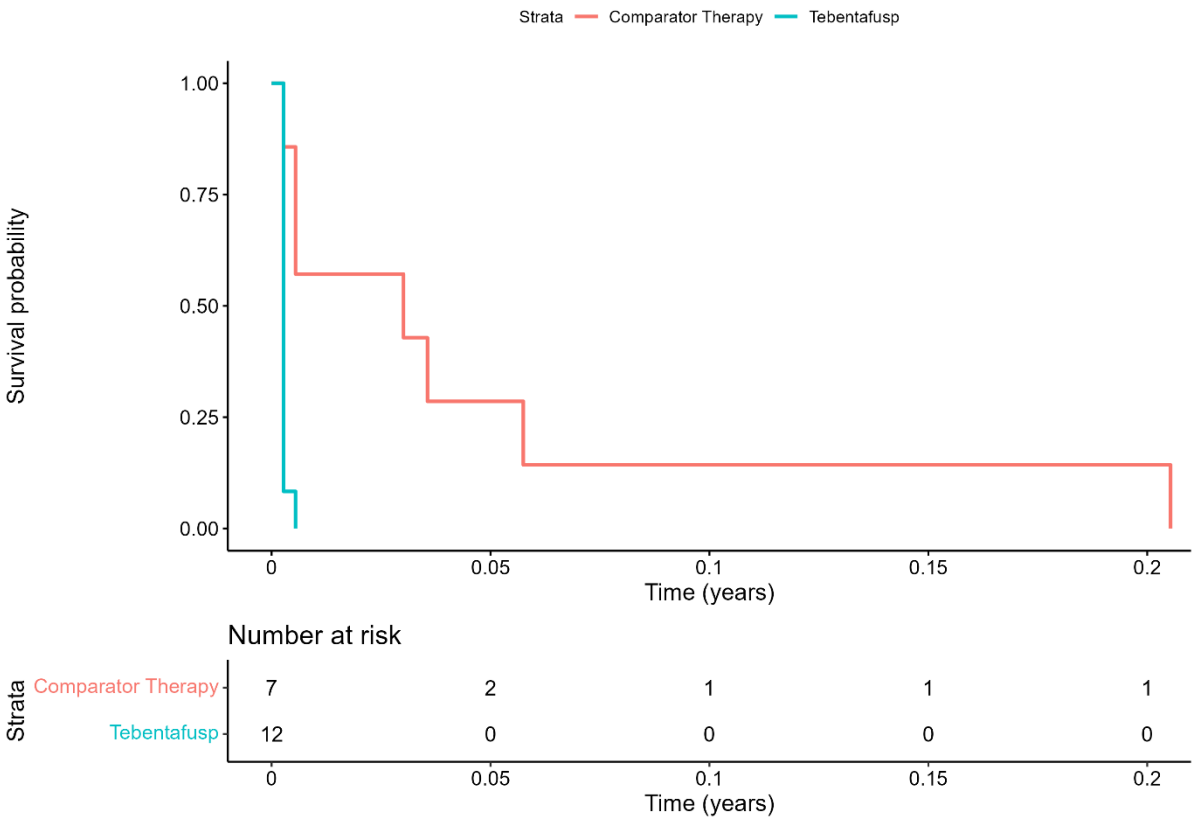
Region: Nordamerika



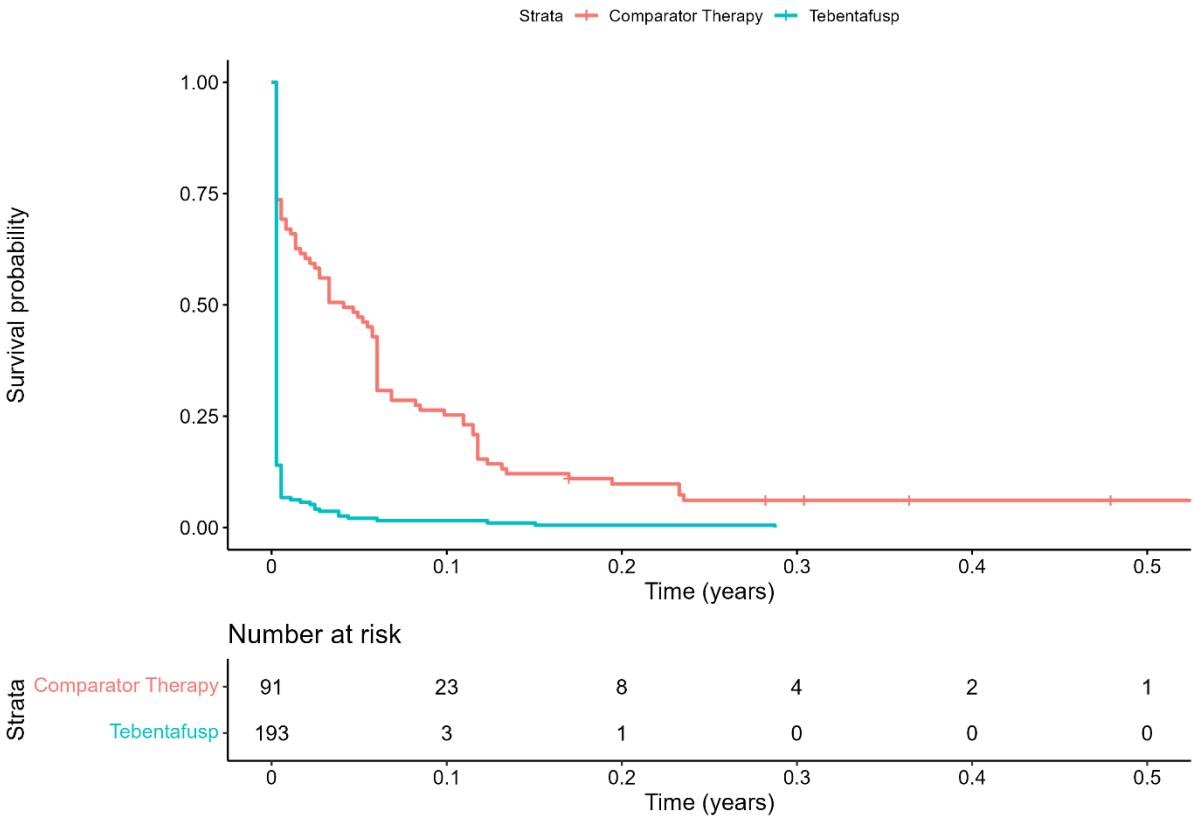
Region: Nicht-Nordamerika



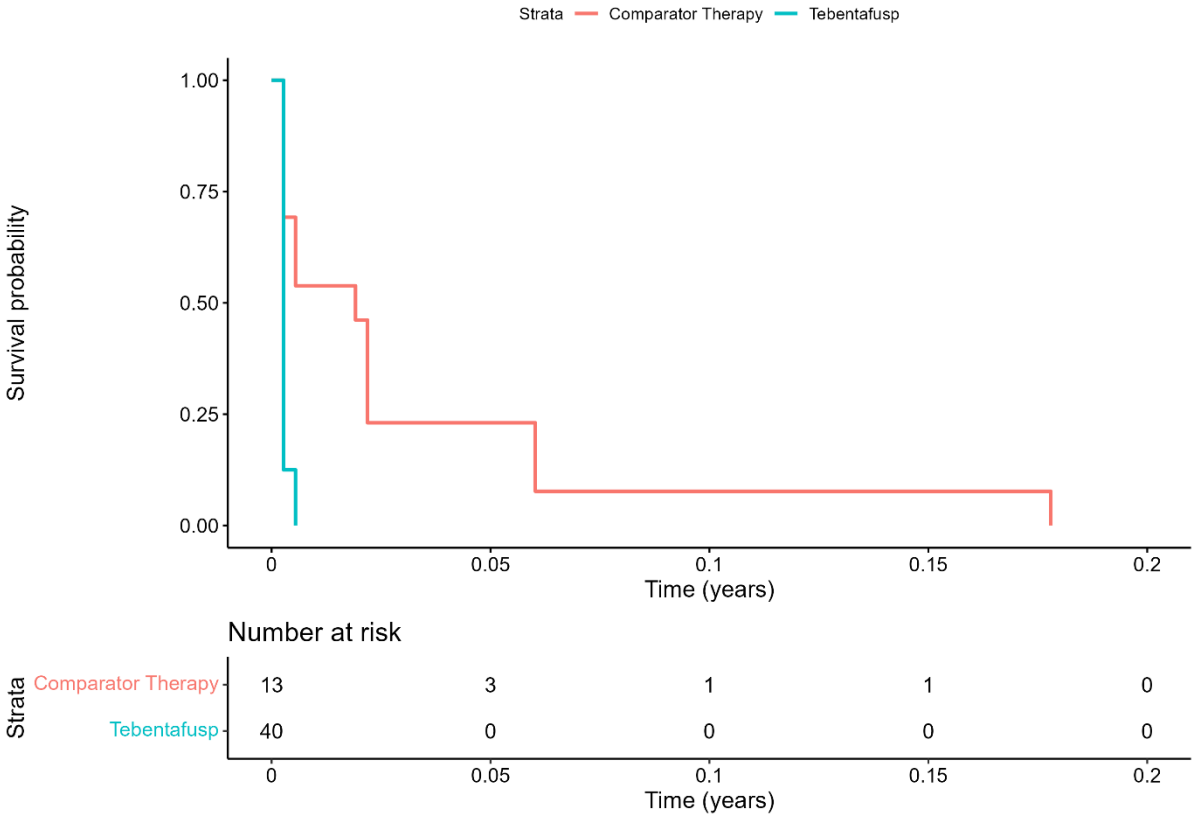
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

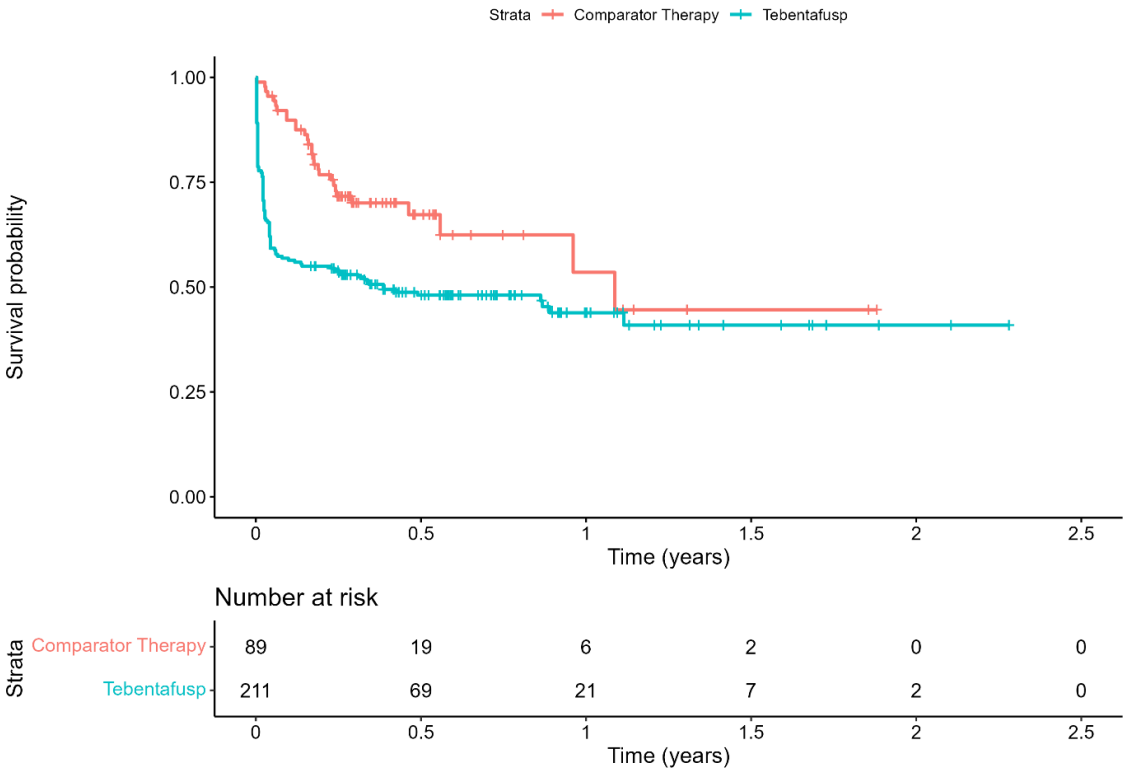


Vorauswahl der Chemotherapie: Ipilimumab

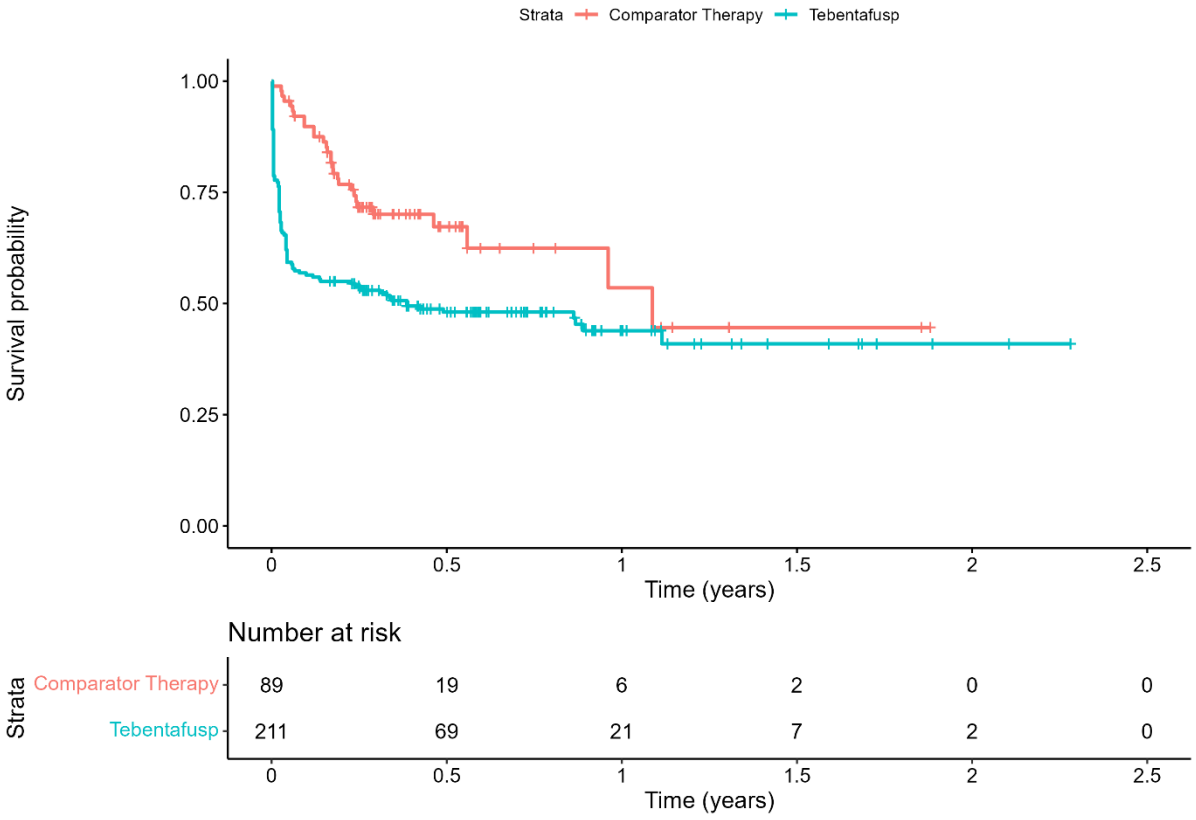


18.1 Jegliches UE mit CTCAE-Grad ≥ 3 (Tabelle 4-89)

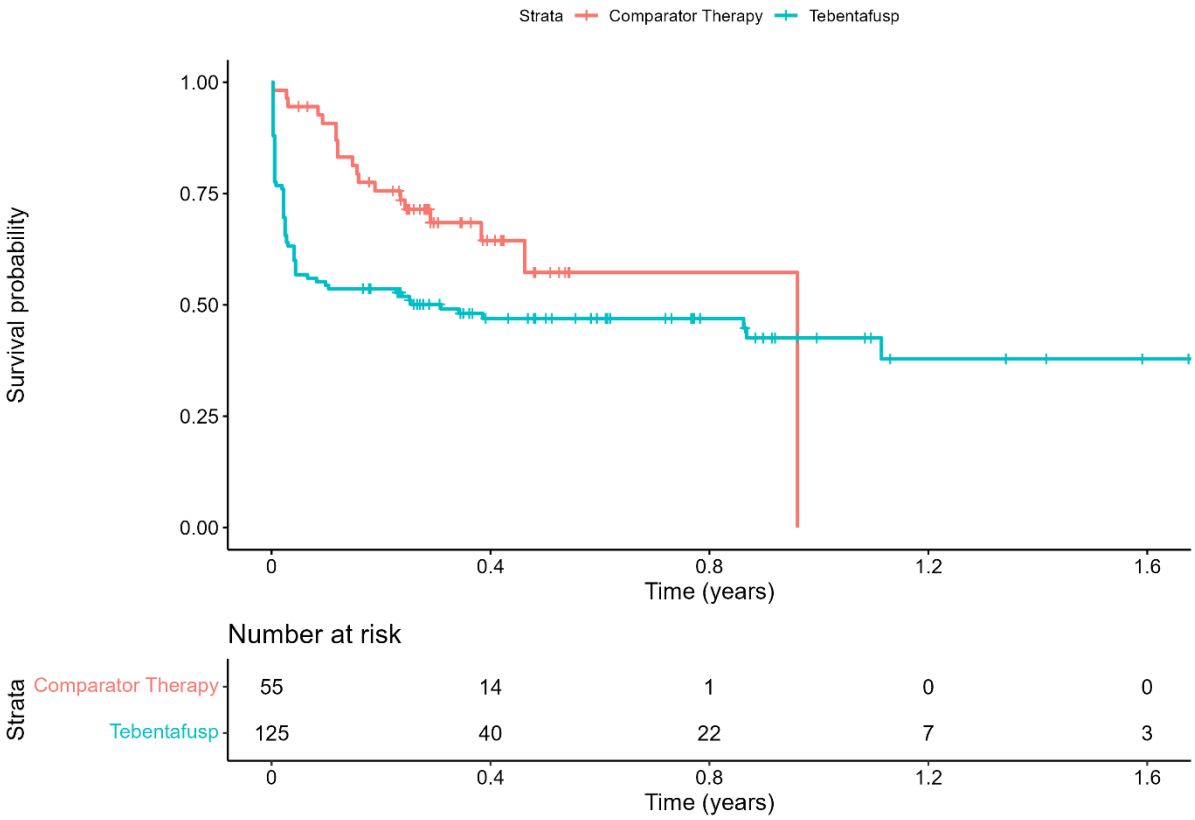
Herkunft: Hispanisch



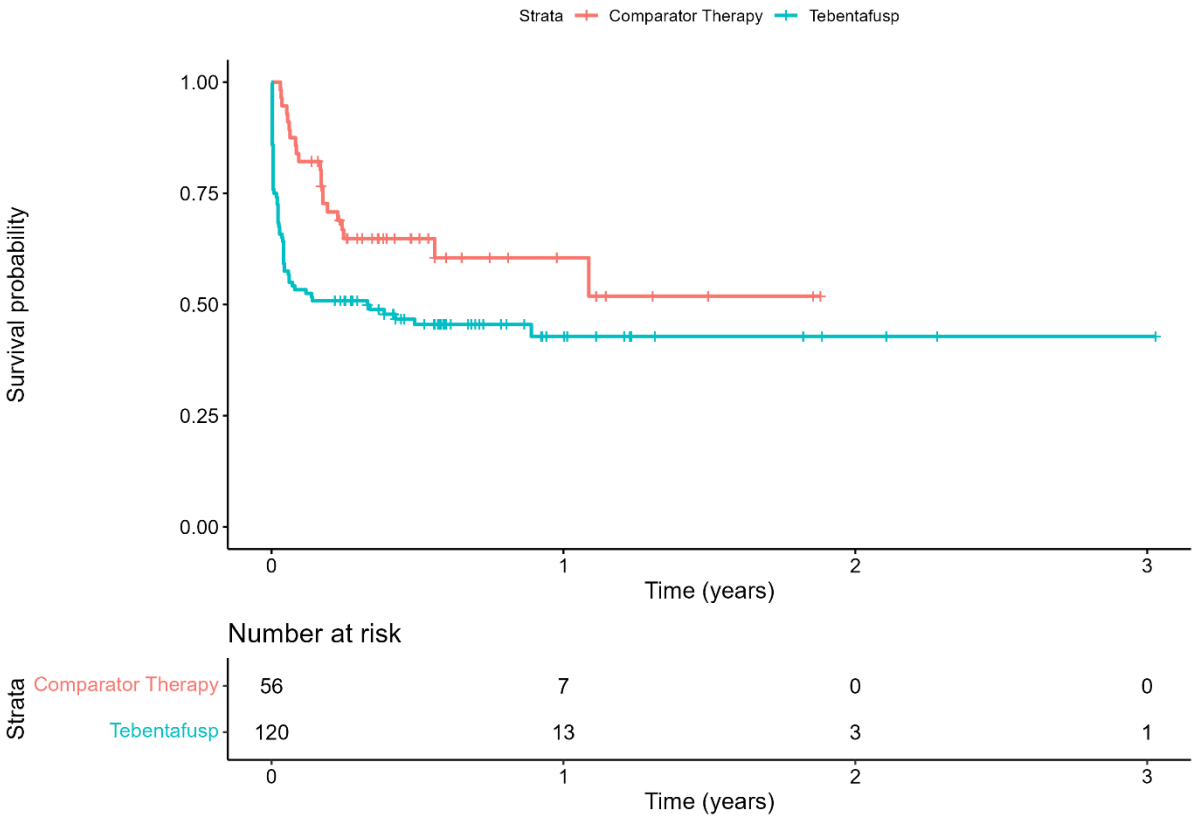
Herkunft: Nicht-hispanisch



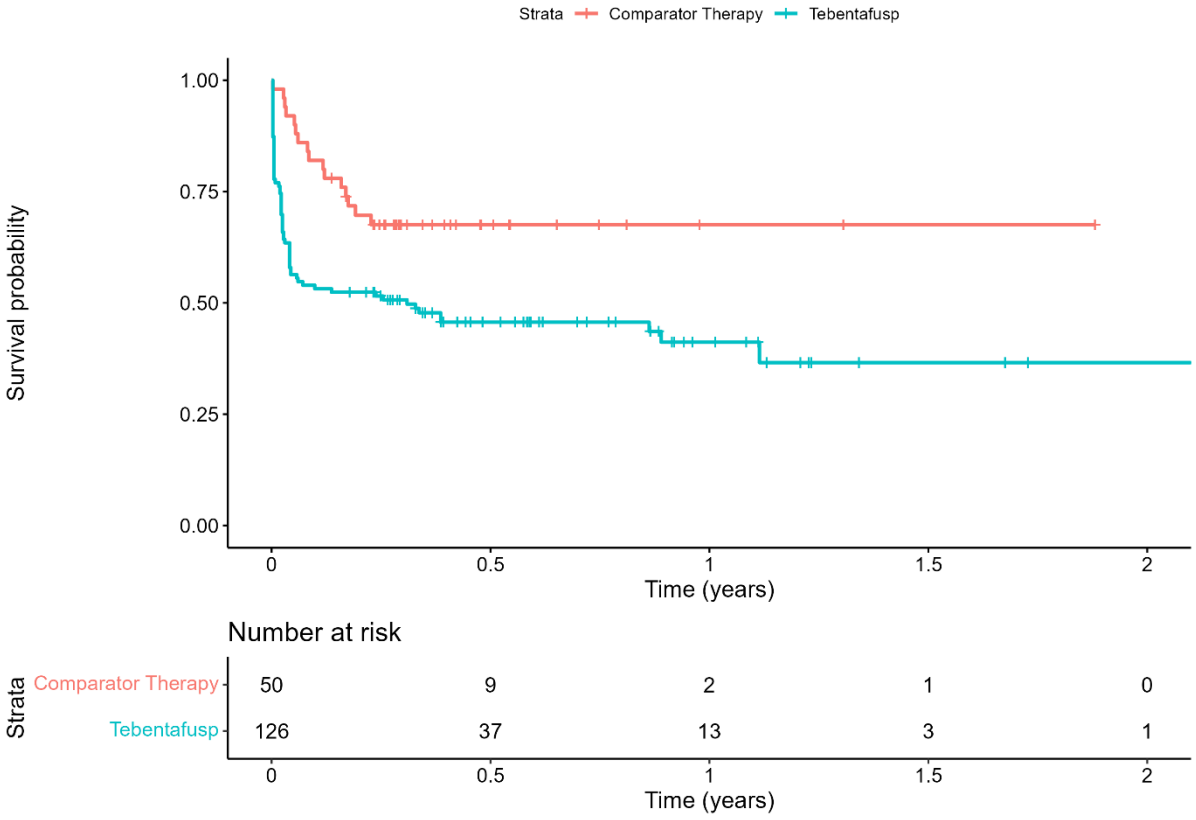
Geschlecht: Männlich



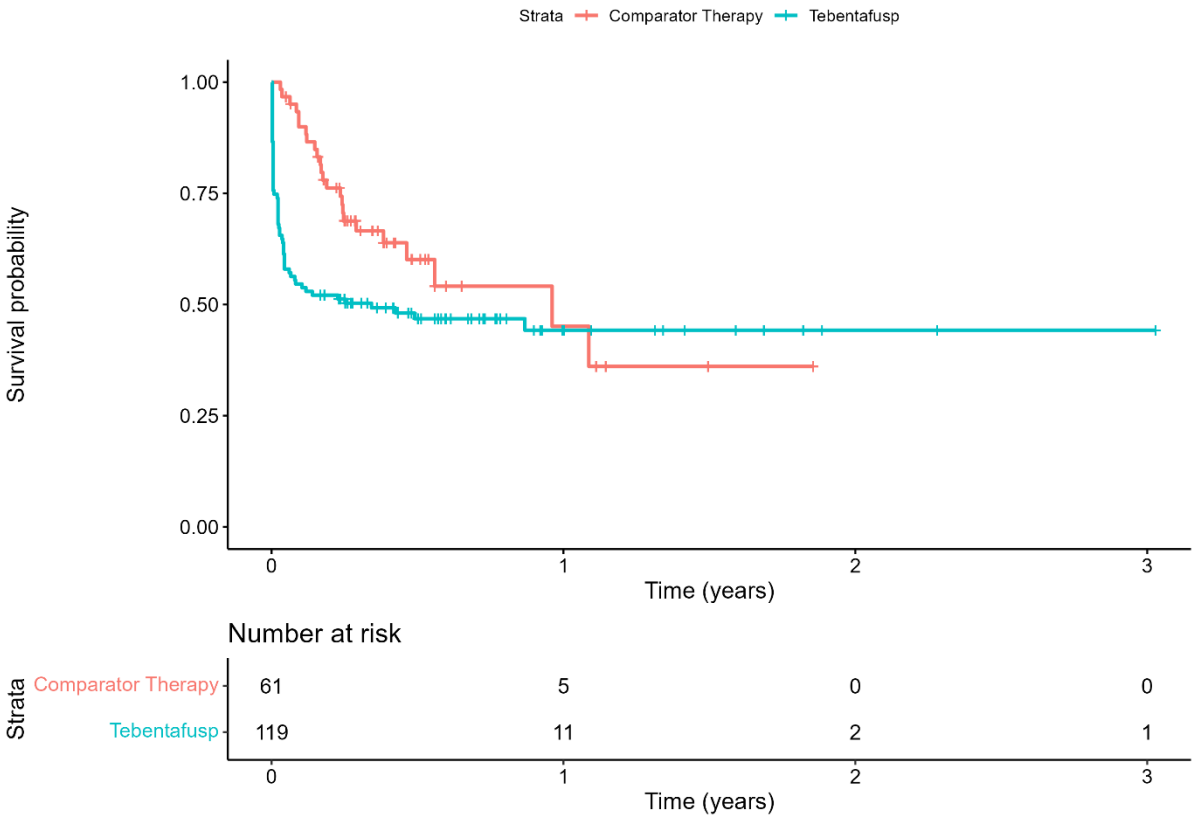
Geschlecht: Weiblich



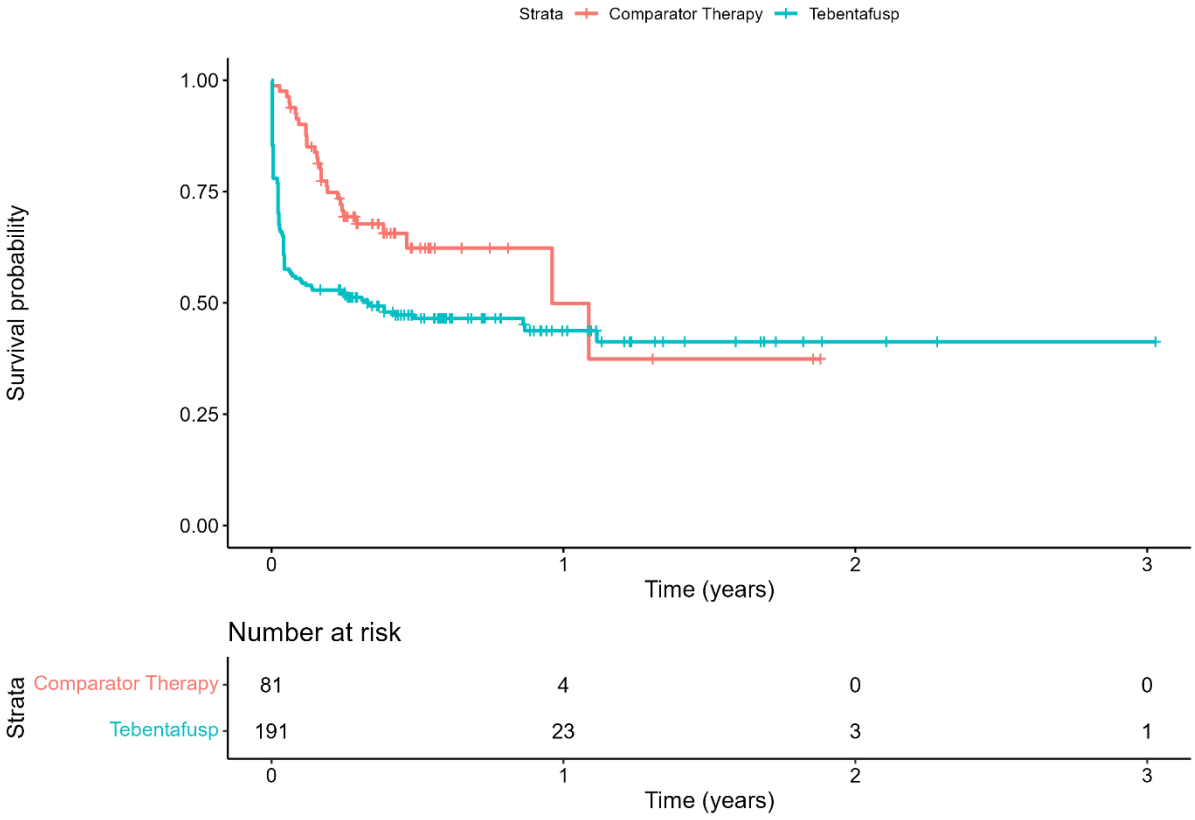
Alter: <65 Jahre



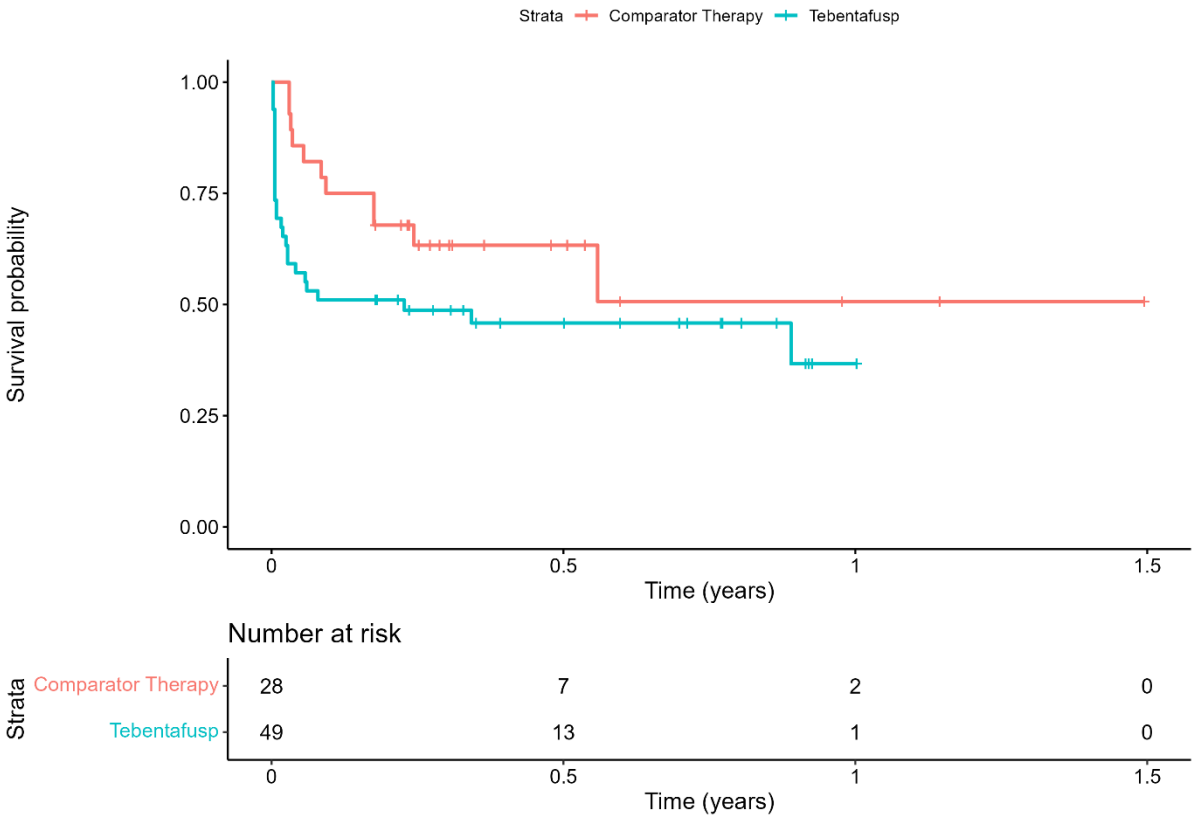
Alter: ≥65 Jahre



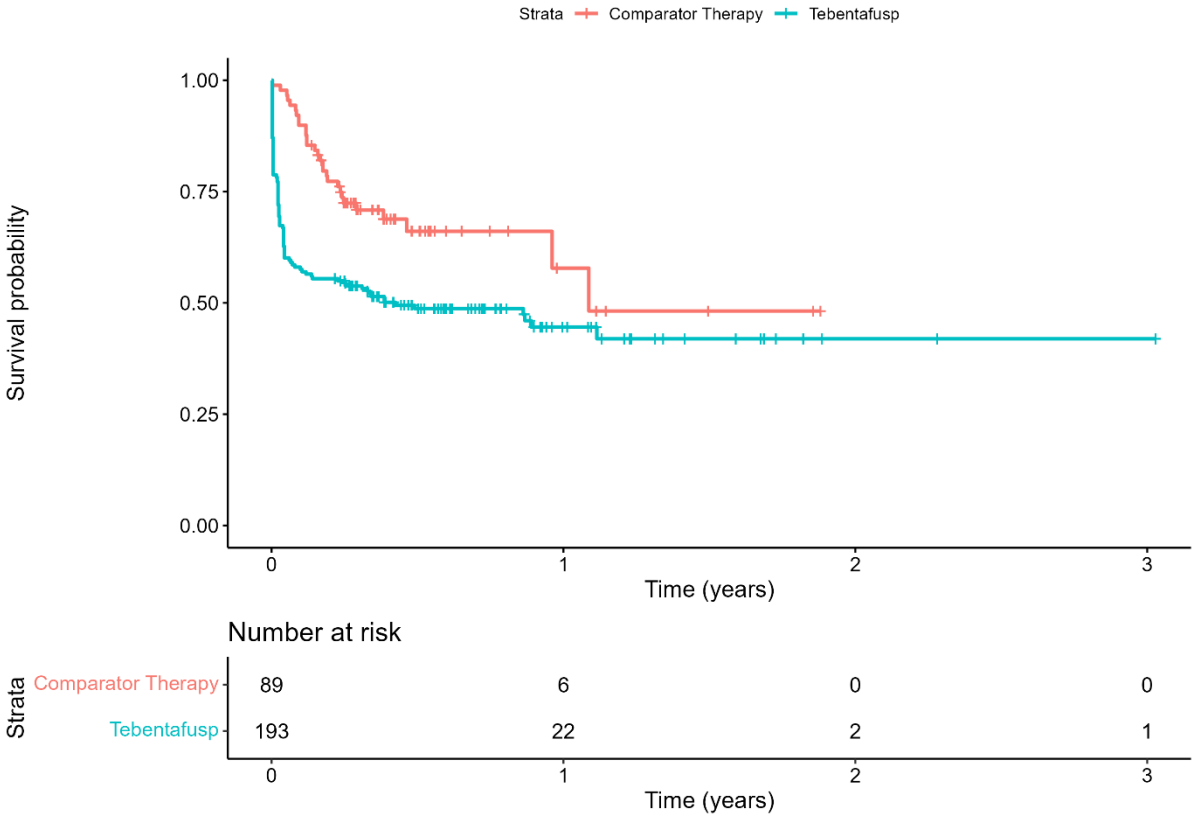
ECOG-Performance-Status: 0



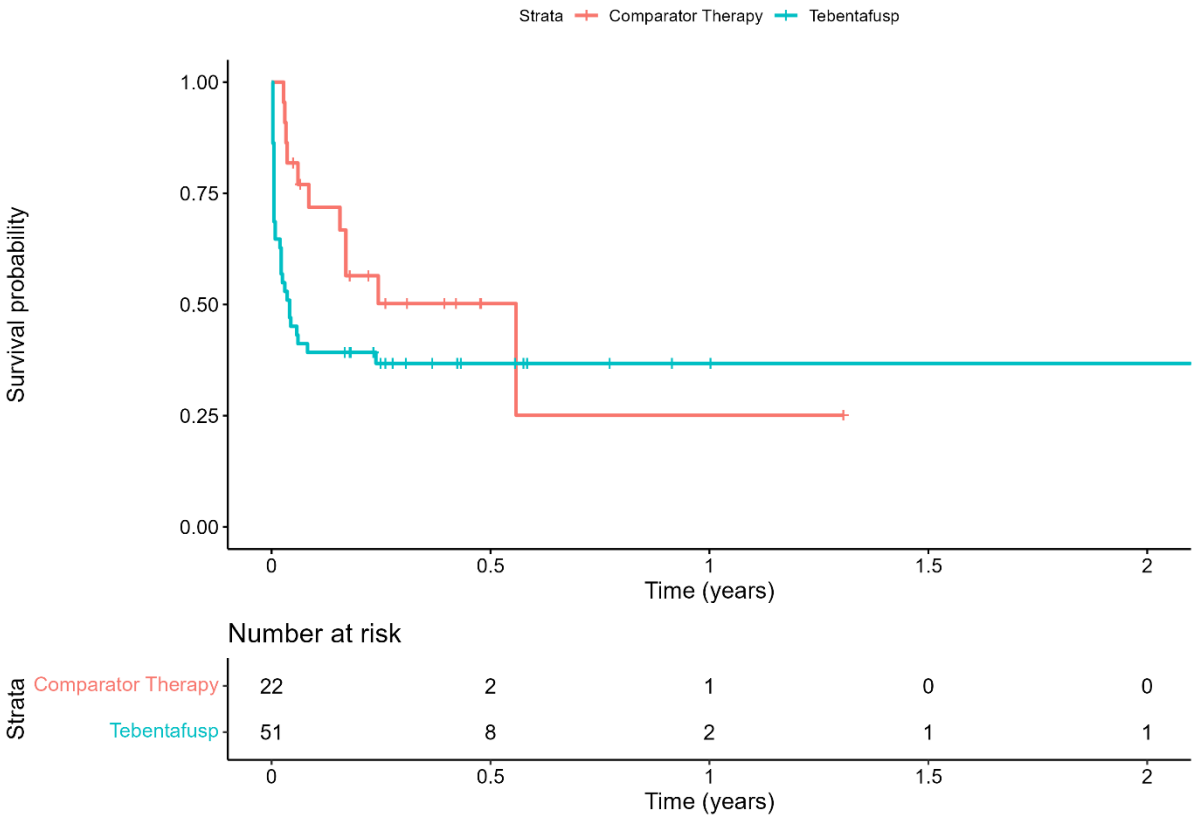
ECOG-Performance-Status: 1



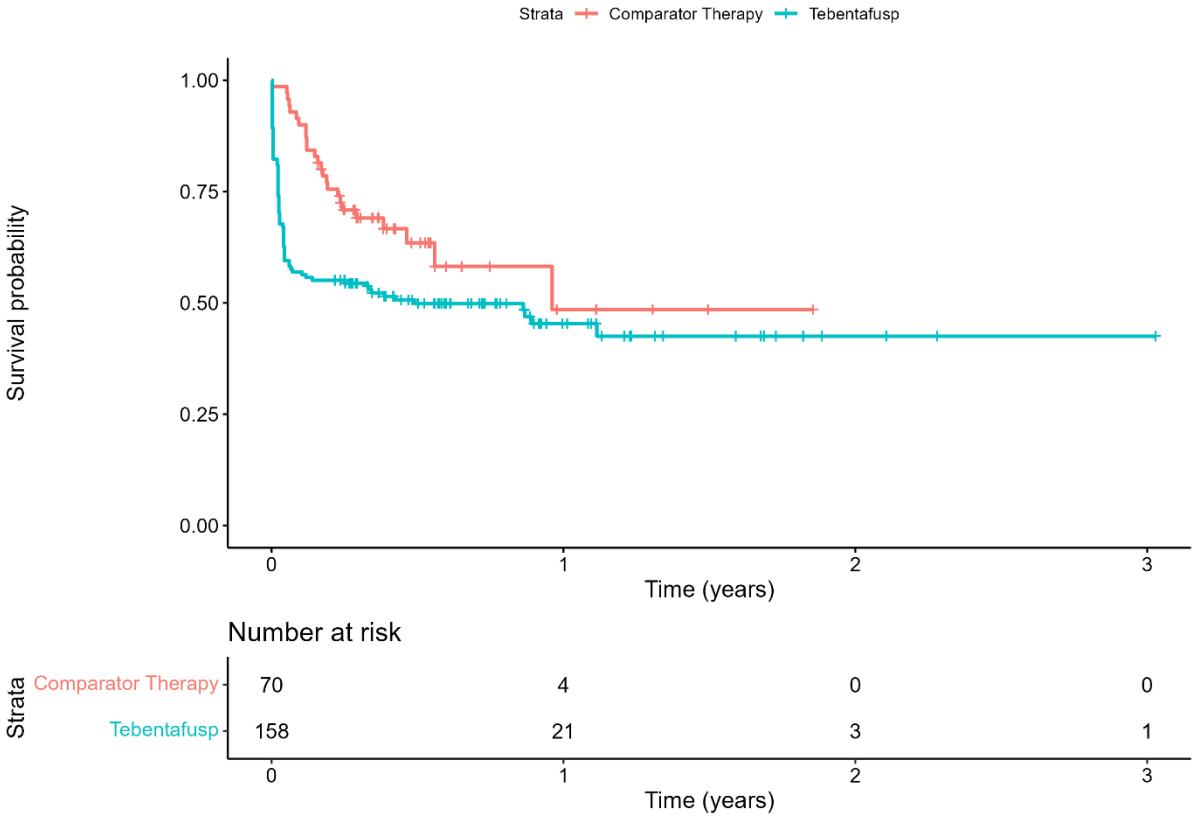
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



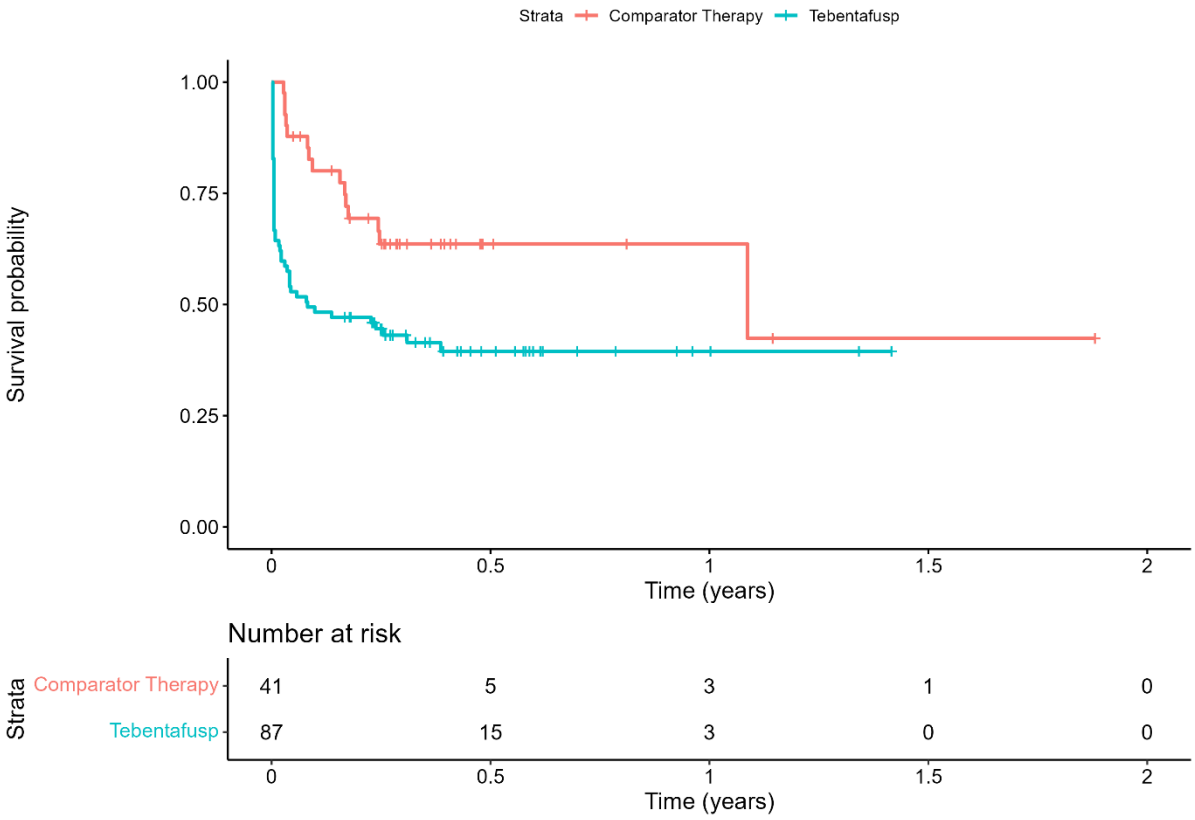
Alkalische Phosphatase (ALP) (Baseline): >ULN



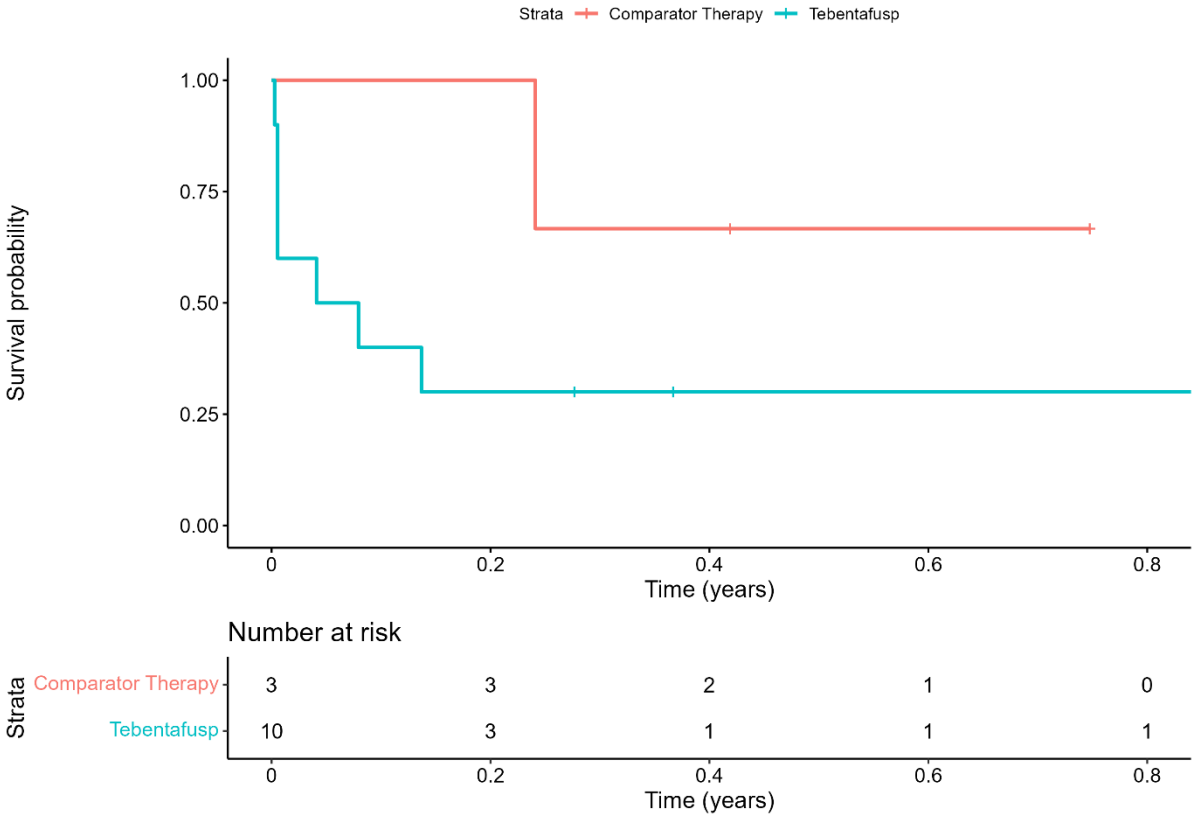
LDH: ≤ULN



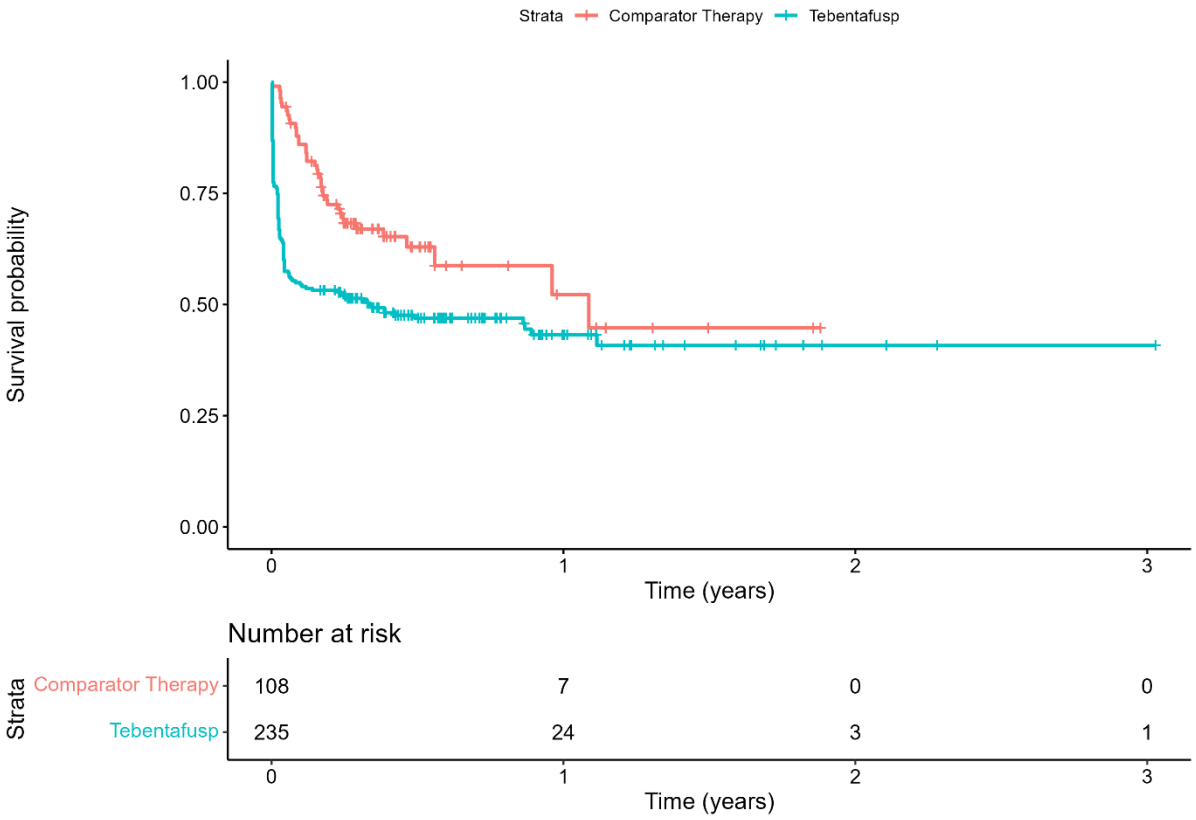
LDH: >ULN



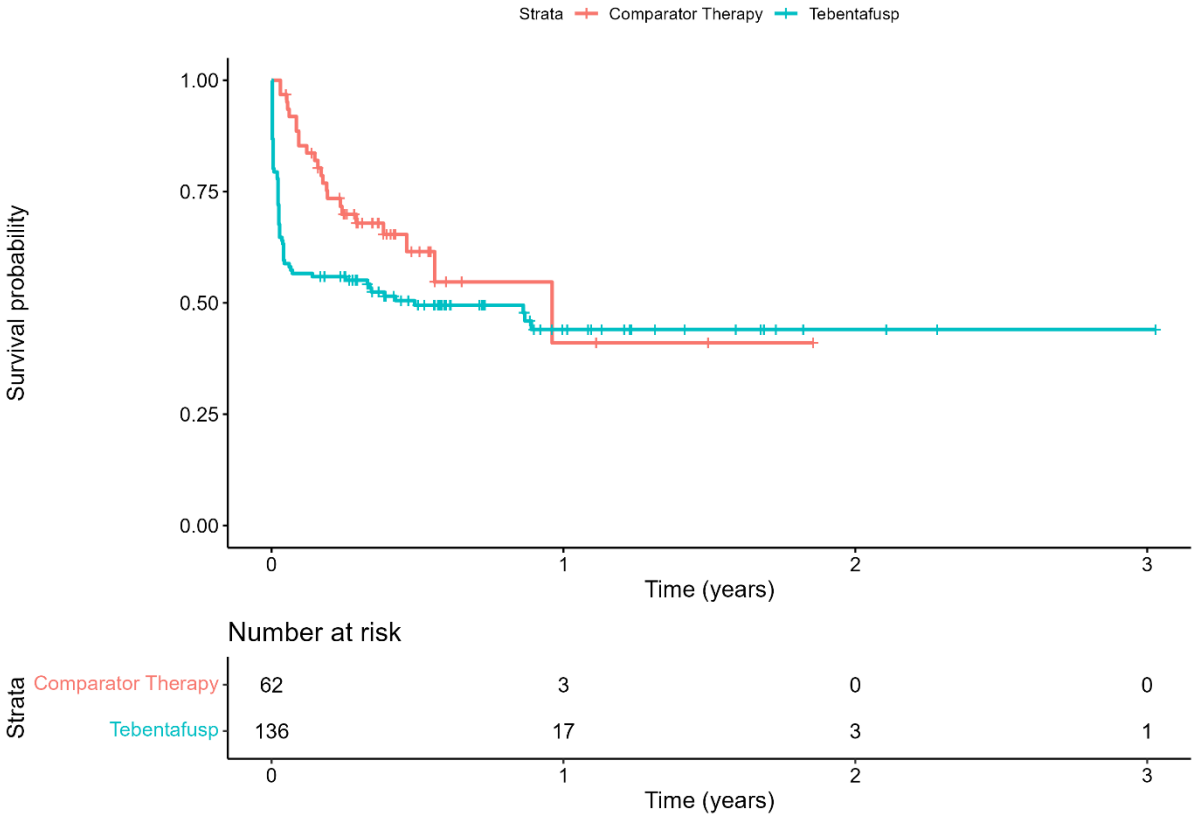
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



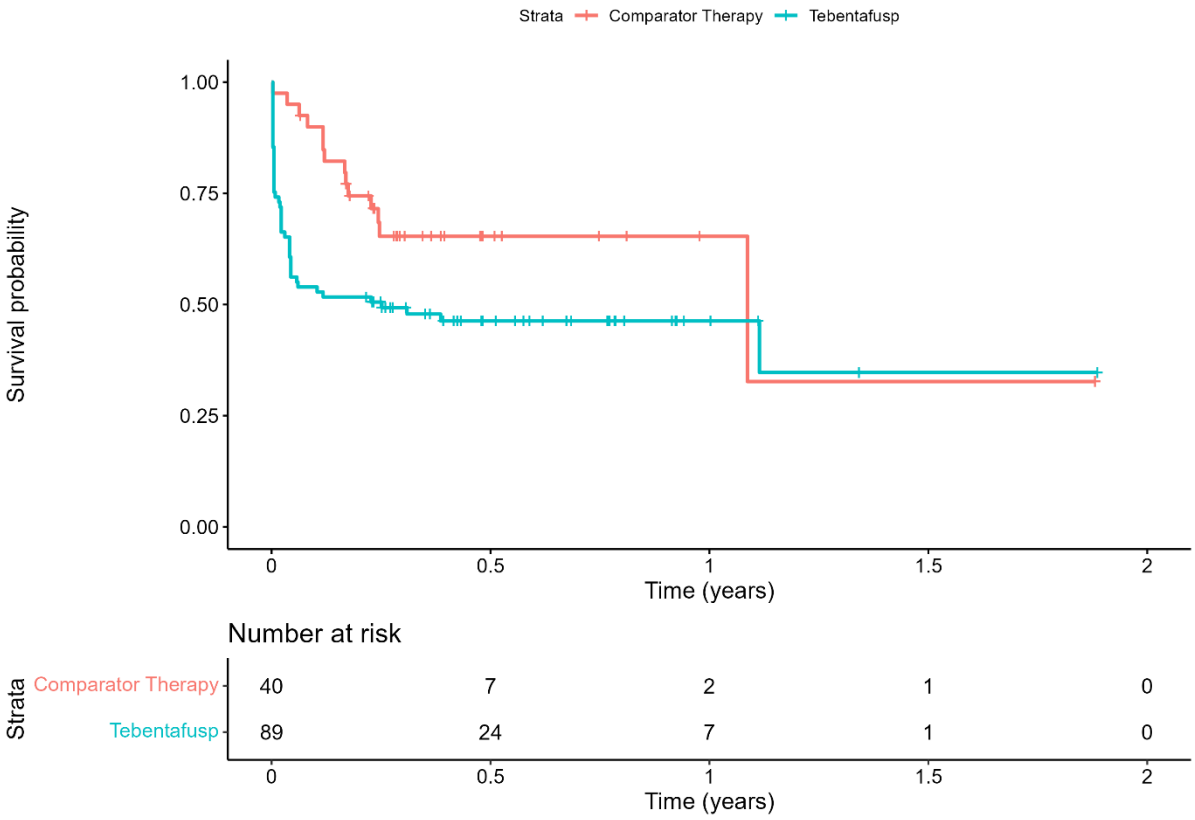
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



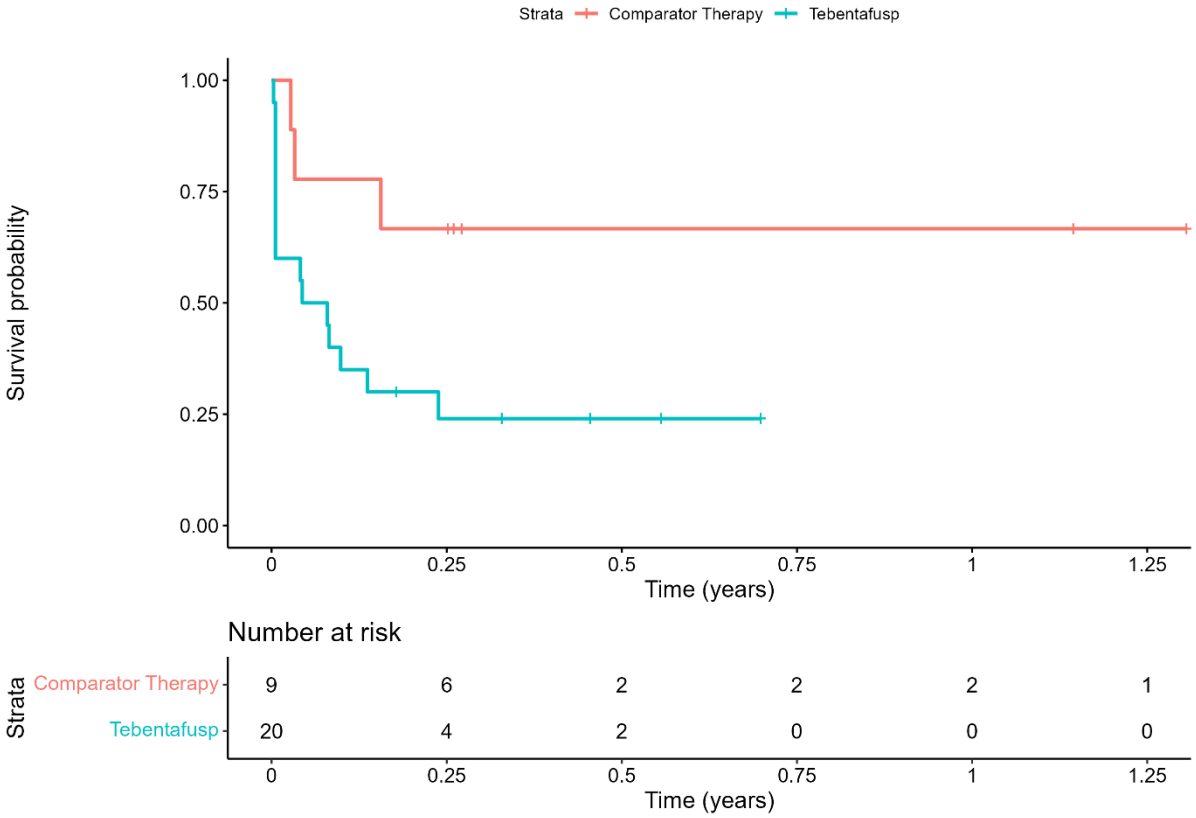
Größte metastatische Läsion (Baseline): ≤3,0 cm



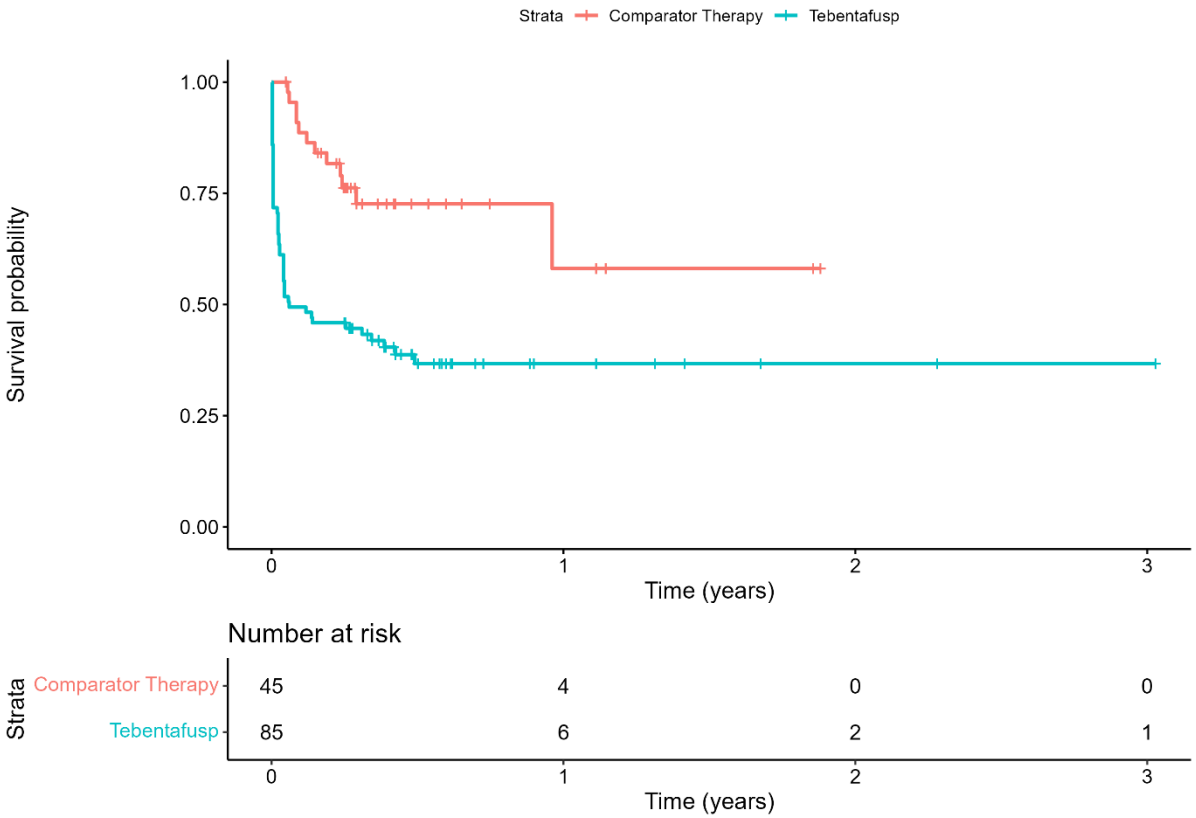
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



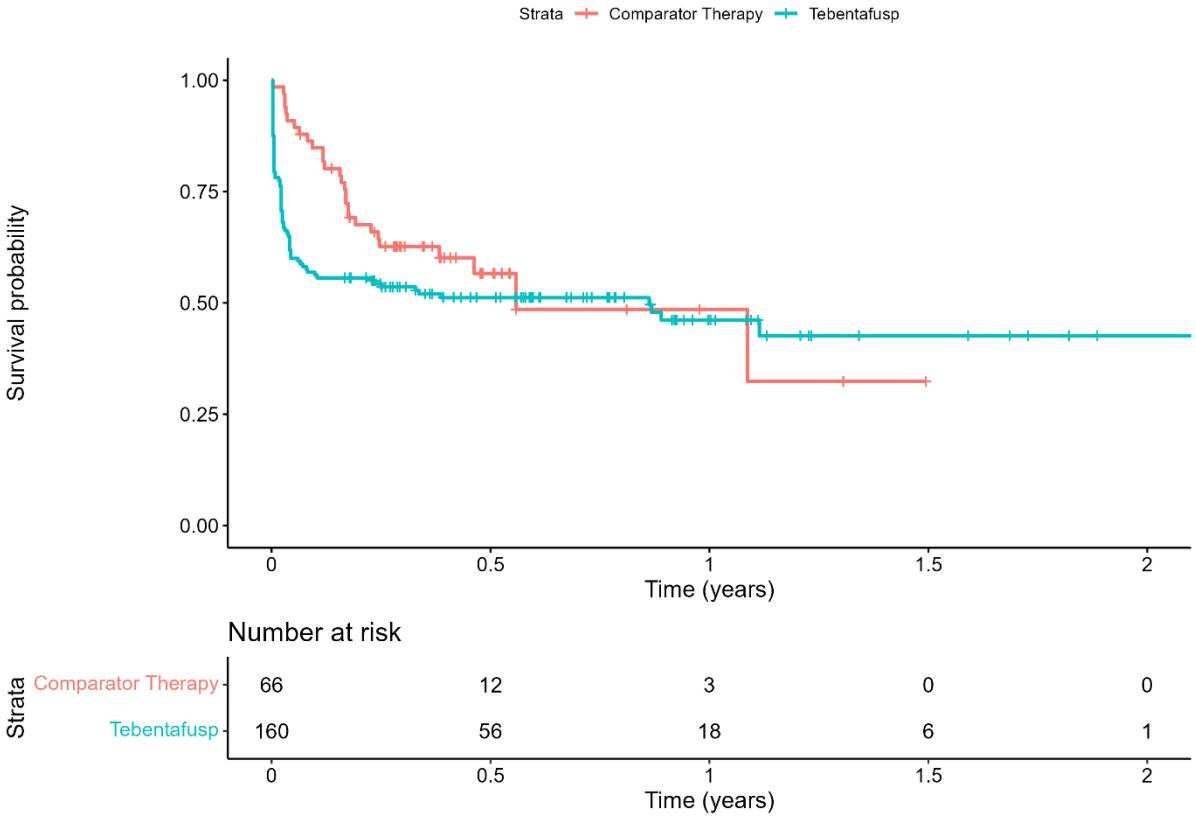
Größte metastatische Läsion (Baseline): ≥8,1 cm



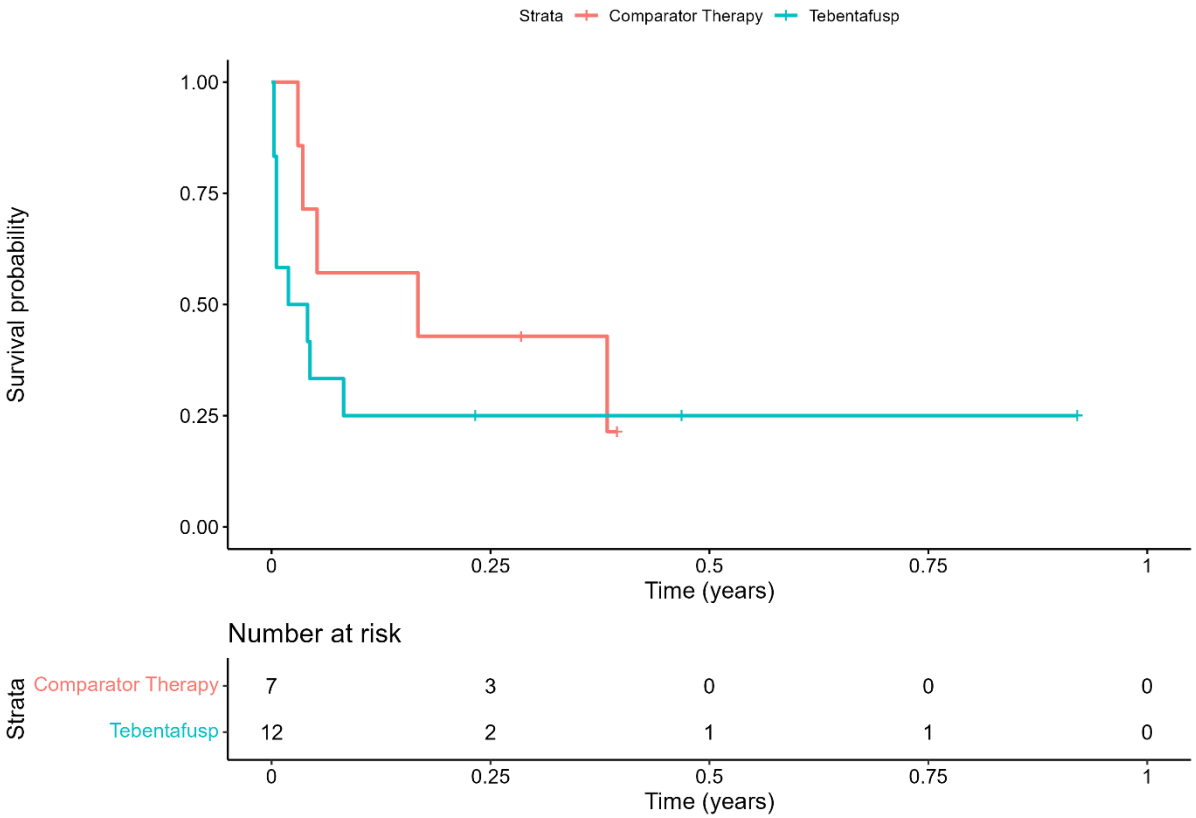
Region: Nordamerika



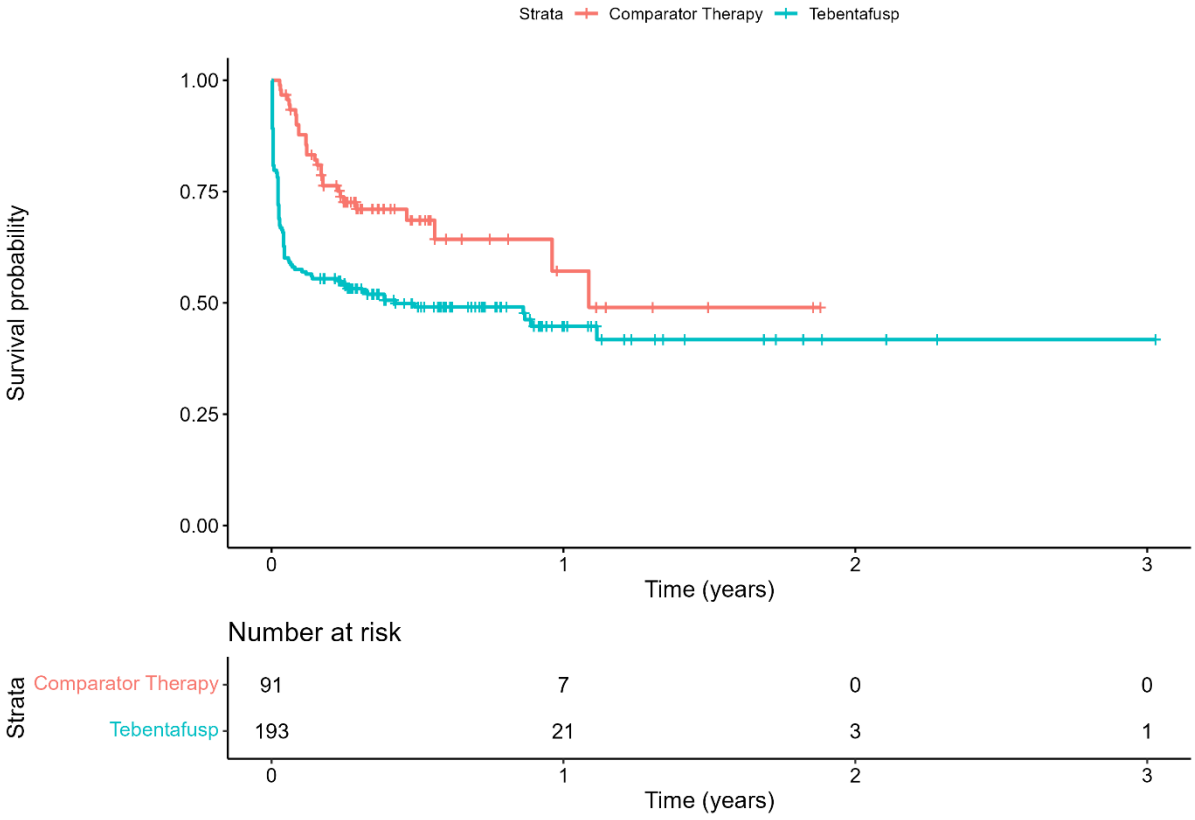
Region: Nicht-Nordamerika



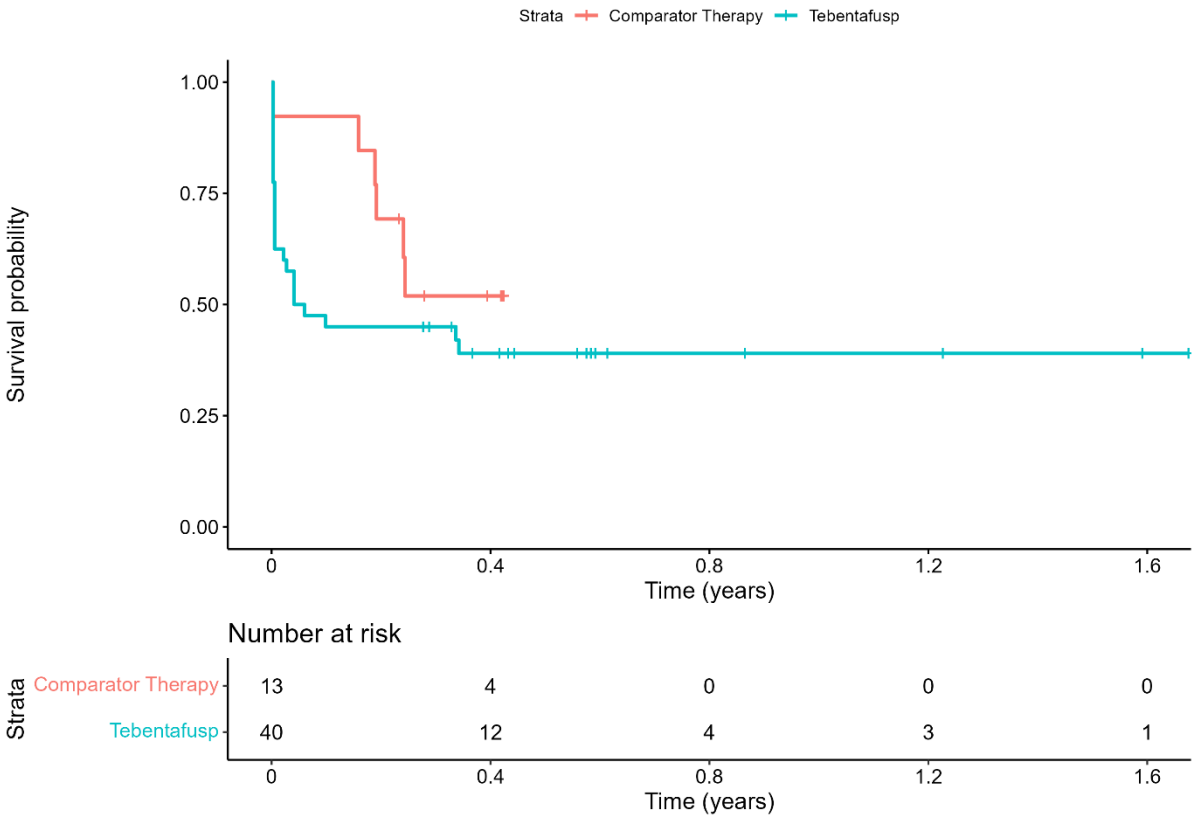
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

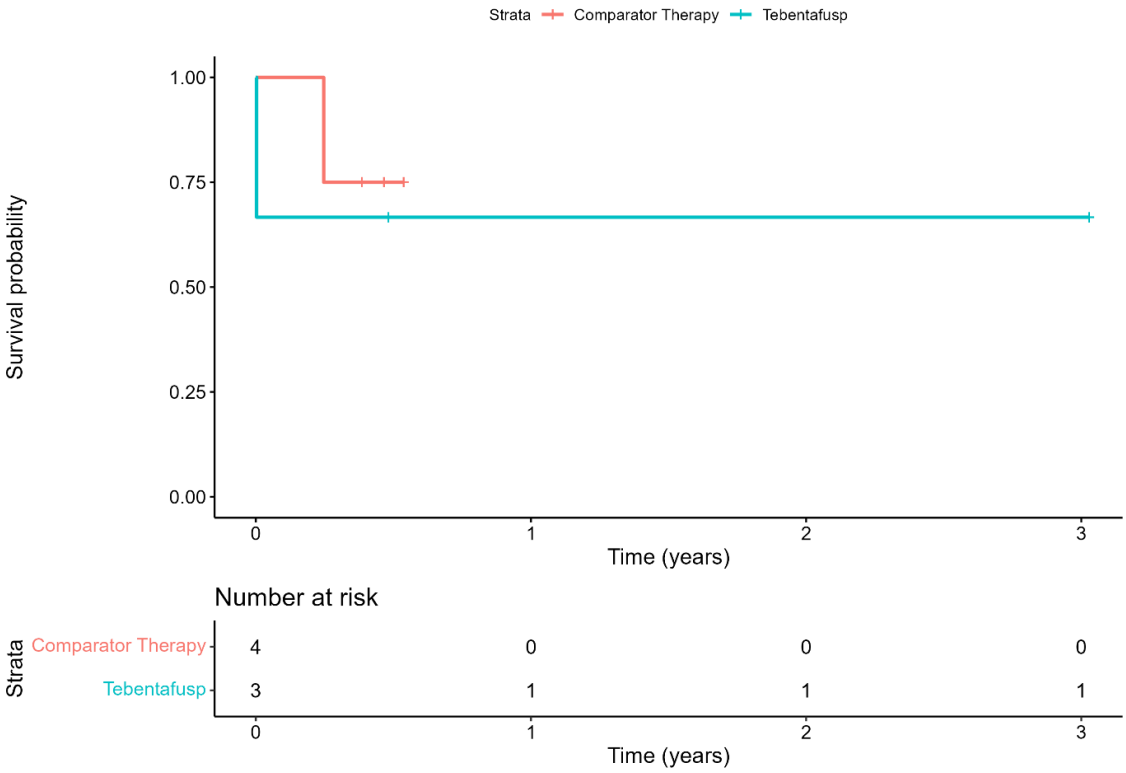


Vorauswahl der Chemotherapie: Ipilimumab

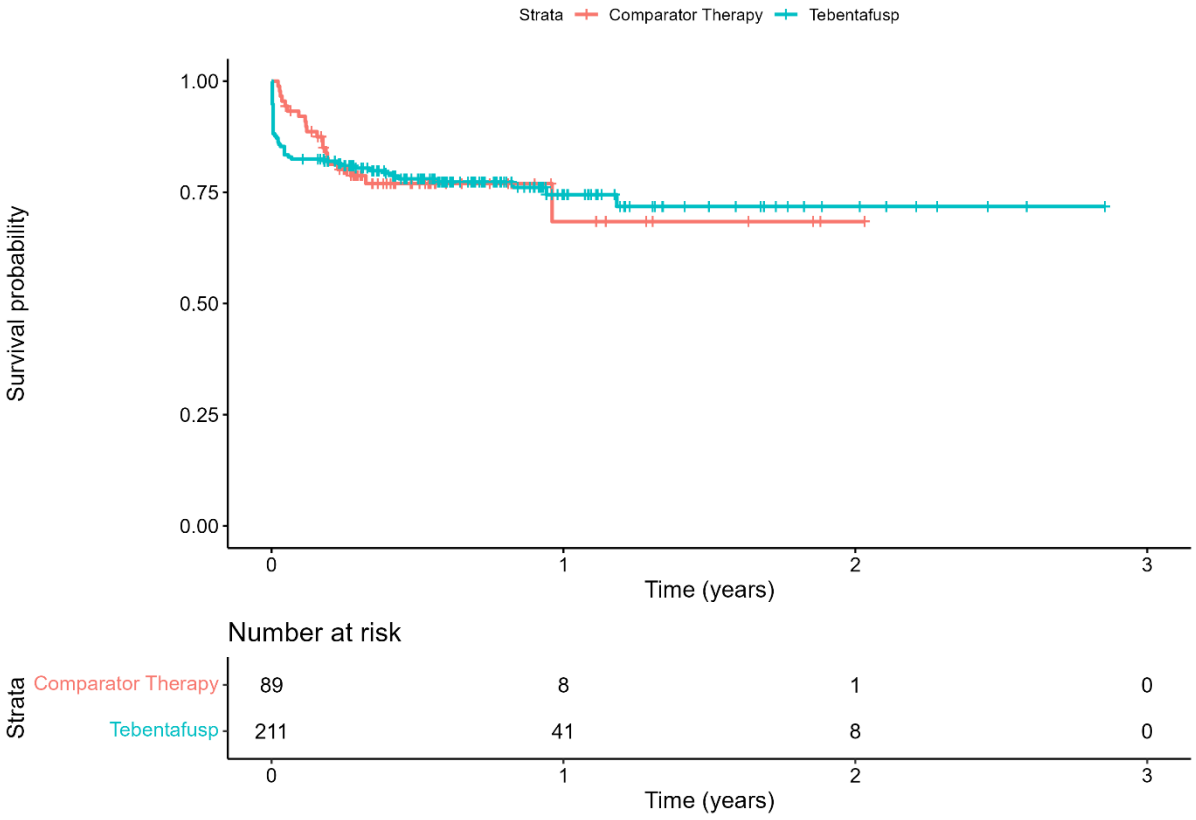


19.1 Jegliches SUE (Tabelle 4-91)

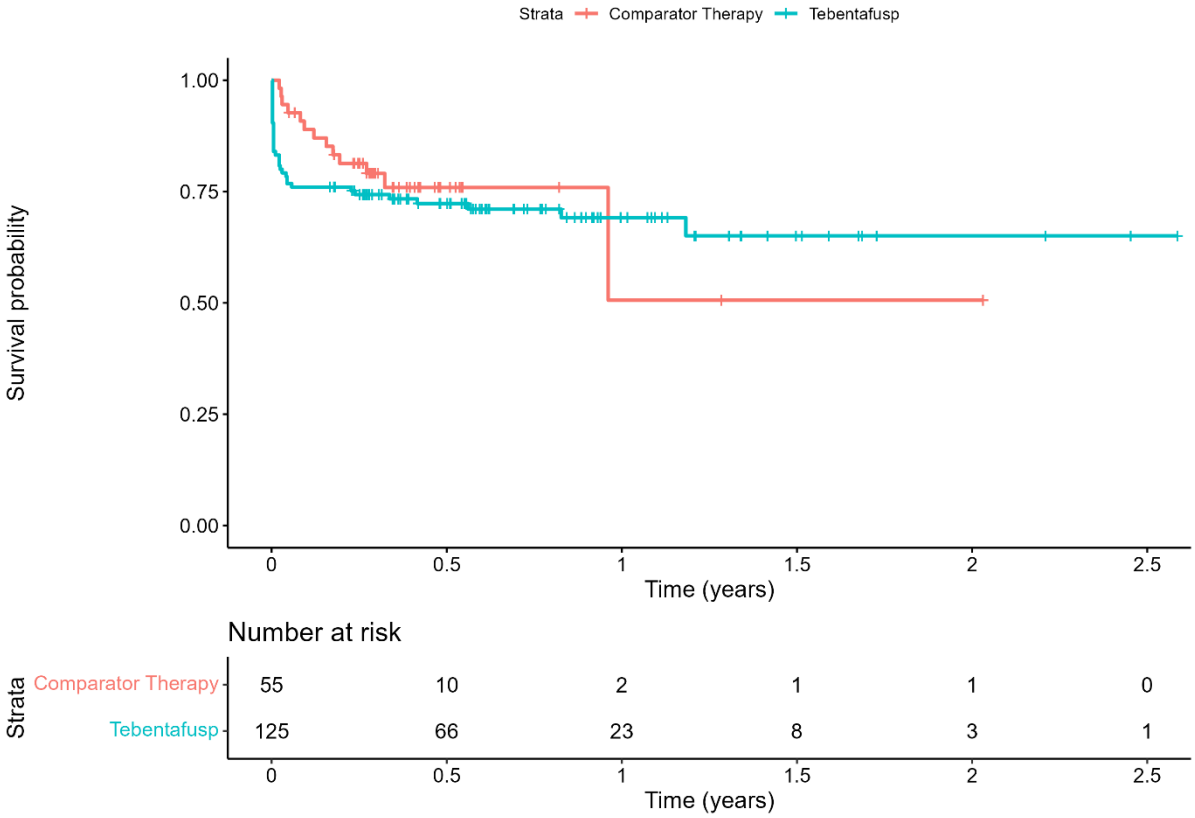
Herkunft: Hispanisch



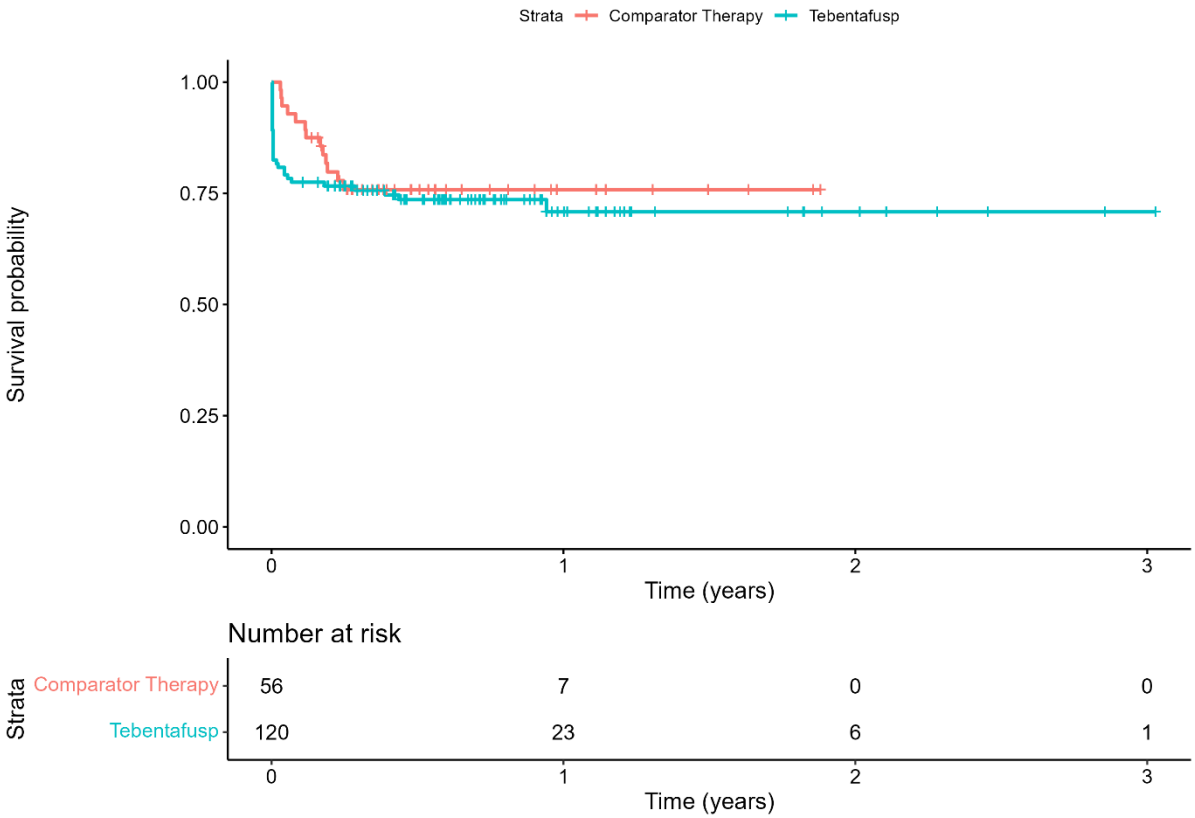
Herkunft: Nicht-hispanisch



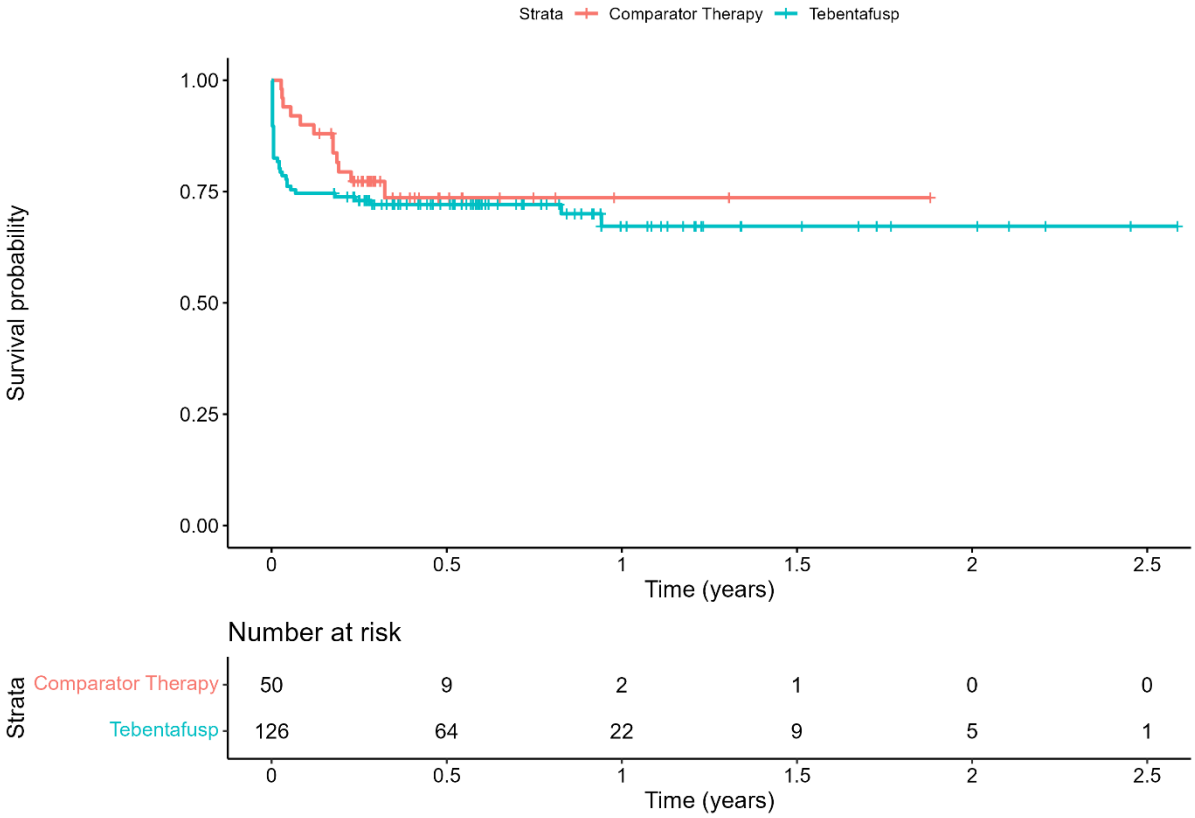
Geschlecht: Männlich



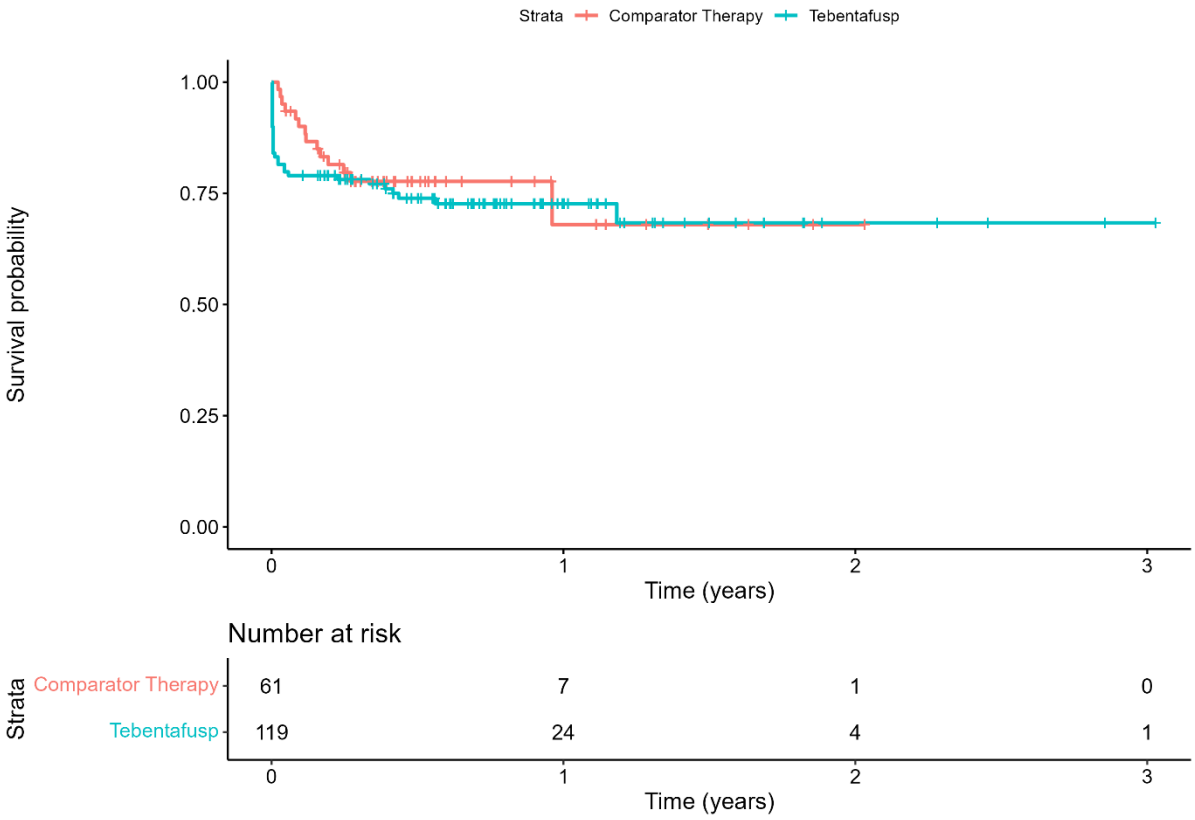
Geschlecht: Weiblich



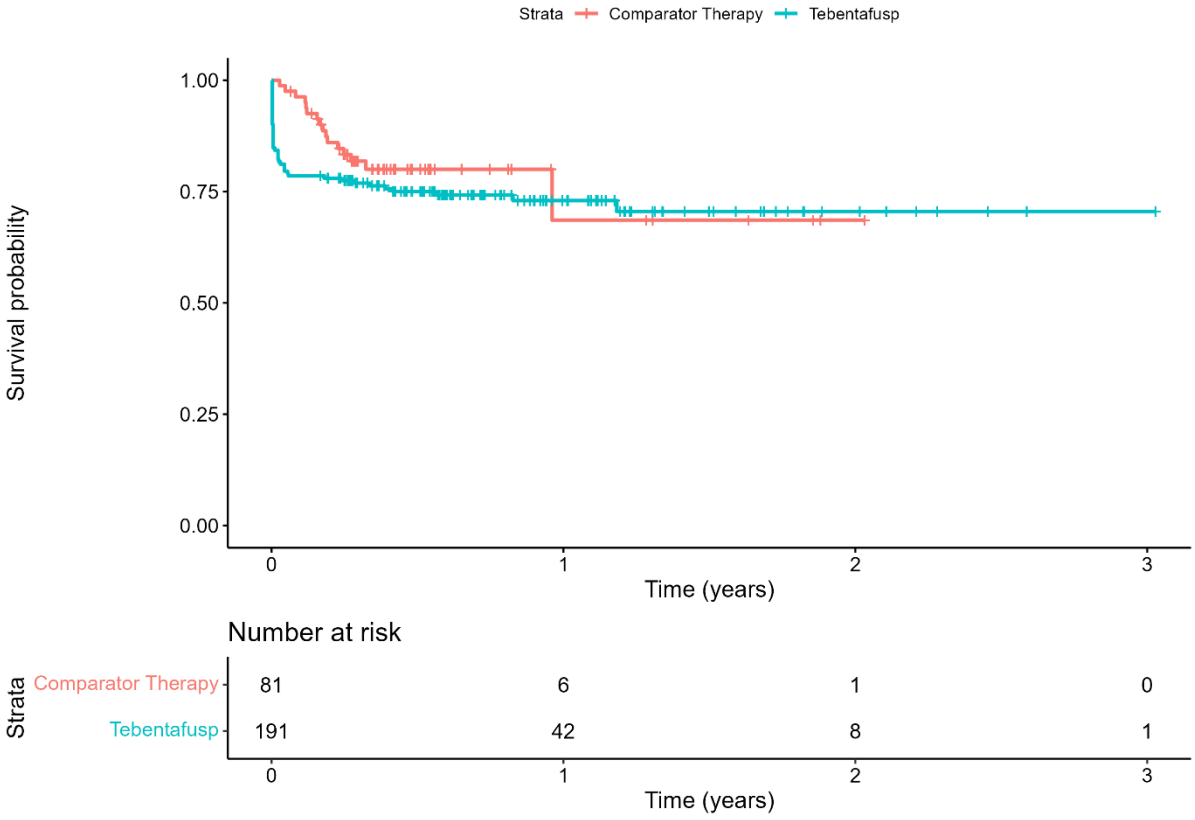
Alter: <65 Jahre



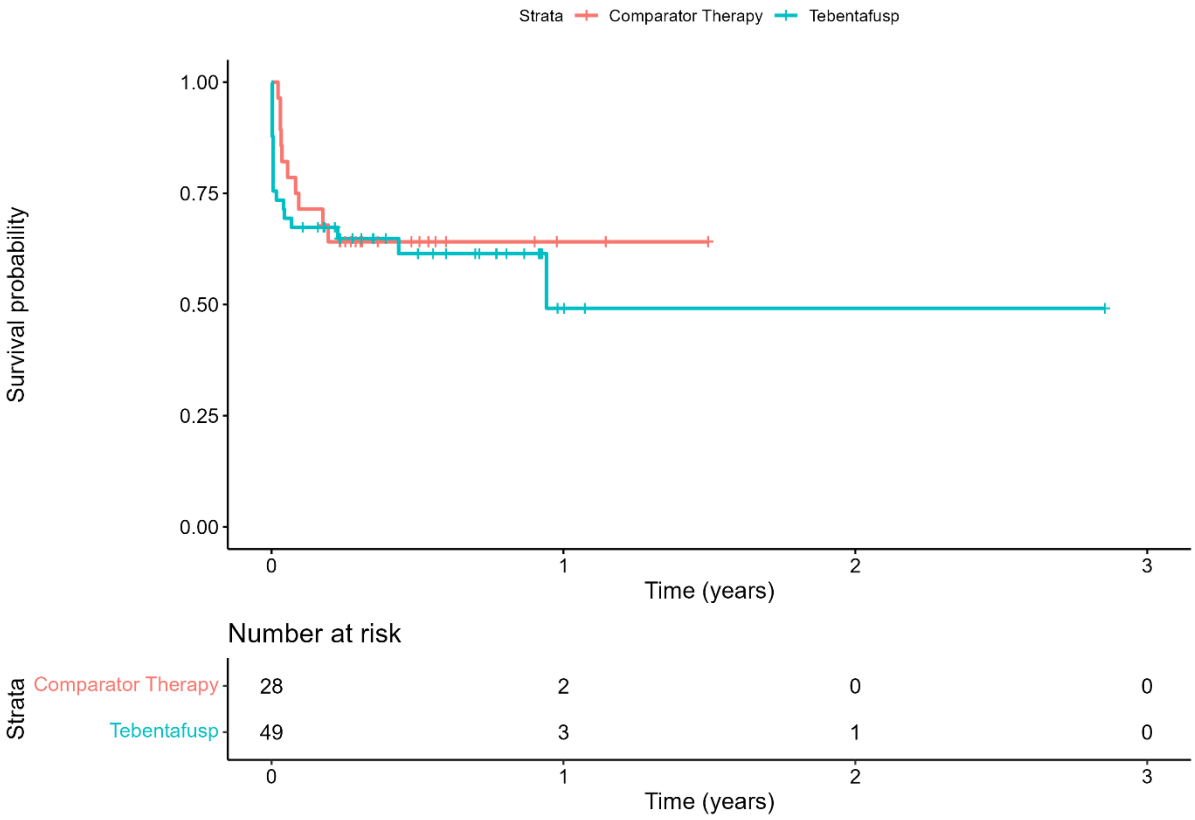
Alter: ≥65 Jahre



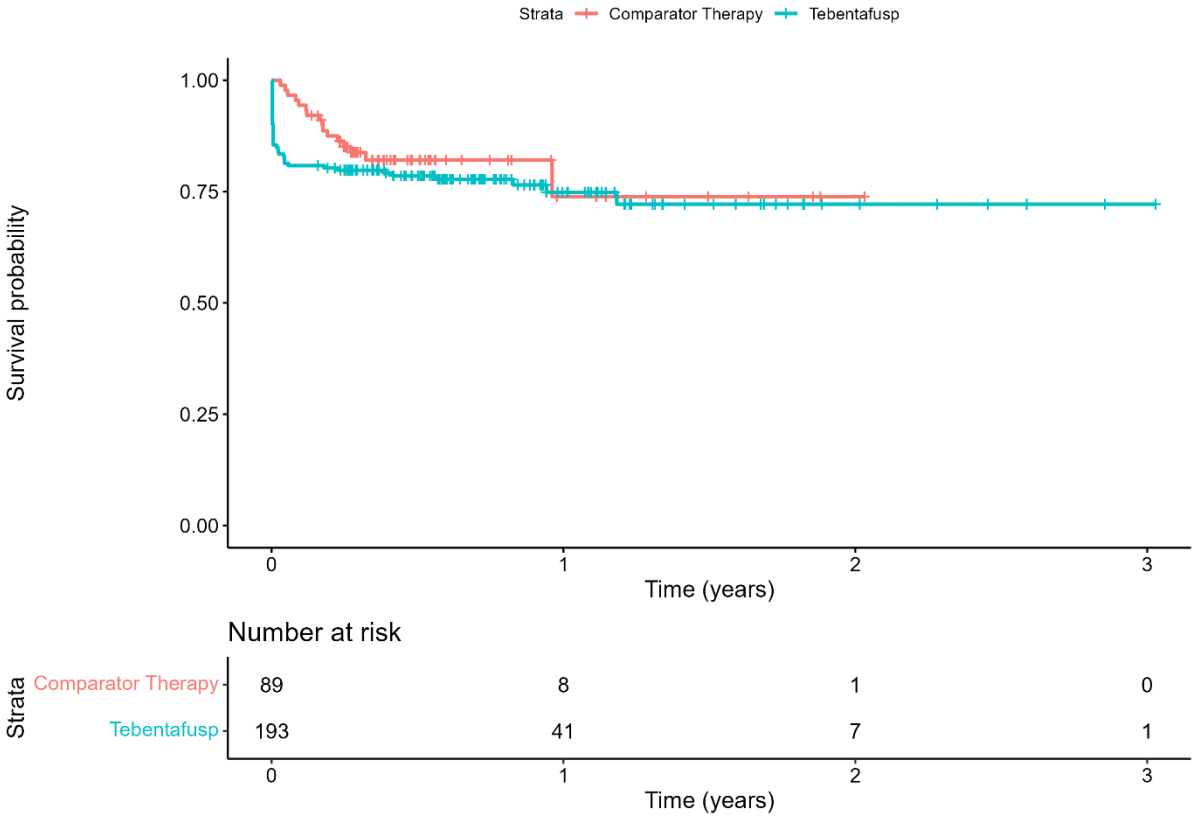
ECOG-Performance-Status: 0



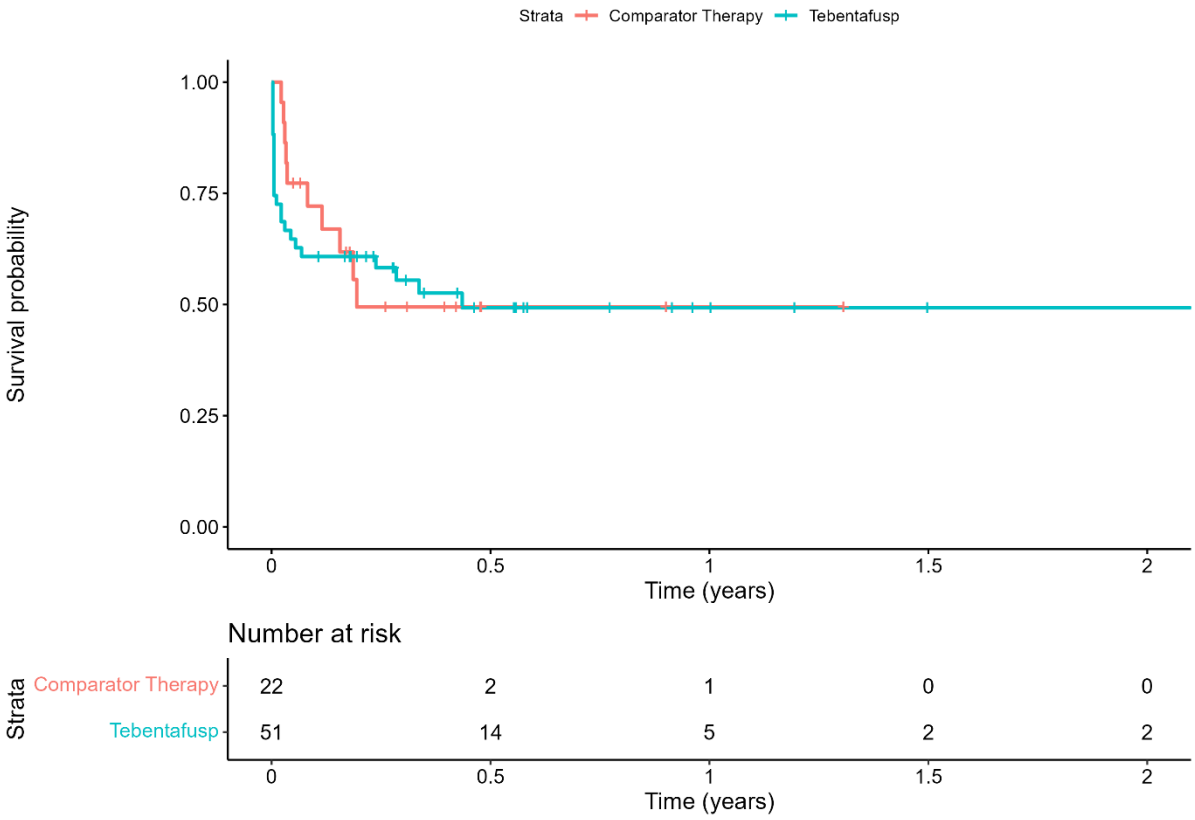
ECOG-Performance-Status: 1



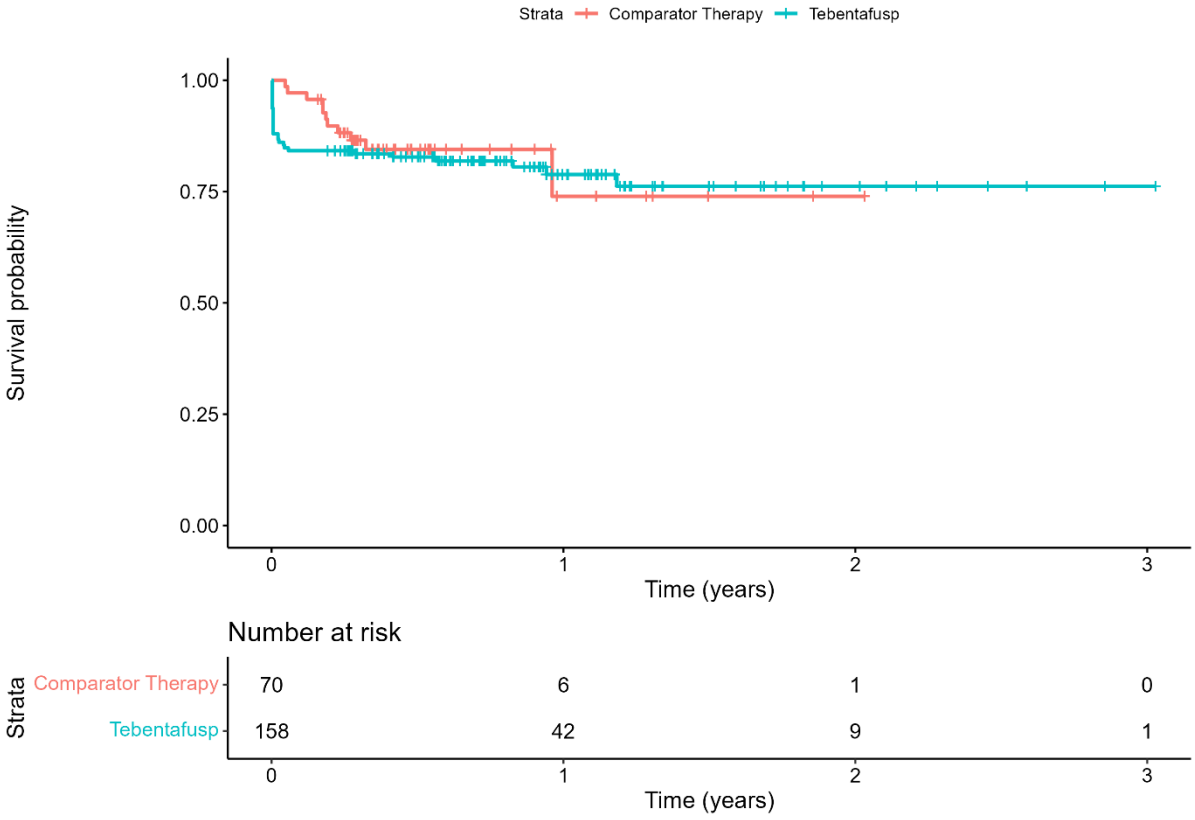
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



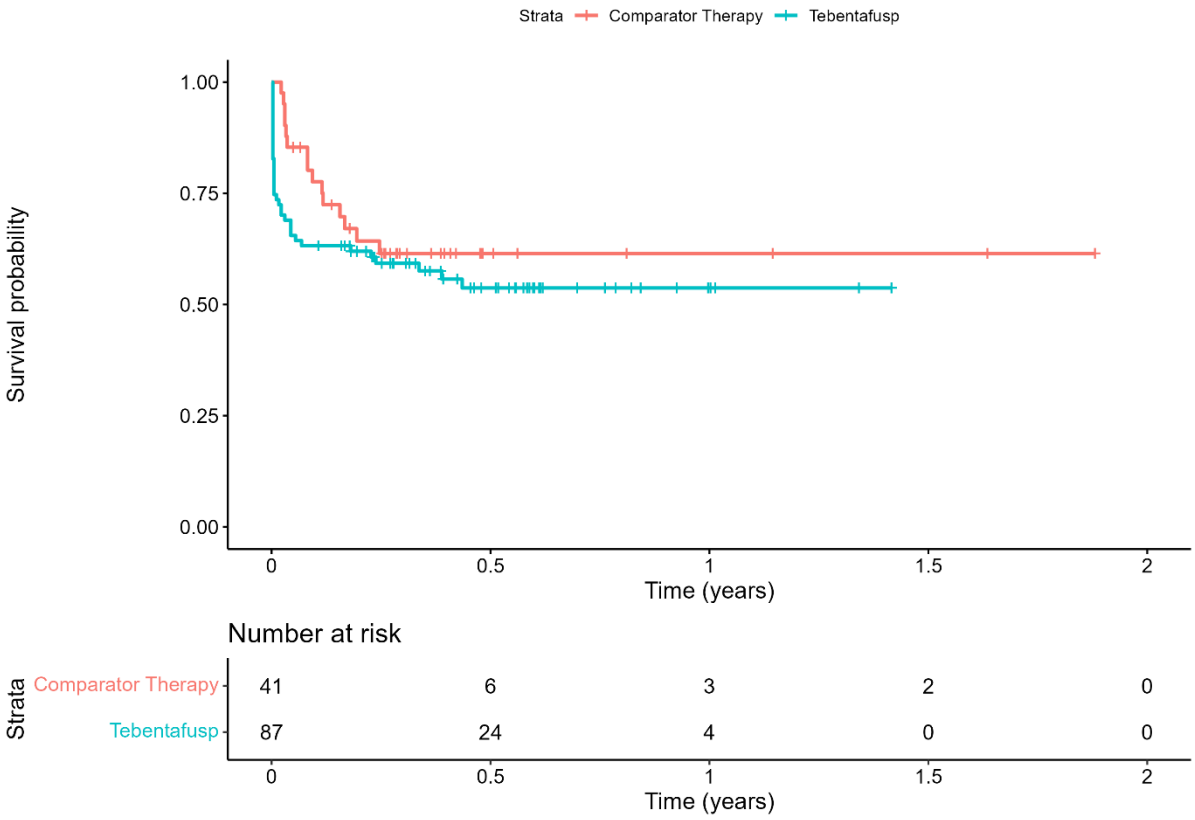
Alkalische Phosphatase (ALP) (Baseline): >ULN



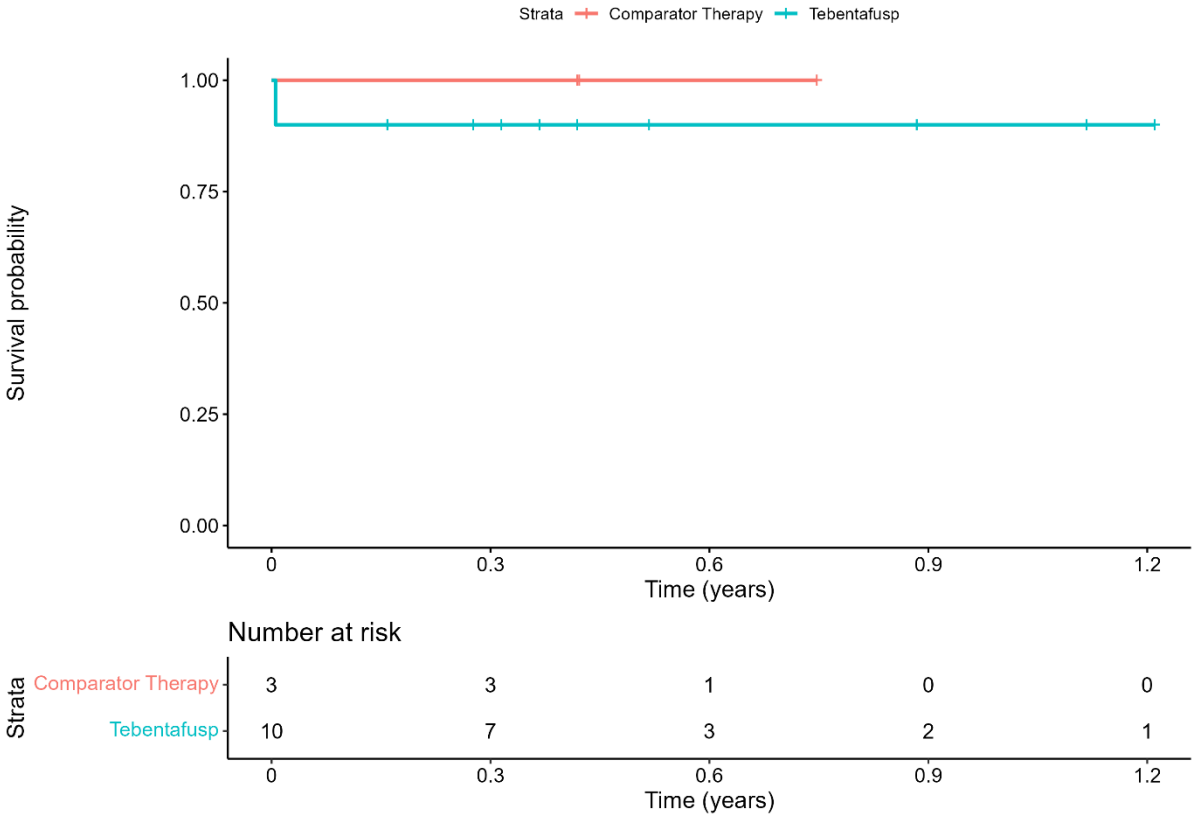
LDH: ≤ULN



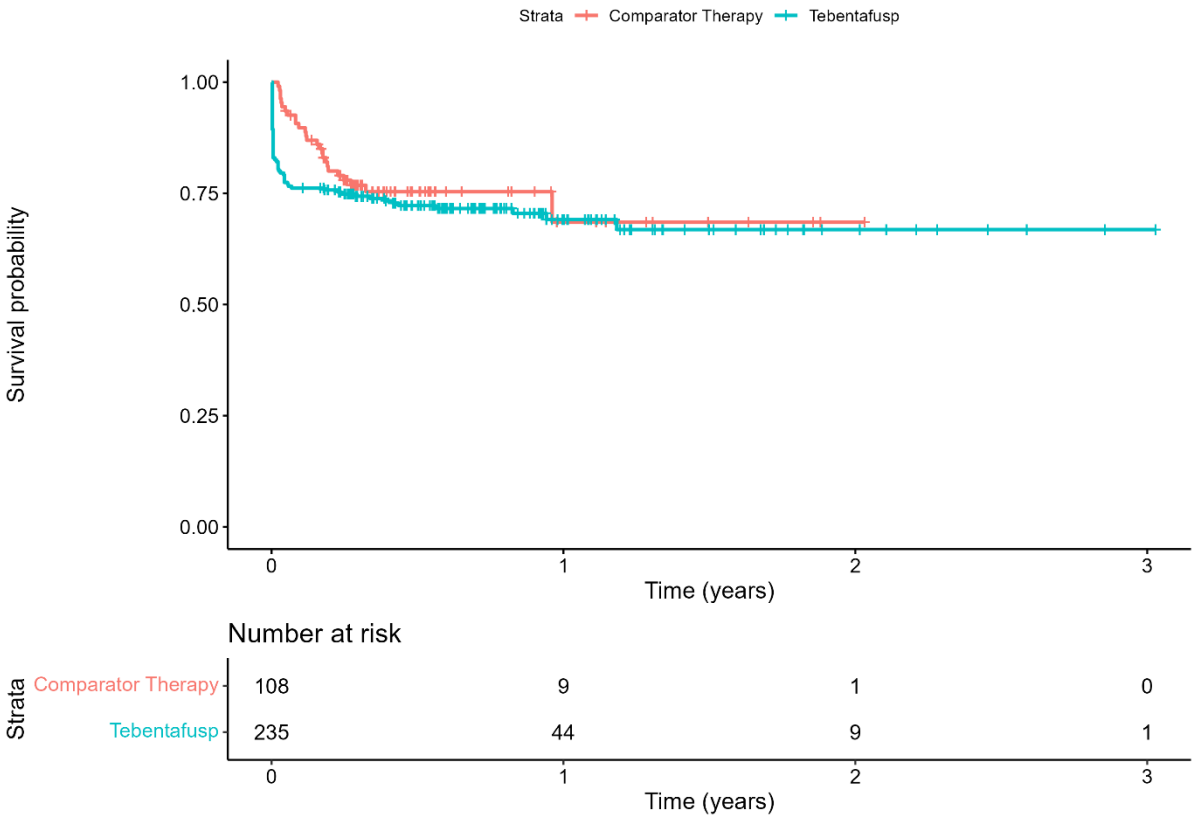
LDH: >ULN



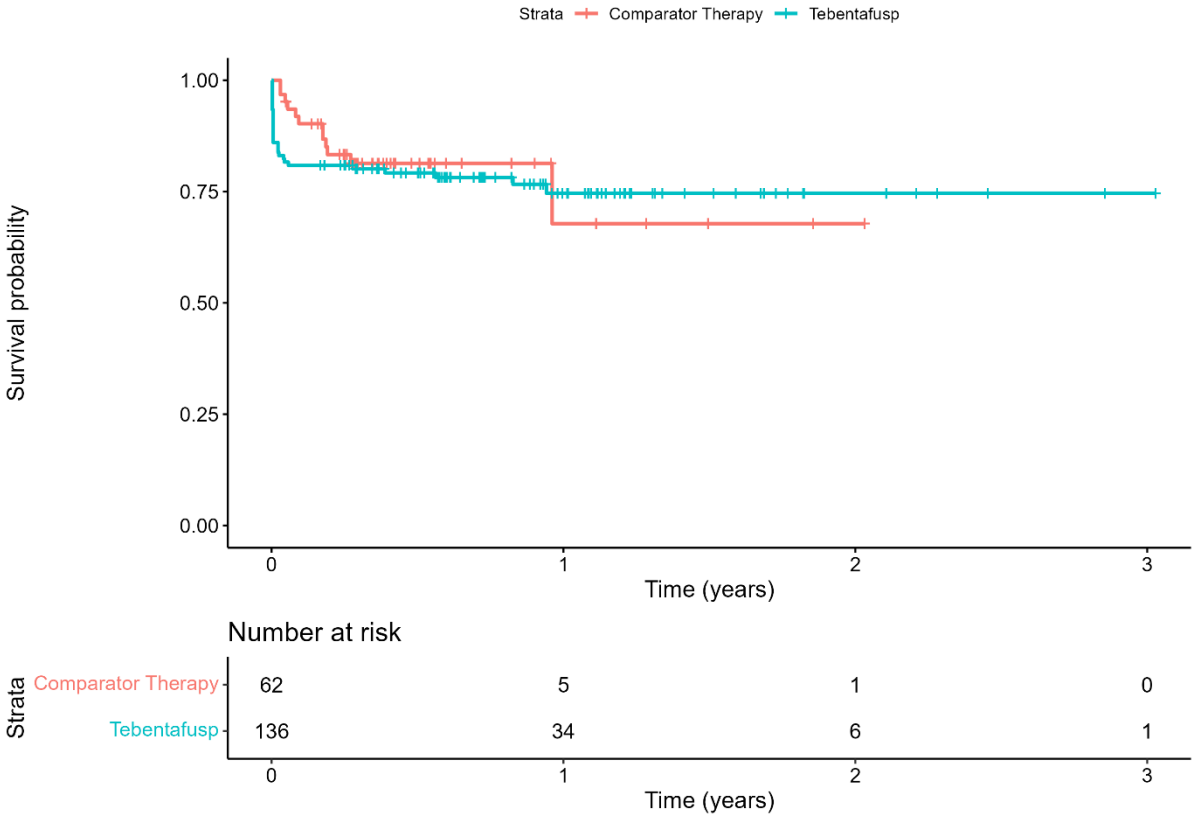
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



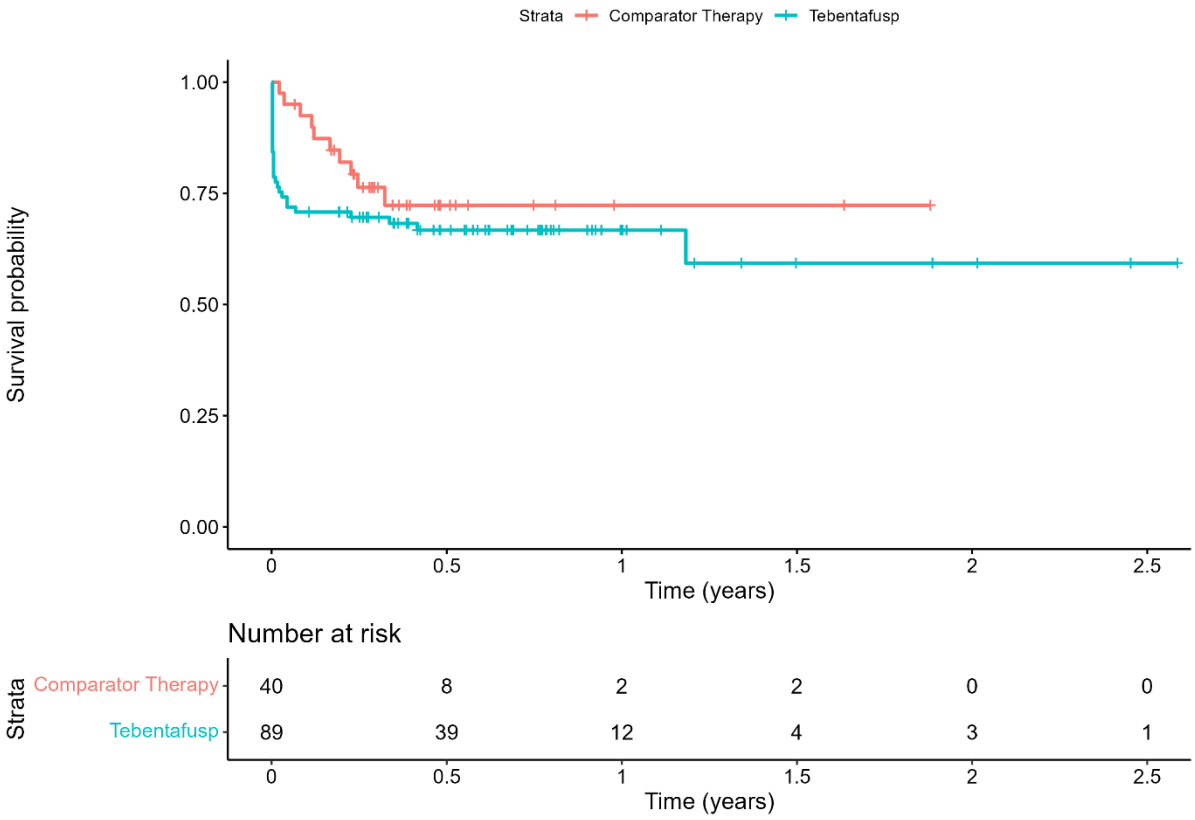
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



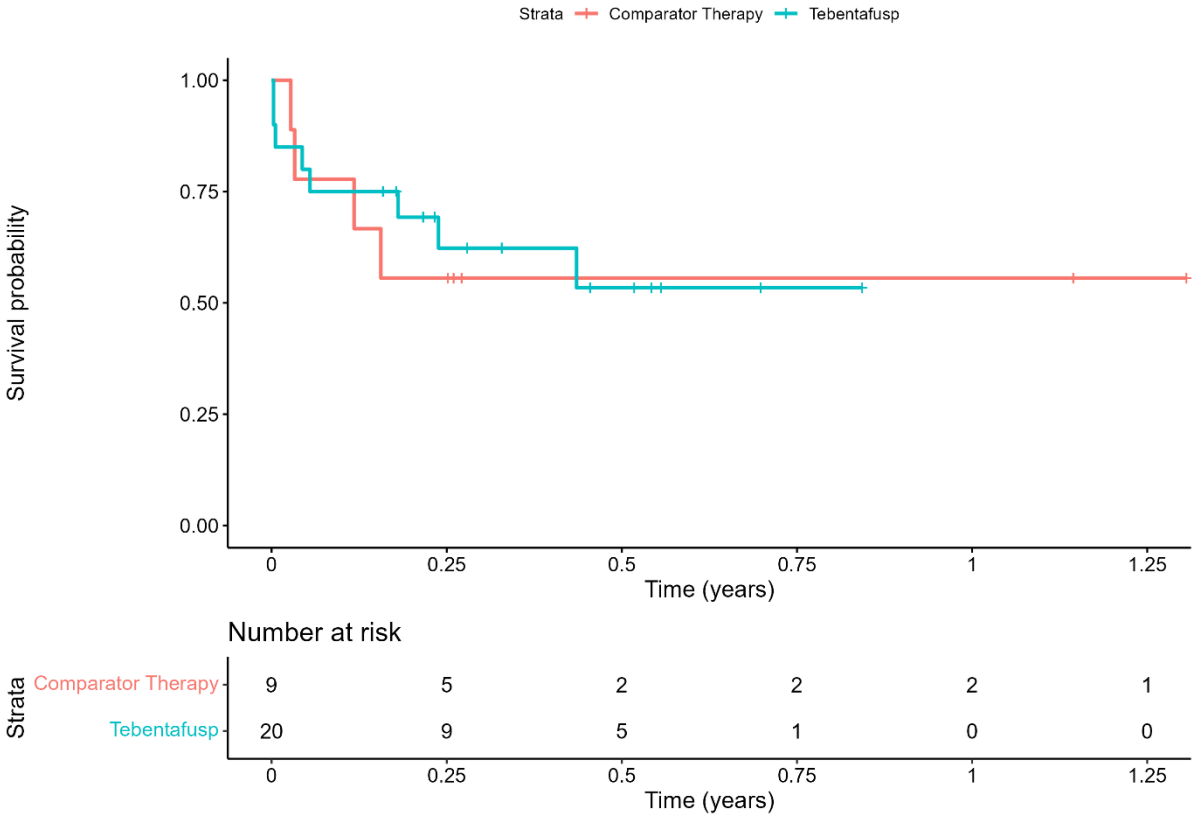
Größte metastatische Läsion (Baseline): ≤3,0 cm



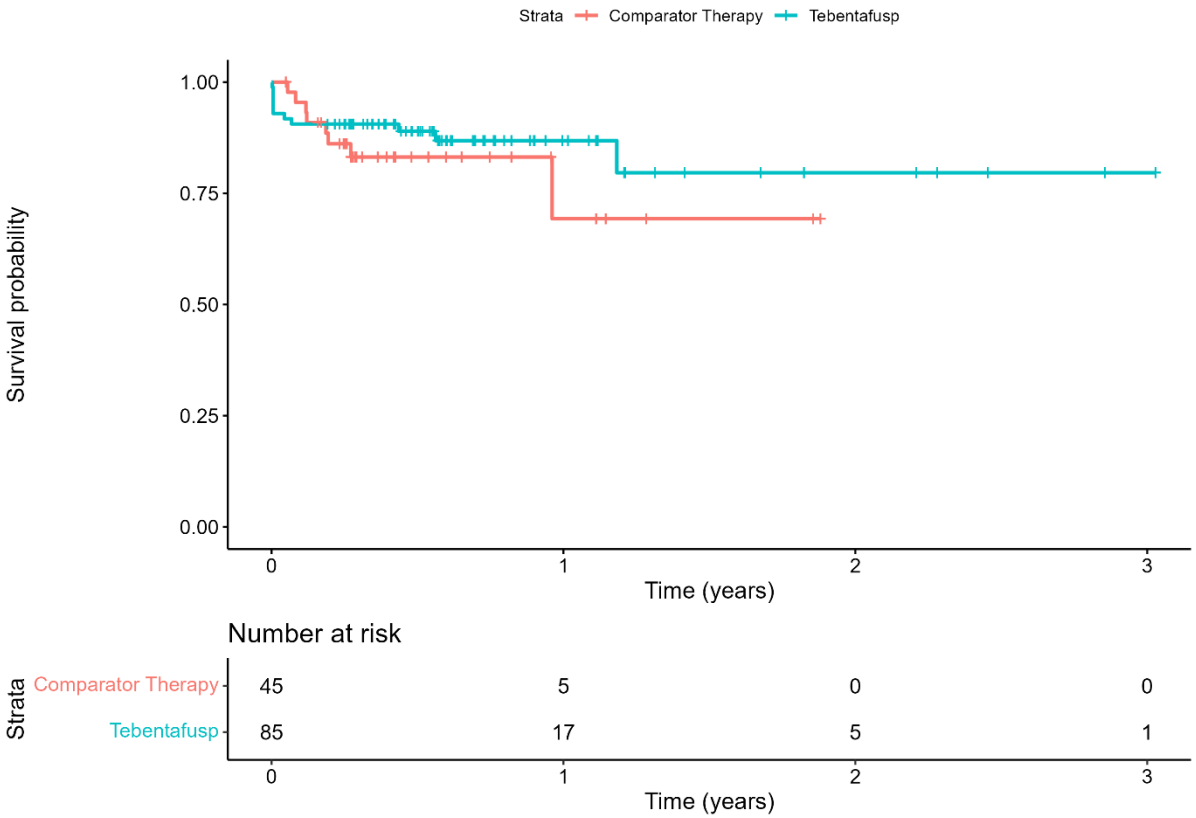
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



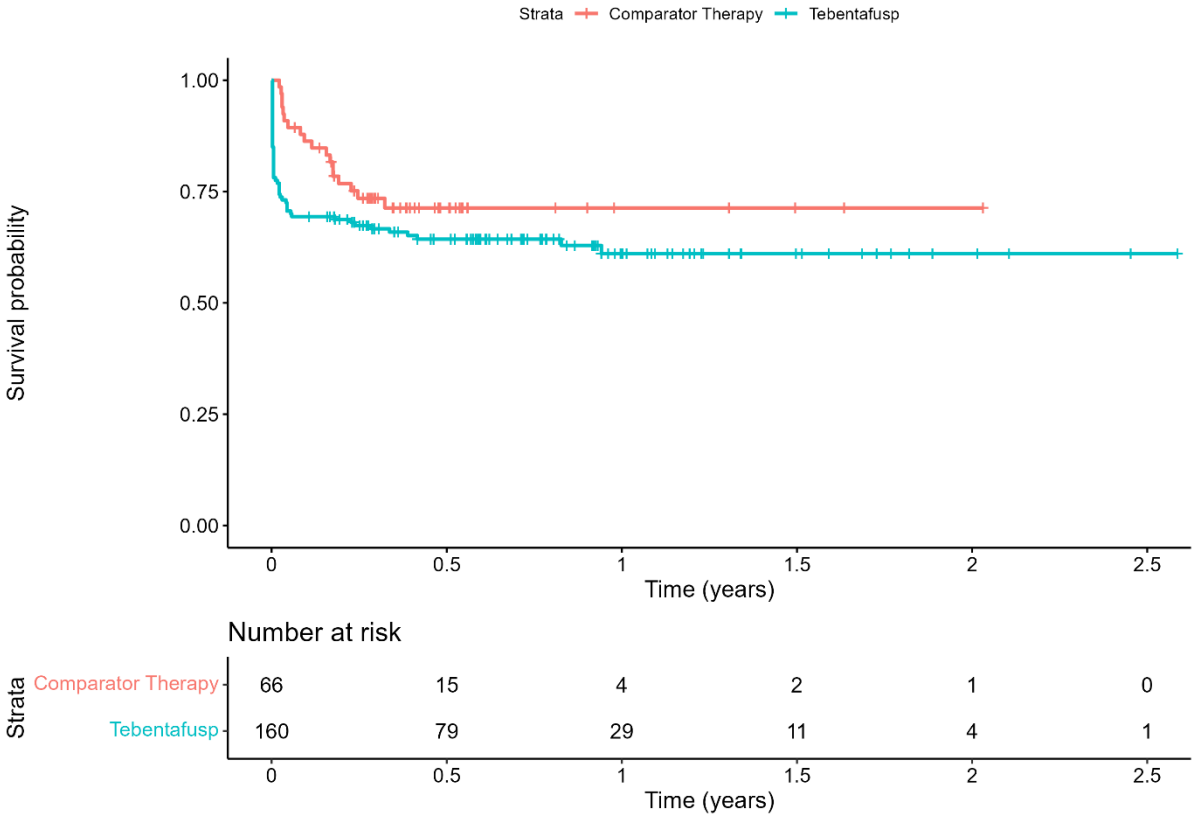
Größte metastatische Läsion (Baseline): ≥8,1 cm



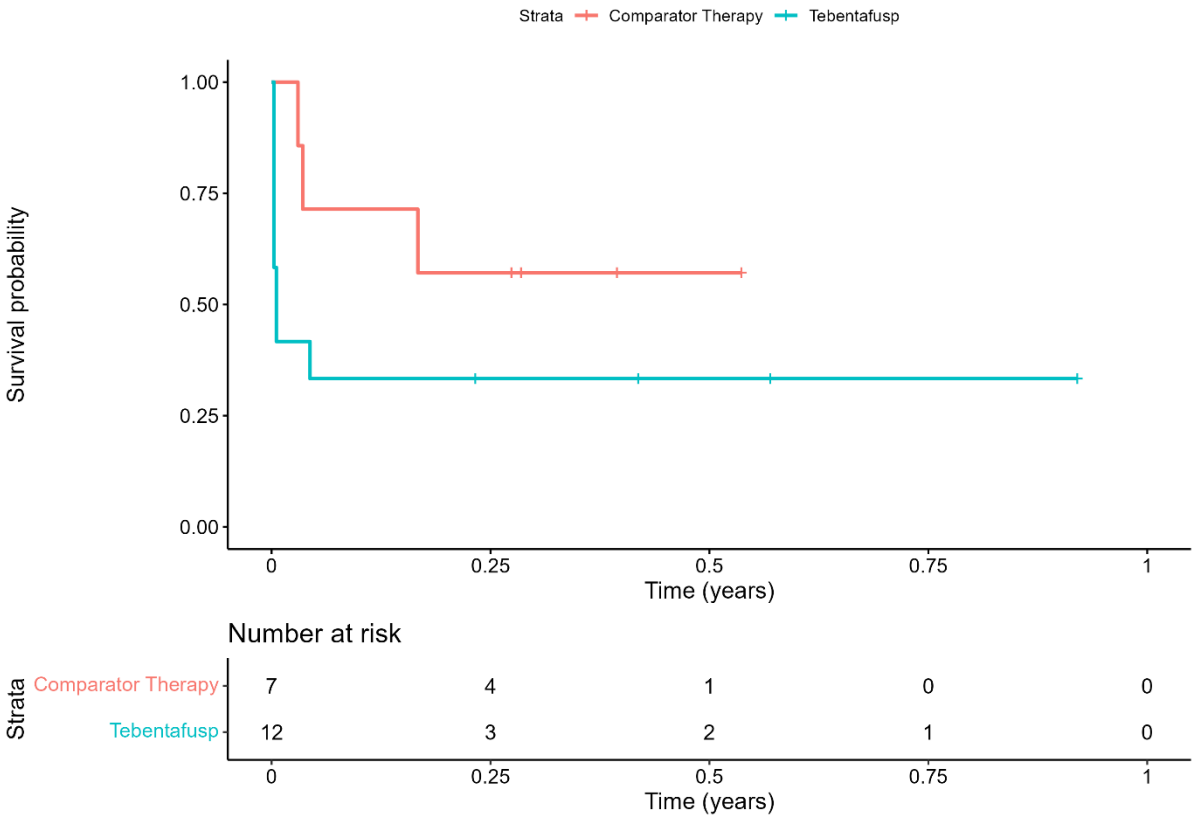
Region: Nordamerika



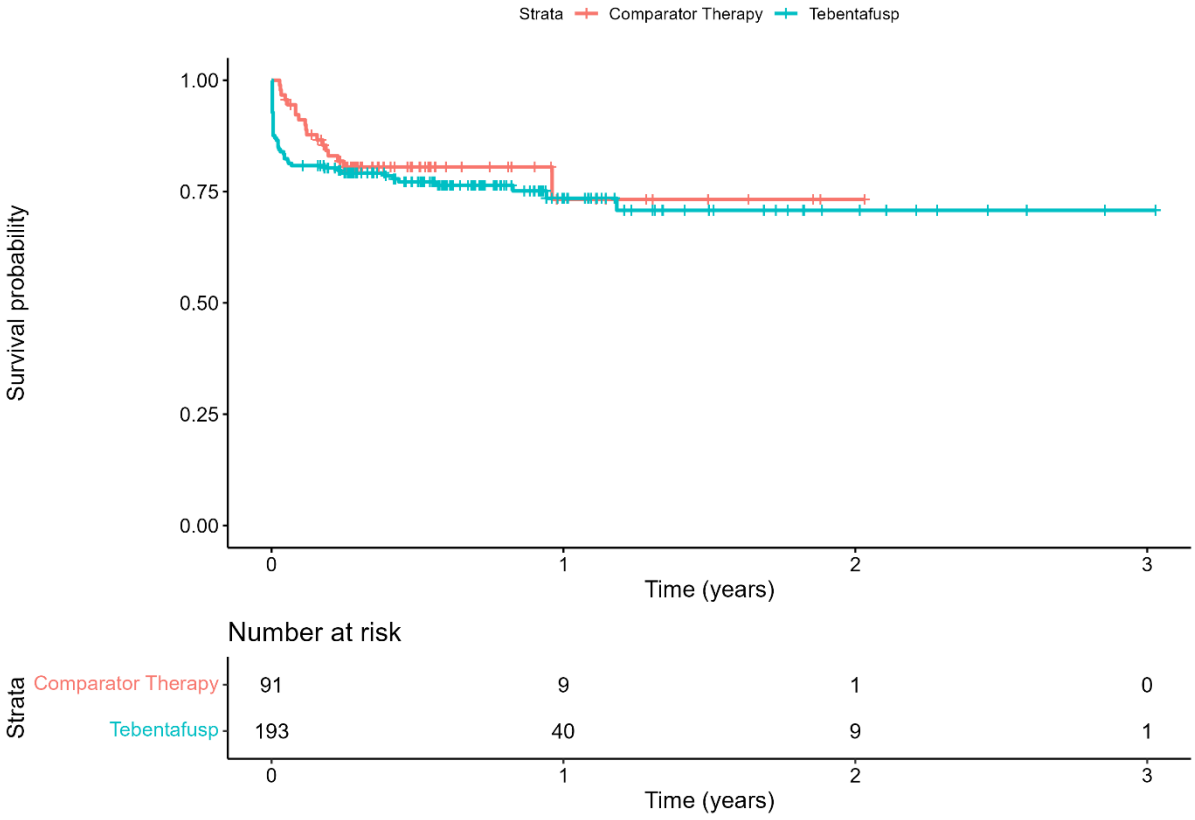
Region: Nicht-Nordamerika



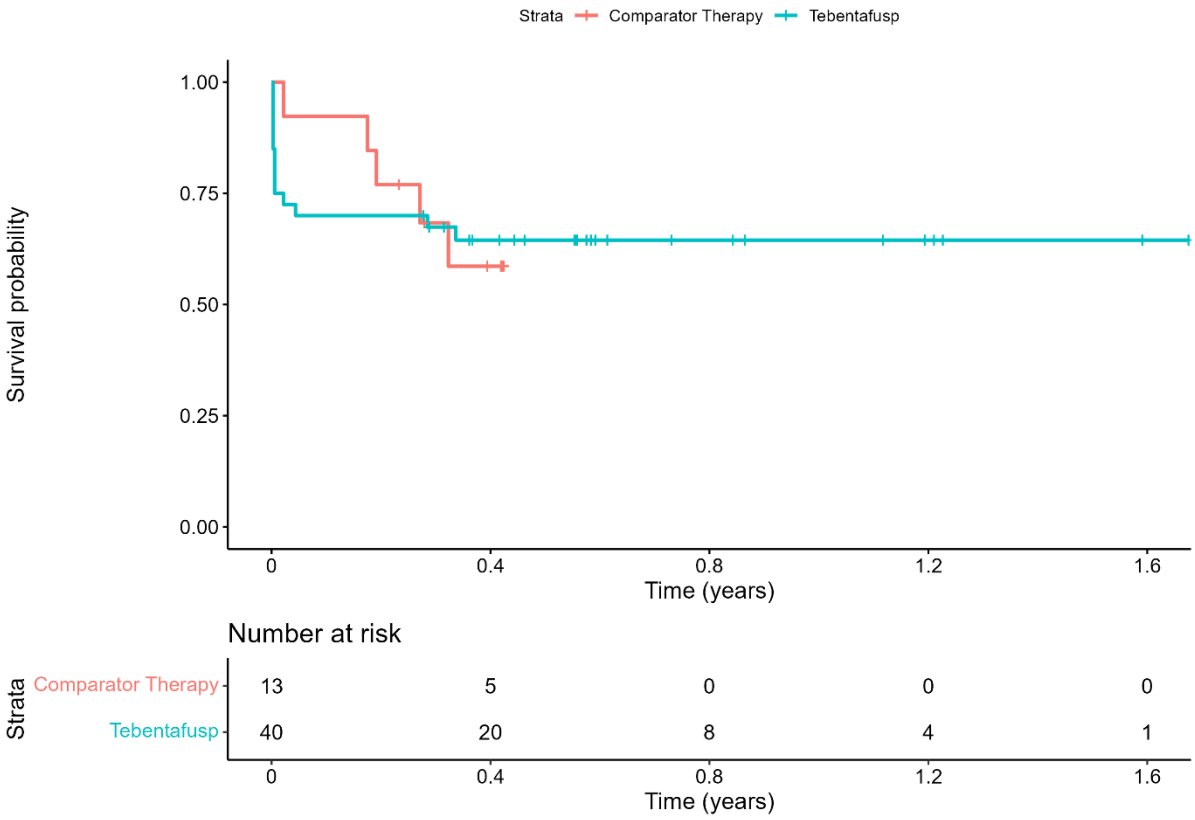
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

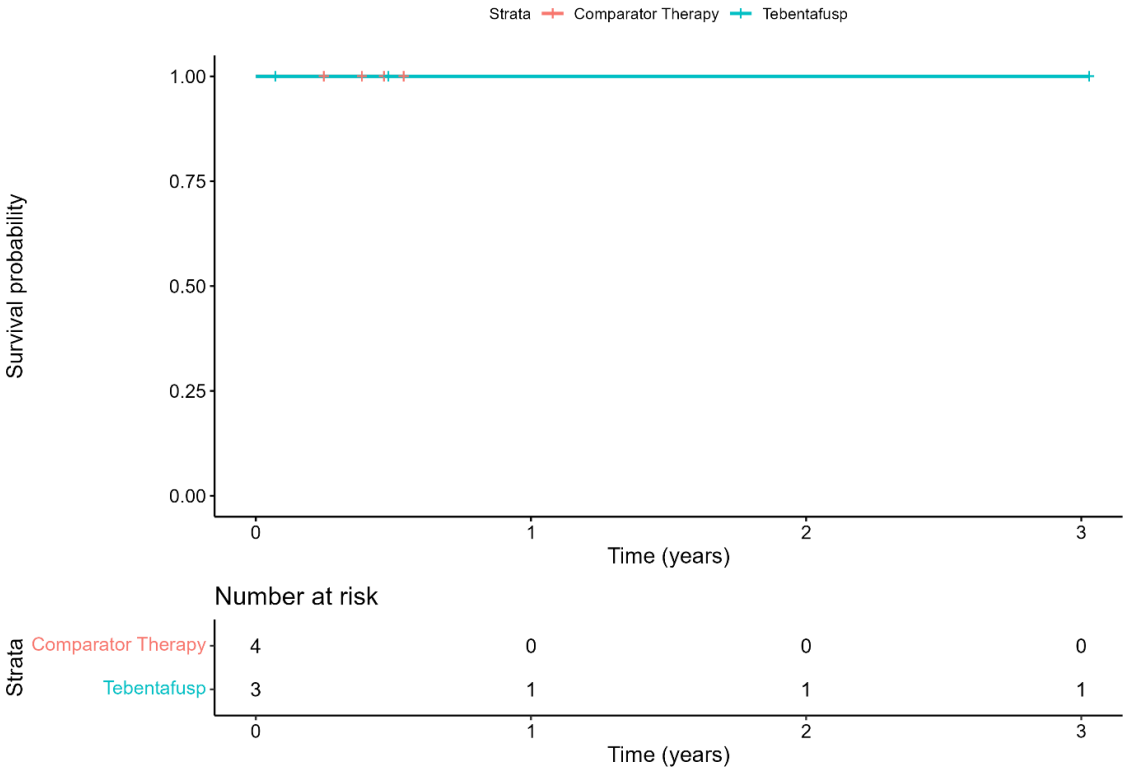


Vorauswahl der Chemotherapie: Ipilimumab

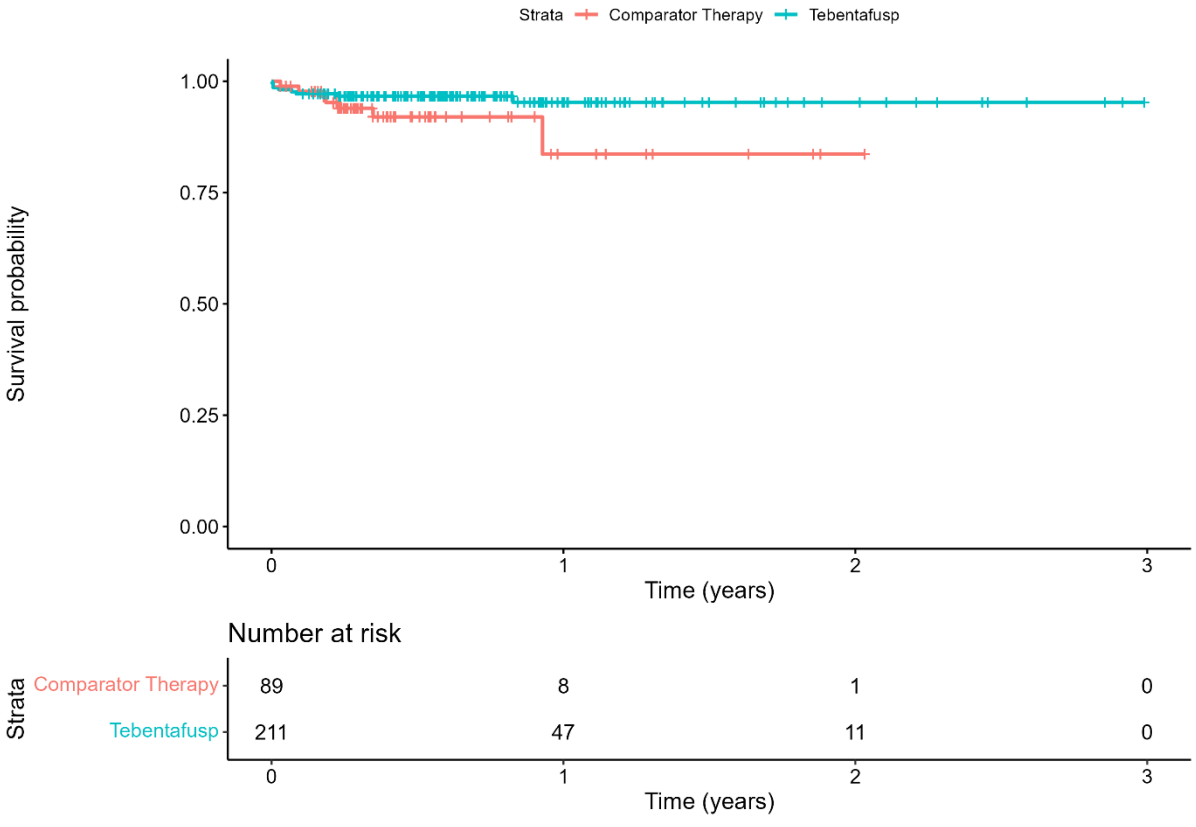


19.3 Jegliches UE, das zum Absetzen des Studienmedikaments führte (Tabelle 4-93)

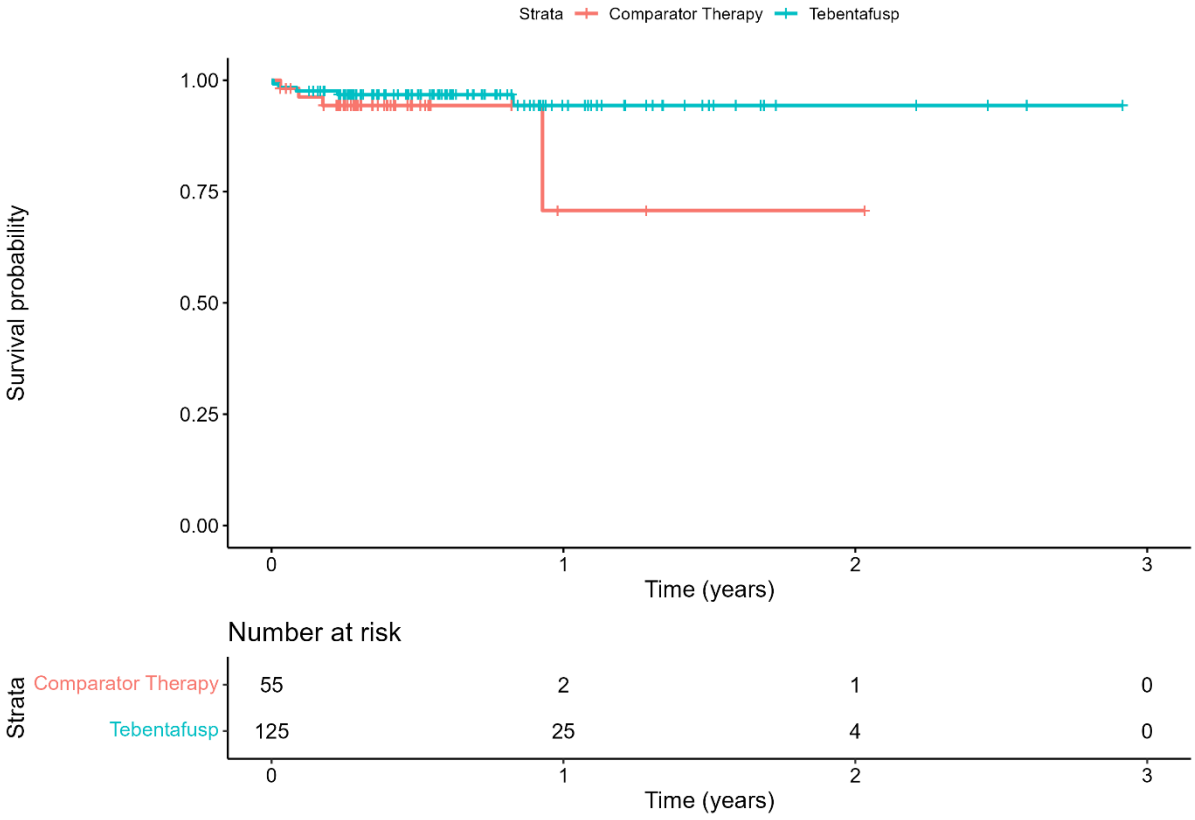
Herkunft: Hispanisch



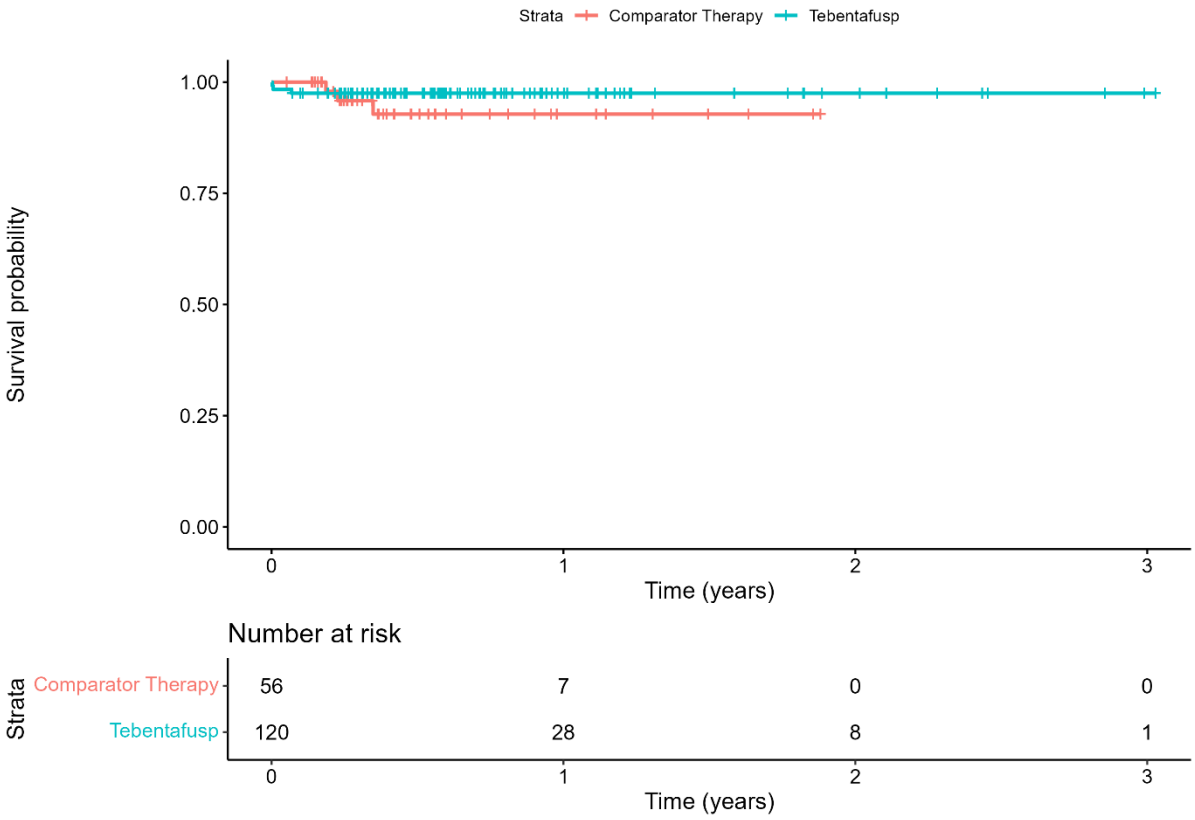
Herkunft: Nicht-hispanisch



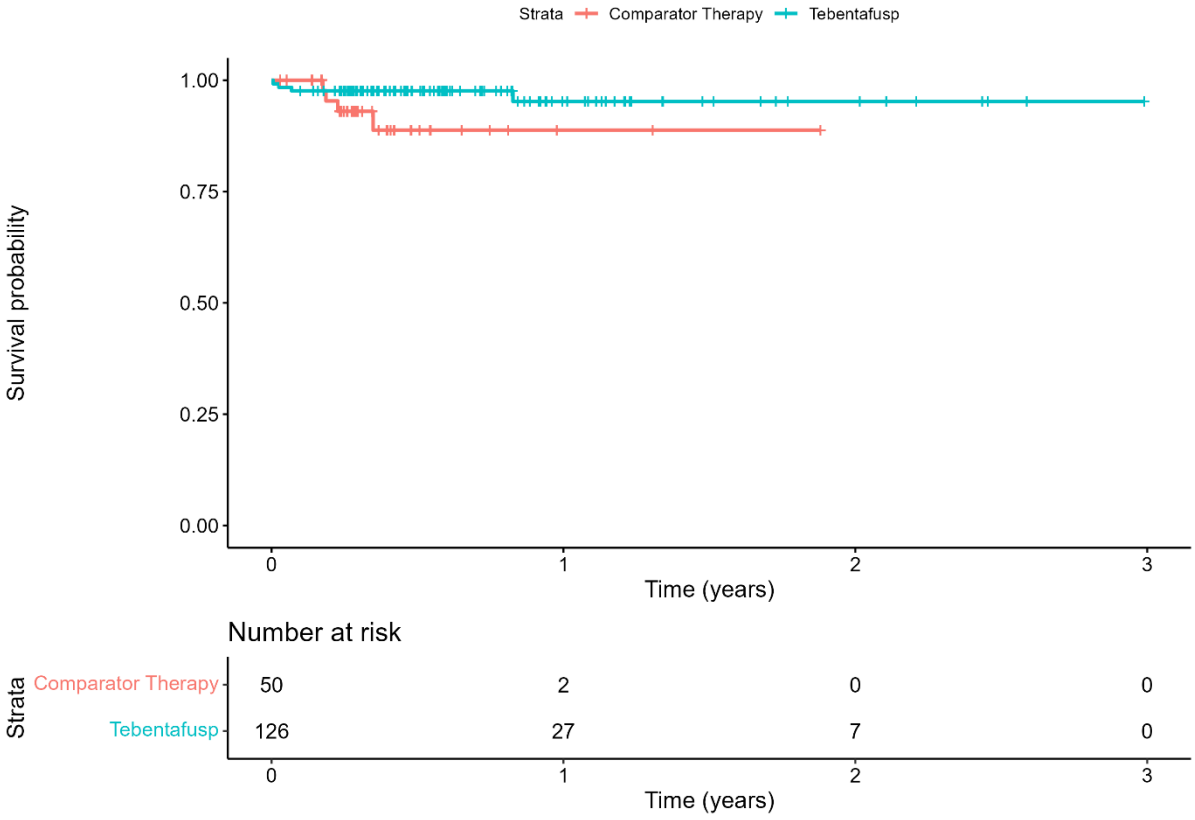
Geschlecht: Männlich



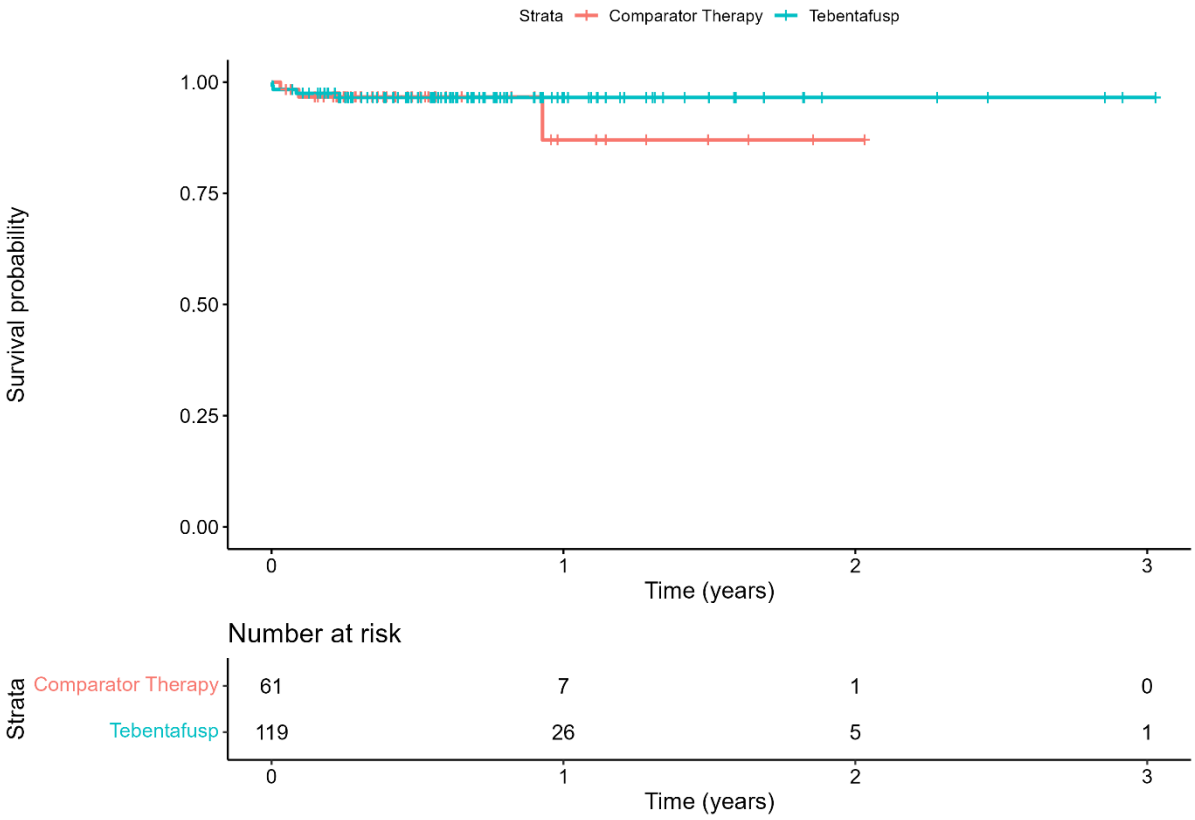
Geschlecht: Weiblich



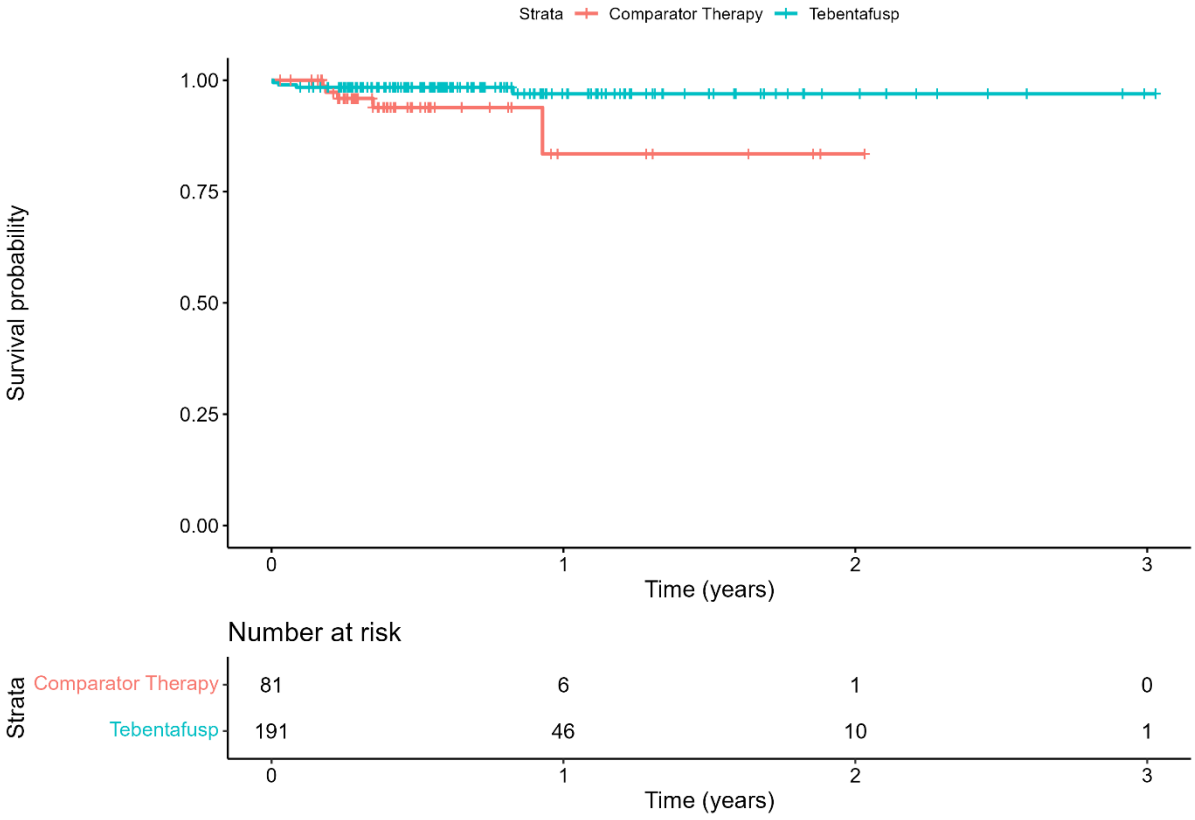
Alter: <65 Jahre



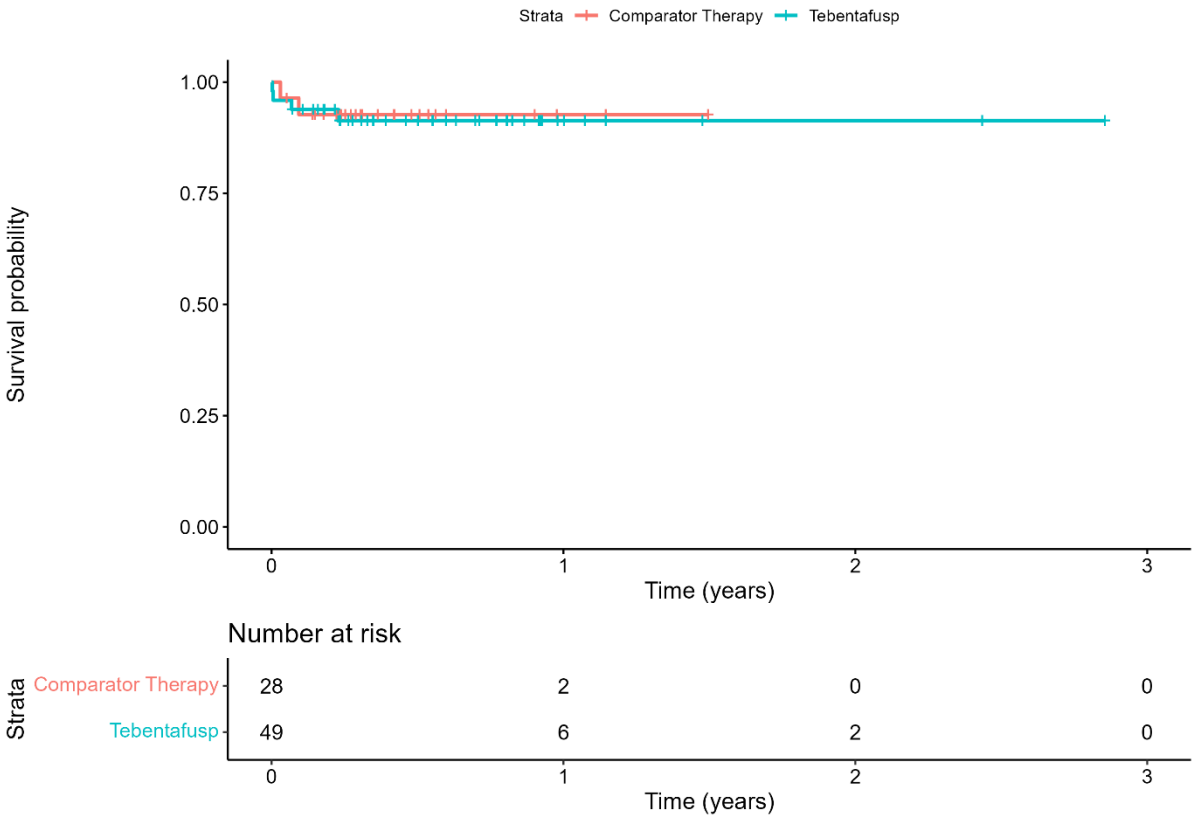
Alter: ≥65 Jahre



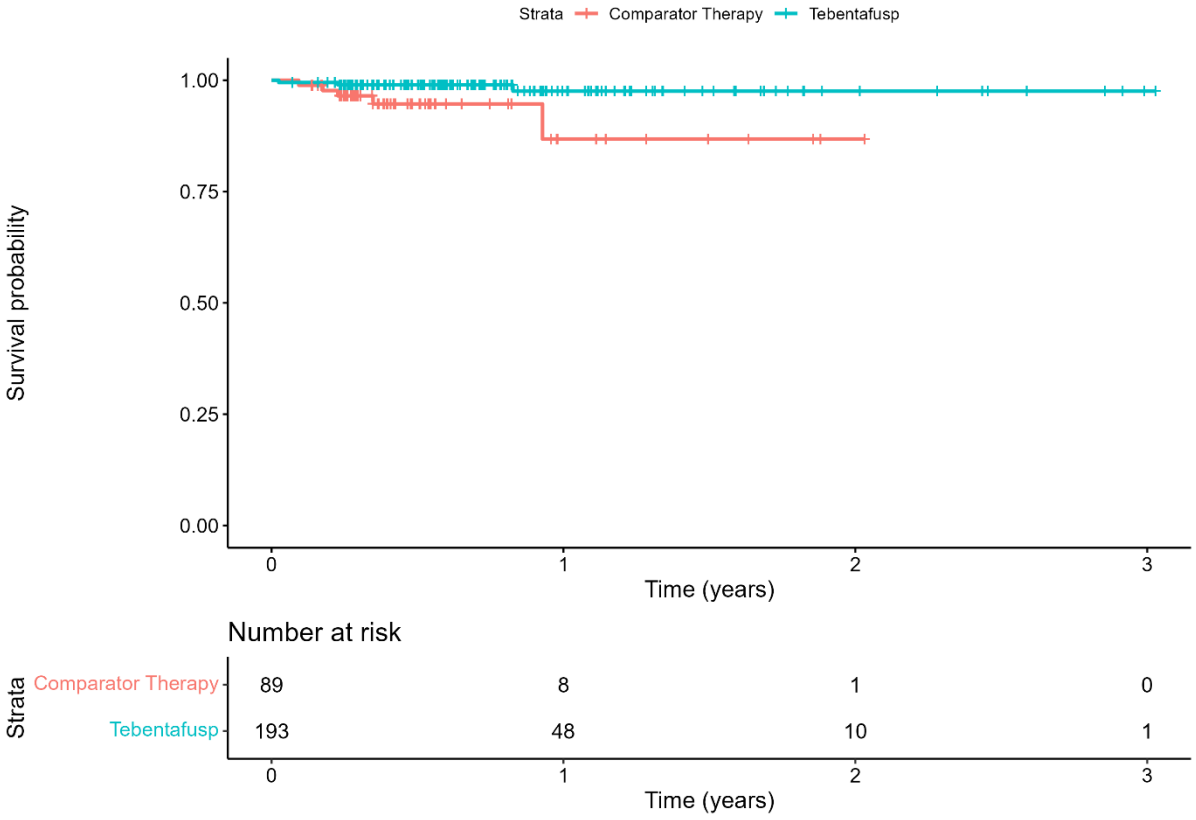
ECOG-Performance-Status: 0



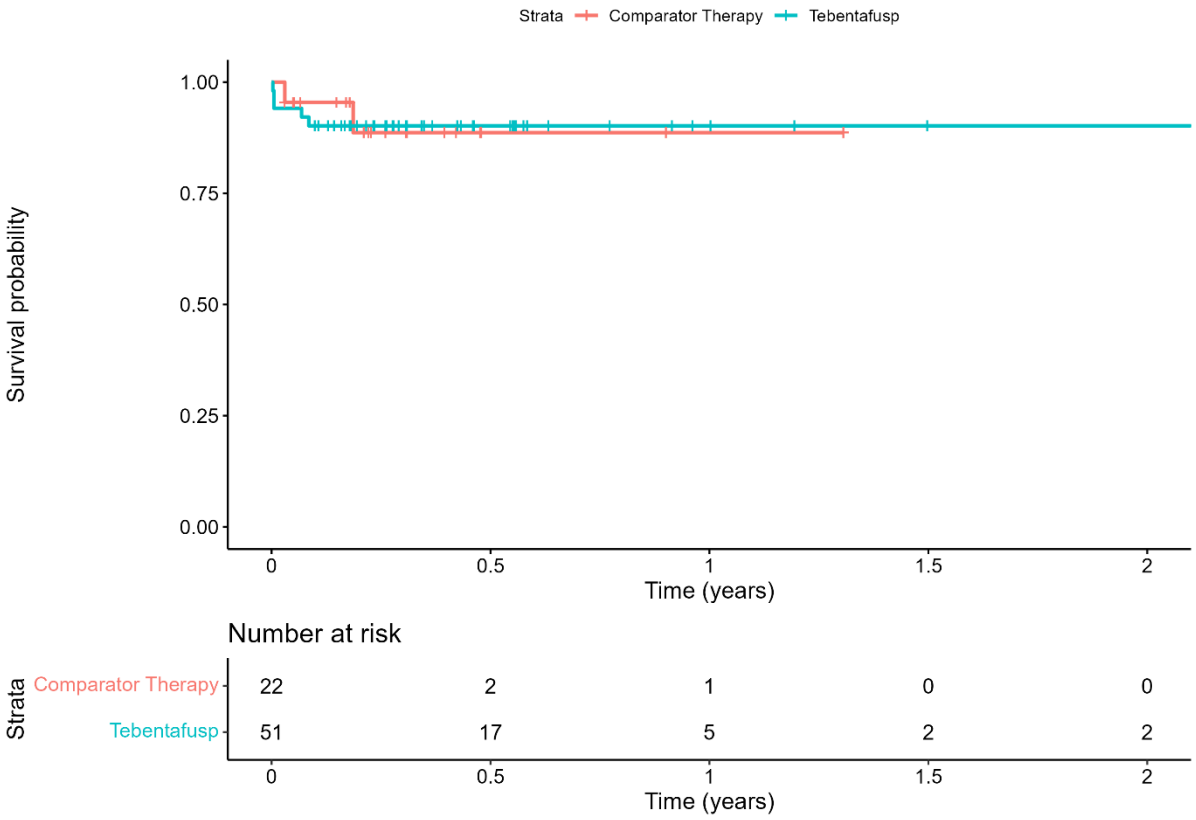
ECOG-Performance-Status: 1



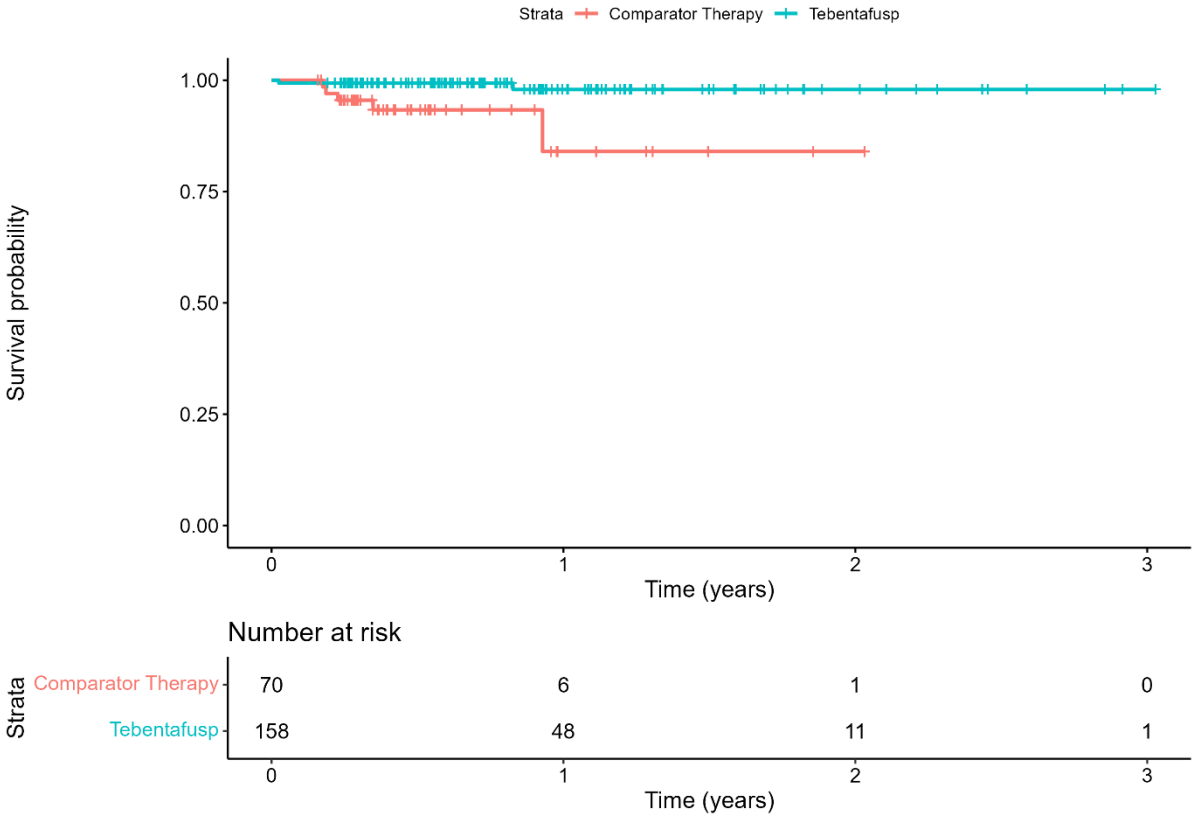
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



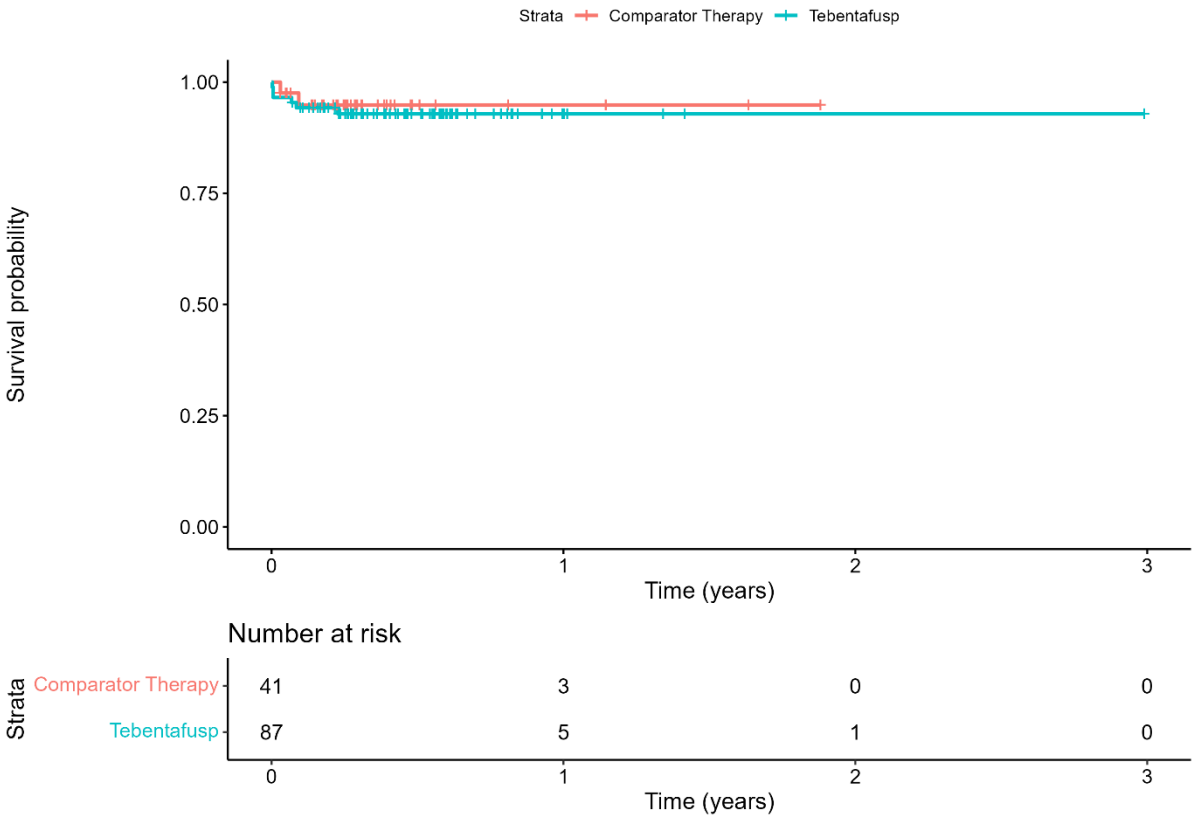
Alkalische Phosphatase (ALP) (Baseline): >ULN



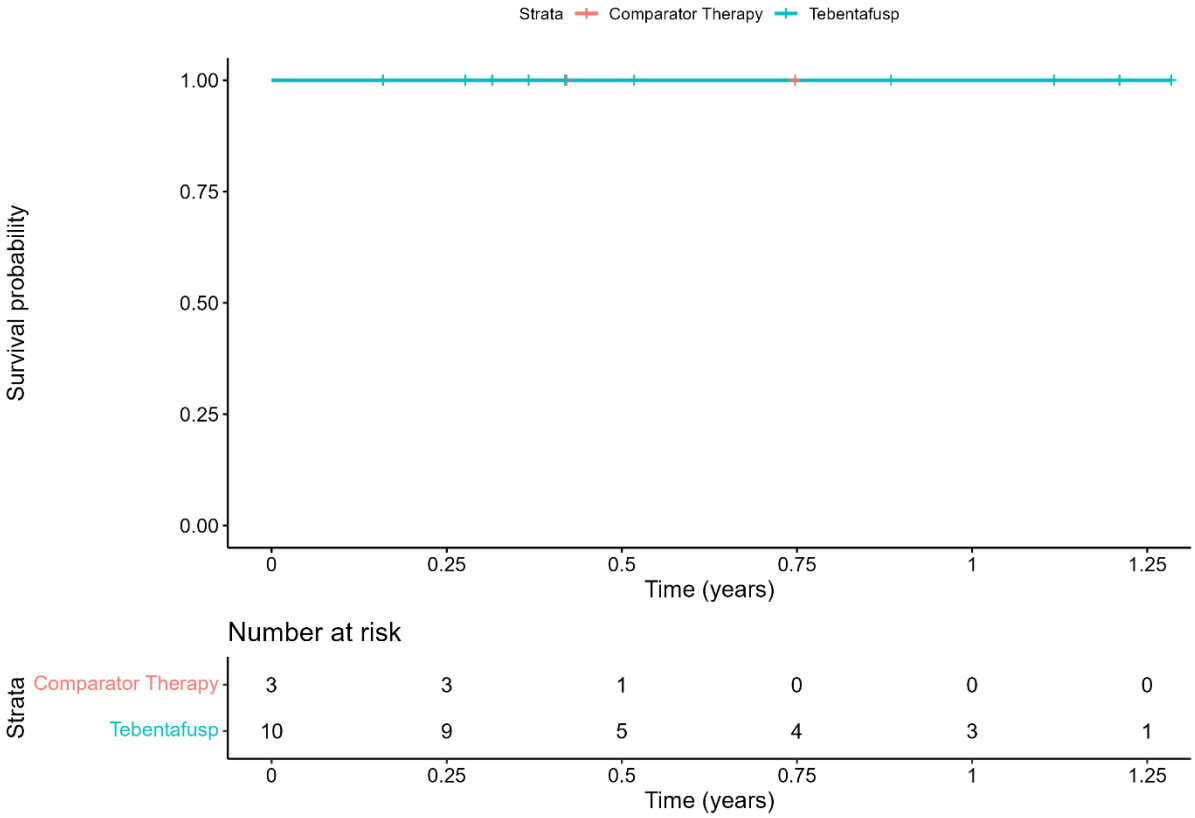
LDH: ≤ULN



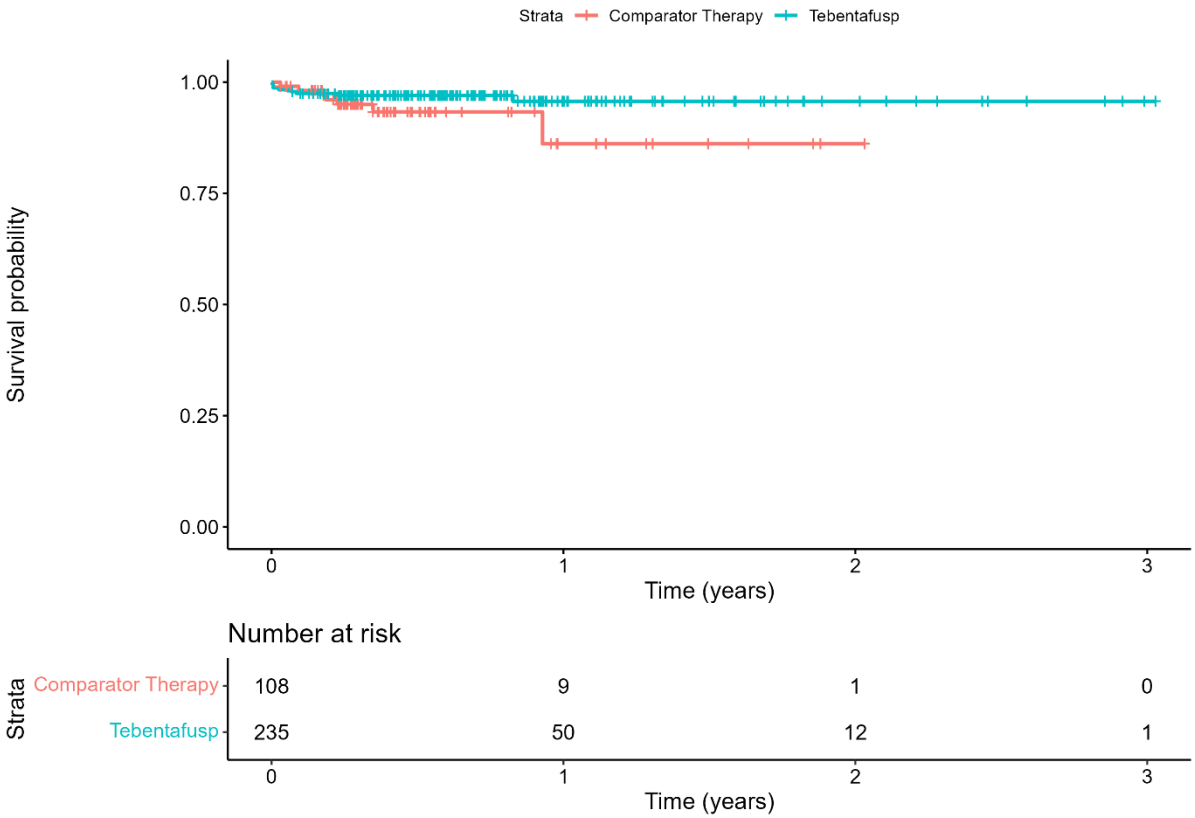
LDH: >ULN



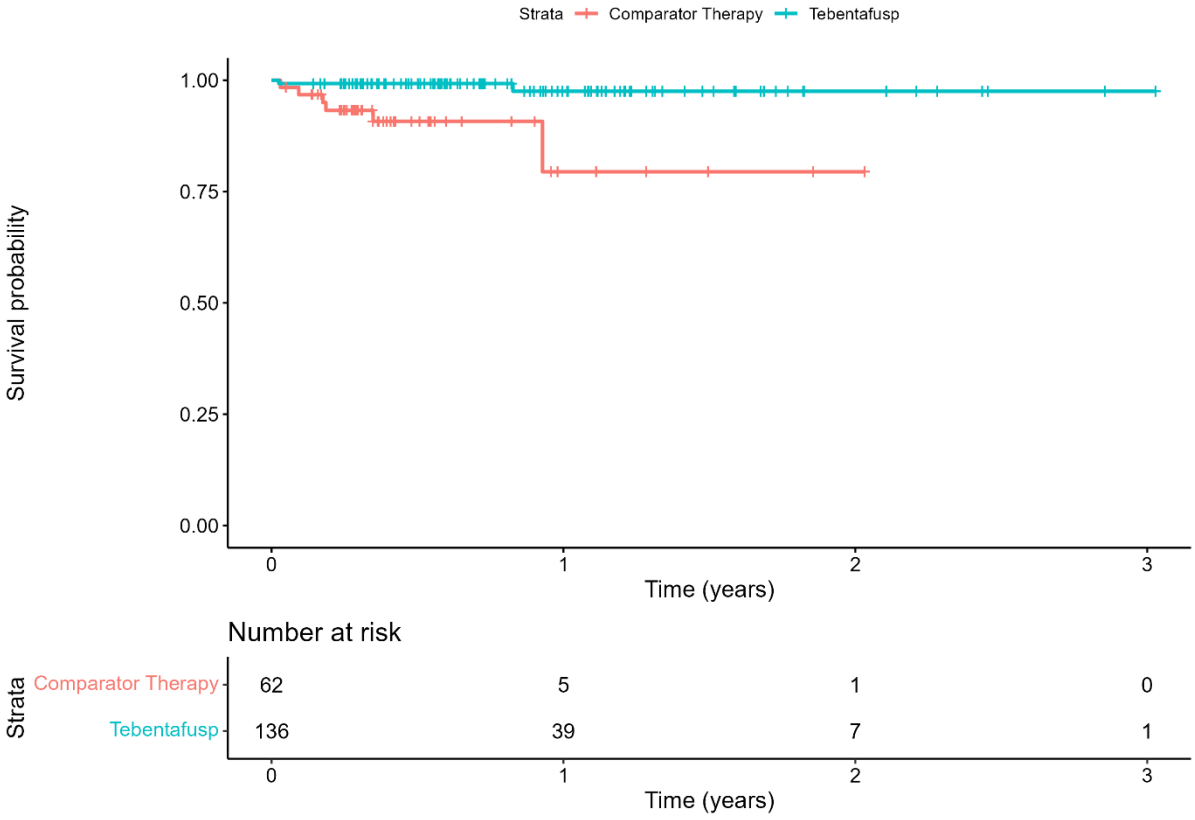
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



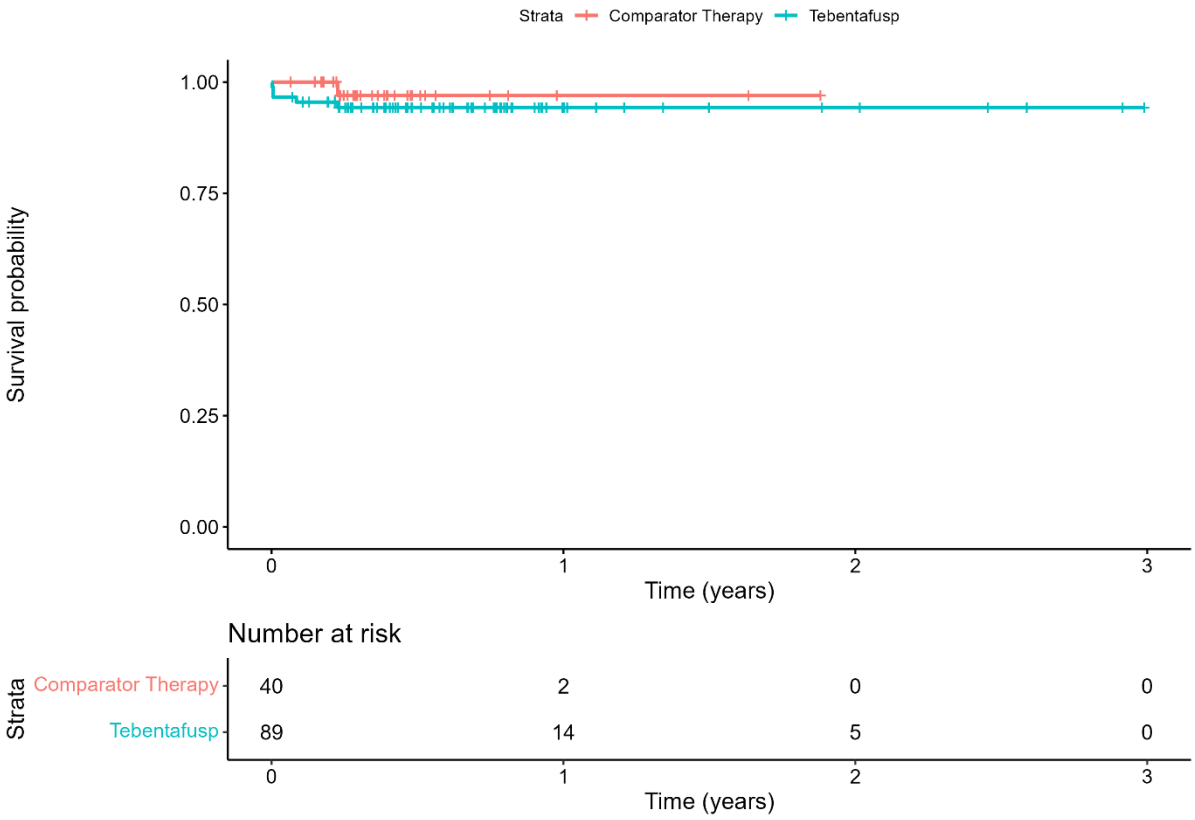
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



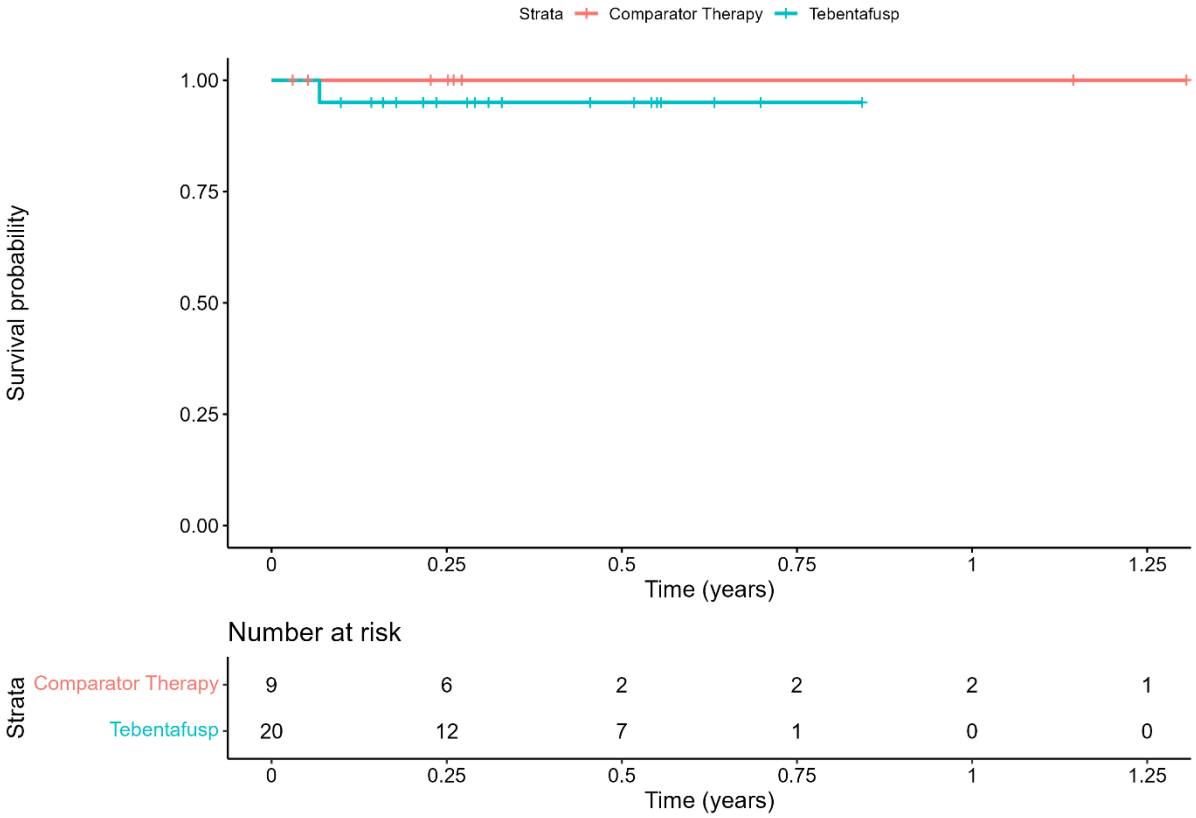
Größte metastatische Läsion (Baseline): ≤3,0 cm



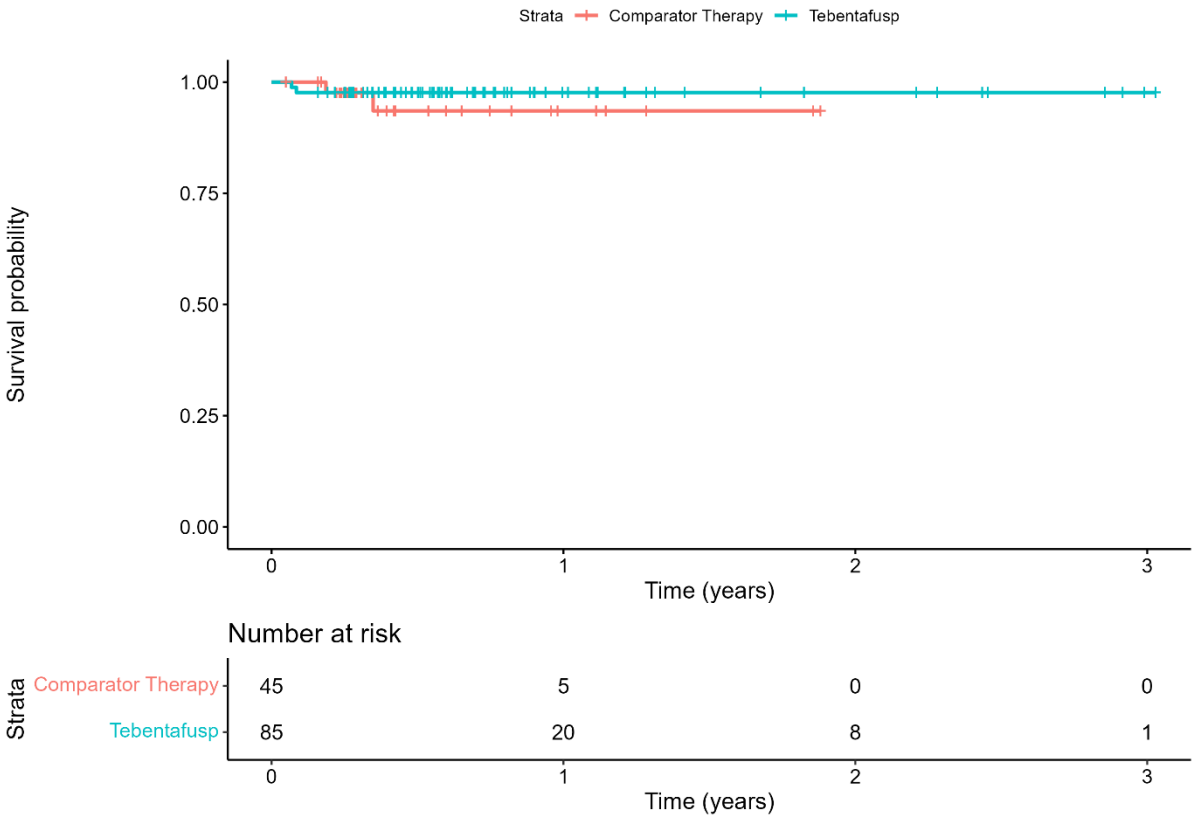
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



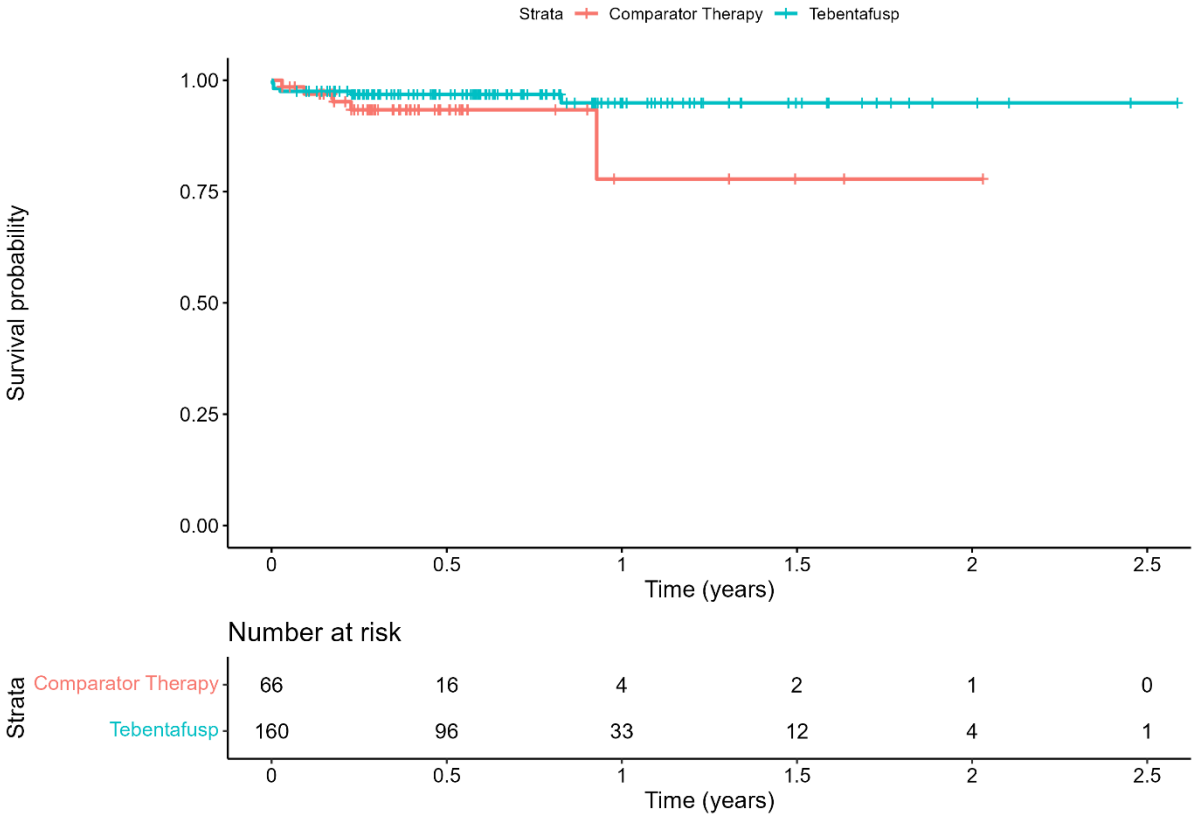
Größte metastatische Läsion (Baseline): ≥8,1 cm



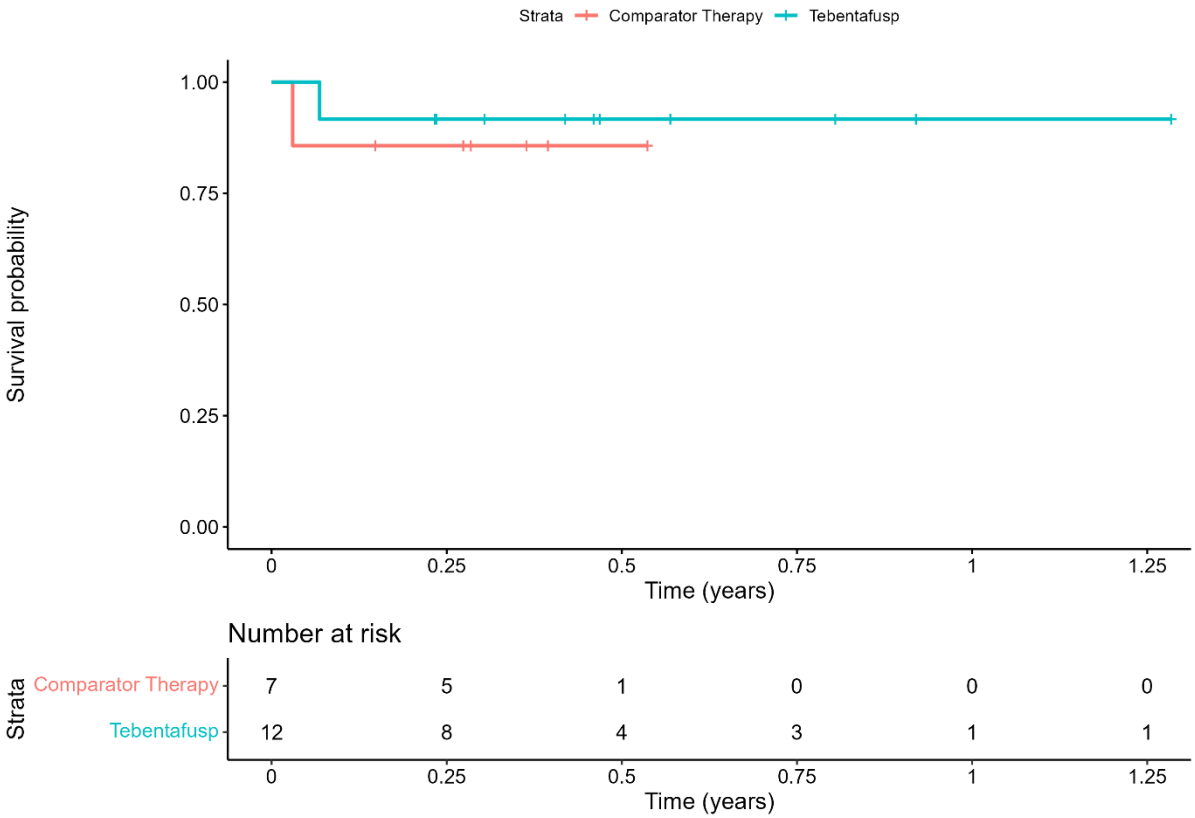
Region: Nordamerika



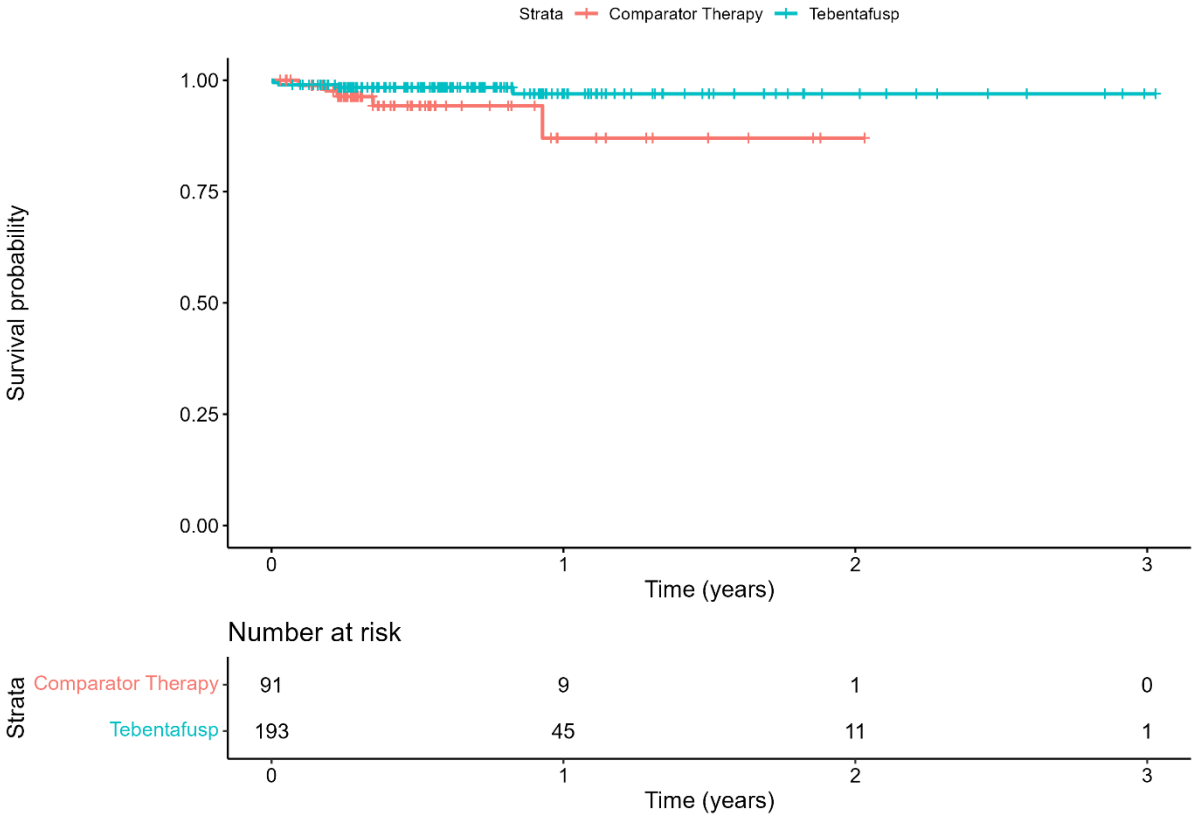
Region: Nicht-Nordamerika



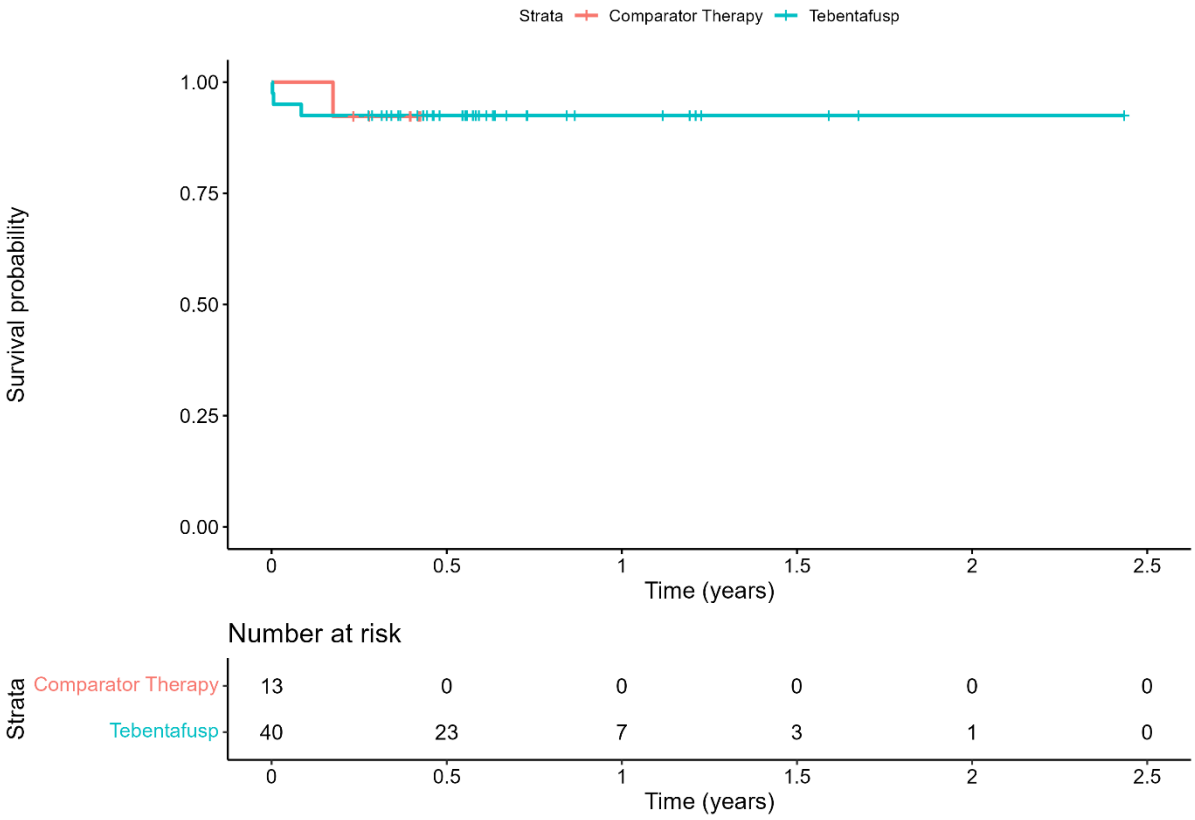
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

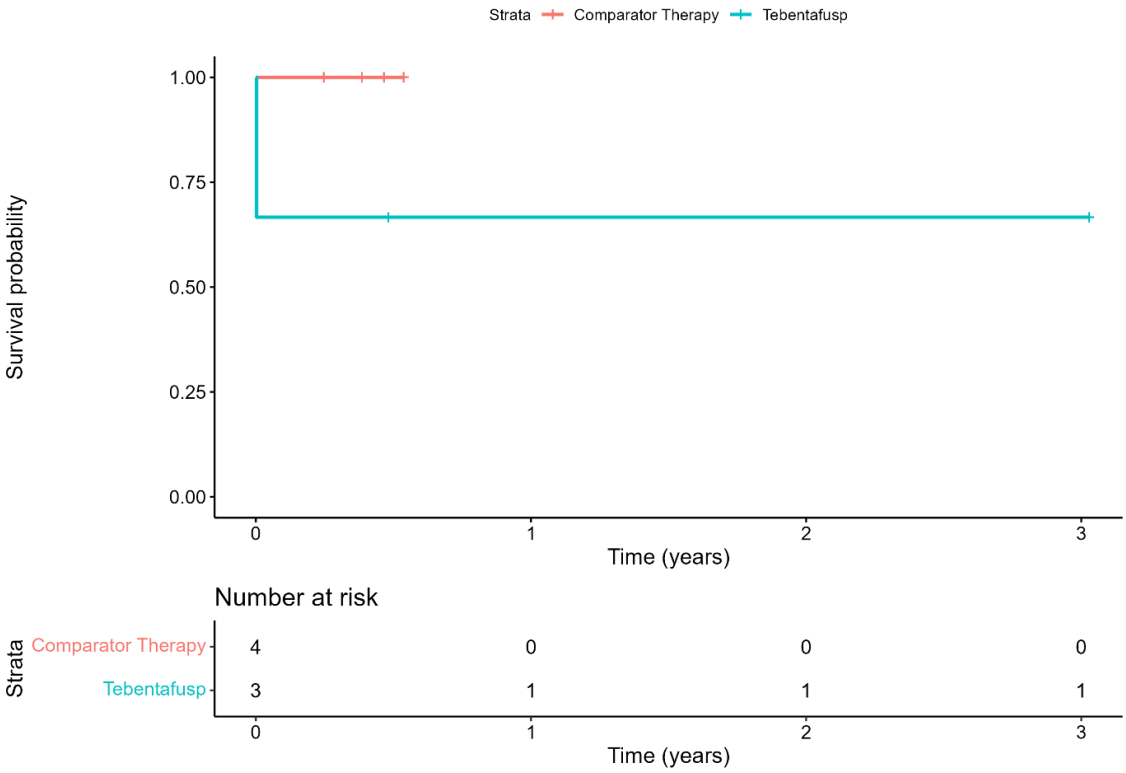


Vorauswahl der Chemotherapie: Ipilimumab

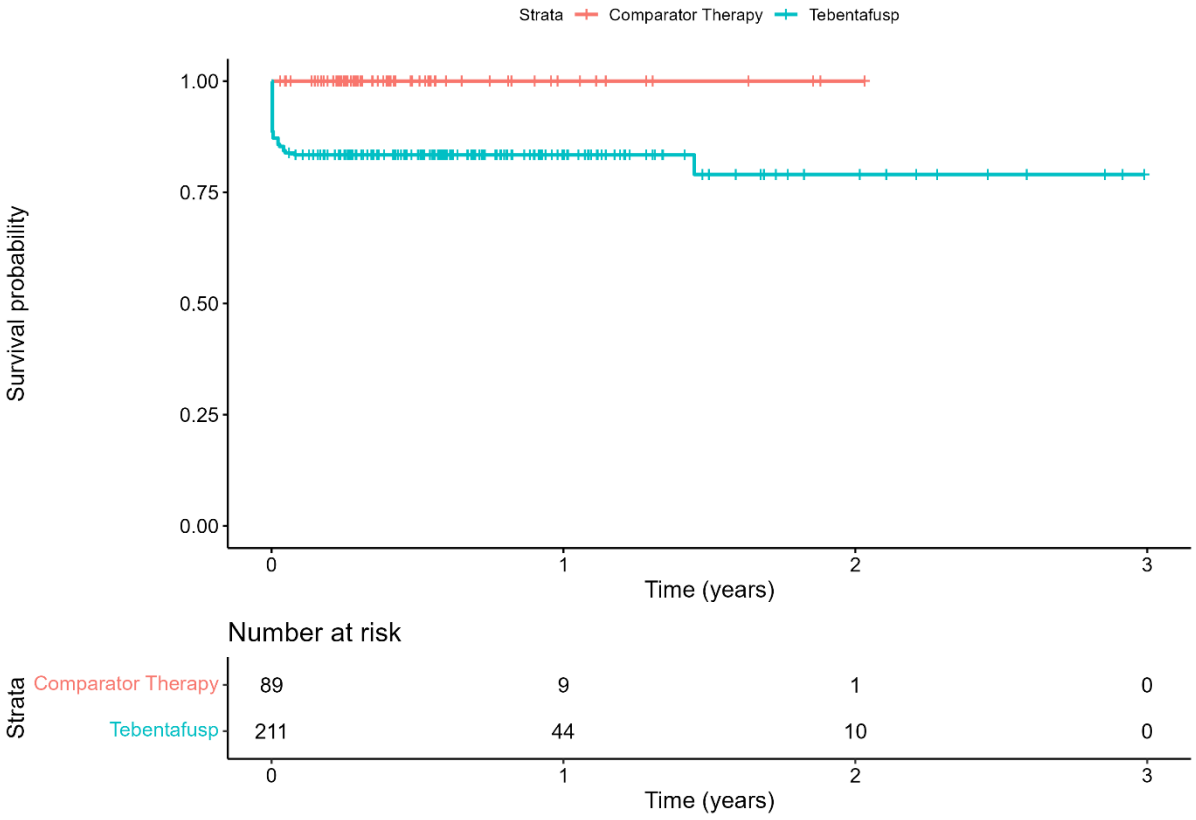


20.1 Zytokin-Freisetzungssyndrom (CRS) (Tabelle 4-95)

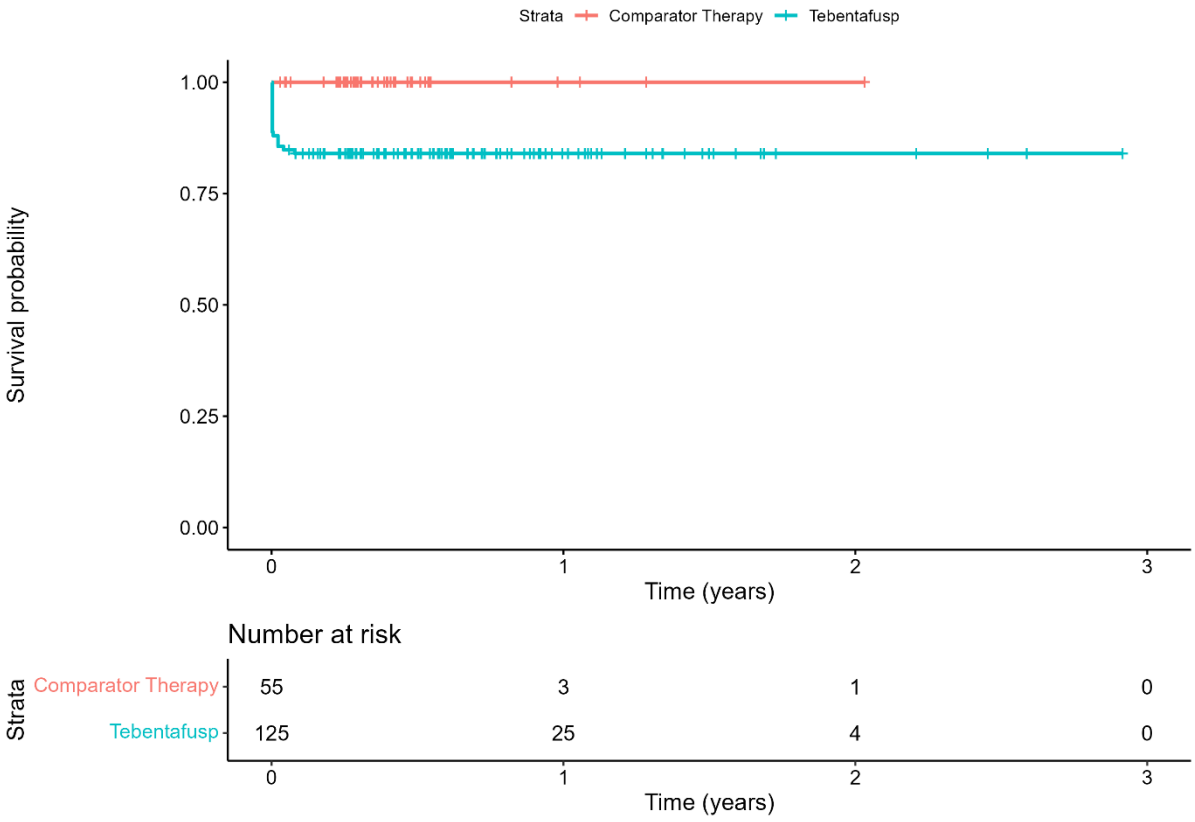
Herkunft: Hispanisch



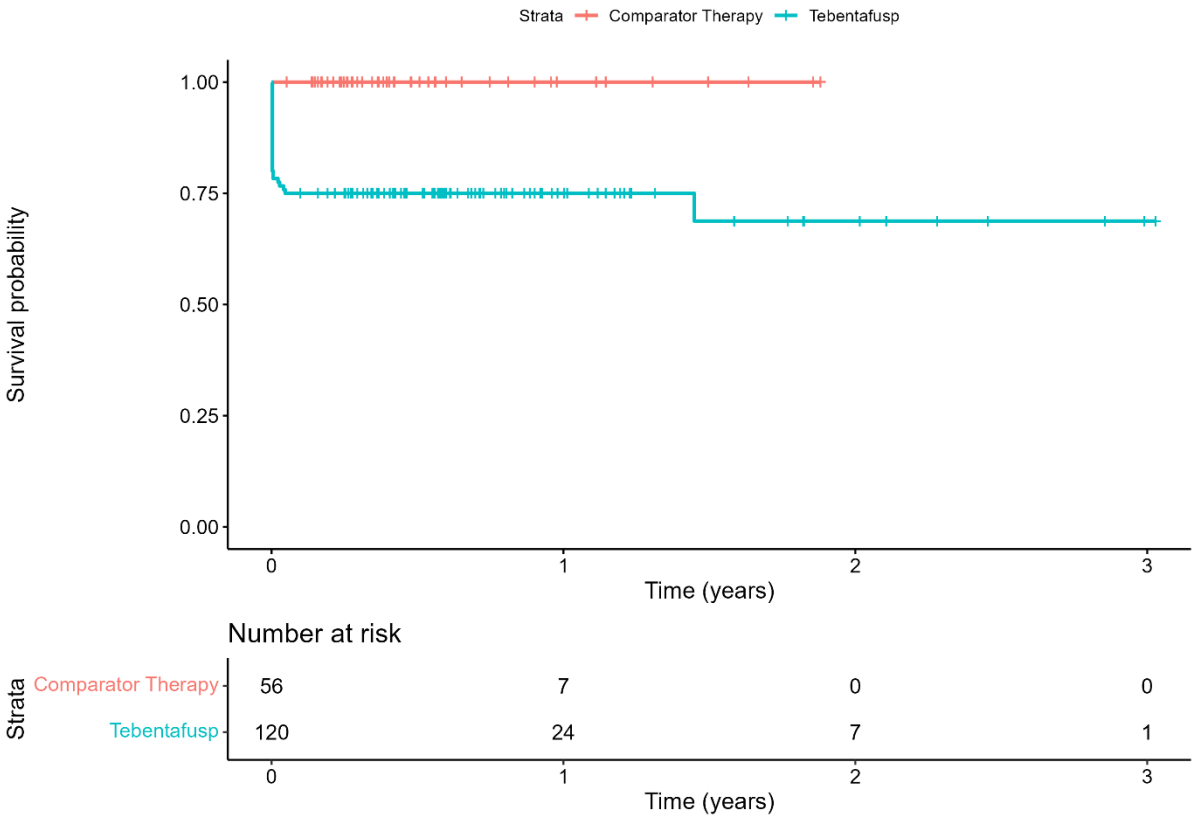
Herkunft: Nicht-hispanisch



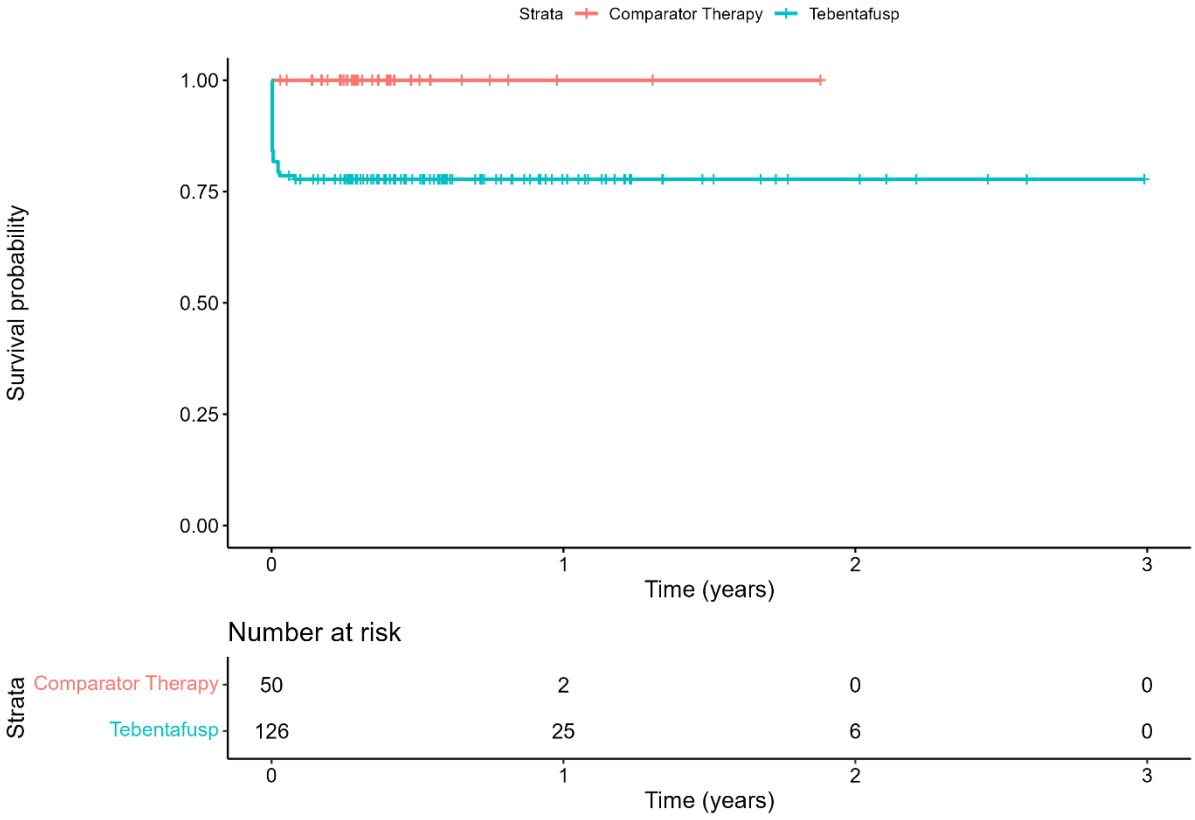
Geschlecht: Männlich



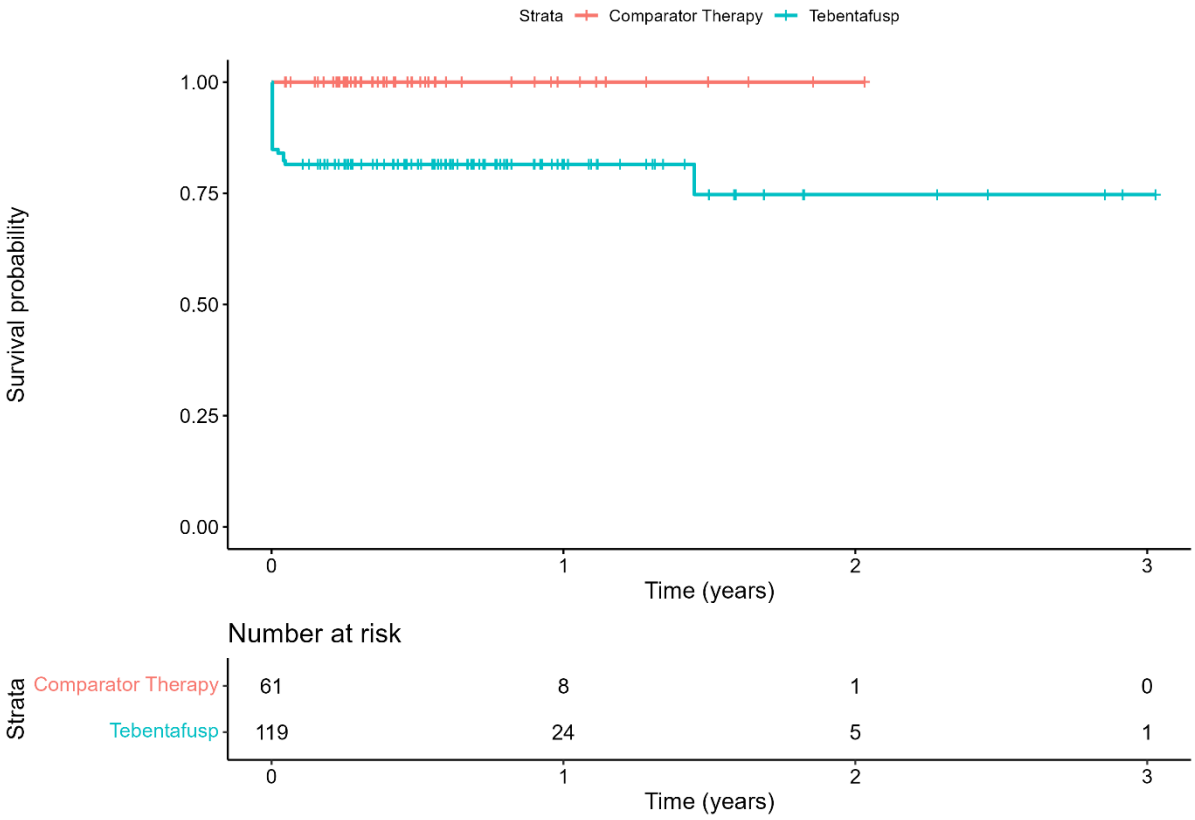
Geschlecht: Weiblich



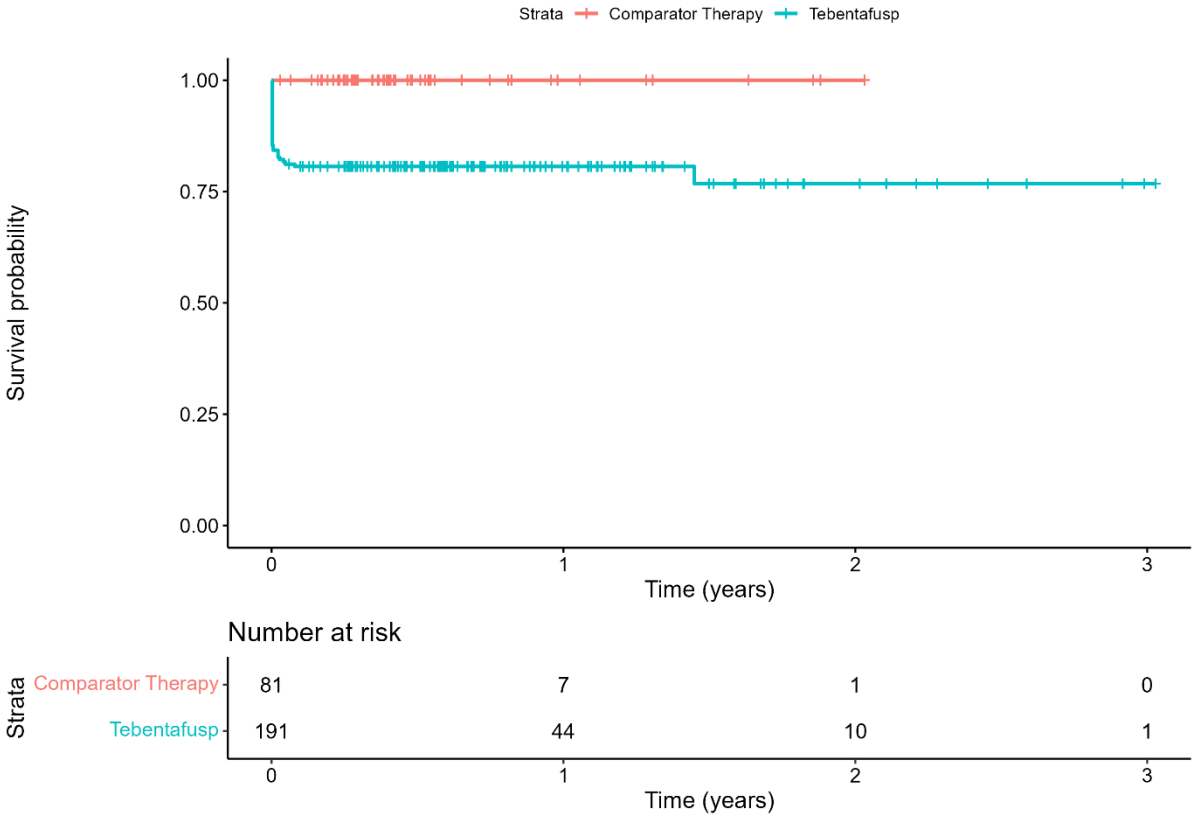
Alter: <65 Jahre



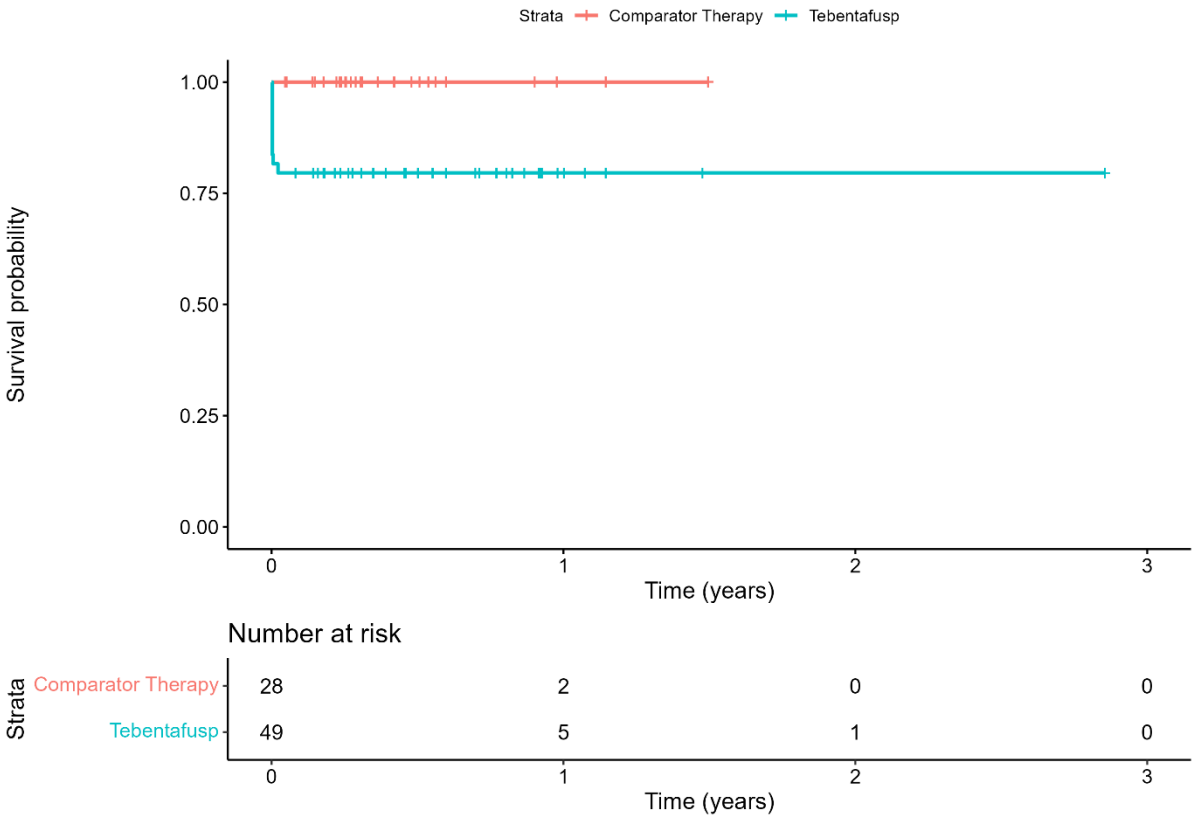
Alter: ≥65 Jahre



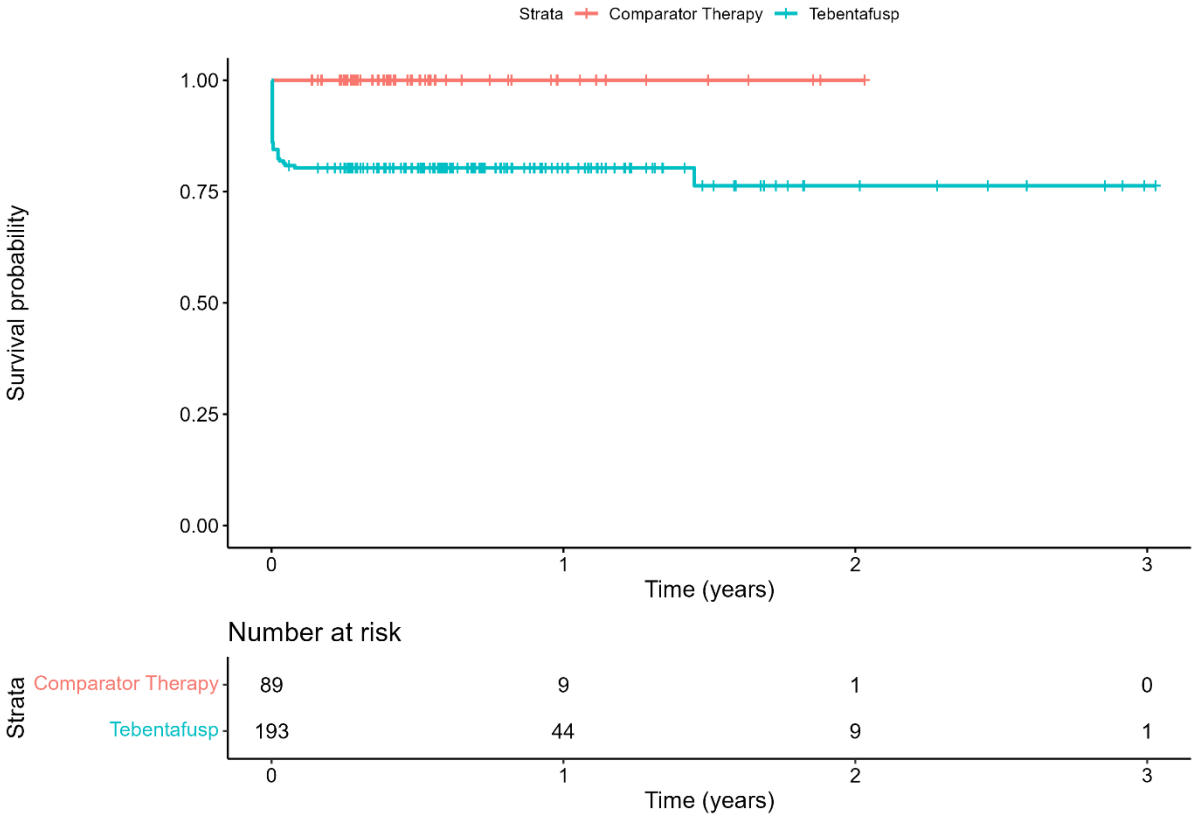
ECOG-Performance-Status: 0



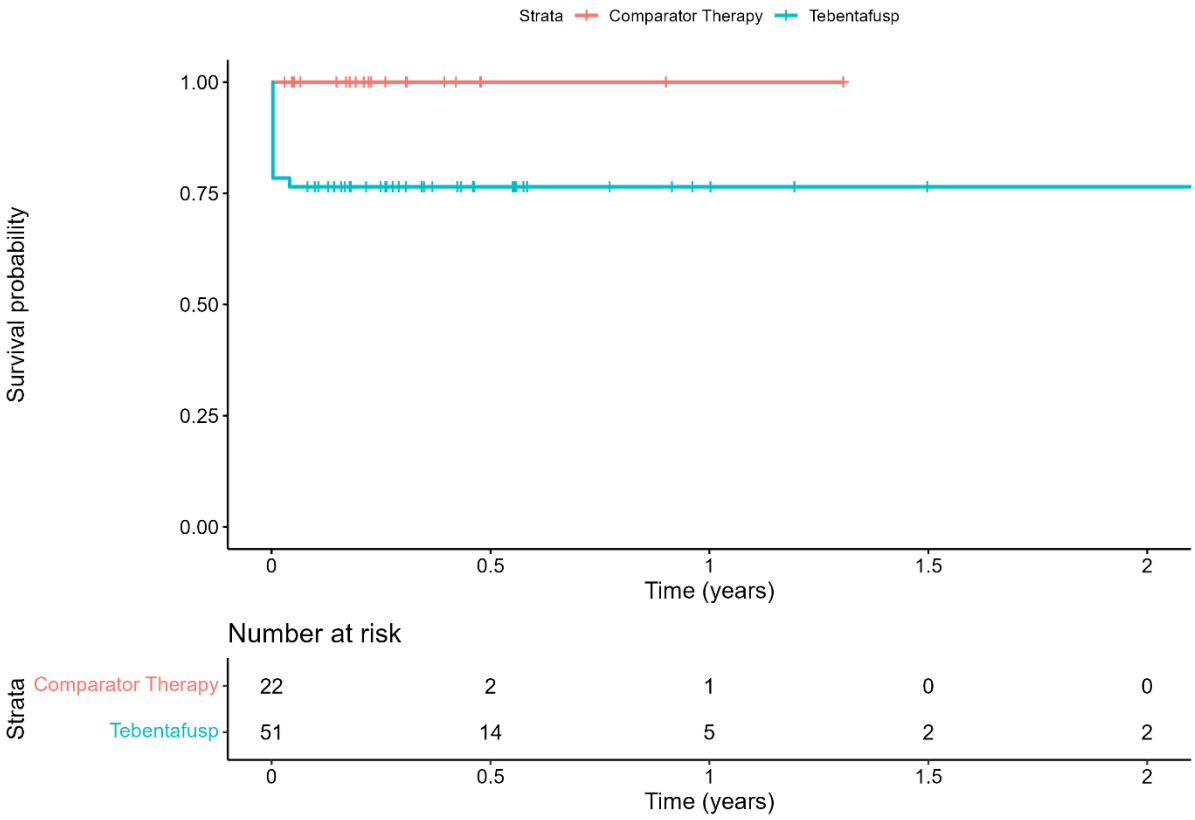
ECOG-Performance-Status: 1



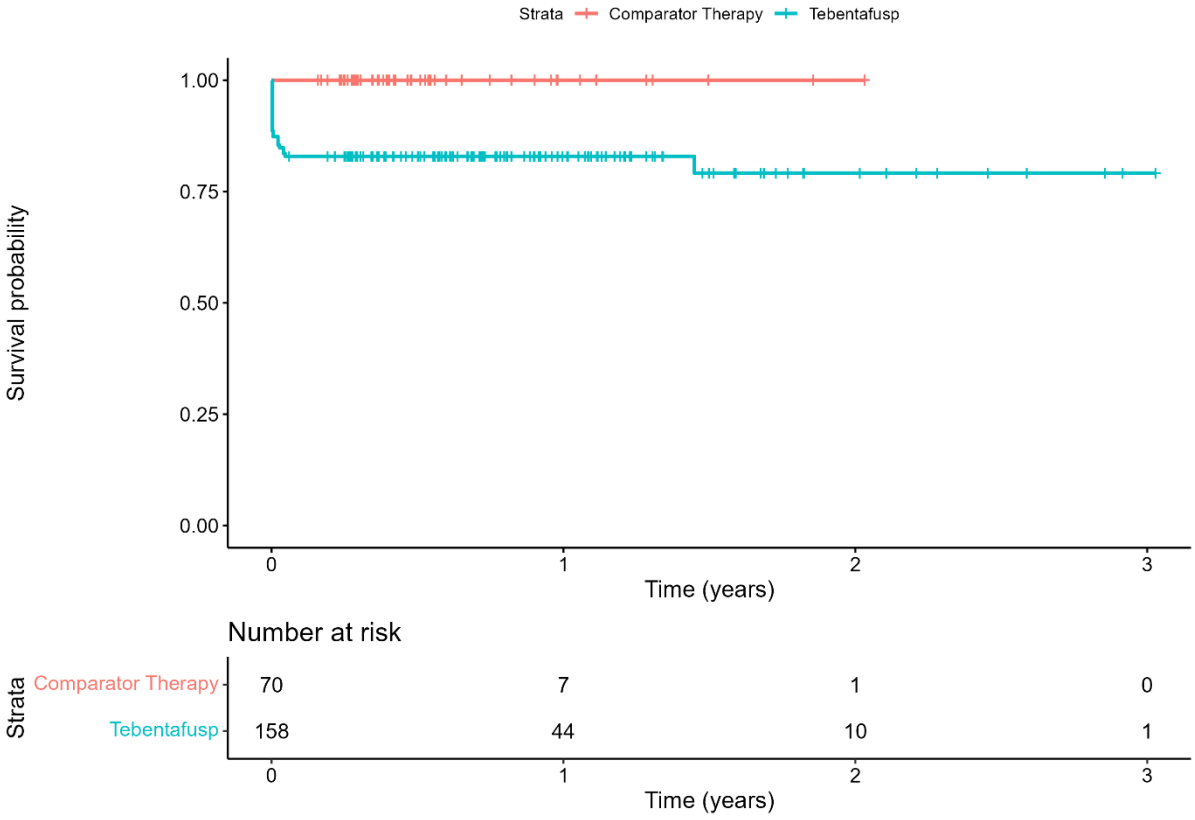
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



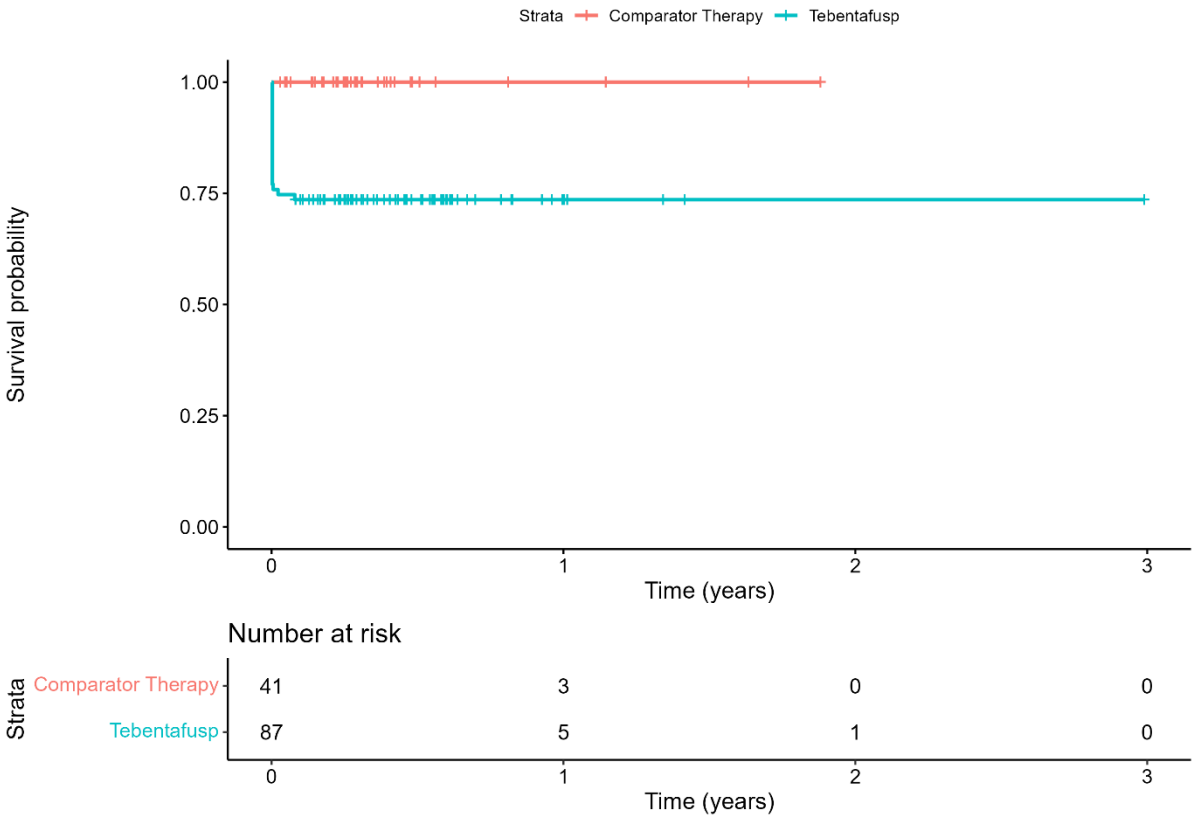
Alkalische Phosphatase (ALP) (Baseline): >ULN



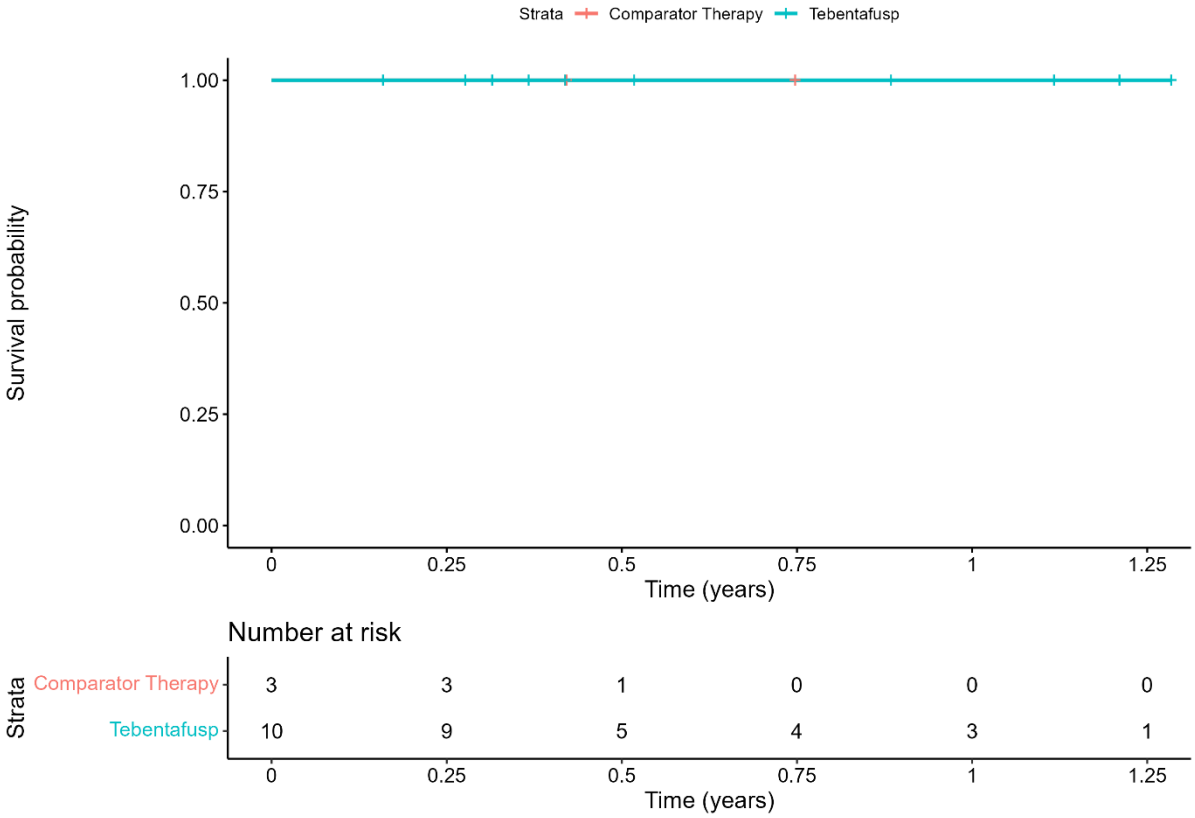
LDH: ≤ULN



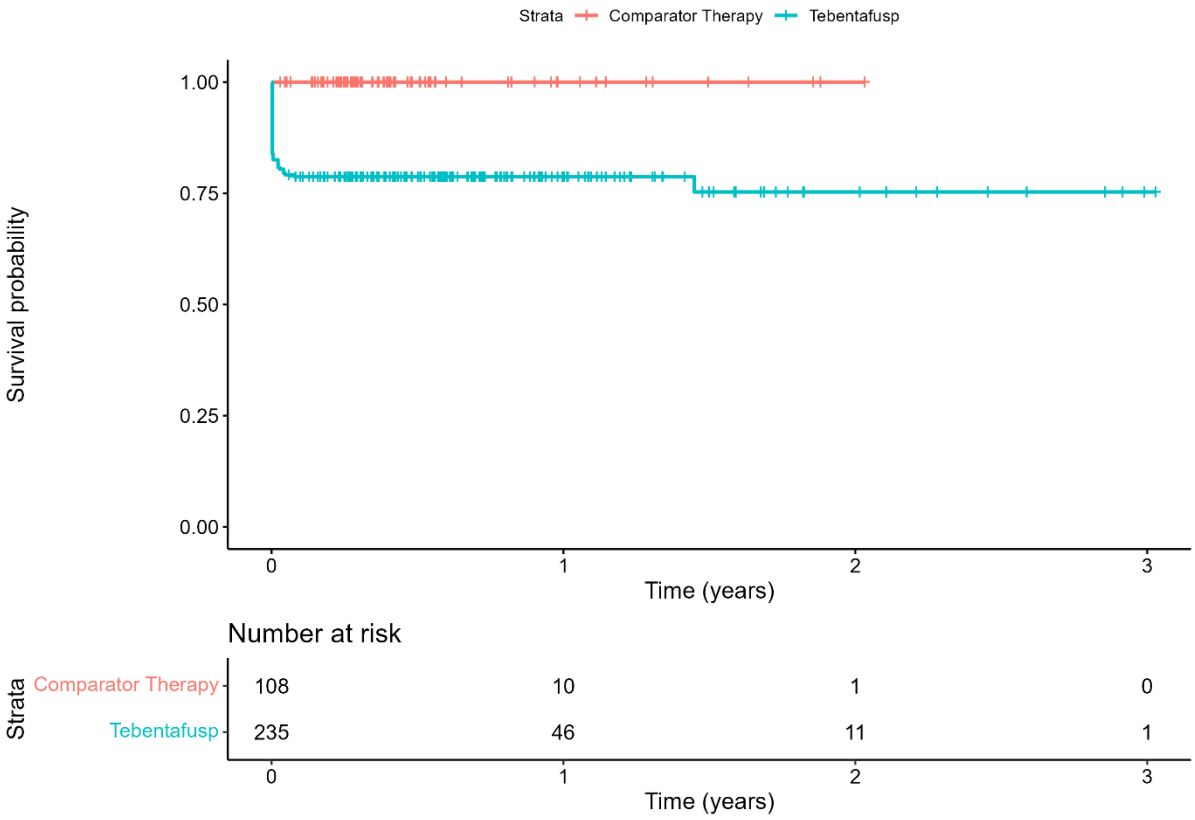
LDH: >ULN



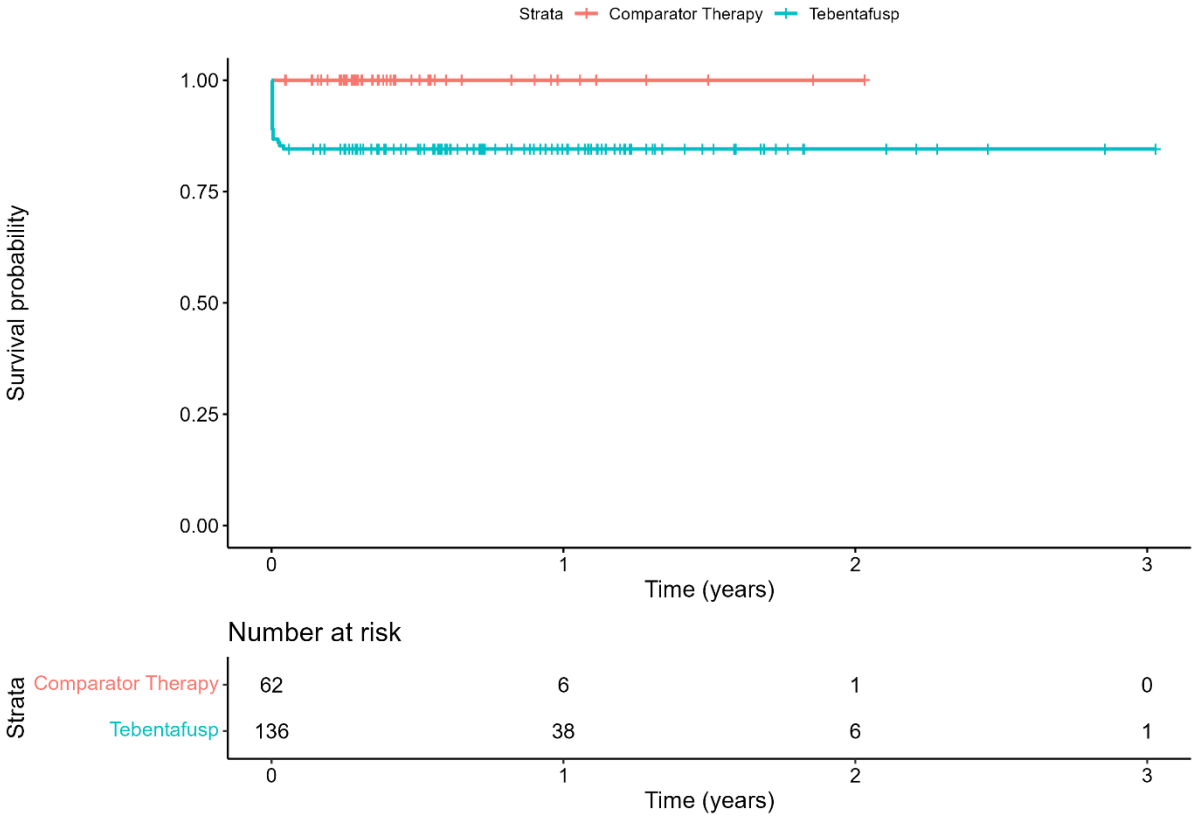
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



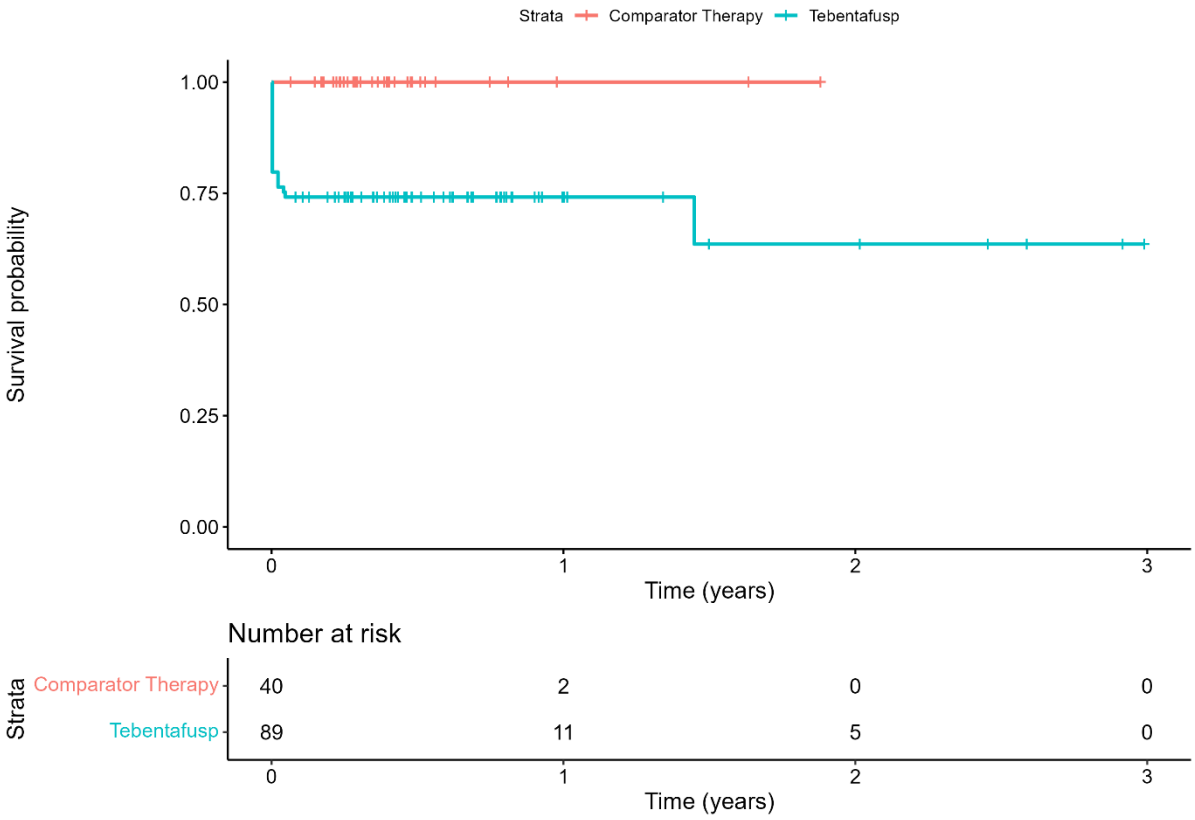
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



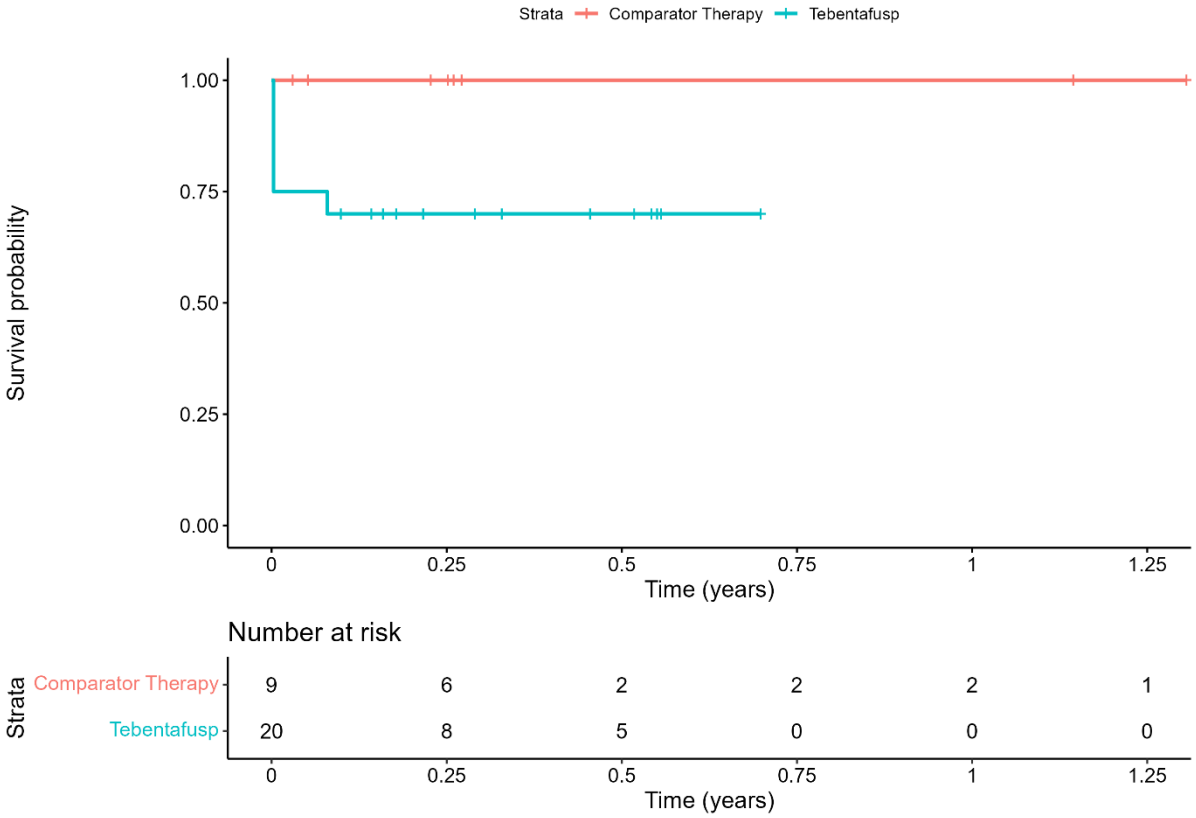
Größte metastatische Läsion (Baseline): ≤3,0 cm



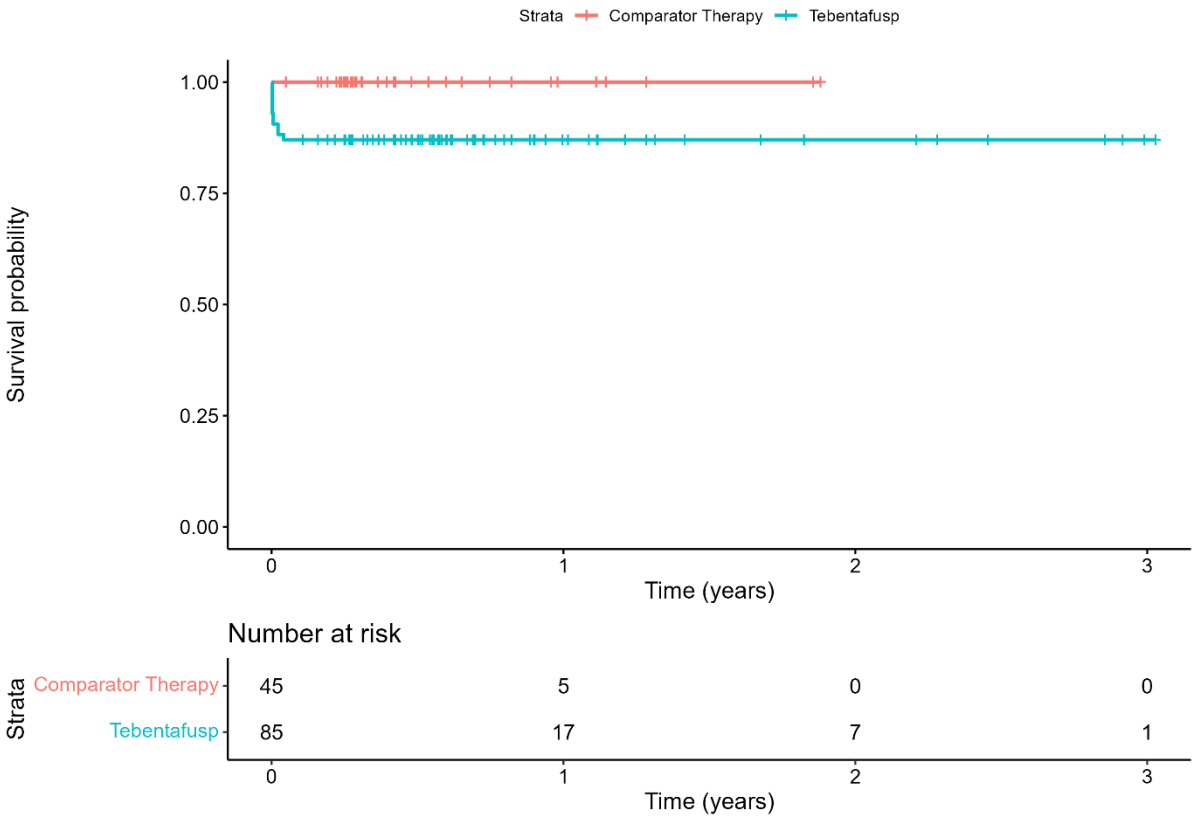
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



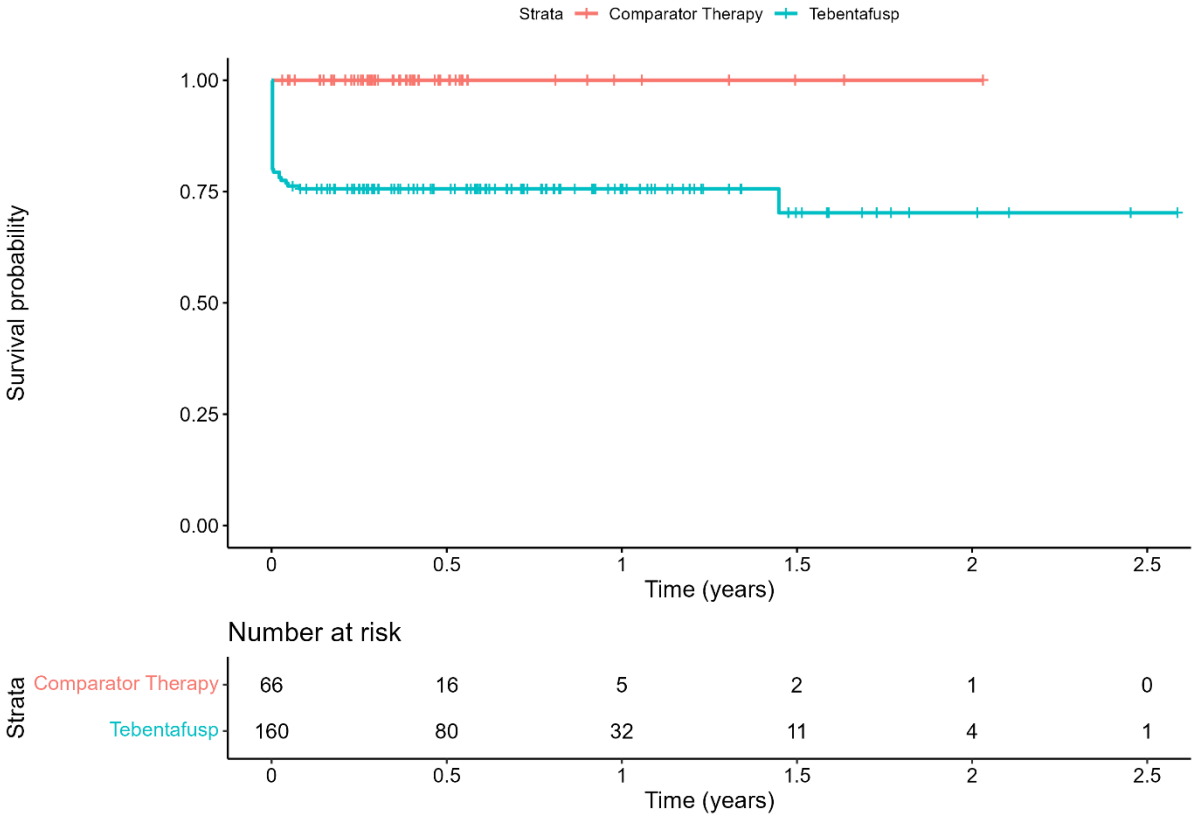
Größte metastatische Läsion (Baseline): ≥8,1 cm



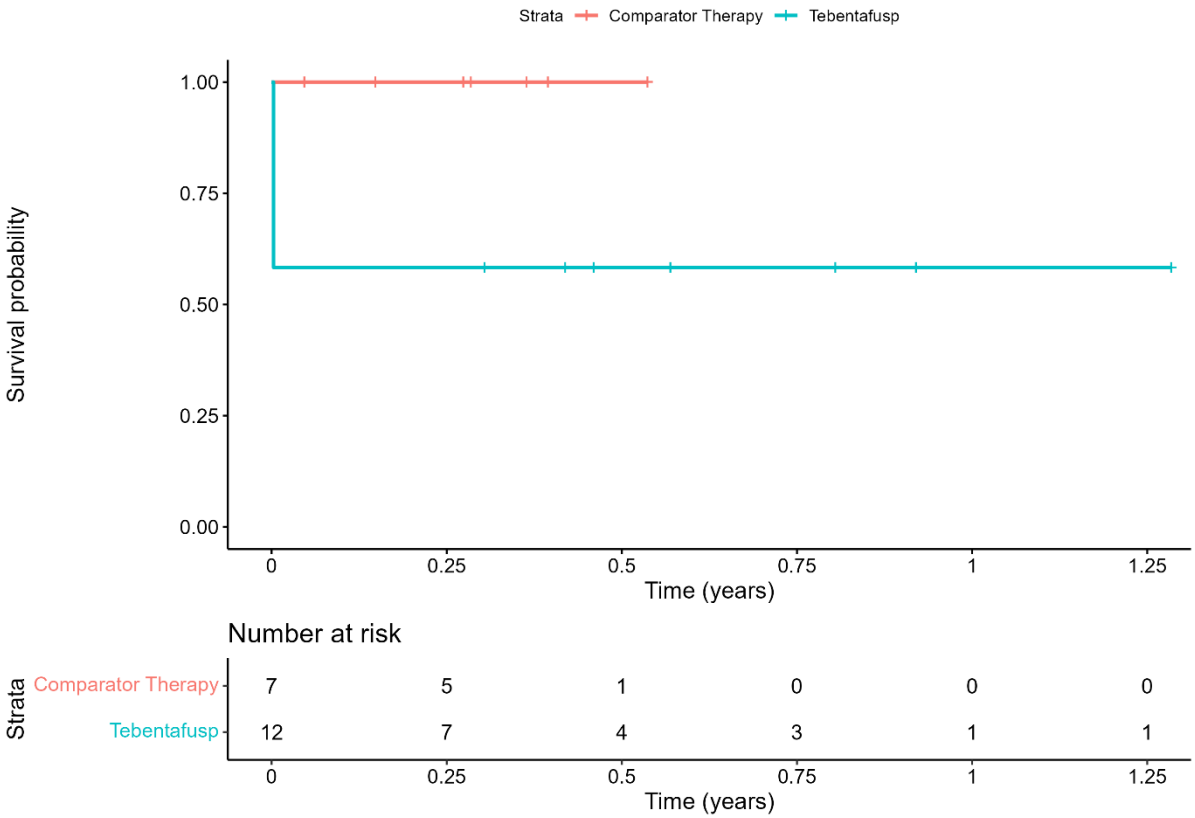
Region: Nordamerika



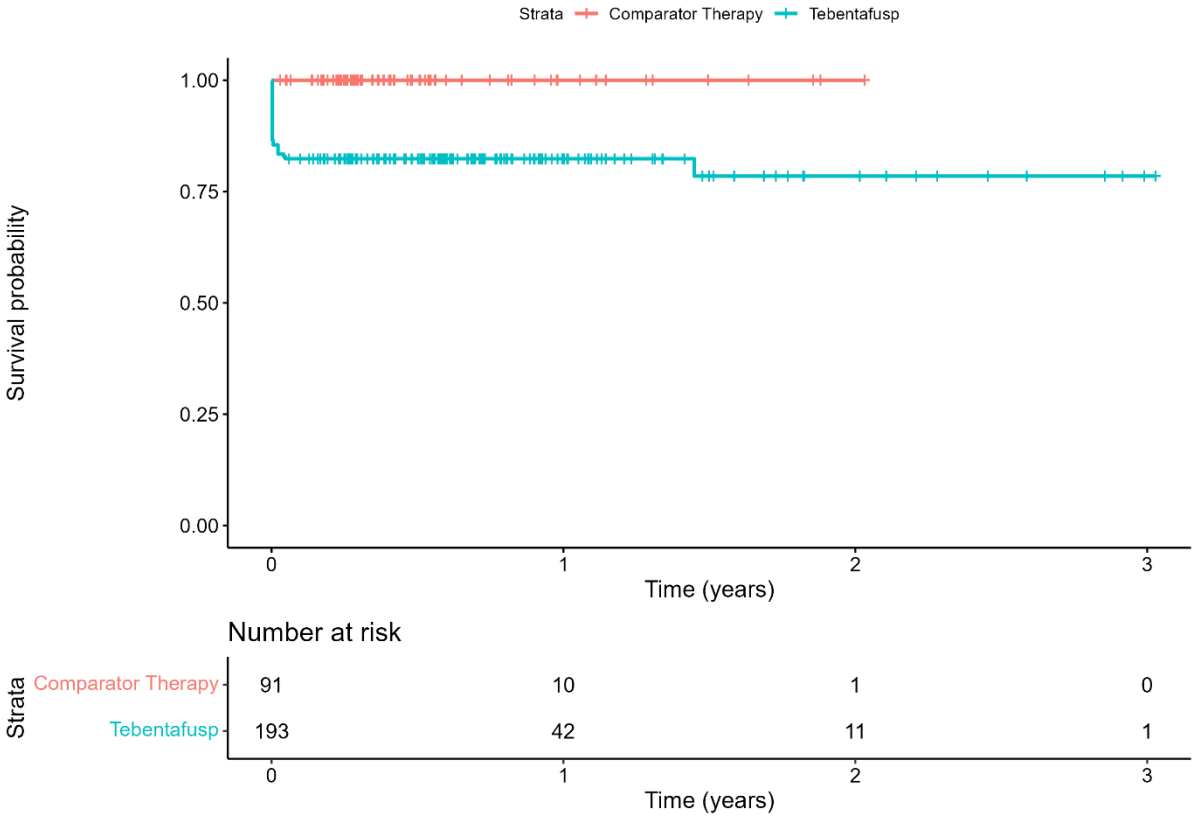
Region: Nicht-Nordamerika



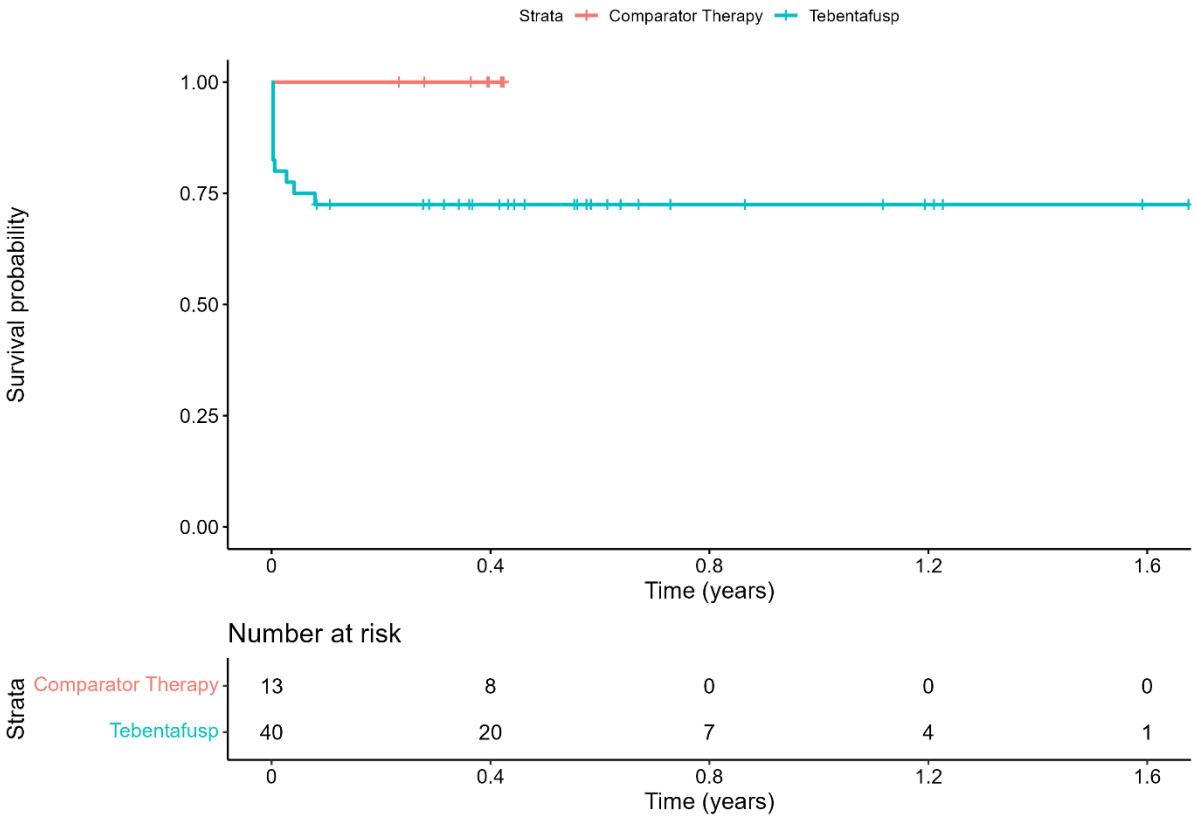
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

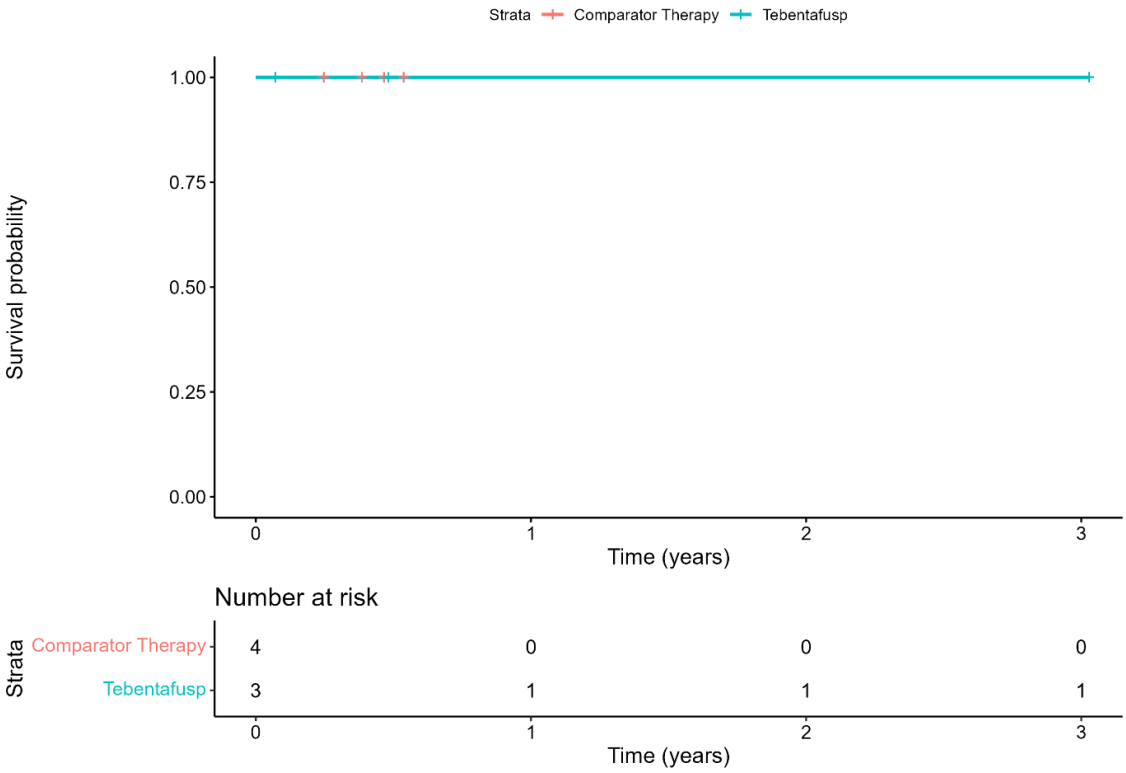


Vorauswahl der Chemotherapie: Ipilimumab

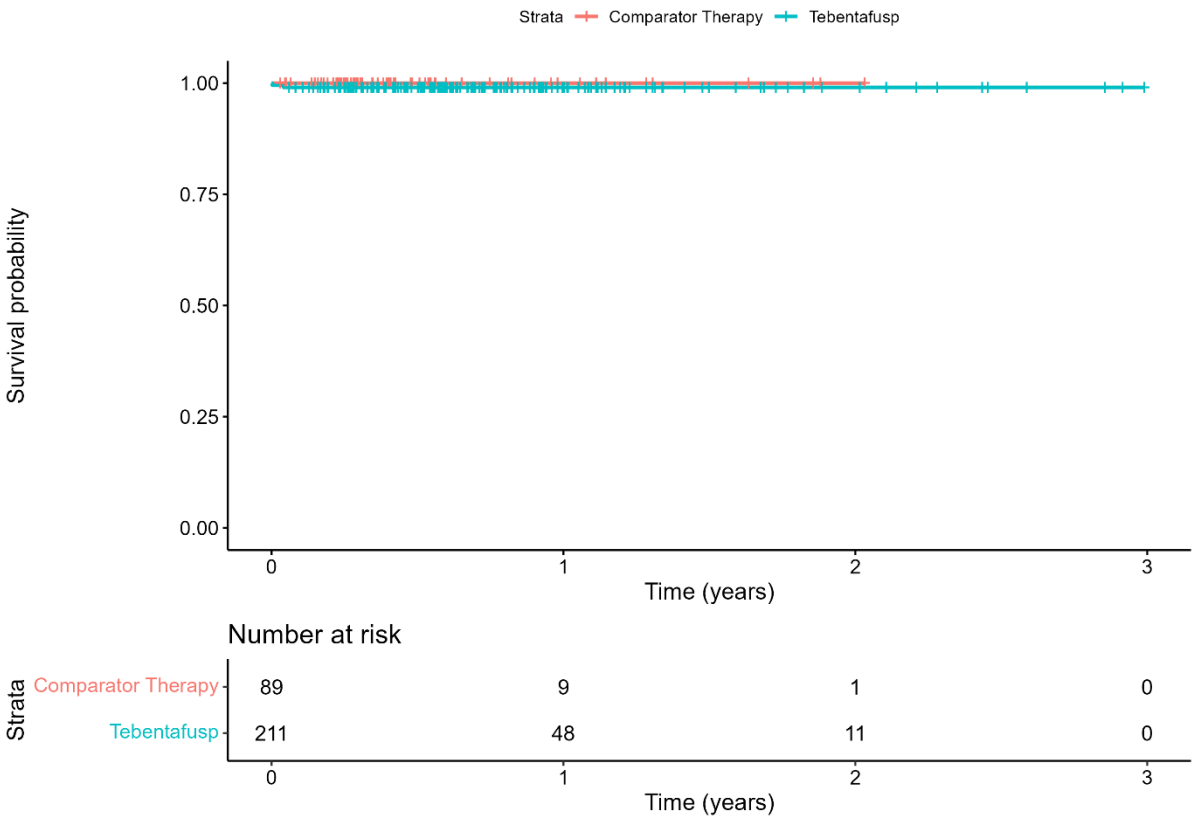


21.1 Zytokin-Freisetzungssyndrom mit CTCAE-Grad ≥ 3 (Tabelle 4-97)

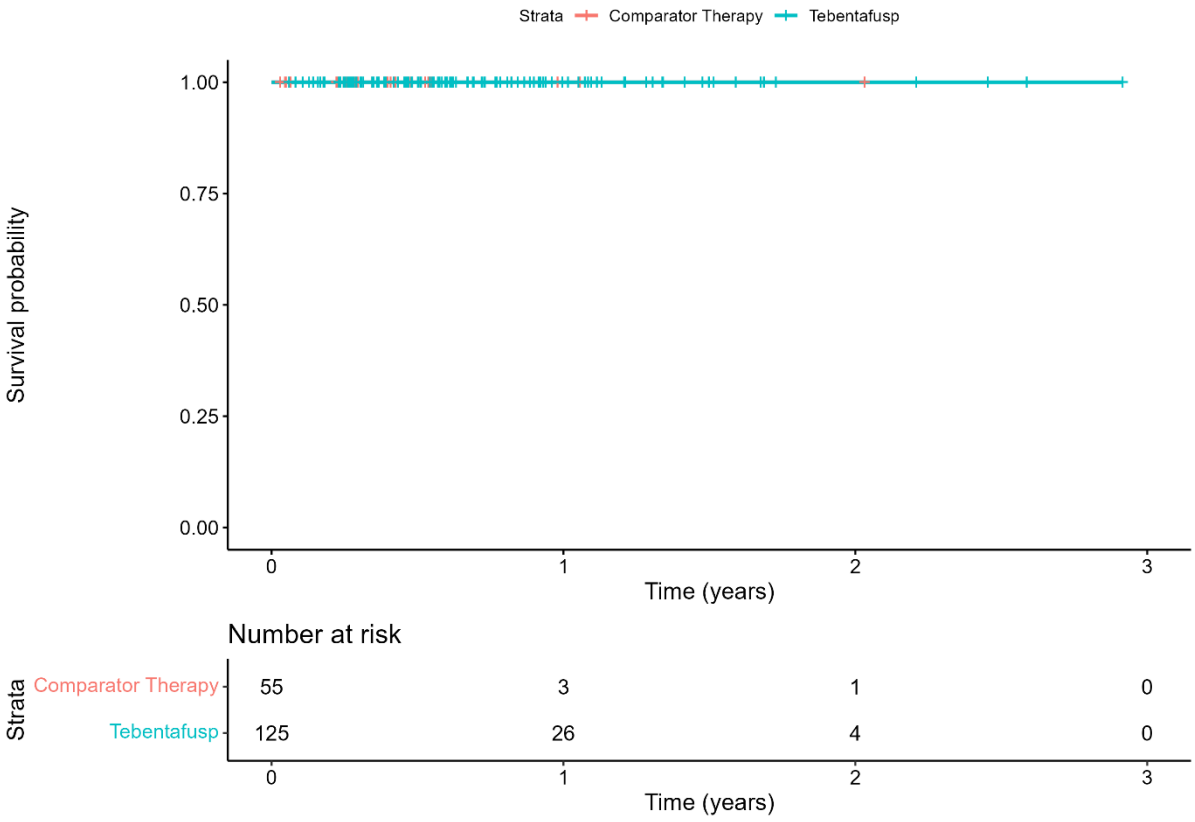
Herkunft: Hispanisch



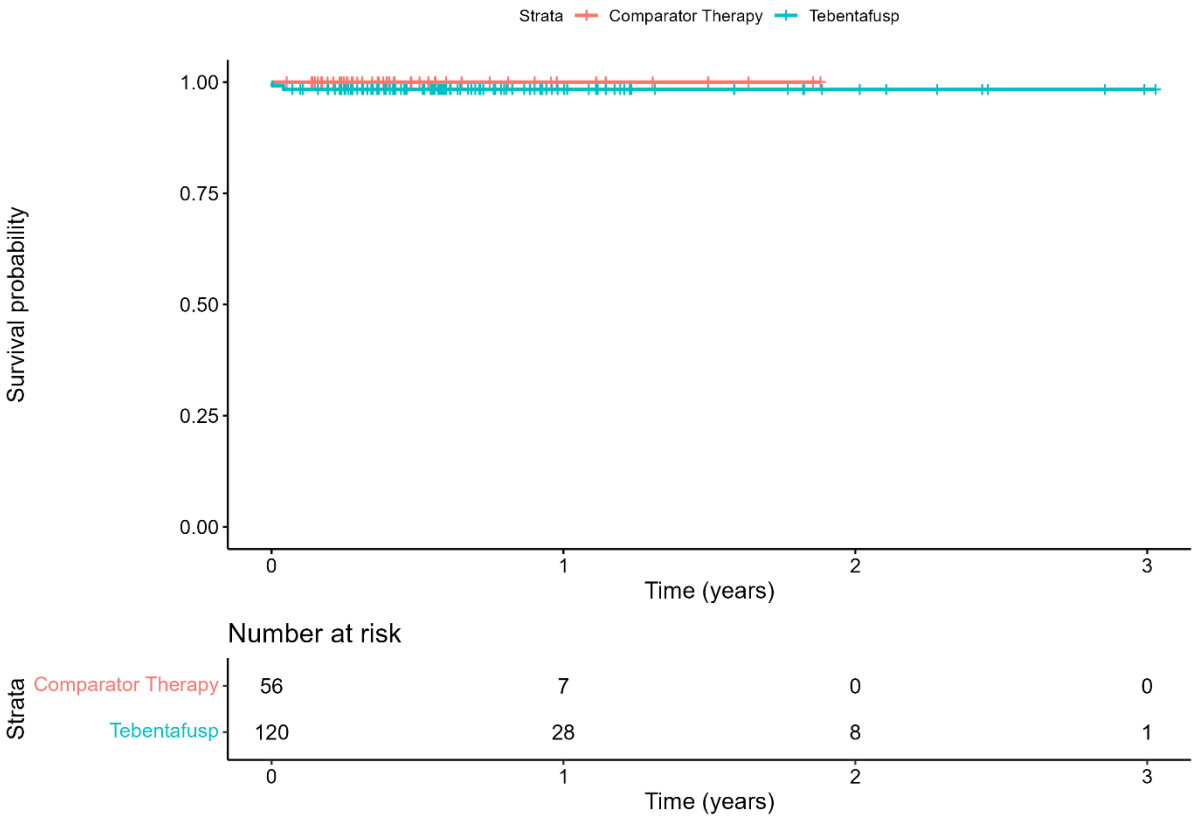
Herkunft: Nicht-hispanisch



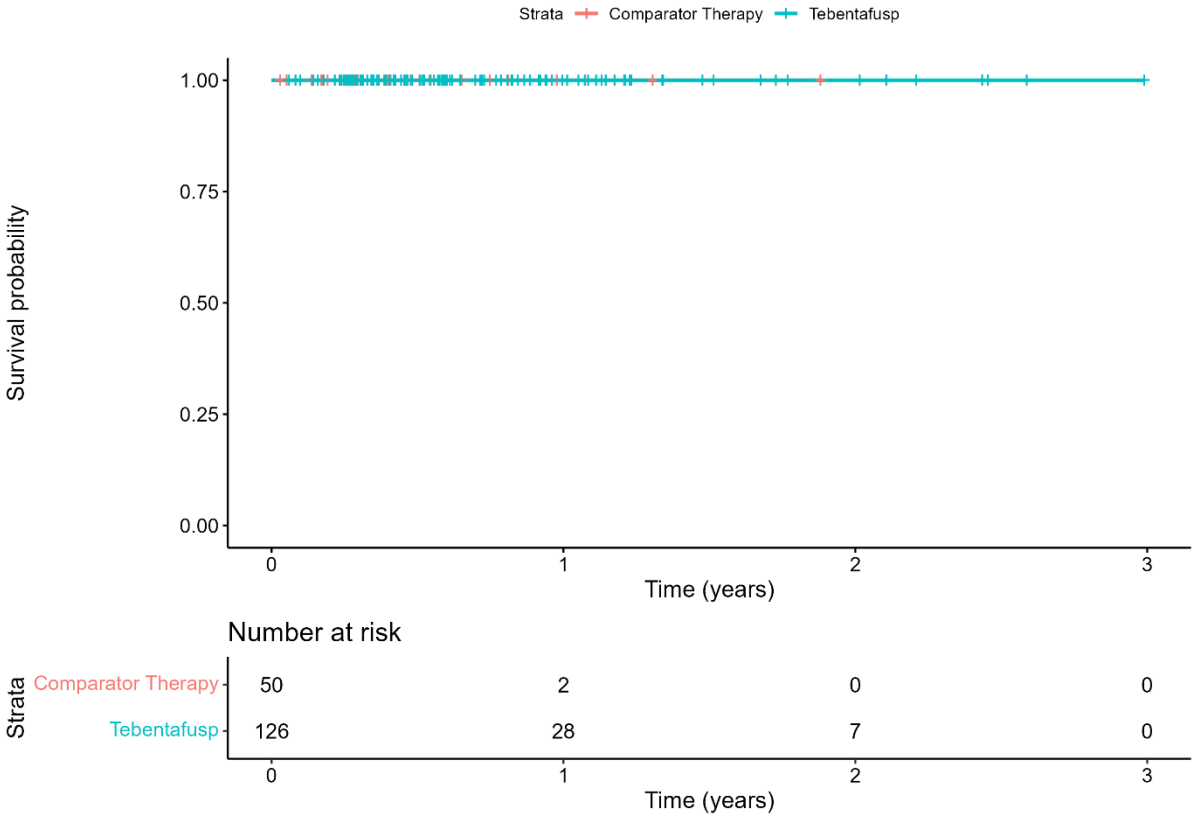
Geschlecht: Männlich



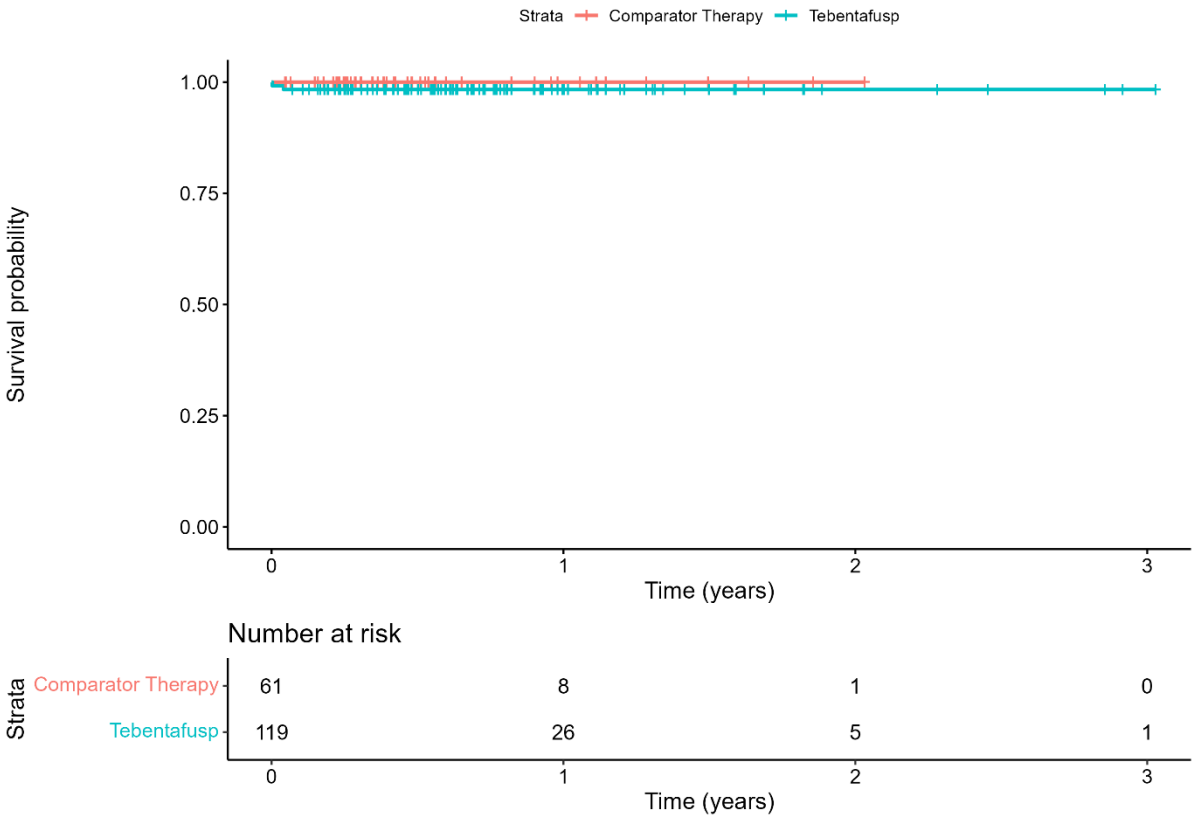
Geschlecht: Weiblich



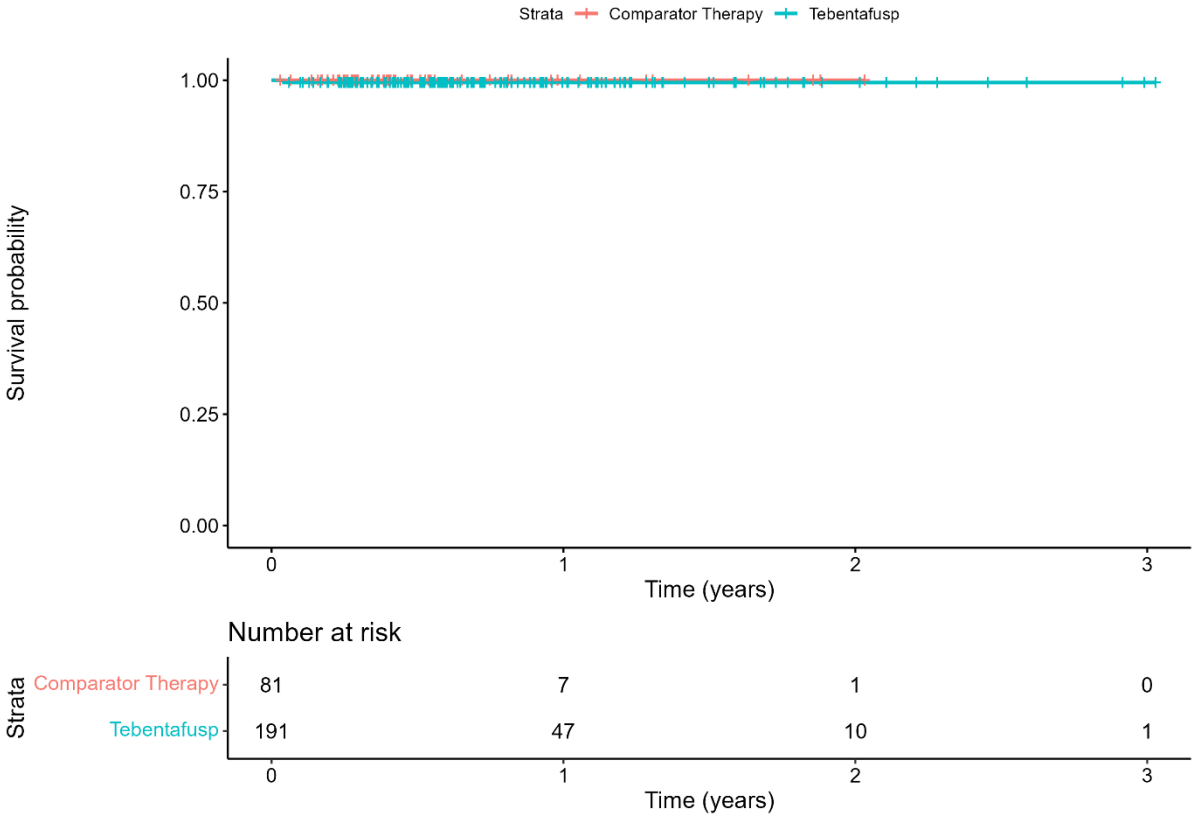
Alter: <65 Jahre



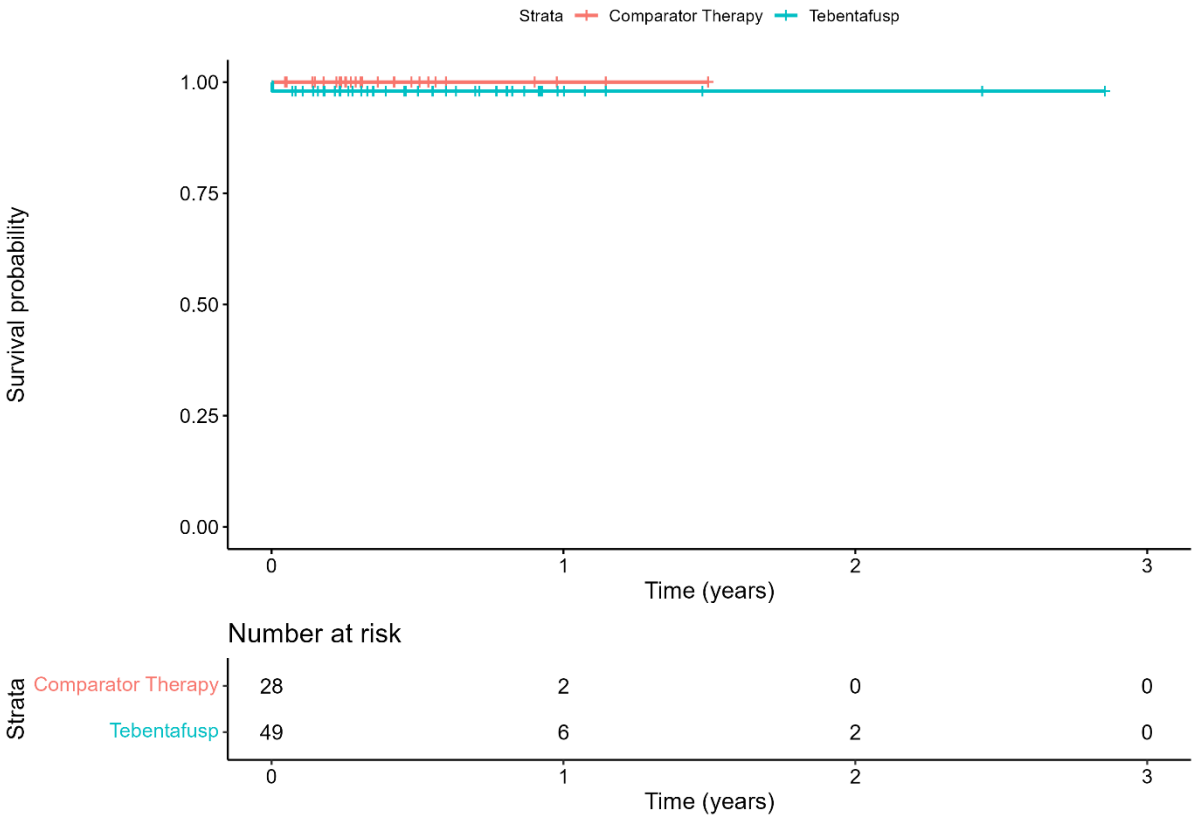
Alter: ≥65 Jahre



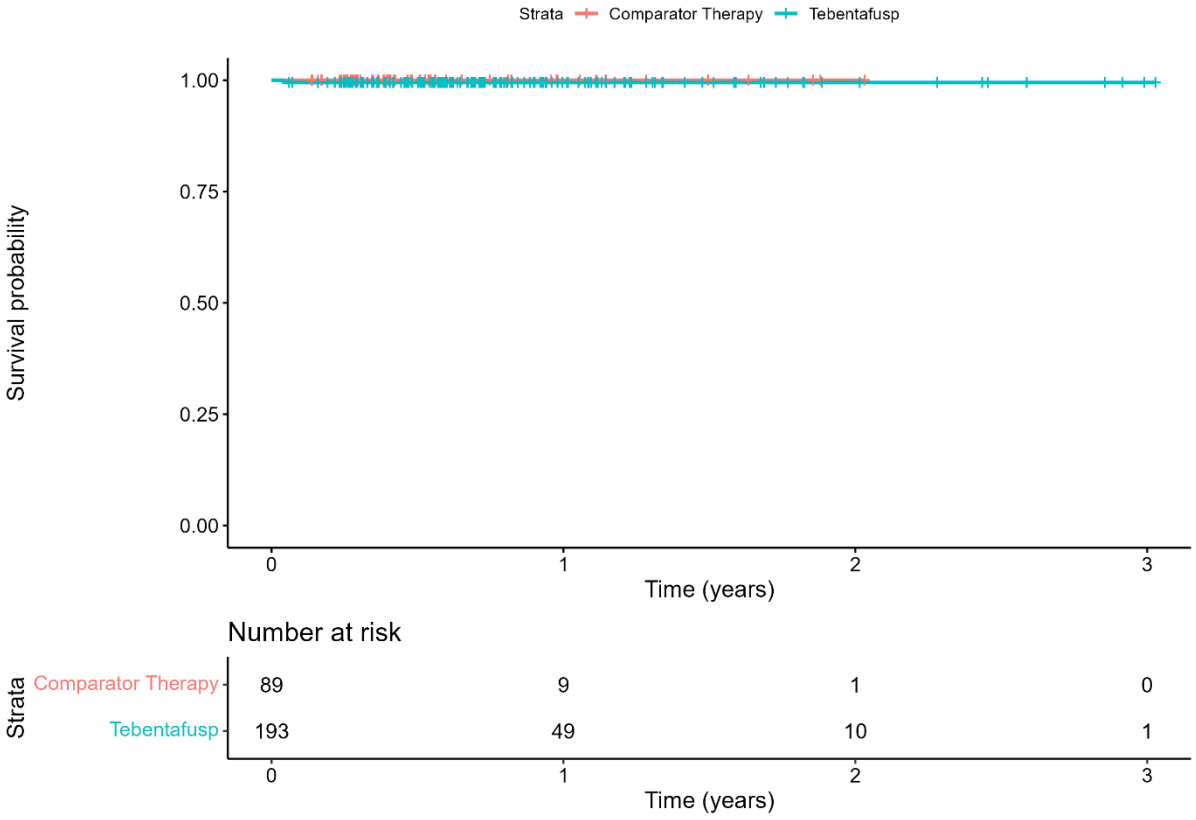
ECOG-Performance-Status: 0



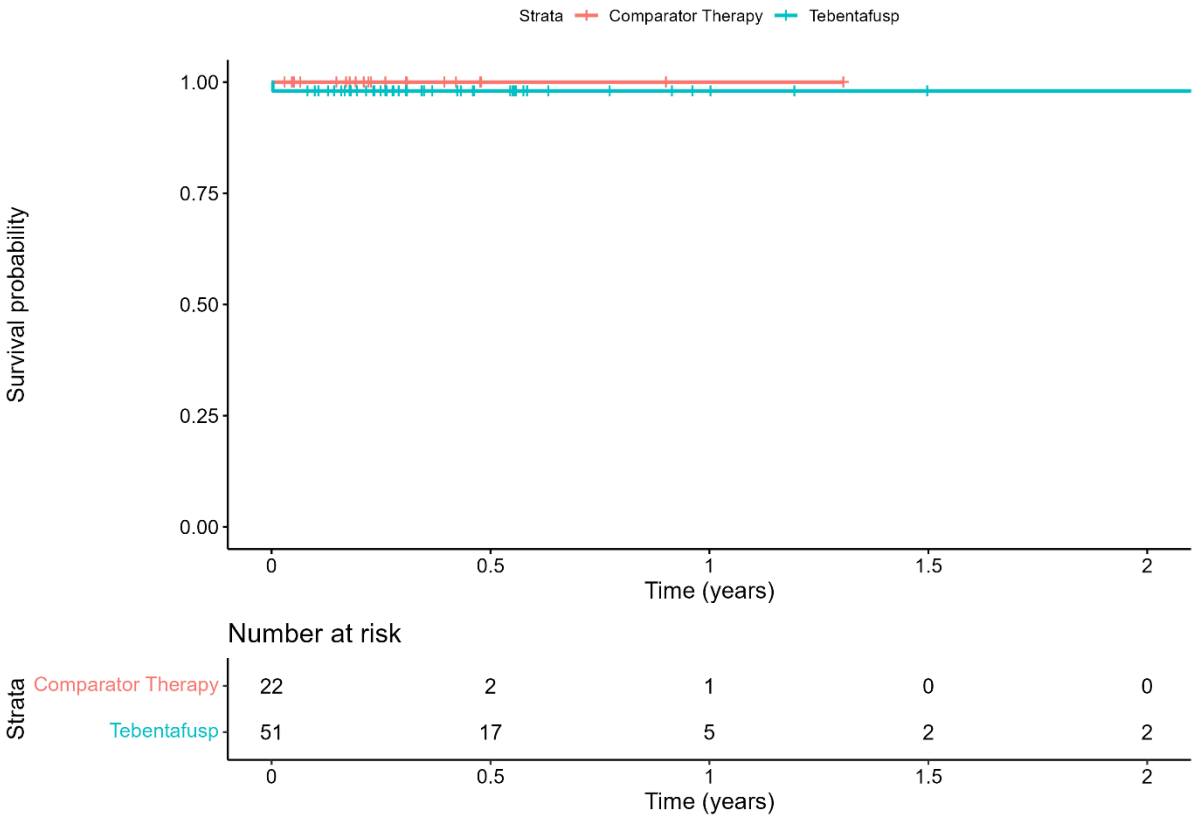
ECOG-Performance-Status: 1



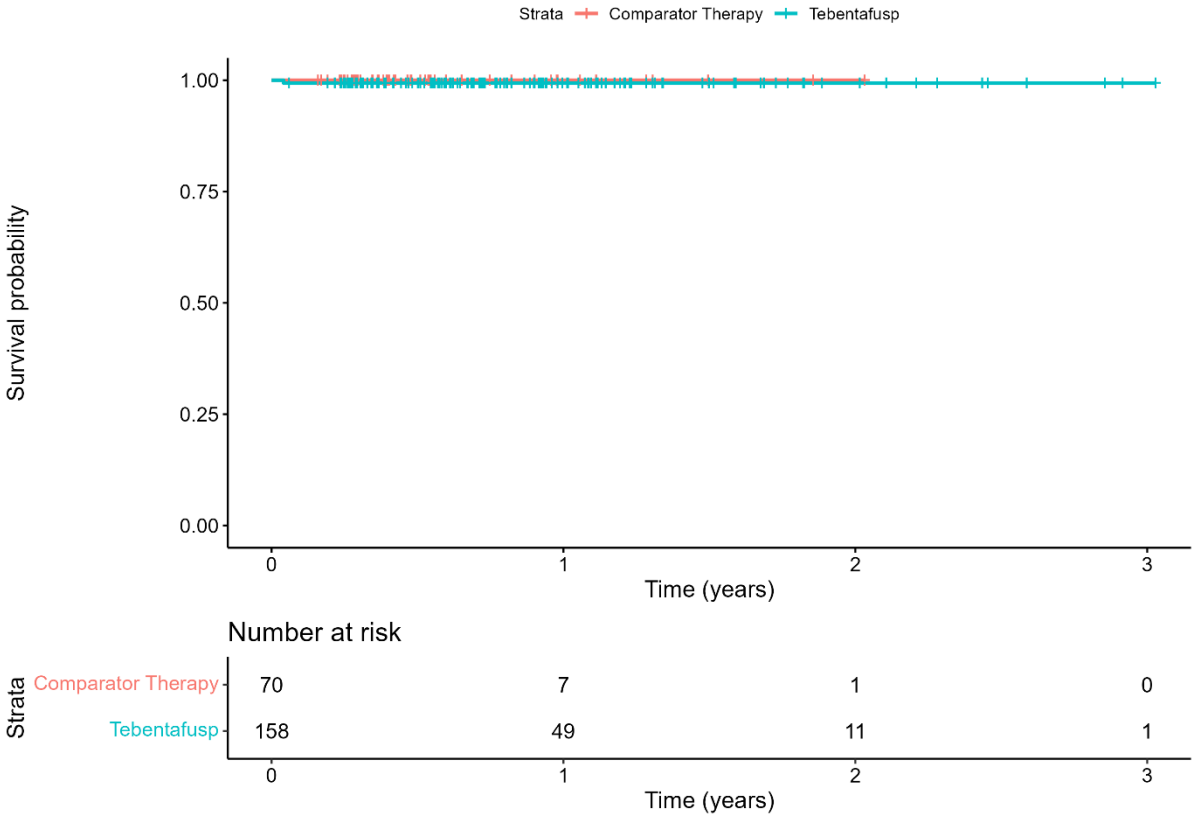
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



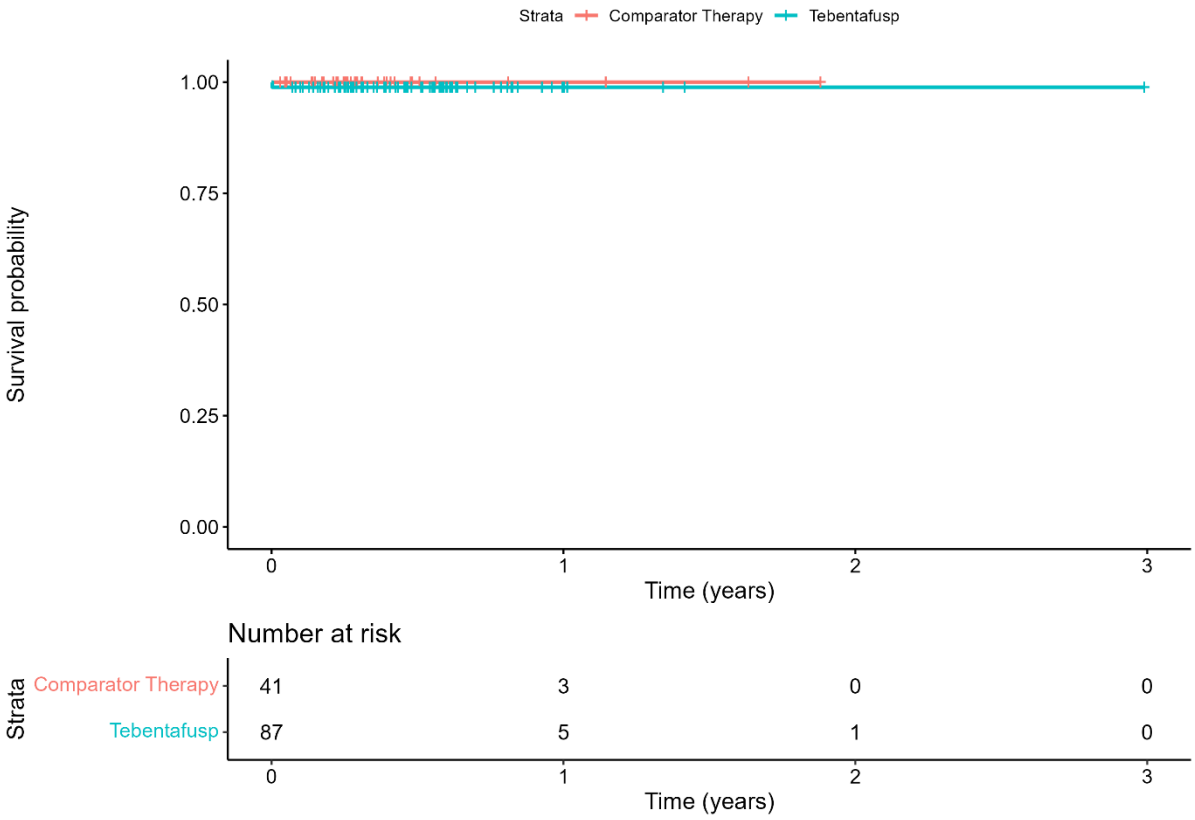
Alkalische Phosphatase (ALP) (Baseline): >ULN



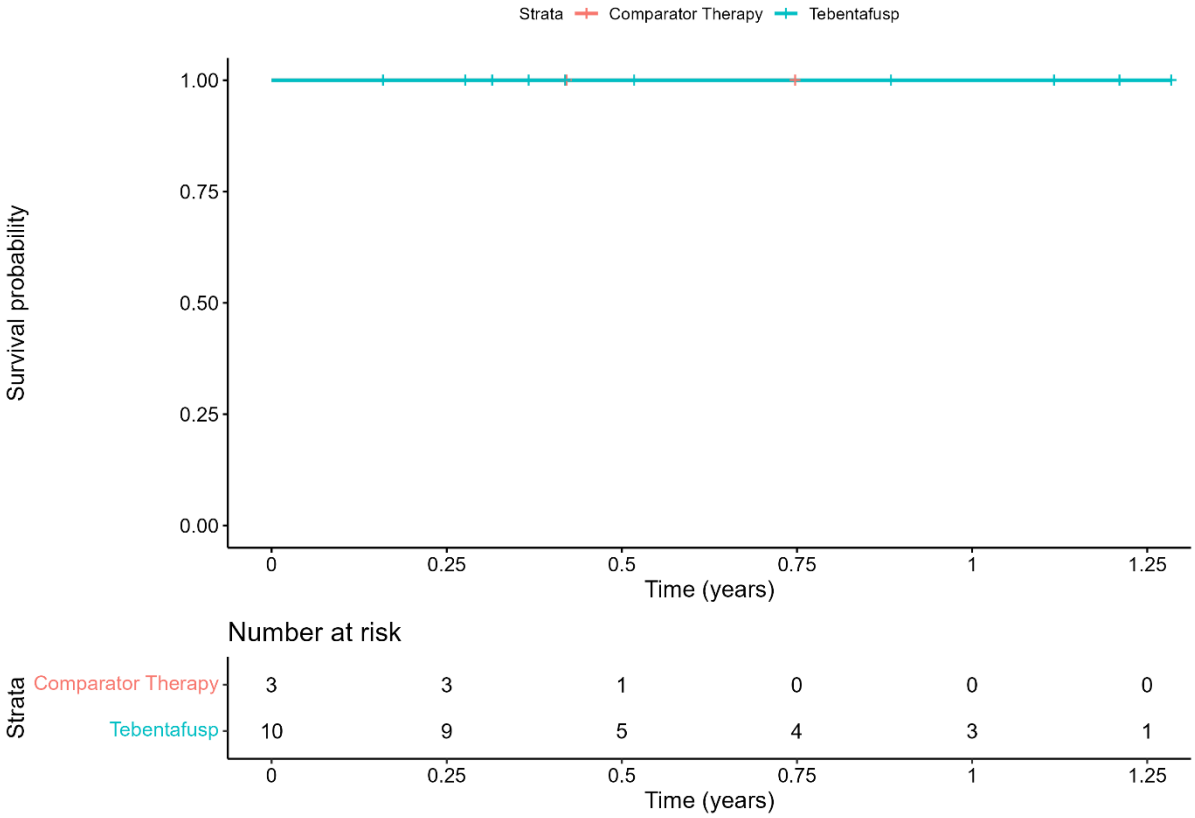
LDH: ≤ULN



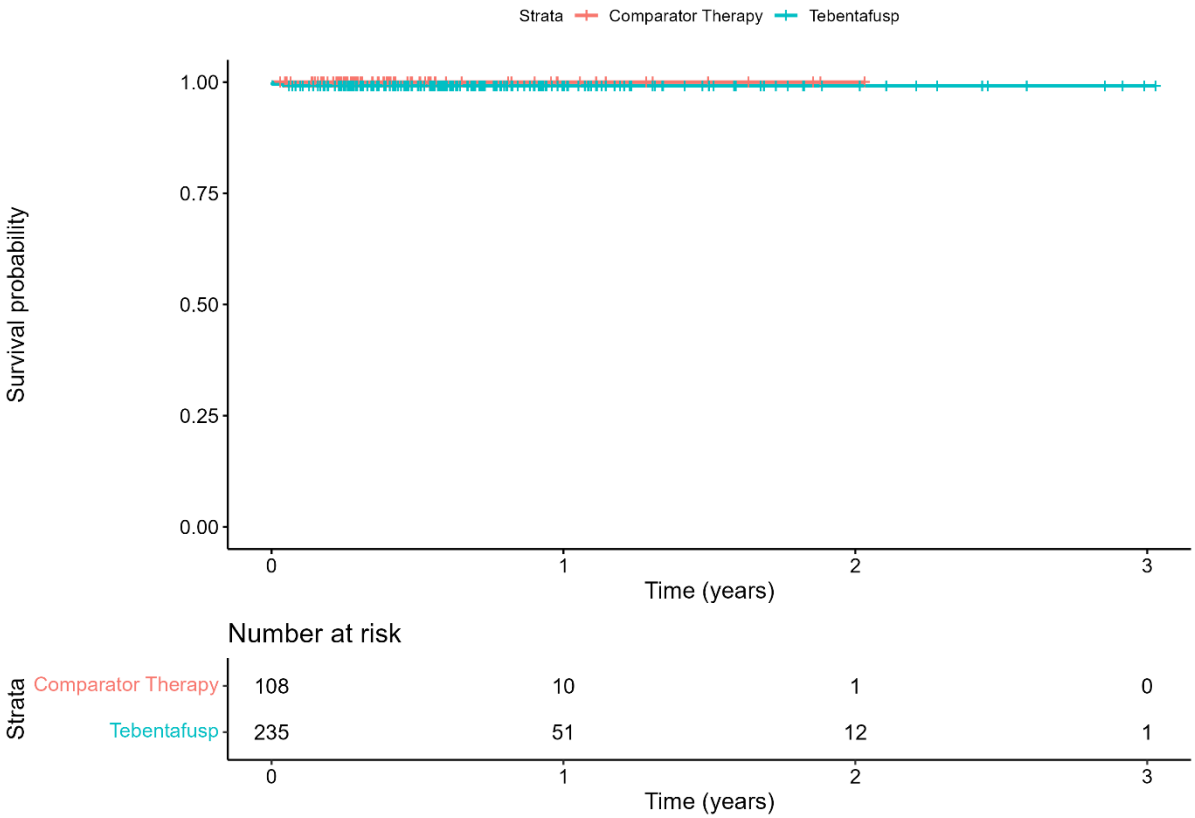
LDH: >ULN



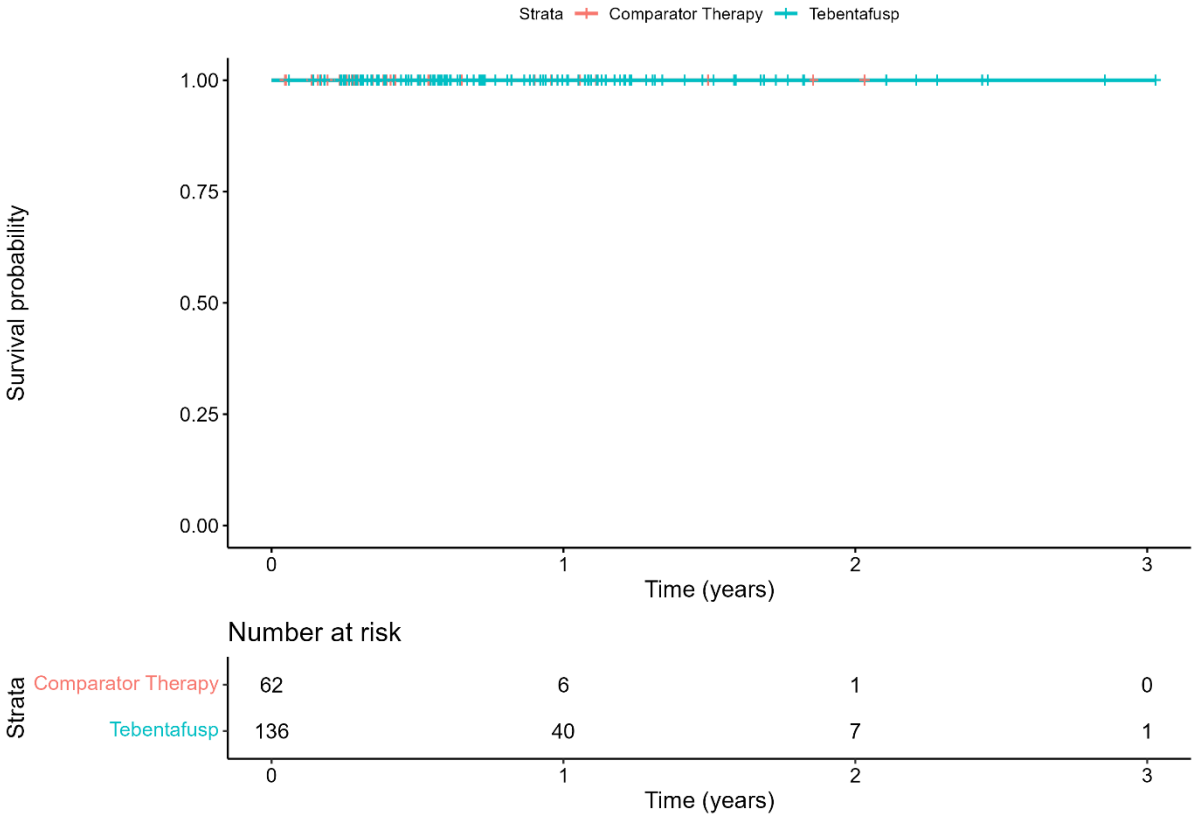
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



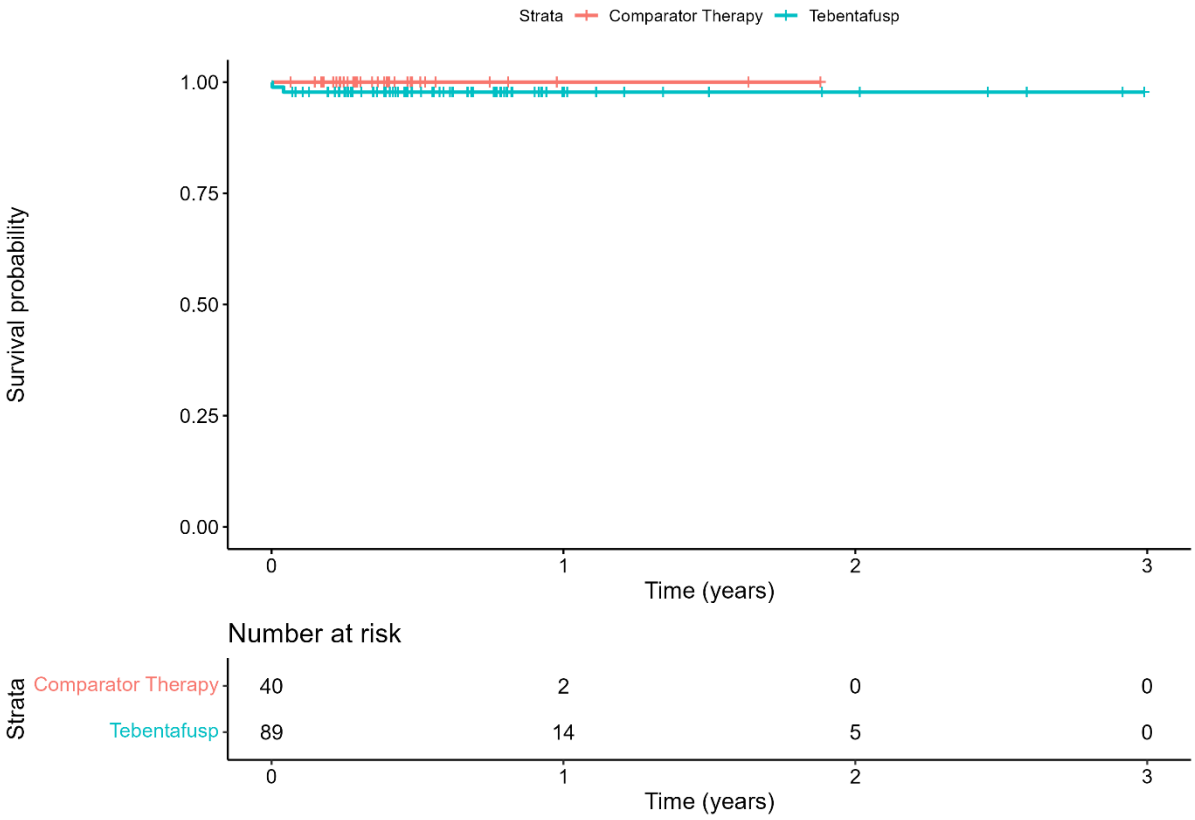
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



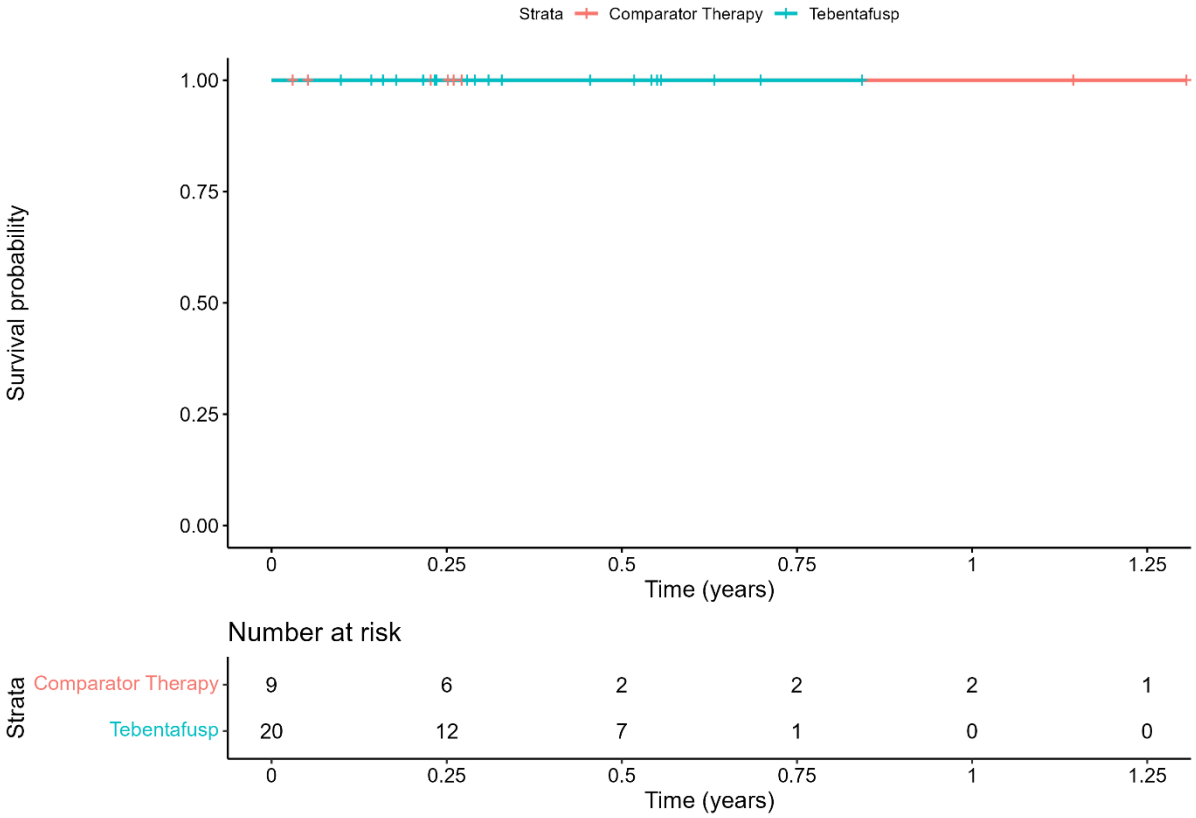
Größte metastatische Läsion (Baseline): ≤3,0 cm



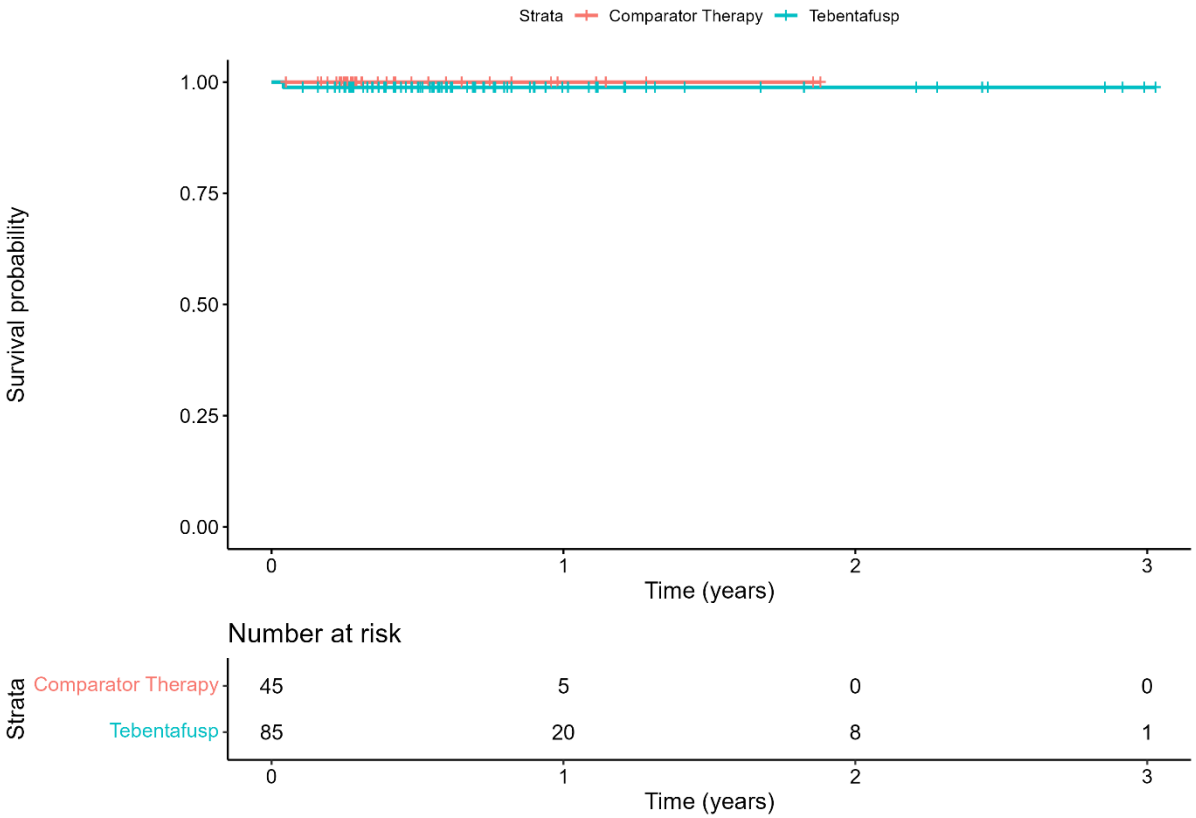
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



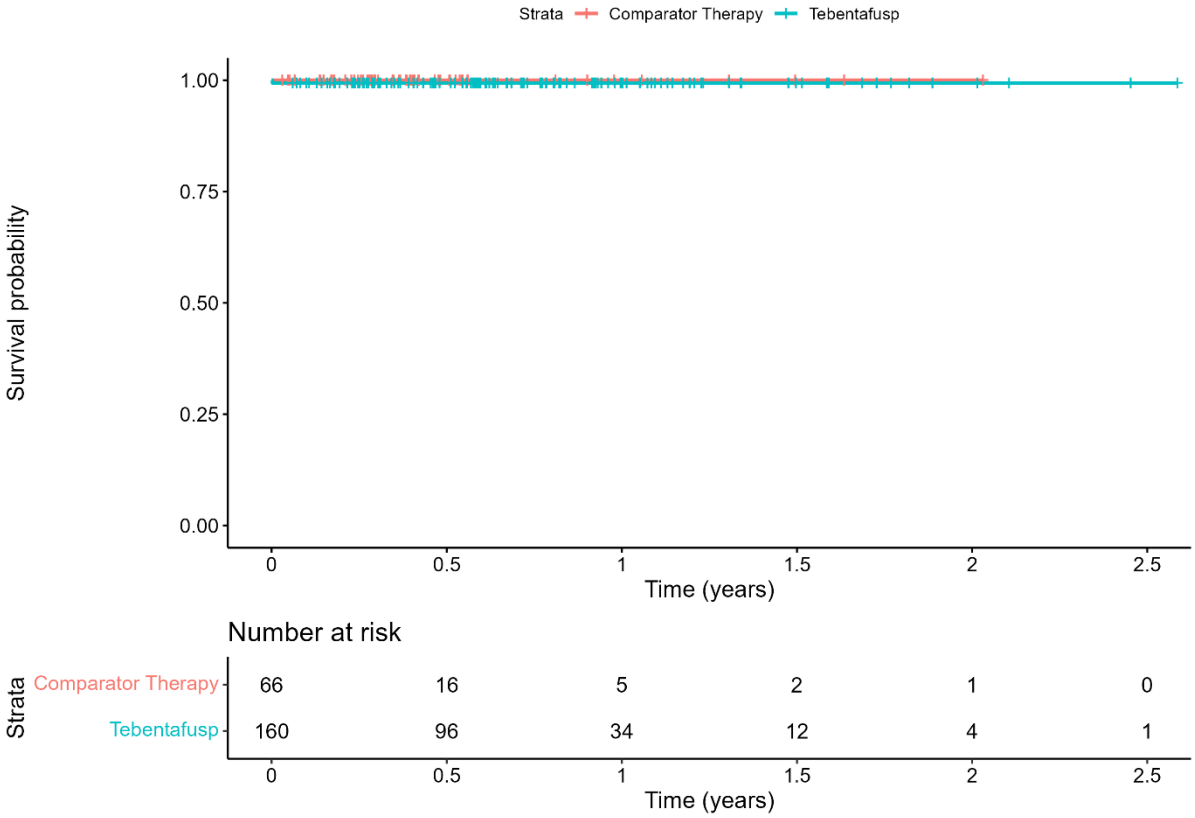
Größte metastatische Läsion (Baseline): ≥8,1 cm



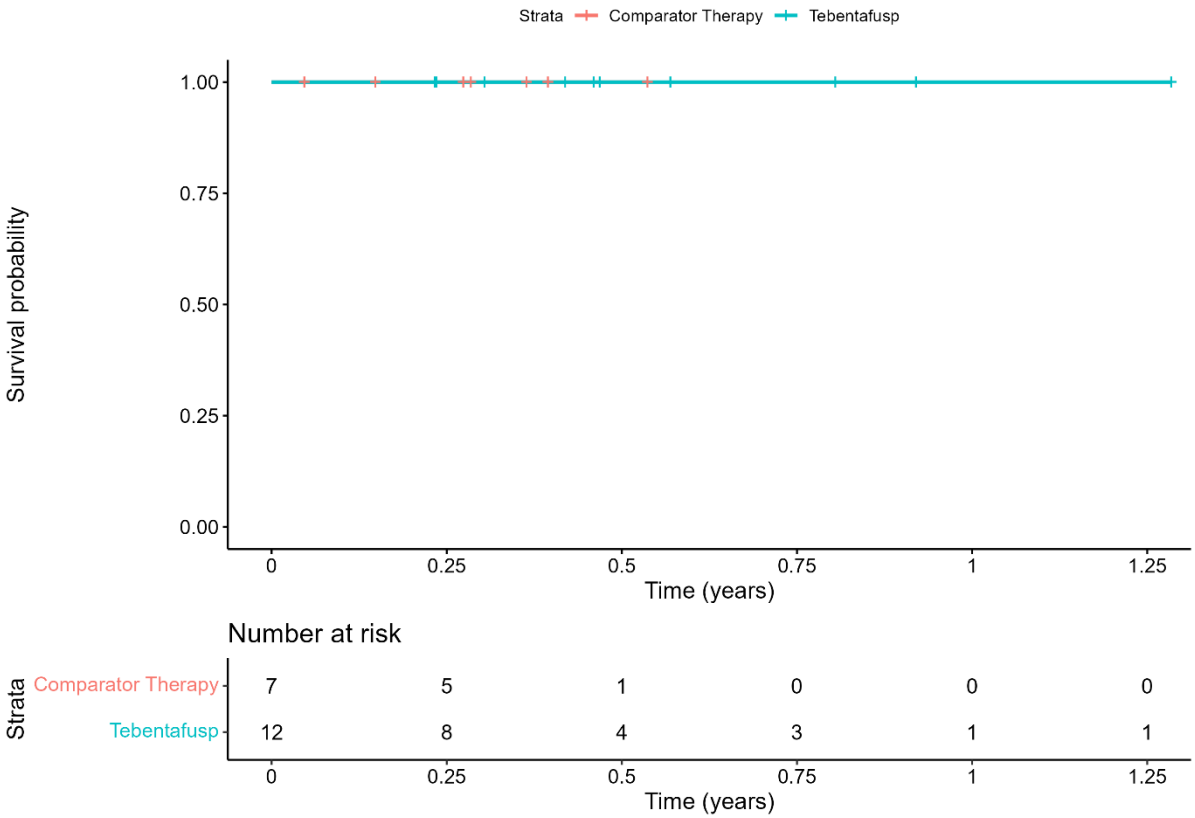
Region: Nordamerika



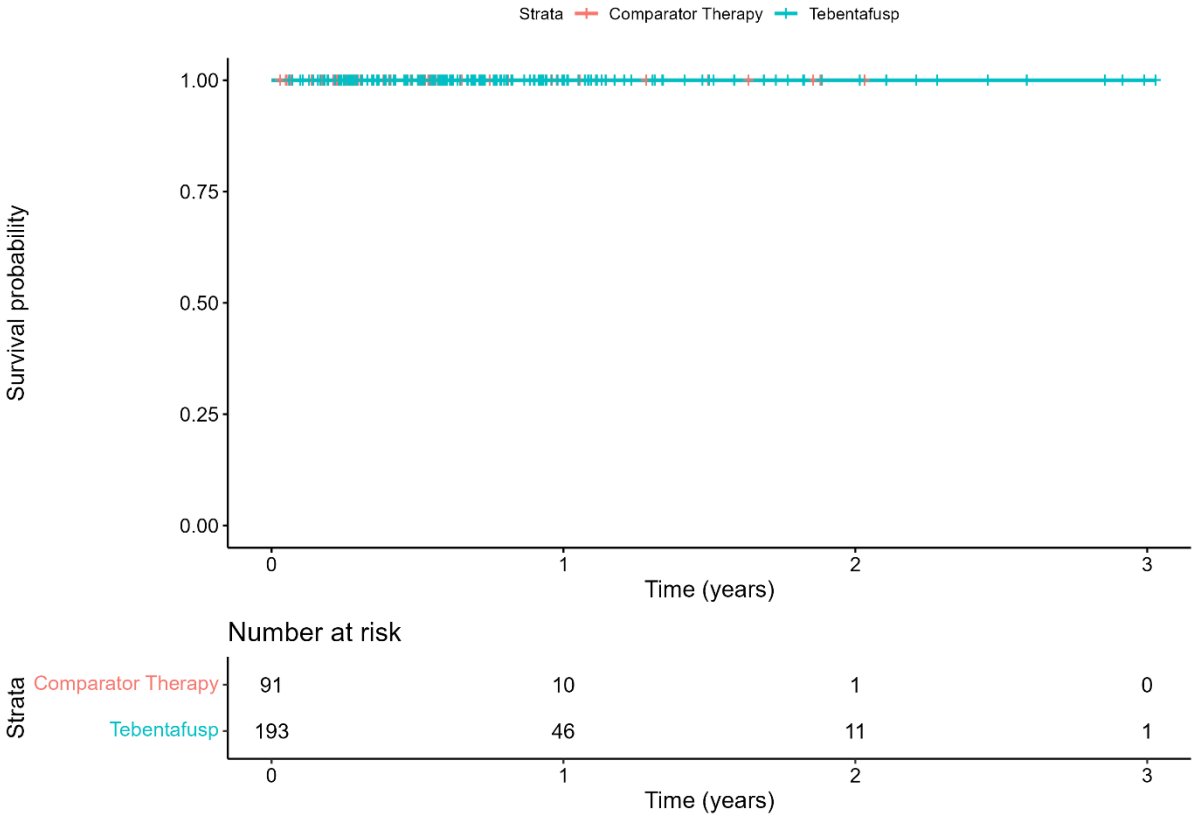
Region: Nicht-Nordamerika



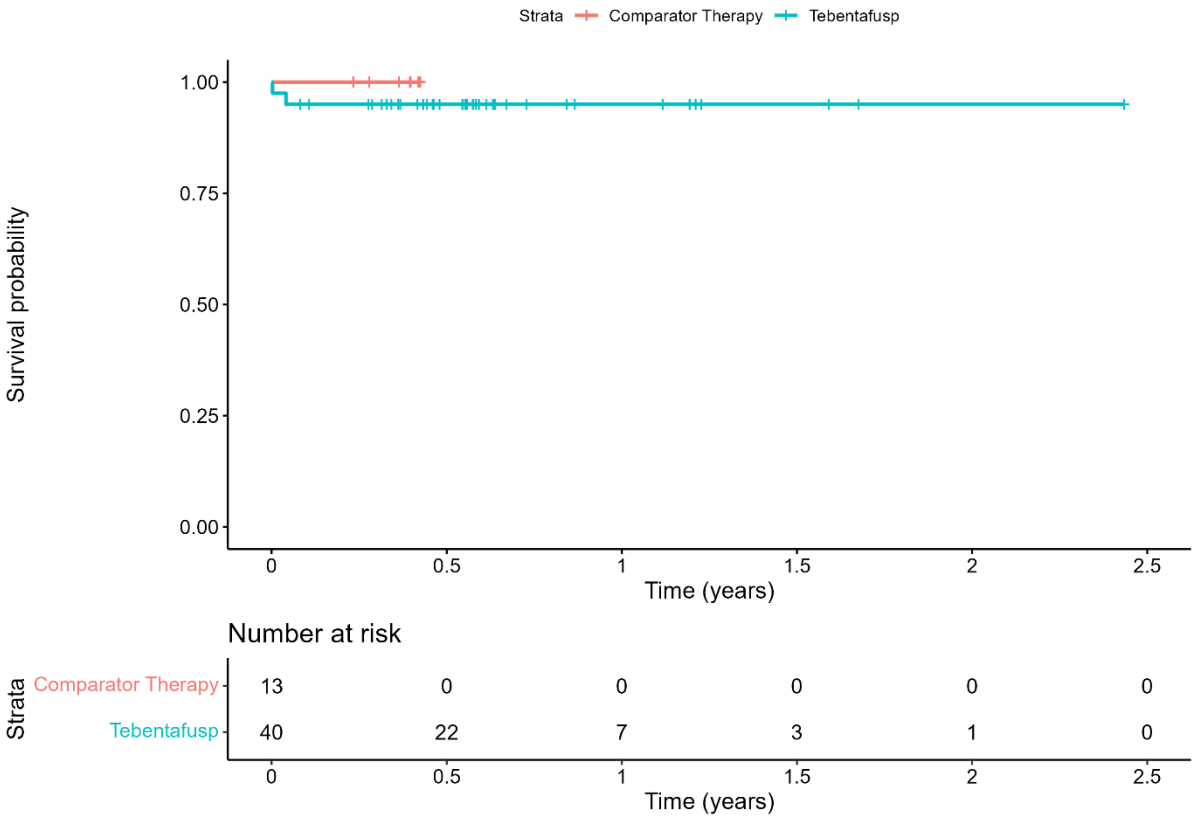
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

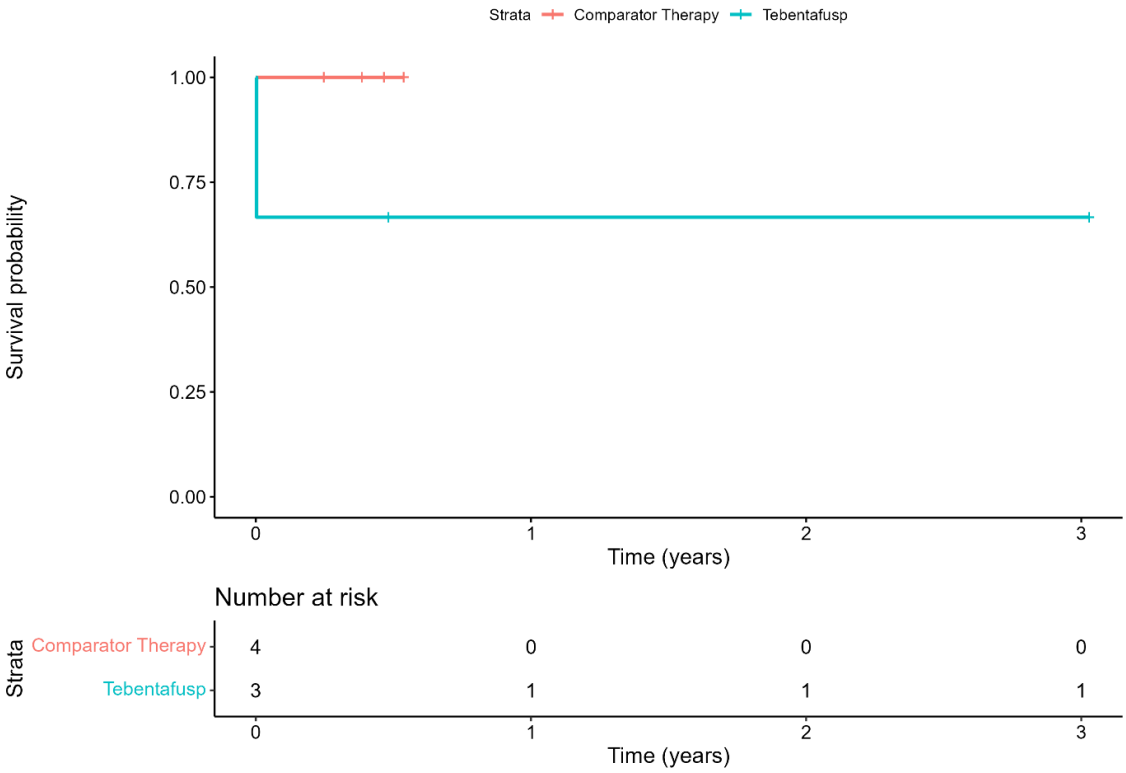


Vorauswahl der Chemotherapie: Ipilimumab

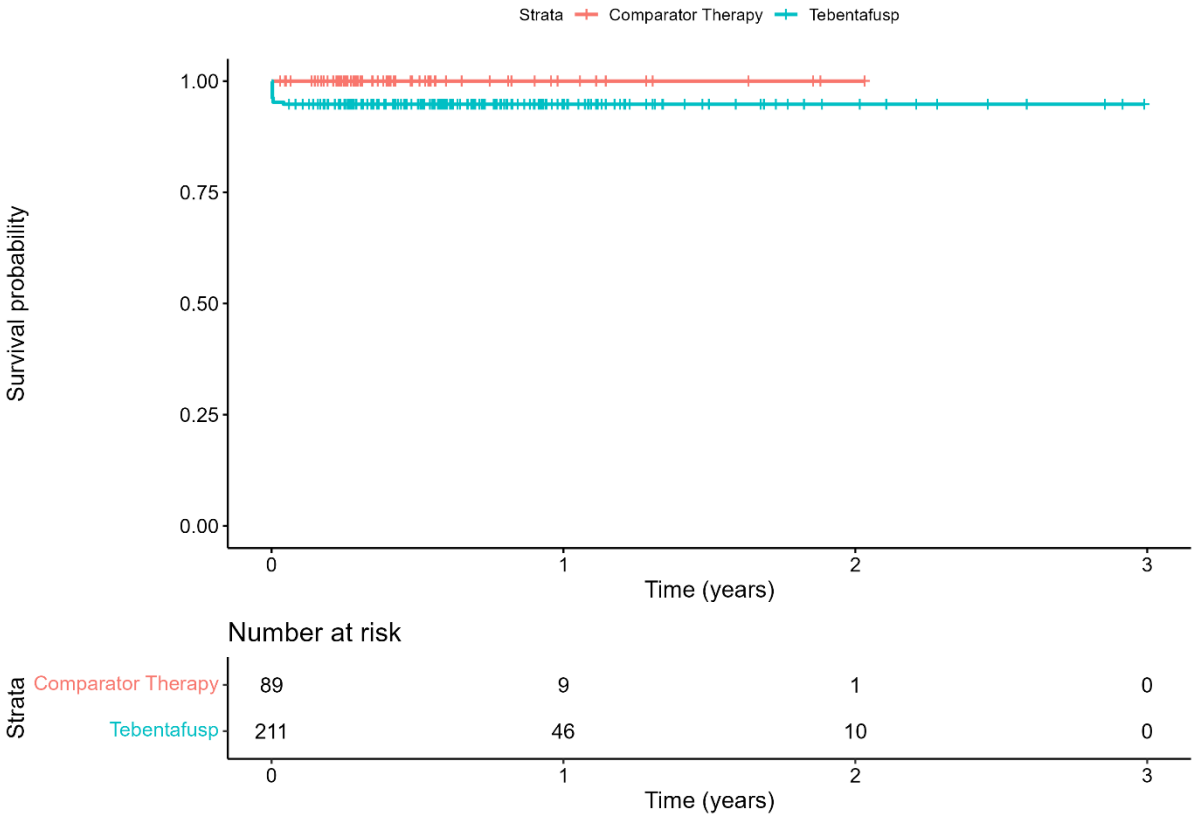


21.3 Schwerwiegendes Zytokin-Freisetzungssyndrom (Tabelle 4-99)

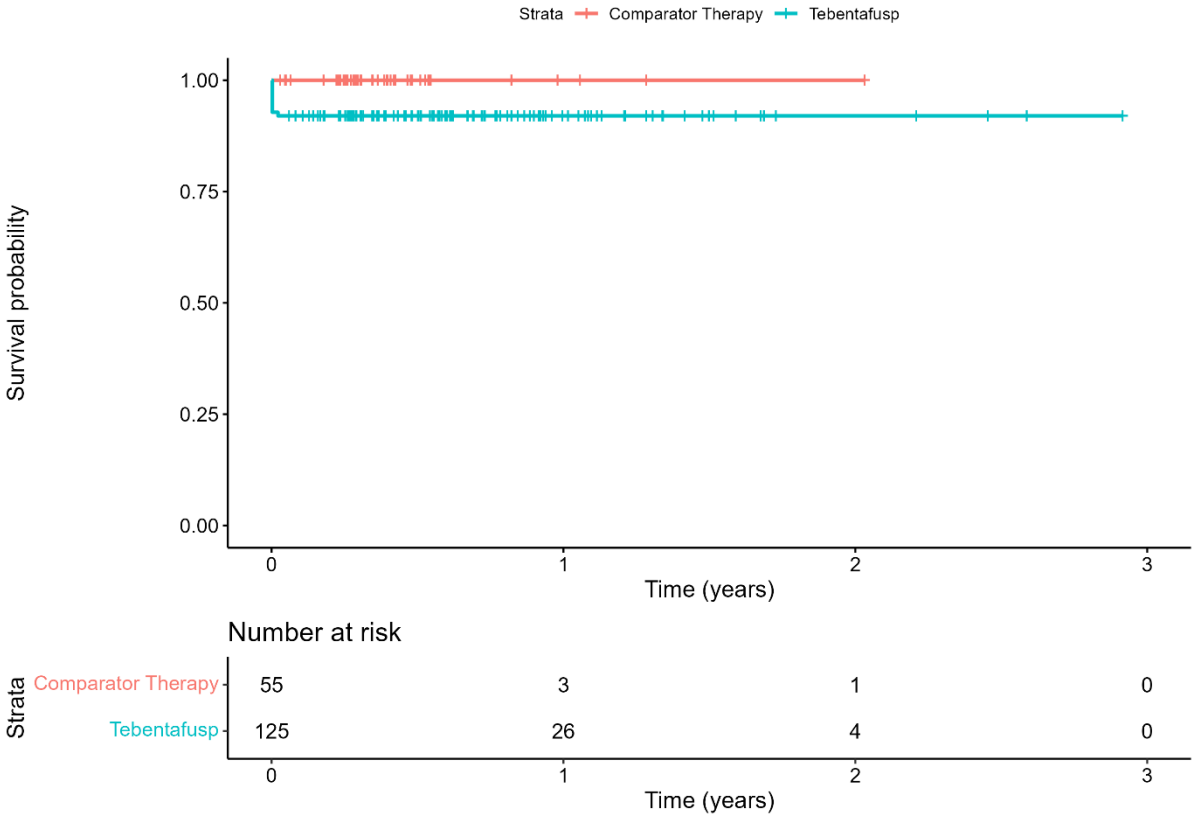
Herkunft: Hispanisch



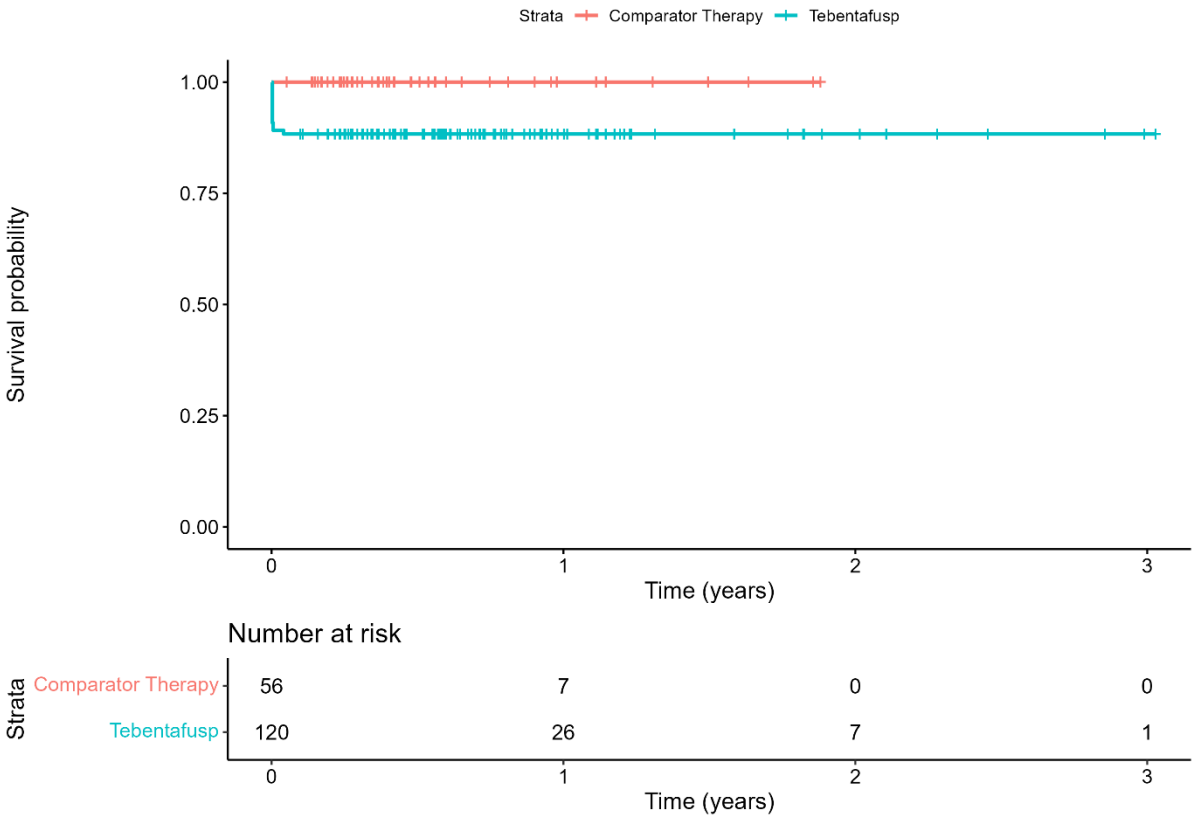
Herkunft: Nicht-hispanisch



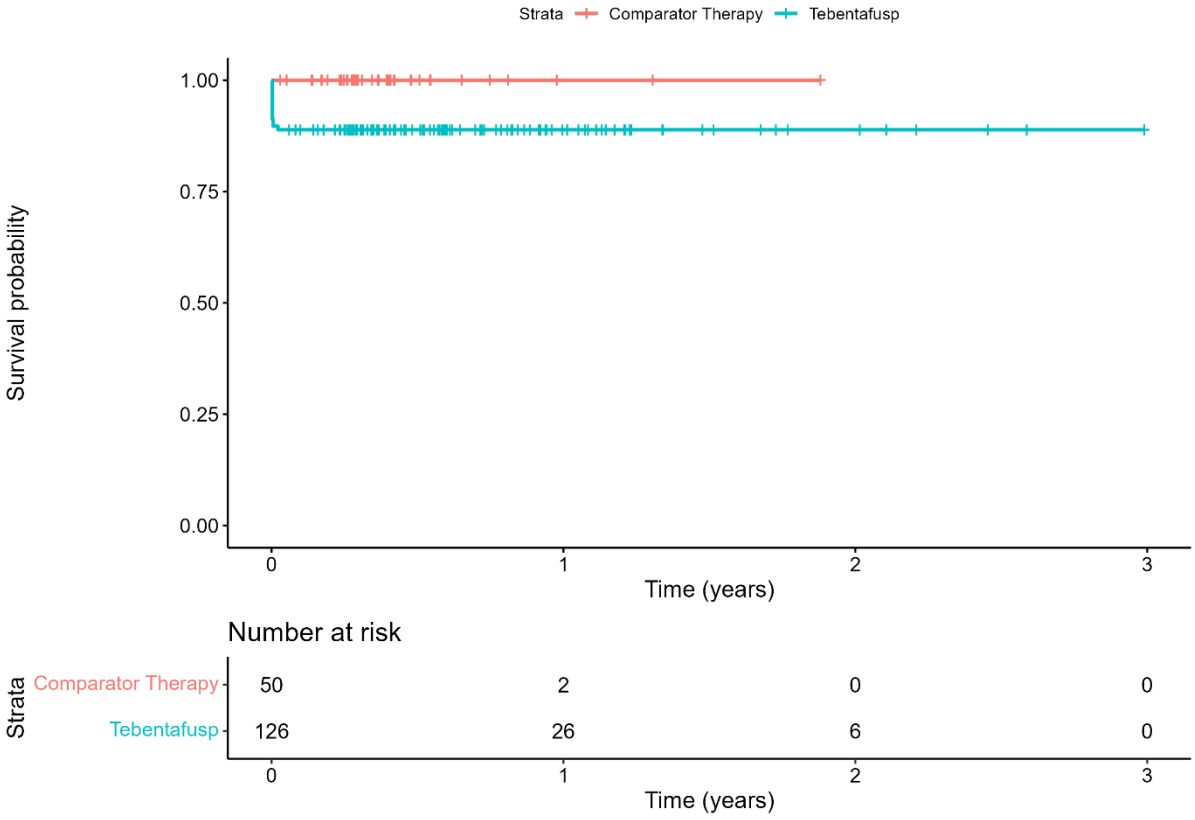
Geschlecht: Männlich



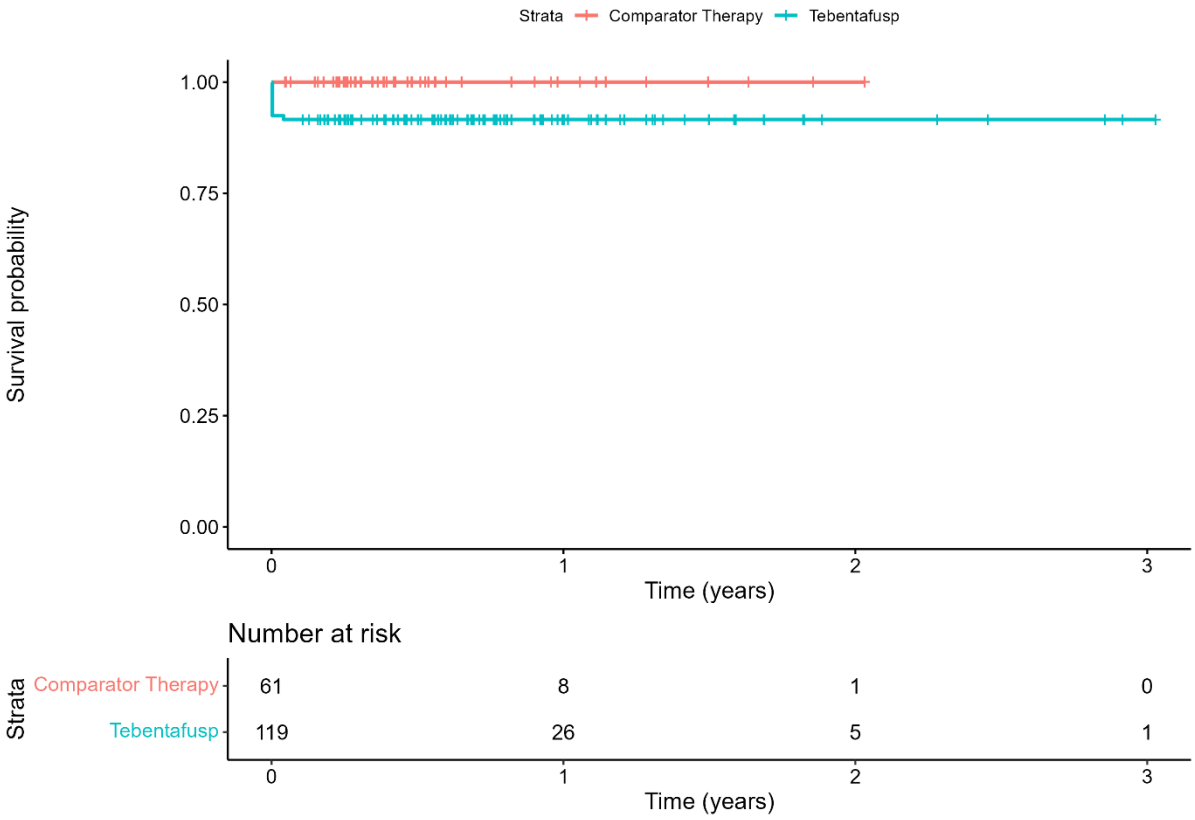
Geschlecht: Weiblich



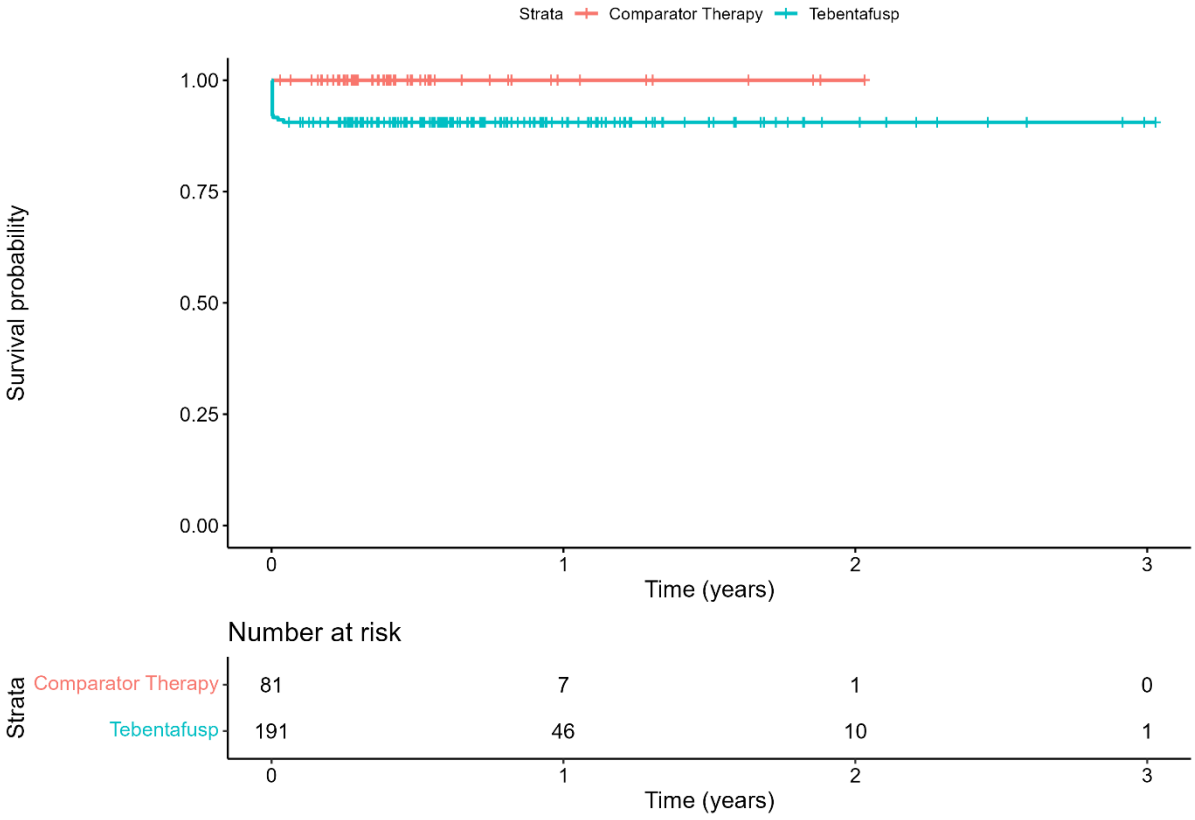
Alter: <65 Jahre



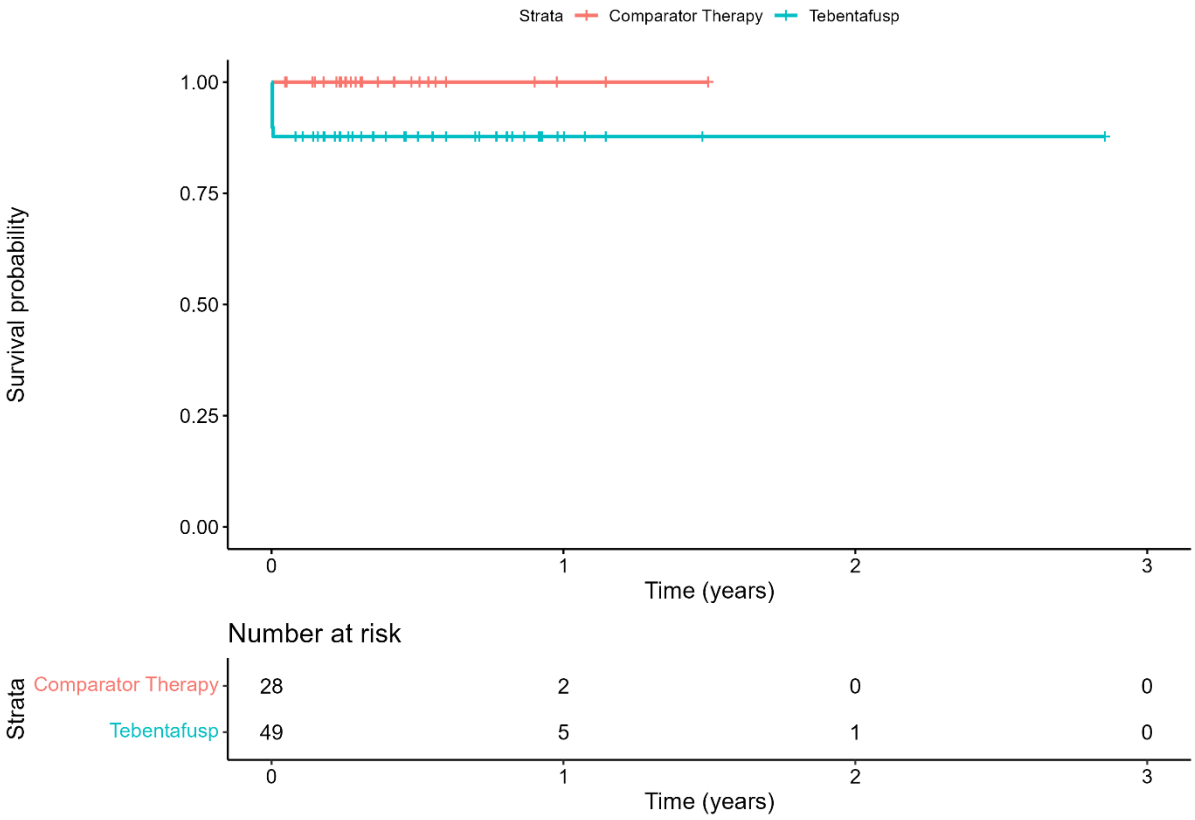
Alter: ≥65 Jahre



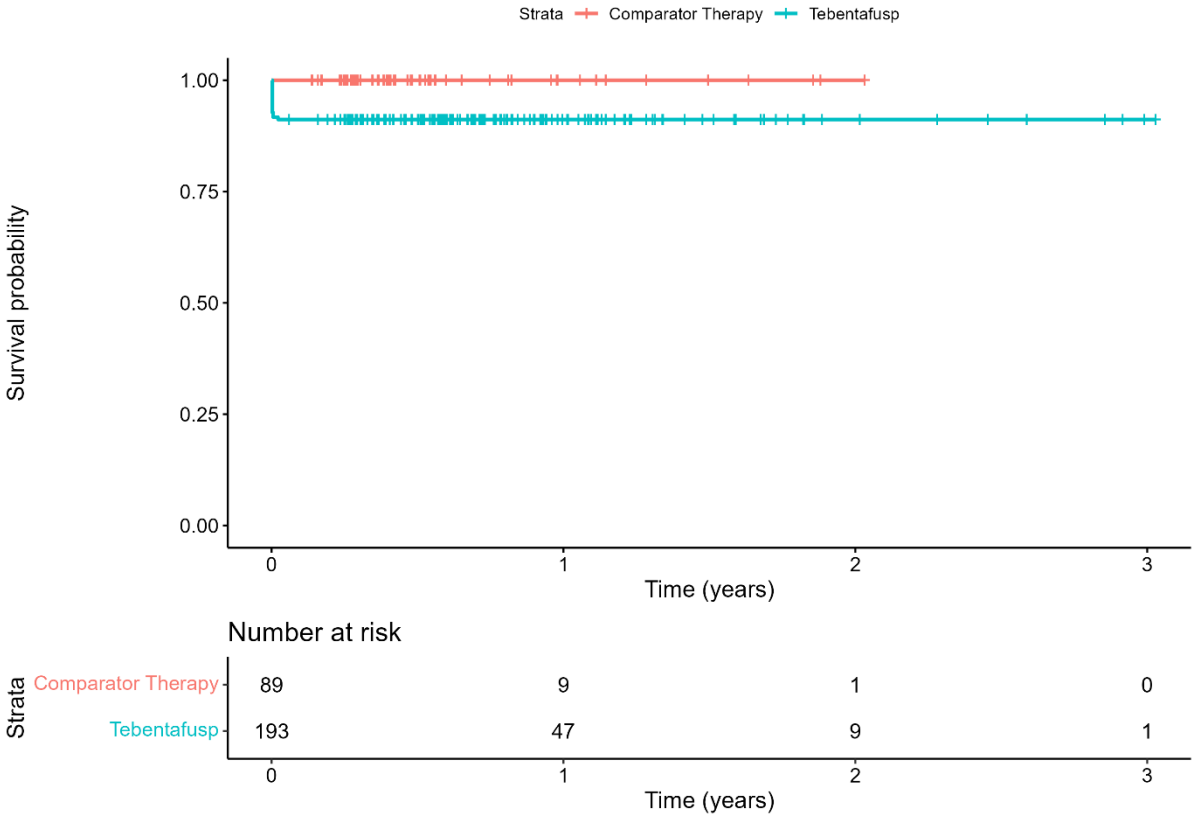
ECOG-Performance-Status: 0



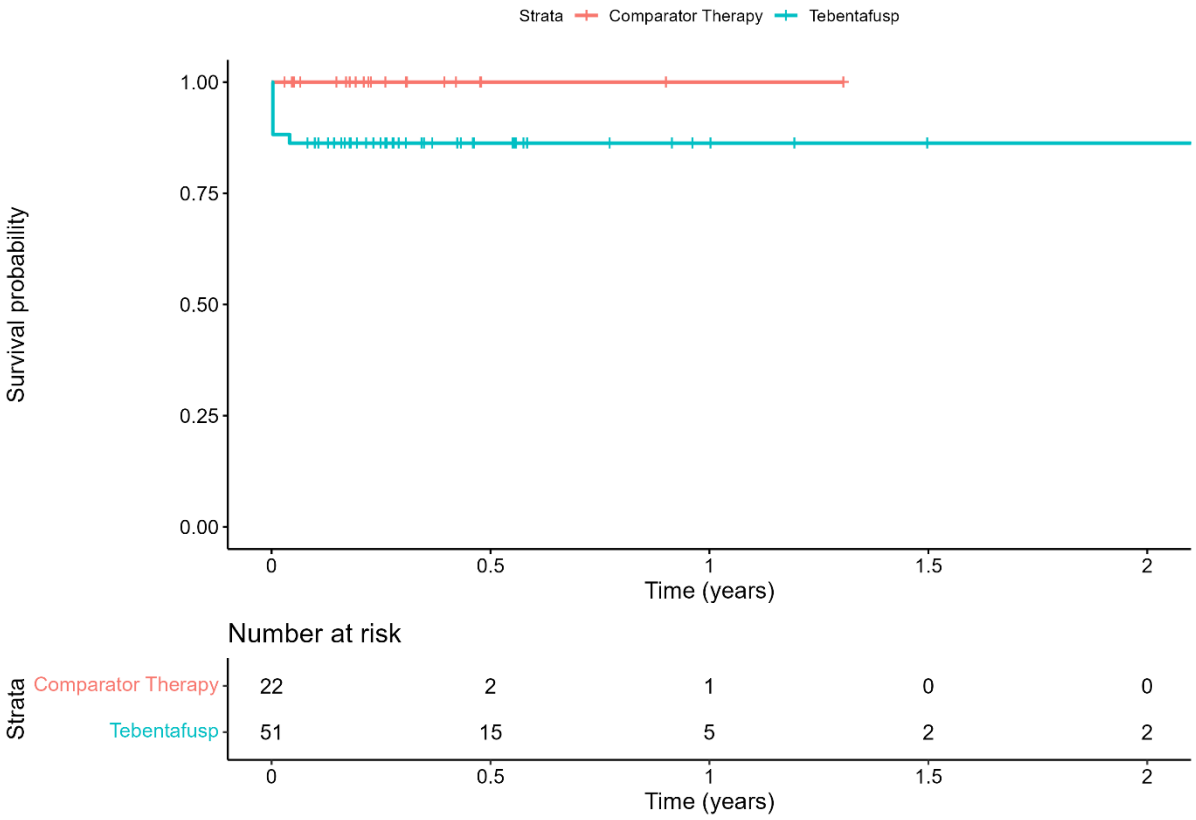
ECOG-Performance-Status: 1



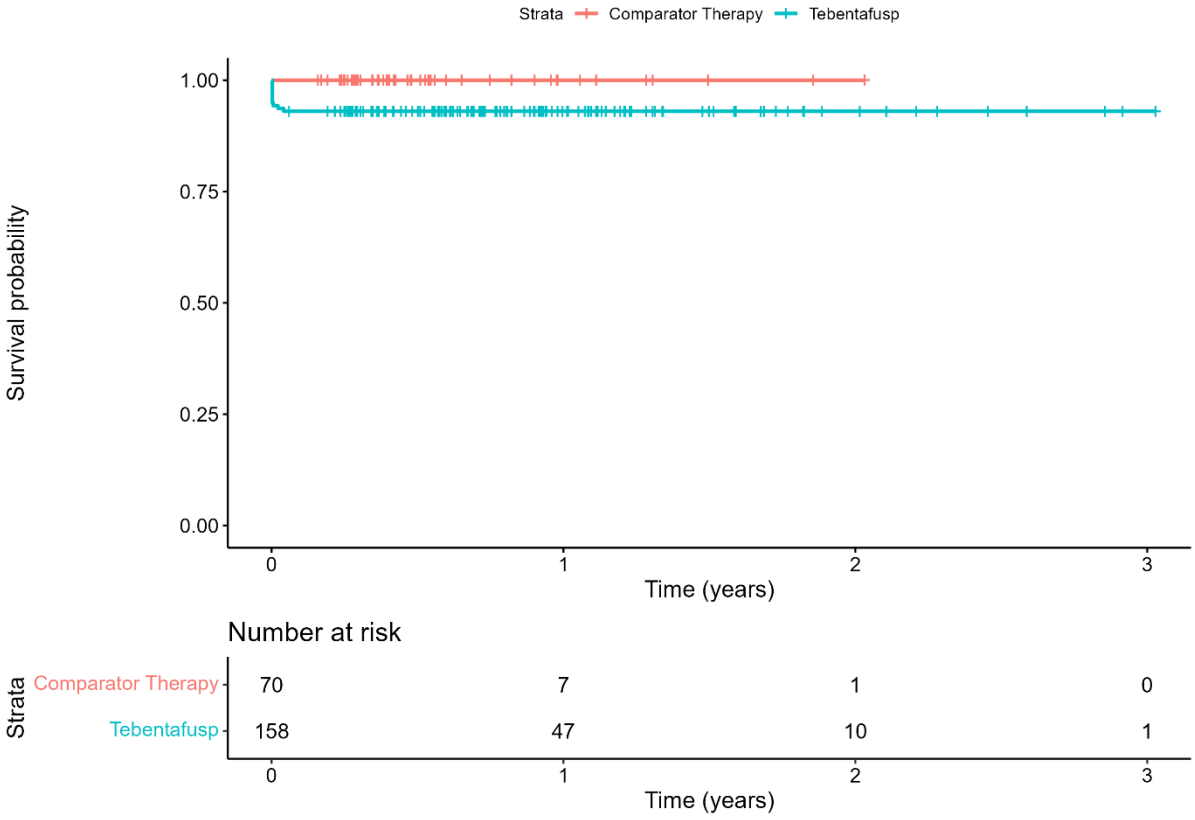
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



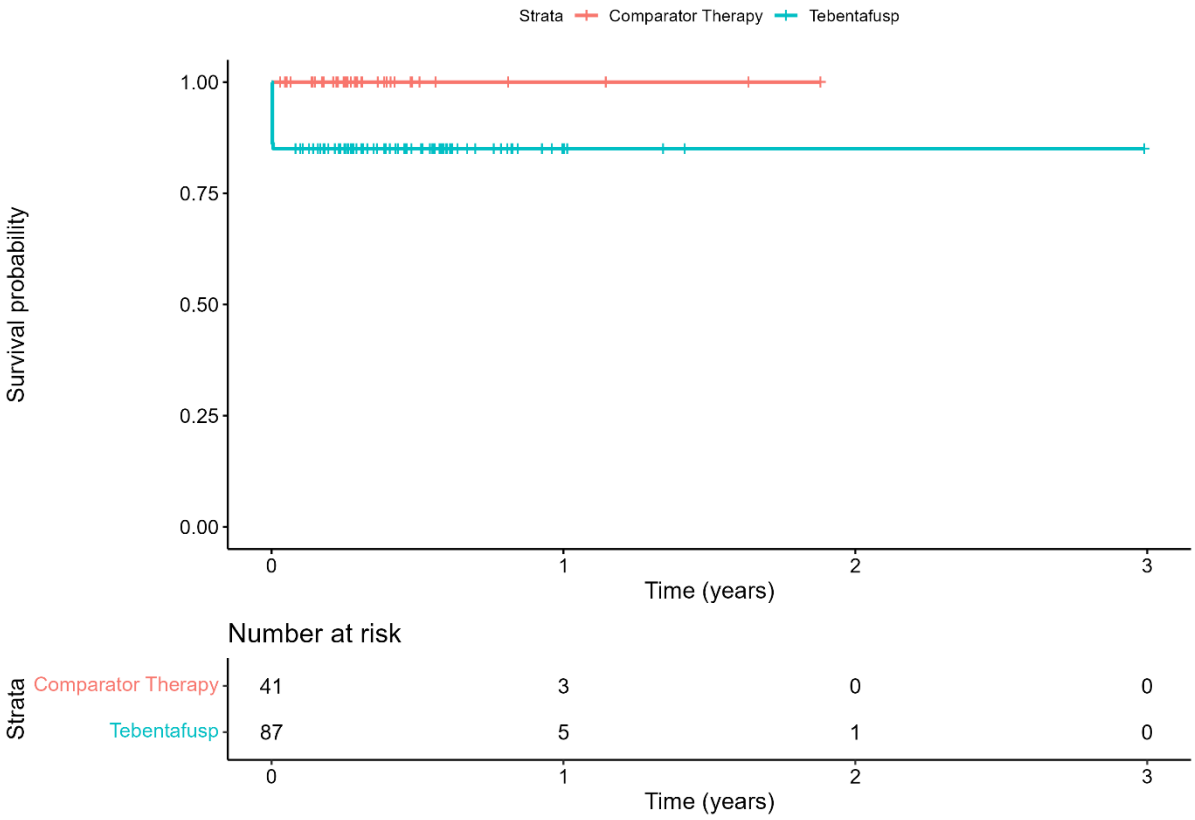
Alkalische Phosphatase (ALP) (Baseline): >ULN



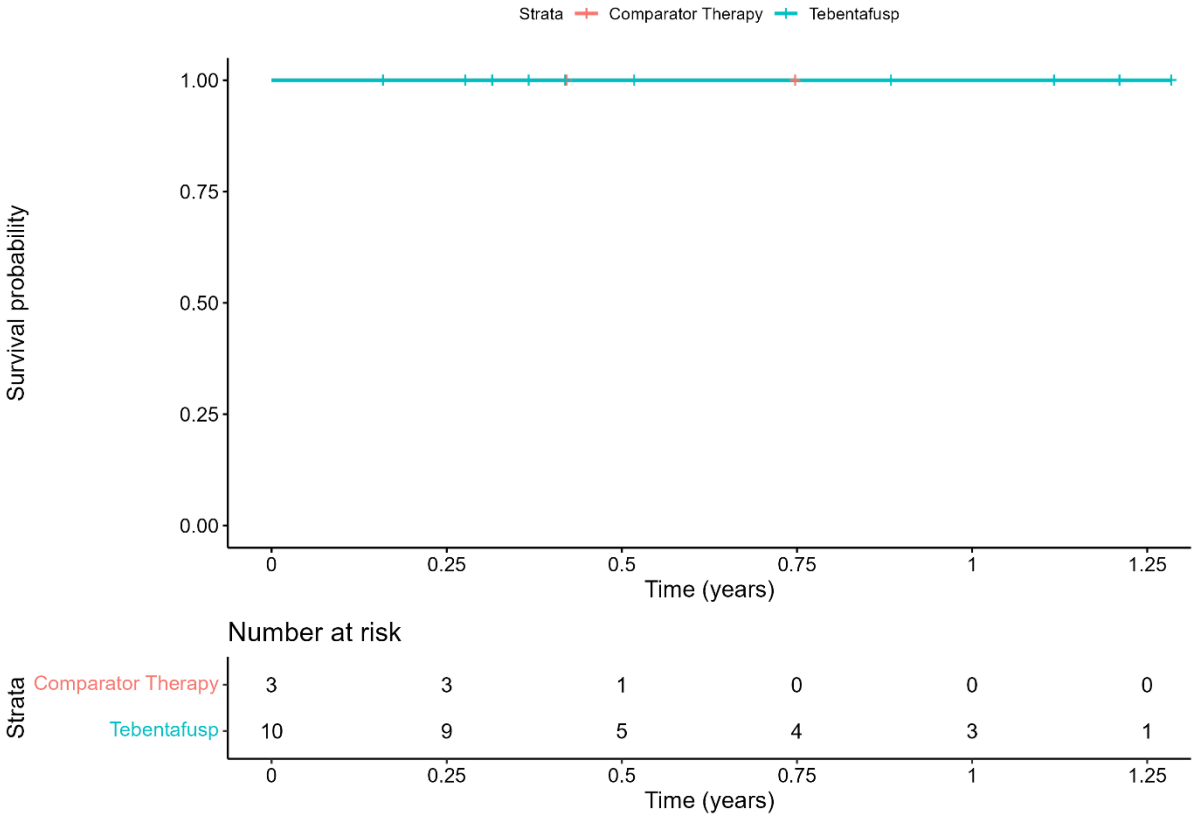
LDH: ≤ULN



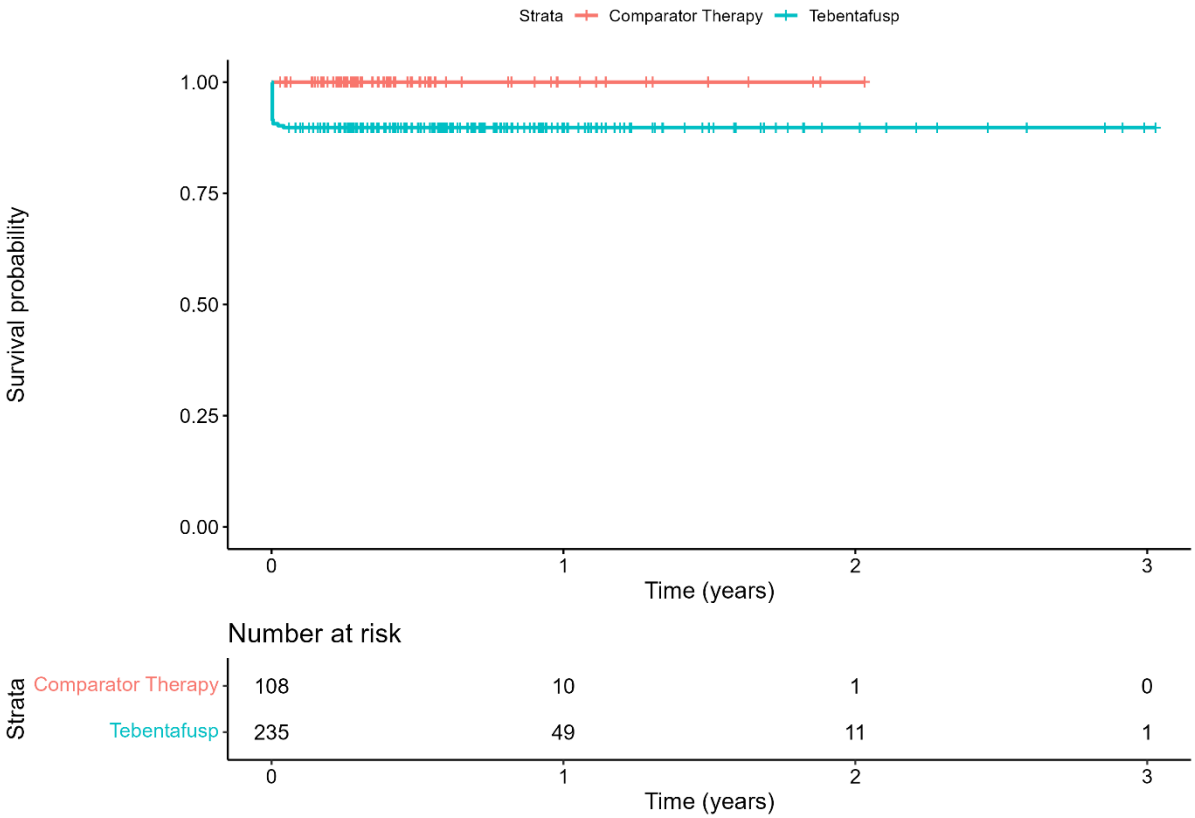
LDH: >ULN



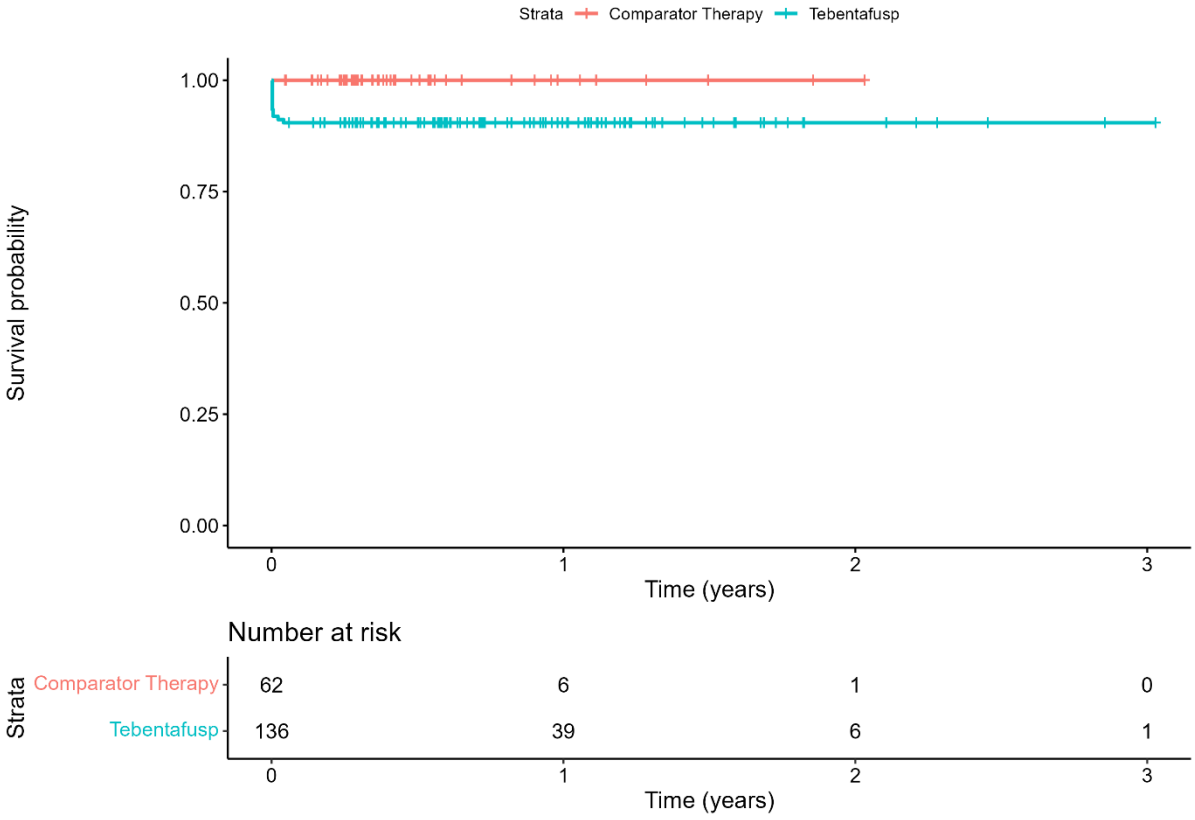
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



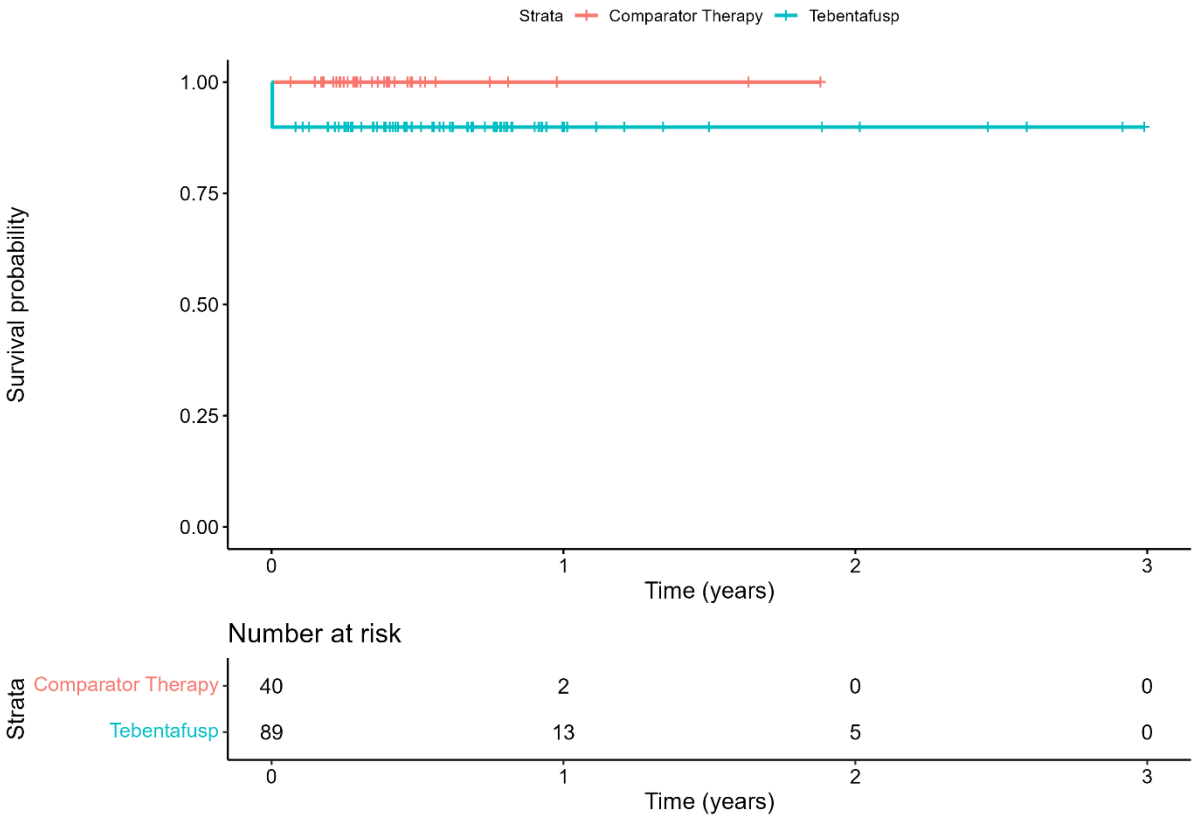
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



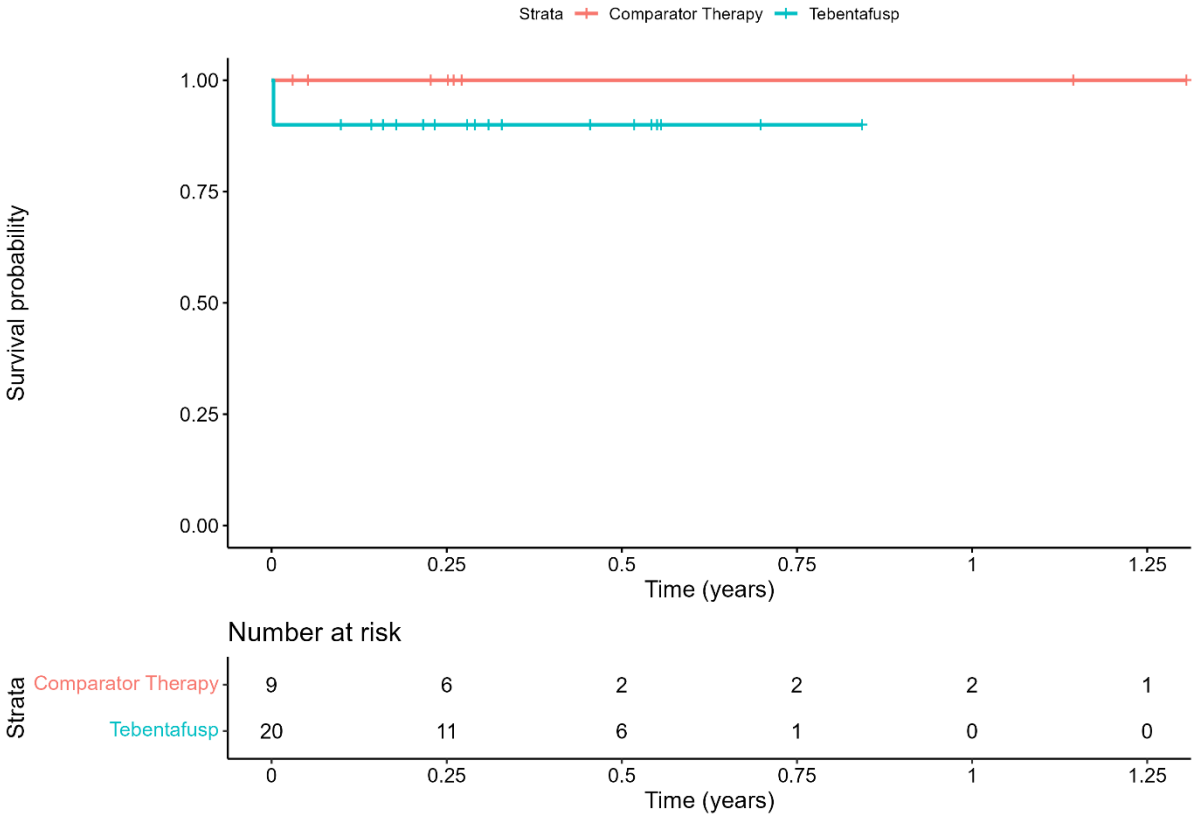
Größte metastatische Läsion (Baseline): ≤3,0 cm



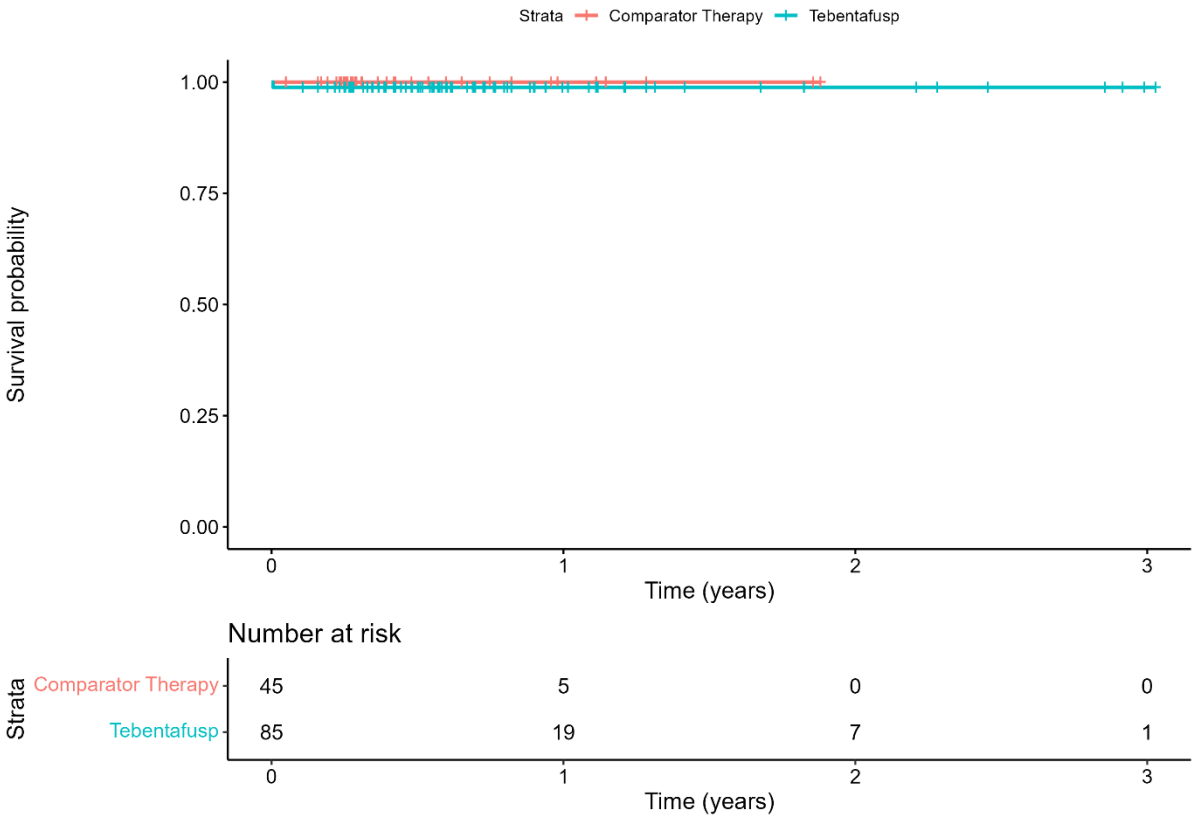
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



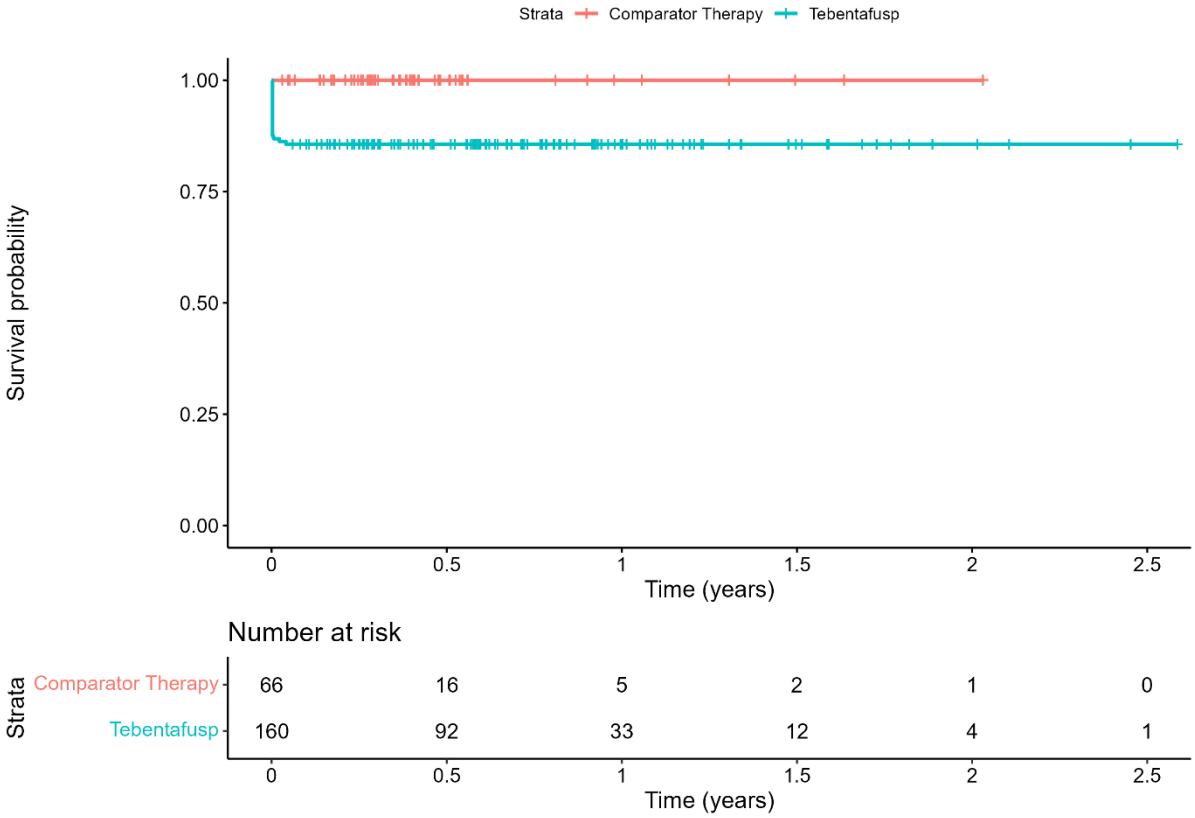
Größte metastatische Läsion (Baseline): ≥8,1 cm



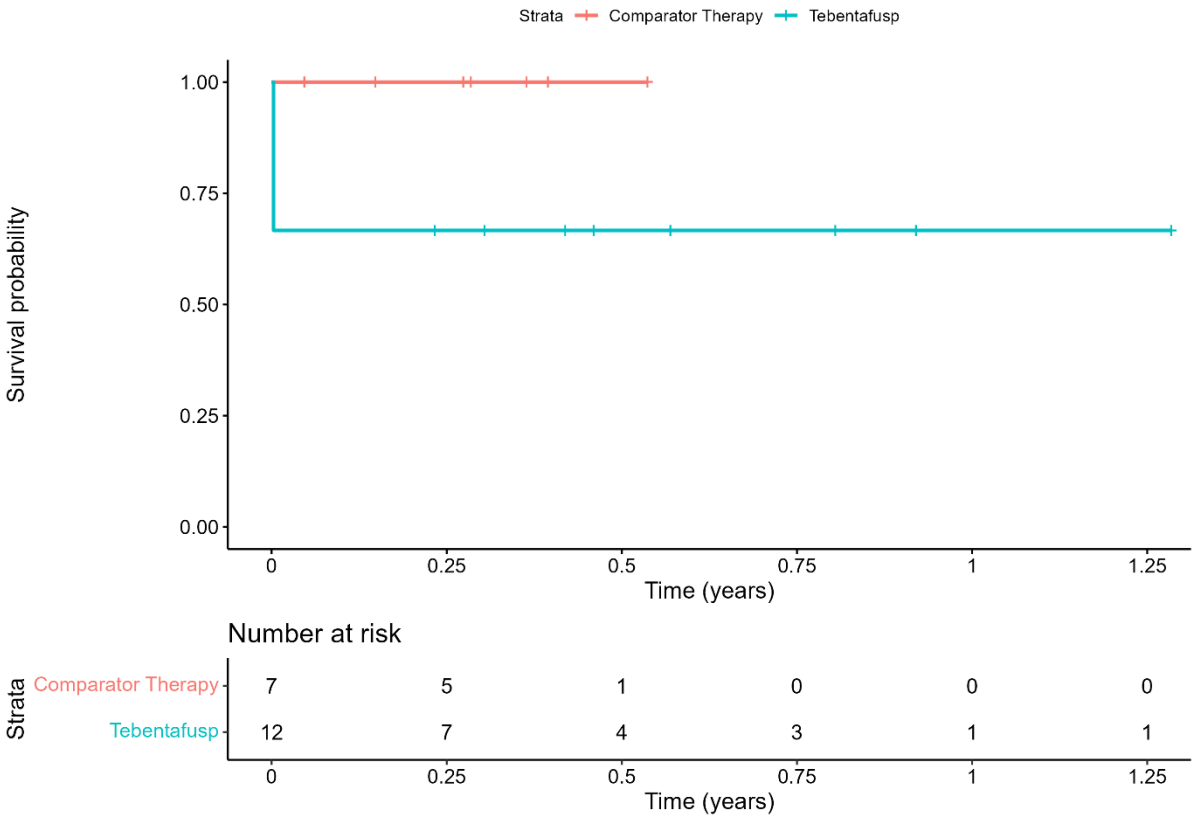
Region: Nordamerika



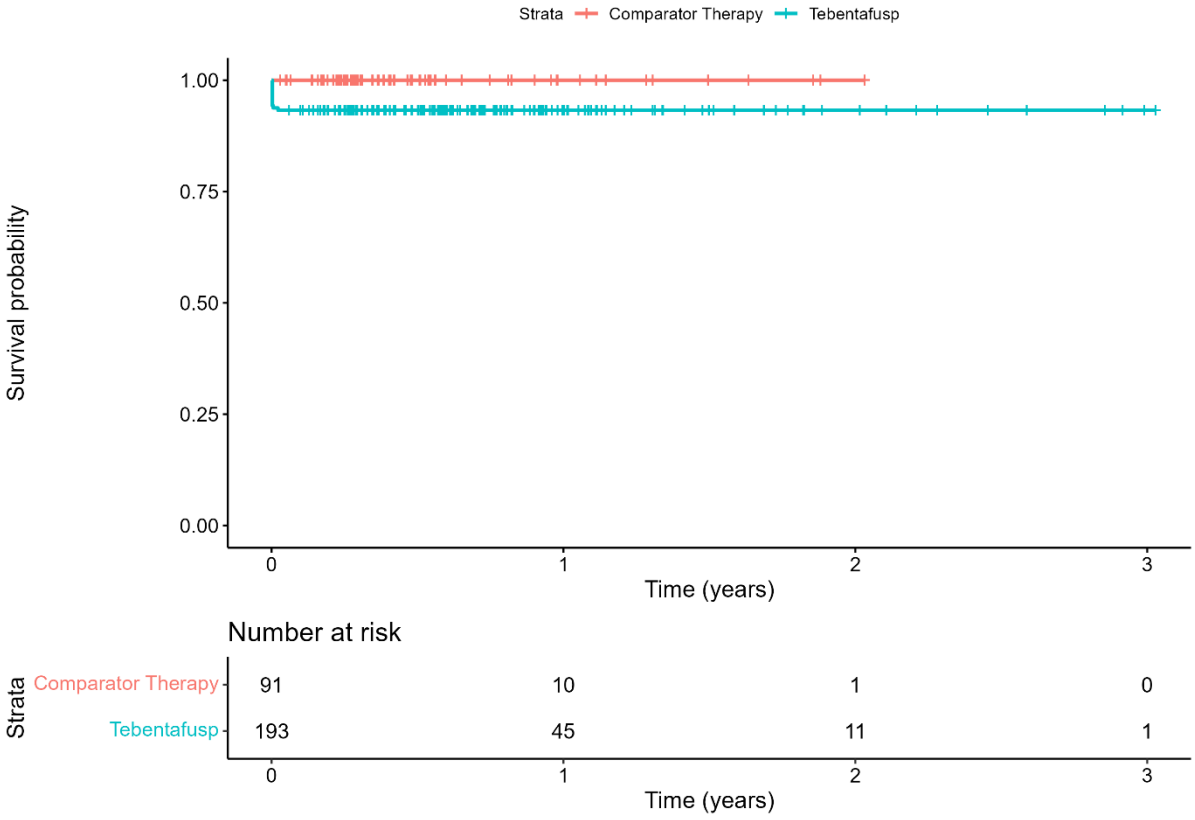
Region: Nicht-Nordamerika



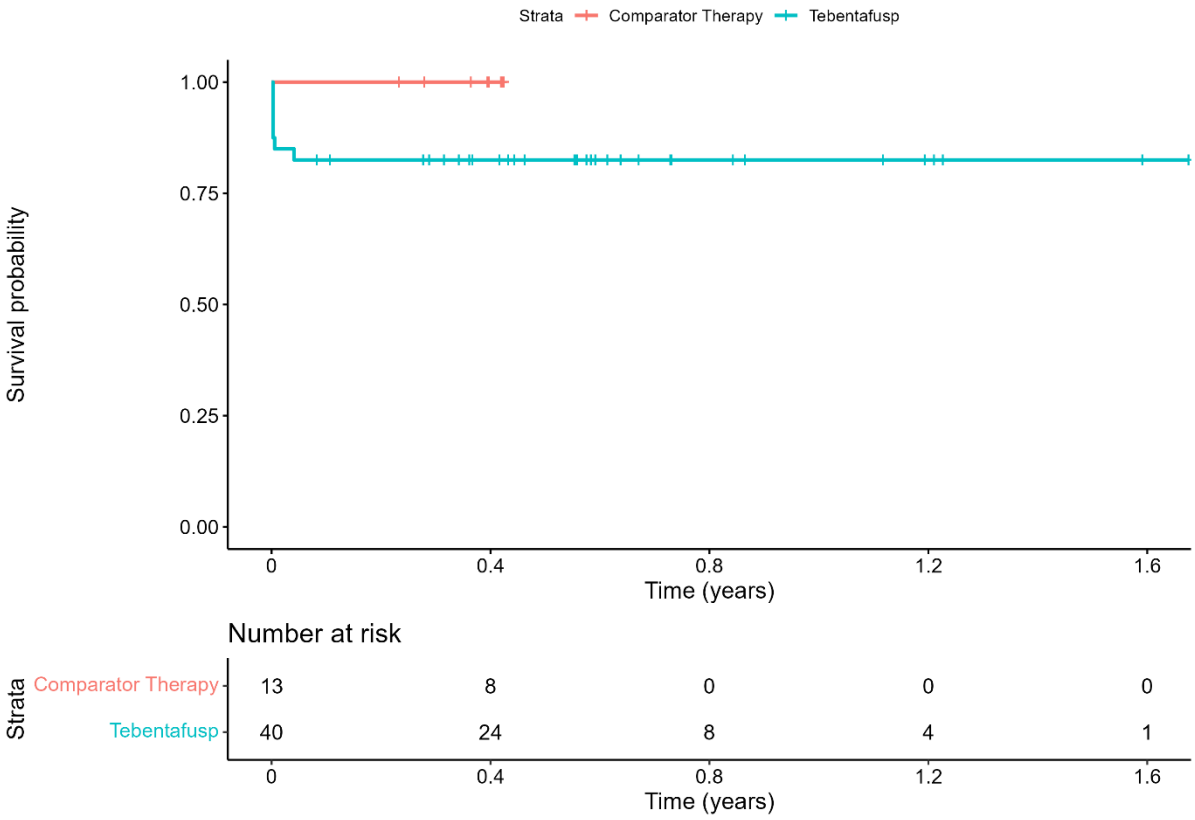
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

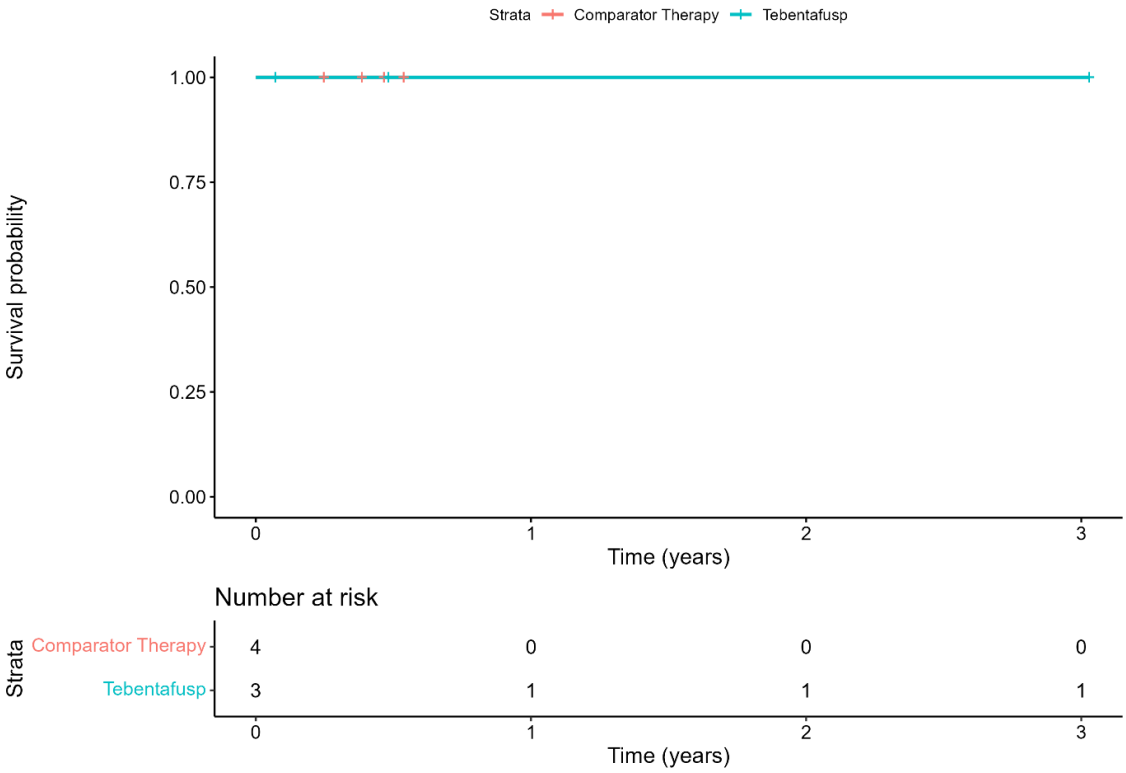


Vorauswahl der Chemotherapie: Ipilimumab

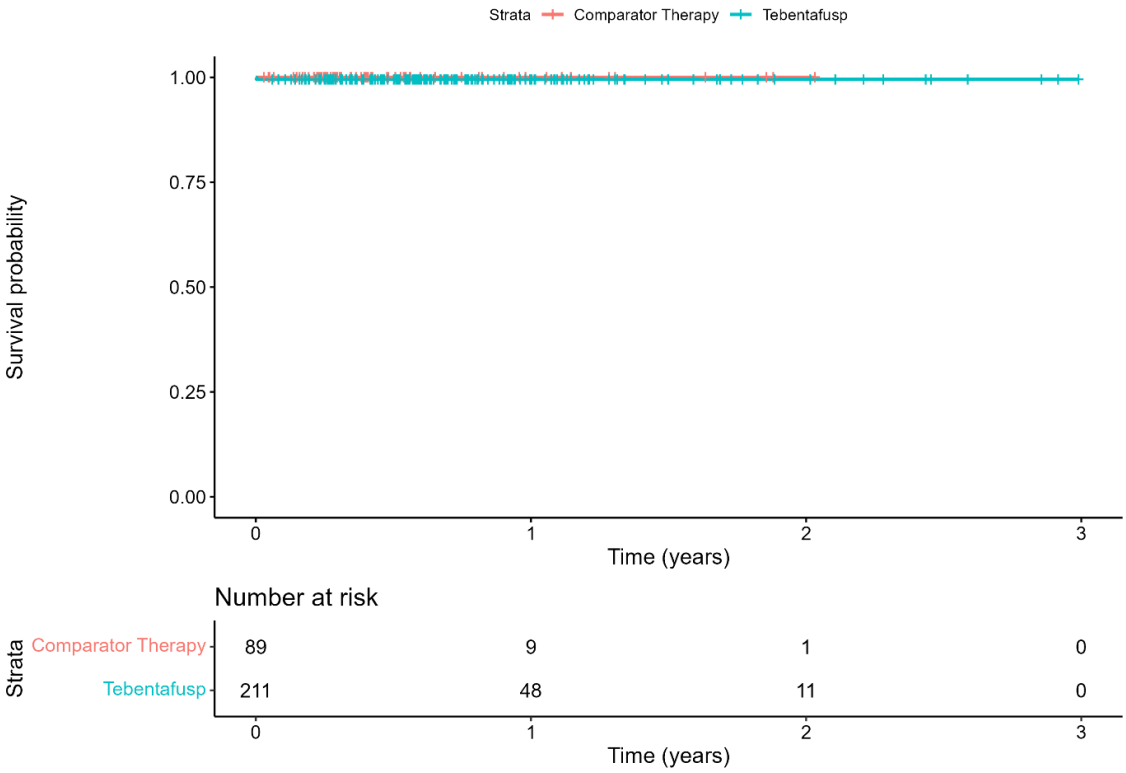


22.1 Zytokin-Freisetzungssyndrom, das zum Absetzen des Studienmedikaments führte (Tabelle 4-101)

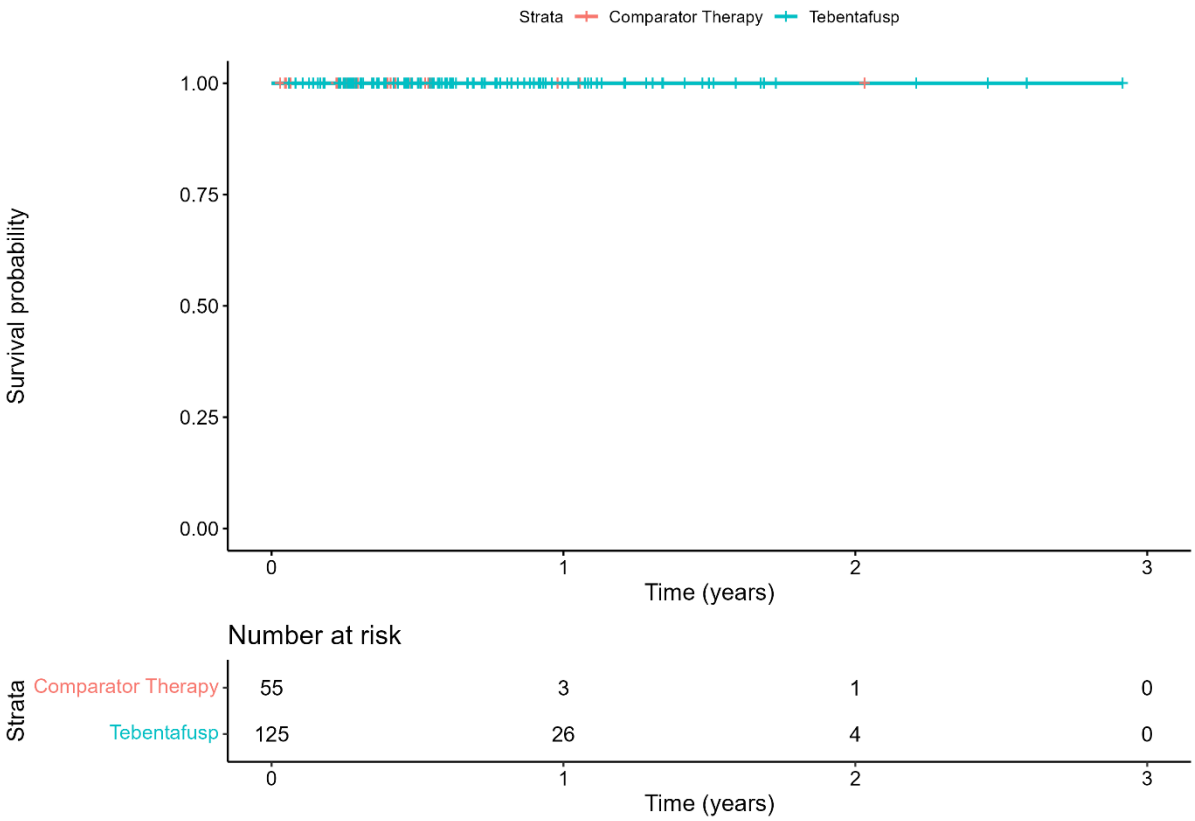
Herkunft: Hispanisch



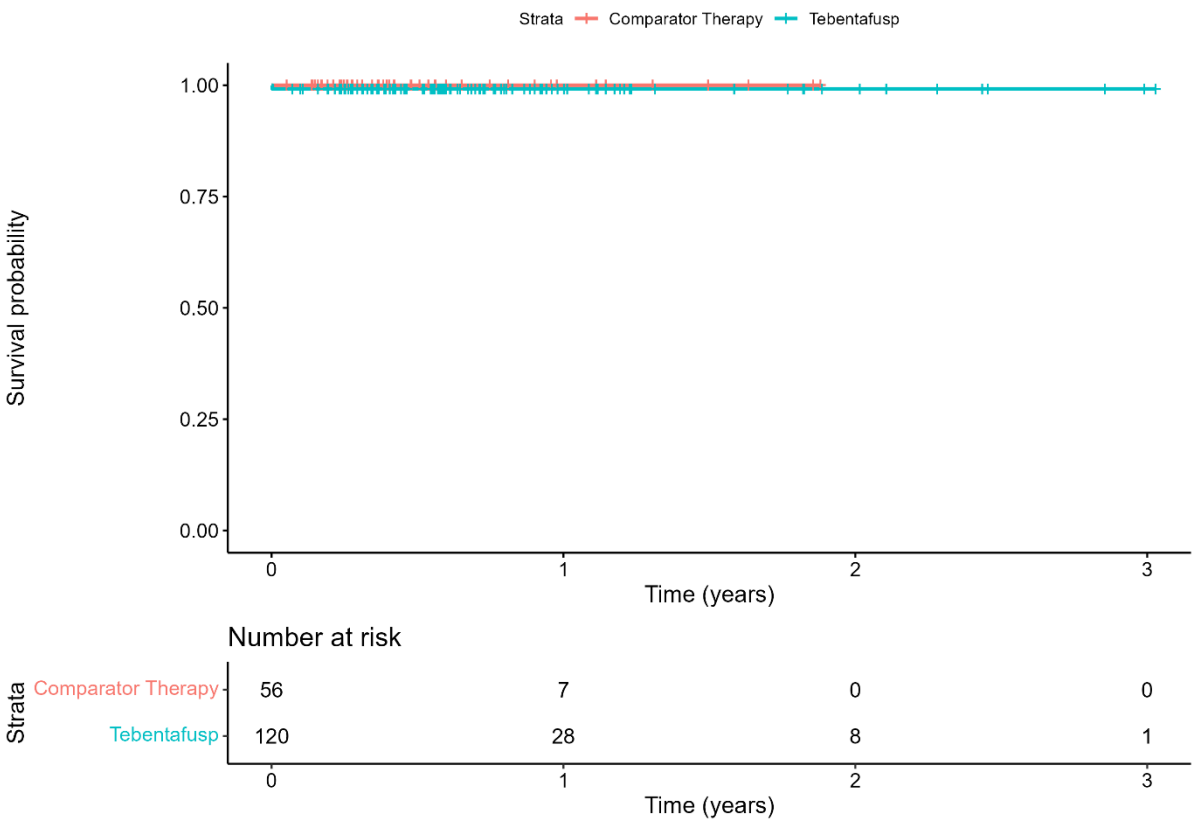
Herkunft: Nicht-hispanisch



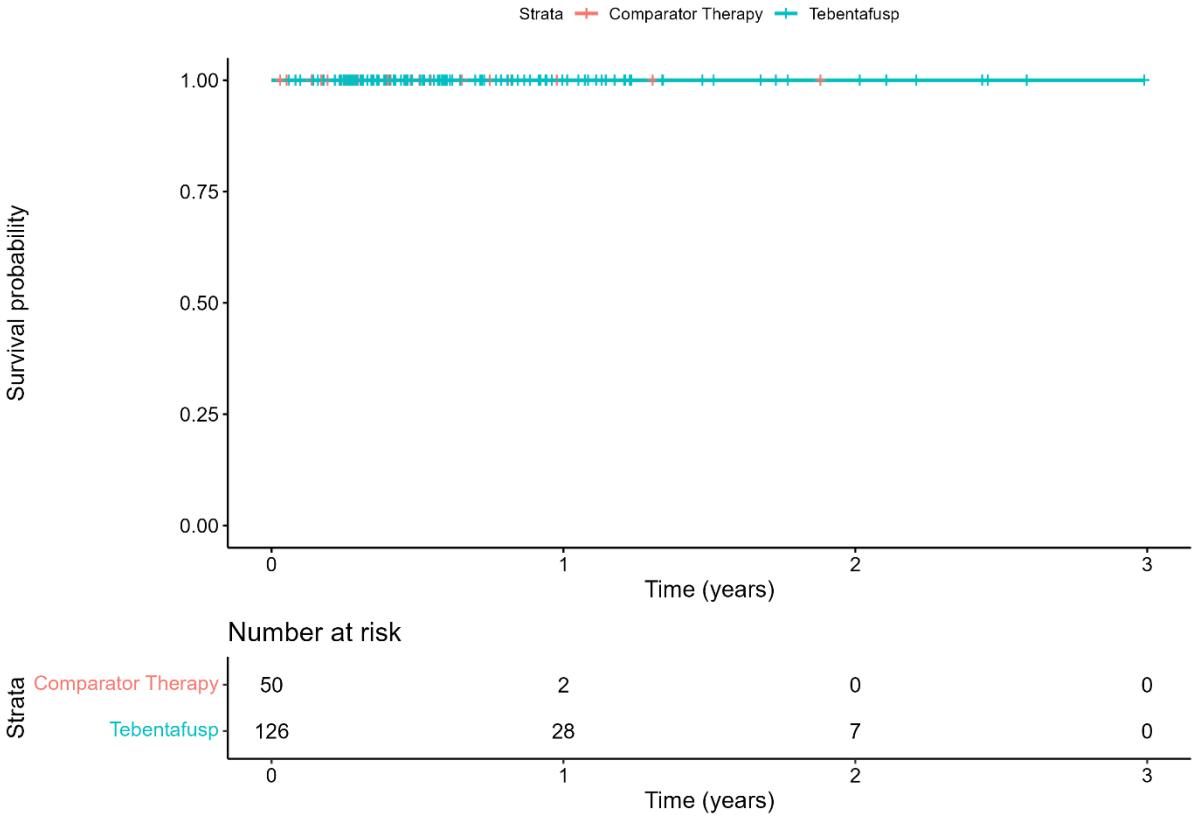
Geschlecht: Männlich



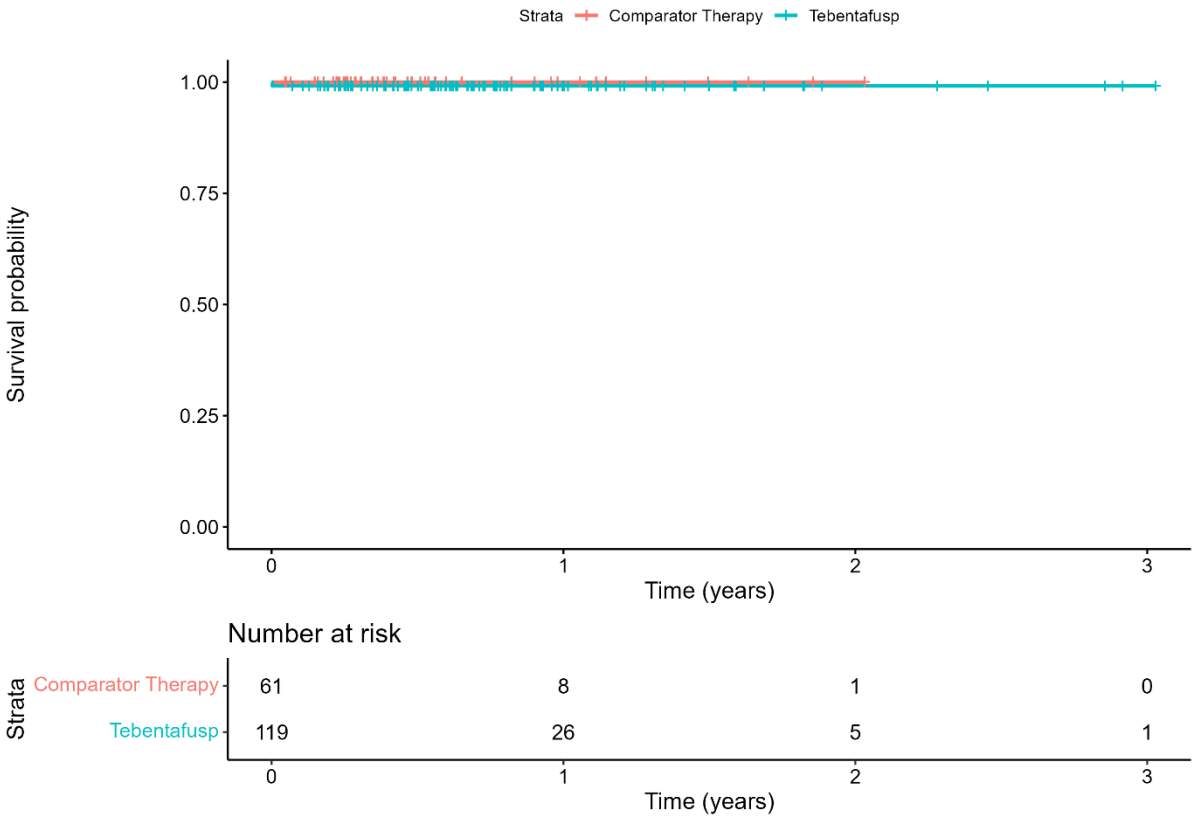
Geschlecht: Weiblich



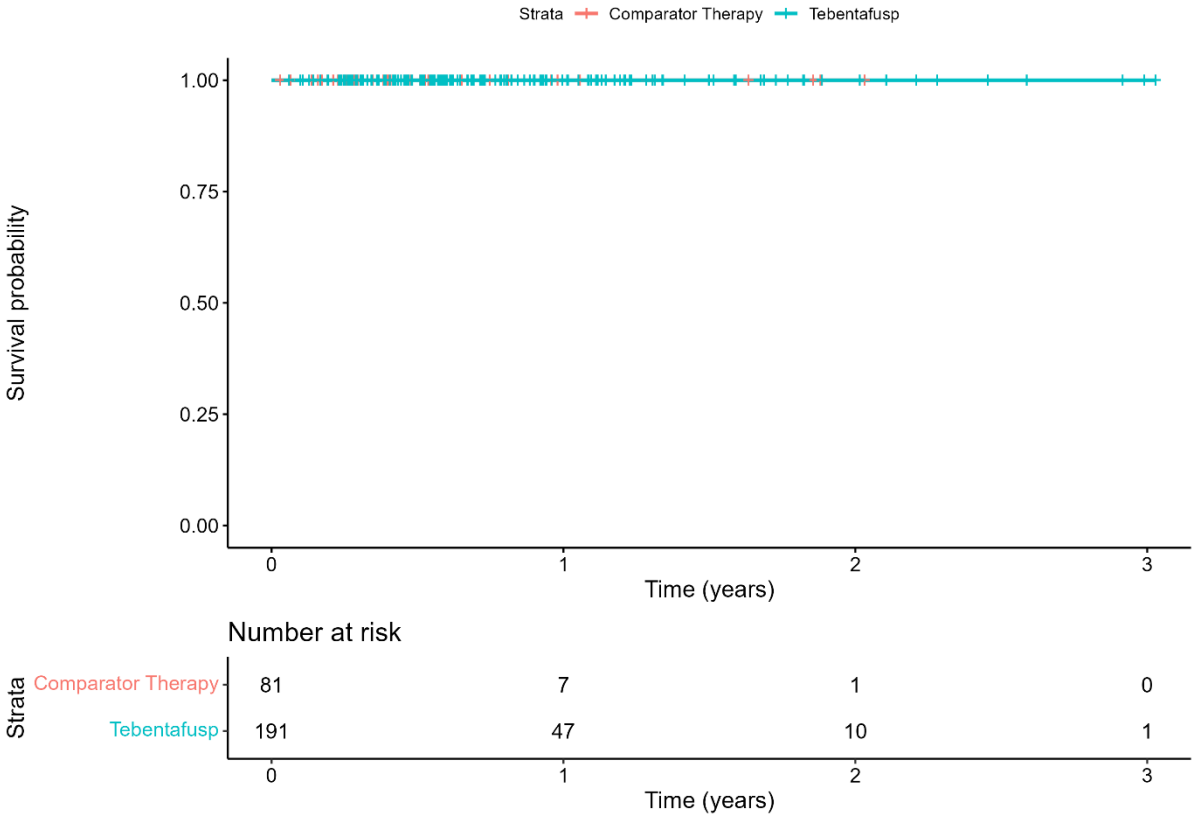
Alter: <65 Jahre



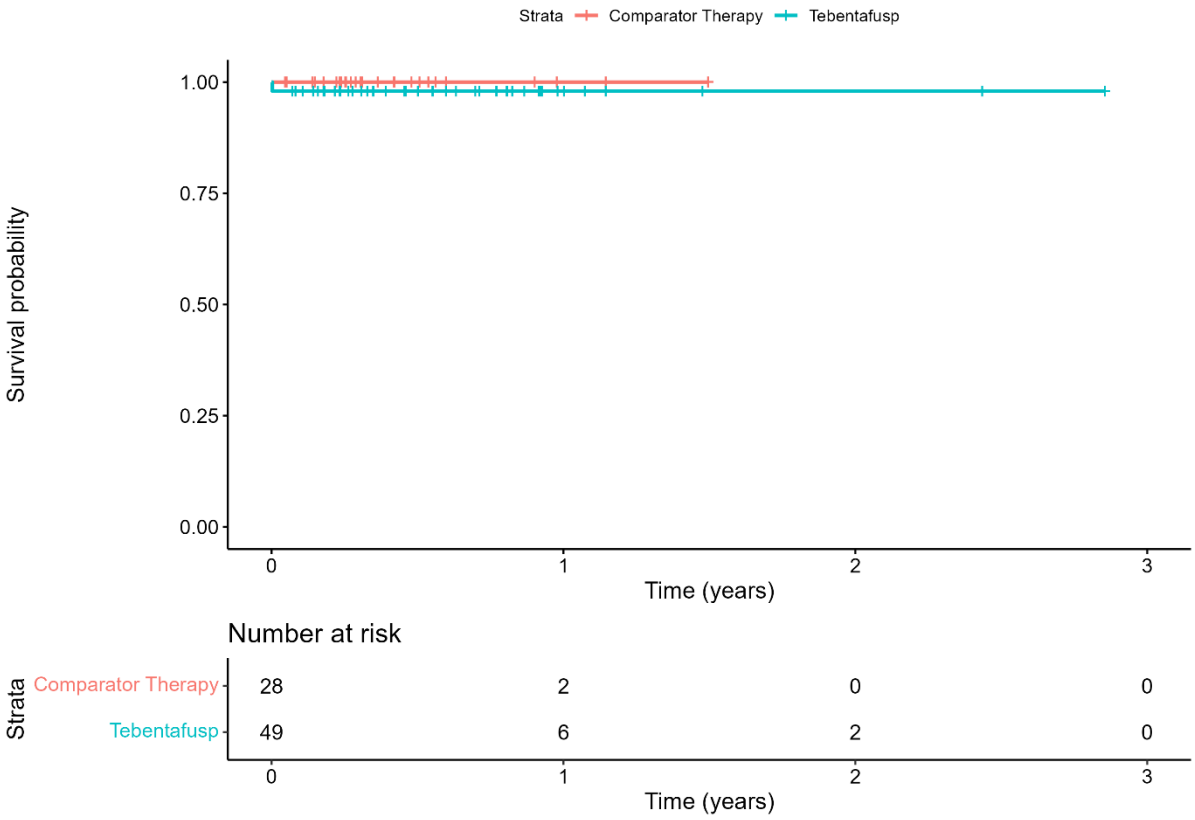
Alter: ≥65 Jahre



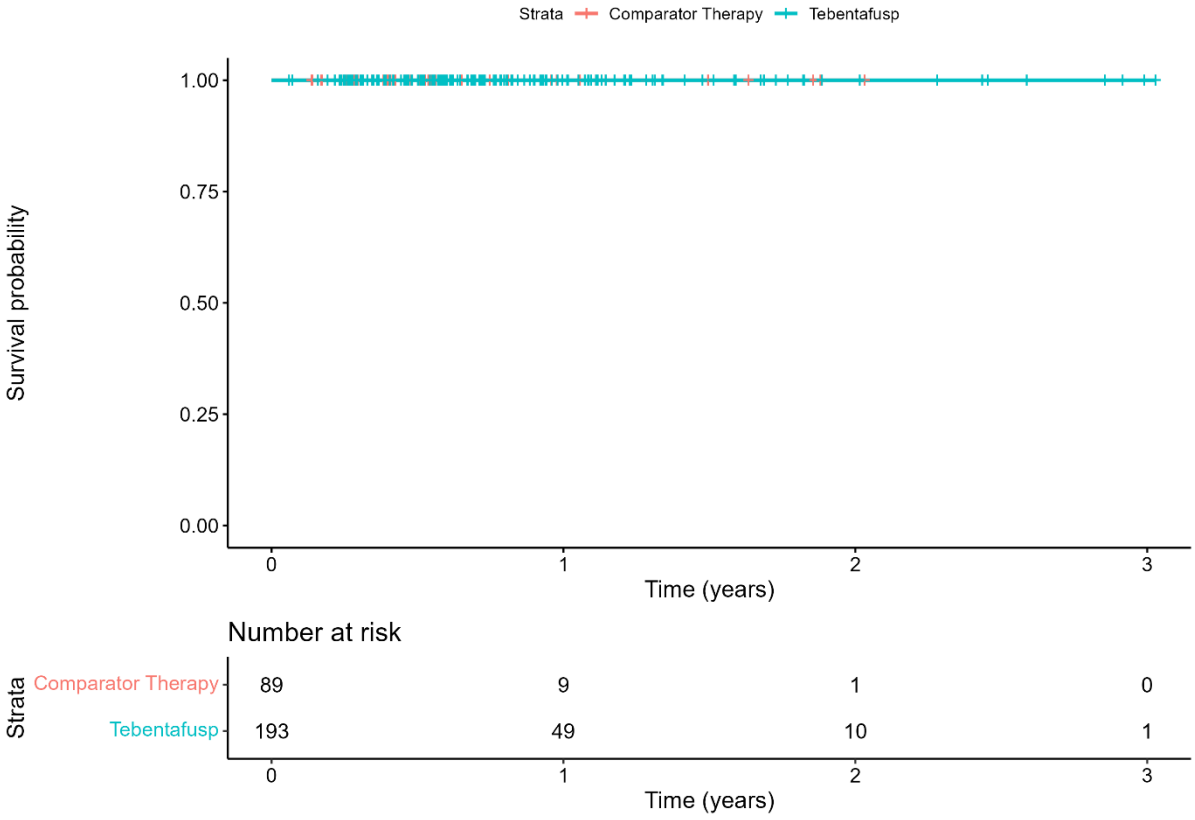
ECOG-Performance-Status: 0



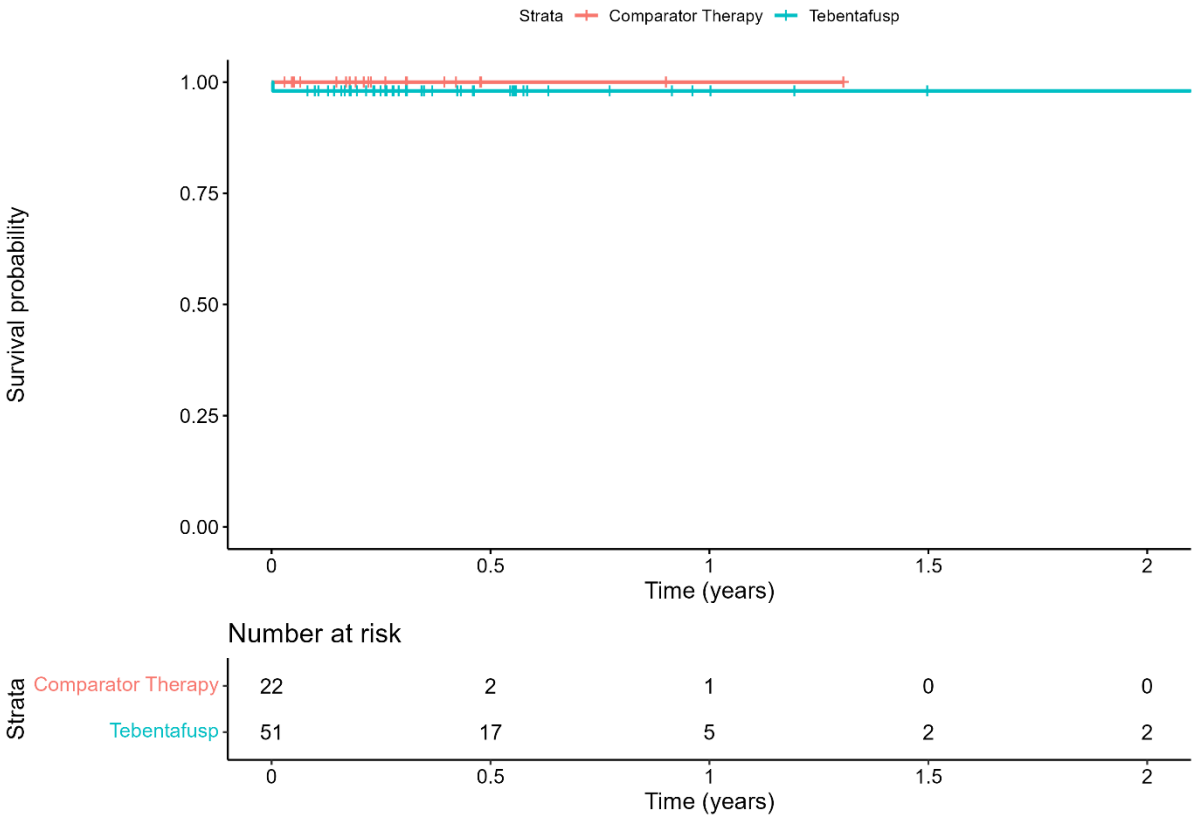
ECOG-Performance-Status: 1



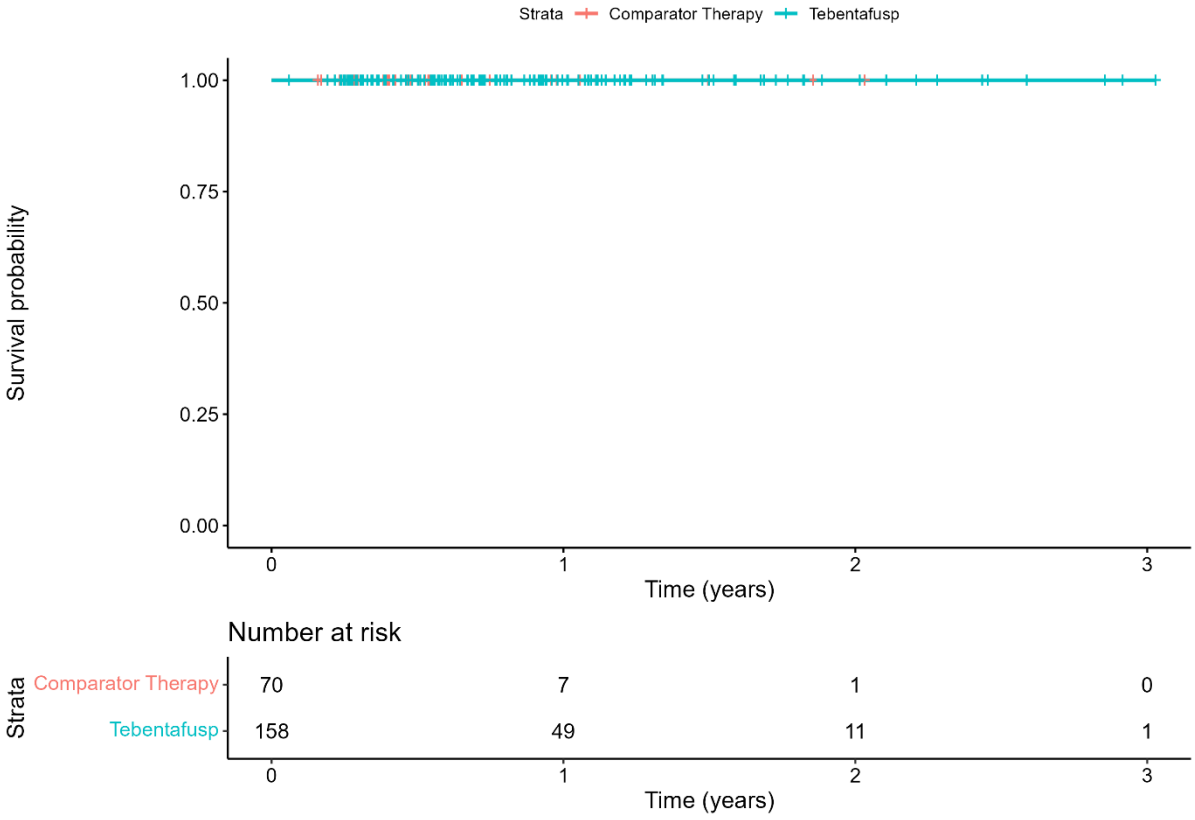
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



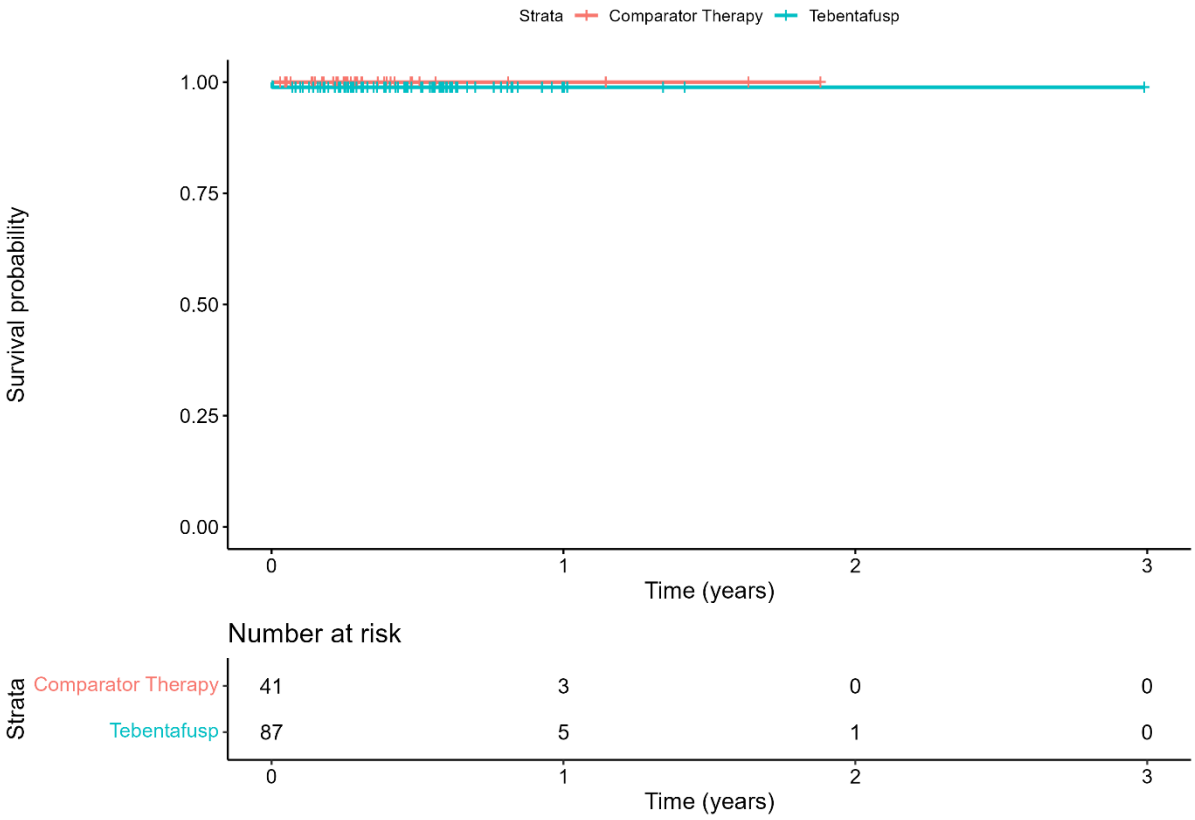
Alkalische Phosphatase (ALP) (Baseline): >ULN



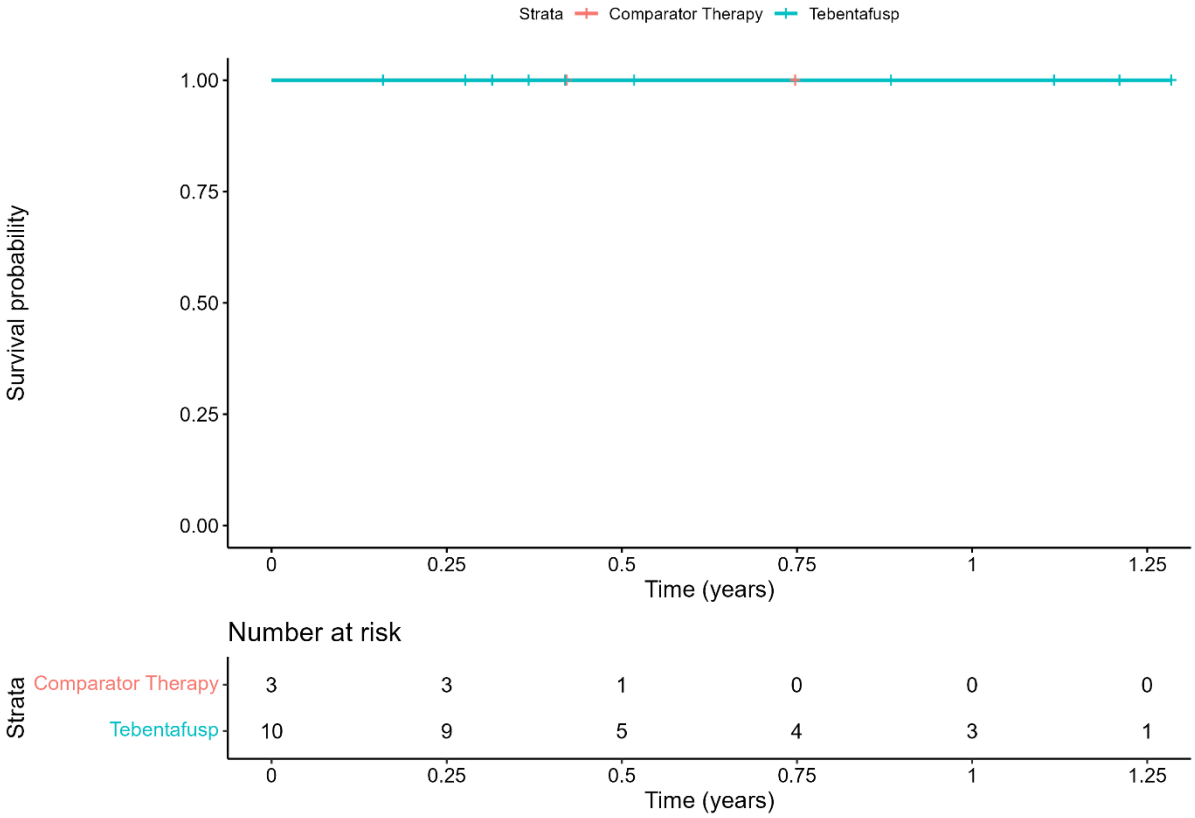
LDH: ≤ULN



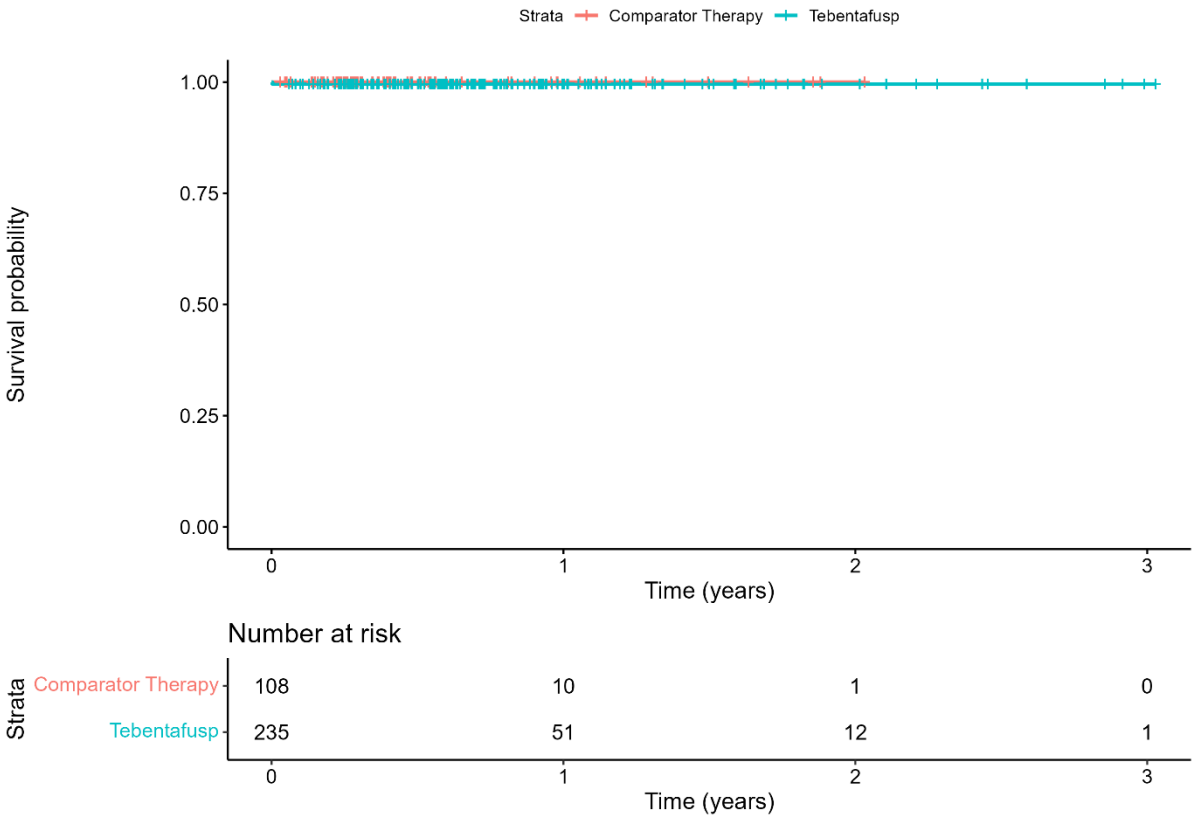
LDH: >ULN



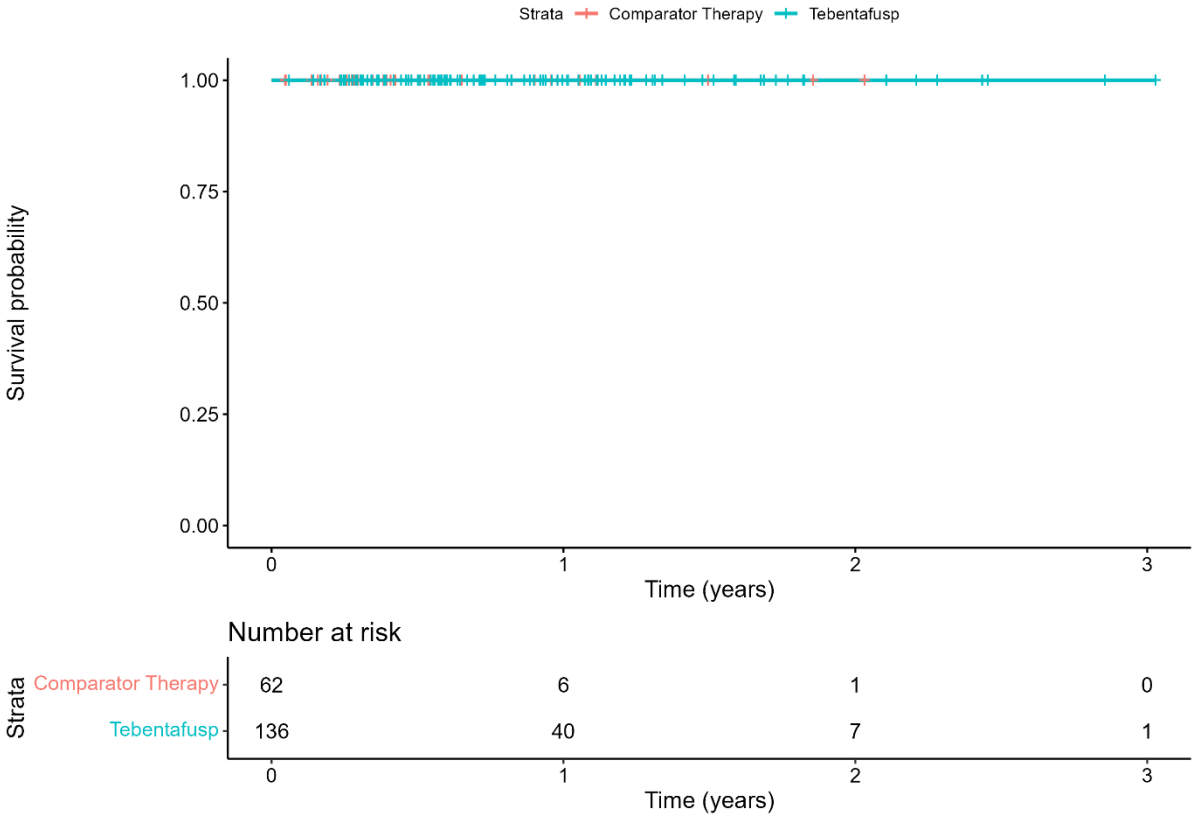
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



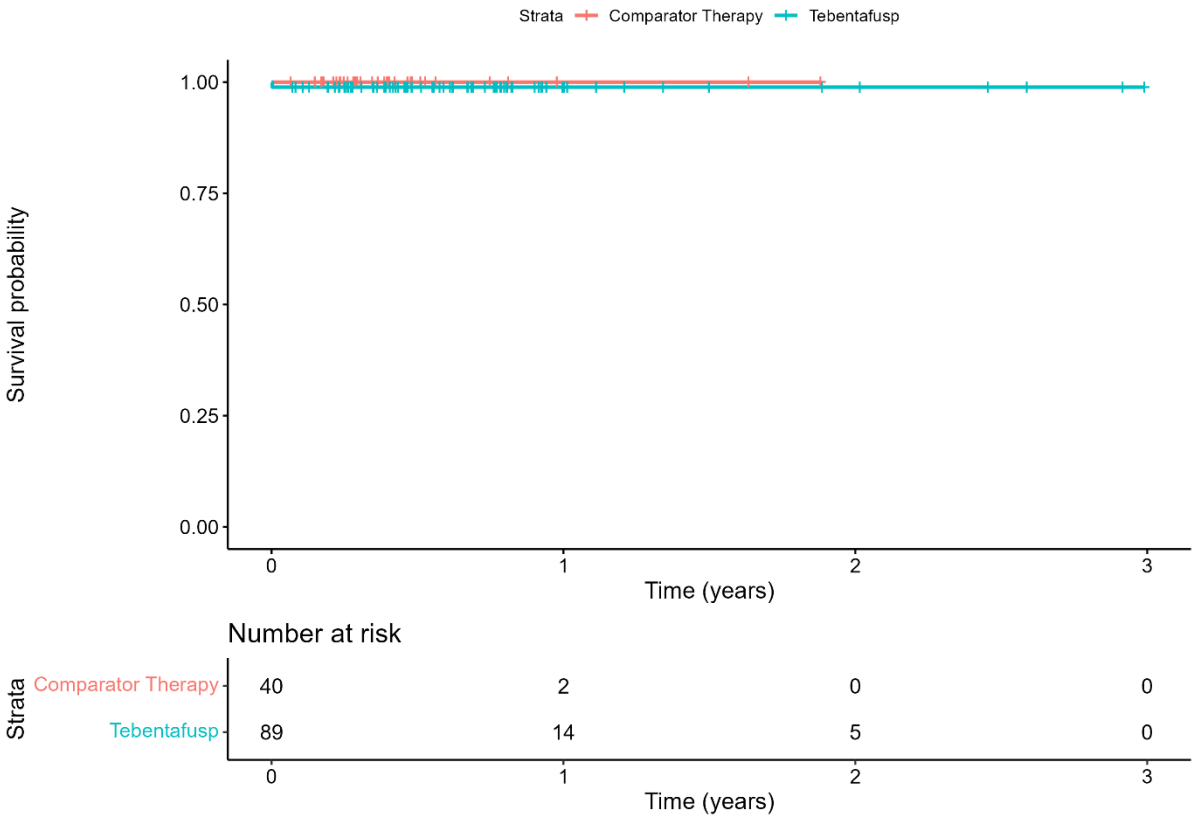
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



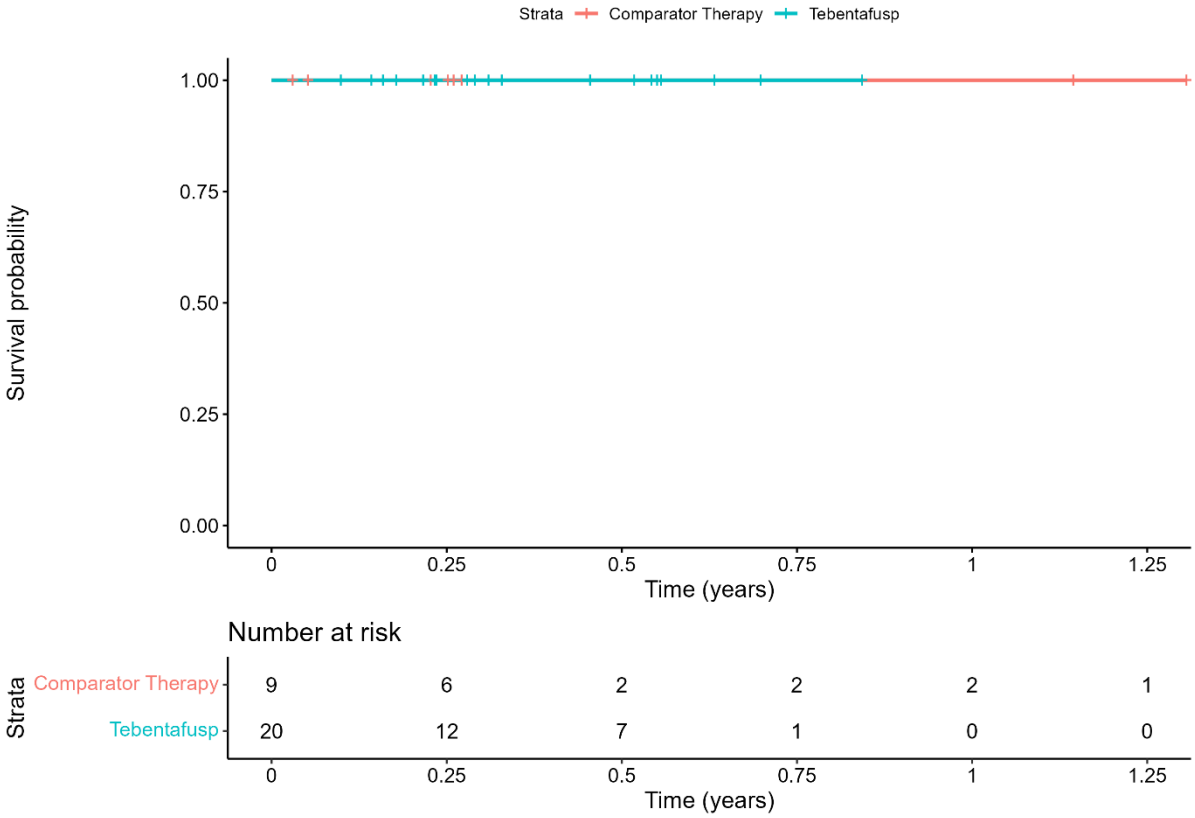
Größte metastatische Läsion (Baseline): ≤3,0 cm



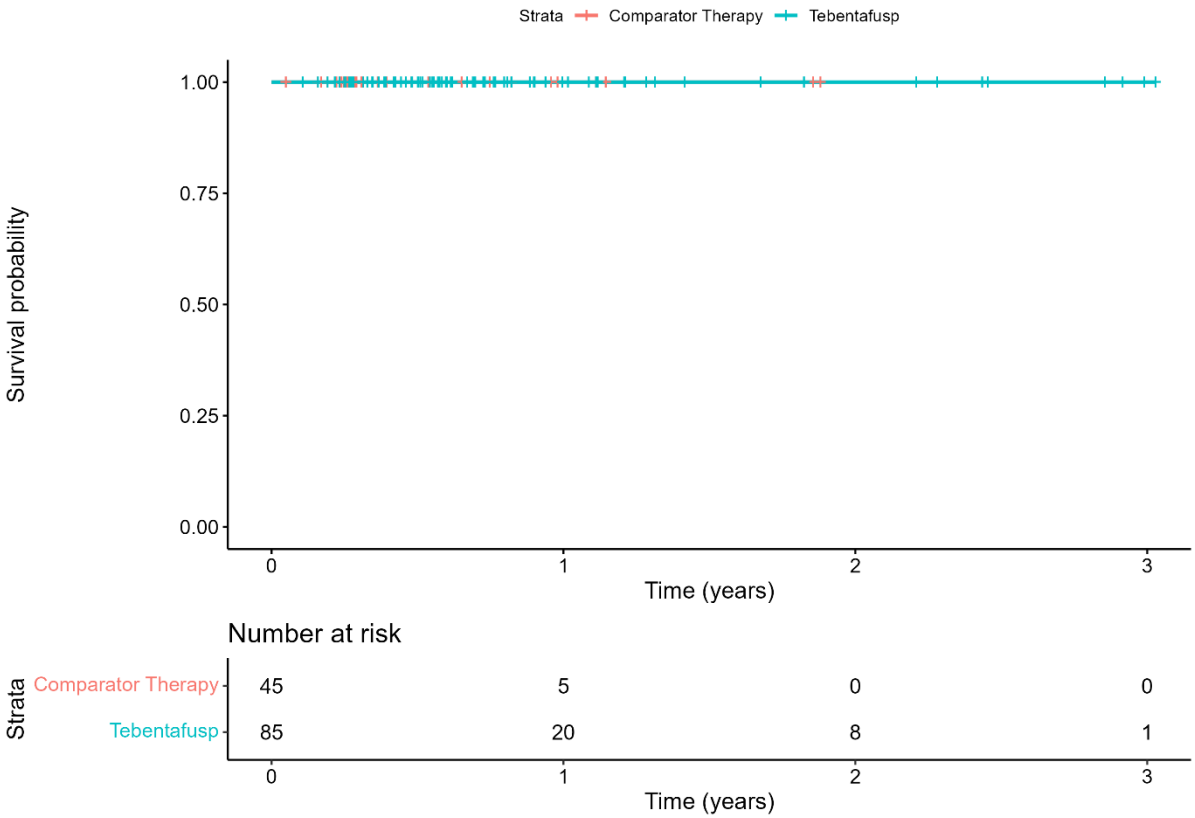
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



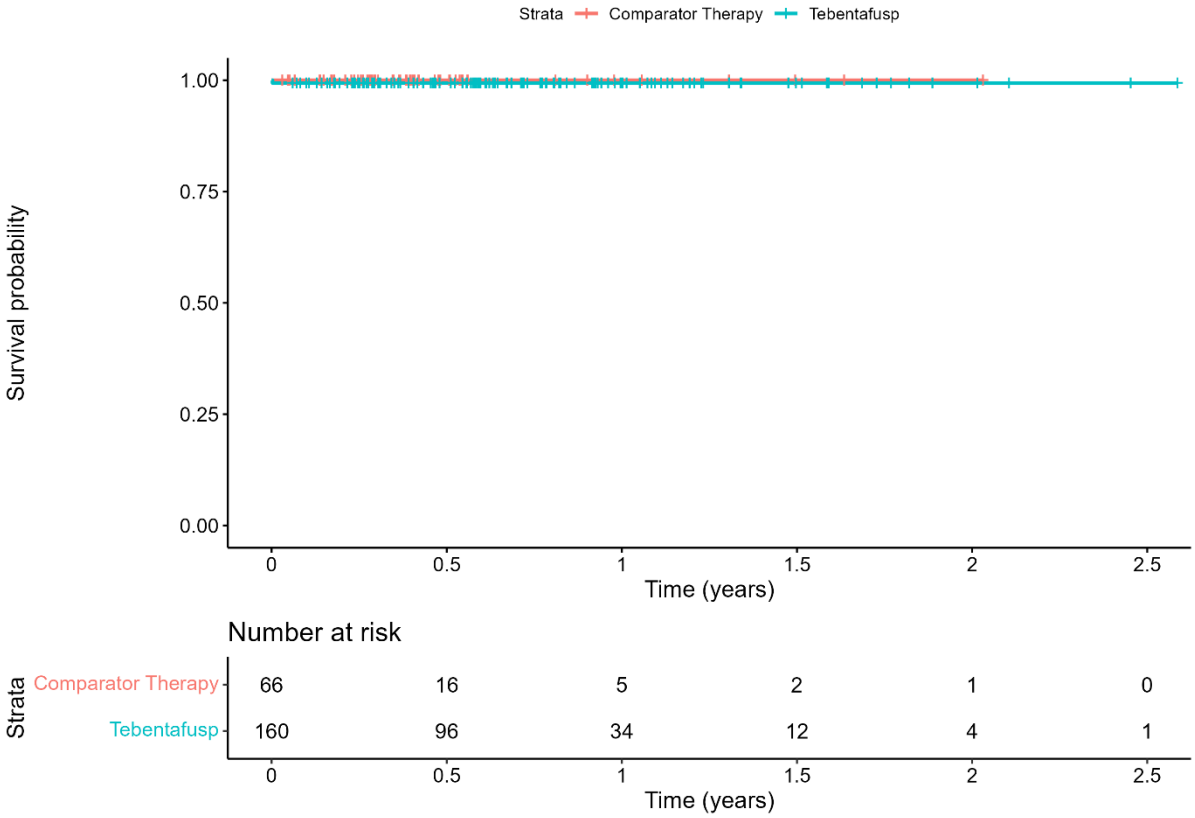
Größte metastatische Läsion (Baseline): ≥8,1 cm



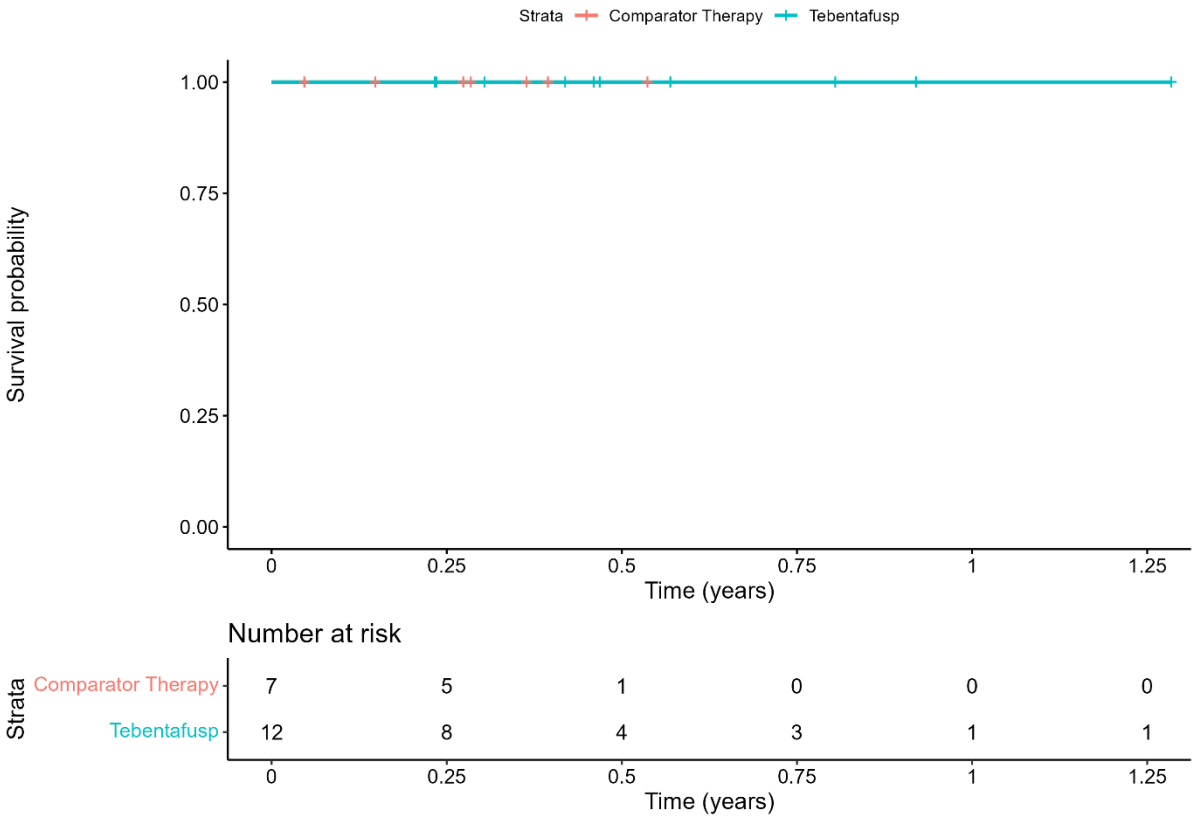
Region: Nordamerika



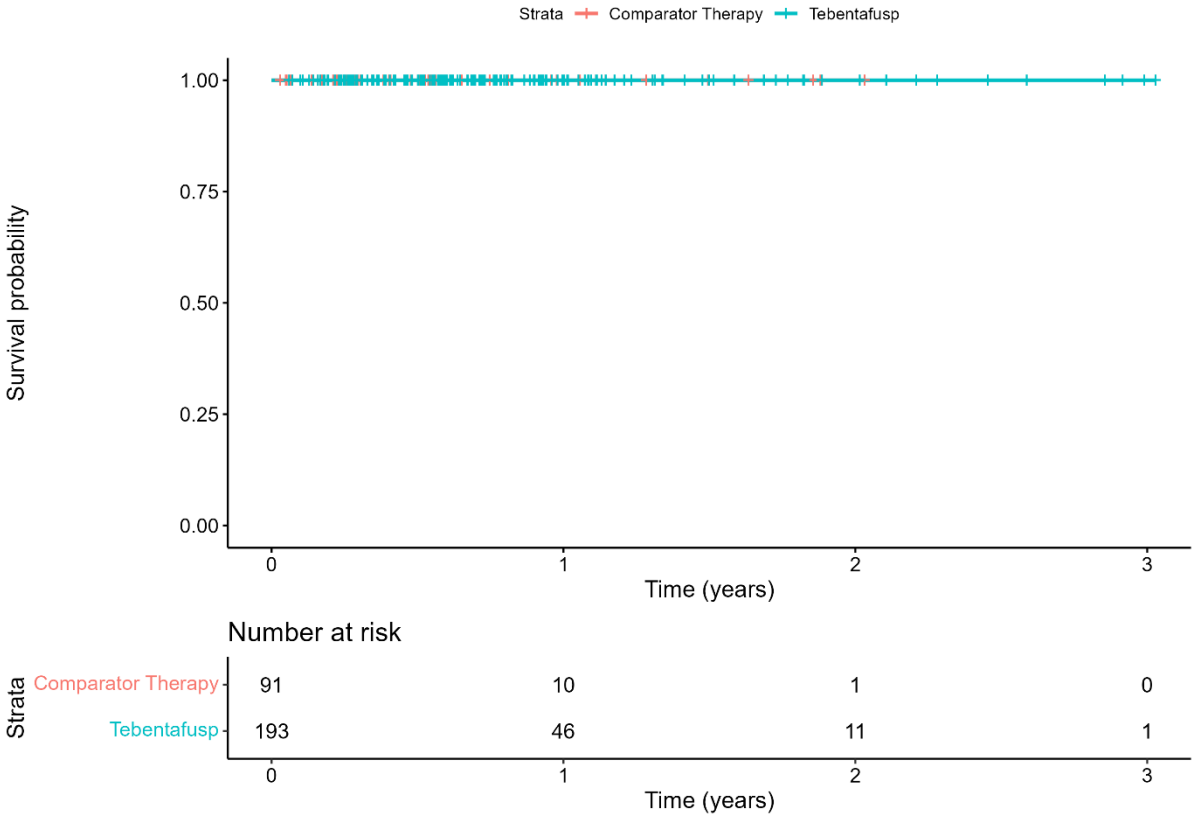
Region: Nicht-Nordamerika



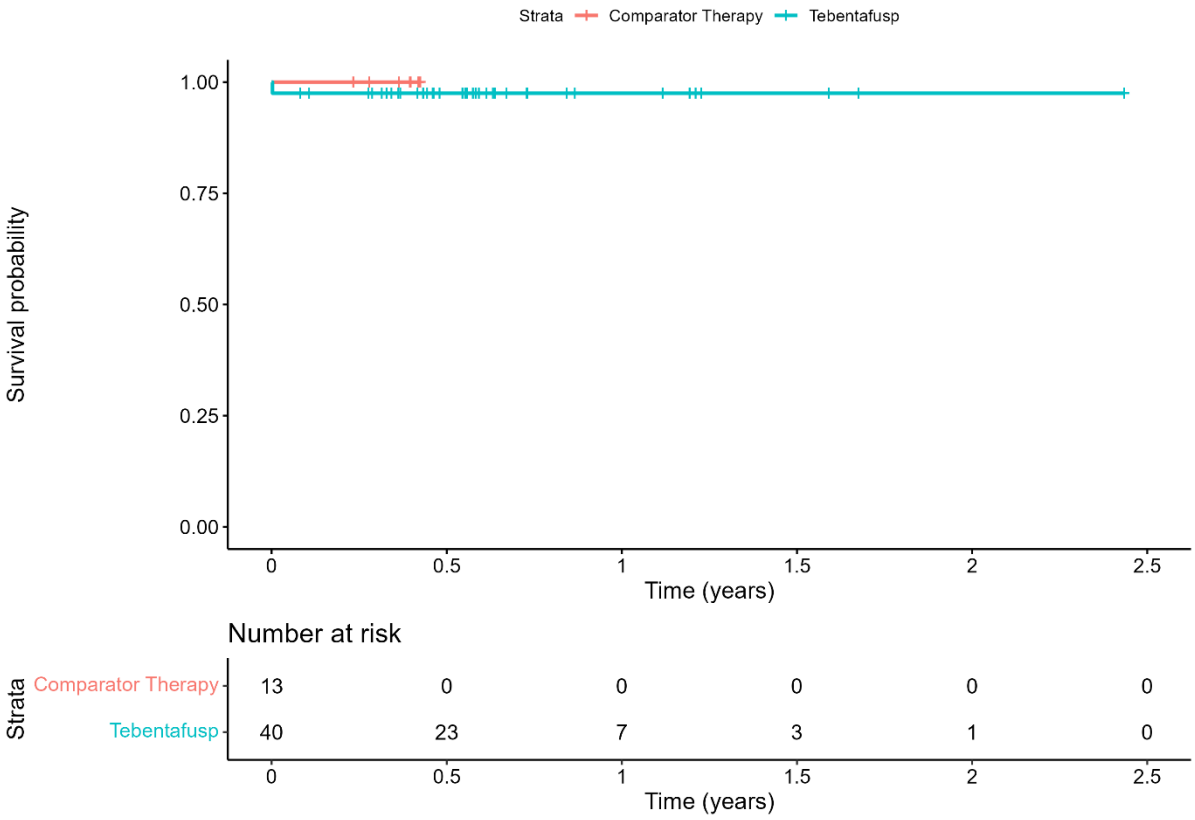
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

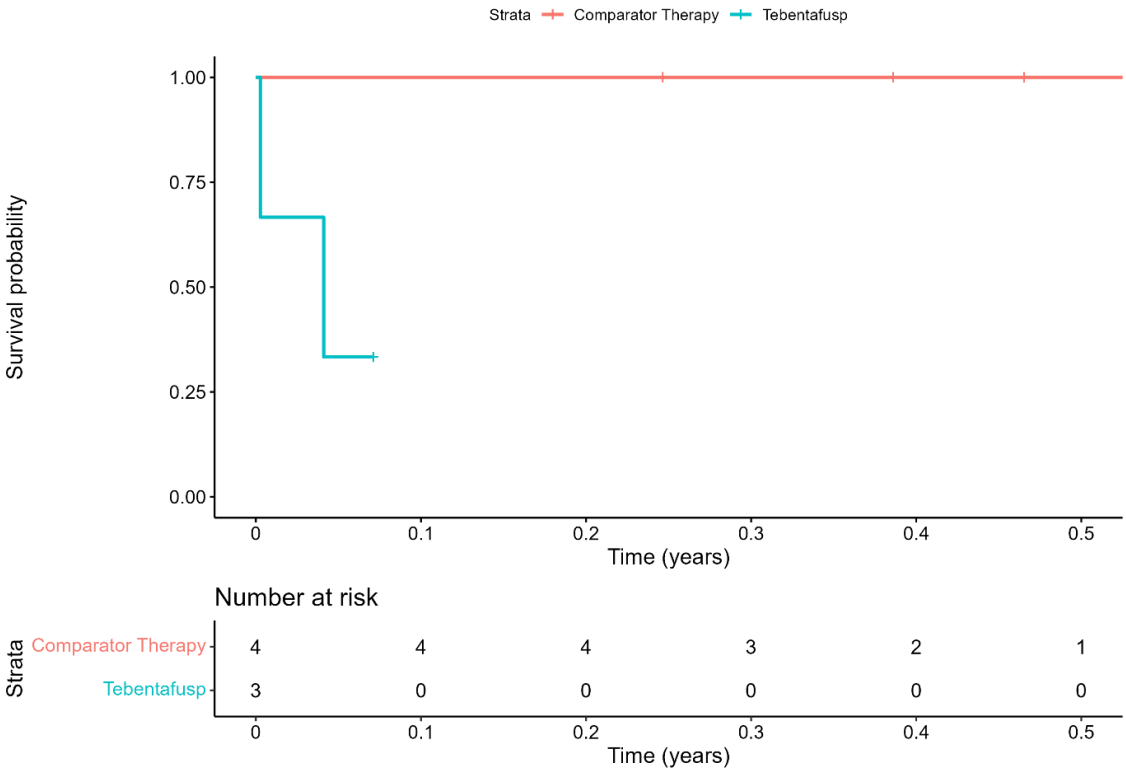


Vorauswahl der Chemotherapie: Ipilimumab

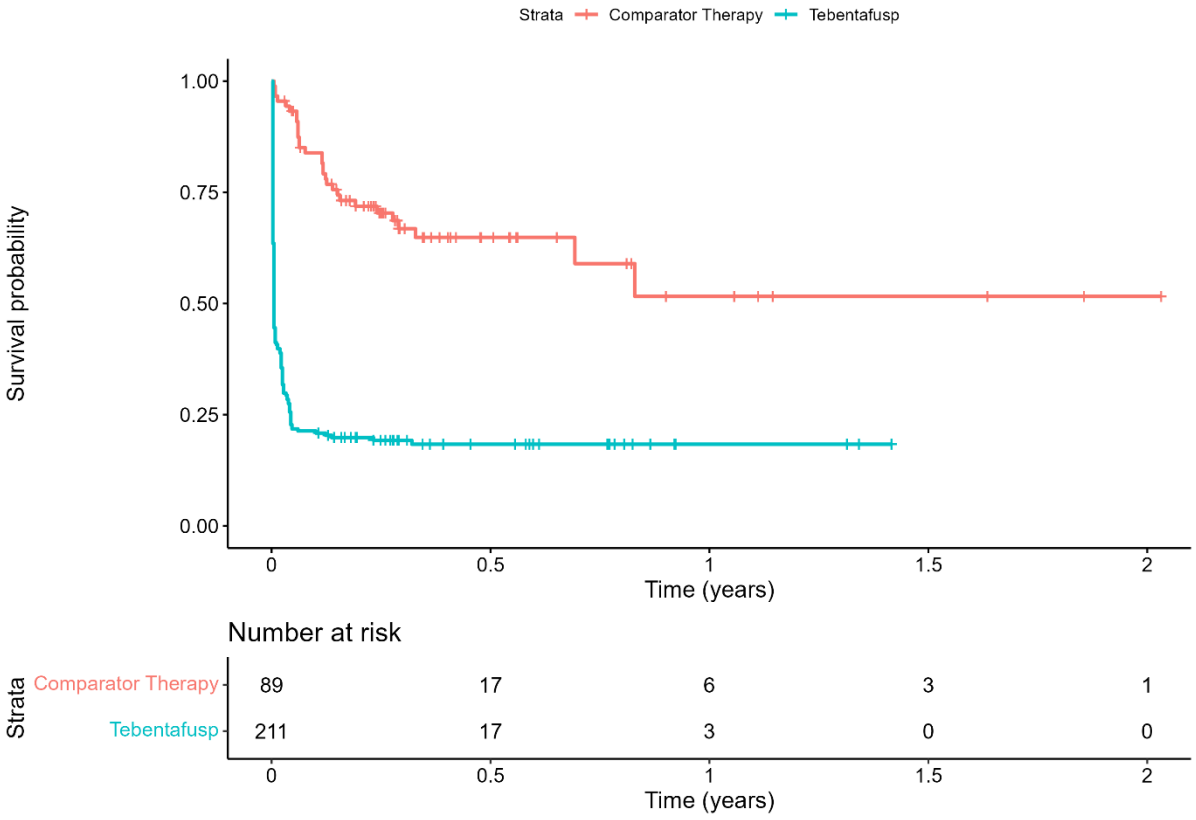


23.1 Hautausschlag (Tabelle 4-103)

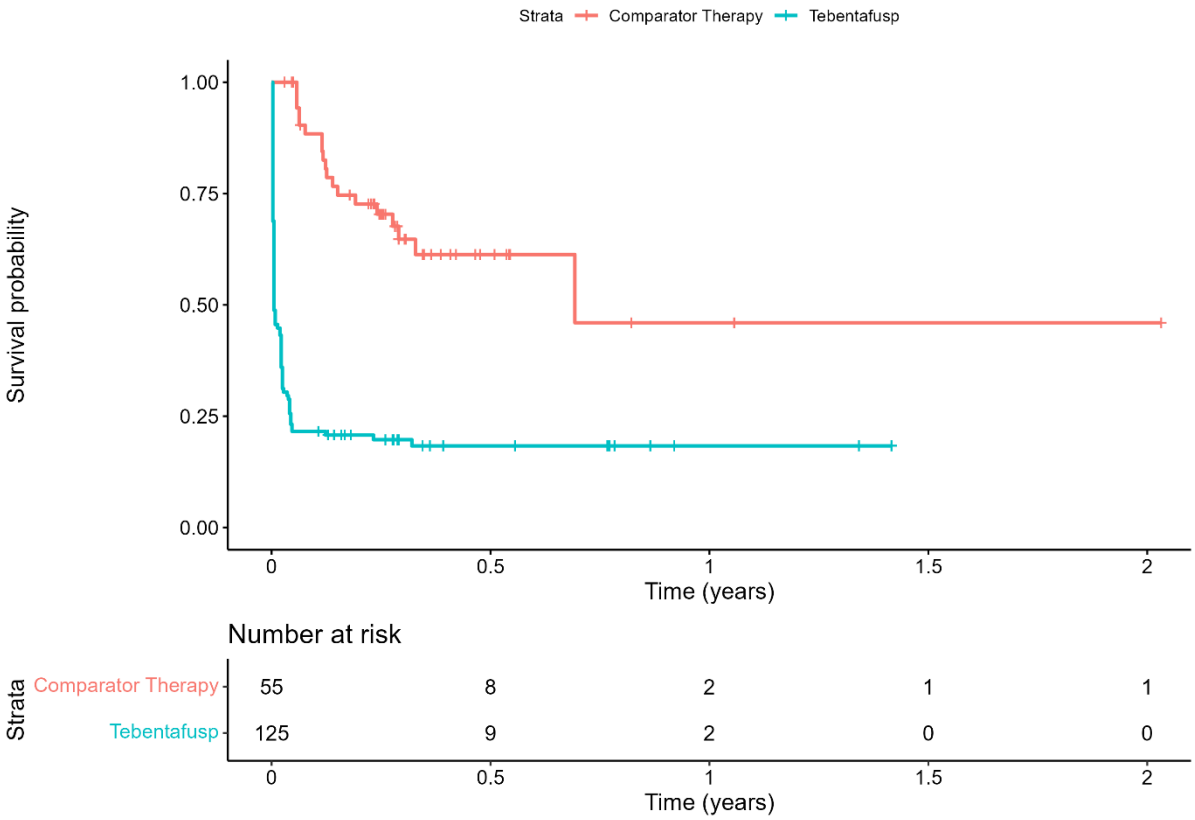
Herkunft: Hispanisch



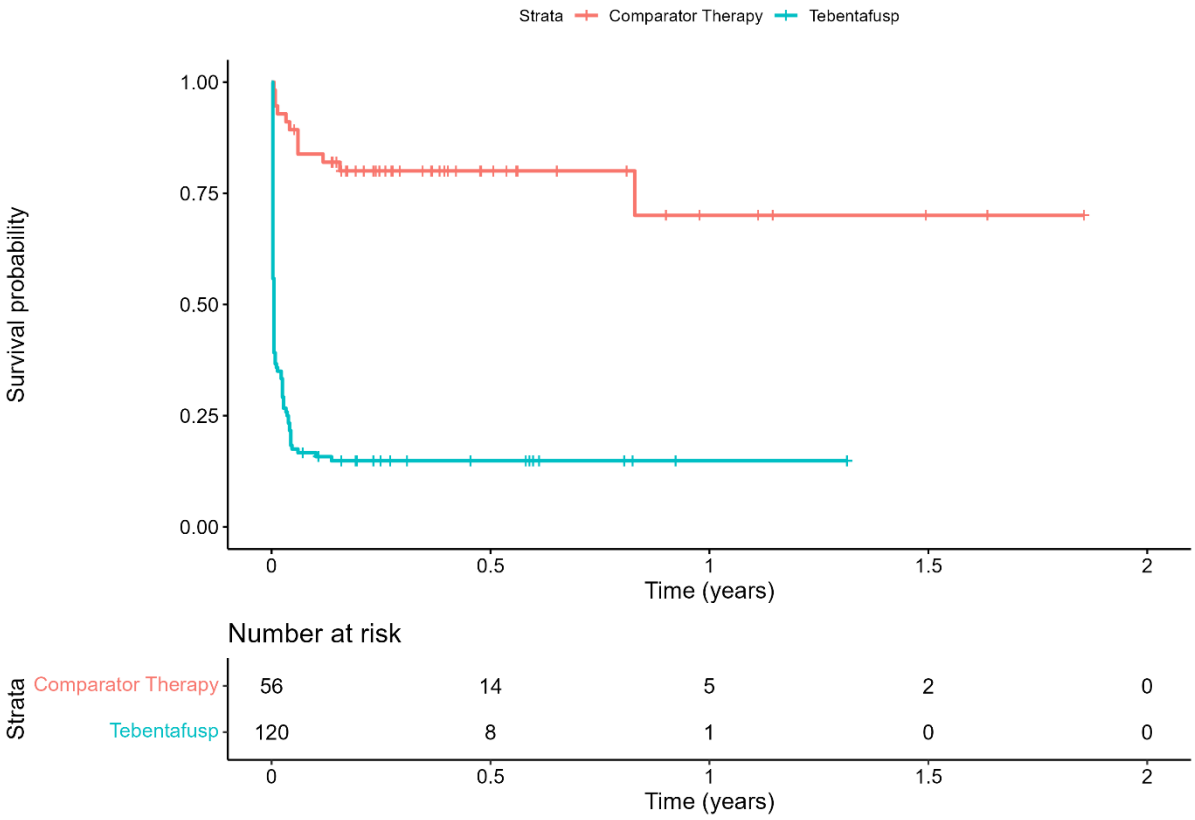
Herkunft: Nicht-hispanisch



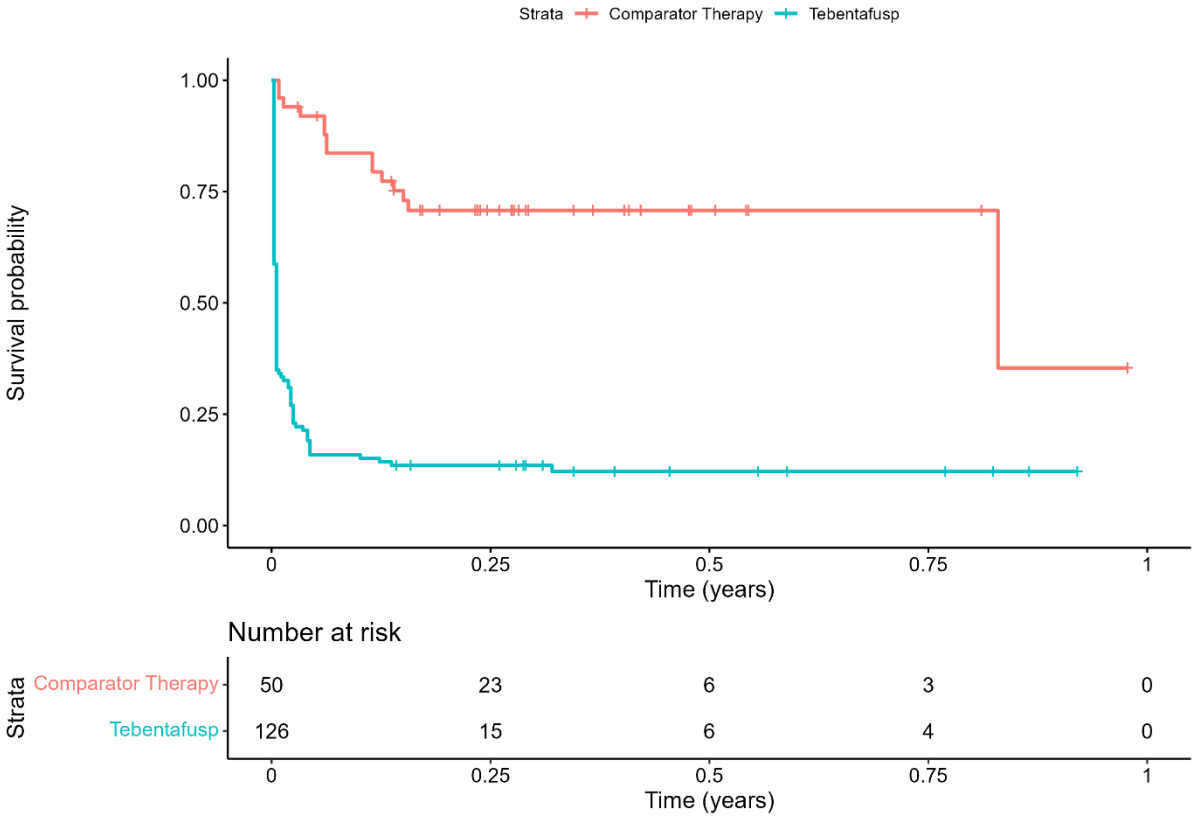
Geschlecht: Männlich



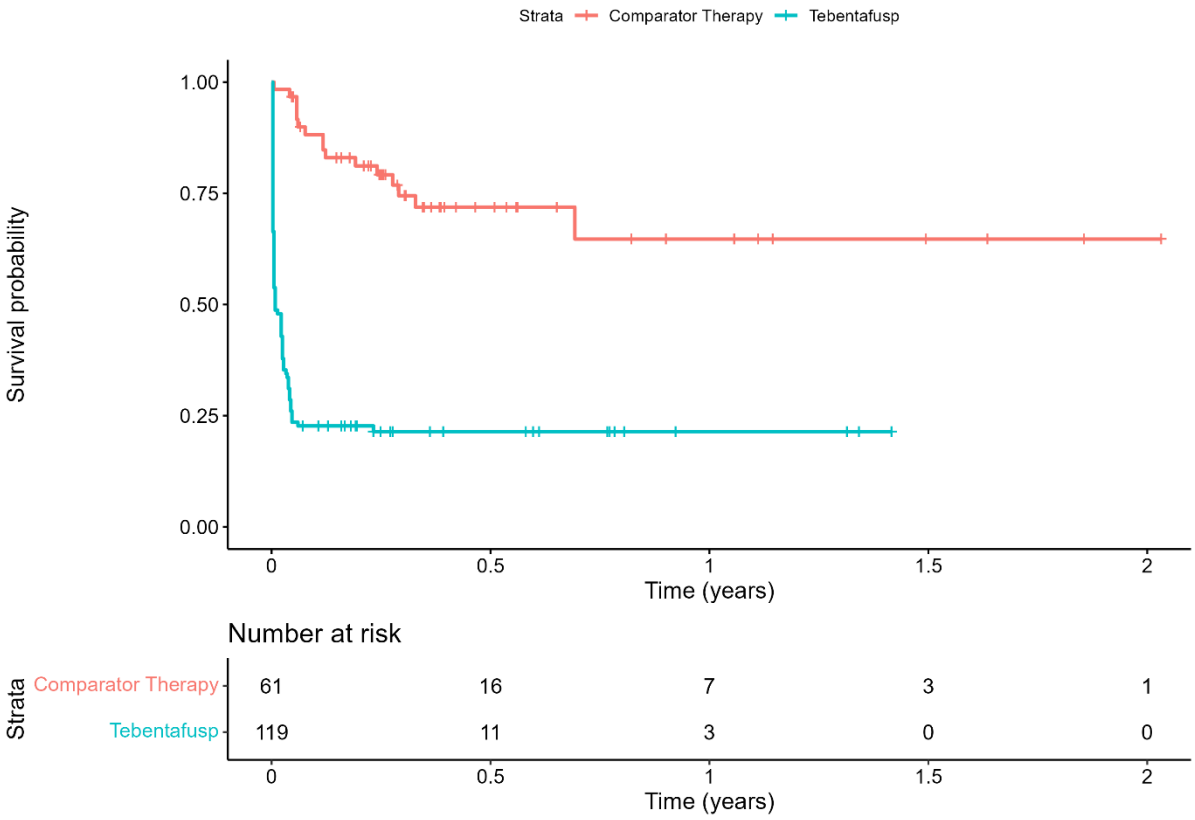
Geschlecht: Weiblich



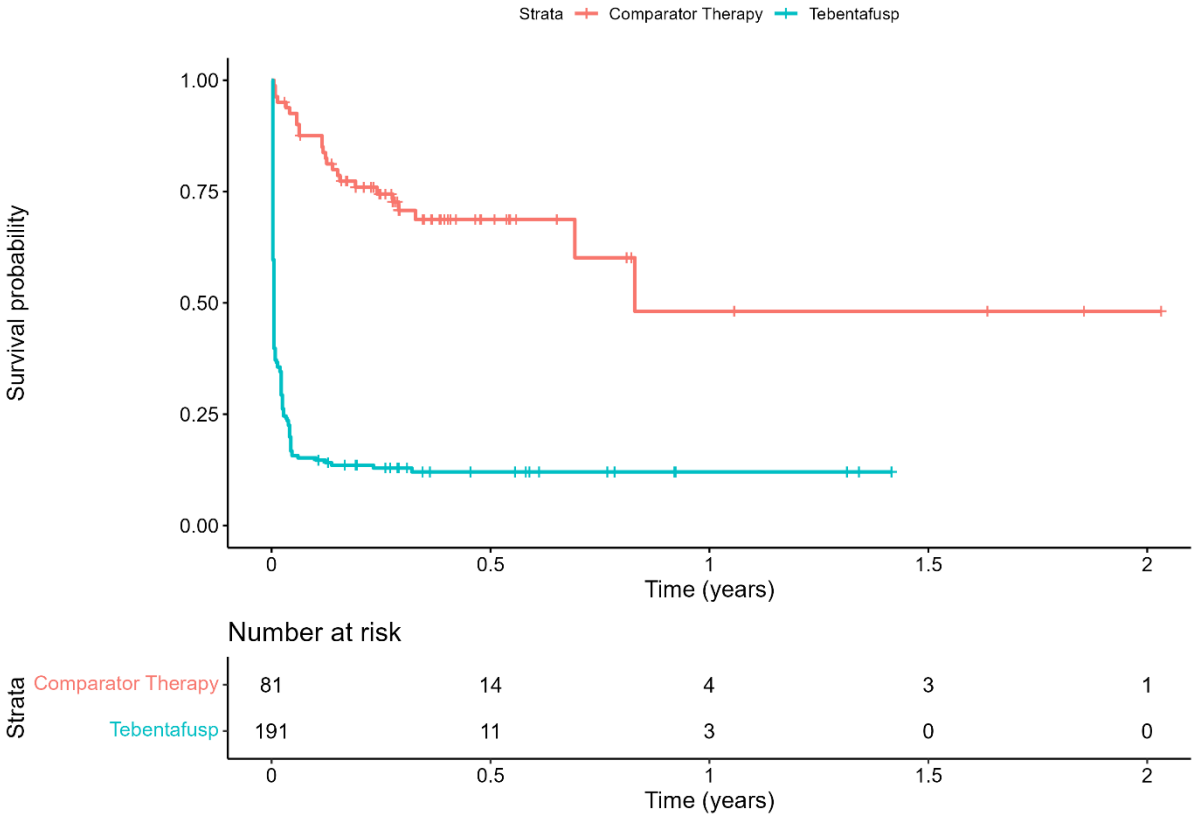
Alter: <65 Jahre



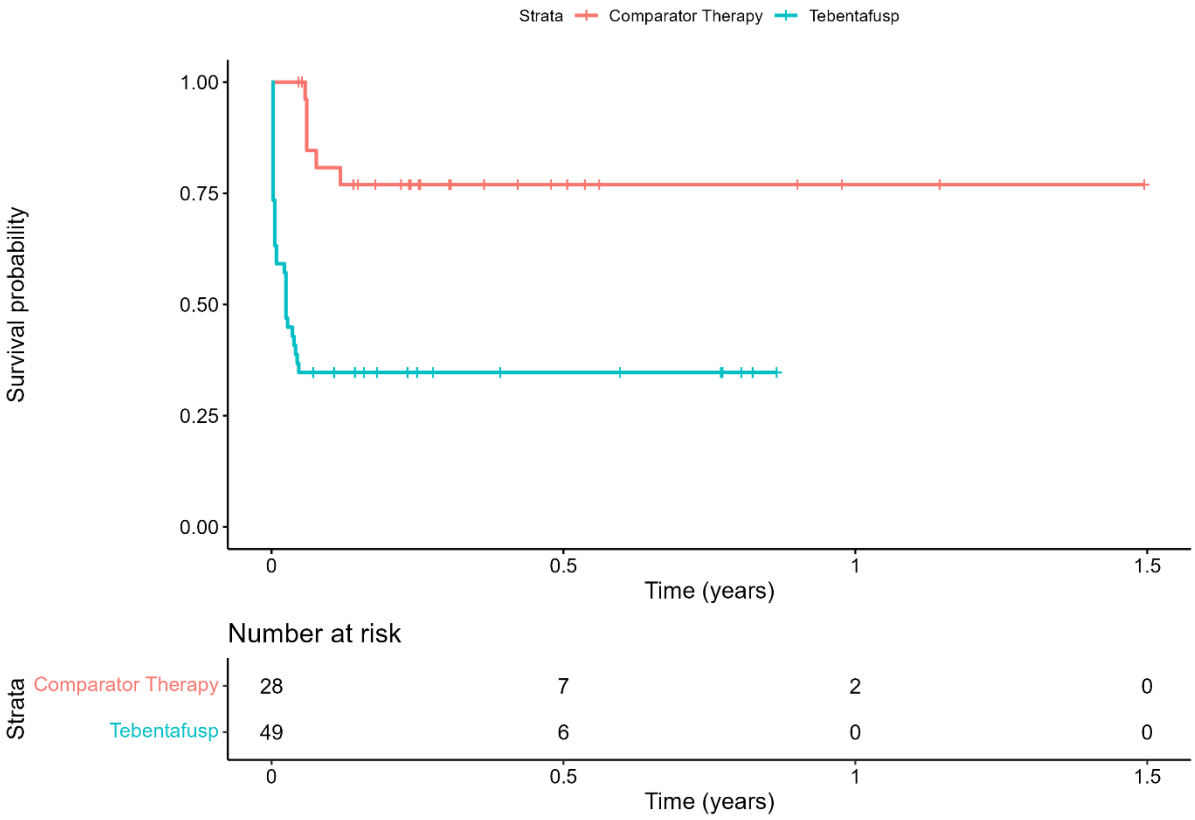
Alter: ≥65 Jahre



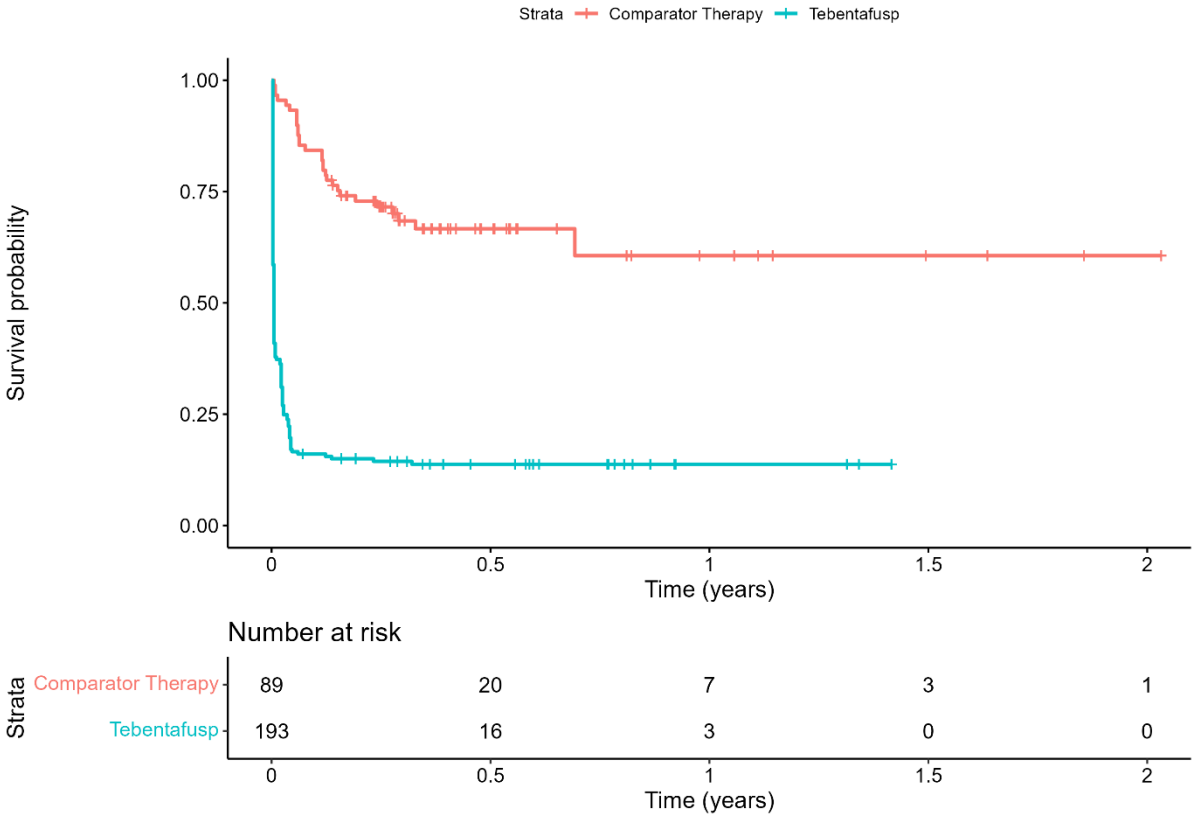
ECOG-Performance-Status: 0



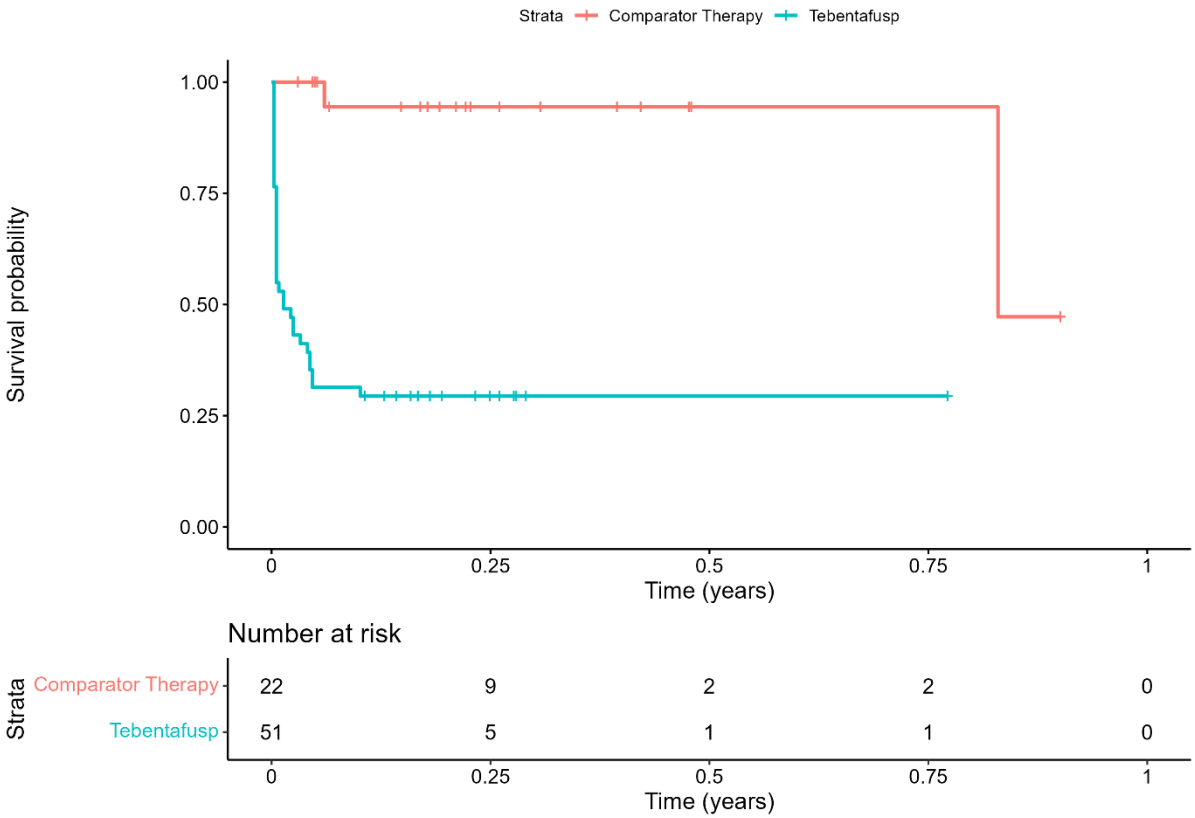
ECOG-Performance-Status: 1



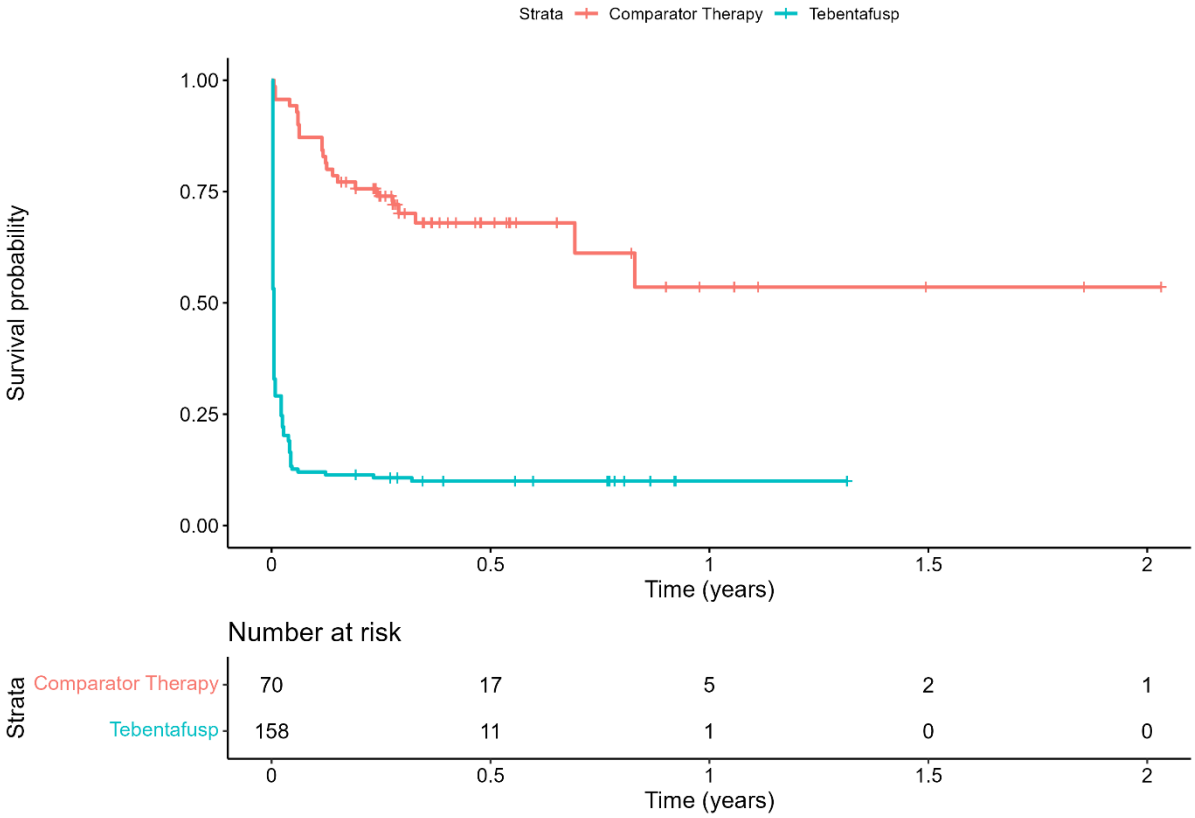
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



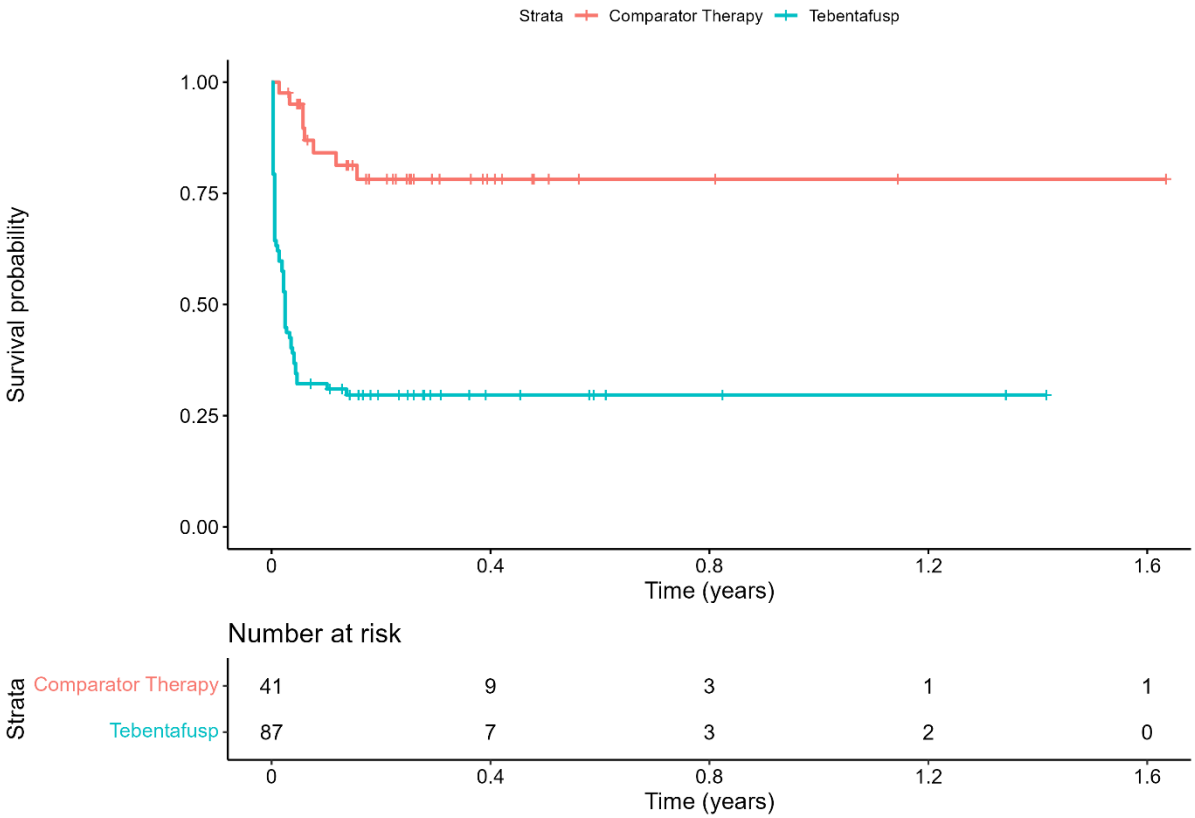
Alkalische Phosphatase (ALP) (Baseline): >ULN



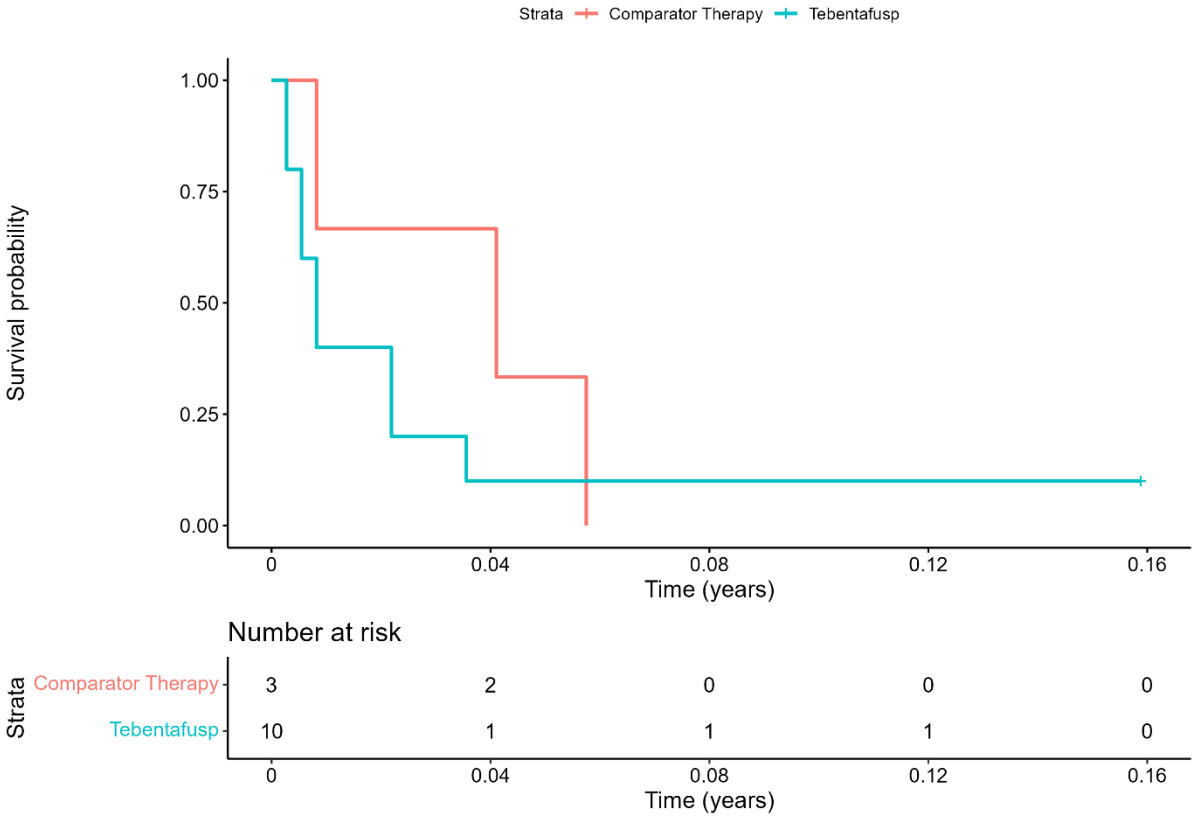
LDH: ≤ULN



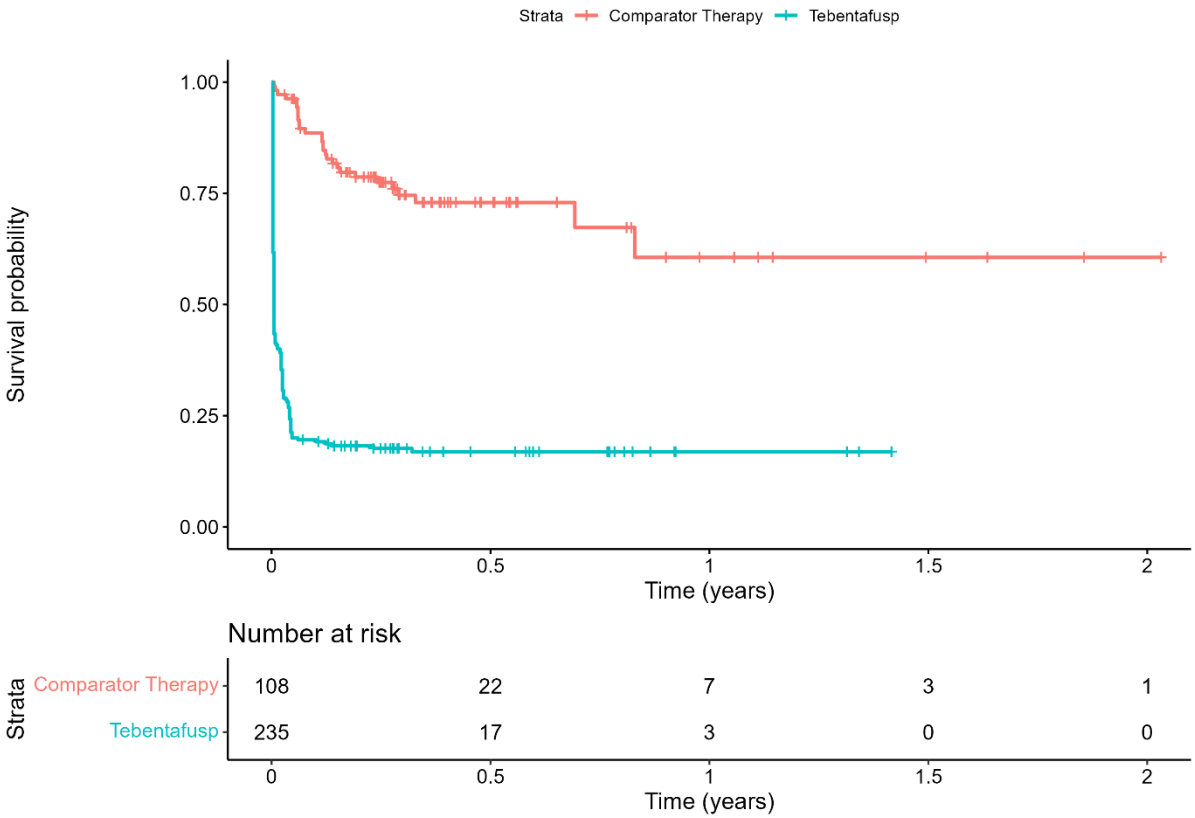
LDH: >ULN



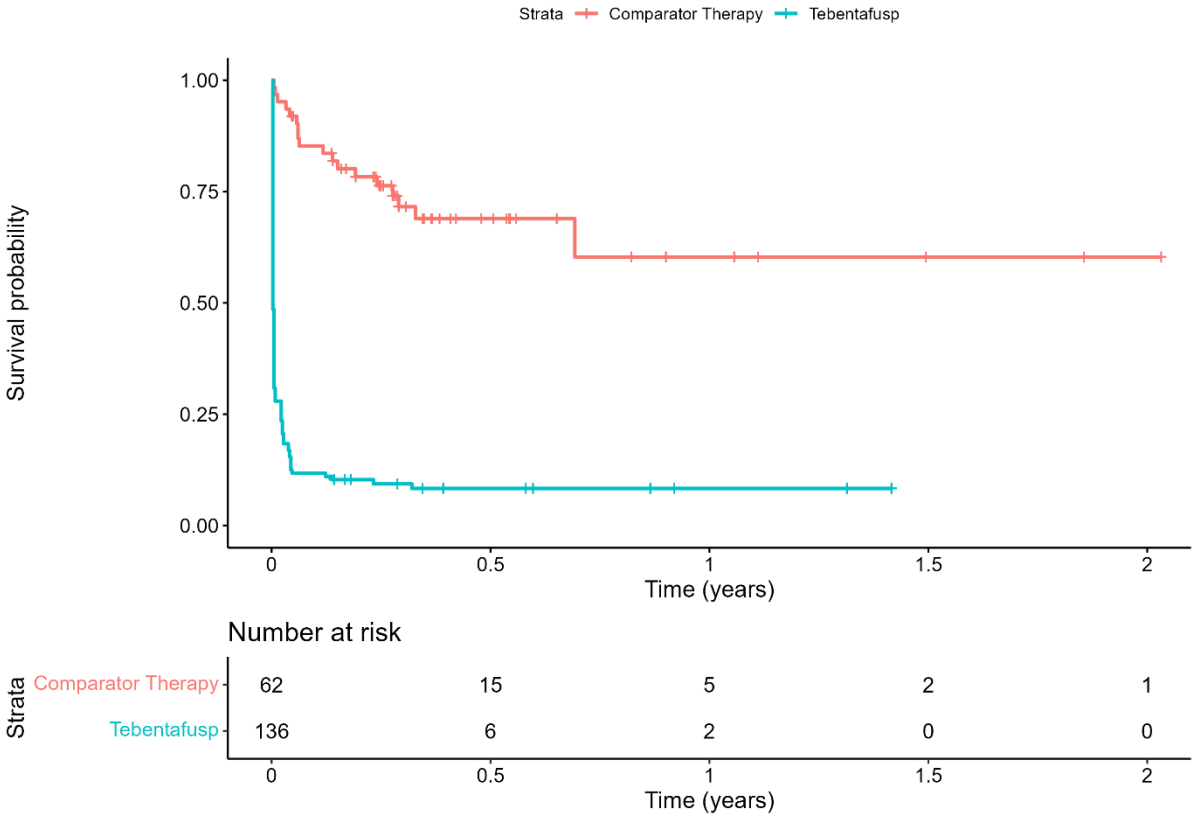
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



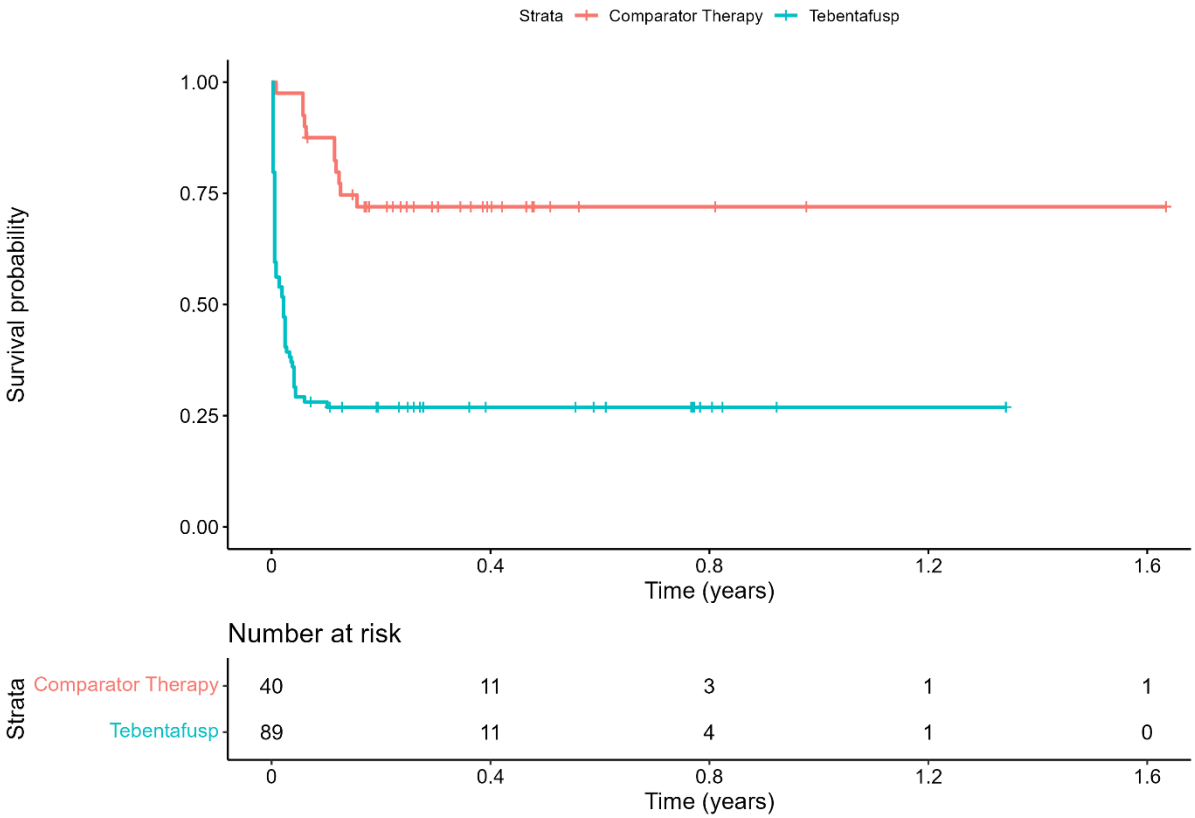
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



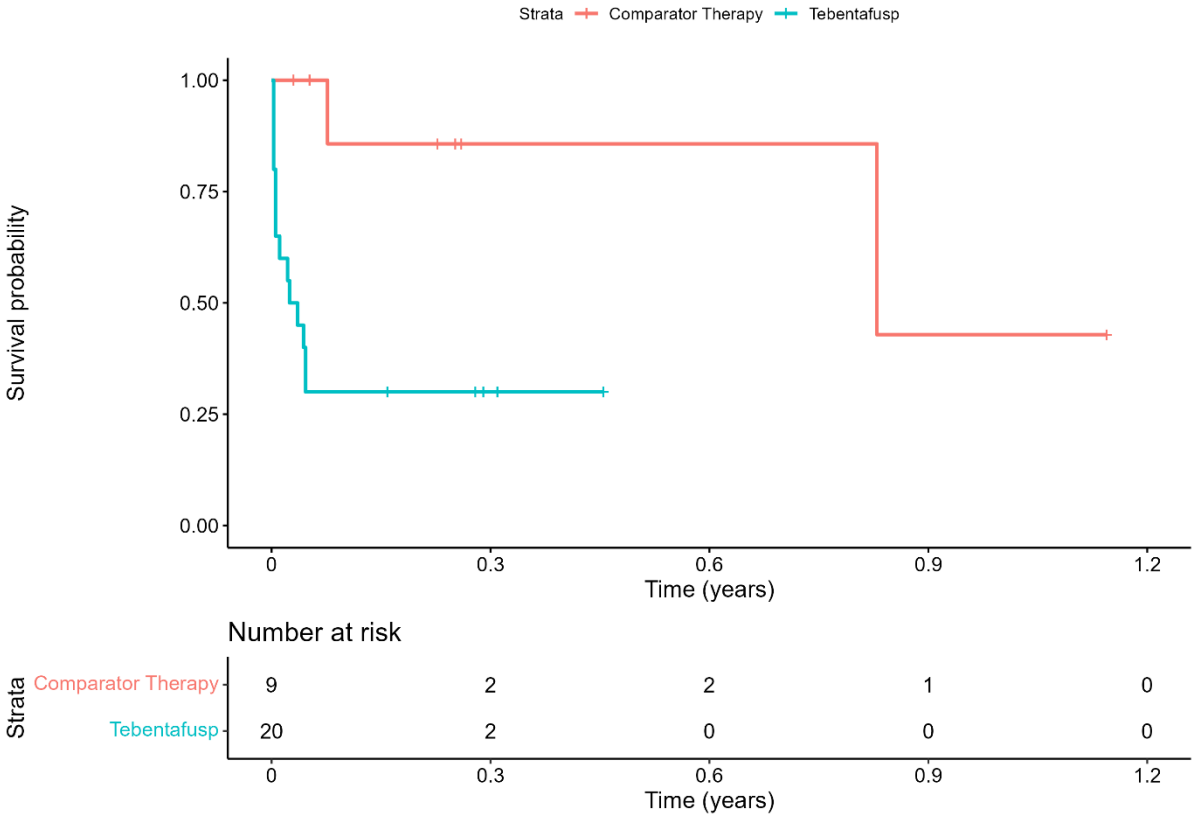
Größte metastatische Läsion (Baseline): ≤3,0 cm



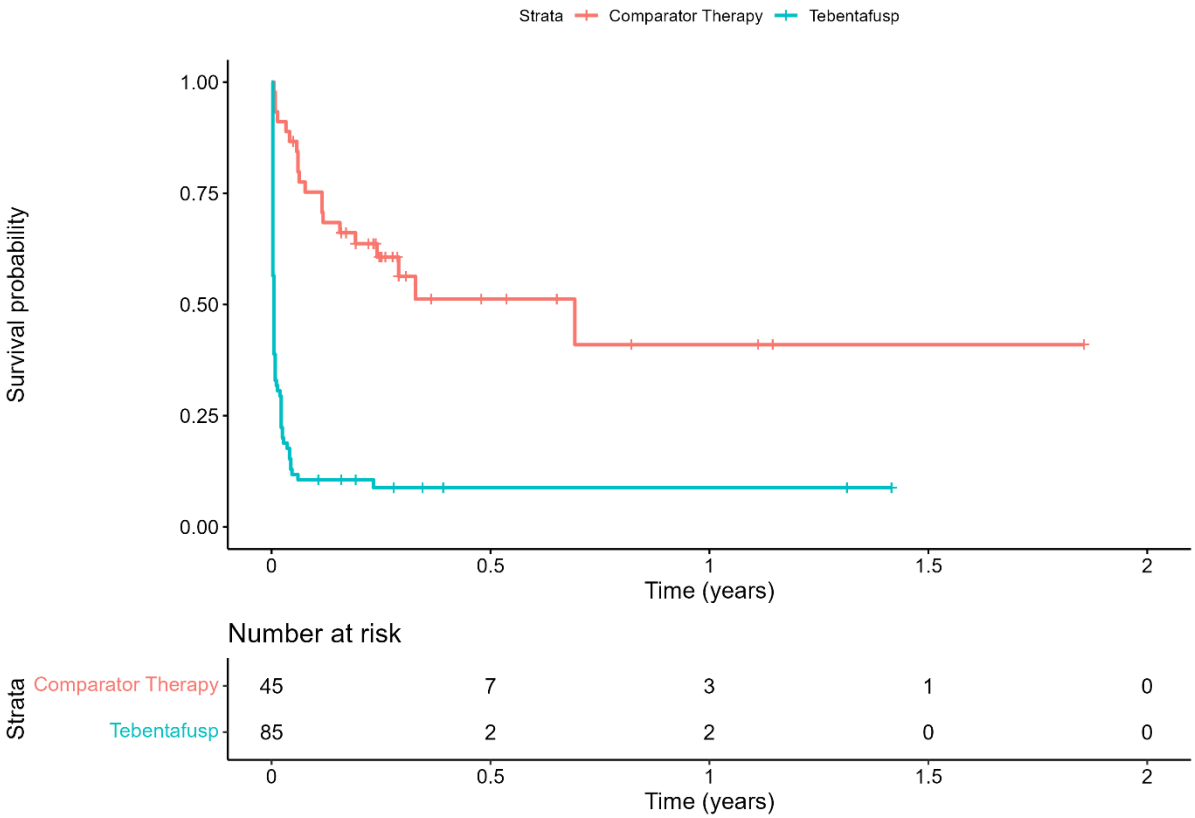
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



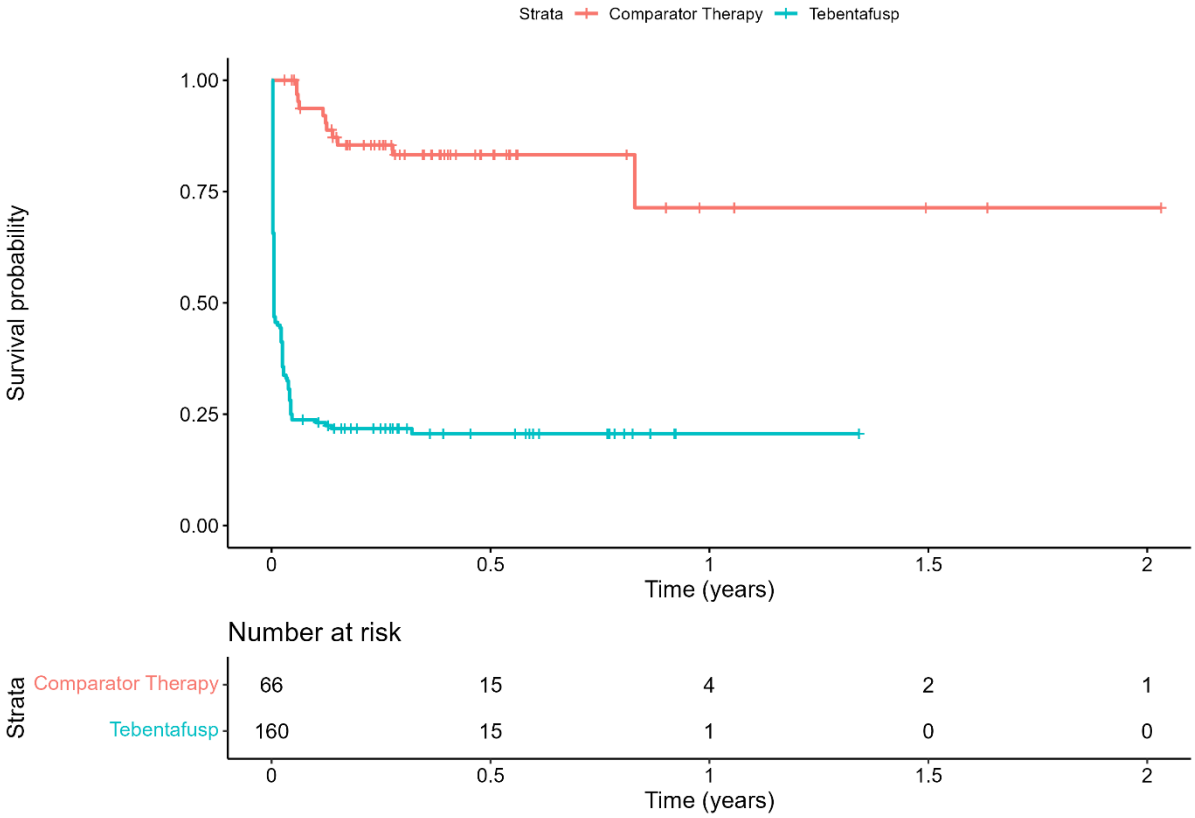
Größte metastatische Läsion (Baseline): ≥8,1 cm



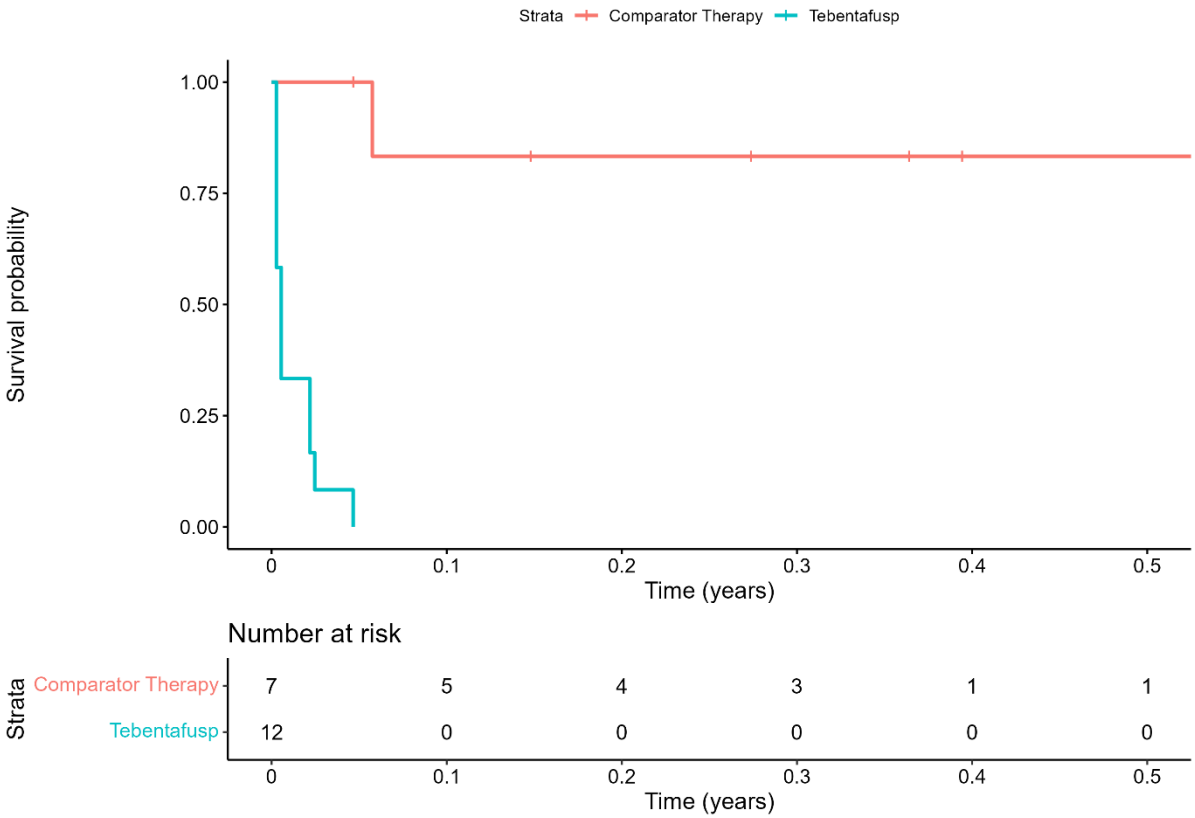
Region: Nordamerika



Region: Nicht-Nordamerika



Vorauswahl der Chemotherapie: Dacarbazin

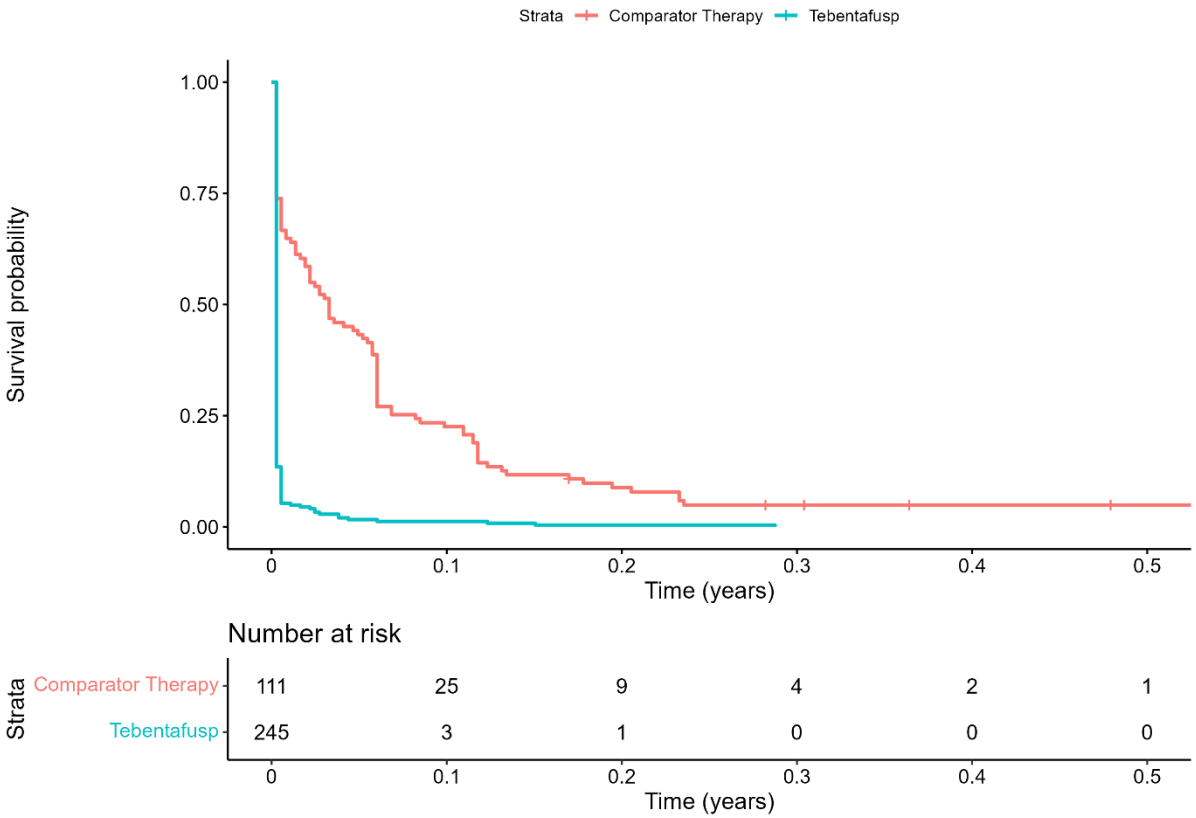


24 Vorauswahl der Chemotherapie: Pembrolizumab4.3.1.3.4 Endpunkt Sicherheit und Verträglichkeit – RCT

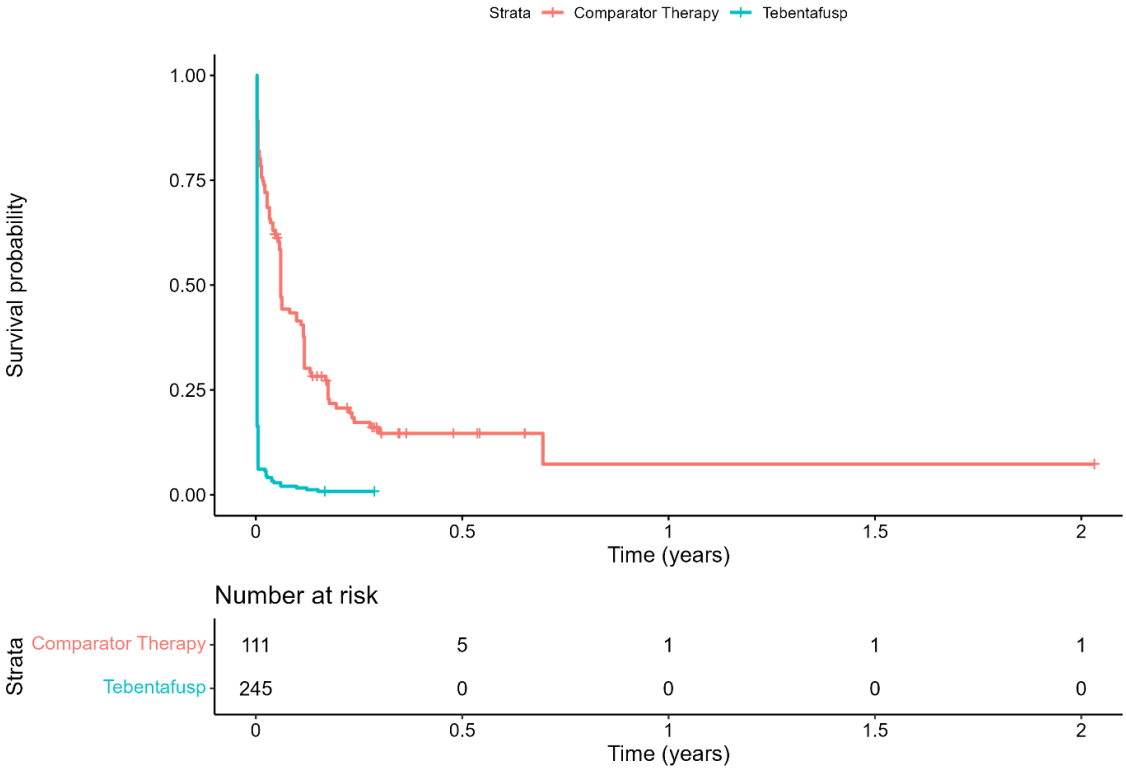
24.1 Kurze Zusammenfassung der unerwünschten Ereignisse

24.2 Primäranalyse (Oktober 2020) (Tabelle 4-51)

Jegliches UE

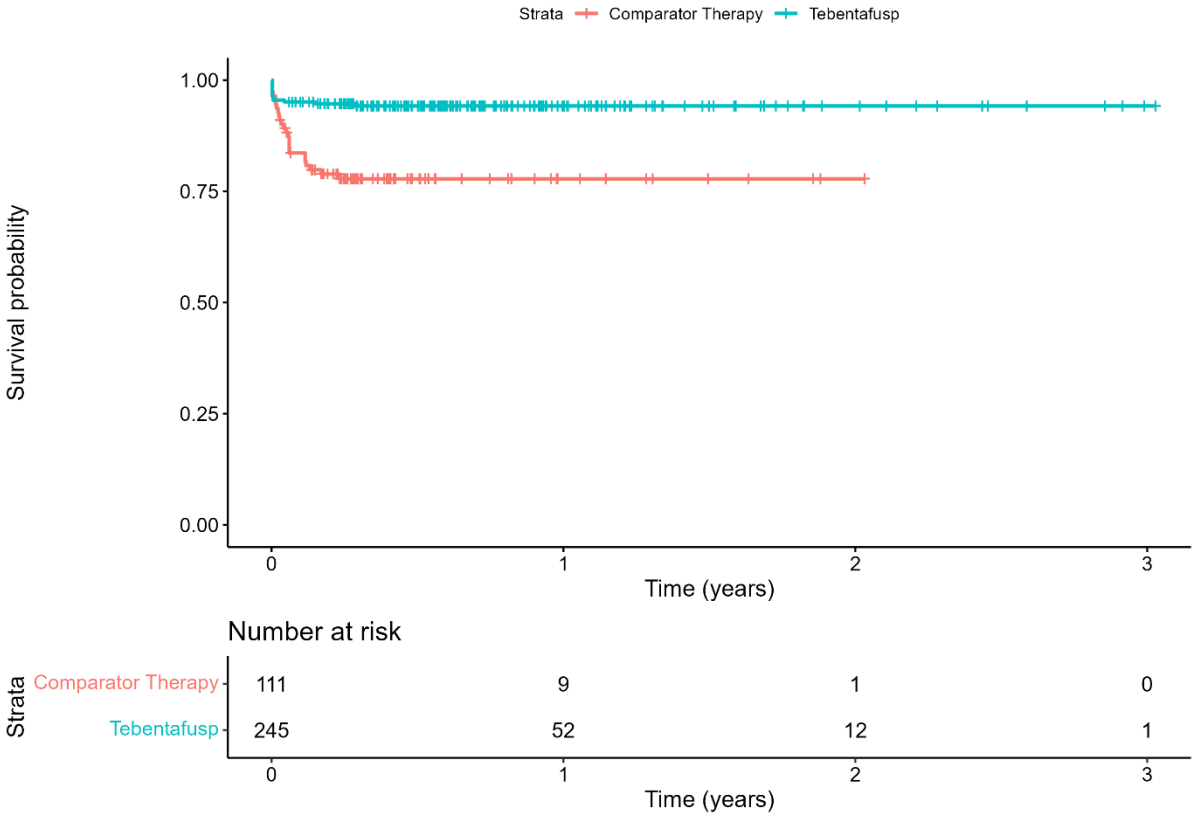


Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE



UE nach höchstem CTCAE-Grad

1



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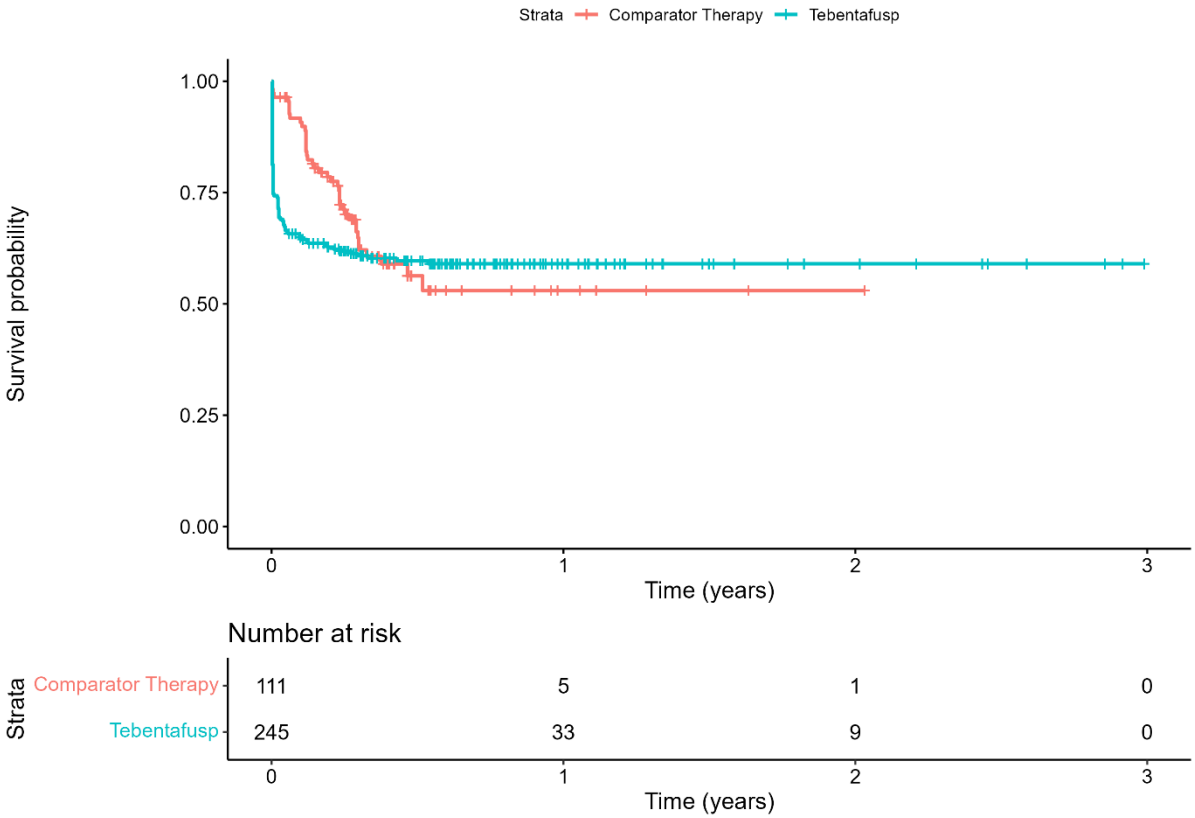
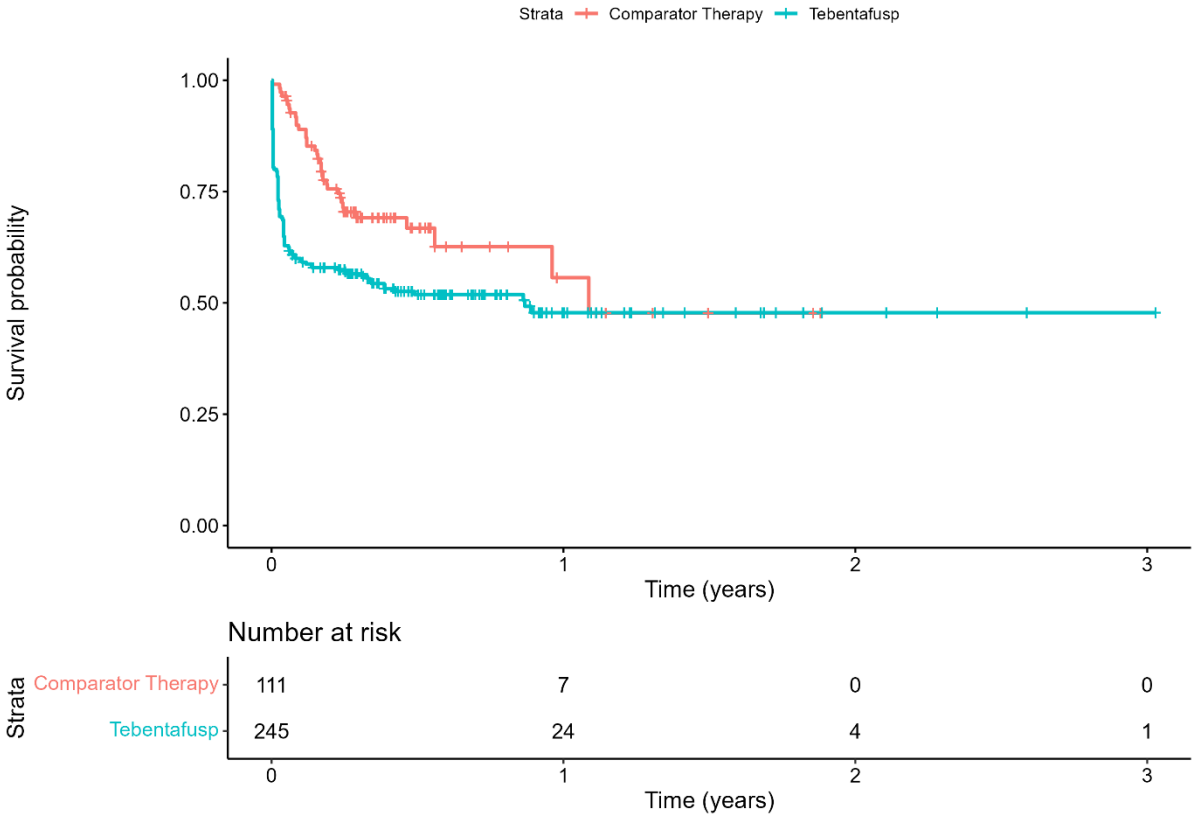
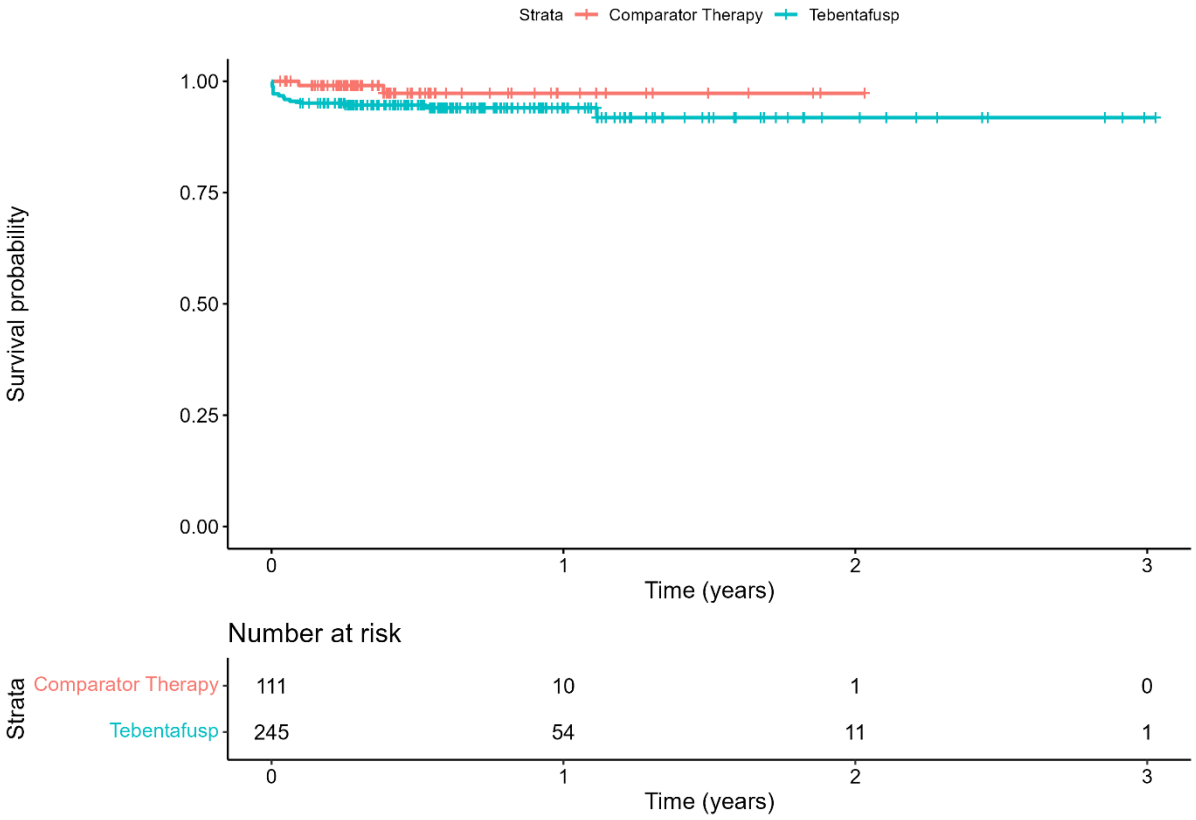

Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 5 1 0
Tebentafusp 245 33 9 0
0
1
2
3
Time (years)

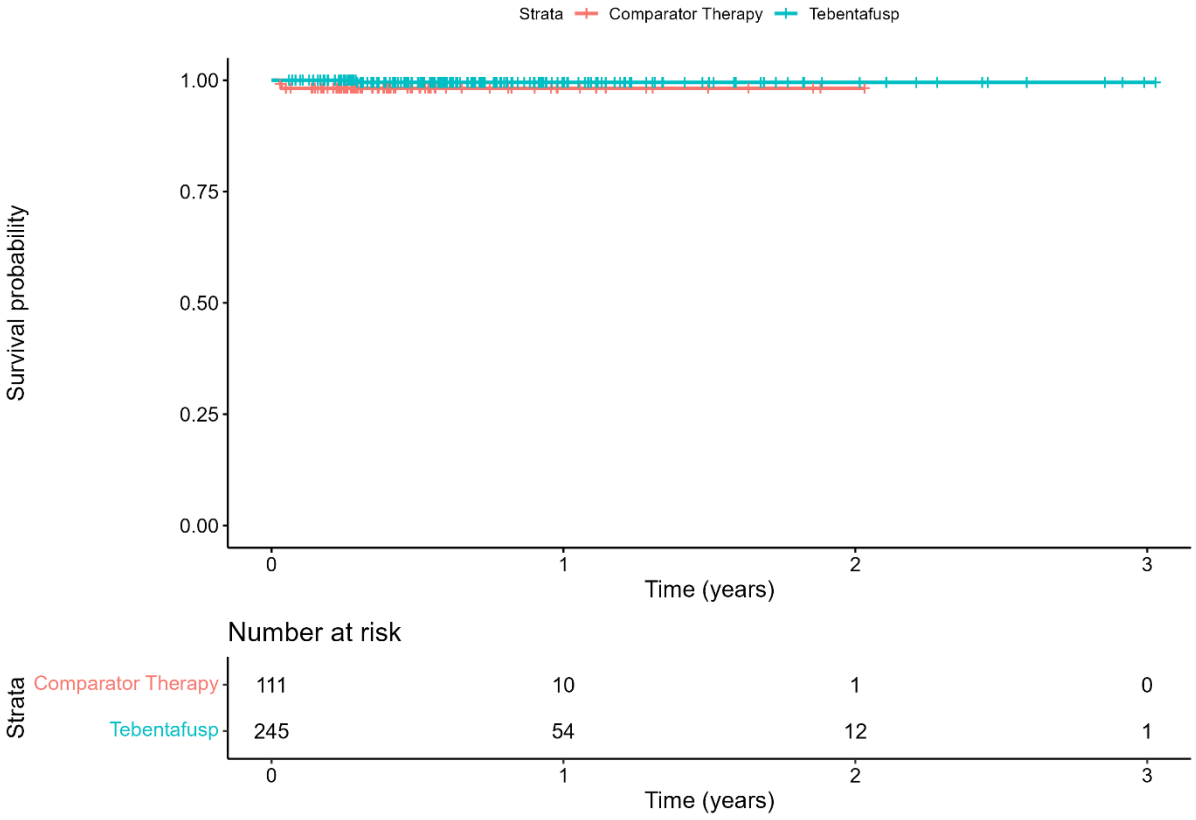
3


Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 7 0 0
Tebentafusp 245 24 4 1
0
1
2
3
Time (years)

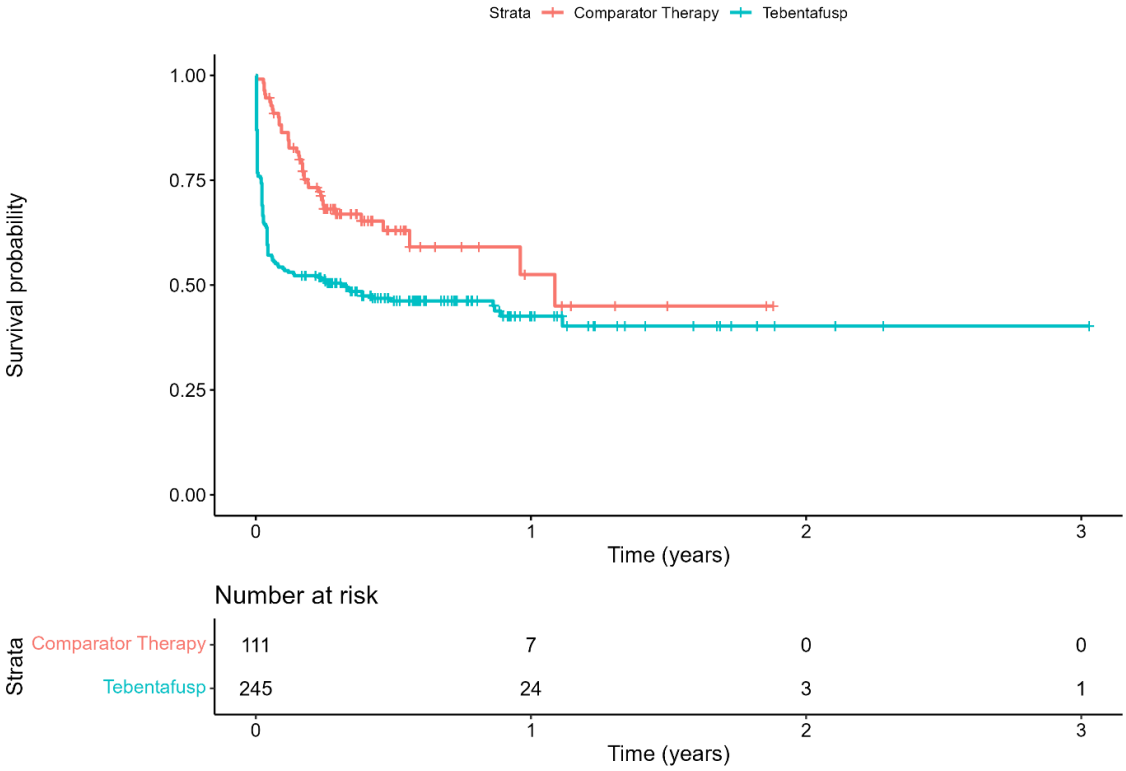
4


Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 10 1 0
Tebentafusp 245 54 11 1
0
1
2
3
Time (years)

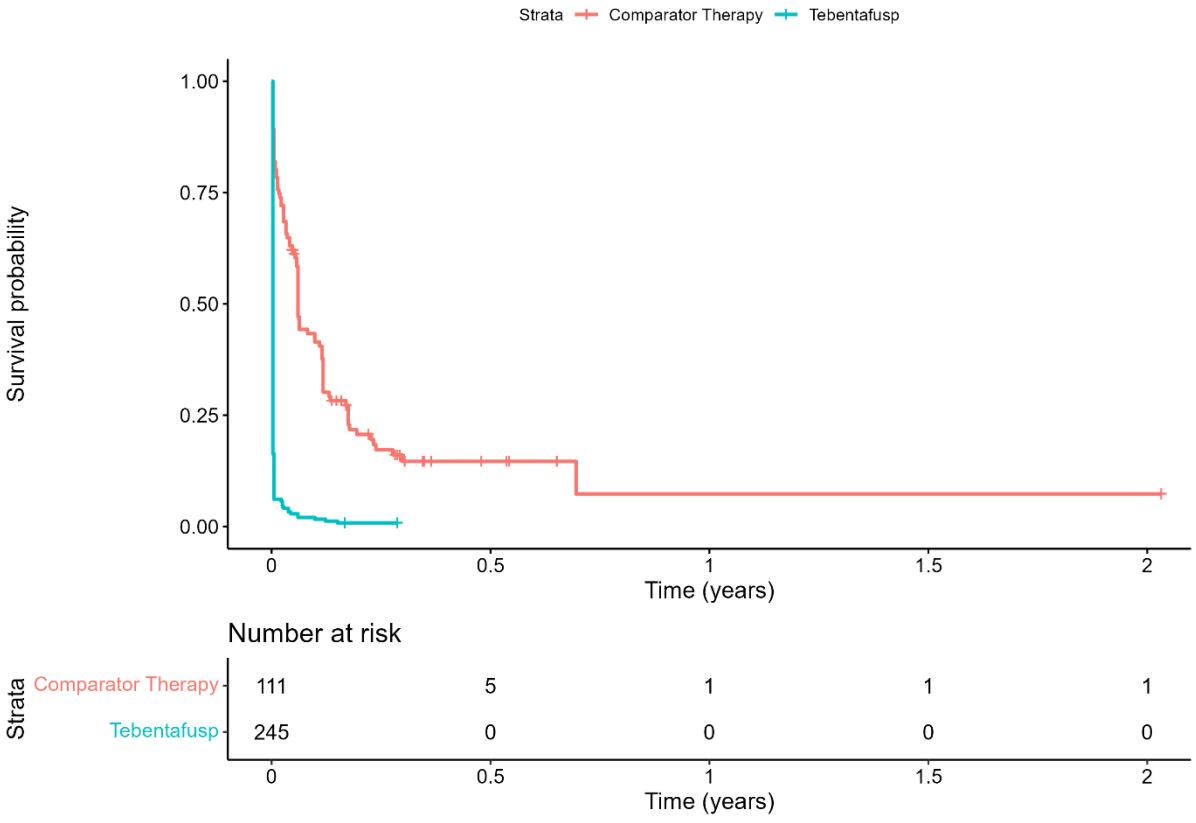
5


Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 10 1 0
Tebentafusp 245 54 12 1
0
1
2
3
Time (years)

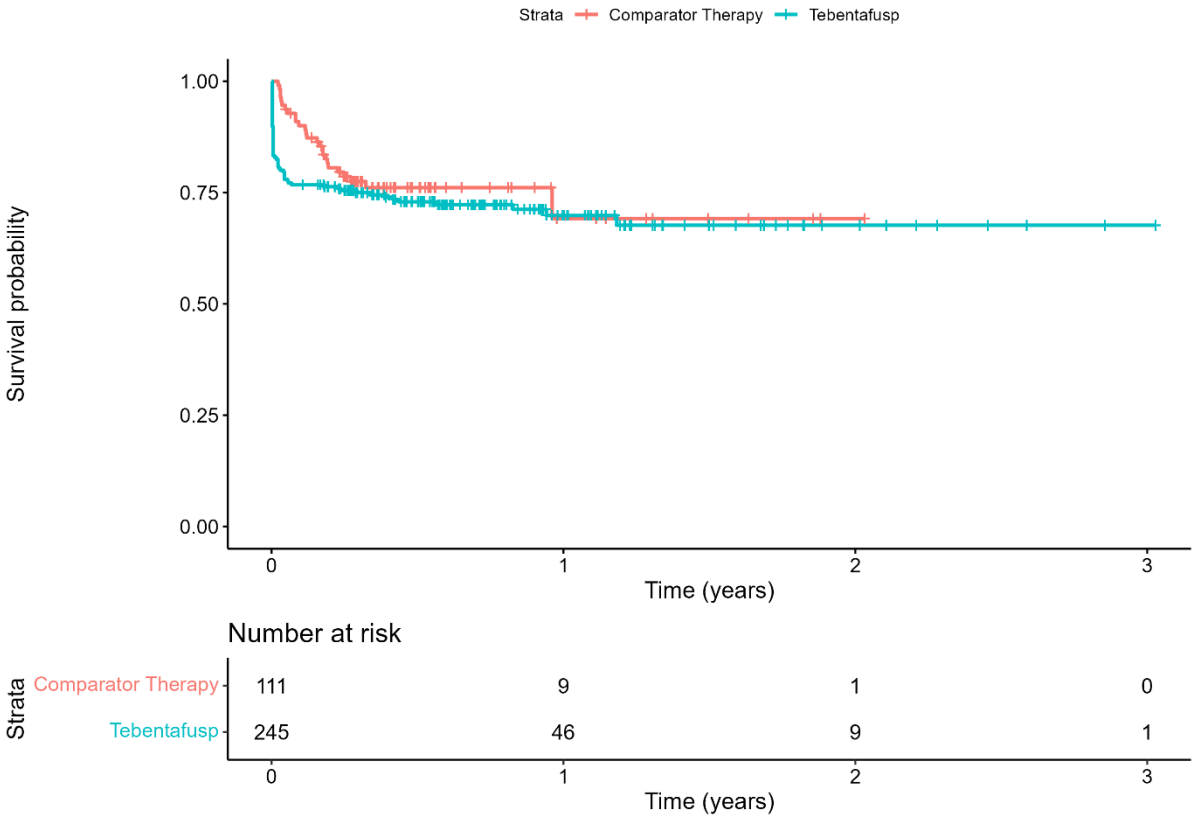
Jegliches UE mit CTCAE-Grad ≥ 3



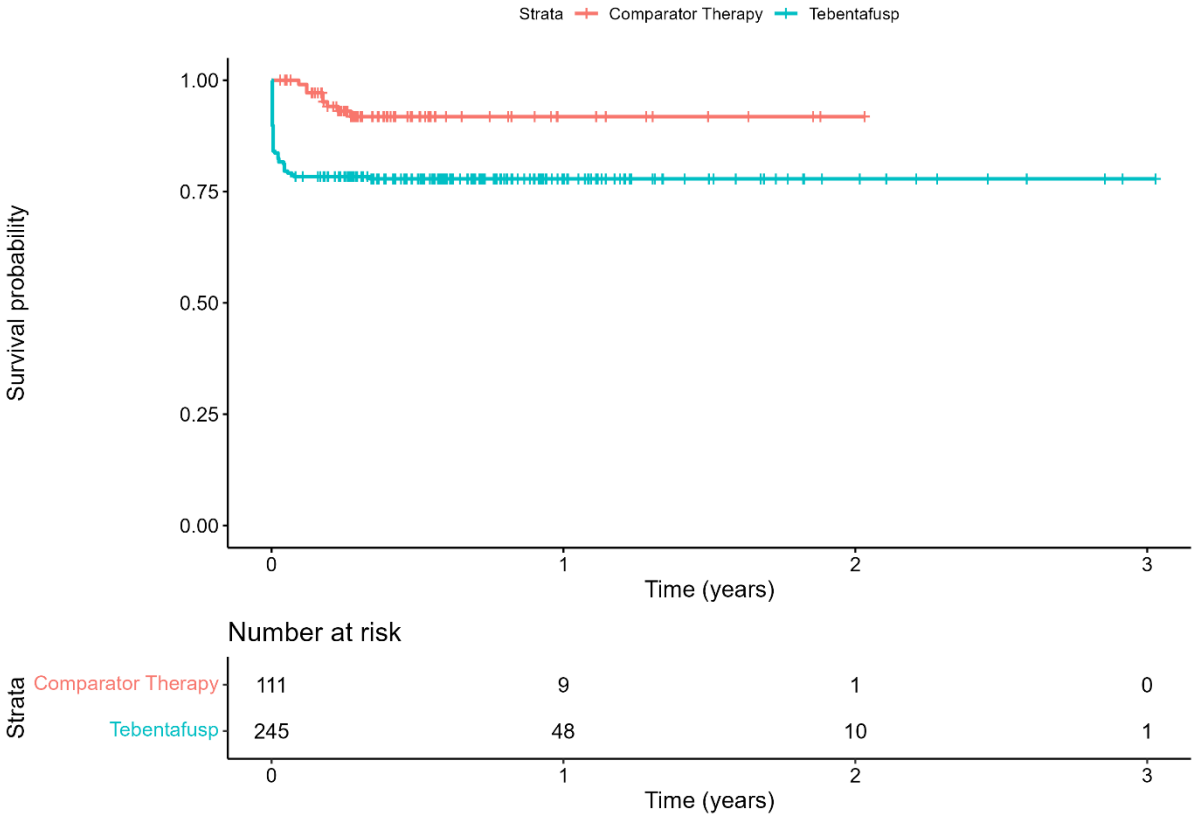
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE mit CTCAE-Grad ≥ 3



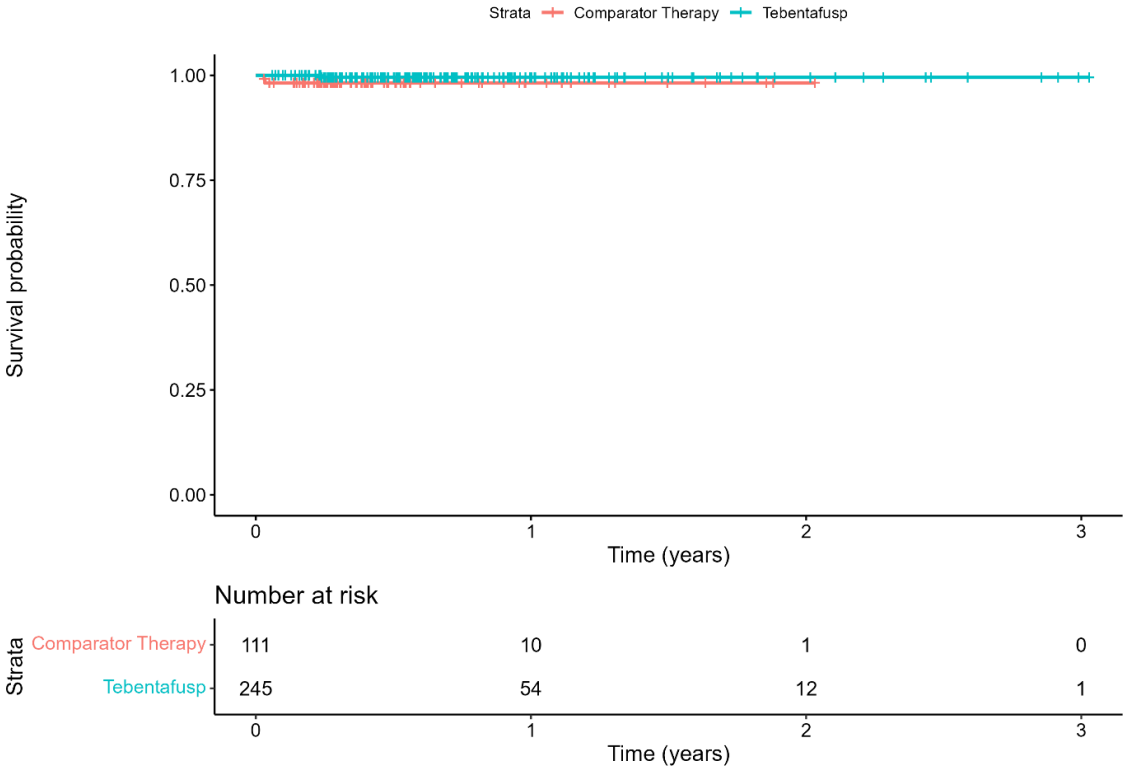
Jegliches SUE



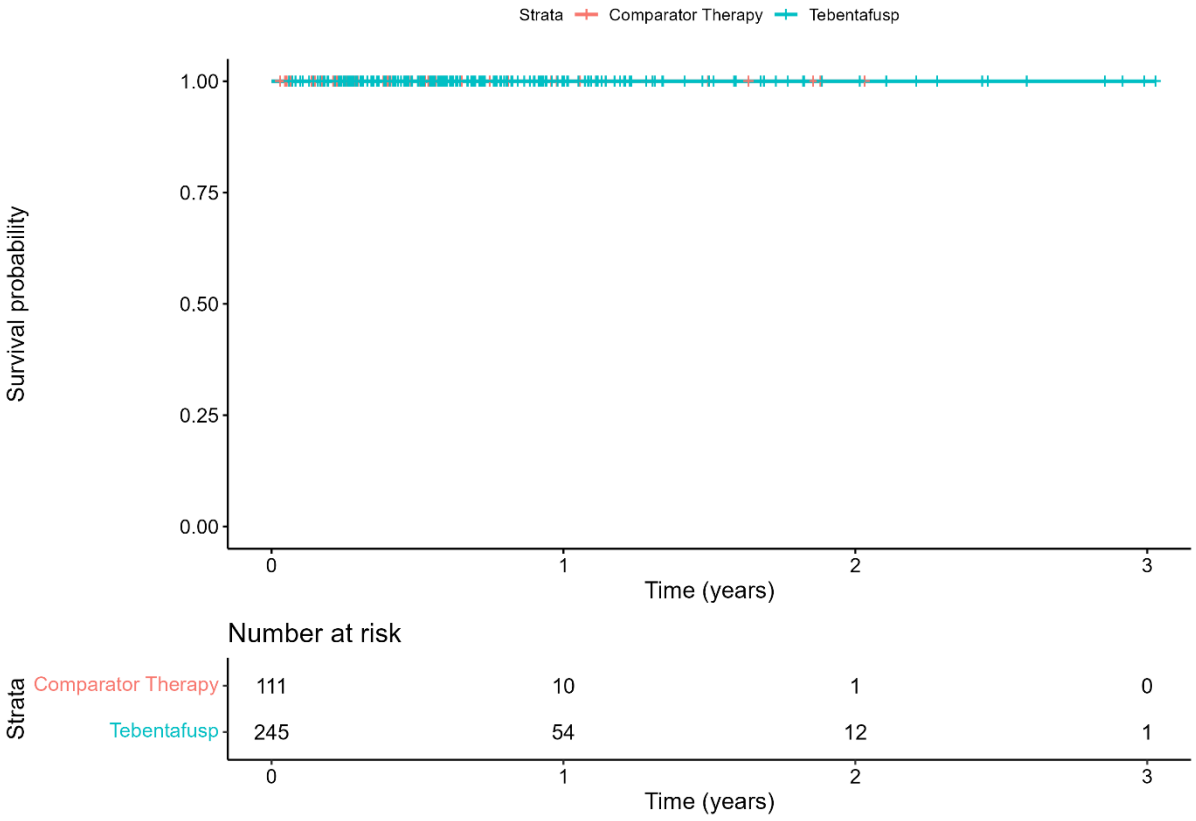
Jegliches mit dem Studienmedikament in Zusammenhang stehendes SUE



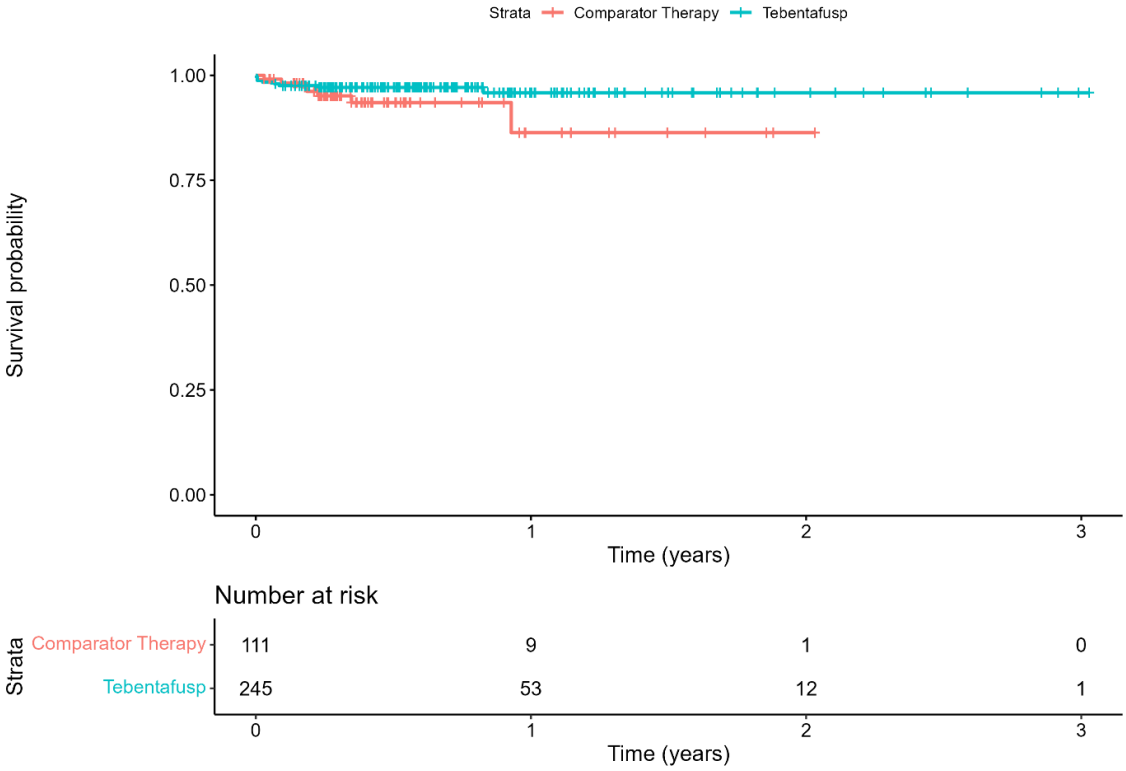
Jegliches UE, das zum Tod führte



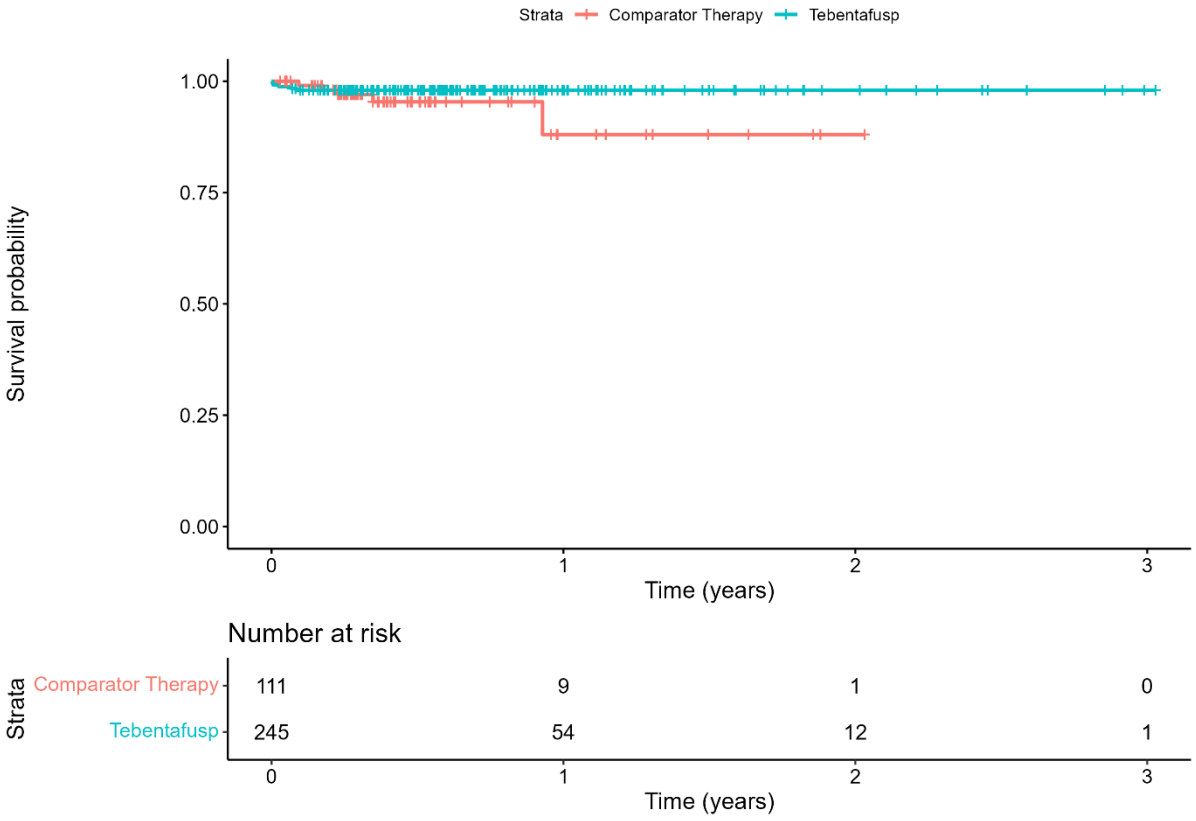
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zum Tod führte



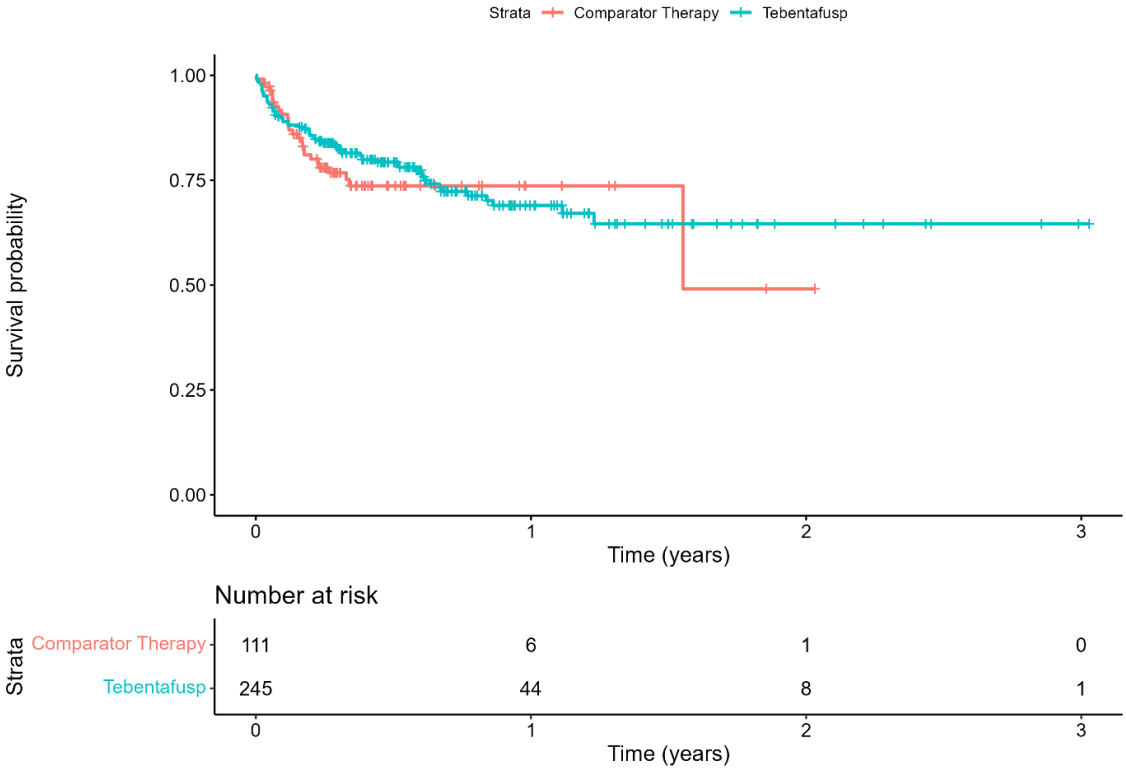
Jegliches UE, das zum Absetzen des Studienmedikaments führte



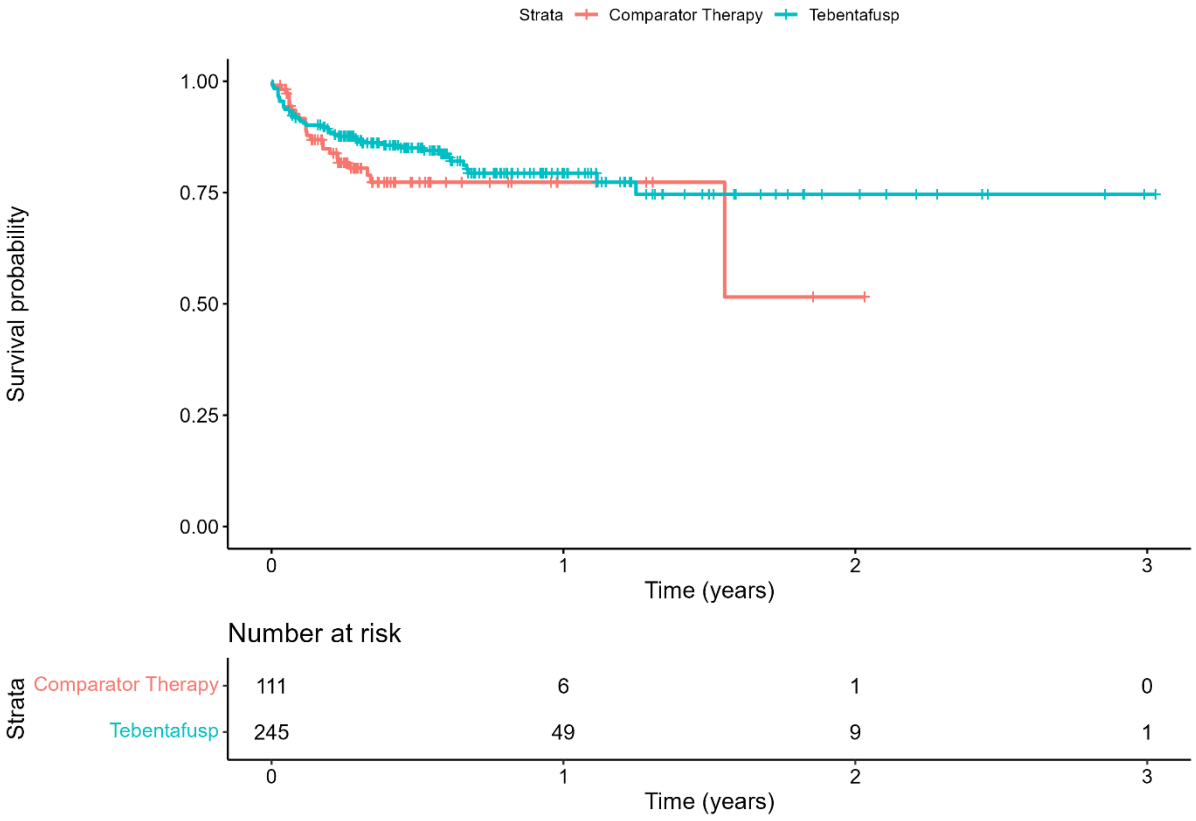
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zum Absetzen des Studienmedikaments führte



Jegliches UE, das zu einer Dosis- oder Infusionsunterbrechung führte

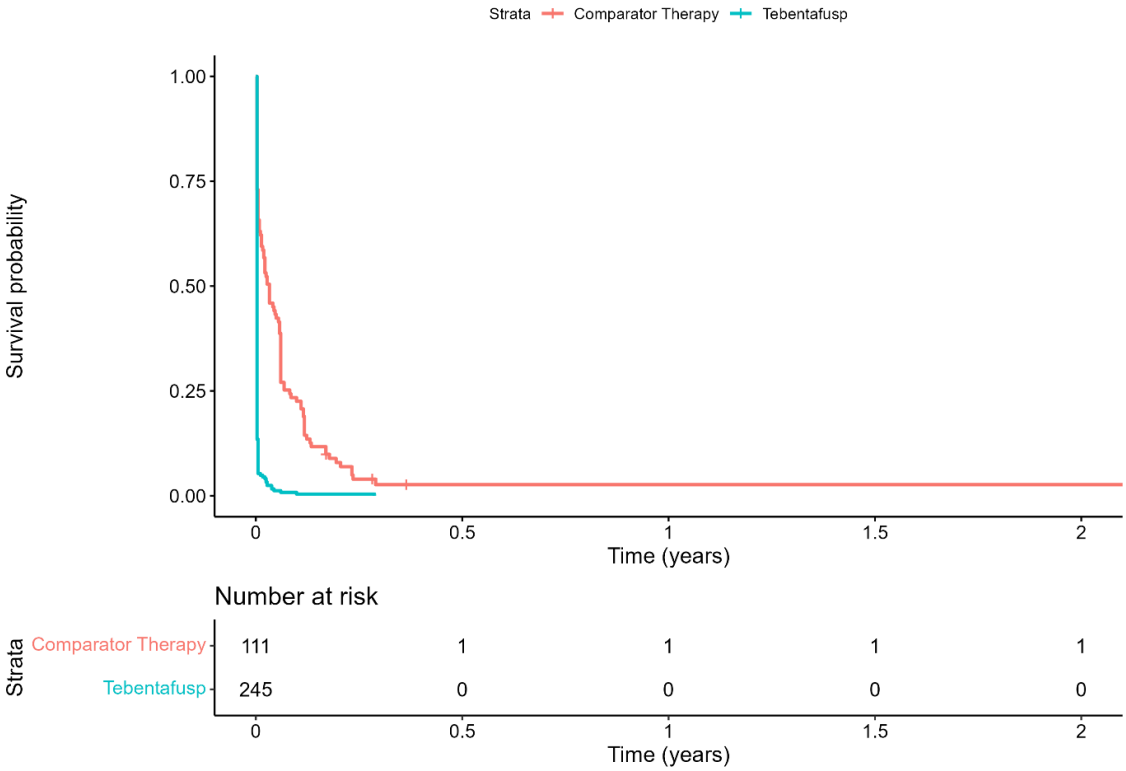


Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zu einer Dosis- oder Infusionsunterbrechung führte

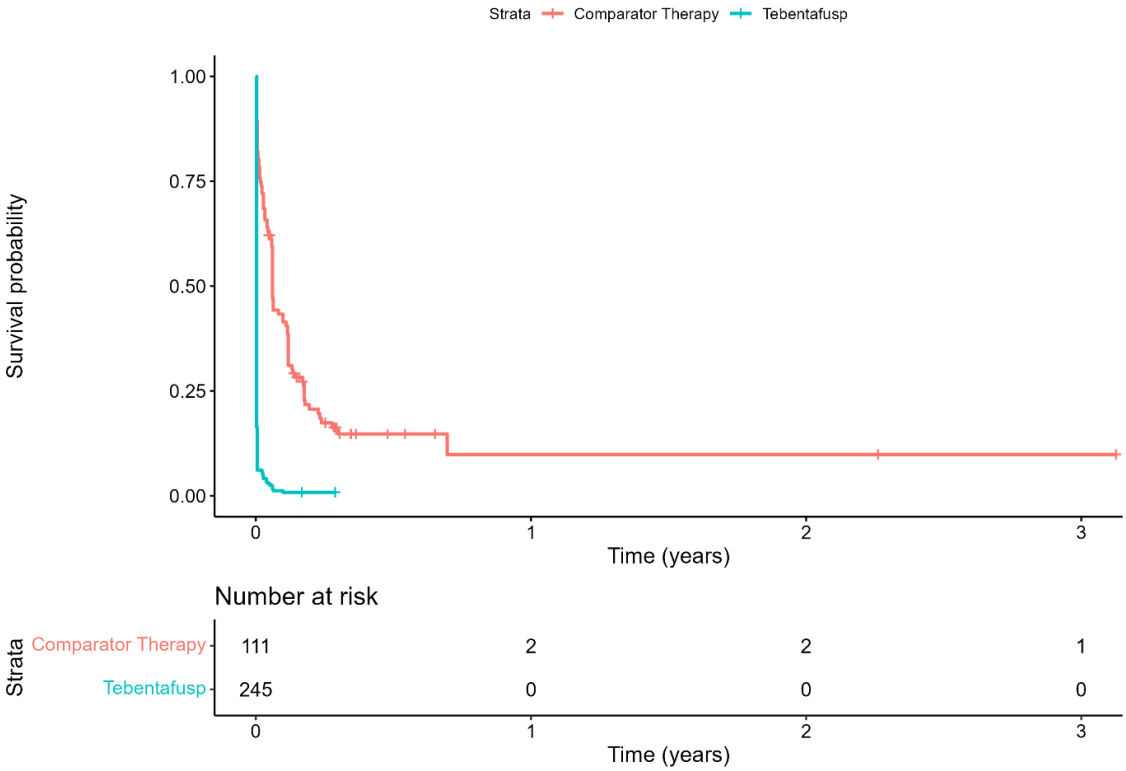


24.3 3-Jahres-Analyse (Juni 2023) (Tabelle 4-52)

Jegliches UE

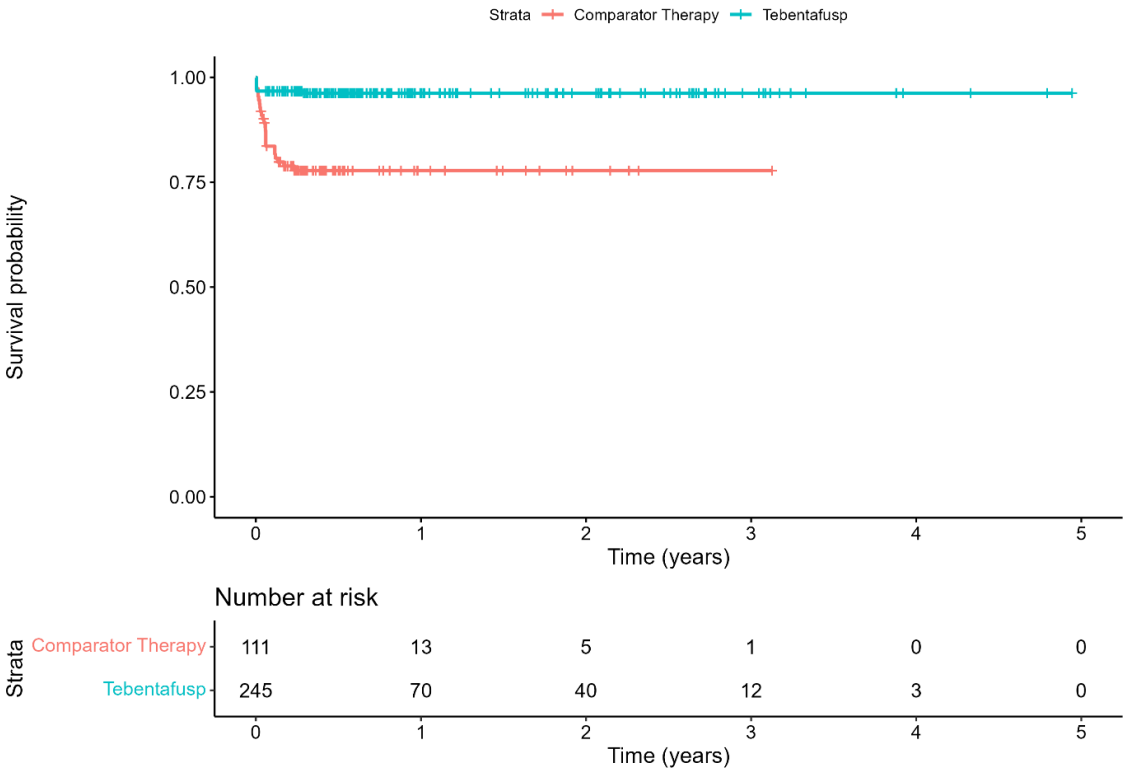


Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE



UE nach höchstem CTCAE-Grad

1



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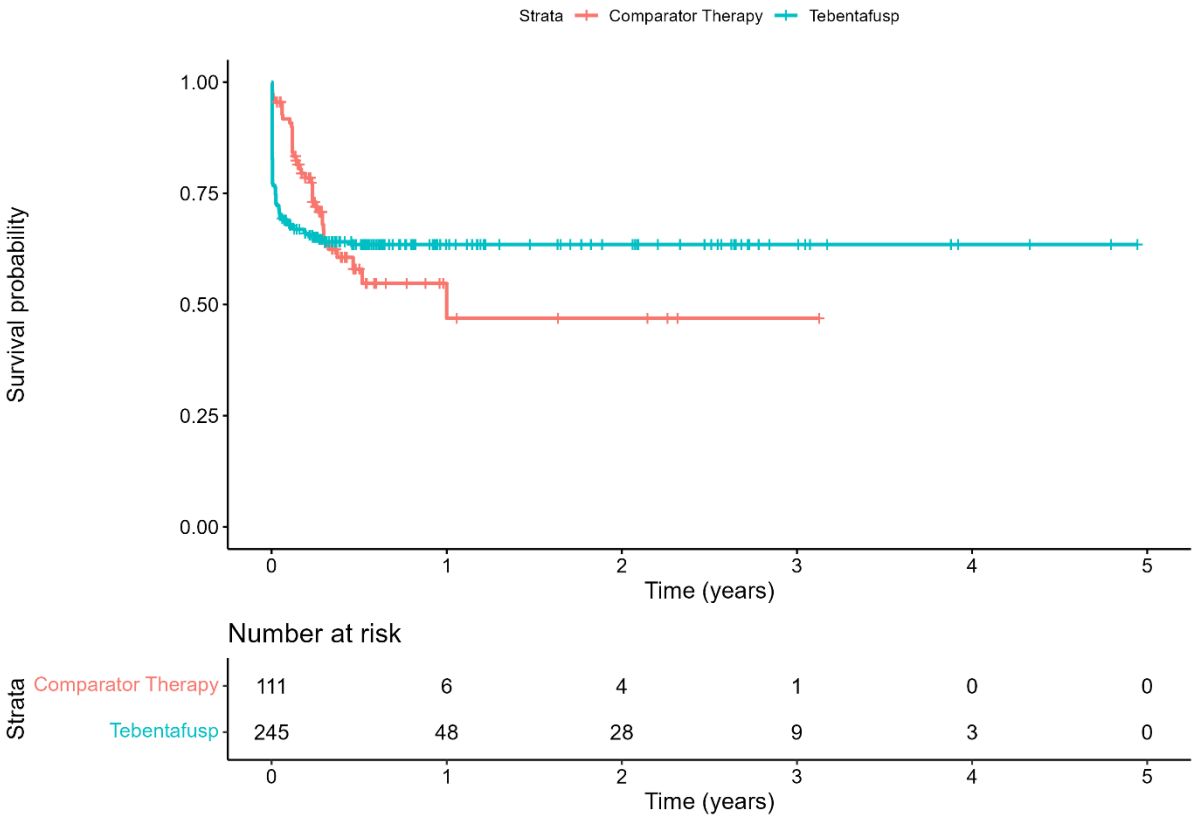

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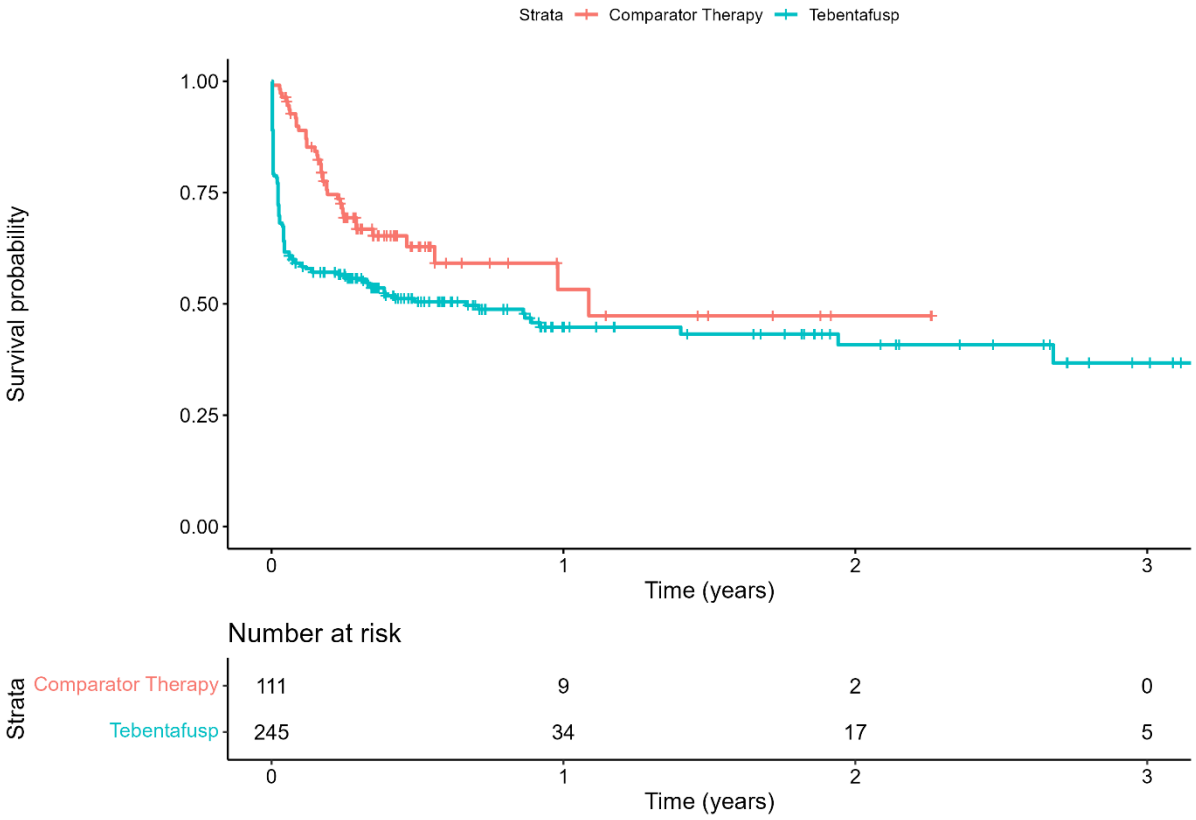
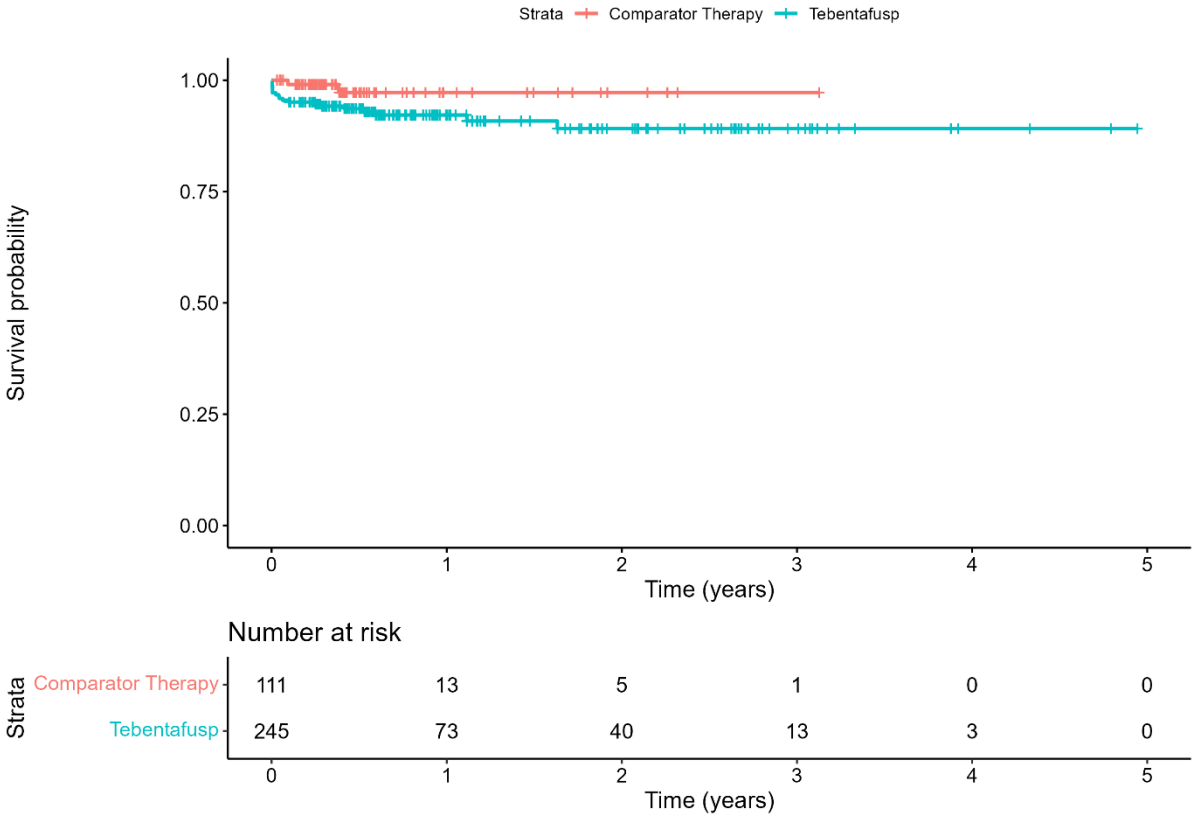
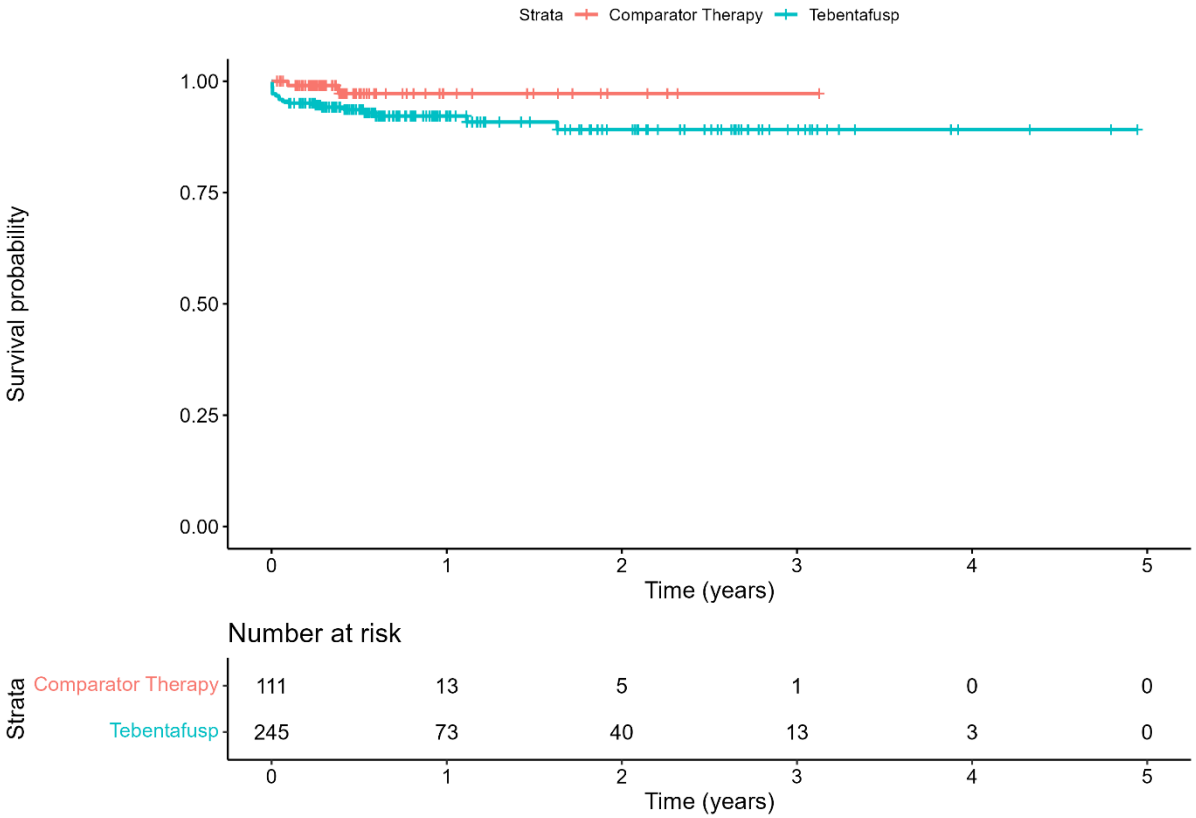

Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy 111 9 2 0
Tebentafusp 245 34 17 5
0
1
2
3
Time (years)

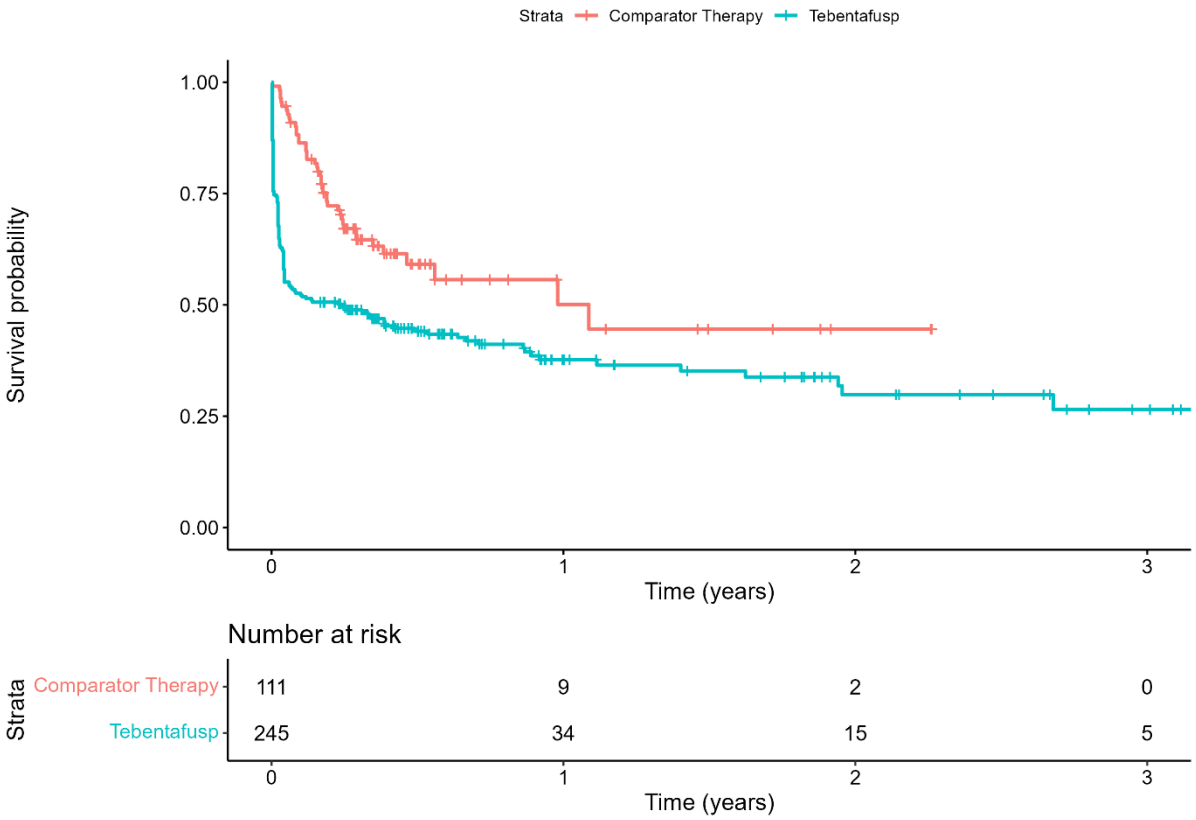
4


Strata Comparator Therapy Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy 111 13 5 1 0 0
Tebentafusp 245 73 40 13 3 0
0
1
2
3
4
5
Time (years)

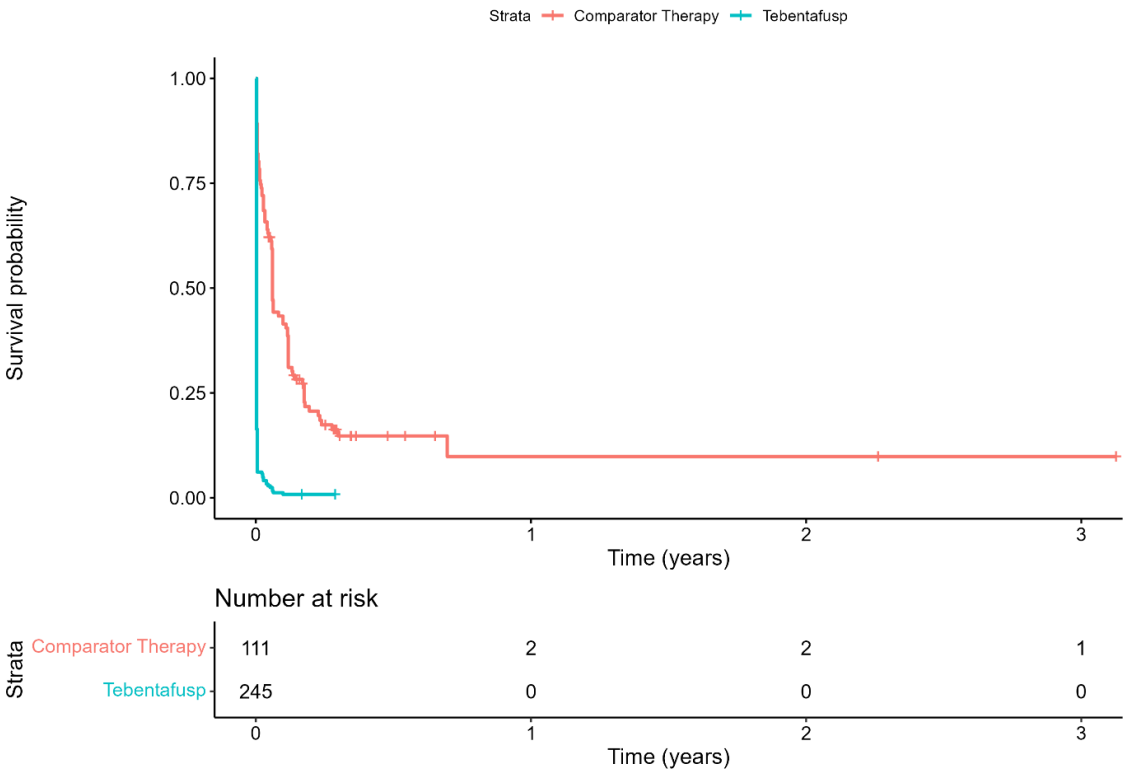
5



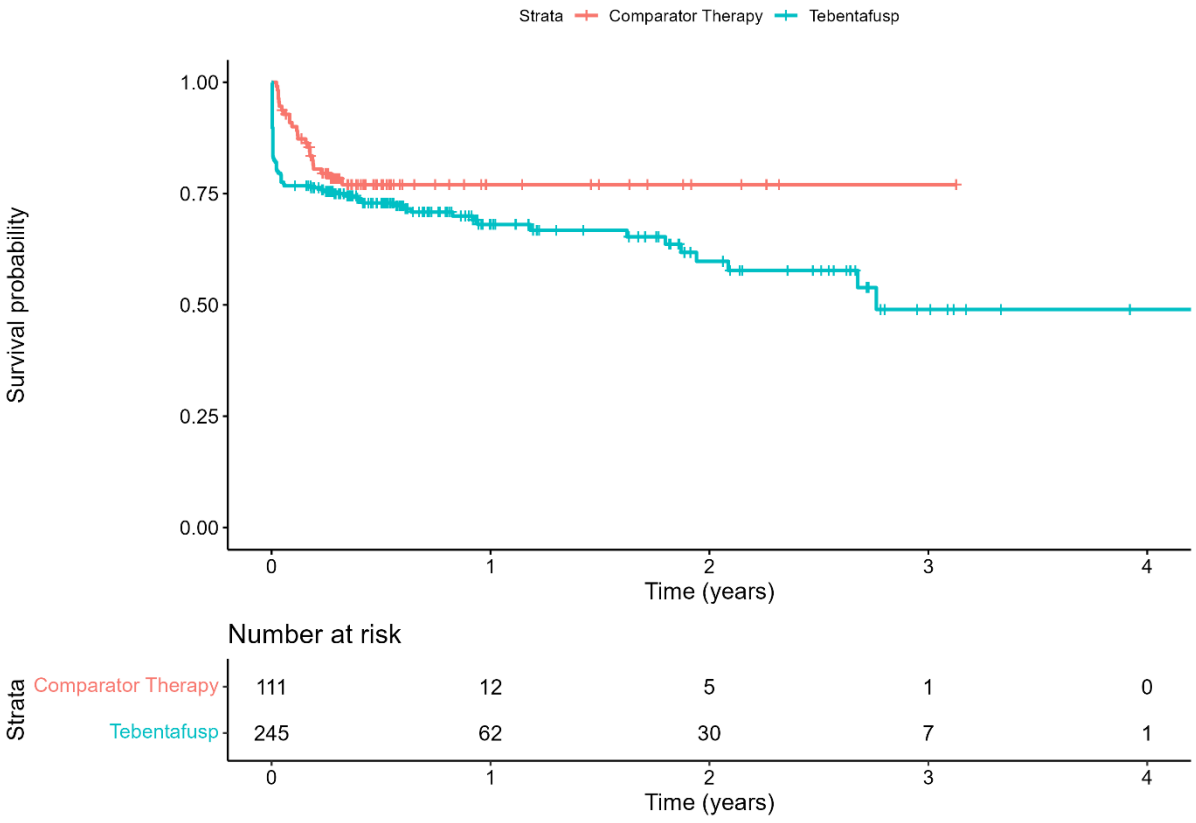
Jegliches UE mit CTCAE-Grad ≥ 3



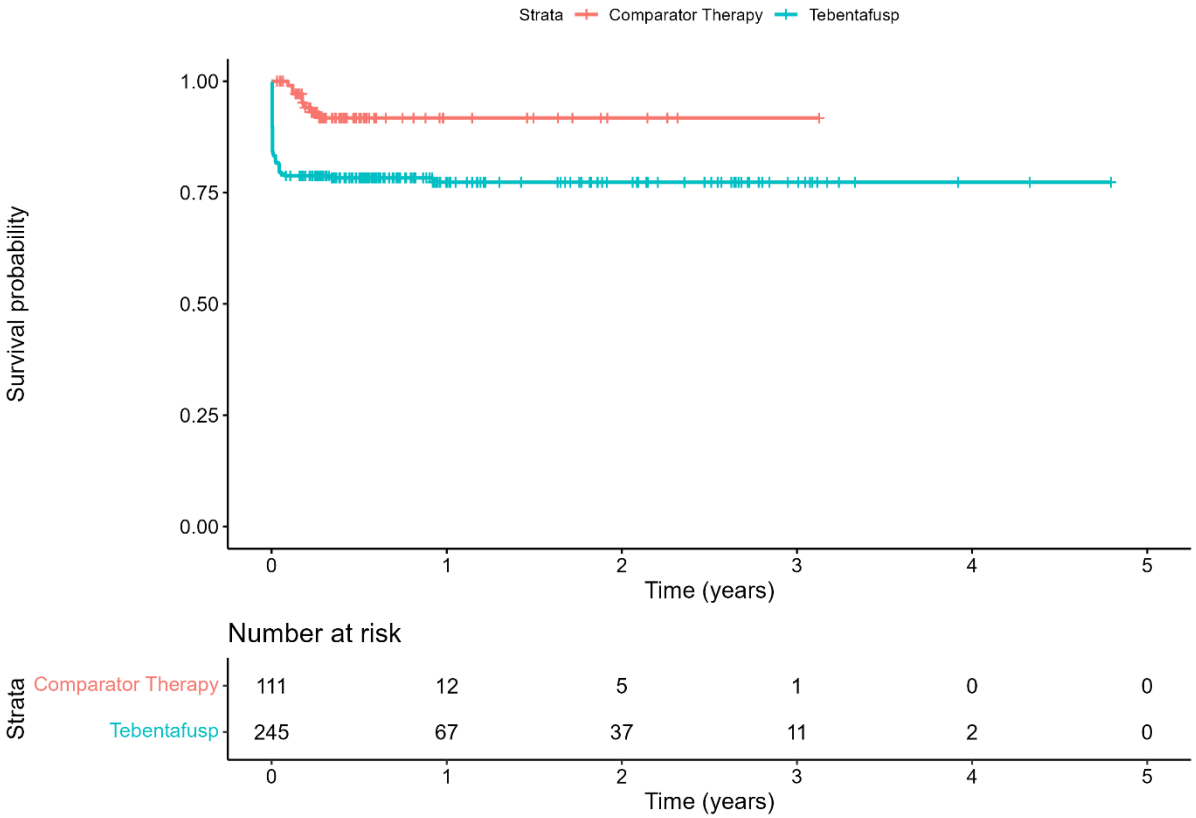
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE mit CTCAE-Grad ≥ 3



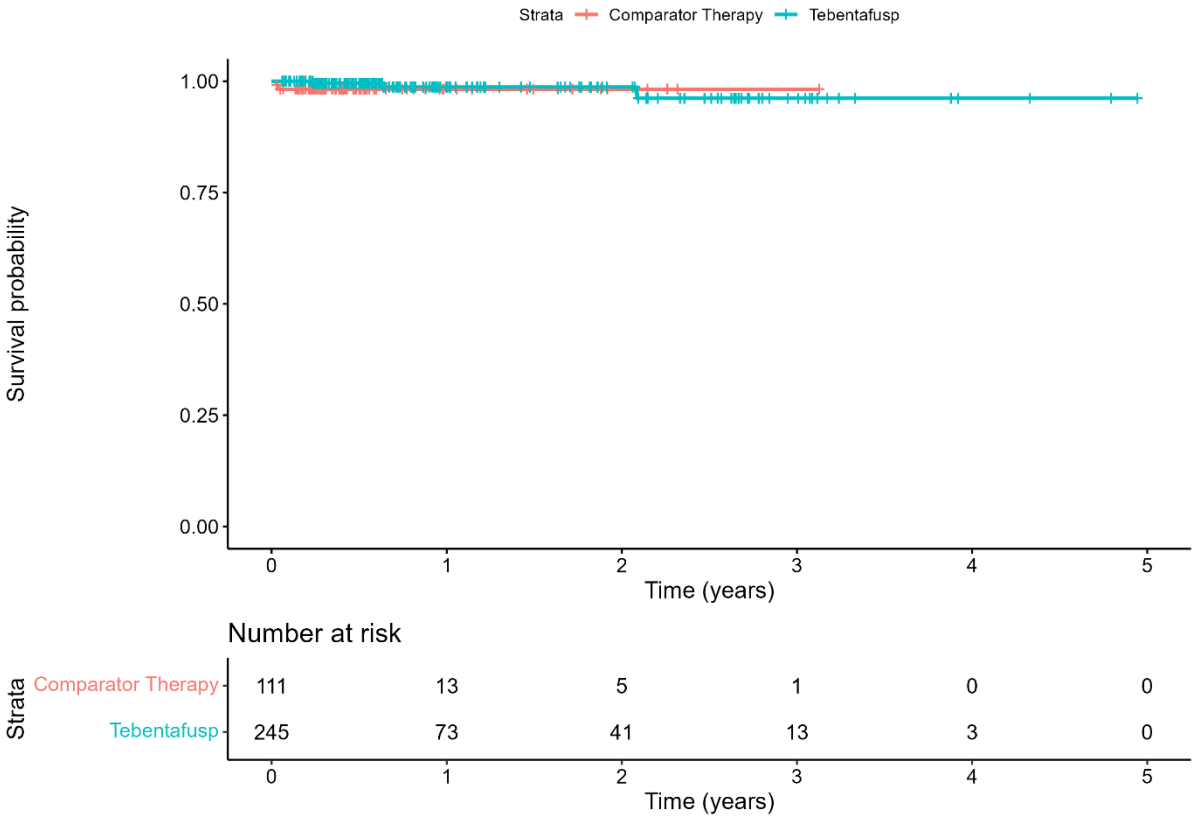
Jegliches SUE



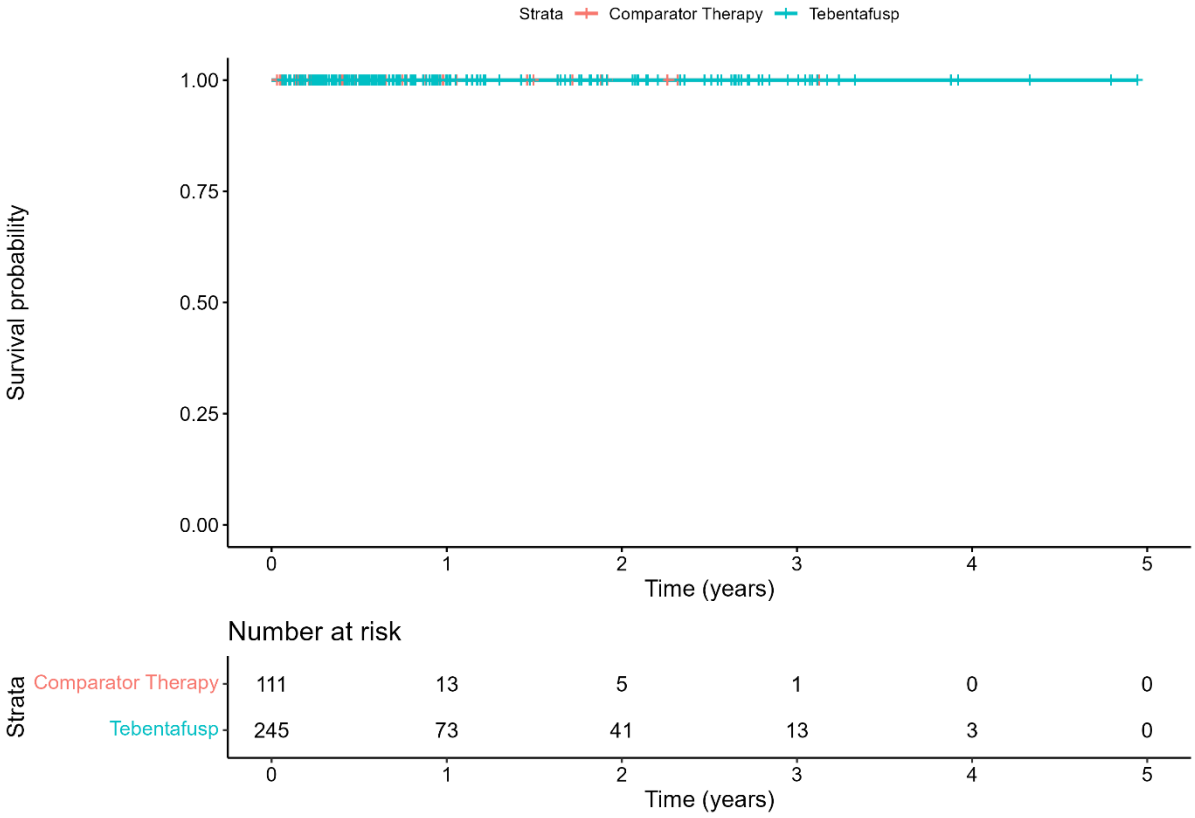
Jegliches mit dem Studienmedikament in Zusammenhang stehendes SUE



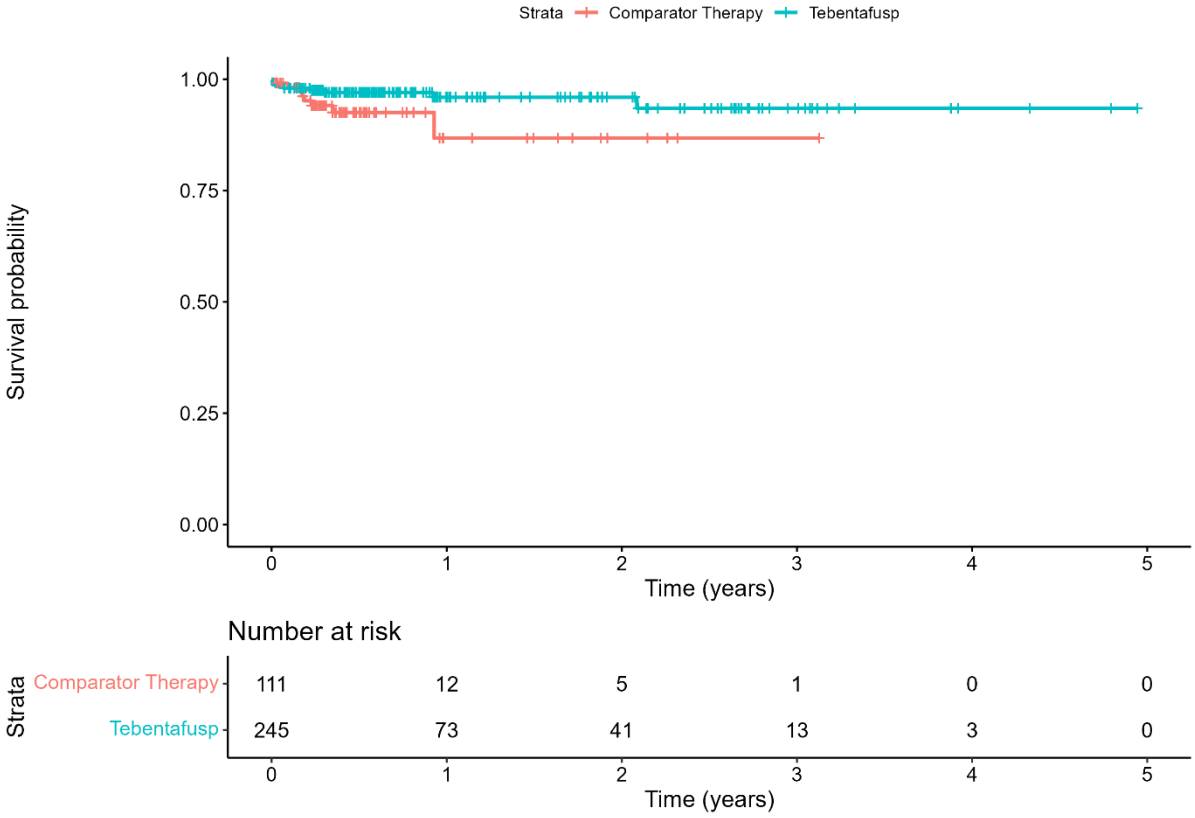
Jegliches UE, das zum Tod führte



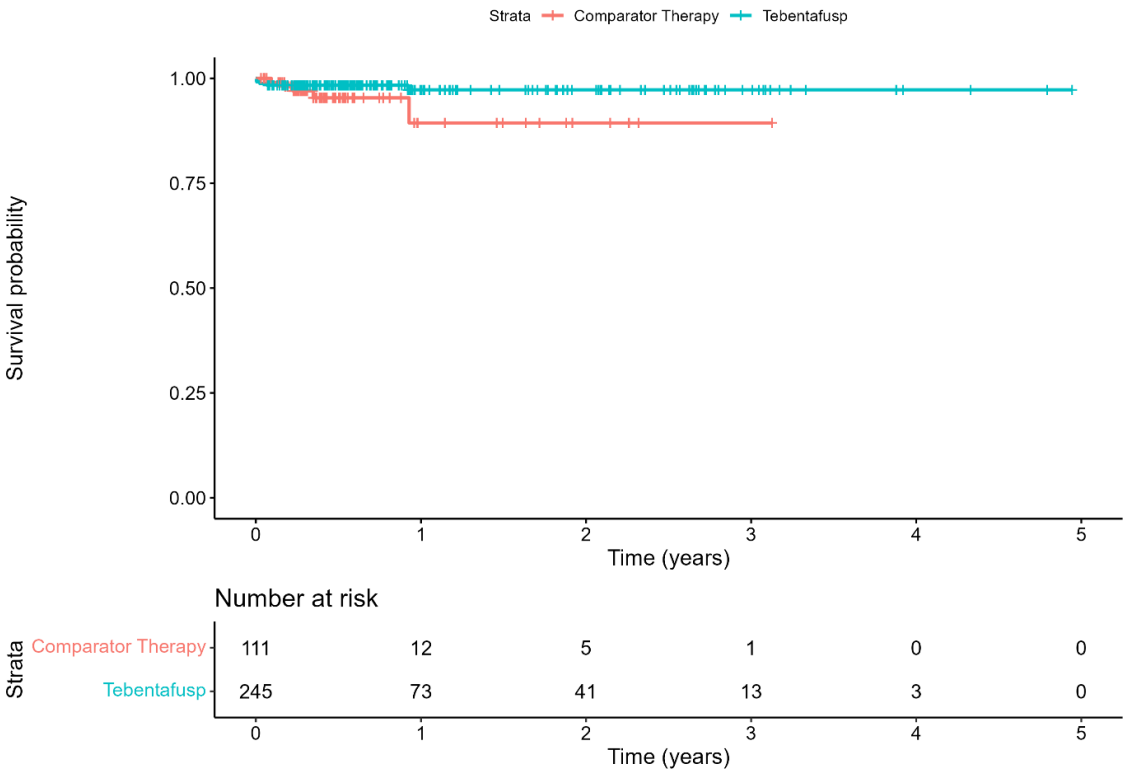
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zum Tod führte



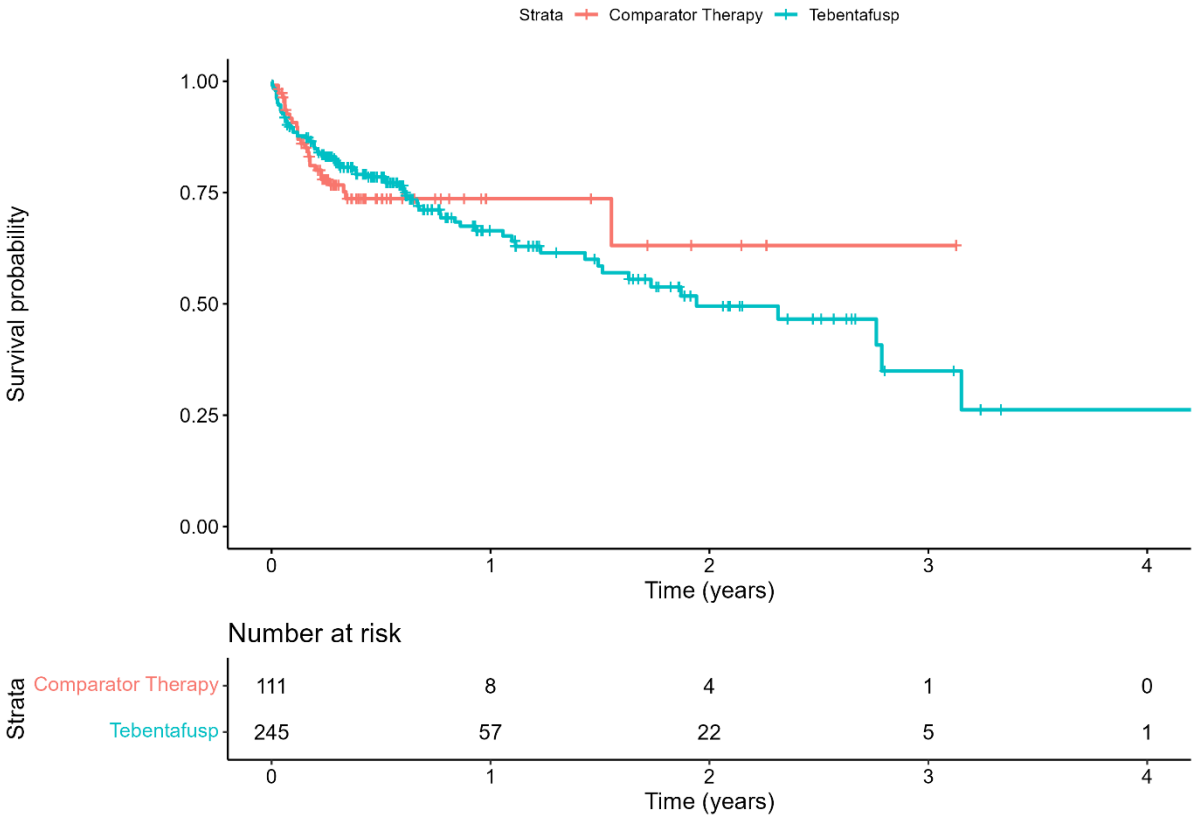
Jegliches UE, das zum Absetzen des Studienmedikaments führte



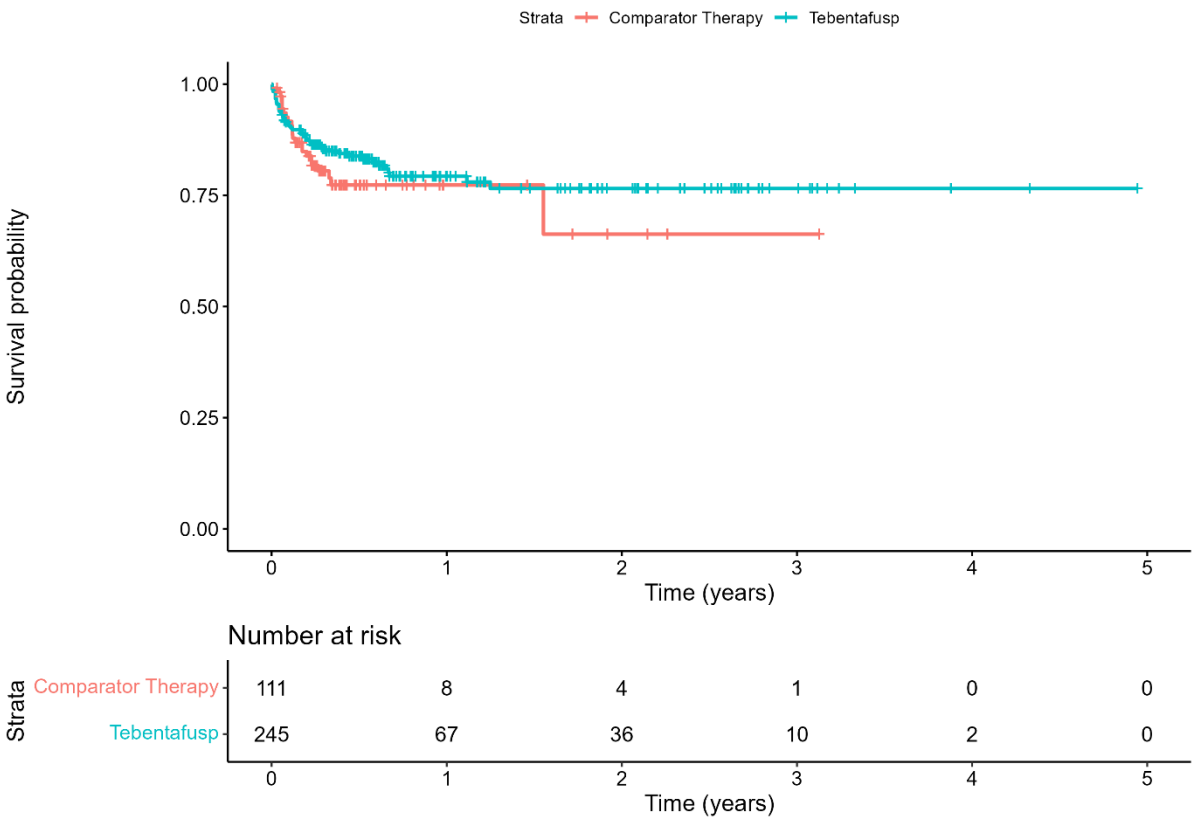
Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zum Absetzen des Studienmedikaments führte



Jegliches UE, das zu einer Dosis- oder Infusionsunterbrechung führte



Jegliches mit dem Studienmedikament in Zusammenhang stehendes UE, das zu einer Dosis- oder Infusionsunterbrechung führte

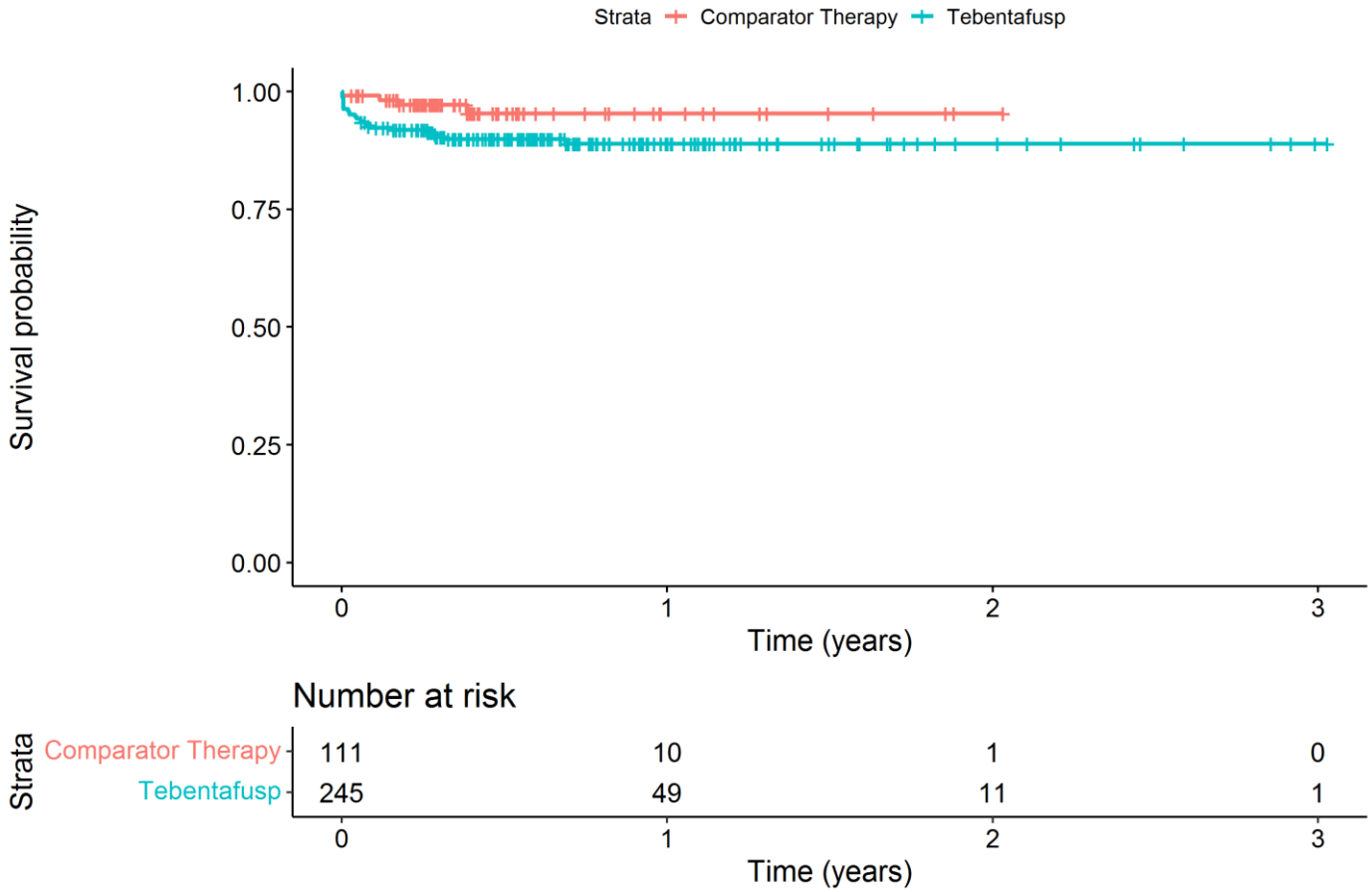


24.4 **Analyse der unerwünschten Ereignisse nach SOC und PT**

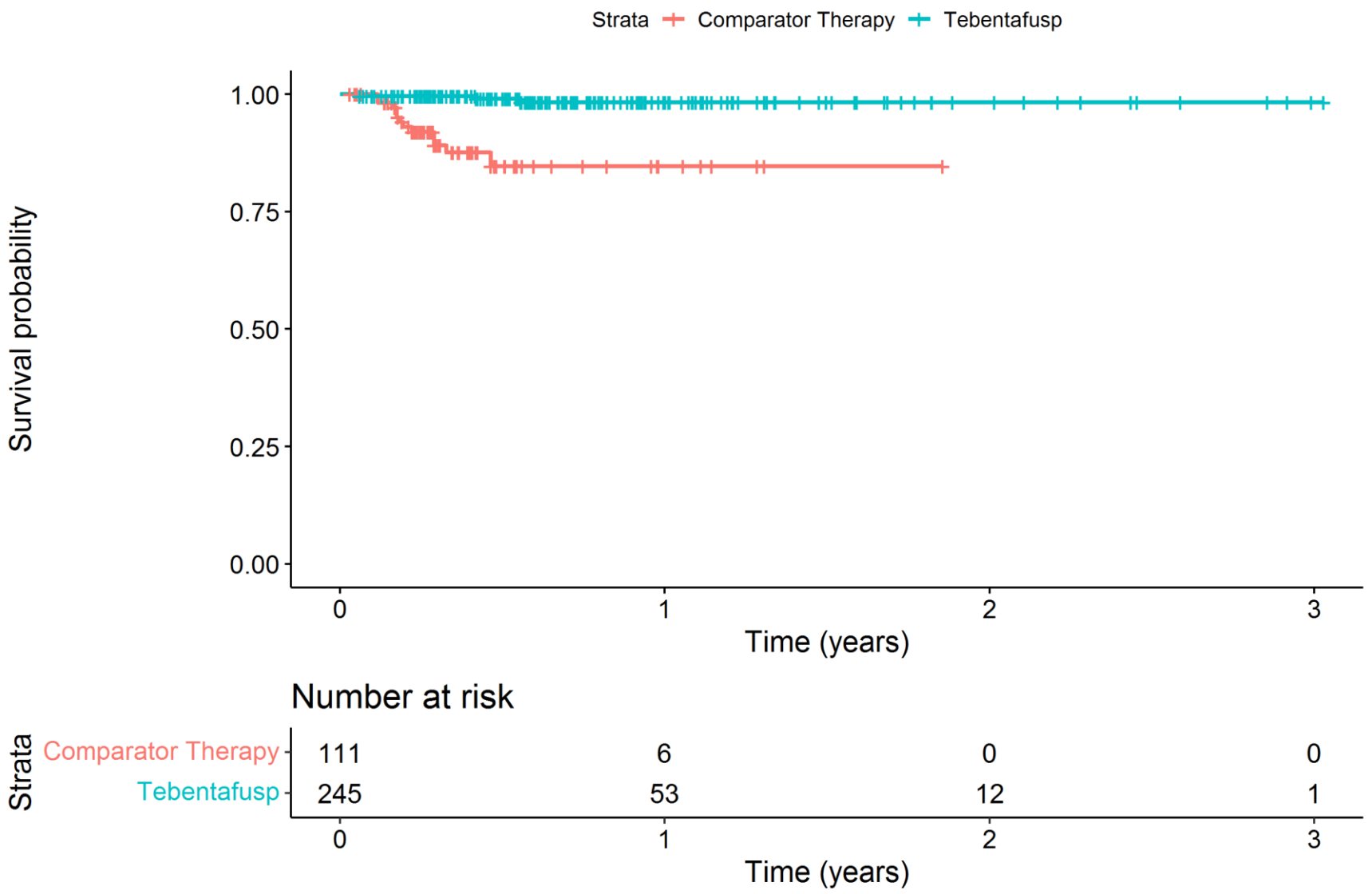
24.5 Alle unerwünschten Ereignisse – Primäranalyse (Oktober 2020) (Tabelle 4-53)

25 UEs (PT), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten

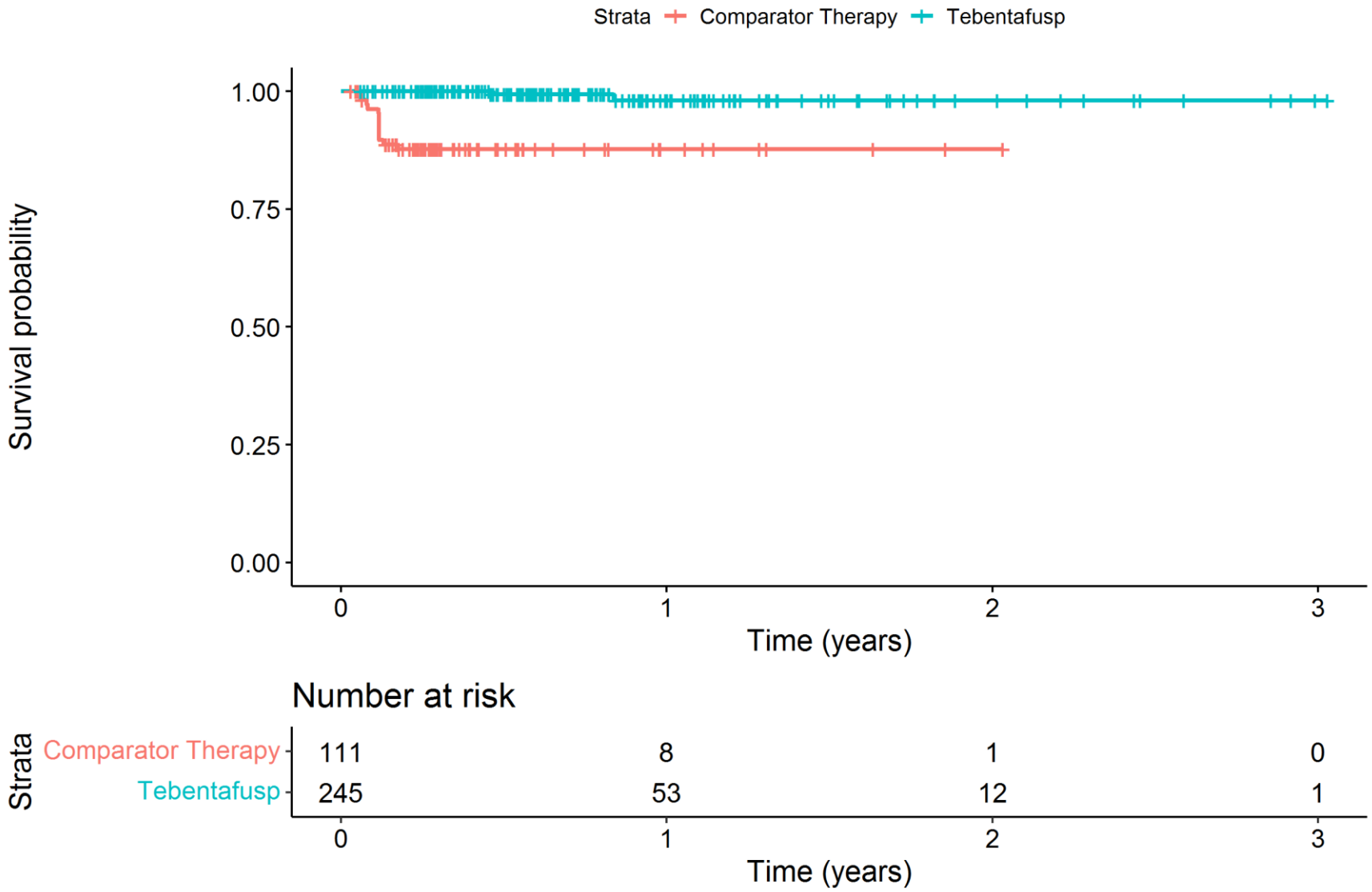
25.1 Anämie



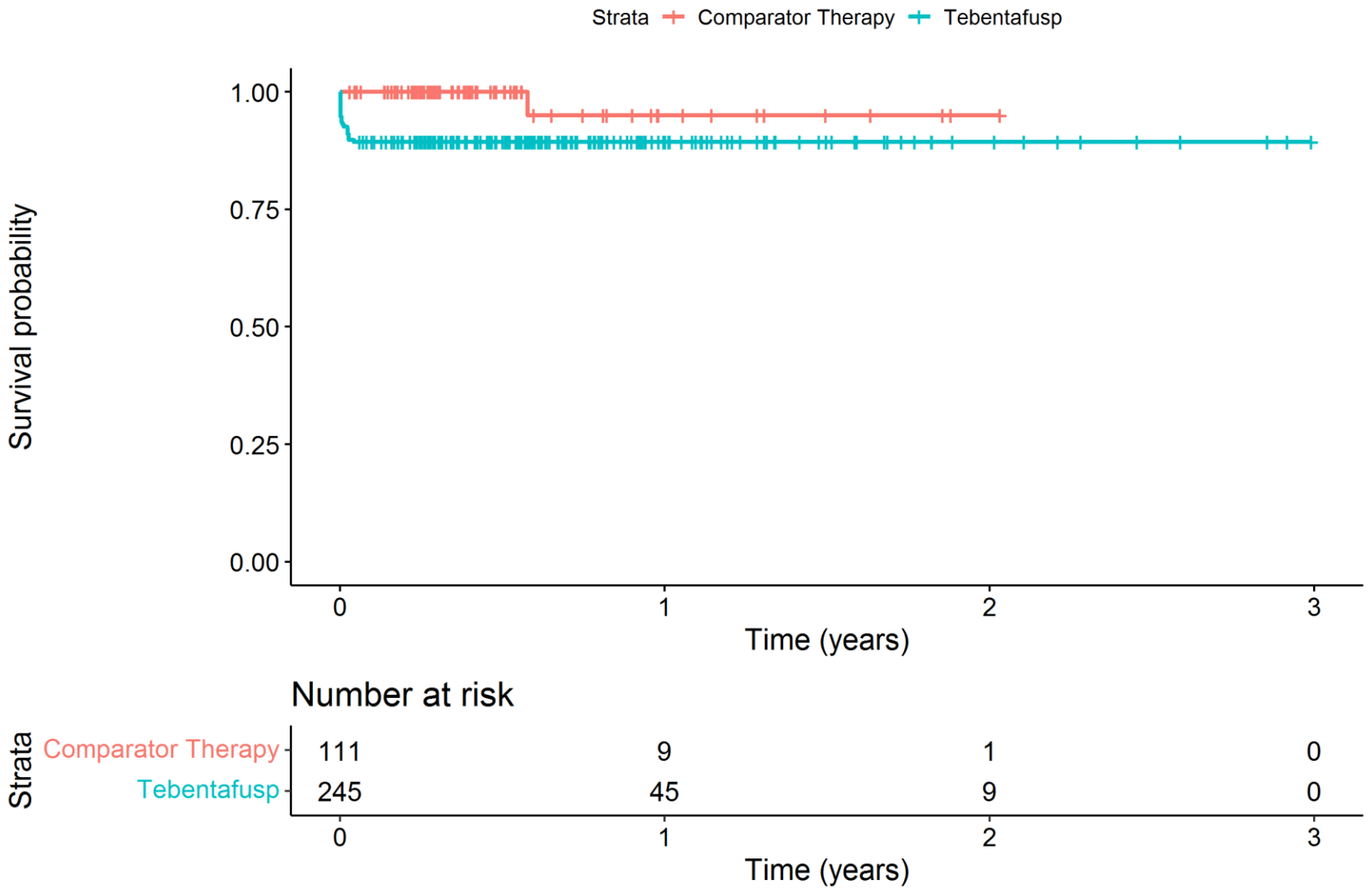
25.2 Hypothyreose



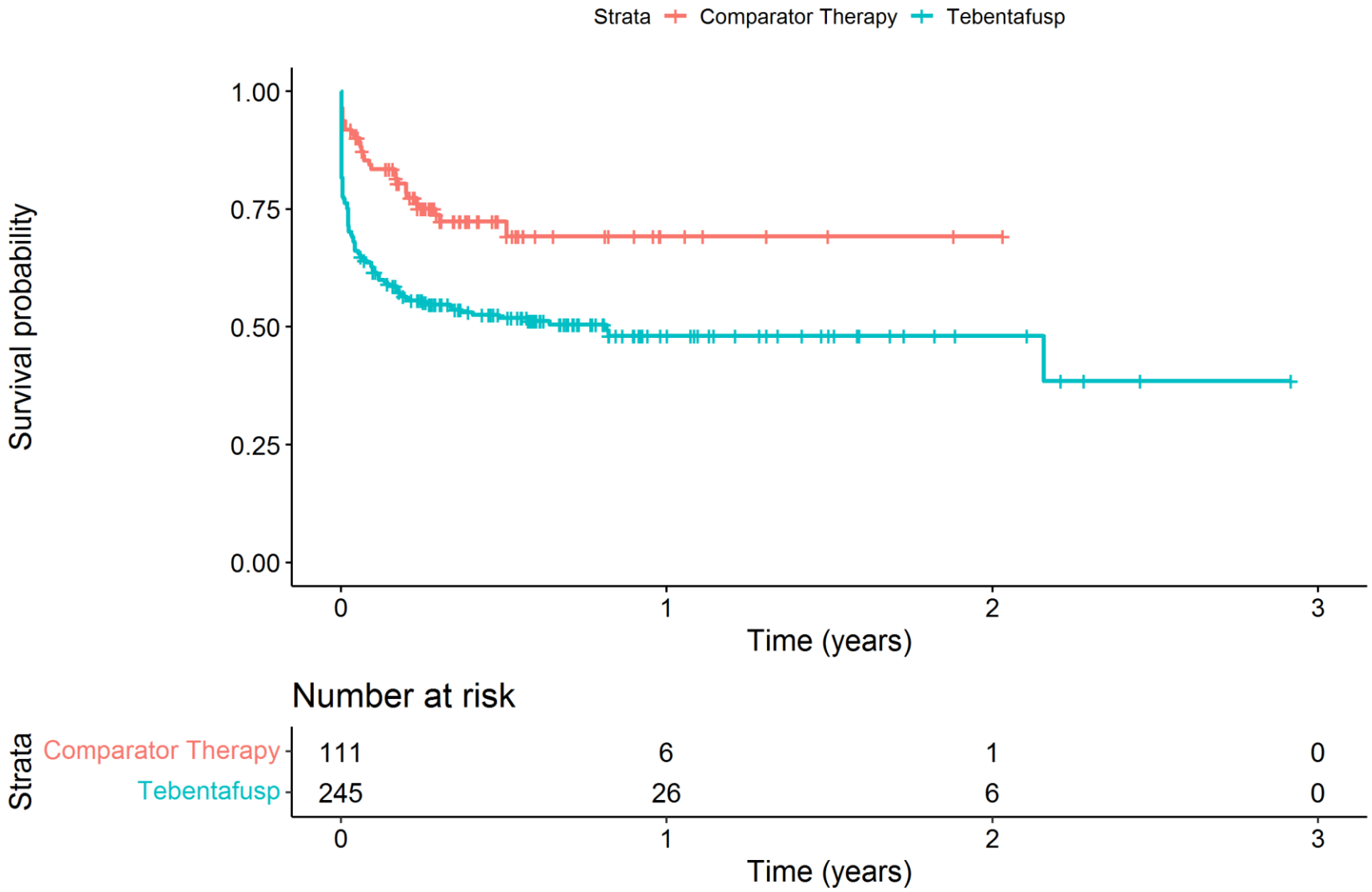
25.3 Hyperthyreose



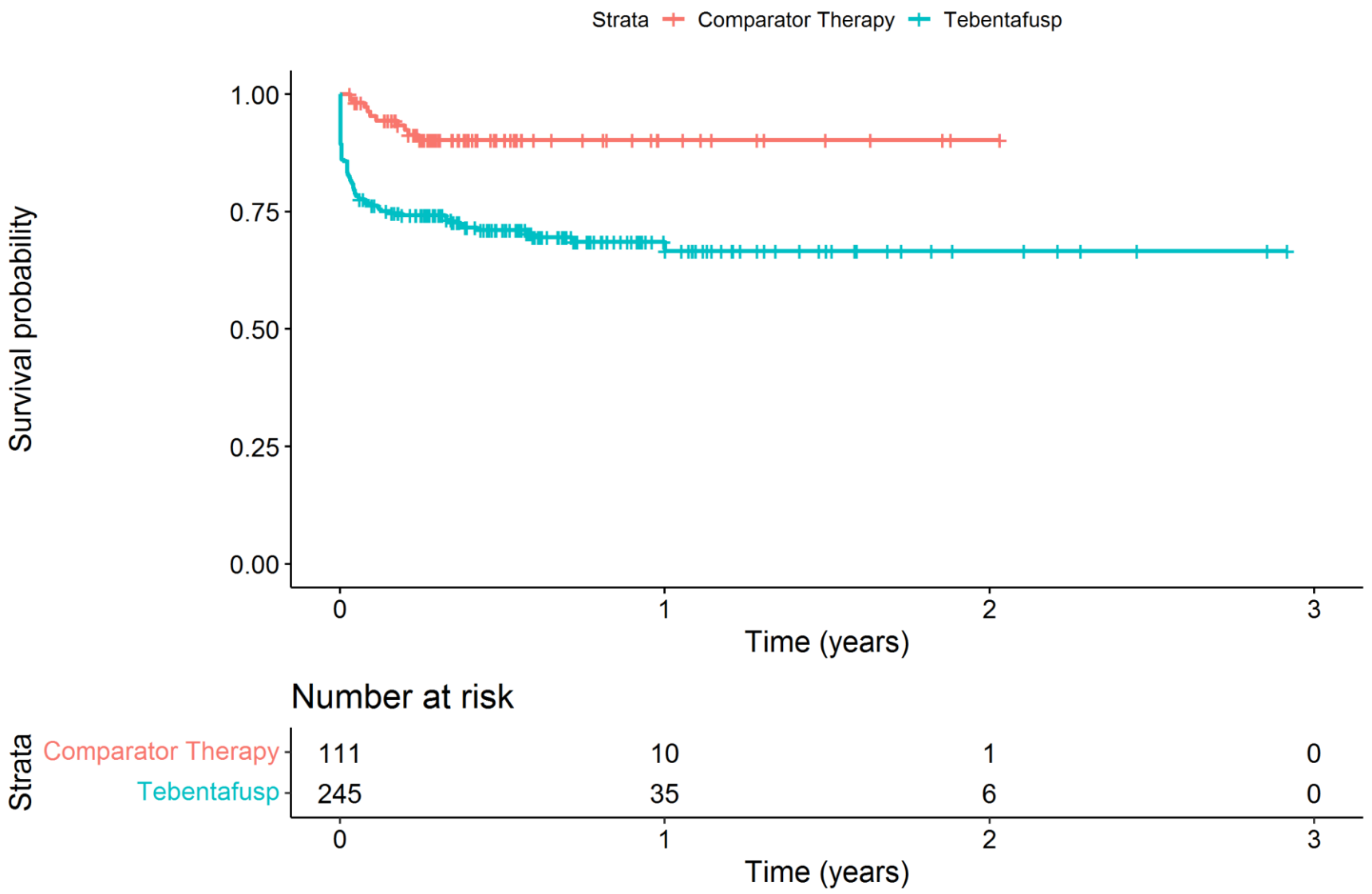
25.4 Periorbitales Ödem



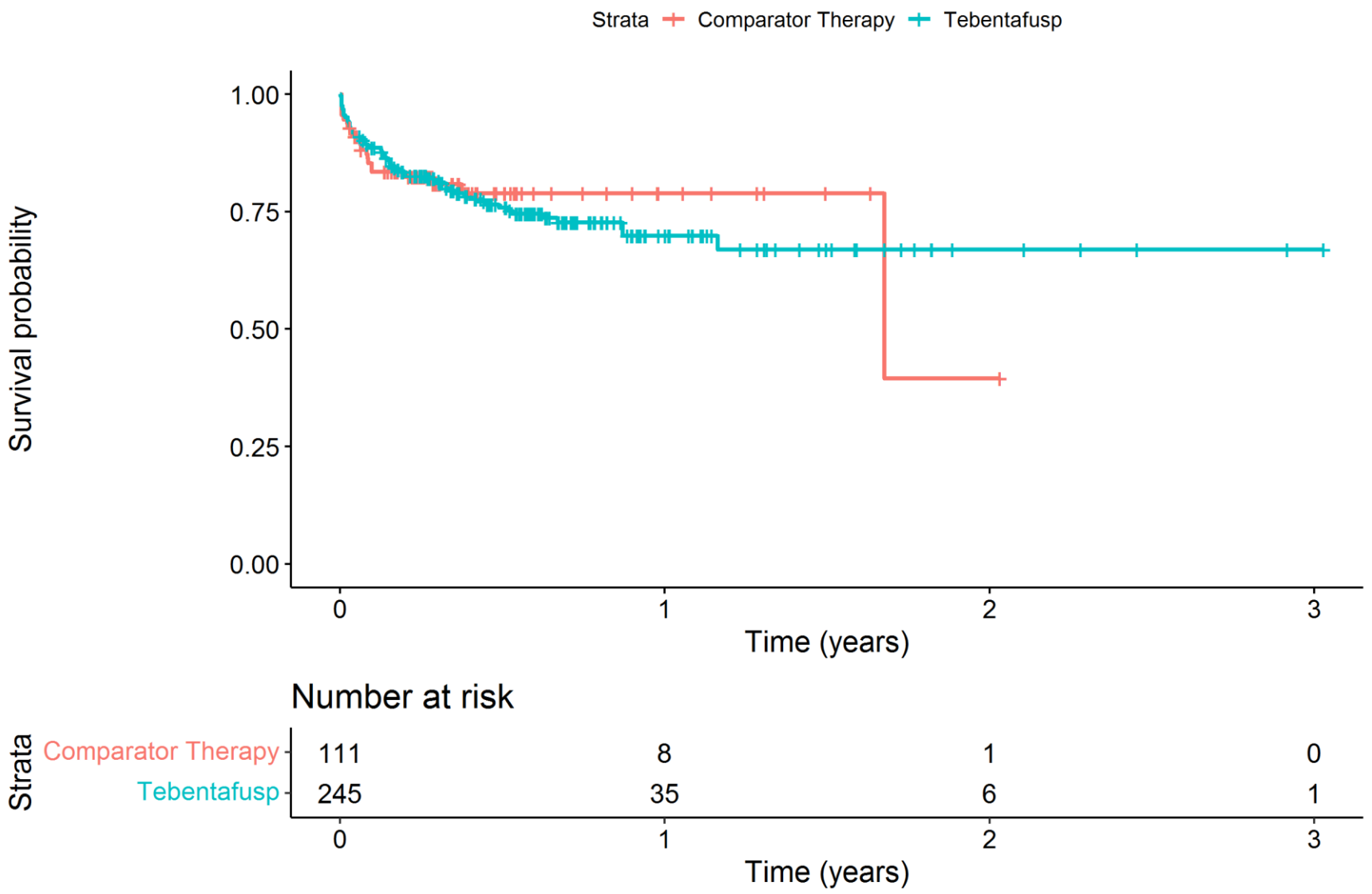
25.5 Übelkeit



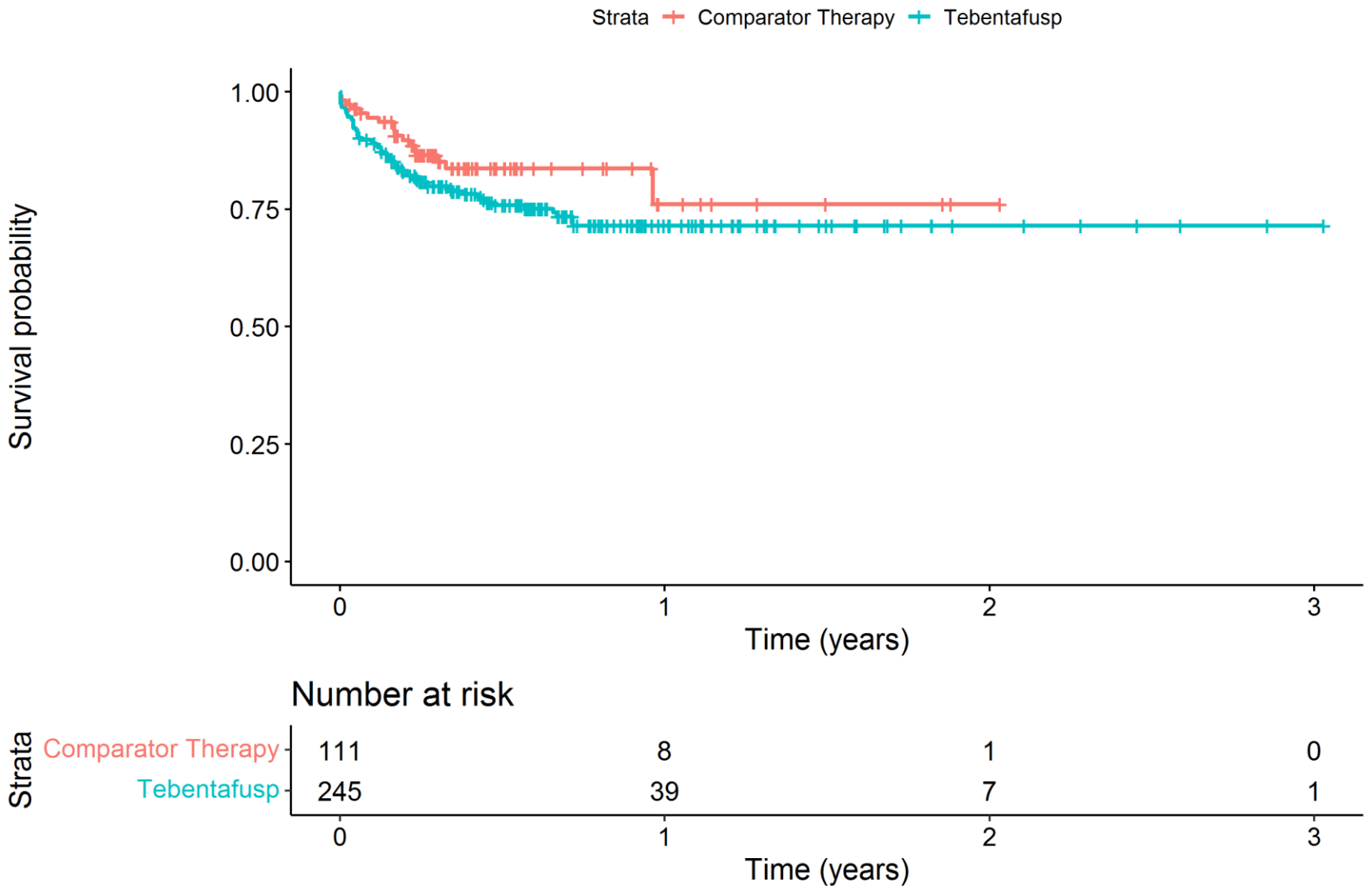
25.6 Erbrechen



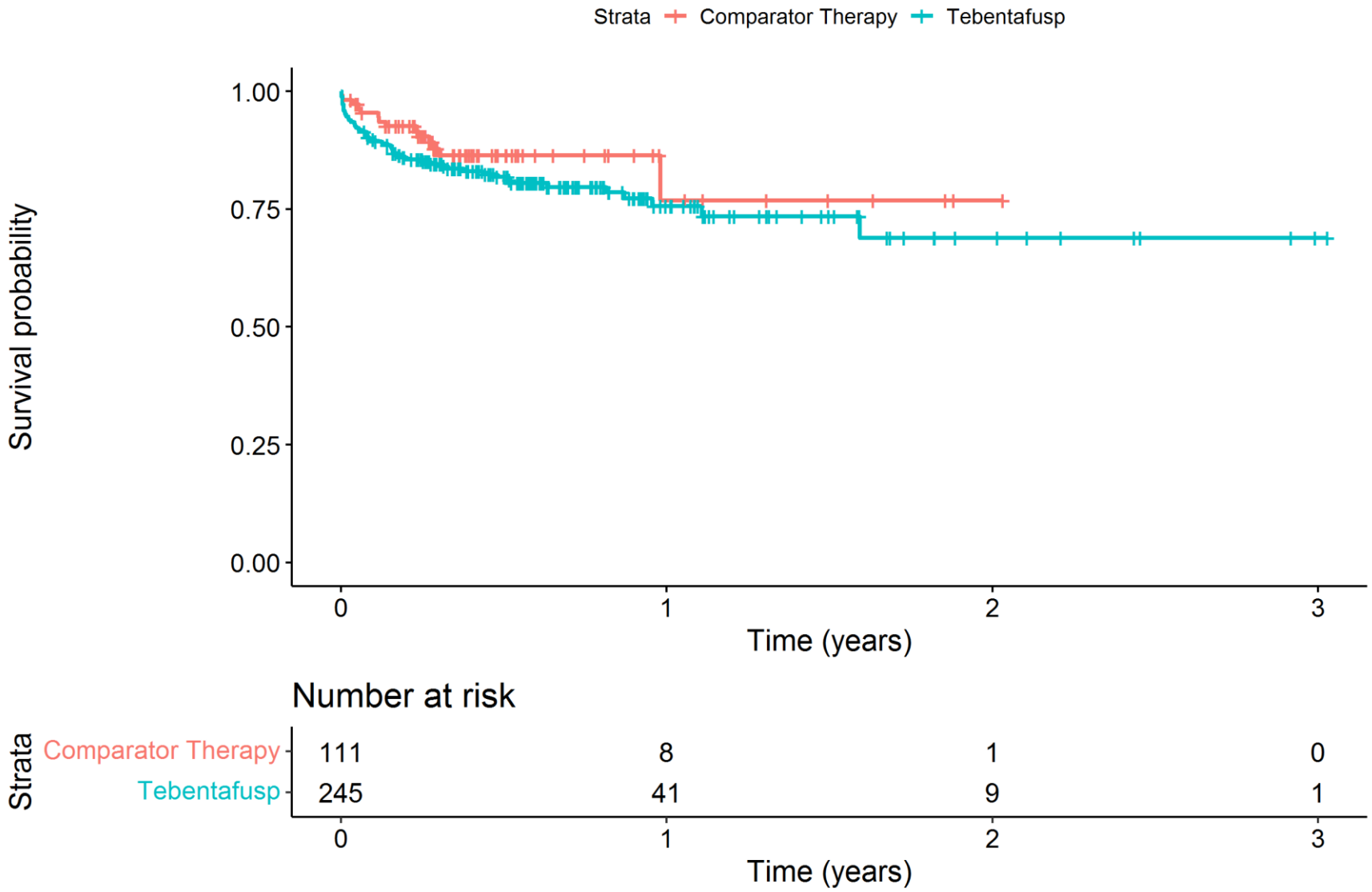
25.7 Diarrhoe



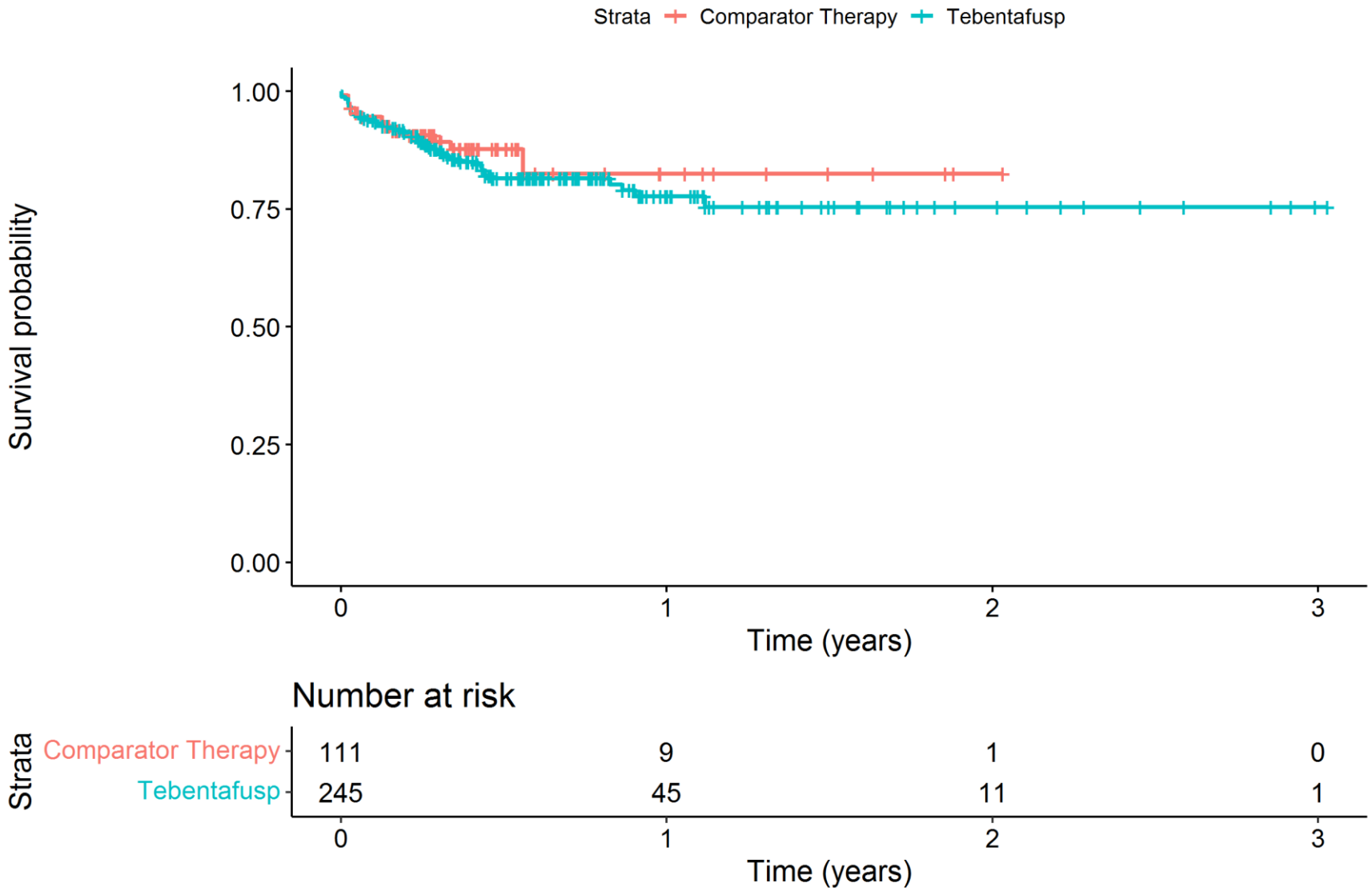
25.8 Unterleibschmerzen



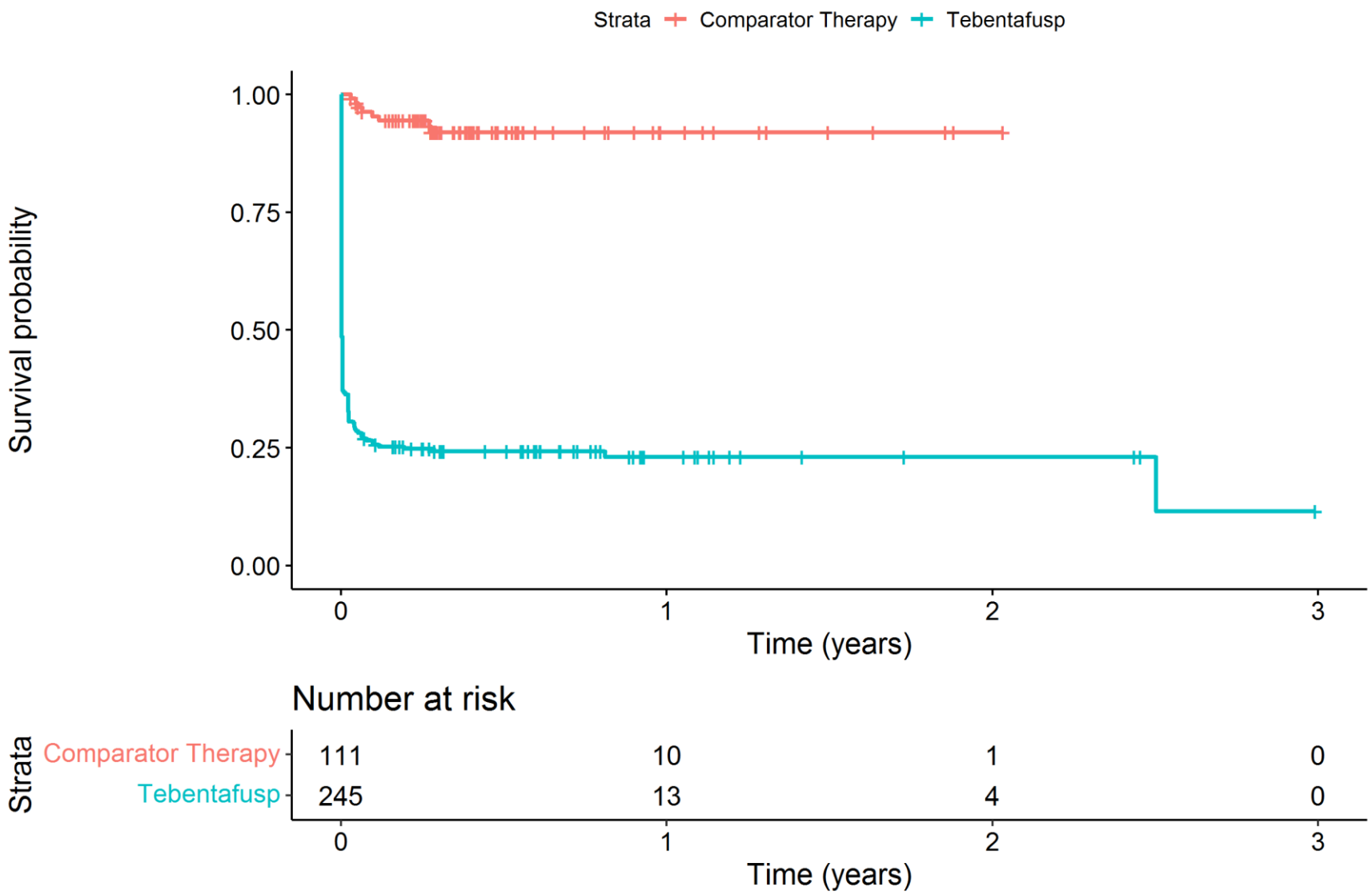
25.9 Oberbauchschmerzen



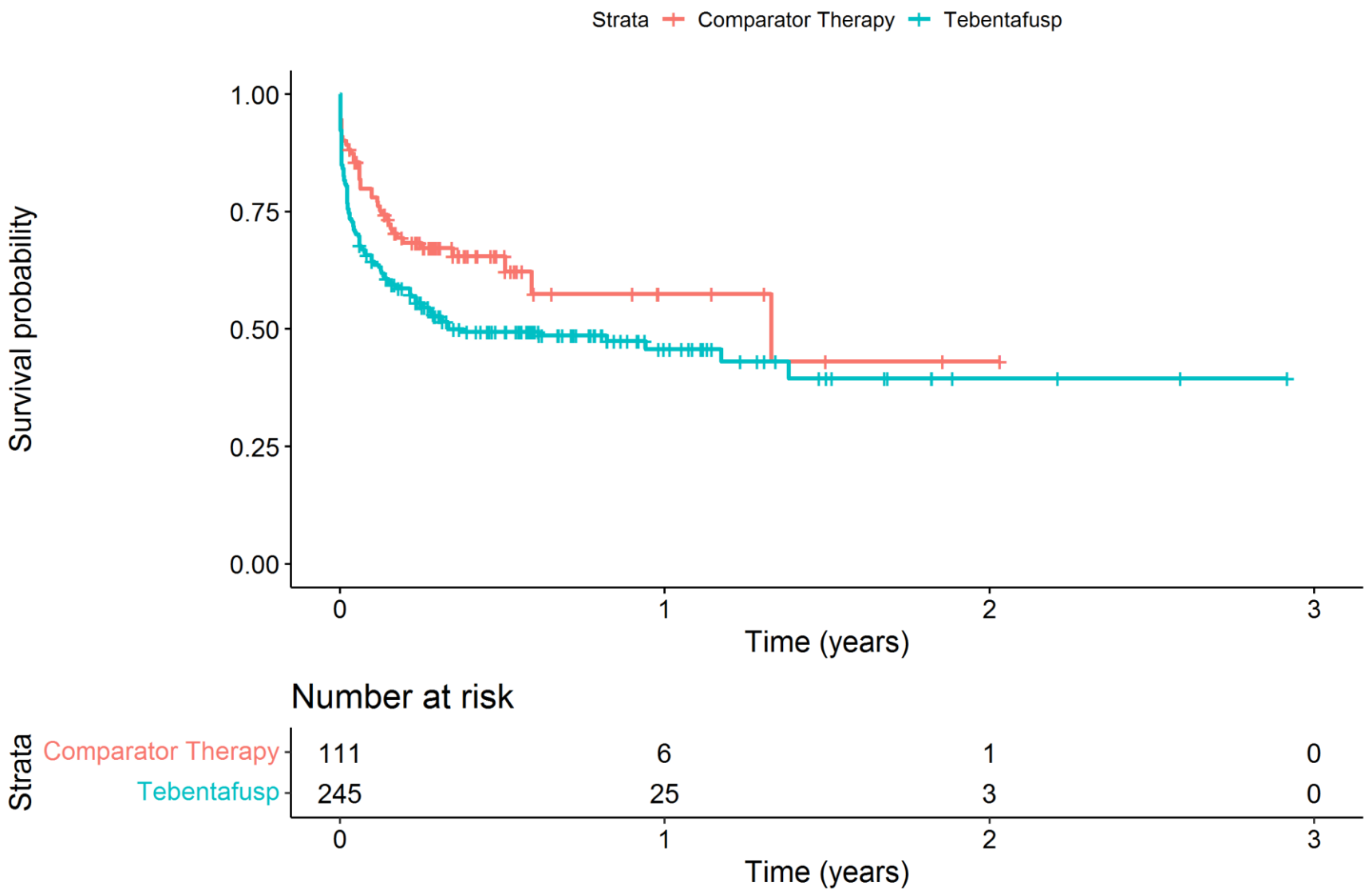
25.10 Verstopfung



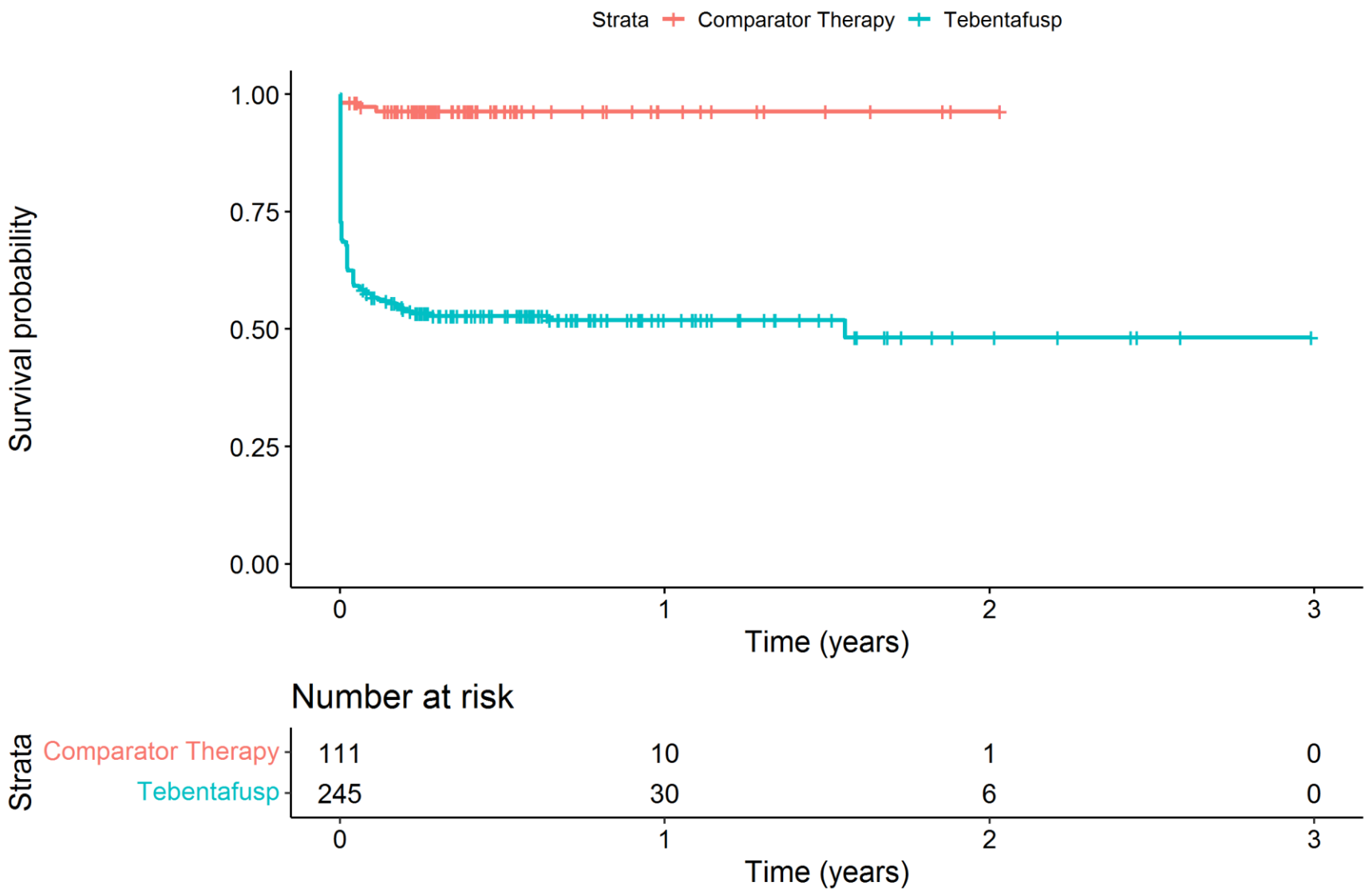
25.11 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
13
4
0
0
1
2
3
Time (years)

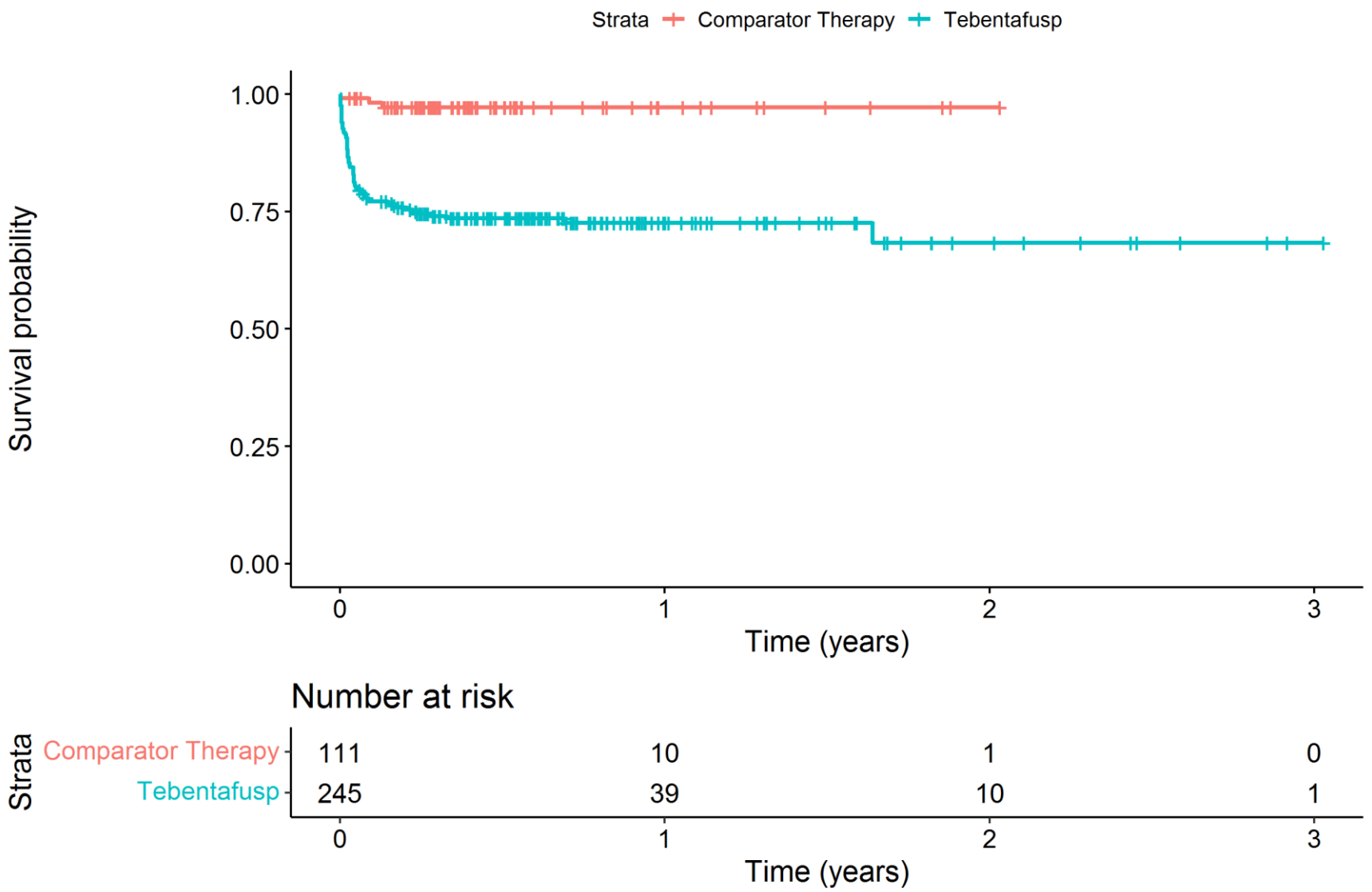
25.12 Müdigkeit



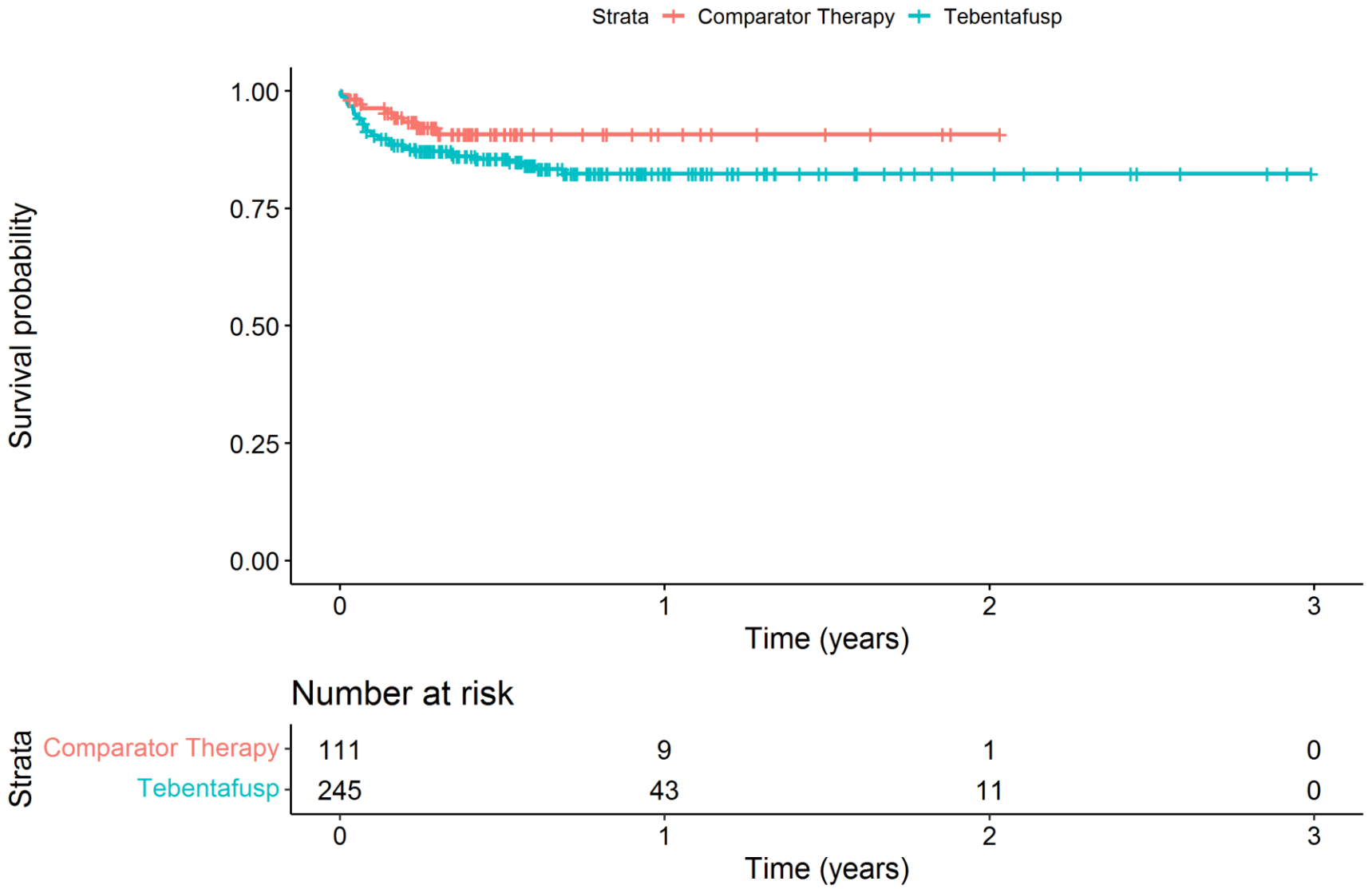
25.13 Schüttelfrost



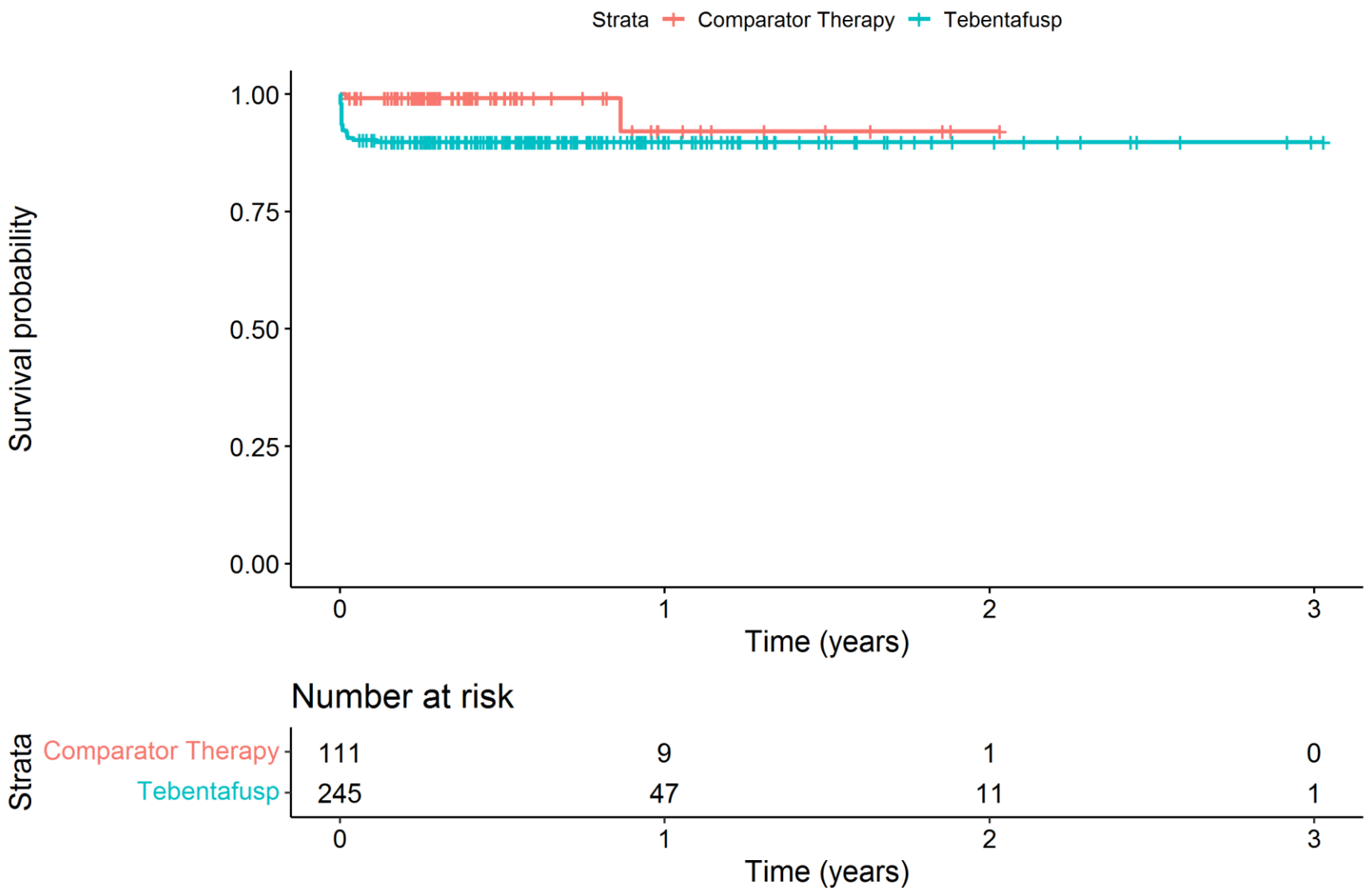
25.14 Periphere Öd eme



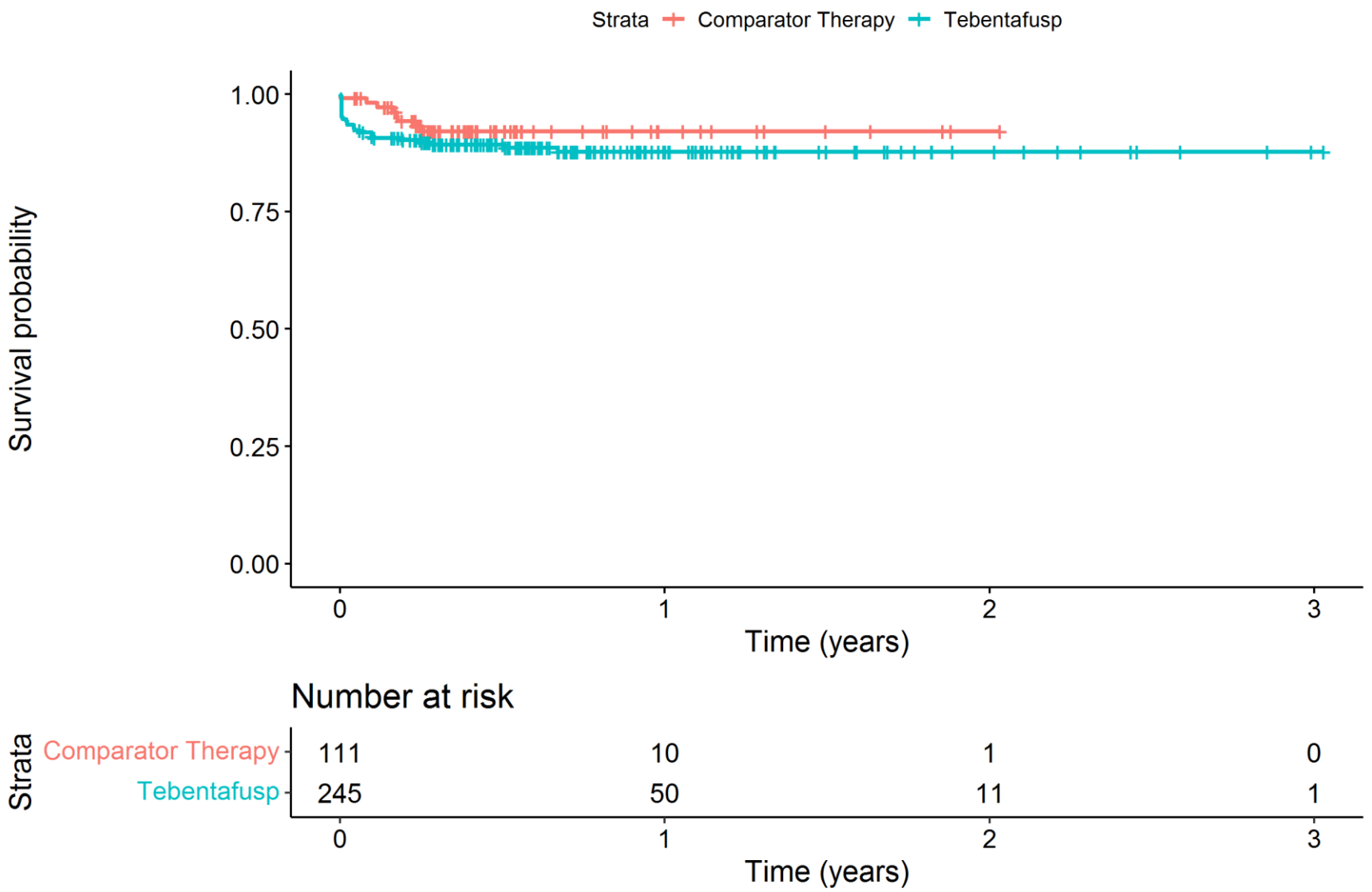
25.15 Asthenie



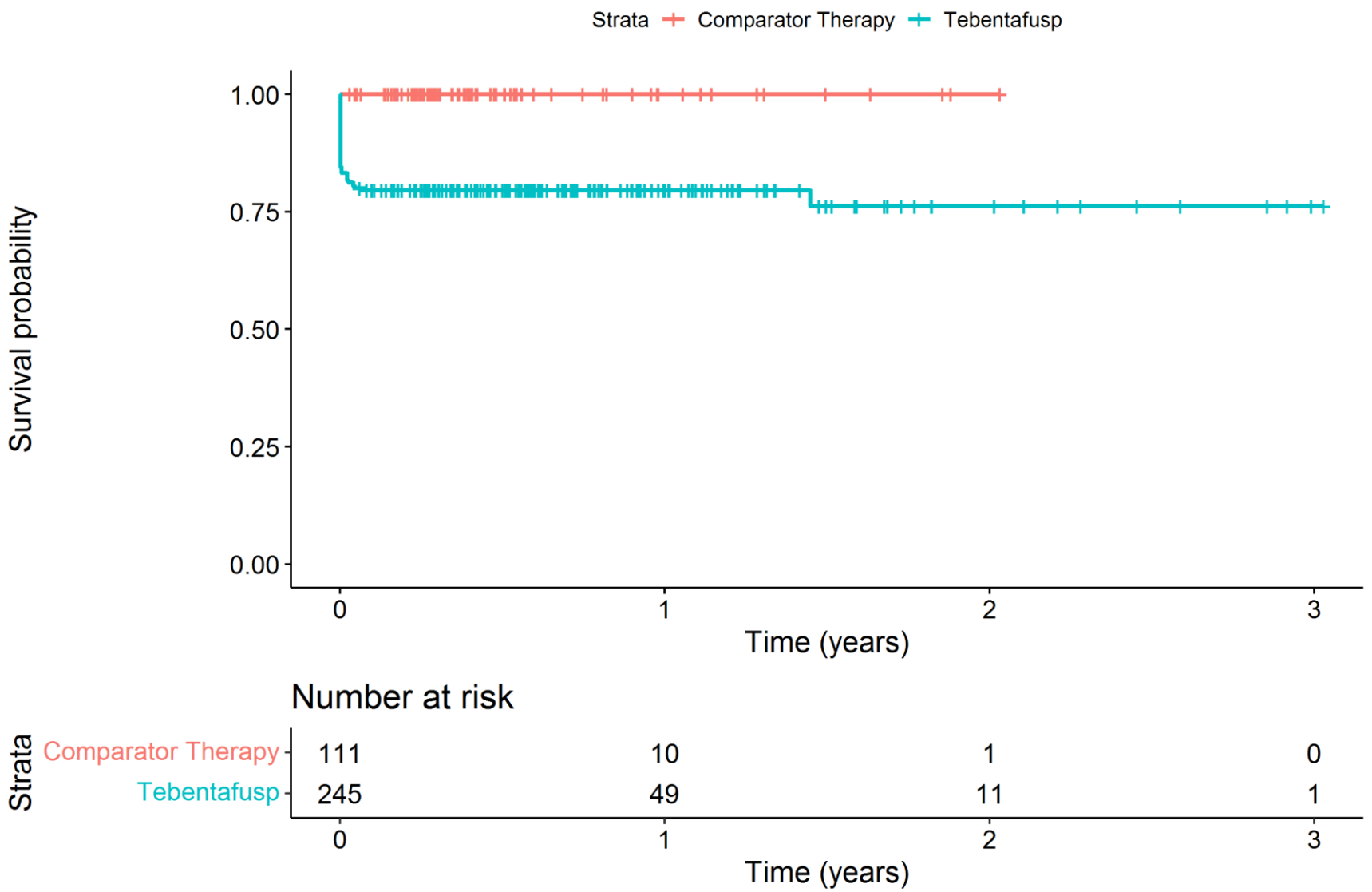
25.16 Gesichtsödeme



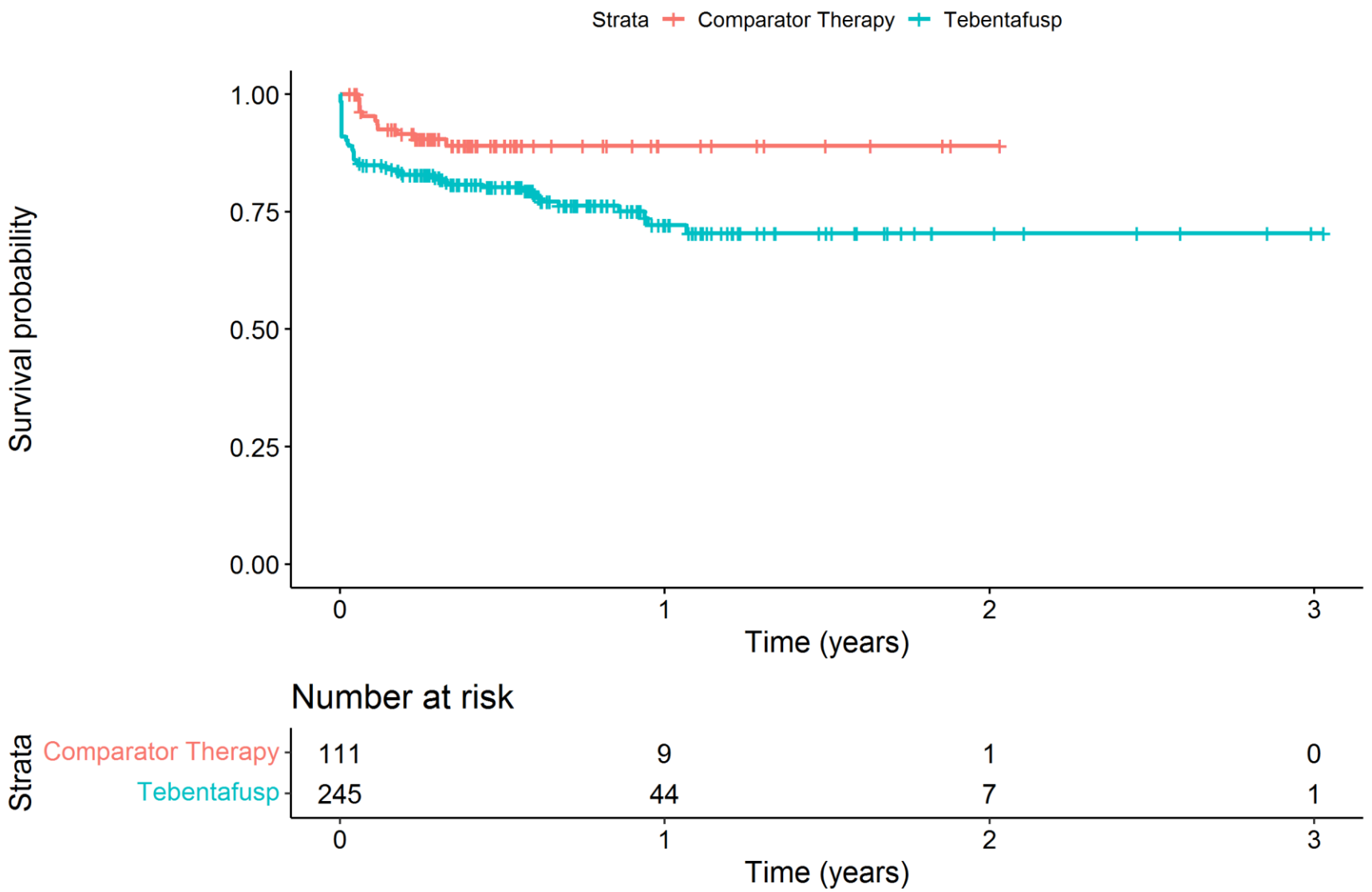
25.17 Hyperbilirubinämie



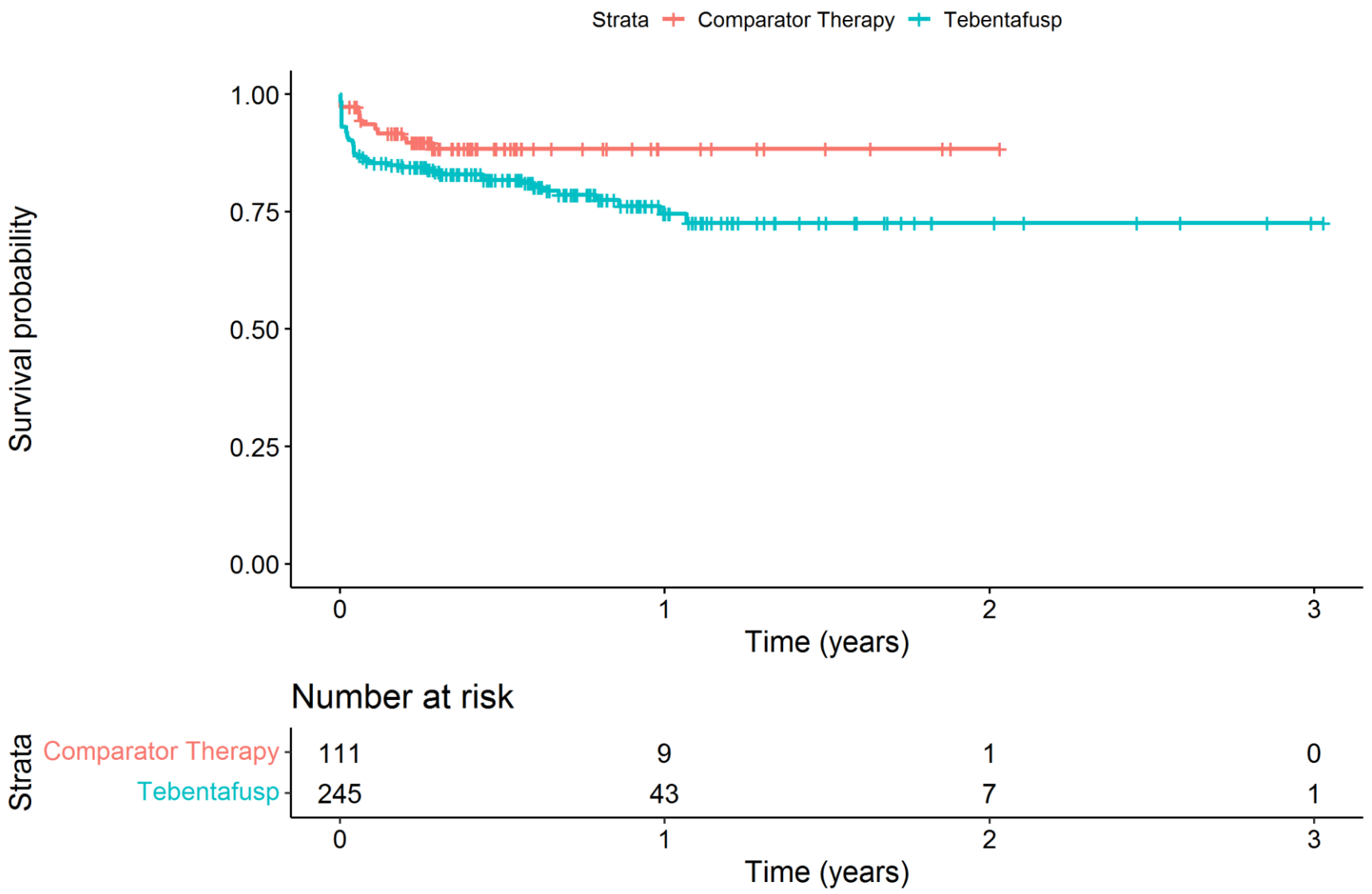
25.18 Zytokin-Freisetzungssyndrom



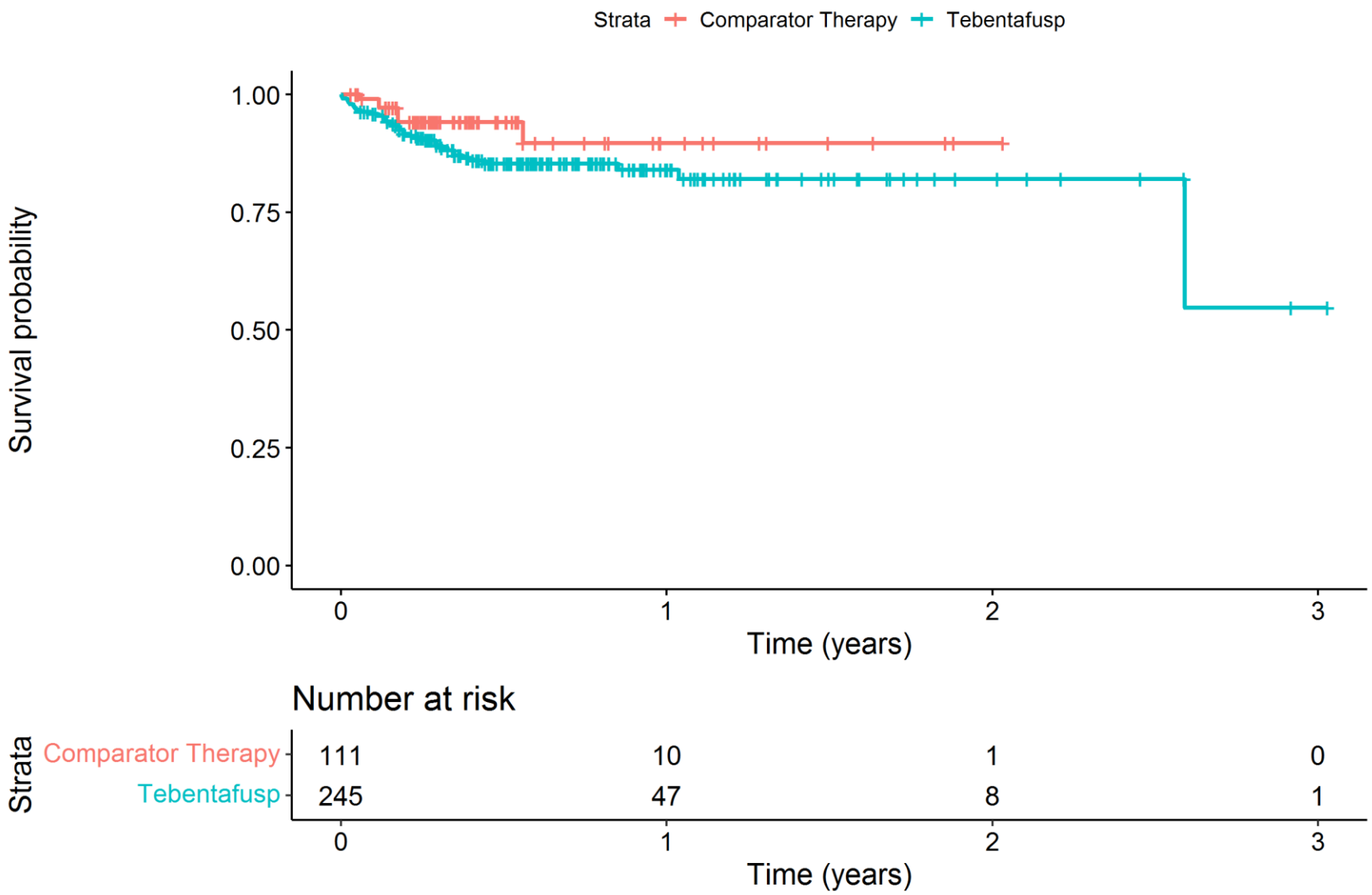
25.19 Erhöhte Aspartat-Aminotransferase



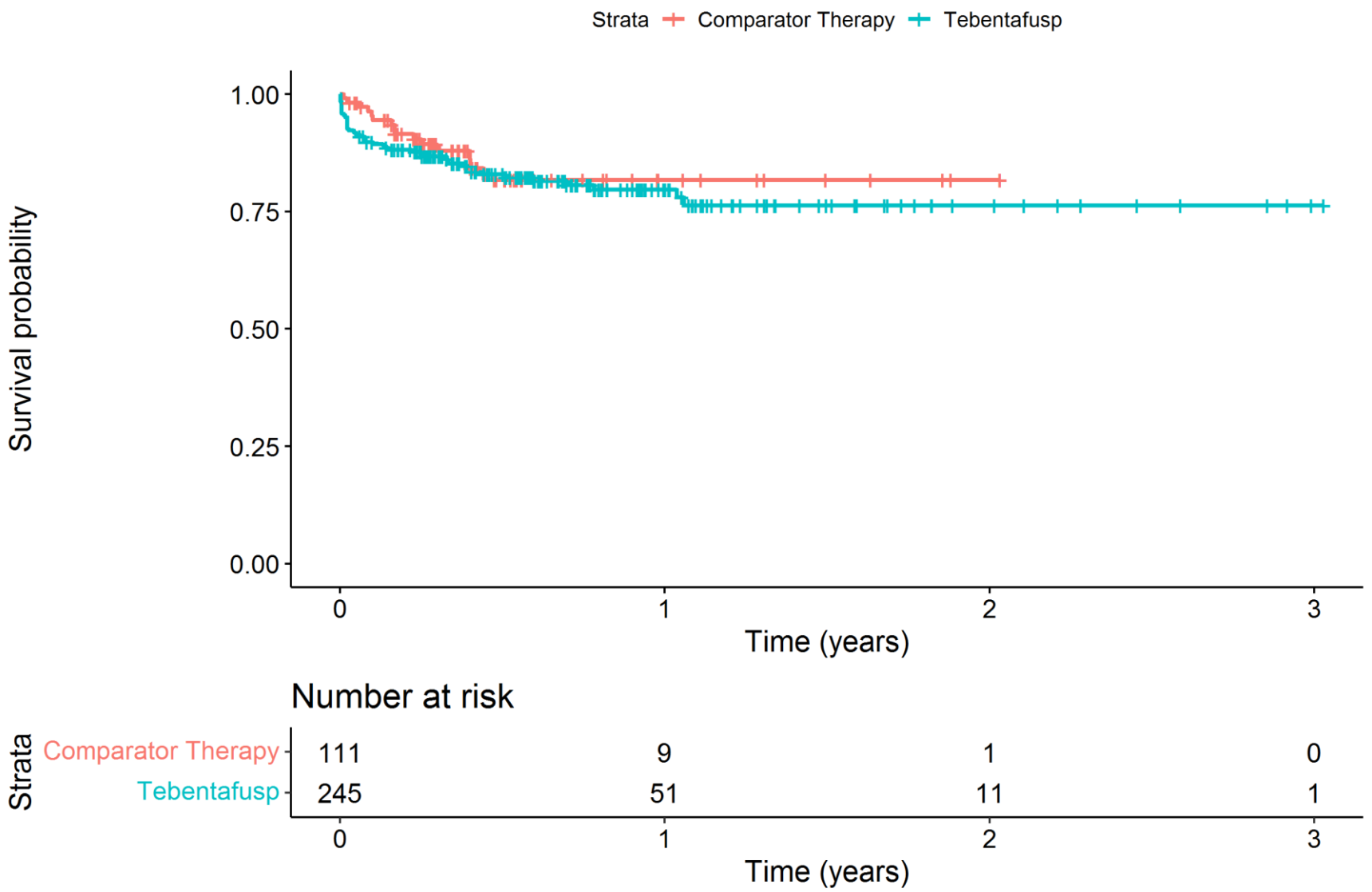
25.20 Erhöhte Alanin-Aminotransferase



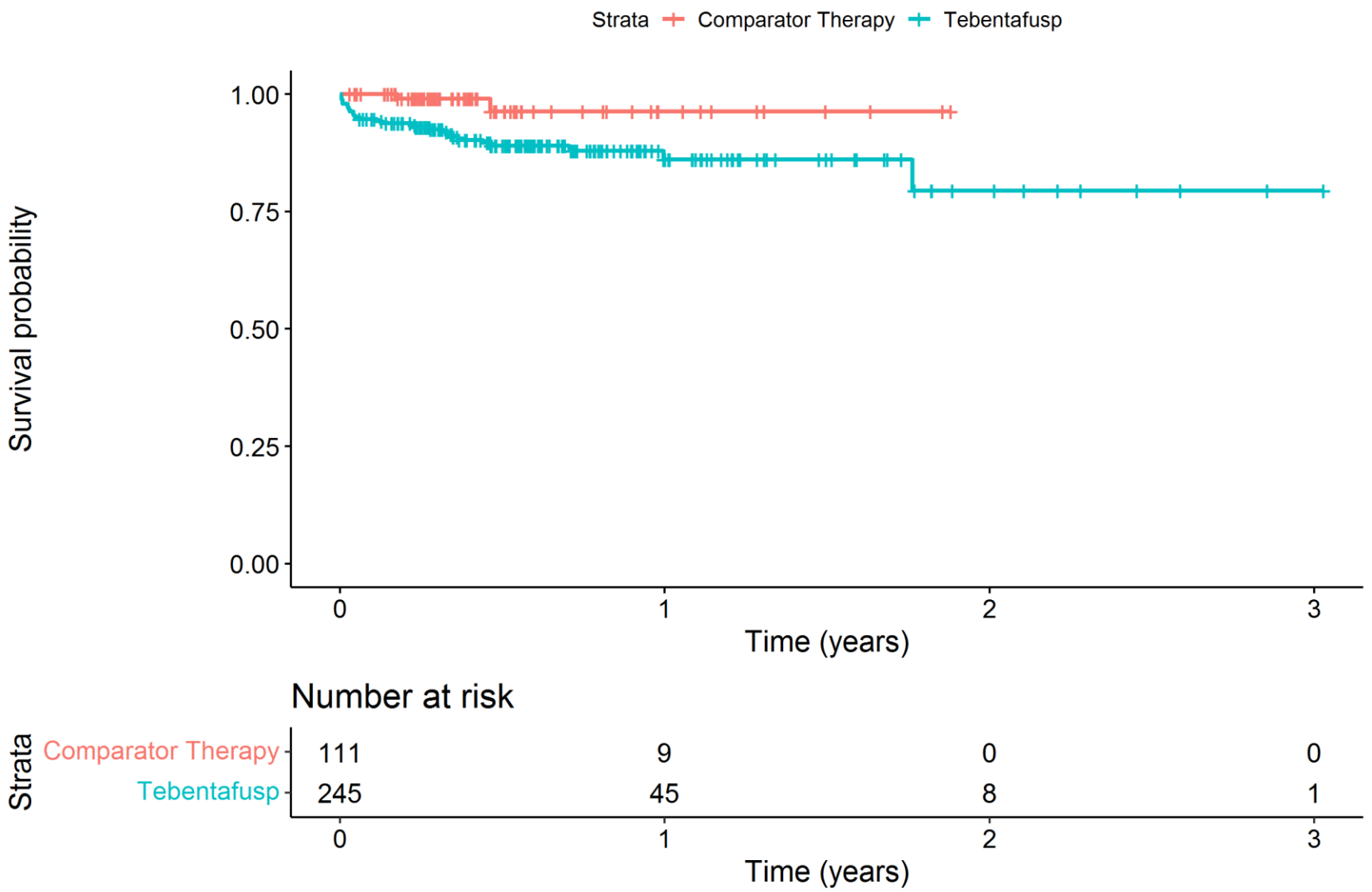
25.21 Erhöhte Lipase



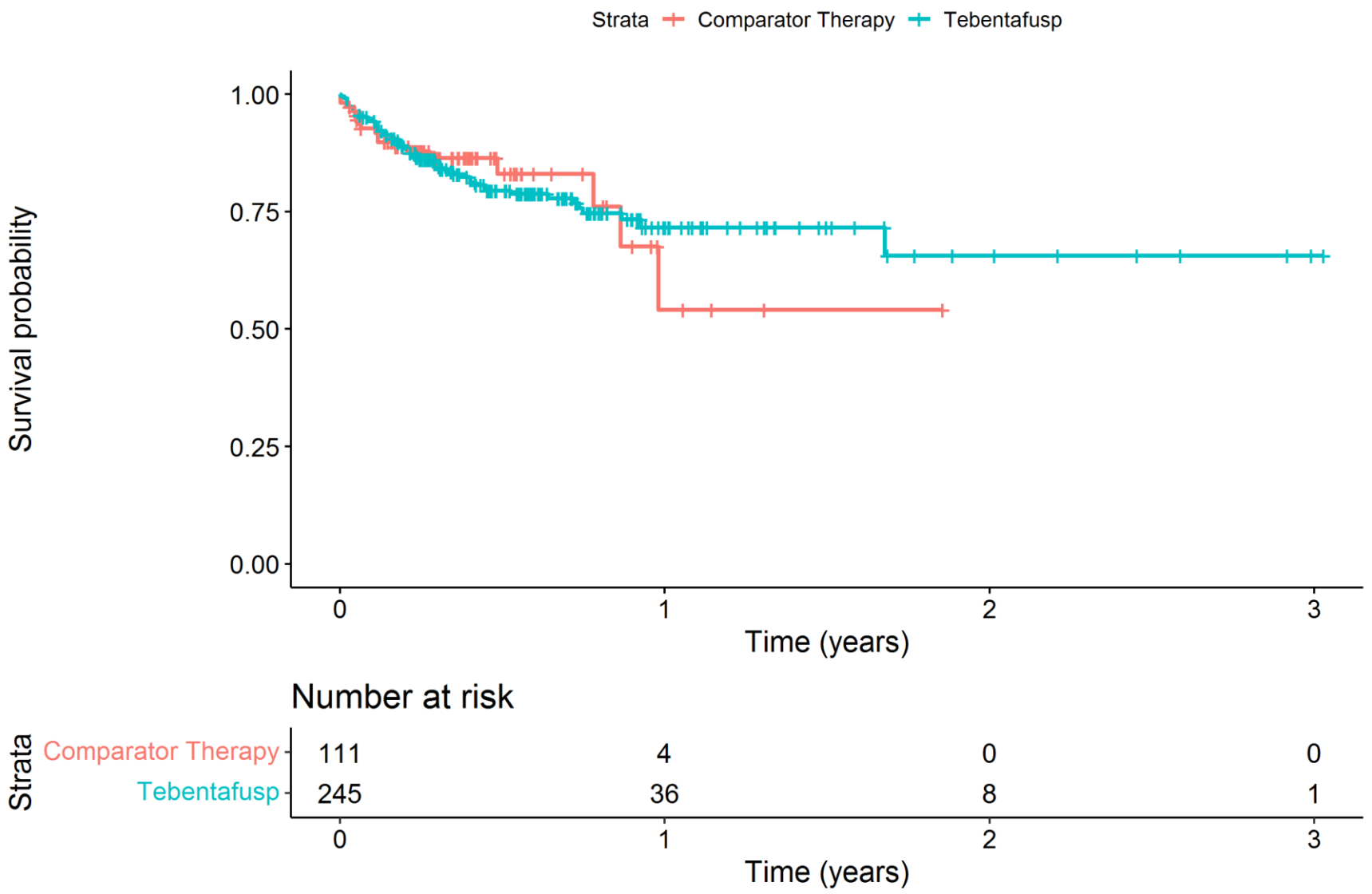
25.22 Verminderter Appetit



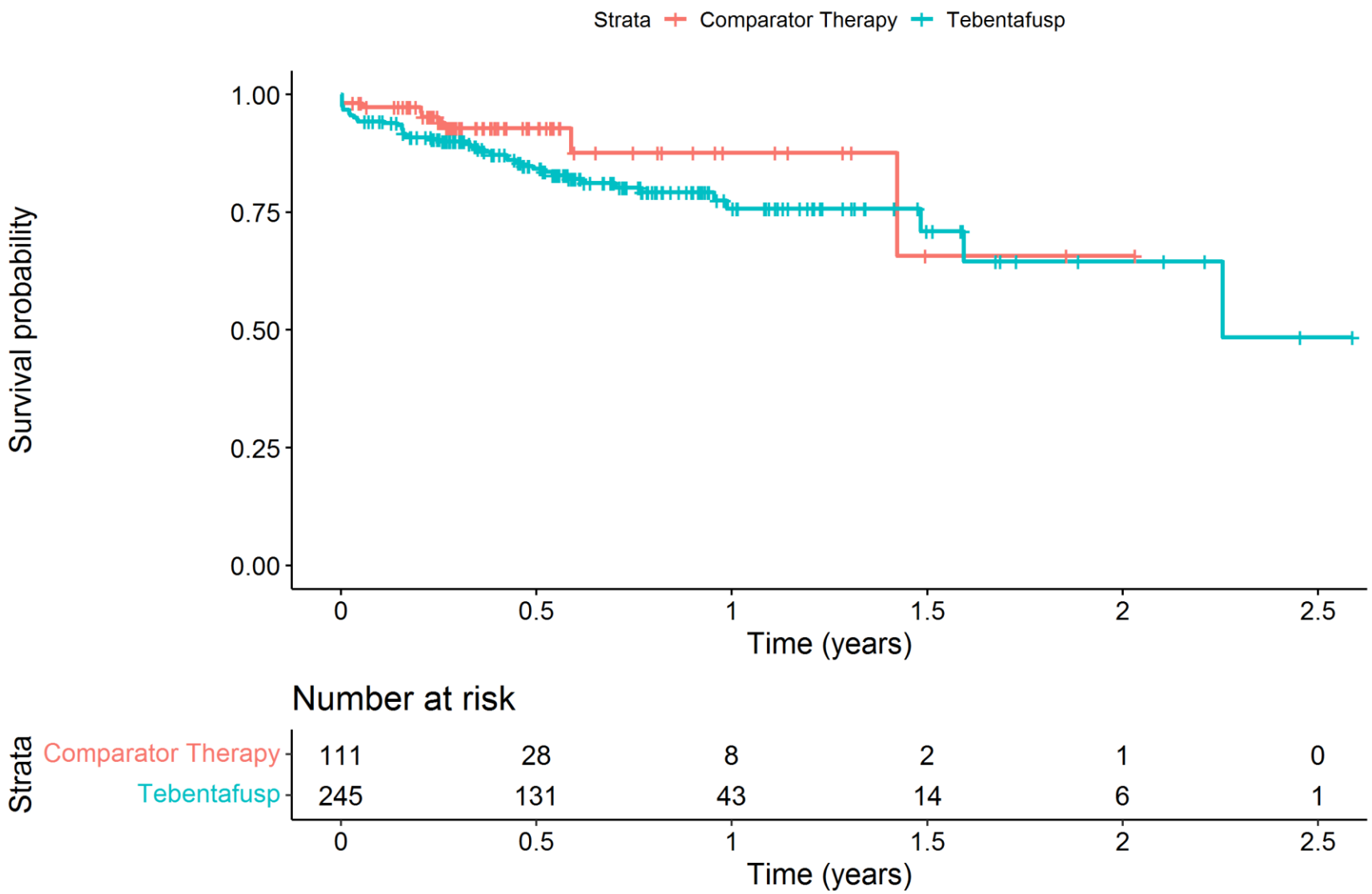
25.23 Hypophosphatämie



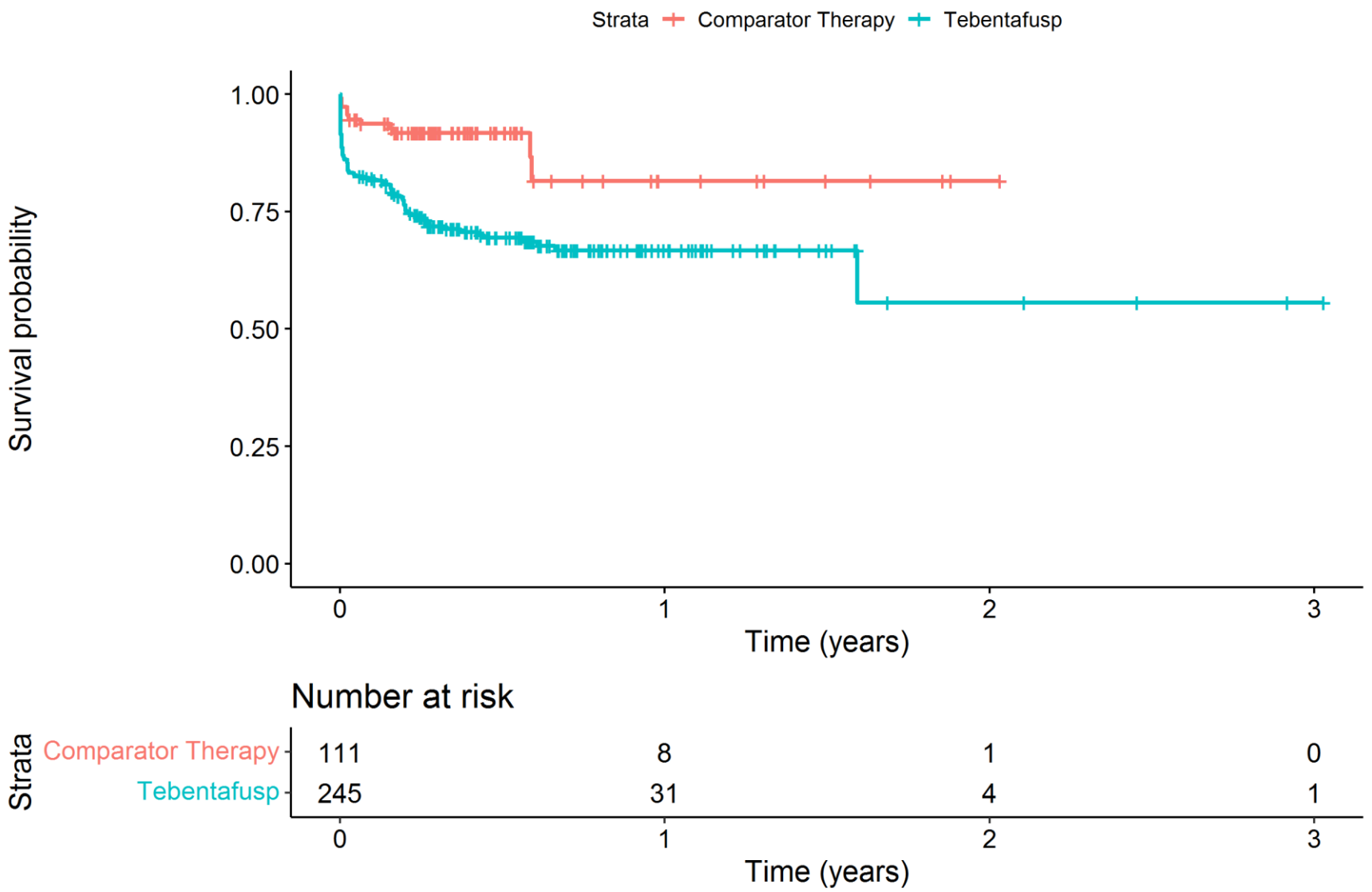
25.24 Arthralgie



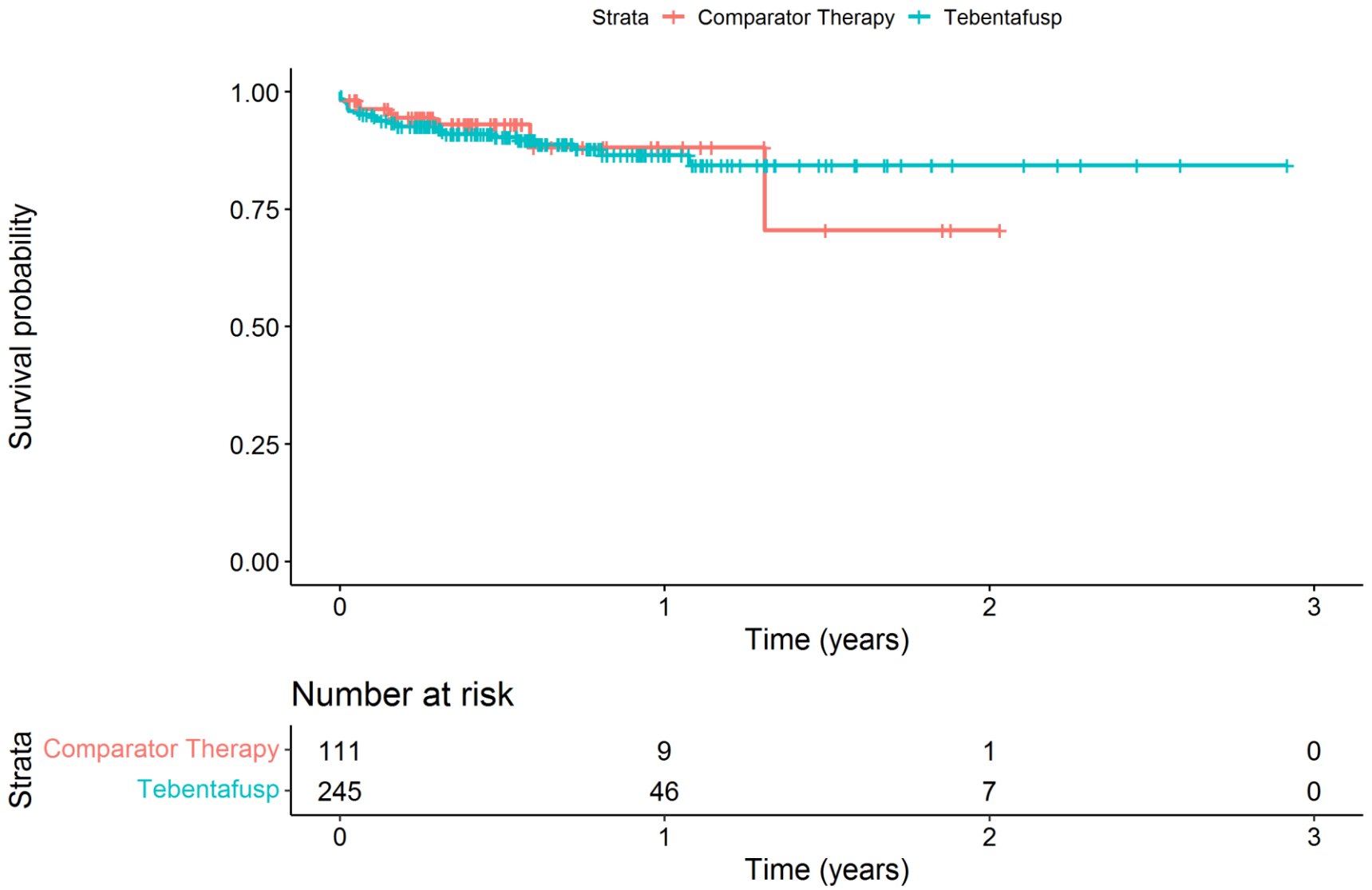
25.25 Rückenschmerzen



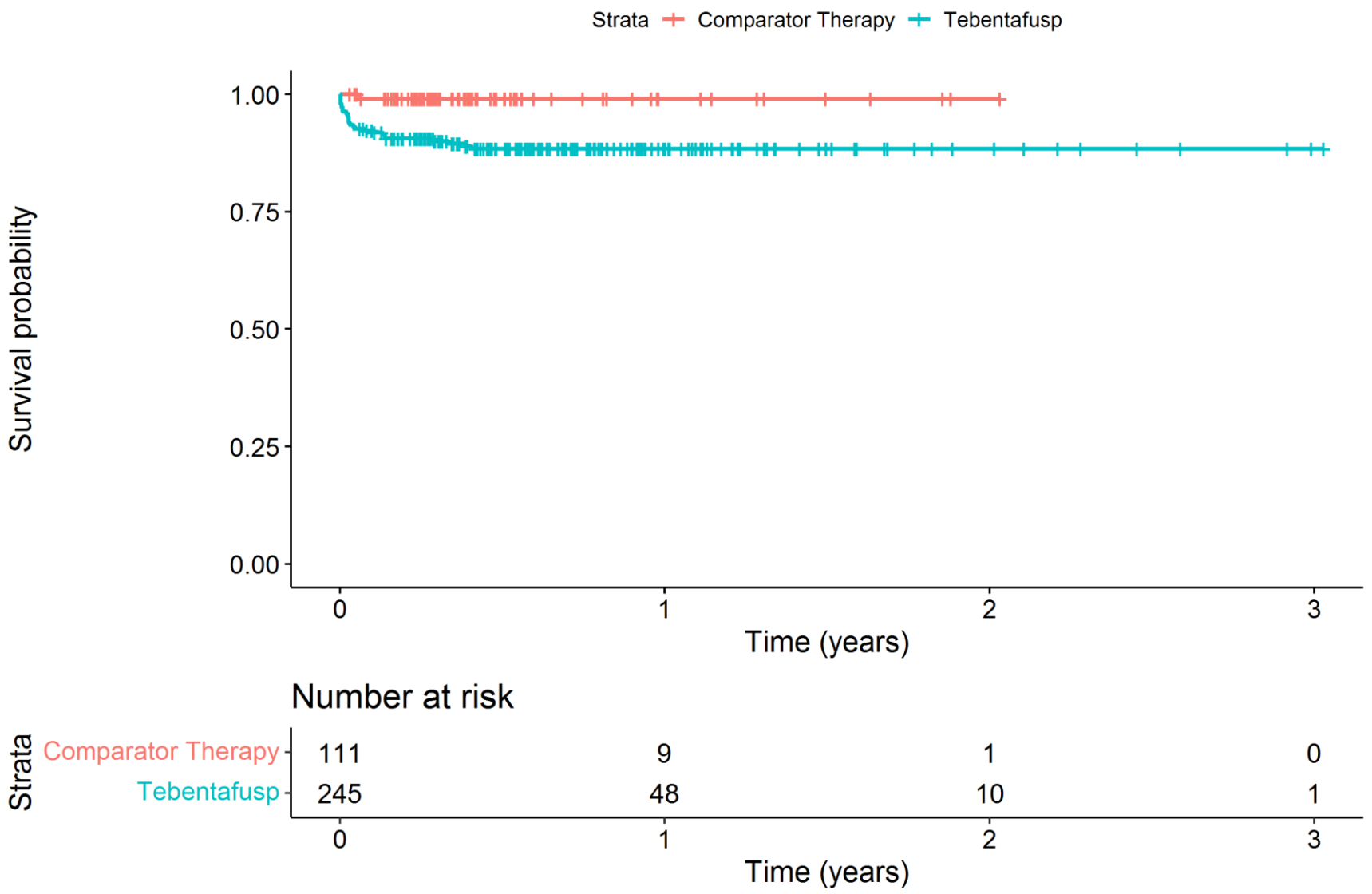
25.26 Kopfschmerzen



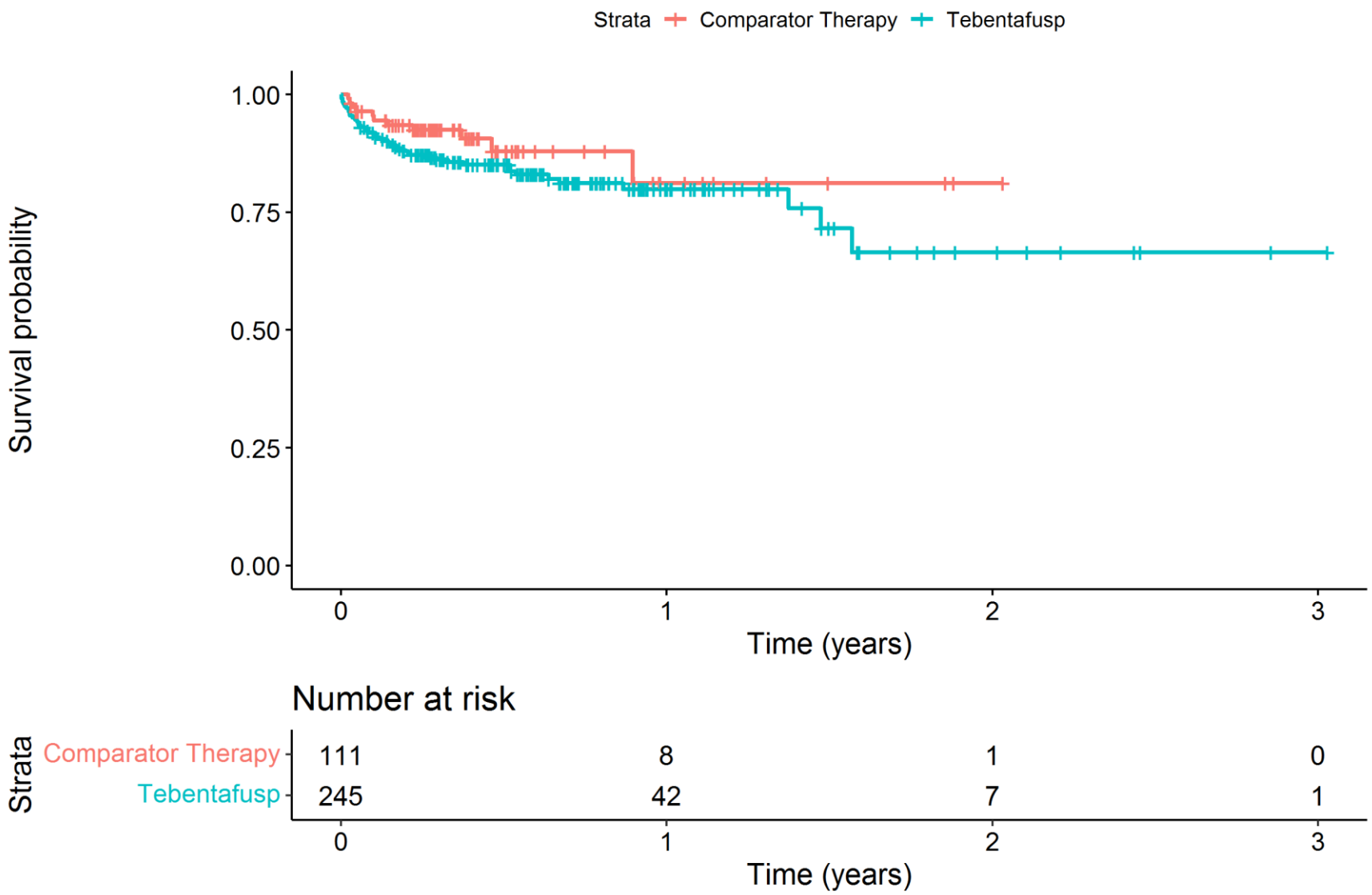
25.27 Schwindel



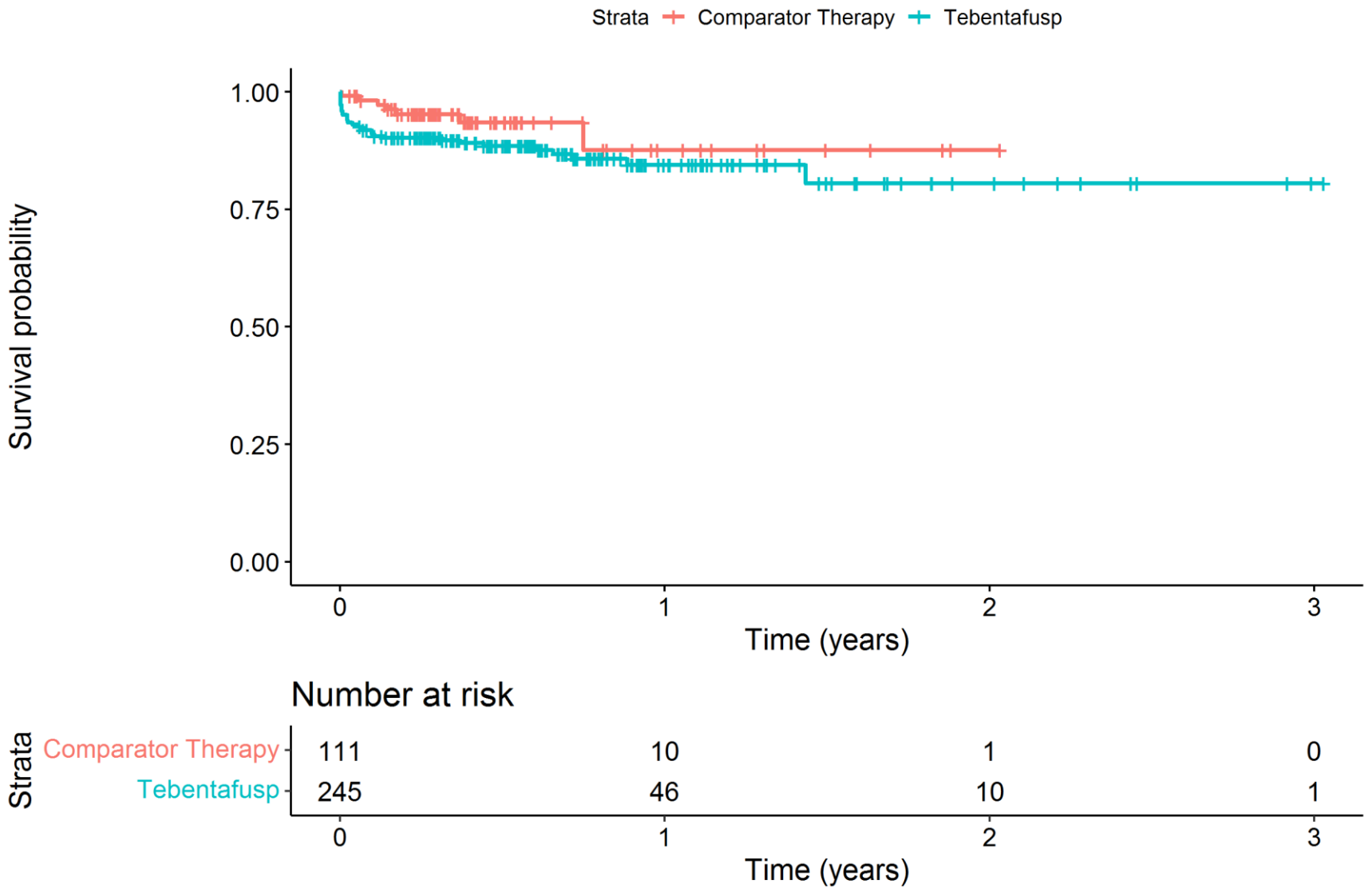
25.28 Parästhesie



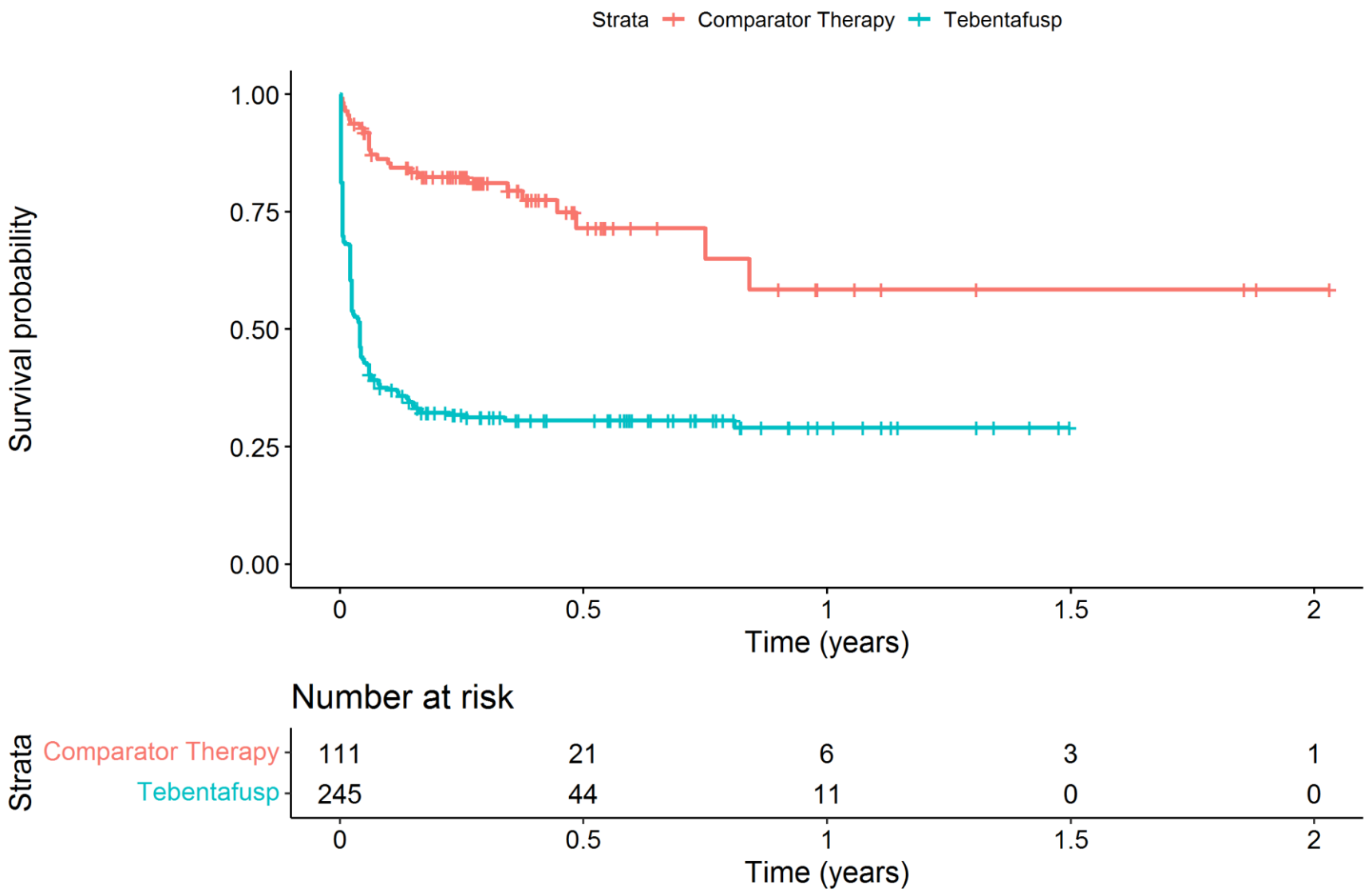
25.29 Husten


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
8
1
0
245
42
7
1
0
1
2
3
Time (years)

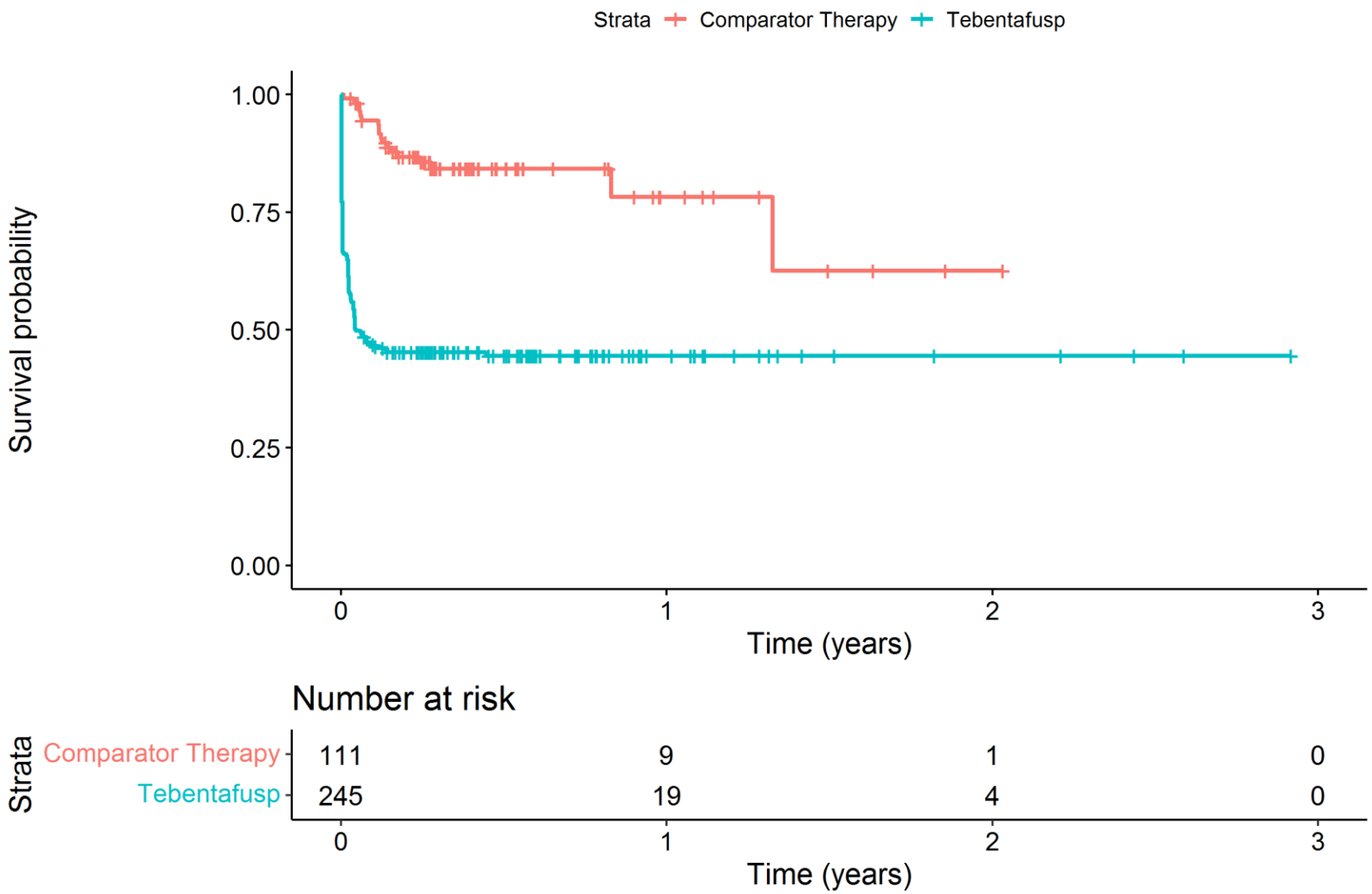
25.30 Dyspnoe



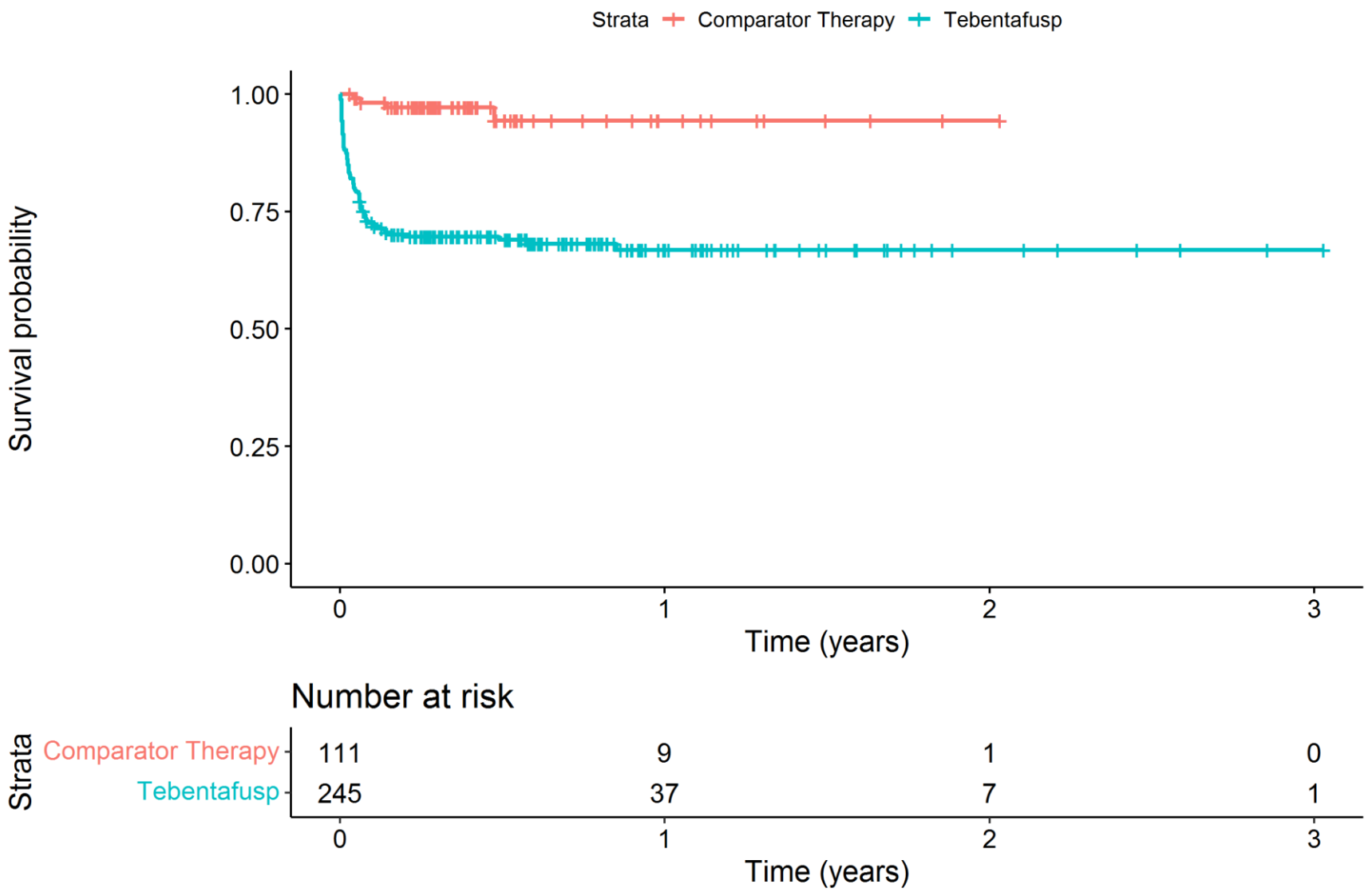
25.31 Pruritus



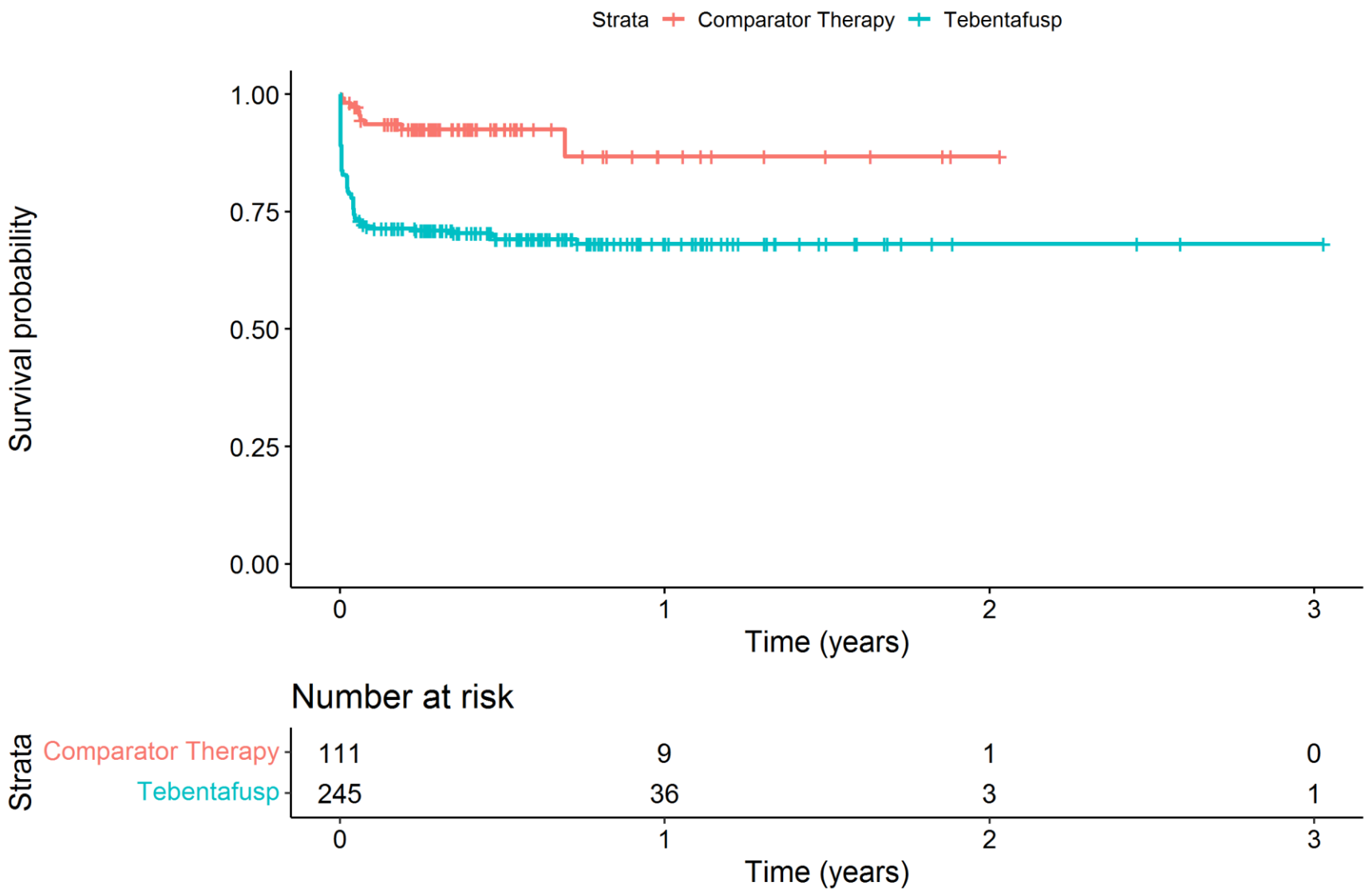
25.32 Hautausschlag



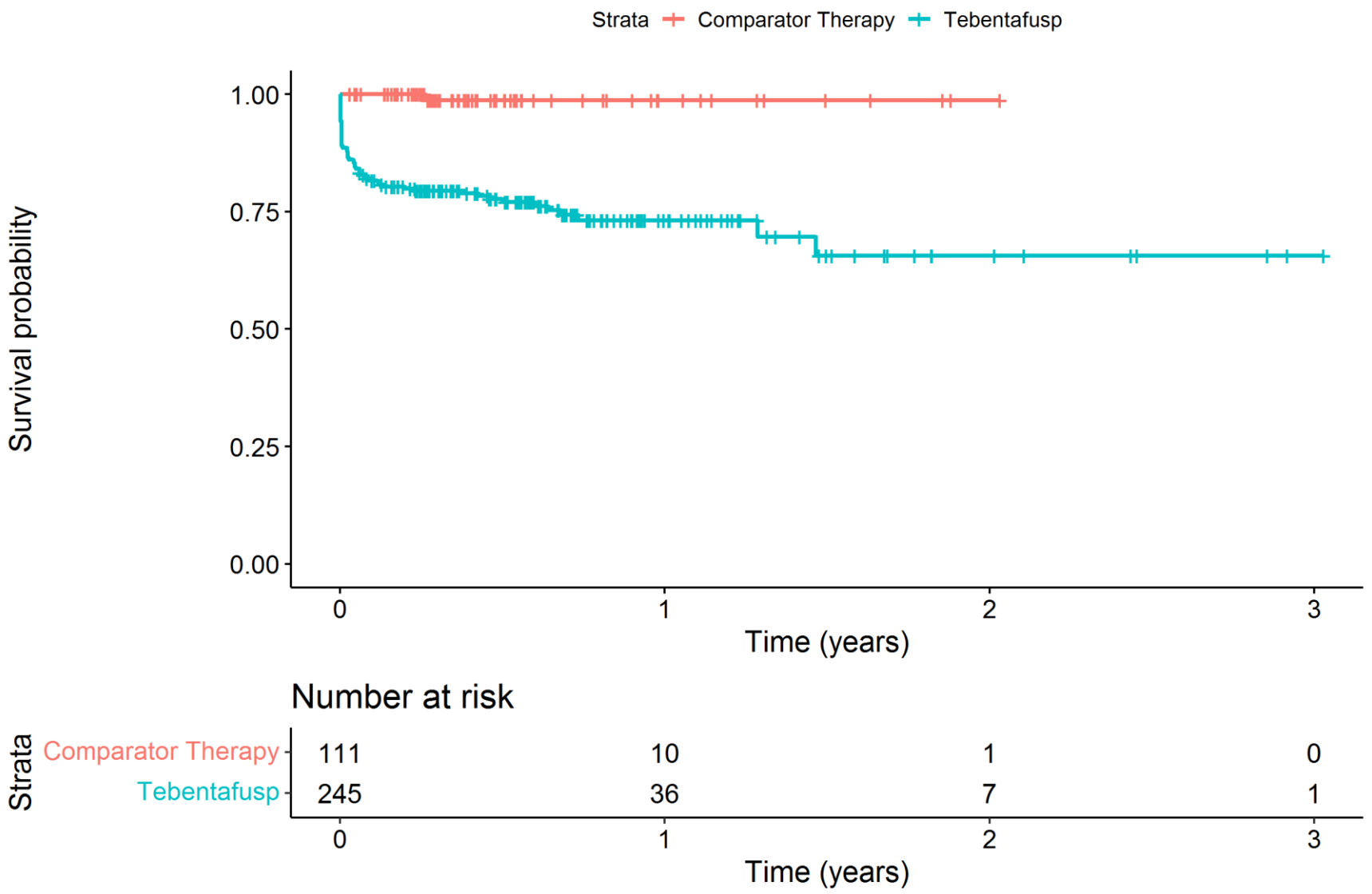
25.33 Trockene Haut



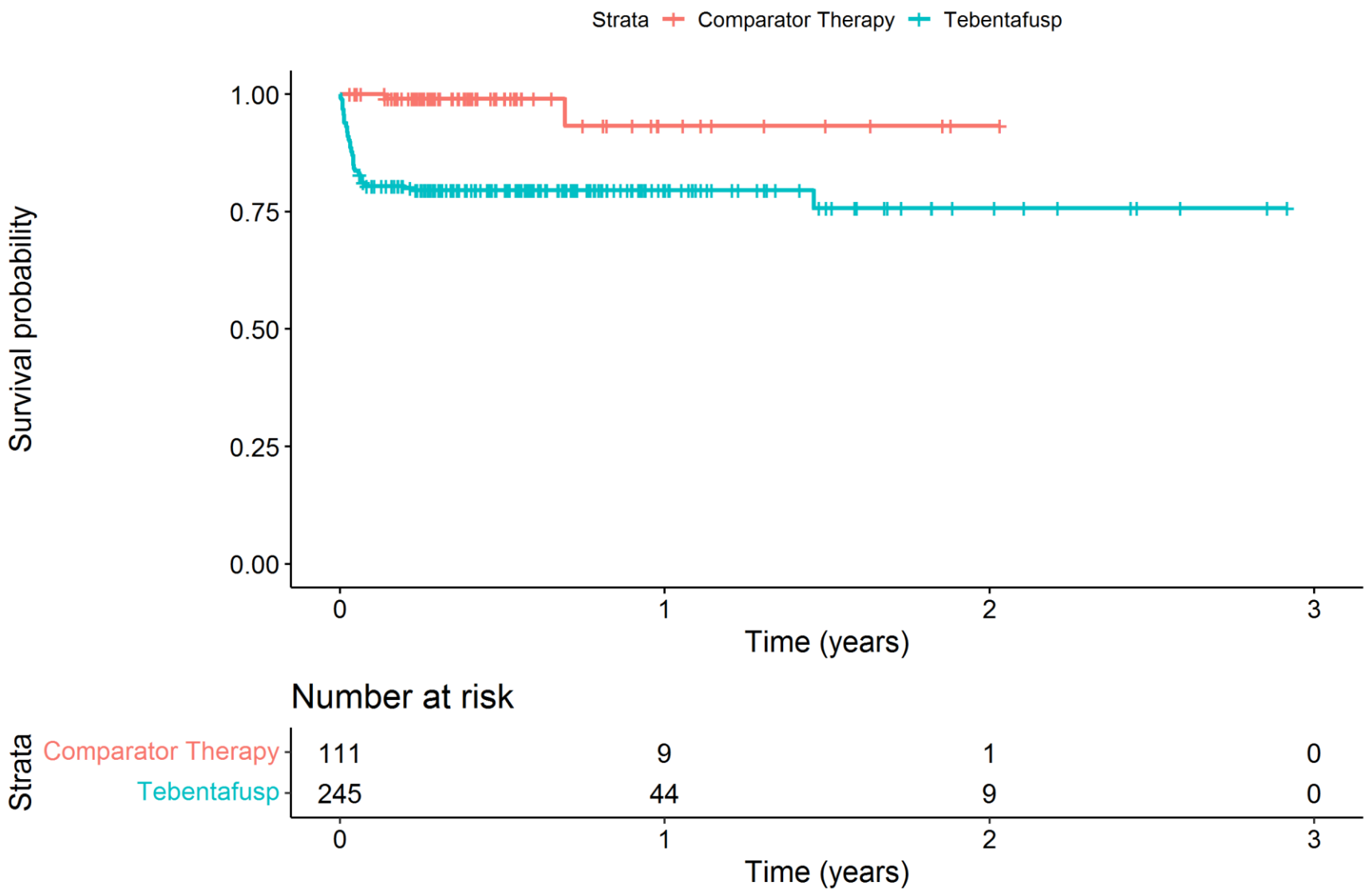
25.34 Makulo-papulöser Hautausschlag



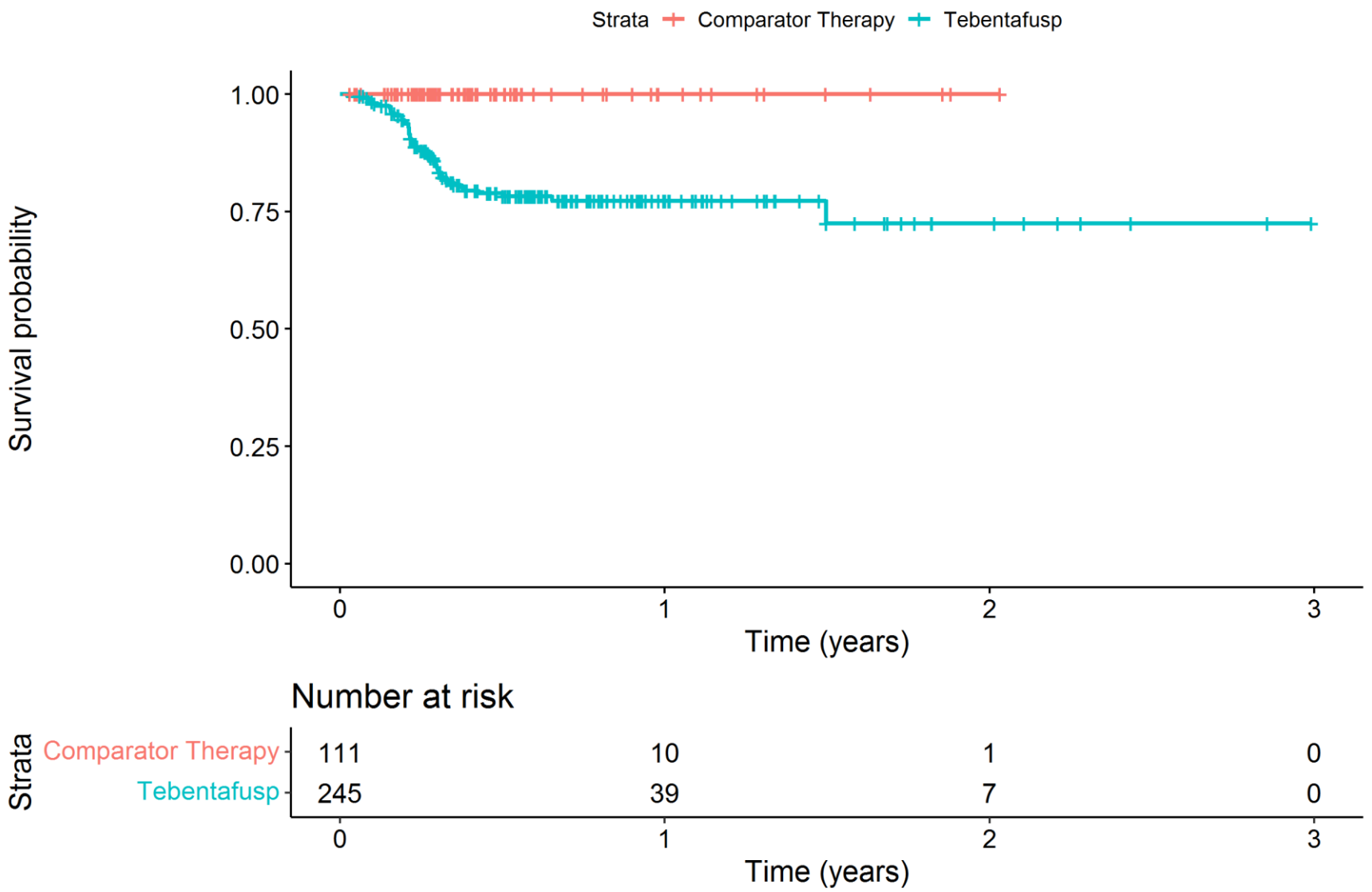
25.35 Erythem



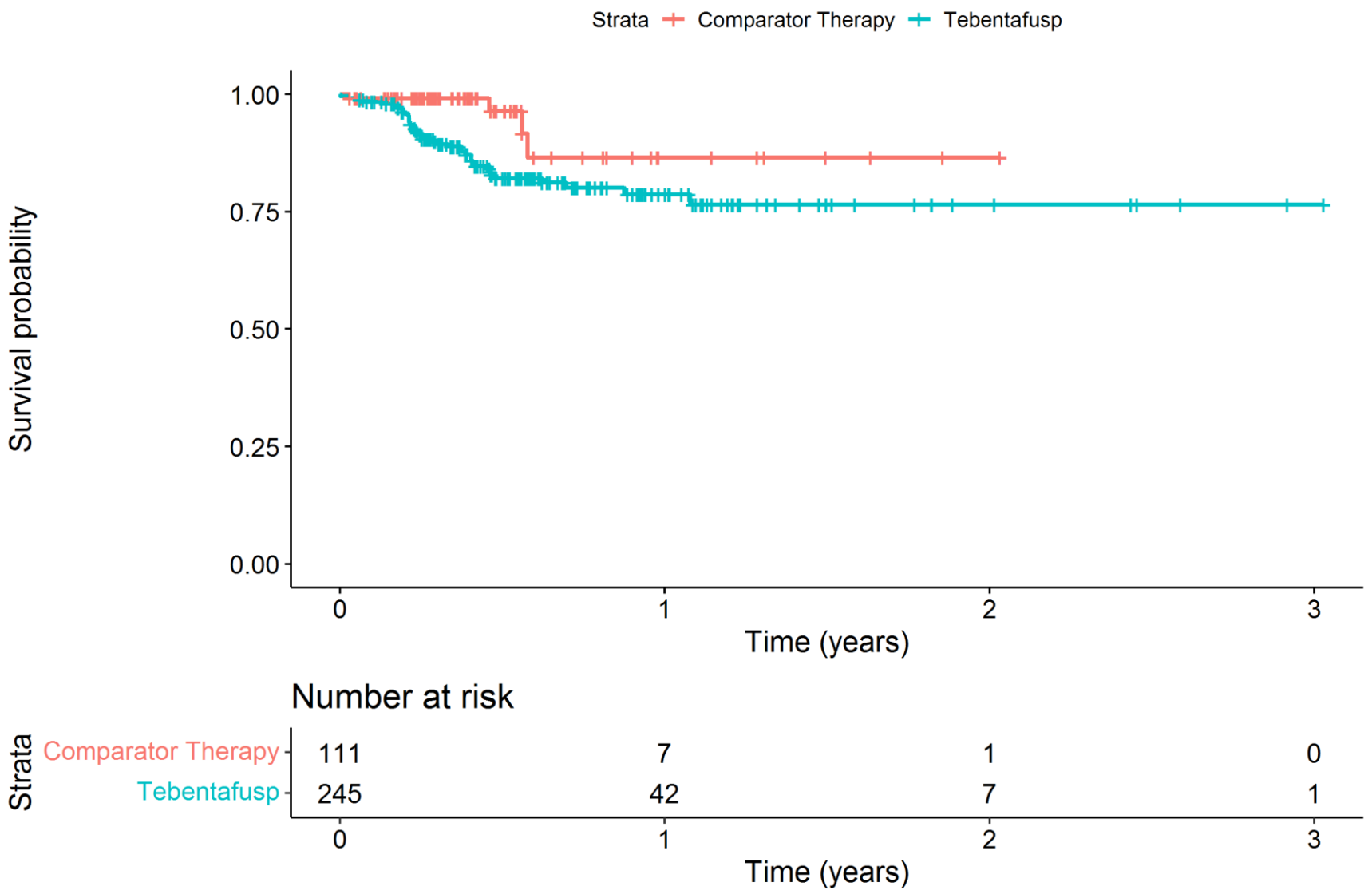
25.36 Hautabschälung



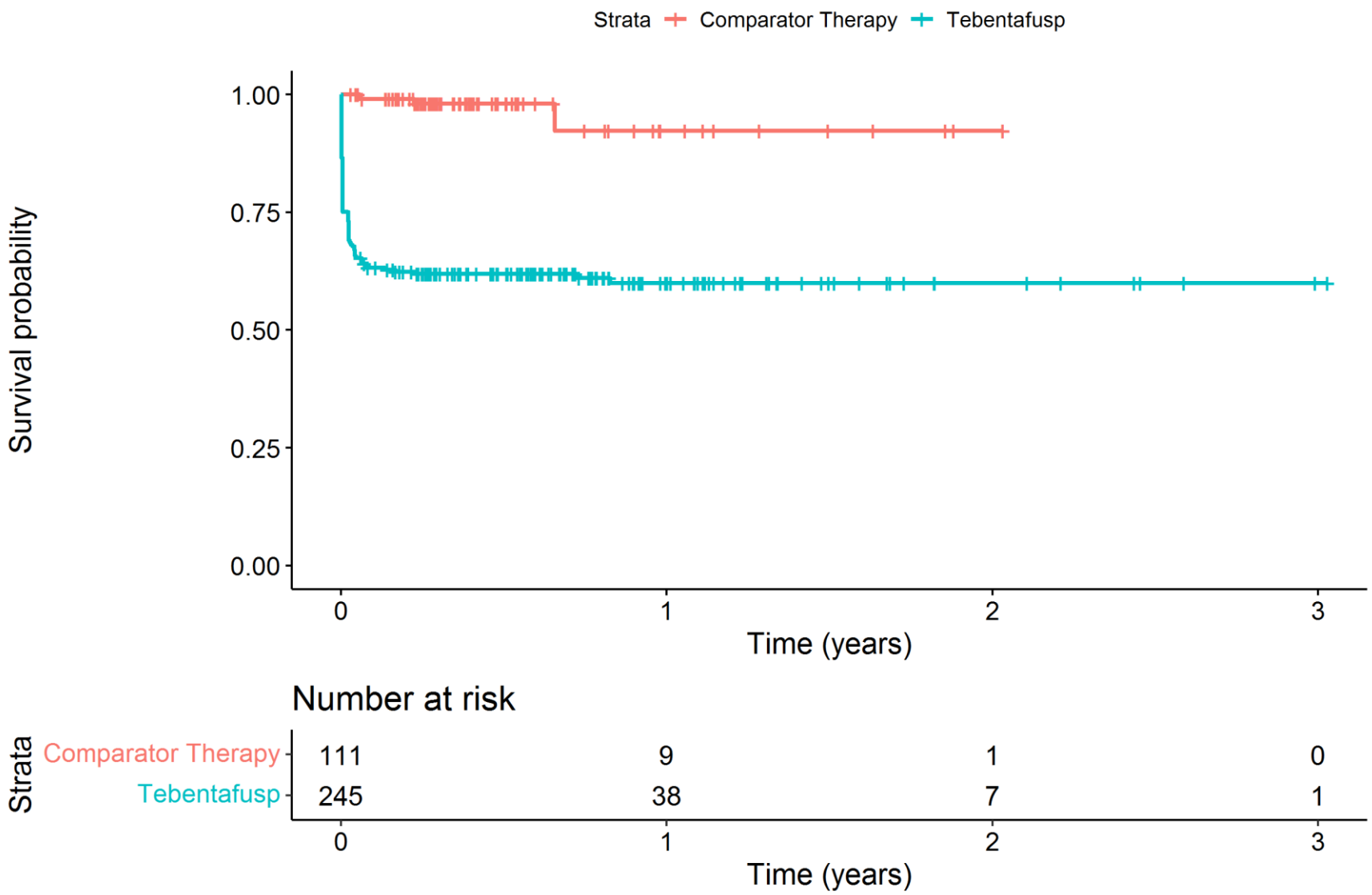
25.37 Veränderung der Haarfarbe



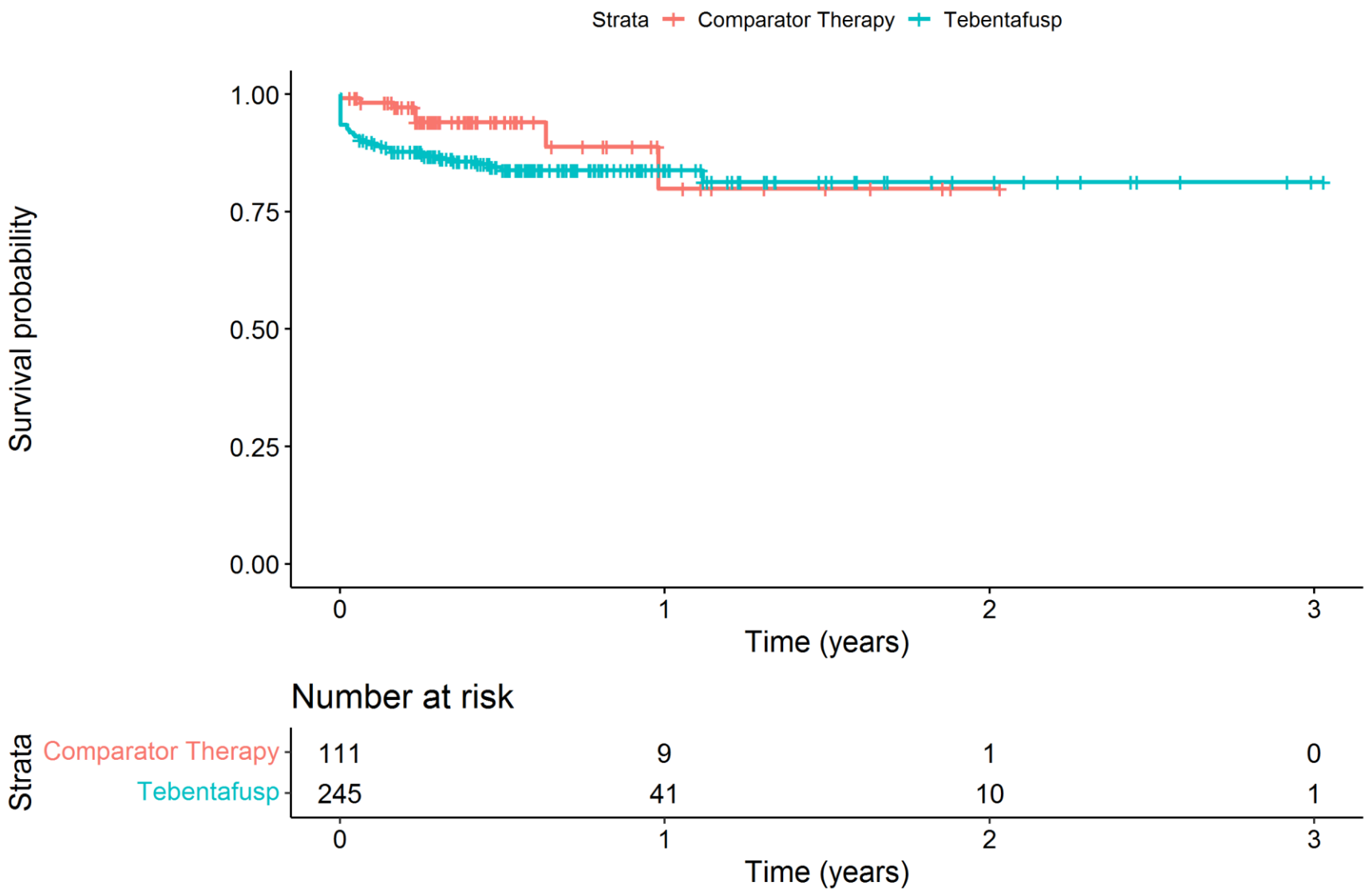
25.38 Vitiligo



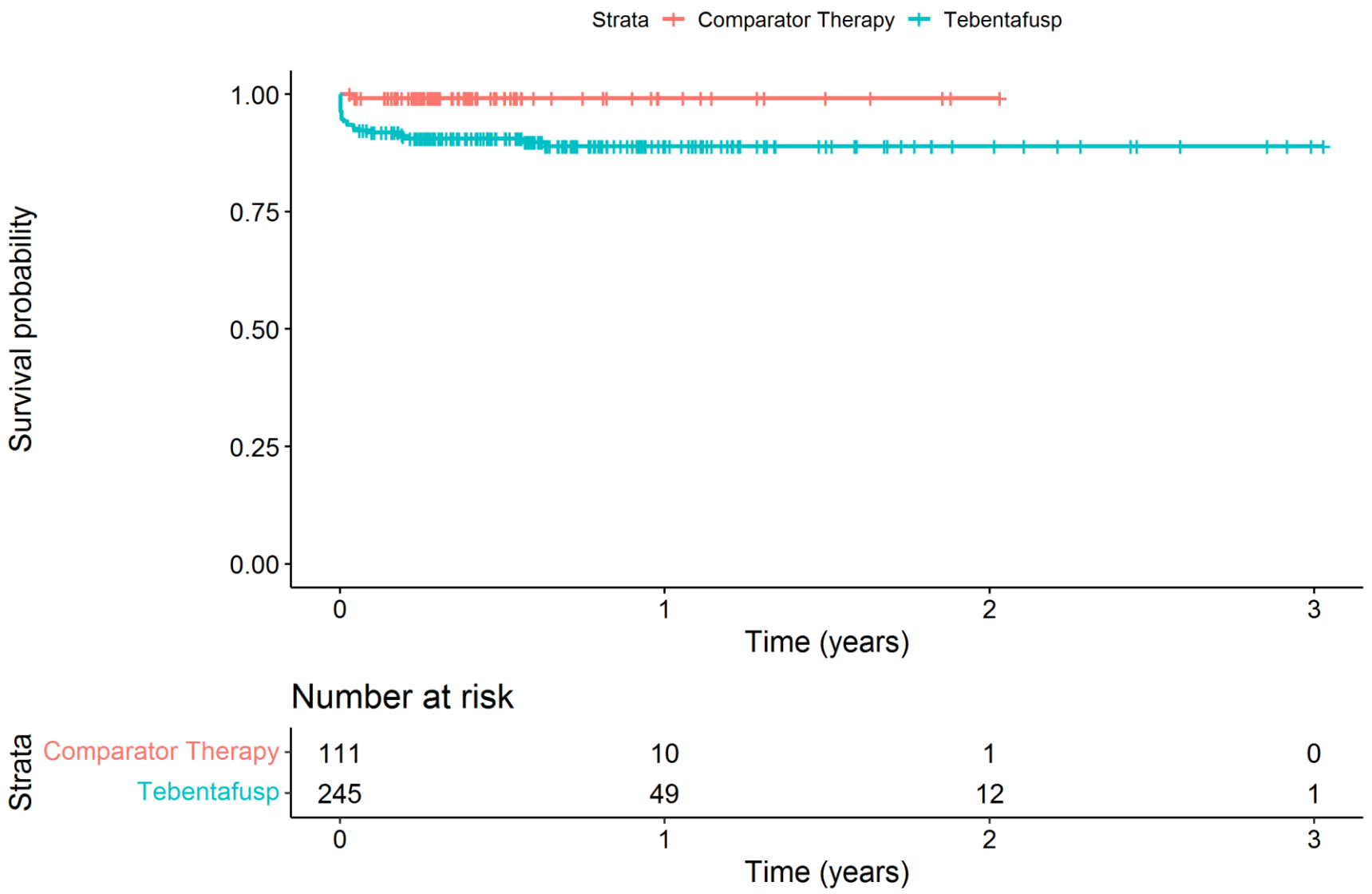
25.39 Hypotonie



25.40 Hypertonie

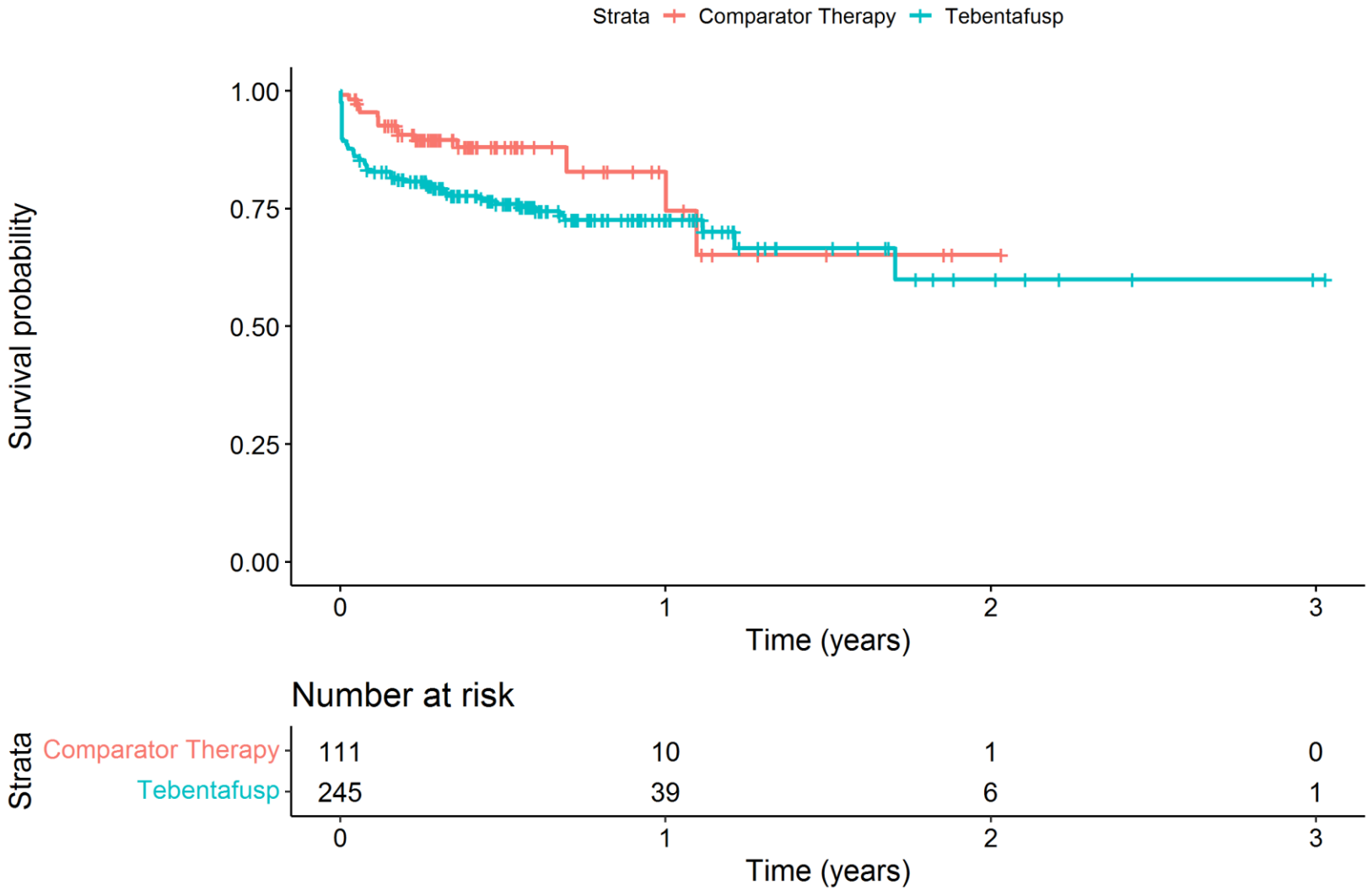


25.41 Hautrötung

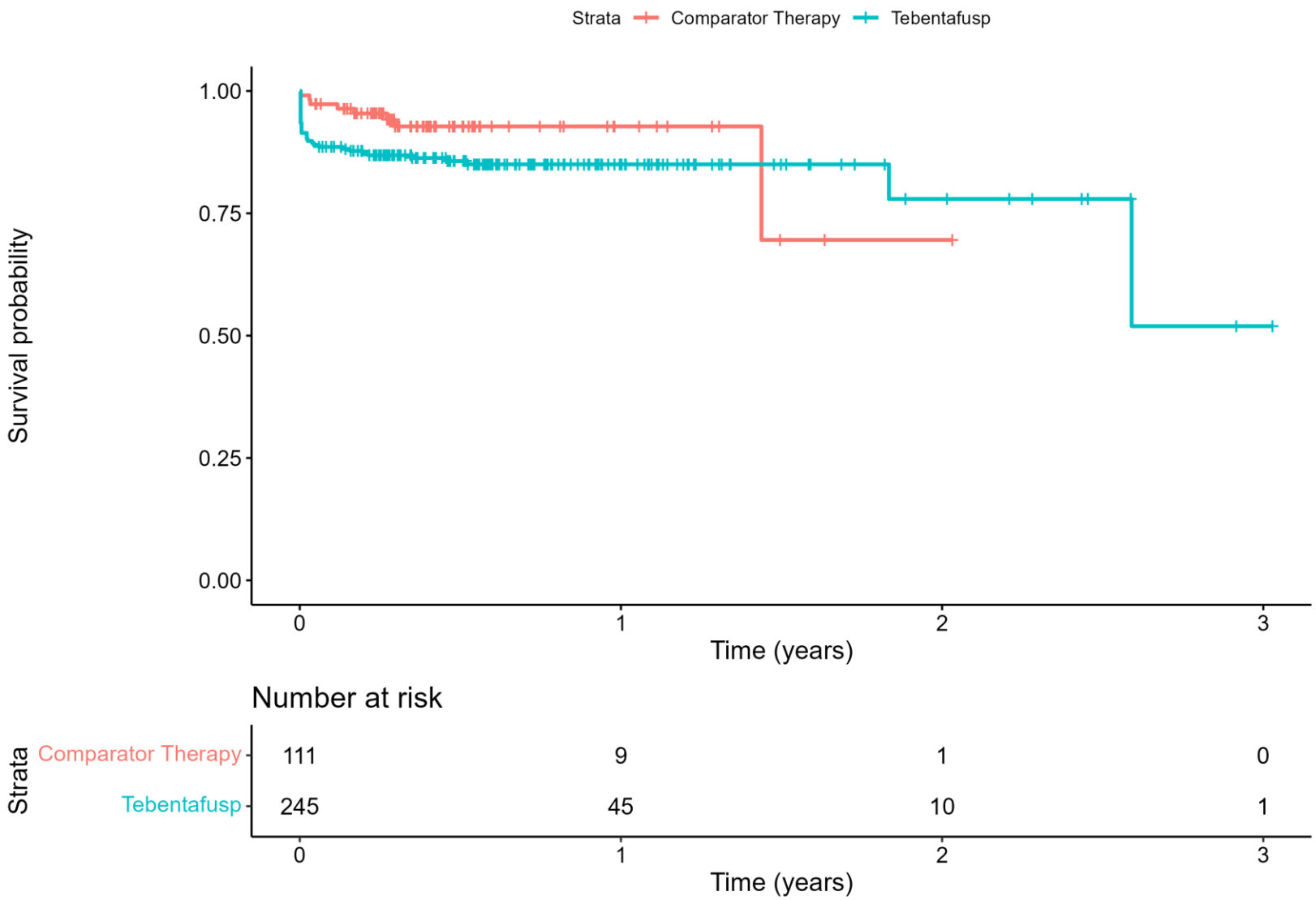


26 UEs (SOC), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten

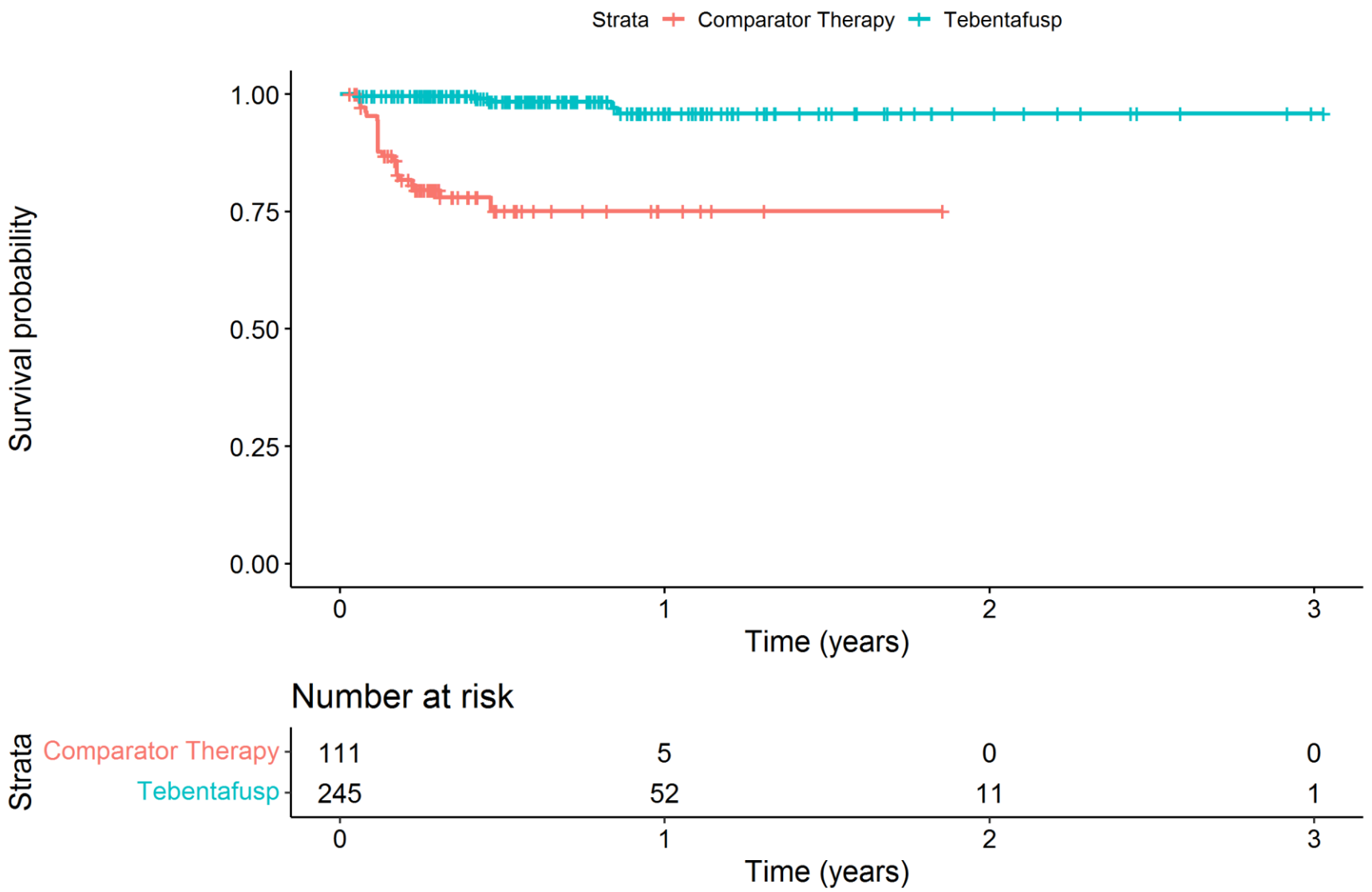
26.1 Erkrankungen des Blutes und des Lymphsystems


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
39
6
1
0
1
2
3
Time (years)

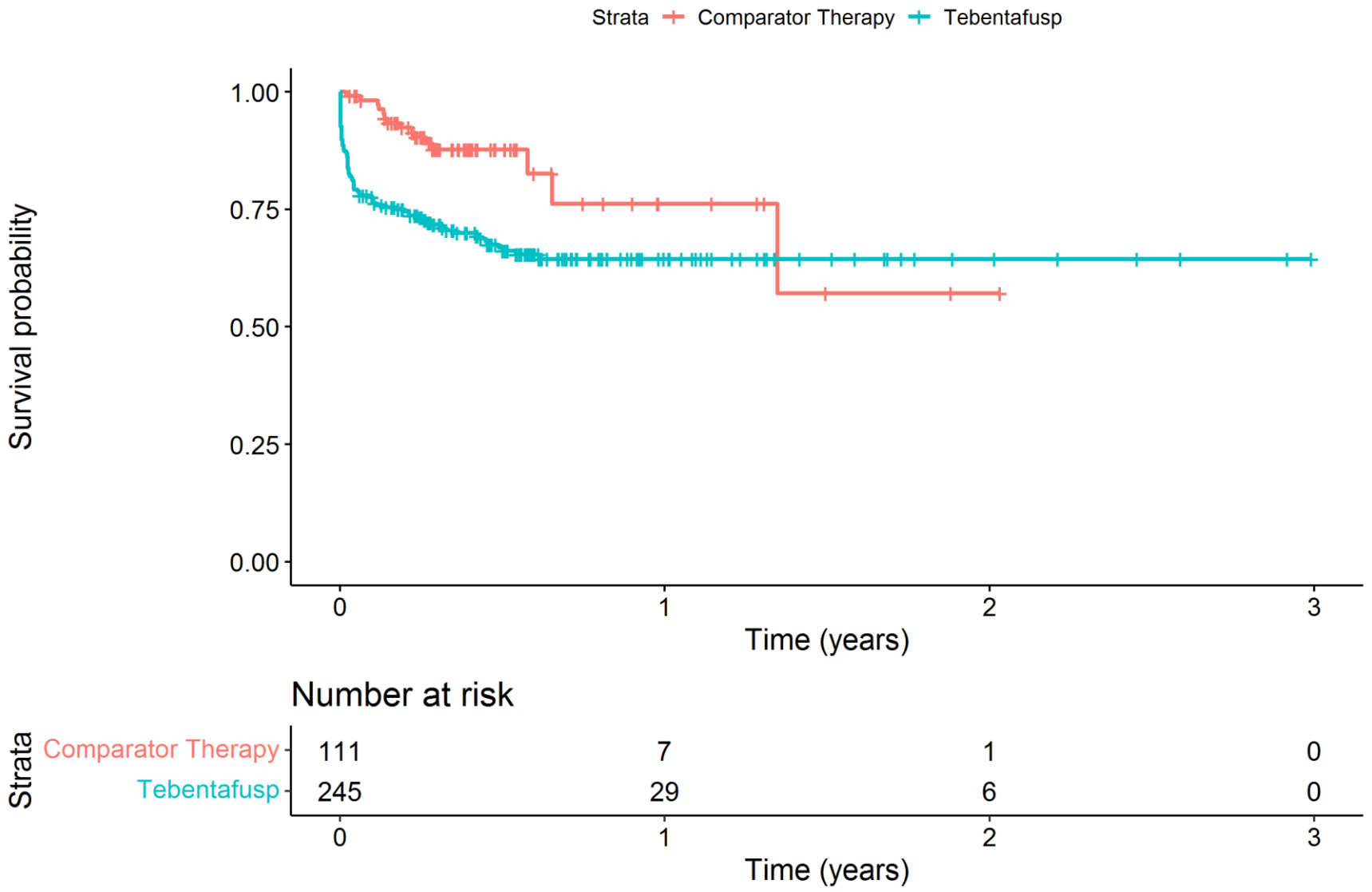
26.2 Herzerkrankungen



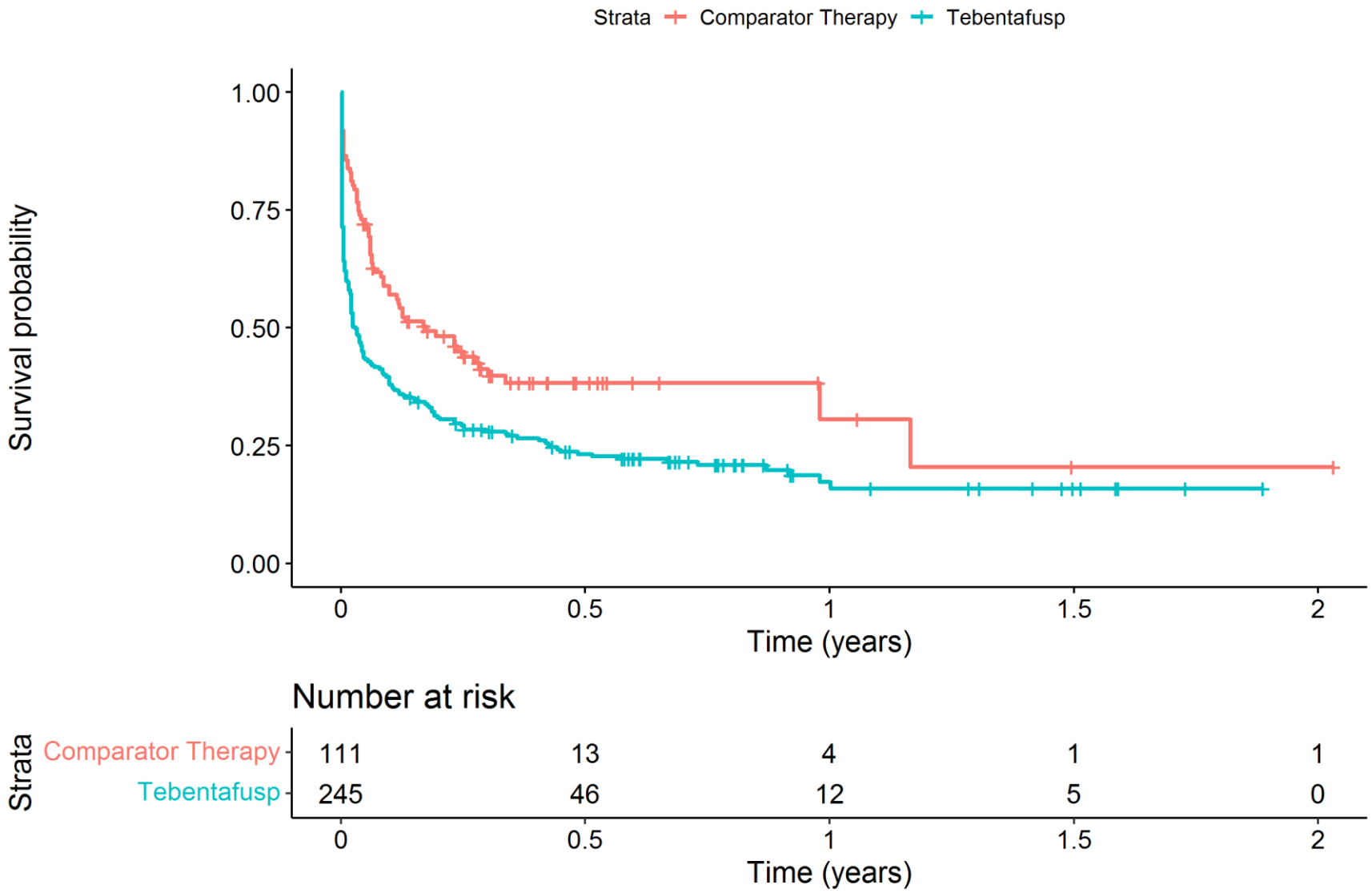
26.3 Endokrine Erkrankungen



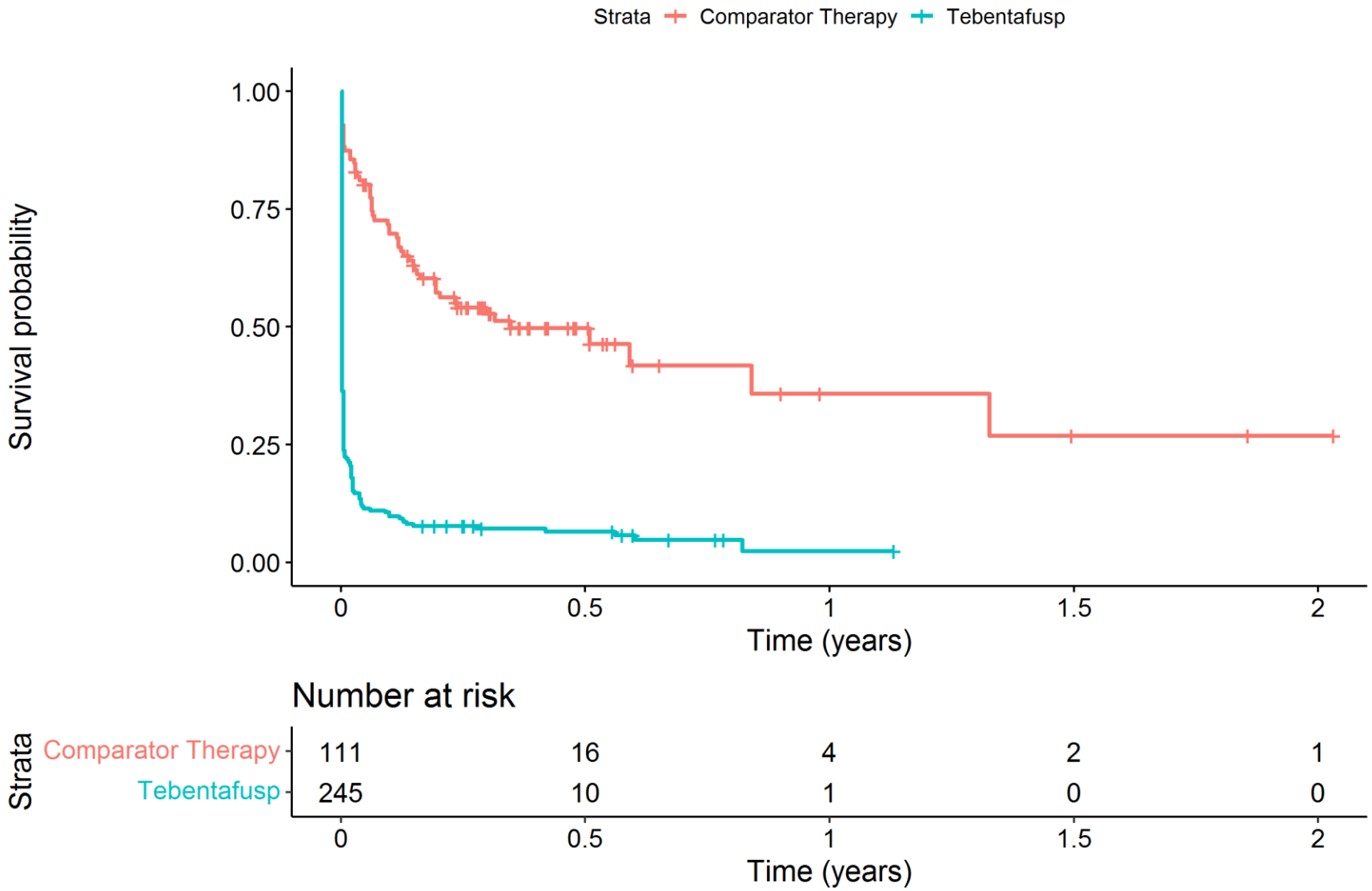
26.4 Augenerkrankungen



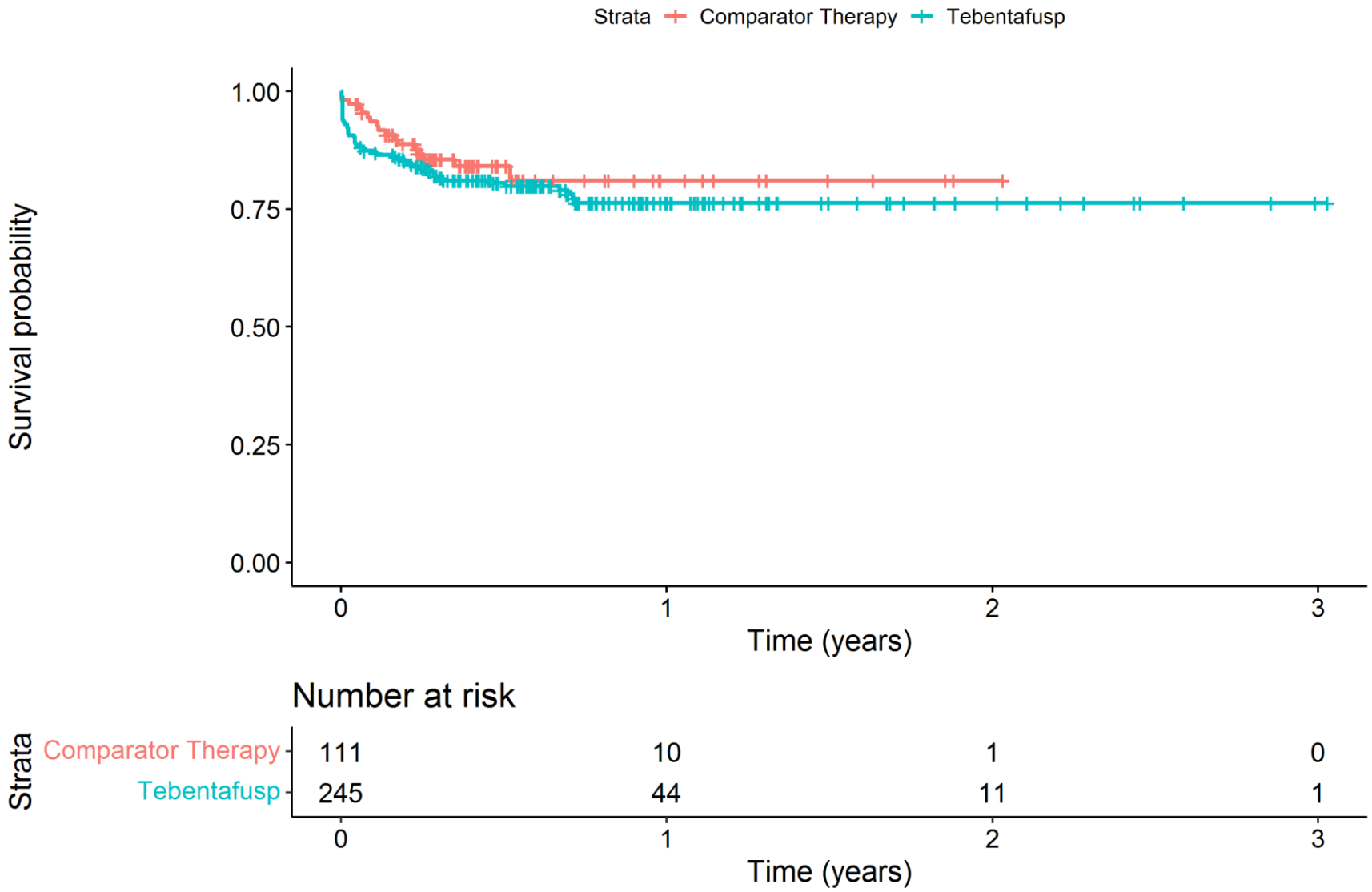
26.5 Erkrankungen des Gastrointestinaltrakts



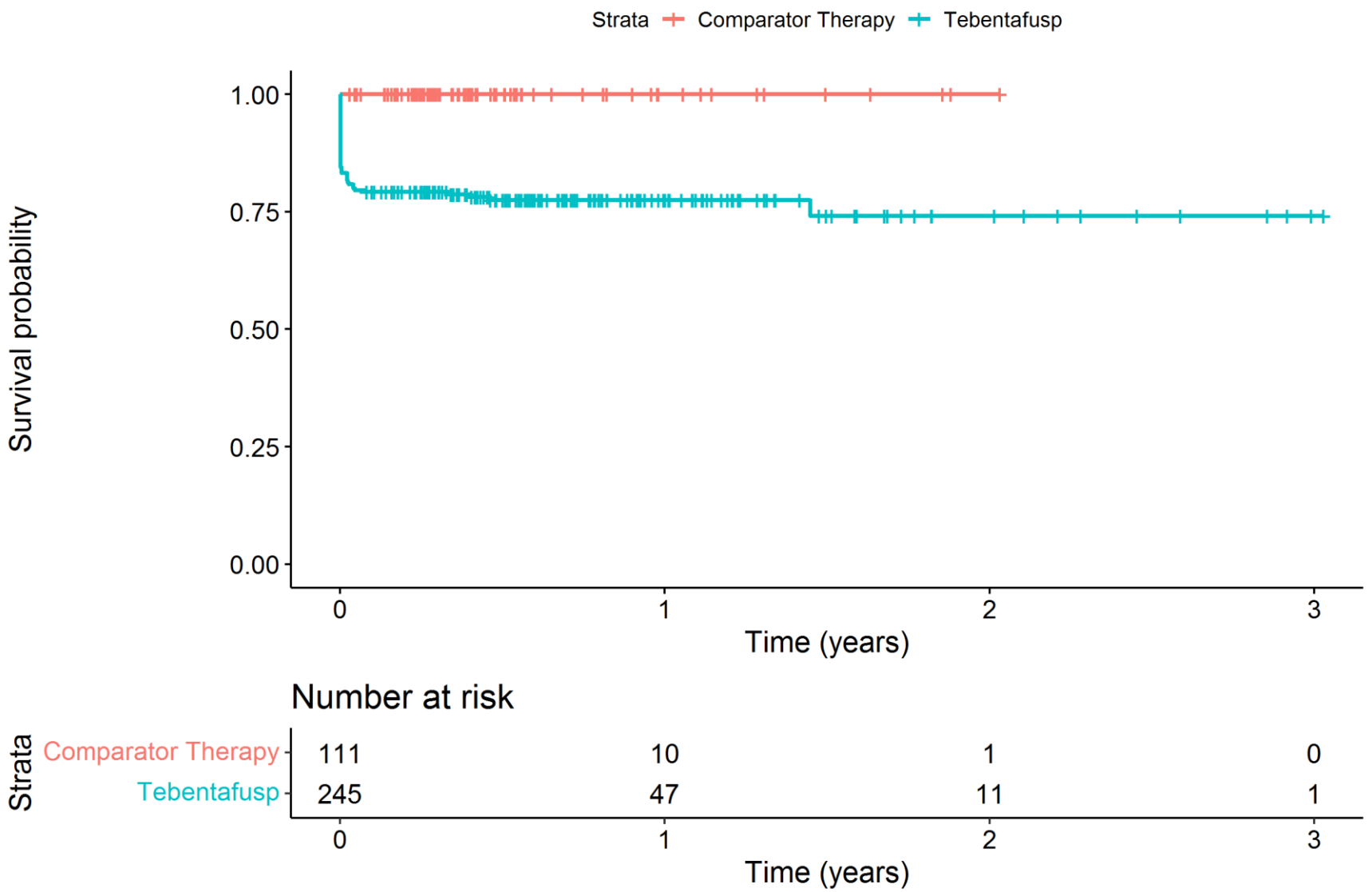
26.6 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



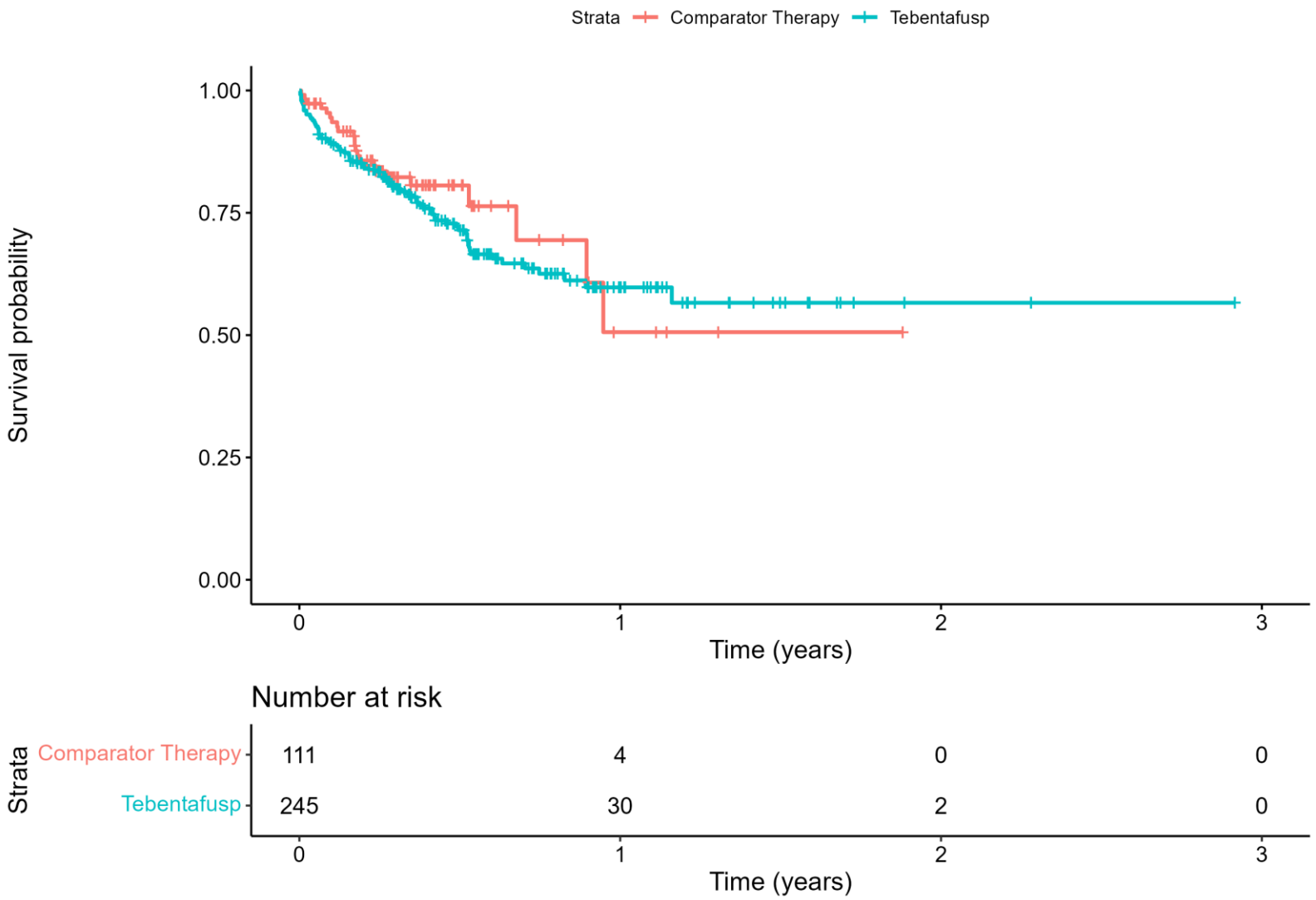
26.7 Leber- und Gallenerkrankungen



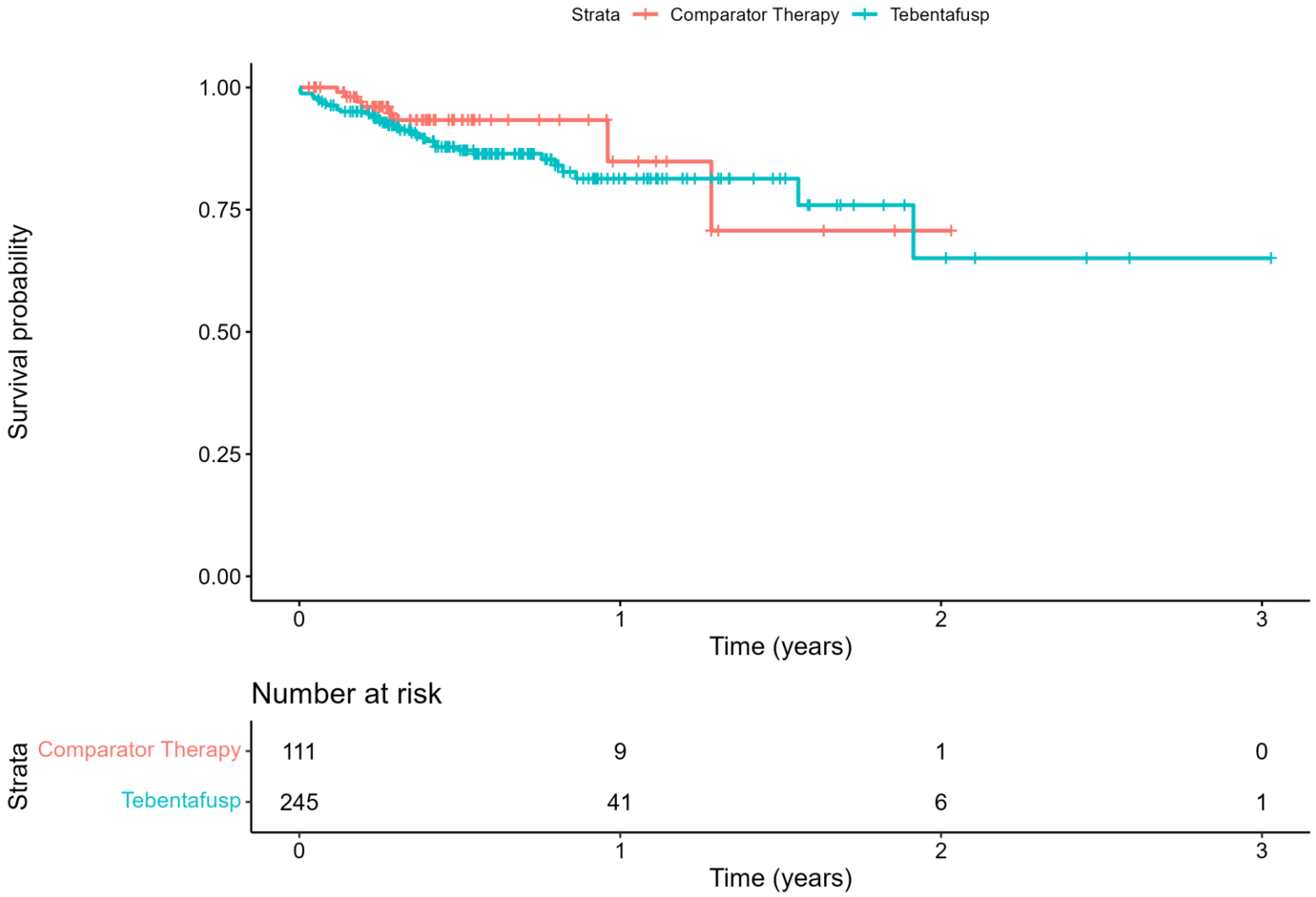
26.8 Erkrankungen des Immunsystems



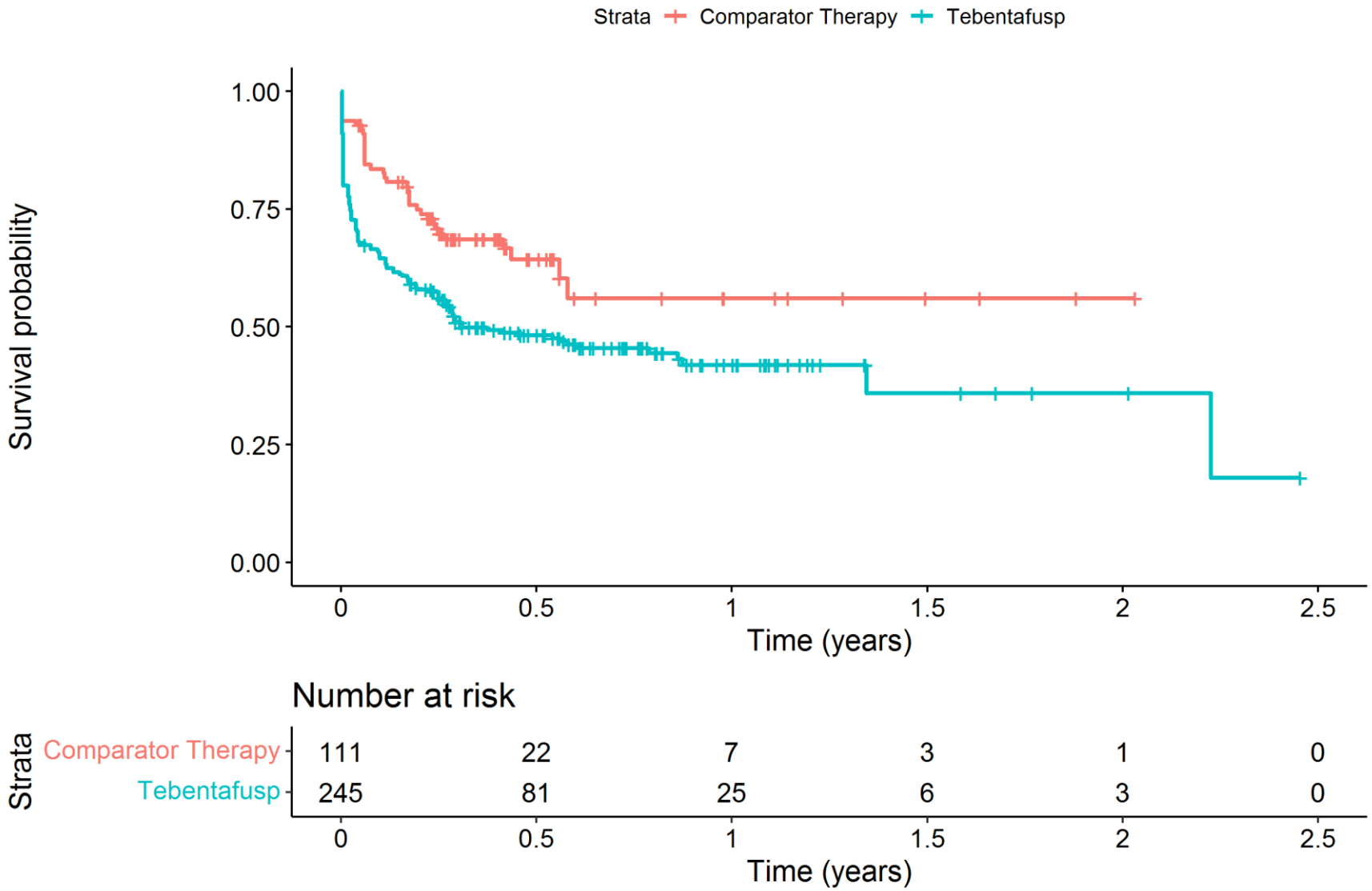
26.9 Infektionen und parasitäre Erkrankungen



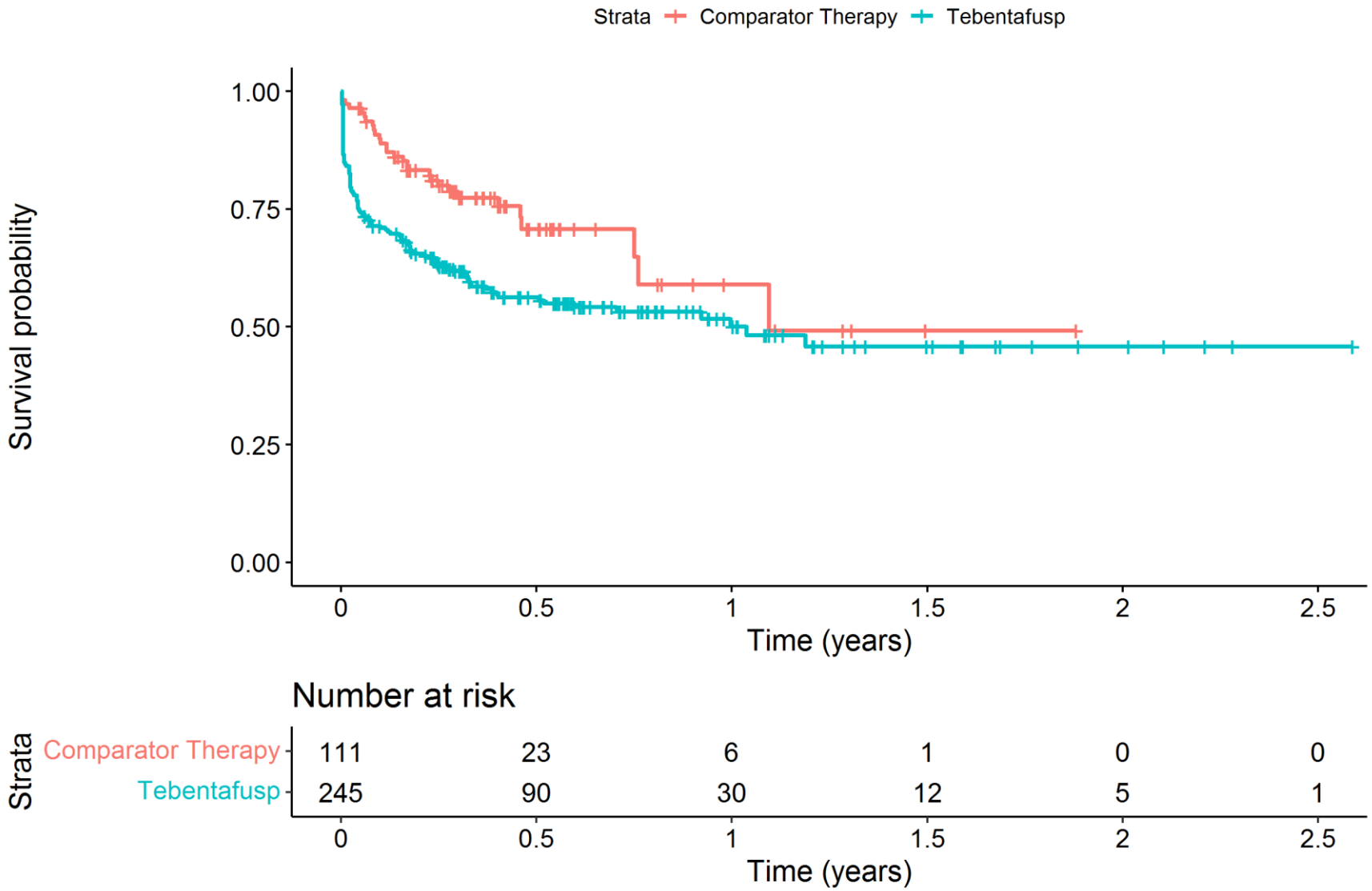
26.10 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



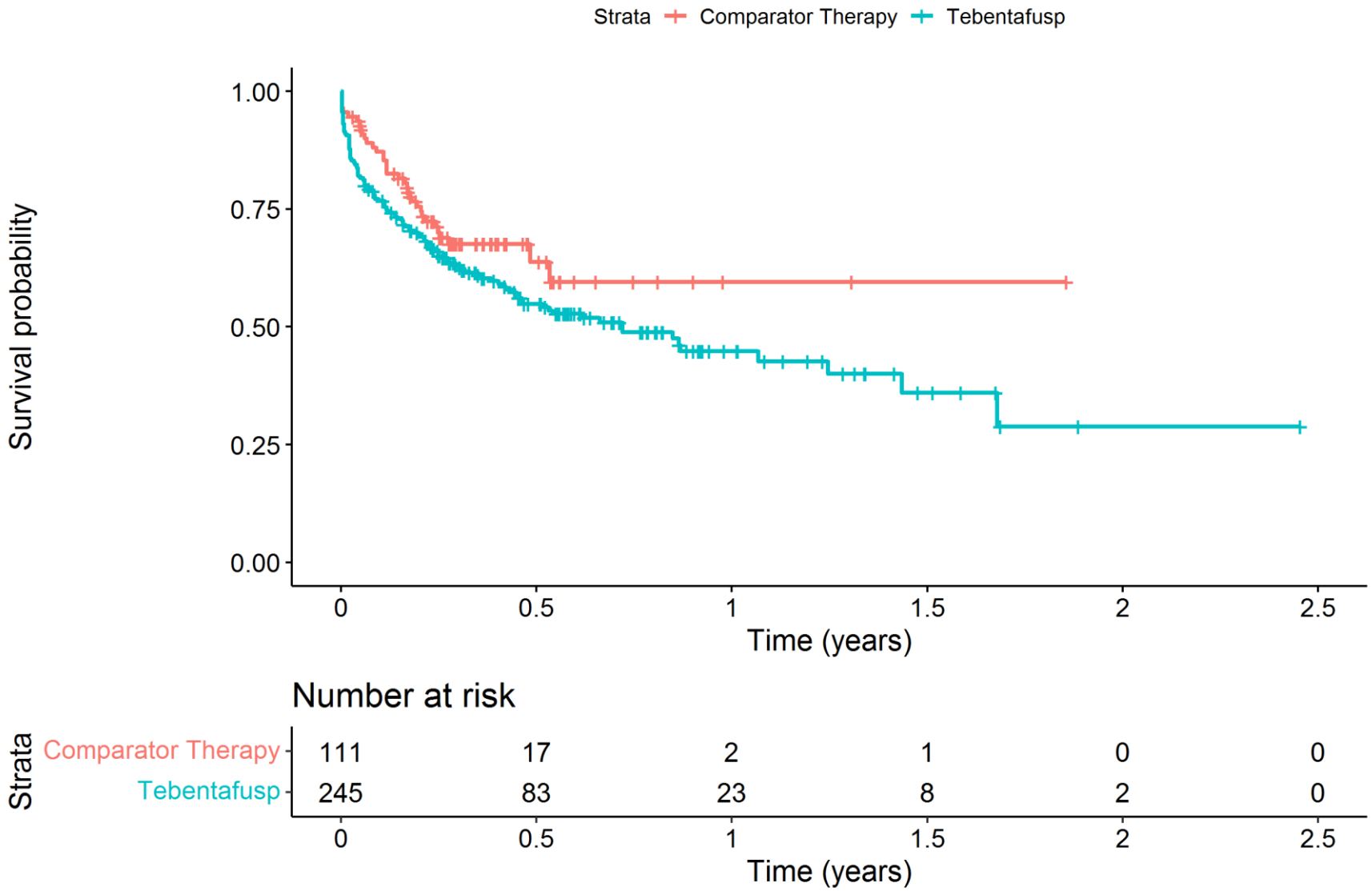
26.11 Untersuchungen



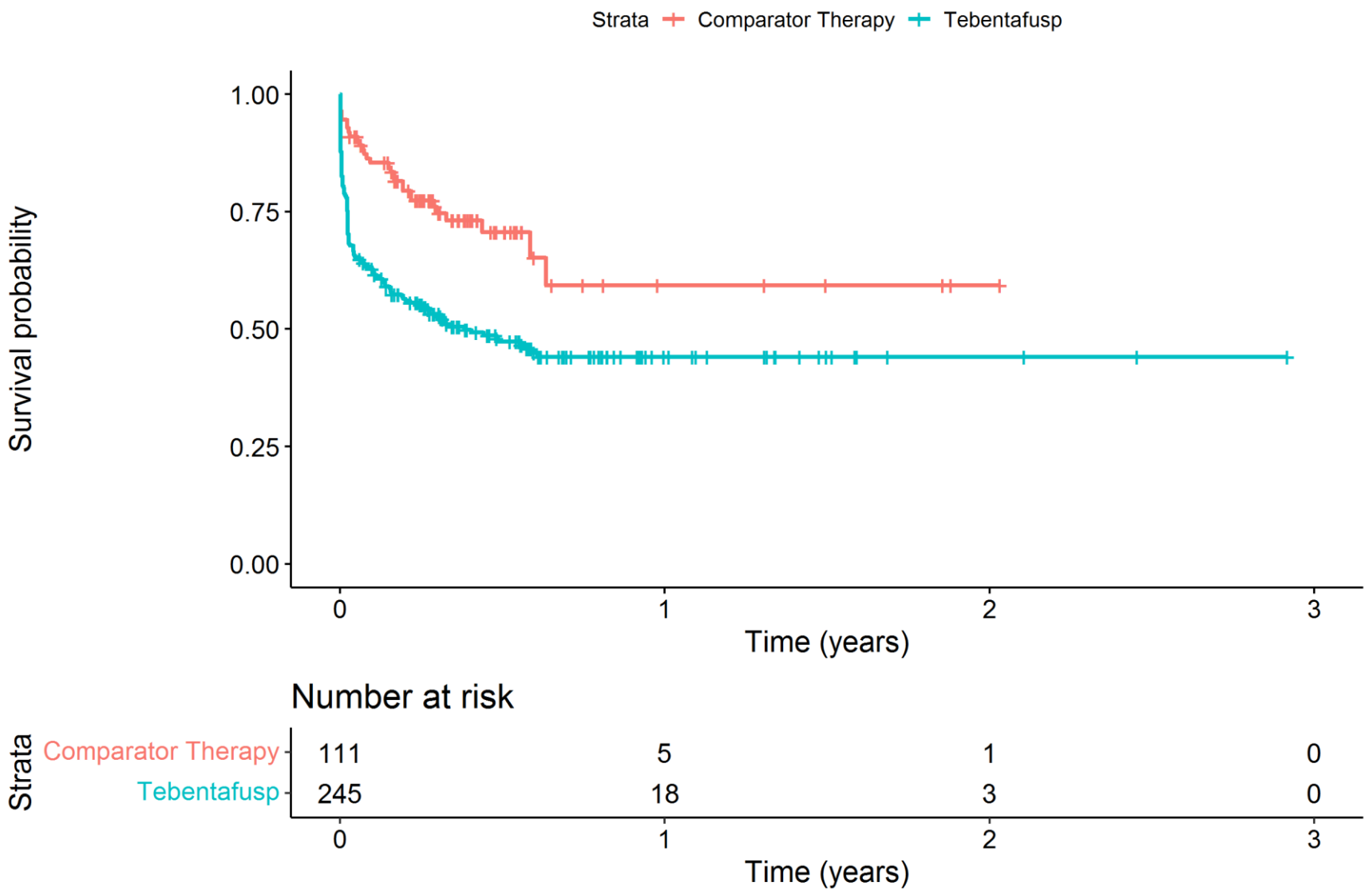
26.12 Stoffwechsel- und Ernährungsstörungen



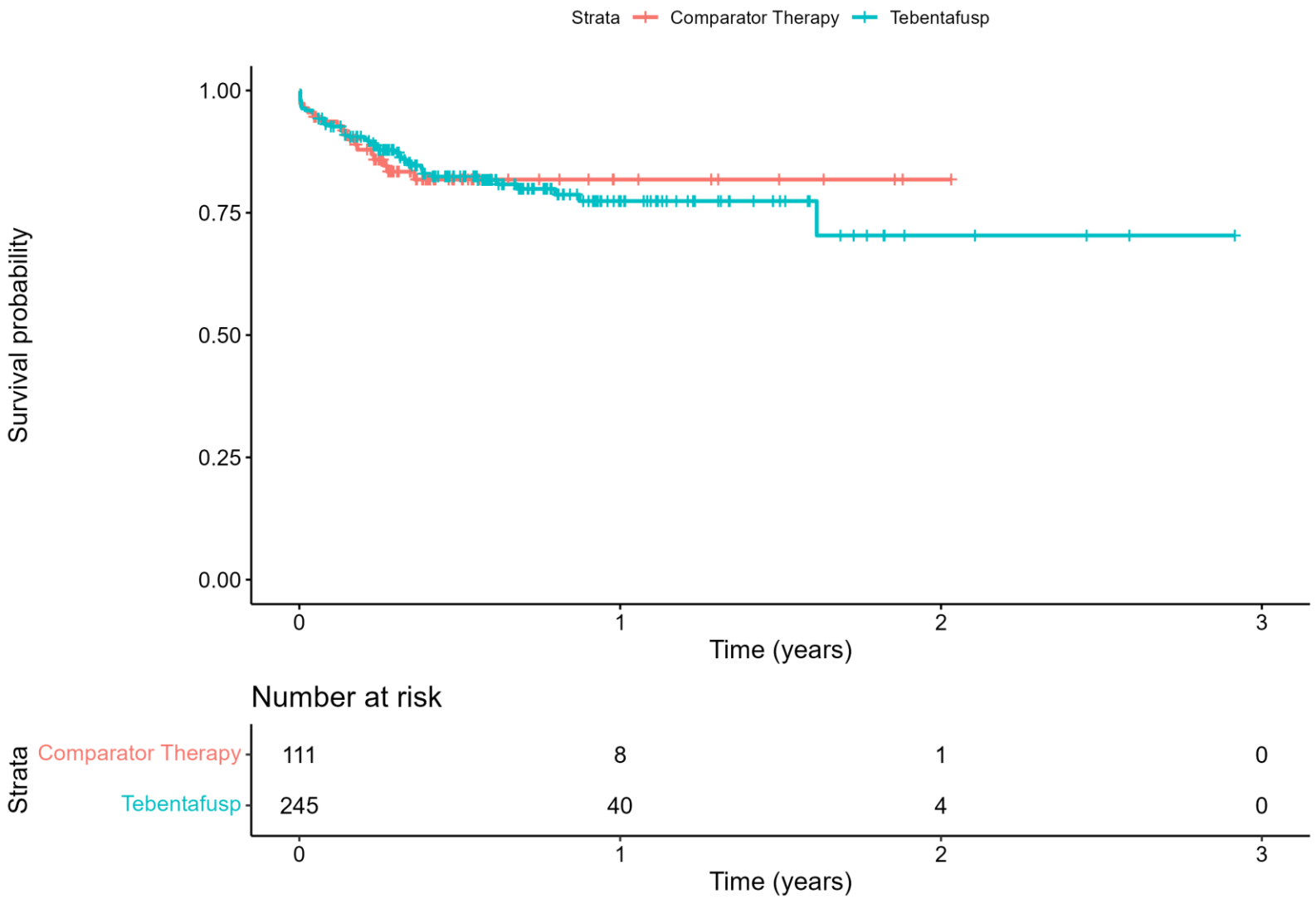
26.13 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



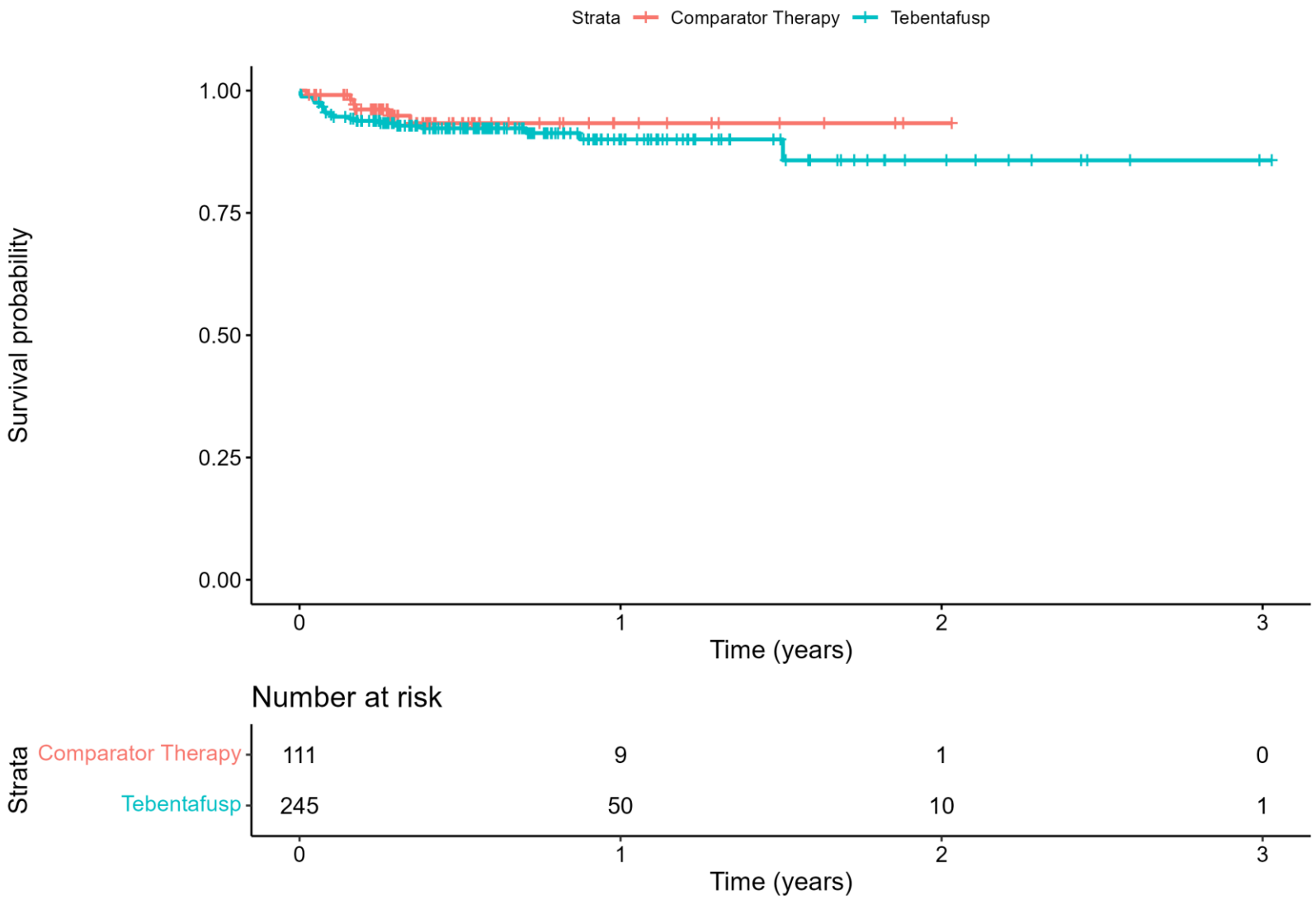
26.14 Erkrankungen des Nervensystems



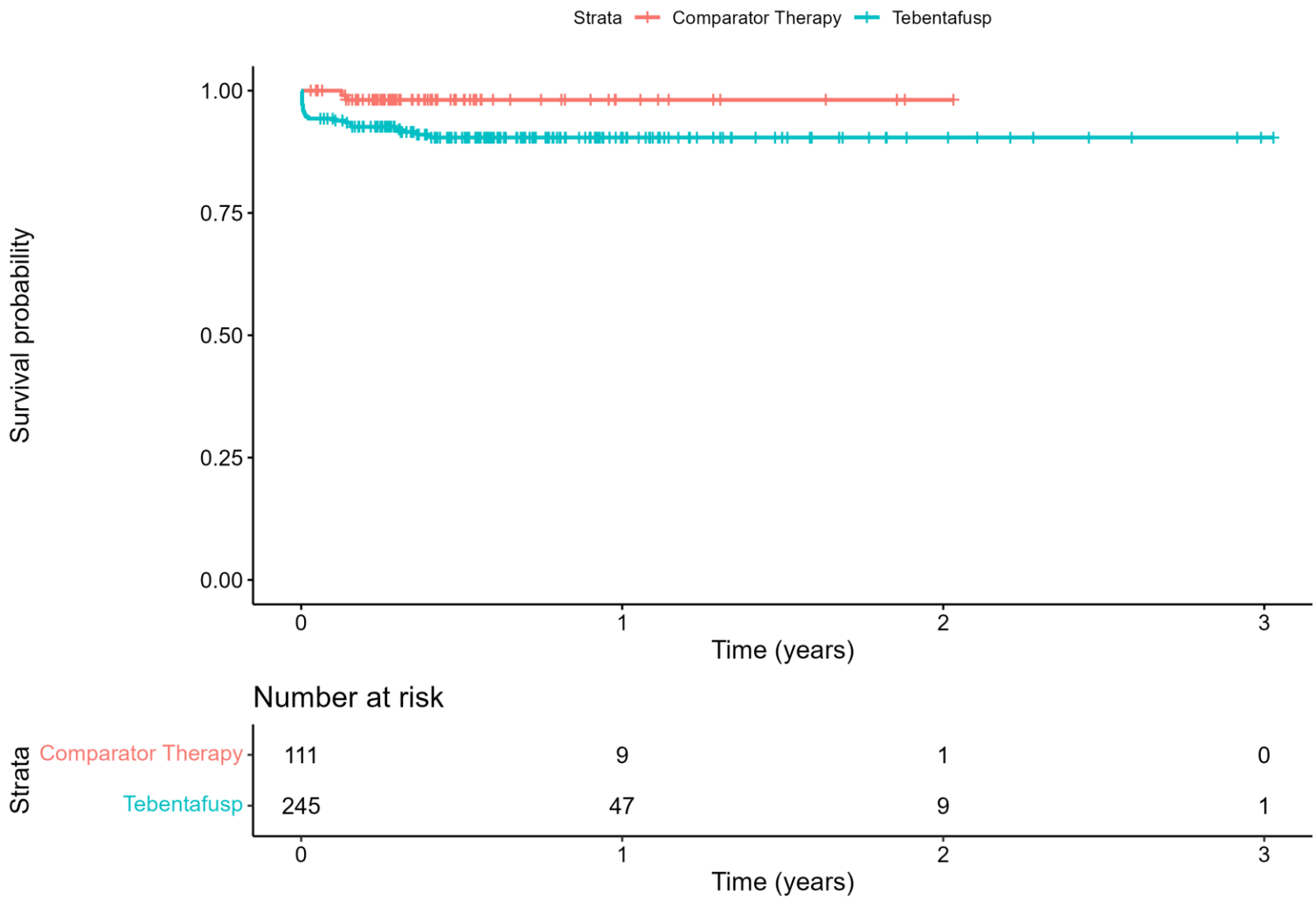
26.15 Psychiatrische Erkrankungen



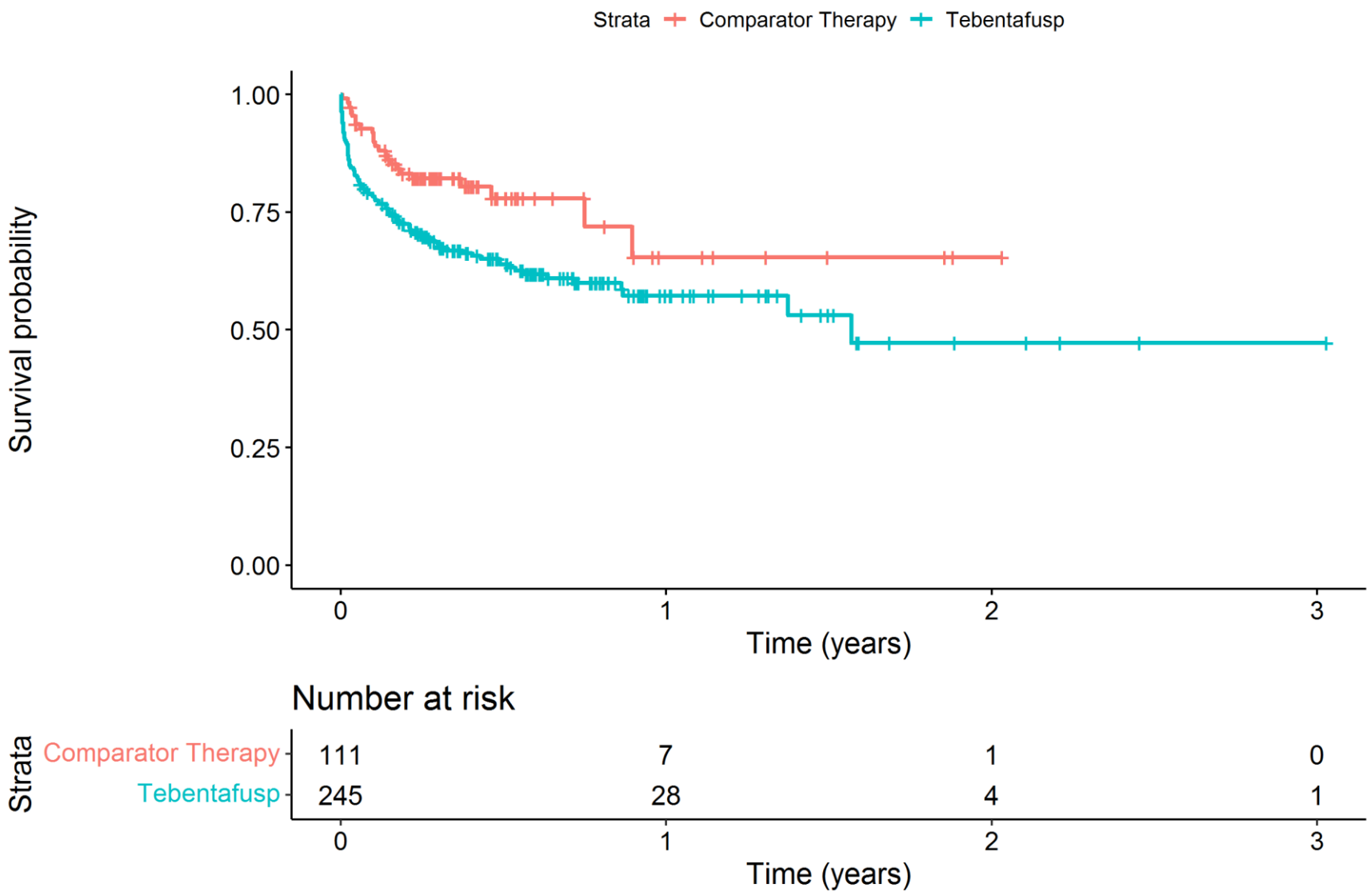
26.16 Erkrankungen der Nieren und Harnwege



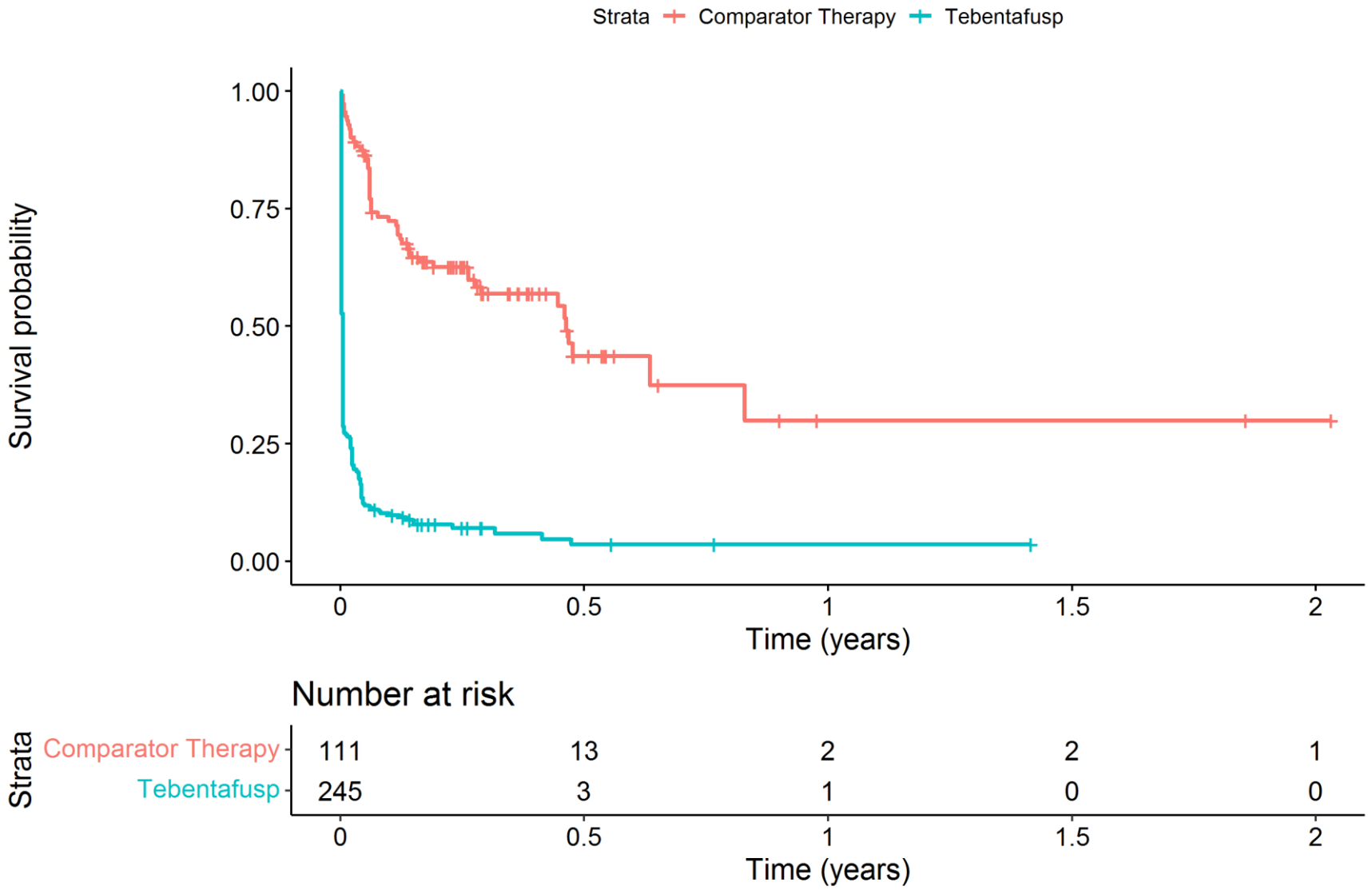
26.17 Erkrankungen der Geschlechtsorgane und der Brustdruese



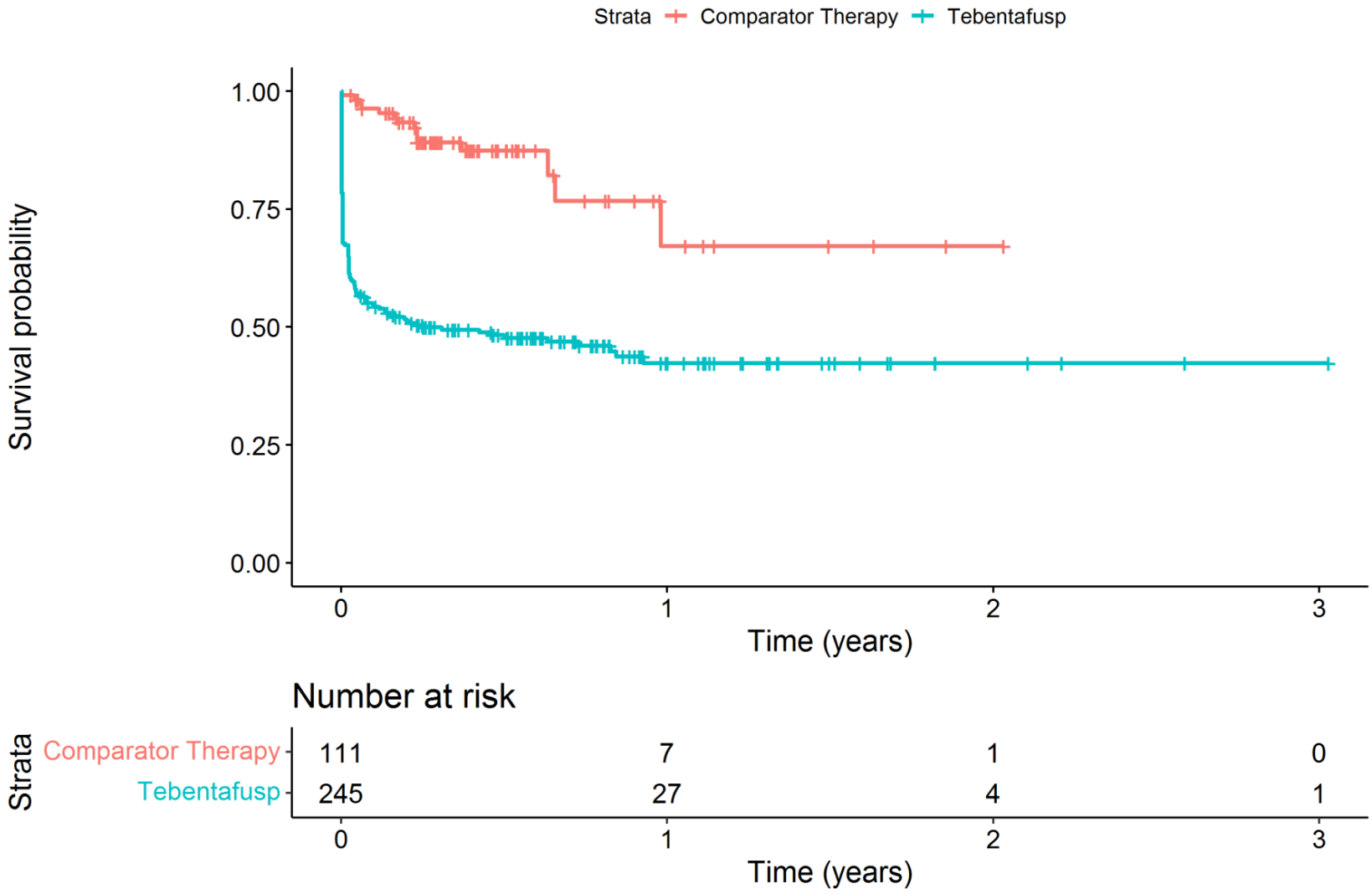
26.18 Erkrankungen der Atemwege, des Brustraums und Mediastinums



26.19 Erkrankungen der Haut und des Unterhautgewebes



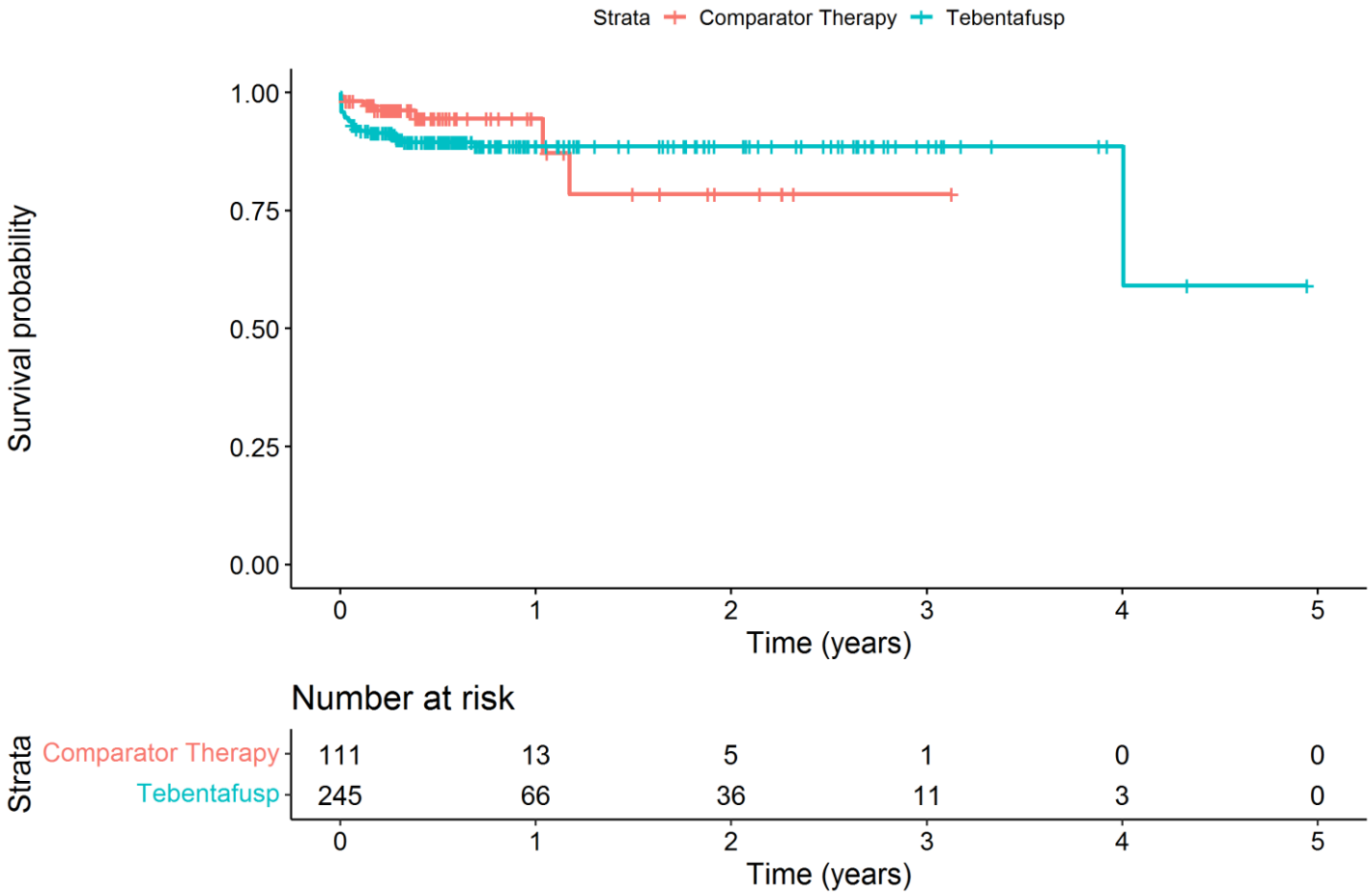
26.20 Gefäßerkrankungen



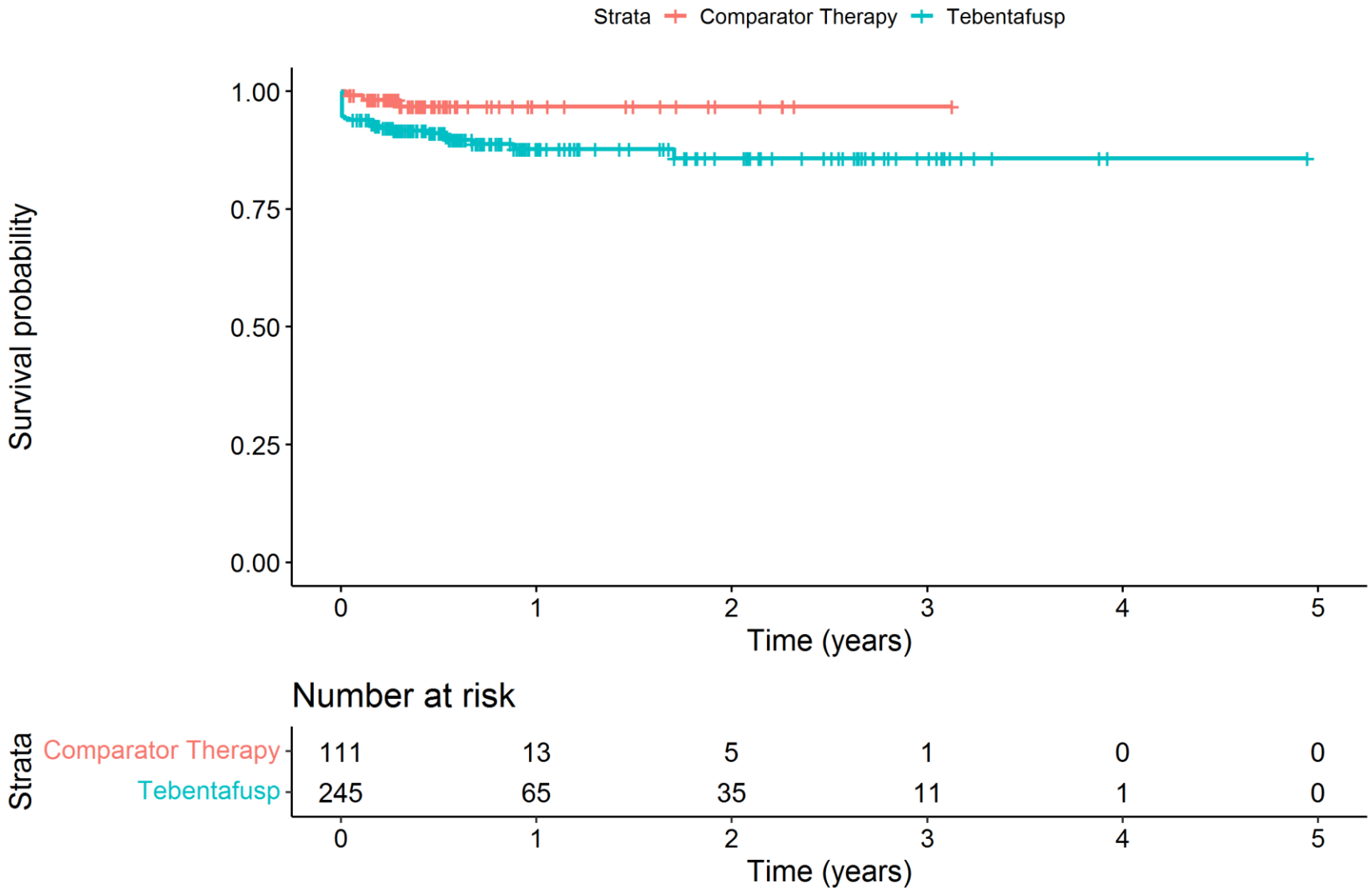
26.21 Alle unerwünschten Ereignisse – 3-Jahres-Analyse (Juni 2023) (Tabelle 4-54)

27 UEs (PT), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten

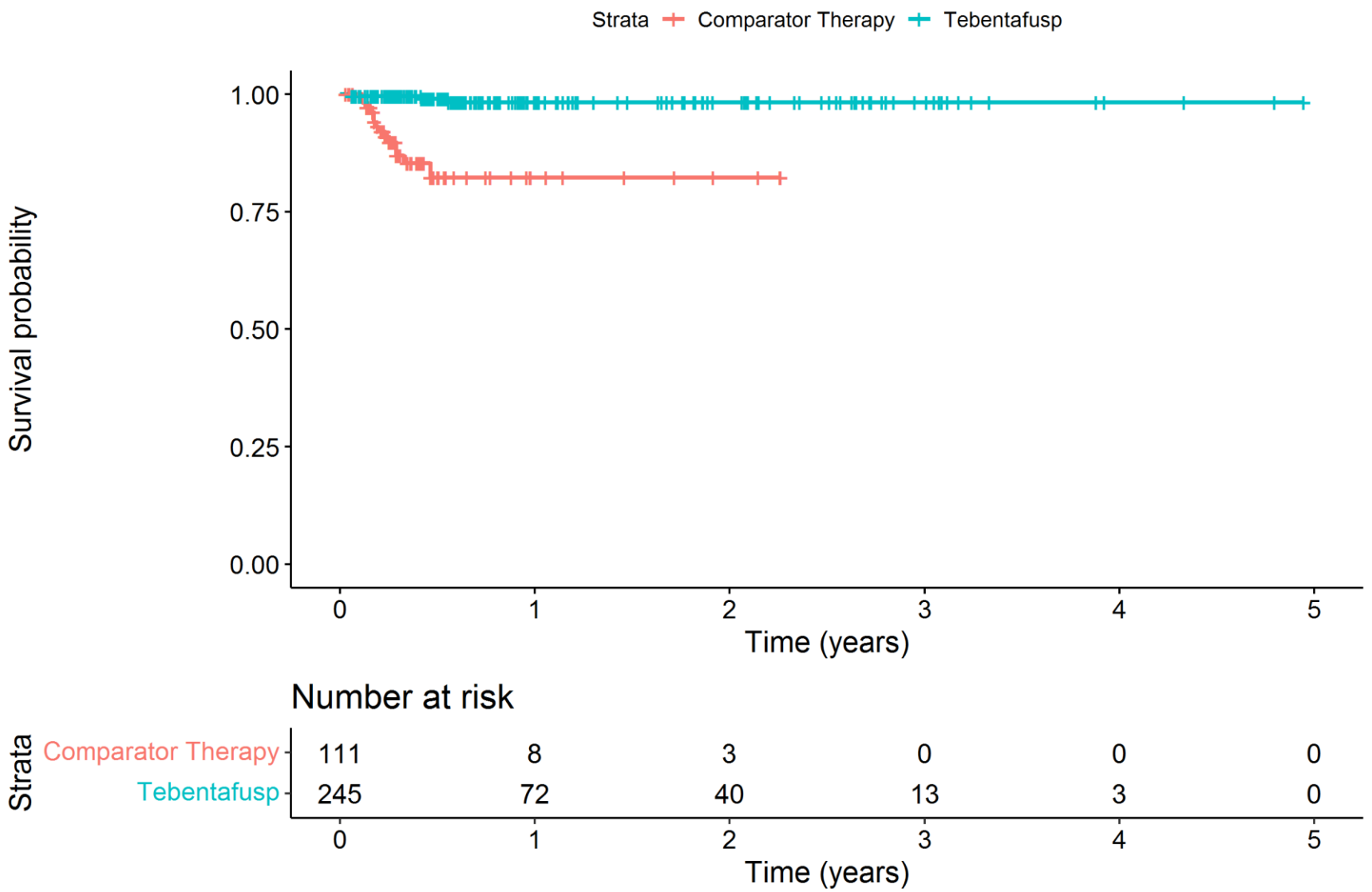
27.1 Anämie



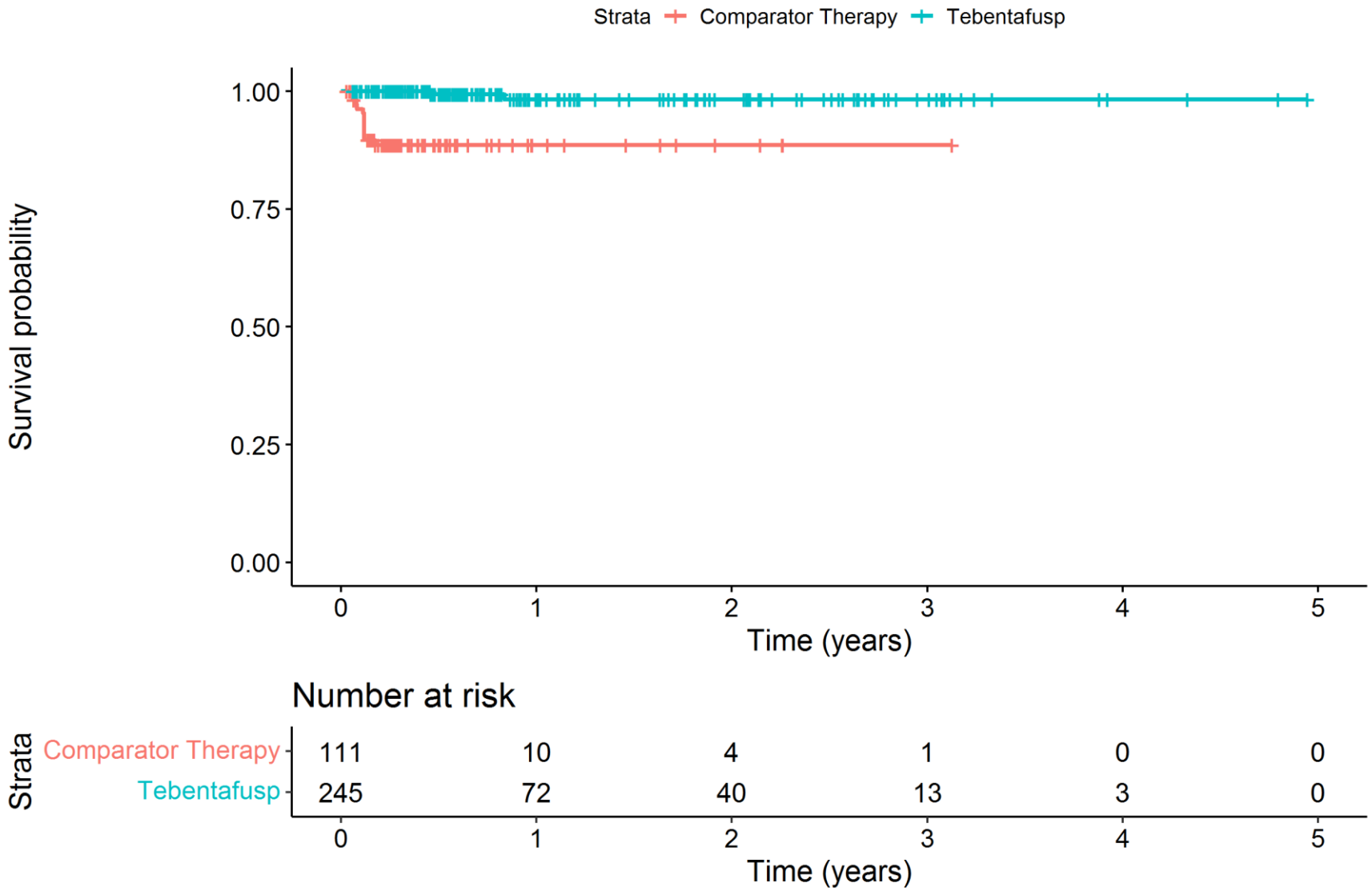
27.2 Lymphopenie



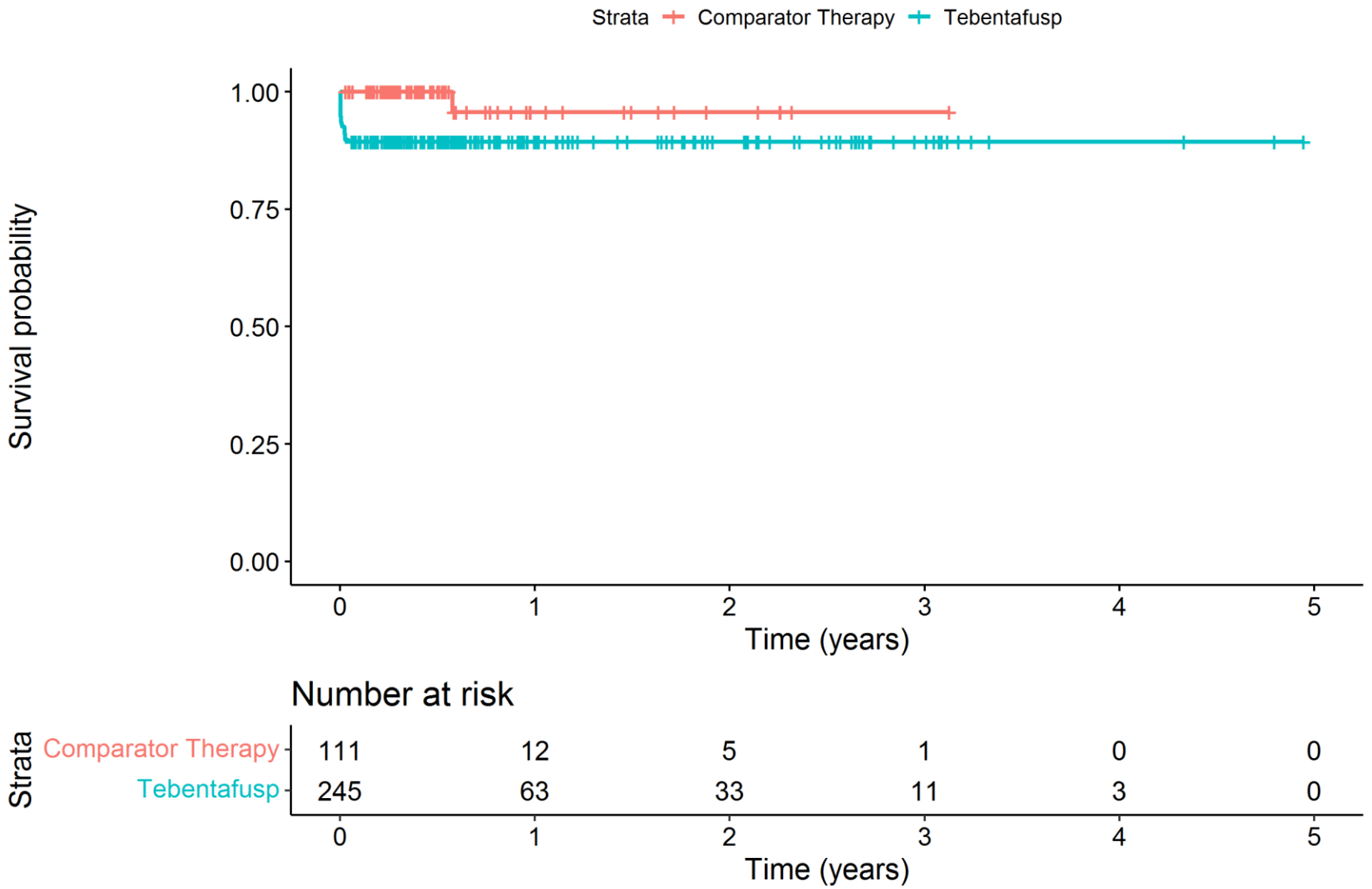
27.3 Hypothyreose



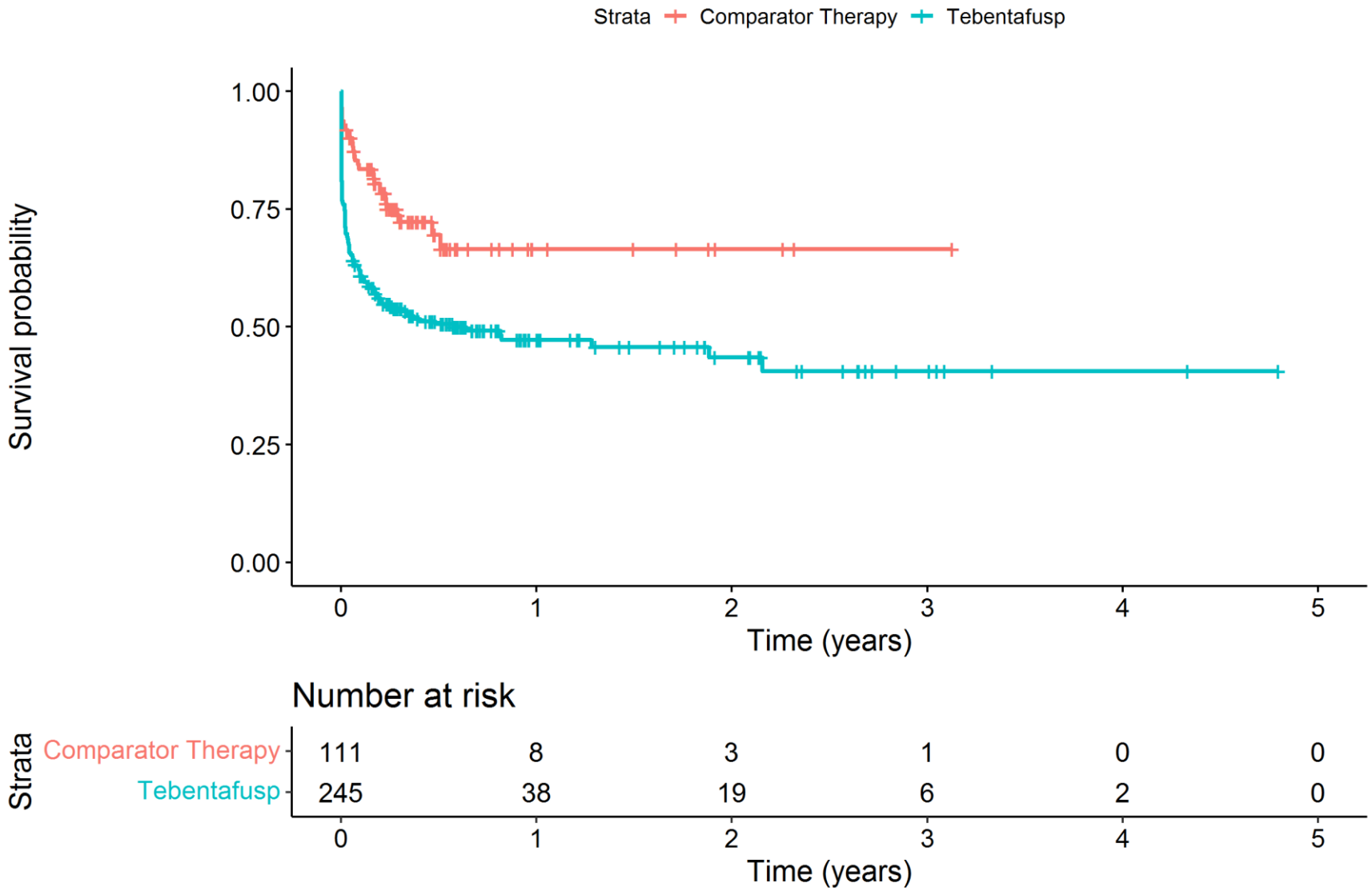
27.4 Hyperthyreose



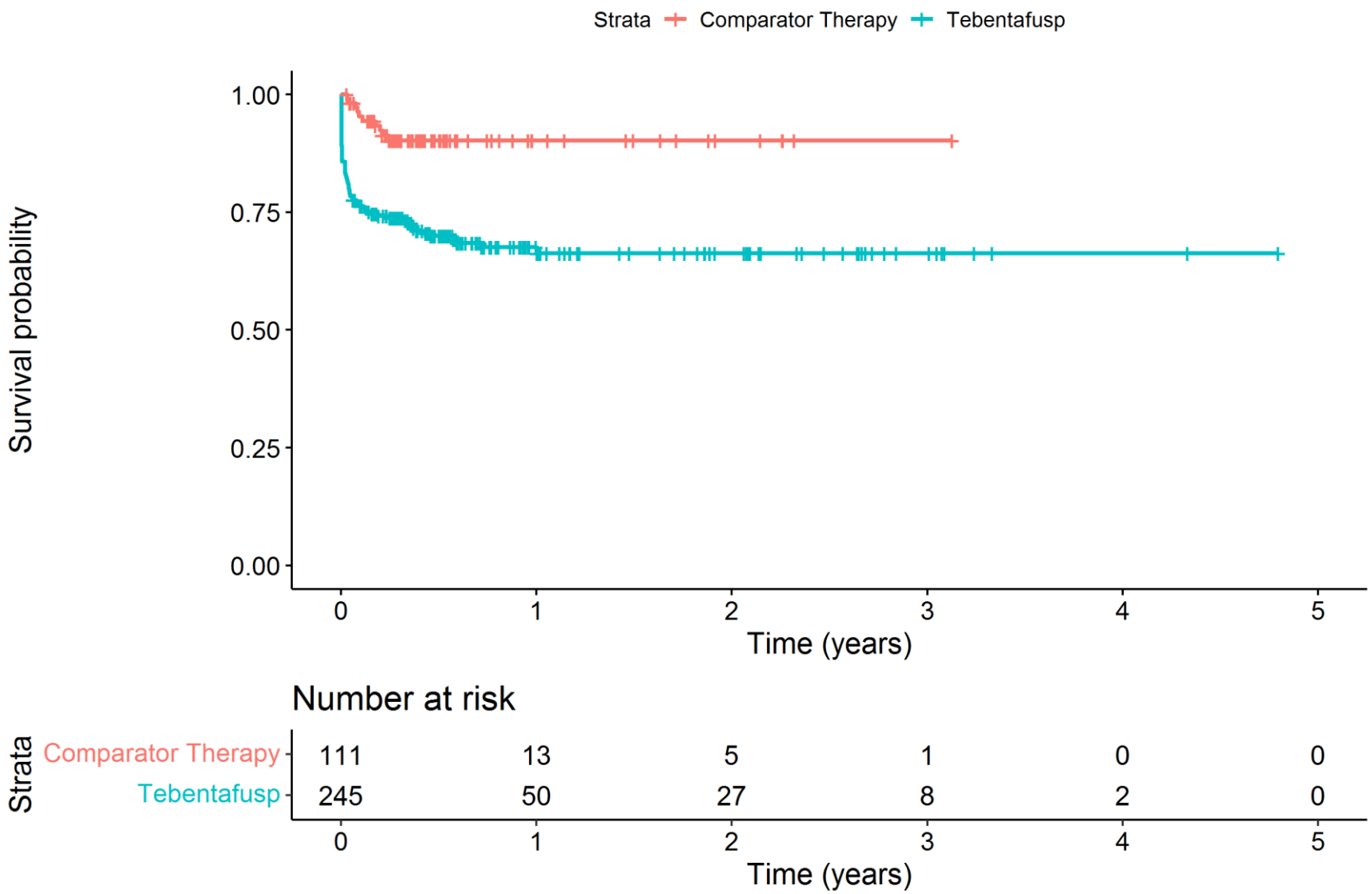
27.5 Periorbitales Ödem



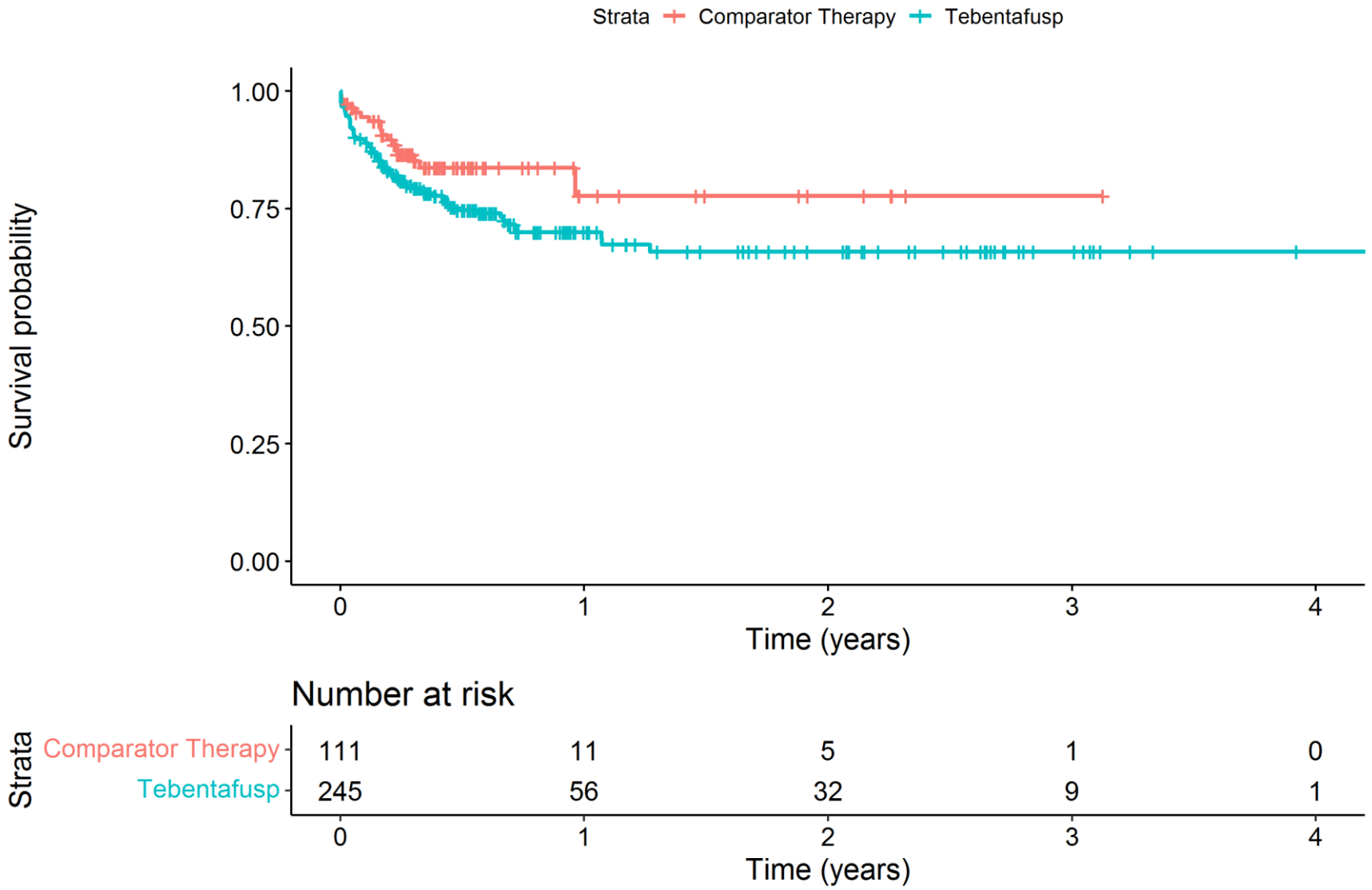
27.6 Übelkeit



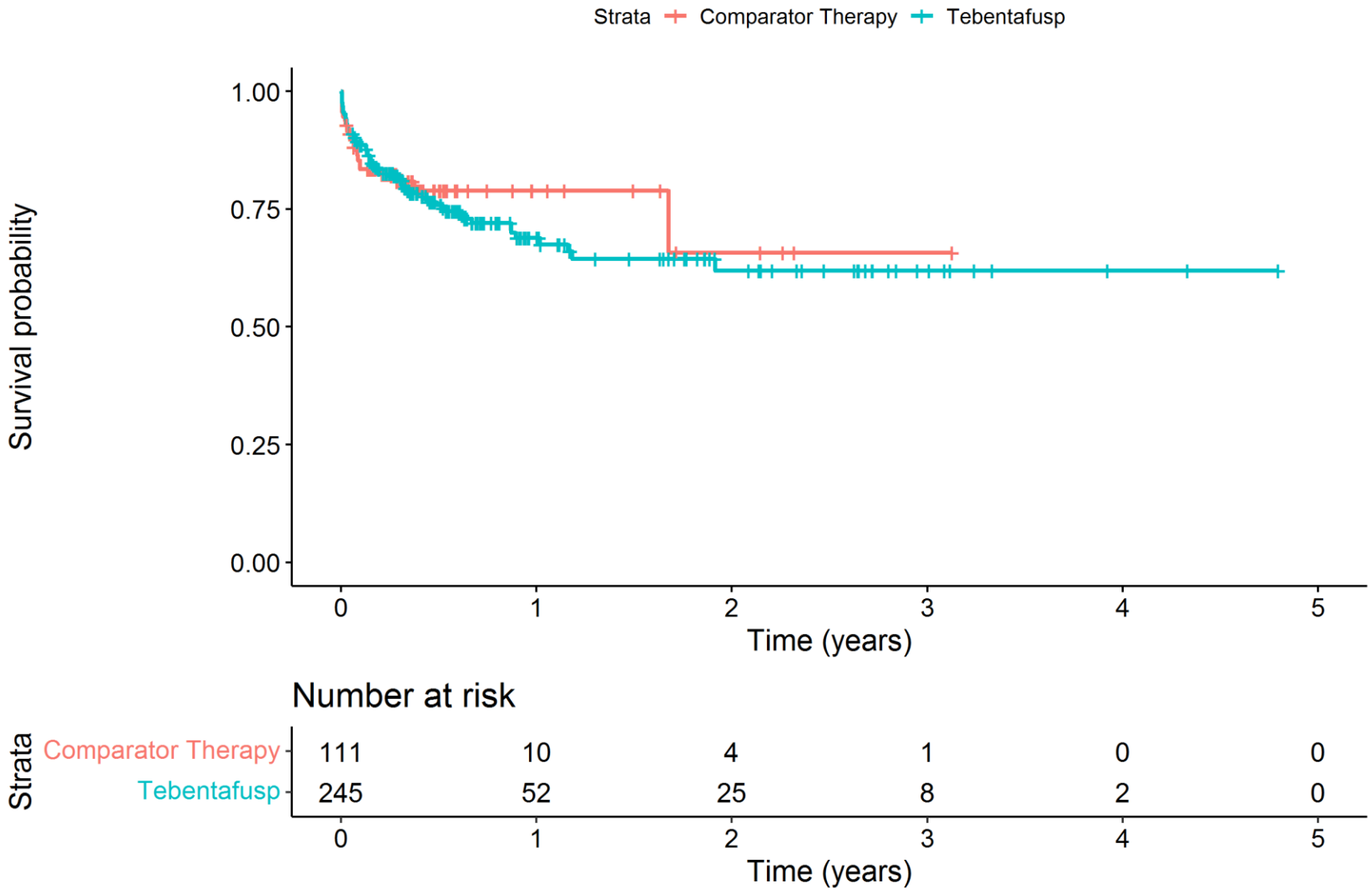
27.7 Erbrechen



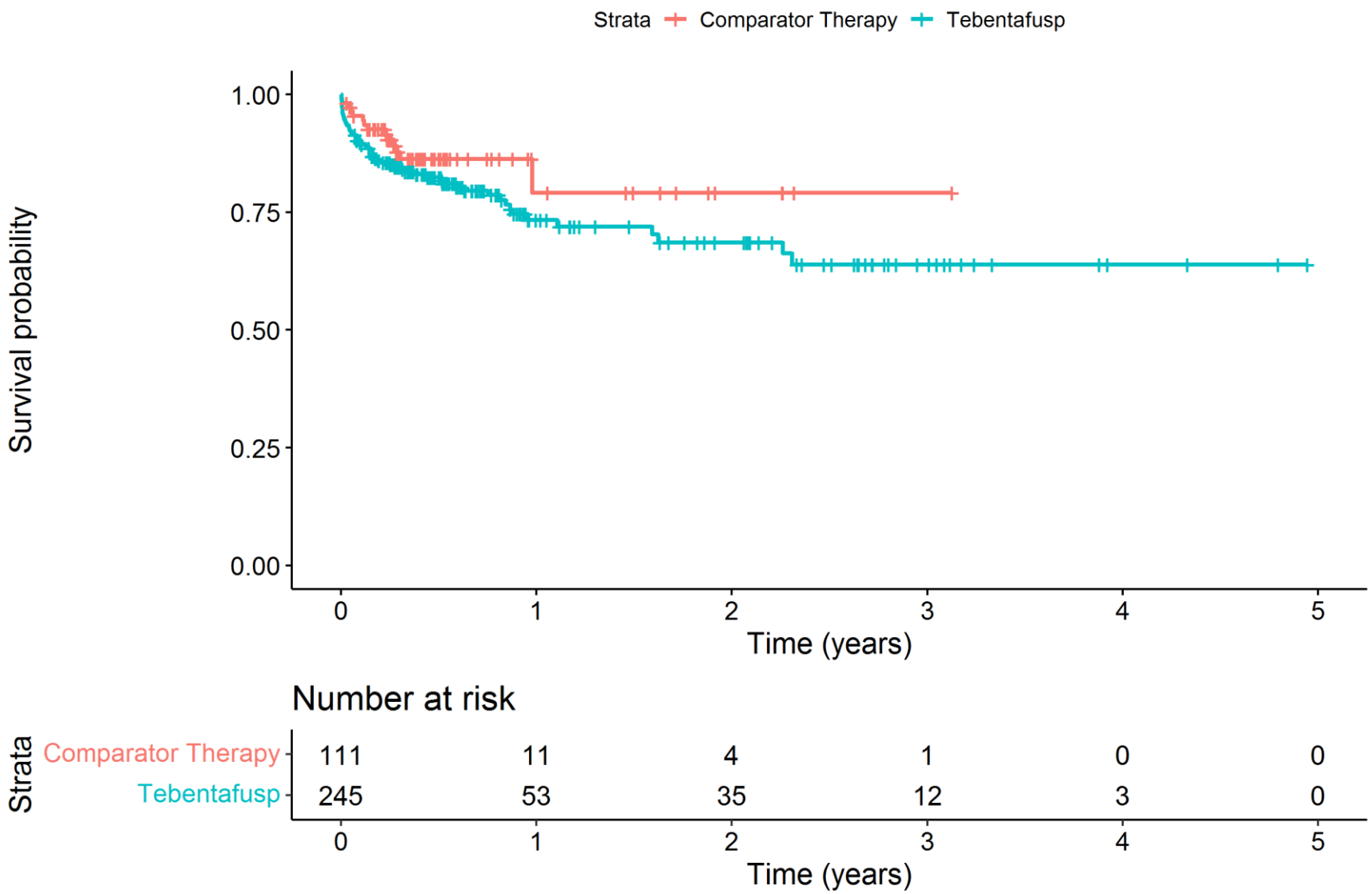
27.8 Unterleibsschmerzen



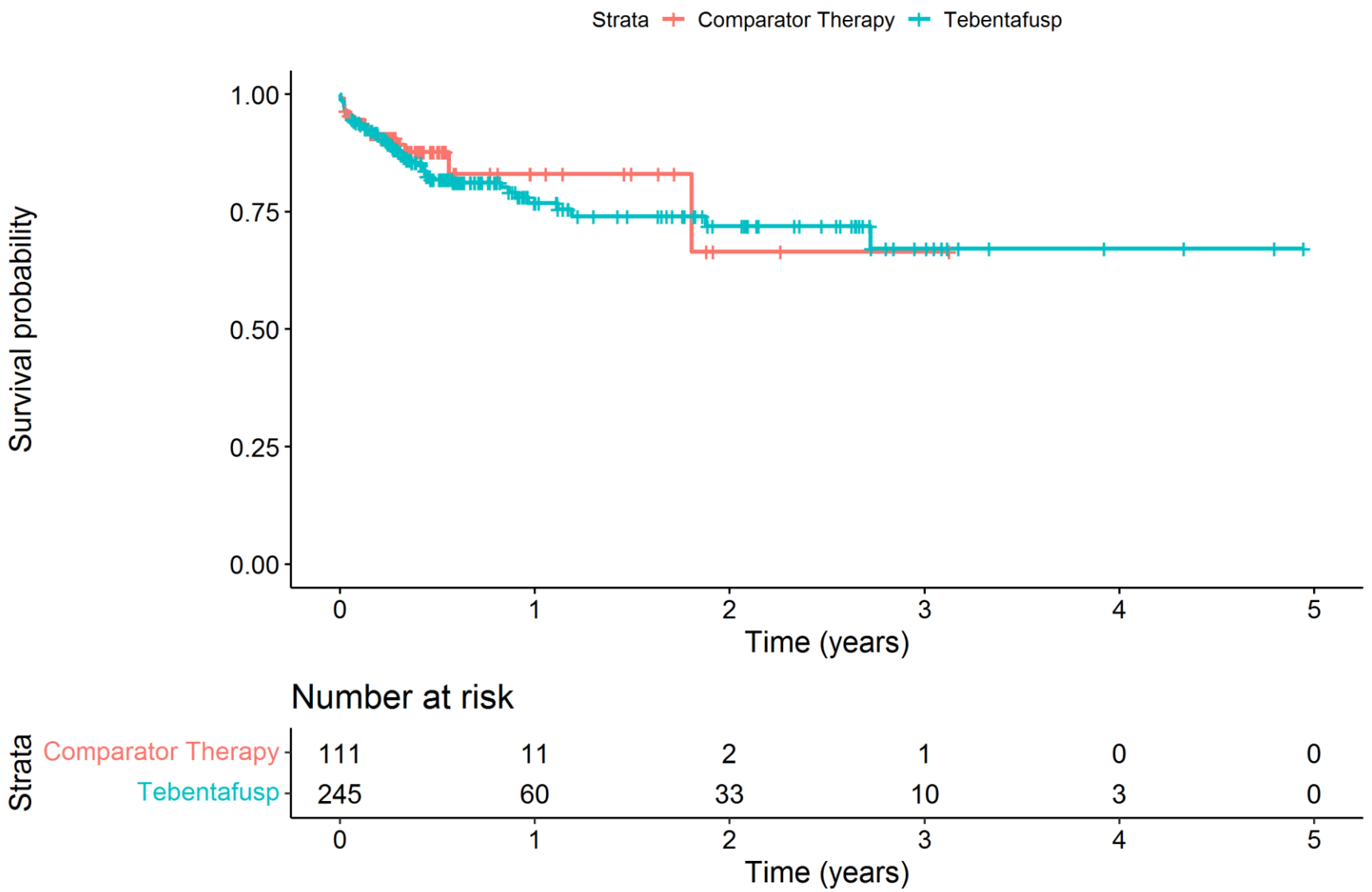
27.9 Diarrhoe



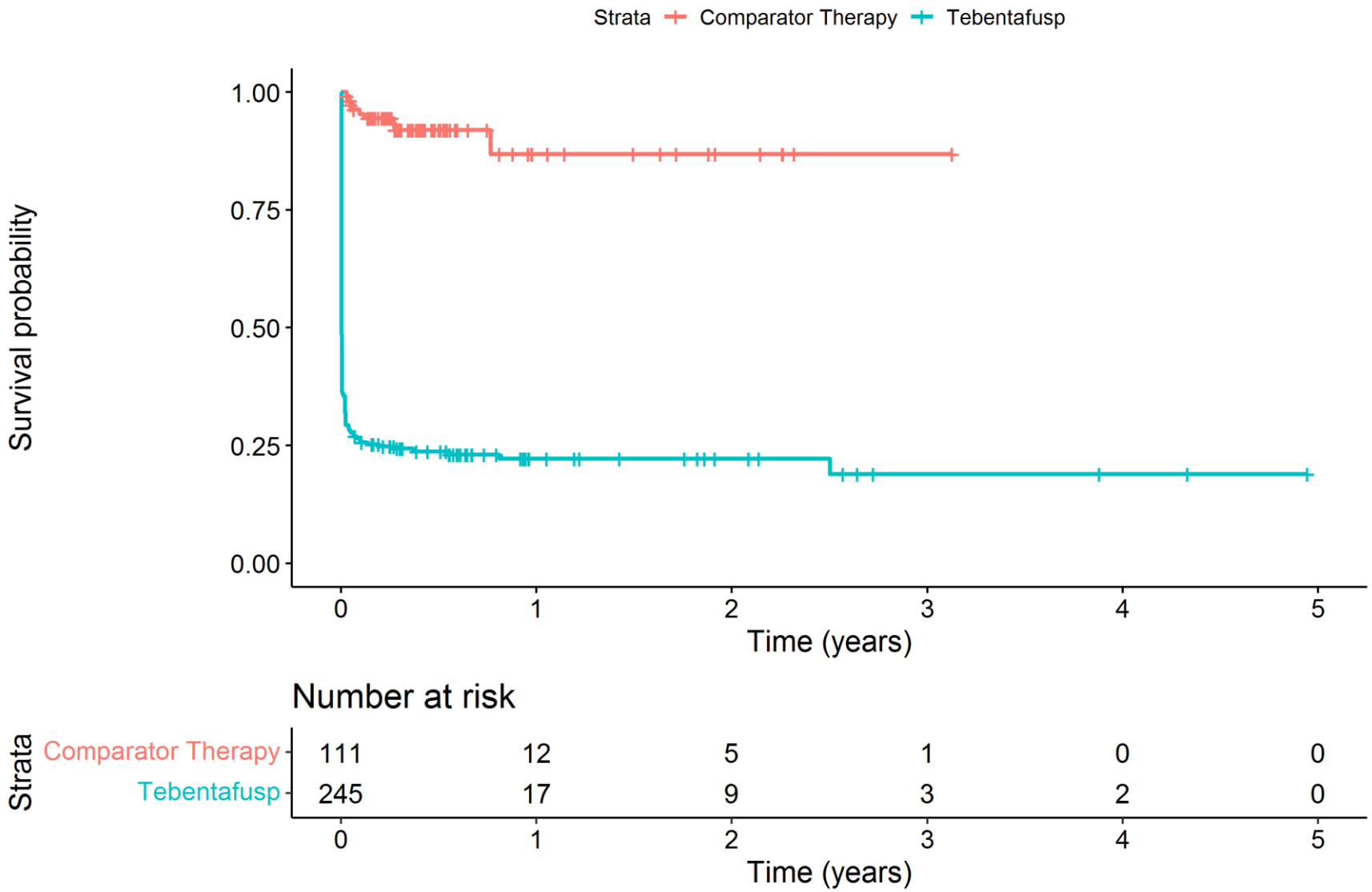
27.10 Oberbauchschmerzen



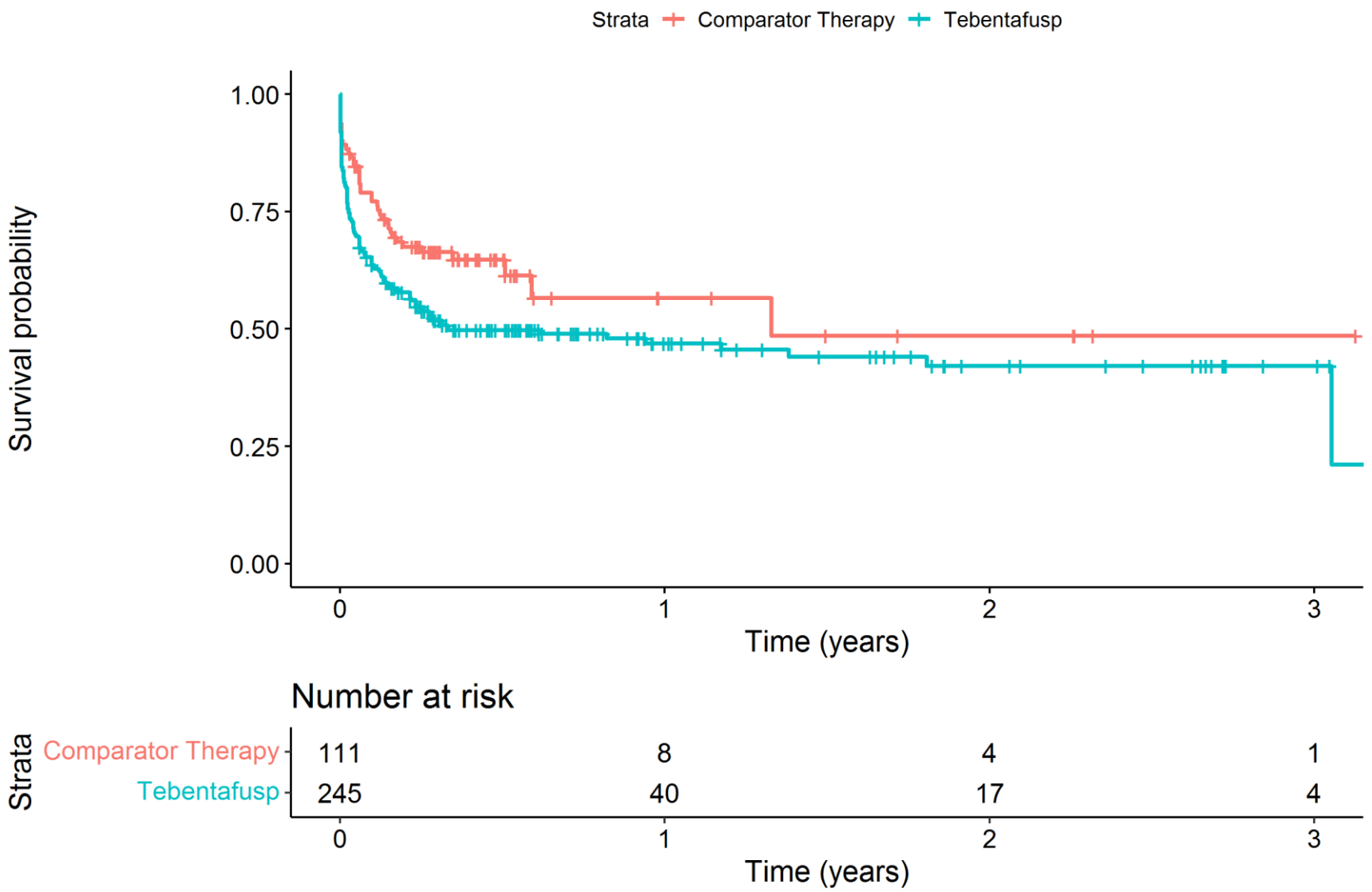
27.11 Verstopfung



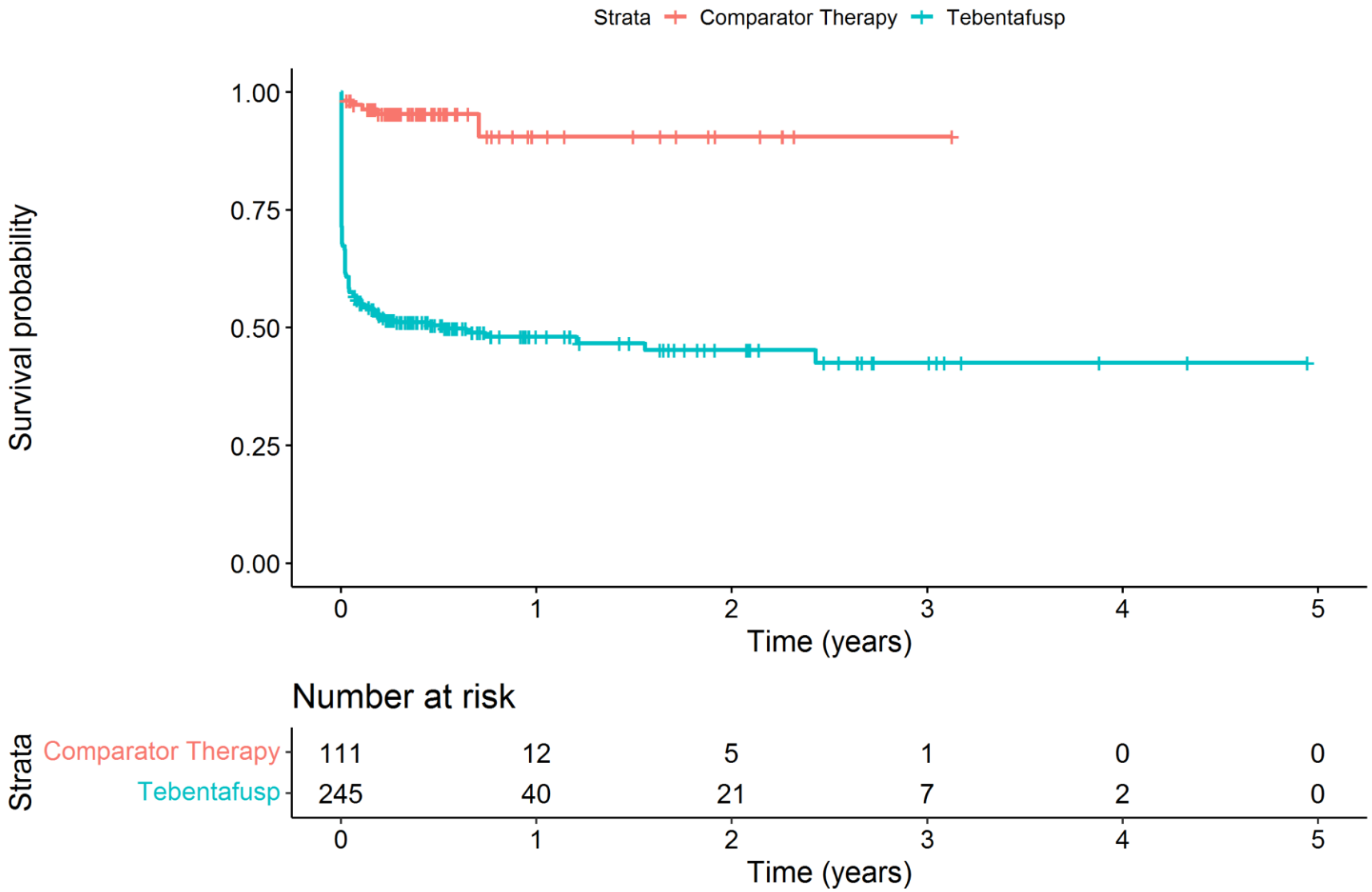
27.12 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
12
5
1
0
0
245
17
9
3
2
0
0
1
2
3
4
5
Time (years)

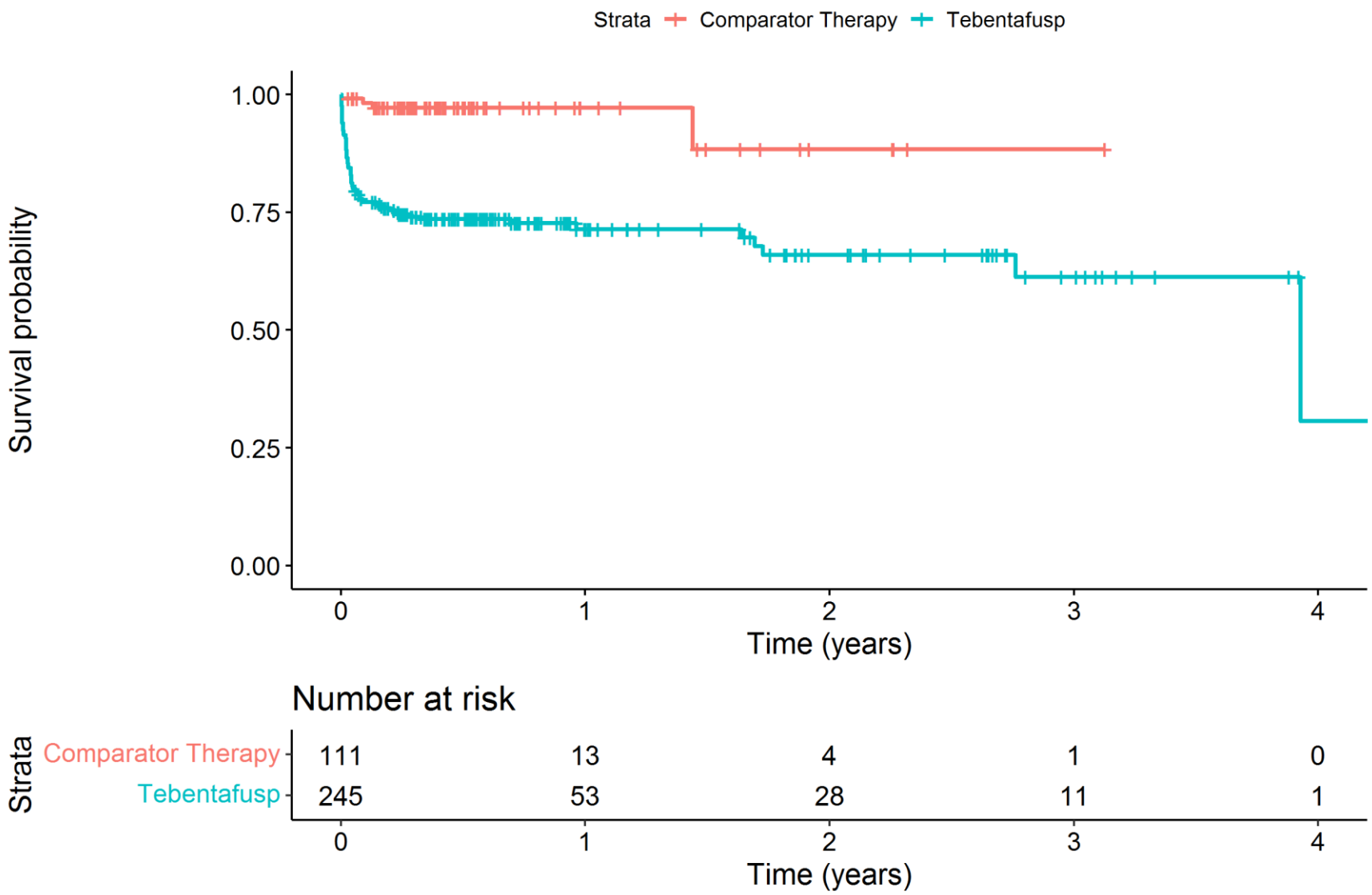
27.13 Müdigkeit



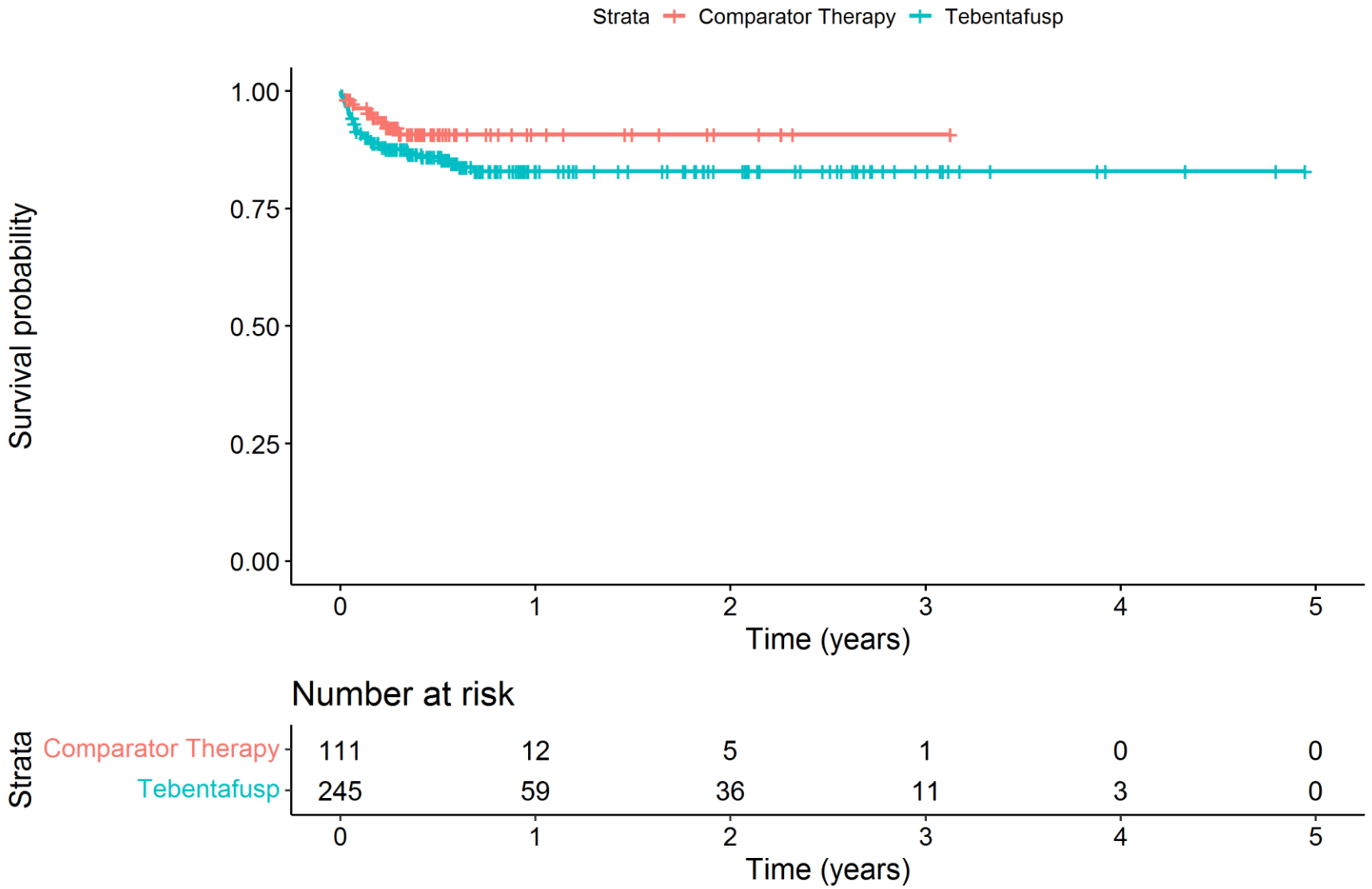
27.14 Schüttelfrost



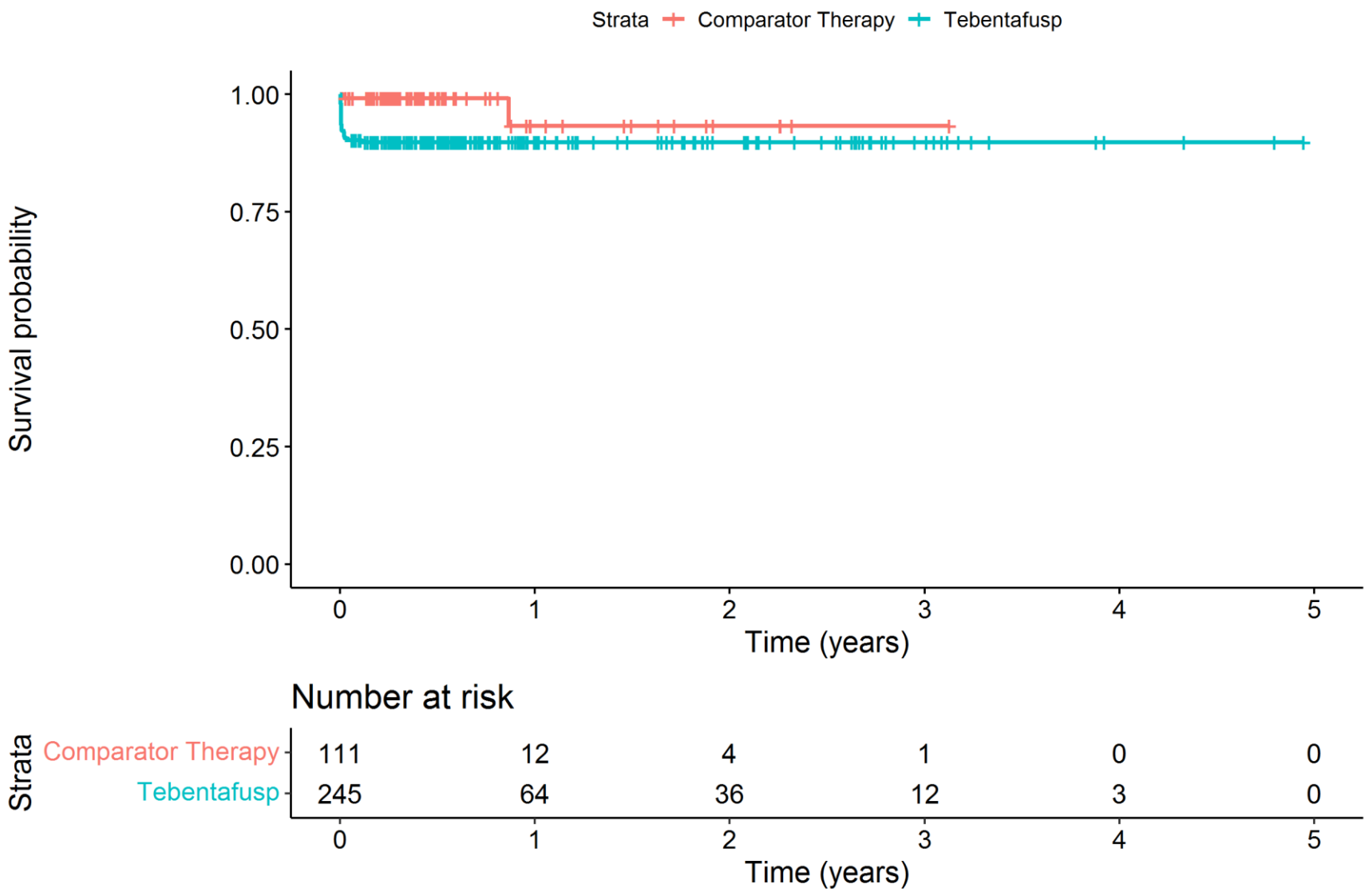
27.15 Periphere Ödeme



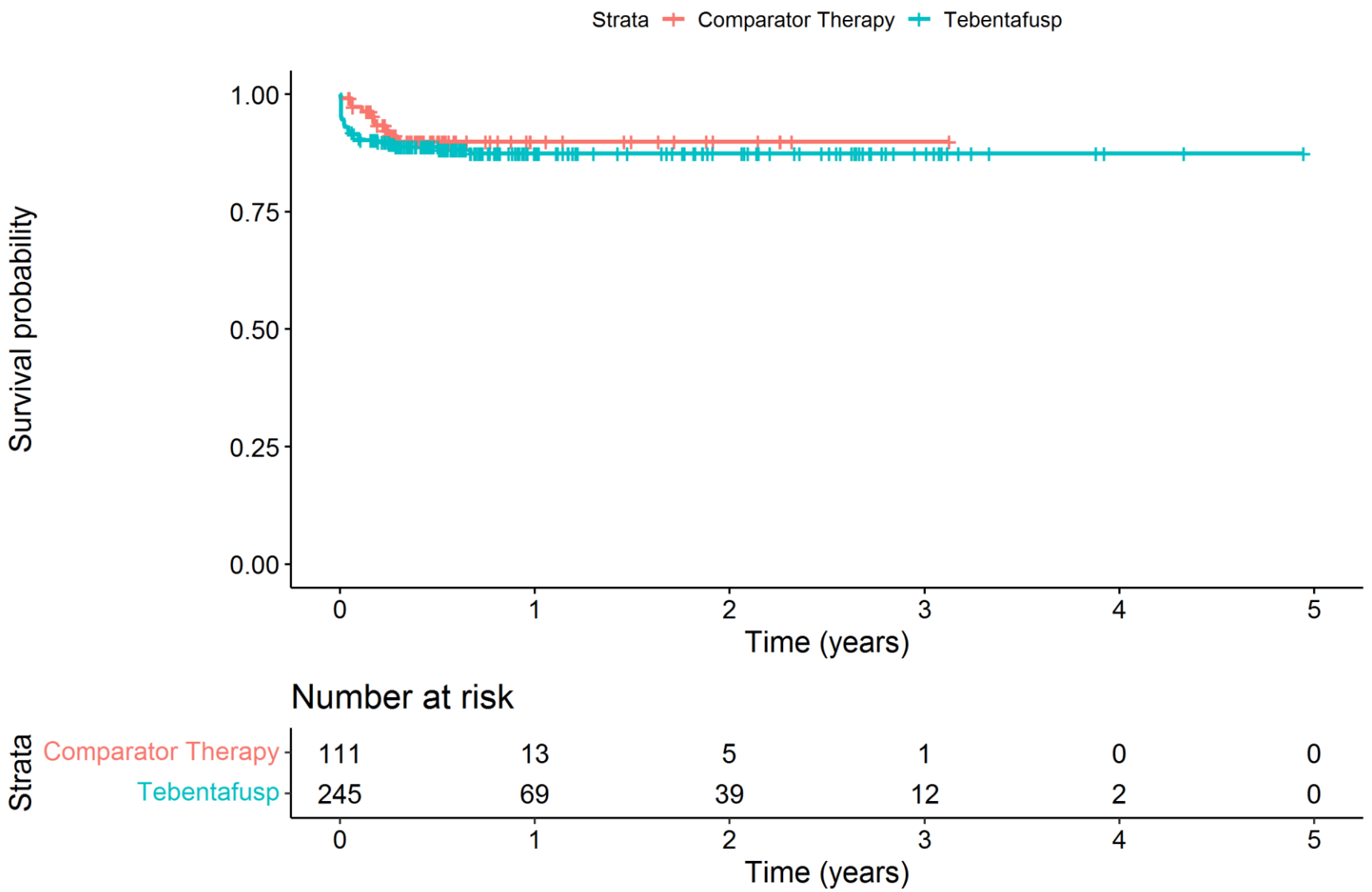
27.16 Asthenie



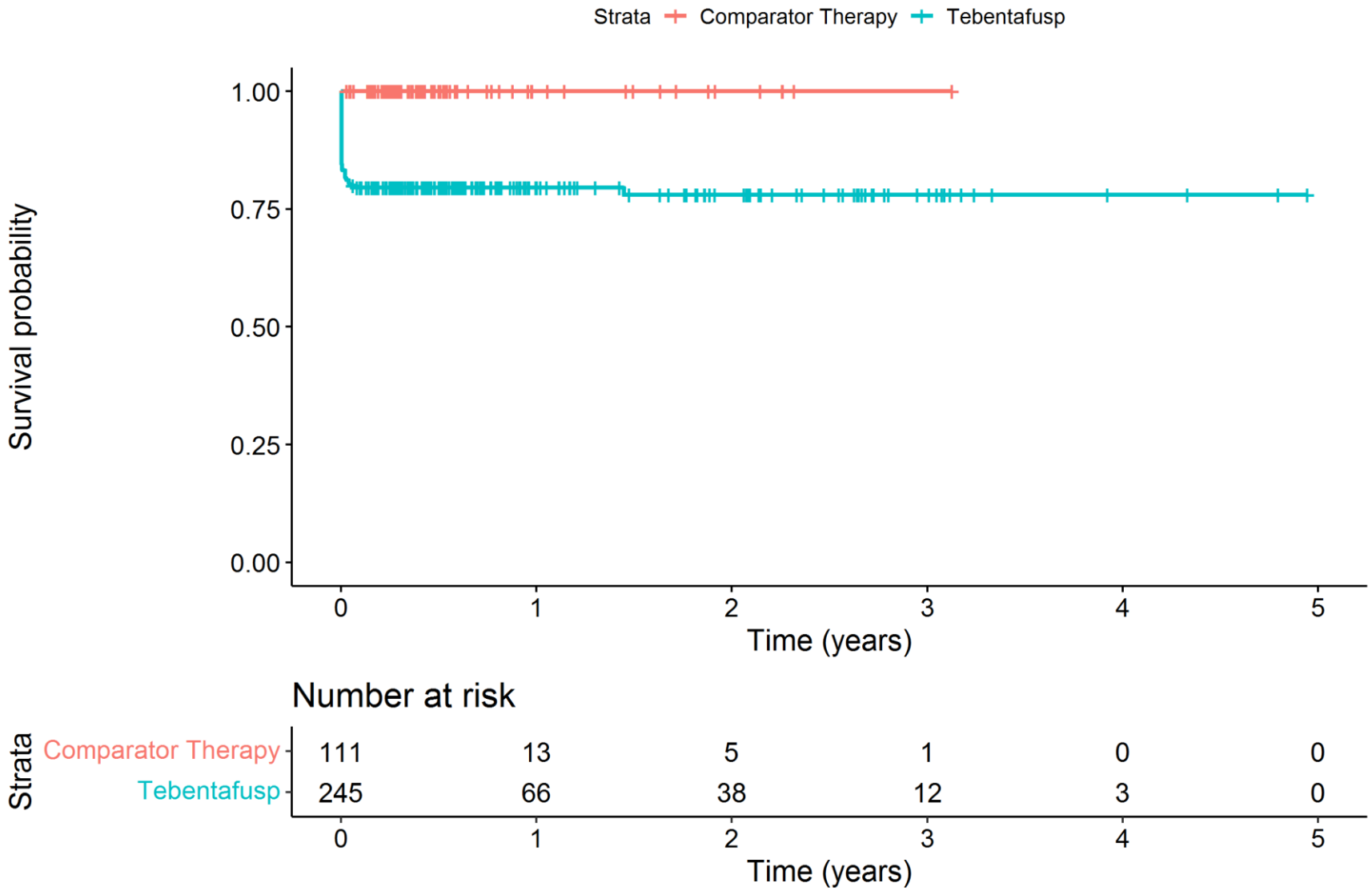
27.17 Gesichtsödeme



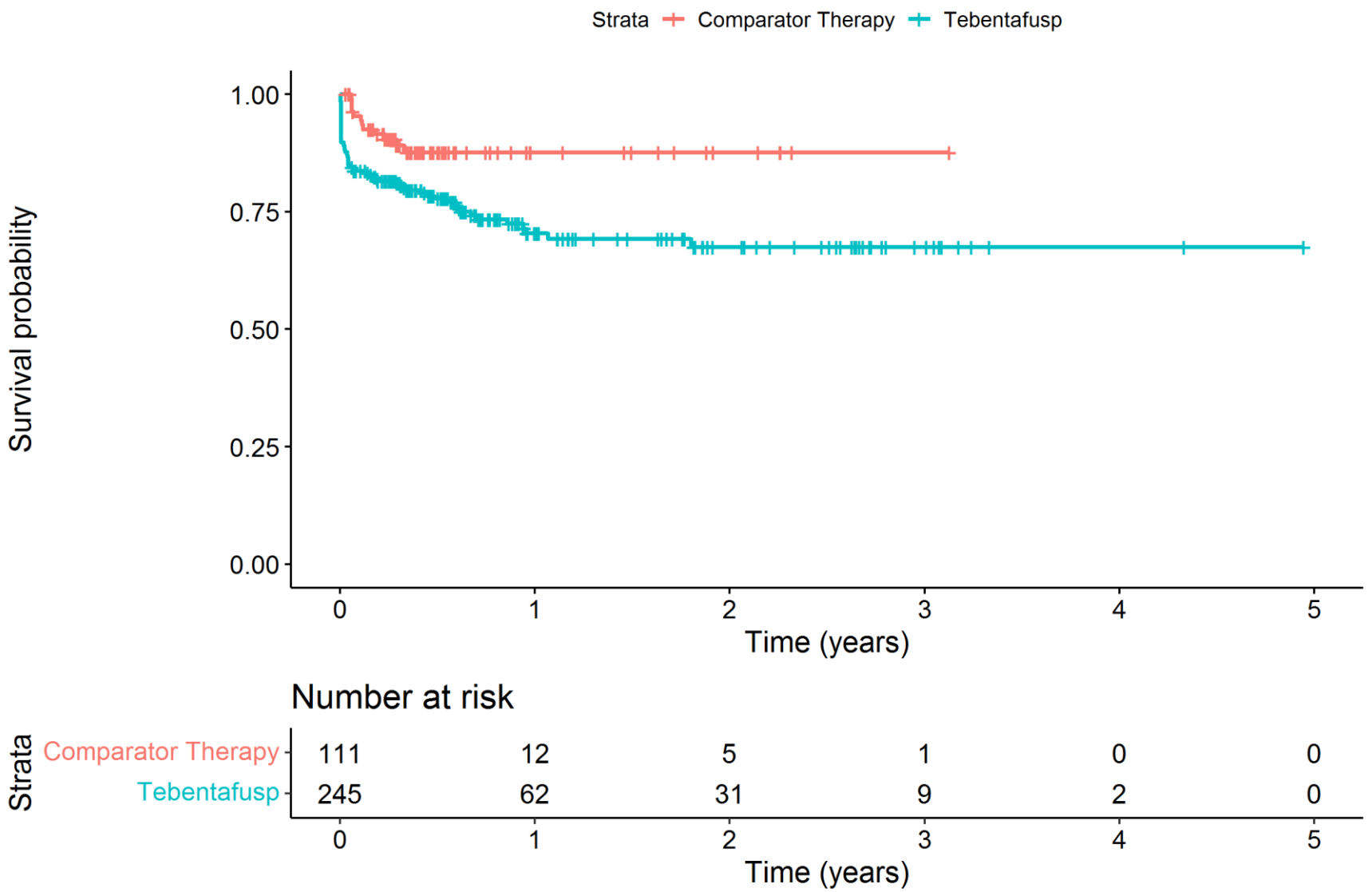
27.18 Hyperbilirubinämie



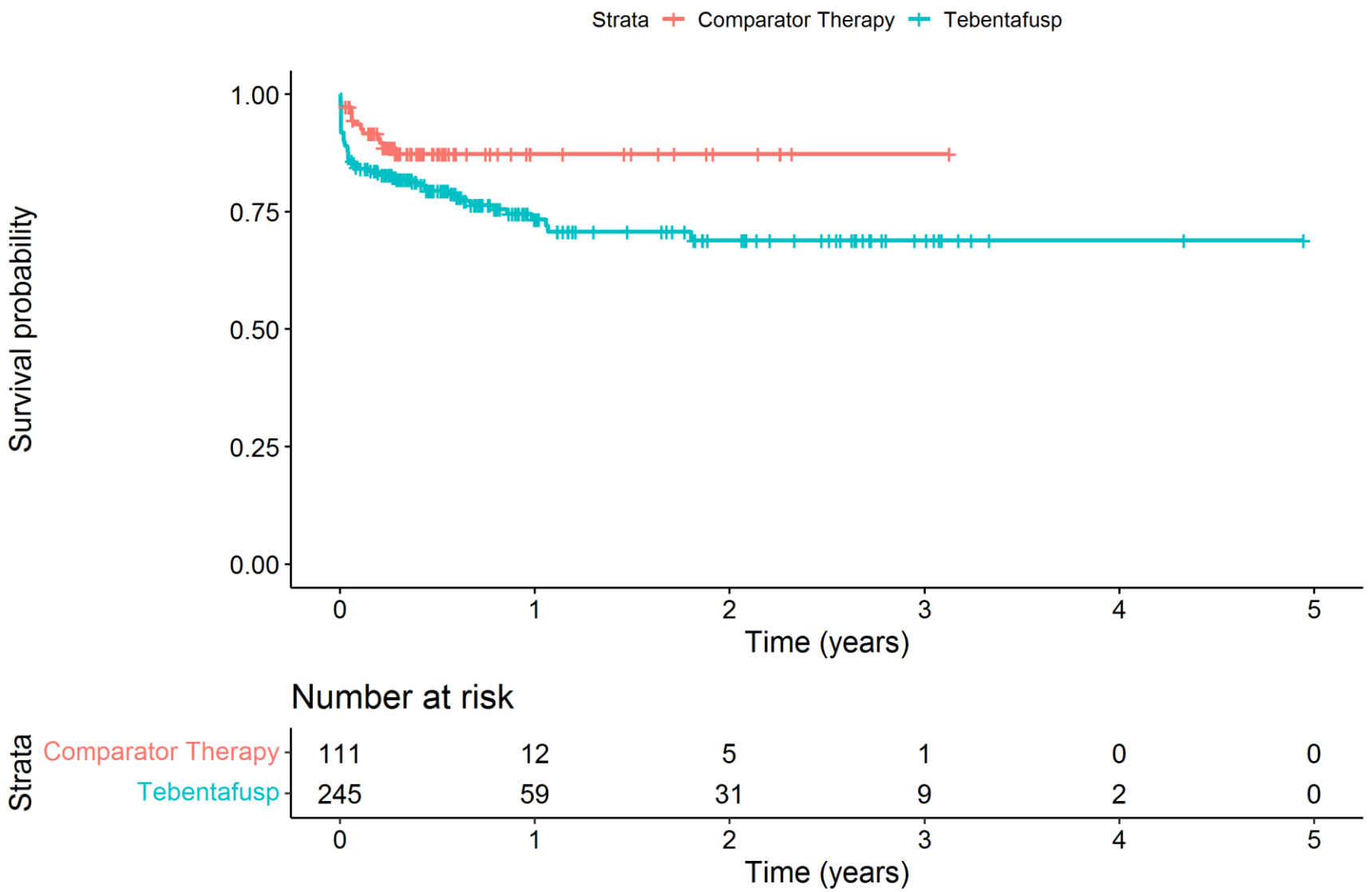
27.19 Zytokin-Freisetzungssyndrom



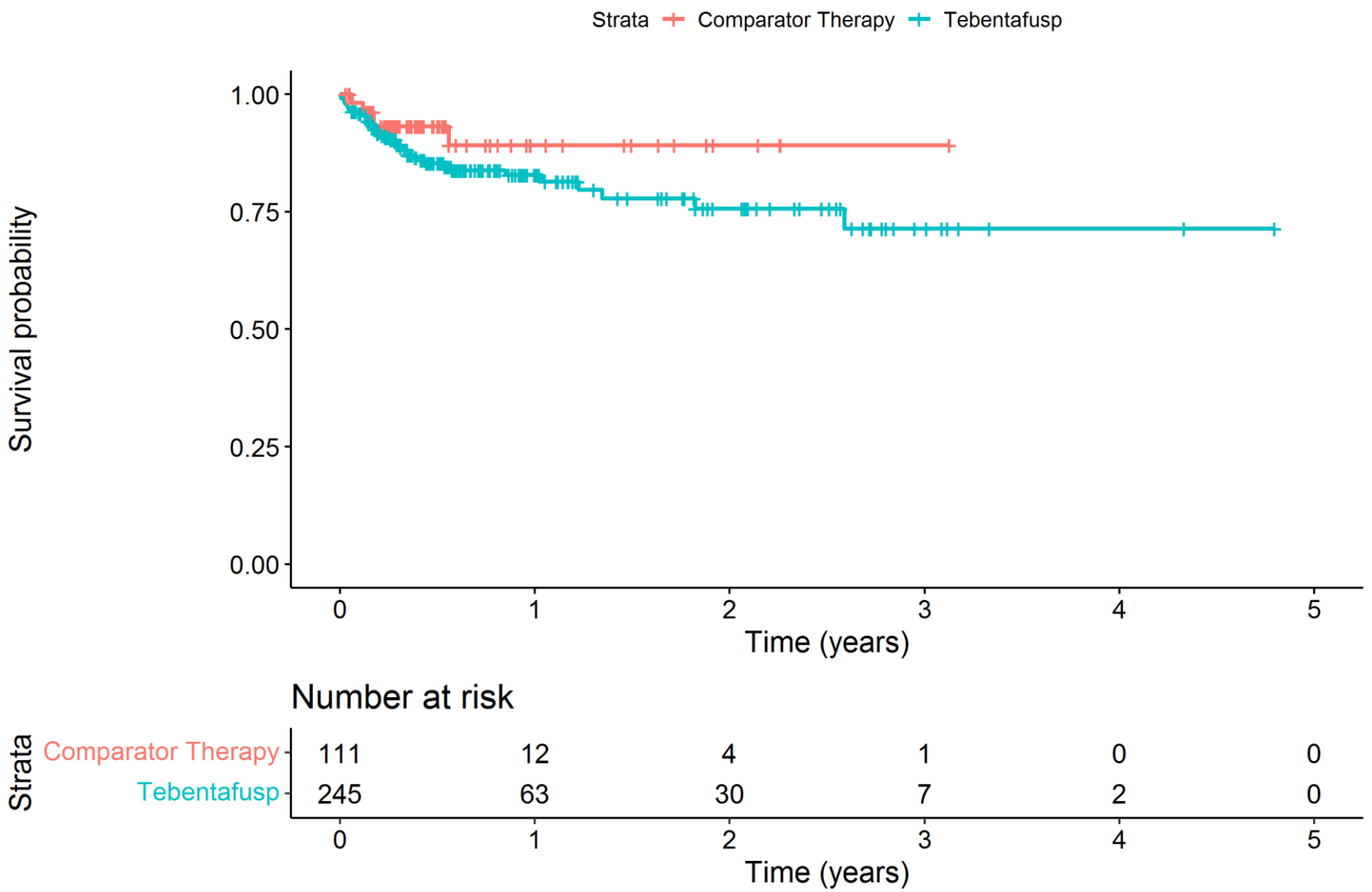
27.20 Erhöhte Aspartat-Aminotransferase



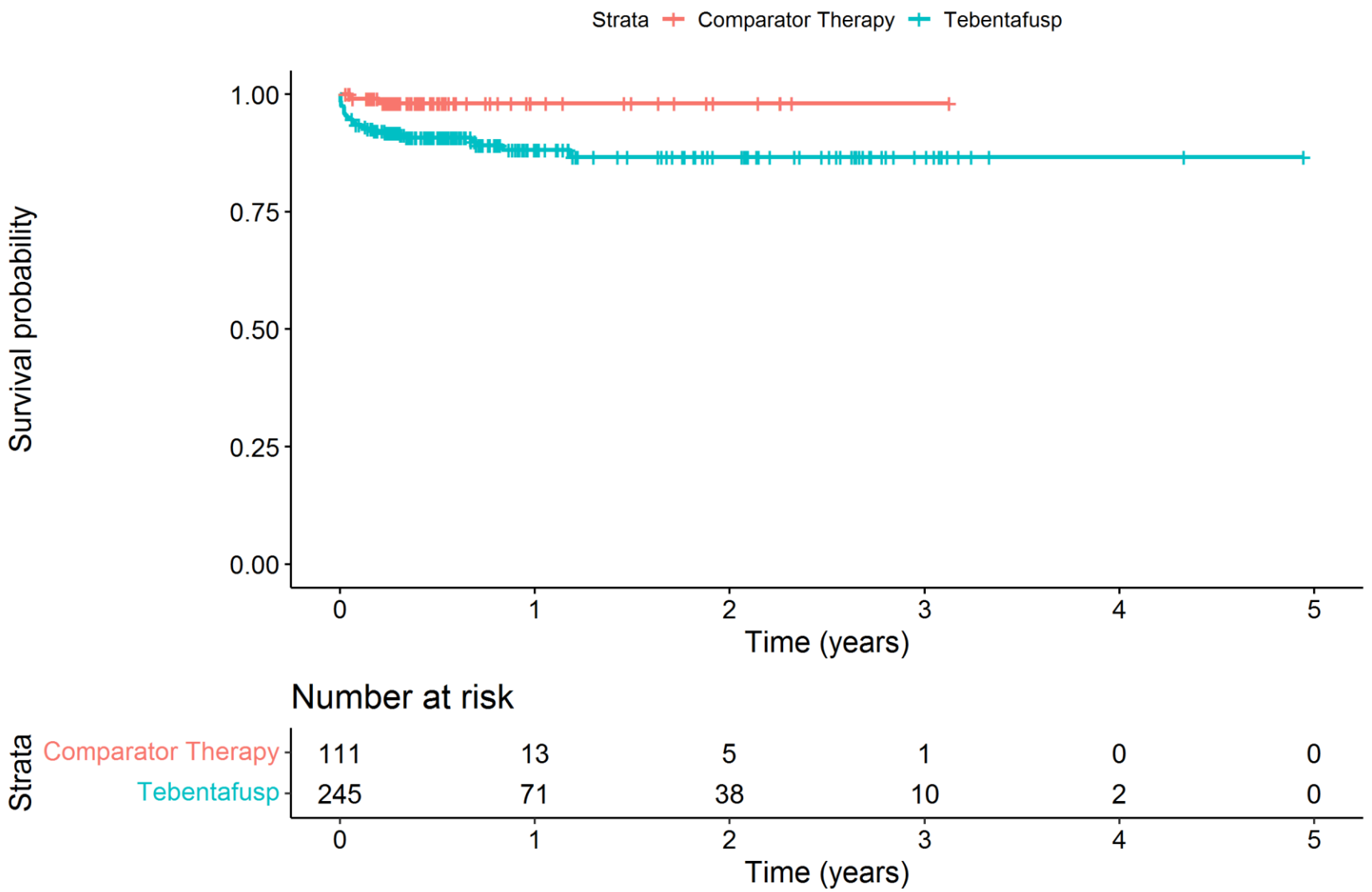
27.21 Erhöhte Alanin-Aminotransferase



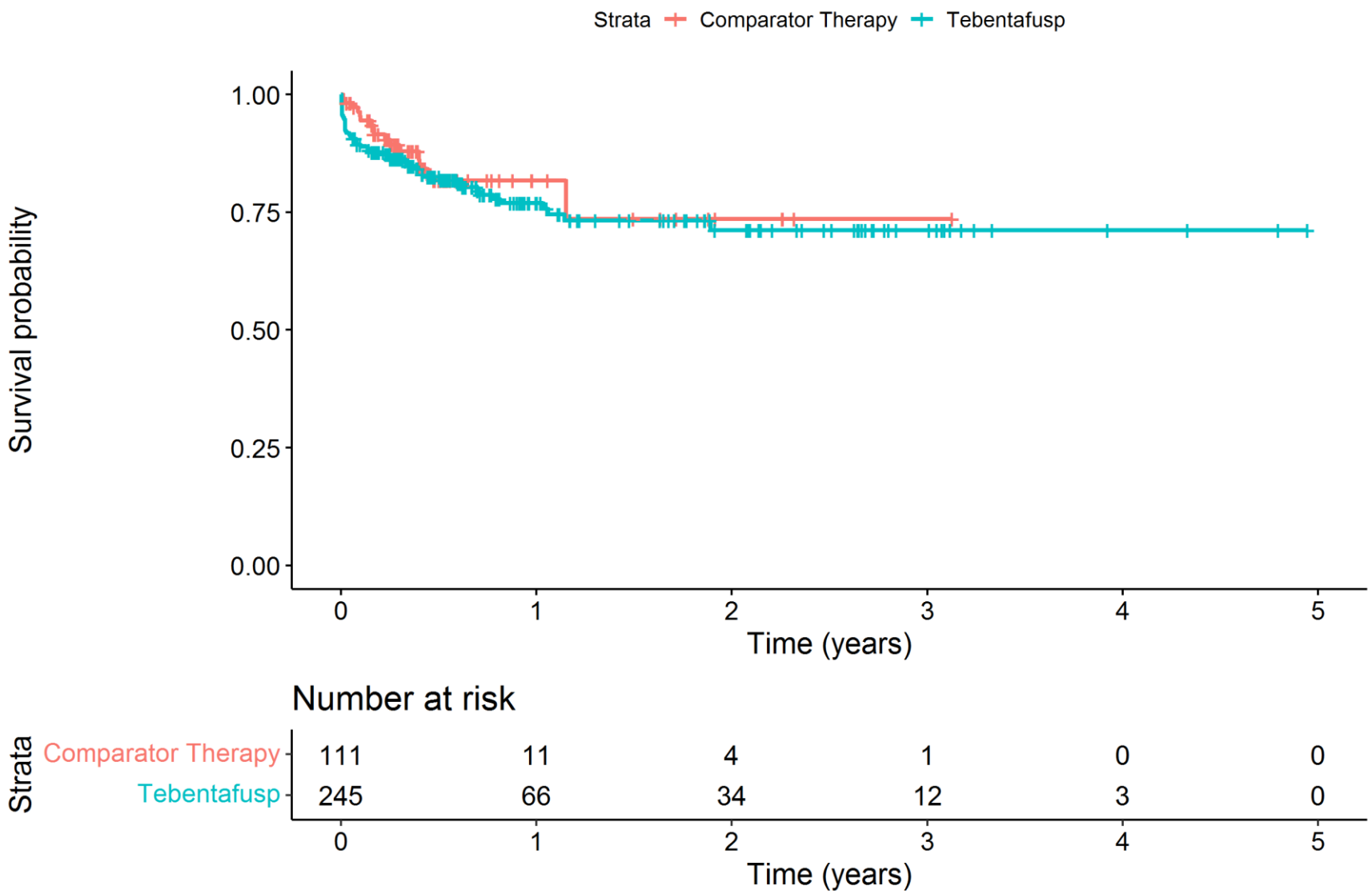
27.22 Erhöhte Lipase



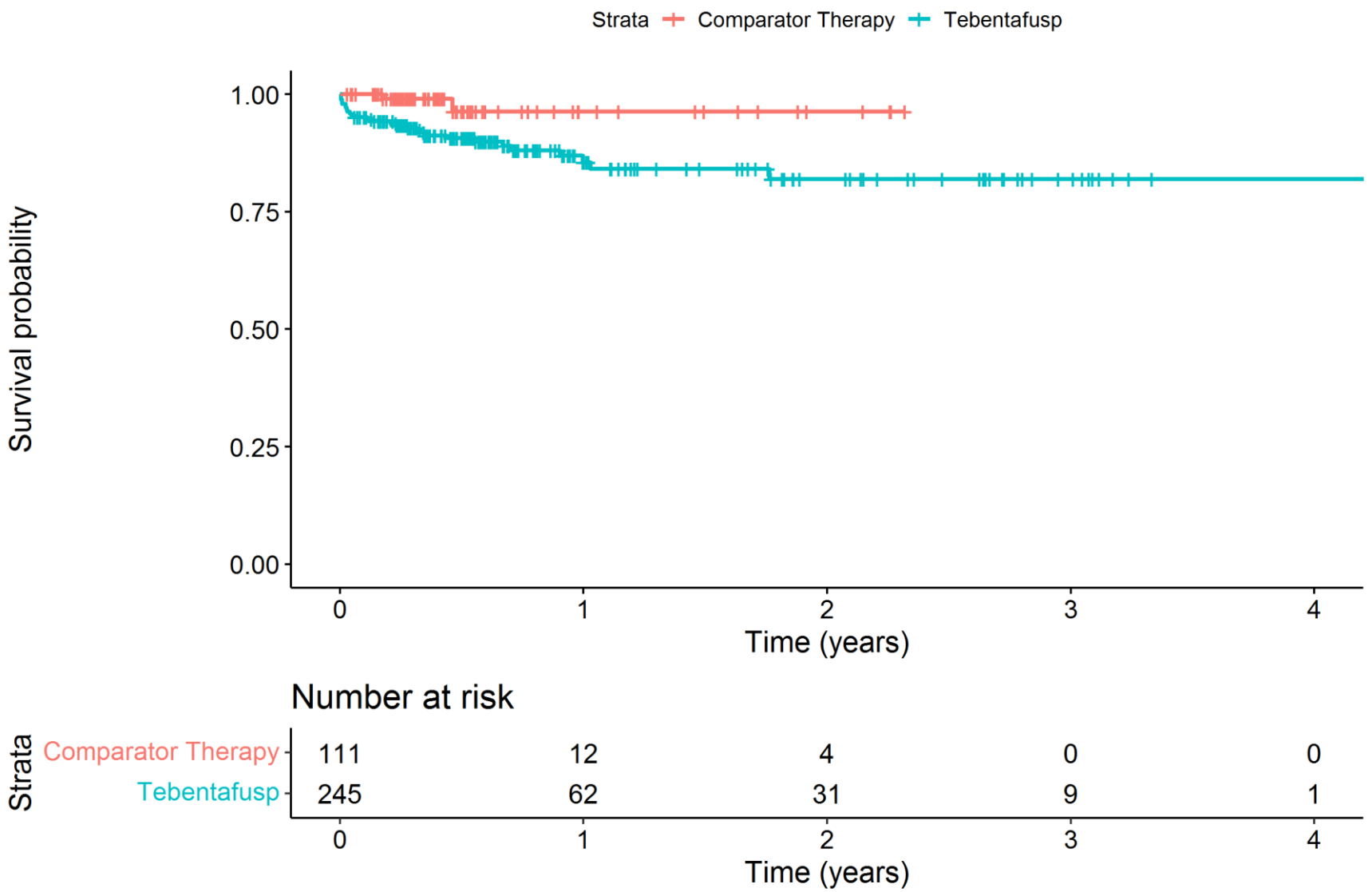
27.23 Erhöhte alkalische Phosphatase im Blut



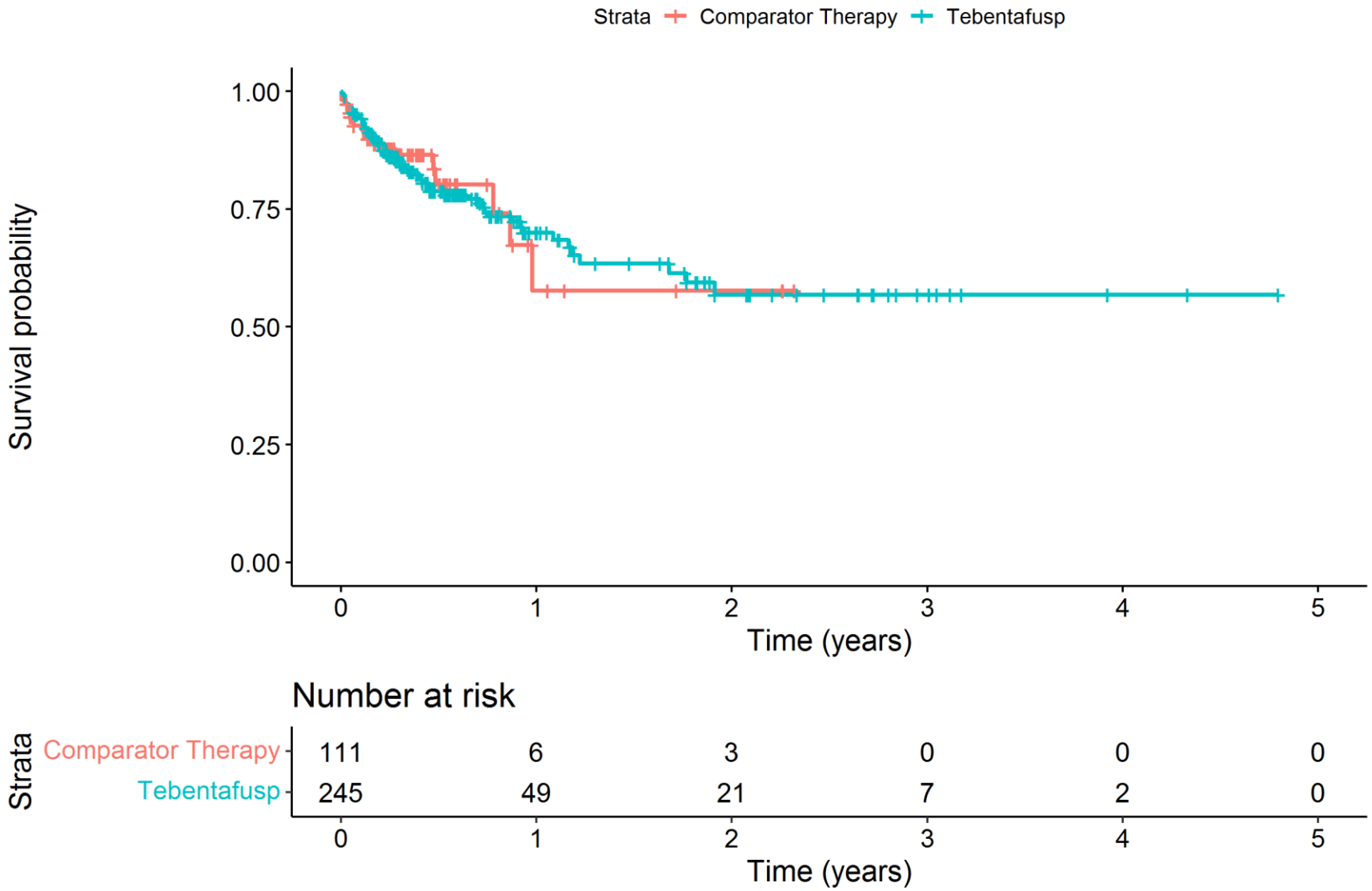
27.24 Verminderter Appetit



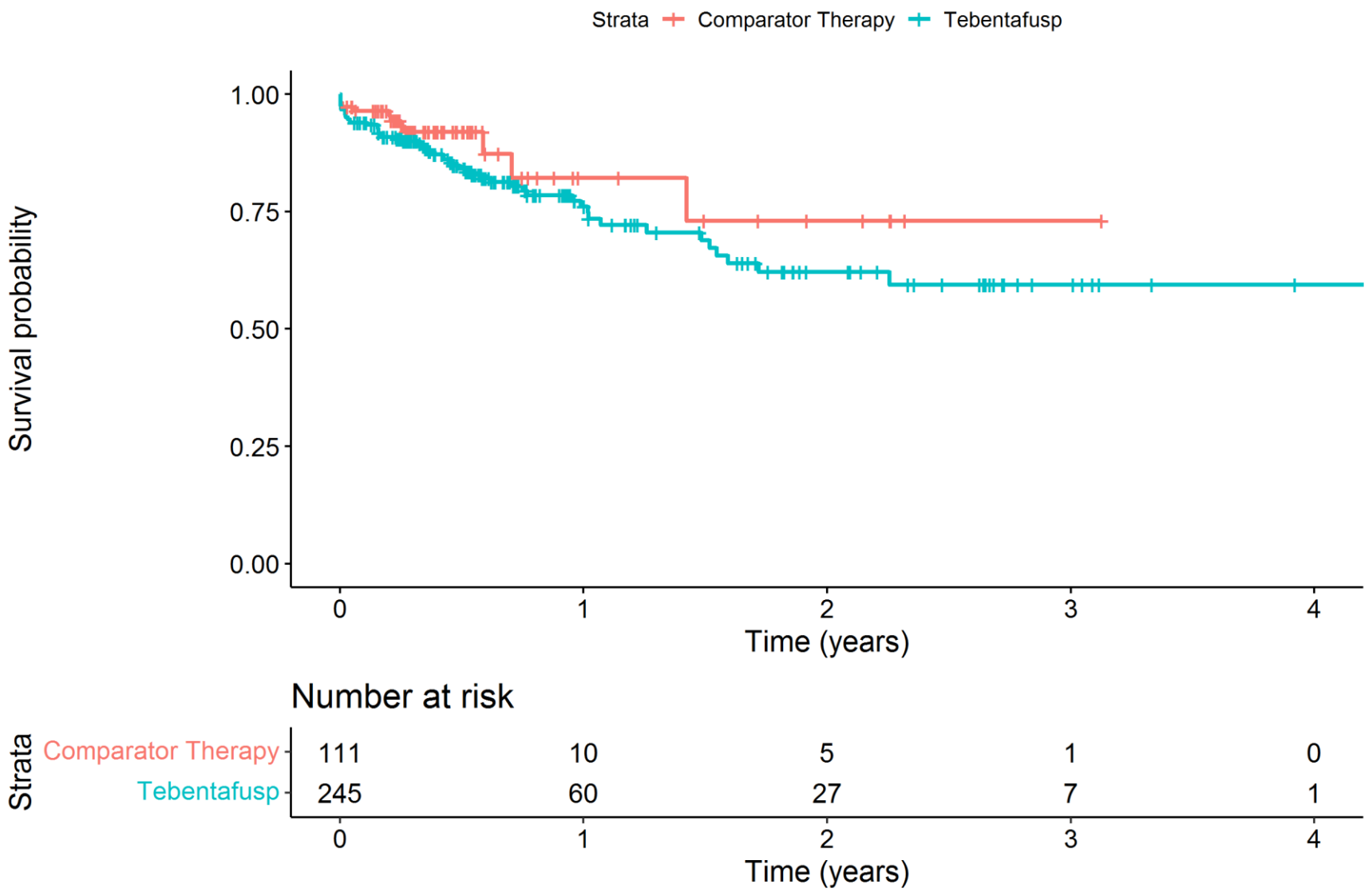
27.25 Hypophosphatämie



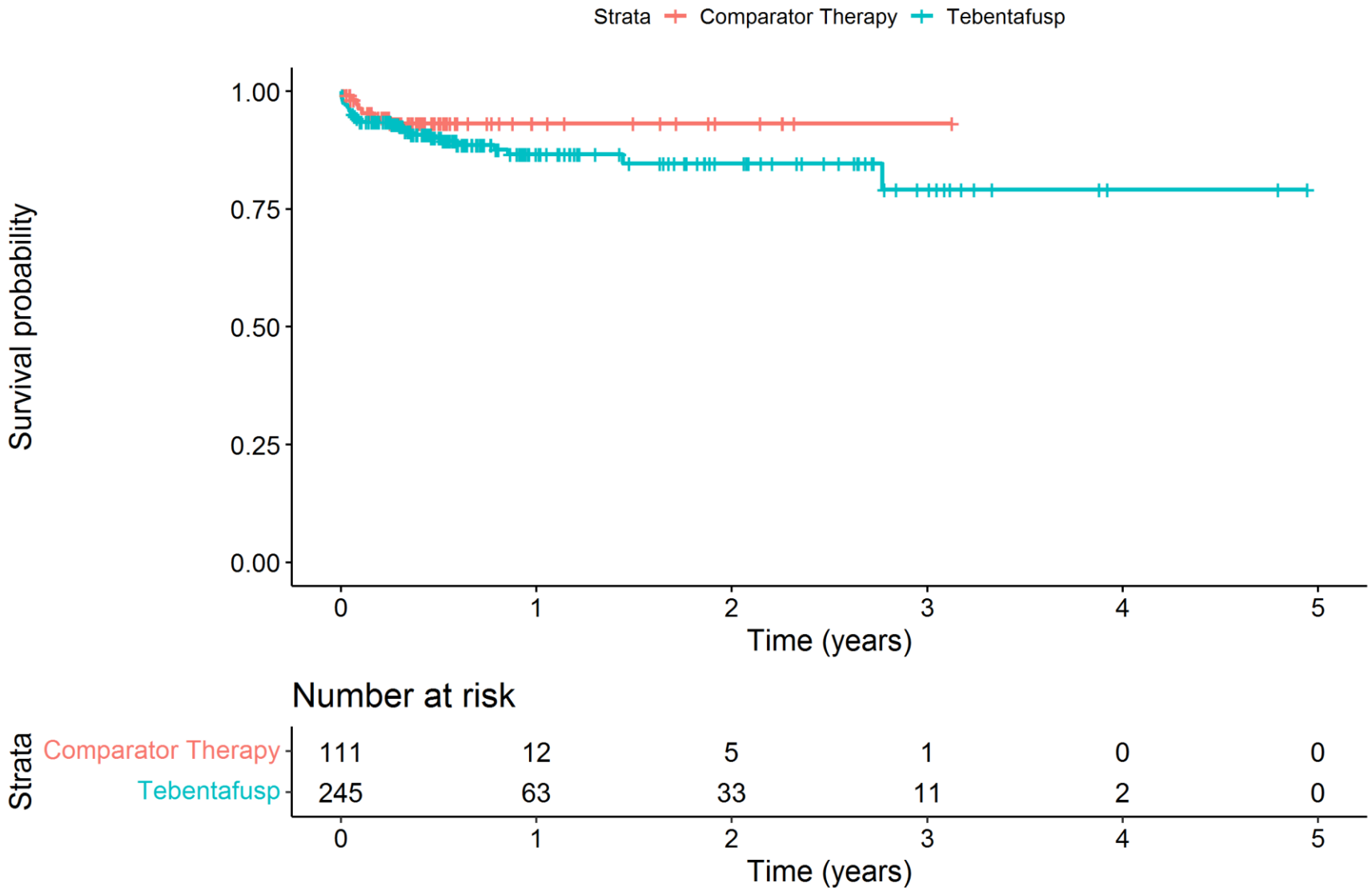
27.26 Arthralgie



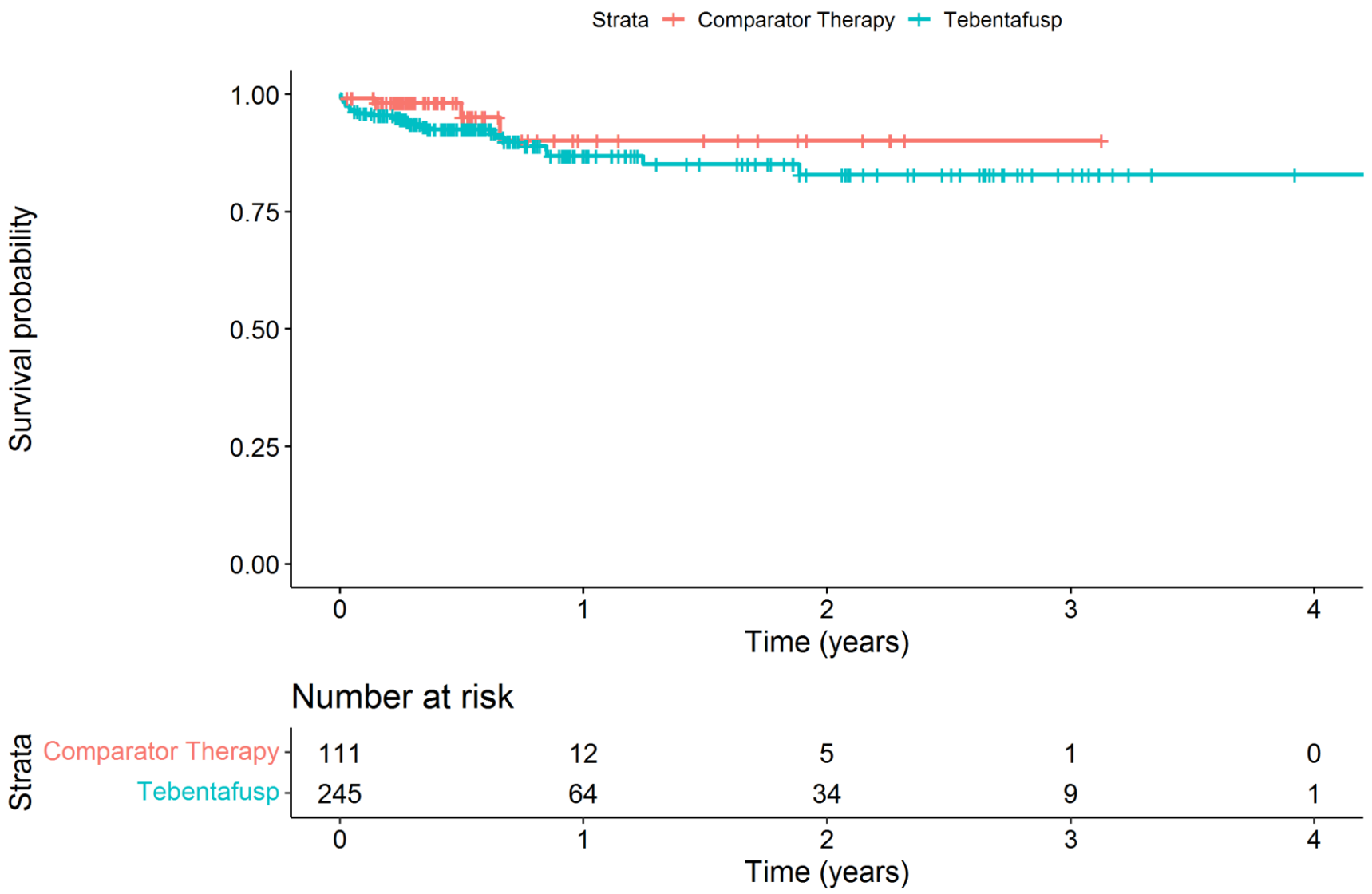
27.27 Rückenschmerzen



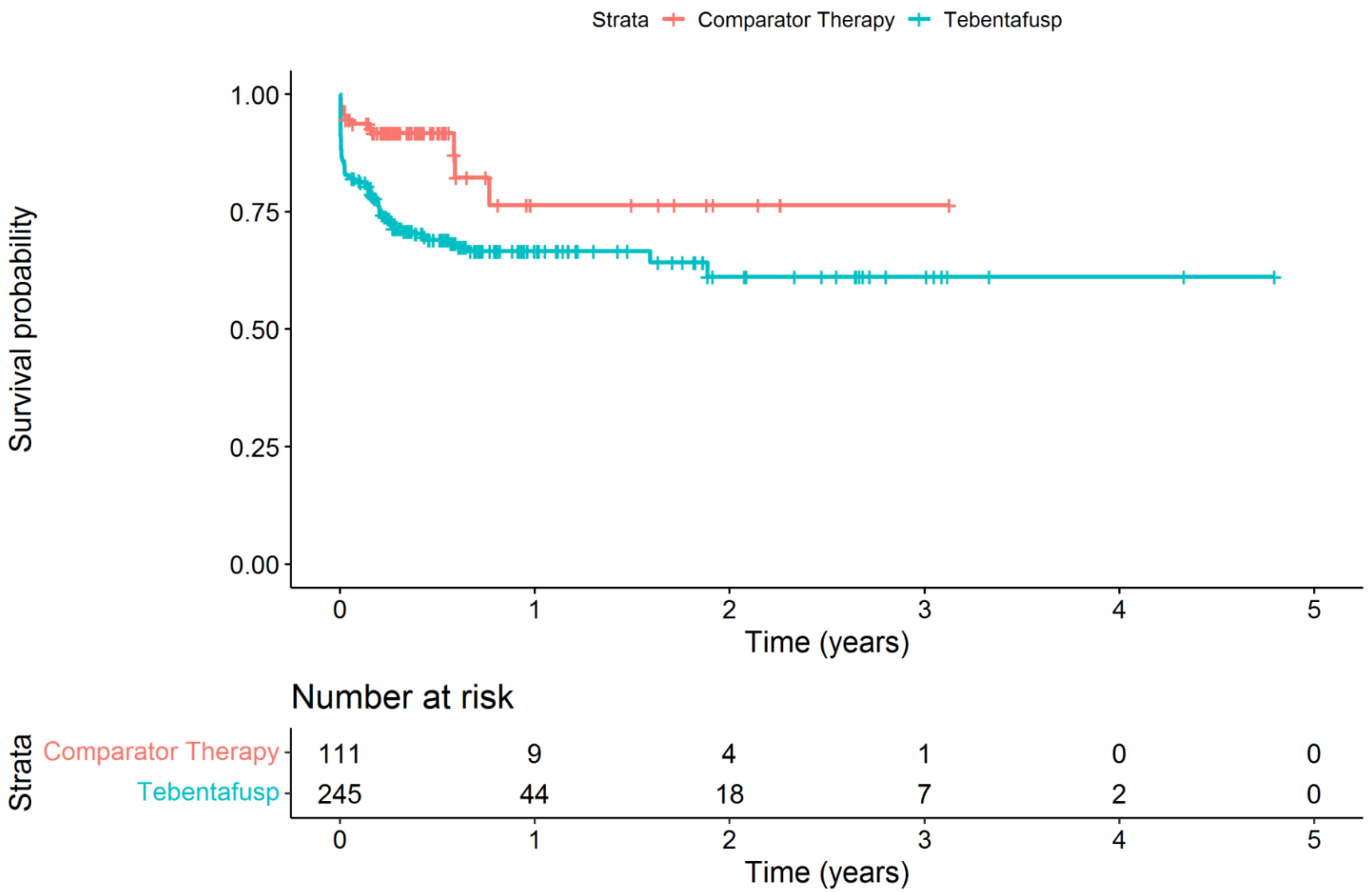
27.28 Myalgie



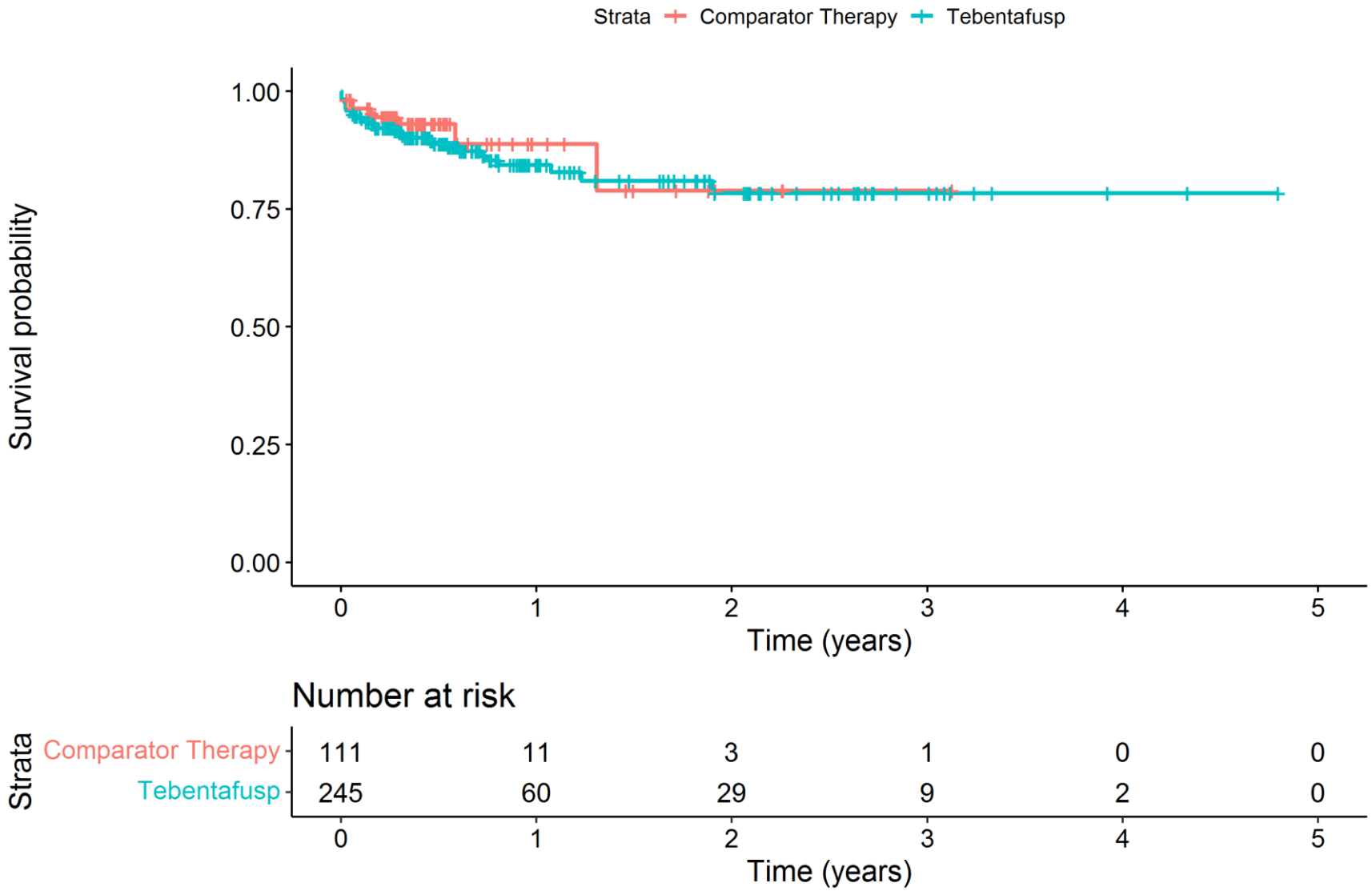
27.29 Schmerzen in den Extremitäten



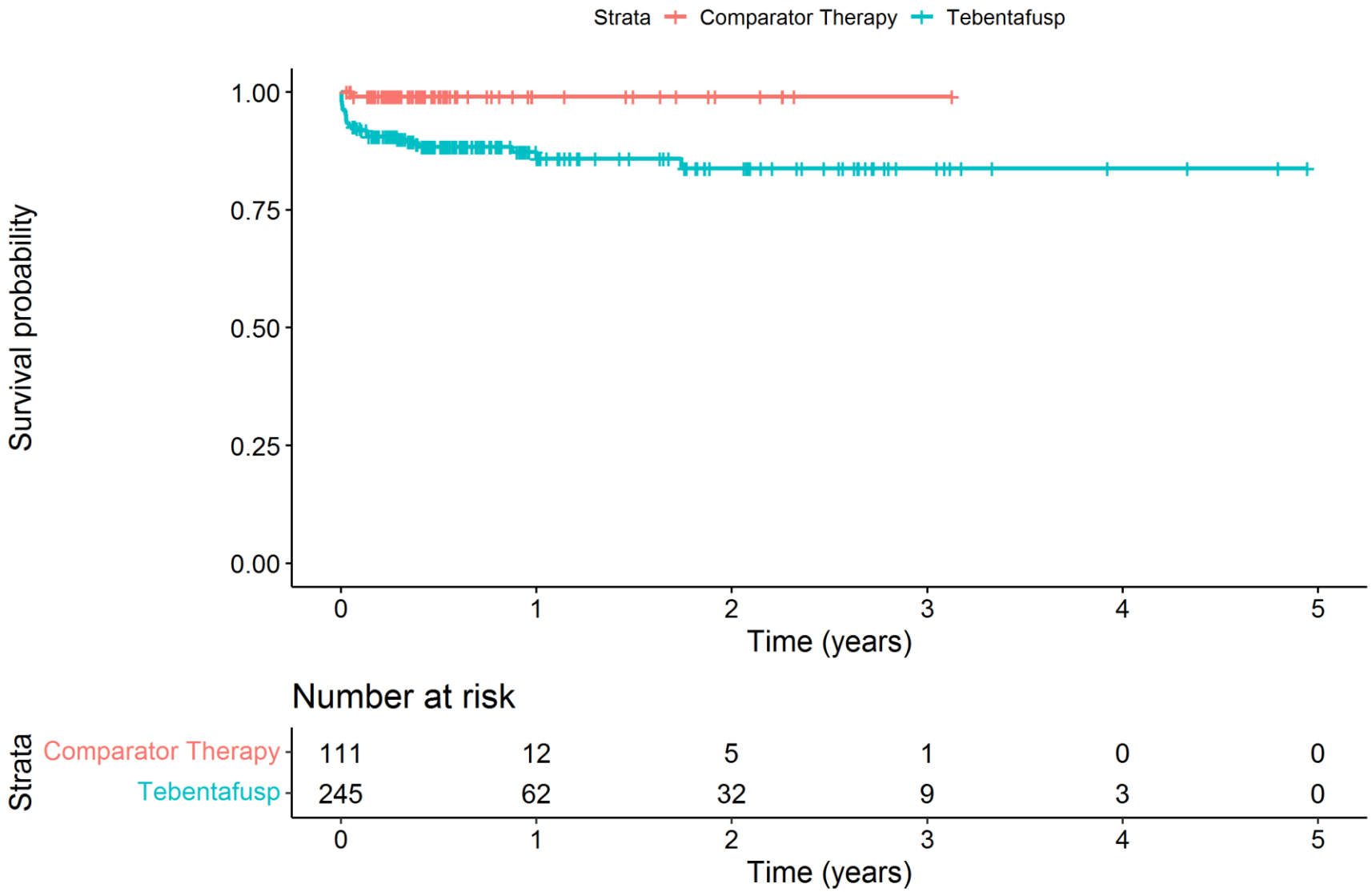
27.30 Kopfschmerzen



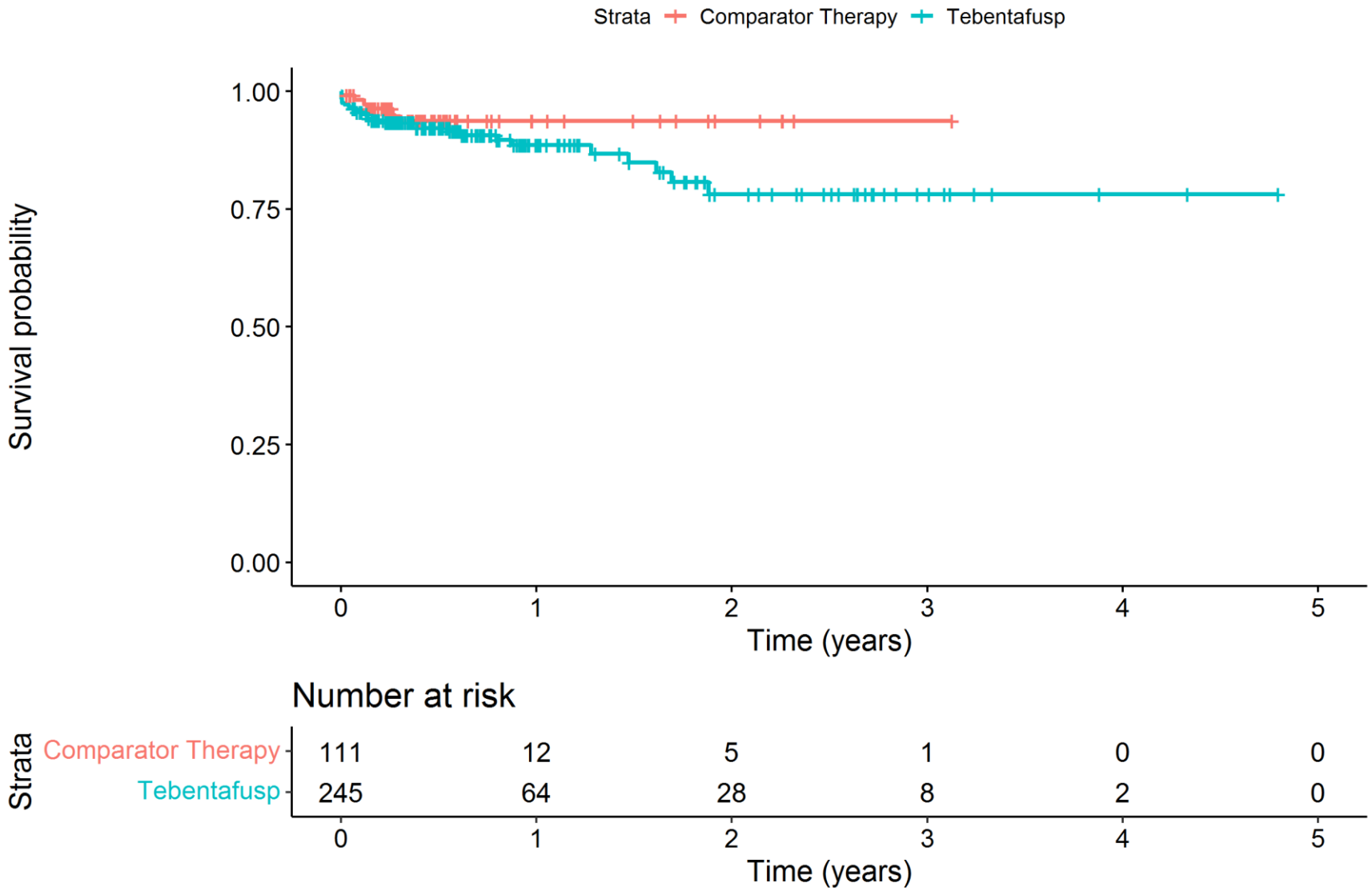
27.31 Schwindel



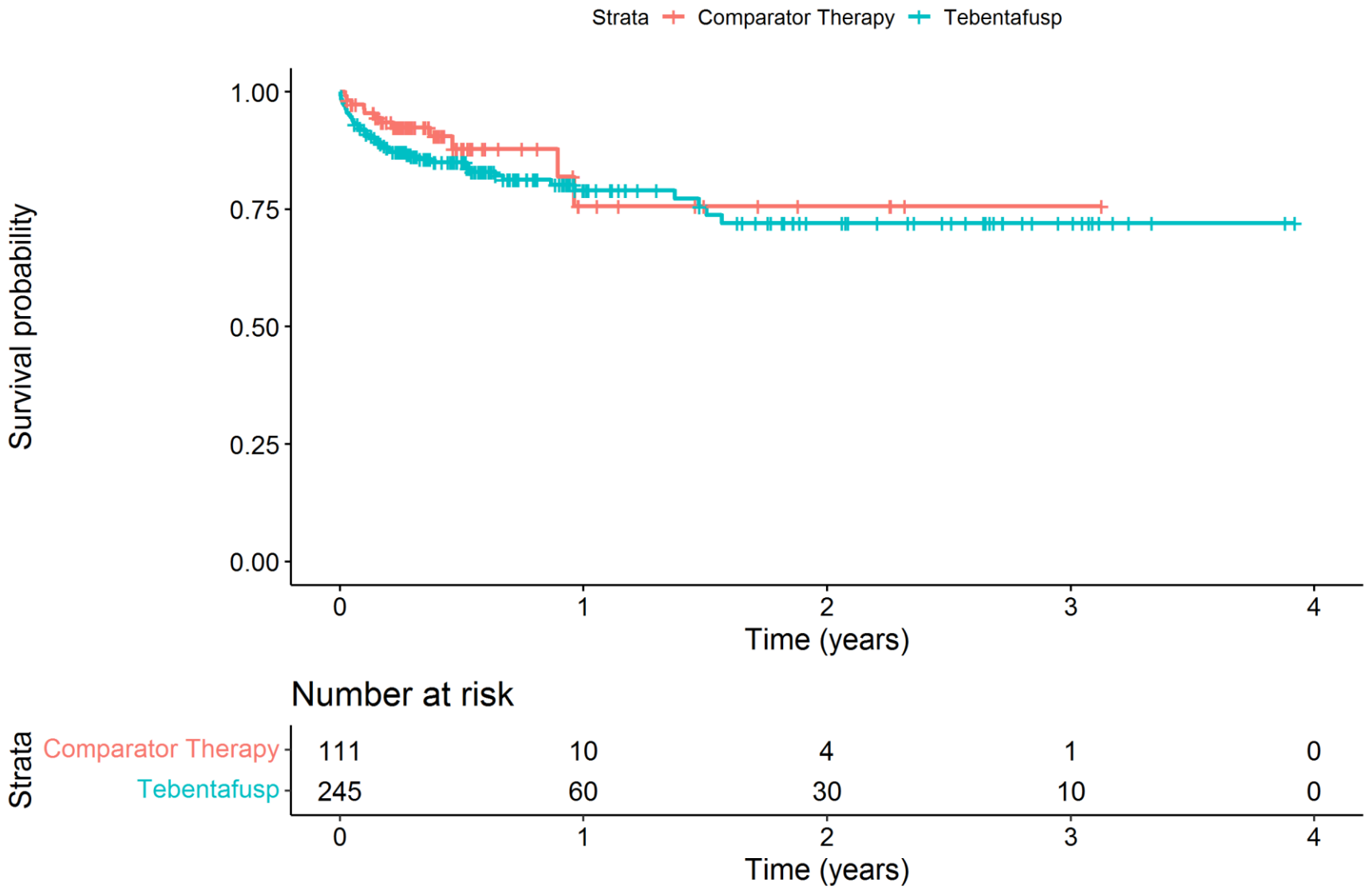
27.32 Parästhesie



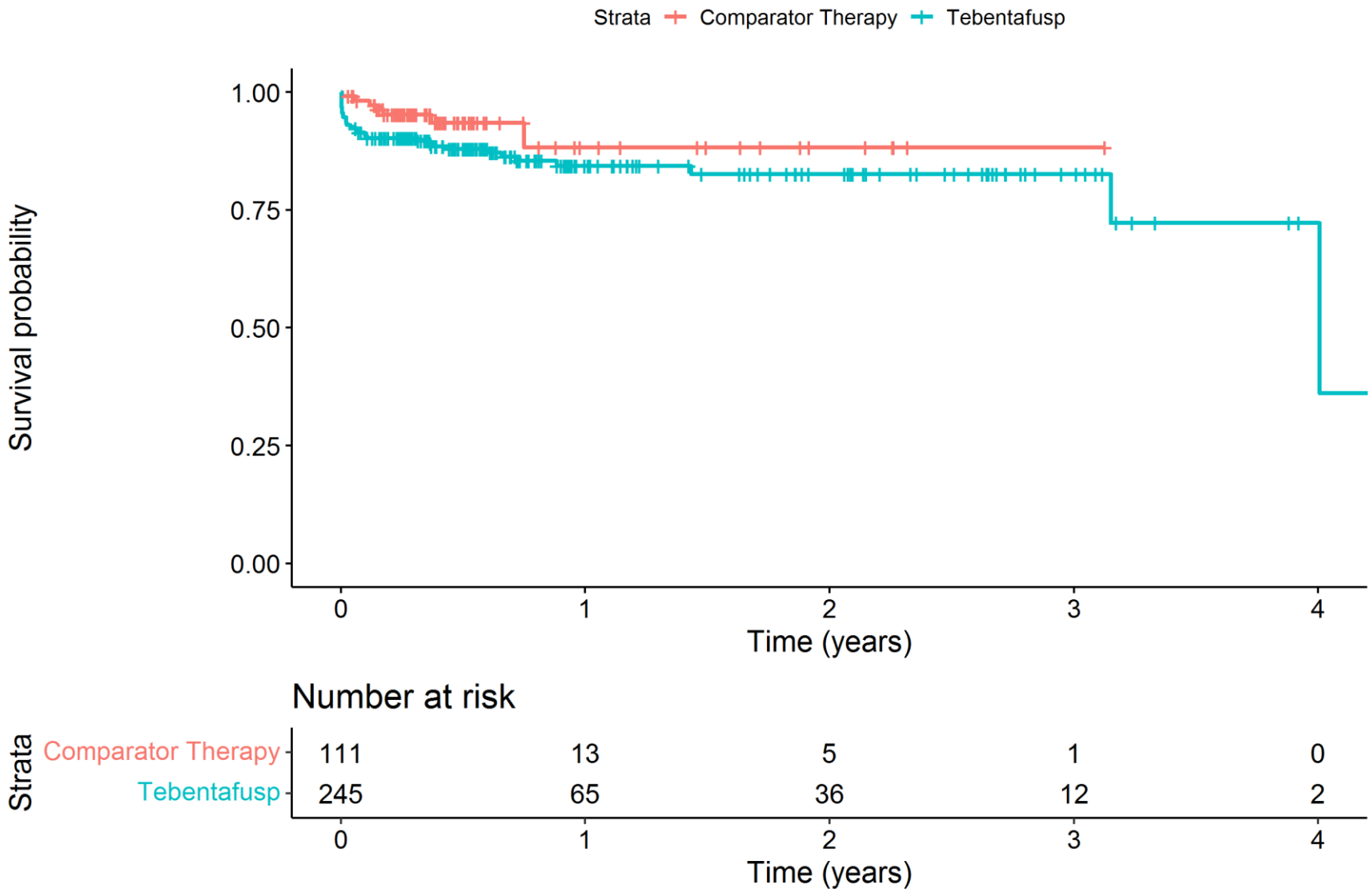
27.33 Schlaflosigkeit



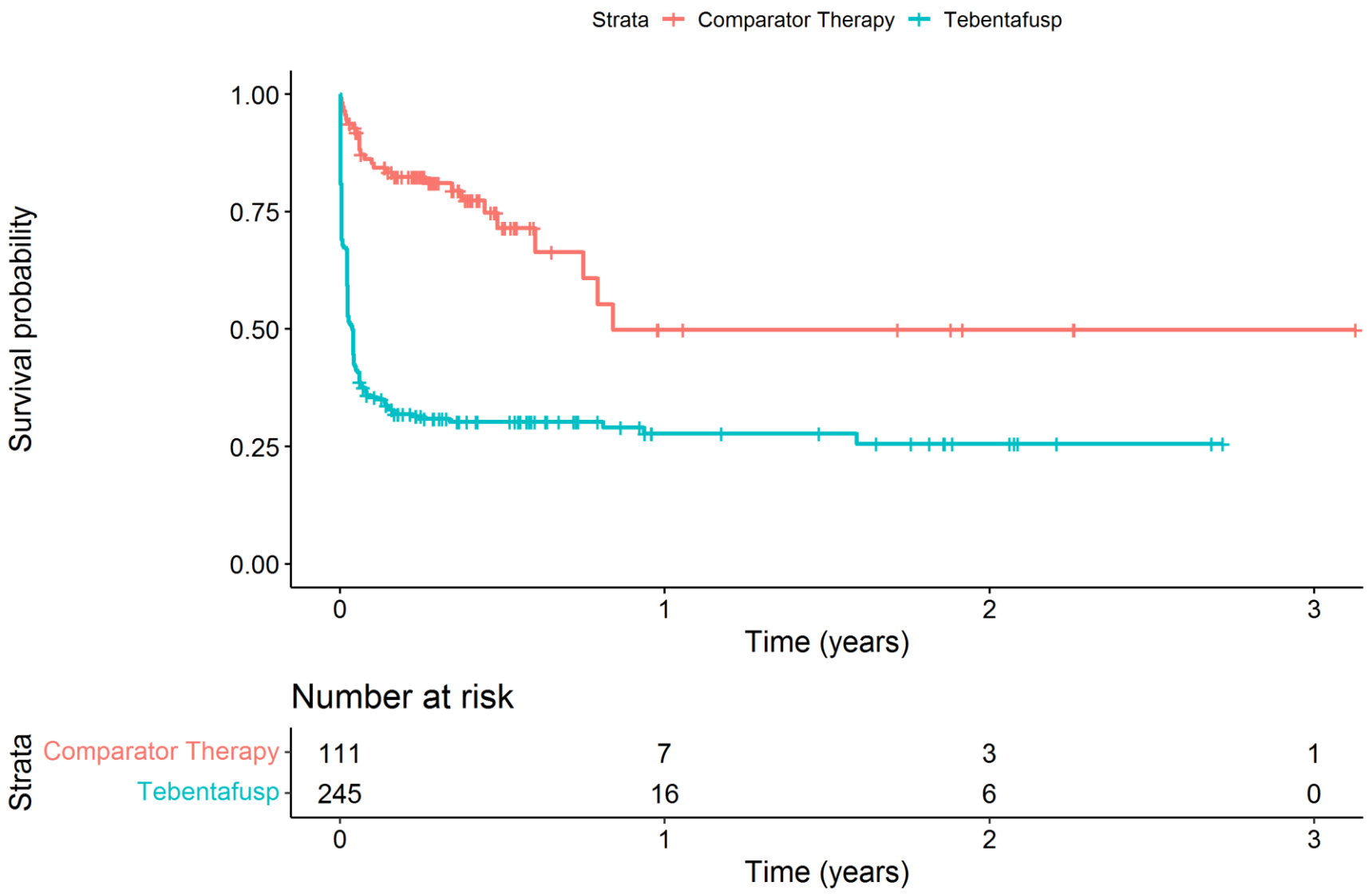
27.34 Husten


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
4
1
0
245
60
30
10
0
0
1
2
3
4
Time (years)

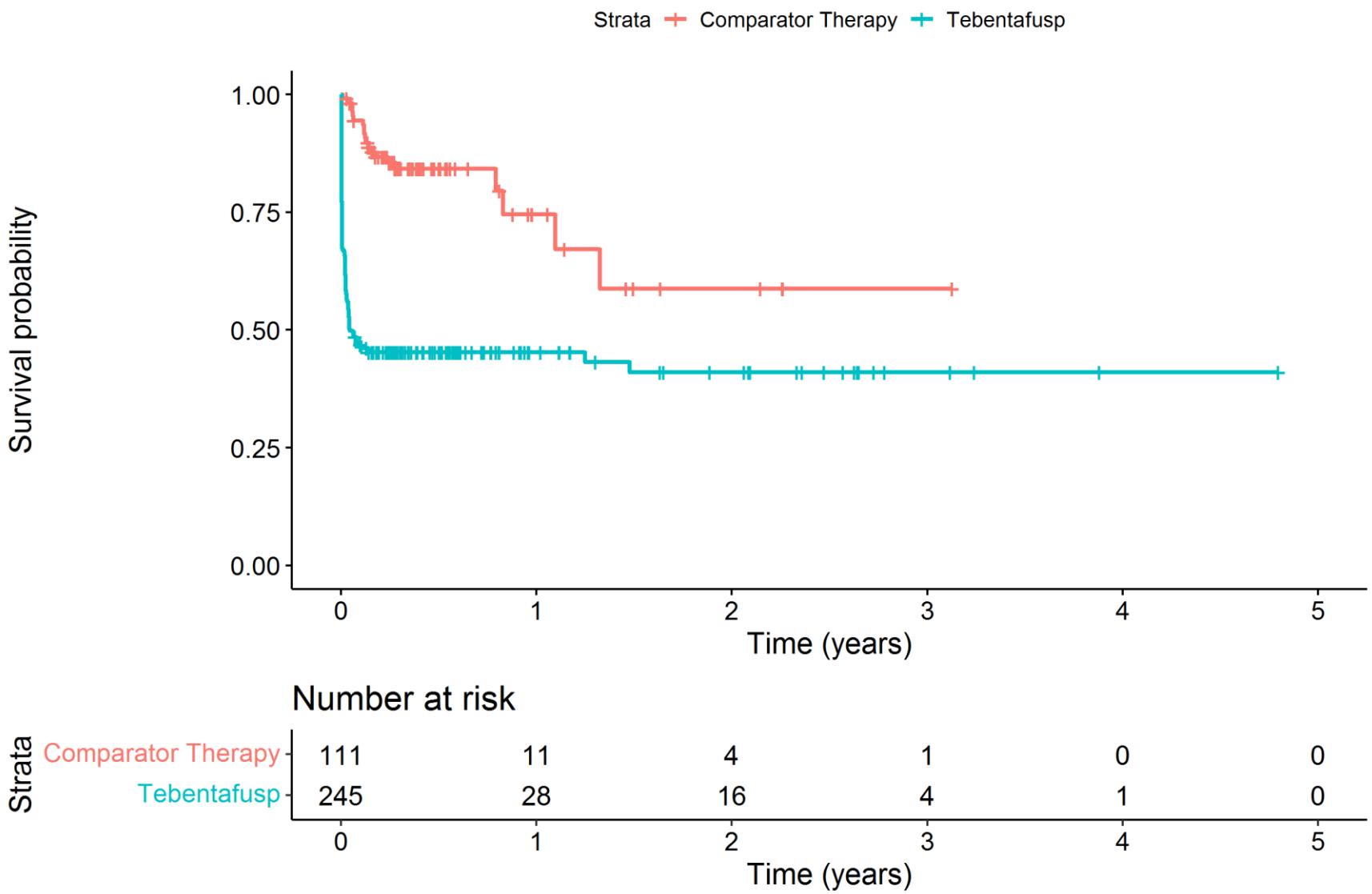
27.35 Dyspnoe



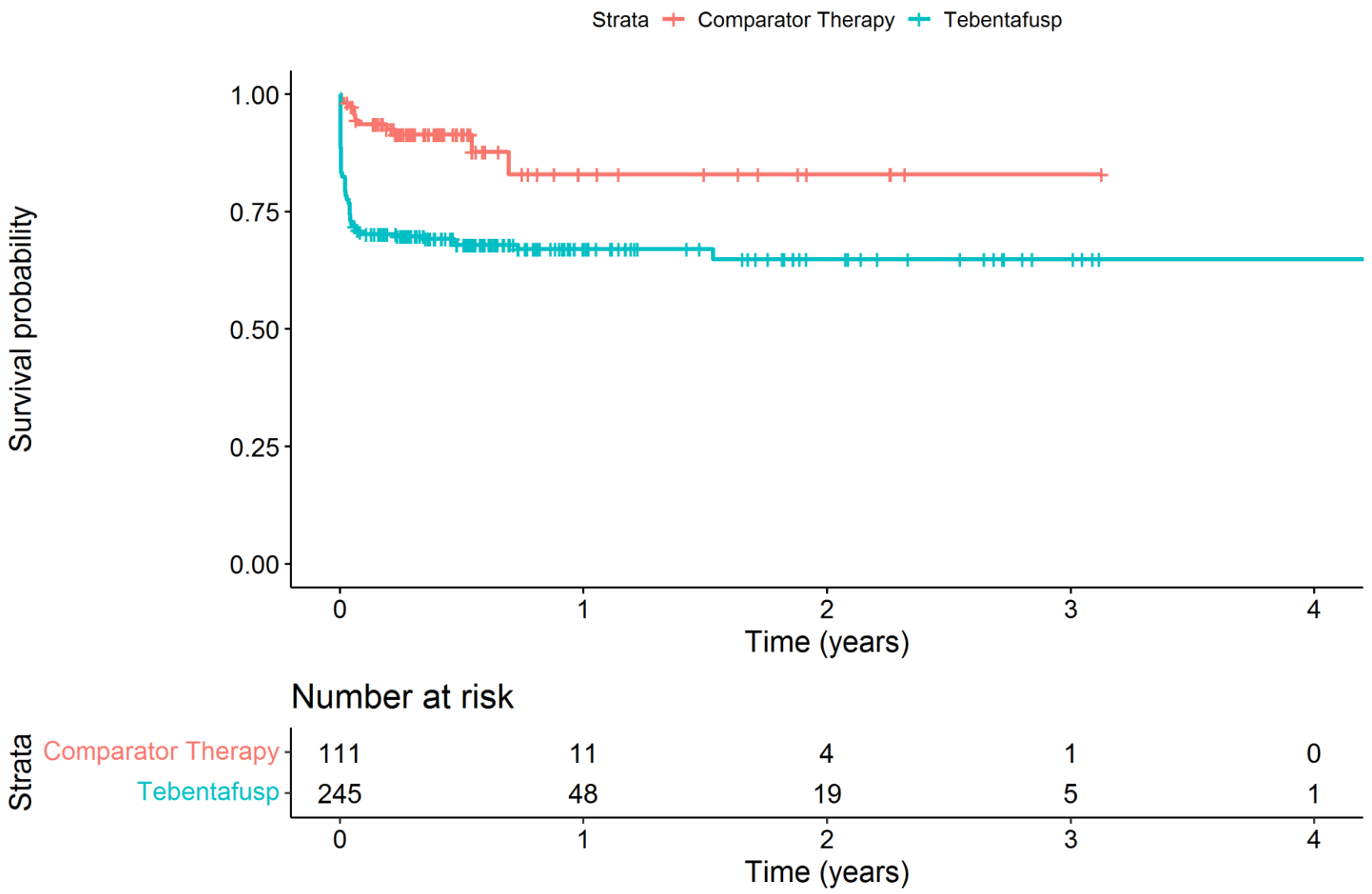
27.36 Pruritus



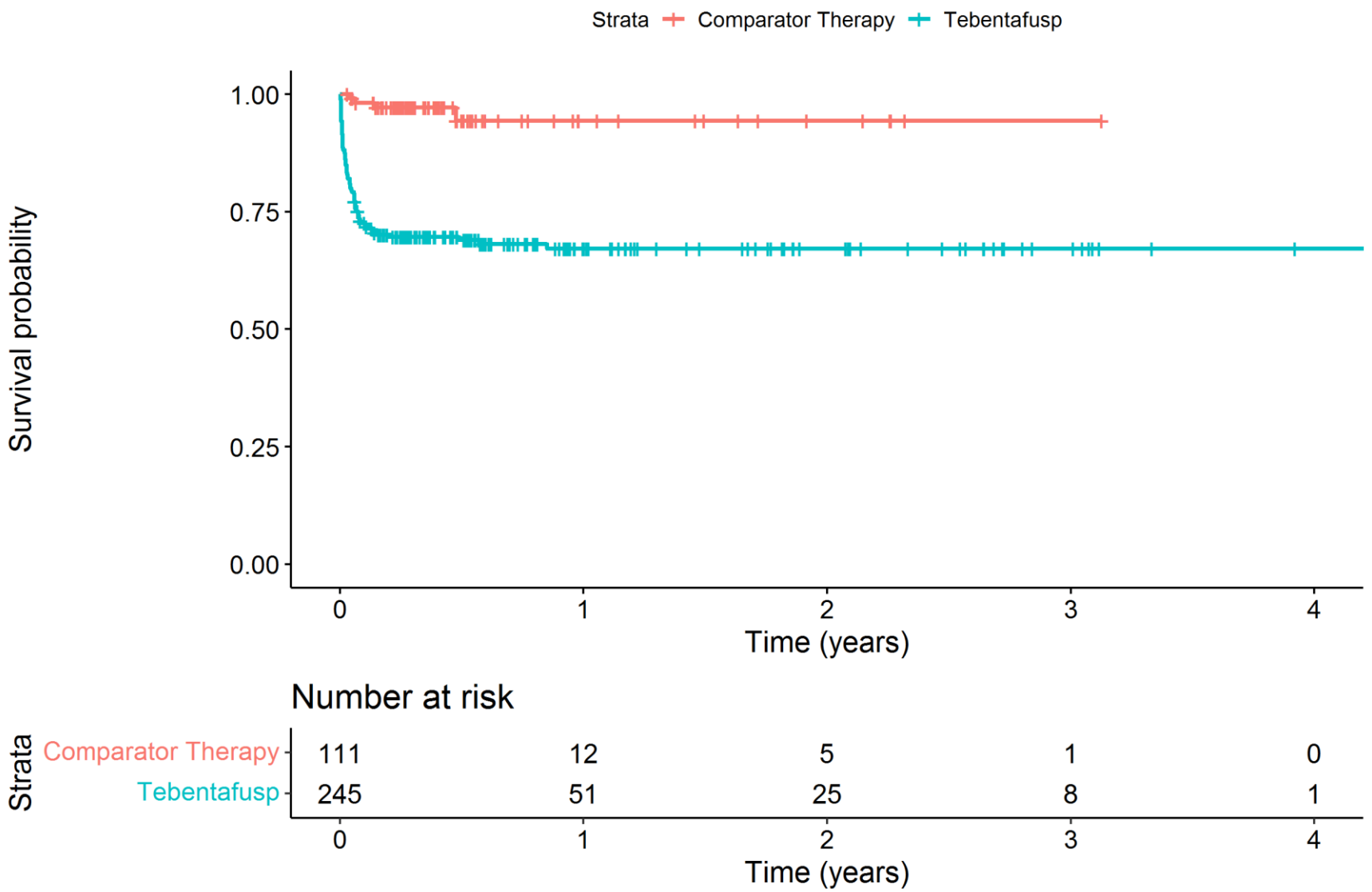
27.37 Hautausschlag



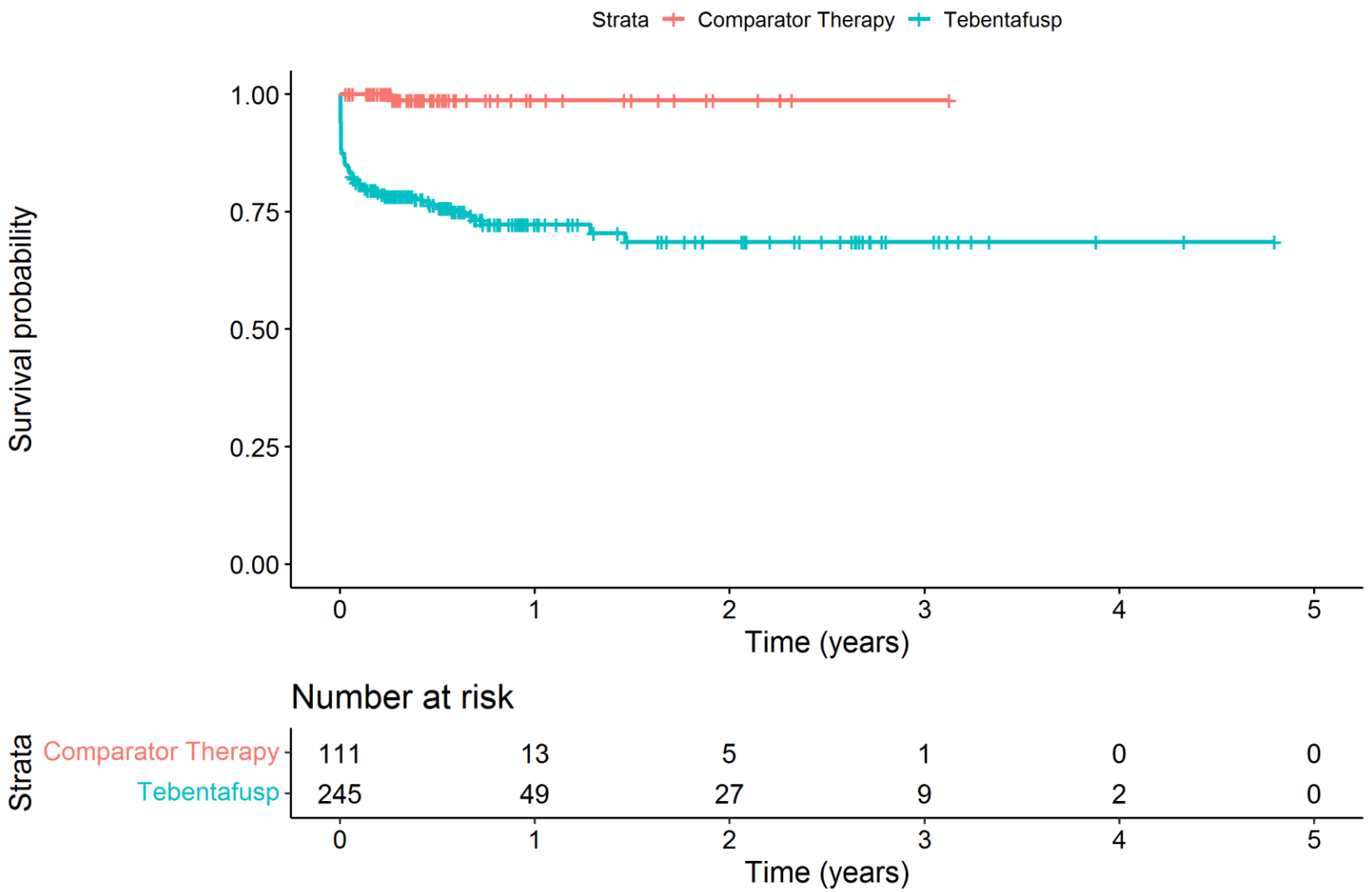
27.38 Makulo-papulöser Hautausschlag



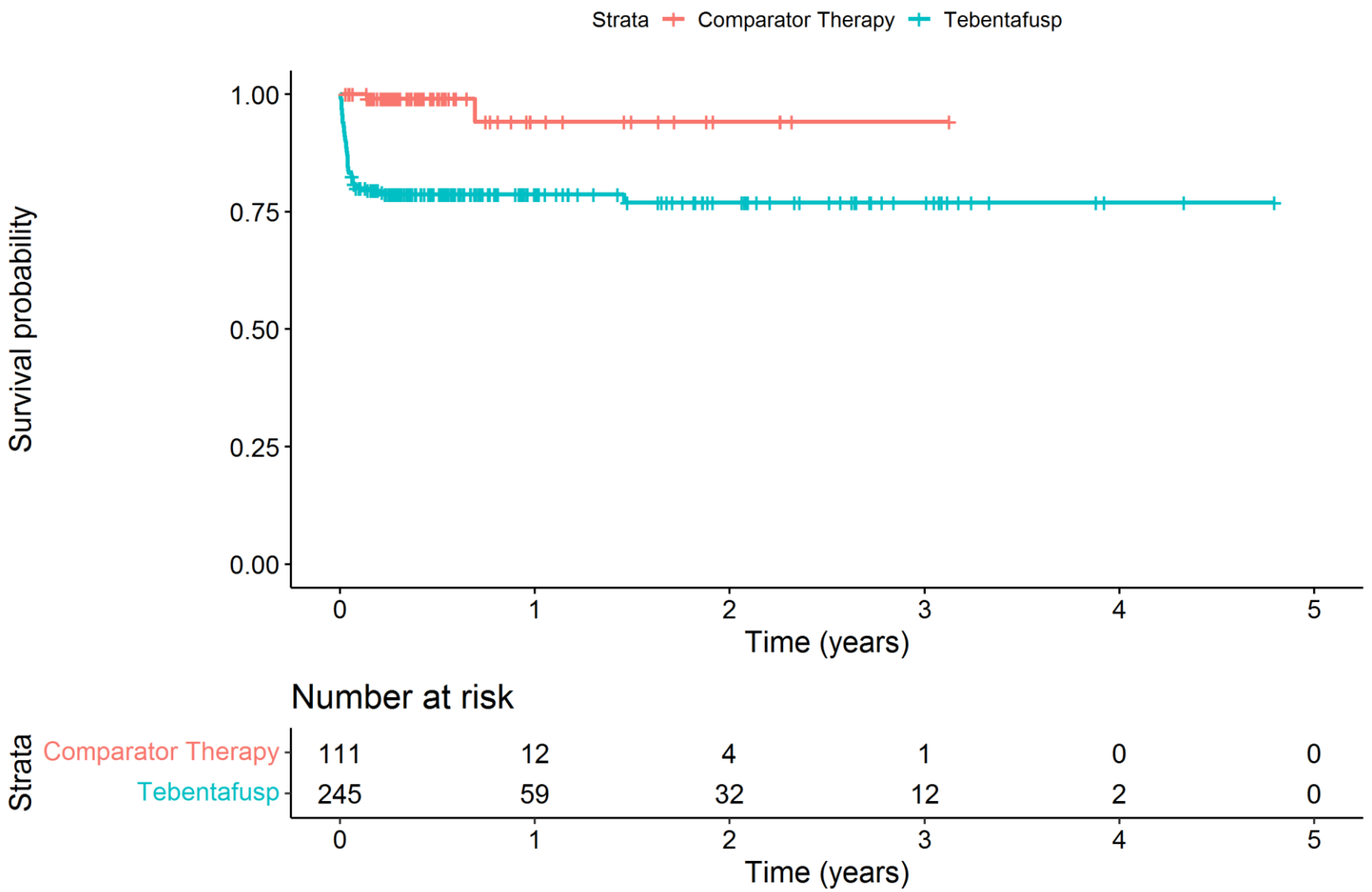
27.39 Trockene Haut



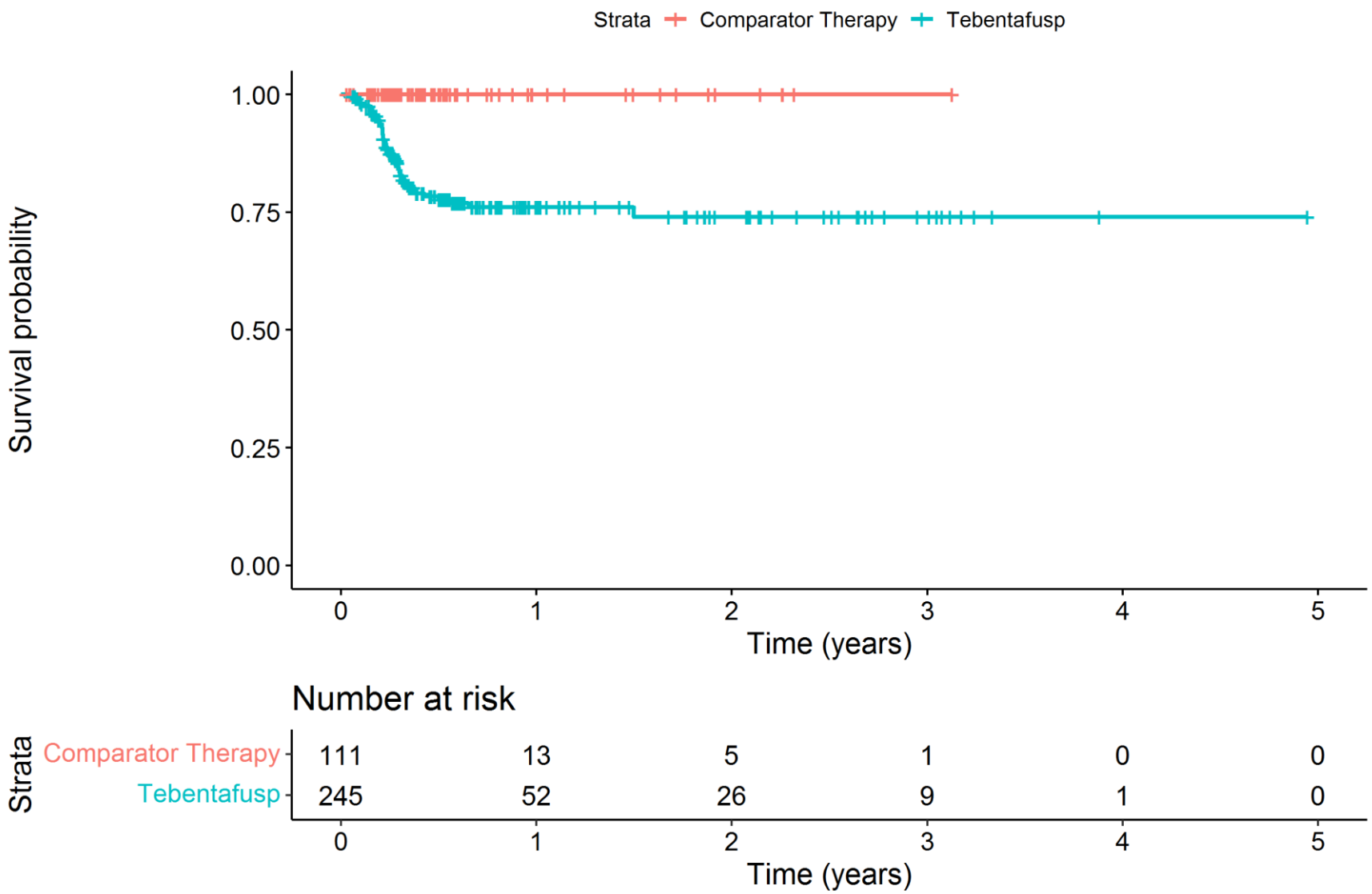
27.40 Erythem



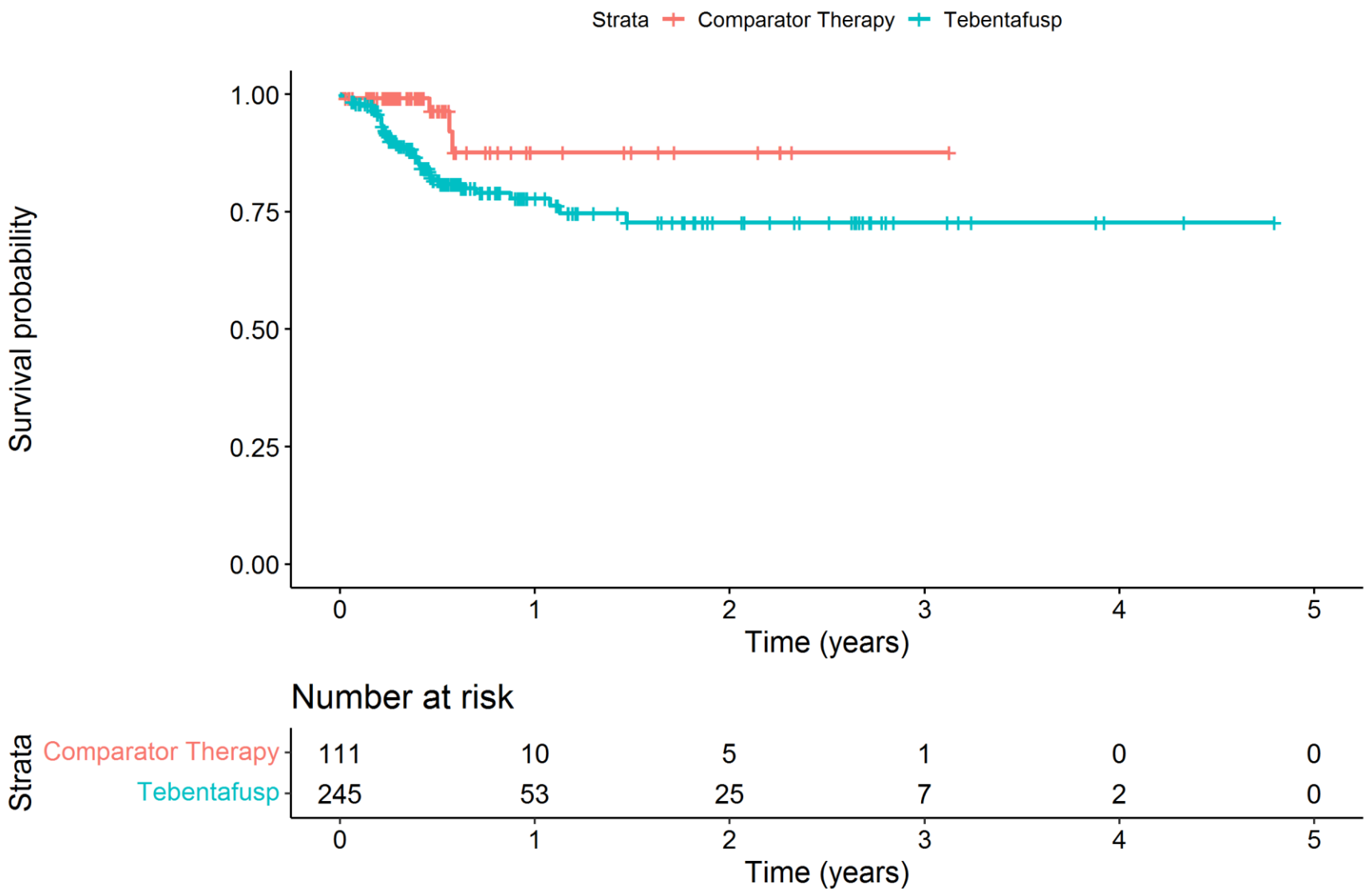
27.41 Hautabschälung



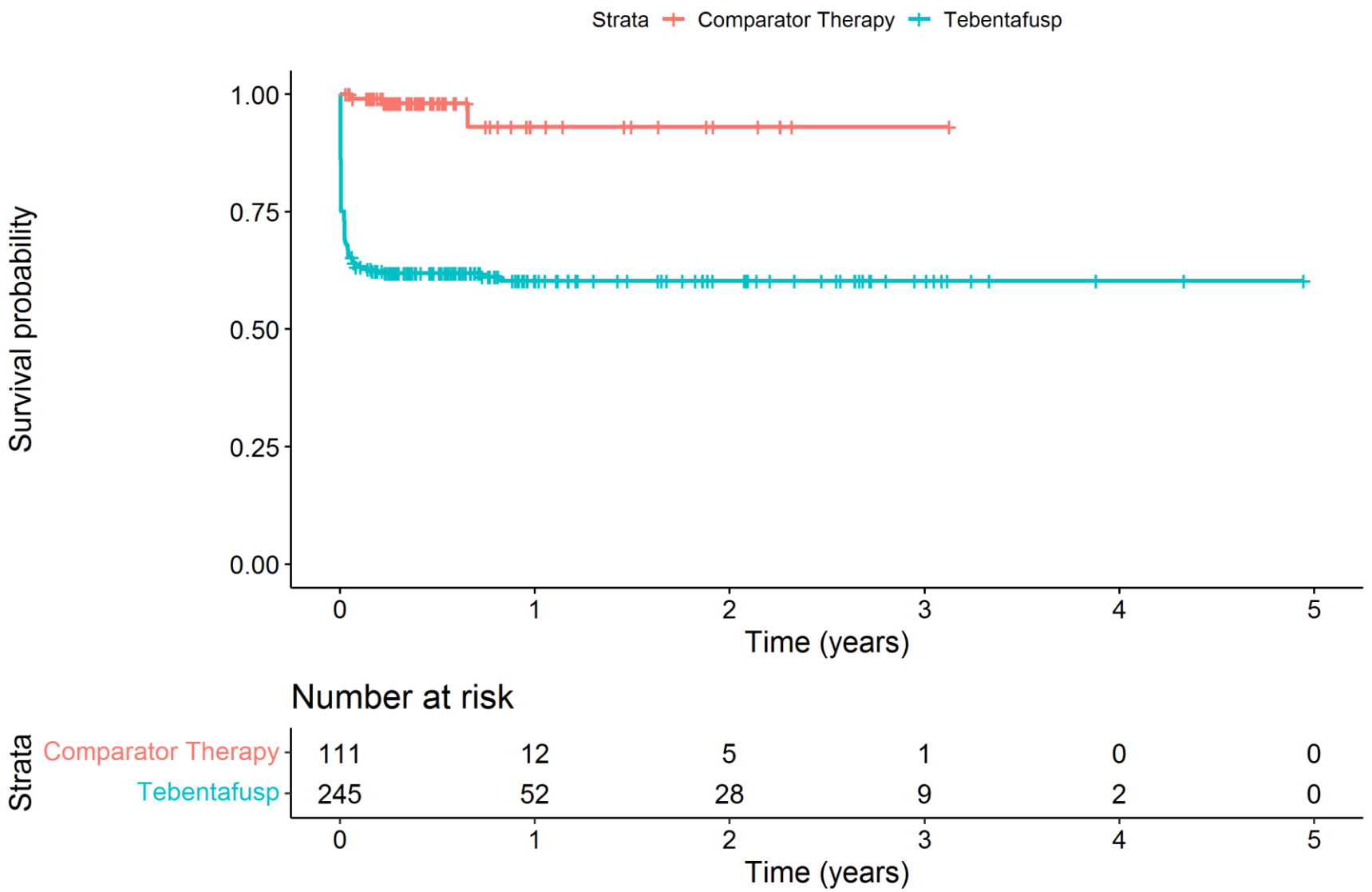
27.42 Veränderung der Haarfarbe



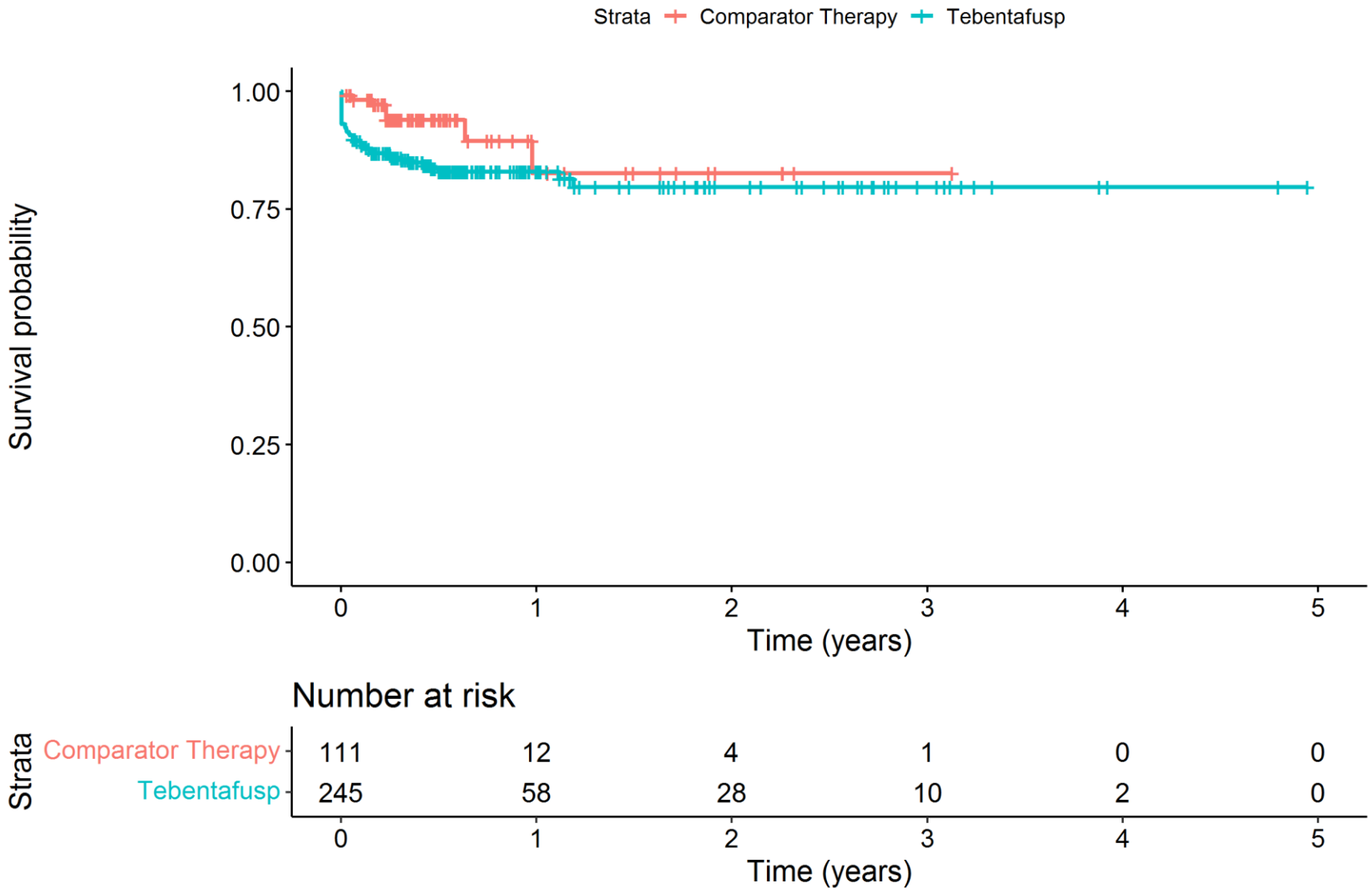
27.43 Vitiligo



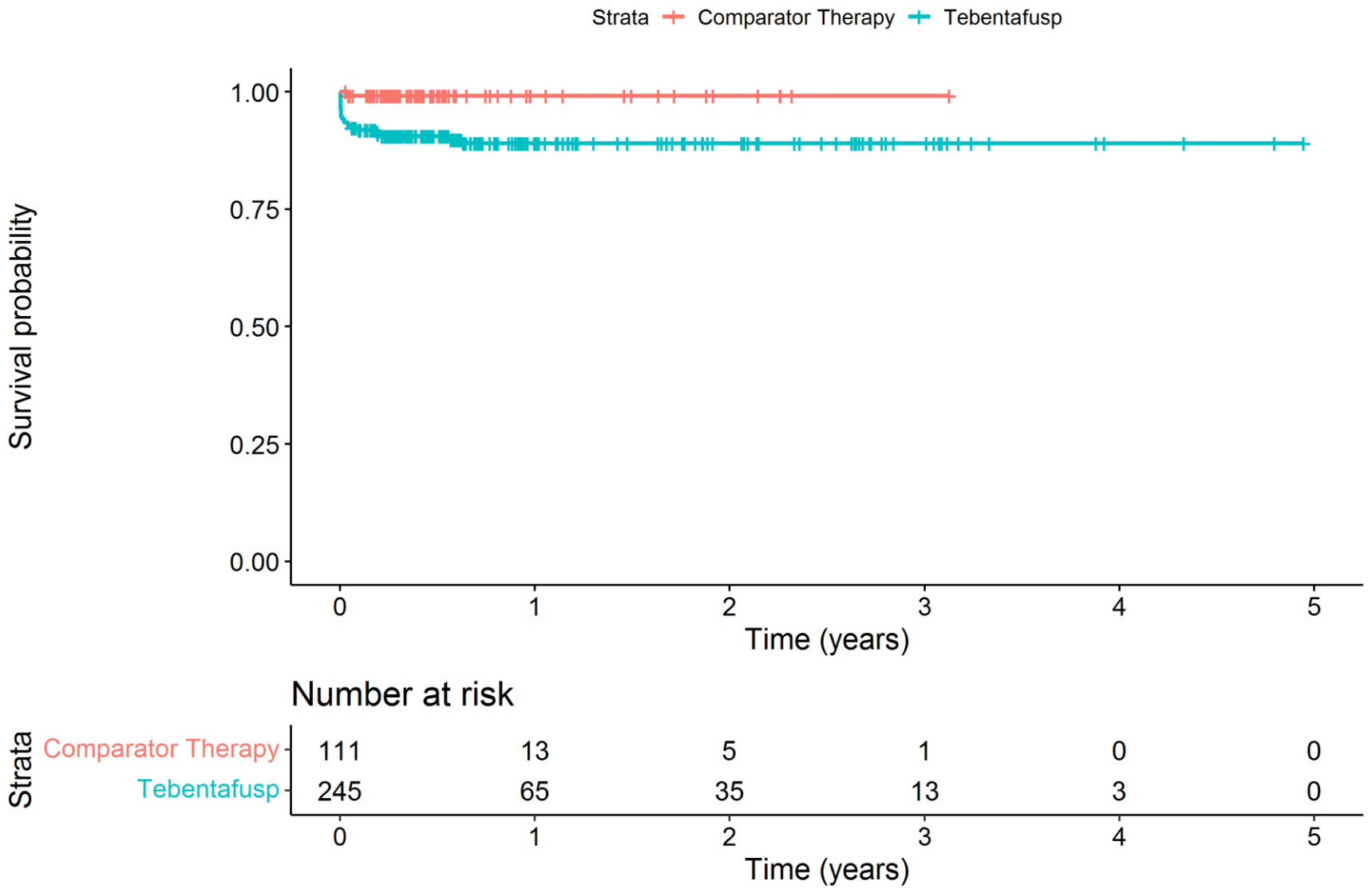
27.44 Hypotonie



27.45 Hypertonie

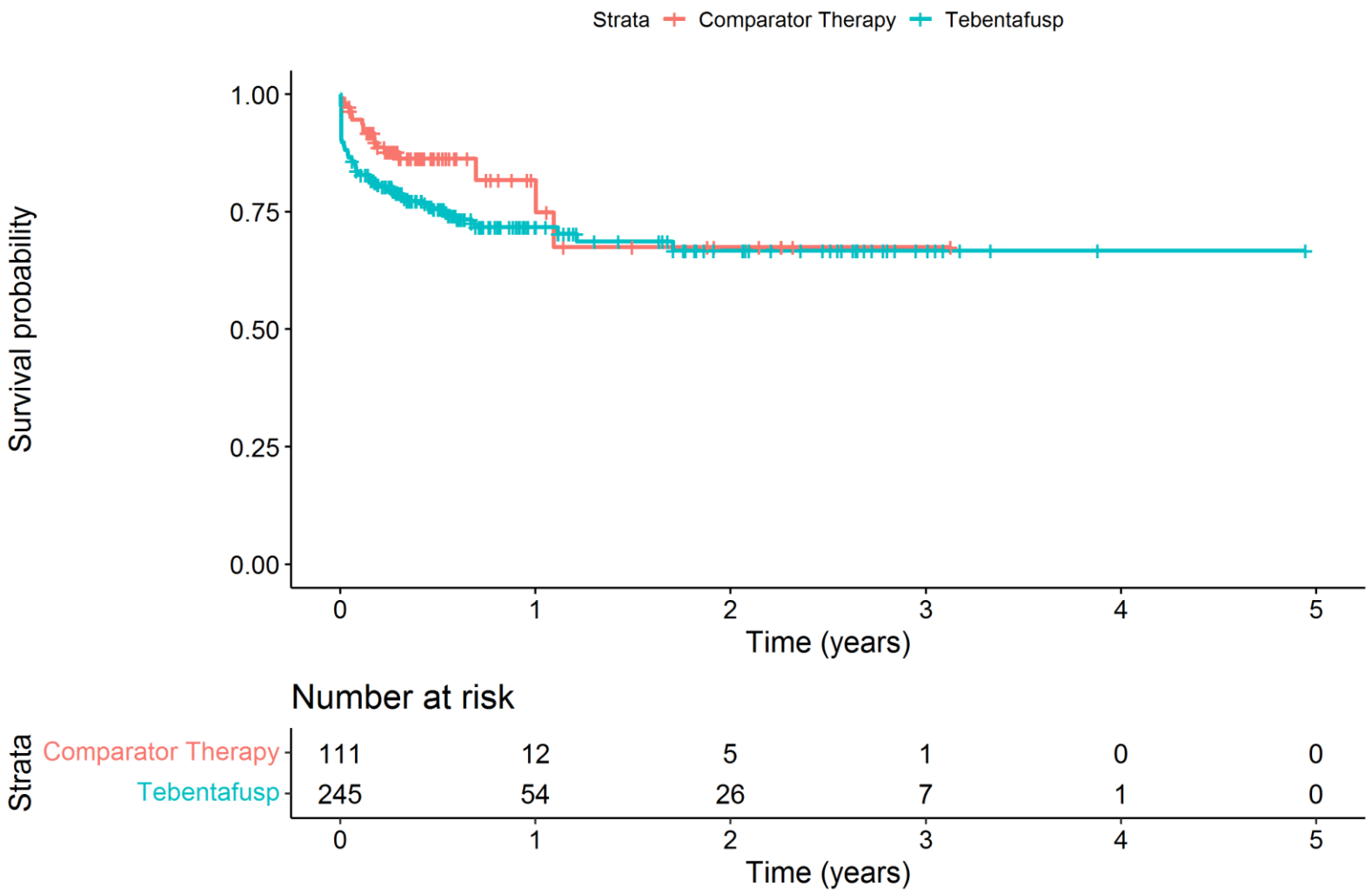


27.46 Hautrötung

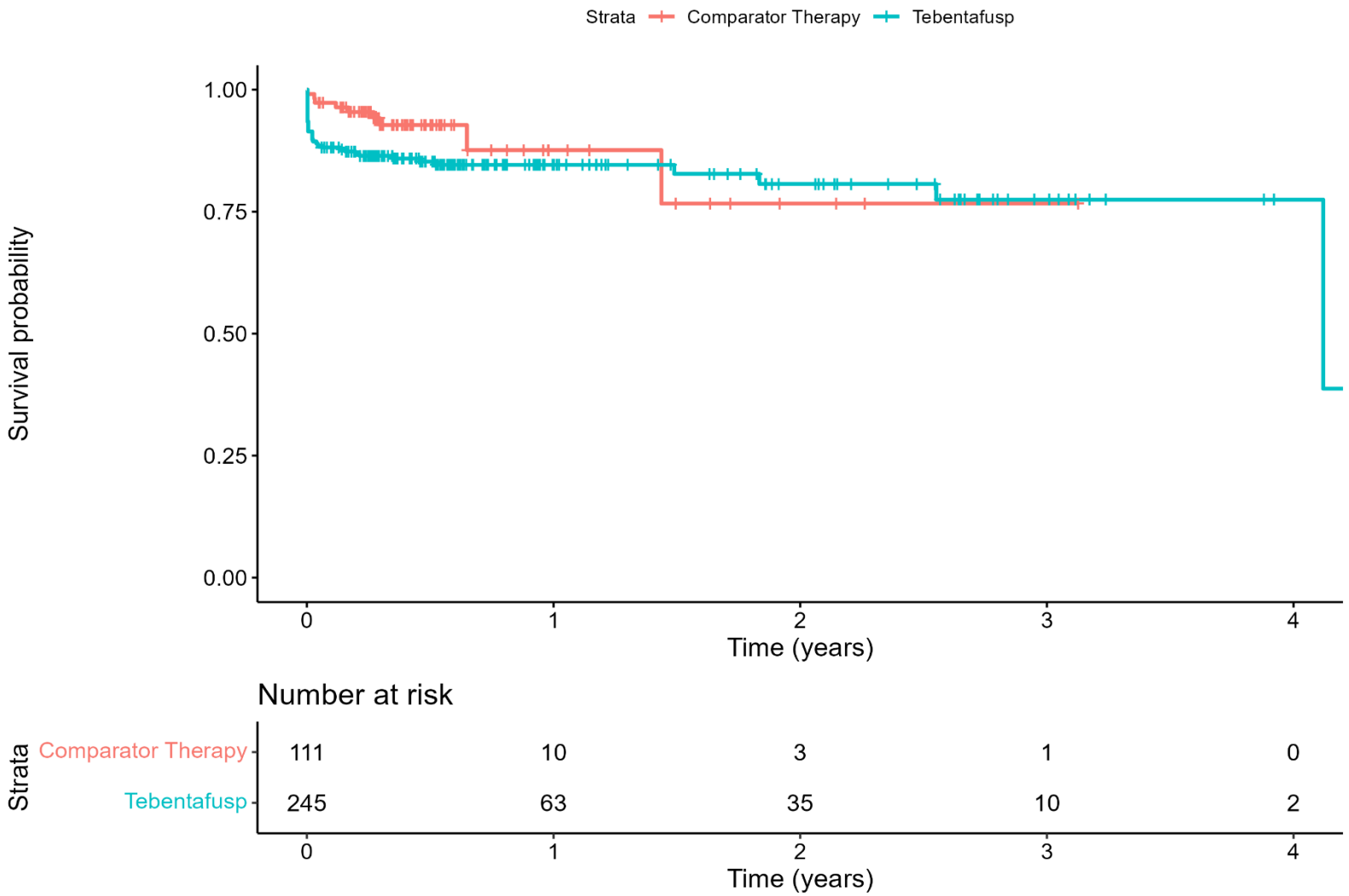


28 UEs (SOC), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten

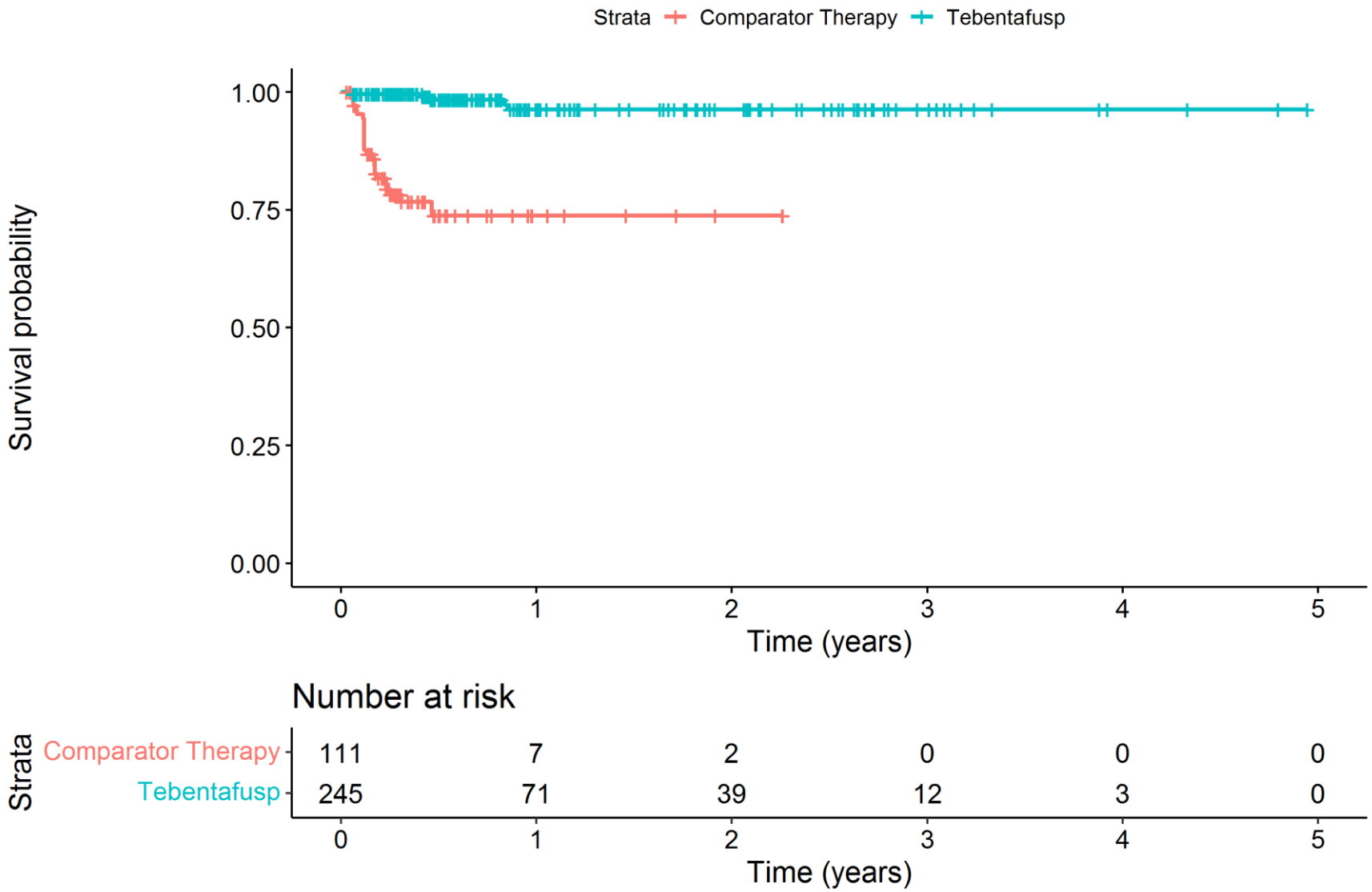
28.1 Erkrankungen des Blutes und des Lymphsystems



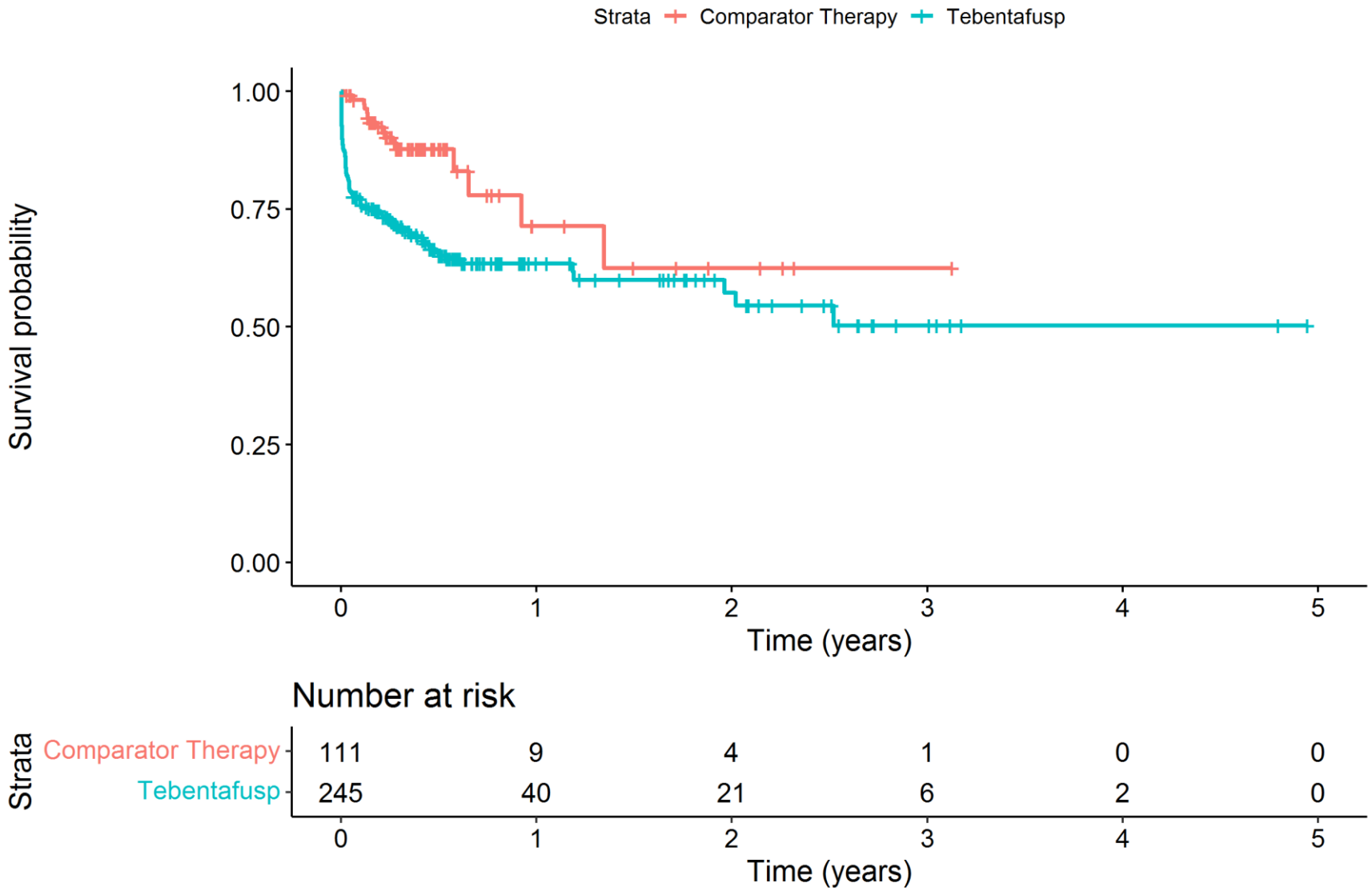
28.2 Herzerkrankungen



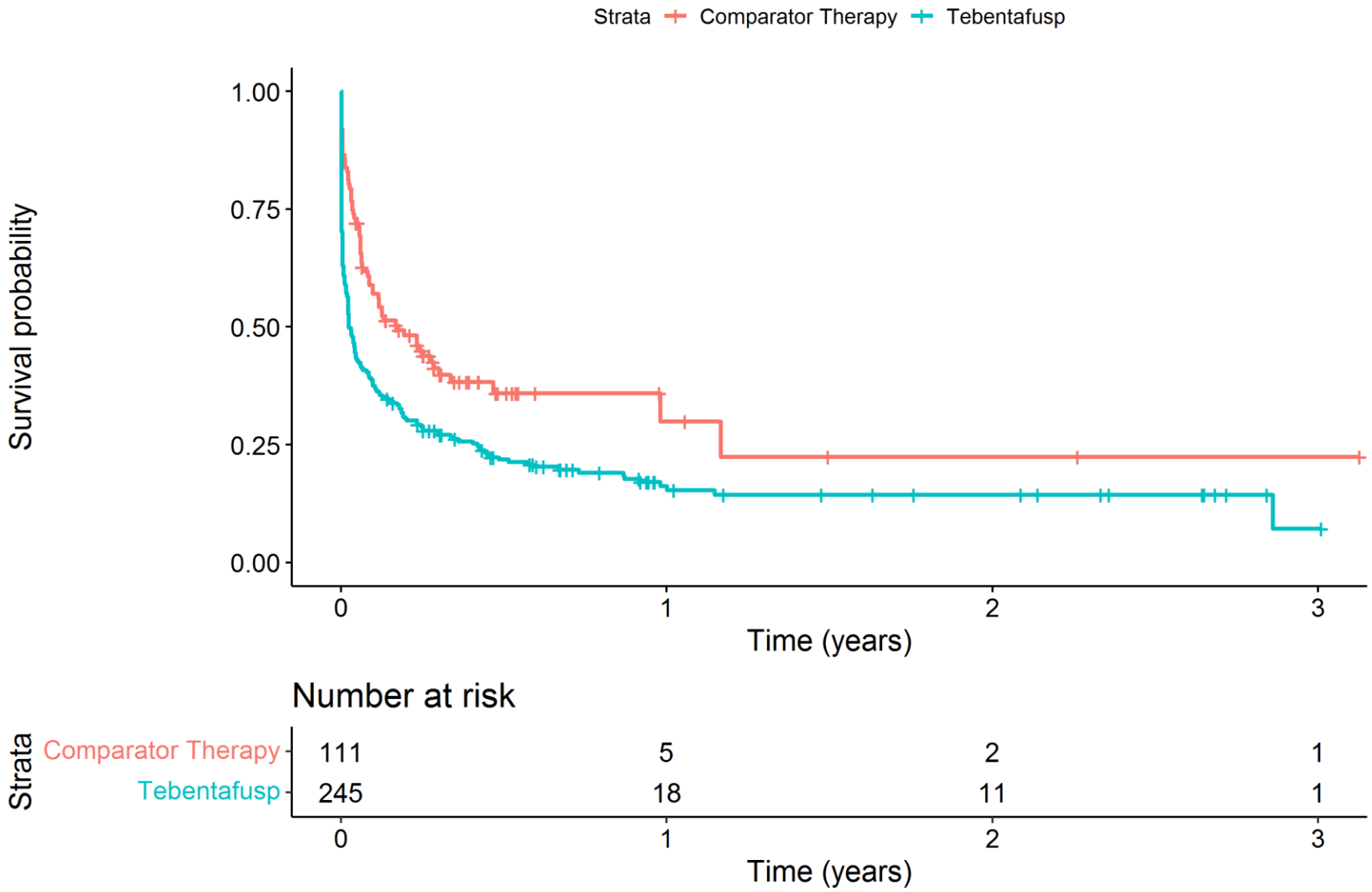
28.3 Endokrine Erkrankungen



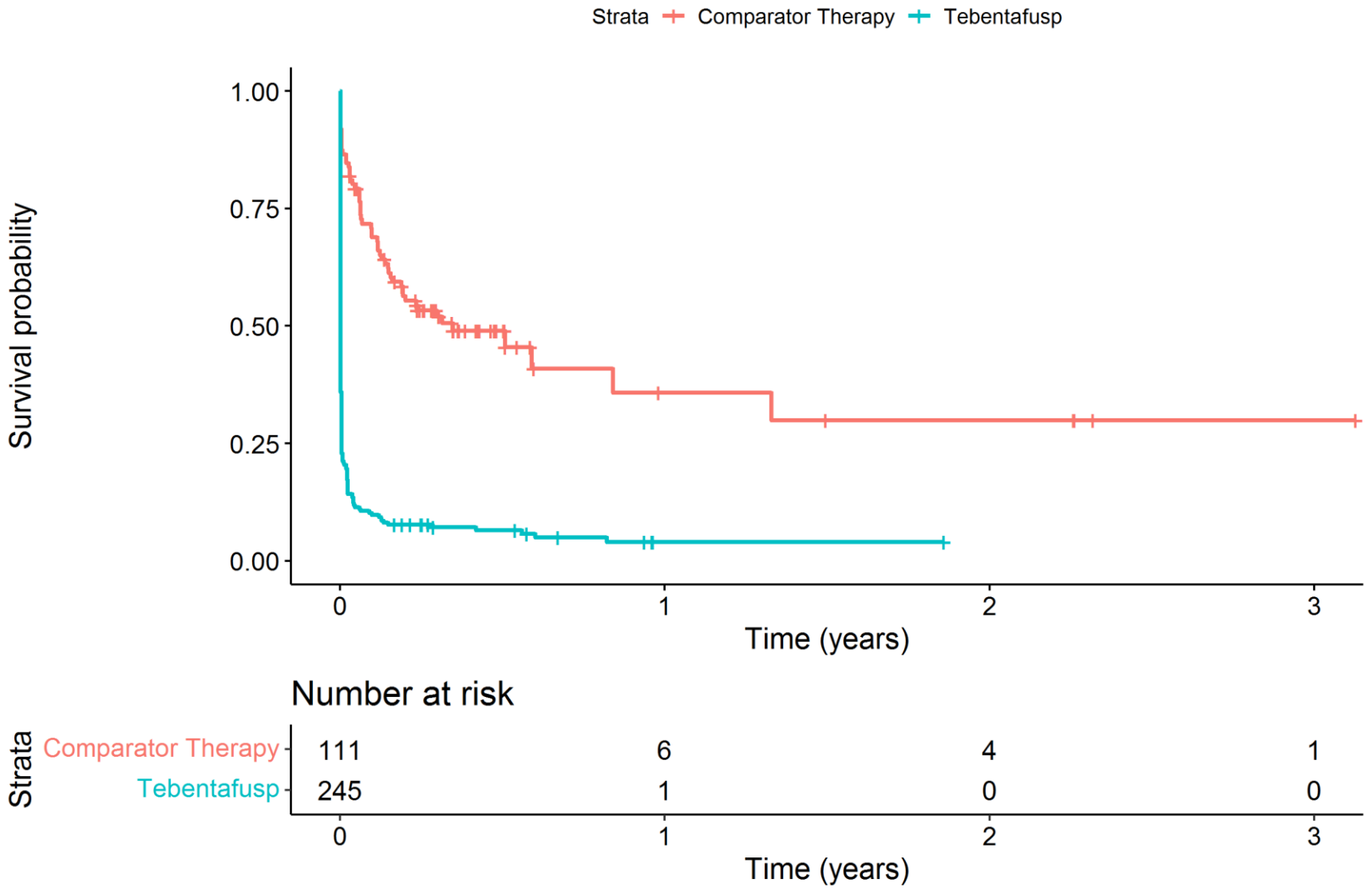
28.4 Augenerkrankungen



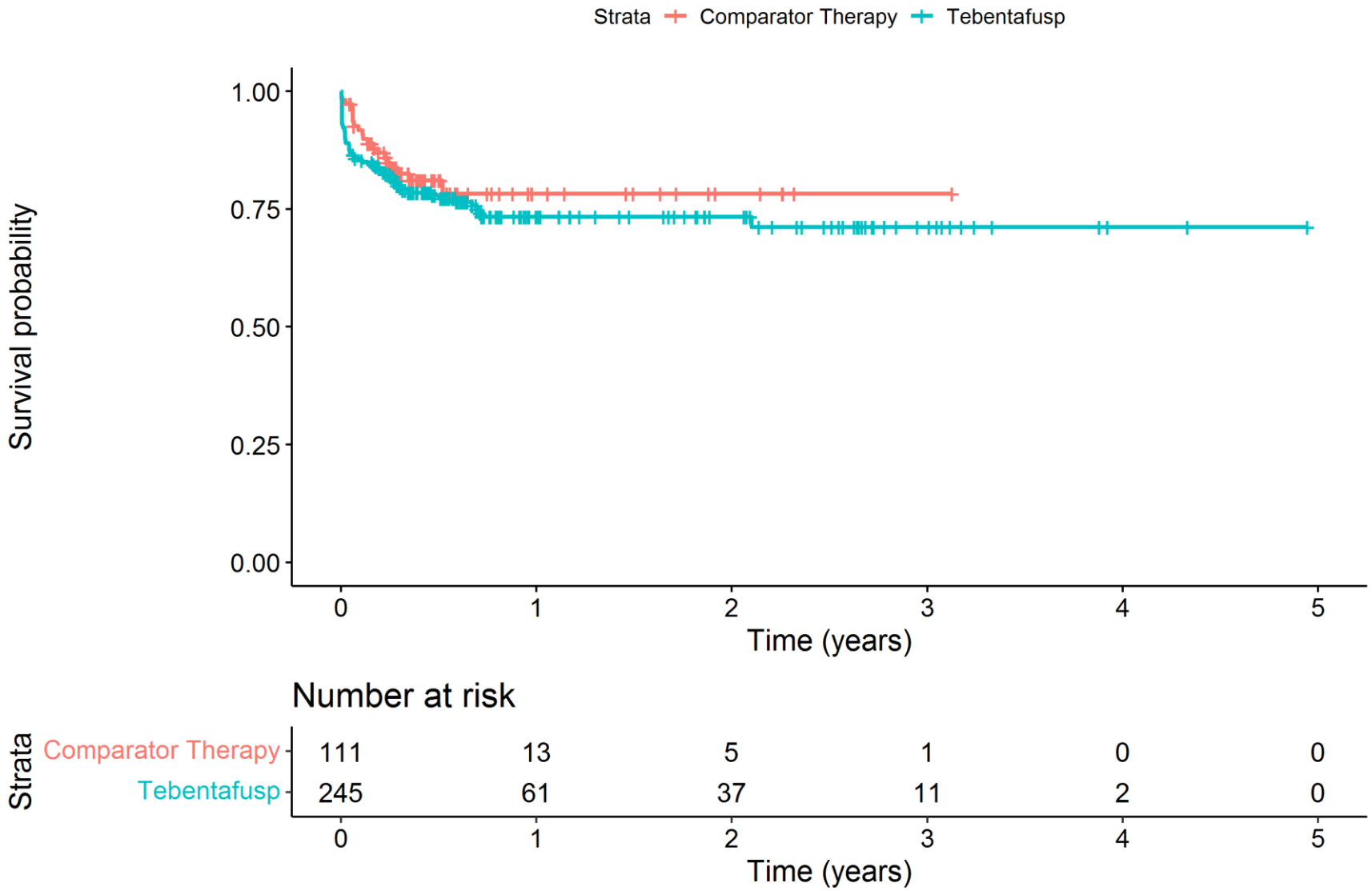
28.5 Erkrankungen des Gastrointestinaltrakts



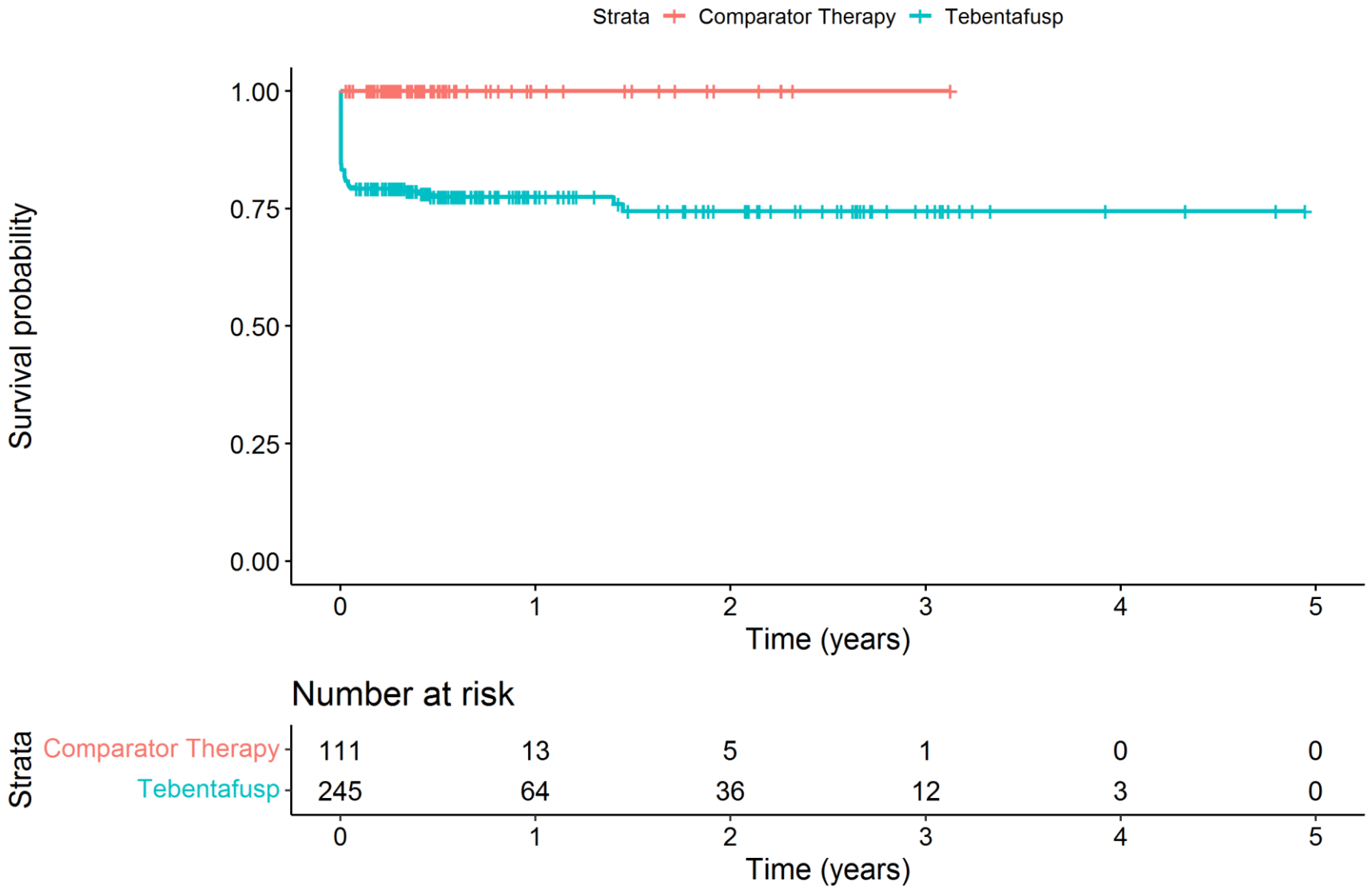
28.6 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



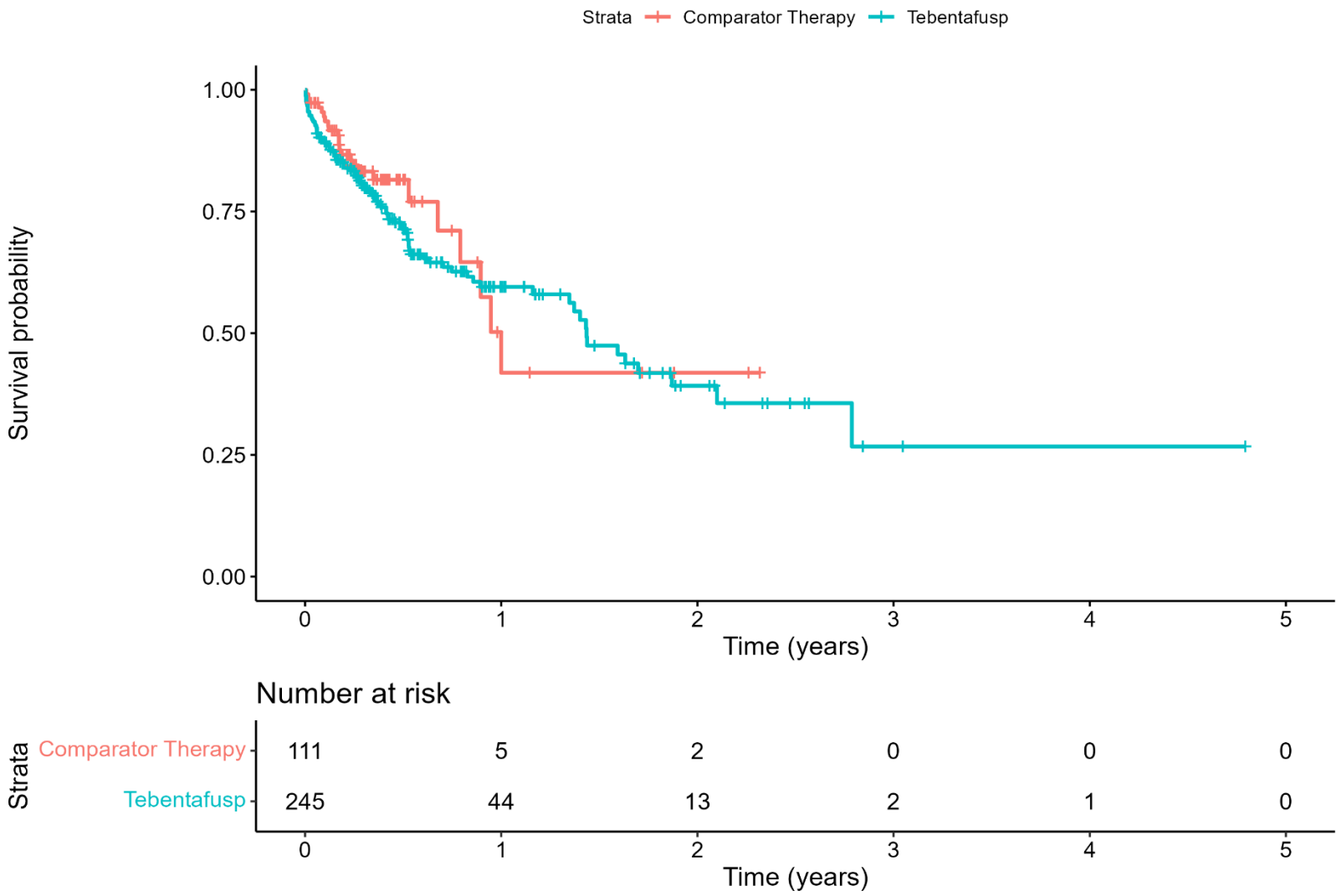
28.7 Leber- und Gallenerkrankungen



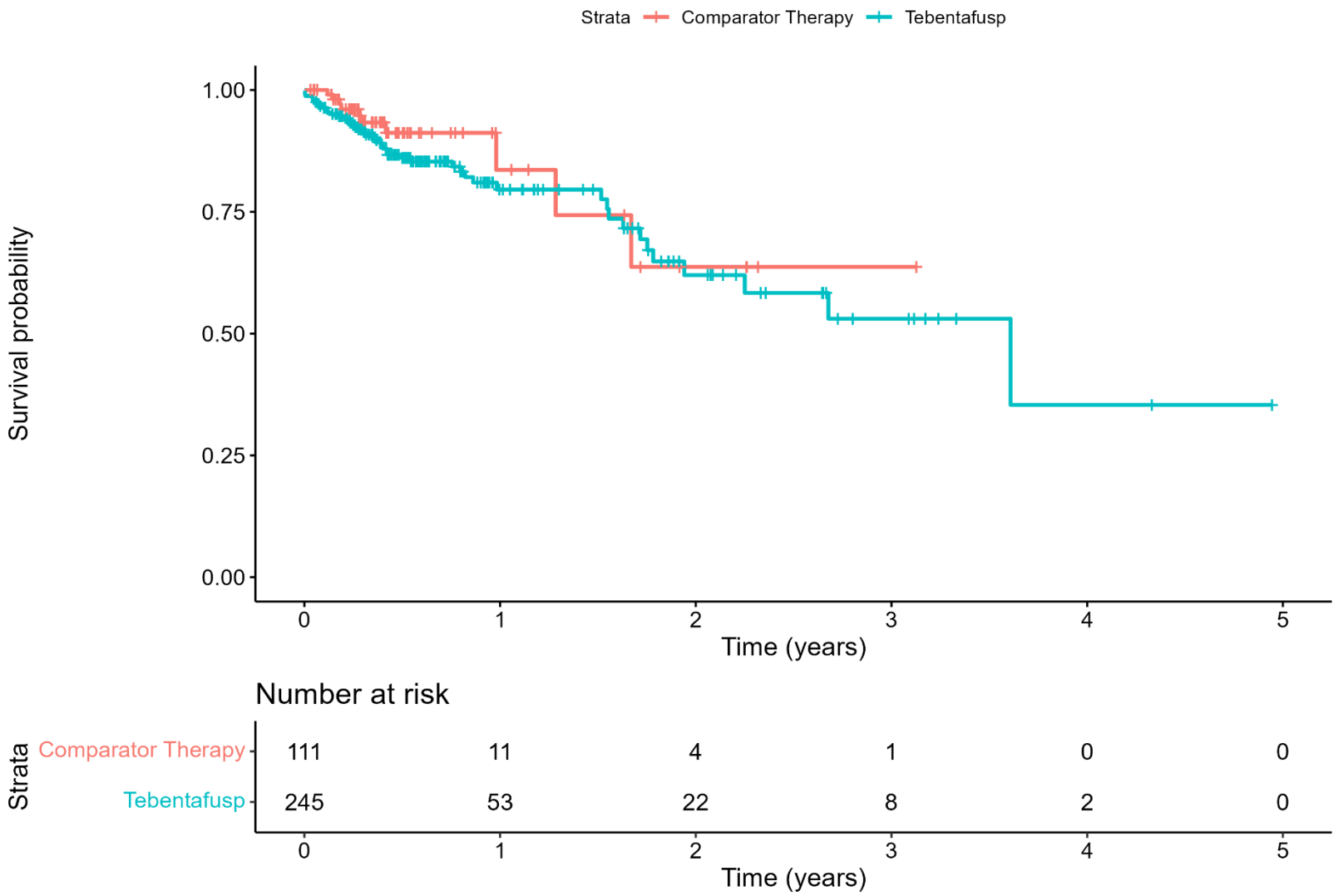
28.8 Erkrankungen des Immunsystems



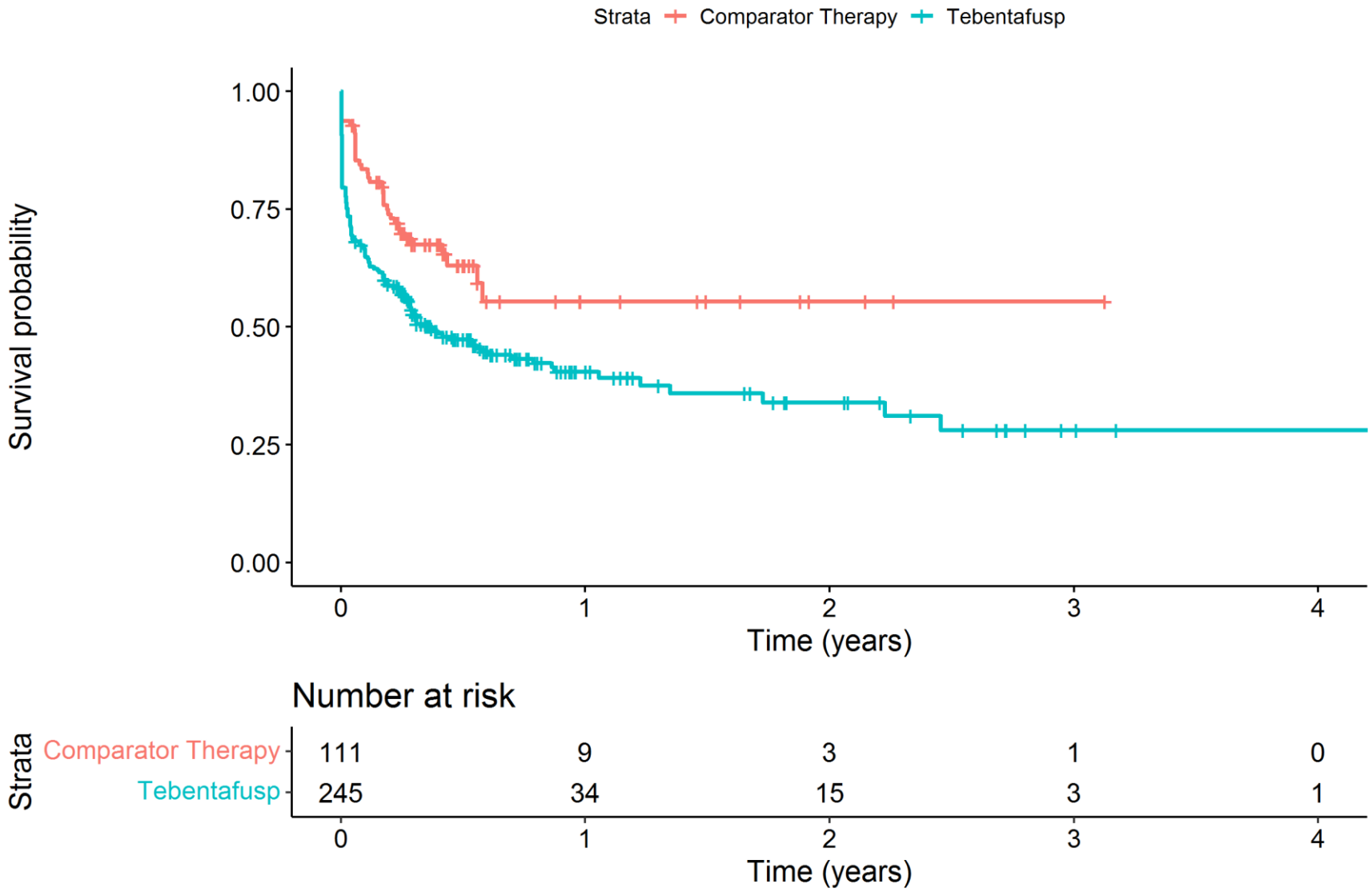
28.9 Infektionen und parasitäre Erkrankungen



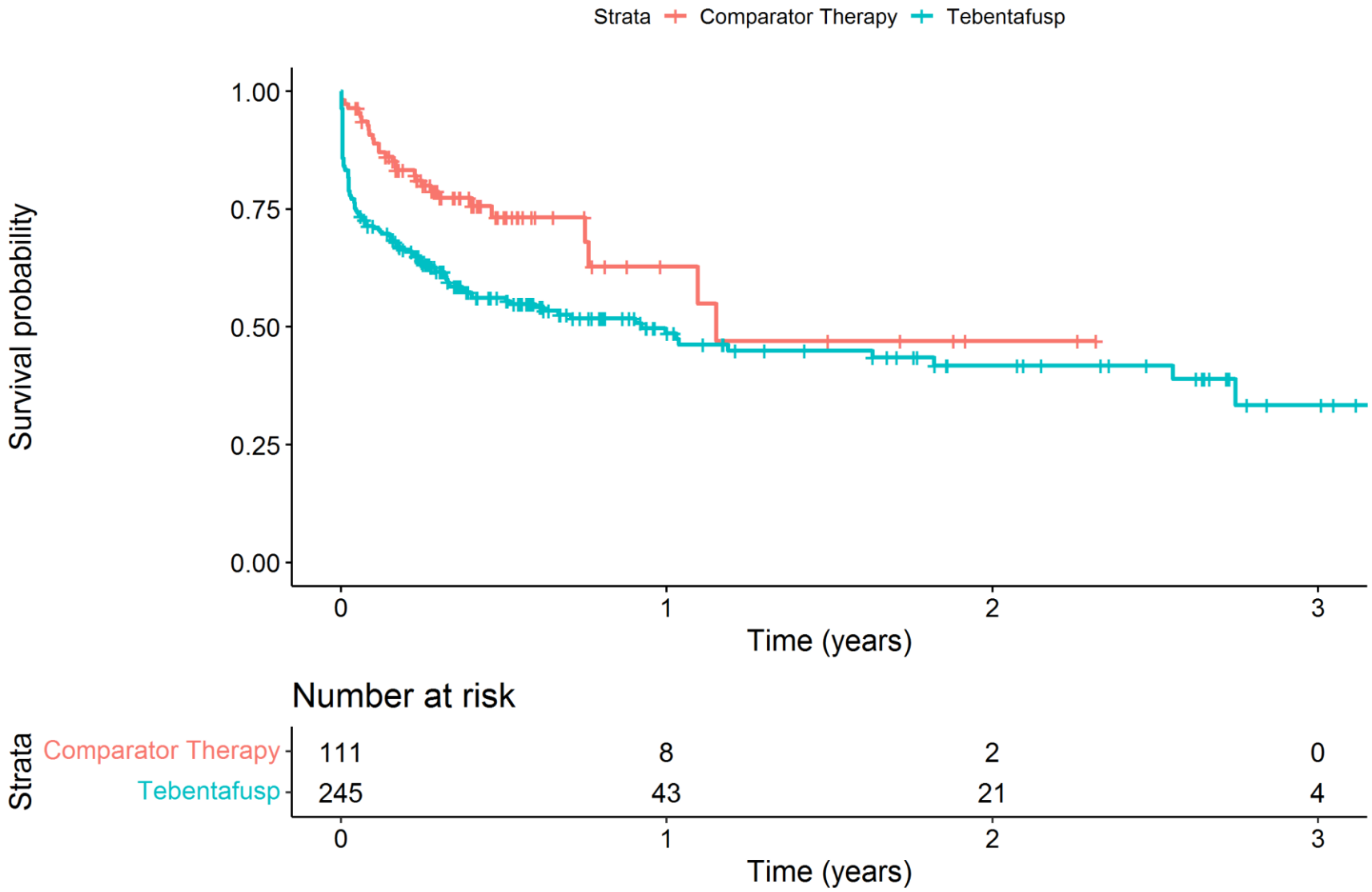
28.10 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



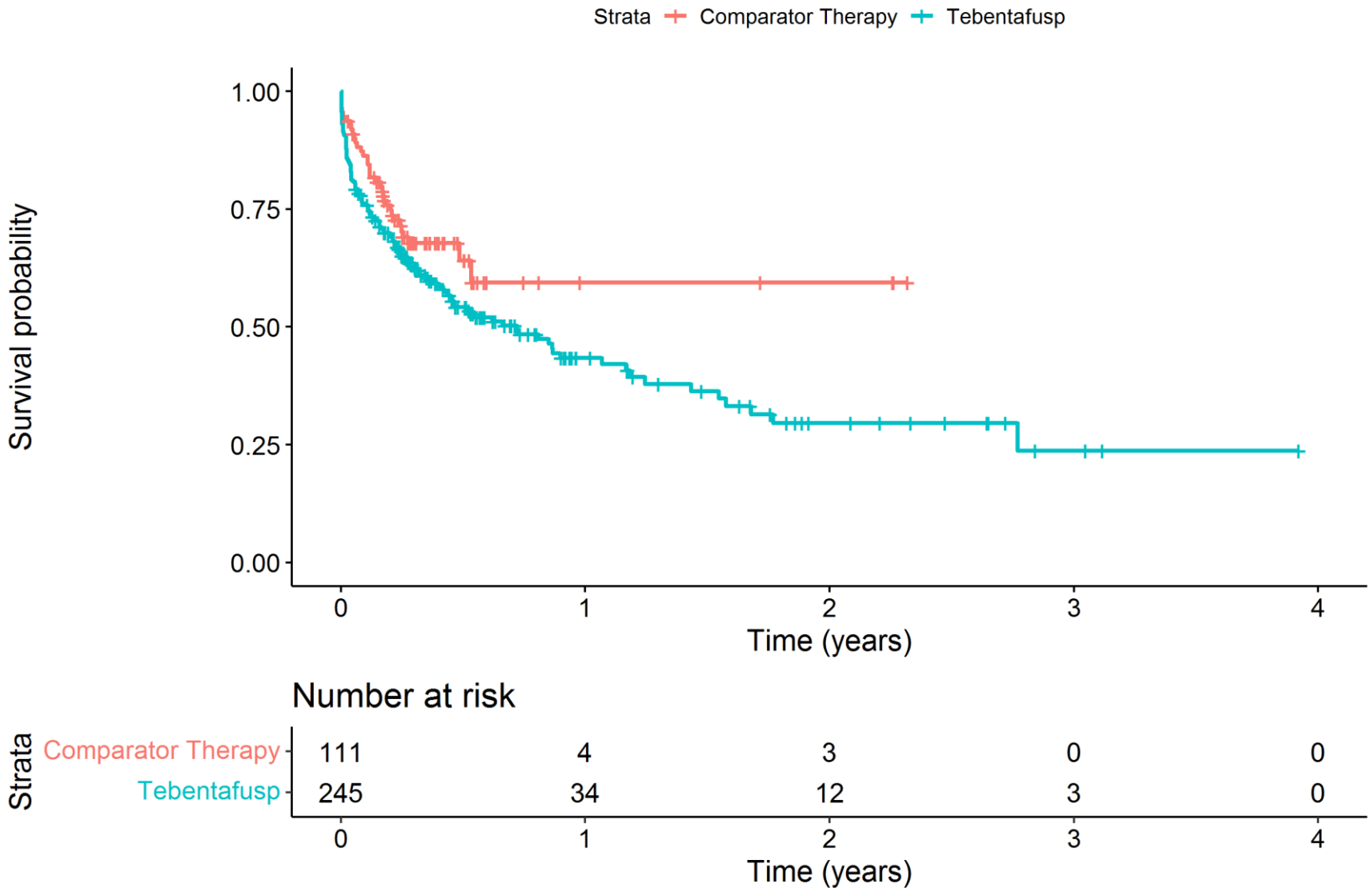
28.11 Untersuchungen



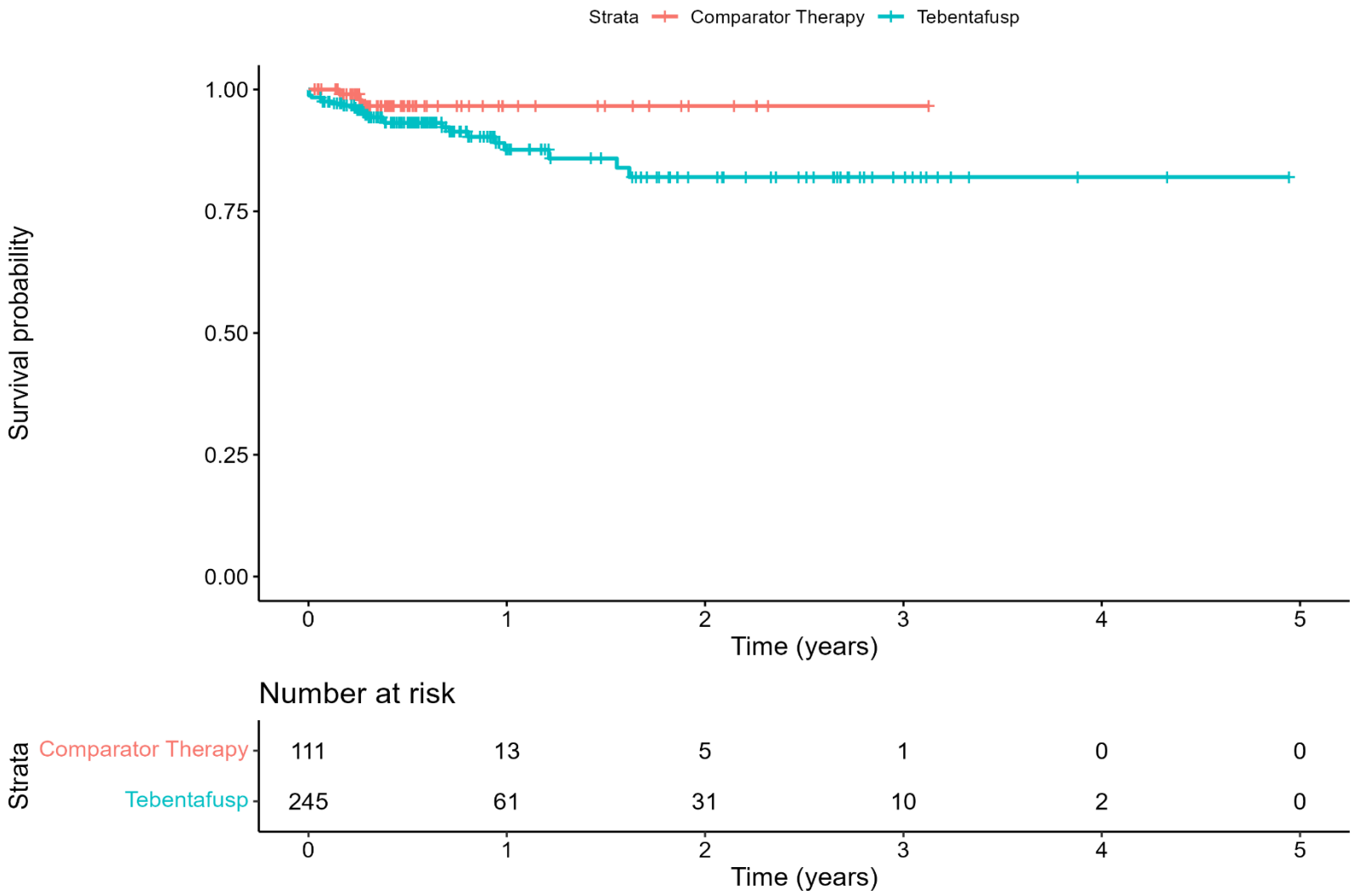
28.12 Stoffwechsel- und Ernährungsstörungen



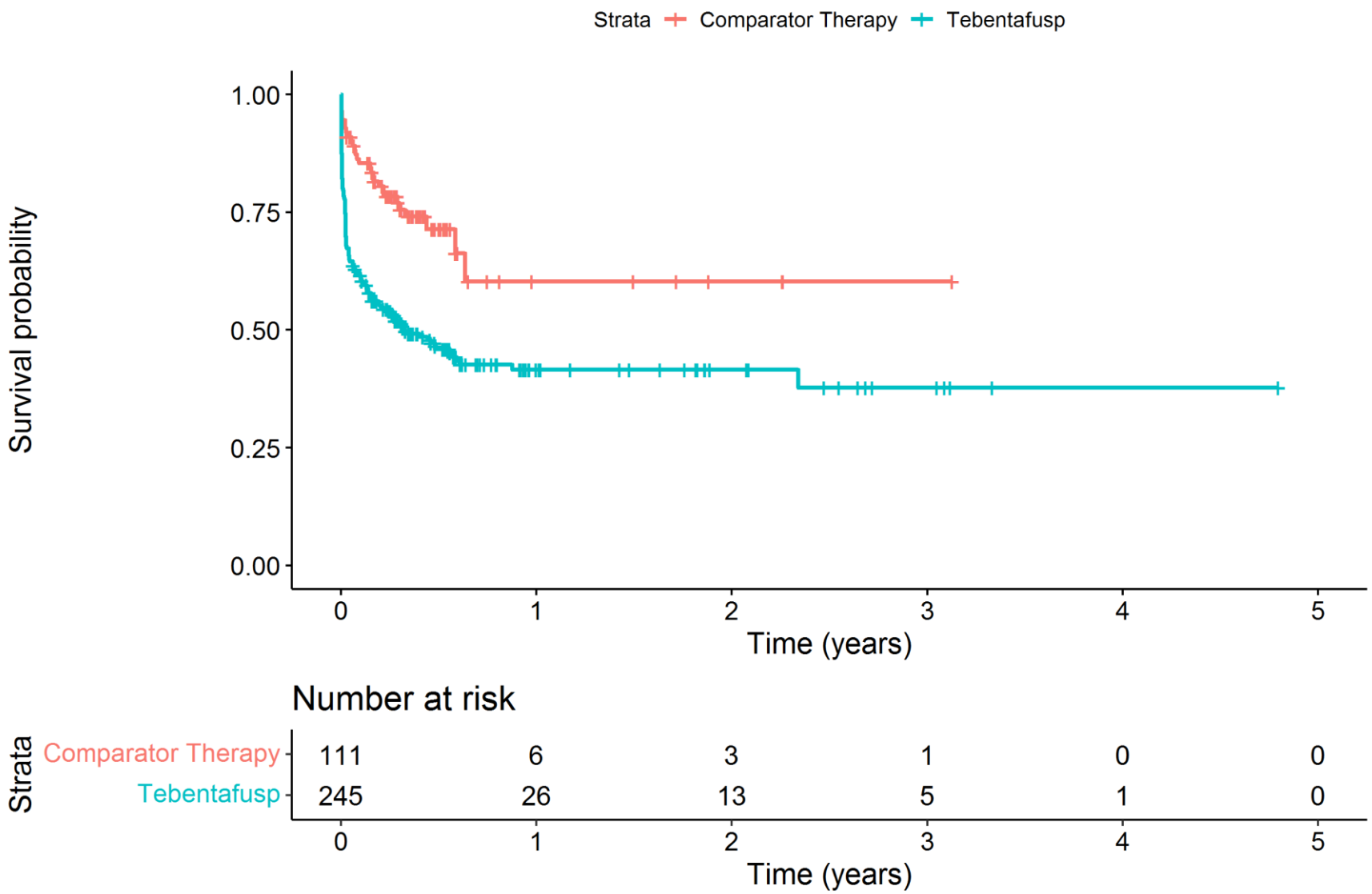
28.13 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



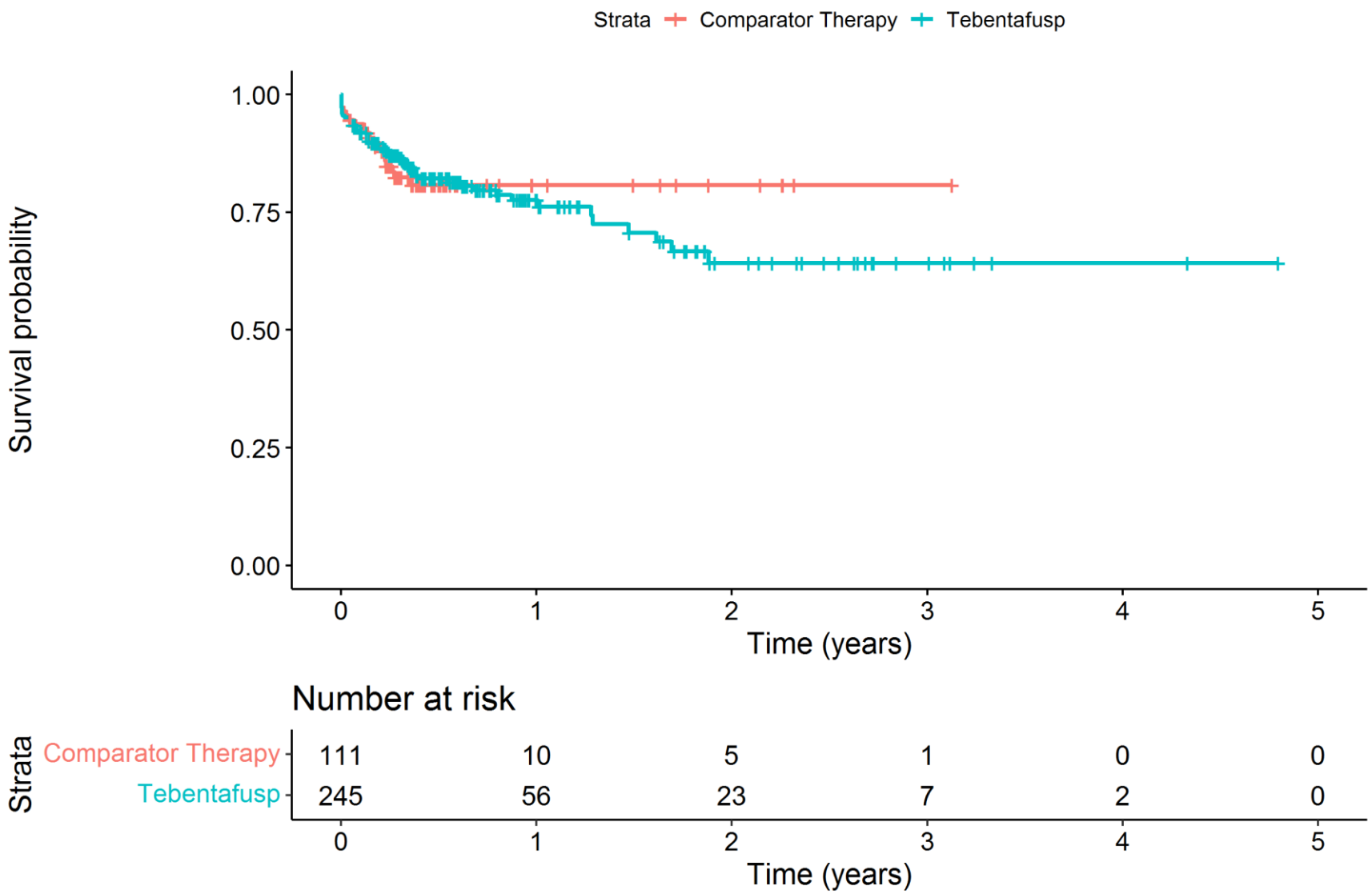
28.14 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



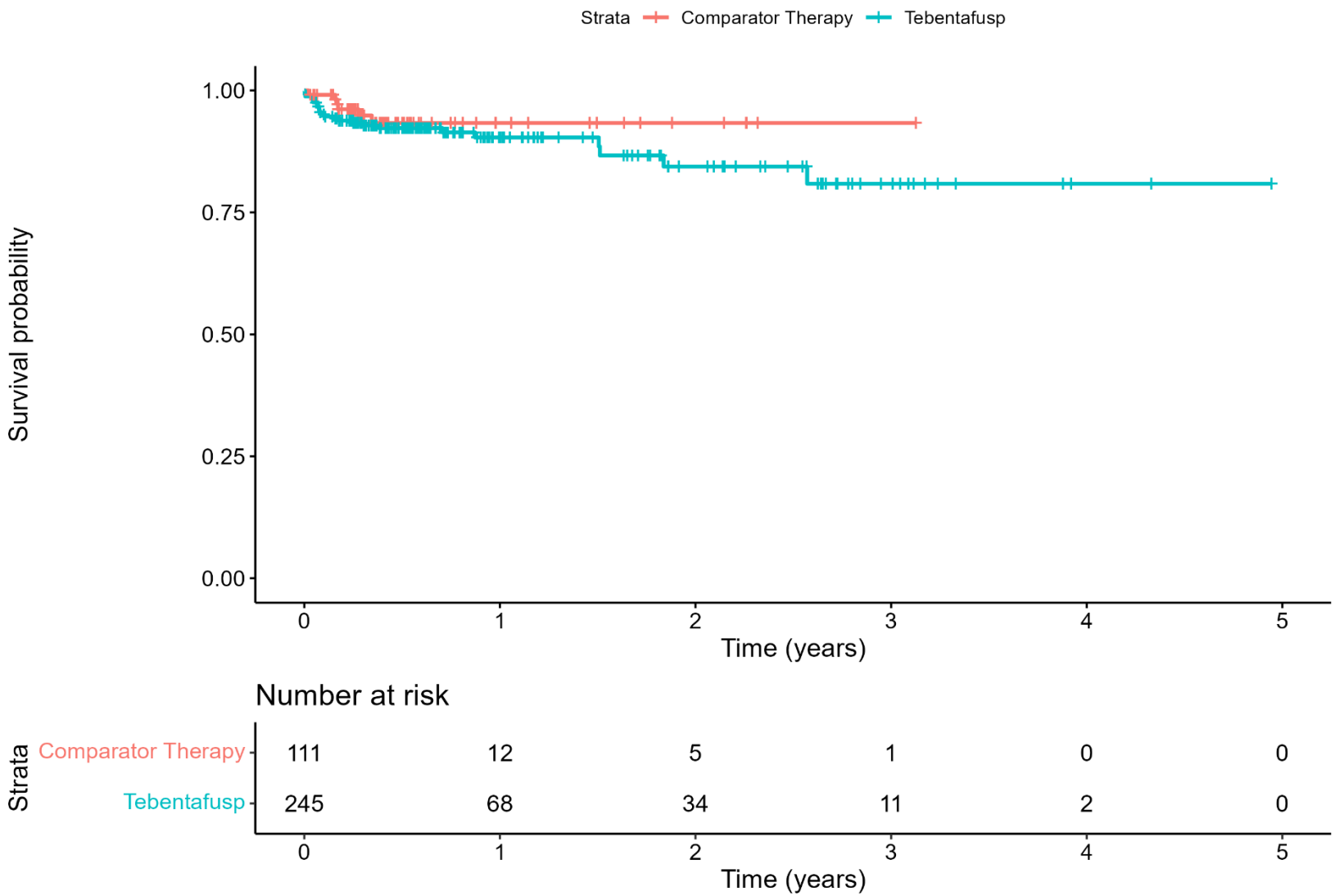
28.15 Erkrankungen des Nervensystems



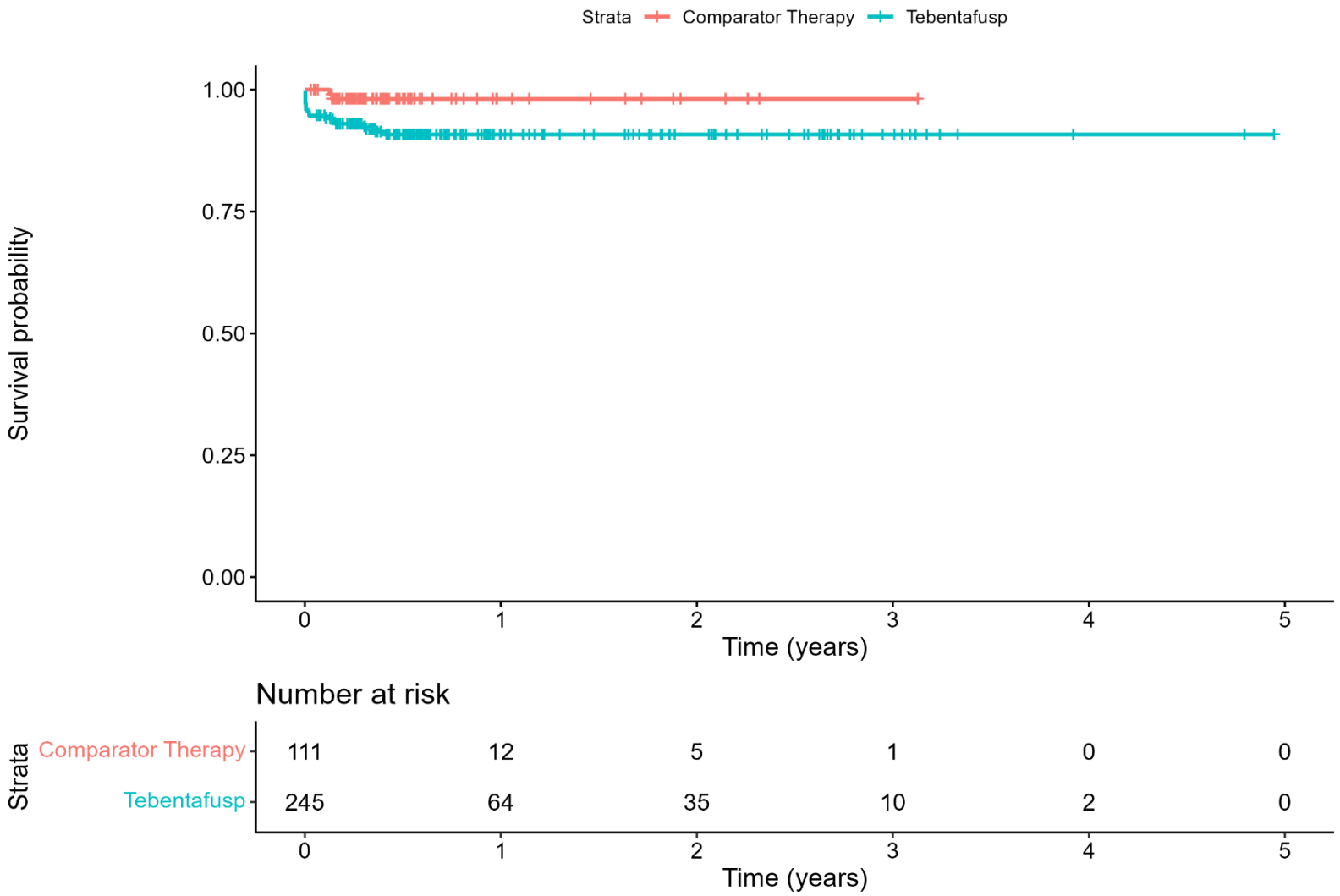
28.16 Psychiatrische Erkrankungen



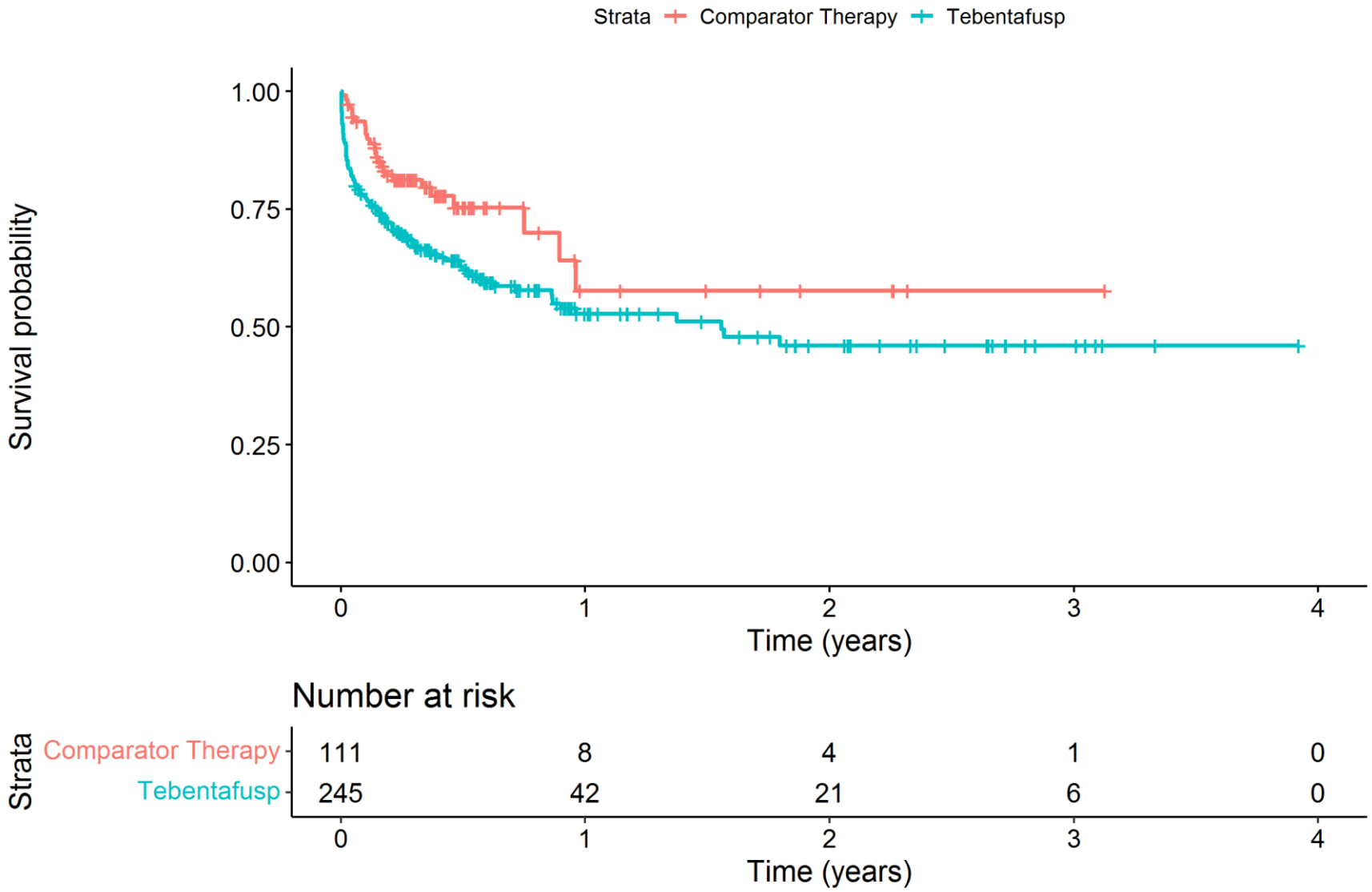
28.17 Erkrankungen der Nieren und Harnwege



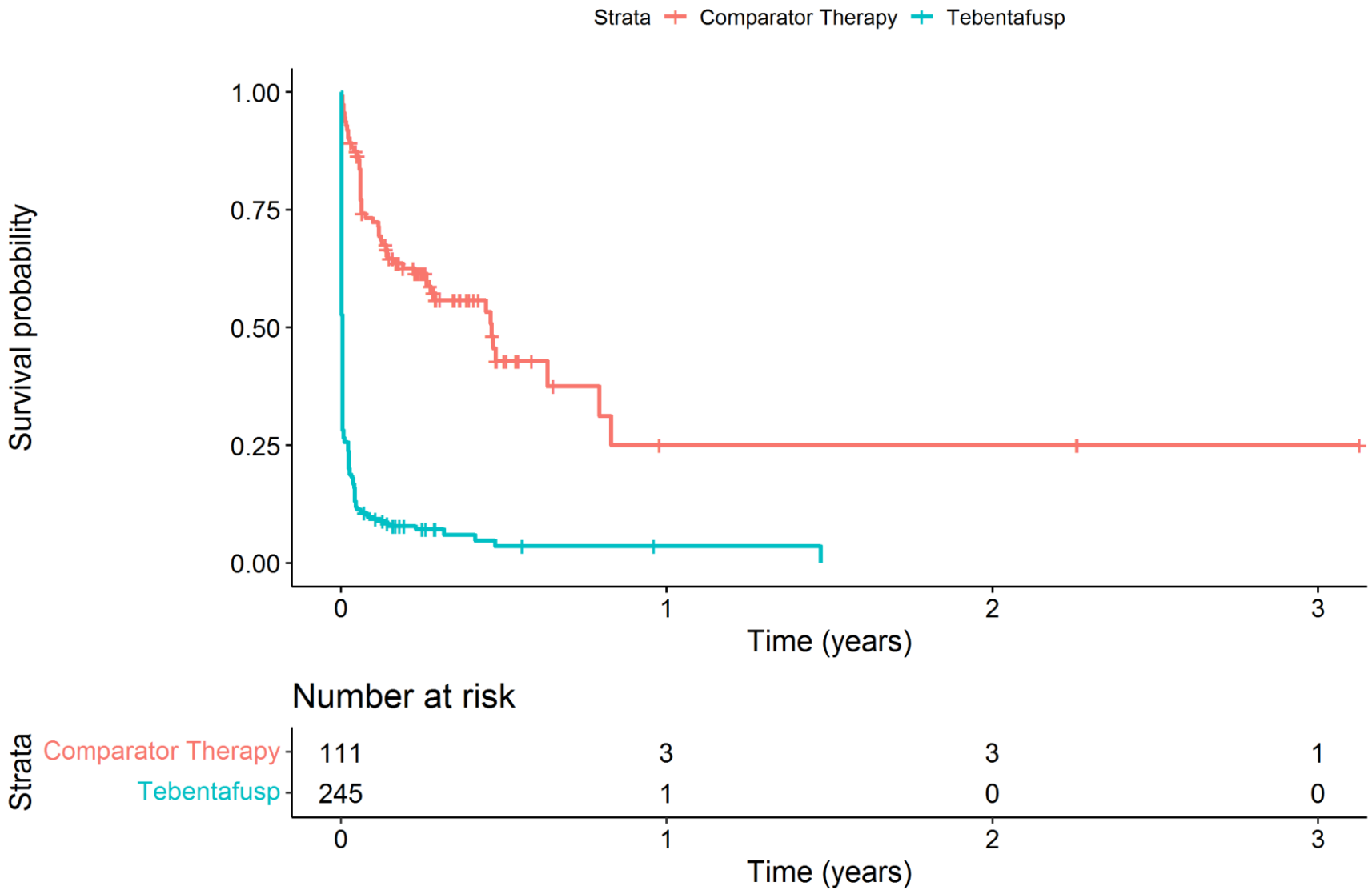
28.18 Erkrankungen der Geschlechtsorgane und der Brustdruese



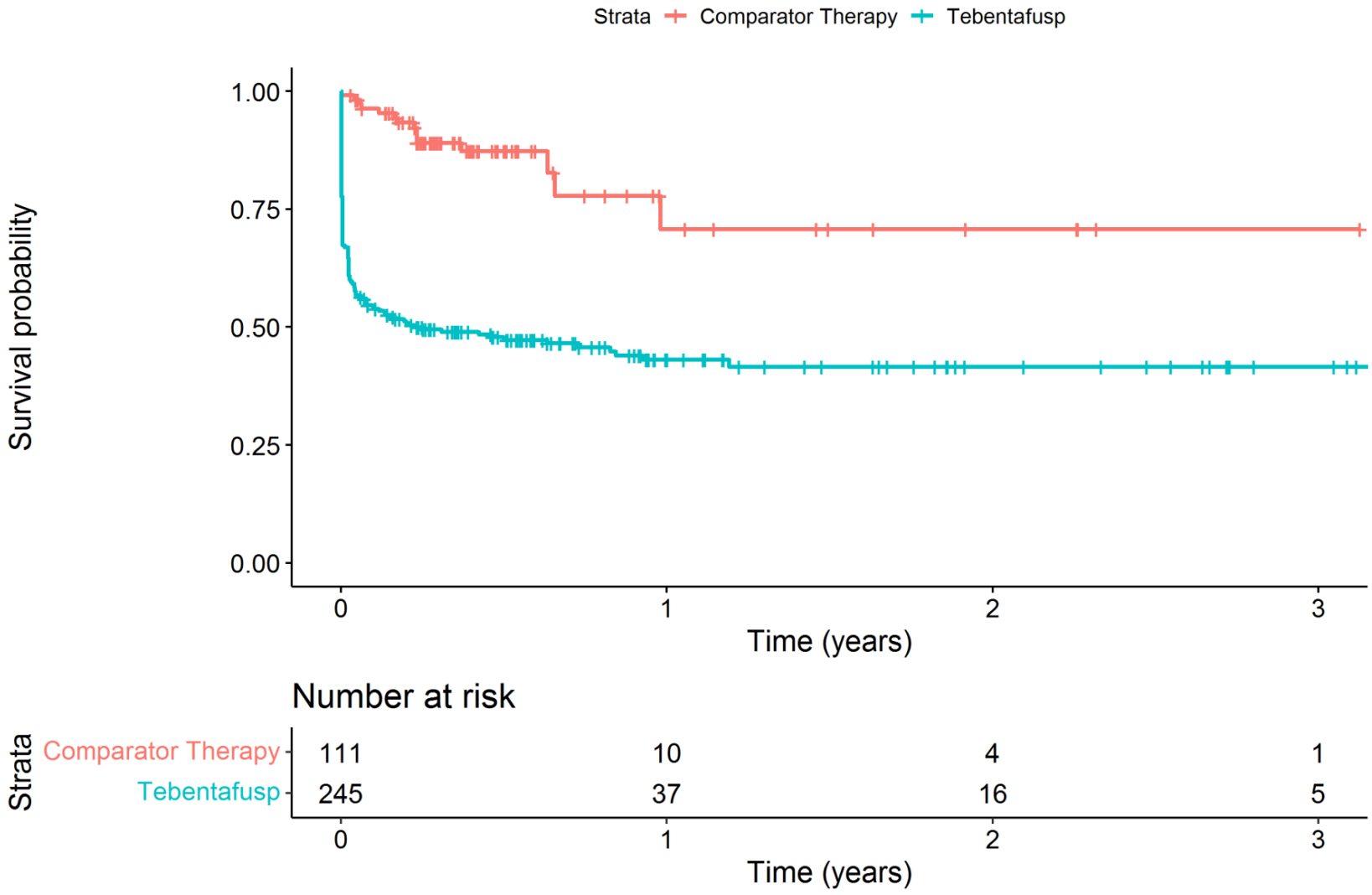
28.19 Erkrankungen der Atemwege, des Brustraums und Mediastinums



28.20 Erkrankungen der Haut und des Unterhautgewebes



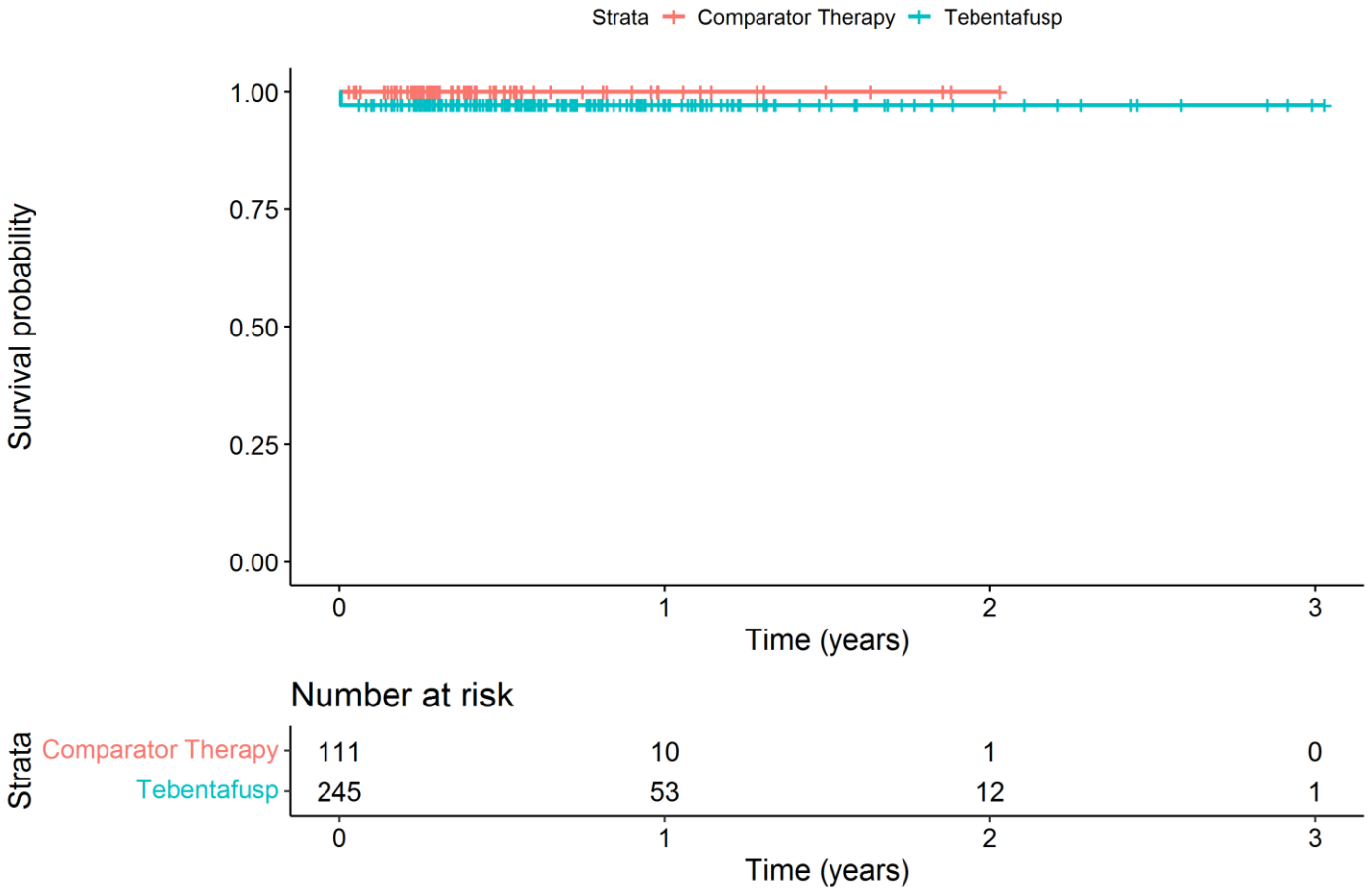
28.21 Gefäßerkrankungen



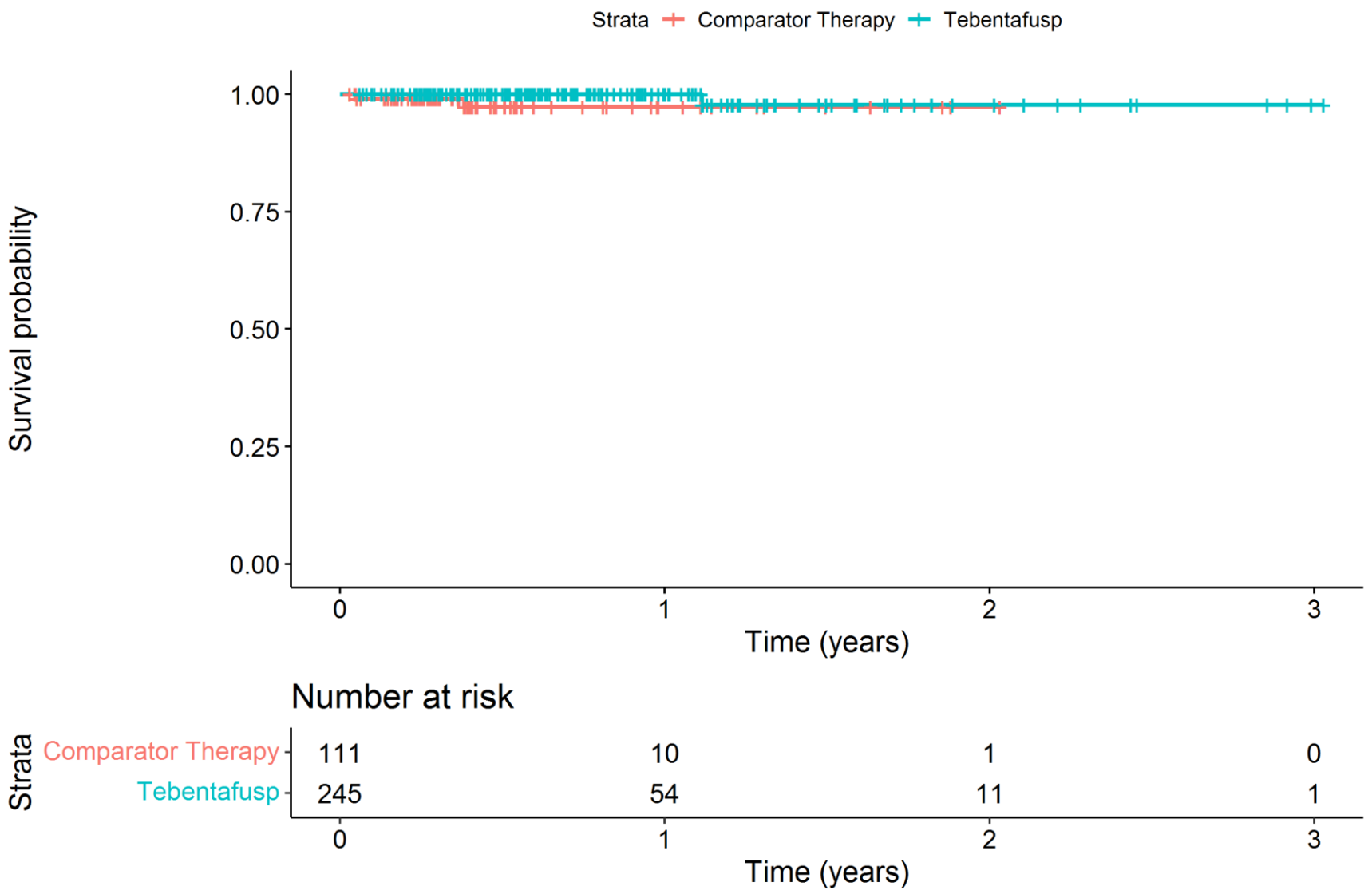
28.22 Unerwünschte Ereignisse nach Schweregrad – Primäranalyse (Oktober 2020) (Tabelle 4-55)

29 UEs (PT) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten

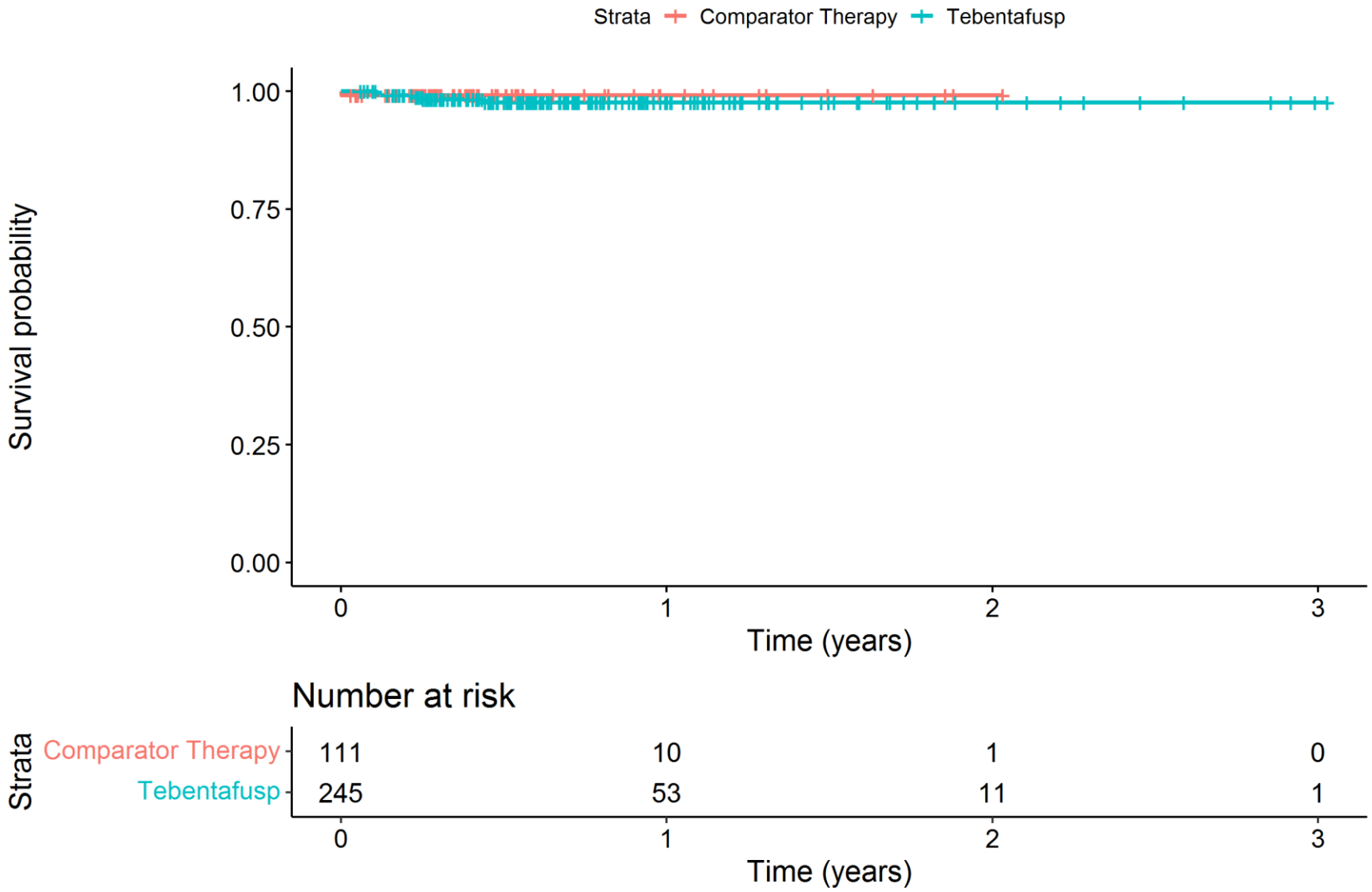
29.1 Lymphopenie



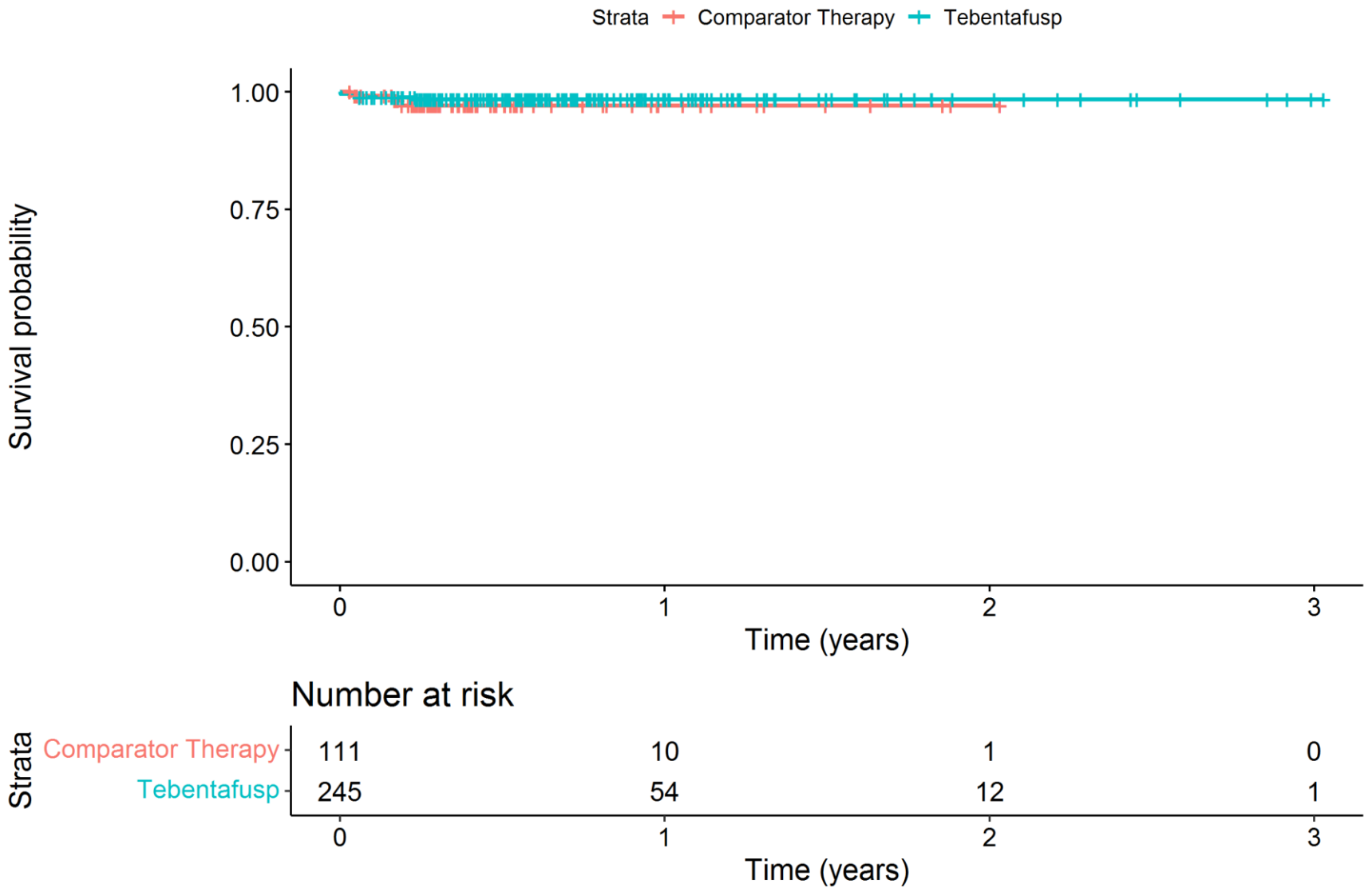
29.2 Neutropenie



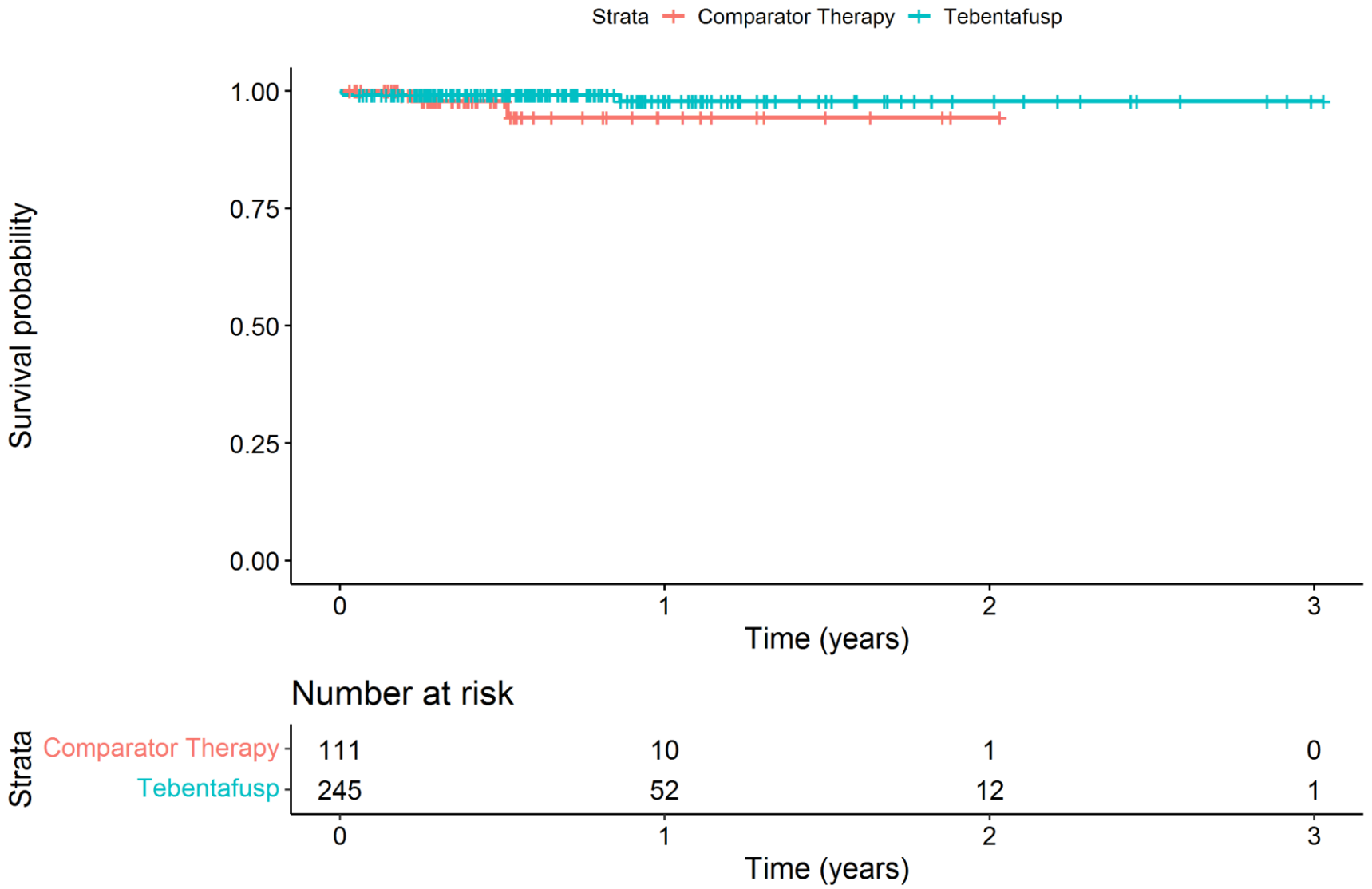
29.3 Übelkeit



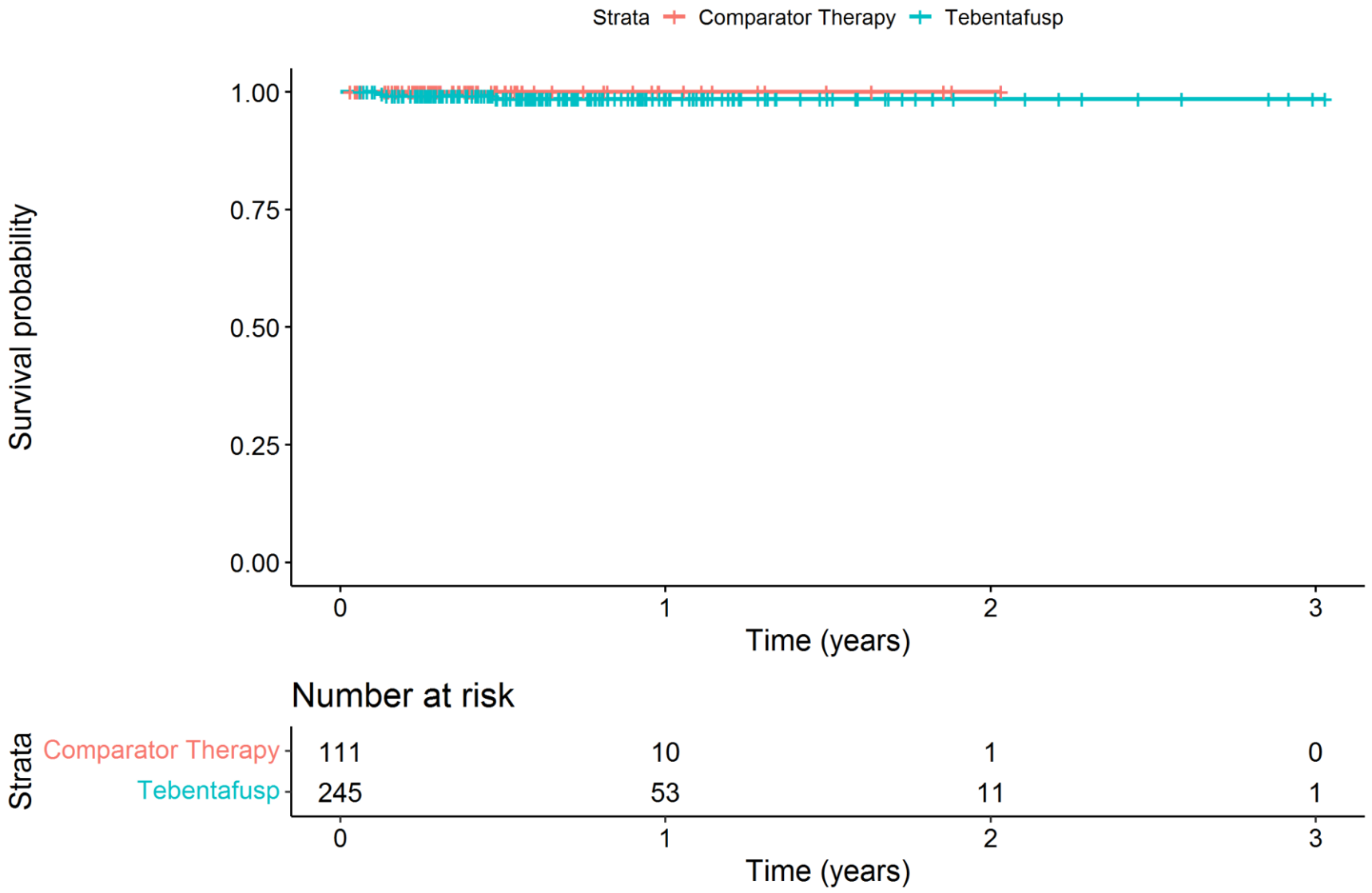
29.4 Unterleibsschmerzen



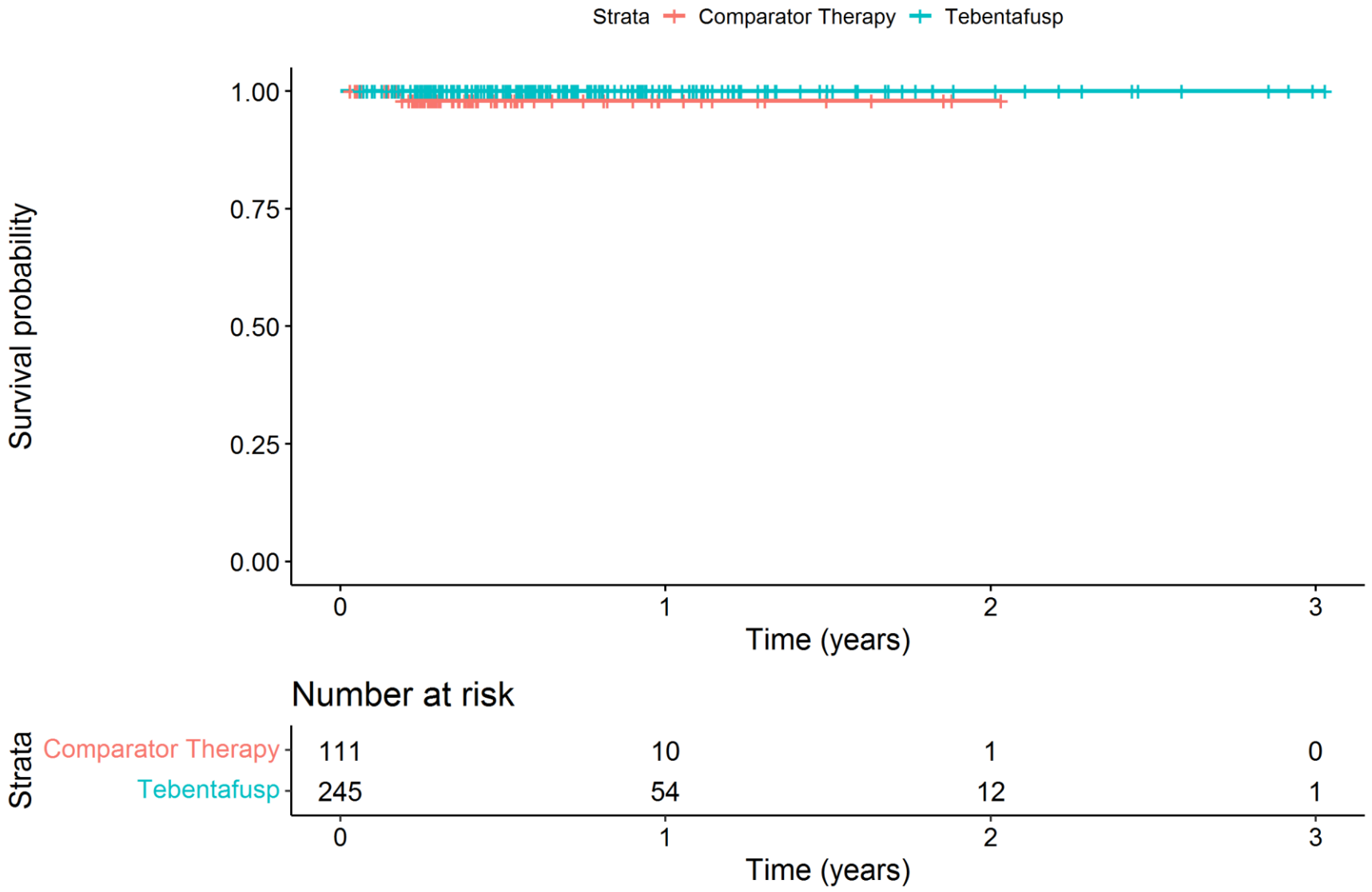
29.5 Diarrhoe



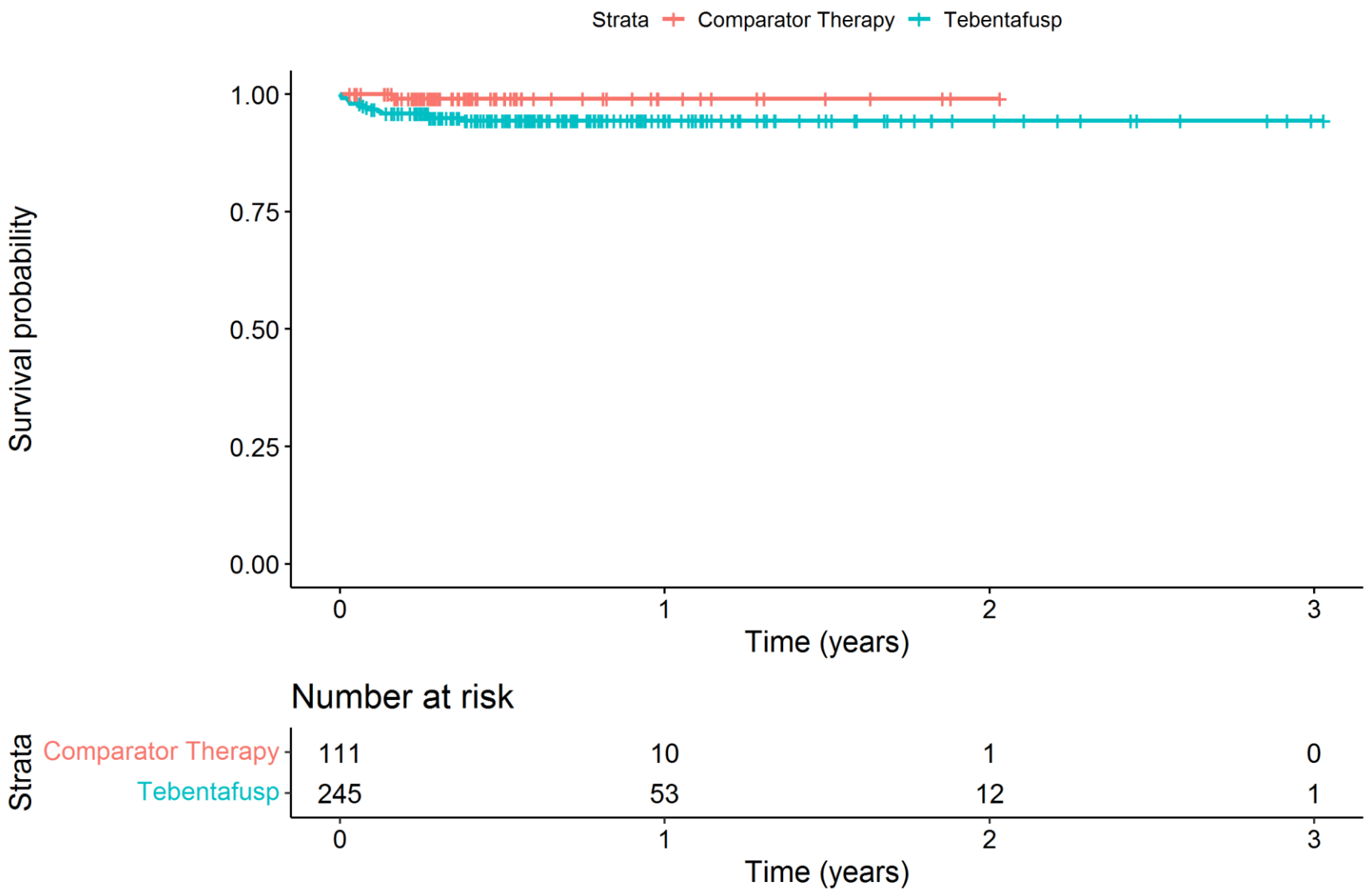
29.6 Erbrechen



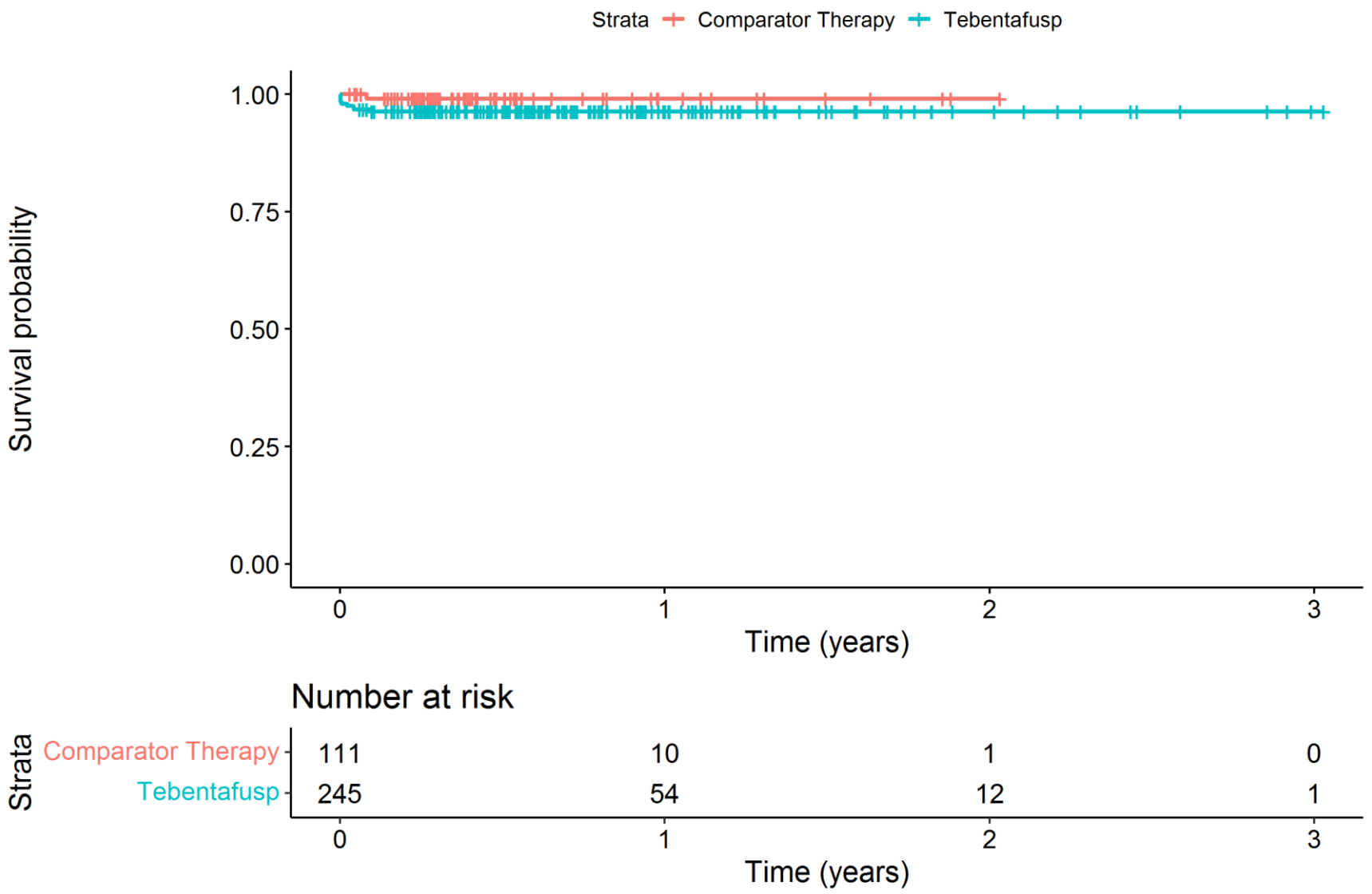
29.7 Colitis


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
54
12
1
0
1
2
3
Time (years)

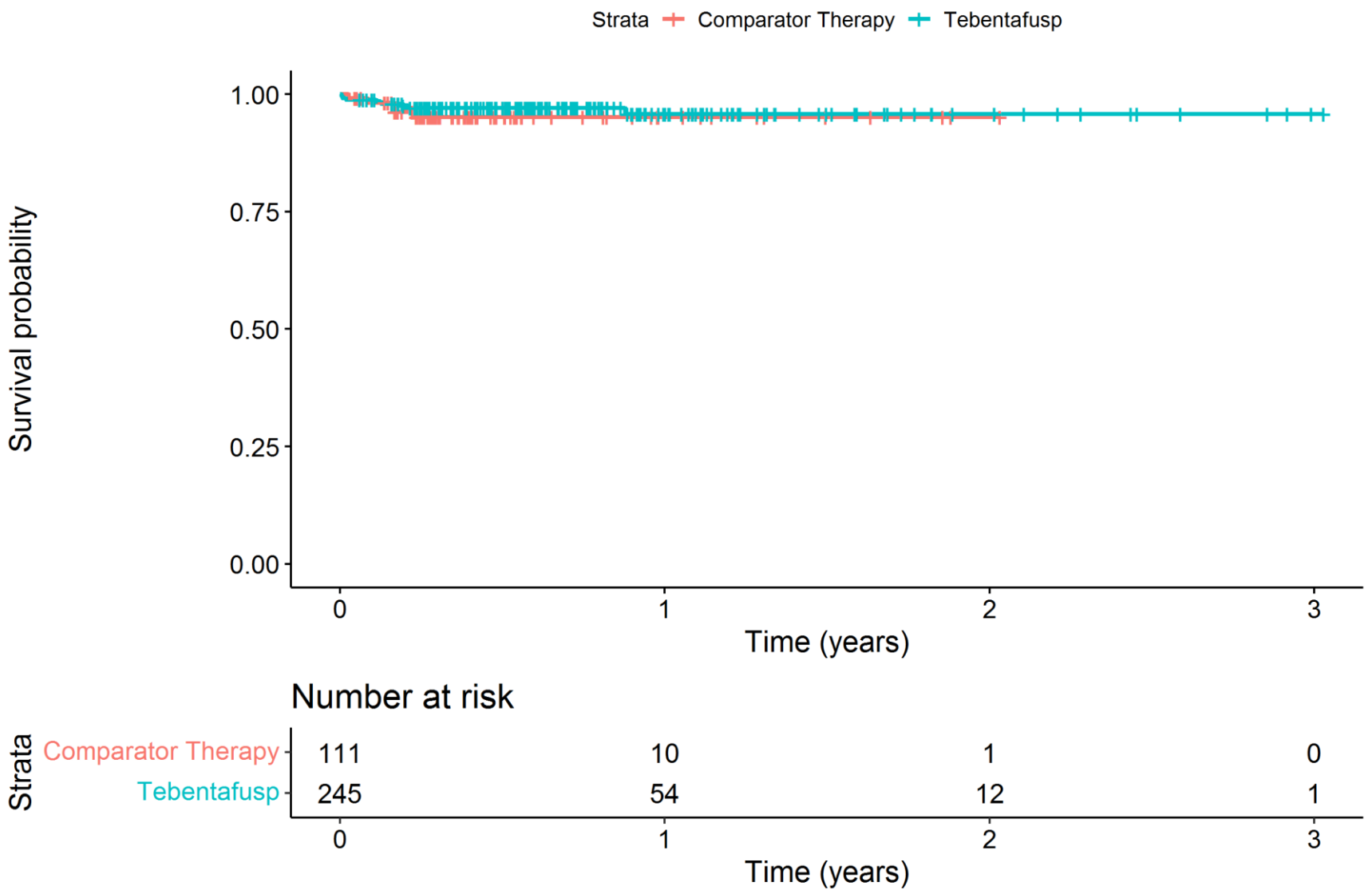
29.8 Müdigkeit



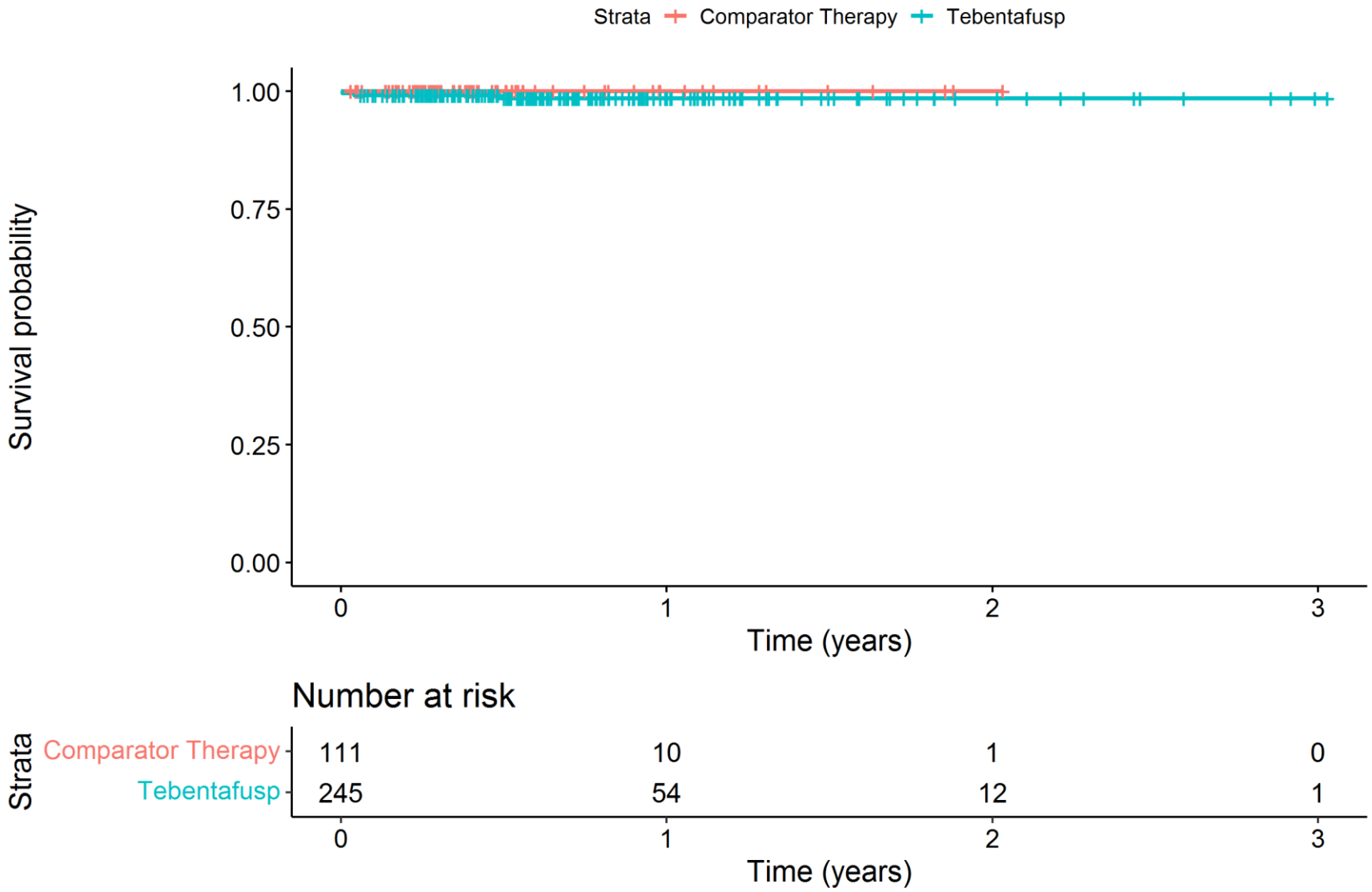
29.9 Fieber


Strata
Comparator Therapy
Tebentafusp
1.00
0.75
0.50
0.25
0.00
Survival probability
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
54
12
1
0
1
2
3
Time (years)

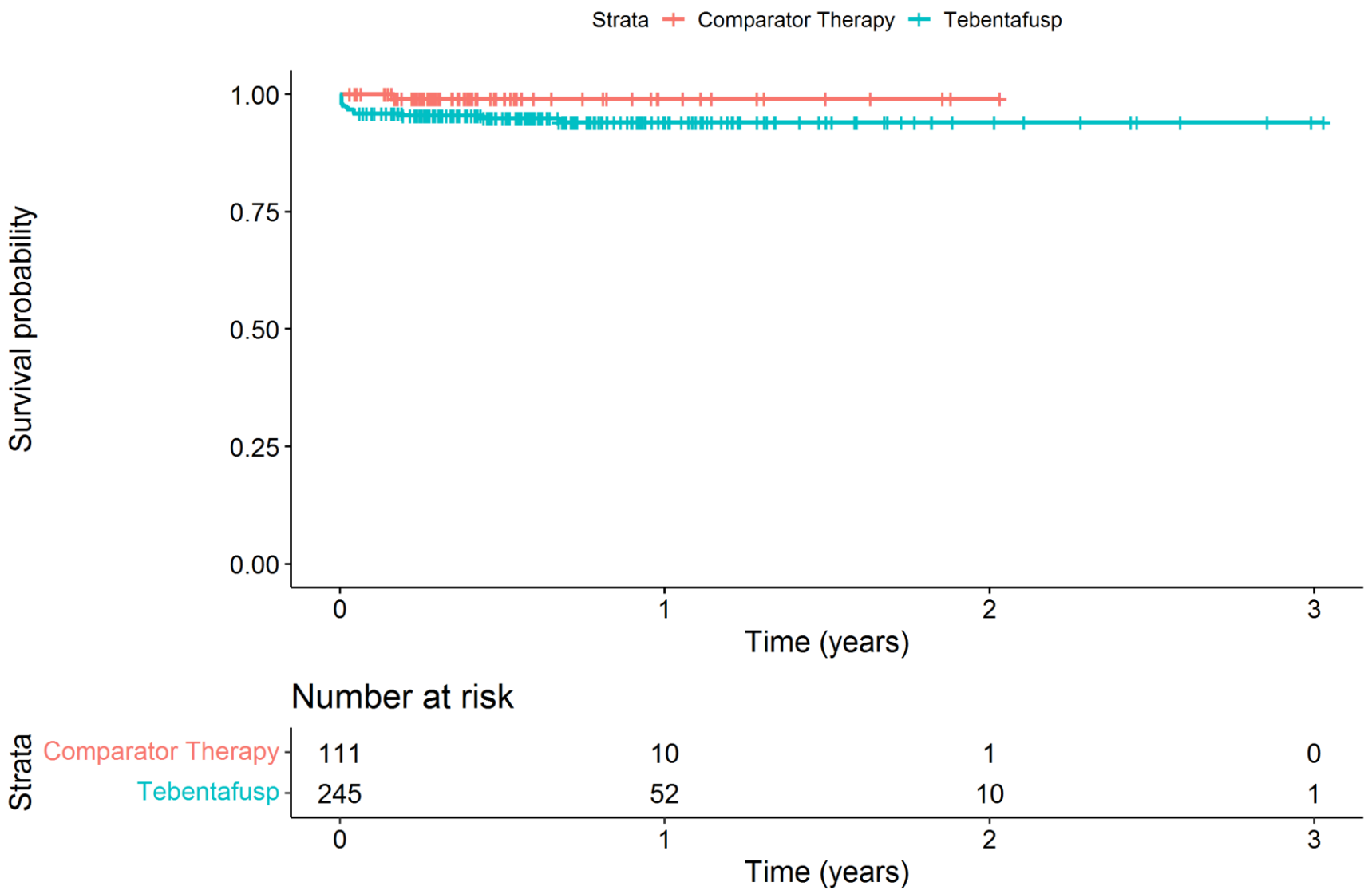
29.10 Hyperbilirubinämie



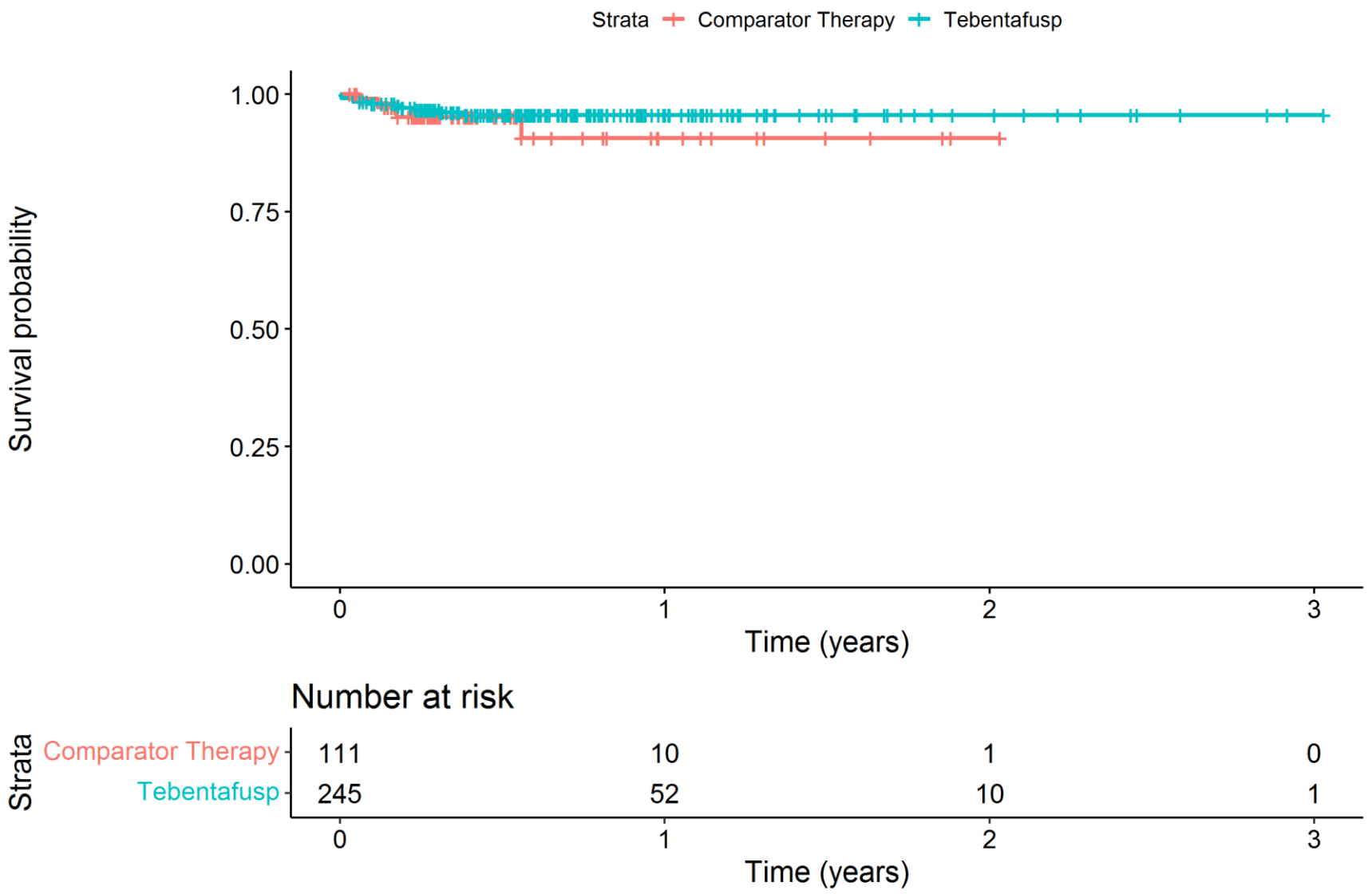
29.11 Harnwegsinfektion



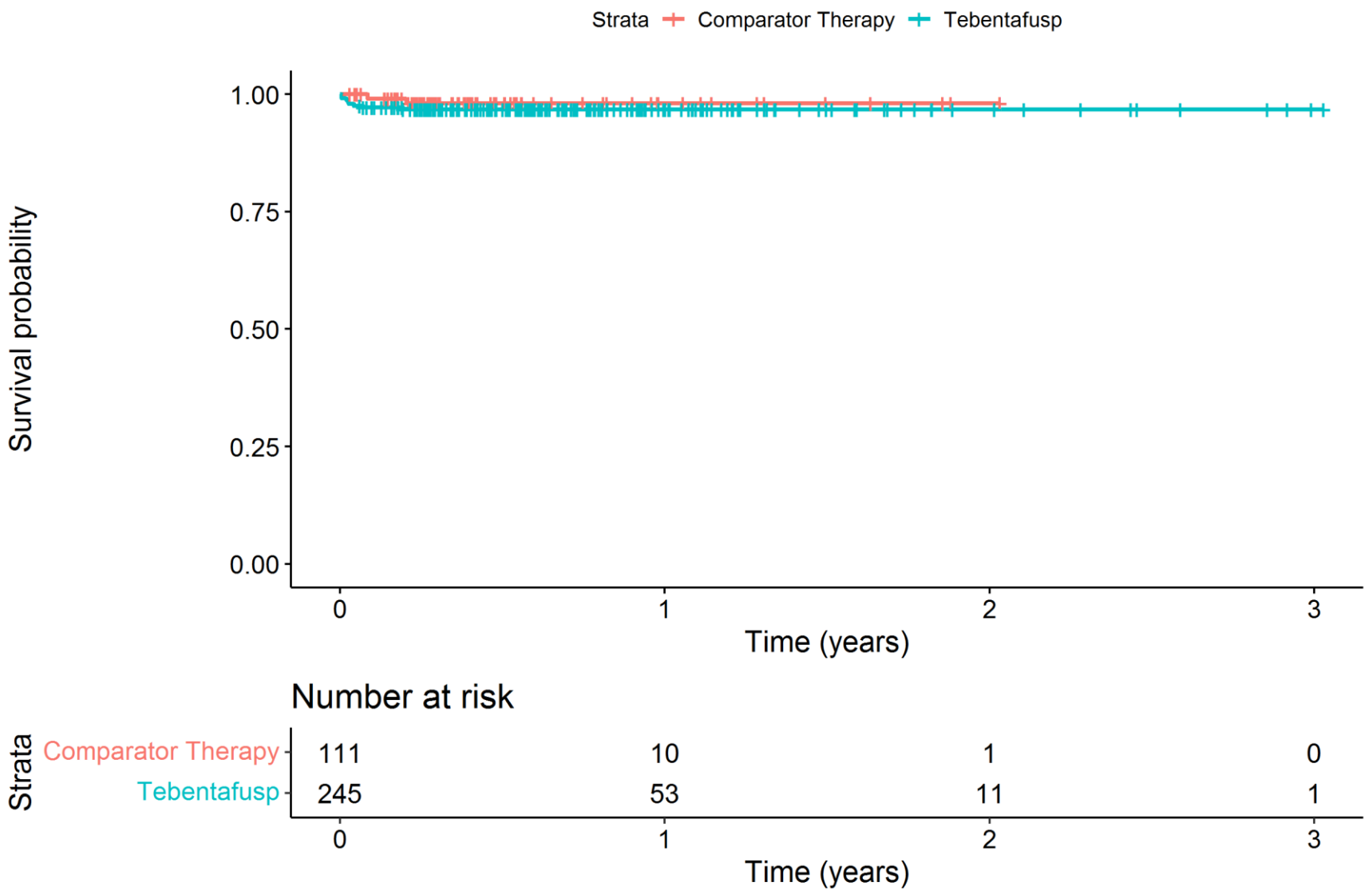
29.12 Erhöhte Aspartat-Aminotransferase



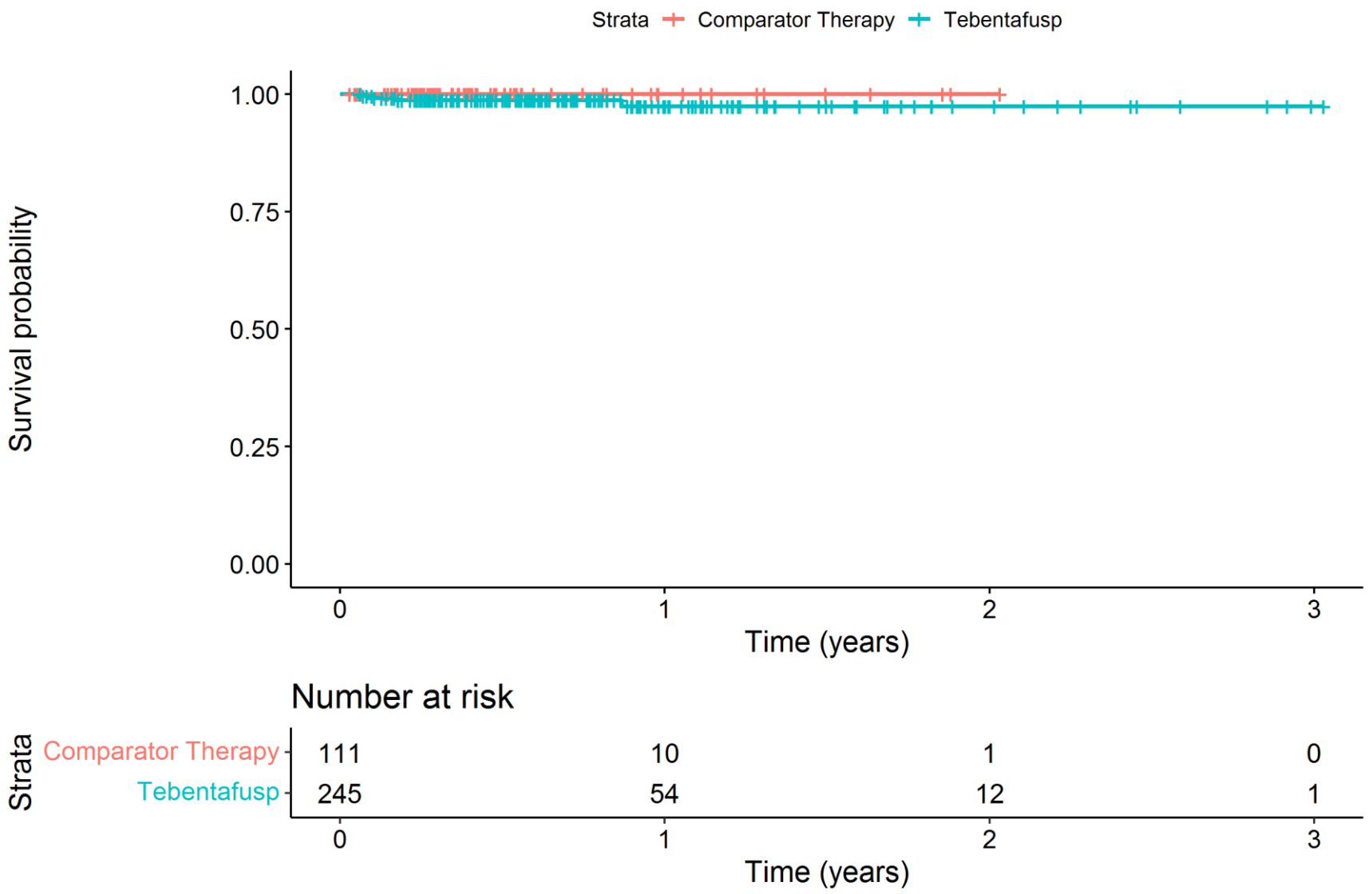
29.13 Erhöhte Lipase



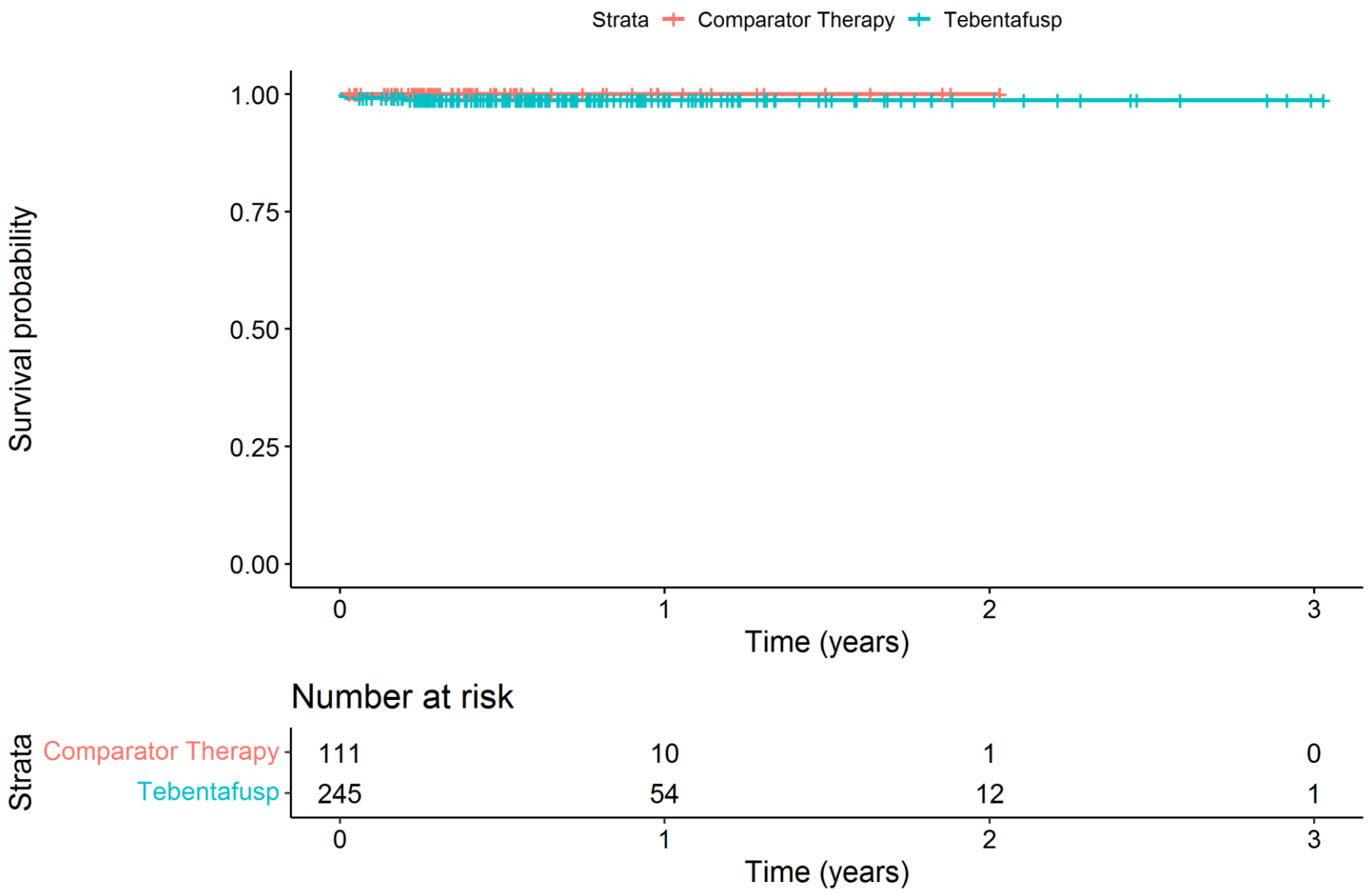
29.14 Erhöhte Alanin-Aminotransferase



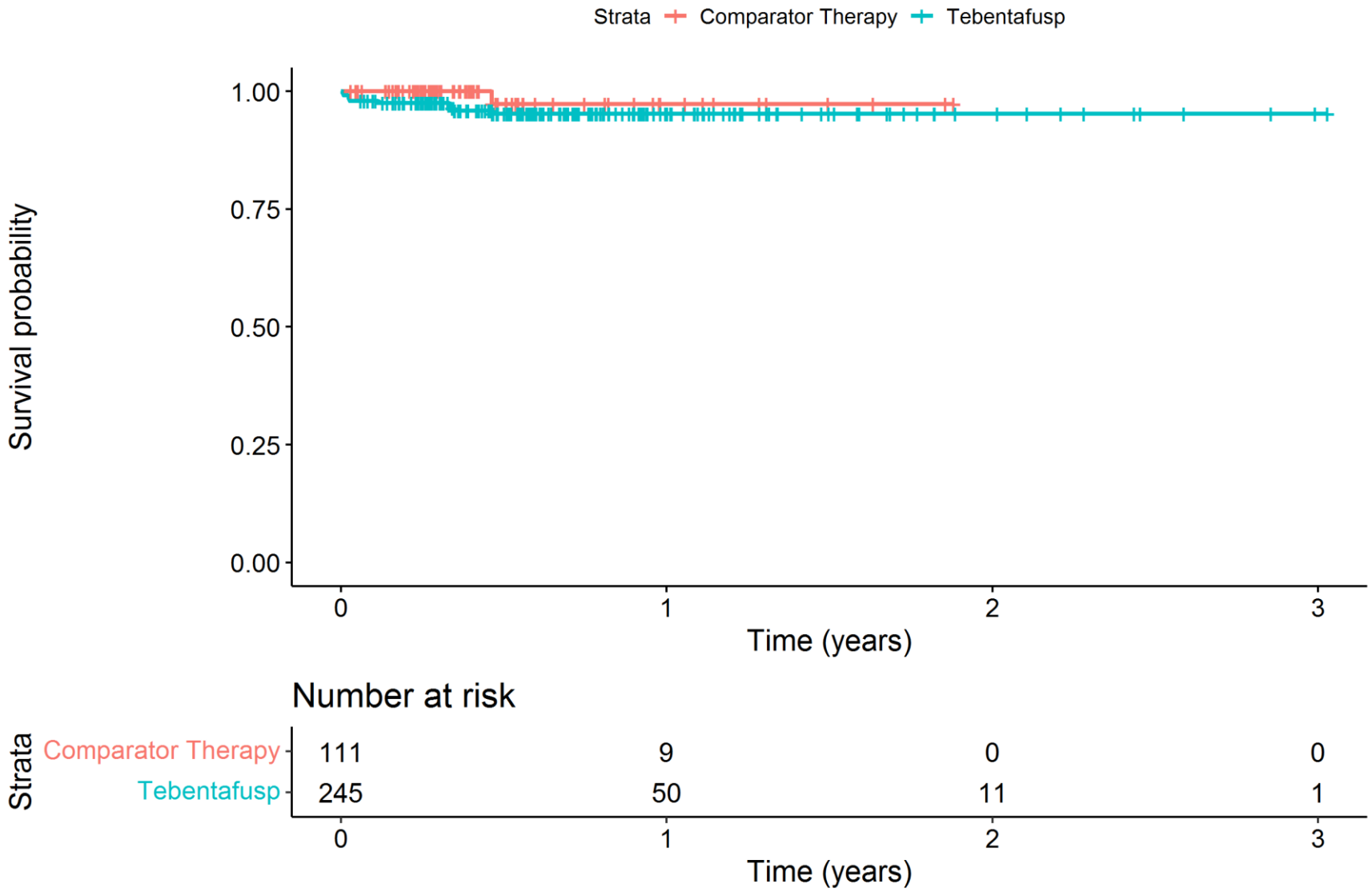
29.15 Erhöhte Gamma-Glutamyltransferase



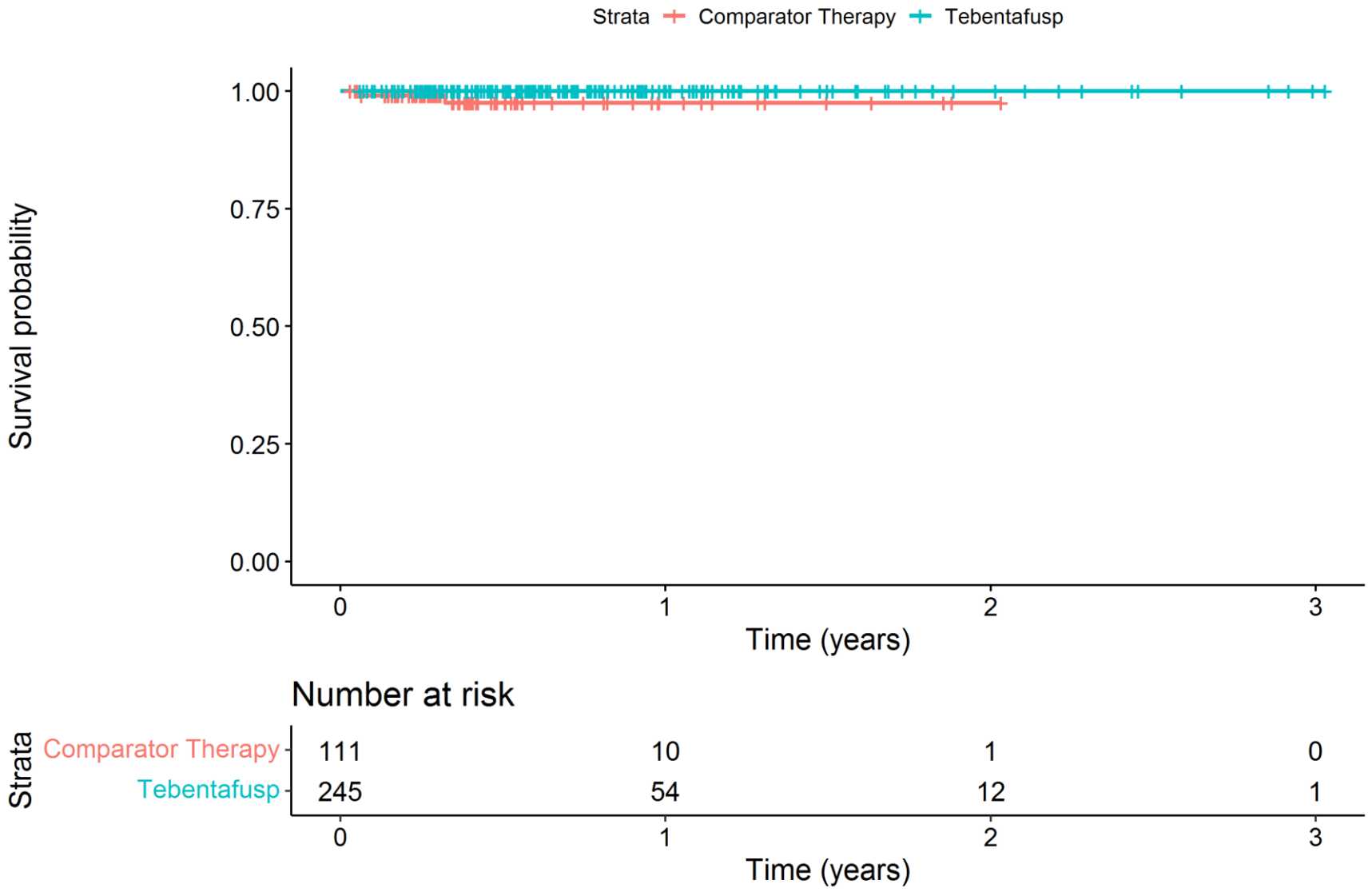
29.16 Erhöhte alkalische Phosphatase im Blut



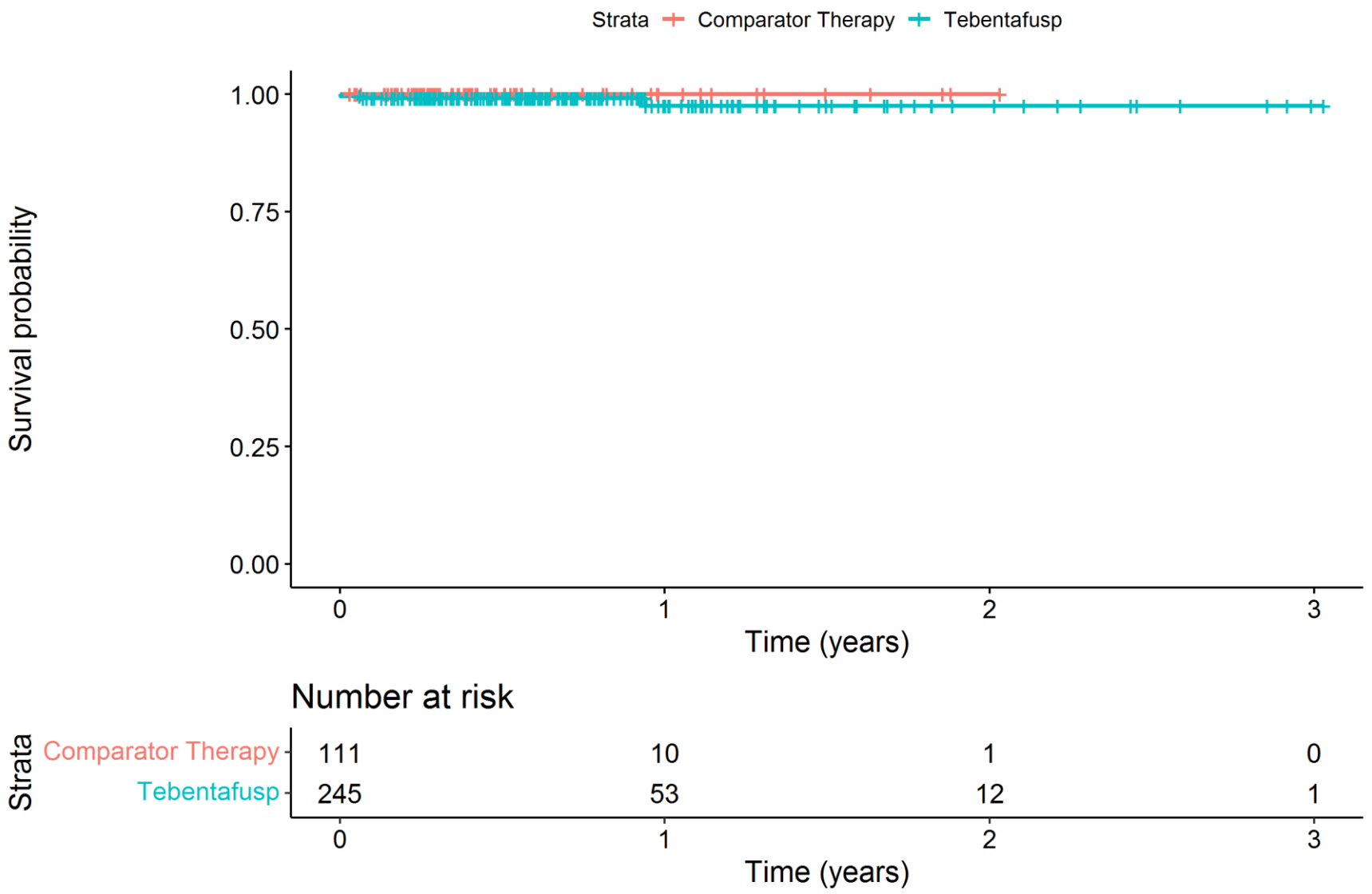
29.17 Hypophosphatämie



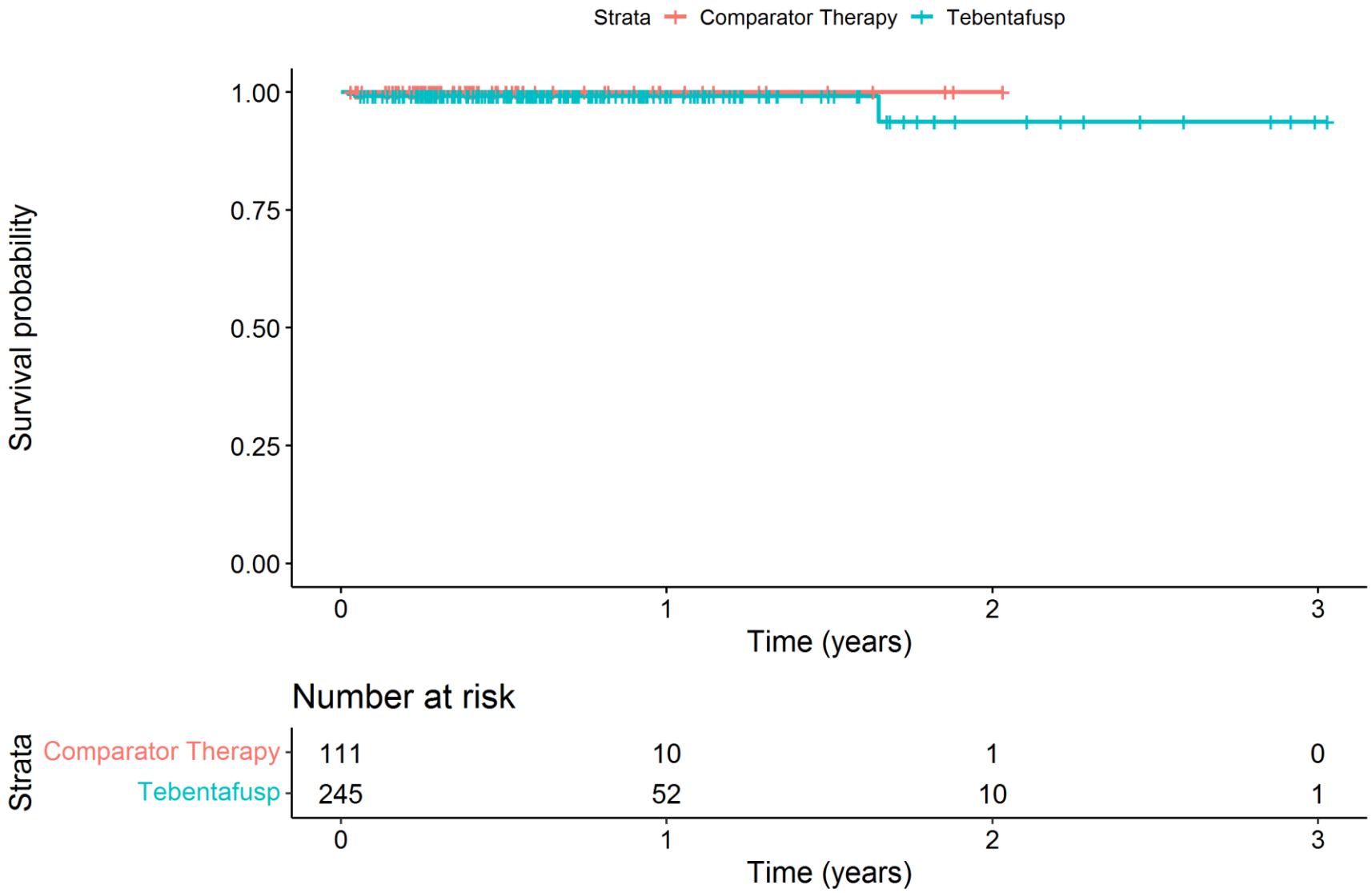
29.18 Dehydrierung



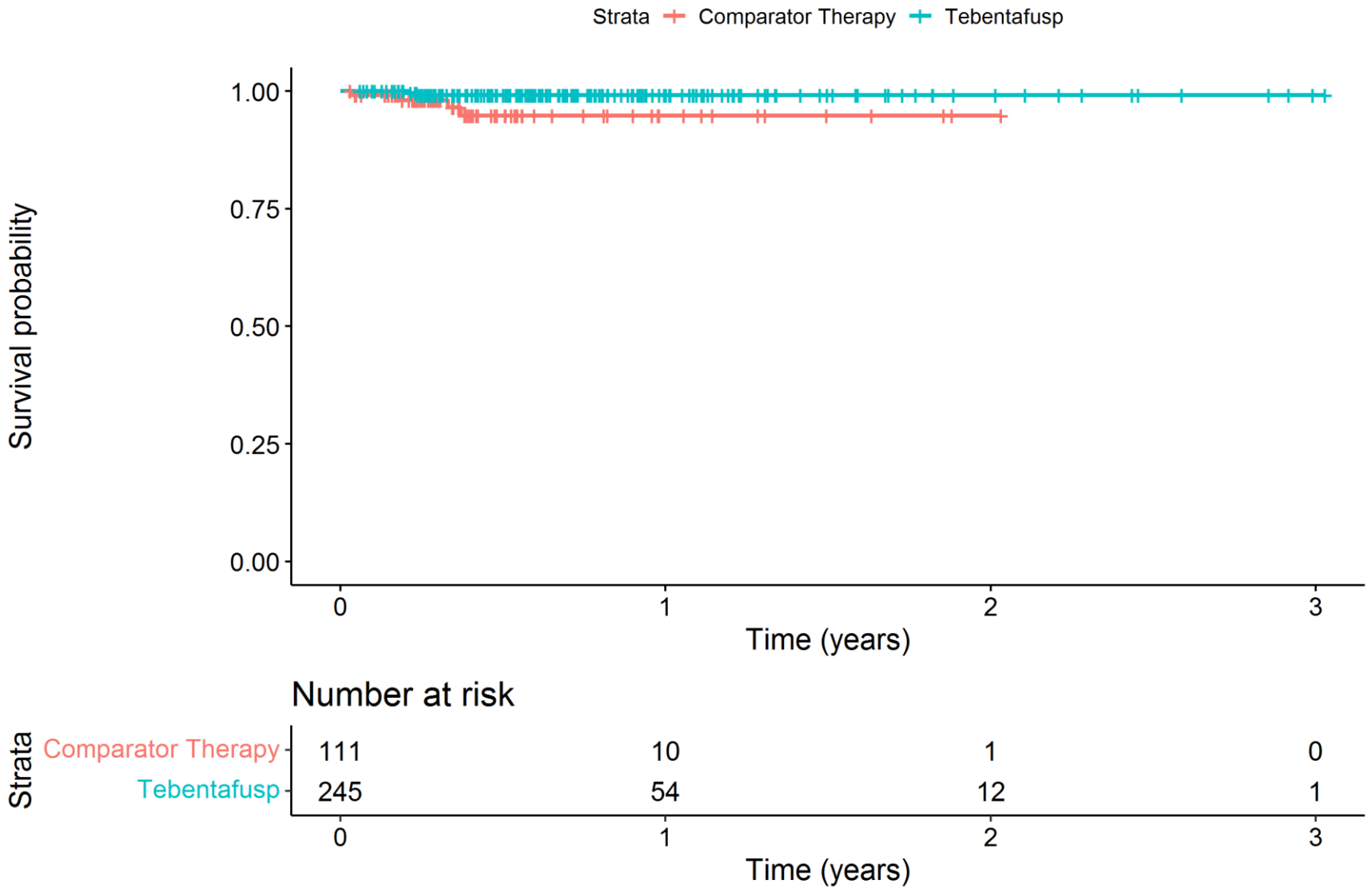
29.19 Tumorschmerzen



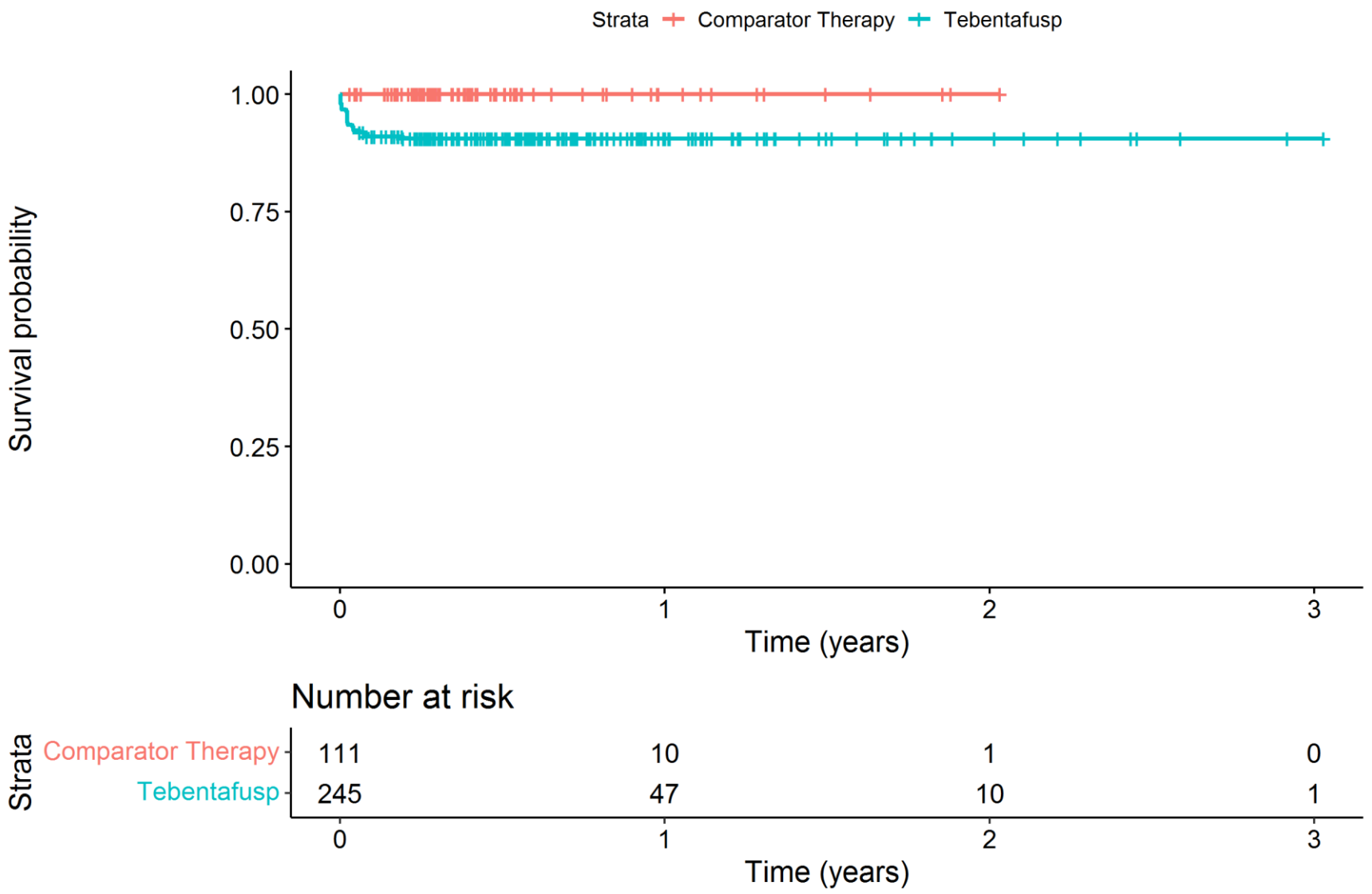
29.20 Synkope



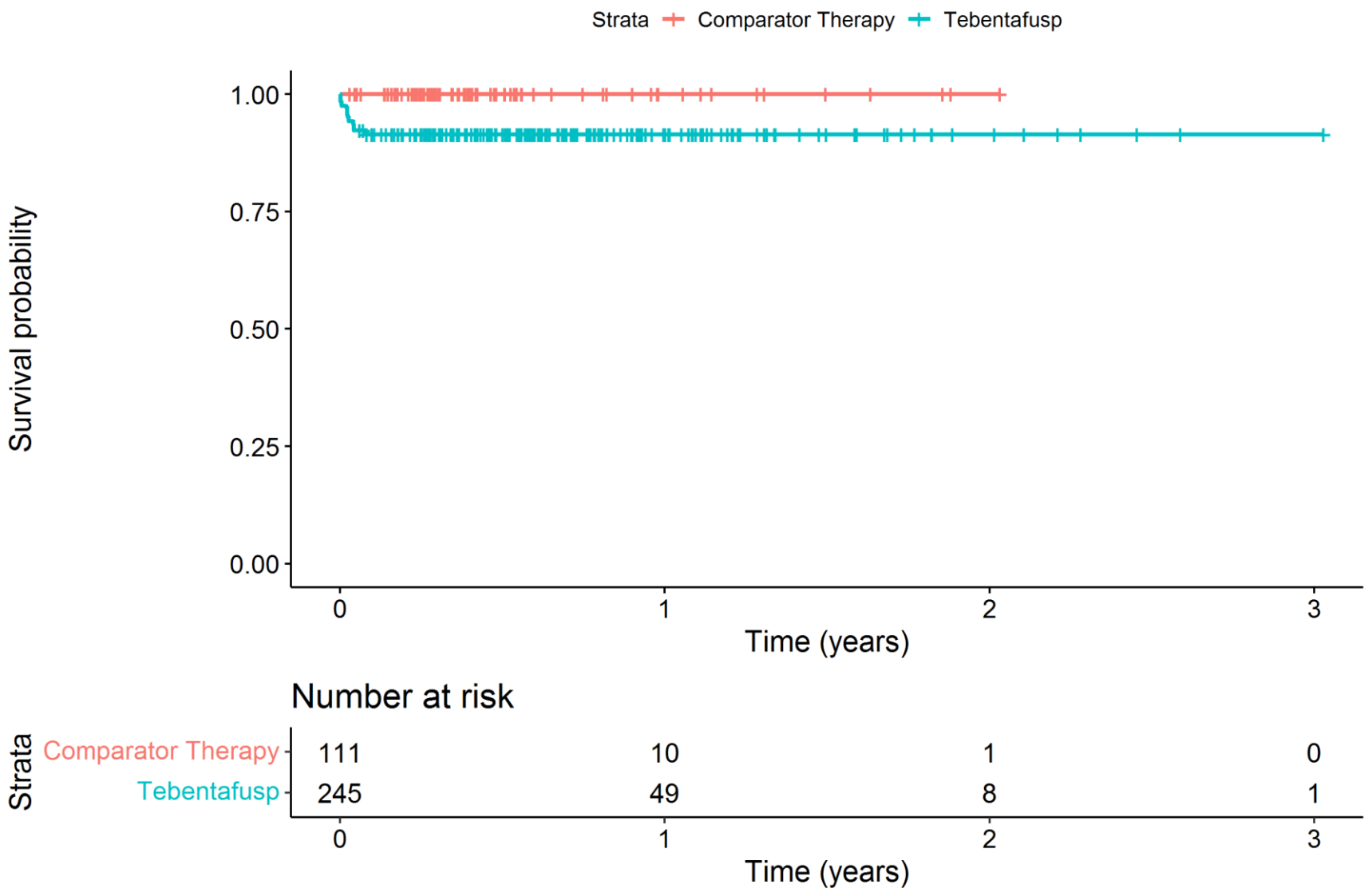
29.21 Lungenembolie



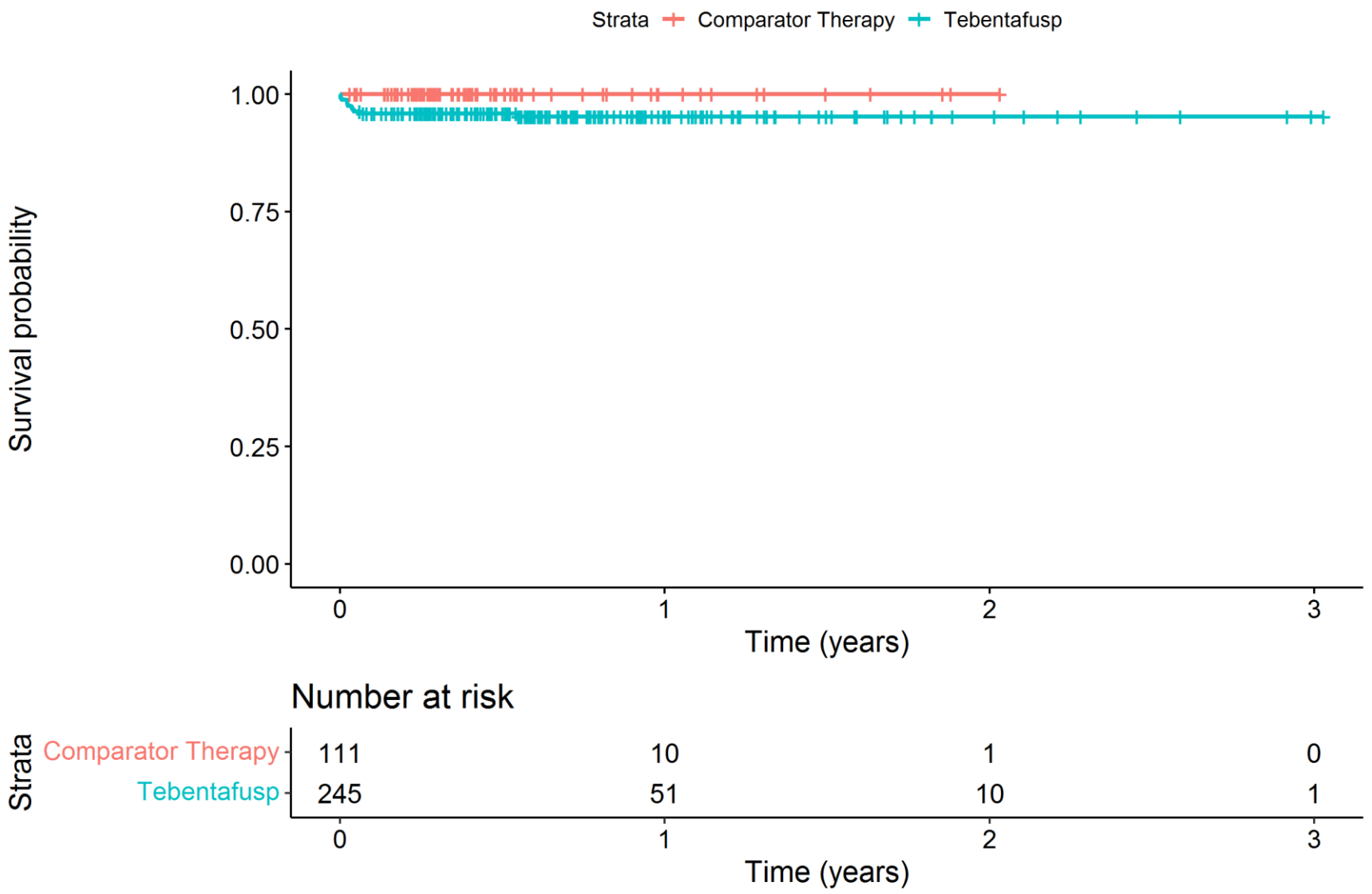
29.22 Hautausschlag



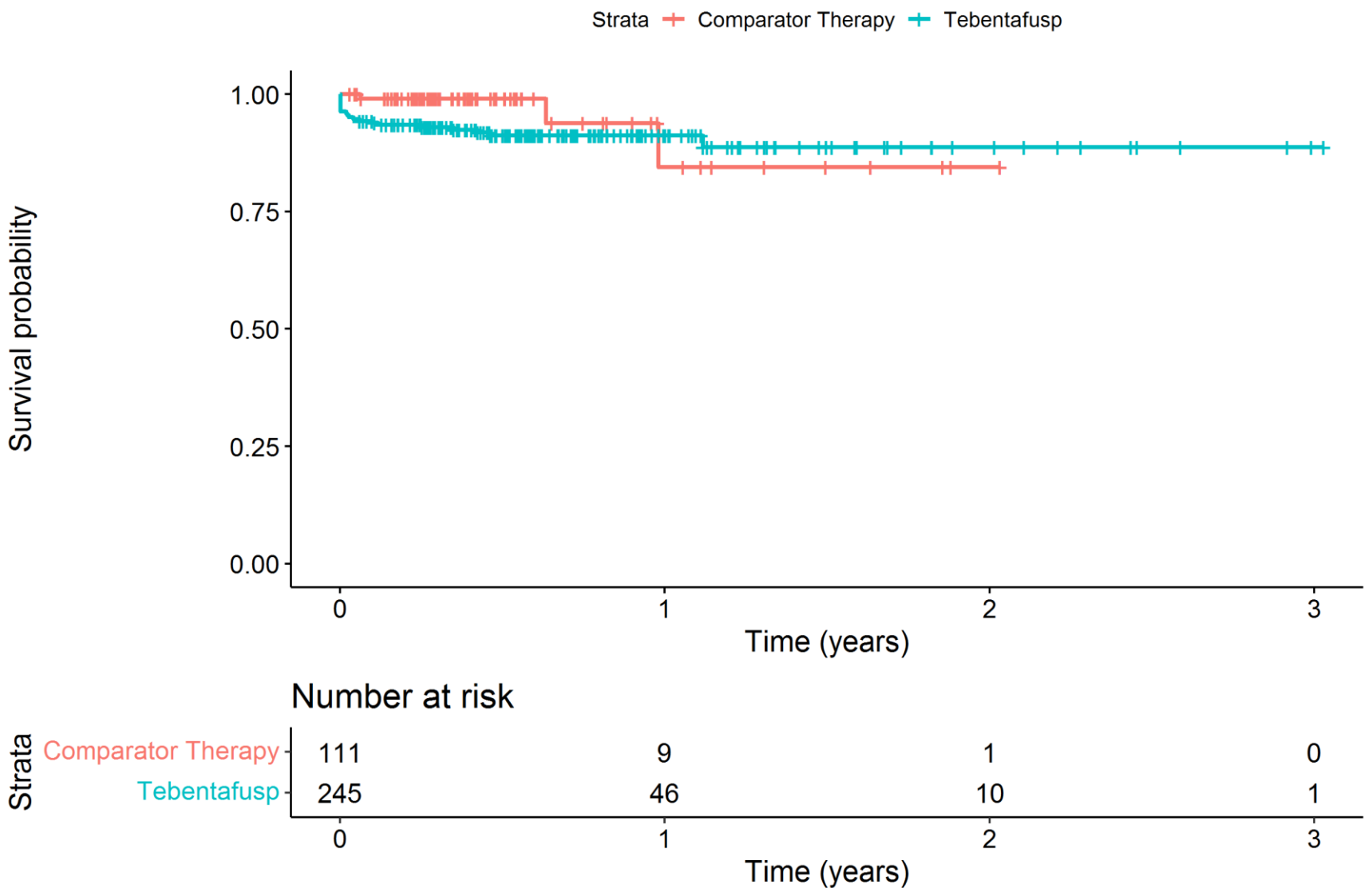
29.23 Makulo-papulöser Hautausschlag



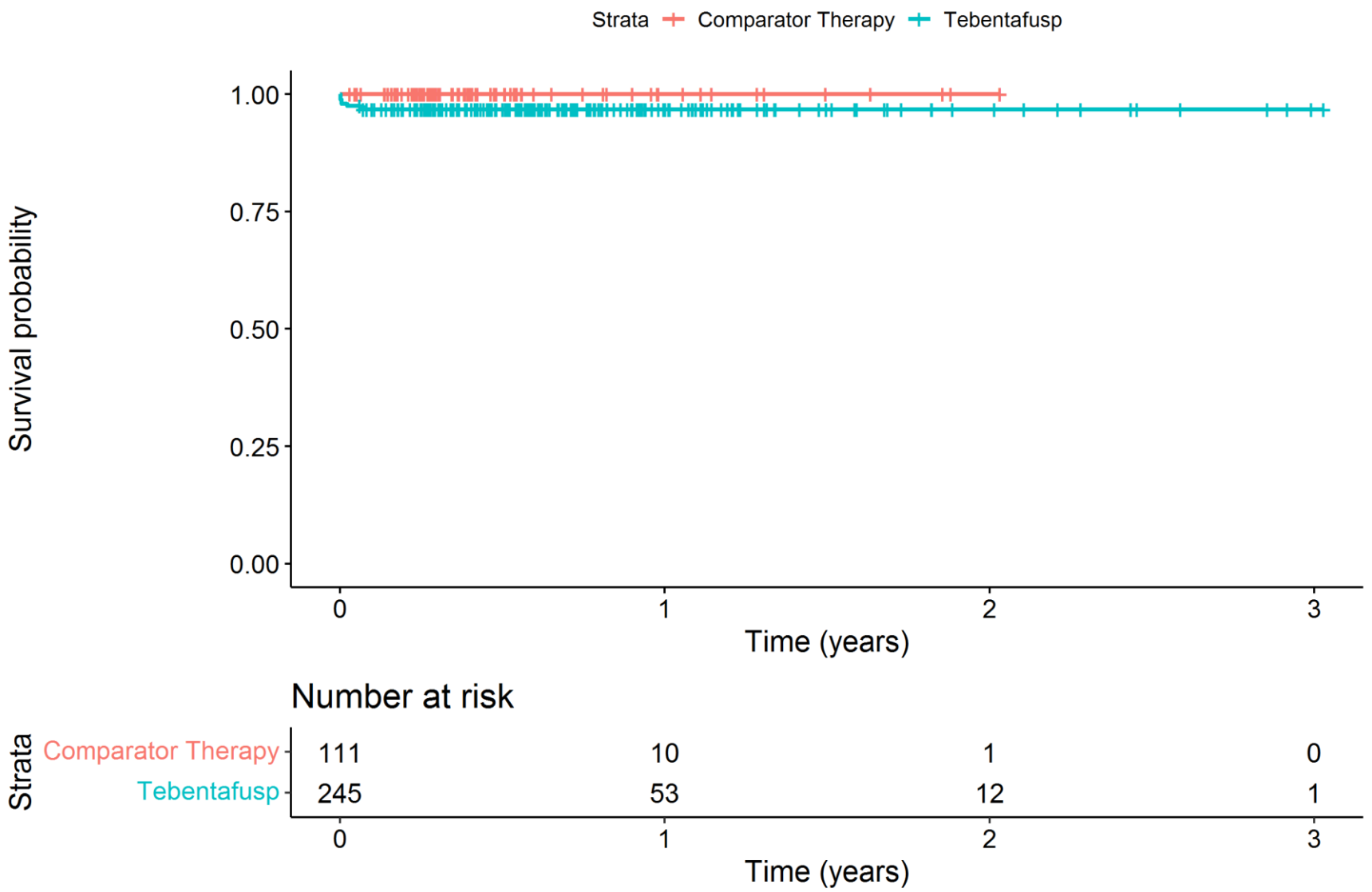
29.24 Pruritus



29.25 Hypertonie

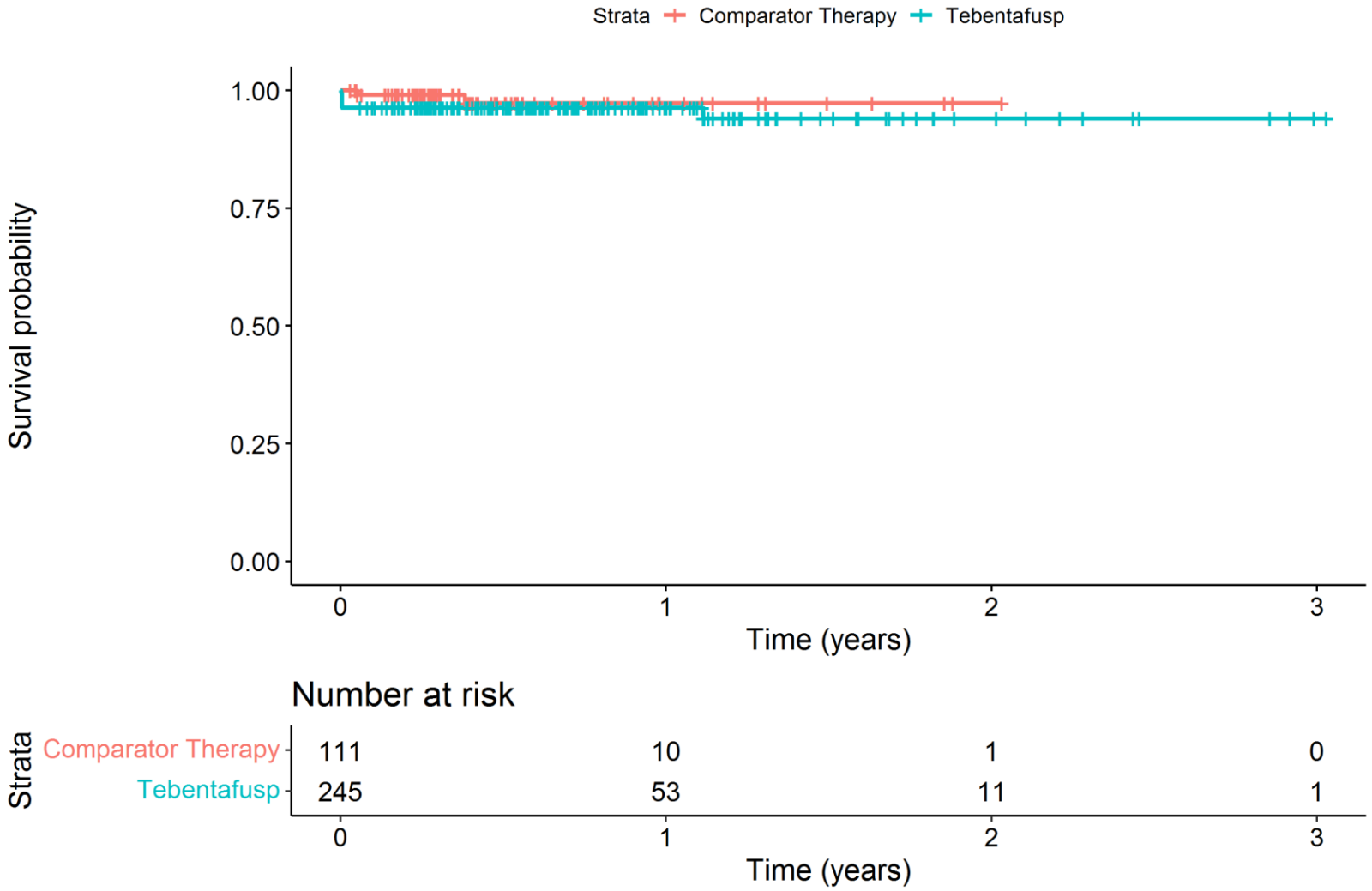


29.26 Hypotonie

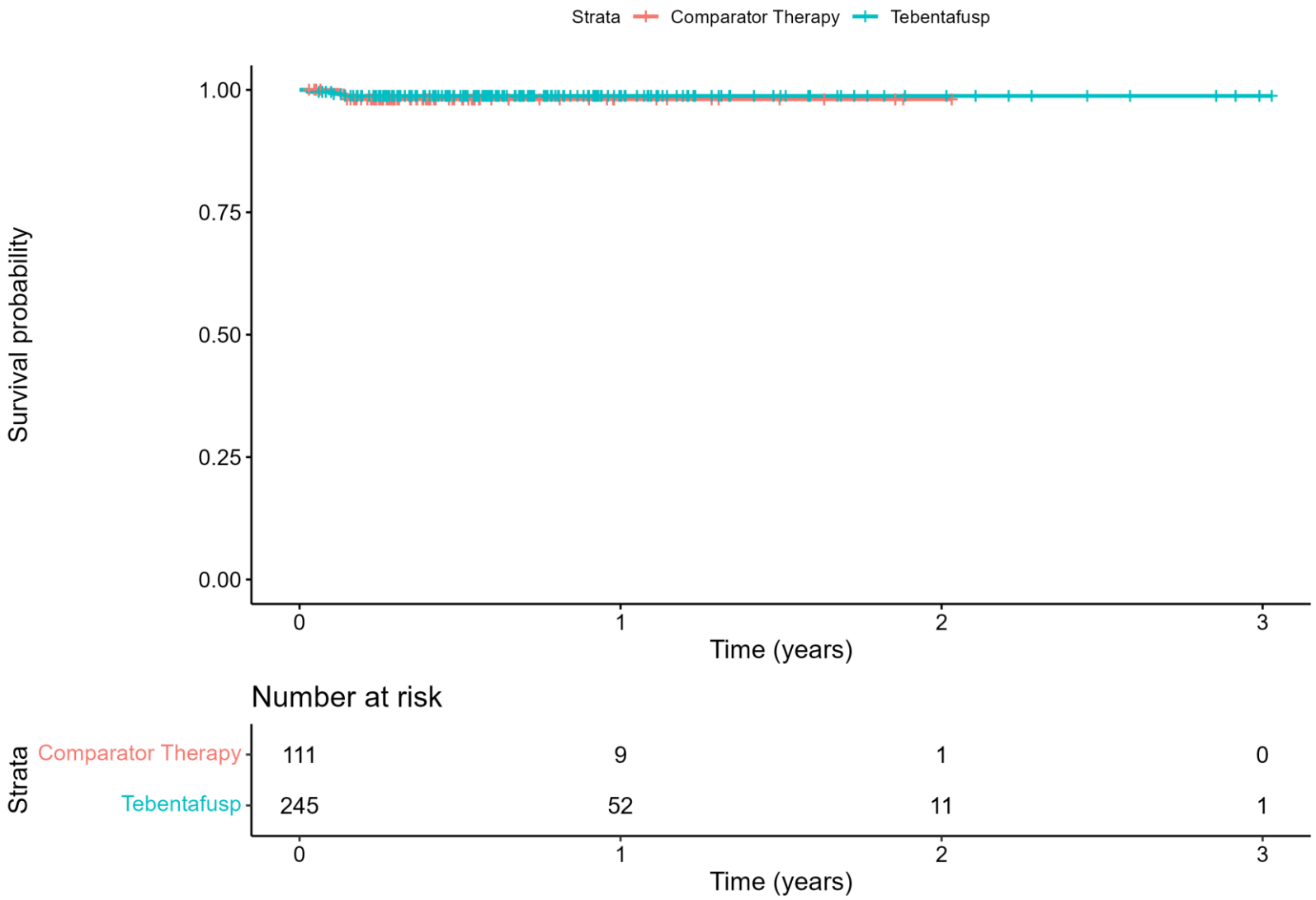


30 UEs (SOC) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten

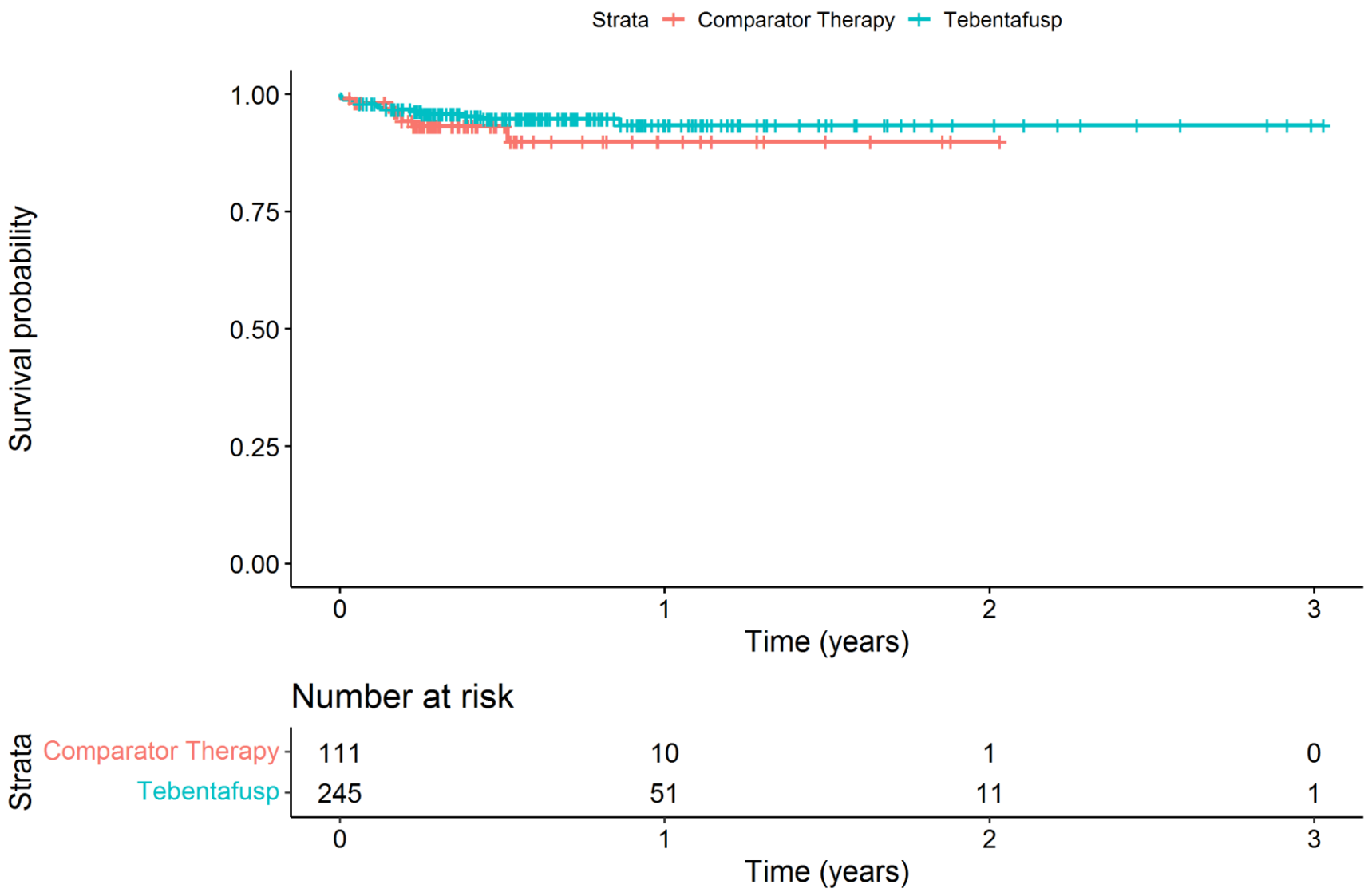
30.1 Erkrankungen des Blutes und des Lymphsystems



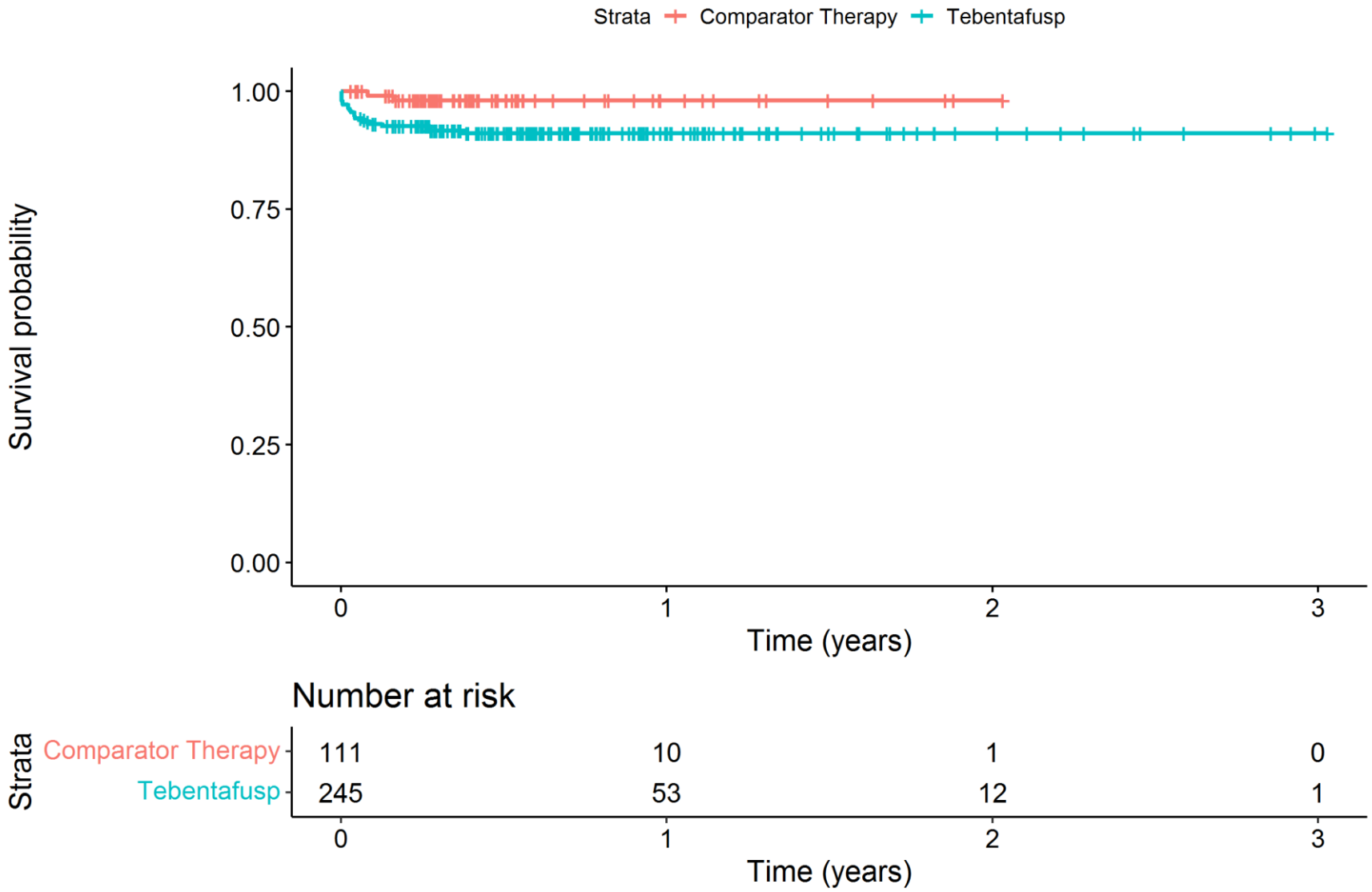
30.2 Augenerkrankungen



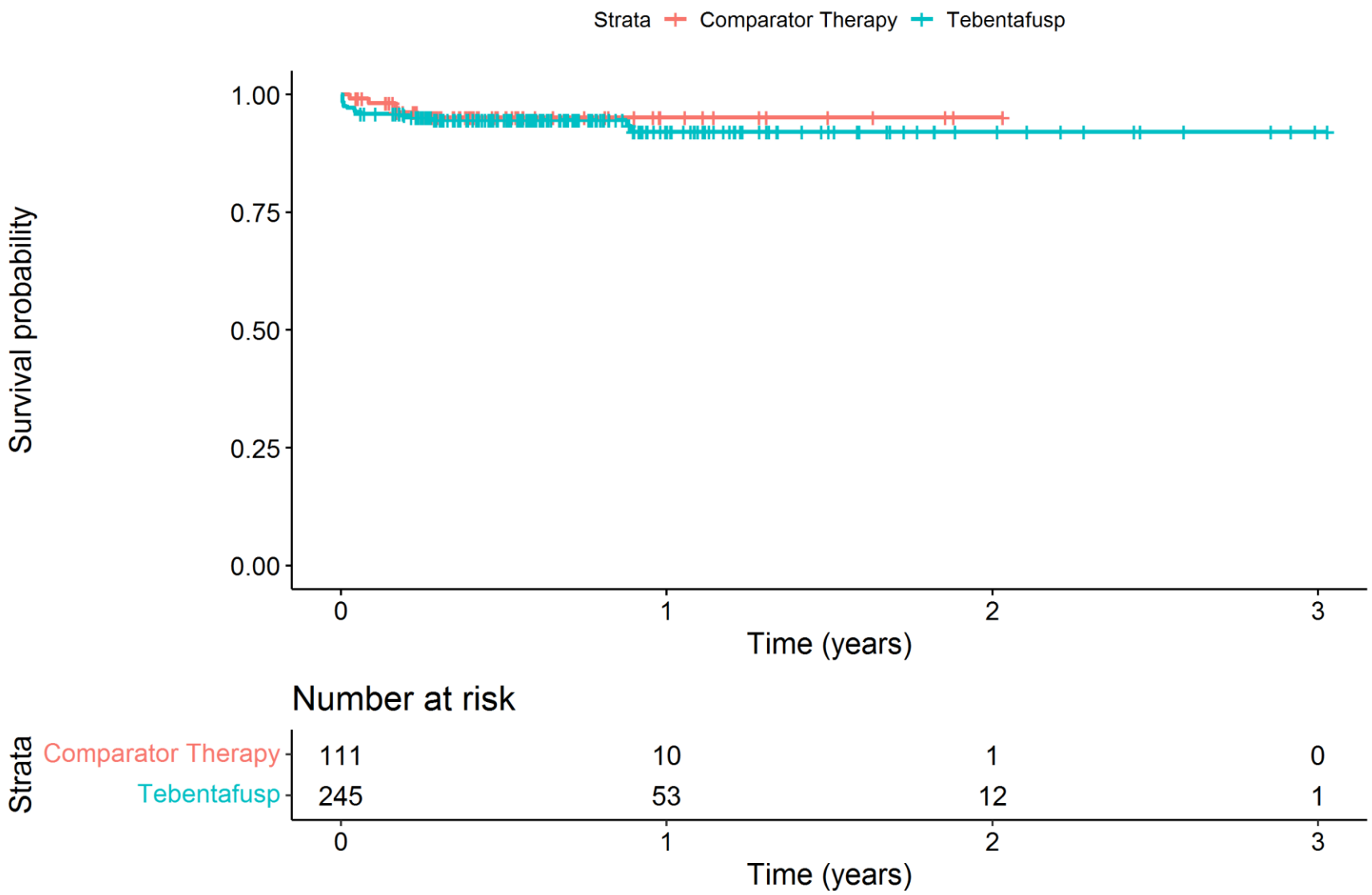
30.3 Erkrankungen des Gastrointestinaltrakts



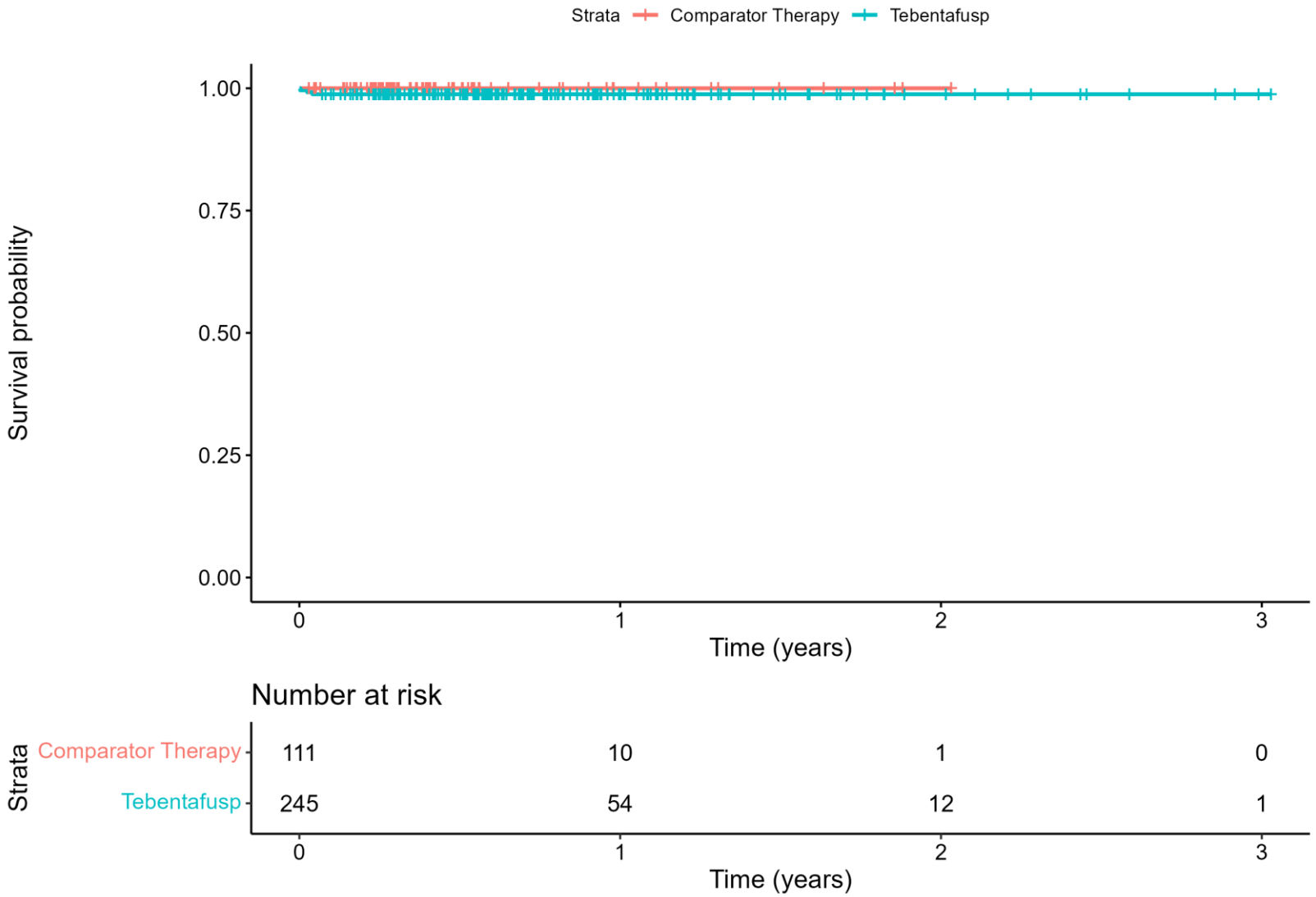
30.4 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



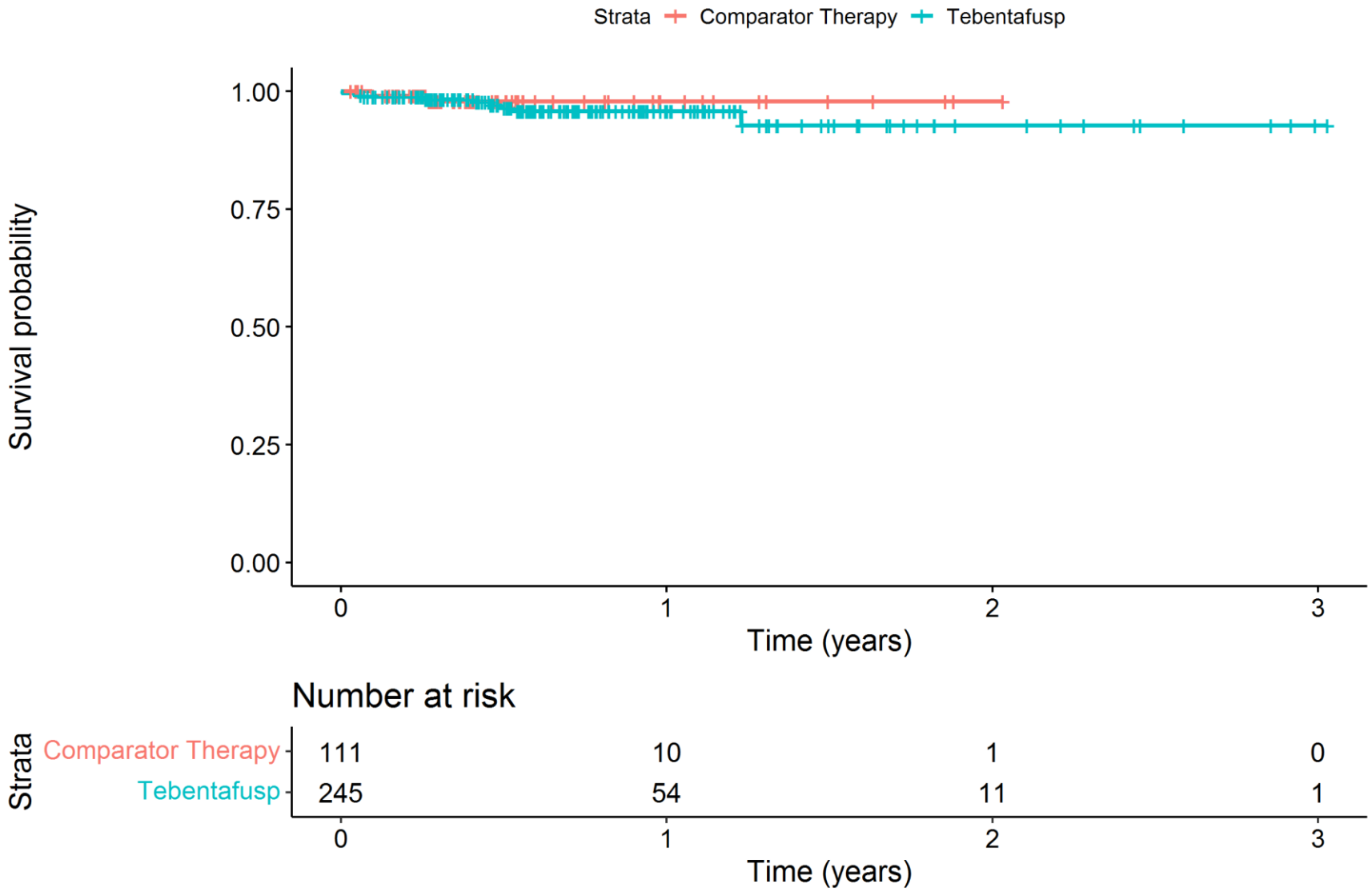
30.5 Leber- und Gallenerkrankungen



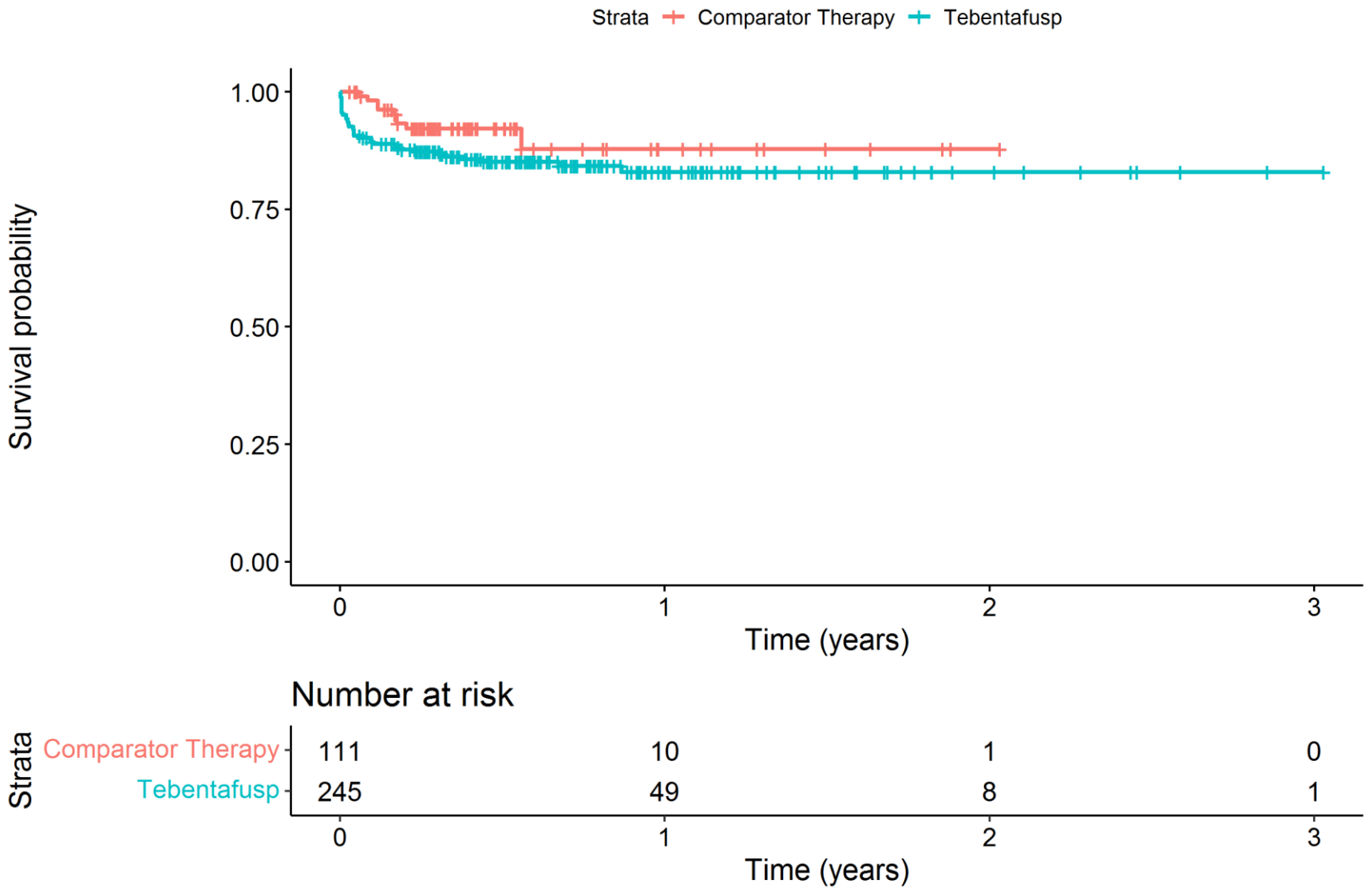
30.6 Erkrankungen des Immunsystems



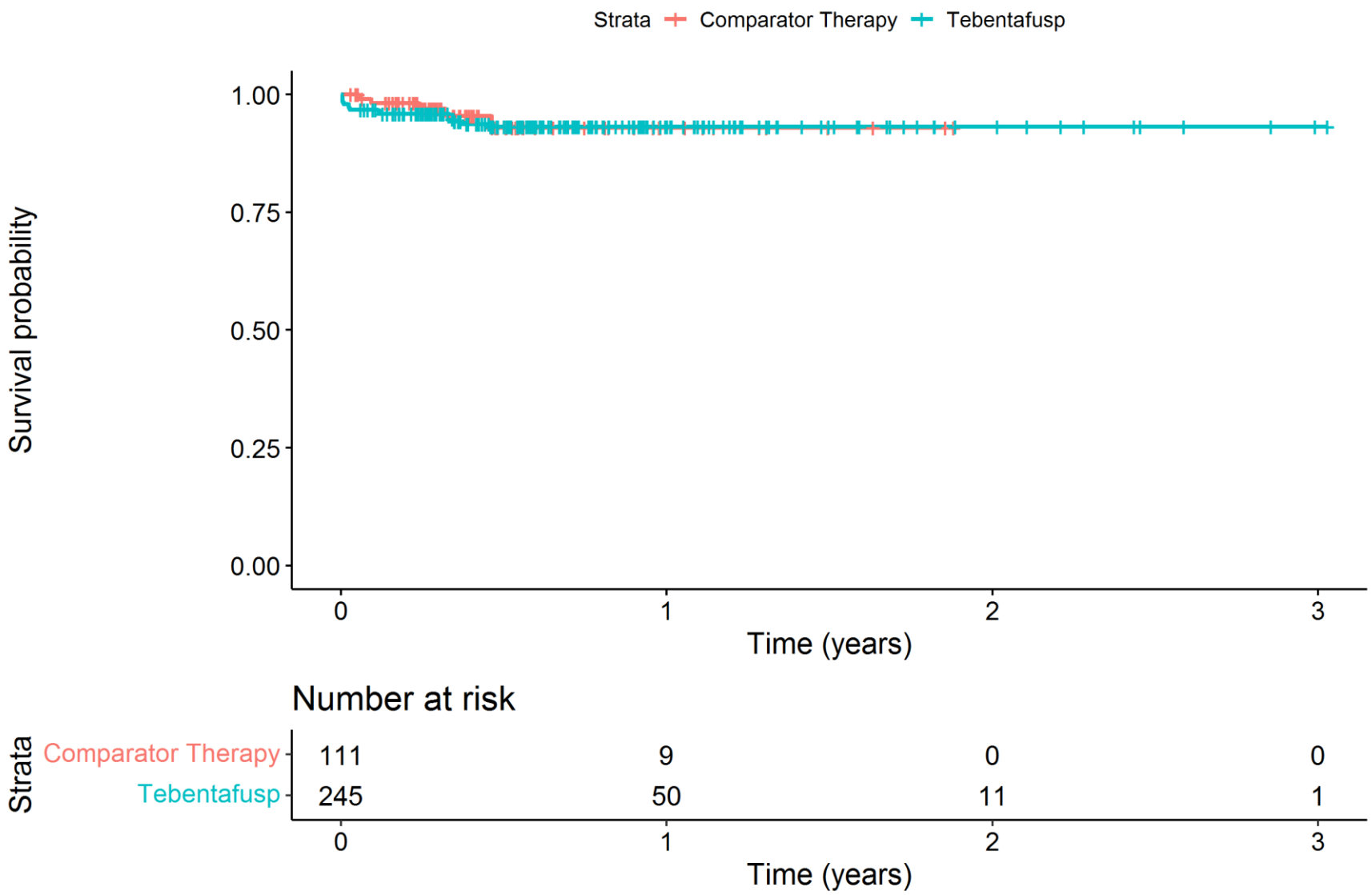
30.7 Infektionen und parasitäre Erkrankungen



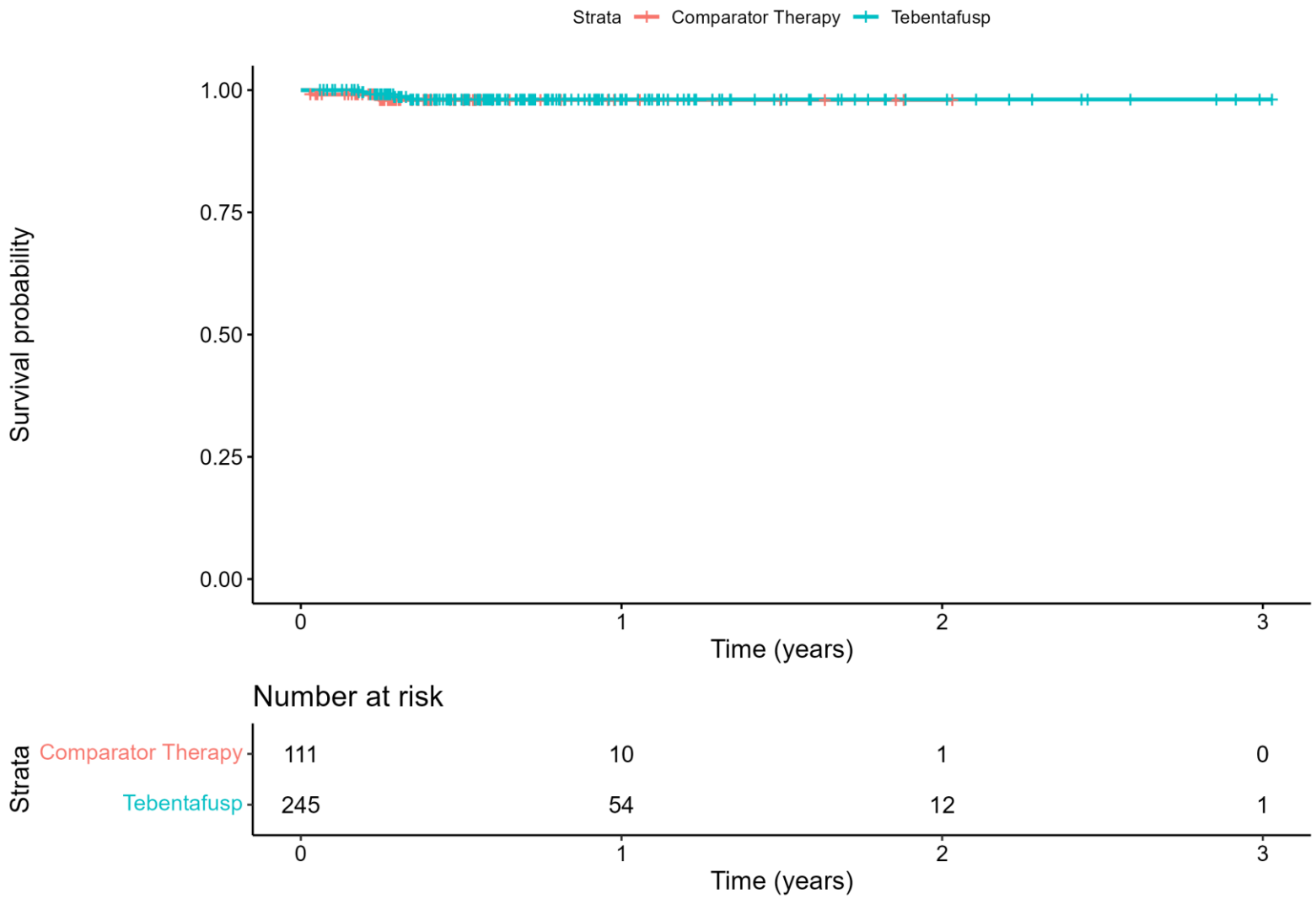
30.8 Untersuchungen



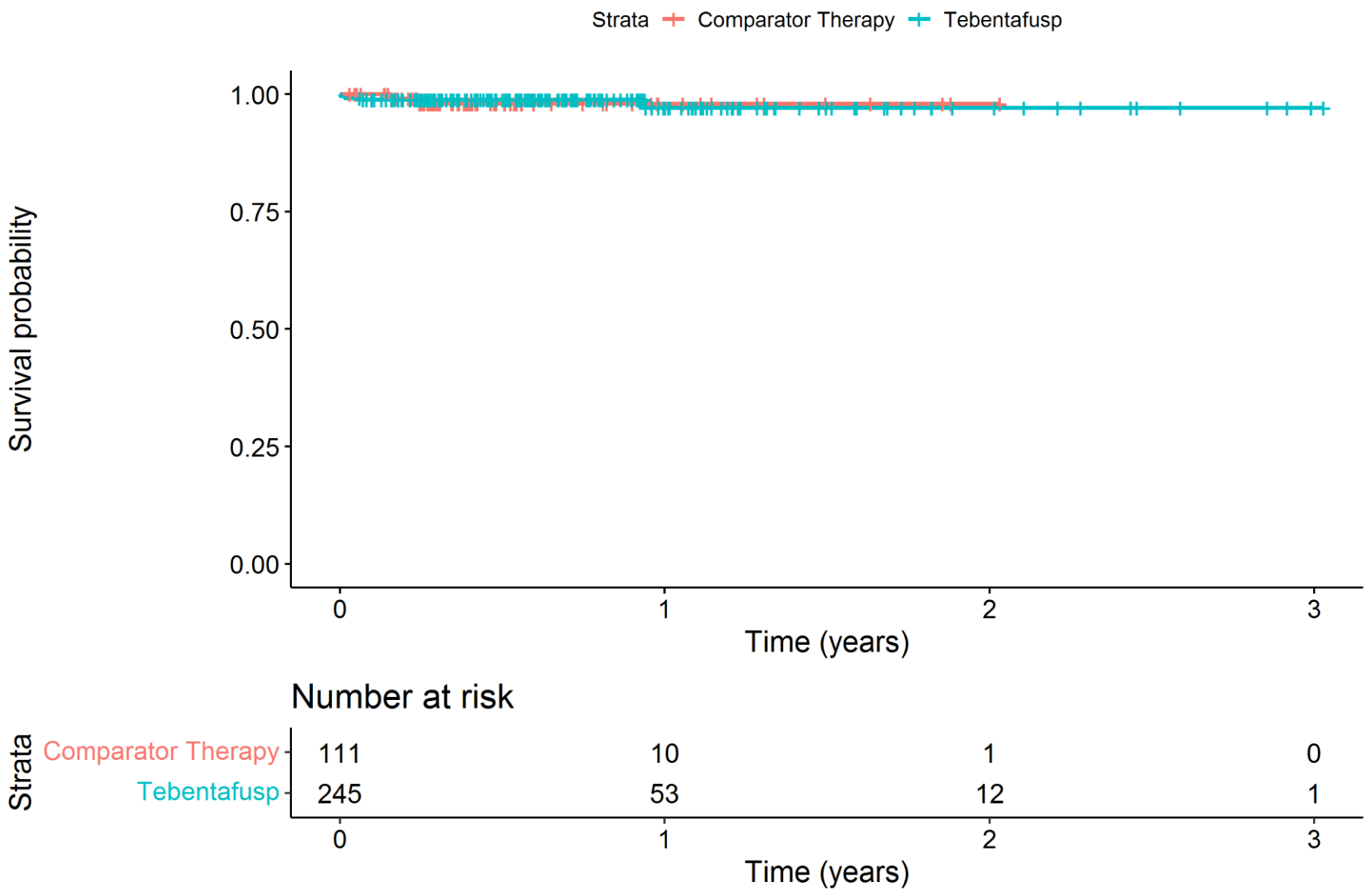
30.9 Stoffwechsel- und Ernährungsstörungen



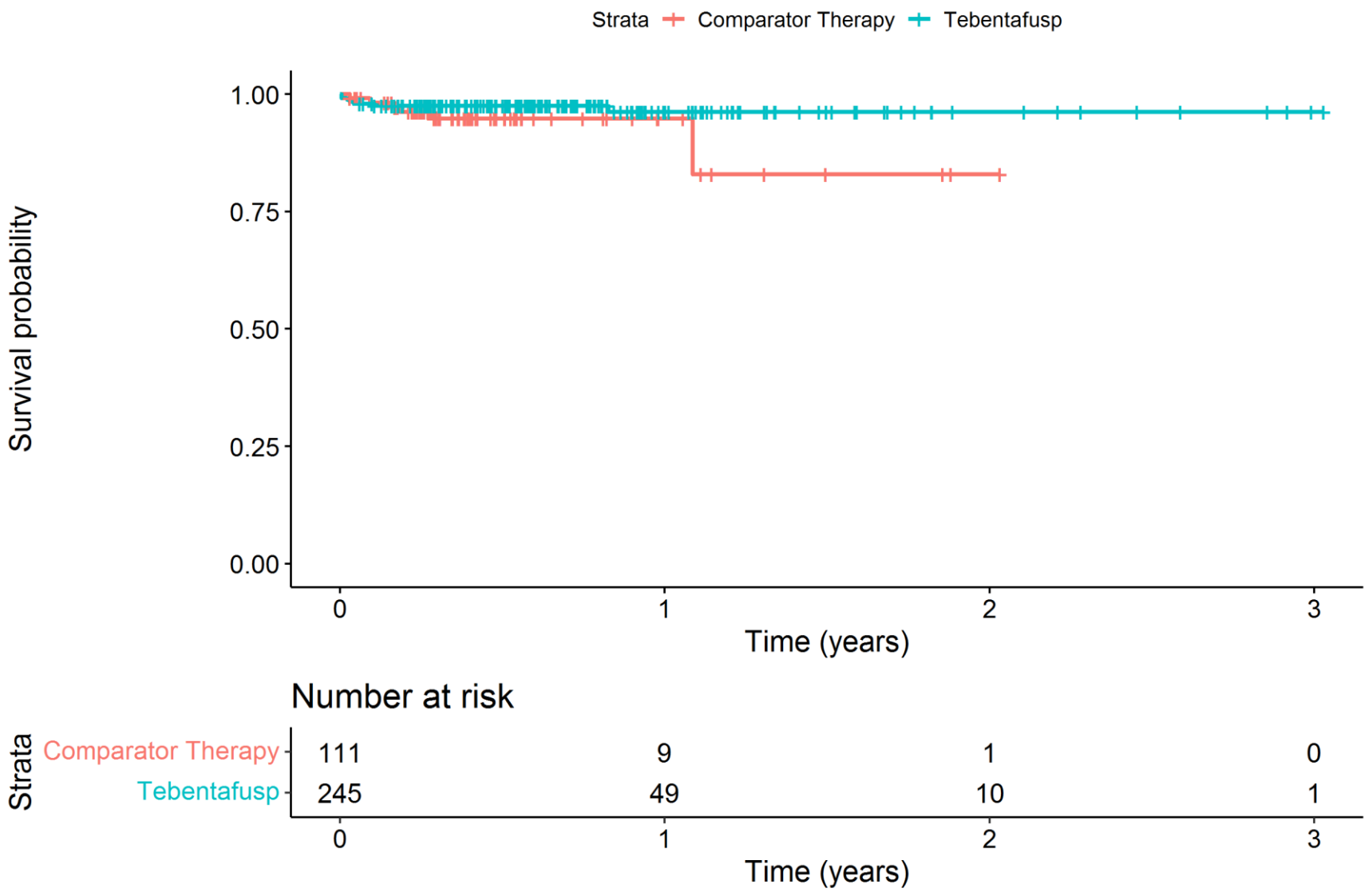
30.10 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



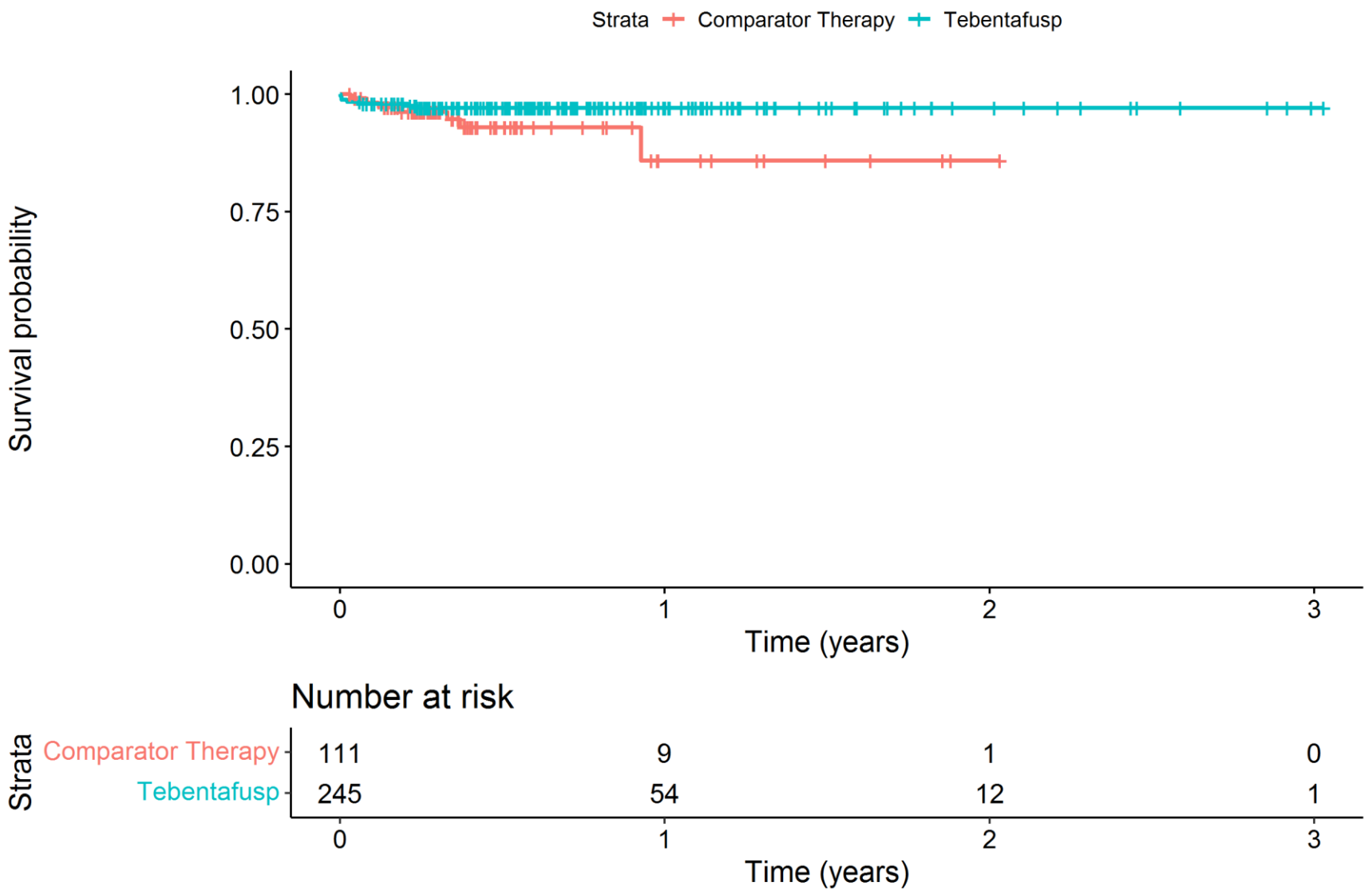
30.11 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



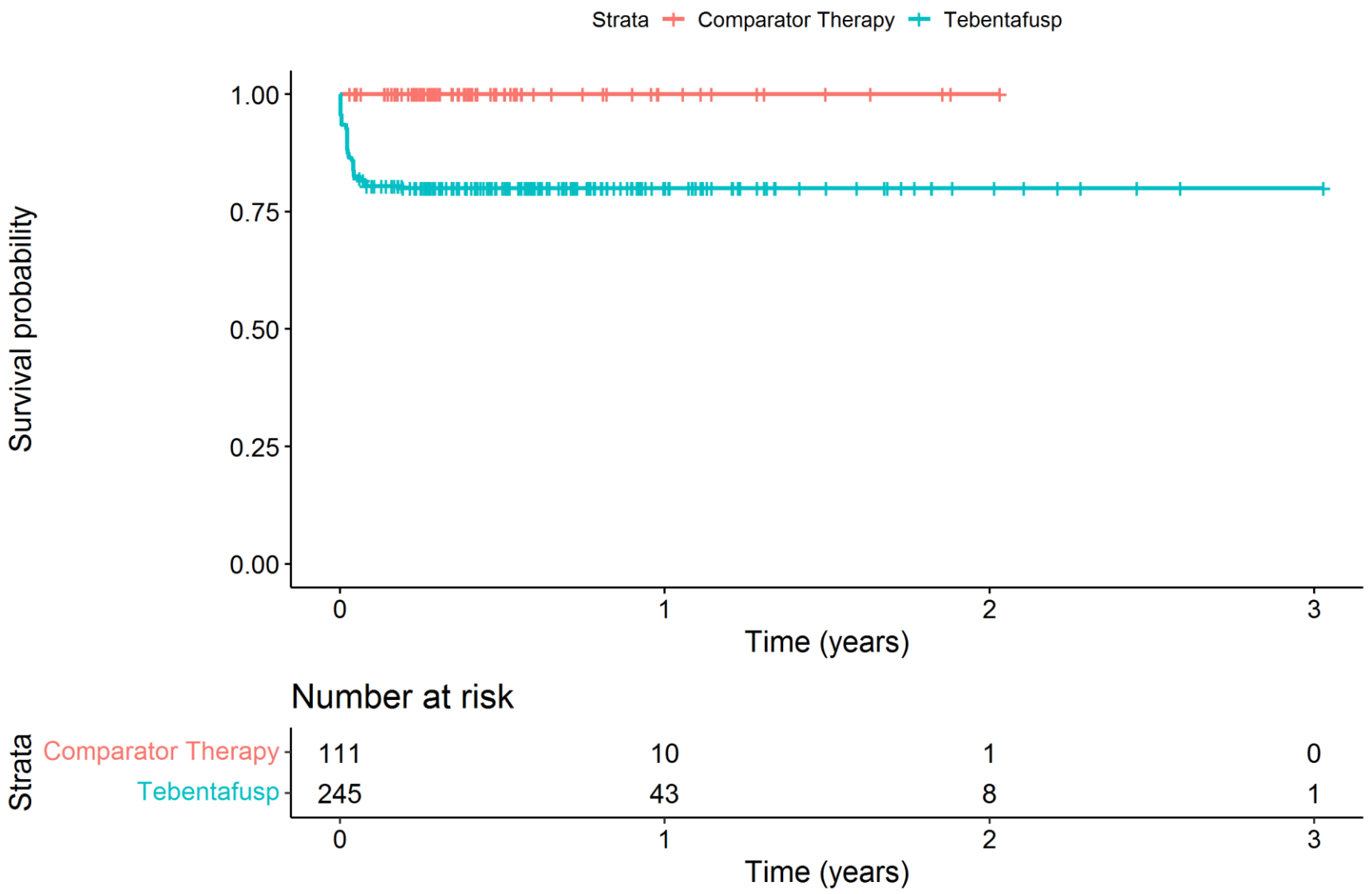
30.12 Erkrankungen des Nervensystems



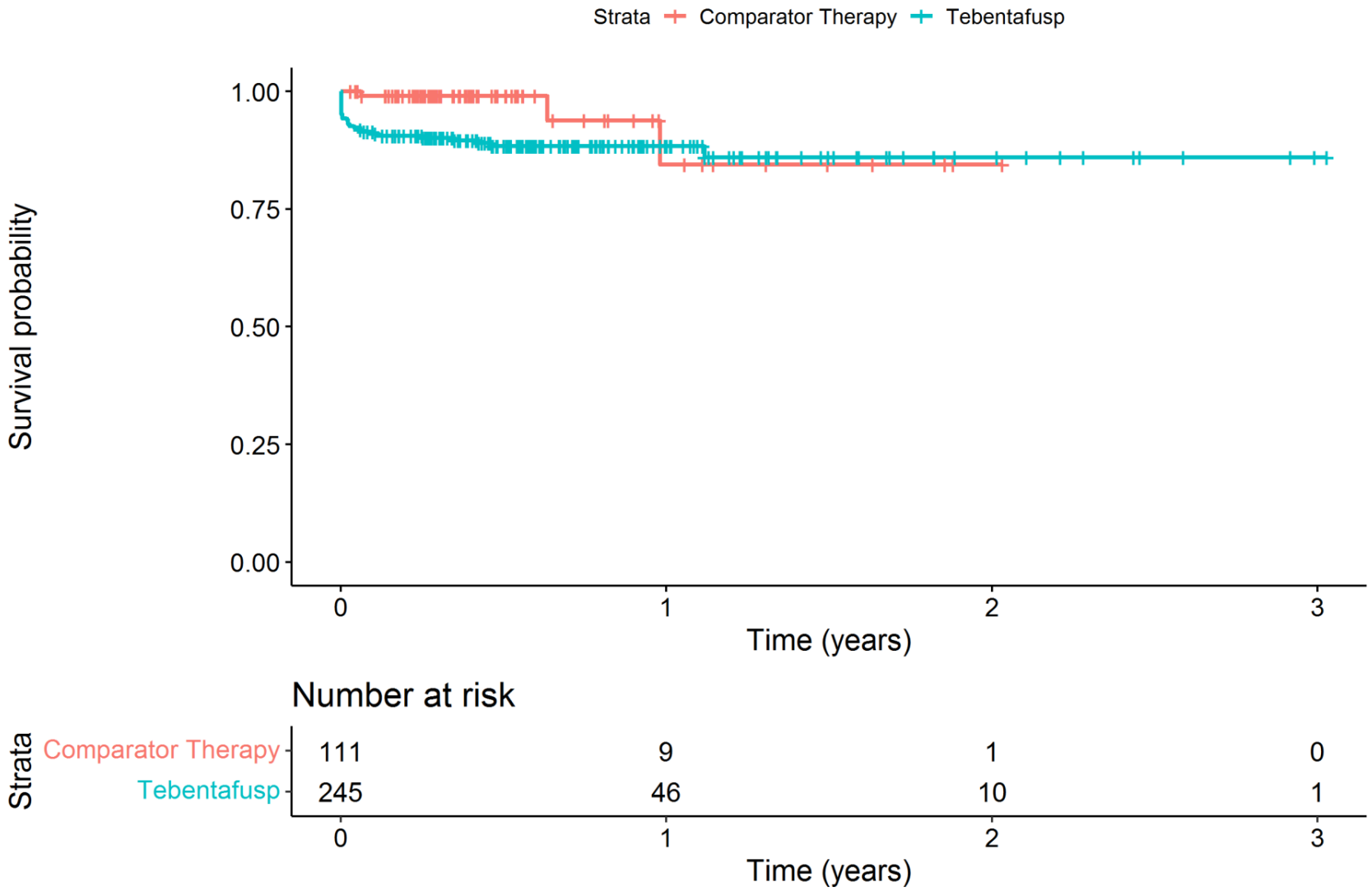
30.13 Erkrankungen der Atemwege, des Brustraums und Mediastinums



30.14 Erkrankungen der Haut und des Unterhautgewebes



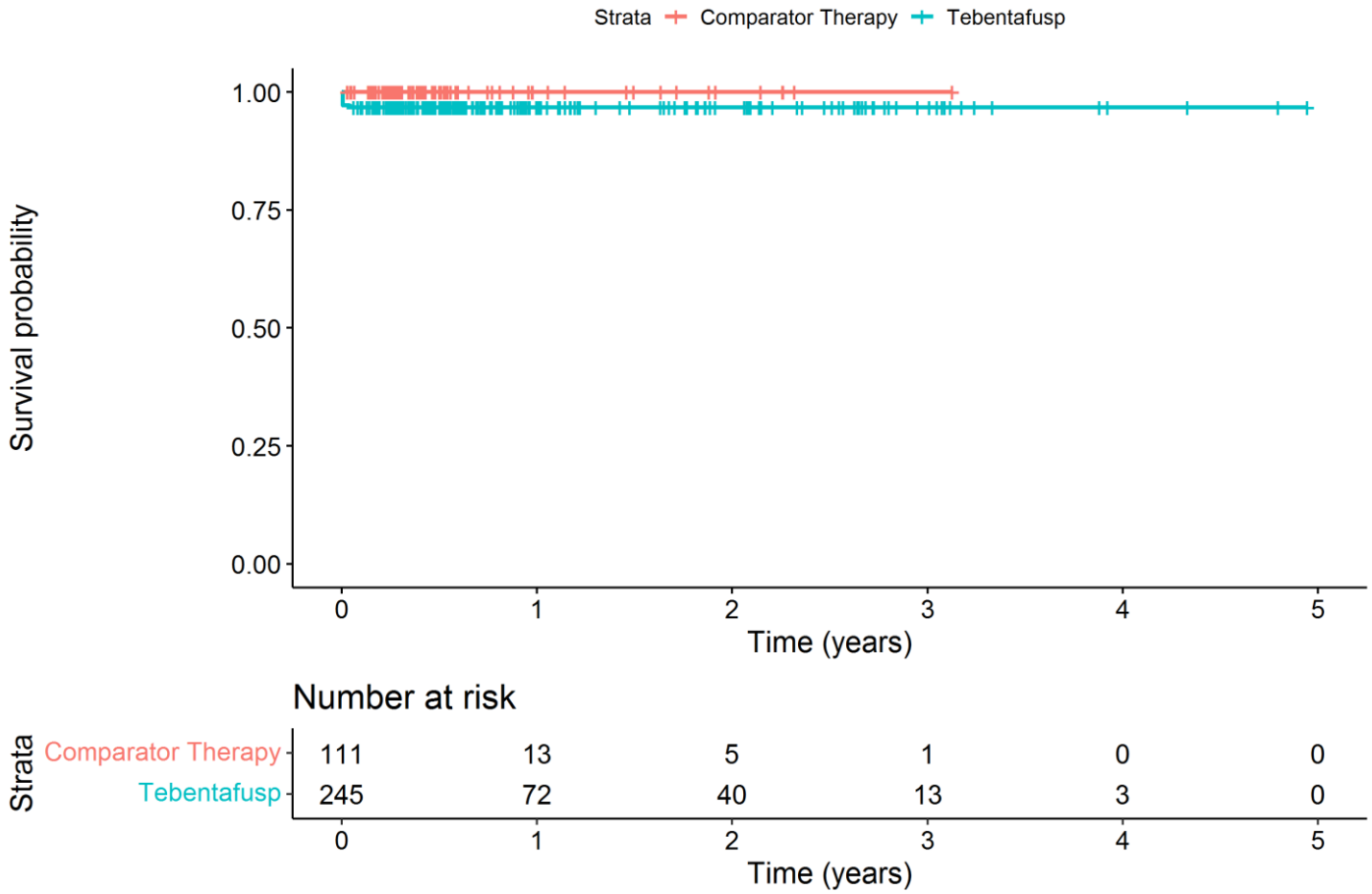
30.15 Gefäßerkrankungen



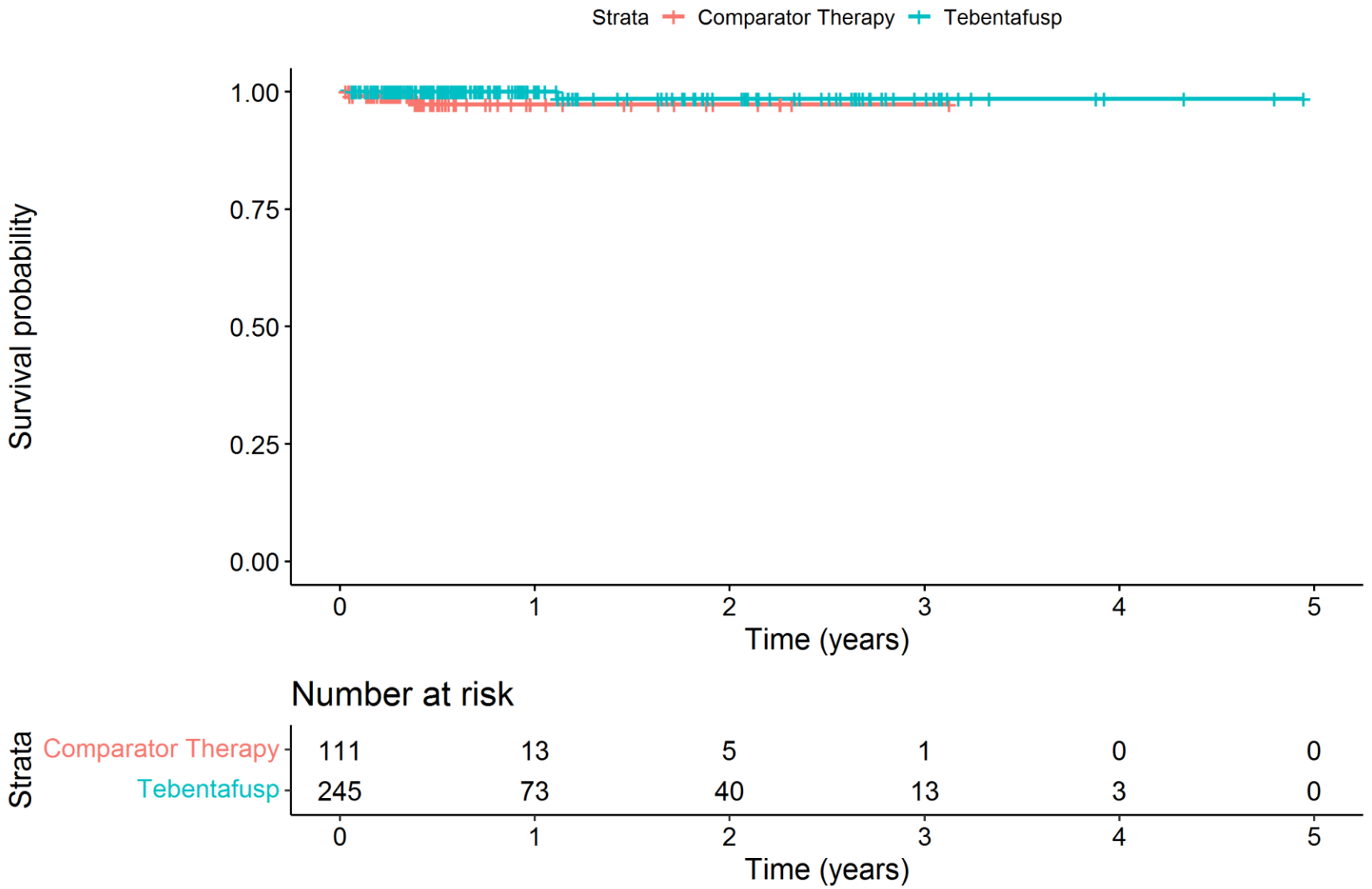
30.16 Unerwünschte Ereignisse nach Schweregrad – 3-Jahres-Analyse (Juni 2023) (Tabelle 4-56)

31 UEs (PT) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten

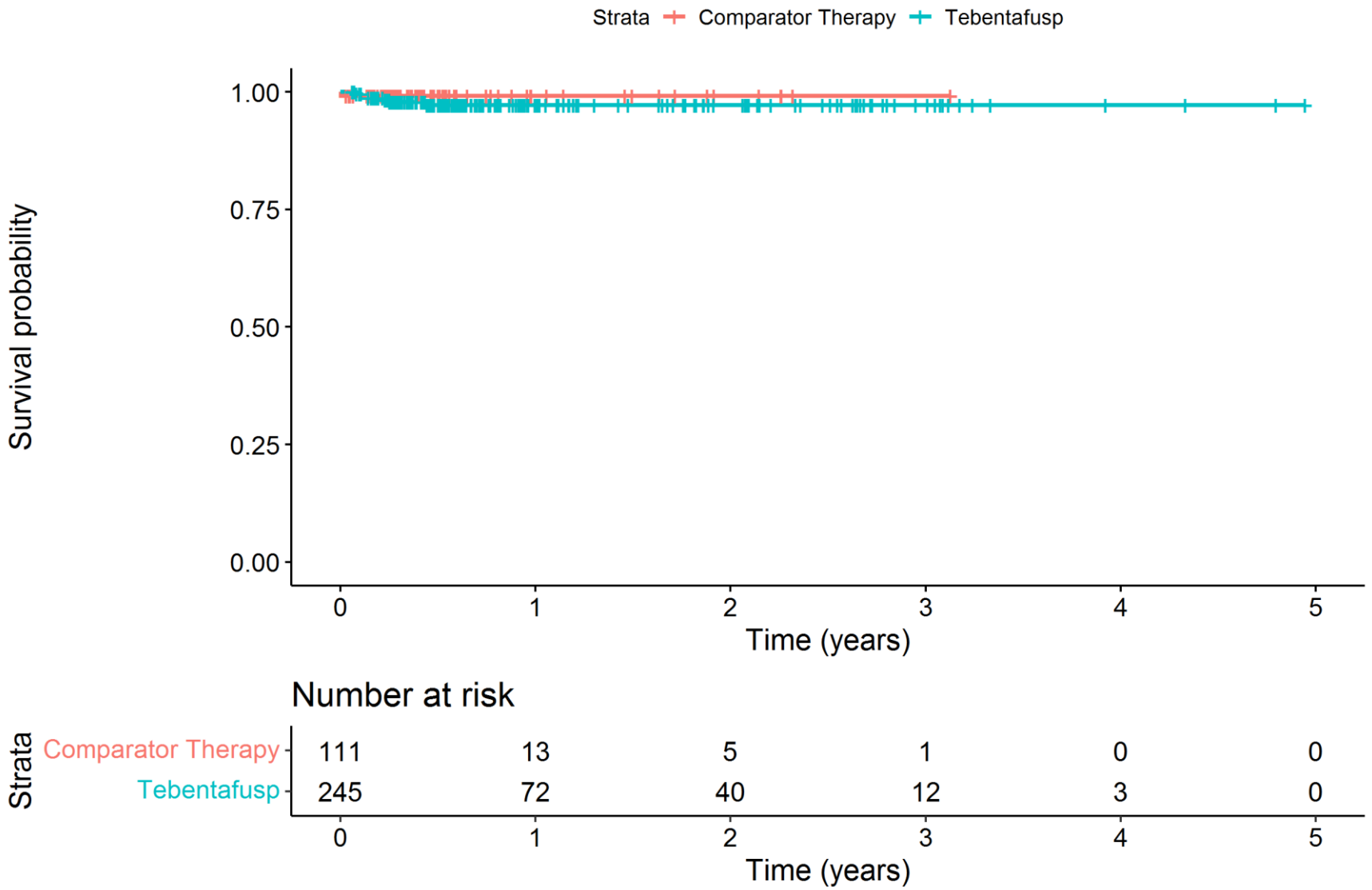
31.1 Lymphopenie



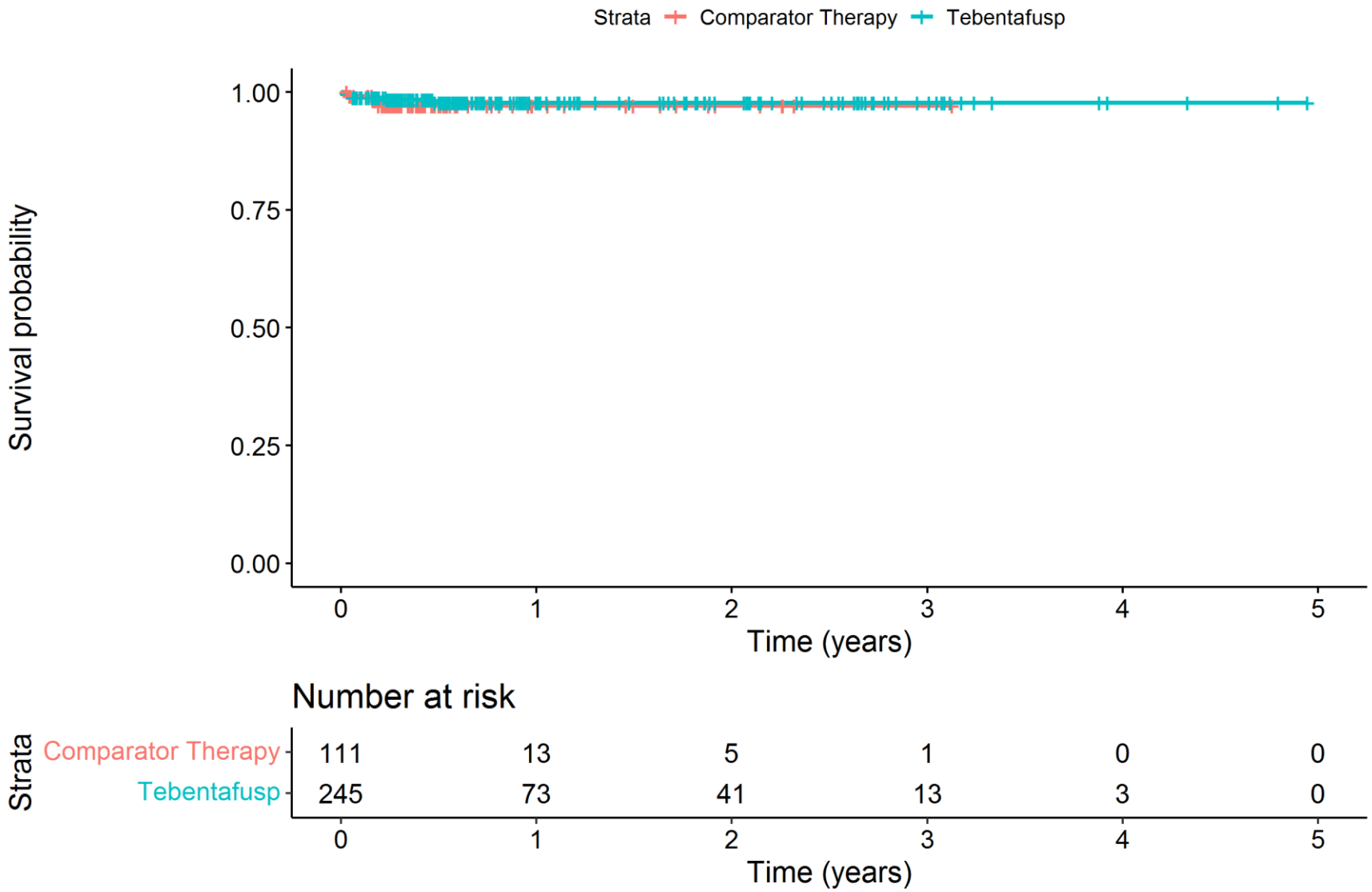
31.2 Neutropenie



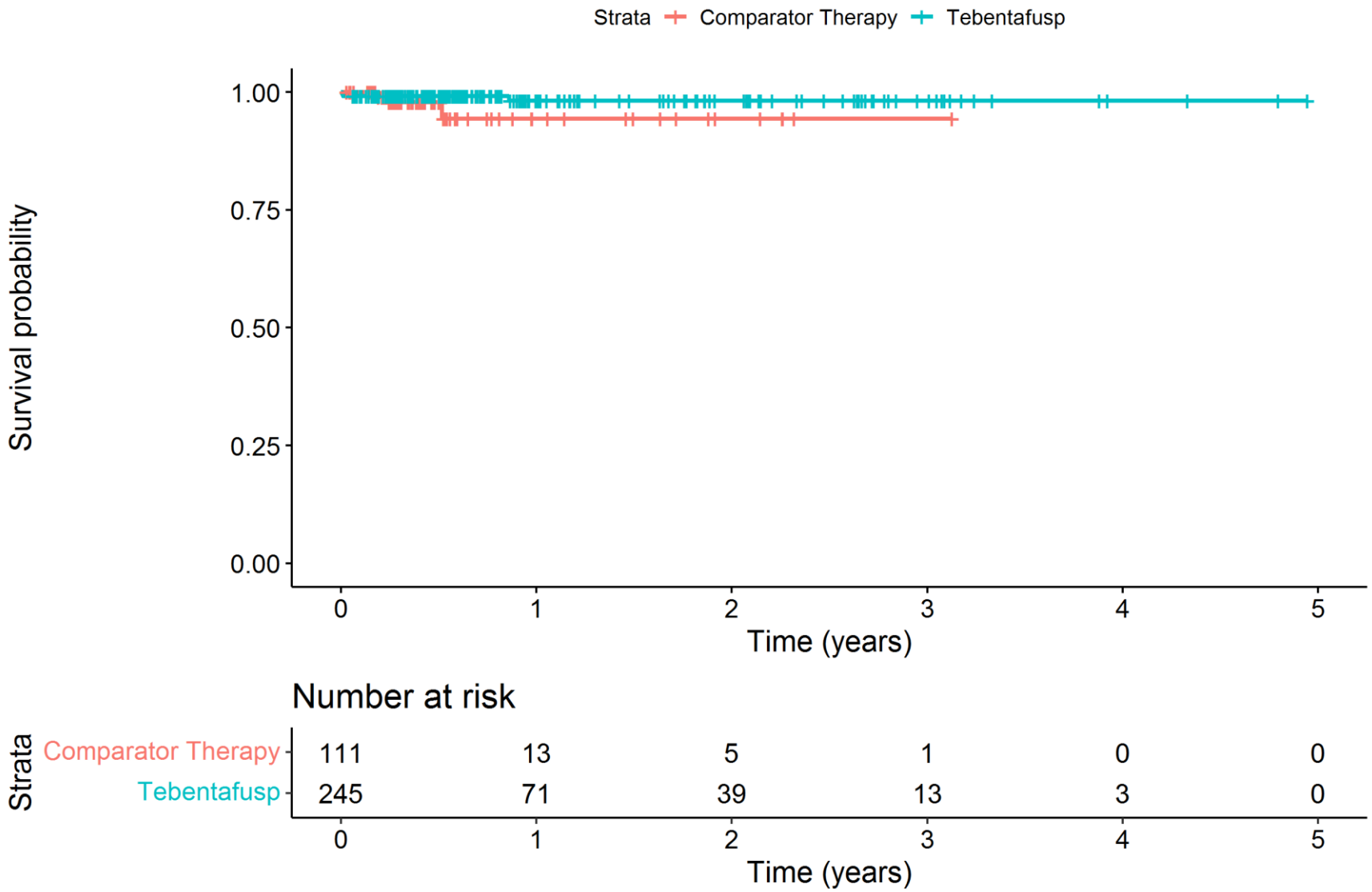
31.3 Übelkeit



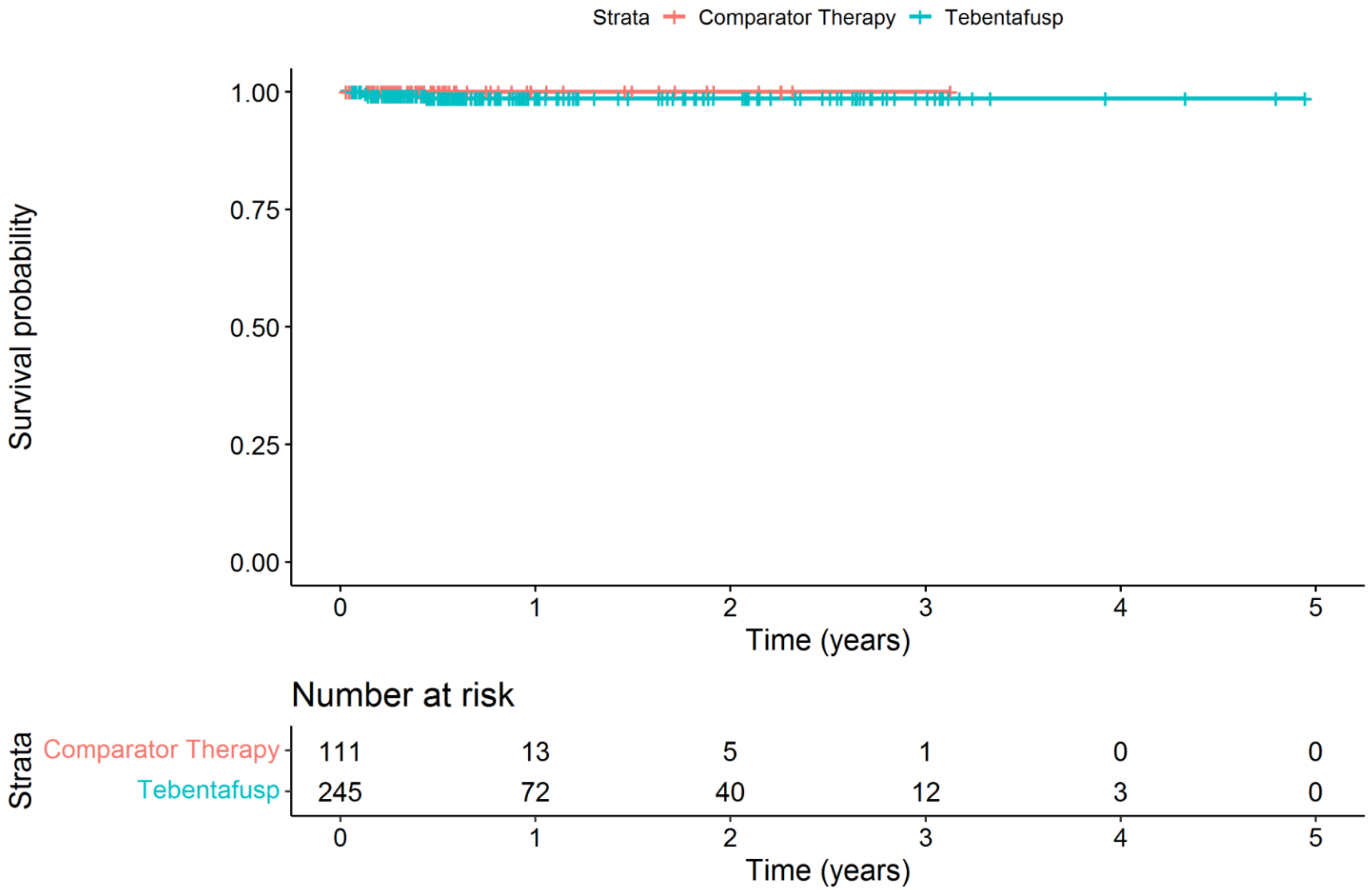
31.4 Unterleibsschmerzen



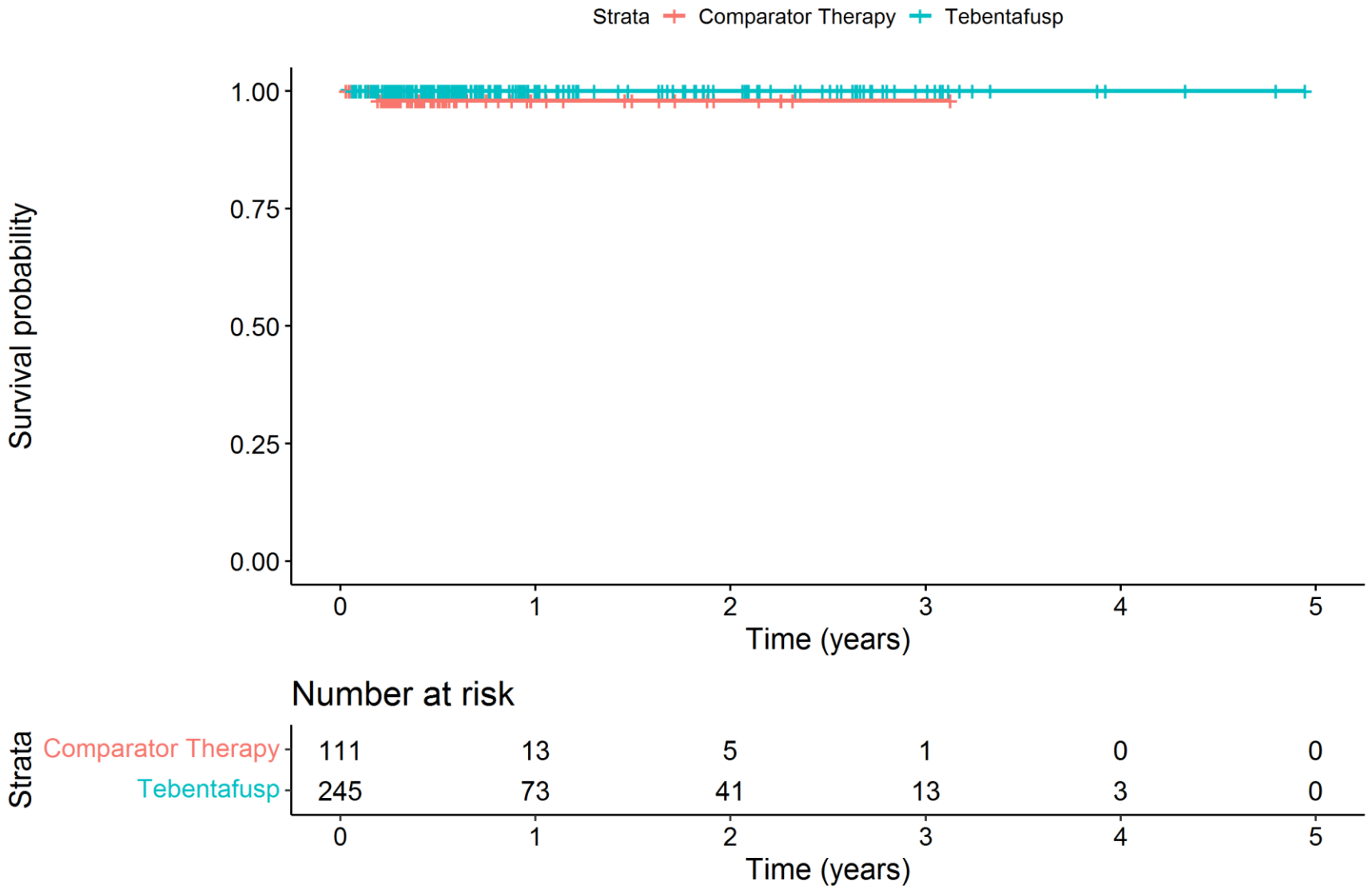
31.5 Diarrhoe



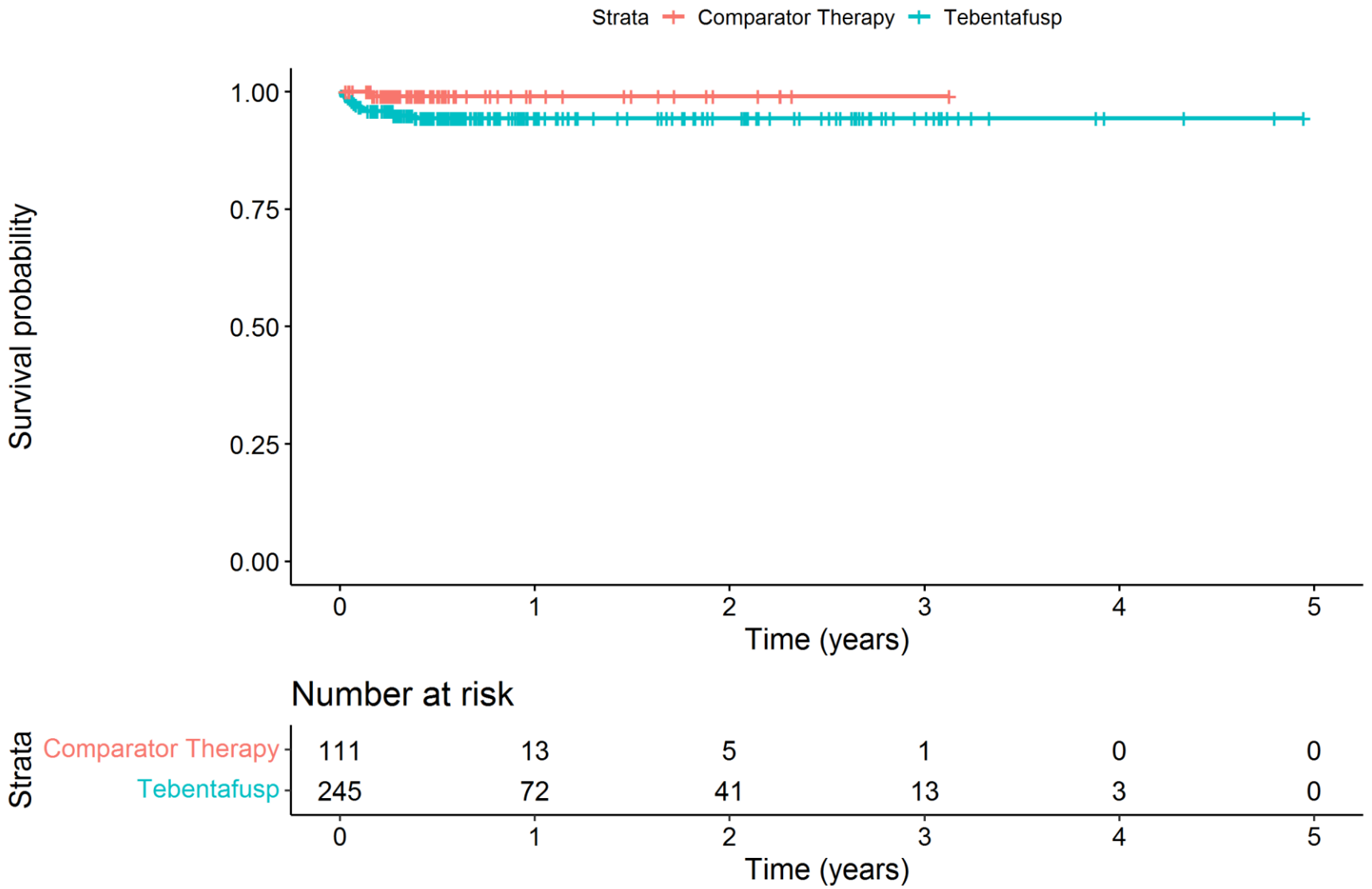
31.6 Erbrechen



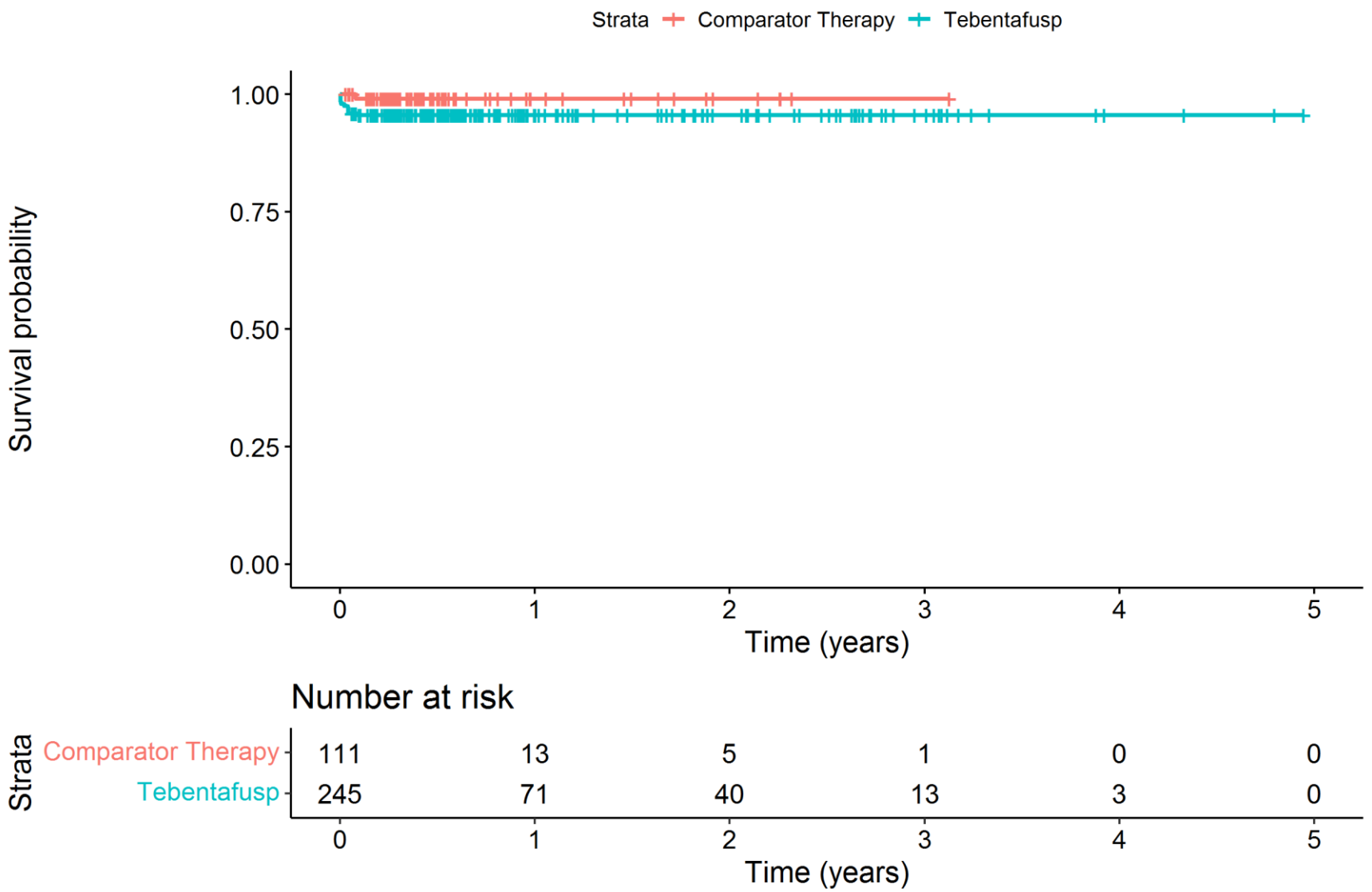
31.7 Colitis


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
73
41
13
3
0
0
1
2
3
4
5
Time (years)

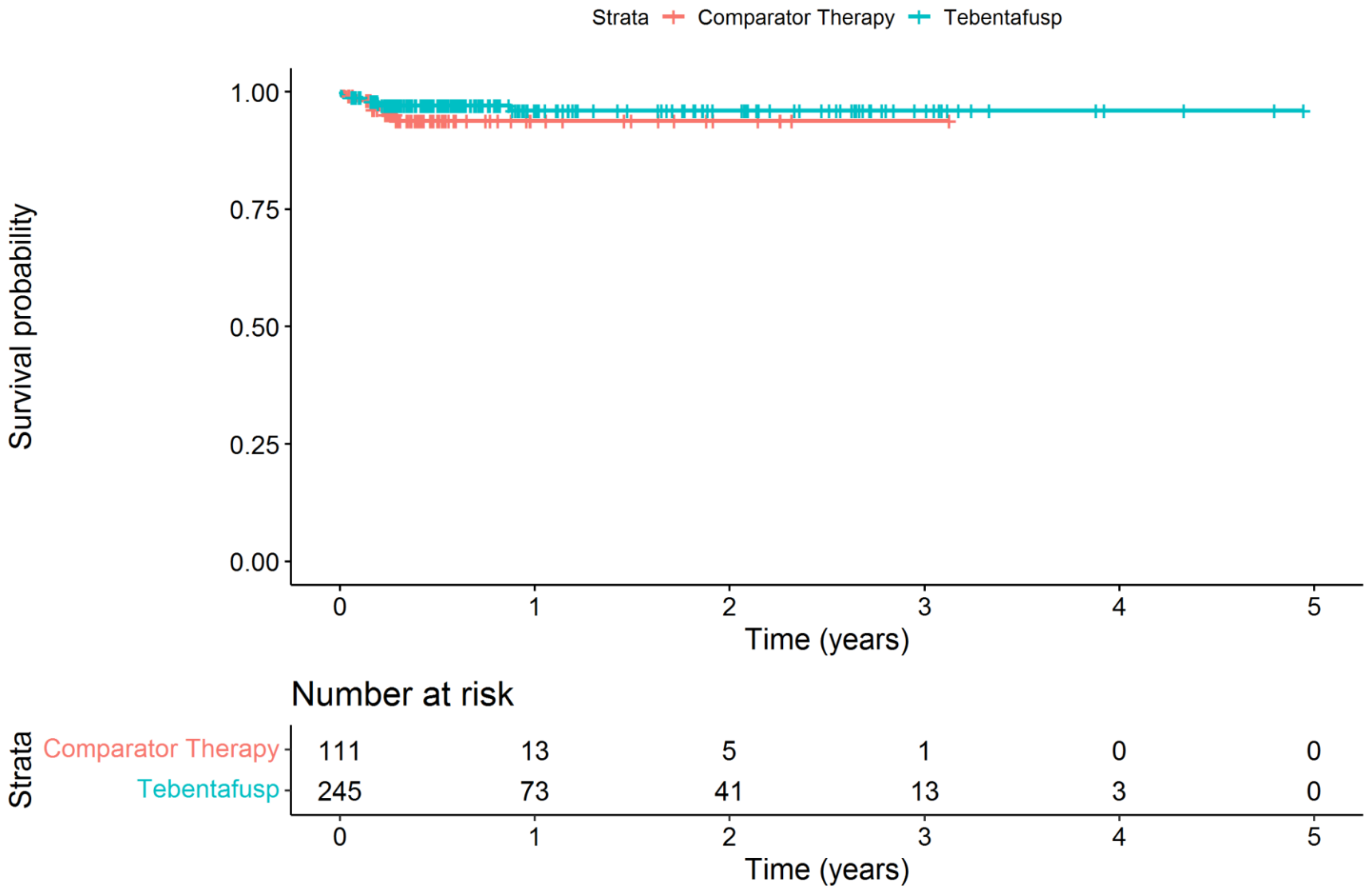
31.8 Müdigkeit



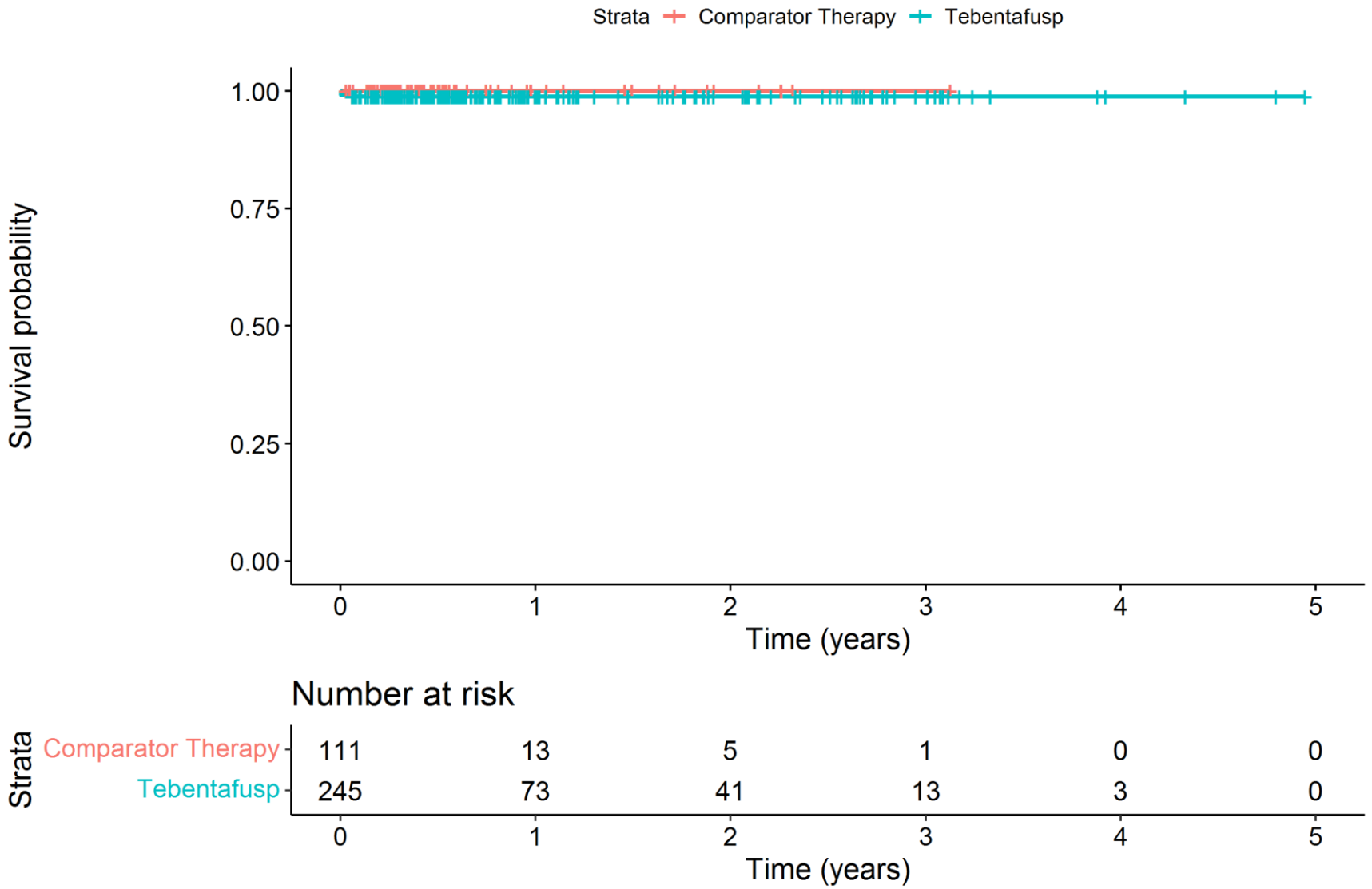
31.9 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
71
40
13
3
0
0
1
2
3
4
5
Time (years)

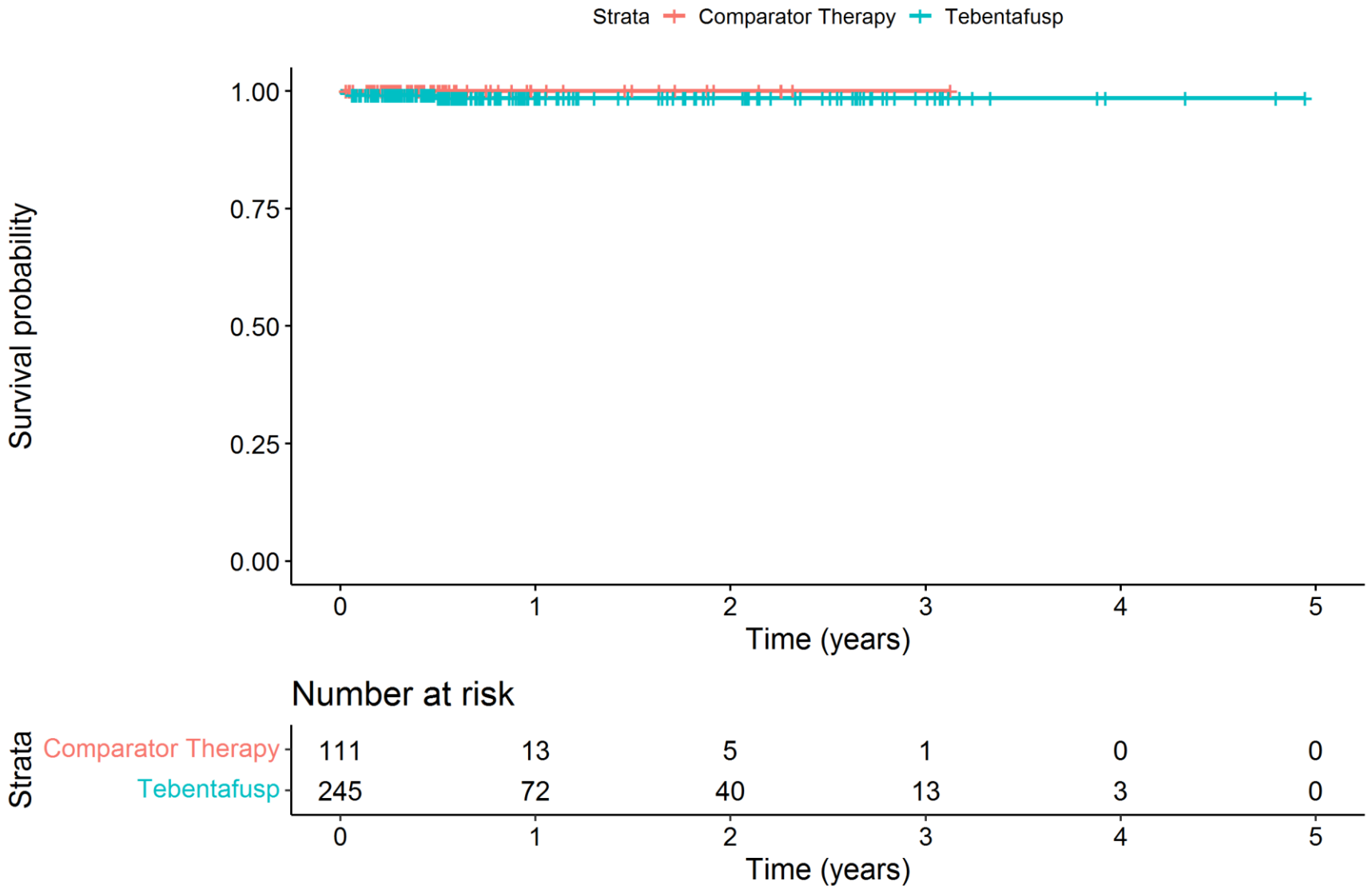
31.10 Hyperbilirubinämie



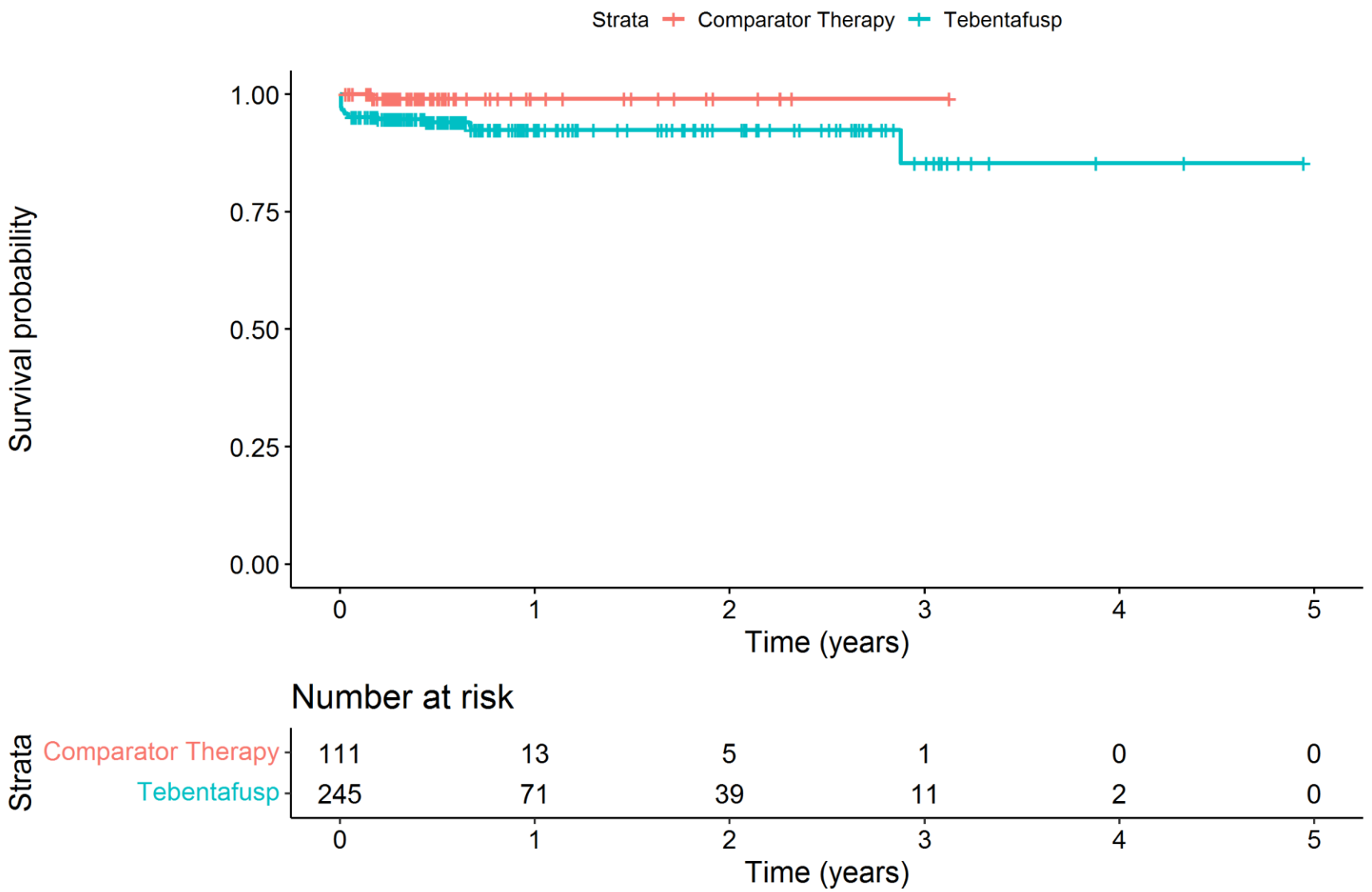
31.11 Zytokin-Freisetzungssyndrom



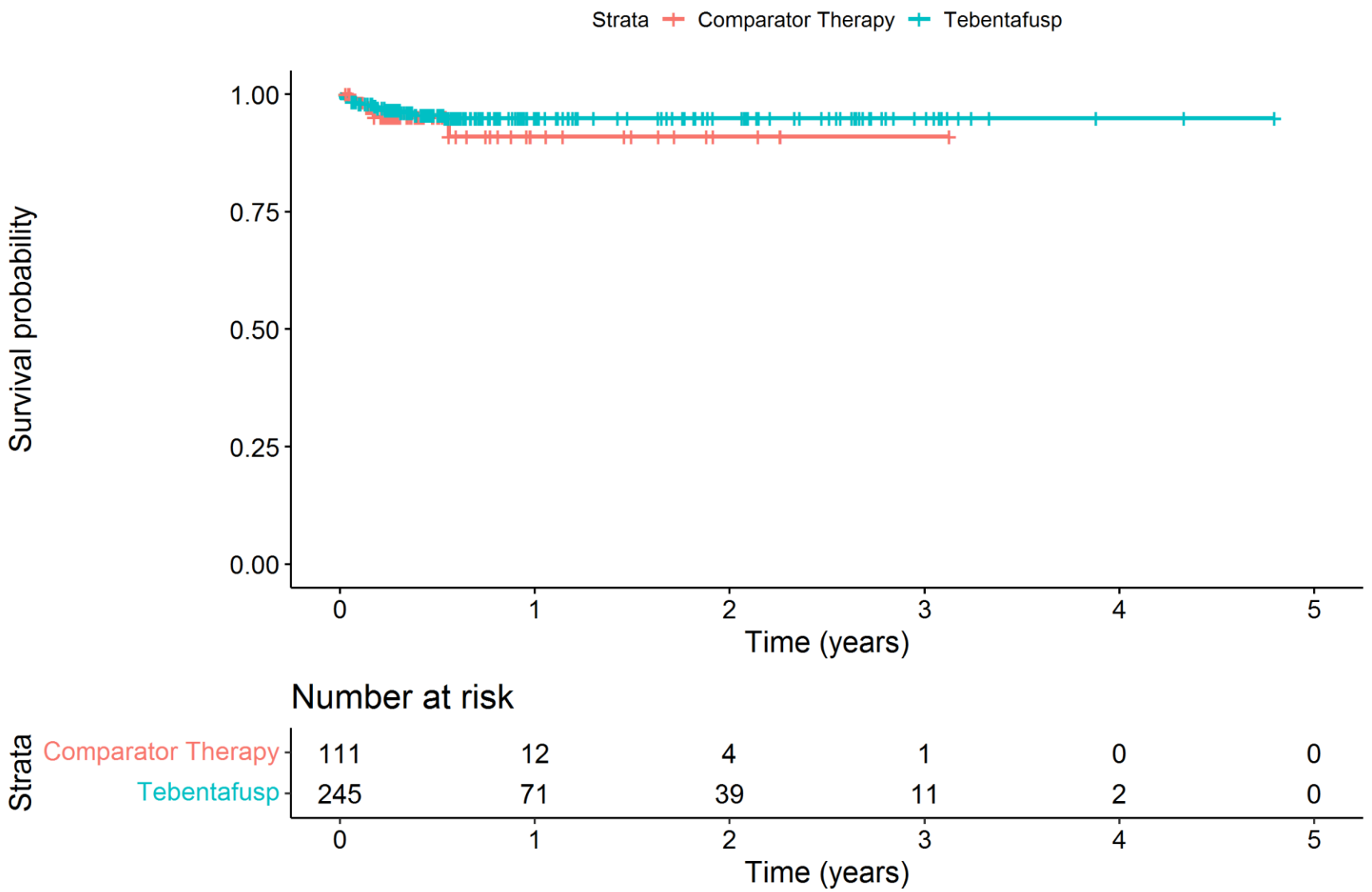
31.12 Harnwegsinfektion



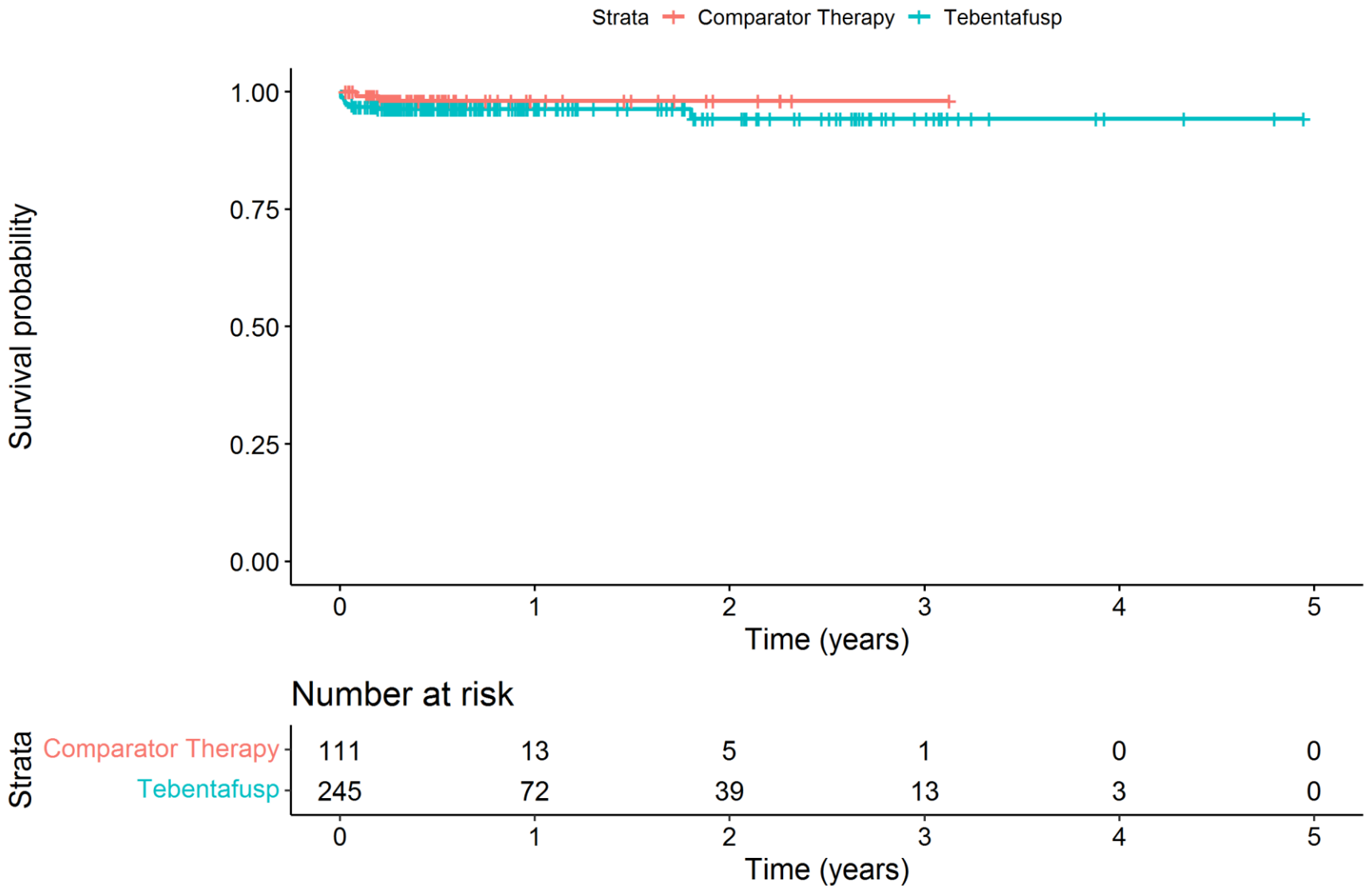
31.13 Erhöhte Aspartat-Aminotransferase



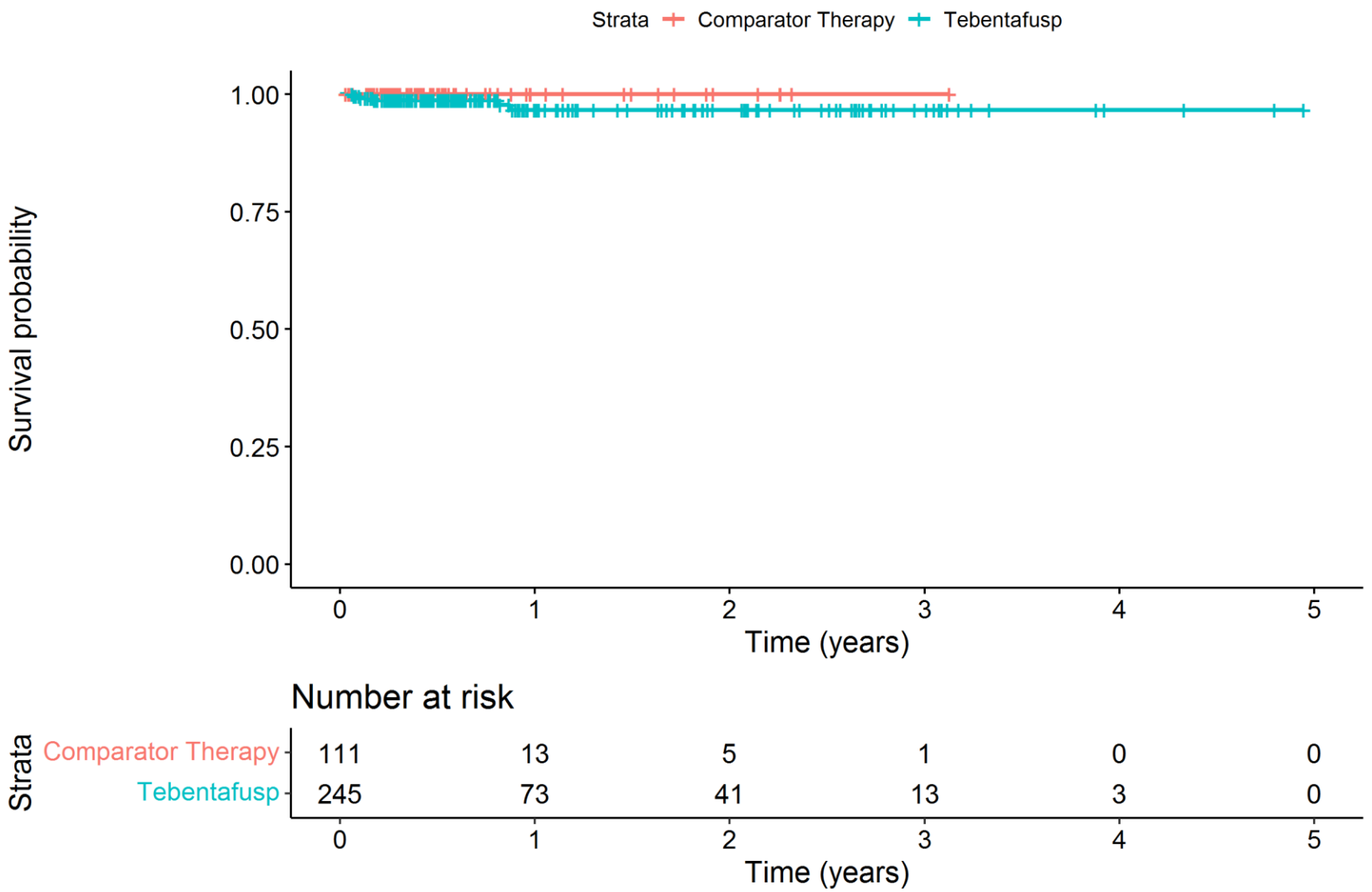
31.14 Erhöhte Lipase



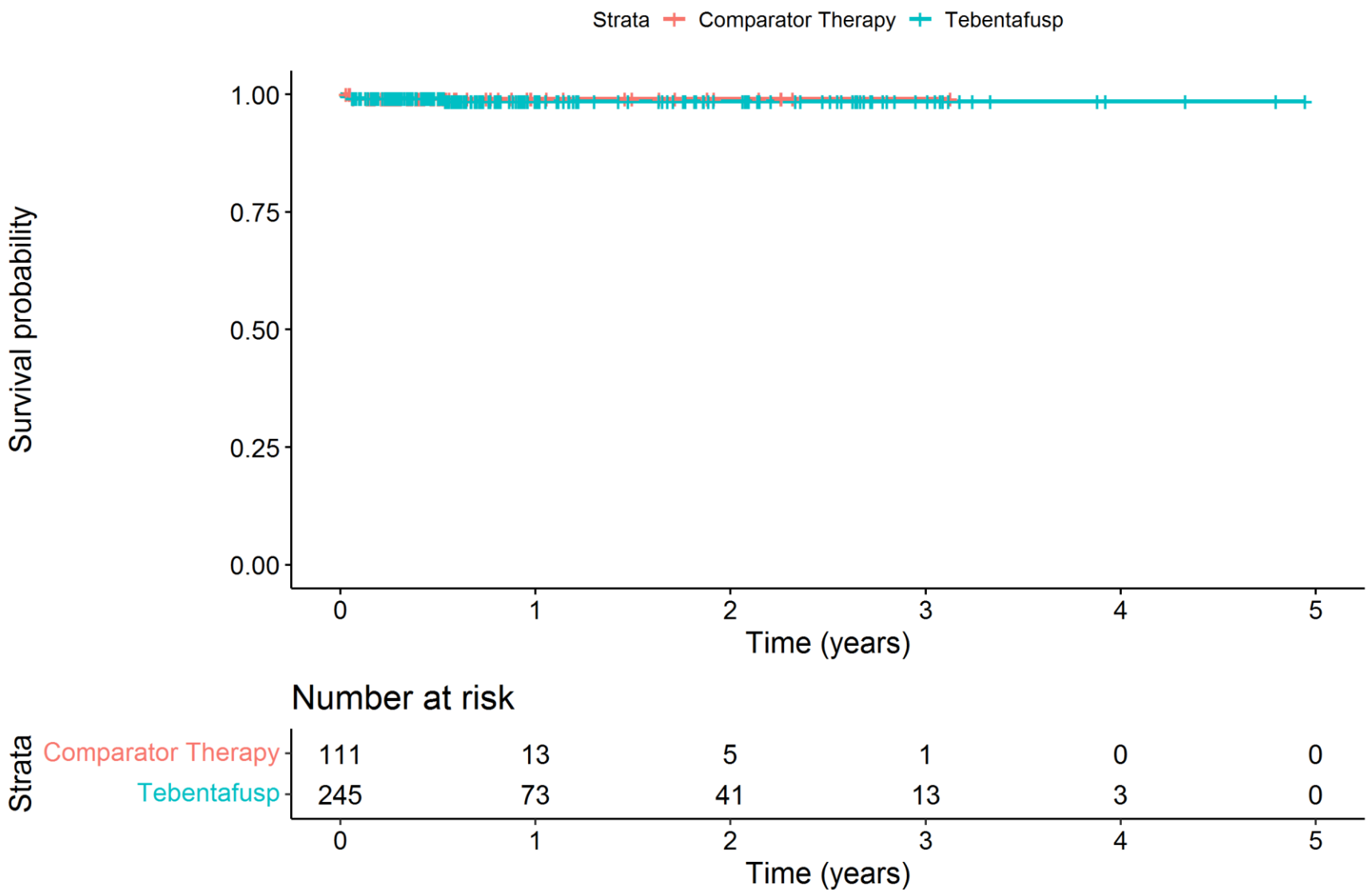
31.15 Erhöhte Alanin-Aminotransferase



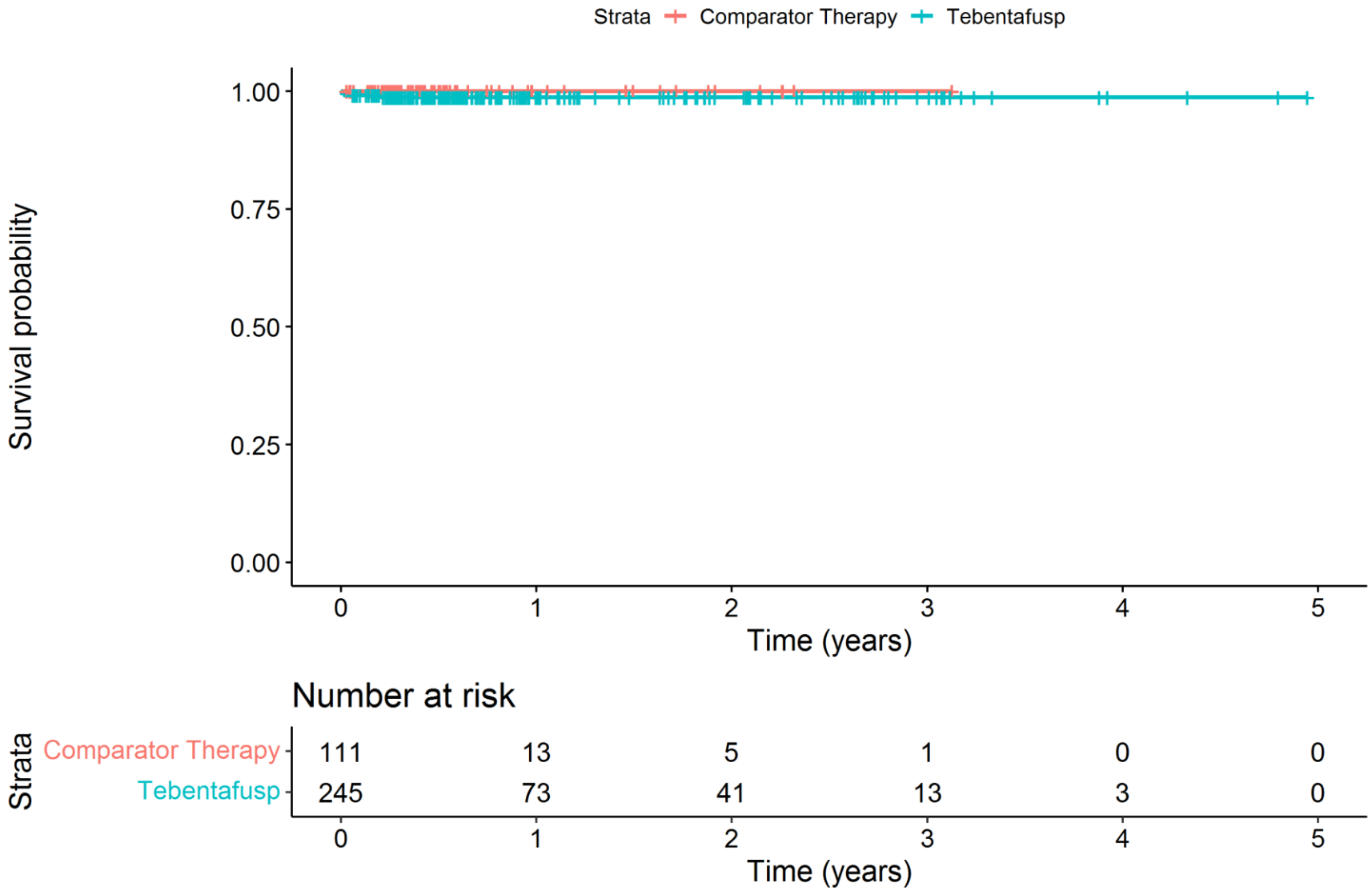
31.16 Erhöhte Gamma-Glutamyltransferase



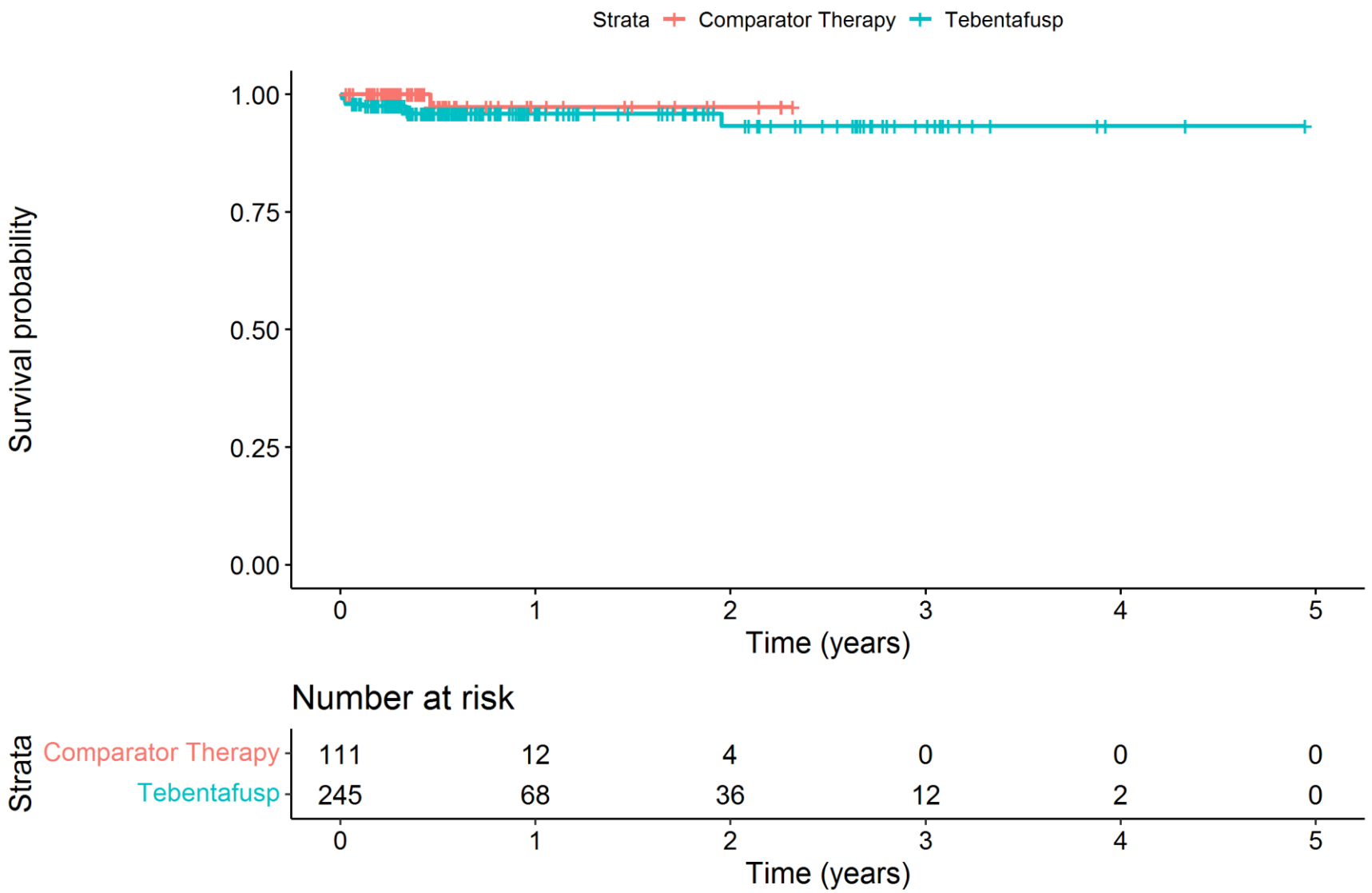
31.17 Erhöhte Amylase



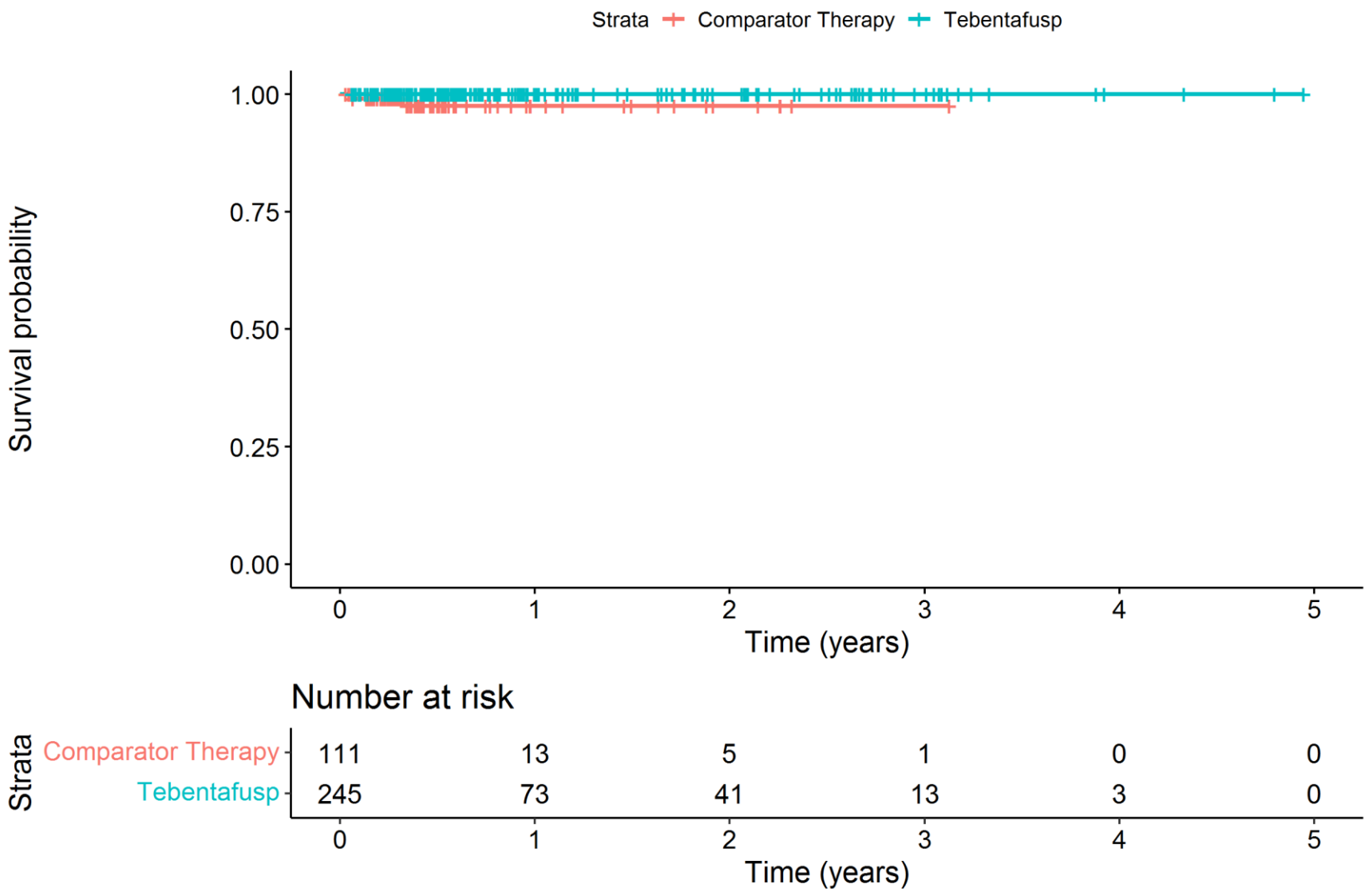
31.18 Erhöhte alkalische Phosphatase im Blut



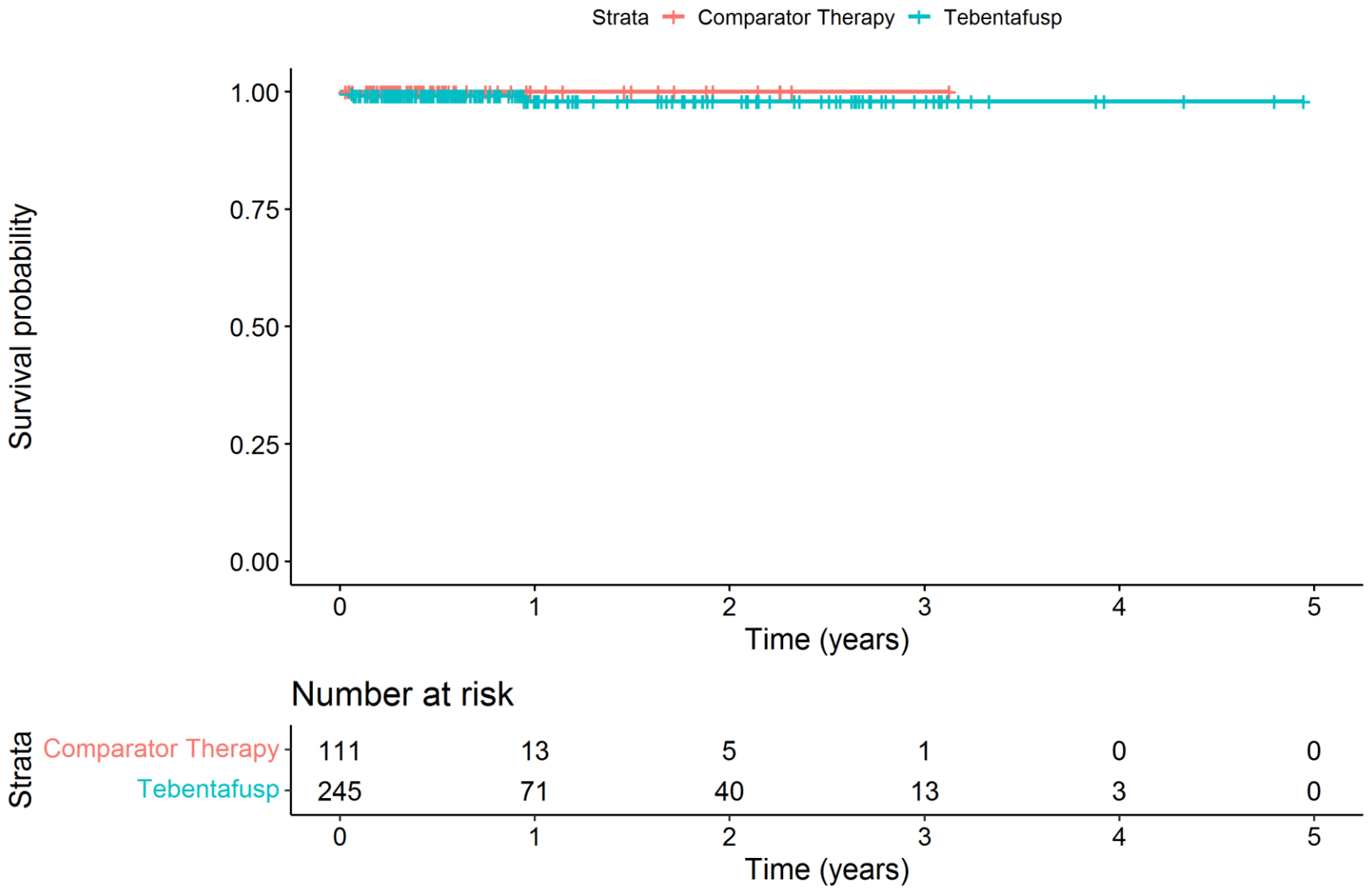
31.19 Hypophosphatämie



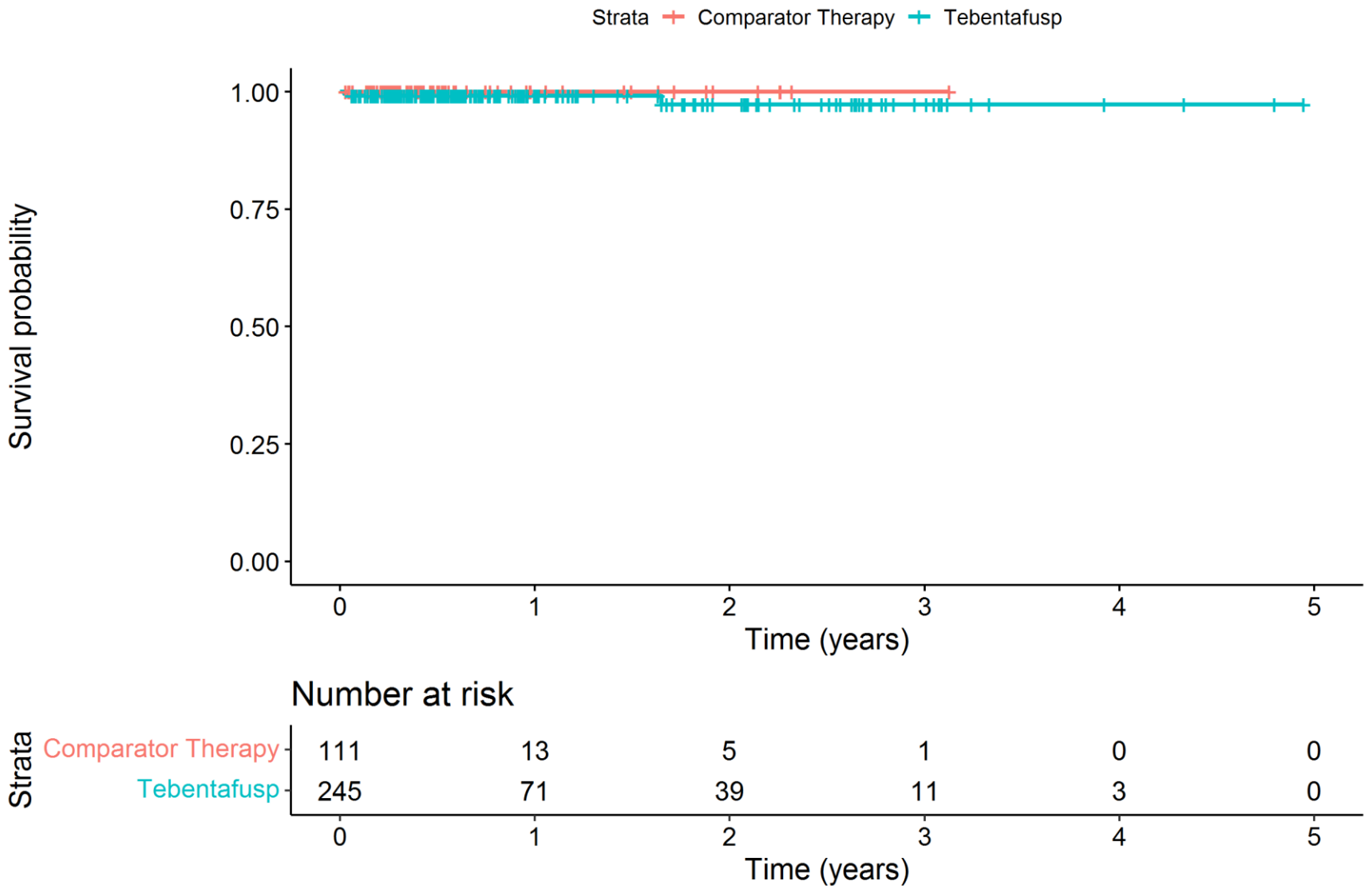
31.20 Dehydrierung



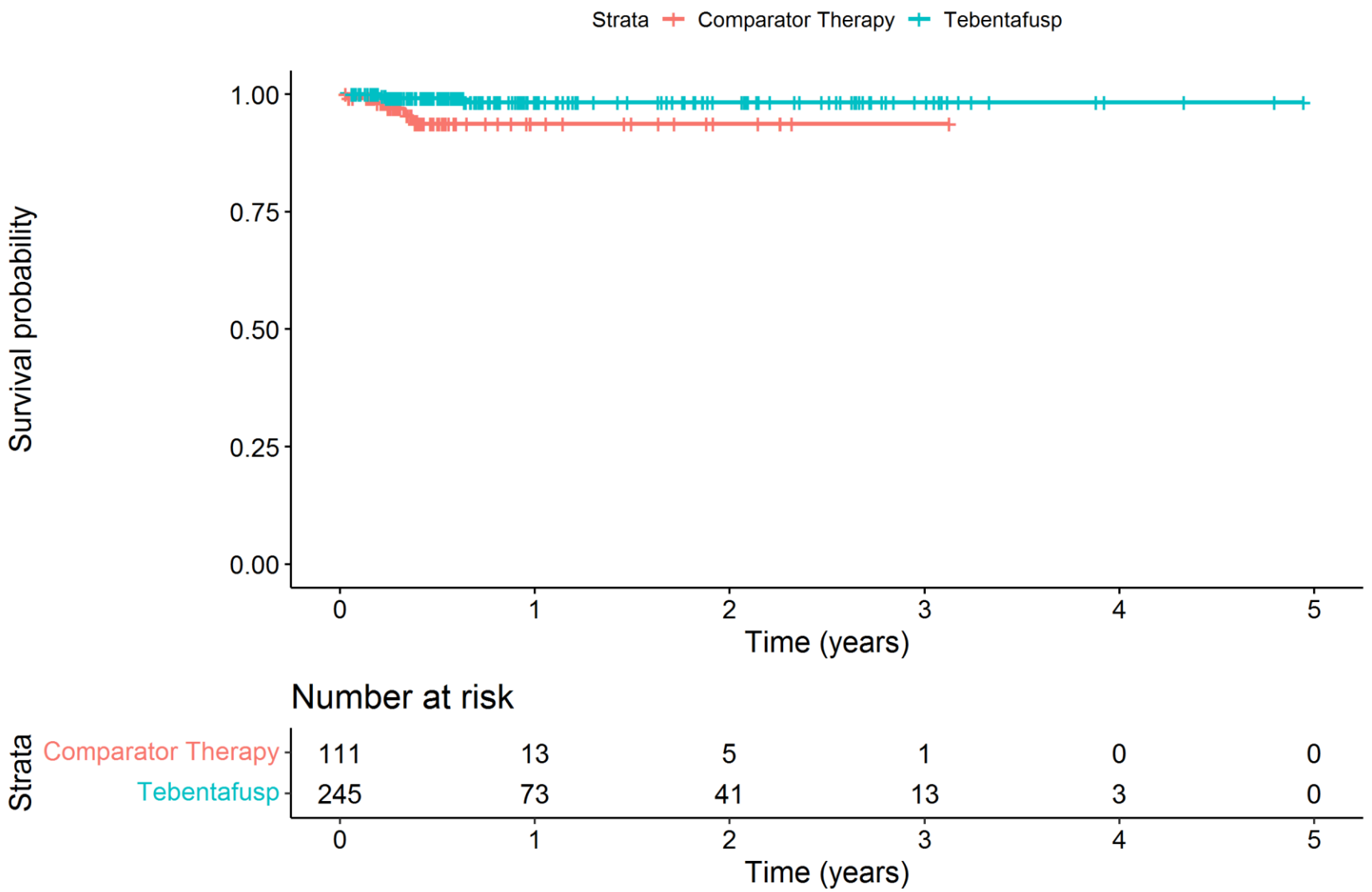
31.21 Tumorschmerzen



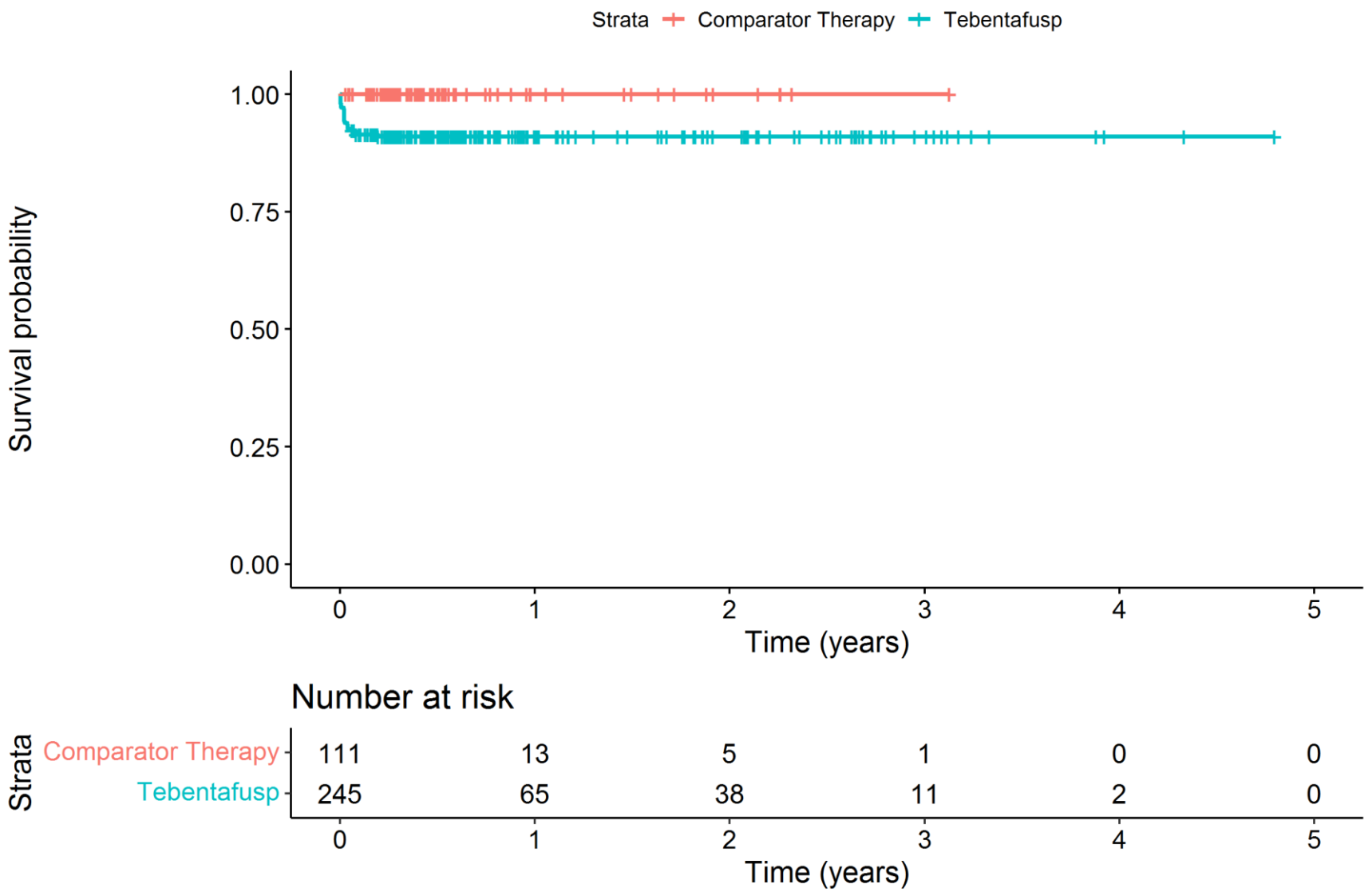
31.22 Synkope



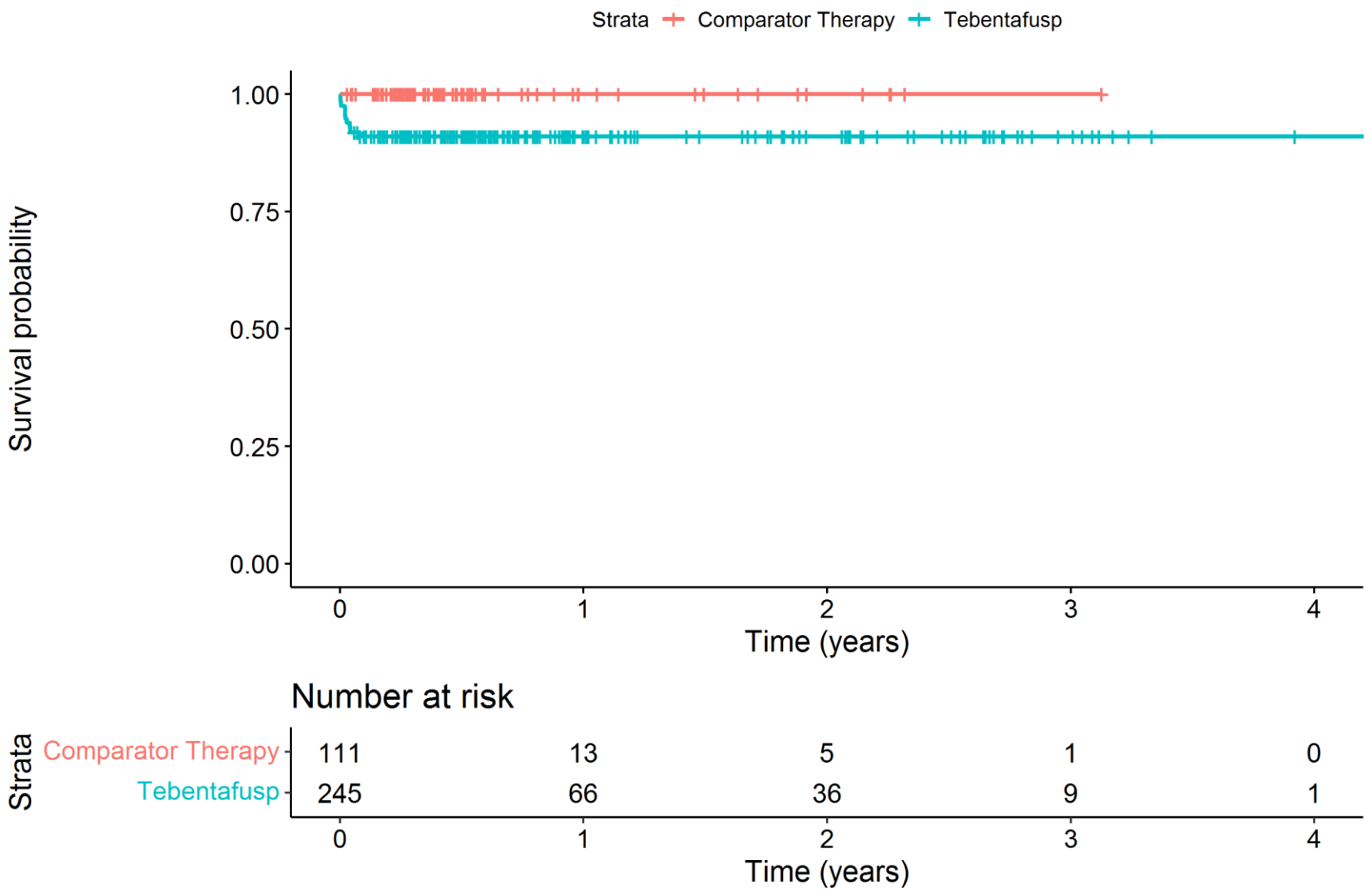
31.23 Lungenembolie



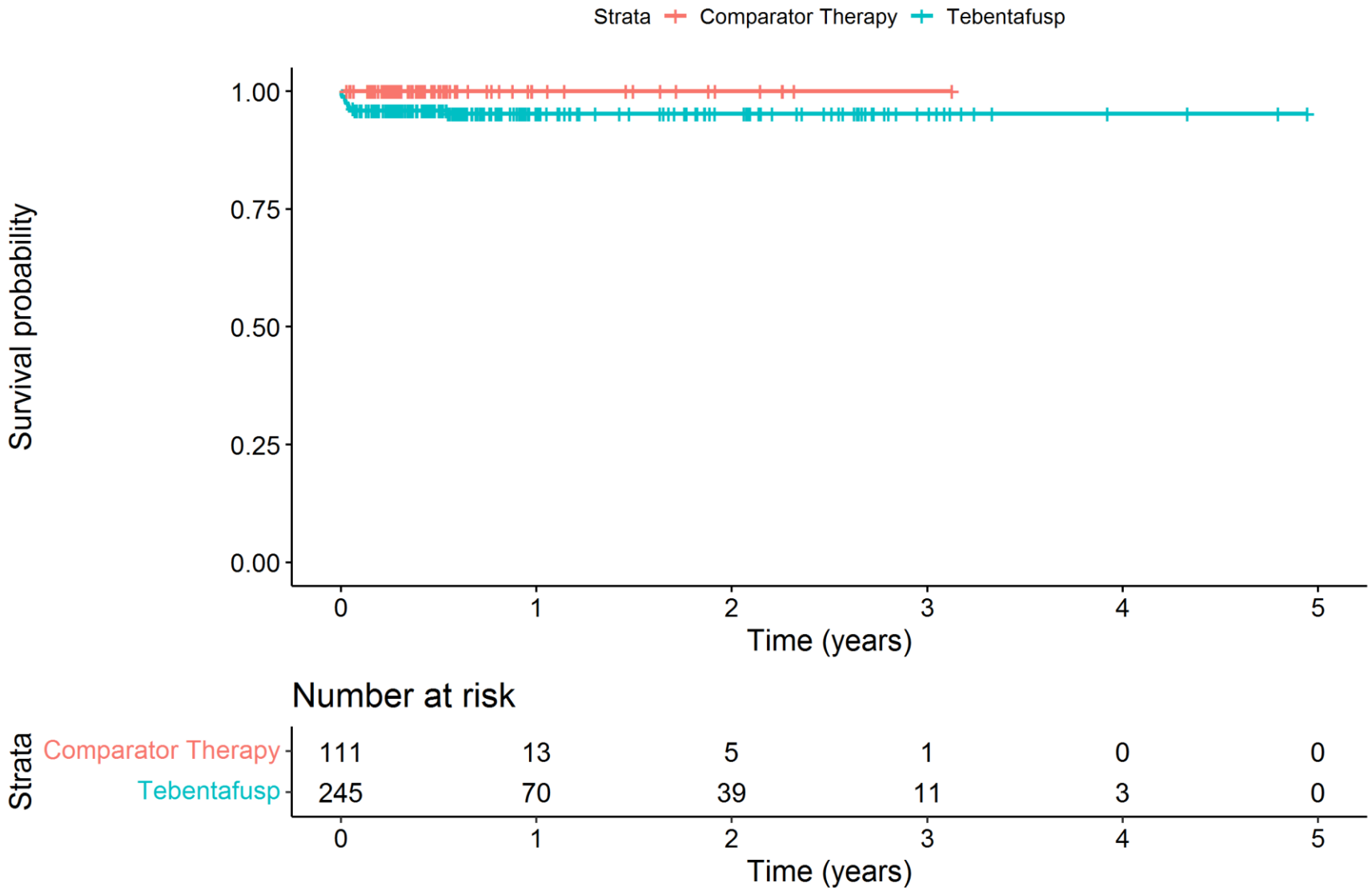
31.24 Hautausschlag



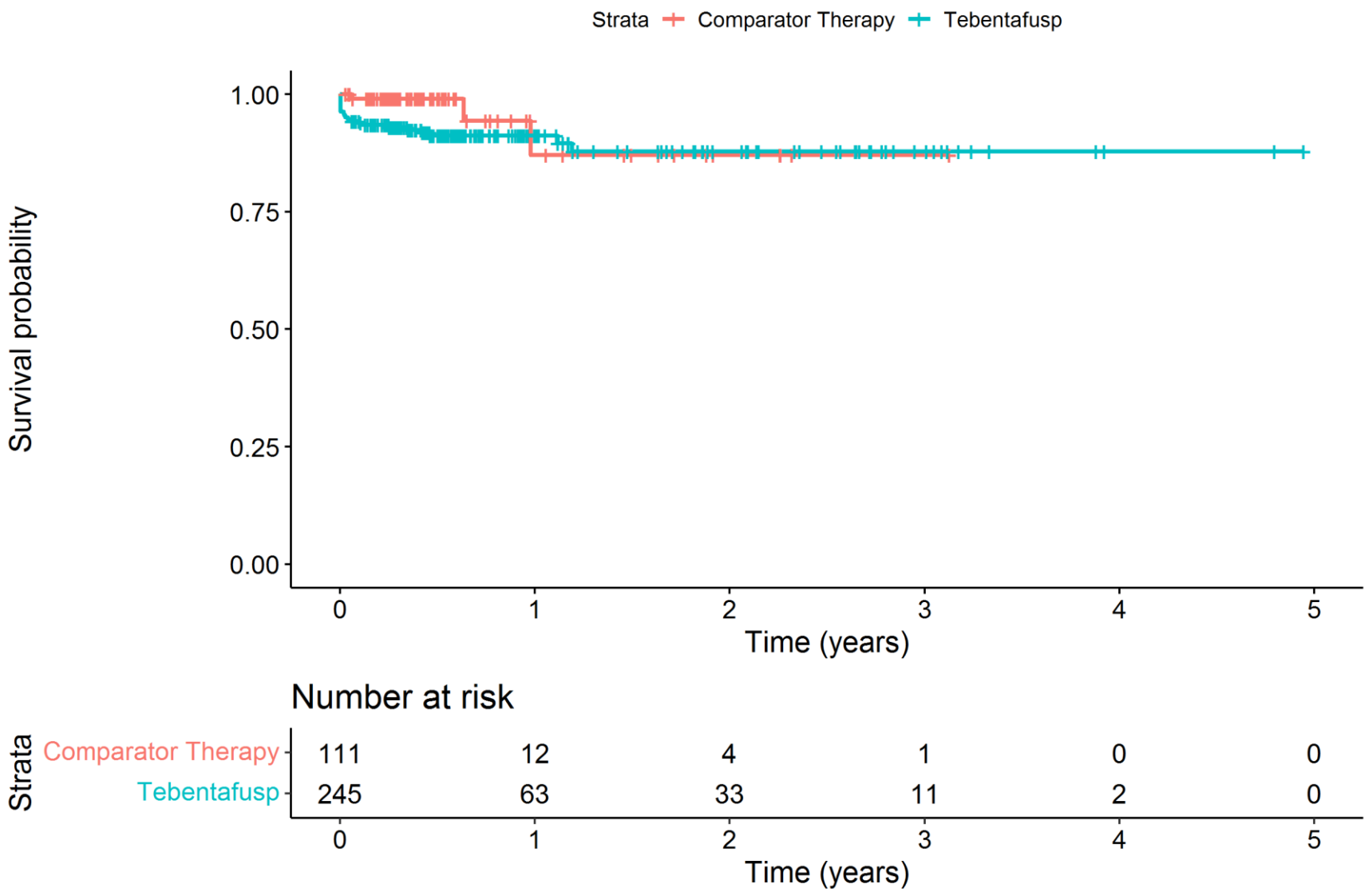
31.25 Makulo-papulöser Hautausschlag



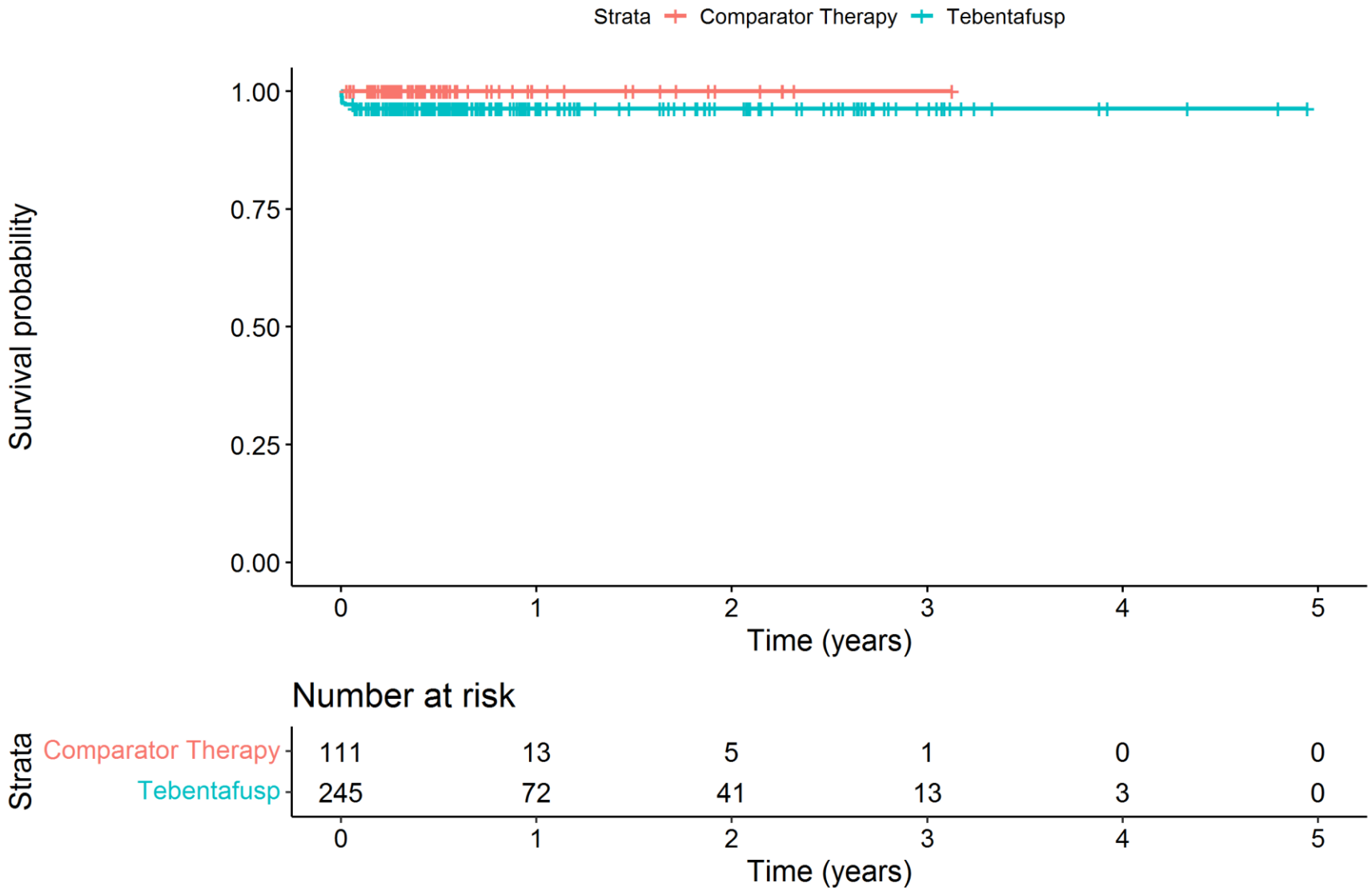
31.26 Pruritus



31.27 Hypertonie

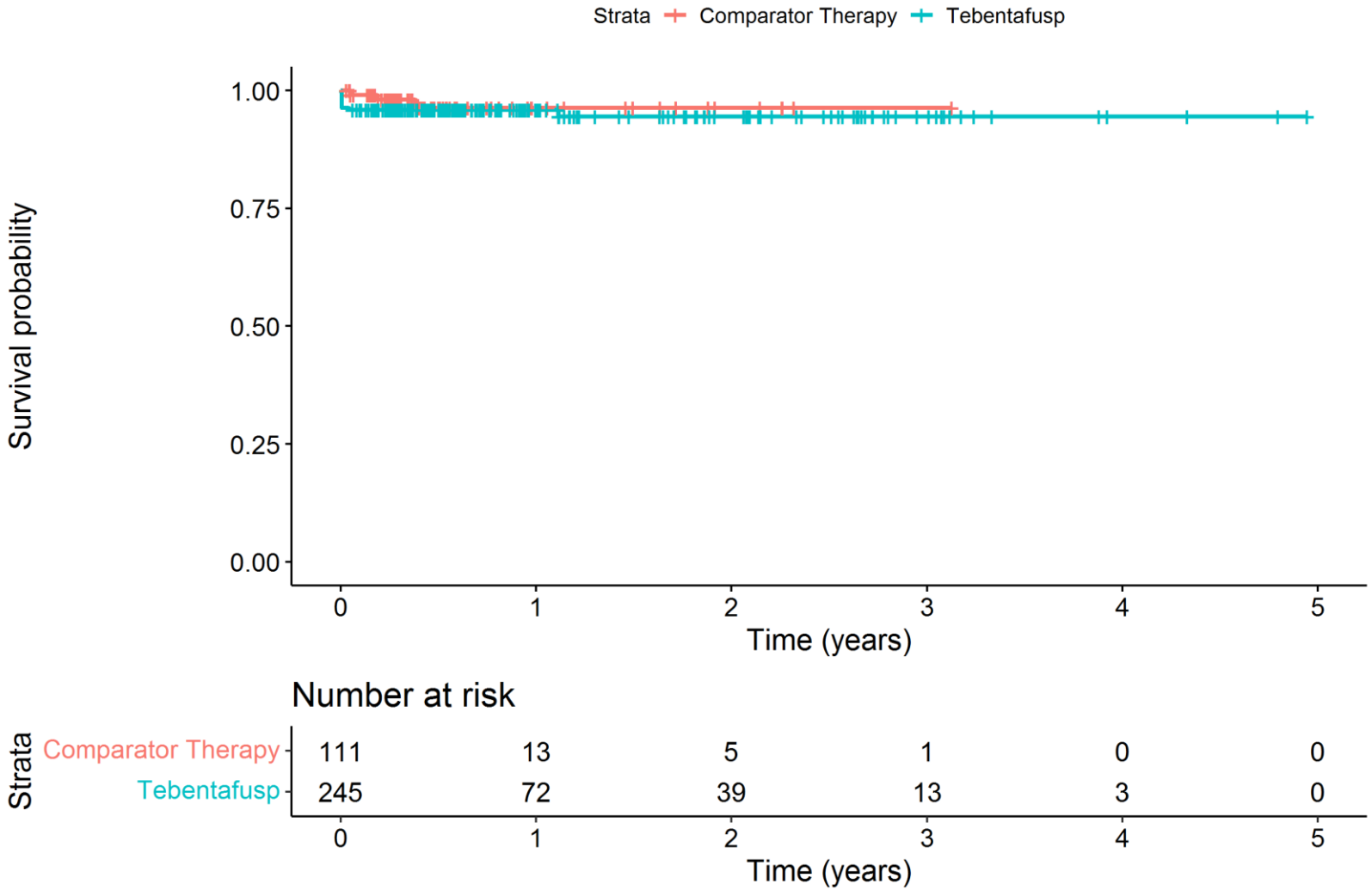


31.28 Hypotonie

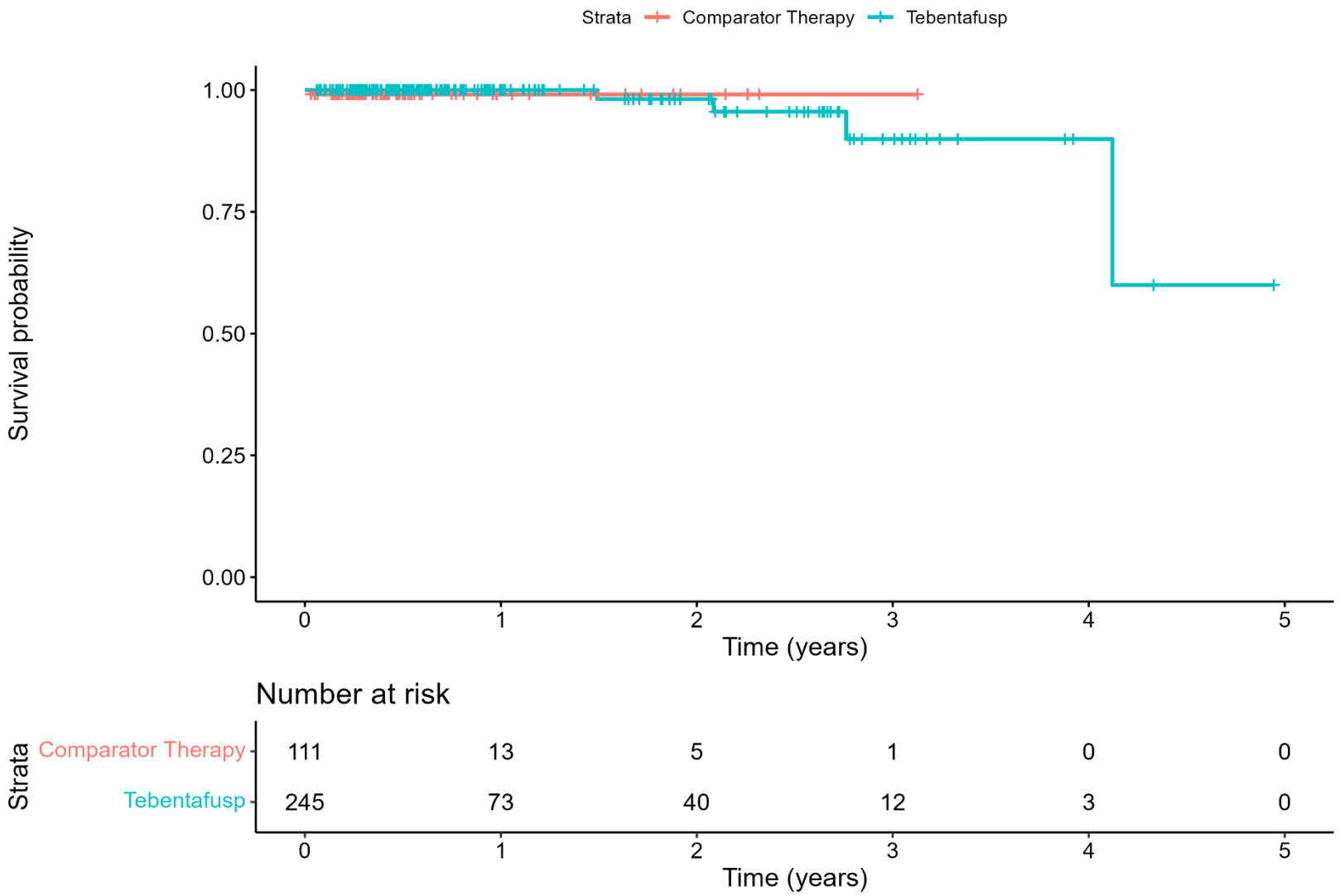


32 UEs (PT) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten

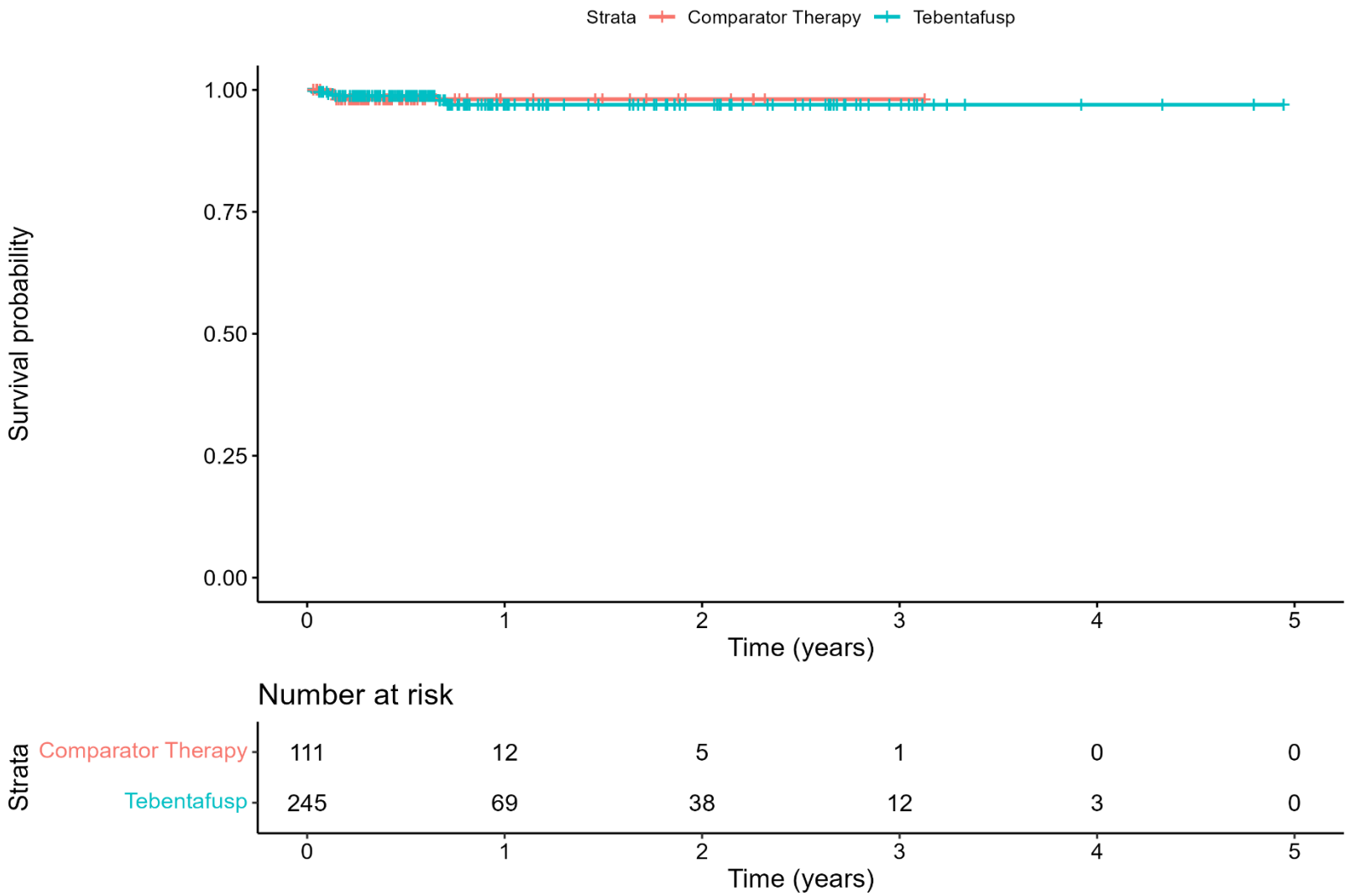
32.1 Erkrankungen des Blutes und des Lymphsystems



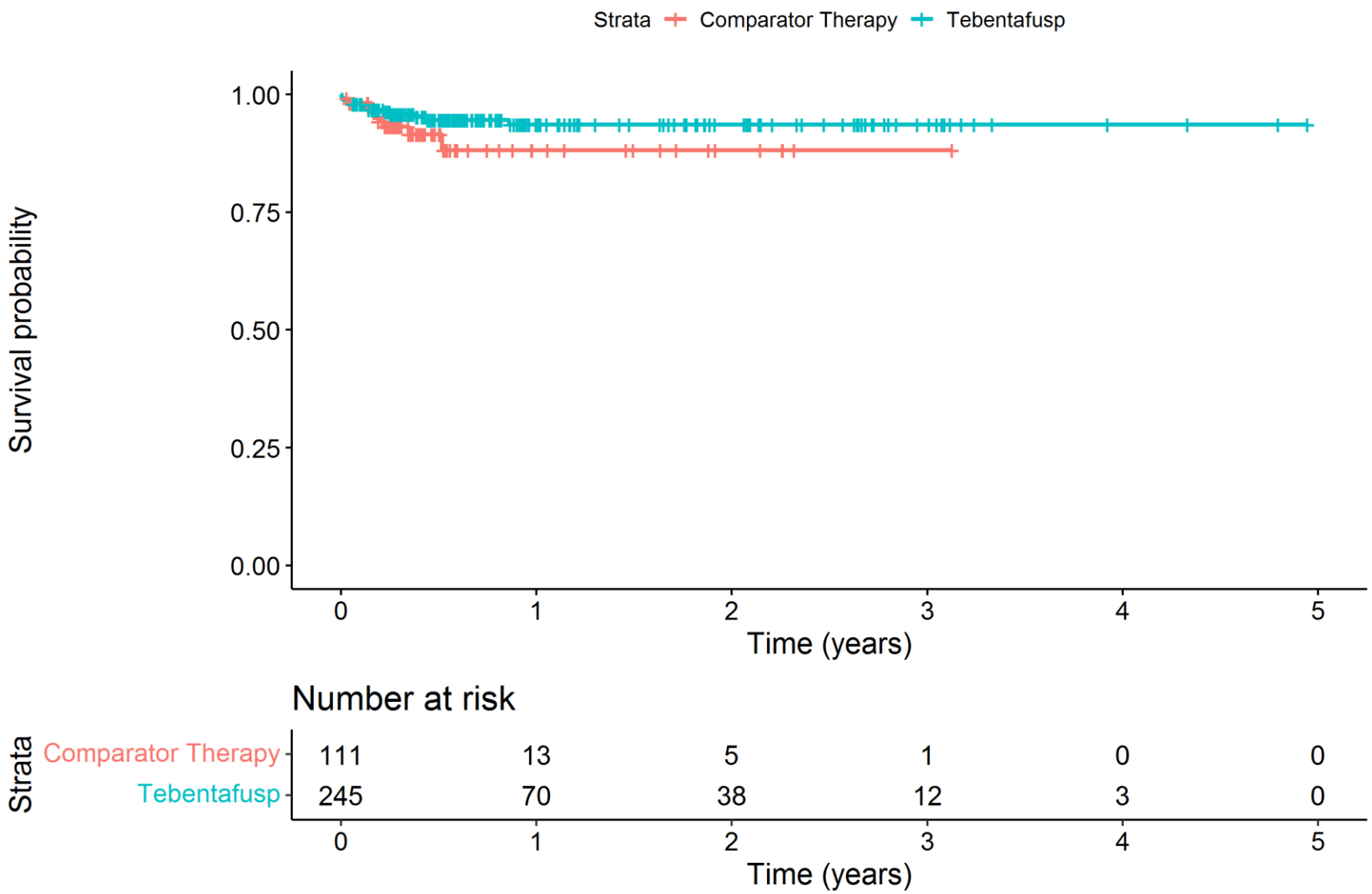
32.2 Herzerkrankungen



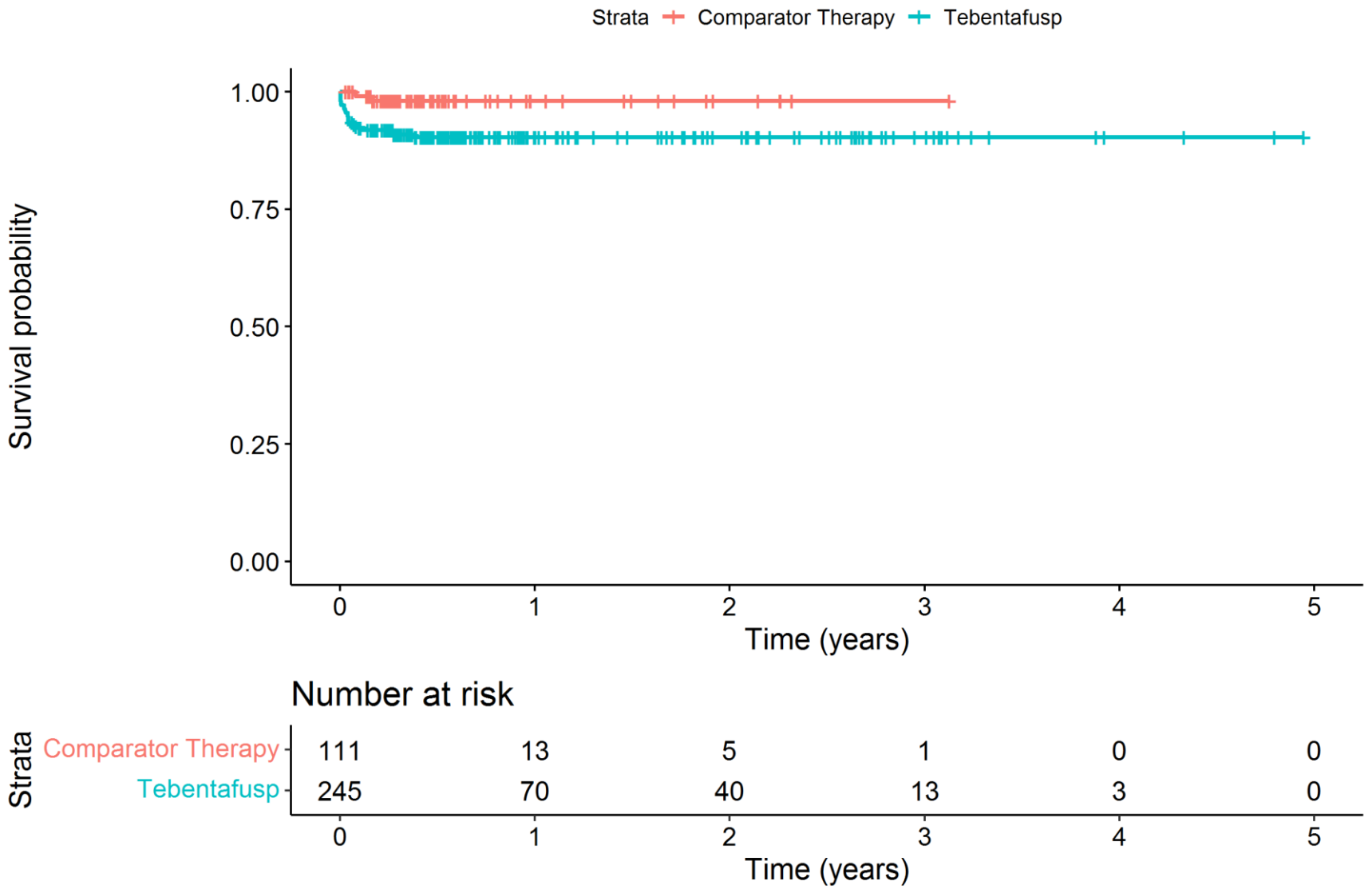
32.3 Augenerkrankungen



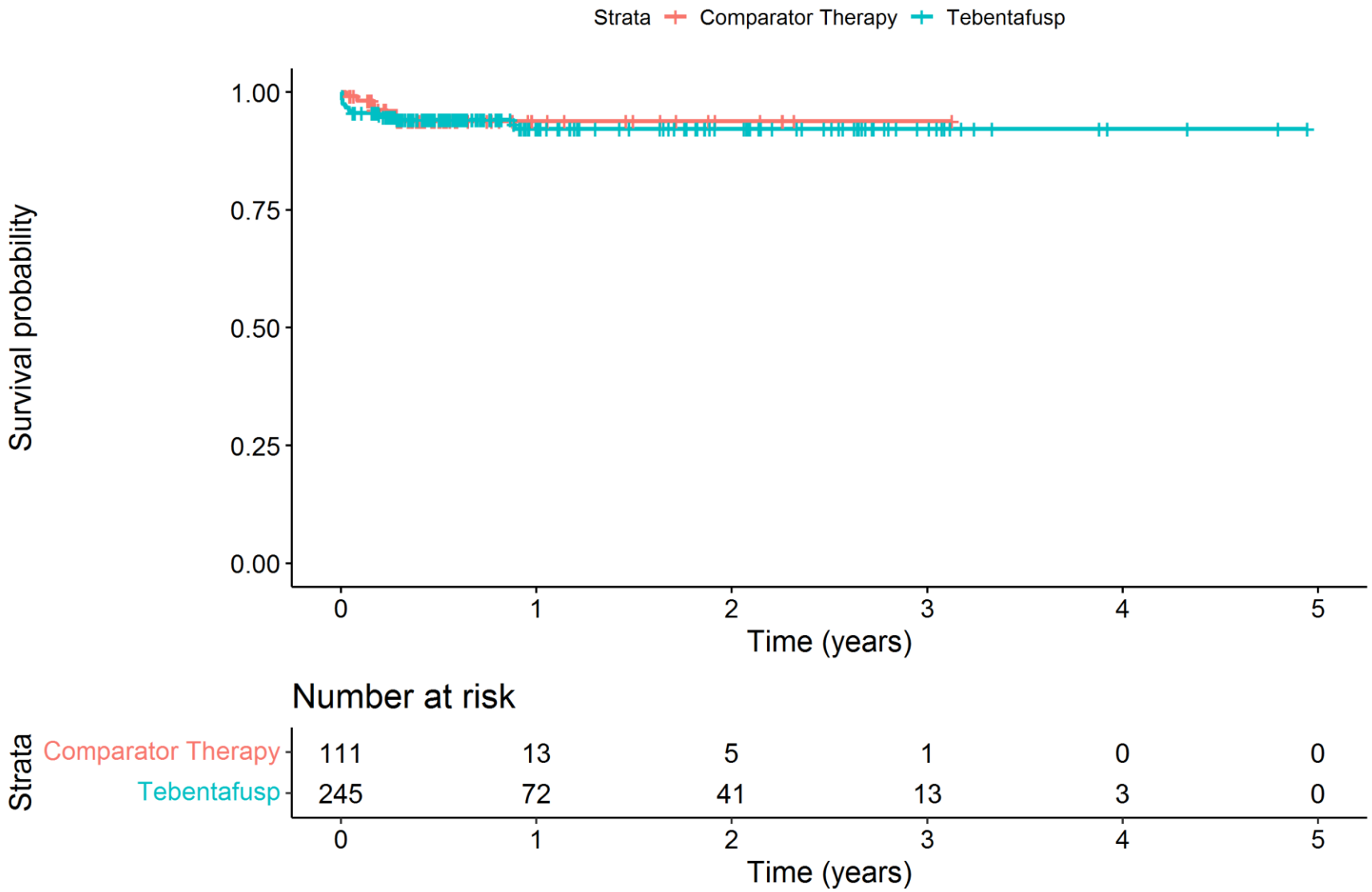
32.4 Erkrankungen des Gastrointestinaltrakts



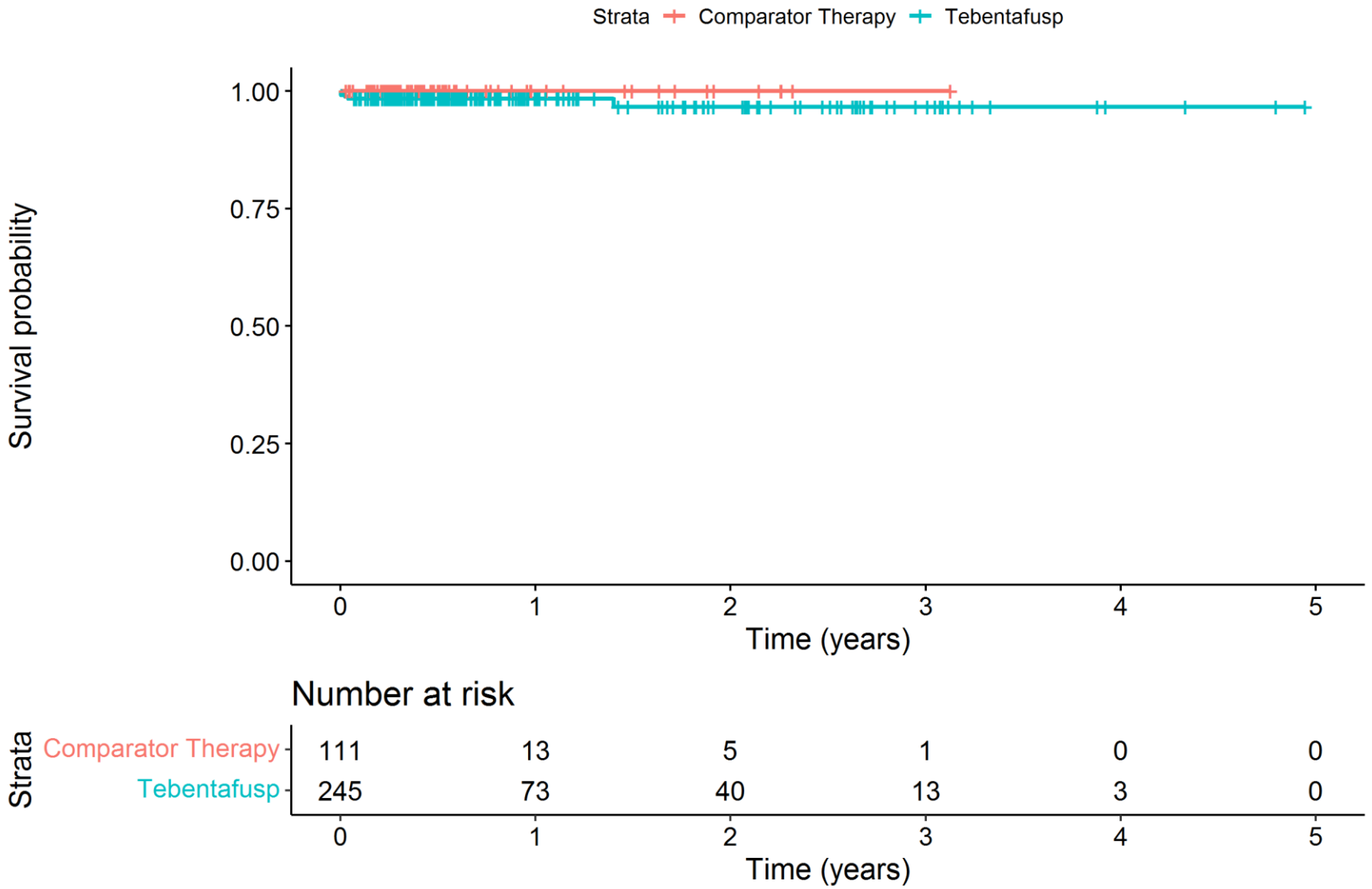
32.5 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



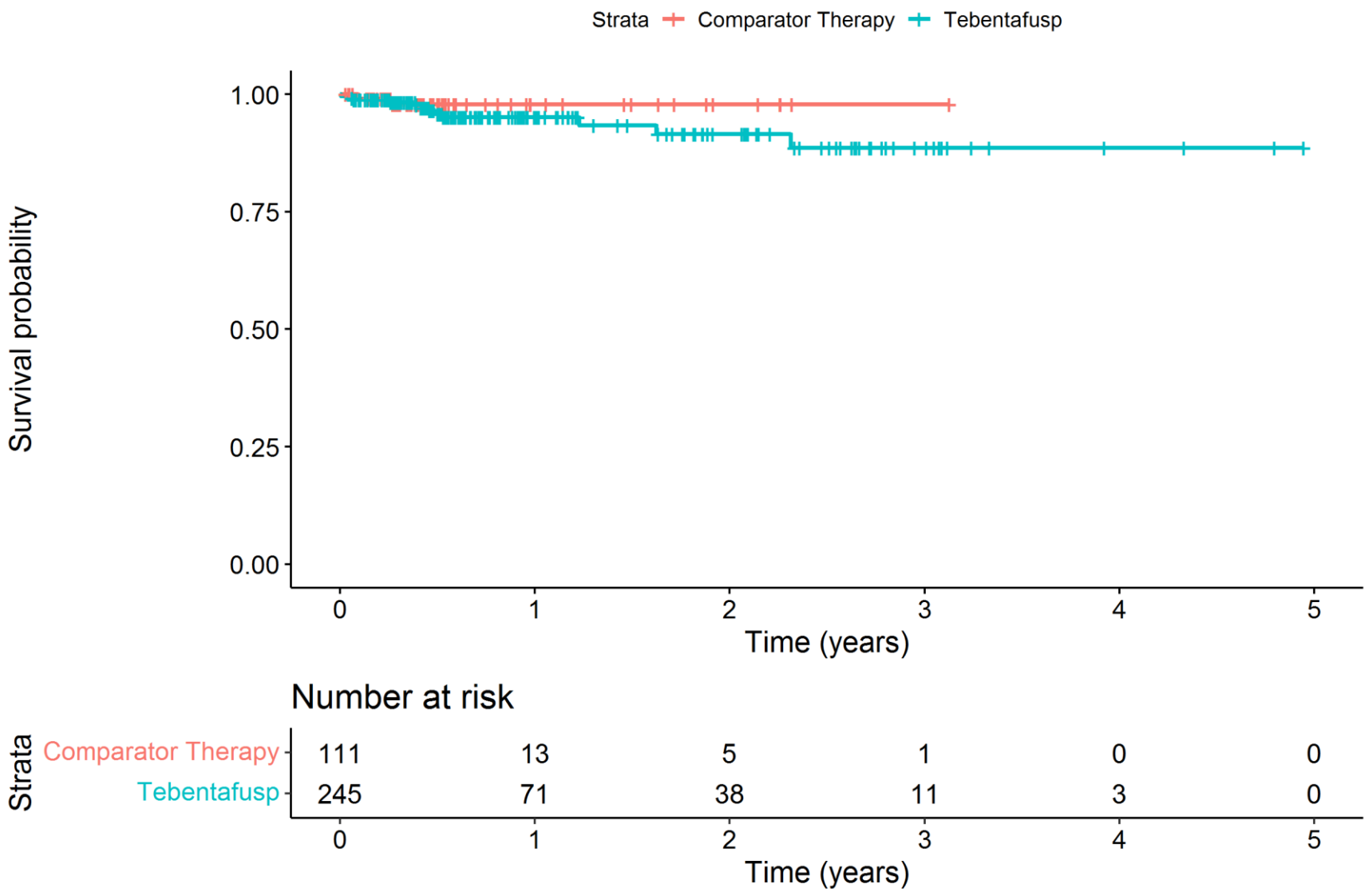
32.6 Leber- und Gallenerkrankungen



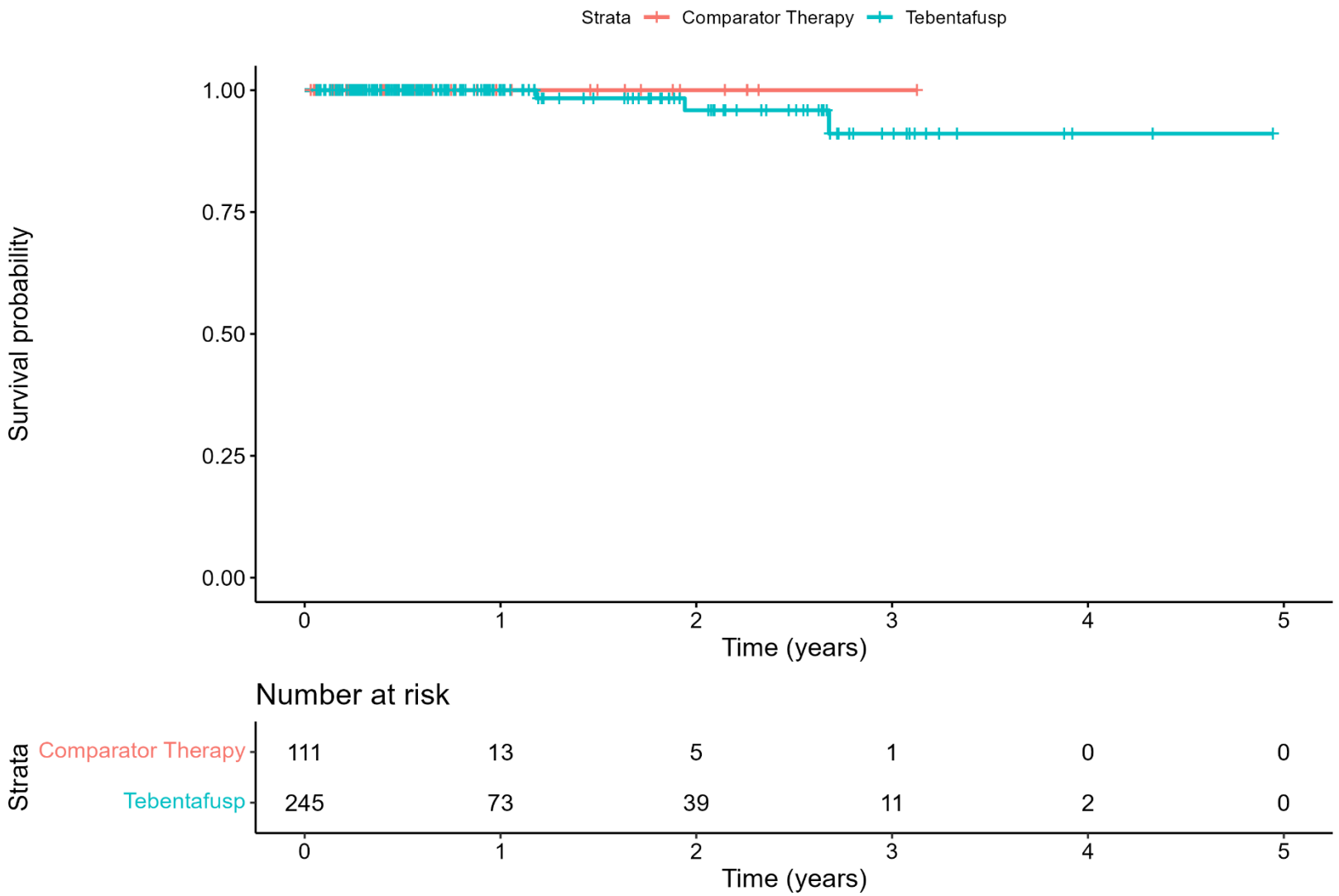
32.7 Erkrankungen des Immunsystems



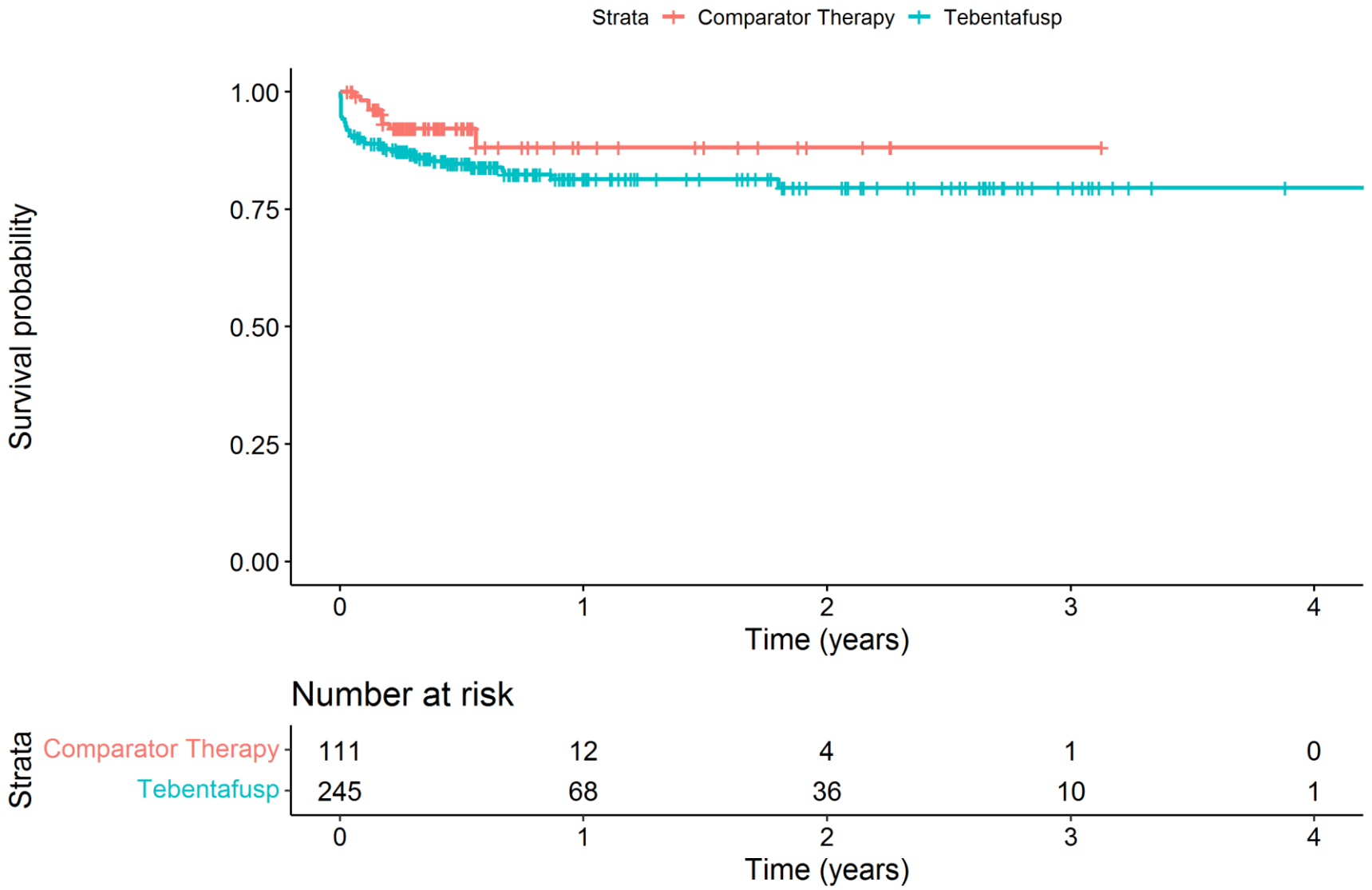
32.8 Infektionen und parasitäre Erkrankungen



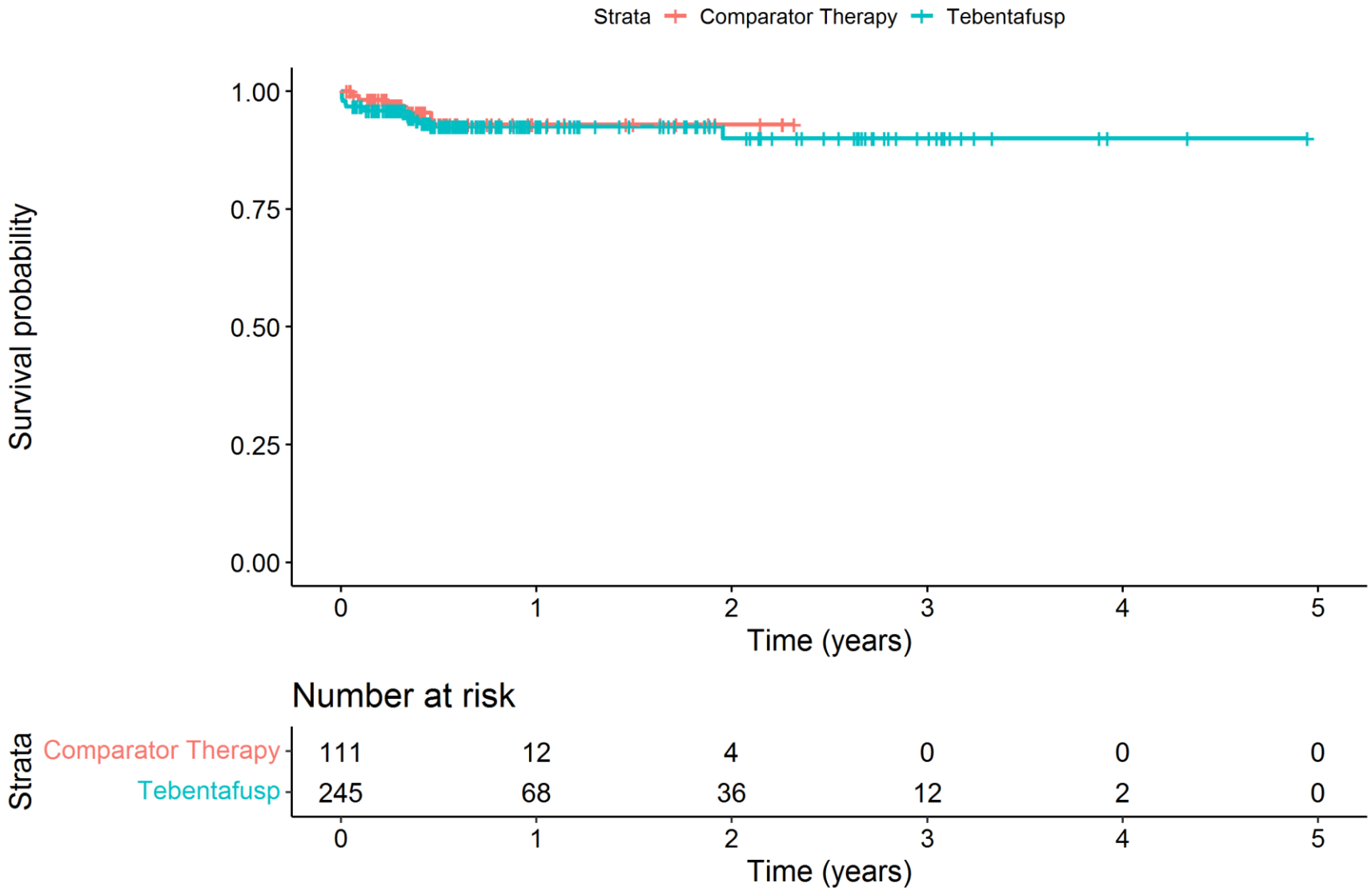
32.9 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



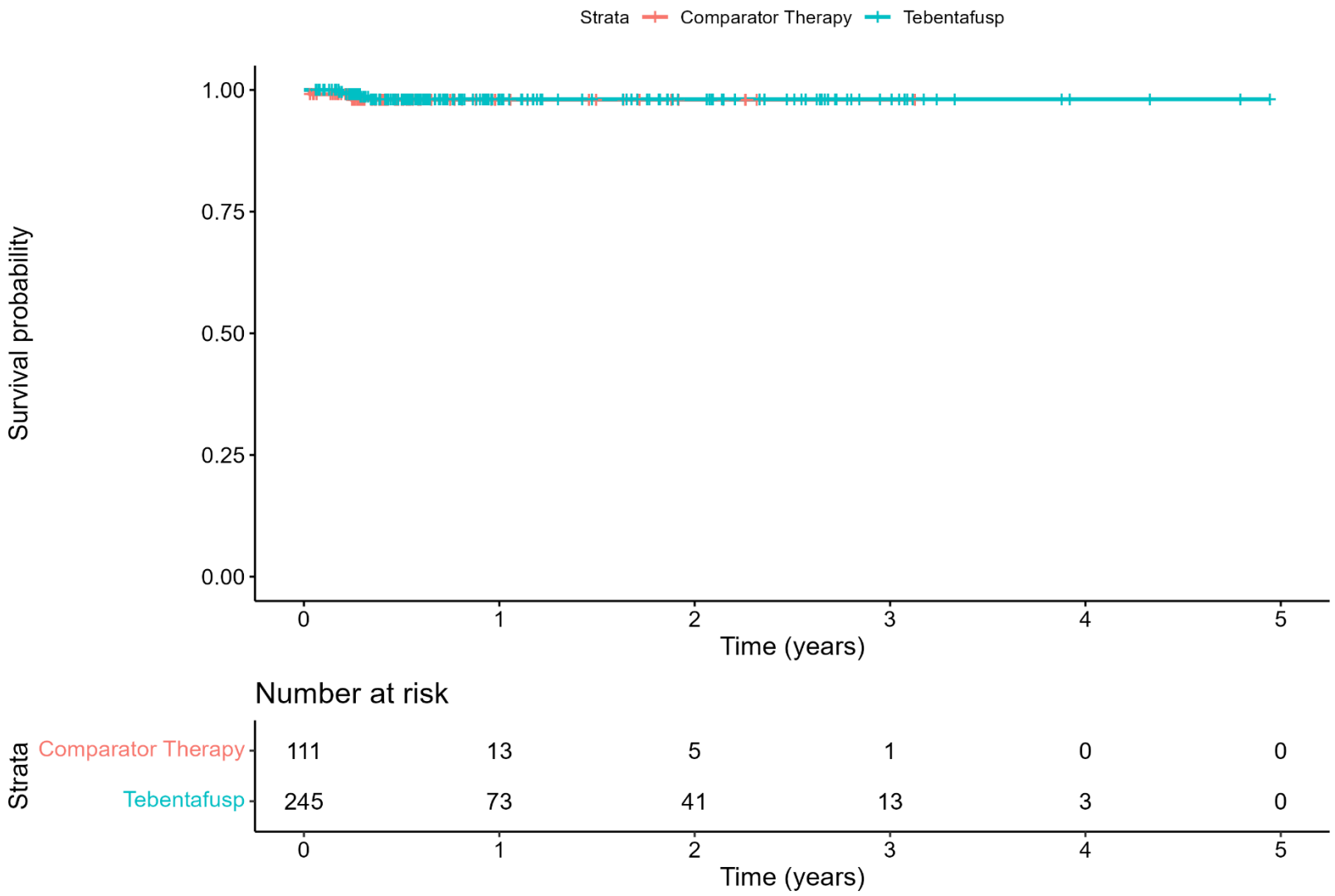
32.10 Untersuchungen



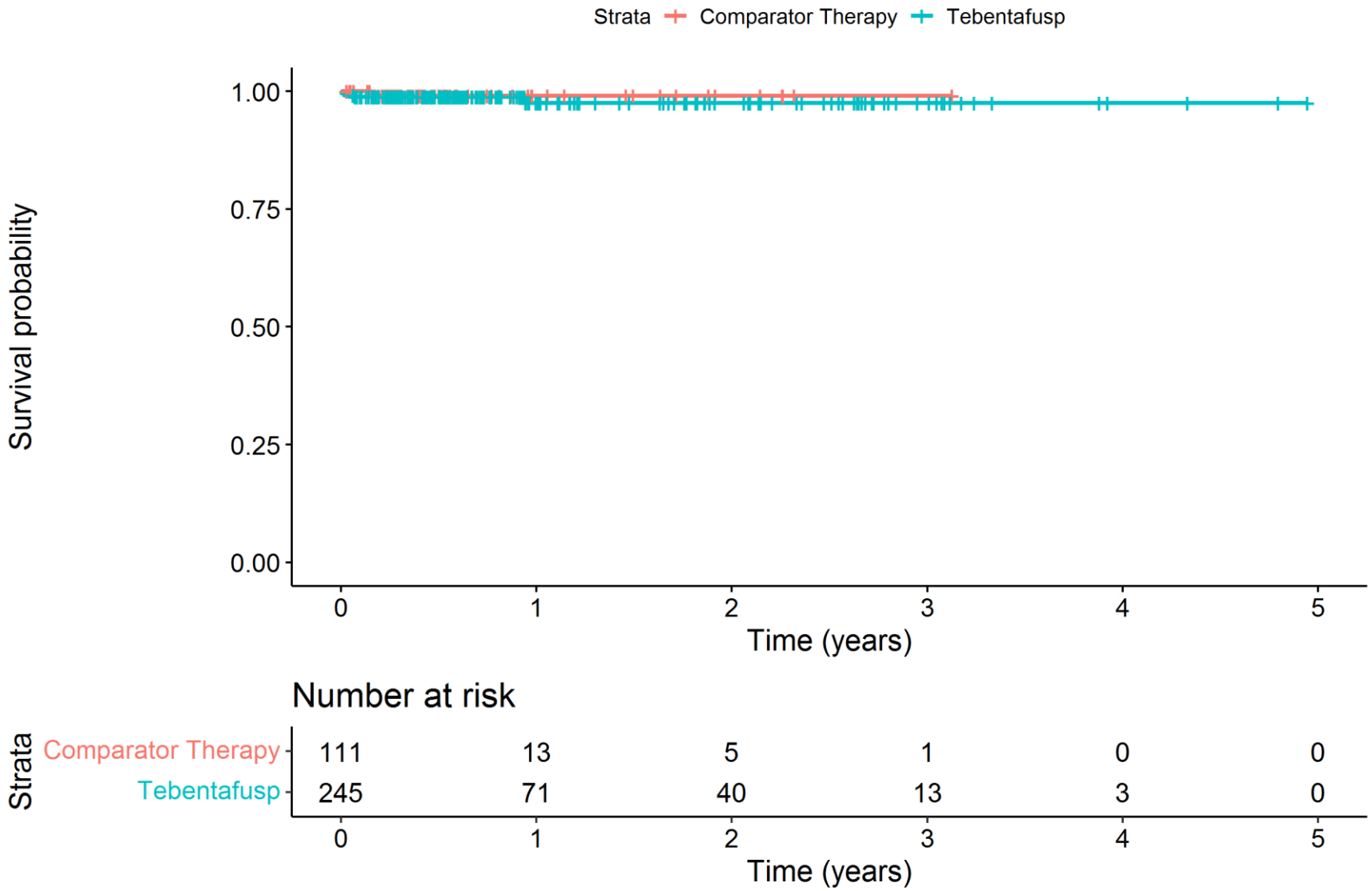
32.11 Stoffwechsel- und Ernährungsstörungen



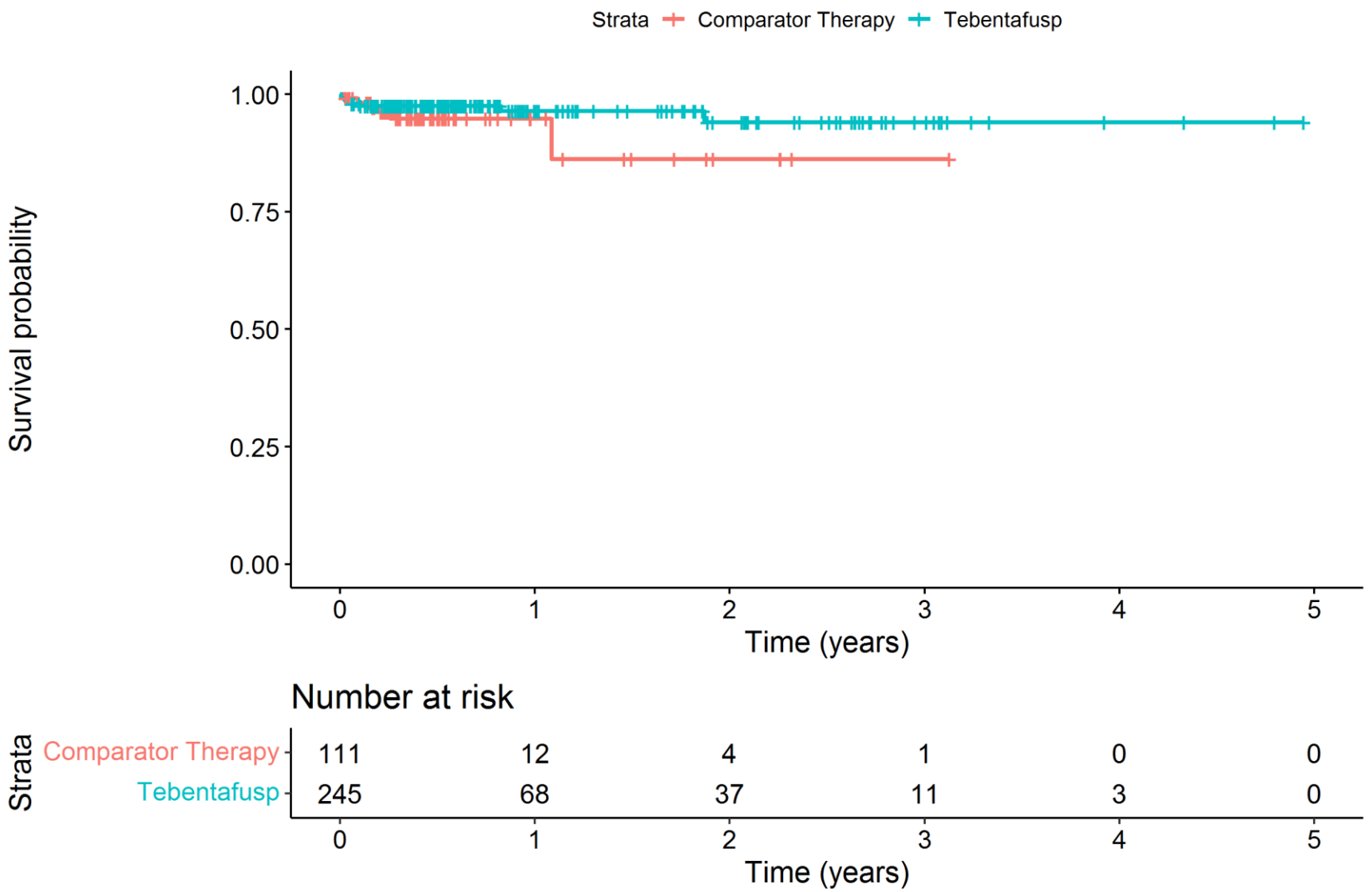
32.12 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



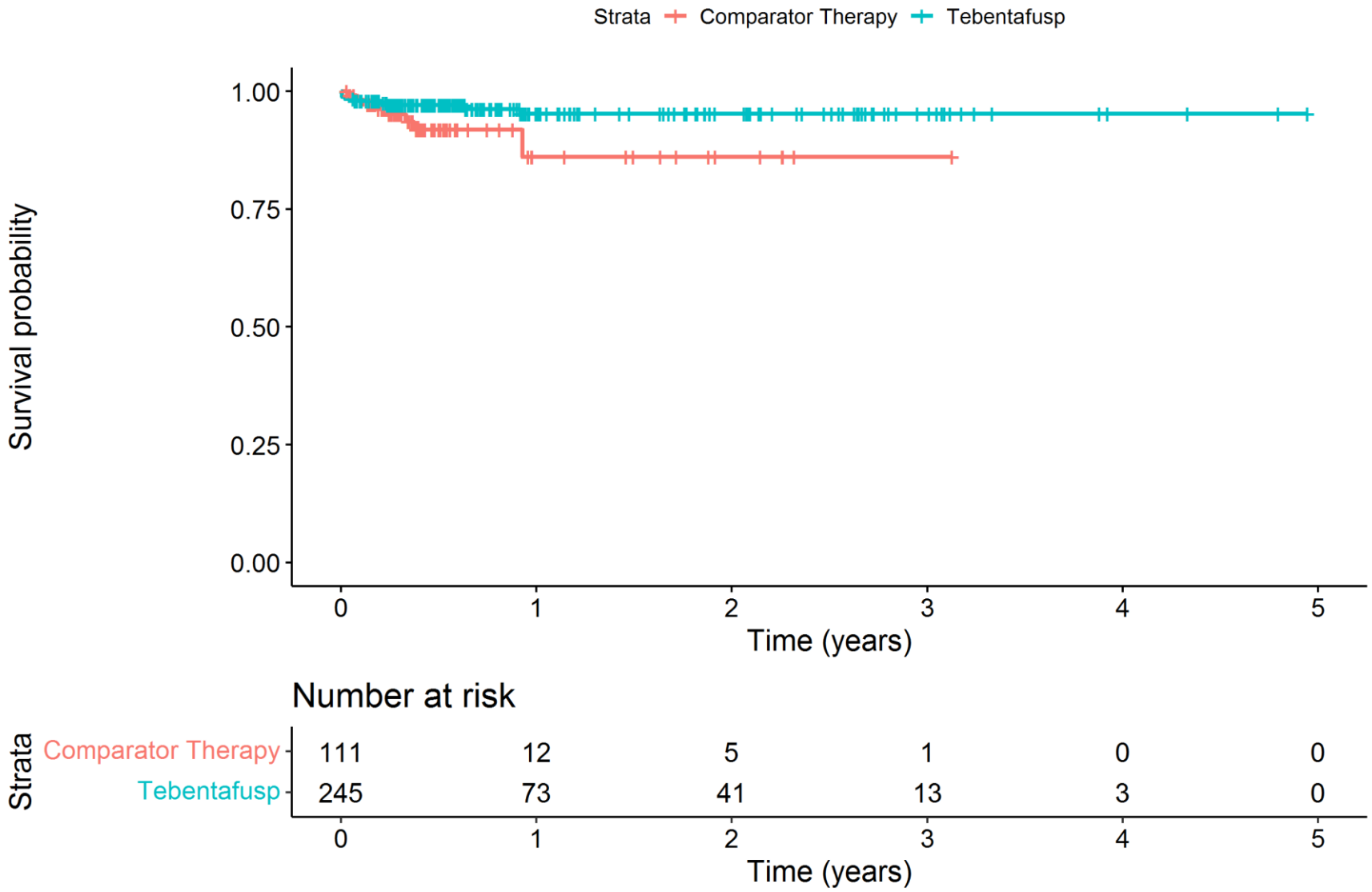
32.13 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



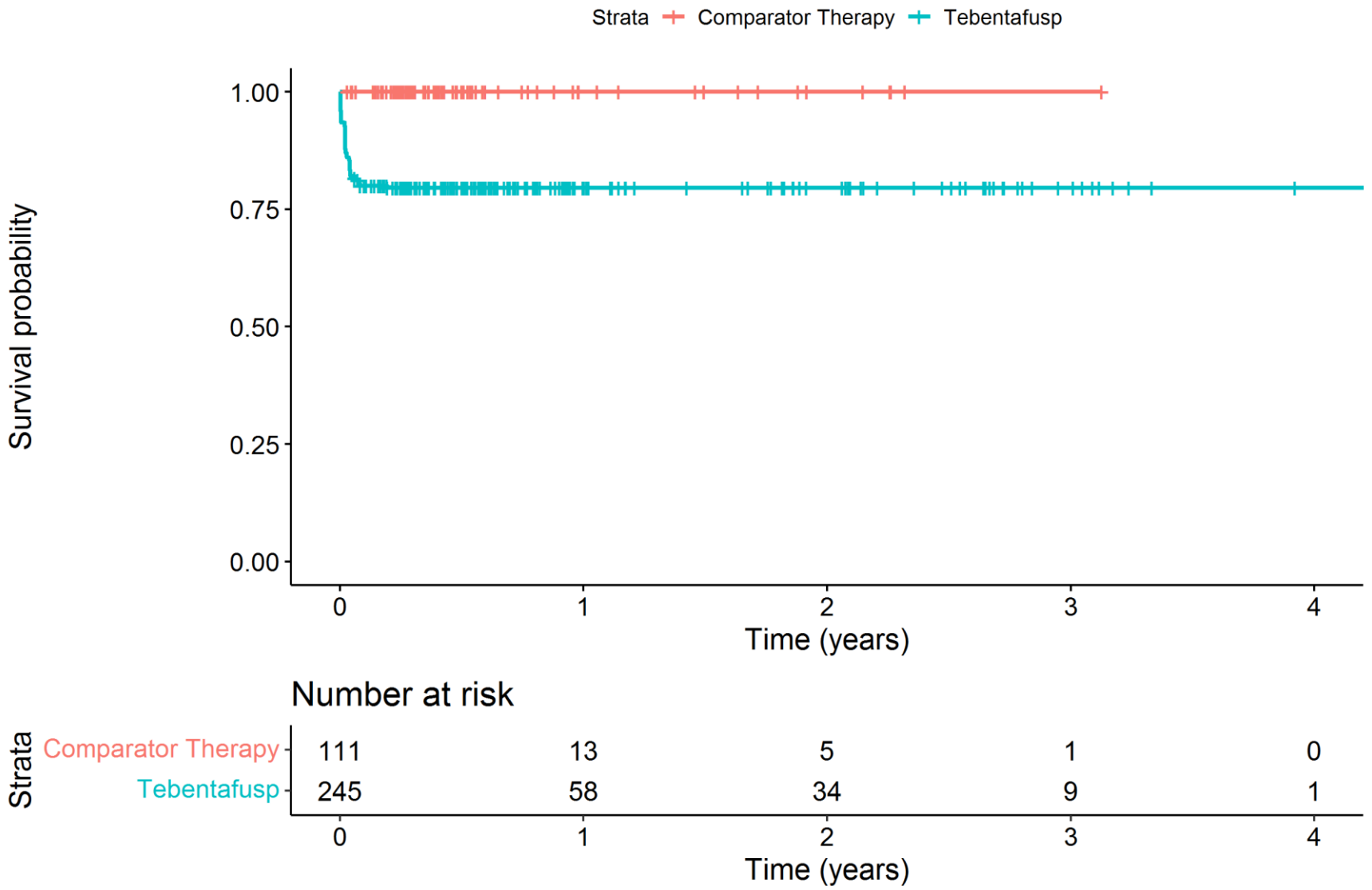
32.14 Erkrankungen des Nervensystems



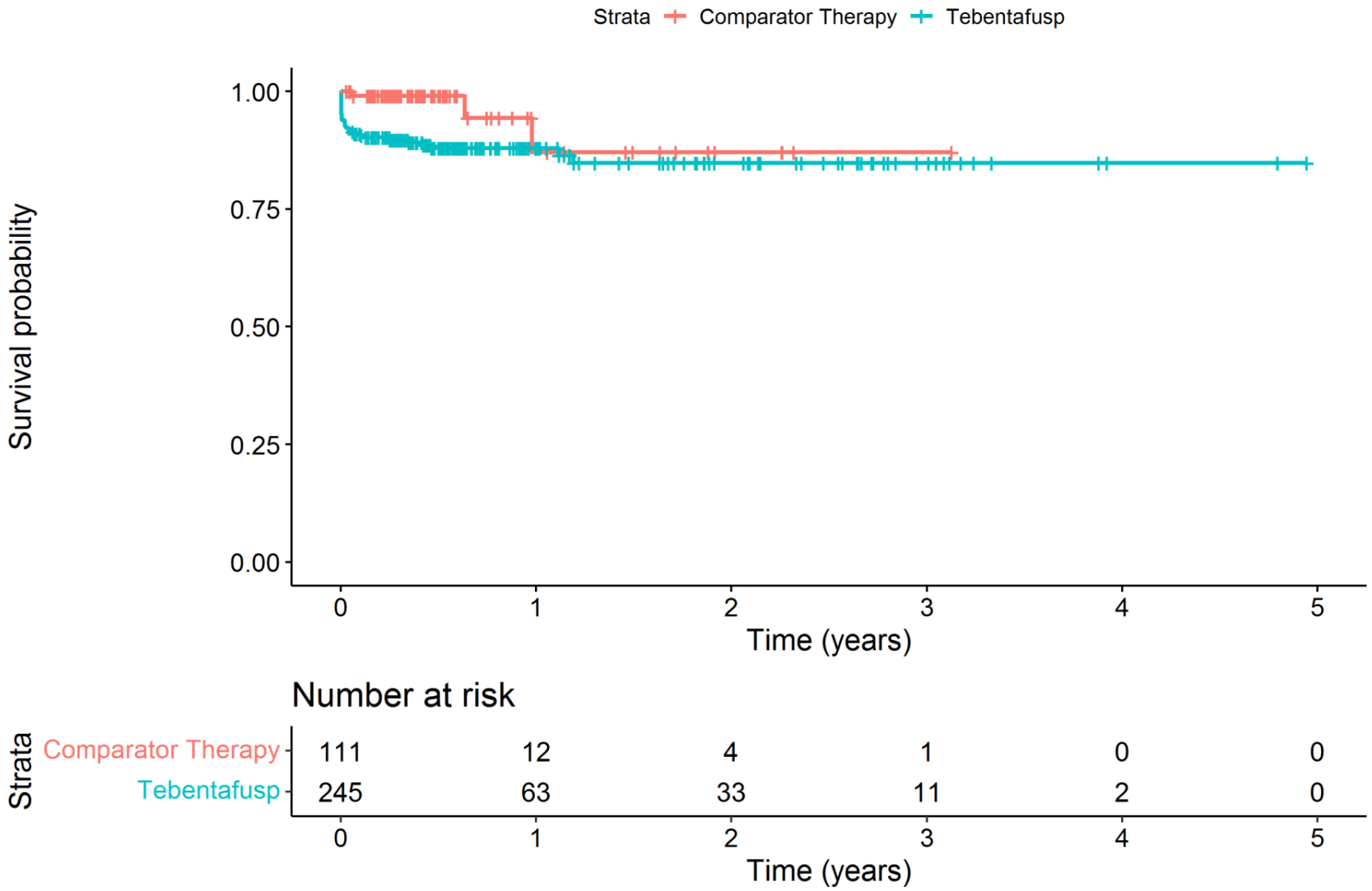
32.15 Erkrankungen der Atemwege, des Brustraums und Mediastinums



32.16 Erkrankungen der Haut und des Unterhautgewebes



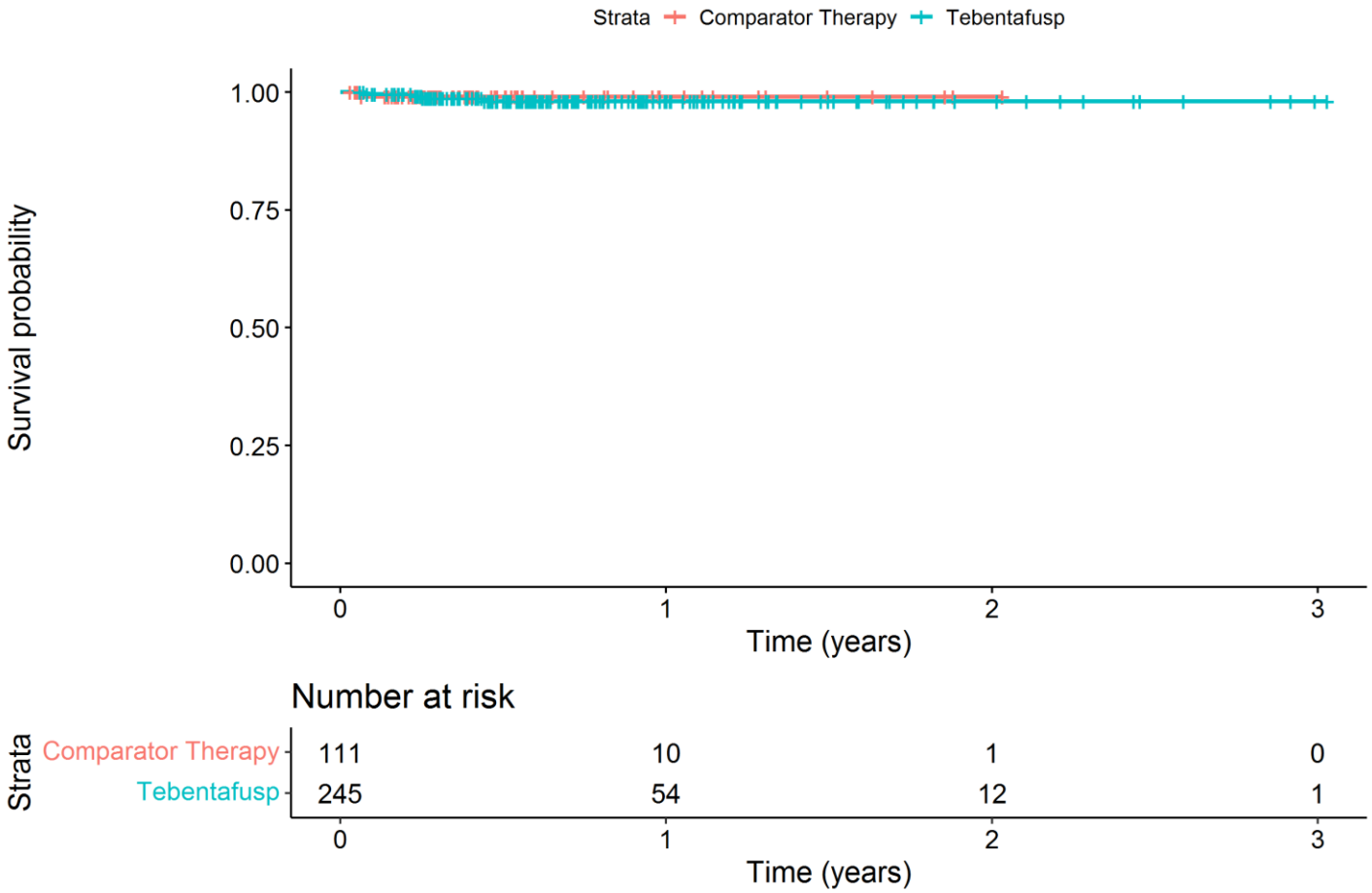
32.17 Gefäßerkrankungen



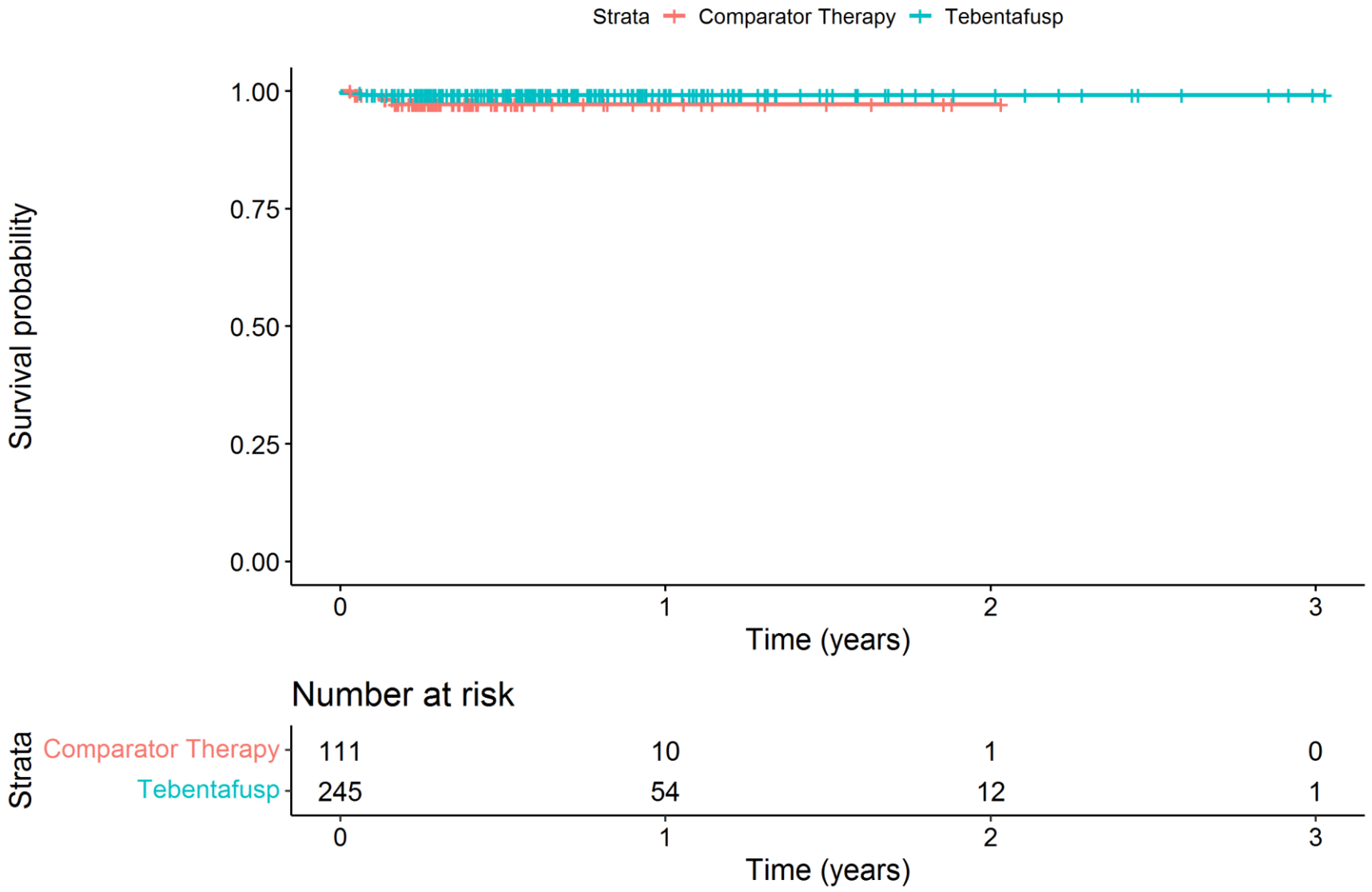
32.18 Schwerwiegende unerwünschte Ereignisse (SUEs) nach SOC und PT – Primäranalyse (Oktober 2020) (Tabelle 4-65)

33 SUEs (PT) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten

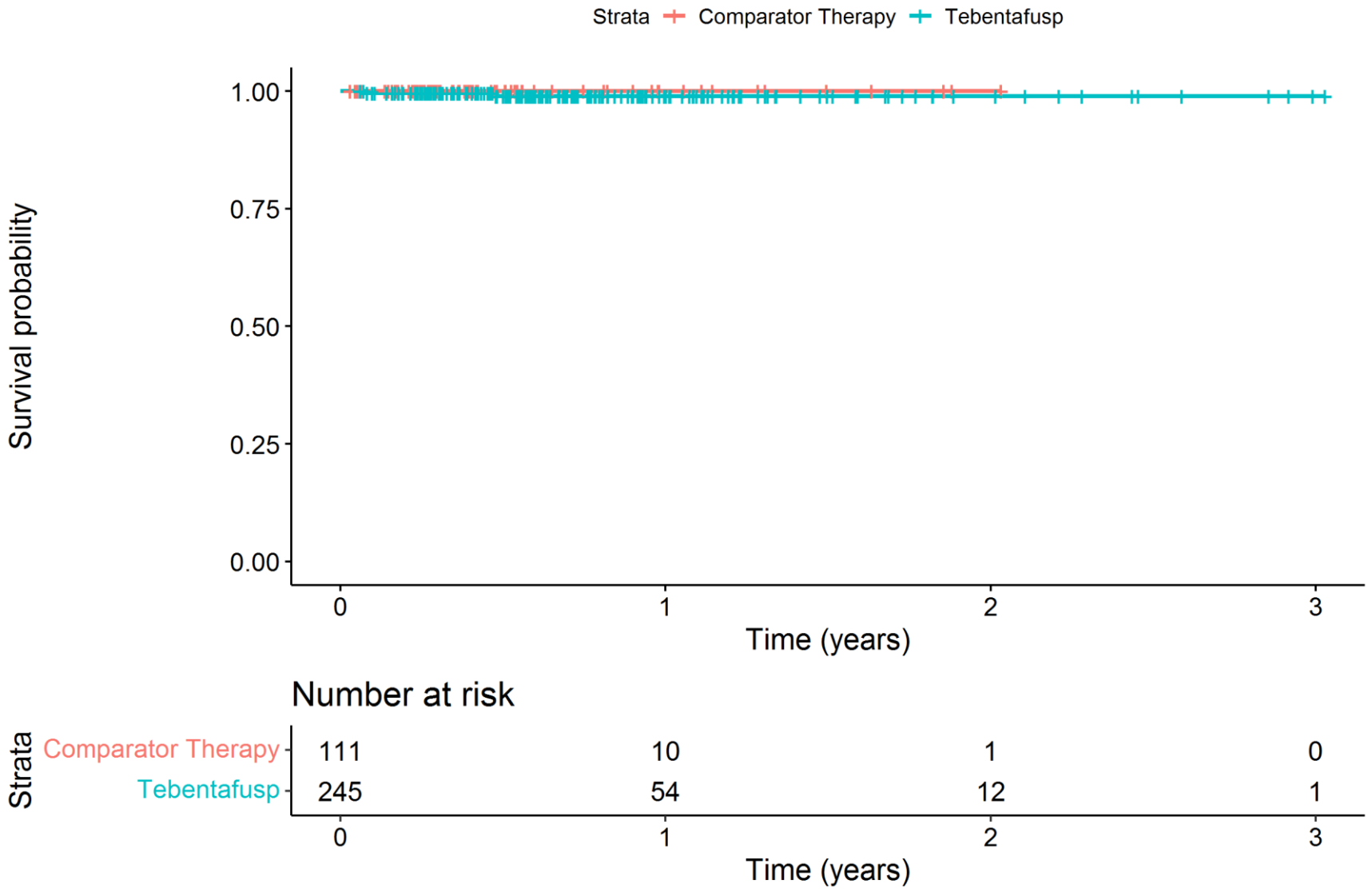
33.1 Übelkeit



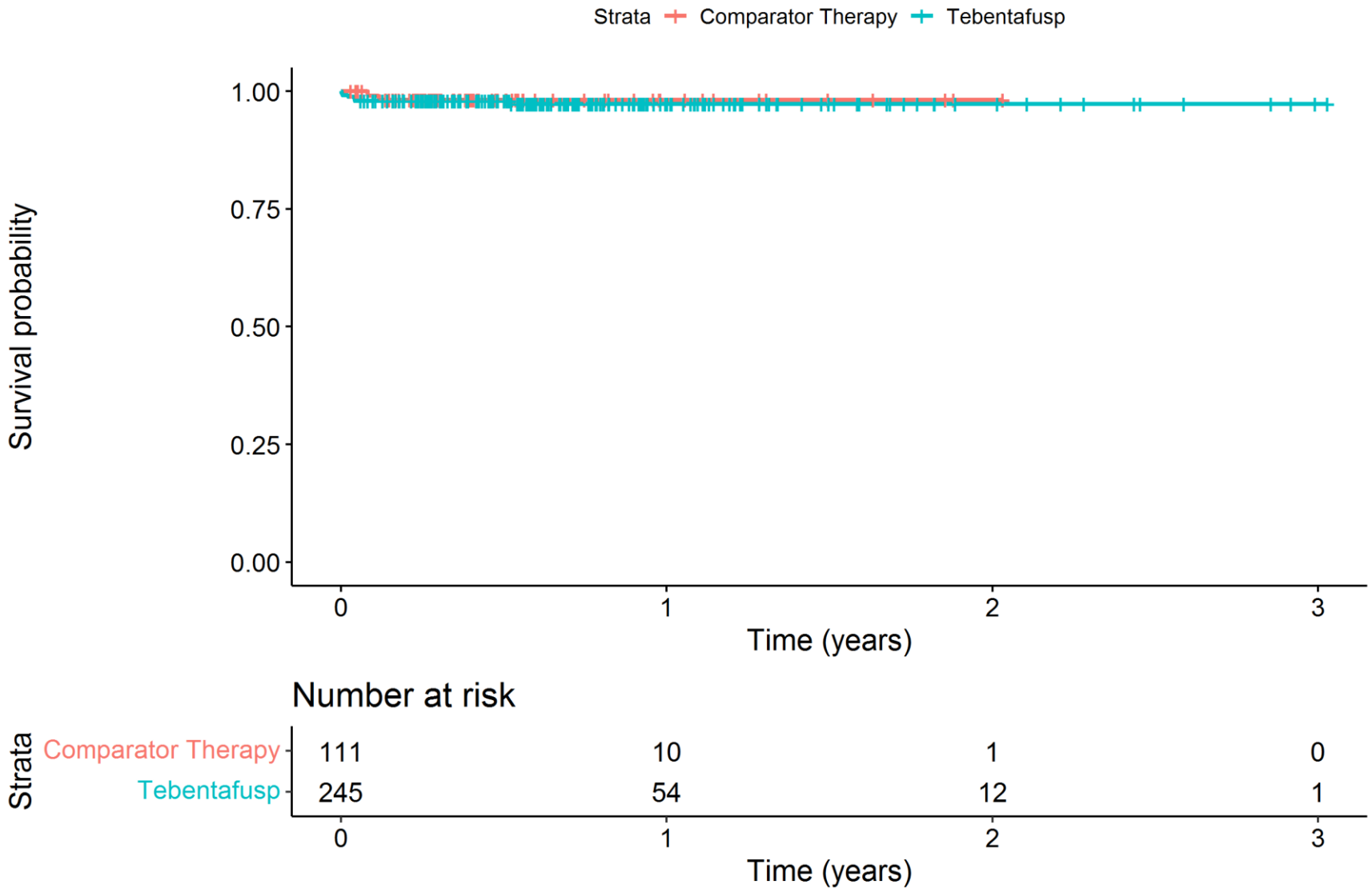
33.2 Unterleibsschmerzen



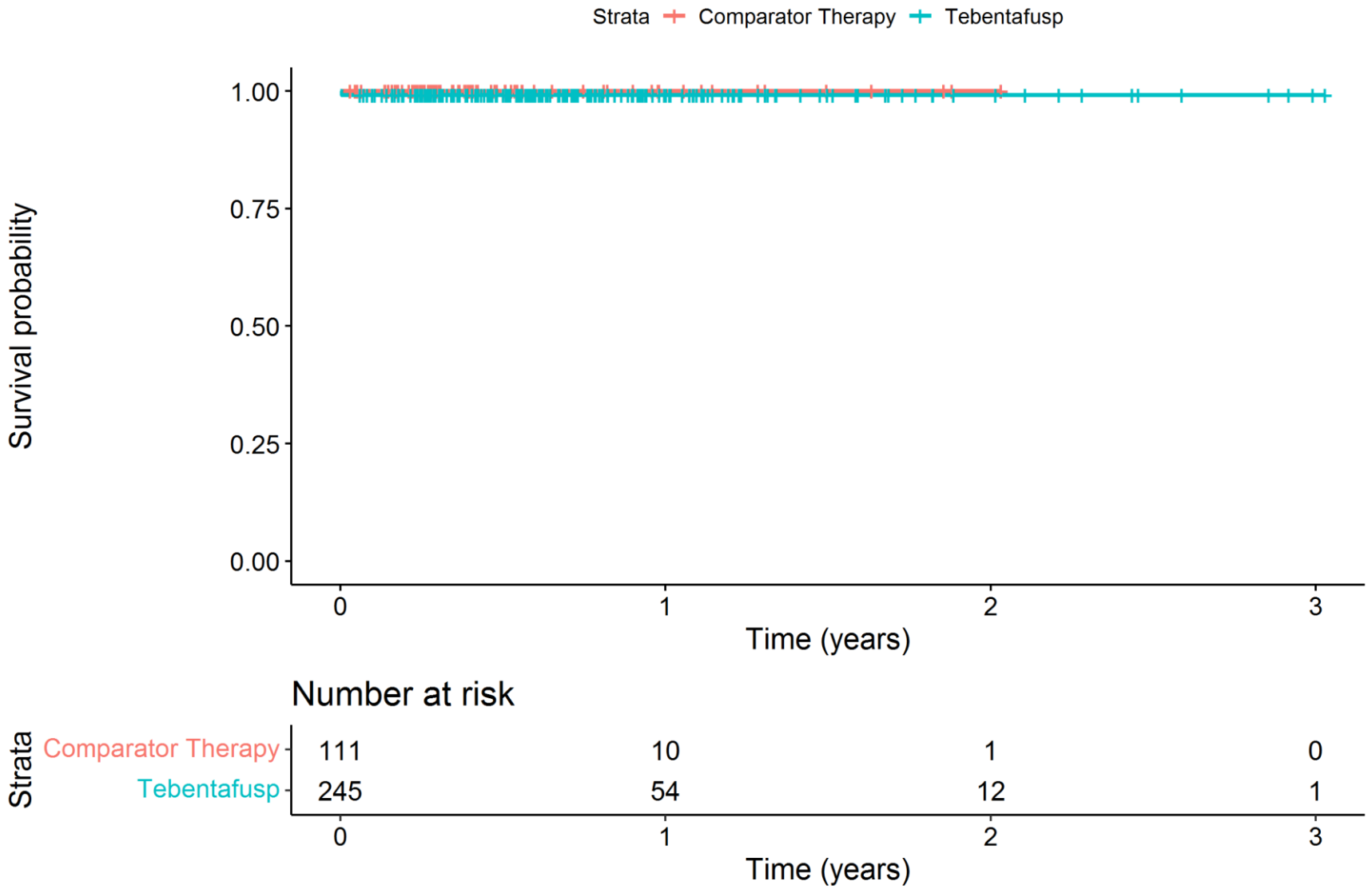
33.3 Erbrechen



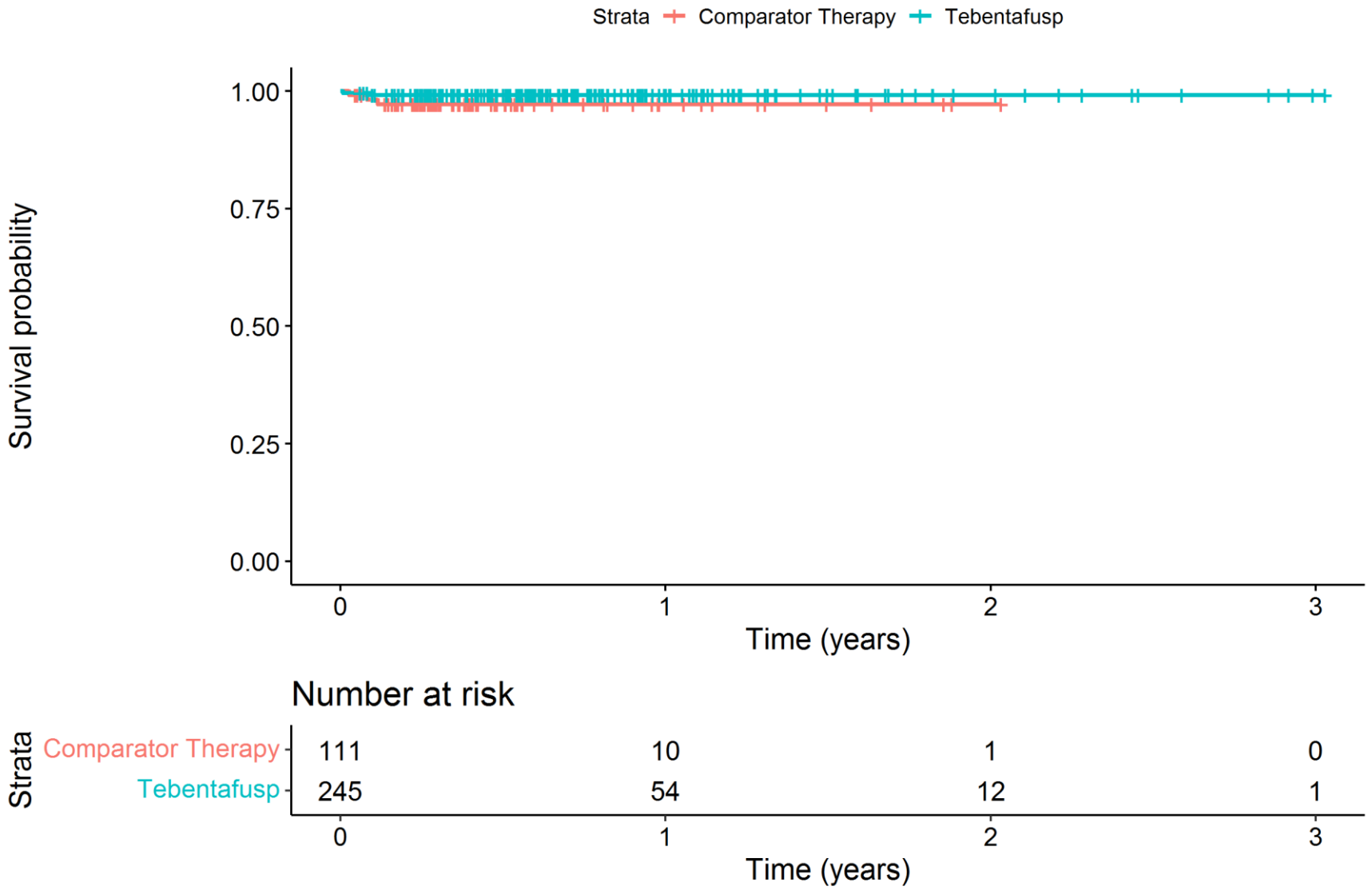
33.4 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
10
1
0
245
54
12
1
0
1
2
3
Time (years)

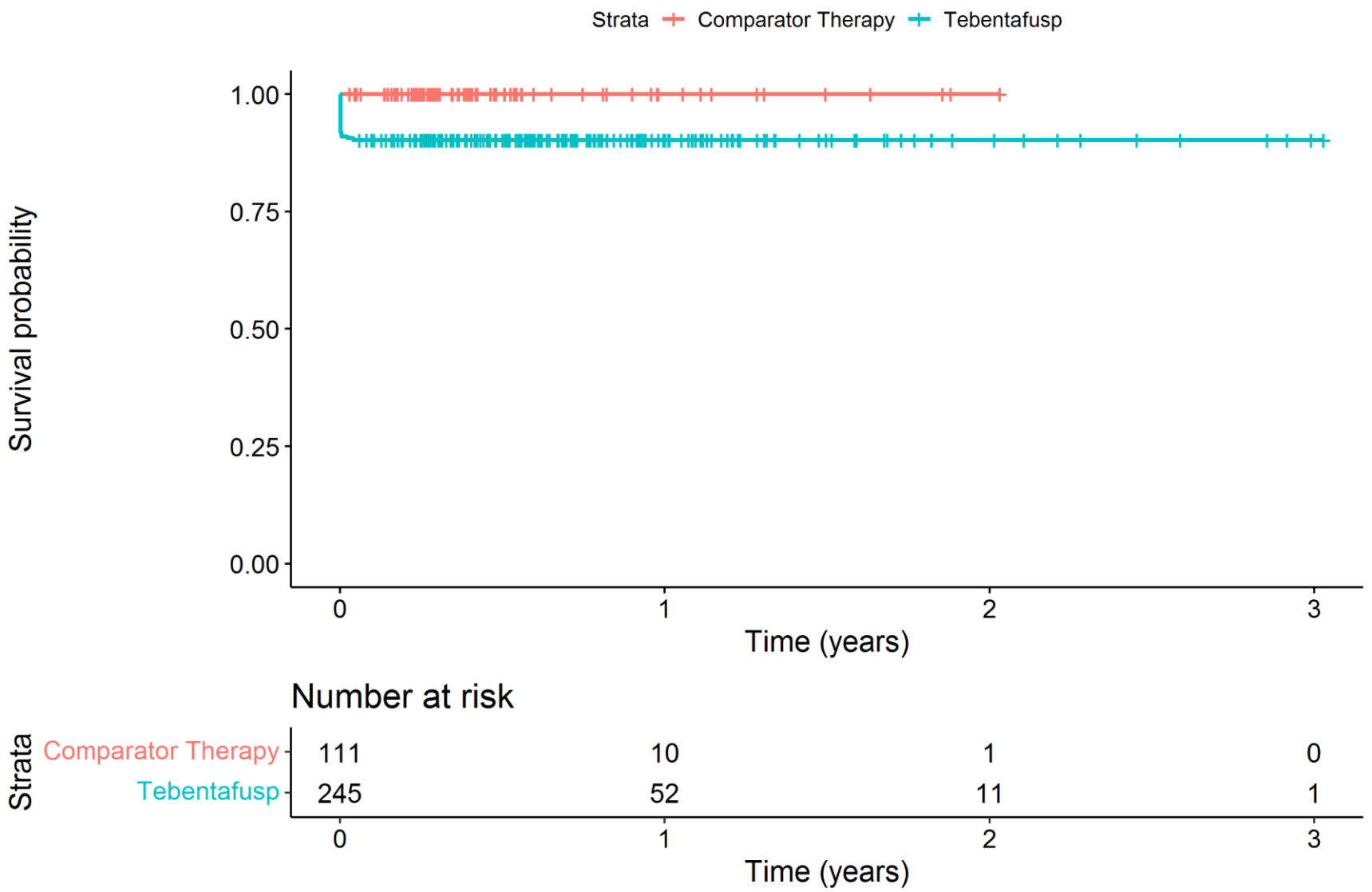
33.5 Hepatotoxizität



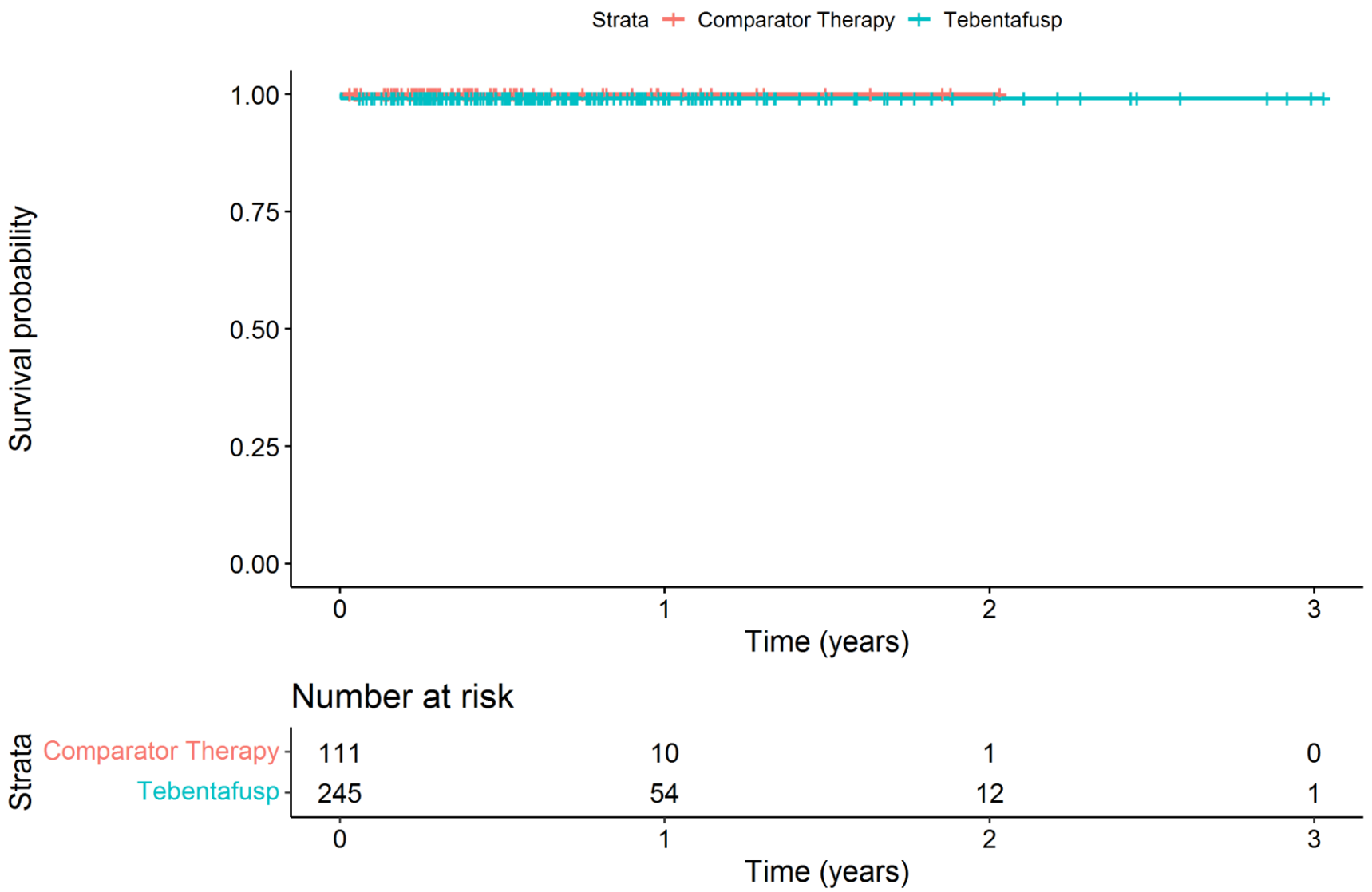
33.6 Hyperbilirubinämie



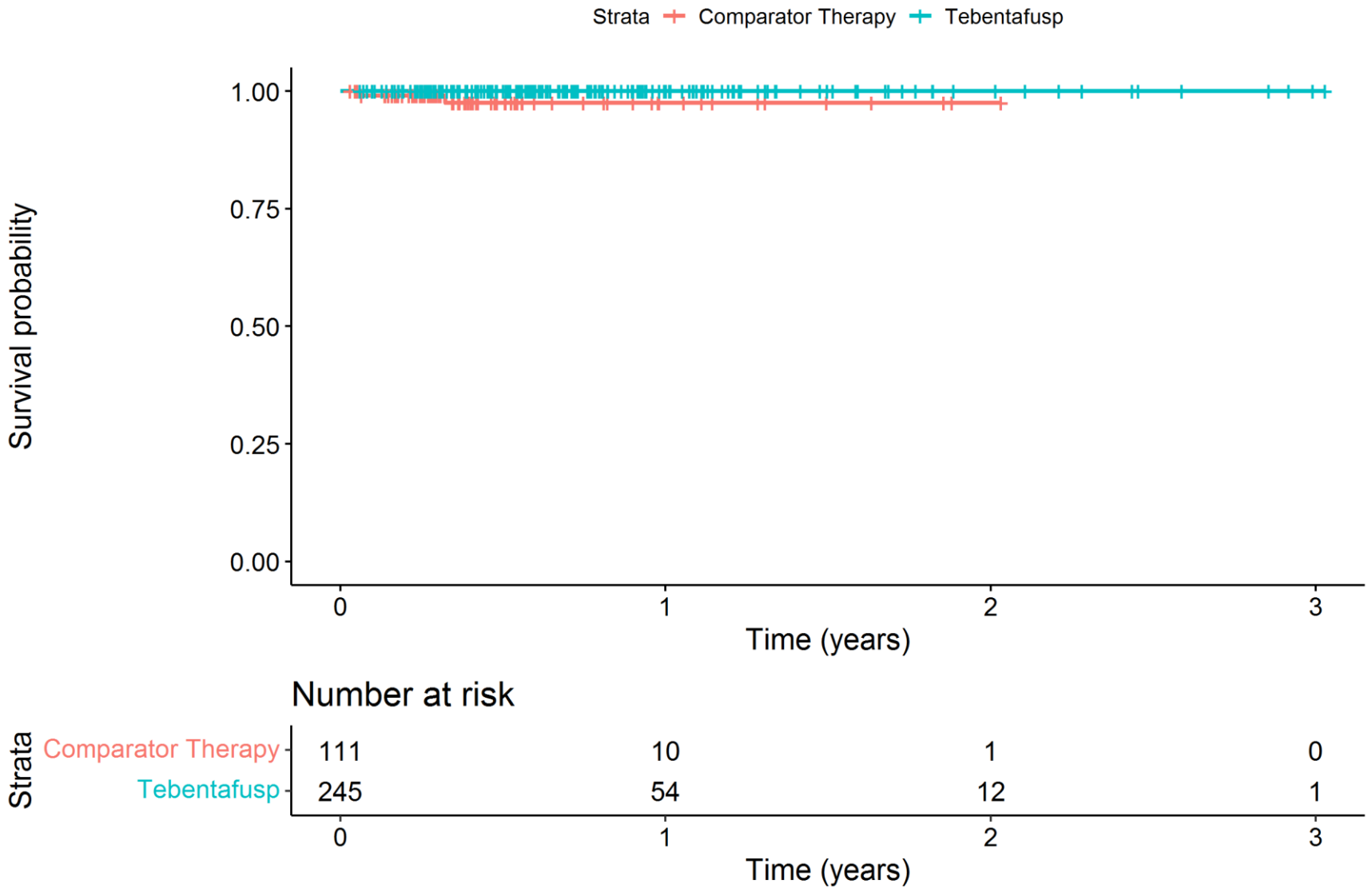
33.7 Zytokin-Freisetzungssyndrom



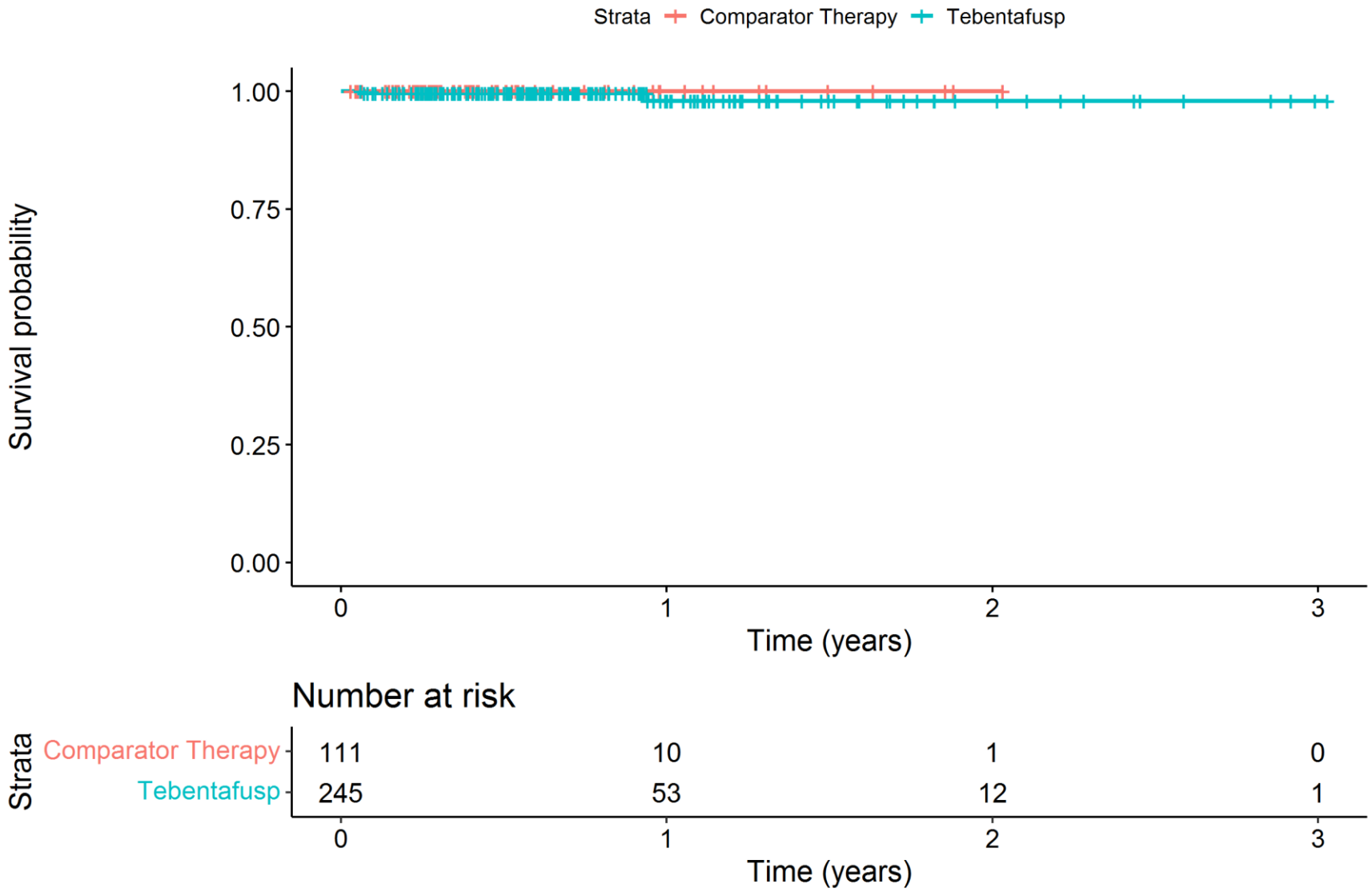
33.8 Kreatinin im Blut erhöht



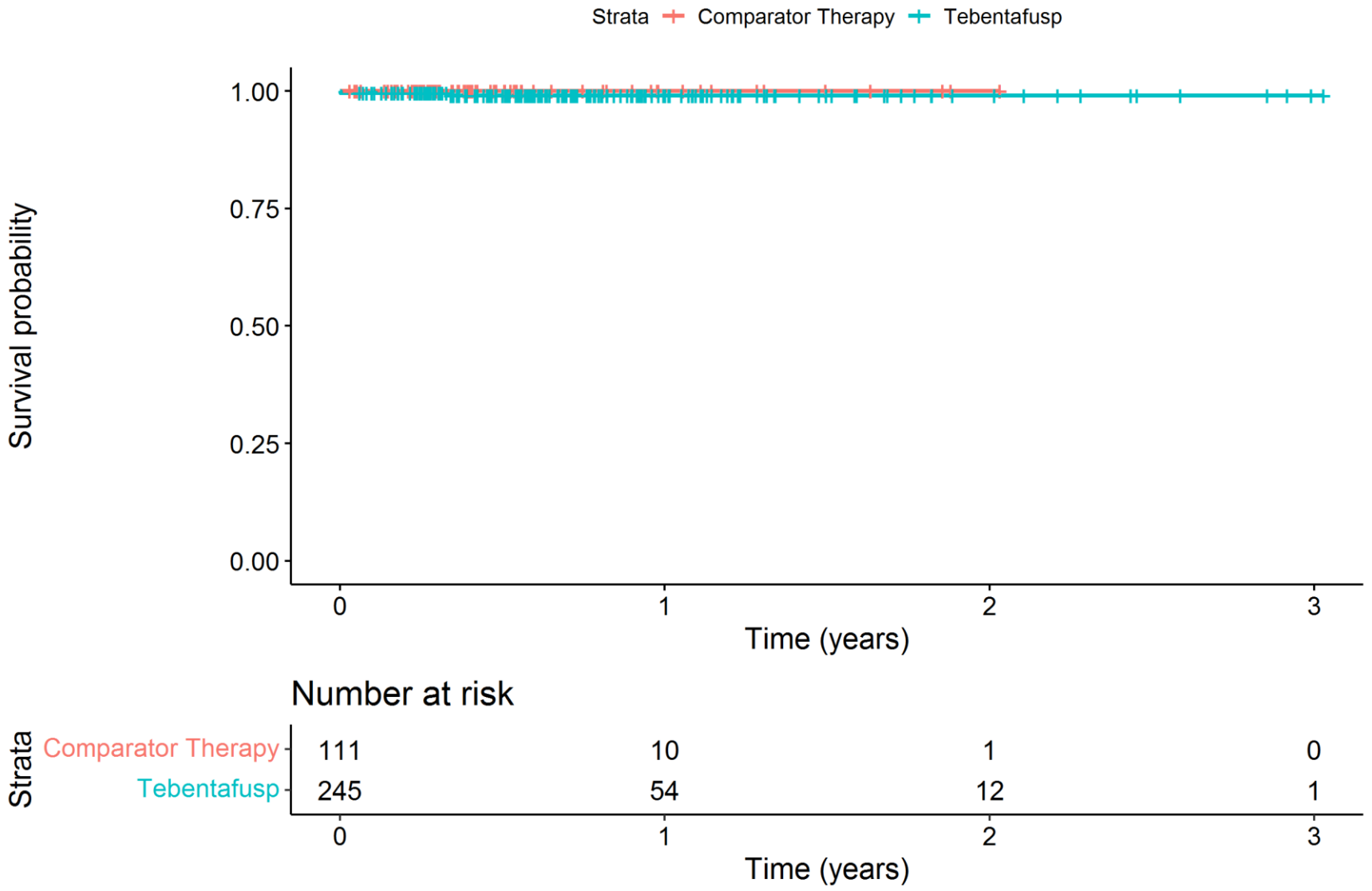
33.9 Dehydrierung



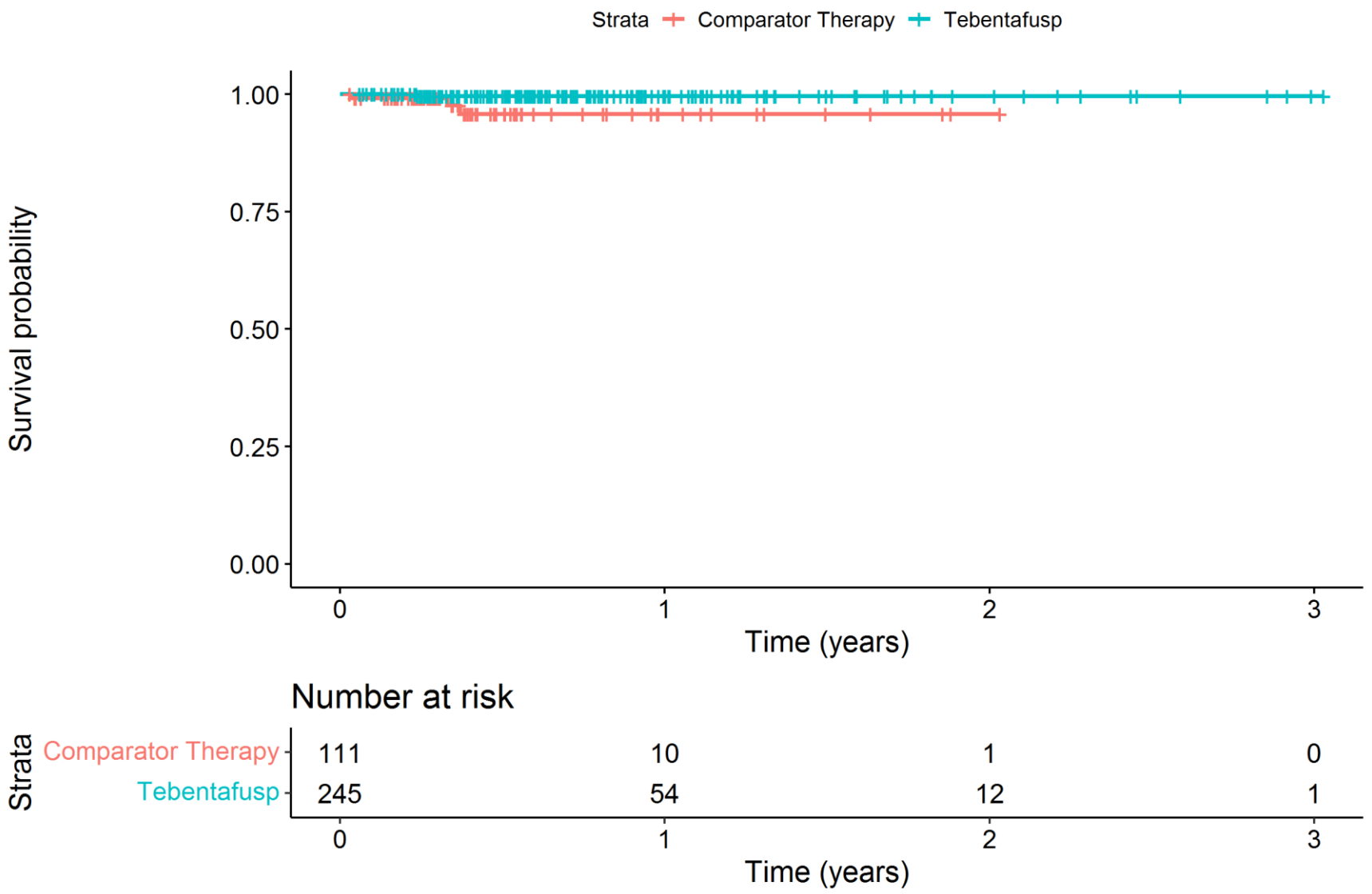
33.10 Tumorschmerzen



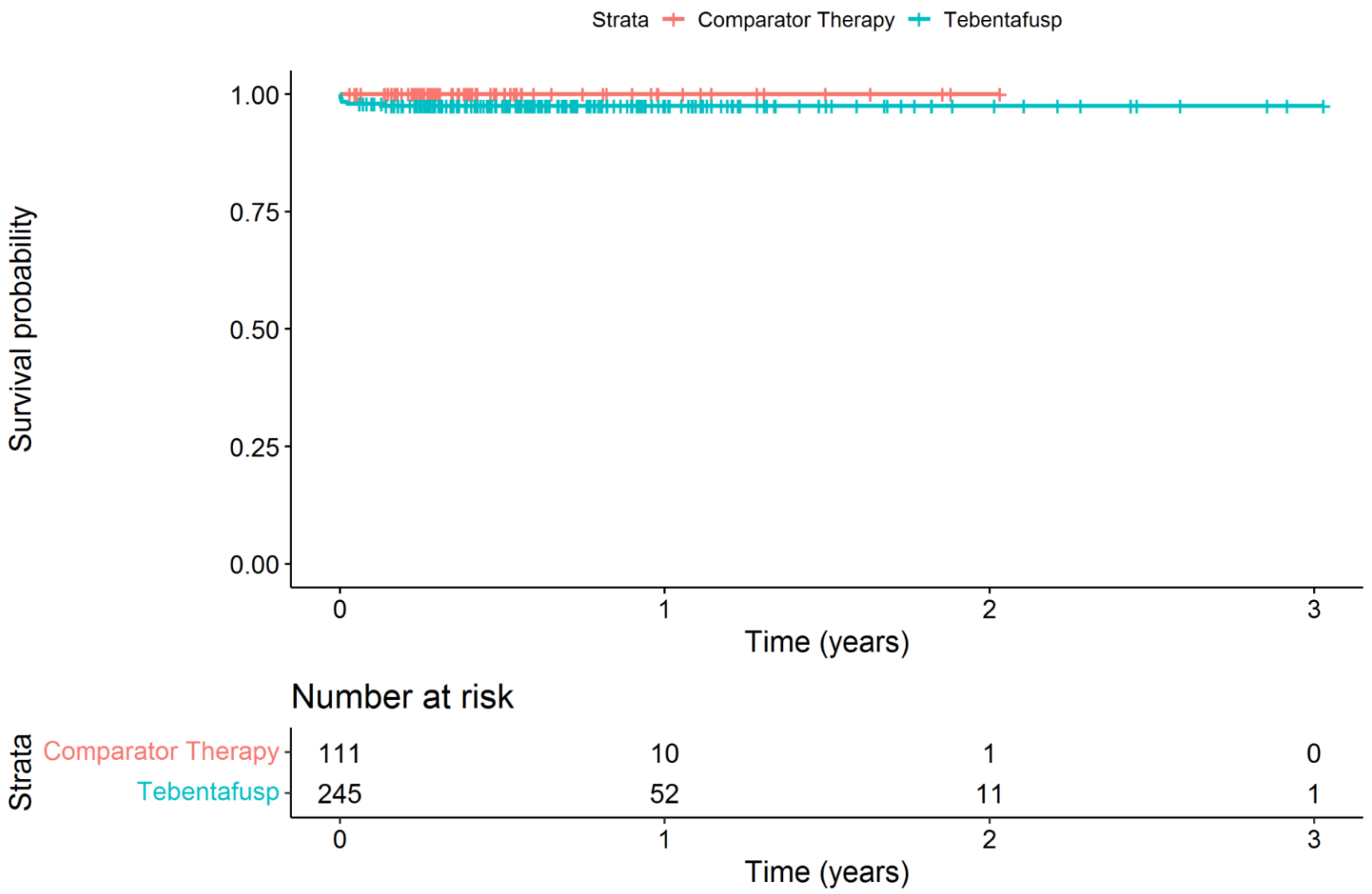
33.11 Dyspnoe



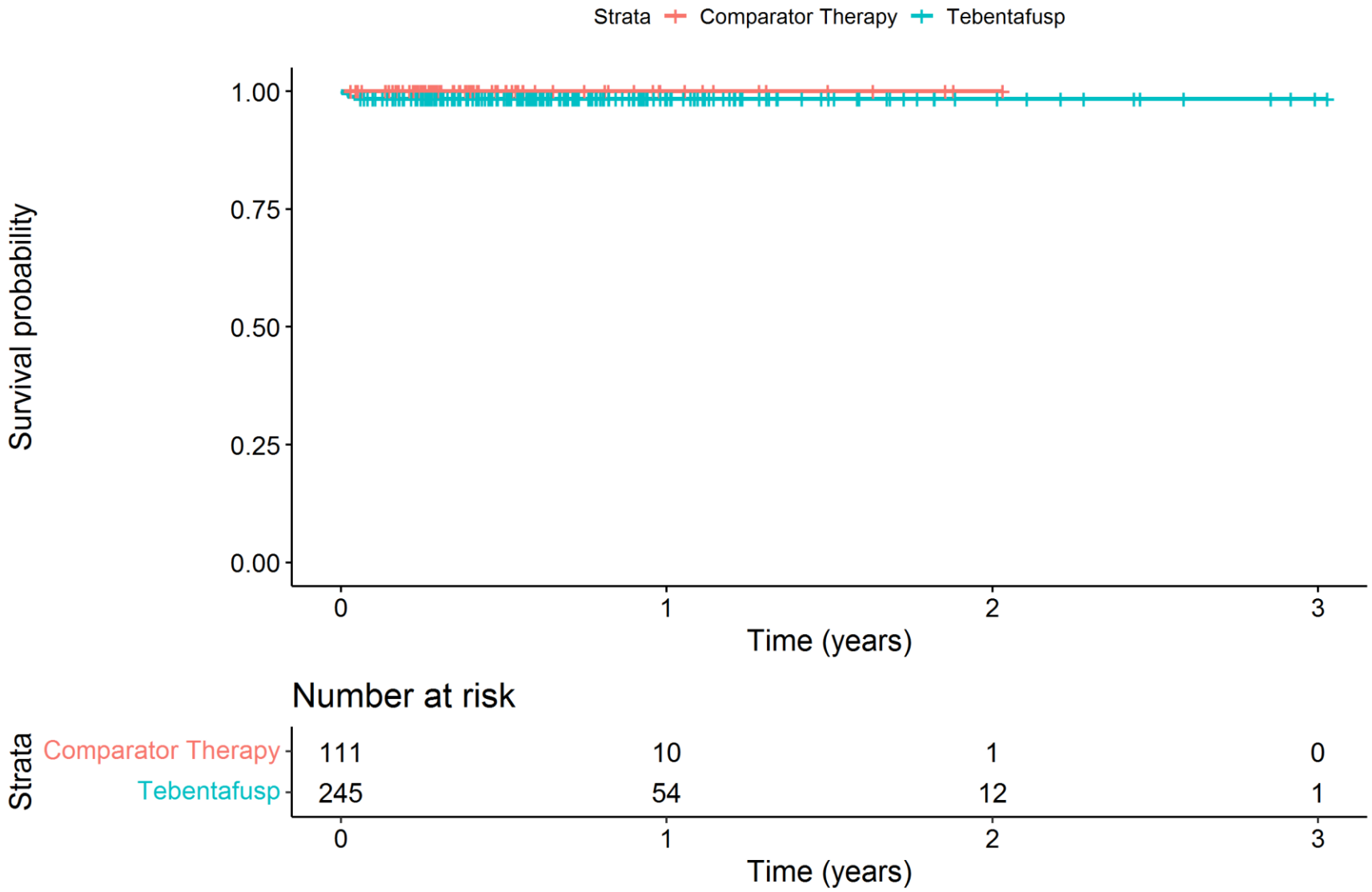
33.12 Lungenembolie



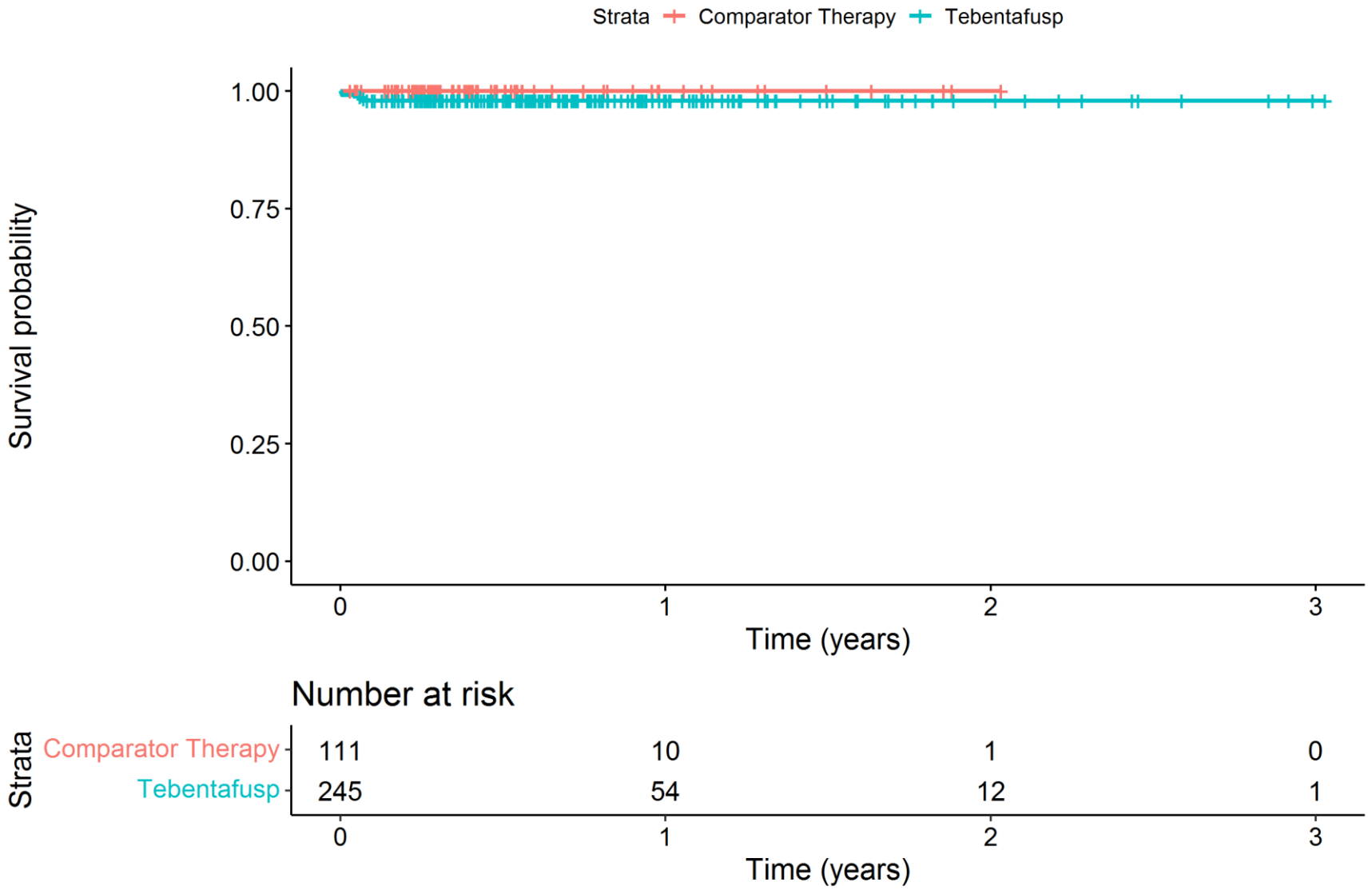
33.13 Hautausschlag



33.14 Makulo-papulöser Hautausschlag

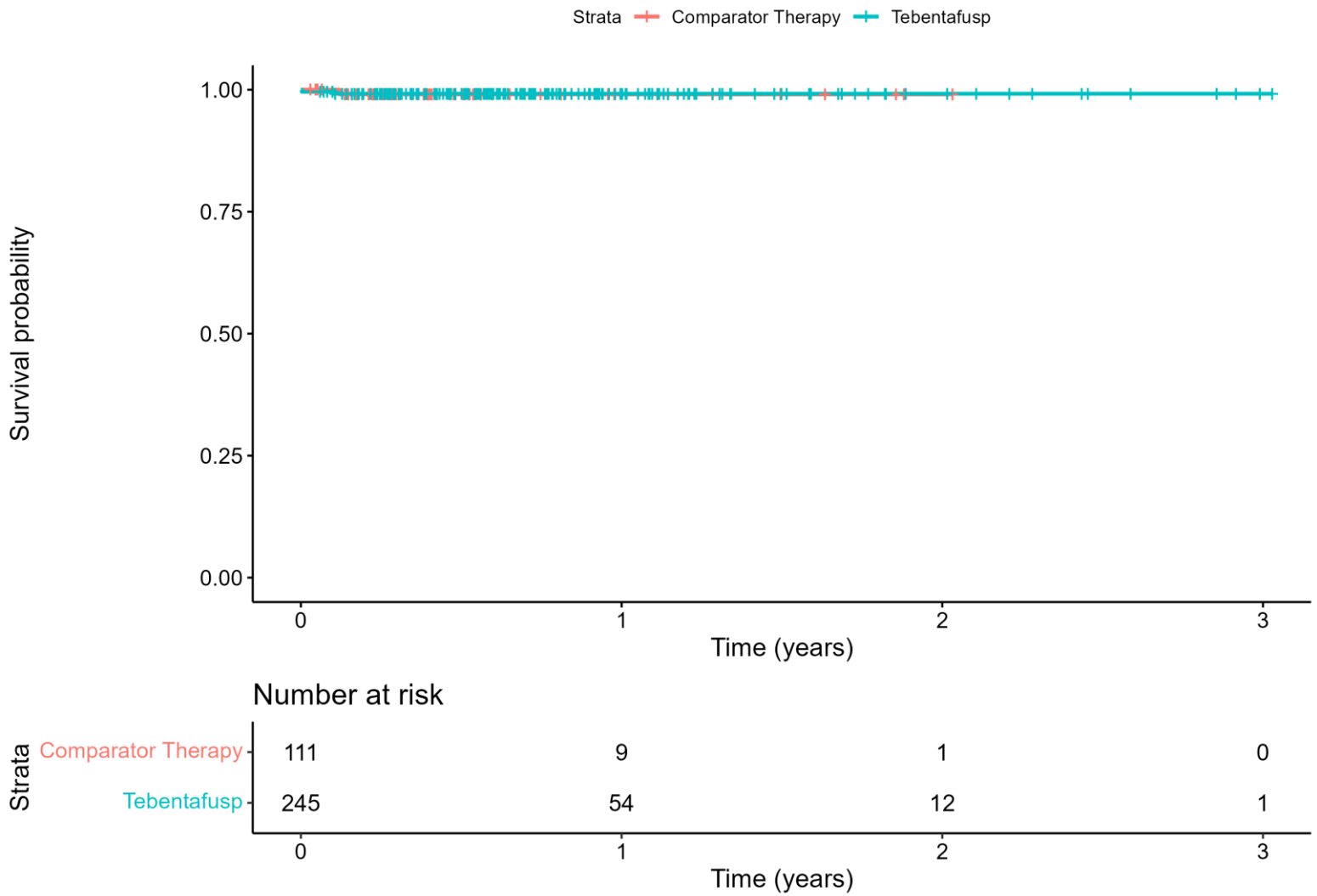


33.15 Hypotonie

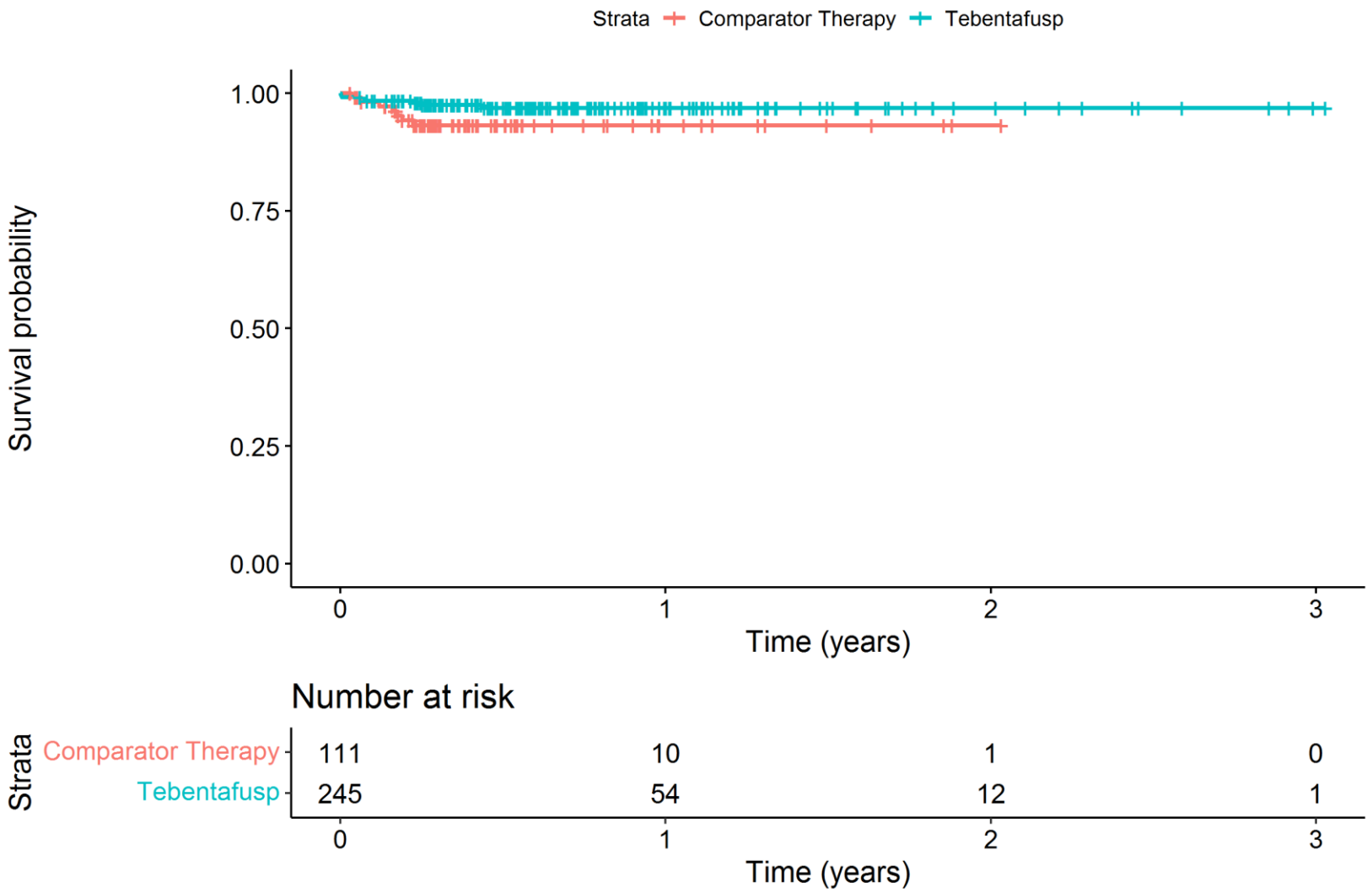


34 SUEs (SOC) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten

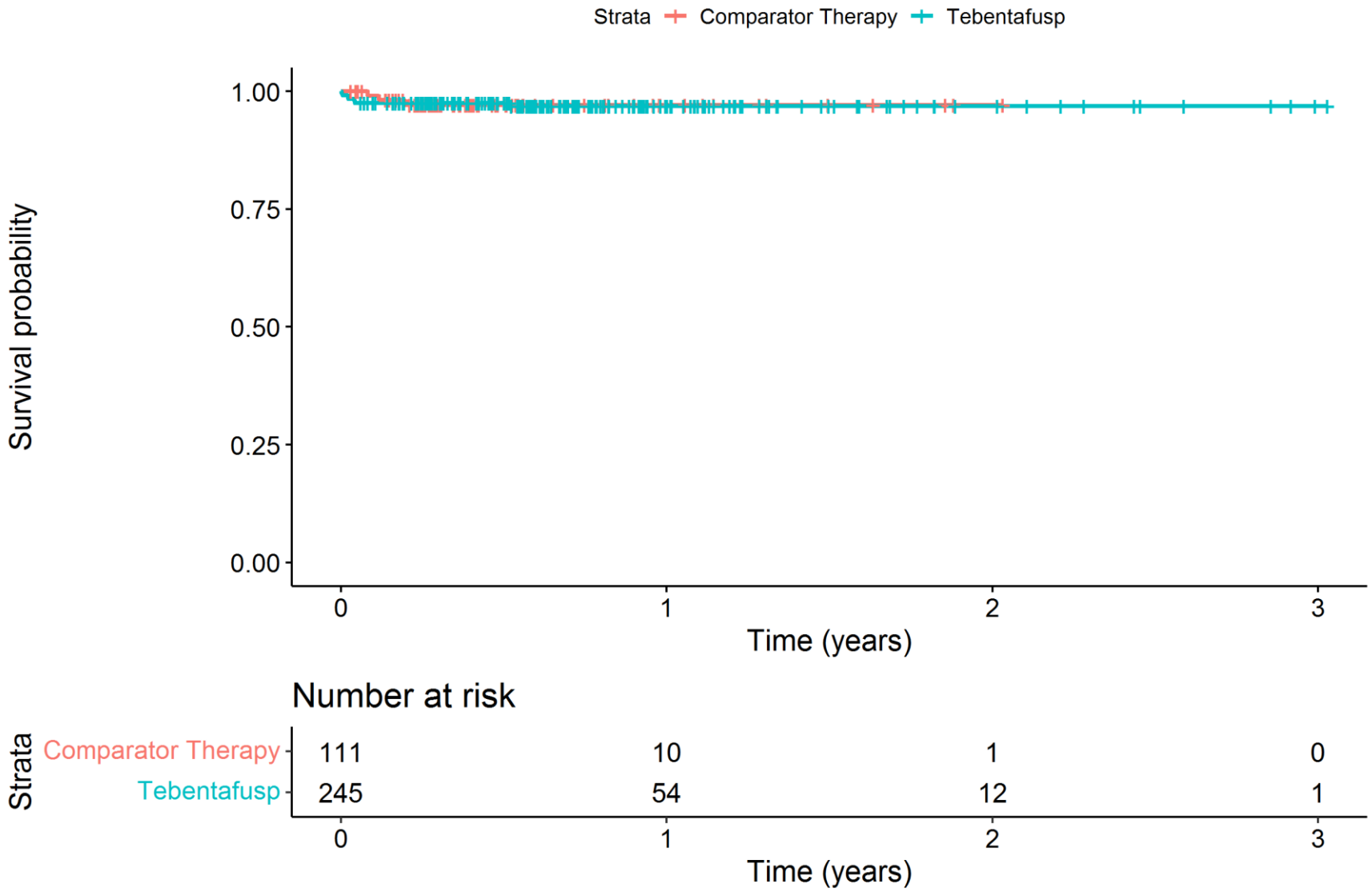
34.1 Augenerkrankungen


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
9
1
0
245
54
12
1
0
1
2
3
Time (years)

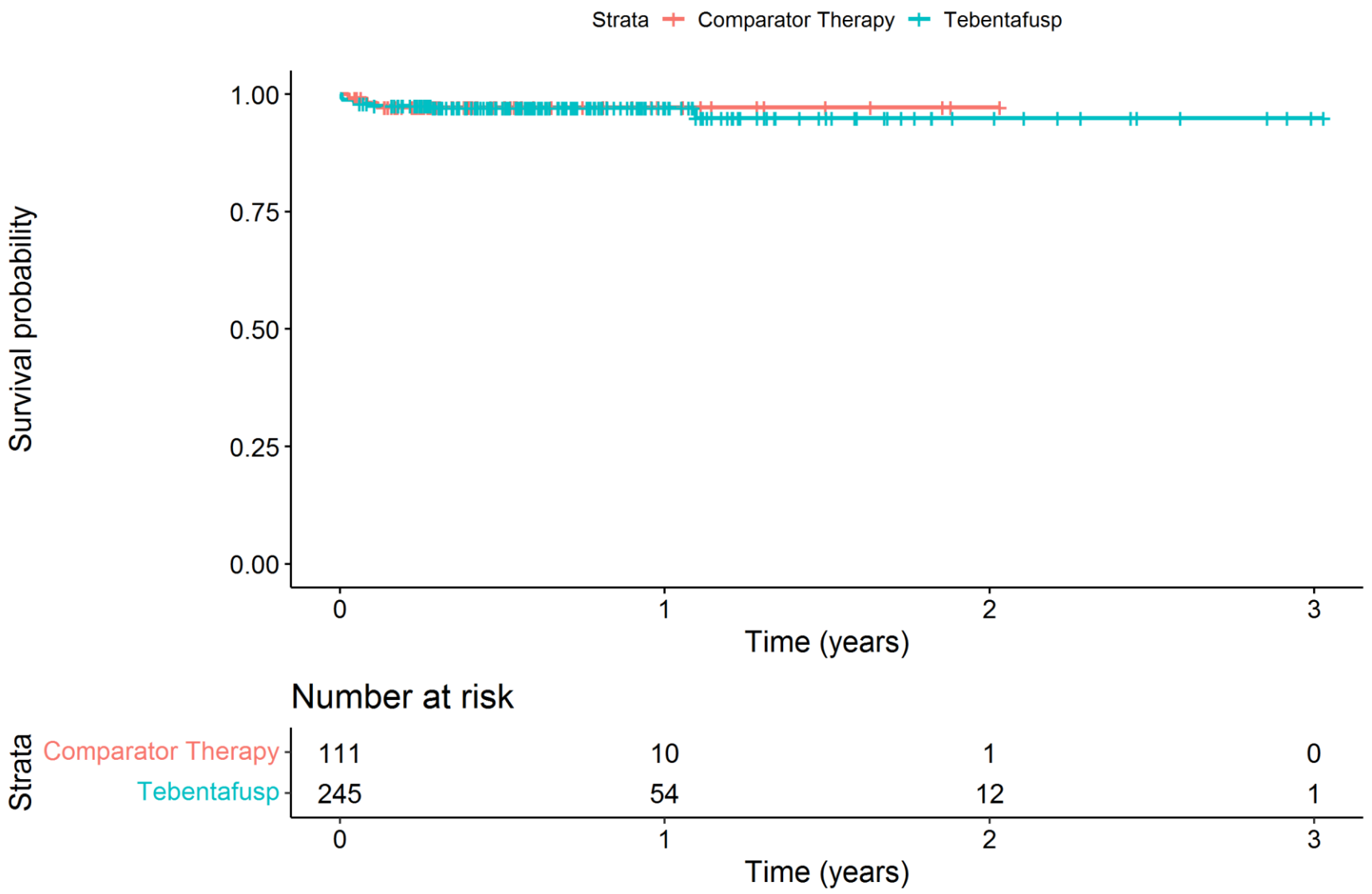
34.2 Erkrankungen des Gastrointestinaltrakts



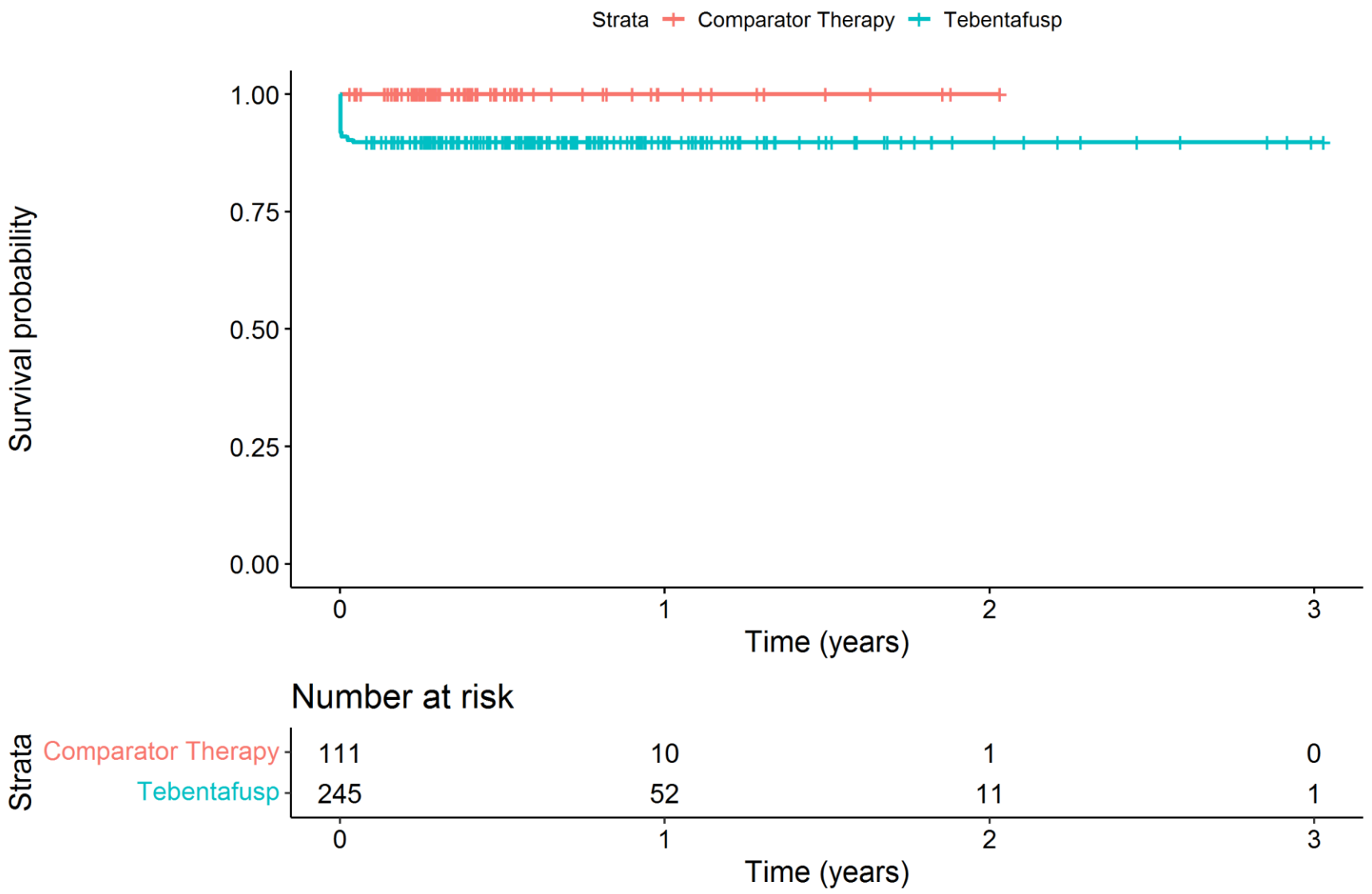
34.3 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



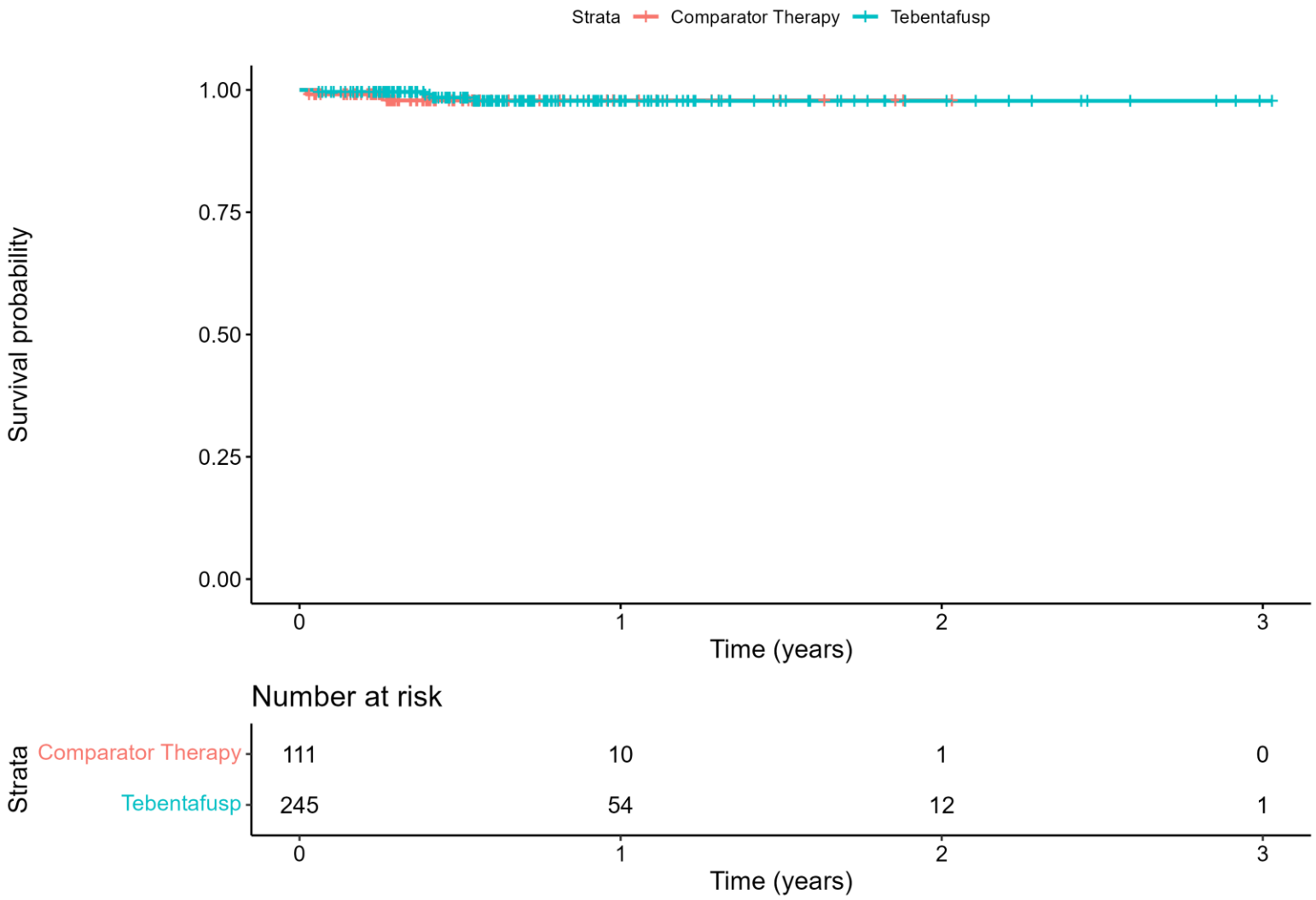
34.4 Leber- und Gallenerkrankungen



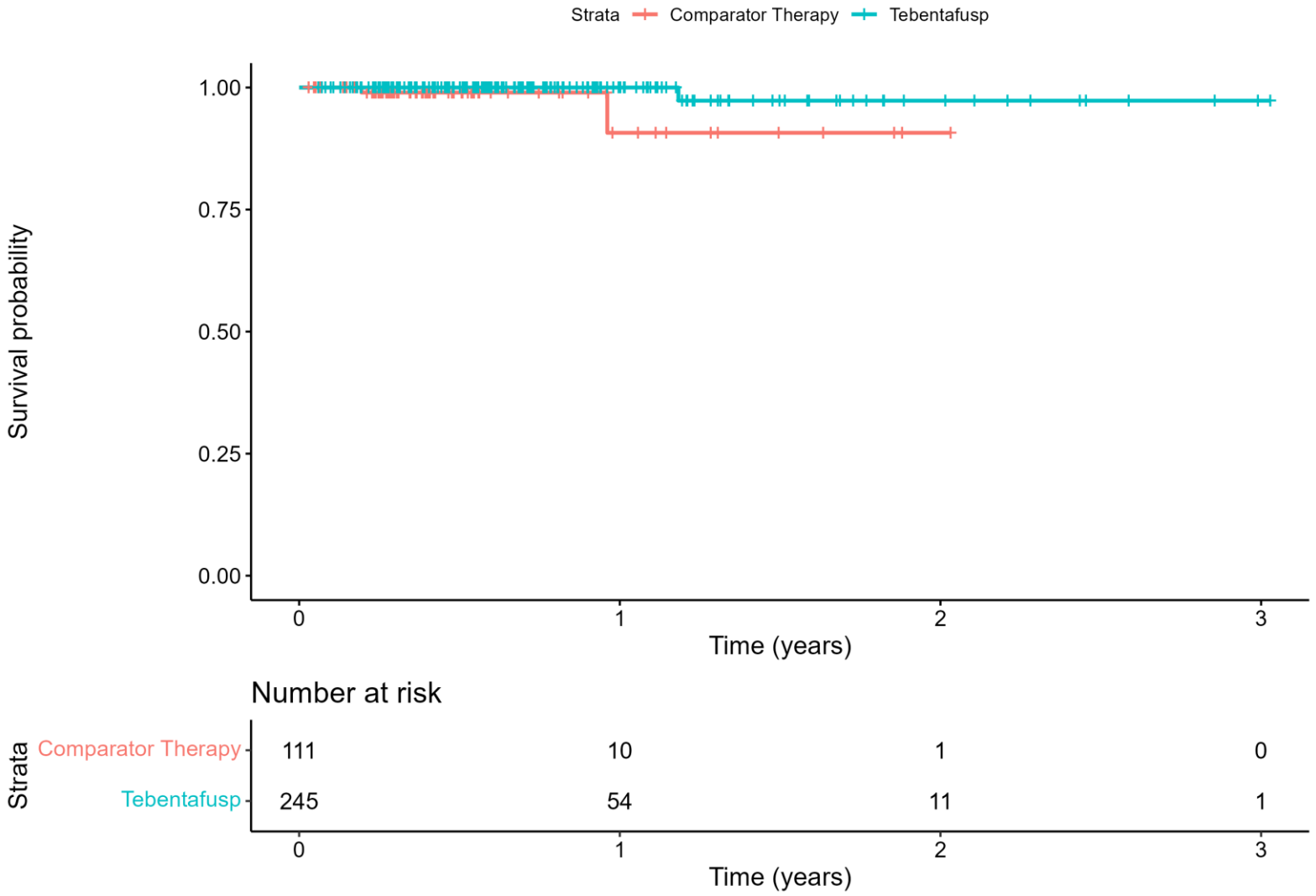
34.5 Erkrankungen des Immunsystems



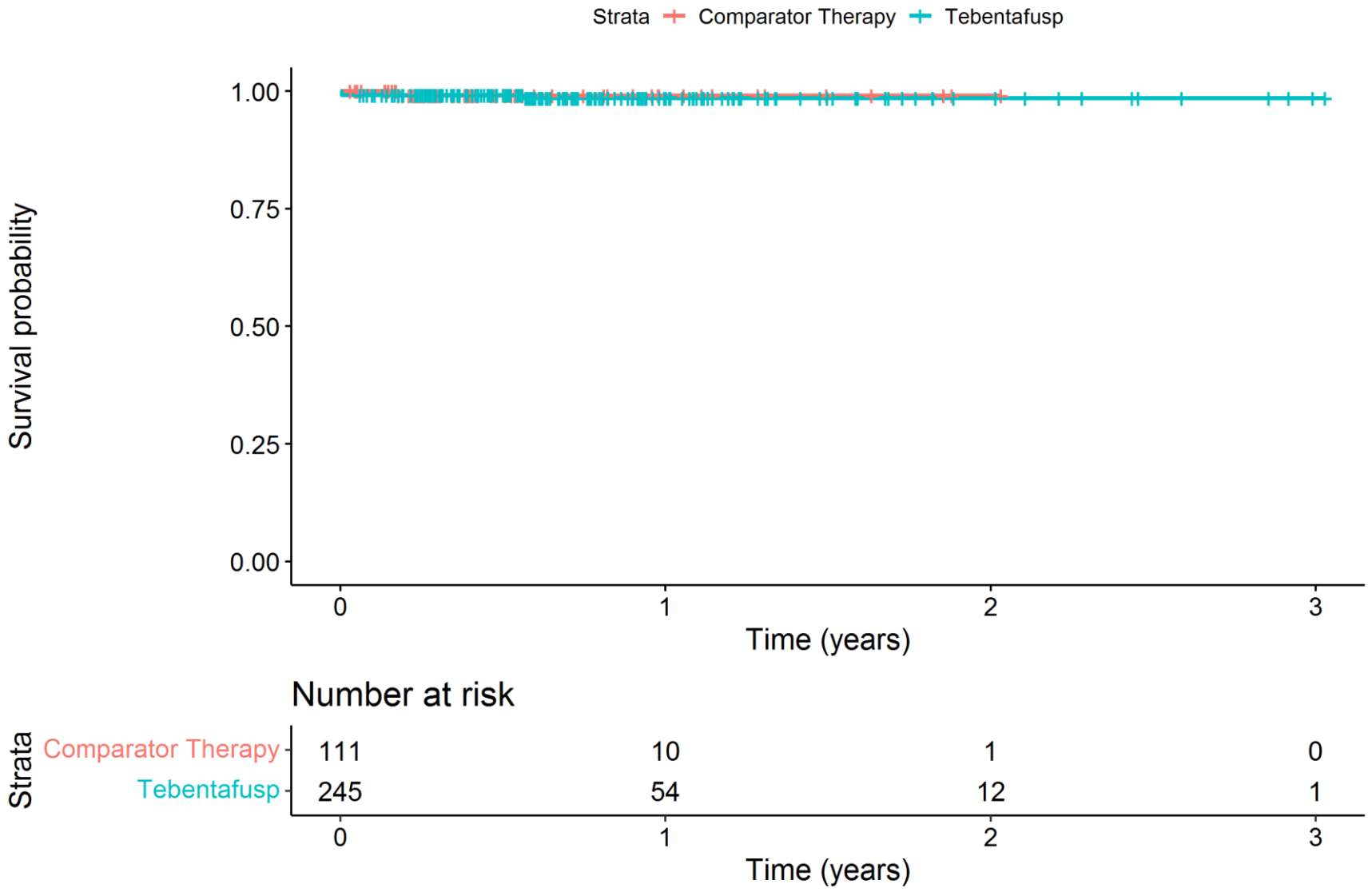
34.6 Infektionen und parasitäre Erkrankungen



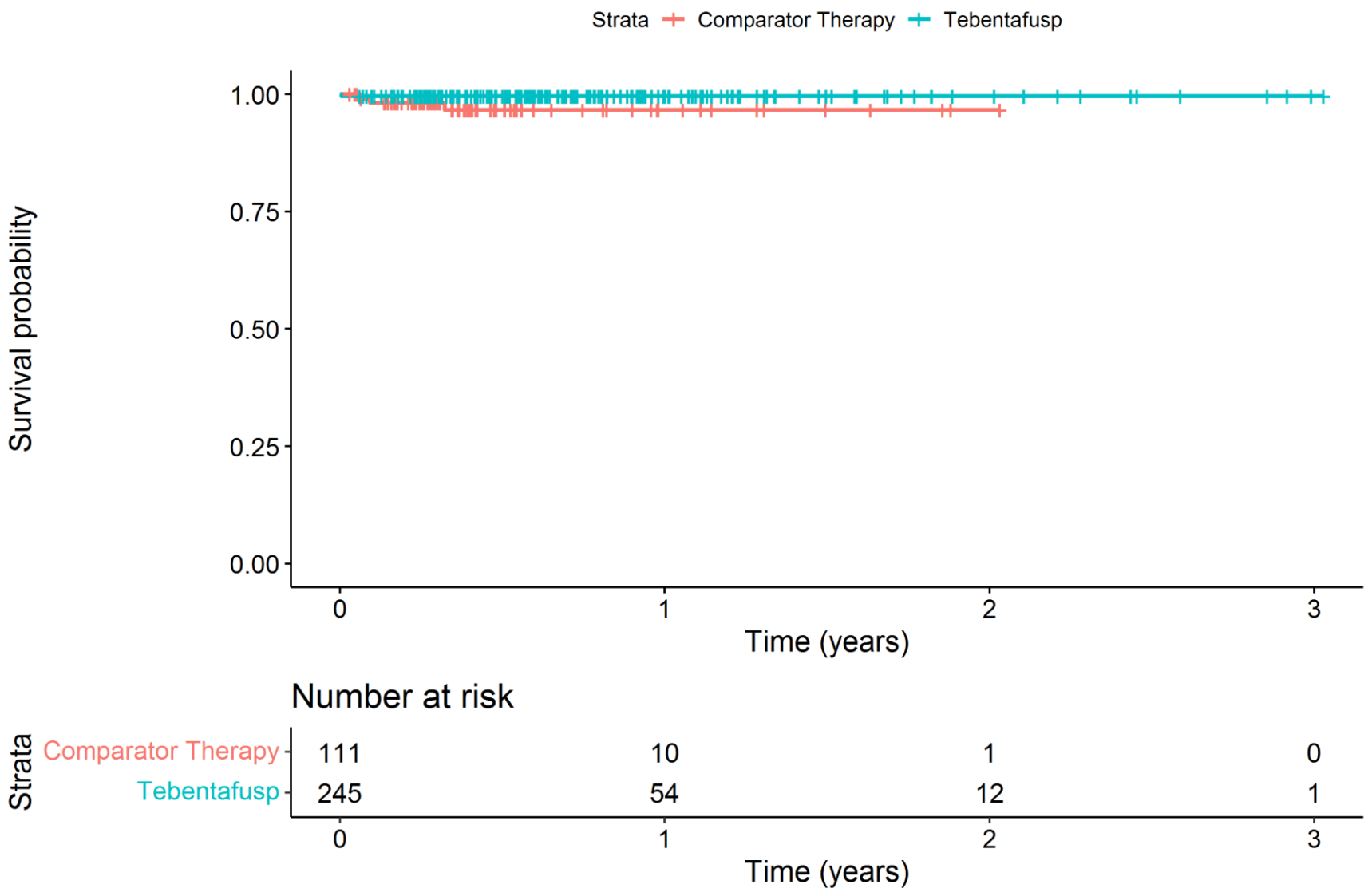
34.7 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



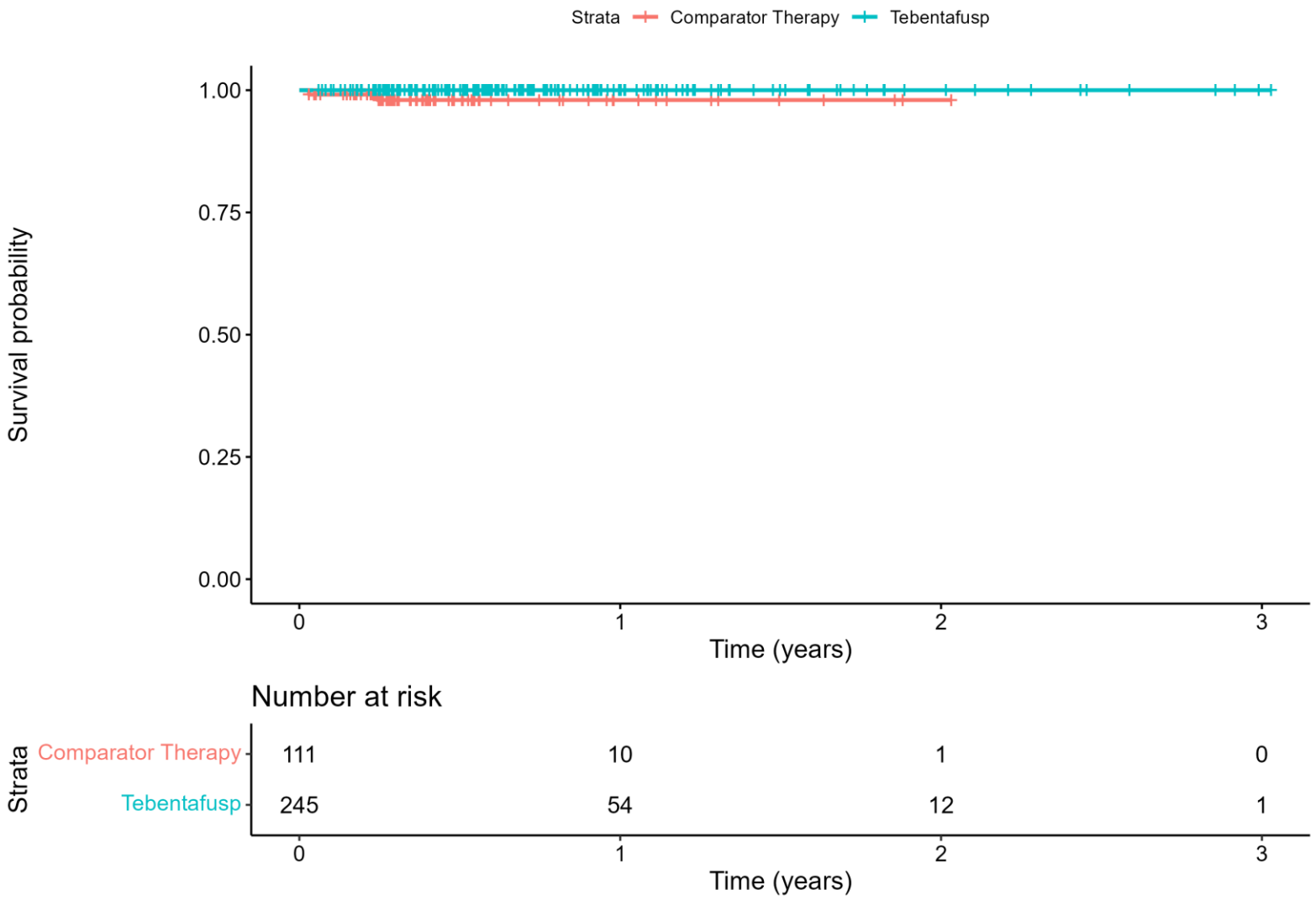
34.8 Untersuchungen



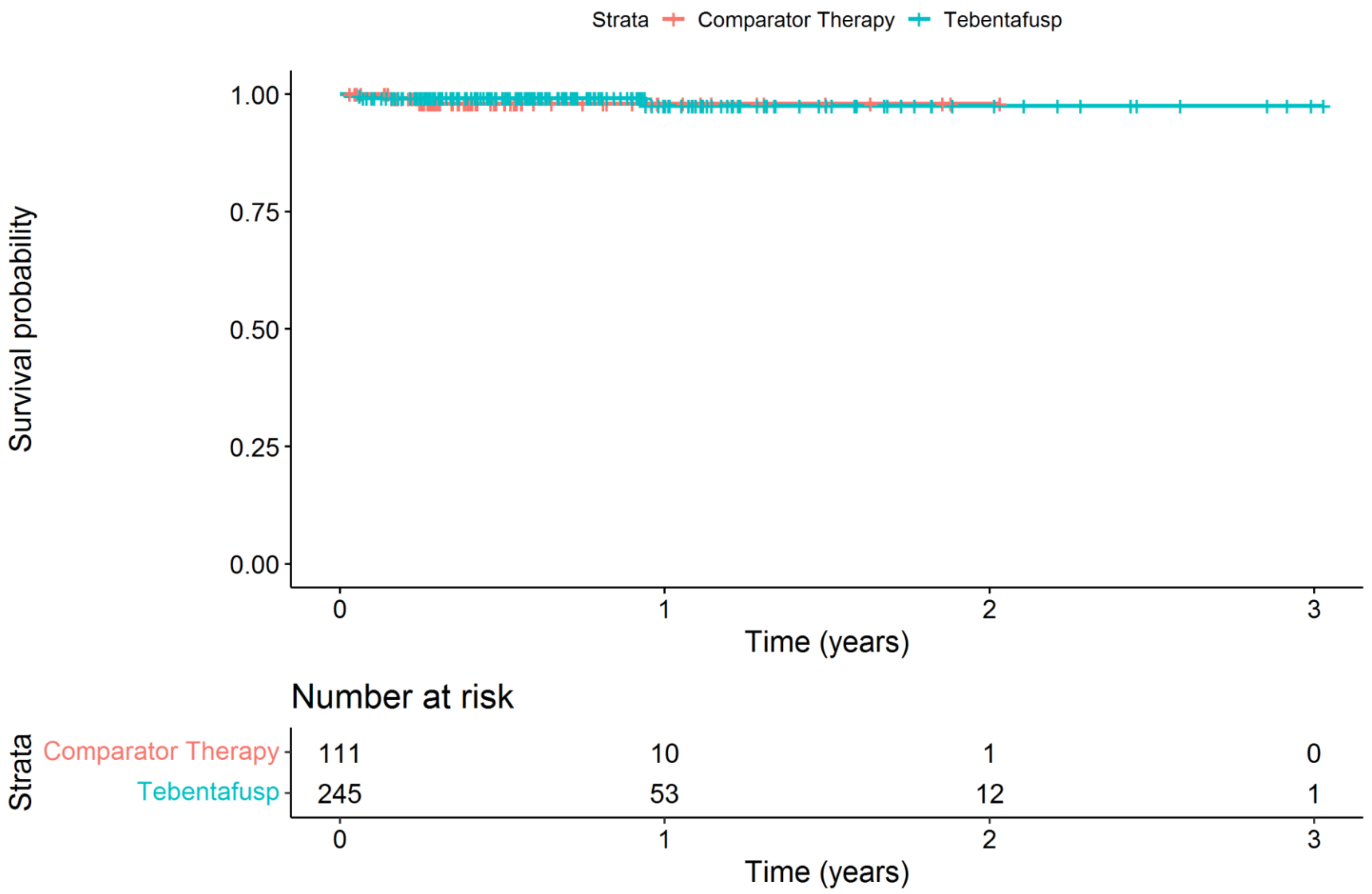
34.9 Stoffwechsel- und Ernährungsstörungen



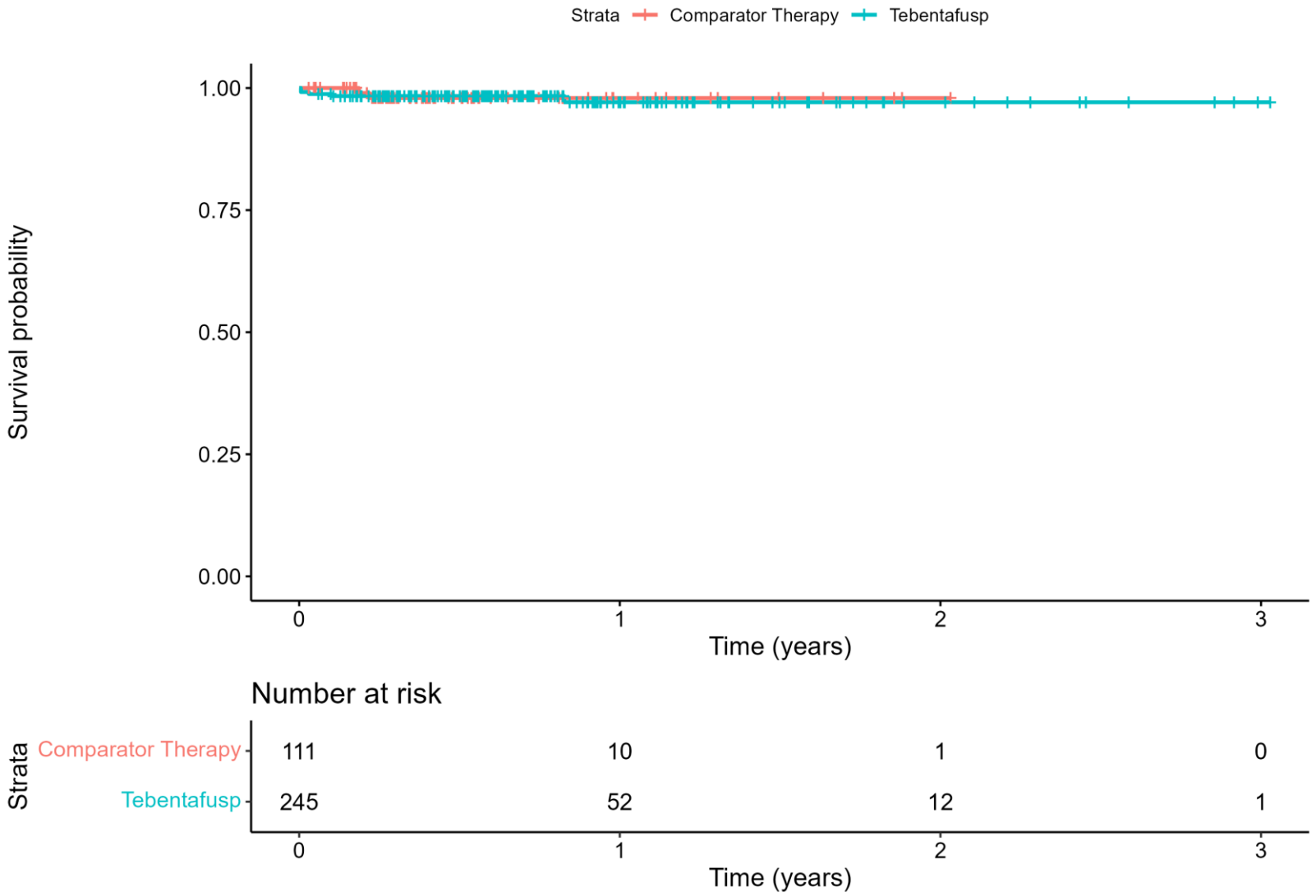
34.10 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



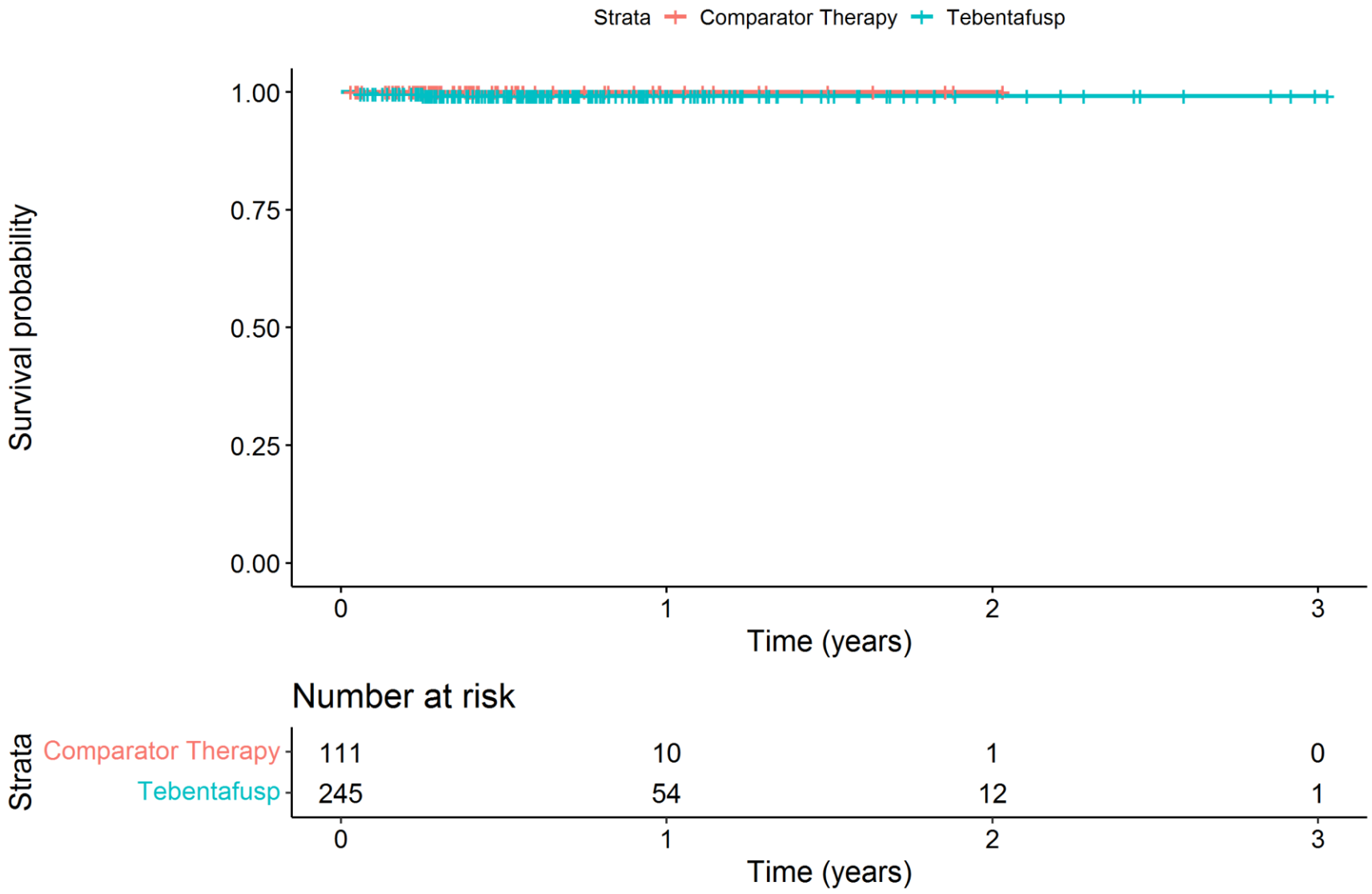
34.11 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



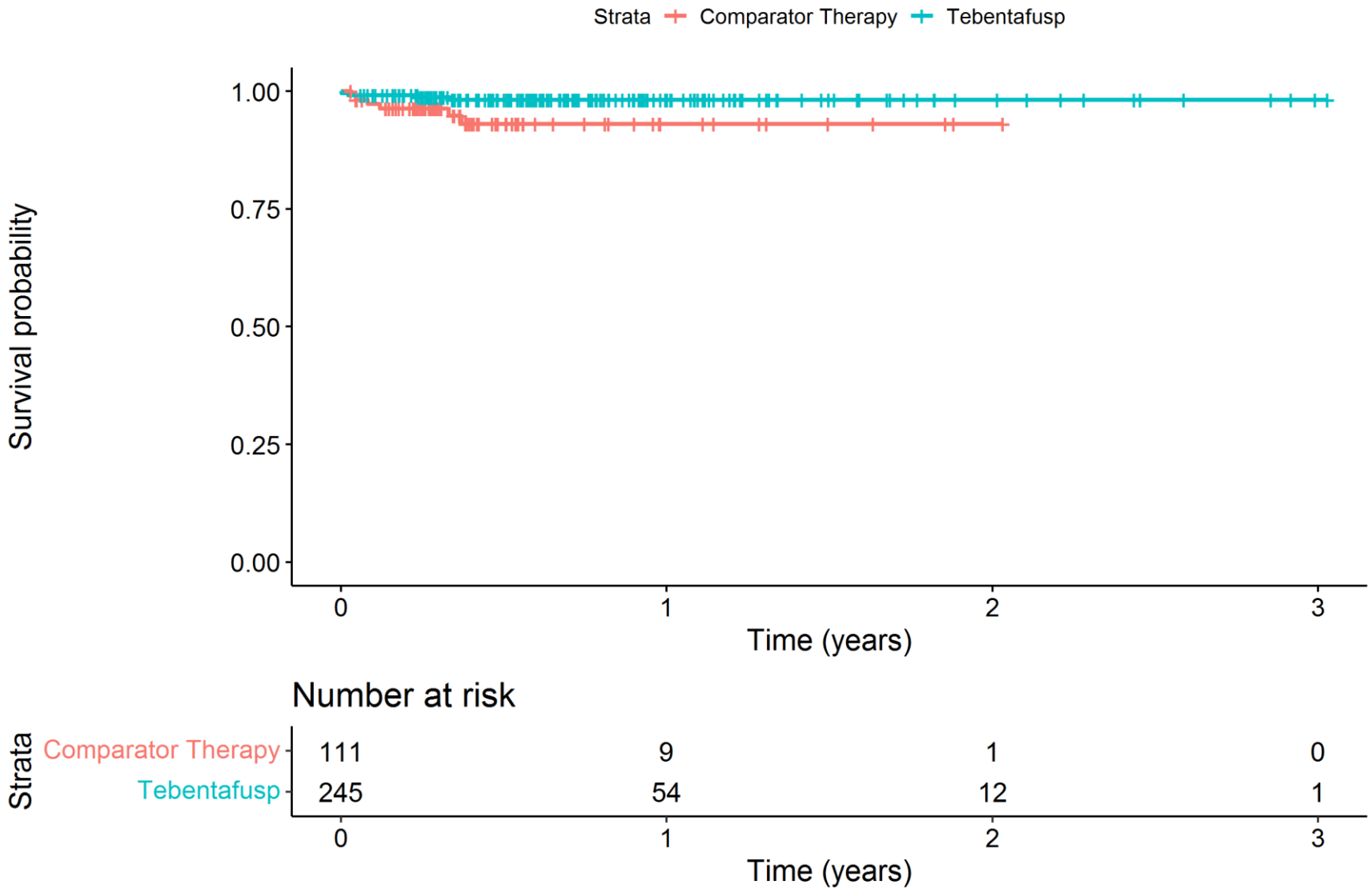
34.12 Erkrankungen des Nervensystems



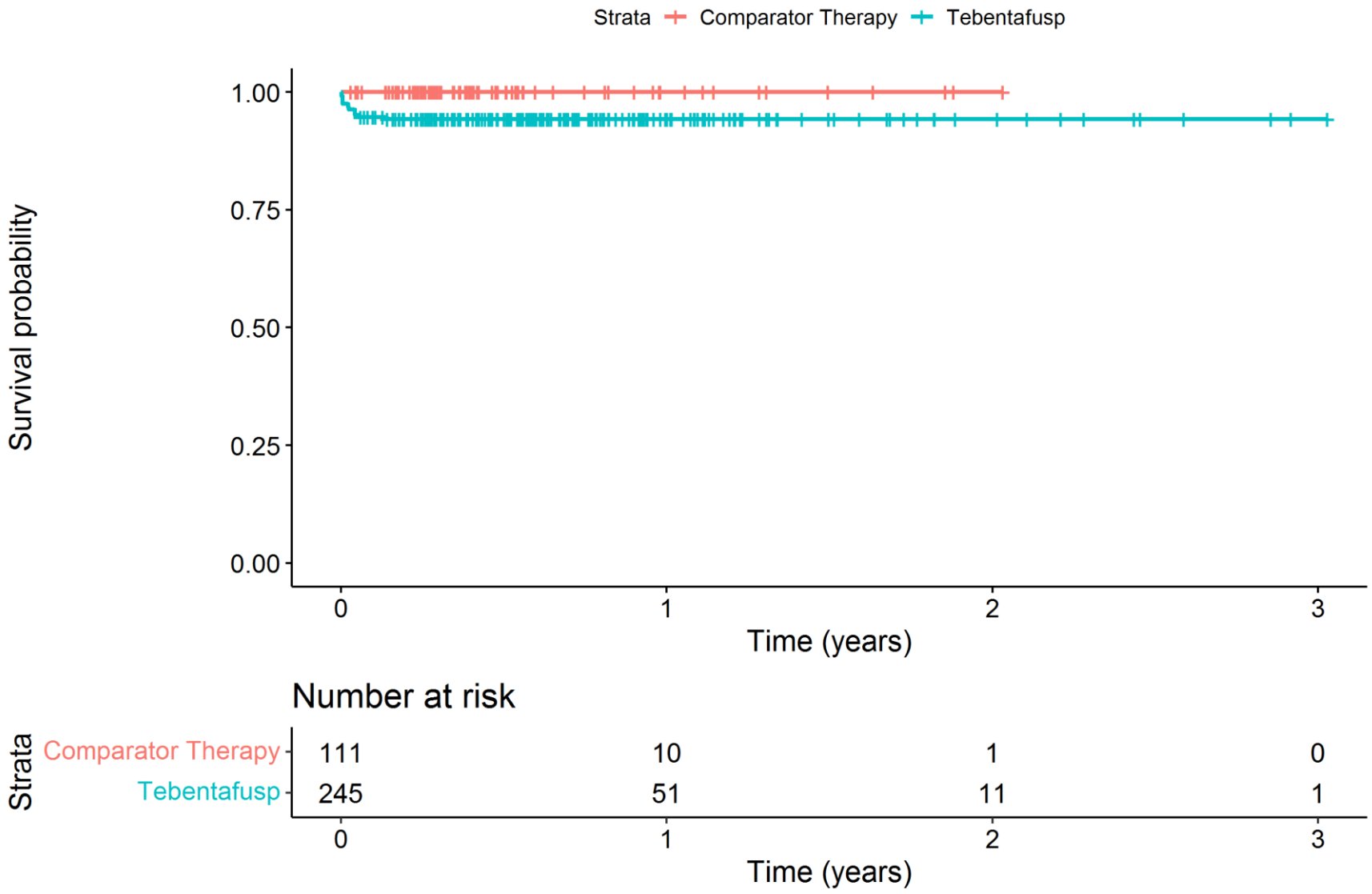
34.13 Erkrankungen der Nieren und Harnwege



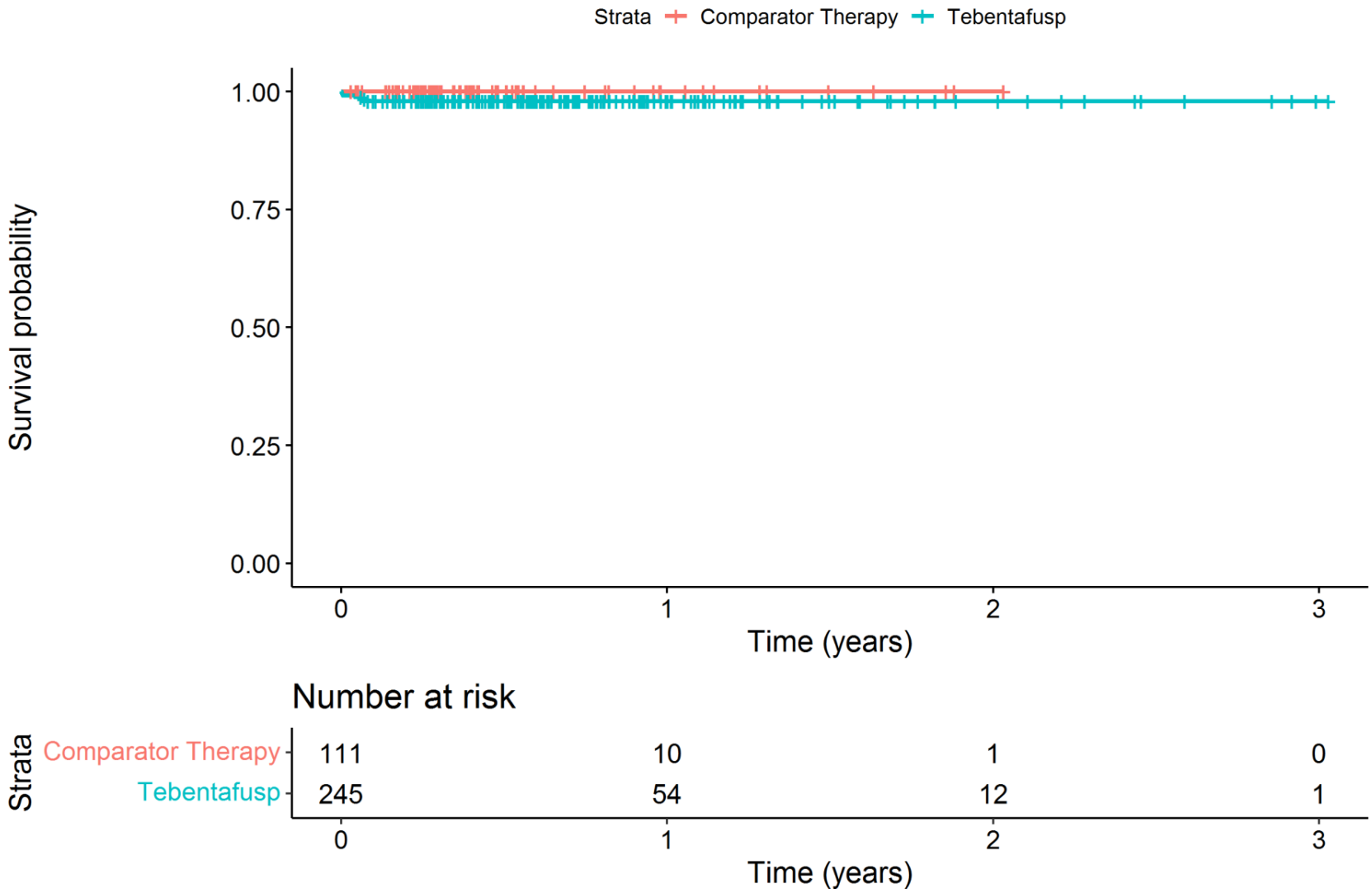
34.14 Erkrankungen der Atemwege, des Brustraums und Mediastinums



34.15 Erkrankungen der Haut und des Unterhautgewebes



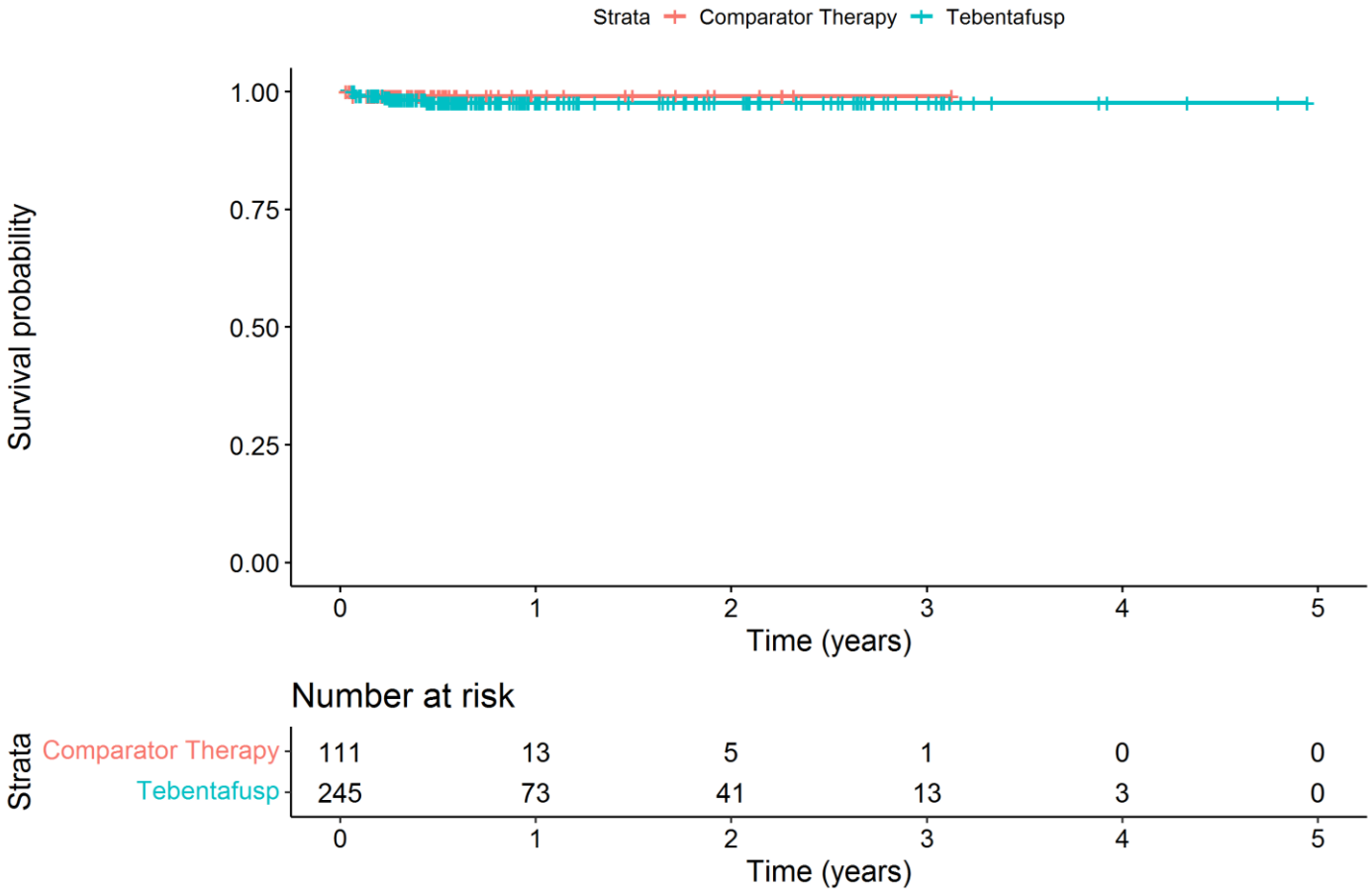
34.16 Gefäßerkrankungen



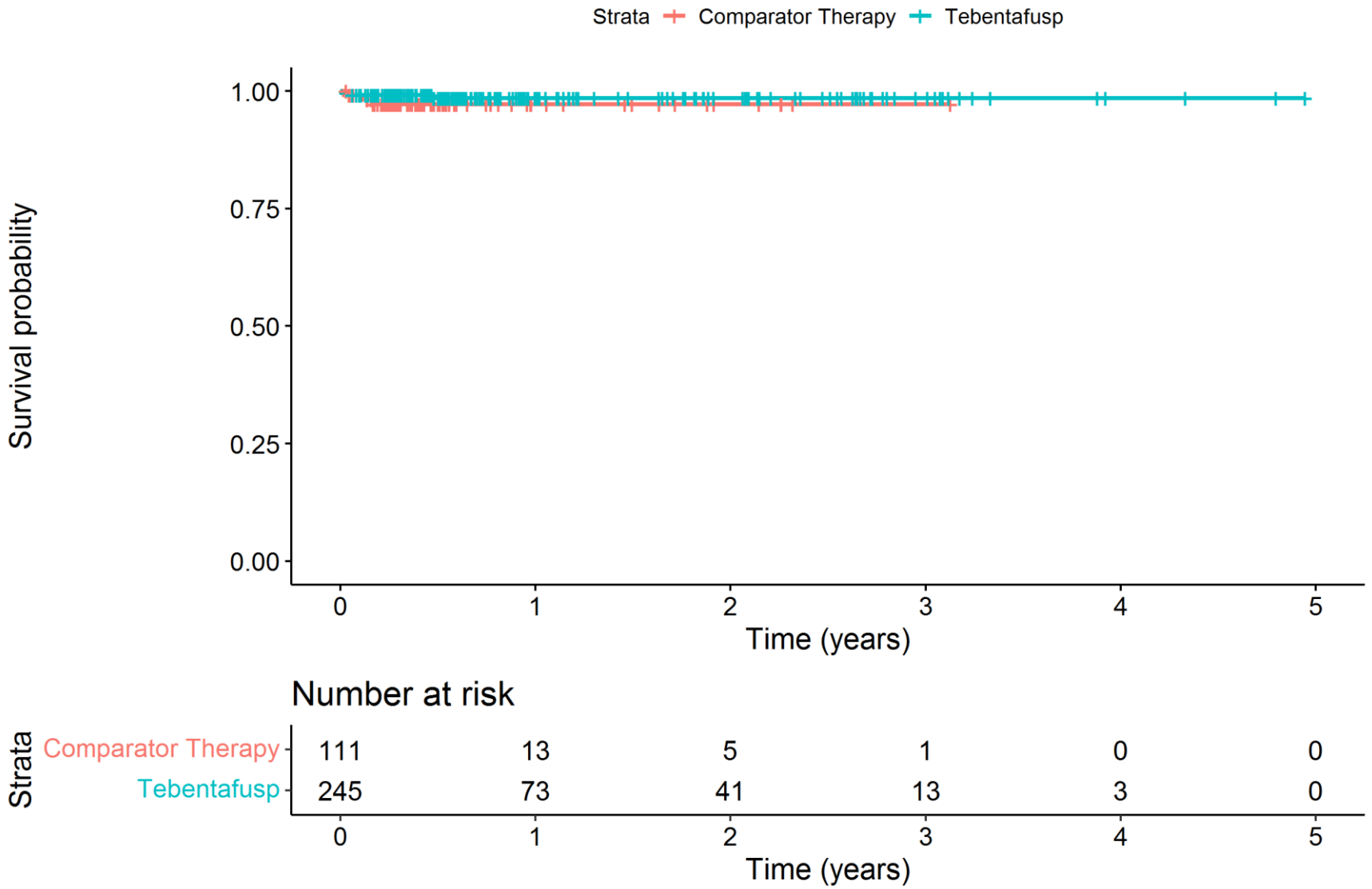
34.17 Schwerwiegende unerwünschte Ereignisse (SUEs) nach SOC und PT – 3-Jahres-Analyse (Juni 2023) (Tabelle 4-66)

35 SUEs (PT) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten

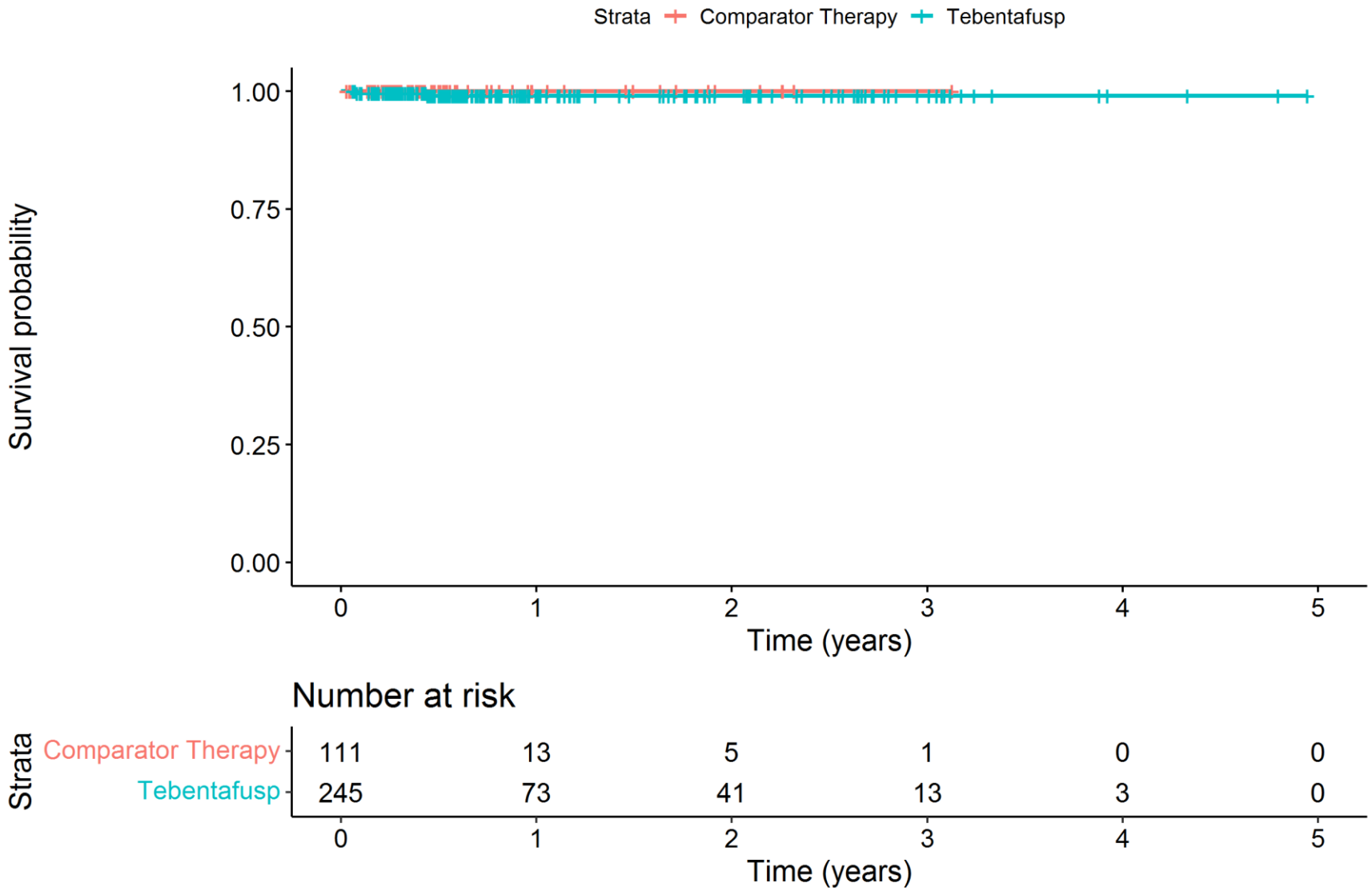
35.1 Übelkeit



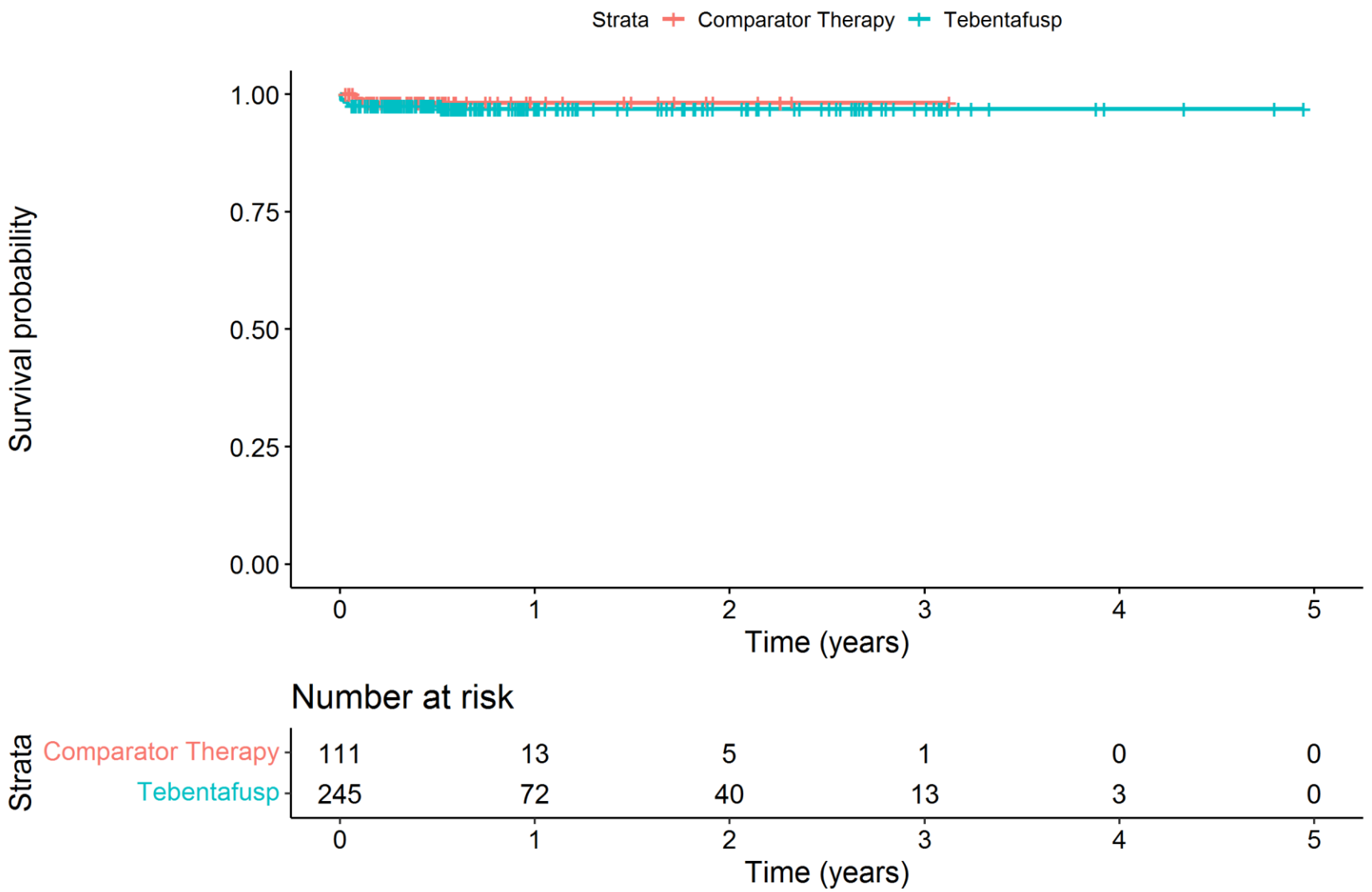
35.2 Unterleibsschmerzen



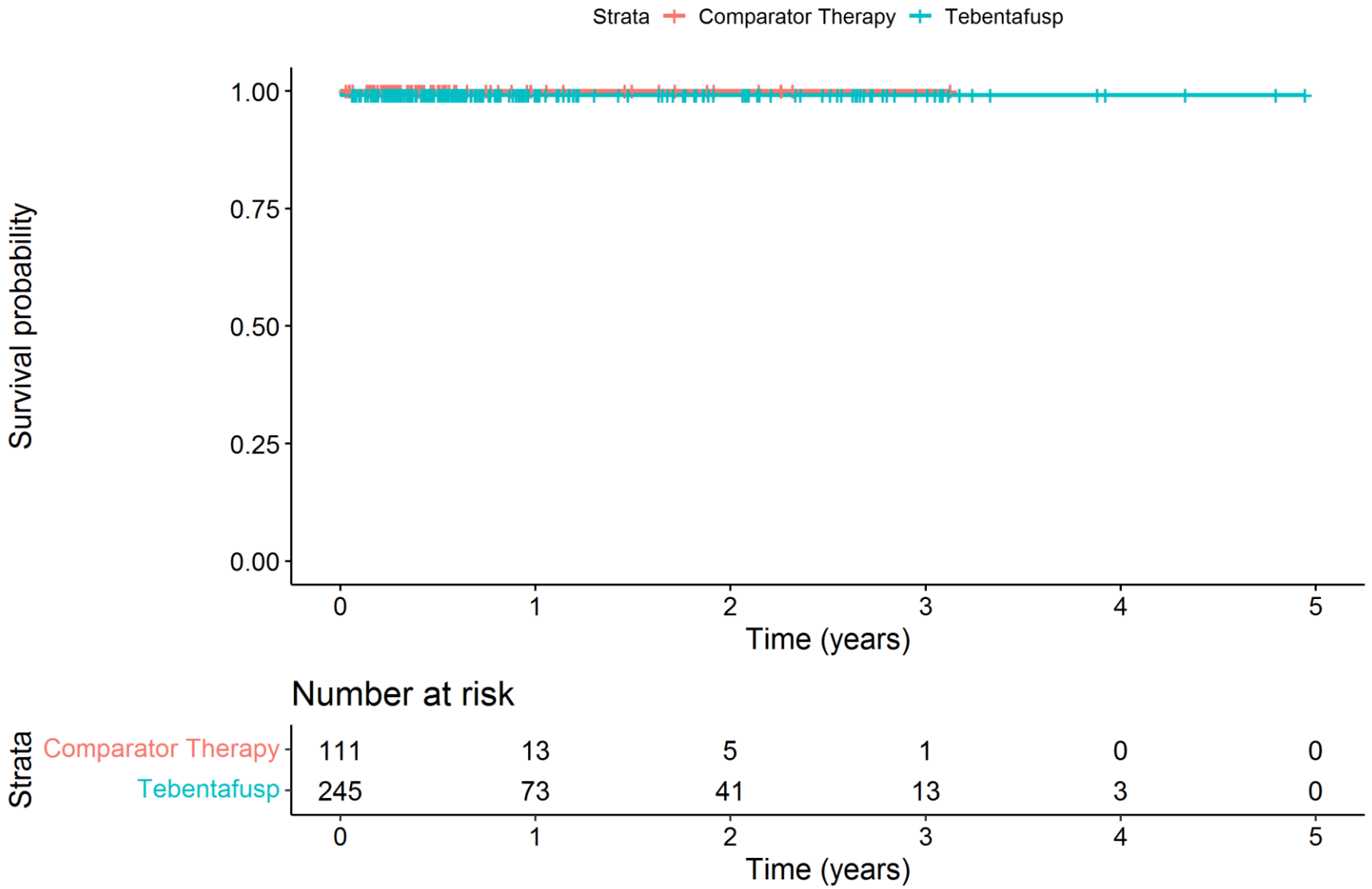
35.3 Erbrechen



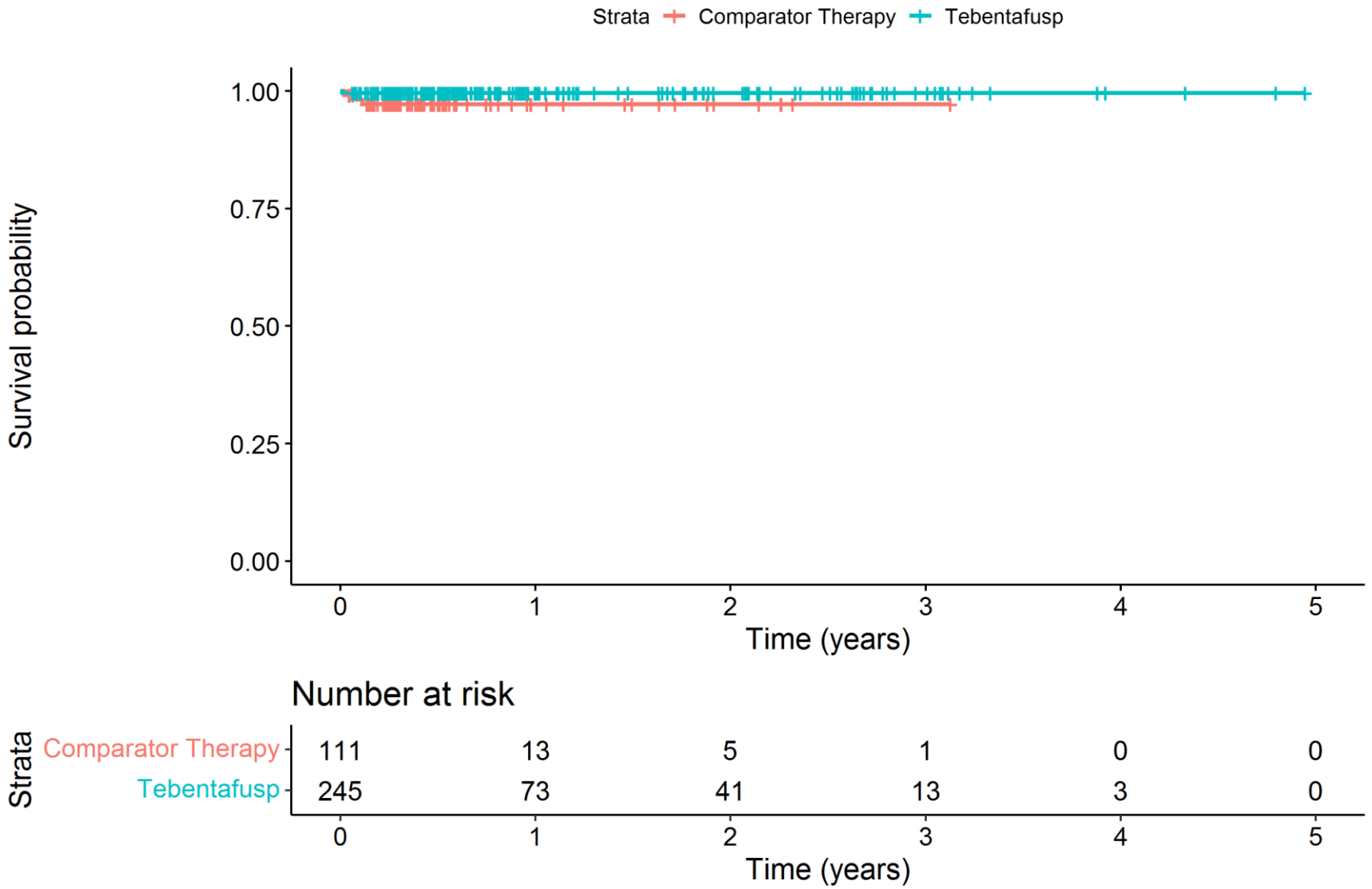
35.4 Fieber


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
72
40
13
3
0
0
1
2
3
4
5
Time (years)

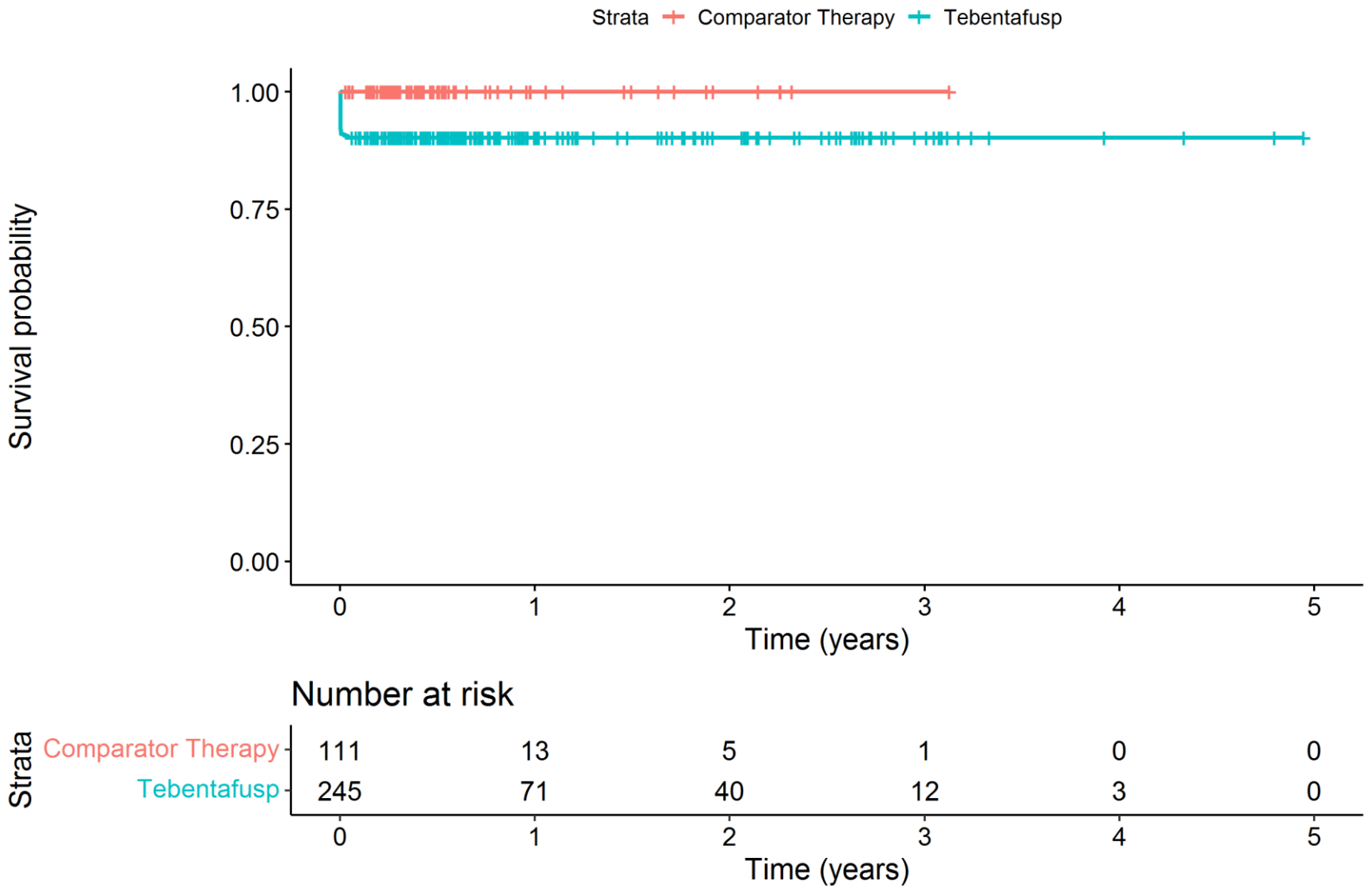
35.5 Hepatotoxizität



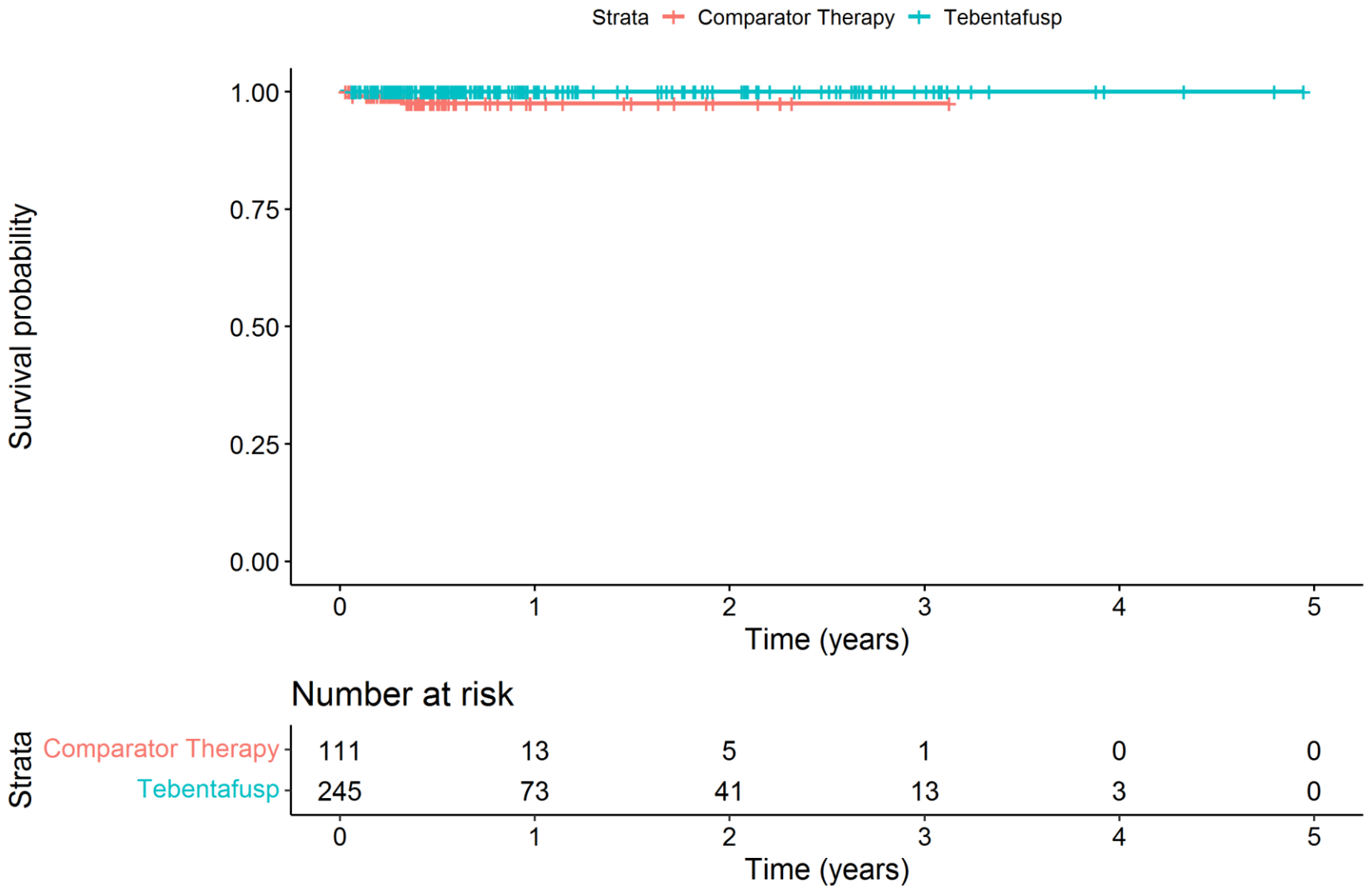
35.6 Hyperbilirubinämie



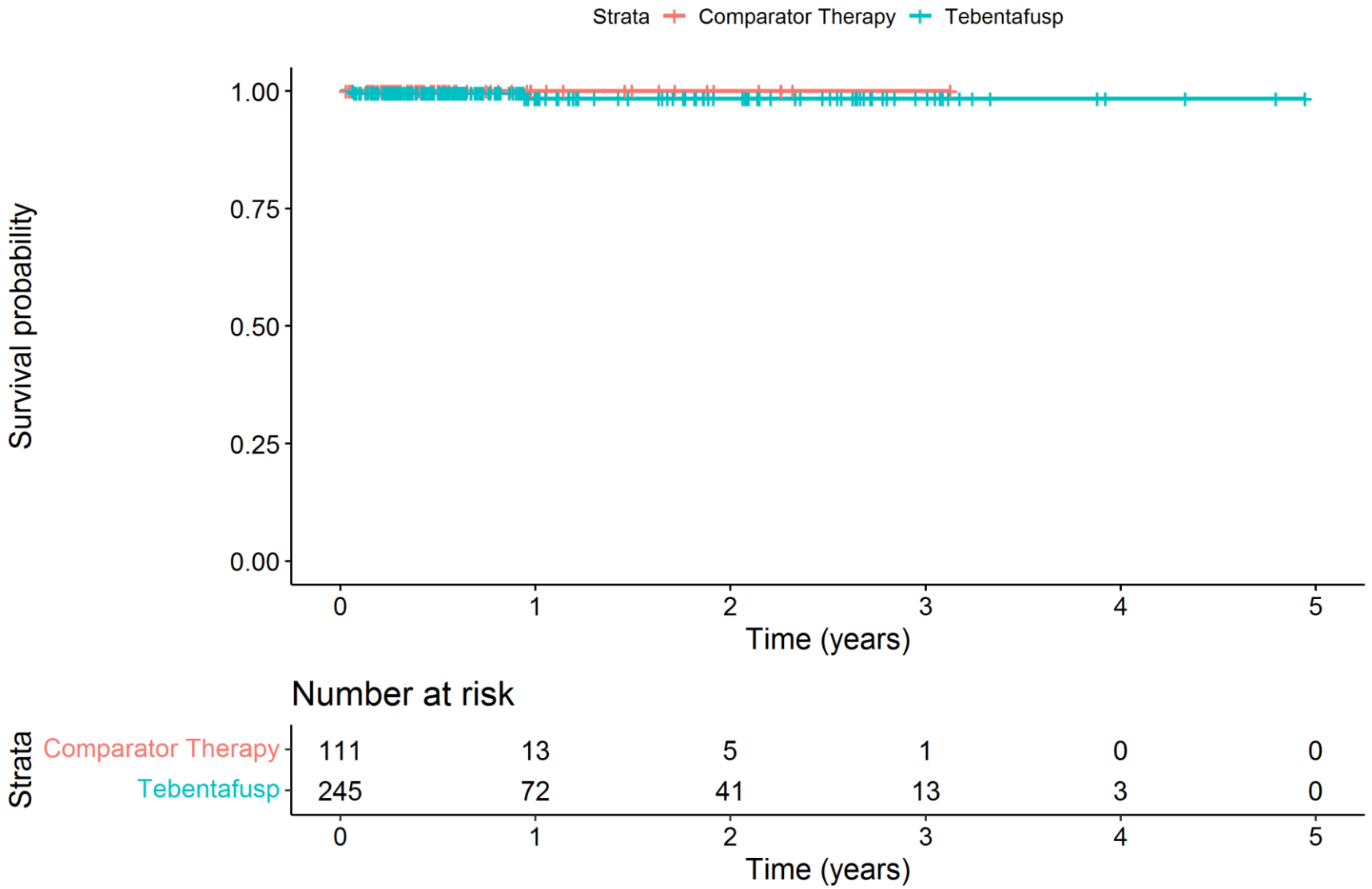
35.7 Zytokin-Freisetzungssyndrom



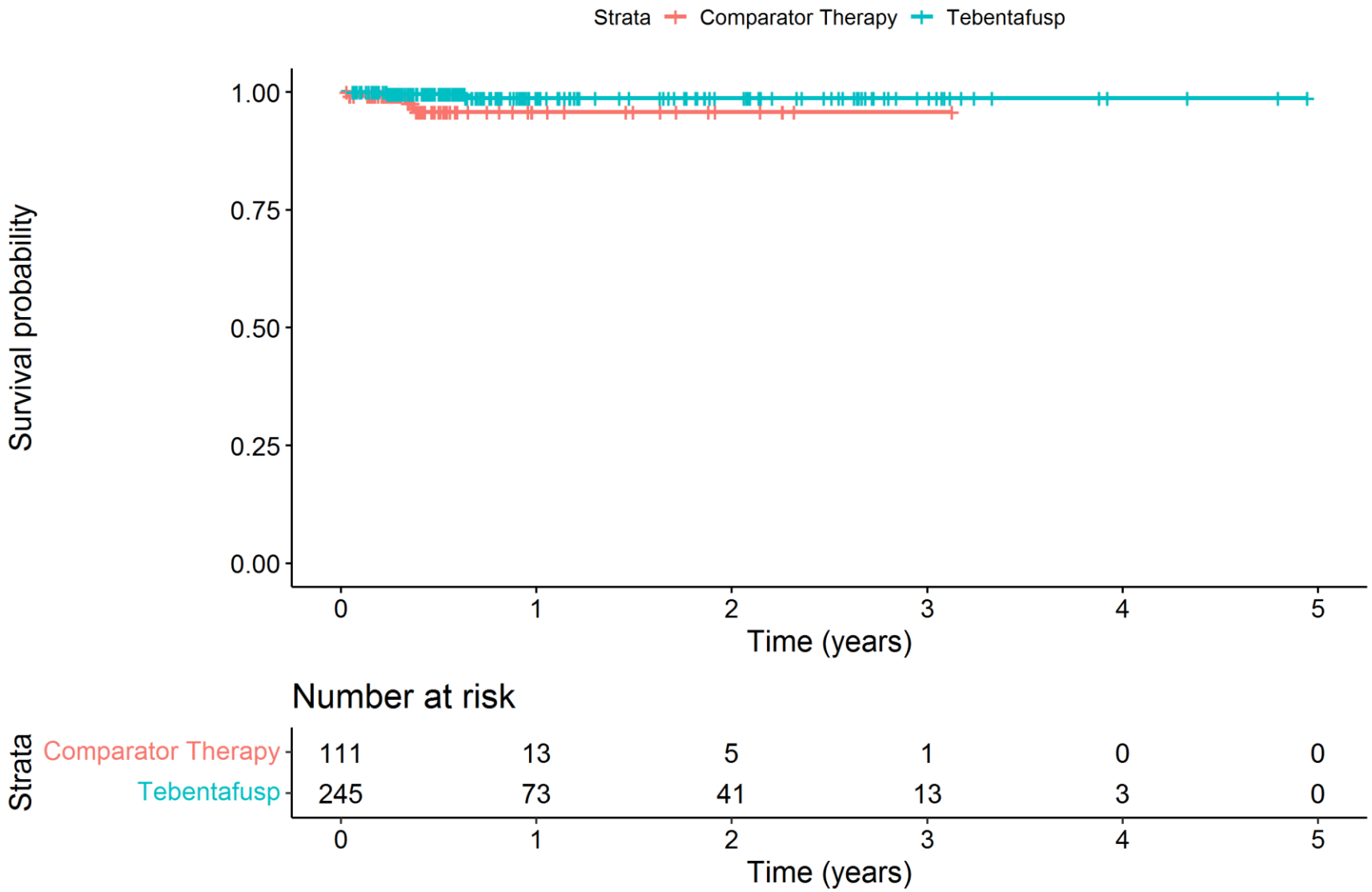
35.8 Dehydrierung



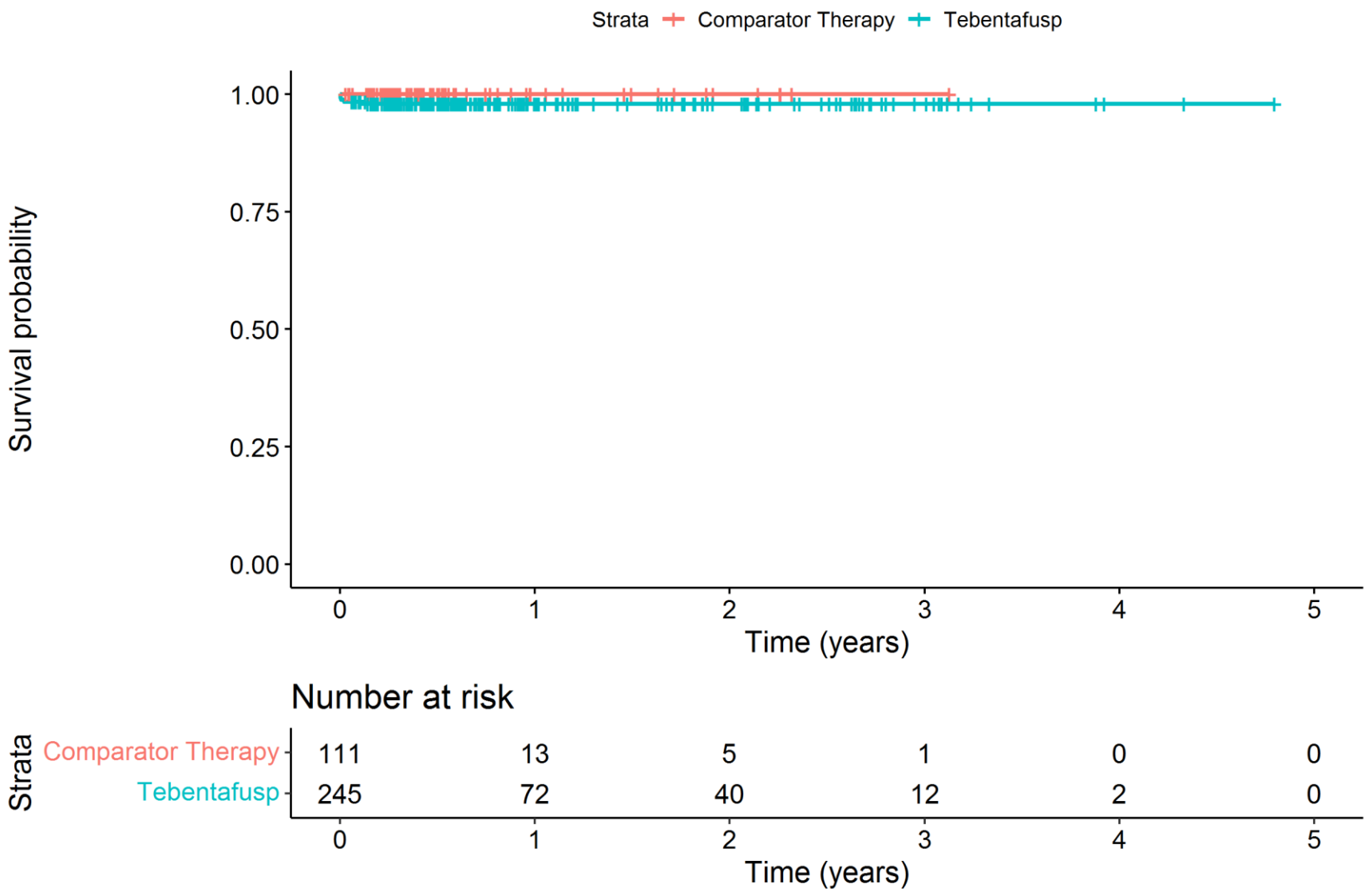
35.9 Tumorschmerzen



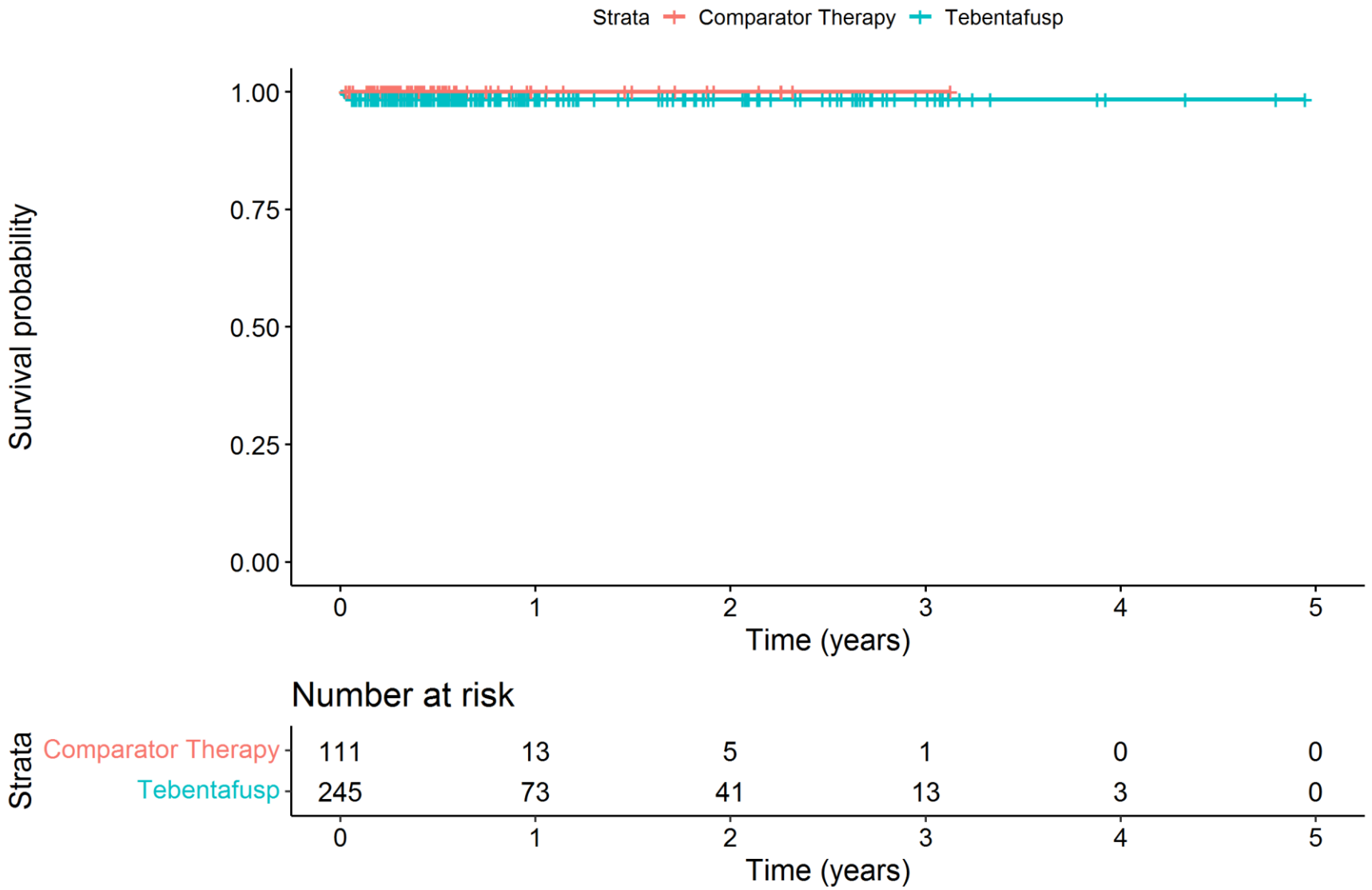
35.10 Lungenembolie



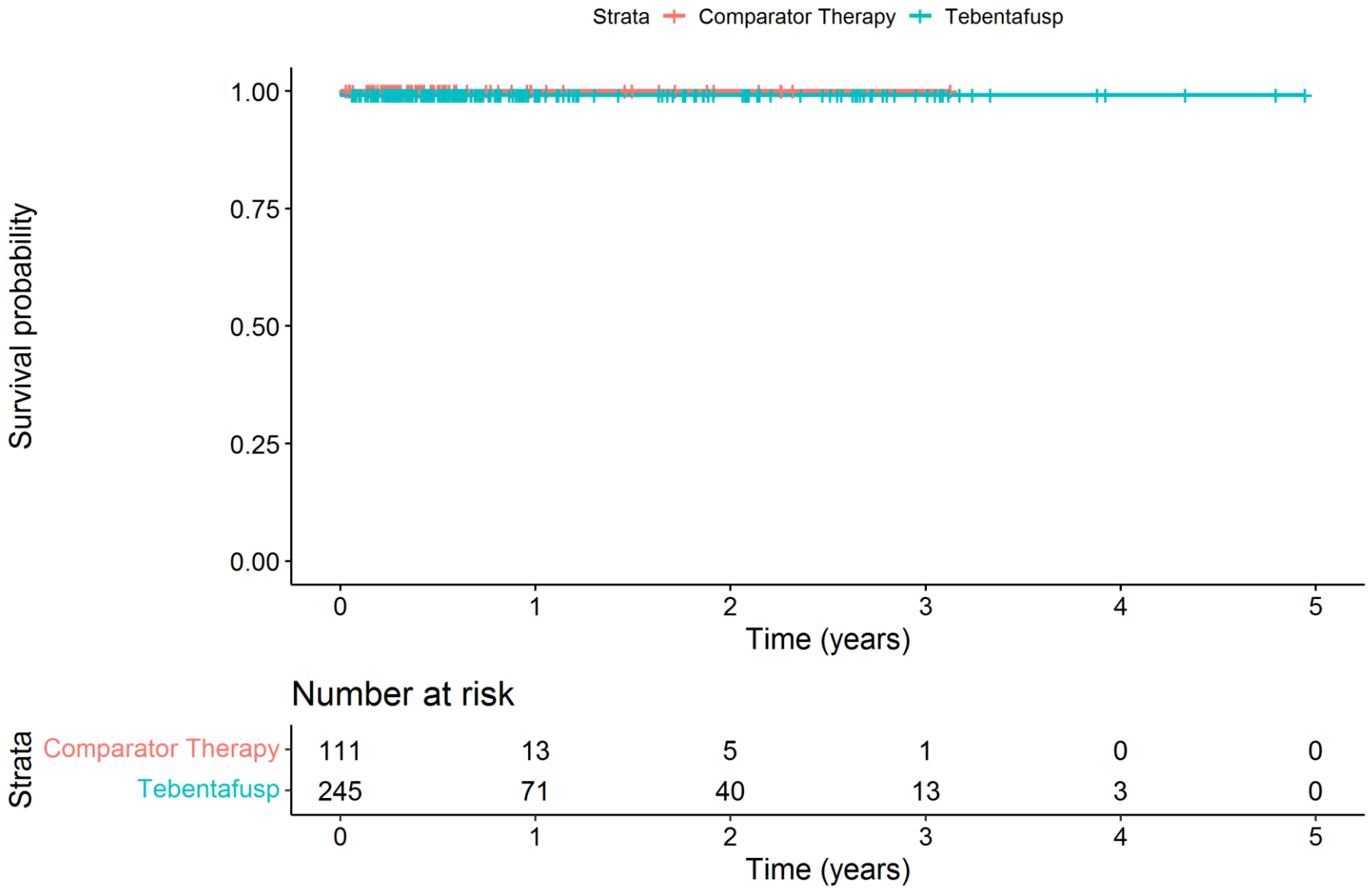
35.11 Hautausschlag



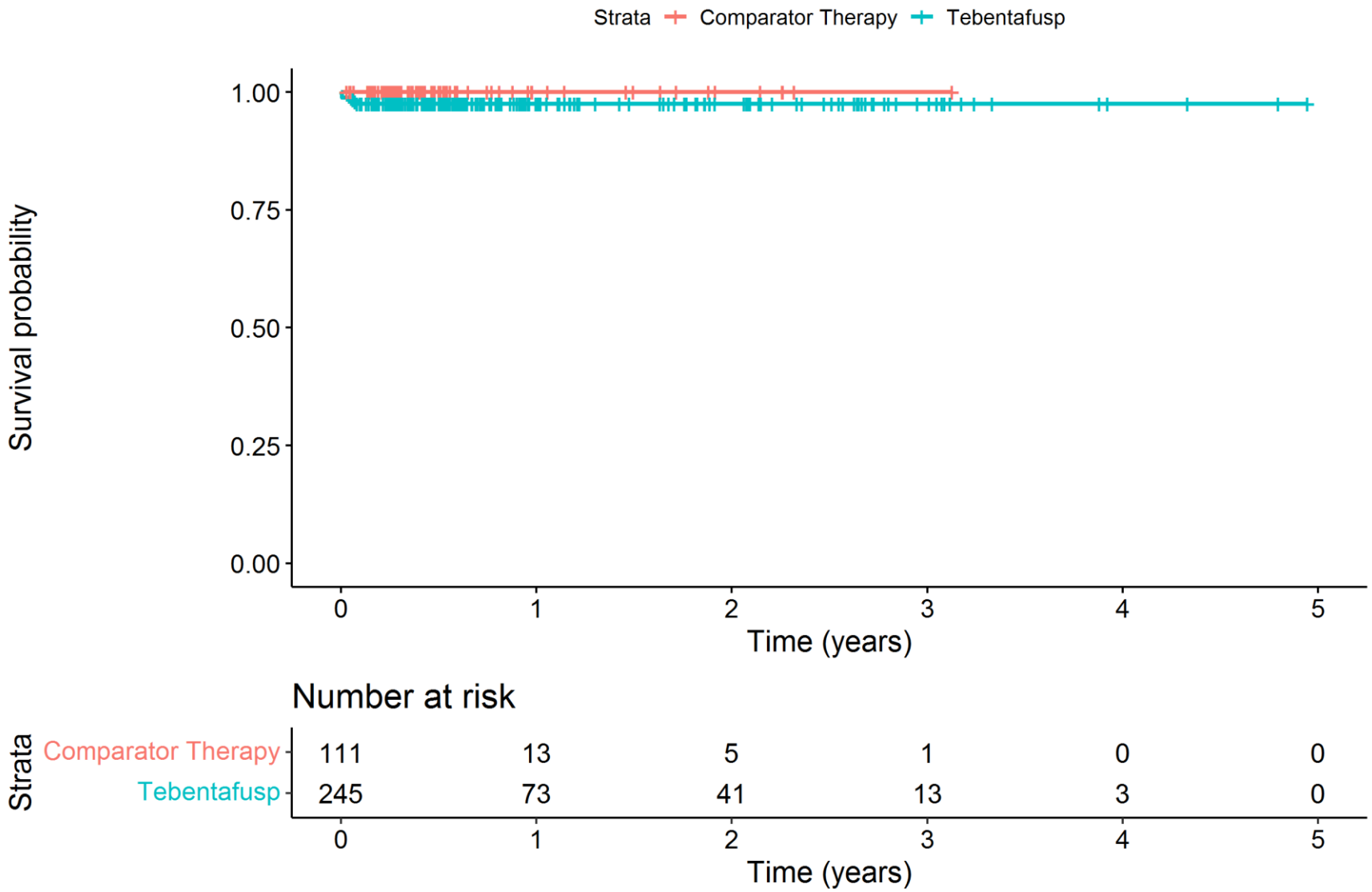
35.12 Makulo-papulöser Hautausschlag



35.13 Makulo-papulöser Hautausschlag

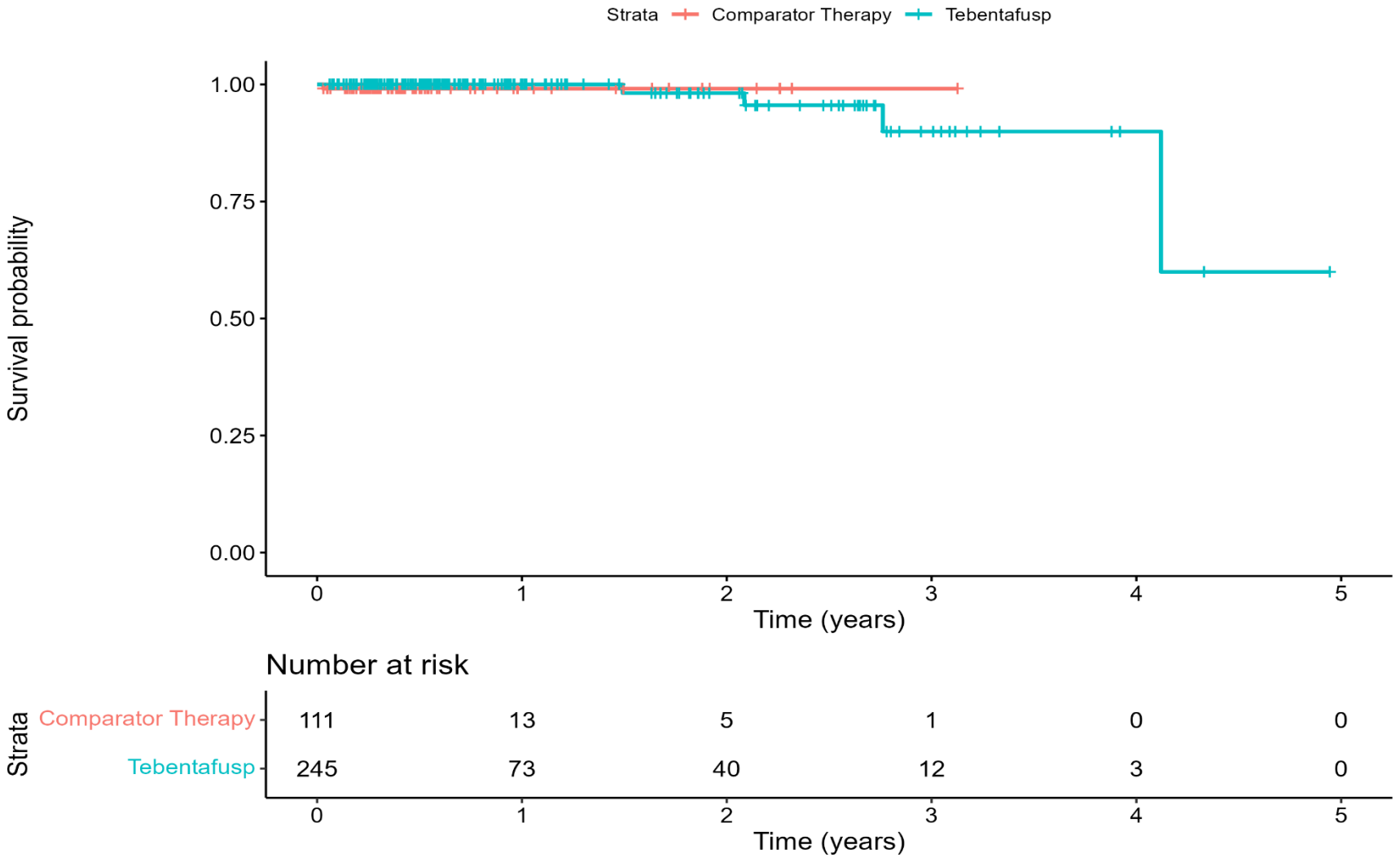


35.14 Hypotonie

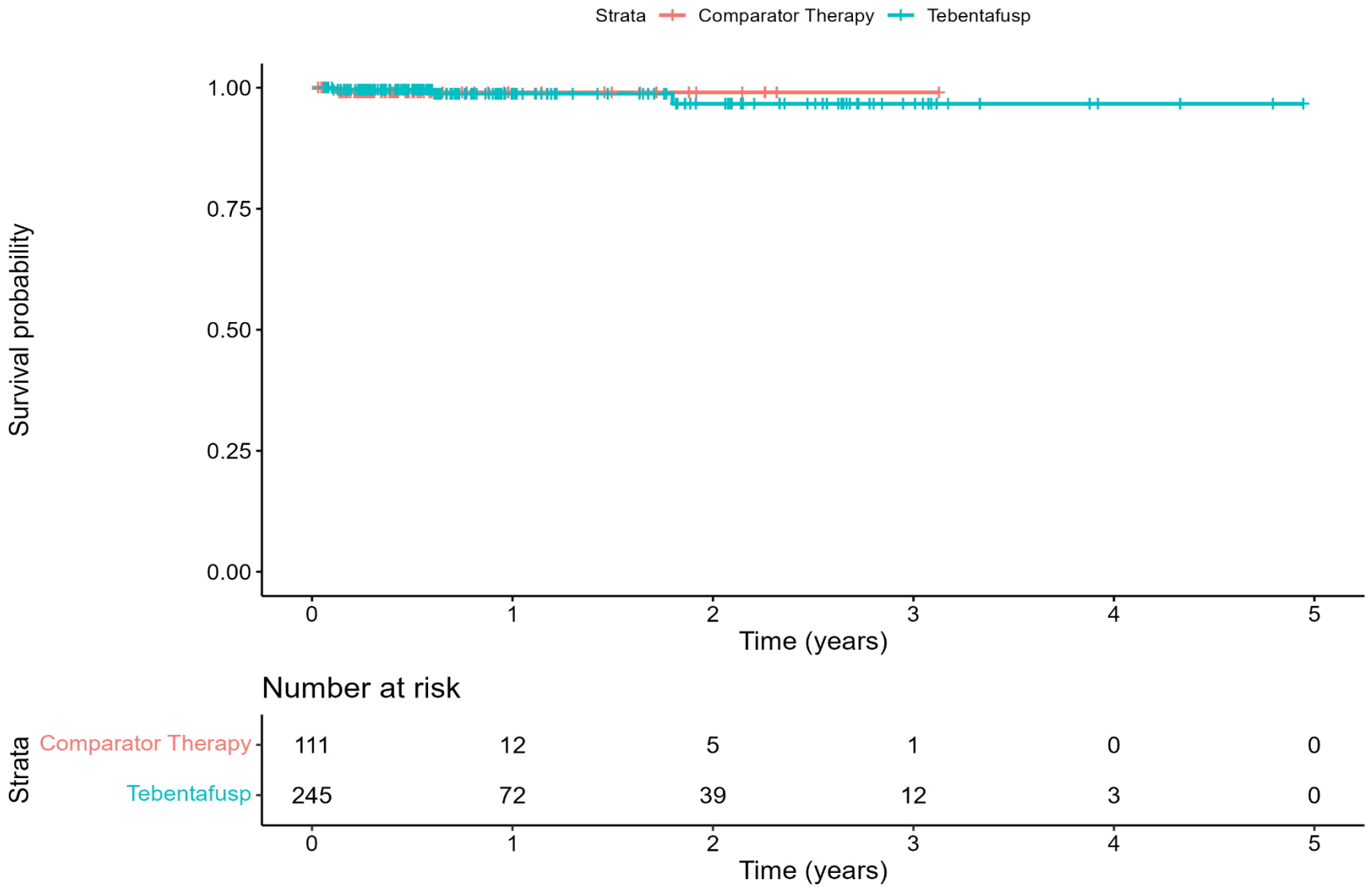


36 SUEs (SOC) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten

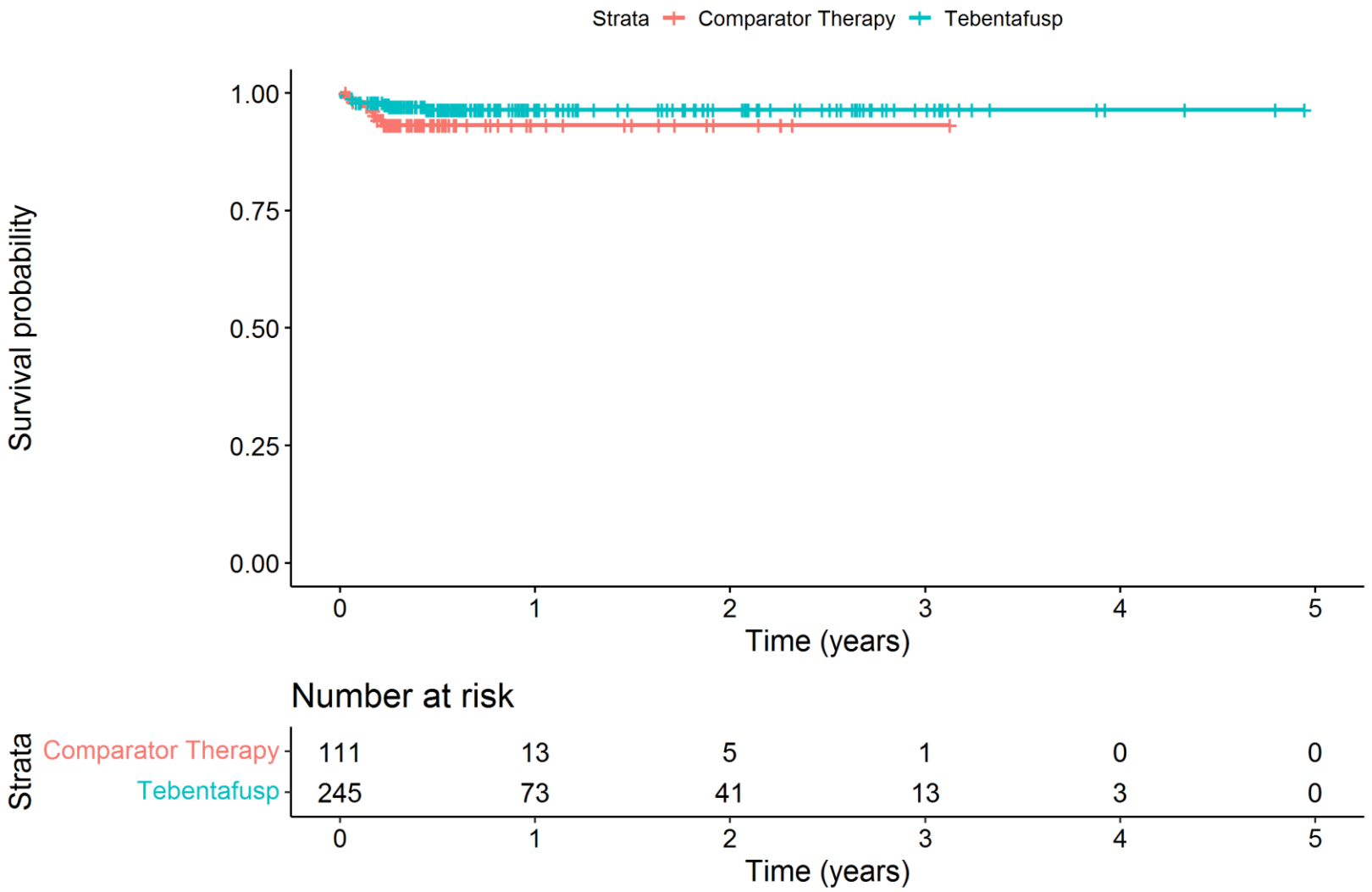
36.1 Herzerkrankungen


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
13
5
1
0
0
245
73
40
12
3
0
0
1
2
3
4
5
Time (years)

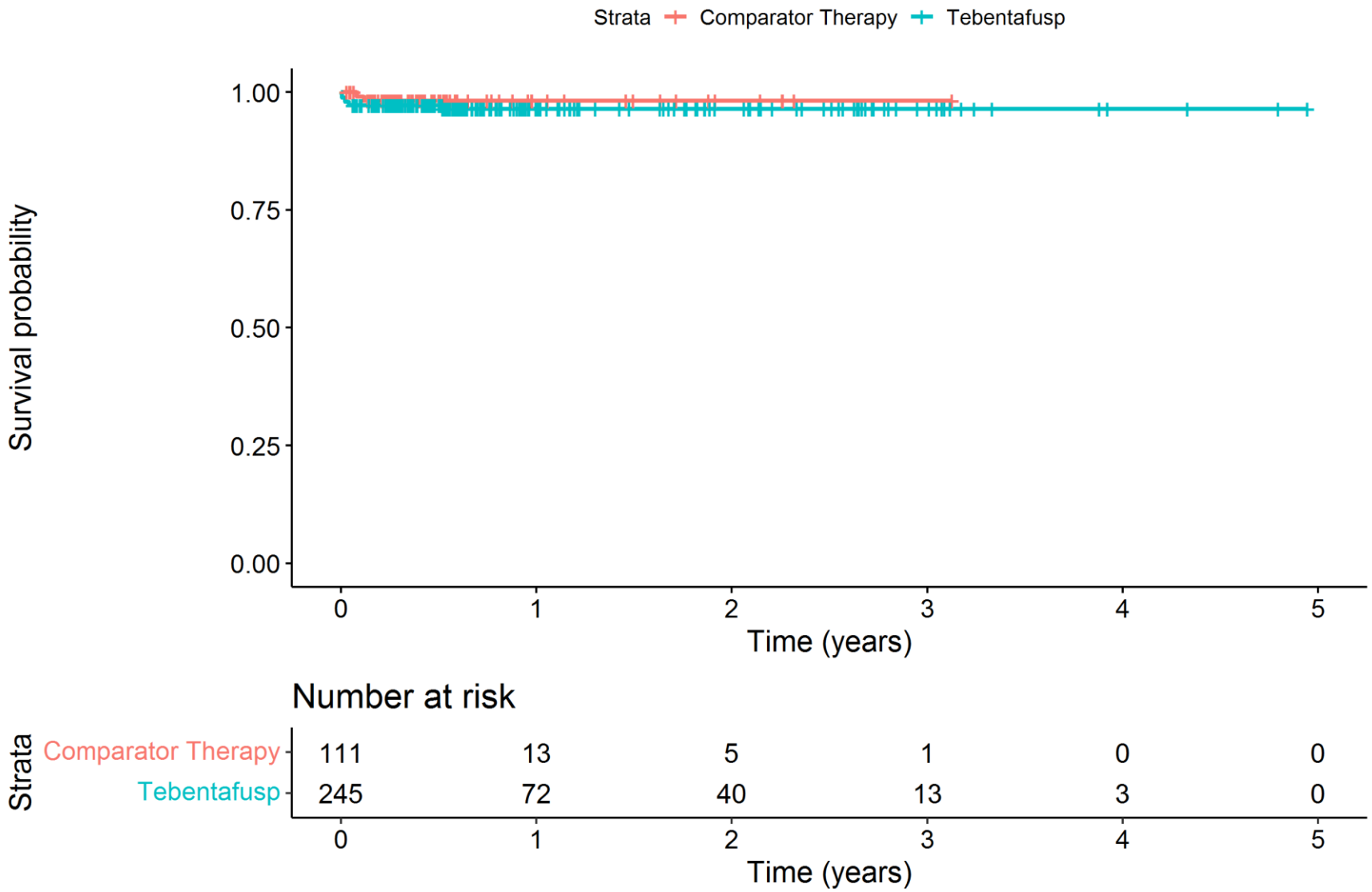
Augenerkrankungen



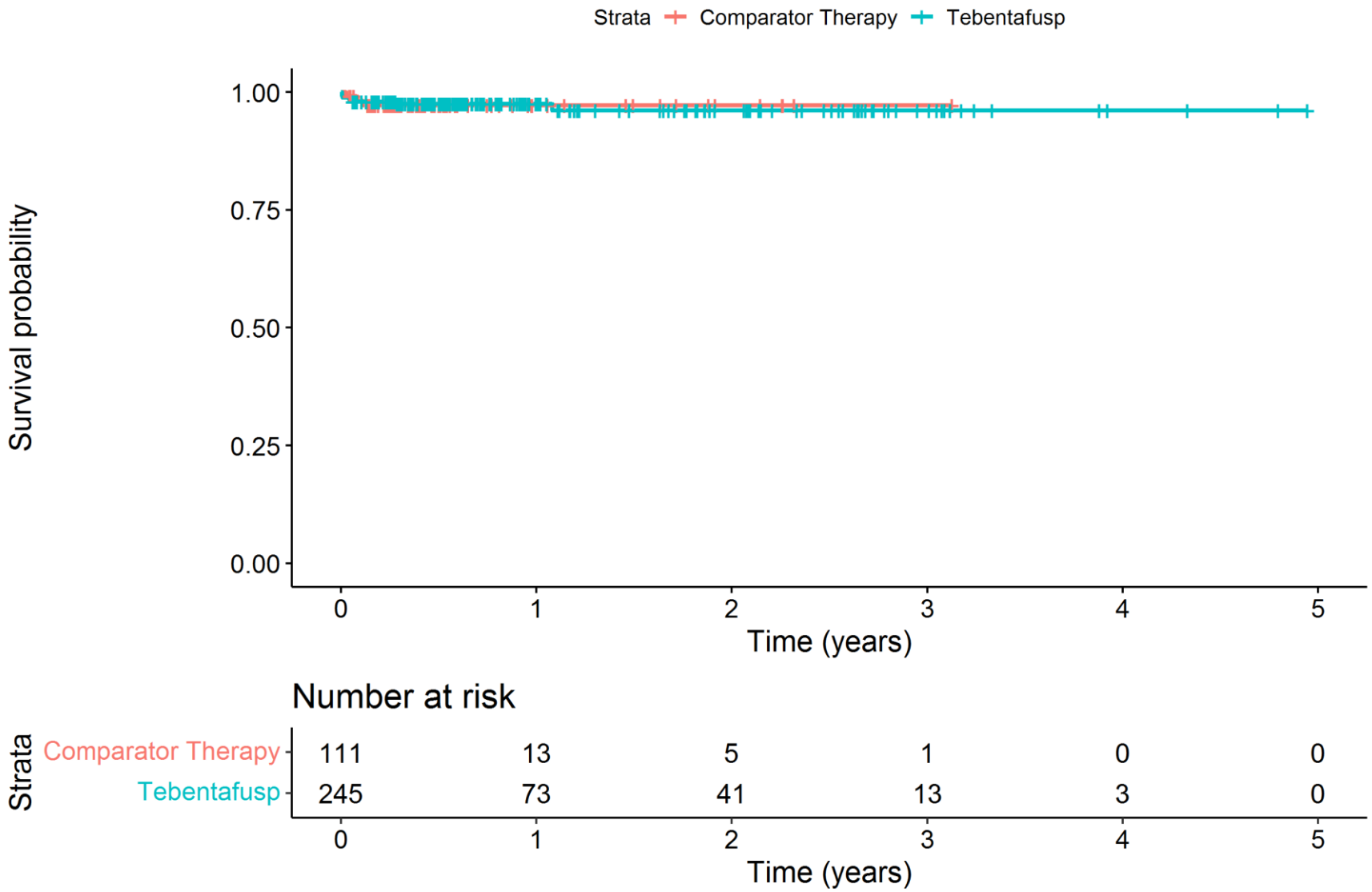
36.2 Erkrankungen des Gastrointestinaltrakts



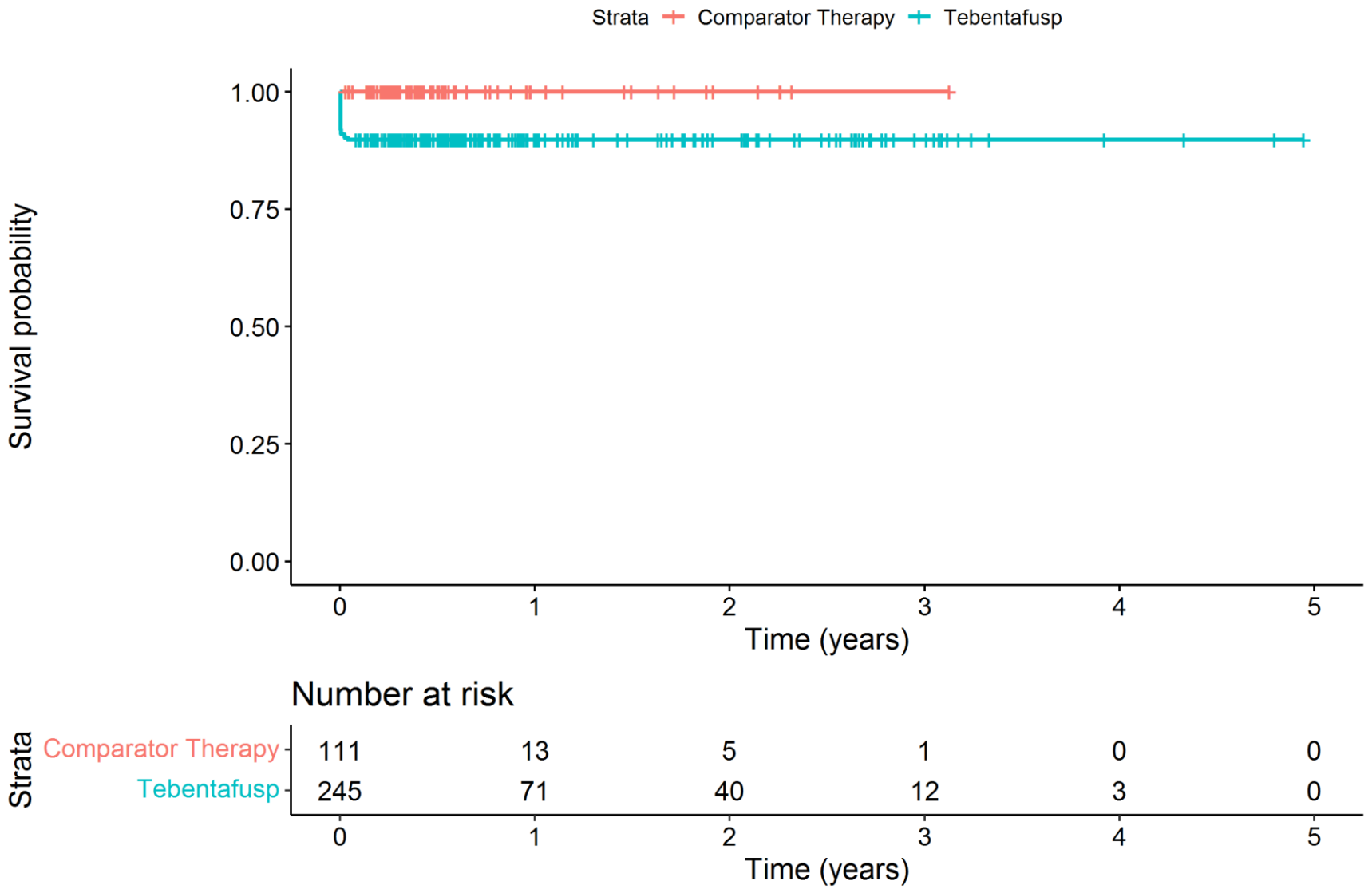
36.3 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort



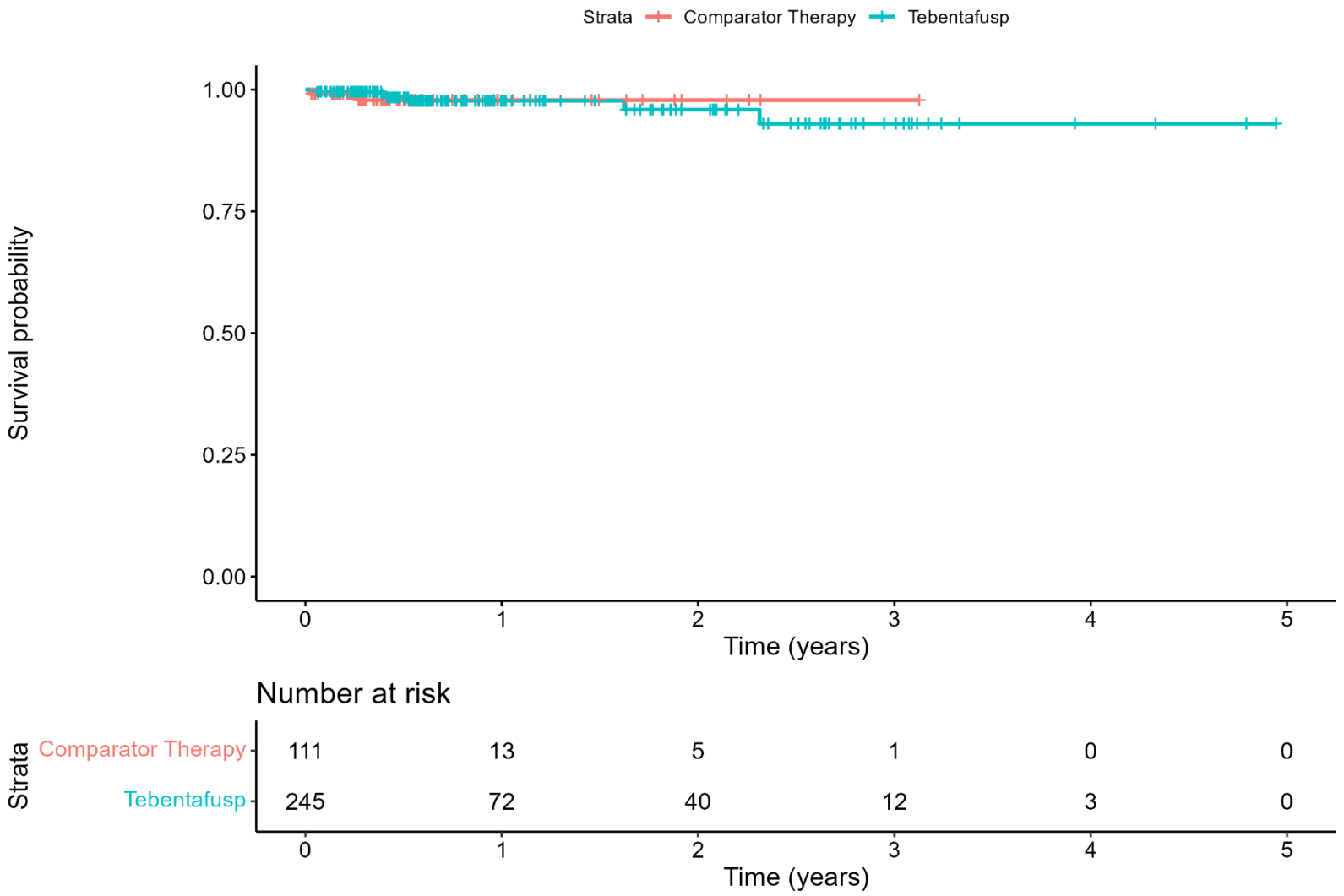
36.4 Leber- und Gallenerkrankungen



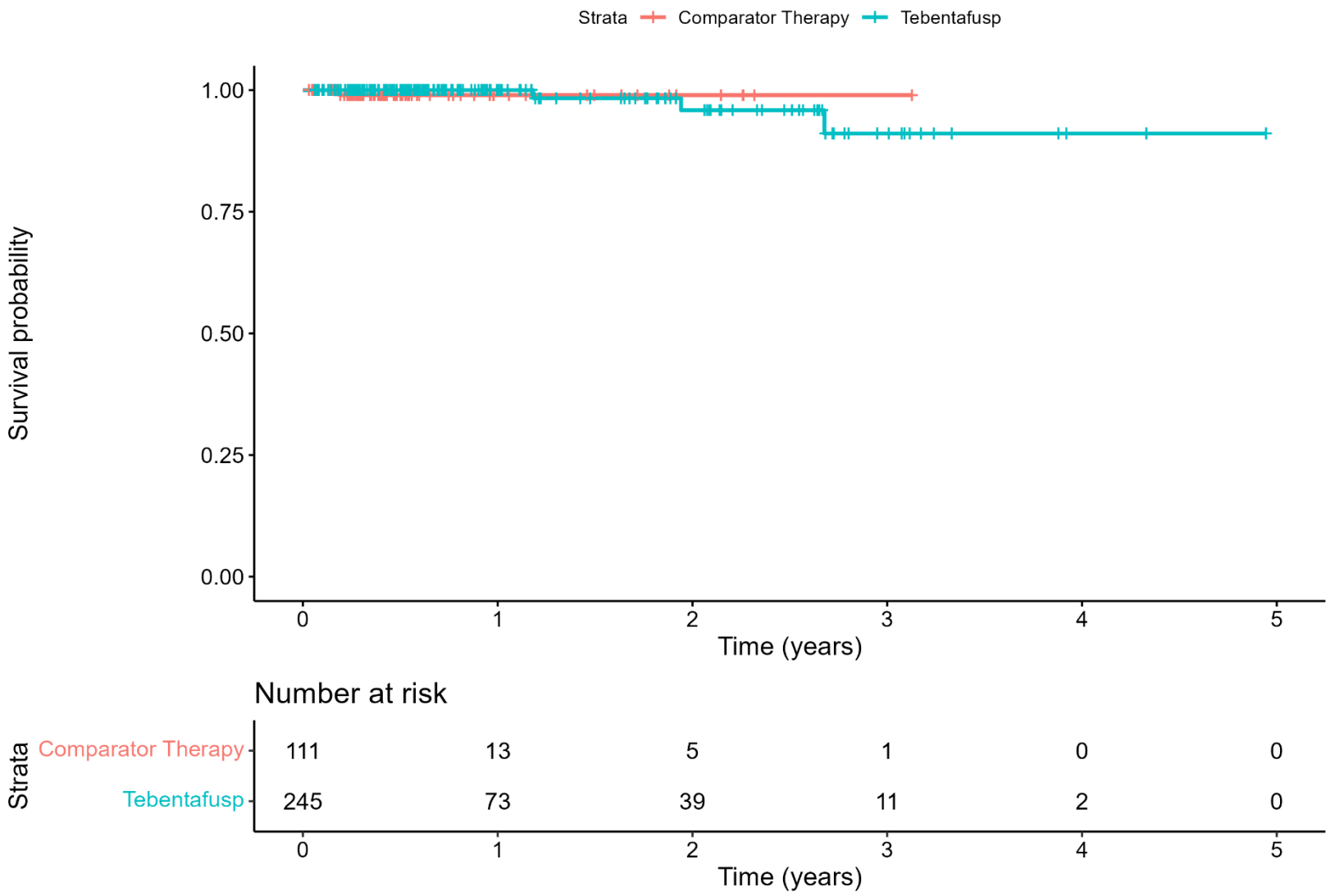
36.5 Erkrankungen des Immunsystems



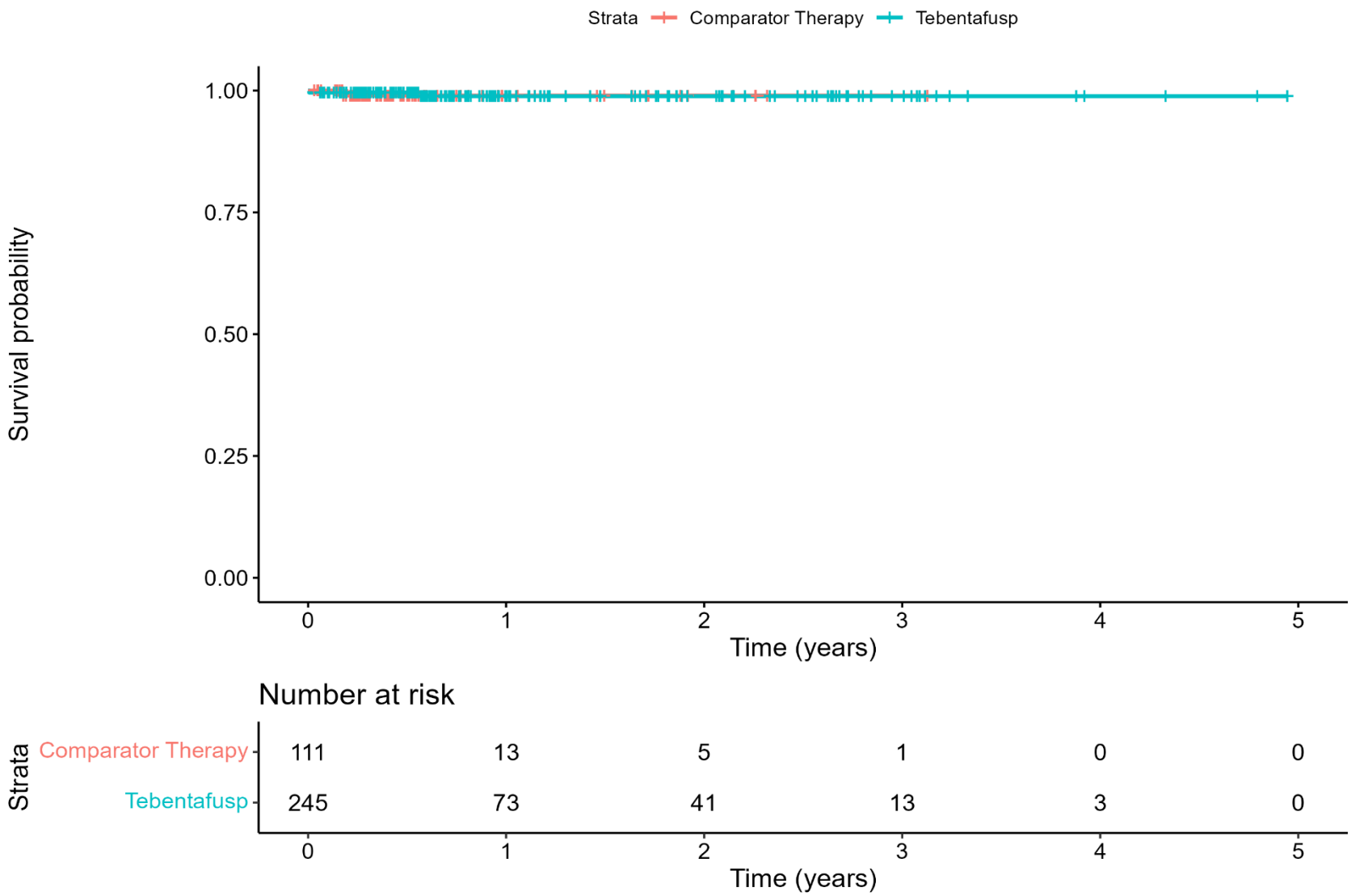
36.6 Infektionen und parasitäre Erkrankungen



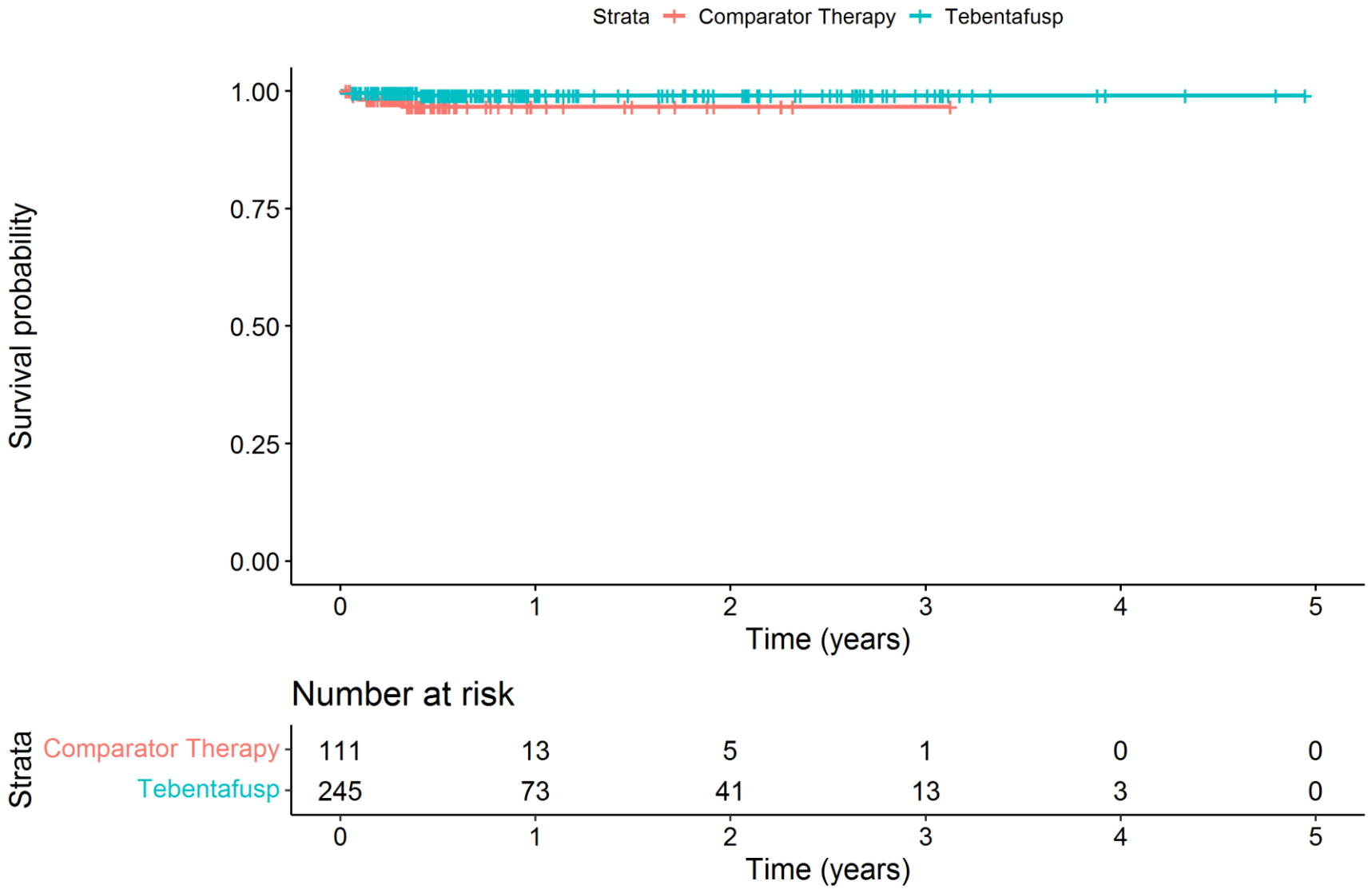
36.7 Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen



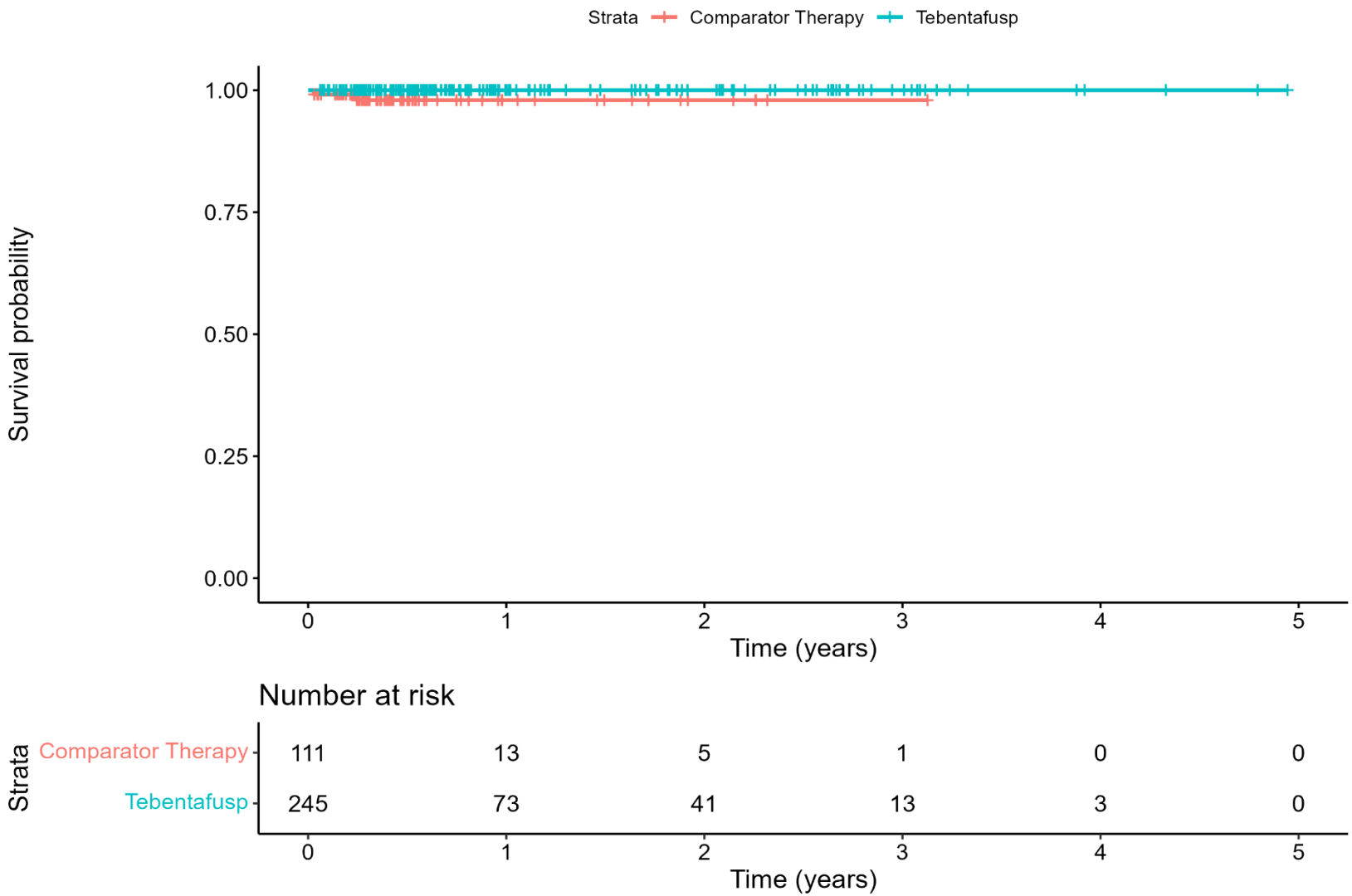
36.8 Untersuchungen



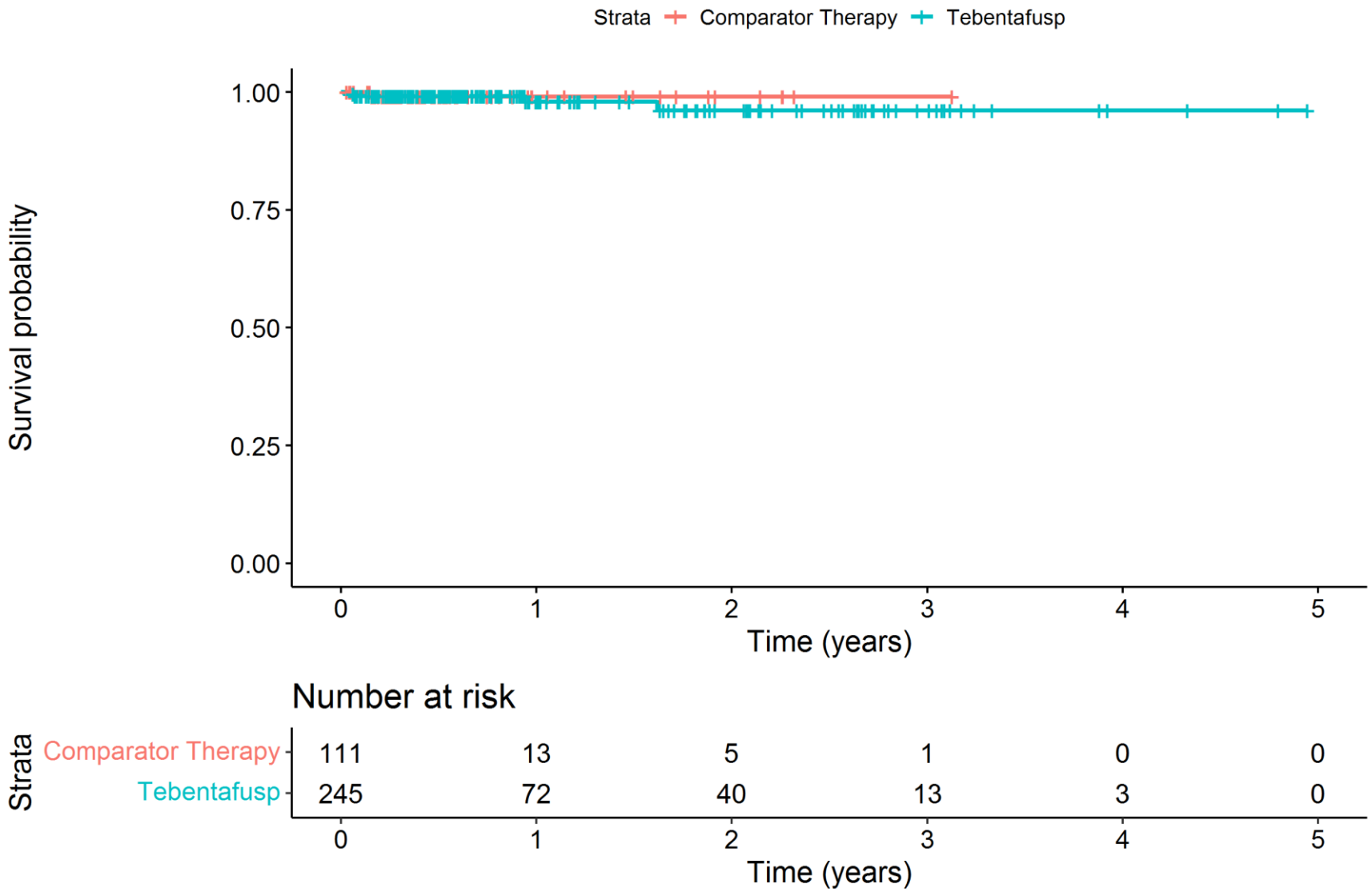
36.9 Stoffwechsel- und Ernährungsstörungen



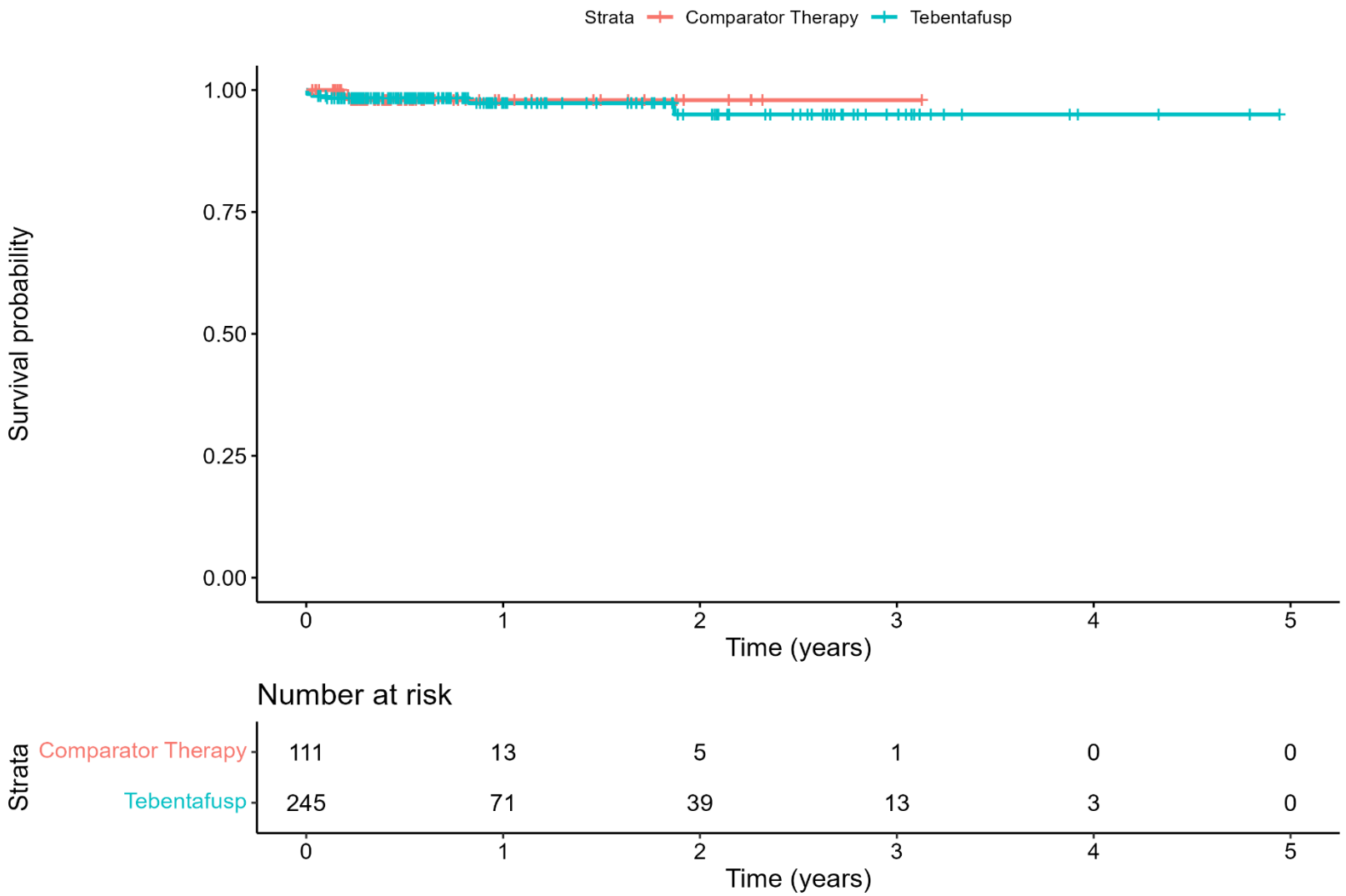
36.10 Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen



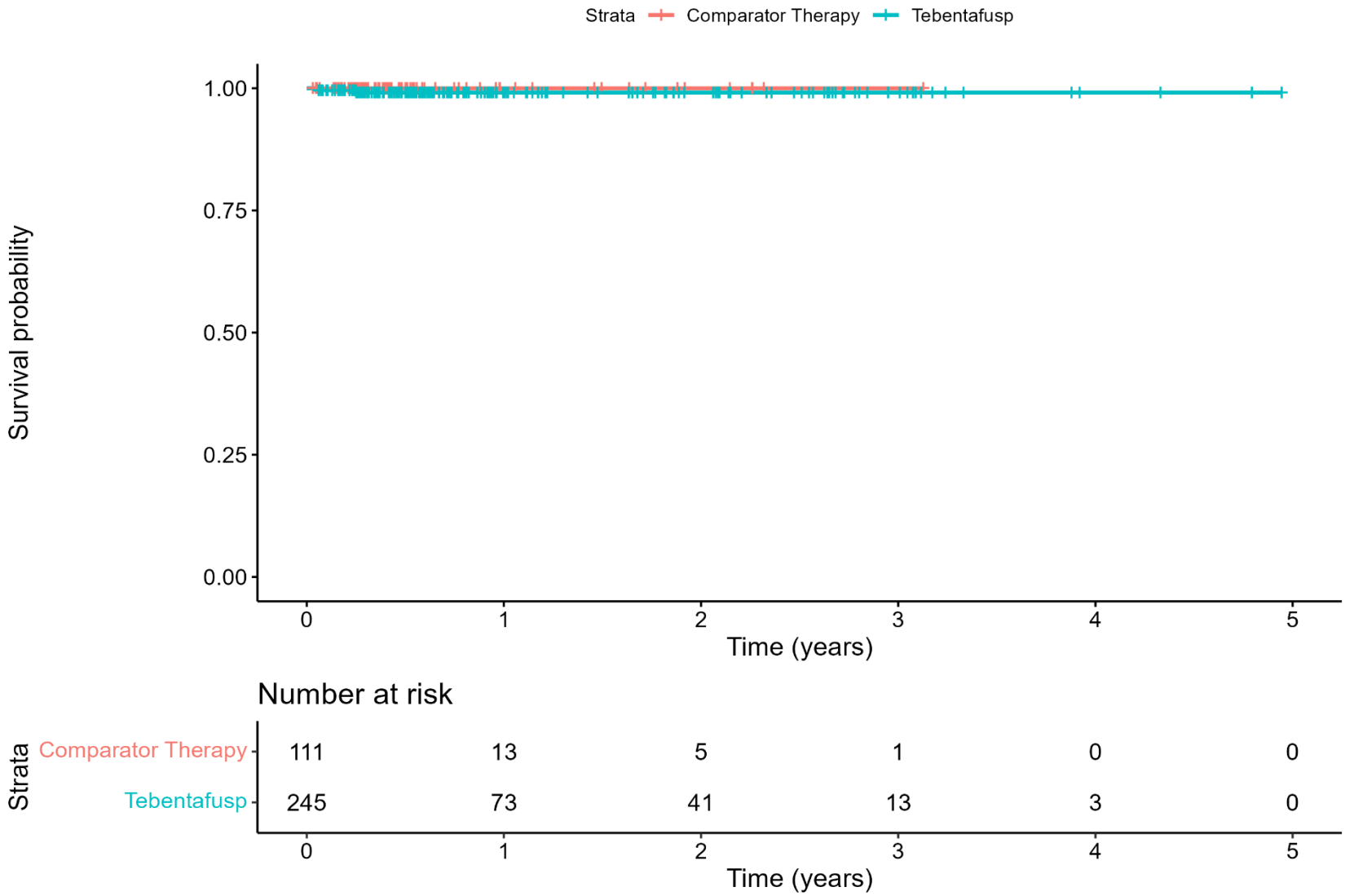
36.11 Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)



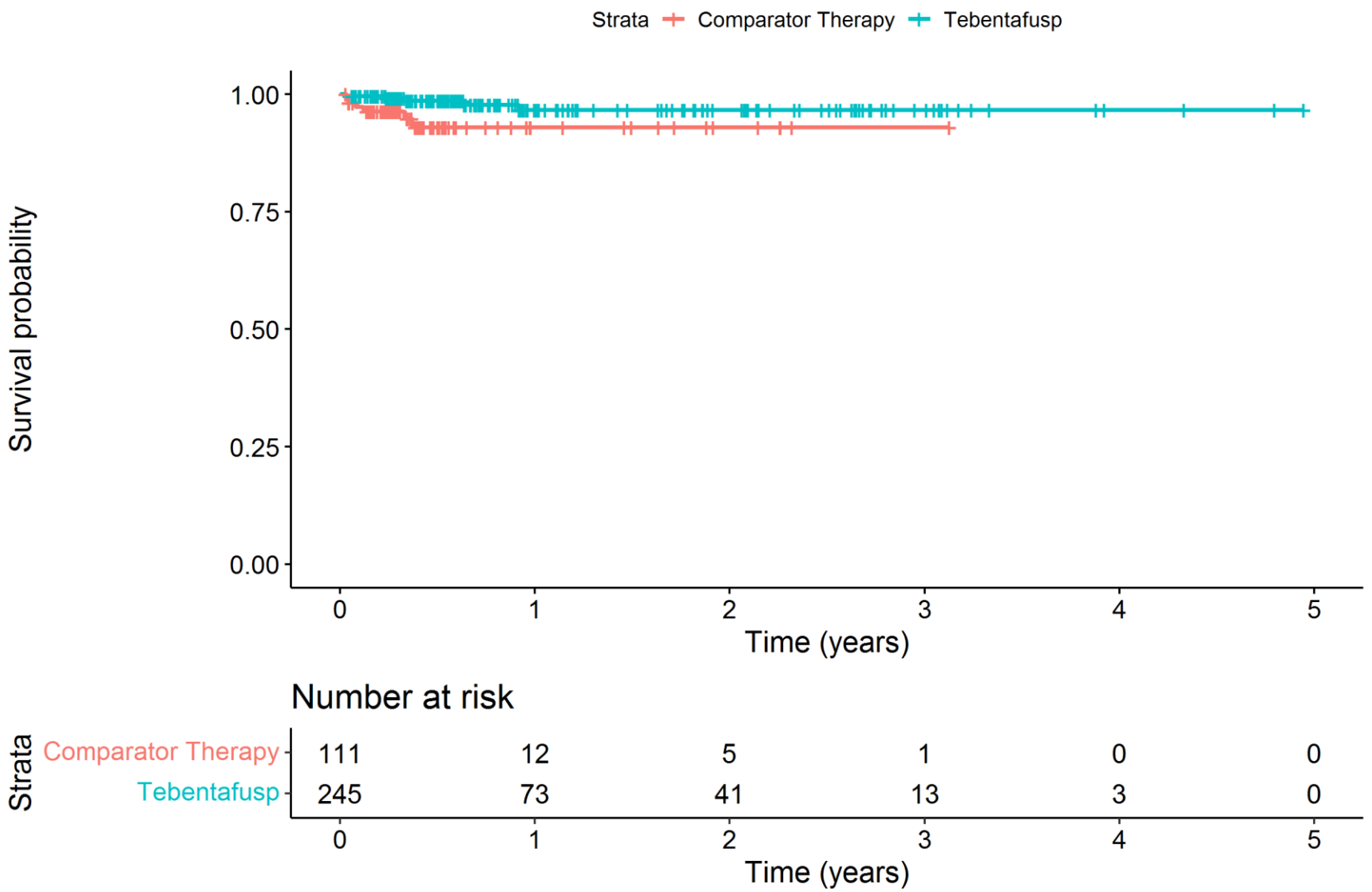
36.12 Erkrankungen des Nervensystems



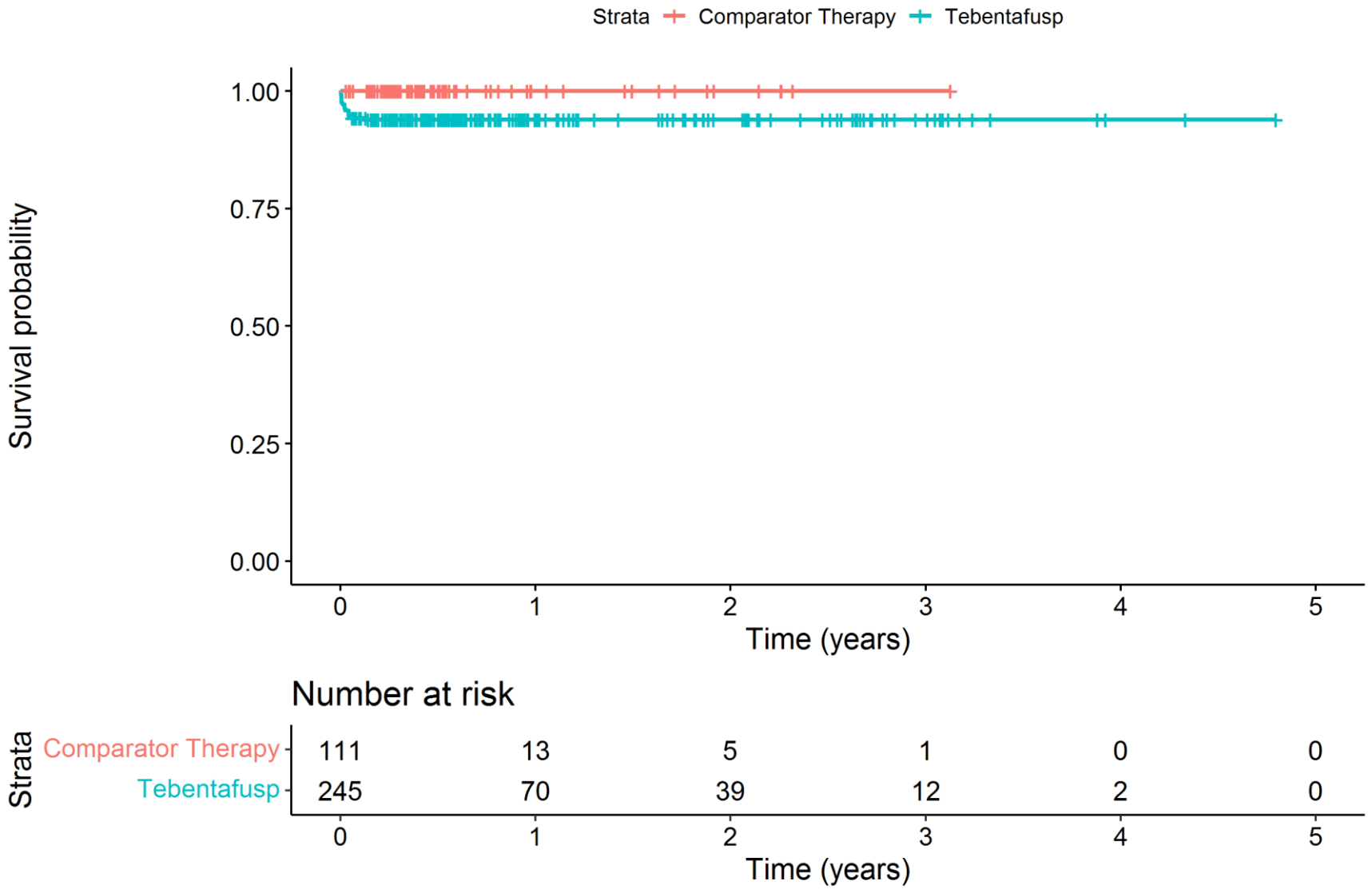
36.13 Erkrankungen der Nieren und Harnwege



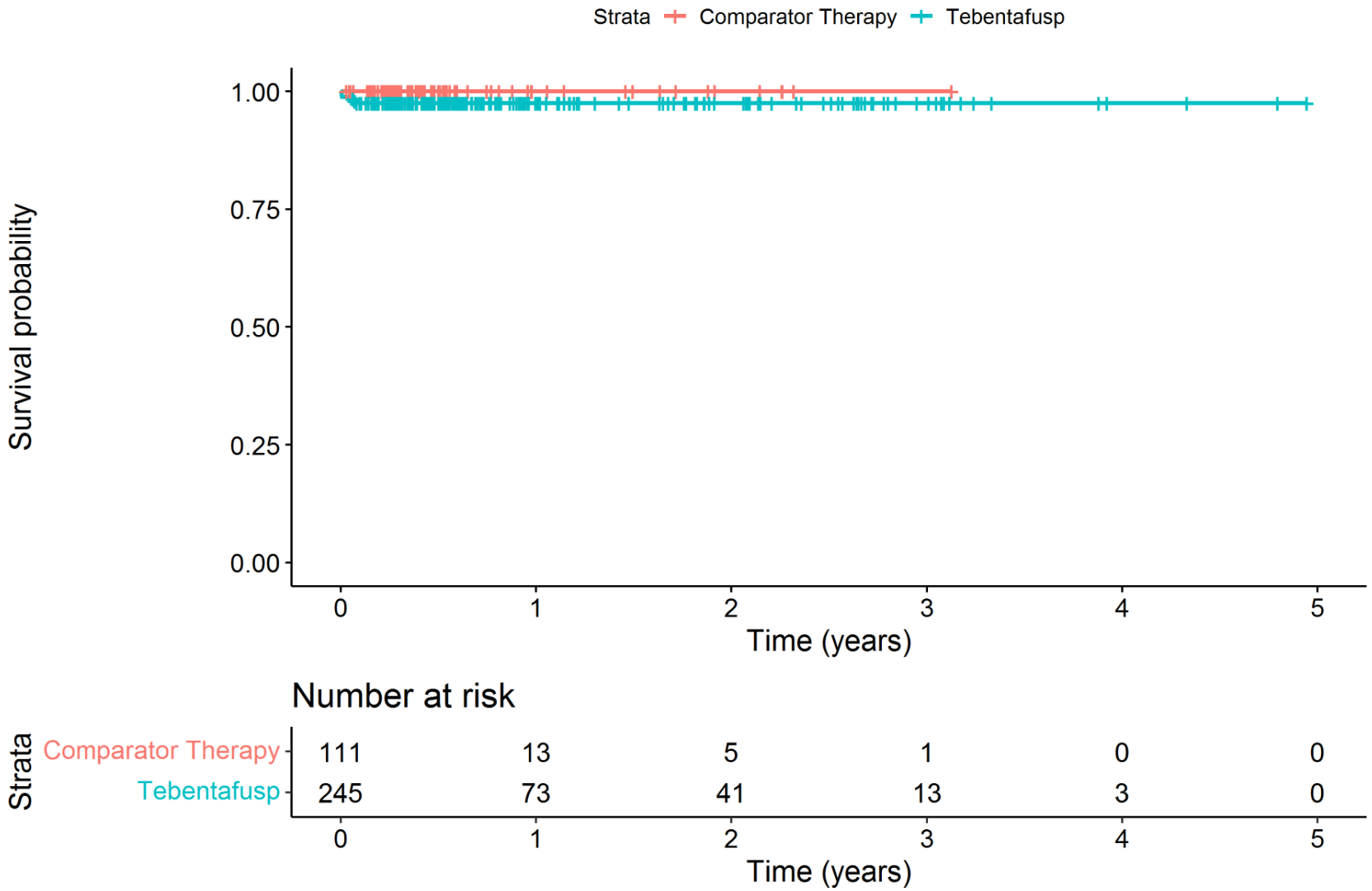
36.14 Erkrankungen der Atemwege, des Brustraums und Mediastinums



36.15 Erkrankungen der Haut und des Unterhautgewebes



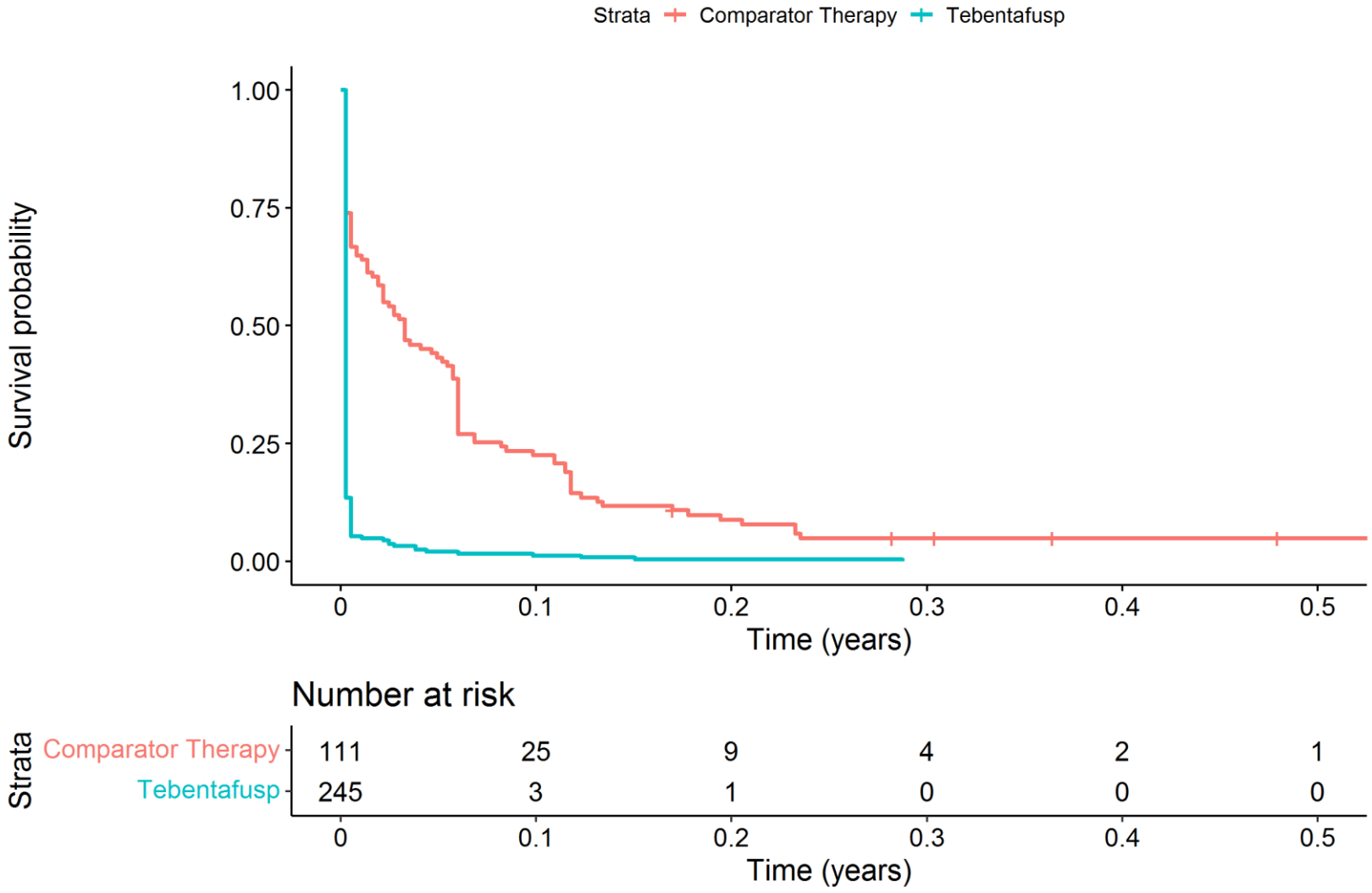
36.16 Gefäßerkrankungen



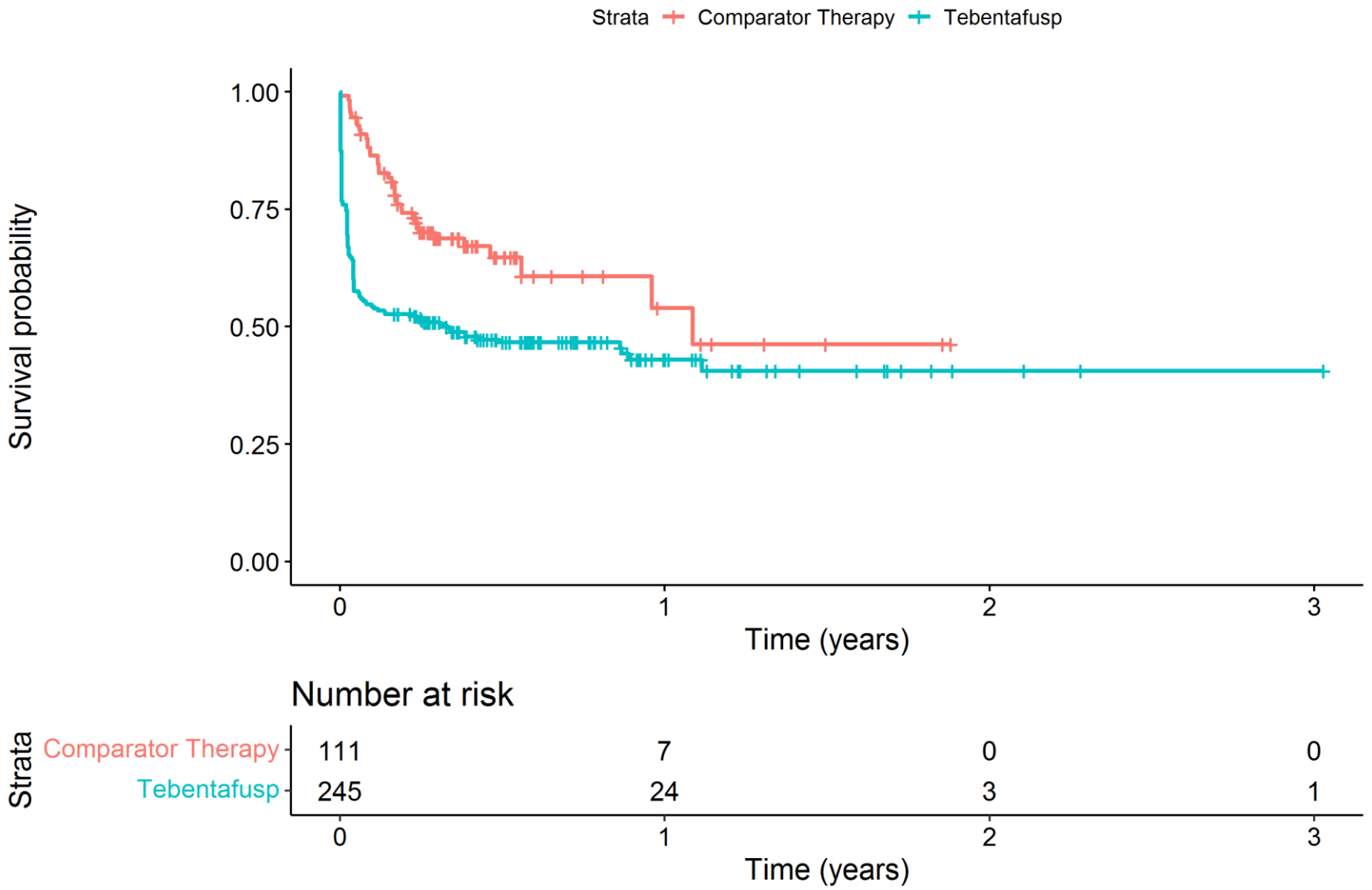
37 Unerwünschte Ereignisse ohne mit der Krankheitsprogression zusammenhängenden UEs

37.1 **Primäranalyse (Oktober 2020) (Tabelle 4-67)**

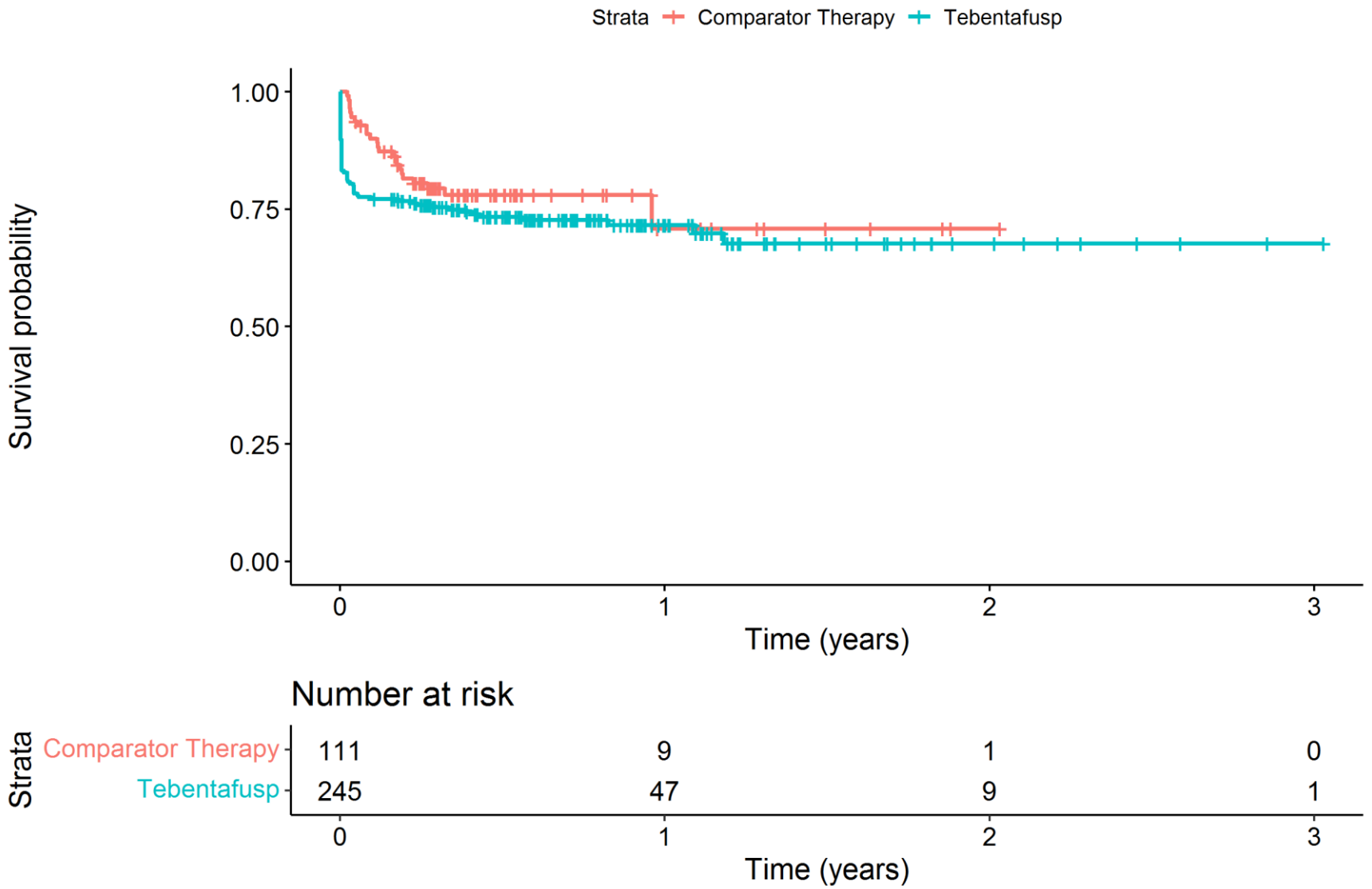
Unter der Behandlung aufgetretene UEs ohne krankheitsbedingte Ereignisse



Unter der Behandlung aufgetretene UEs des Grades ≥ 3 ohne krankheitsbedingte Ereignisse

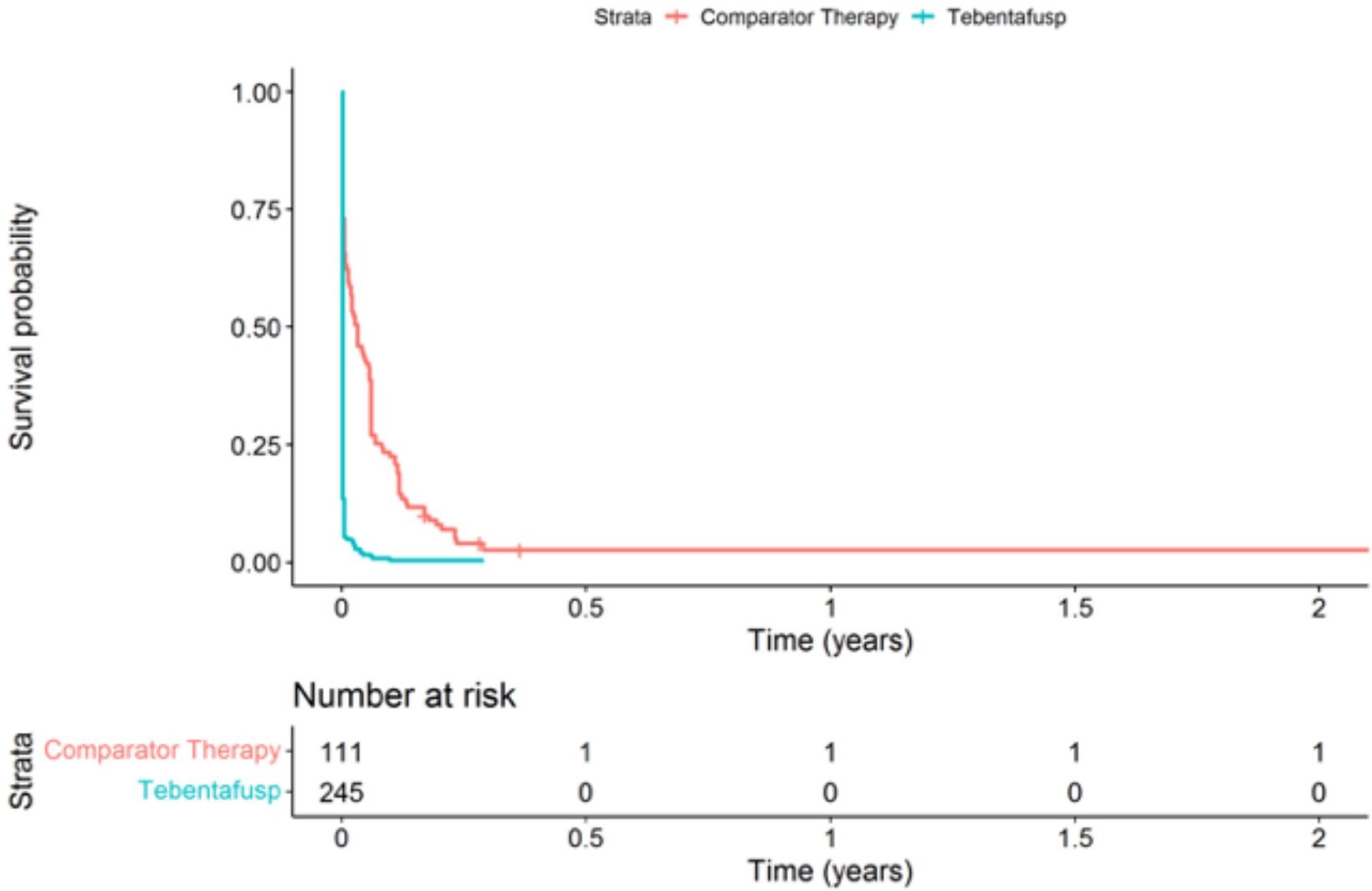


SUEs ohne krankheitsbedingte Ereignisse

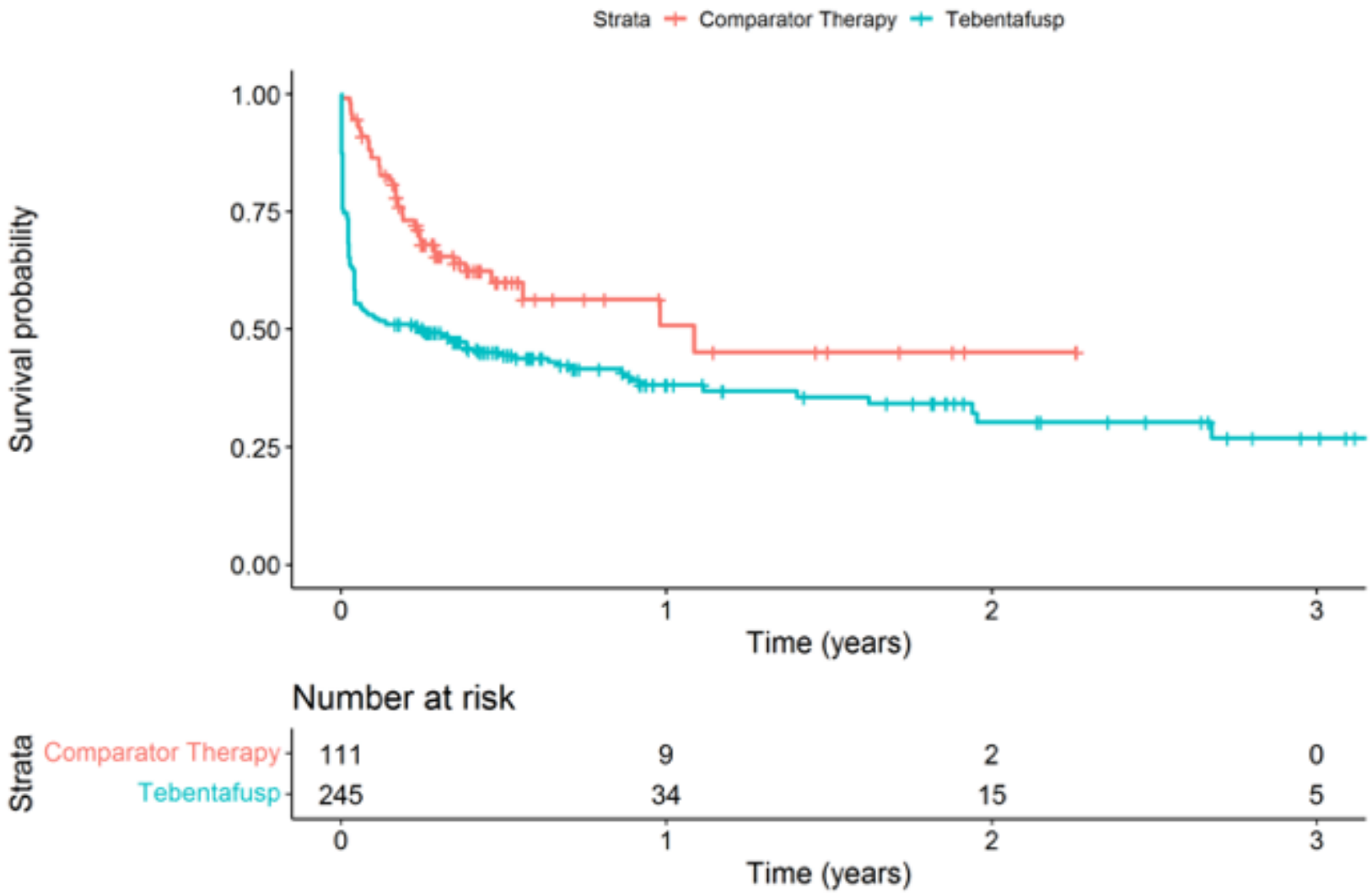


37.2 **3-Jahres-Analyse (Juni 2023) (Tabelle 4-68)**

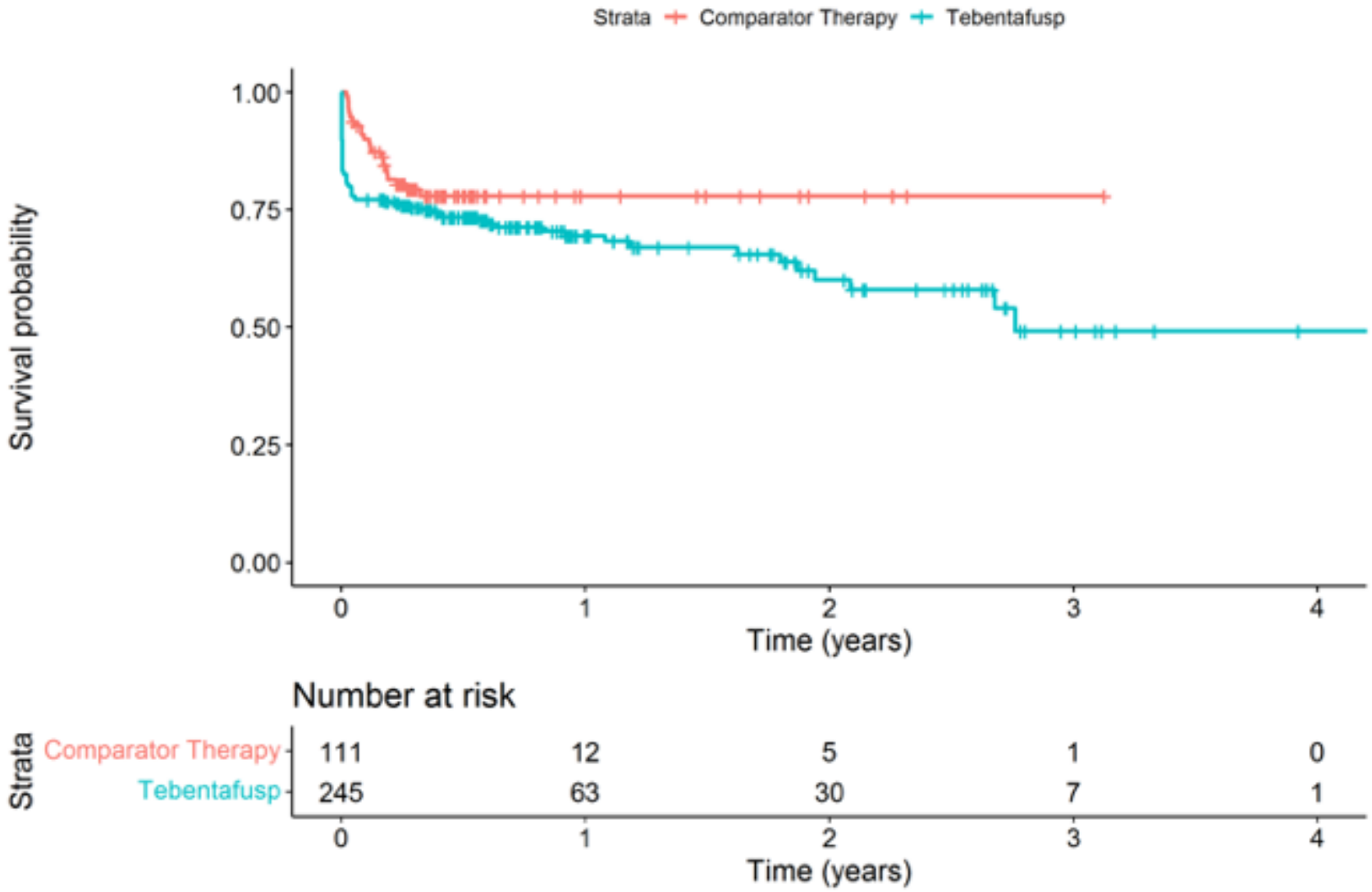
37.3 Unter der Behandlung aufgetretene UEs ohne krankheitsbedingte Ereignisse


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
0.5
1
1.5
2
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
111
1
1
1
1
245
0
0
0
0
0
0.5
1
1.5
2
Time (years)

37.4 Unter der Behandlung aufgetretene UEs des Grades ≥ 3 ohne krankheitsbedingte Ereignisse



37.5 SUEs ohne krankheitsbedingte Ereignisse

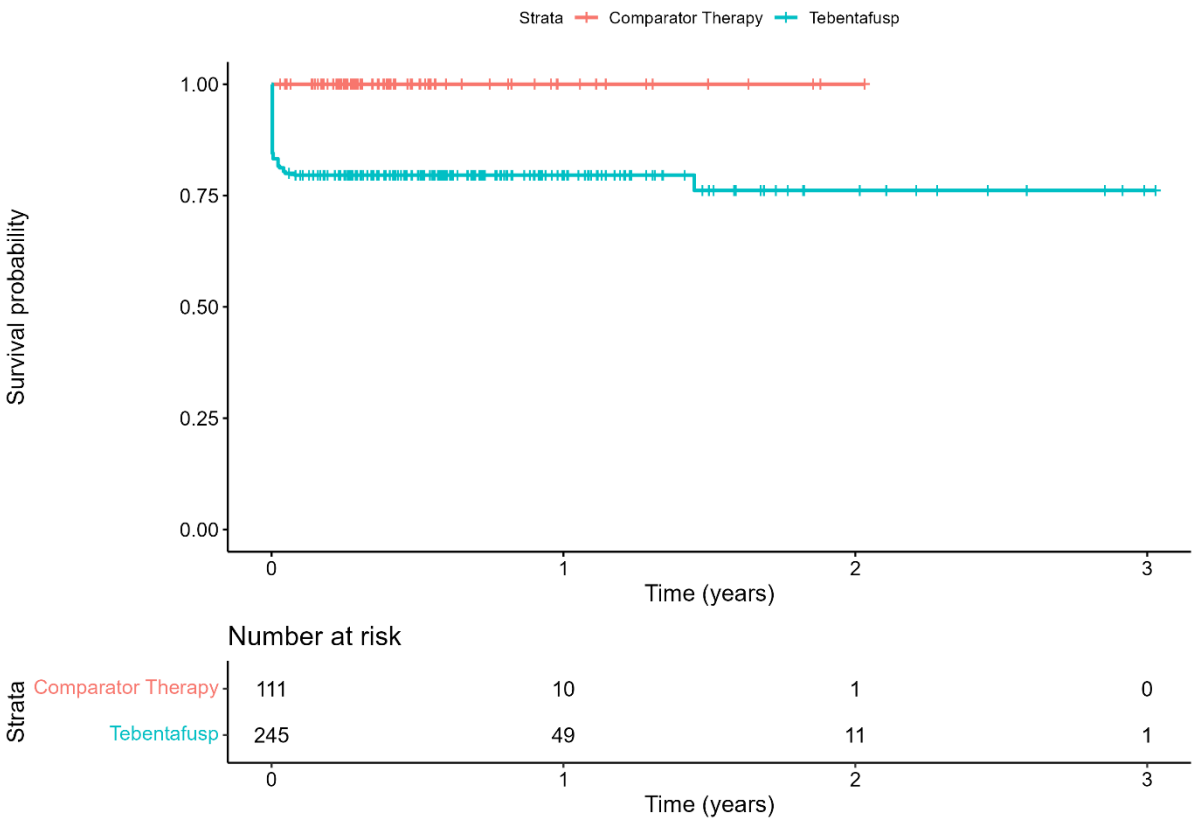


37.6 Unerwünschte Ereignisse von besonderem Interesse (AESIs)

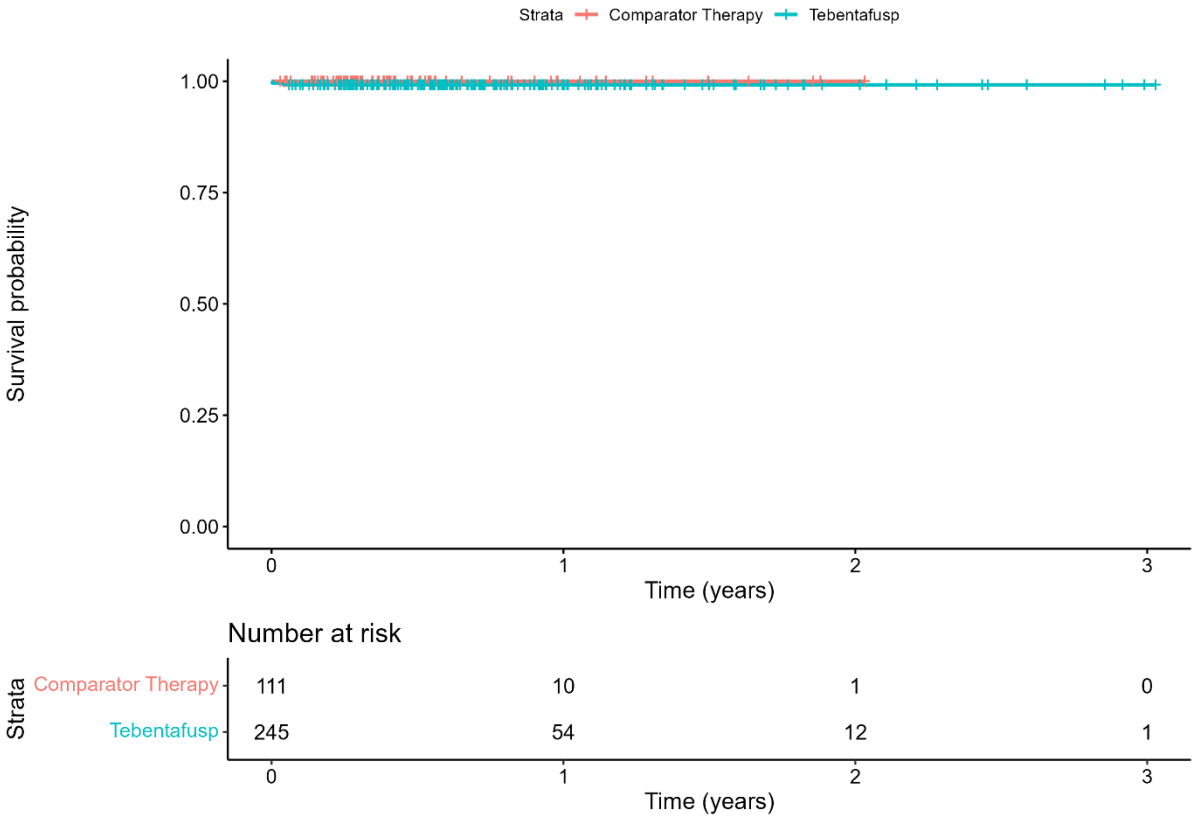
37.7 Zusammenfassung der AESIs

37.8 Primäranalyse (Oktober 2020) (Tabelle 4-58)

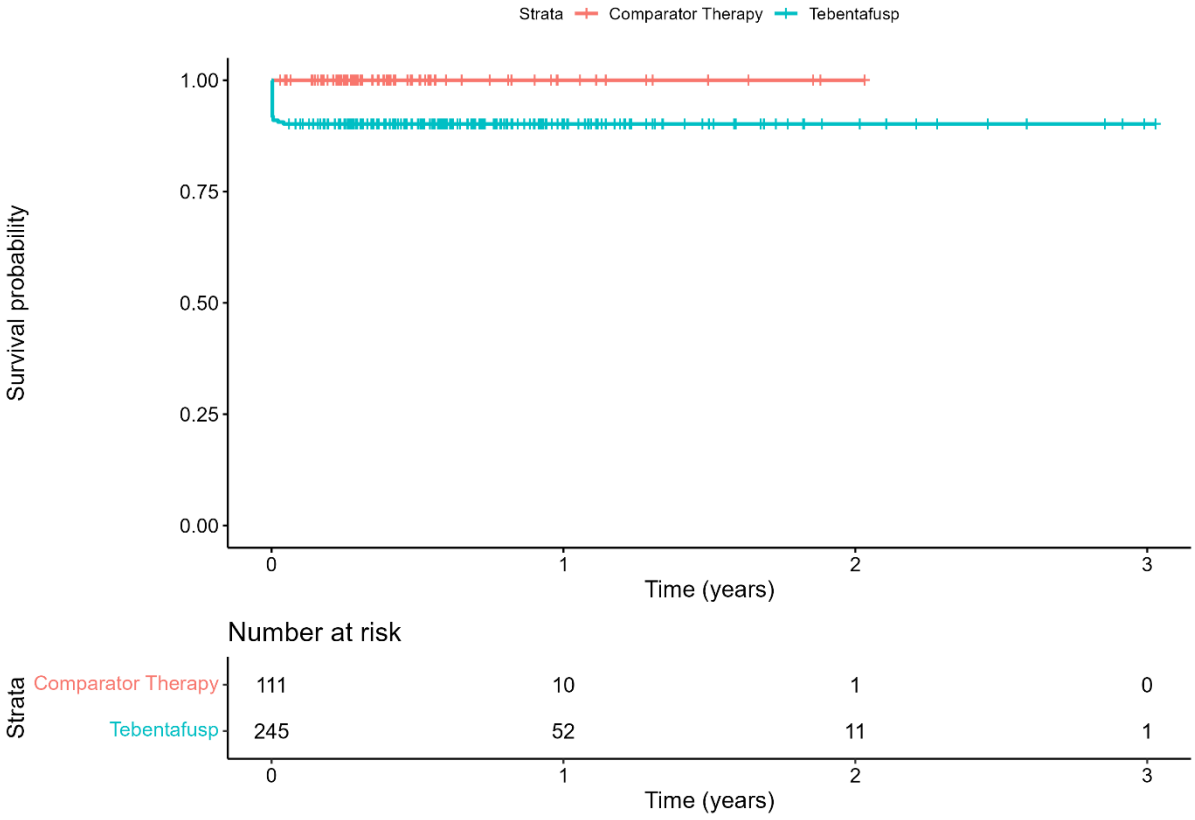
Zytokin-Freisetzungssyndrom



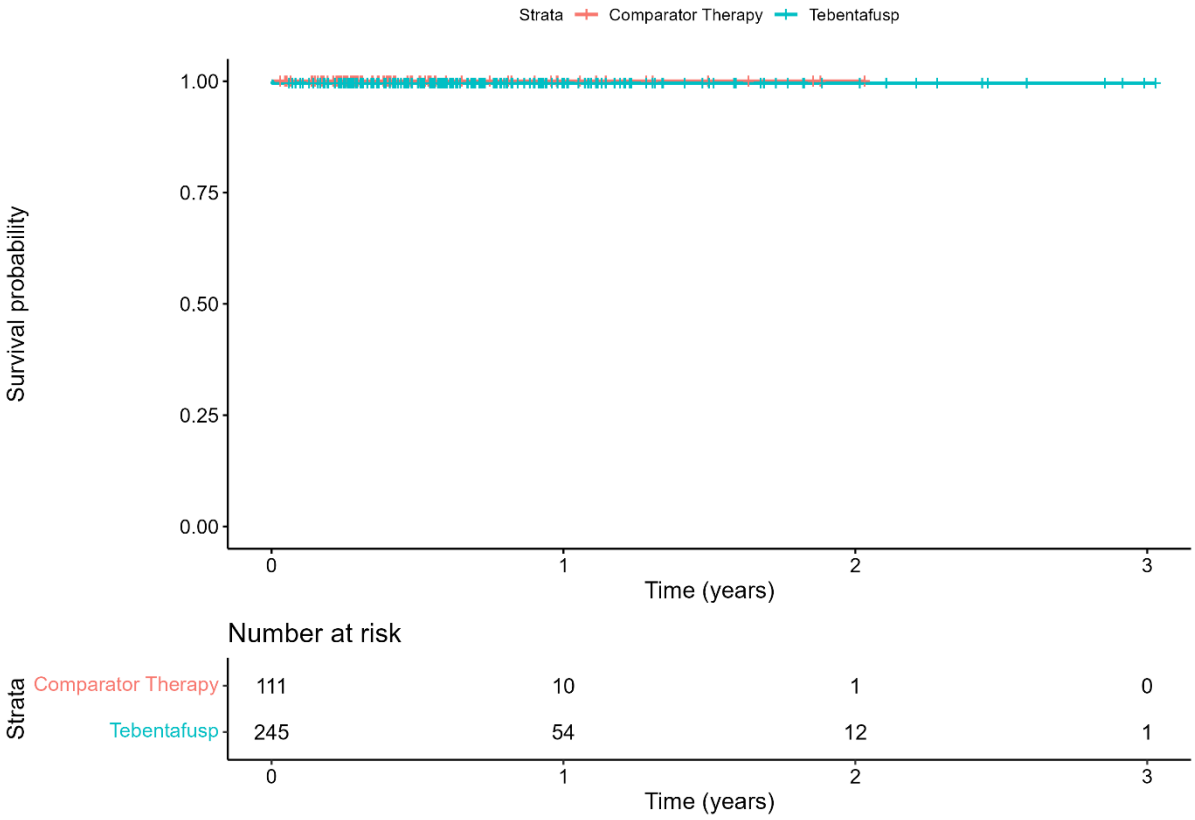
Zytokin-Freisetzungssyndrom mit CTCAE-Grad ≥ 3



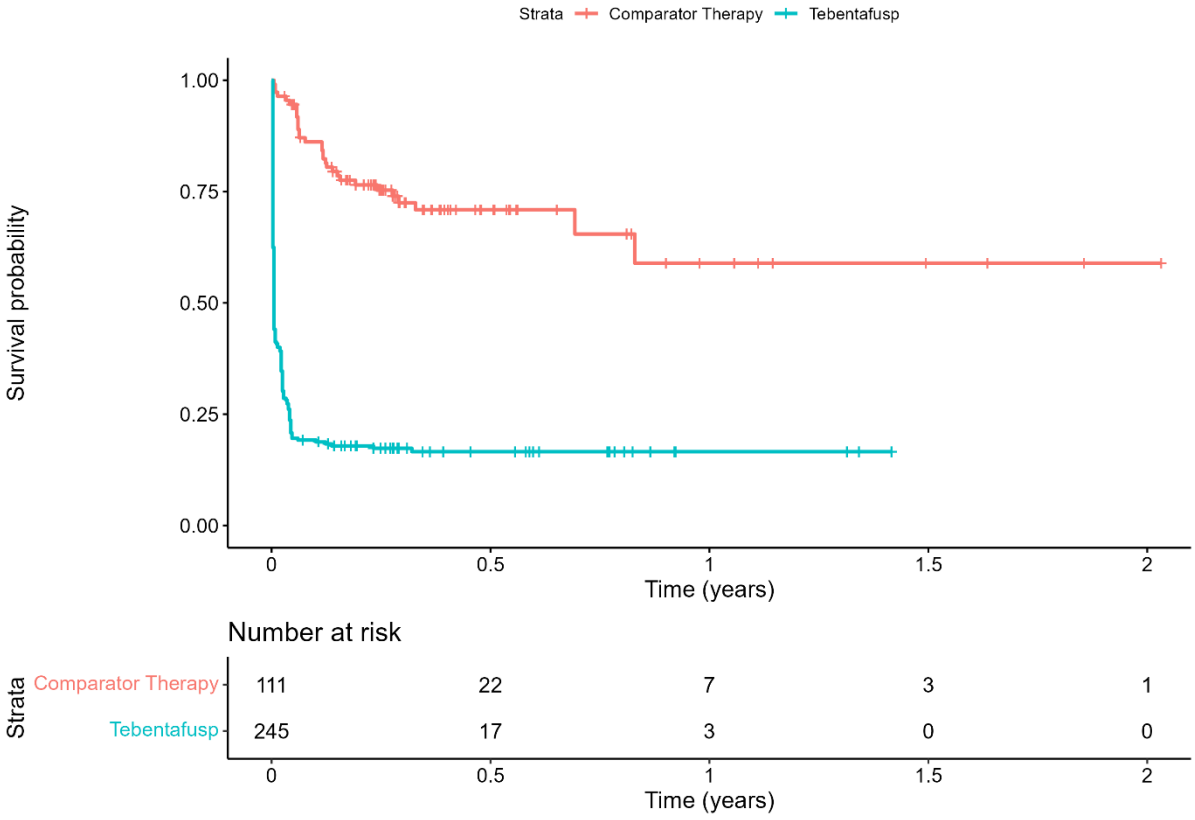
Schwerwiegendes Zytokin-Freisetzungssyndrom



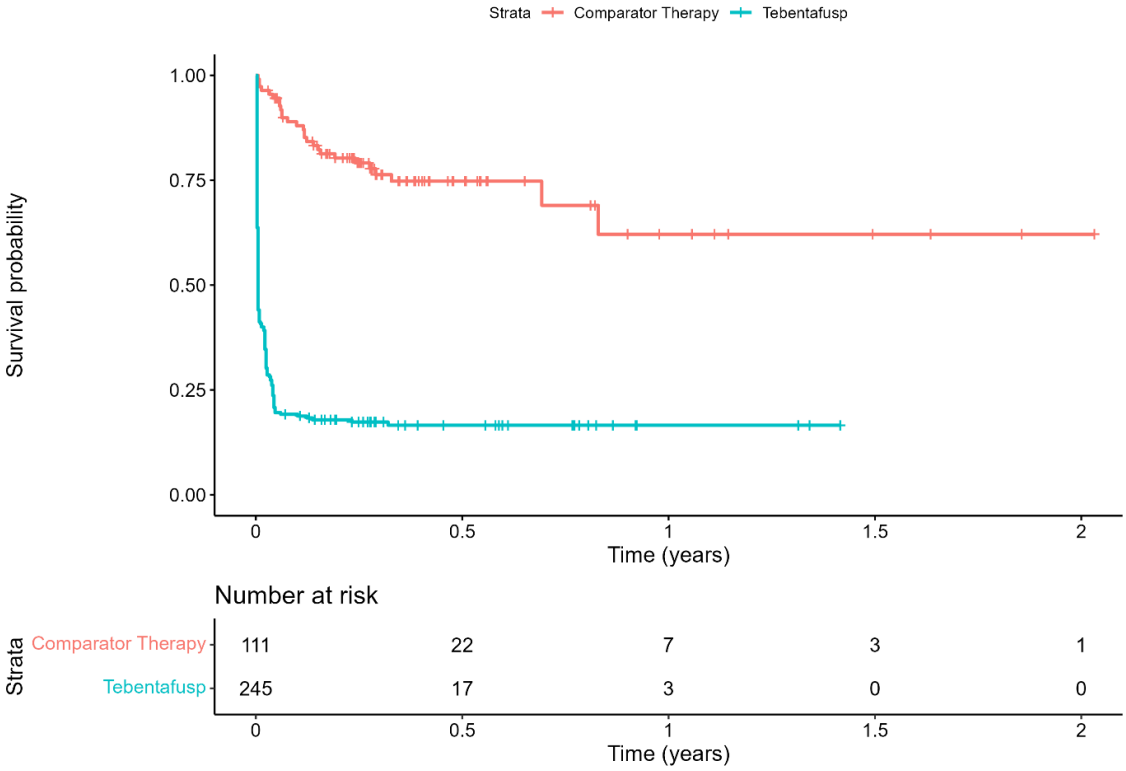
Zytokin-Freisetzungssyndrom, das zum Absetzen des Studienmedikaments führte



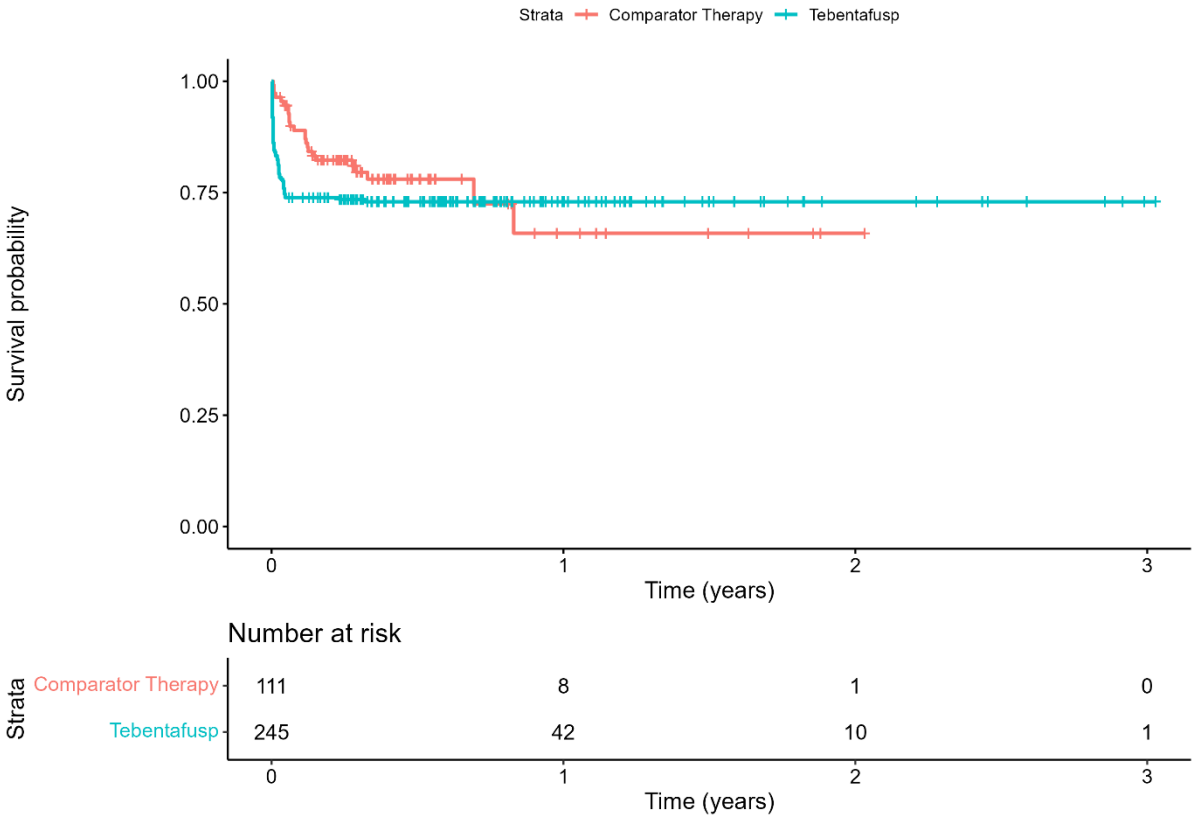
Hautausschlag



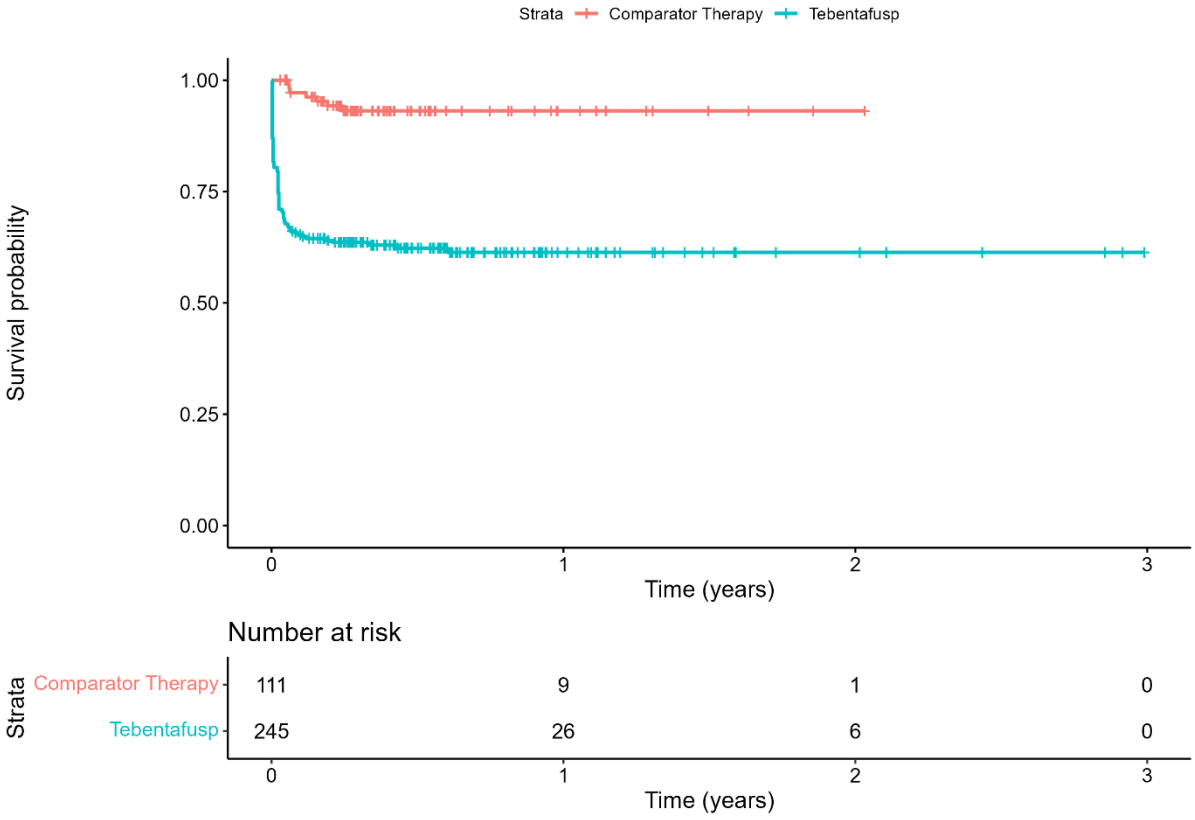
Hautausschlag in kausalem Zusammenhang mit der Behandlung



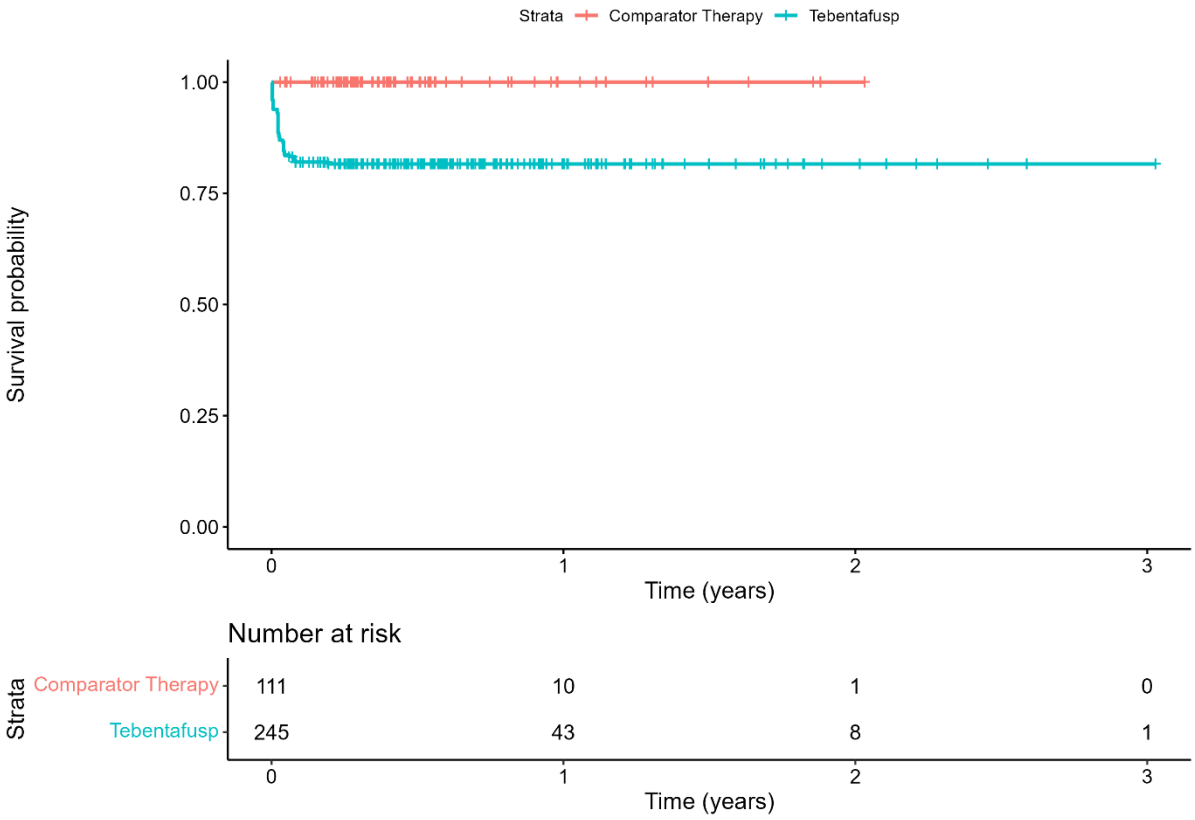
Hautausschlag nach höchstem CTCAE-Grad1



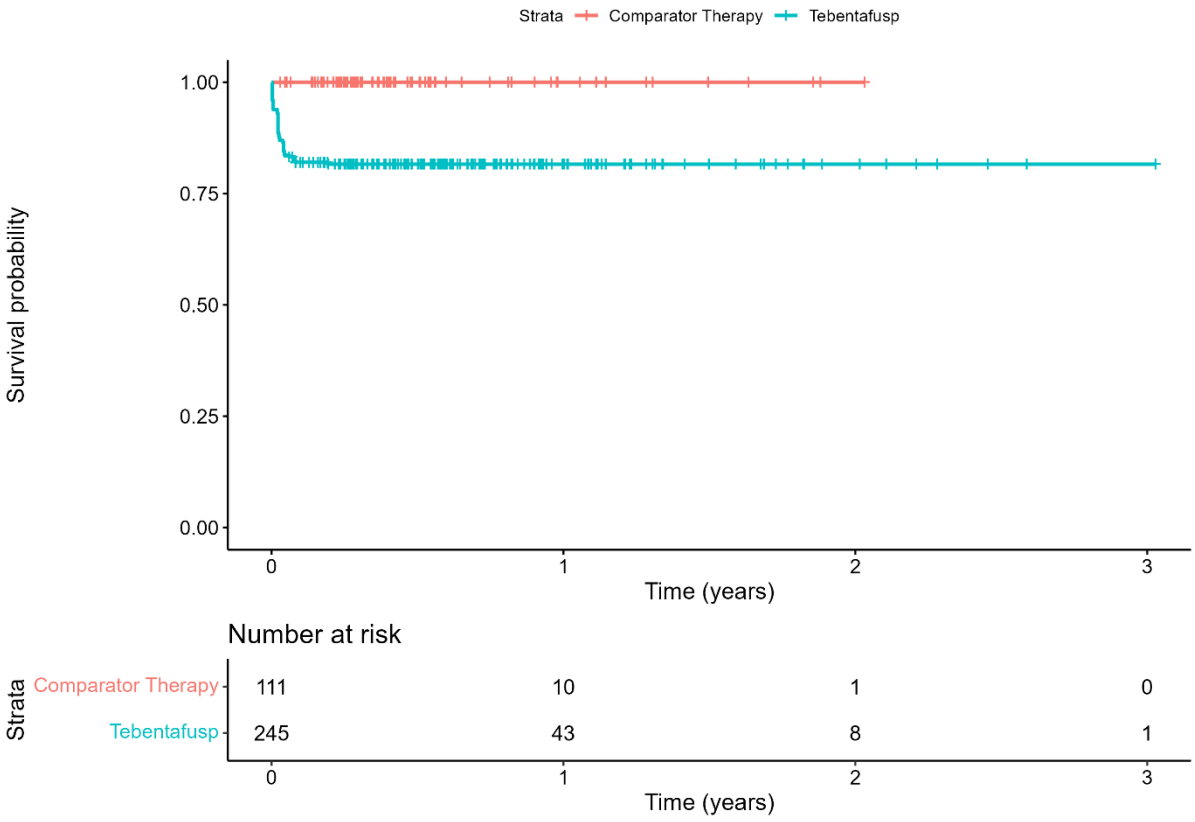
Hautausschlag nach höchstem CTCAE-Grad 2



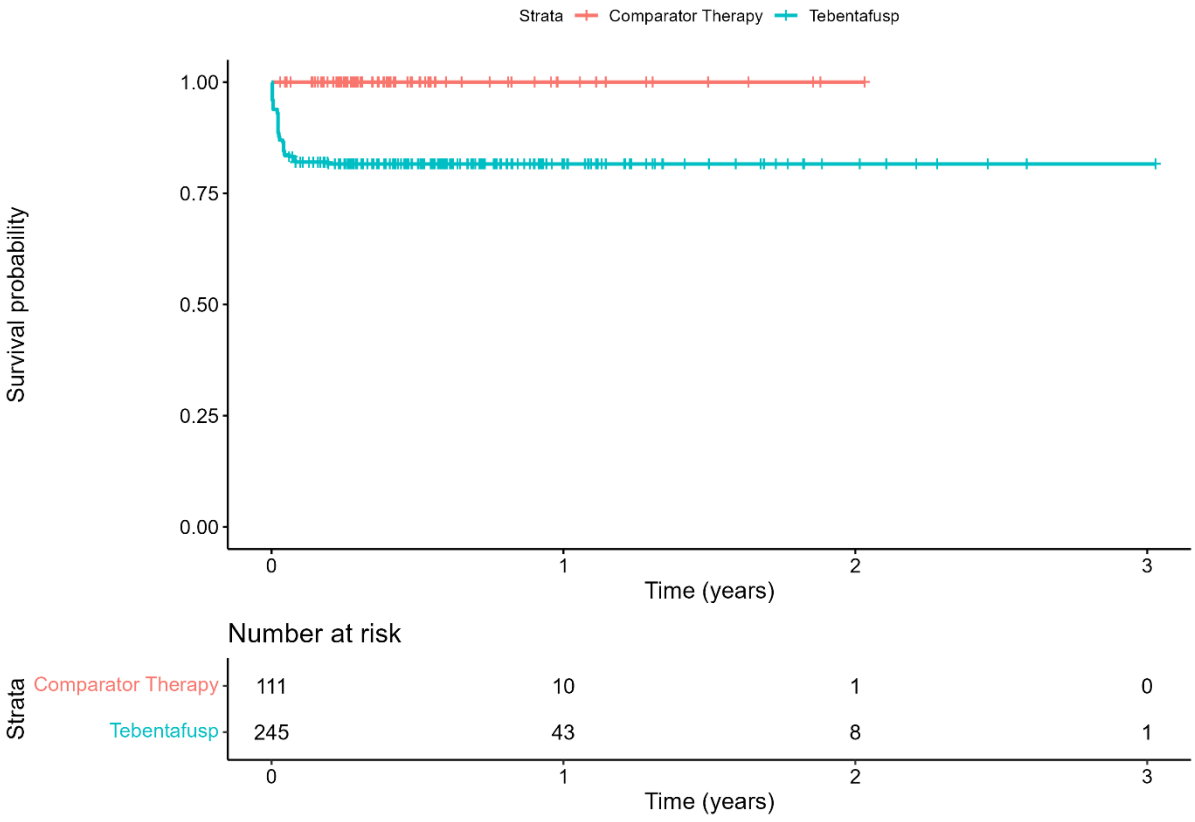
Hautausschlag nach höchstem CTCAE-Grad 3



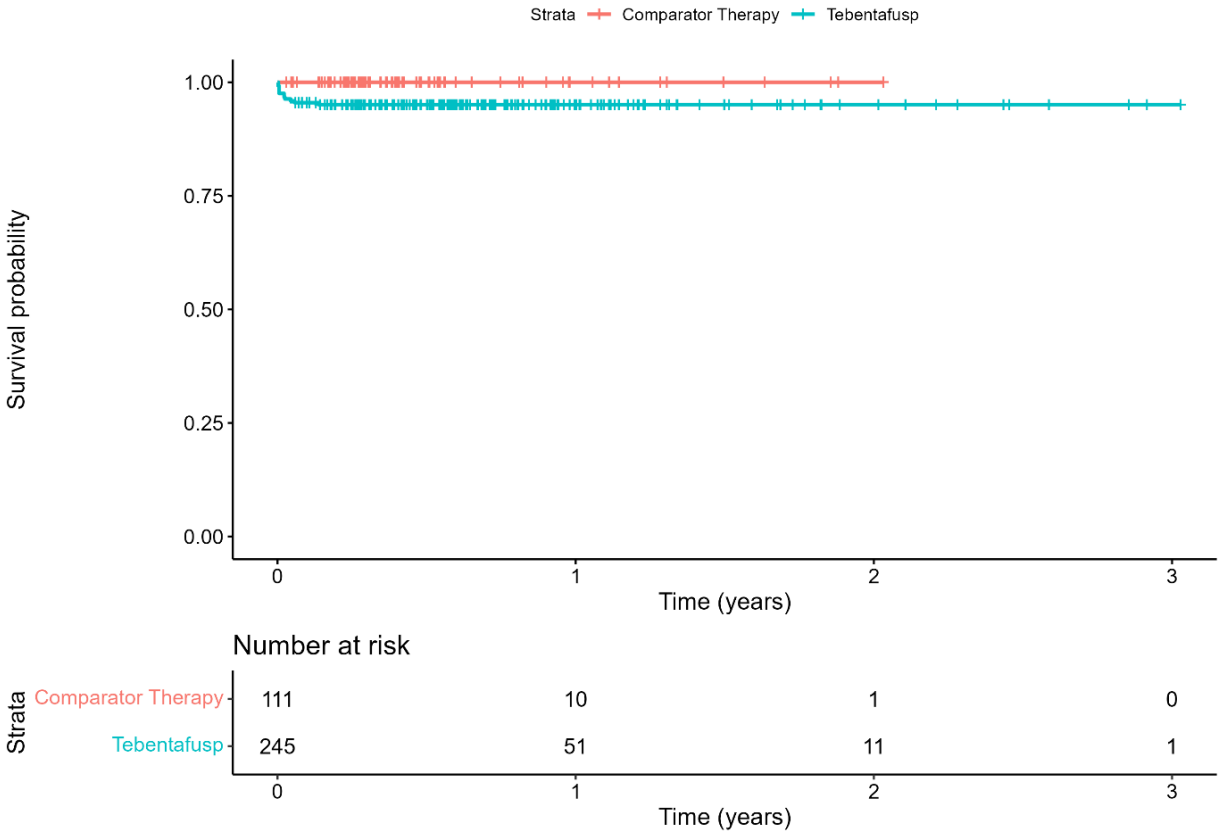
Hautausschlag mit CTCAE-Grad ≥ 3



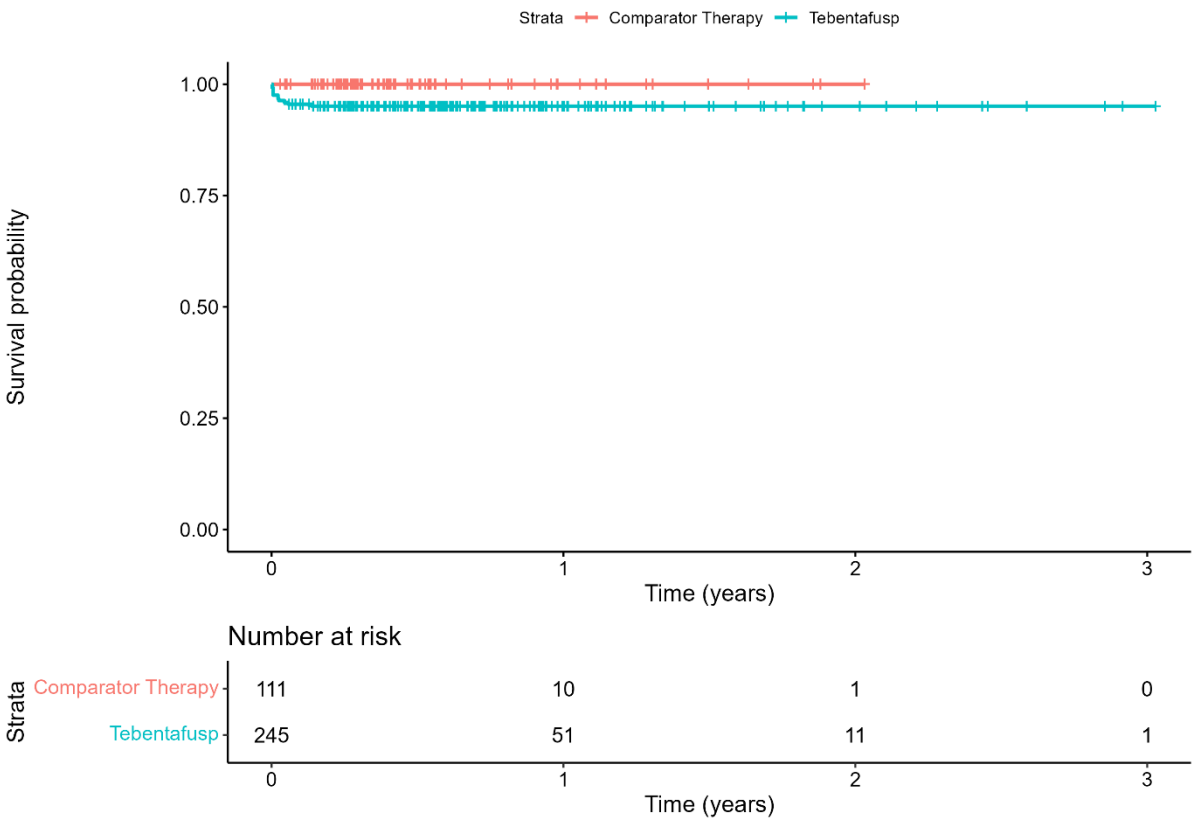
Hautausschlag mit CTCAE-Grad ≥ 3, in kausalem Zusammenhang mit der Behandlung



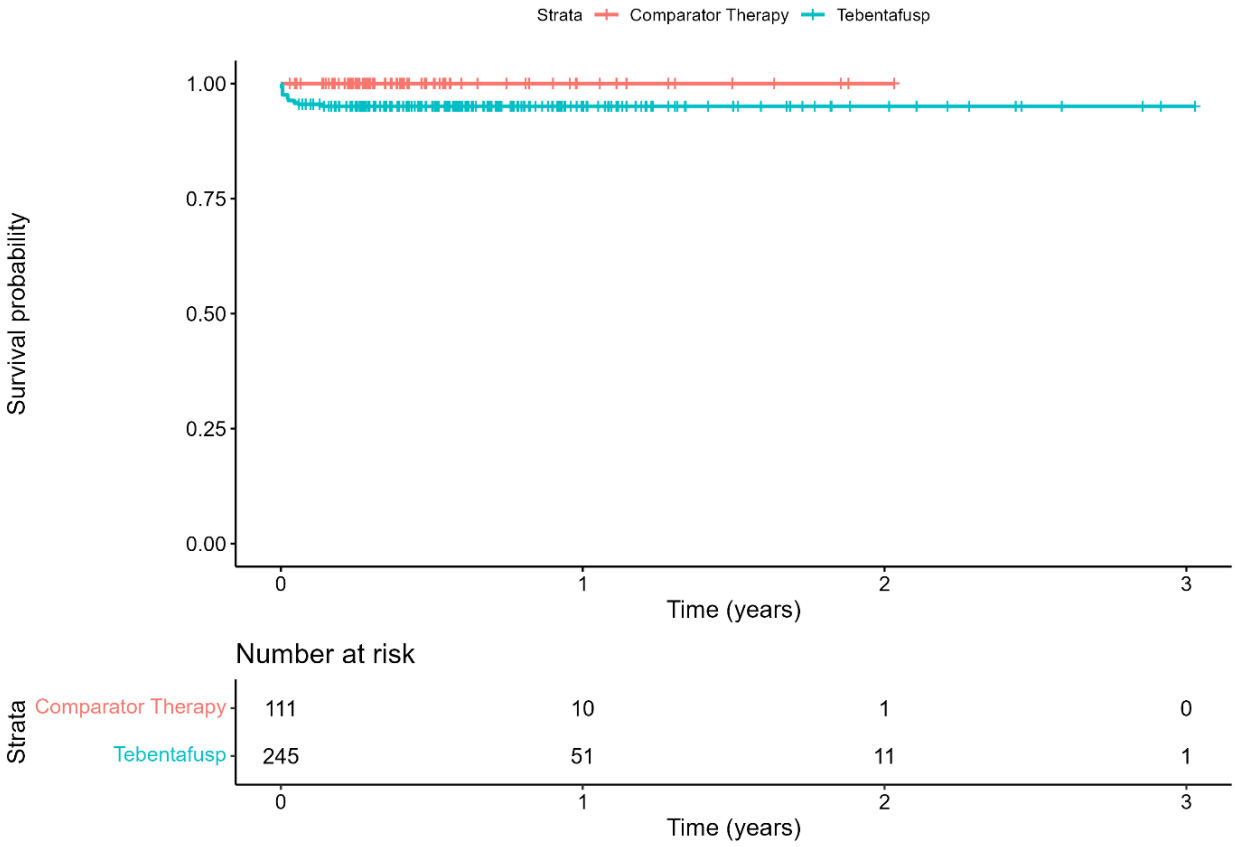
Schwerwiegender Hautausschlag



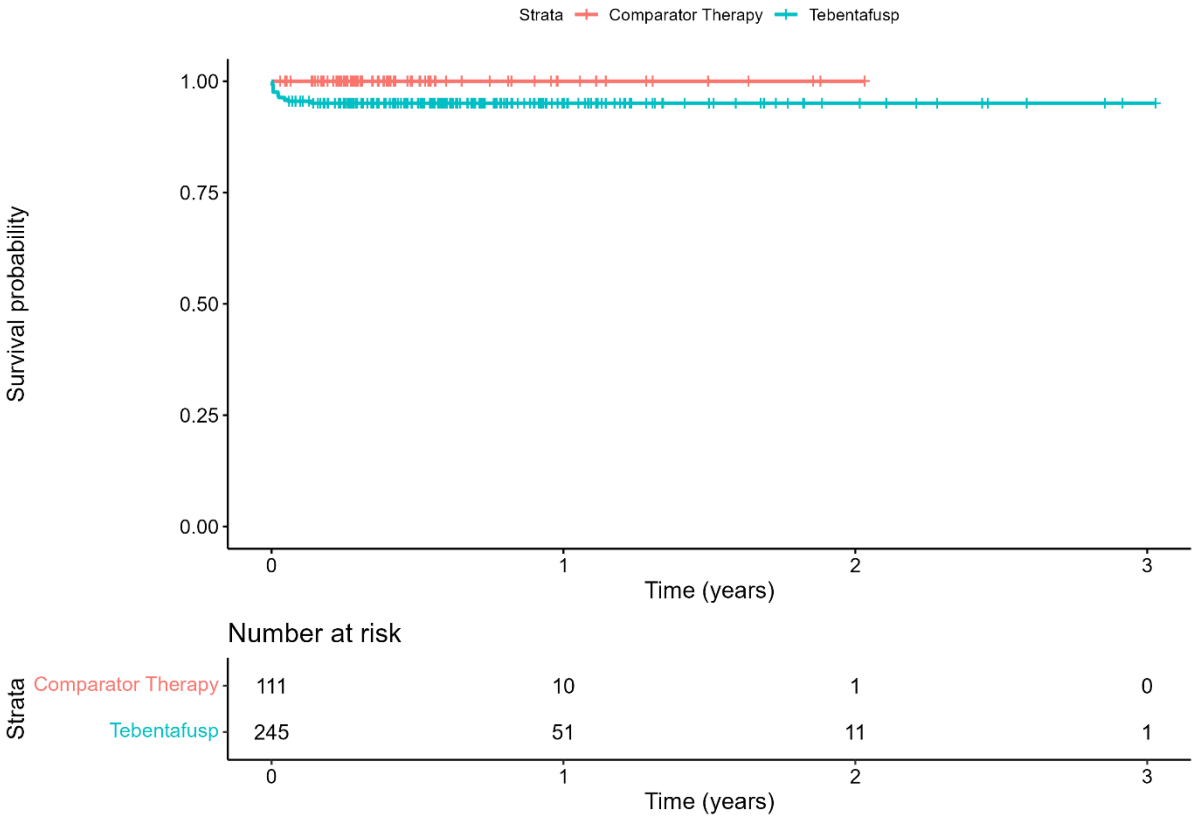
Schwerwiegender Hautausschlag, in kausalem Zusammenhang mit der Behandlung



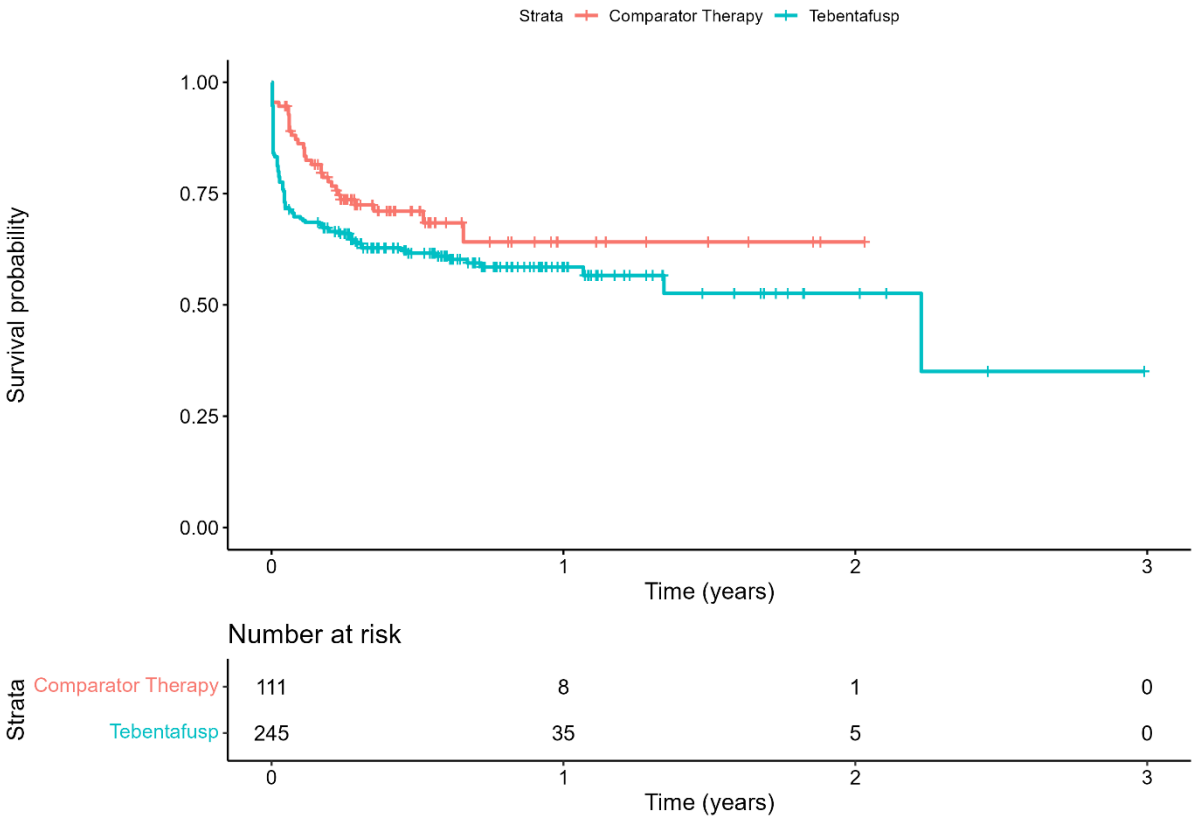
Hautausschlag, der zu einem Krankenhausaufenthalt führte



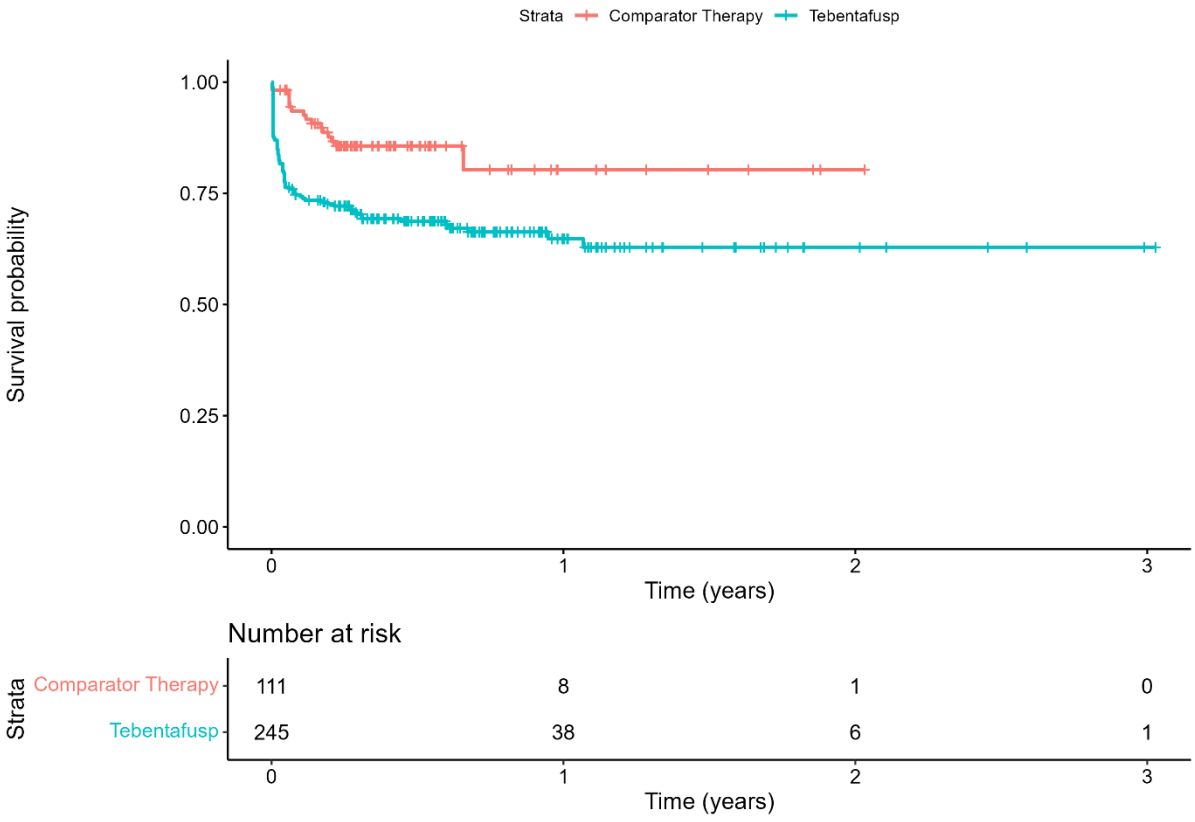
Hautausschlag, der zu einem Krankenhausaufenthalt führte, in kausalem Zusammenhang mit der Behandlung



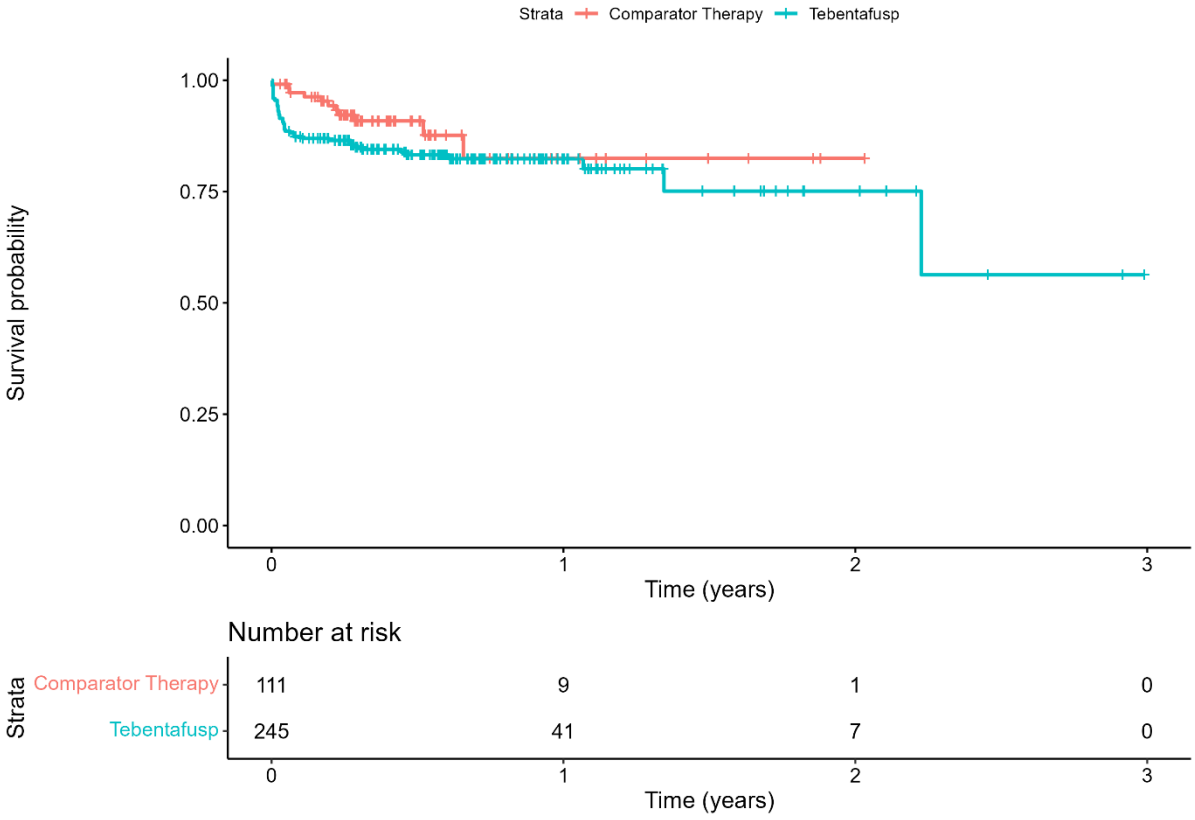
LFT-Erhöhung



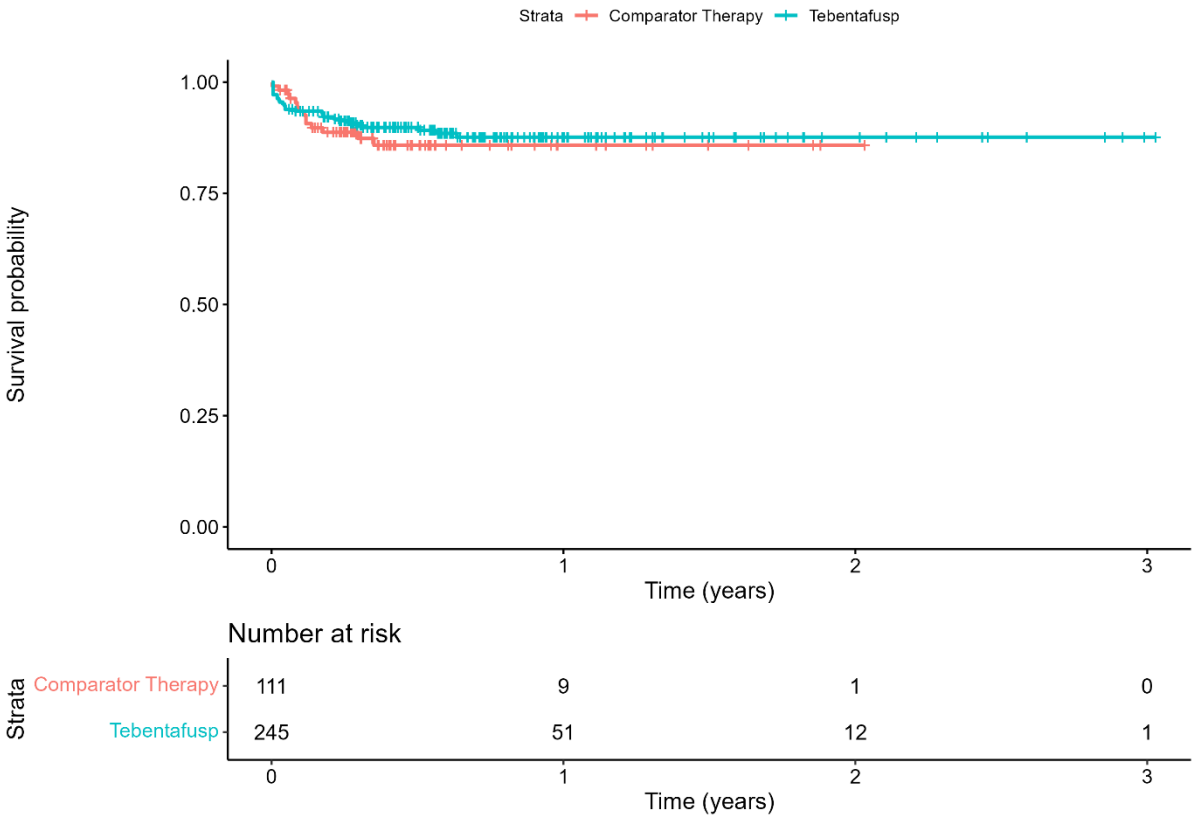
LFT-Erhöhung in kausalem Zusammenhang mit der Behandlung



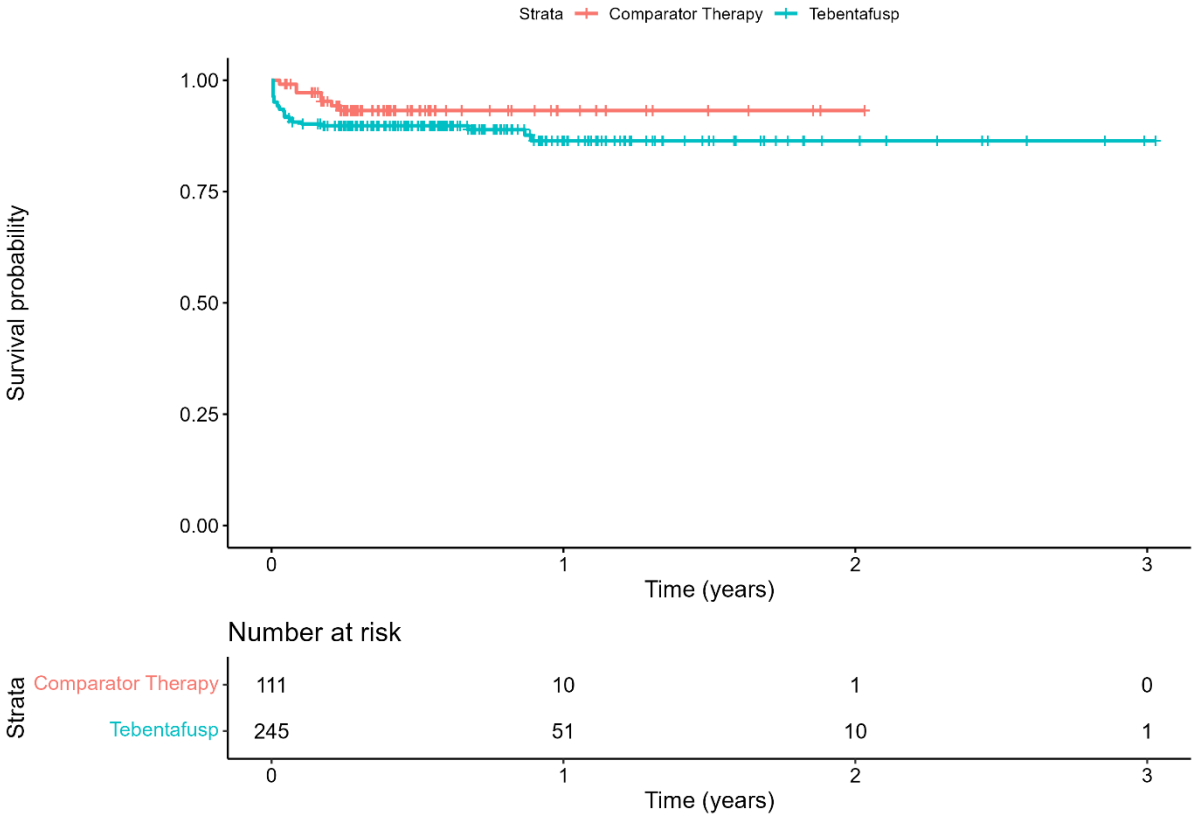
LFT-Erhöhung nach höchstem CTCAE-Grad1



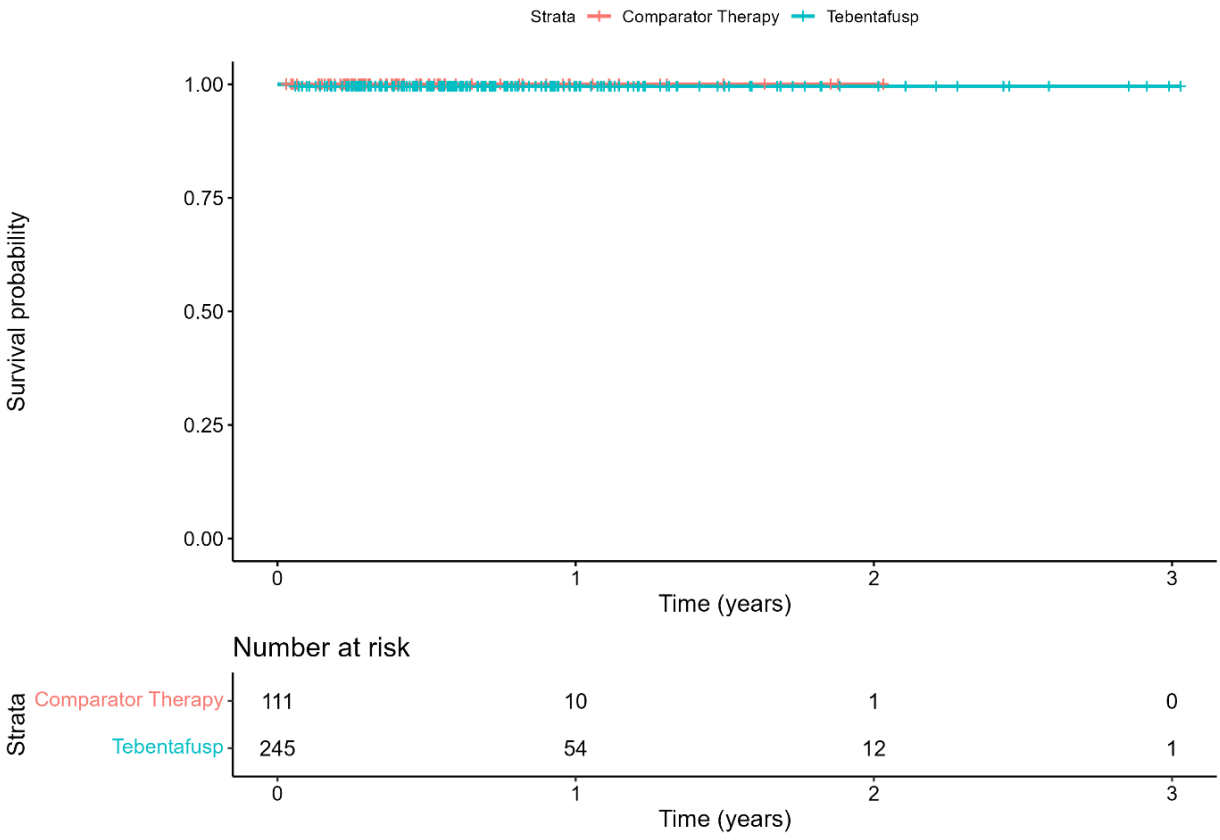
LFT-Erhöhung nach höchstem CTCAE-Grad 2



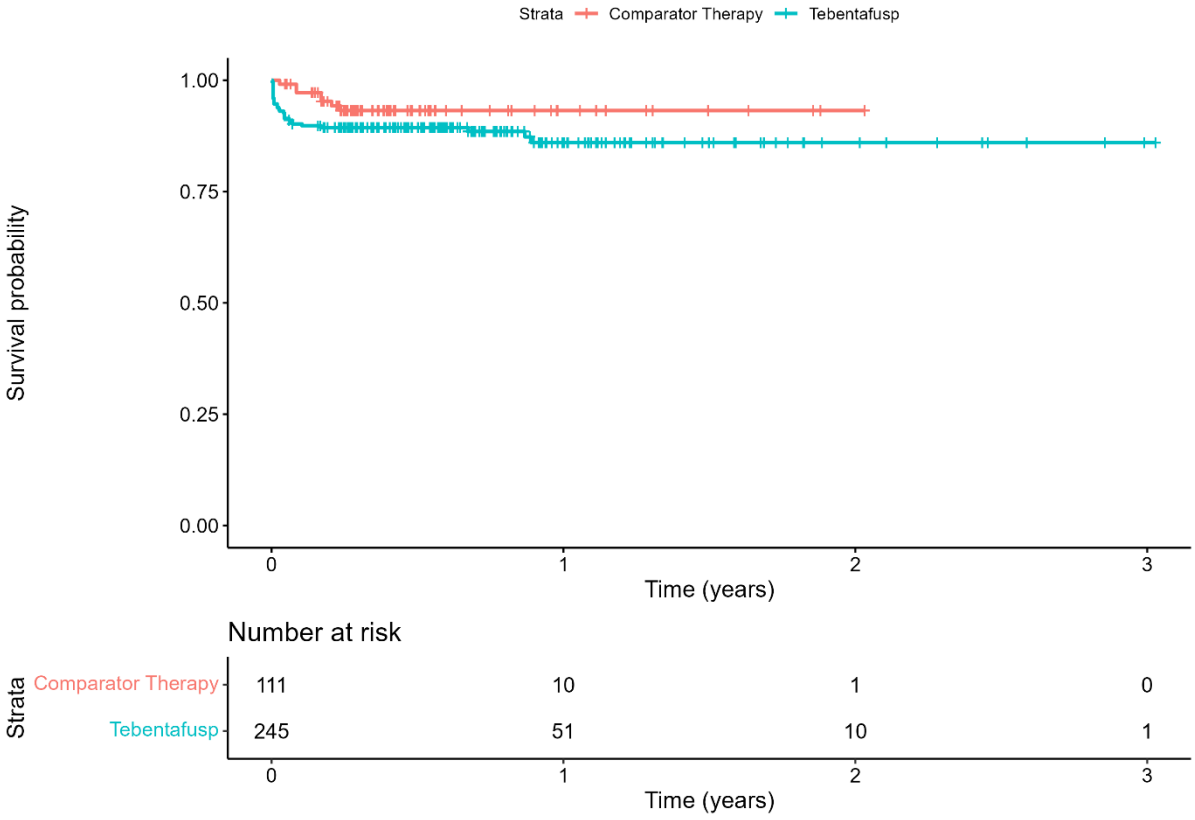
LFT-Erhöhung nach höchstem CTCAE-Grad 3



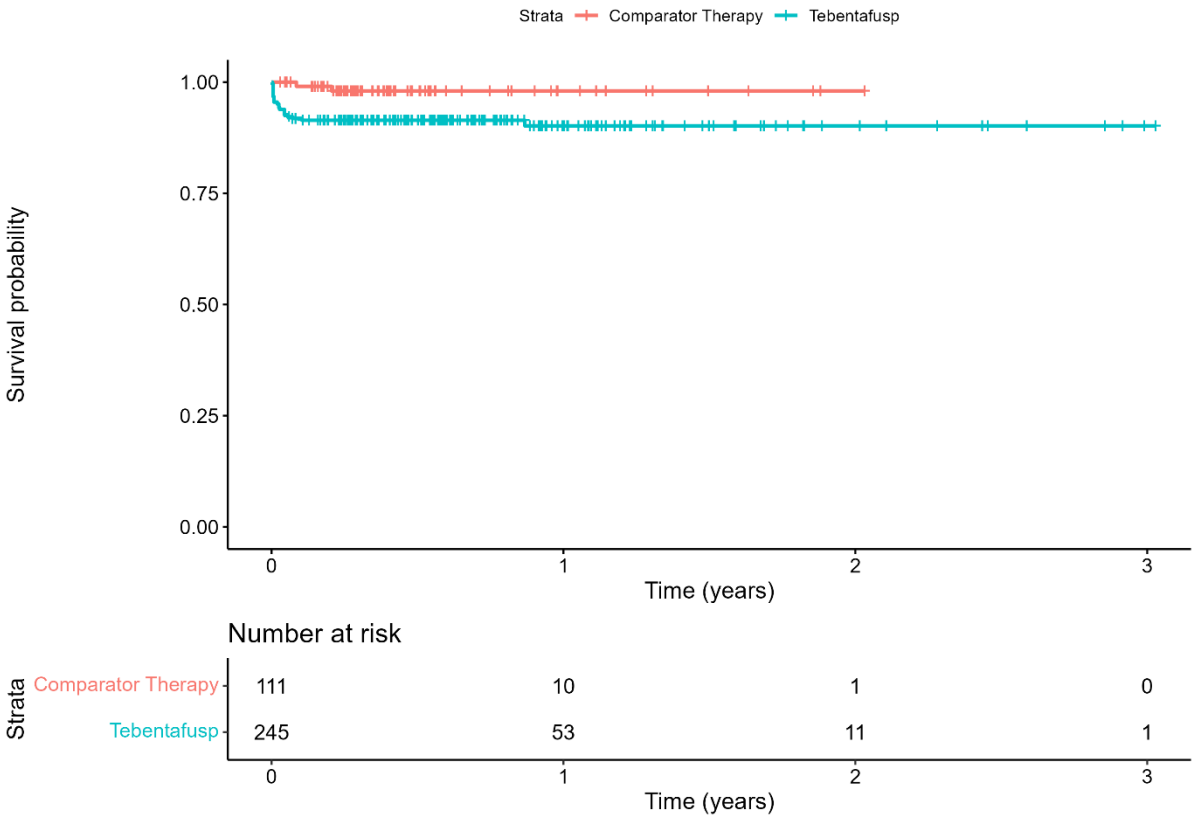
LFT-Erhöhung nach höchstem CTCAE-Grad 4



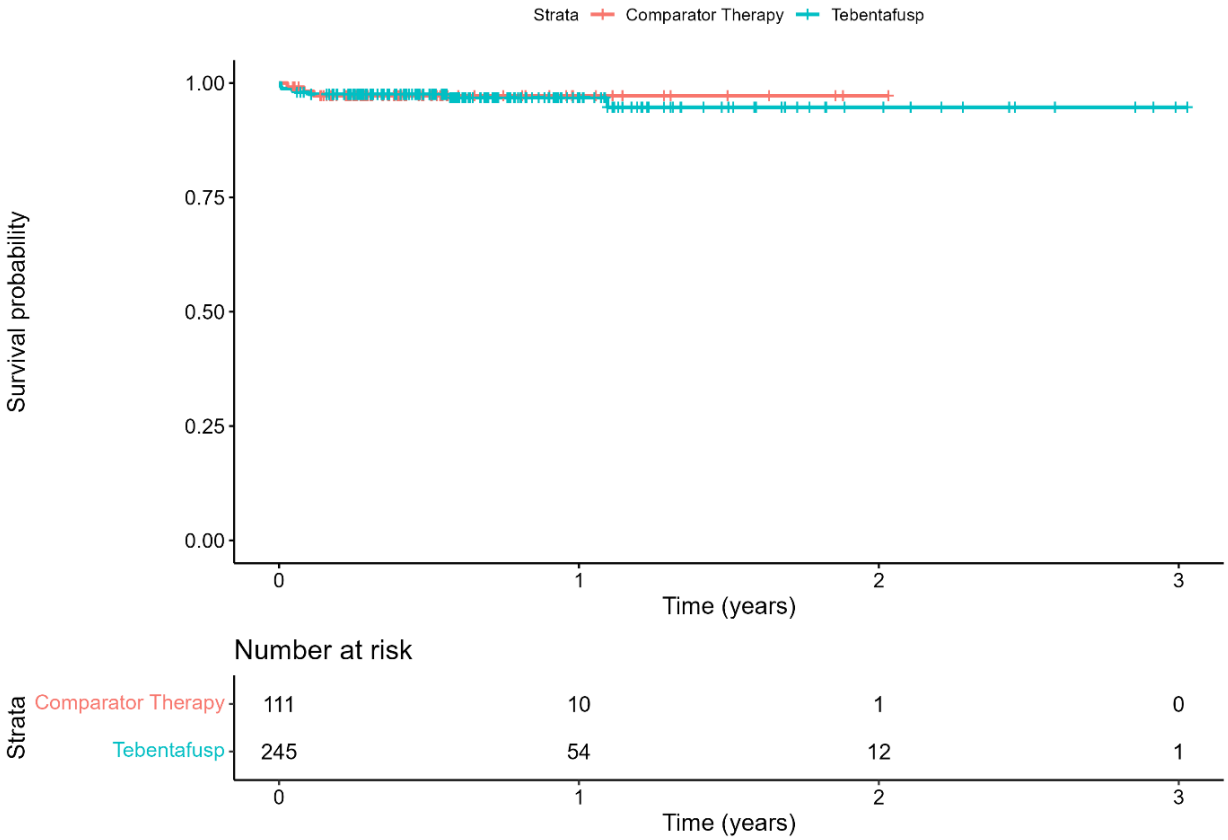
LFT-Erhöhung mit CTCAE-Grad ≥ 3



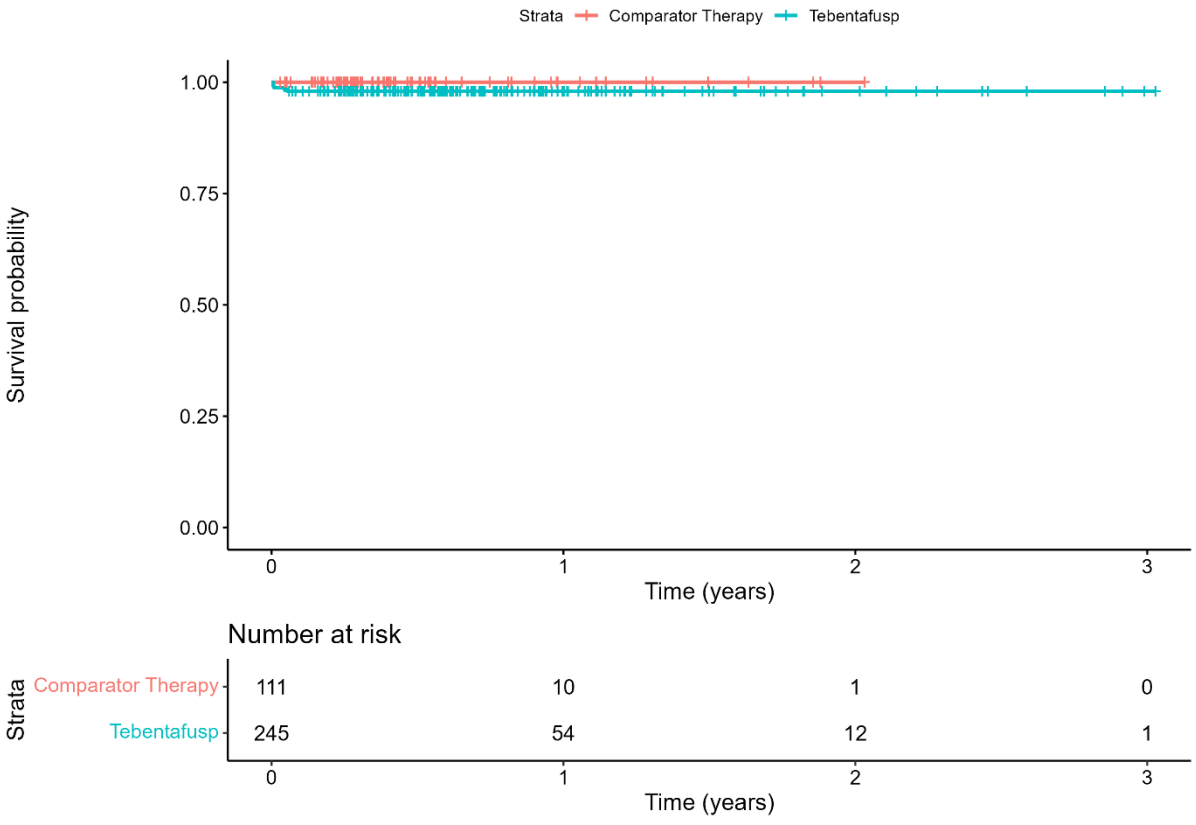
LFT-Erhöhung mit CTCAE-Grad ≥ 3, in kausalem Zusammenhang mit der Behandlung



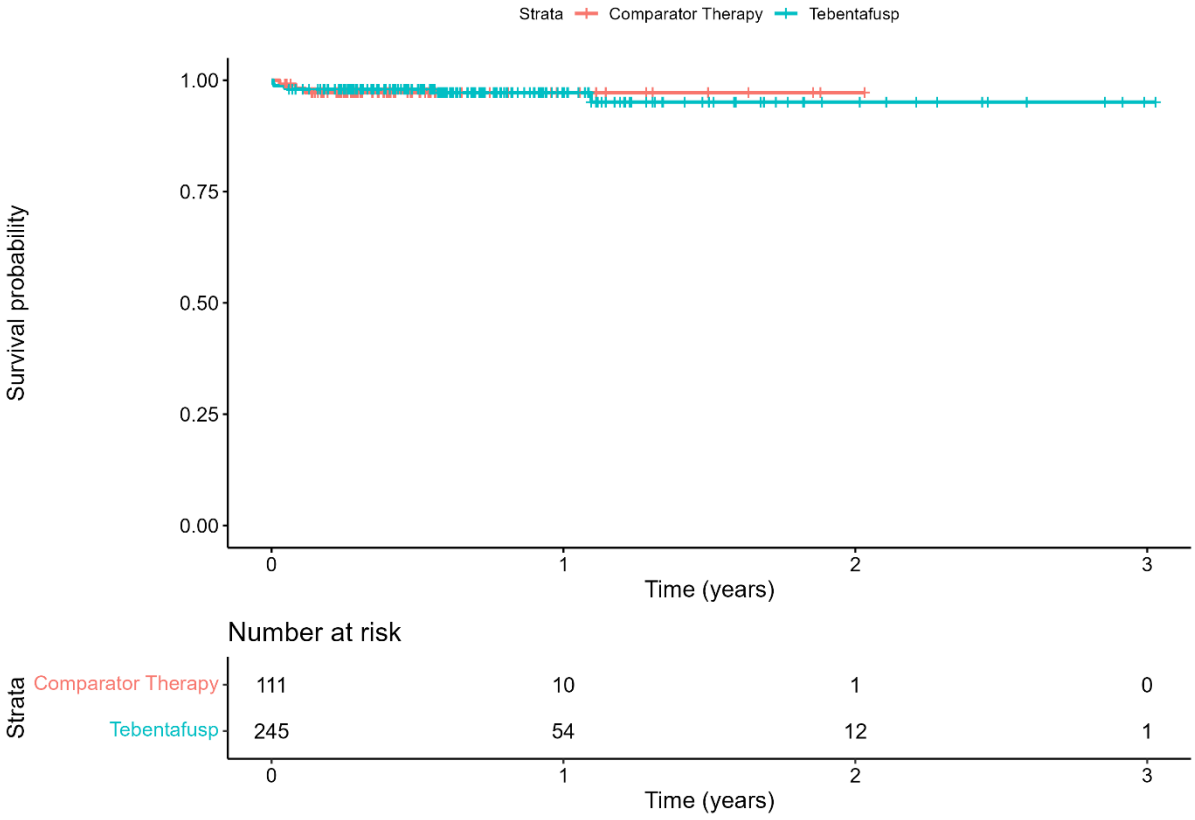
Schwerwiegende LFT-Erhöhung



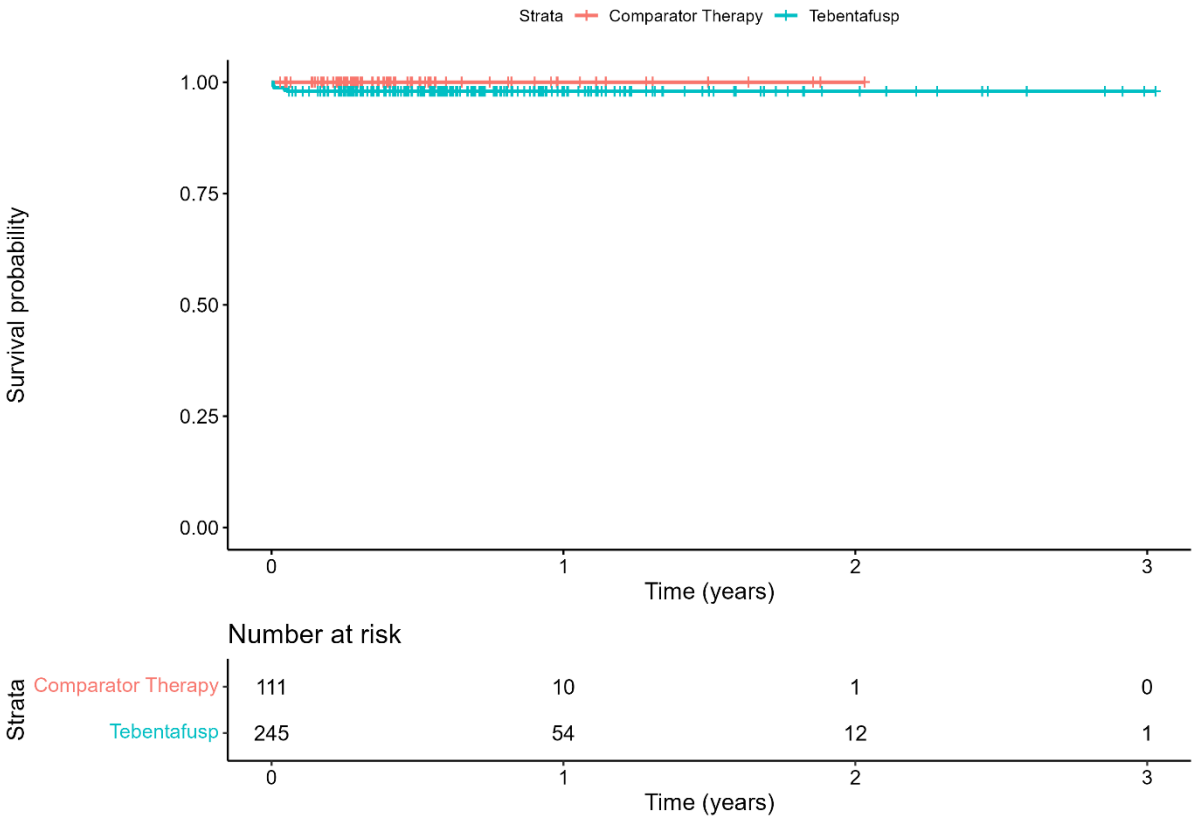
Schwerwiegende LFT-Erhöhung, in kausalem Zusammenhang mit der Behandlung



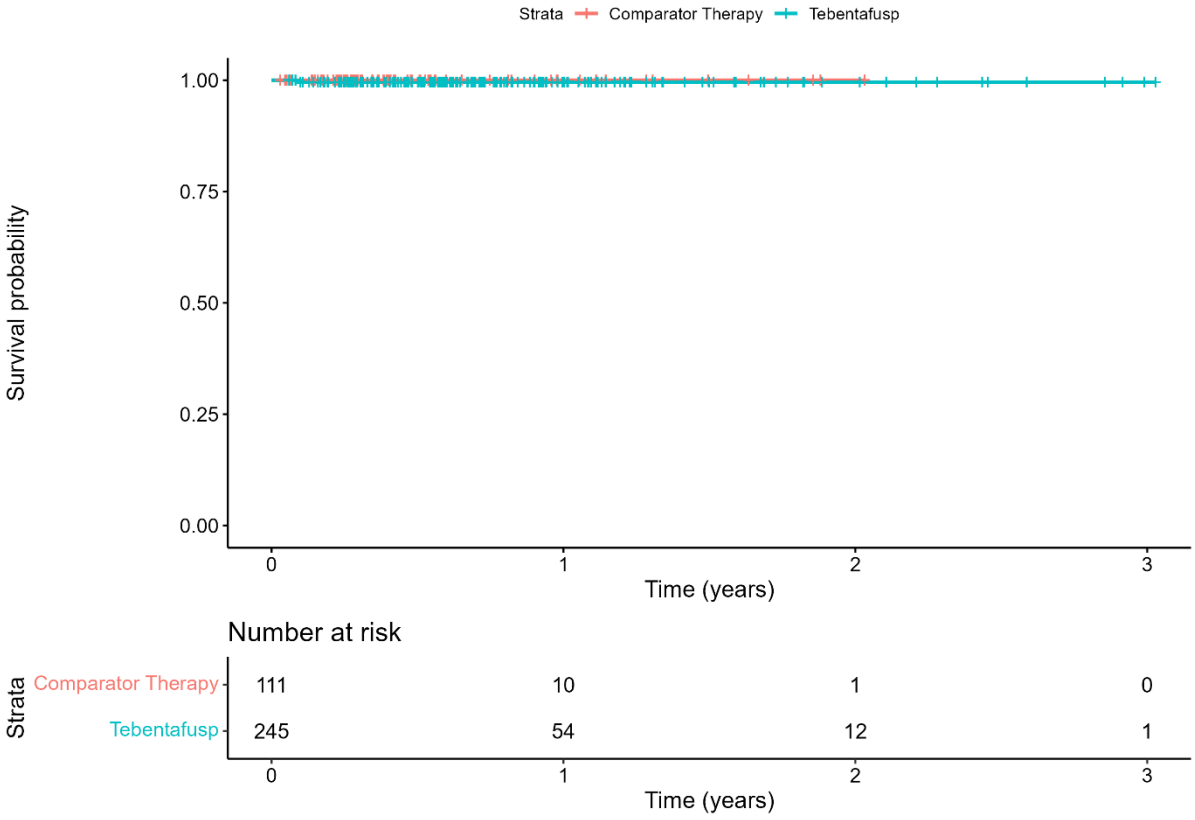
LFT-Erhöhung, die zu einem Krankenhausaufenthalt führte



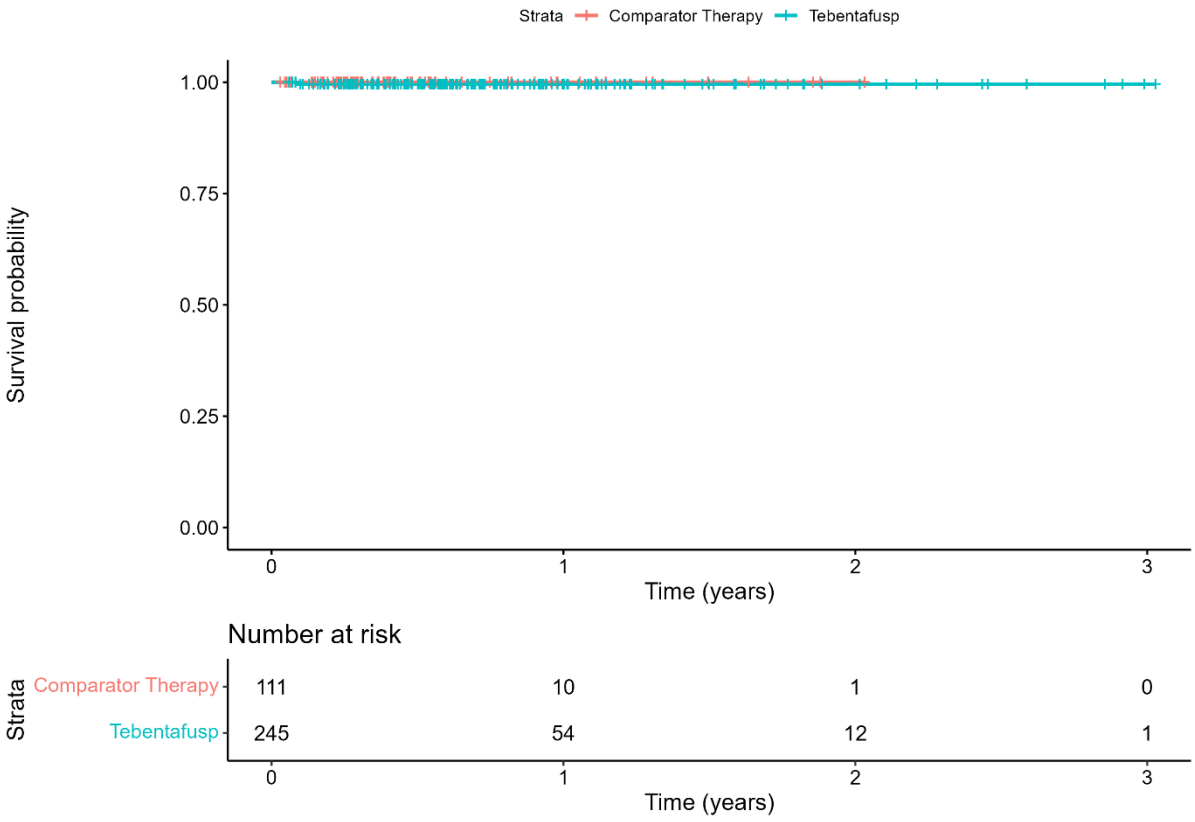
LFT-Erhöhung, die zu einem Krankenhausaufenthalt führte, in kausalem Zusammenhang mit der Behandlung



LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte

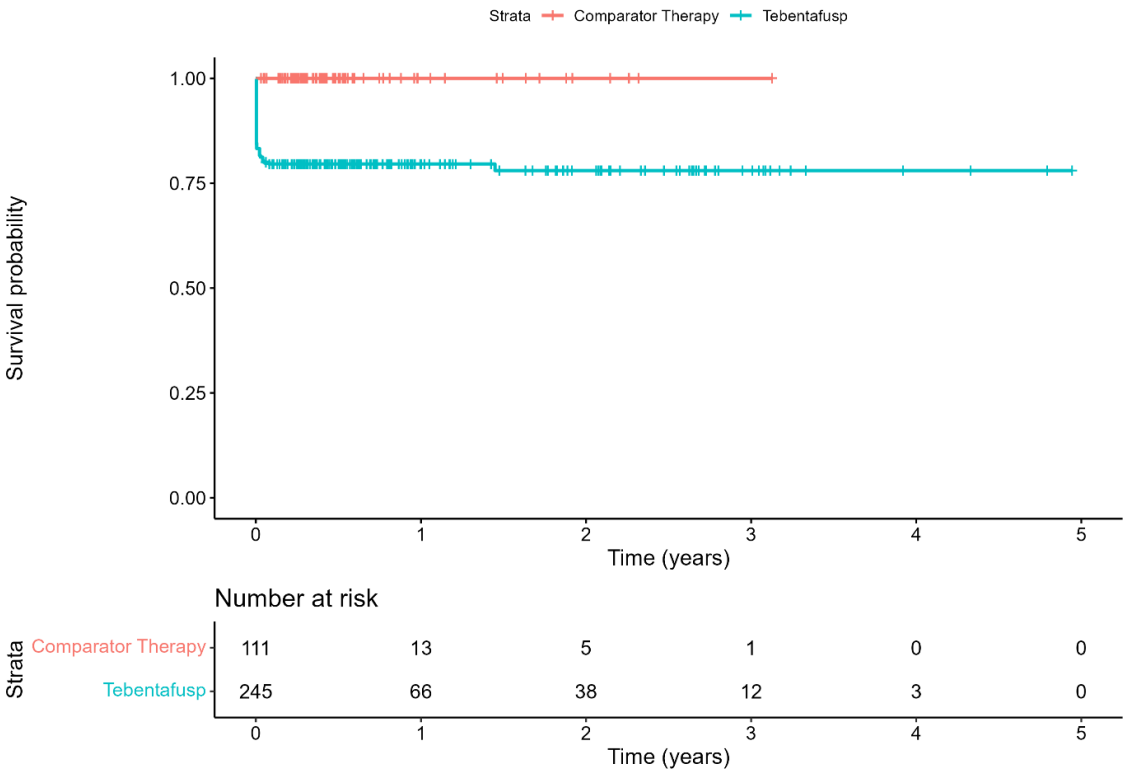


LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte, in kausalem Zusammenhang mit der Behandlung

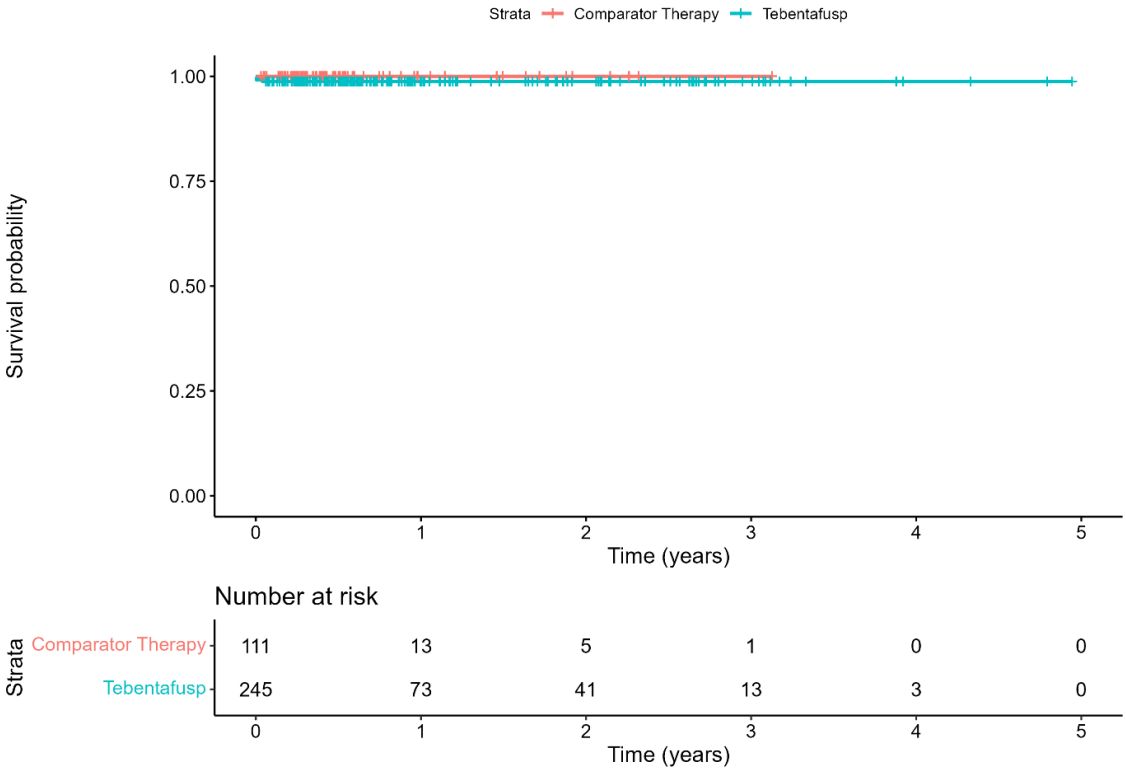


37.9 3-Jahres-Analyse (Juni 2023) (Tabelle 4-59)

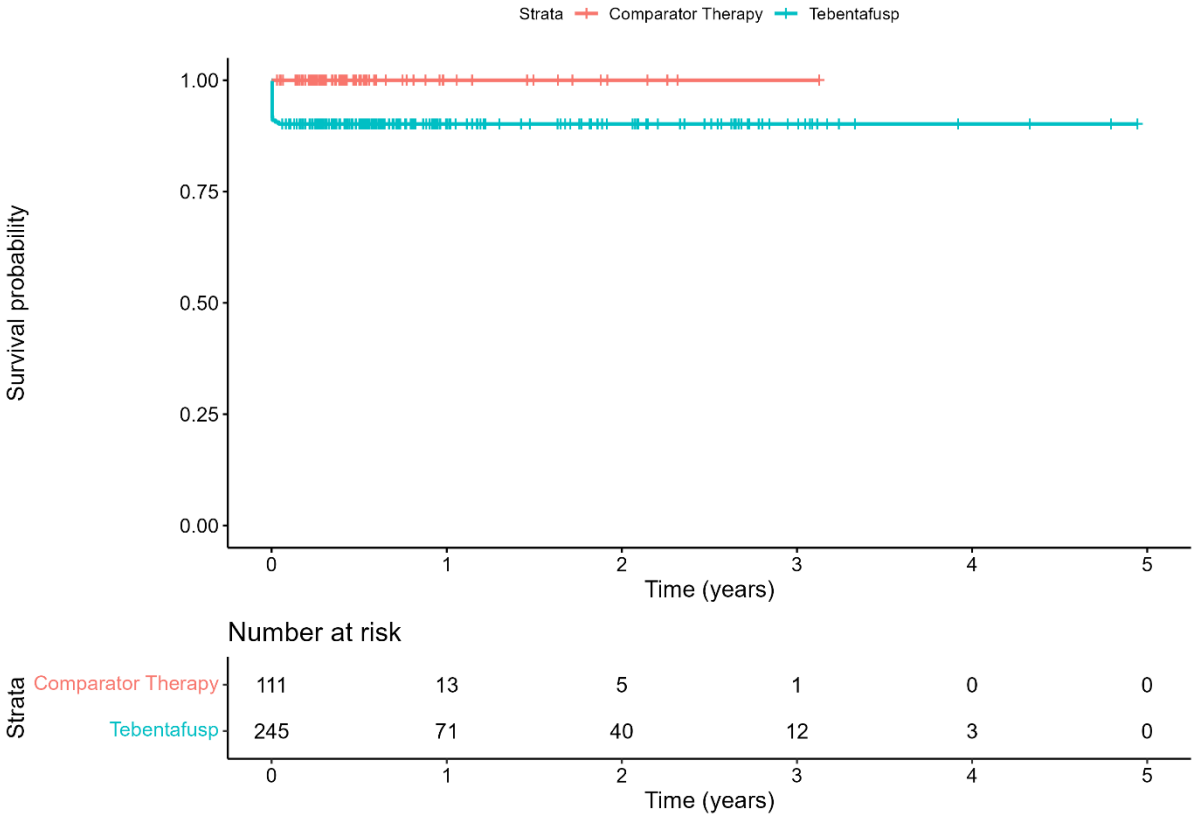
Zytokin-Freisetzungssyndrom



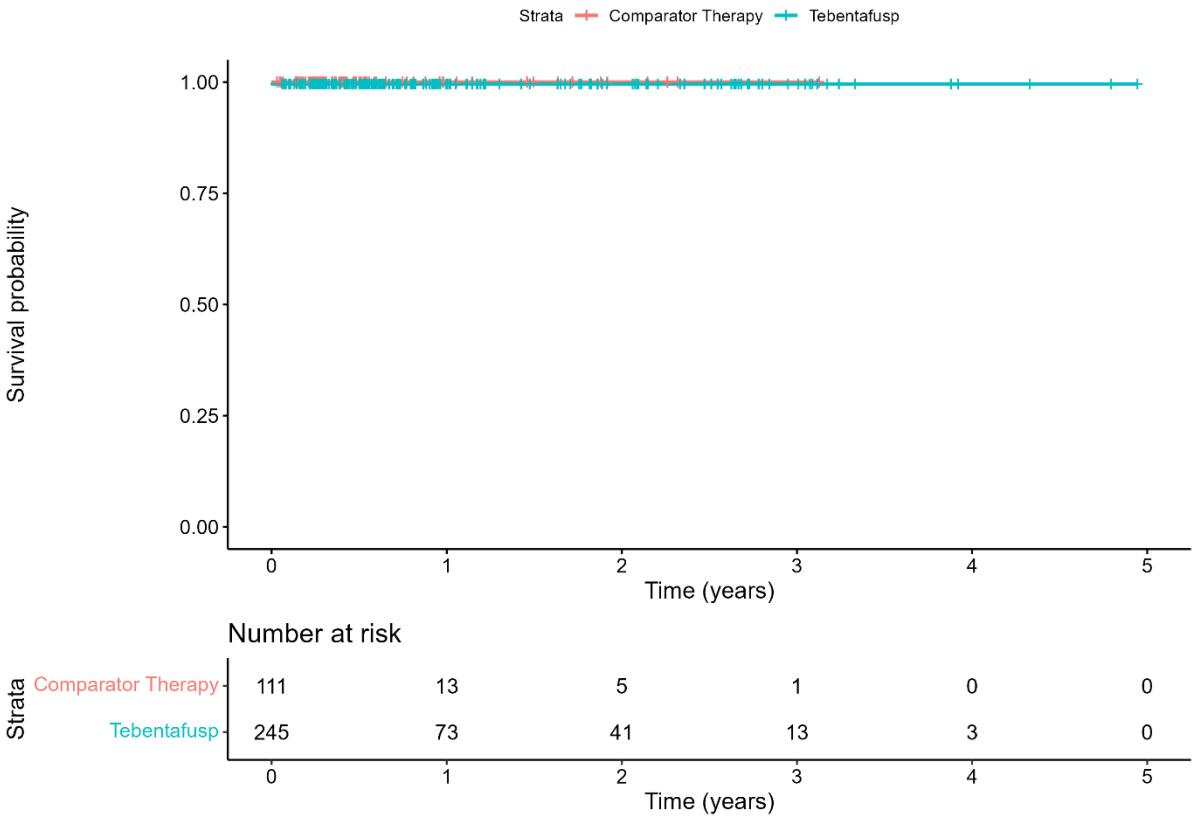
Zytokin-Freisetzungssyndrom mit CTCAE-Grad ≥ 3



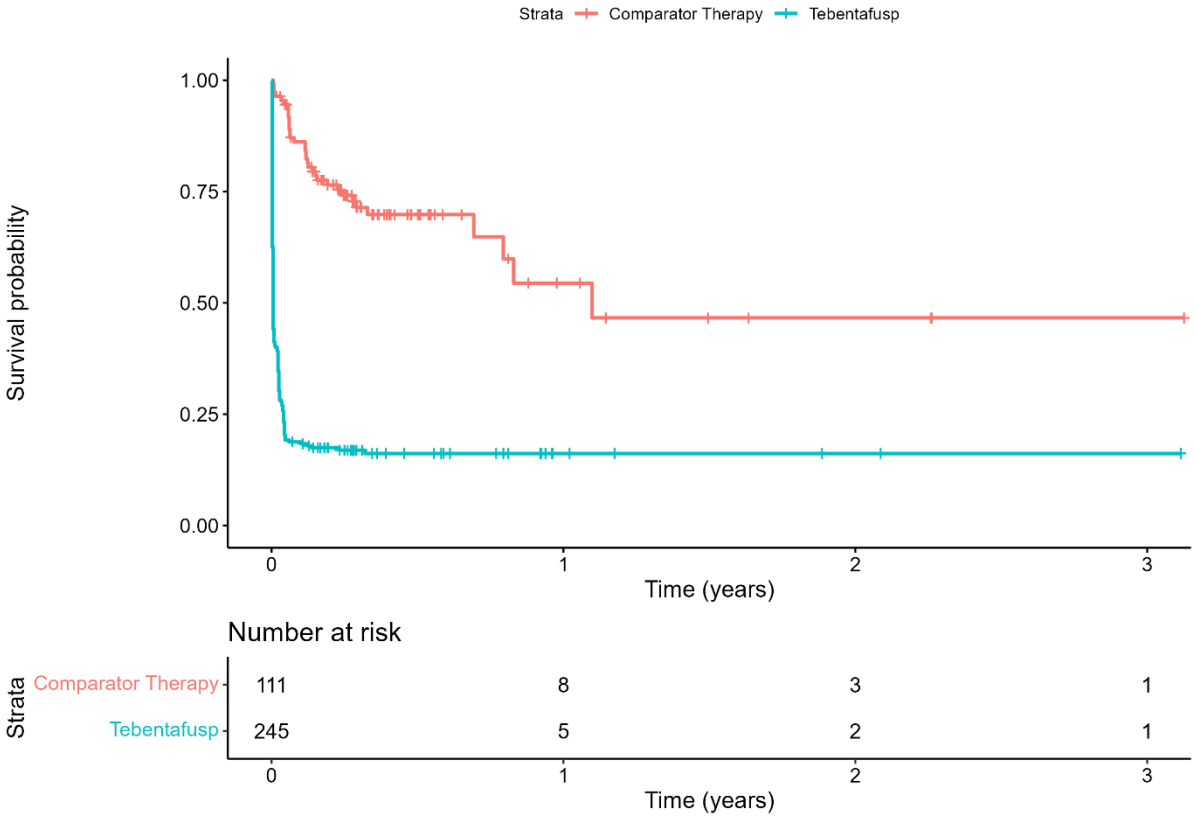
Schwerwiegendes Zytokin-Freisetzungssyndrom



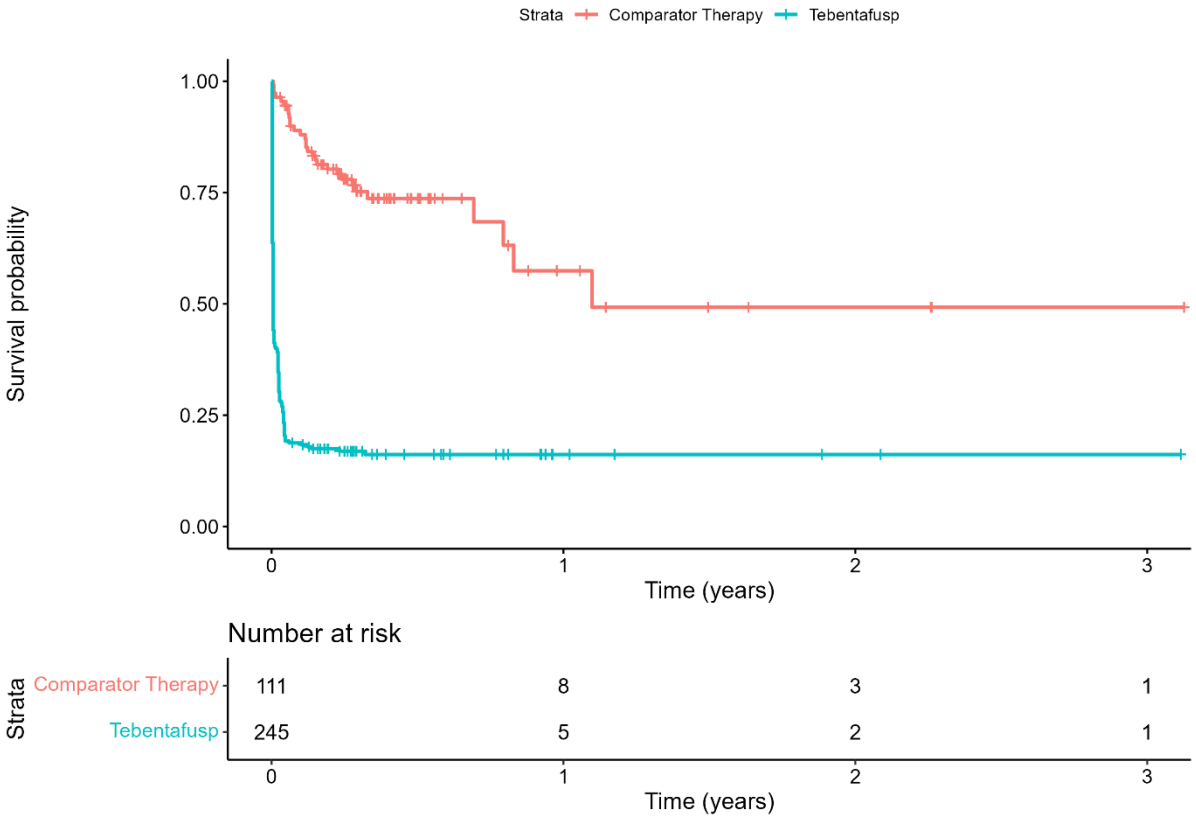
Zytokin-Freisetzungssyndrom, das zum Absetzen des Studienmedikaments führte



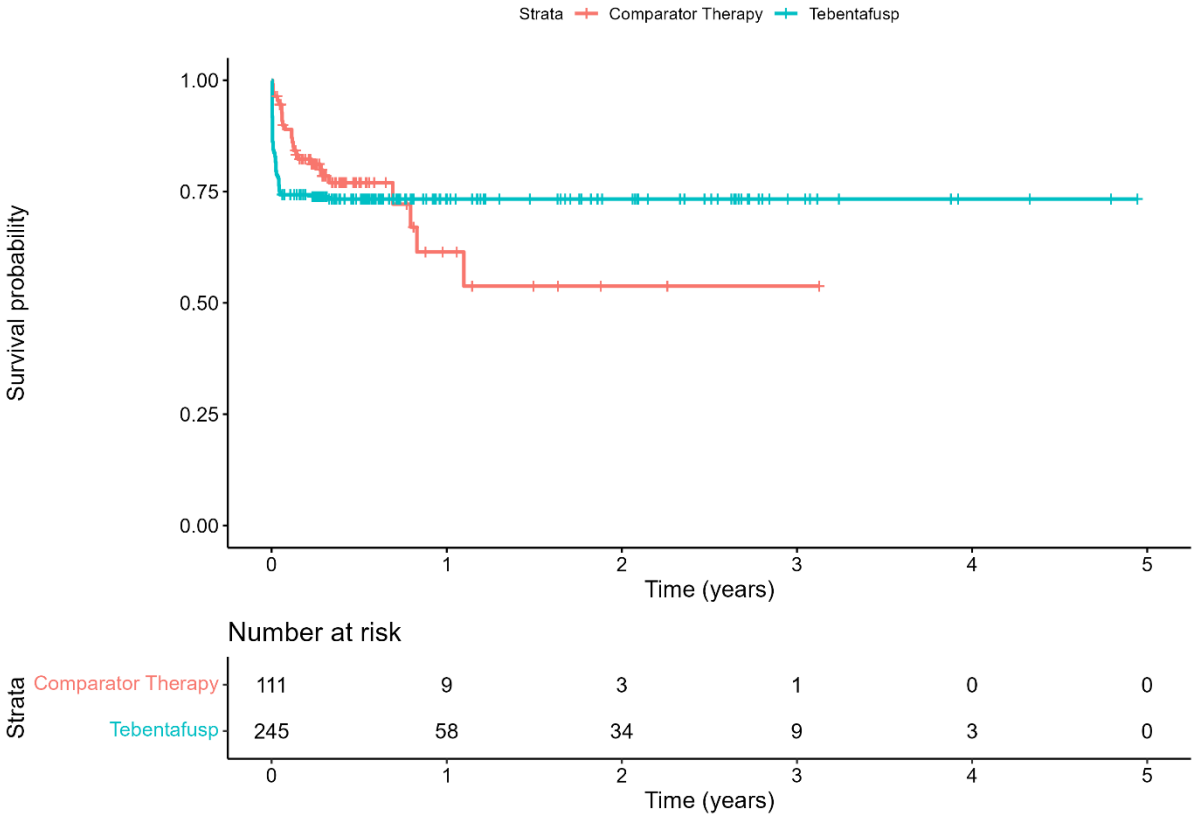
Hautausschlag



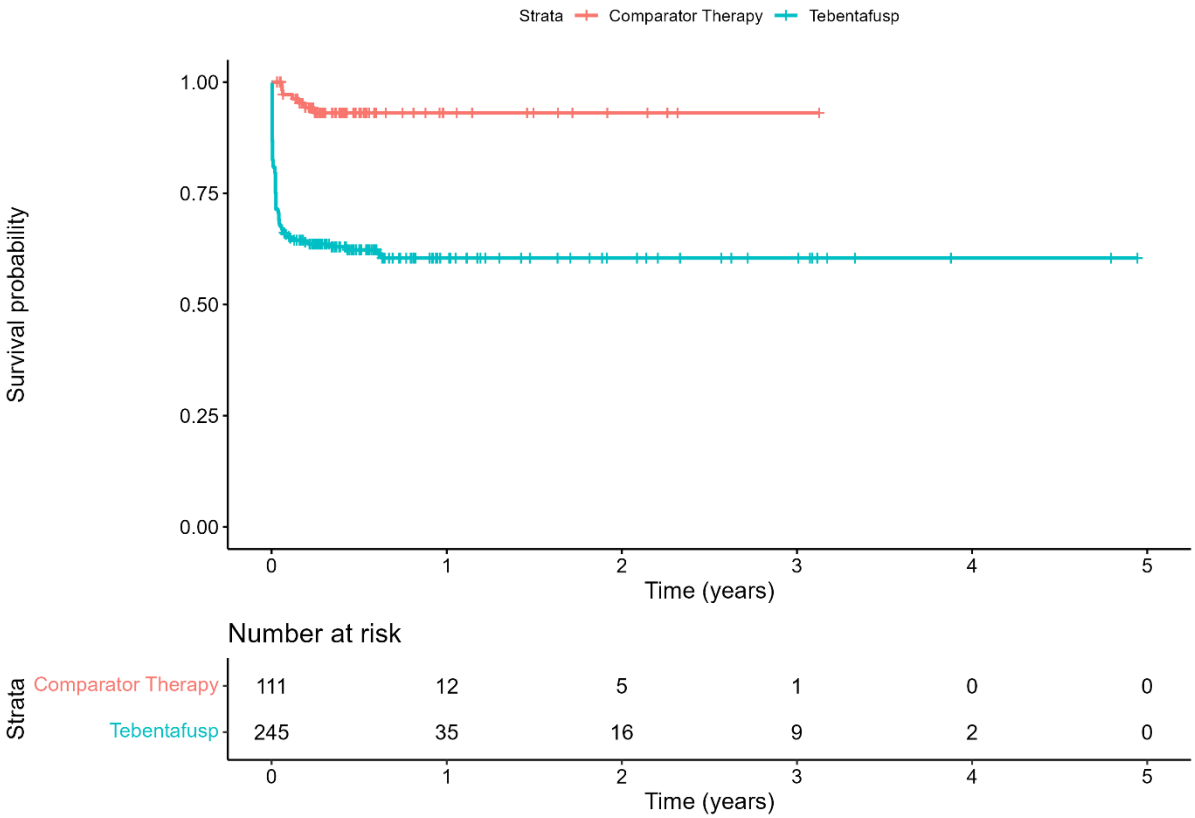
Hautausschlag in kausalem Zusammenhang mit der Behandlung



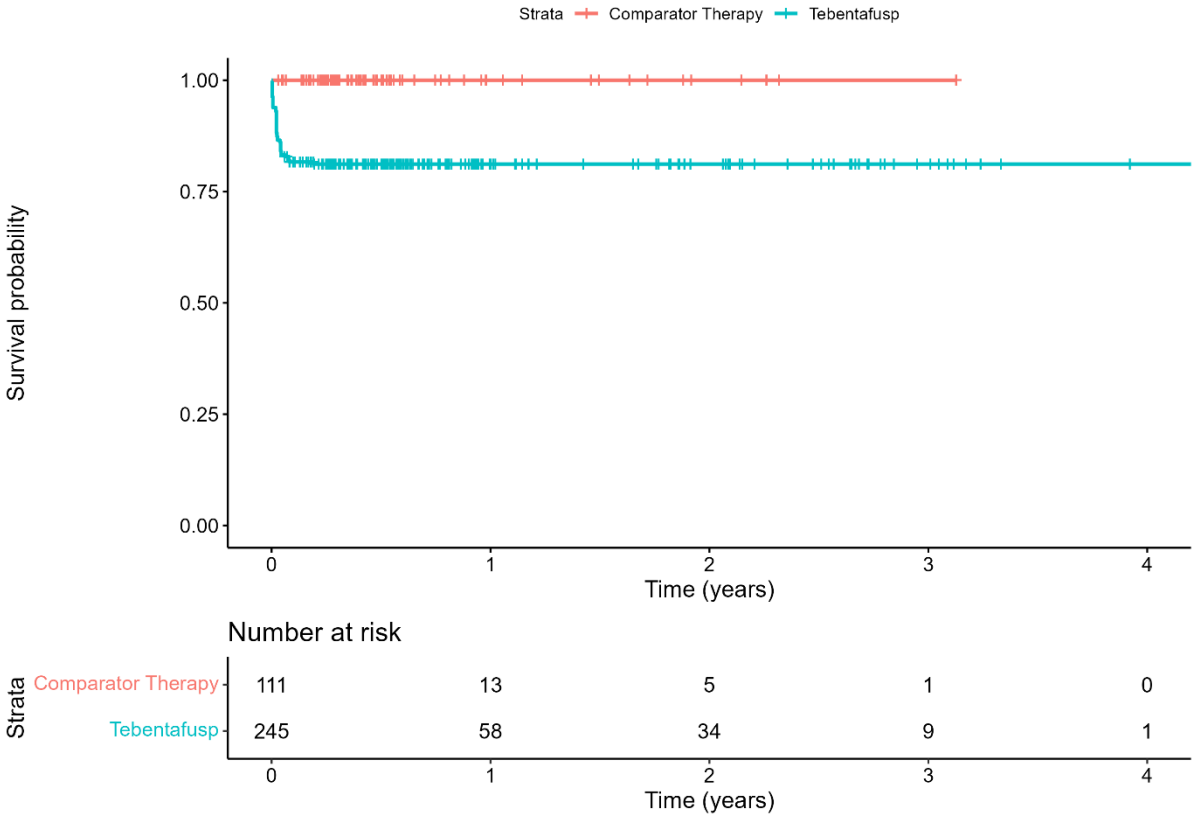
Hautausschlag nach höchstem CTCAE-Grad 1



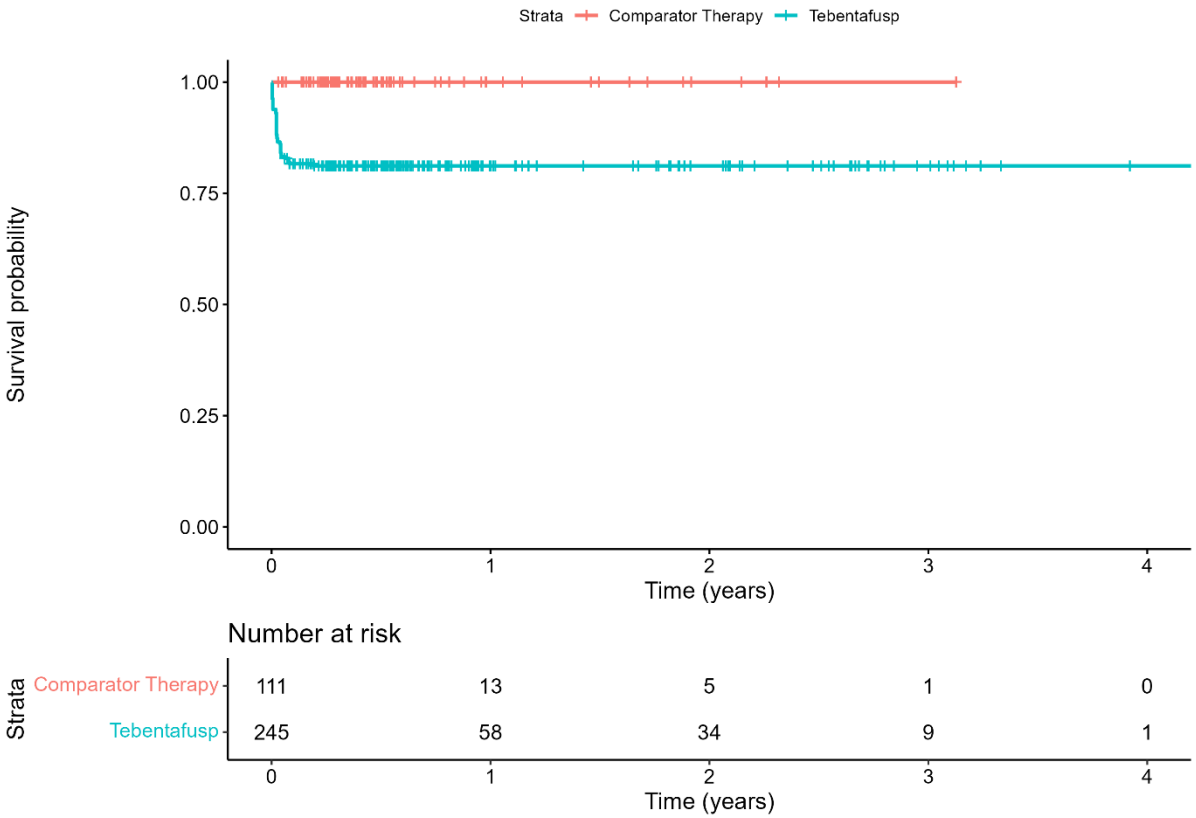
Hautausschlag nach höchstem CTCAE-Grad 2



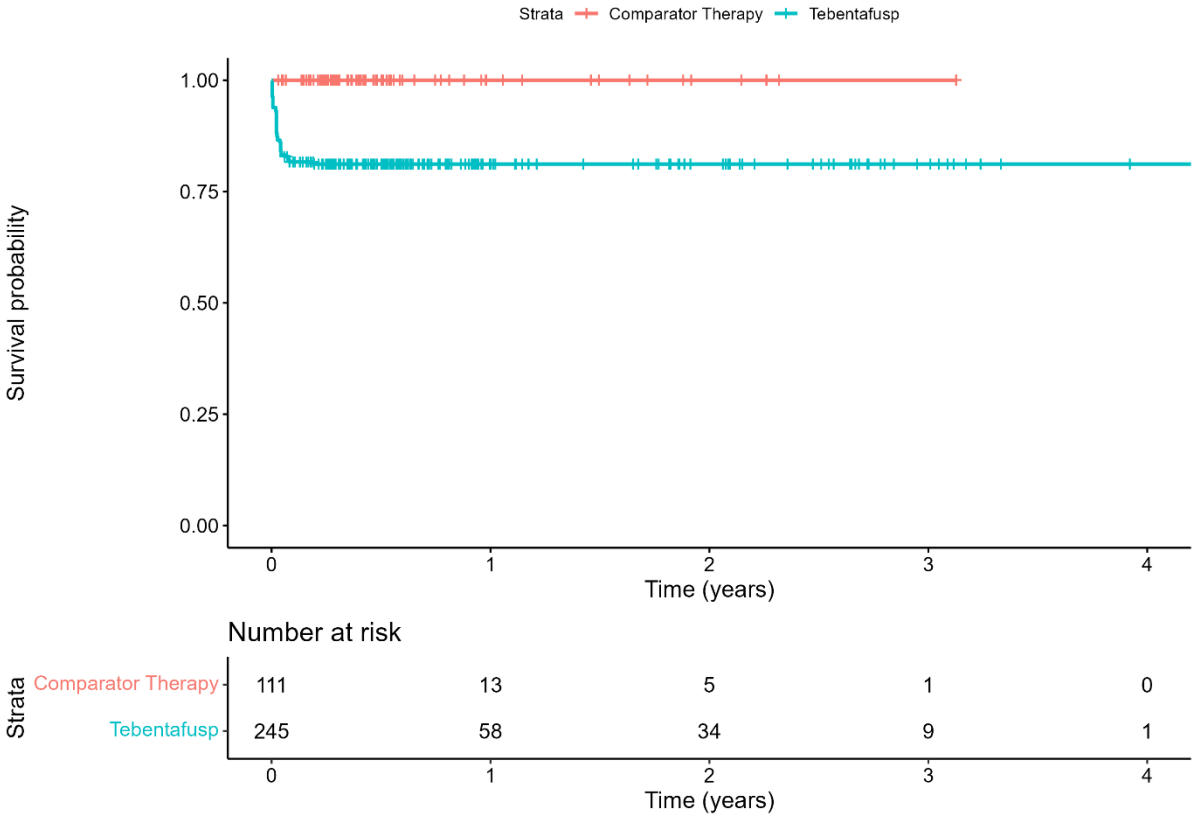
Hautausschlag nach höchstem CTCAE-Grad 3



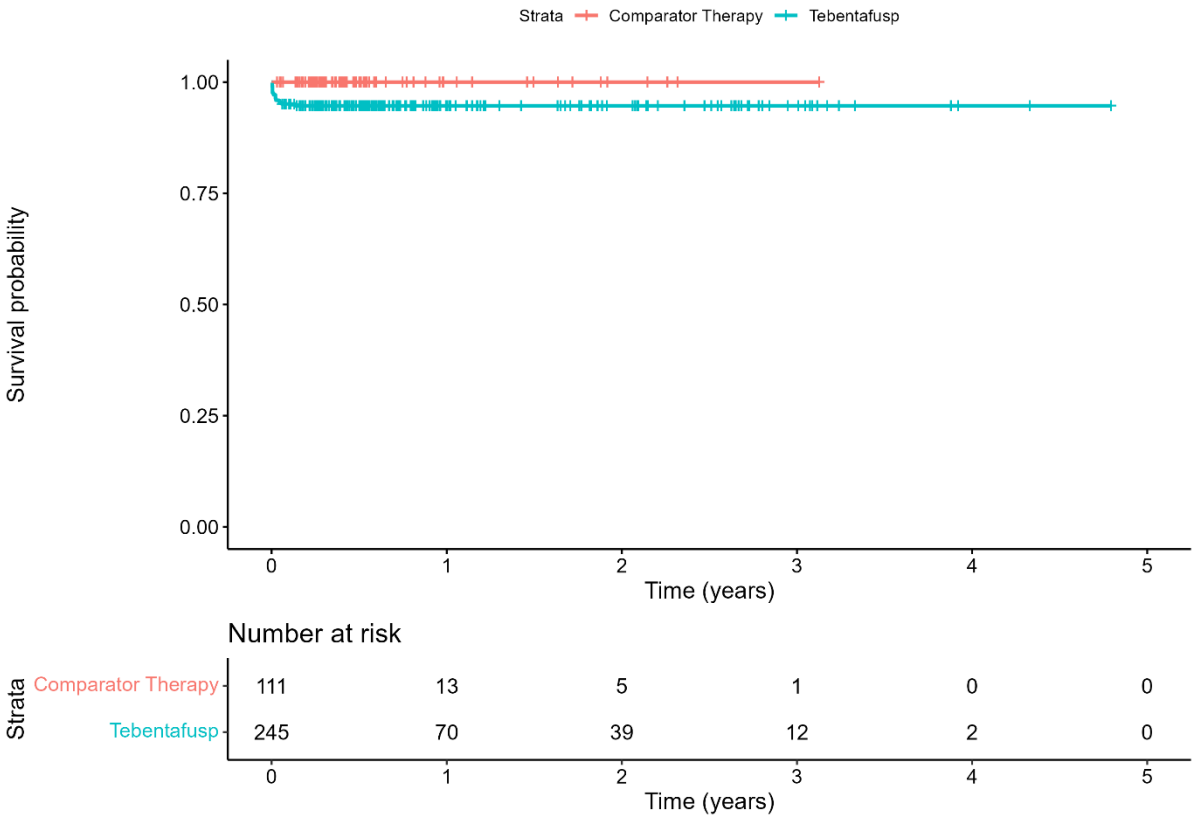
Hautausschlag mit CTCAE-Grad ≥ 3



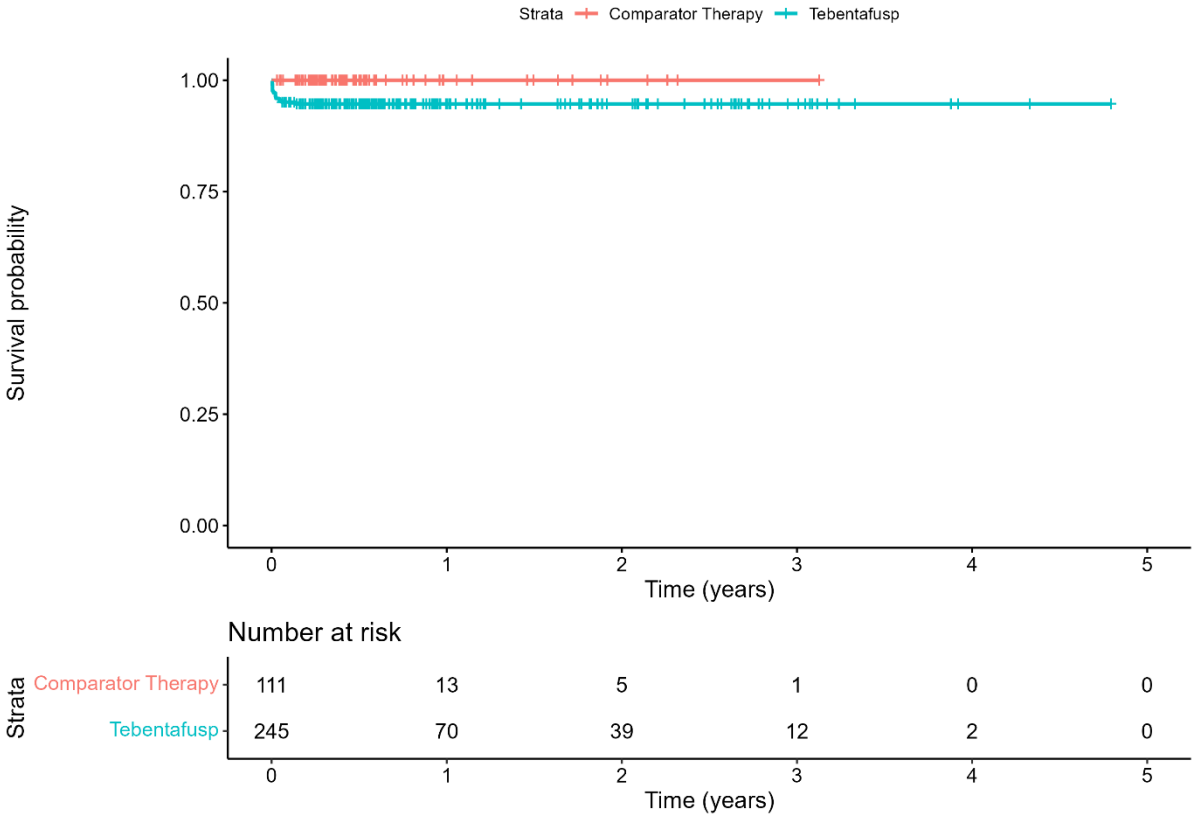
Hautausschlag mit CTCAE-Grad ≥ 3, in kausalem Zusammenhang mit der Behandlung



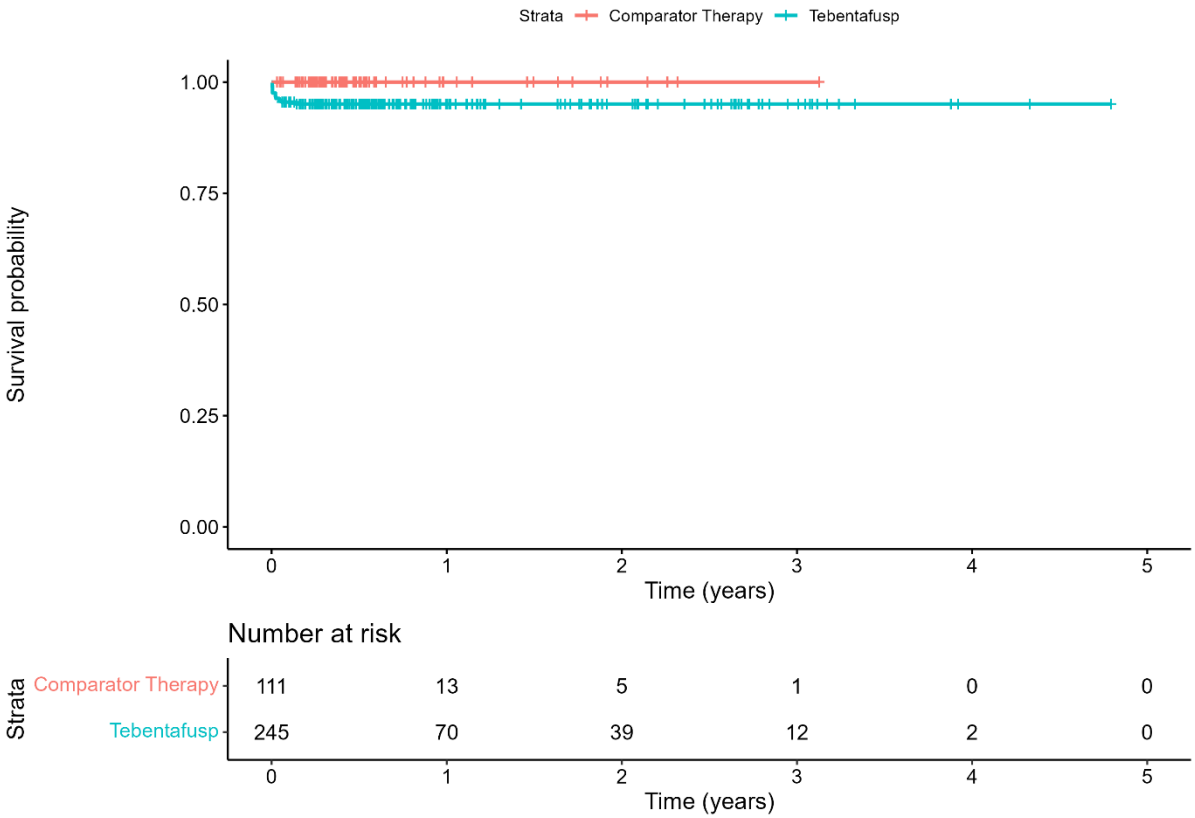
Schwerwiegender Hautausschlag



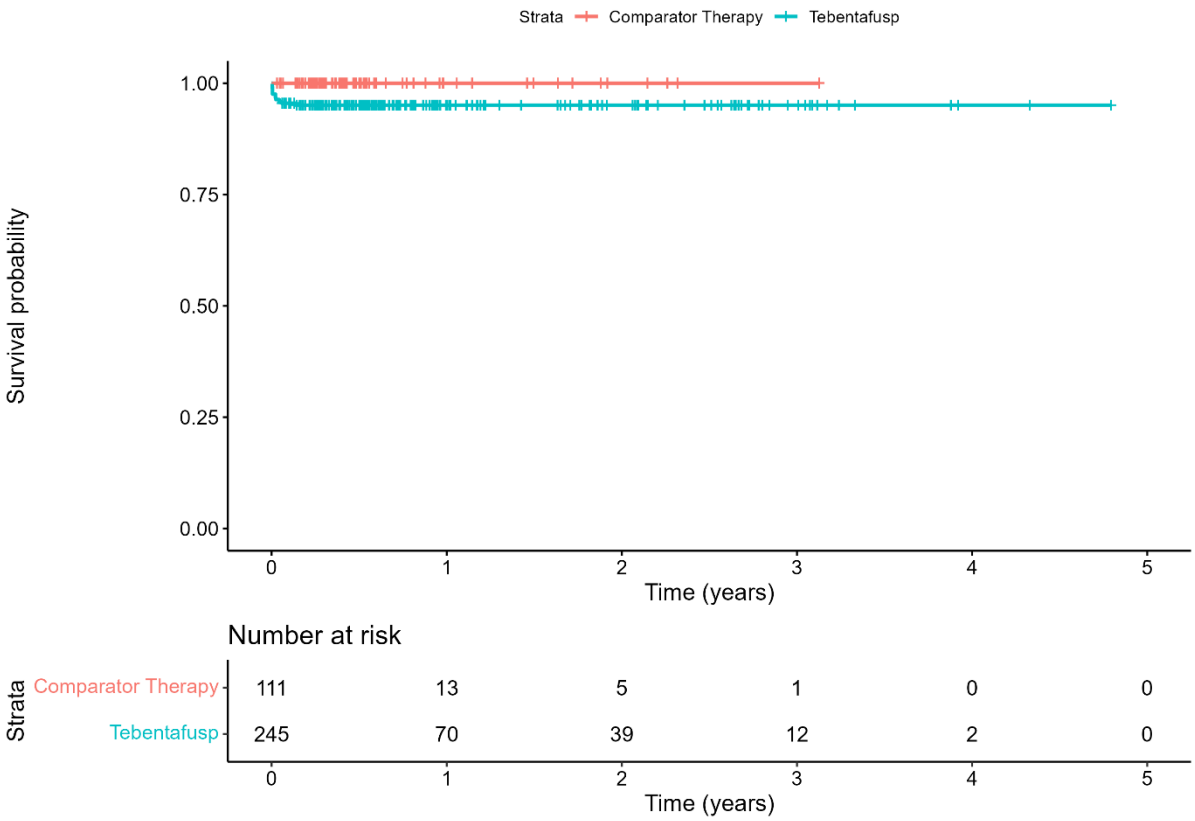
Schwerwiegender Hautausschlag, in kausalem Zusammenhang mit der Behandlung



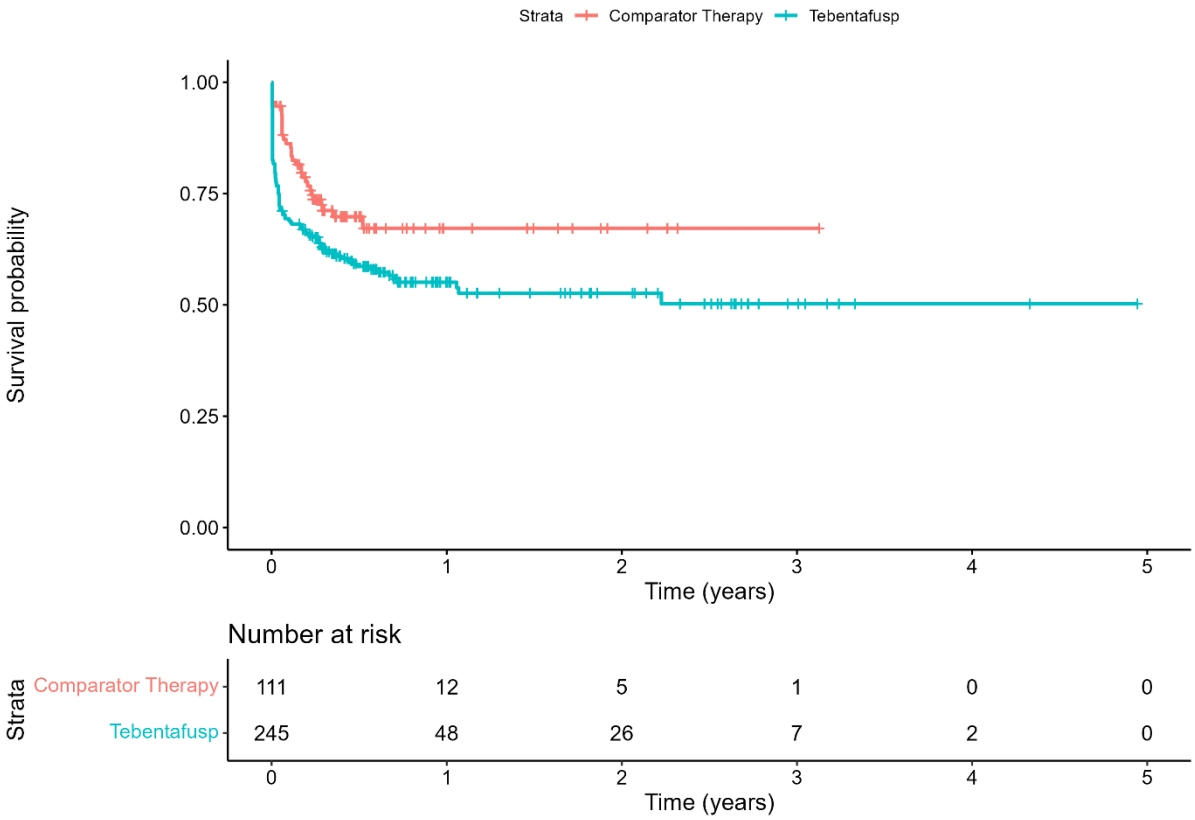
Hautausschlag, der zu einem Krankenhausaufenthalt führte



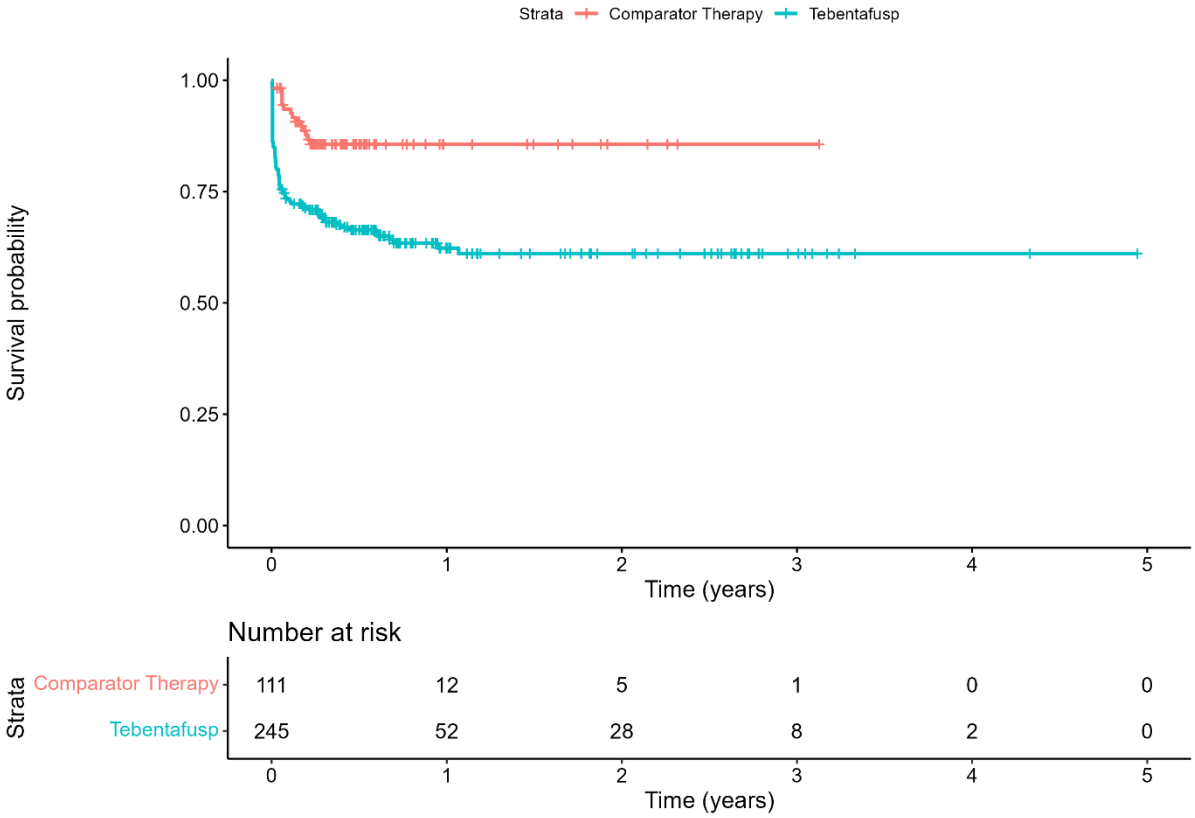
Hautausschlag, der zu einem Krankenhausaufenthalt führte, in kausalem Zusammenhang mit der Behandlung



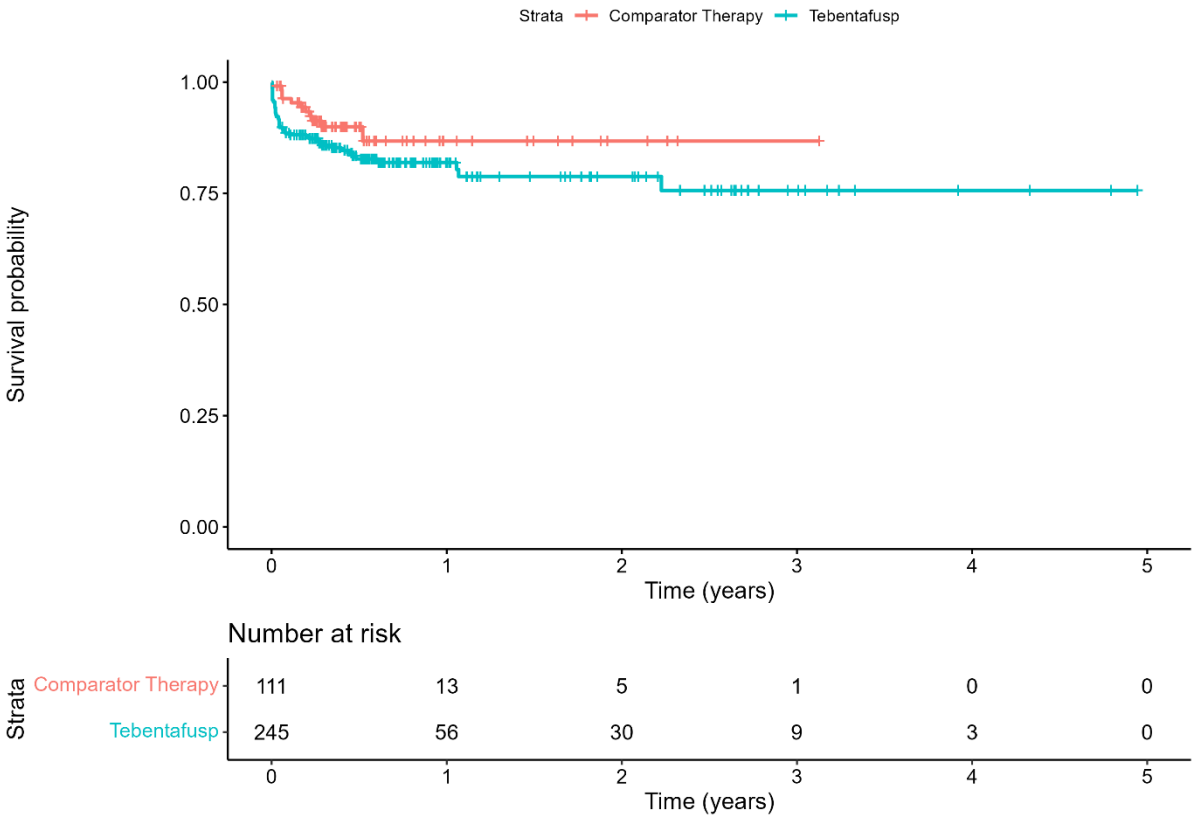
LFT-Erhöhung



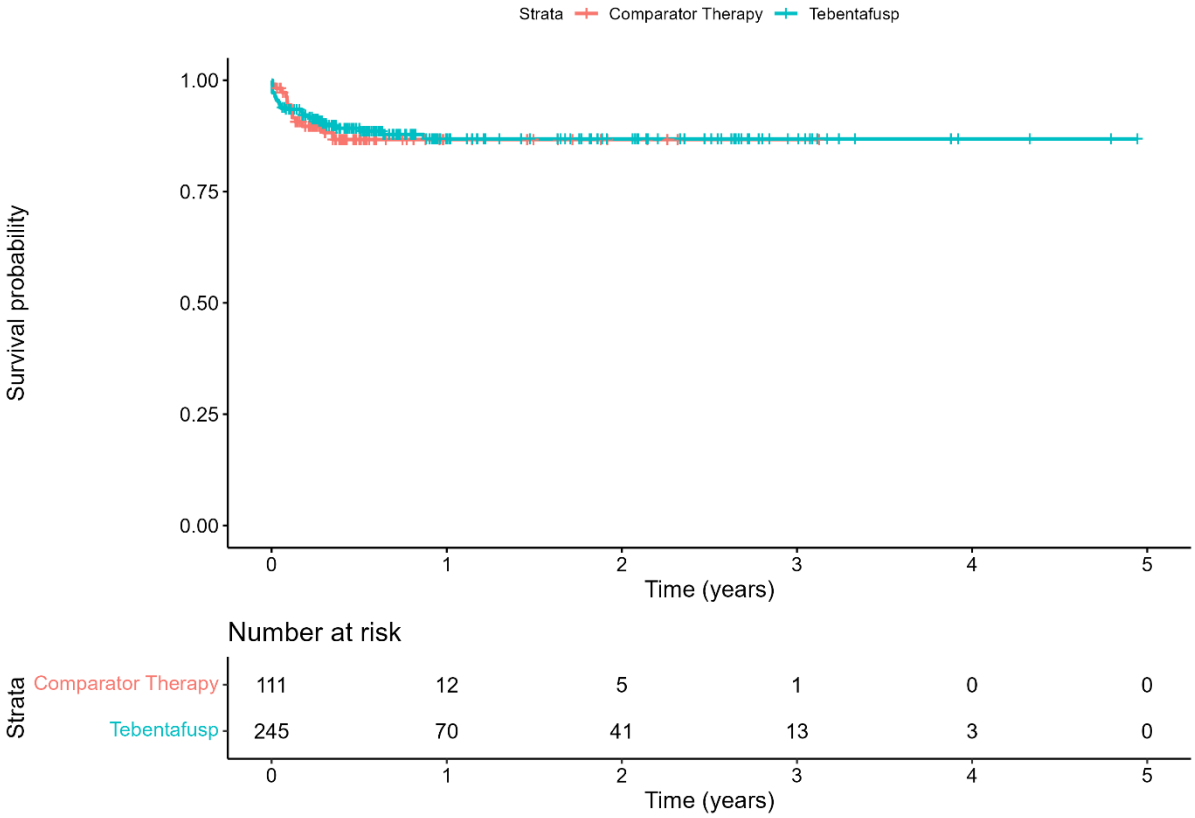
LFT-Erhöhung in kausalem Zusammenhang mit der Behandlung



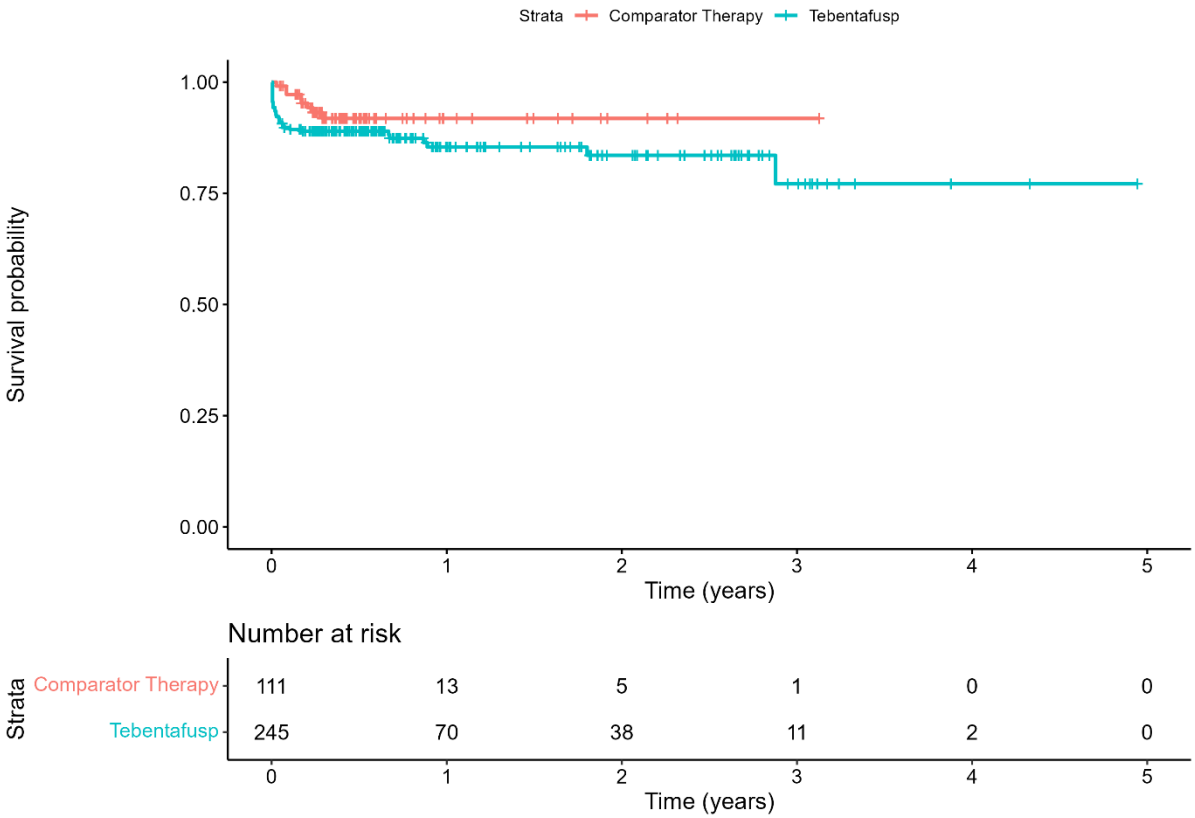
LFT-Erhöhung nach höchstem CTCAE-Grad 1



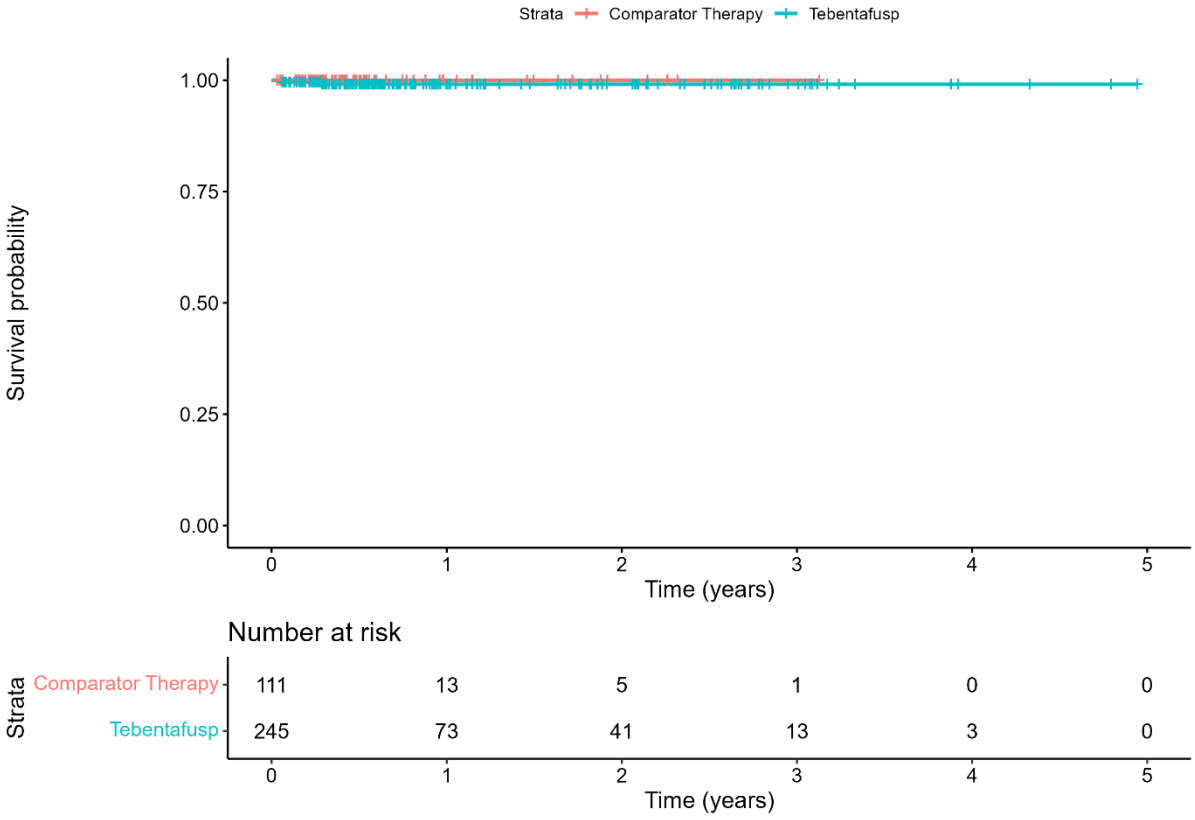
LFT-Erhöhung nach höchstem CTCAE-Grad 2



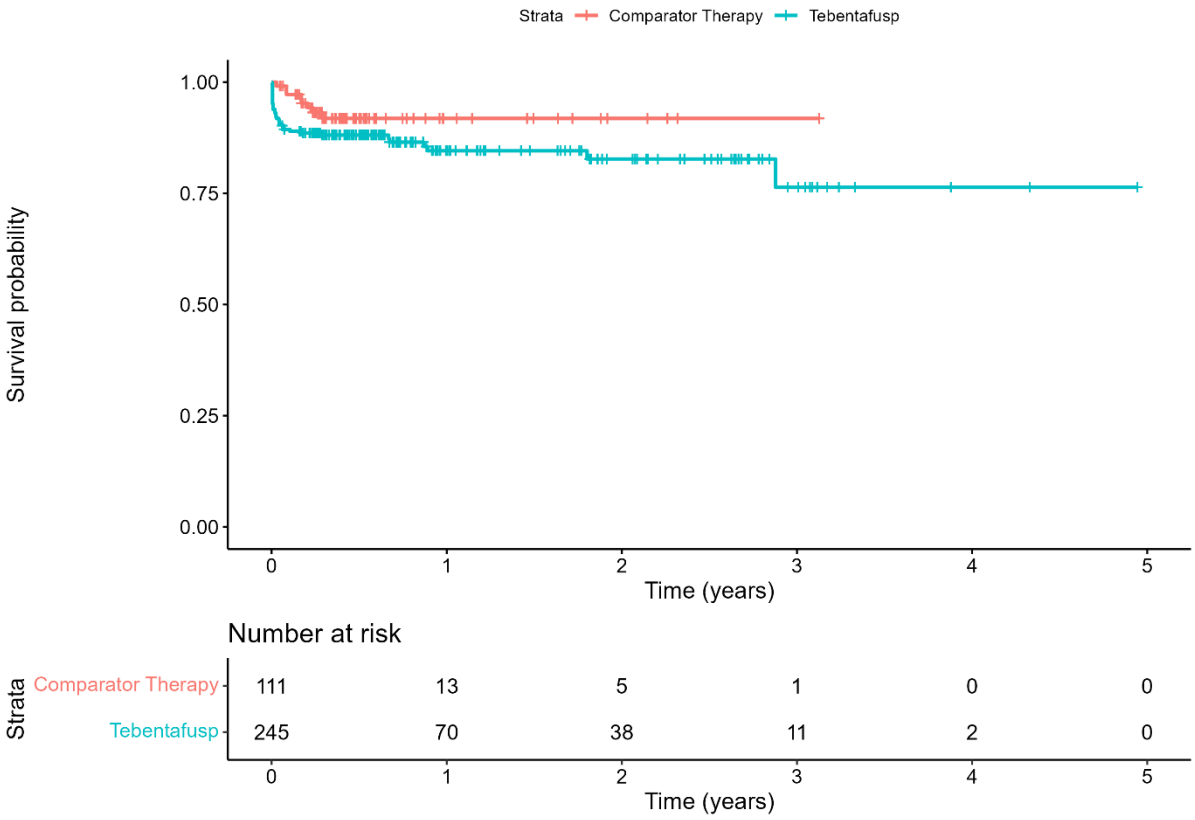
LFT-Erhöhung nach höchstem CTCAE-Grad 3



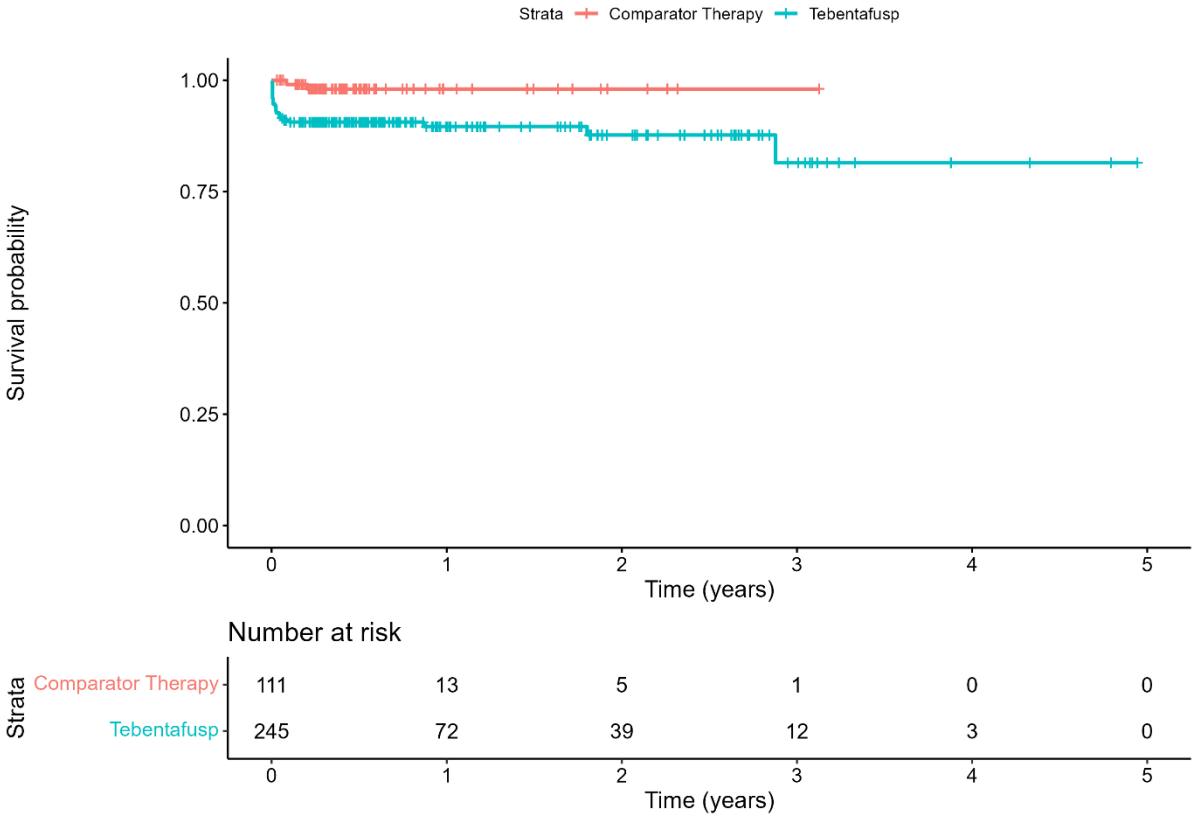
LFT-Erhöhung nach höchstem CTCAE-Grad 4



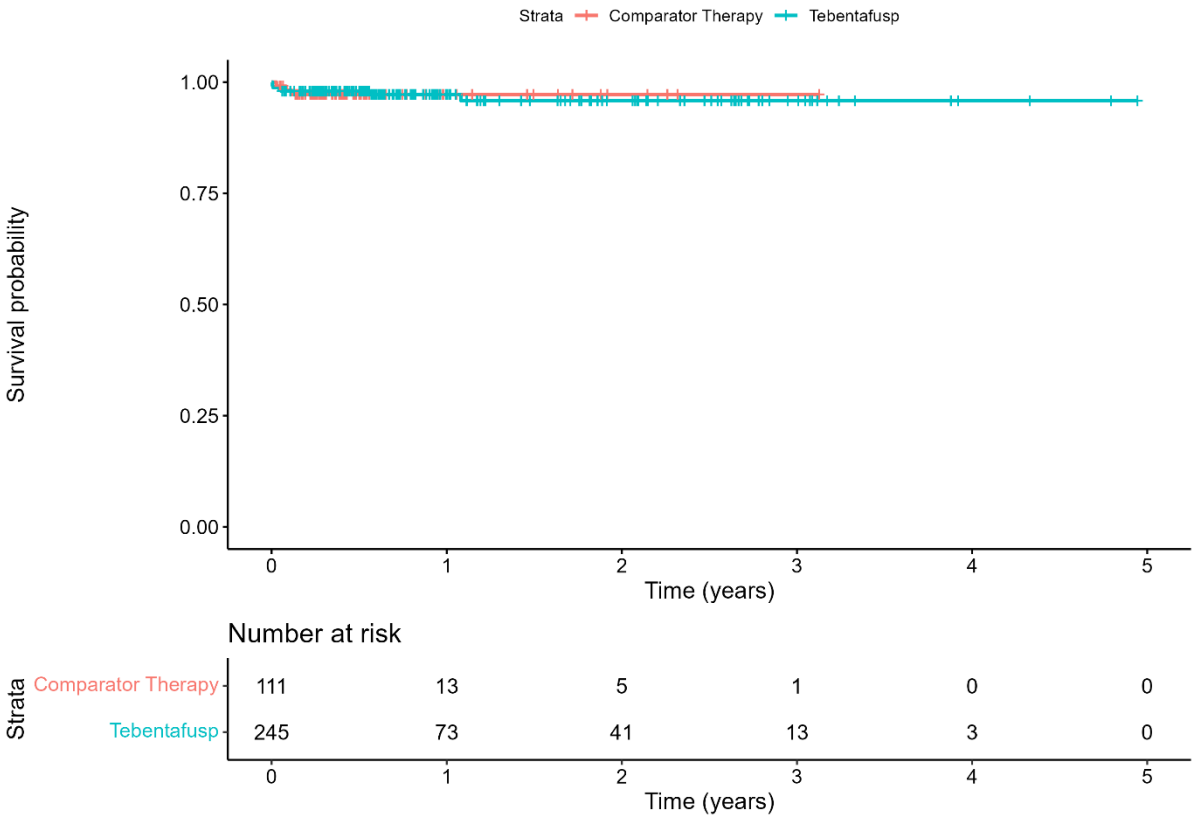
LFT-Erhöhung mit CTCAE-Grad ≥ 3



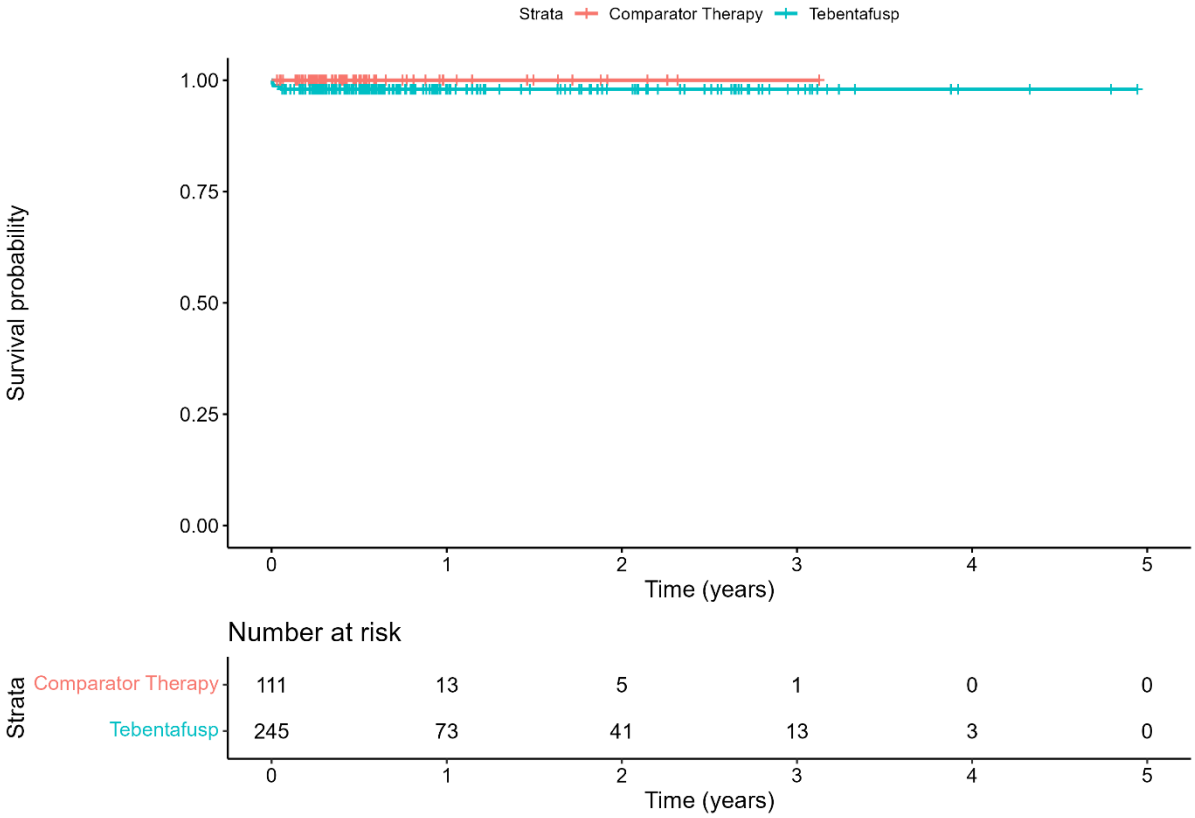
LFT-Erhöhung mit CTCAE-Grad ≥ 3, in kausalem Zusammenhang mit der Behandlung



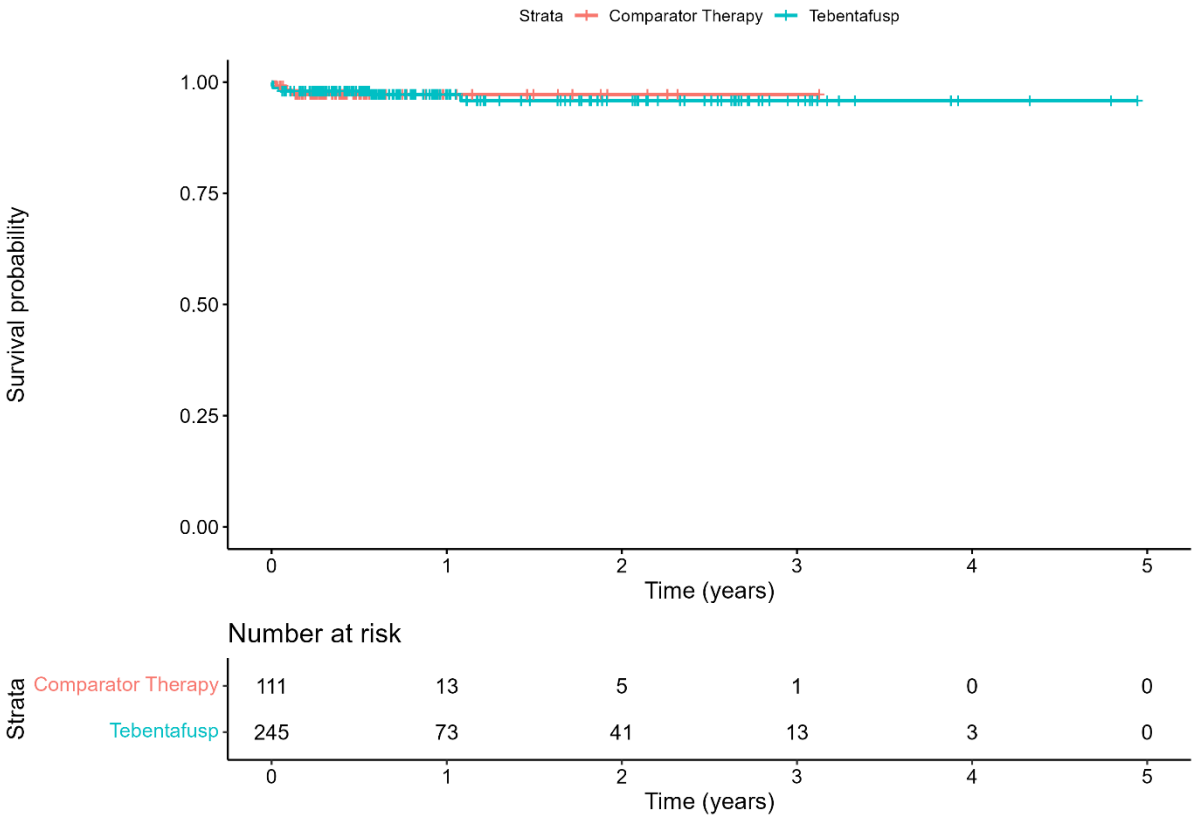
Schwerwiegende LFT-Erhöhung



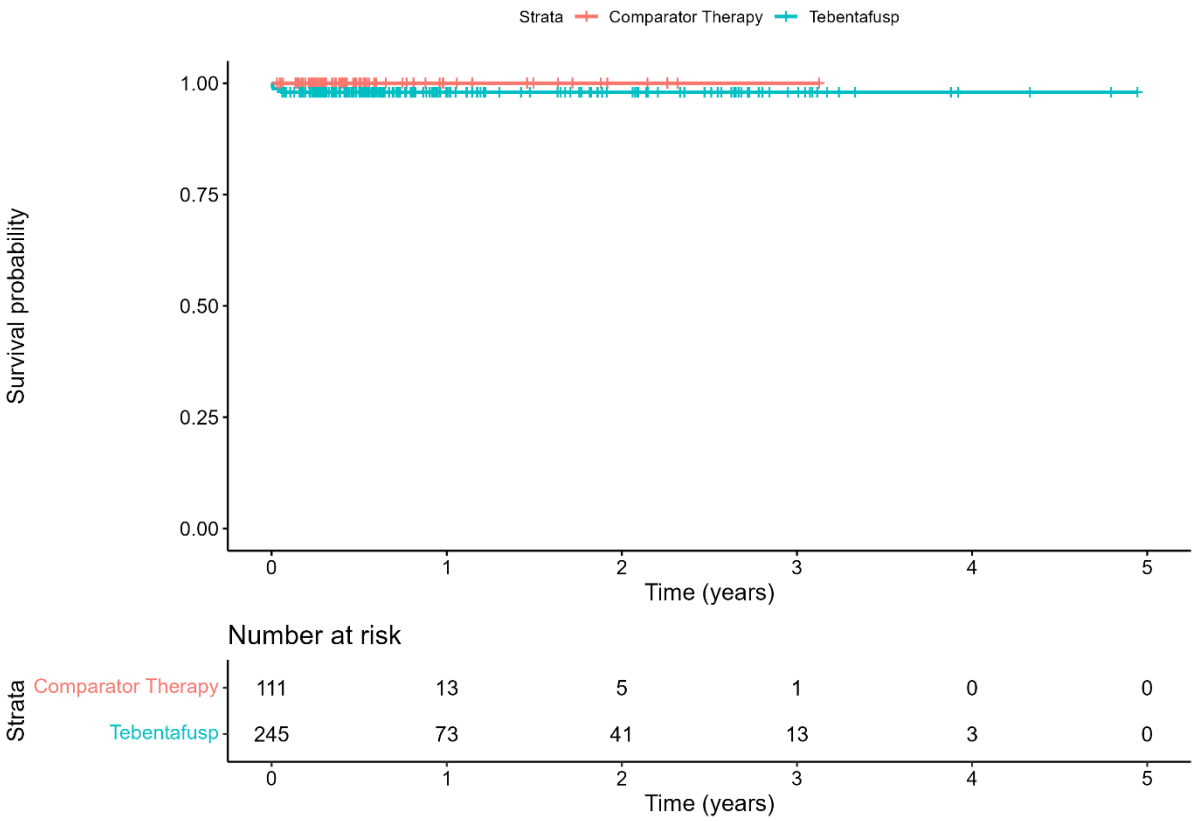
Schwerwiegende LFT-Erhöhung, in kausalem Zusammenhang mit der Behandlung



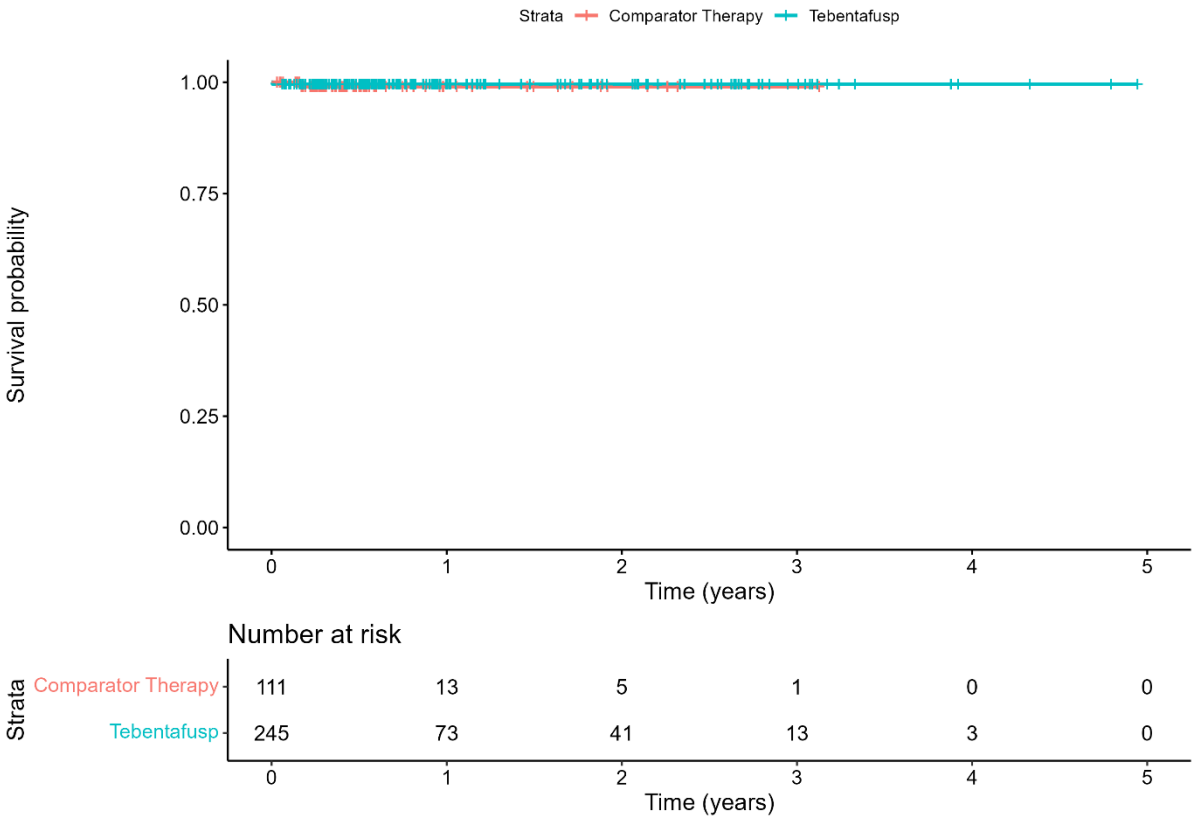
LFT-Erhöhung, die zu einem Krankenhausaufenthalt führte



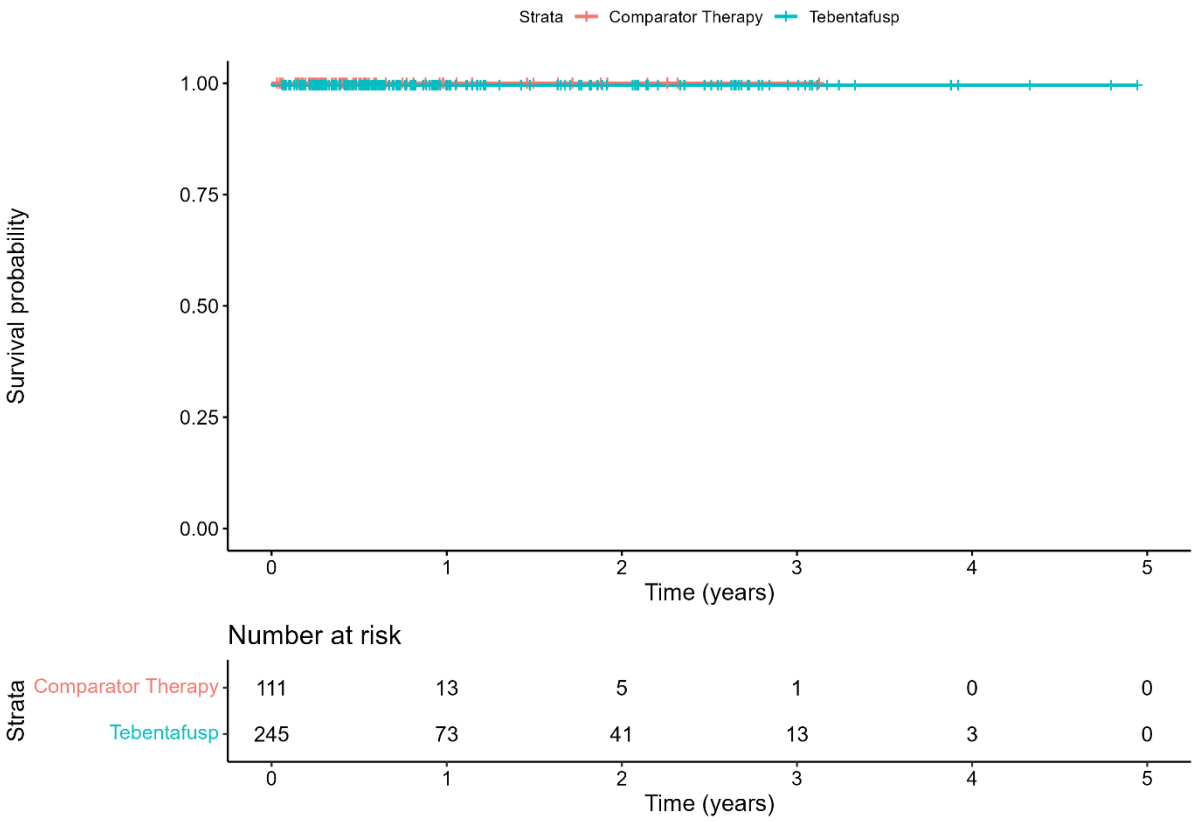
LFT-Erhöhung, die zu einem Krankenhausaufenthalt führte, in kausalem Zusammenhang mit der Behandlung



LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte



LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte, in kausalem Zusammenhang mit der Behandlung



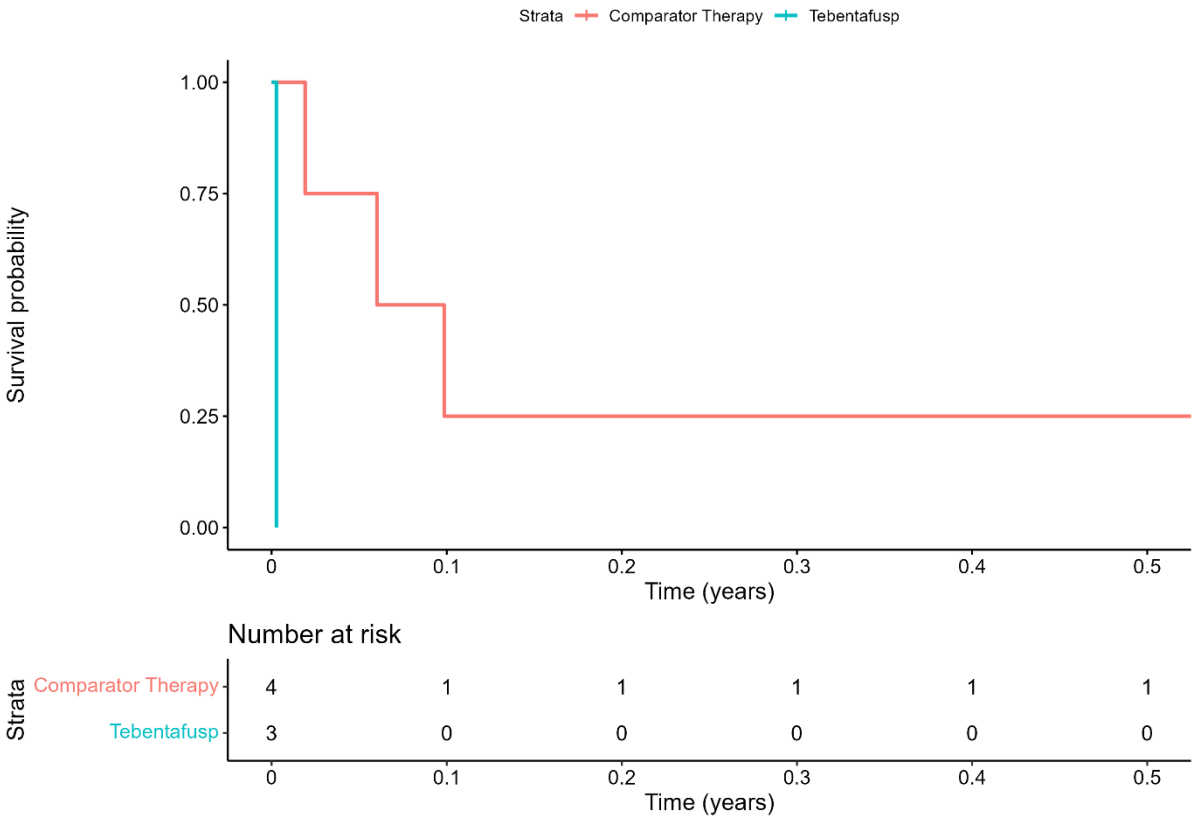
39 **4.3.1.3.5 Subgruppenanalysen – RCT**

39.1 **Endpunkt Sicherheit und Verträglichkeit**

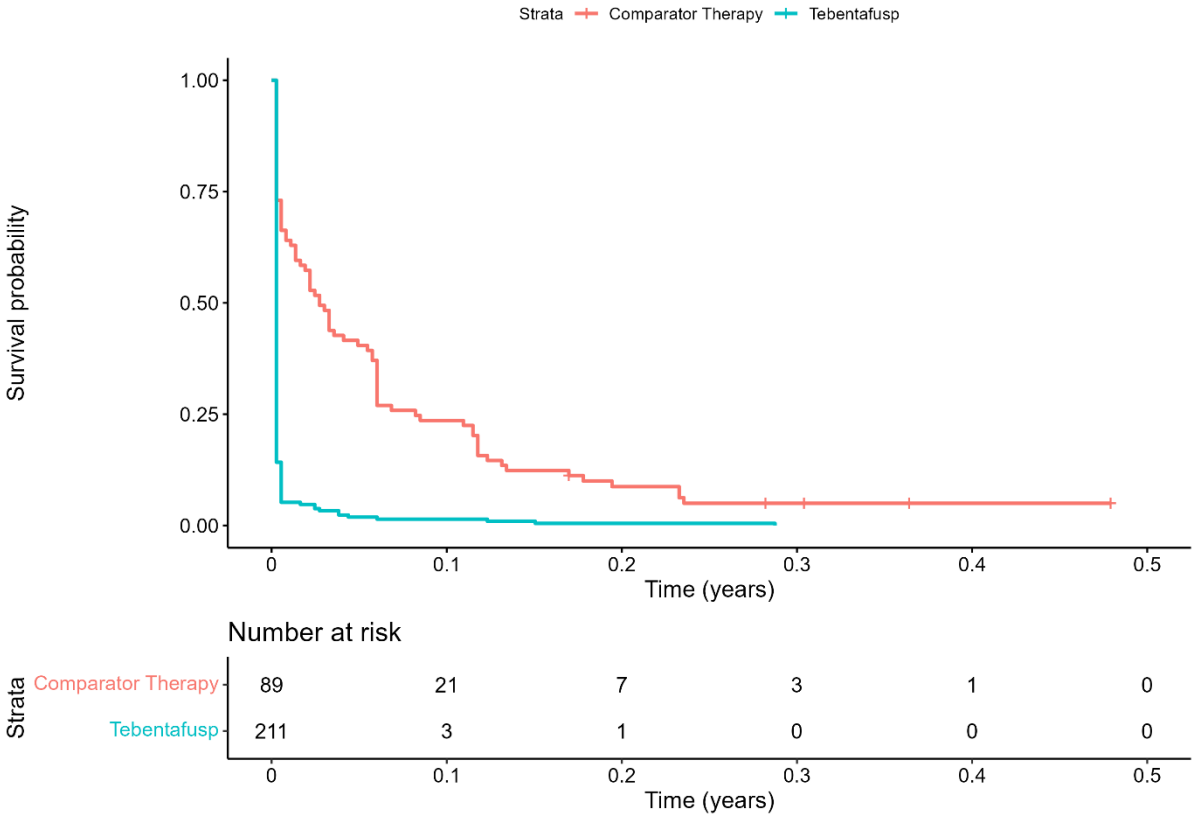
40 Primäranalyse (Oktober 2020)

40.1 Jegliches UE (Tabelle 4-87)

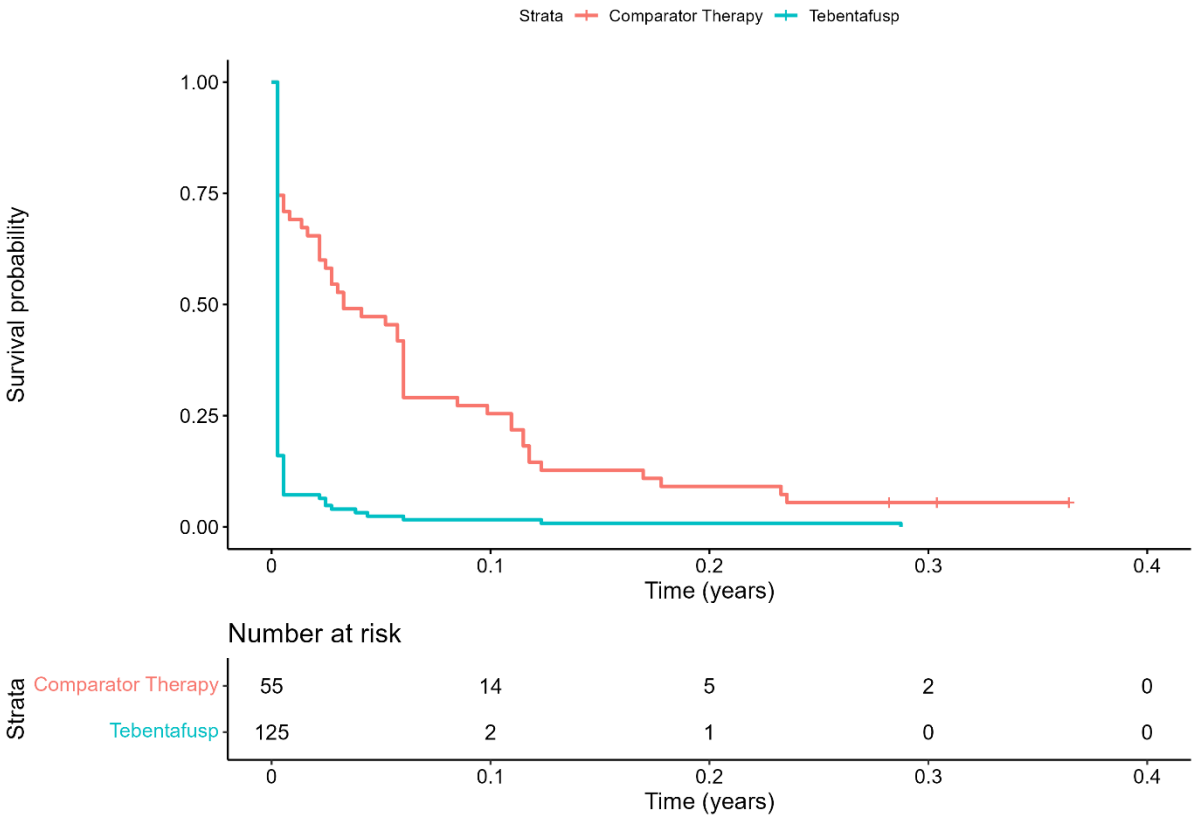
Herkunft: Hispanisch



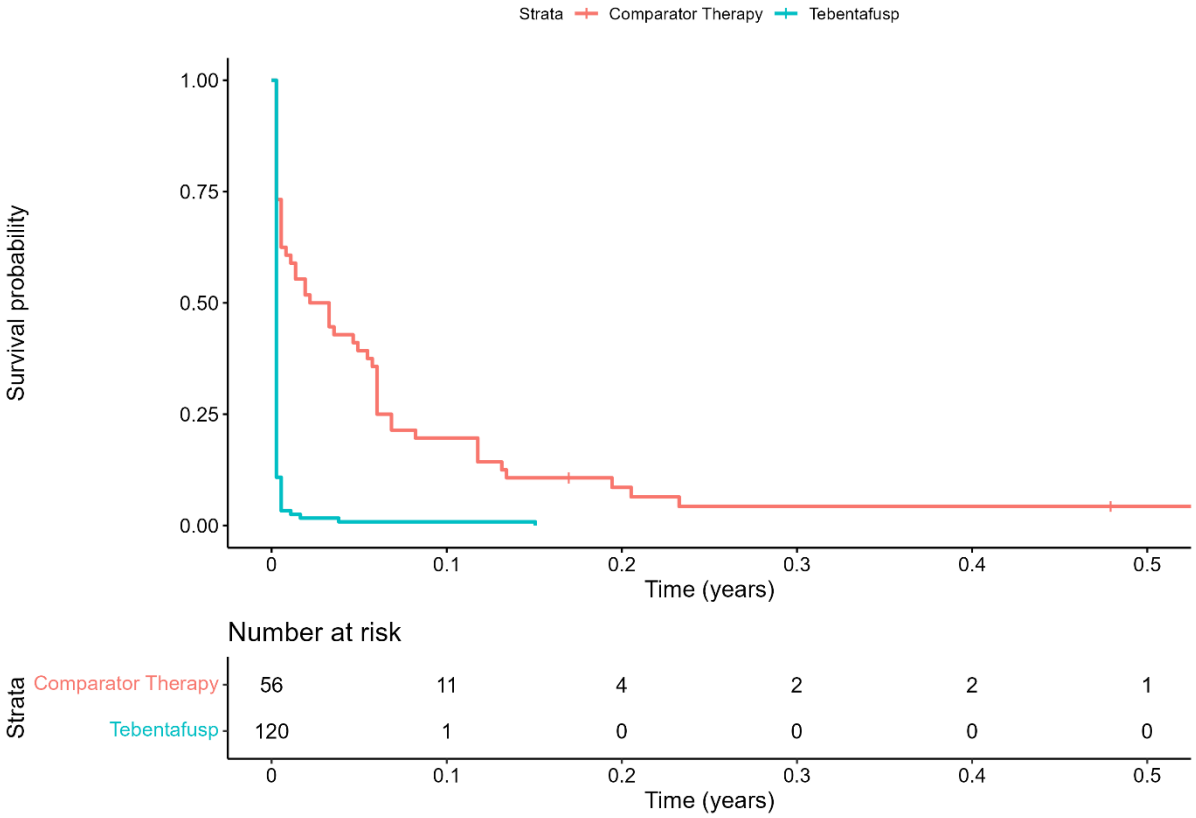
Herkunft: Nicht-hispanisch



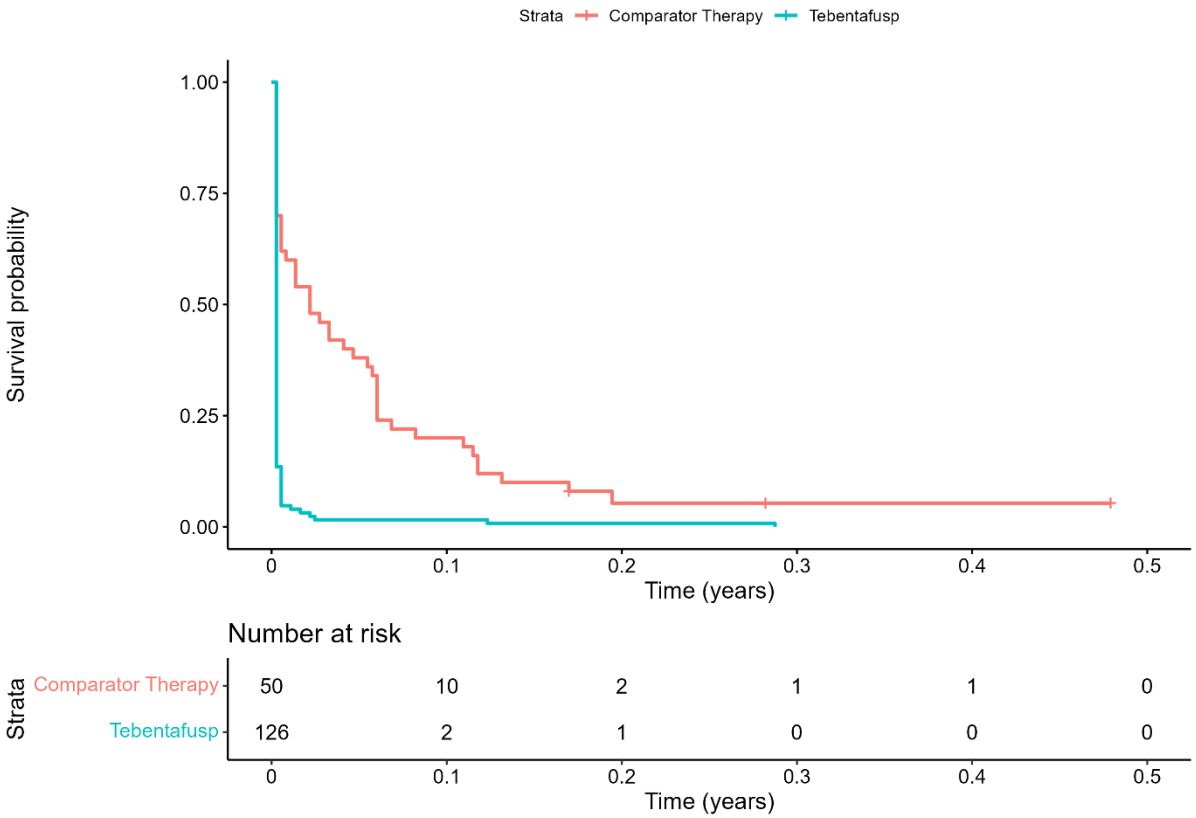
Geschlecht: Männlich



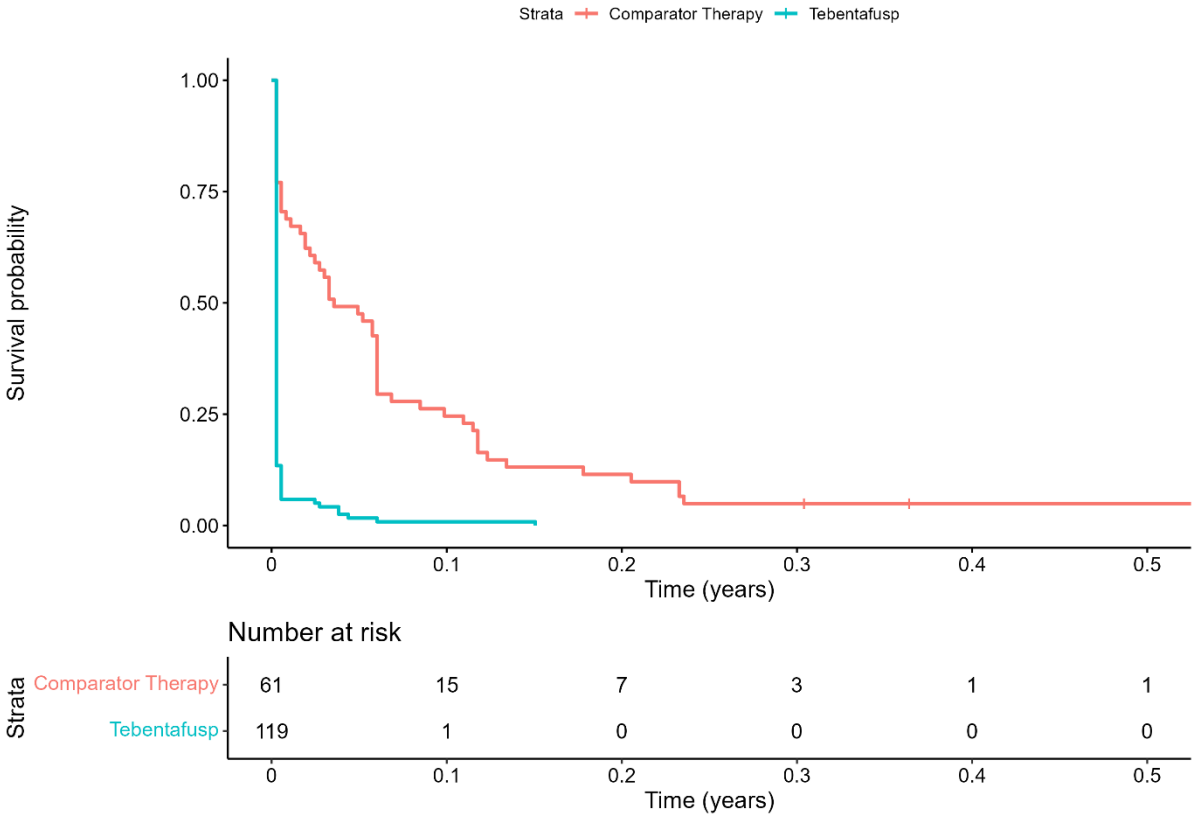
Geschlecht: Weiblich



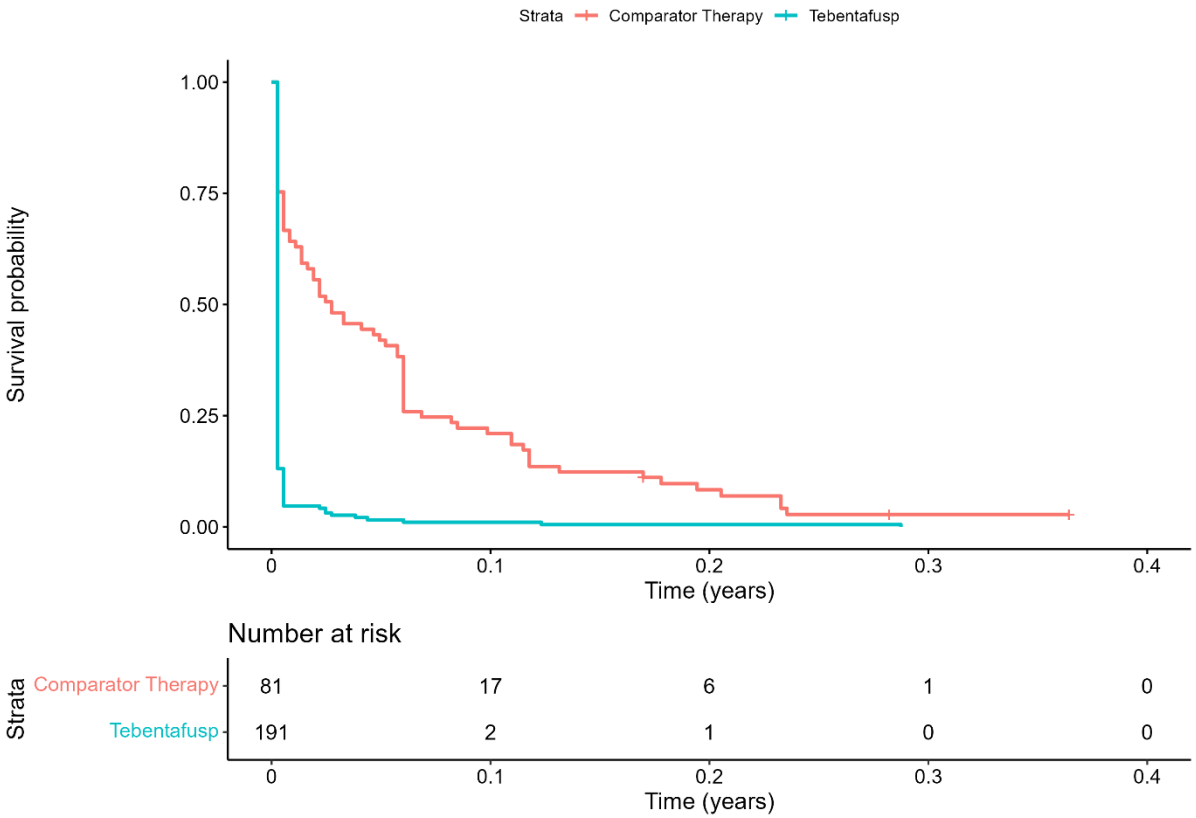
Alter: <65 Jahre



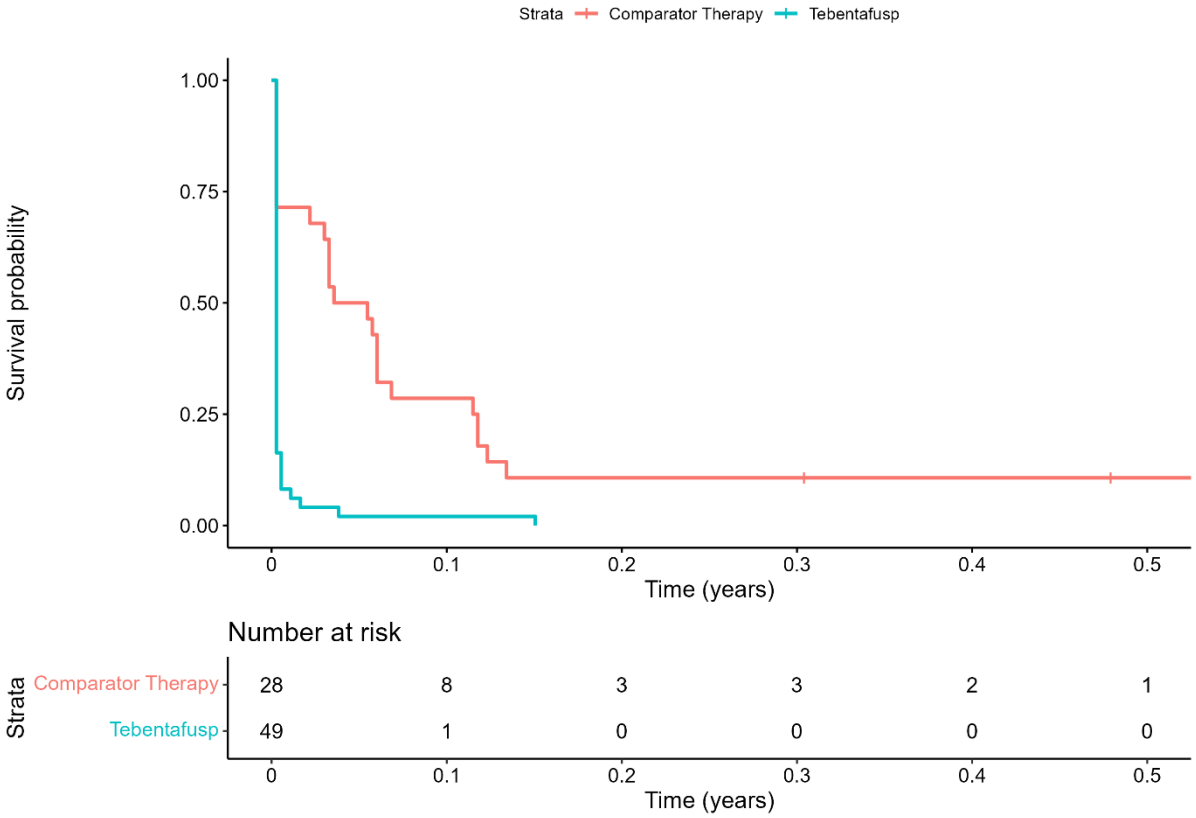
Alter: ≥65 Jahre



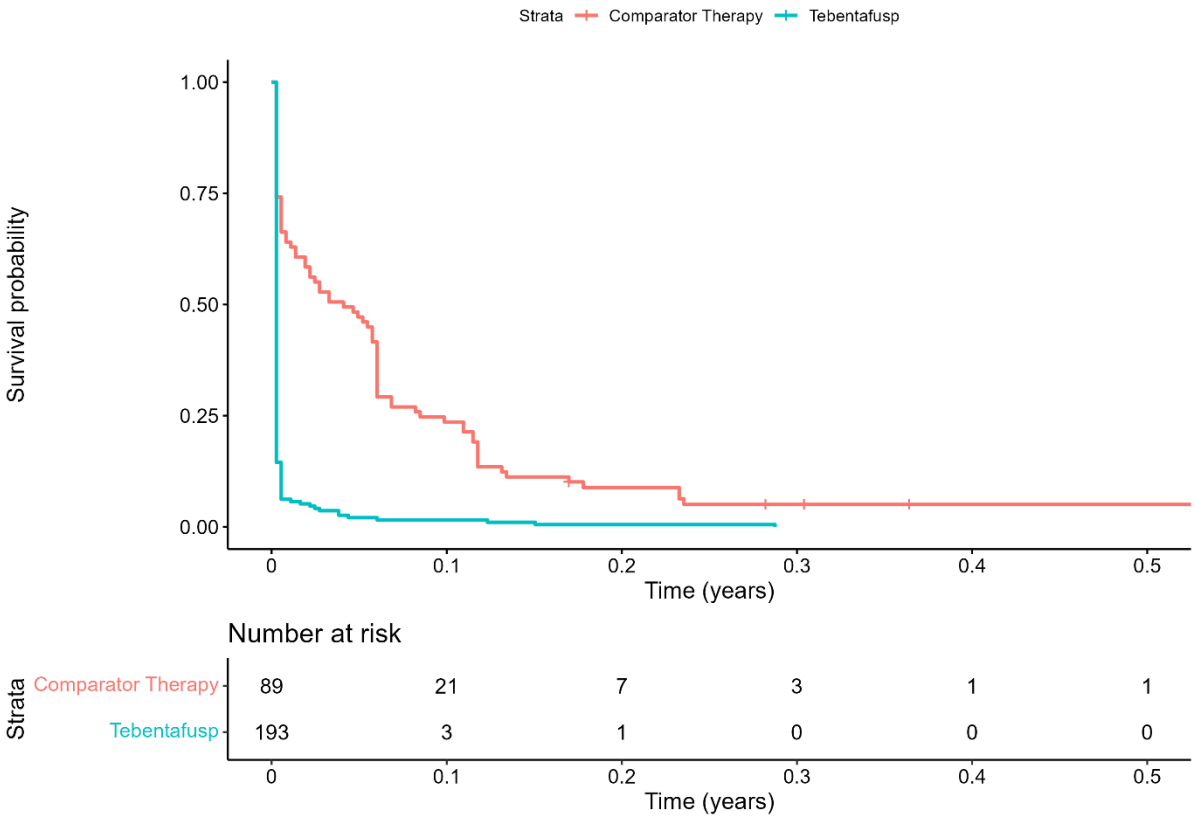
ECOG-Performance-Status: 0



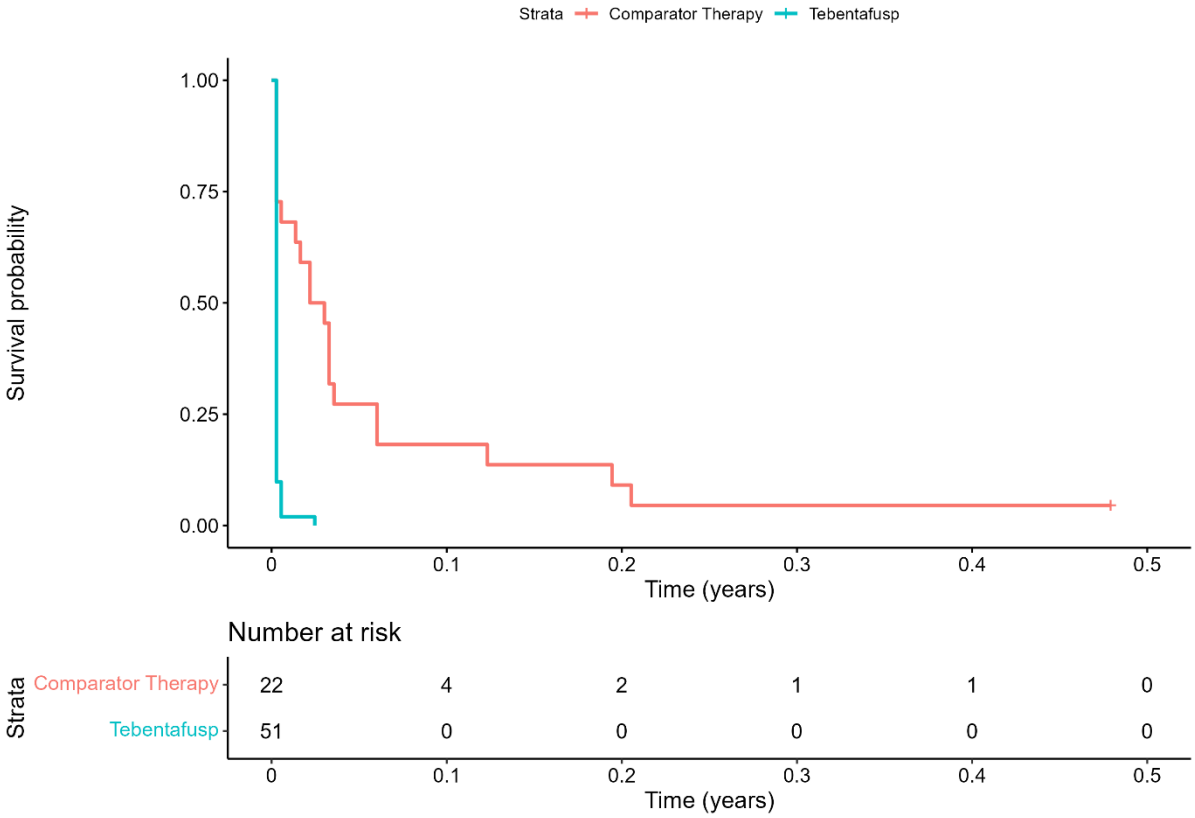
ECOG-Performance-Status: 1



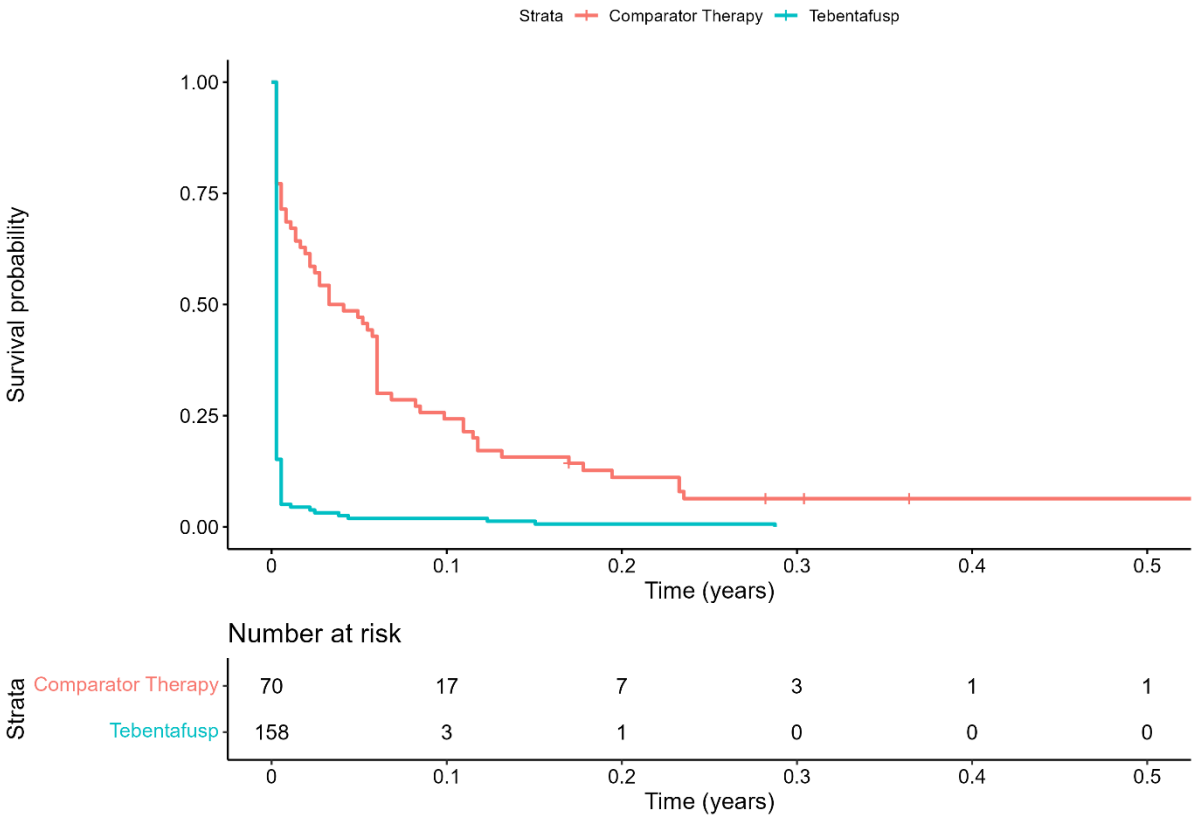
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



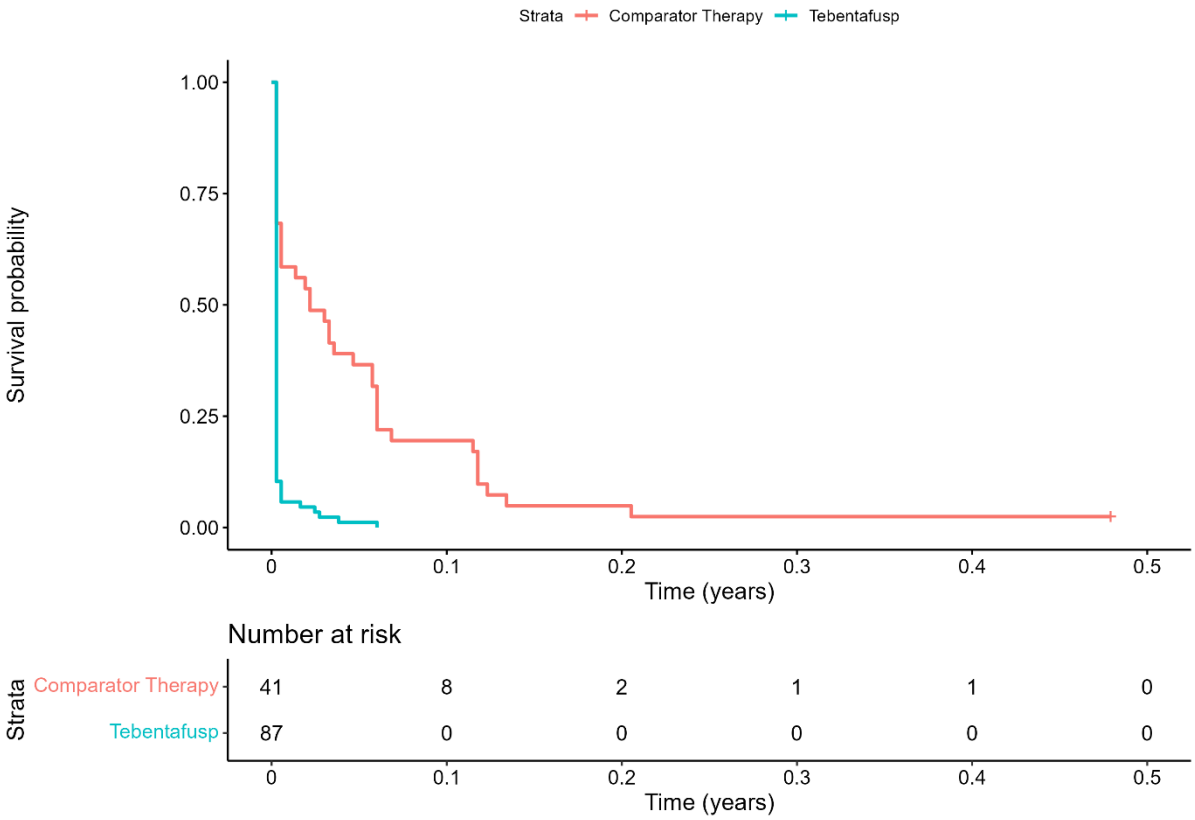
Alkalische Phosphatase (ALP) (Baseline): >ULN



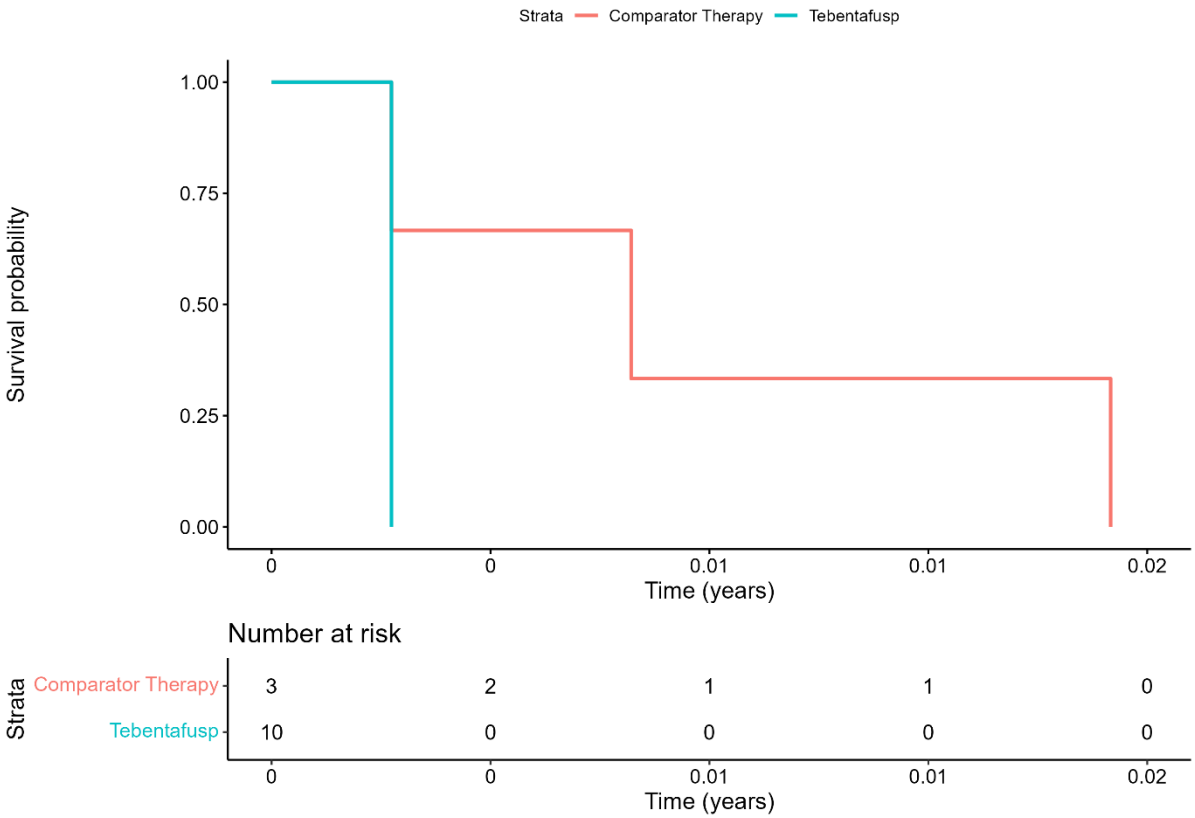
LDH: ≤ULN



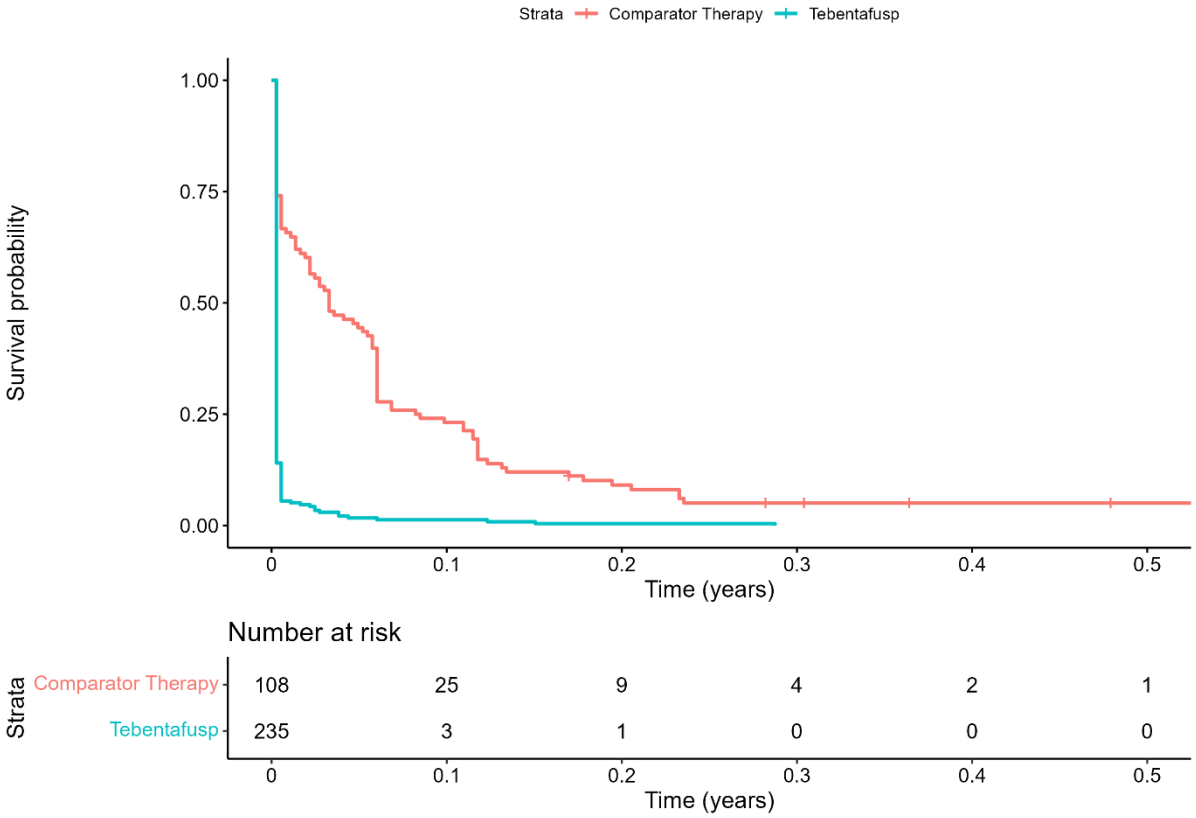
LDH: >ULN



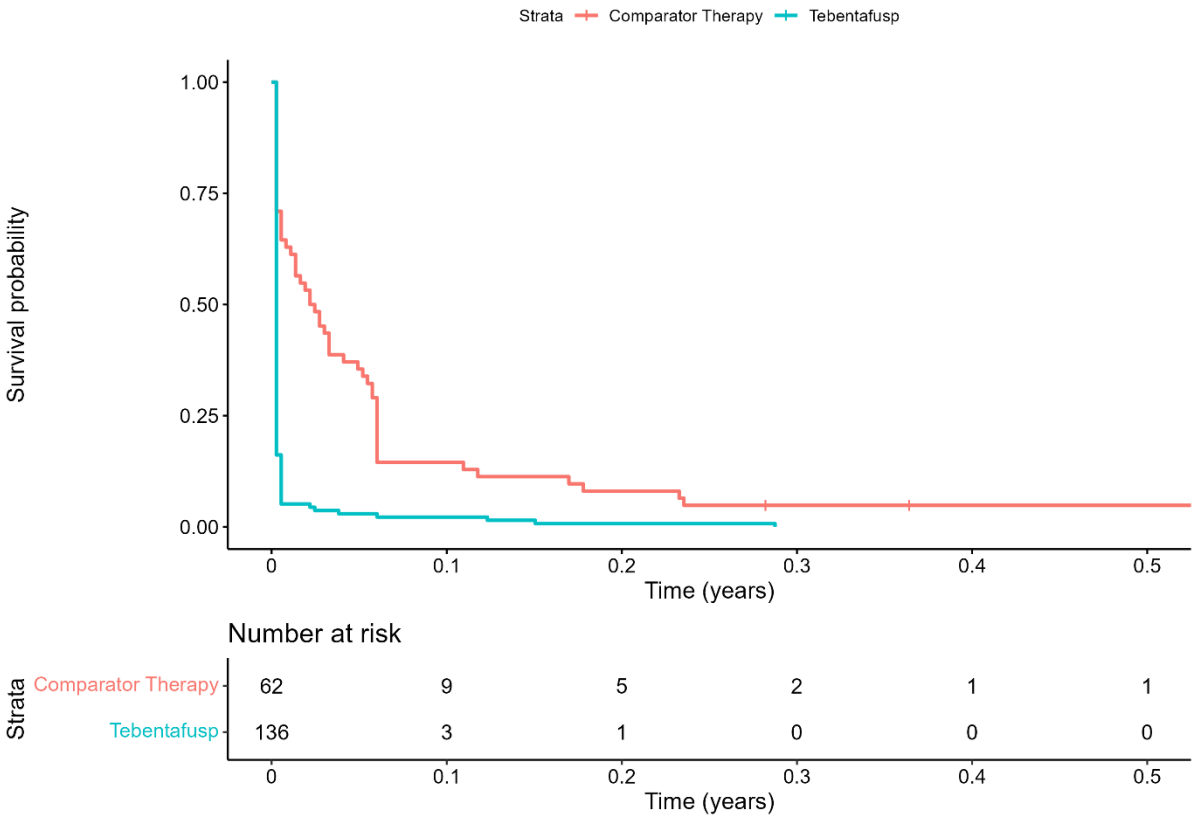
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



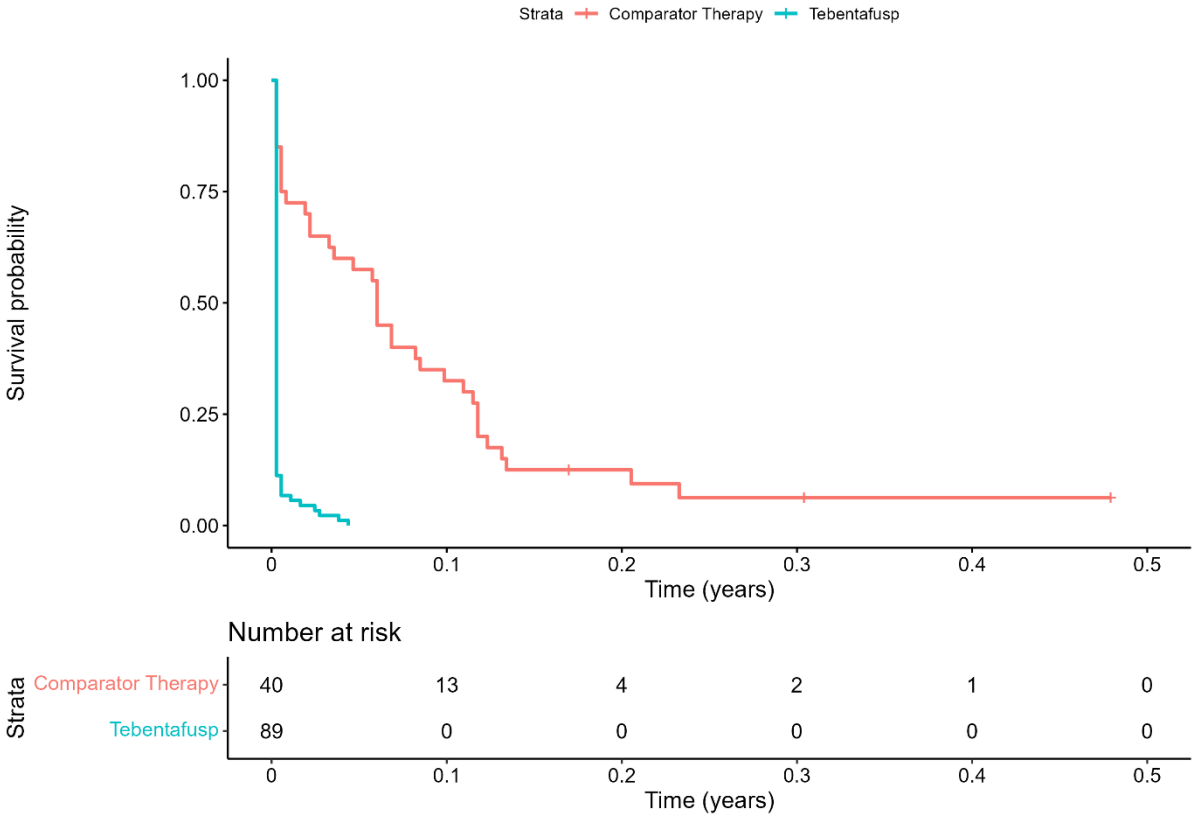
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



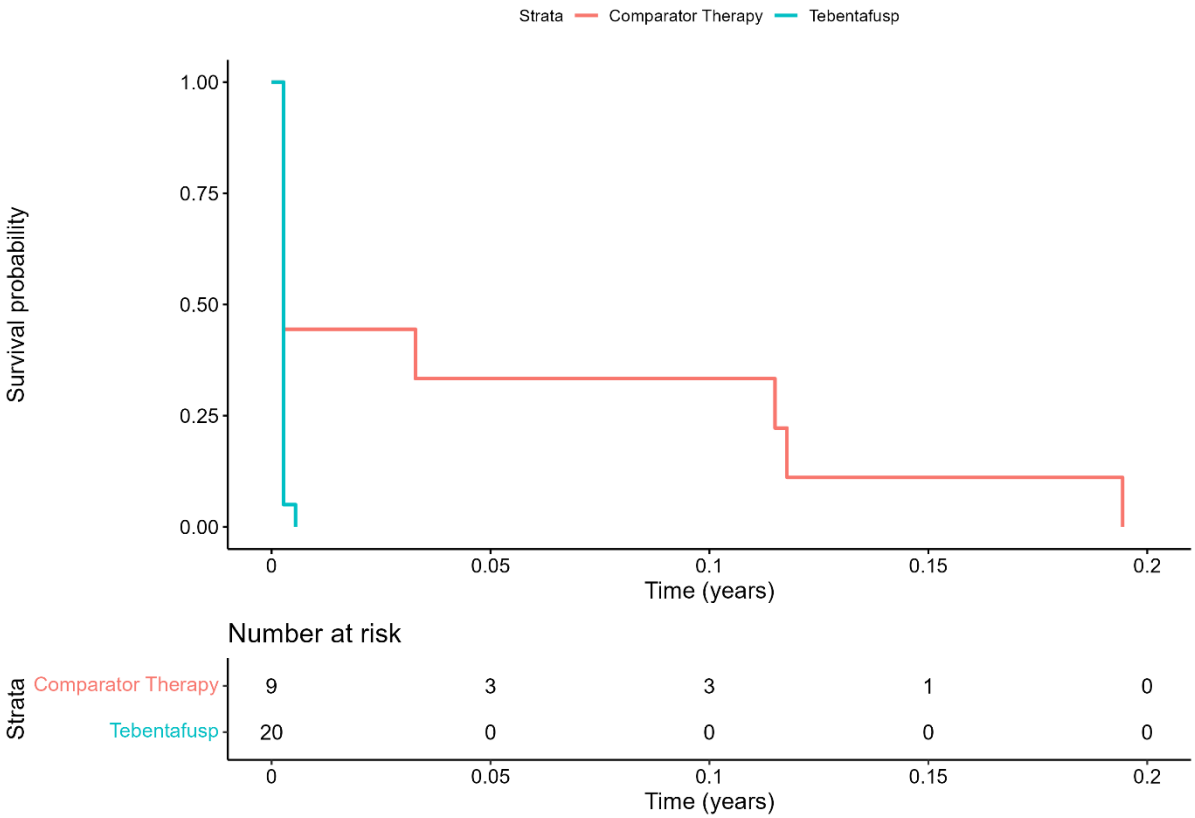
Größte metastatische Läsion (Baseline): ≤3,0 cm



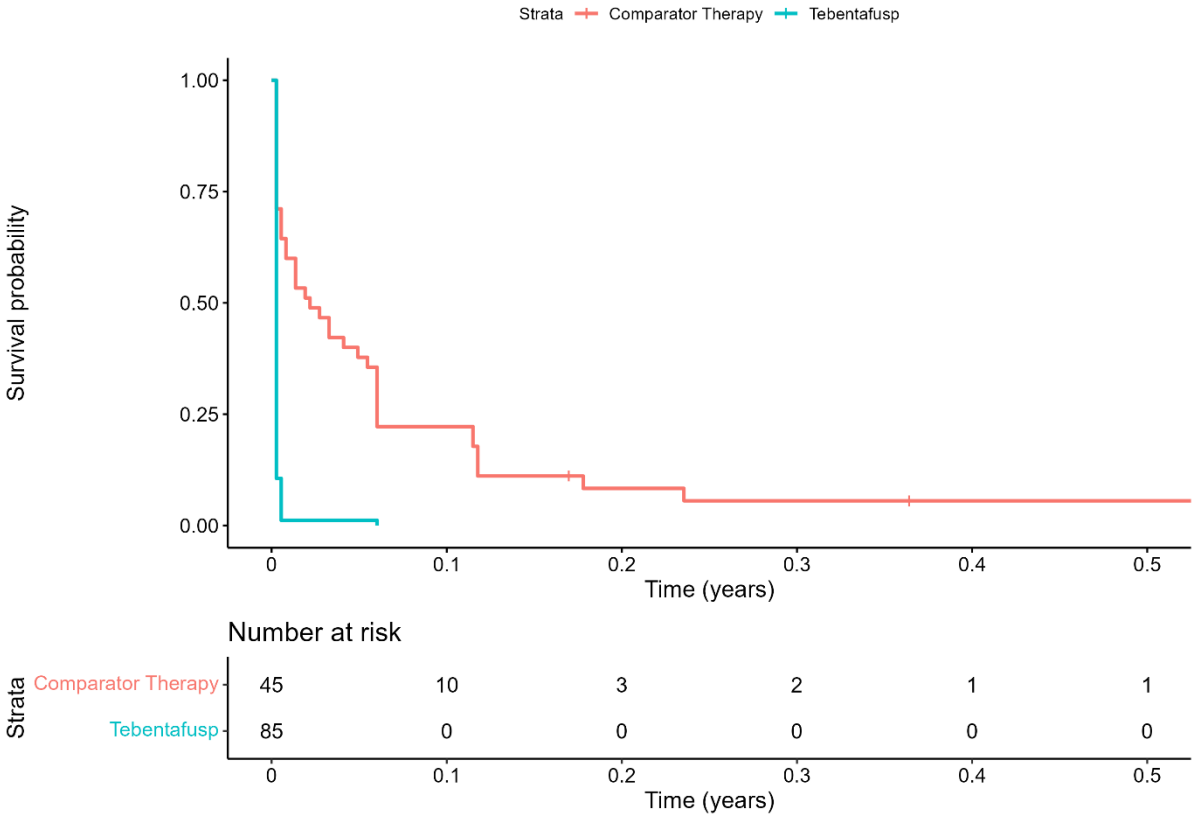
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



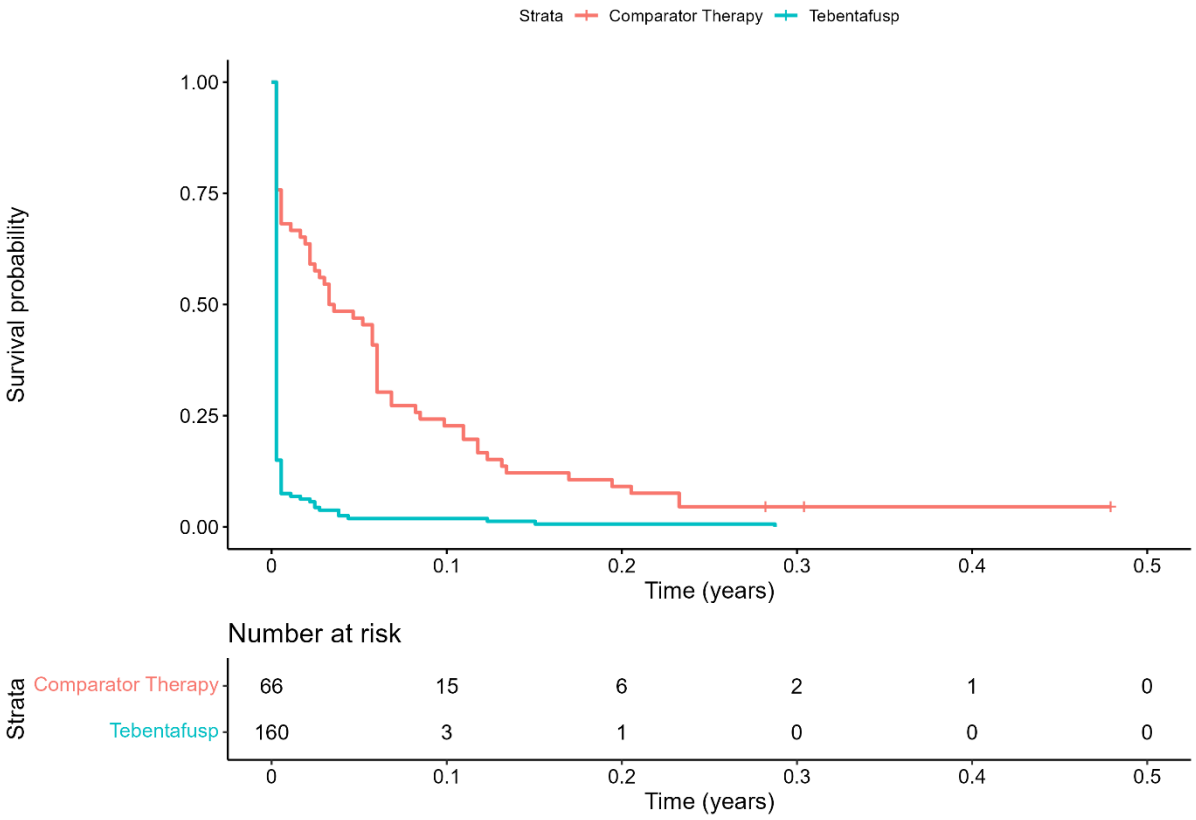
Größte metastatische Läsion (Baseline): ≥8,1 cm



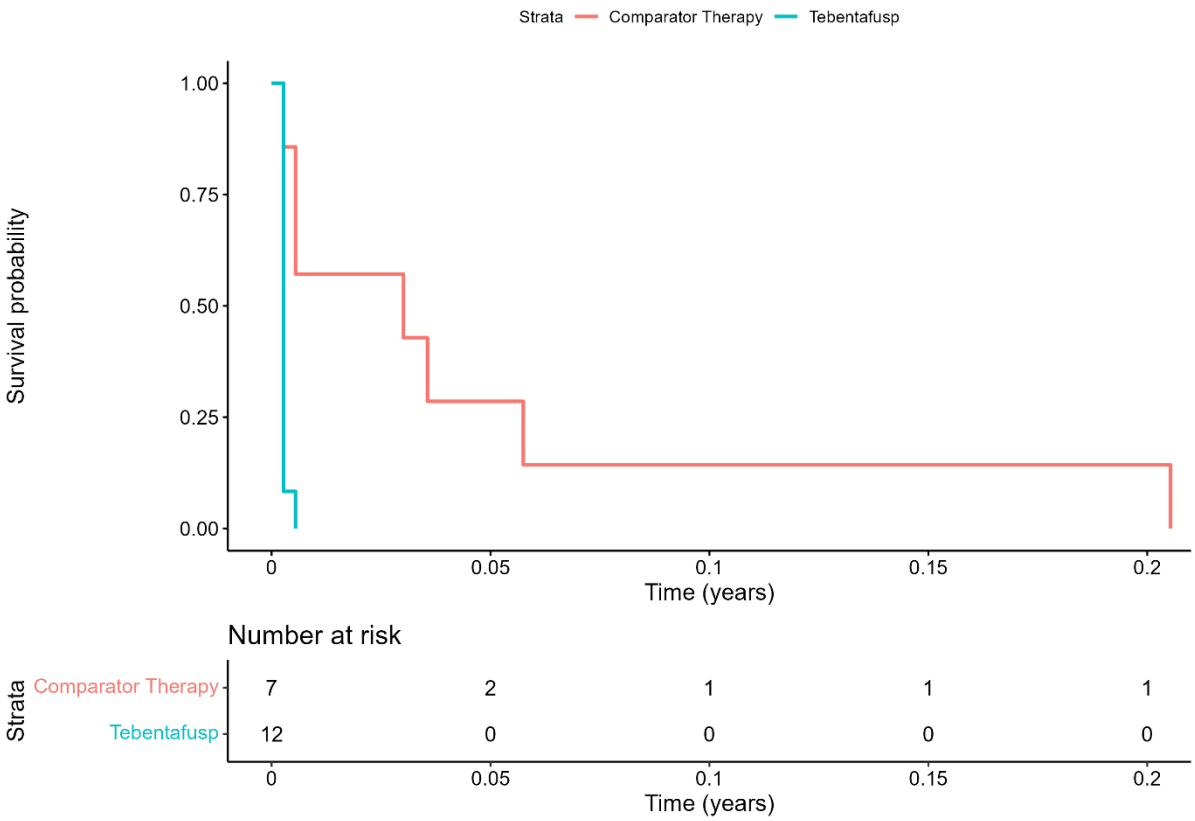
Region: Nordamerika



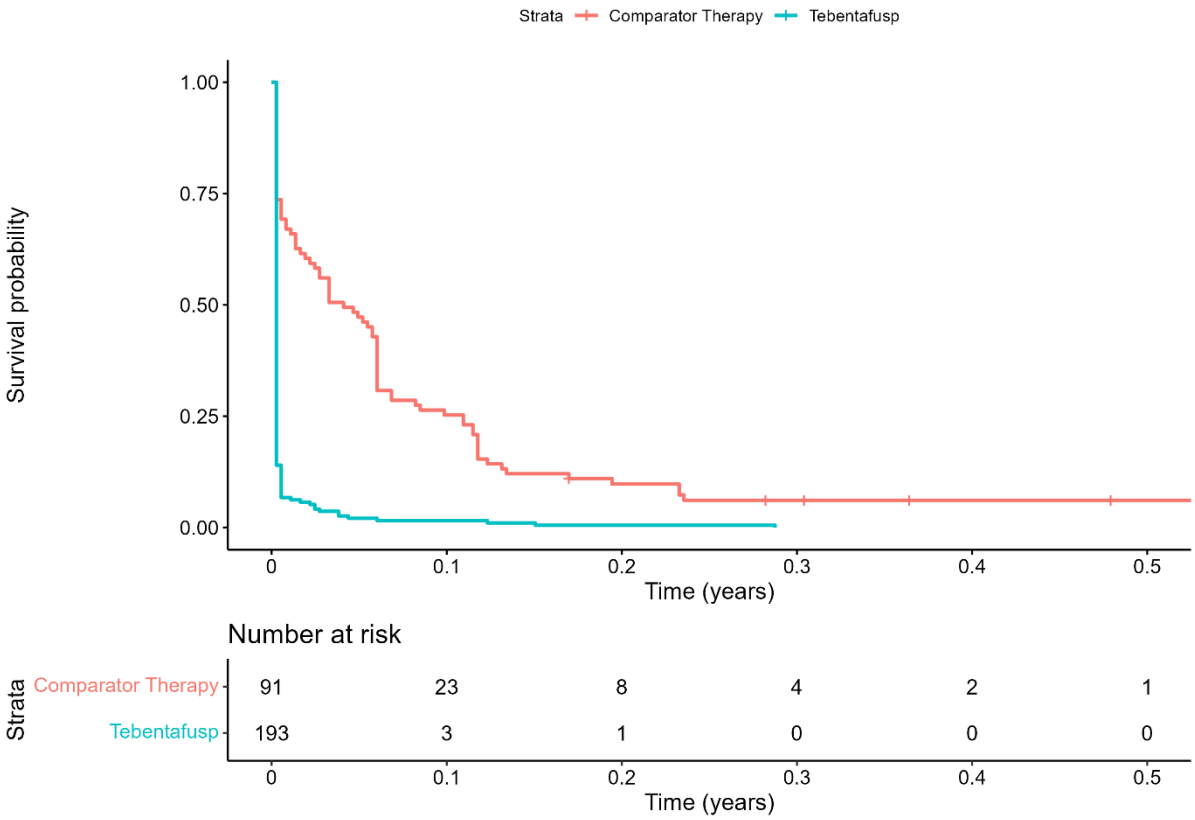
Region: Nicht-Nordamerika



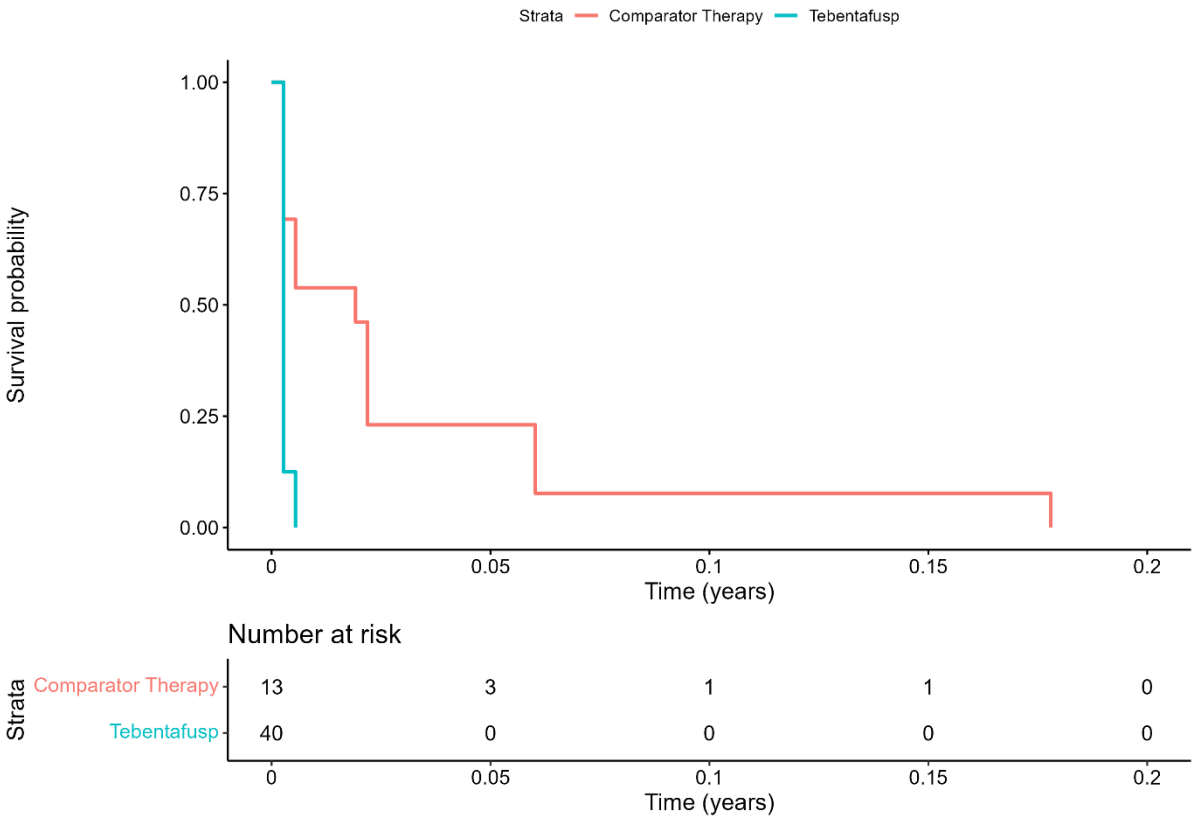
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

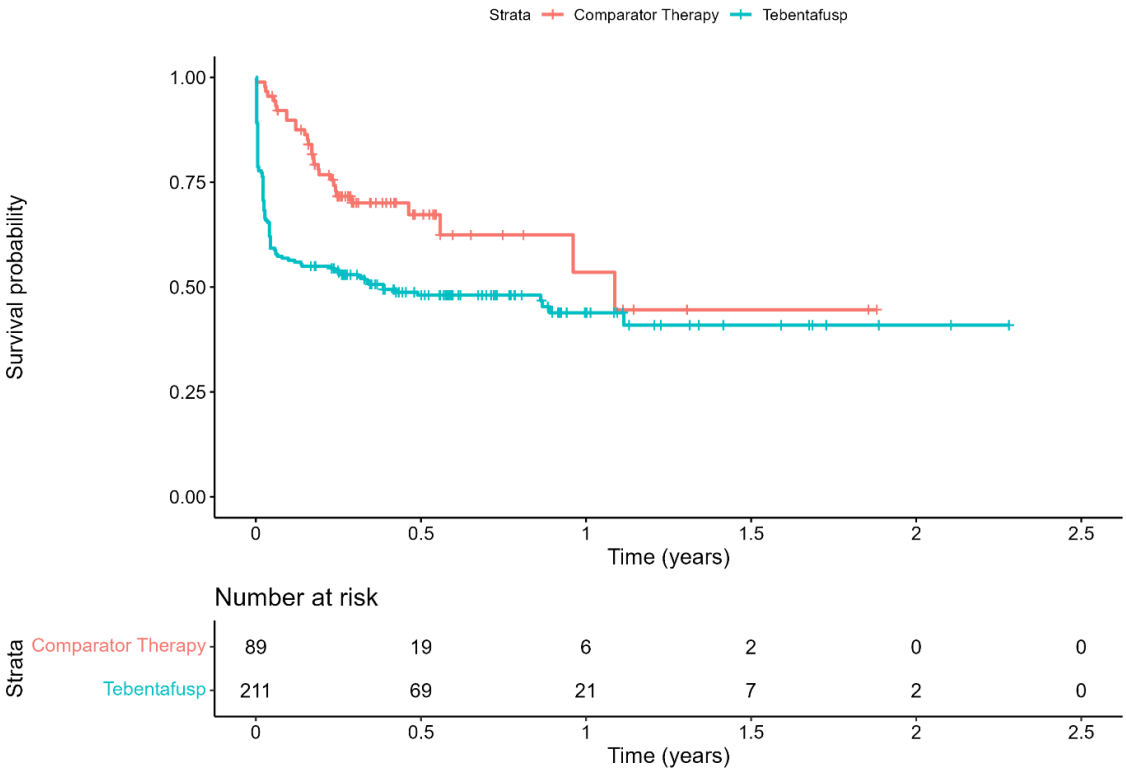


Vorauswahl der Chemotherapie: Ipilimumab

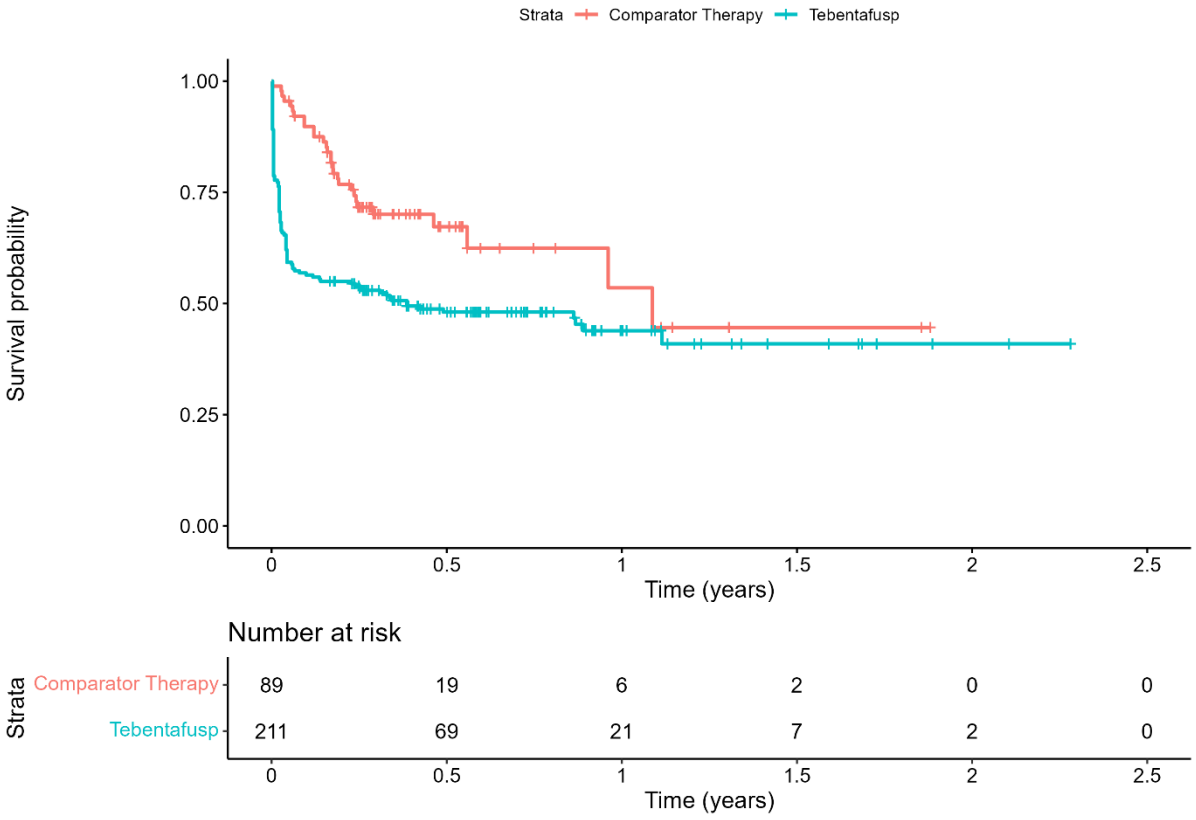


41.1 Jegliches UE mit CTCAE-Grad ≥ 3 (Tabelle 4-89)

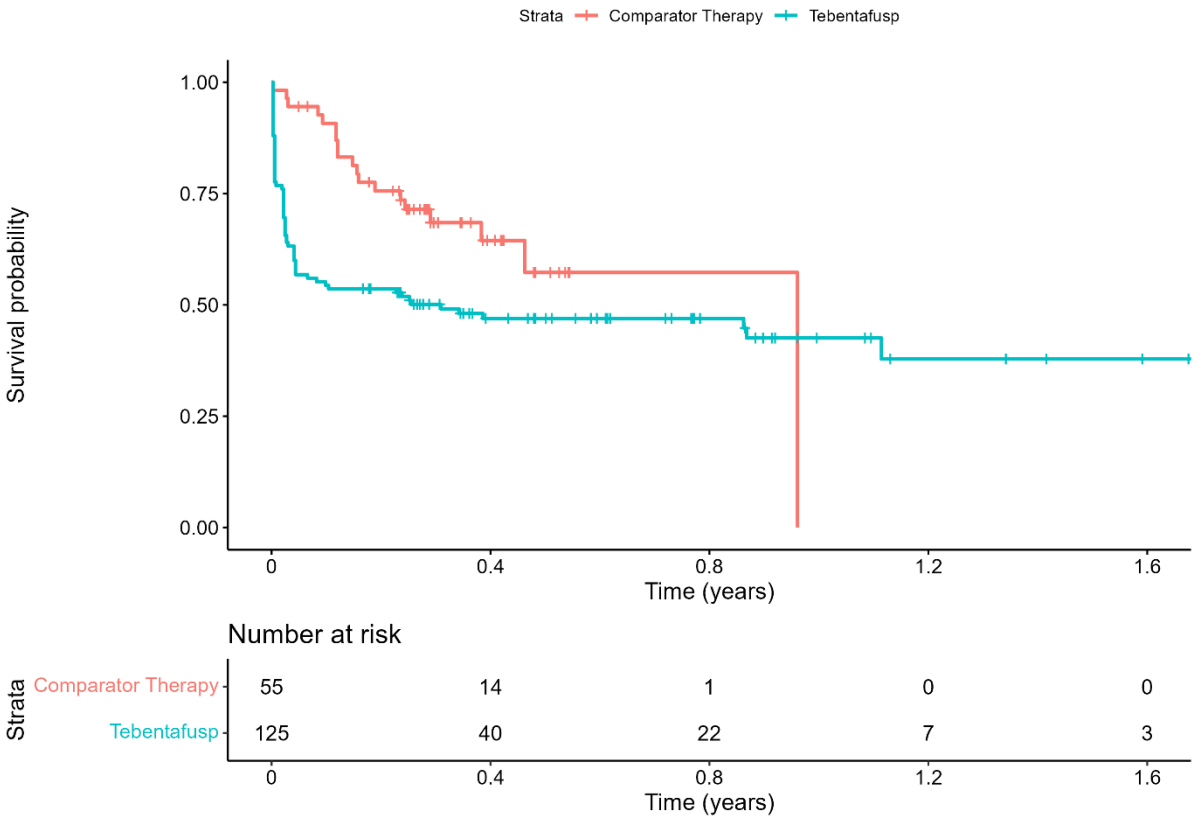
Herkunft: Hispanisch



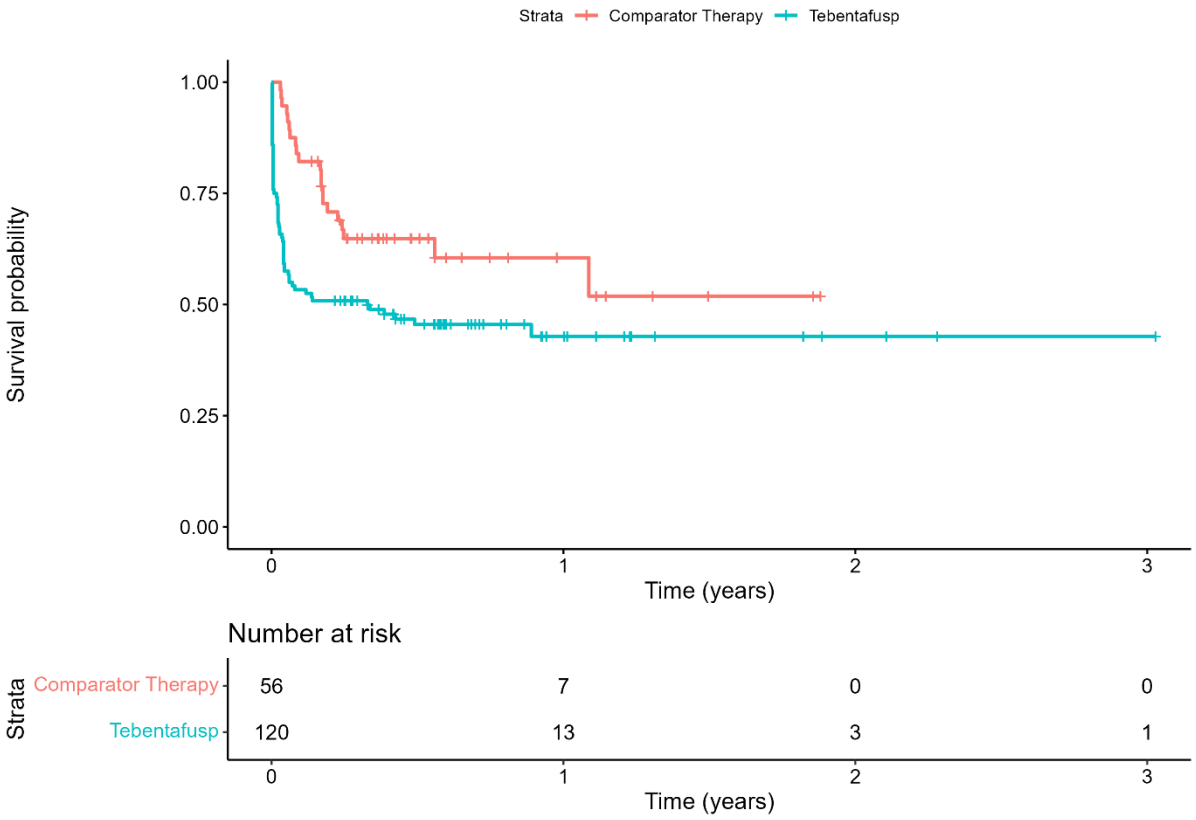
Herkunft: Nicht-hispanisch



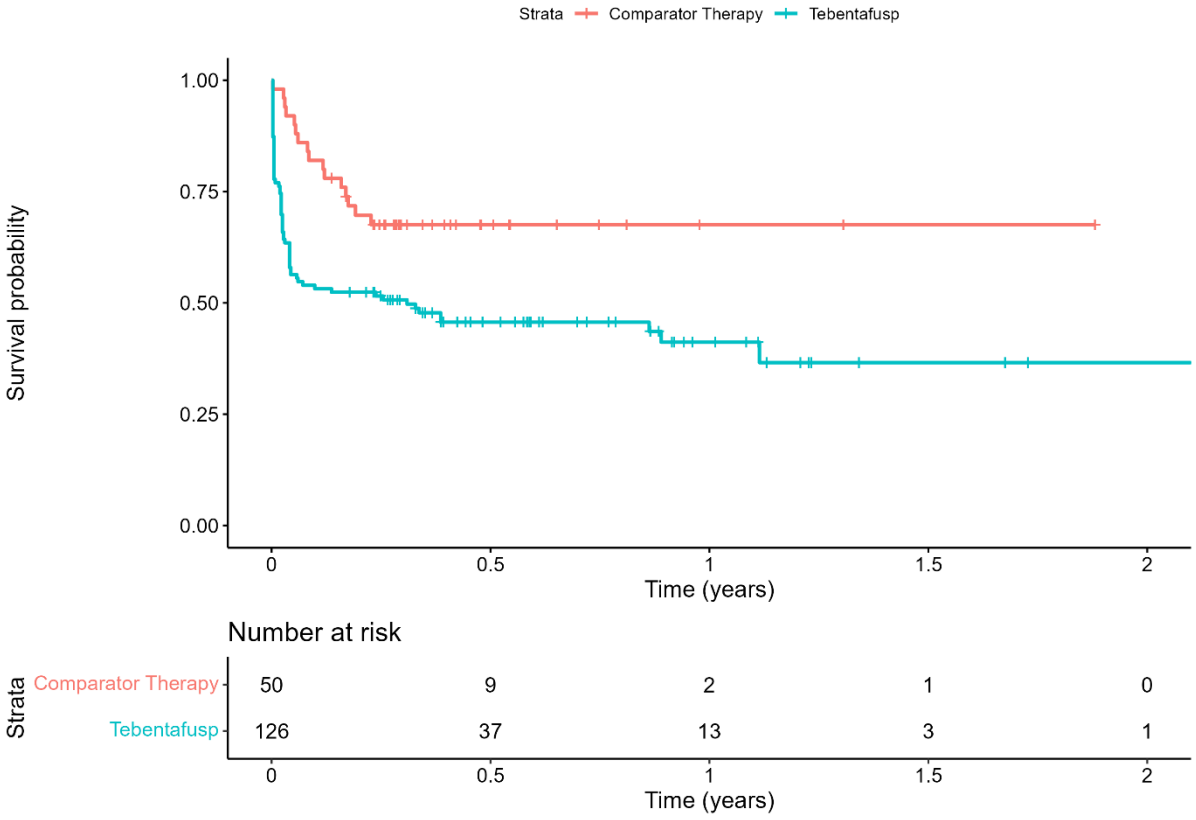
Geschlecht: Männlich



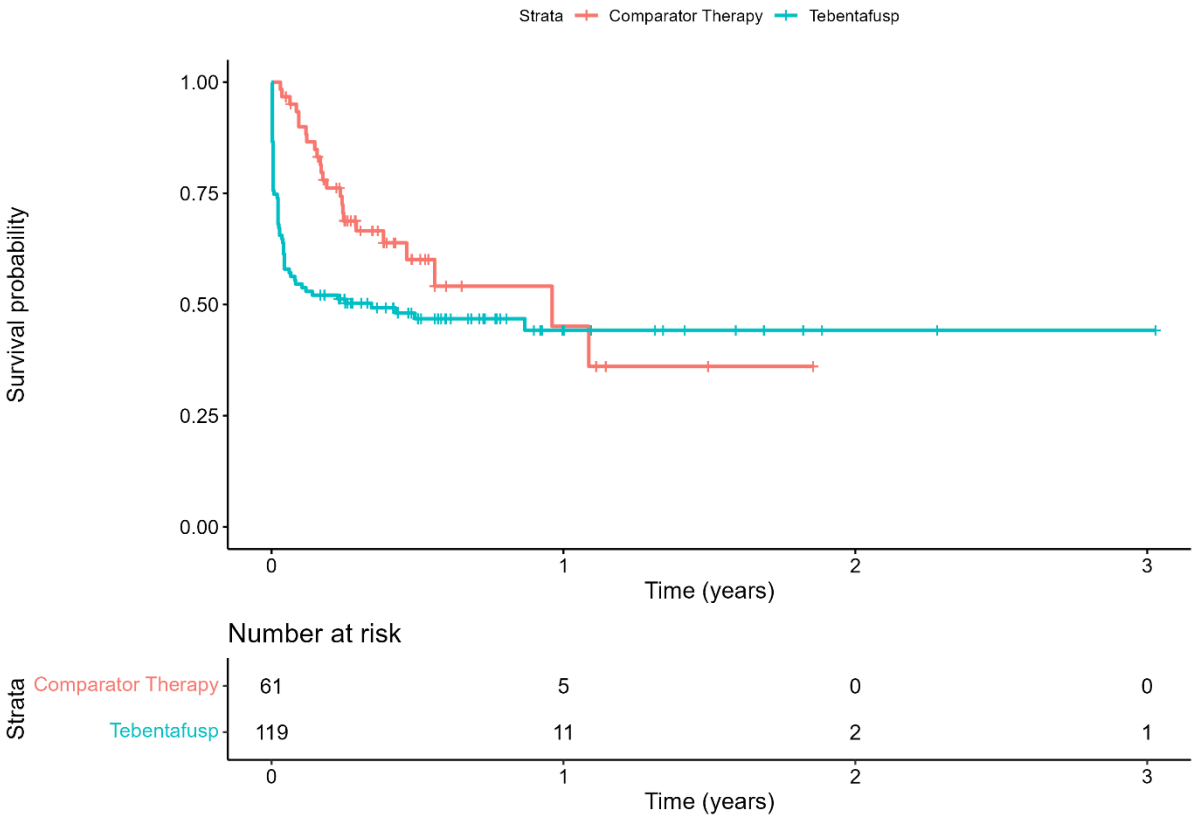
Geschlecht: Weiblich



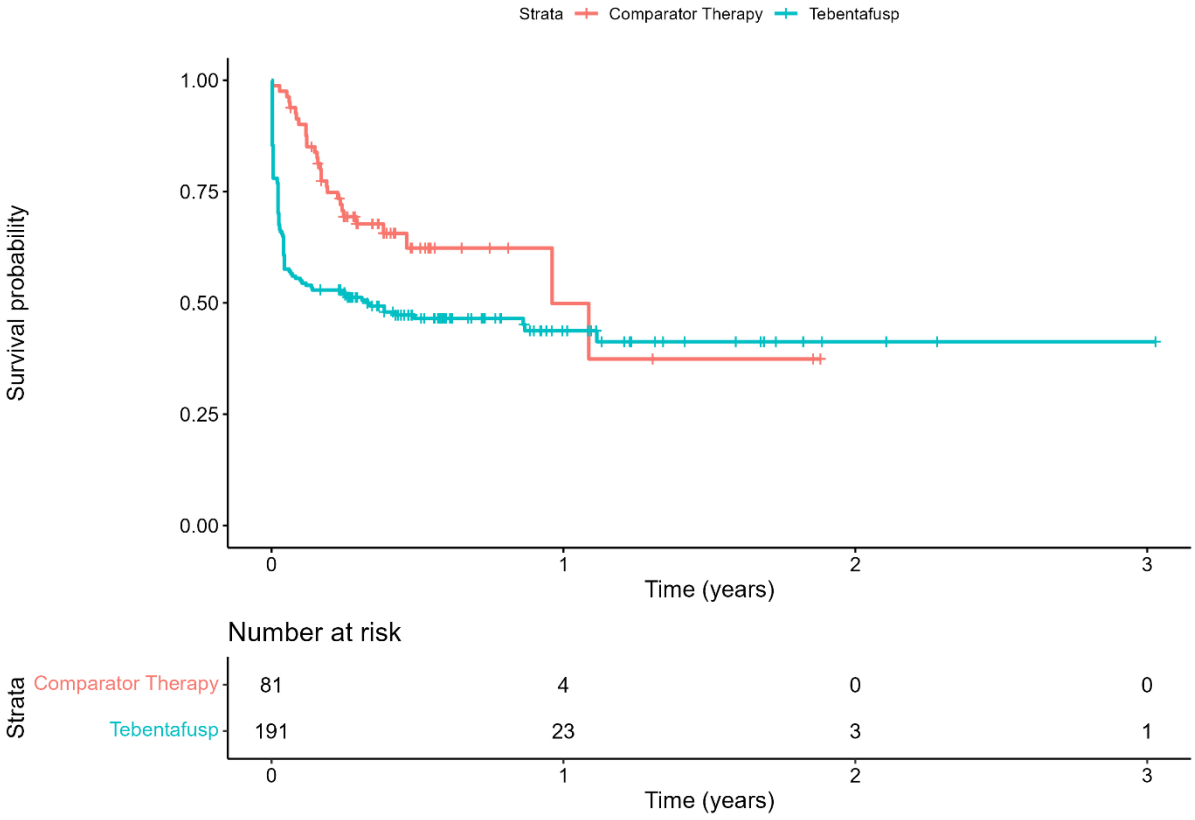
Alter: <65 Jahre



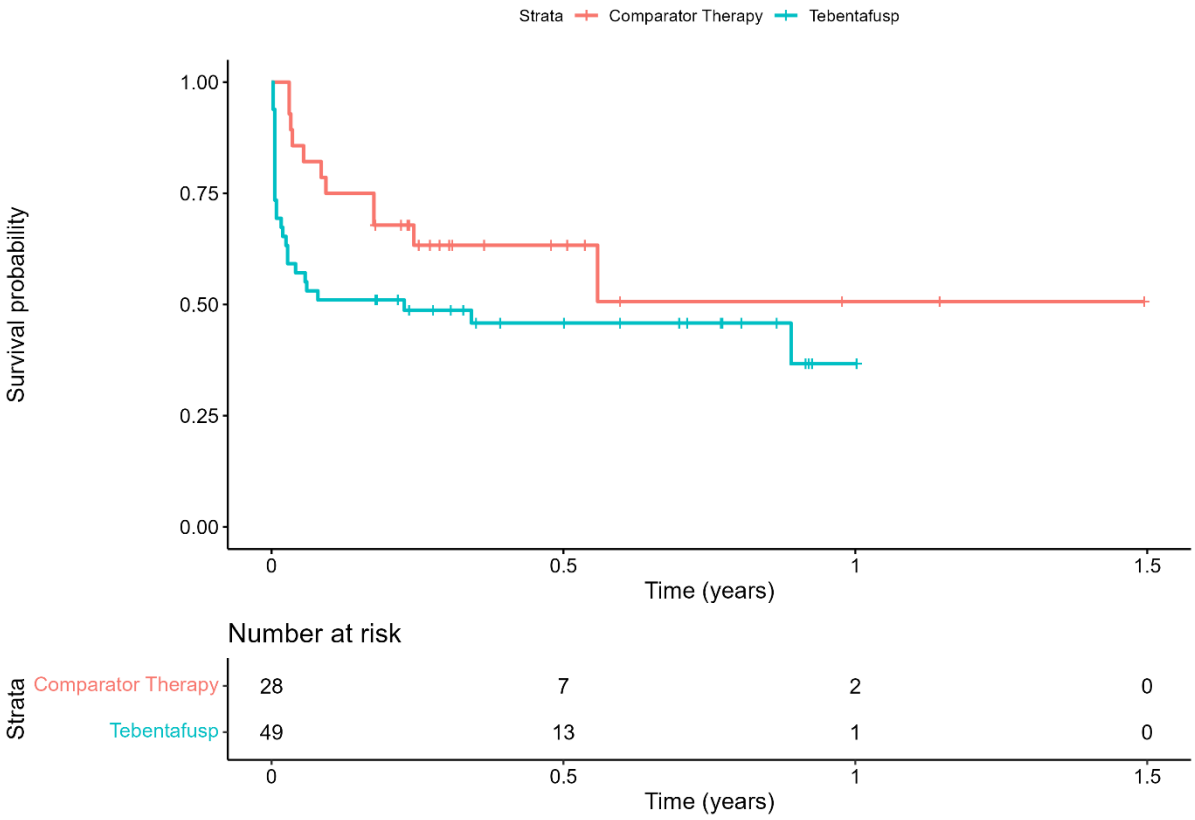
Alter: ≥65 Jahre



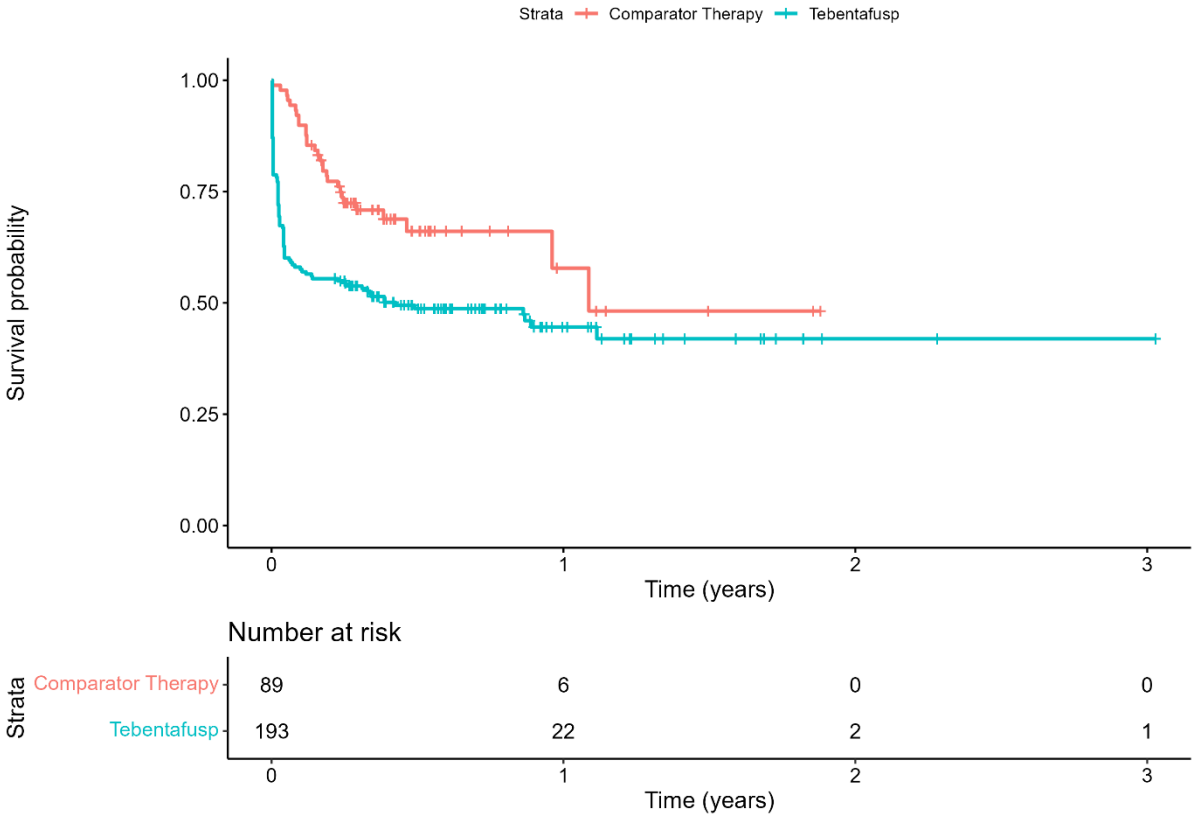
ECOG-Performance-Status: 0



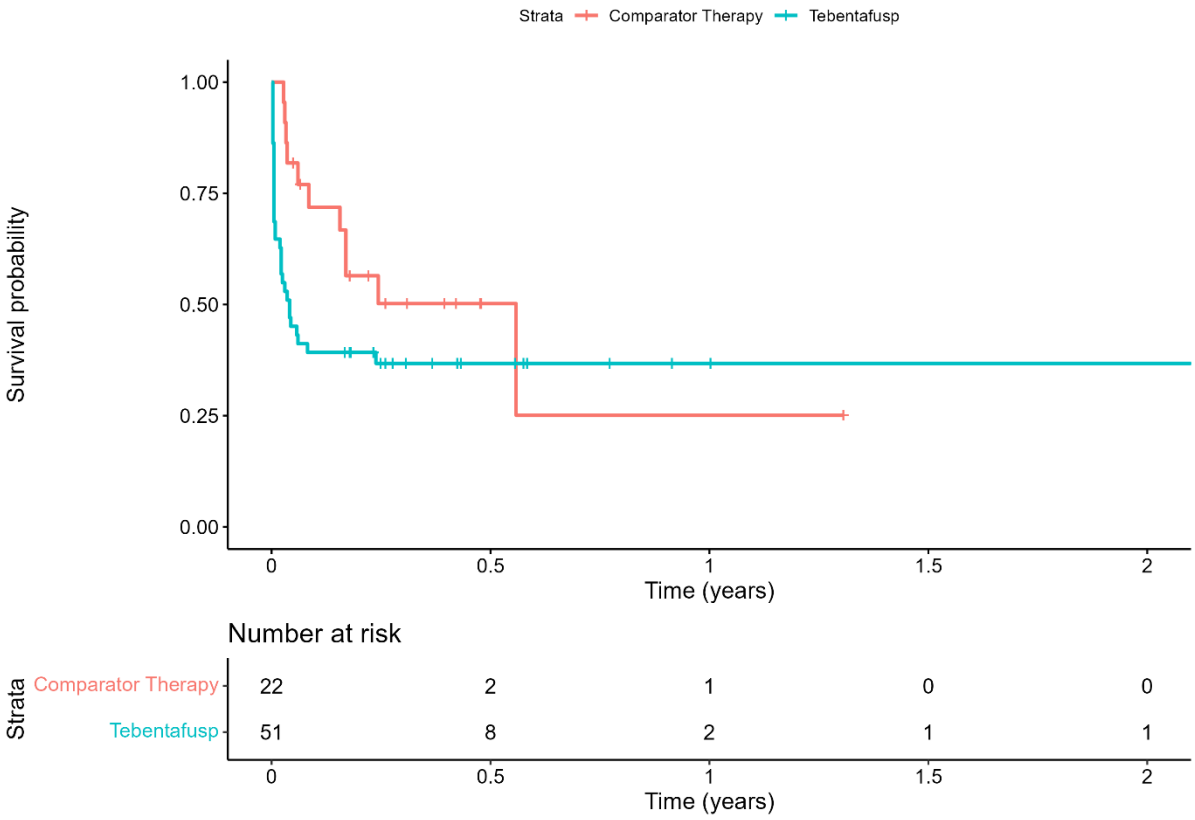
ECOG-Performance-Status: 1



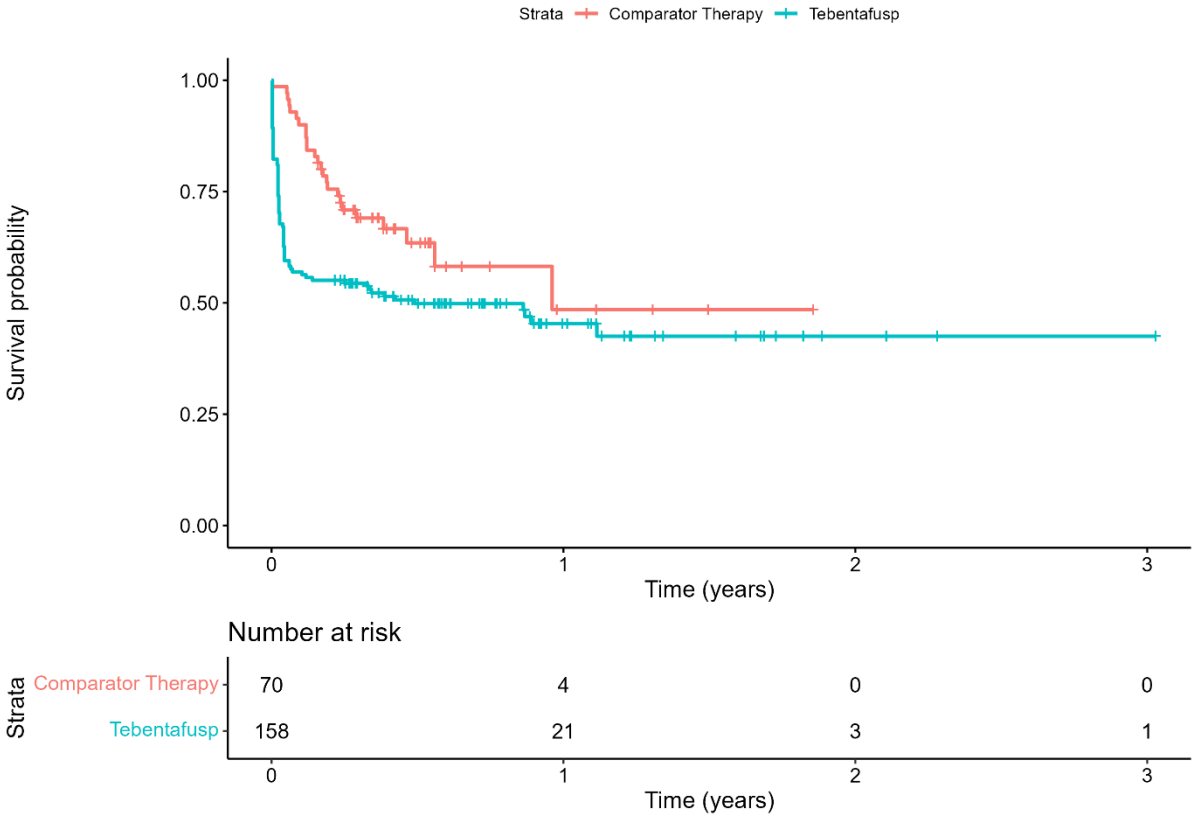
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



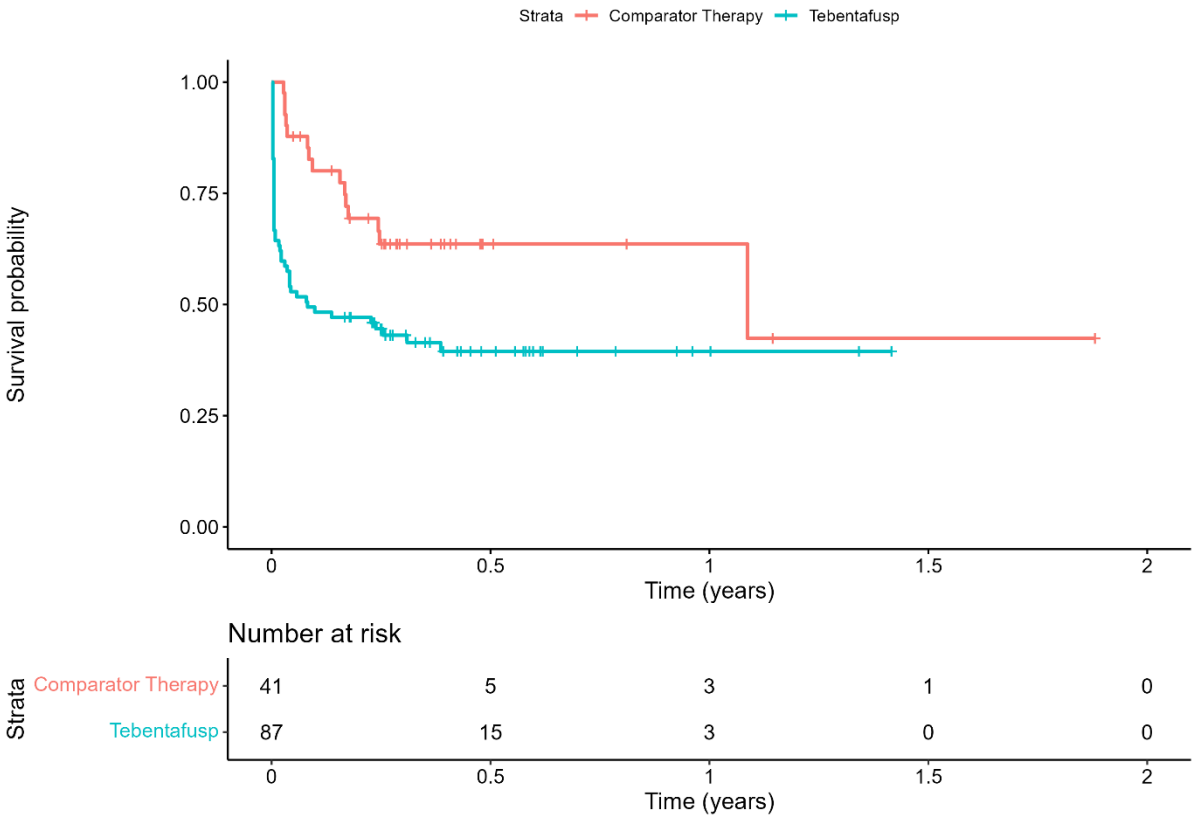
Alkalische Phosphatase (ALP) (Baseline): >ULN



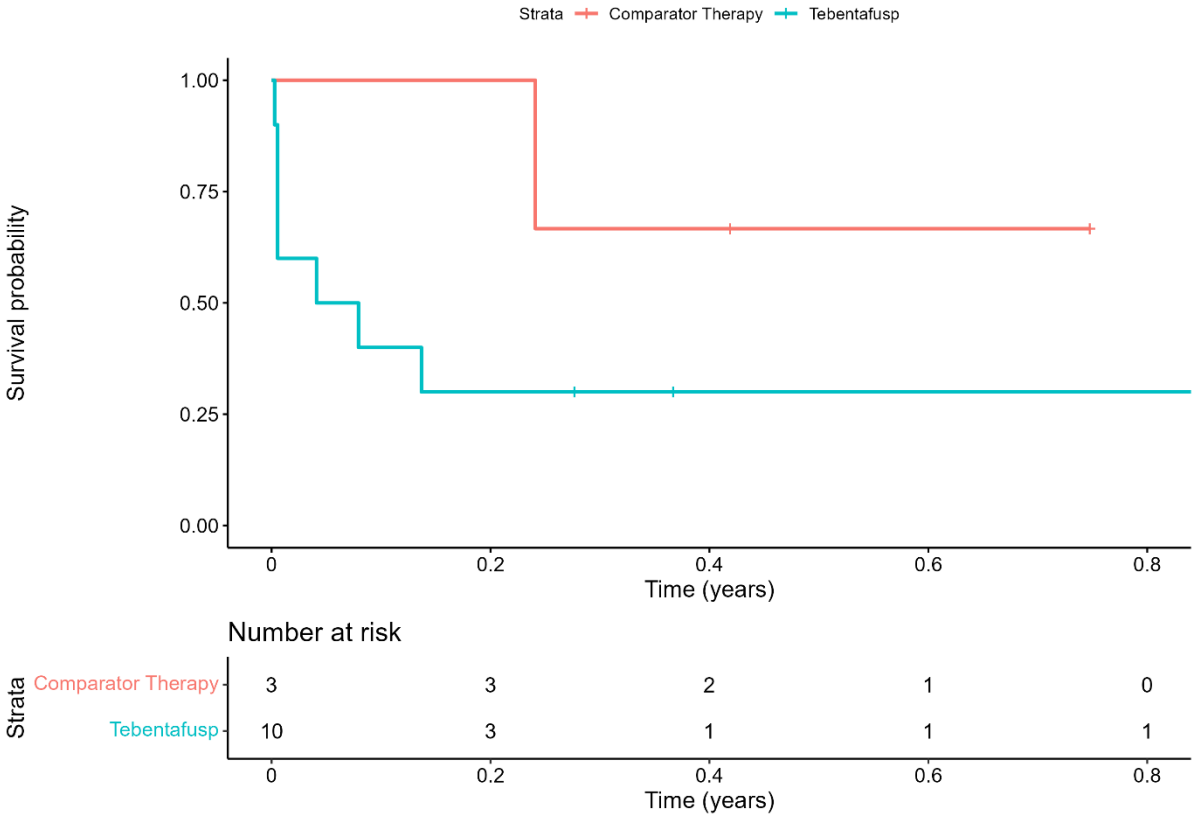
LDH: ≤ULN



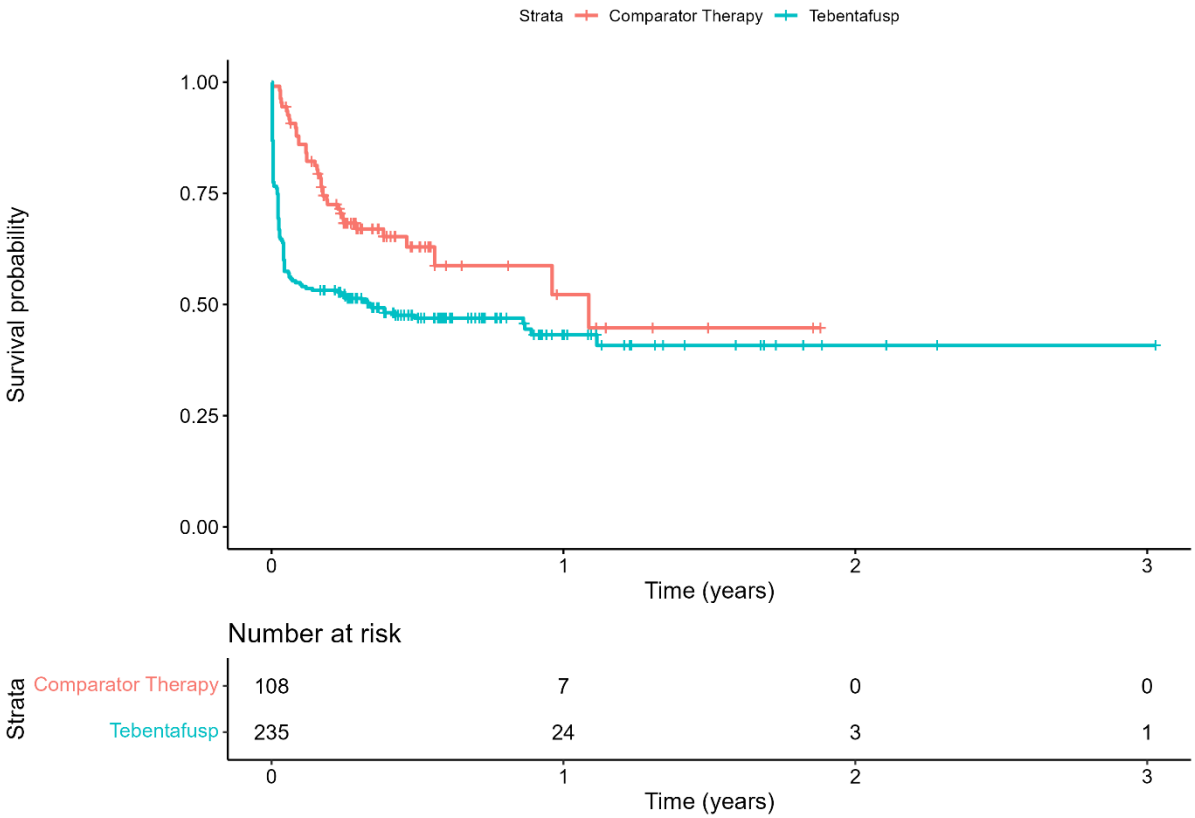
LDH: >ULN



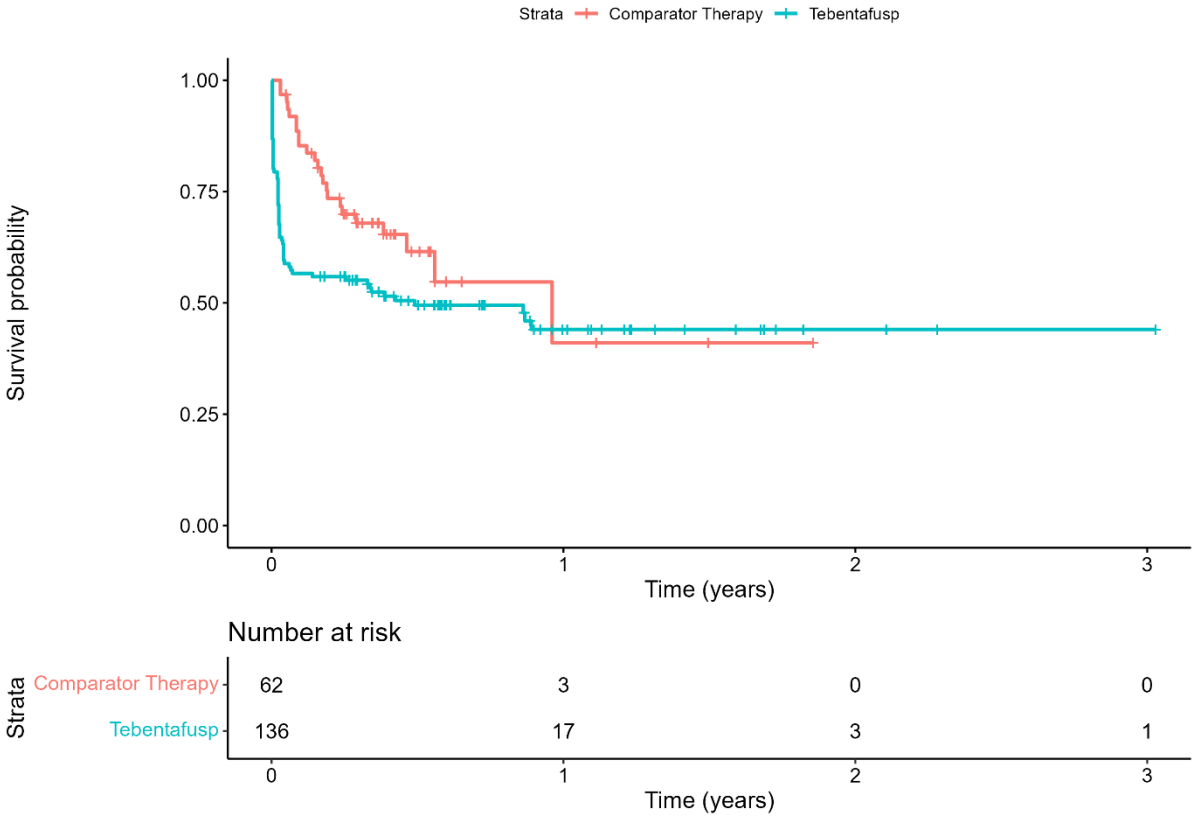
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



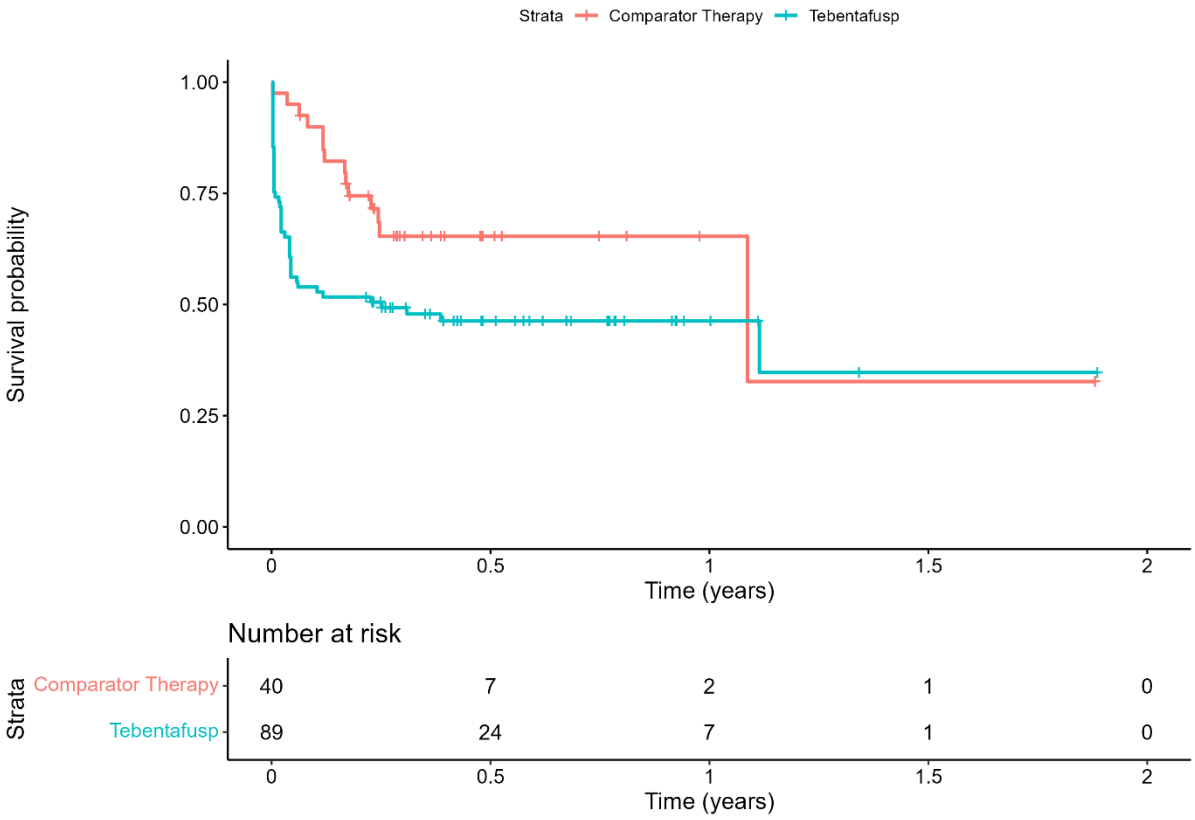
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



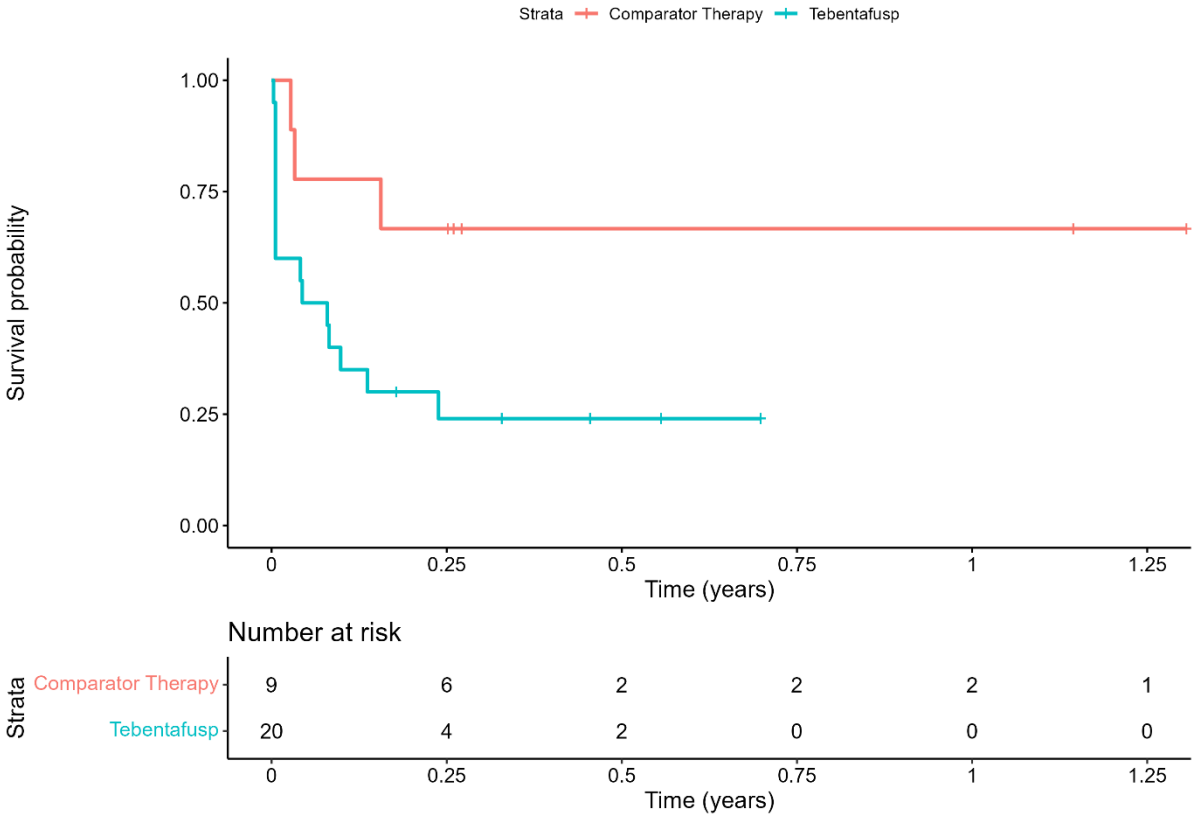
Größte metastatische Läsion (Baseline): ≤3,0 cm



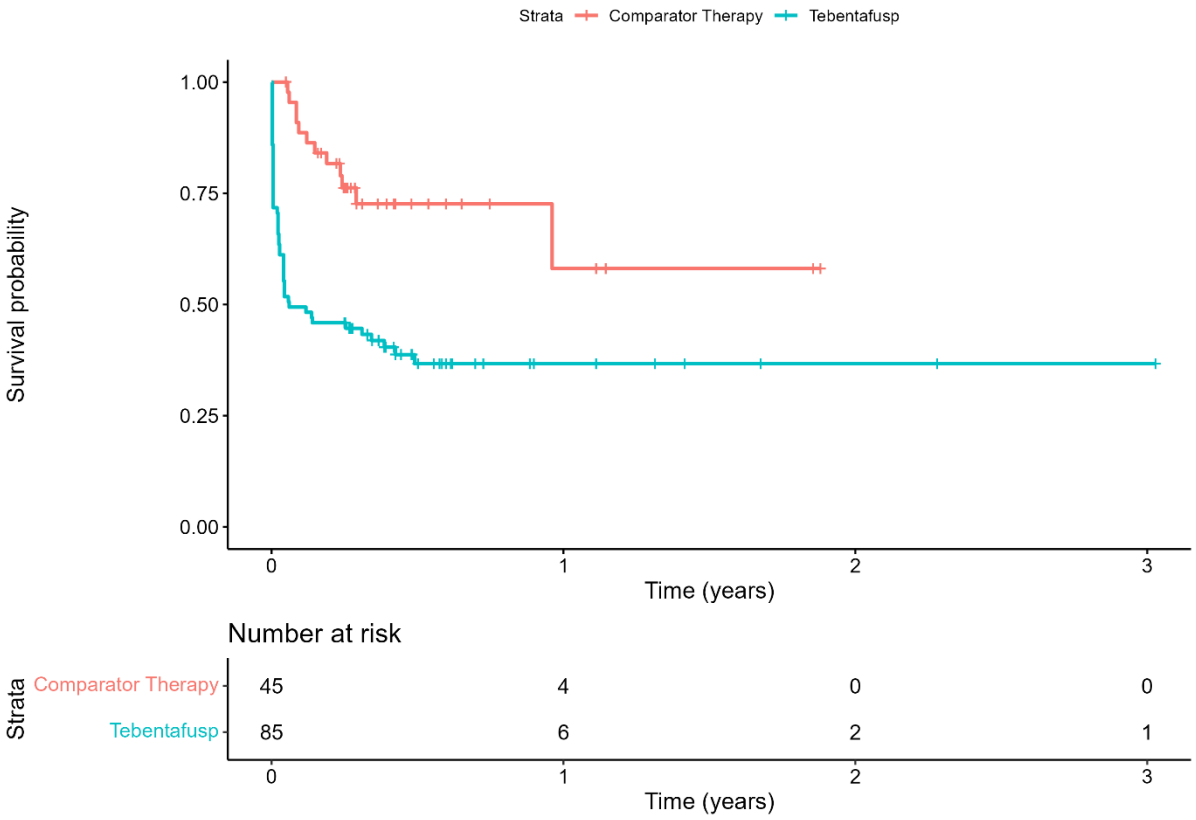
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



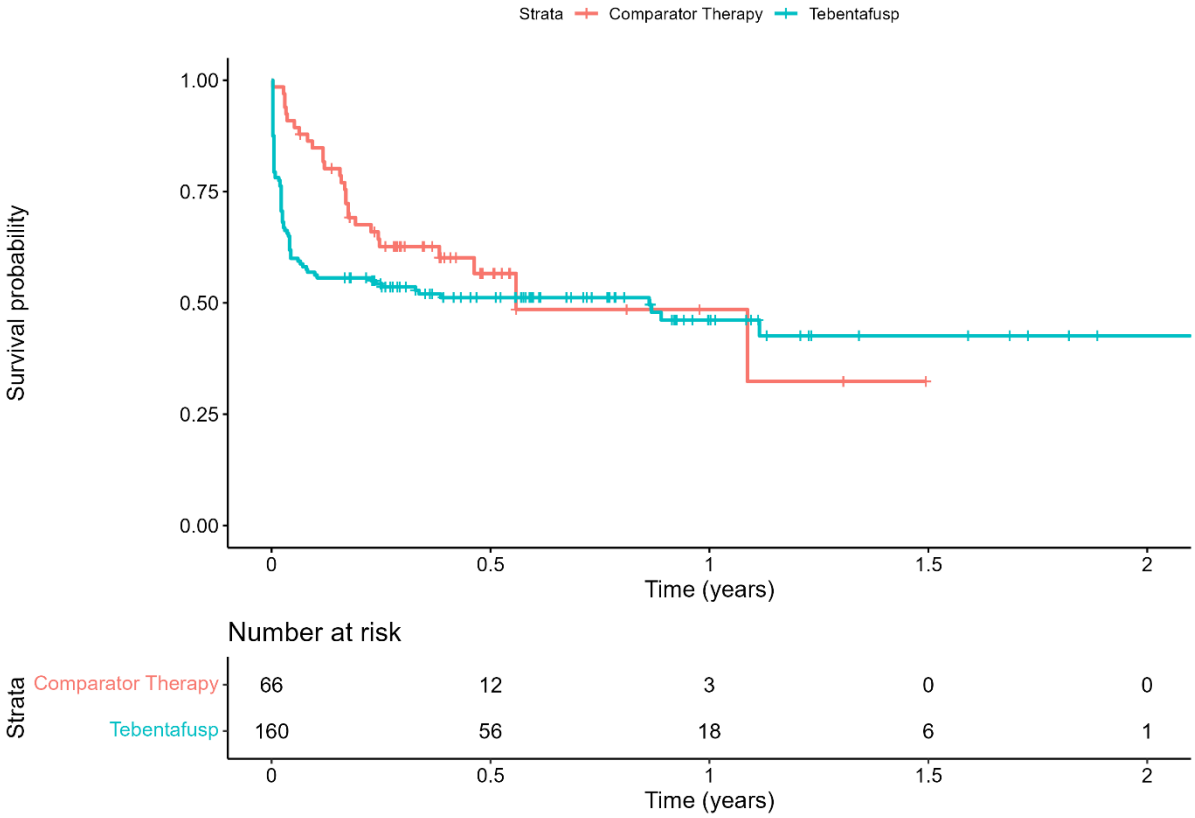
Größte metastatische Läsion (Baseline): ≥8,1 cm



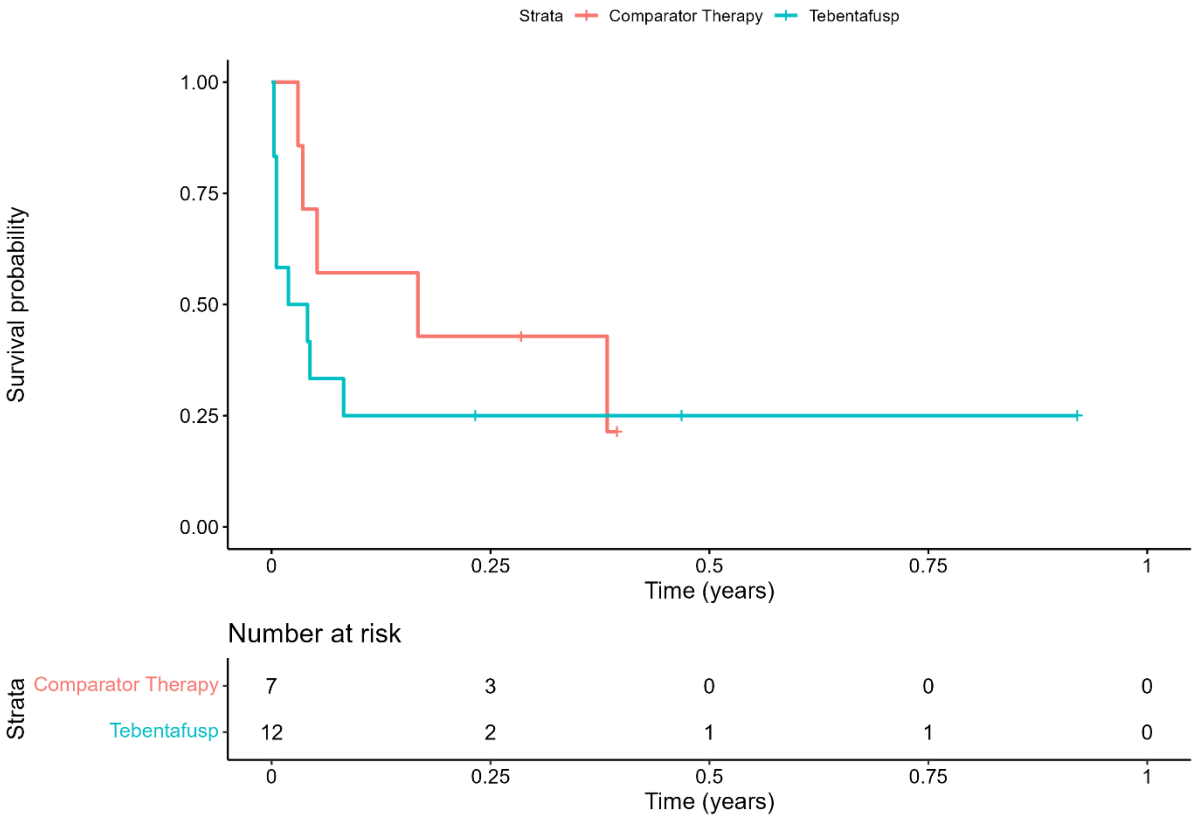
Region: Nordamerika



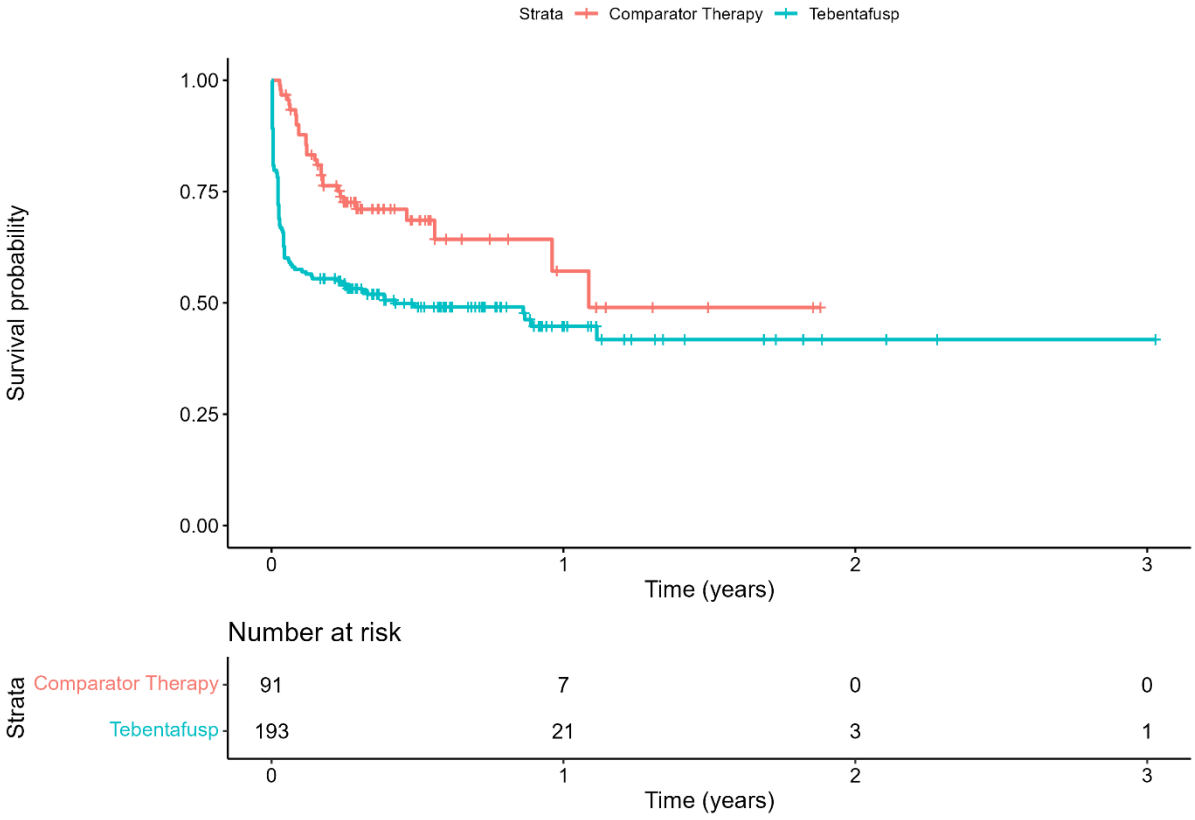
Region: Nicht-Nordamerika



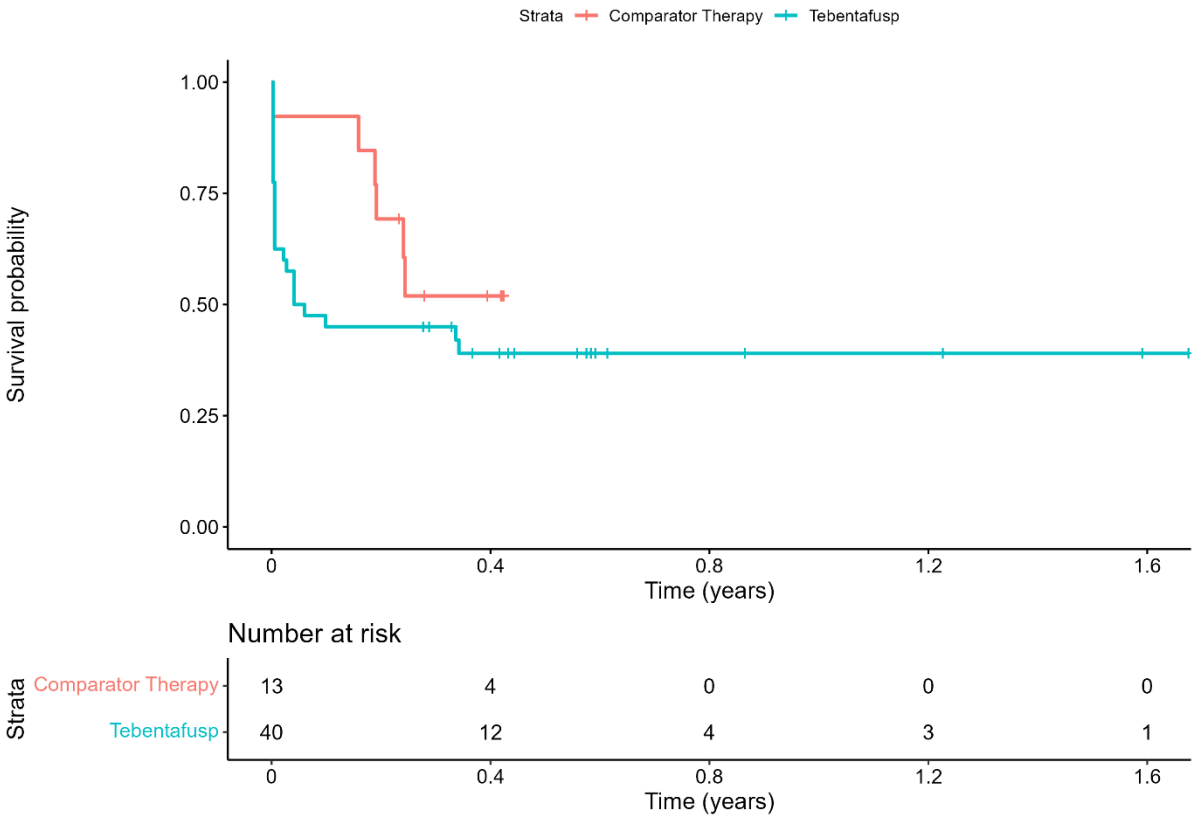
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

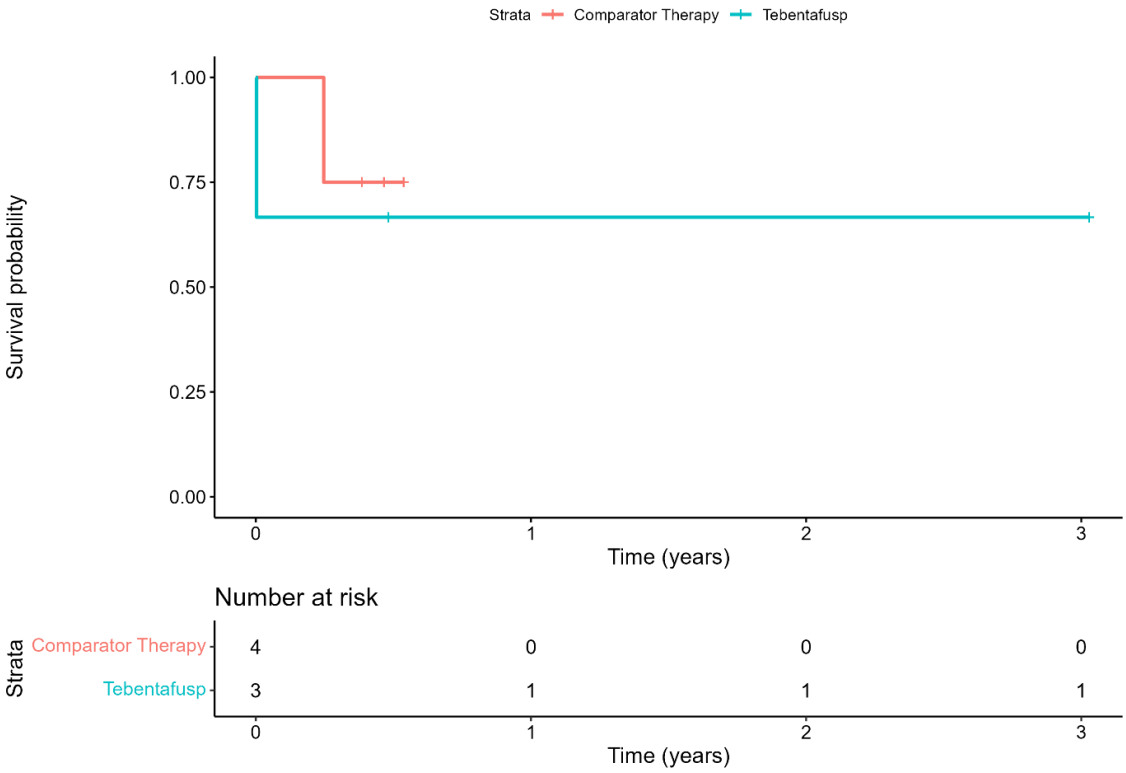


Vorauswahl der Chemotherapie: Ipilimumab

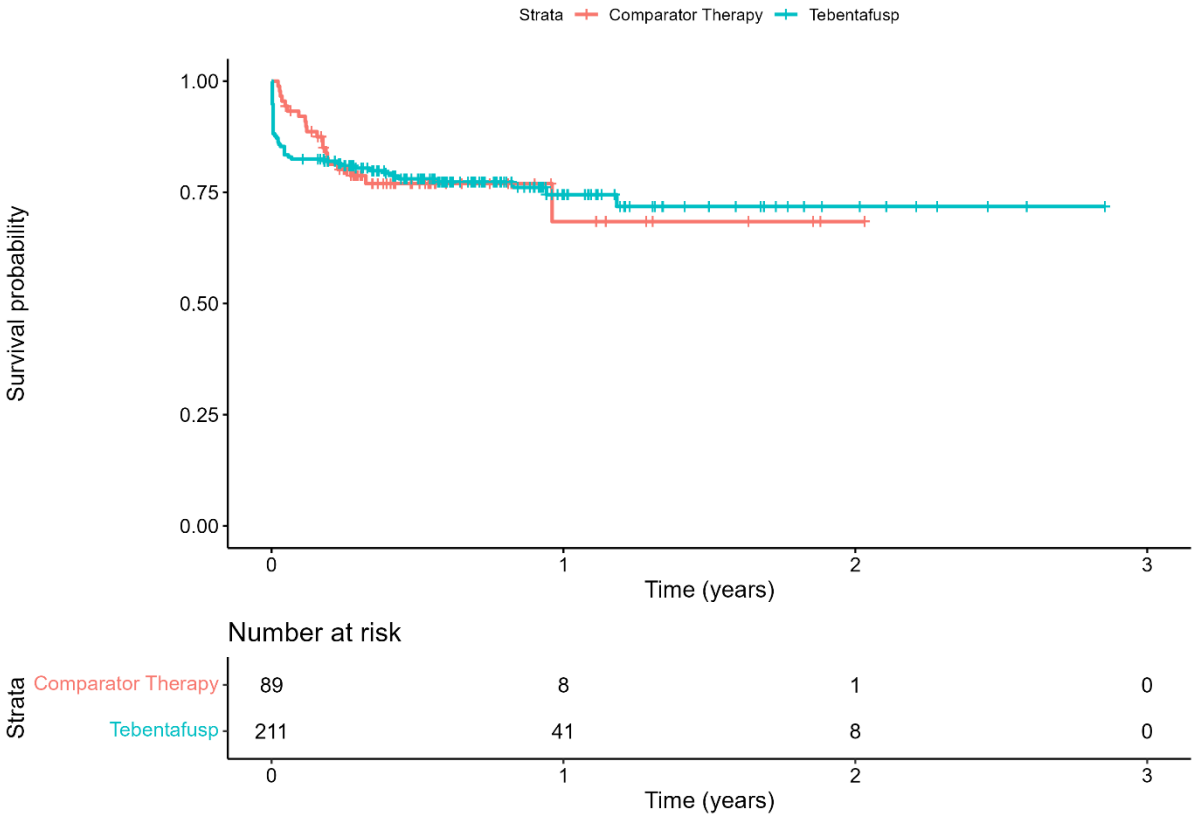


42.1 Jegliches SUE (Tabelle 4-91)

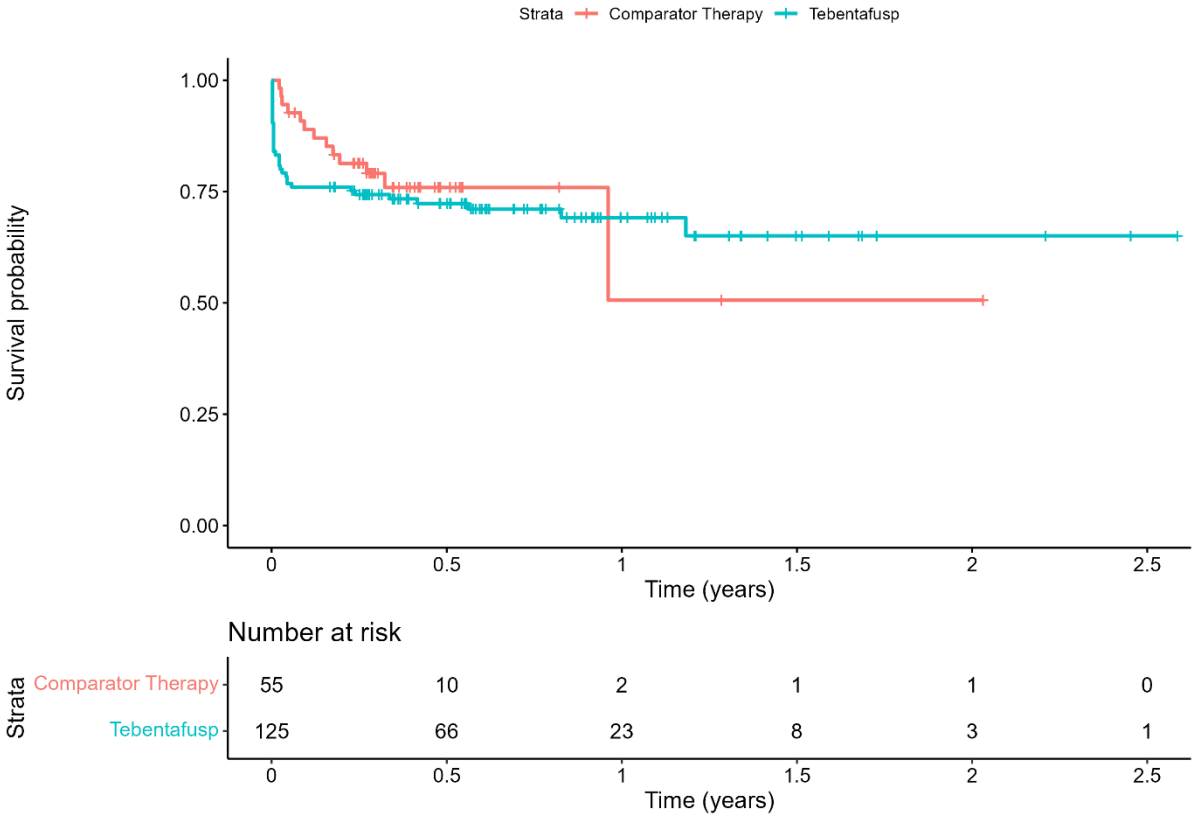
Herkunft: Hispanisch



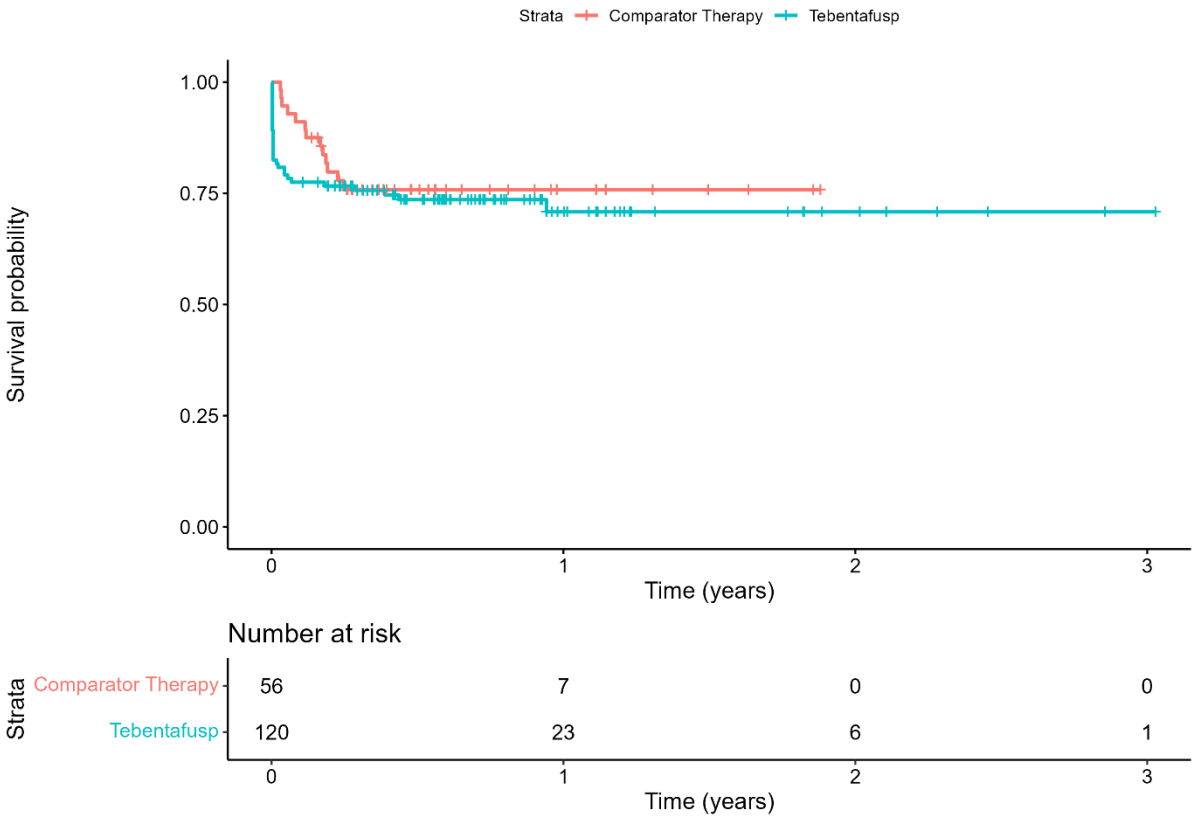
Herkunft: Nicht-hispanisch



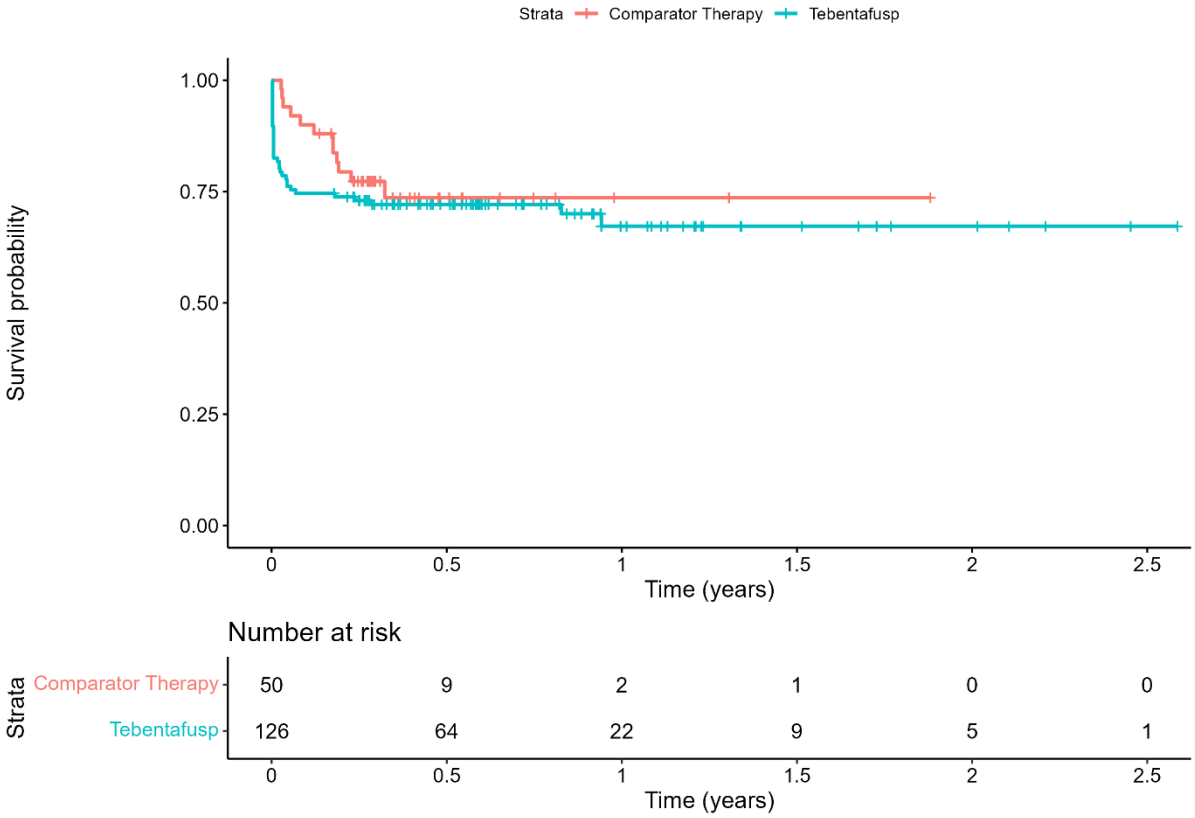
Geschlecht: Männlich



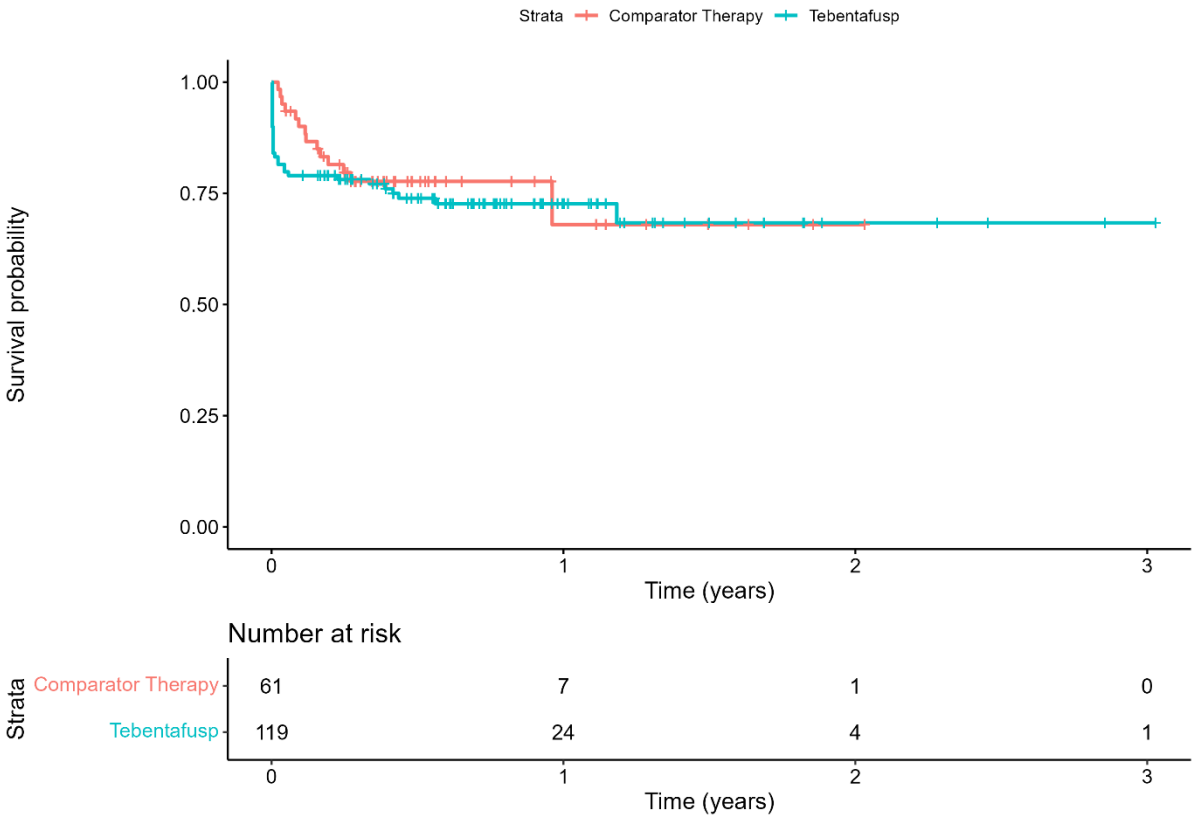
Geschlecht: Weiblich



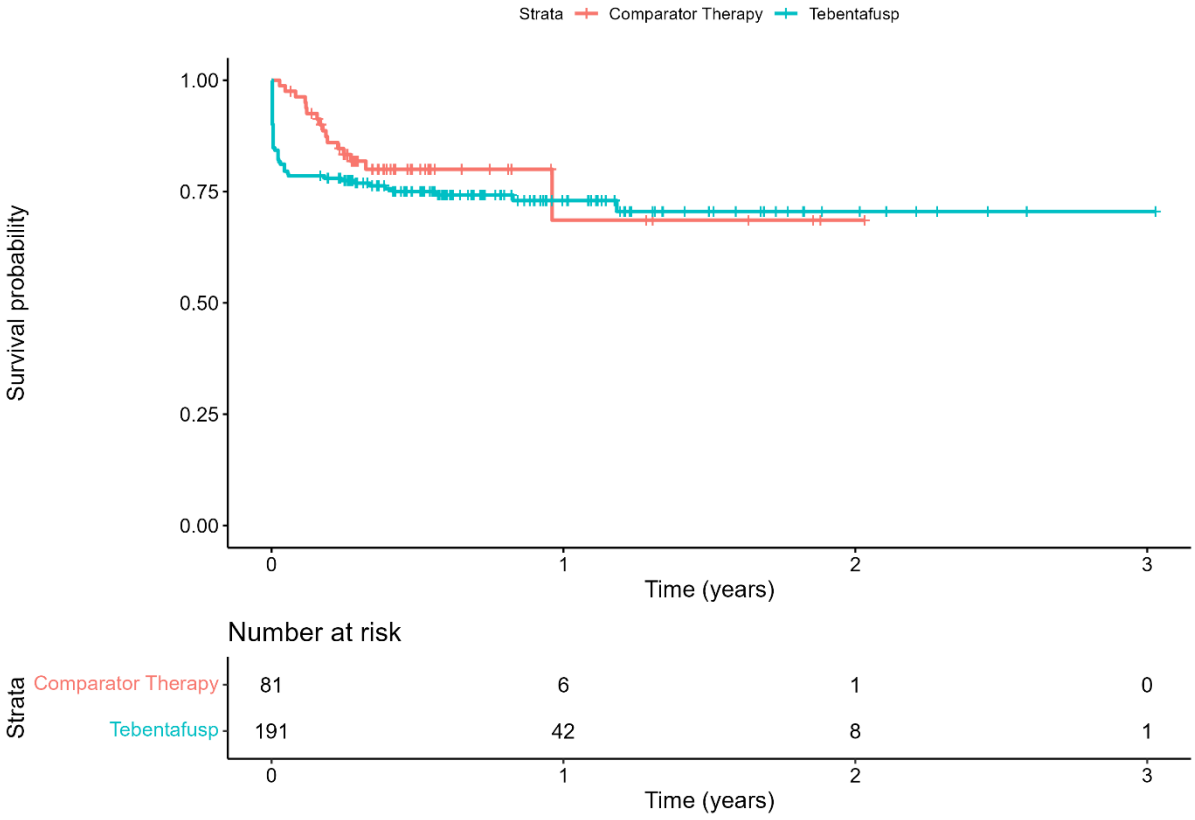
Alter: <65 Jahre



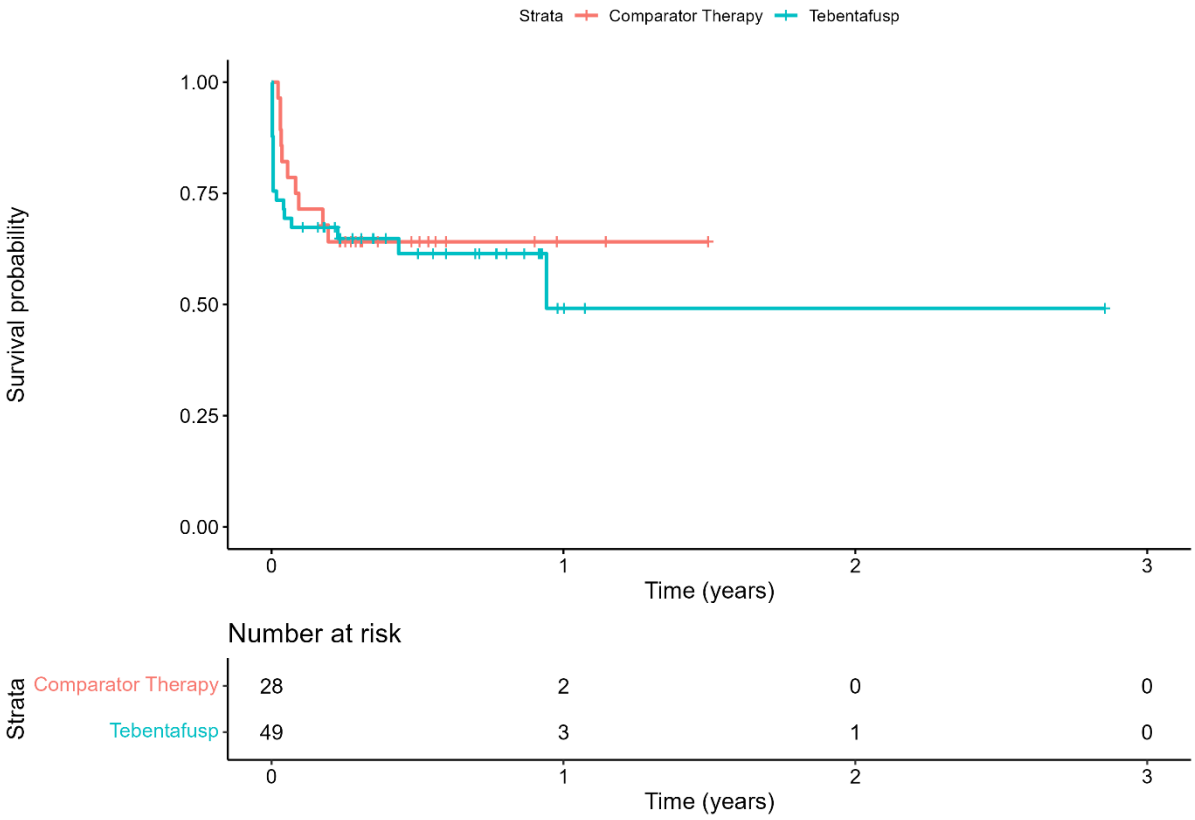
Alter: ≥65 Jahre



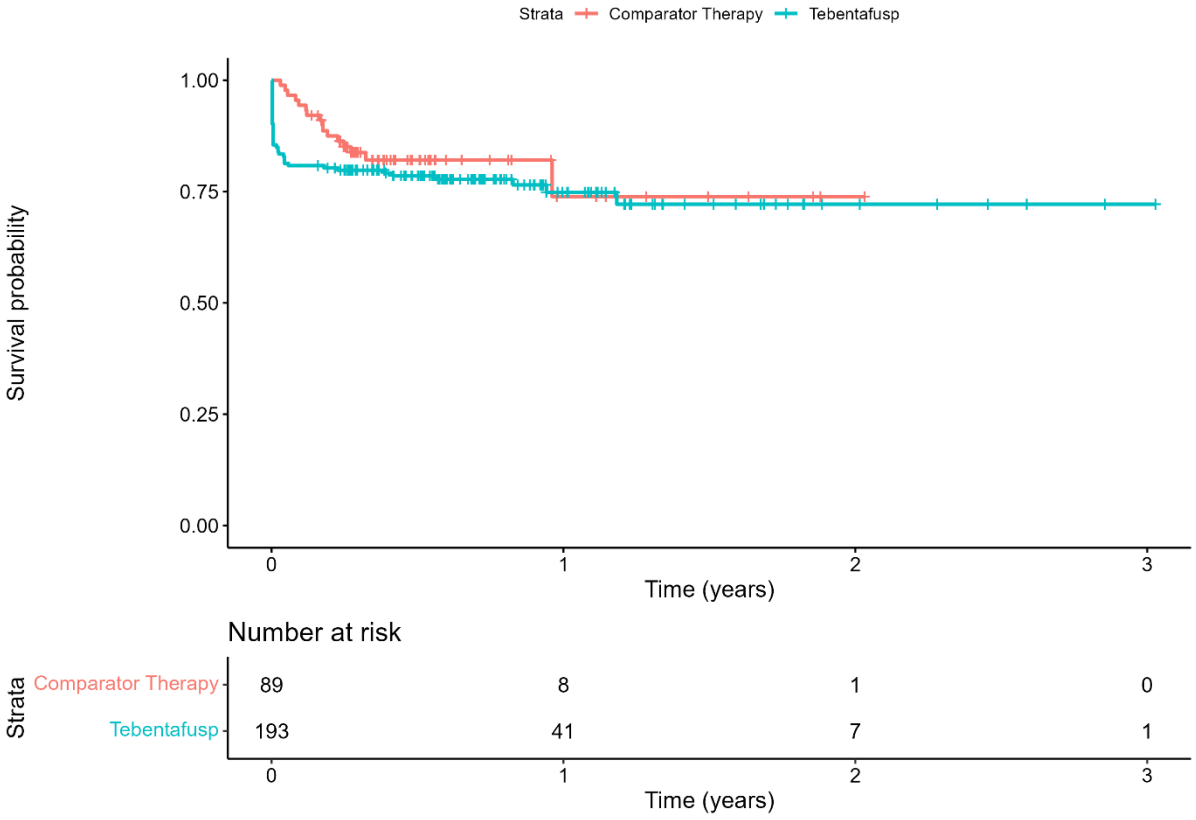
ECOG-Performance-Status: 0



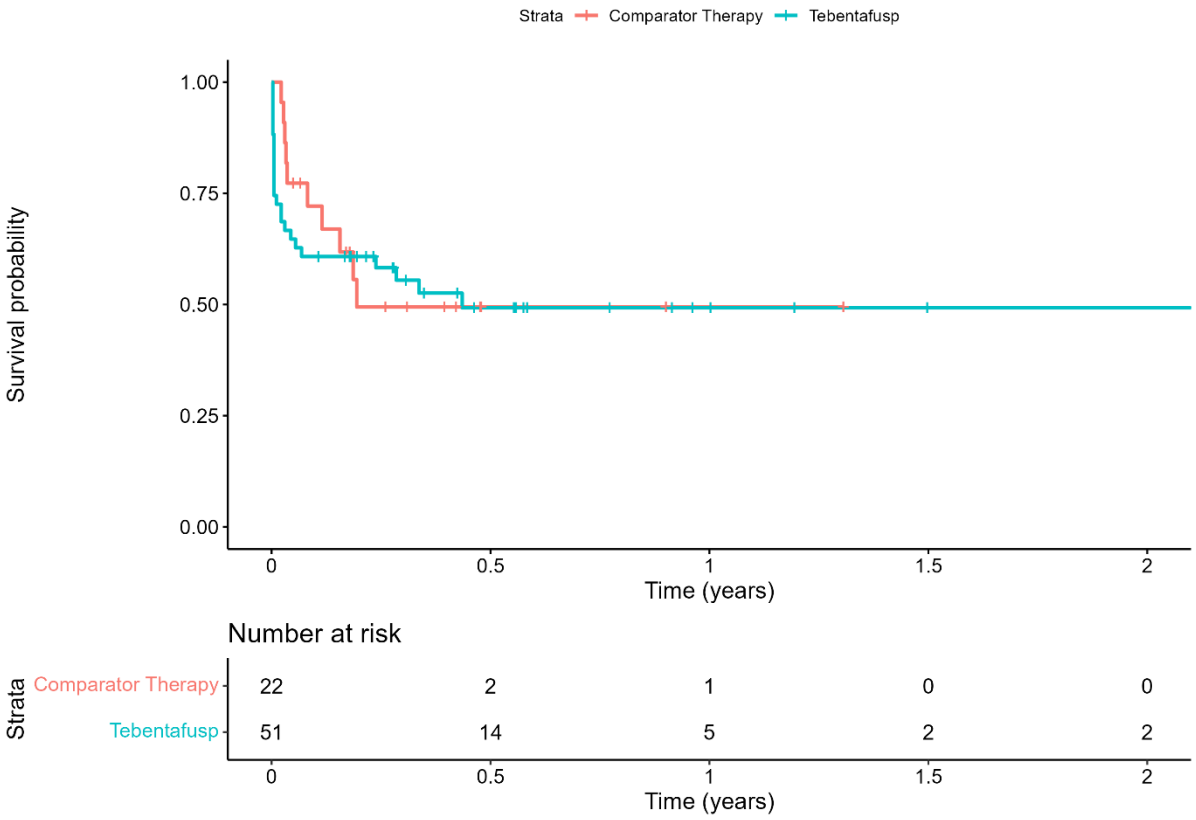
ECOG-Performance-Status: 1



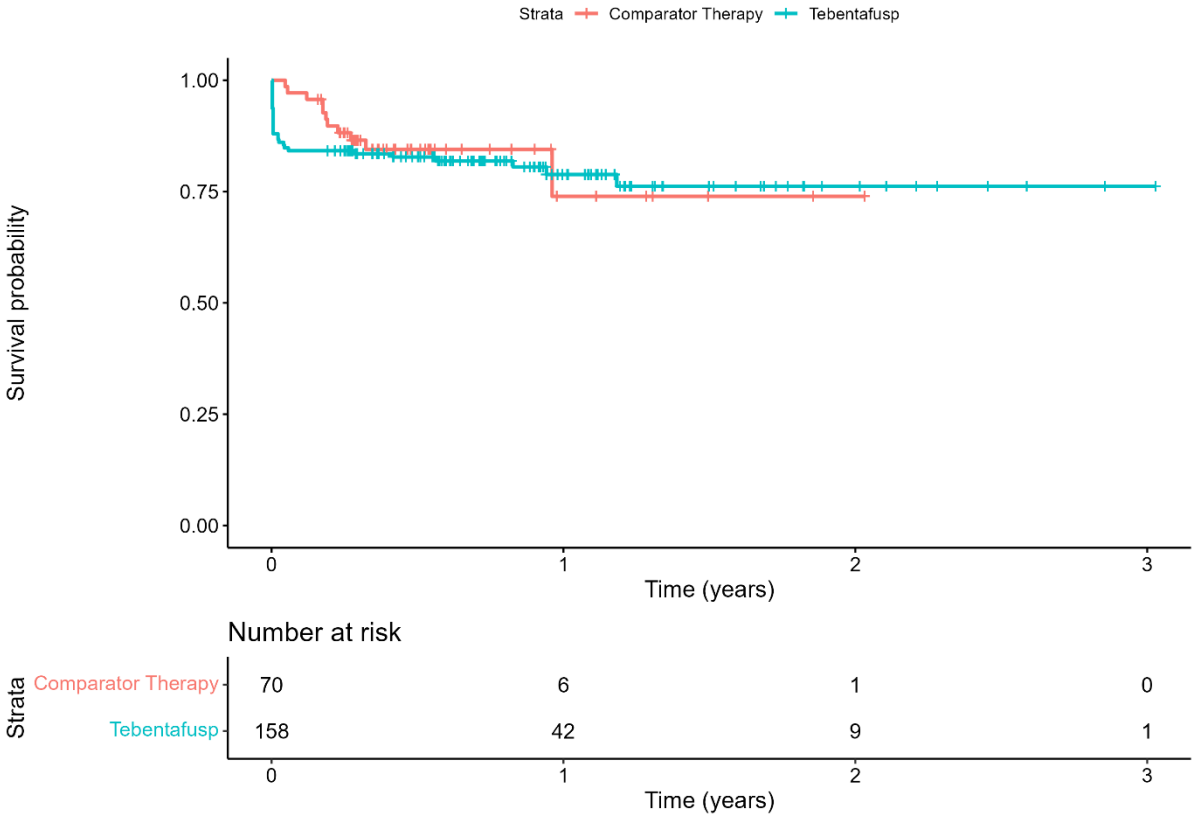
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



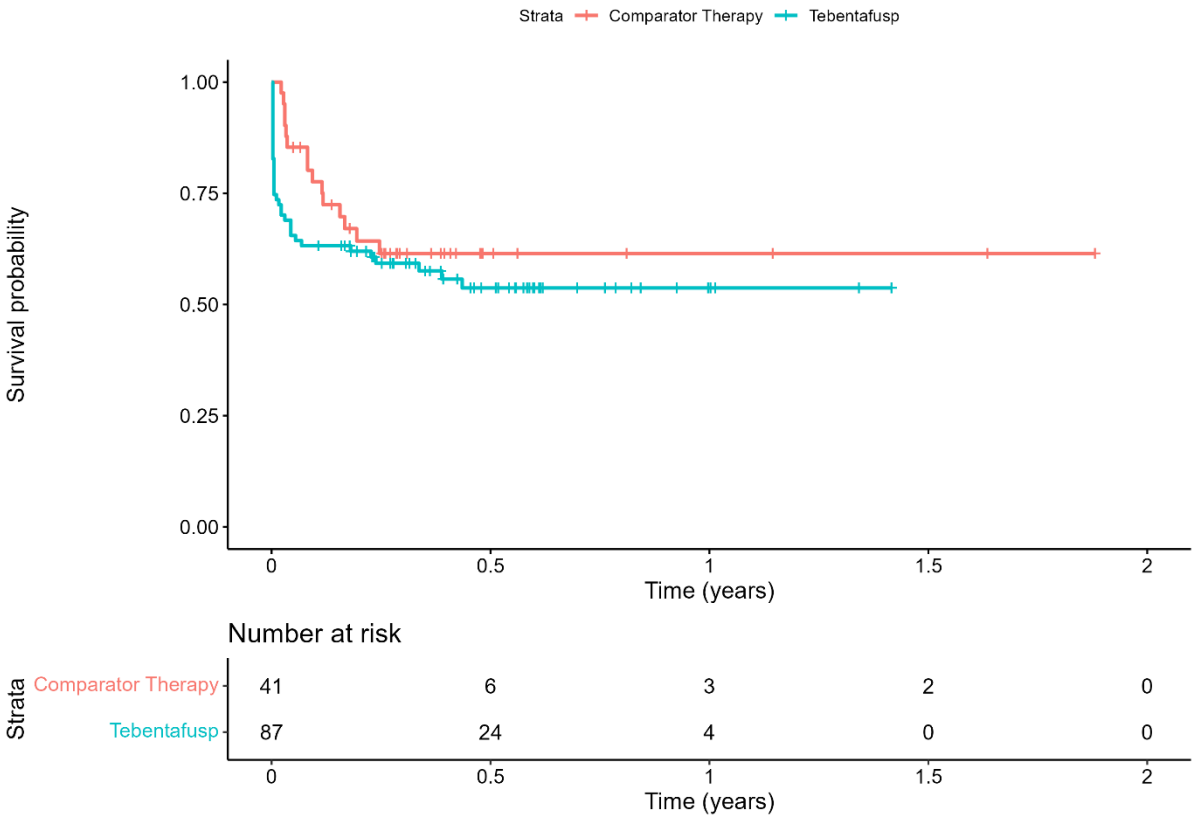
Alkalische Phosphatase (ALP) (Baseline): >ULN



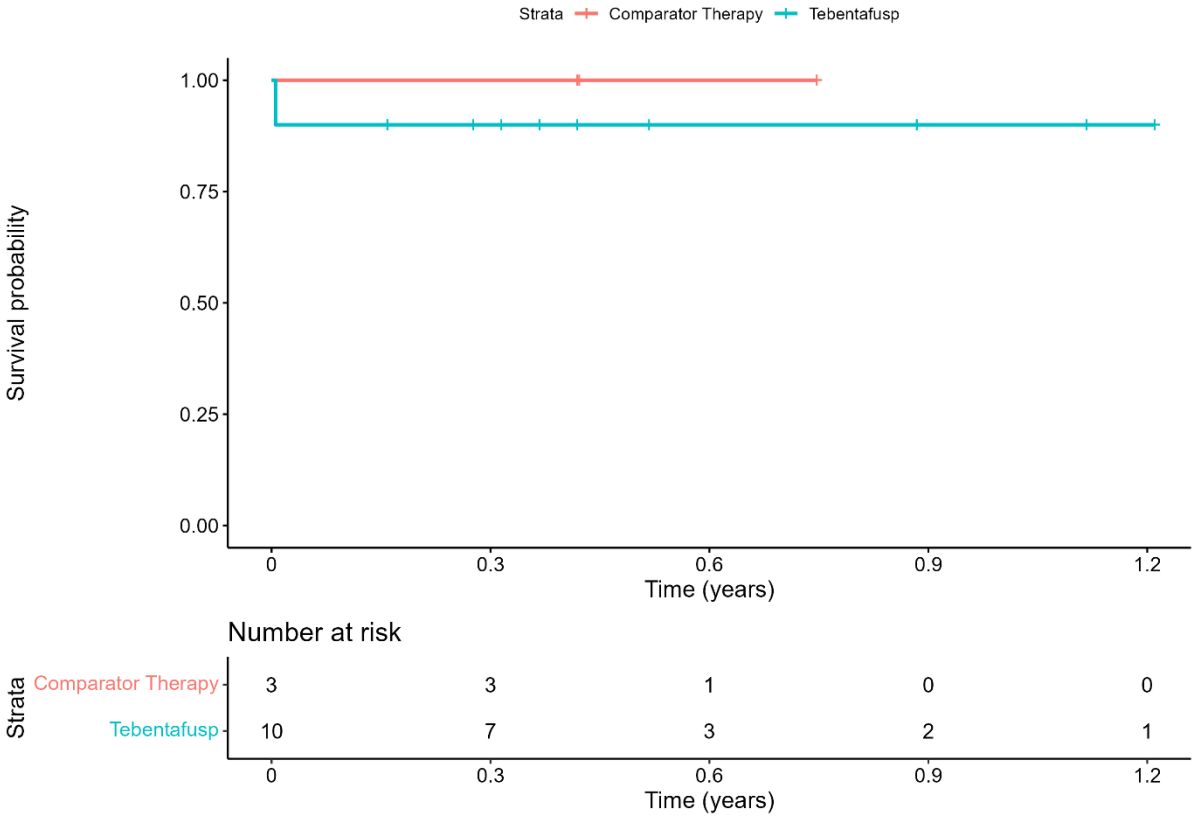
LDH: ≤ULN



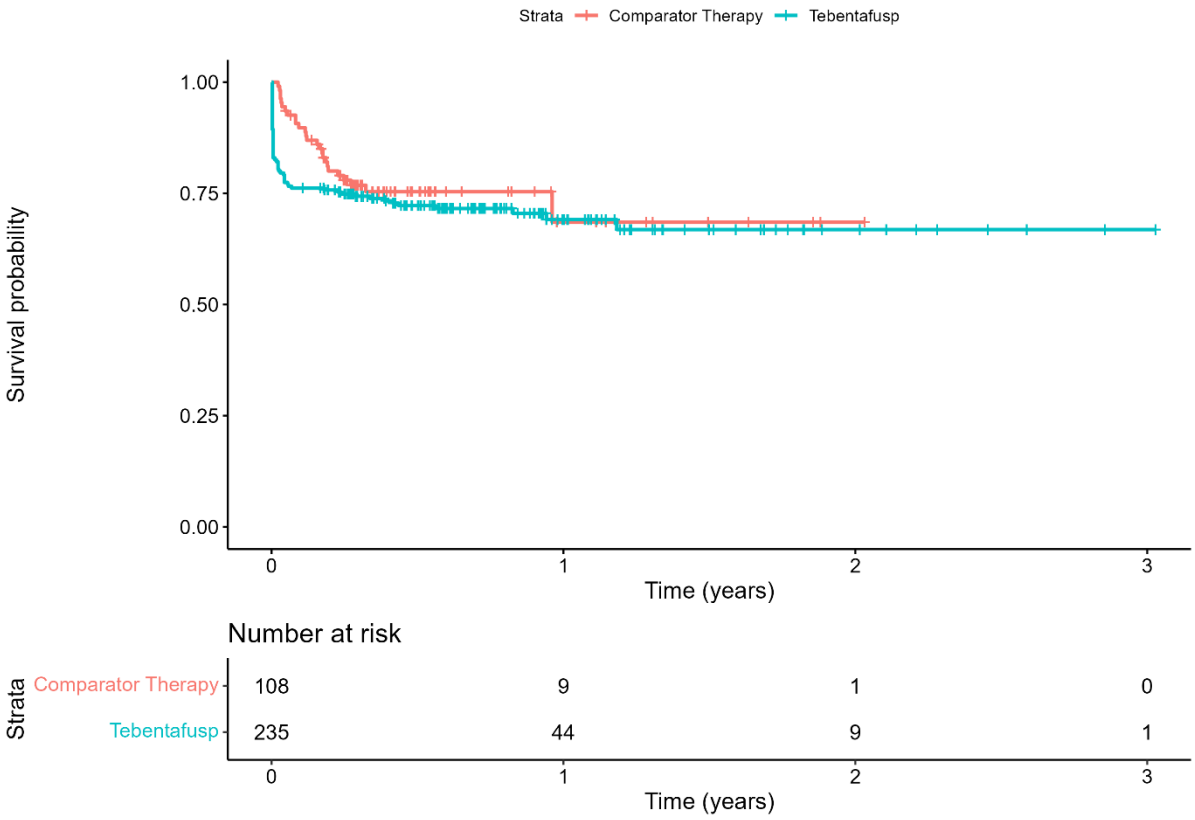
LDH: >ULN



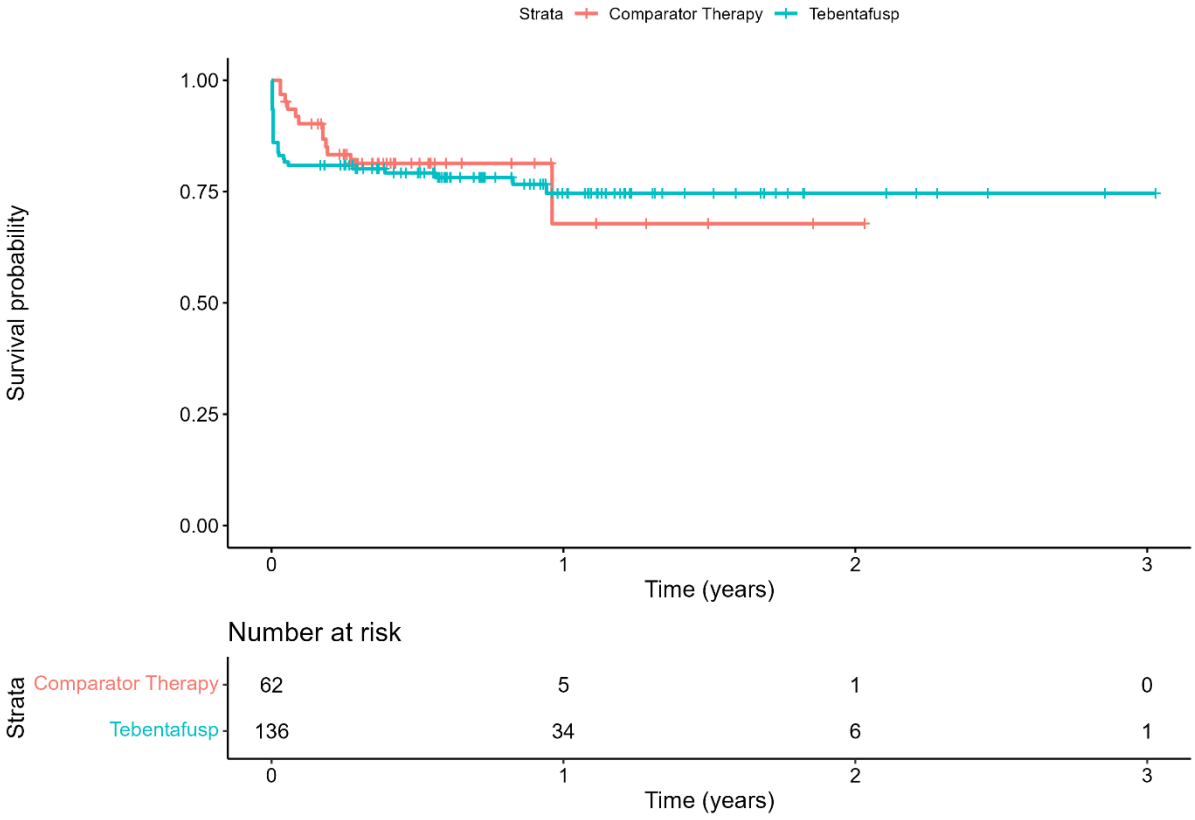
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



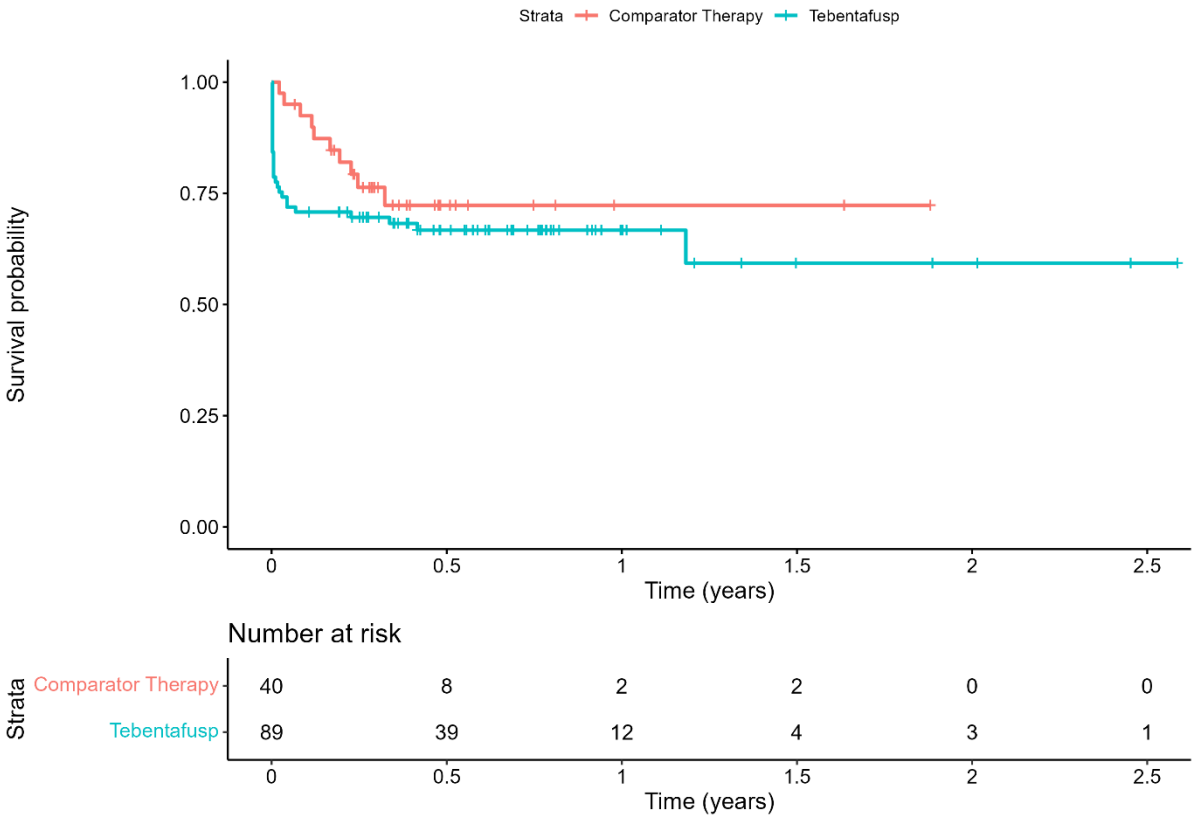
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



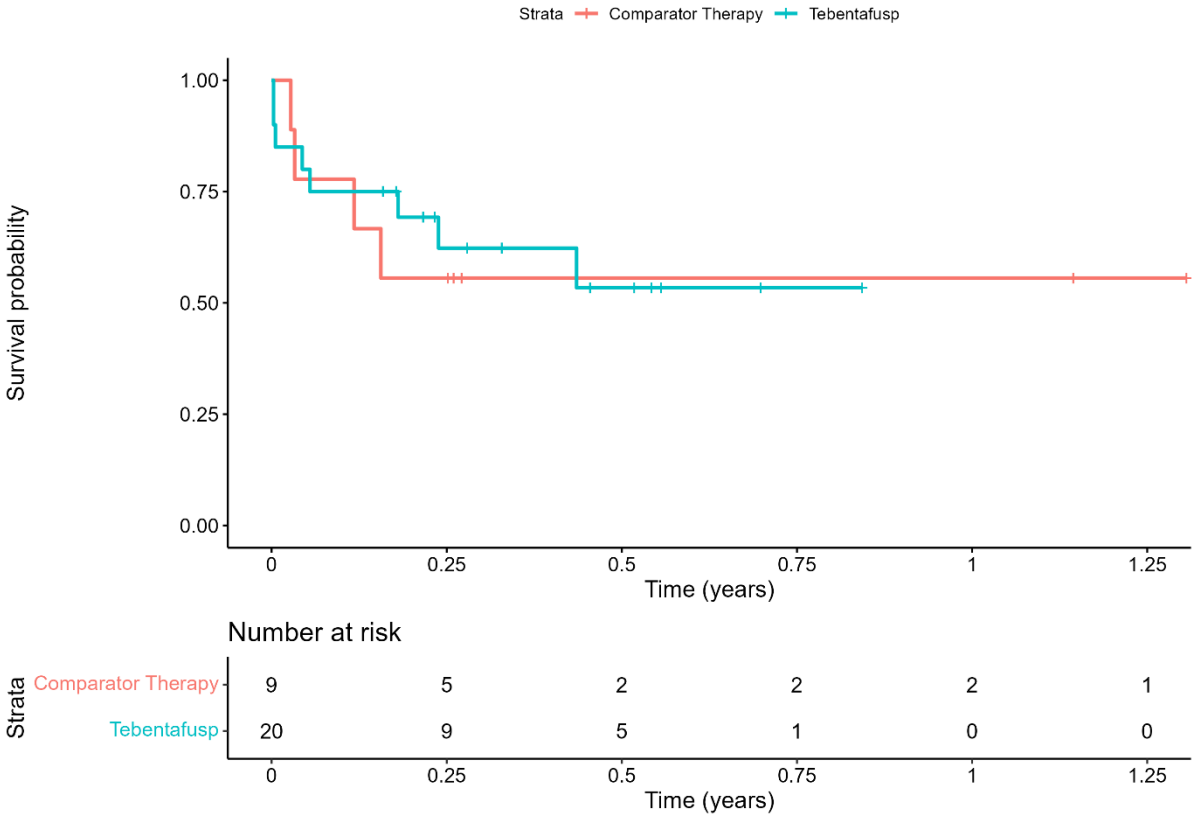
Größte metastatische Läsion (Baseline): ≤3,0 cm



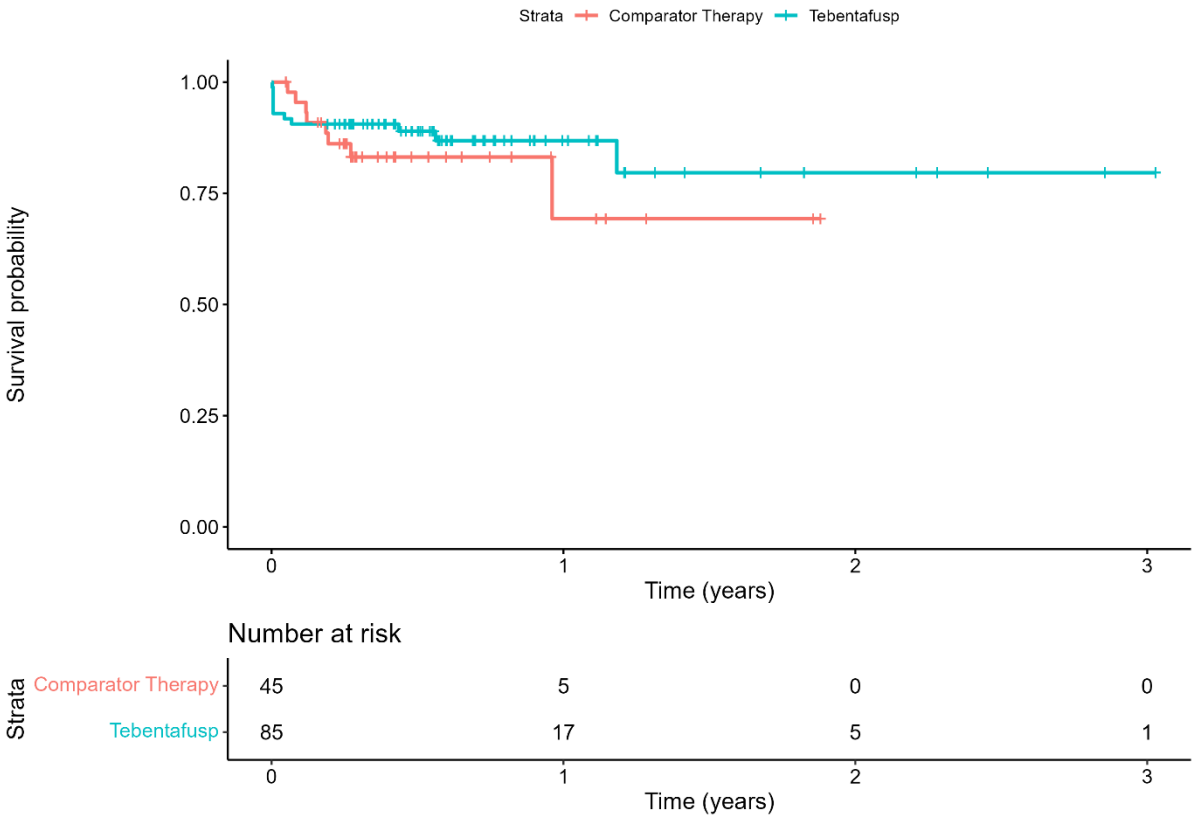
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



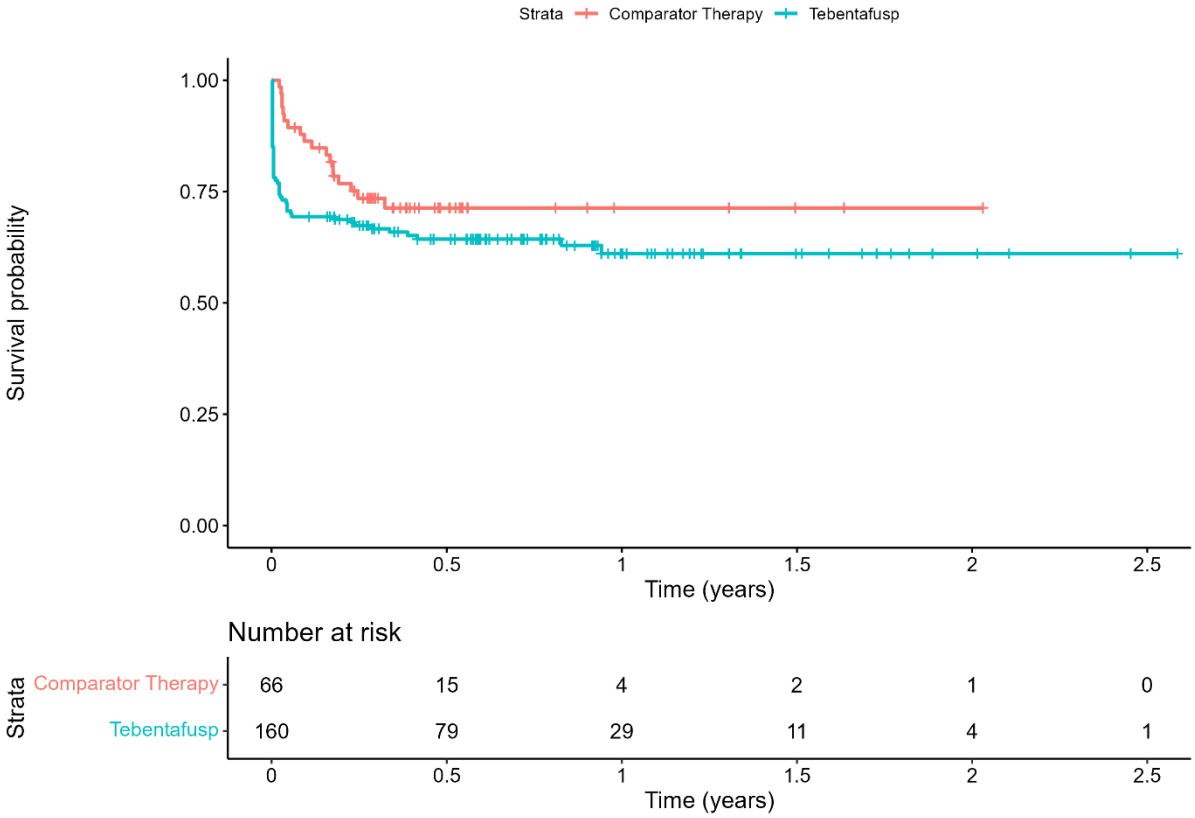
Größte metastatische Läsion (Baseline): ≥8,1 cm



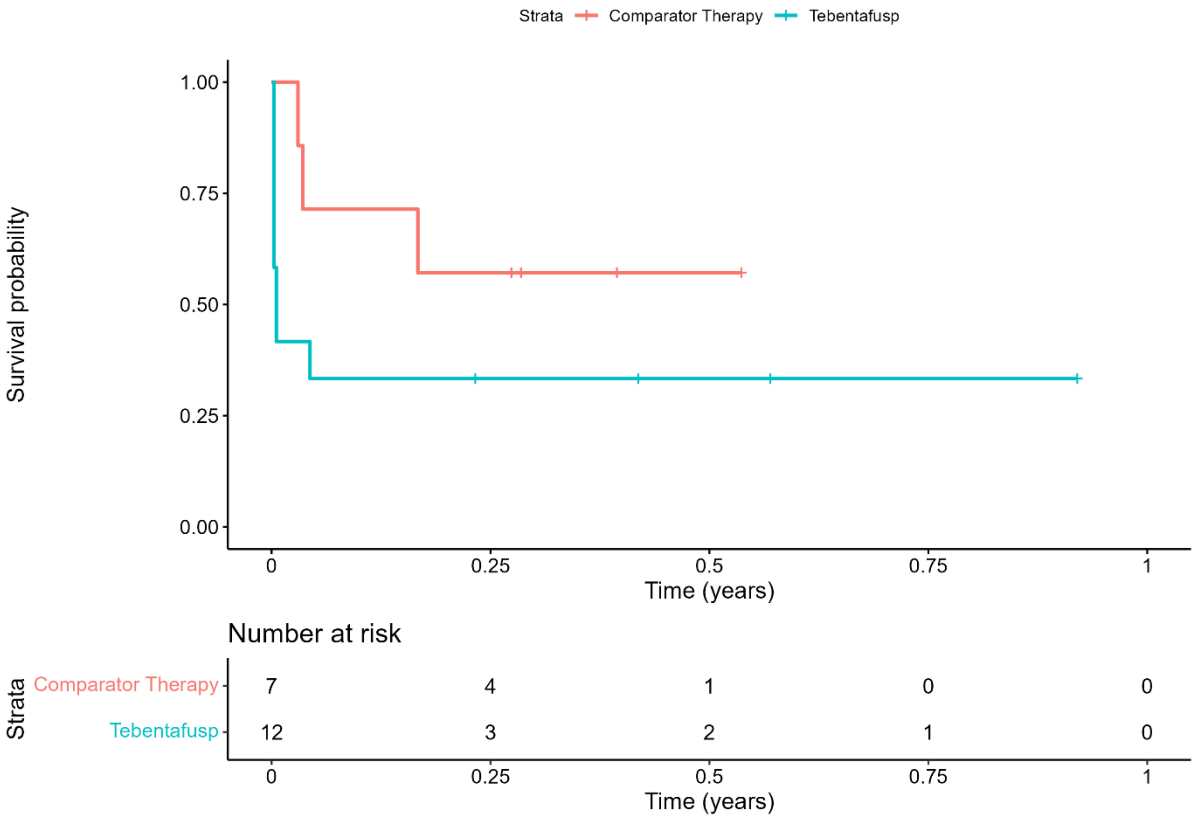
Region: Nordamerika



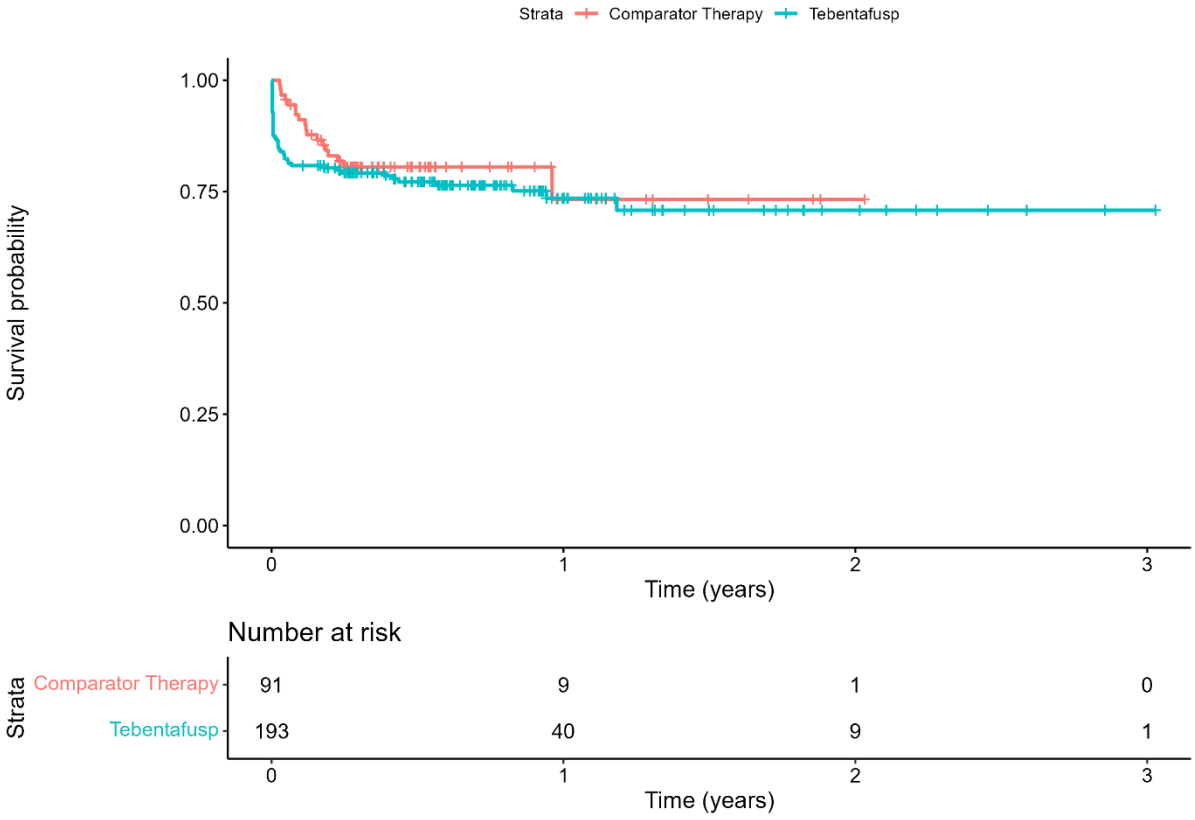
Region: Nicht-Nordamerika



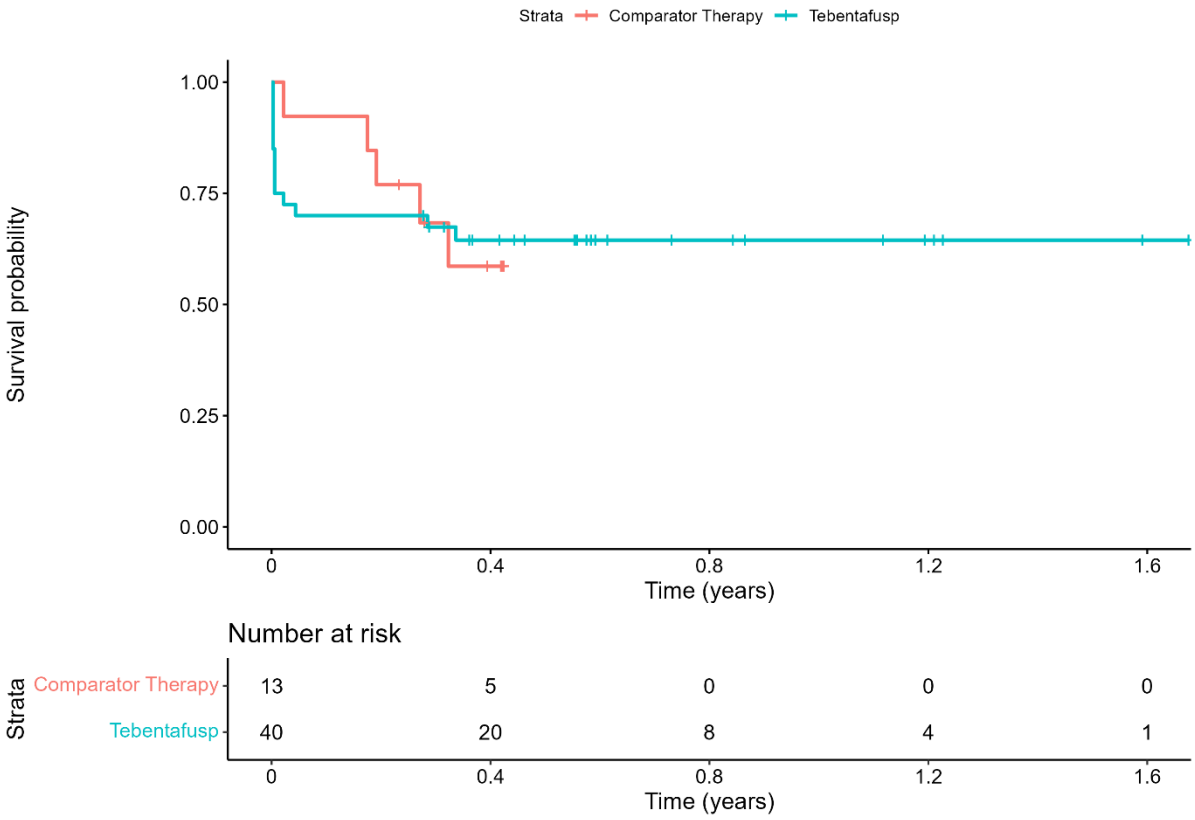
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

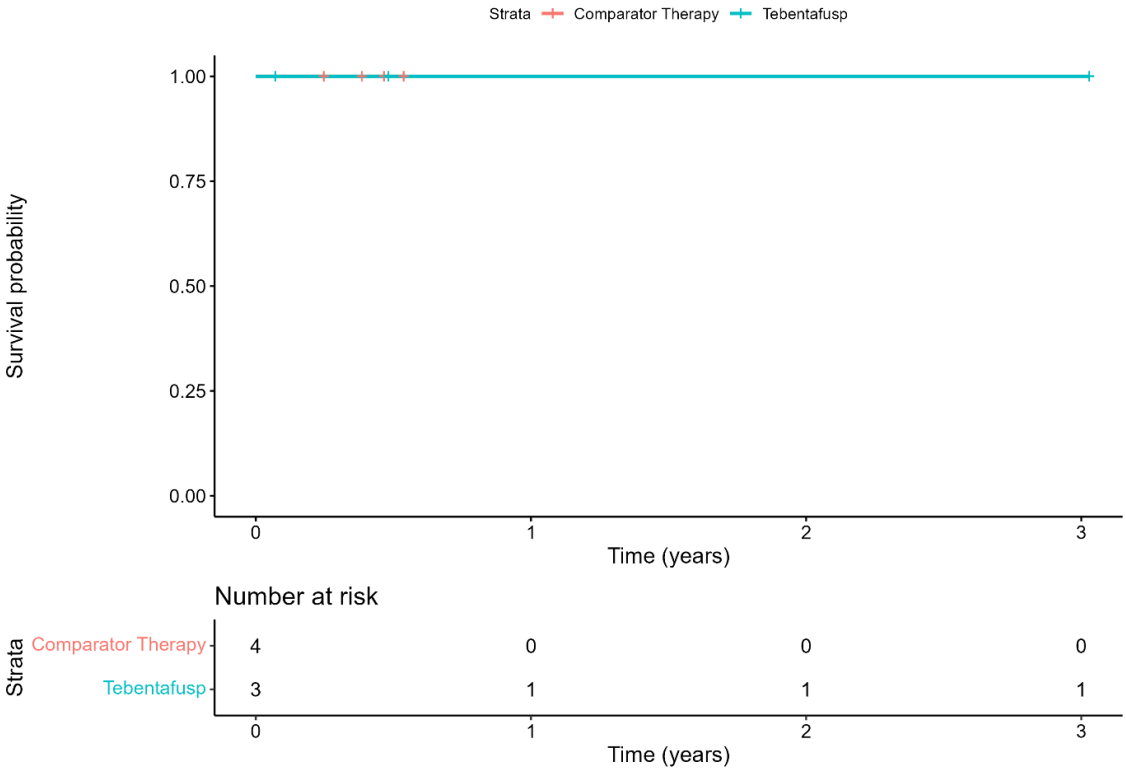


Vorauswahl der Chemotherapie: Ipilimumab

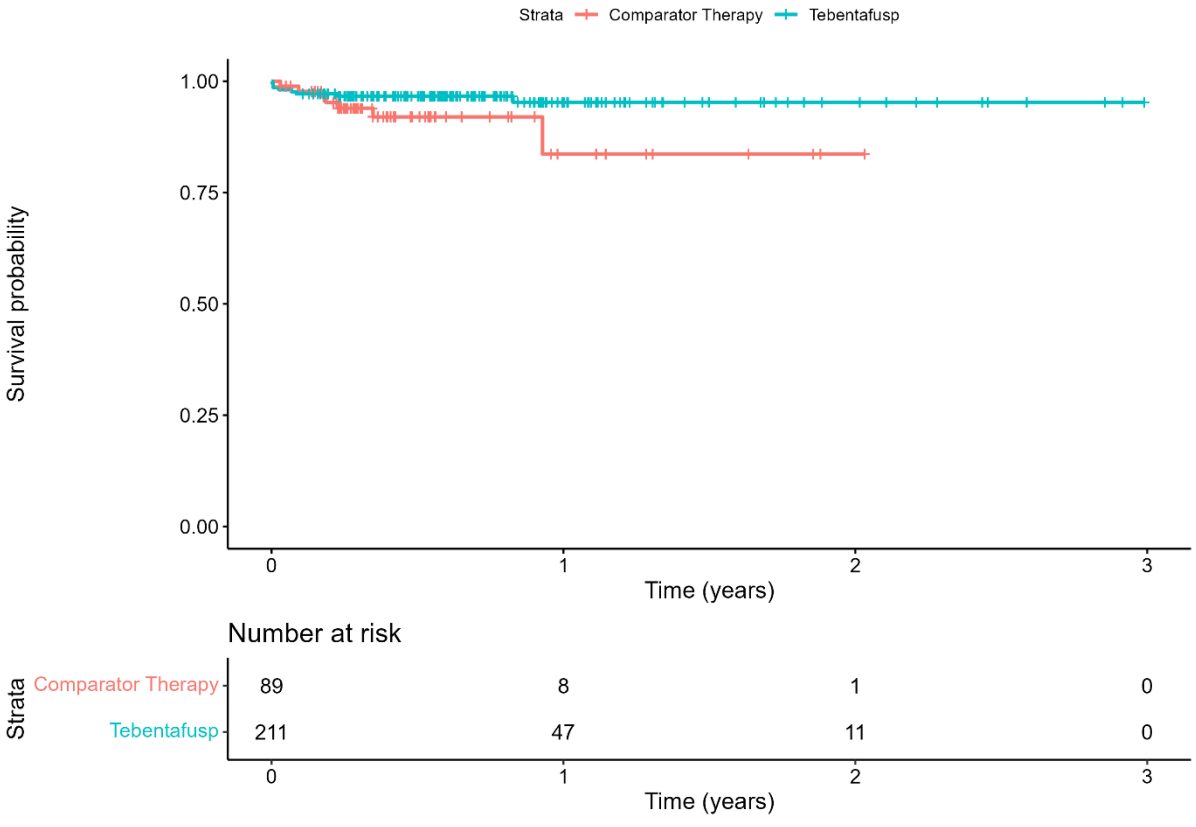


42.3 Jegliches UE, das zum Absetzen des Studienmedikaments führte (Tabelle 4-93)

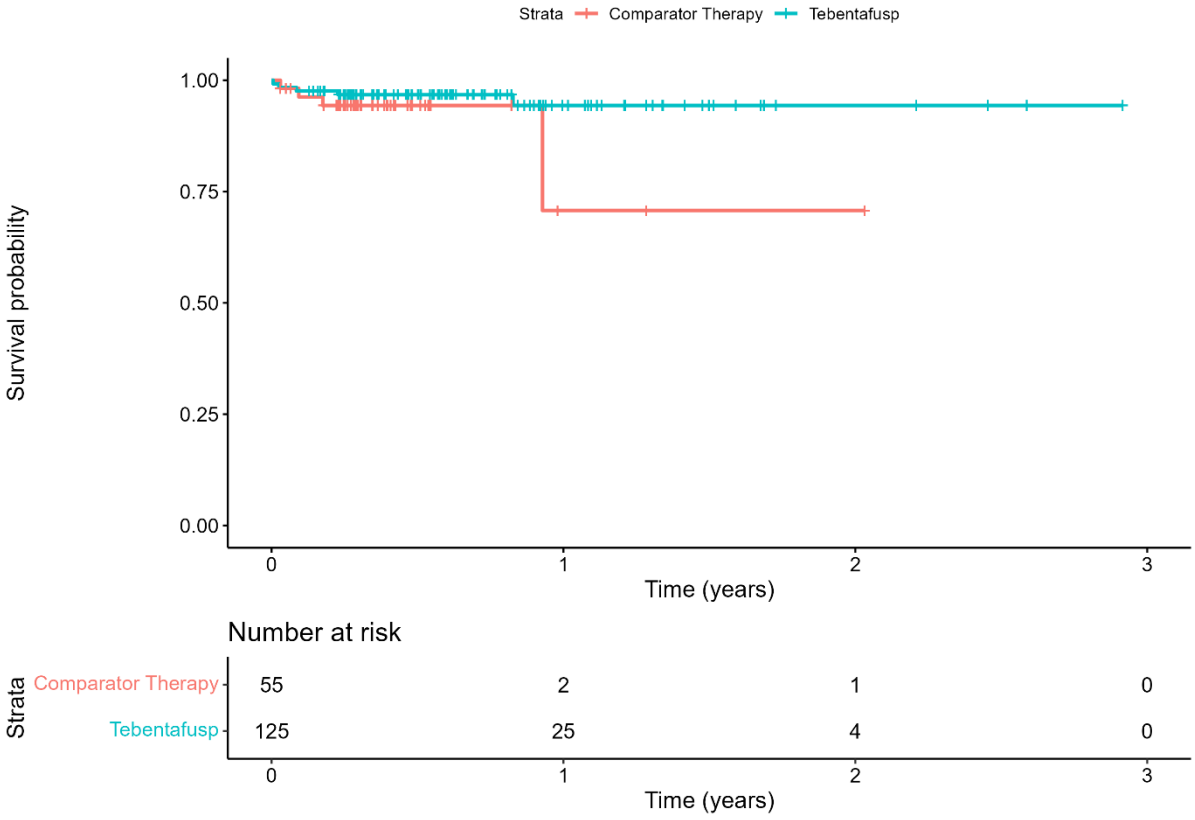
Herkunft: Hispanisch



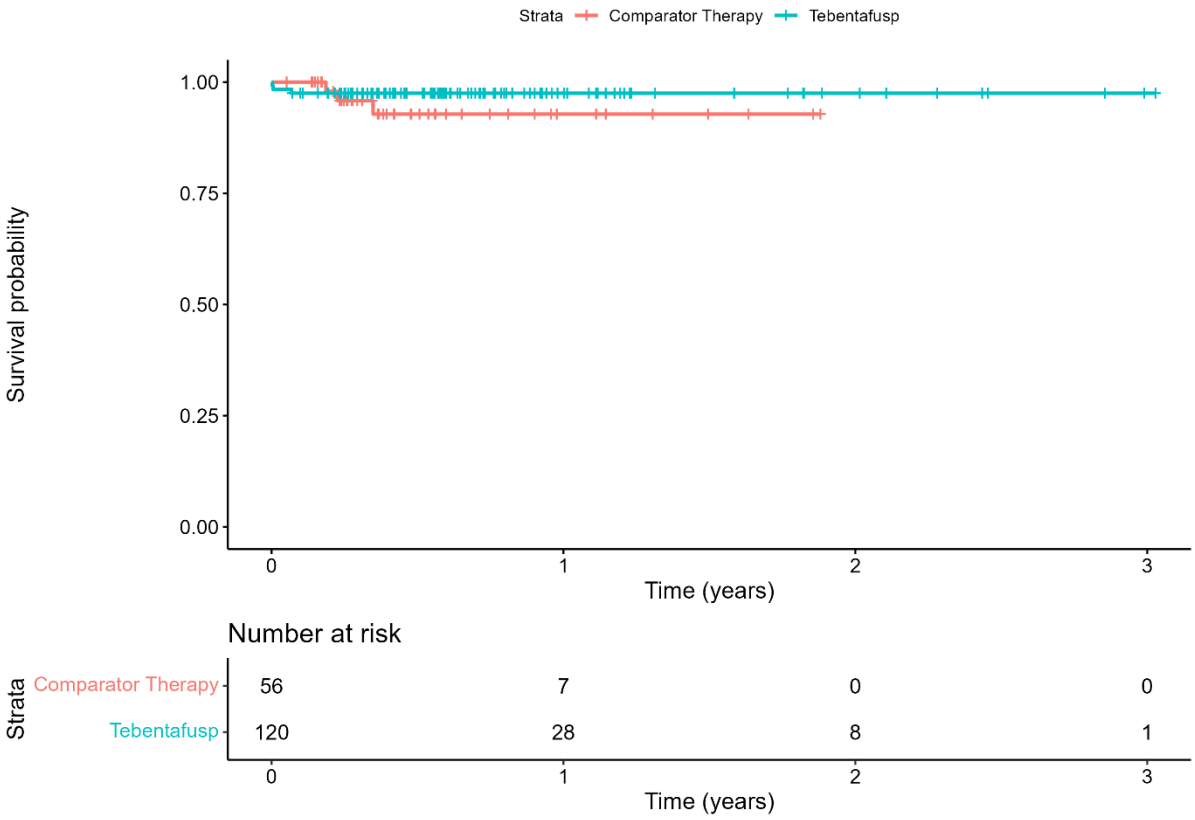
Herkunft: Nicht-hispanisch



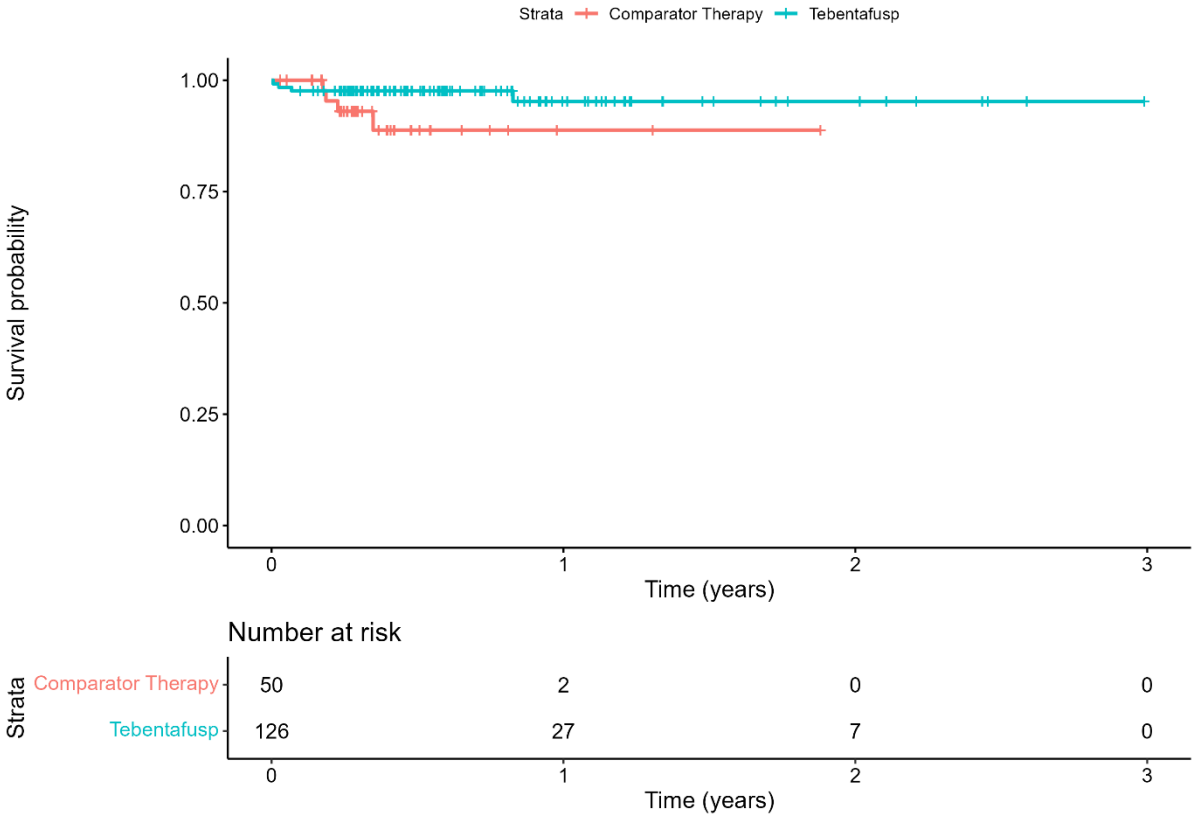
Geschlecht: Männlich



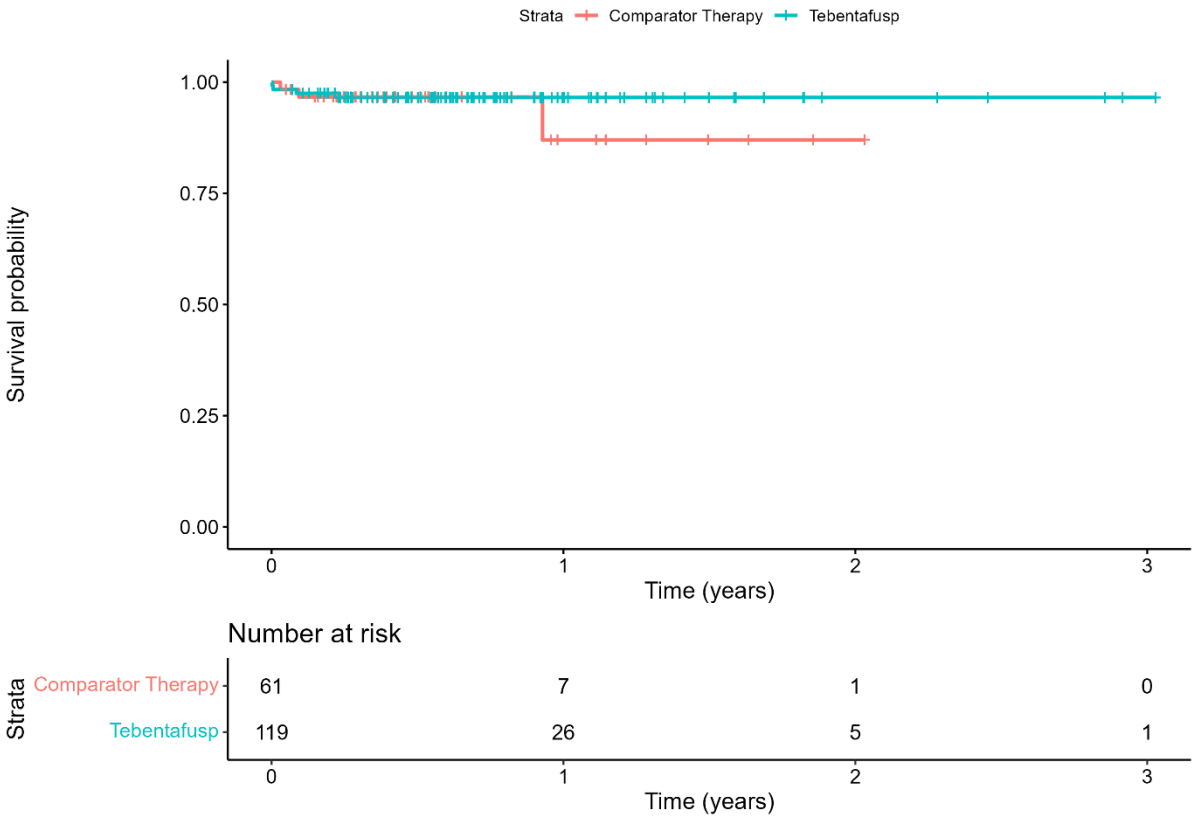
Geschlecht: Weiblich



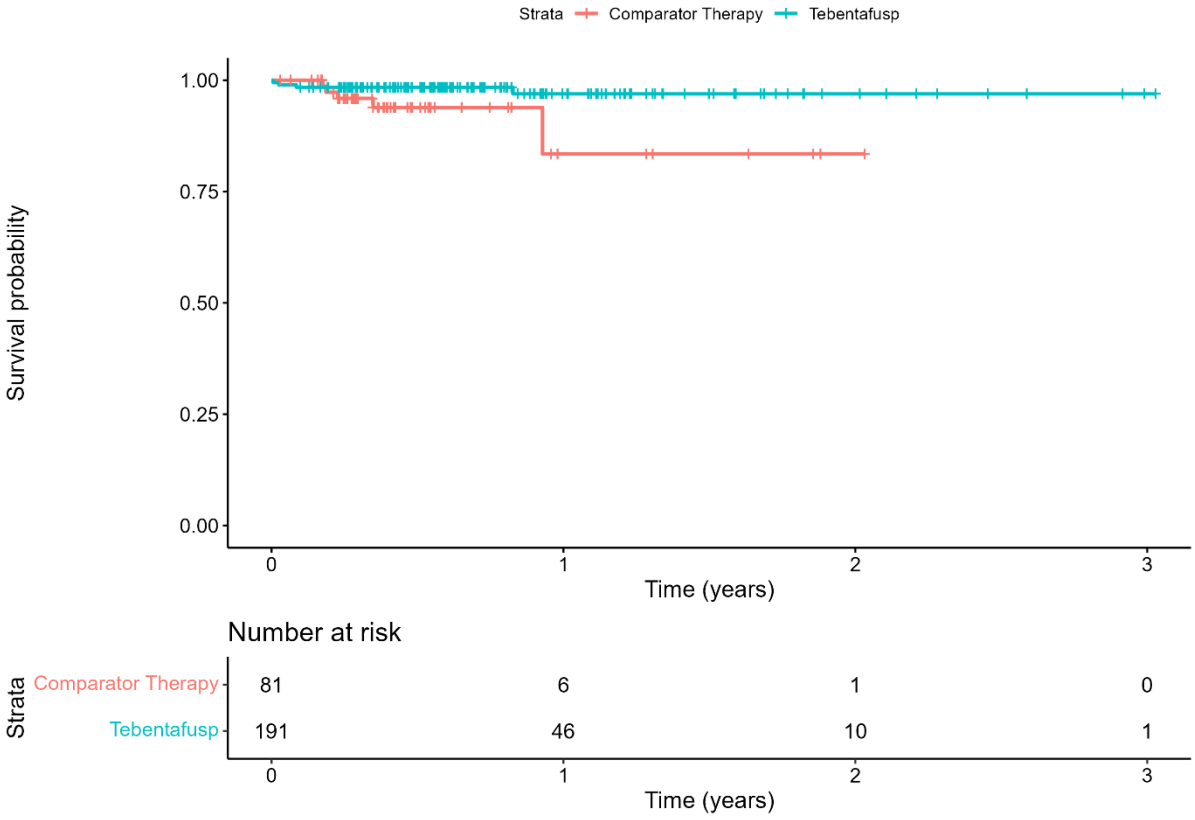
Alter: <65 Jahre



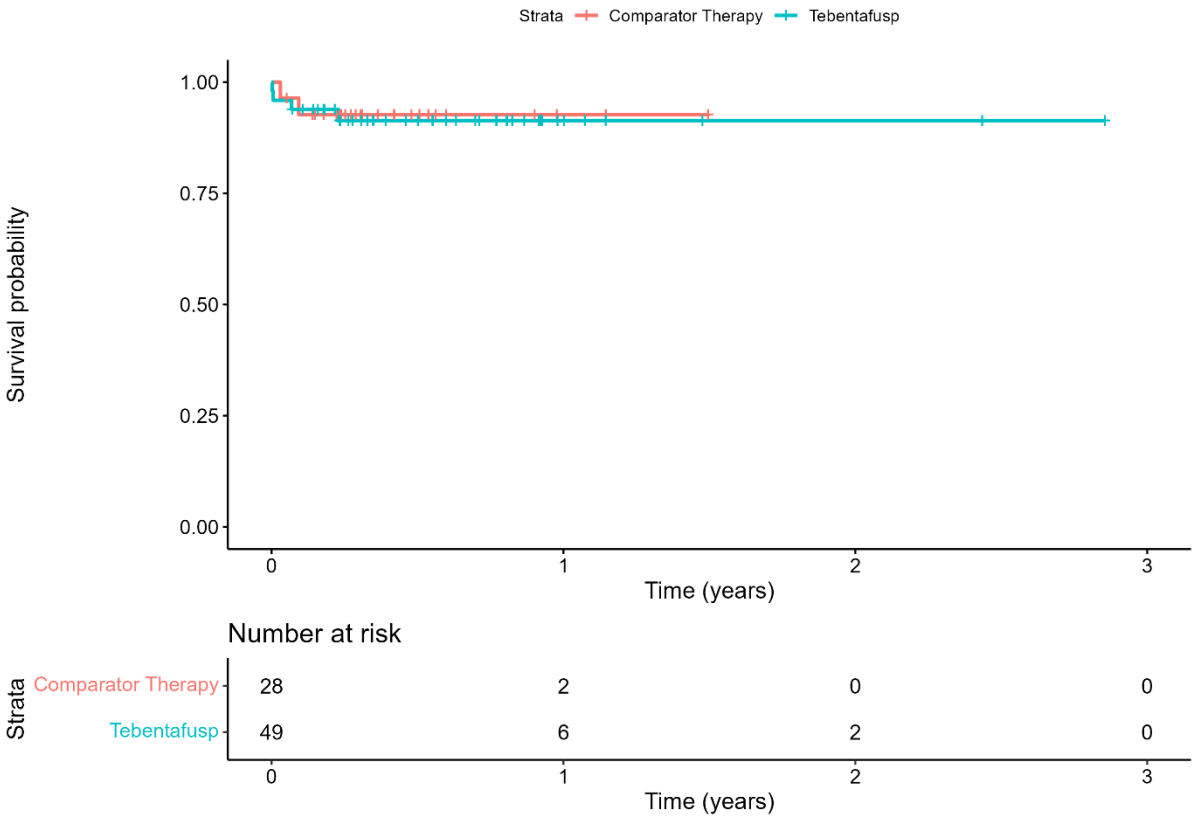
Alter: ≥65 Jahre



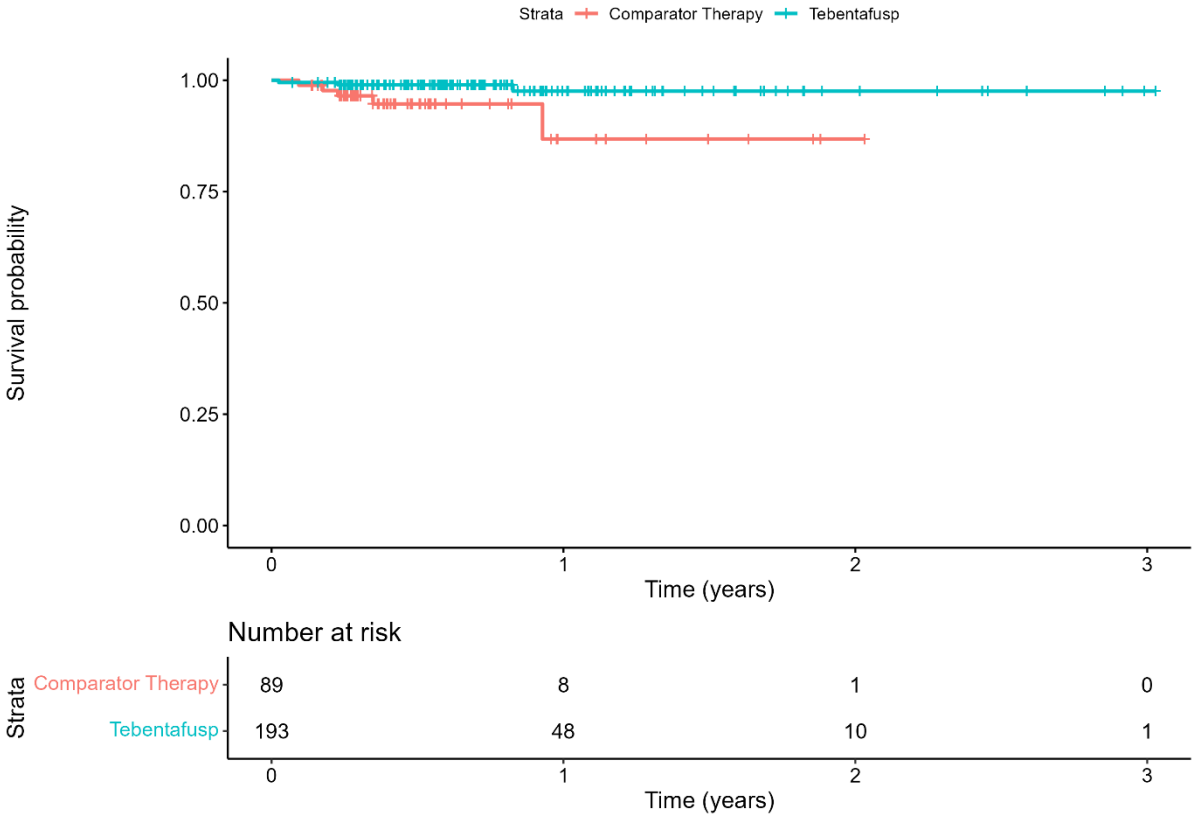
ECOG-Performance-Status: 0



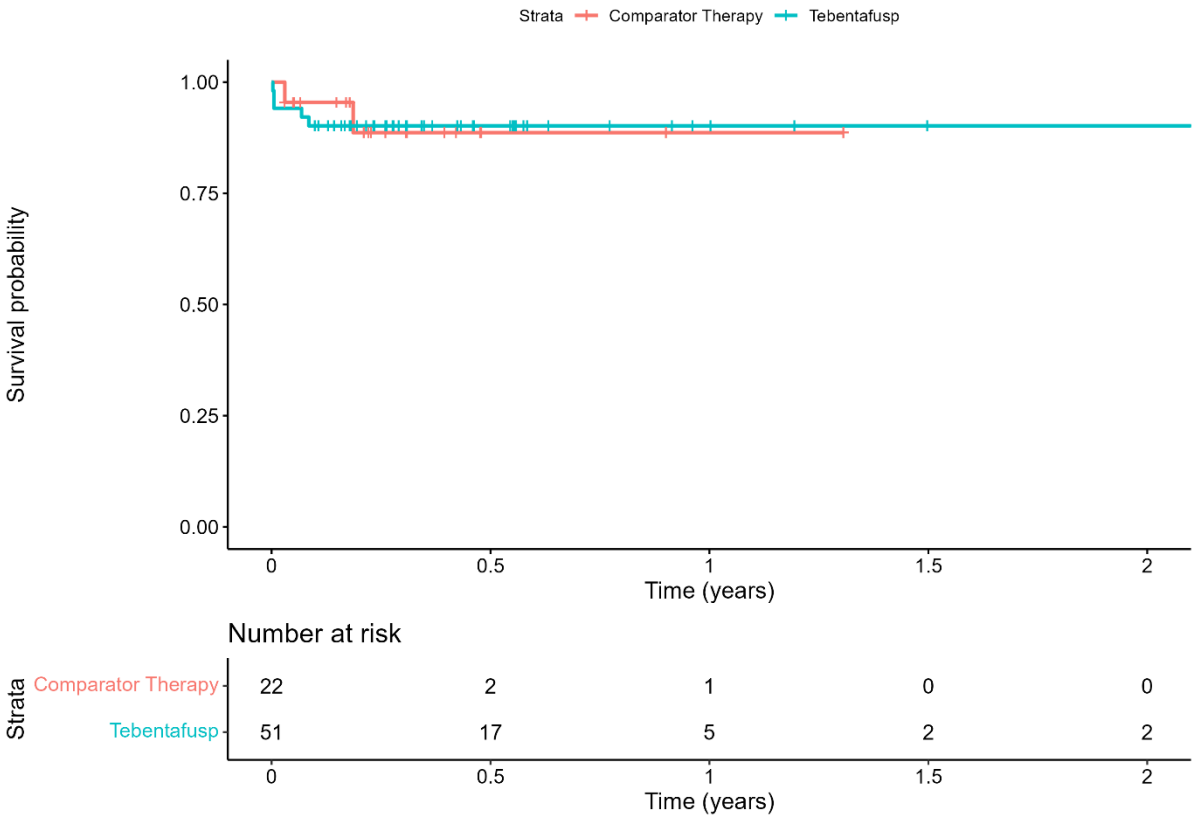
ECOG-Performance-Status: 1



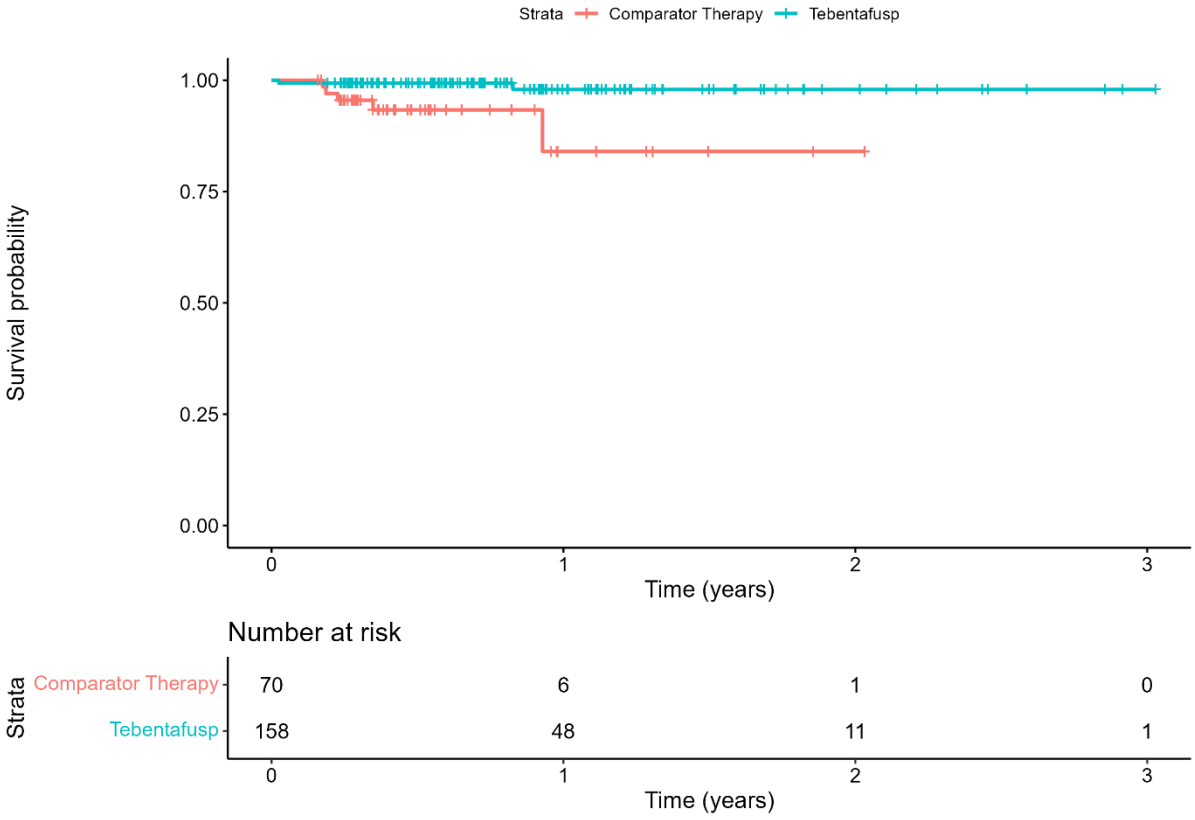
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



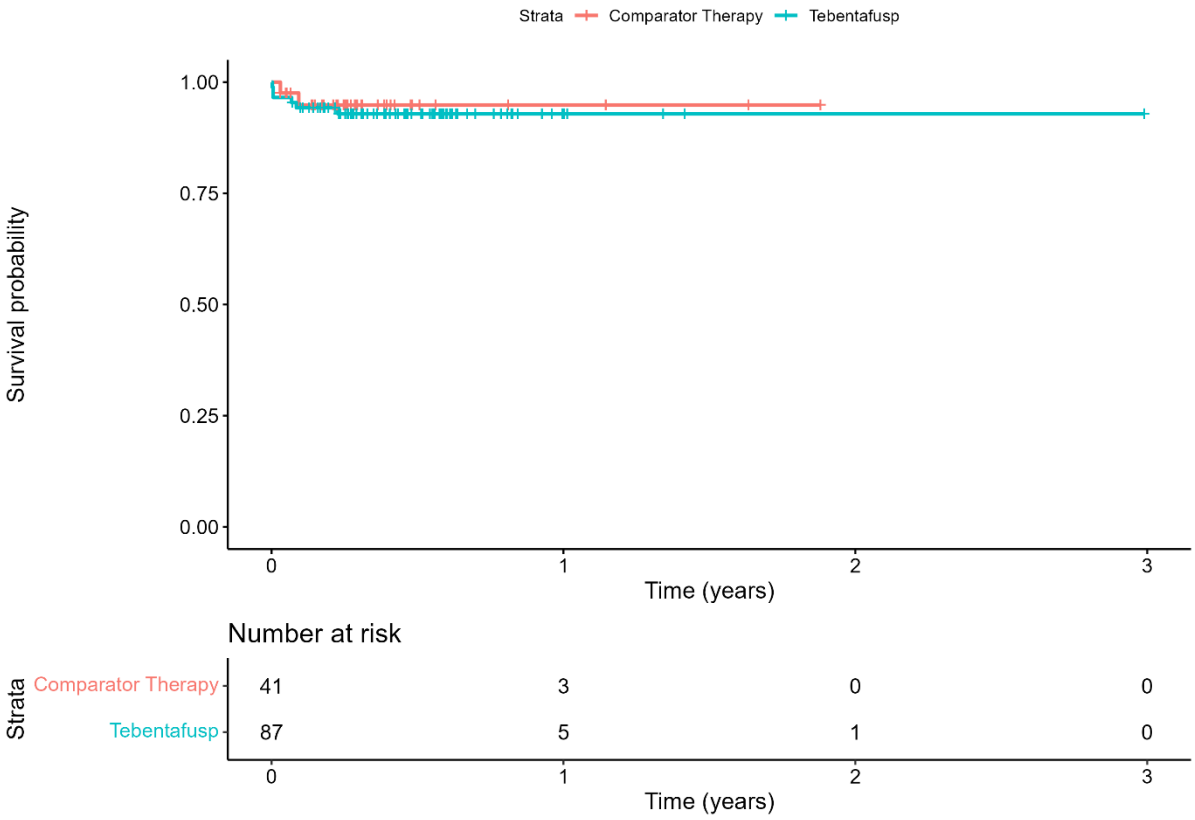
Alkalische Phosphatase (ALP) (Baseline): >ULN



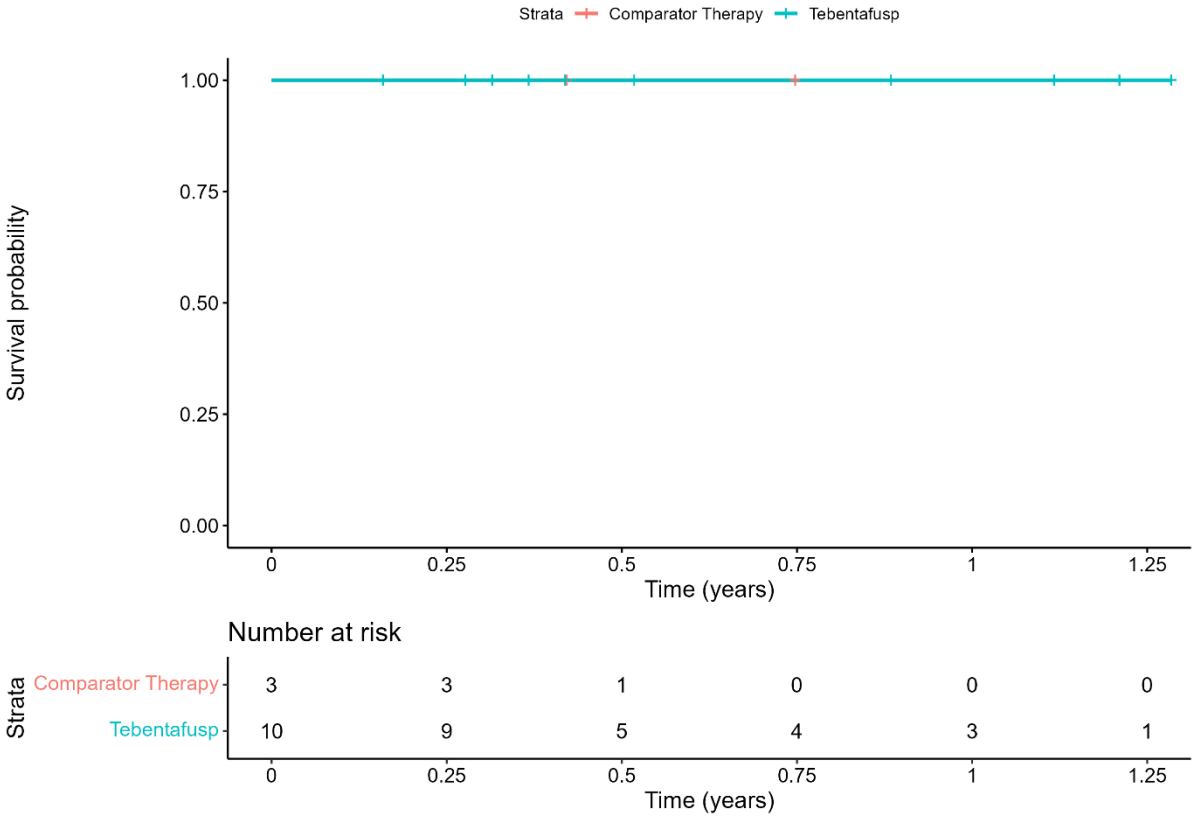
LDH: ≤ULN



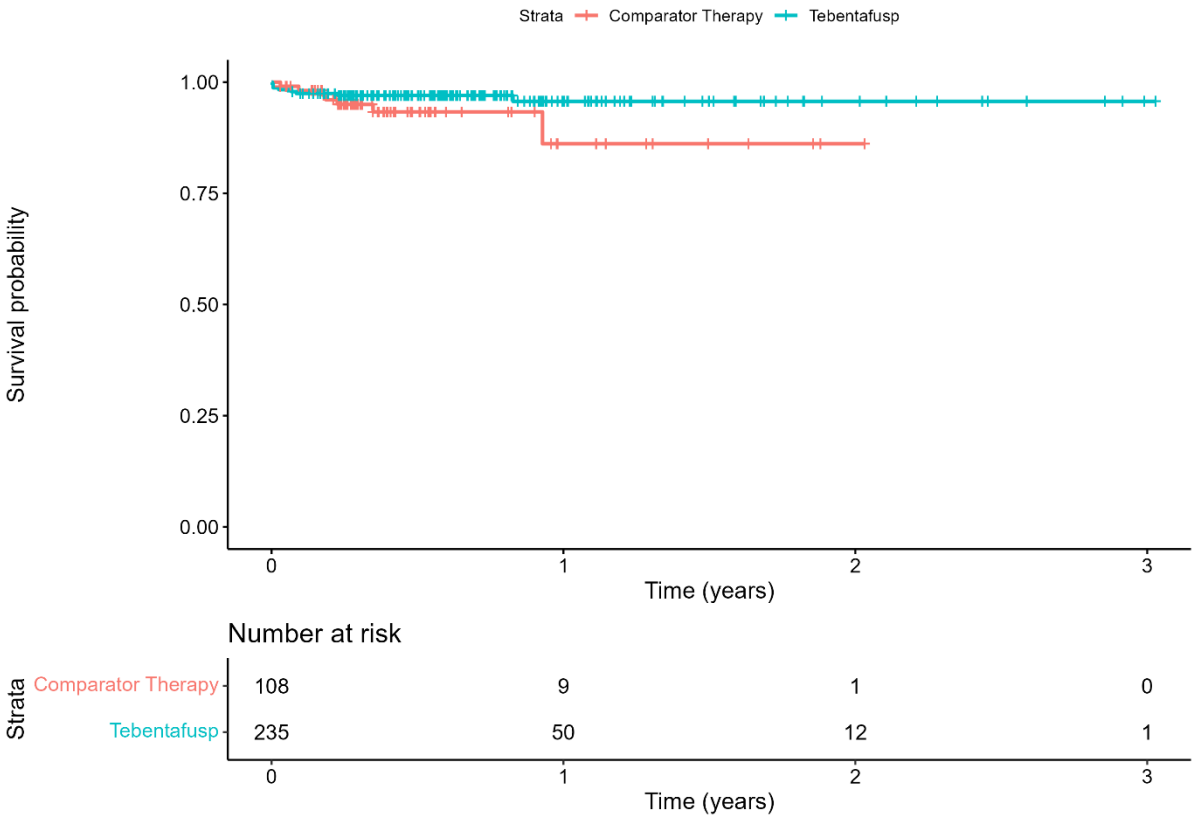
LDH: >ULN



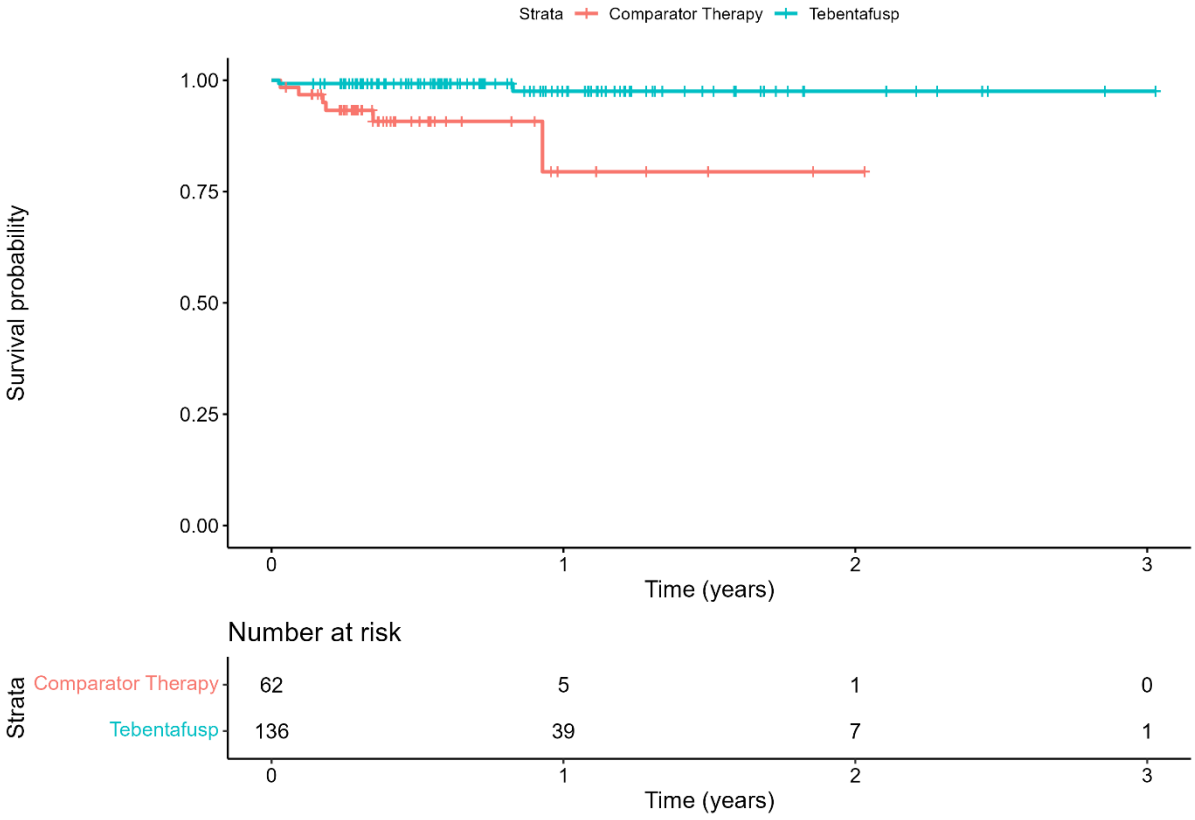
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



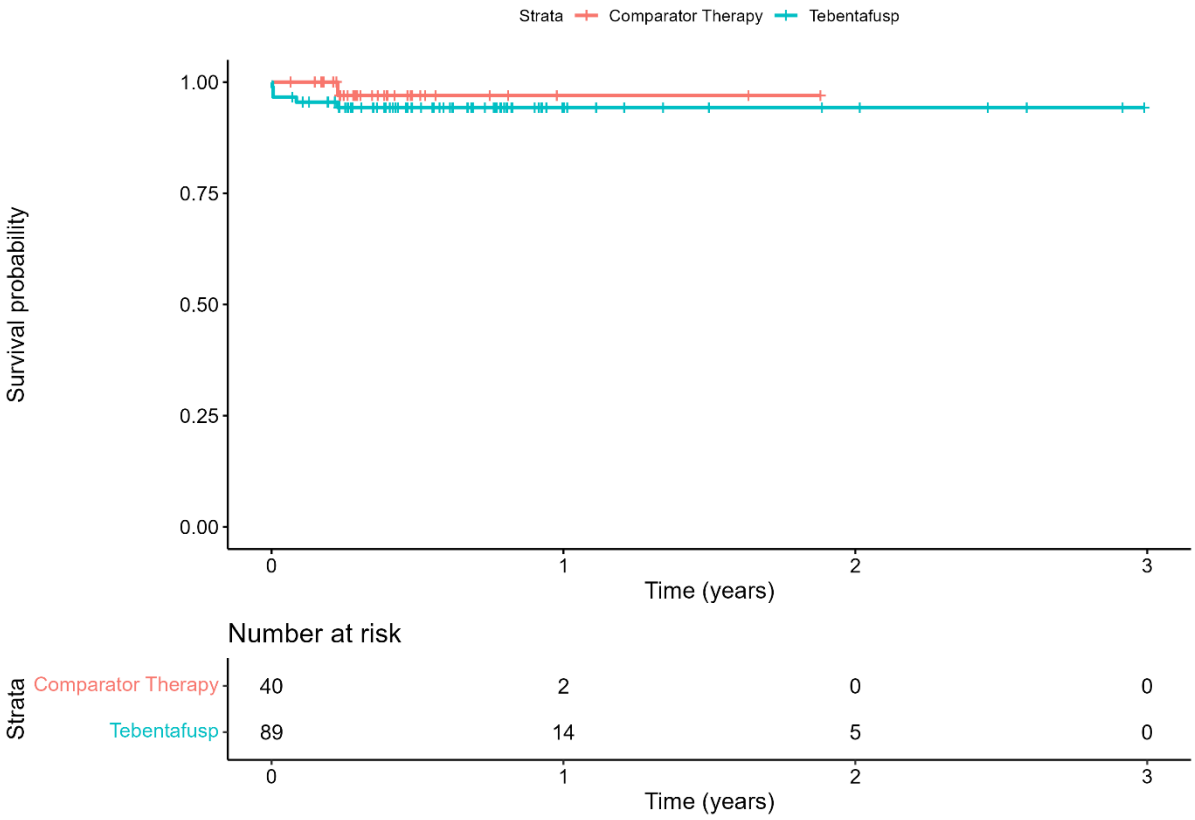
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



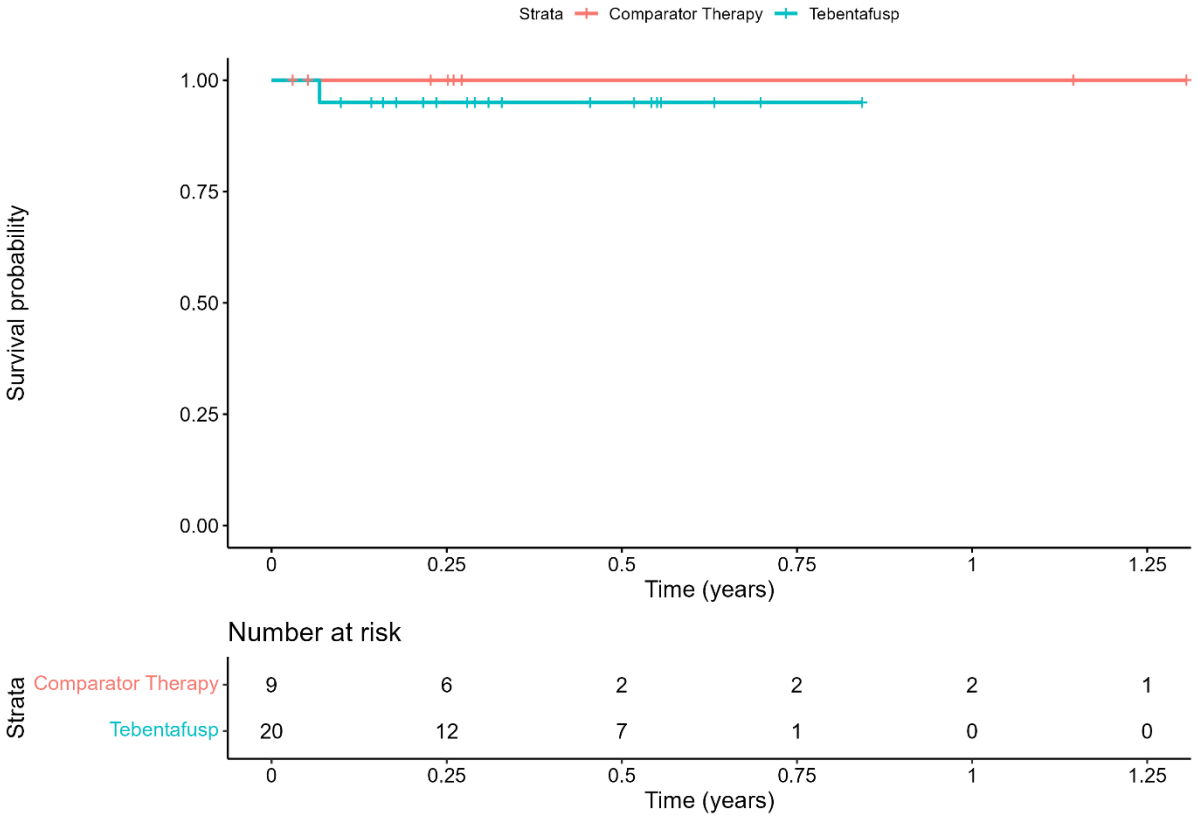
Größte metastatische Läsion (Baseline): ≤3,0 cm



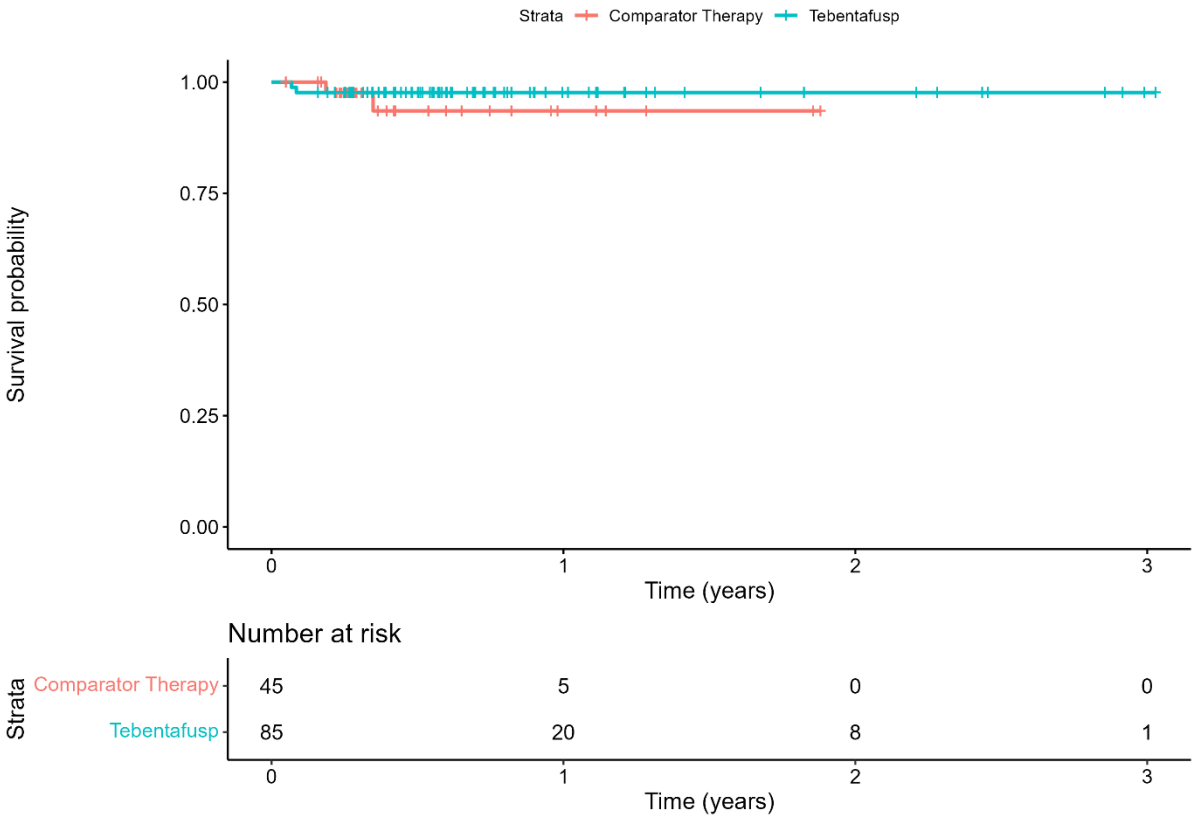
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



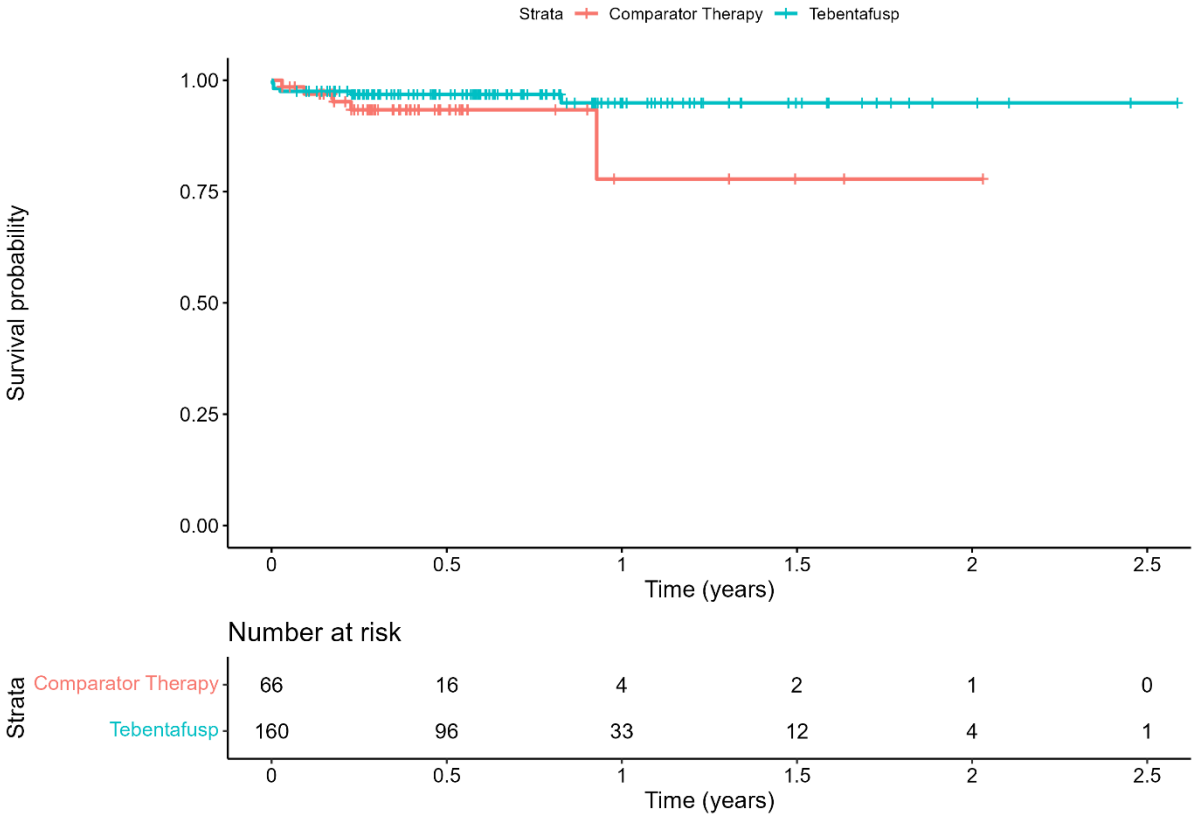
Größte metastatische Läsion (Baseline): ≥8,1 cm



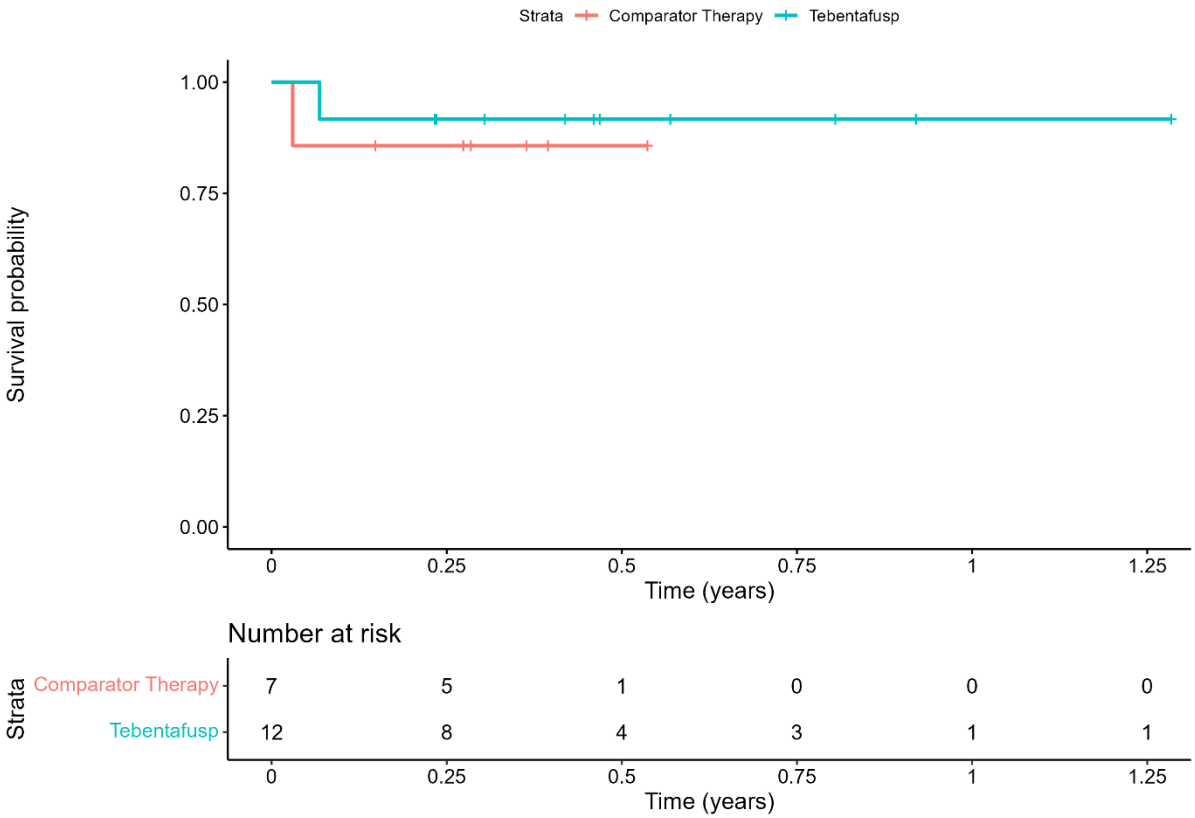
Region: Nordamerika



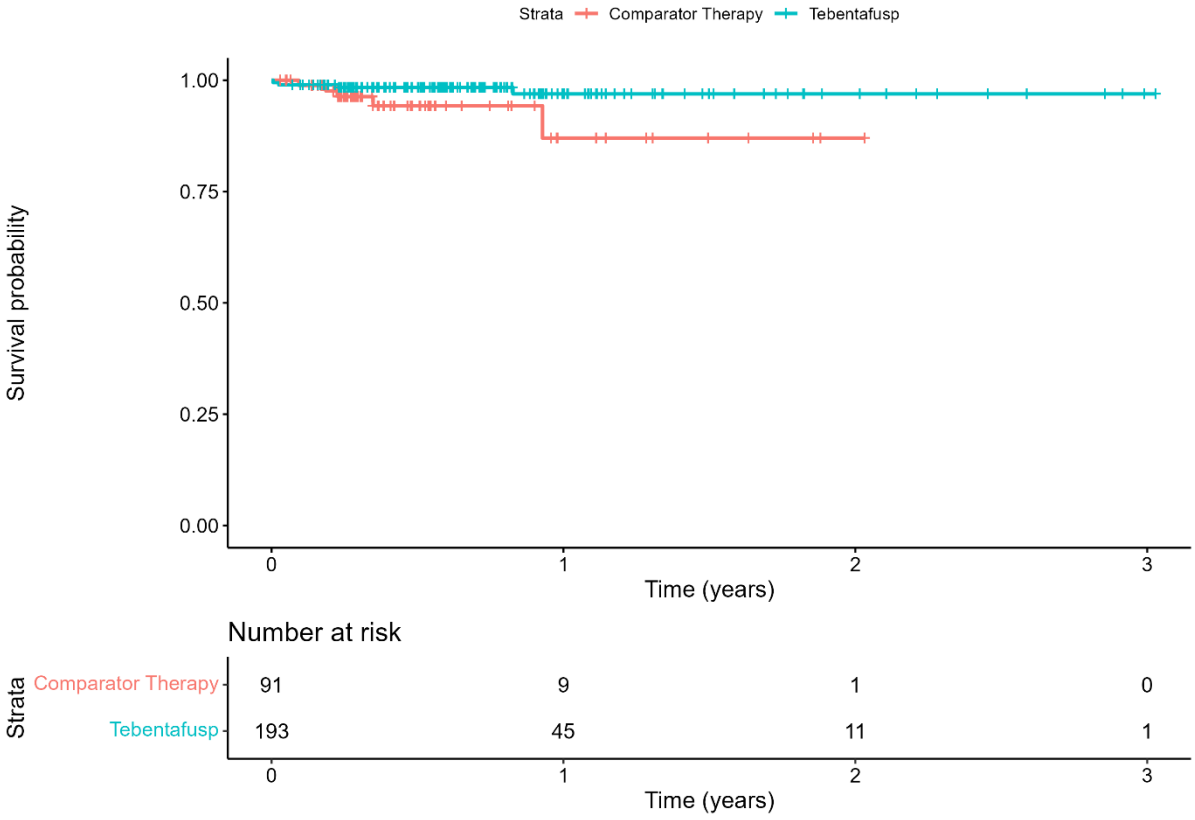
Region: Nicht-Nordamerika



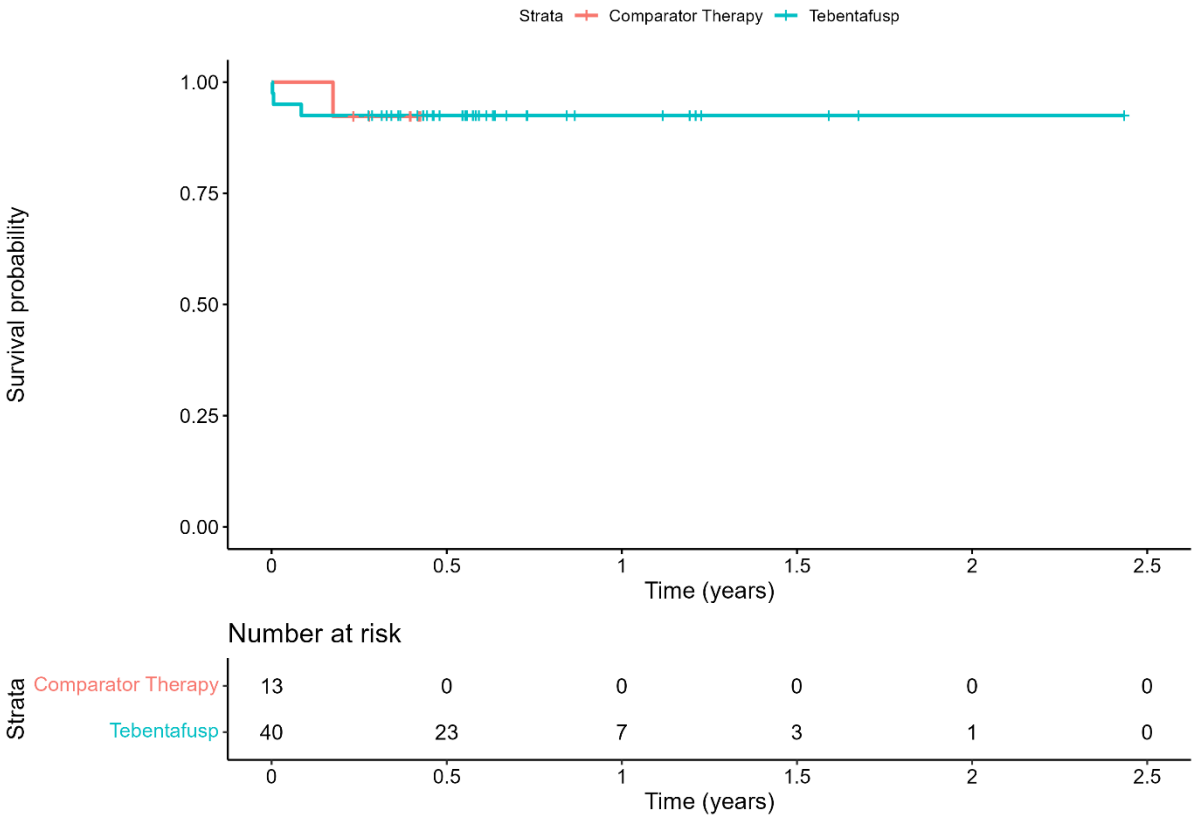
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

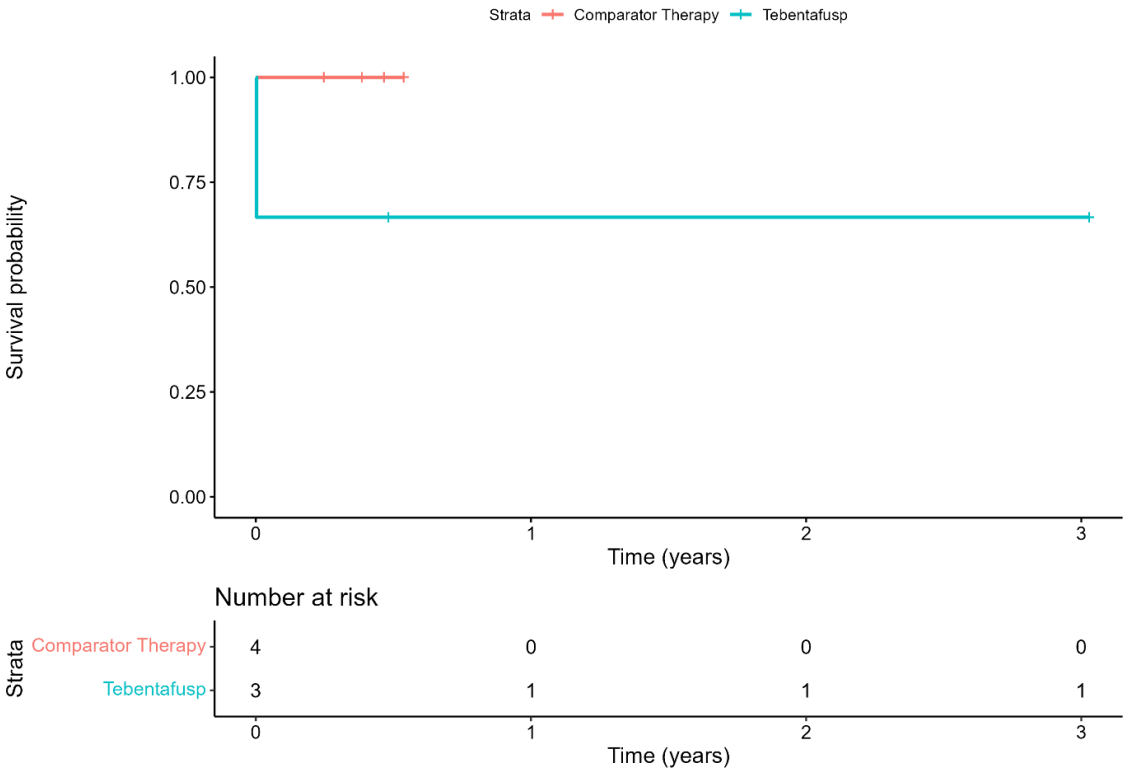


Vorauswahl der Chemotherapie: Ipilimumab

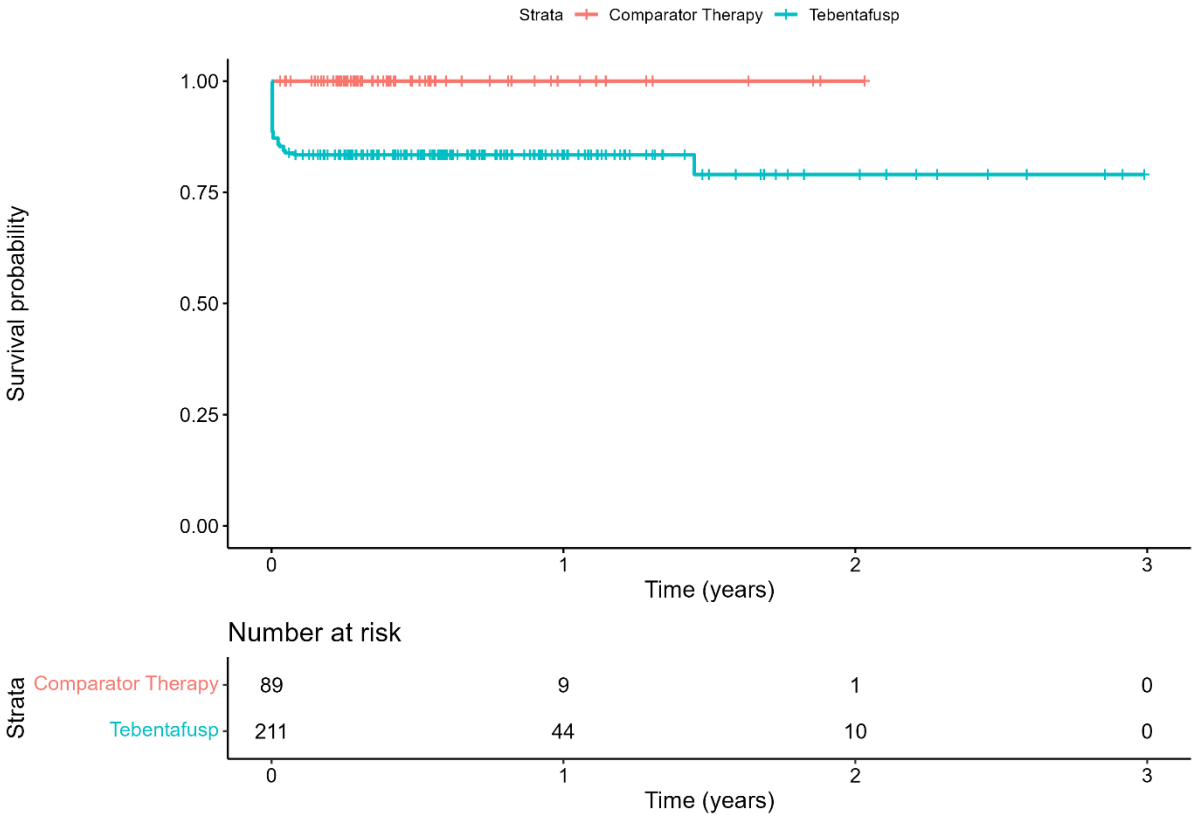


43.1 Zytokin-Freisetzungssyndrom (CRS) (Tabelle 4-95)

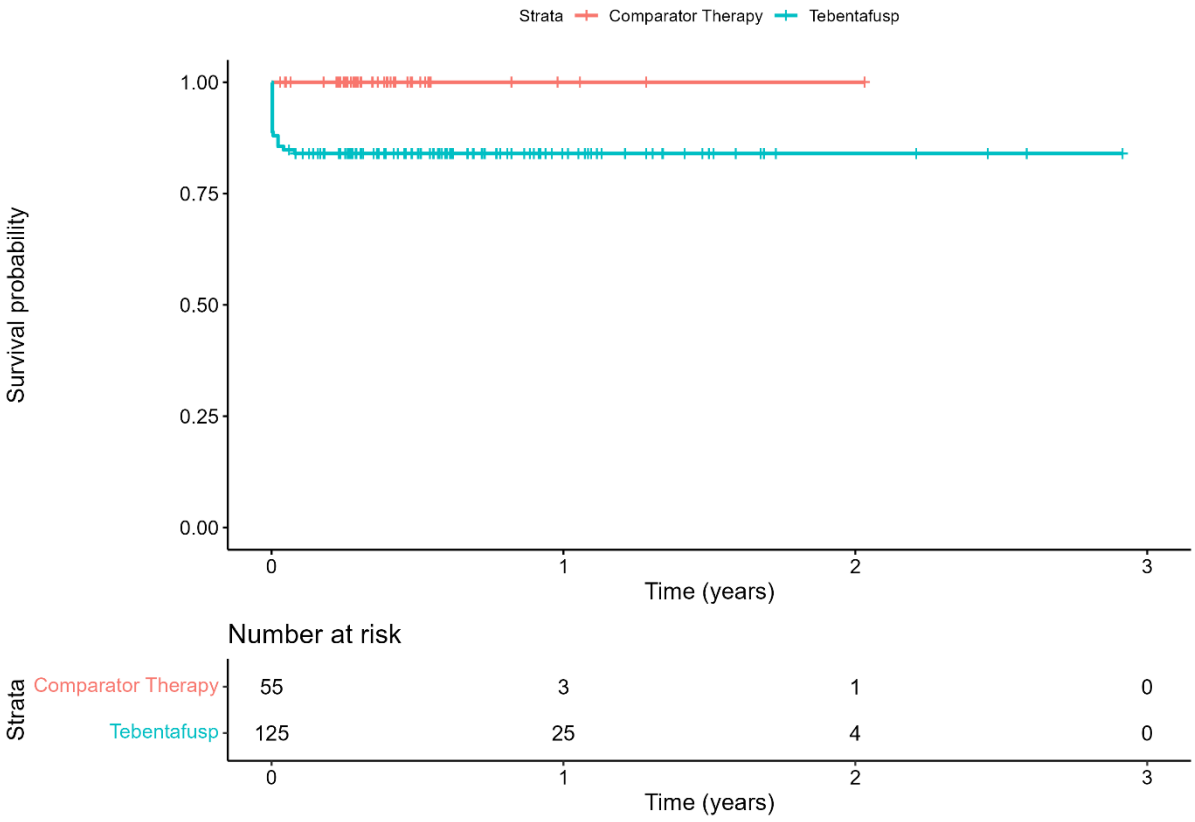
Herkunft: Hispanisch



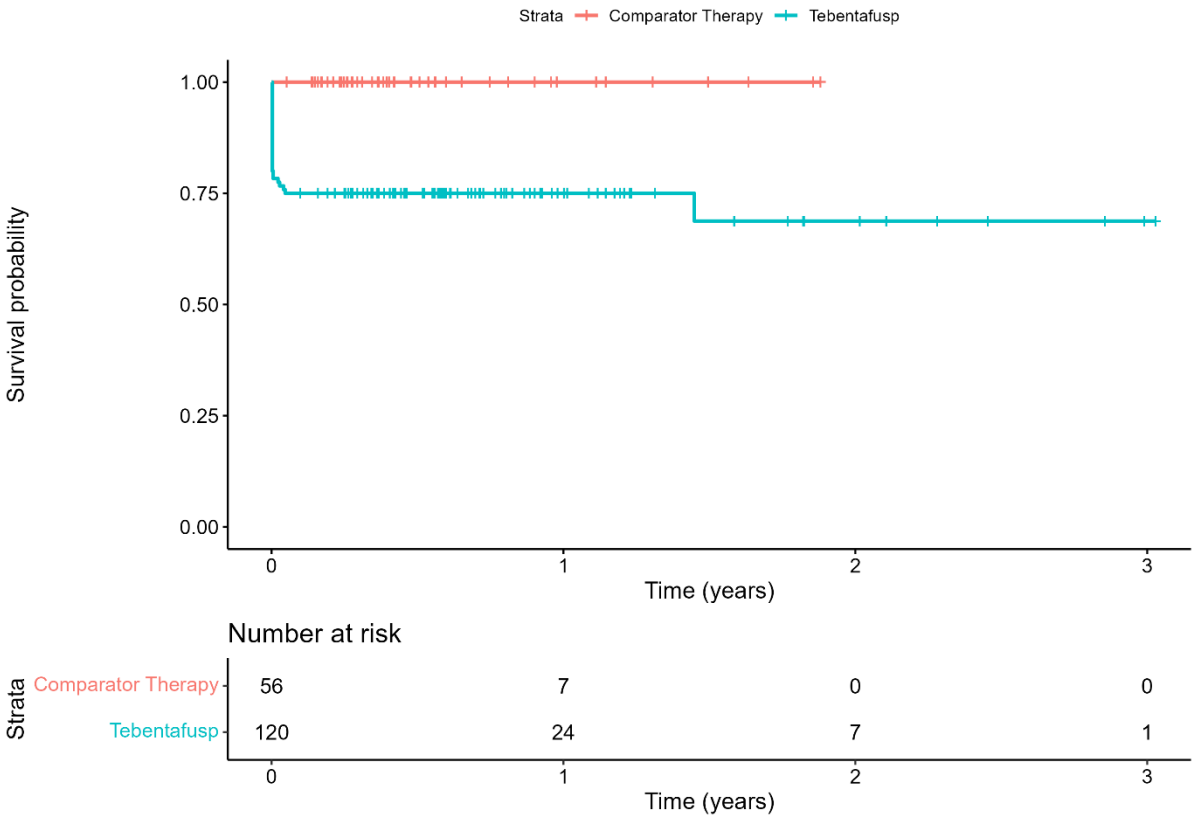
Herkunft: Nicht-hispanisch



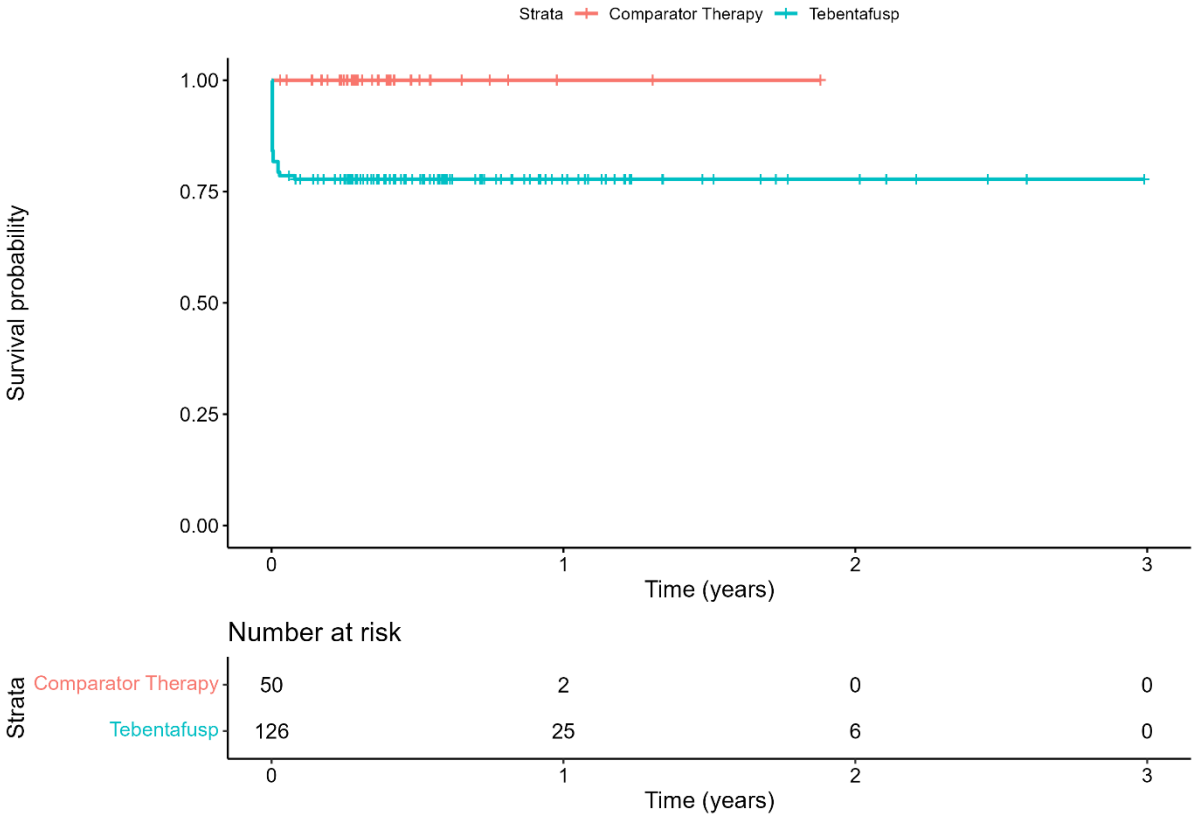
Geschlecht: Männlich



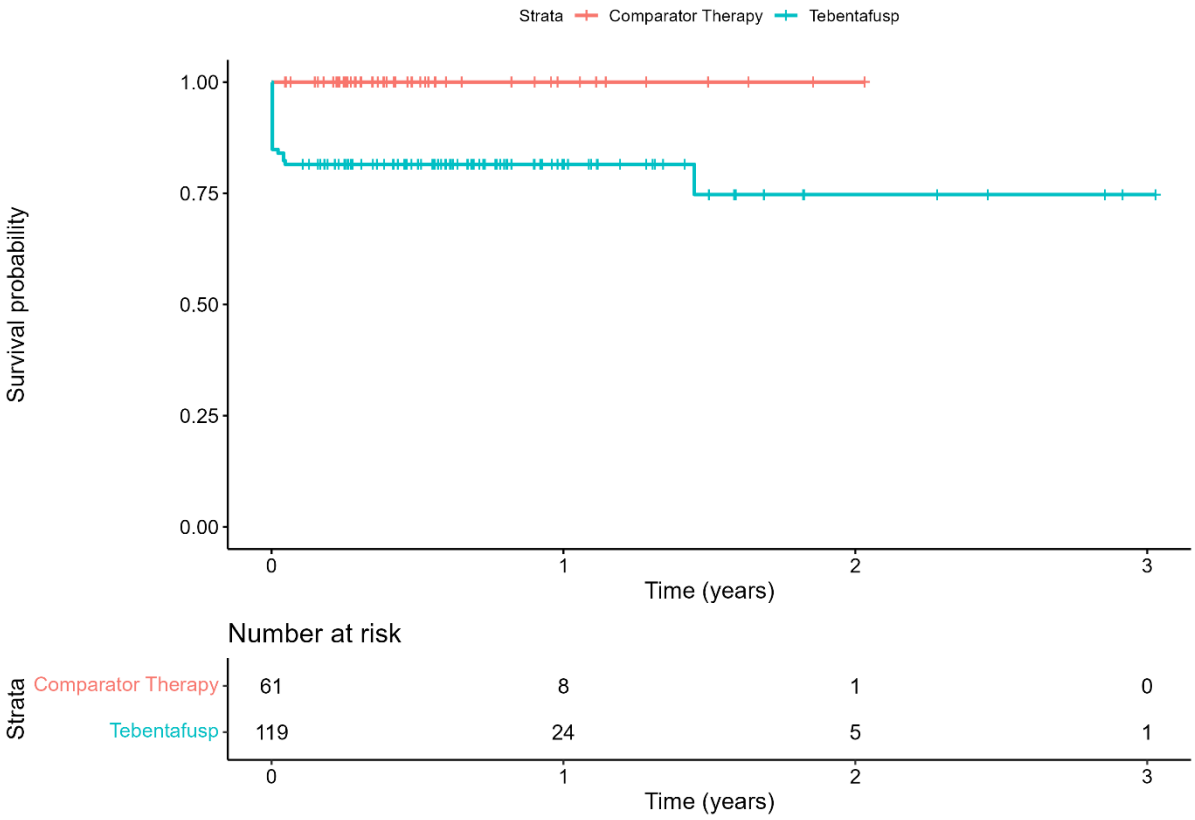
Geschlecht: Weiblich



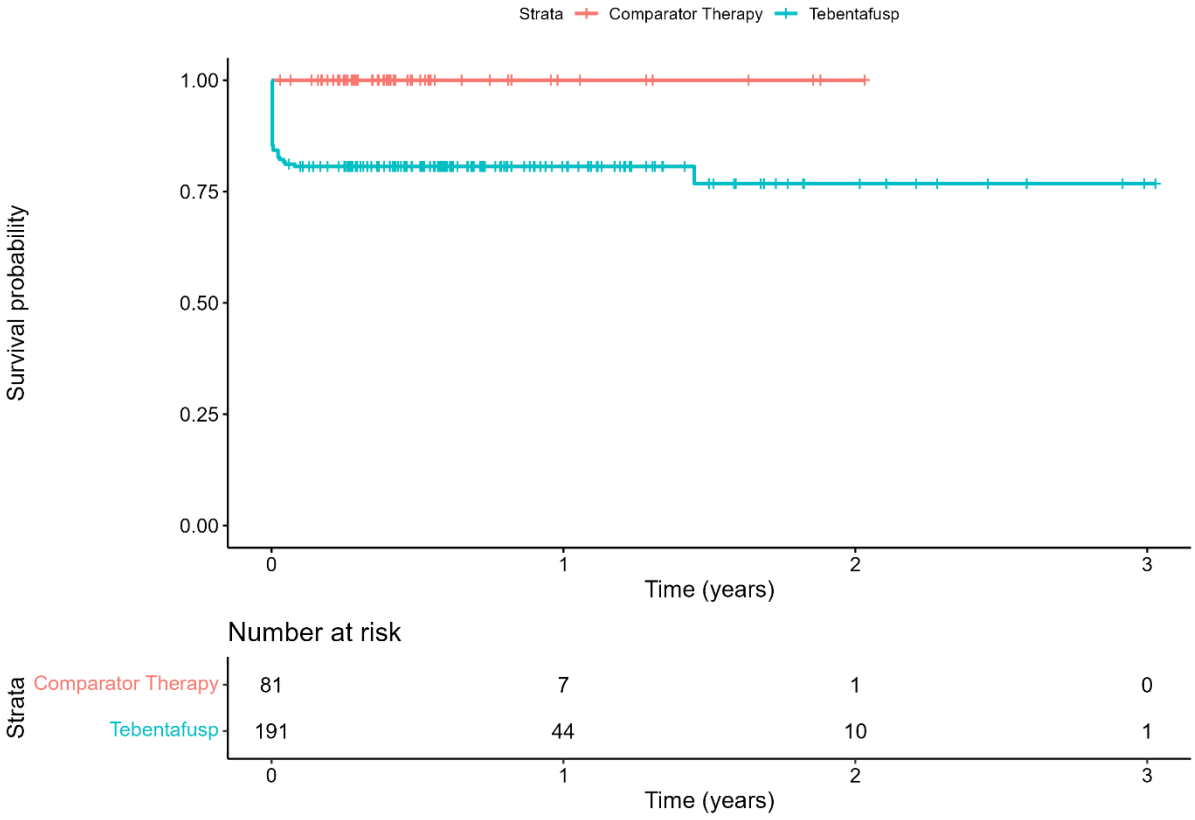
Alter: <65 Jahre



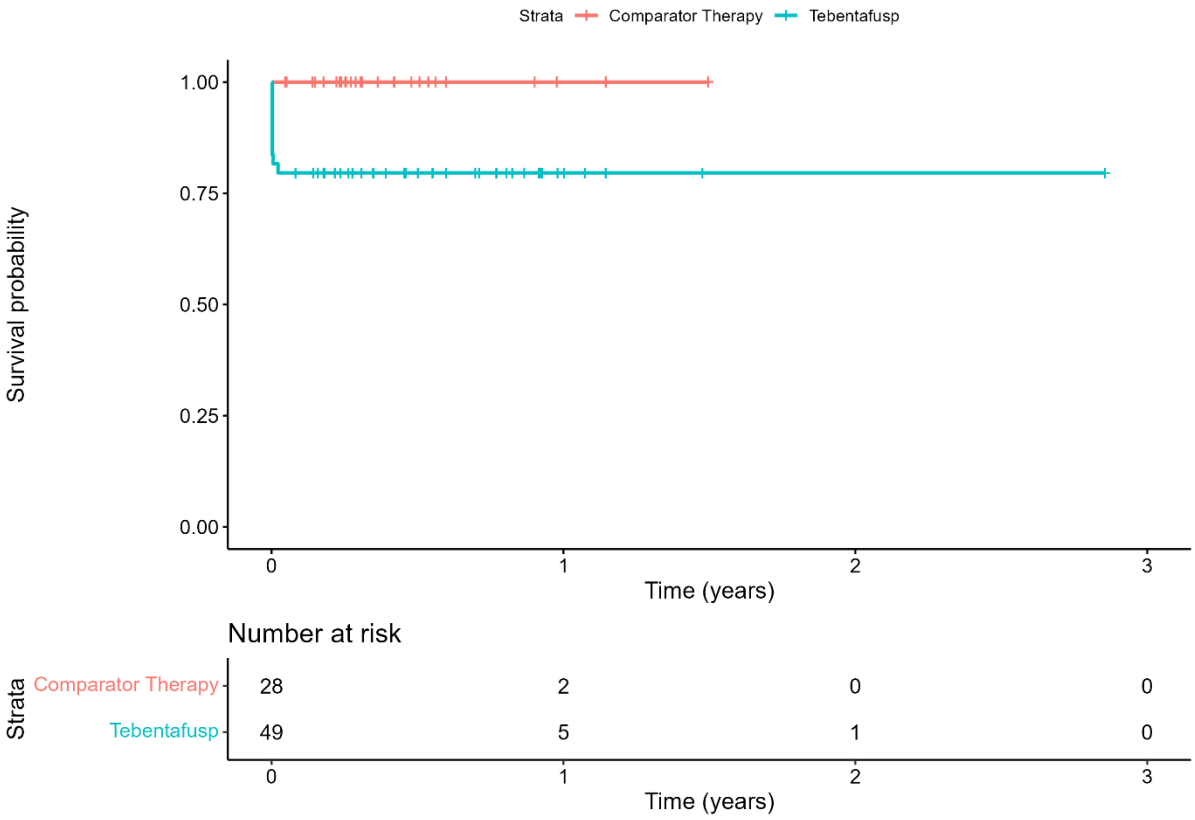
Alter: ≥65 Jahre



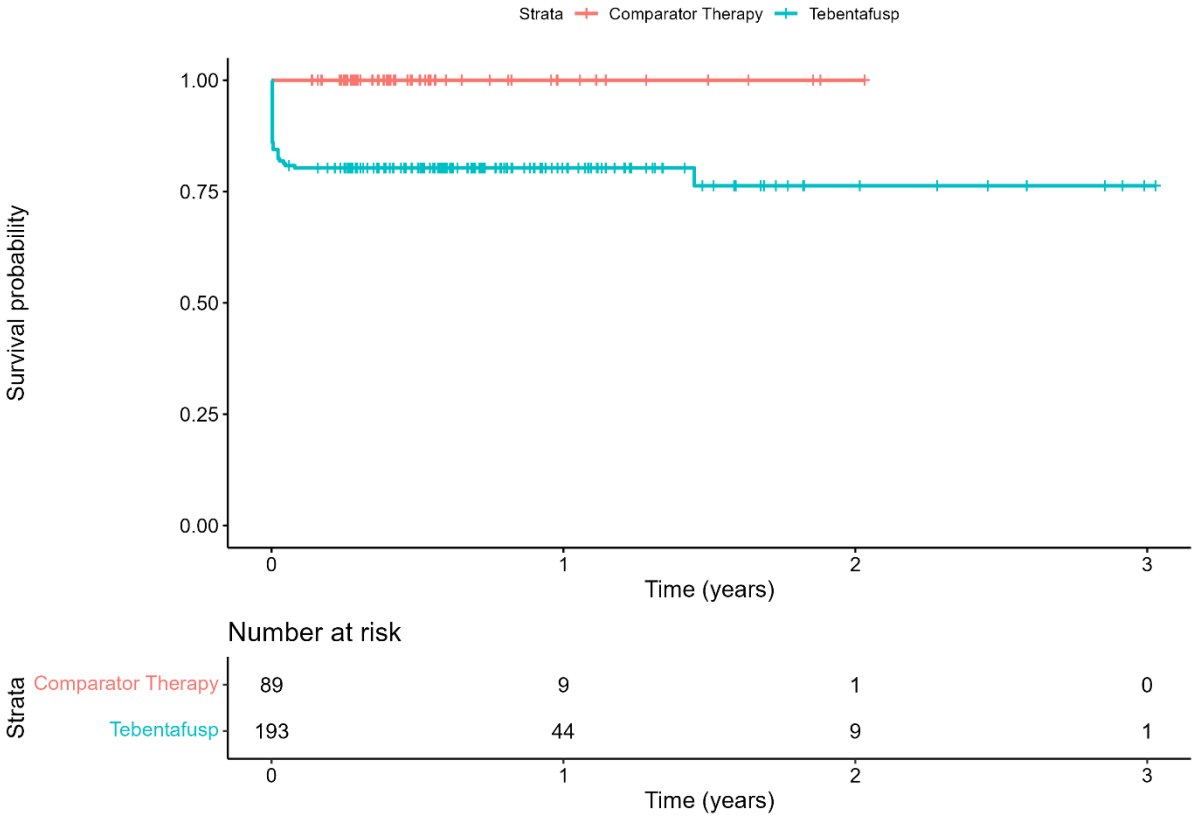
ECOG-Performance-Status: 0



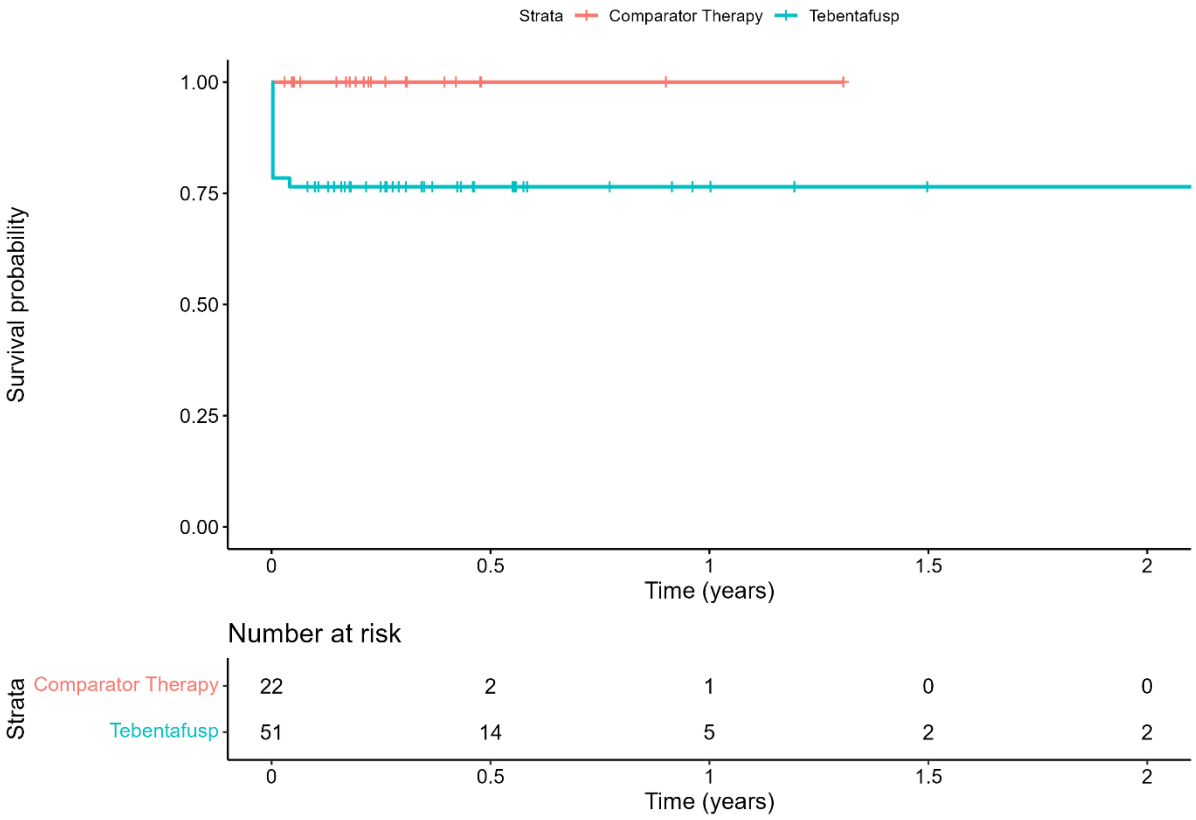
ECOG-Performance-Status: 1



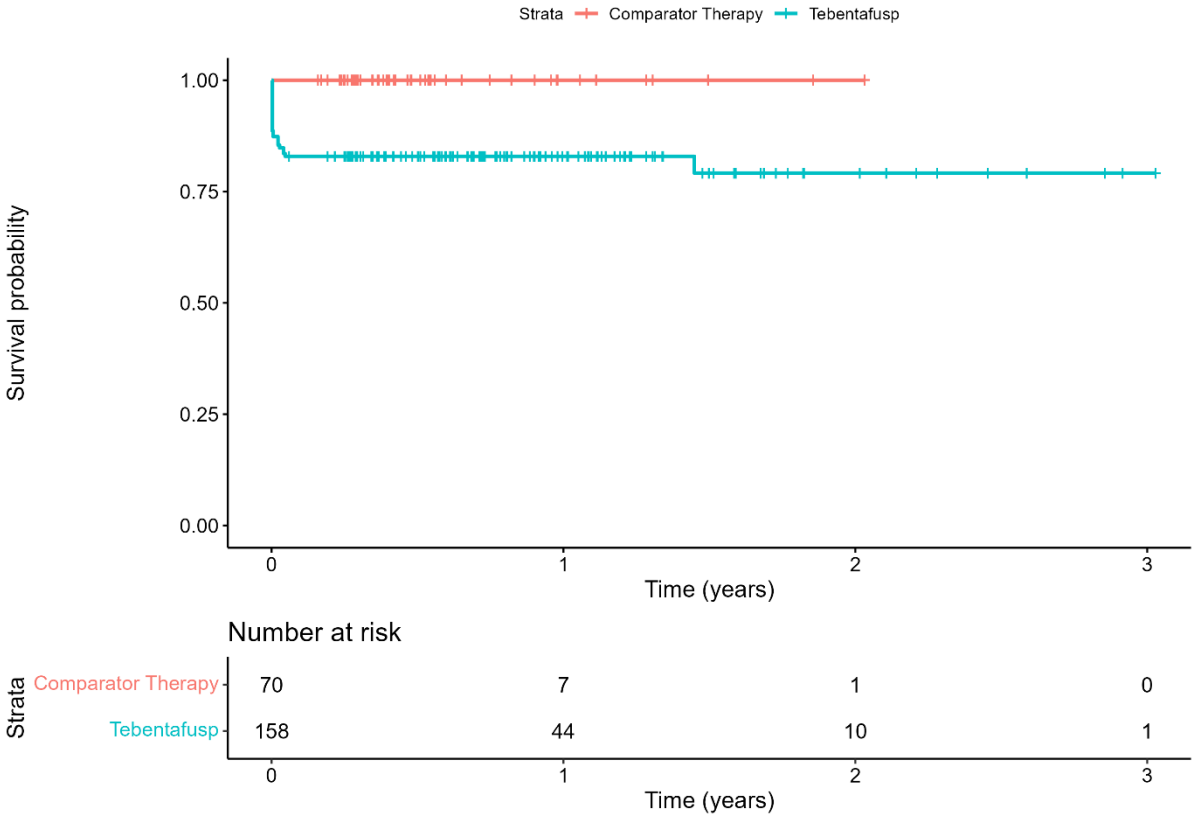
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



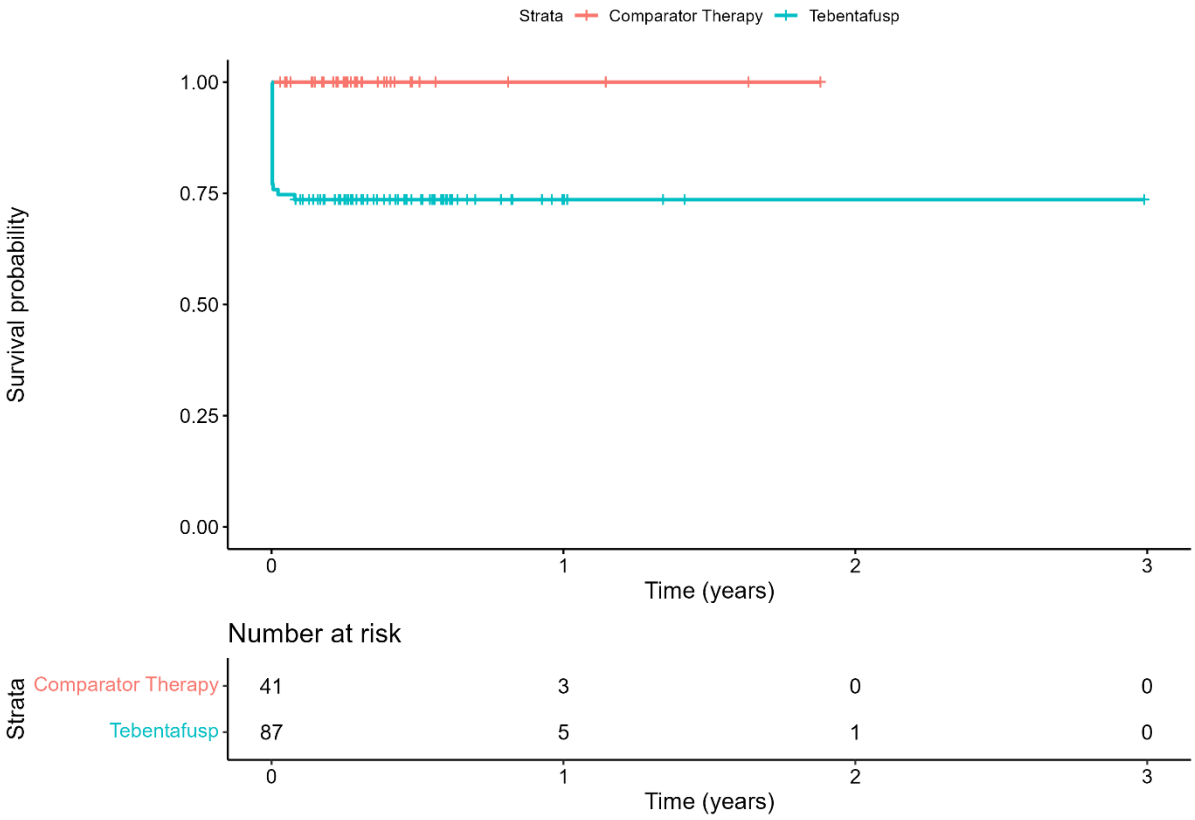
Alkalische Phosphatase (ALP) (Baseline): >ULN



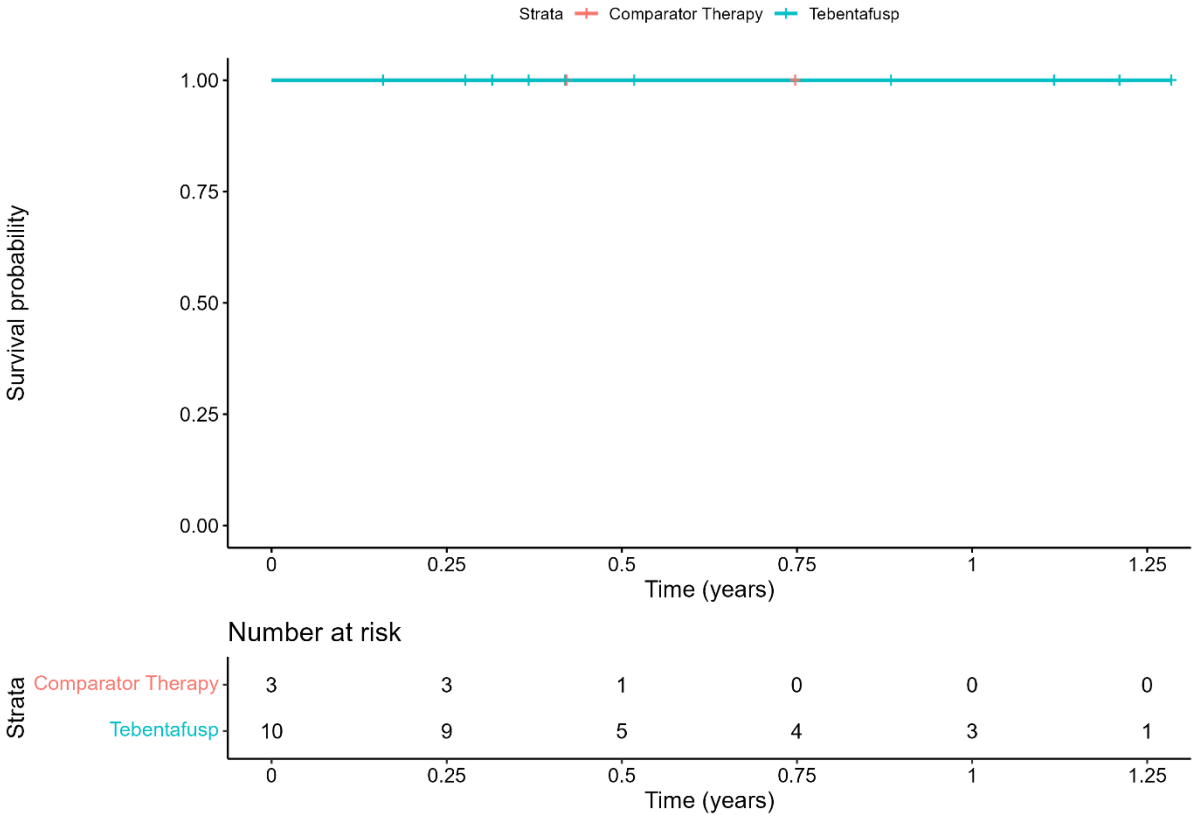
LDH: ≤ULN



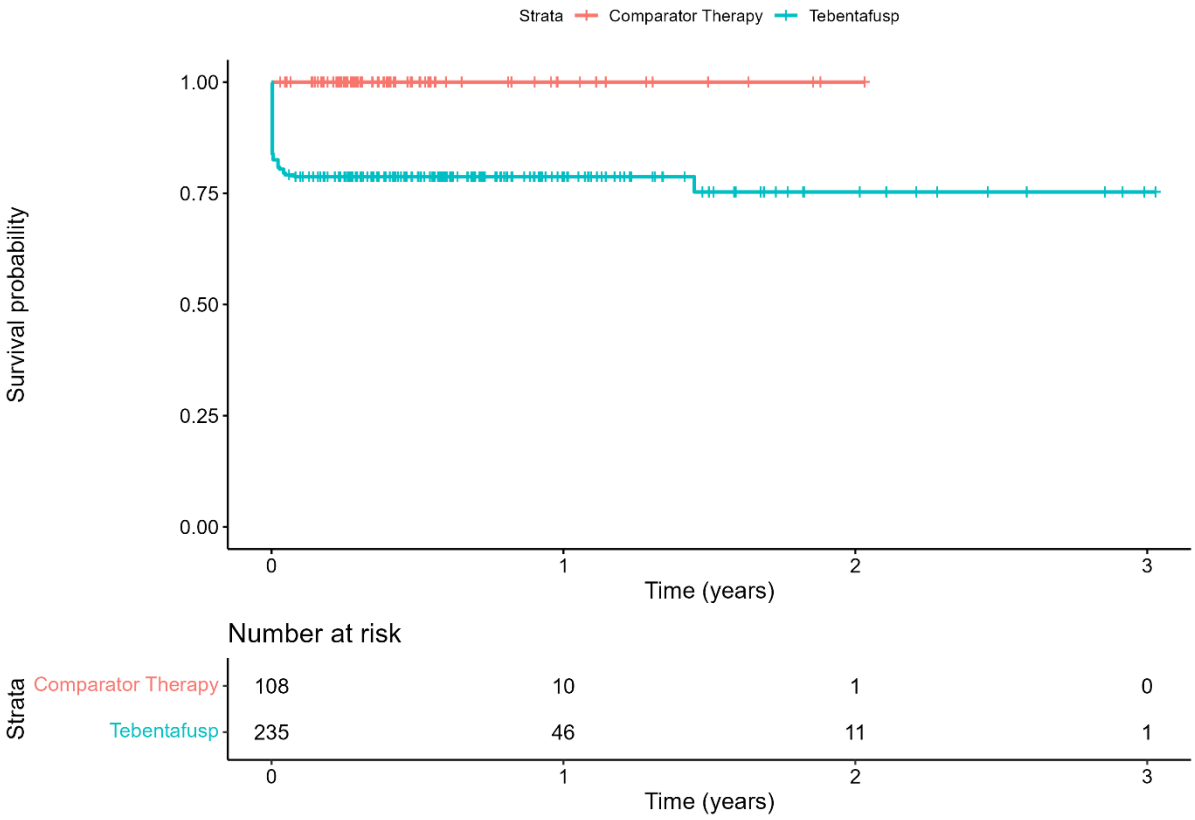
LDH: >ULN



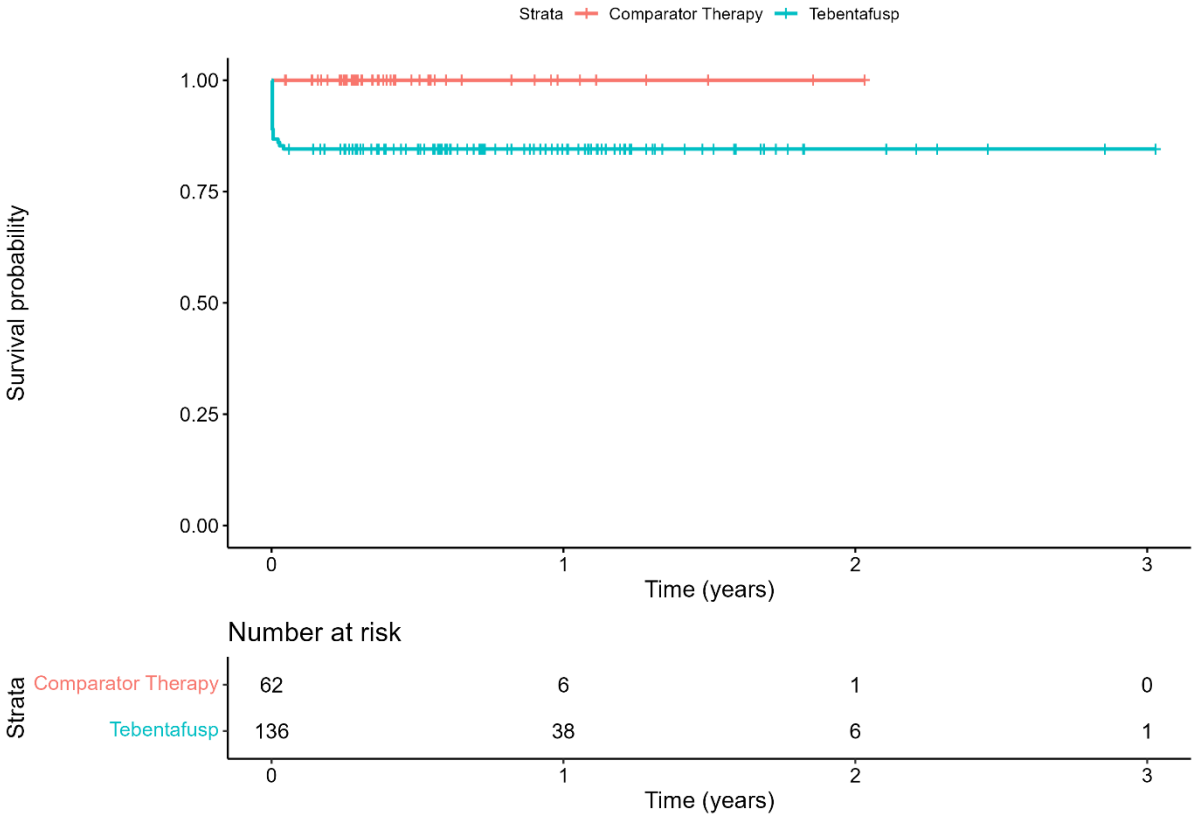
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



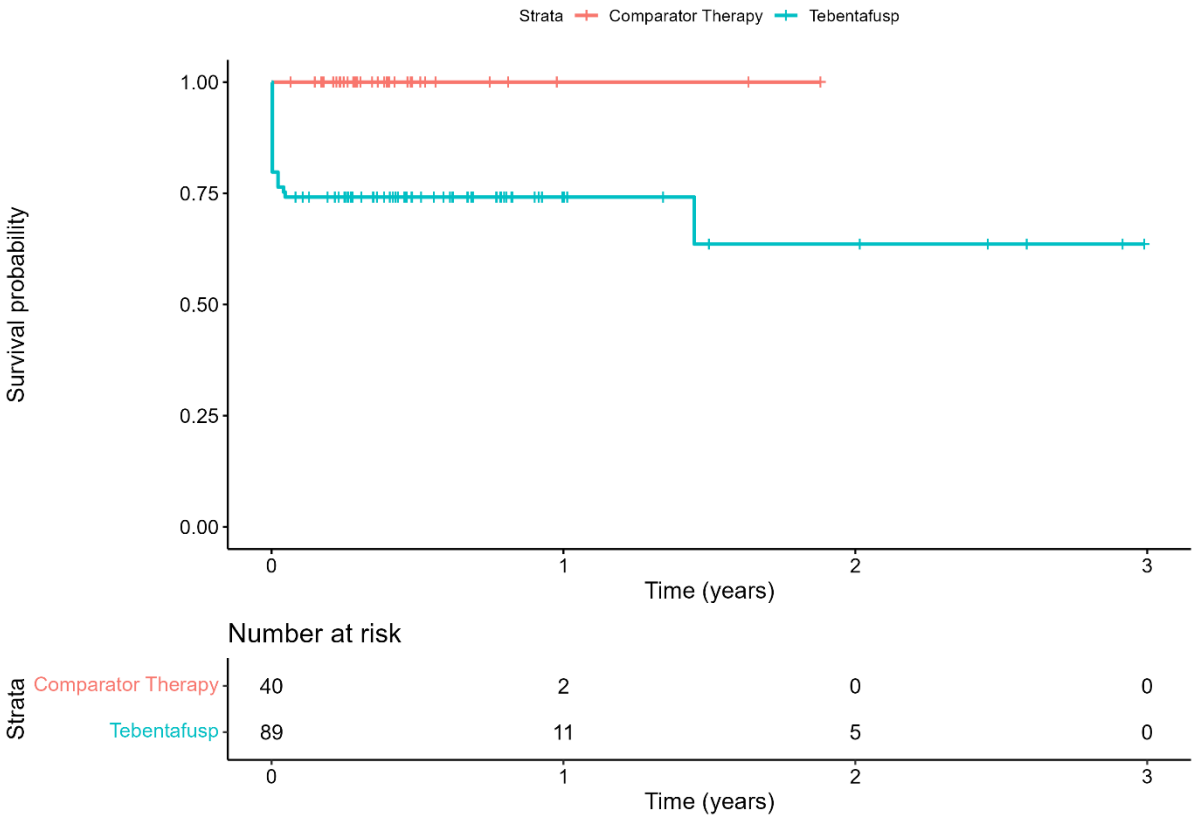
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



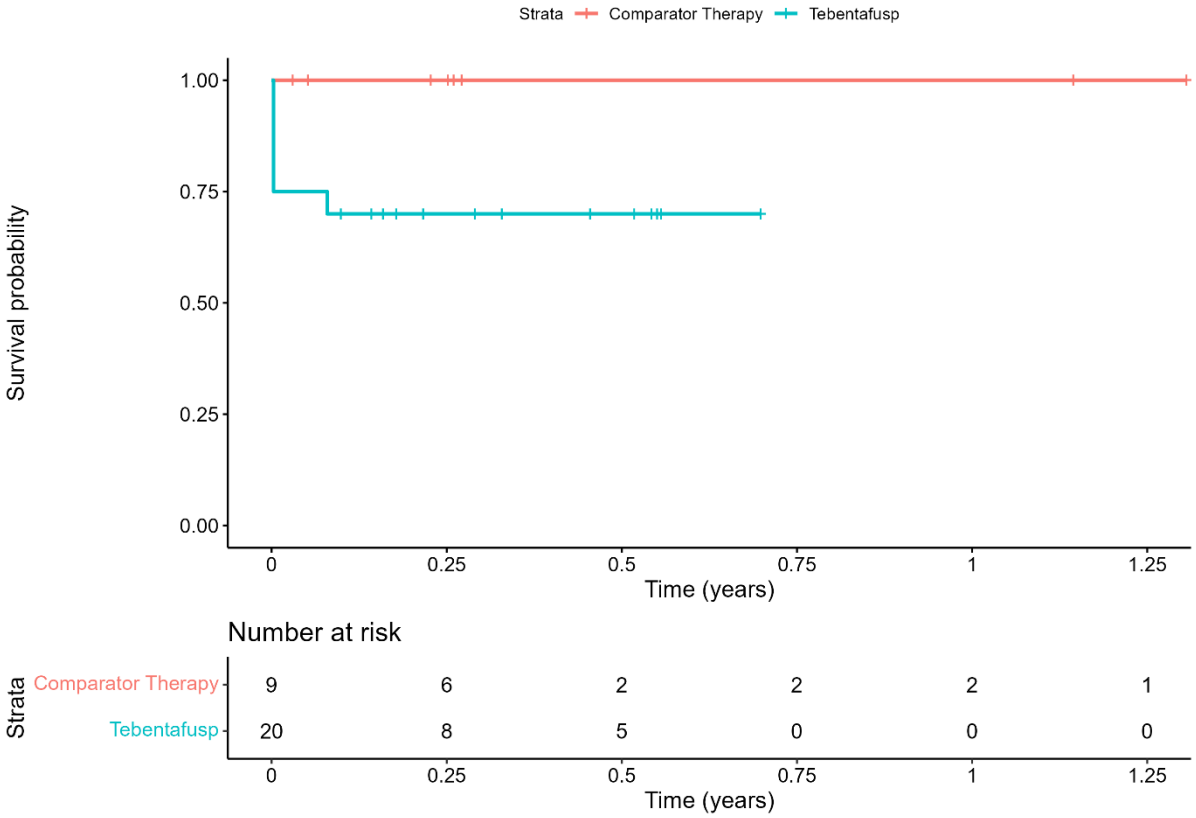
Größte metastatische Läsion (Baseline): ≤3,0 cm



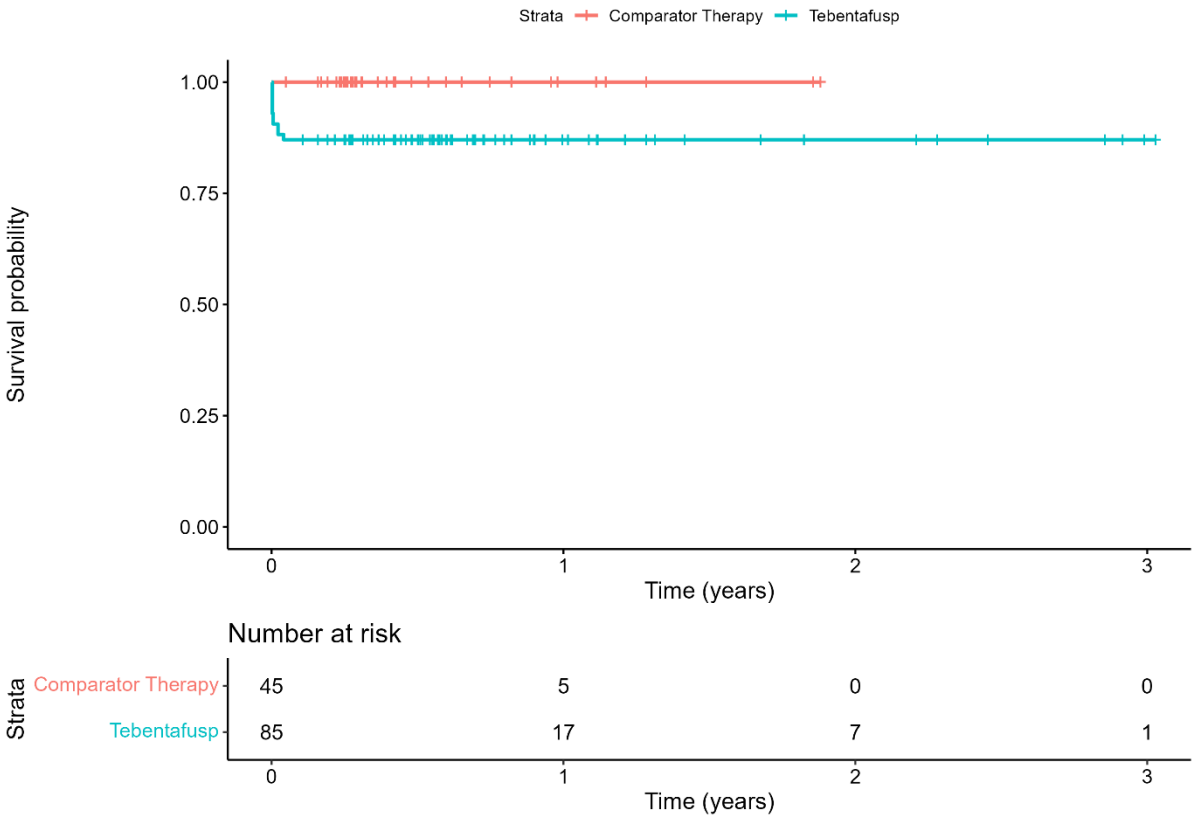
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



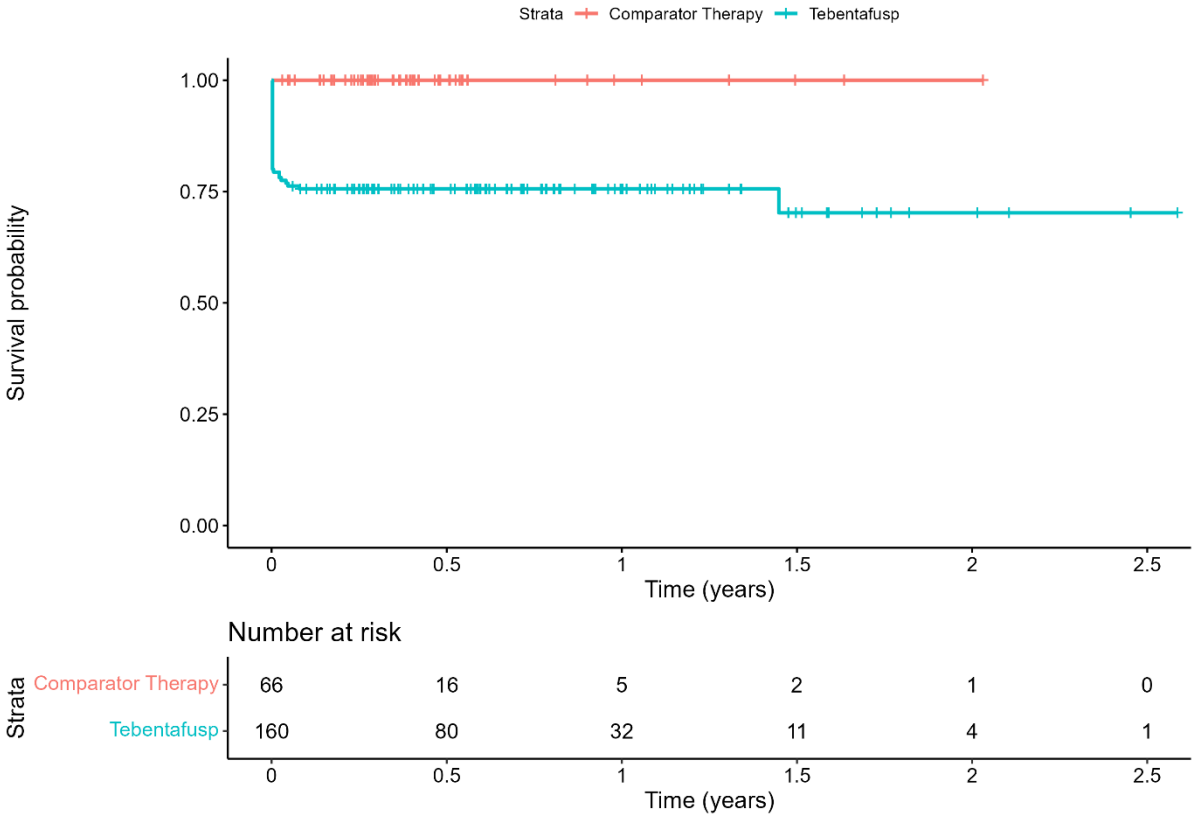
Größte metastatische Läsion (Baseline): ≥8,1 cm



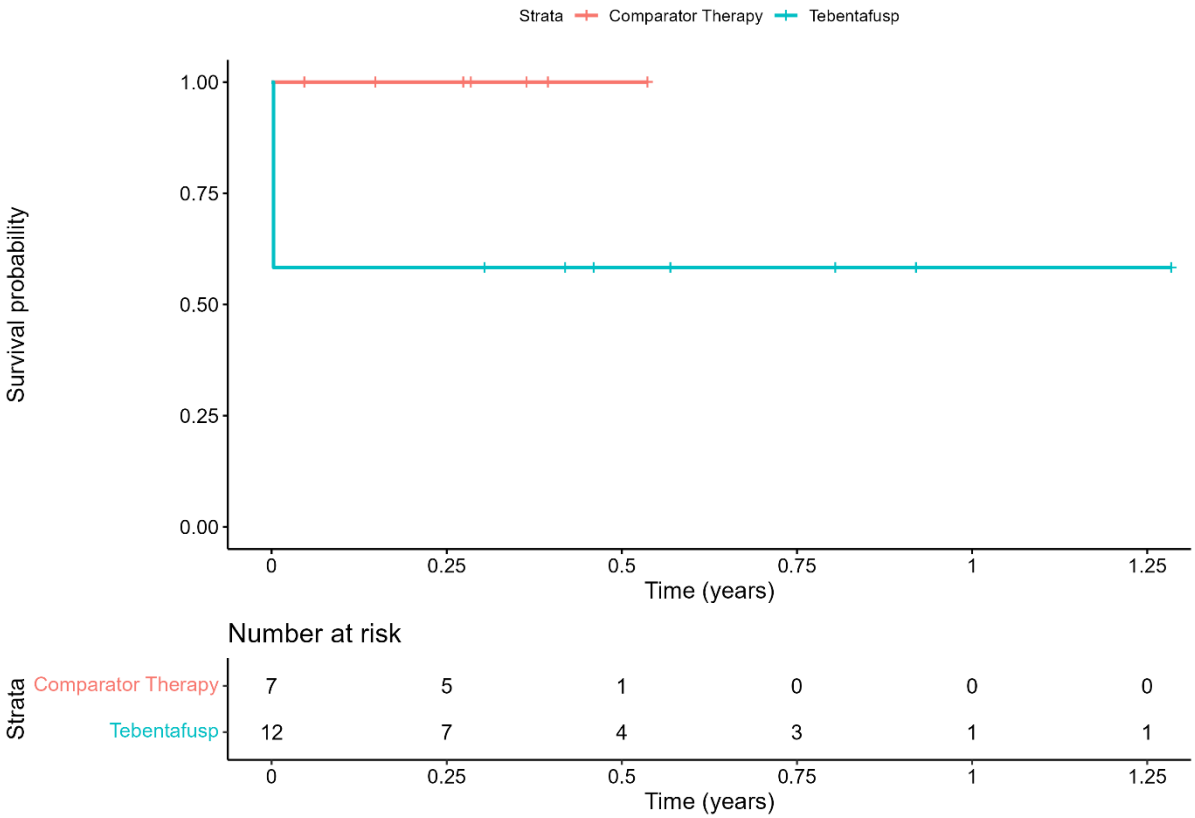
Region: Nordamerika



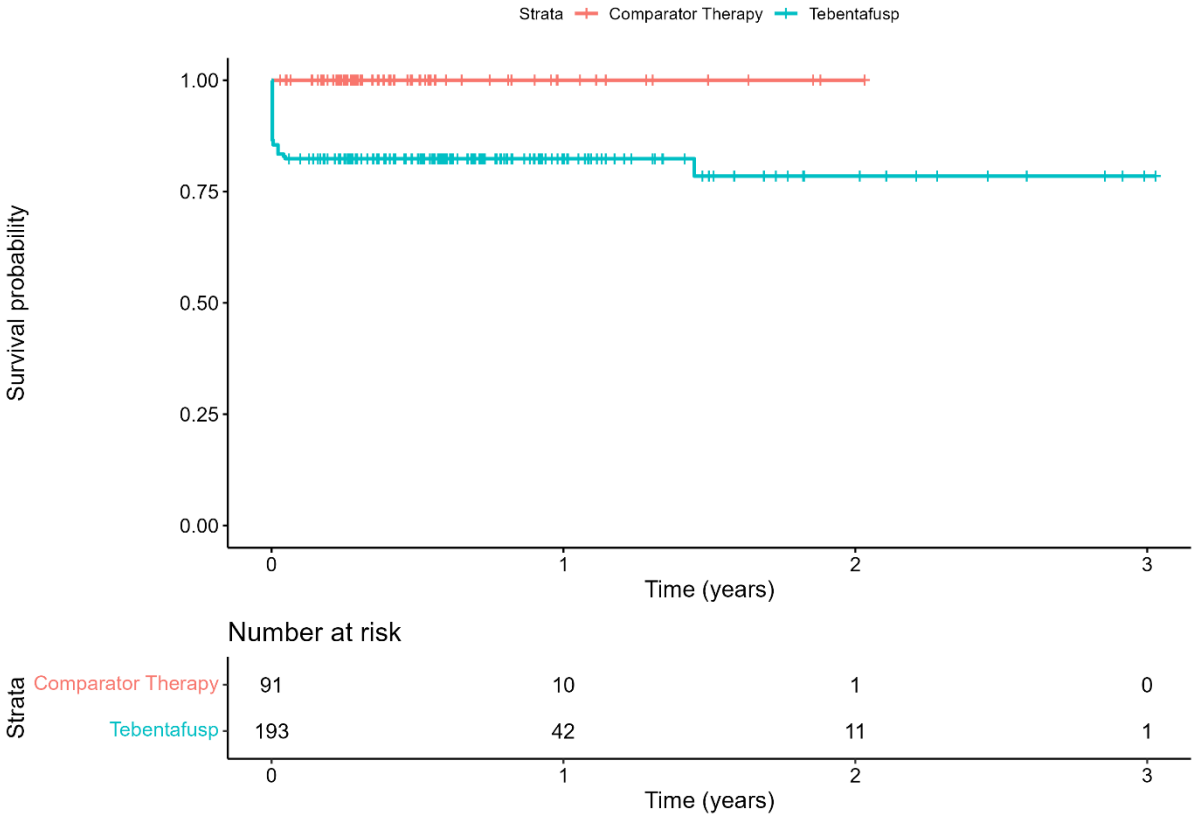
Region: Nicht-Nordamerika



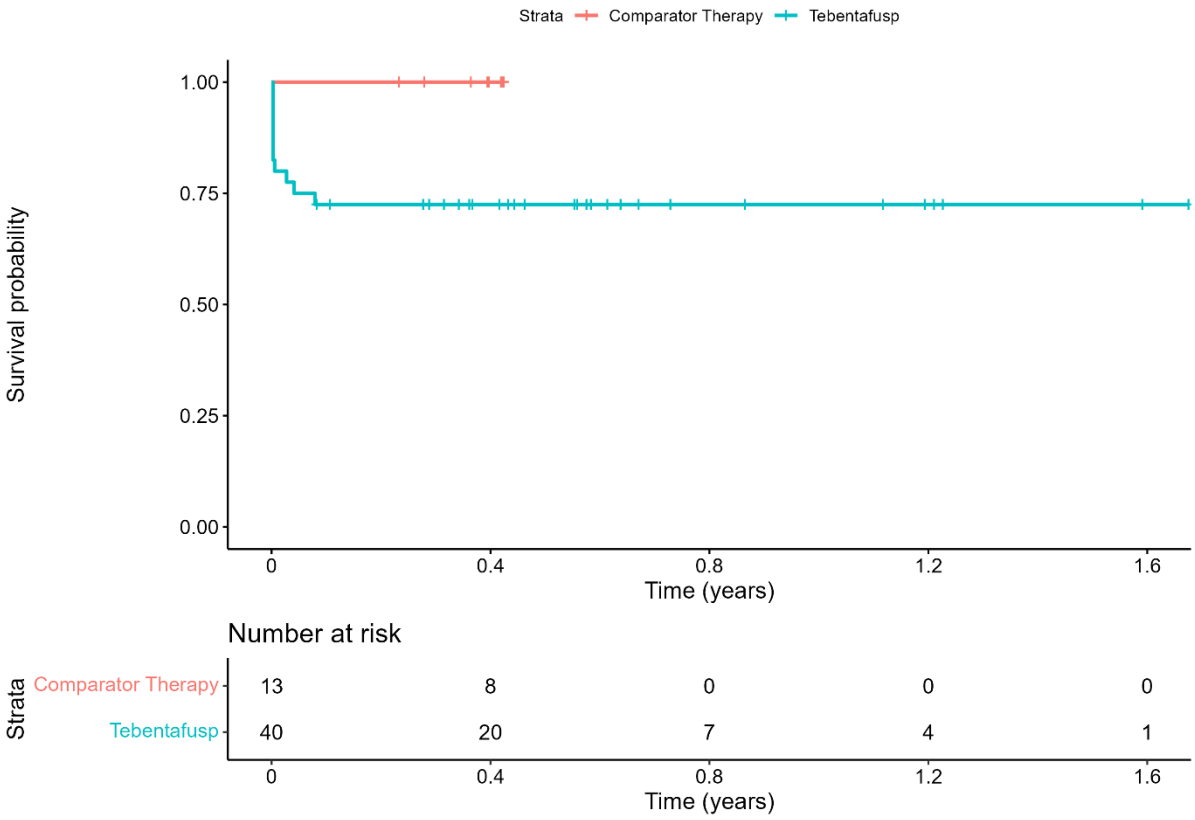
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

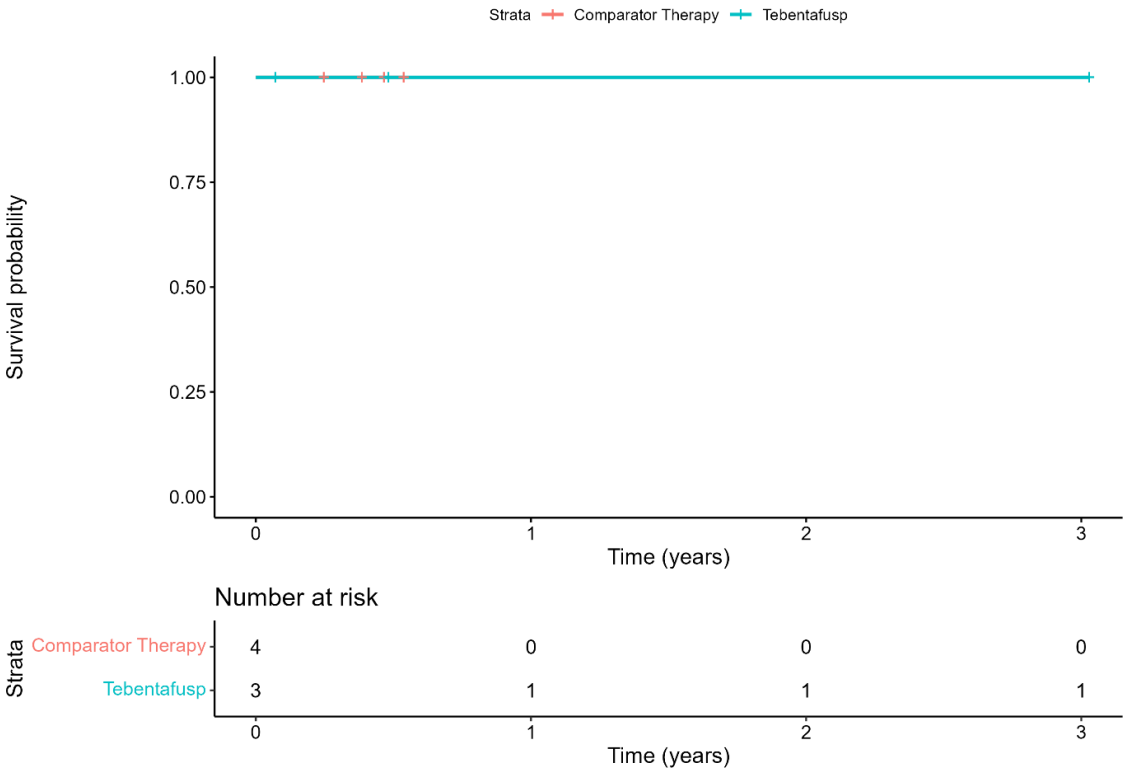


Vorauswahl der Chemotherapie: Ipilimumab

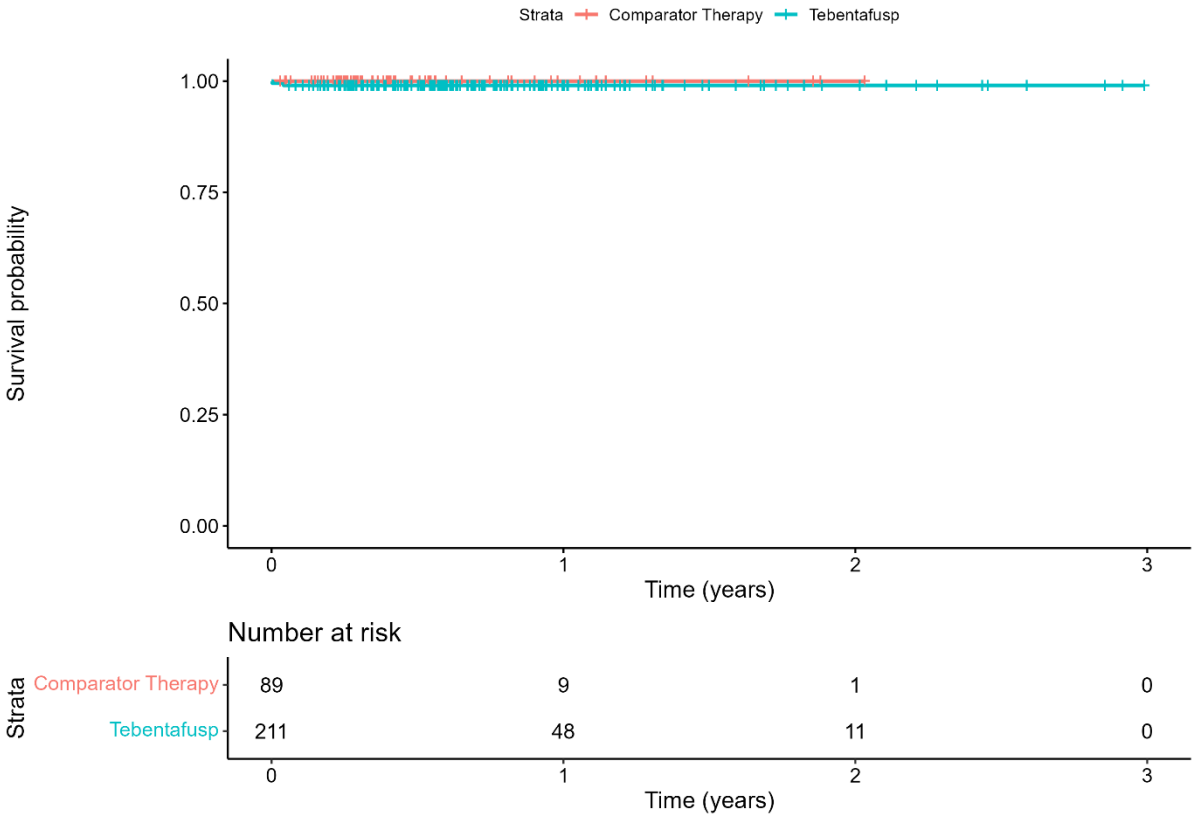


44.1 Zytokin-Freisetzungssyndrom mit CTCAE-Grad ≥ 3 (Tabelle 4-97)

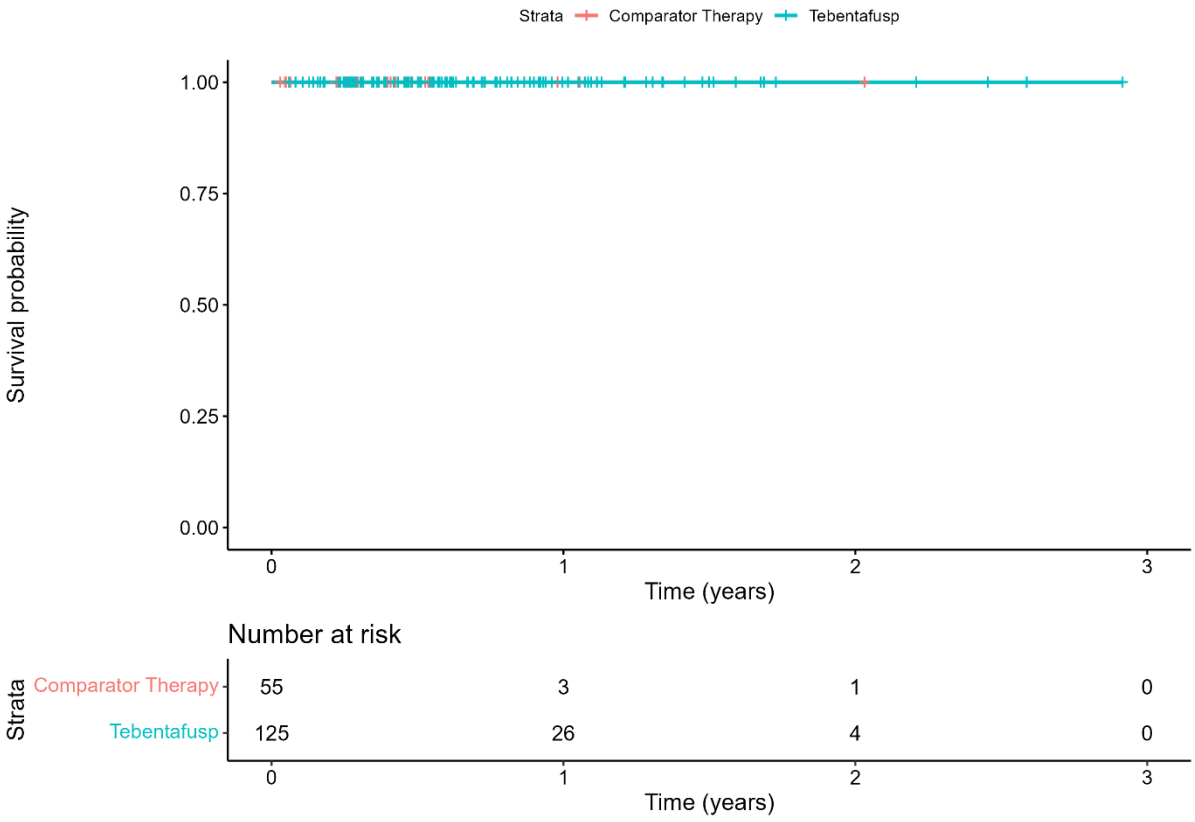
Herkunft: Hispanisch



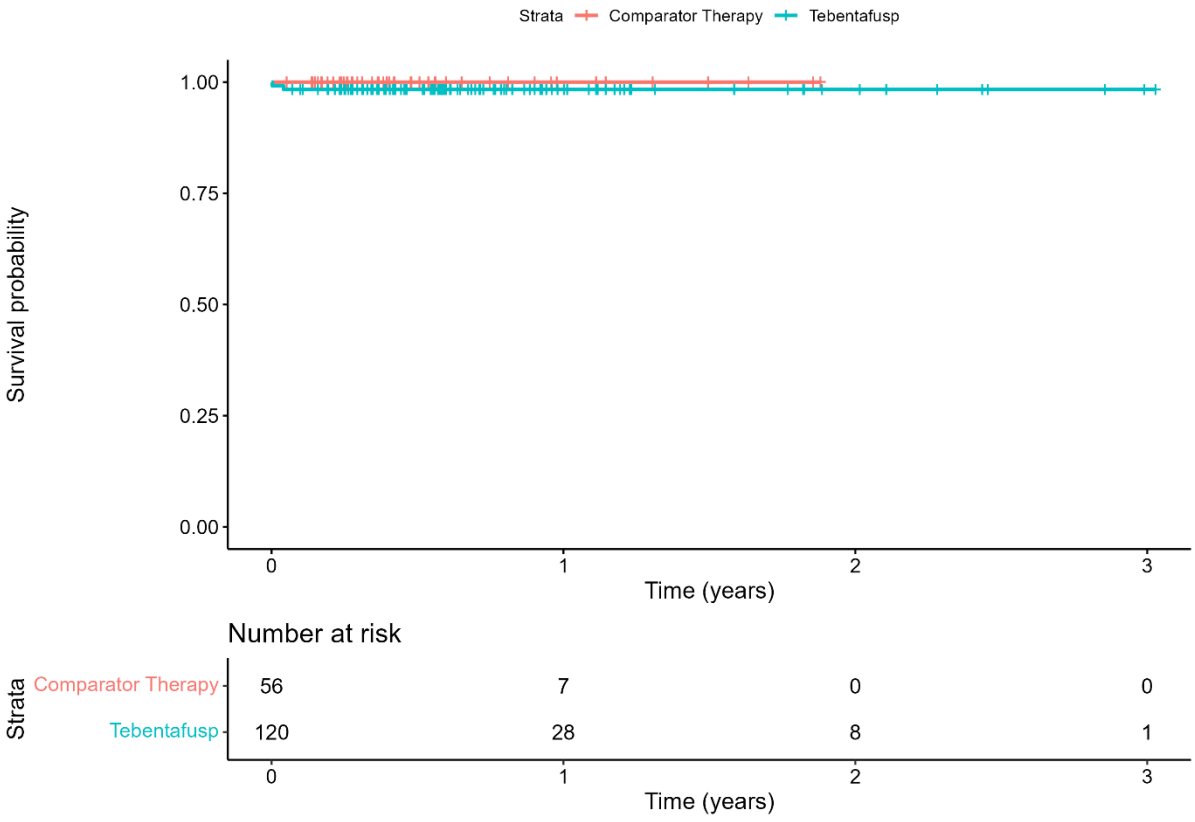
Herkunft: Nicht-hispanisch



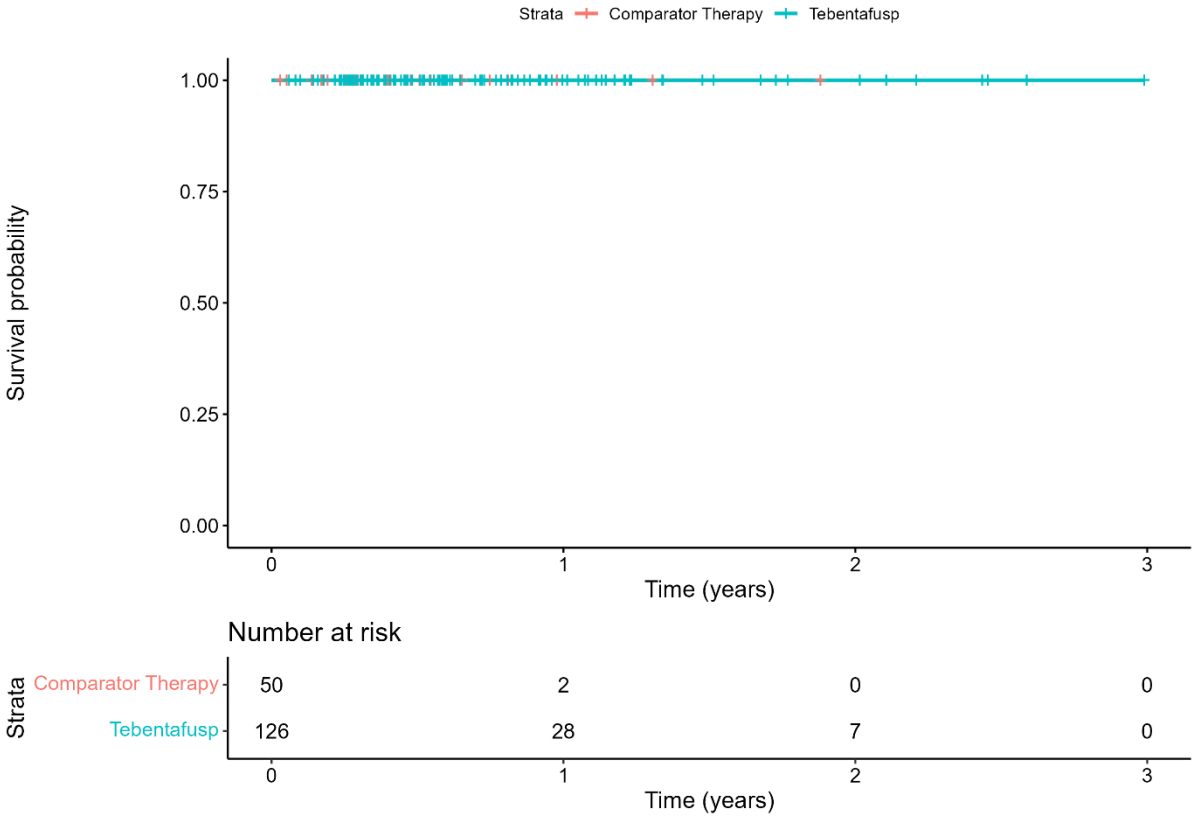
Geschlecht: Männlich



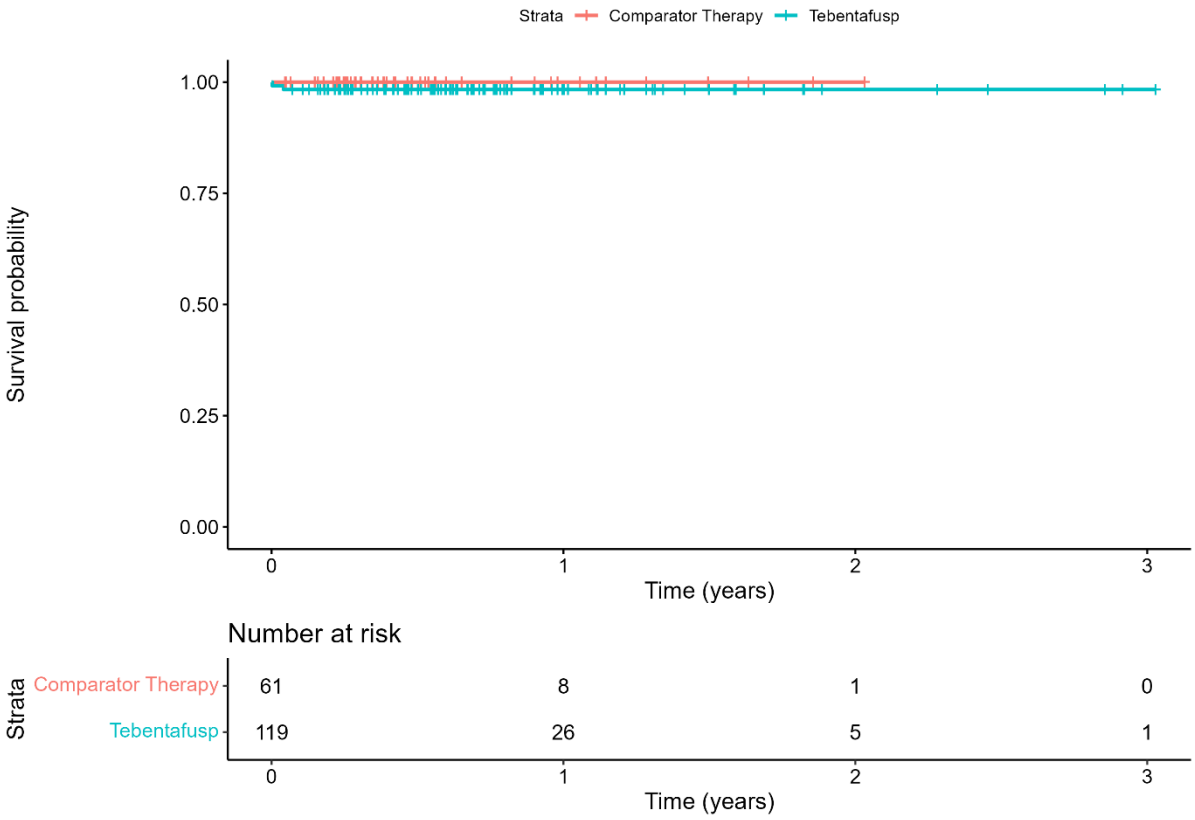
Geschlecht: Weiblich



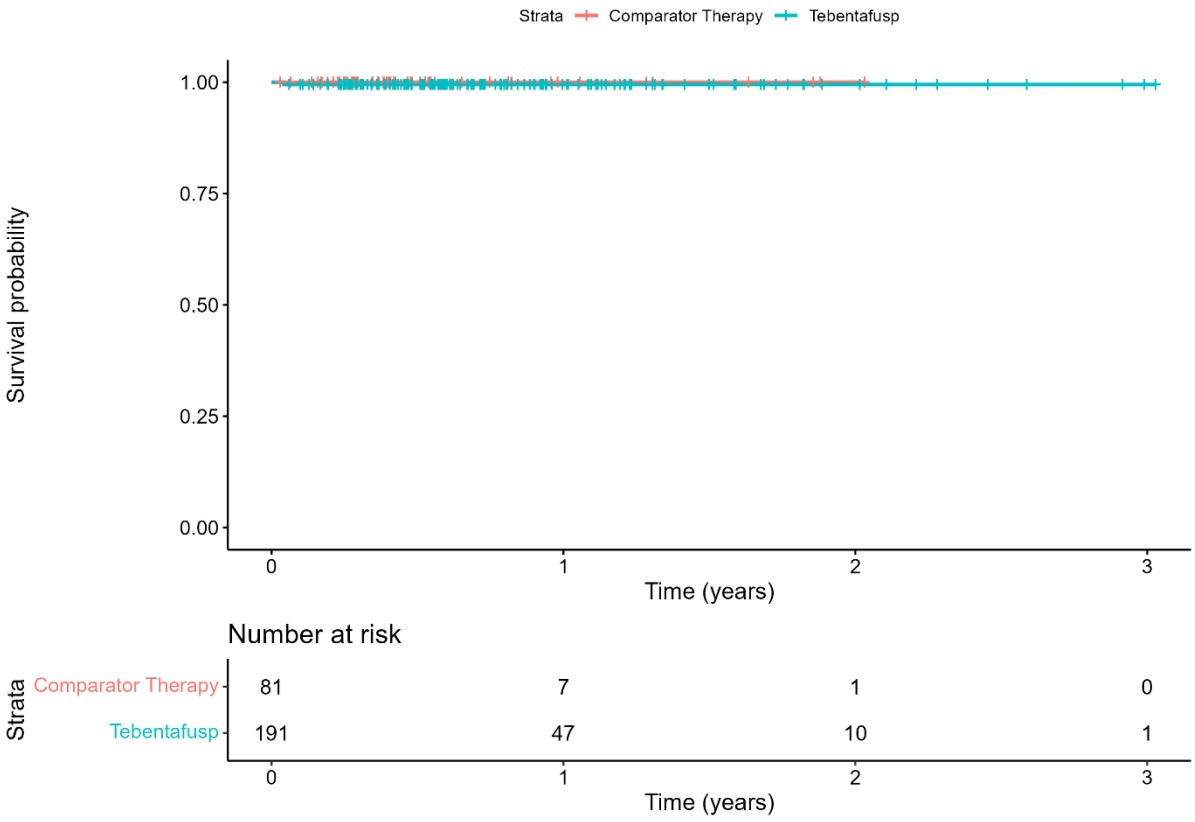
Alter: <65 Jahre



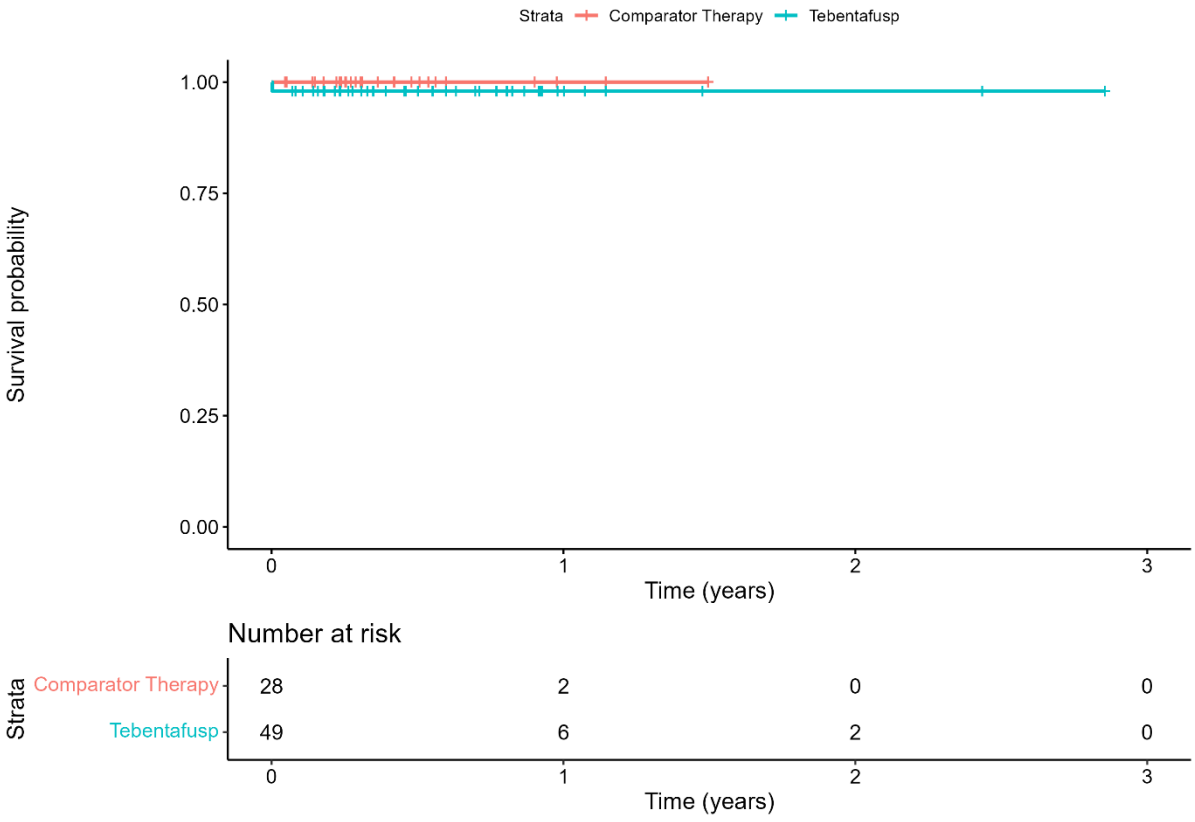
Alter: ≥65 Jahre



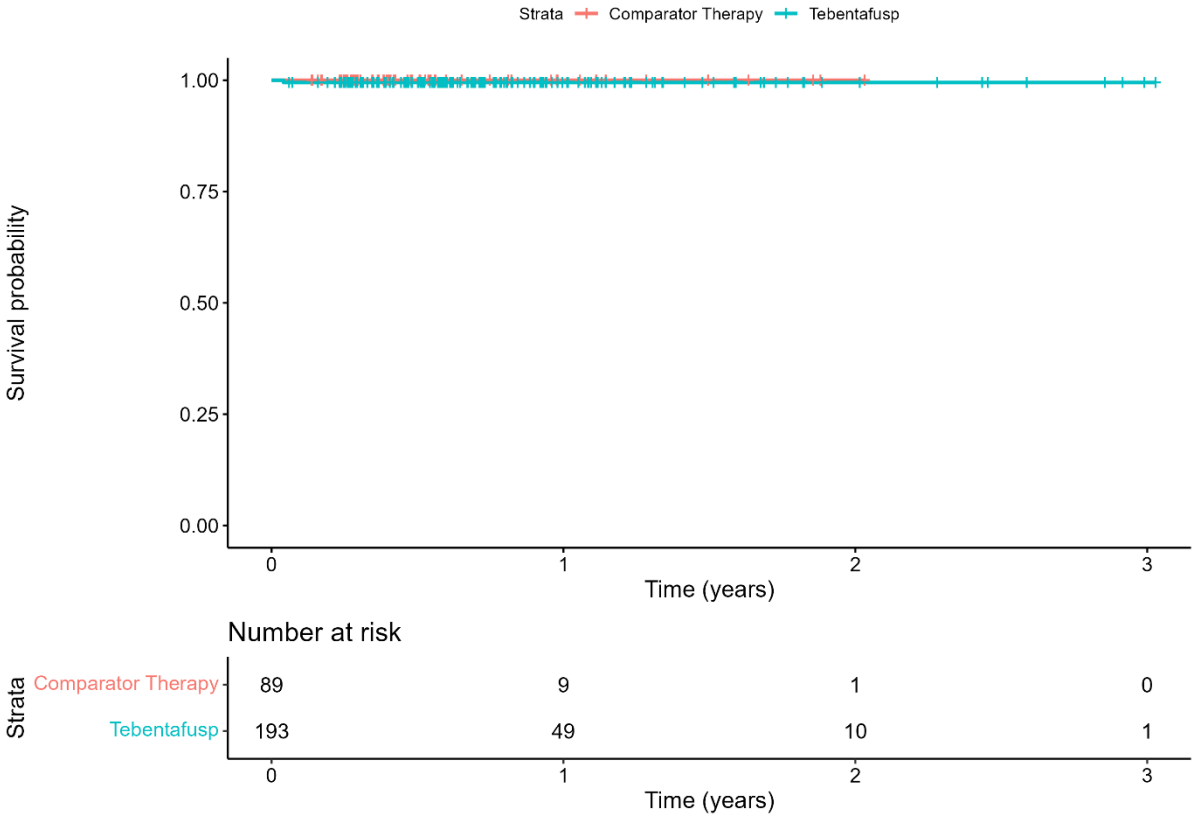
ECOG-Performance-Status: 0



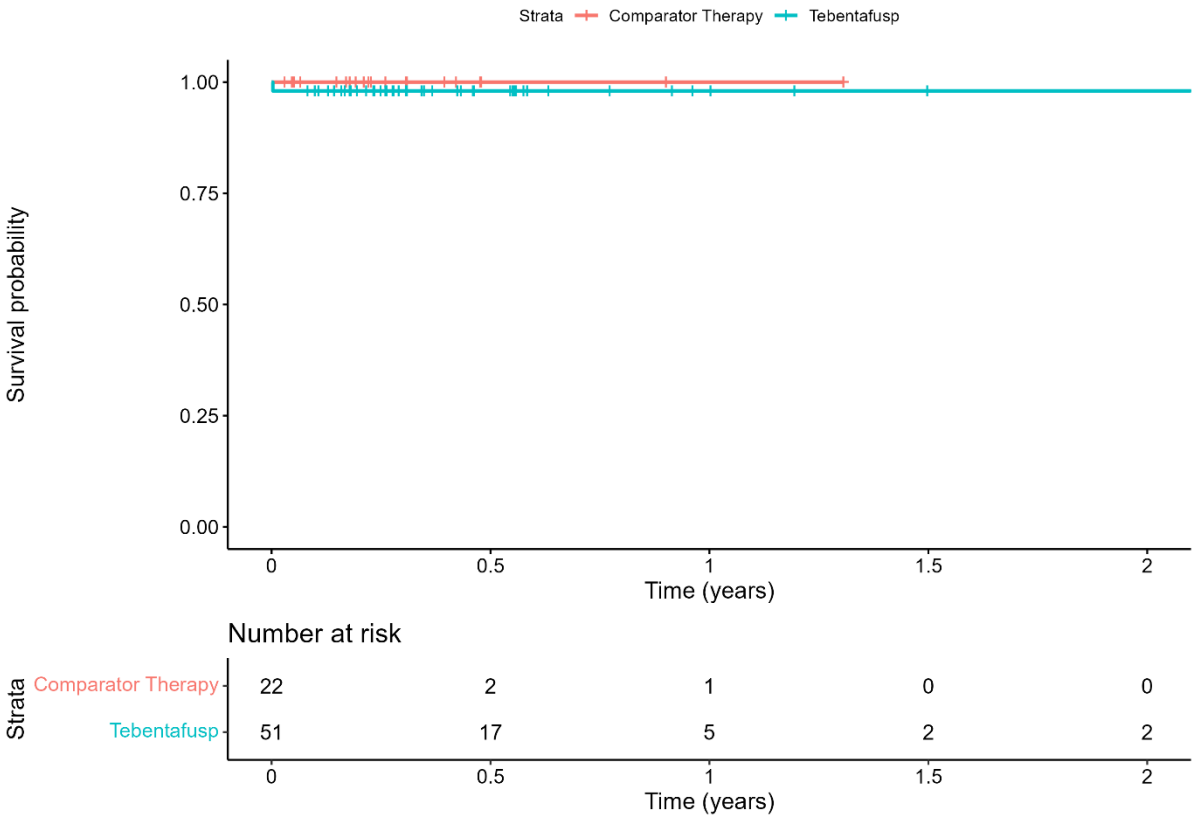
ECOG-Performance-Status: 1



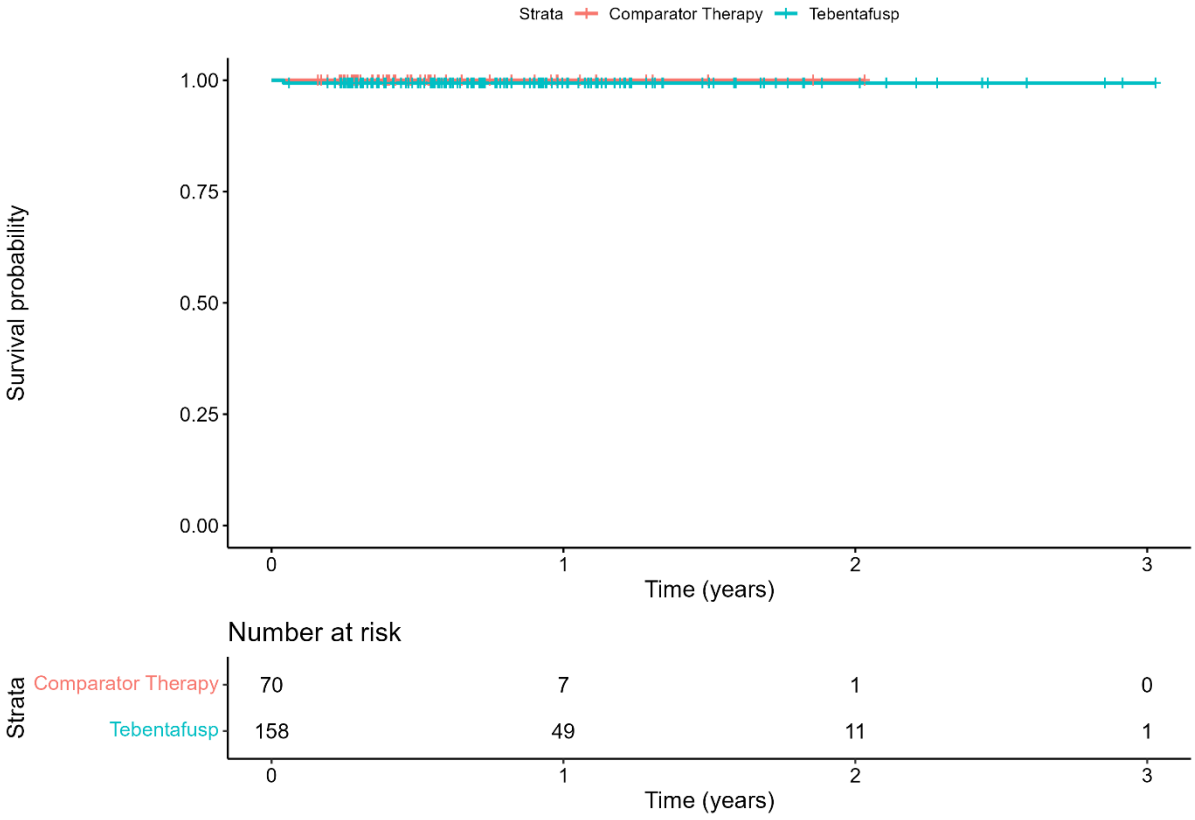
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



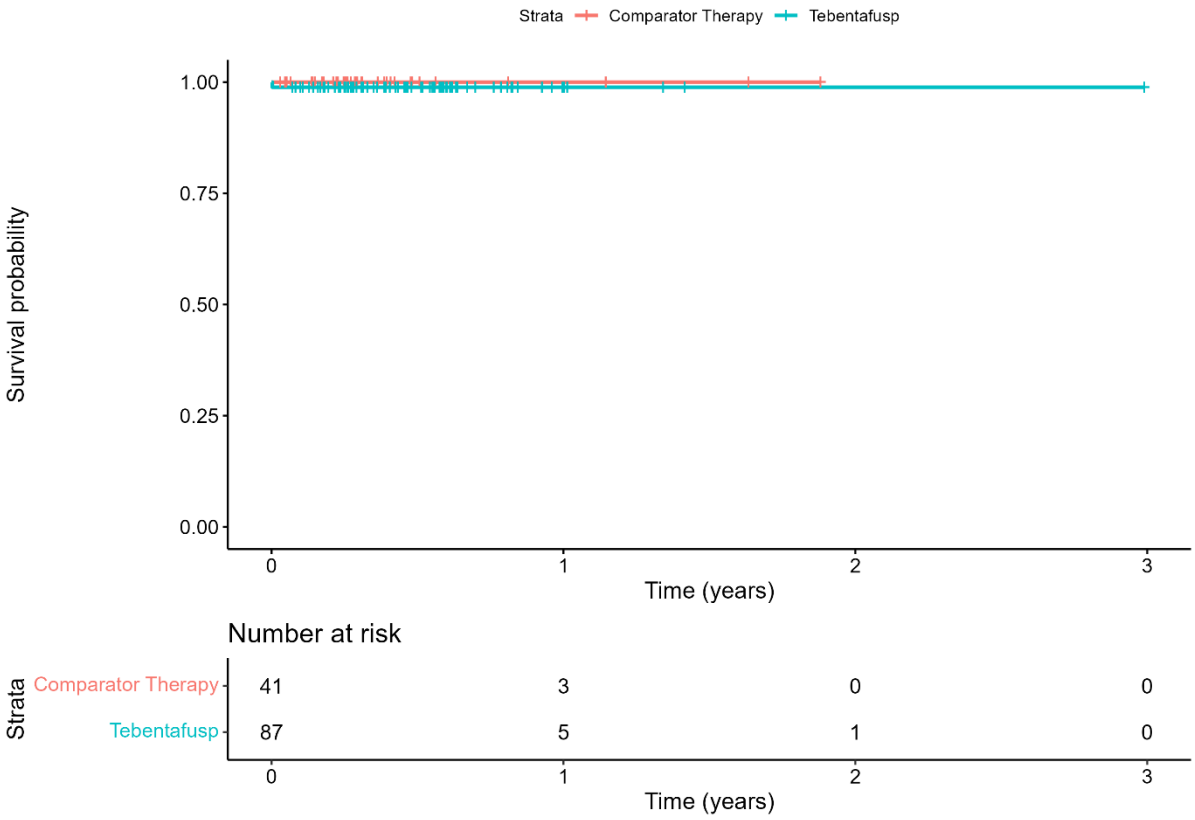
Alkalische Phosphatase (ALP) (Baseline): >ULN



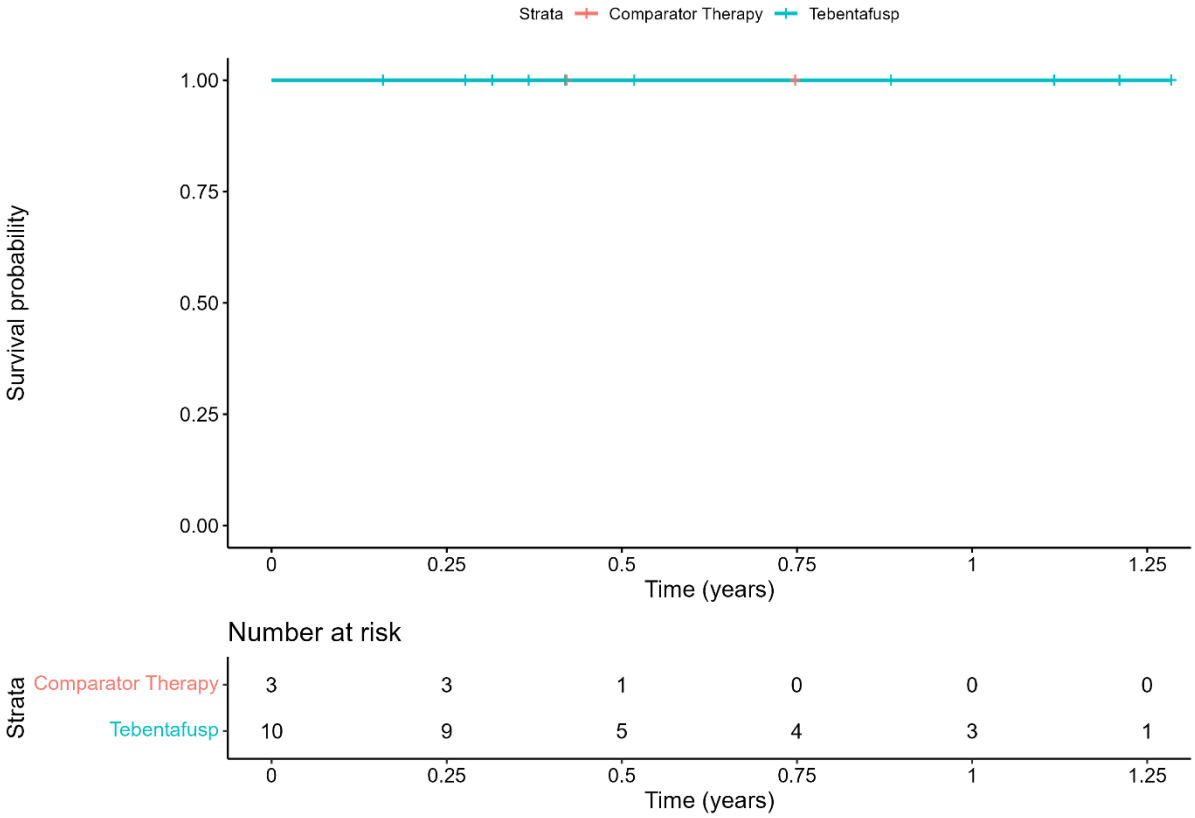
LDH: ≤ULN



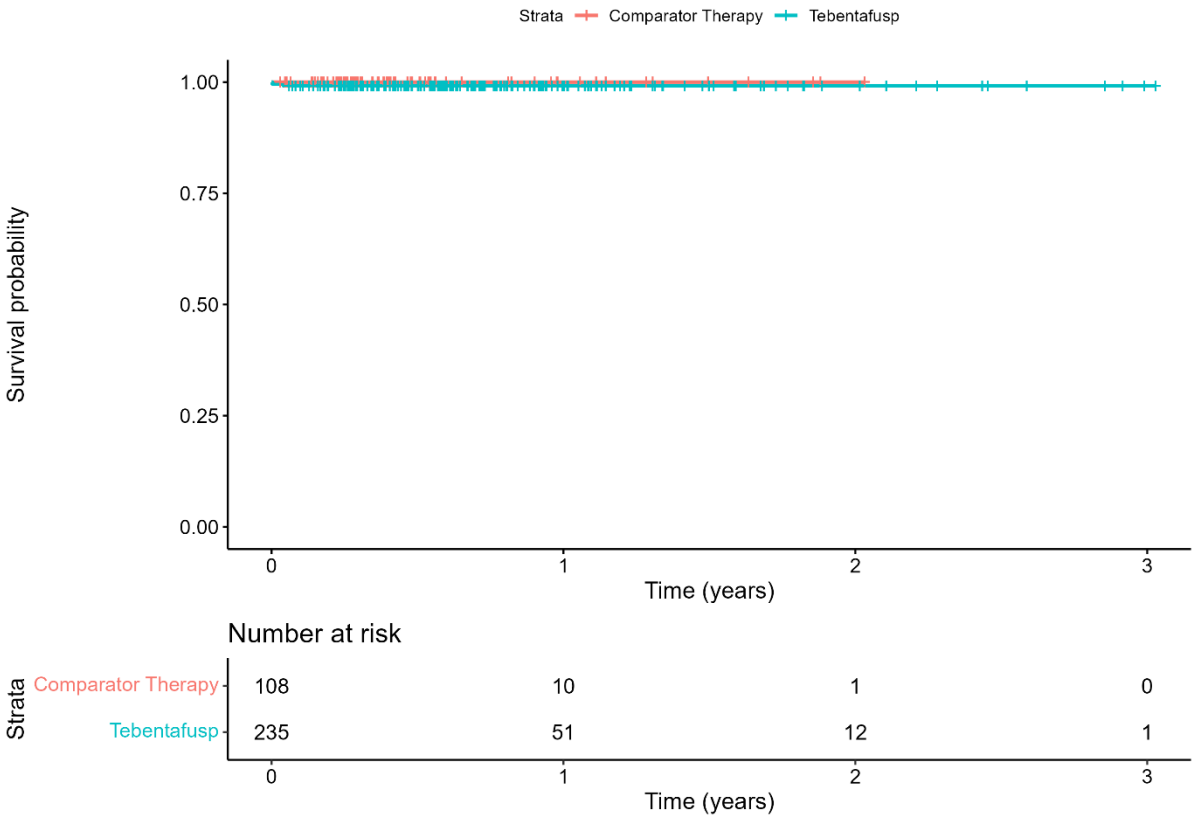
LDH: >ULN



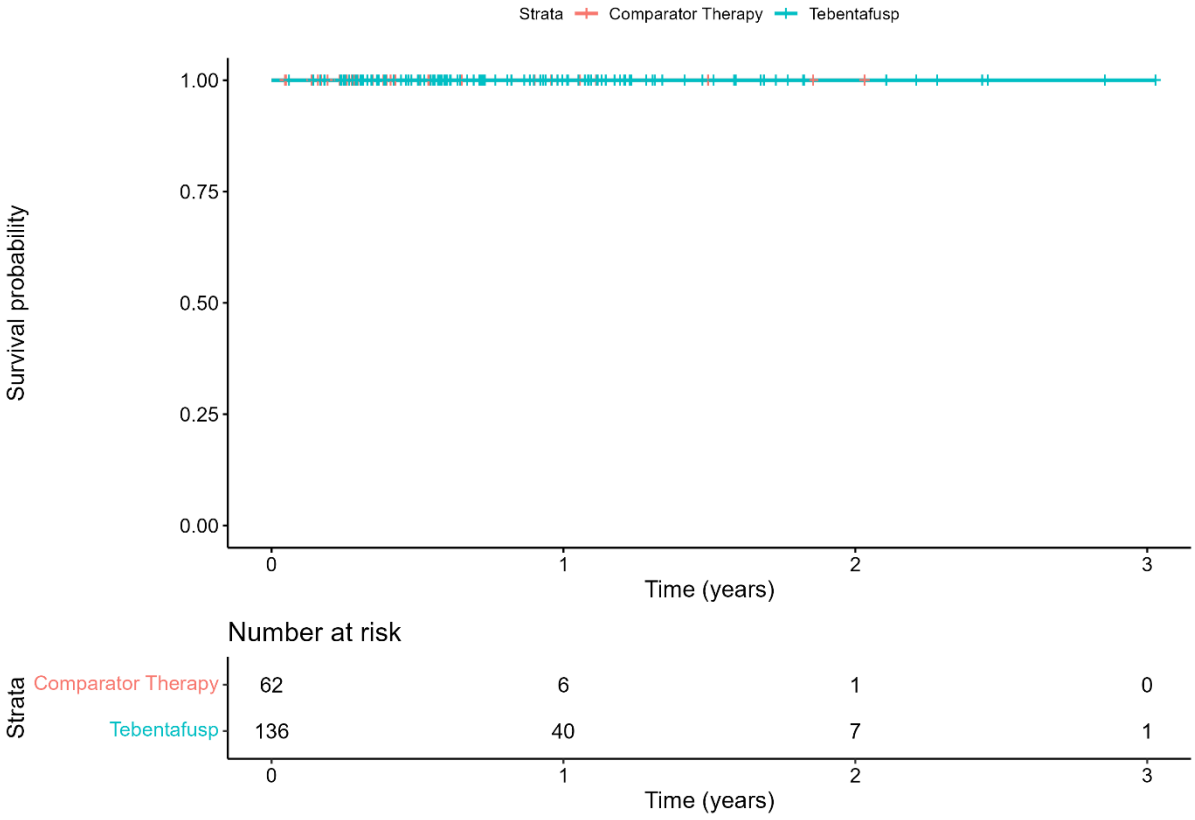
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



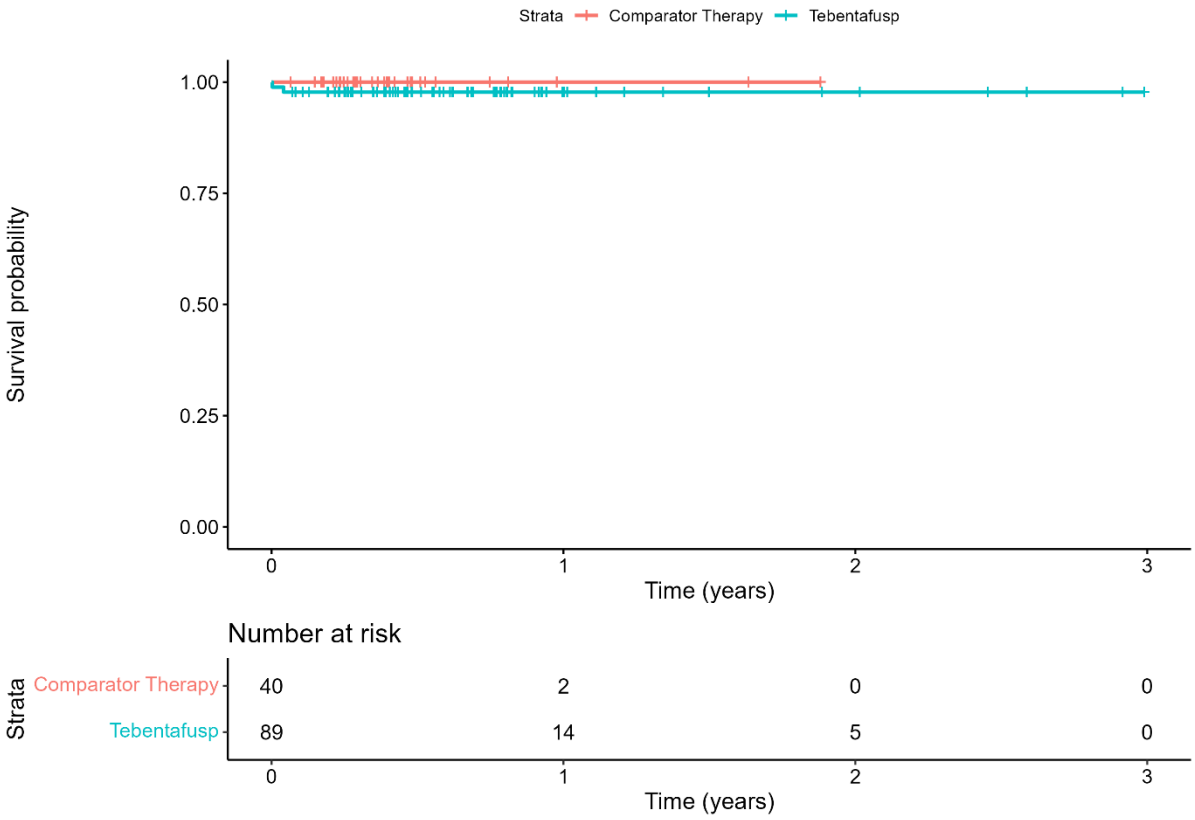
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



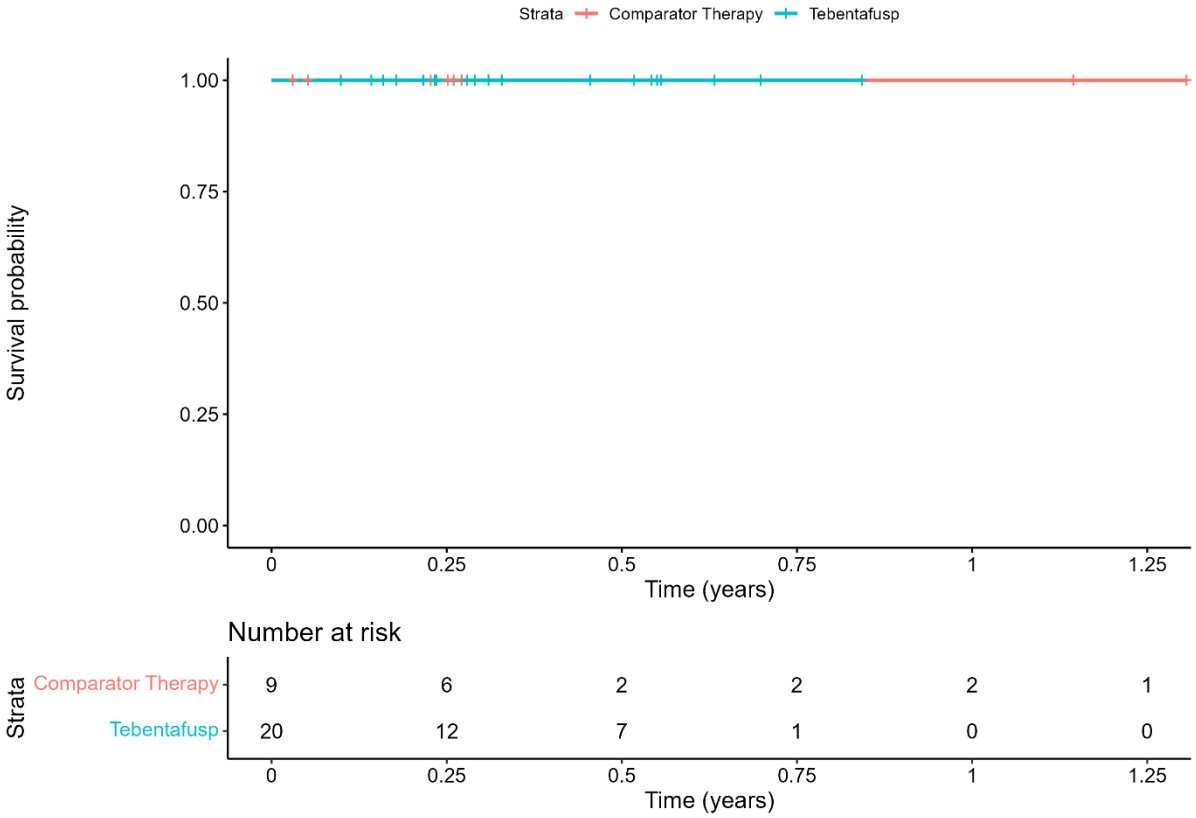
Größte metastatische Läsion (Baseline): ≤3,0 cm



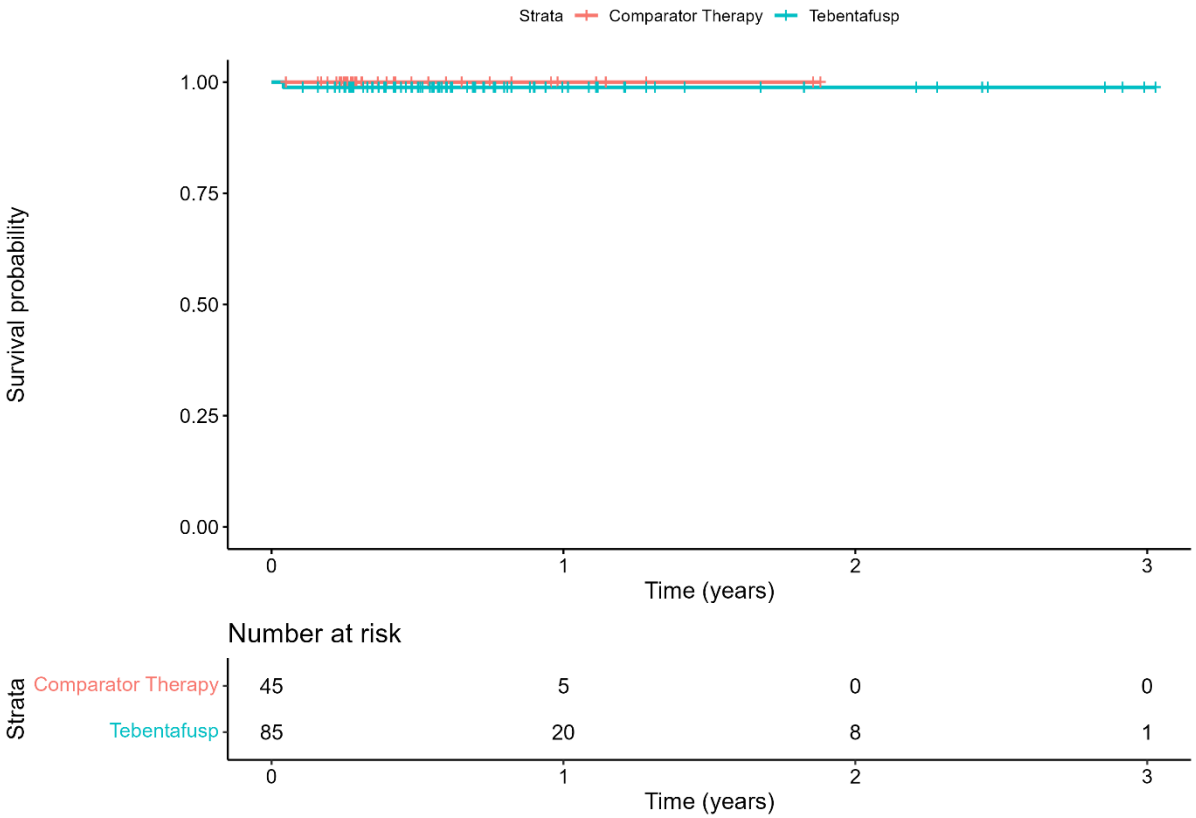
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



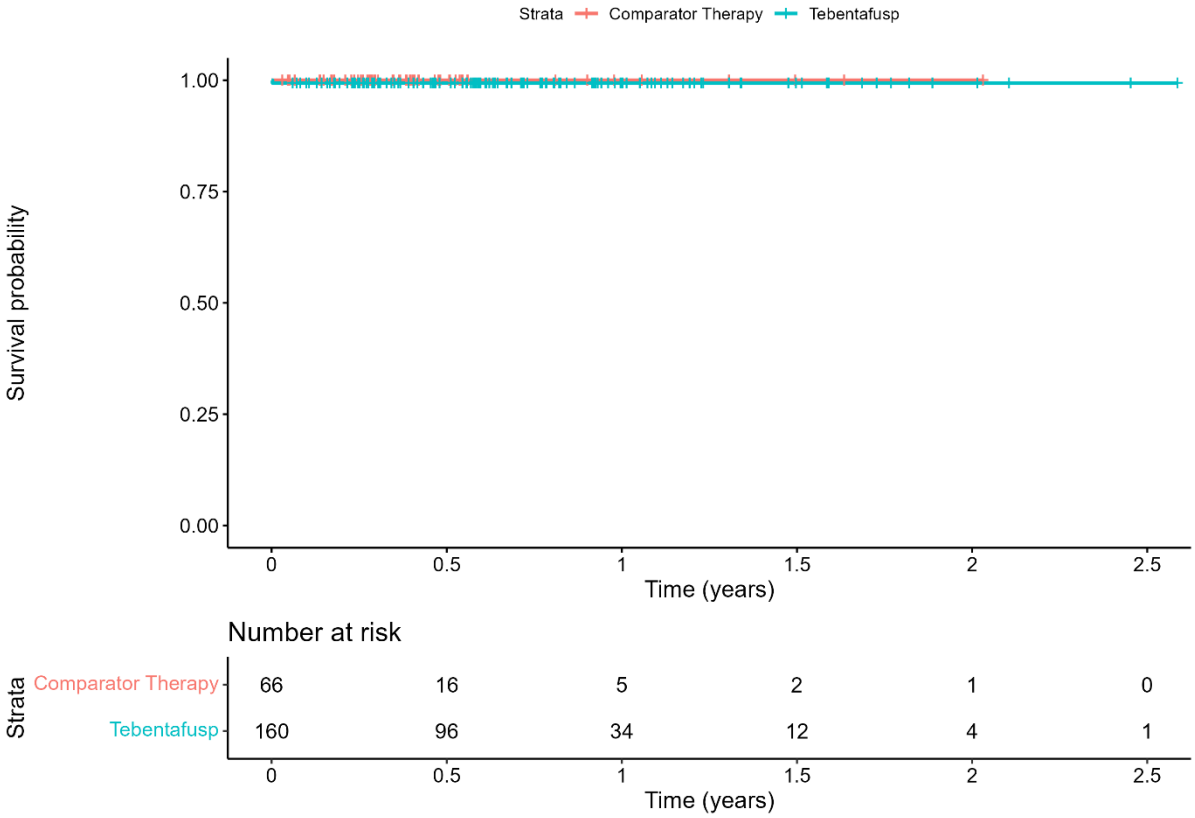
Größte metastatische Läsion (Baseline): ≥8,1 cm



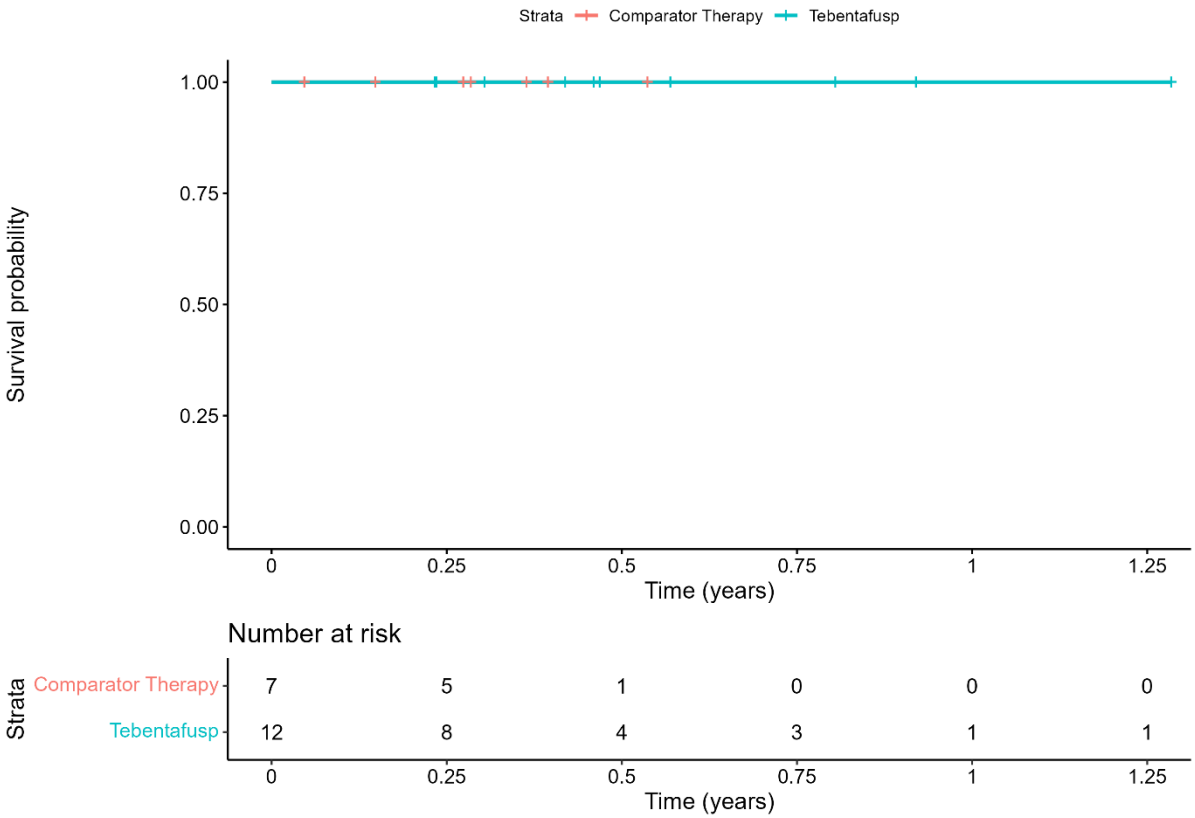
Region: Nordamerika



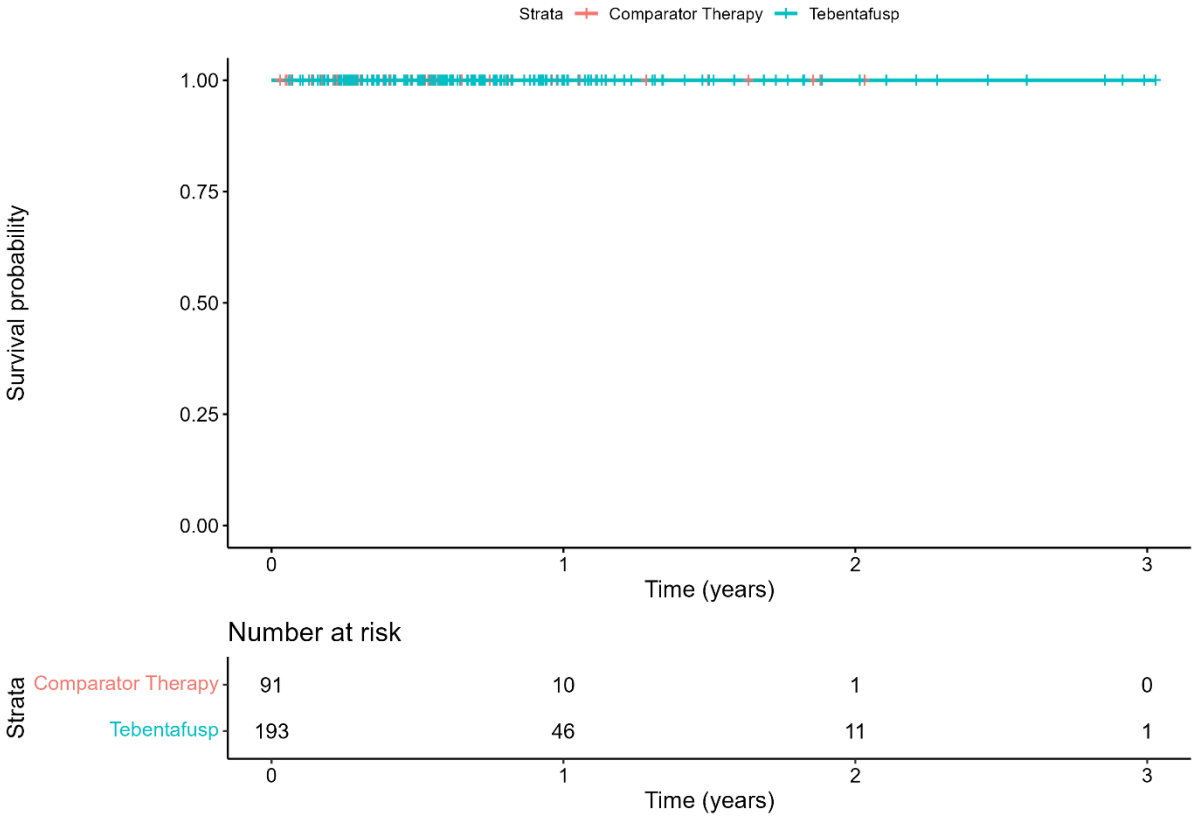
Region: Nicht-Nordamerika



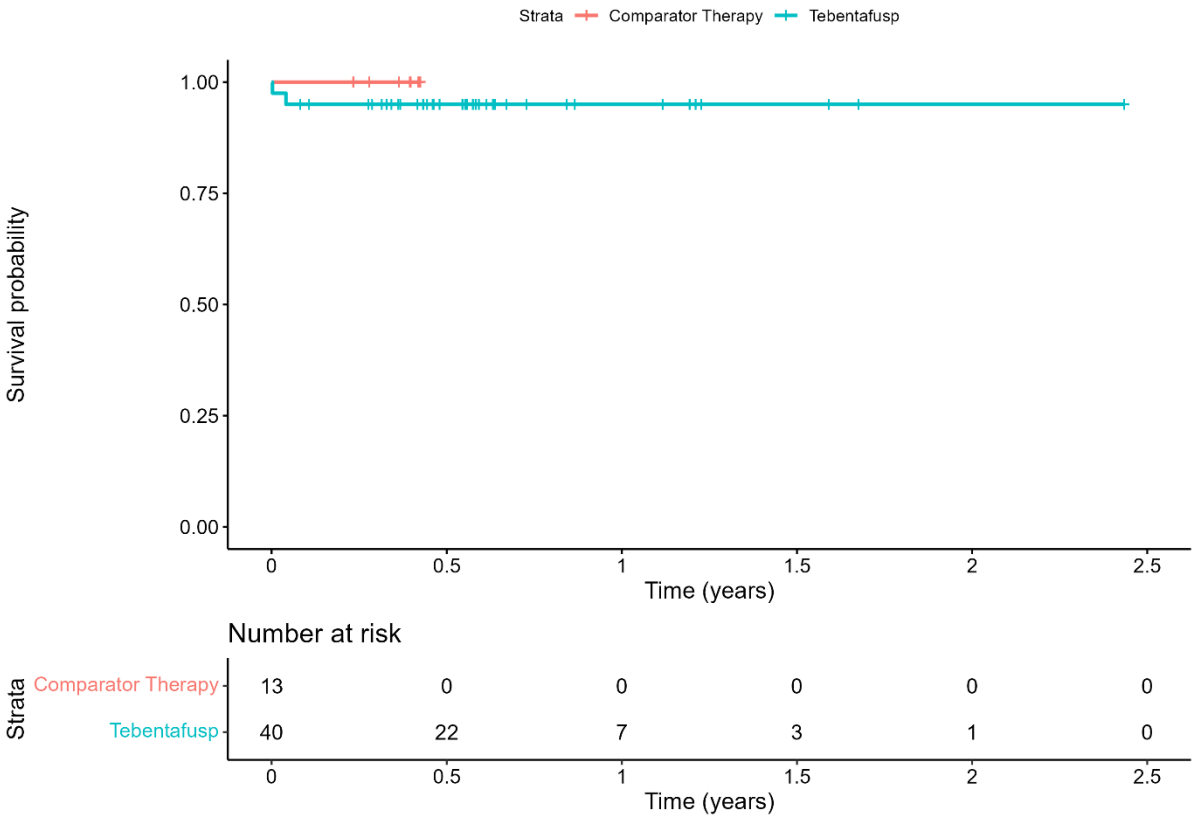
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

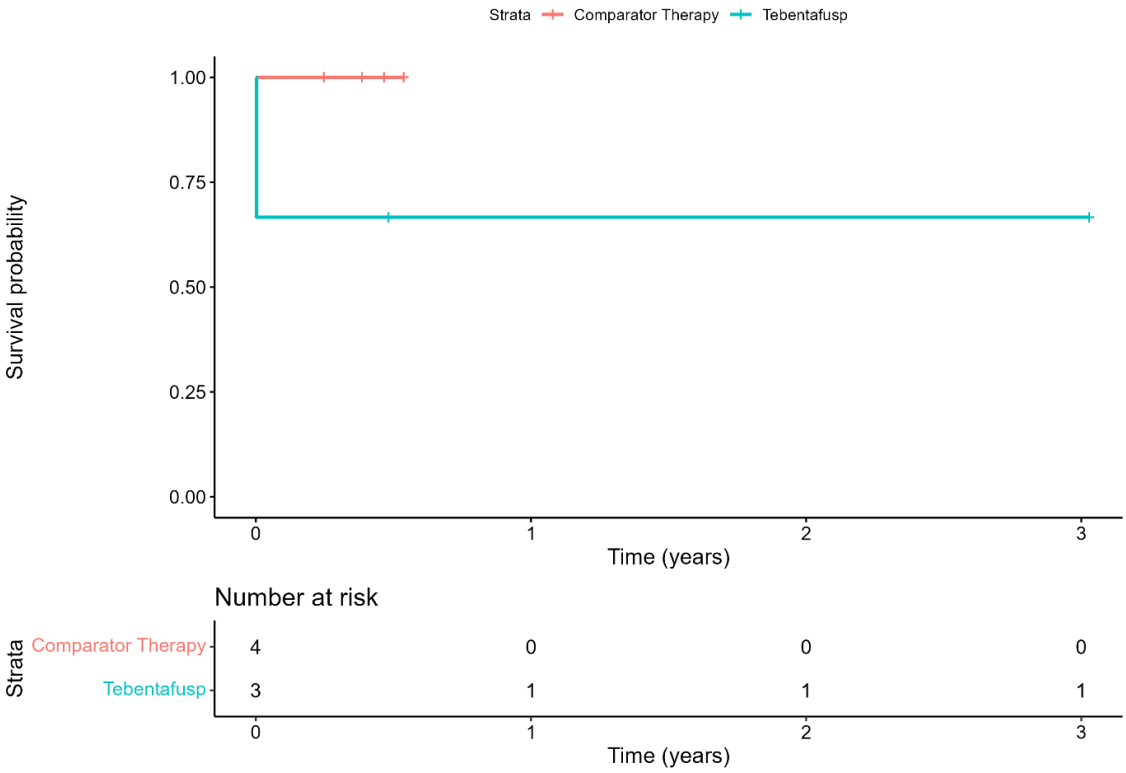


Vorauswahl der Chemotherapie: Ipilimumab

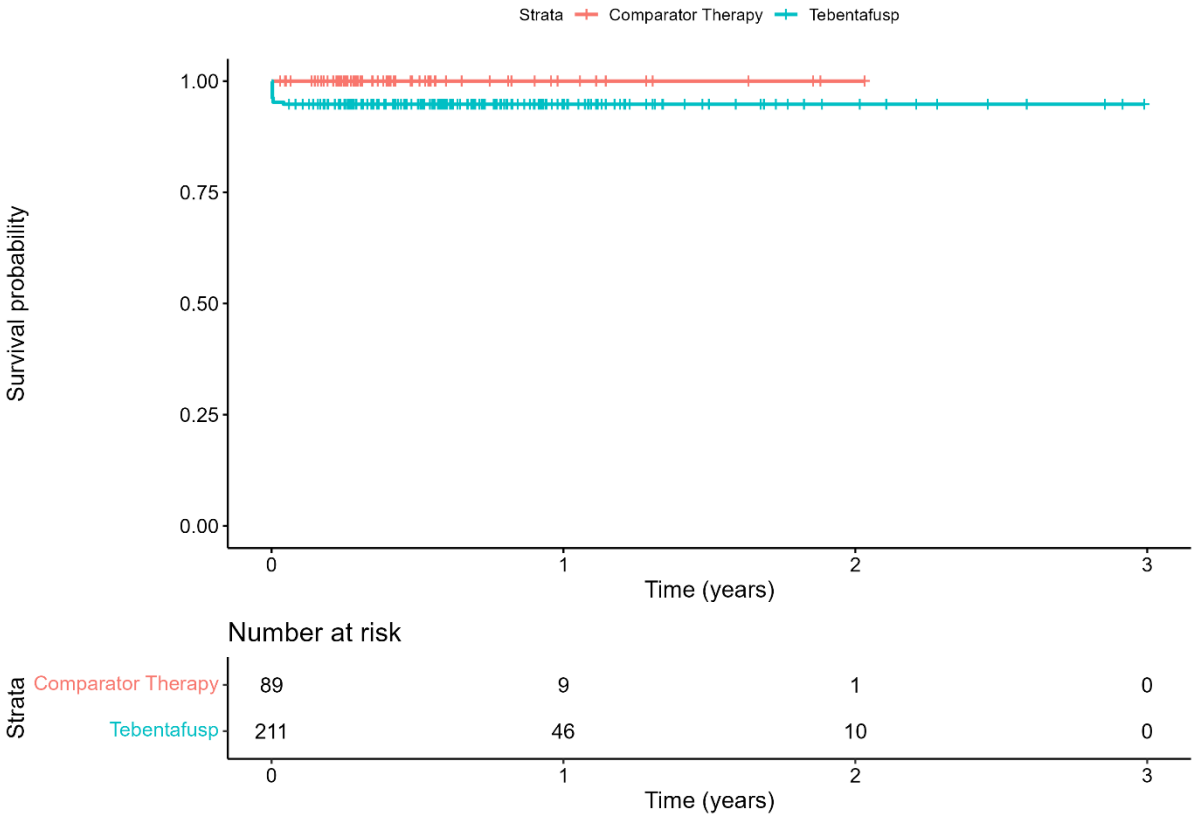


44.3 Schwerwiegendes Zytokin-Freisetzungssyndrom (Tabelle 4-99)

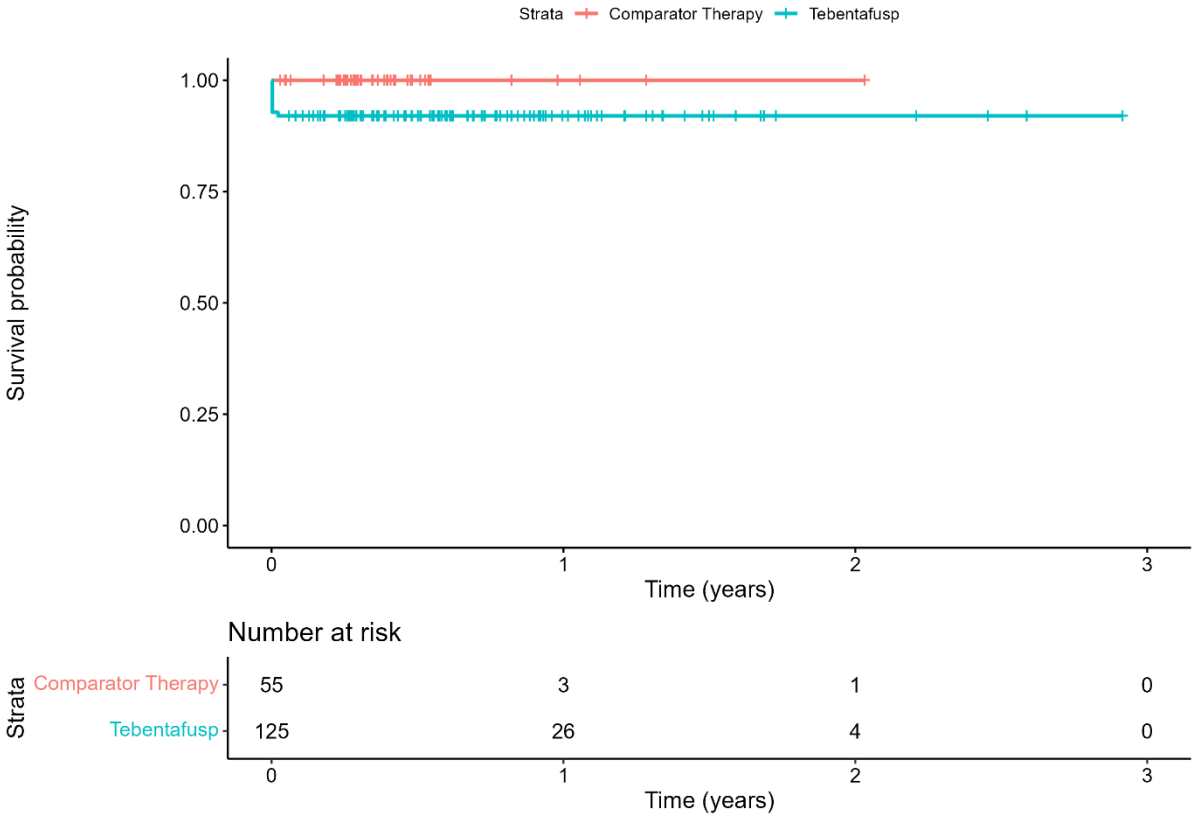
Herkunft: Hispanisch



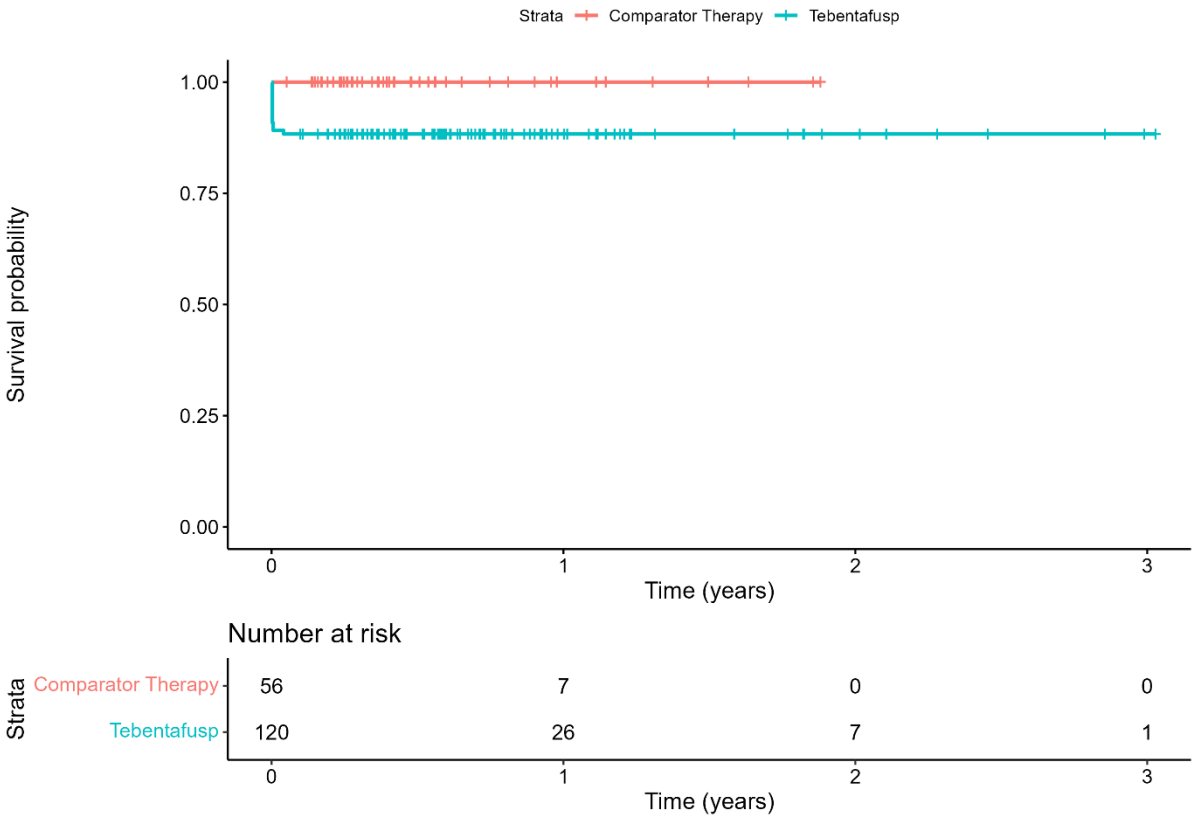
Herkunft: Nicht-hispanisch



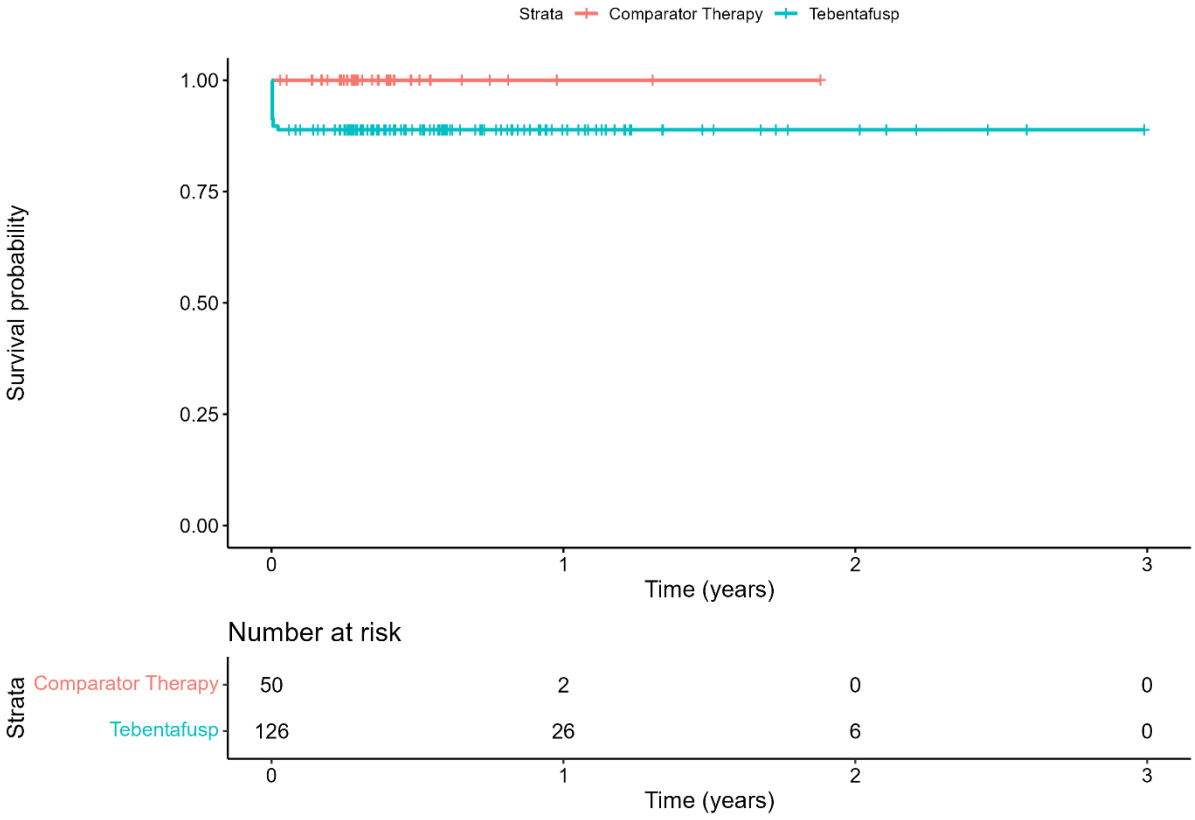
Geschlecht: Männlich



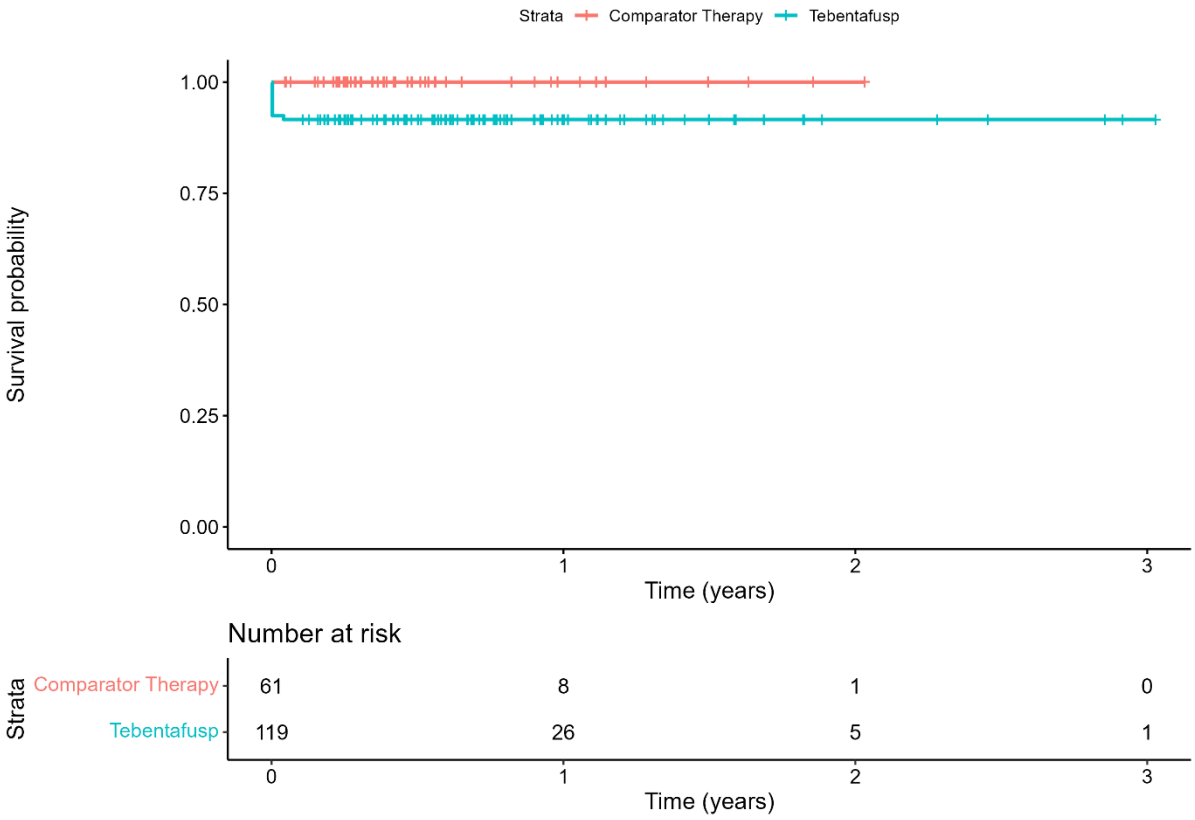
Geschlecht: Weiblich



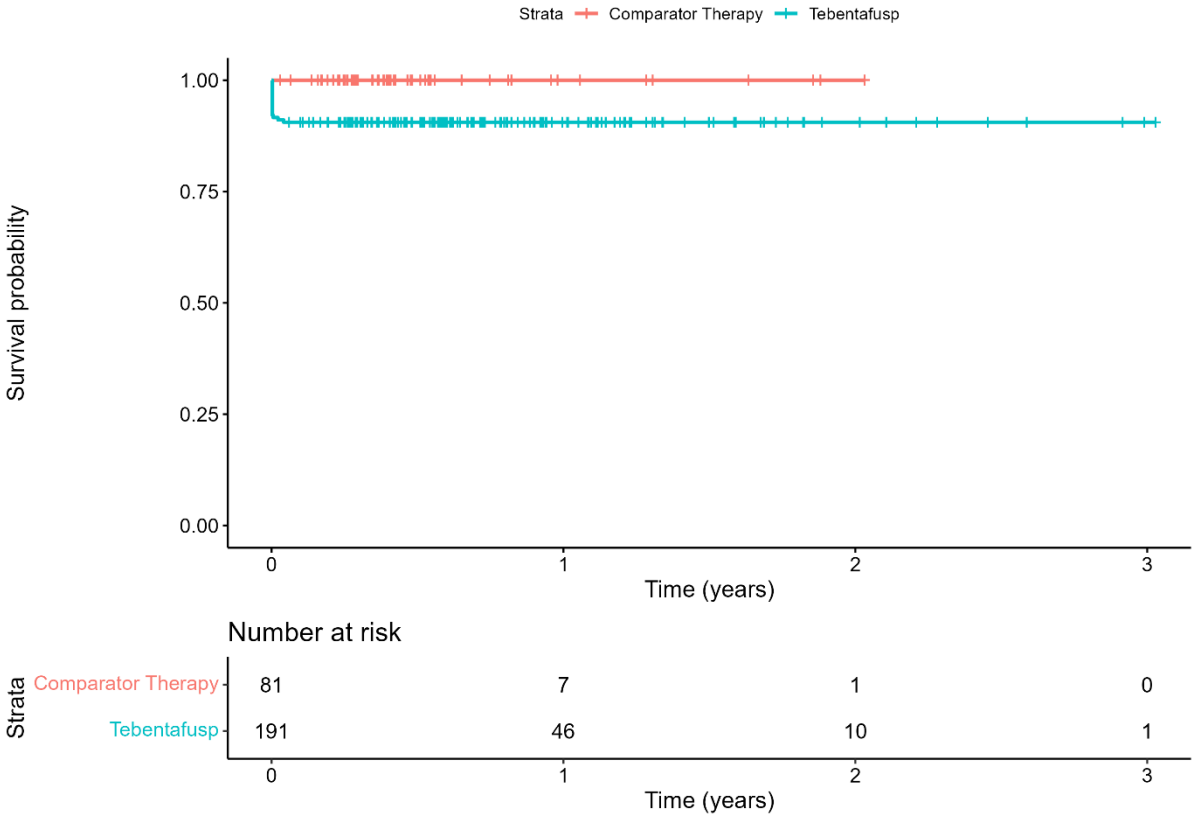
Alter: <65 Jahre



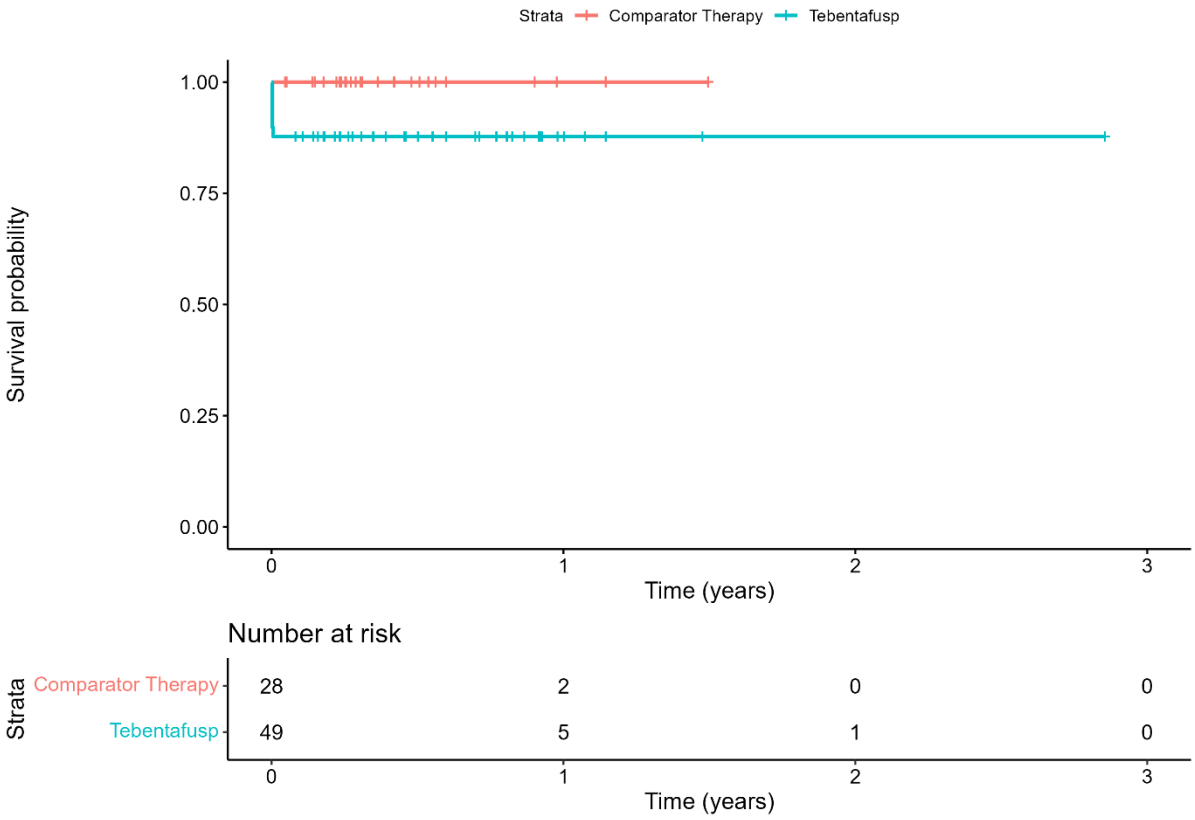
Alter: ≥65 Jahre



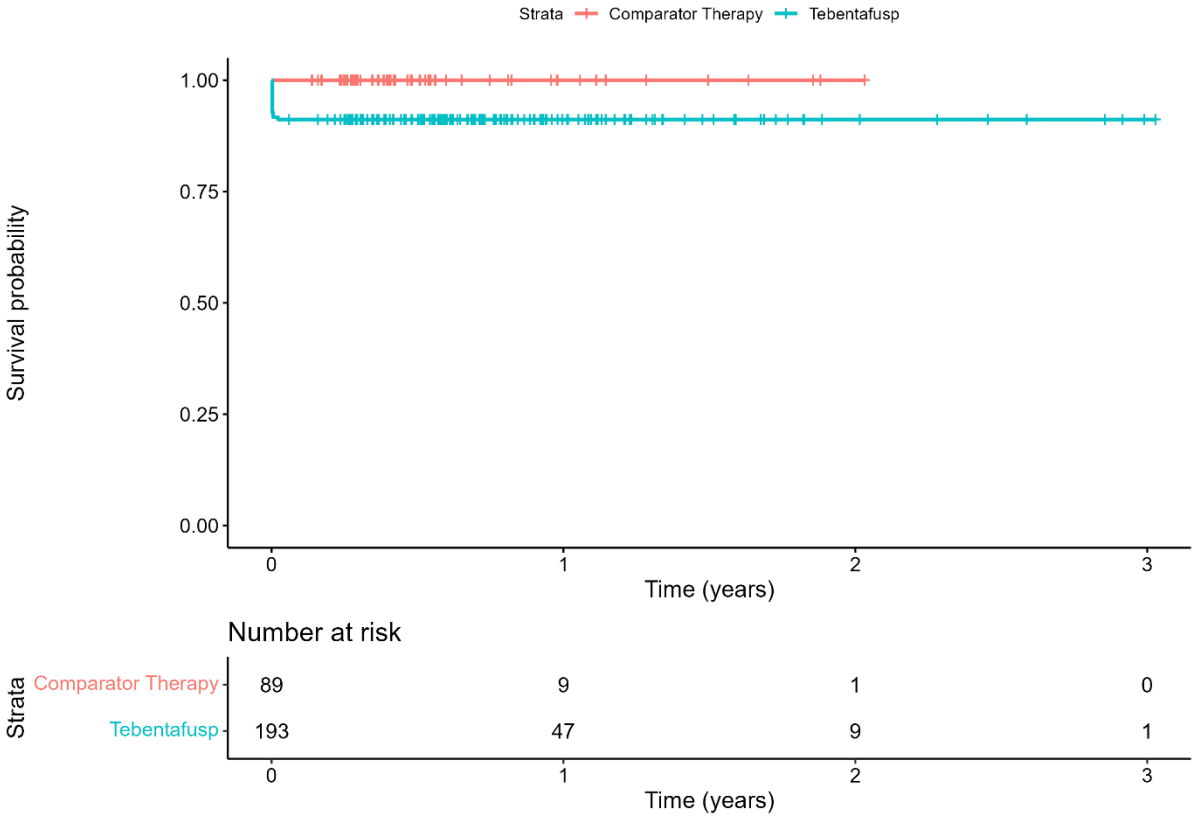
ECOG-Performance-Status: 0



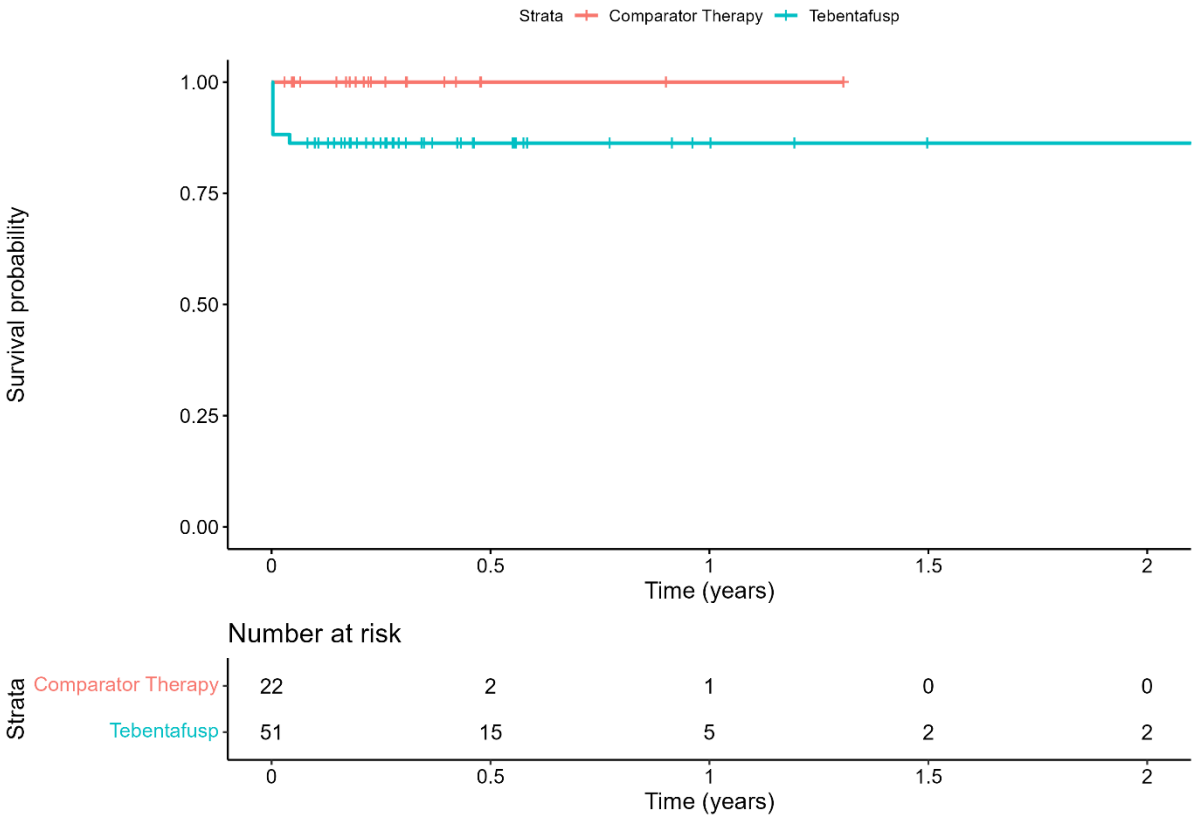
ECOG-Performance-Status: 1



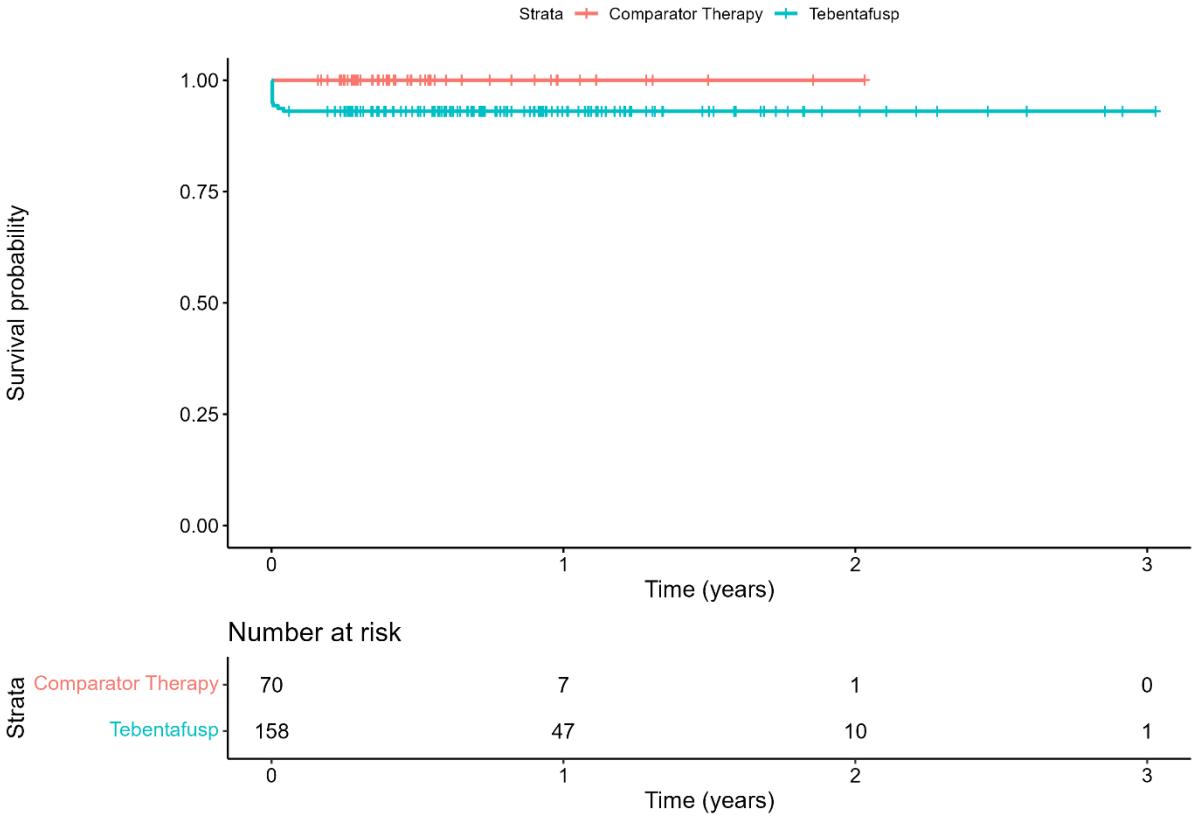
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



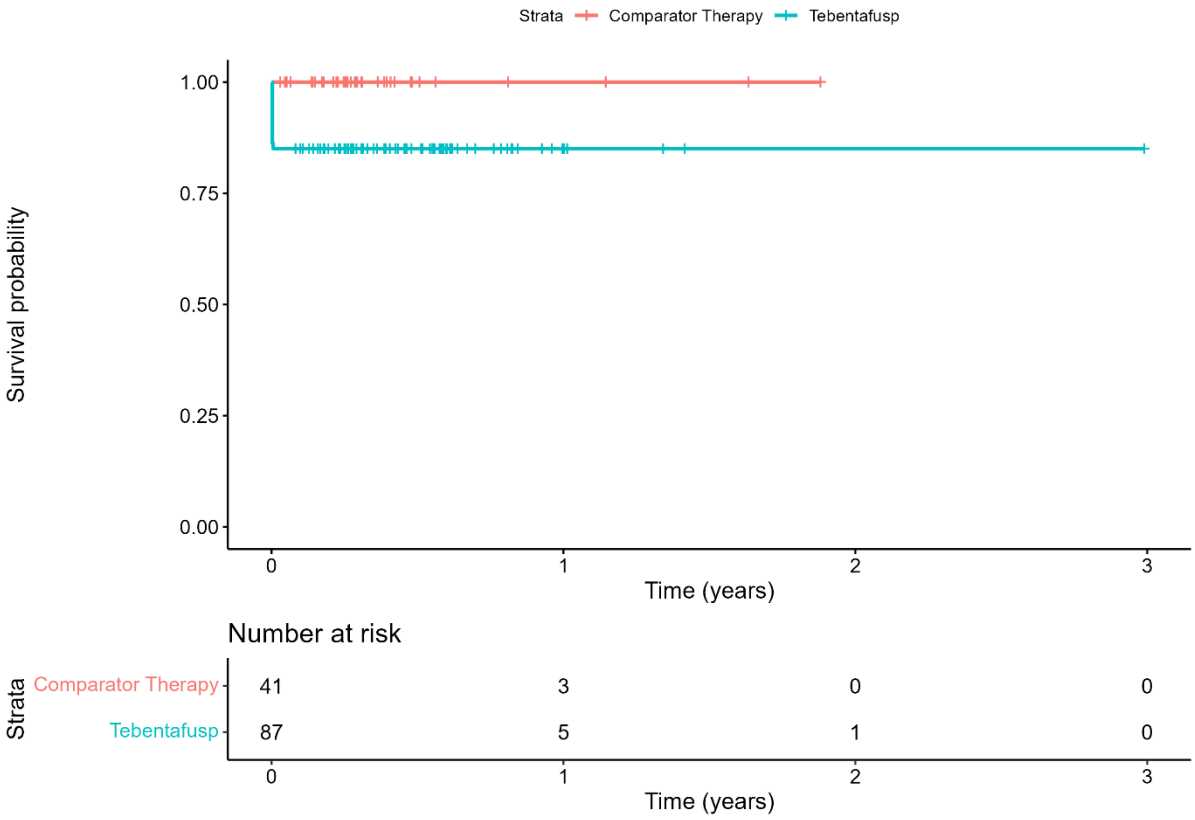
Alkalische Phosphatase (ALP) (Baseline): >ULN



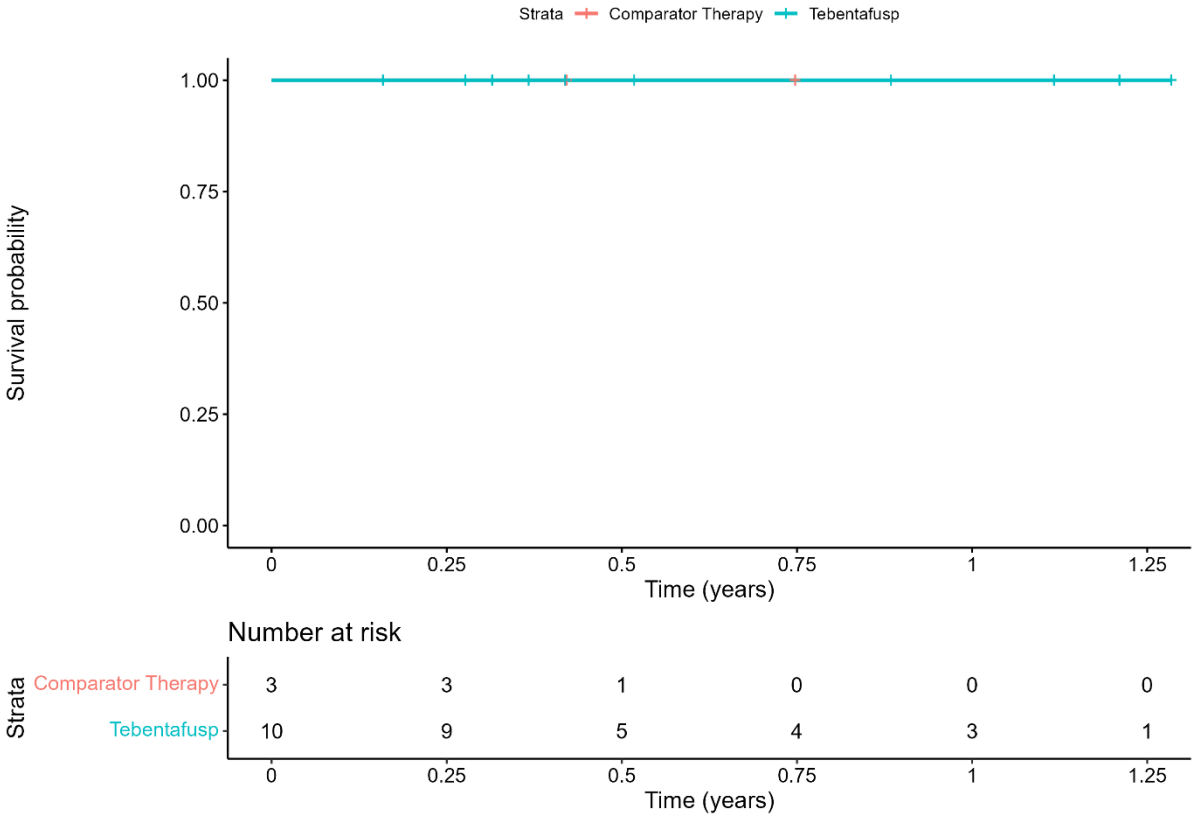
LDH: ≤ULN



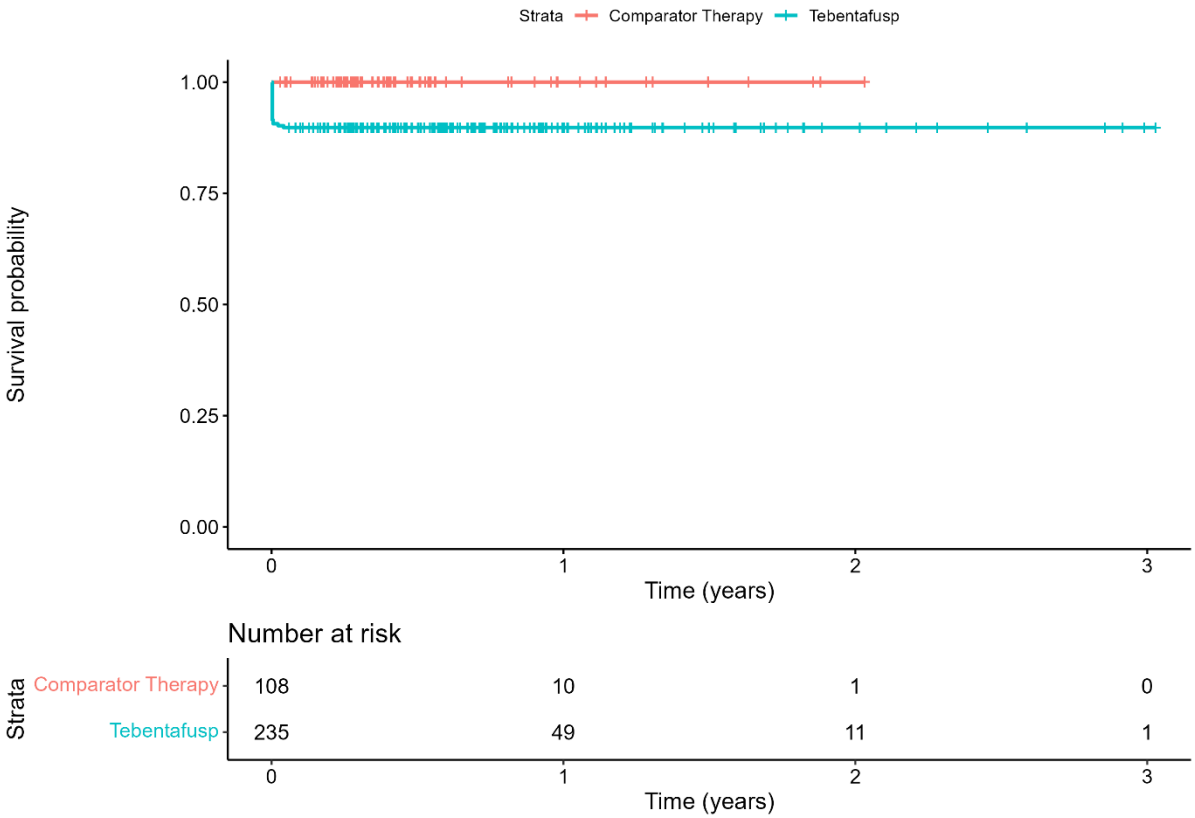
LDH: >ULN



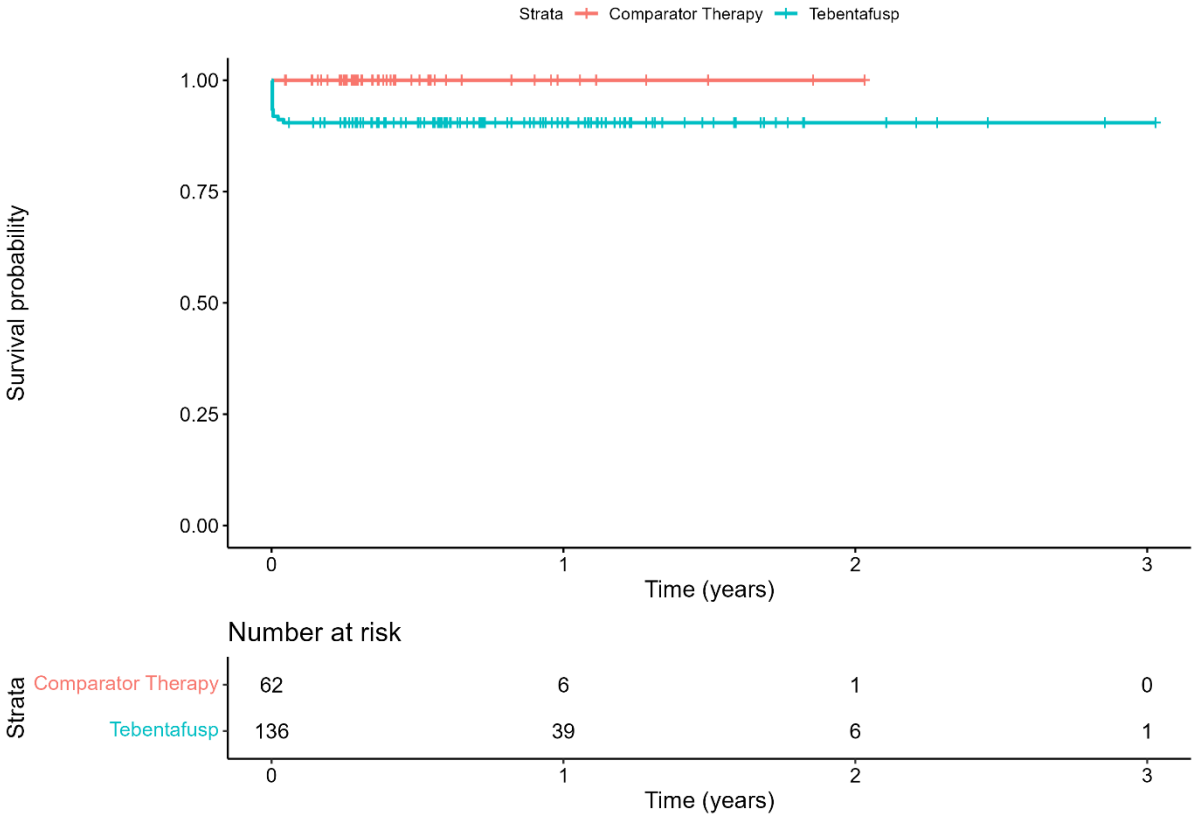
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



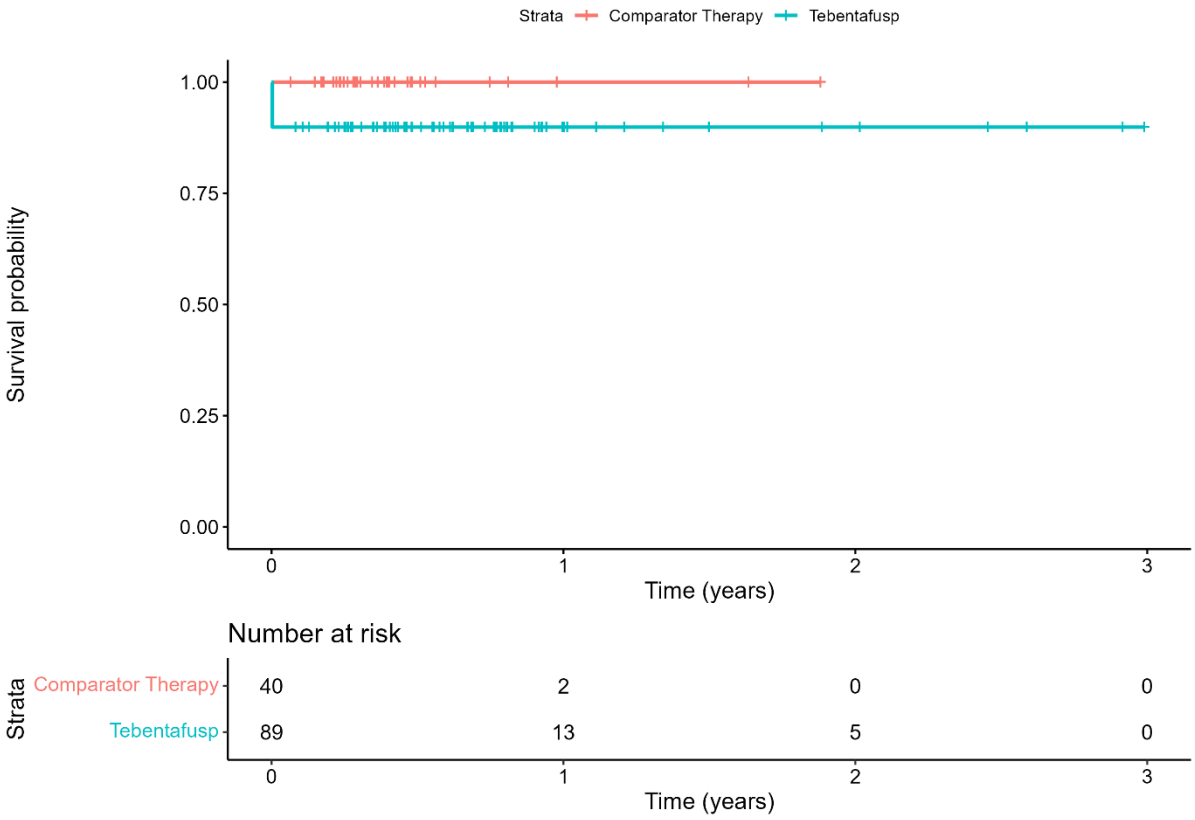
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



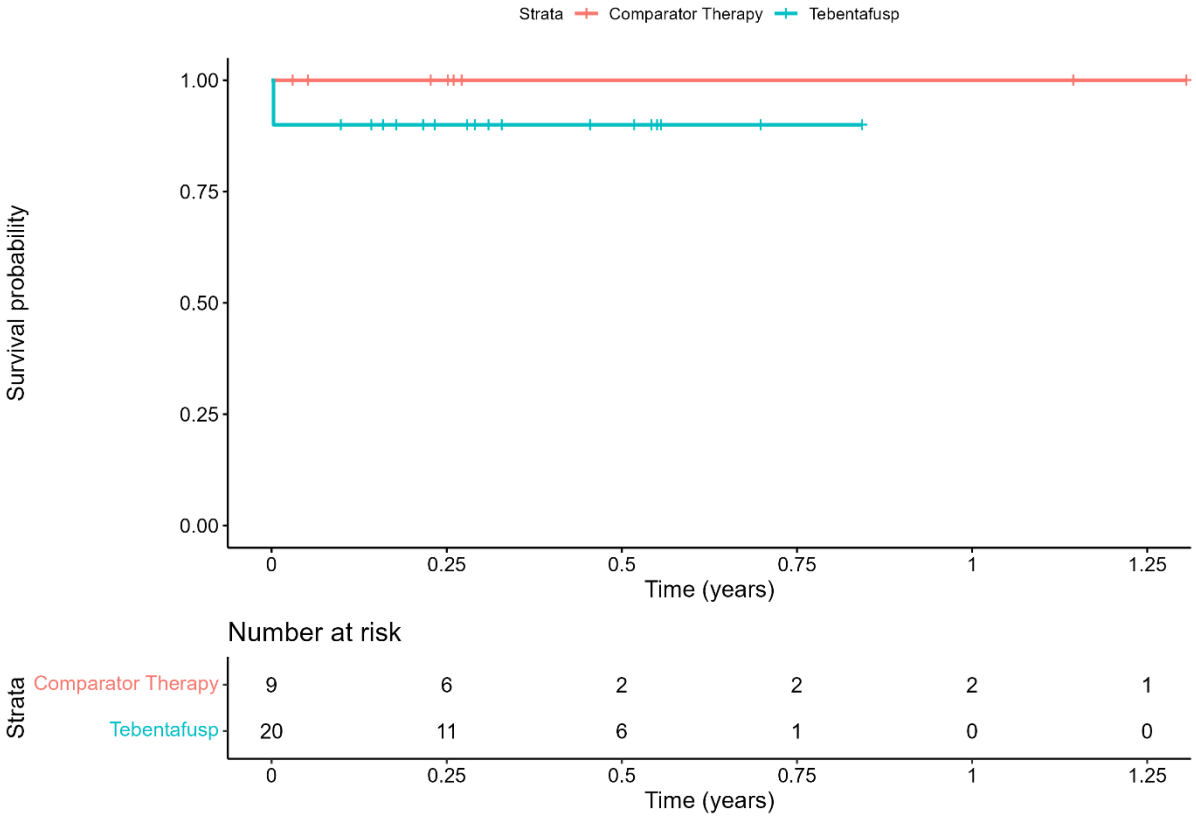
Größte metastatische Läsion (Baseline): ≤3,0 cm



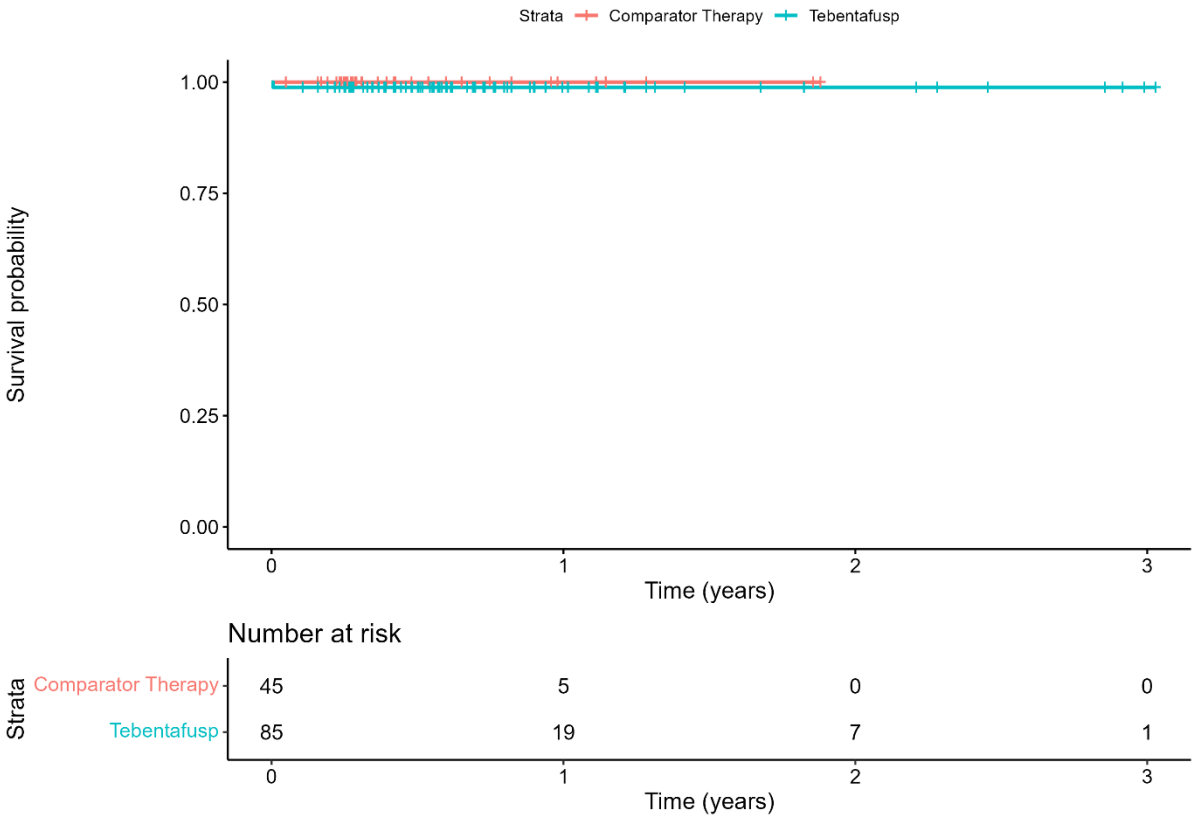
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



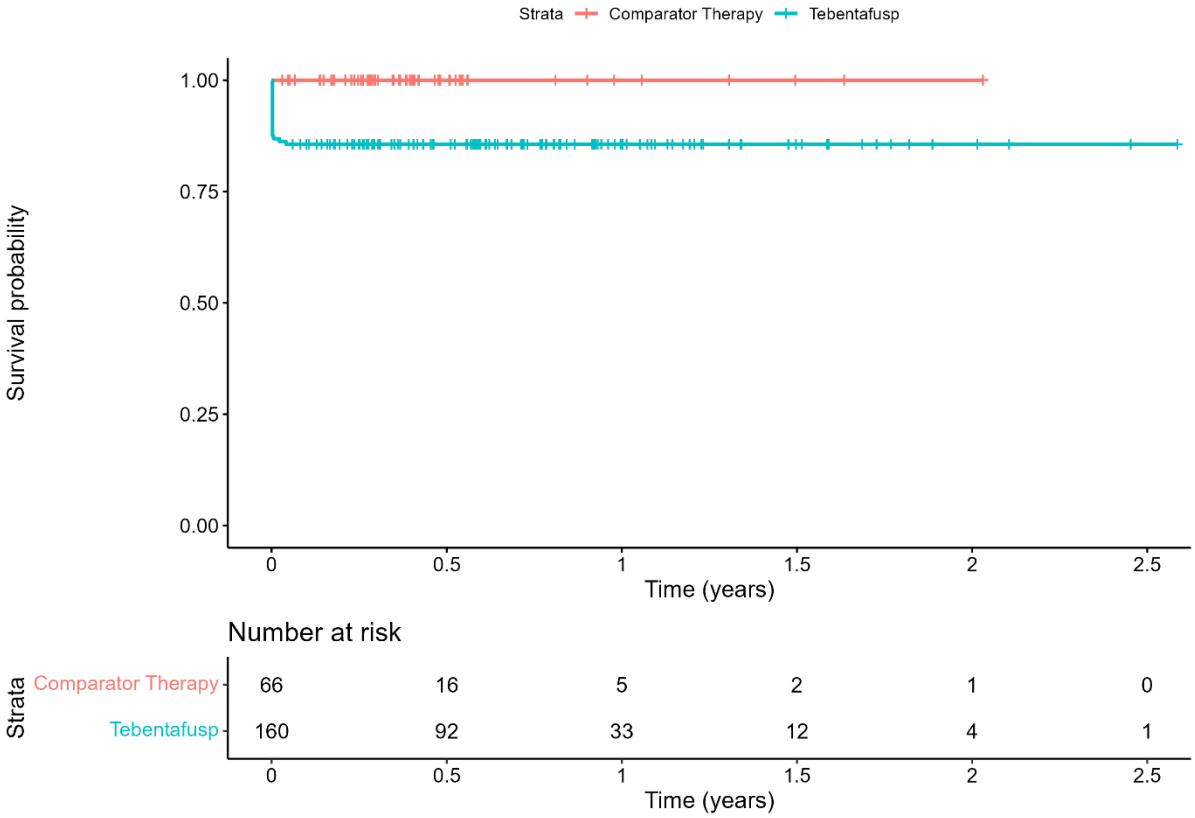
Größte metastatische Läsion (Baseline): ≥8,1 cm



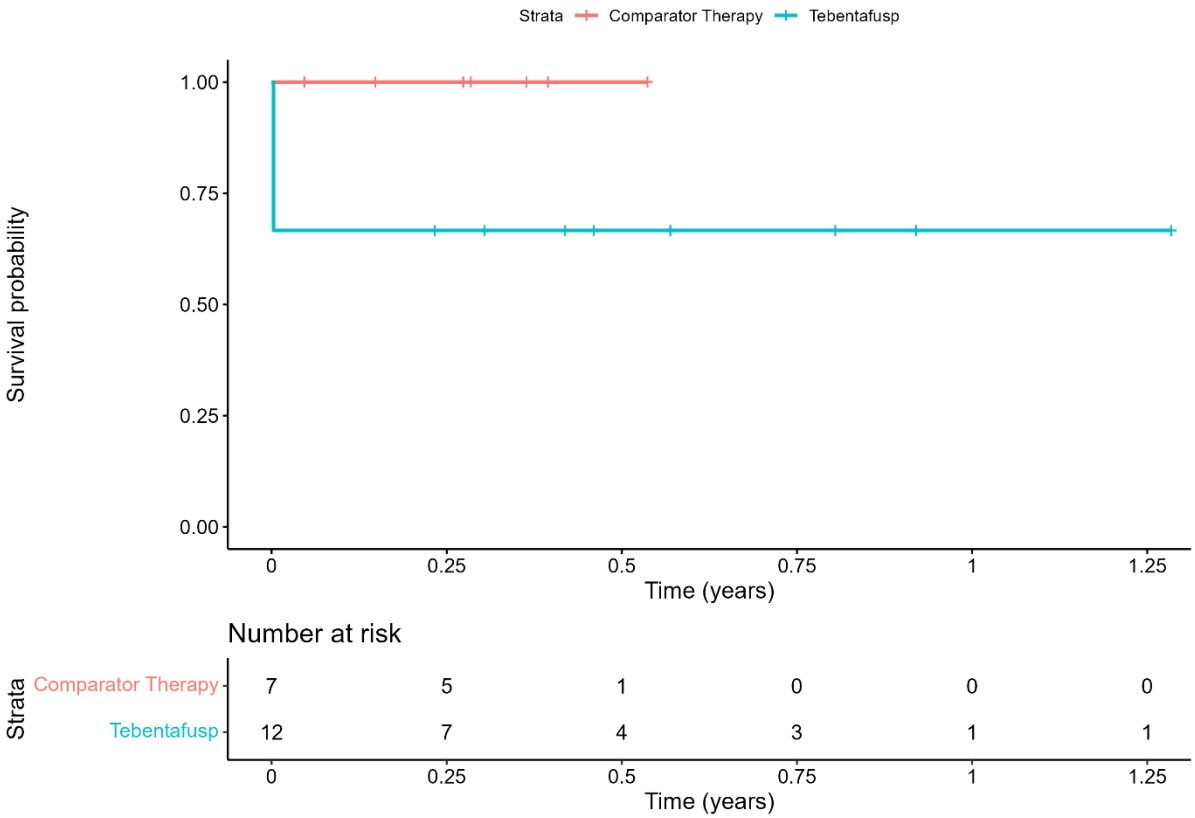
Region: Nordamerika



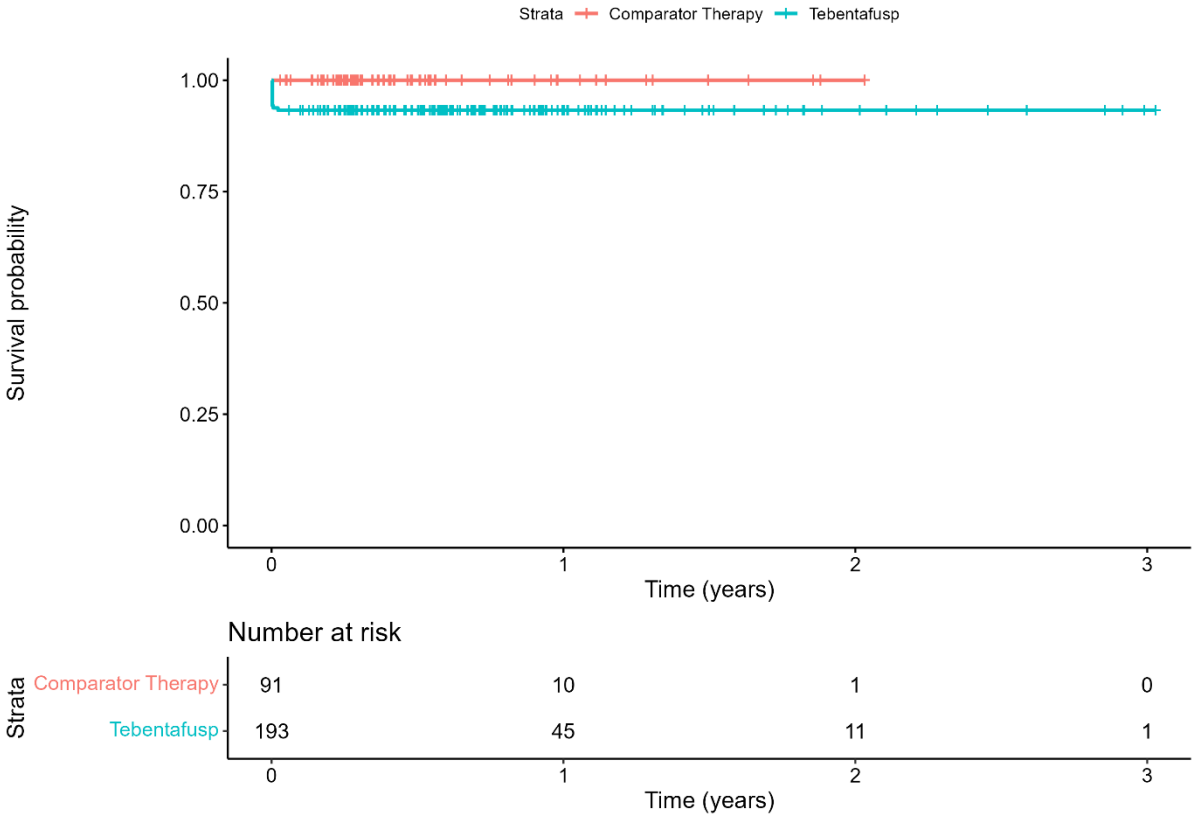
Region: Nicht-Nordamerika



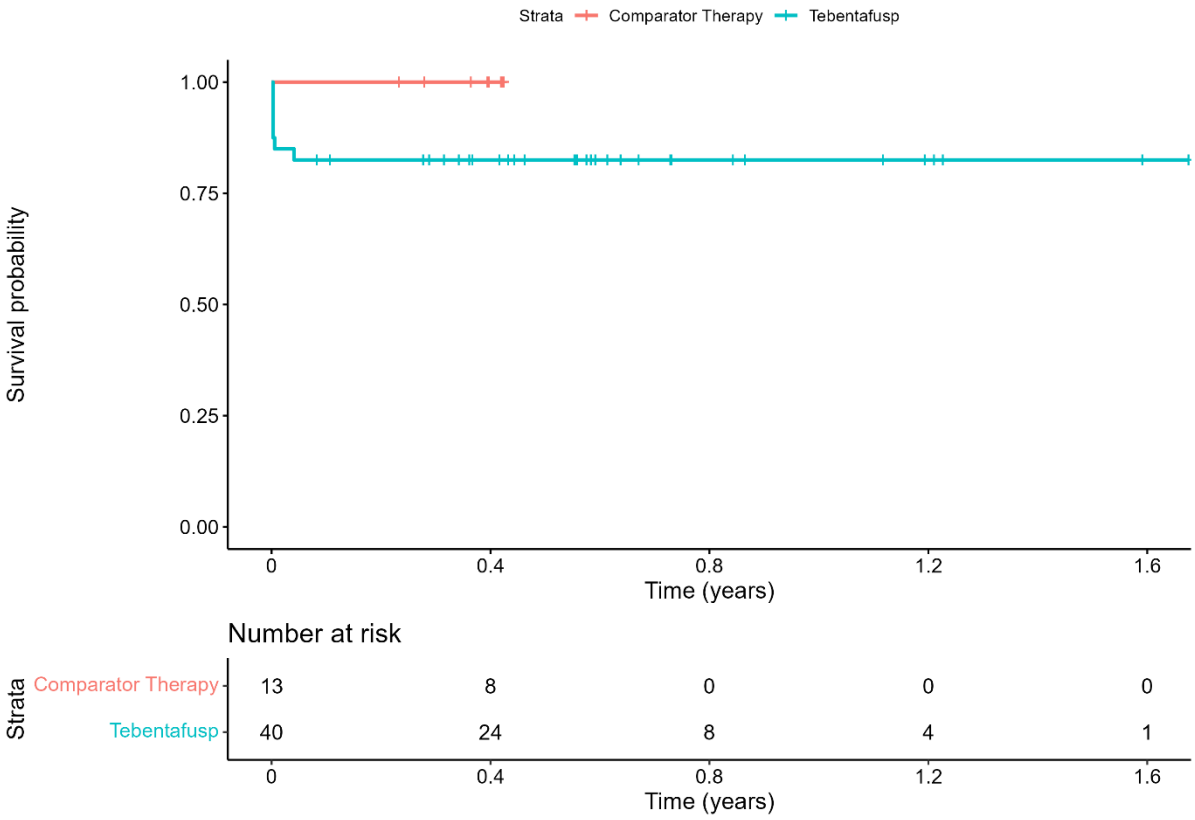
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

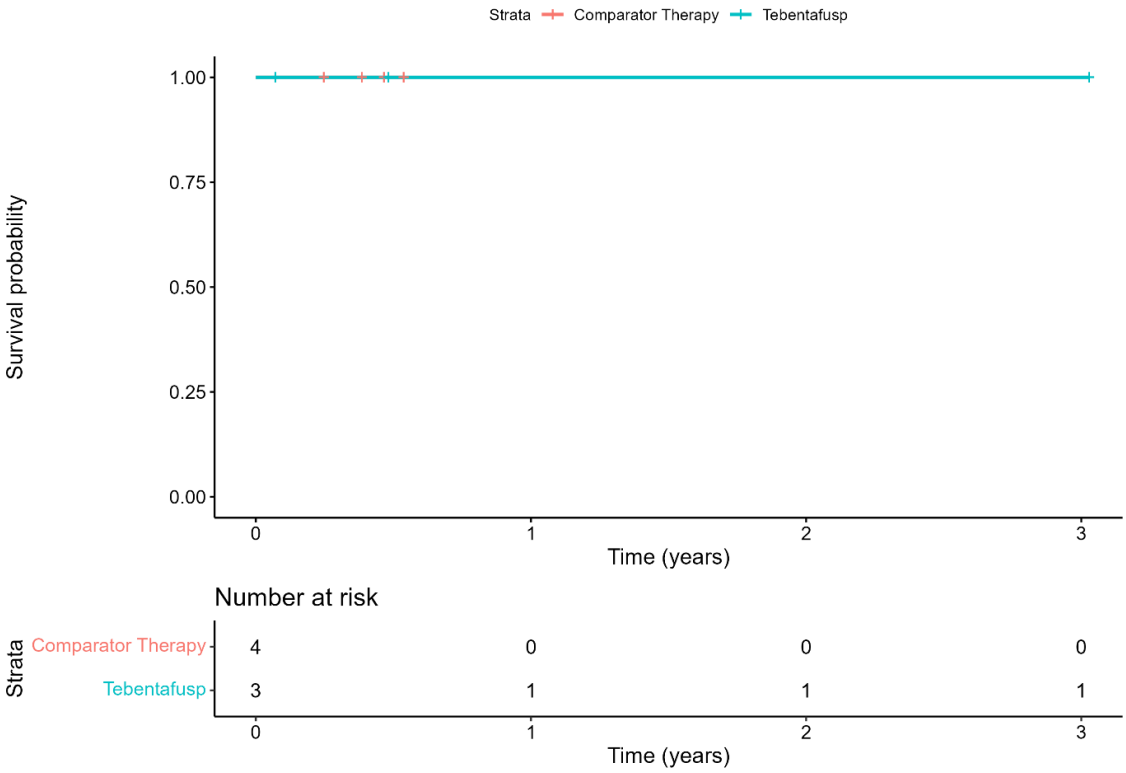


Vorauswahl der Chemotherapie: Ipilimumab

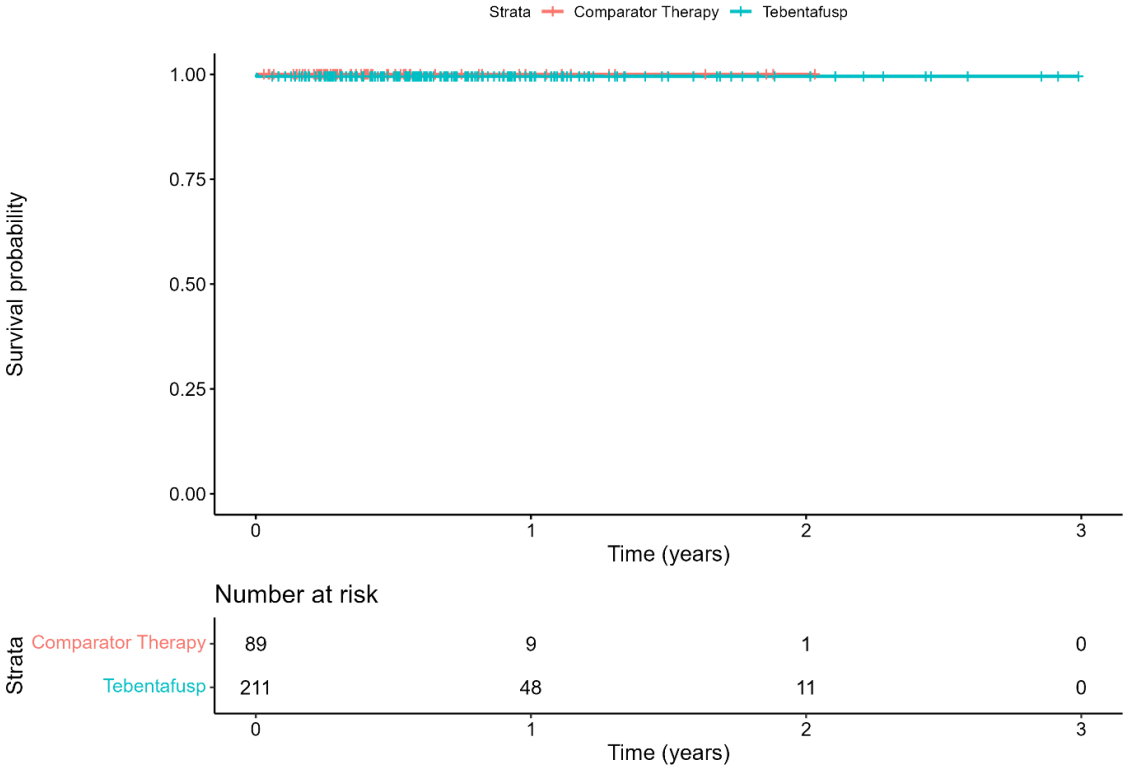


45.1 Zytokin-Freisetzungssyndrom, das zum Absetzen des Studienmedikaments führte (Tabelle 4-101)

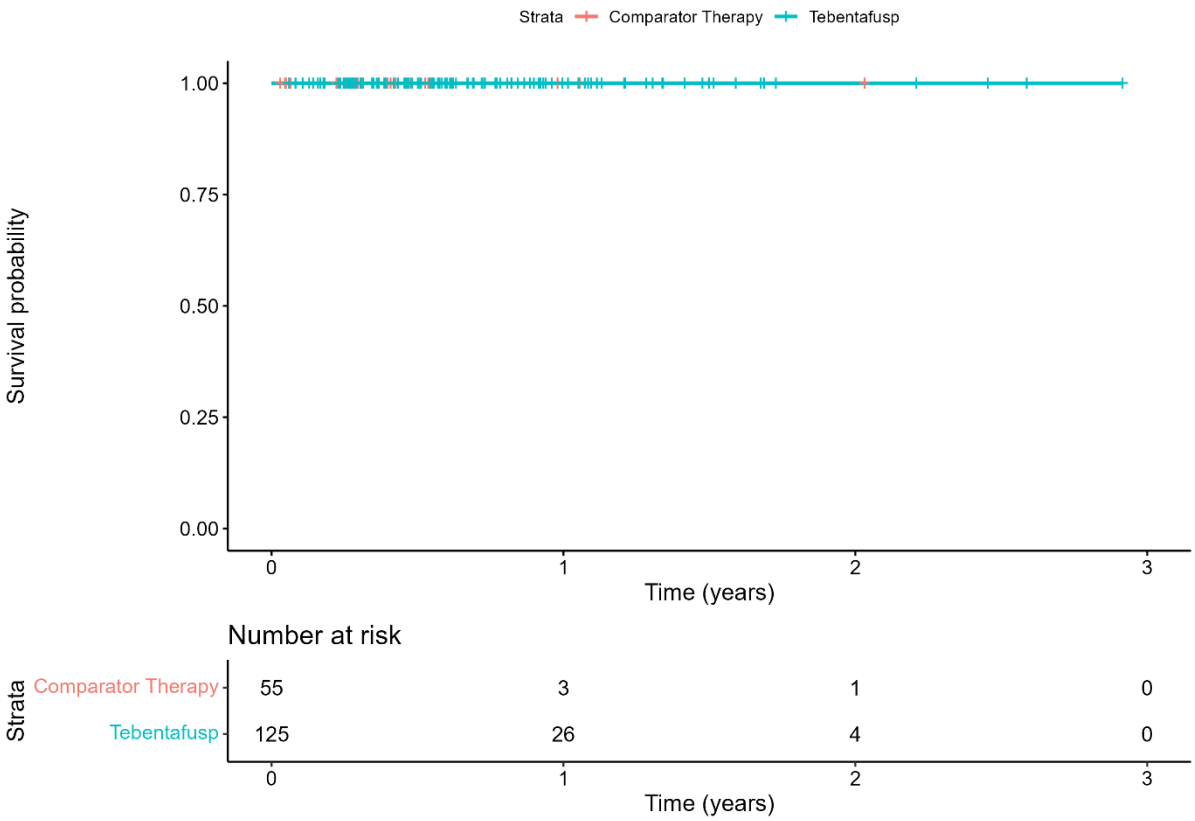
Herkunft: Hispanisch



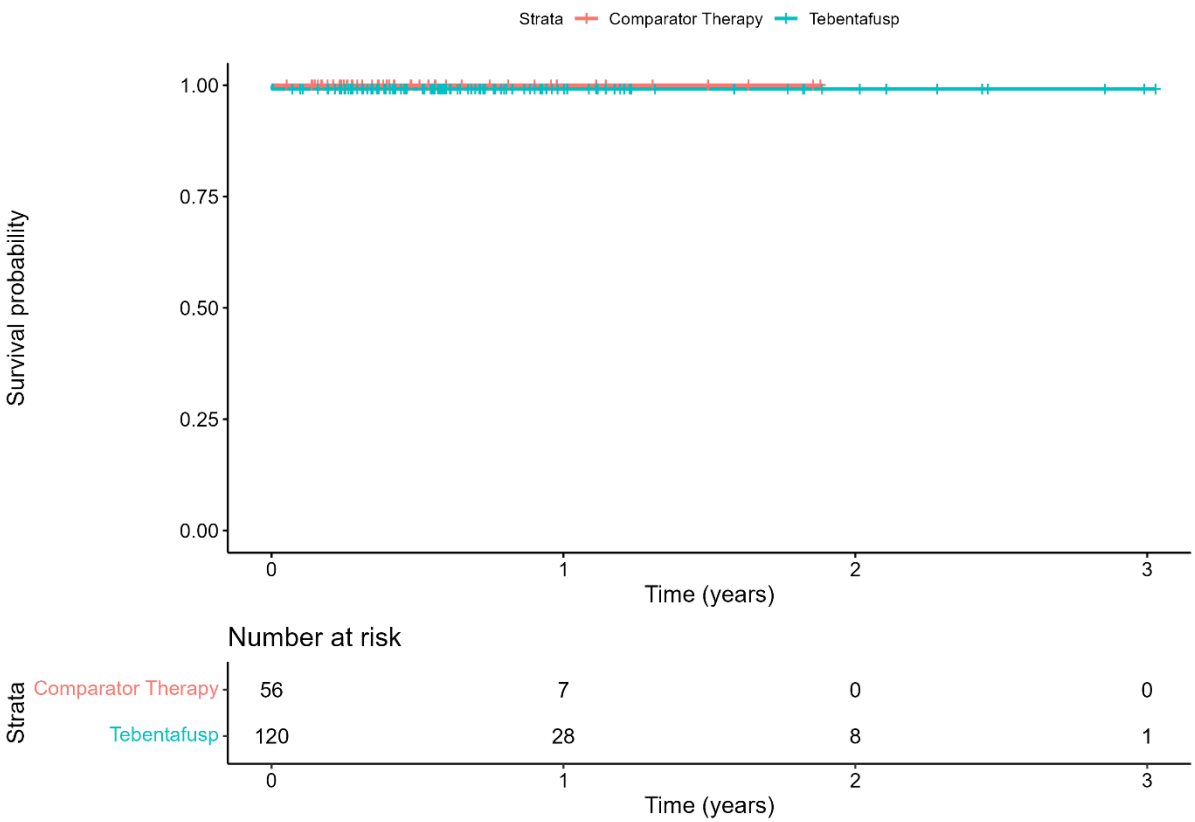
Herkunft: Nicht-hispanisch



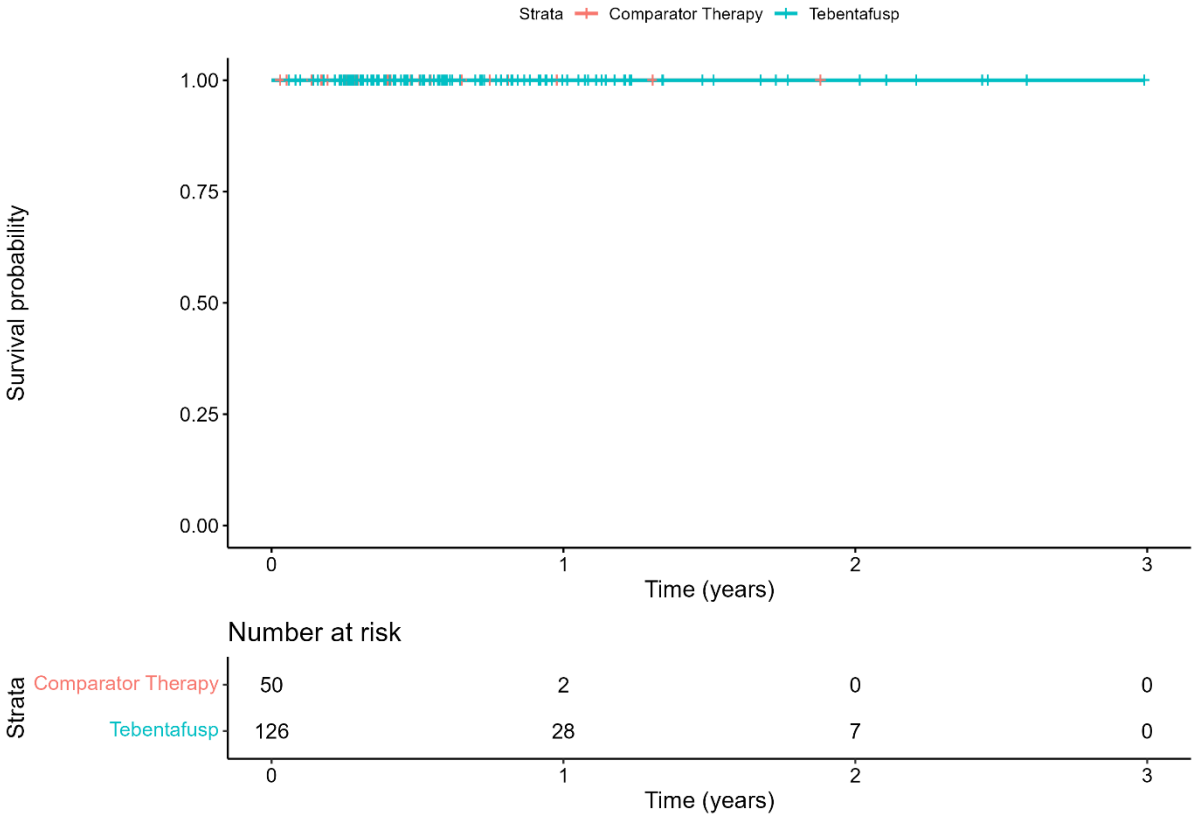
Geschlecht: Männlich



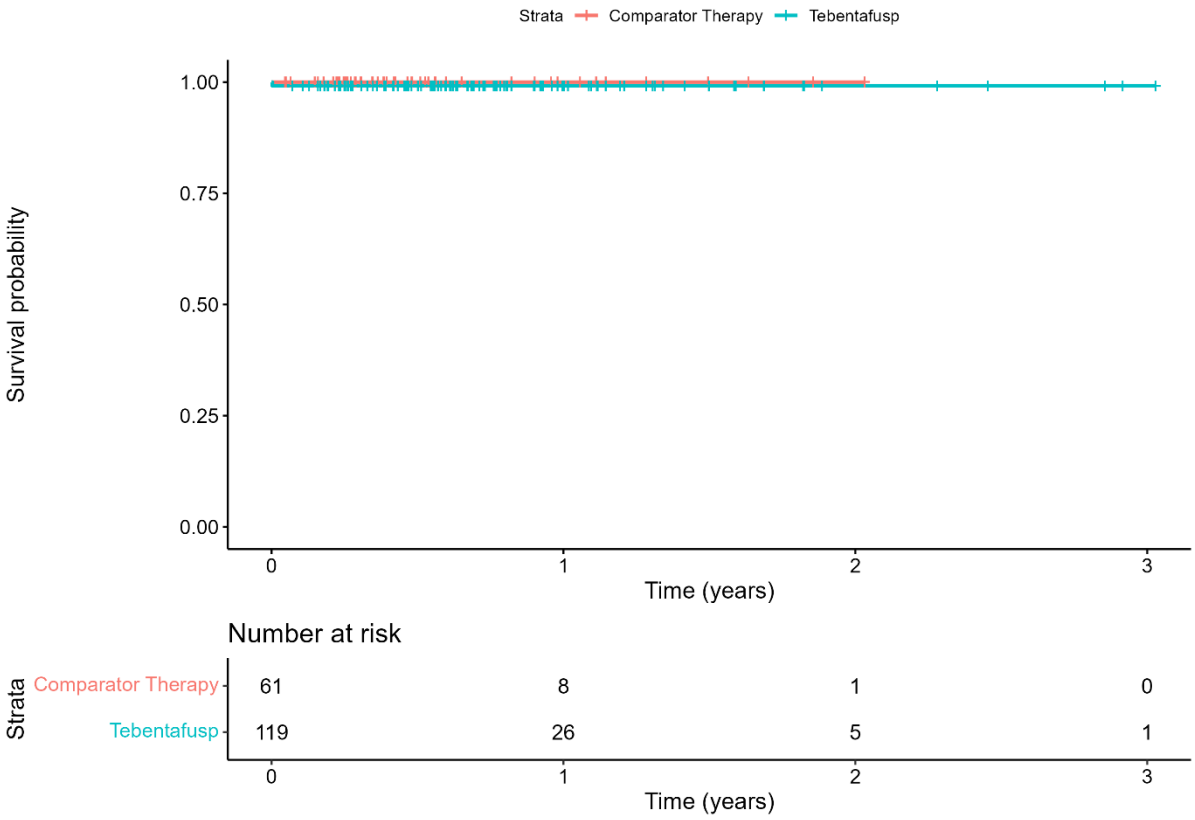
Geschlecht: Weiblich



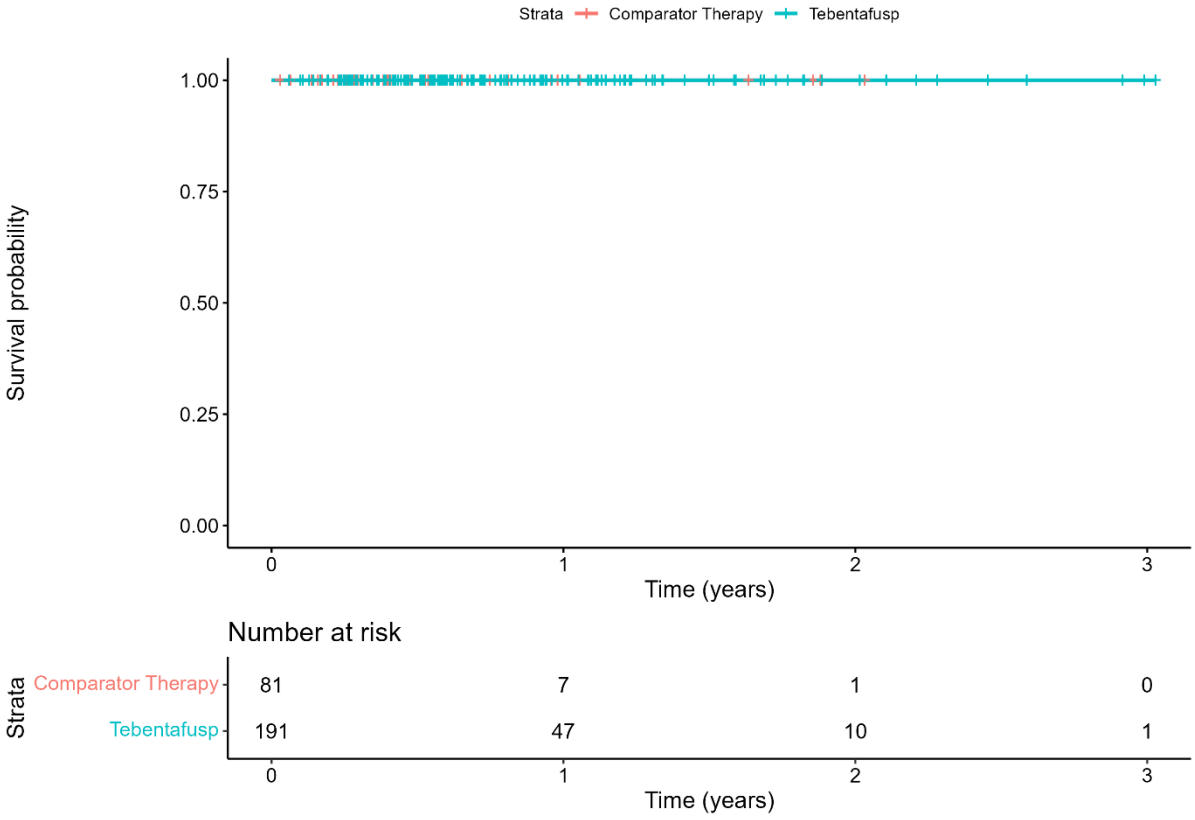
Alter: <65 Jahre



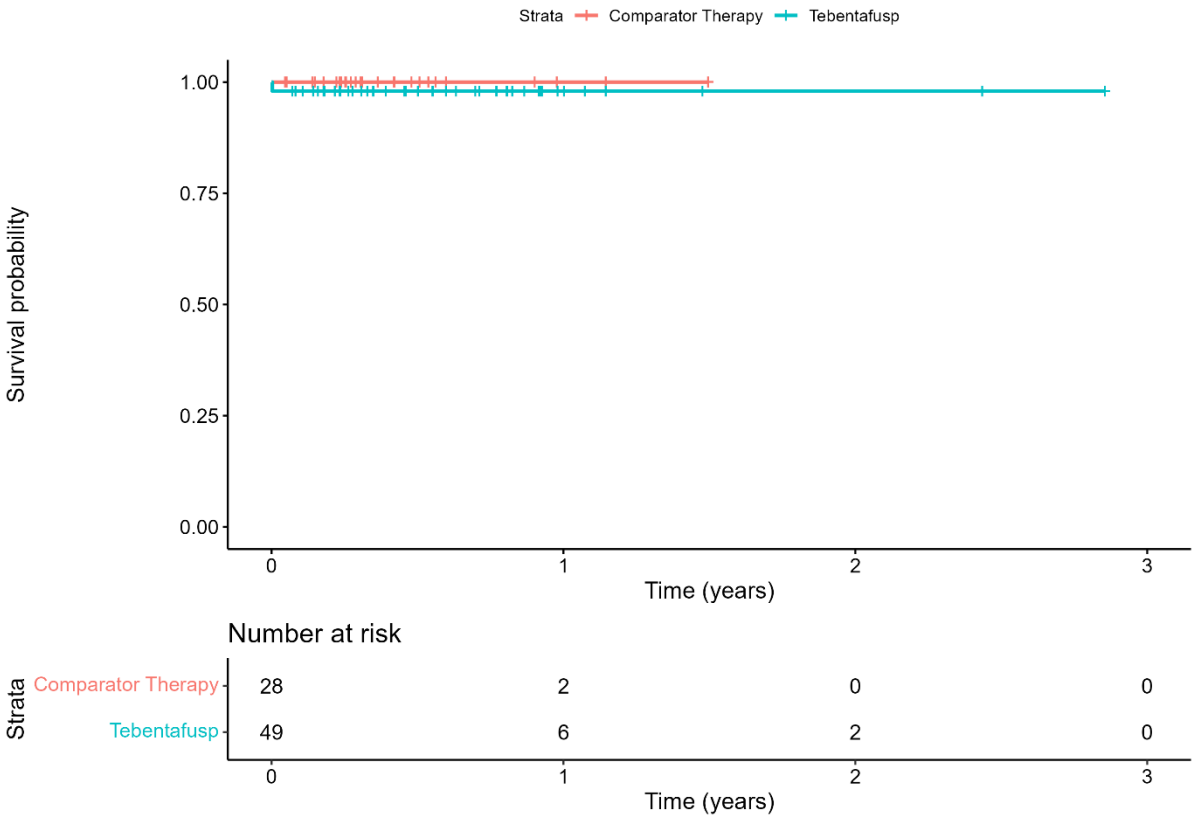
Alter: ≥65 Jahre



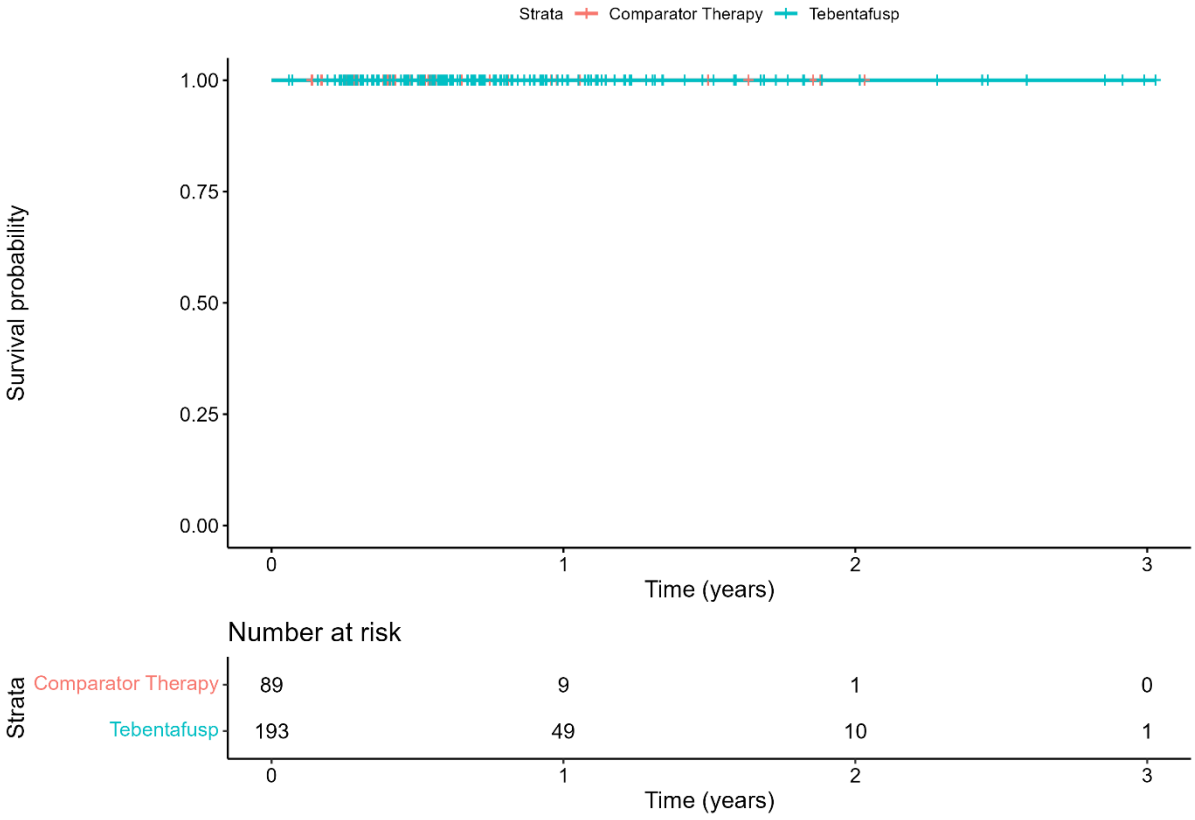
ECOG-Performance-Status: 0



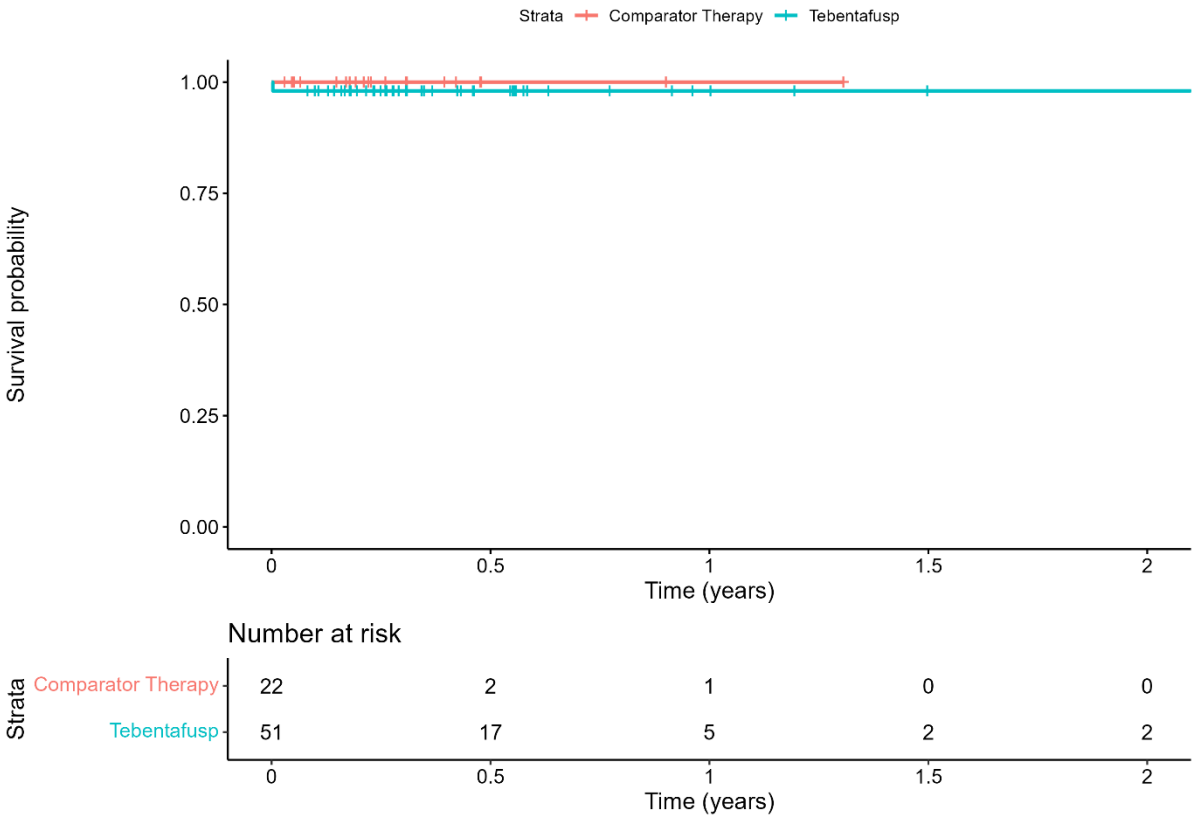
ECOG-Performance-Status: 1



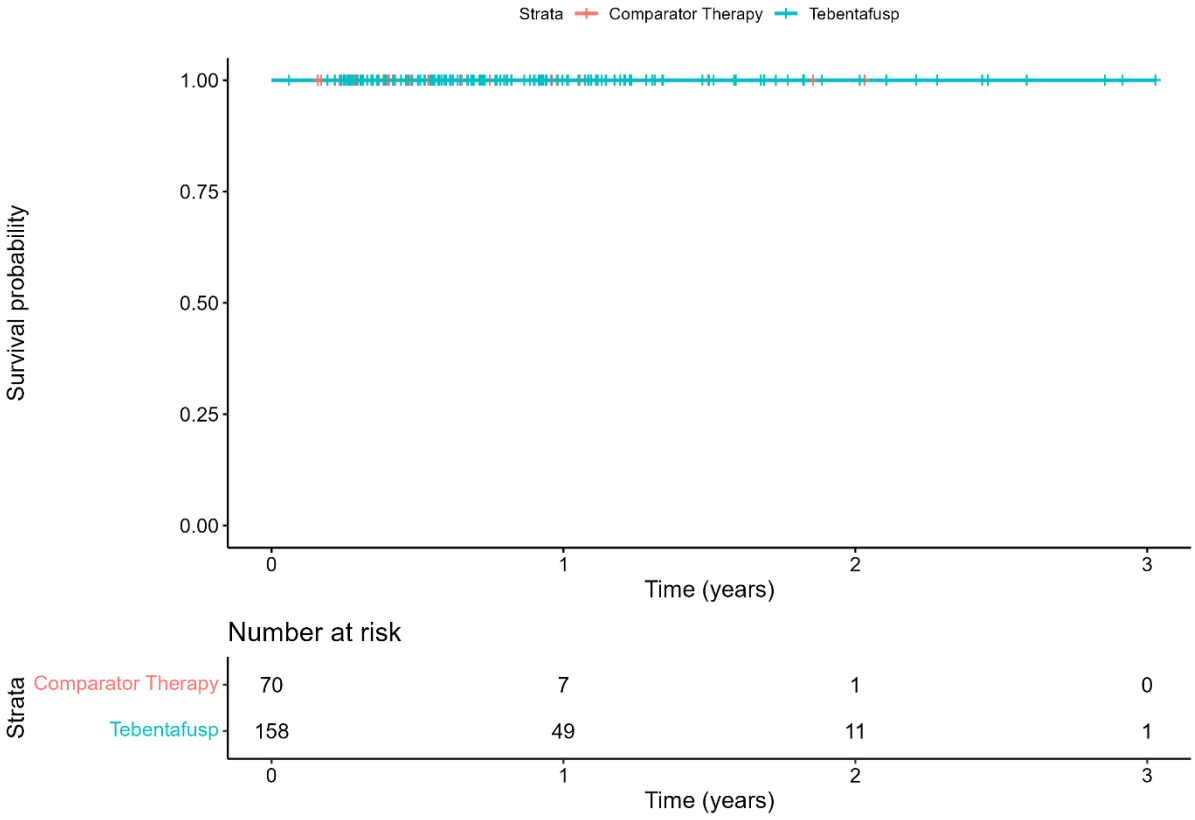
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



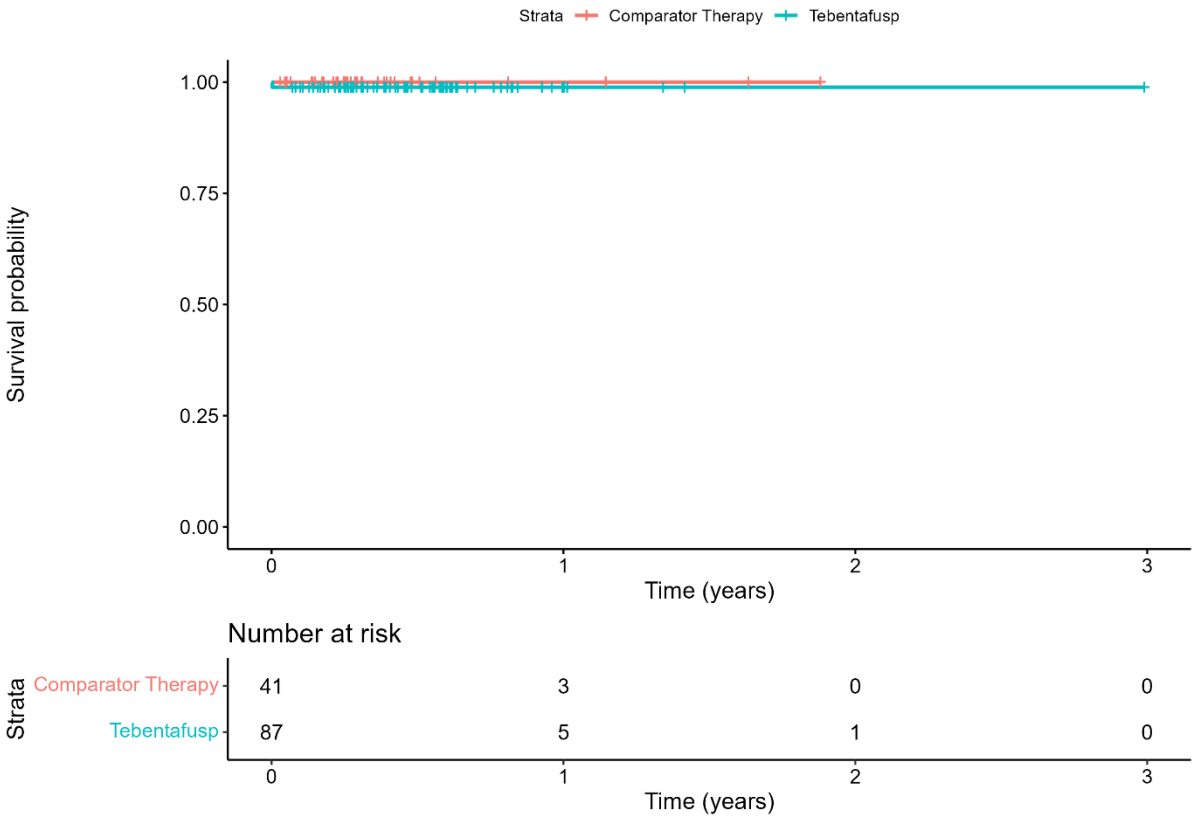
Alkalische Phosphatase (ALP) (Baseline): >ULN



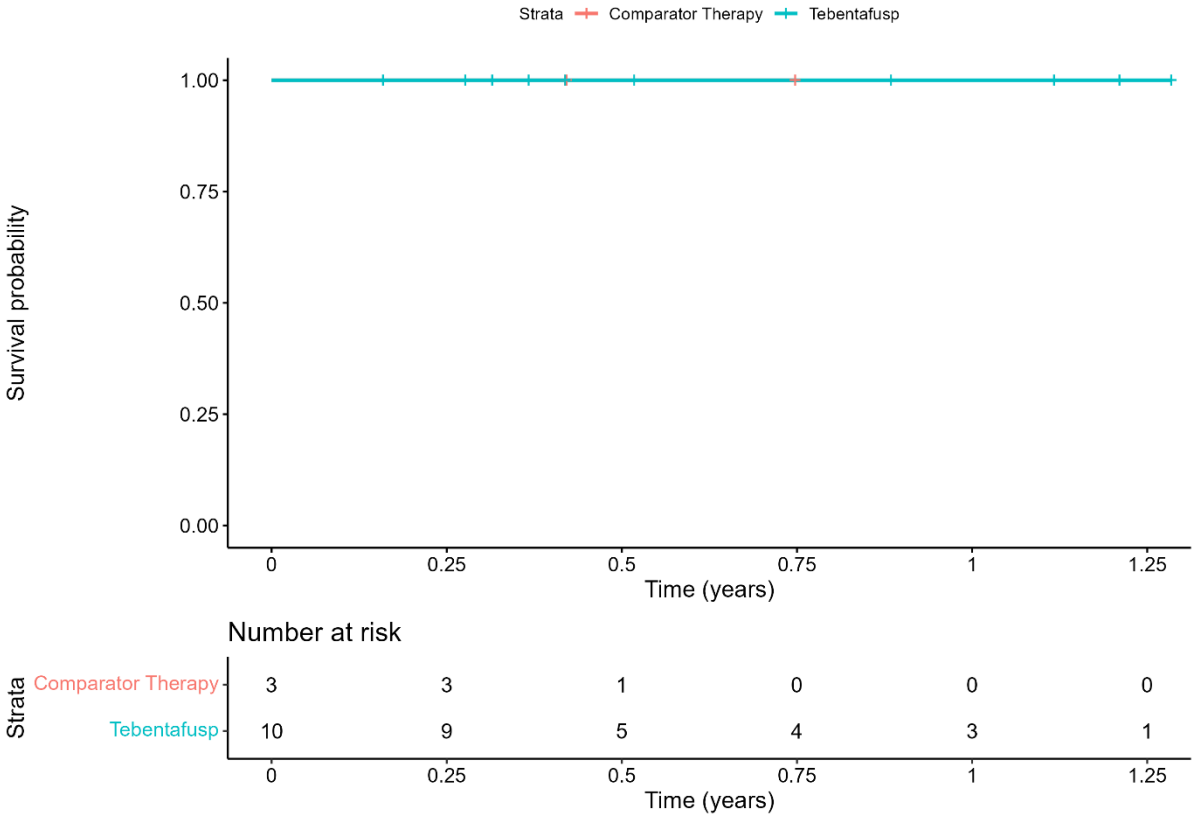
LDH: ≤ULN



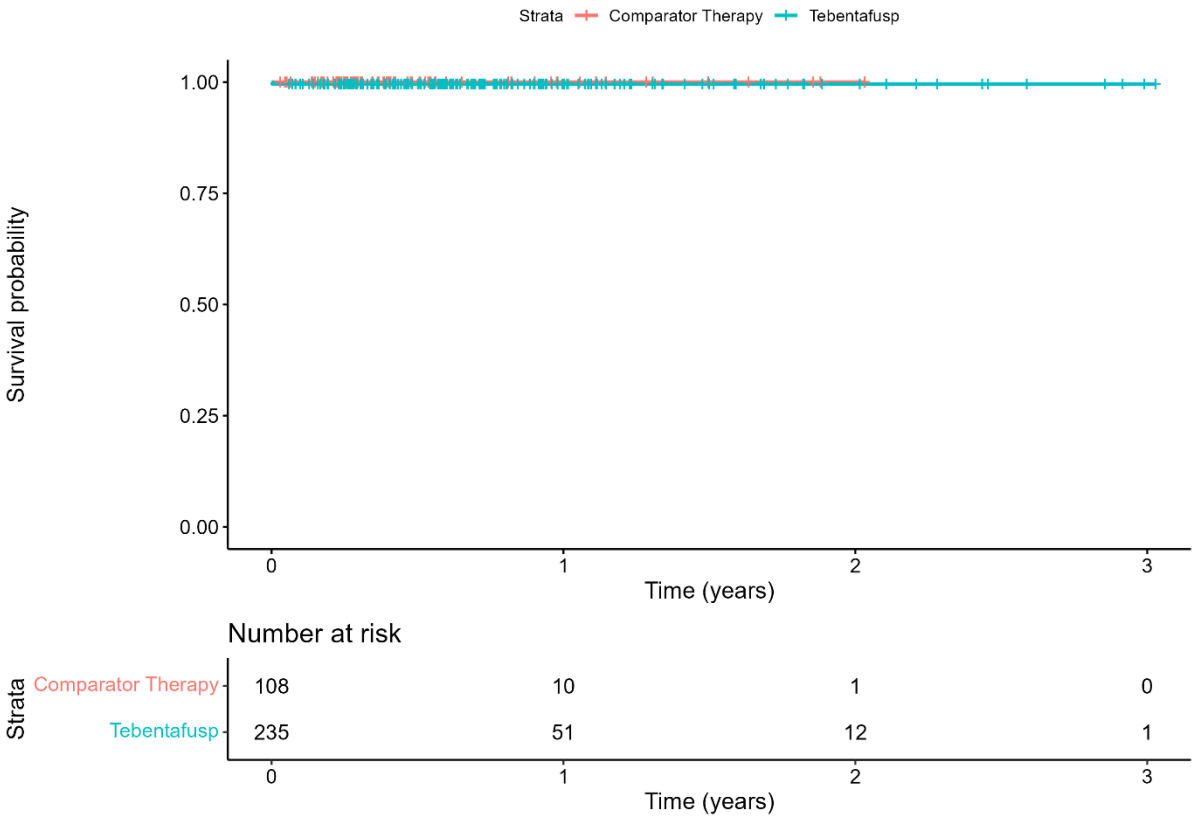
LDH: >ULN



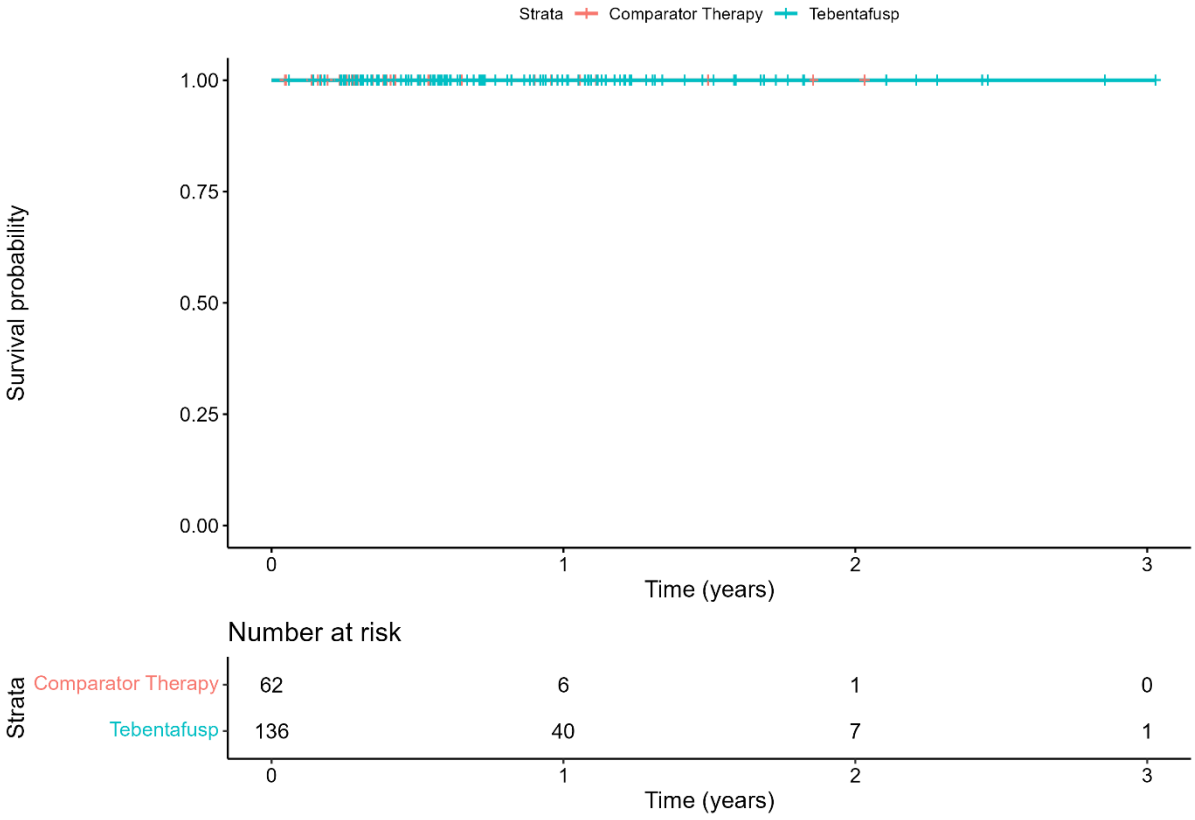
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



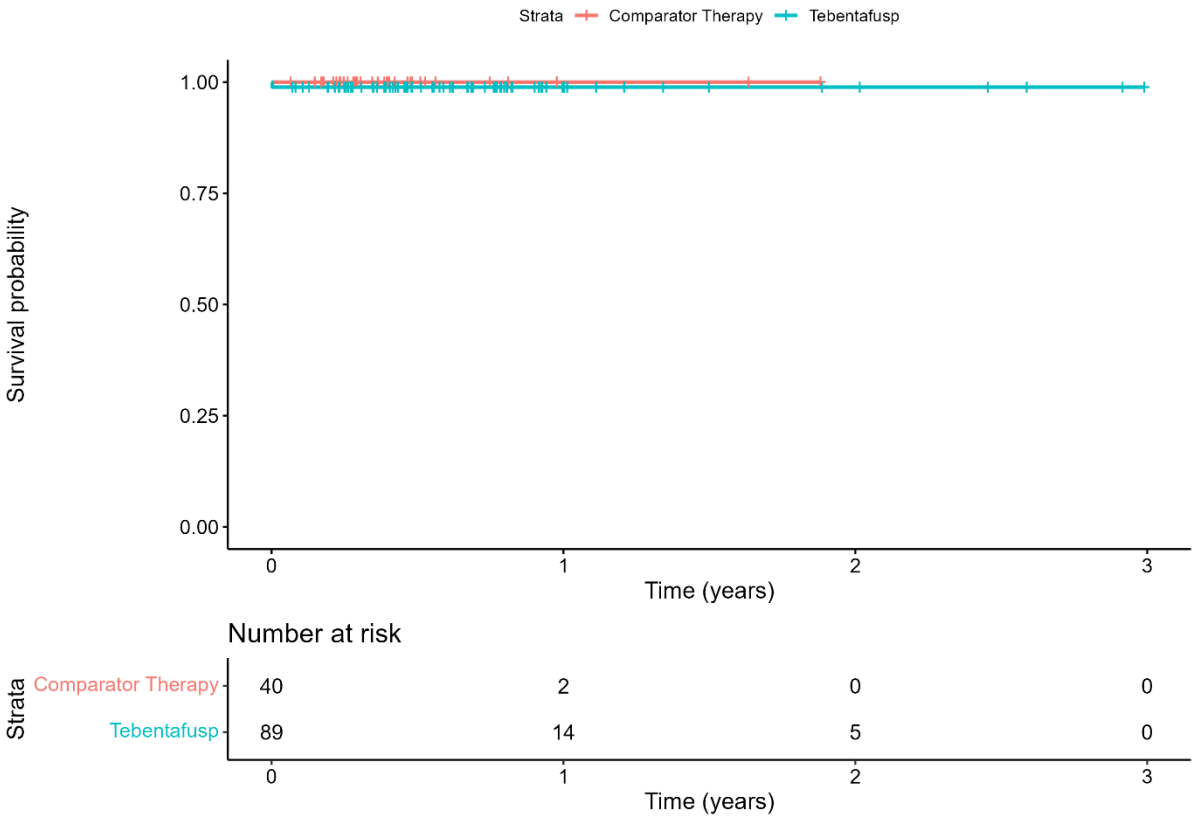
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



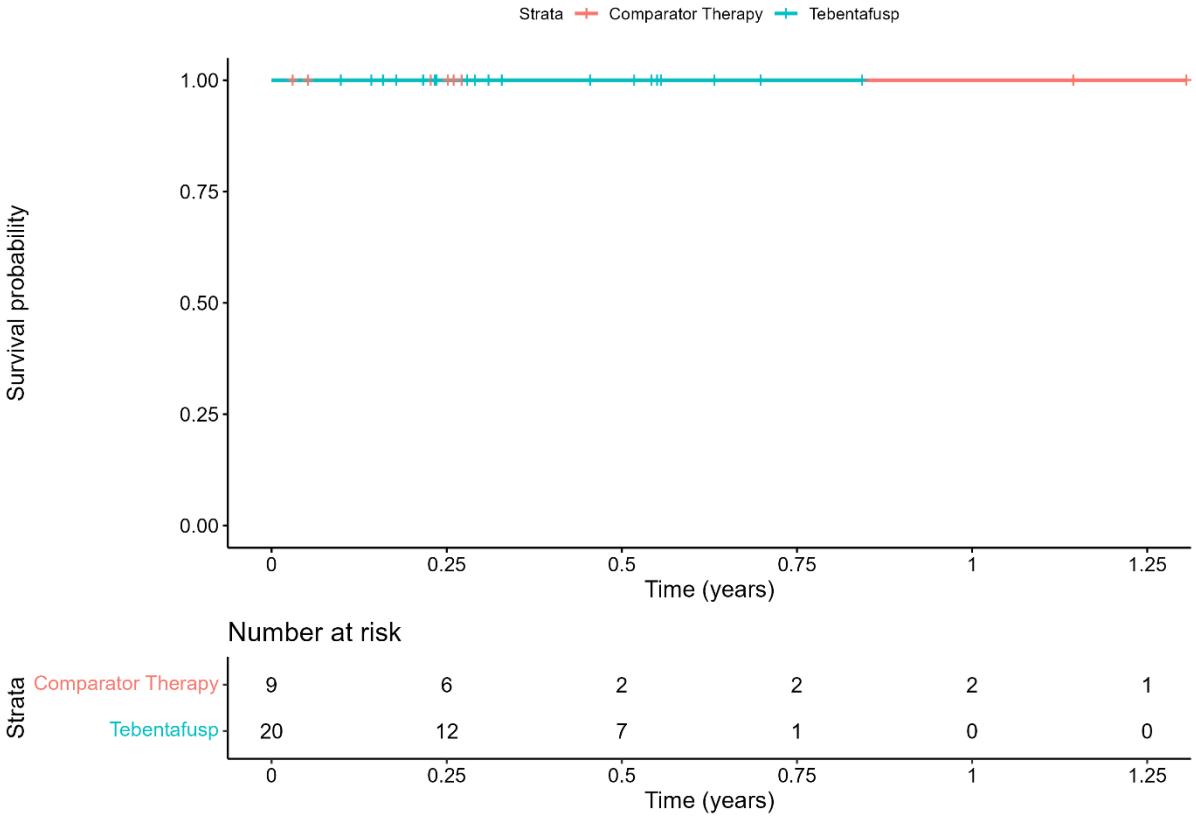
Größte metastatische Läsion (Baseline): ≤3,0 cm



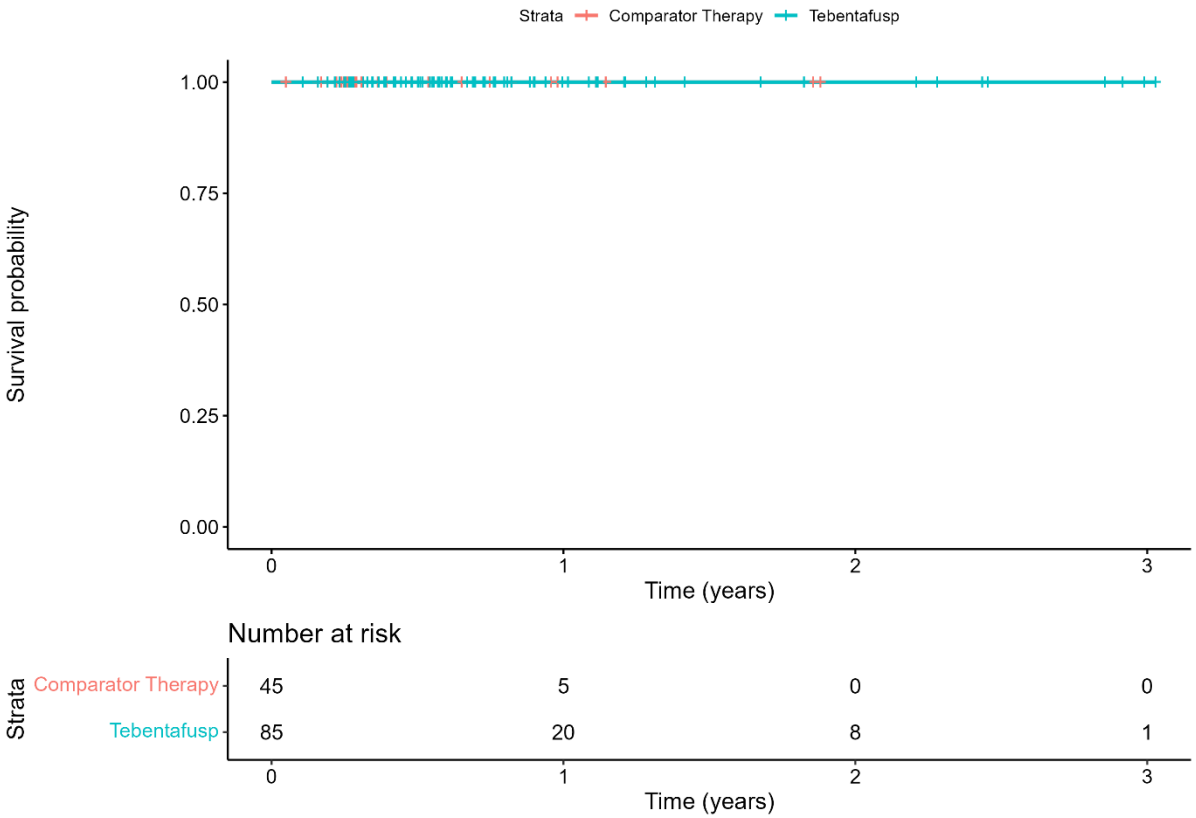
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



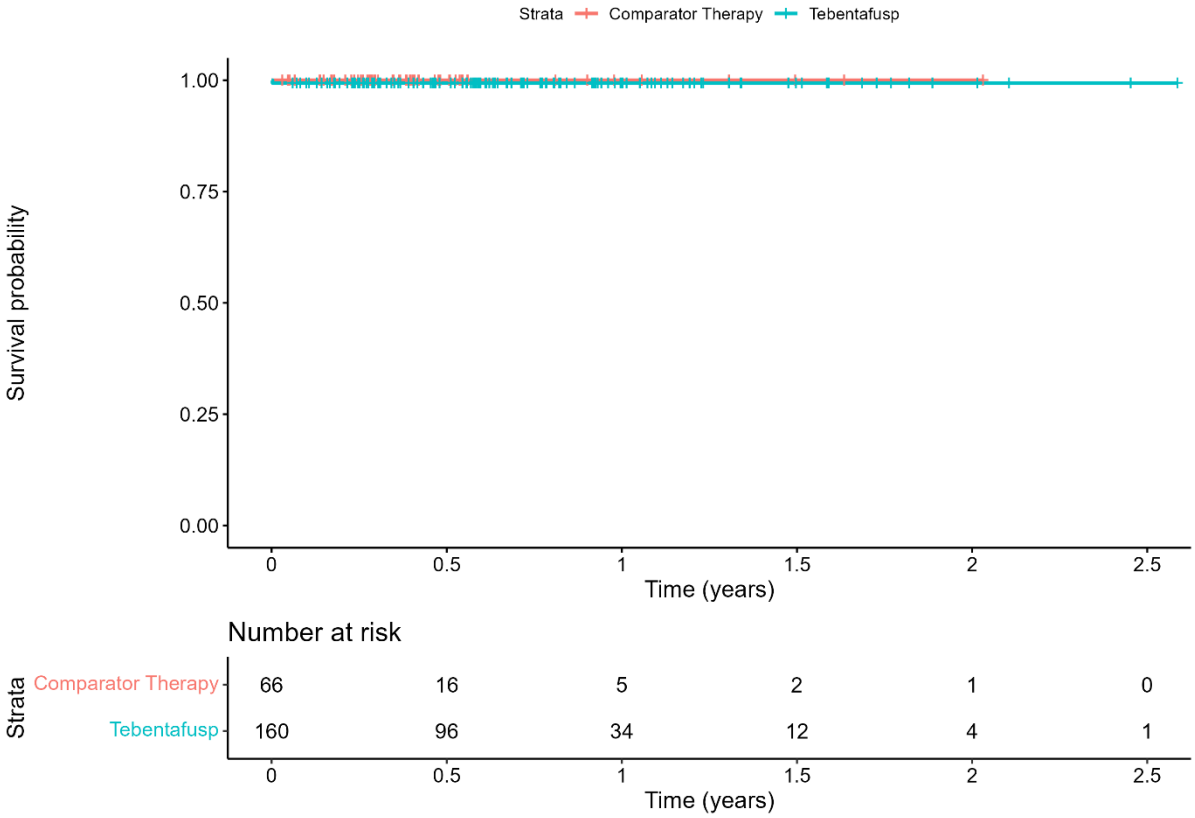
Größte metastatische Läsion (Baseline): ≥8,1 cm



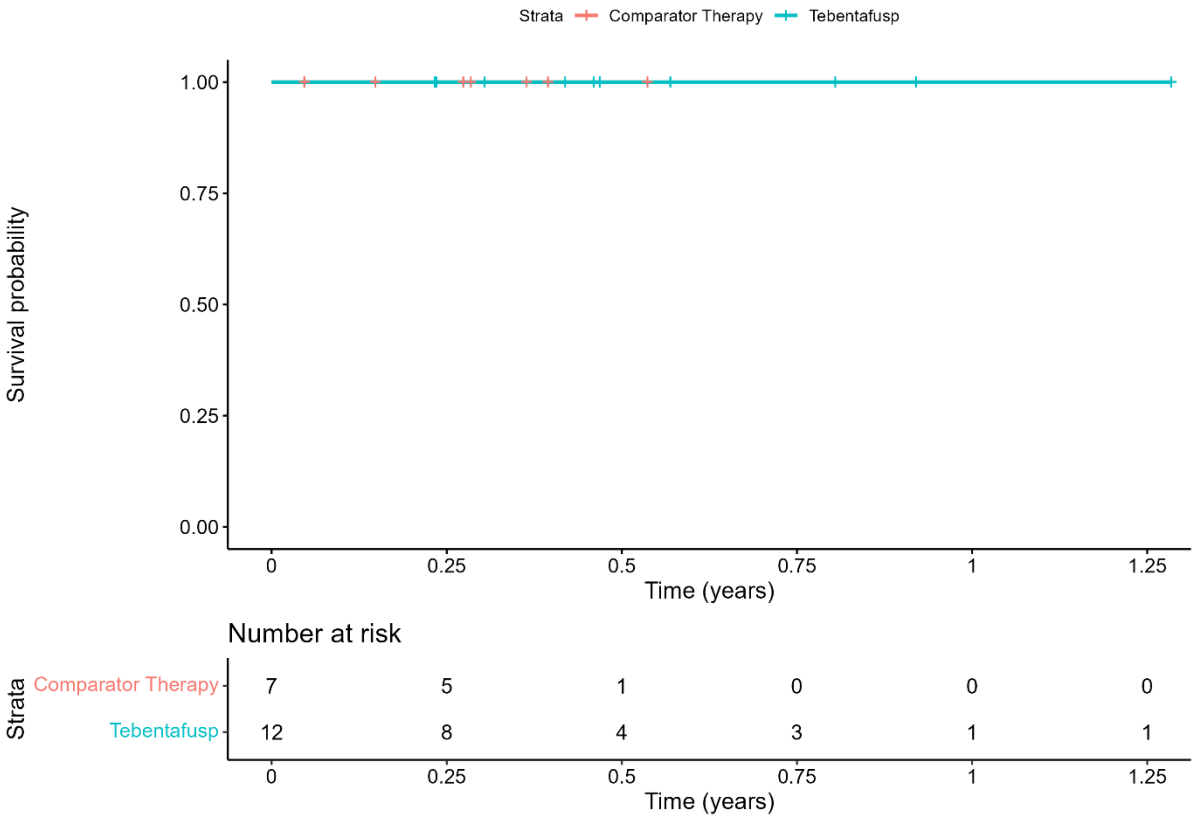
Region: Nordamerika



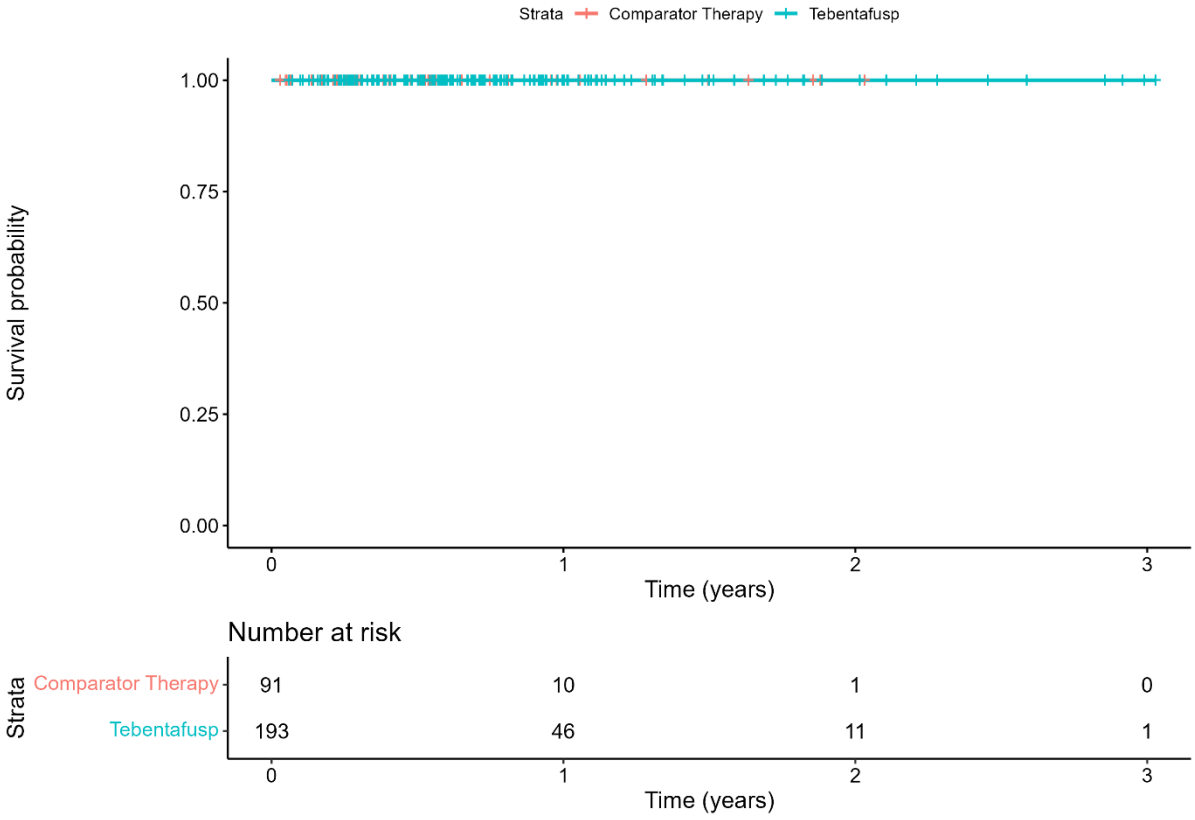
Region: Nicht-Nordamerika



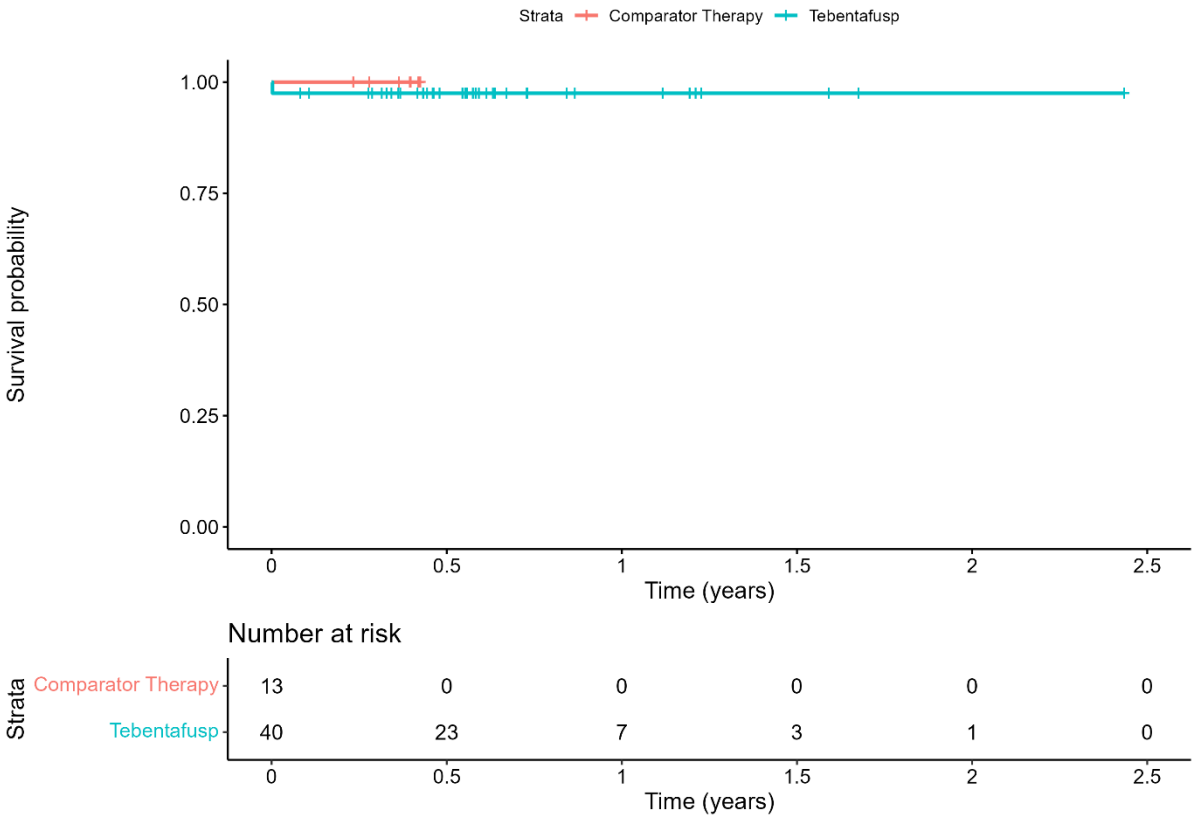
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

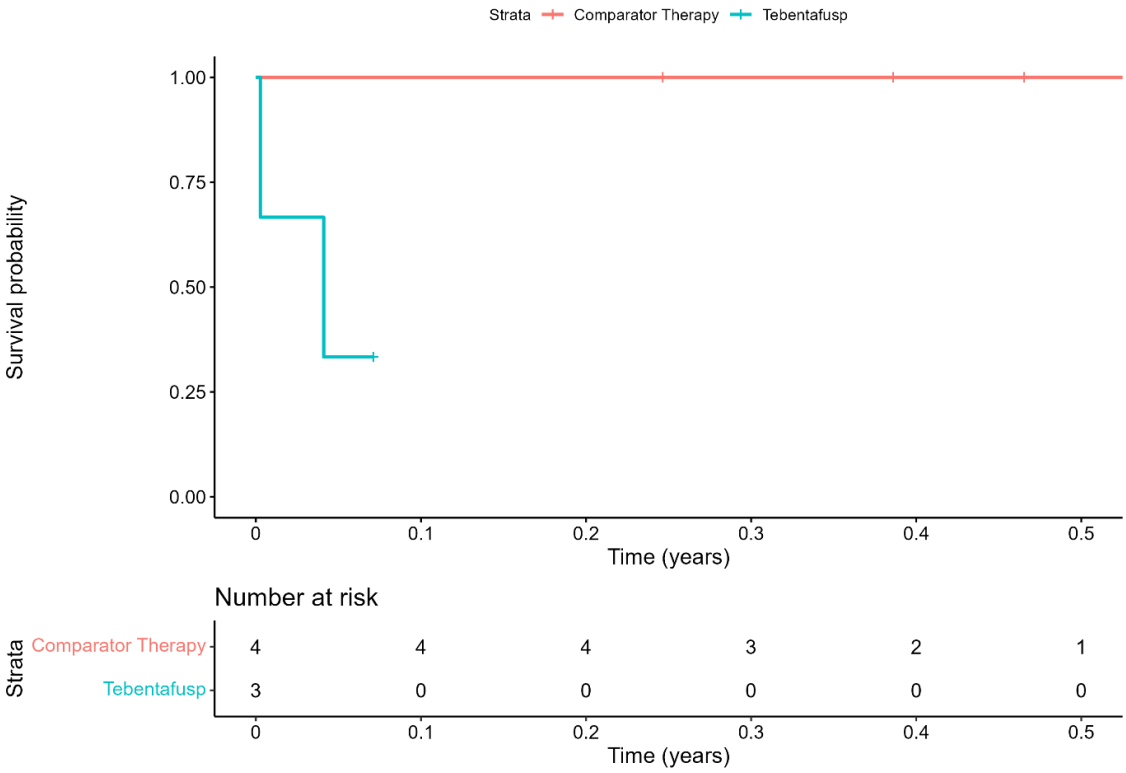


Vorauswahl der Chemotherapie: Ipilimumab

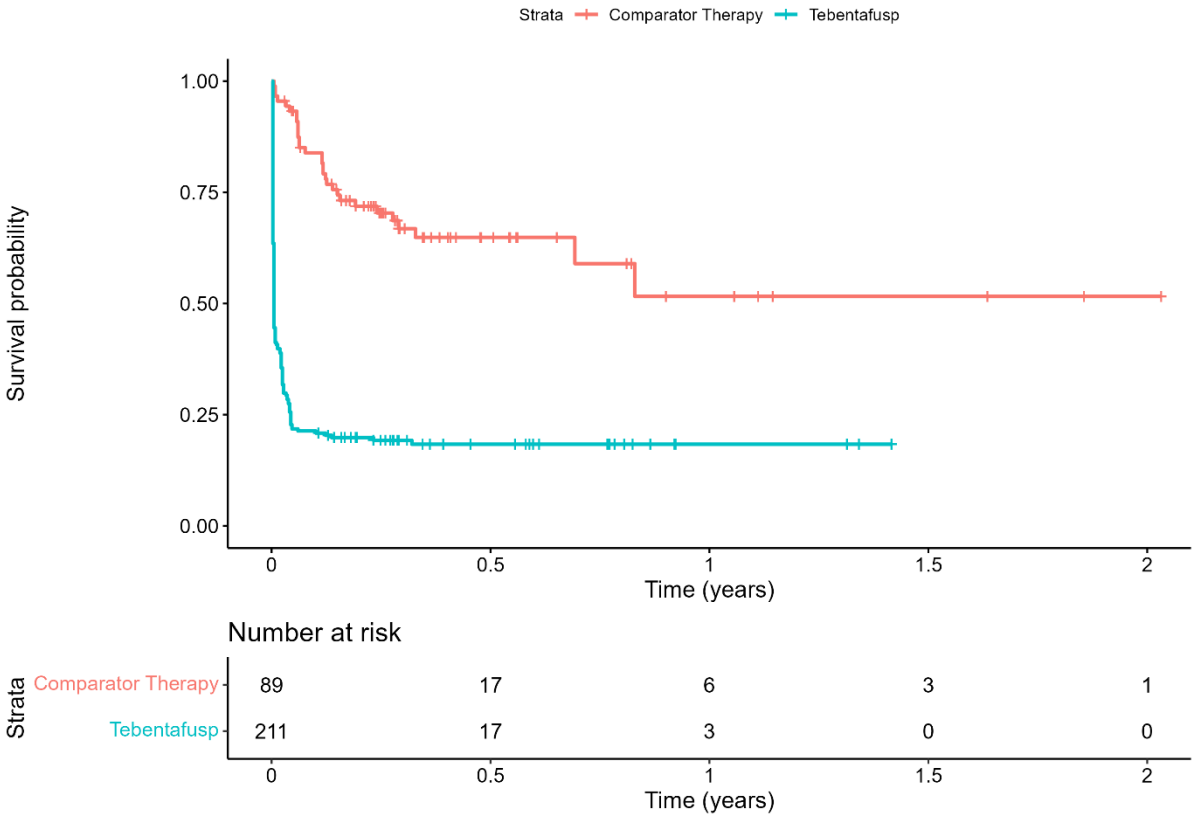


46.1 Hautausschlag (Tabelle 4-103)

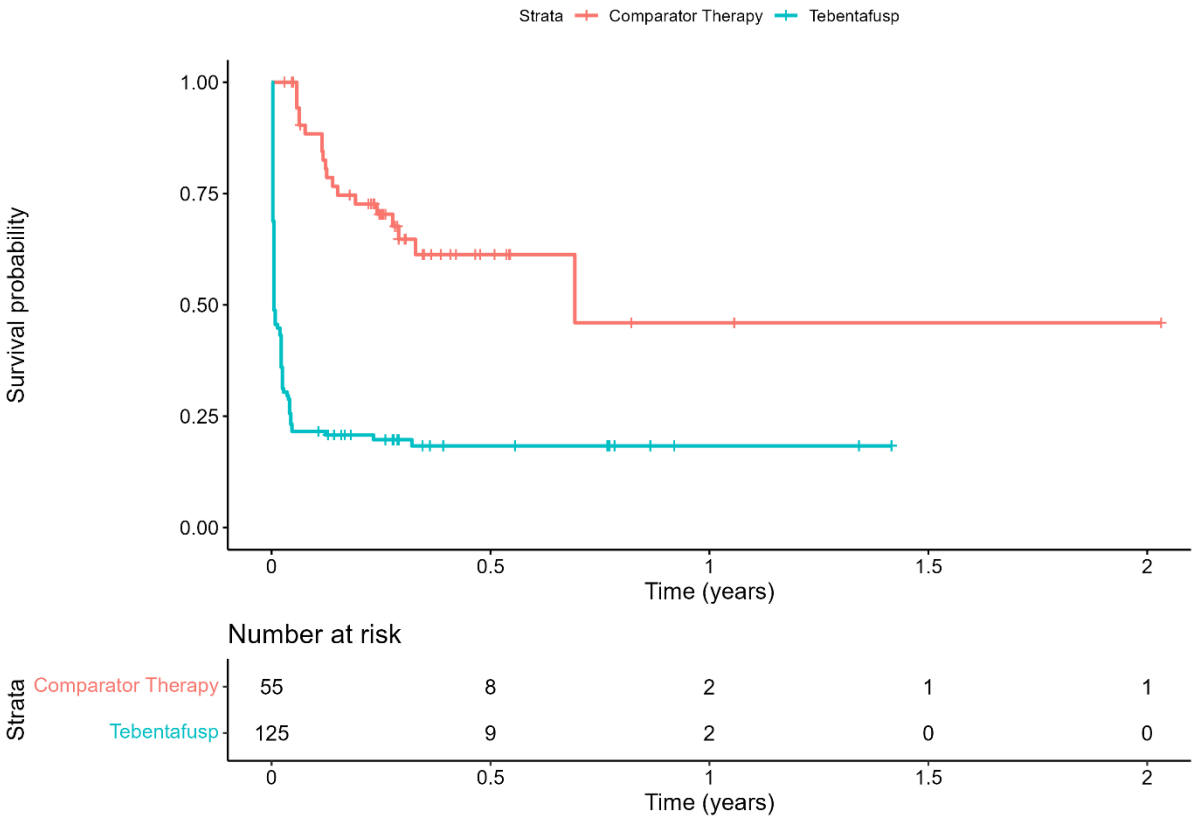
Herkunft: Hispanisch



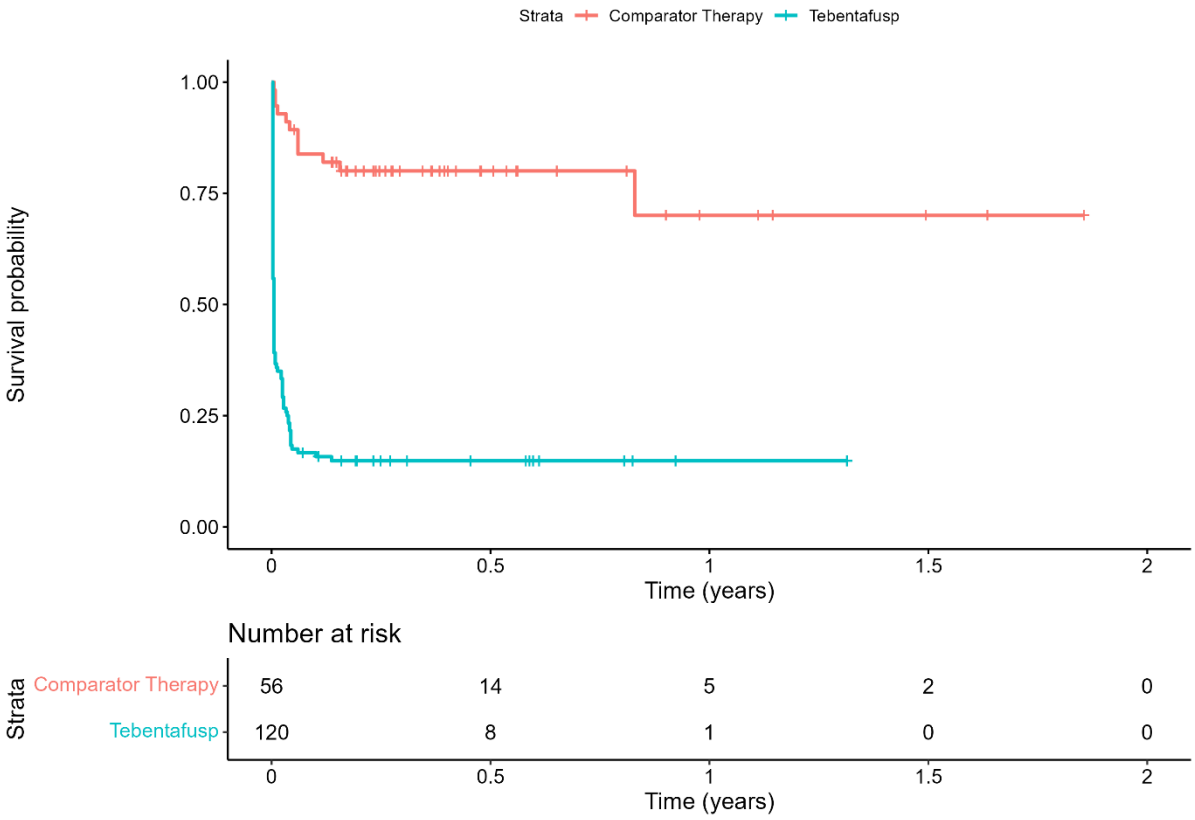
Herkunft: Nicht-hispanisch



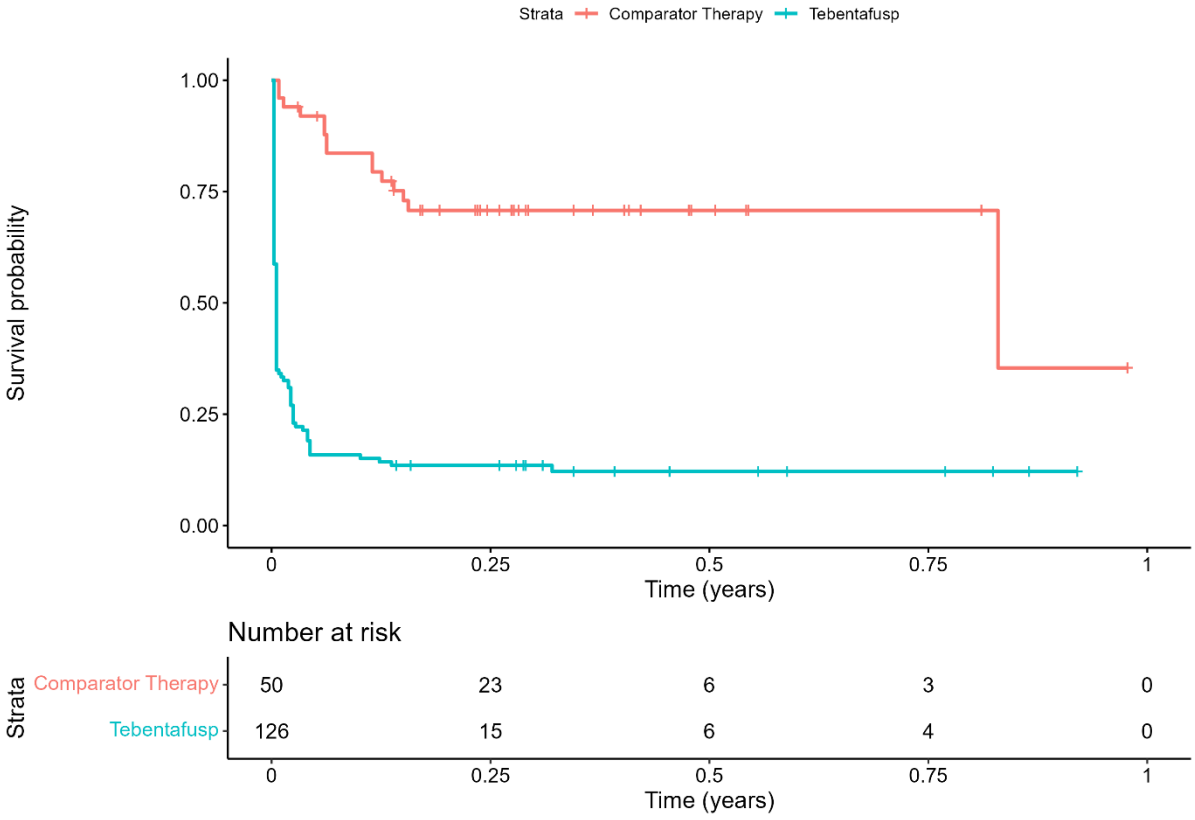
Geschlecht: Männlich



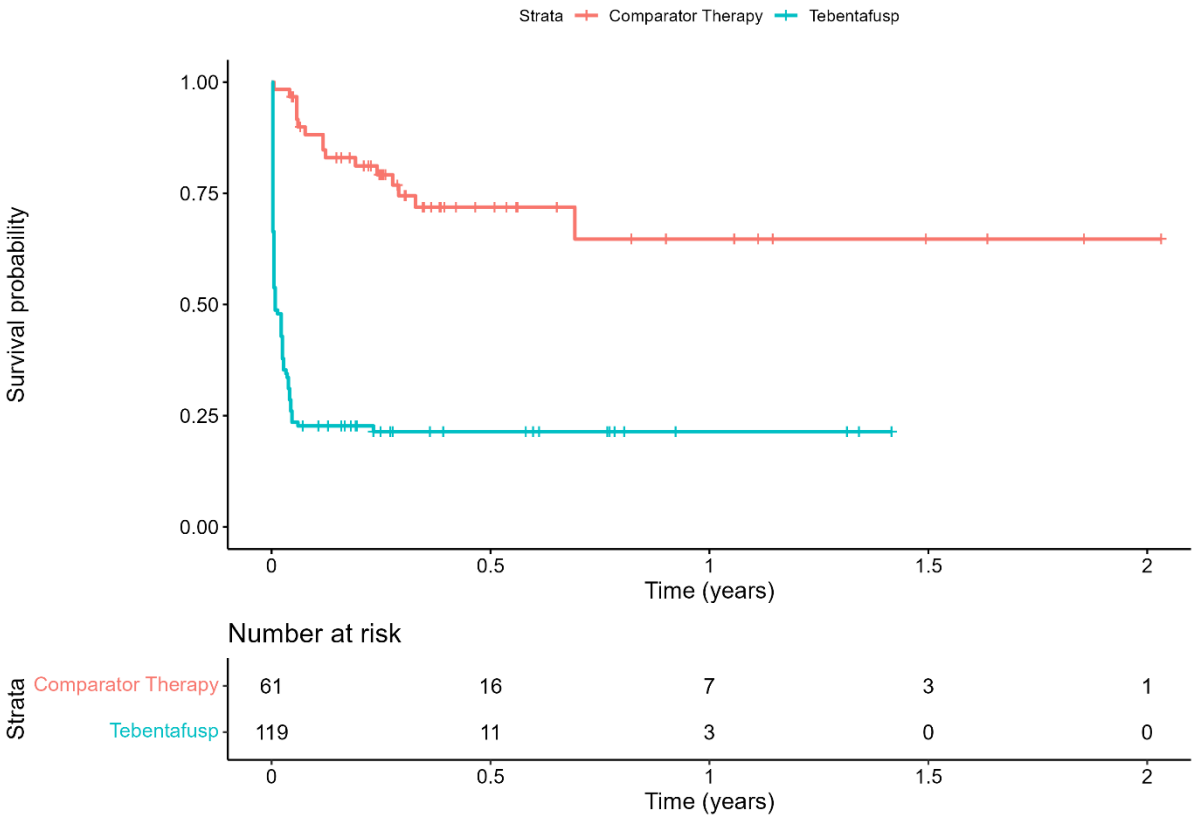
Geschlecht: Weiblich



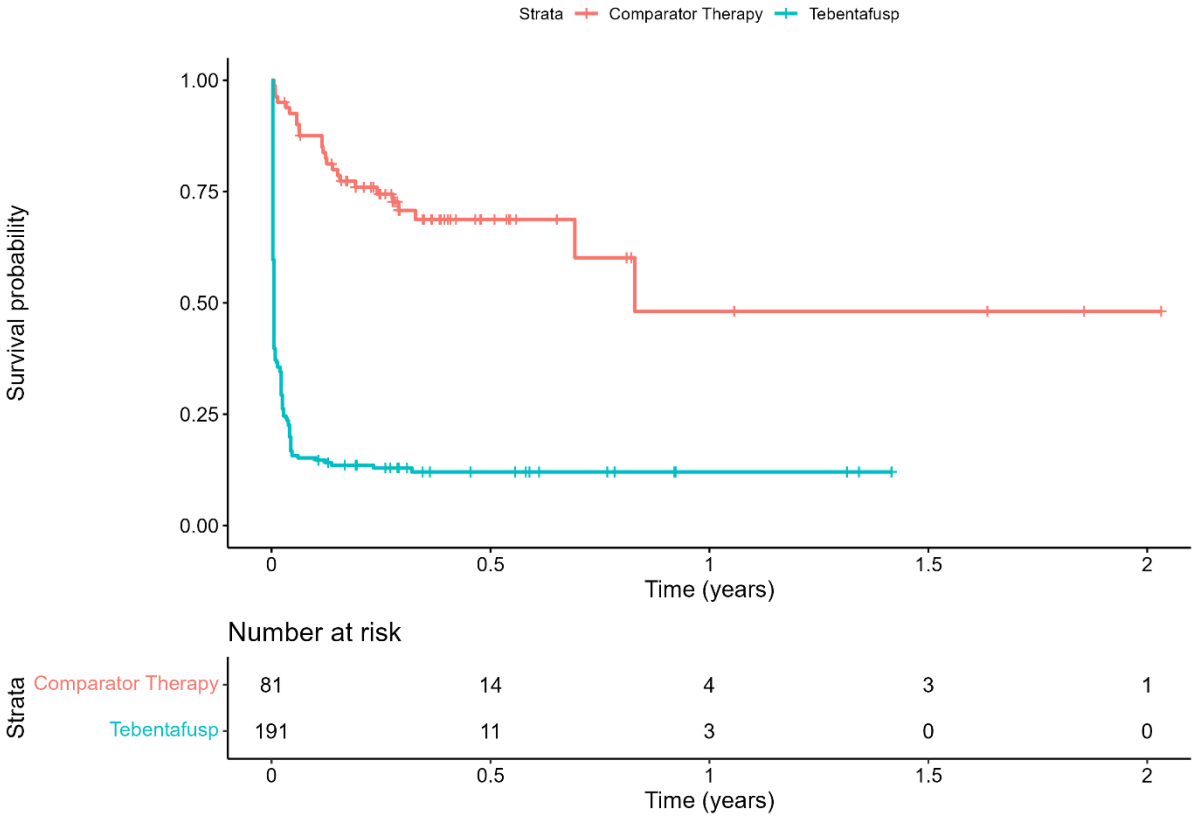
Alter: <65 Jahre



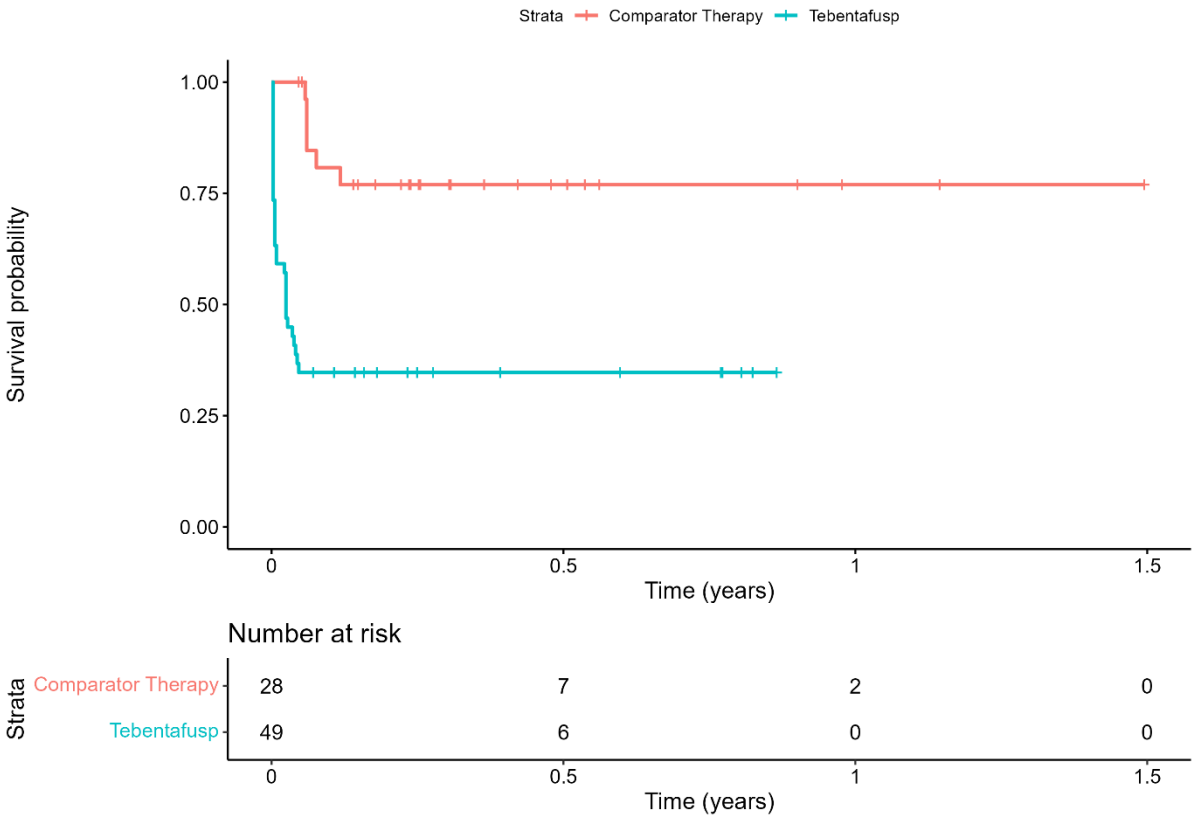
Alter: ≥65 Jahre



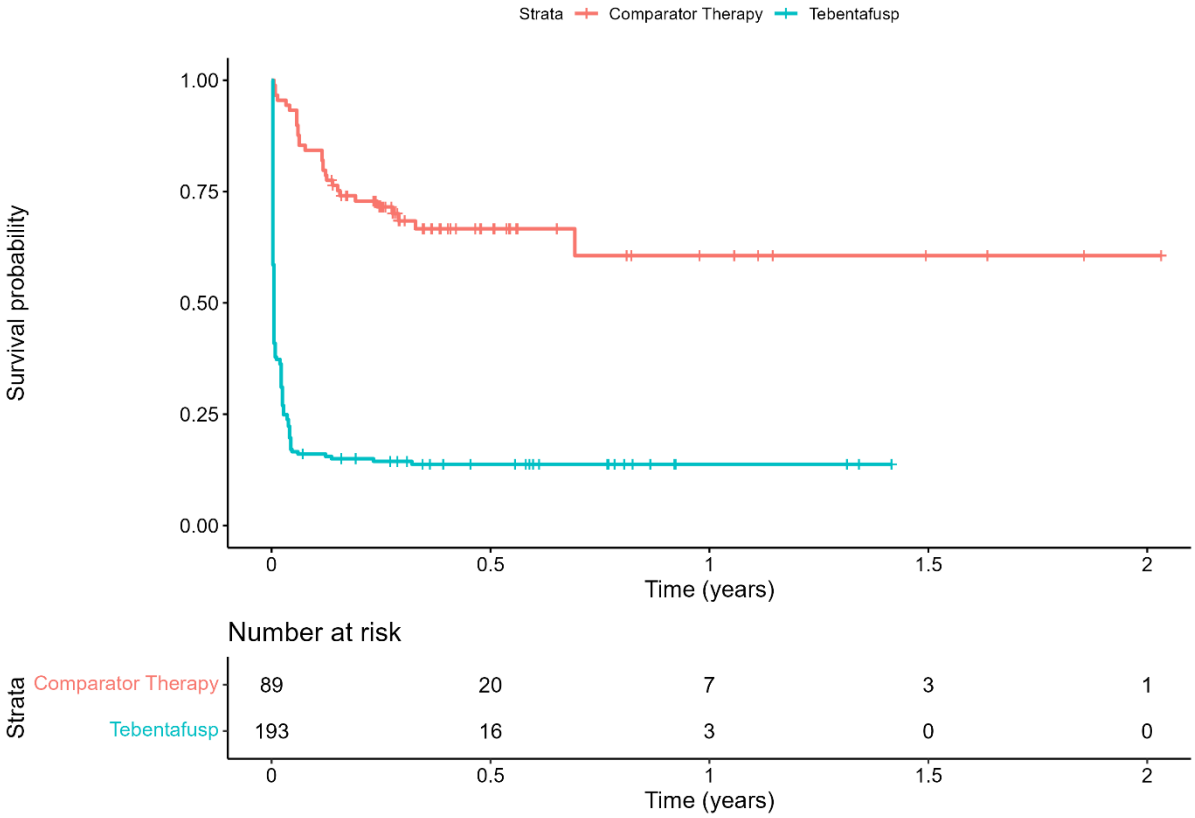
ECOG-Performance-Status: 0



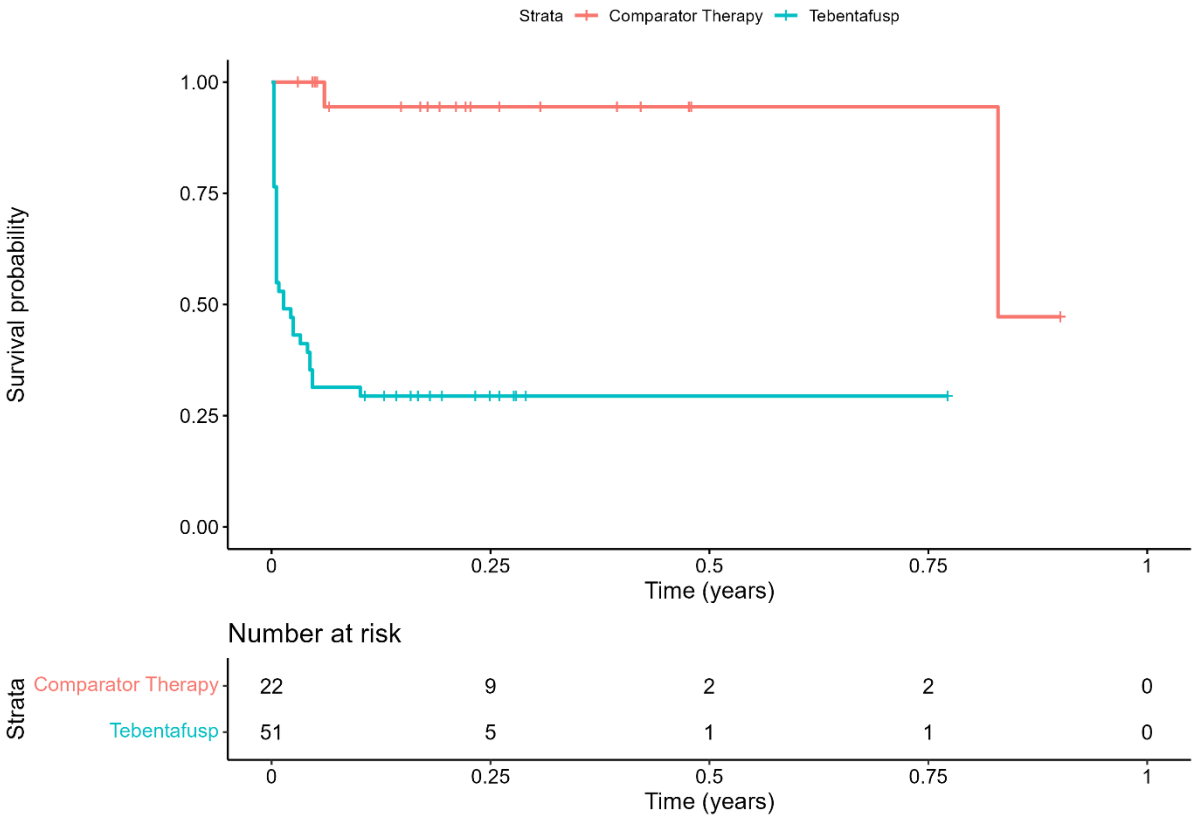
ECOG-Performance-Status: 1



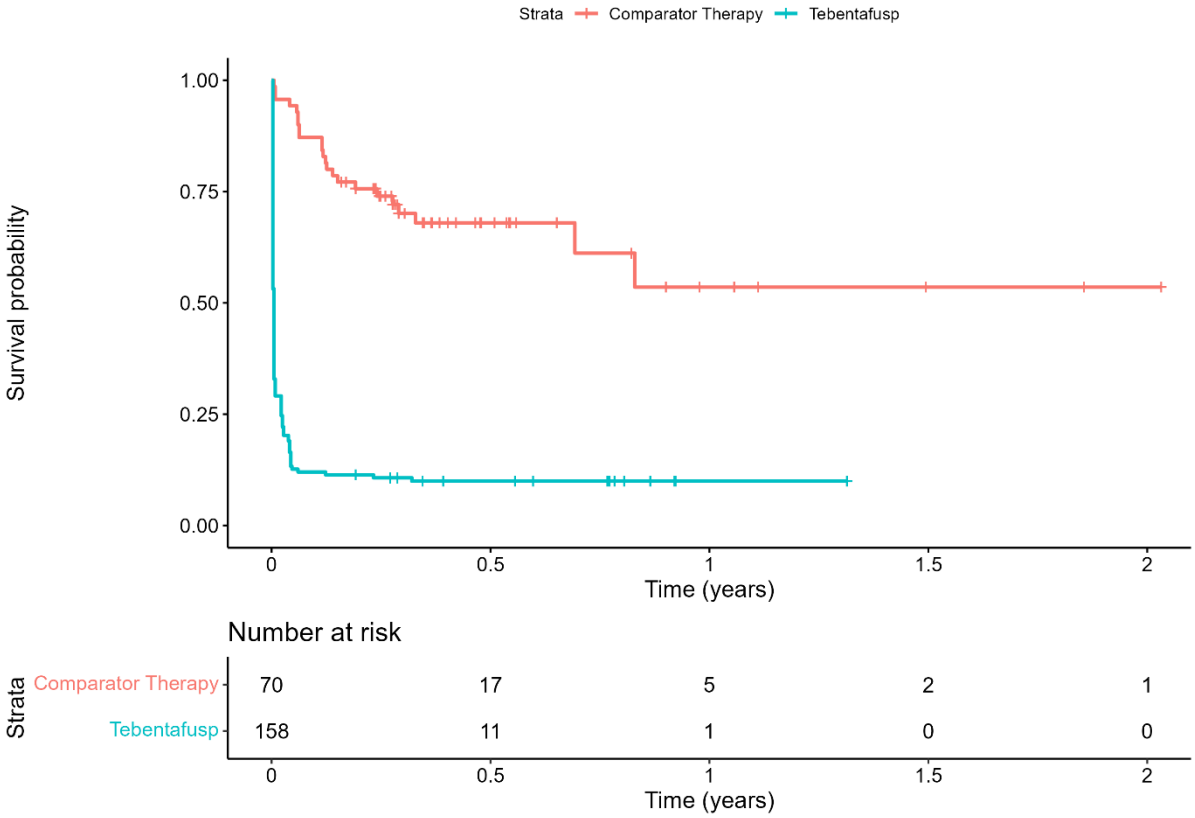
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



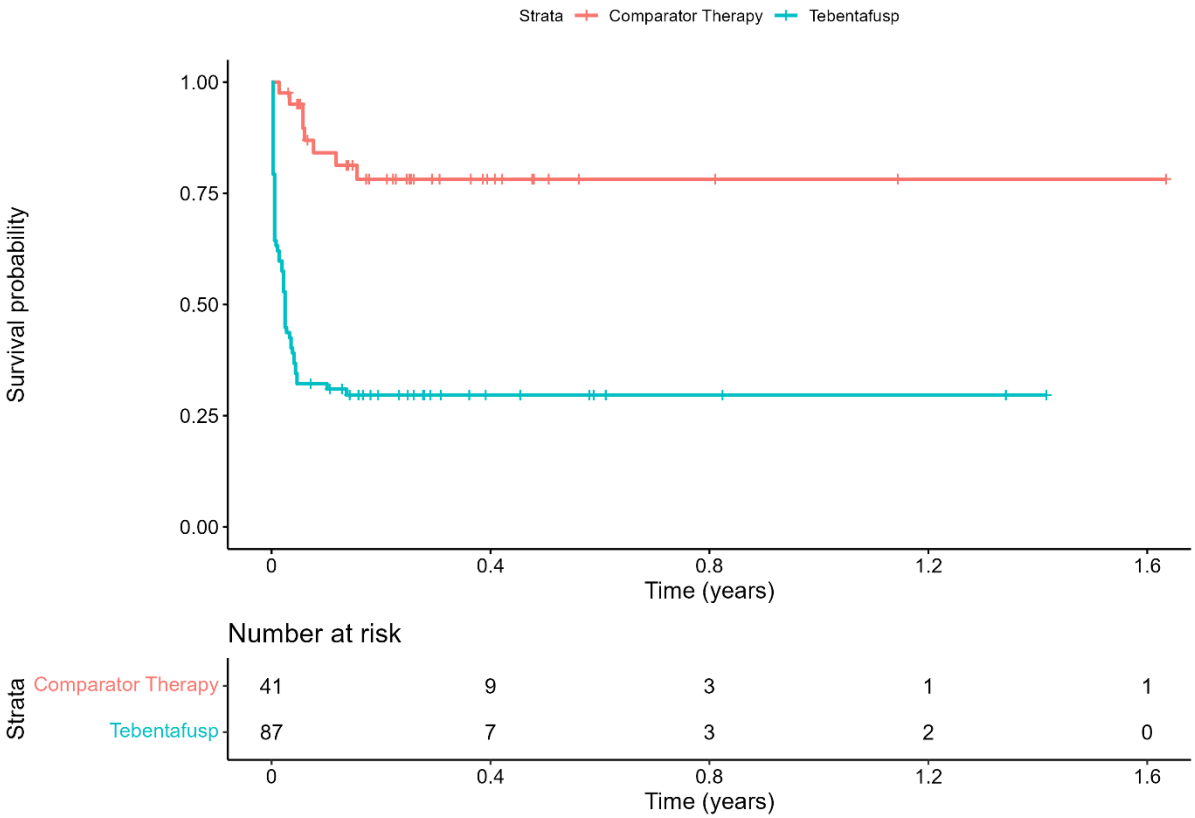
Alkalische Phosphatase (ALP) (Baseline): >ULN



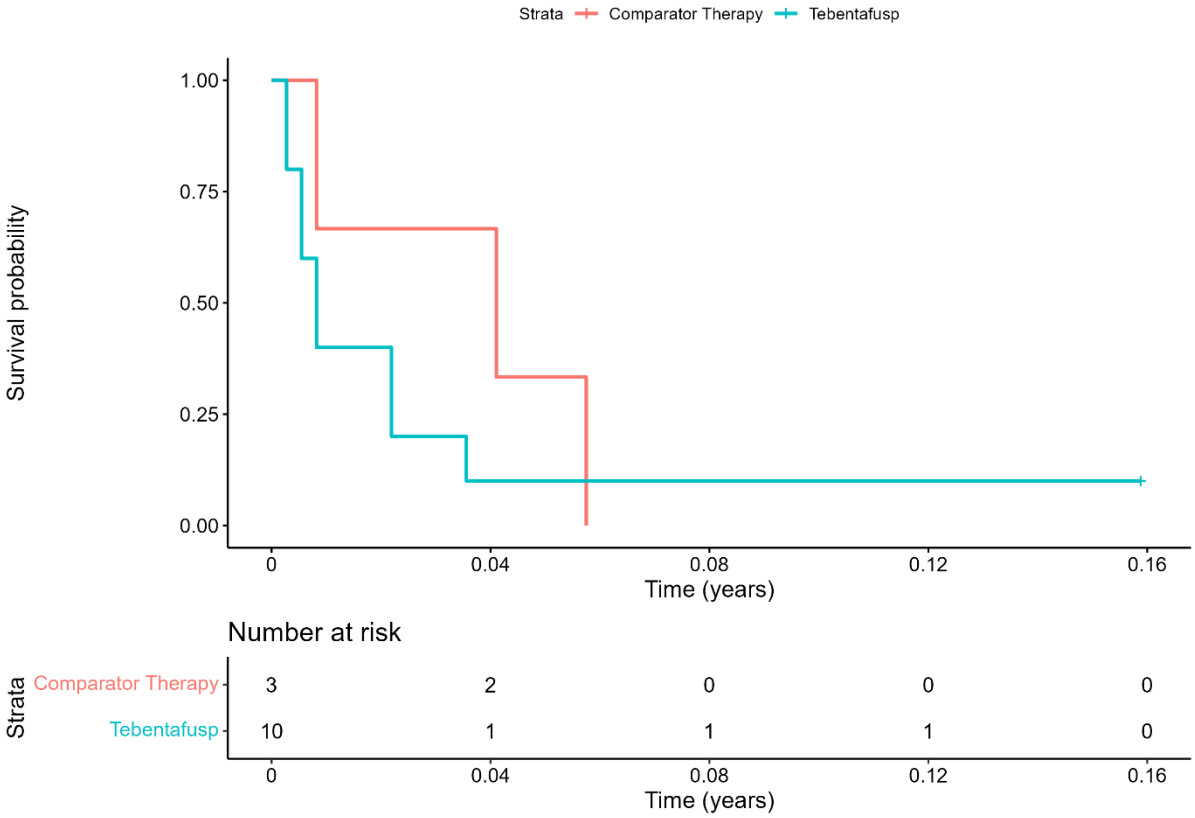
LDH: ≤ULN



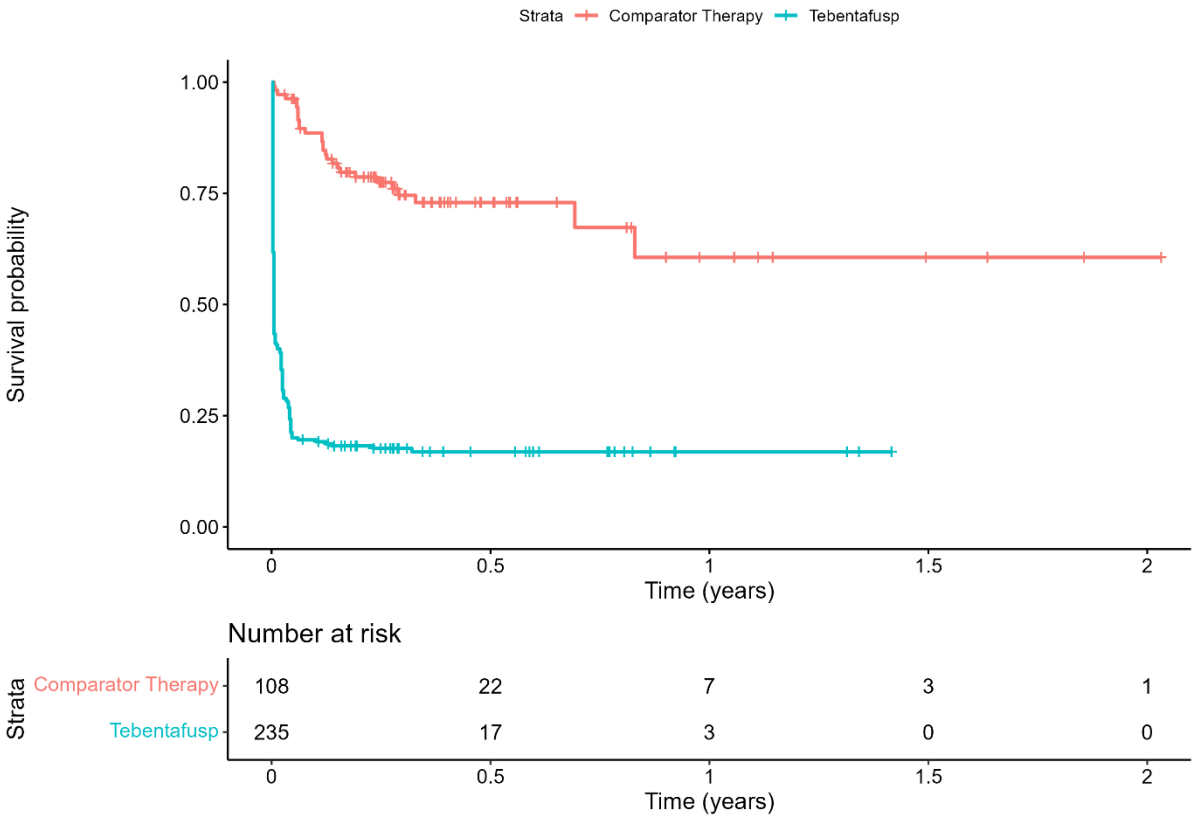
LDH: >ULN



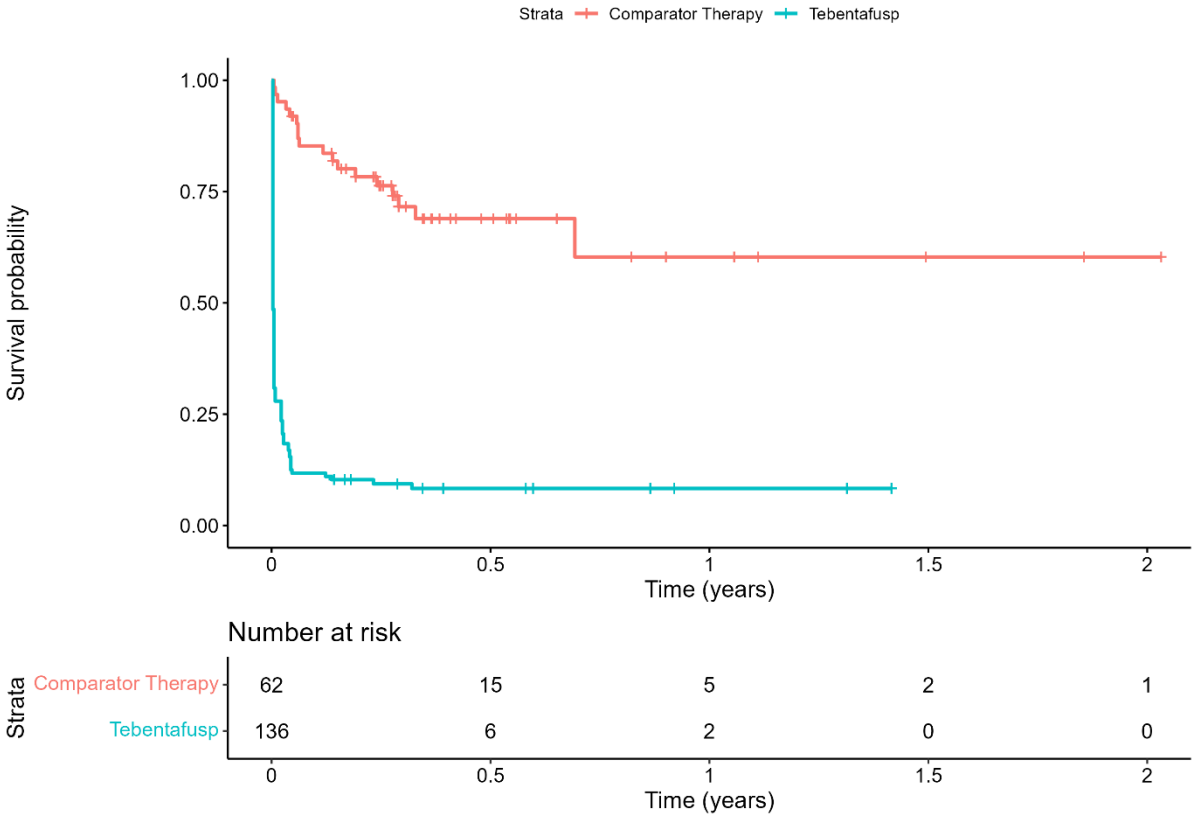
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



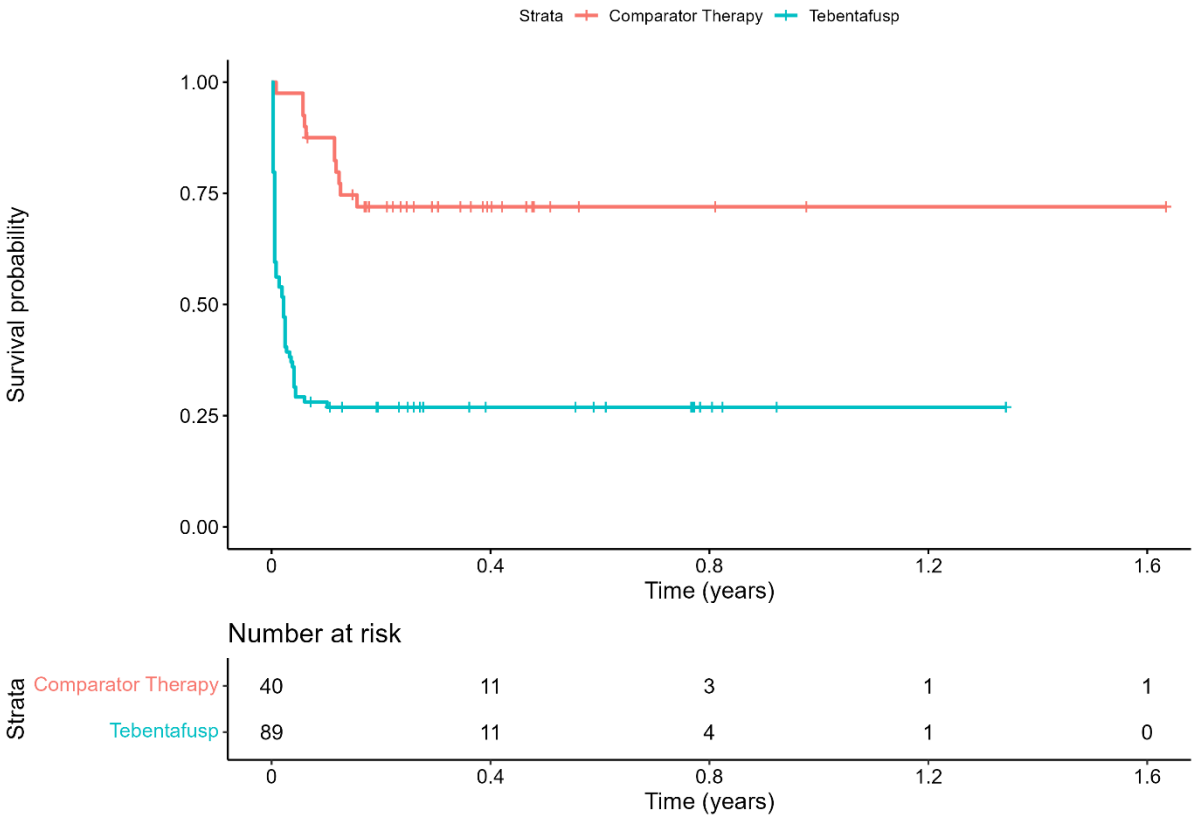
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



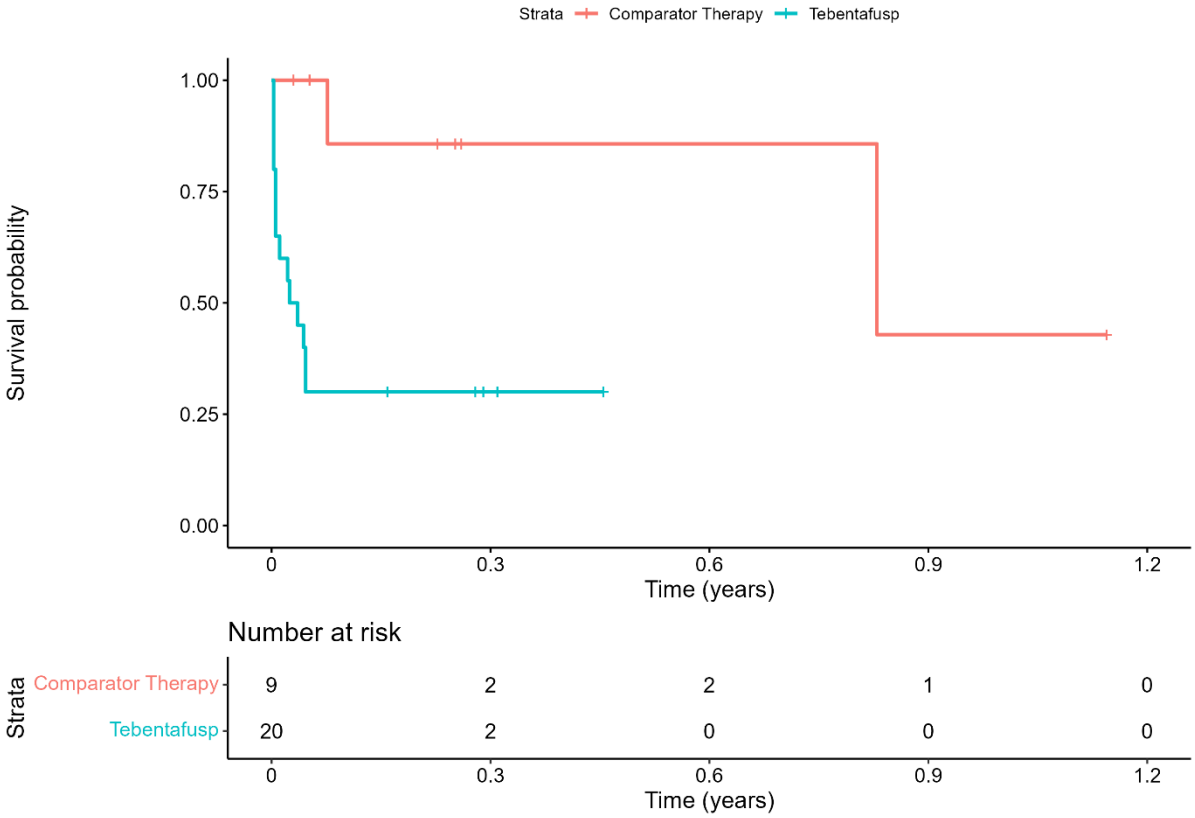
Größte metastatische Läsion (Baseline): ≤3,0 cm



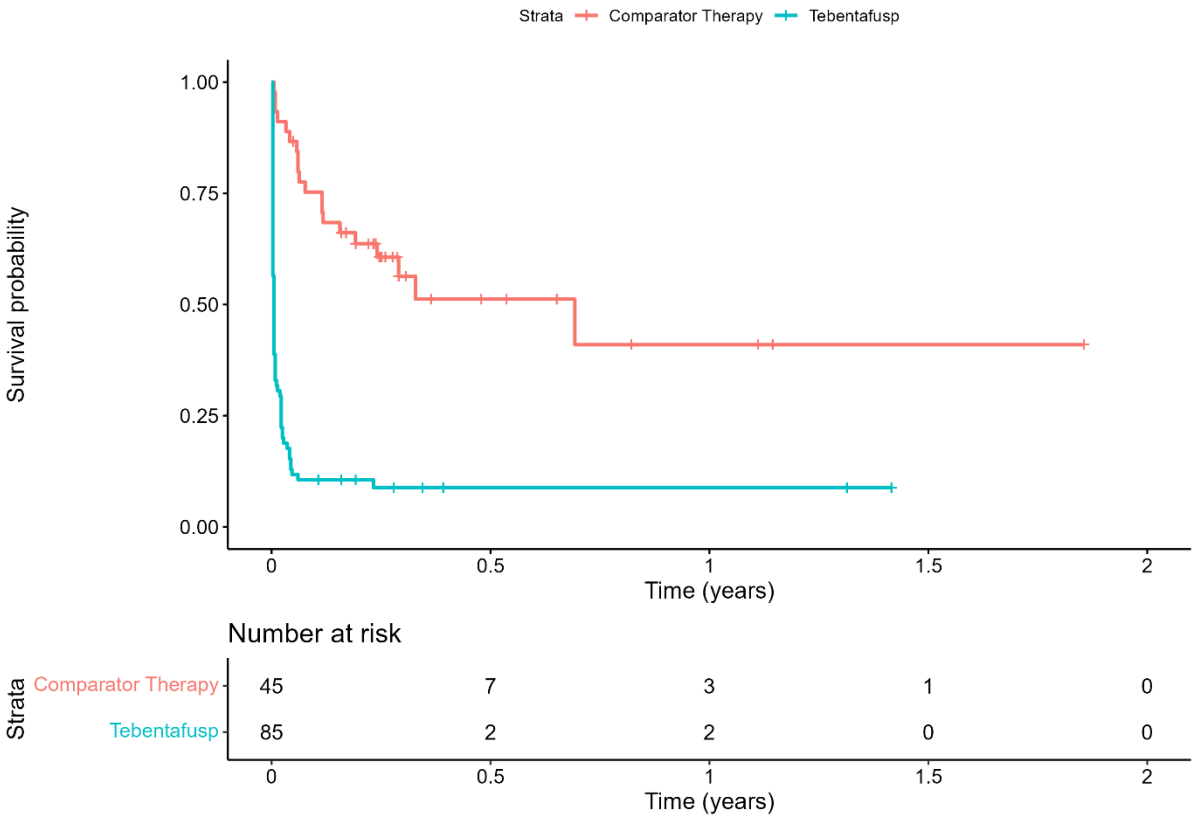
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



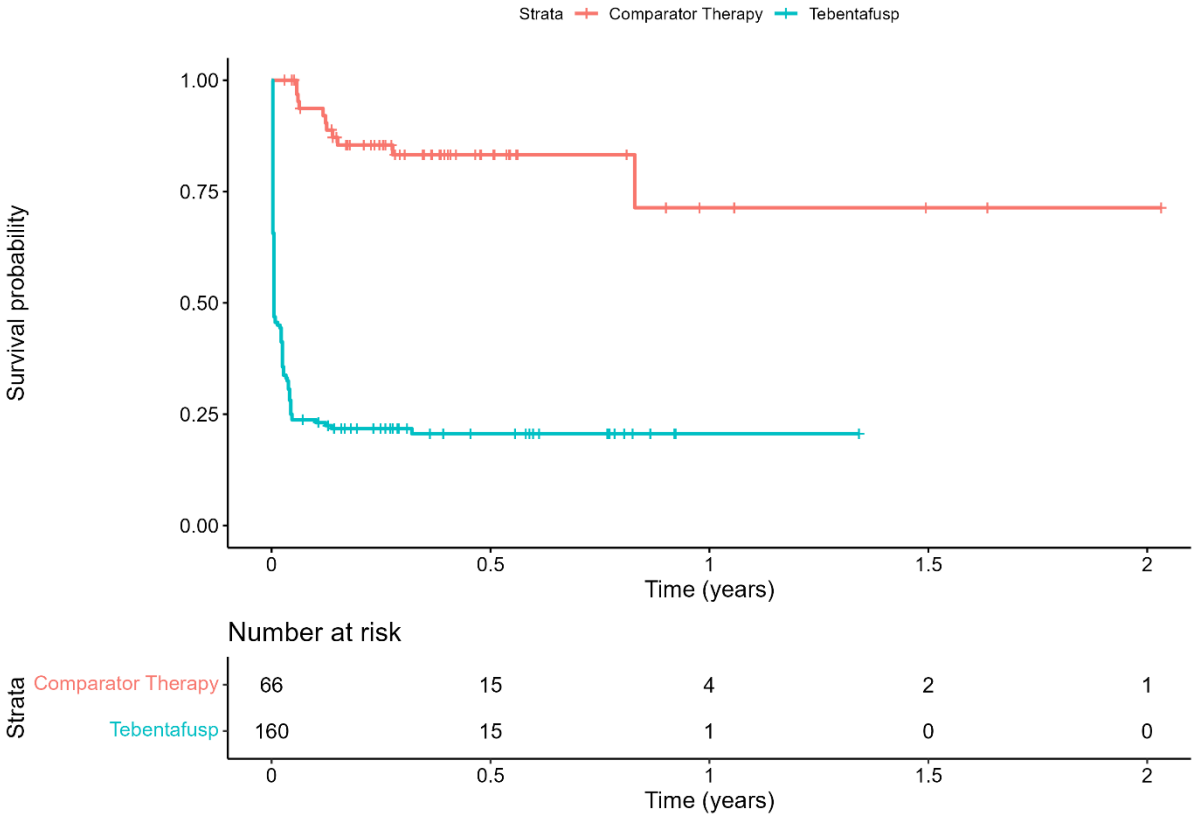
Größte metastatische Läsion (Baseline): ≥8,1 cm



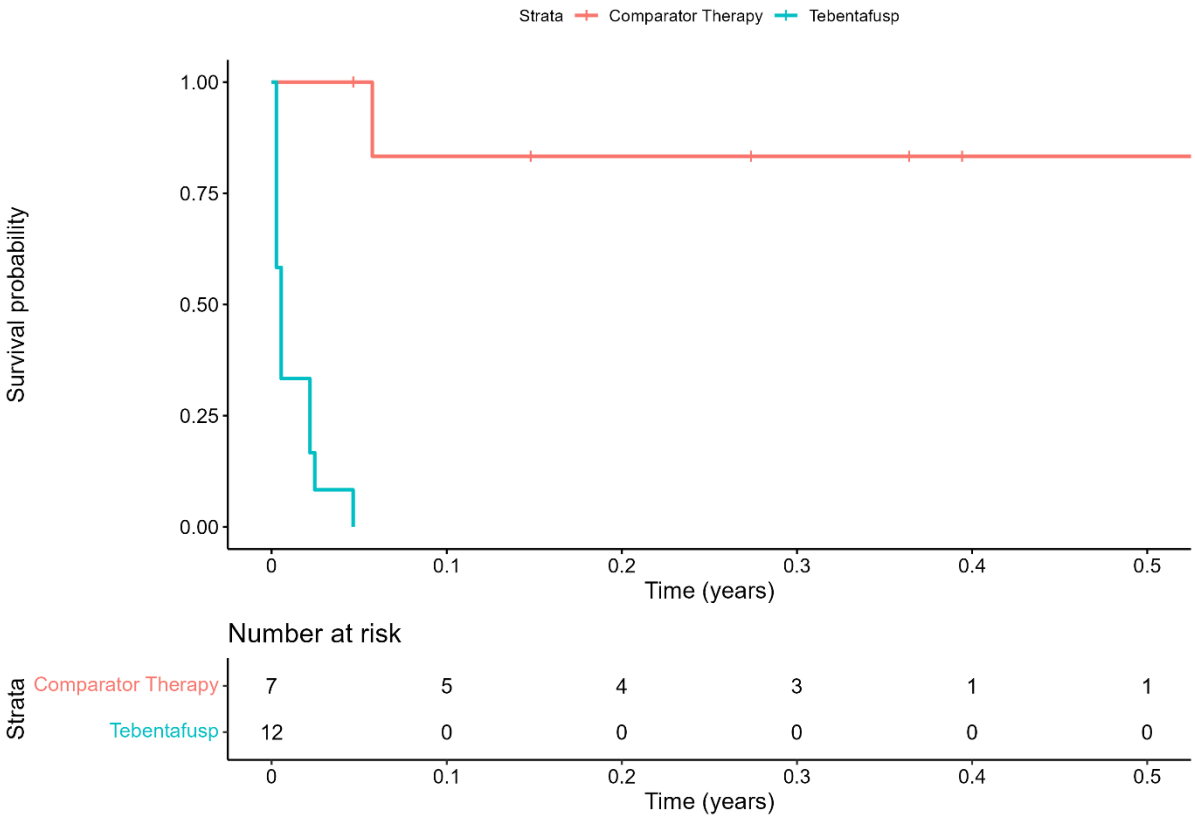
Region: Nordamerika



Region: Nicht-Nordamerika

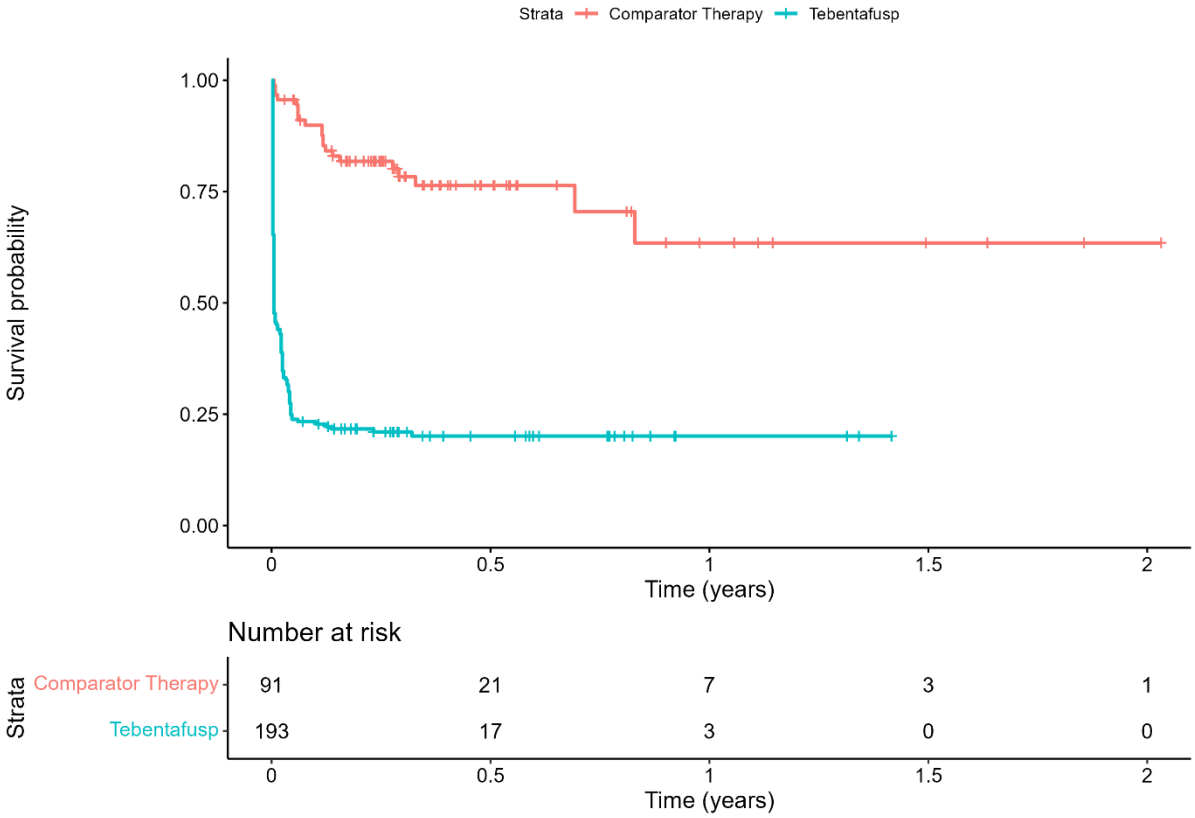


Vorauswahl der Chemotherapie: Dacarbazin

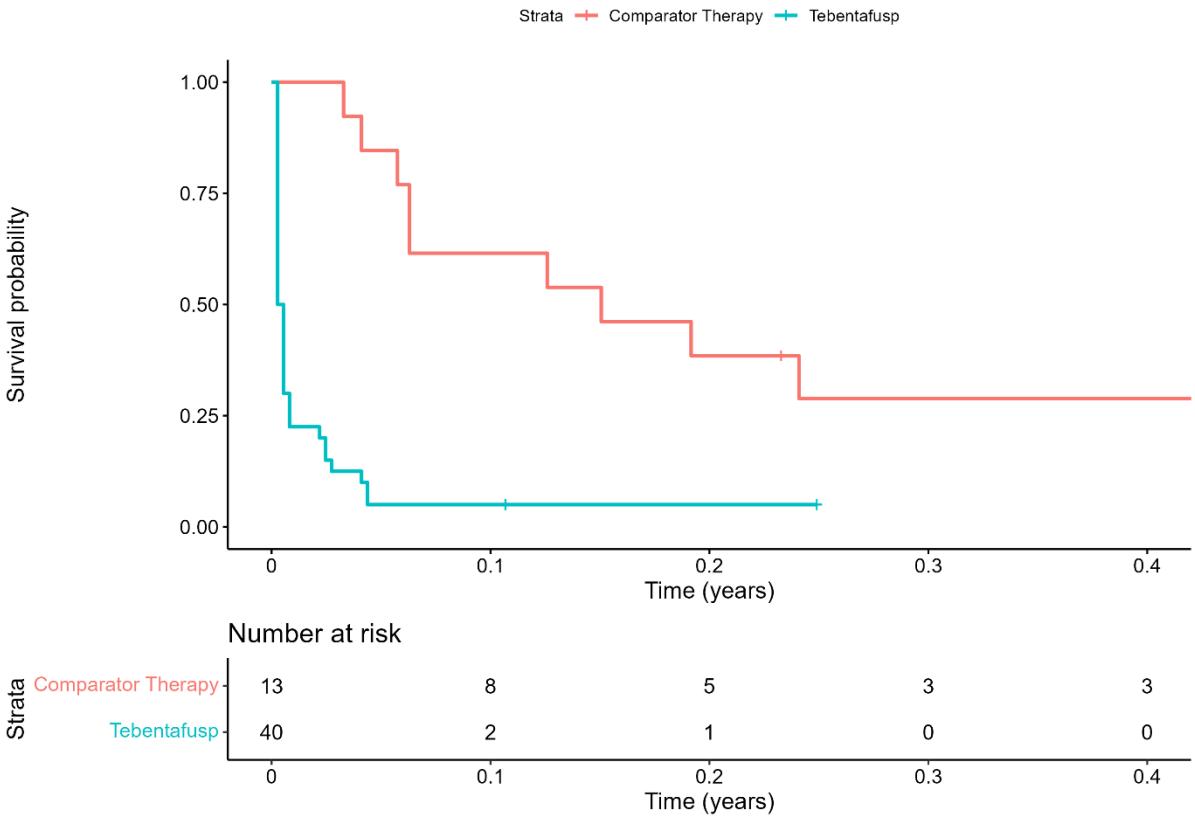


Vorauswahl der Chemotherapie: Pembrolizumab

Vorauswahl der Chemotherapie: Pembrolizumab

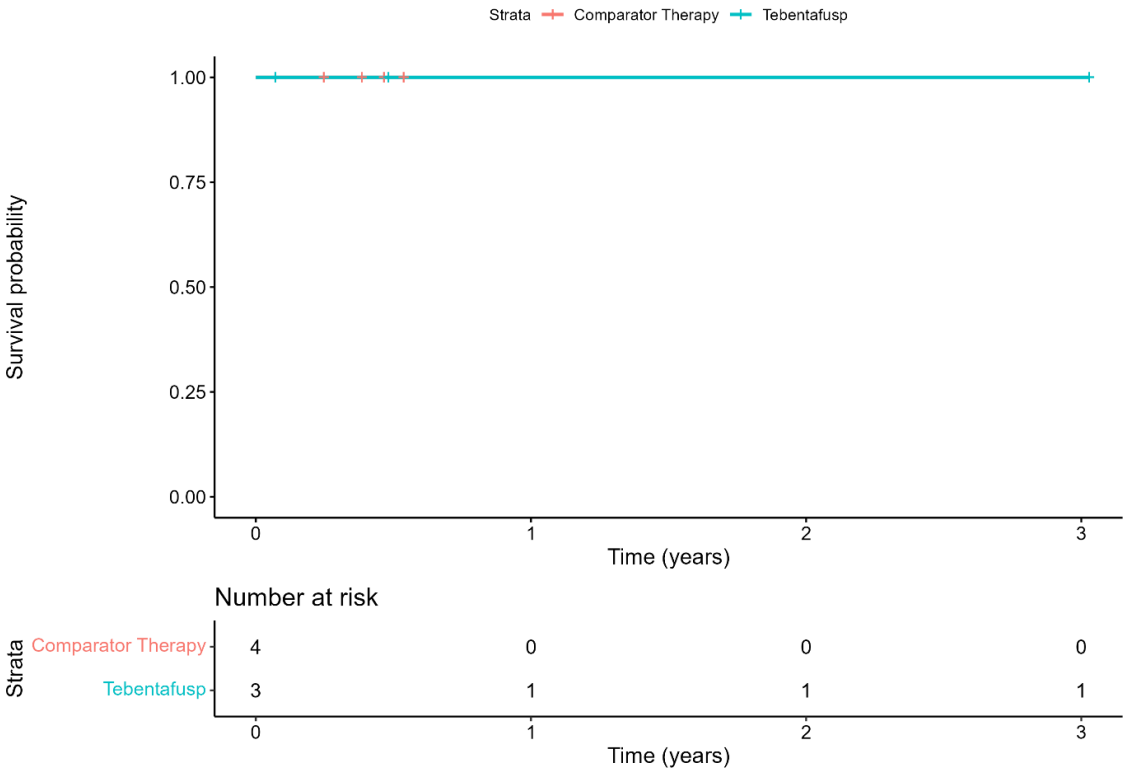


Vorauswahl der Chemotherapie: Ipilimumab

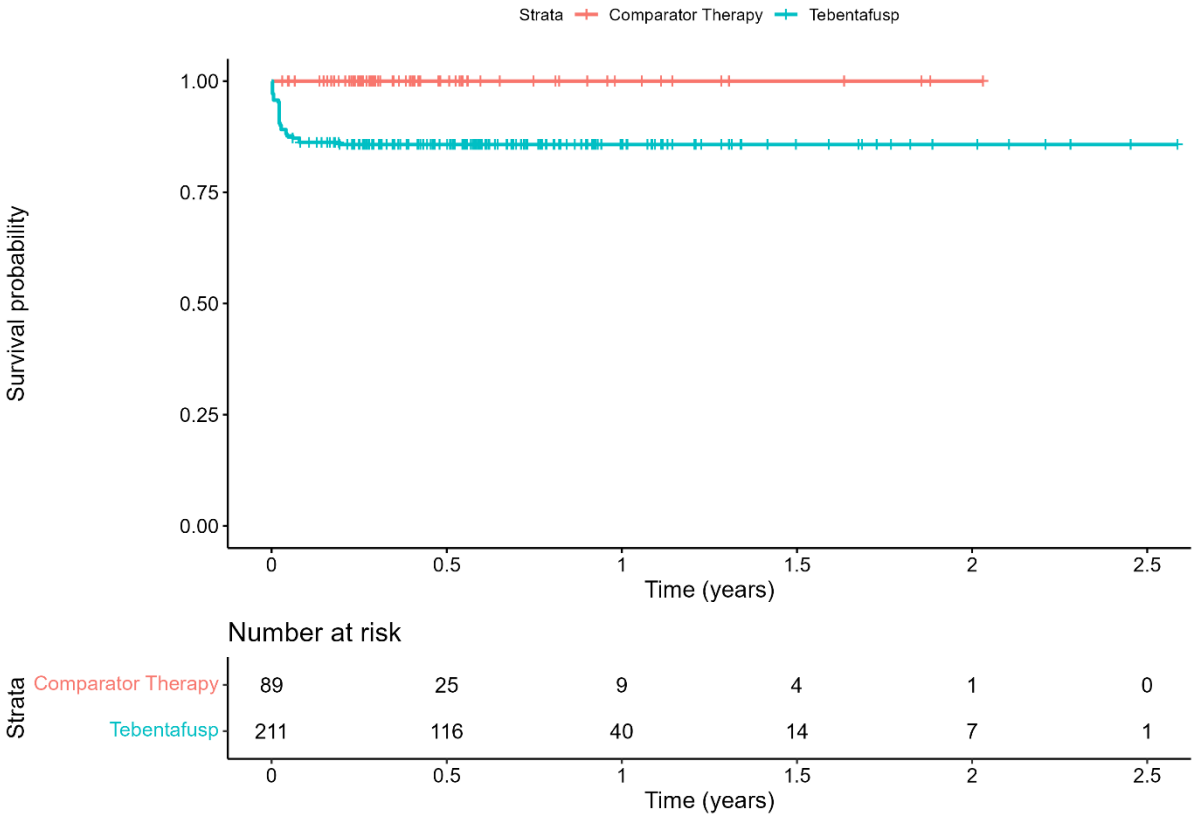


47.1 Hautausschlag mit CTCAE-Grad ≥ 3 (Tabelle 4-105)

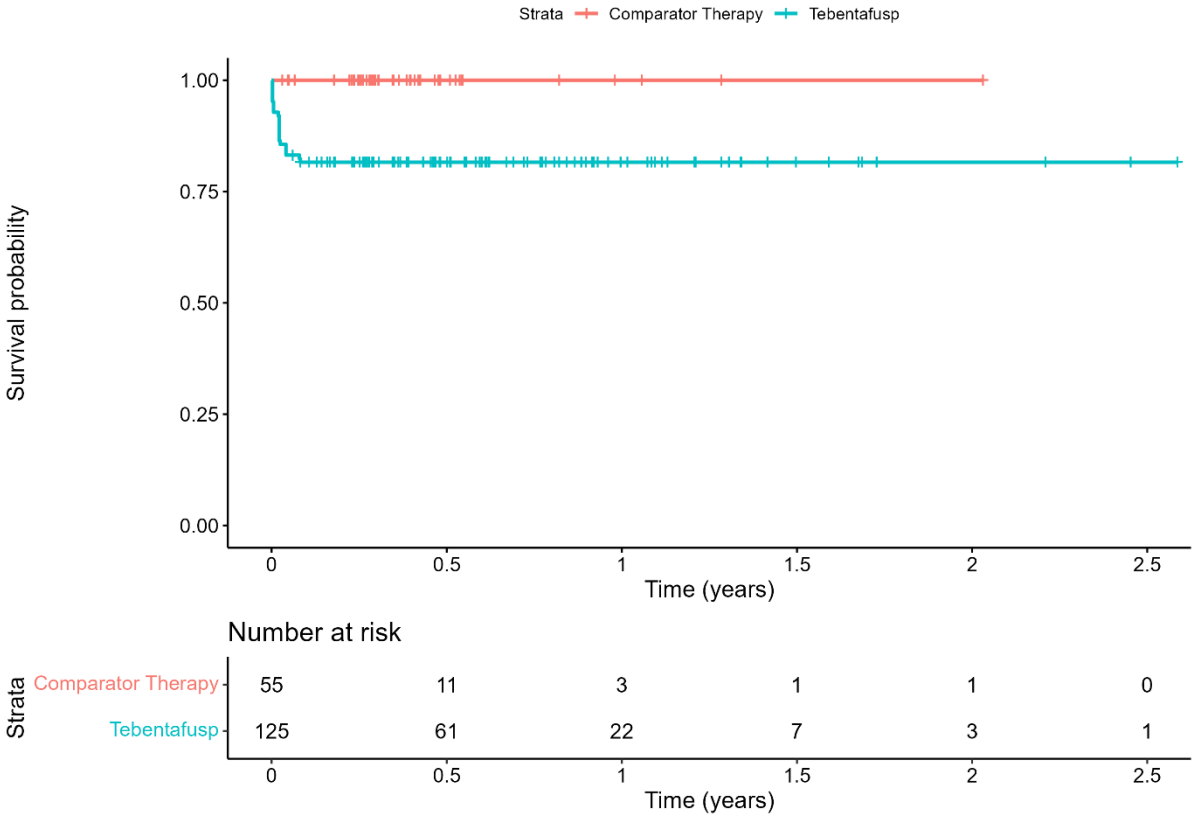
Herkunft: Hispanisch



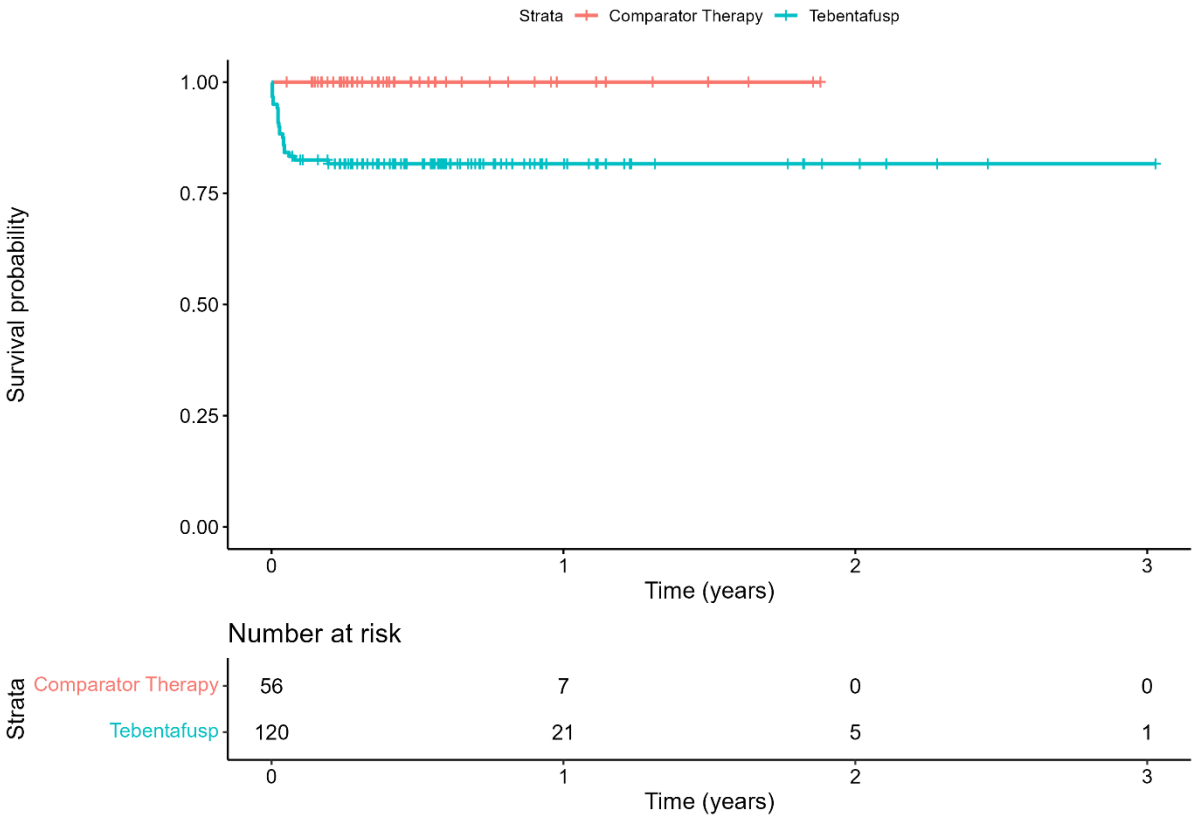
Herkunft: Nicht-hispanisch



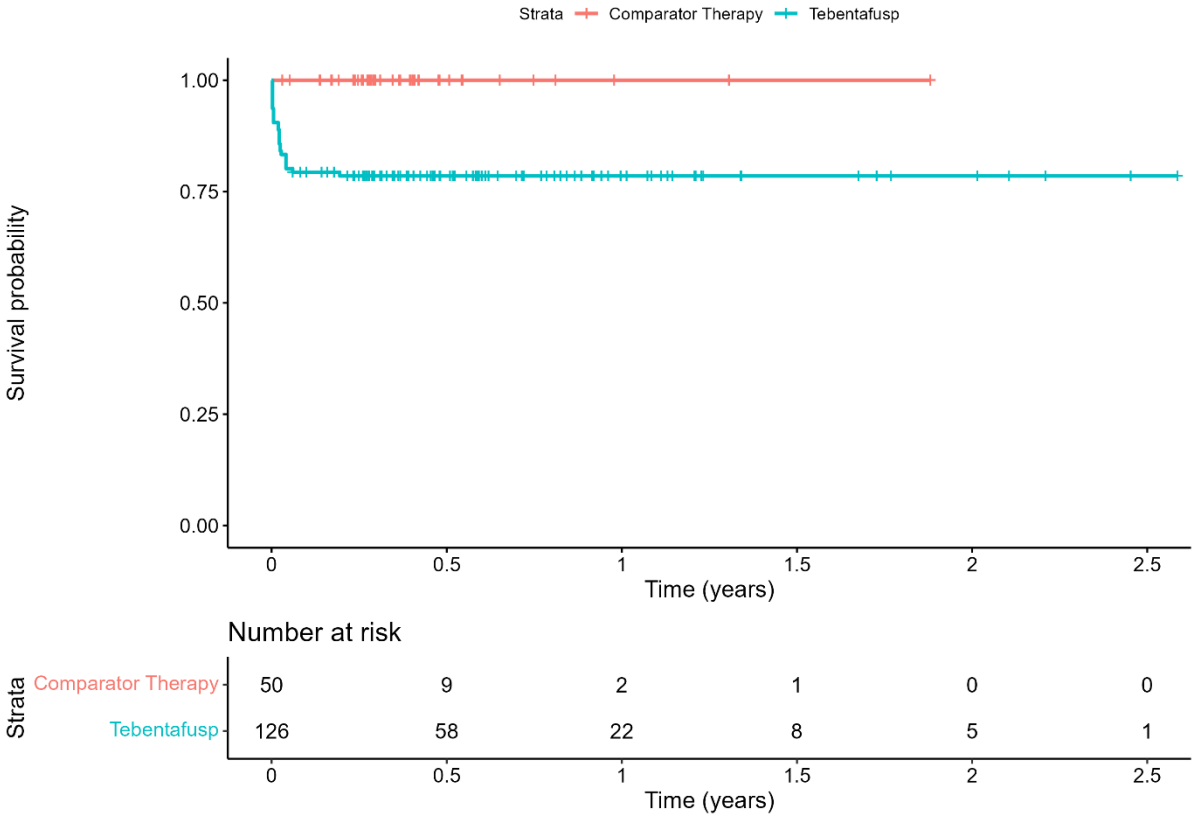
Geschlecht: Männlich



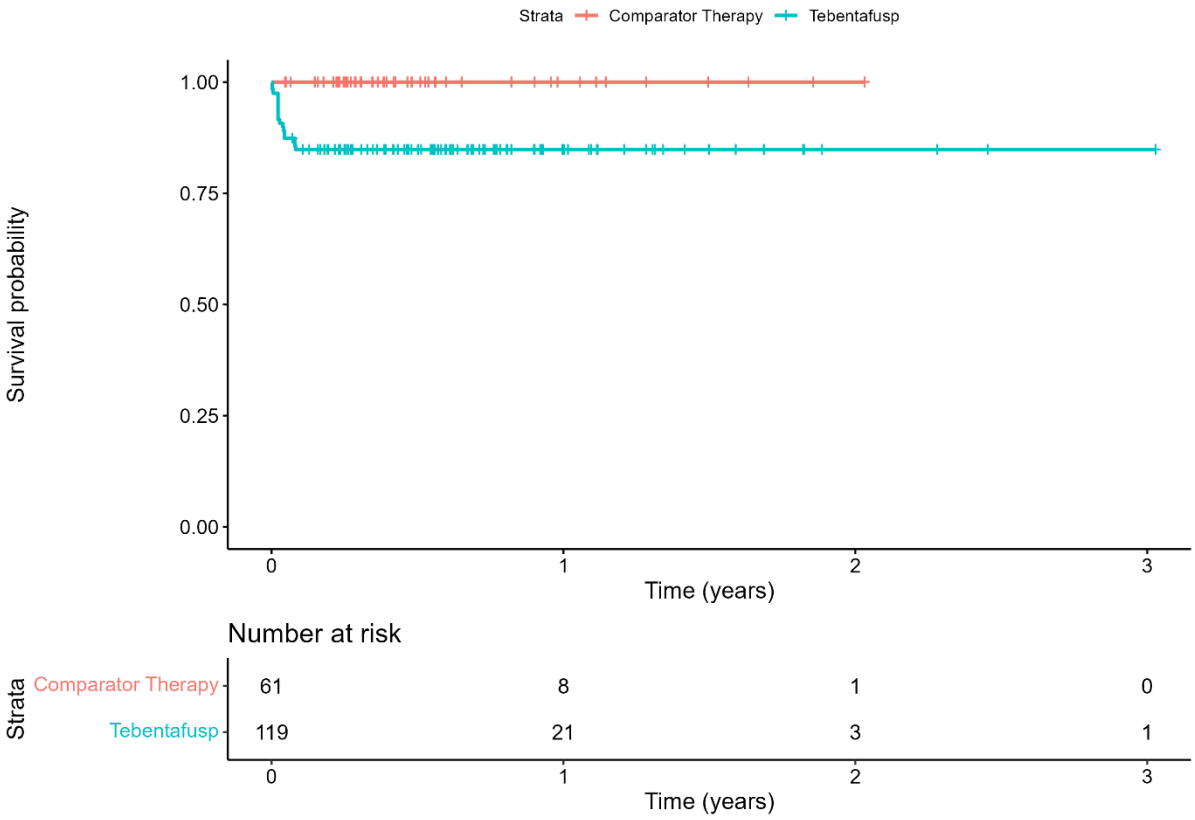
Geschlecht: Weiblich



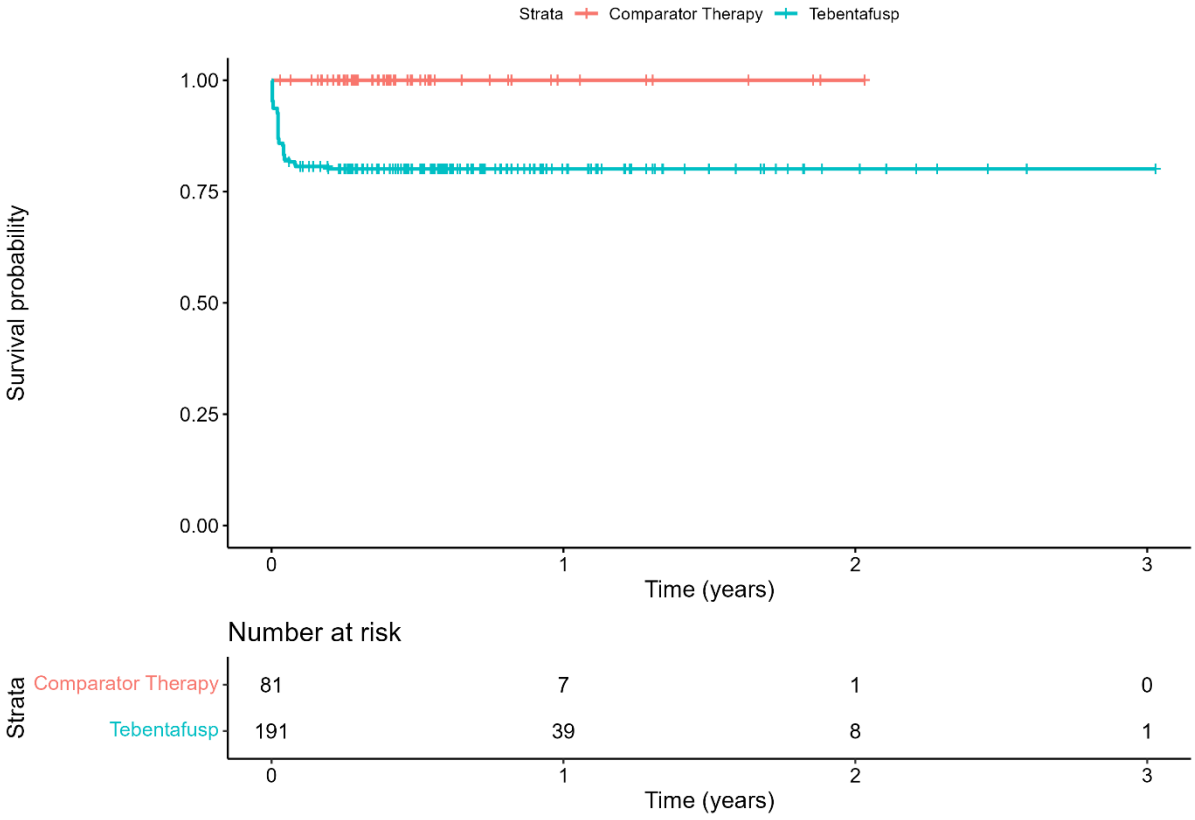
Alter: <65 Jahre



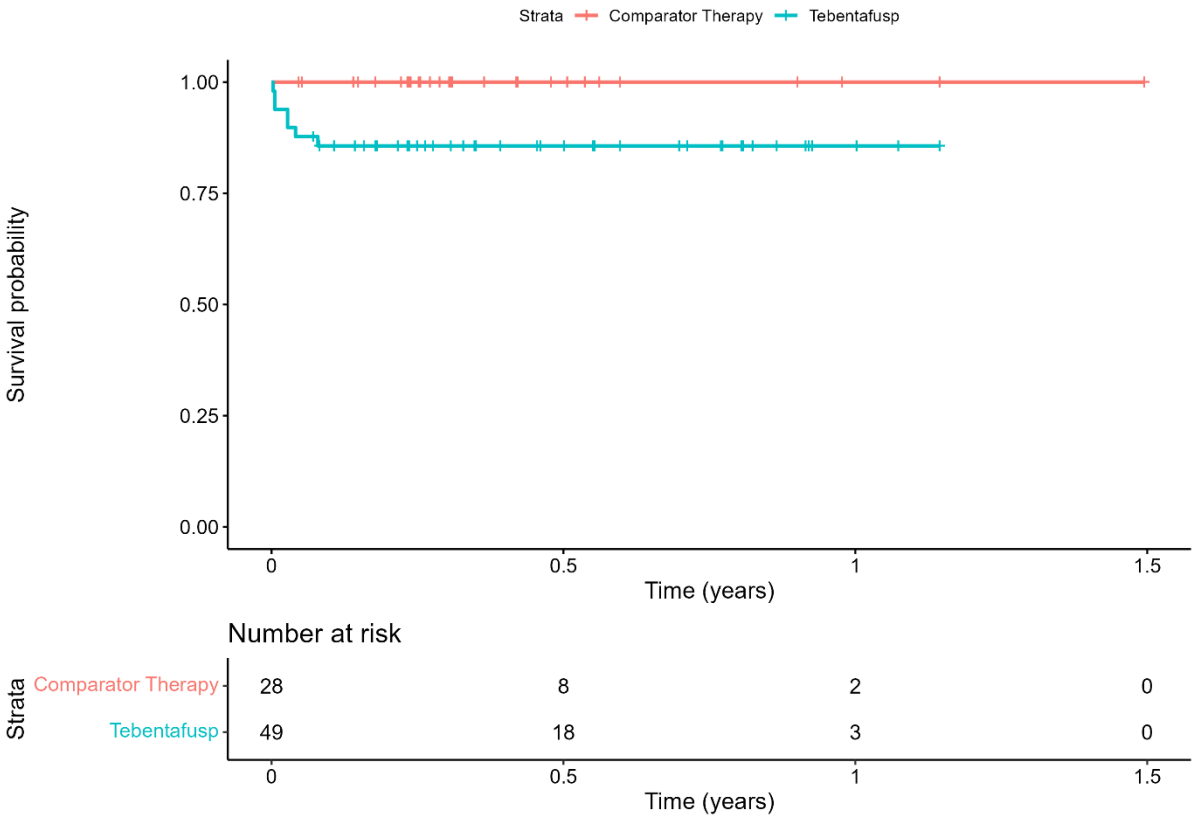
Alter: ≥65 Jahre



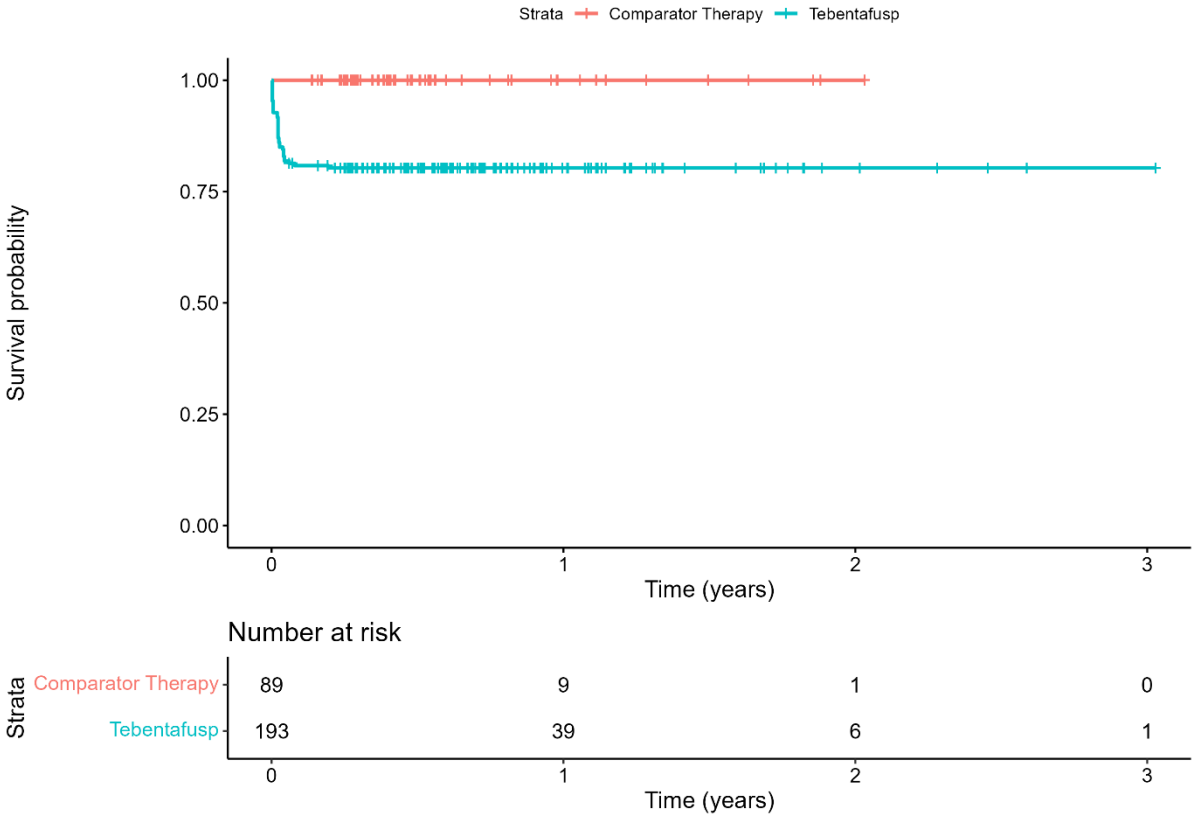
ECOG-Performance-Status: 0



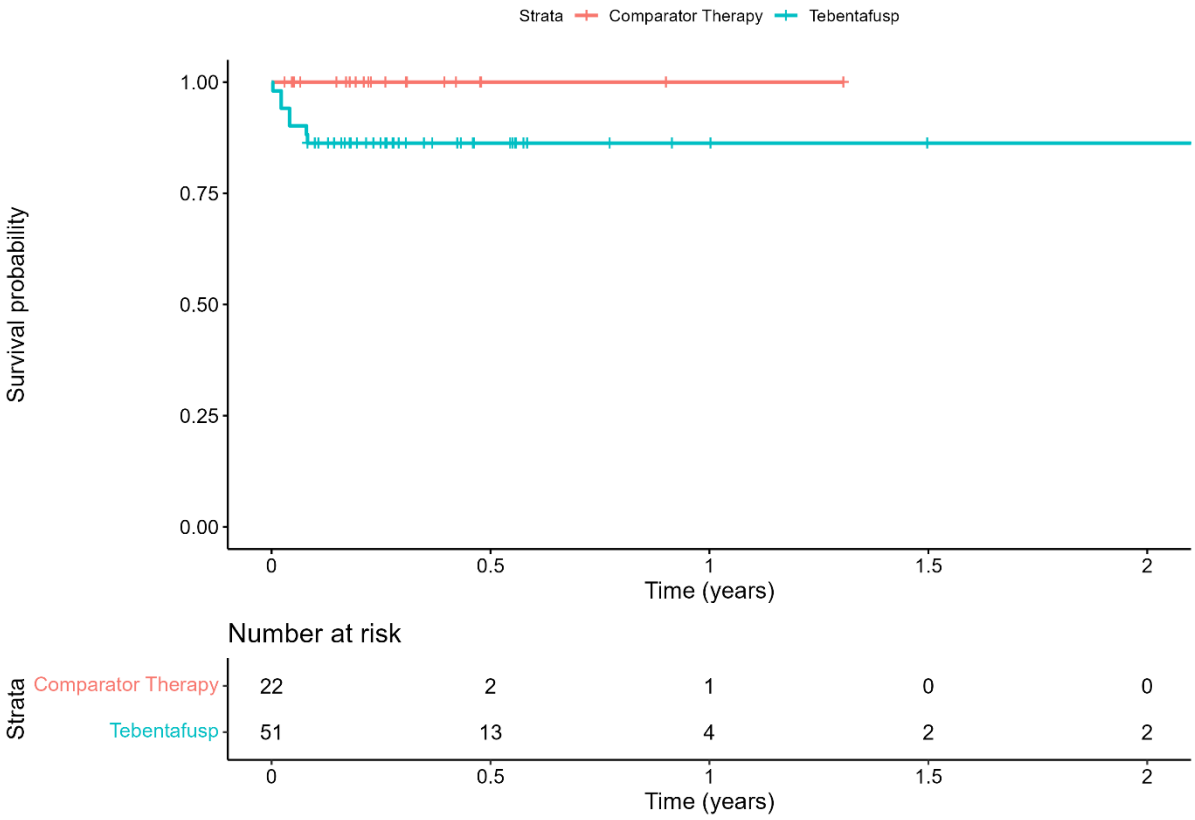
ECOG-Performance-Status: 1



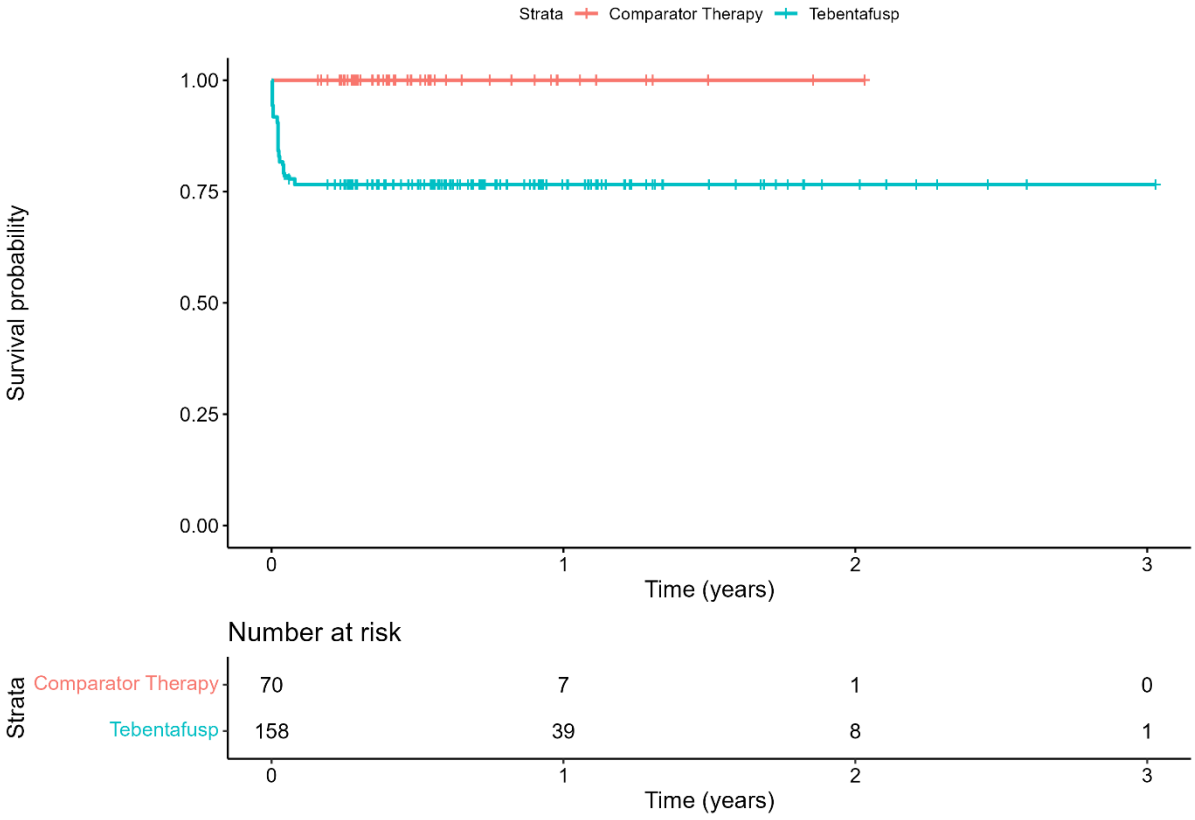
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



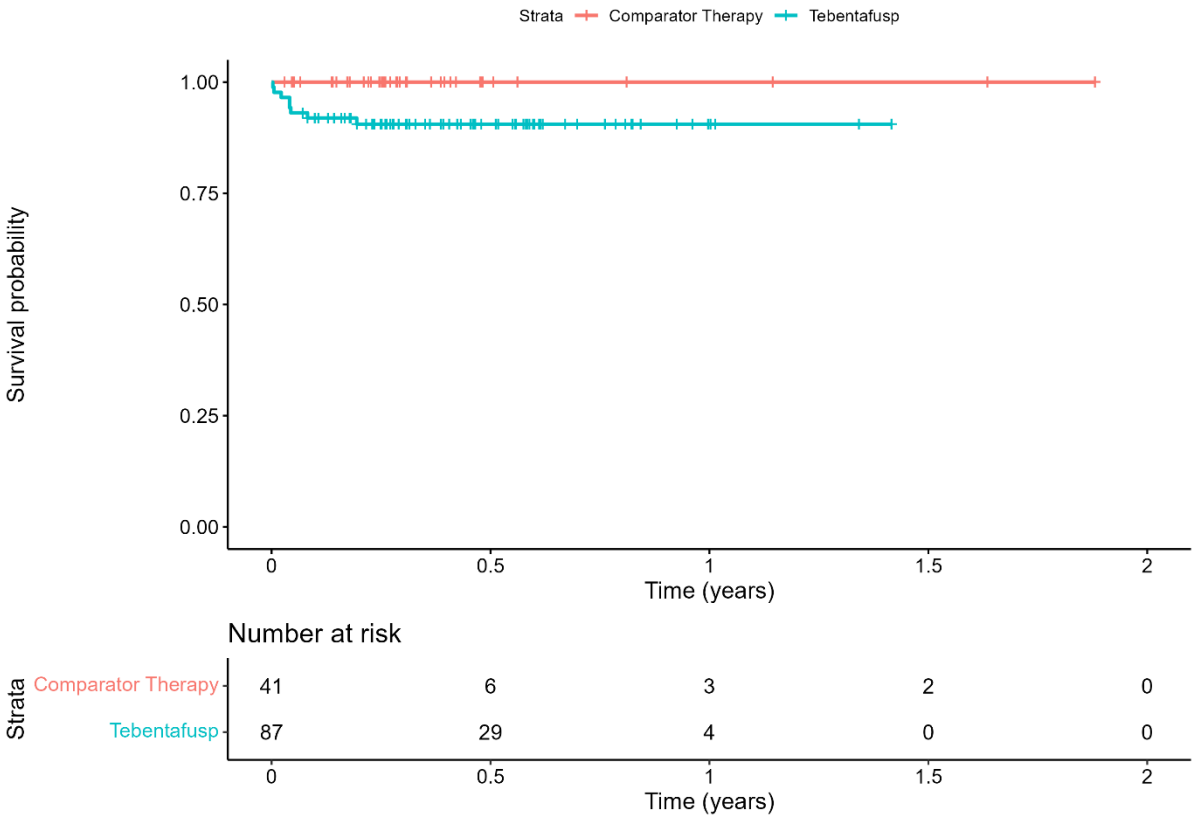
Alkalische Phosphatase (ALP) (Baseline): >ULN



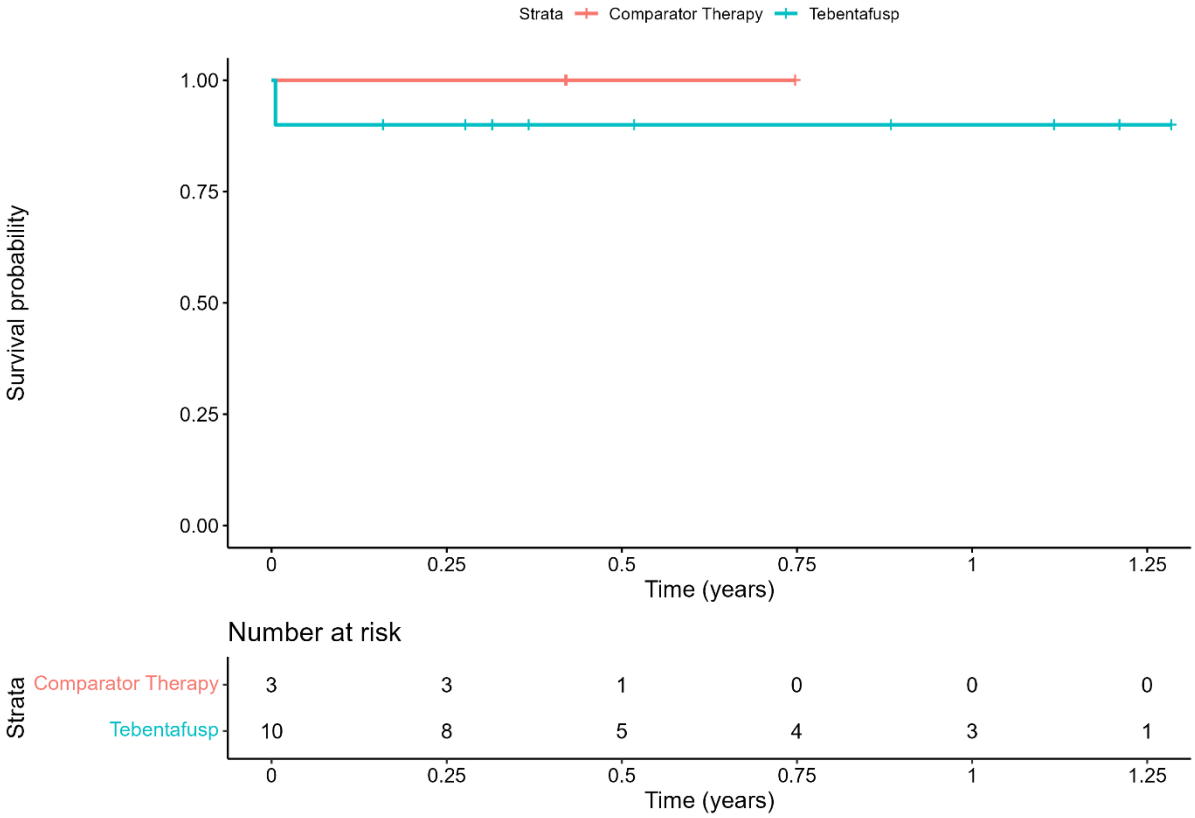
LDH: ≤ULN



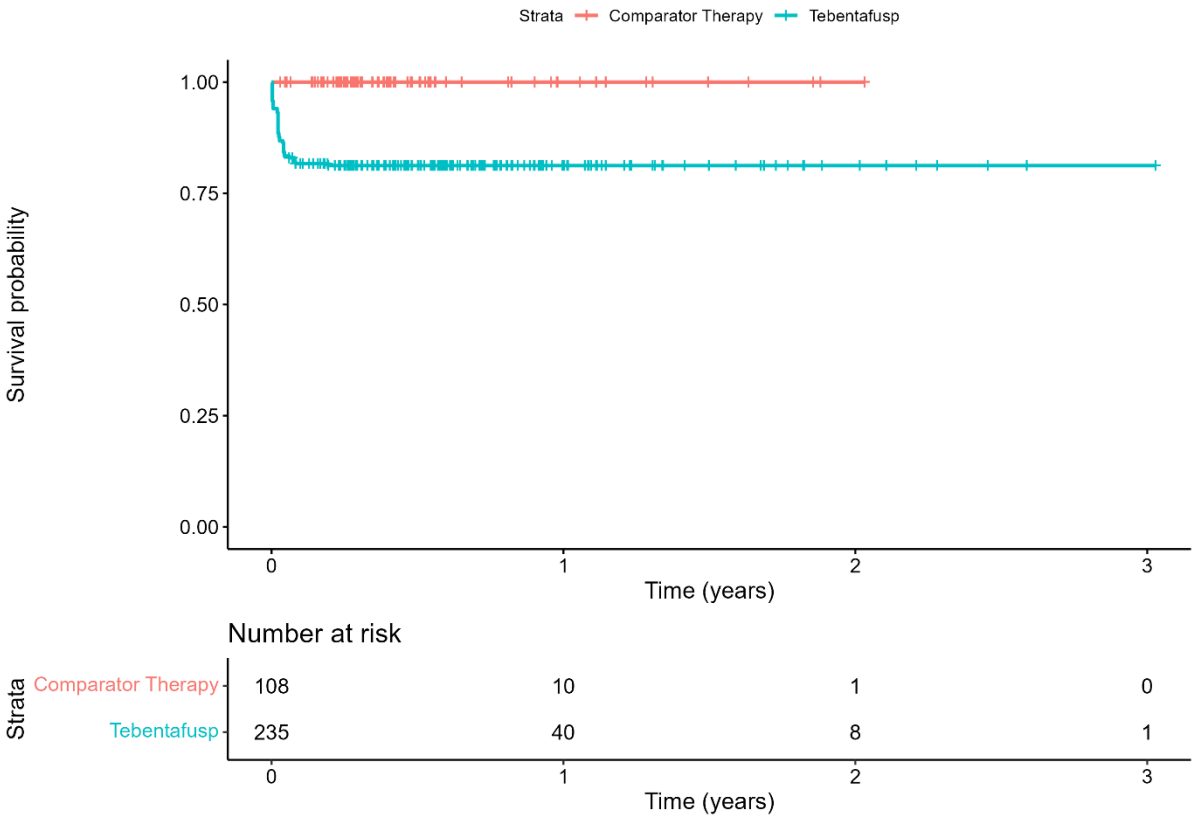
LDH: >ULN



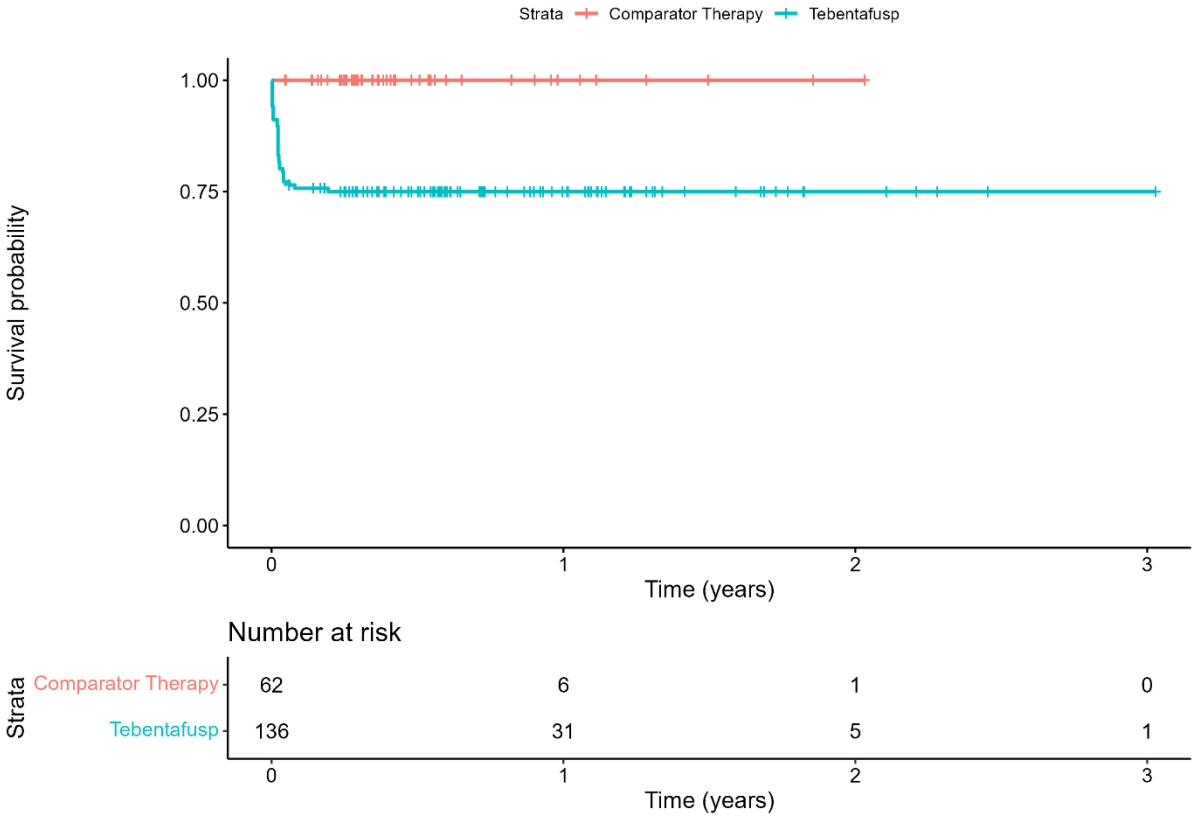
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



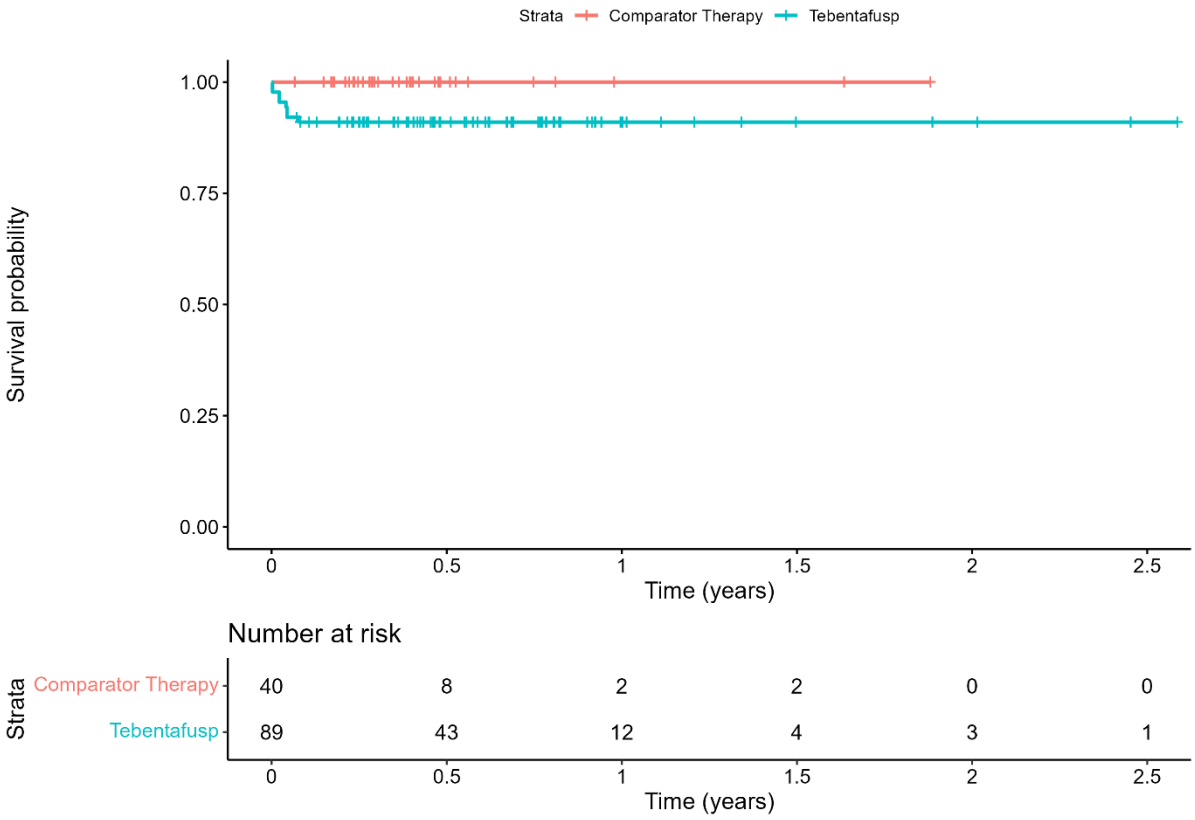
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



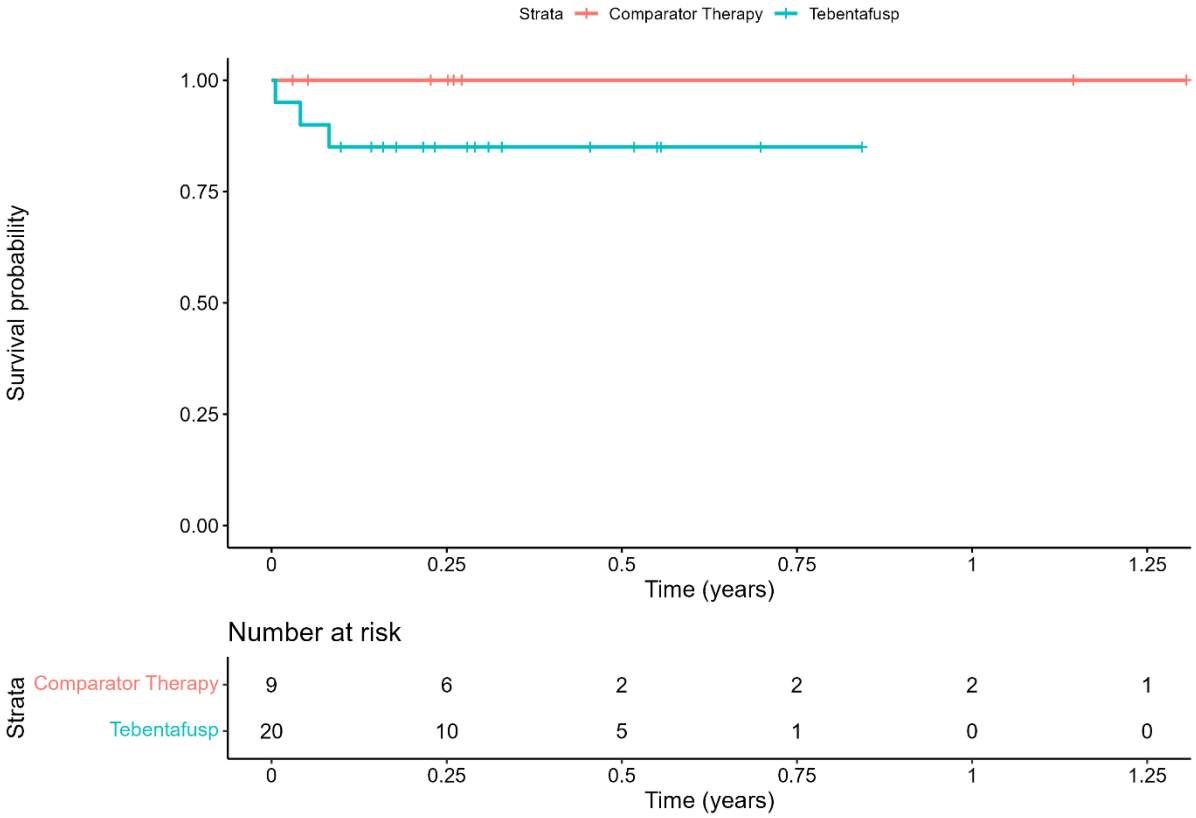
Größte metastatische Läsion (Baseline): ≤3,0 cm



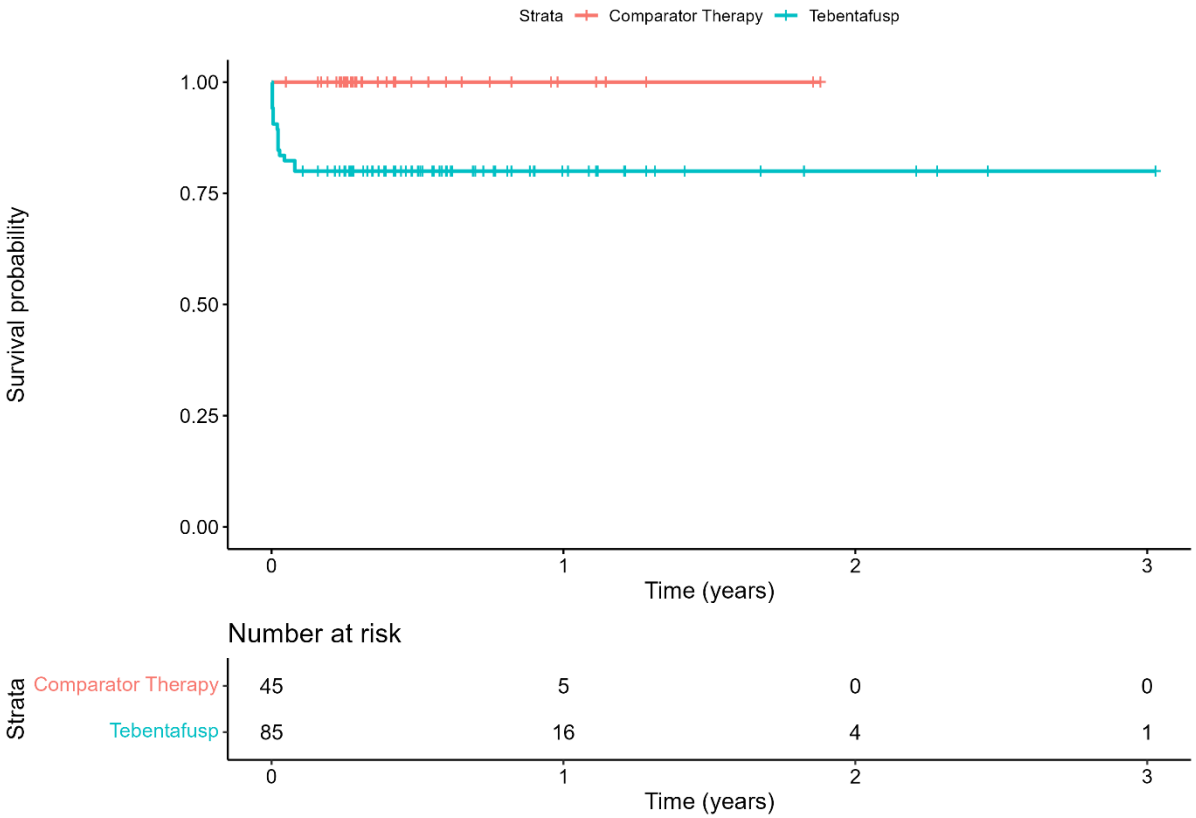
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



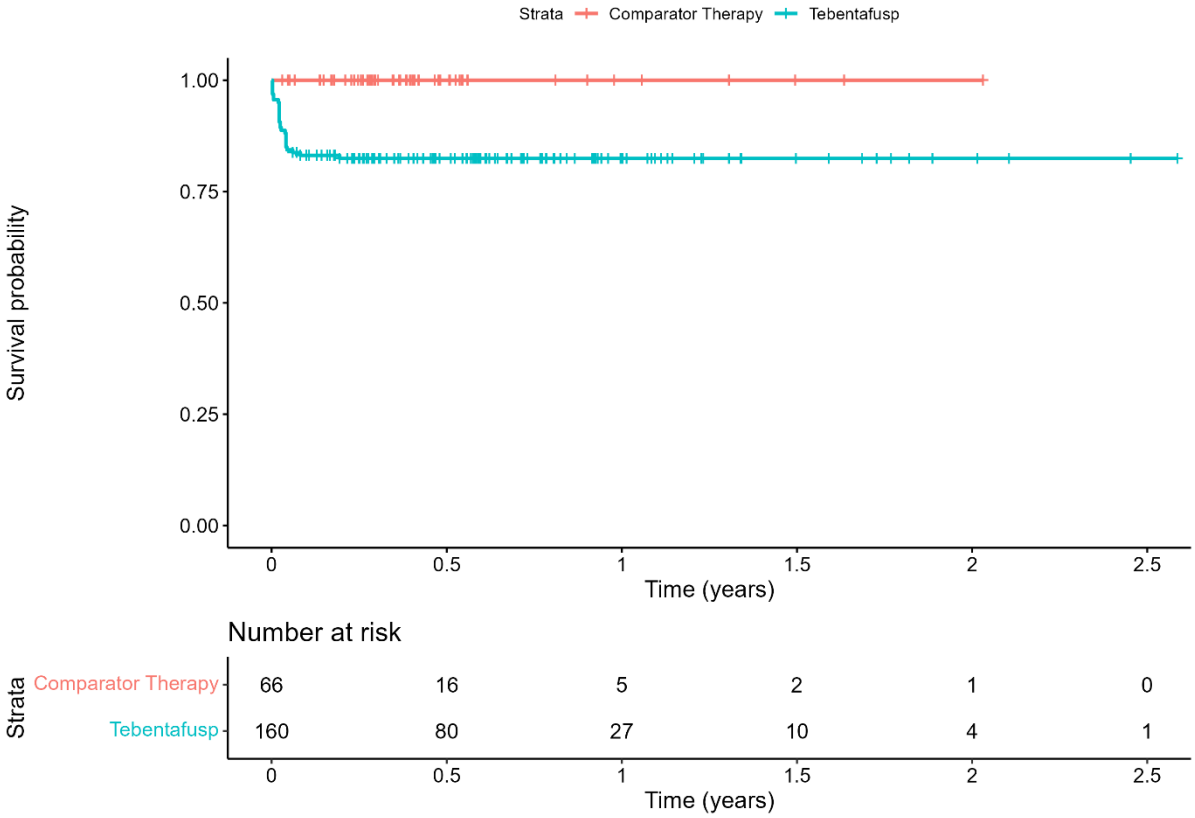
Größte metastatische Läsion (Baseline): ≥8,1 cm



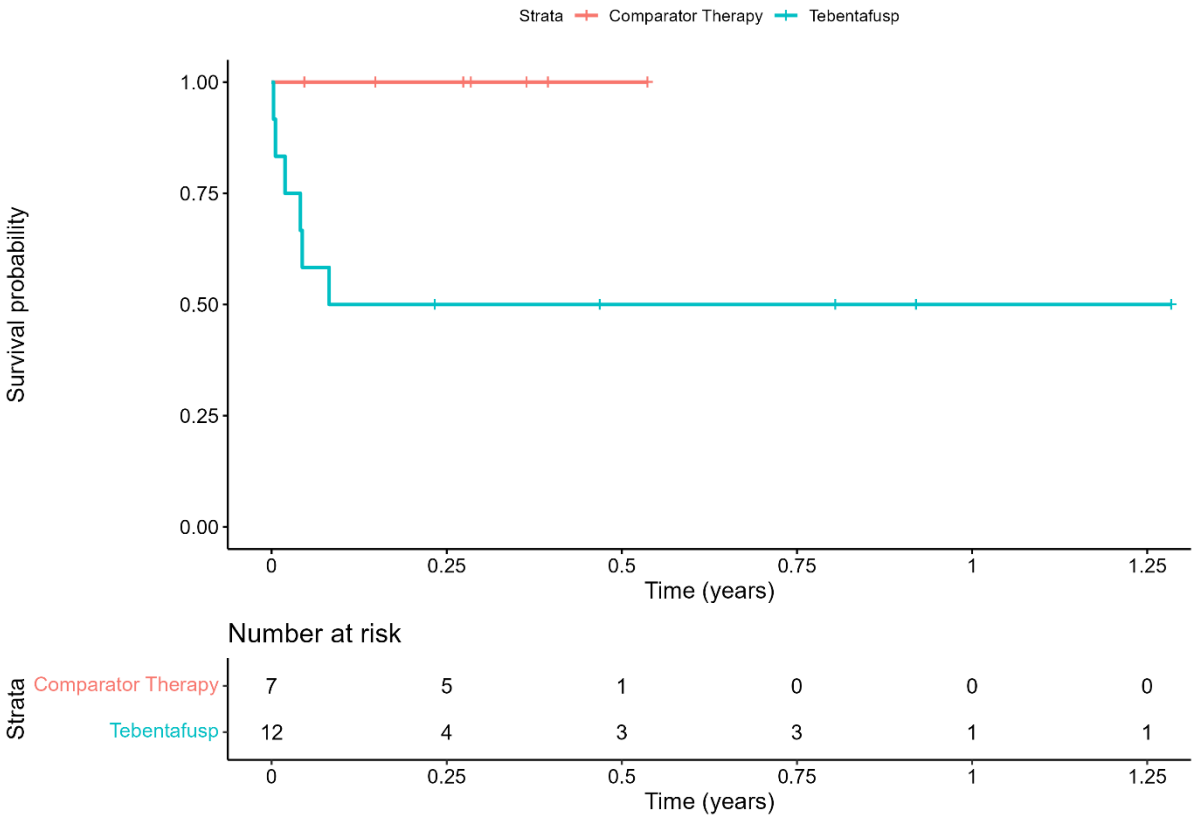
Region: Nordamerika



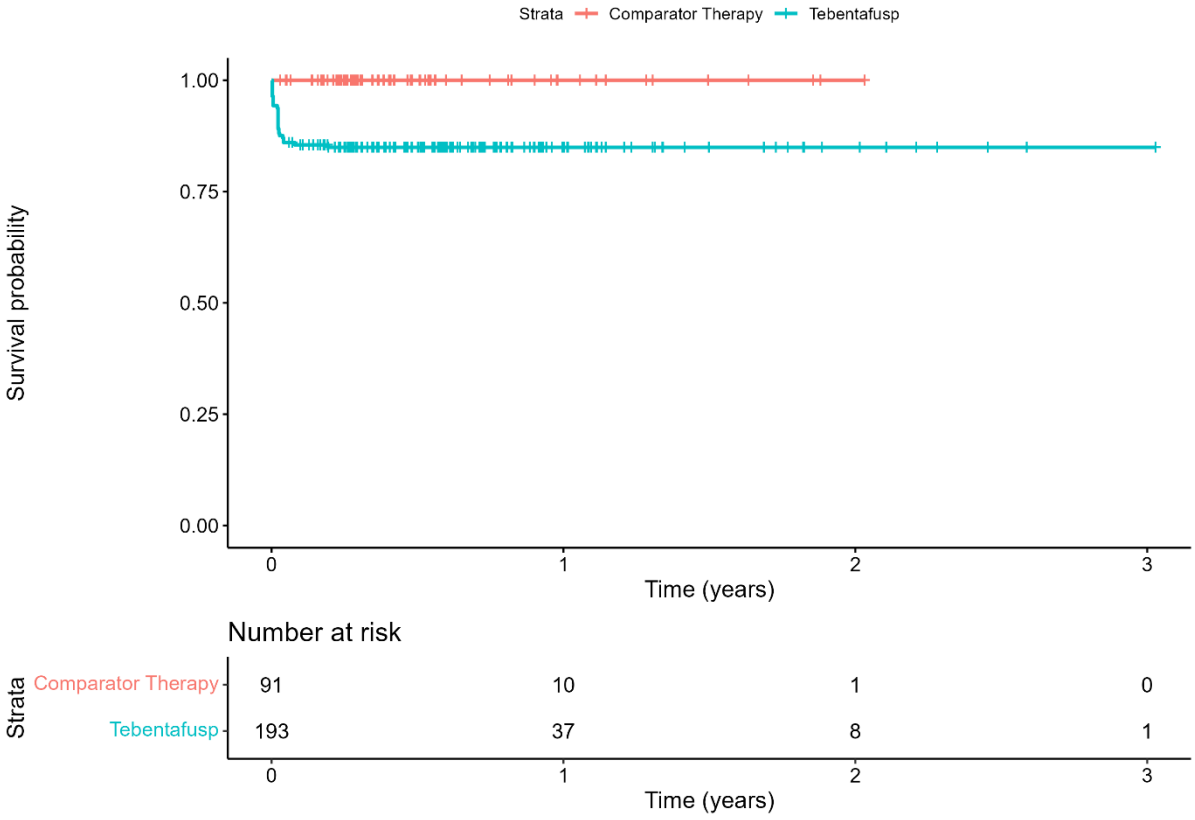
Region: Nicht-Nordamerika



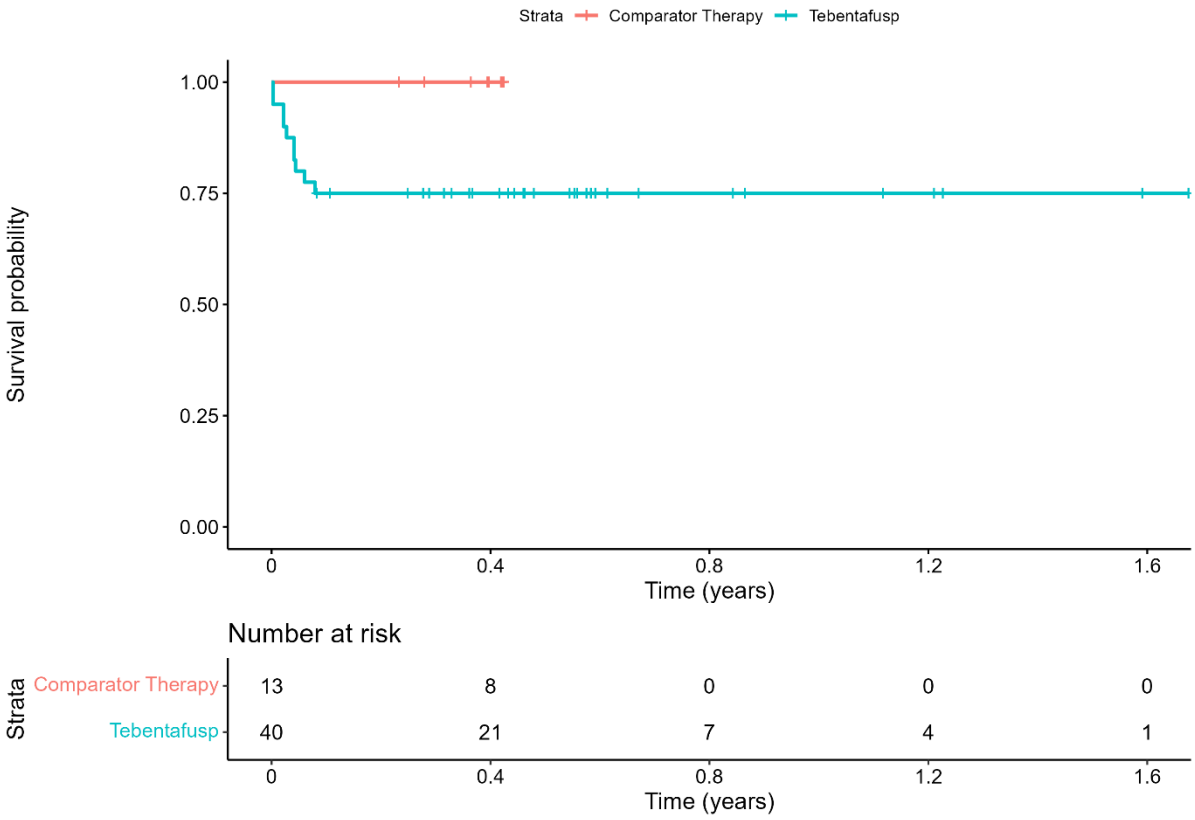
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

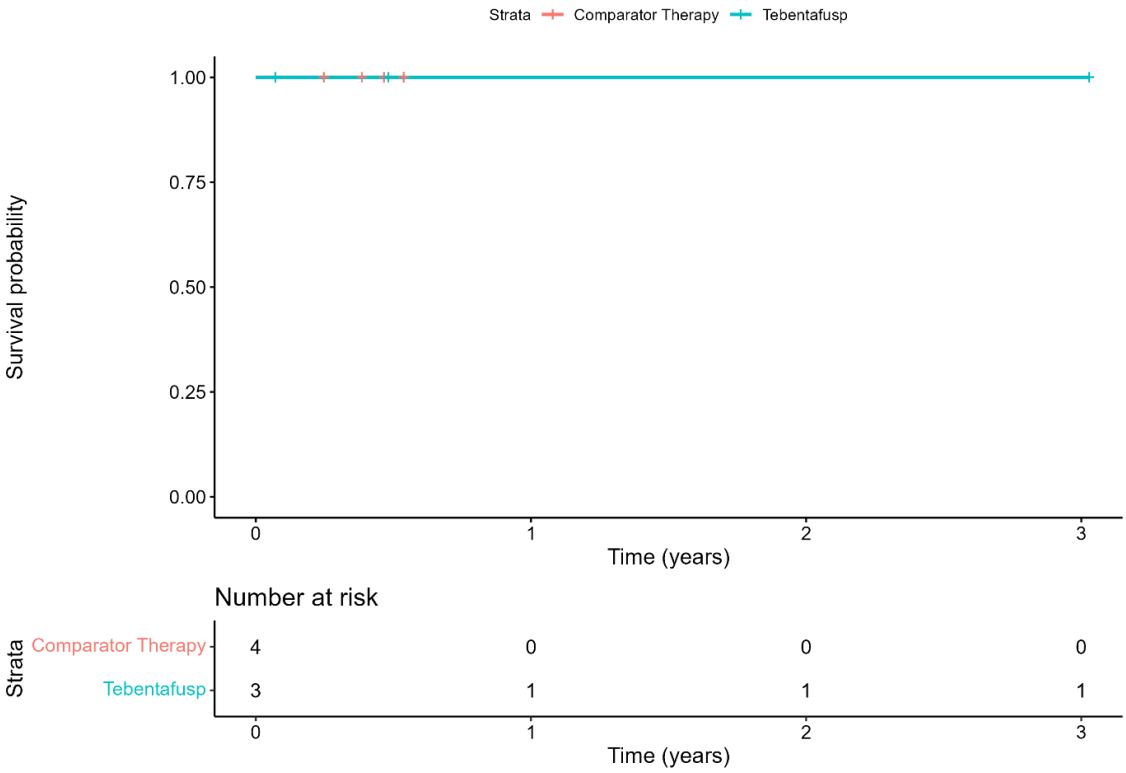


Vorauswahl der Chemotherapie: Ipilimumab

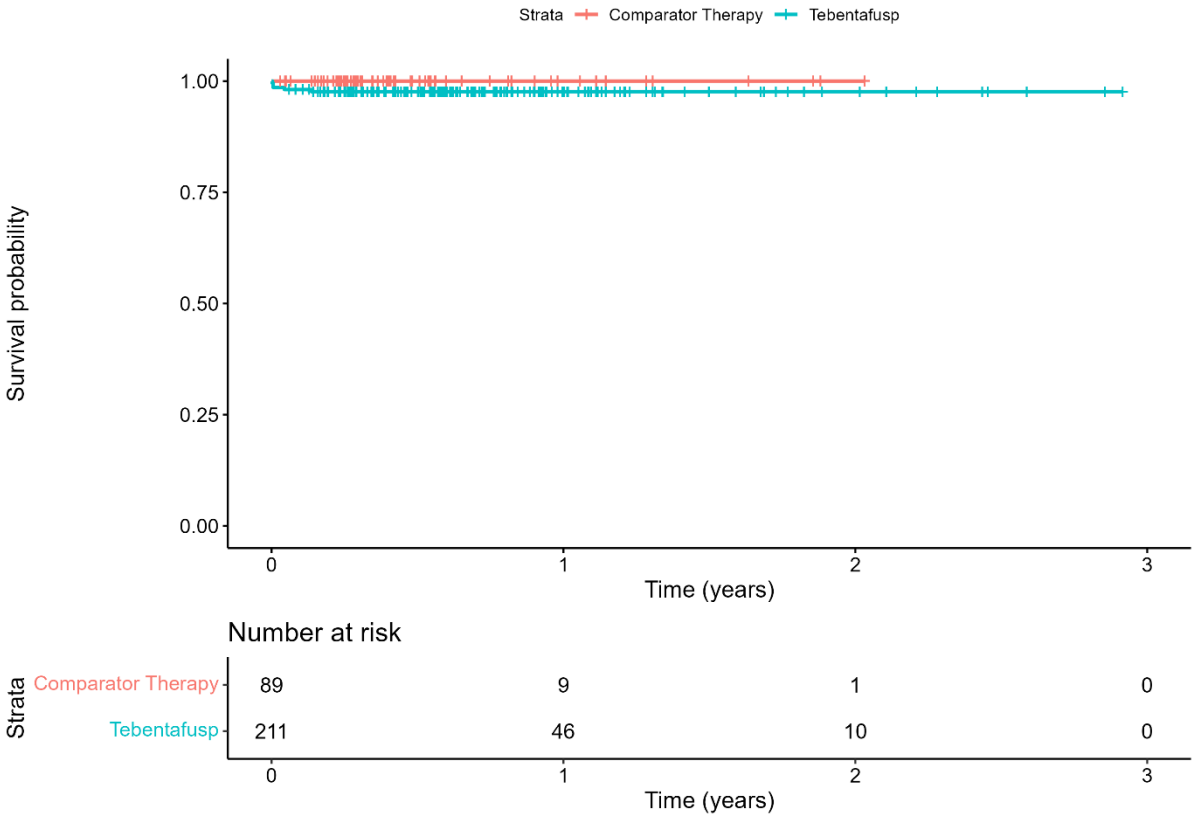


48.1 Schwerwiegender Hautausschlag (Tabelle 4-107)

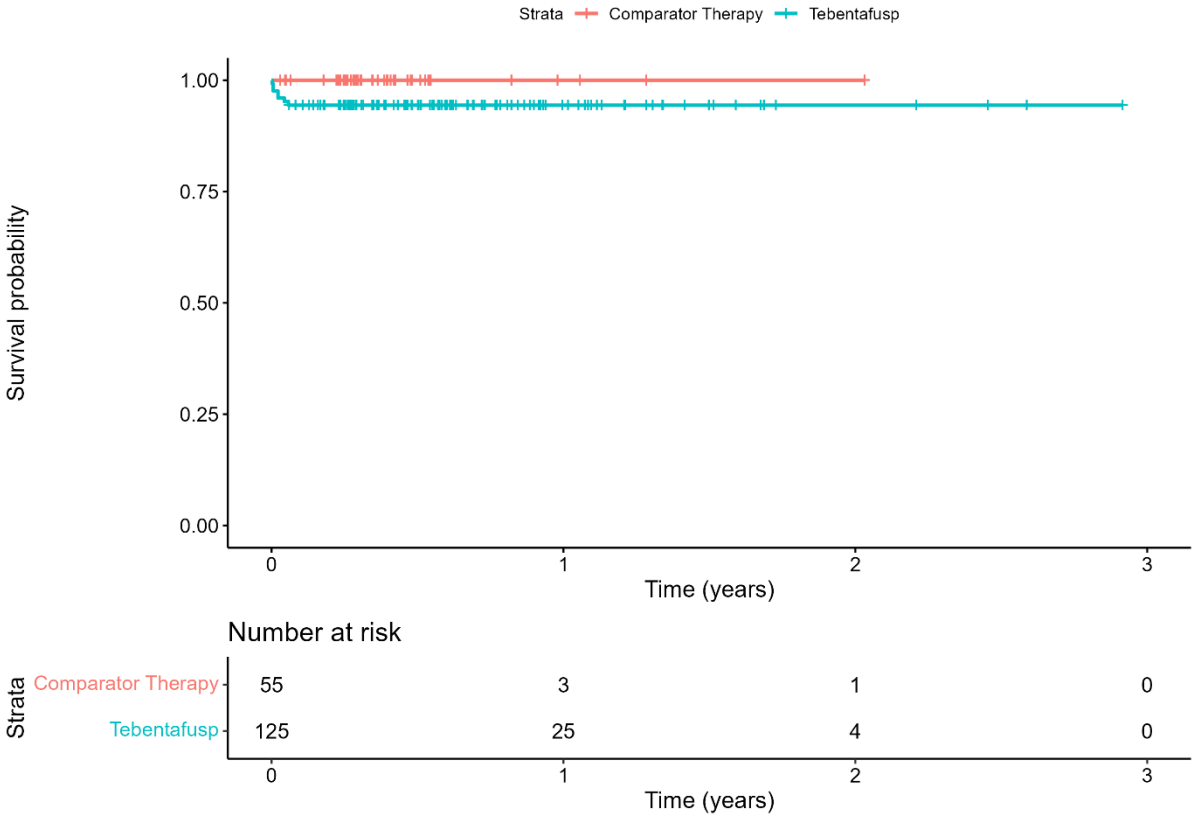
Herkunft: Hispanisch



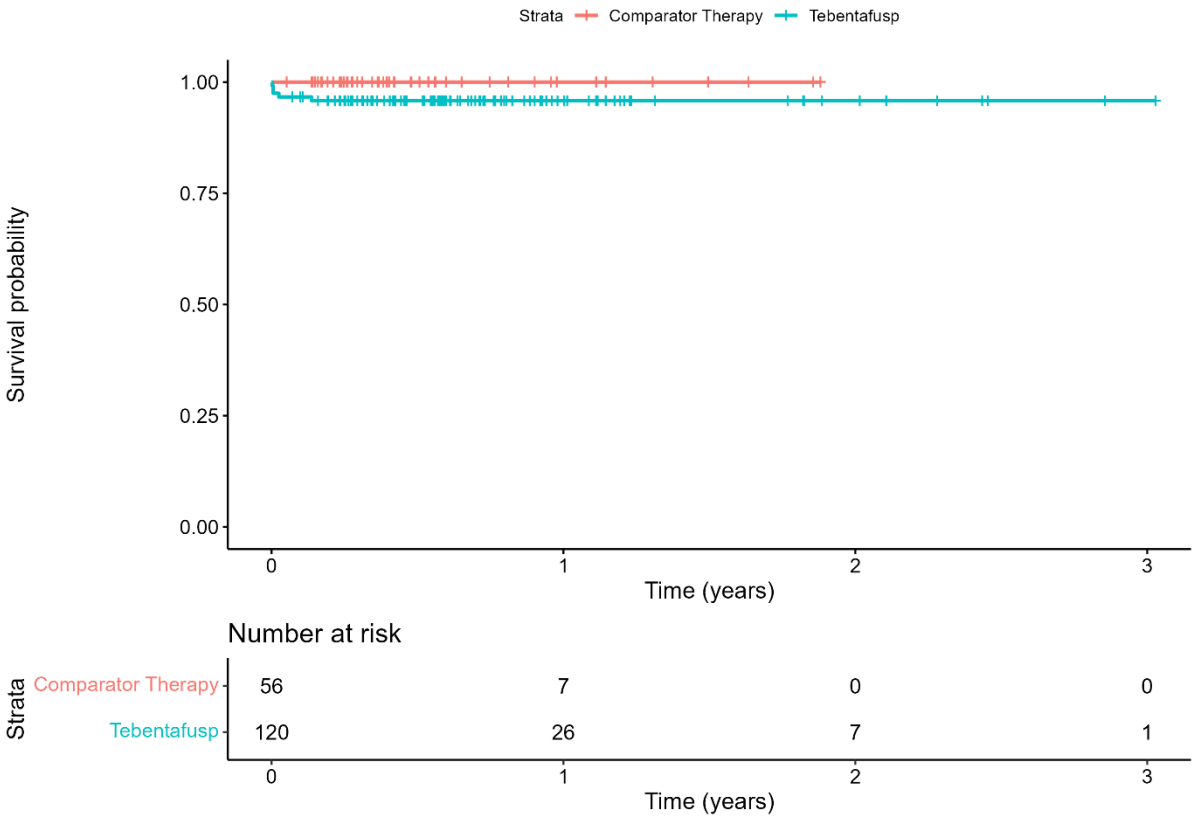
Herkunft: Nicht-hispanisch



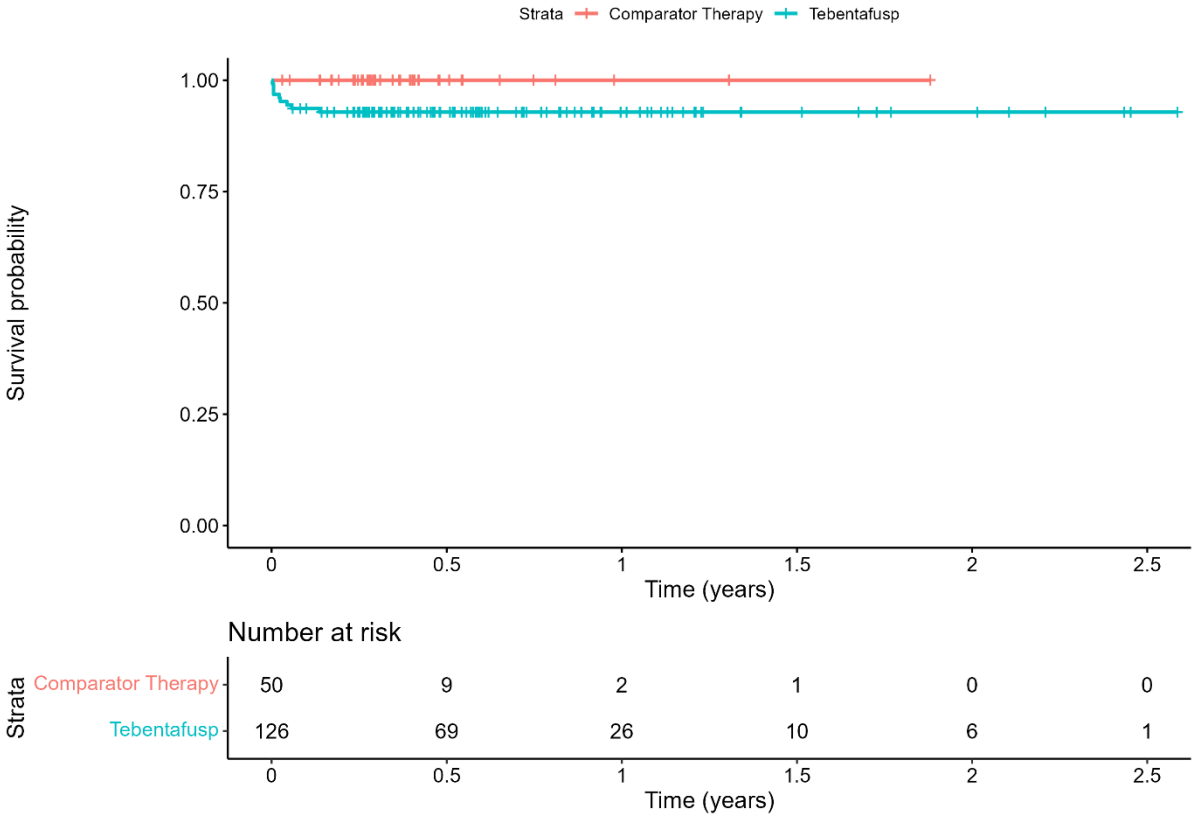
Geschlecht: Männlich



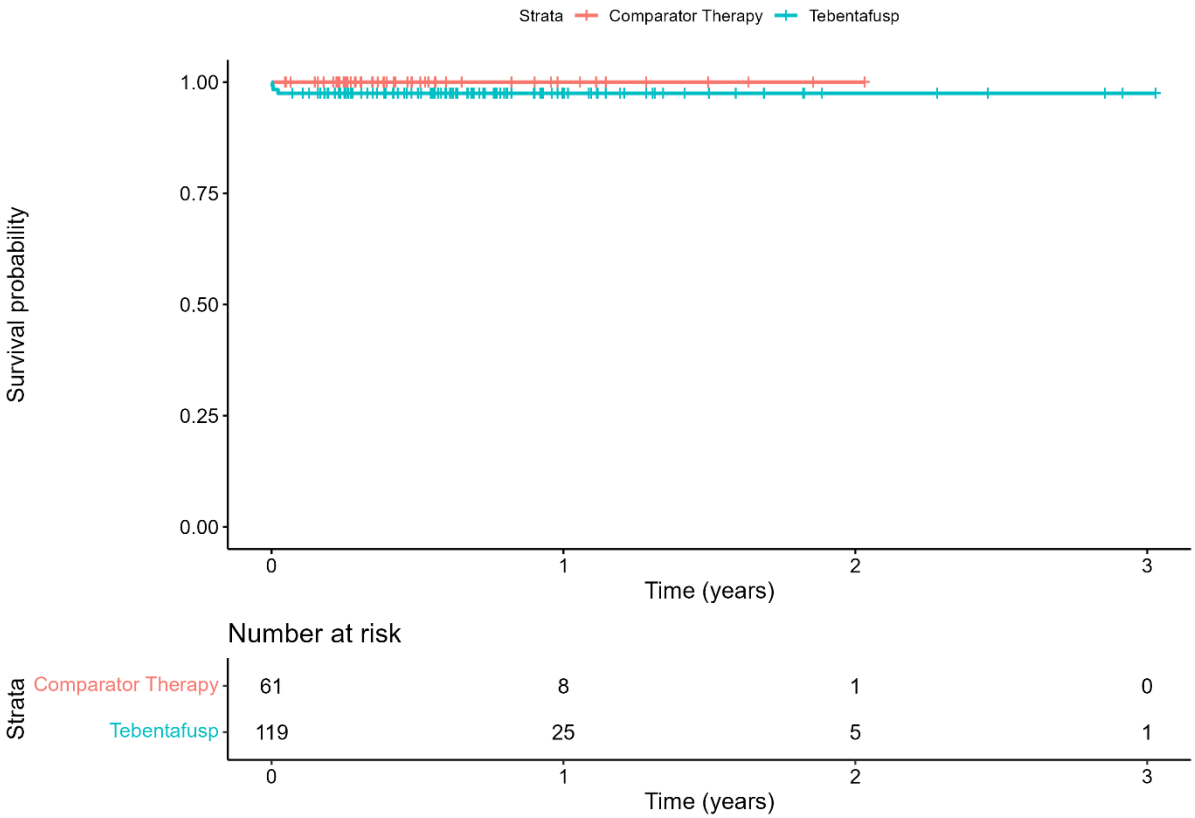
Geschlecht: Weiblich



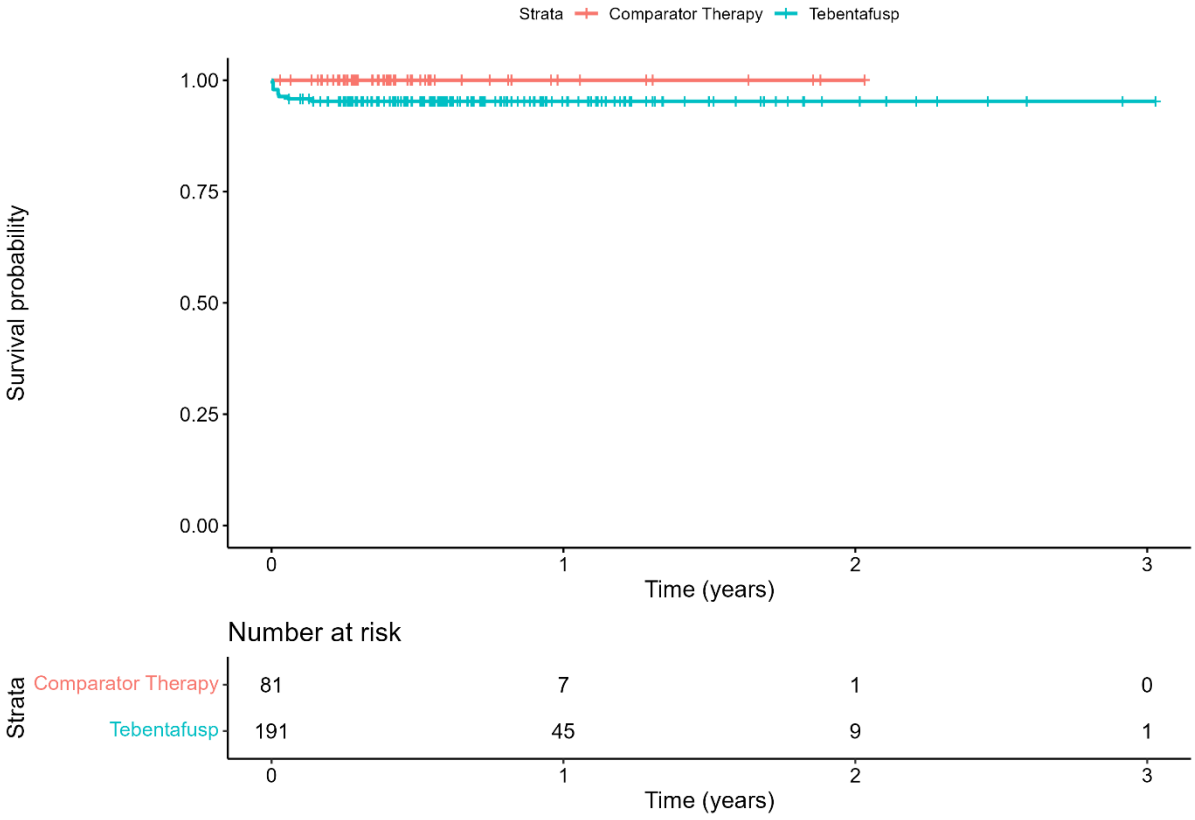
Alter: <65 Jahre



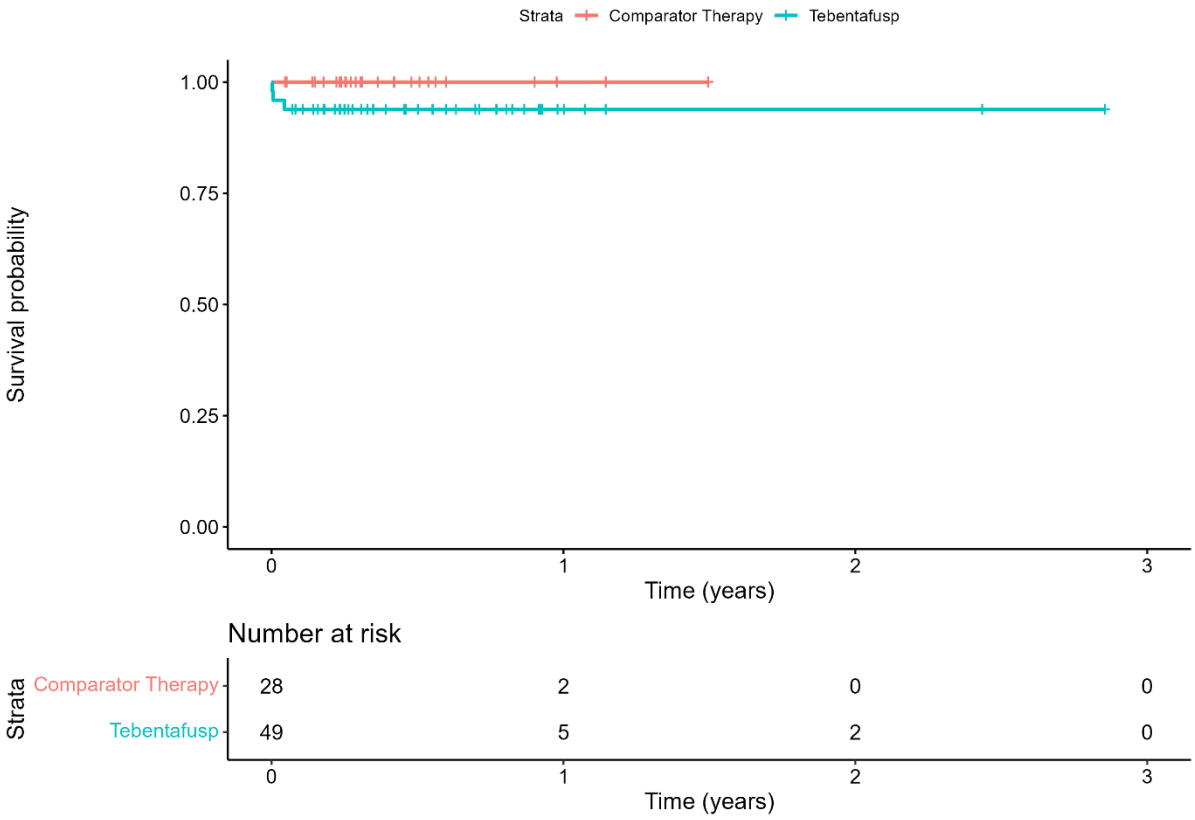
Alter: ≥65 Jahre



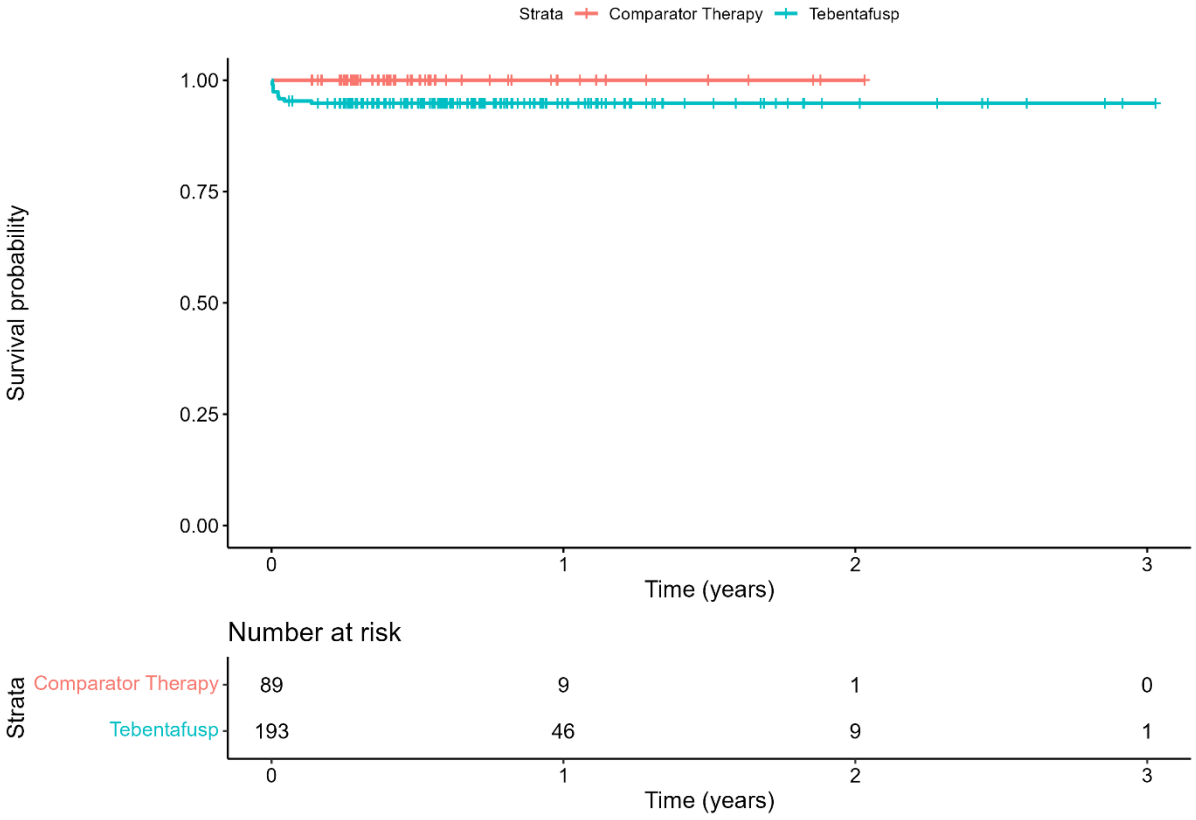
ECOG-Performance-Status: 0



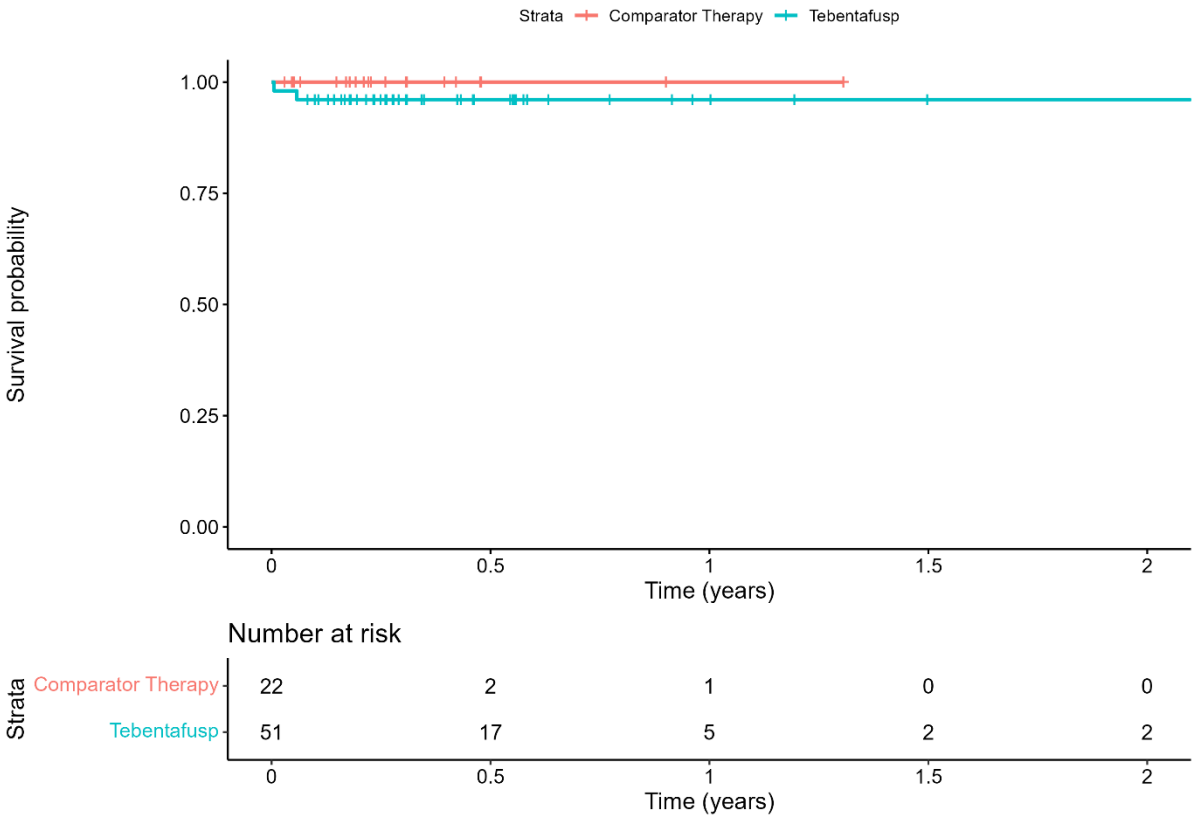
ECOG-Performance-Status: 1



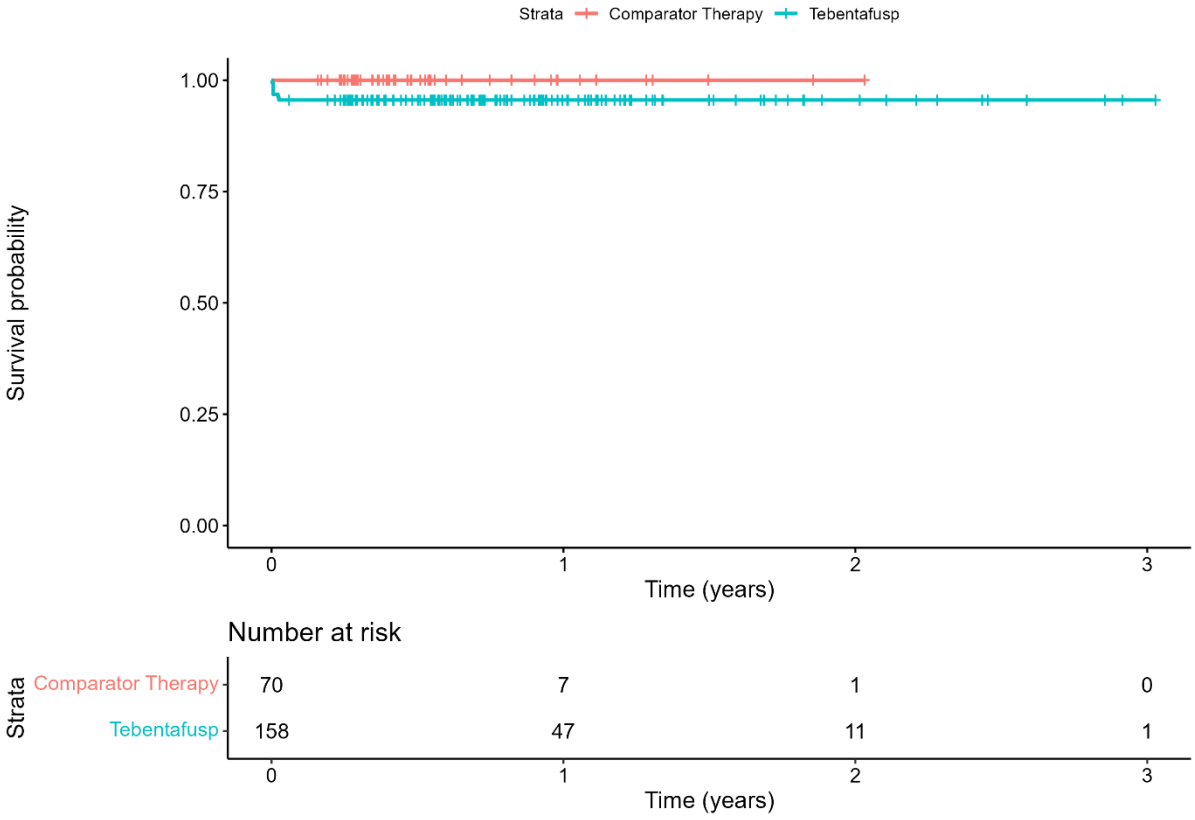
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



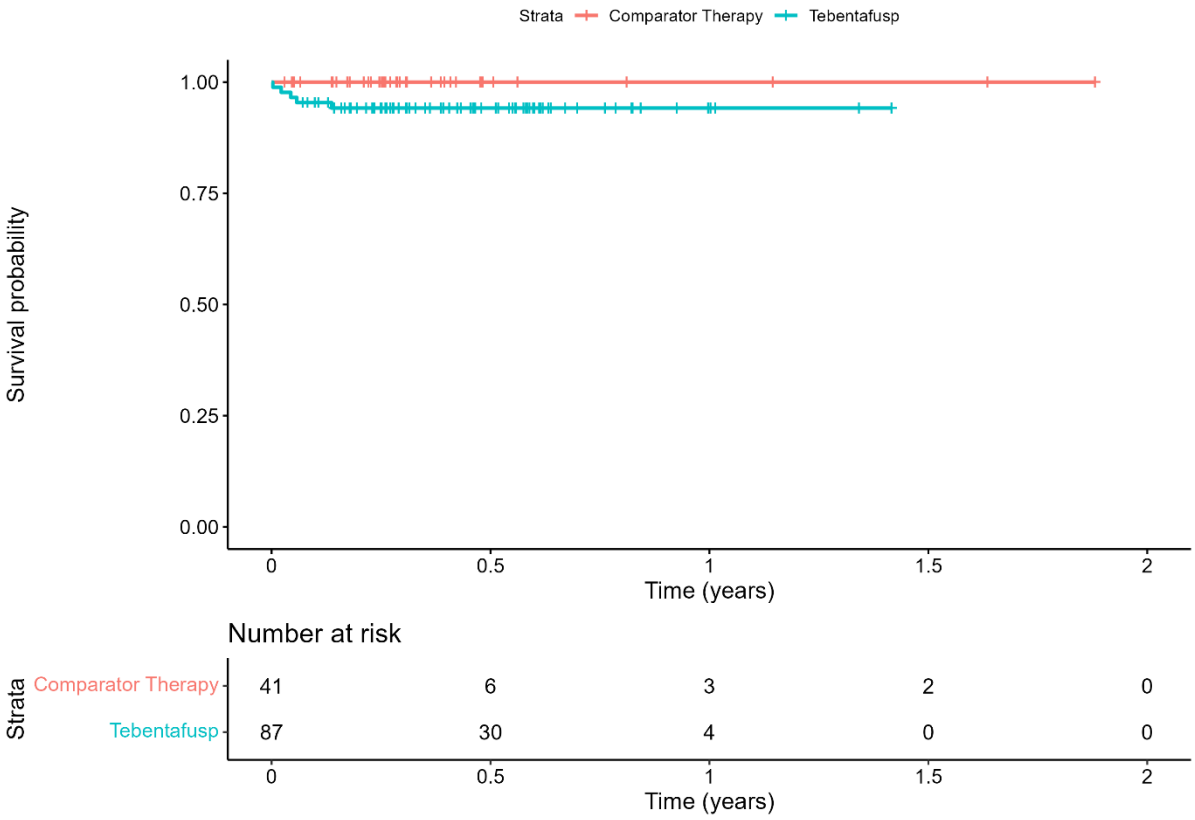
Alkalische Phosphatase (ALP) (Baseline): >ULN



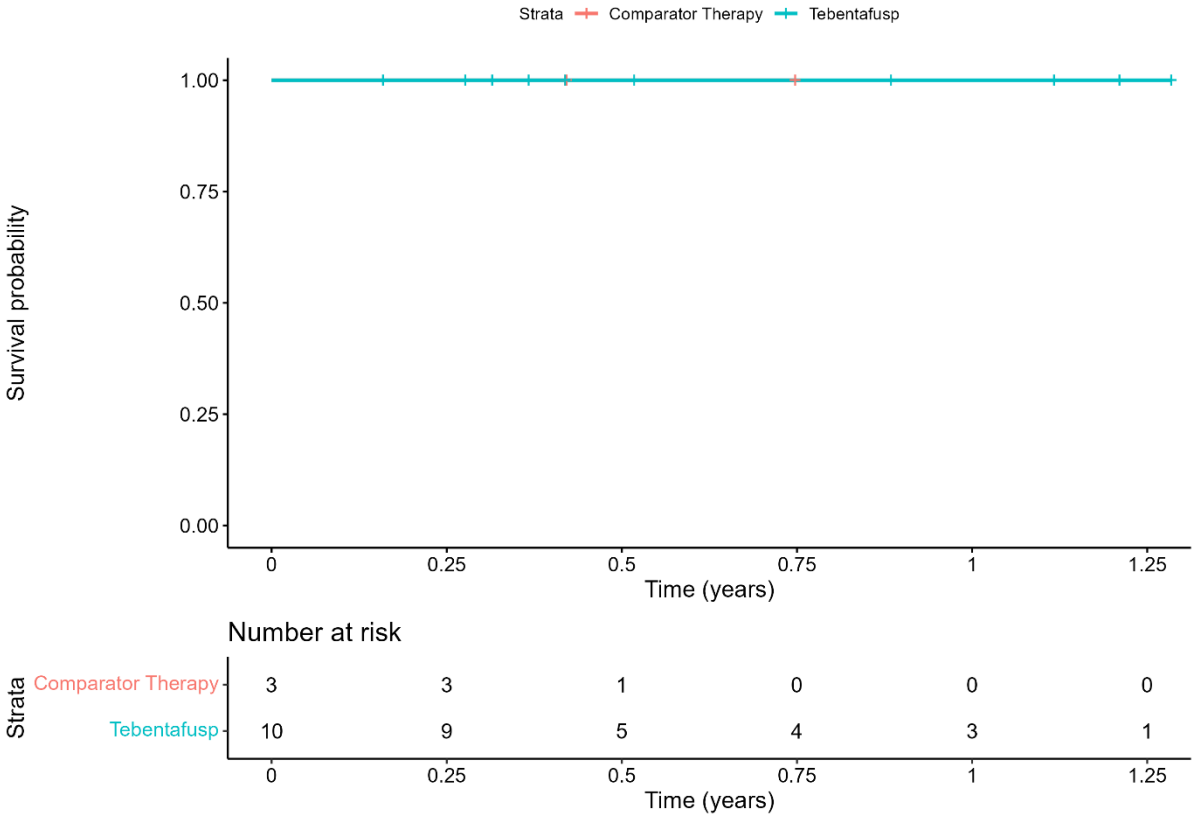
LDH: ≤ULN



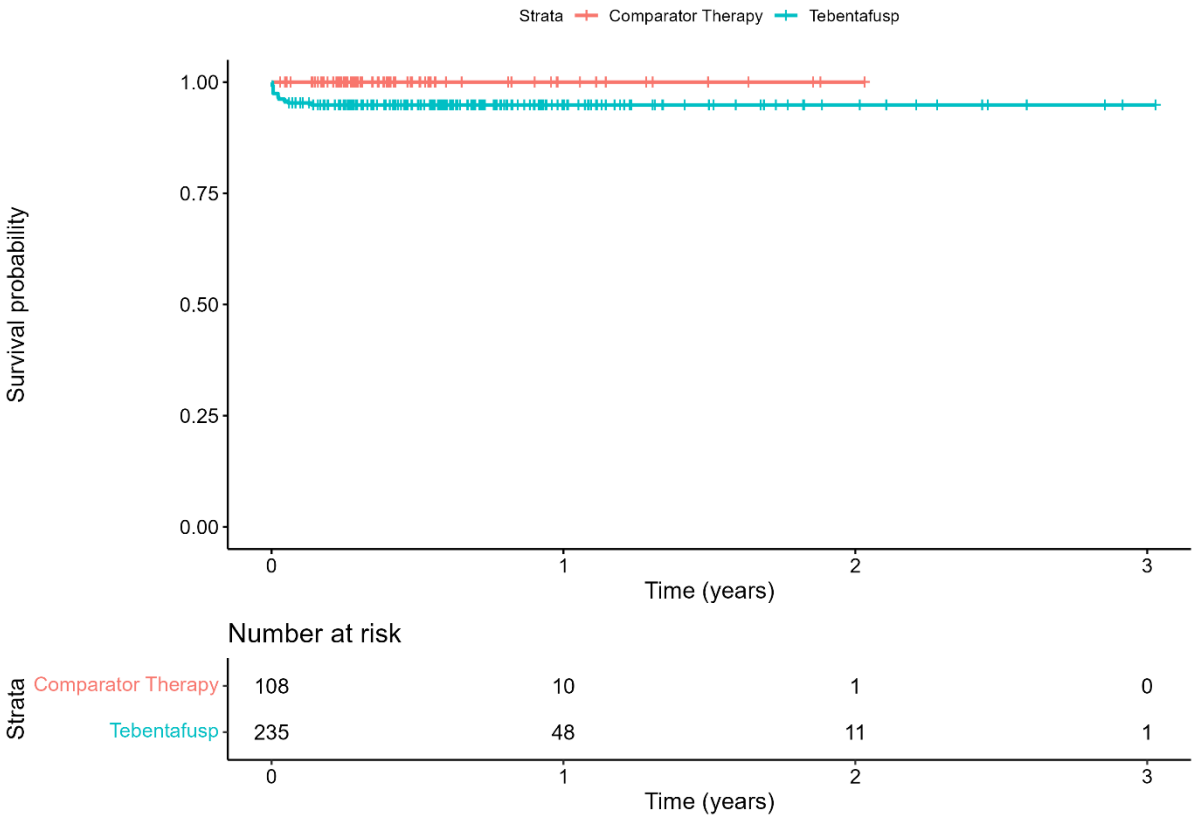
LDH: >ULN



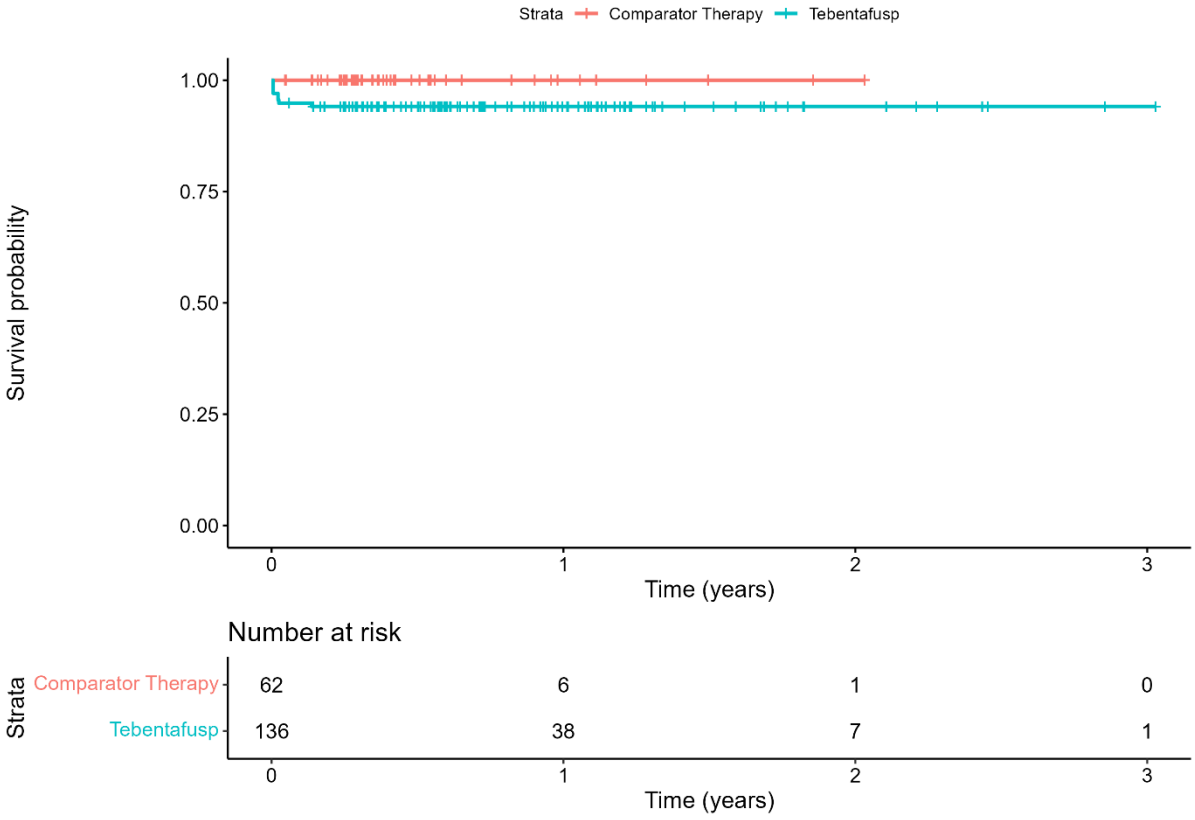
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



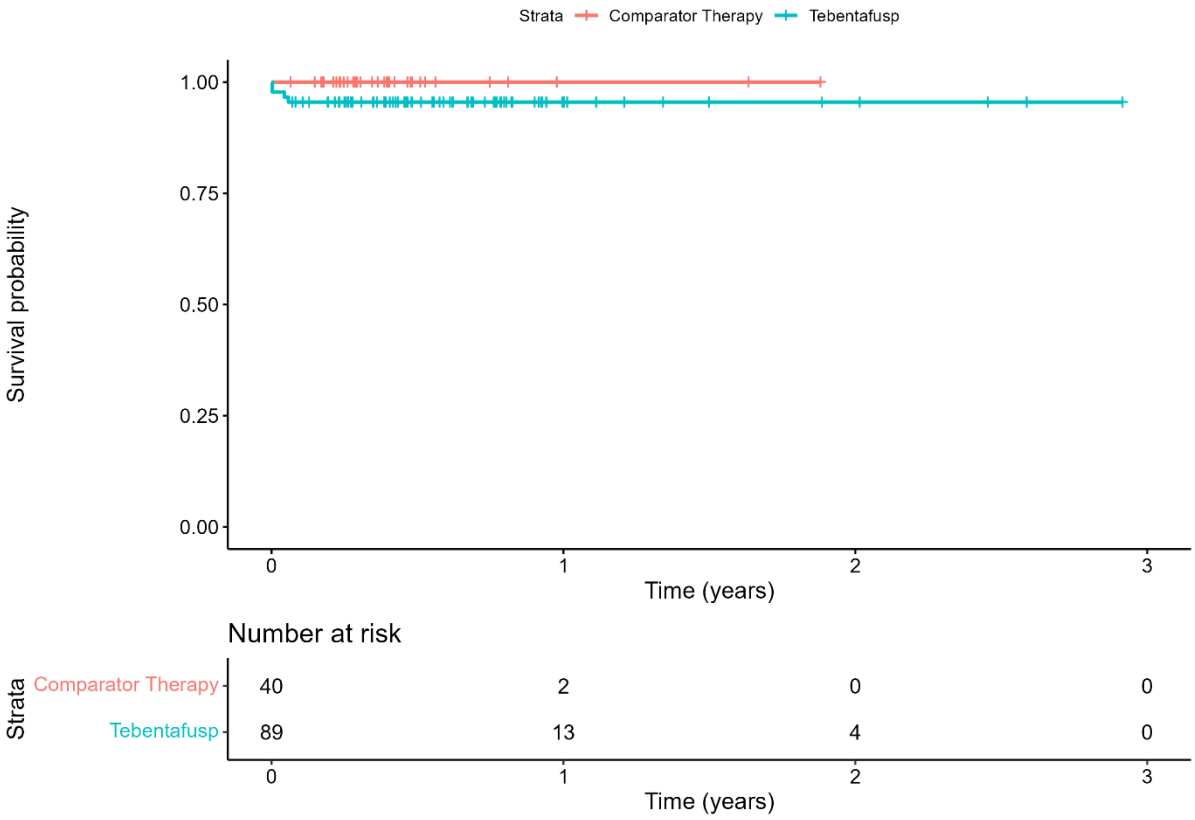
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



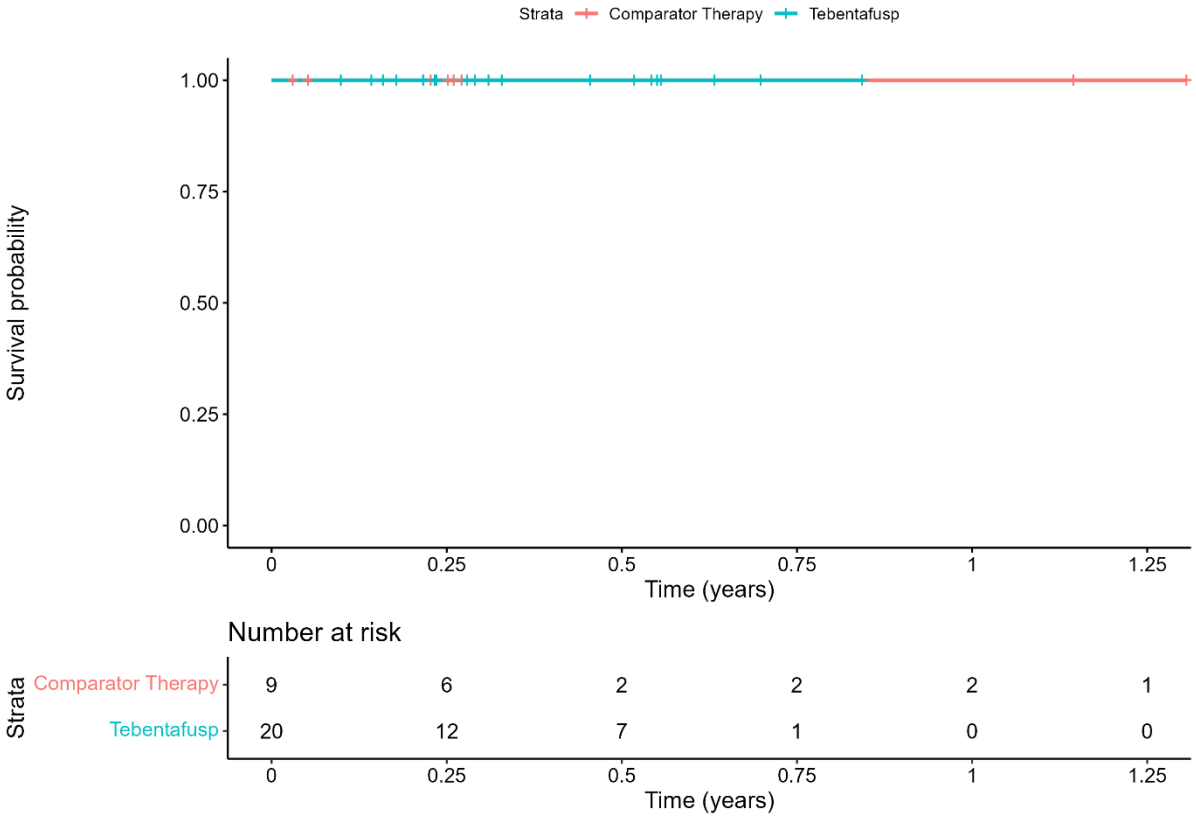
Größte metastatische Läsion (Baseline): ≤3,0 cm



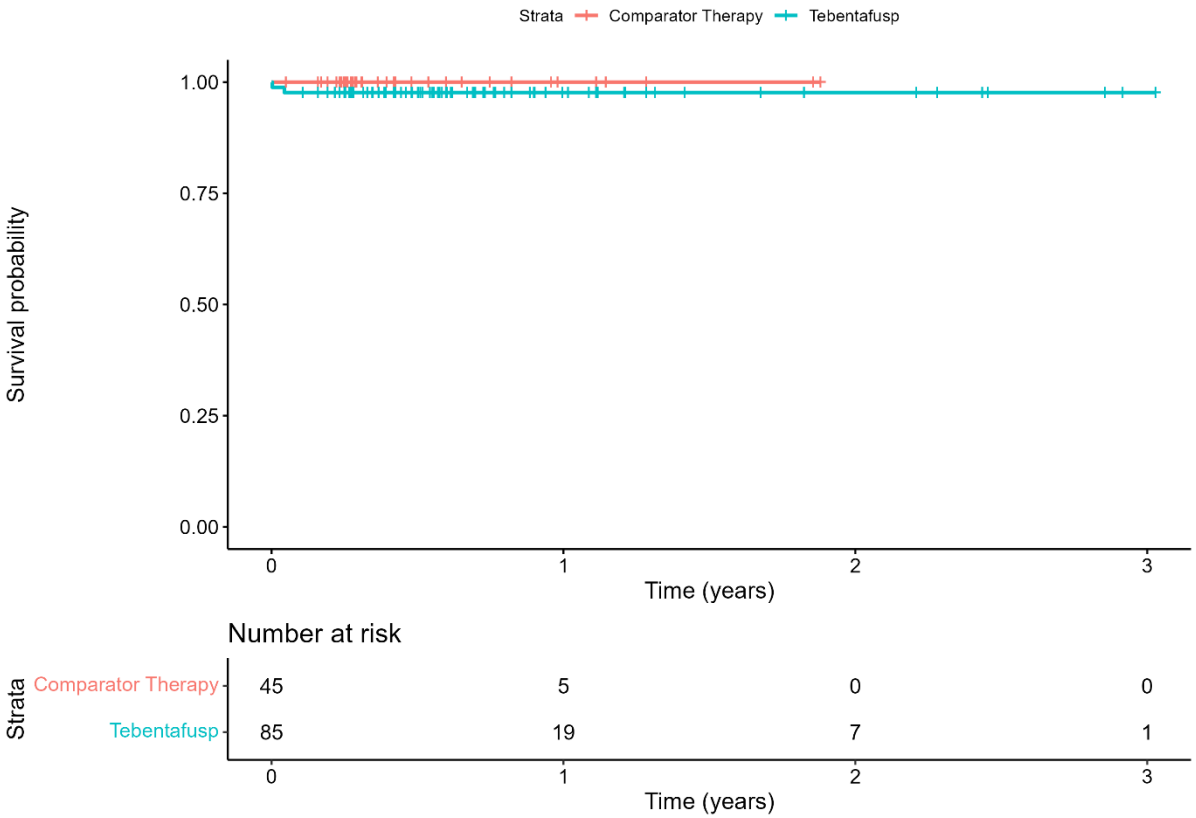
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



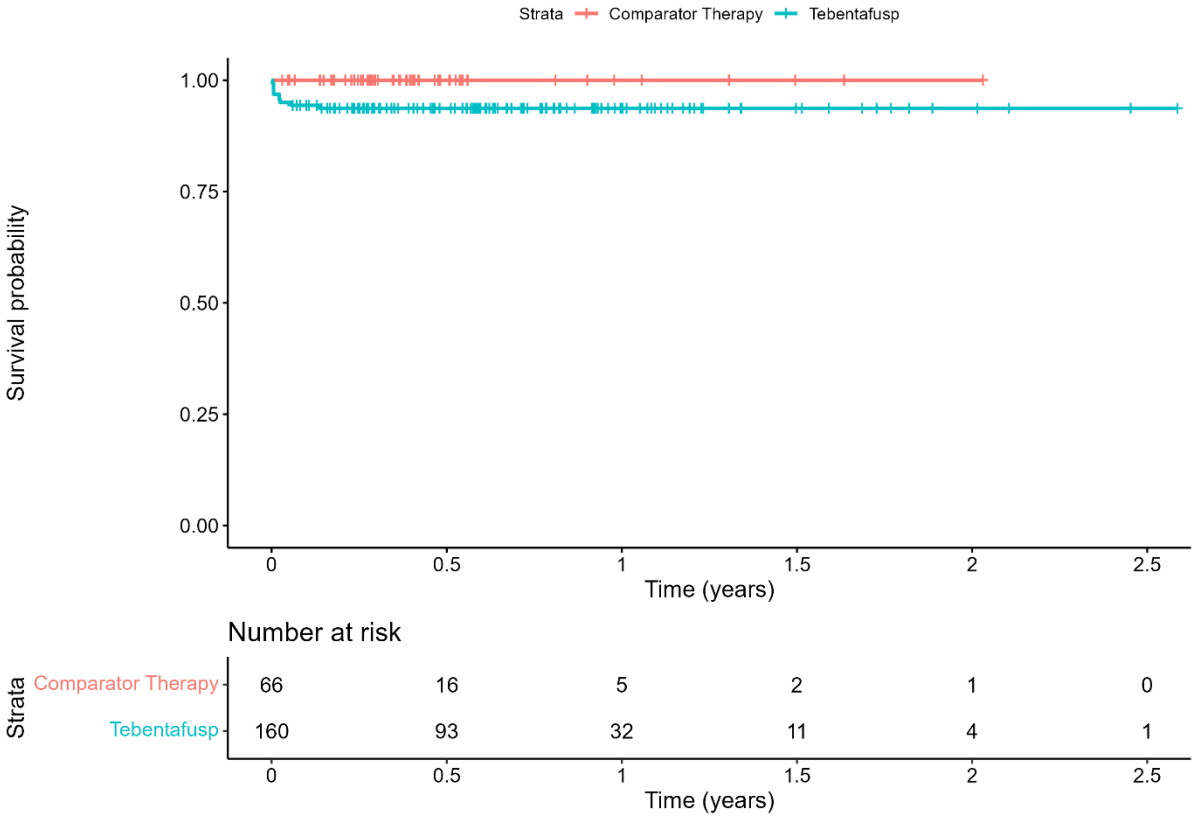
Größte metastatische Läsion (Baseline): ≥8,1 cm



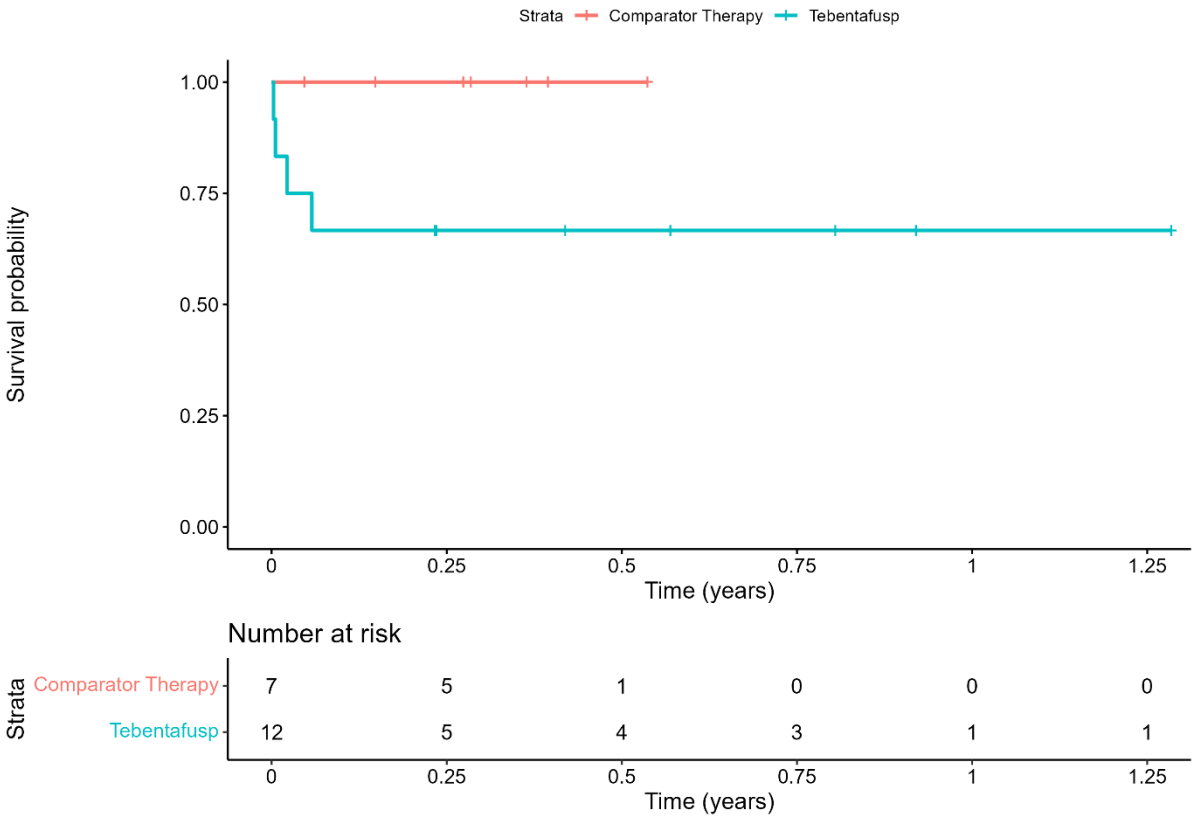
Region: Nordamerika



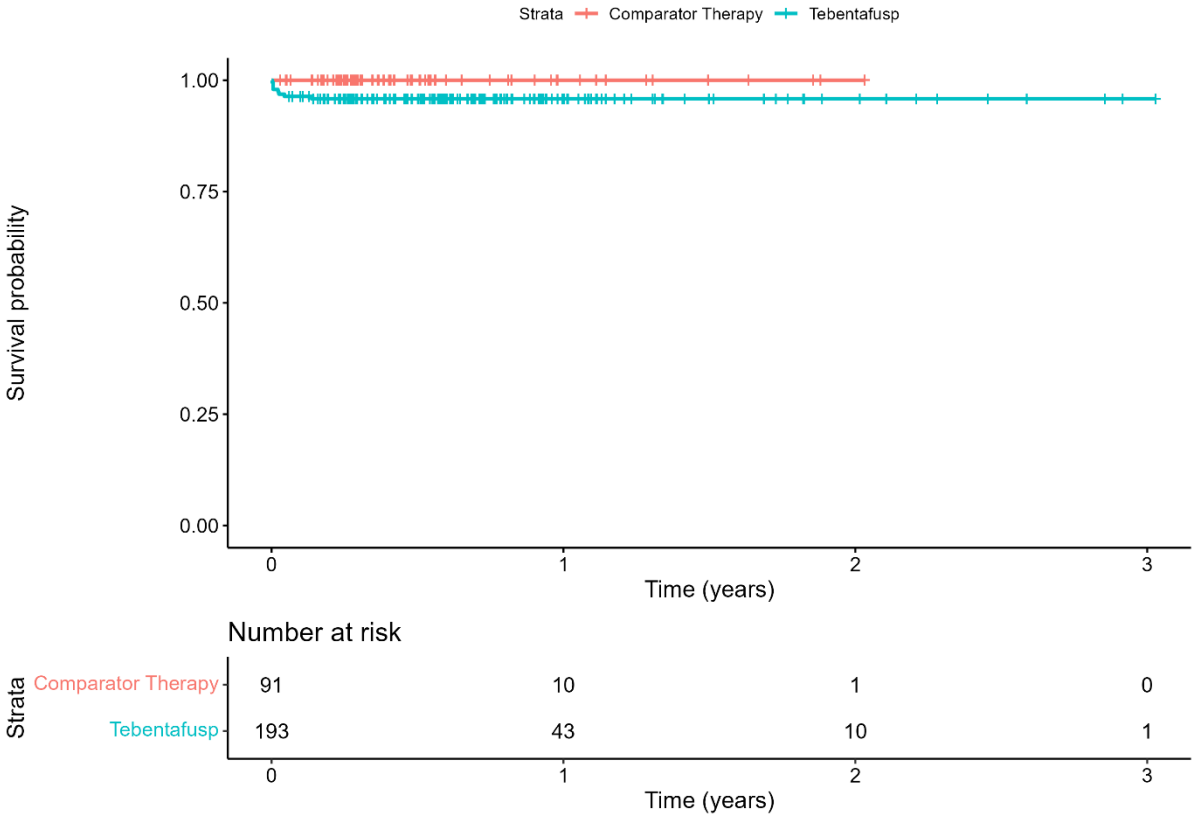
Region: Nicht-Nordamerika



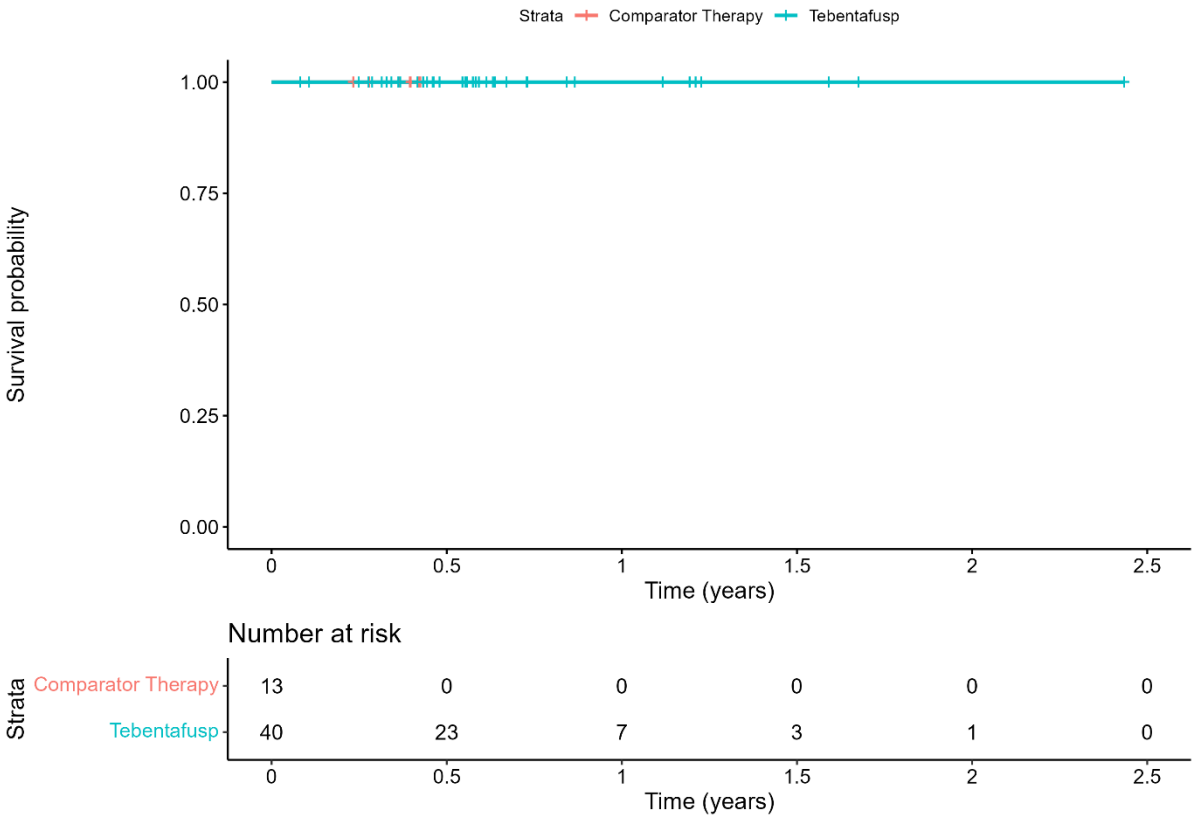
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

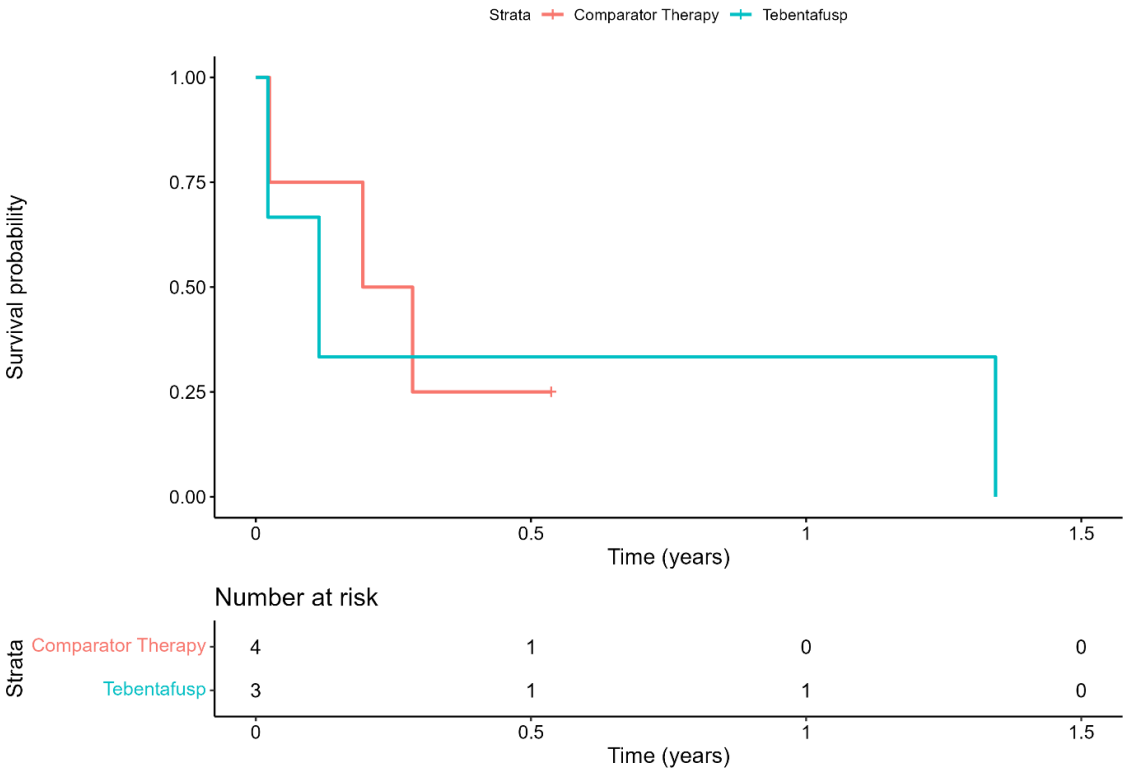


Vorauswahl der Chemotherapie: Ipilimumab

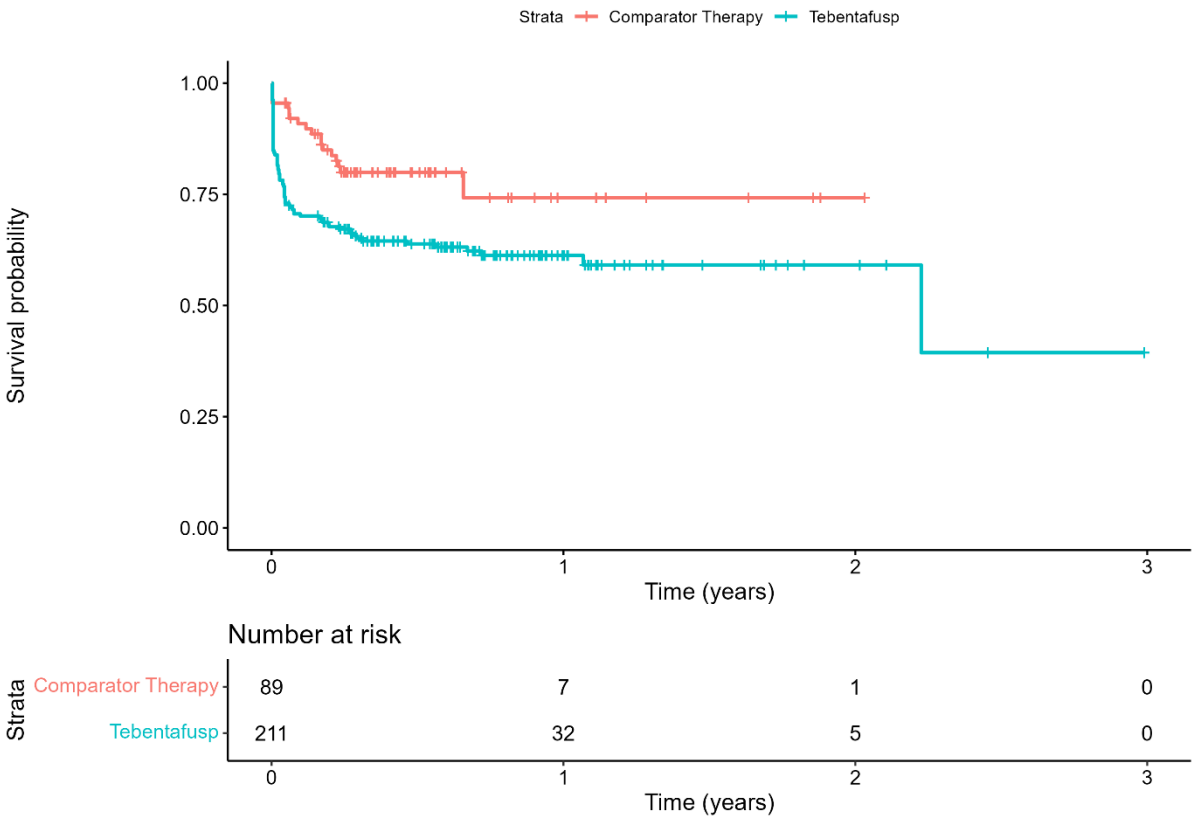


49.1 LFT-Erhöhung (Tabelle 4-110)

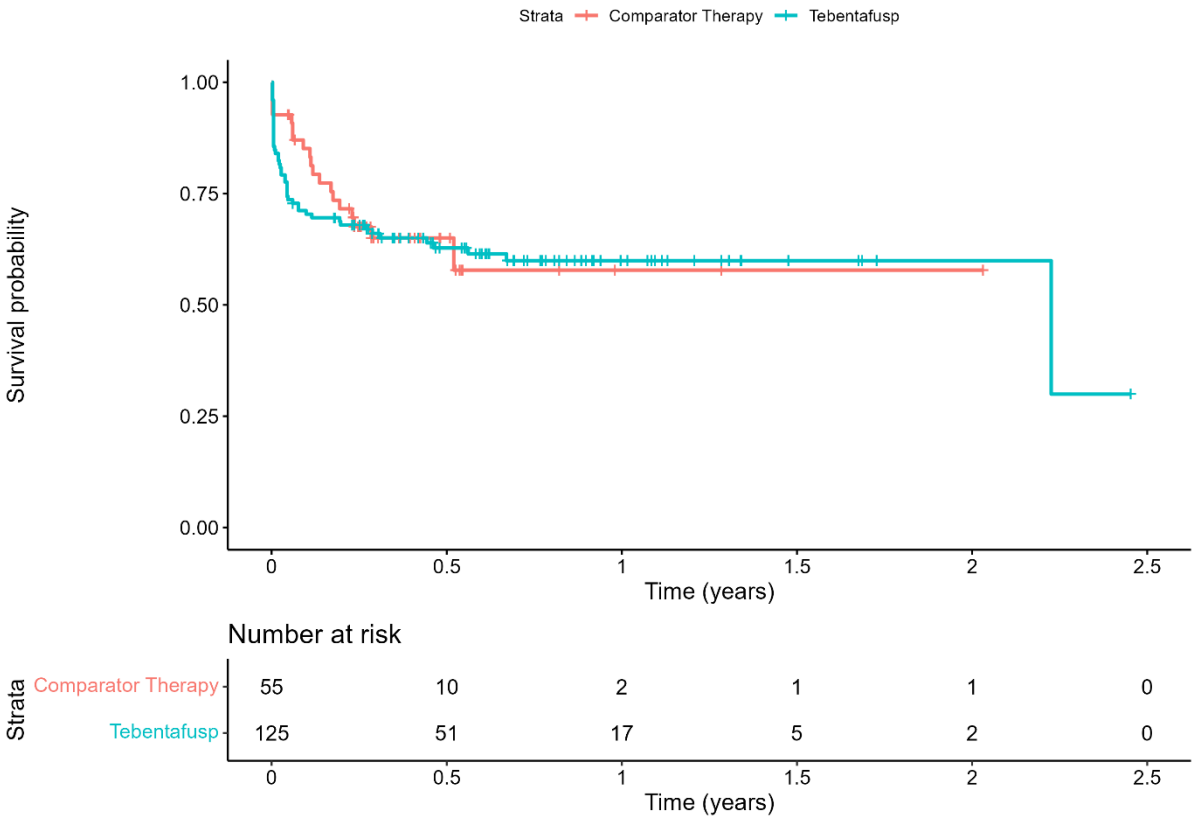
Herkunft: Hispanisch



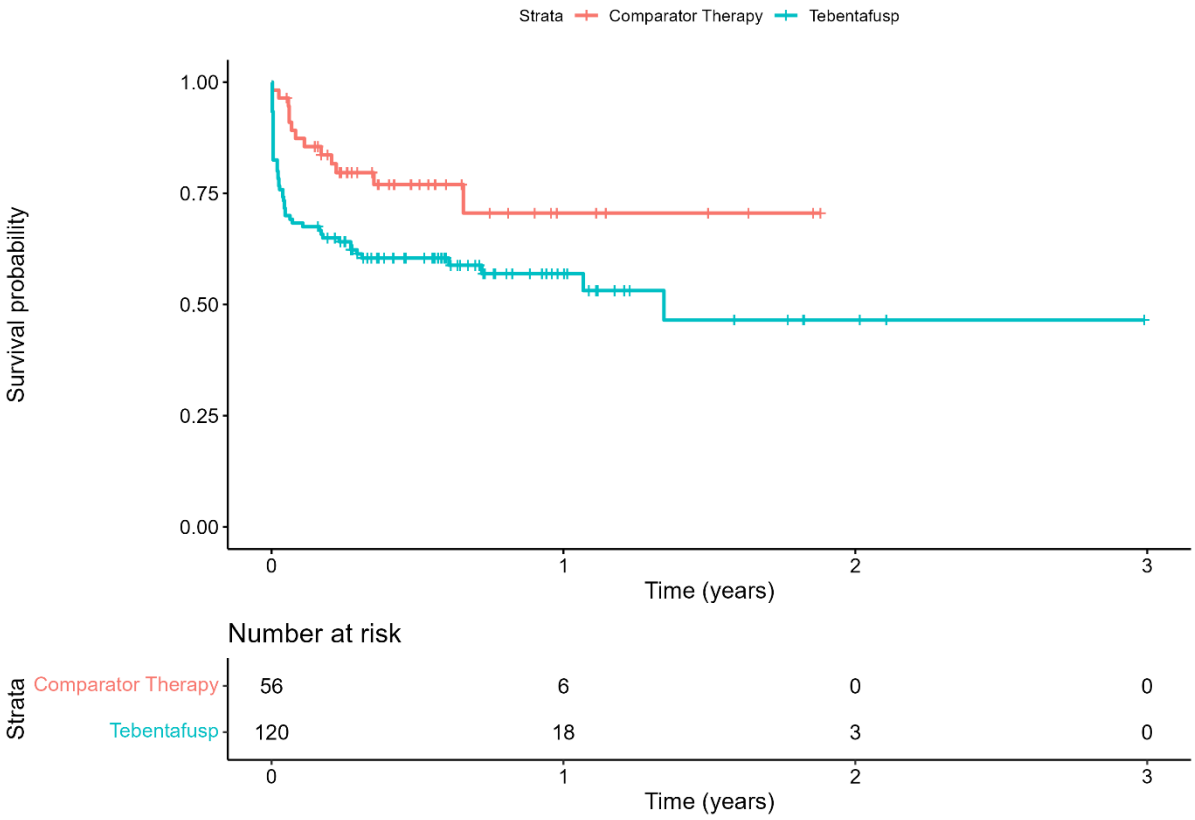
Herkunft: Nicht-hispanisch



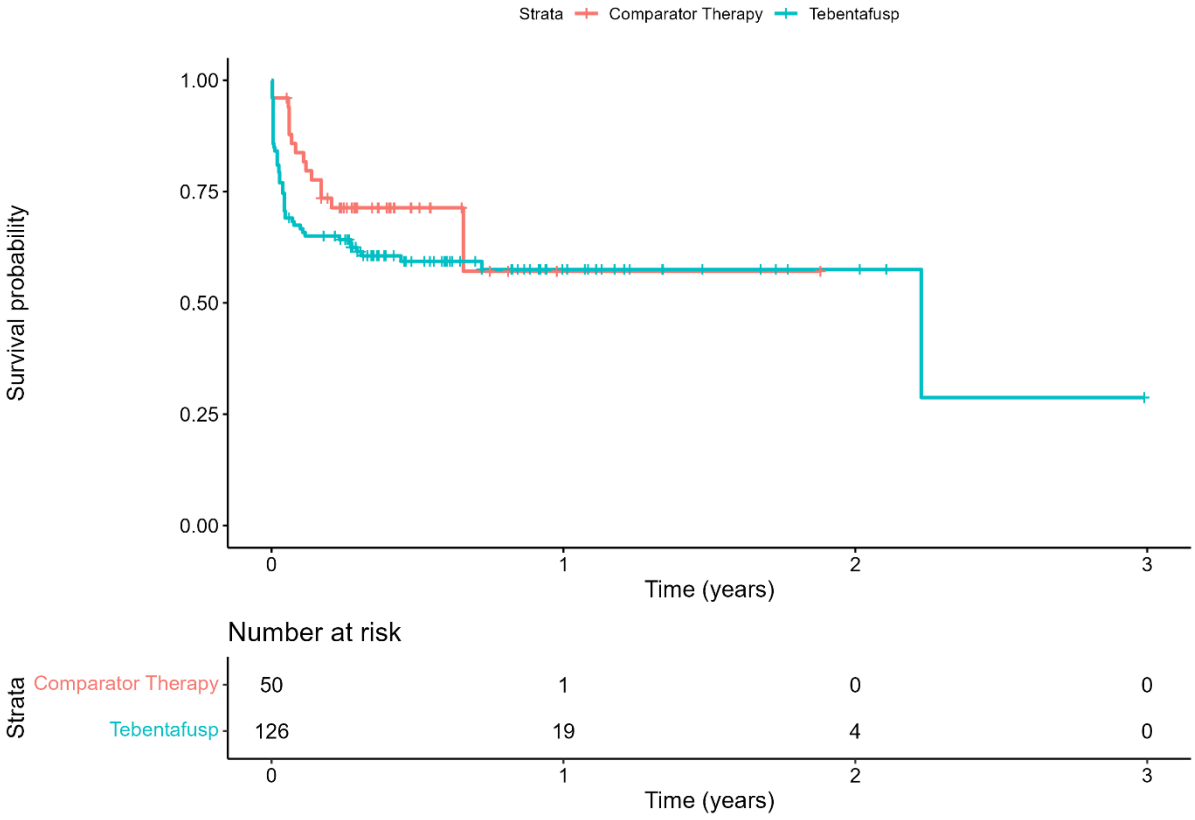
Geschlecht: Männlich



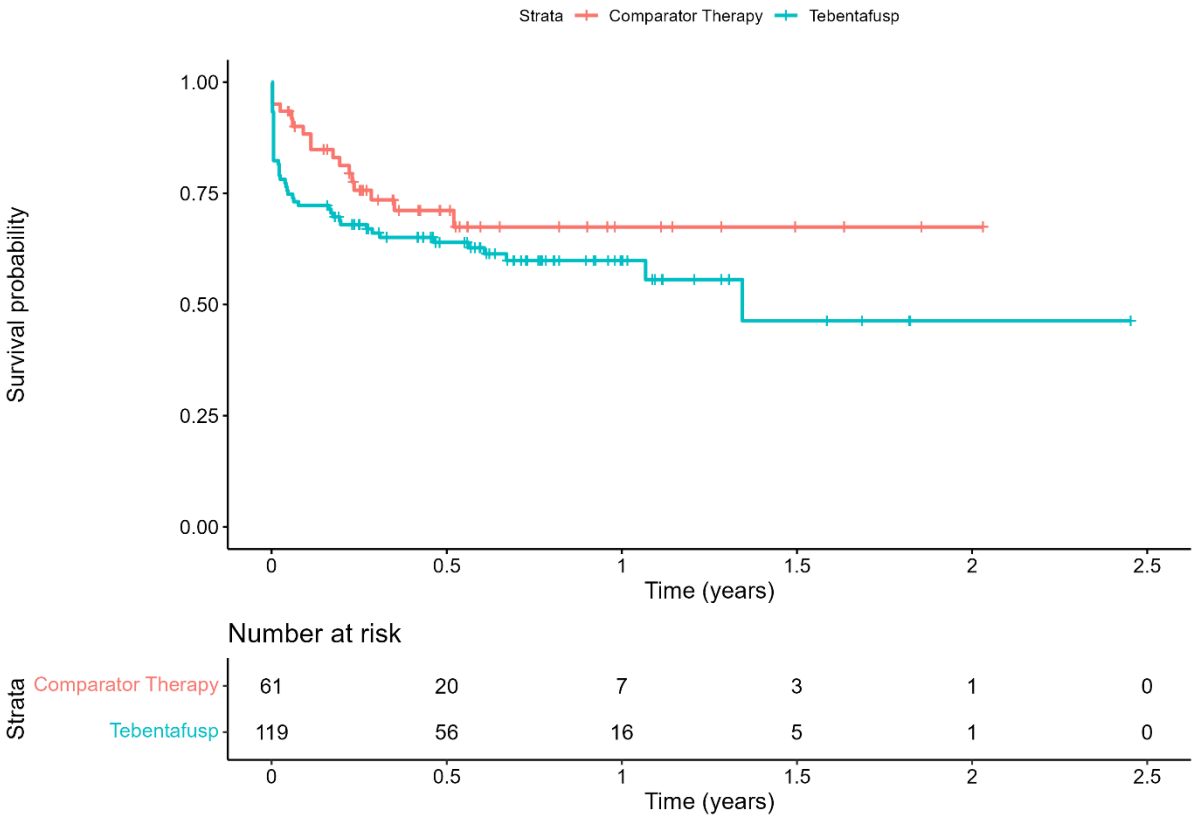
Geschlecht: Weiblich



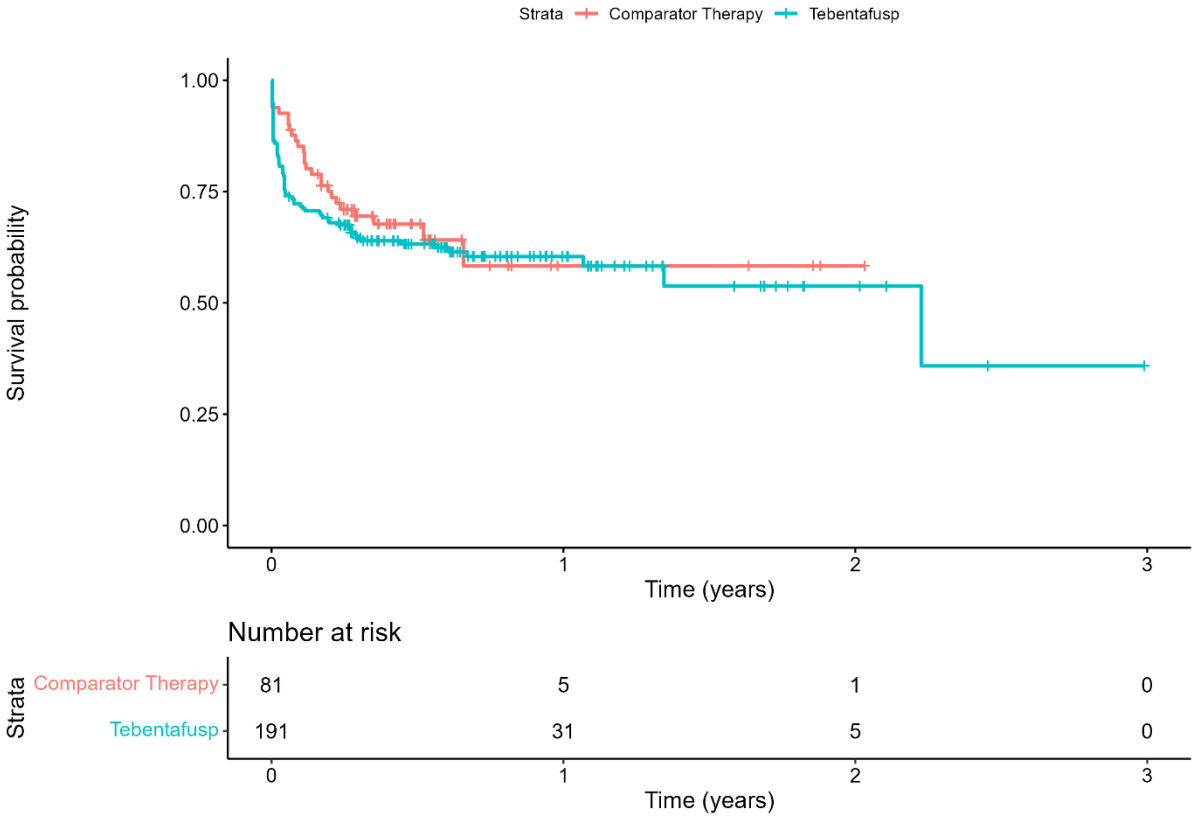
Alter: <65 Jahre



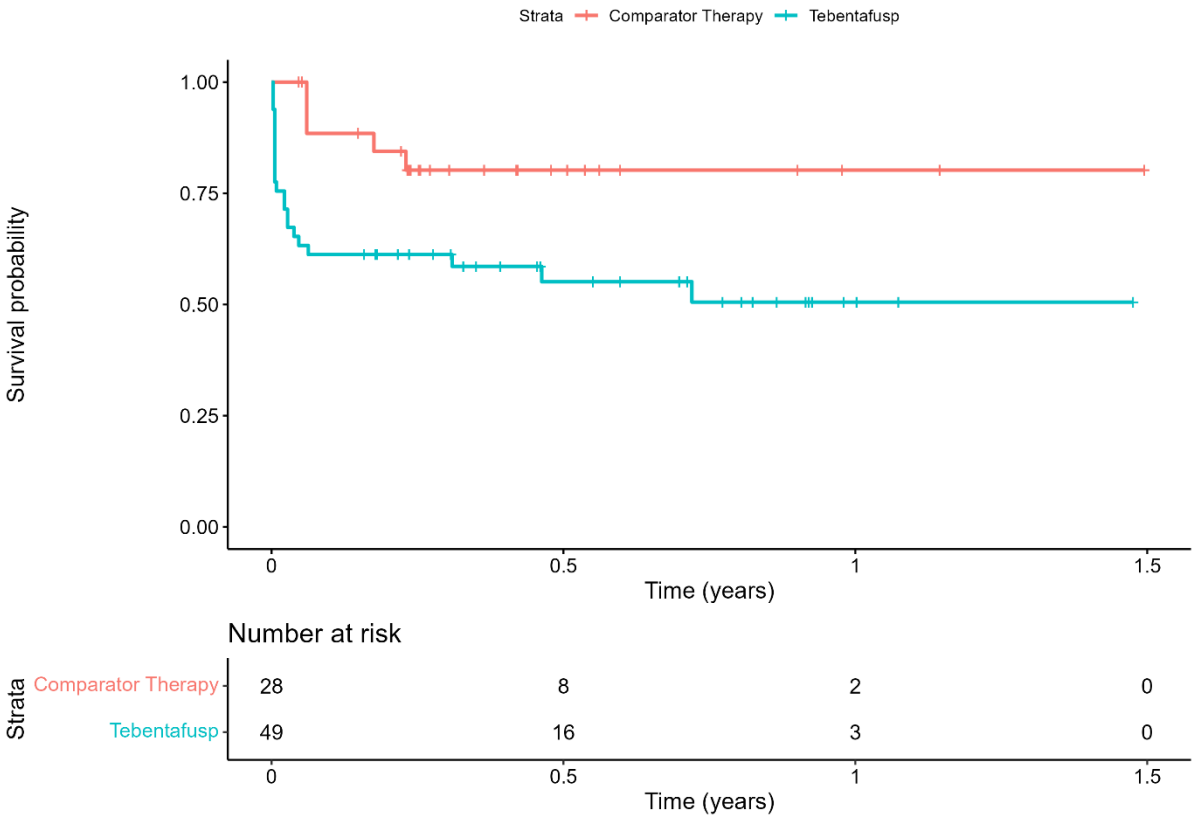
Alter: ≥65 Jahre



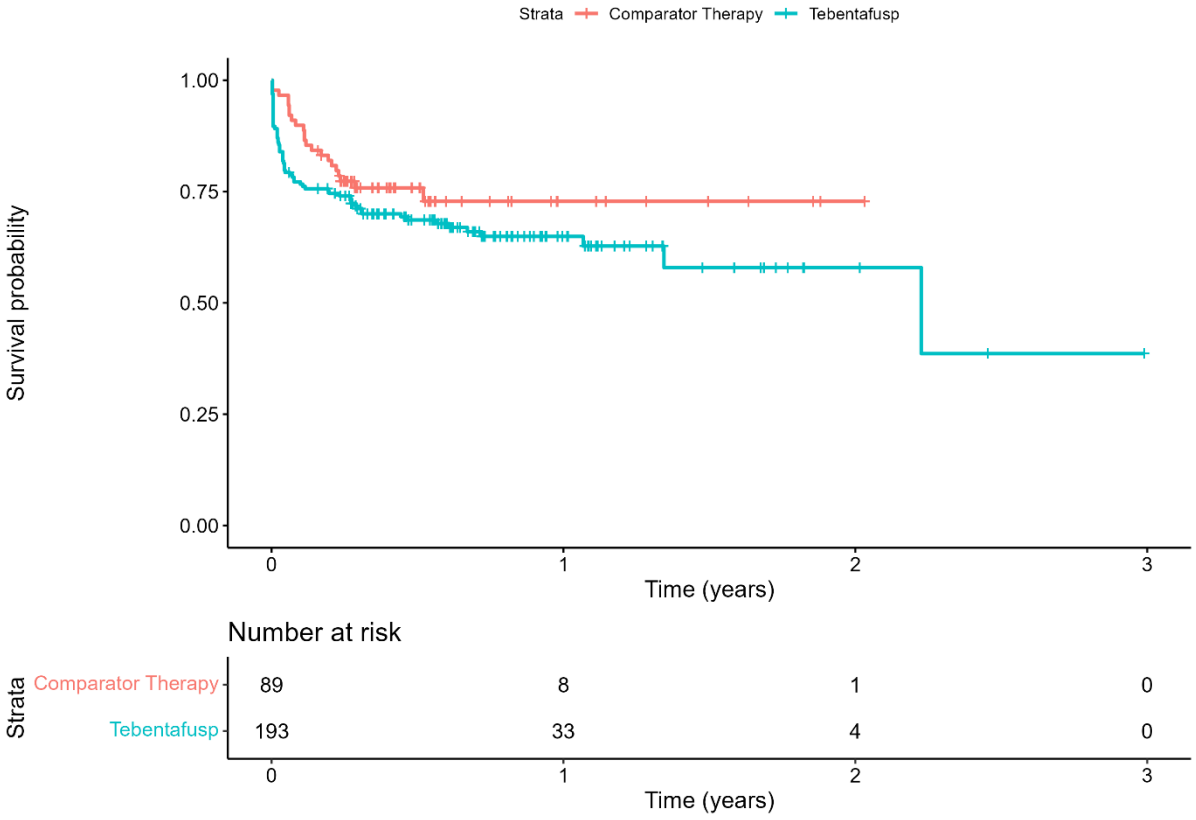
ECOG-Performance-Status: 0



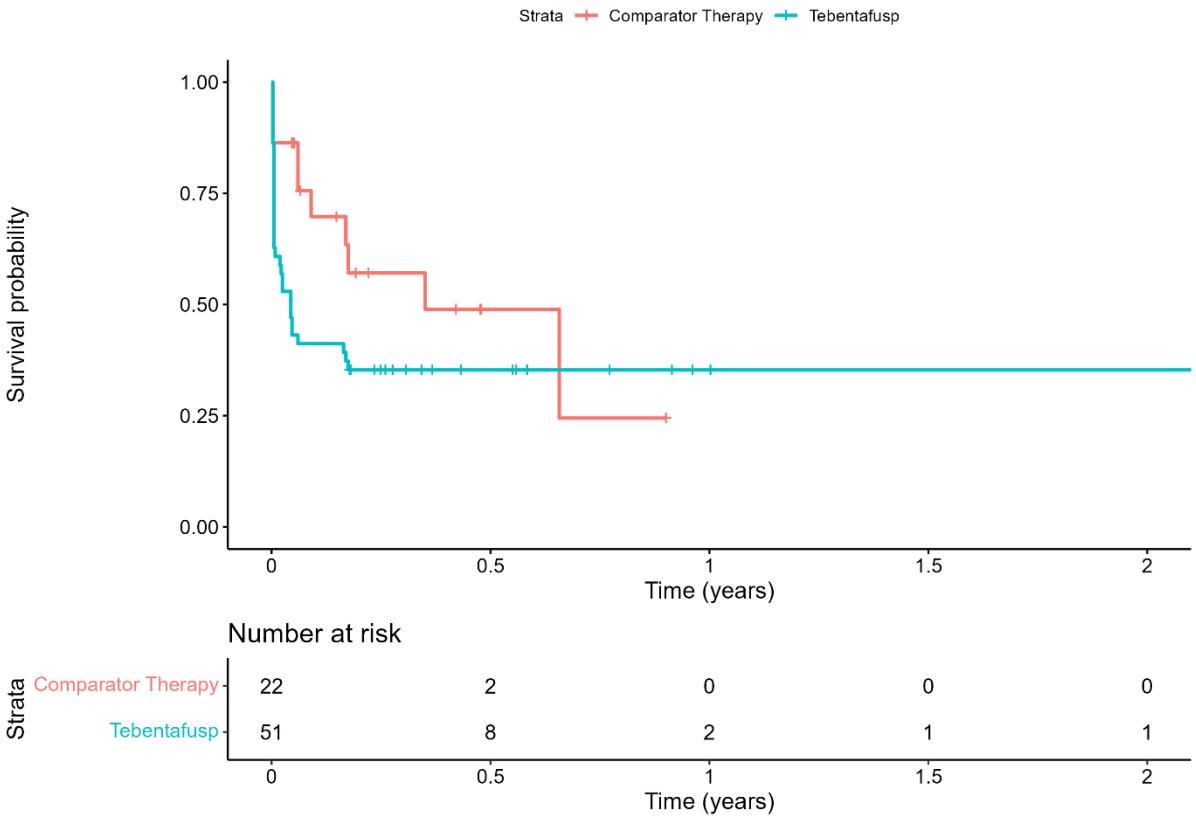
ECOG-Performance-Status: 1



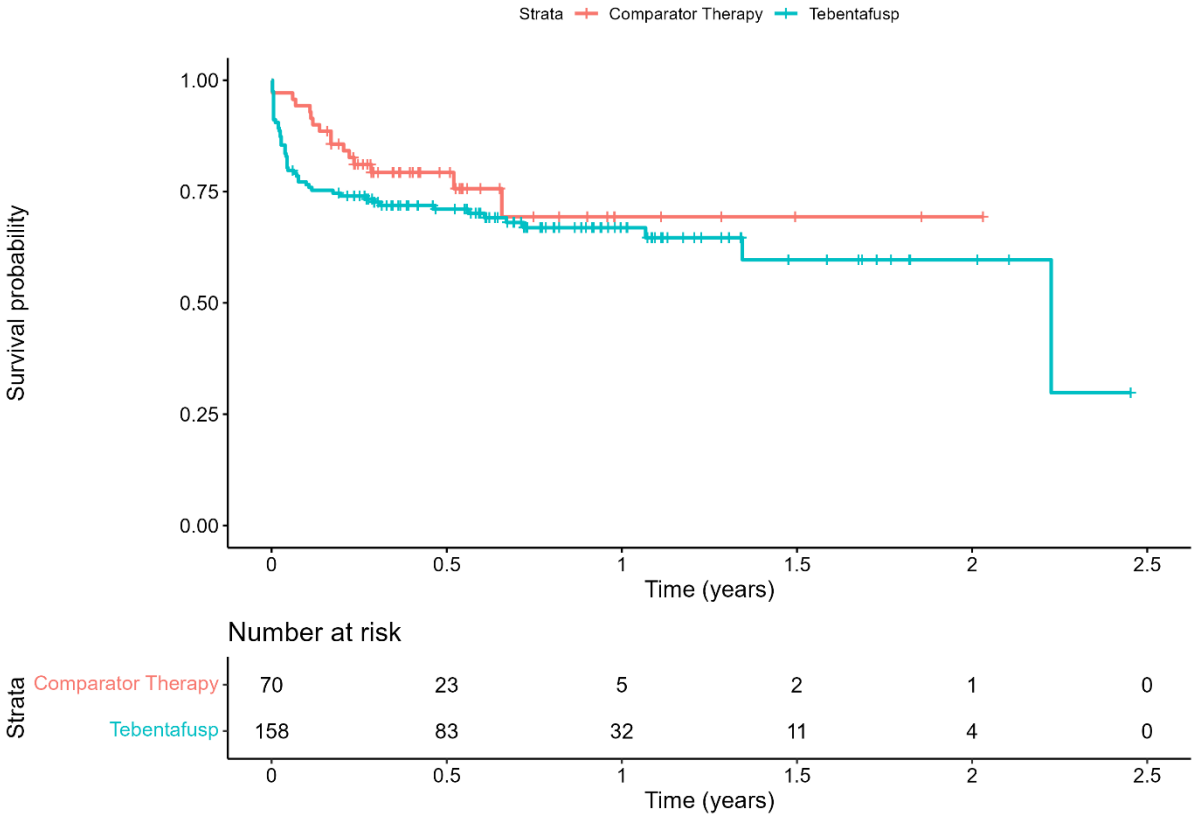
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



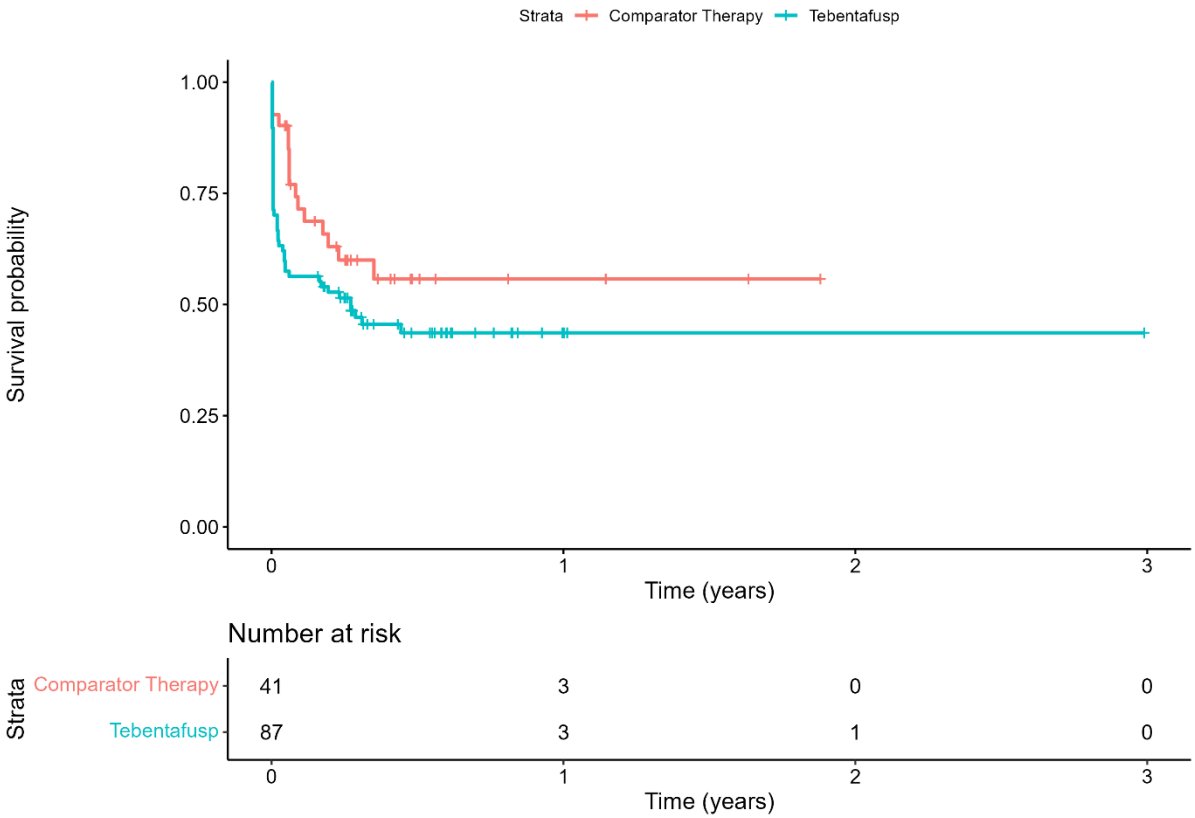
Alkalische Phosphatase (ALP) (Baseline): >ULN



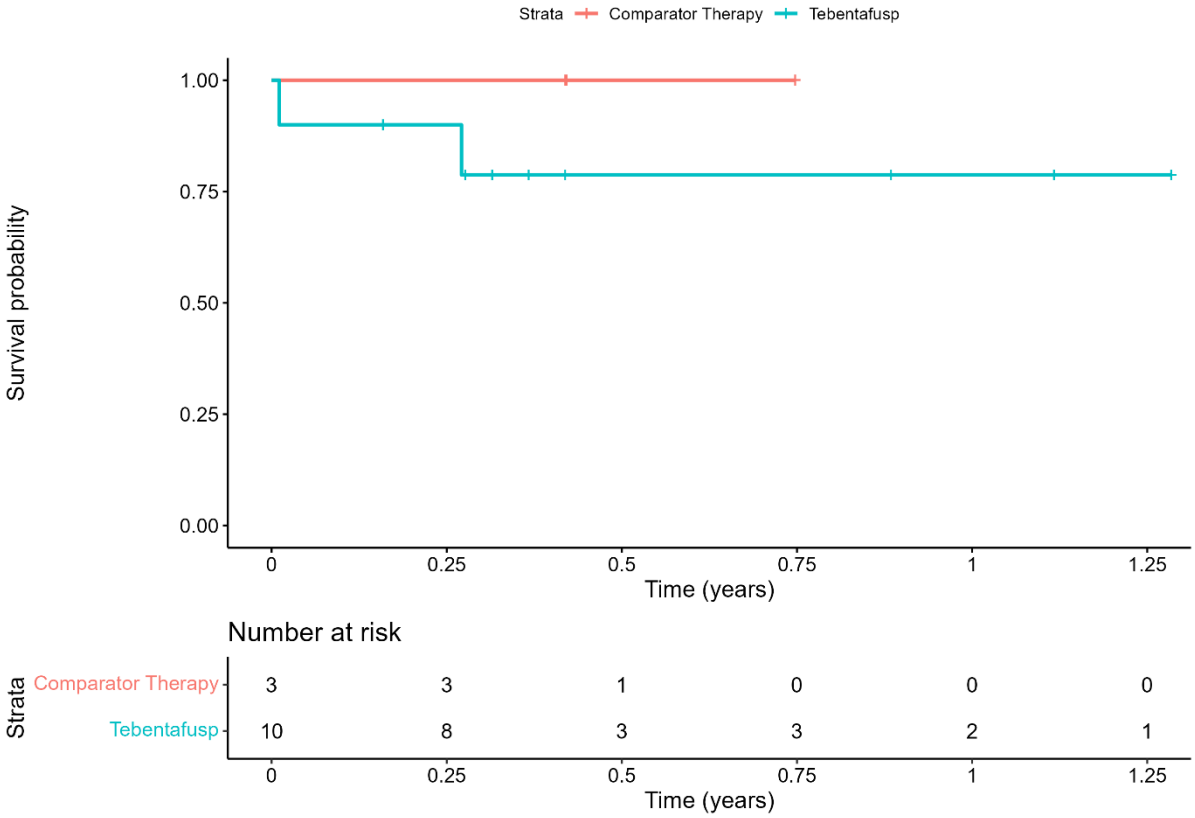
LDH: ≤ULN



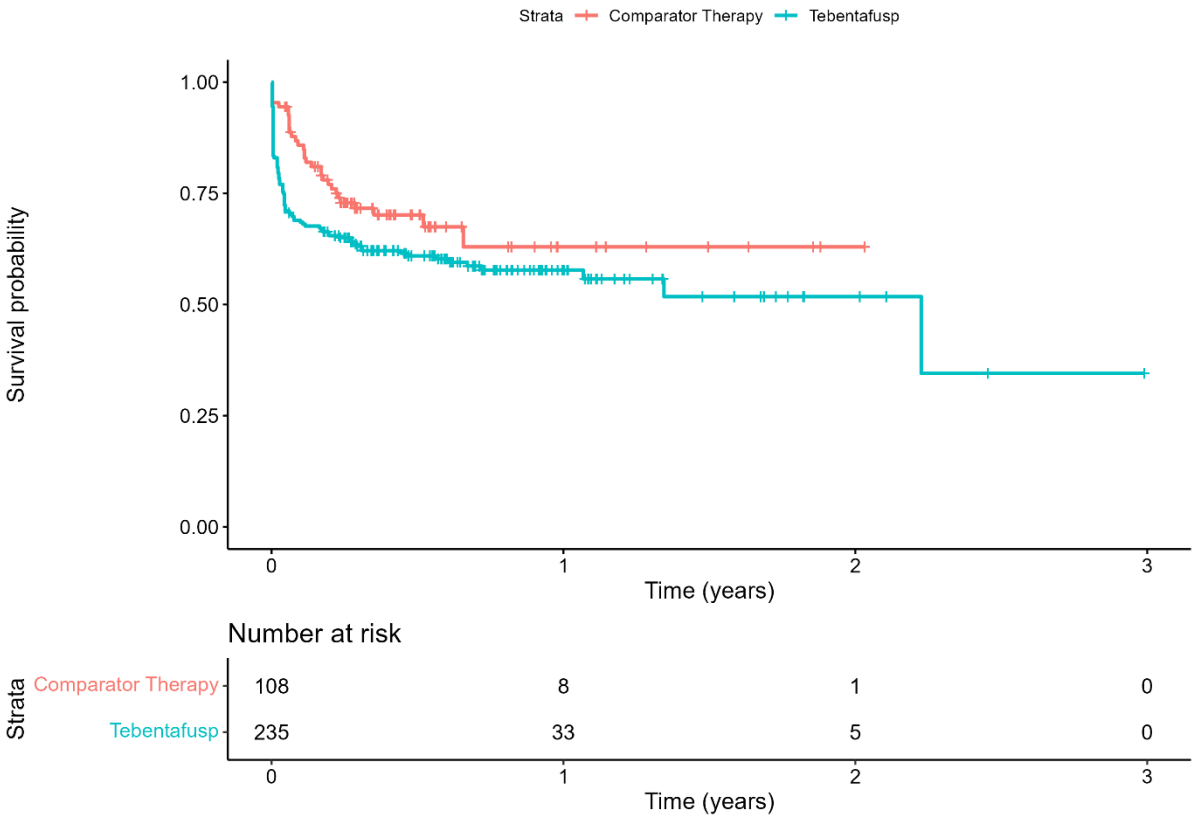
LDH: >ULN



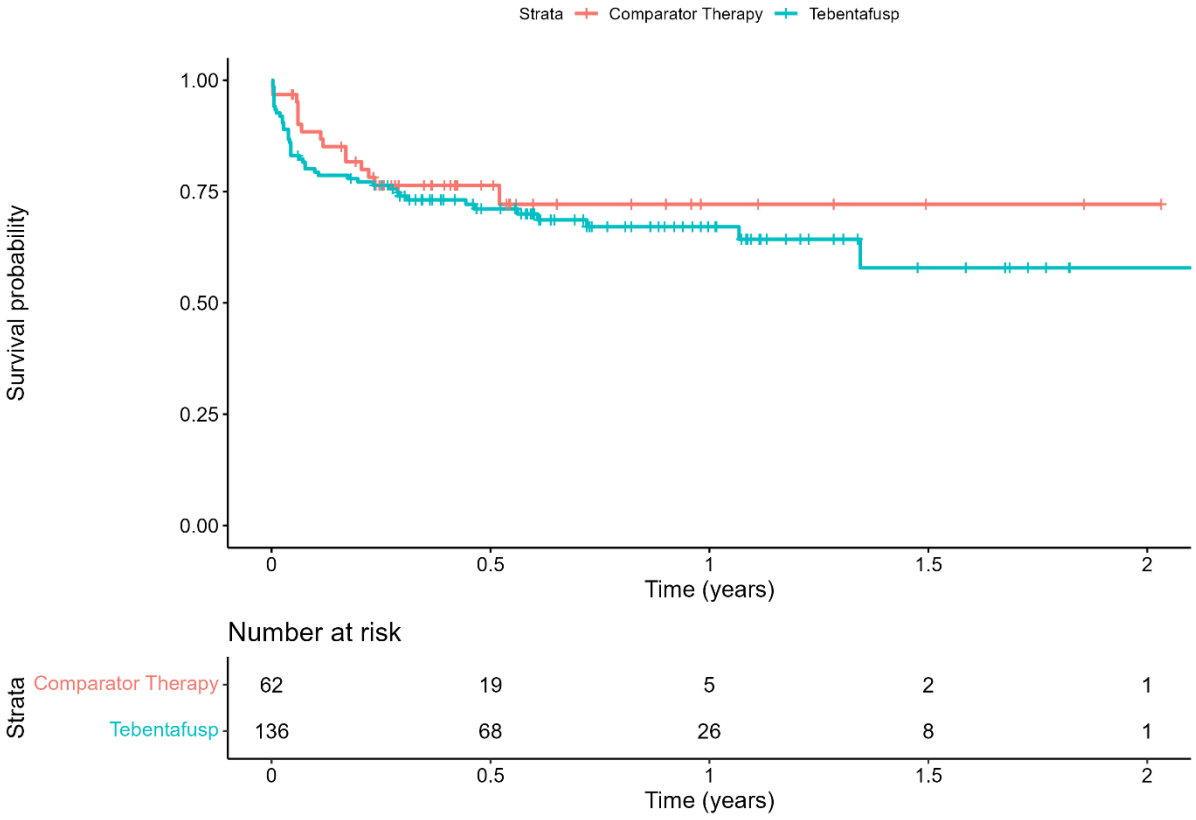
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



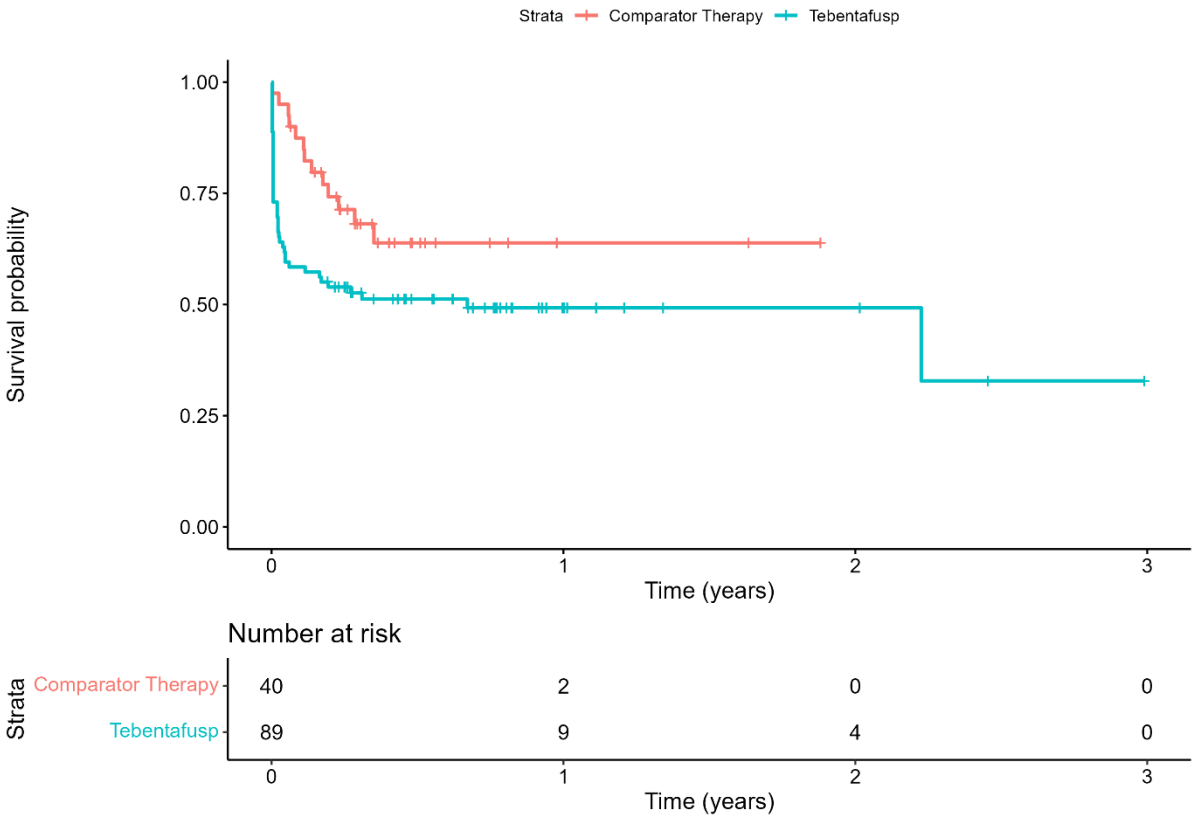
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



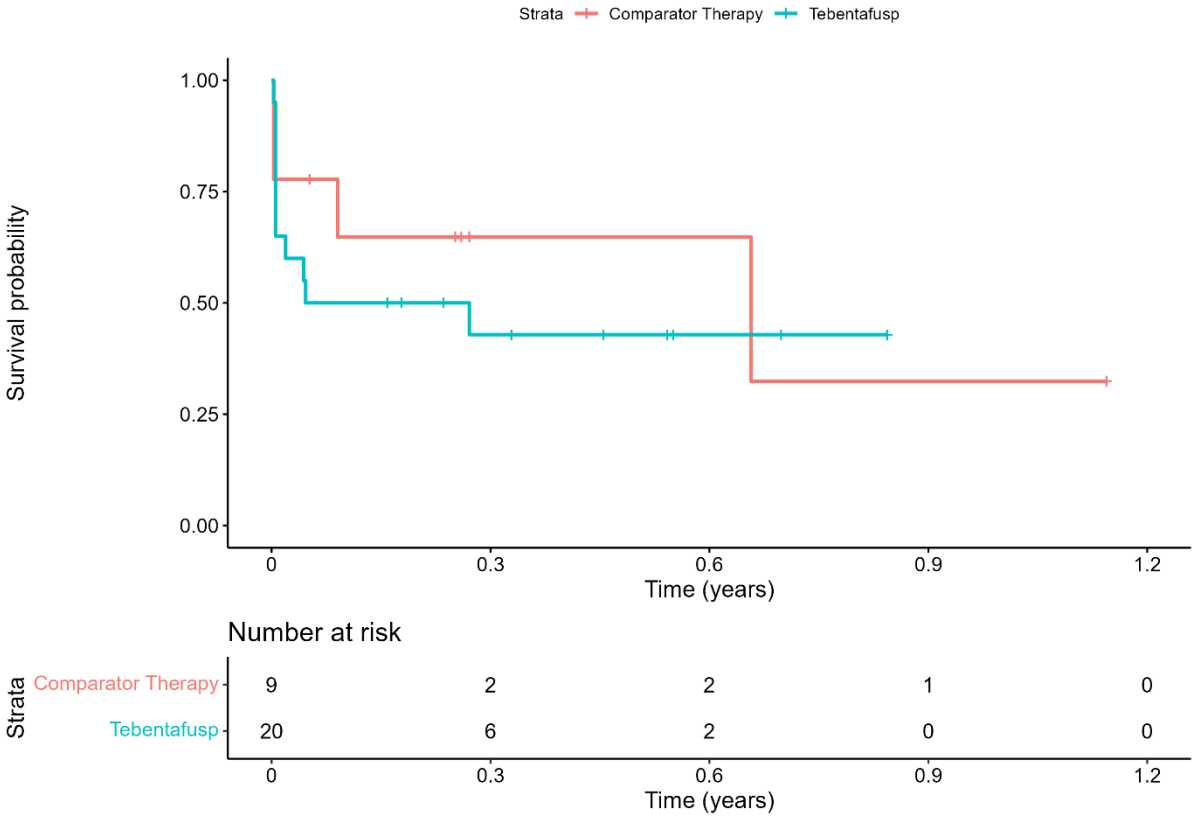
Größte metastatische Läsion (Baseline): ≤3,0 cm



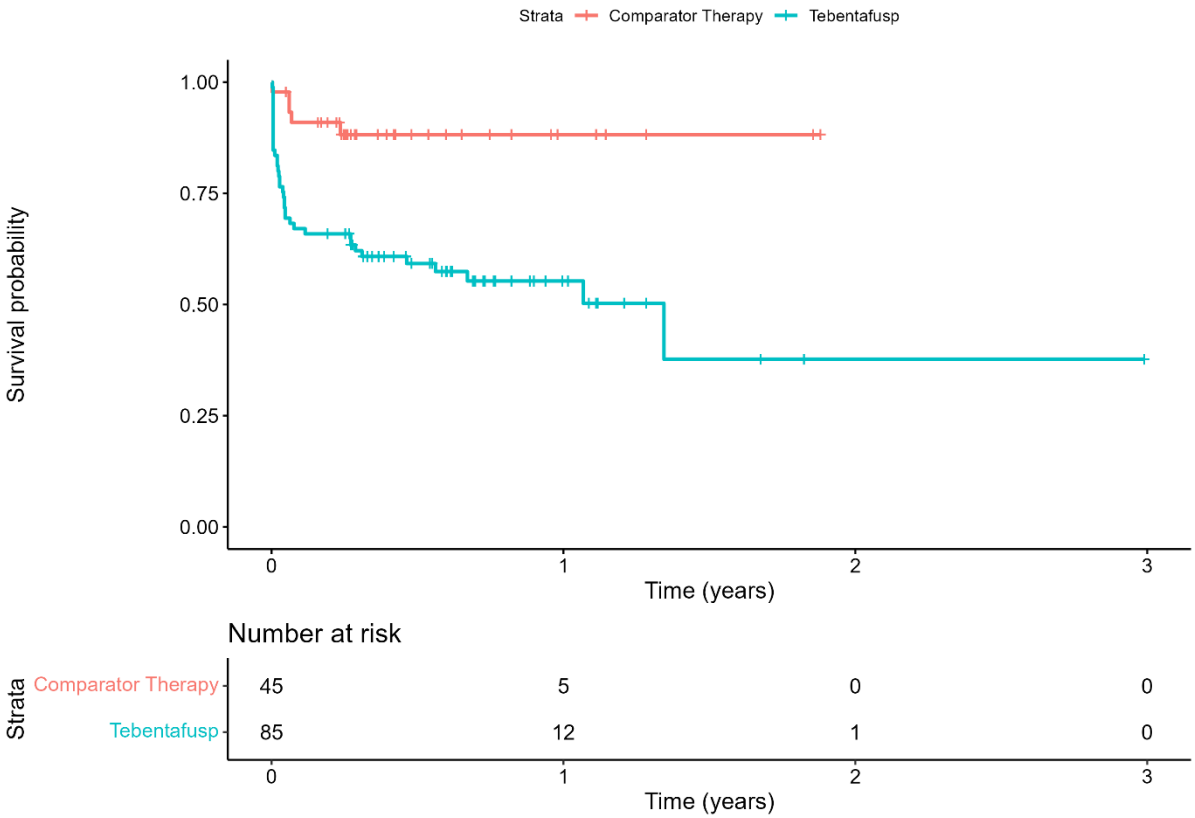
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



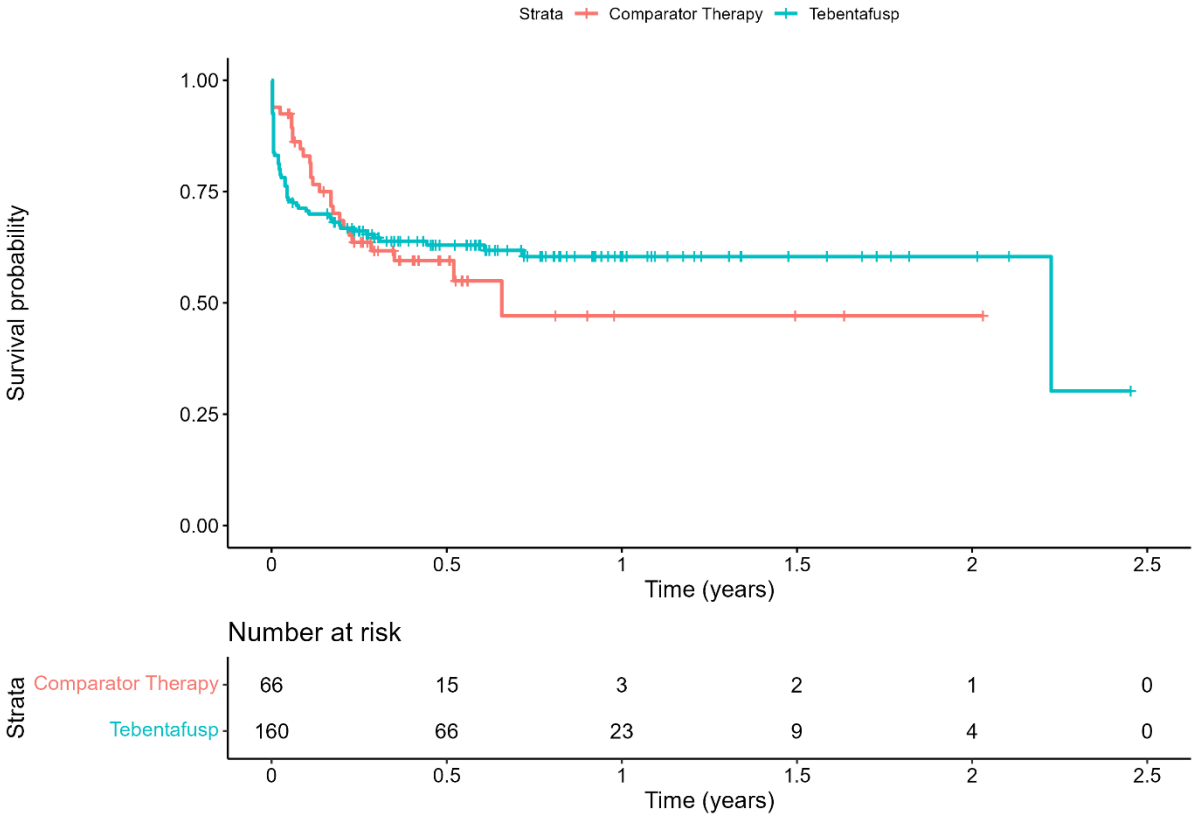
Größte metastatische Läsion (Baseline): ≥8,1 cm



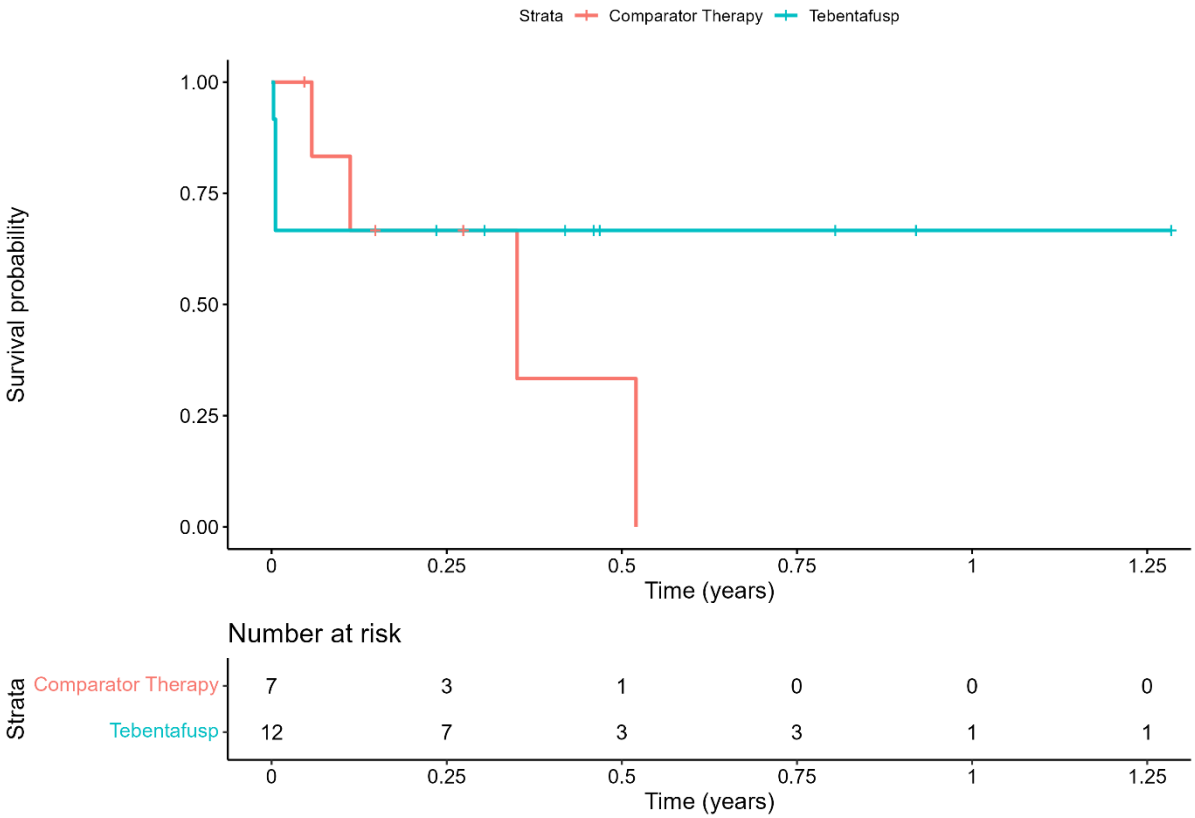
Region: Nordamerika



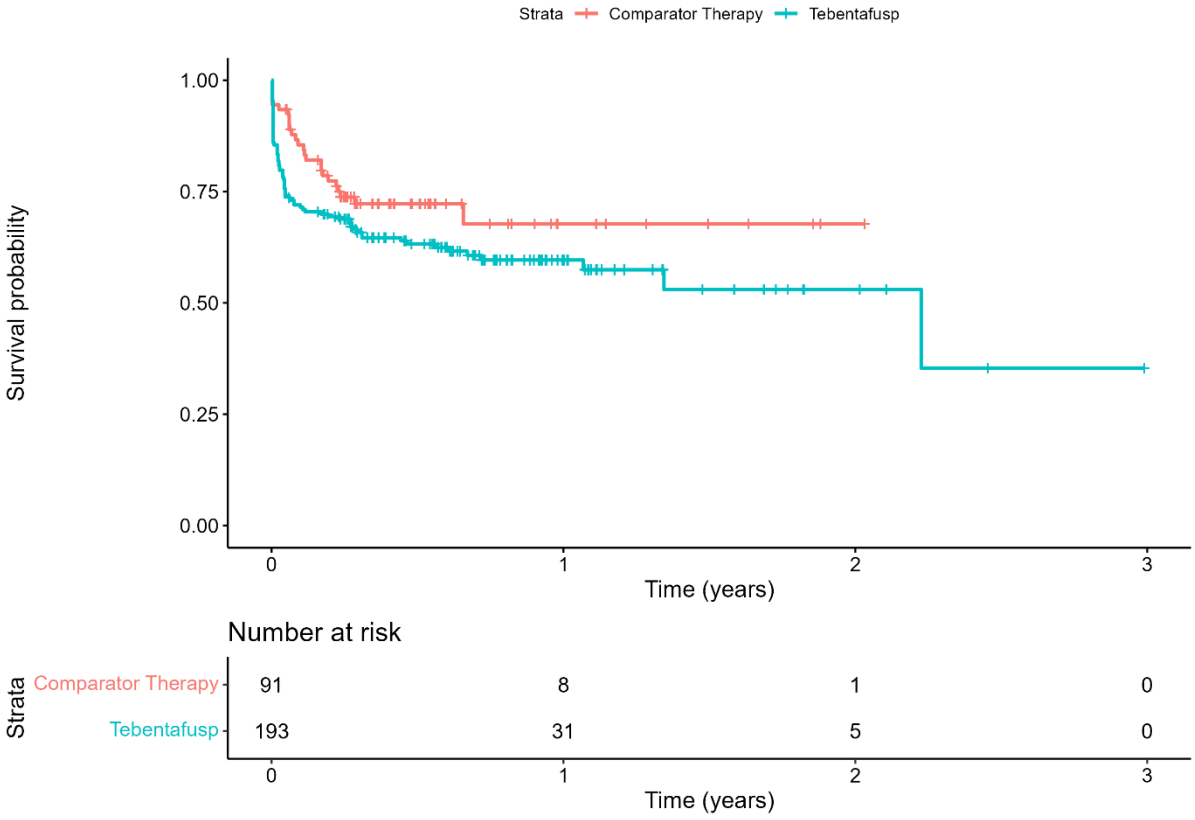
Region: Nicht-Nordamerika



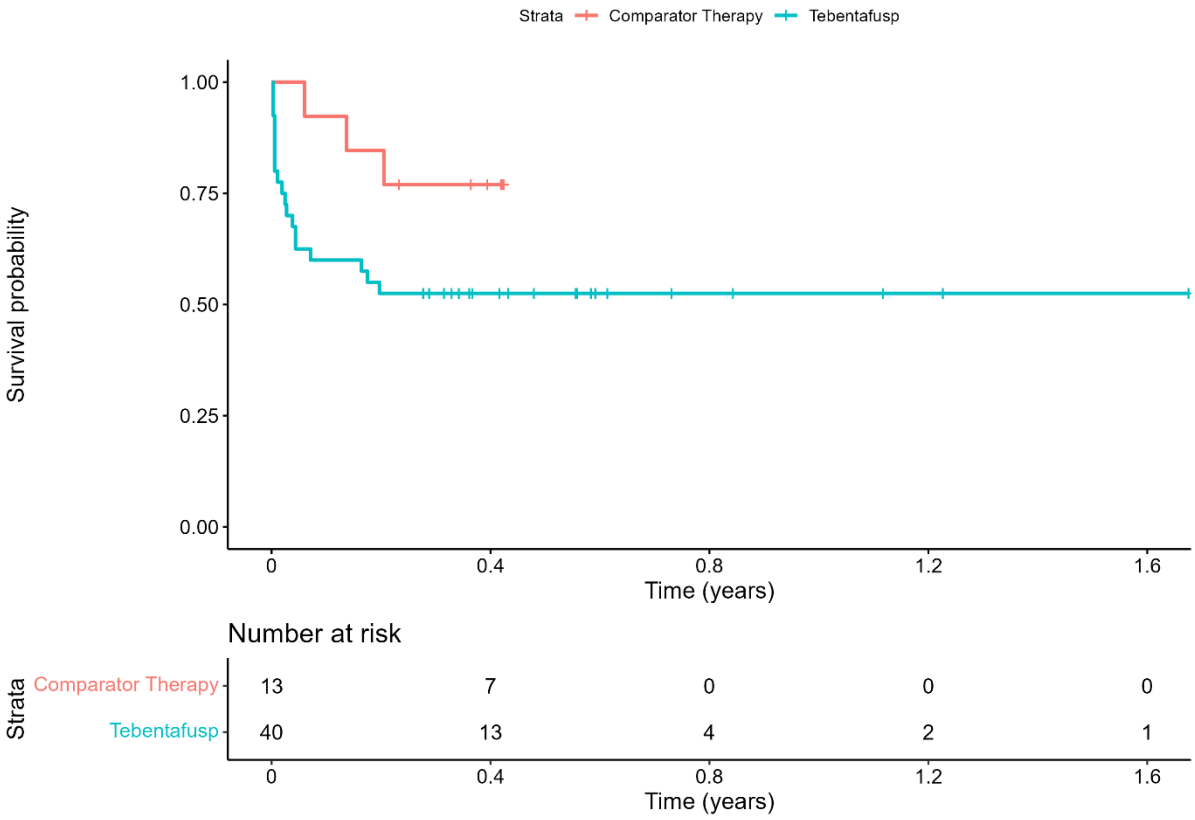
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

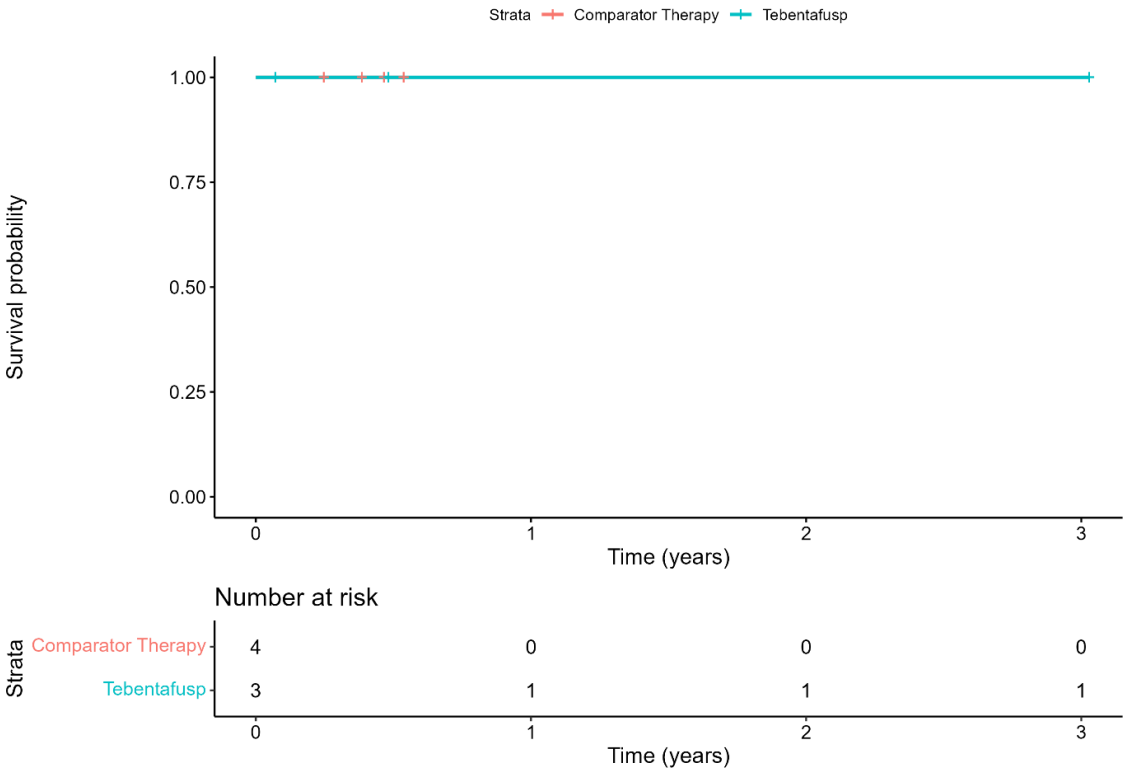


Vorauswahl der Chemotherapie: Ipilimumab

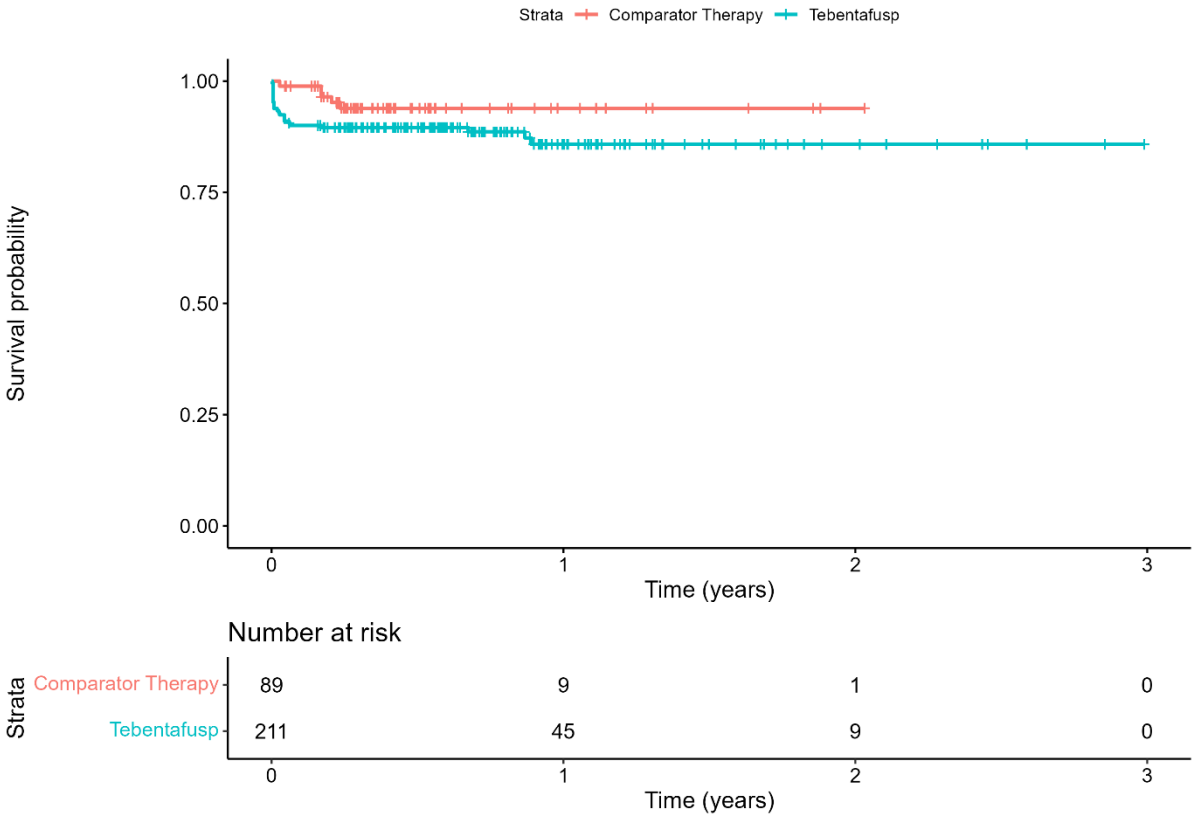


50.1 LFT-Erhöhung mit CTCAE-Grad ≥ 3 (Tabelle 4-112)

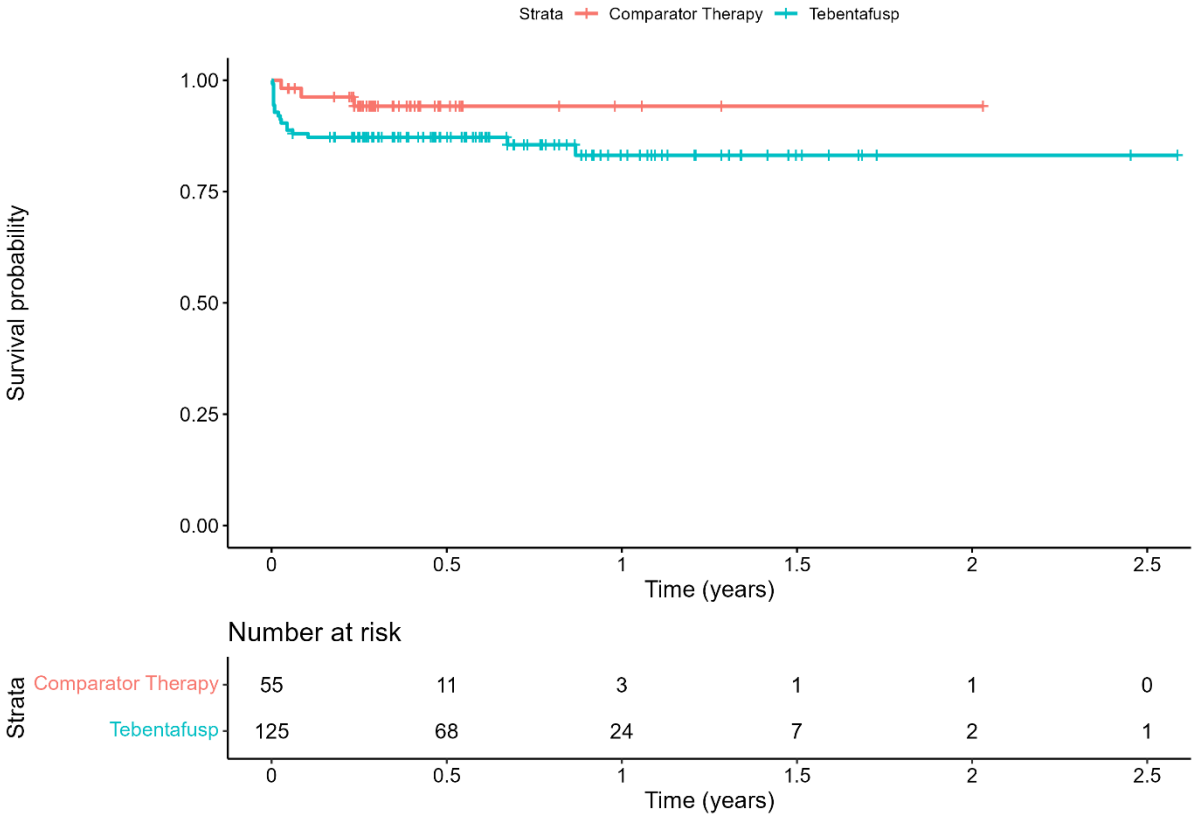
Herkunft: Hispanisch



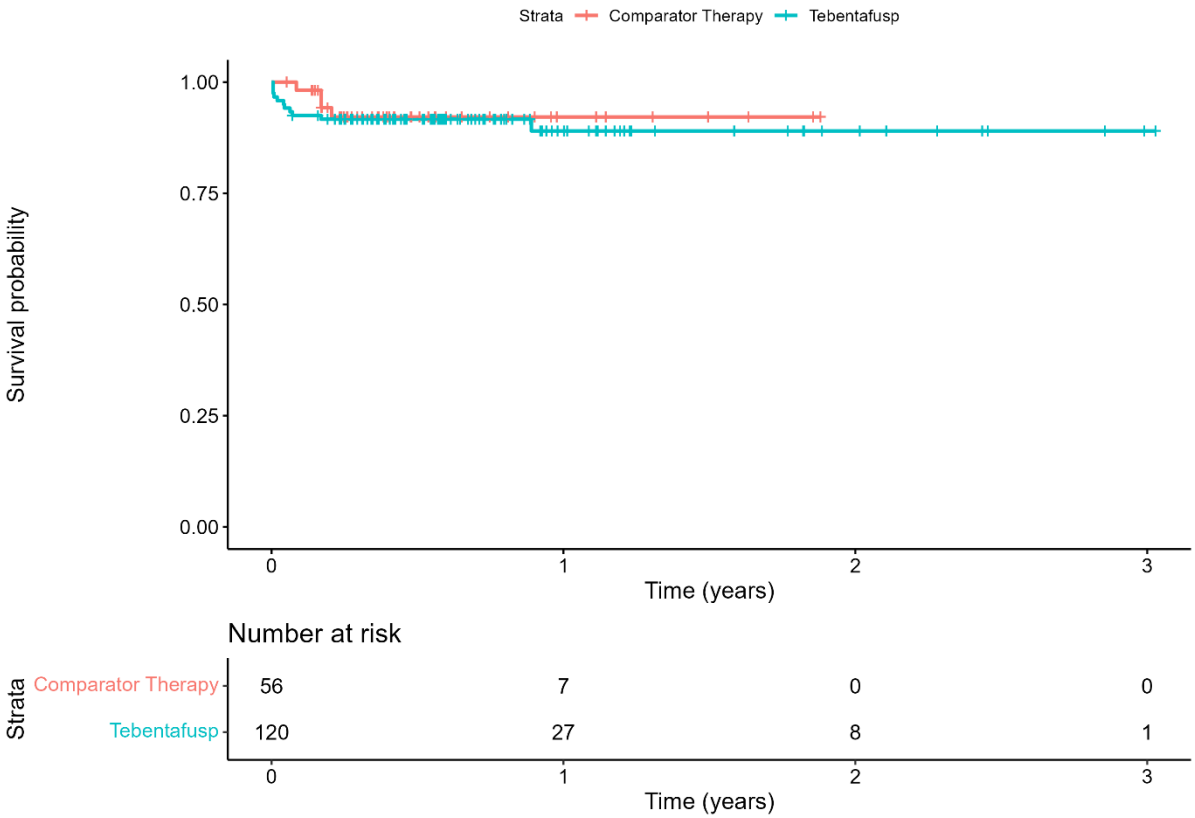
Herkunft: Nicht-hispanisch



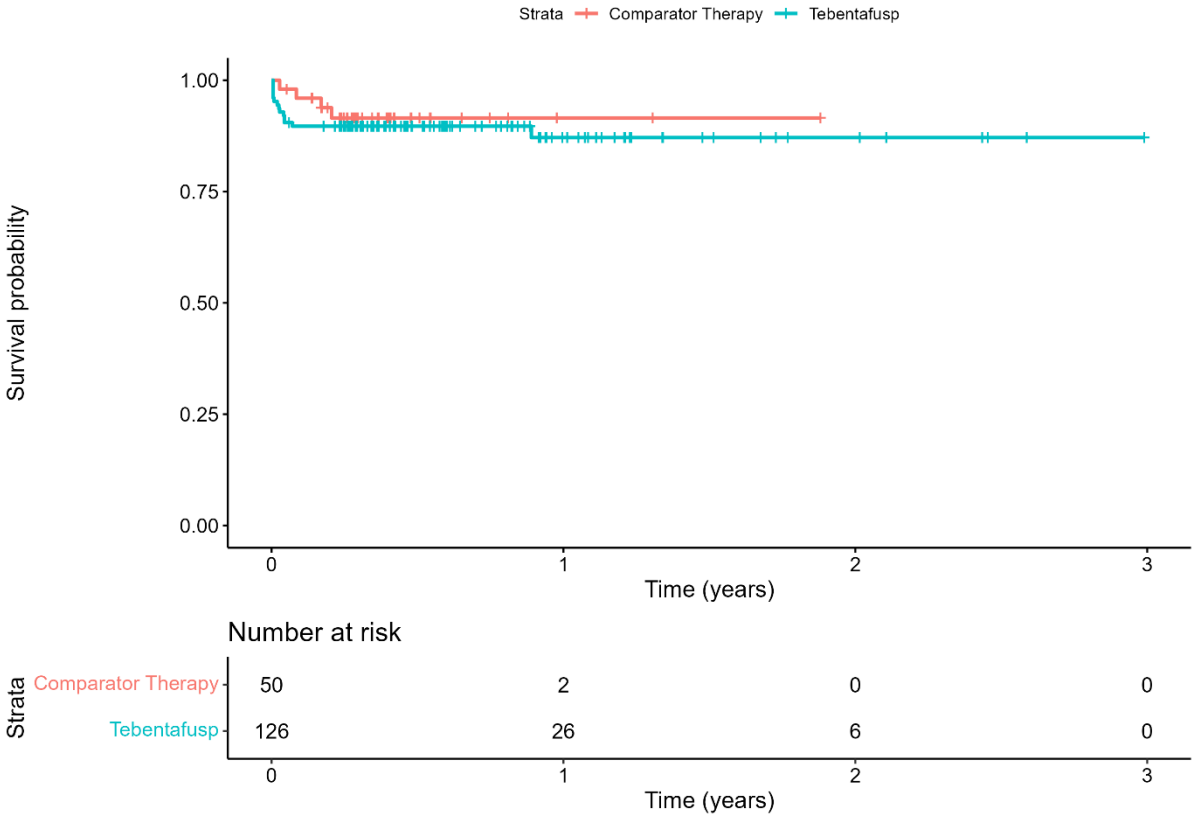
Geschlecht: Männlich



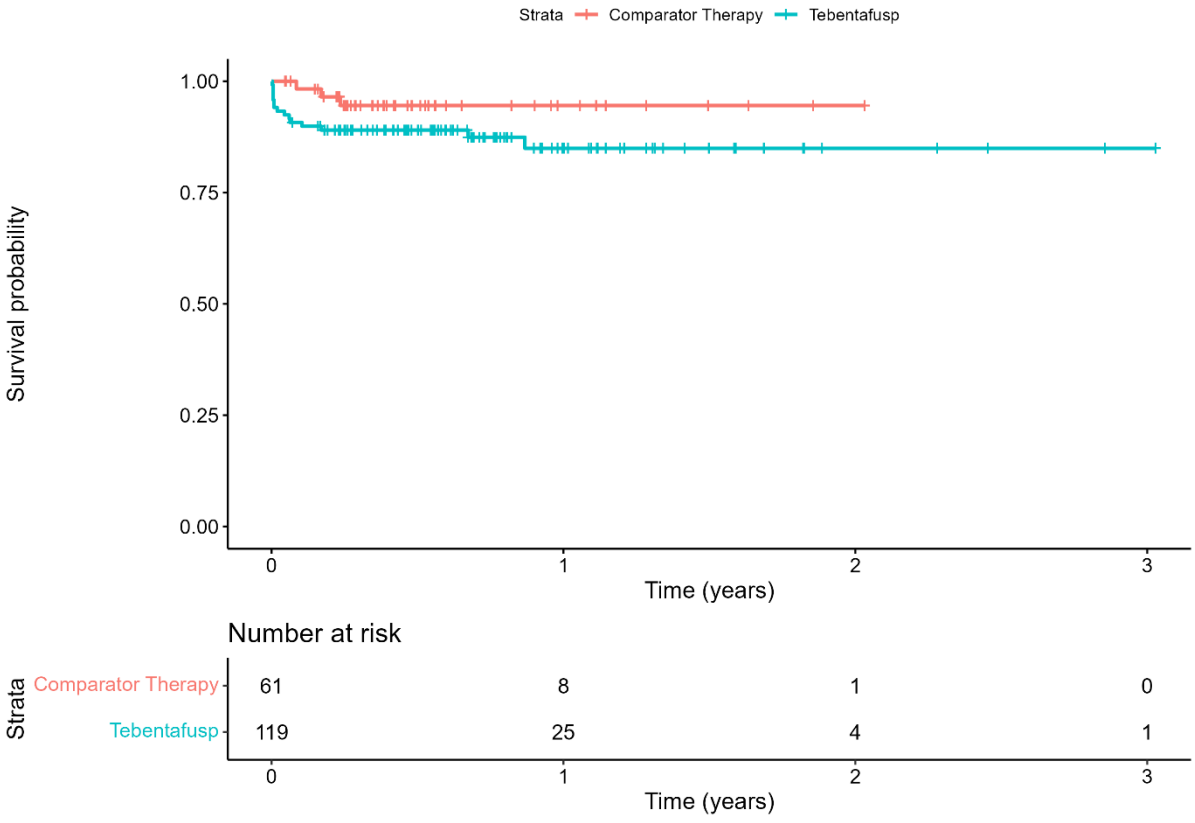
Geschlecht: Weiblich



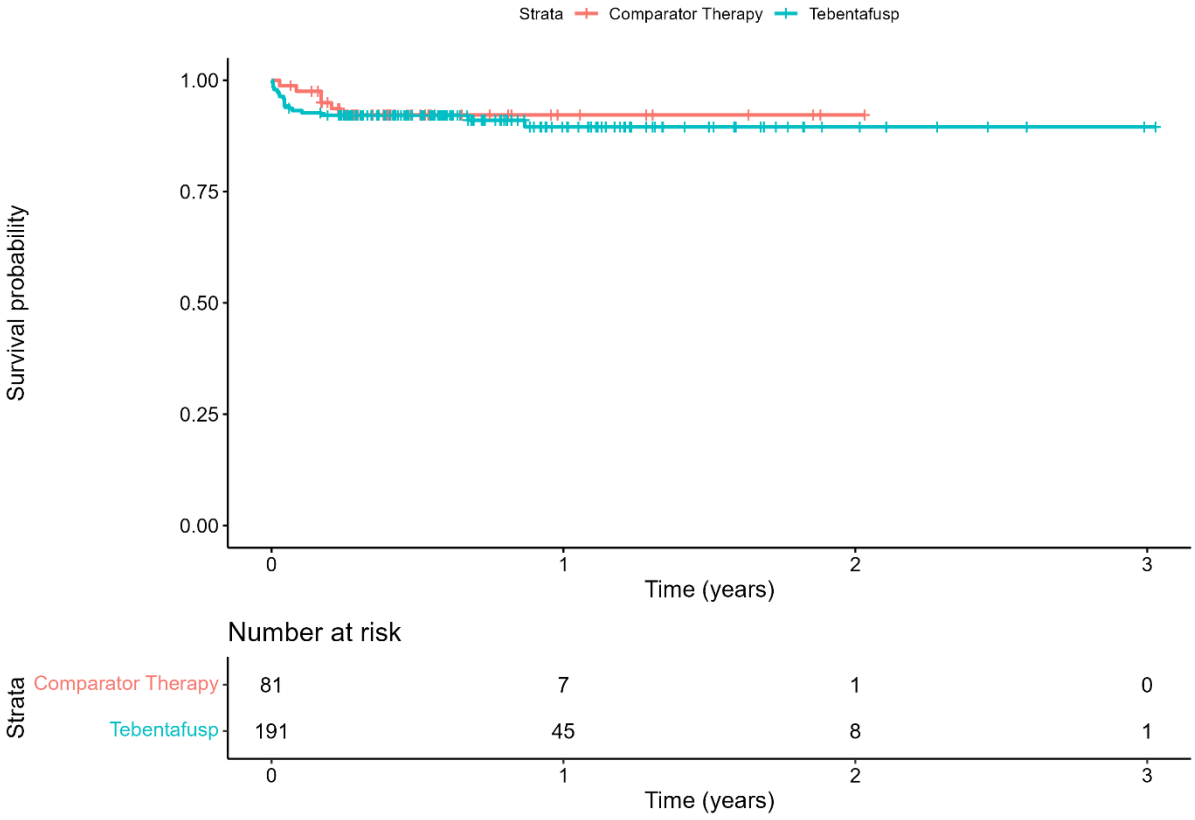
Alter: <65 Jahre



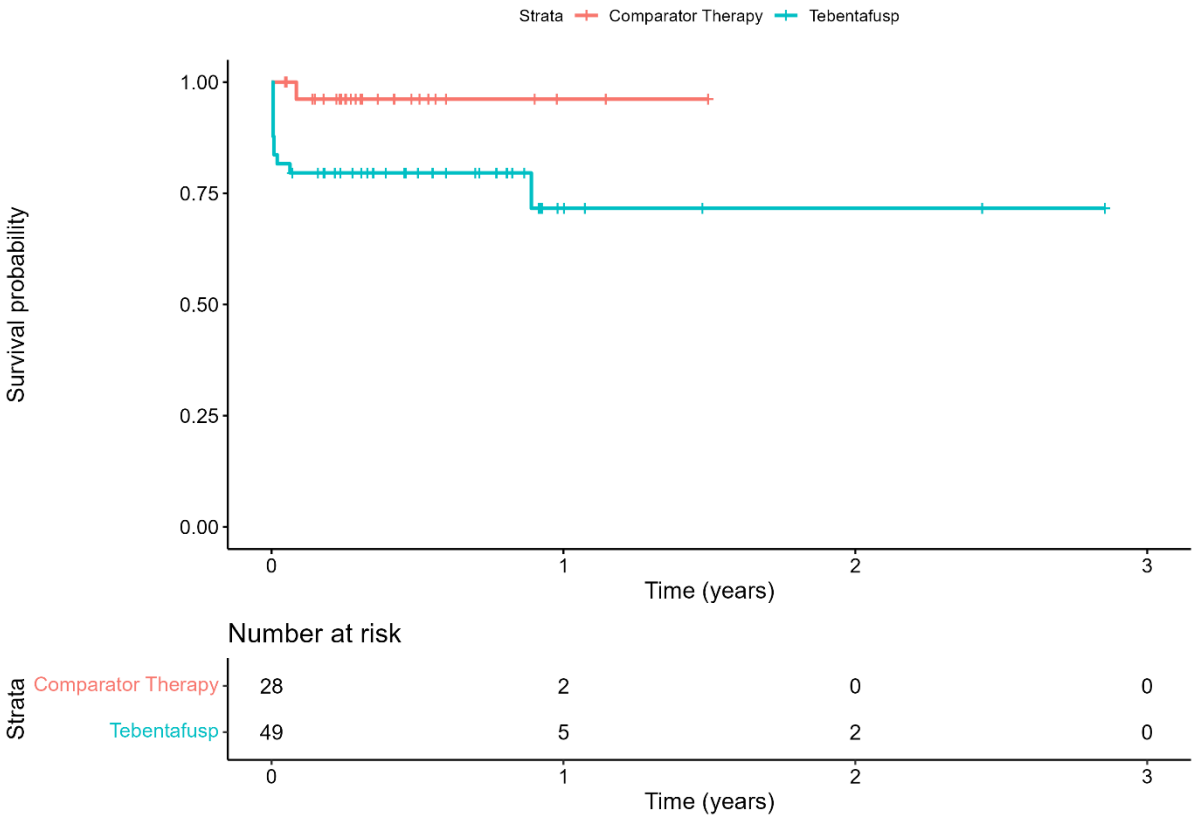
Alter: ≥65 Jahre



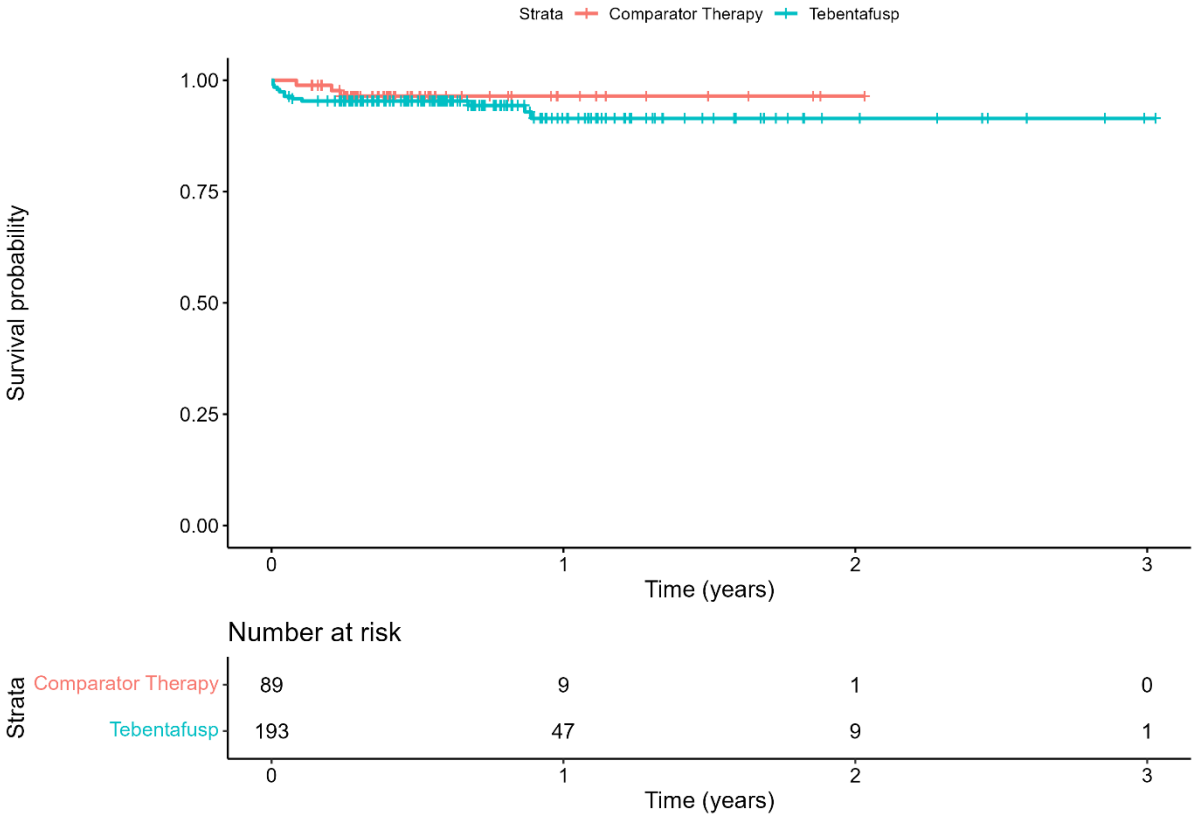
ECOG-Performance-Status: 0



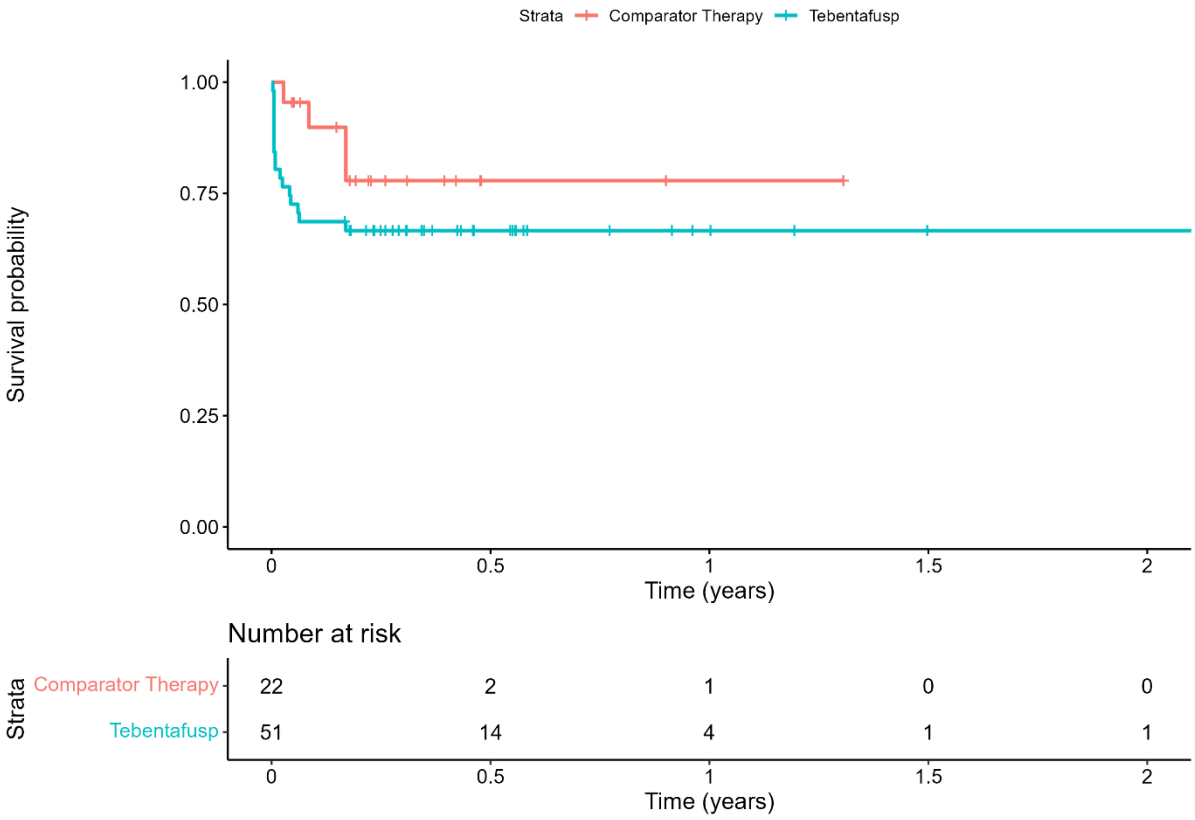
ECOG-Performance-Status: 1



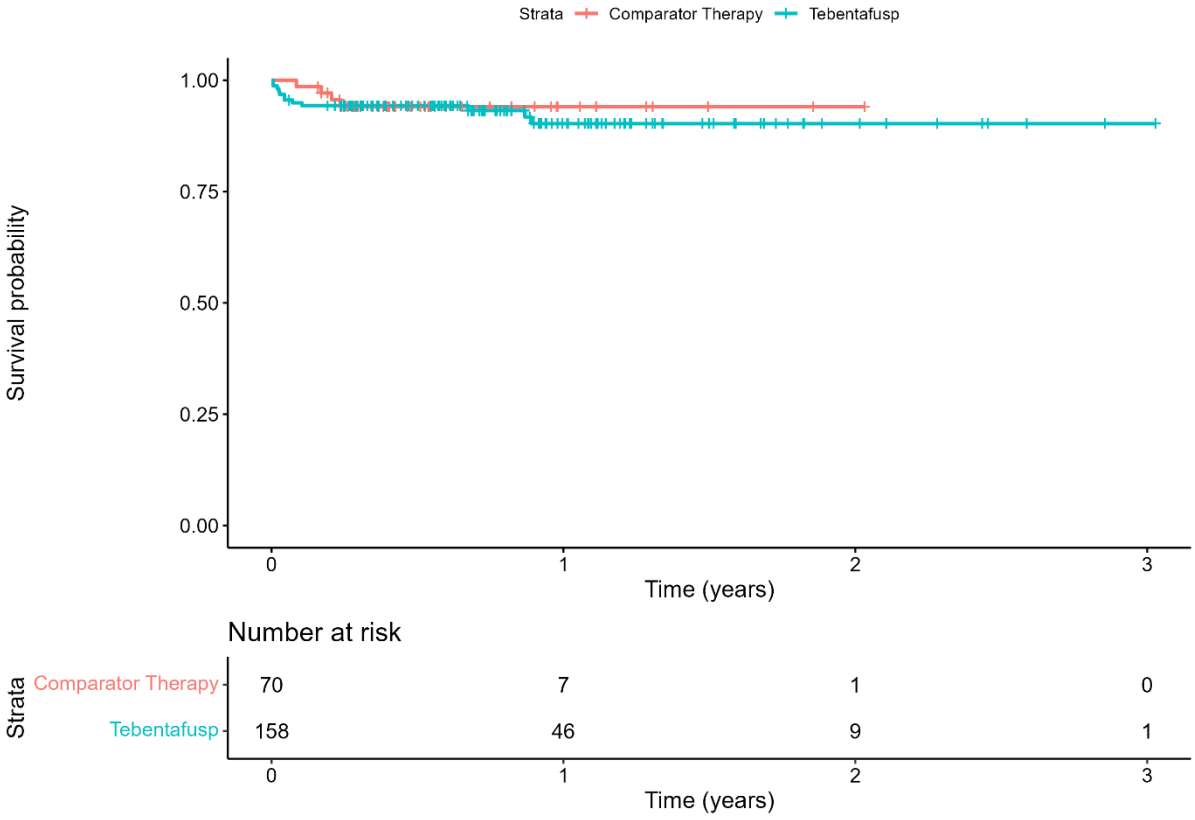
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



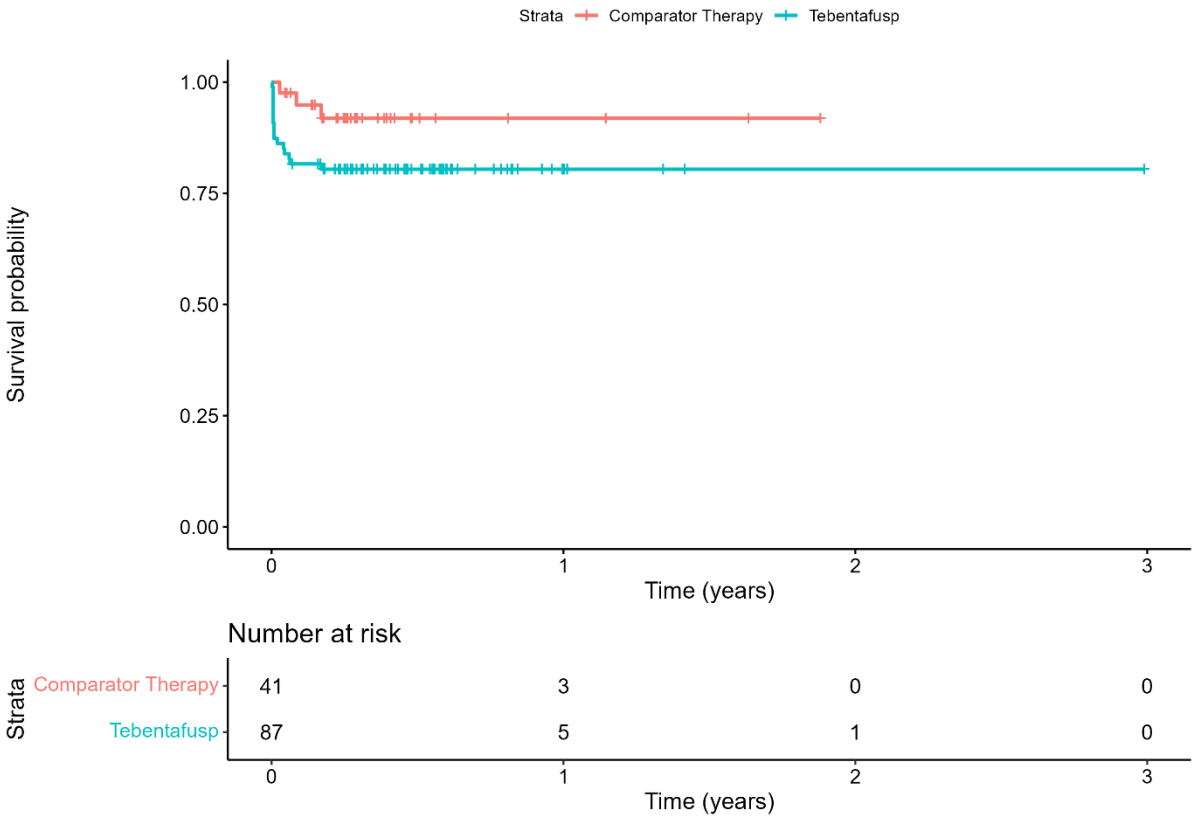
Alkalische Phosphatase (ALP) (Baseline): >ULN



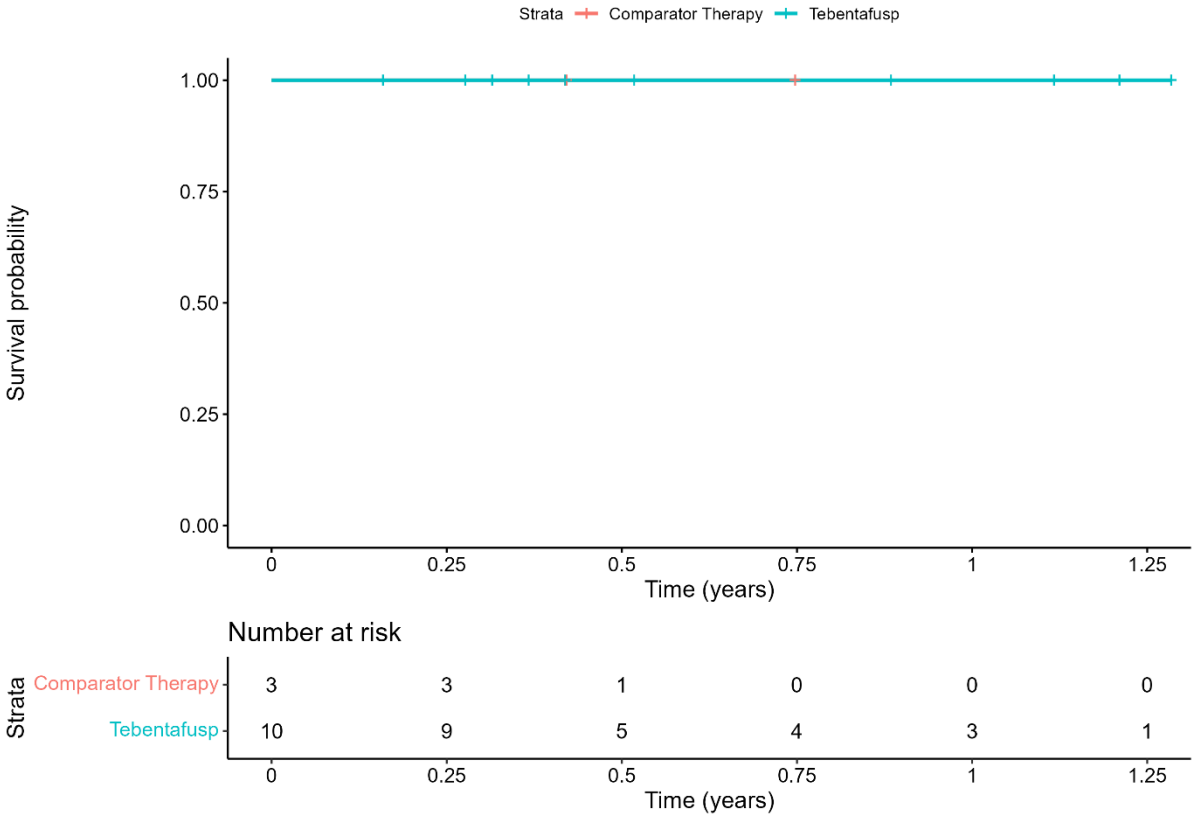
LDH: ≤ULN



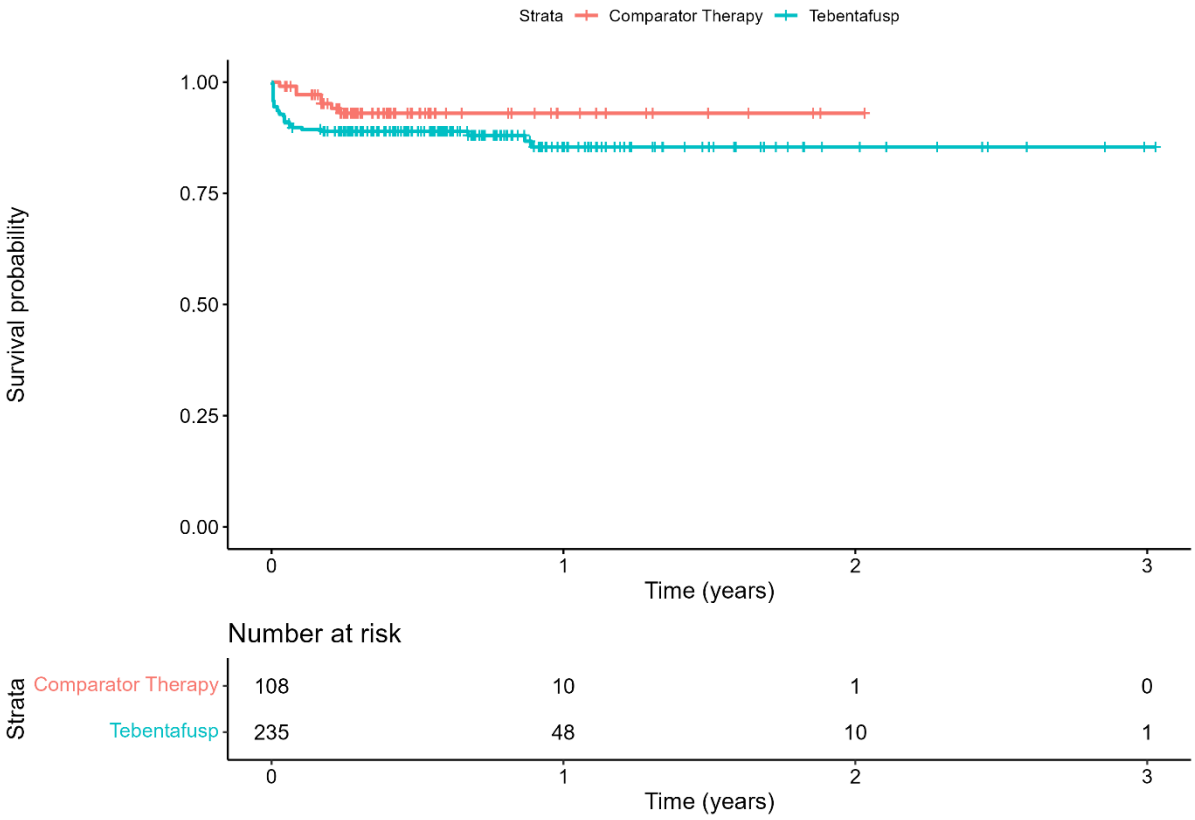
LDH: >ULN



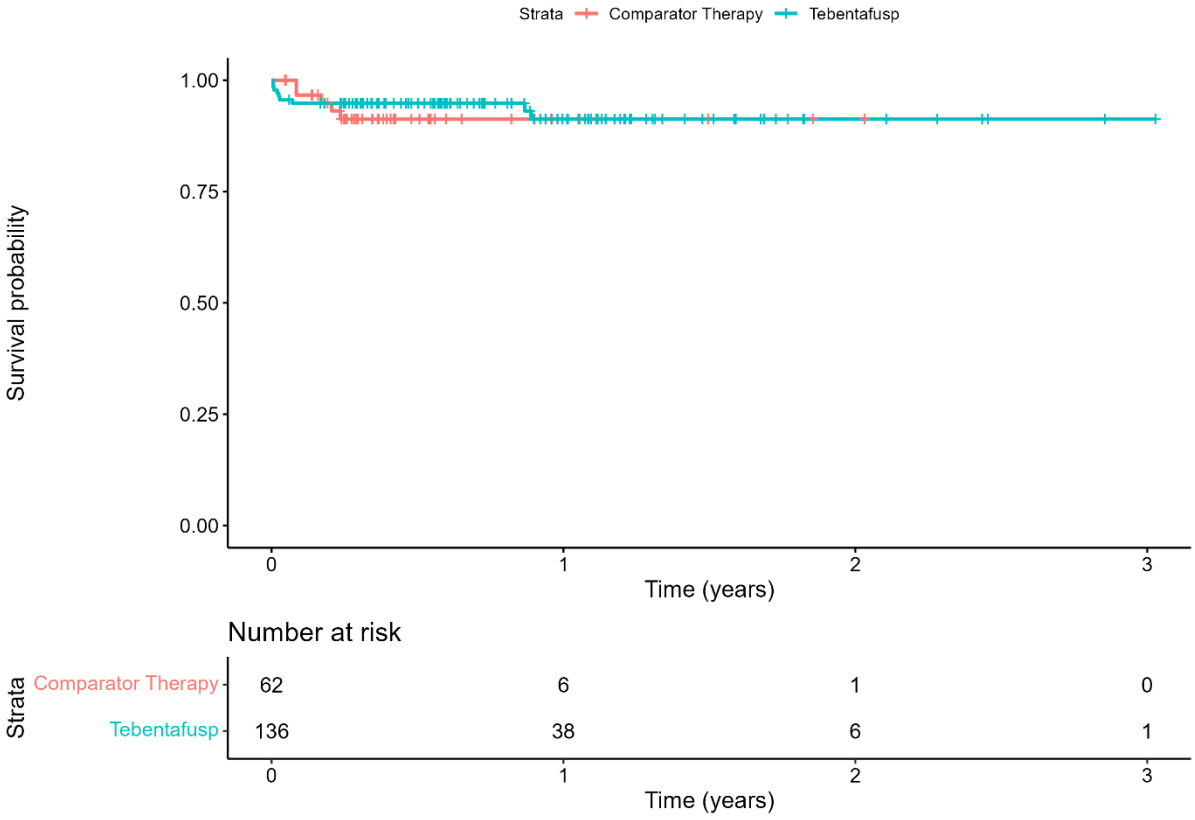
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



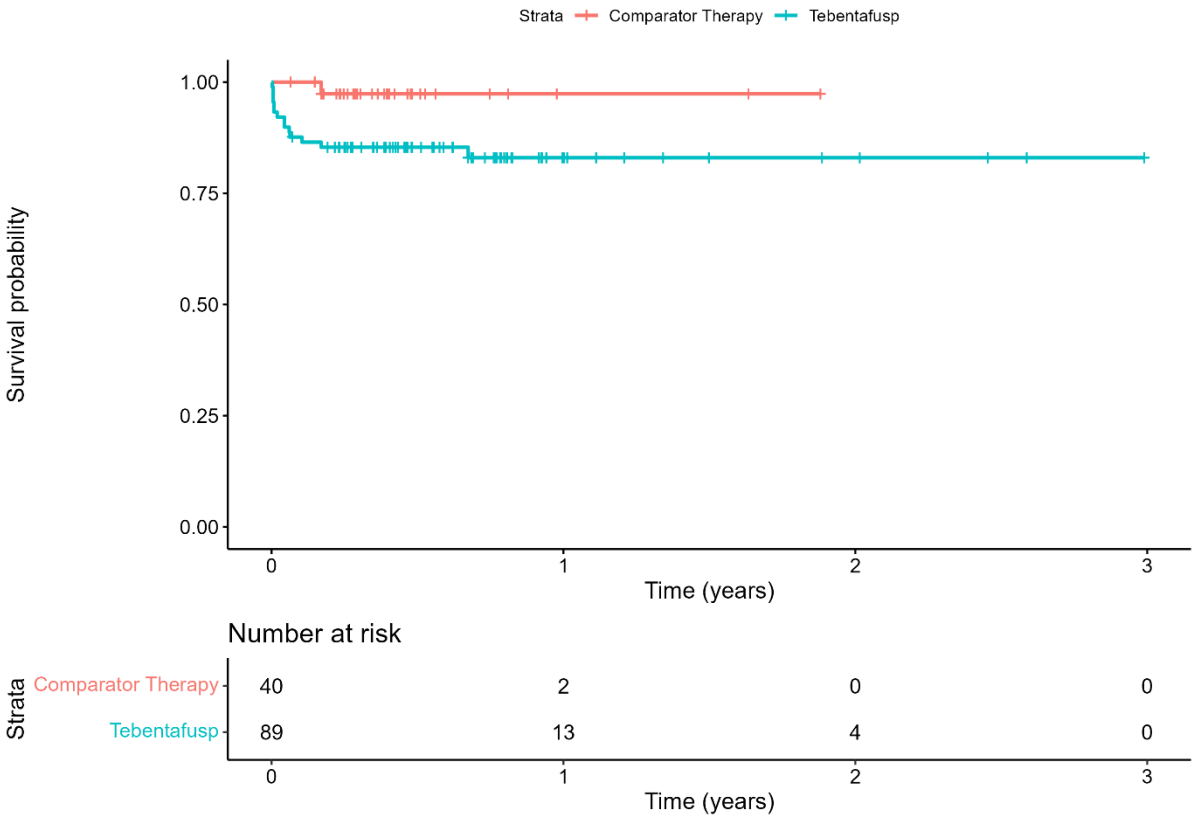
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



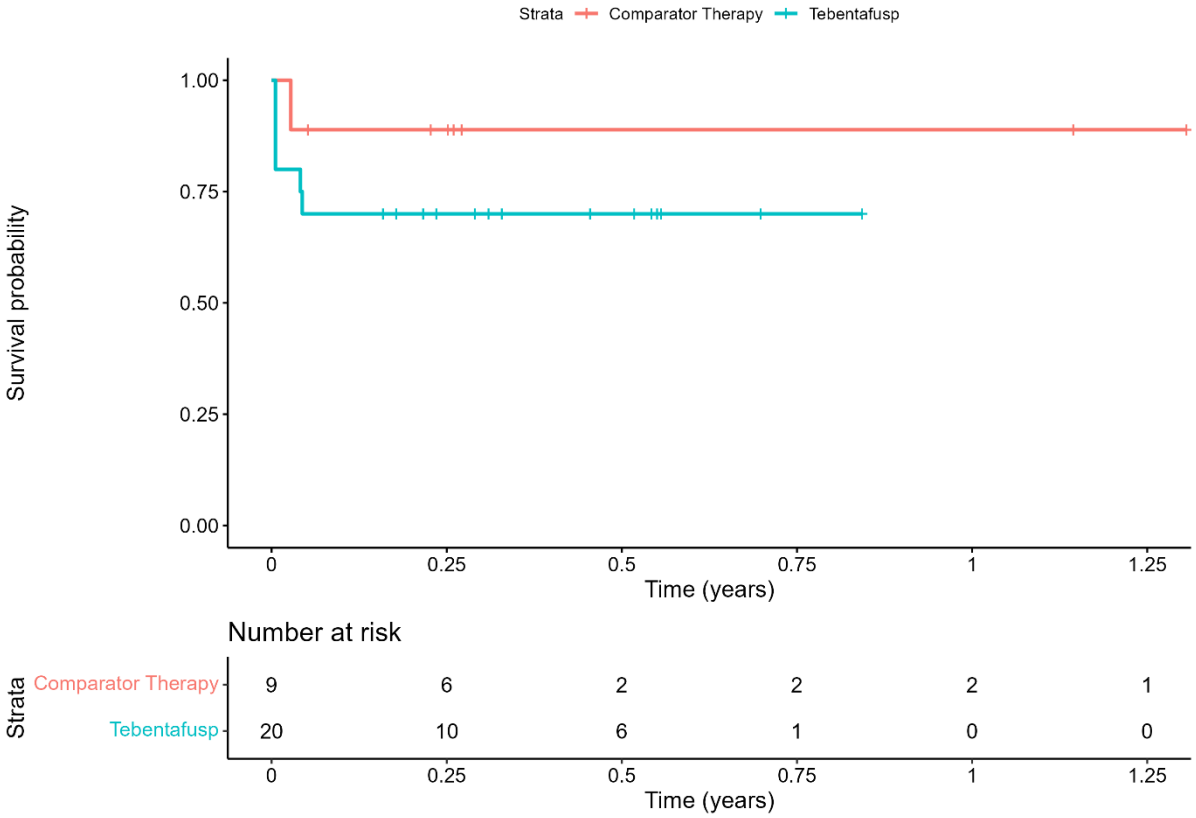
Größte metastatische Läsion (Baseline): ≤3,0 cm



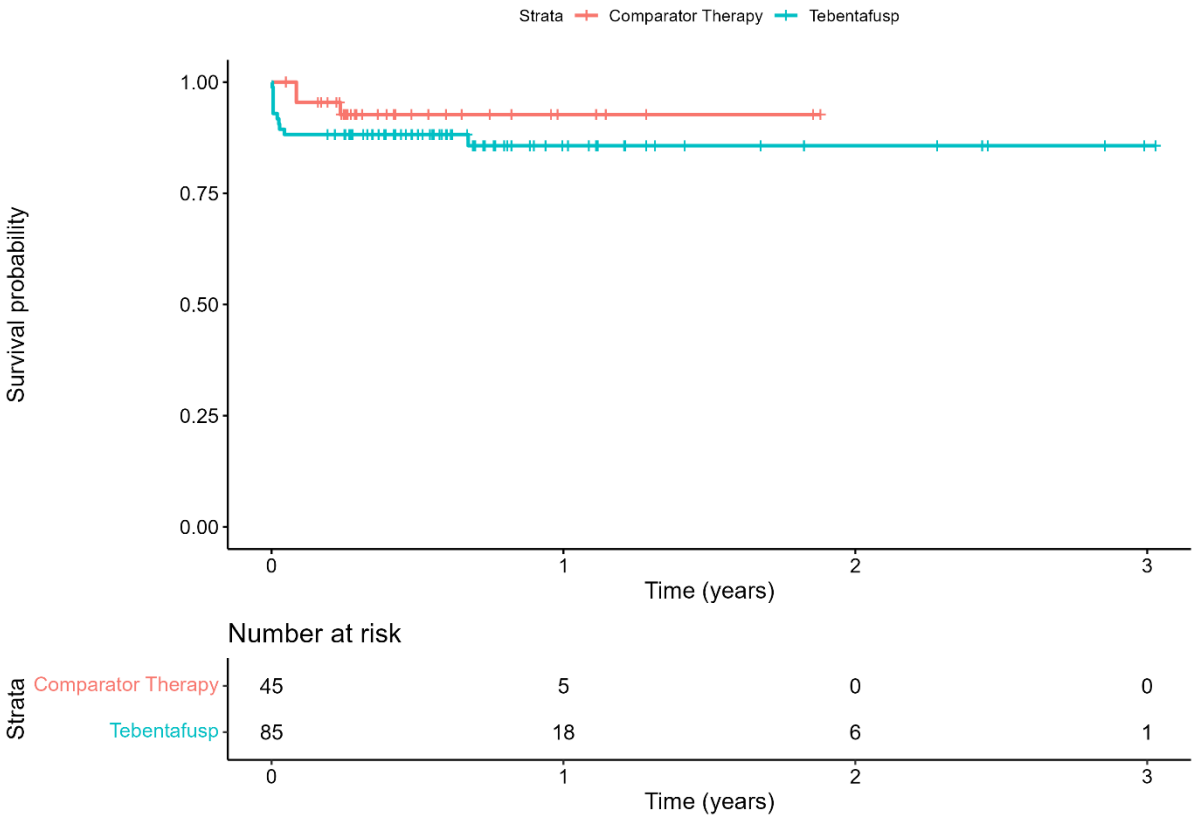
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



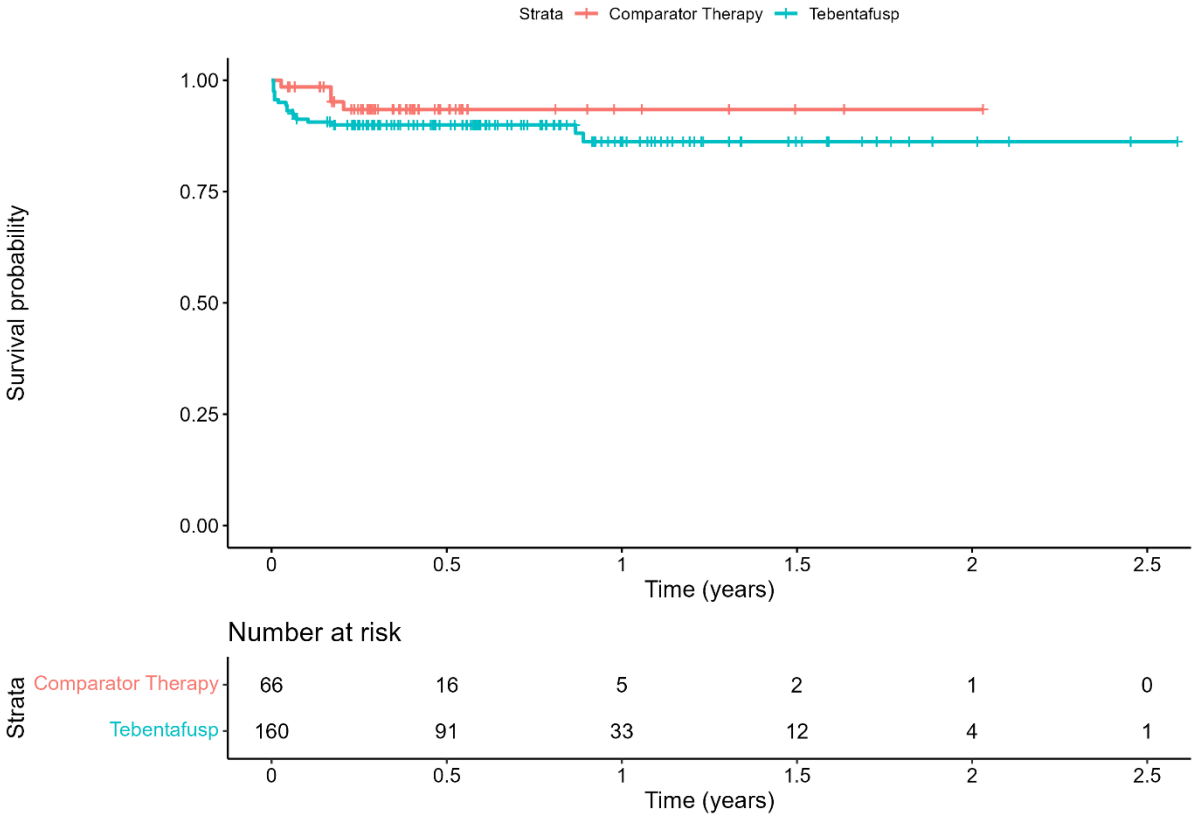
Größte metastatische Läsion (Baseline): ≥8,1 cm



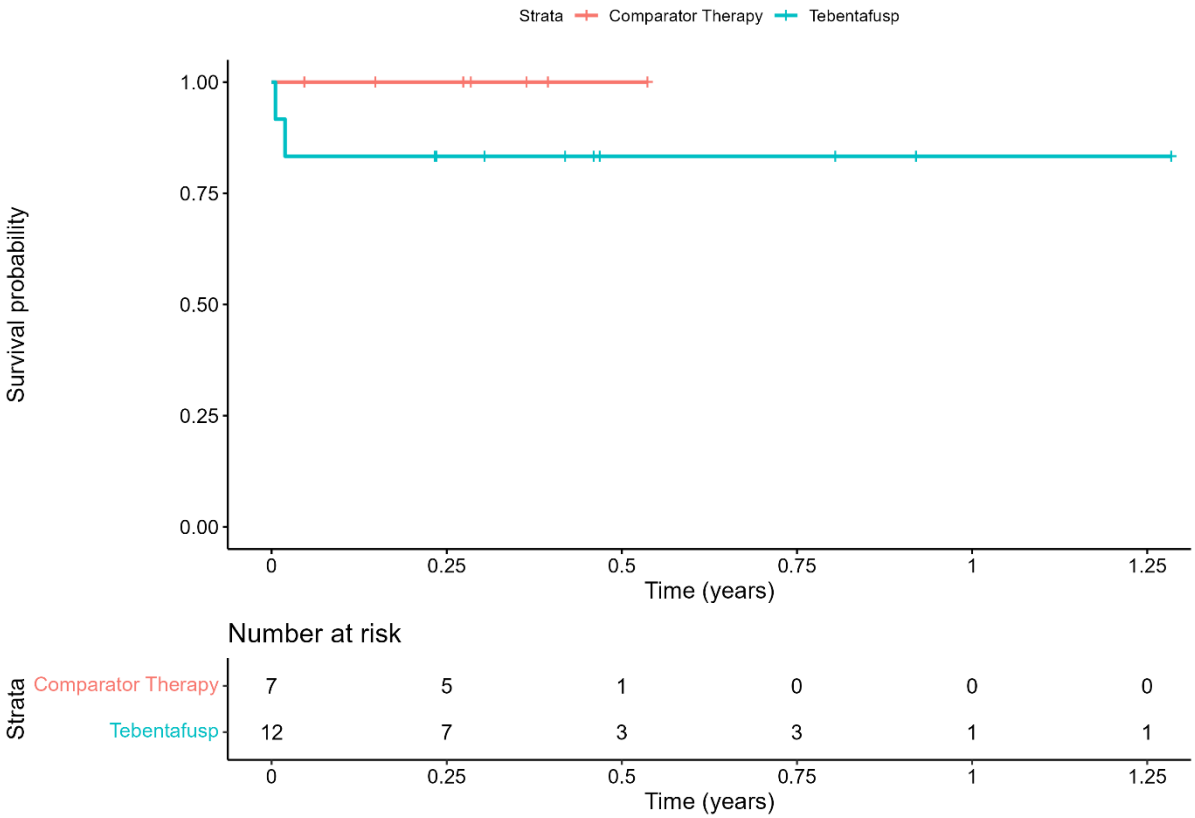
Region: Nordamerika



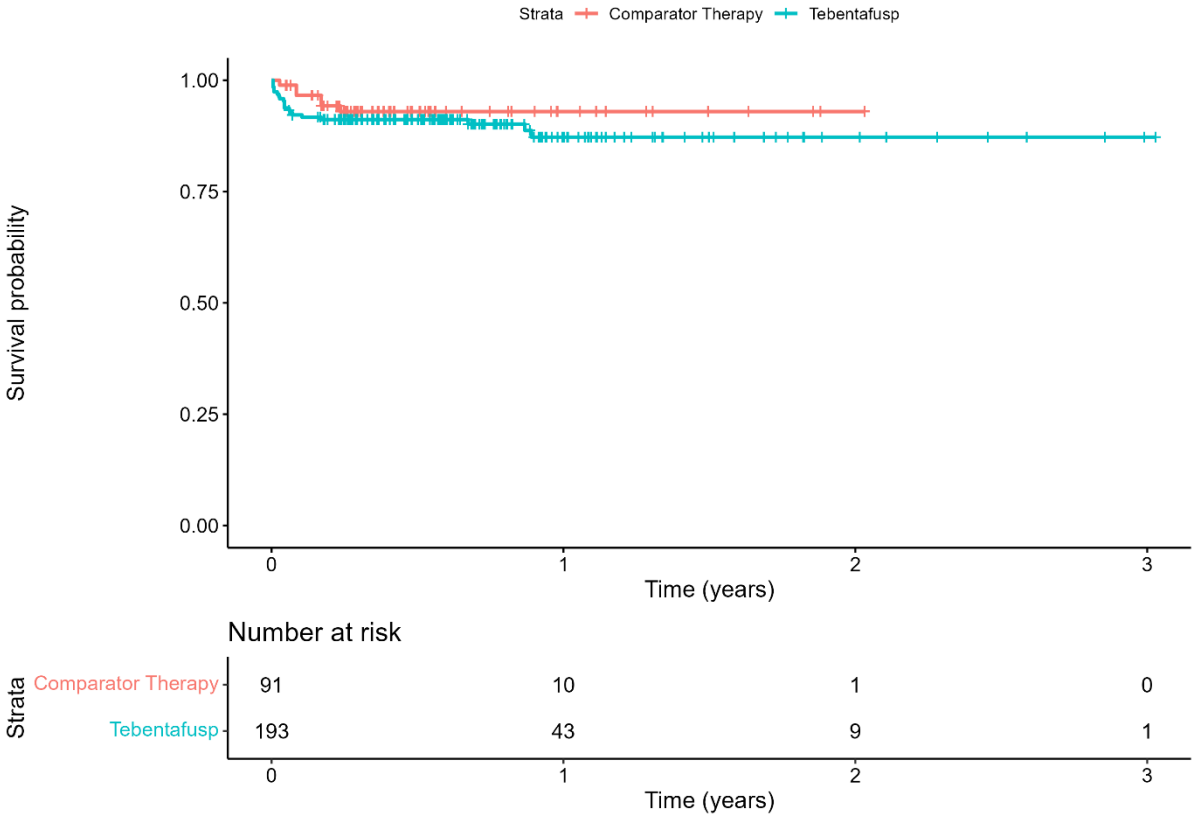
Region: Nicht-Nordamerika



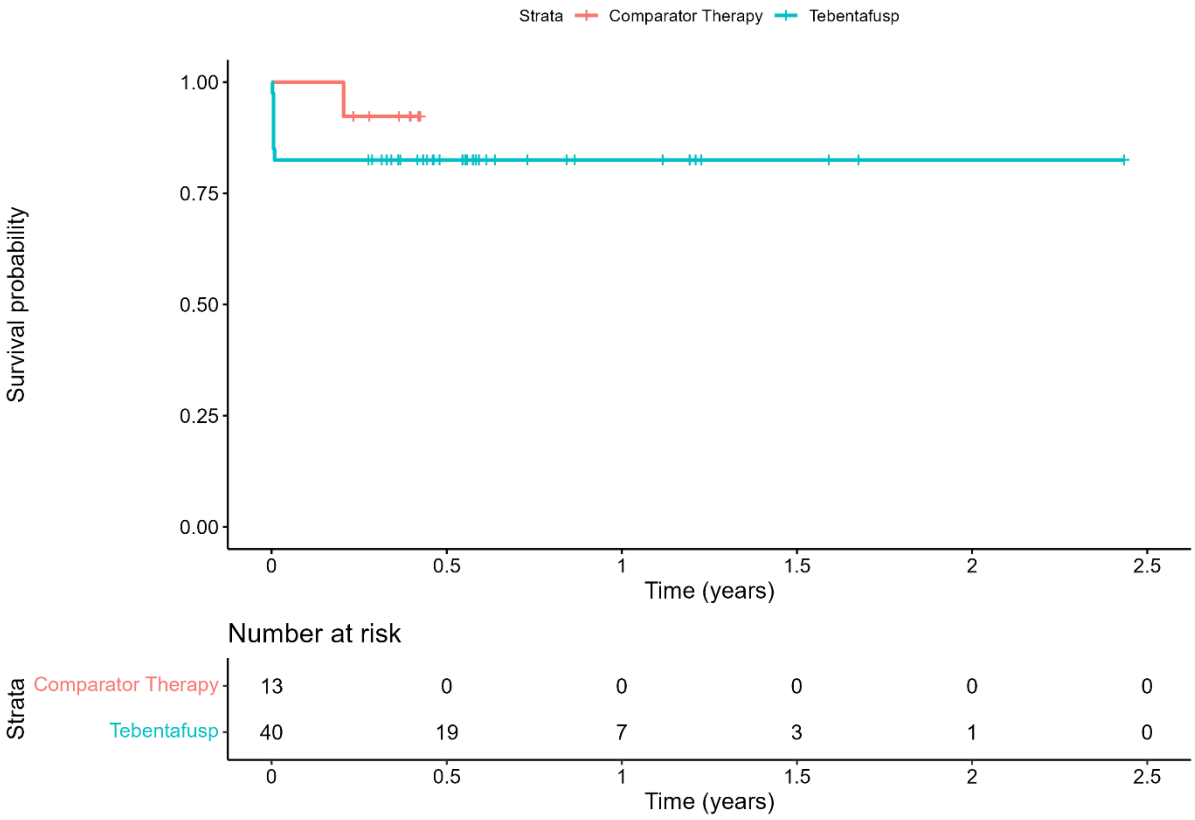
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

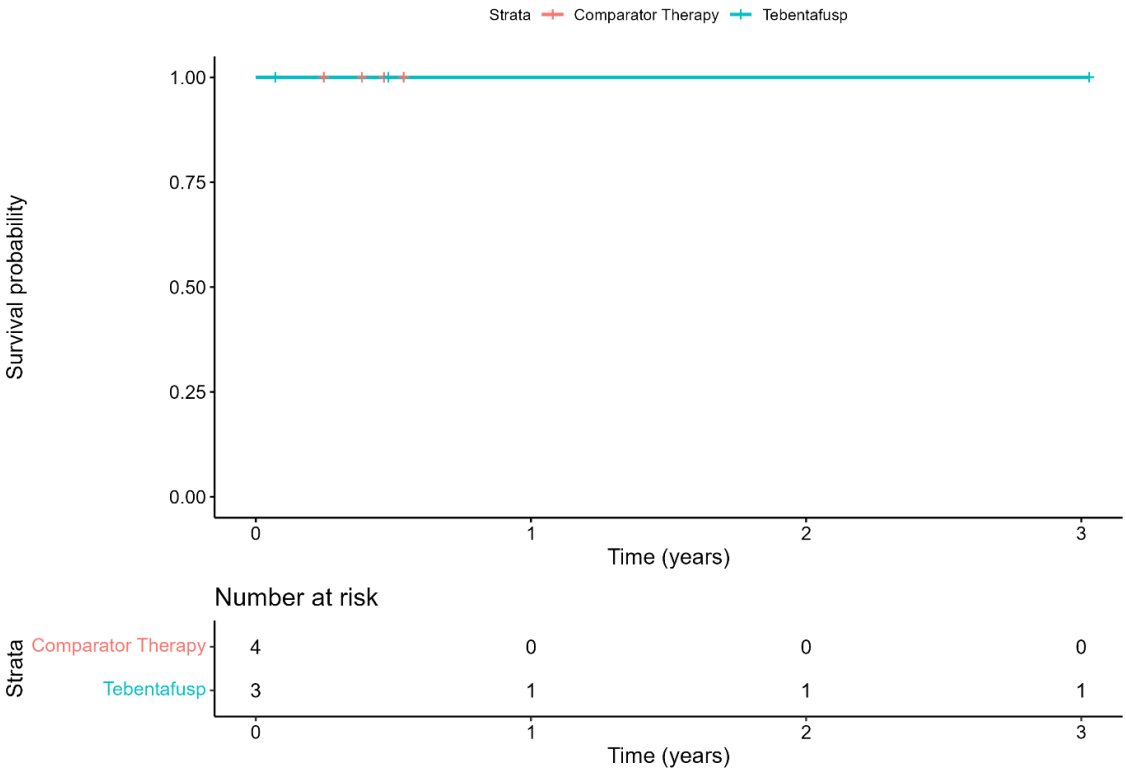


Vorauswahl der Chemotherapie: Ipilimumab

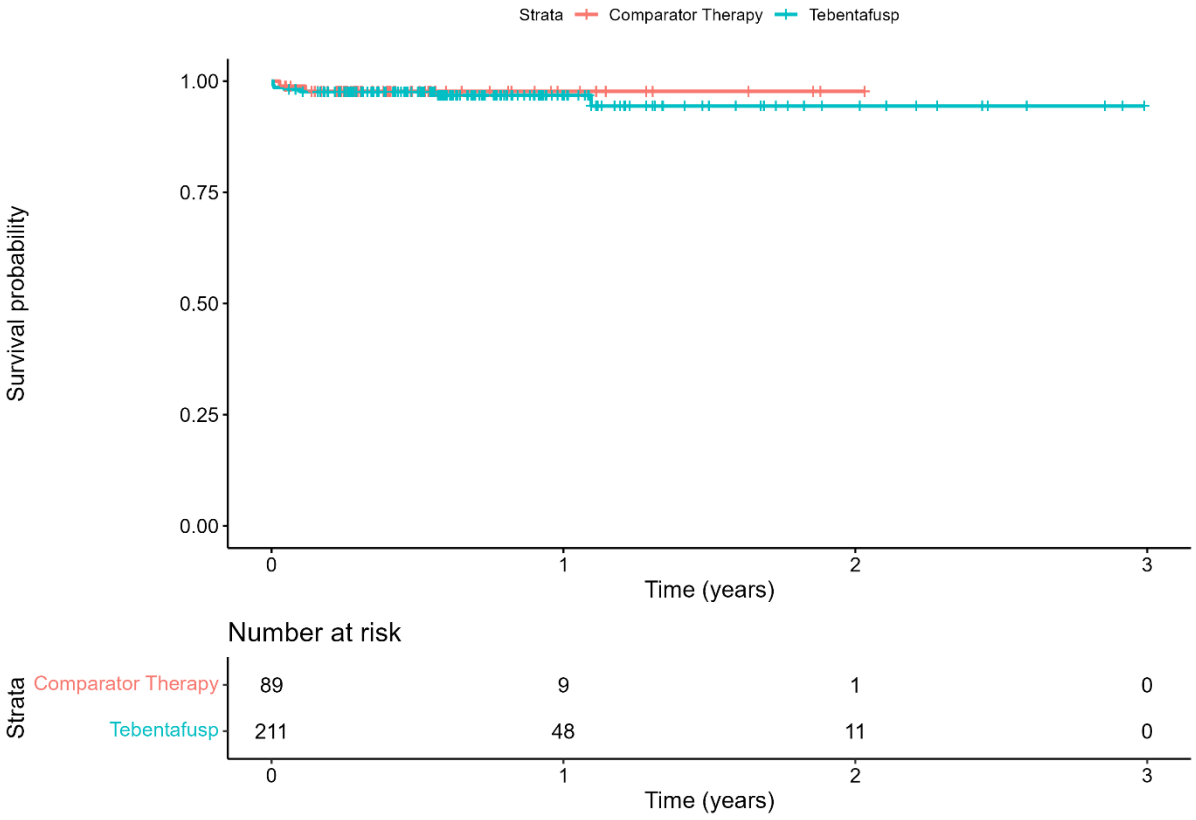


51.1 Schwerwiegende LFT-Erhöhung (Tabelle 4-114)

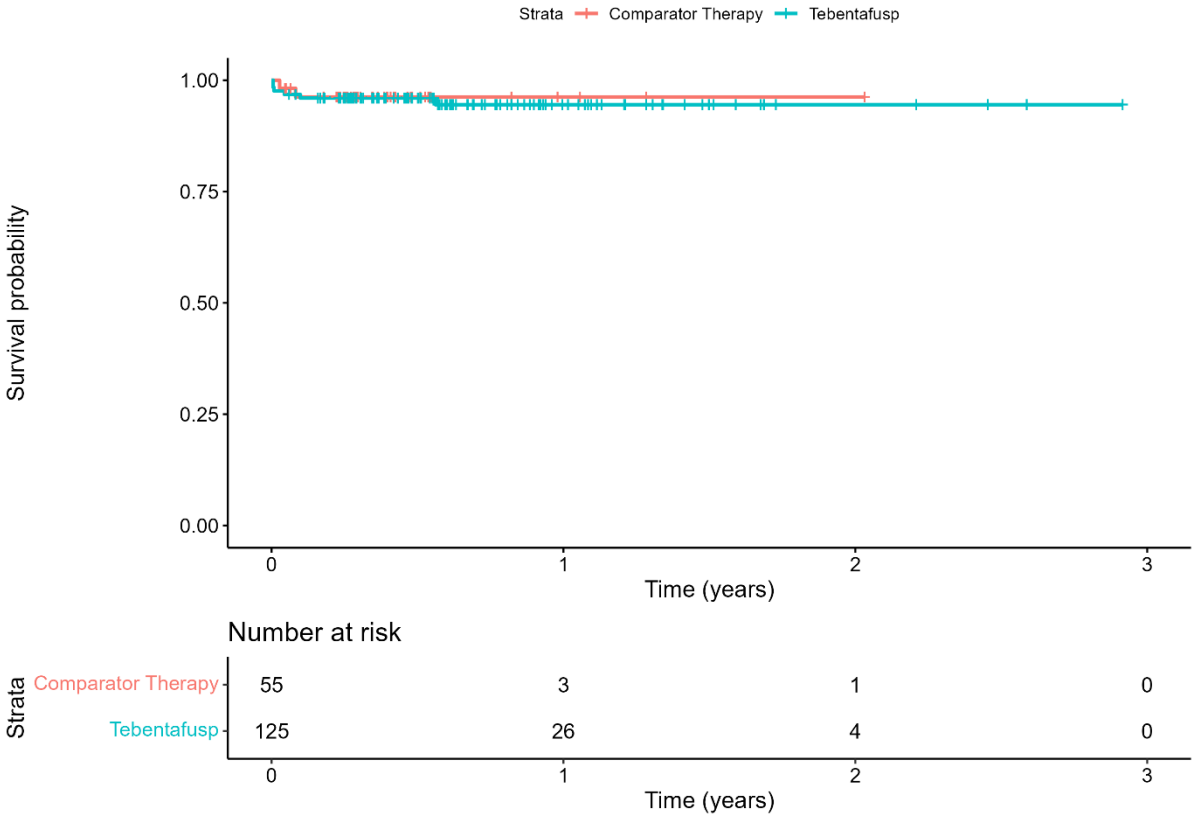
Herkunft: Hispanisch



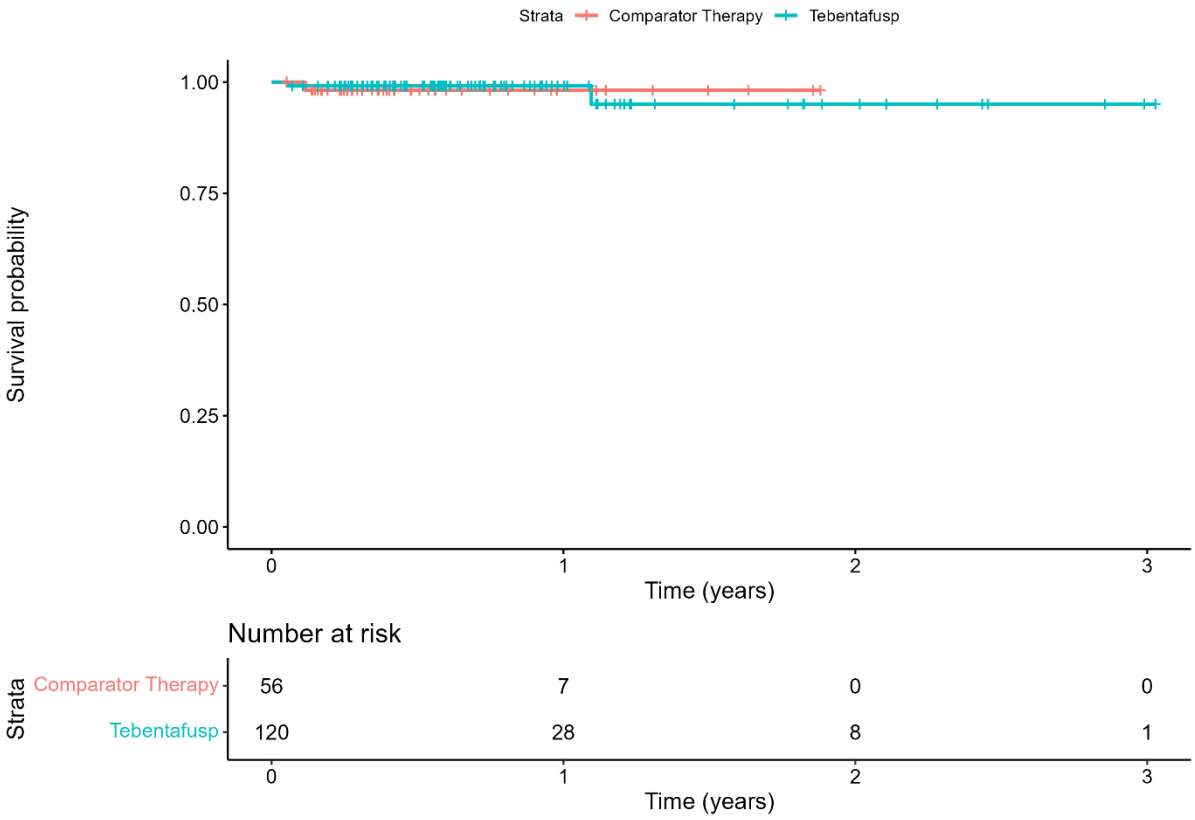
Herkunft: Nicht-hispanisch



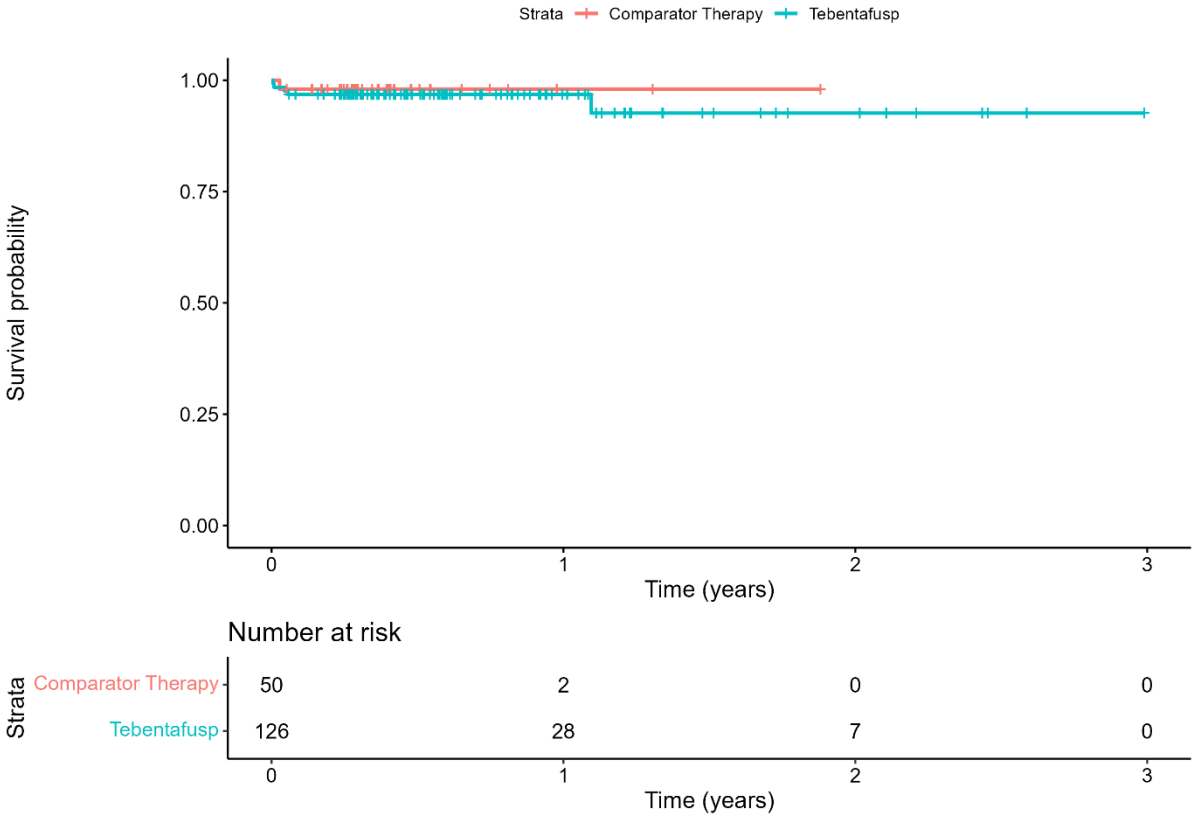
Geschlecht: Männlich



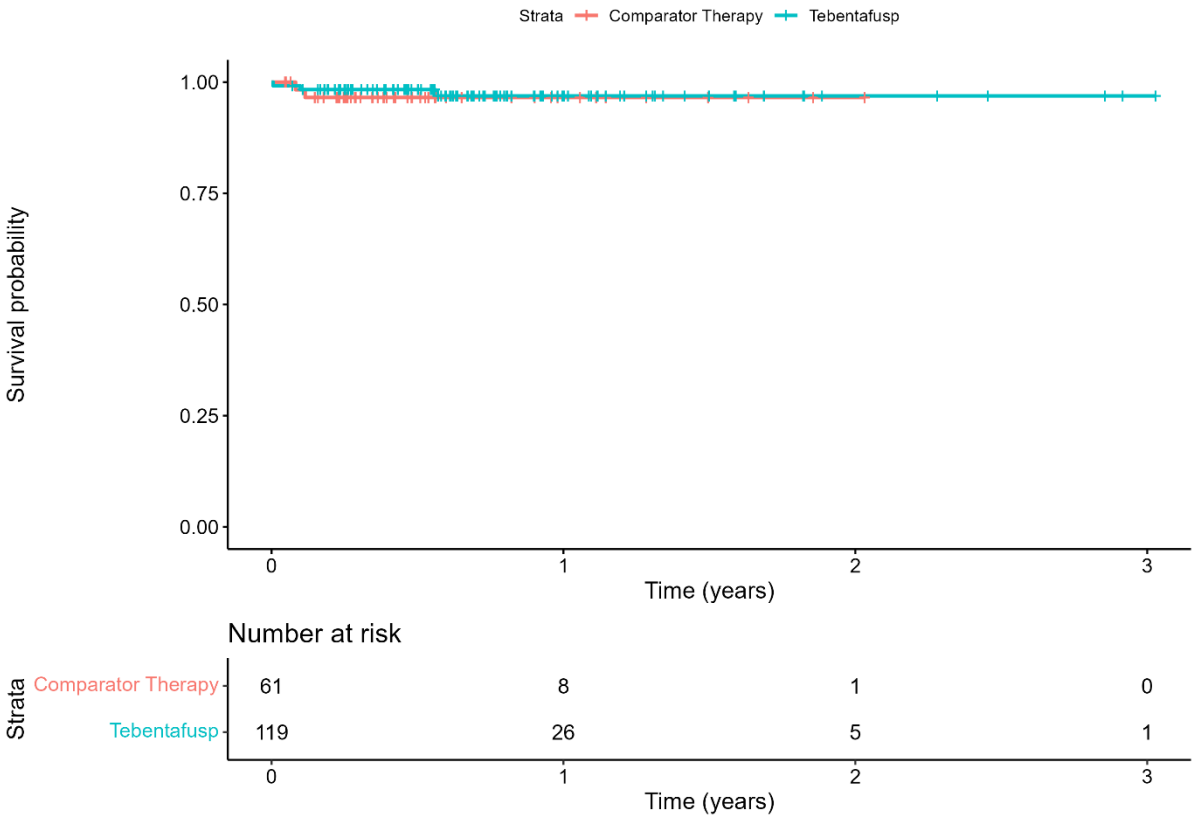
Geschlecht: Weiblich



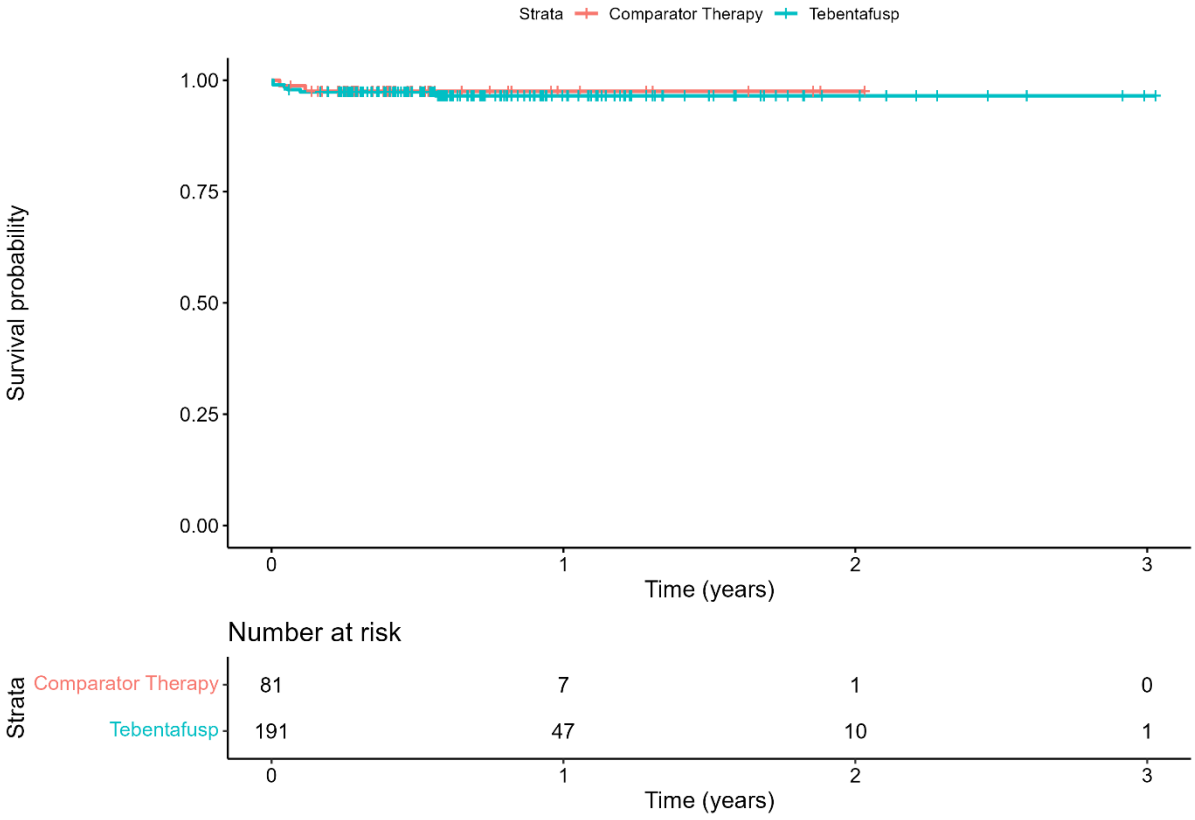
Alter: <65 Jahre



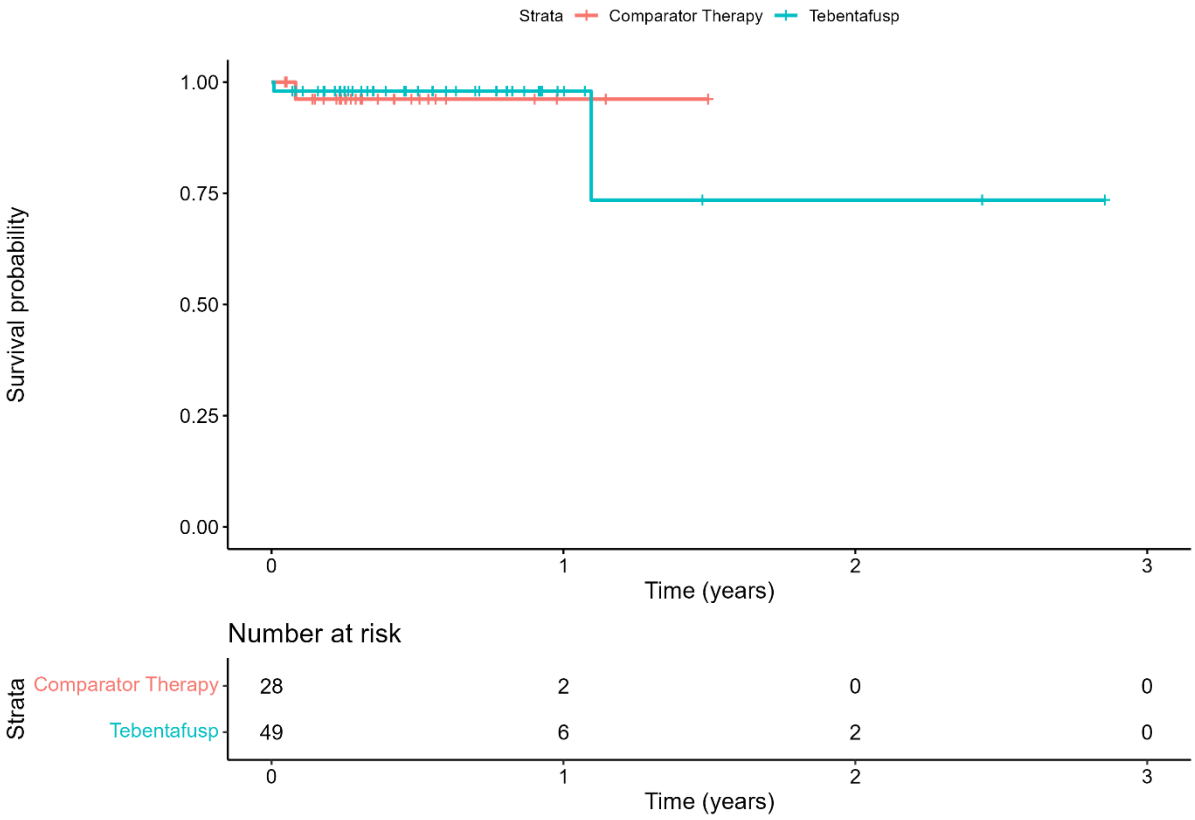
Alter: ≥65 Jahre



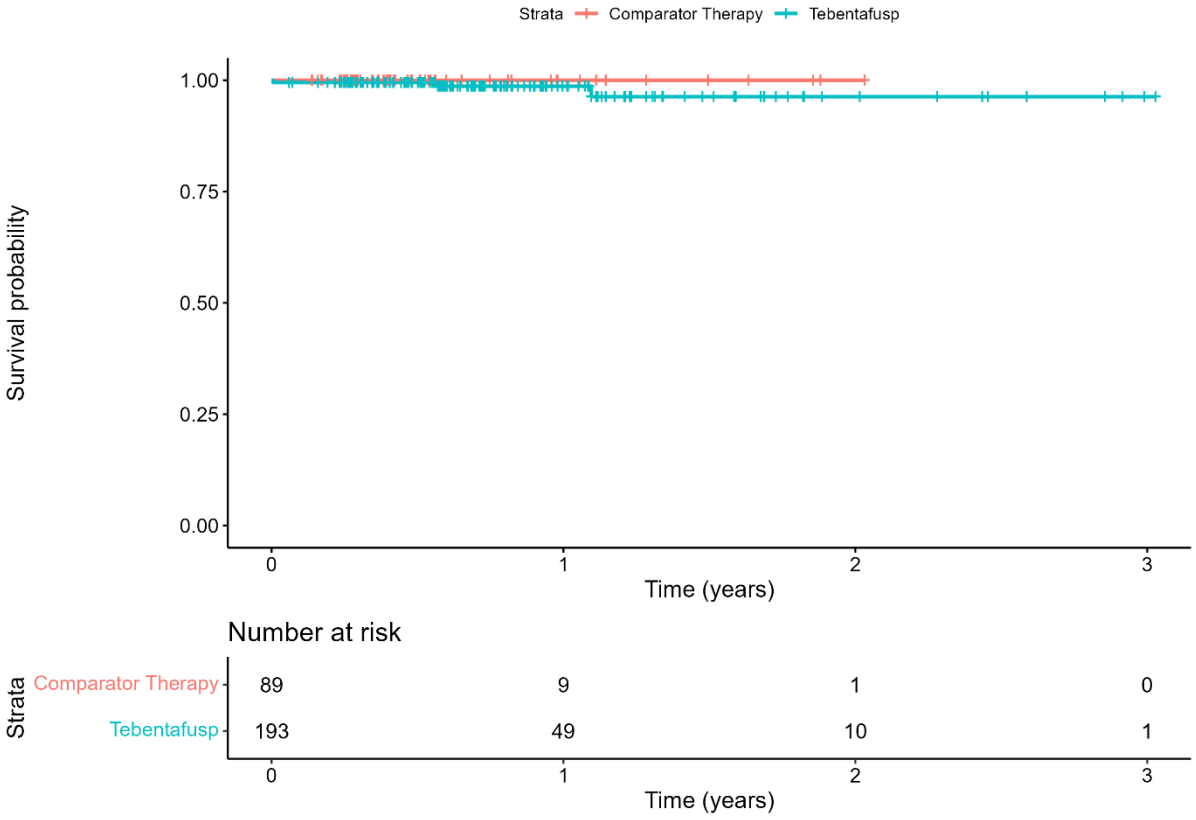
ECOG-Performance-Status: 0



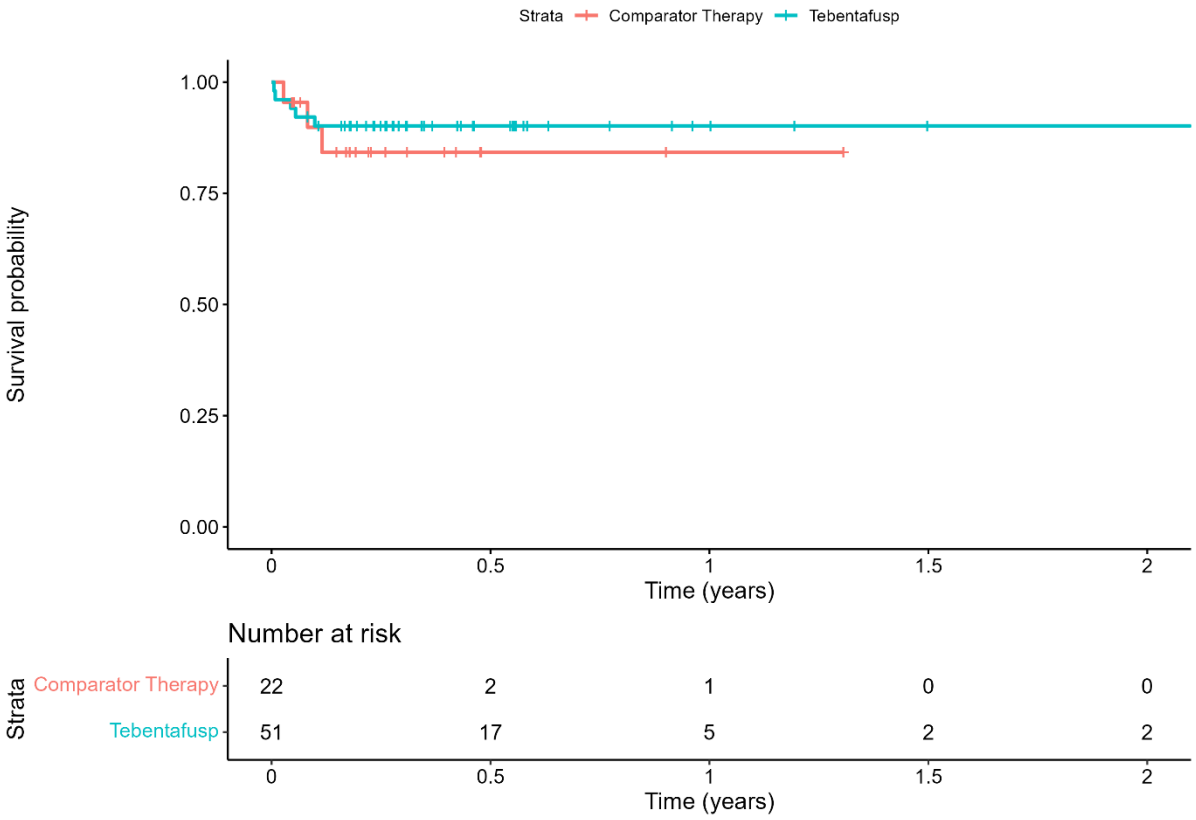
ECOG-Performance-Status: 1



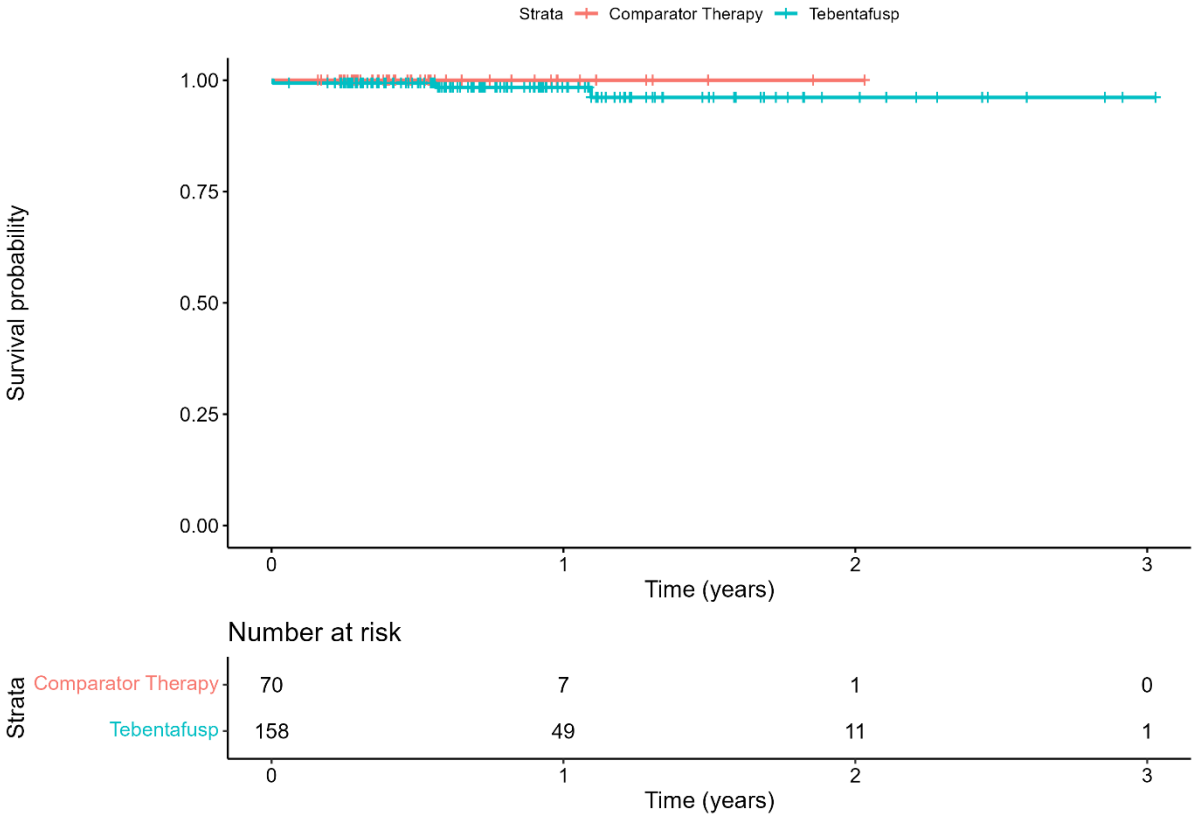
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



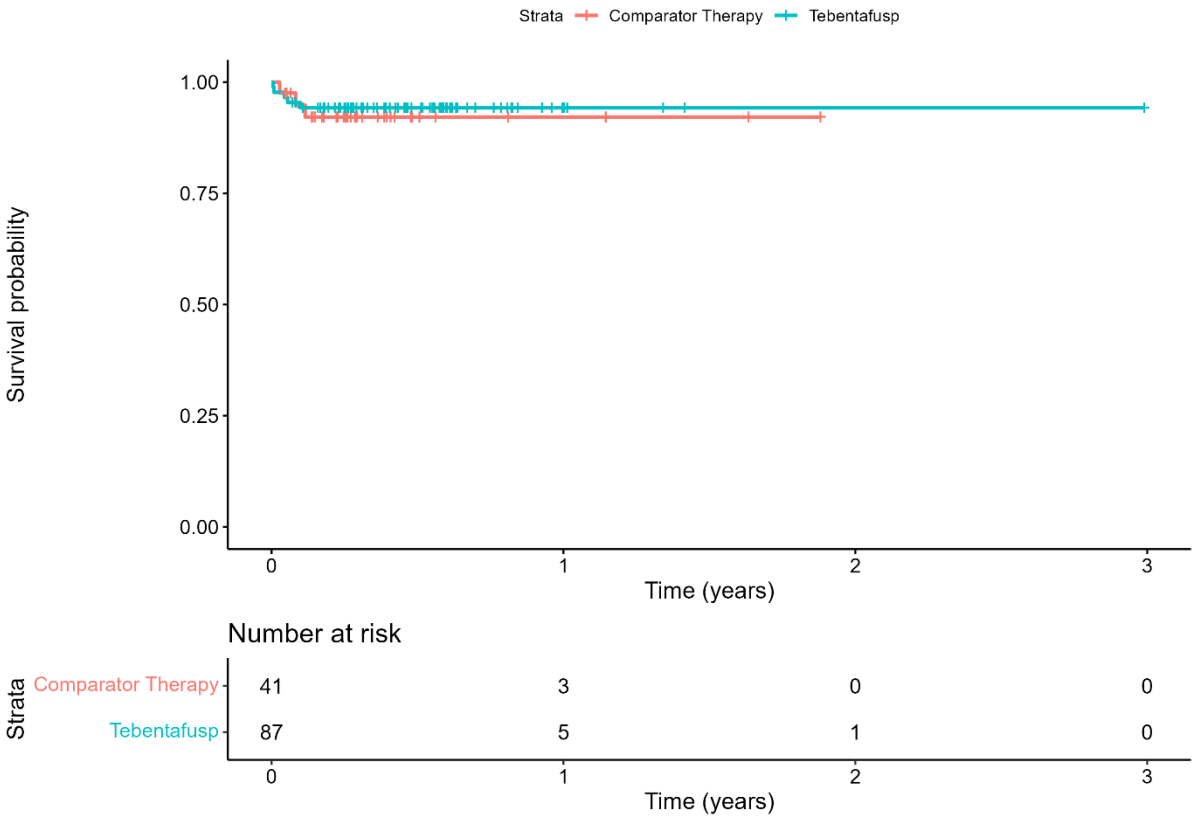
Alkalische Phosphatase (ALP) (Baseline): >ULN



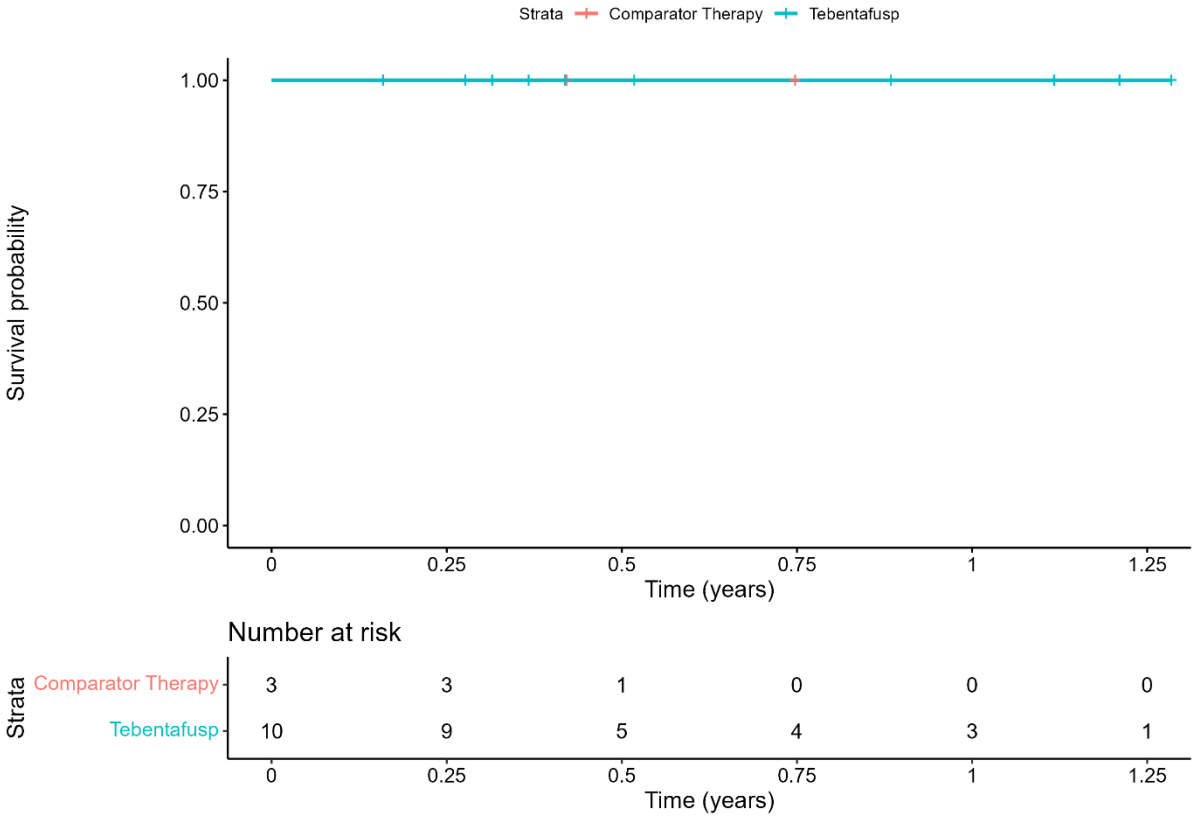
LDH: ≤ULN



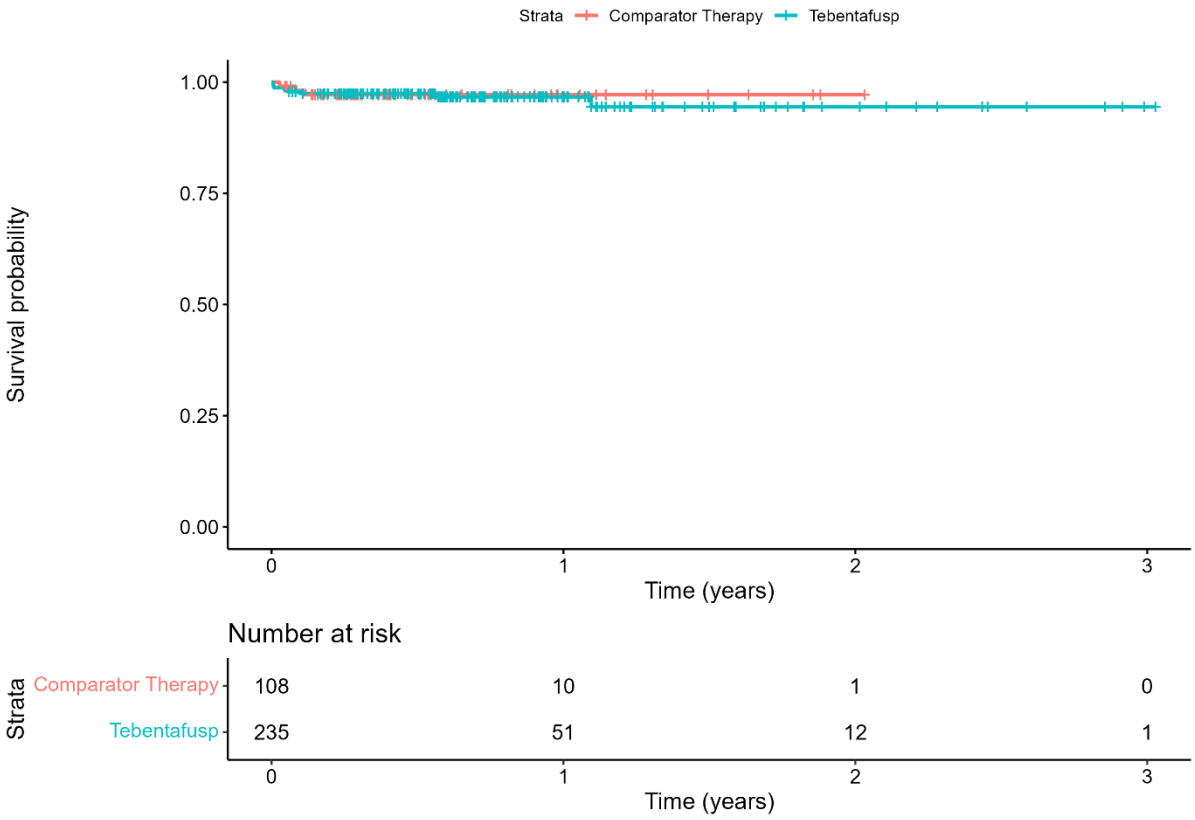
LDH: >ULN



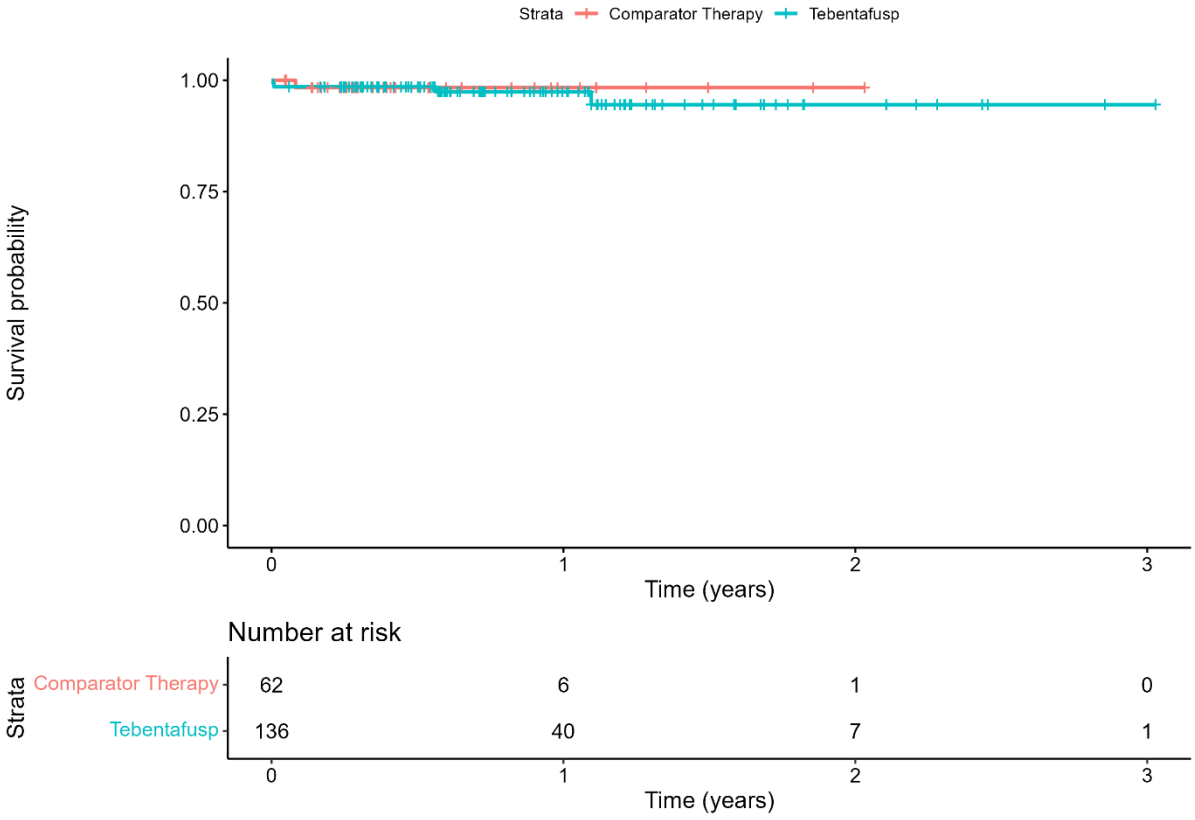
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



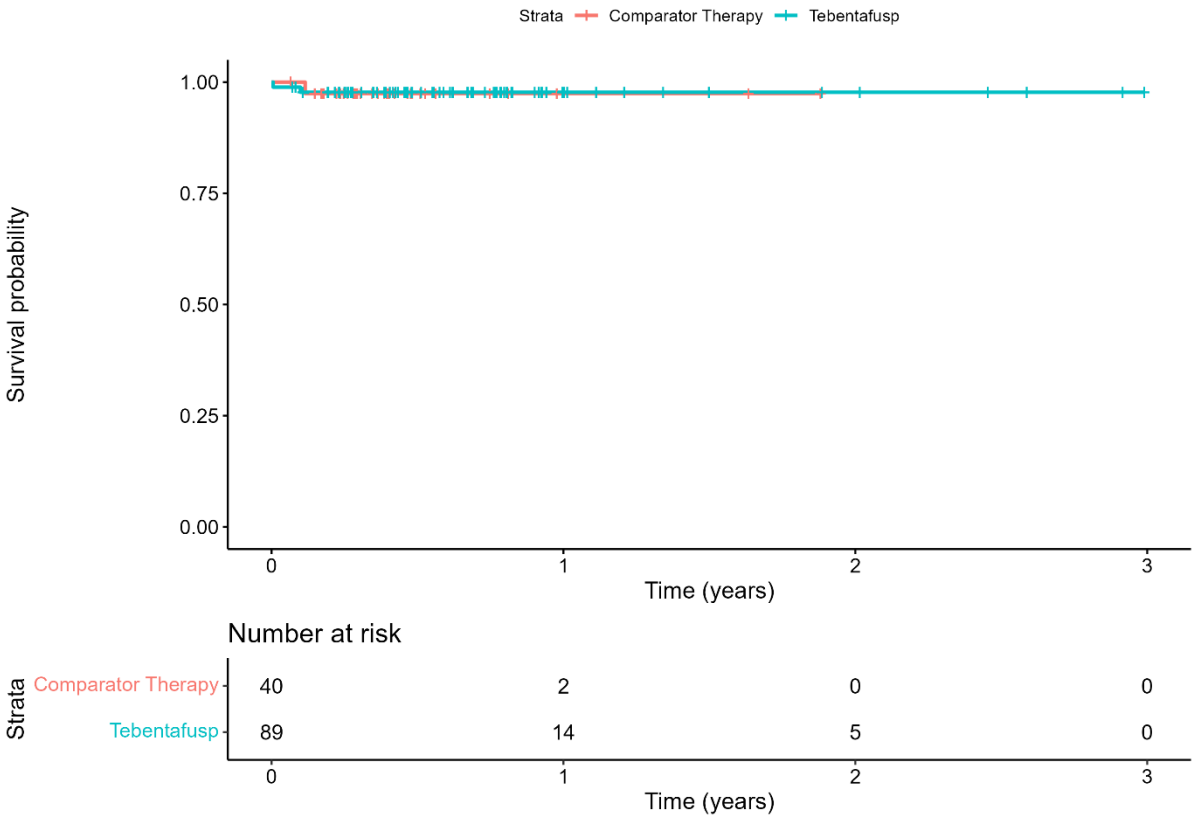
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



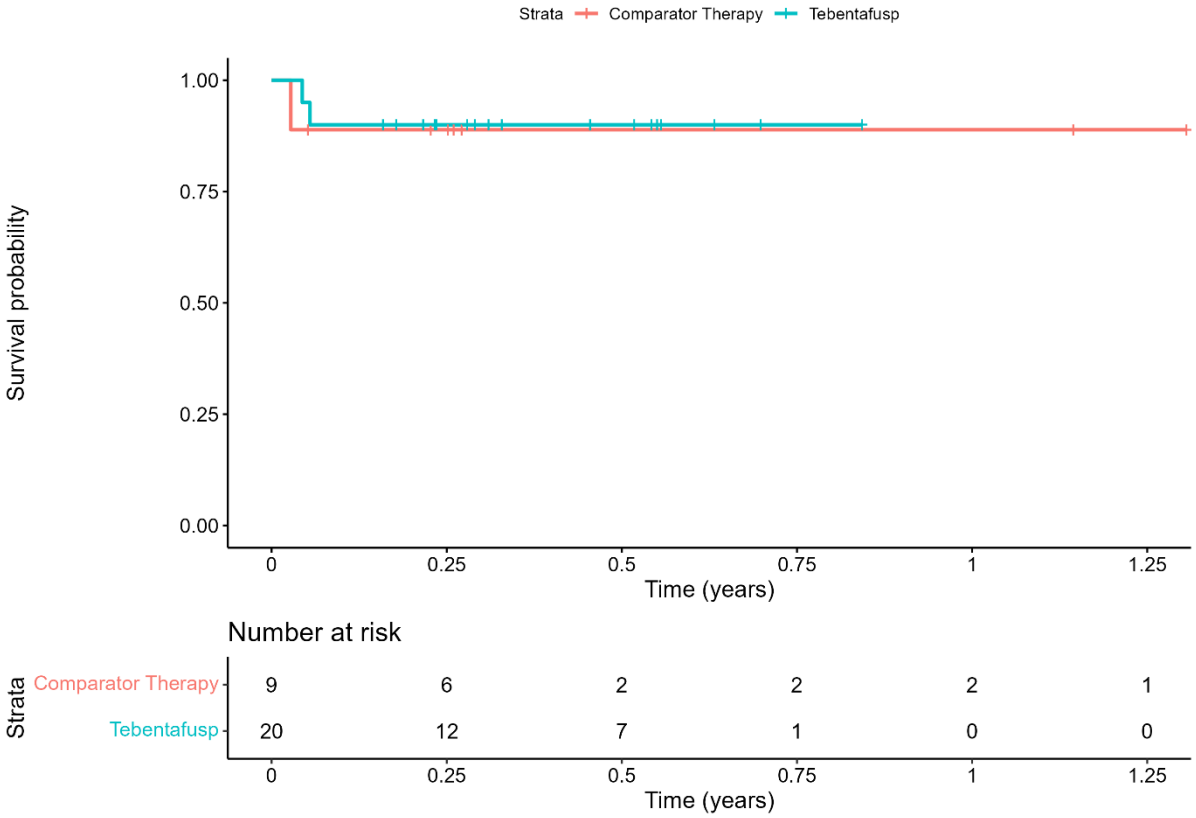
Größte metastatische Läsion (Baseline): ≤3,0 cm



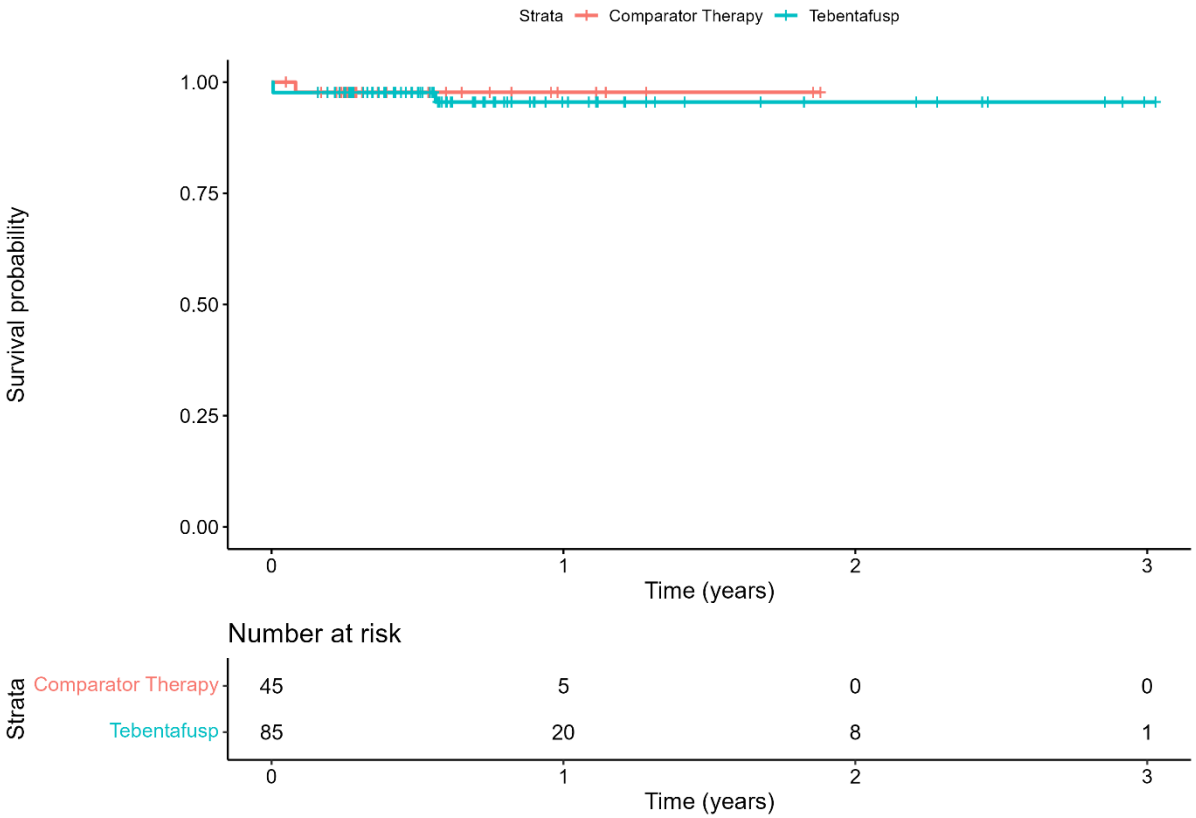
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



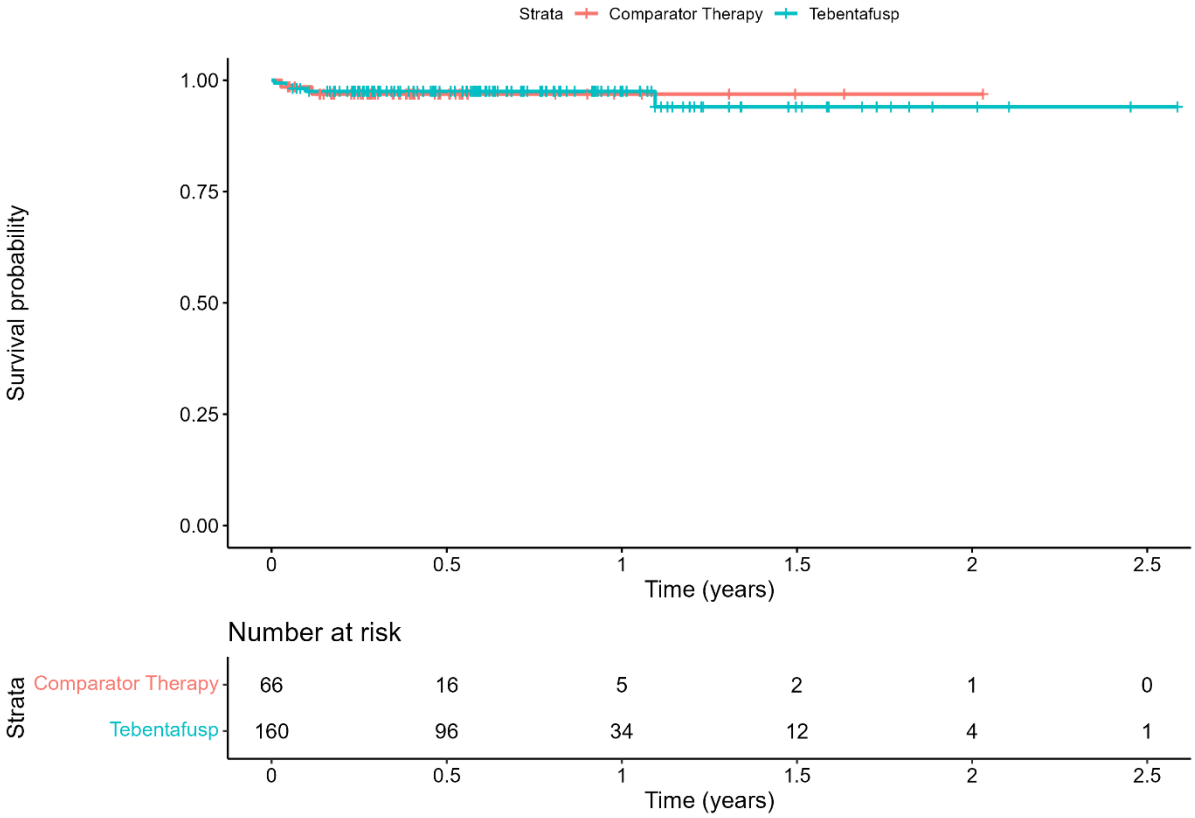
Größte metastatische Läsion (Baseline): ≥8,1 cm



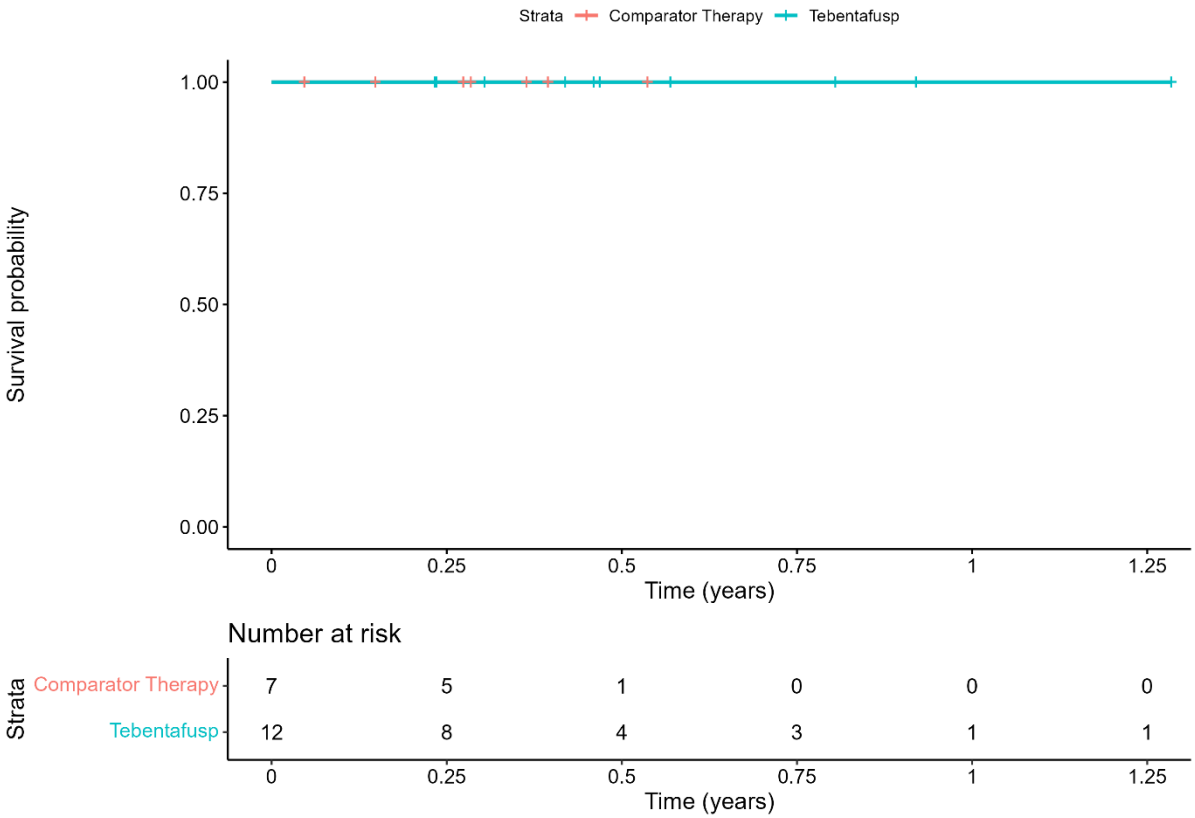
Region: Nordamerika



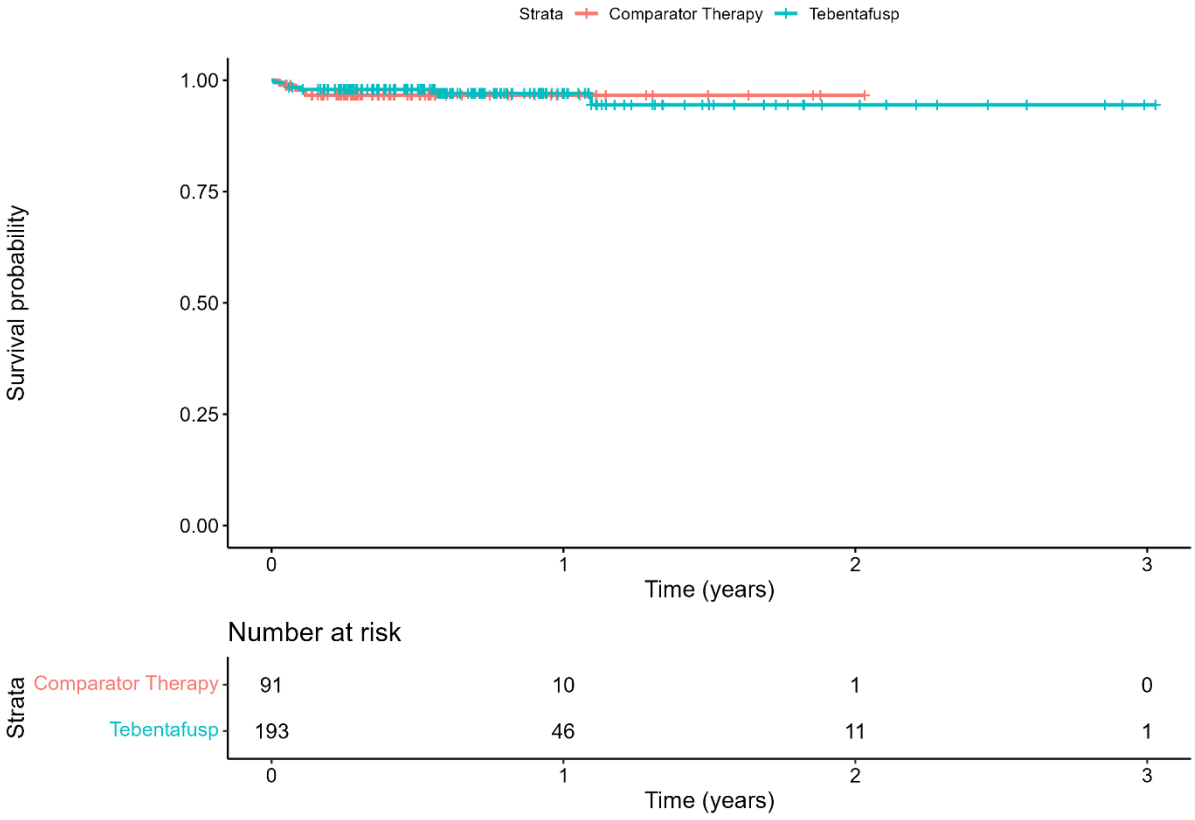
Region: Nicht-Nordamerika



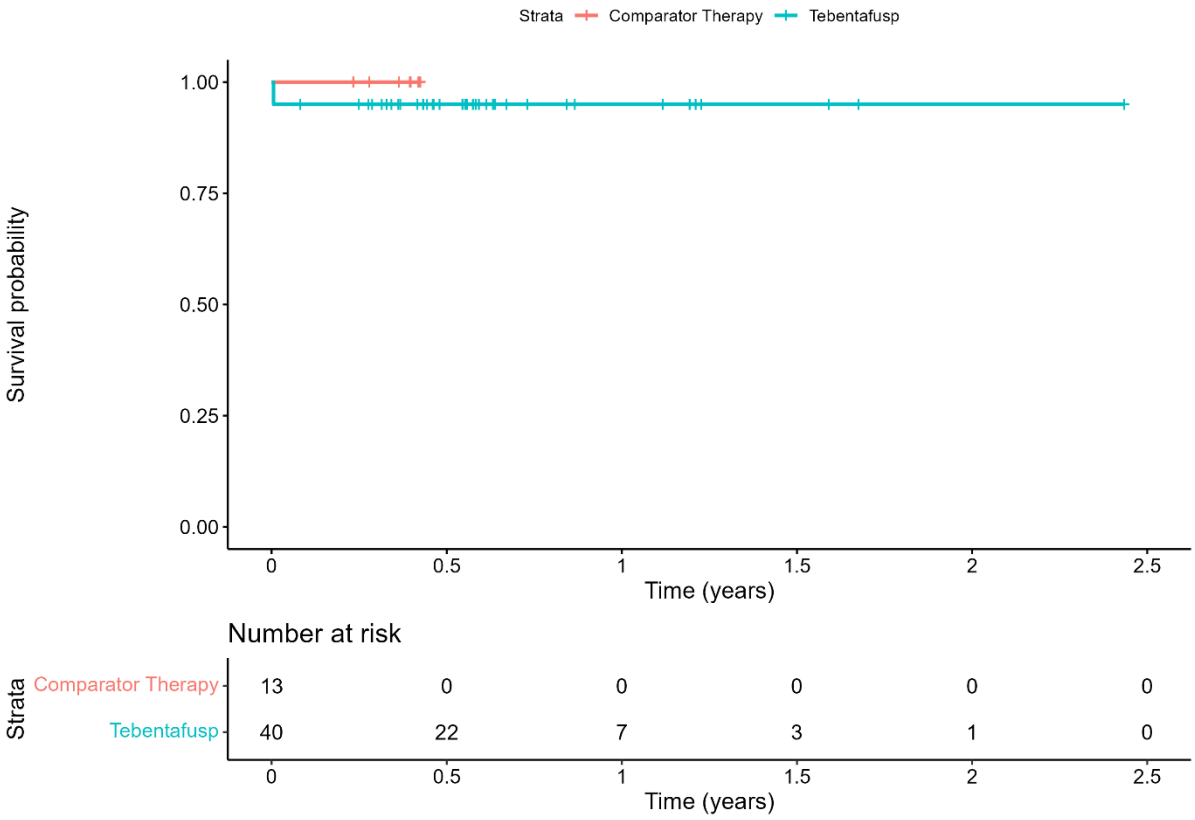
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

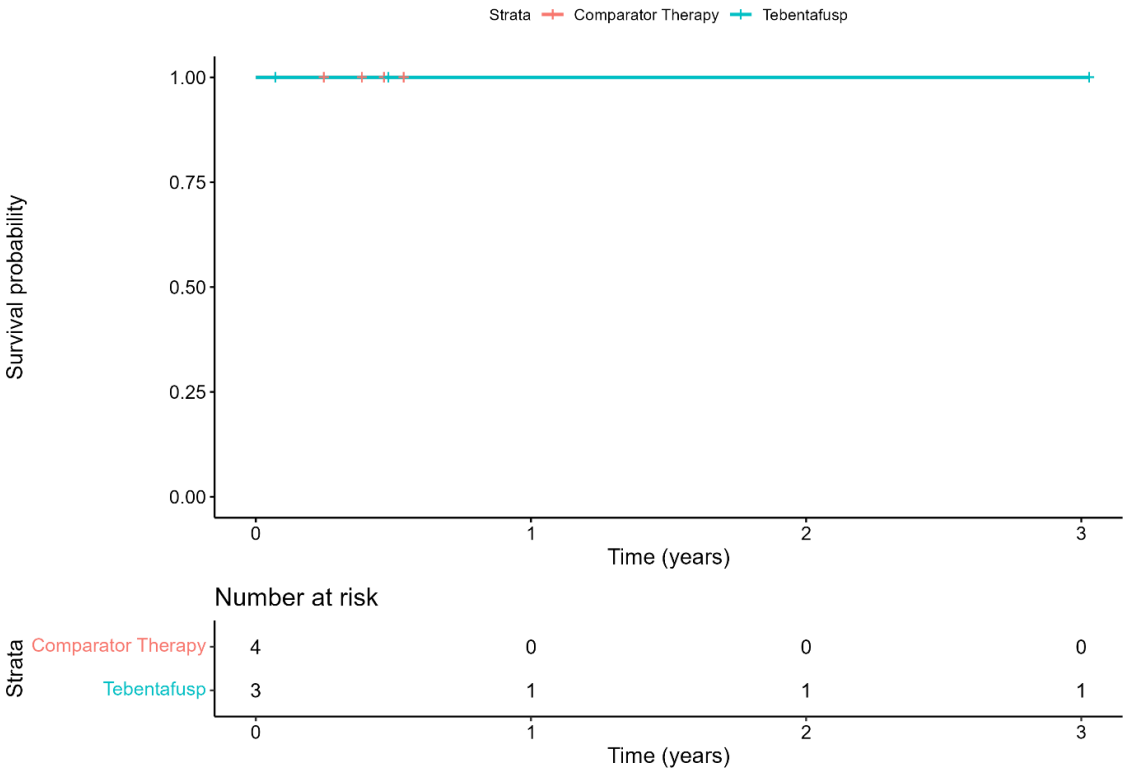


Vorauswahl der Chemotherapie: Ipilimumab

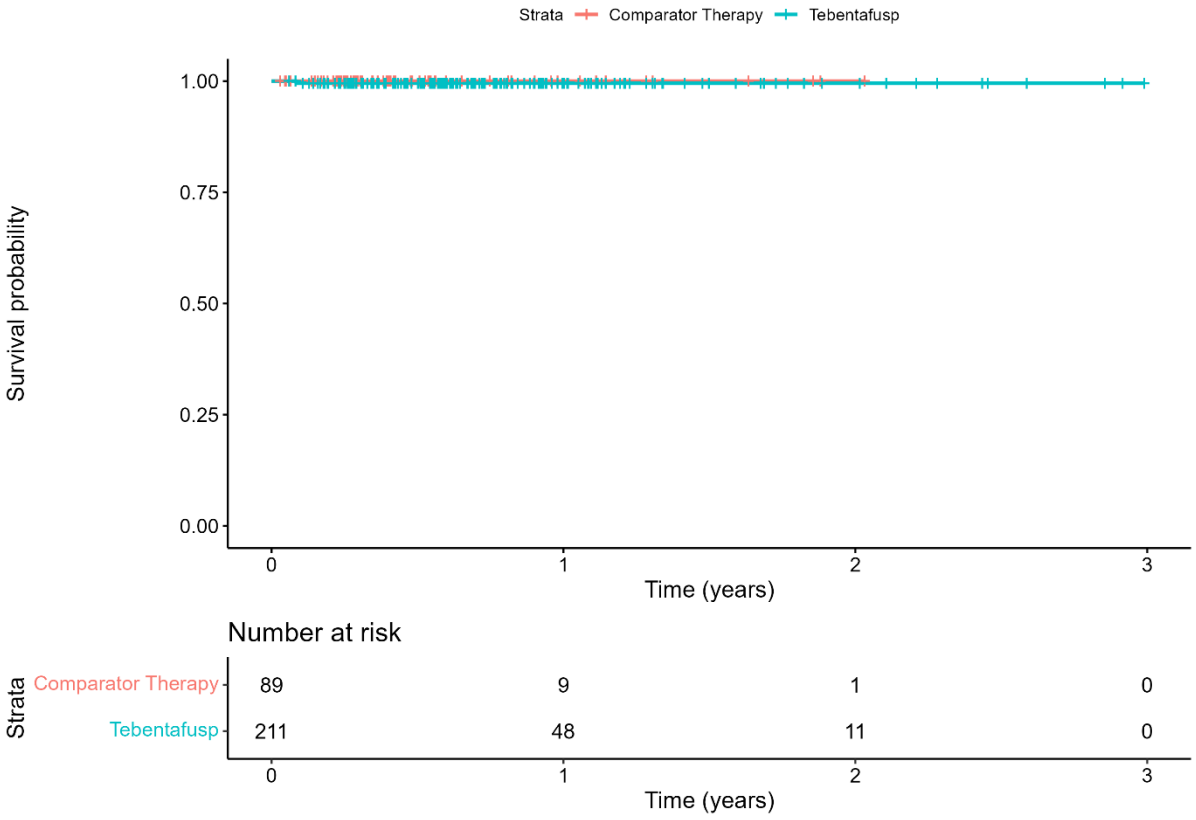


52.1 LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte (Tabelle 4-116)

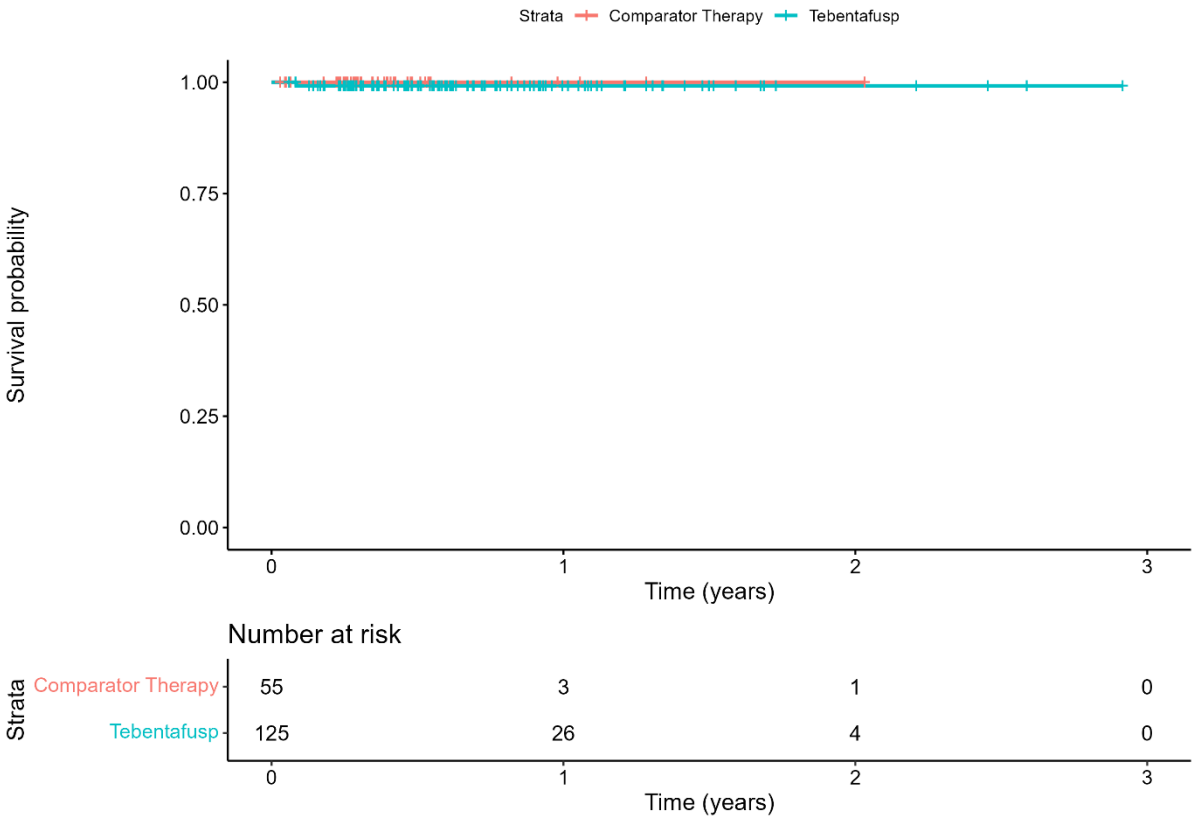
Herkunft: Hispanisch



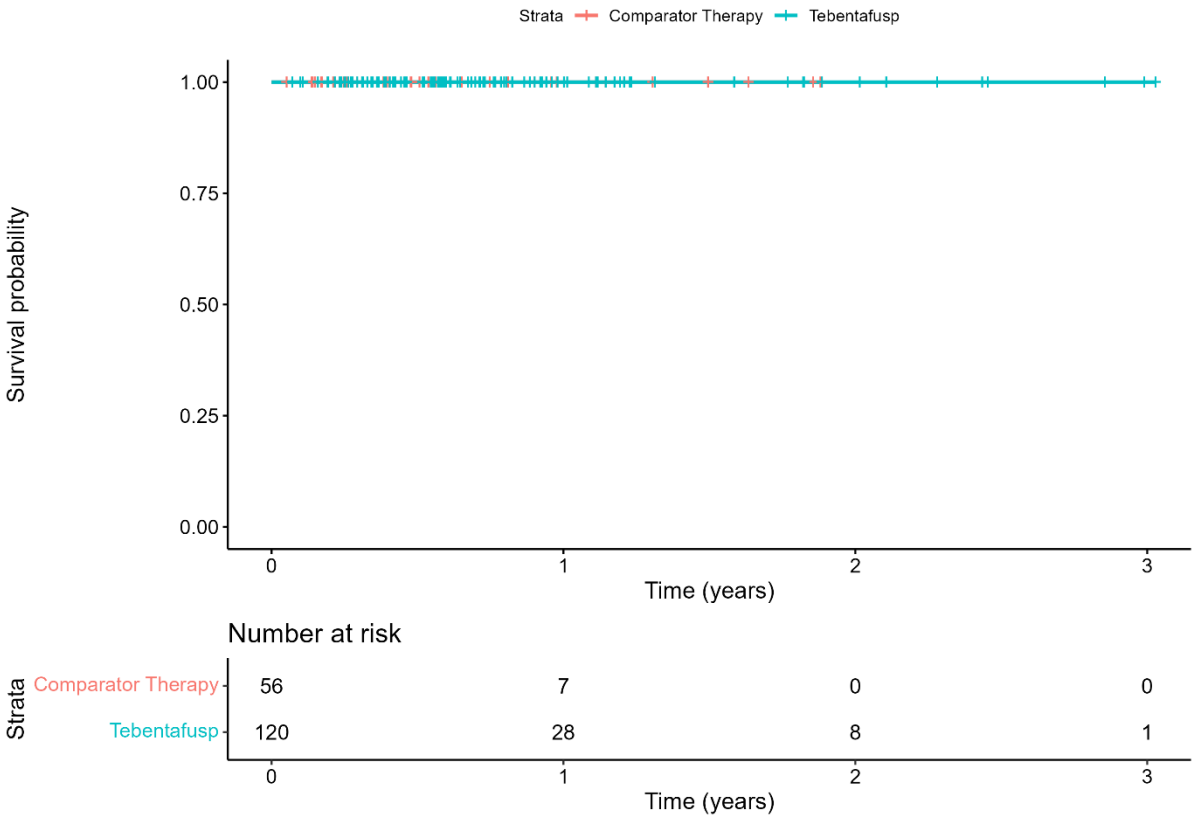
Herkunft: Nicht-hispanisch



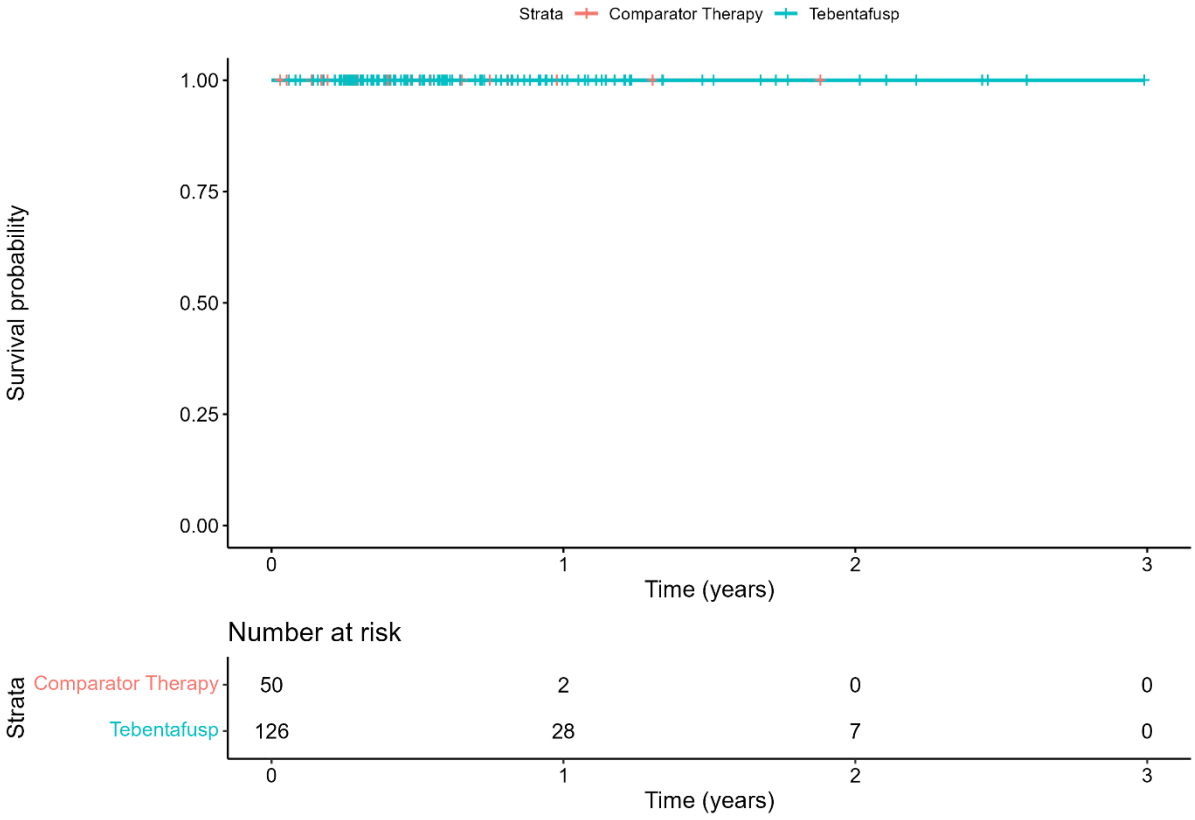
Geschlecht: Männlich



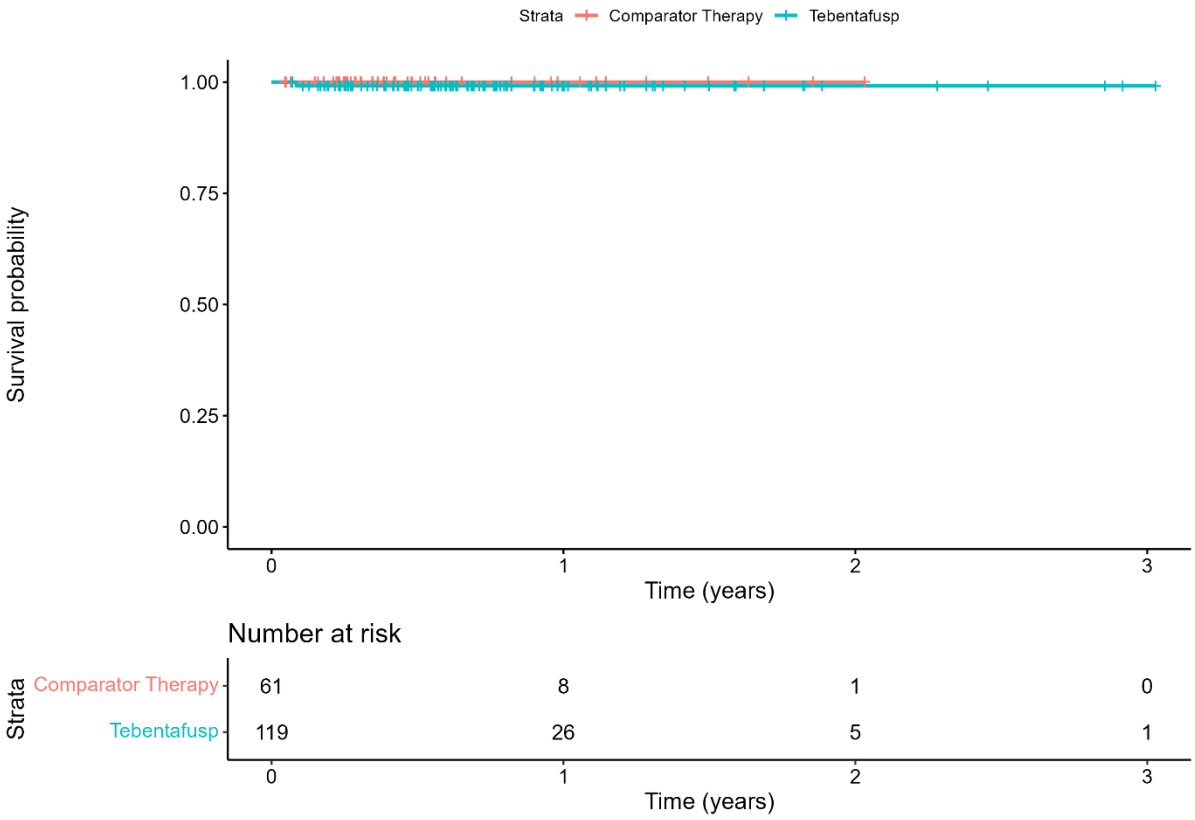
Geschlecht: Weiblich



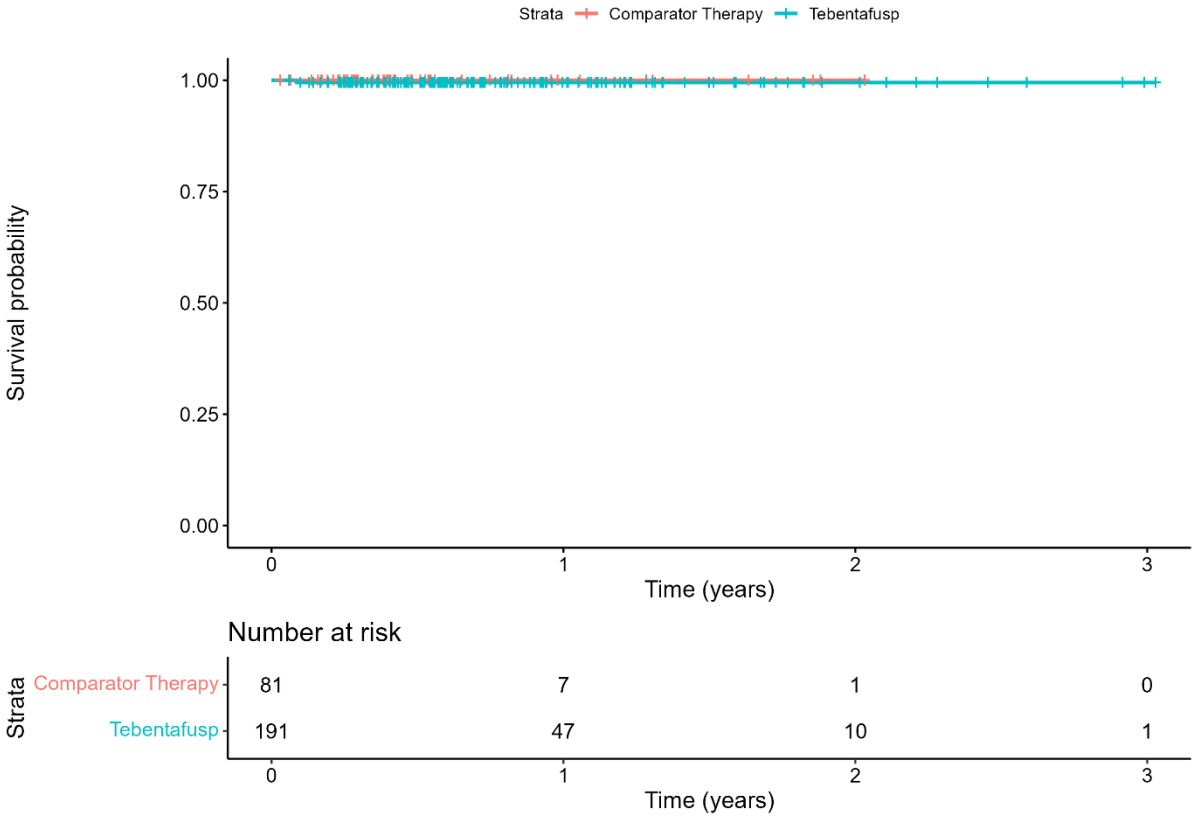
Alter: <65 Jahre



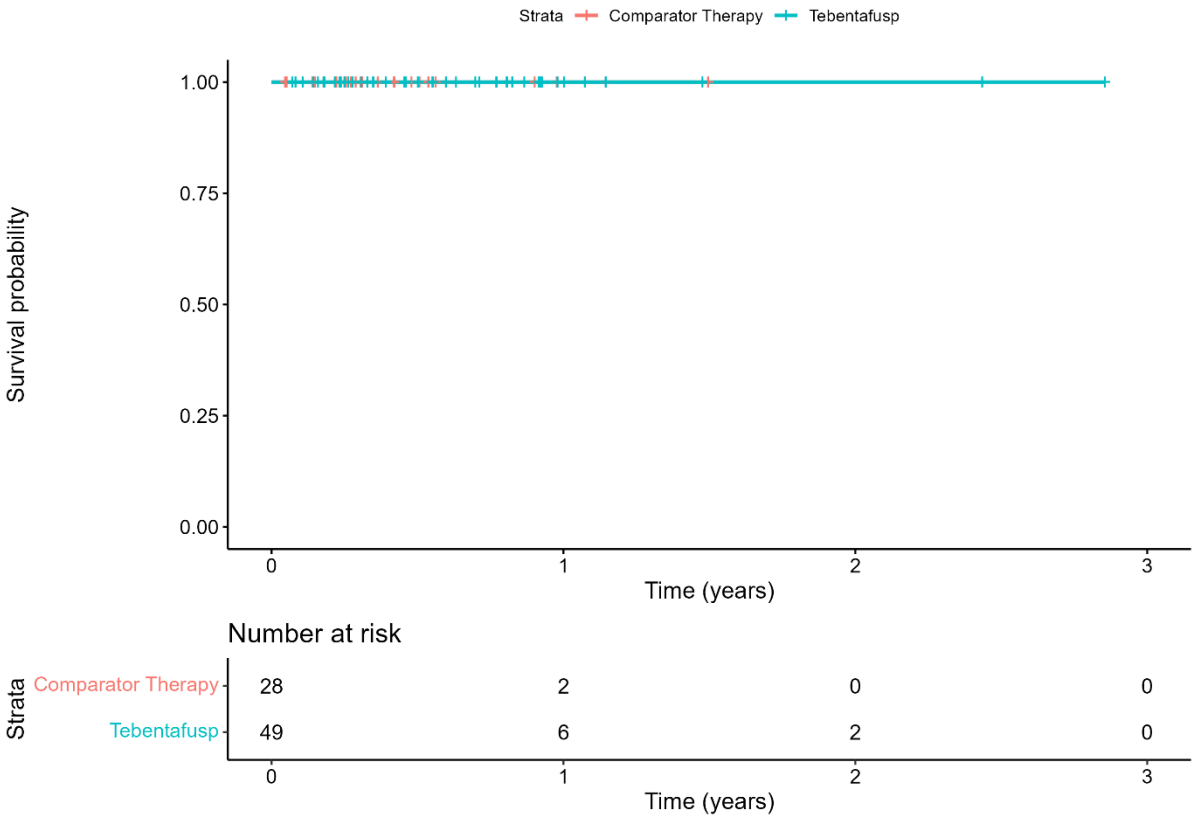
Alter: ≥65 Jahre



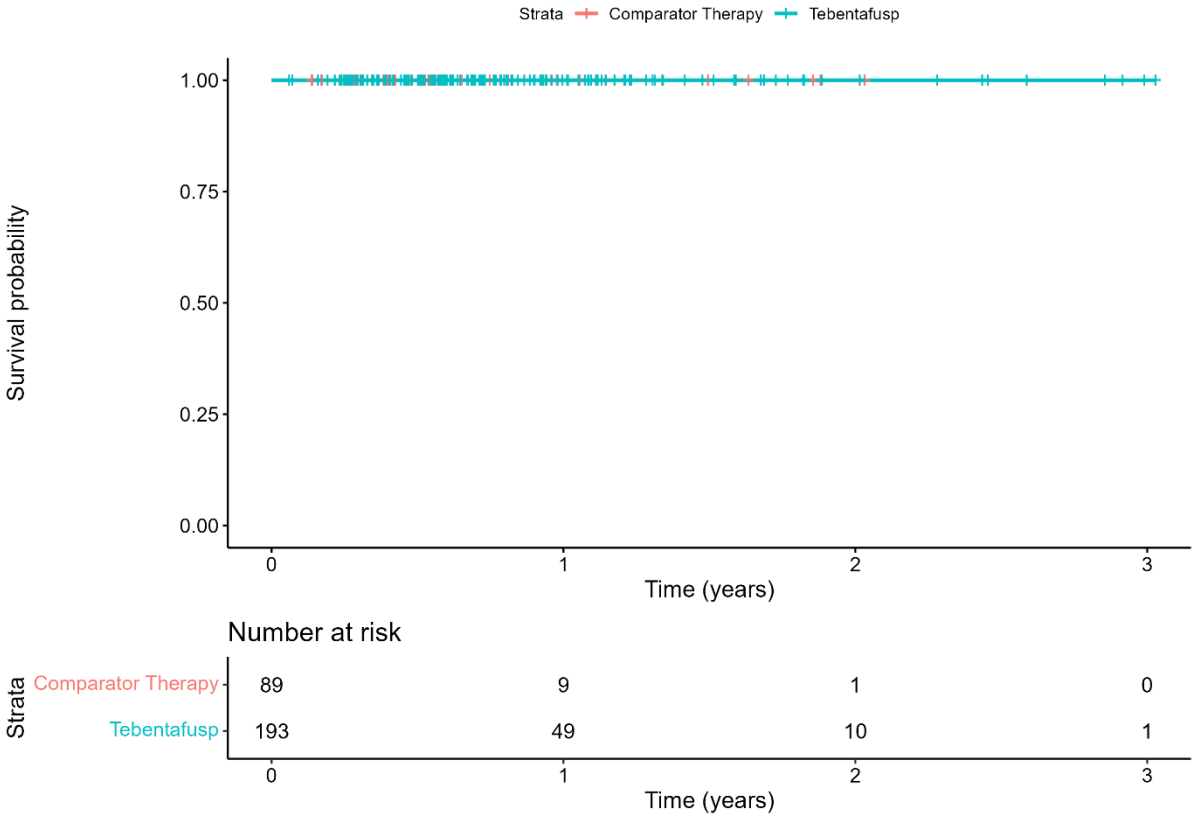
ECOG-Performance-Status: 0



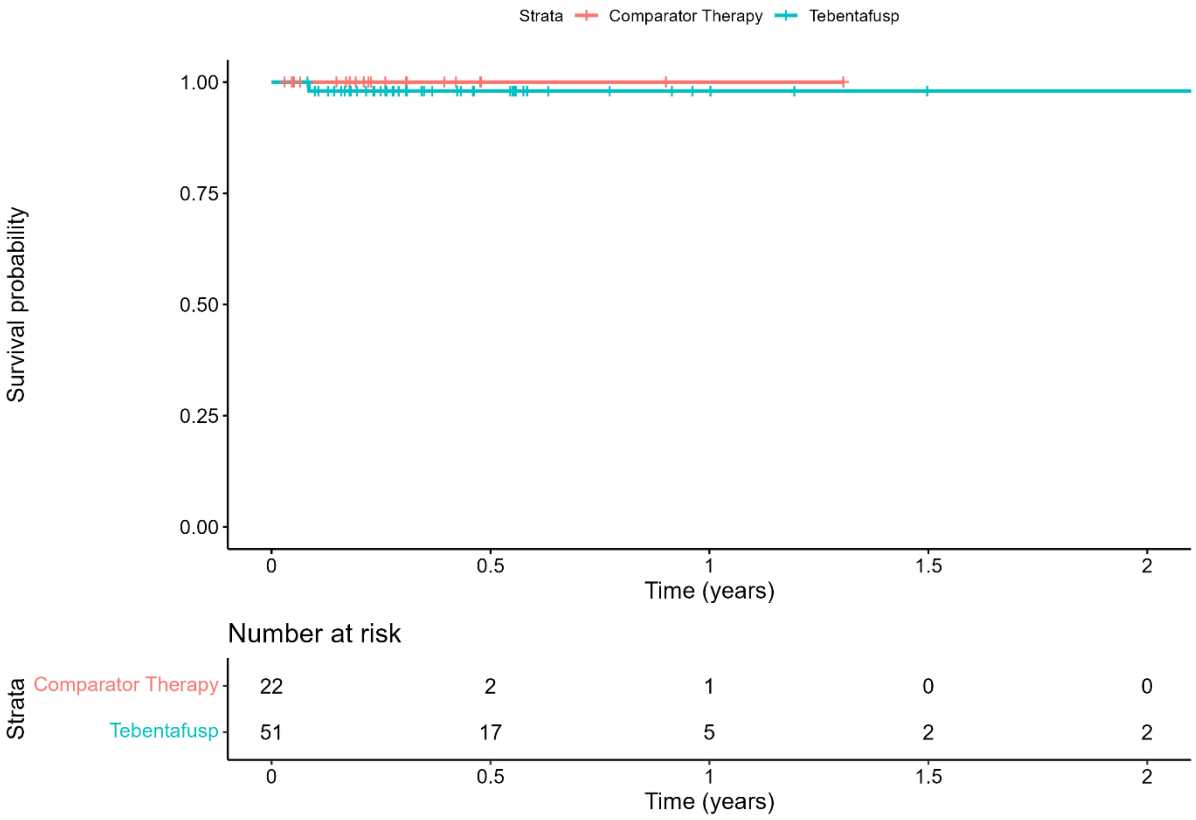
ECOG-Performance-Status: 1



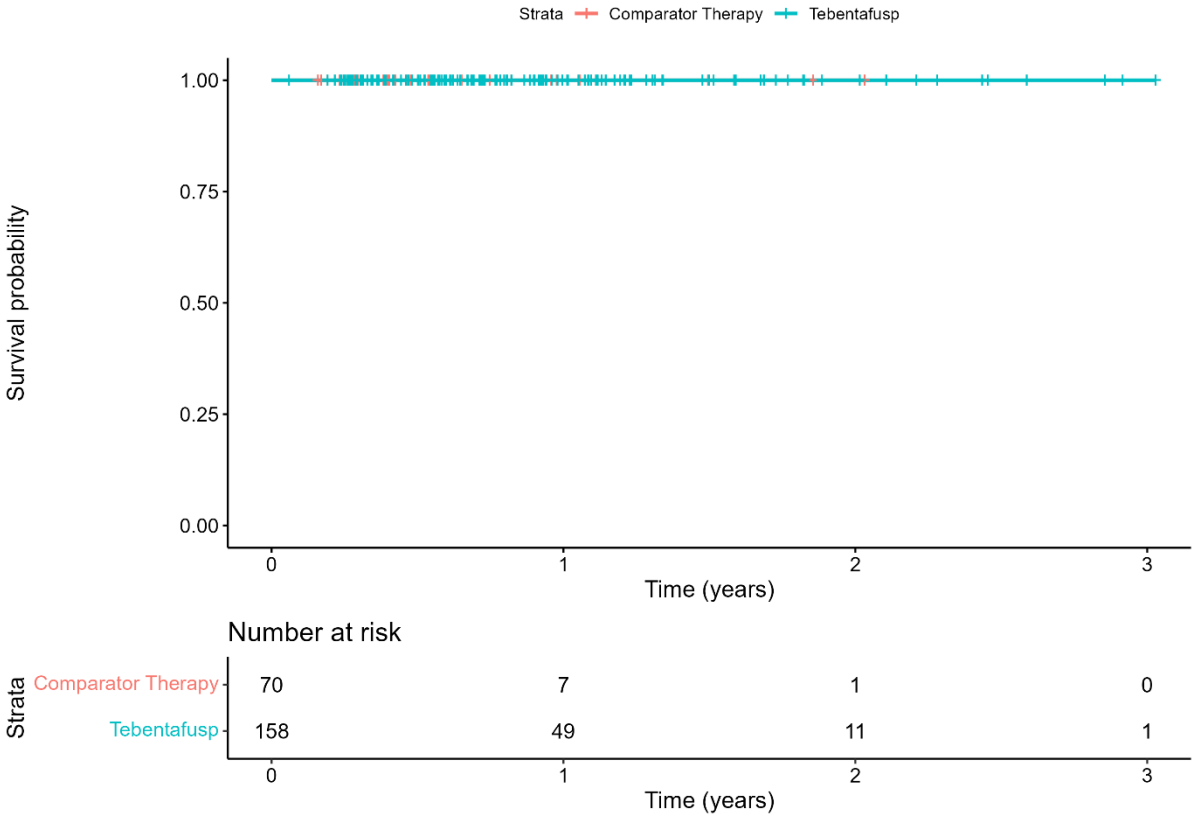
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



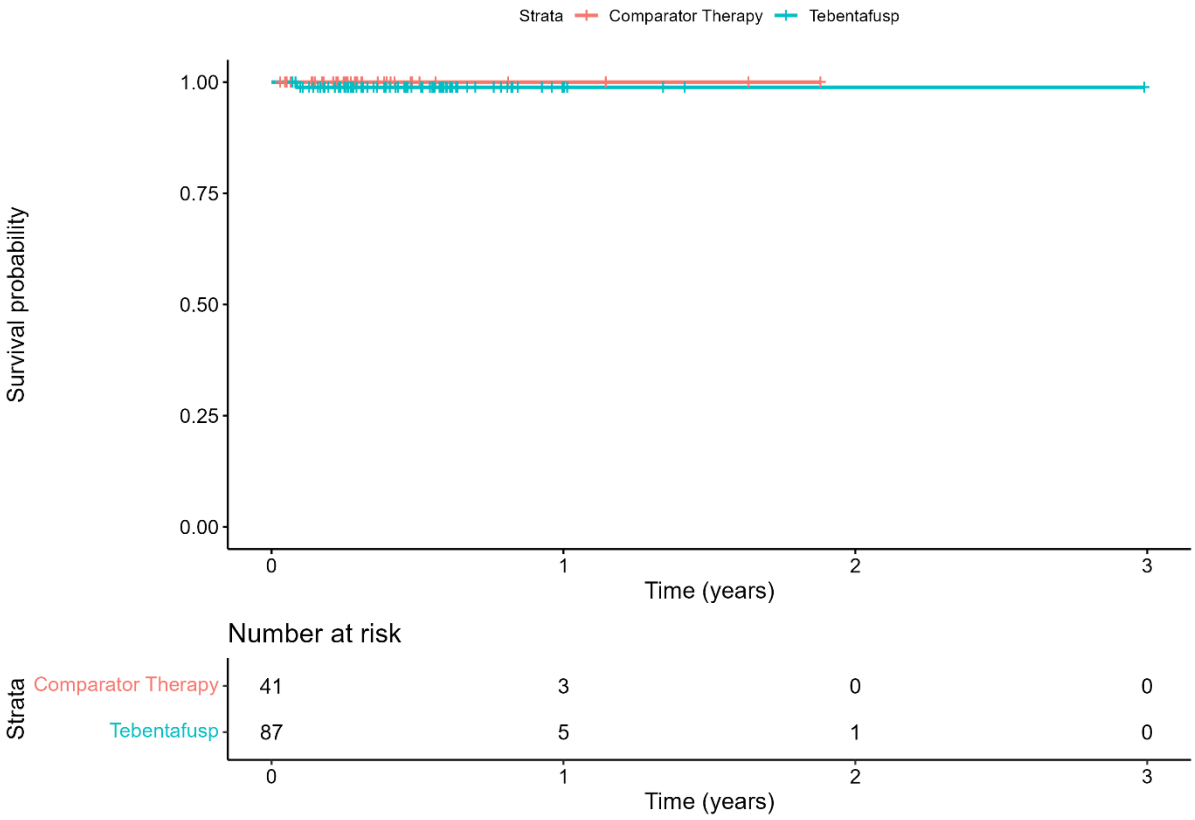
Alkalische Phosphatase (ALP) (Baseline): >ULN



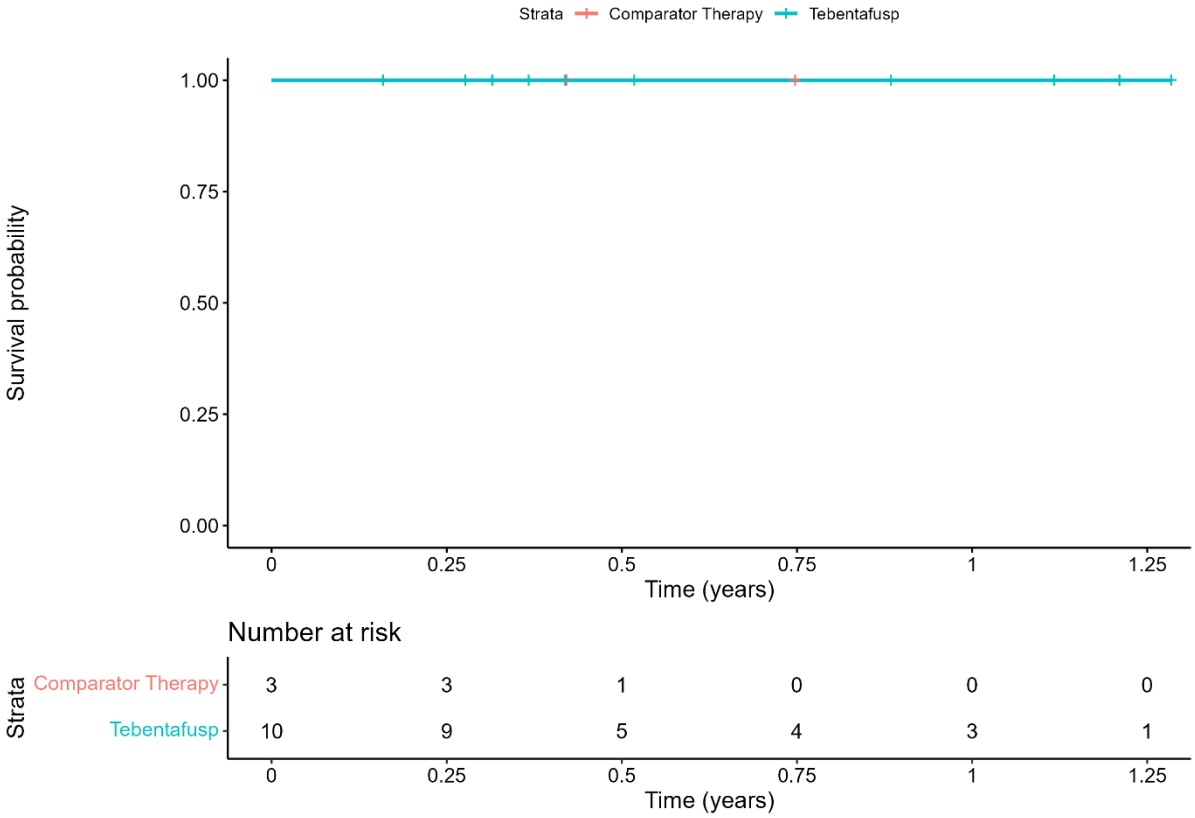
LDH: ≤ULN



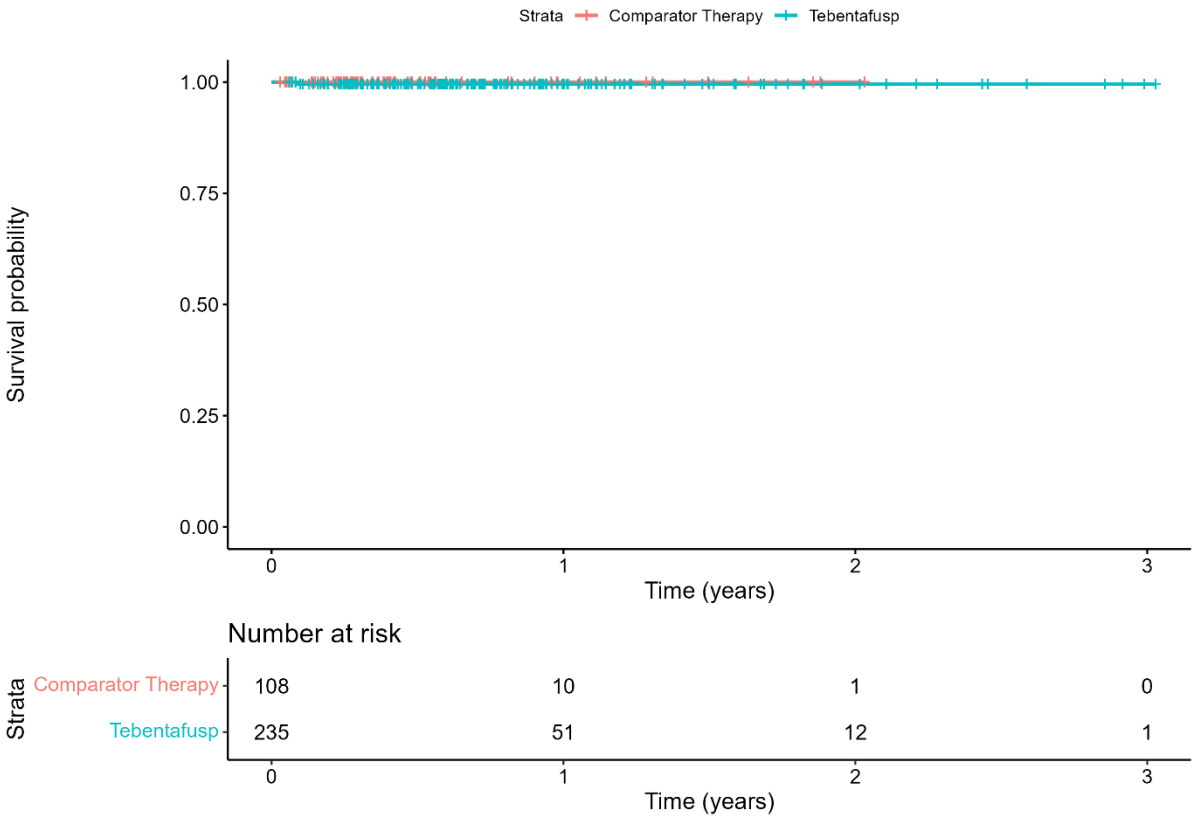
LDH: >ULN



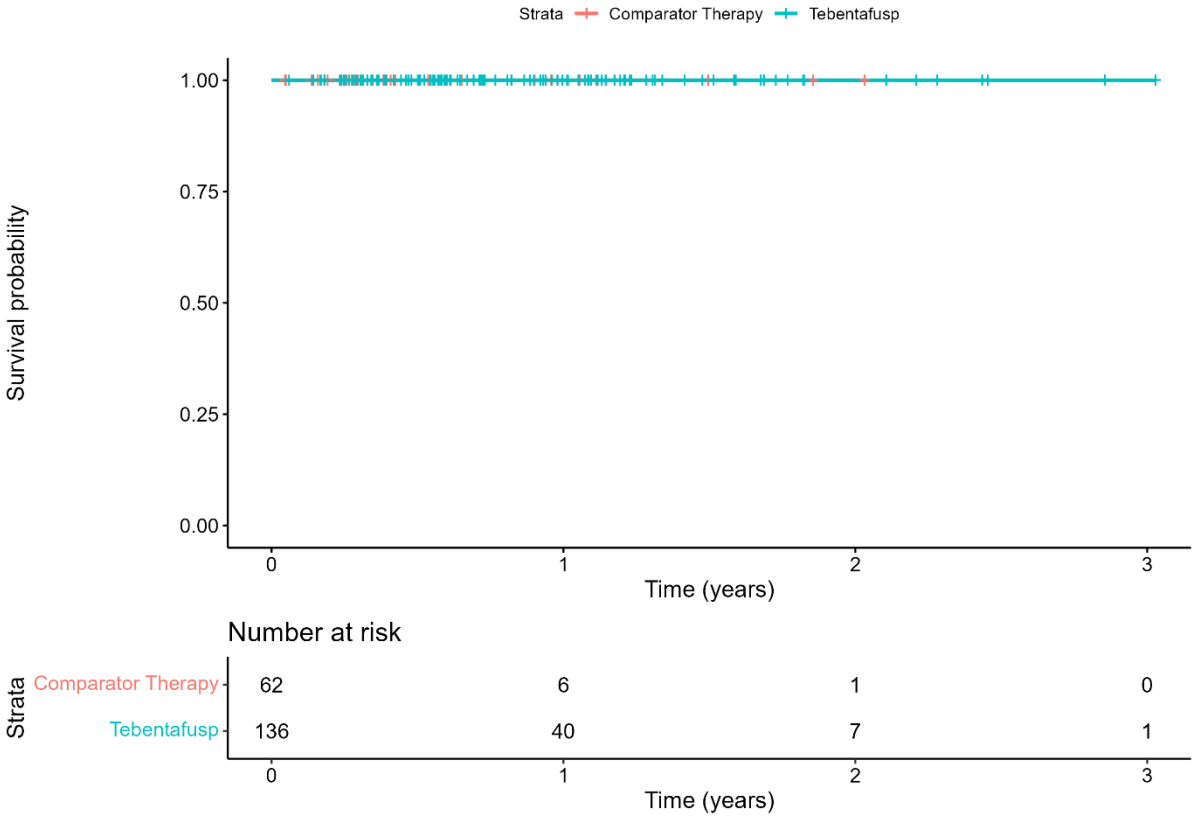
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



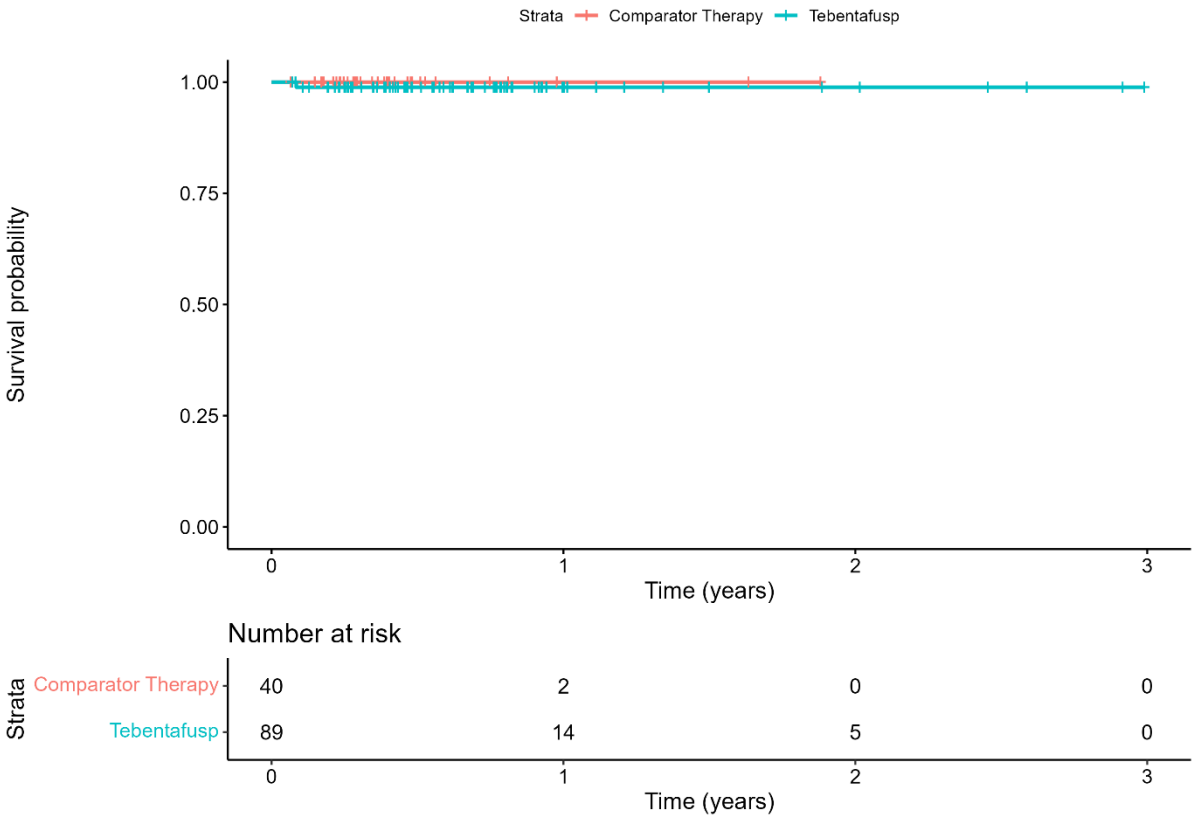
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



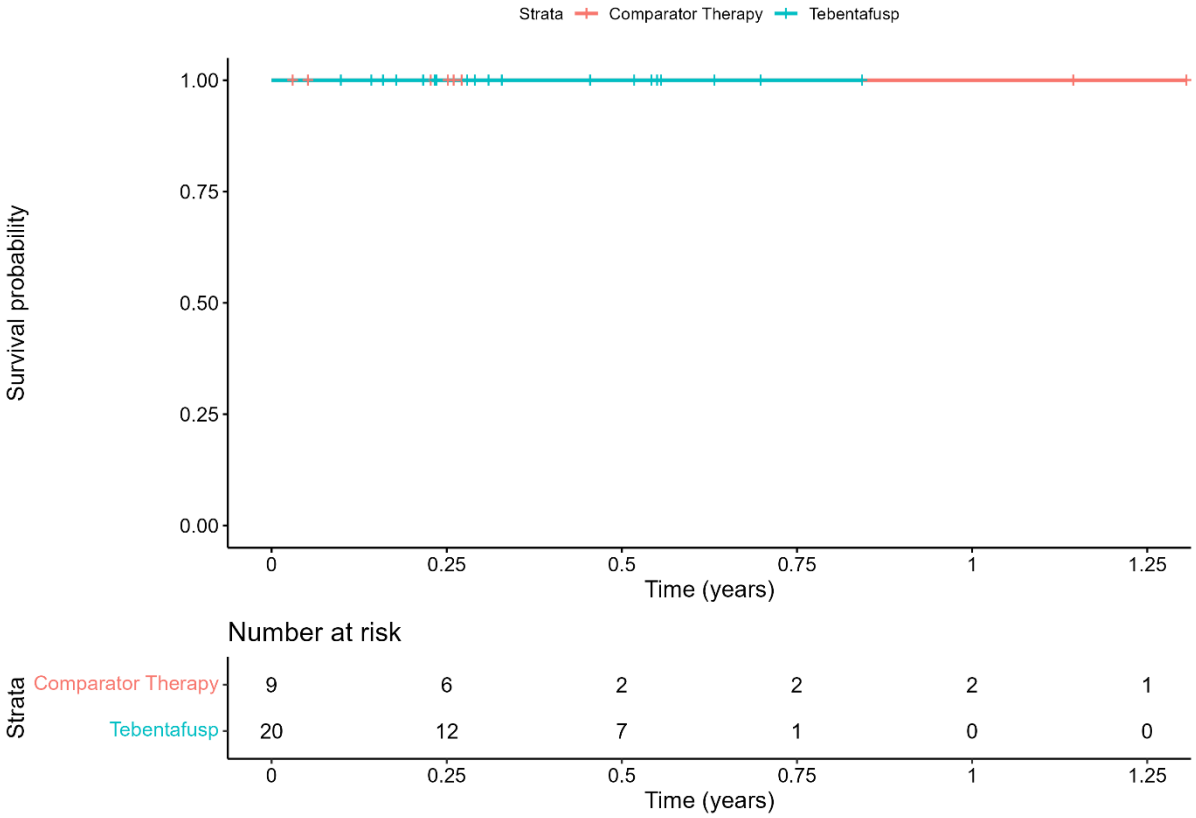
Größte metastatische Läsion (Baseline): ≤3,0 cm



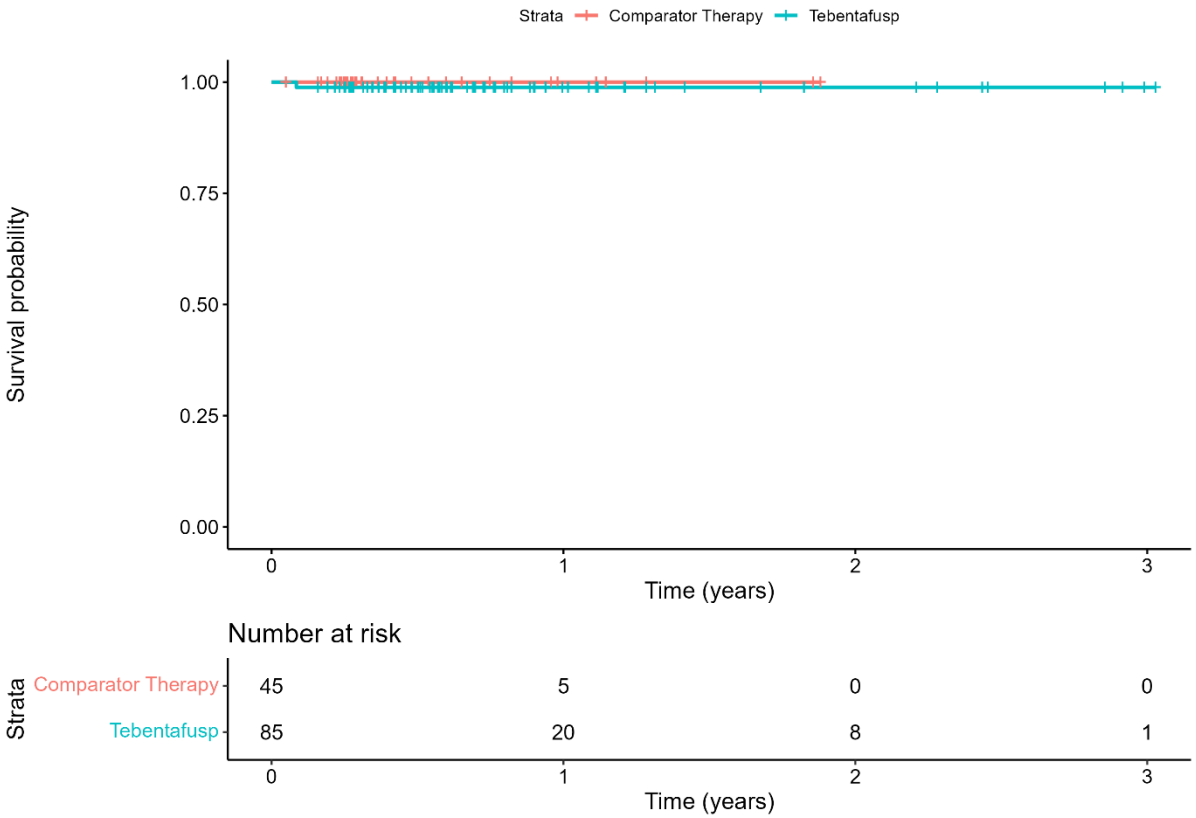
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



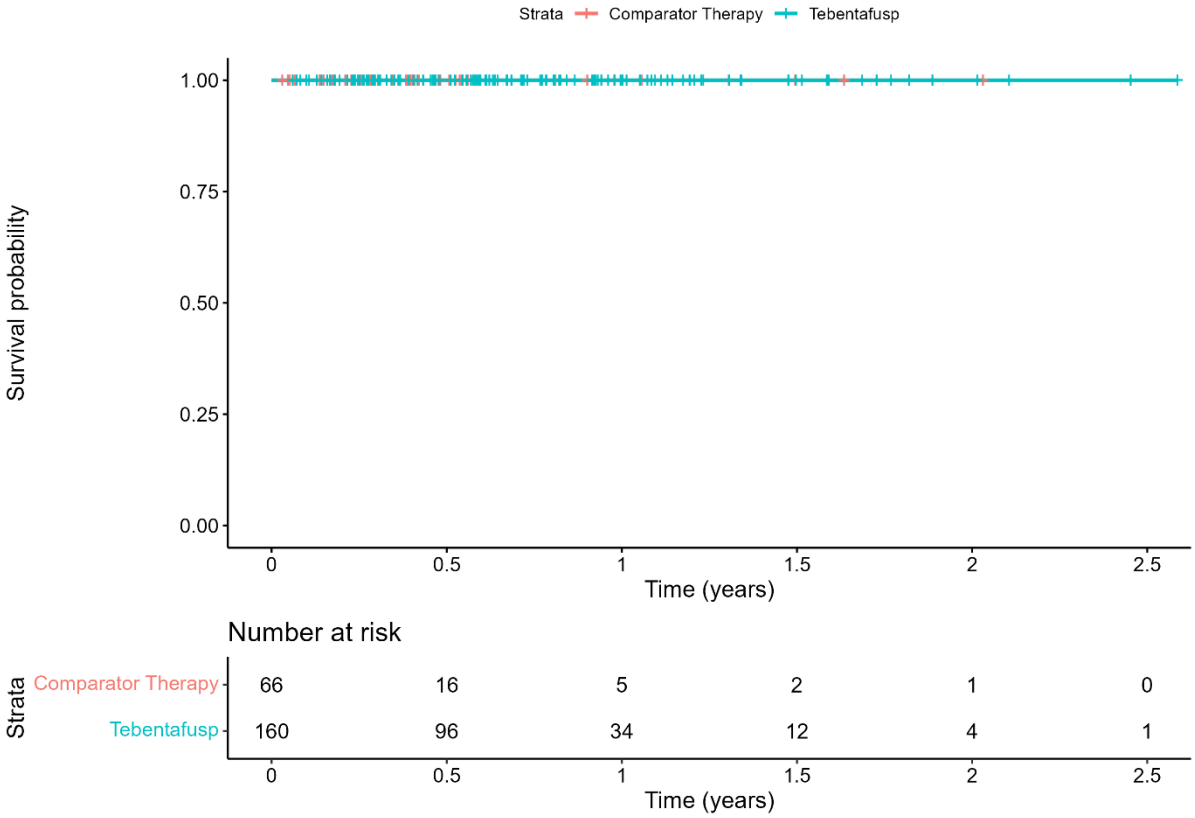
Größte metastatische Läsion (Baseline): ≥8,1 cm



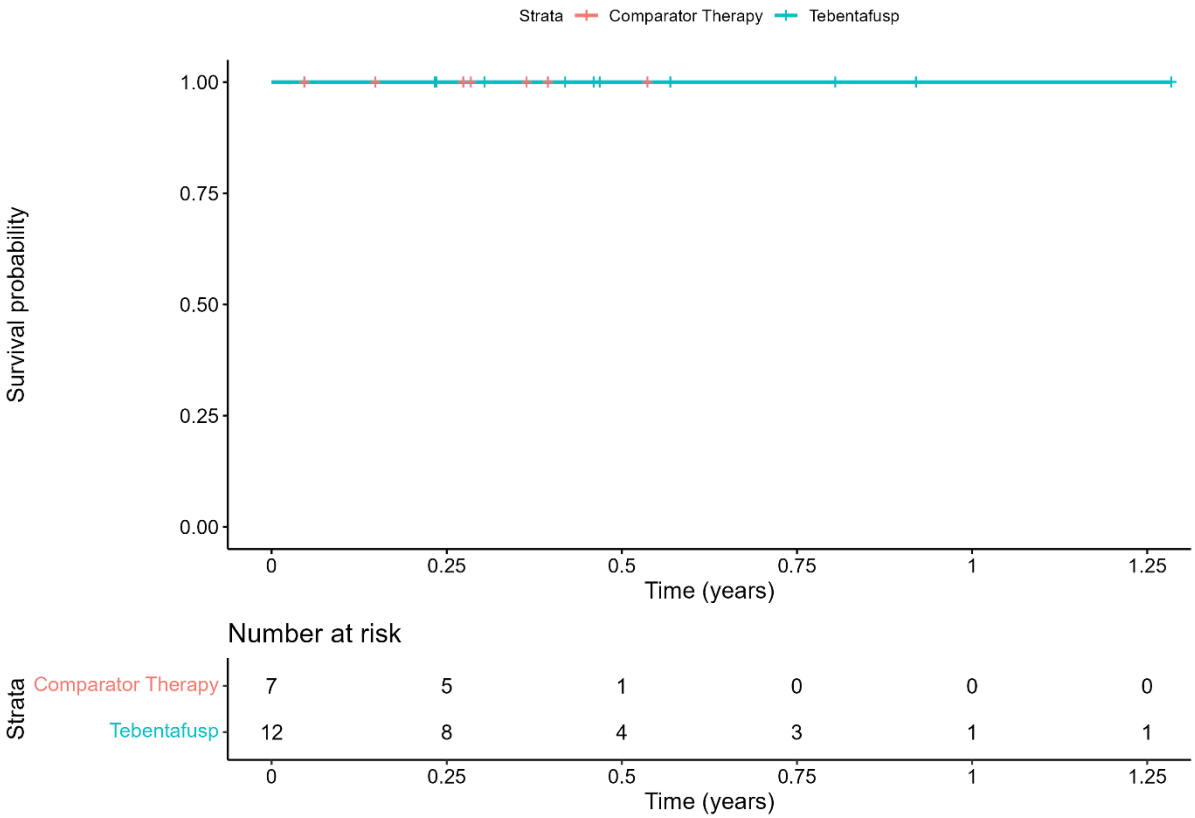
Region: Nordamerika



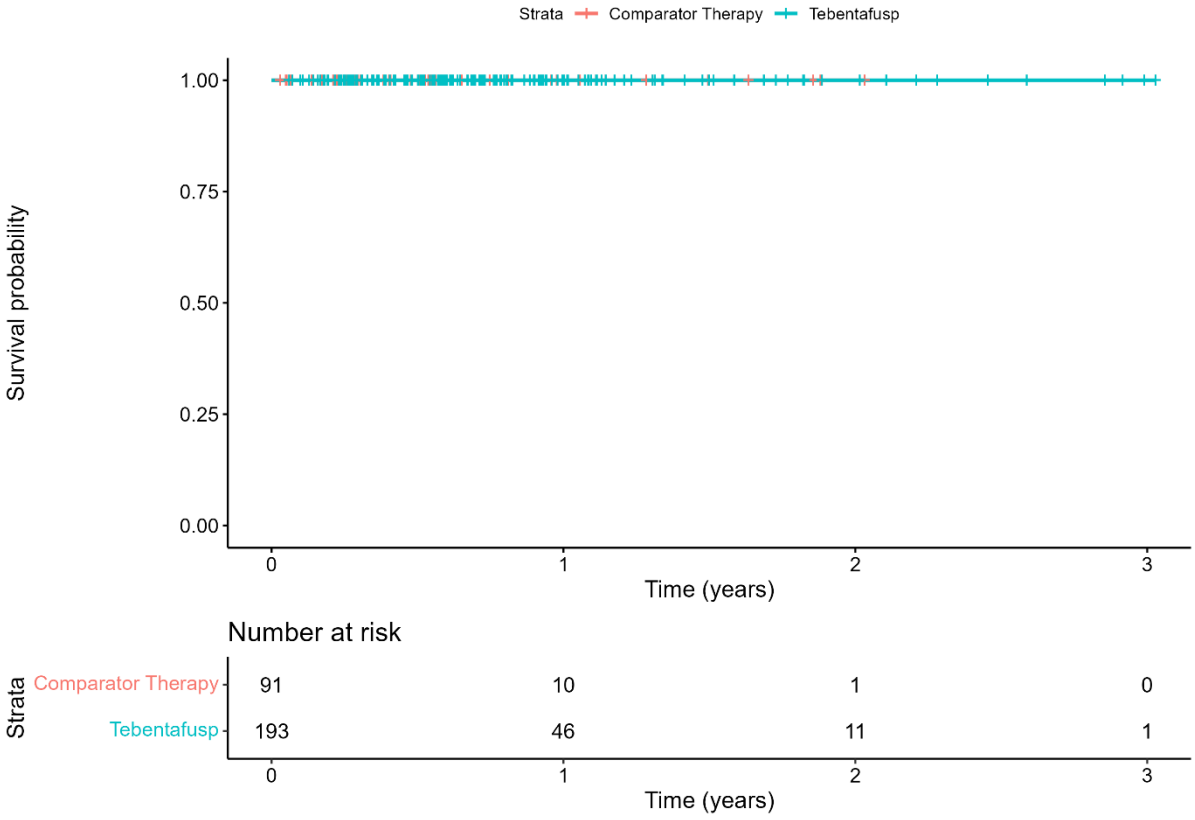
Region: Nicht-Nordamerika



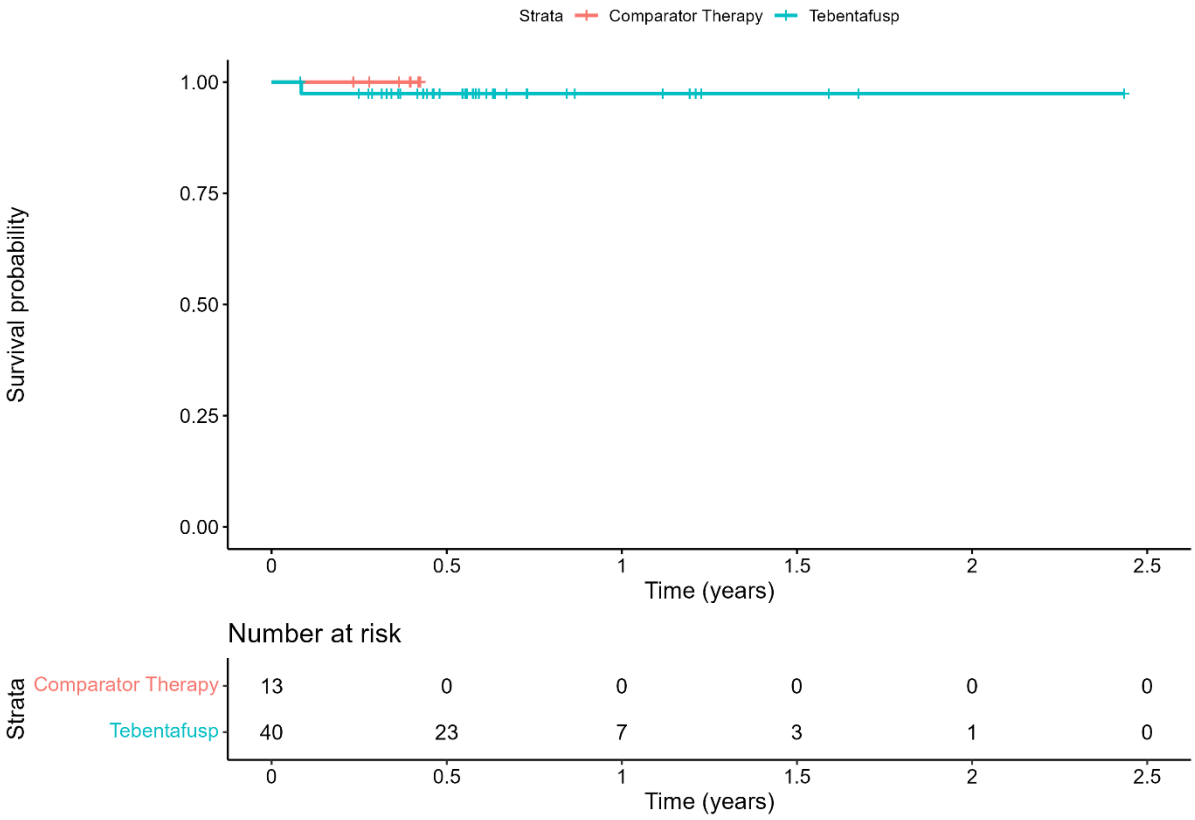
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab



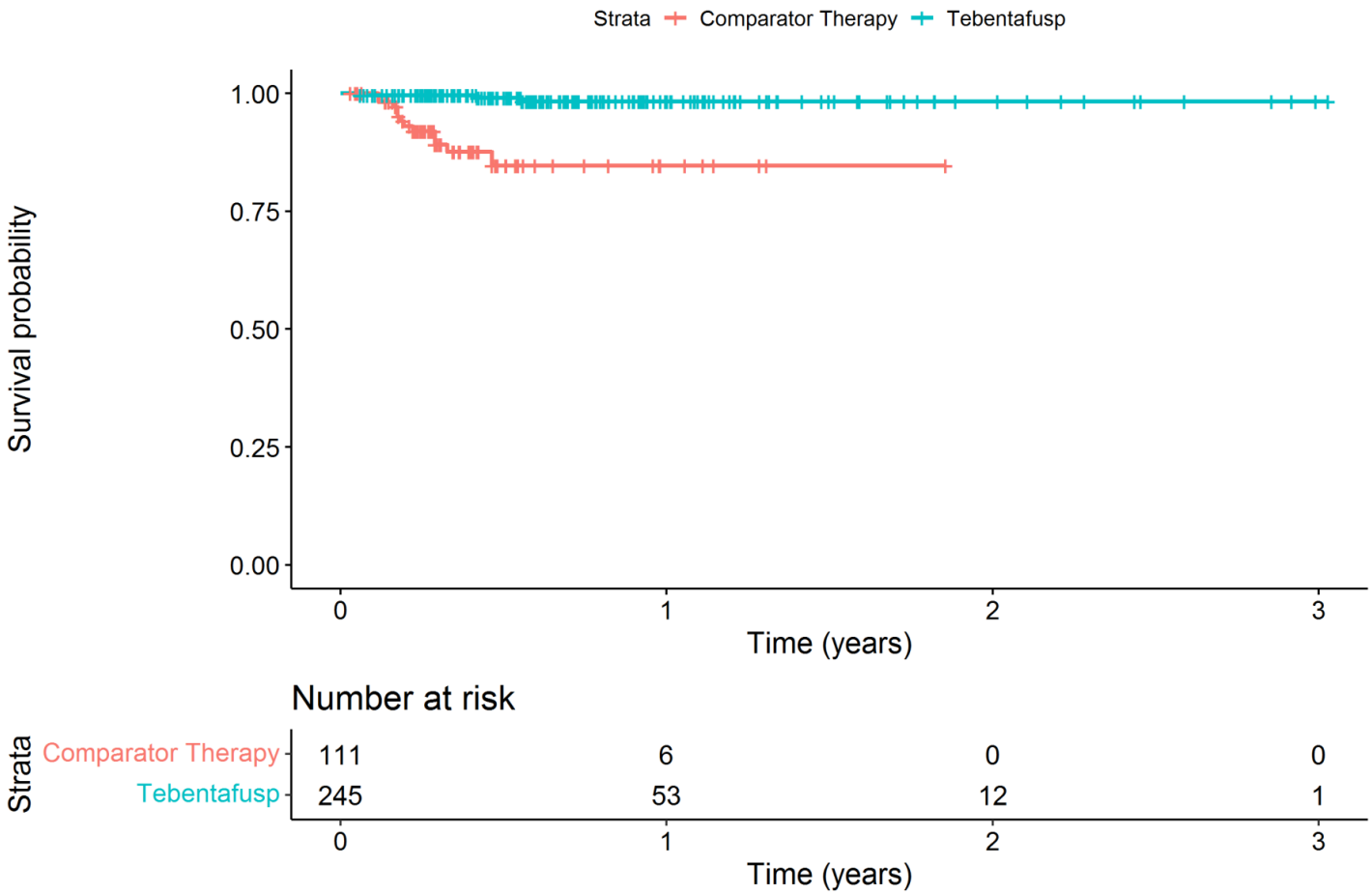
Vorauswahl der Chemotherapie: Ipilimumab



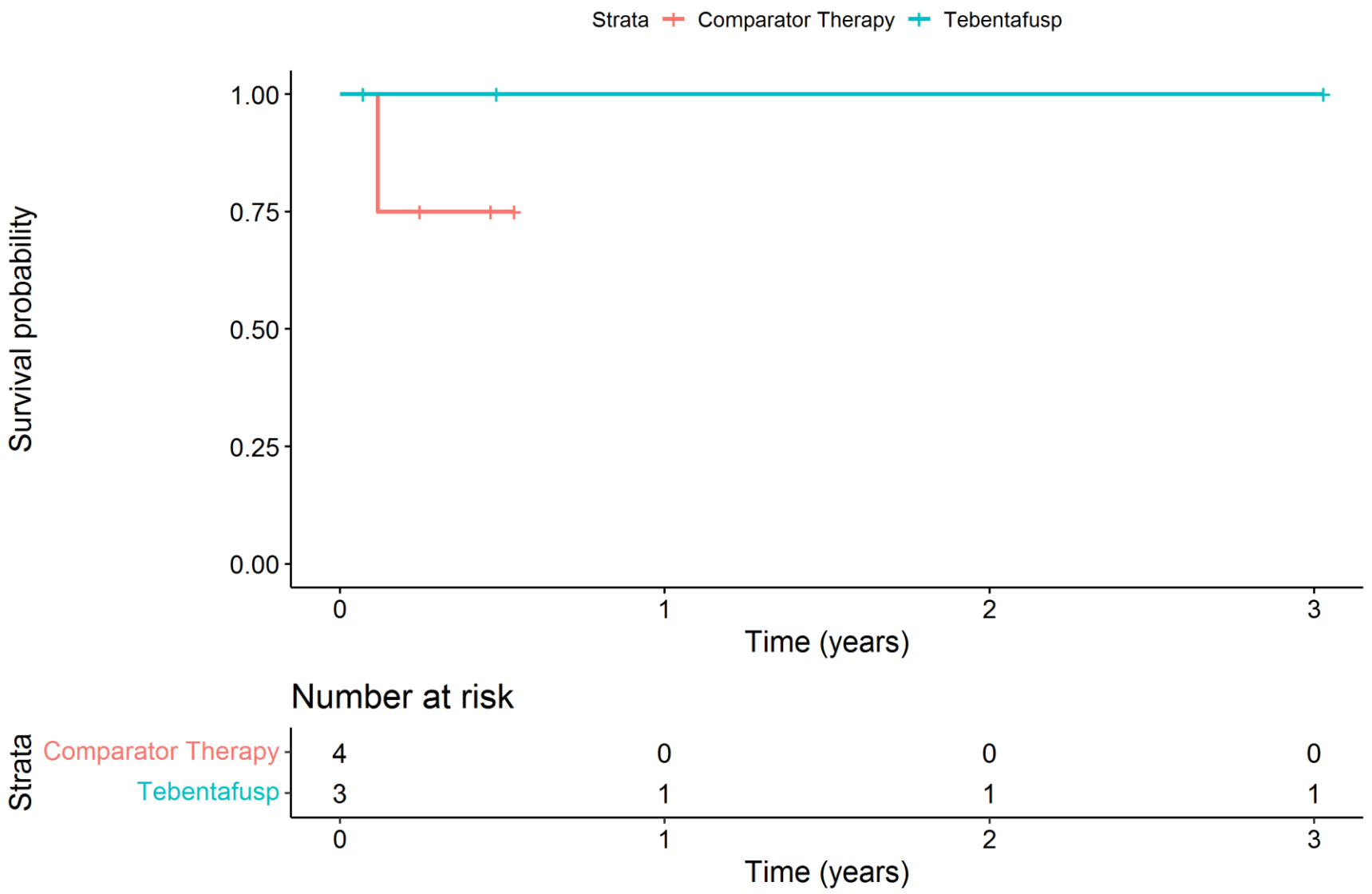
52.2 Unerwünschte Ereignisse nach SOC und PT

53 UEs (PT), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-118)

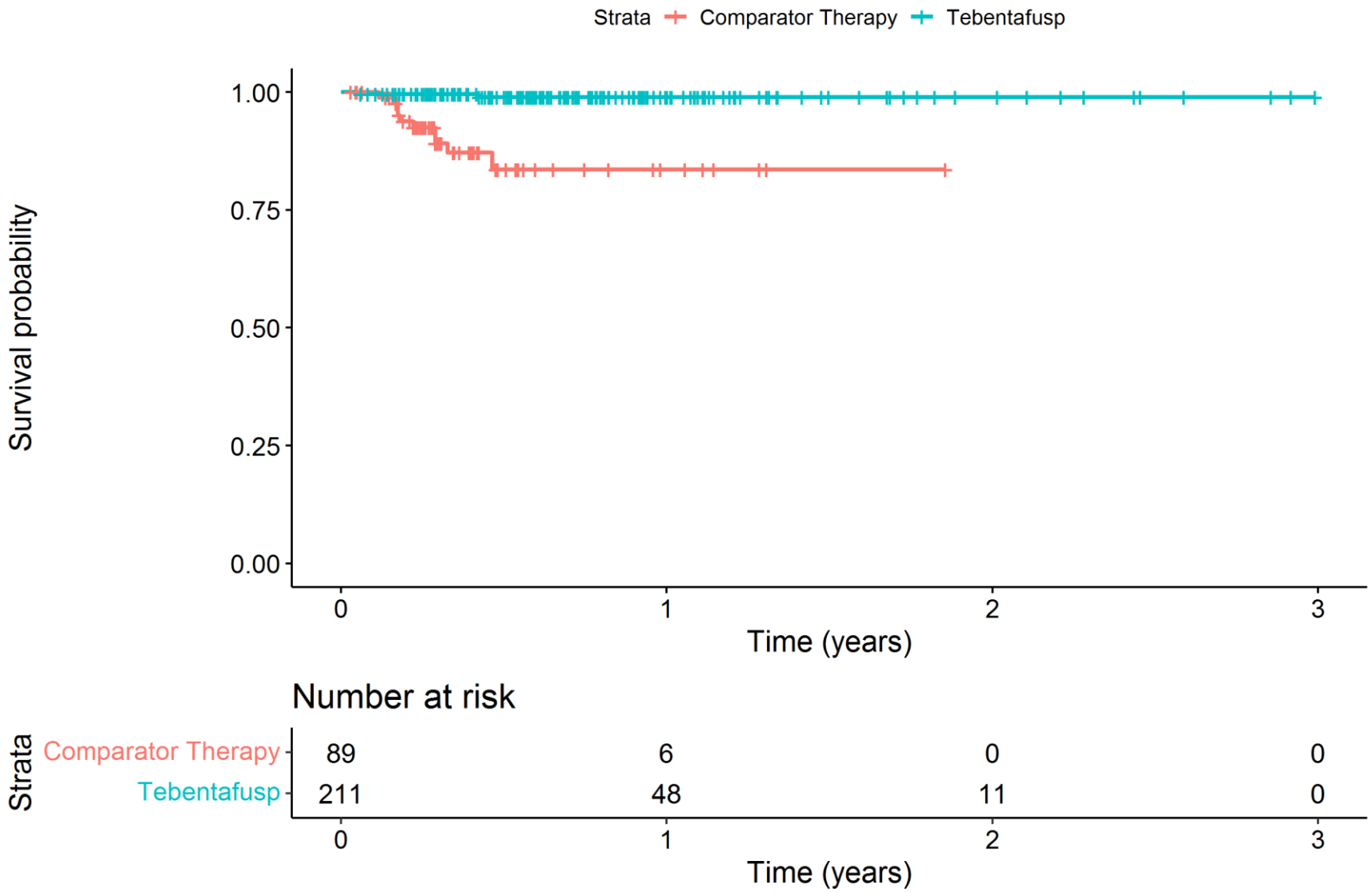
Hypothyreose – Gesamt



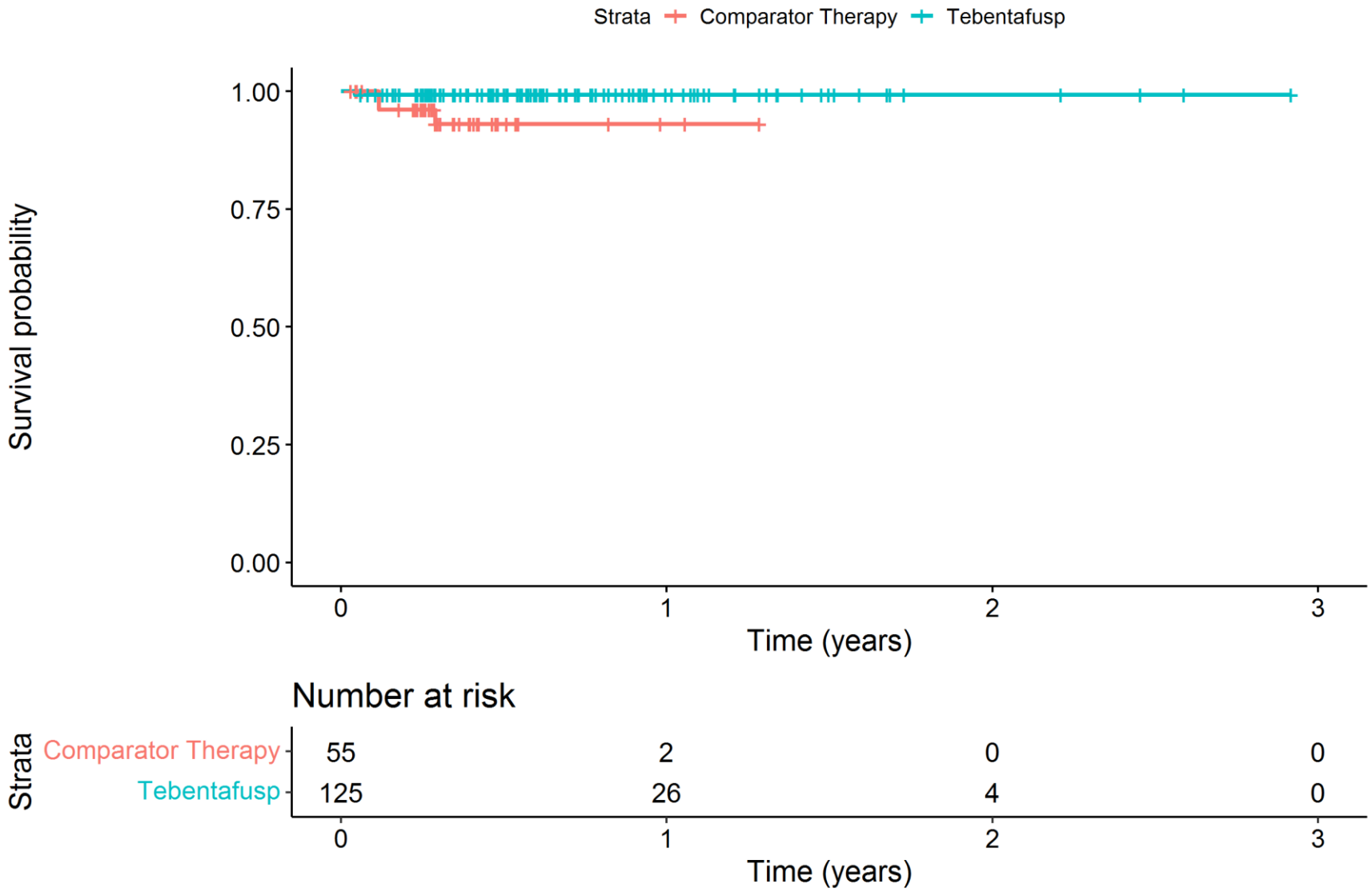
53.1 Hypothyreose - Hispanisch



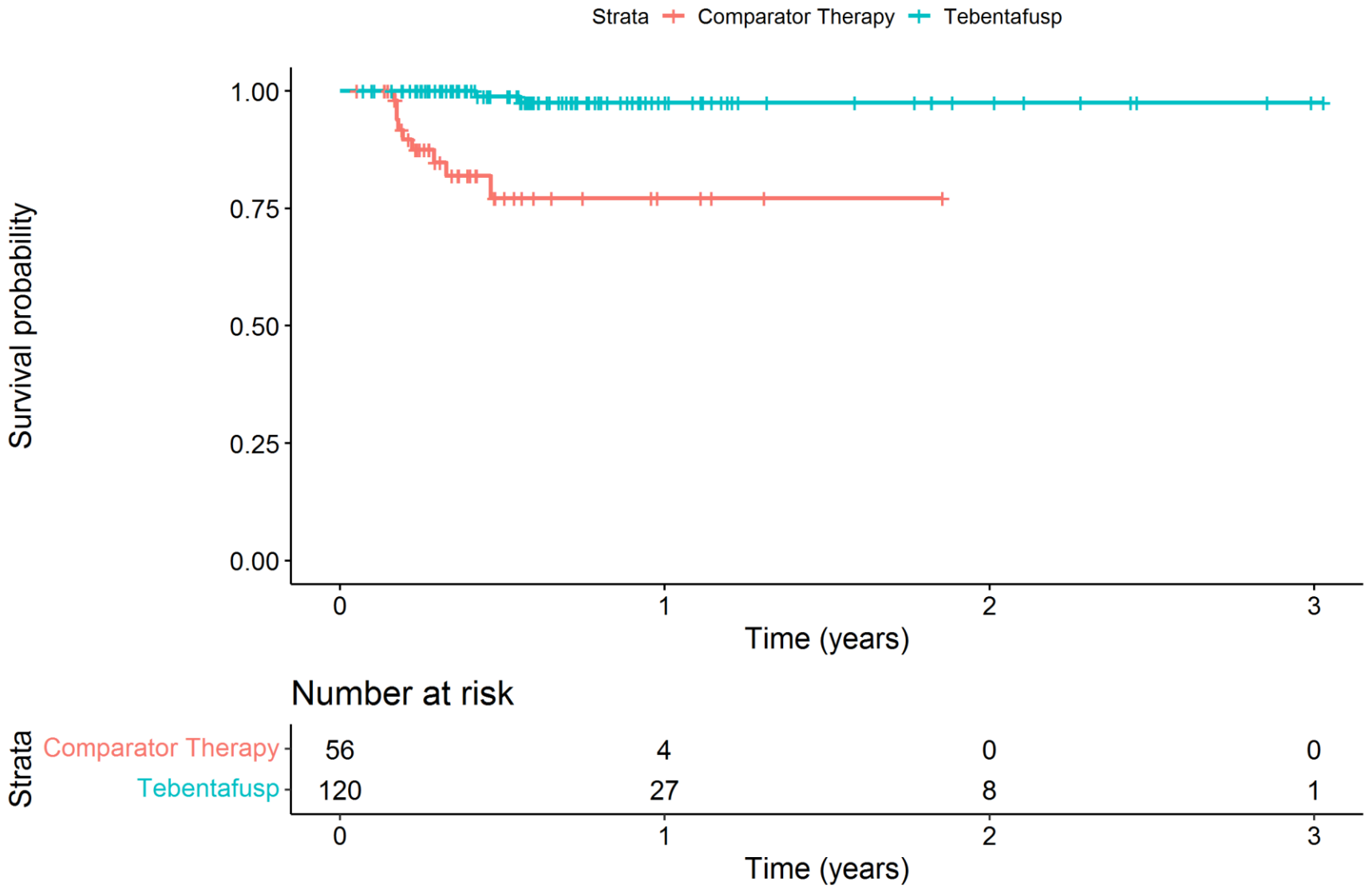
53.2 Hypothyreose - Nicht-hispanisch



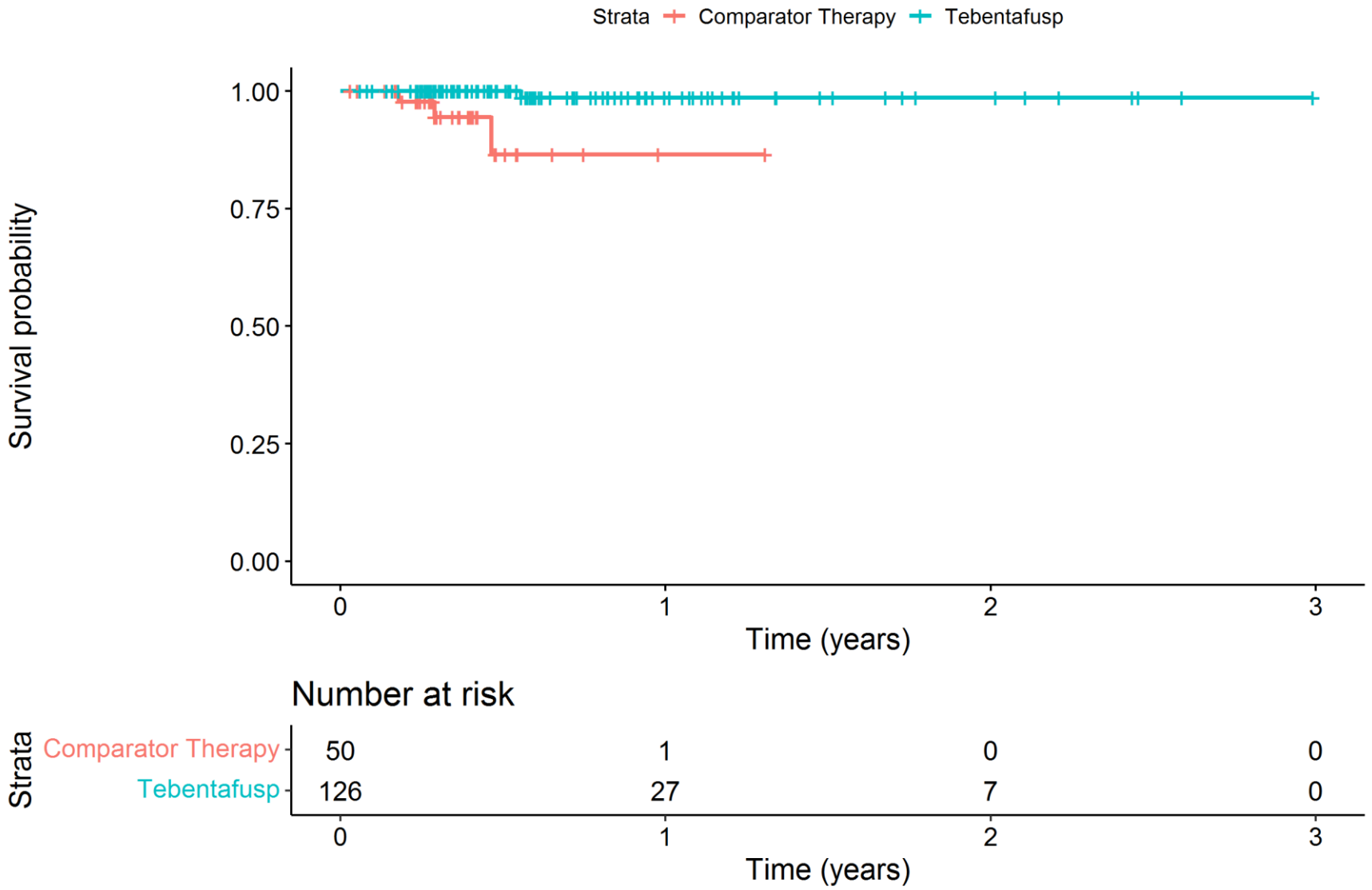
53.3 Hypothyreose - Männlich



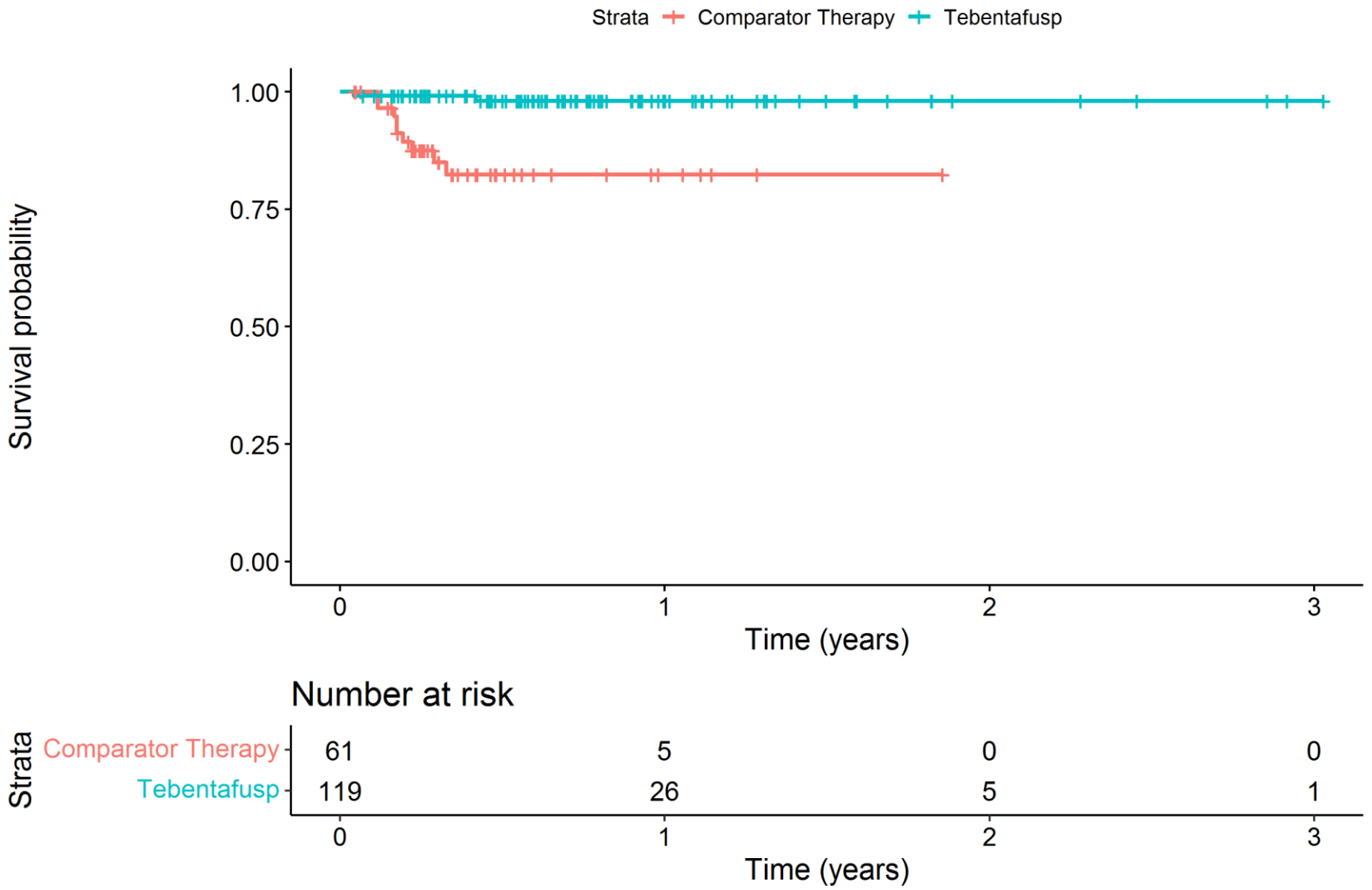
53.4 Hypothyreose - Weiblich



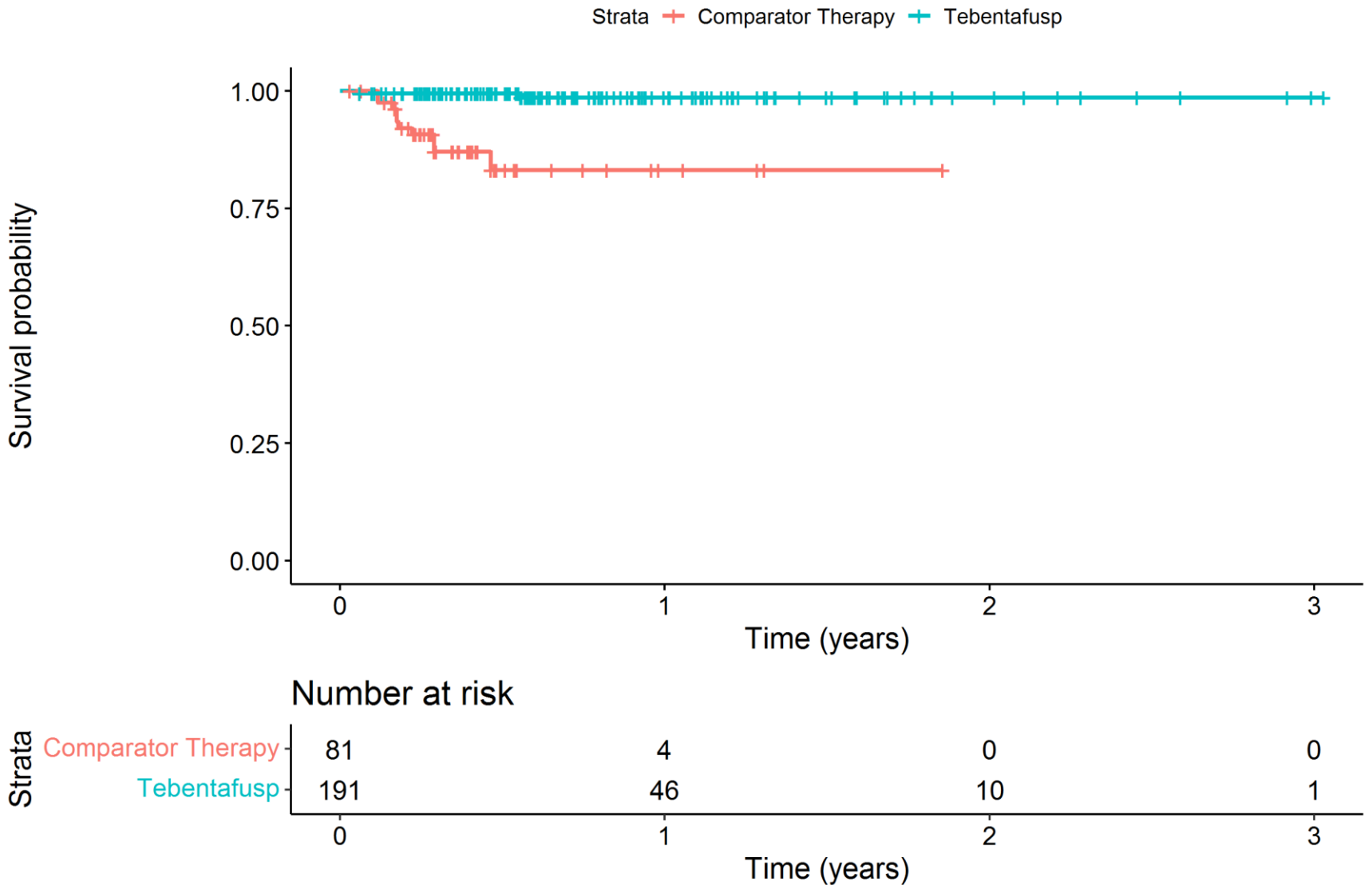
53.5 Hypothyreose - <65



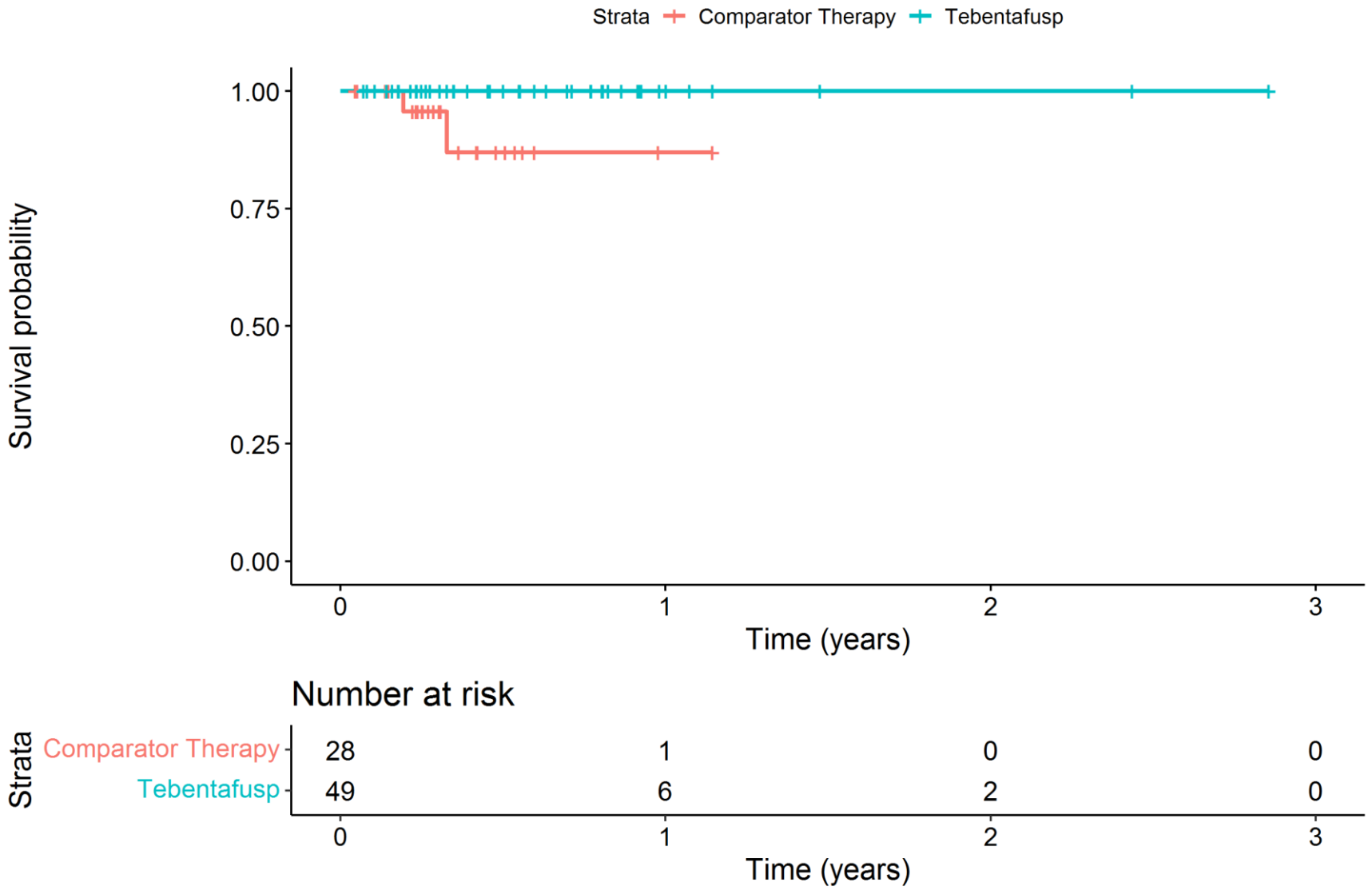
53.6 Hypothyreose - ≥65



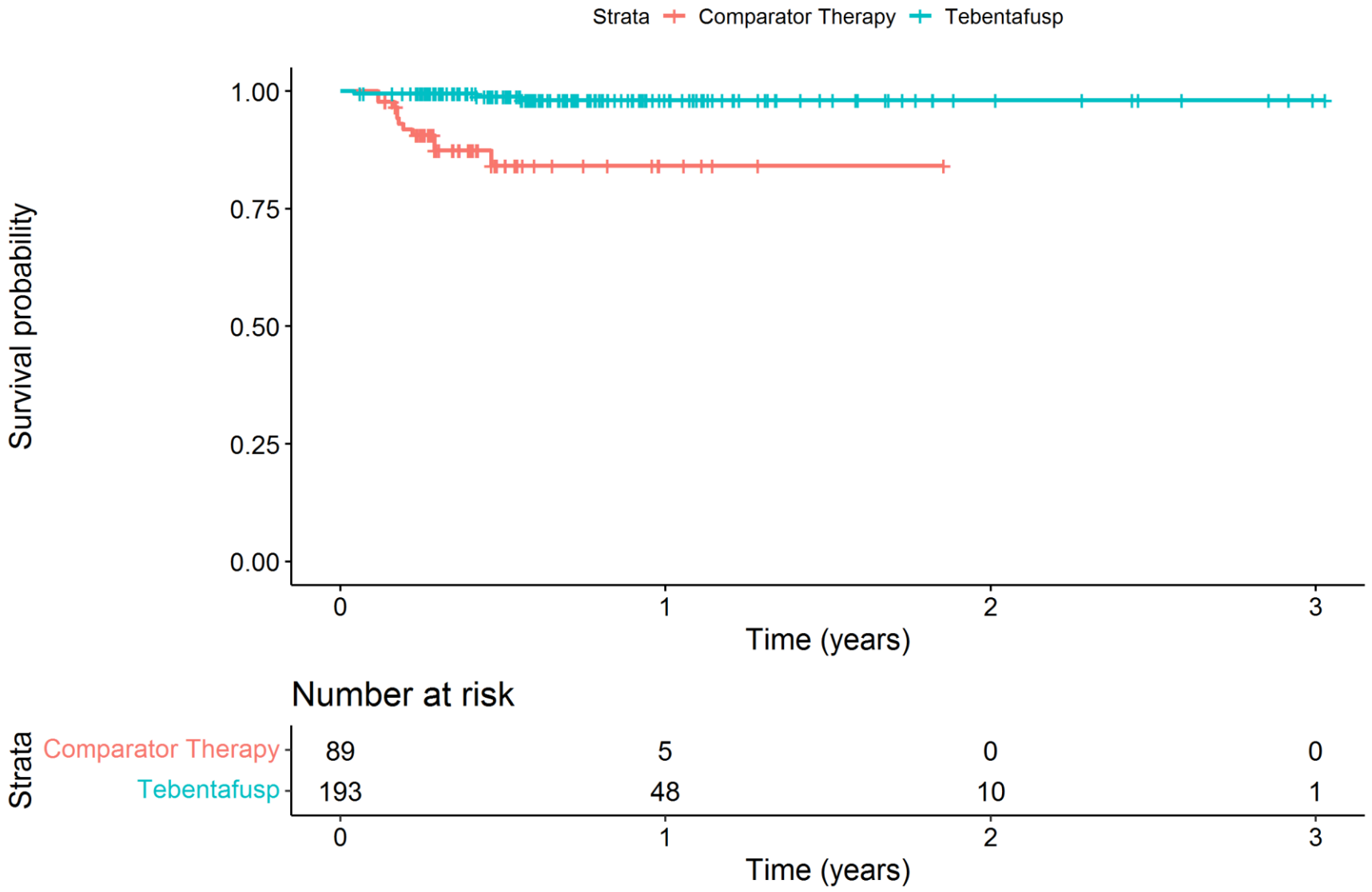
53.7 Hypothyreose - ECOG 0



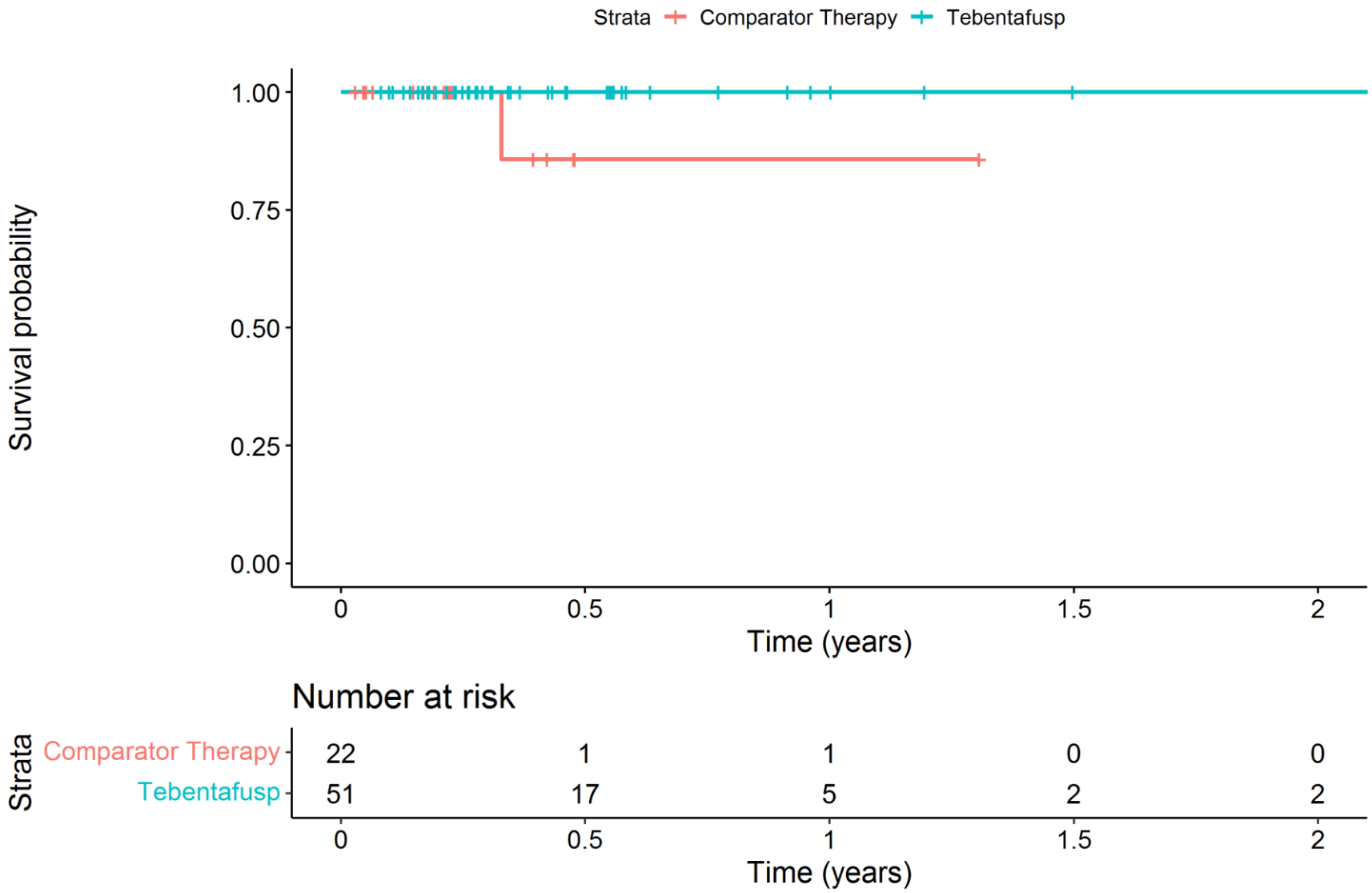
53.8 Hypothyreose - ECOG 1



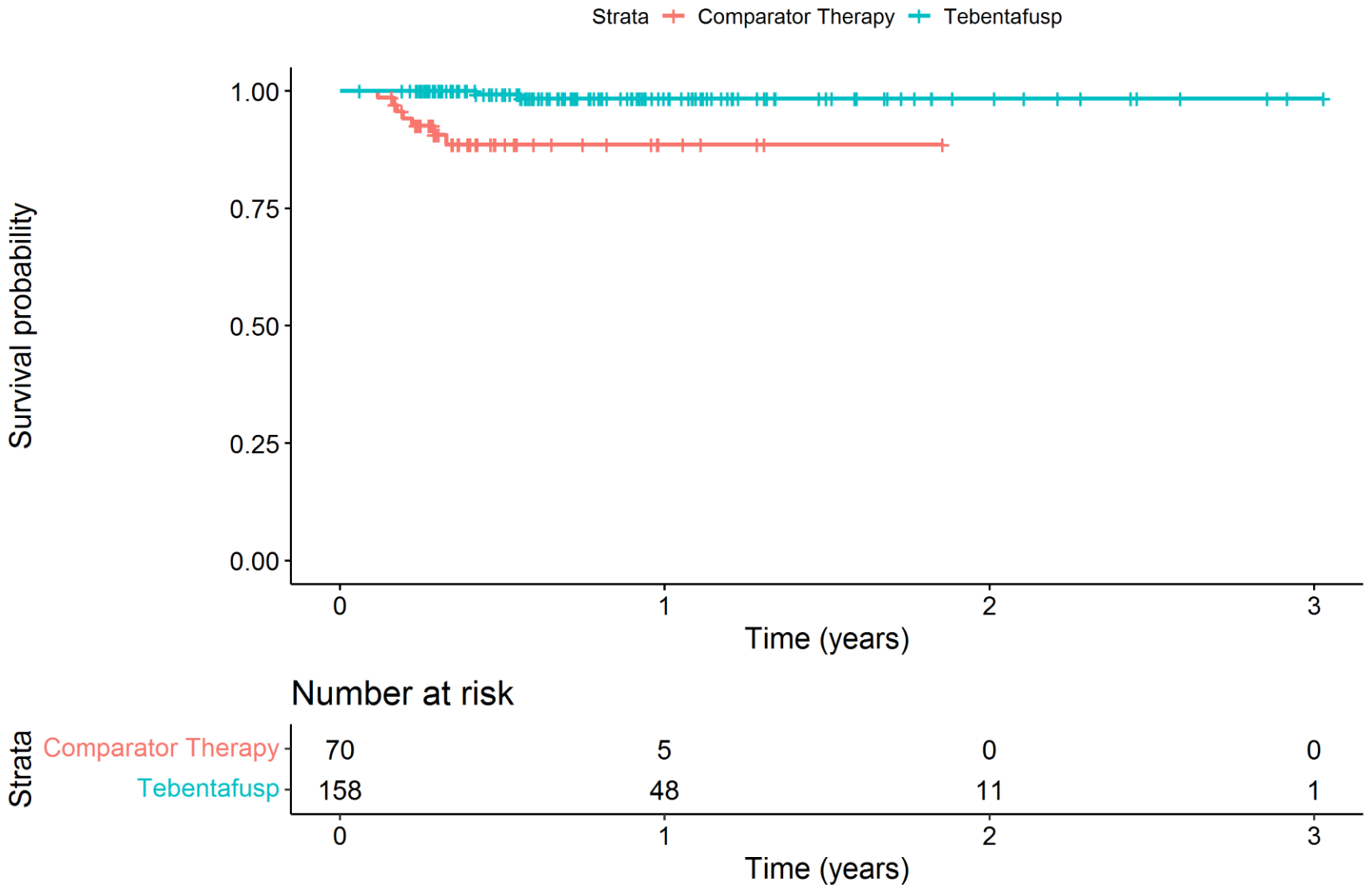
53.9 Hypothyreose - ALP ≤ ULN



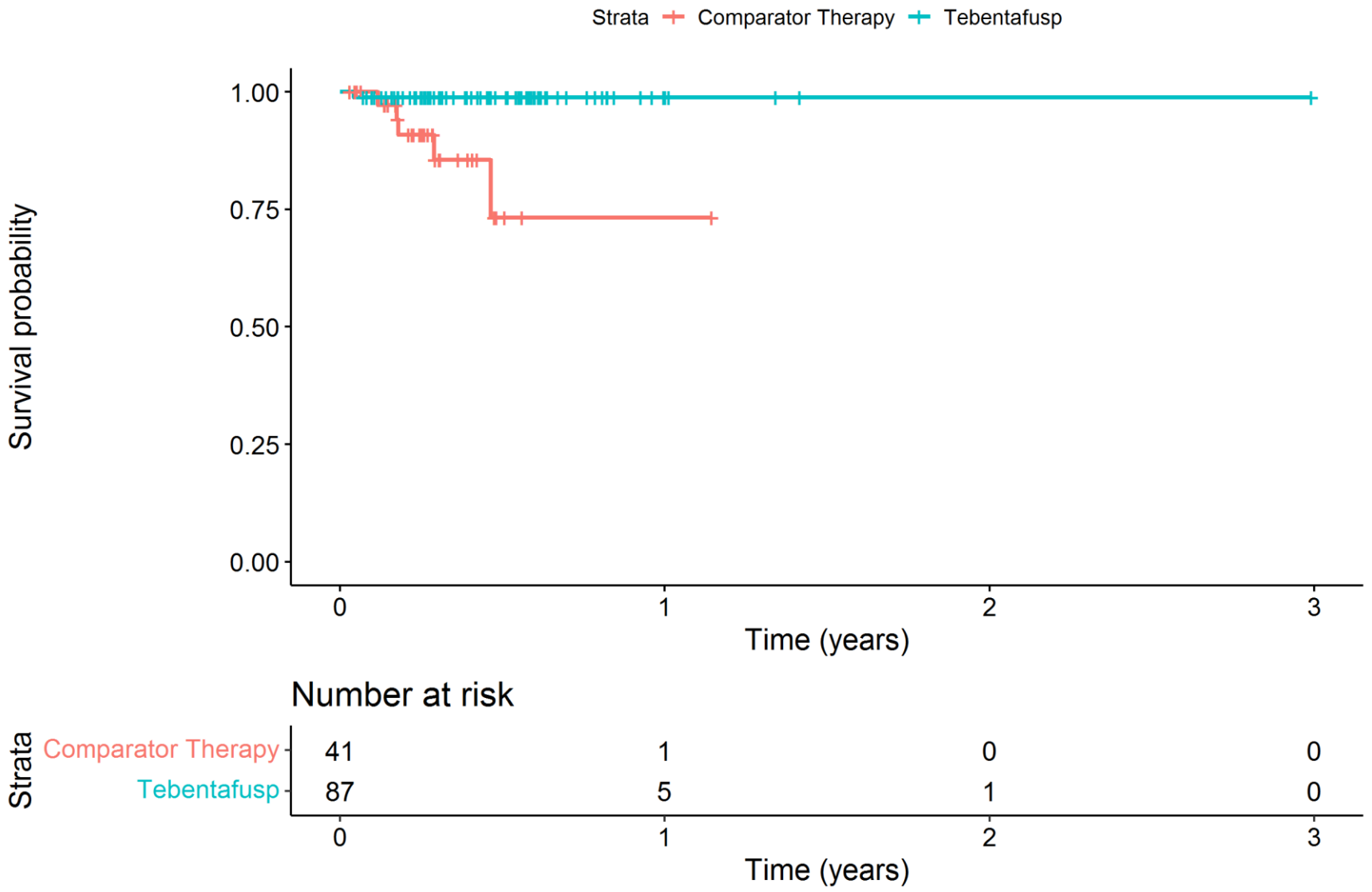
53.10 Hypothyreose - ALP > ULN



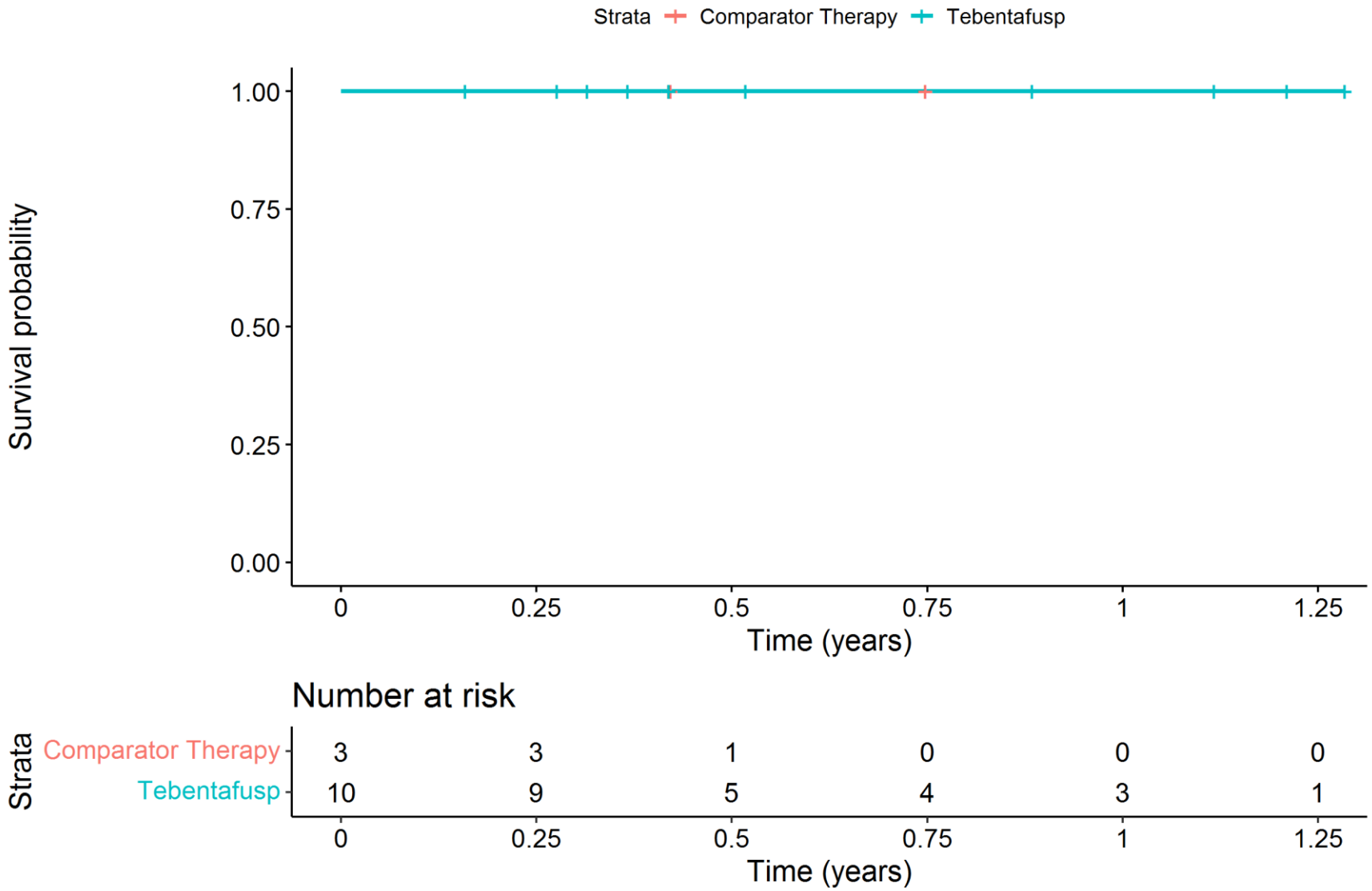
53.11 Hypothyreose - LDH =< ULN



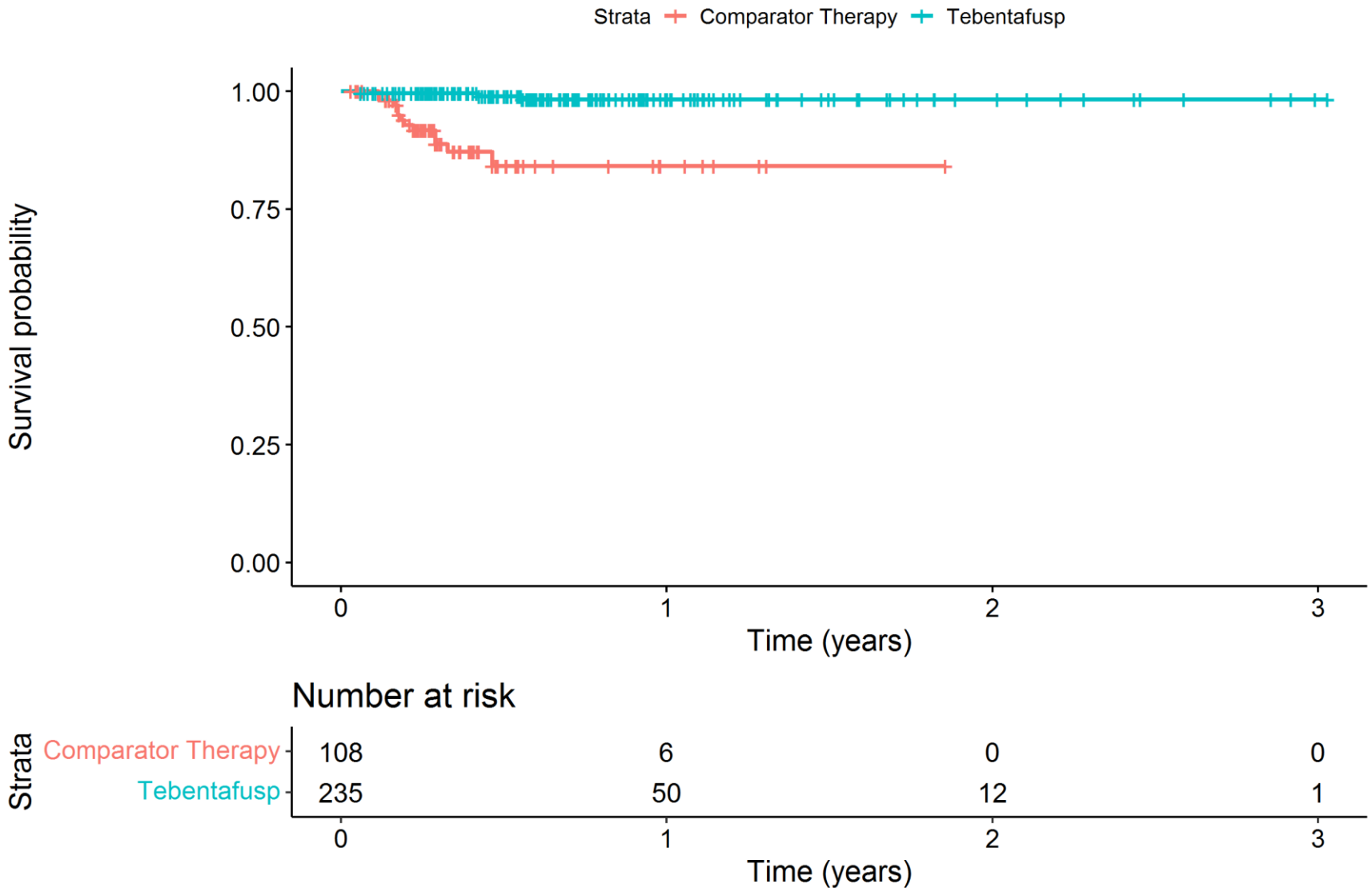
53.12 Hypothyreose - LDH > ULN



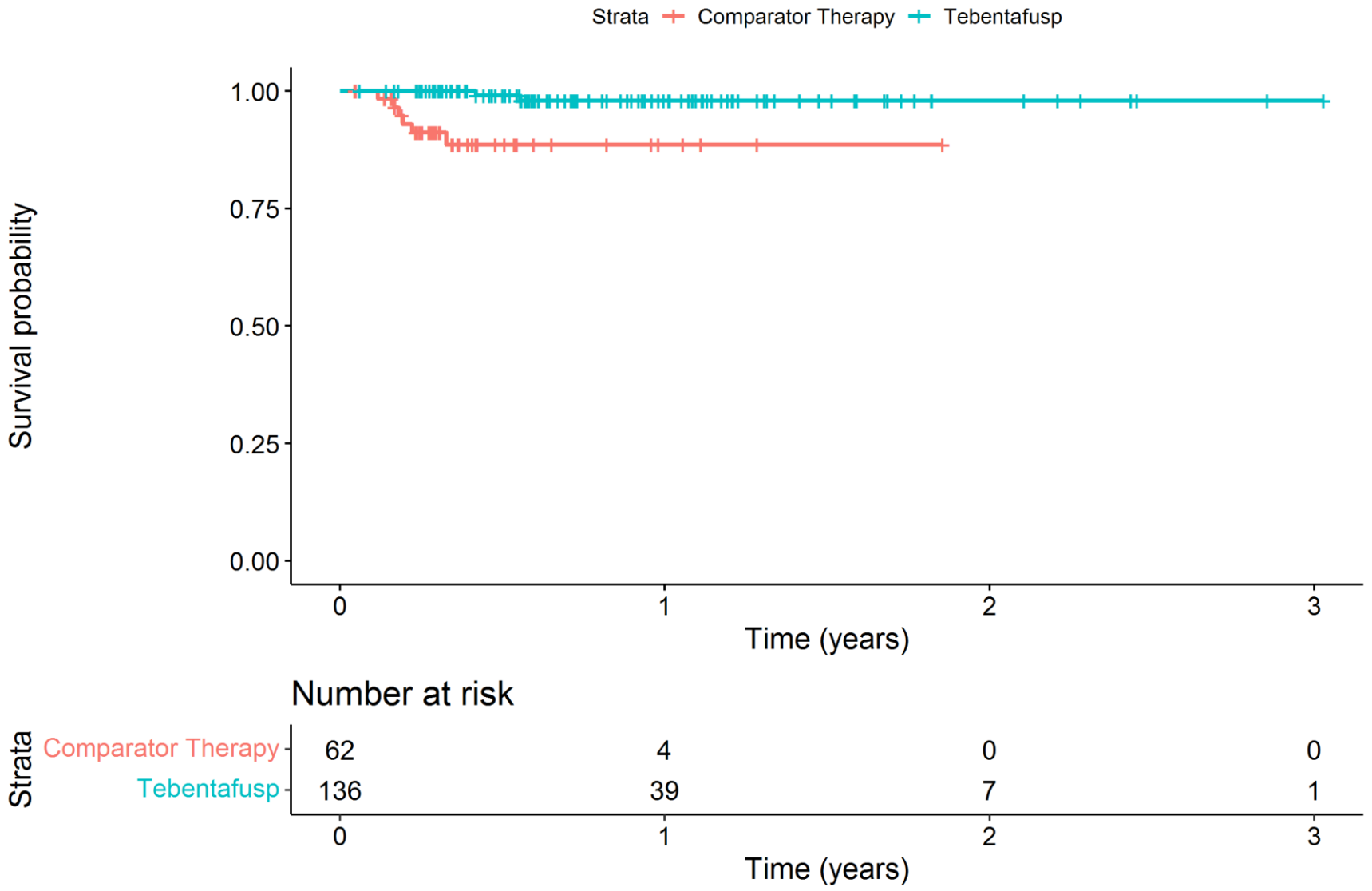
53.13 Hypothyreose - Vorherige Therapie adjuvant/neoadjuvant



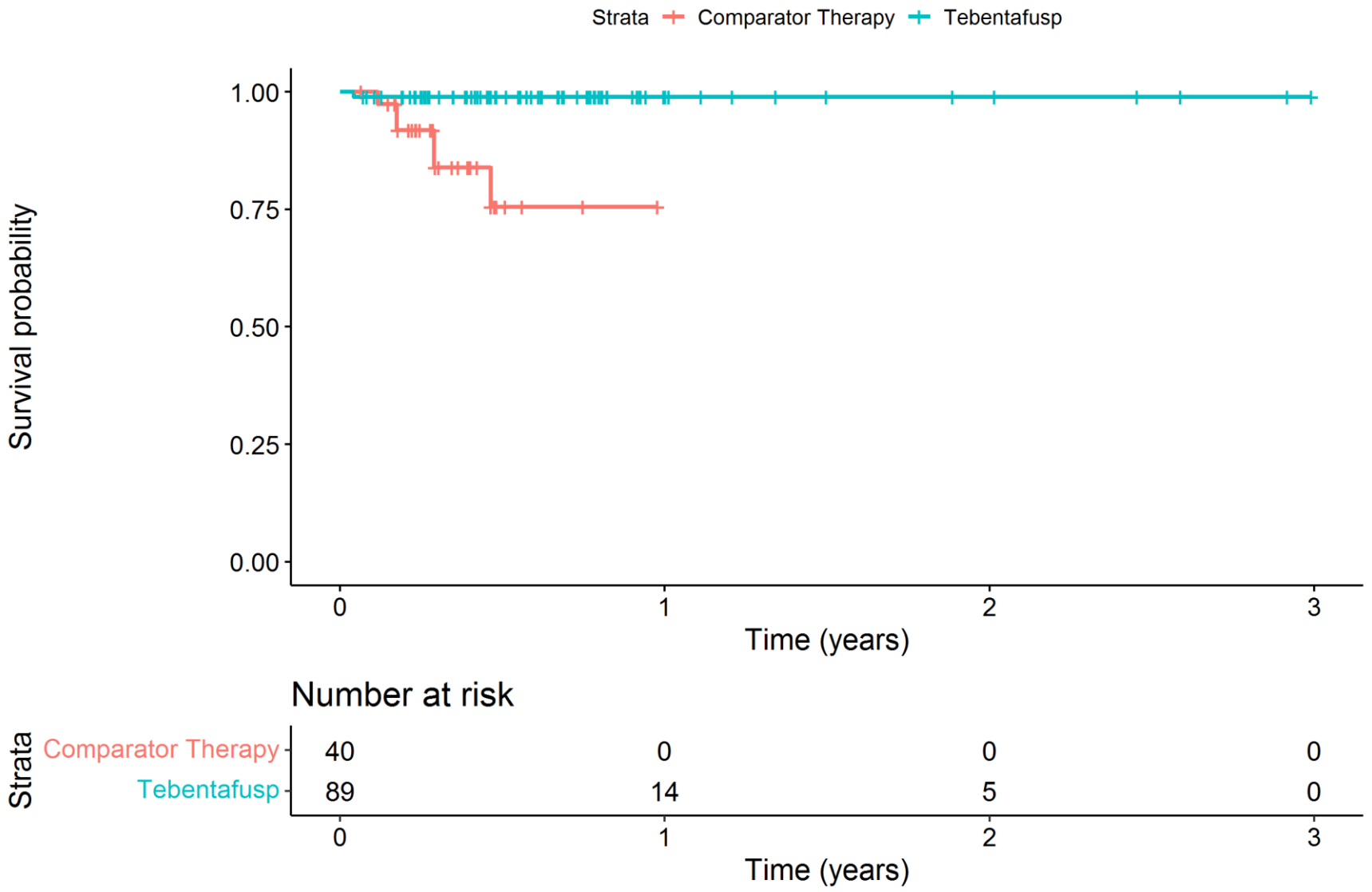
53.14 Hypothyreose - Keine vorherige Therapie adjuvant/neoadjuvant



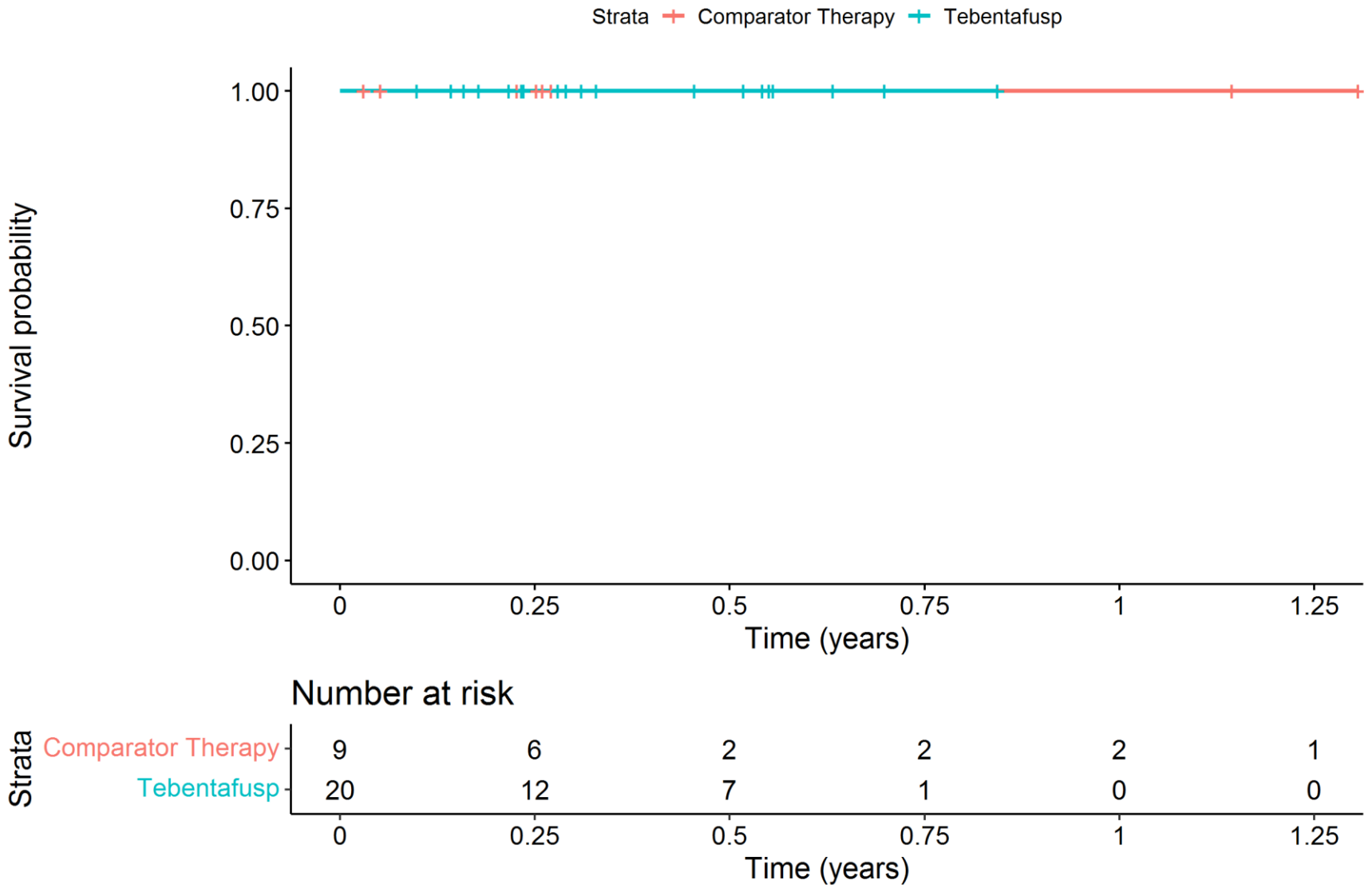
53.15 Hypothyreose - Läsion ≤ 3cm



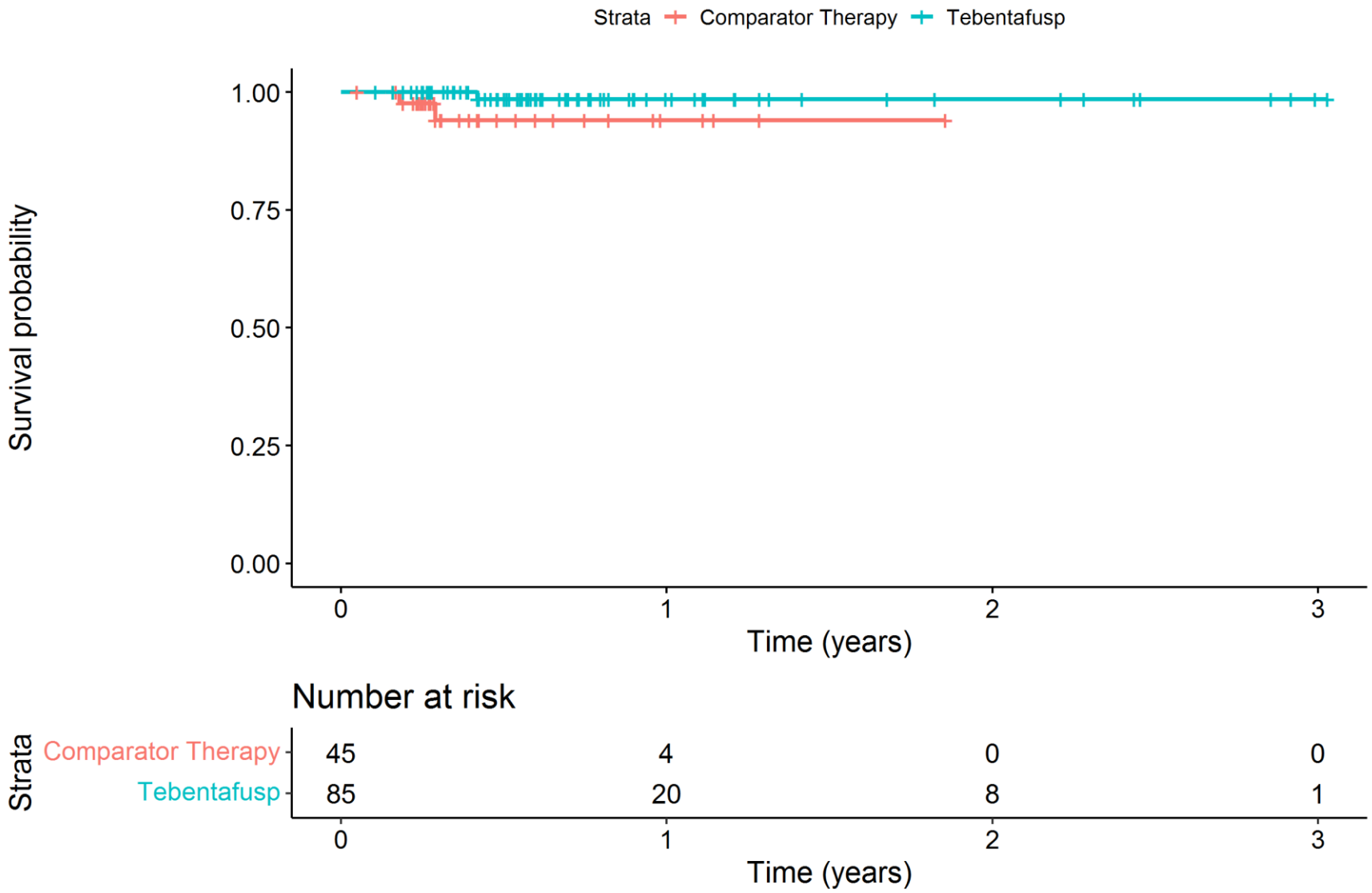
53.16 Hypothyreose - Läsion 3,1-8,0 cm



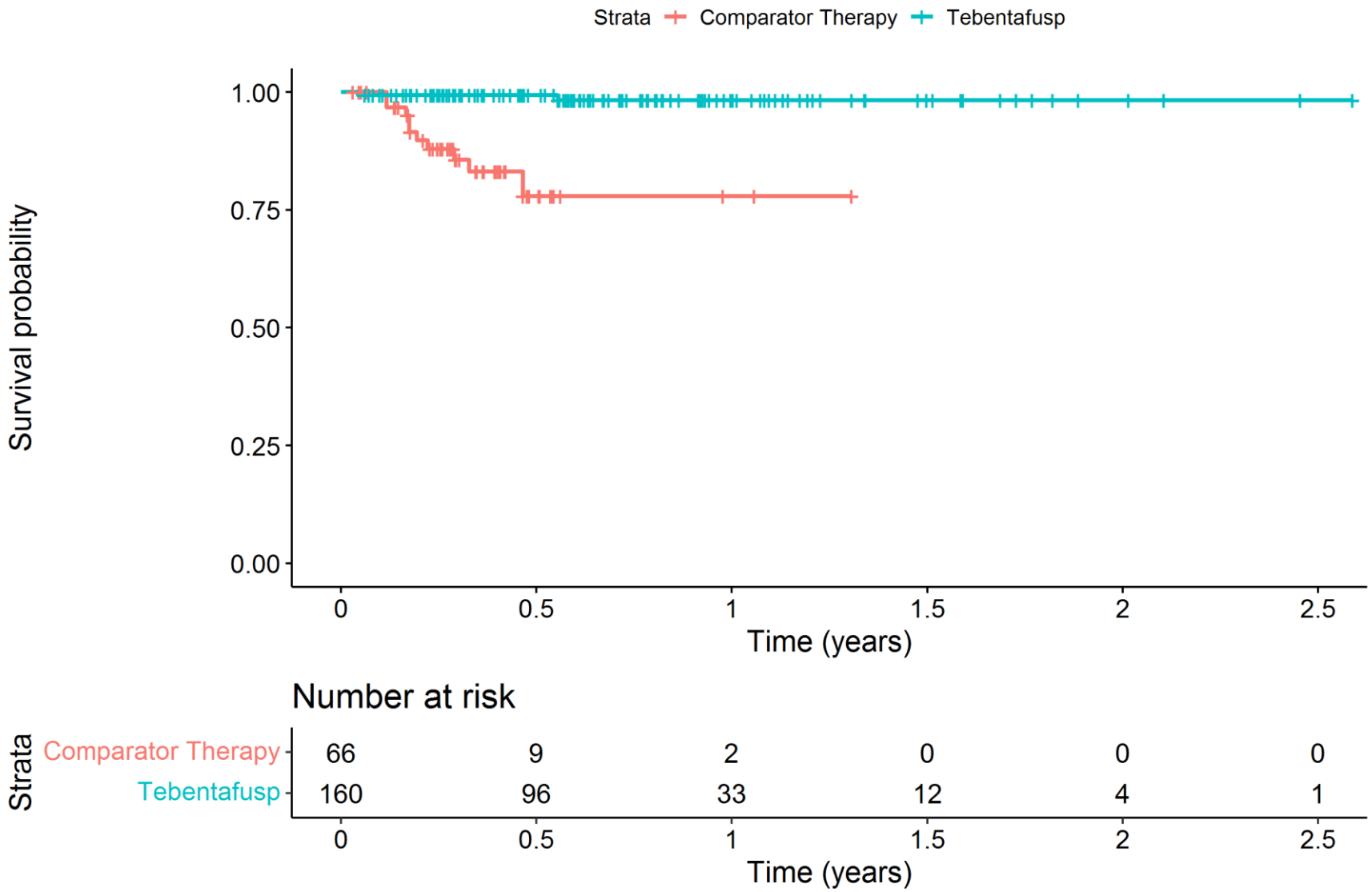
53.17 Hypothyreose - Läsion ≥8,1 cm



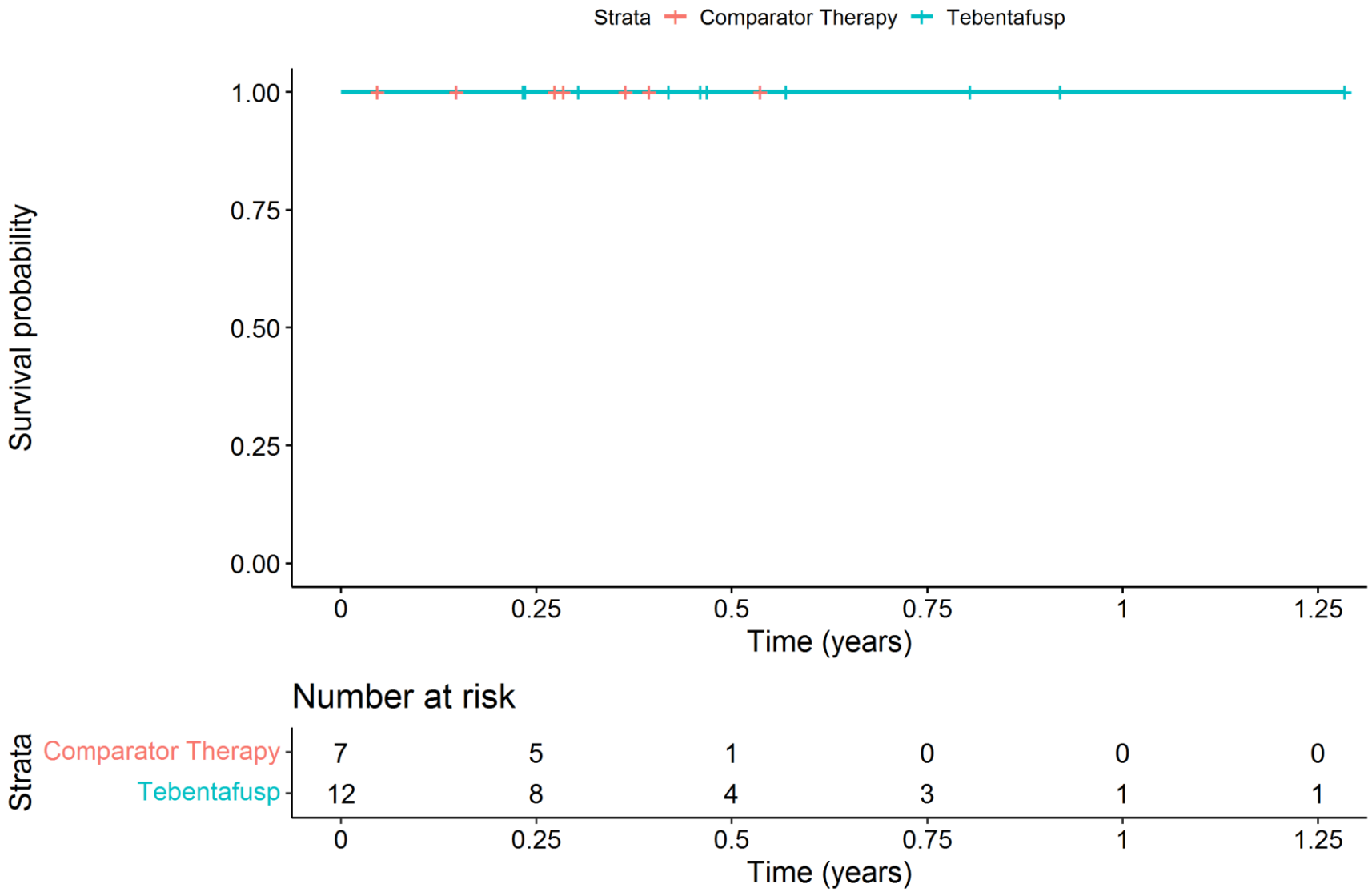
53.18 Hypothyreose - Nordamerika



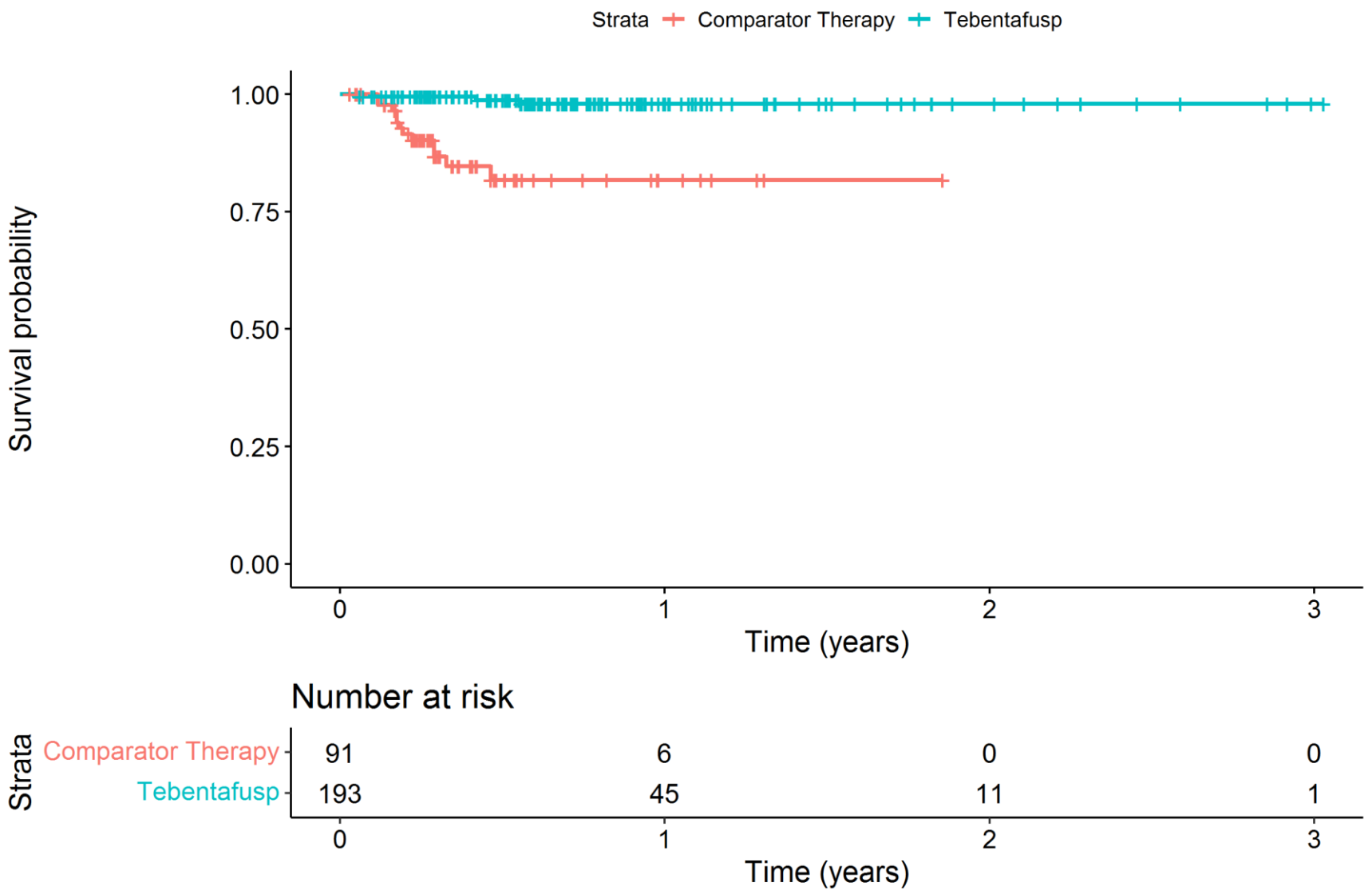
53.19 Hypothyreose - Nicht-Nordamerika



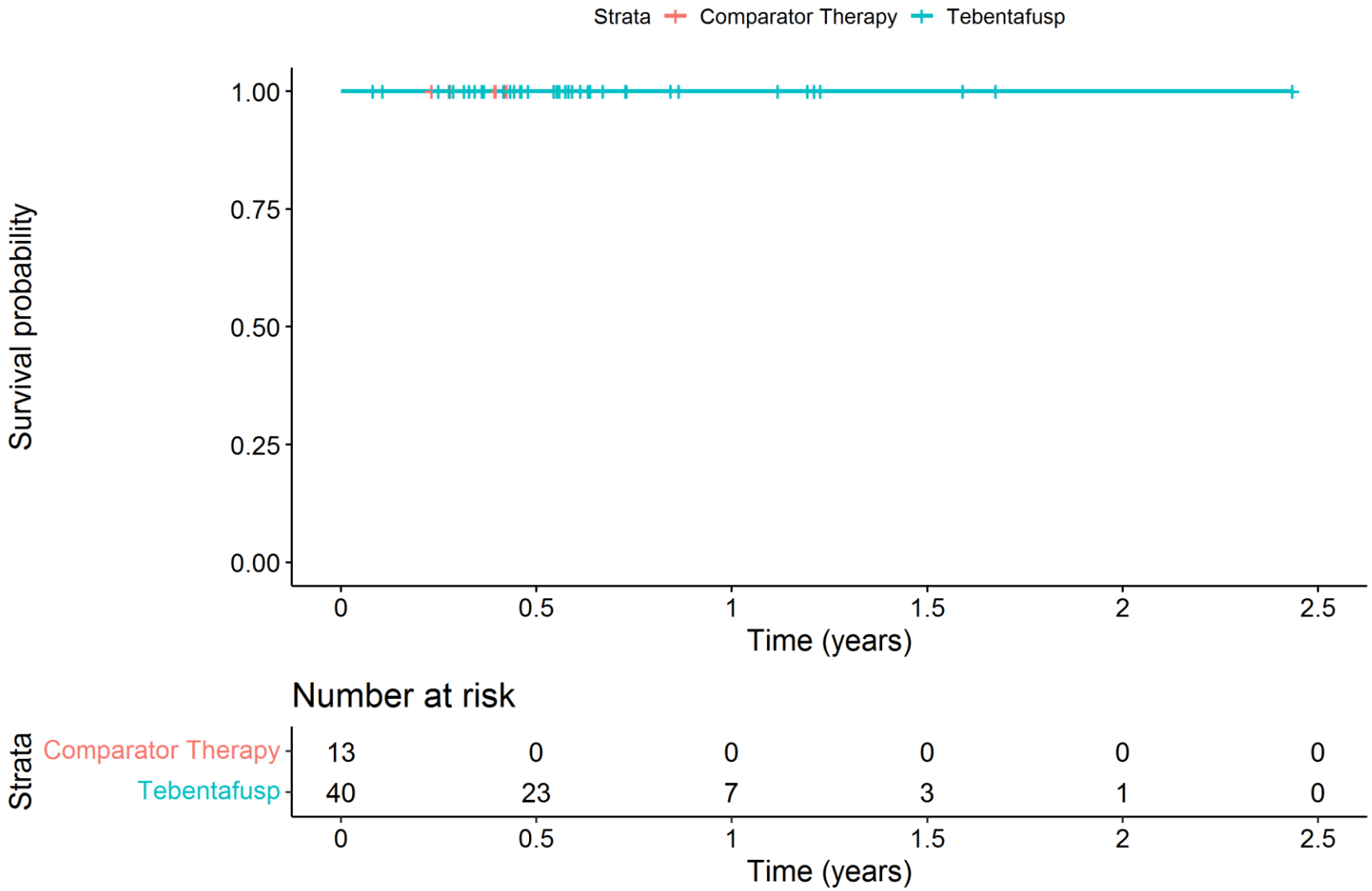
53.20 Hypothyreose - Dacarbazin



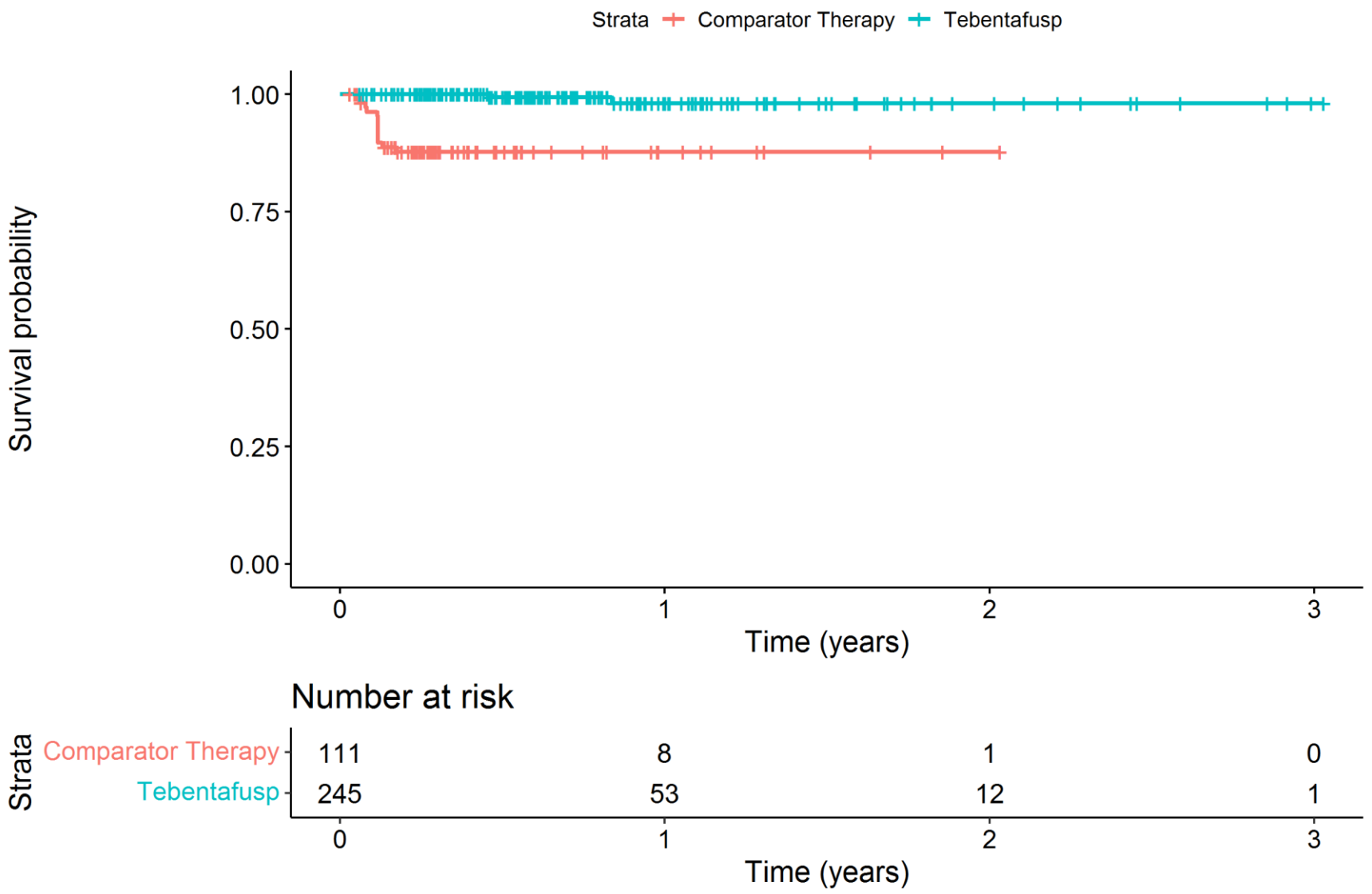
53.21 Hypothyreose - Pembrolizumab



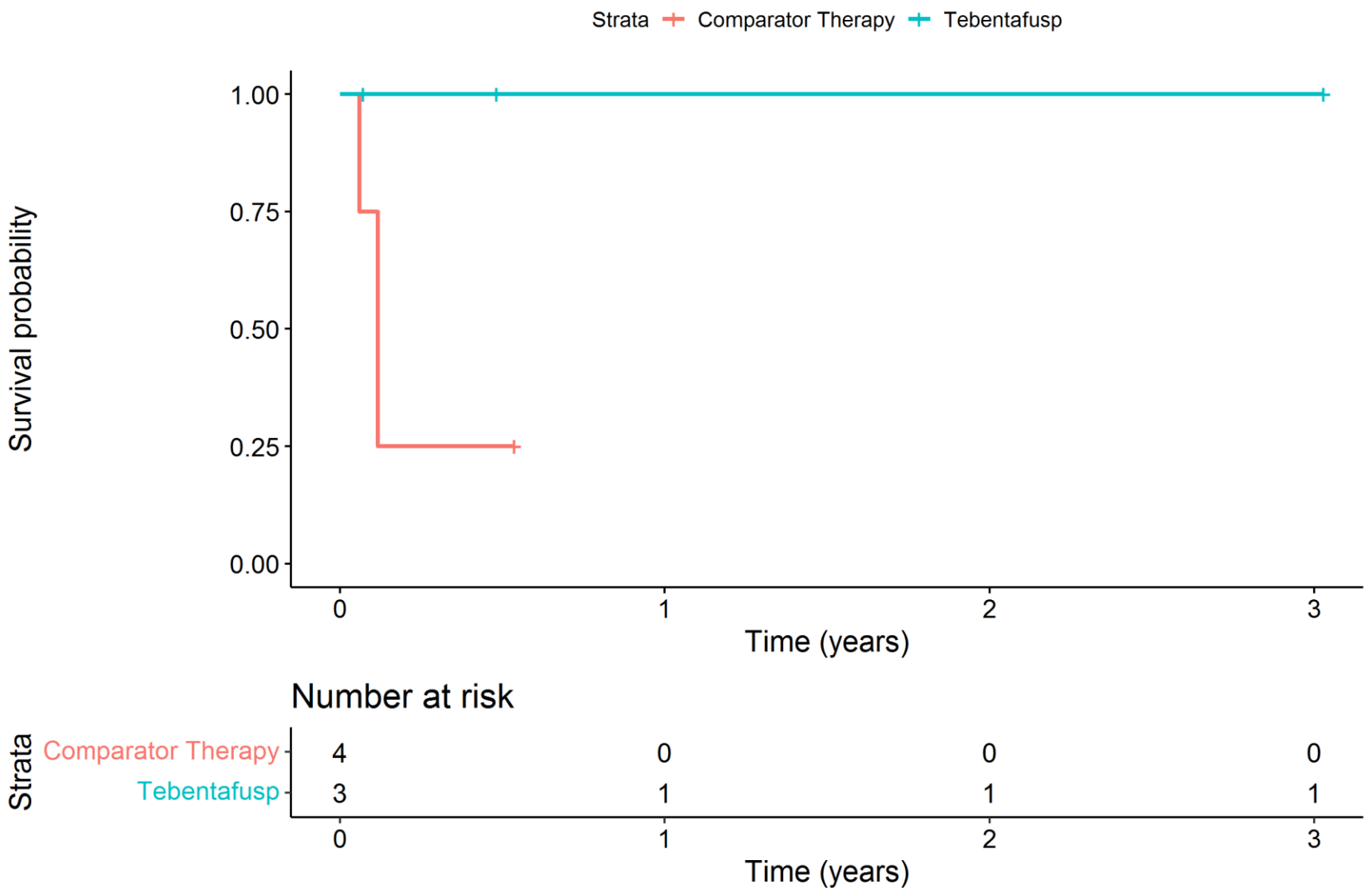
53.22 Hypothyreose - Ipilimumab



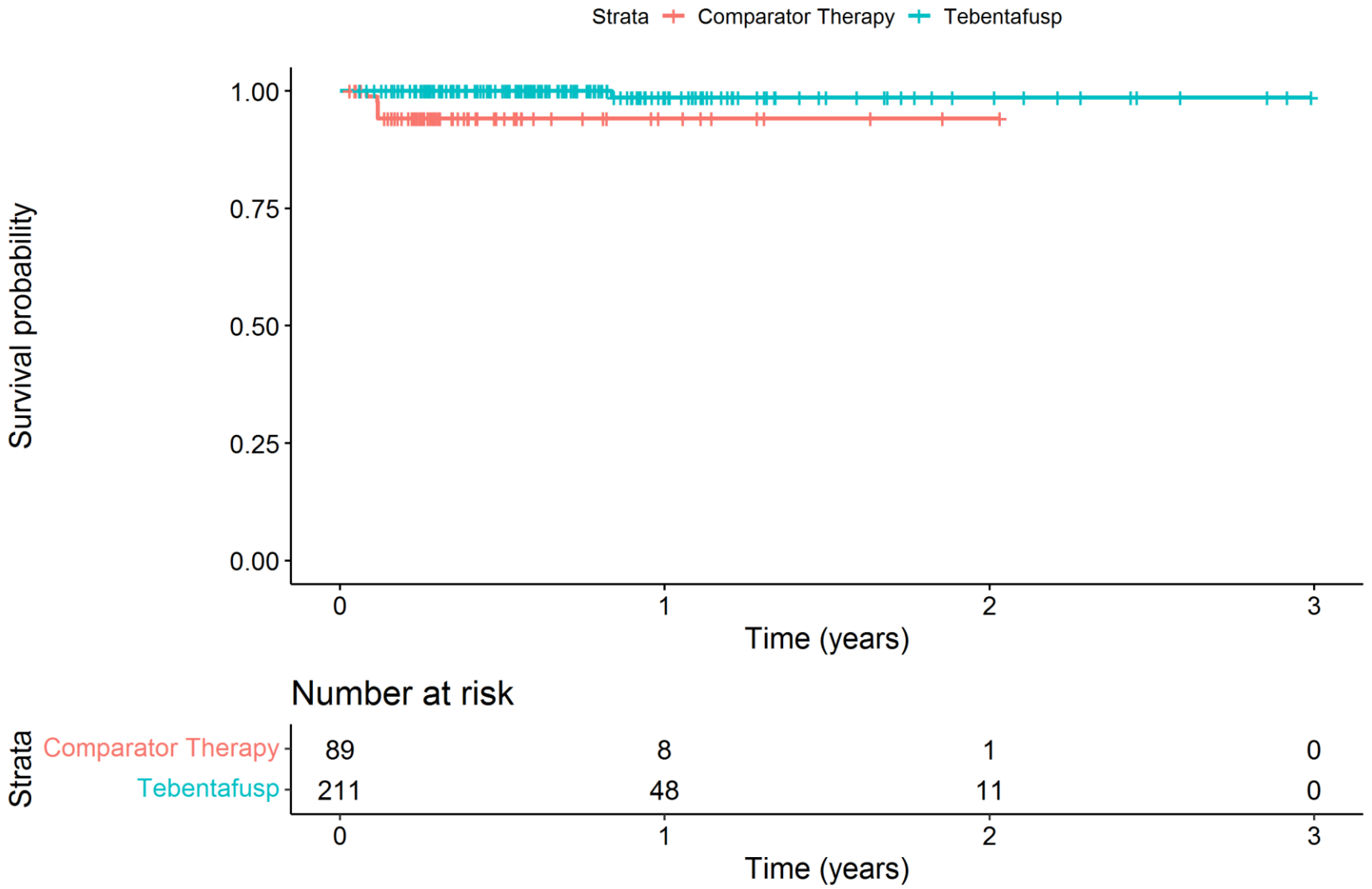
53.23 Hyperthyreose - Gesamt



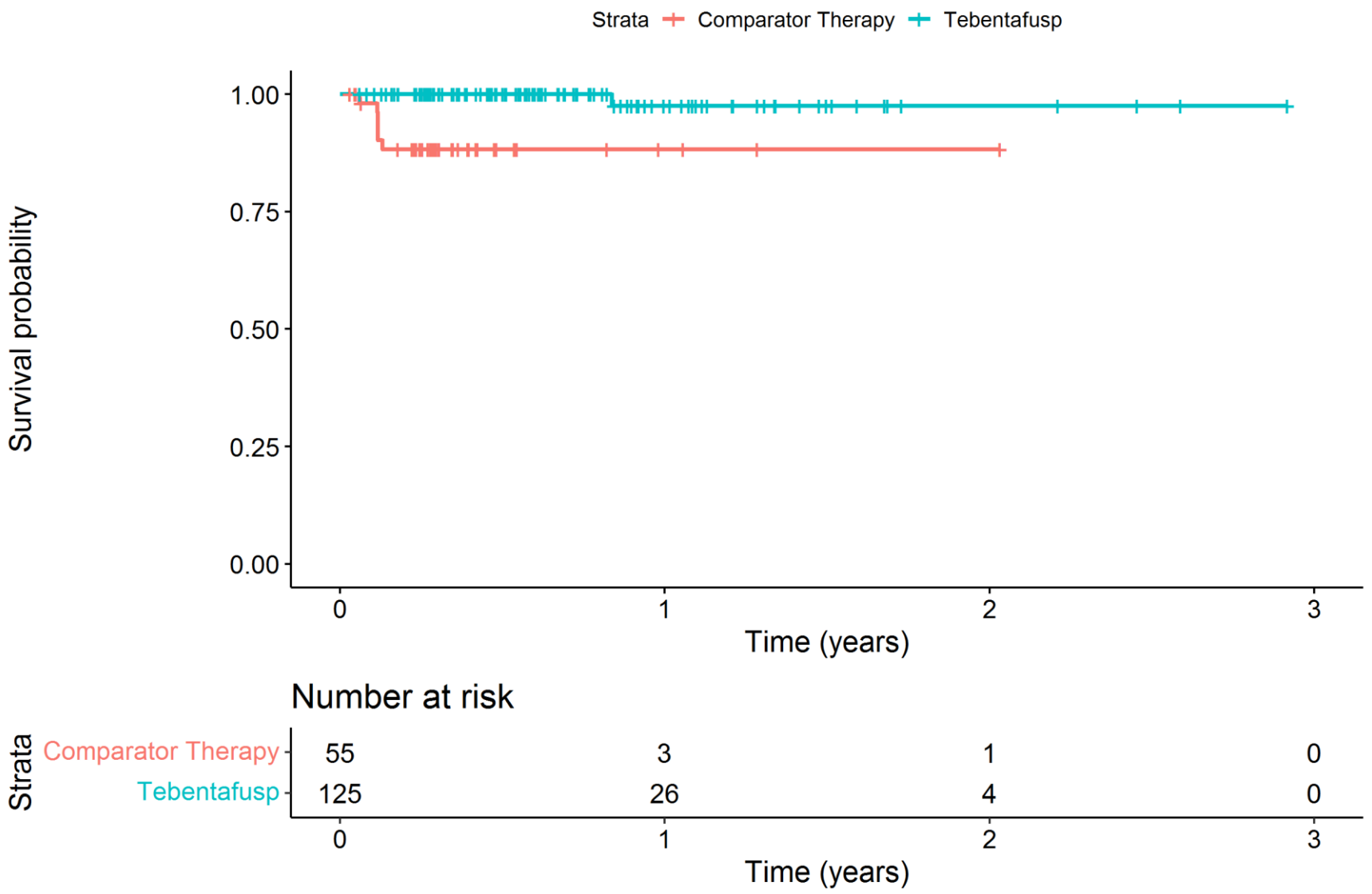
53.24 Hyperthyreose - Hispanisch



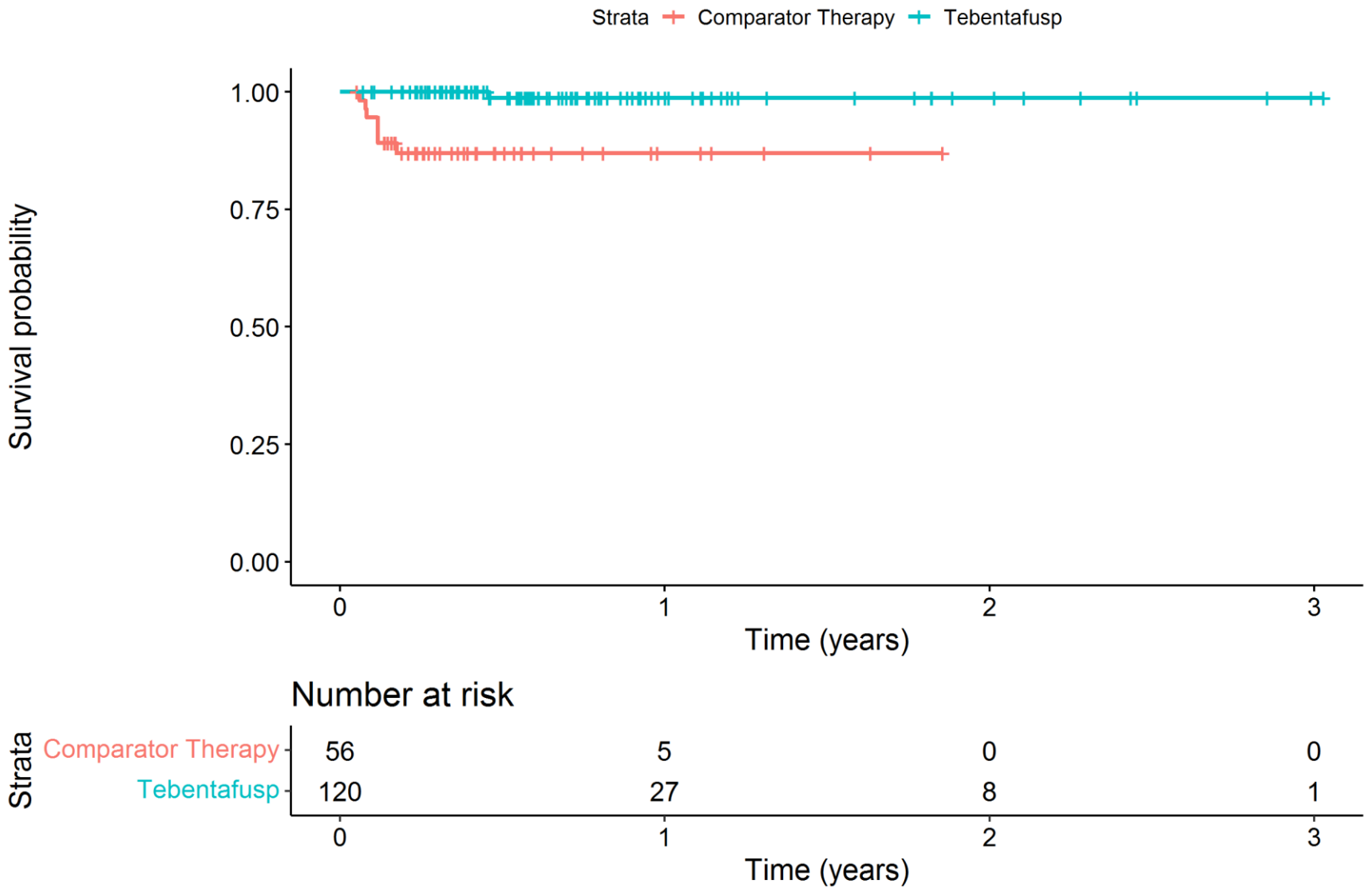
53.25 Hyperthyreose - Nicht-hispanisch



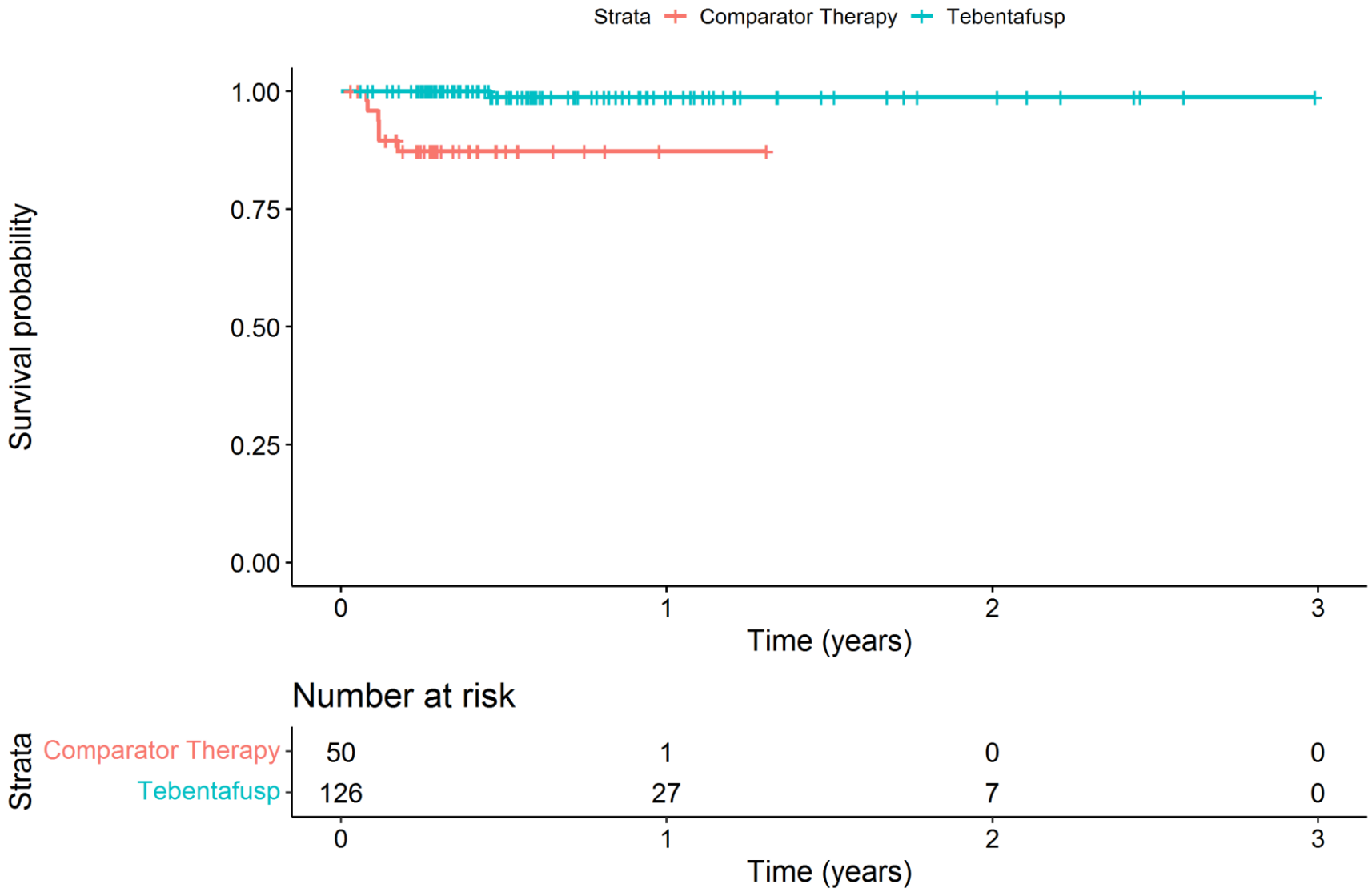
53.26 Hyperthyreose - Männlich



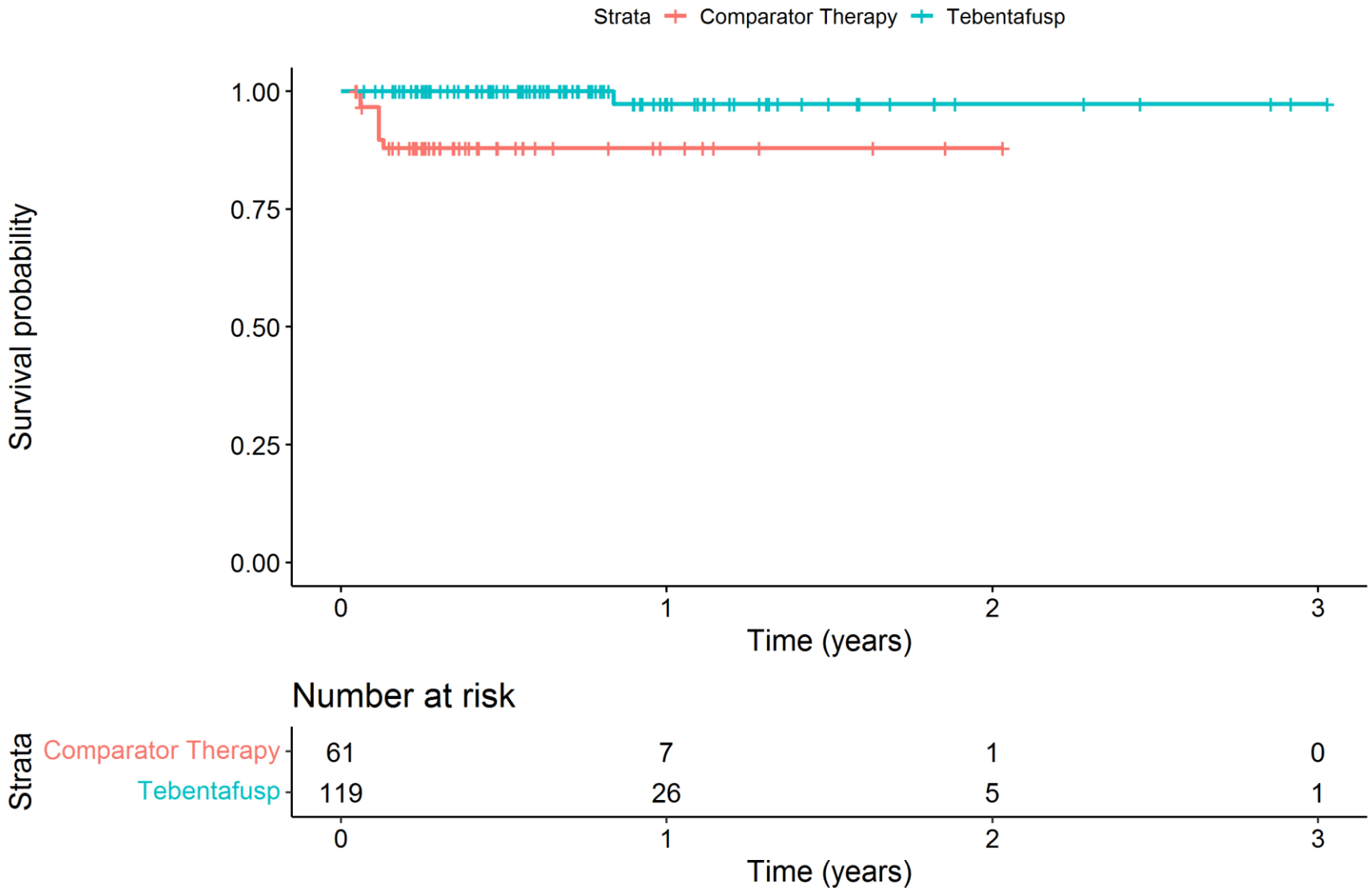
53.27 Hyperthyreose - Weiblich



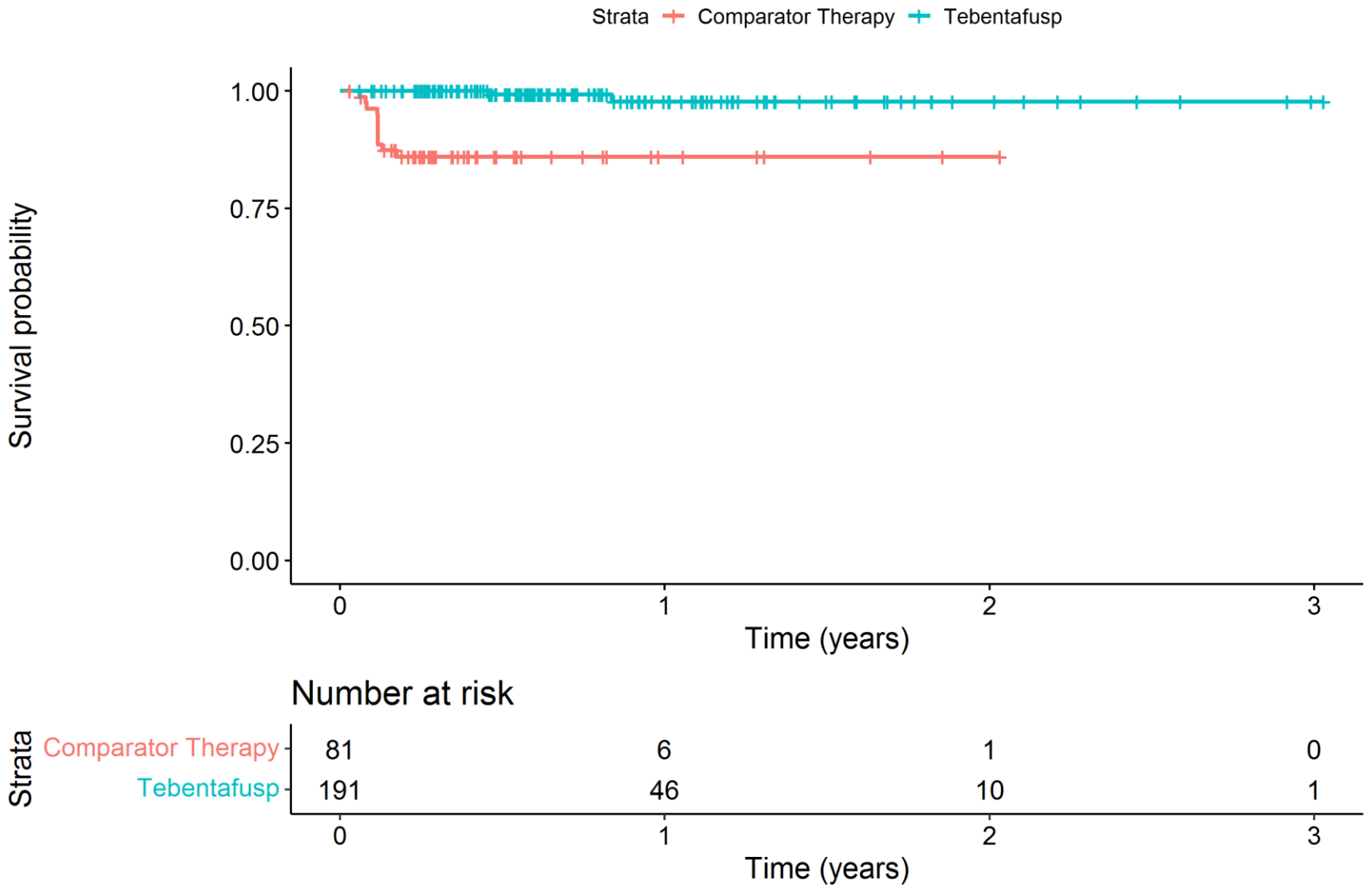
53.28 Hyperthyreose - <65



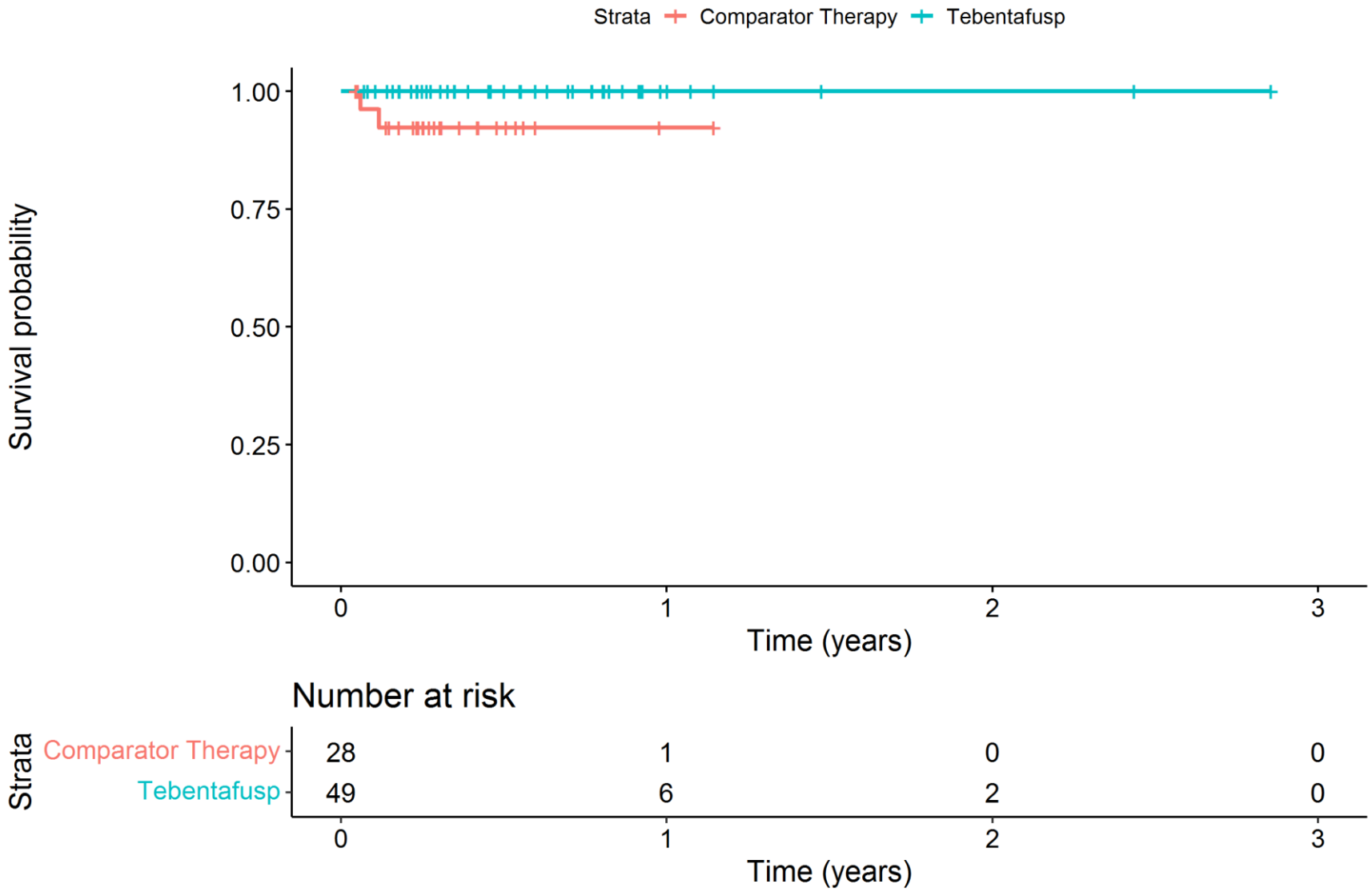
53.29 Hyperthyreose - ≥65



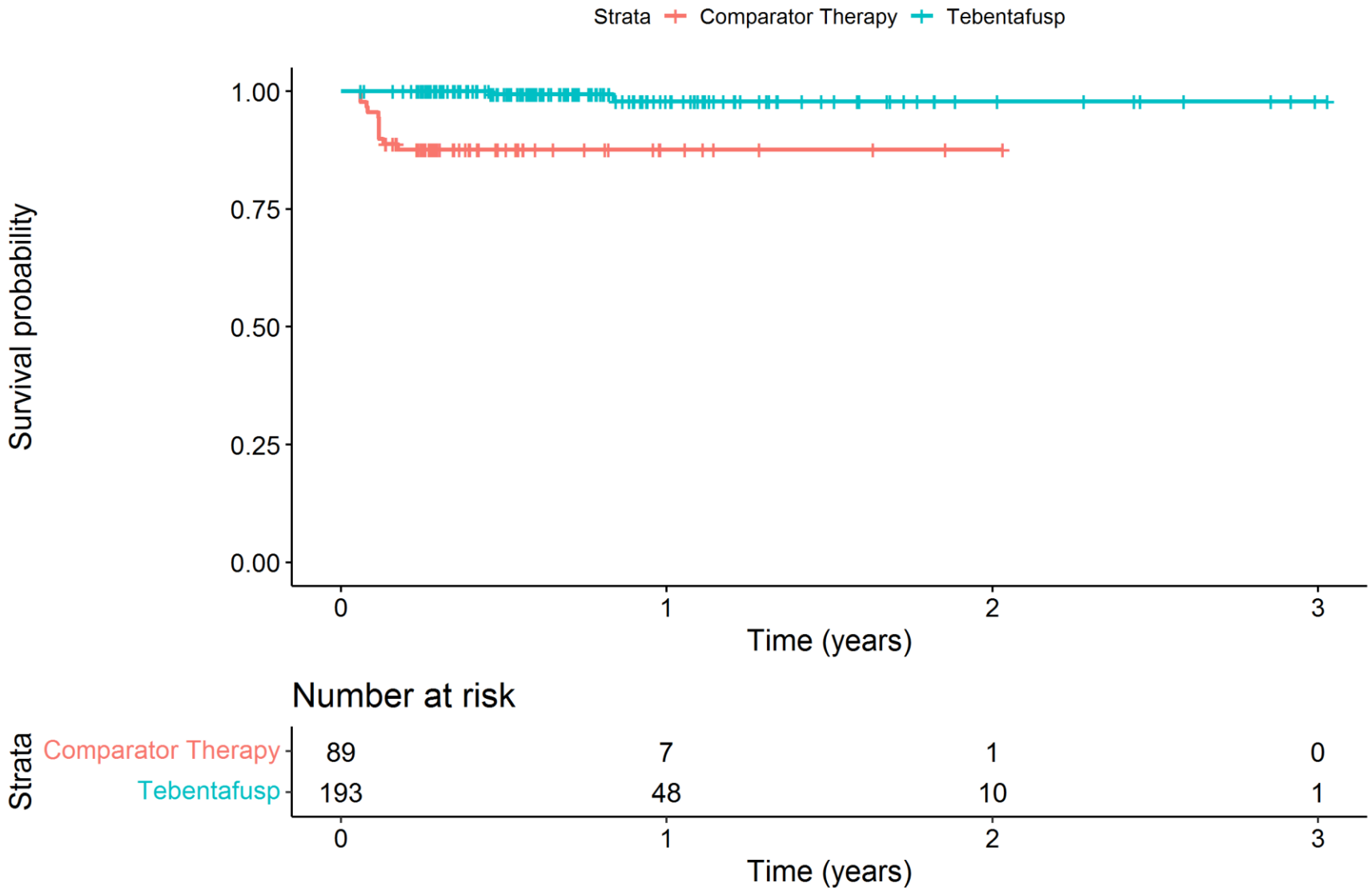
53.30 Hyperthyreose - ECOG 0



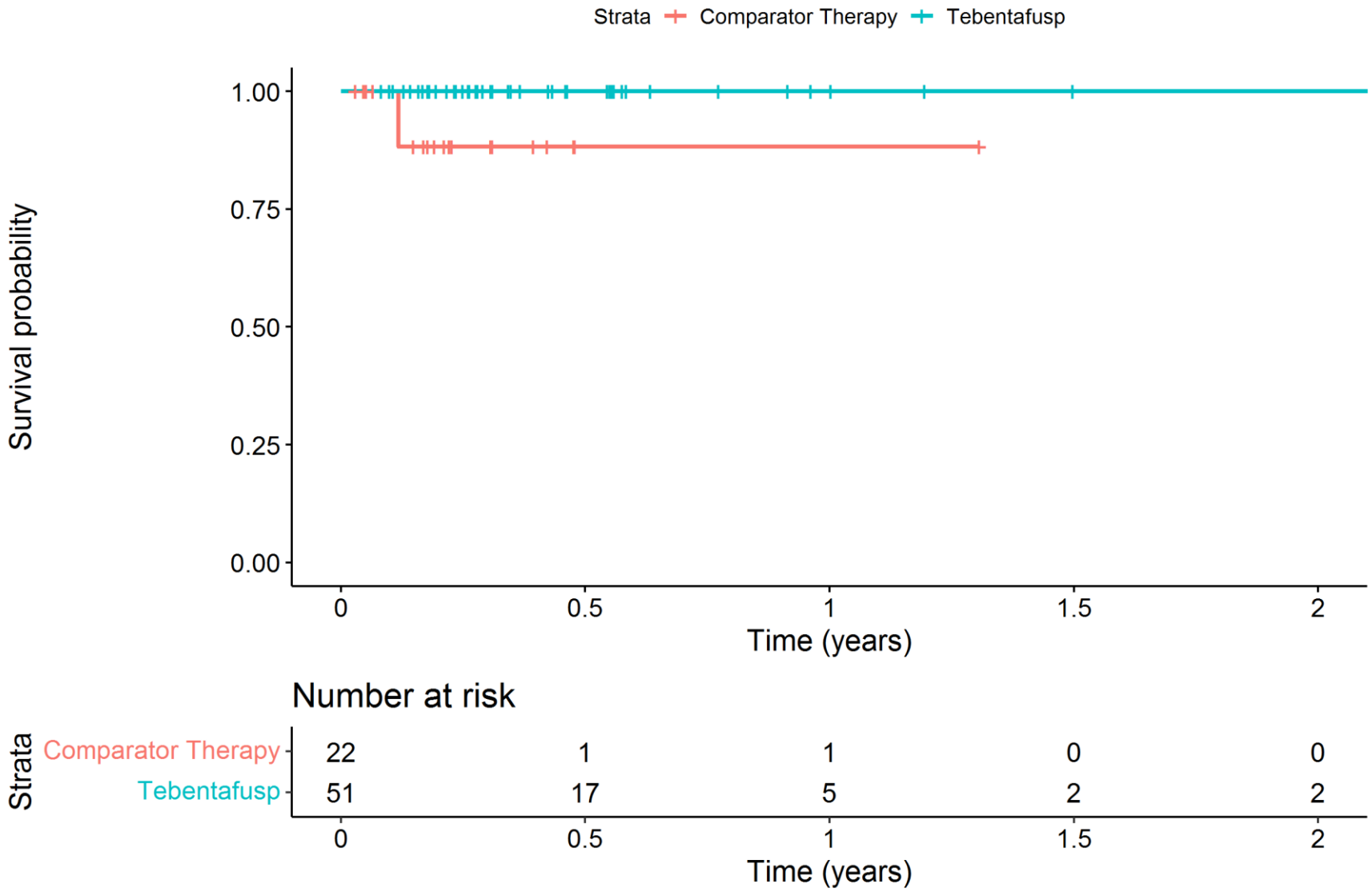
53.31 Hyperthyreose - ECOG 1



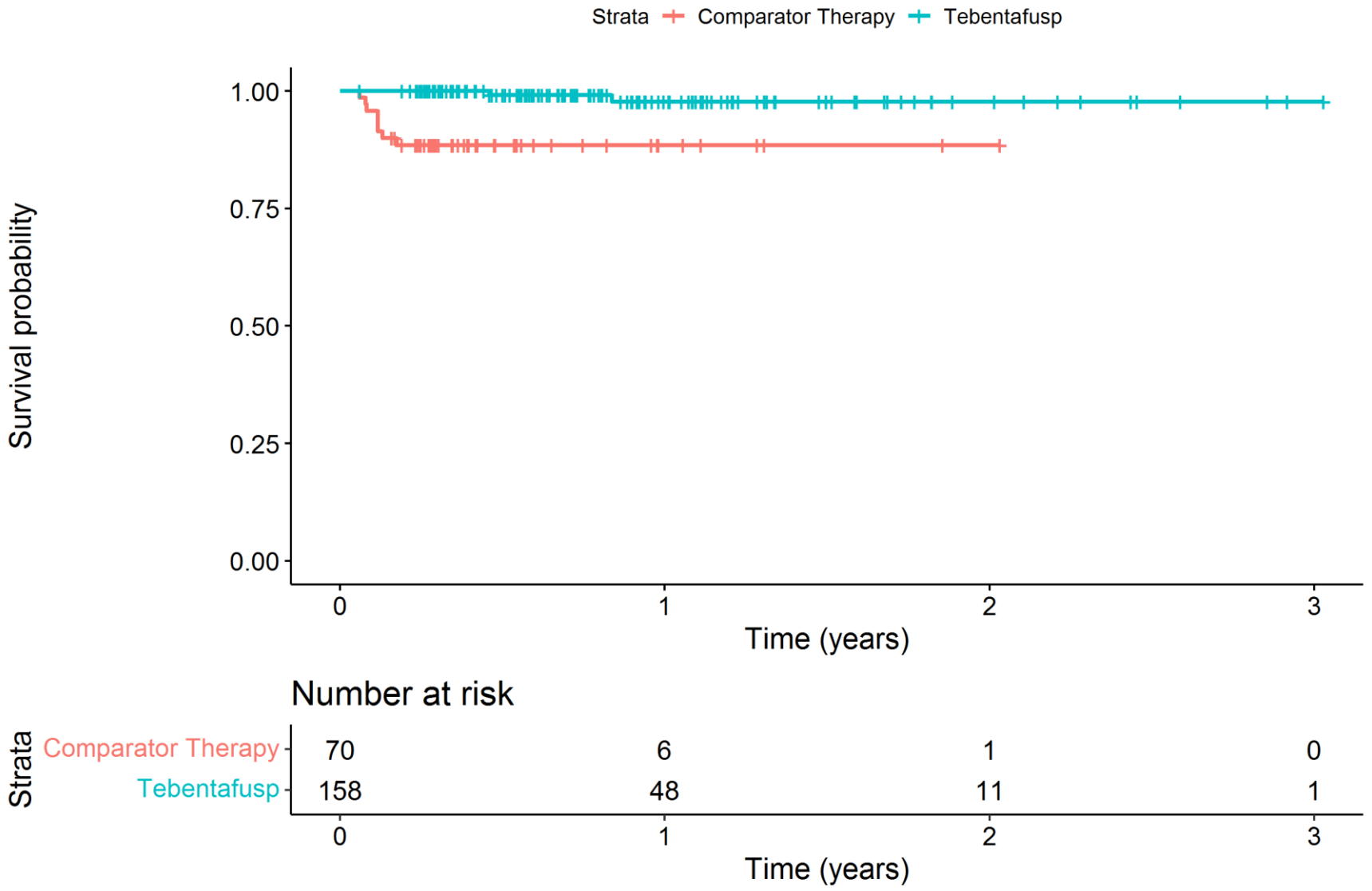
53.32 Hyperthyreose - ALP ≤ ULN



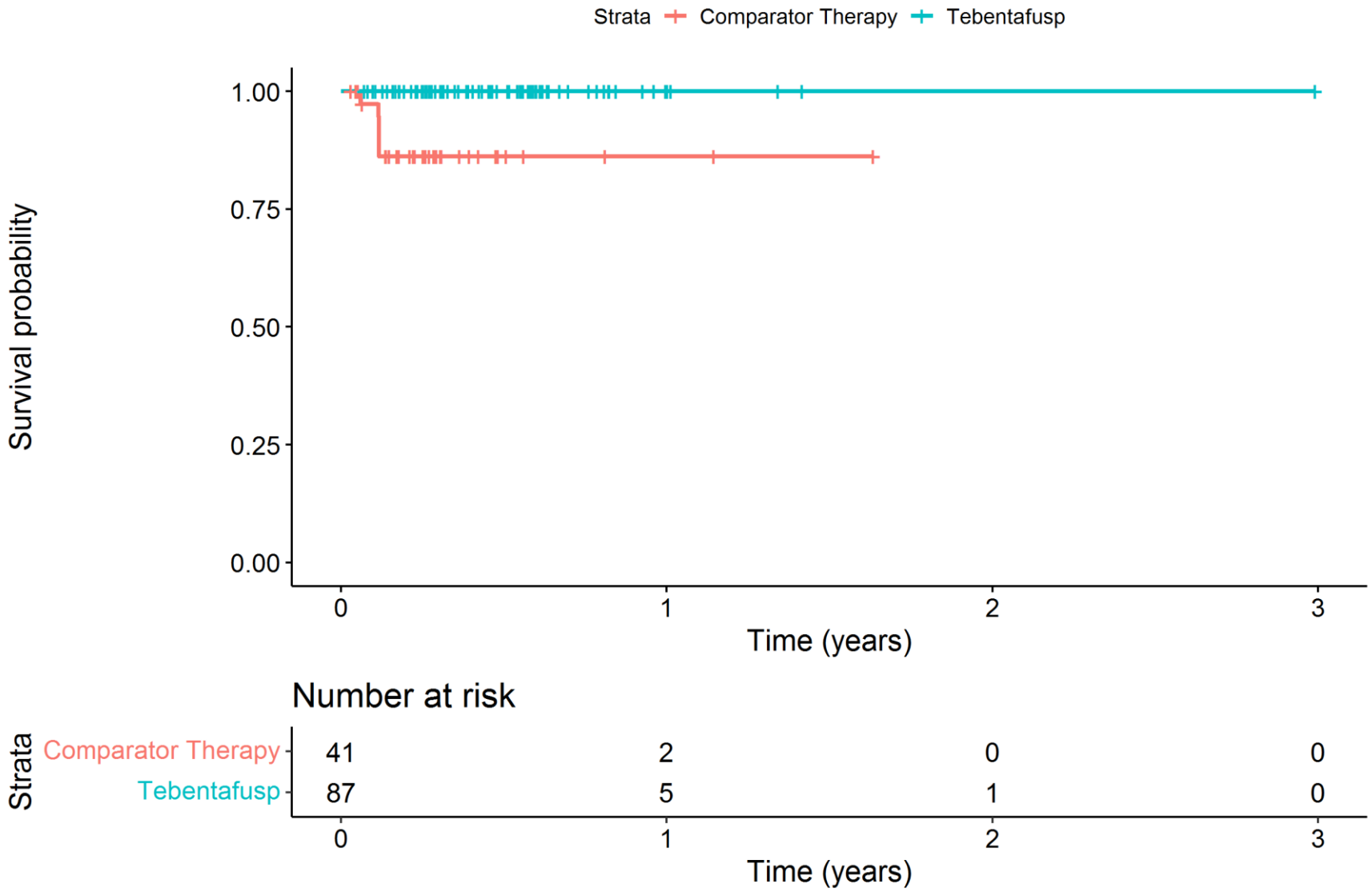
53.33 Hyperthyreose - ALP > ULN



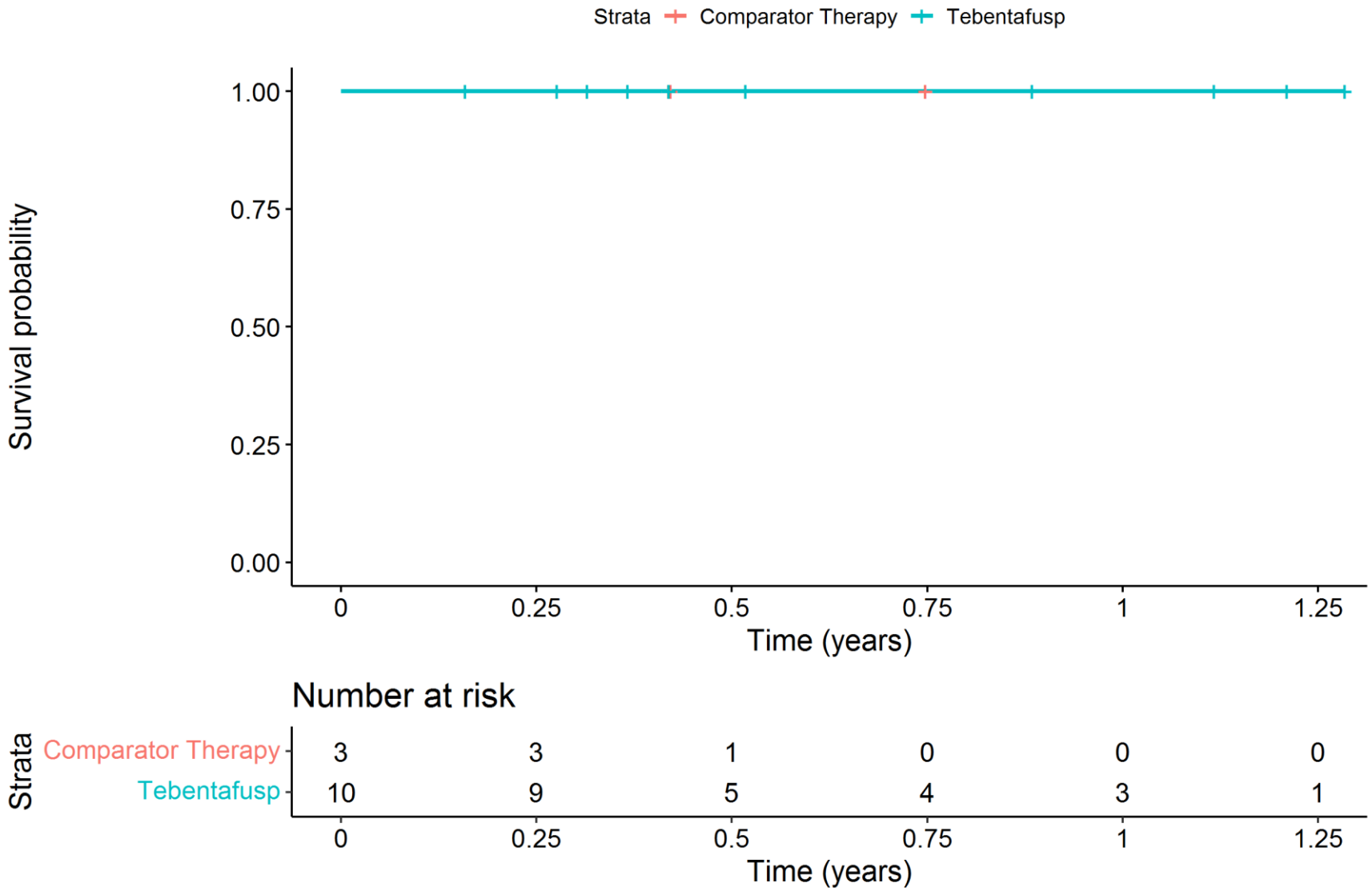
53.34 Hyperthyreose - LDH =< ULN



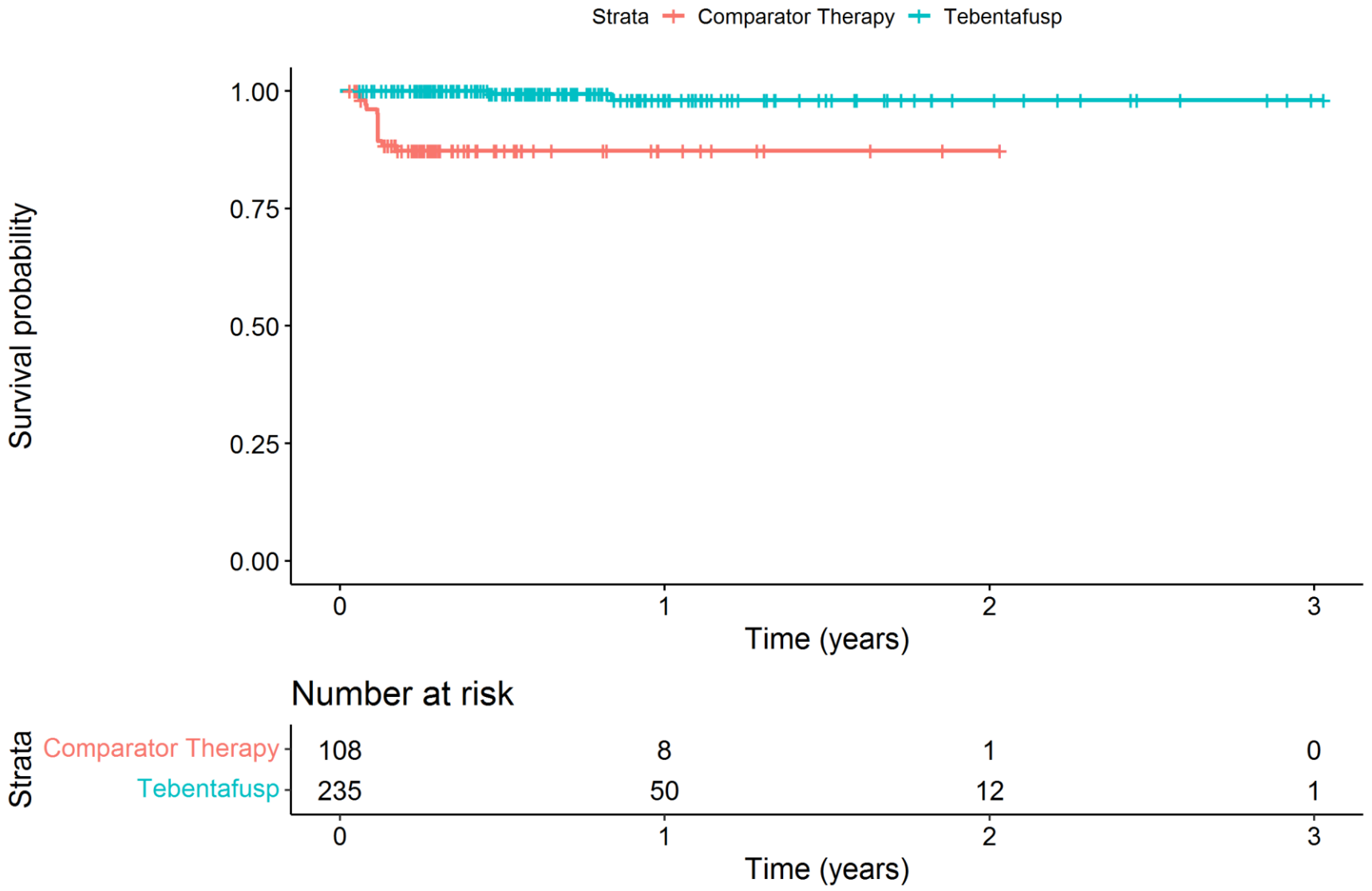
53.35 Hyperthyreose - LDH > ULN



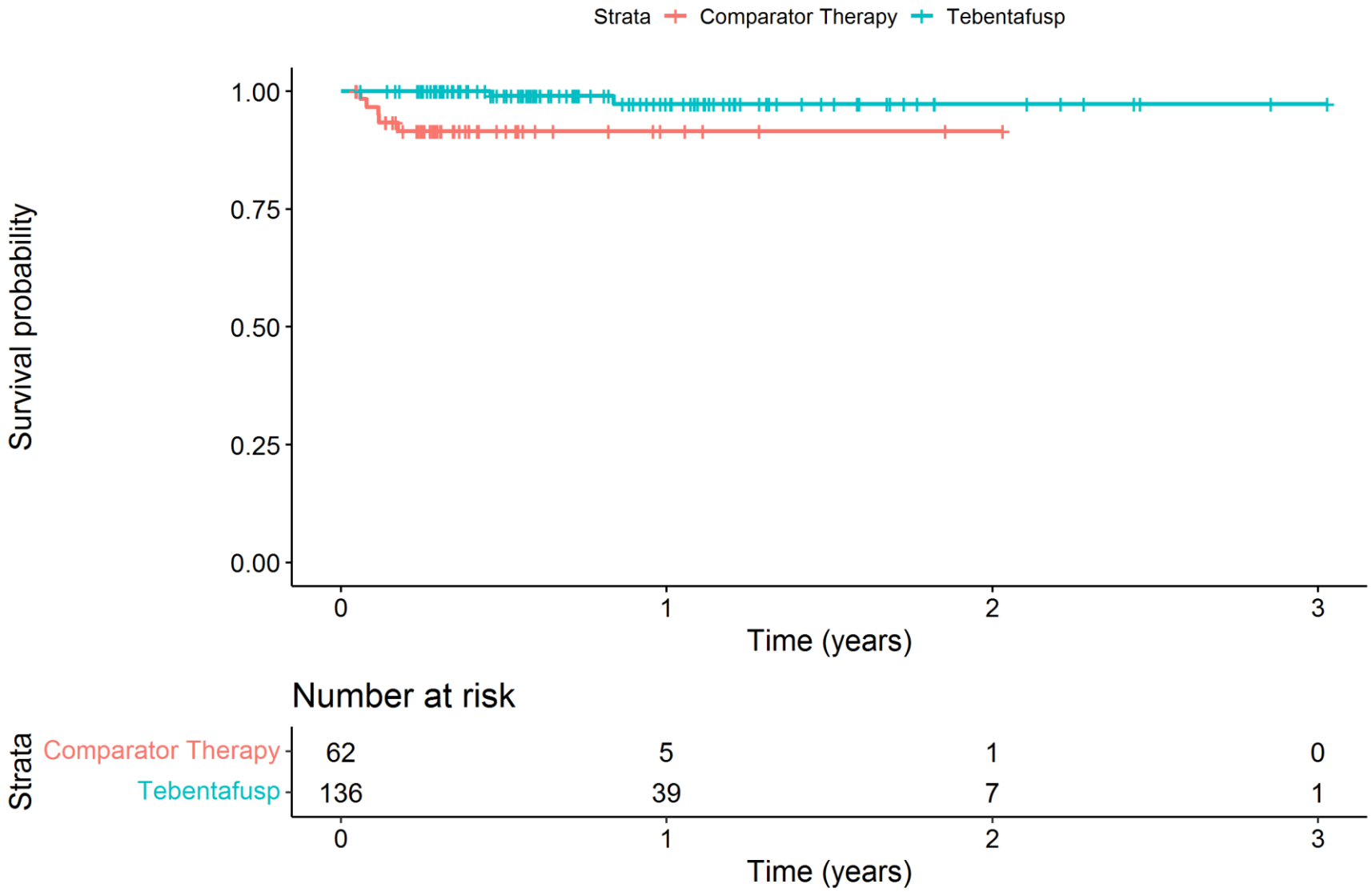
53.36 Hyperthyreose - Vorherige Therapie adjuvant/neoadjuvant



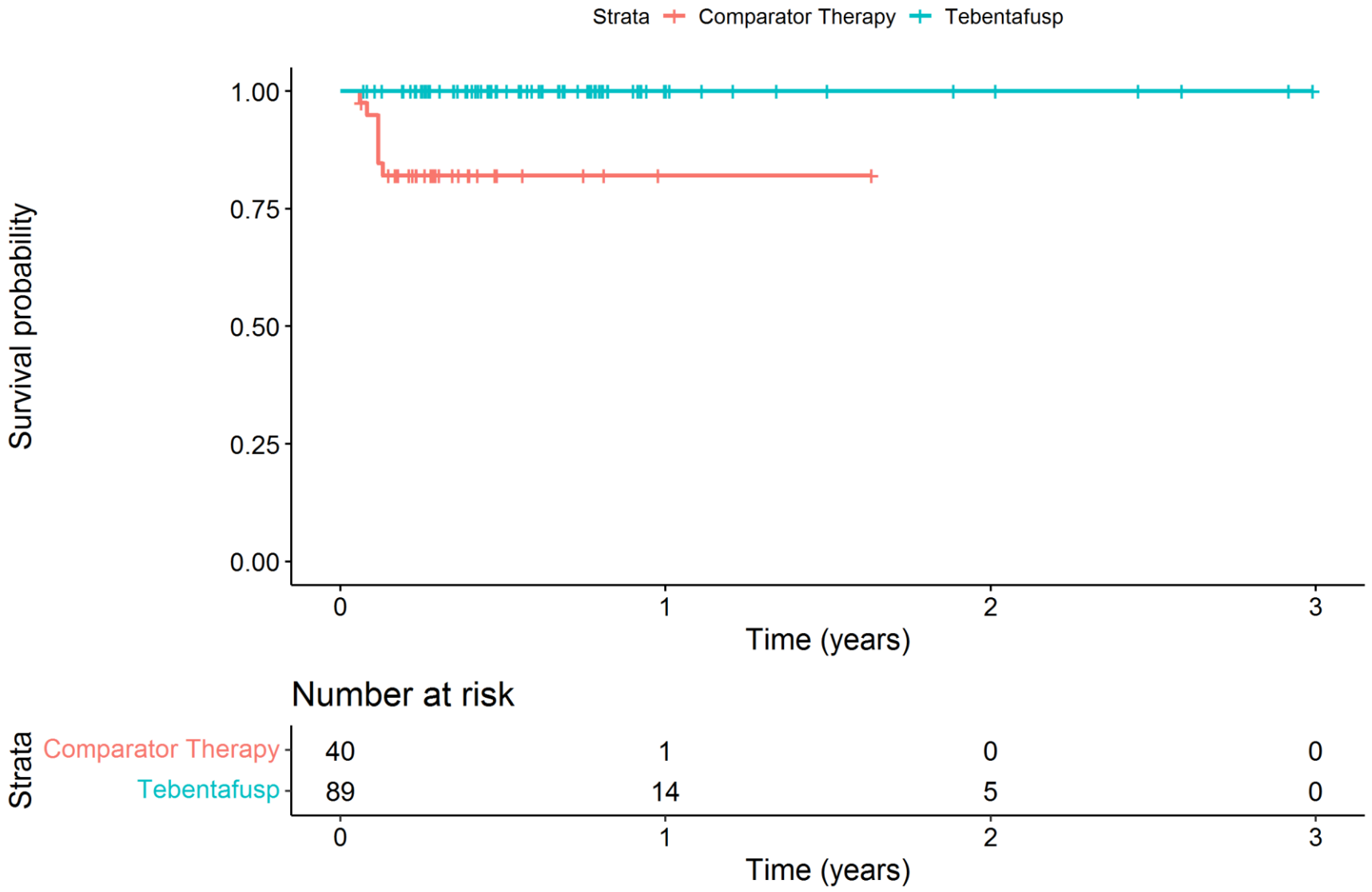
53.37 Hyperthyreose - Keine vorherige Therapie adjuvant/neoadjuvant



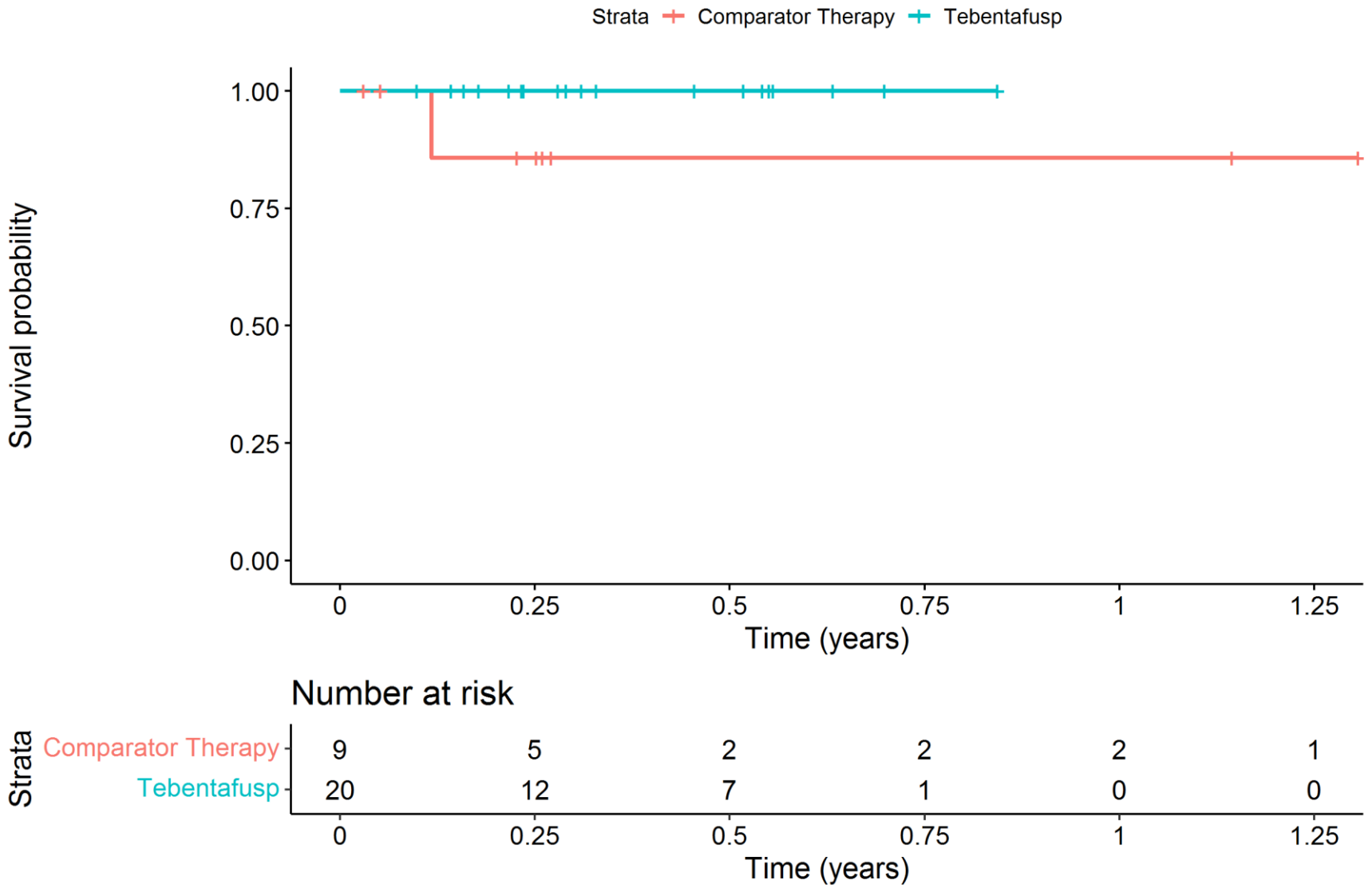
53.38 Hyperthyreose - Läsion ≤ 3cm



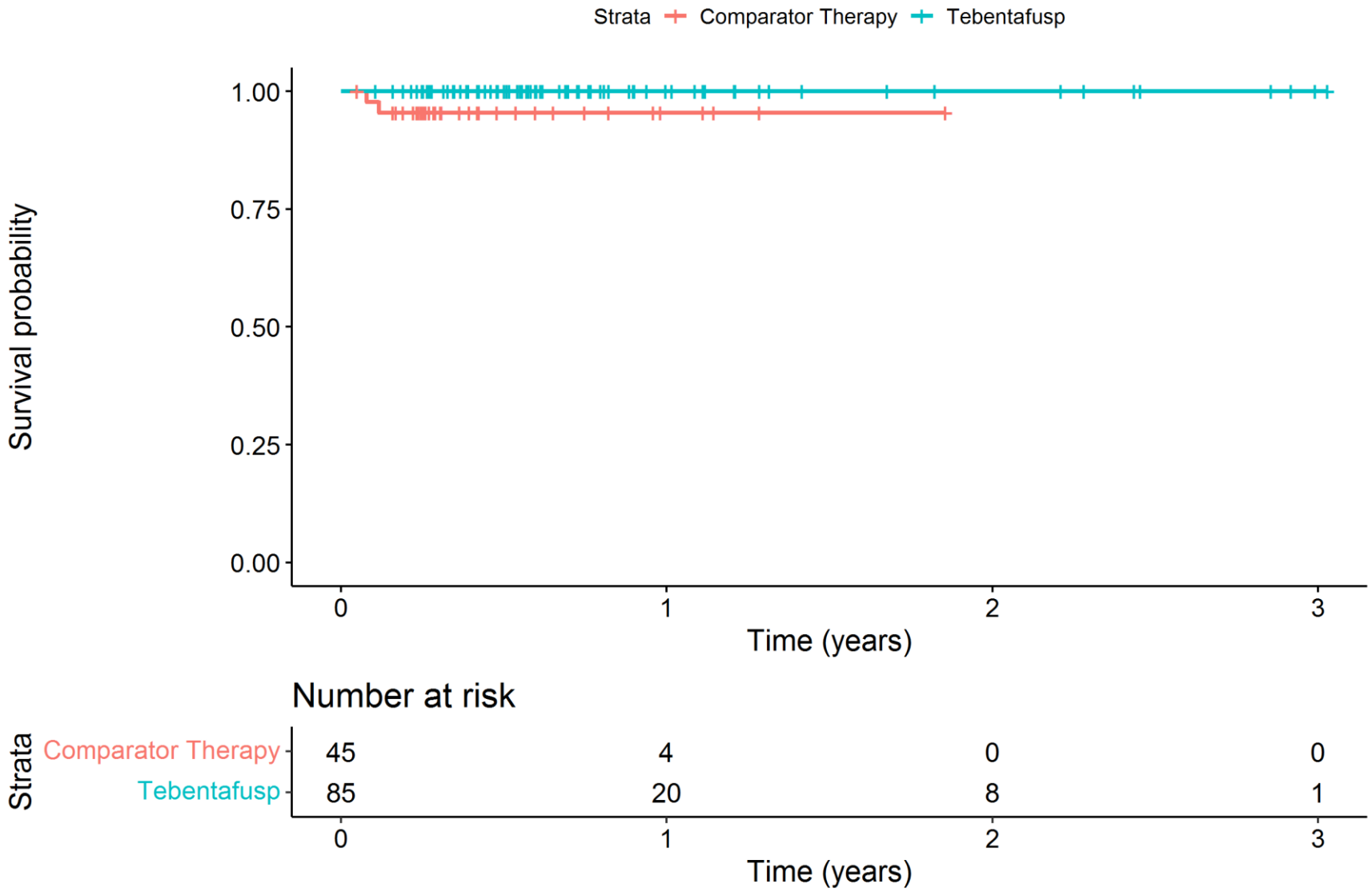
53.39 Hyperthyreose - Läsion 3,1-8,0 cm



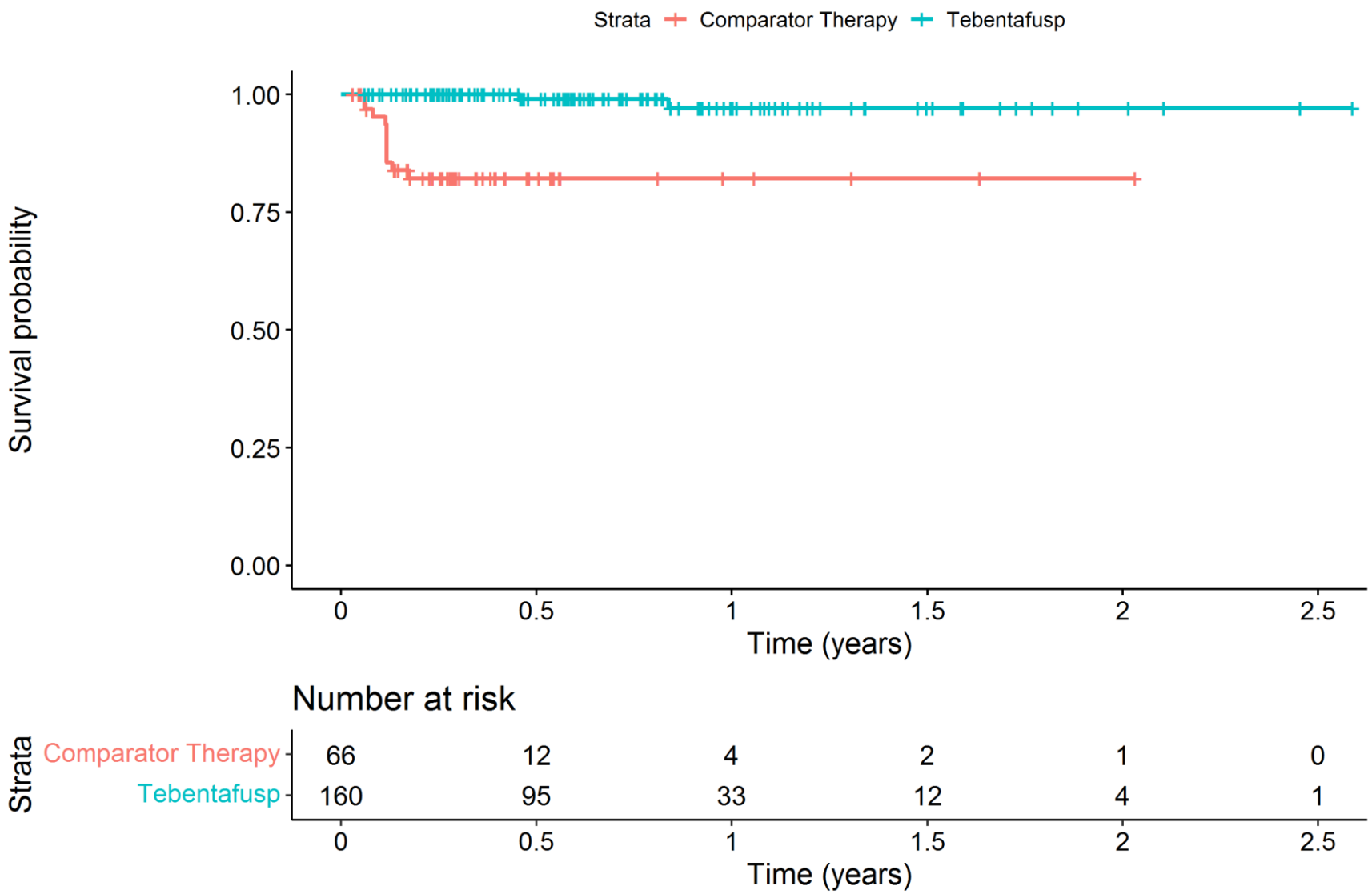
53.40 Hyperthyreose - Läsion ≥8,1 cm



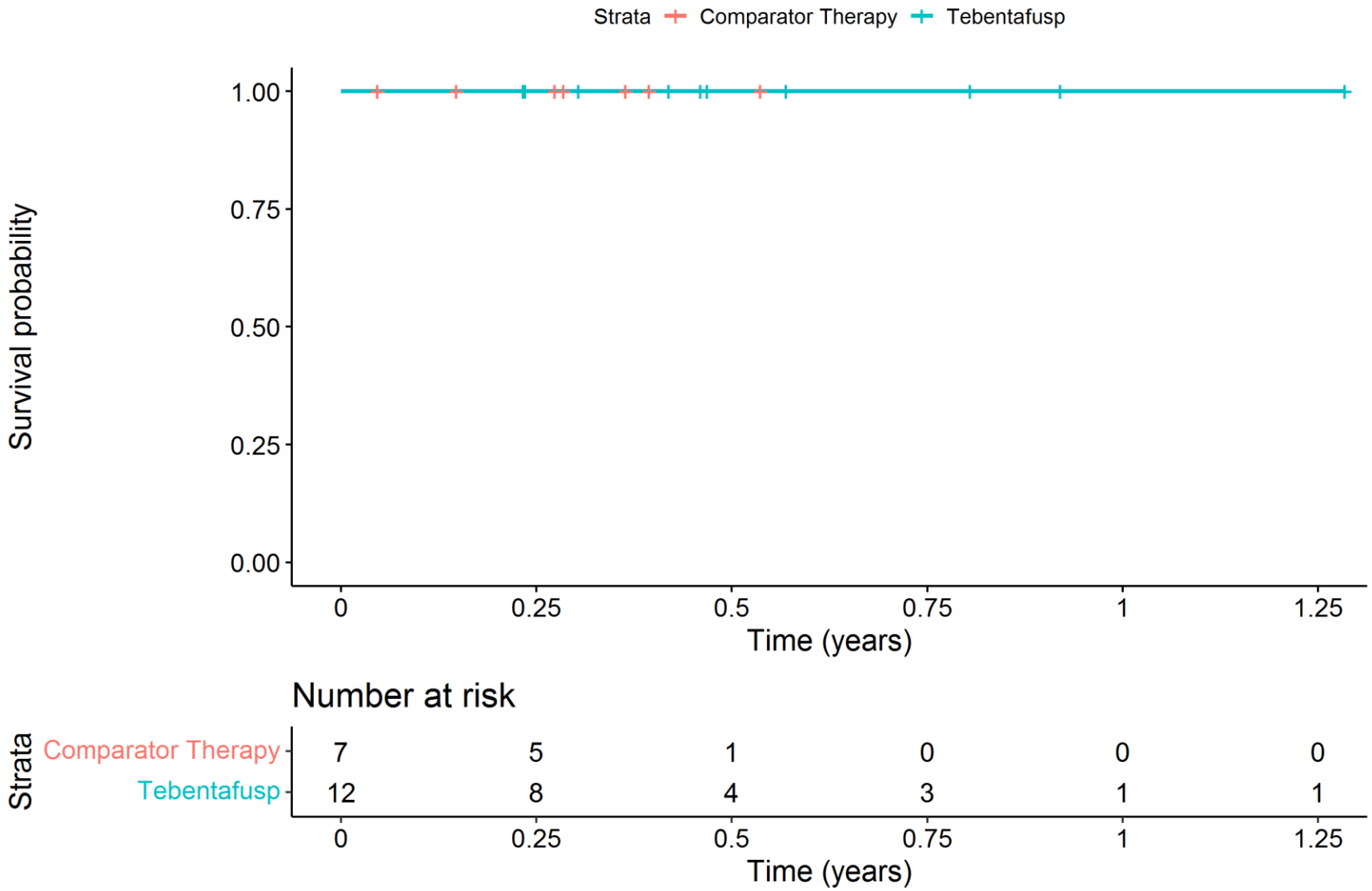
53.41 Hyperthyreose - Nordamerika



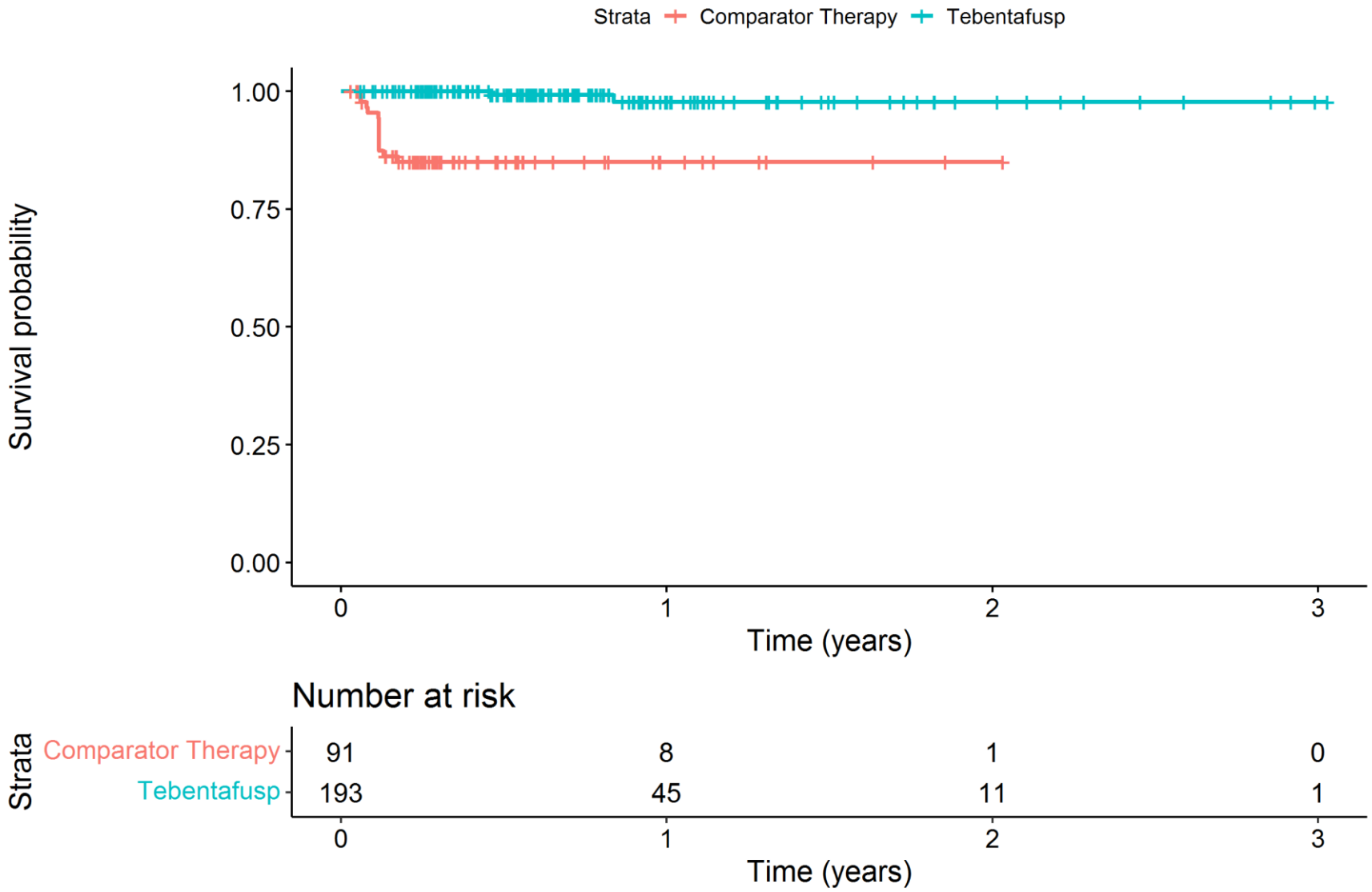
53.42 Hyperthyreose - Nicht-Nordamerika



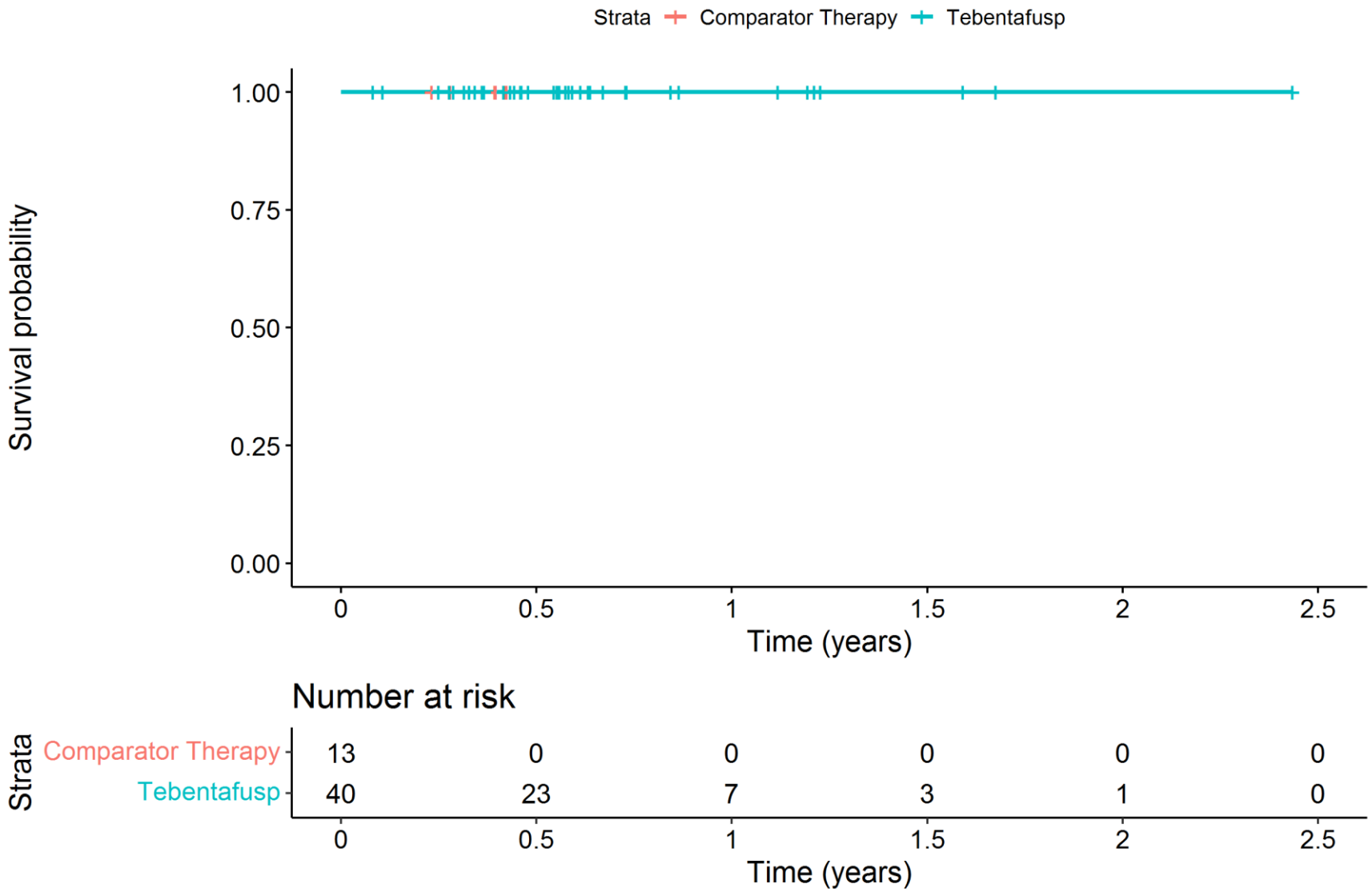
53.43 Hyperthyreose - Dacarbazin



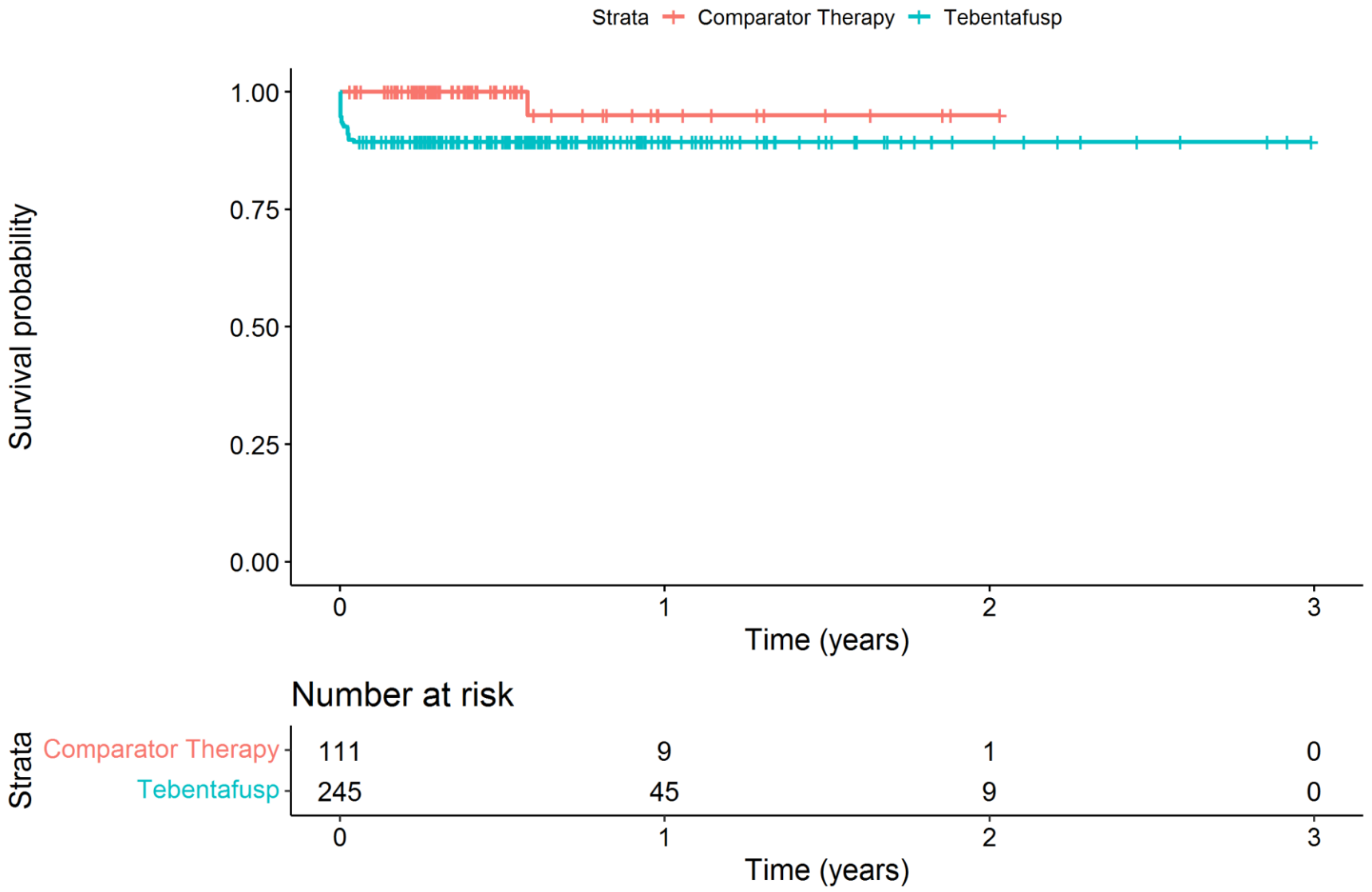
53.44 Hyperthyreose - Pembrolizumab



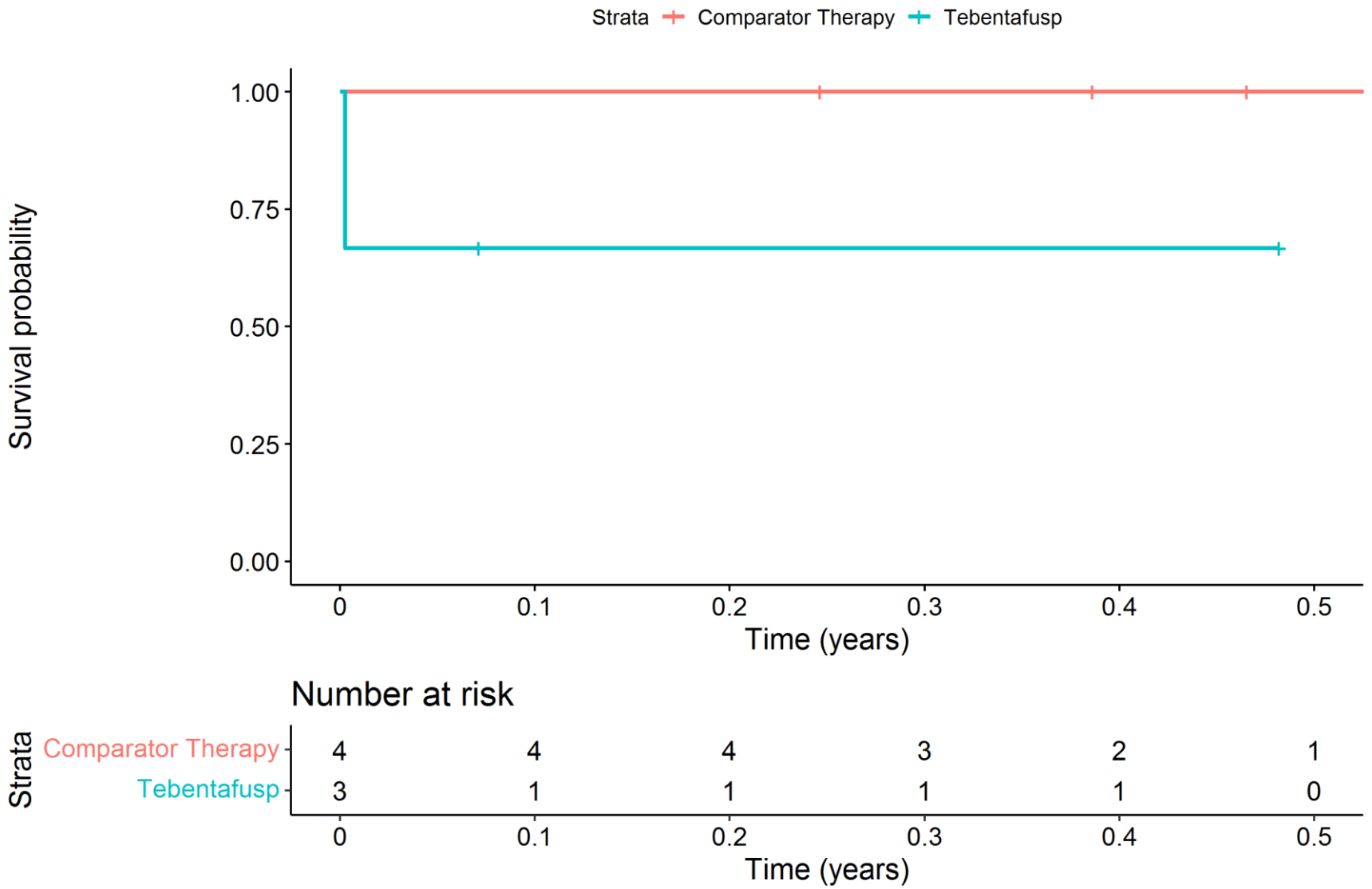
53.45 Hyperthyreose - Ipilimumab



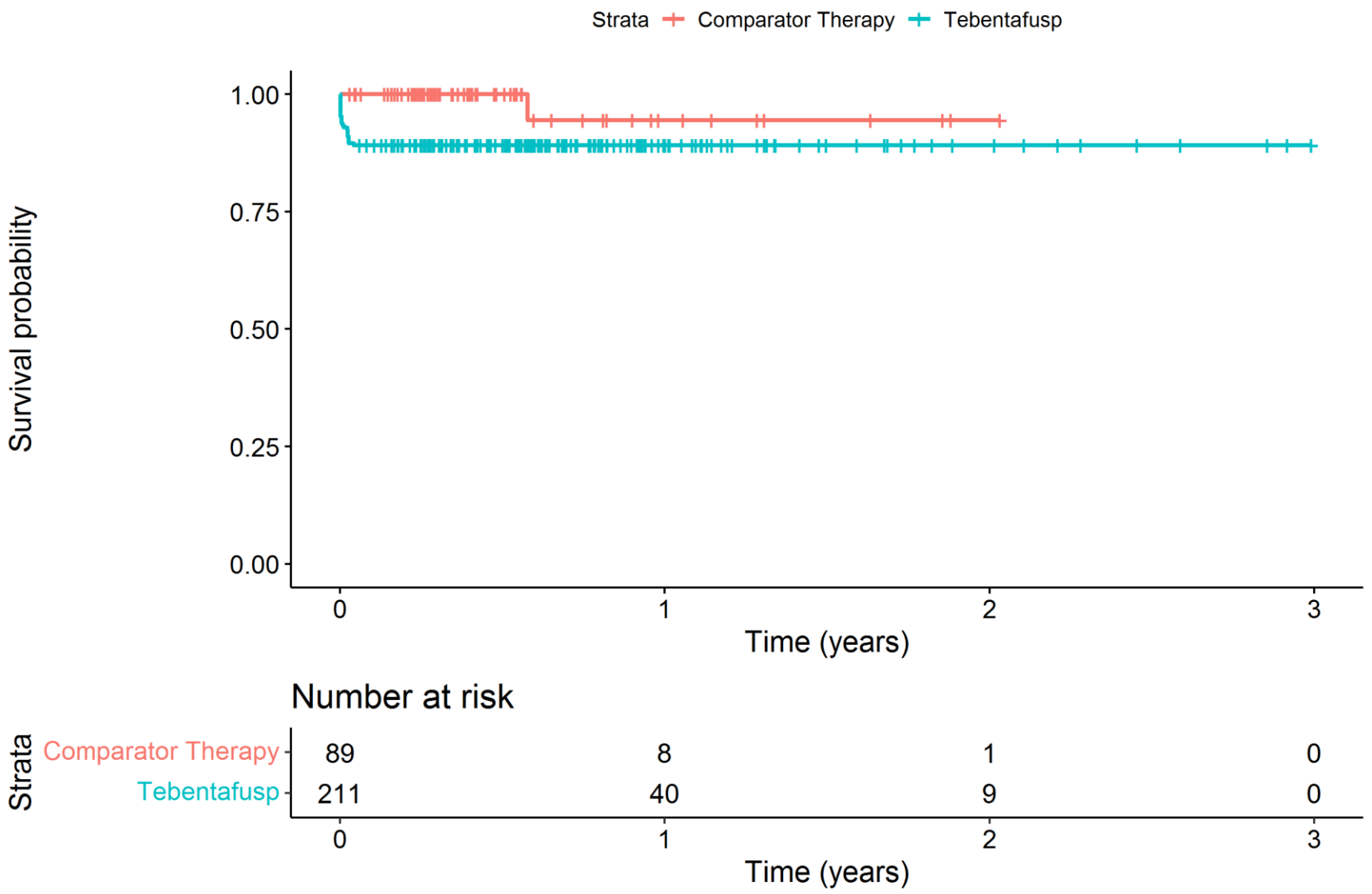
53.46 Periphere Ödeme- Gesamt



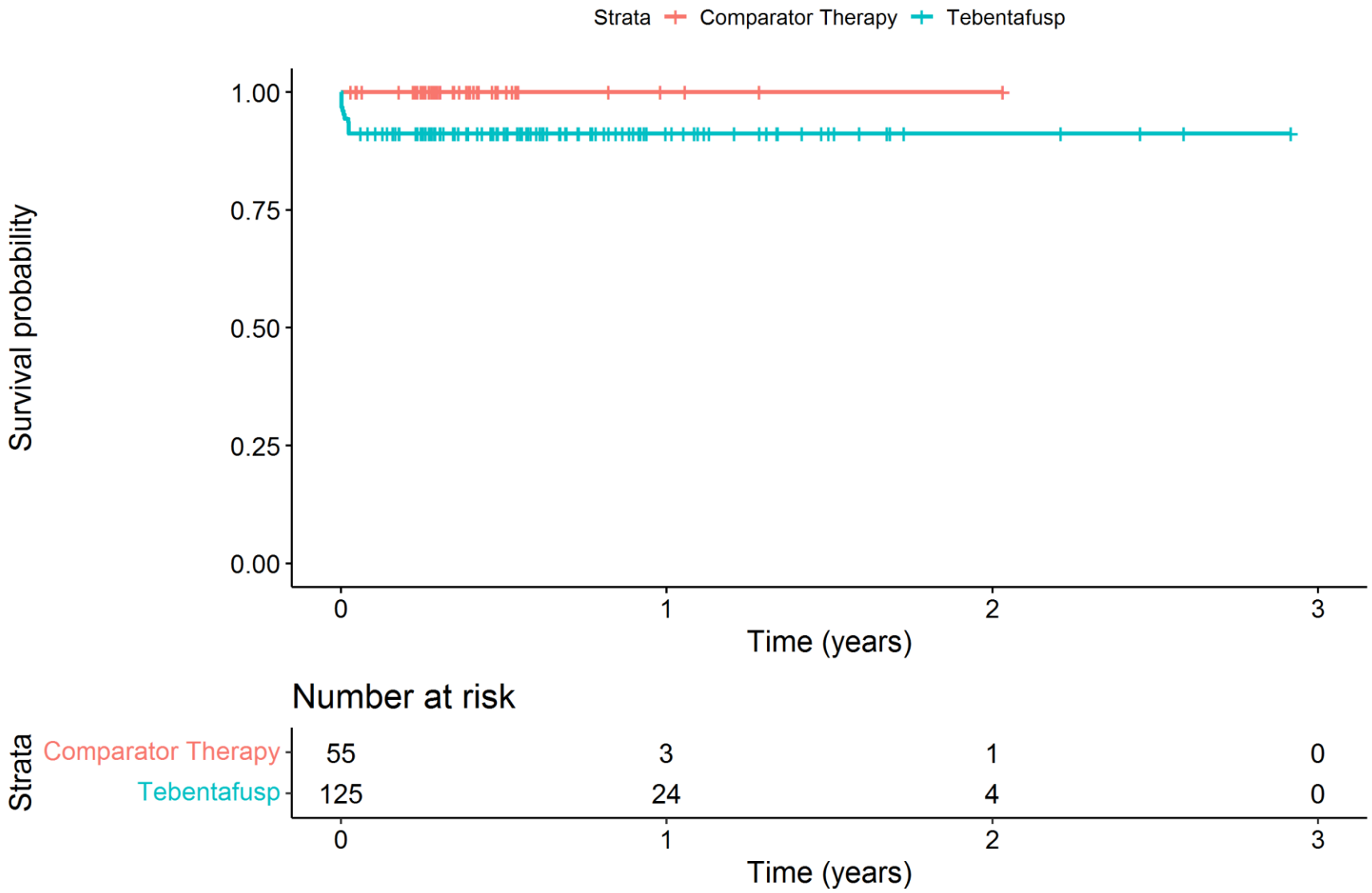
53.47 Periphere Ödeme- Hispanisch



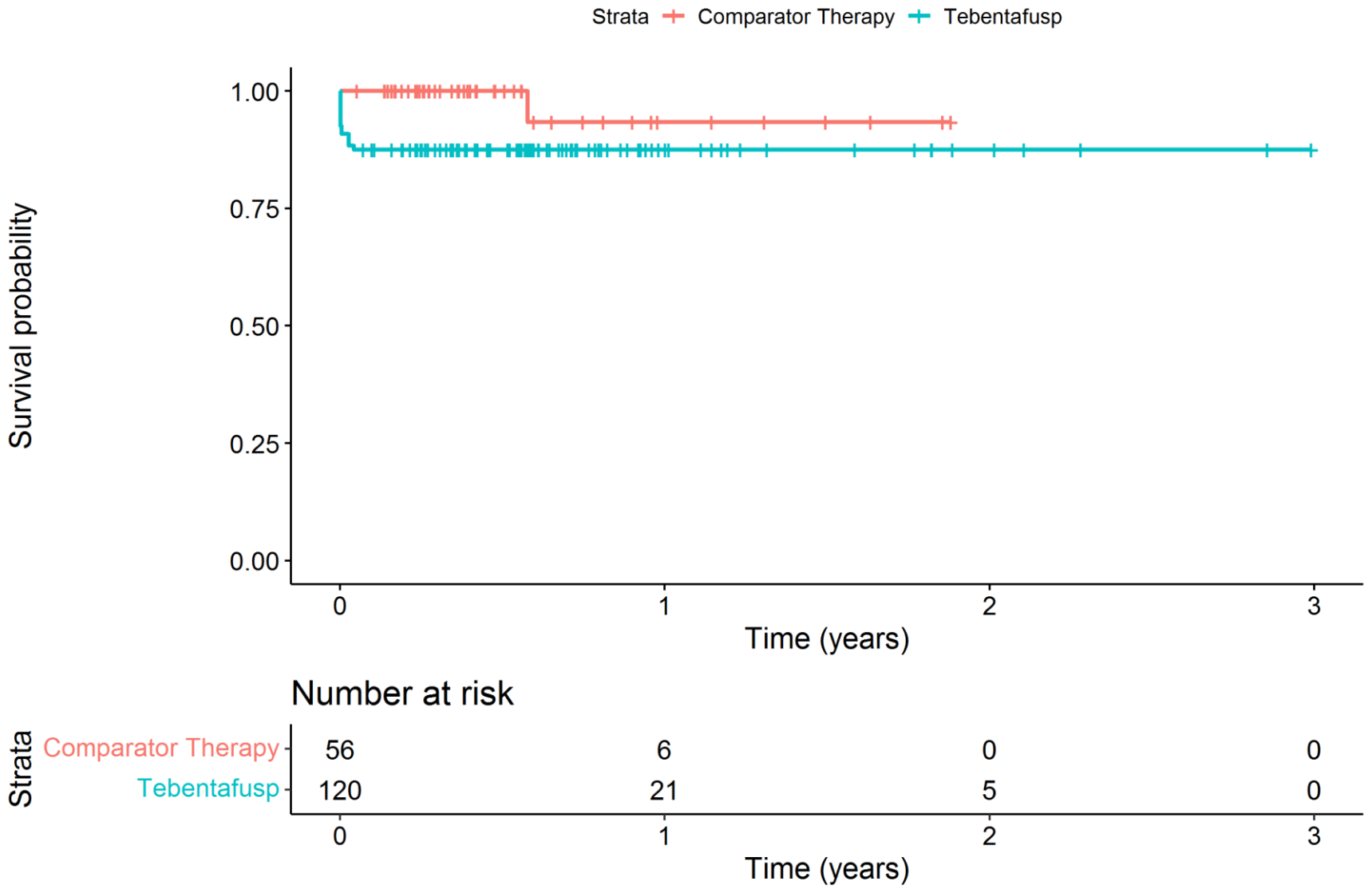
53.48 Periphere Ödeme- Nicht-hispanisch



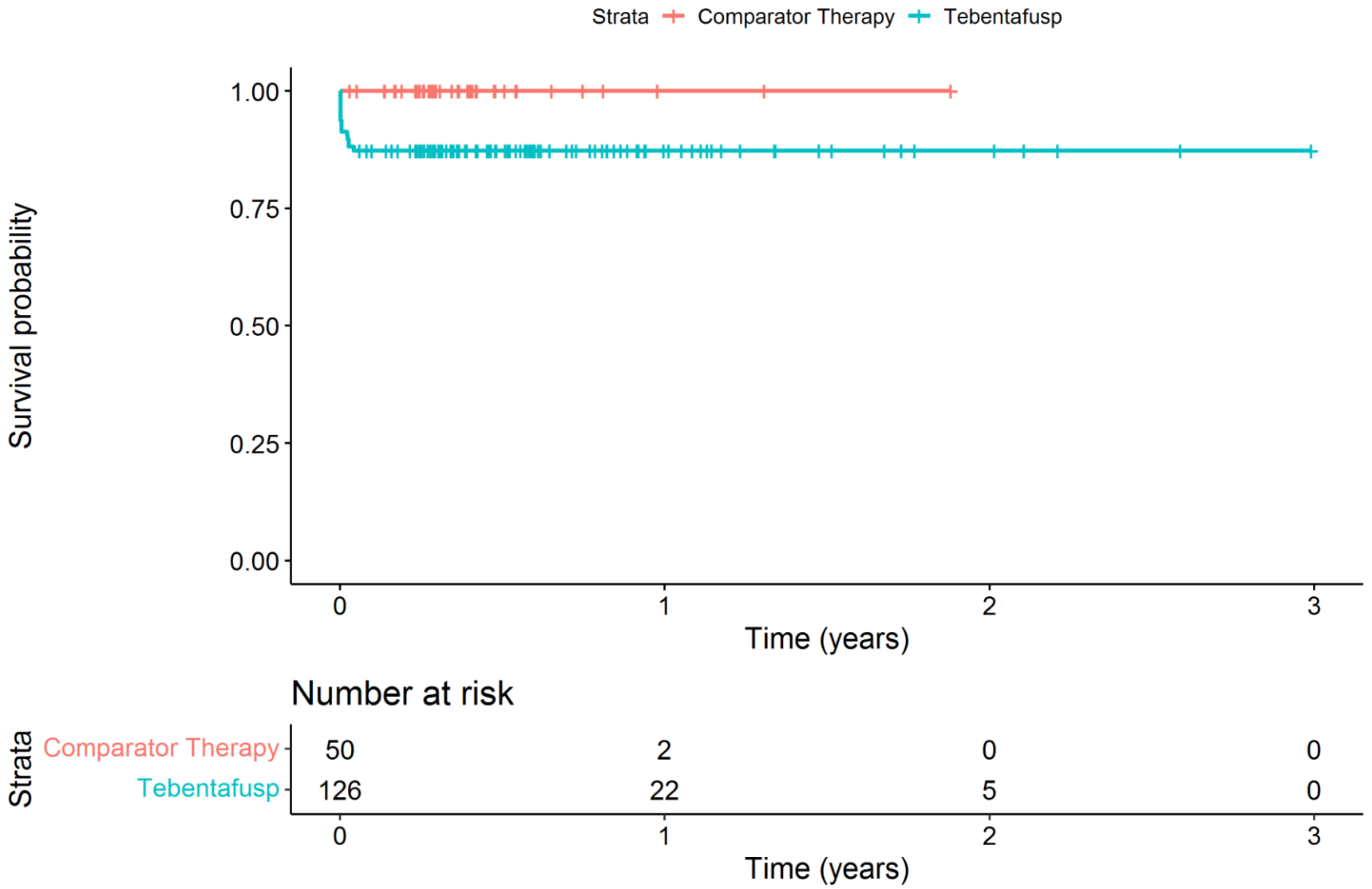
53.49 Periphere Ödeme- Männlich



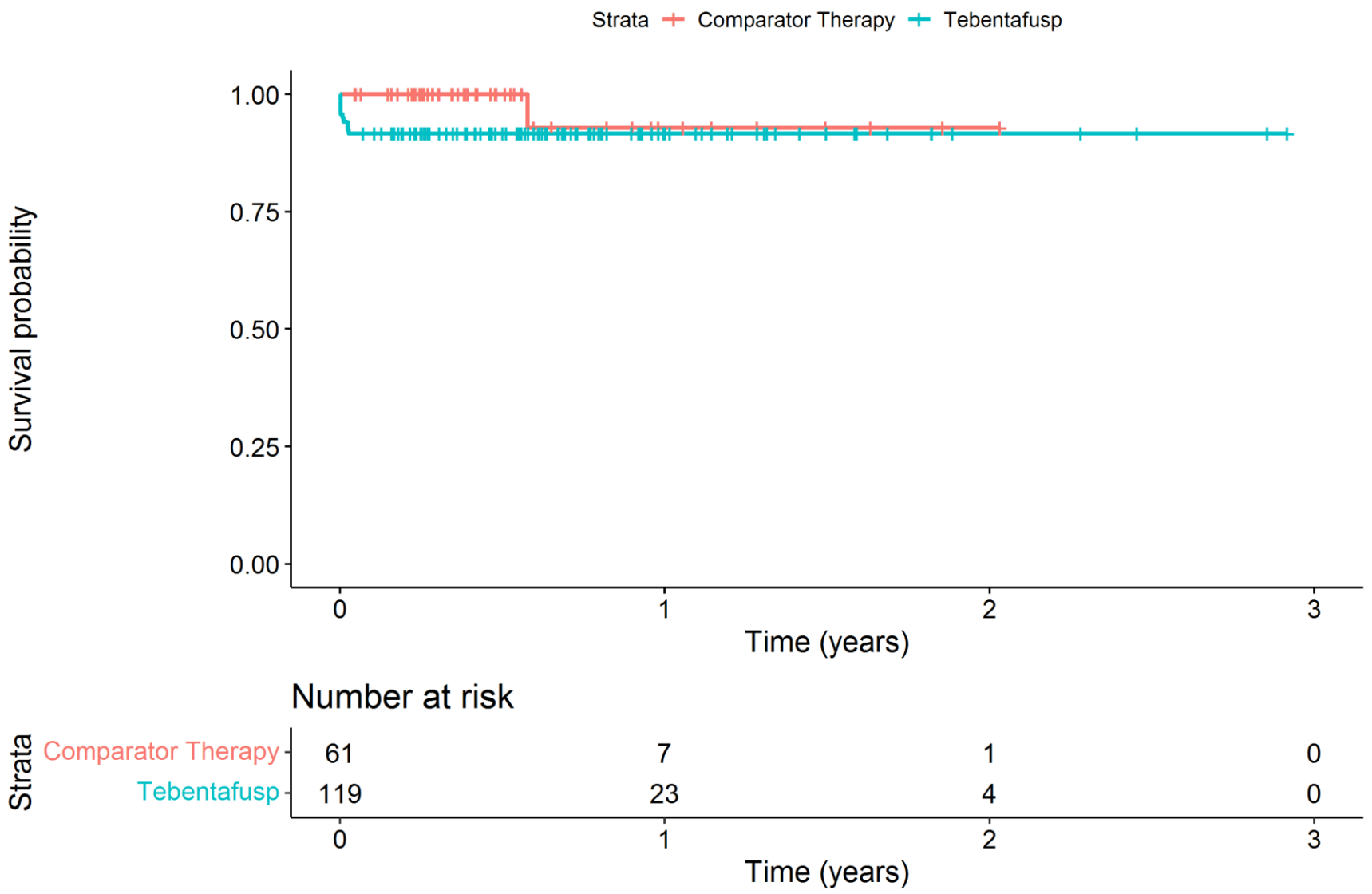
53.50 Periphere Ödeme- Weiblich



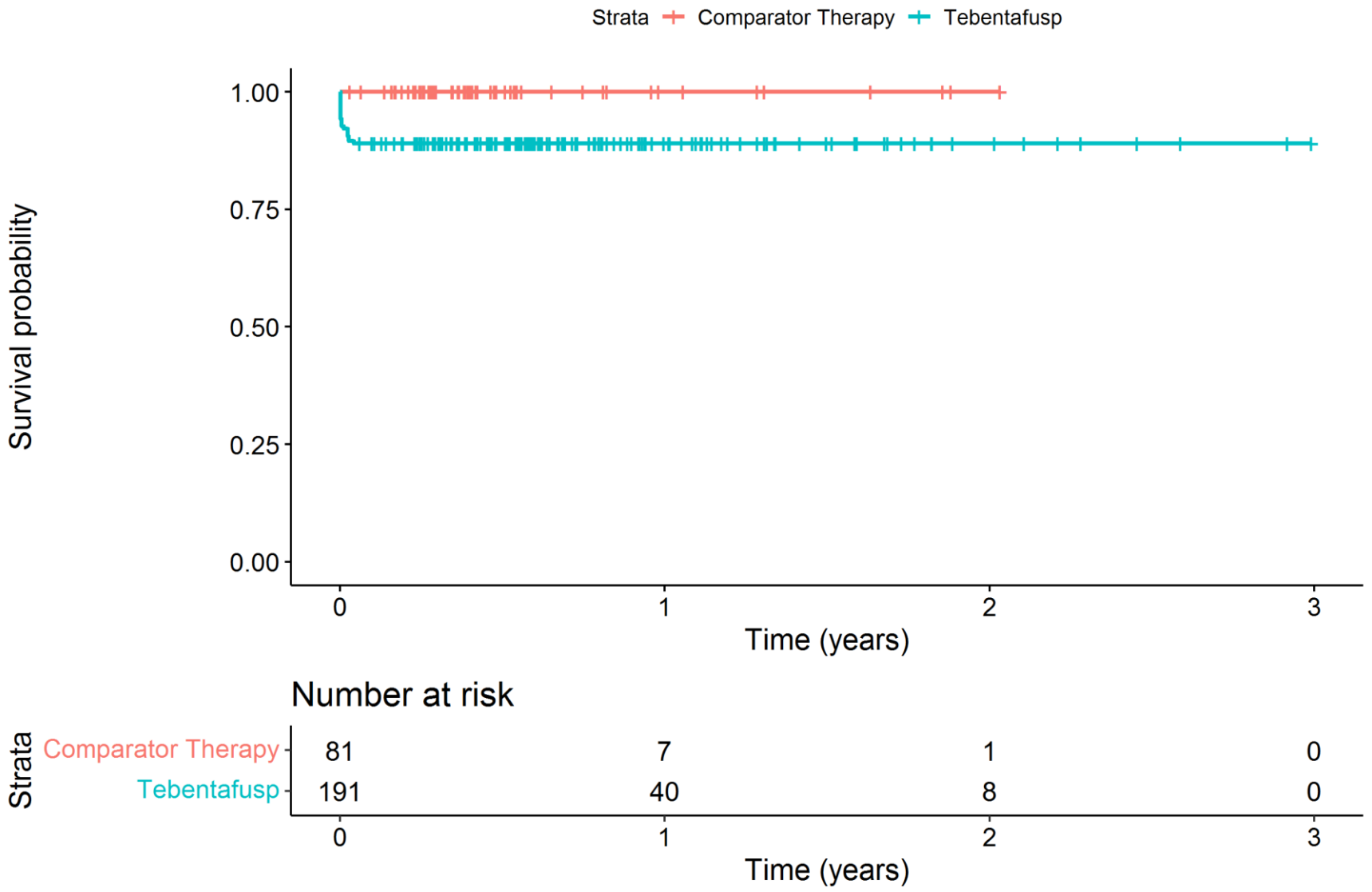
53.51 Periphere Ödeme- <65



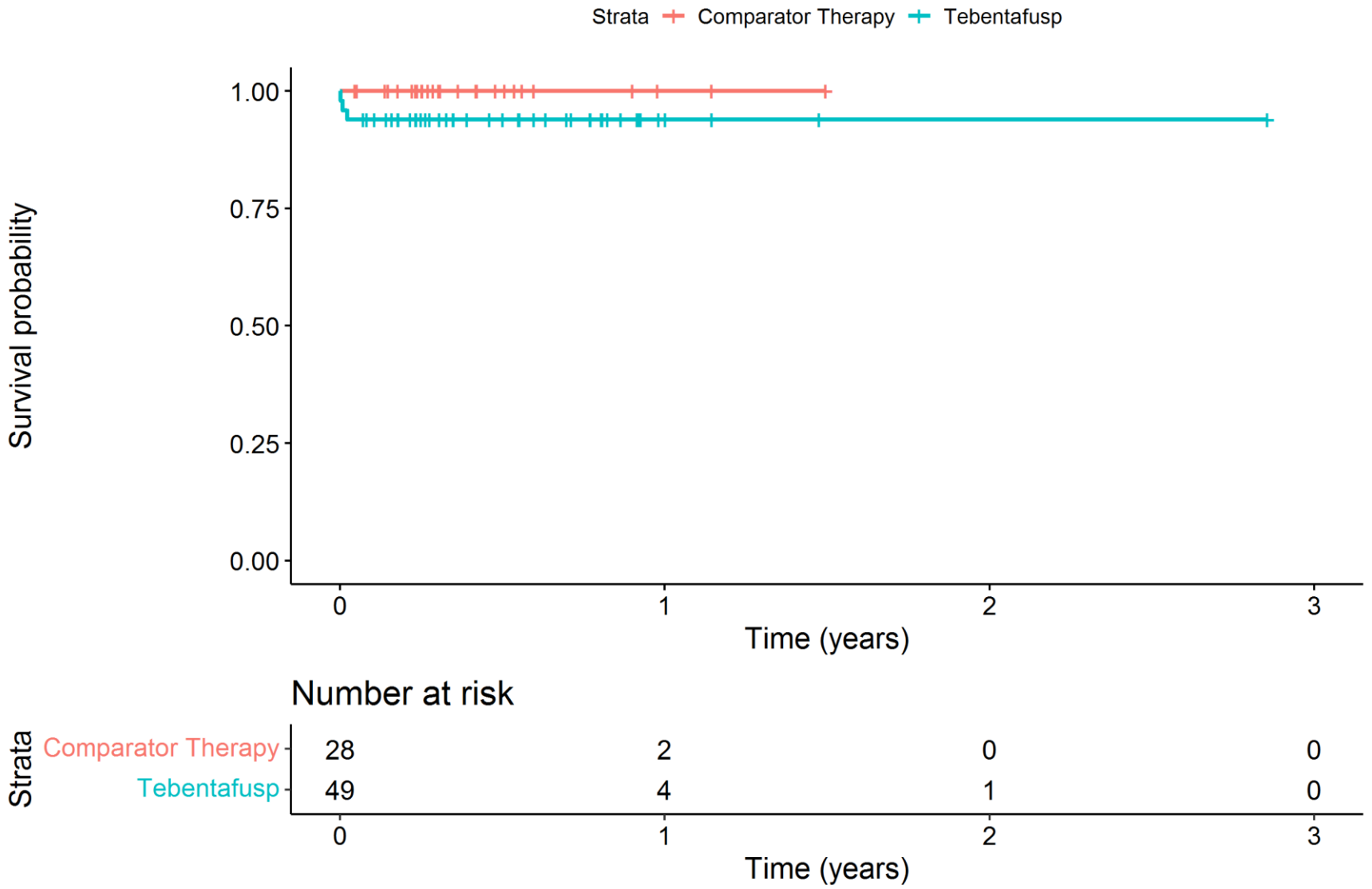
53.52 Periphere Ödeme- ≥65



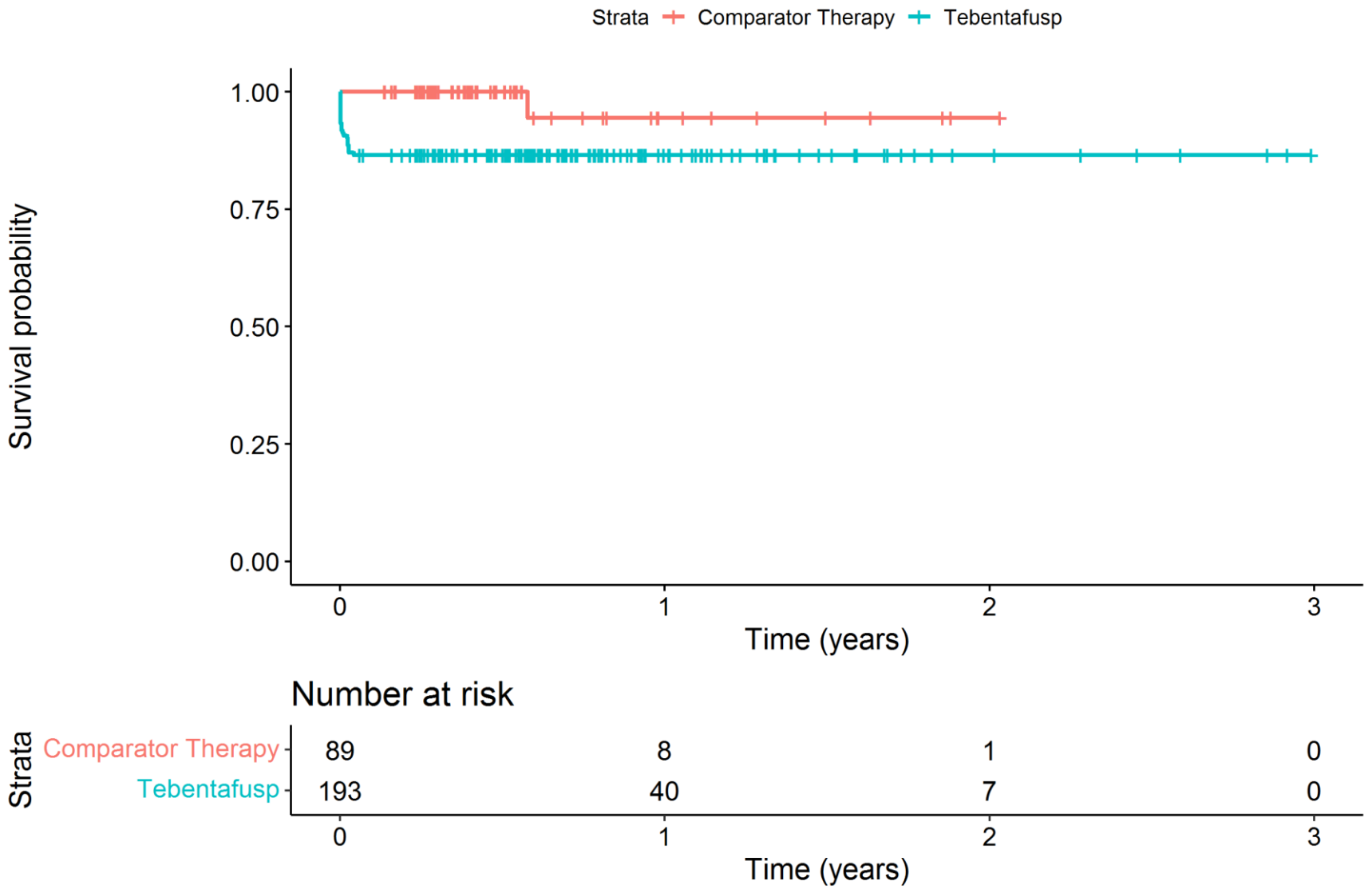
53.53 Periphere Ödeme- ECOG 0



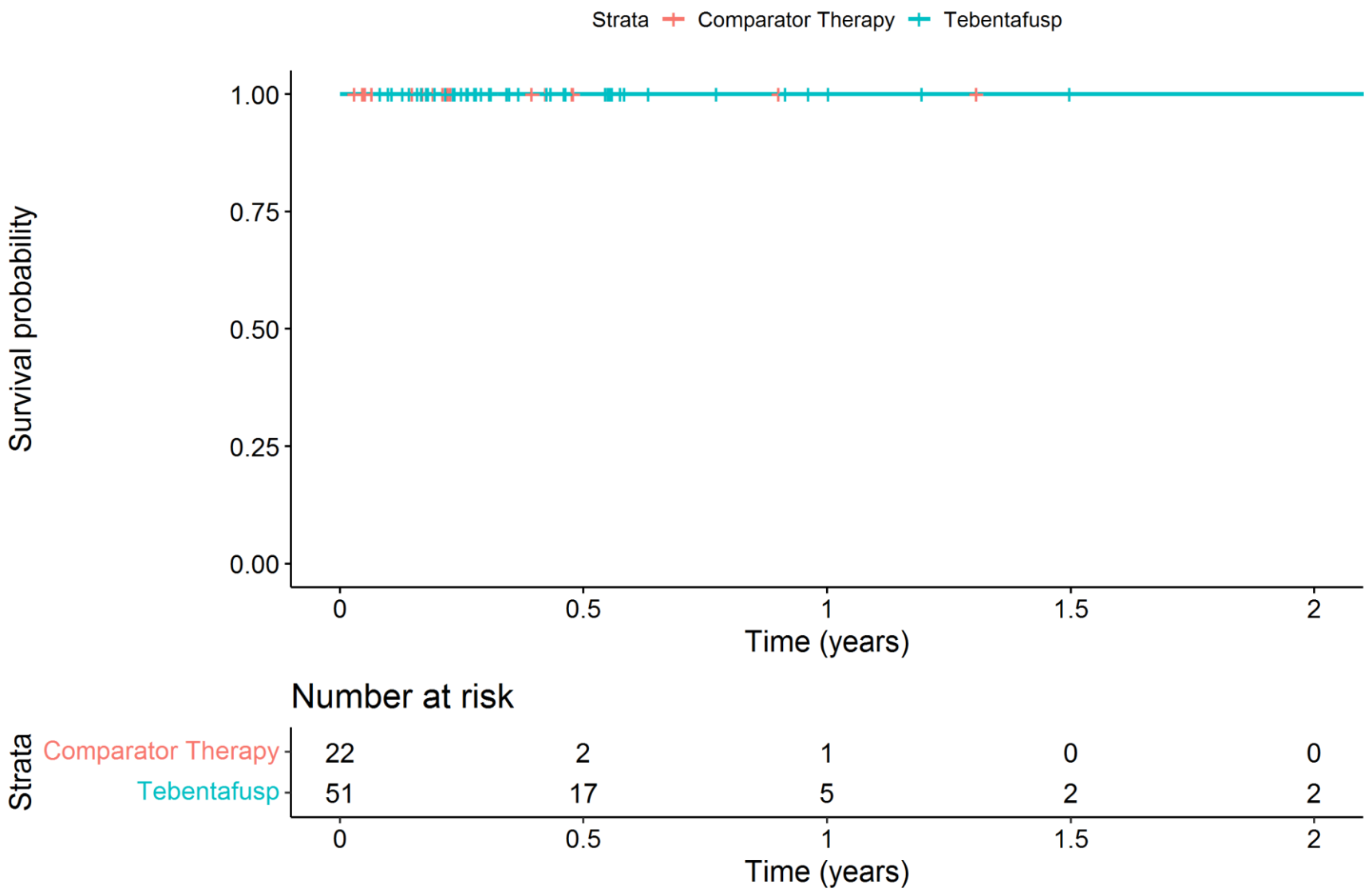
53.54 Periphere Ödeme- ECOG 1



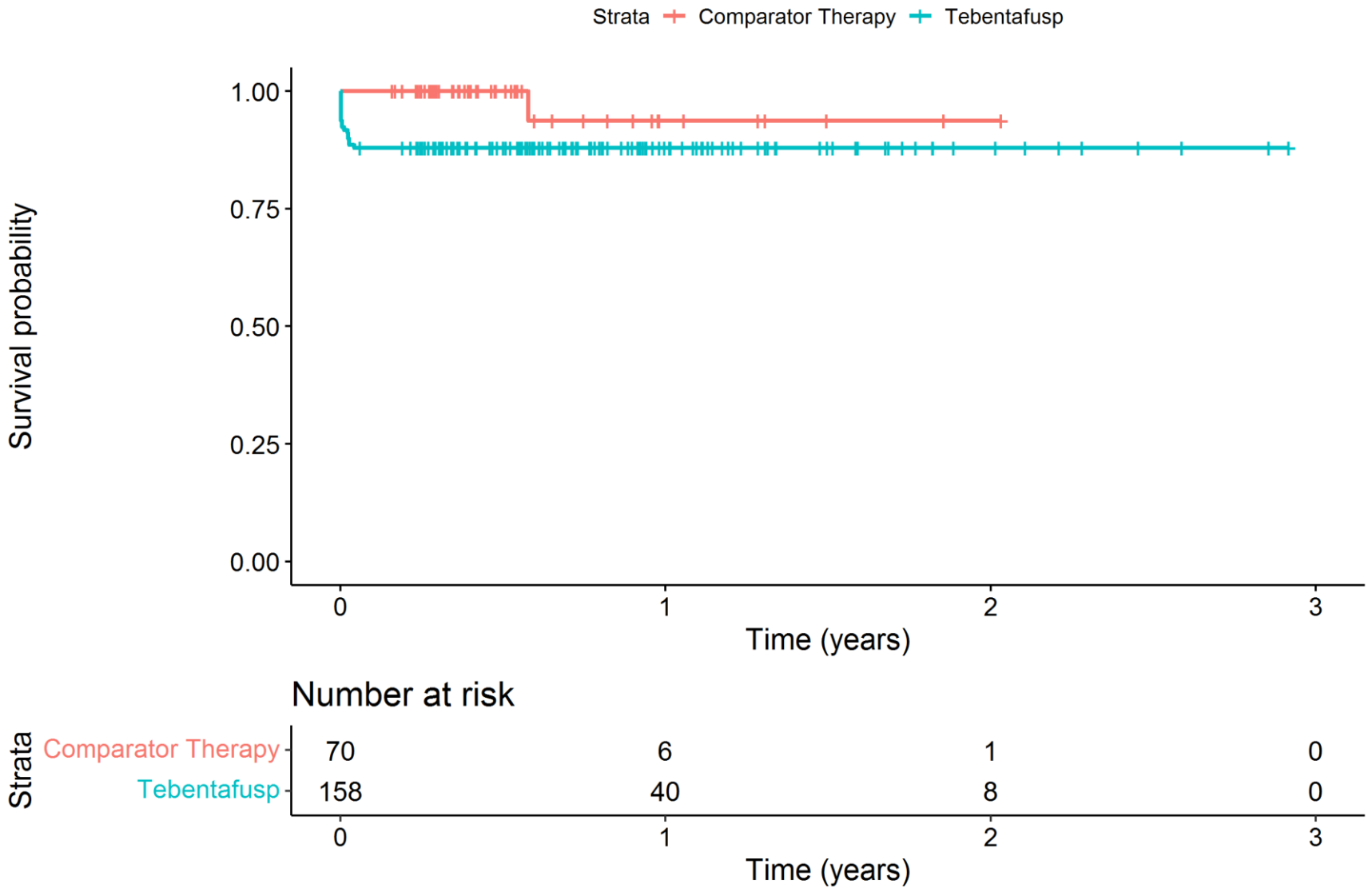
53.55 Periphere Ödeme- ALP ≤ ULN



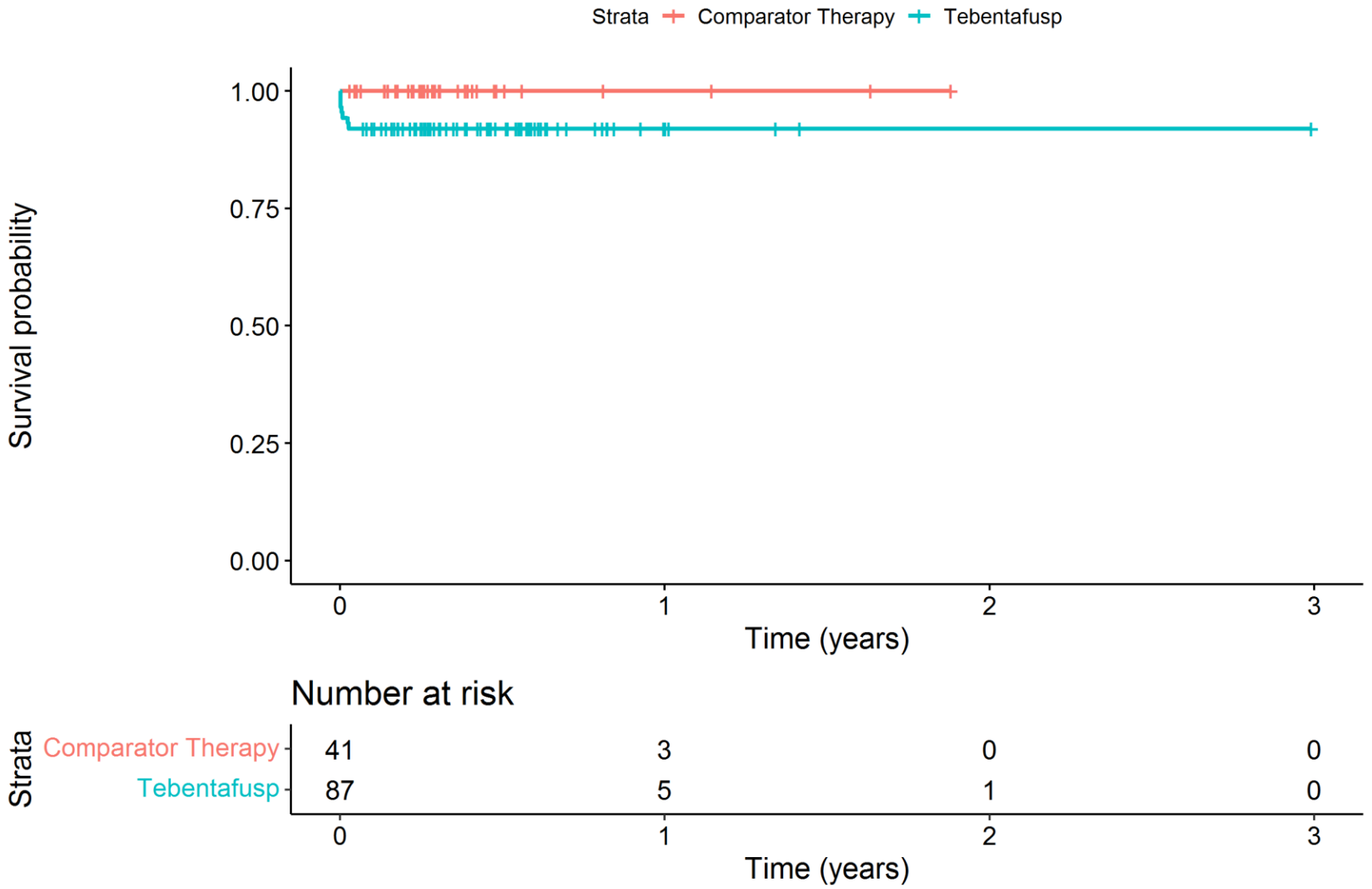
53.56 Periphere Ödeme- ALP > ULN



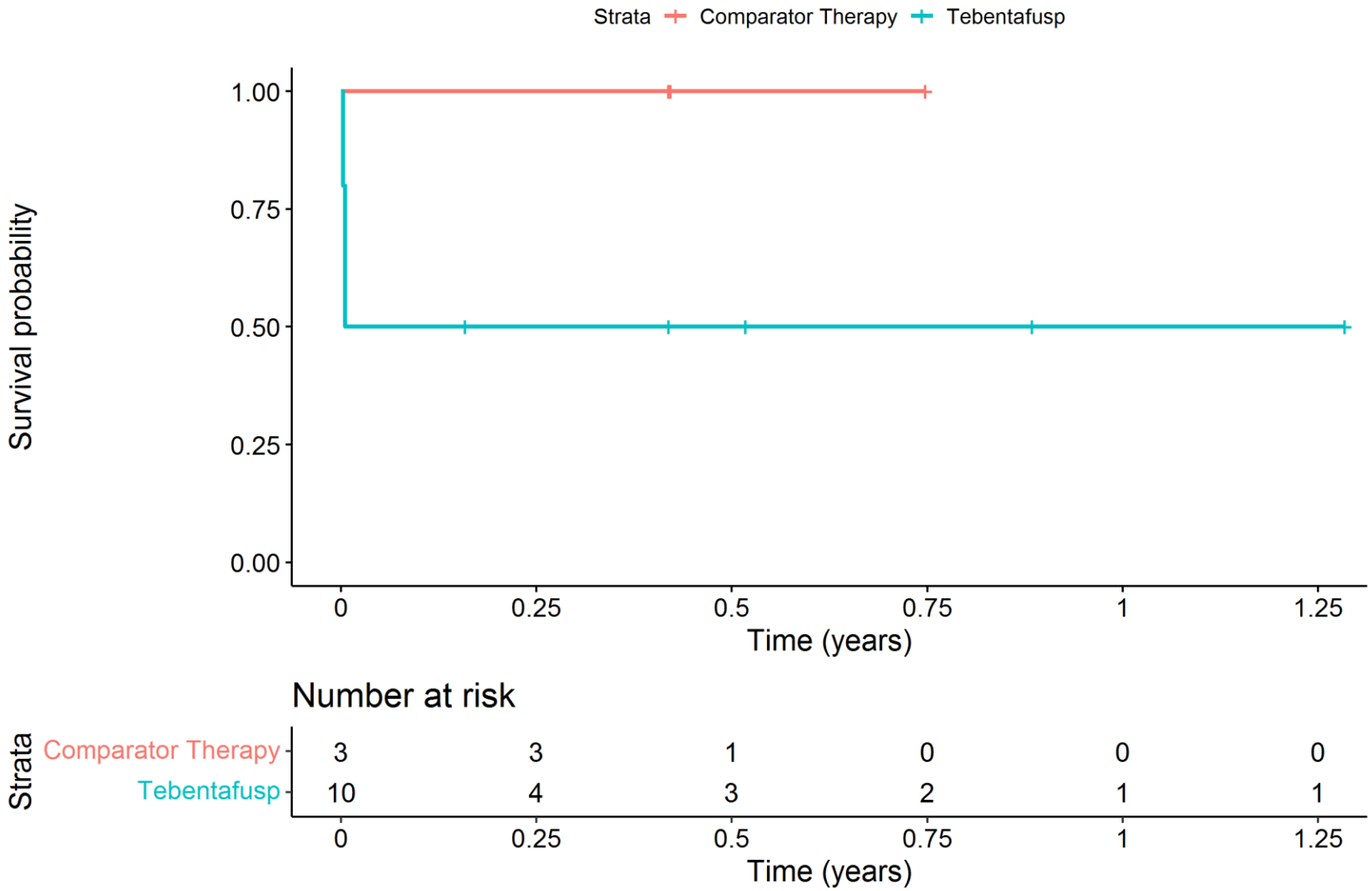
53.57 Periphere Ödeme- LDH =< ULN



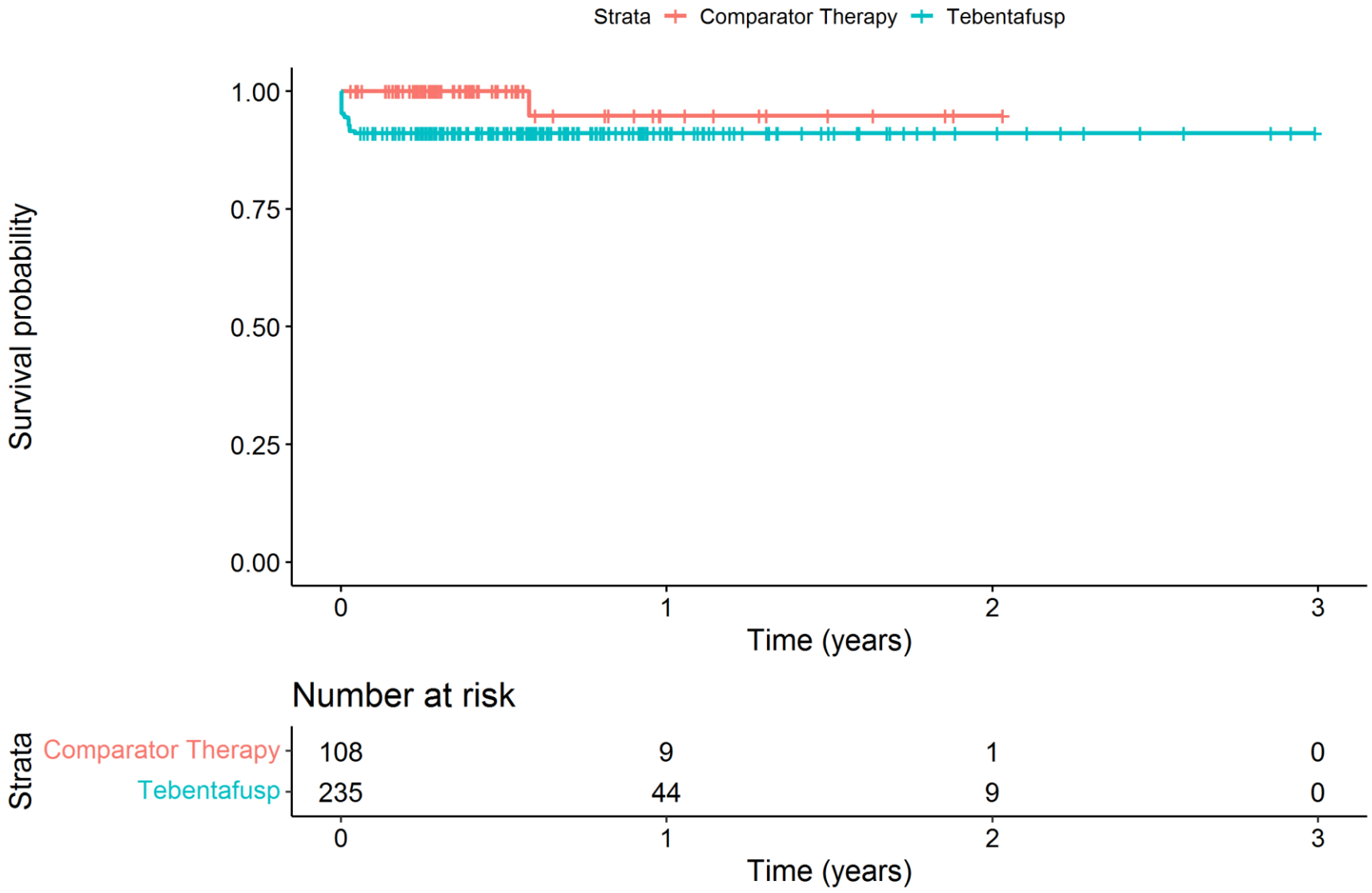
53.58 Periphere Ödeme- LDH > ULN



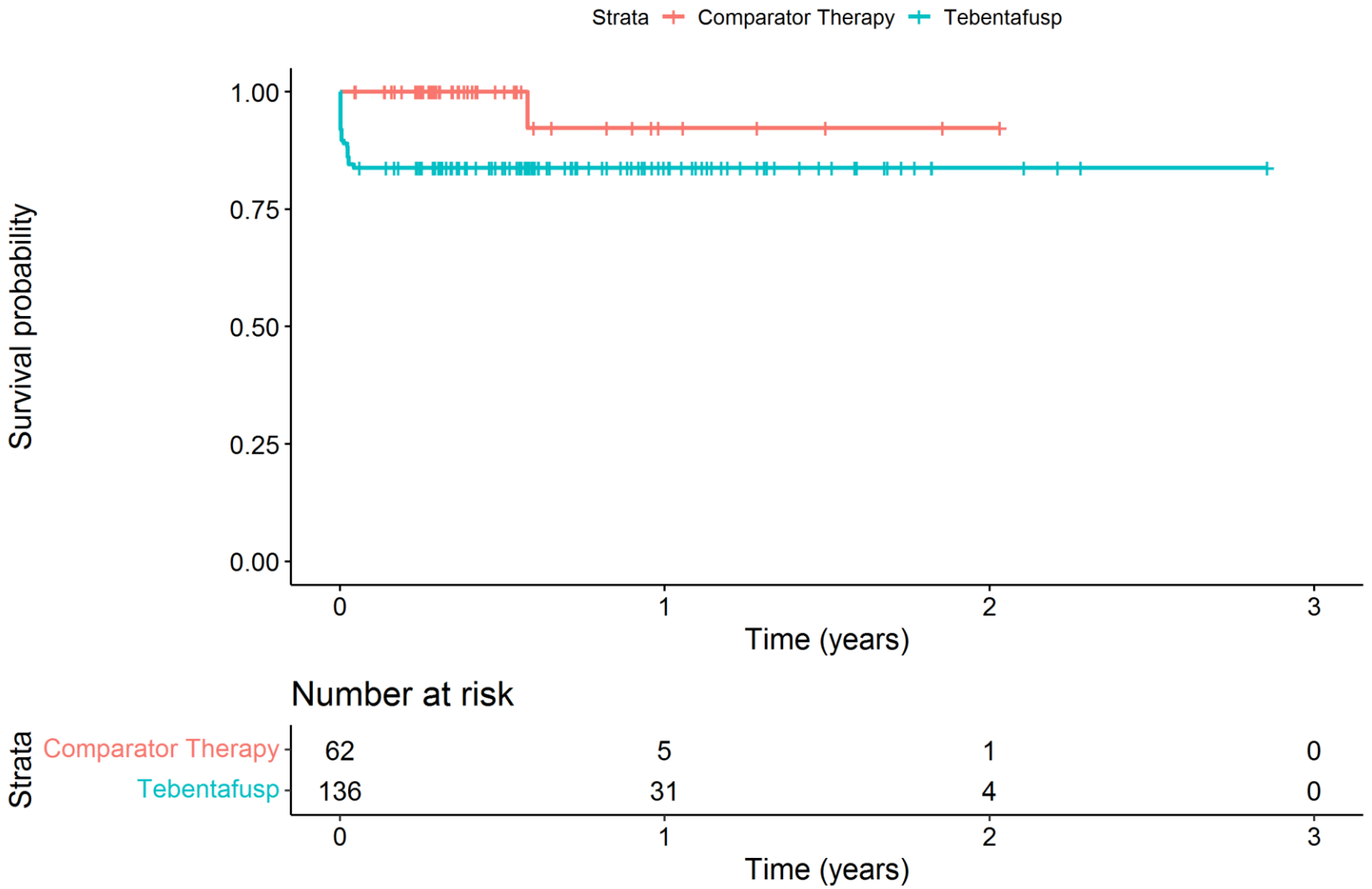
53.59 Periphere Ödeme- Vorherige Therapie adjuvant/neoadjuvant



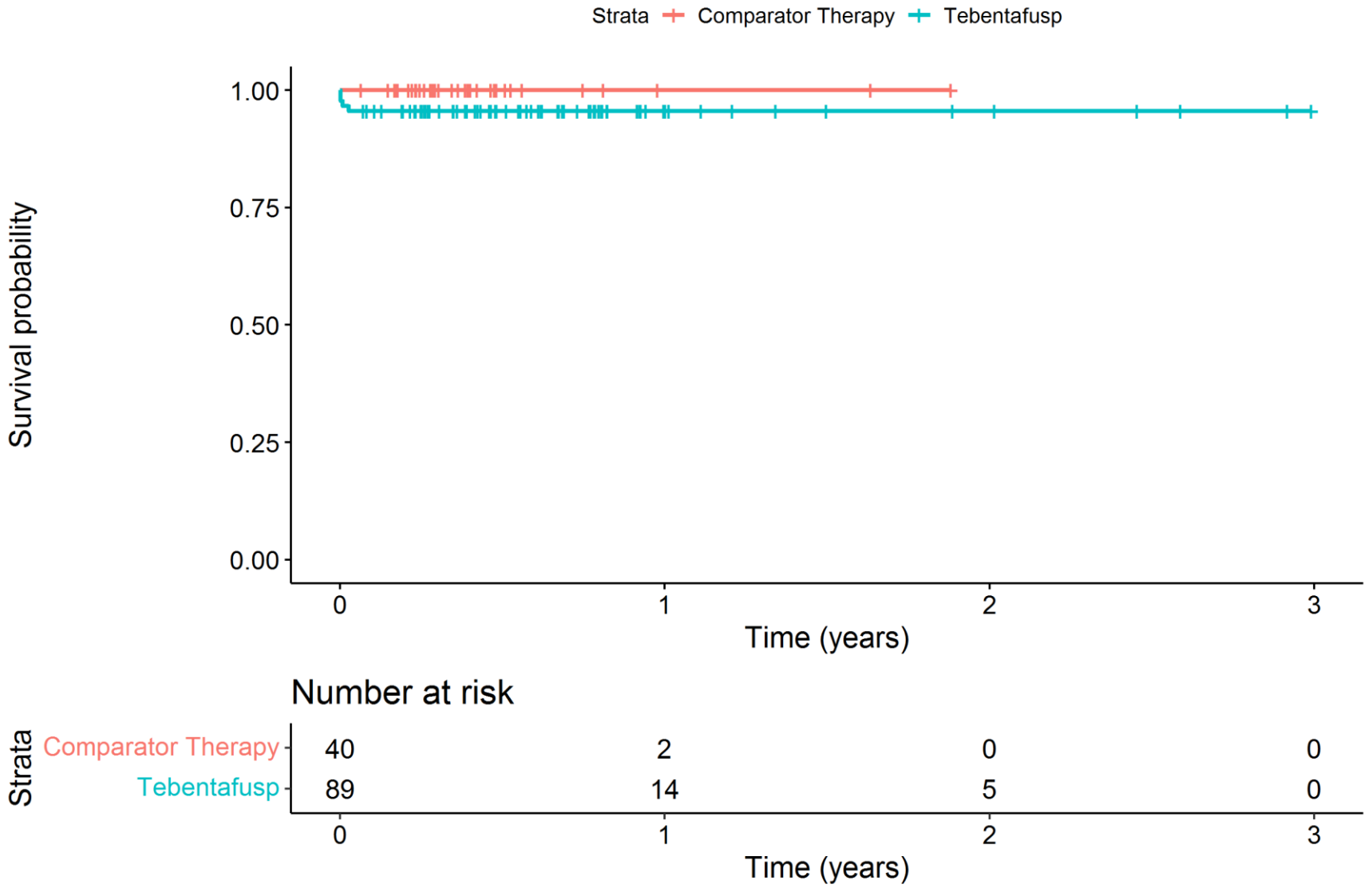
53.60 Periphere Ödeme- Keine vorherige Therapie adjuvant/neoadjuvant



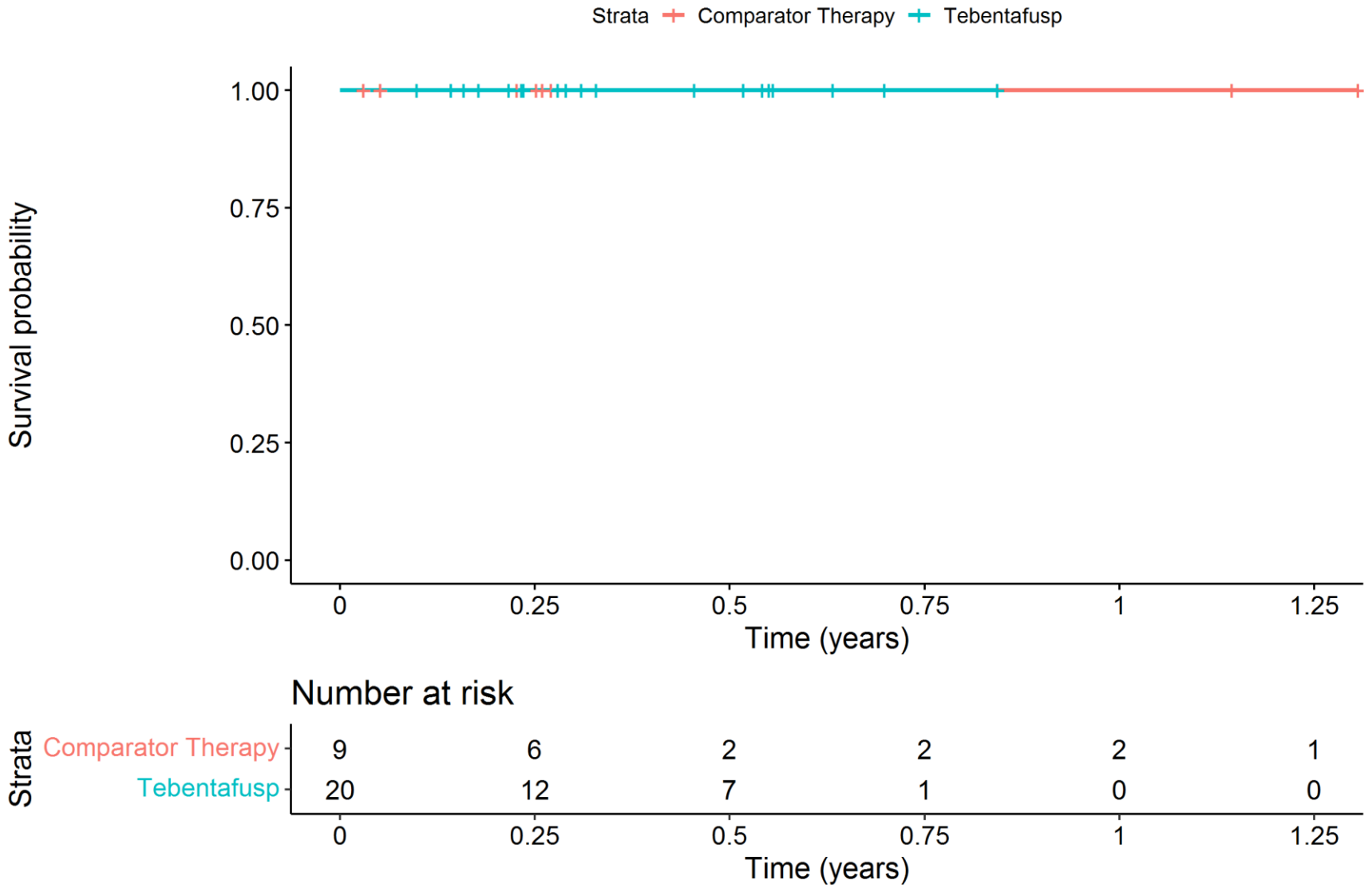
Periphere Ödeme- Läsion ≤ 3cm



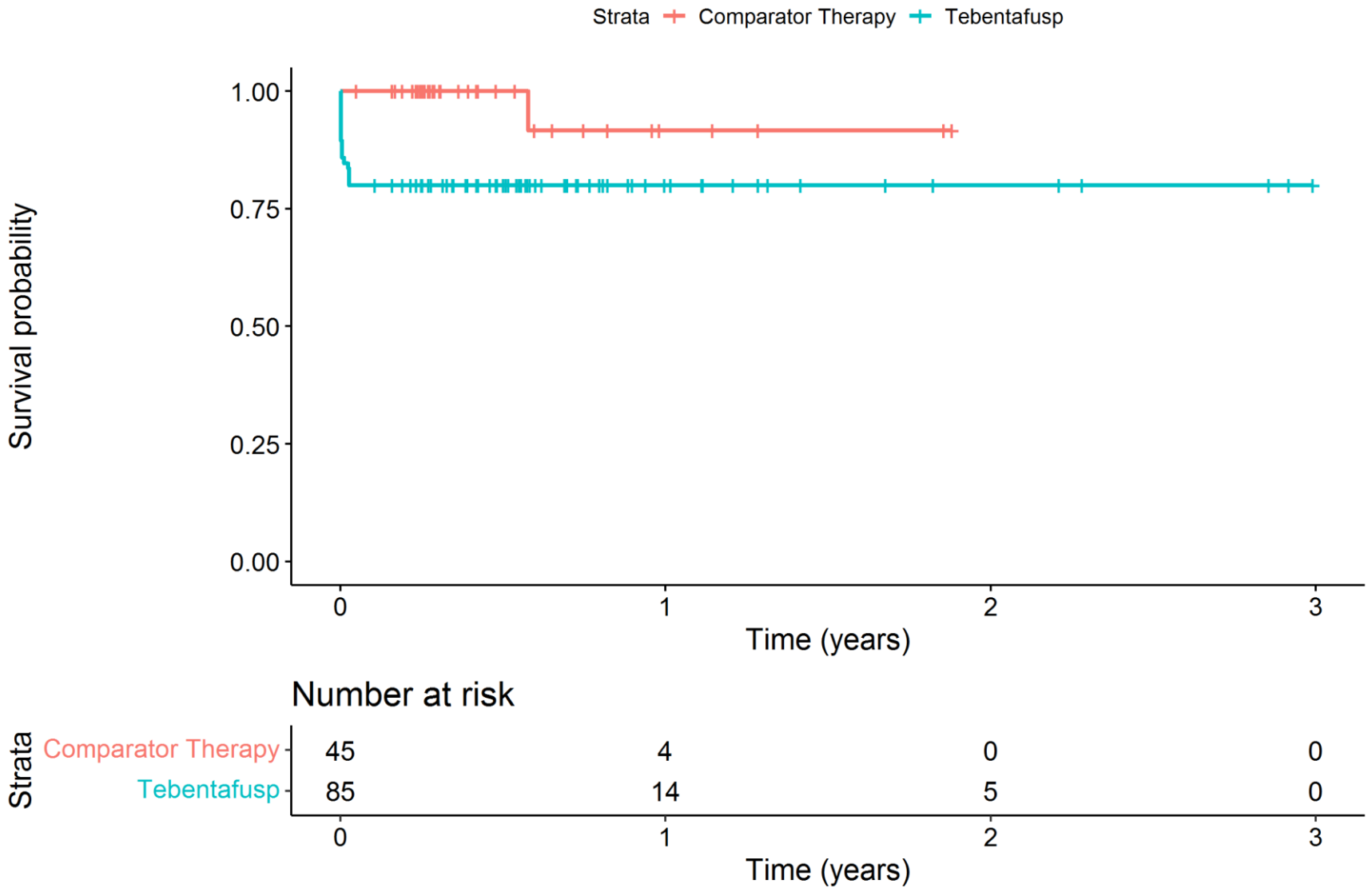
Periphere Ödeme- Läsion 3,1-8,0 cm



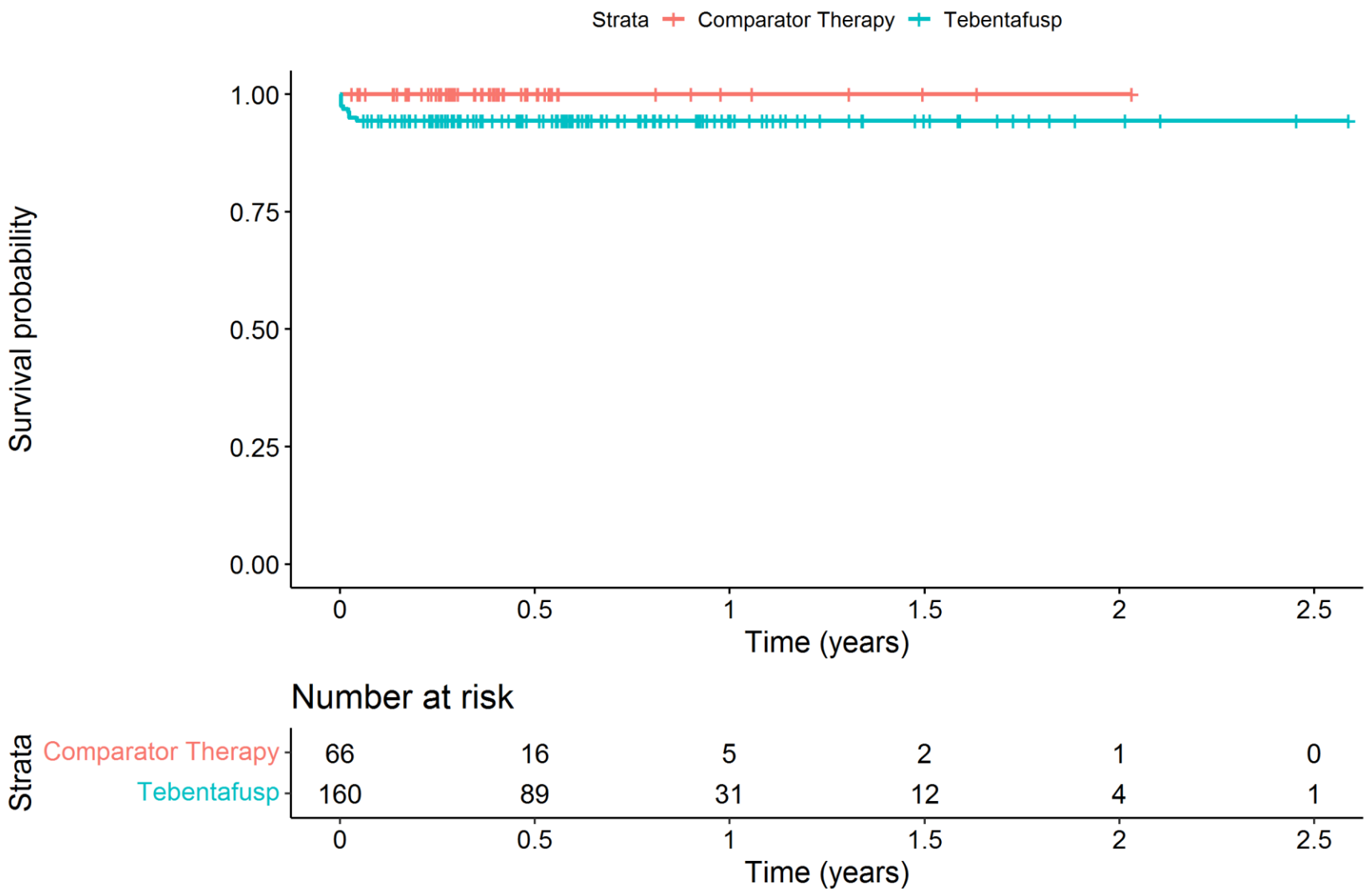
Periphere Ödeme- Läsion ≥8,1 cm



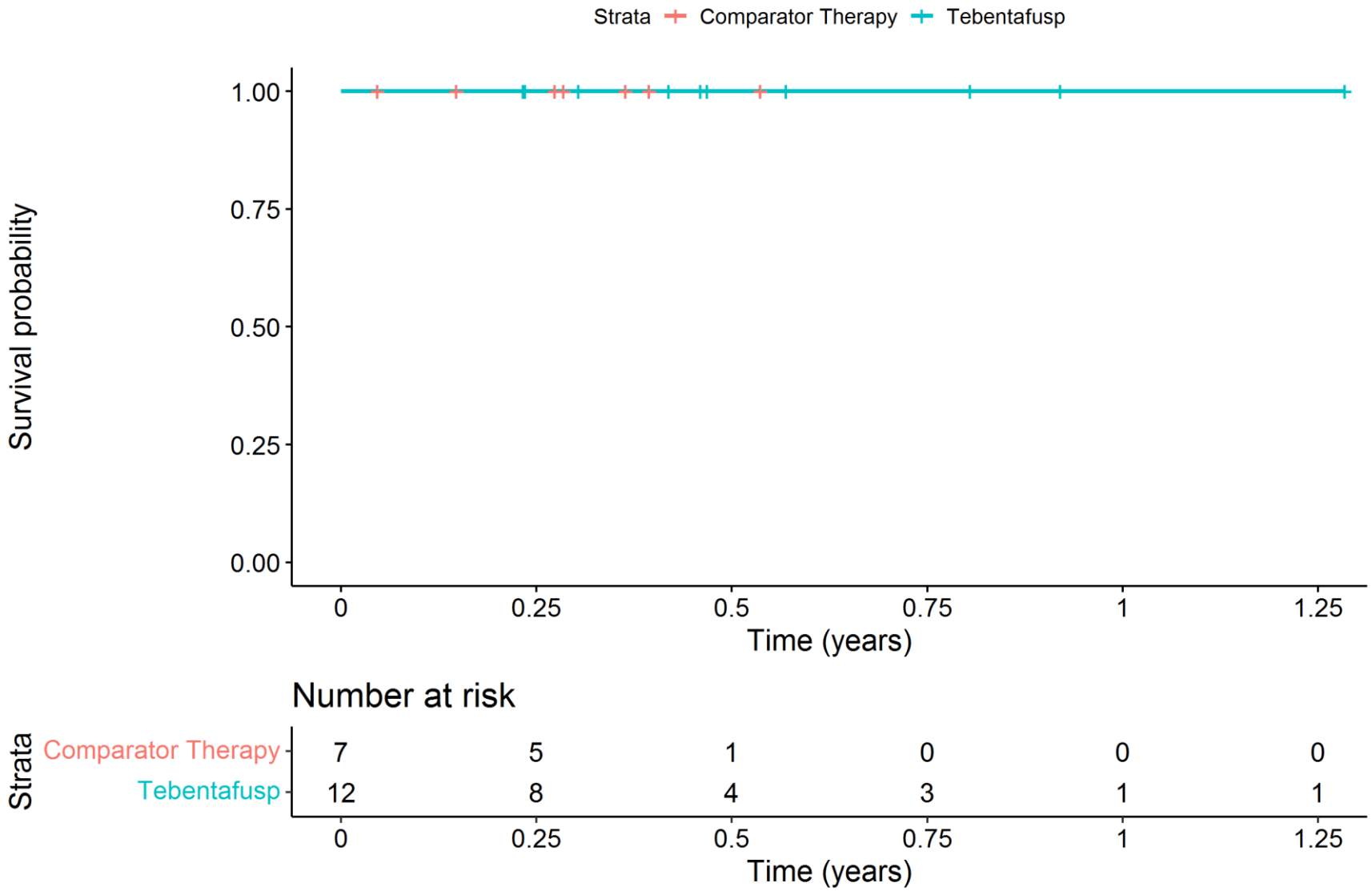
53.61 Periphere Ödeme- Nordamerika



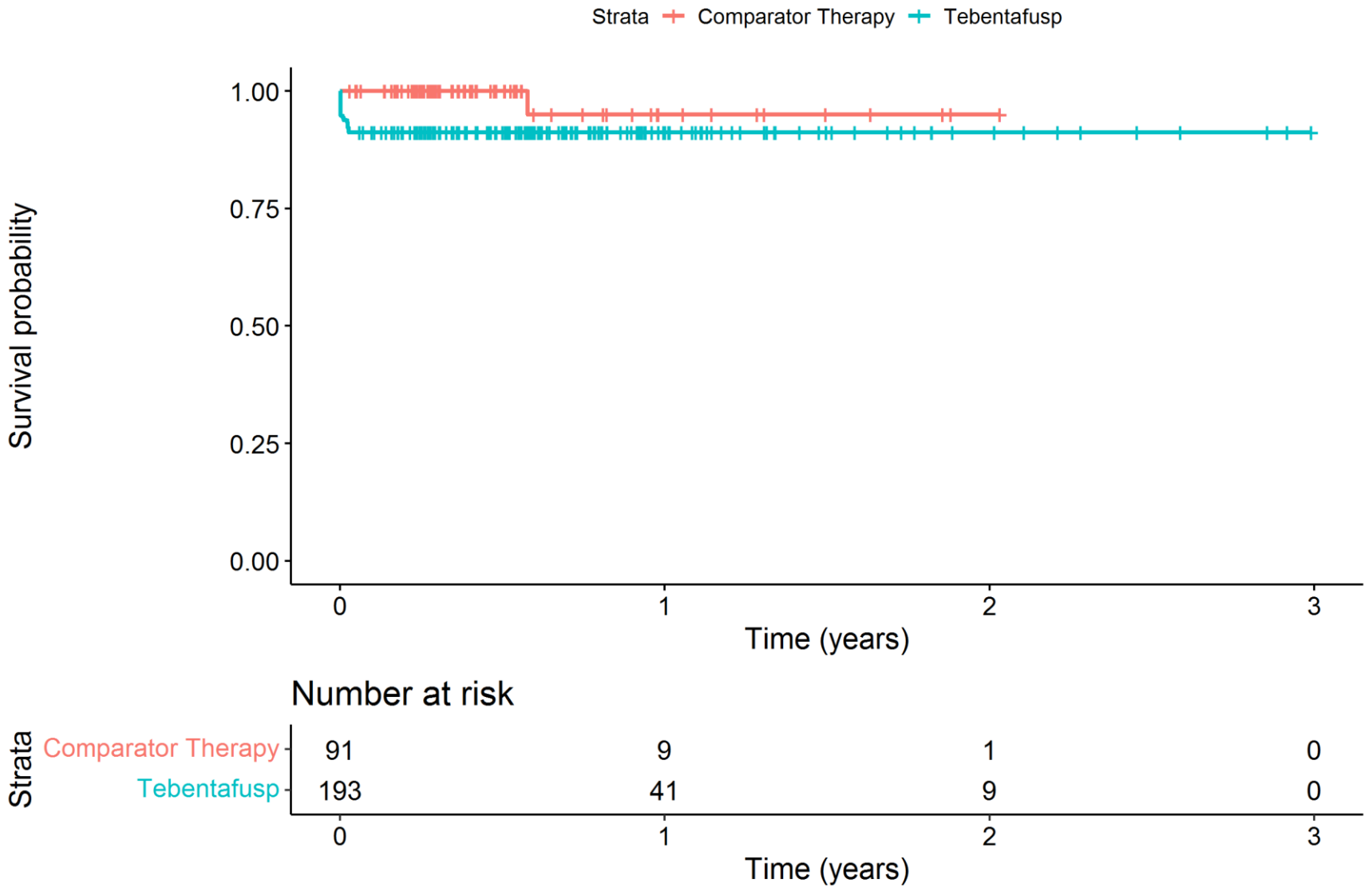
53.62 Periphere Ödeme- Nicht-Nordamerika



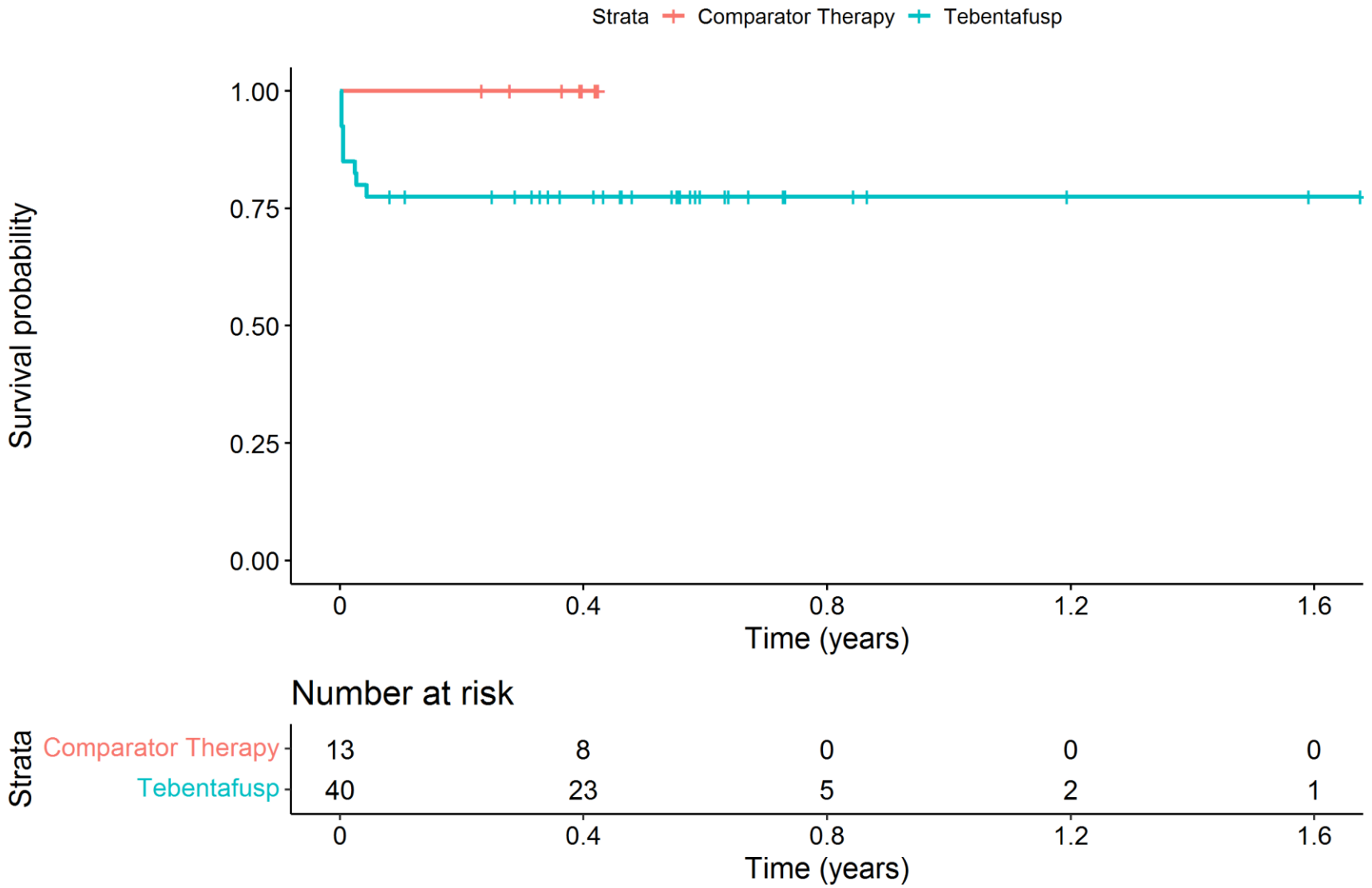
53.63 Periphere Ödeme- Dacarbazin



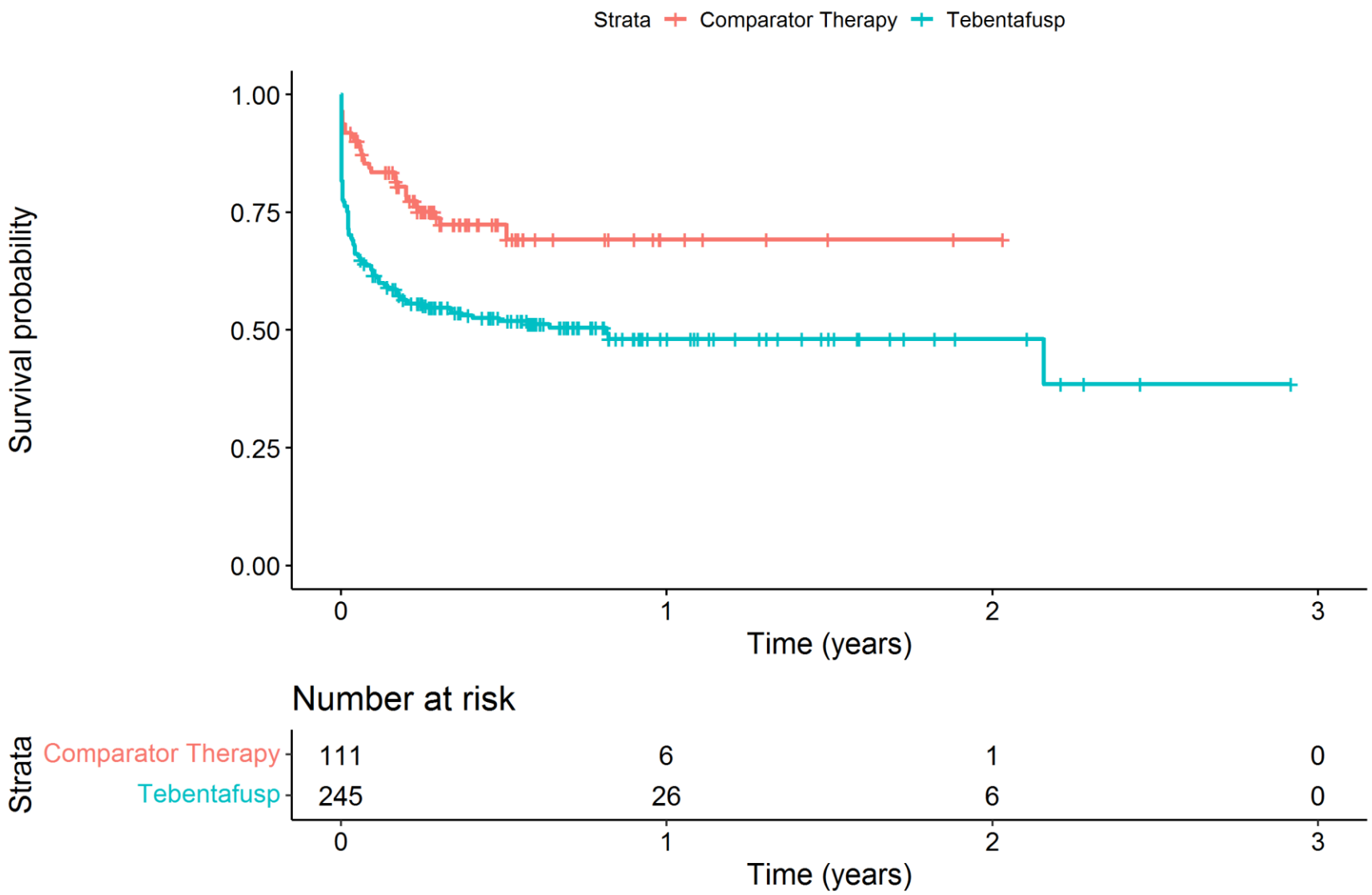
53.64 Periphere Ödeme- Pembrolizumab



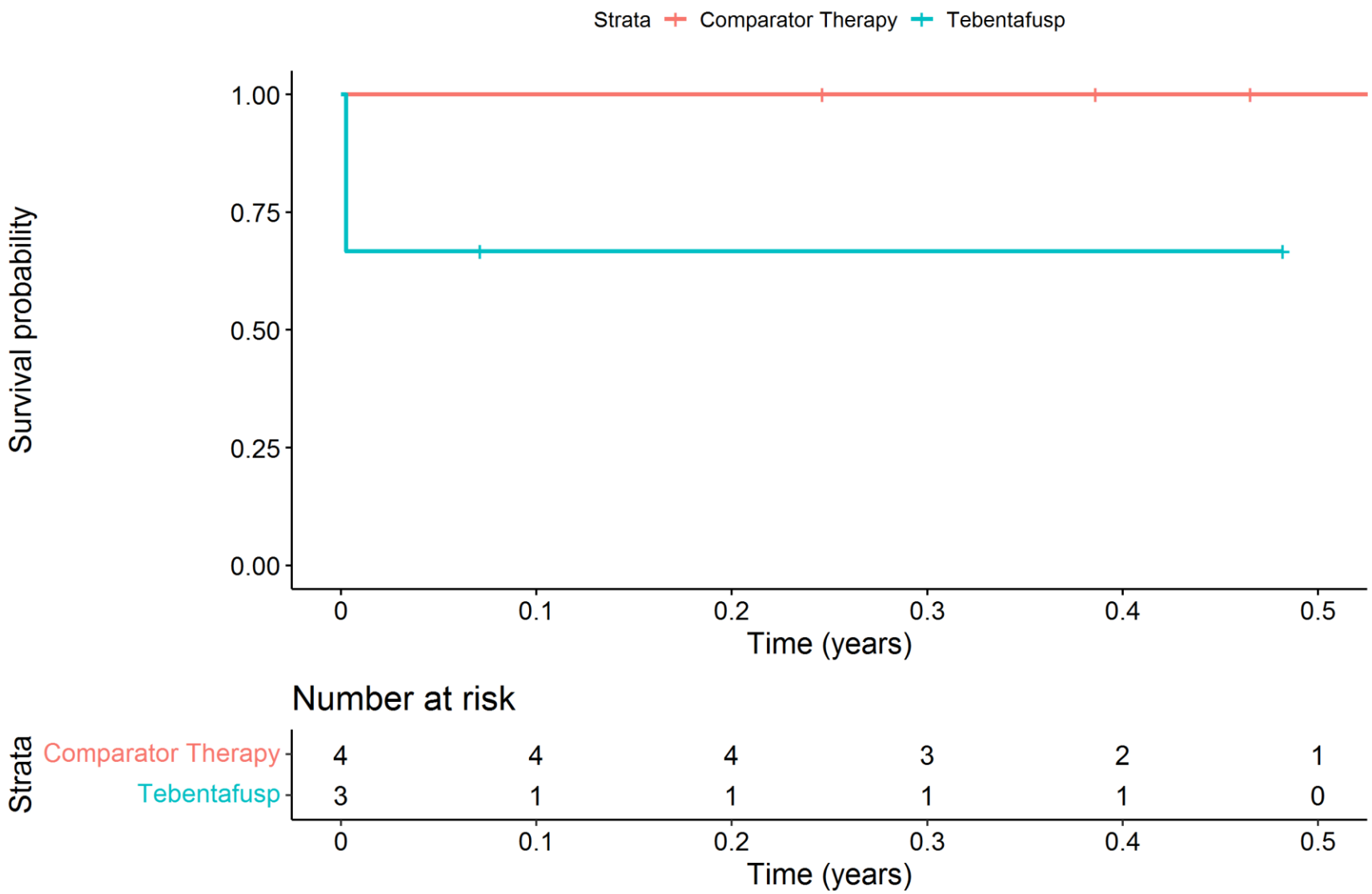
53.65 Periphere Ödeme- Ipilimumab



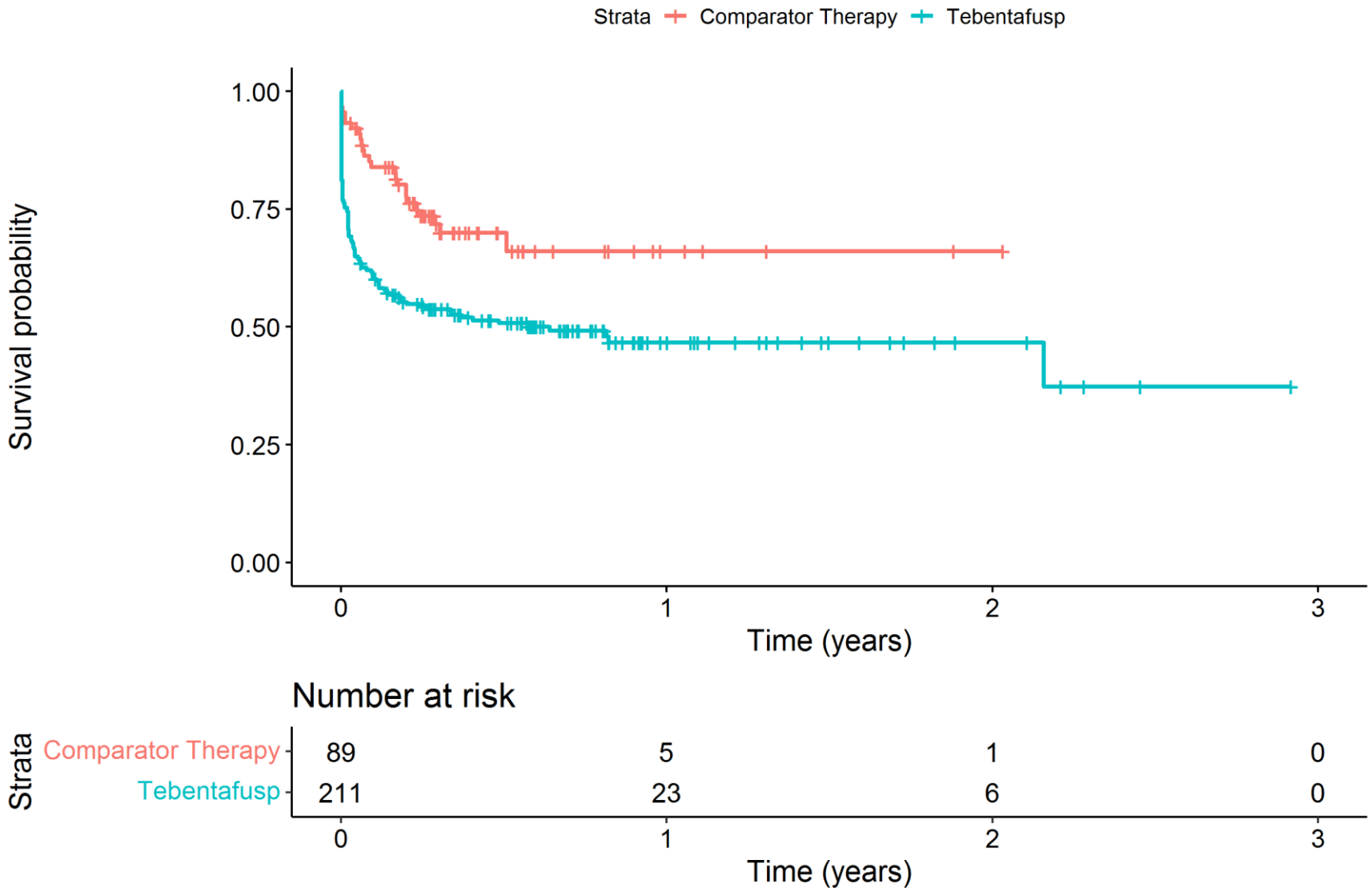
53.66 Übelkeit - Gesamt



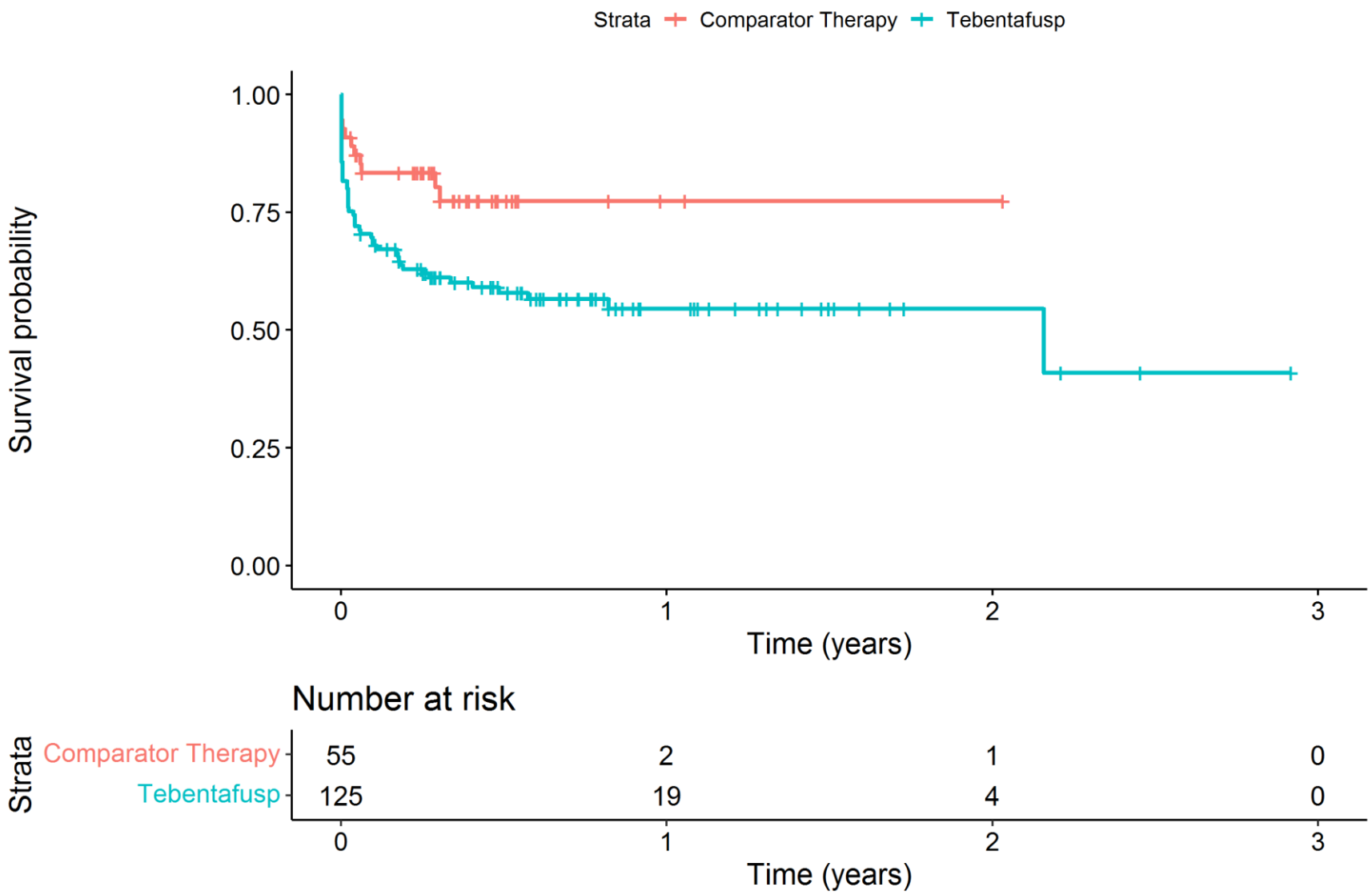
53.67 Übelkeit - Hispanisch



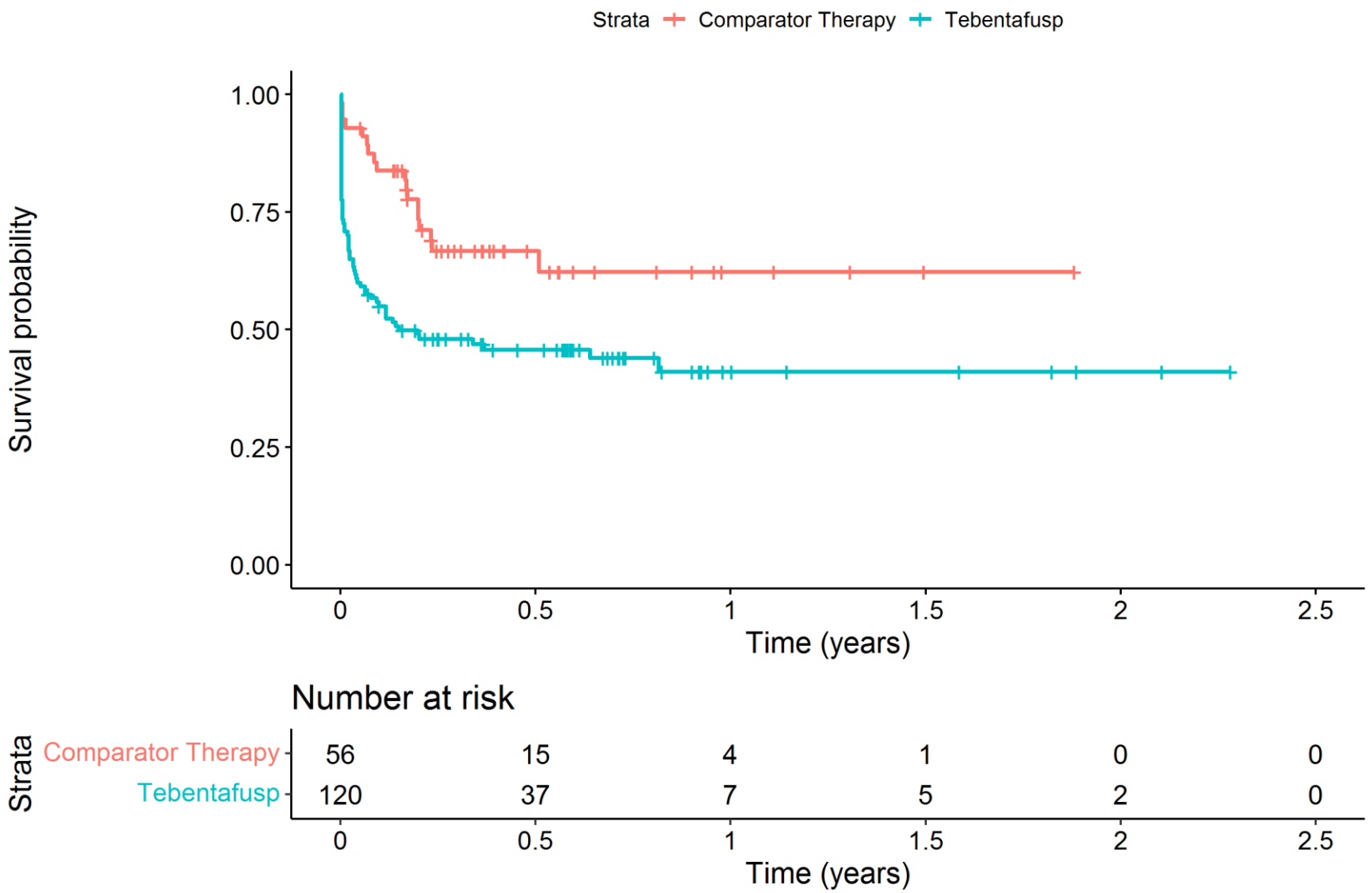
53.68 Übelkeit - Nicht-hispanisch



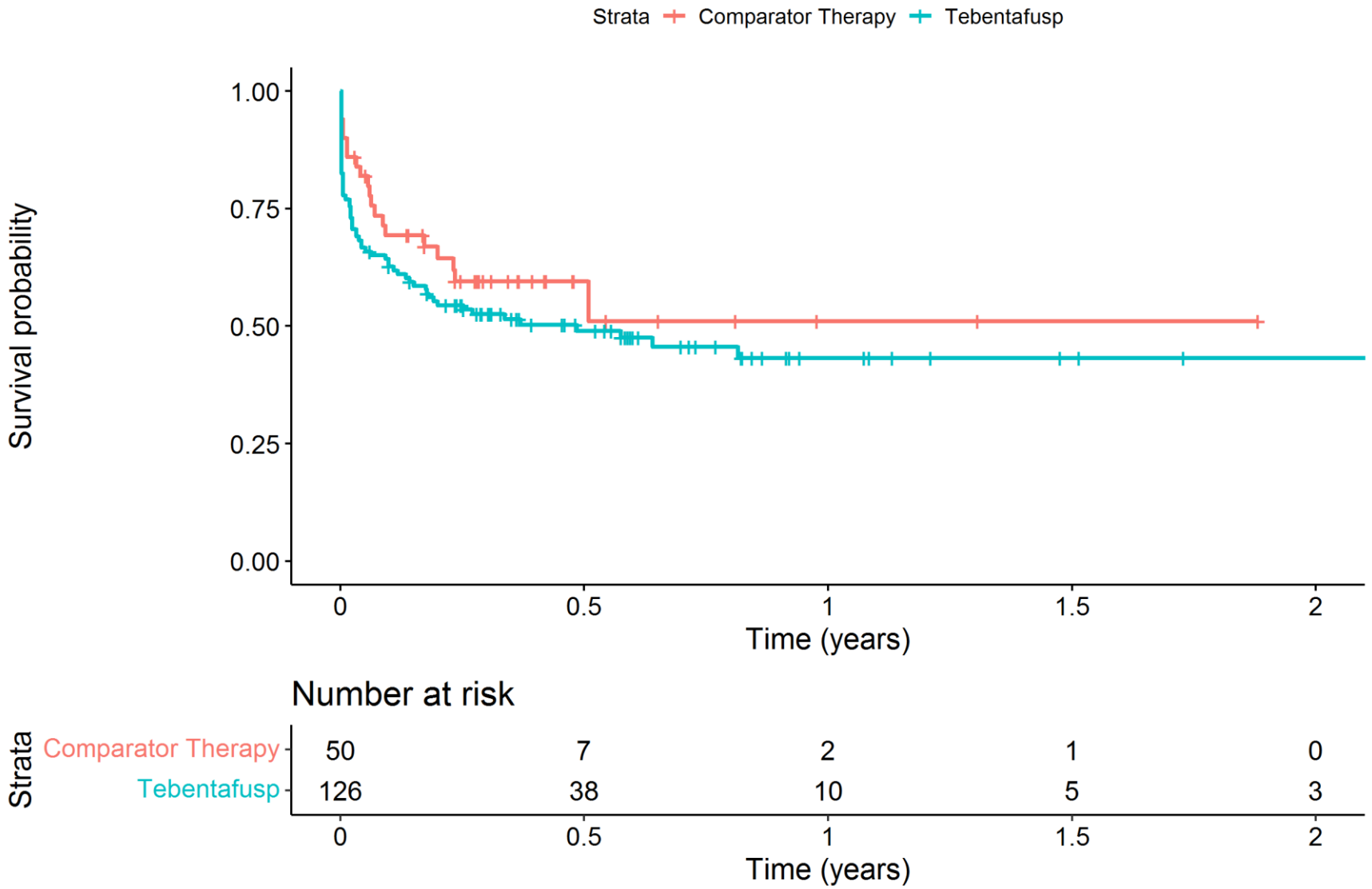
53.69 Übelkeit - Männlich



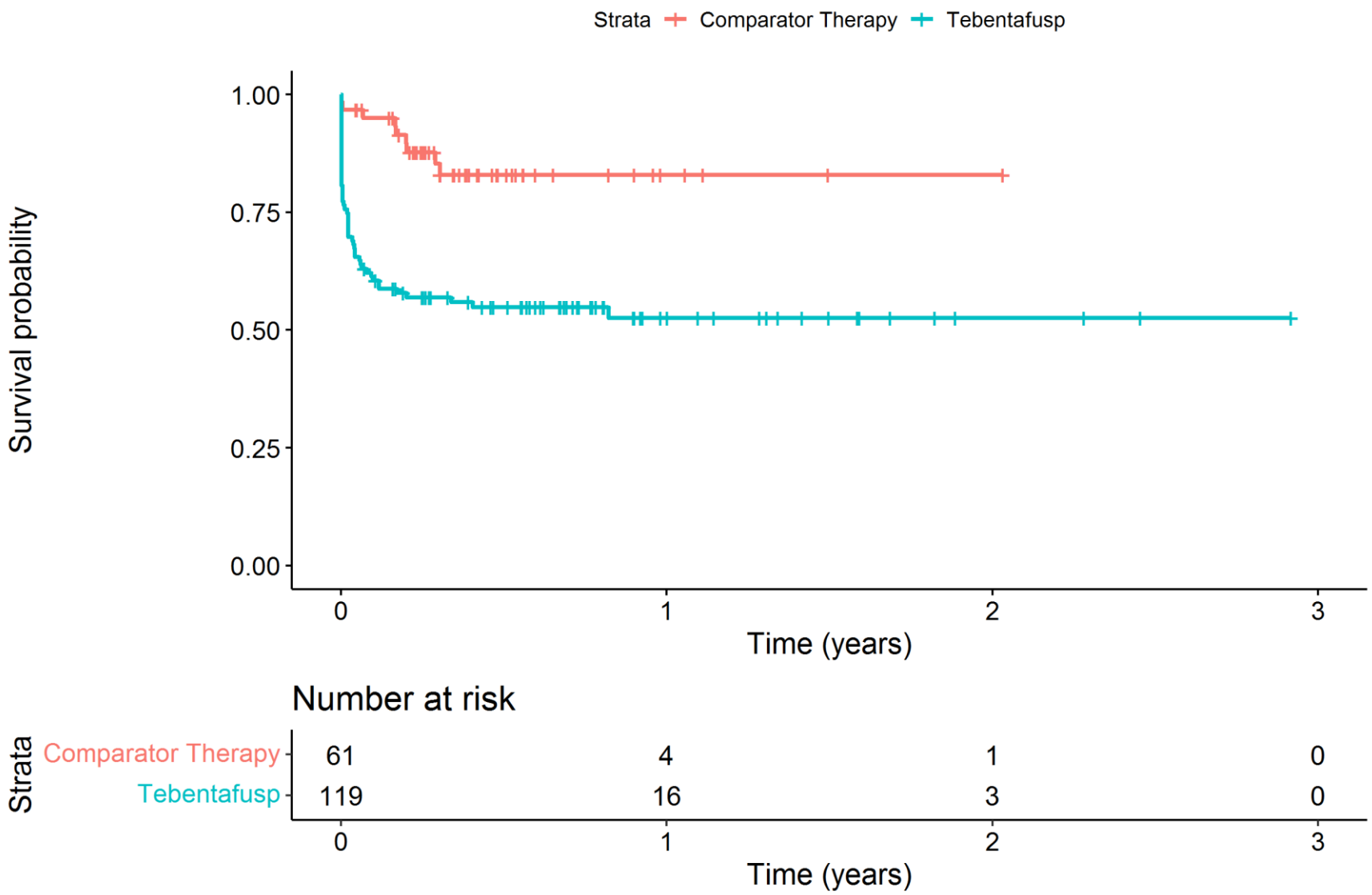
53.70 Übelkeit - Weiblich



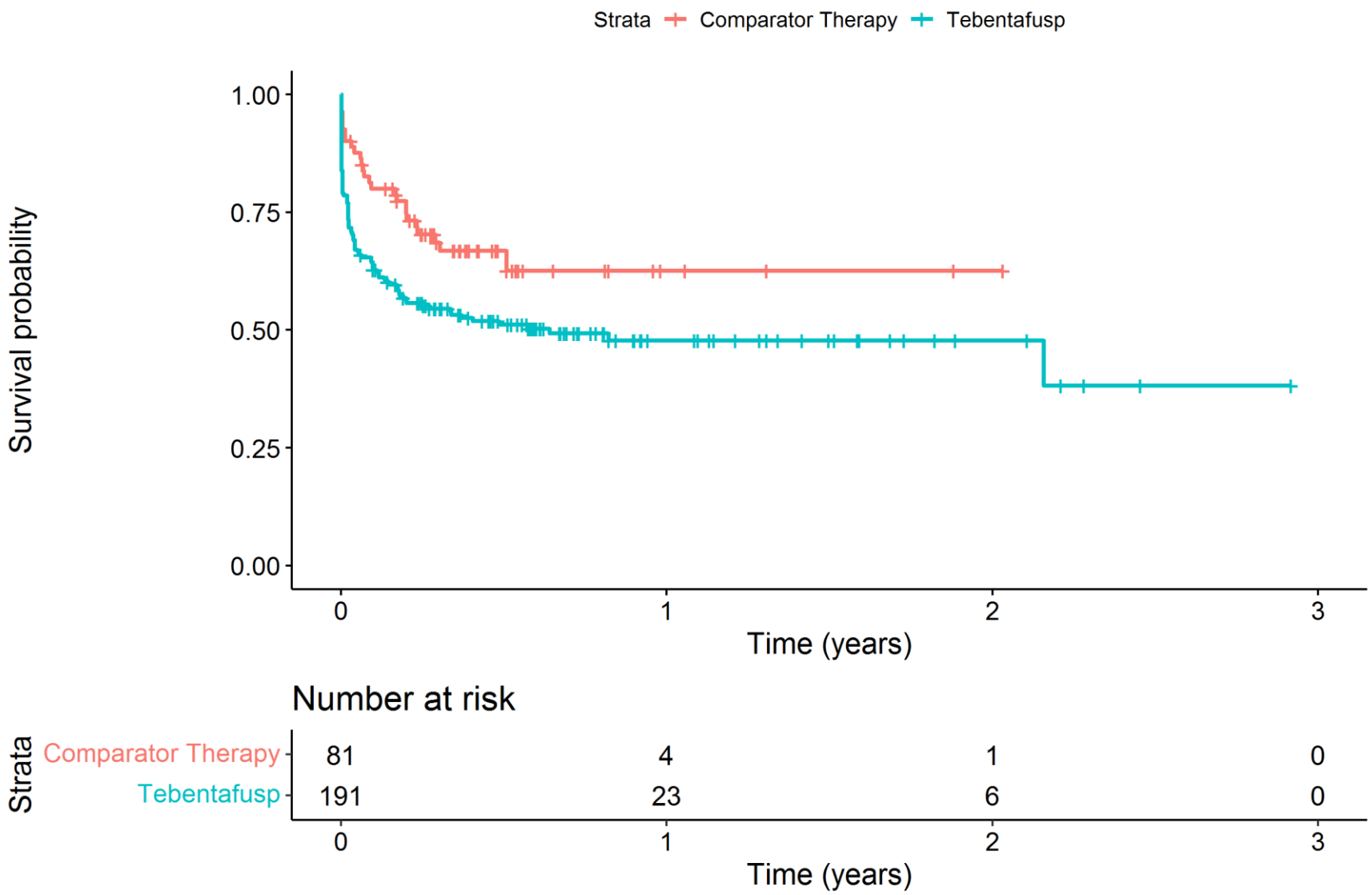
53.71 Übelkeit - <65



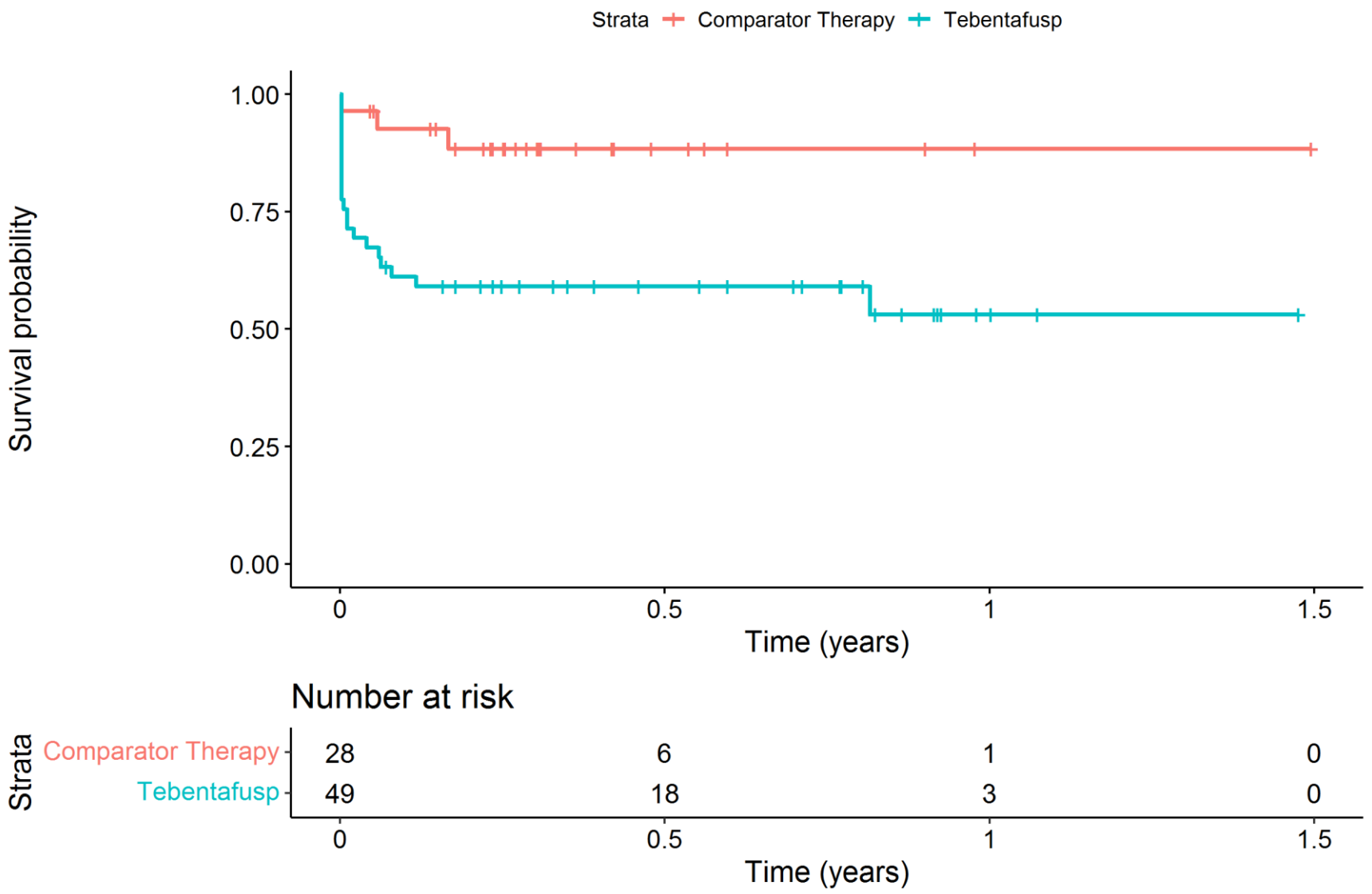
53.72 Übelkeit - ≥65



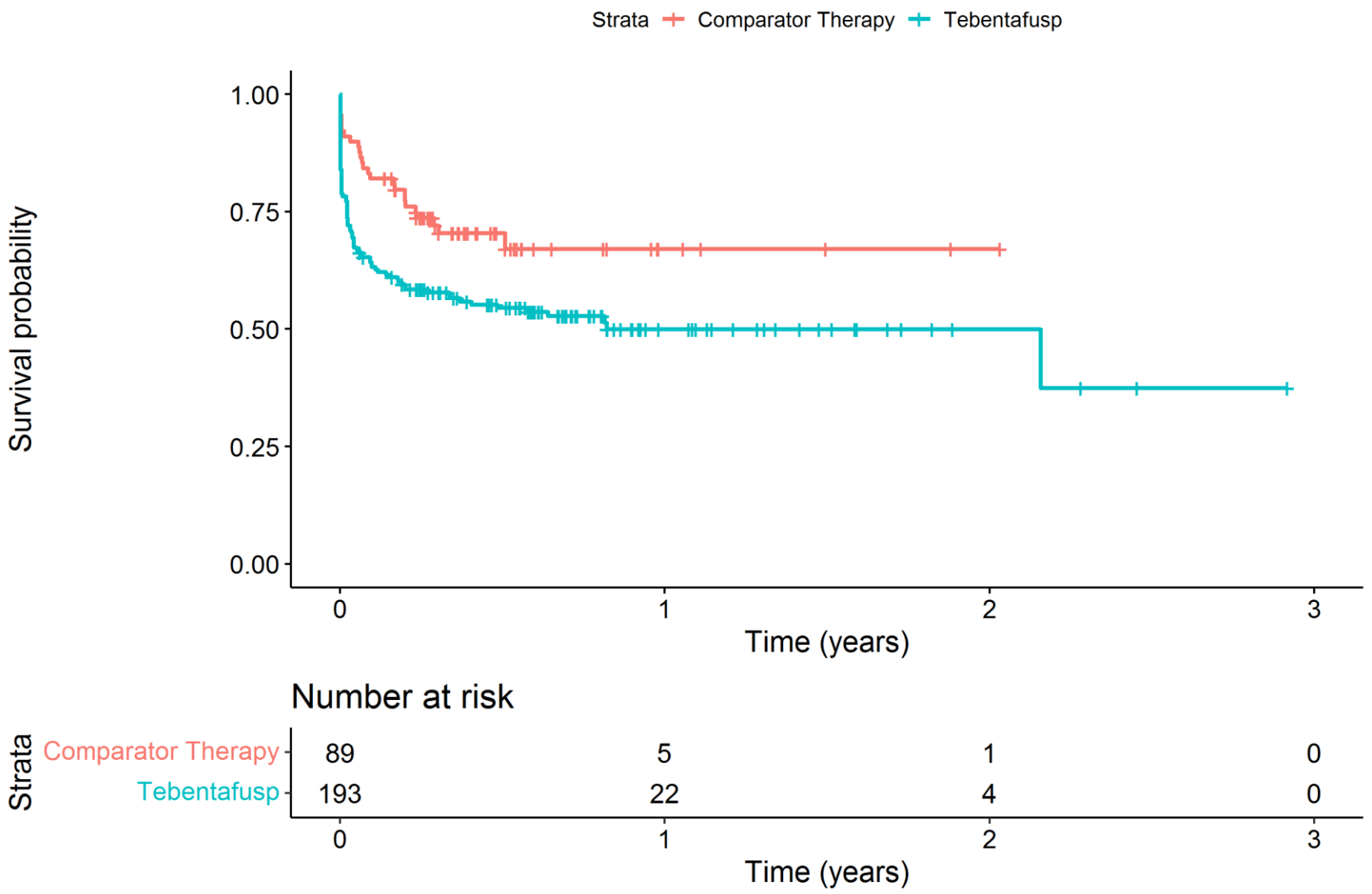
53.73 Übelkeit - ECOG 0



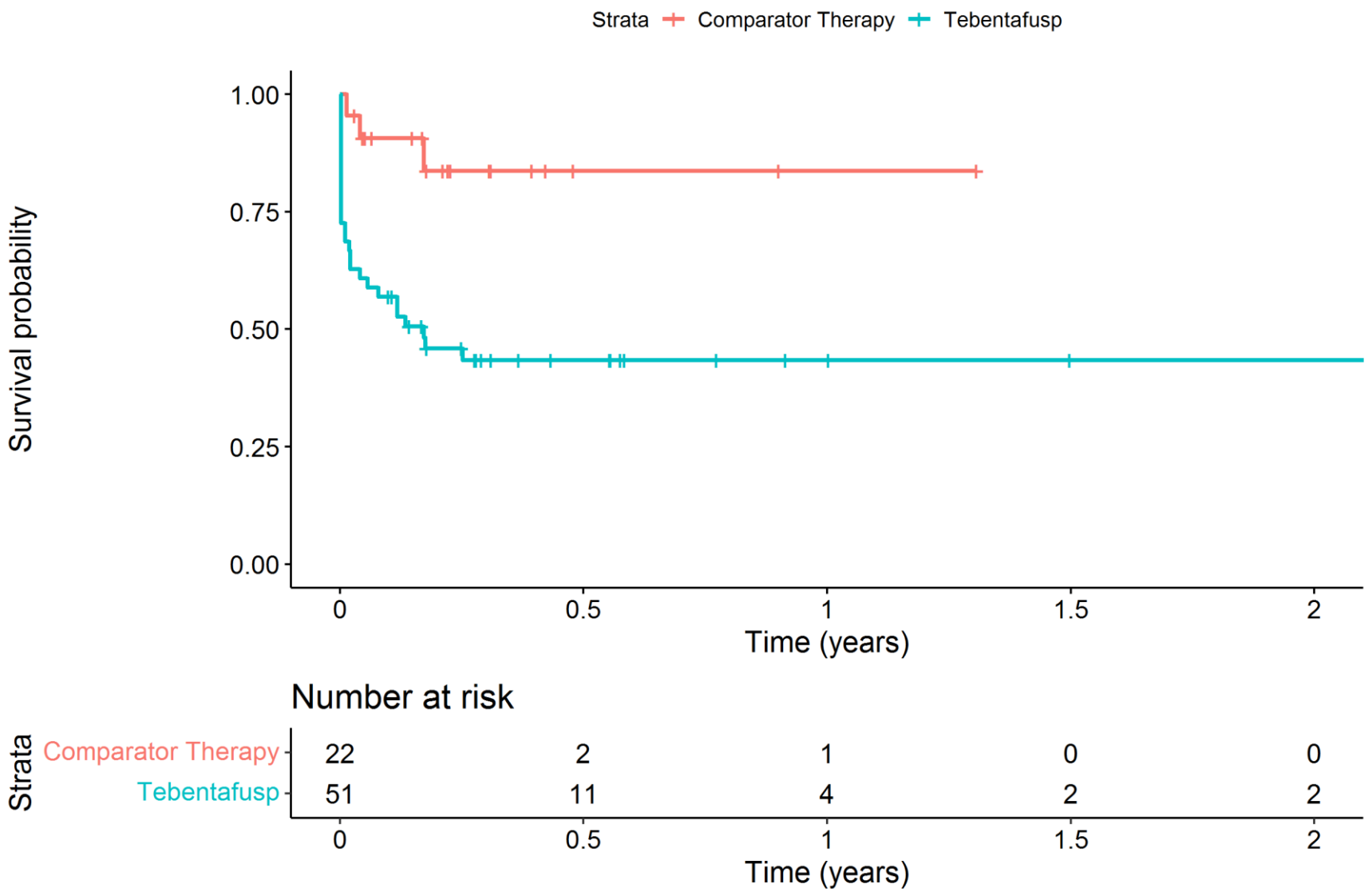
53.74 Übelkeit - ECOG 1



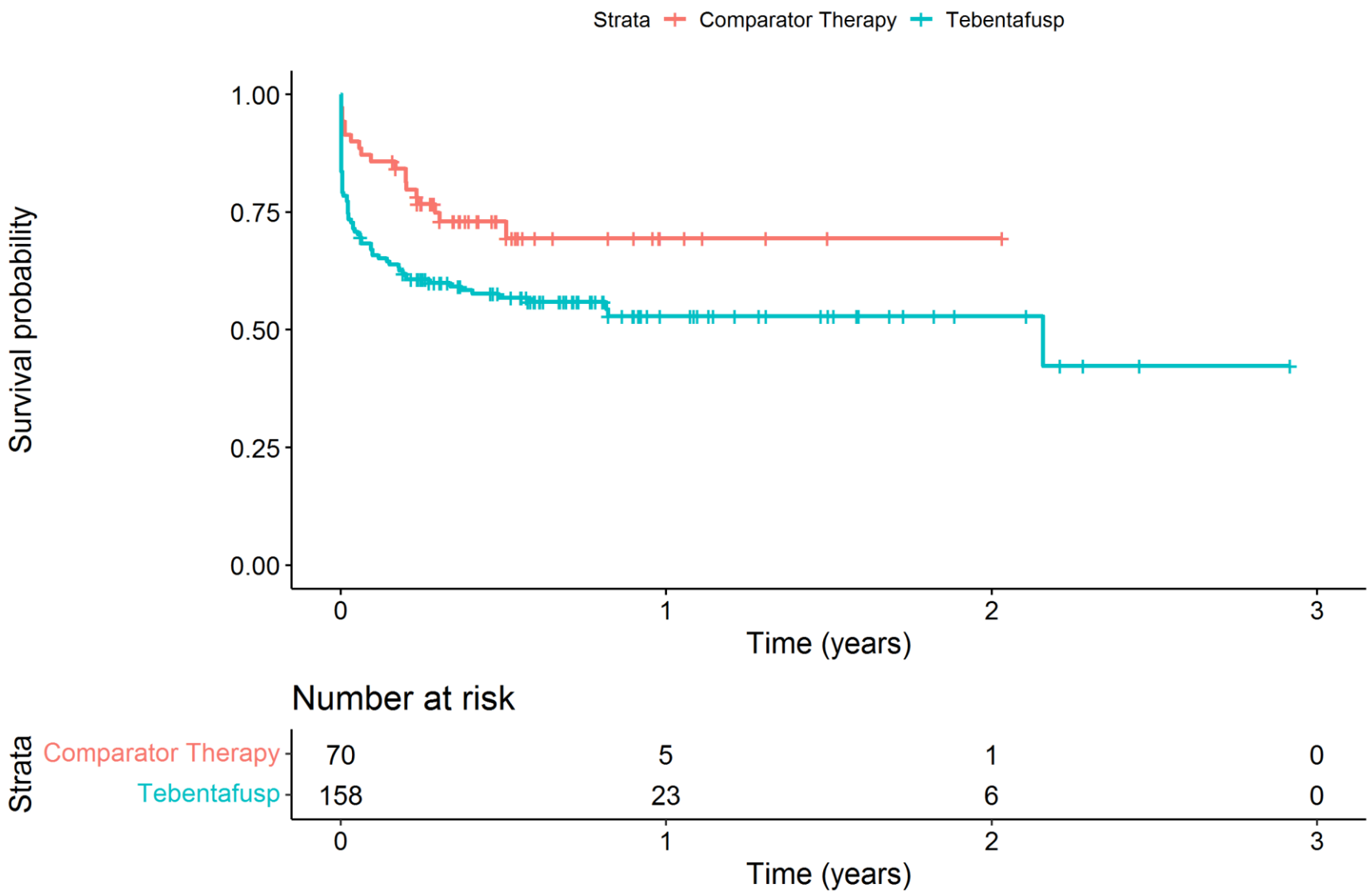
53.75 Übelkeit - ALP ≤ ULN



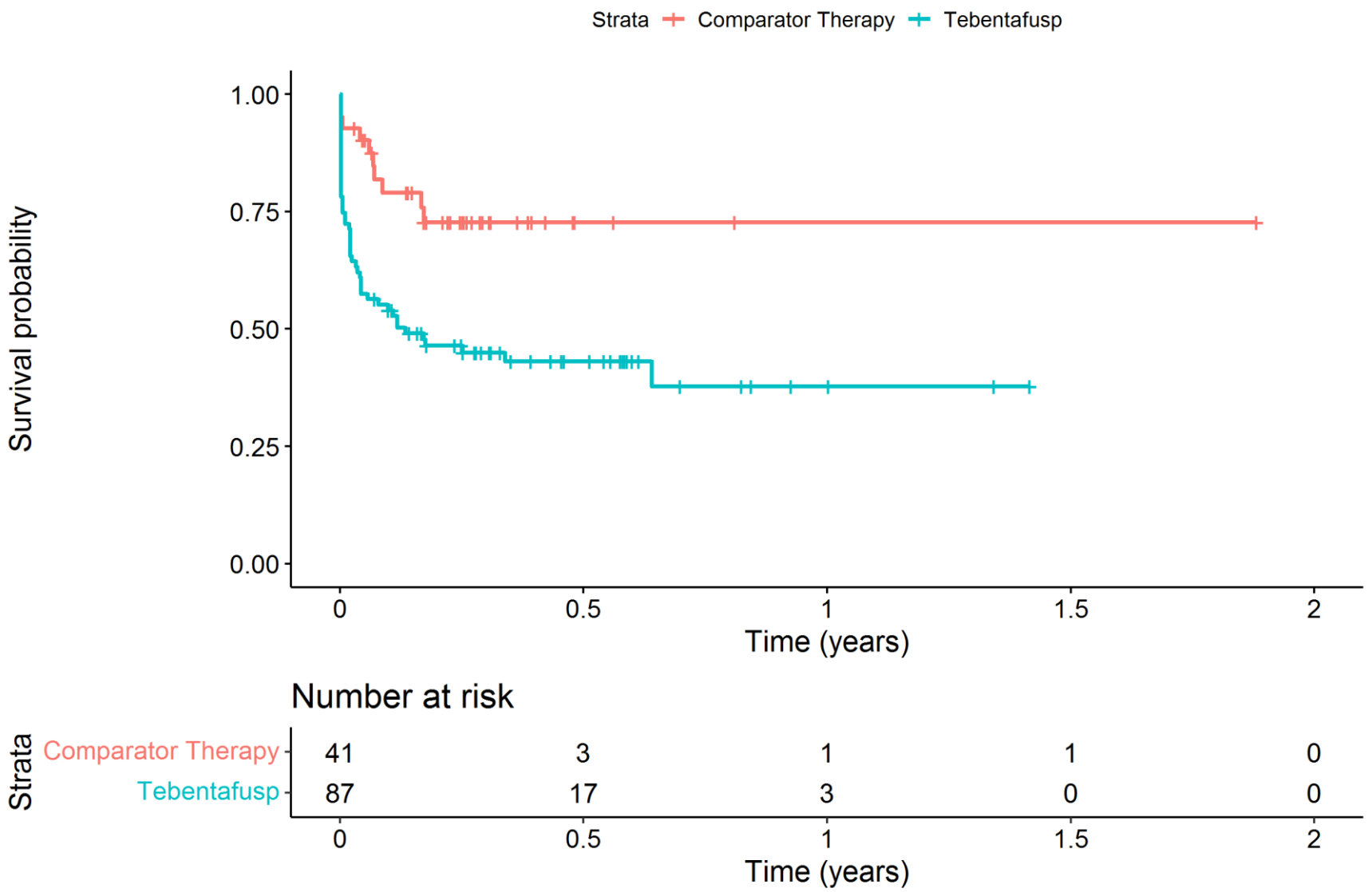
53.76 Übelkeit - ALP > ULN



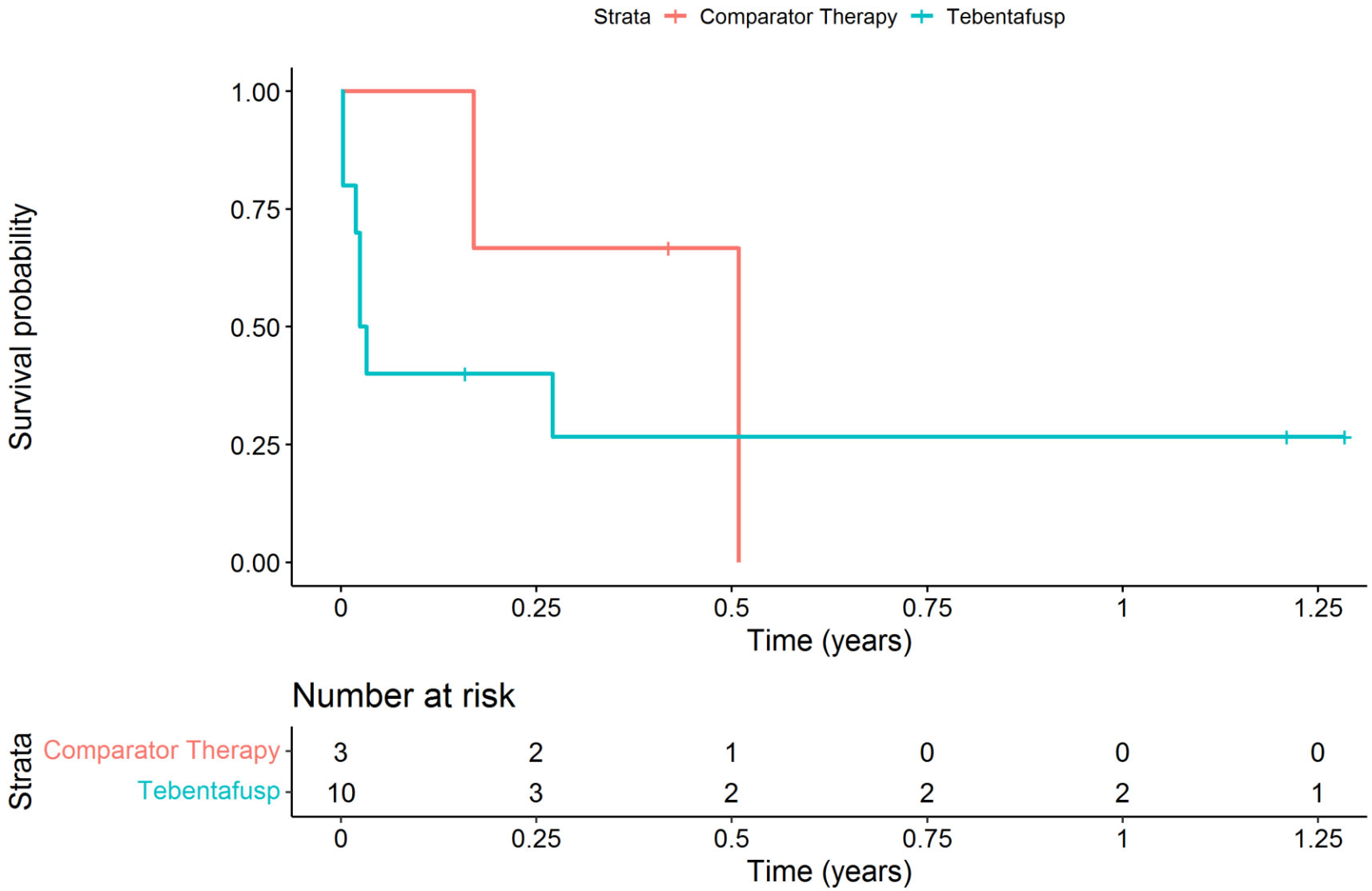
53.77 Übelkeit - LDH =< ULN



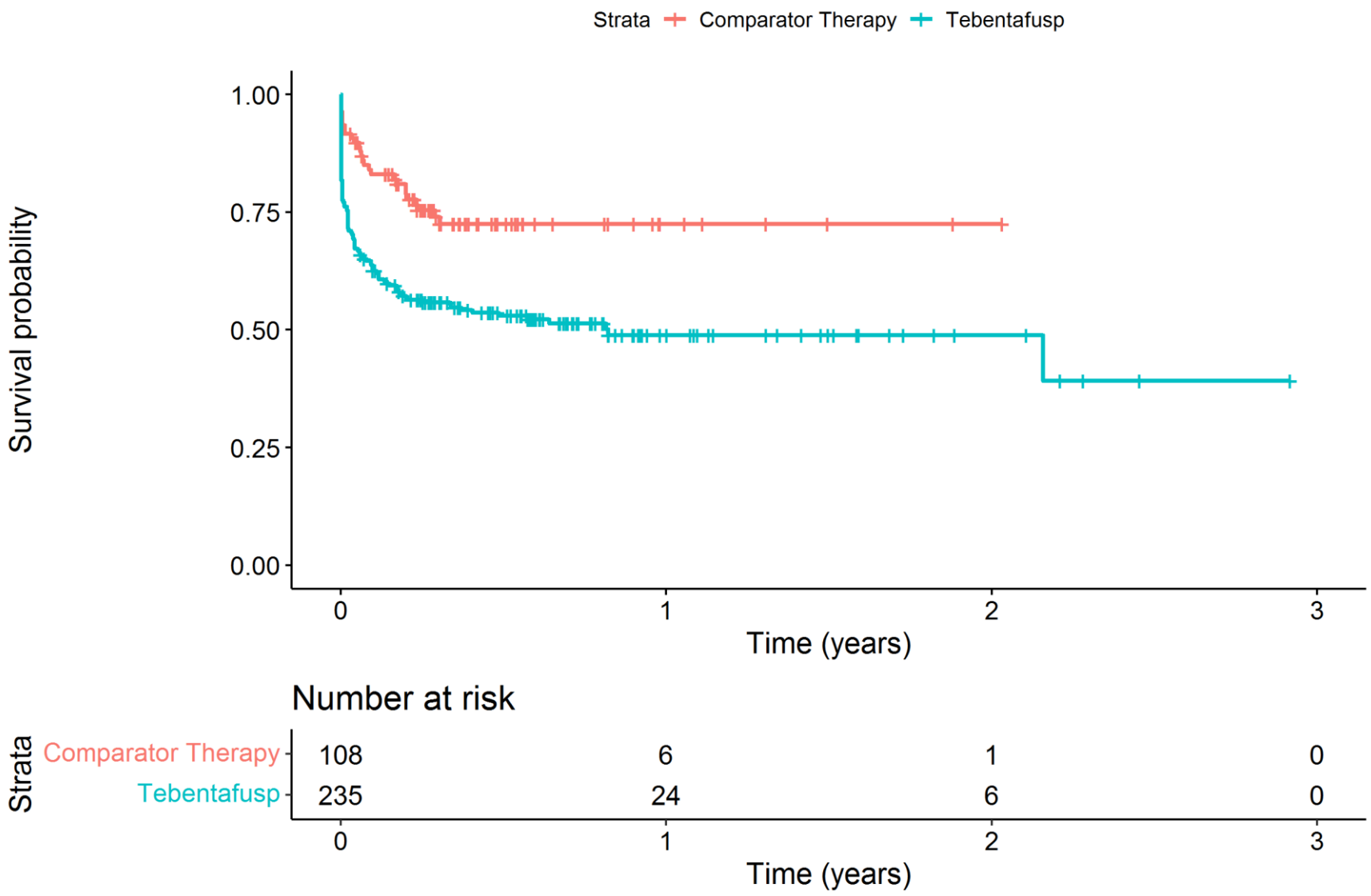
53.78 Übelkeit - LDH > ULN



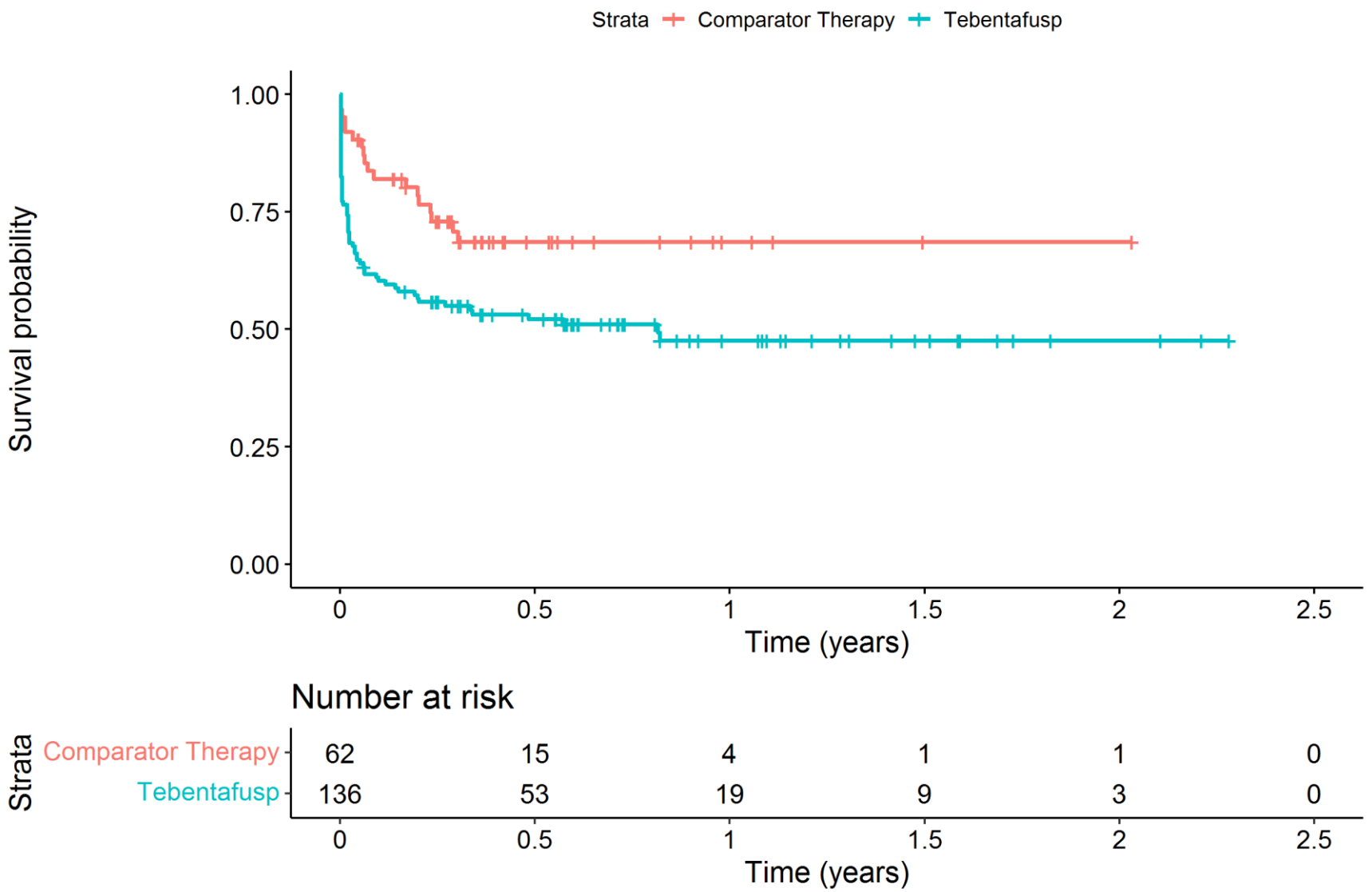
53.79 Übelkeit - Vorherige Therapie adjuvant/neoadjuvant



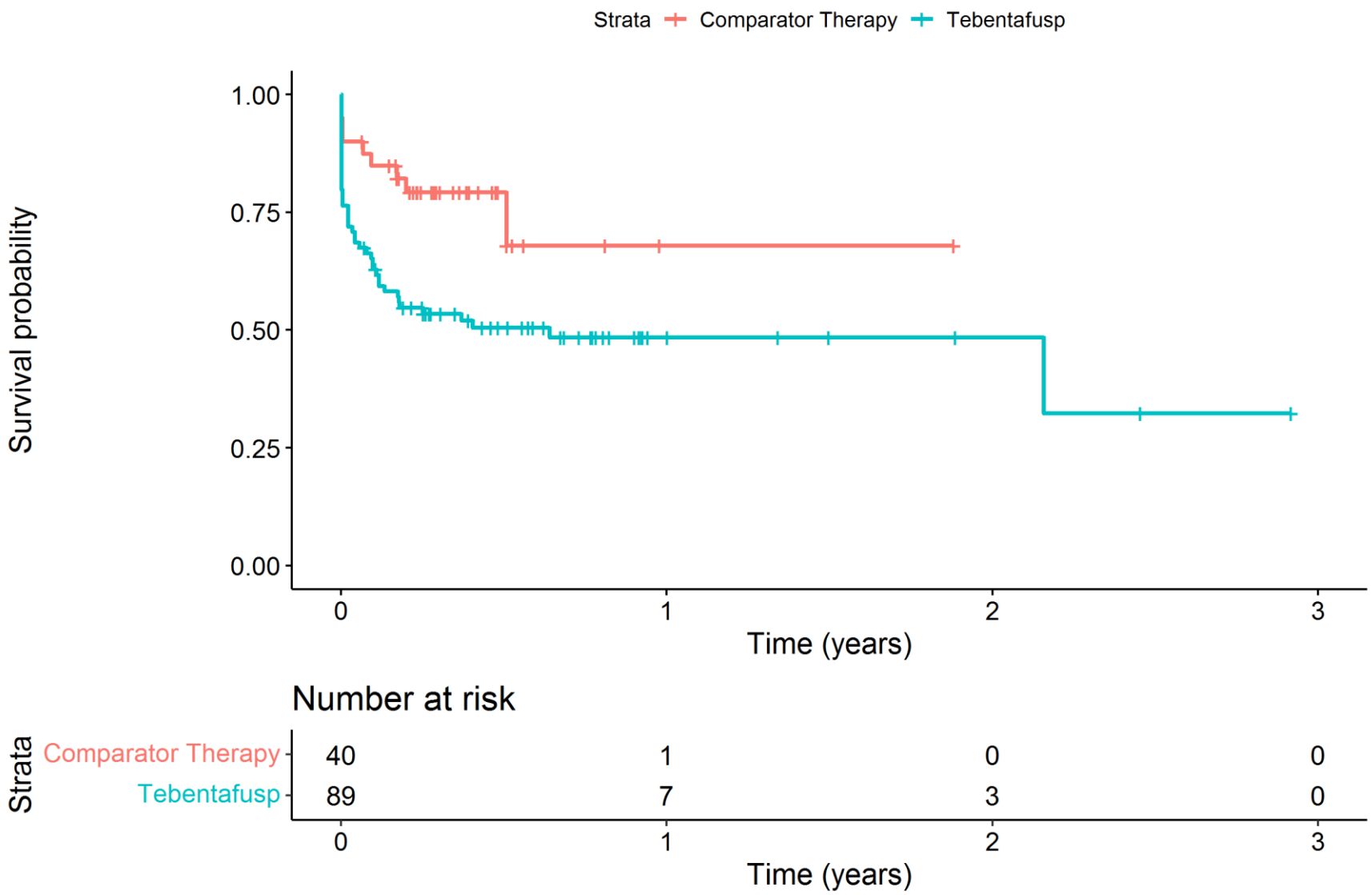
53.80 Übelkeit - Keine vorherige Therapie adjuvant/neoadjuvant



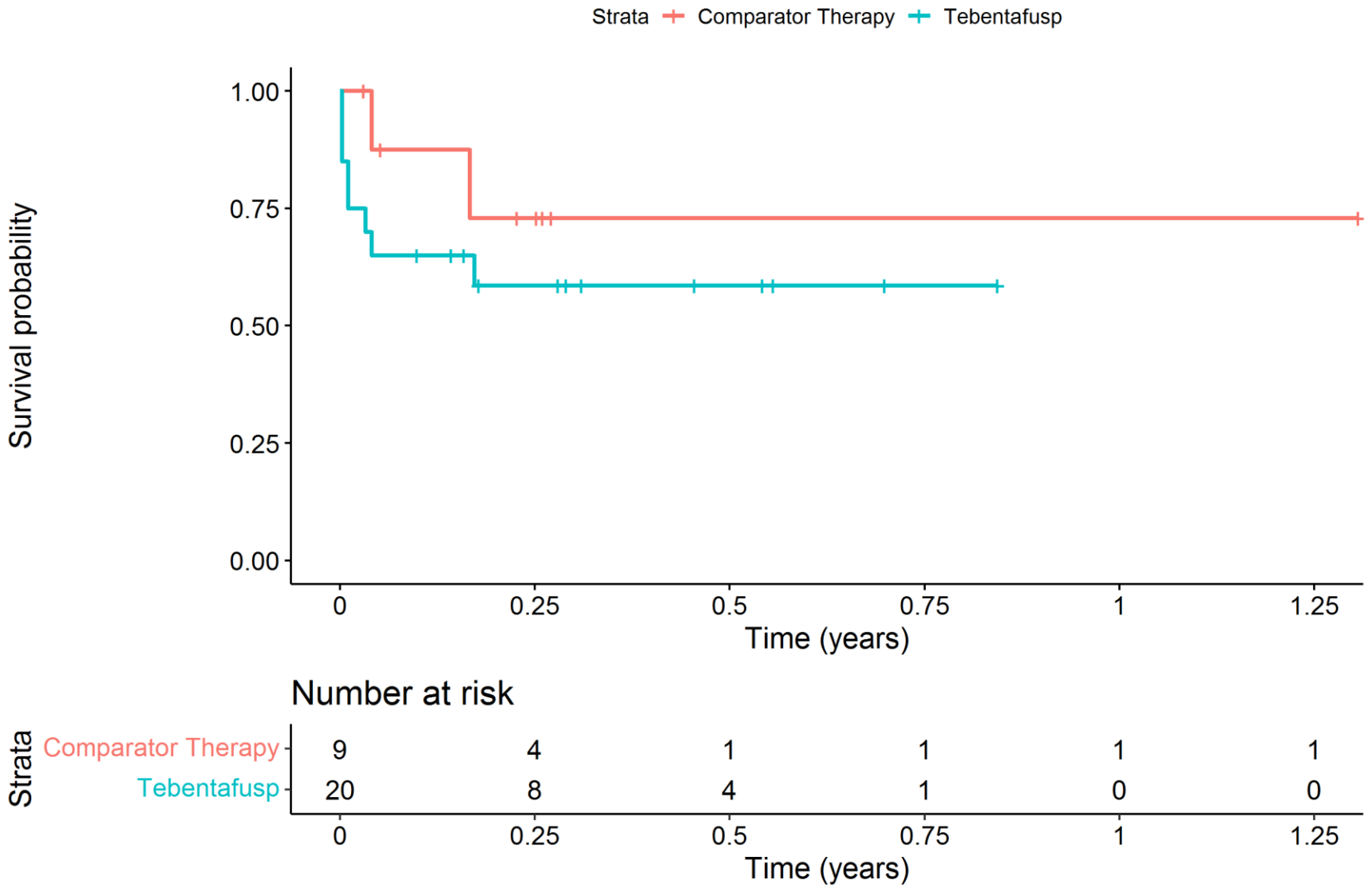
53.81 Übelkeit - Läsion ≤ 3cm



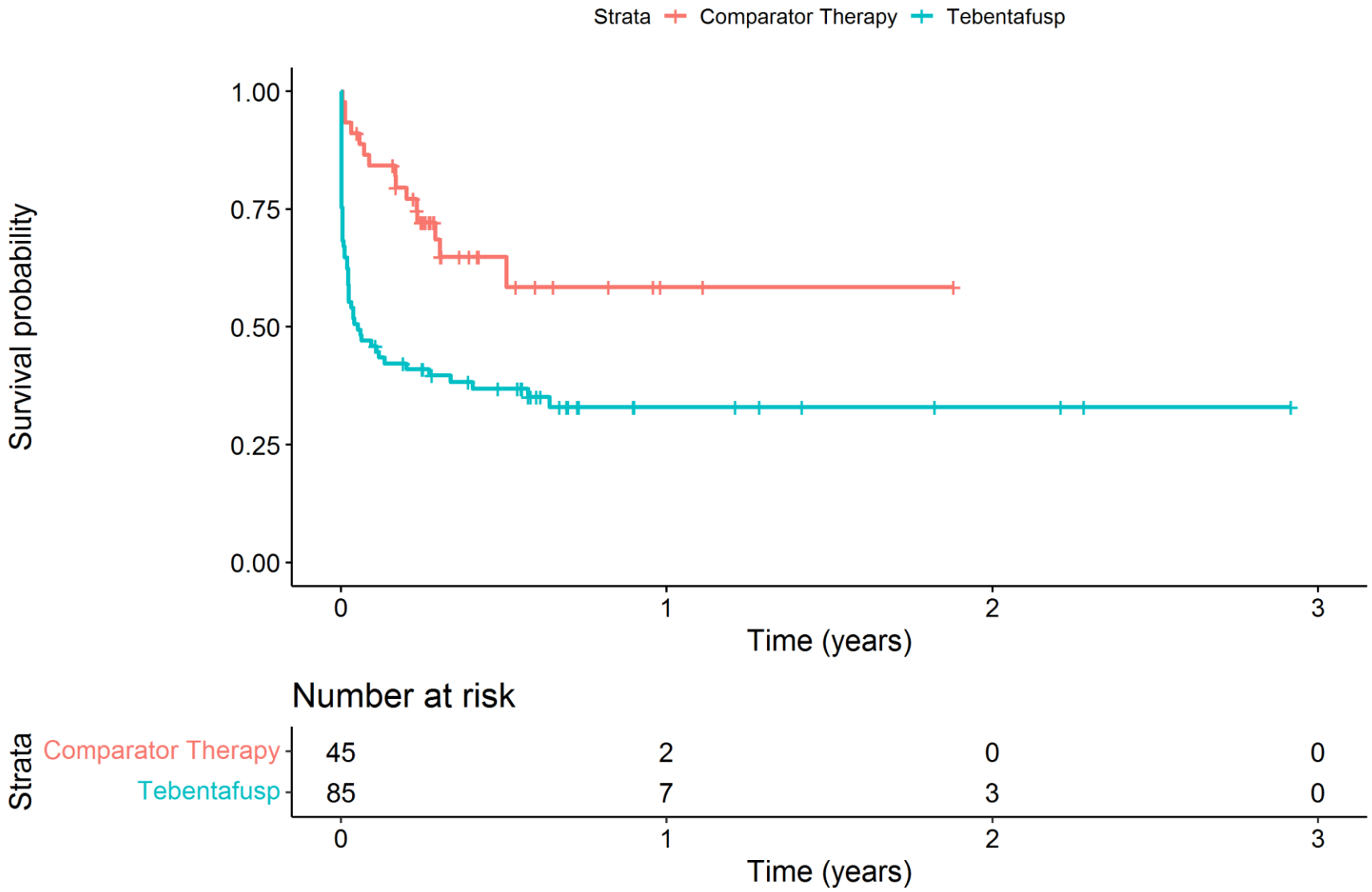
53.82 Übelkeit - Läsion 3,1-8,0 cm



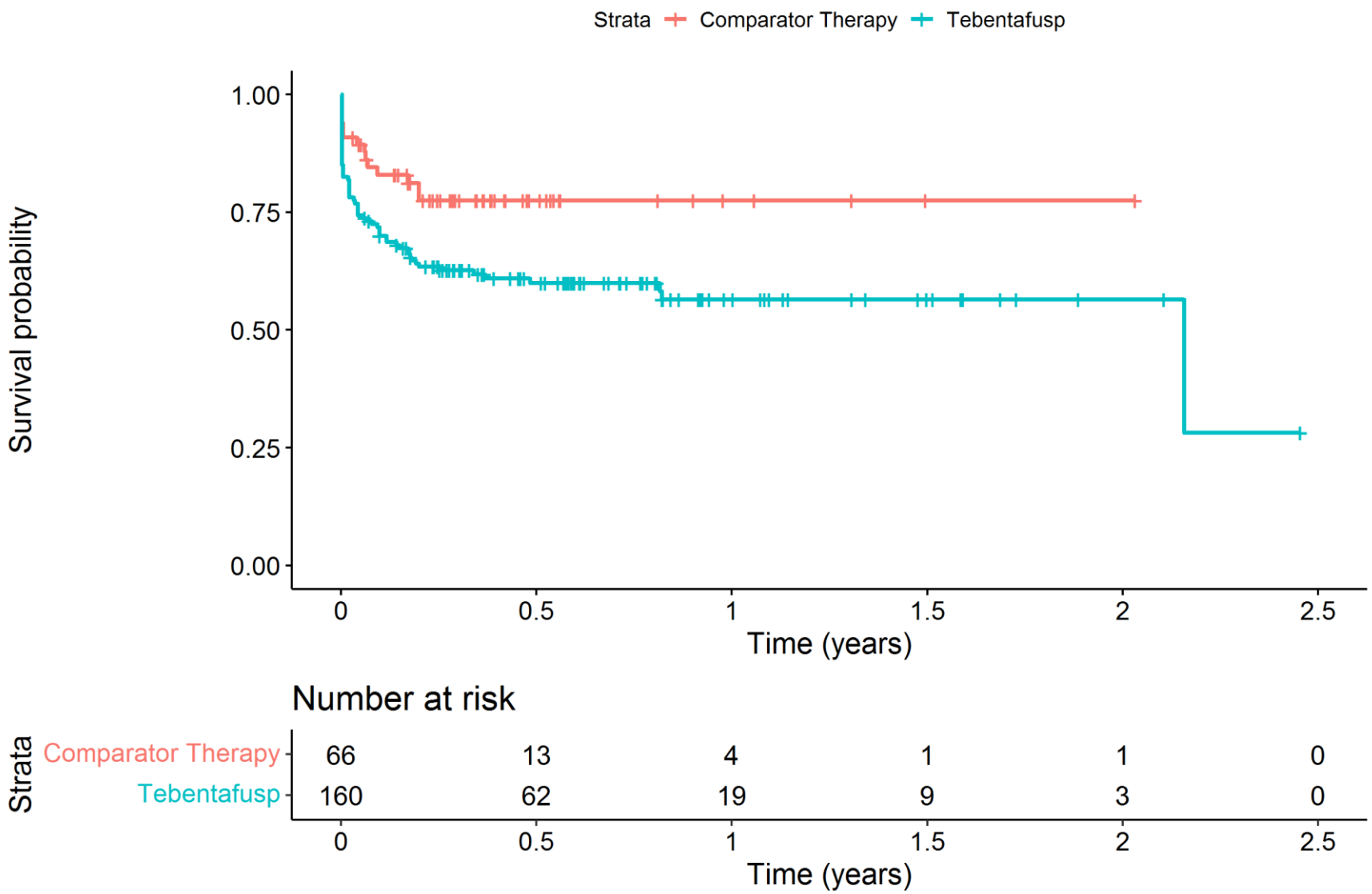
53.83 Übelkeit - Läsion ≥8,1 cm



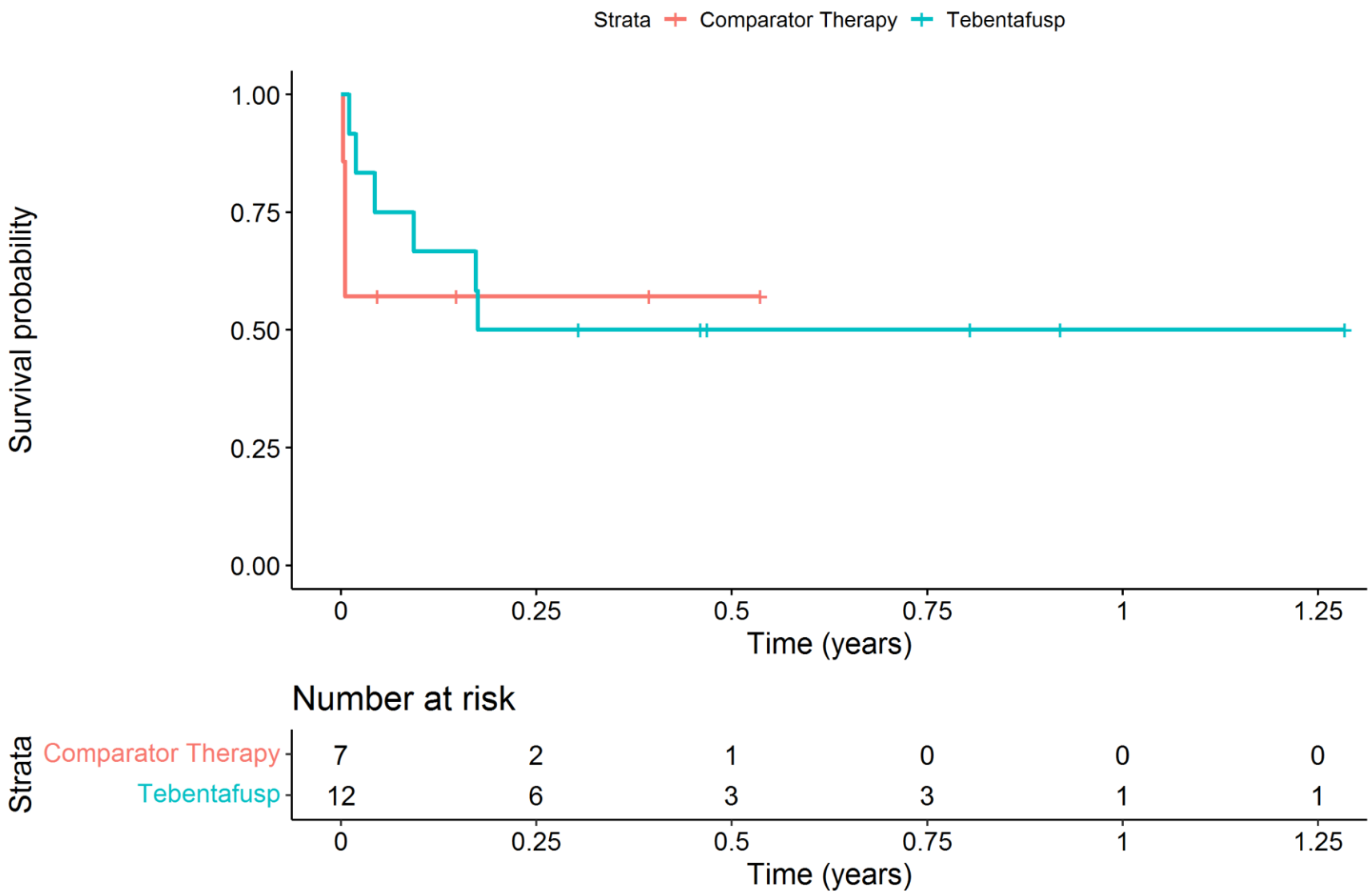
53.84 Übelkeit - Nordamerika



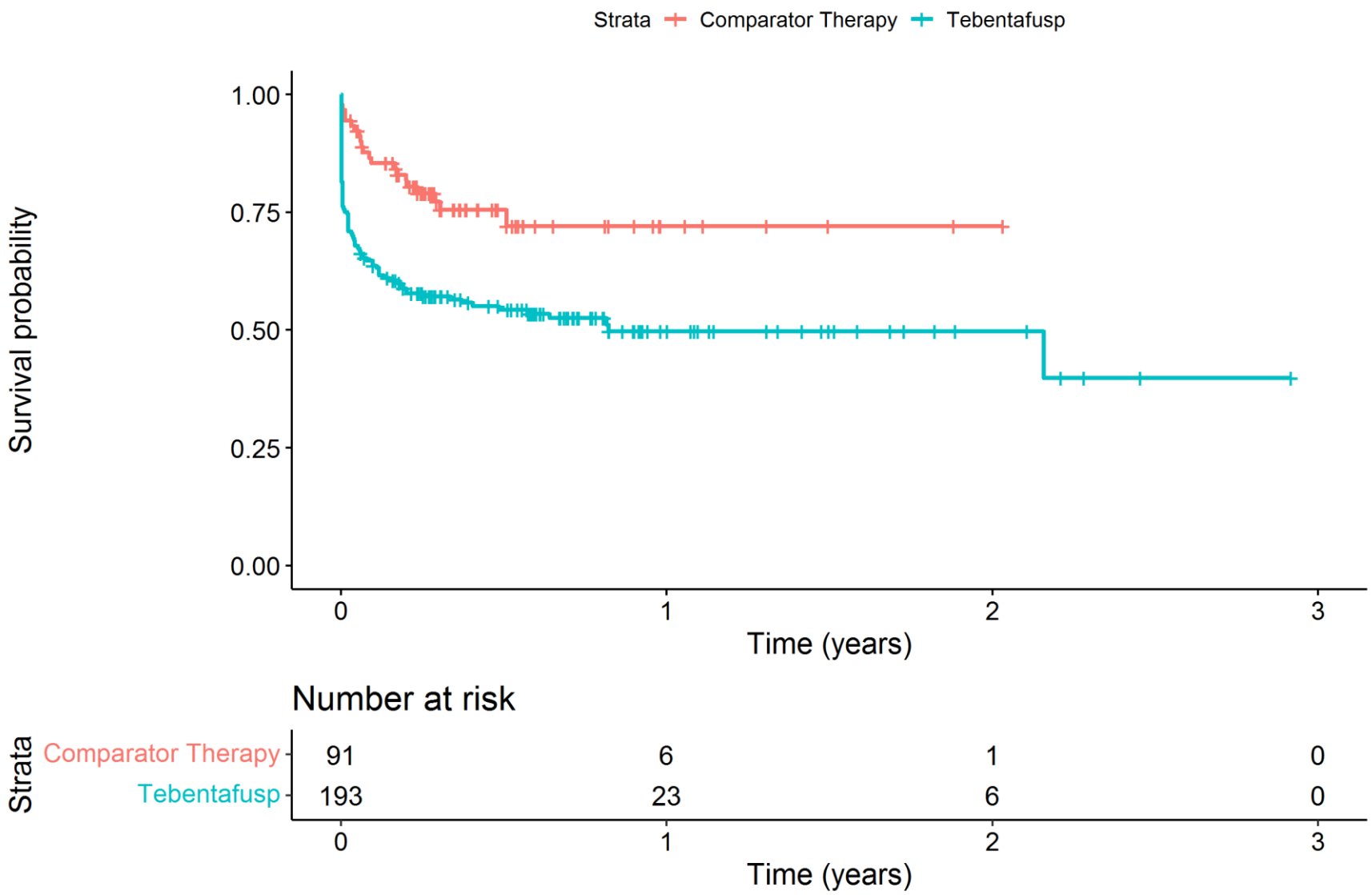
53.85 Übelkeit - Nicht-Nordamerika



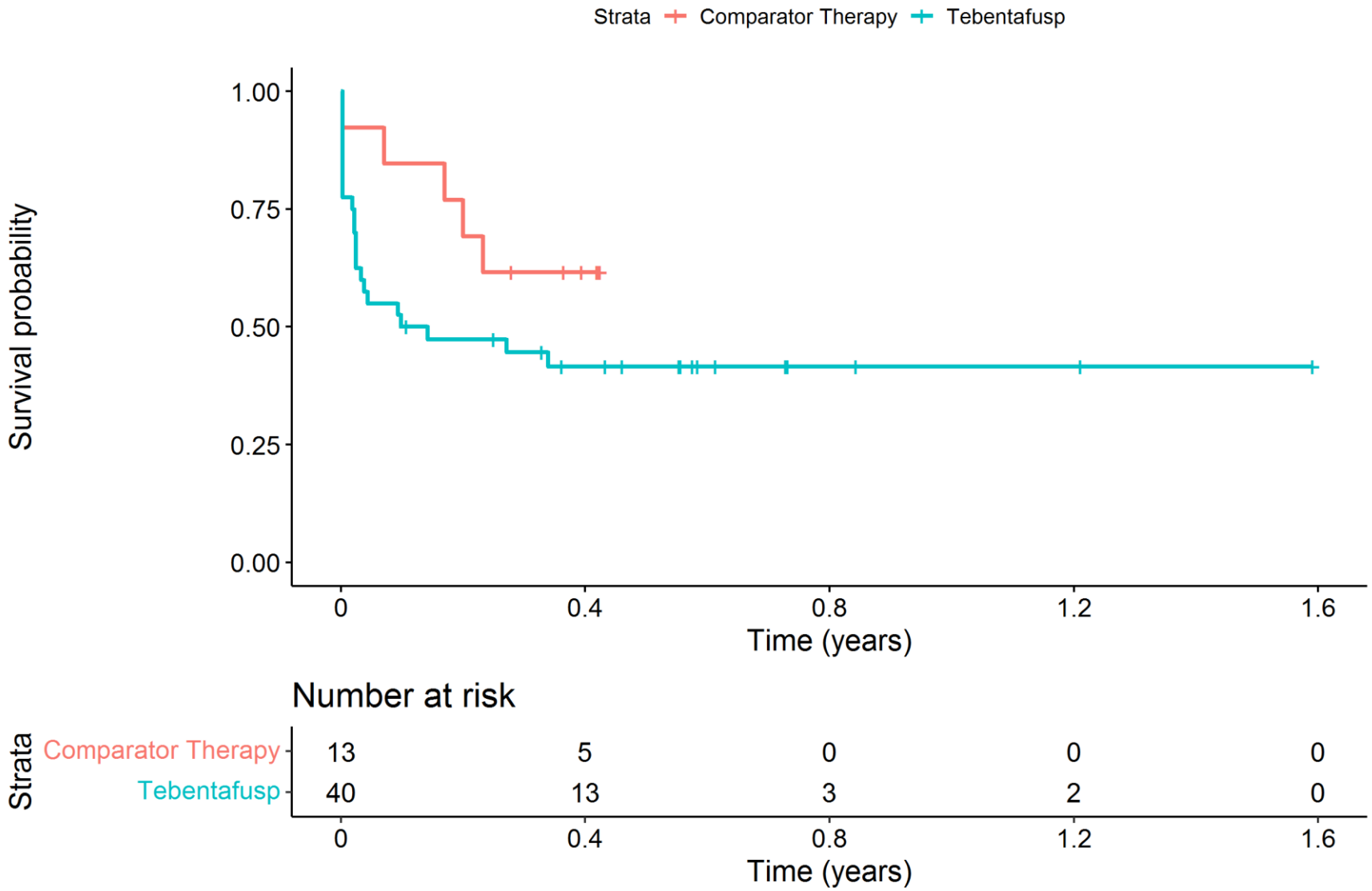
53.86 Übelkeit - Dacarbazin



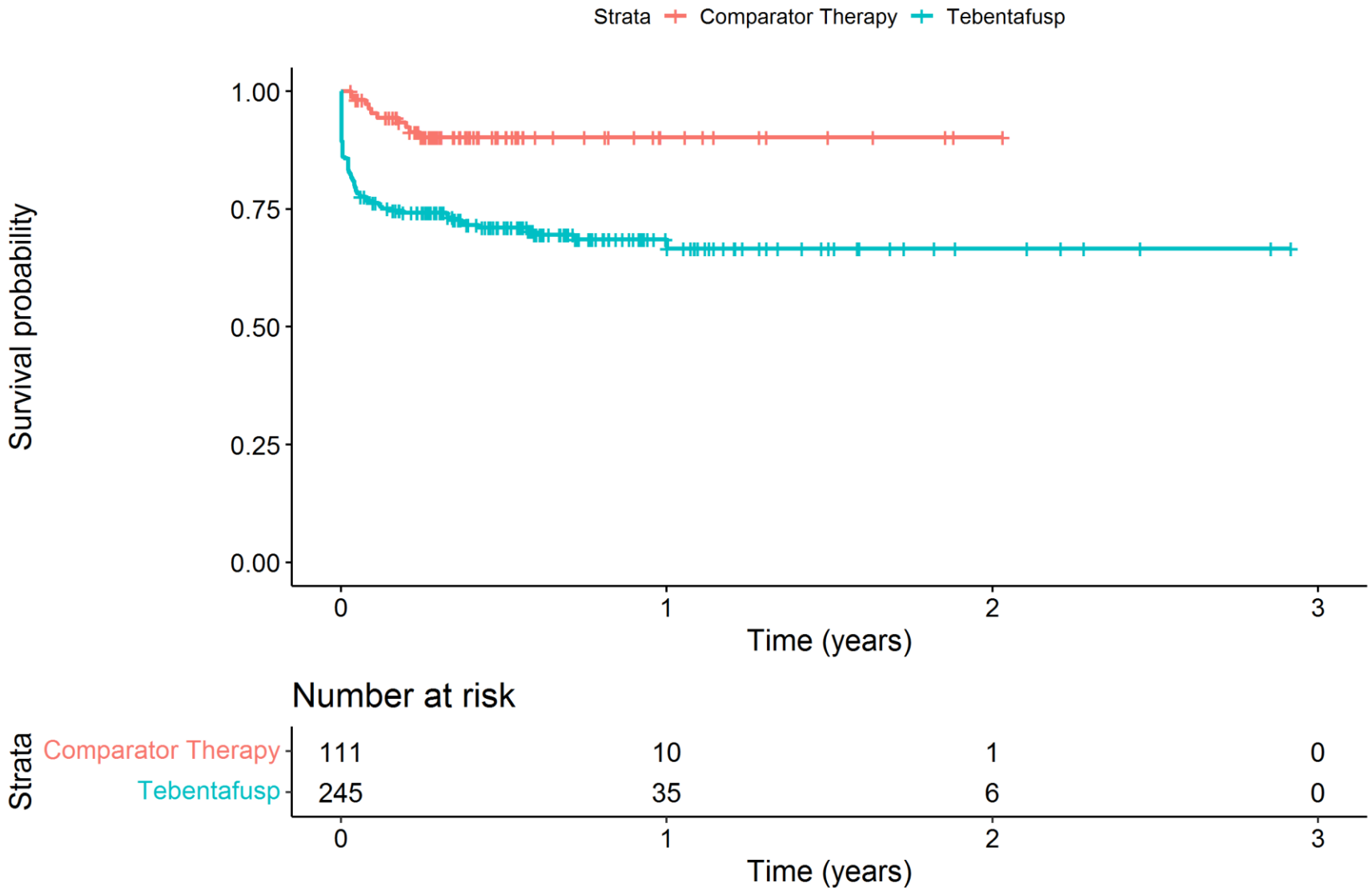
53.87 Übelkeit - Pembrolizumab



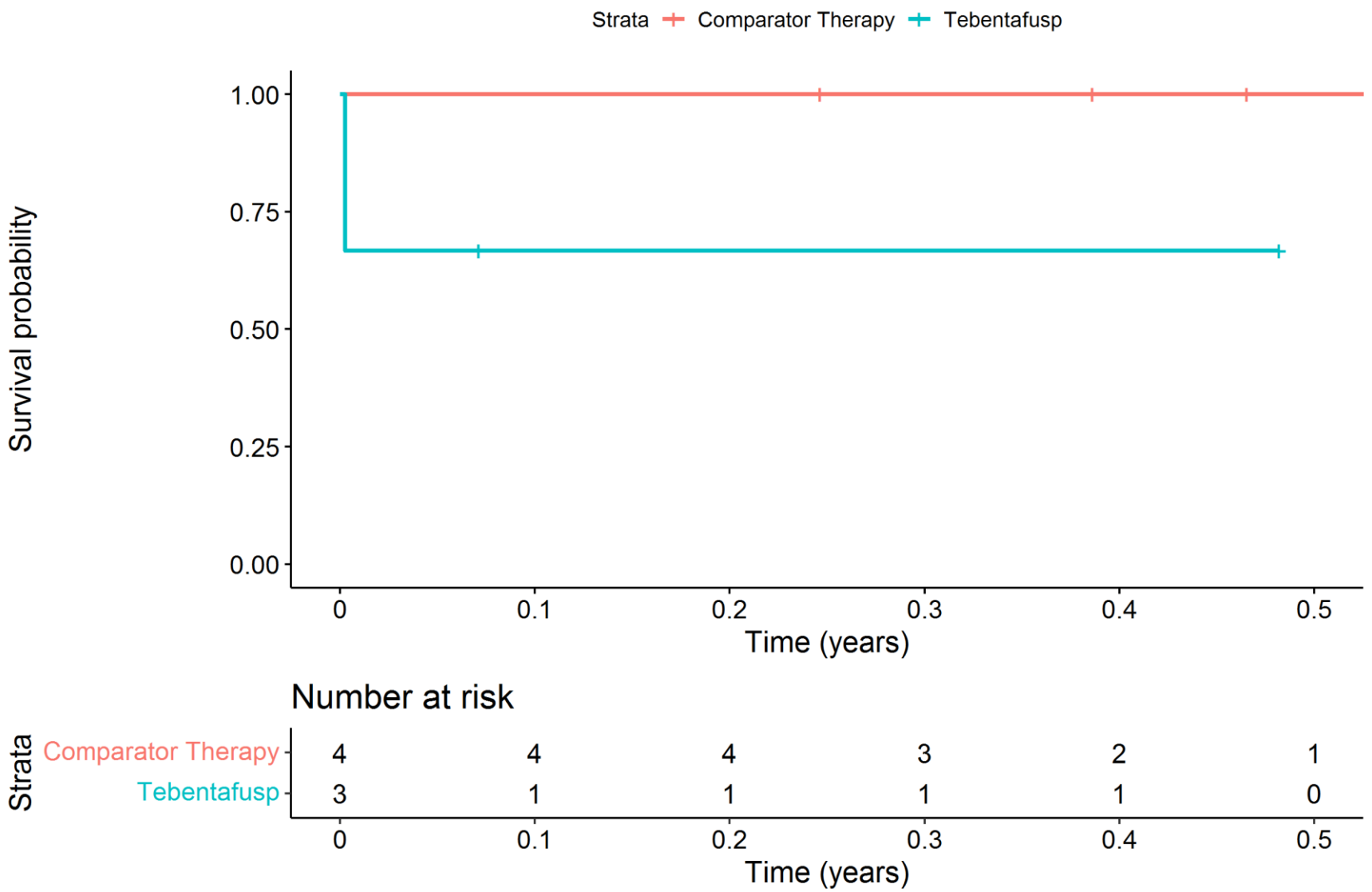
53.88 Übelkeit - Ipilimumab



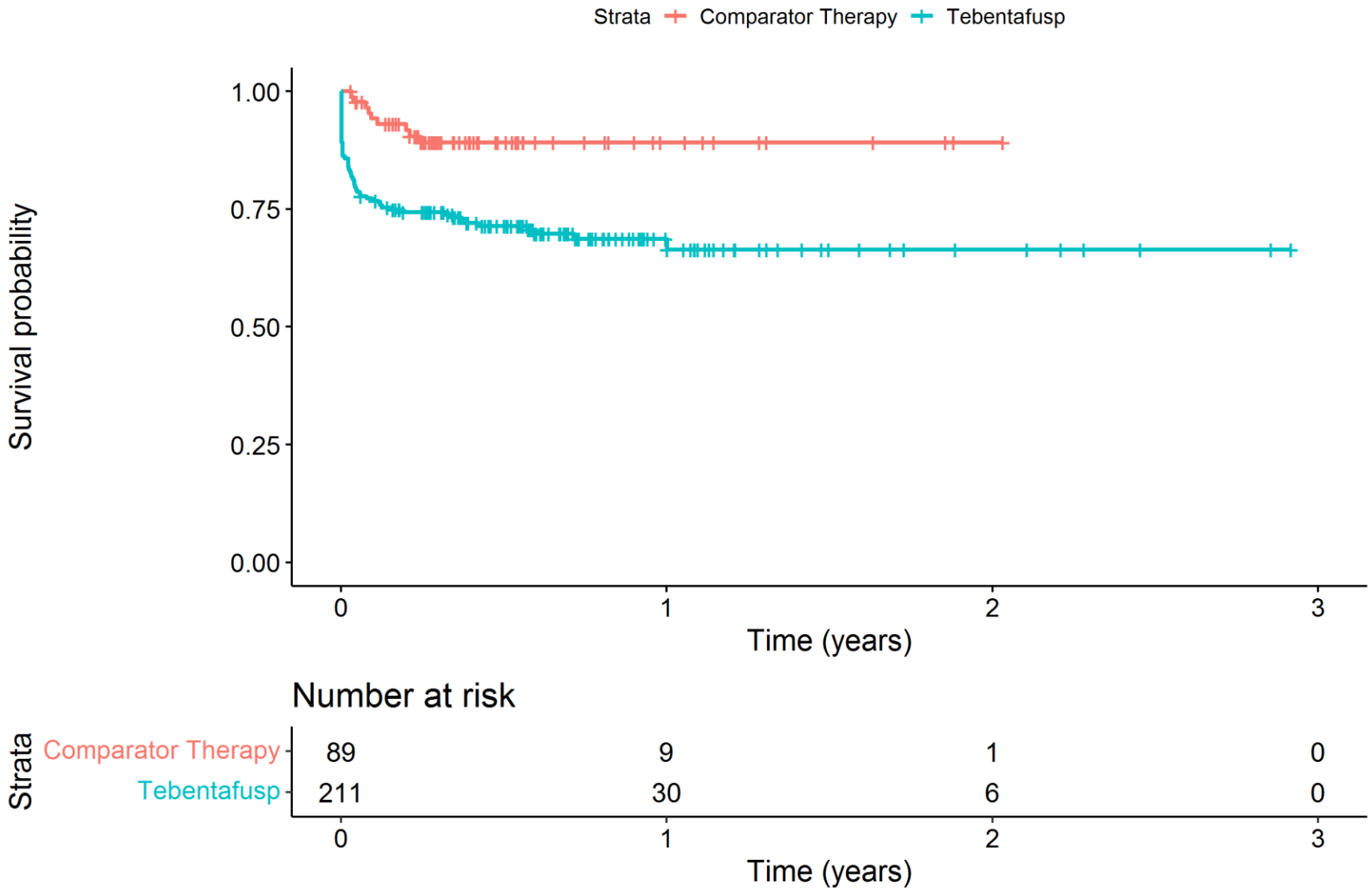
53.89 Erbrechen - Gesamt



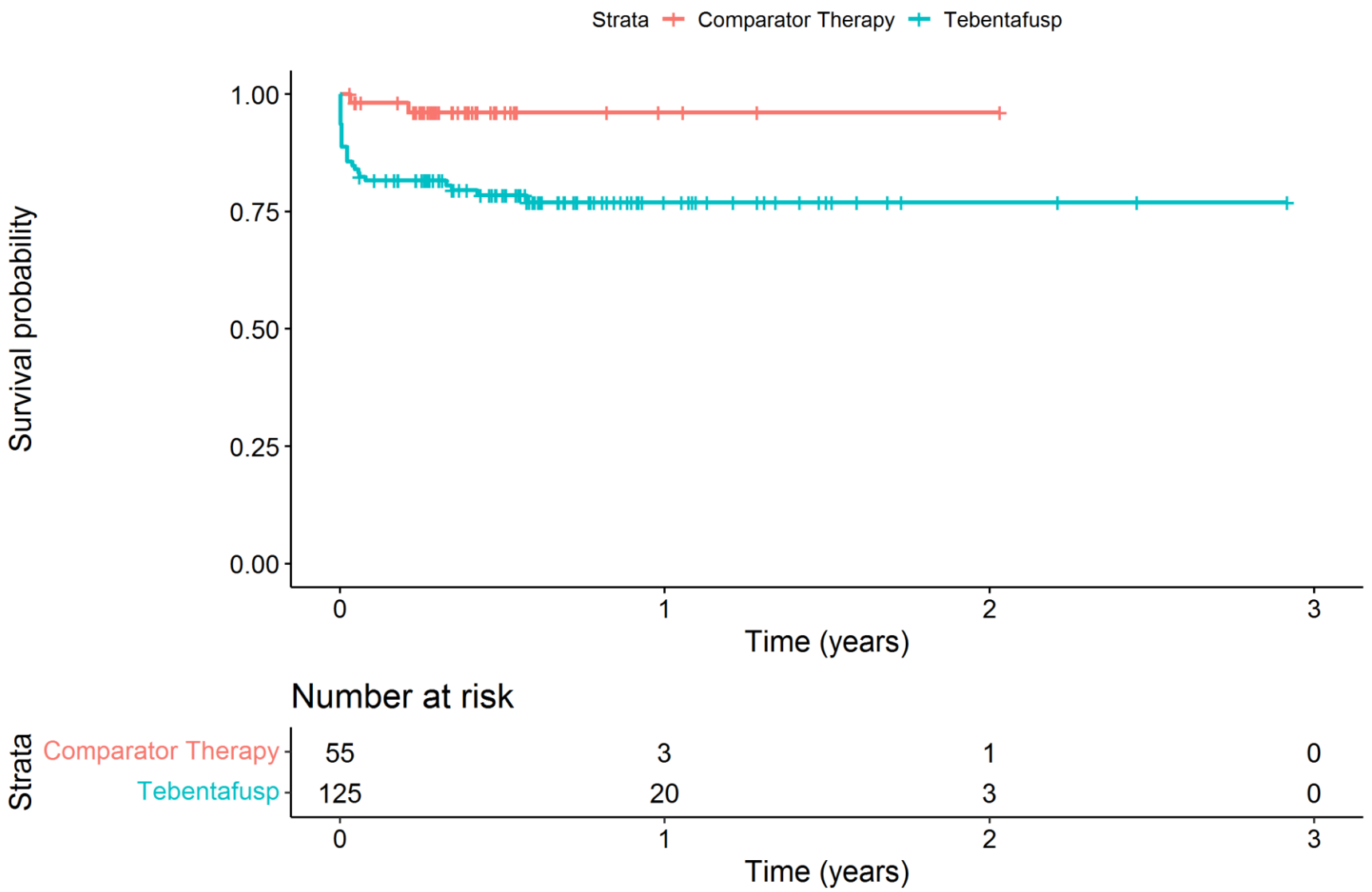
53.90 Erbrechen - Hispanisch



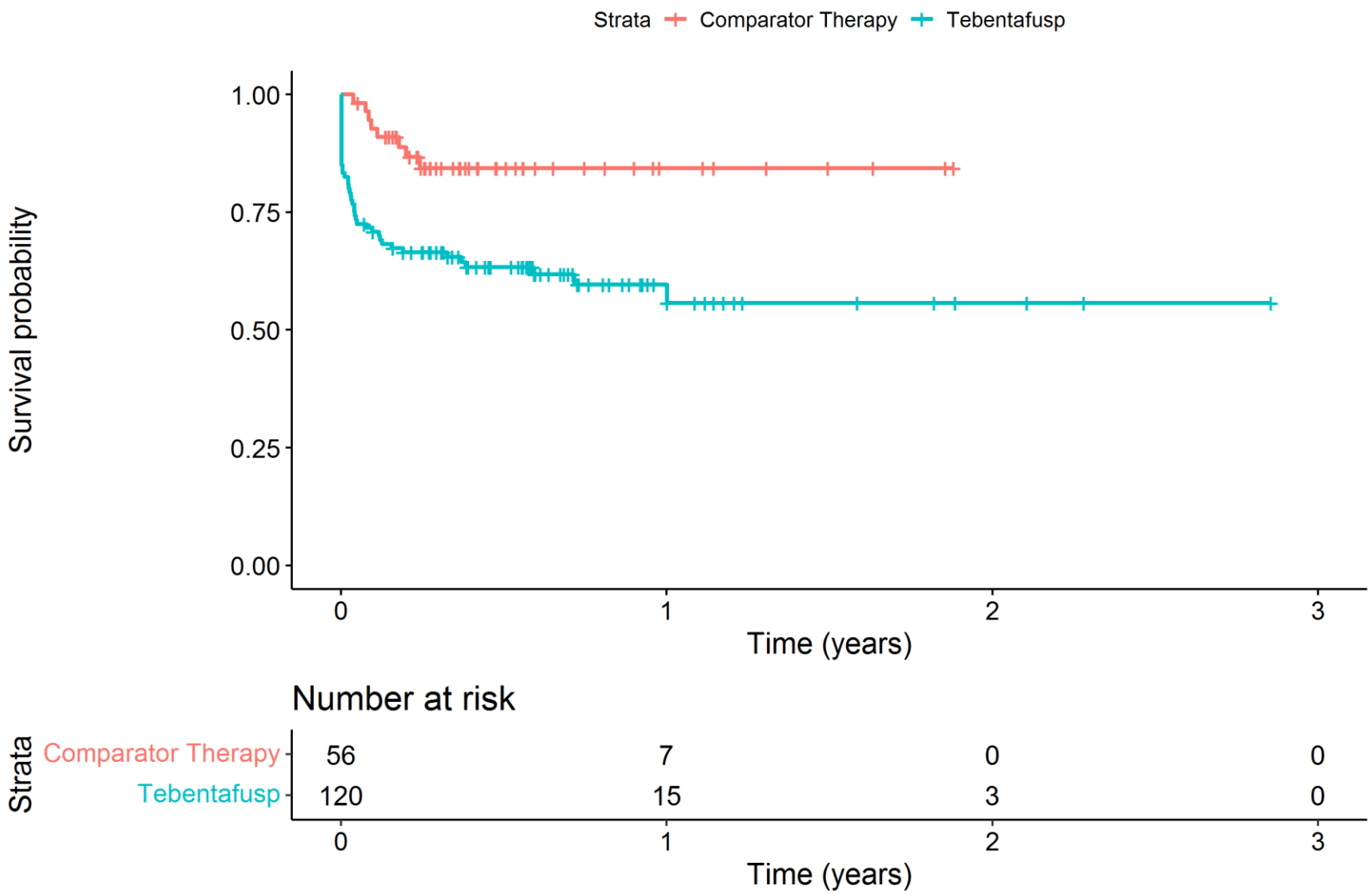
53.91 Erbrechen - Nicht-hispanisch



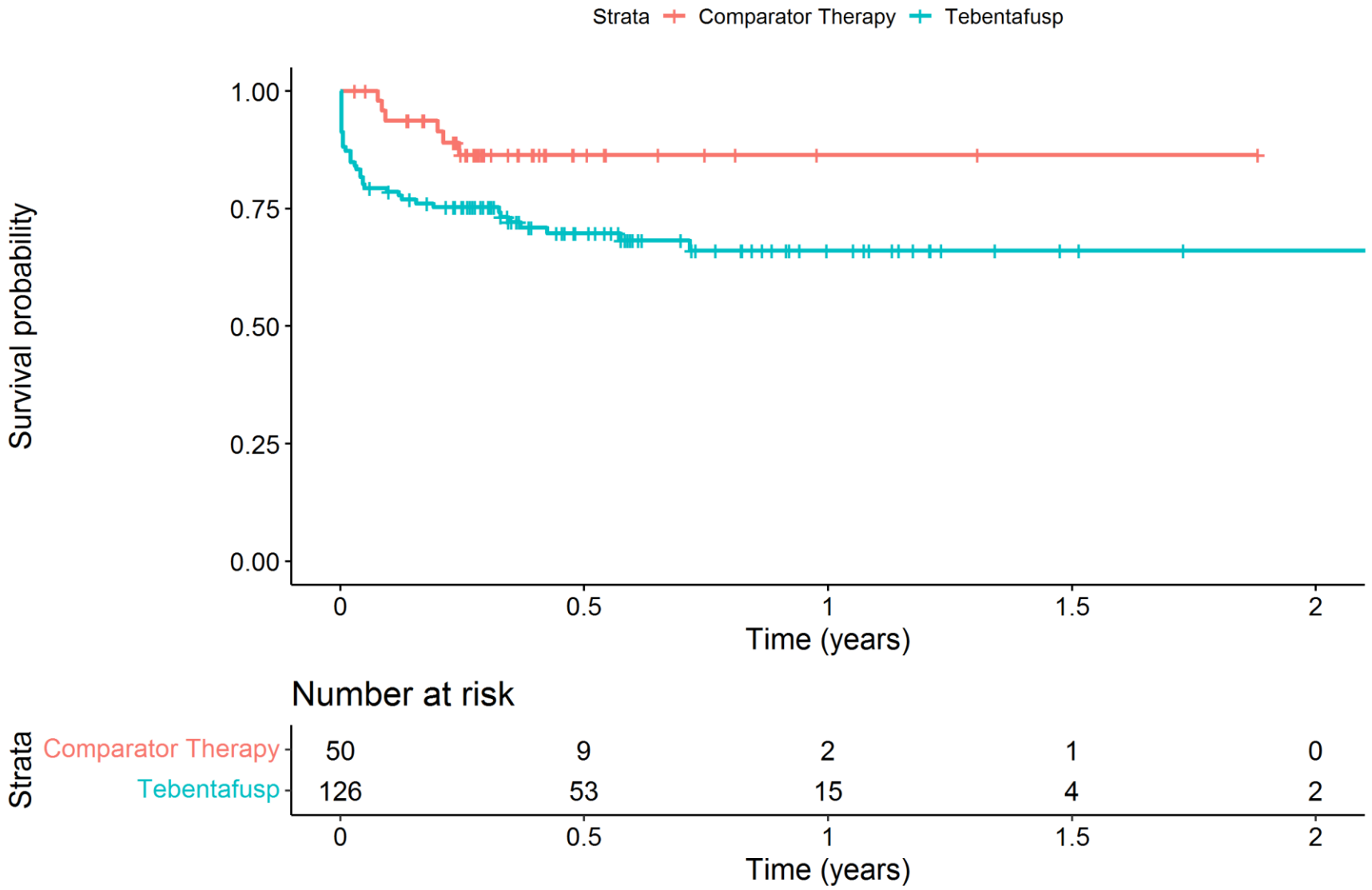
53.92 Erbrechen - Männlich



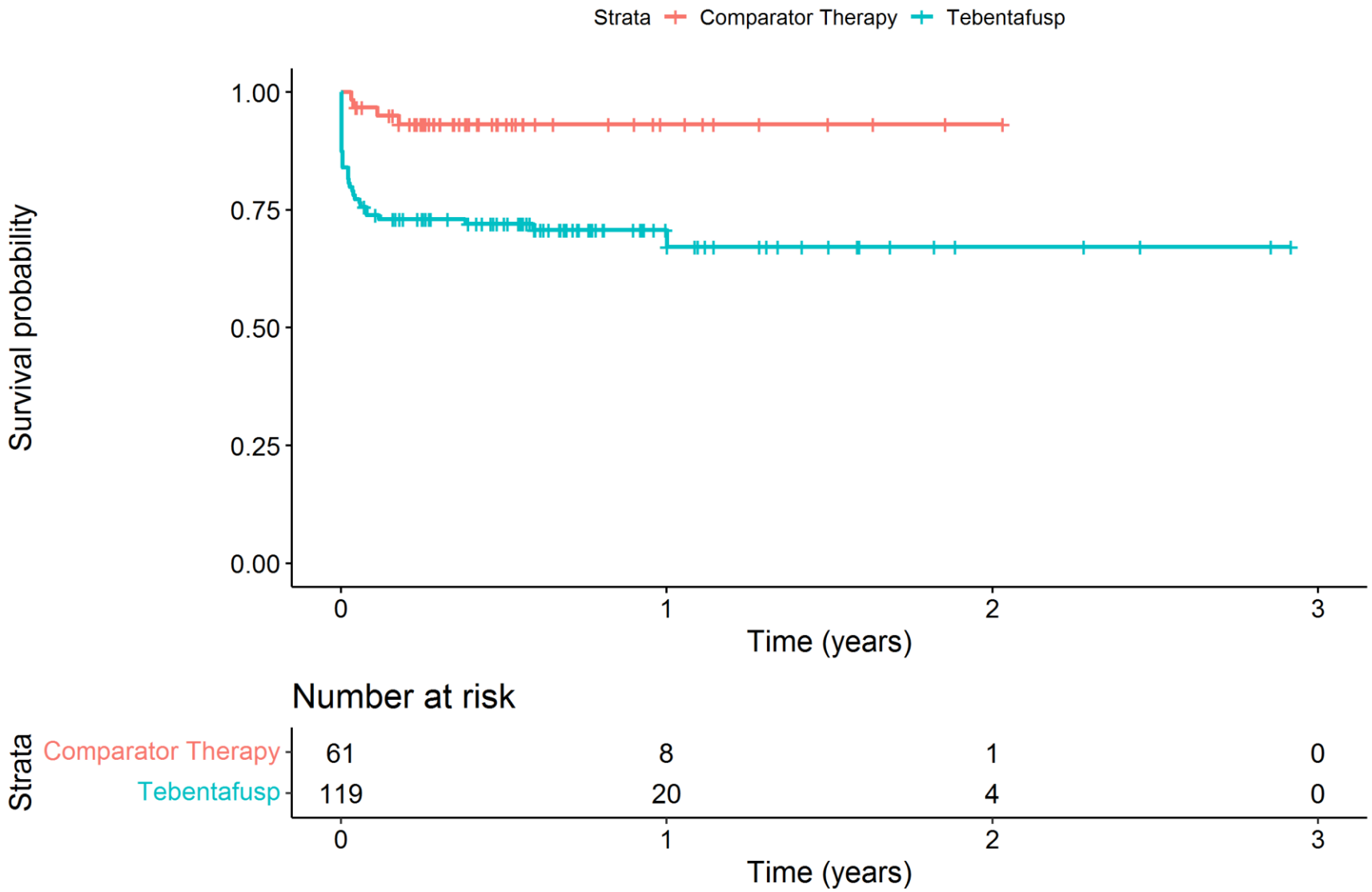
53.93 Erbrechen - Weiblich



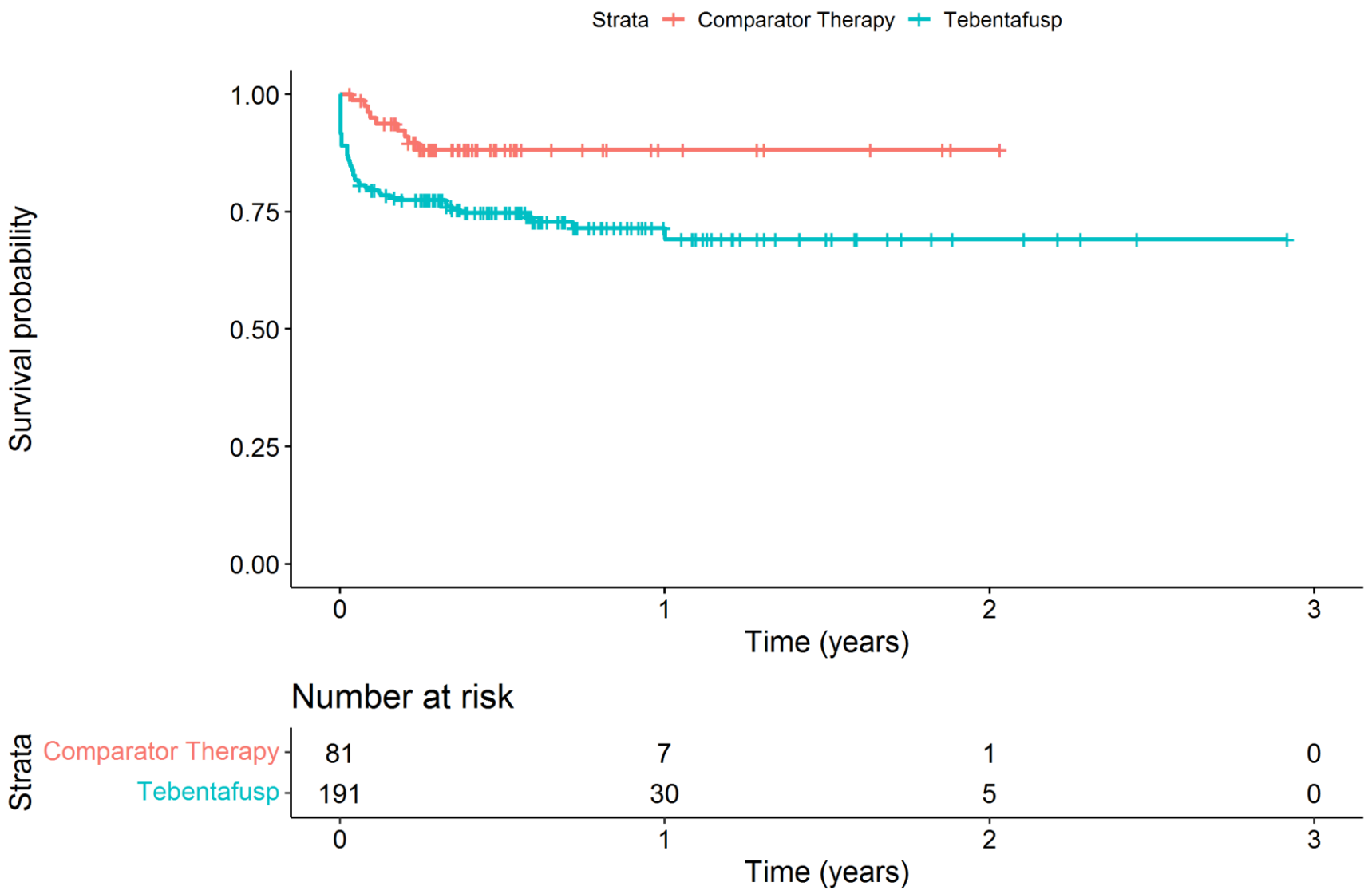
53.94 Erbrechen - <65



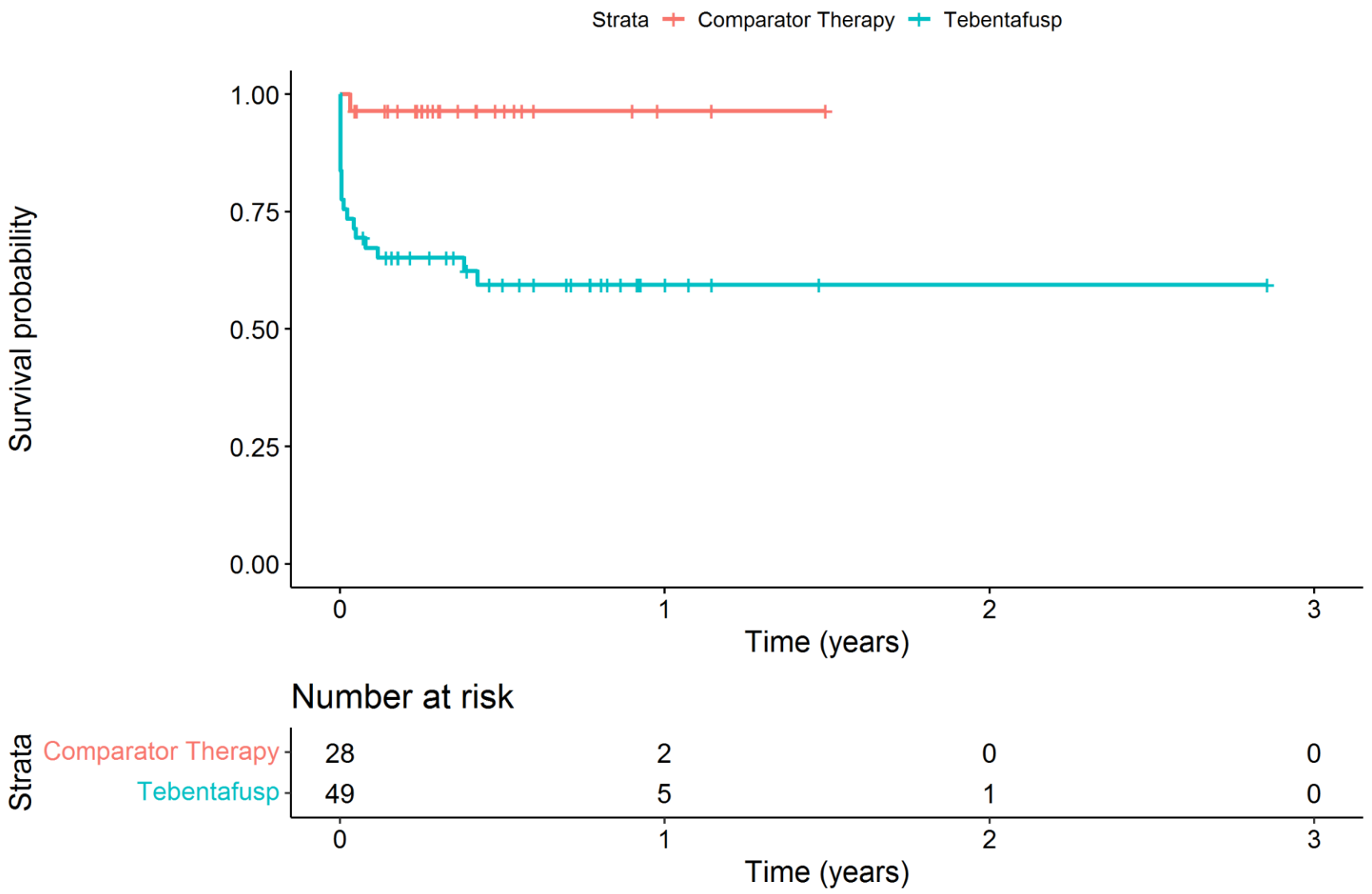
53.95 Erbrechen - ≥65



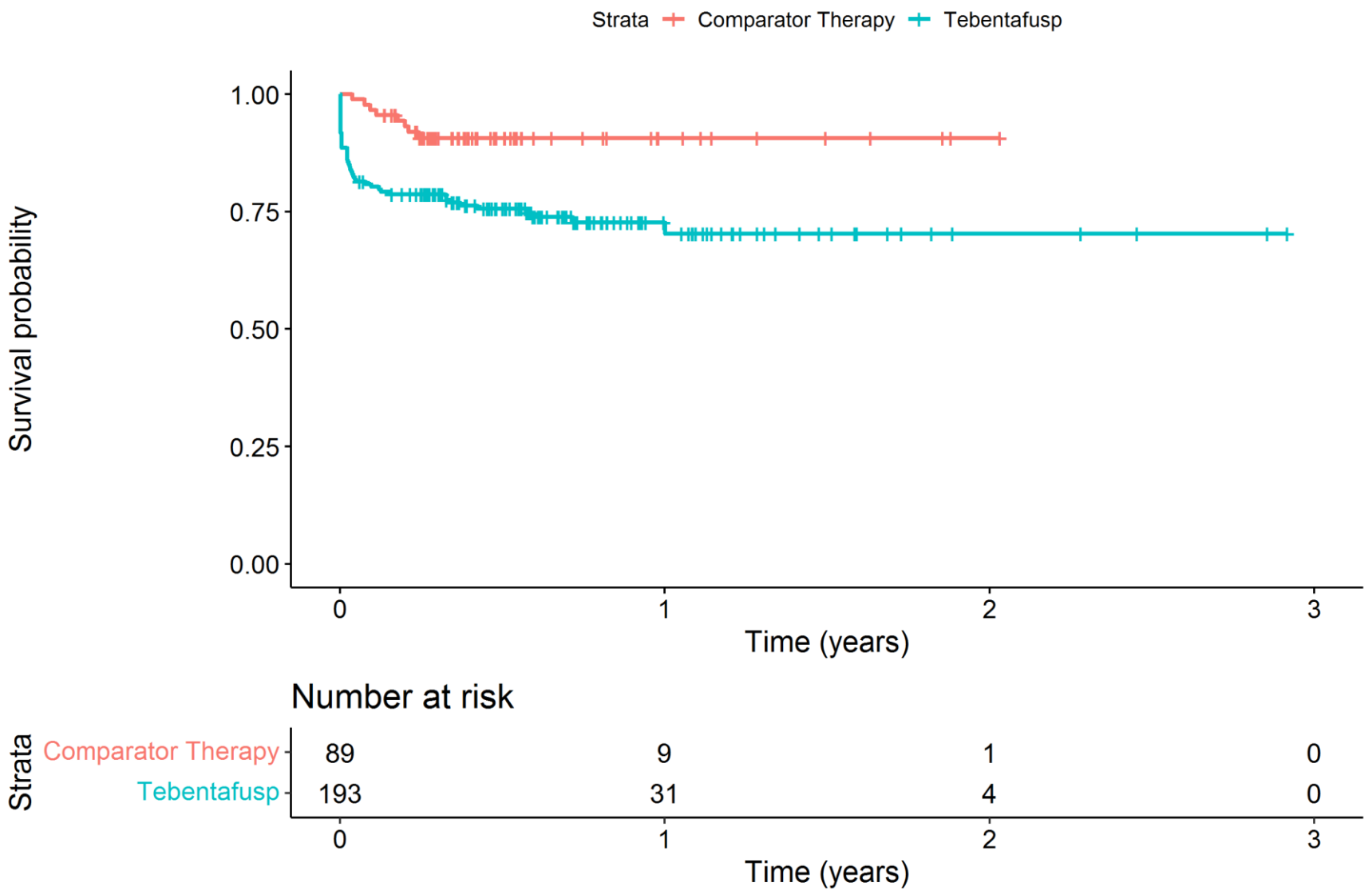
53.96 Erbrechen - ECOG 0



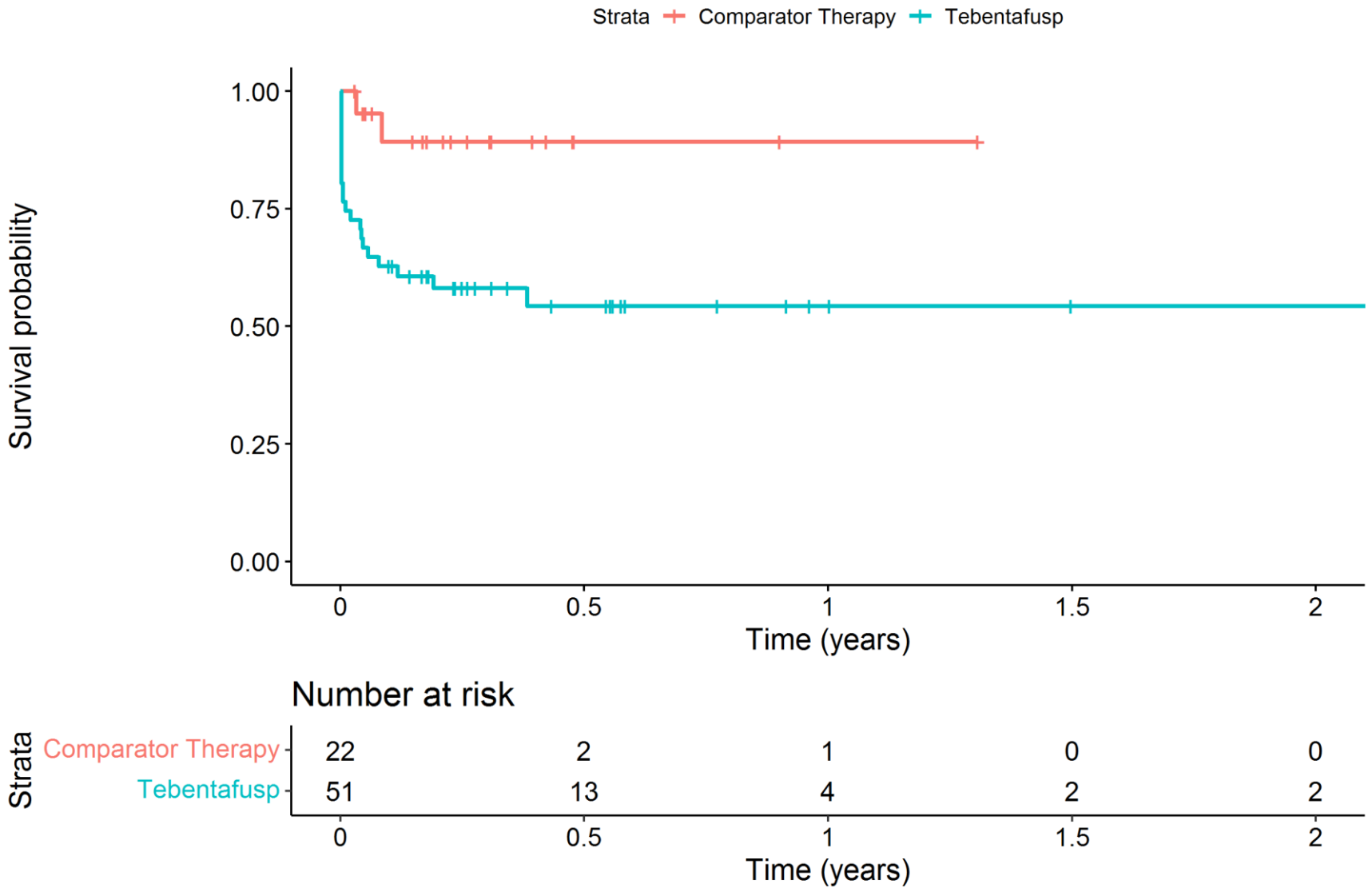
53.97 Erbrechen - ECOG 1



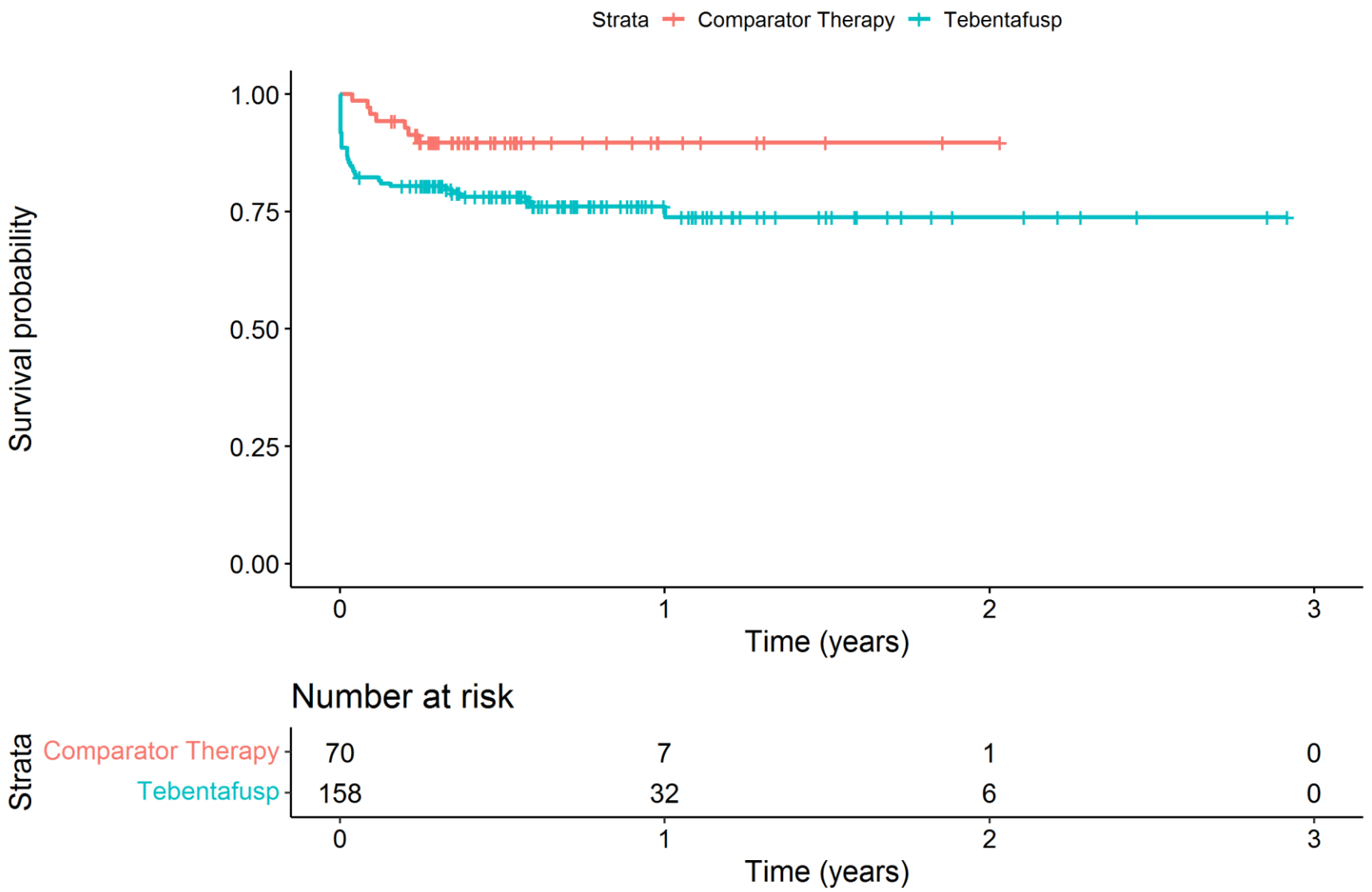
53.98 Erbrechen - ALP ≤ ULN



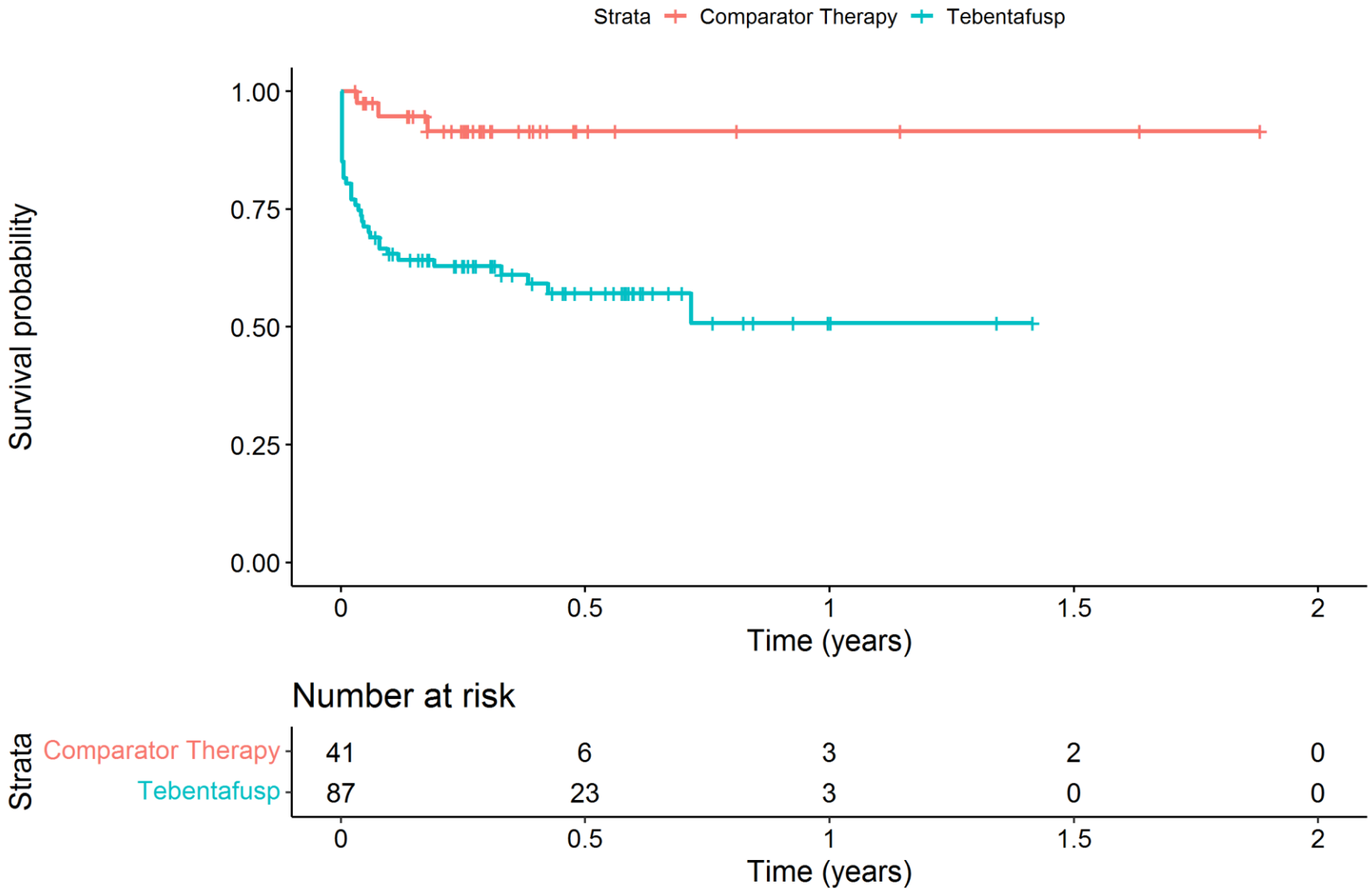
53.99 Erbrechen - ALP > ULN



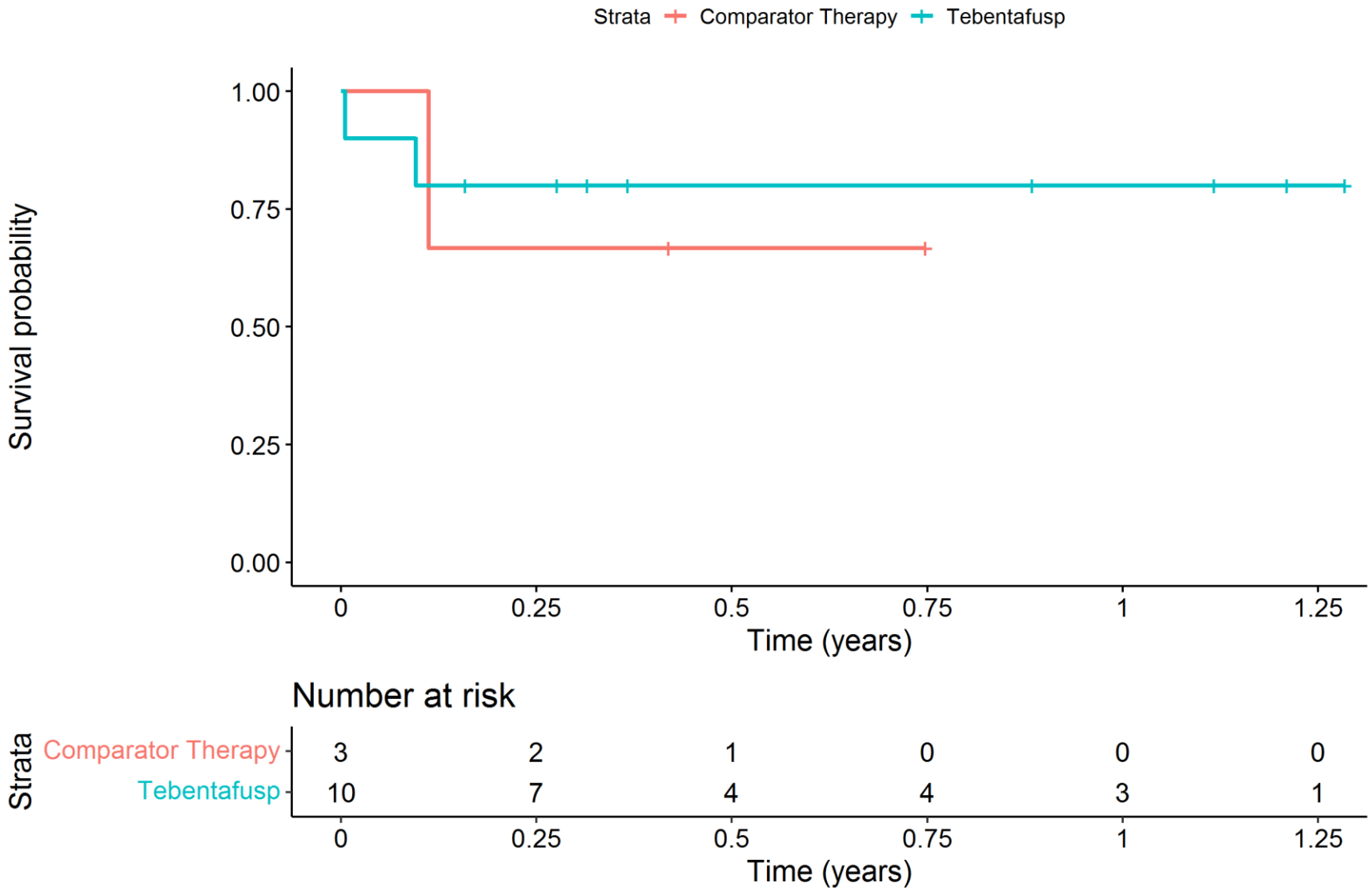
53.100 Erbrechen - LDH =< ULN



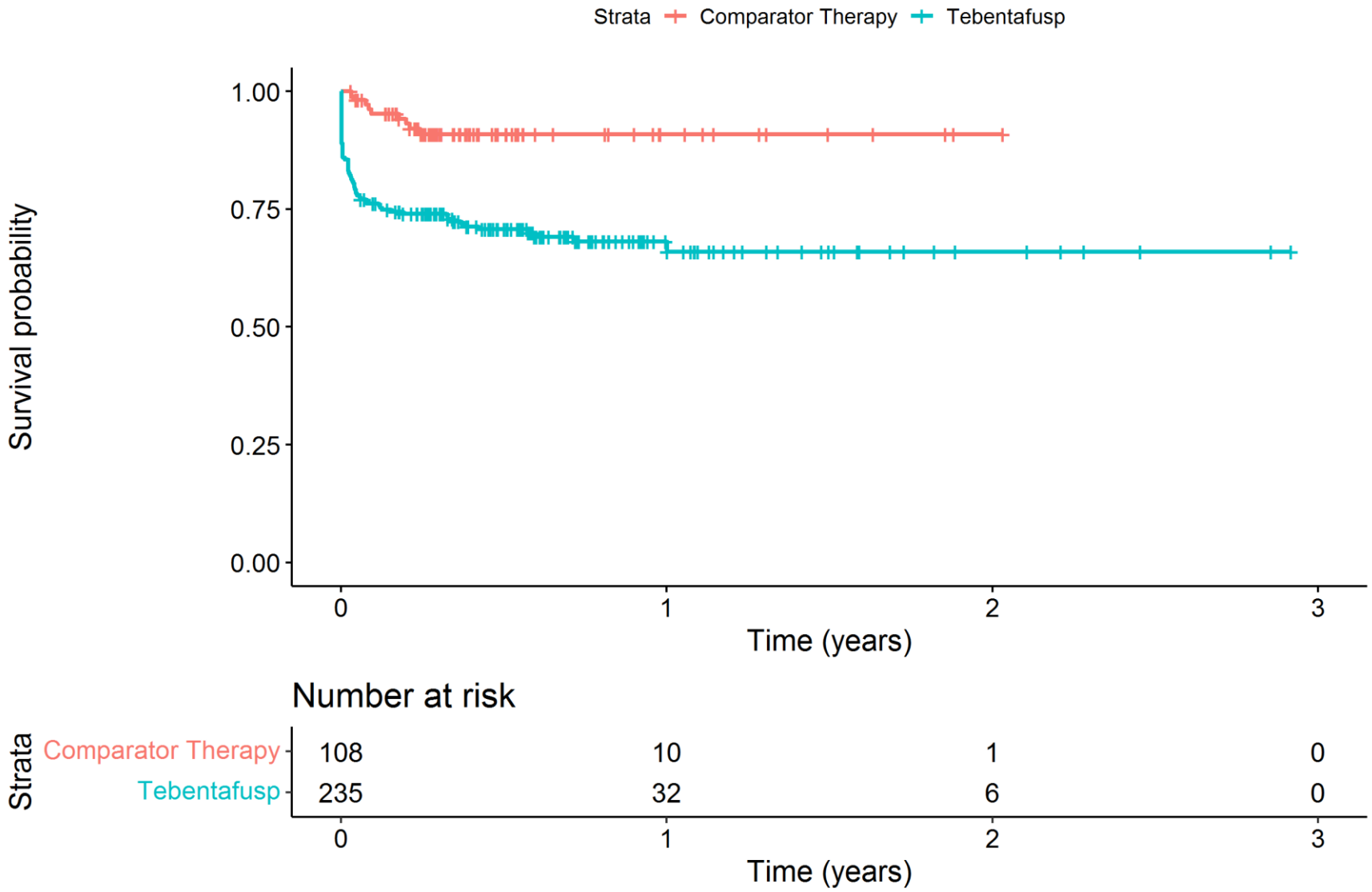
53.101 Erbrechen - LDH > ULN



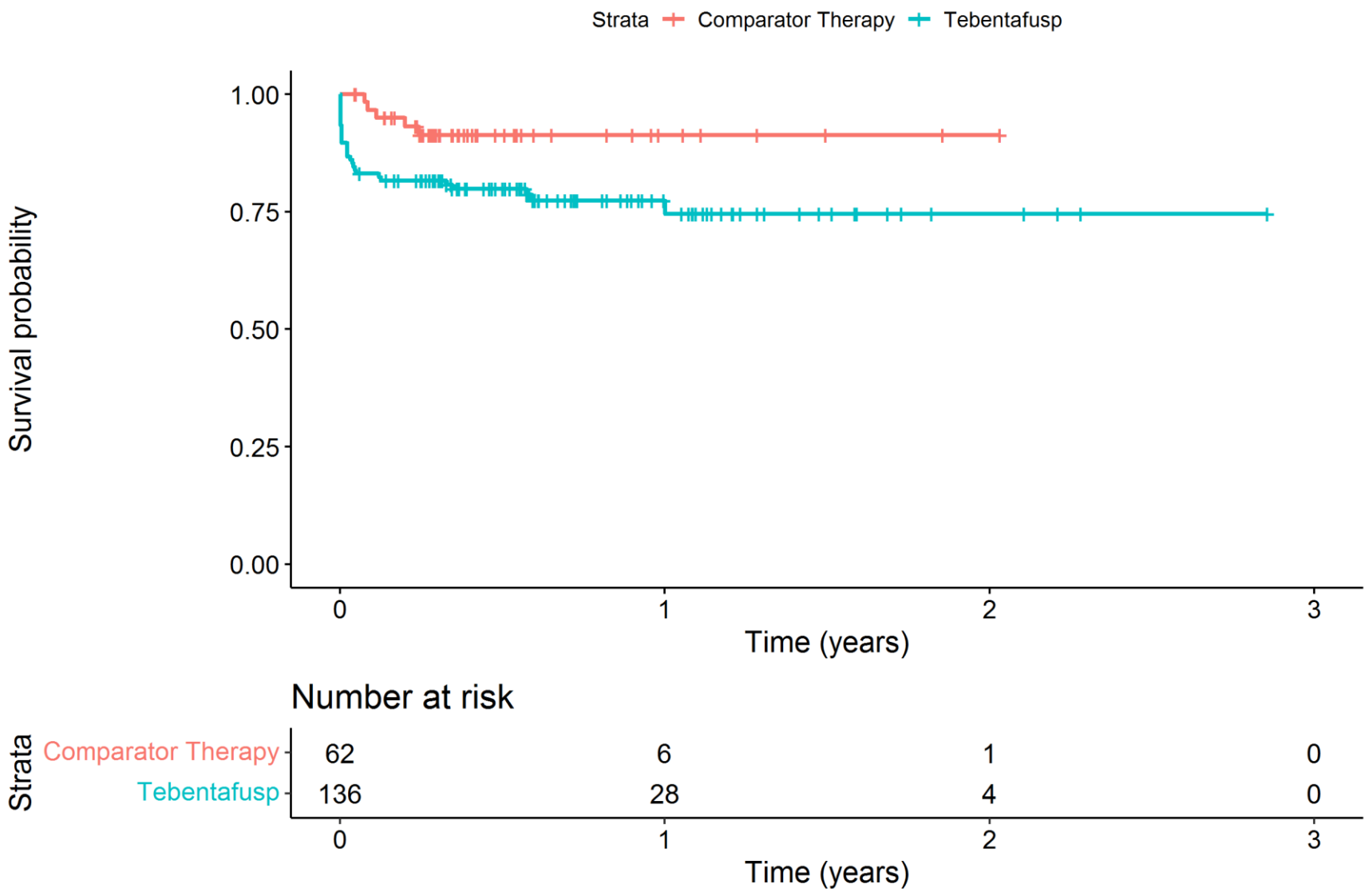
53.102 Erbrechen - Vorherige Therapie adjuvant/neoadjuvant



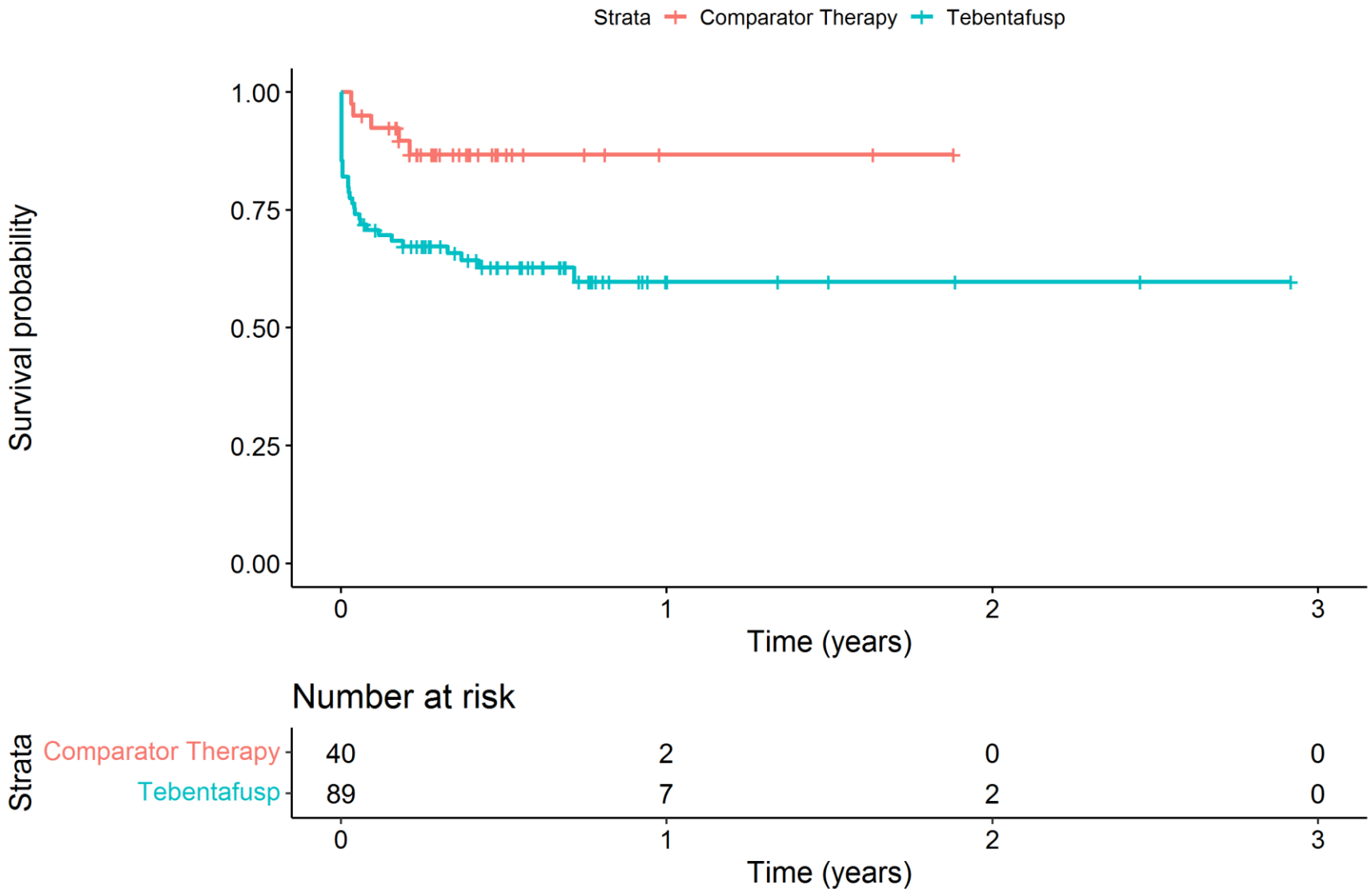
53.103 Erbrechen - Keine vorherige Therapie adjuvant/neoadjuvant



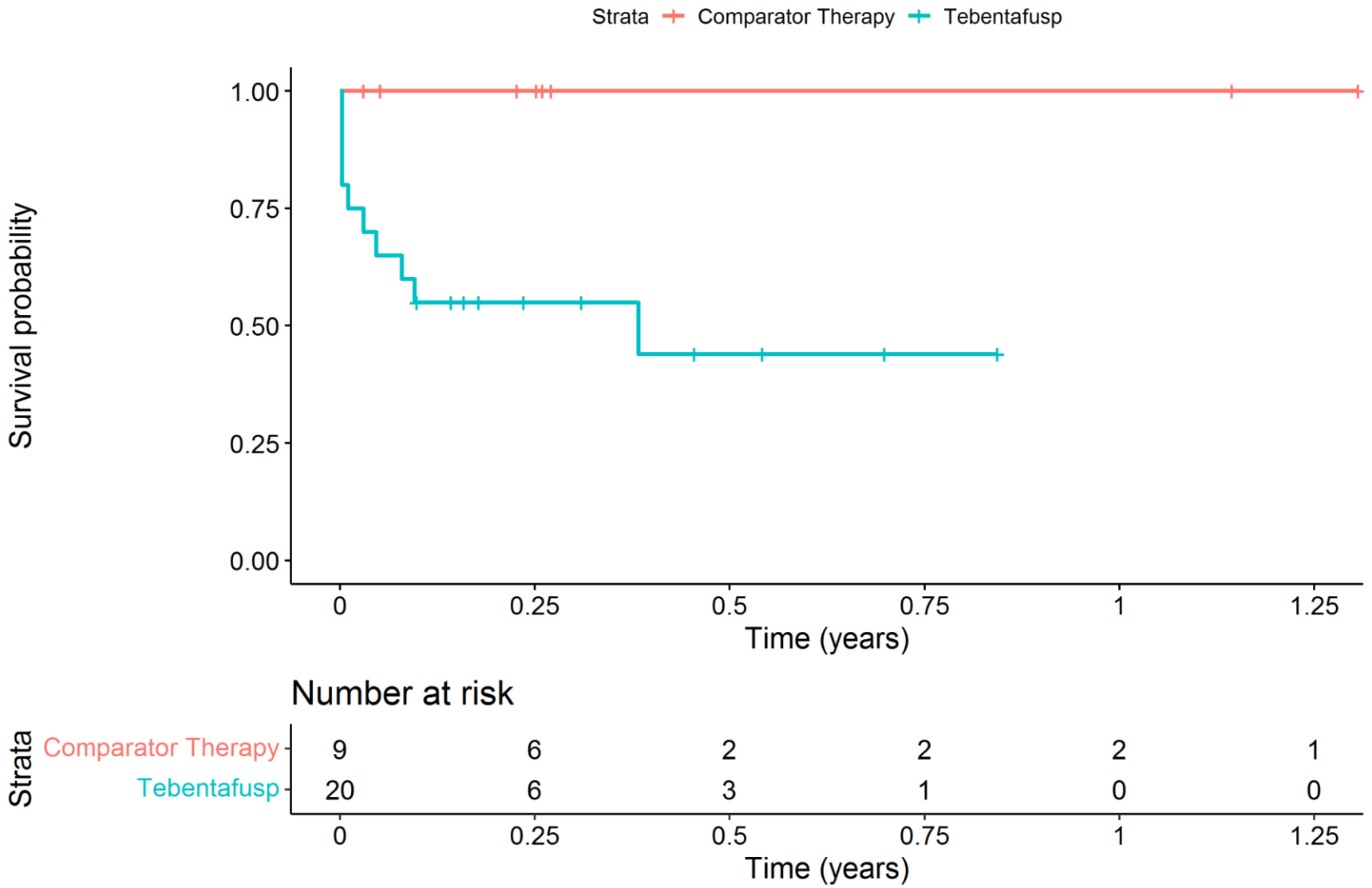
53.104 Erbrechen - Läsion ≤ 3cm



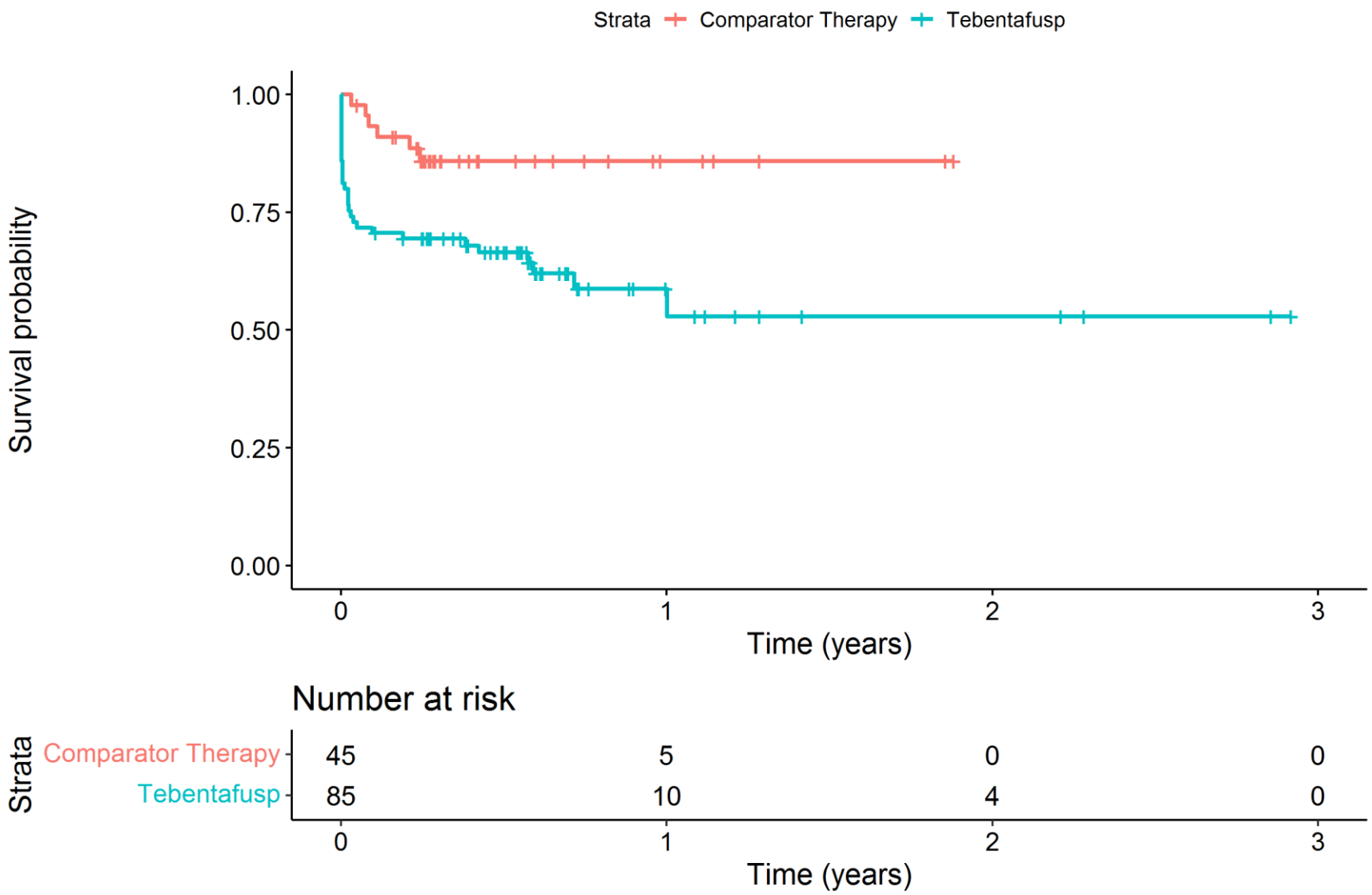
53.105 Erbrechen - Läsion 3,1-8,0 cm



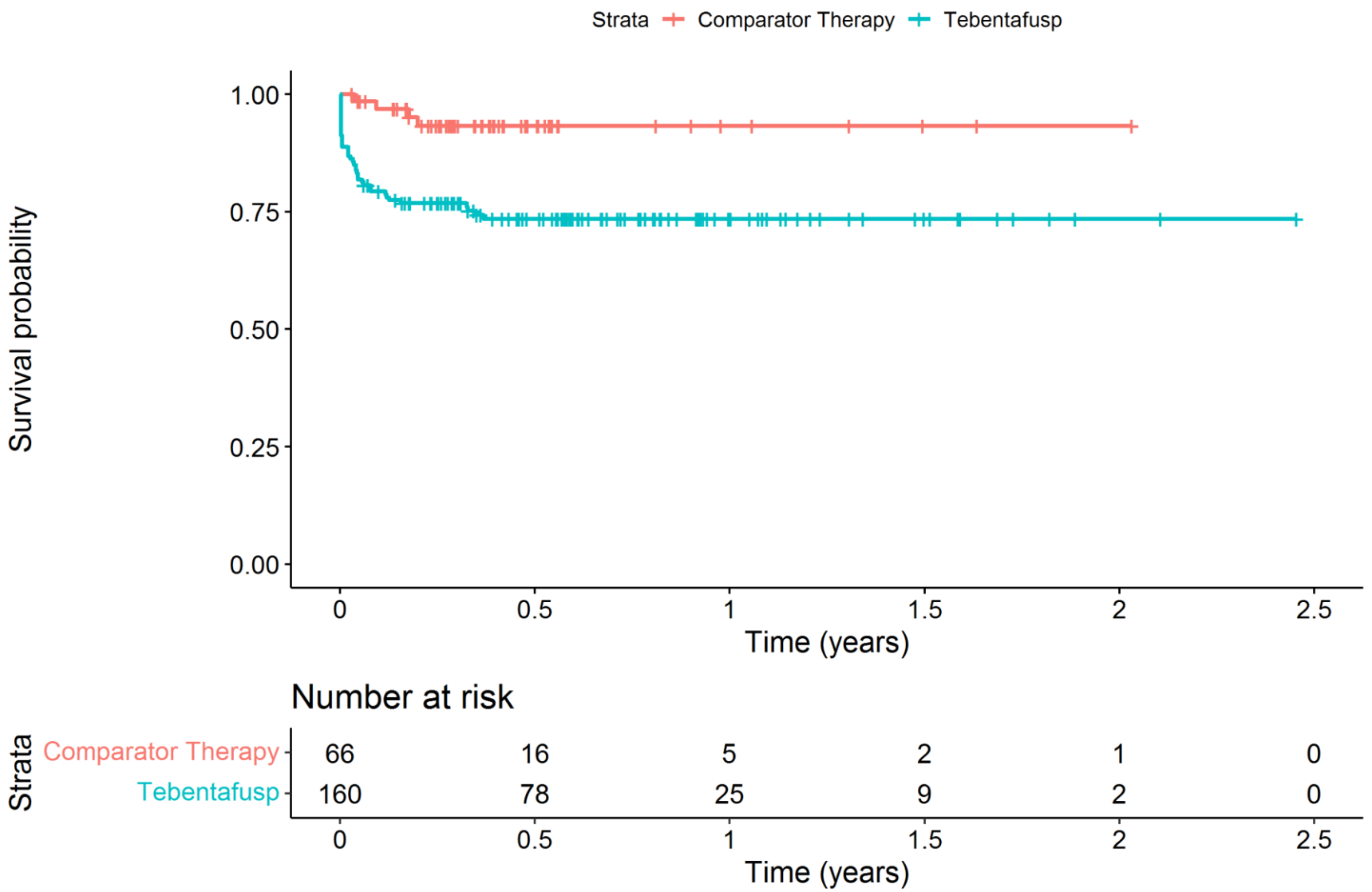
53.106 Erbrechen - Läsion ≥8,1 cm



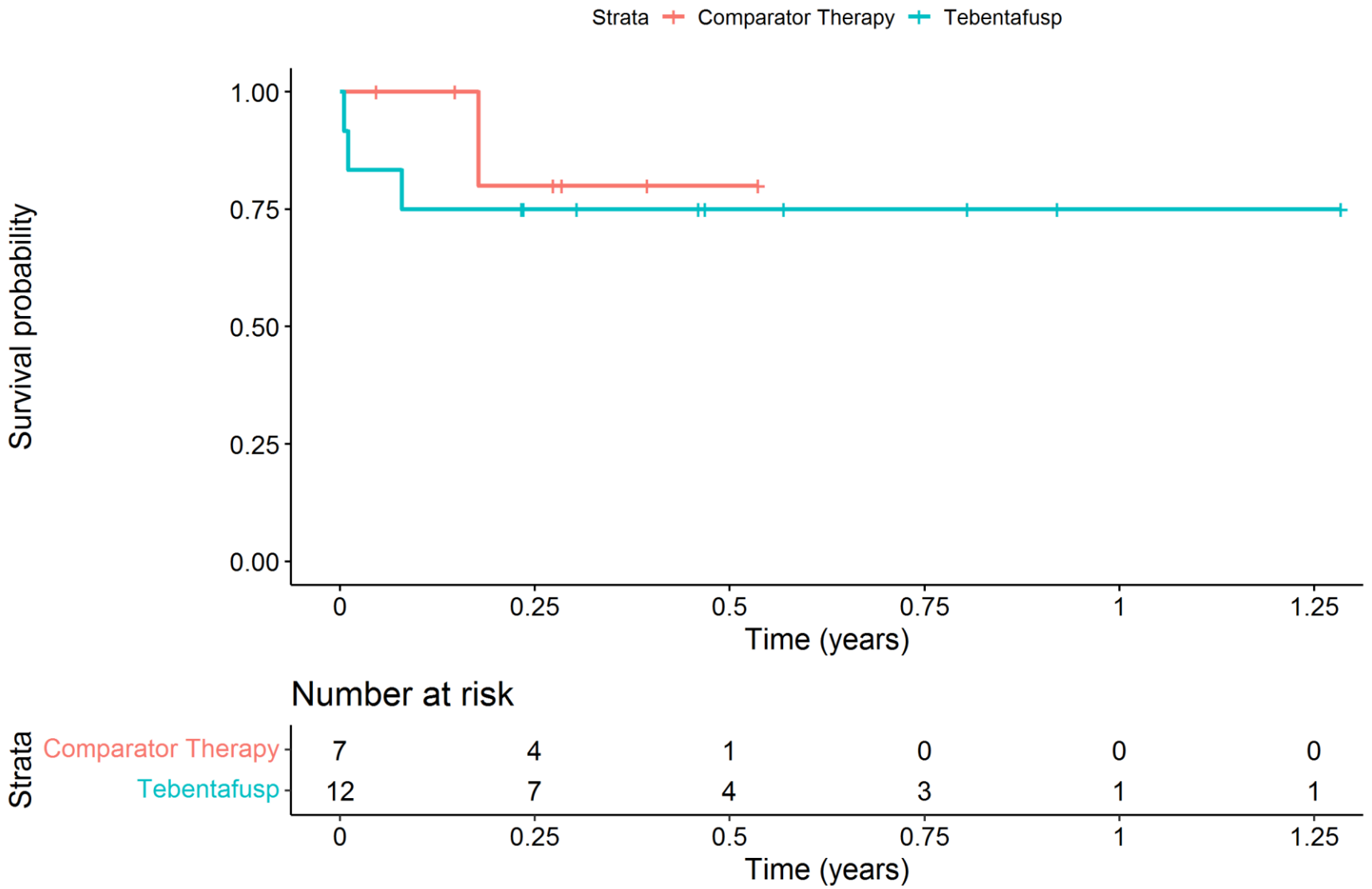
53.107 Erbrechen - Nordamerika



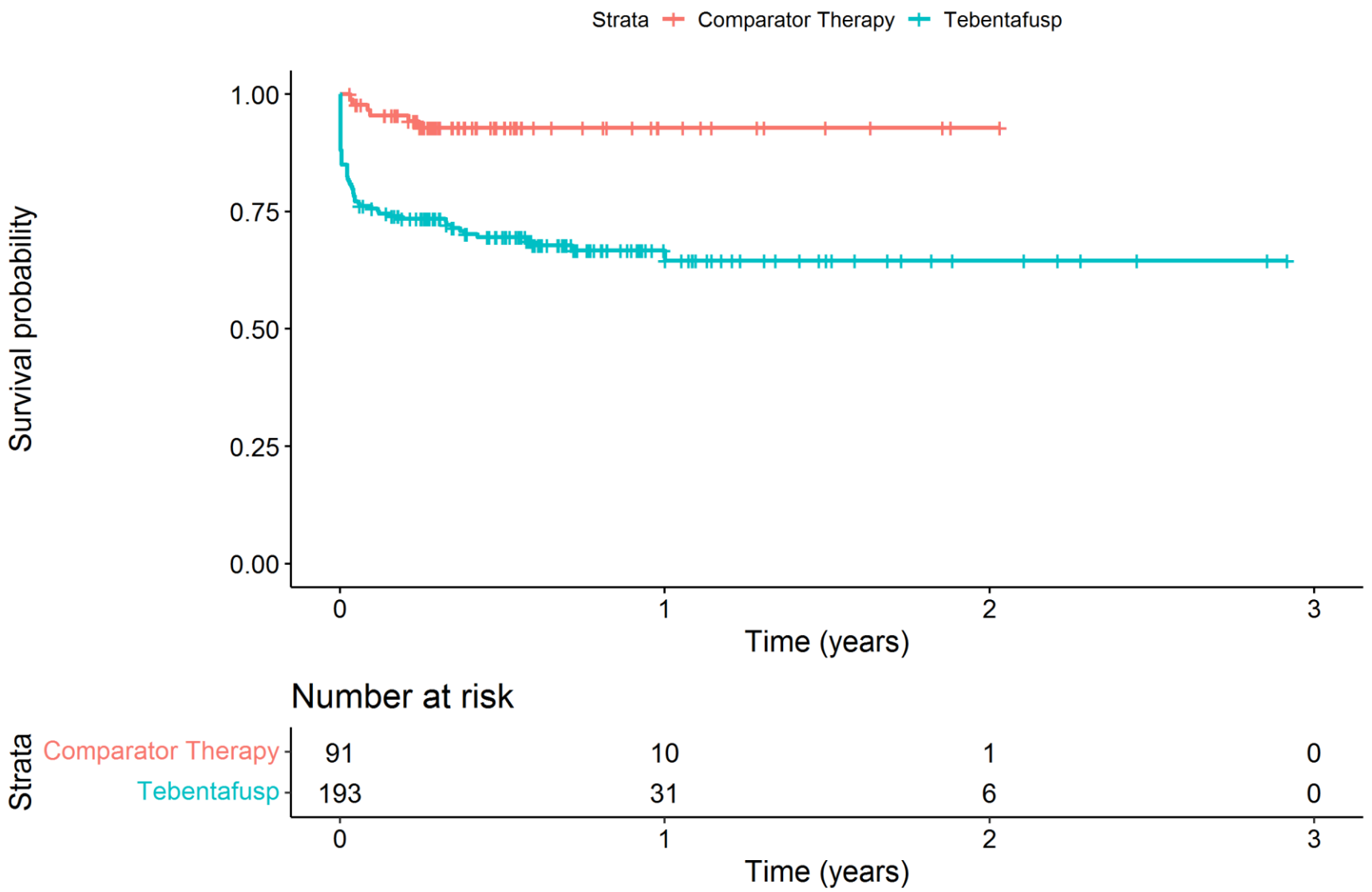
53.108 Erbrechen - Nicht-Nordamerika



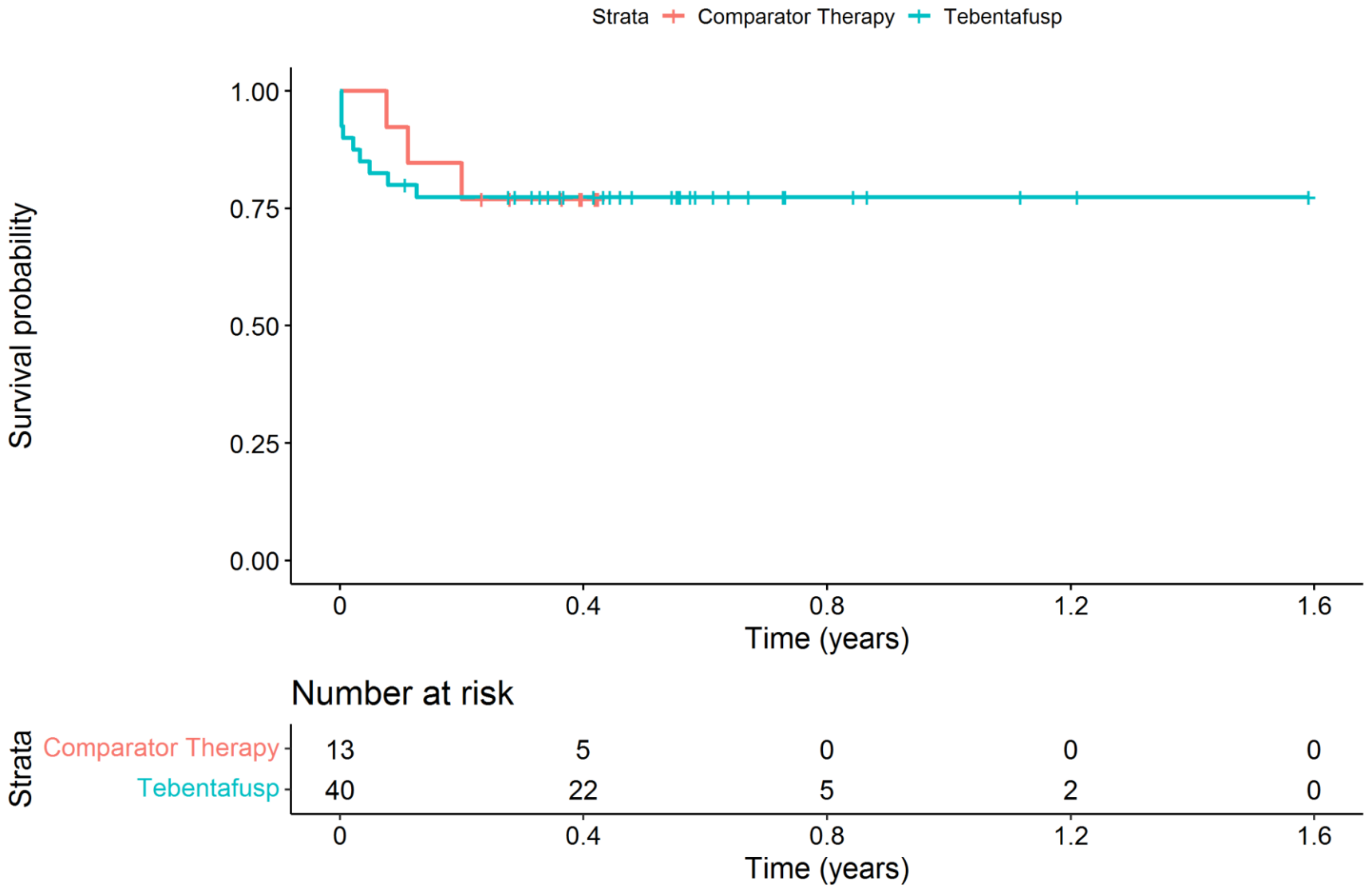
53.109 Erbrechen - Dacarbazin



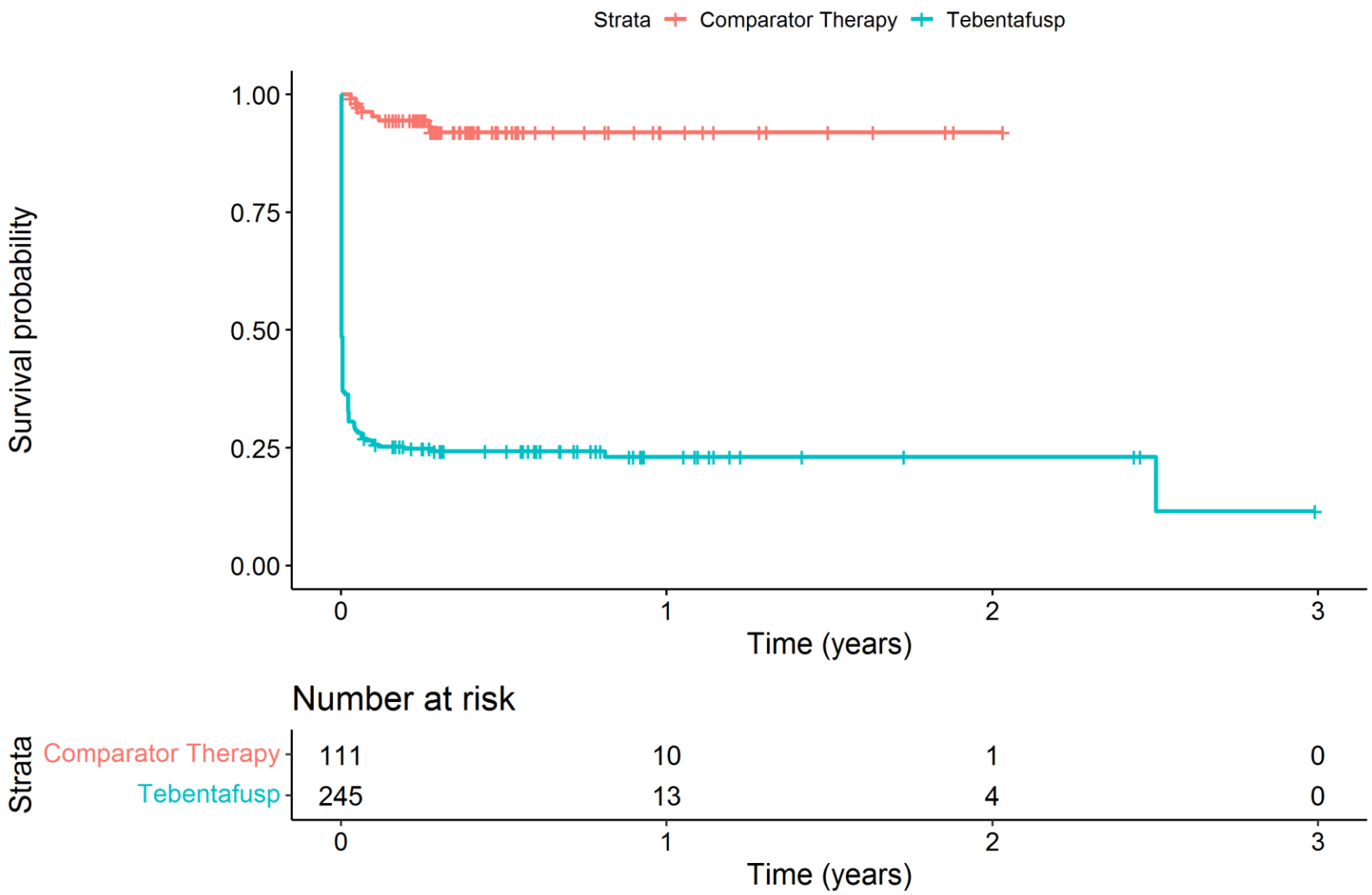
53.110 Erbrechen - Pembrolizumab



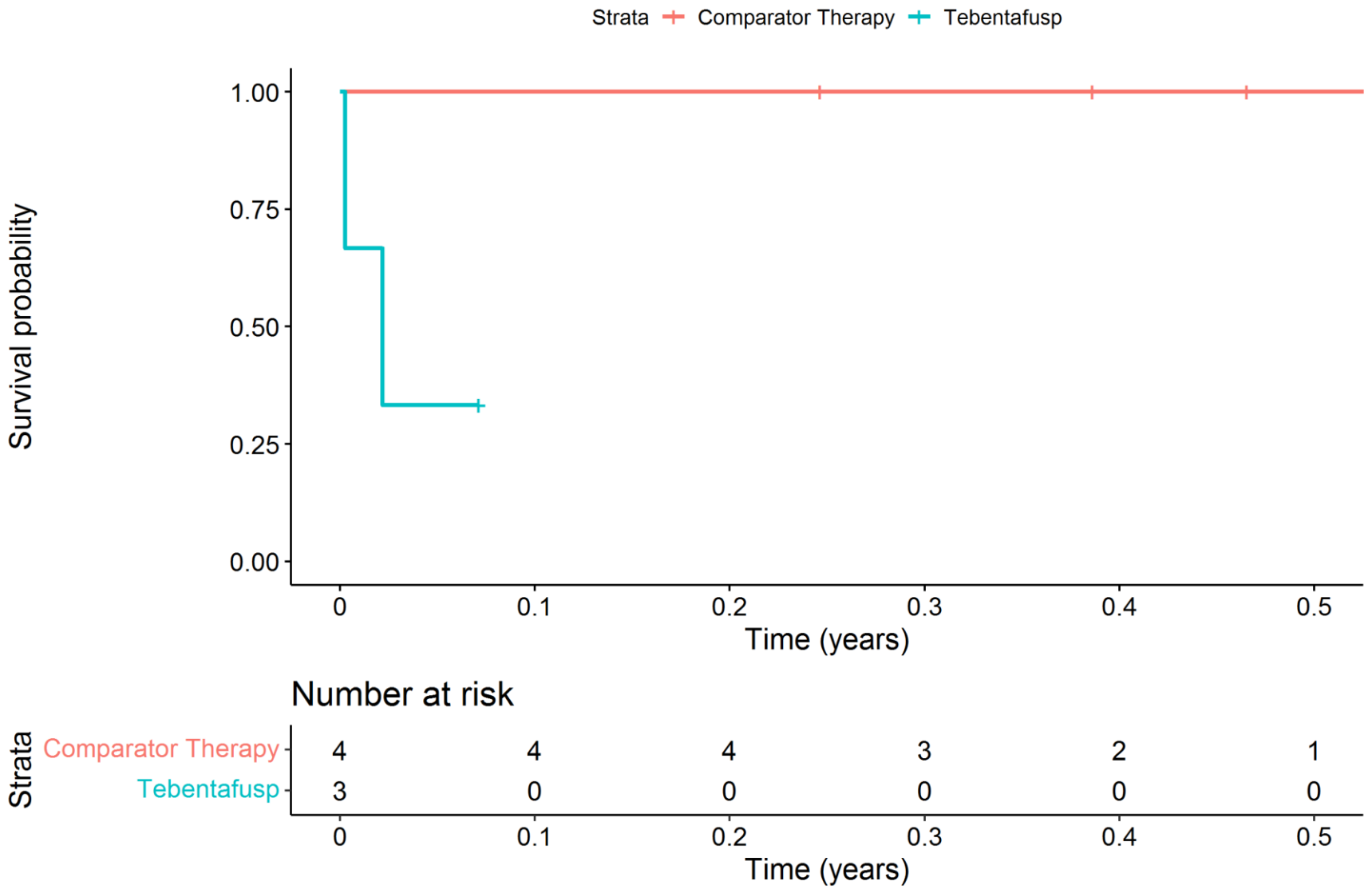
53.111 Erbrechen - Ipilimumab



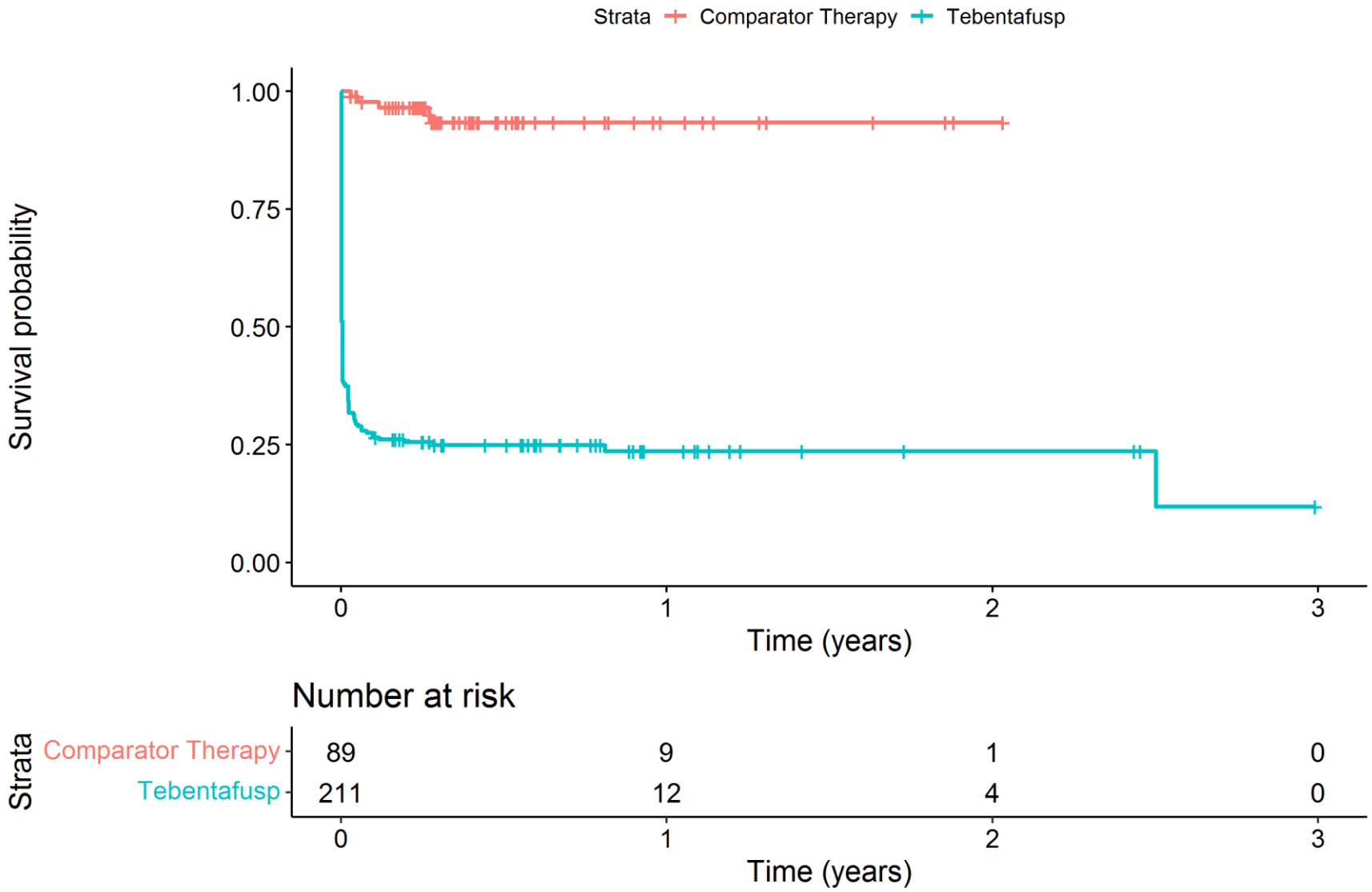
53.112 Fieber - Gesamt



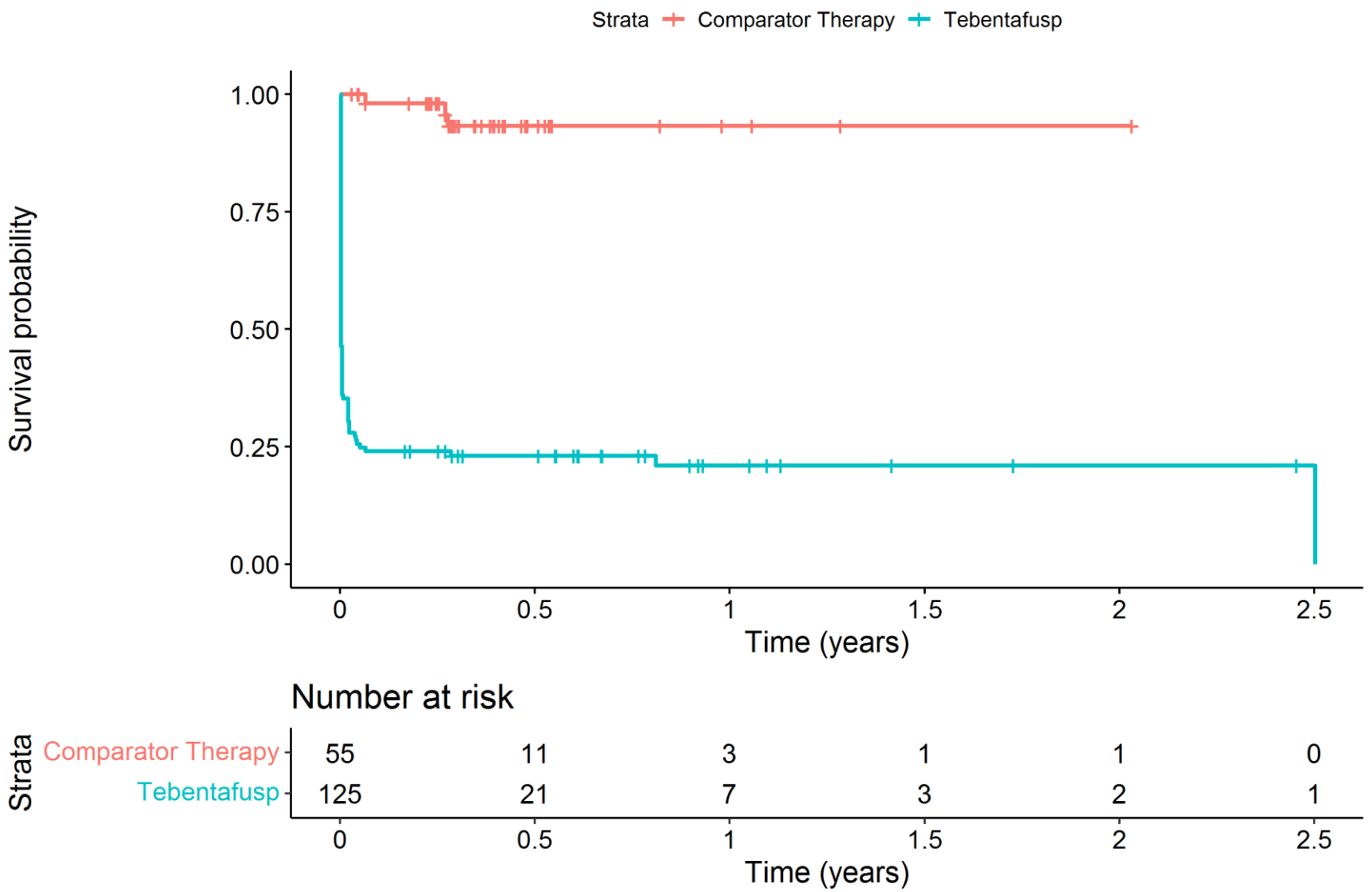
53.113 Fieber - Hispanisch



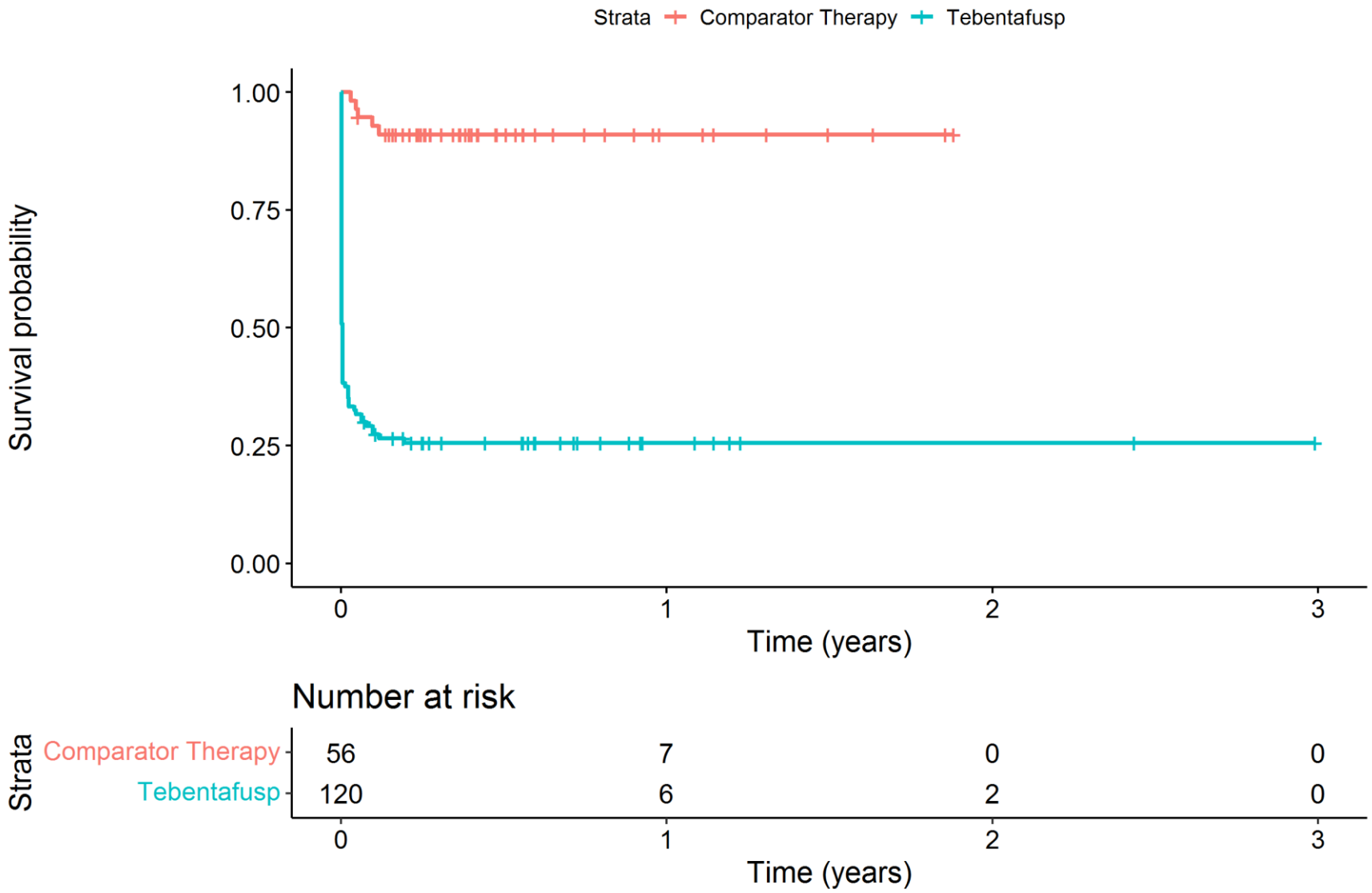
53.114 Fieber - Nicht-hispanisch



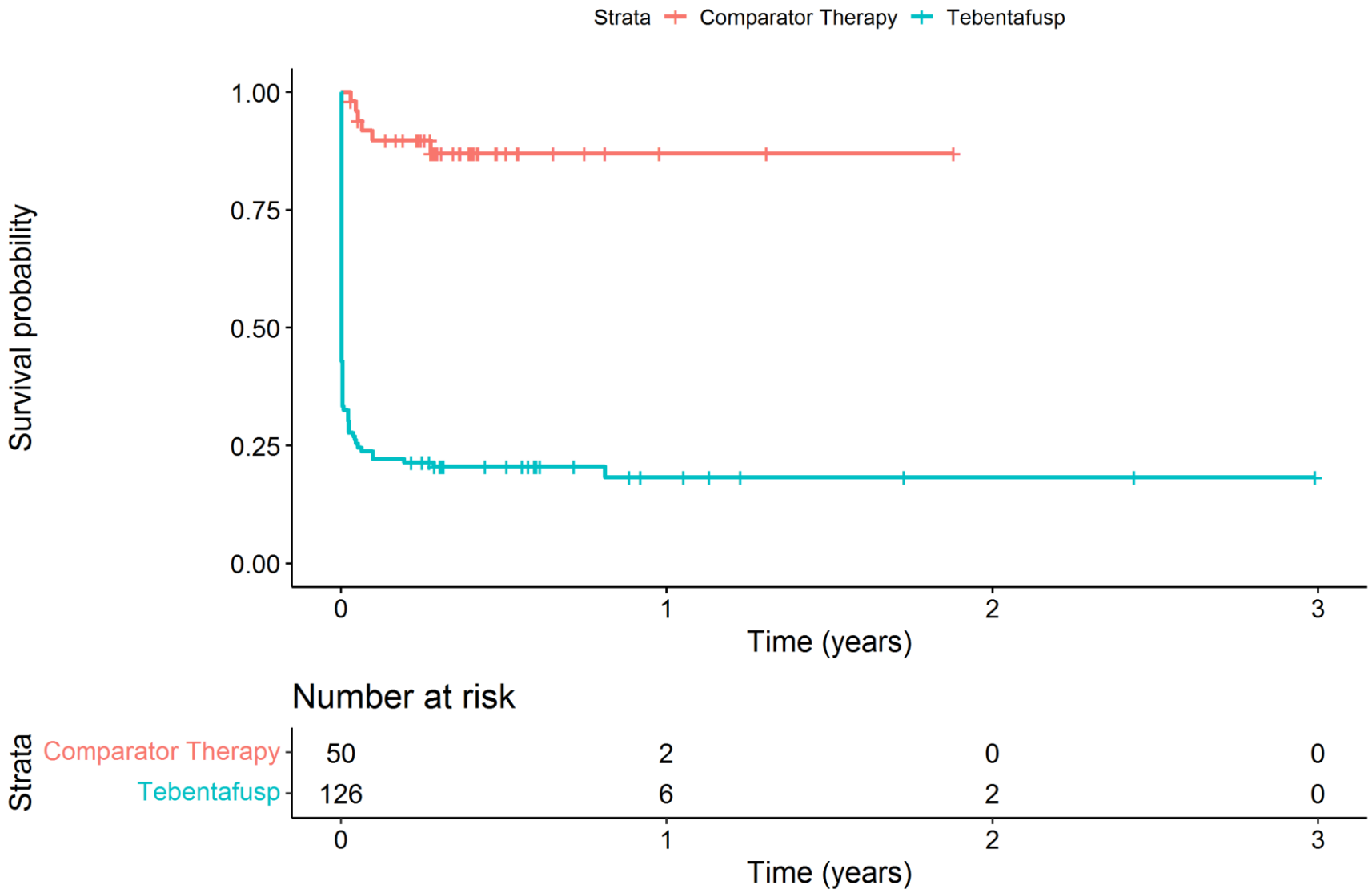
53.115 Fieber - Männlich



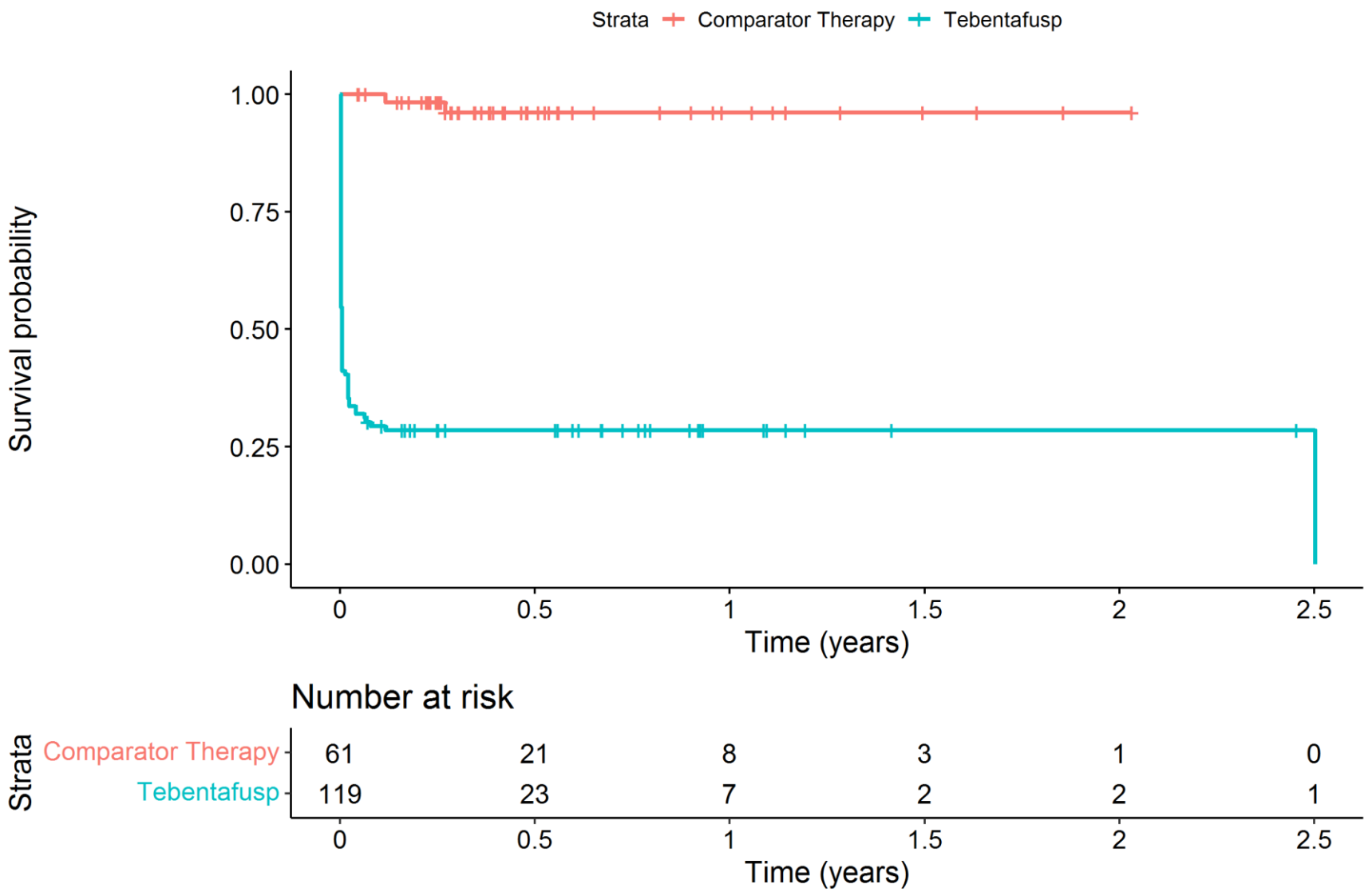
53.116 Fieber - Weiblich



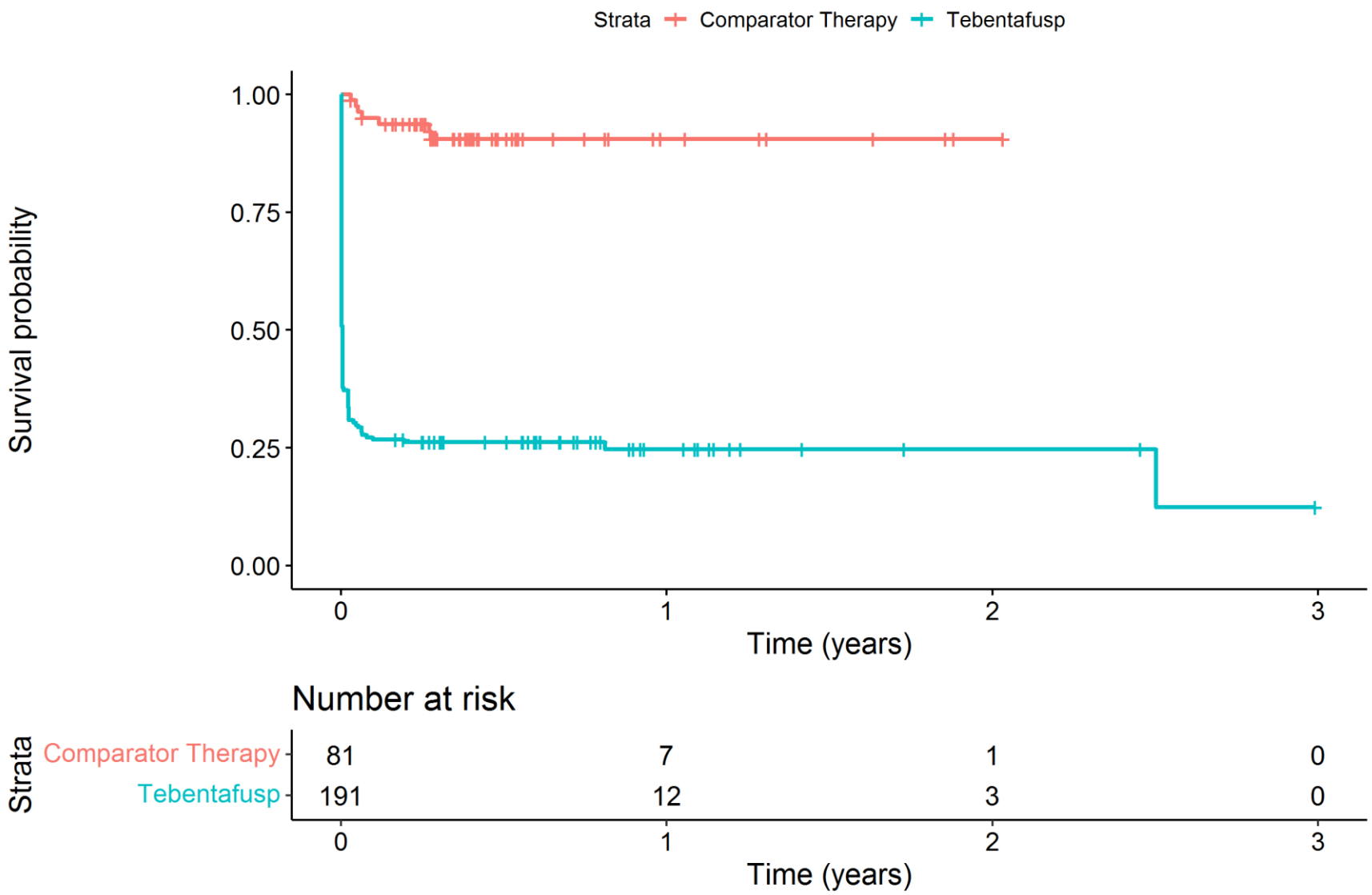
53.117 Fieber - <65



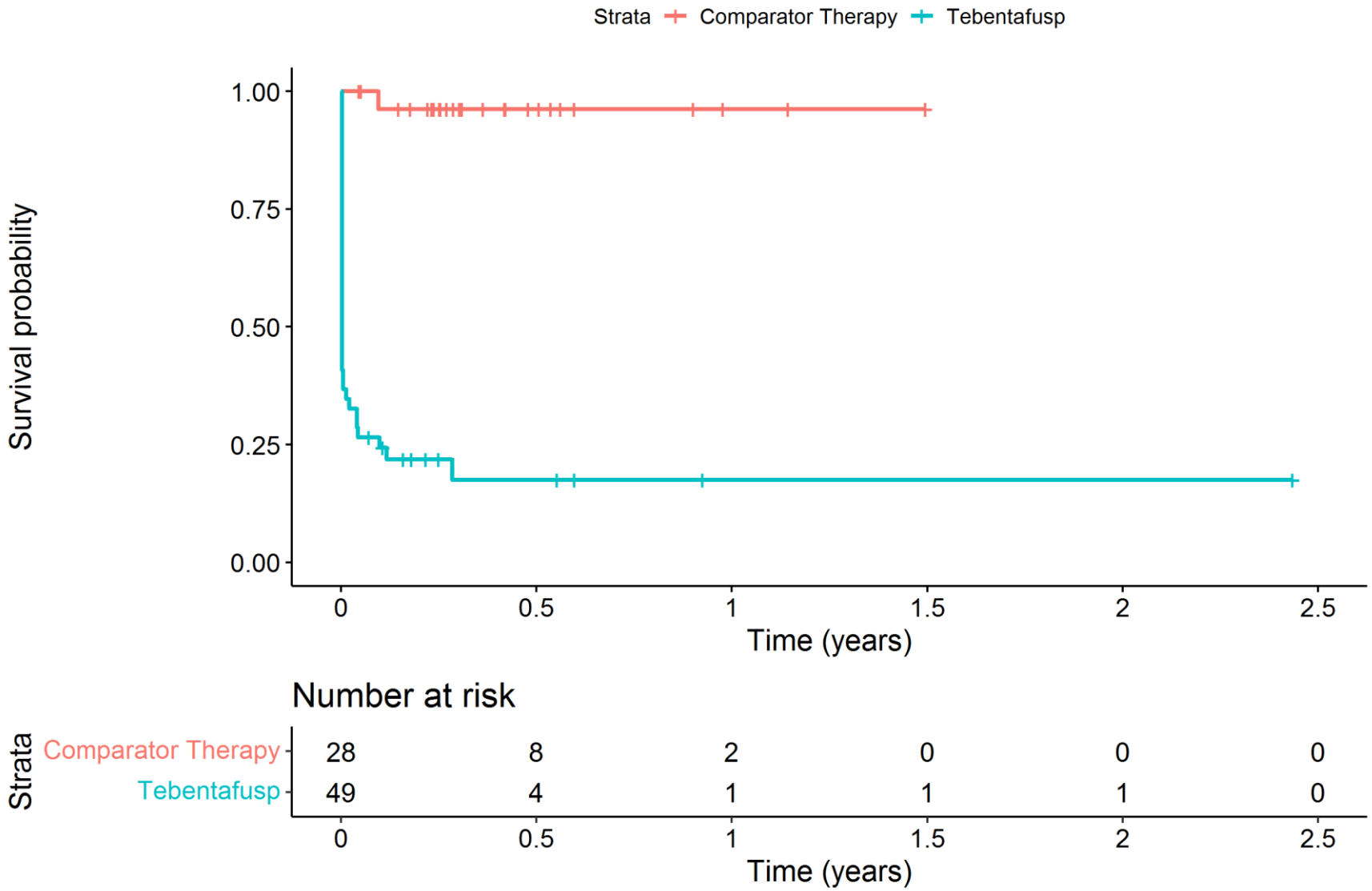
53.118 Fieber - ≥65



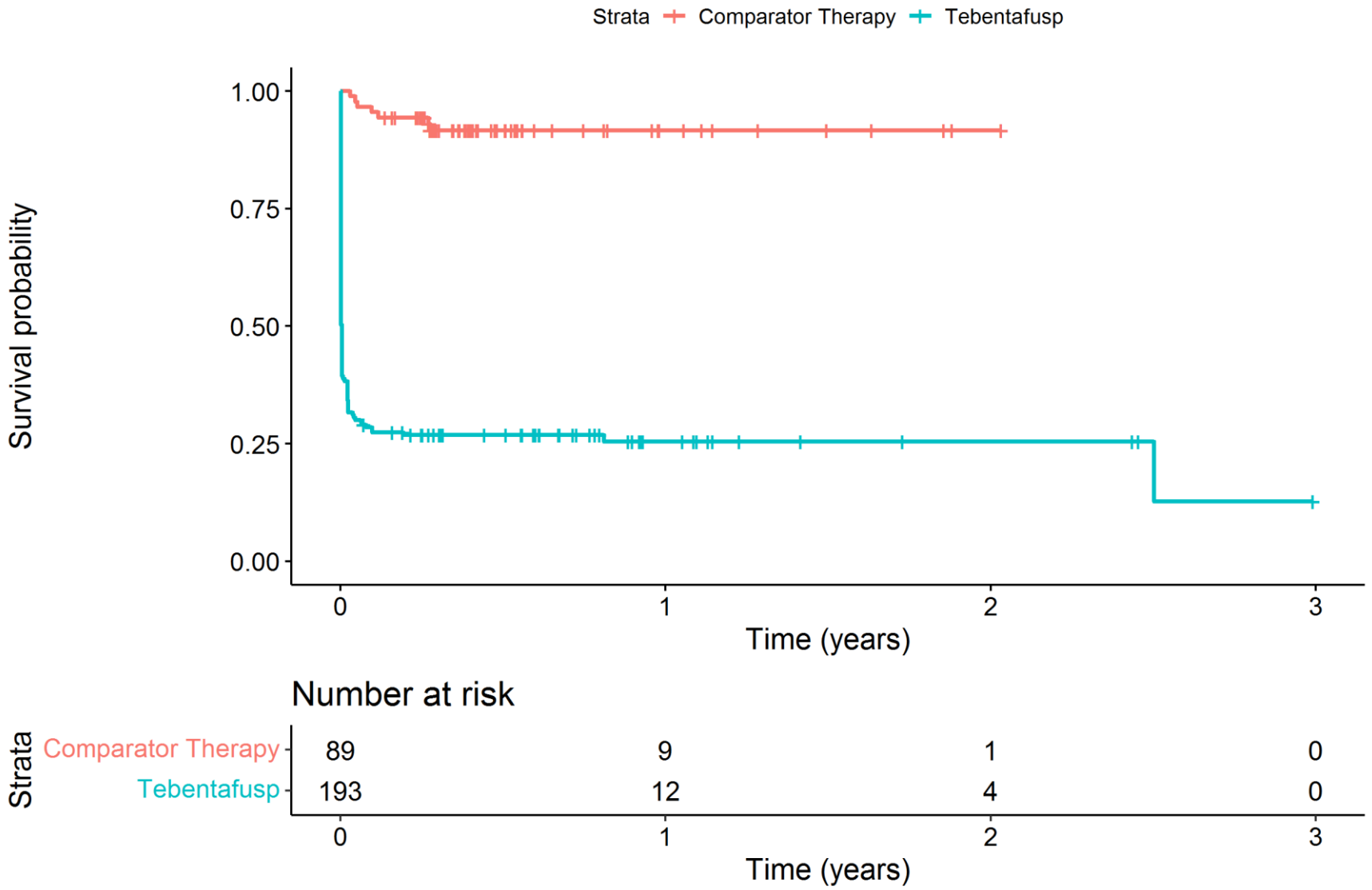
53.119 Fieber - ECOG 0



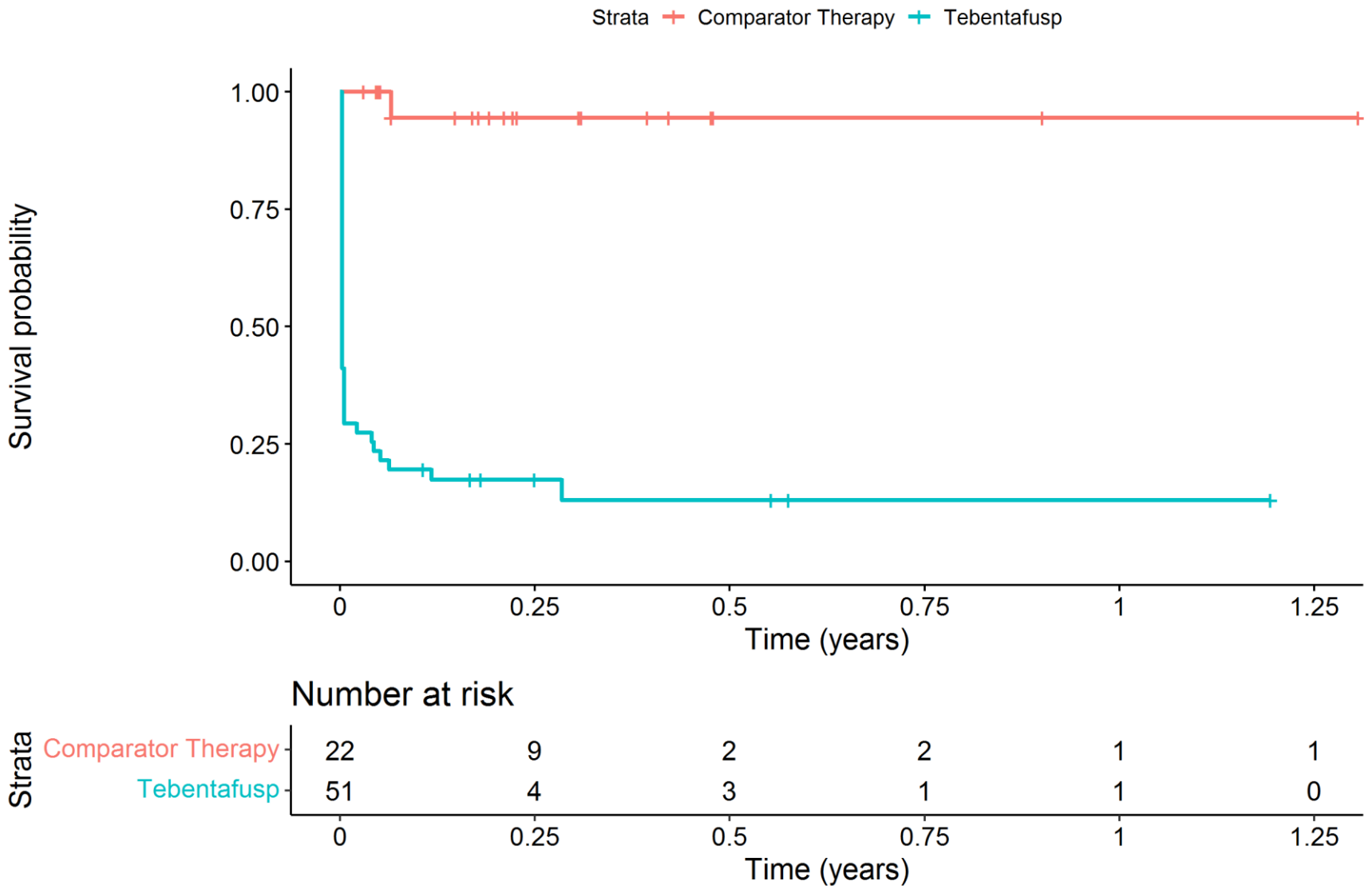
53.120 Fieber - ECOG 1



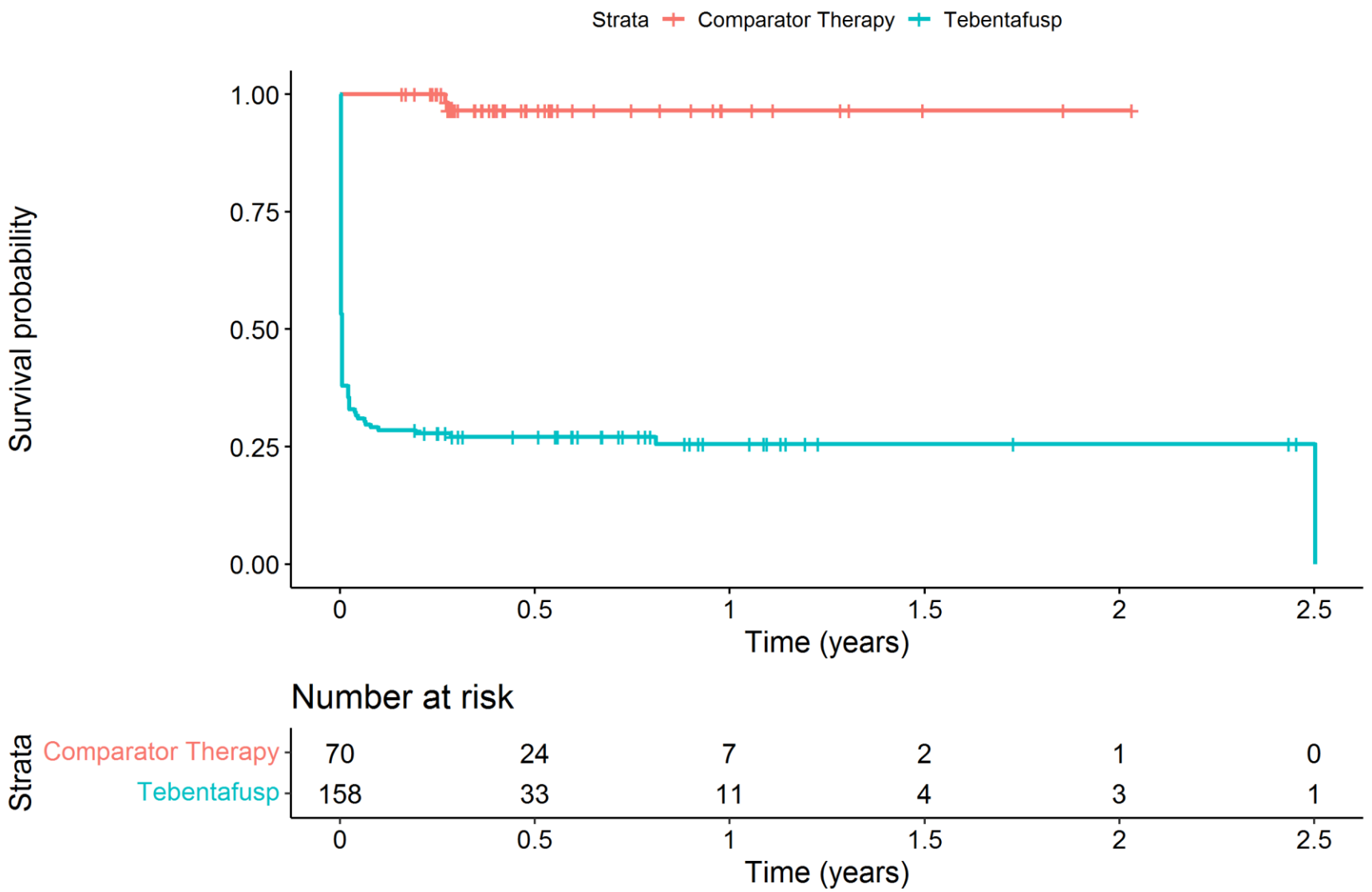
53.121 Fieber - ALP ≤ ULN



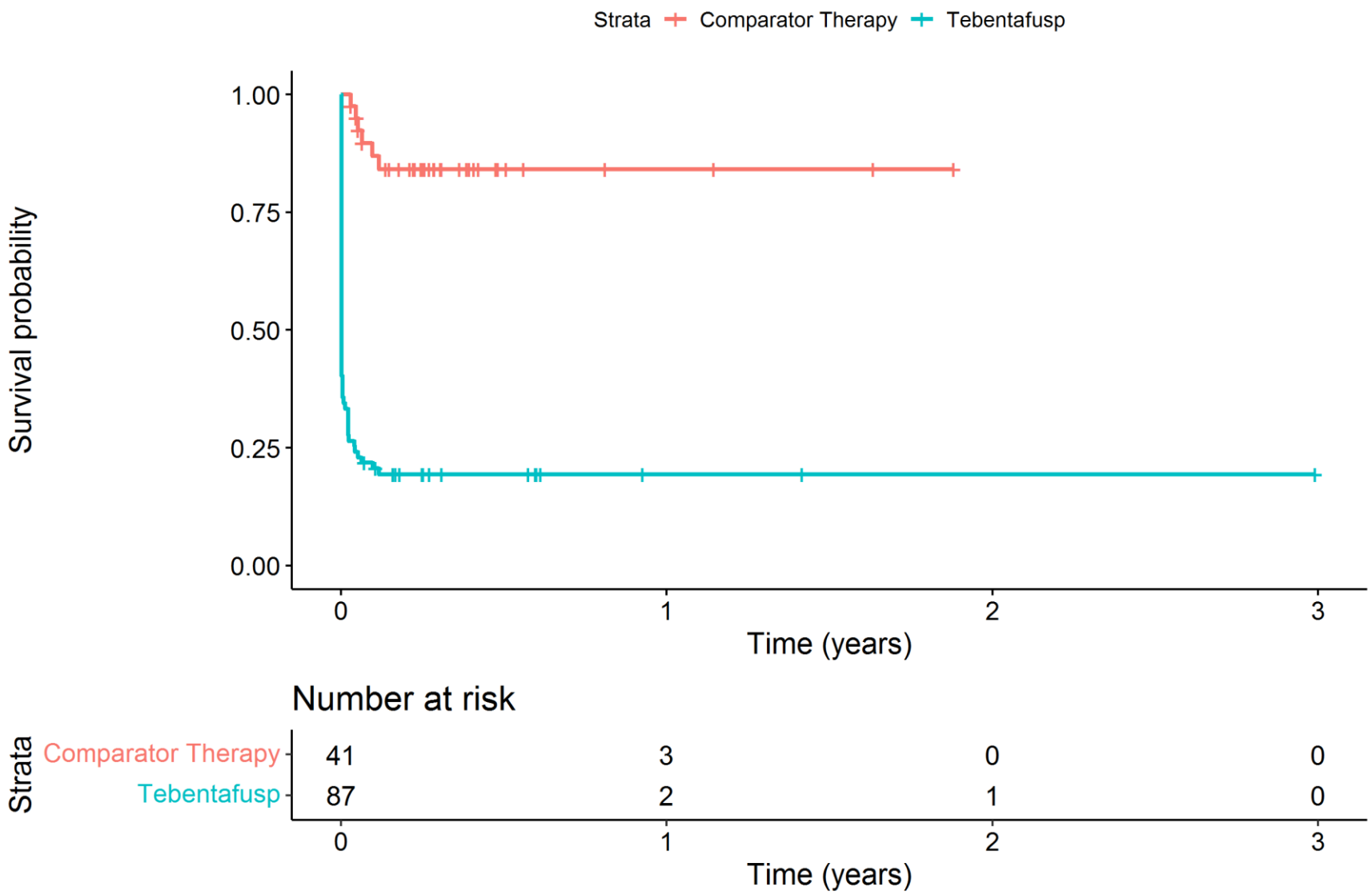
53.122 Fieber - ALP > ULN



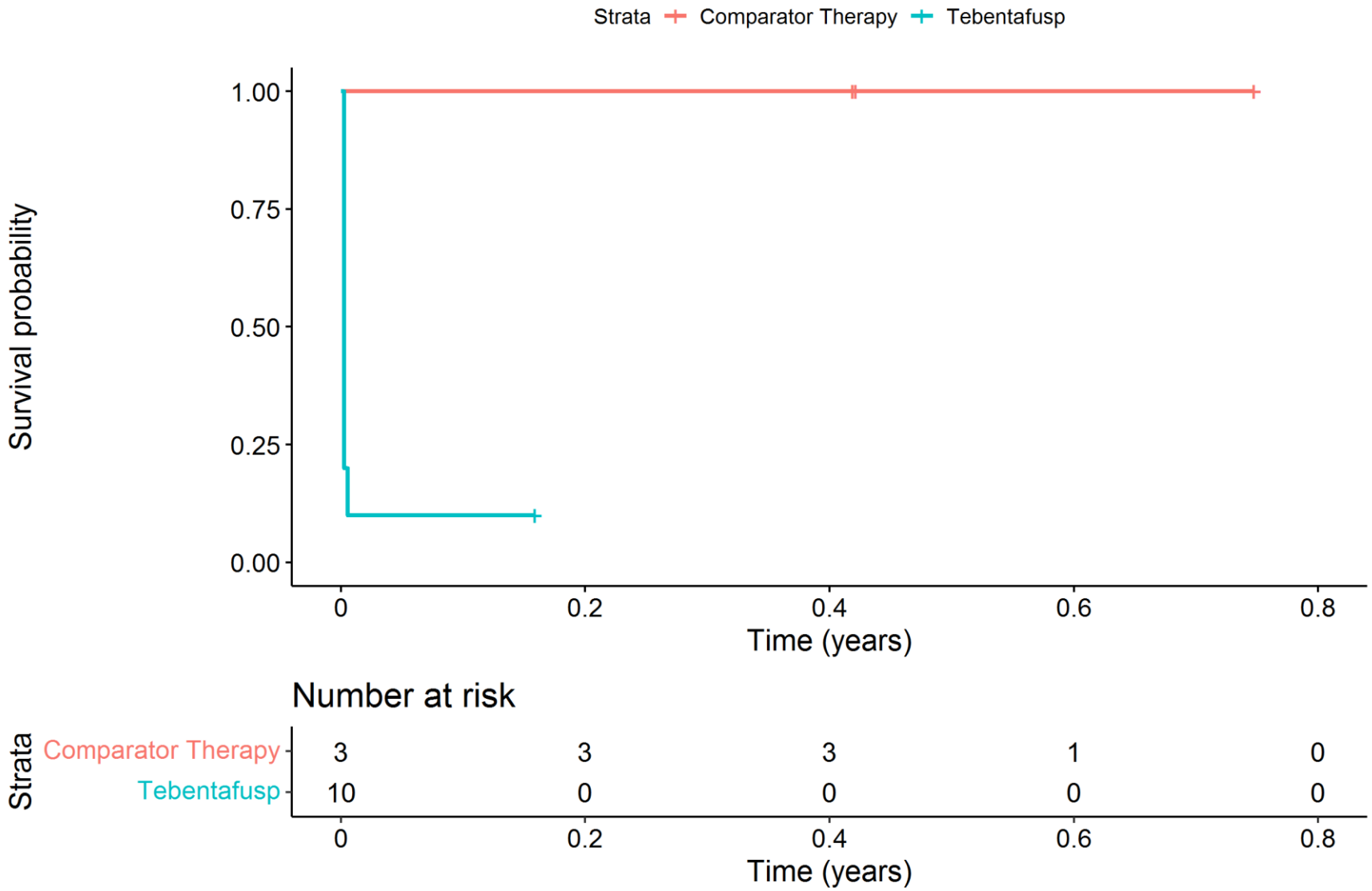
53.123 Fieber - LDH =< ULN



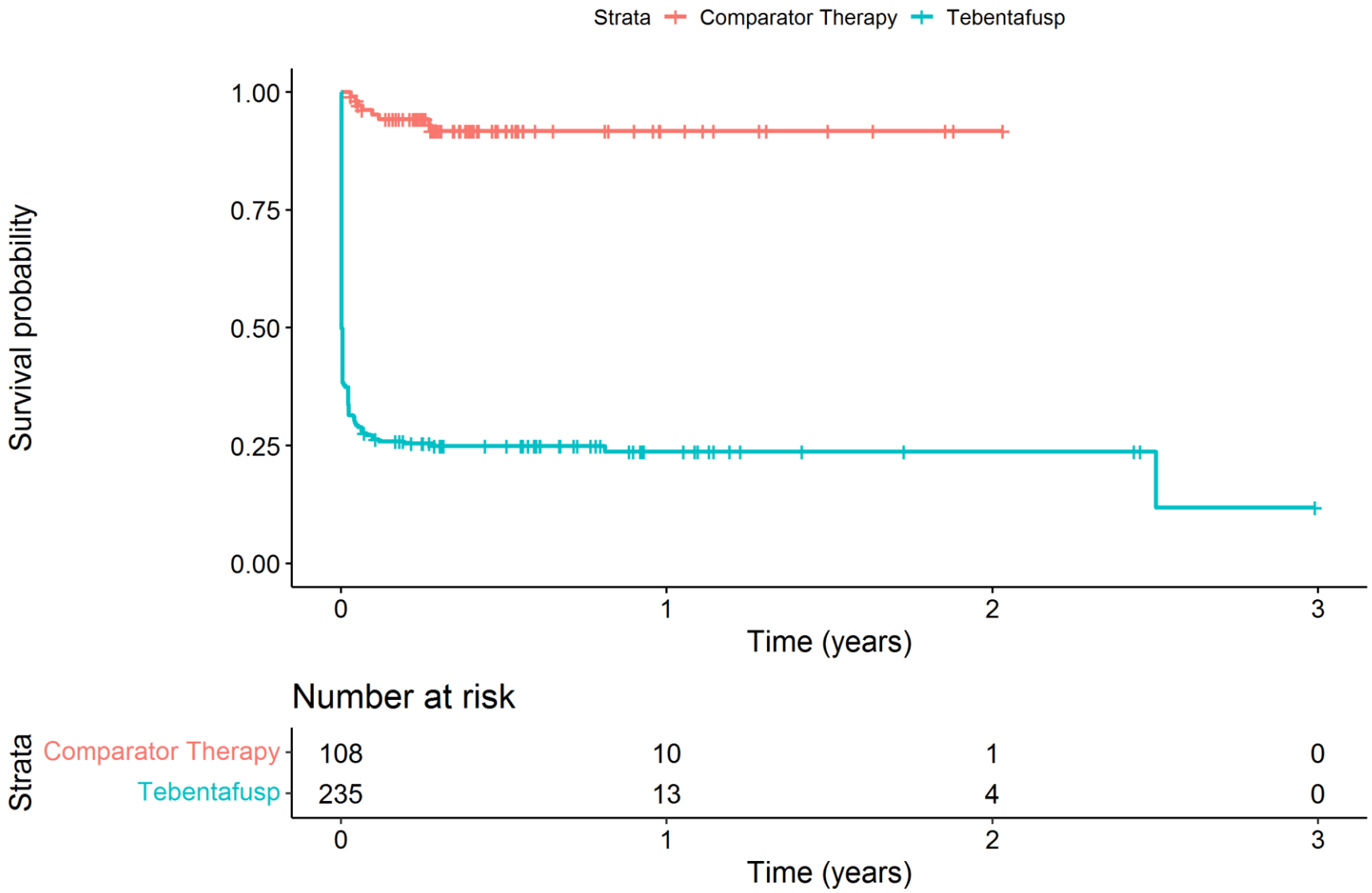
53.124 Fieber - LDH > ULN



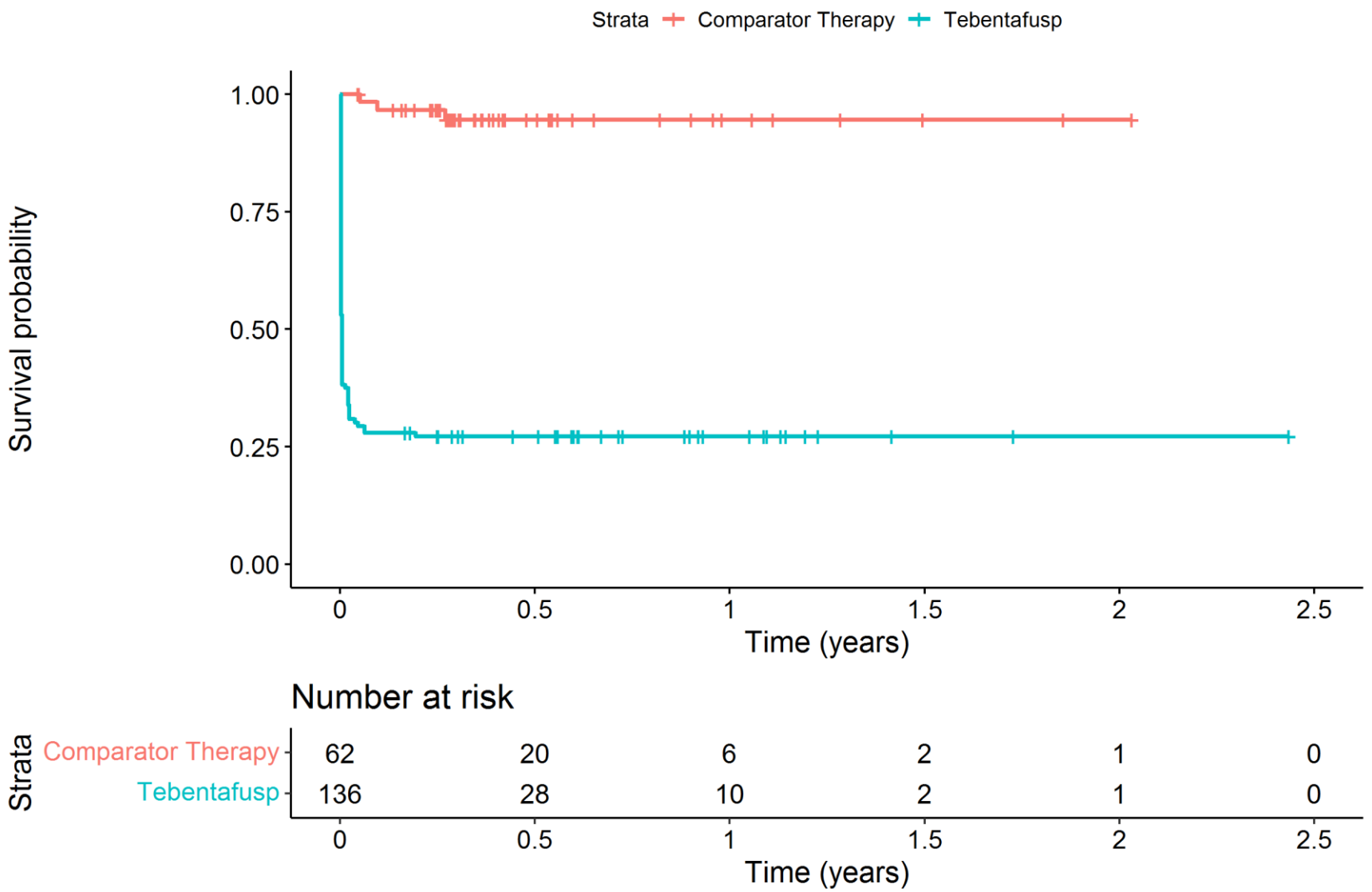
53.125 Fieber - Vorherige Therapie adjuvant/neoadjuvant



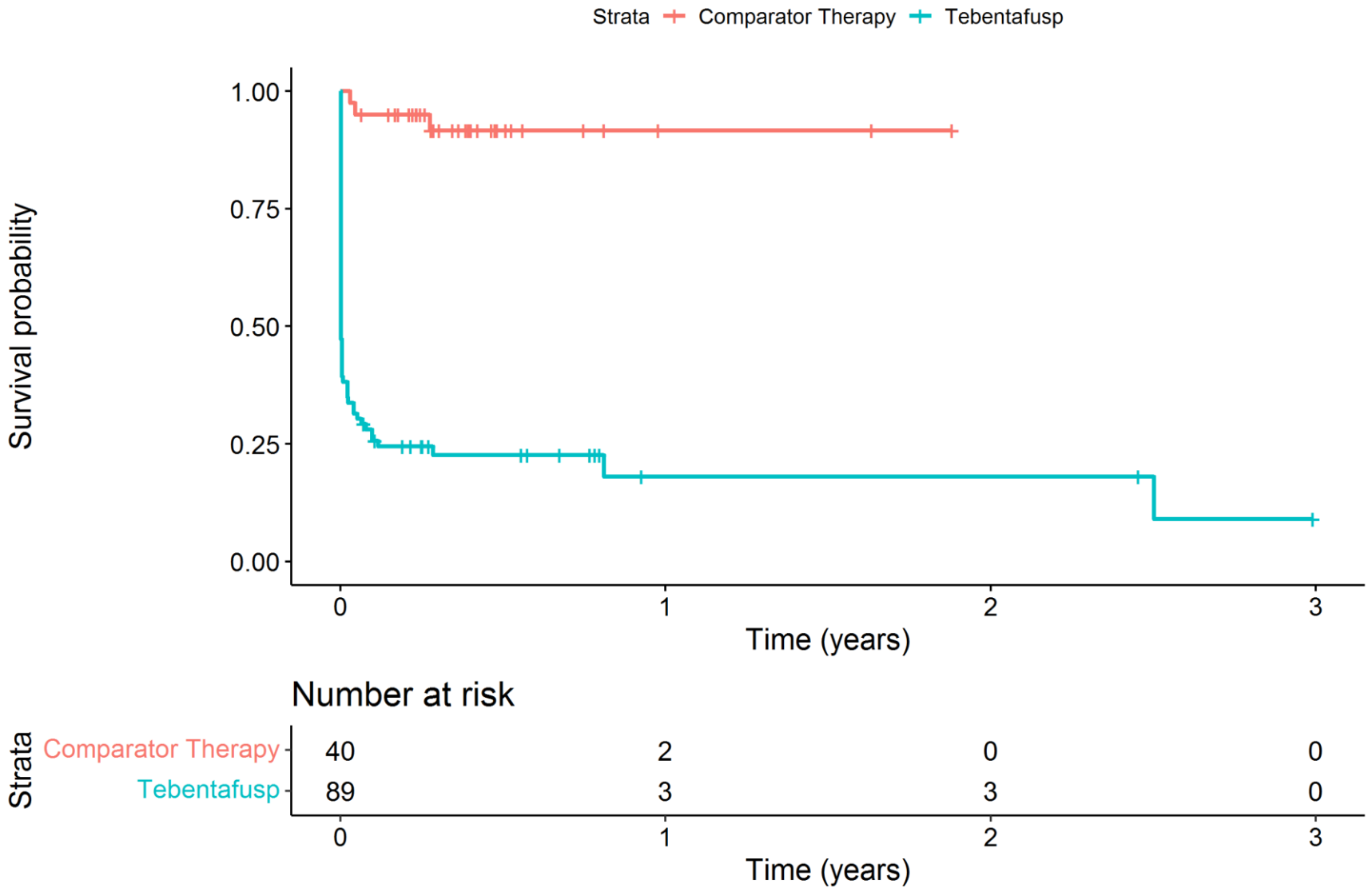
53.126 Fieber - Keine vorherige Therapie adjuvant/neoadjuvant



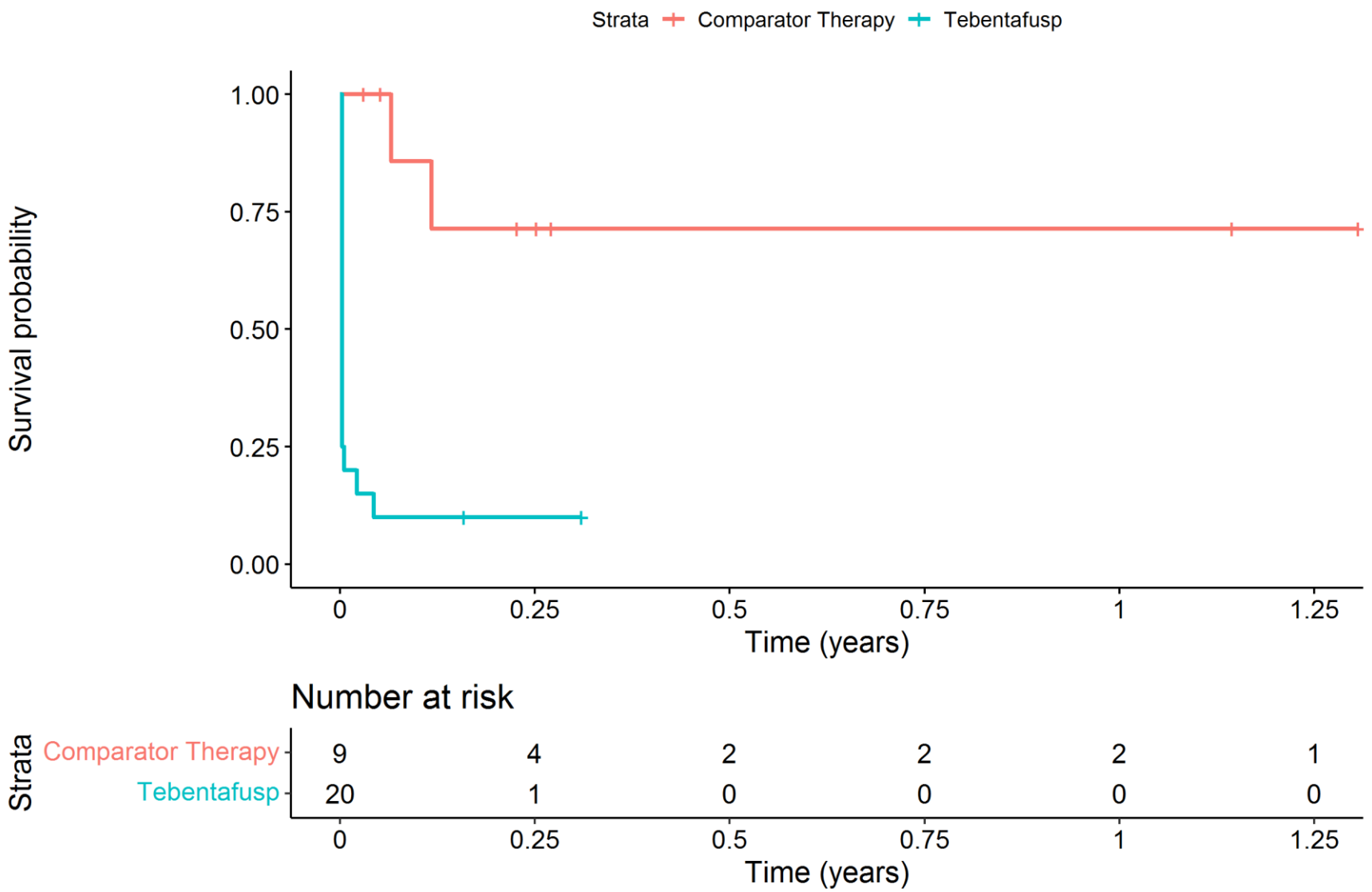
53.127 Fieber - Läsion ≤ 3cm



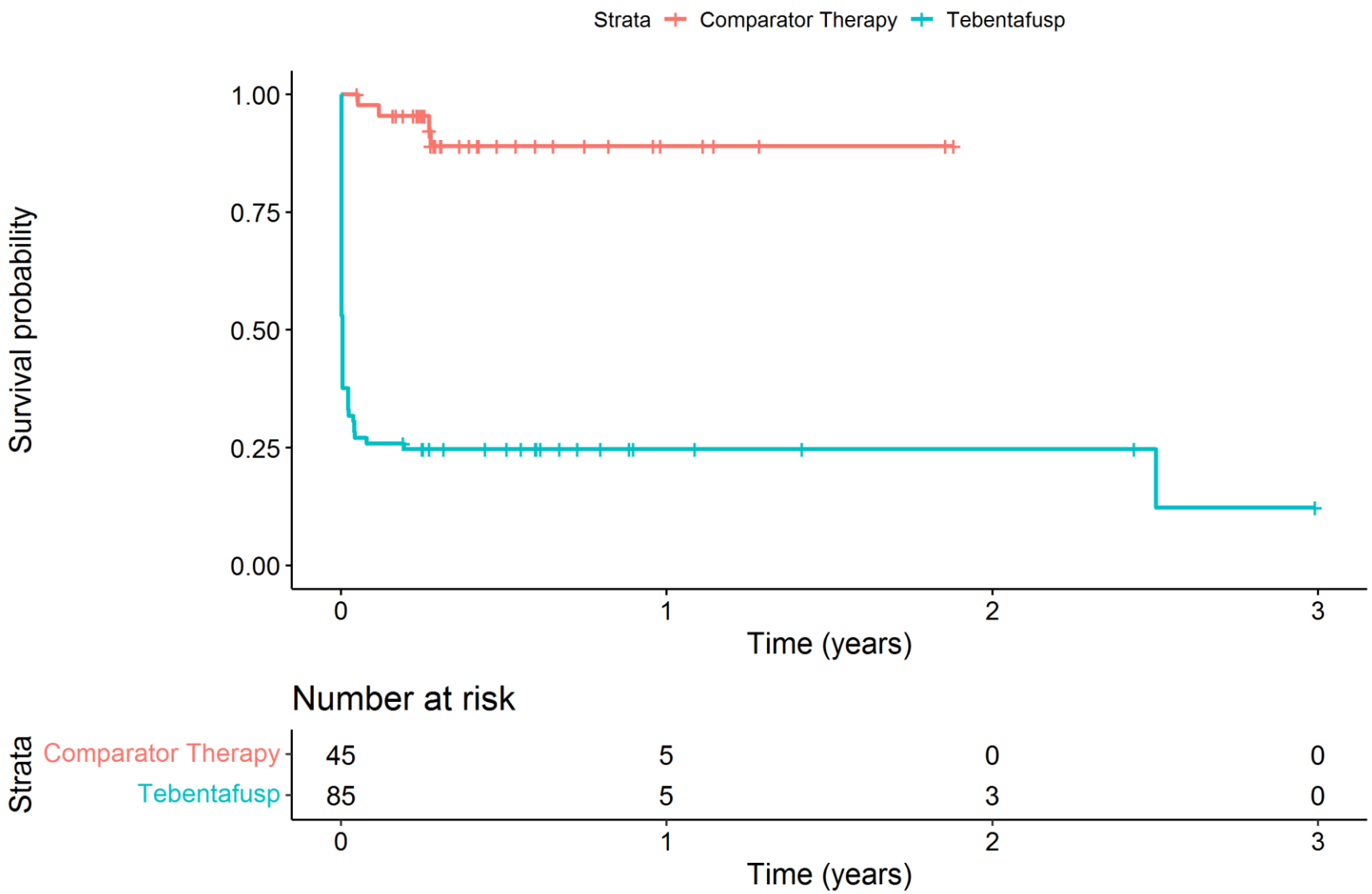
53.128 Fieber - Läsion 3,1-8,0 cm



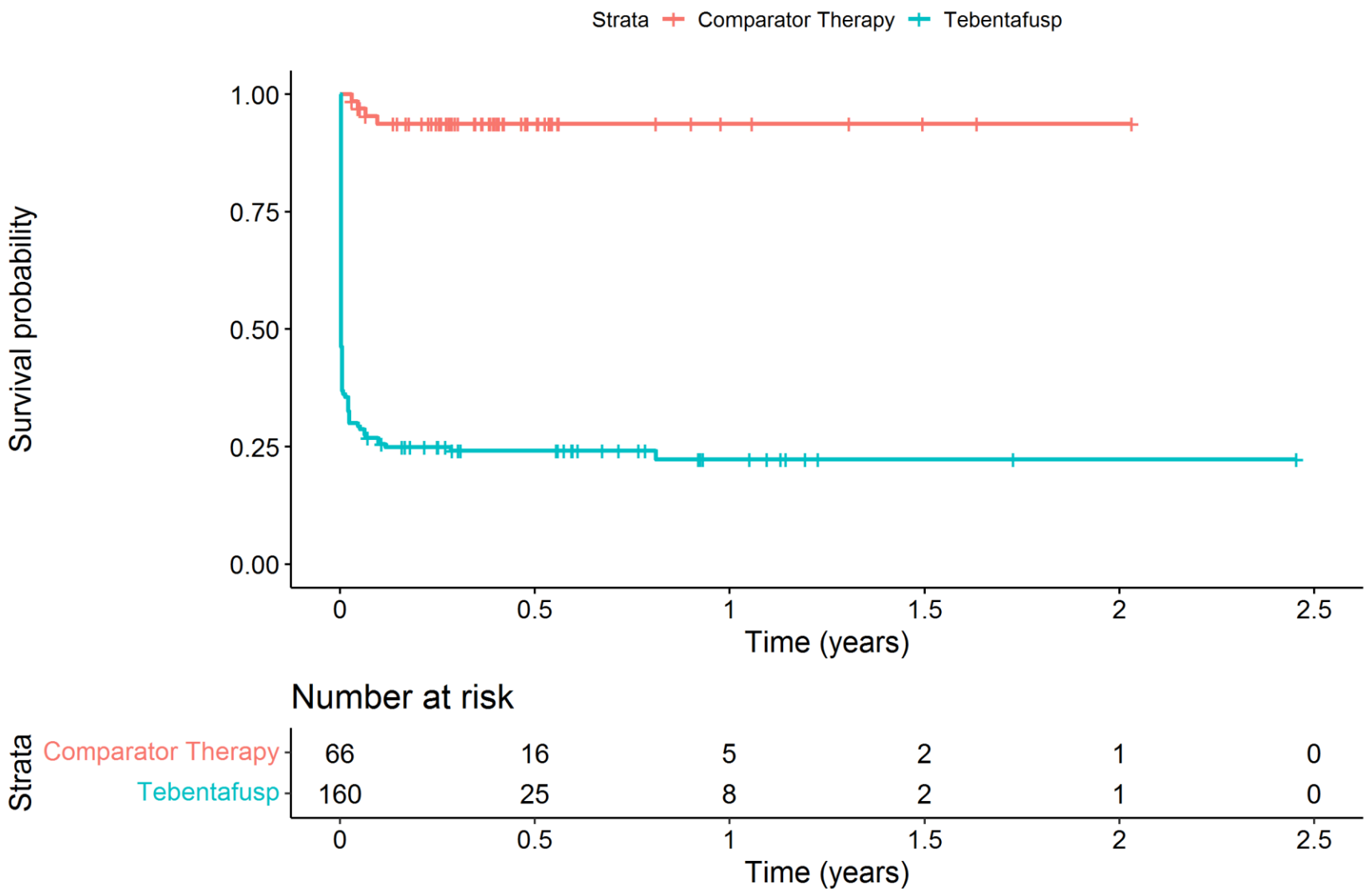
53.129 Fieber - Läsion ≥8,1 cm



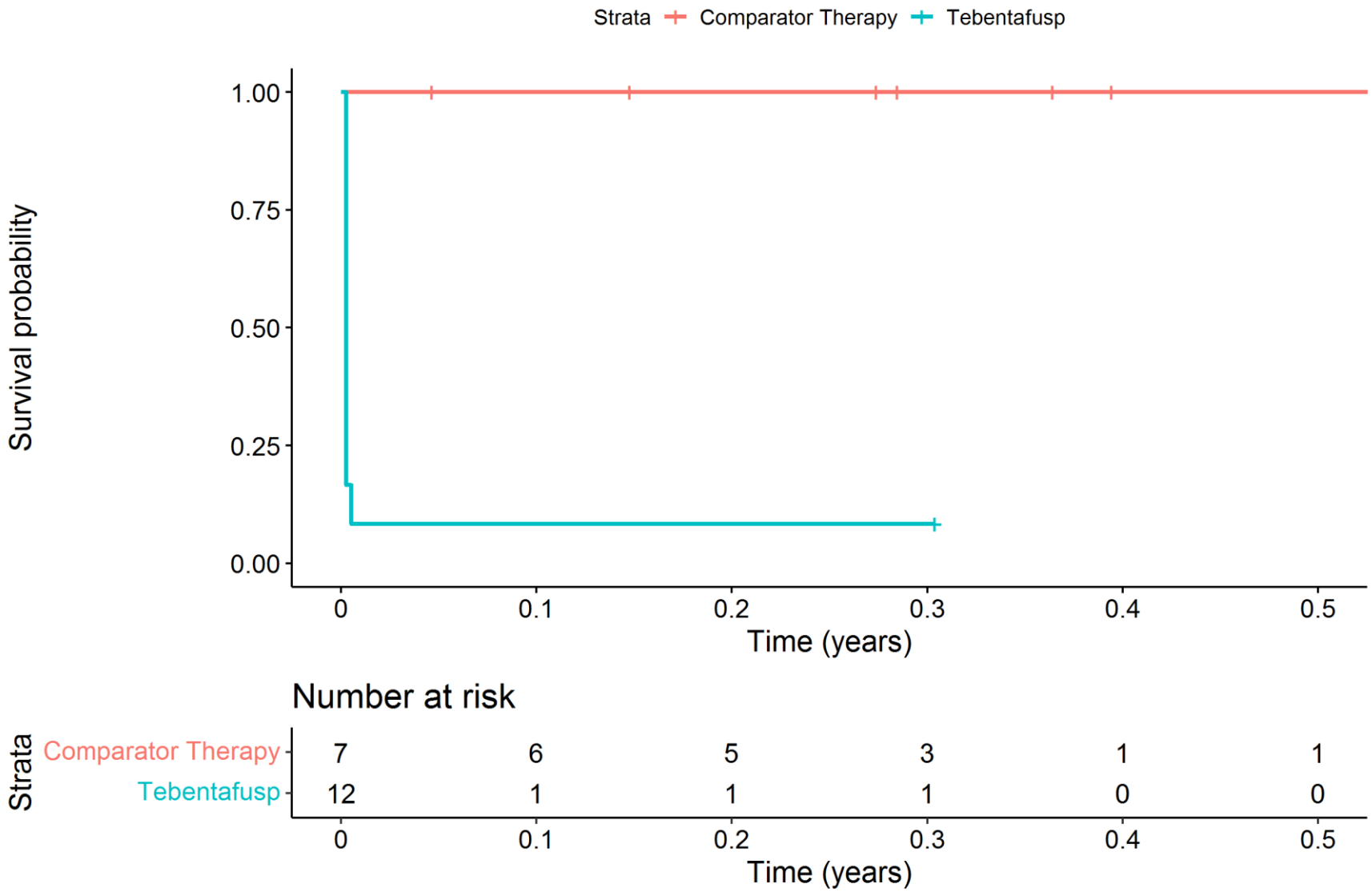
53.130 Fieber - Nordamerika



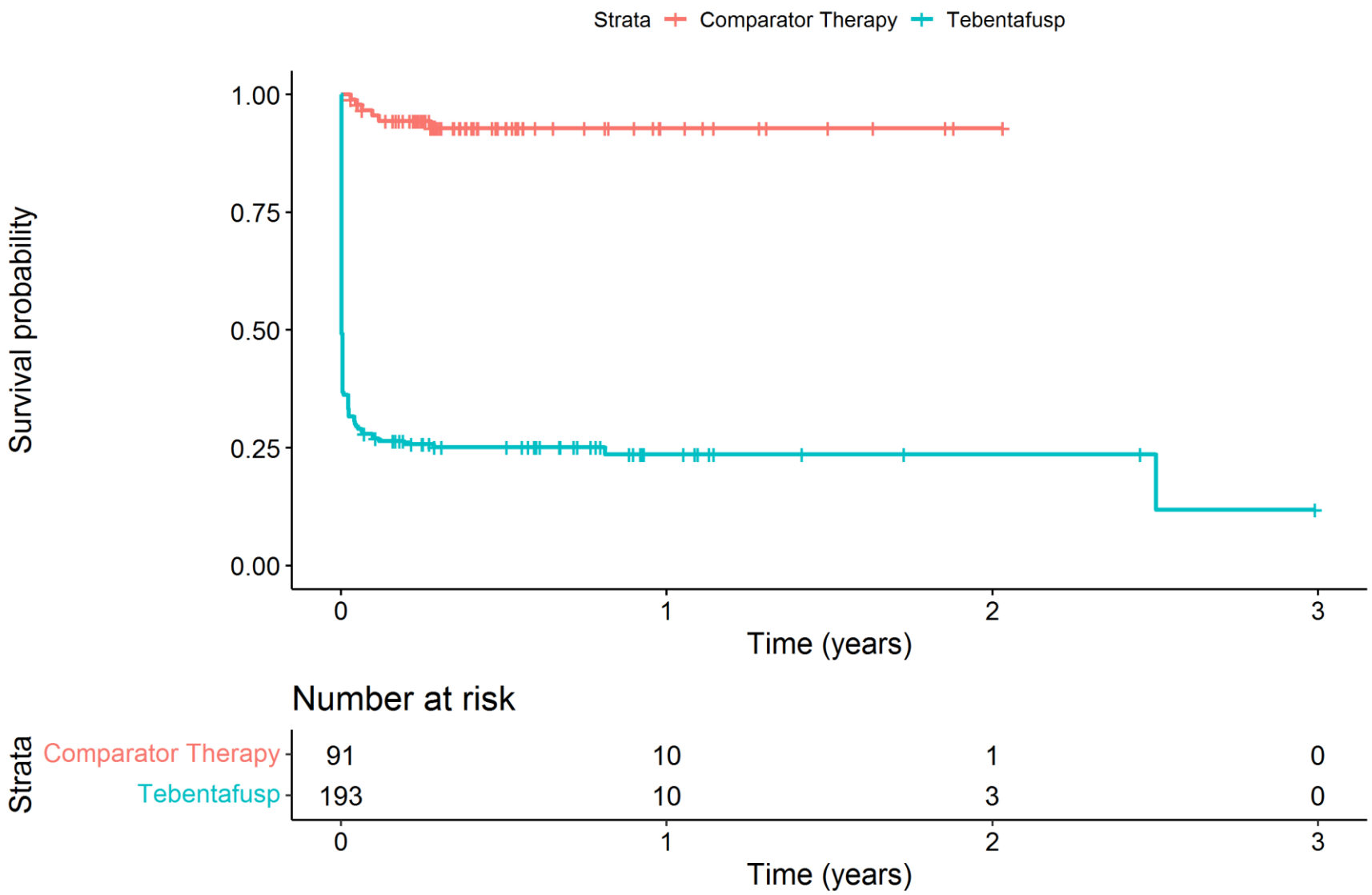
53.131 Fieber - Nicht-Nordamerika



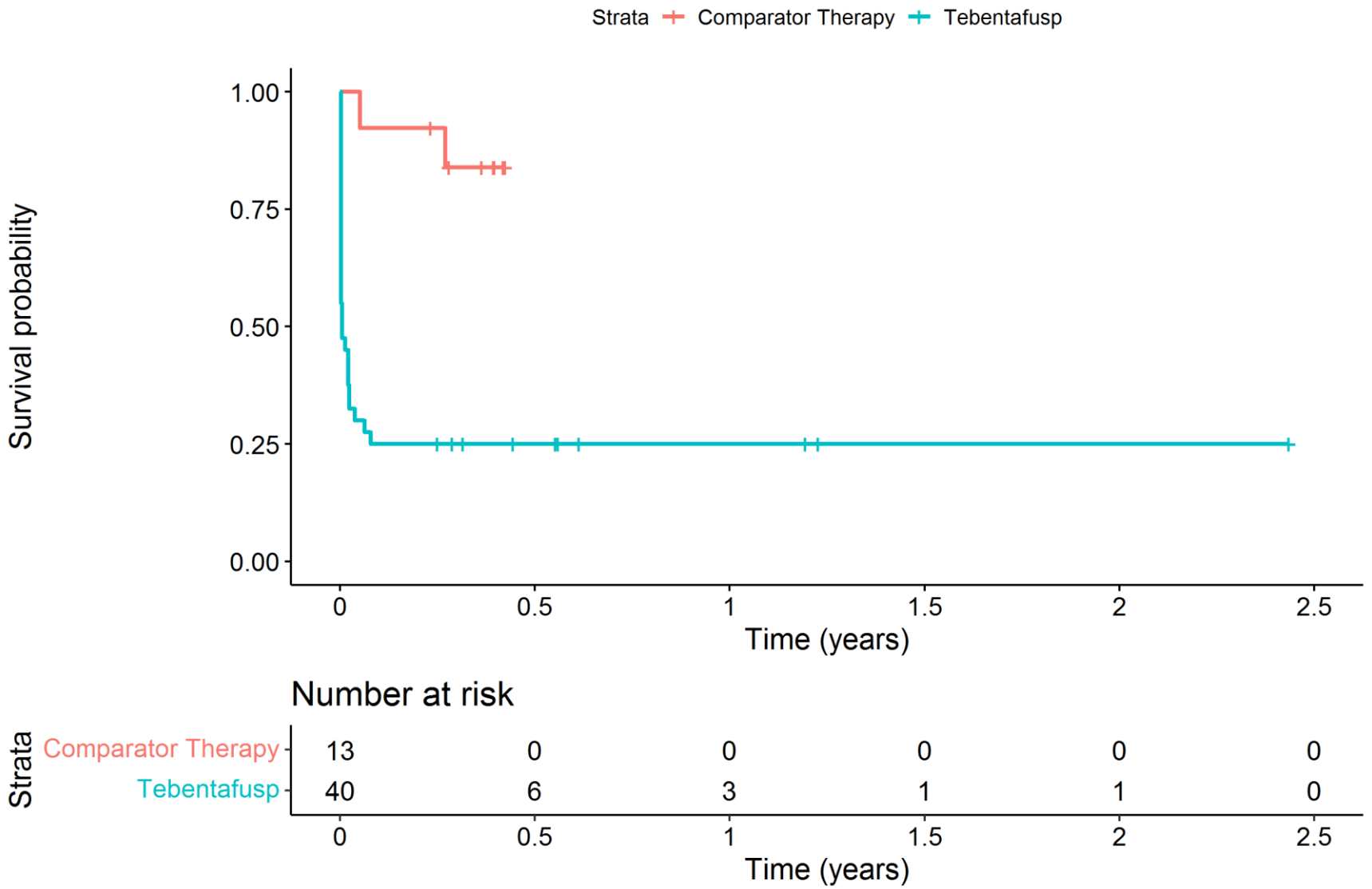
53.132 Fieber - Dacarbazin



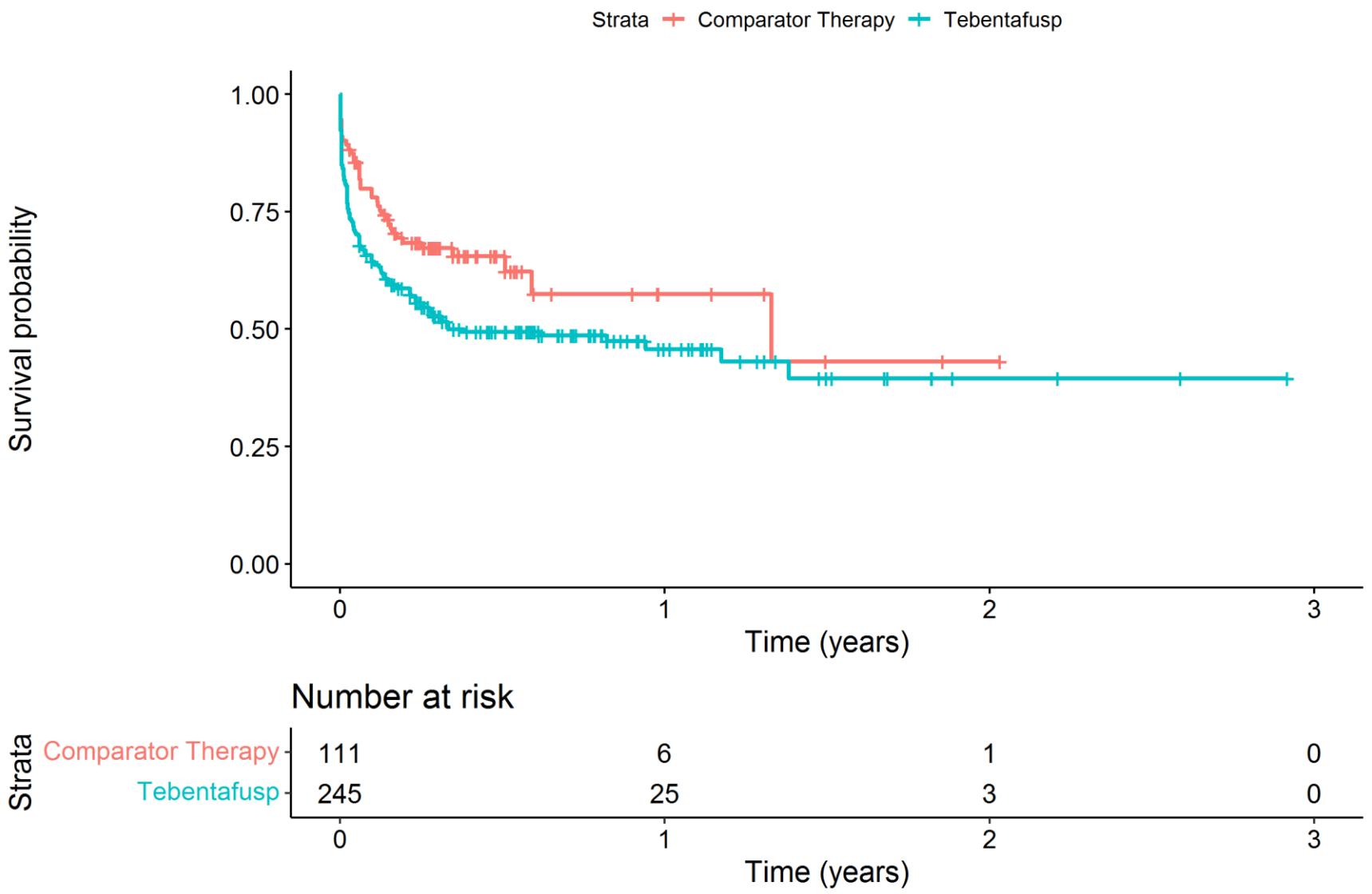
53.133 Fieber - Pembrolizumab



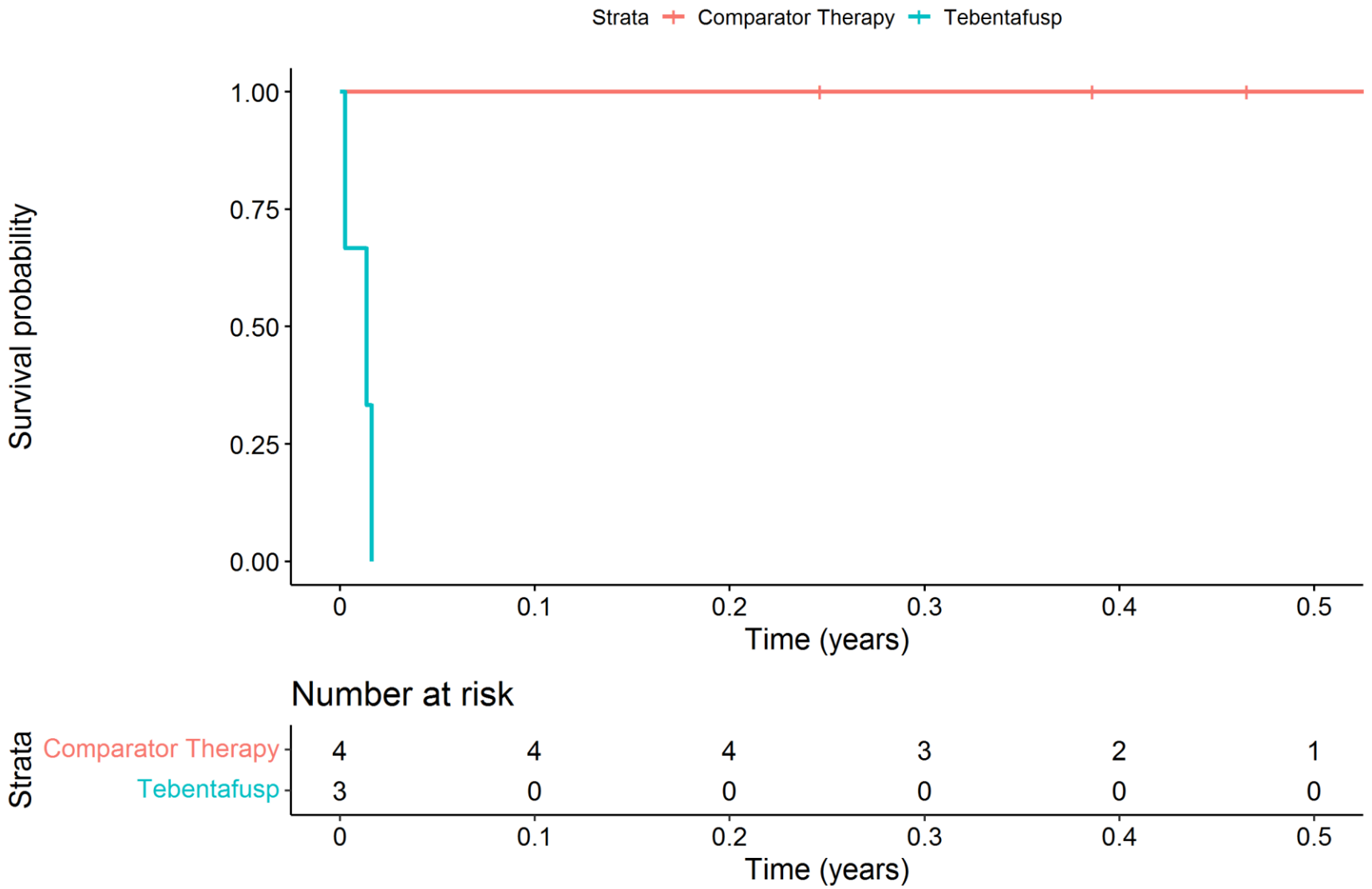
53.134 Fieber - Ipilimumab



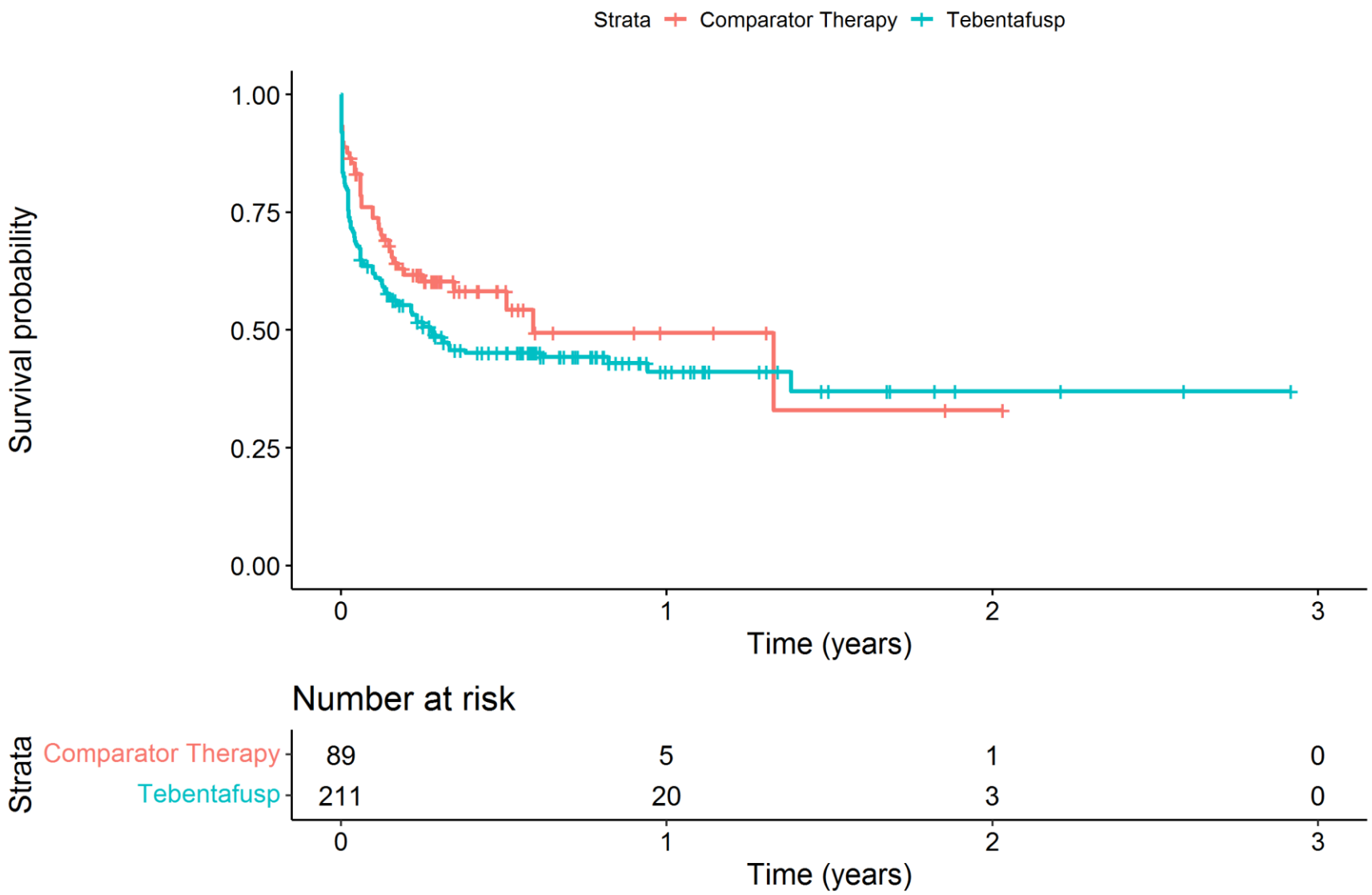
53.135 Müdigkeit - Gesamt



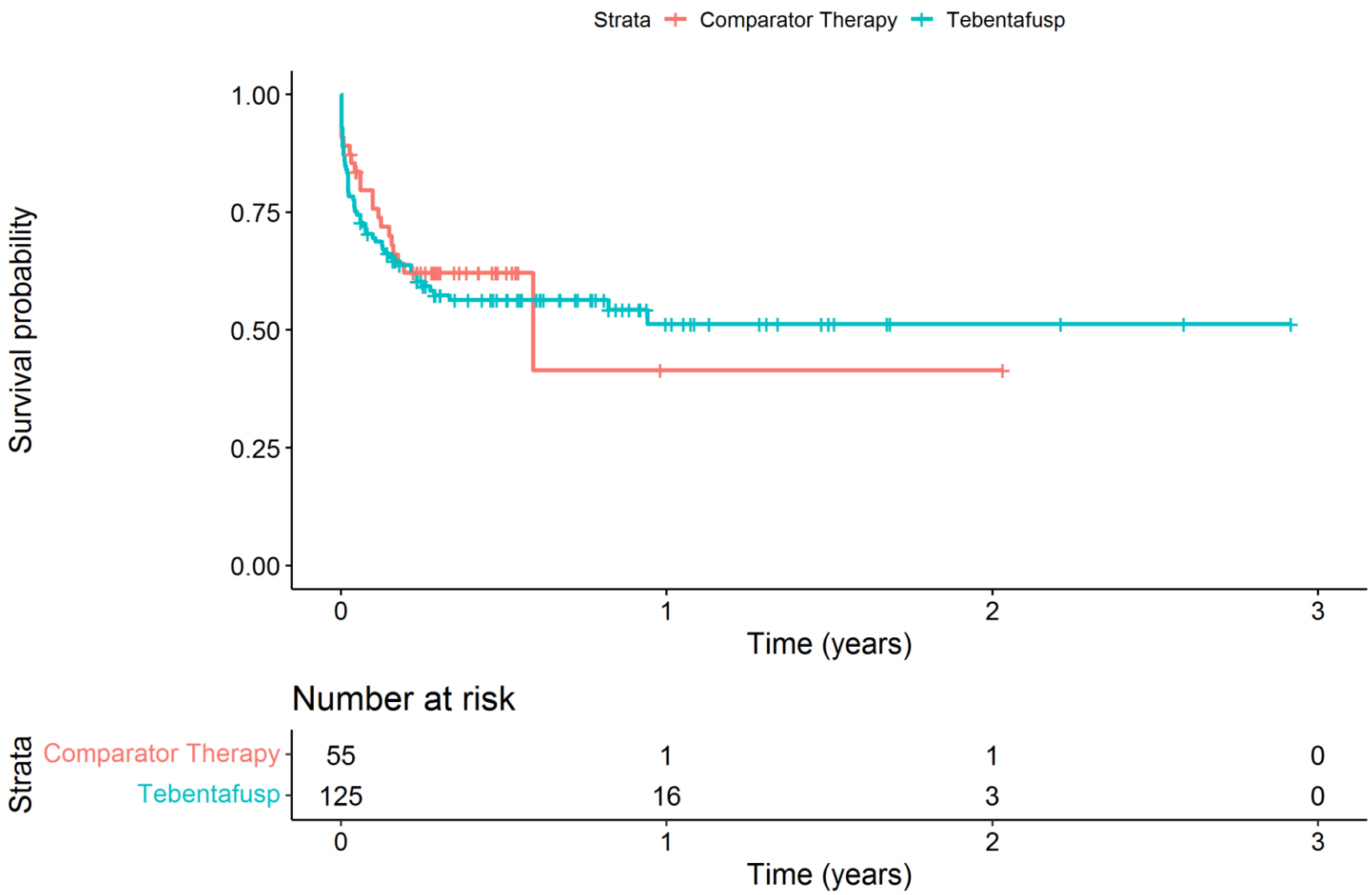
53.136 Müdigkeit - Hispanisch



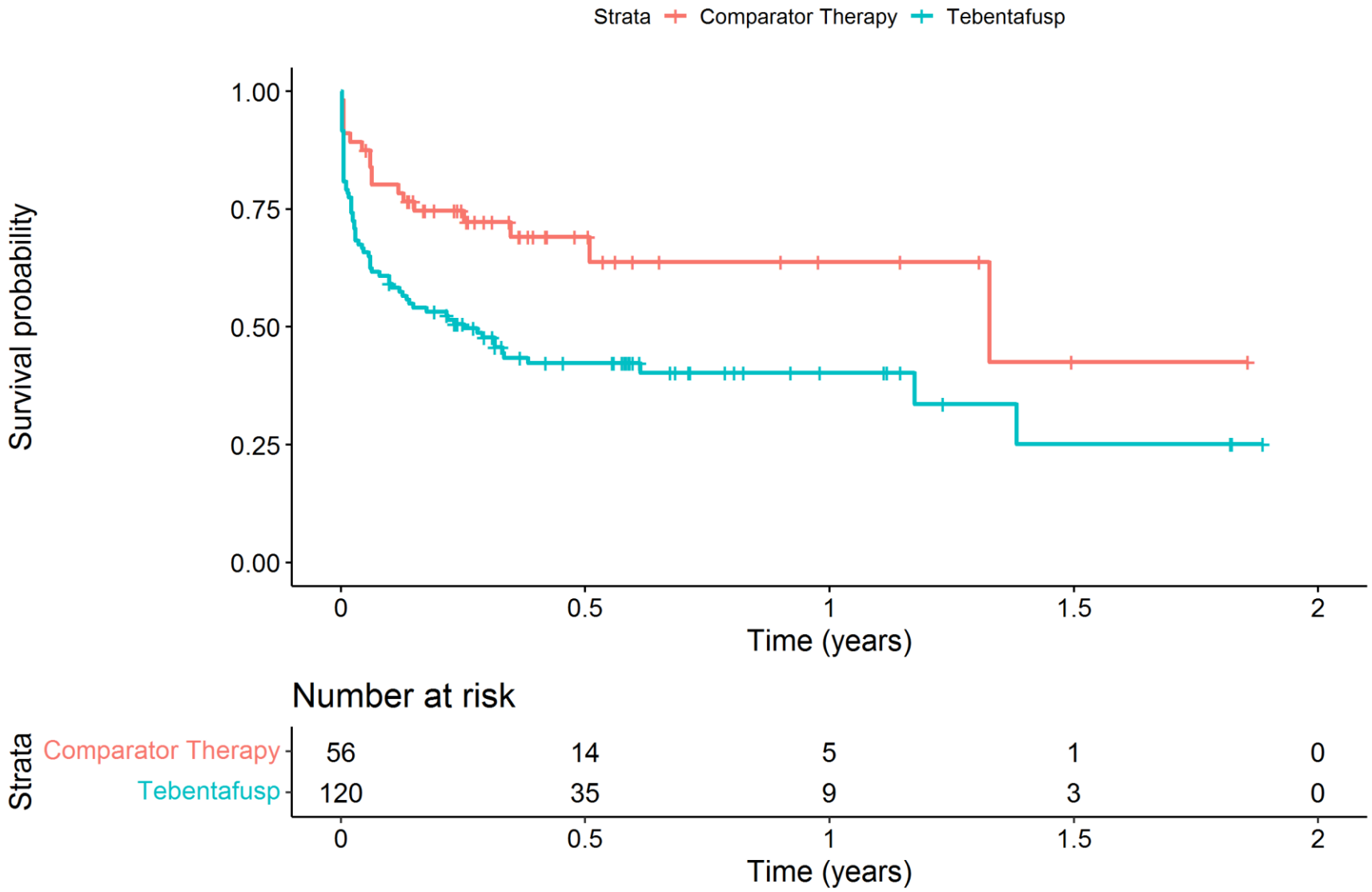
53.137 Müdigkeit - Nicht-hispanisch



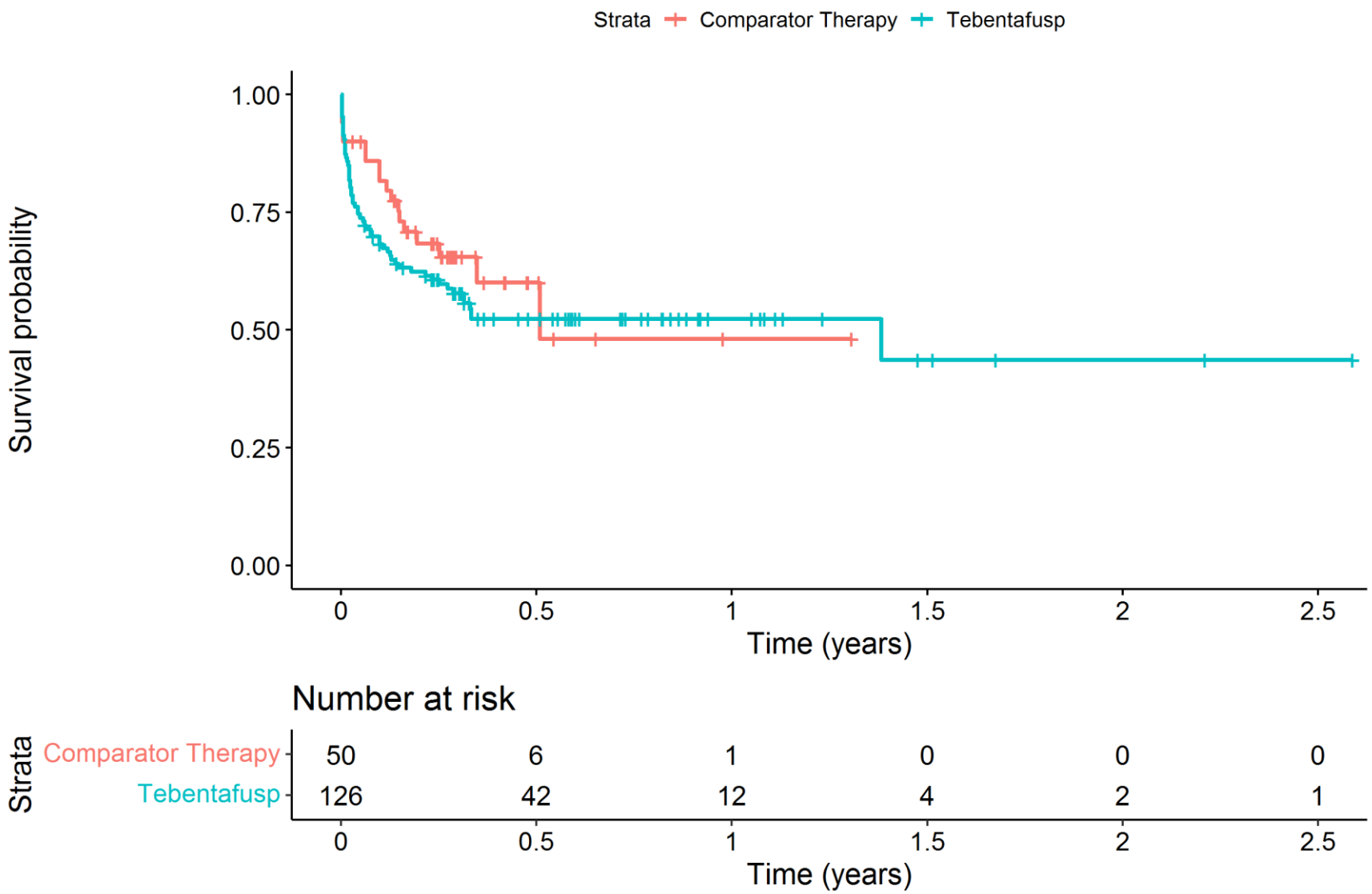
53.138 Müdigkeit - Männlich



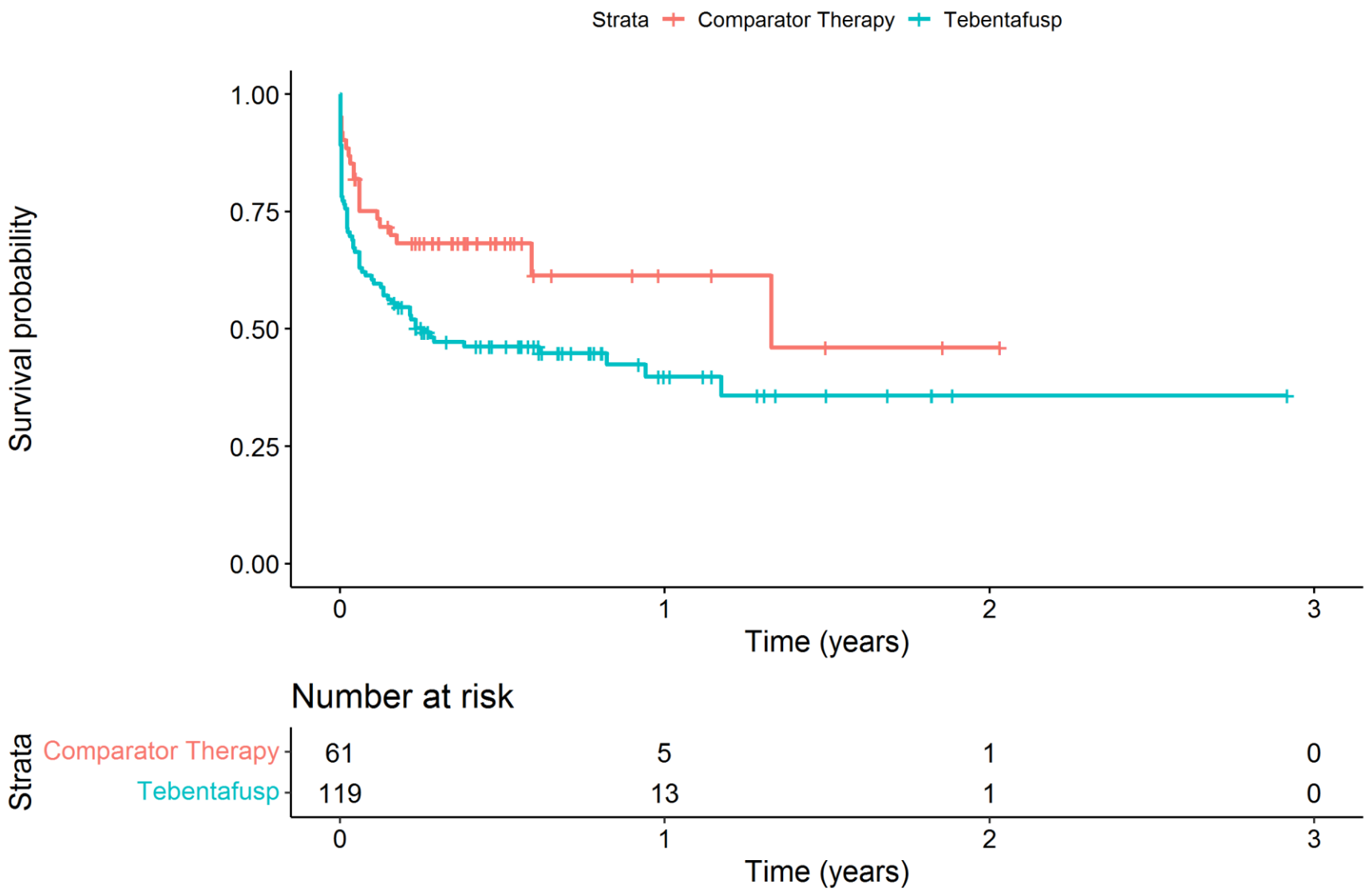
53.139 Müdigkeit - Weiblich



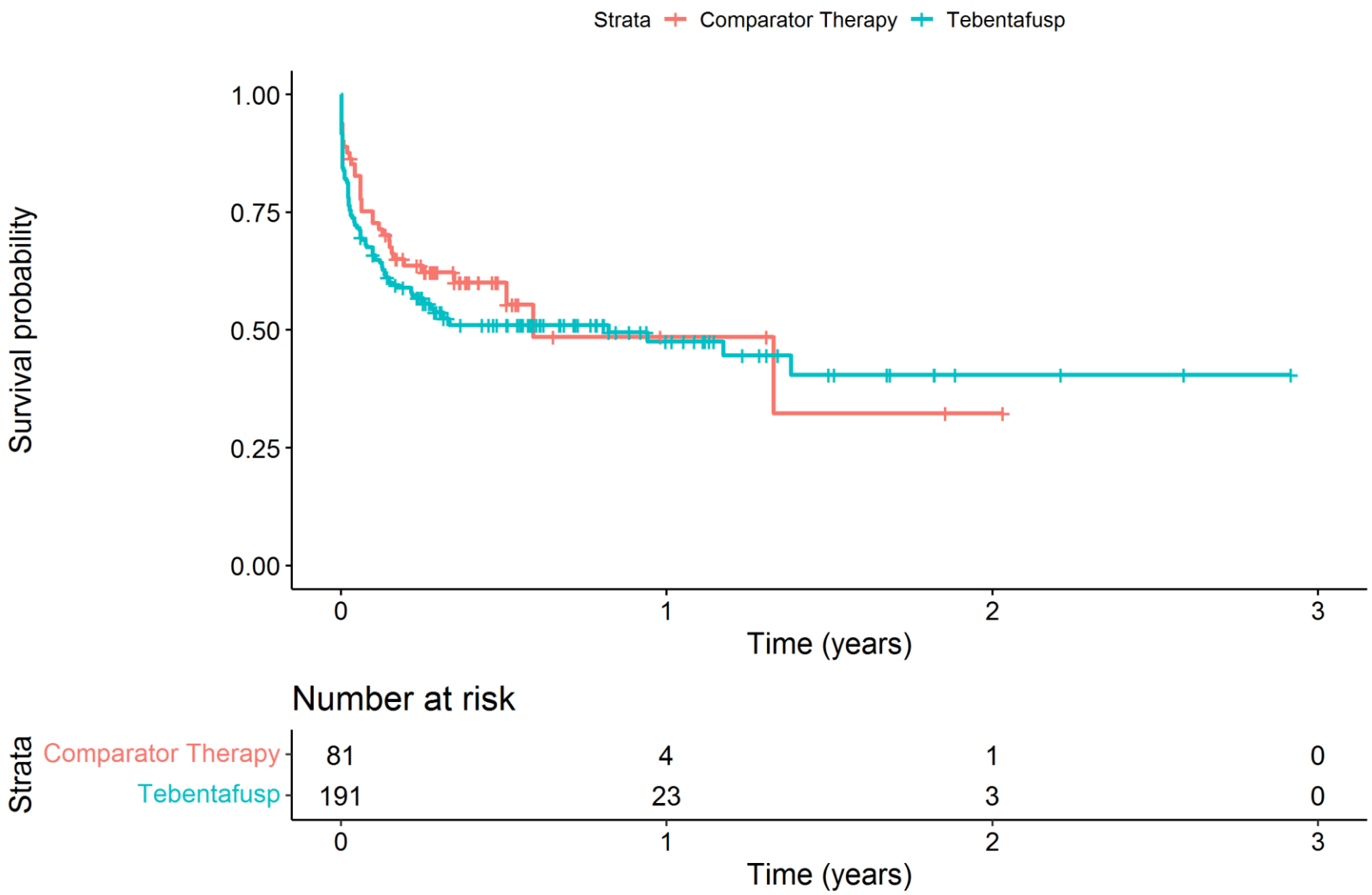
53.140 Müdigkeit - <65



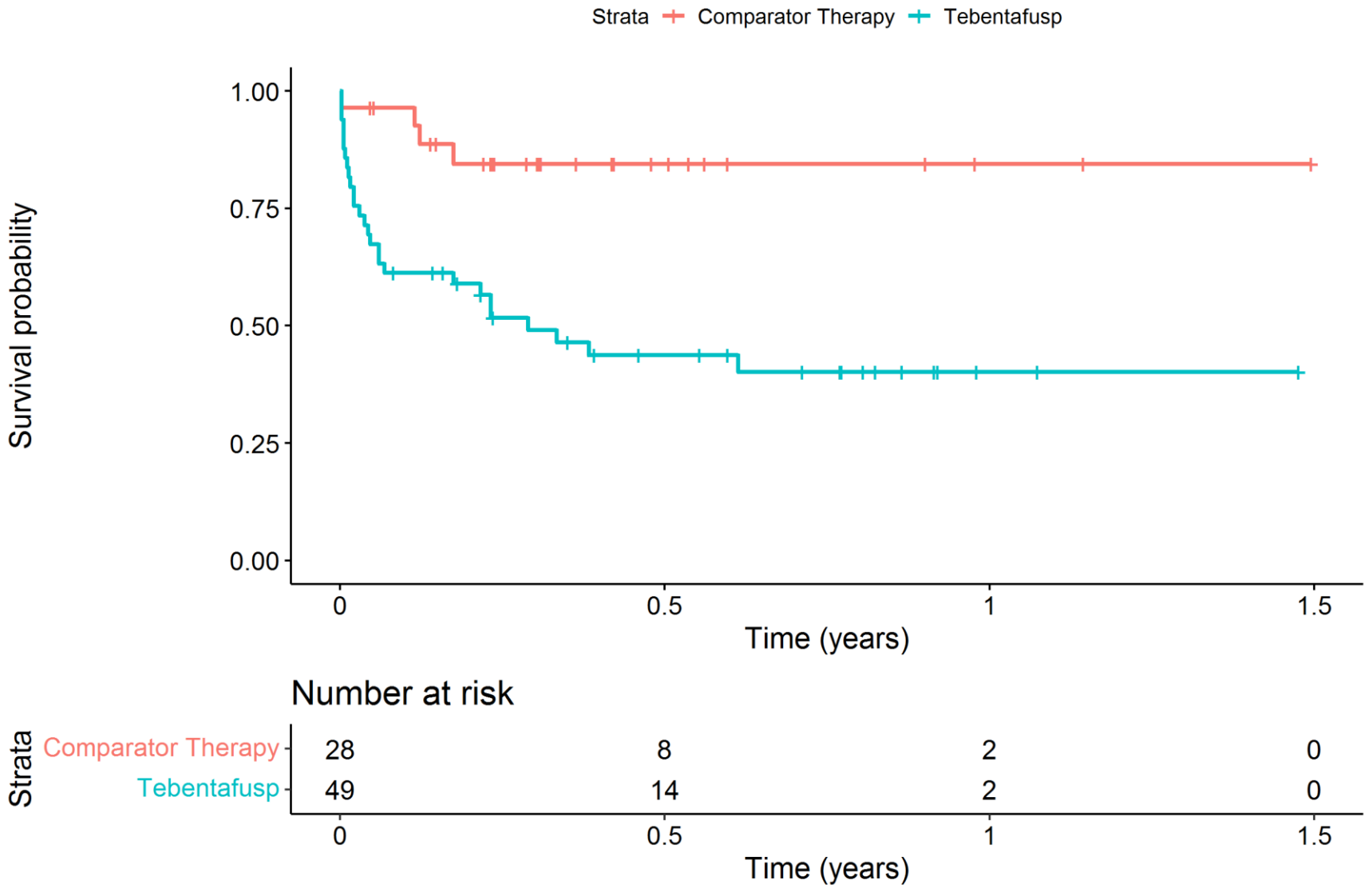
53.141 Müdigkeit - ≥65



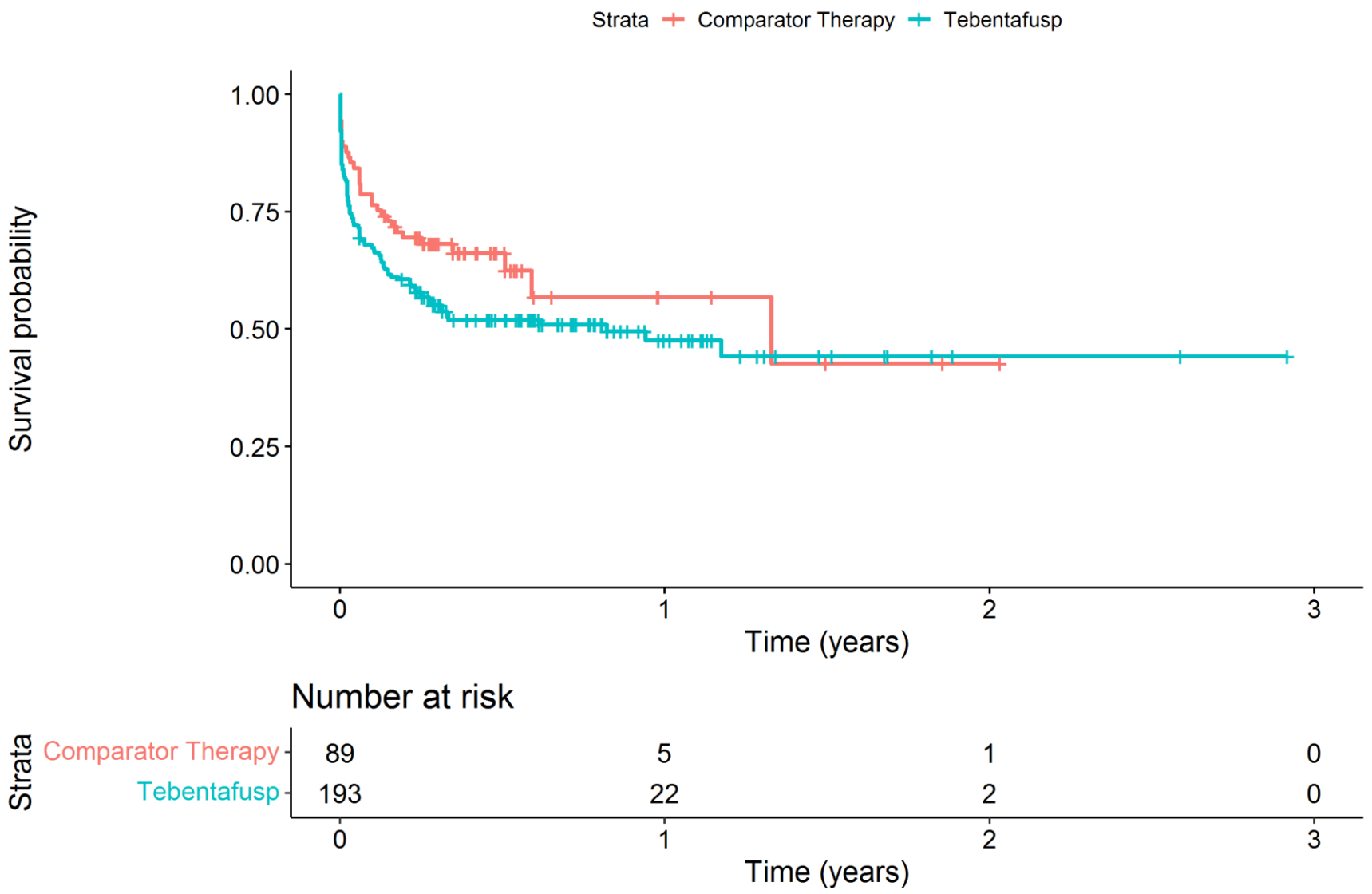
53.142 Müdigkeit - ECOG 0



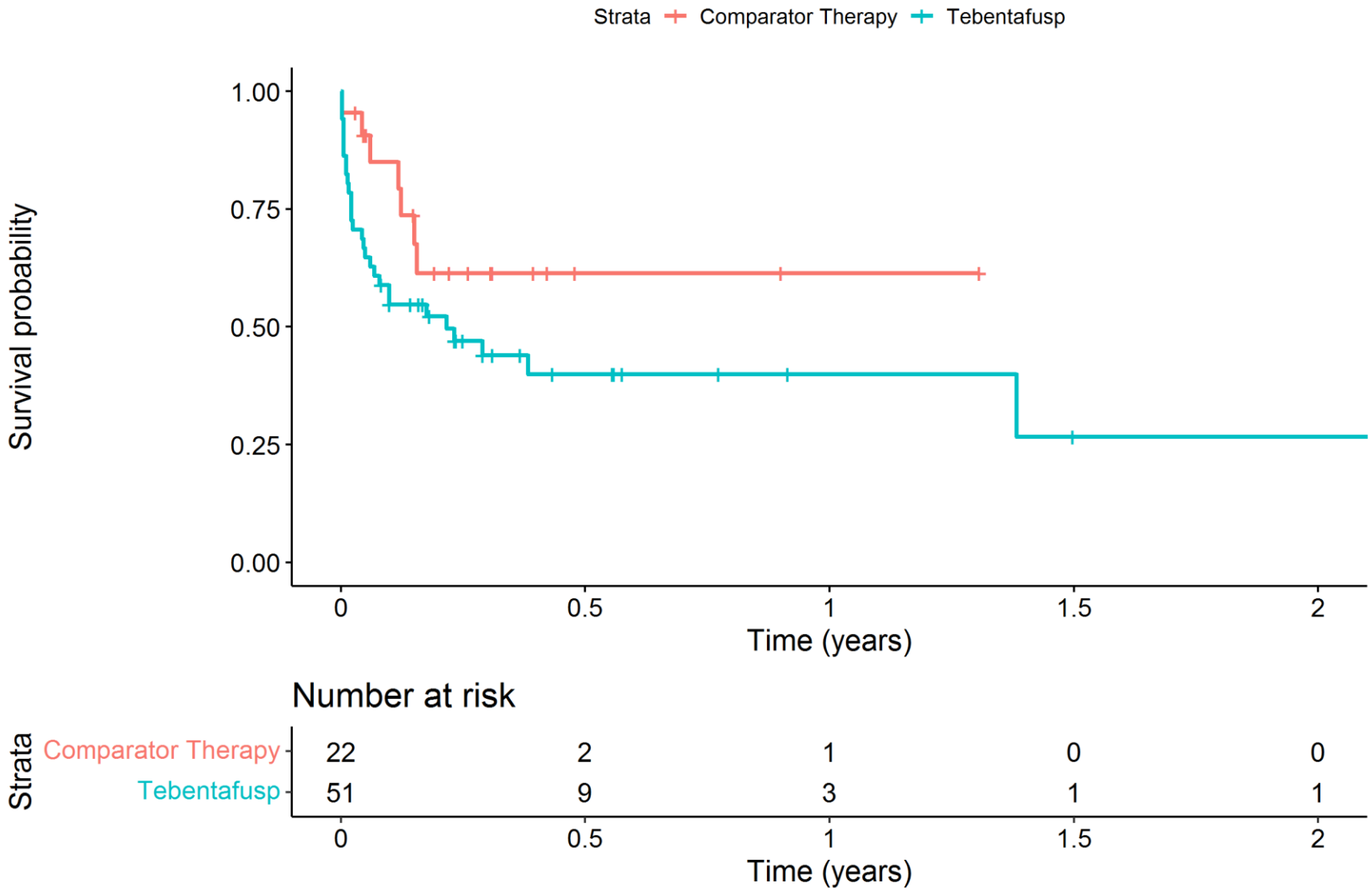
53.143 Müdigkeit - ECOG 1



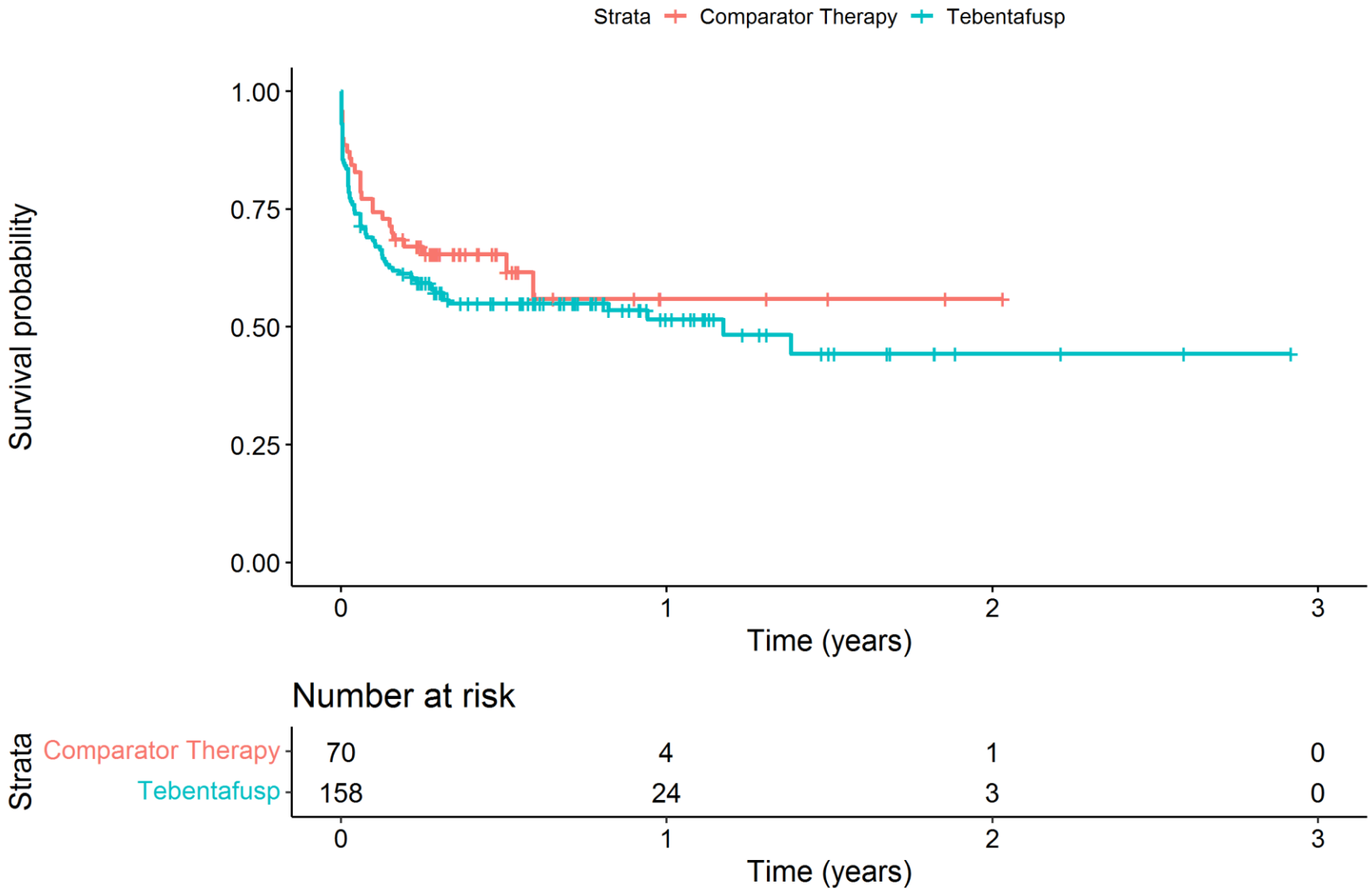
53.144 Müdigkeit - ALP ≤ ULN



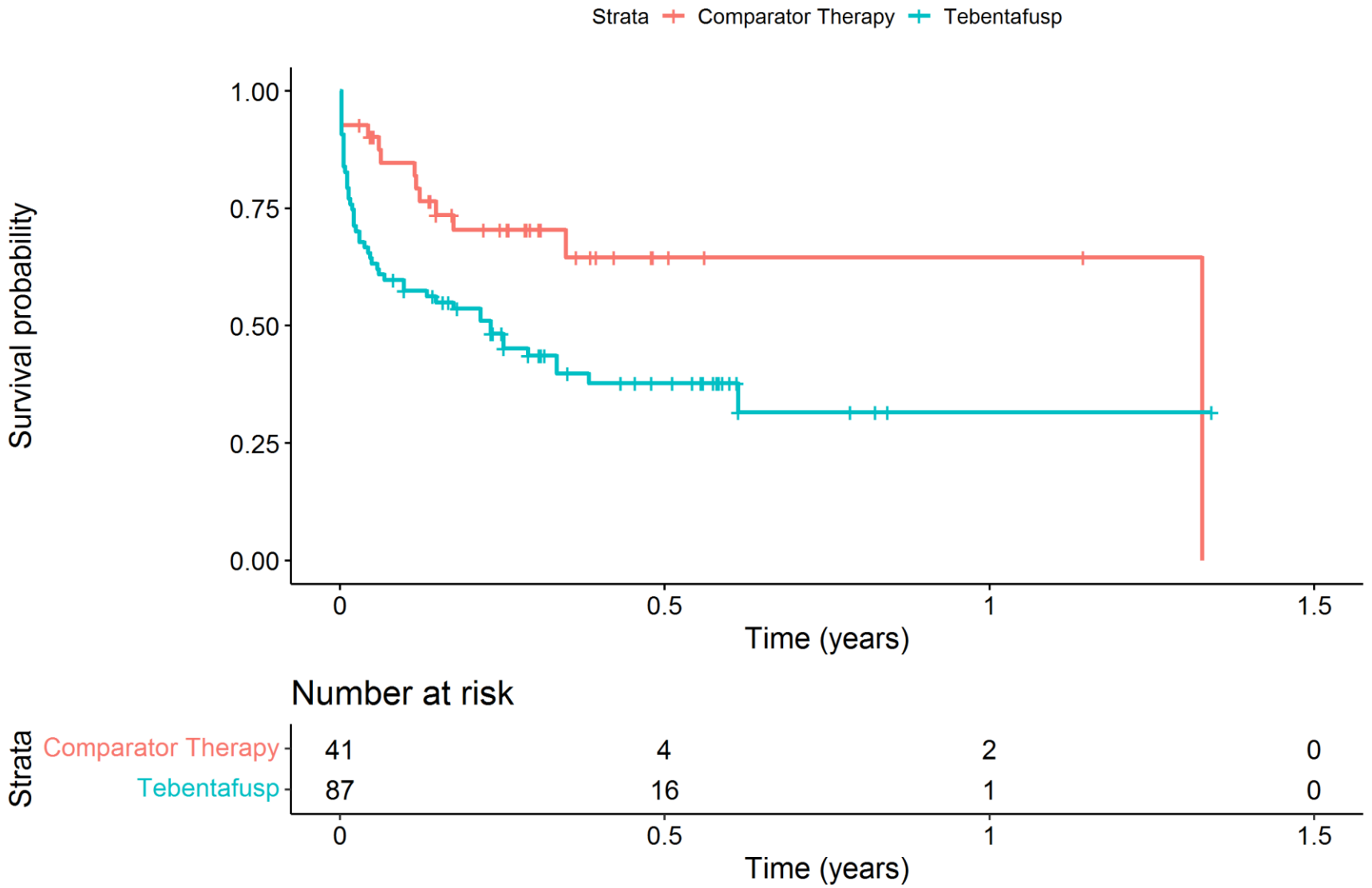
53.145 Müdigkeit - ALP > ULN



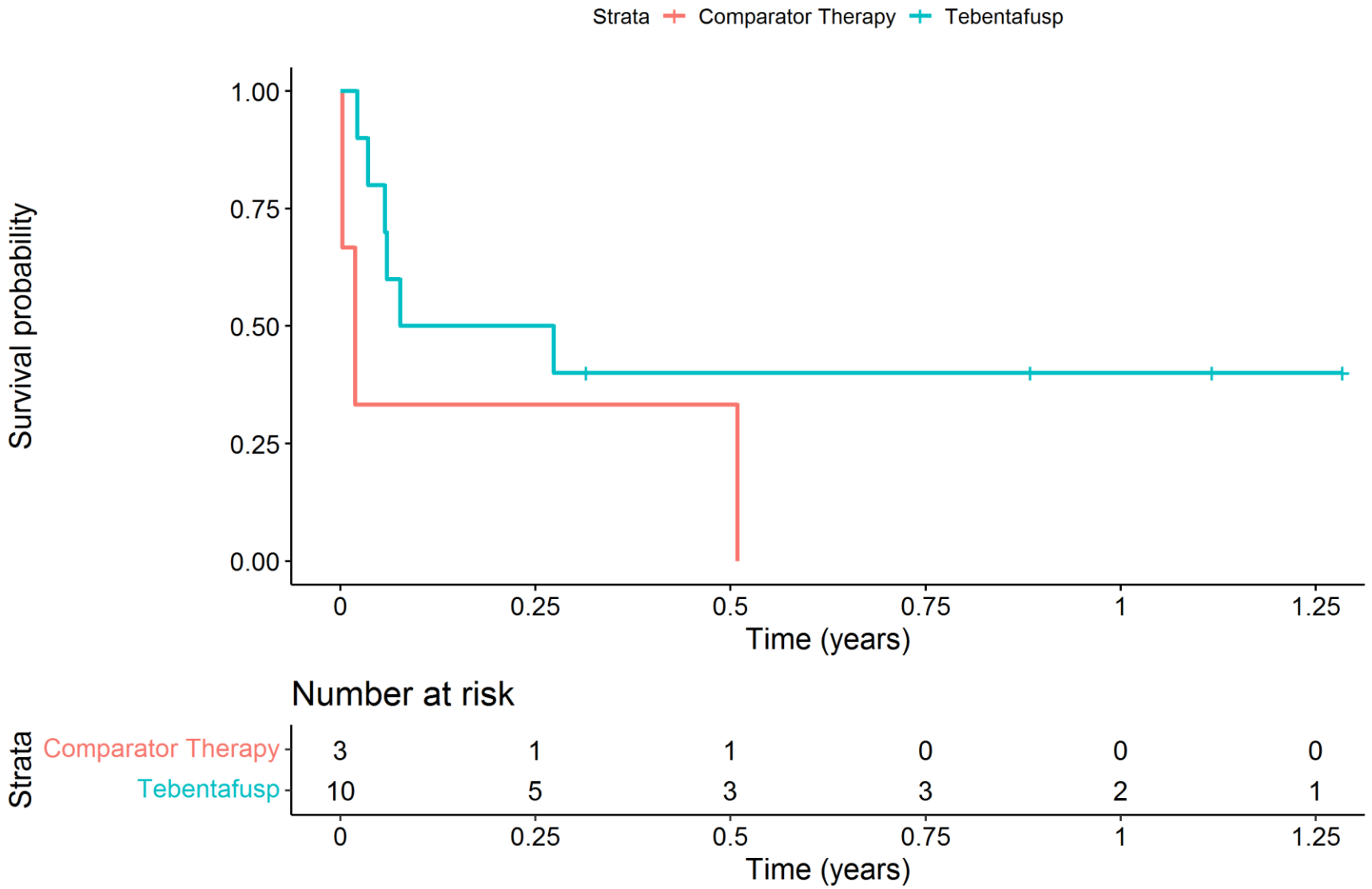
53.146 Müdigkeit - LDH =< ULN



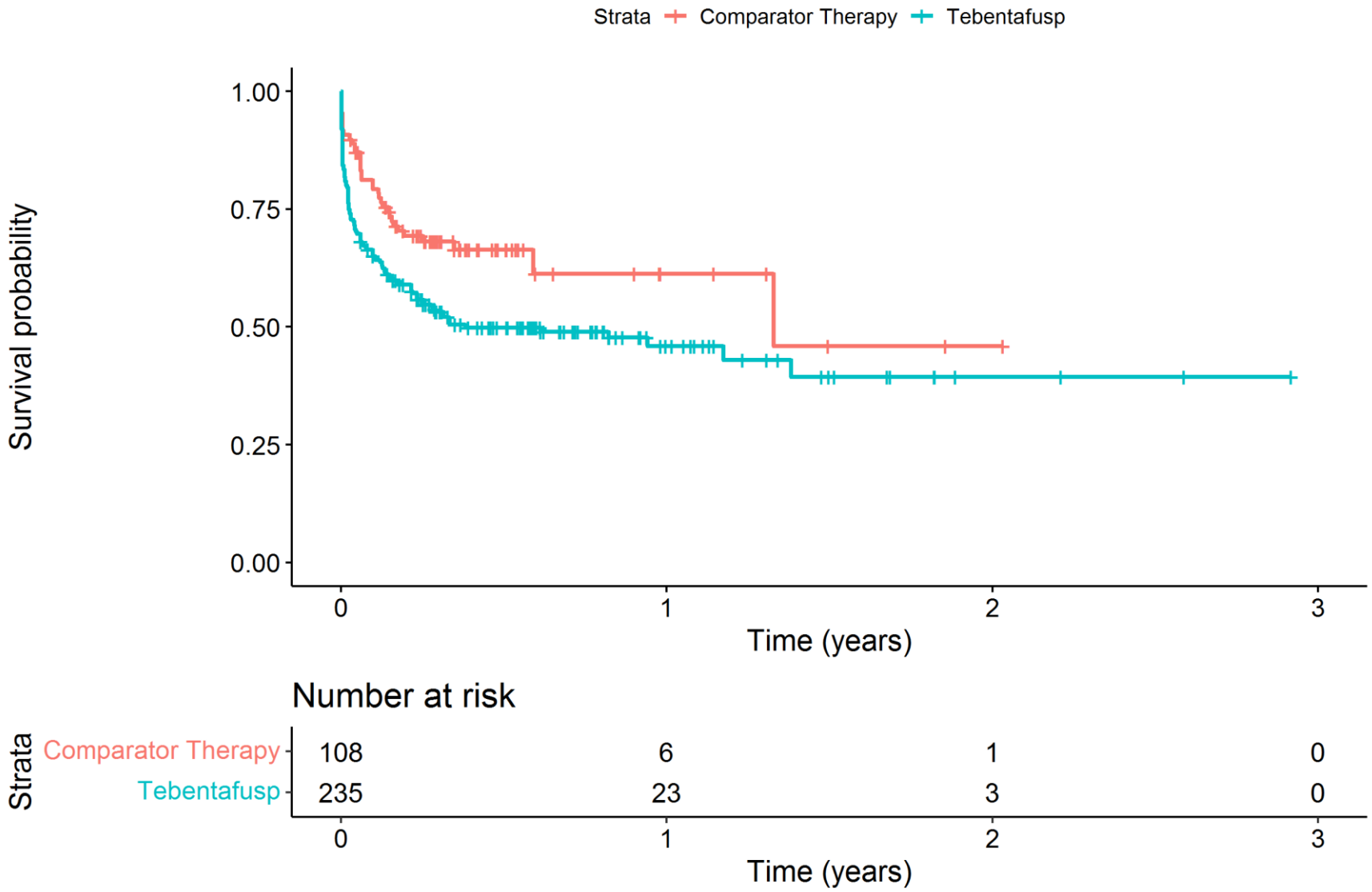
53.147 Müdigkeit - LDH > ULN



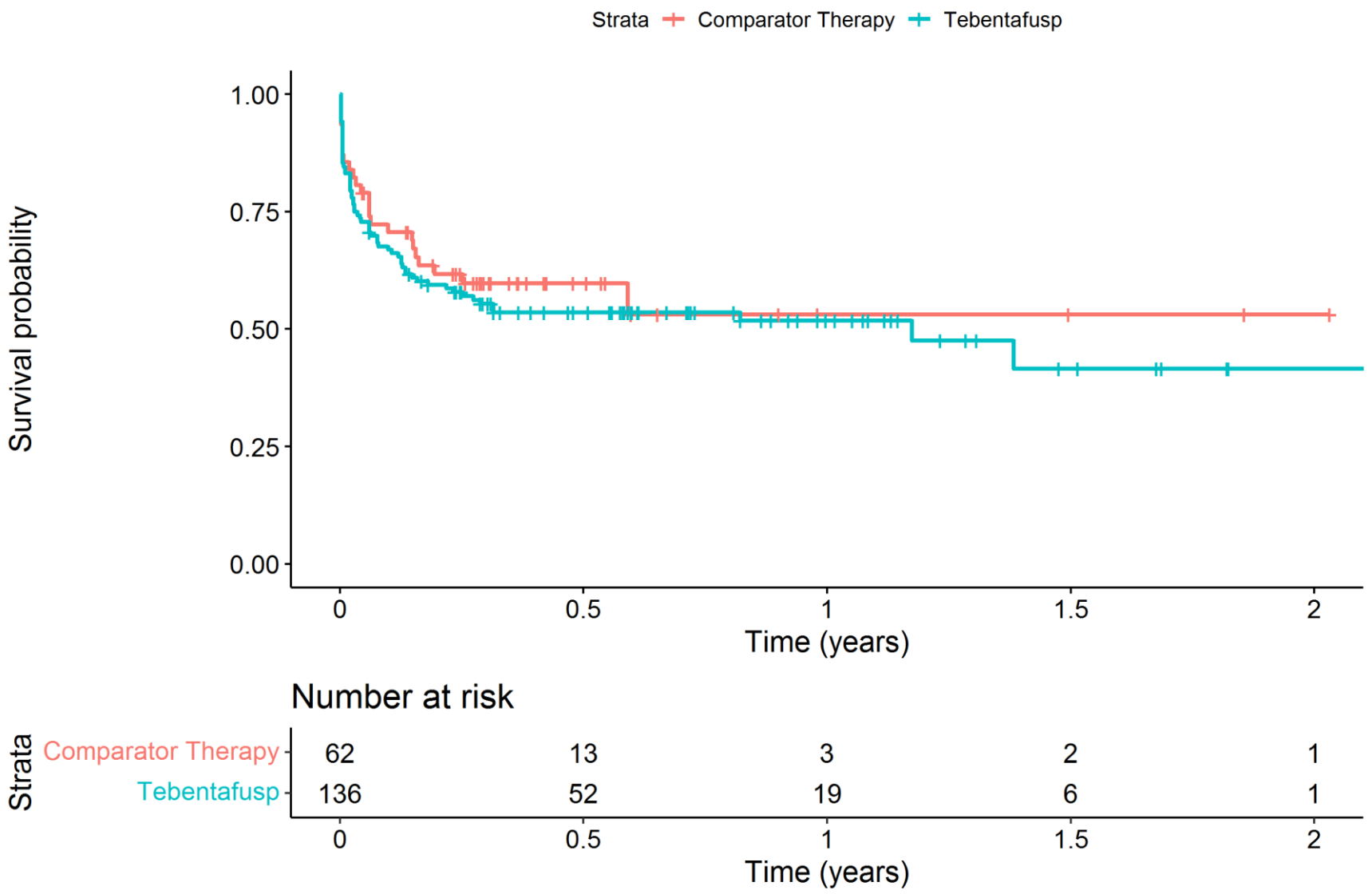
53.148 Müdigkeit - Vorherige Therapie adjuvant/neoadjuvant



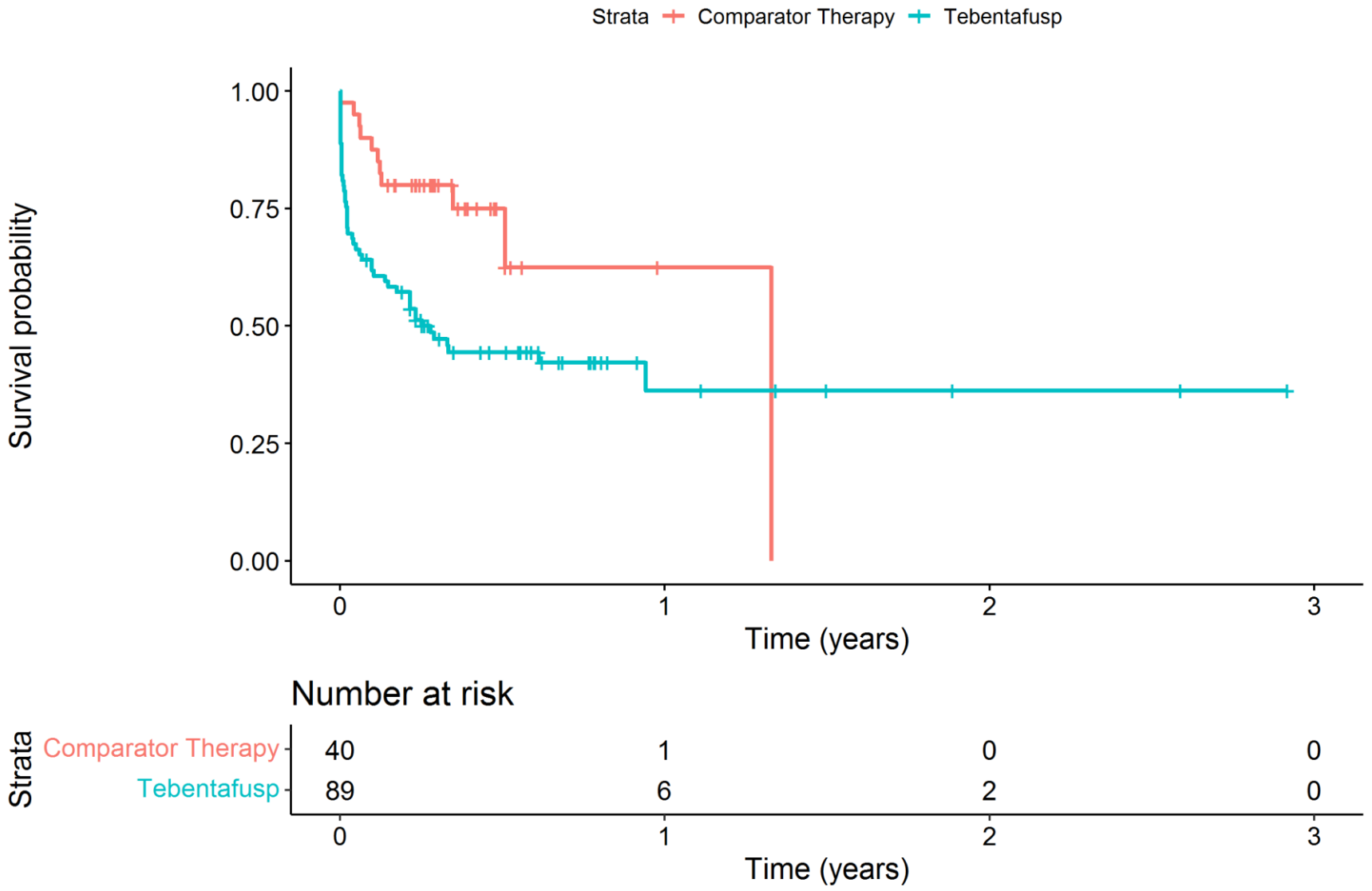
53.149 Müdigkeit - Keine vorherige Therapie adjuvant/neoadjuvant



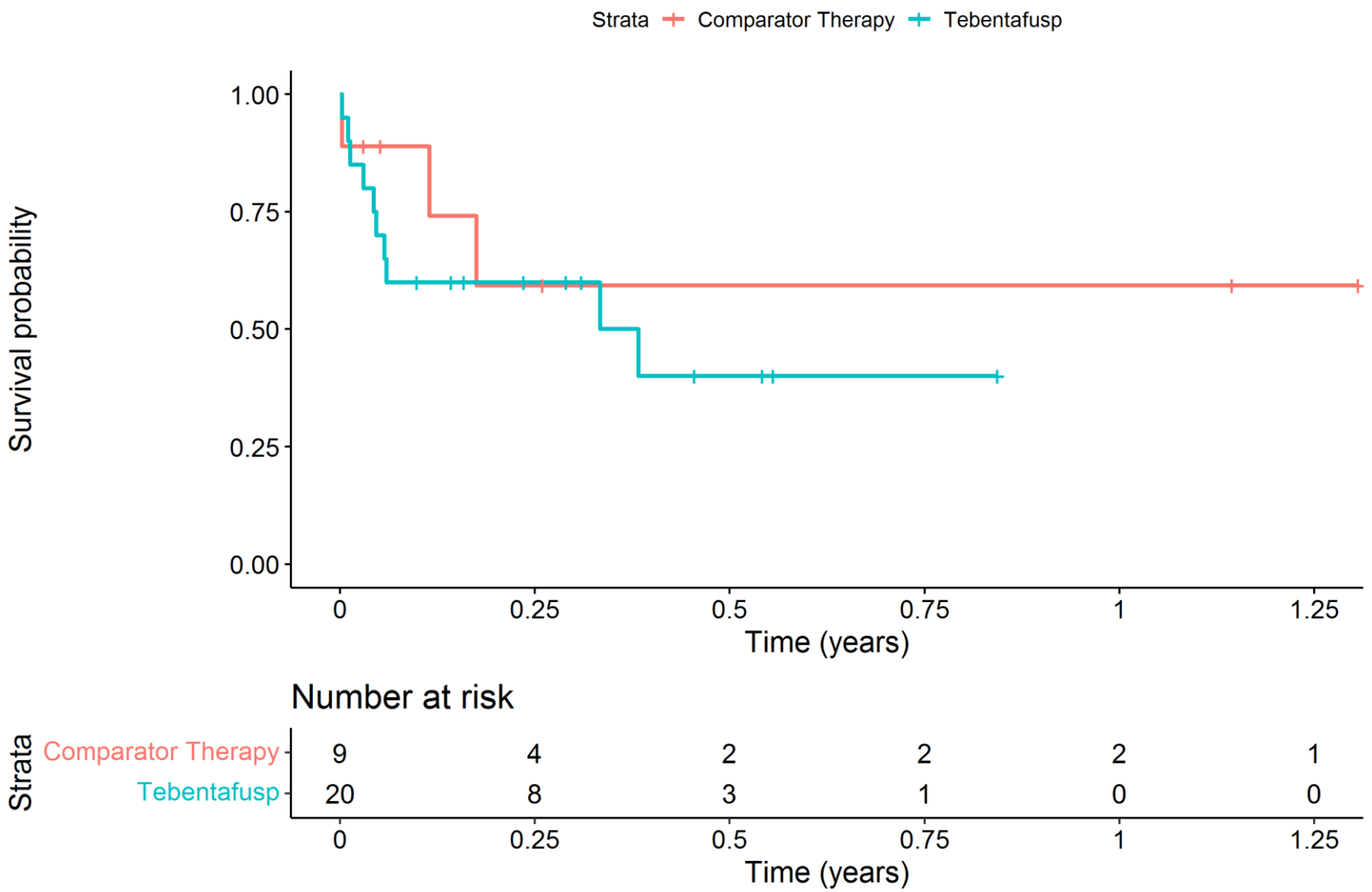
53.150 Müdigkeit - Läsion ≤ 3cm



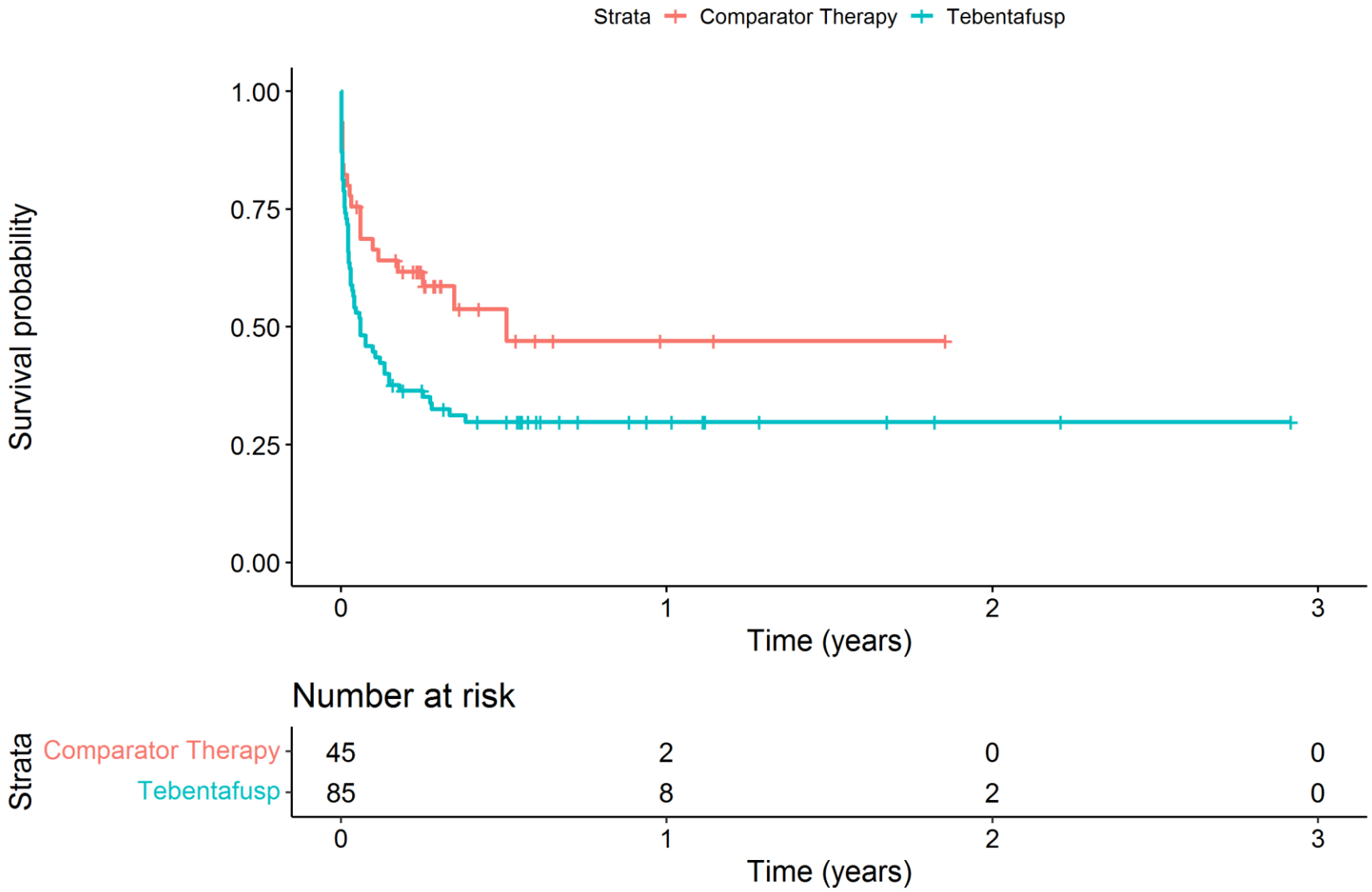
53.151 Müdigkeit - Läsion 3,1-8,0 cm



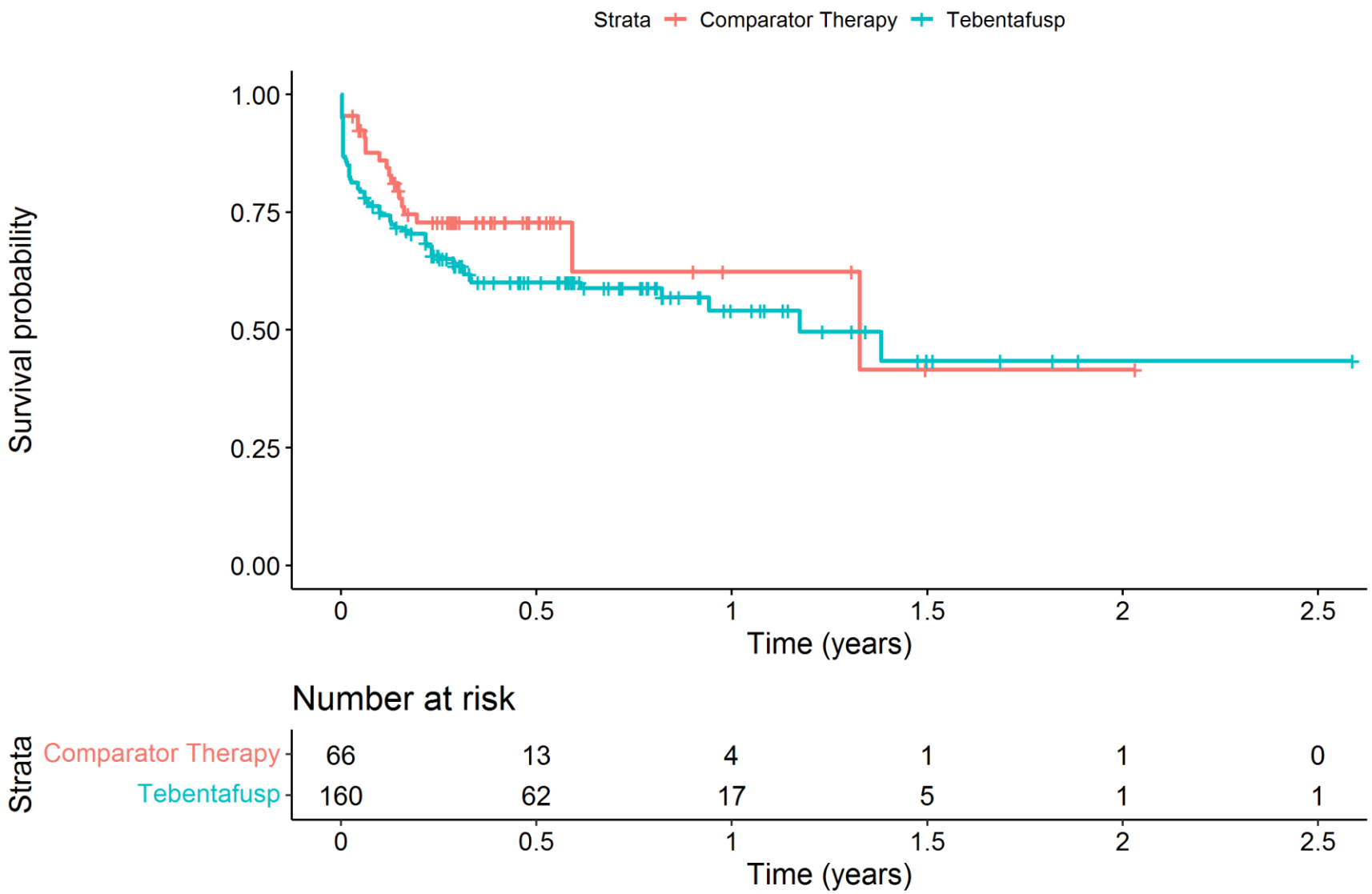
53.152 Müdigkeit - Läsion ≥8,1 cm



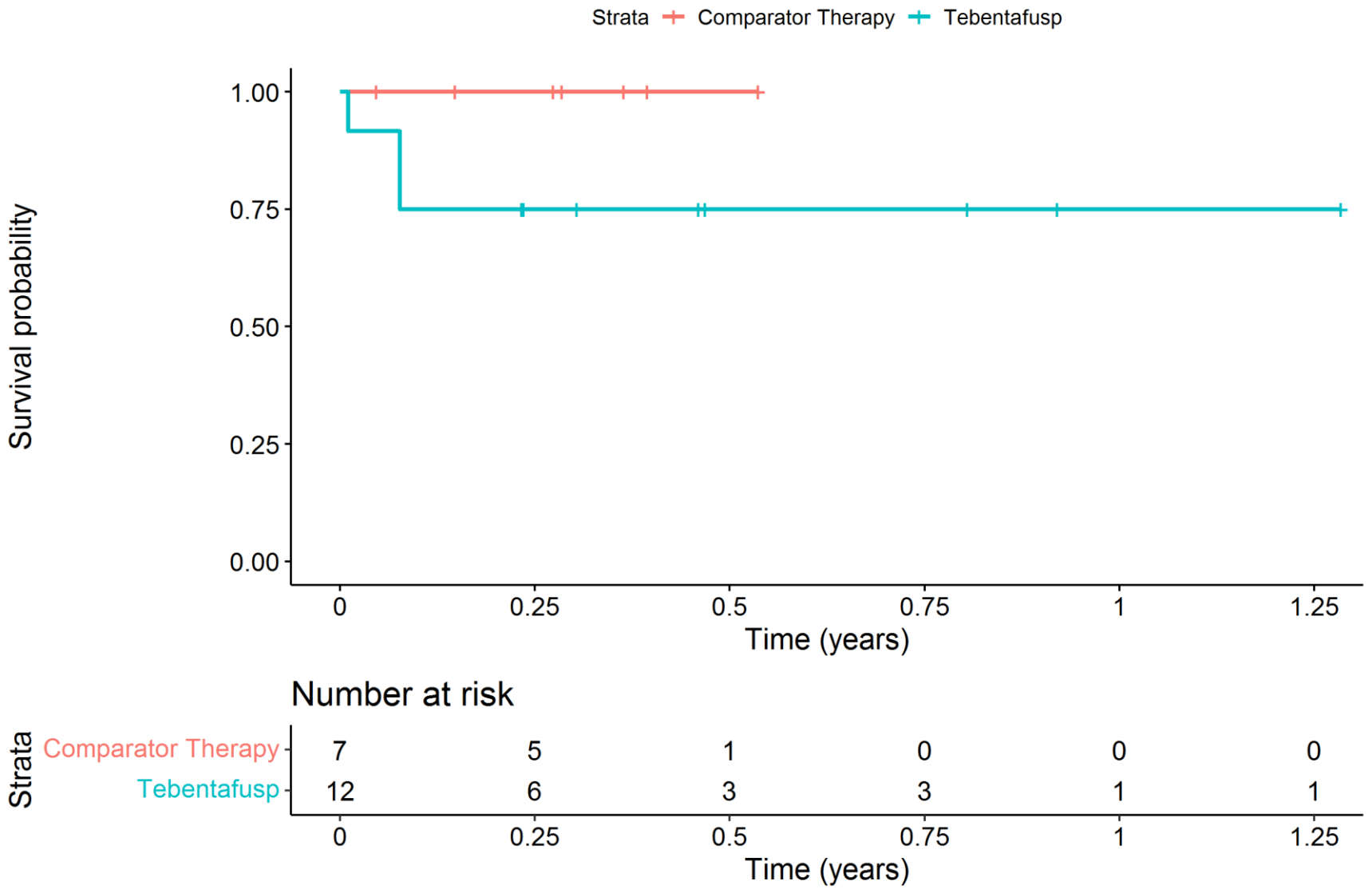
53.153 Müdigkeit - Nordamerika



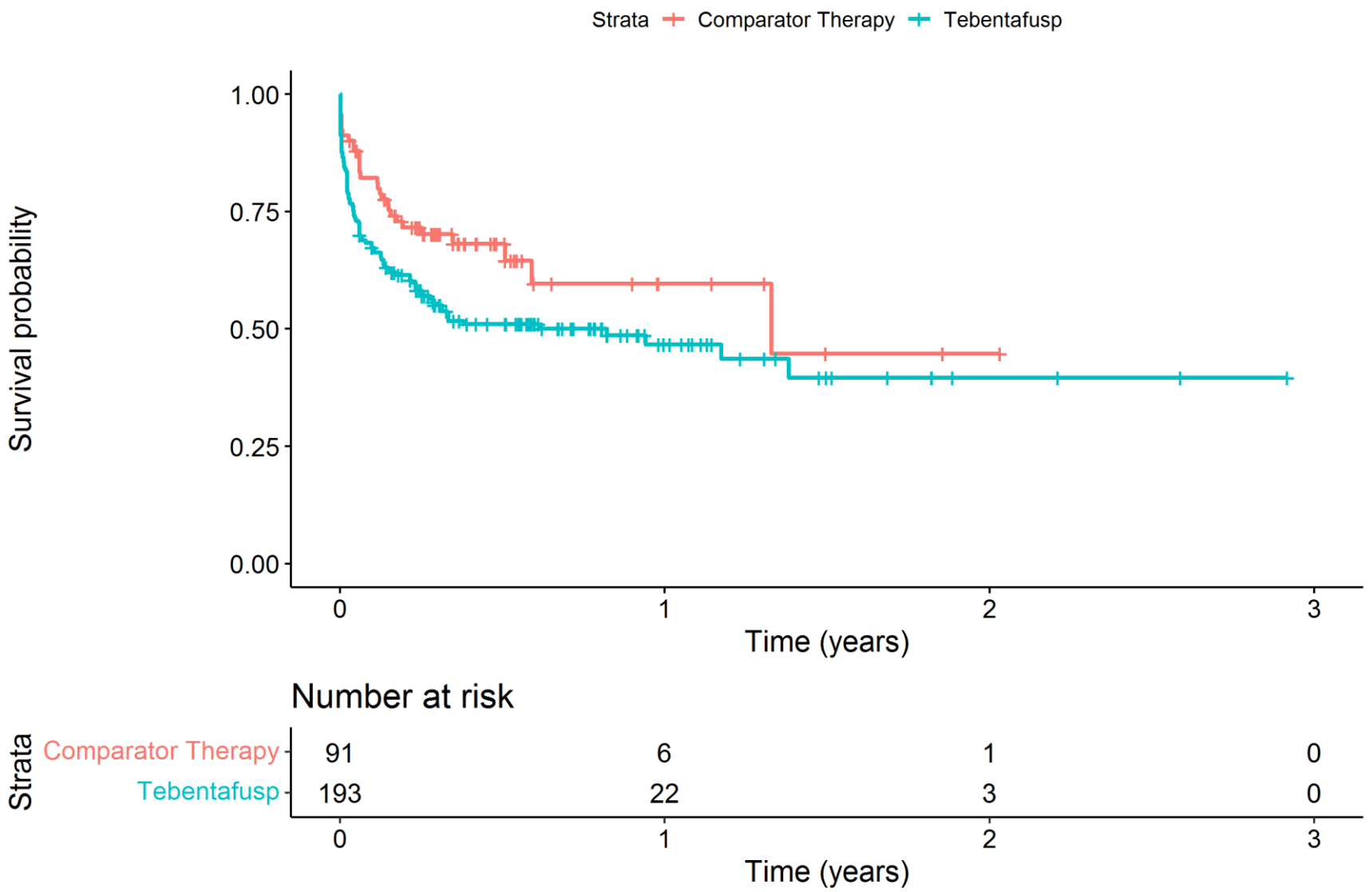
53.154 Müdigkeit - Nicht-Nordamerika



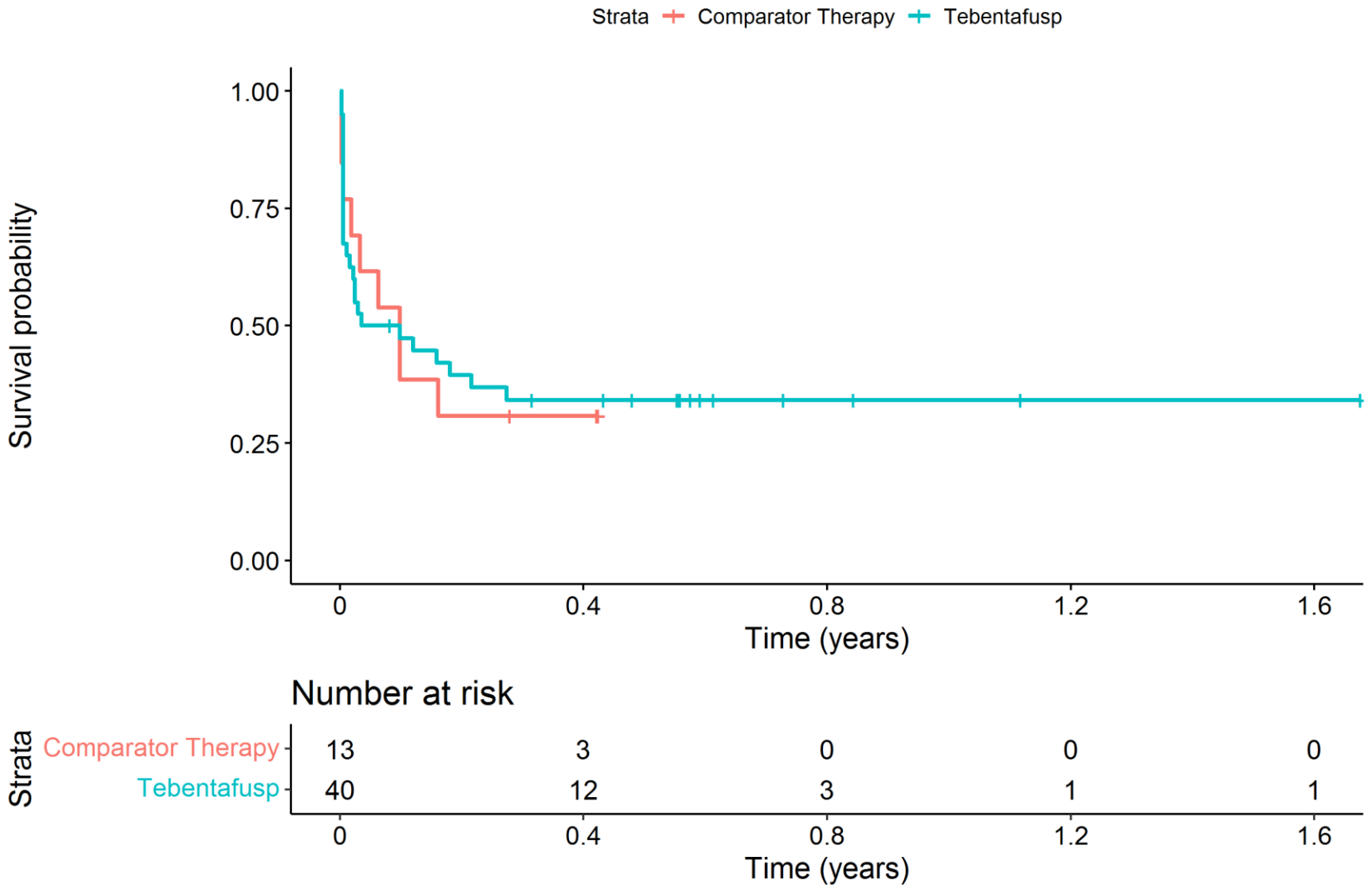
53.155 Müdigkeit - Dacarbazin



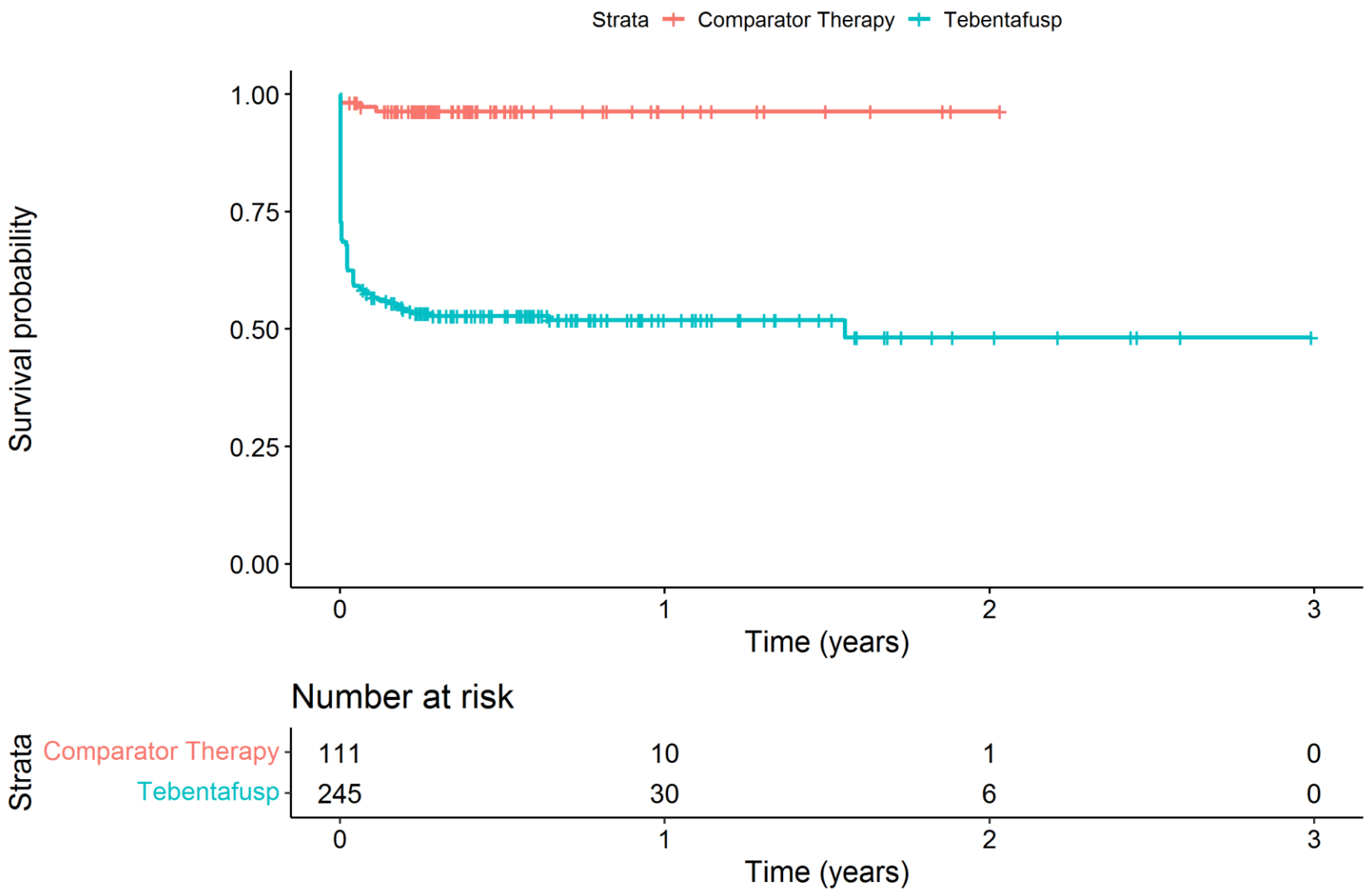
53.156 Müdigkeit - Pembrolizumab



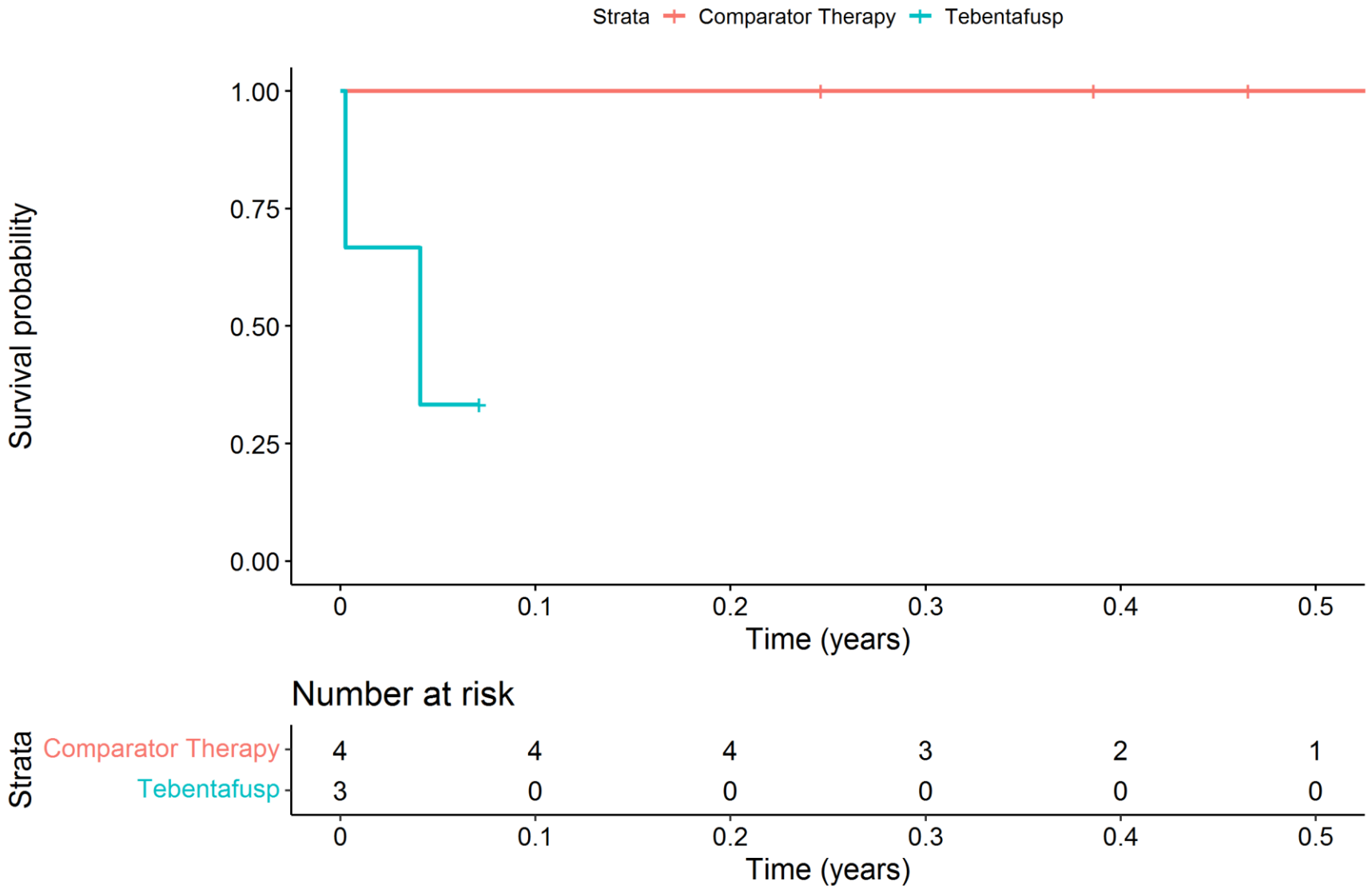
53.157 Müdigkeit - Ipilimumab



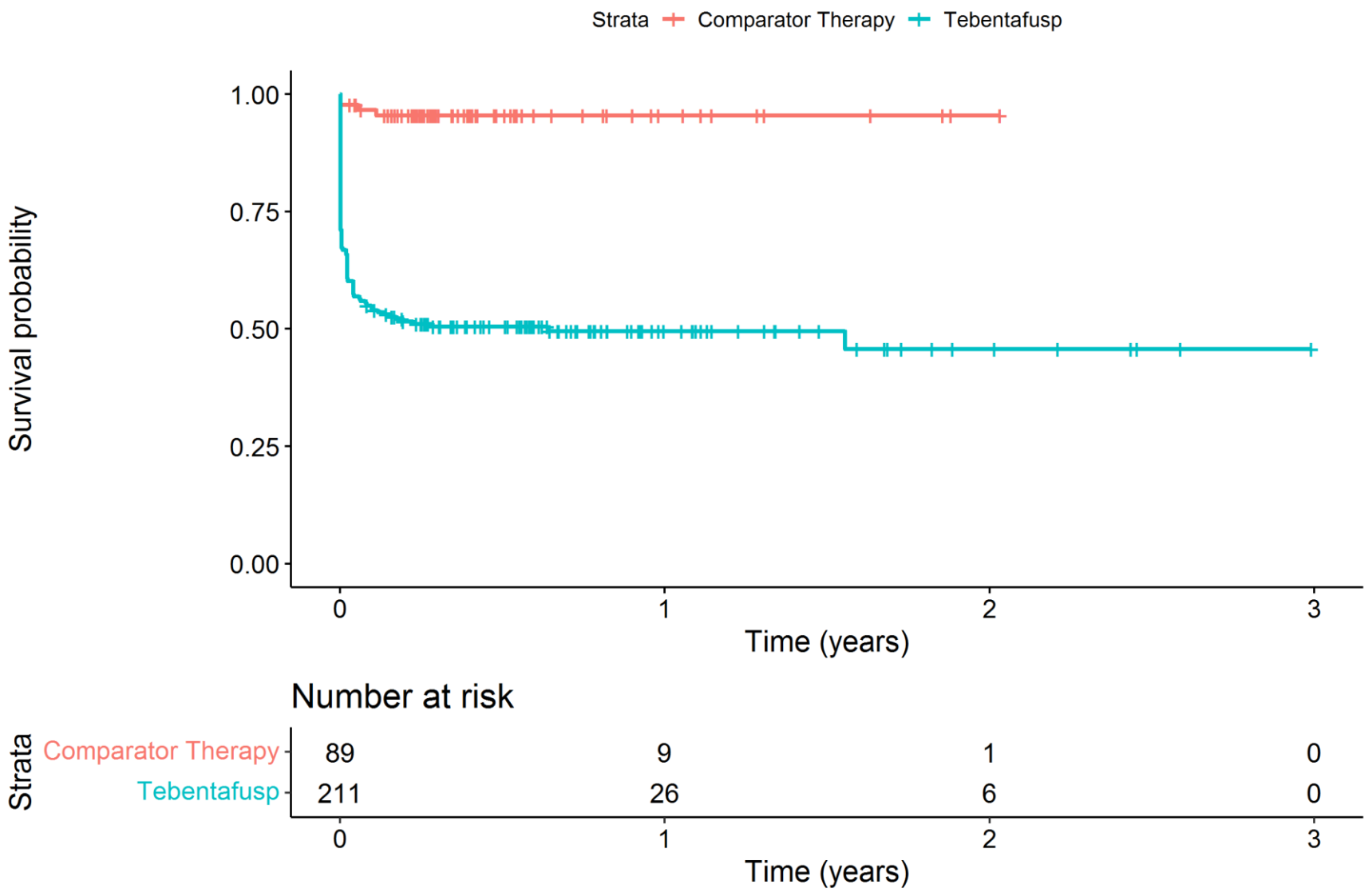
53.158 Schüttelfrost - Gesamt



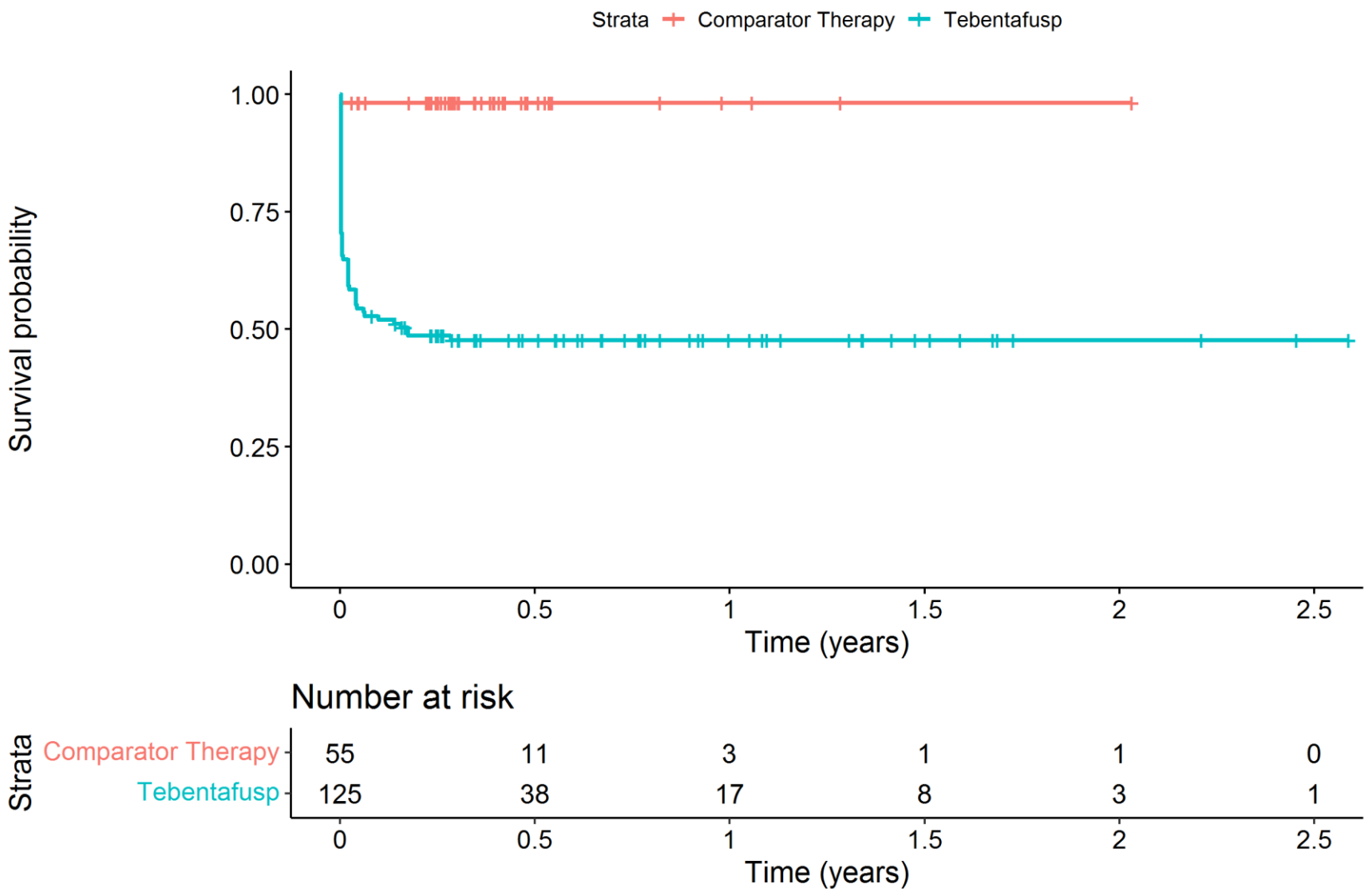
53.159 Schüttelfrost - Hispanisch



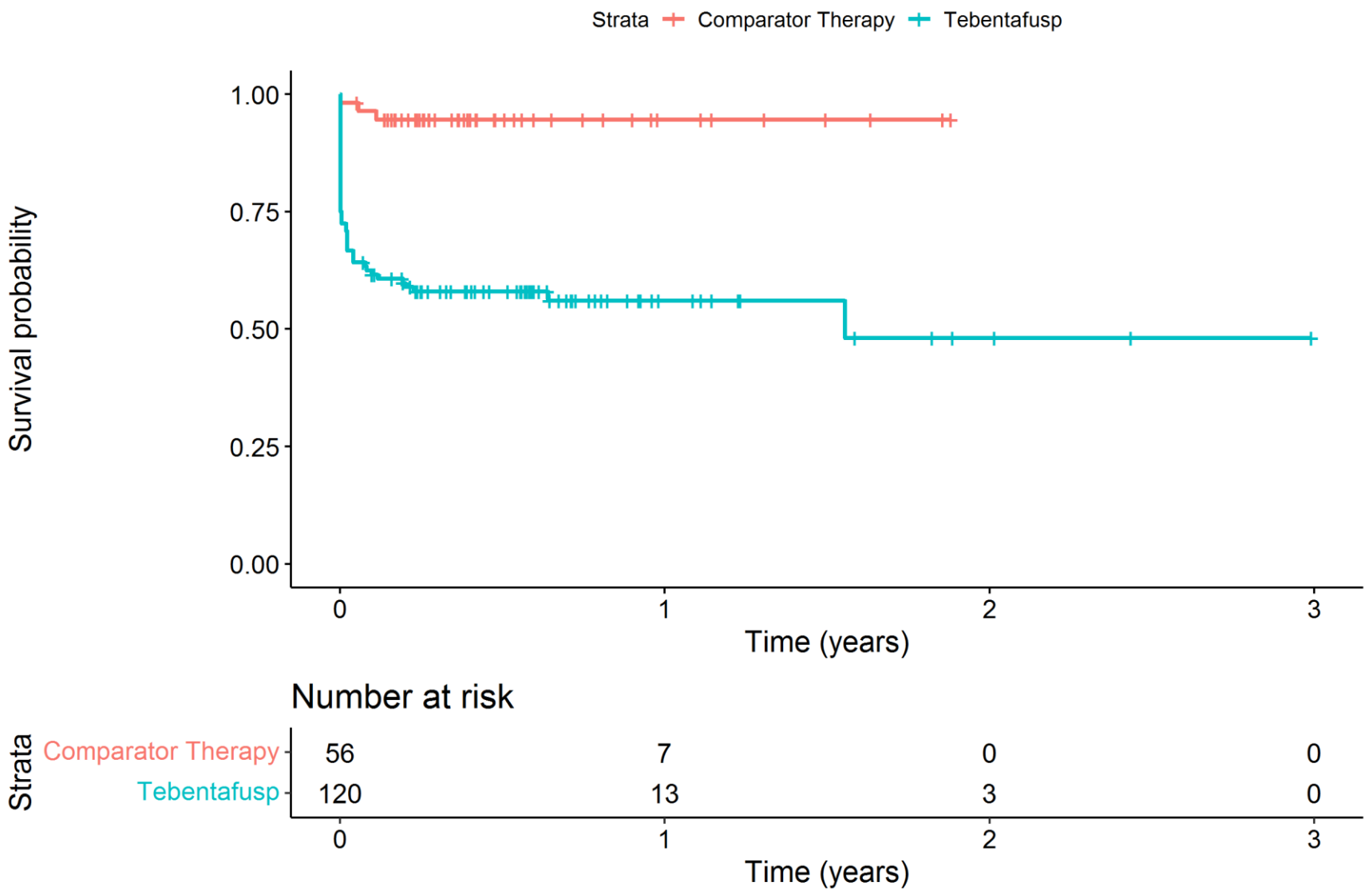
53.160 Schüttelfrost - Nicht-hispanisch



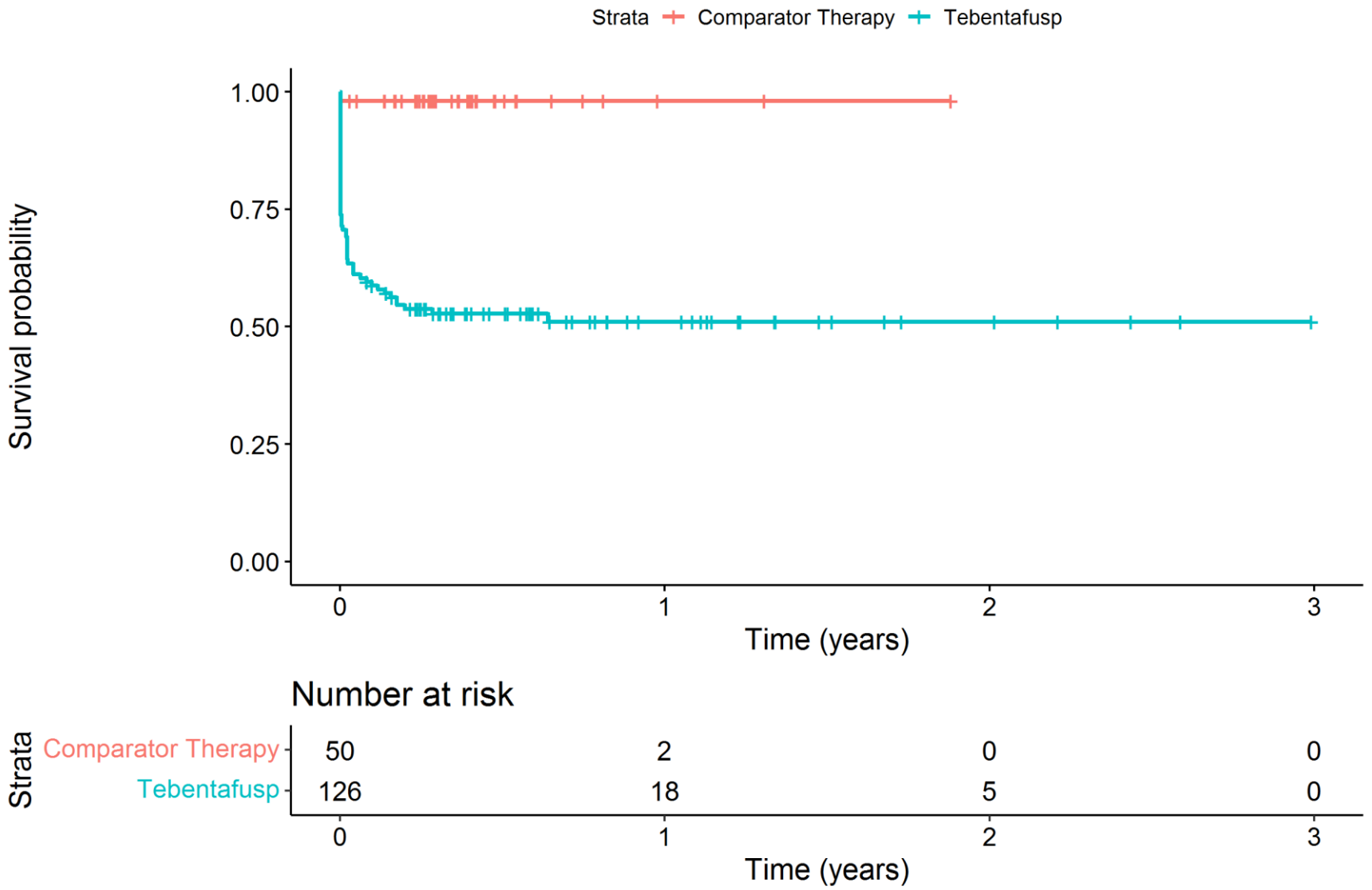
53.161 Schüttelfrost - Männlich



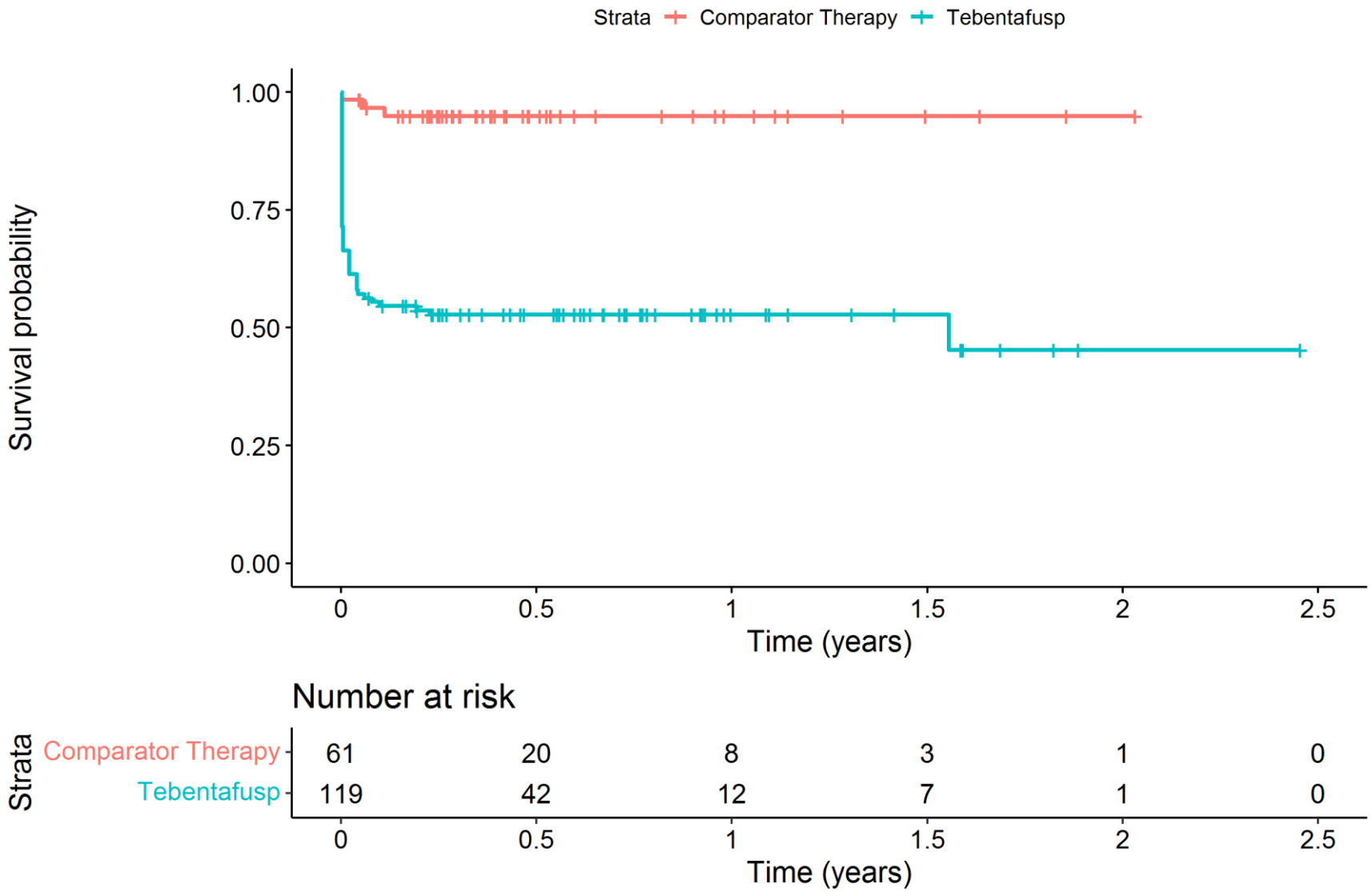
53.162 Schüttelfrost - Weiblich



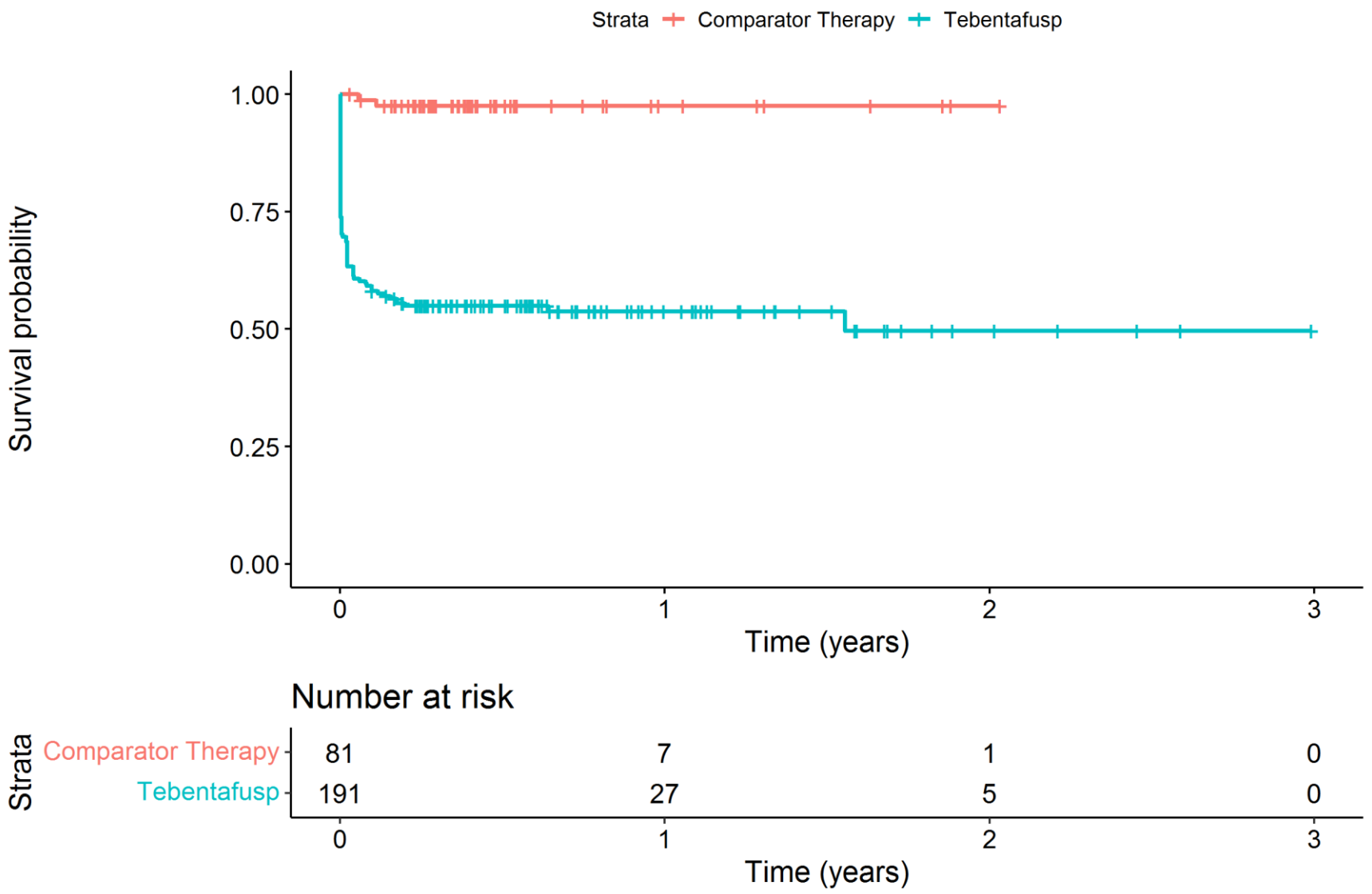
53.163 Schüttelfrost - <65



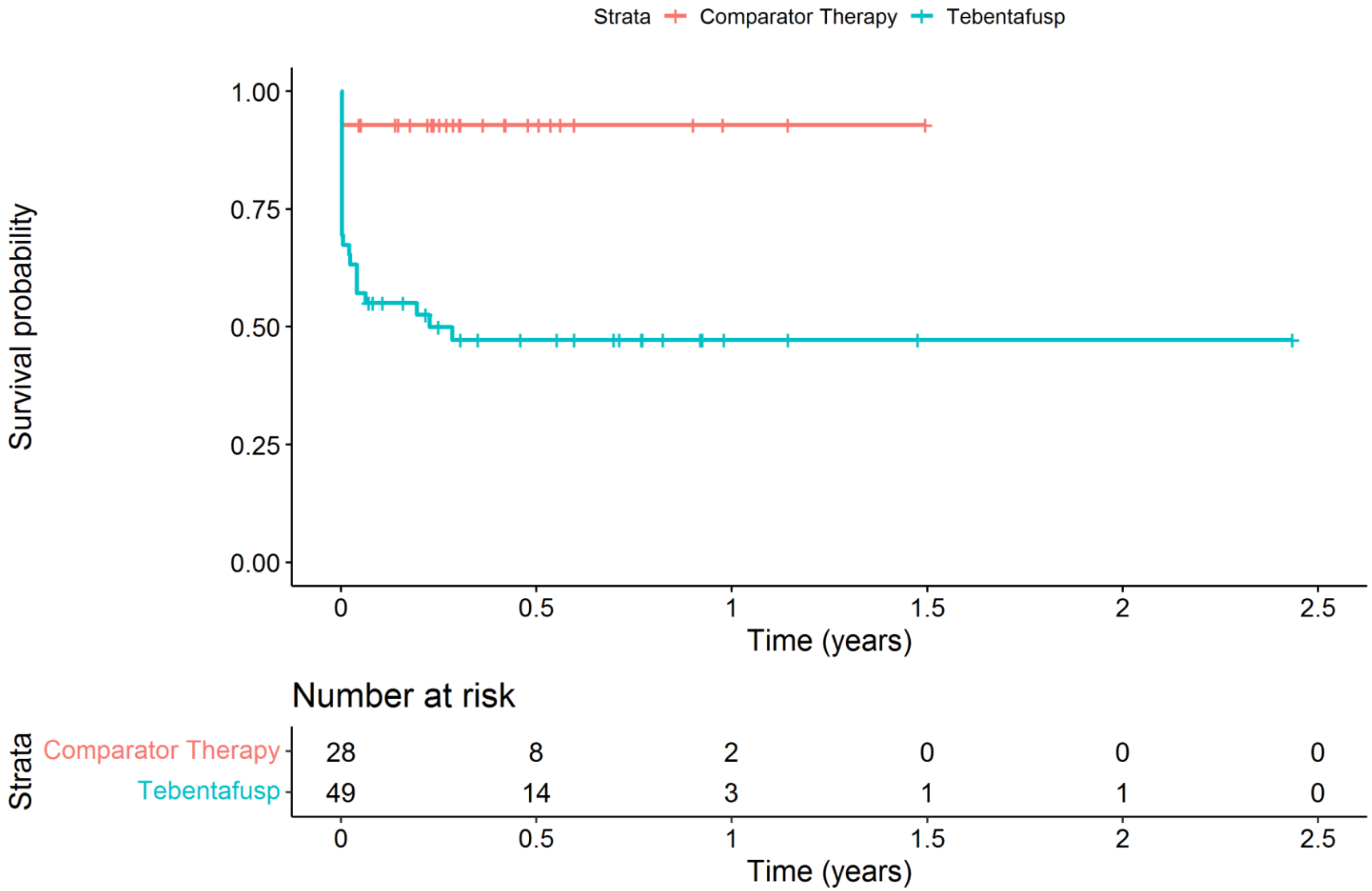
53.164 Schüttelfrost - ≥65



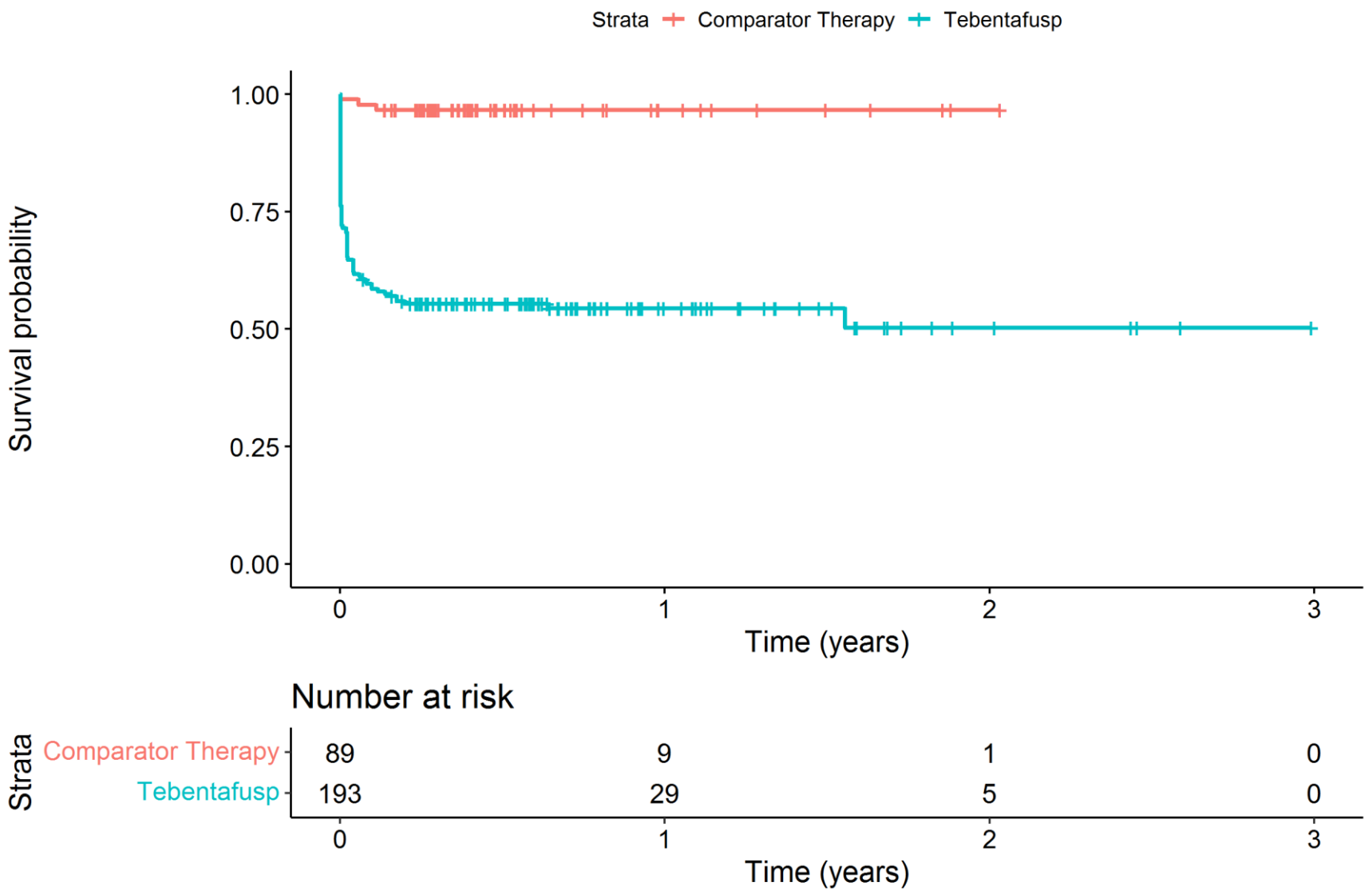
53.165 Schüttelfrost - ECOG 0



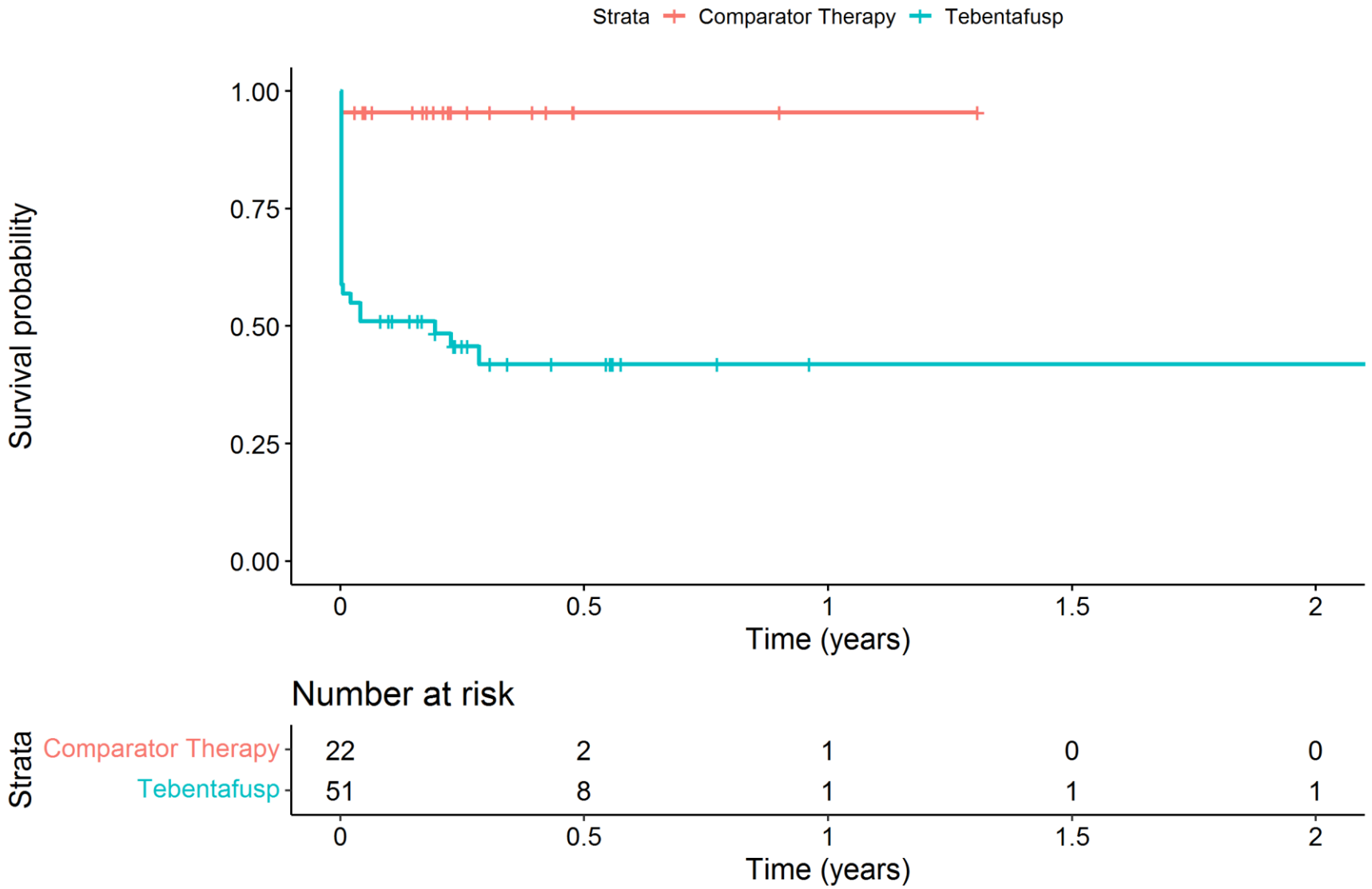
53.166 Schüttelfrost - ECOG 1



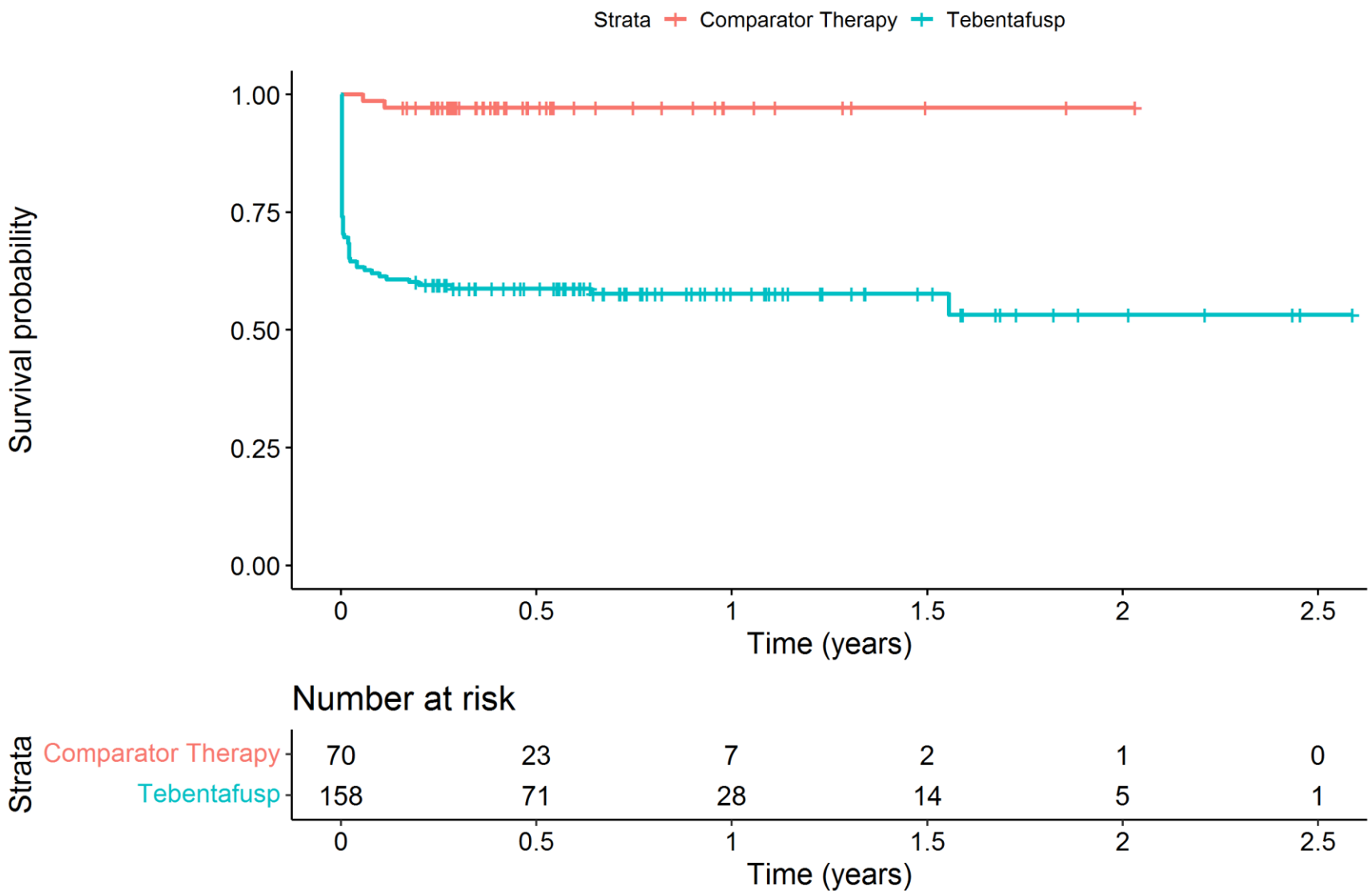
53.167 Schüttelfrost - ALP ≤ ULN



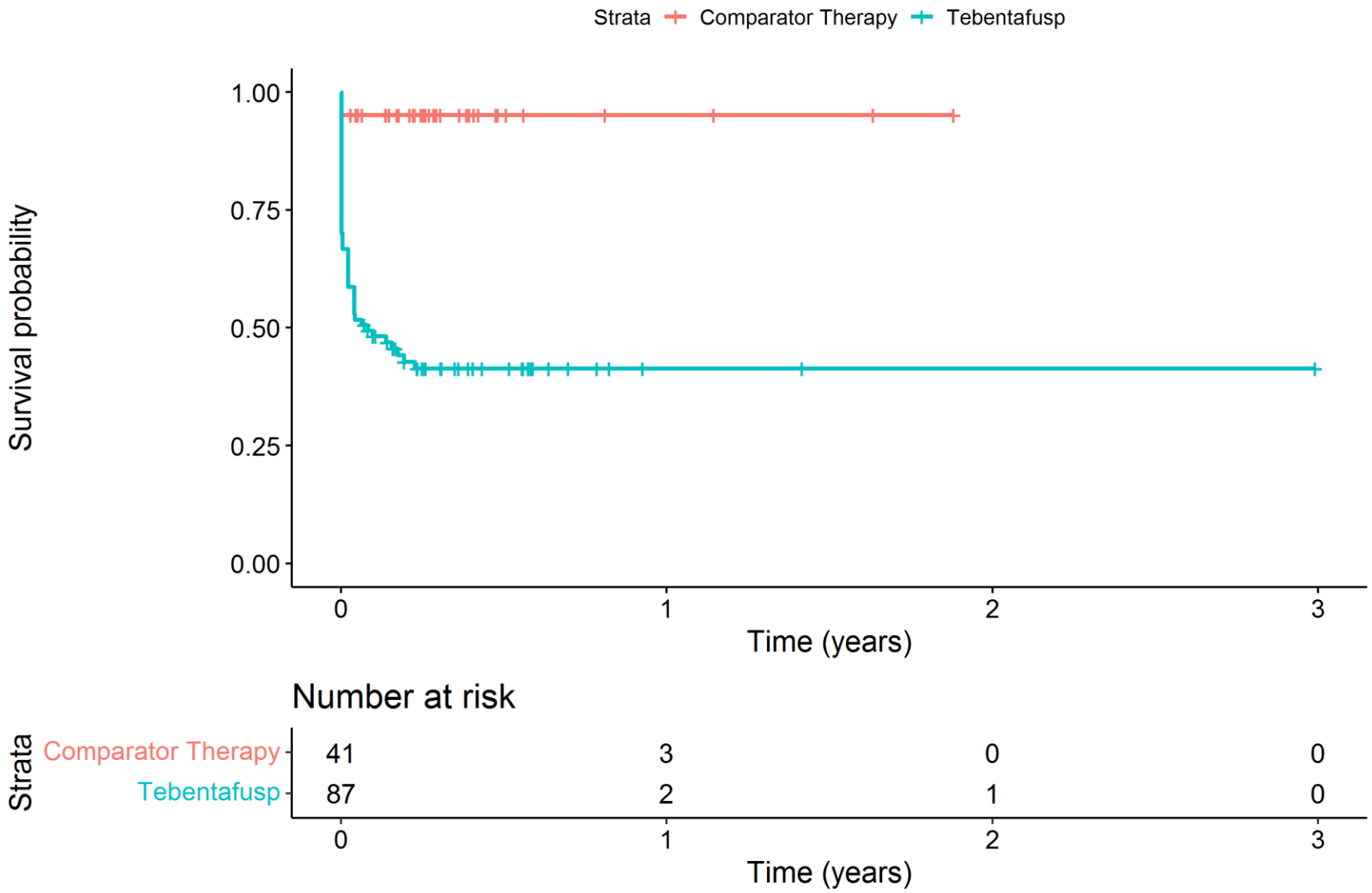
53.168 Schüttelfrost - ALP > ULN



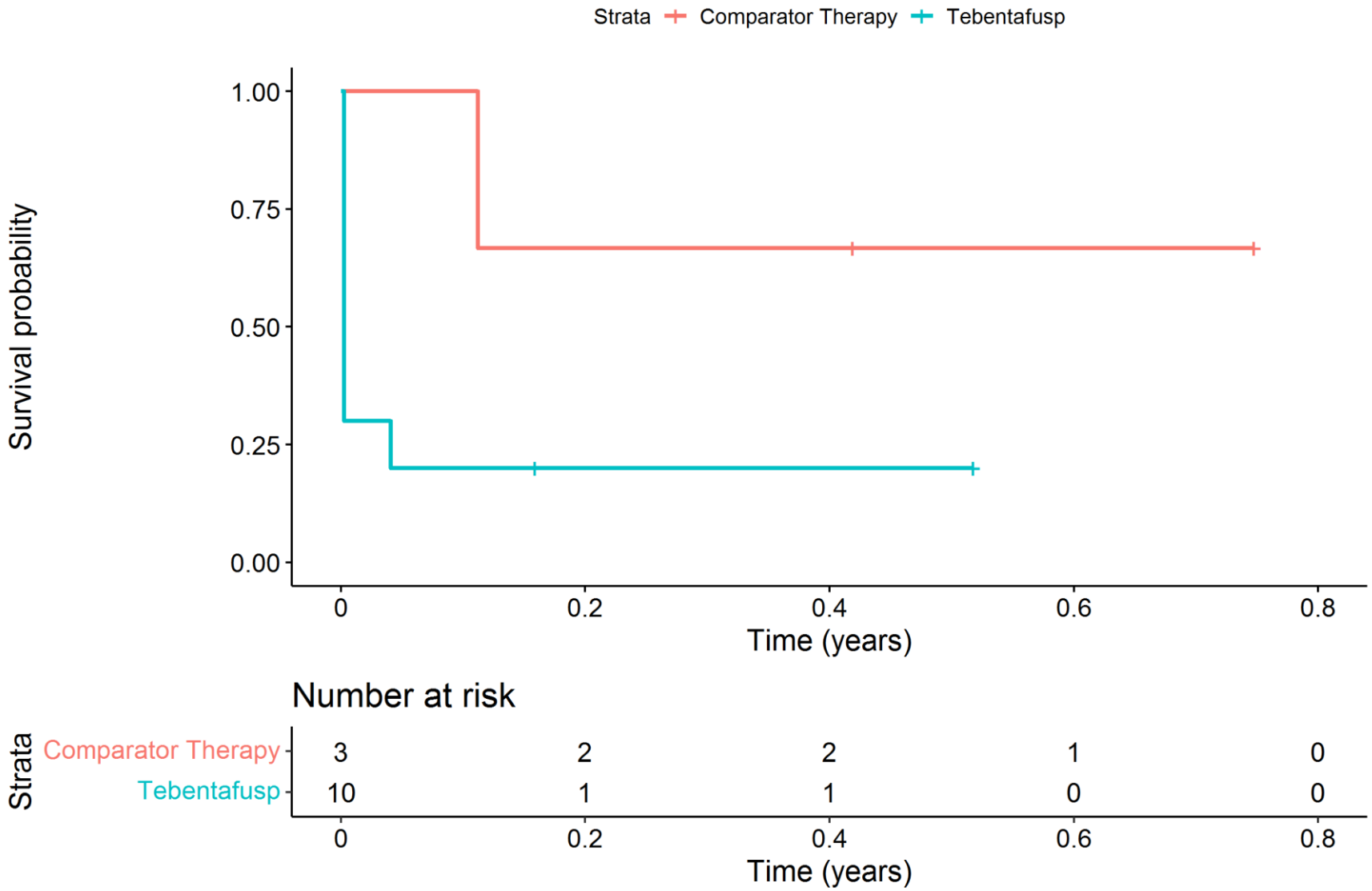
53.169 Schüttelfrost - LDH =< ULN



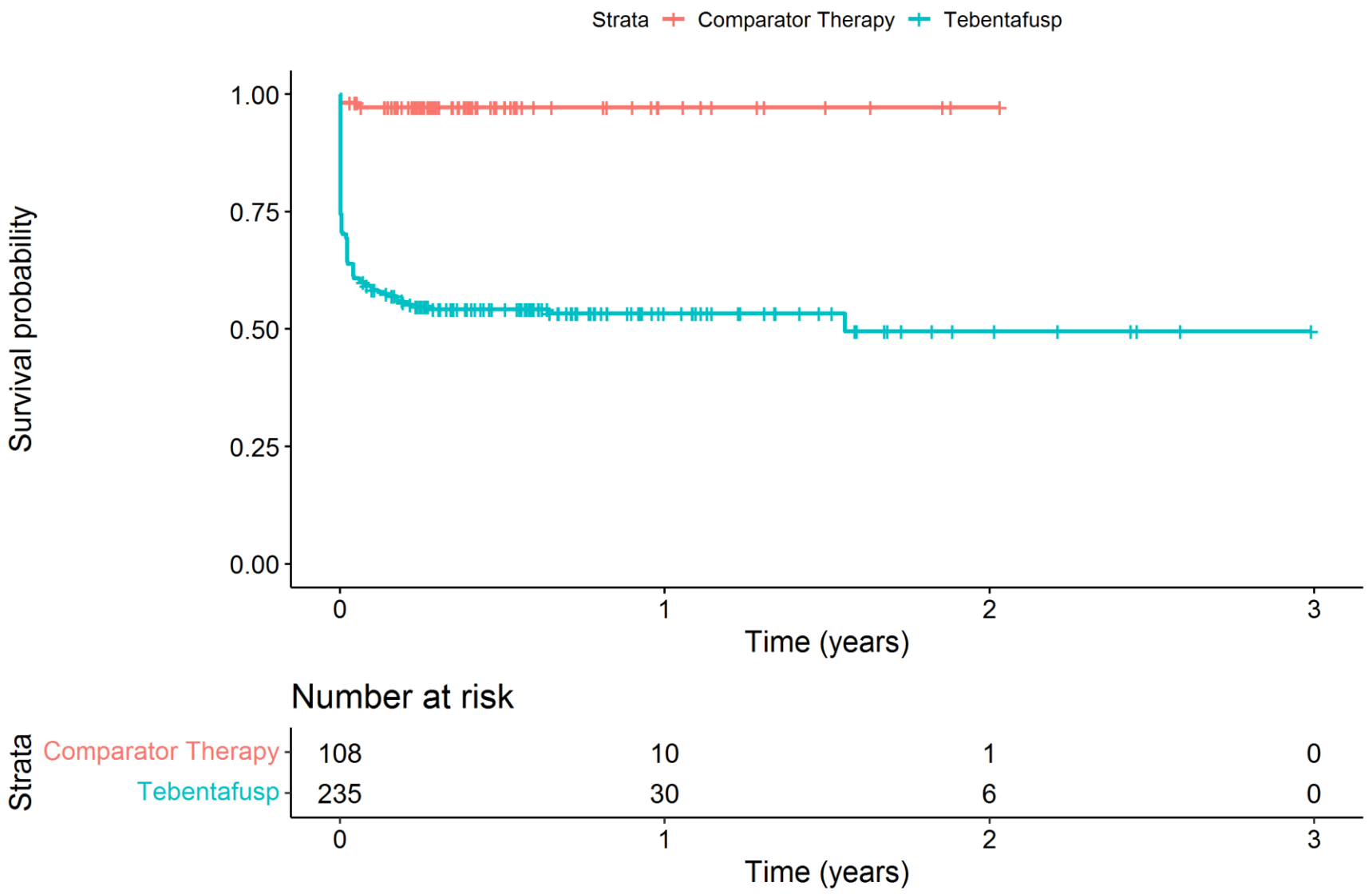
53.170 Schüttelfrost - LDH > ULN



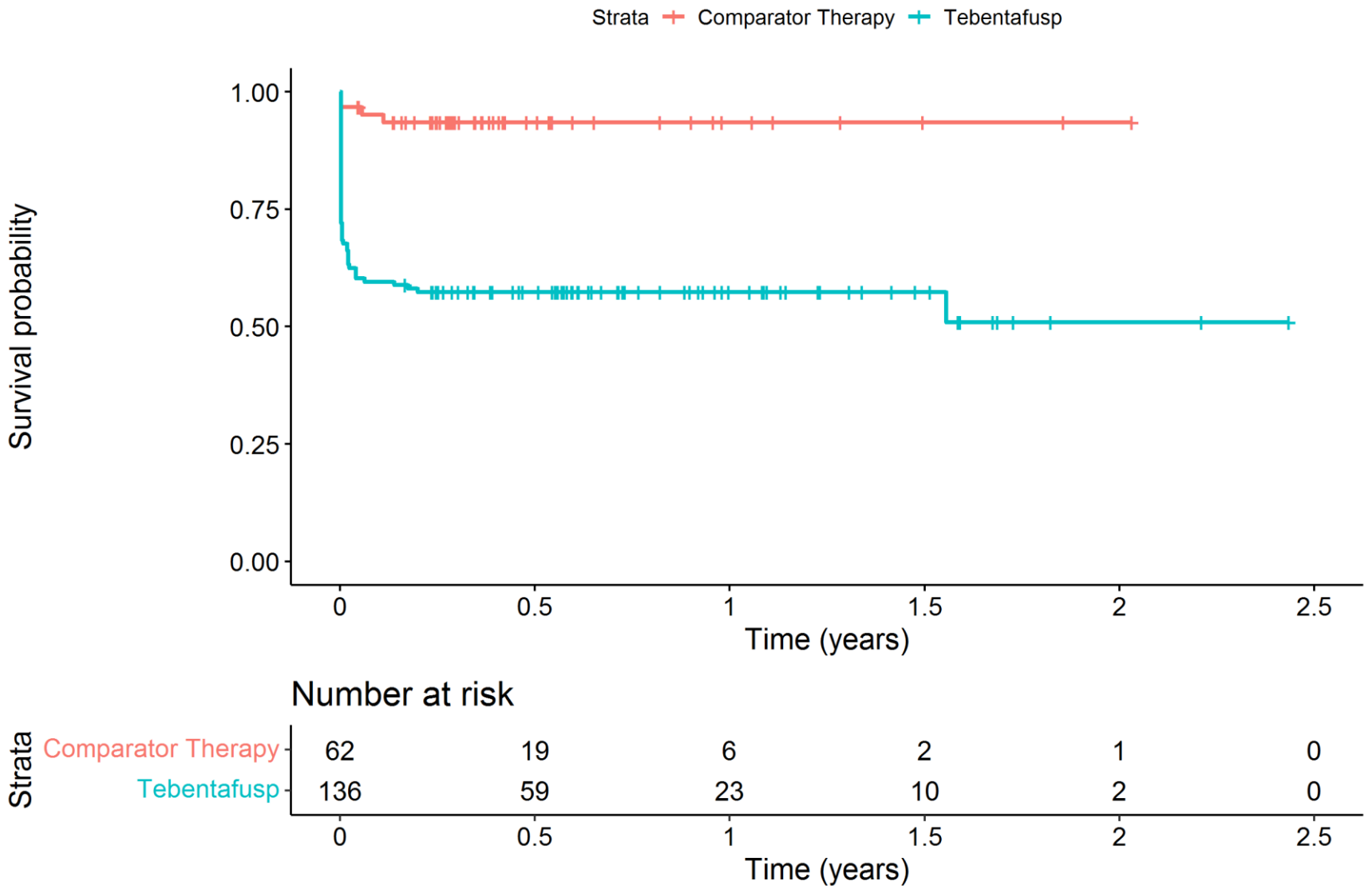
53.171 Schüttelfrost - Vorherige Therapie adjuvant/neoadjuvant



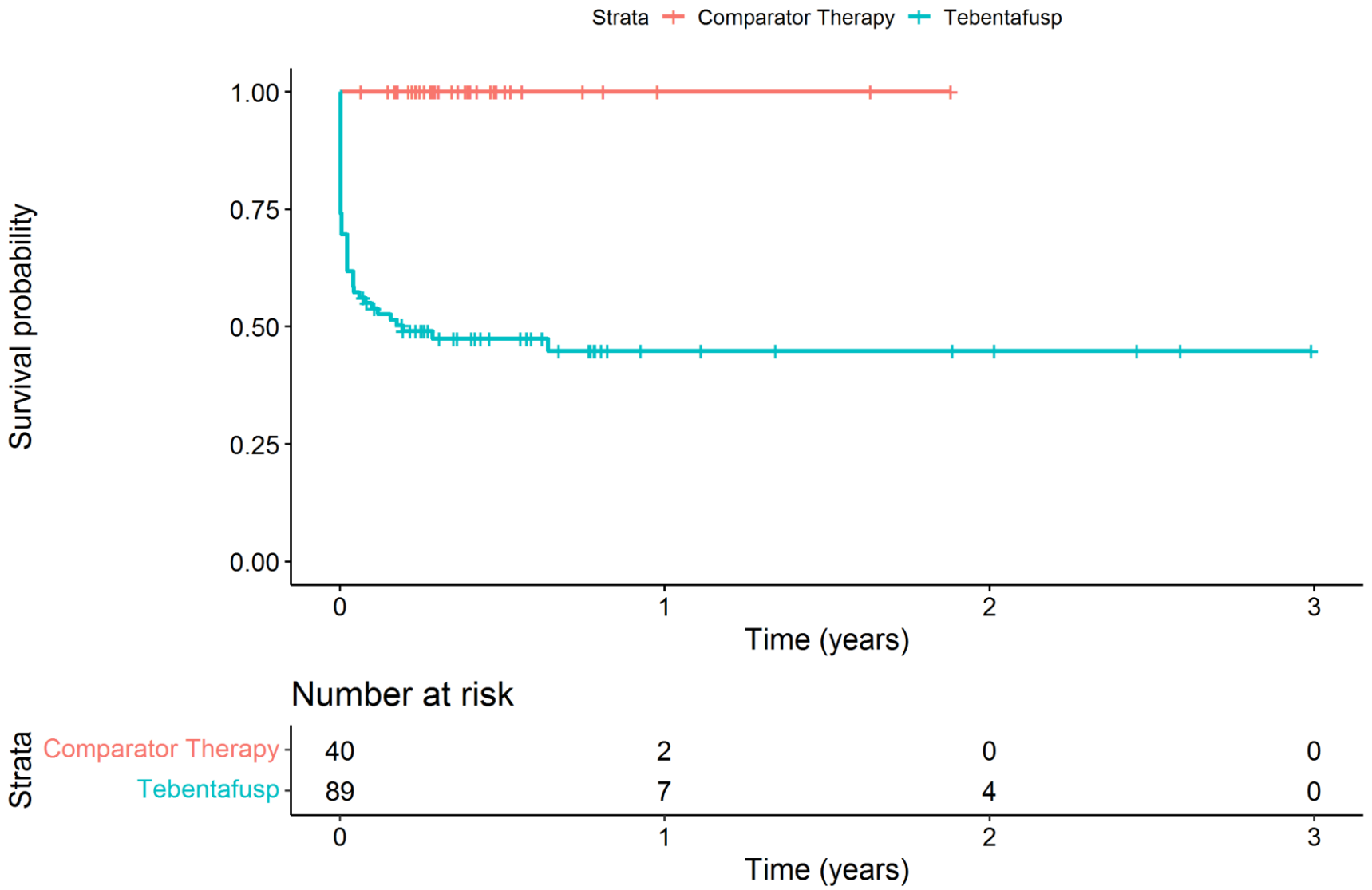
53.172 Schüttelfrost - Keine vorherige Therapie adjuvant/neoadjuvant



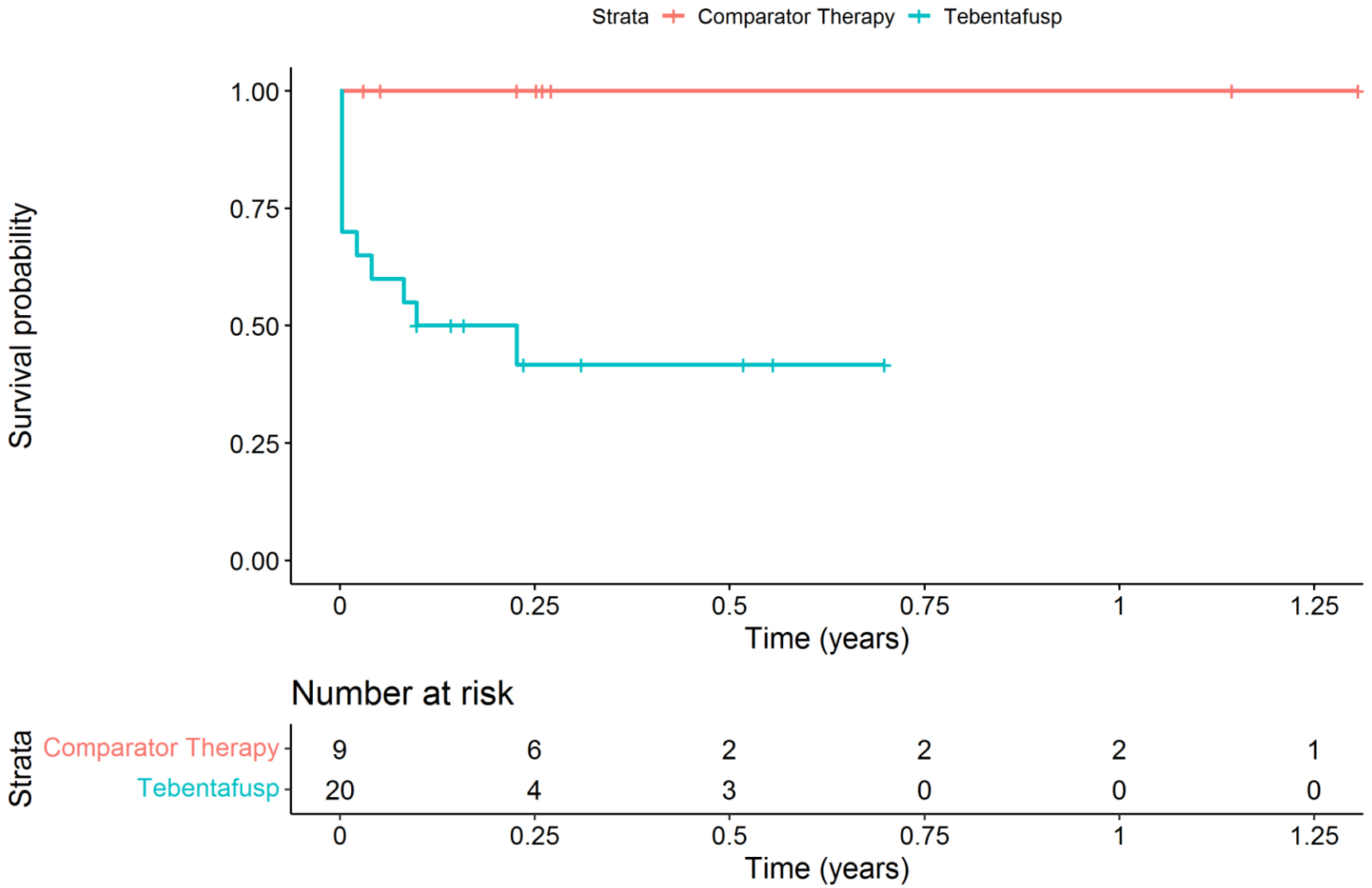
53.173 Schüttelfrost - Läsion ≤ 3cm



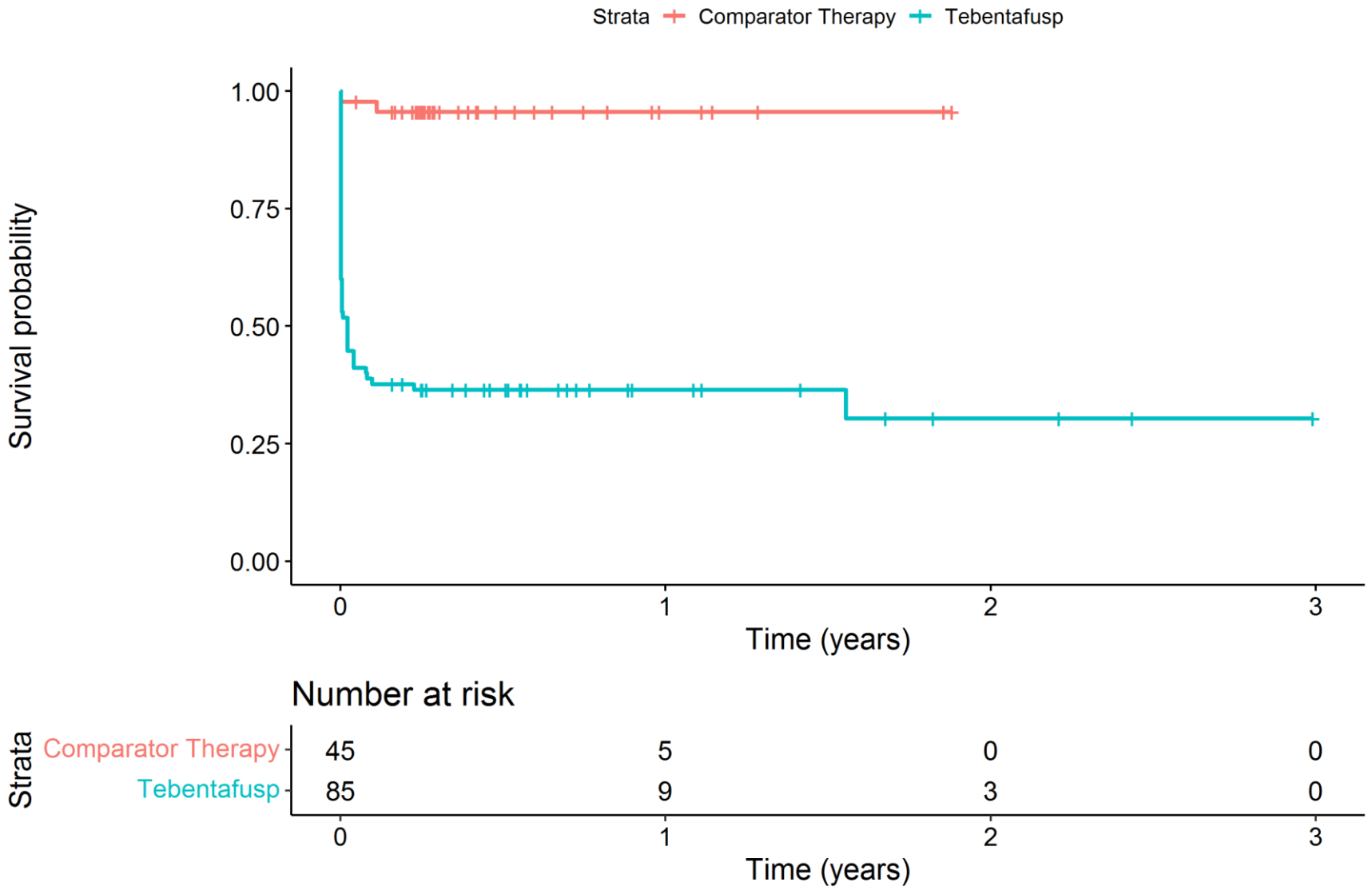
53.174 Schüttelfrost - Läsion 3,1-8,0 cm



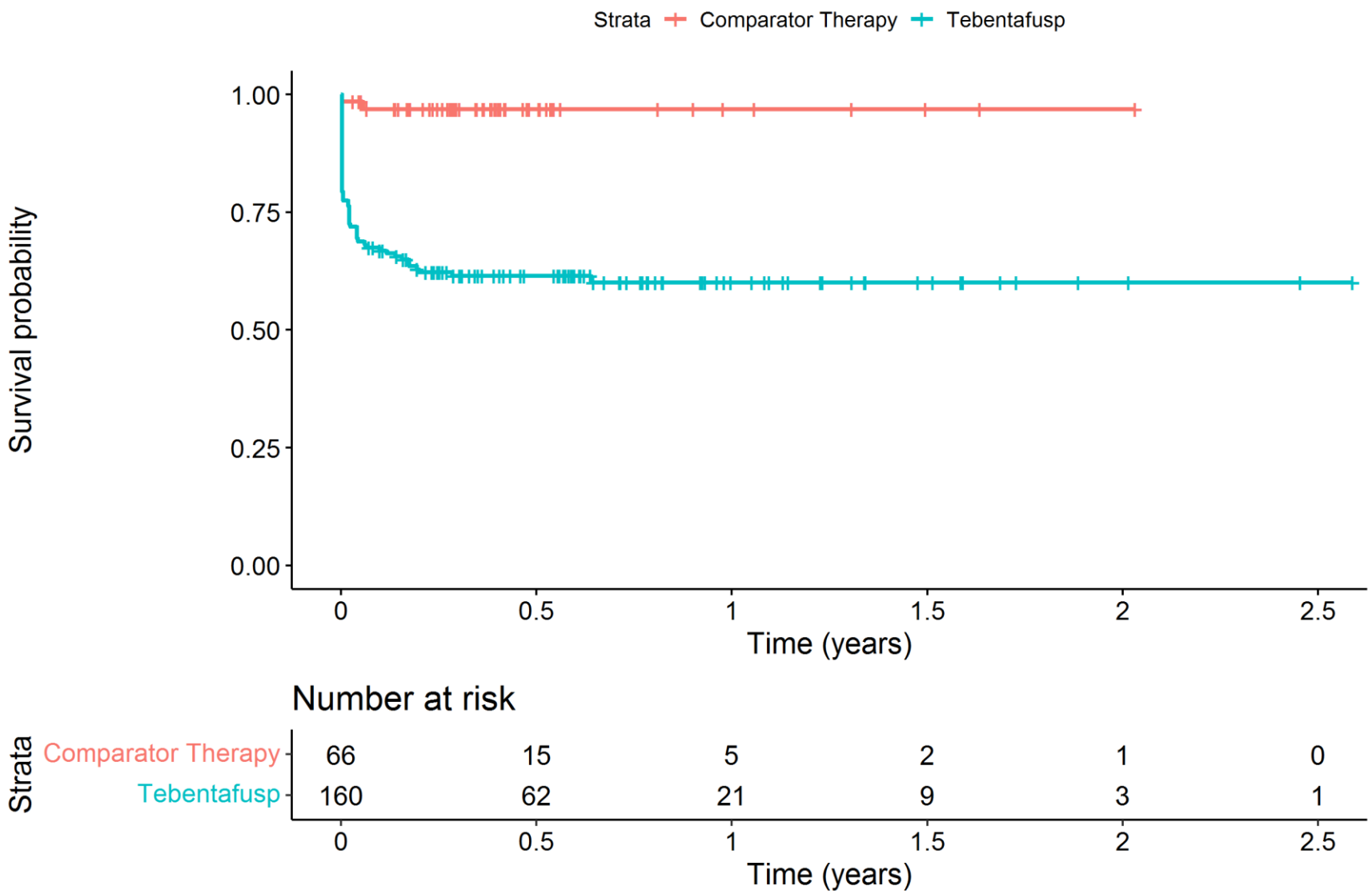
53.175 Schüttelfrost - Läsion ≥8,1 cm



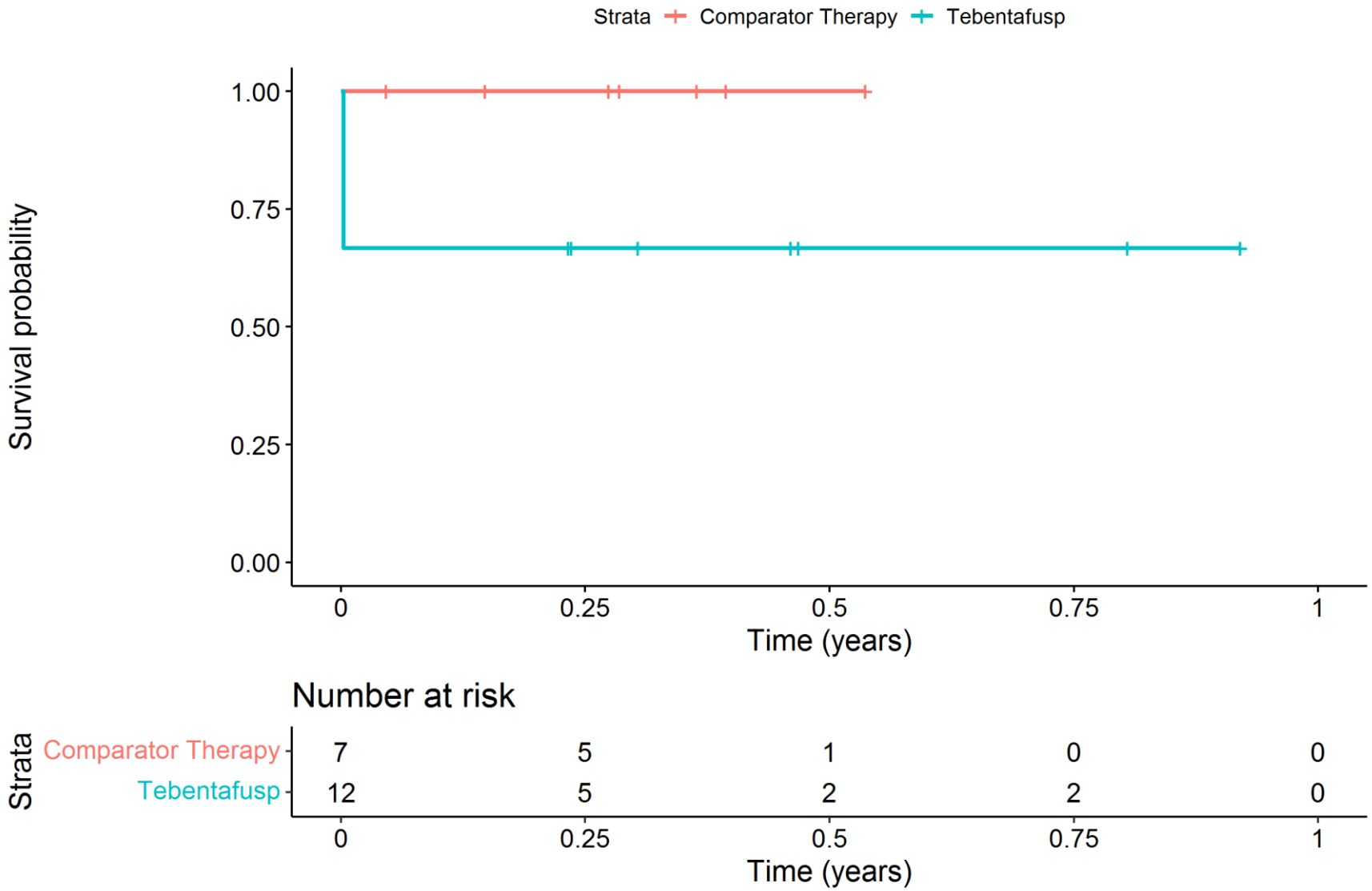
53.176 Schüttelfrost - Nordamerika



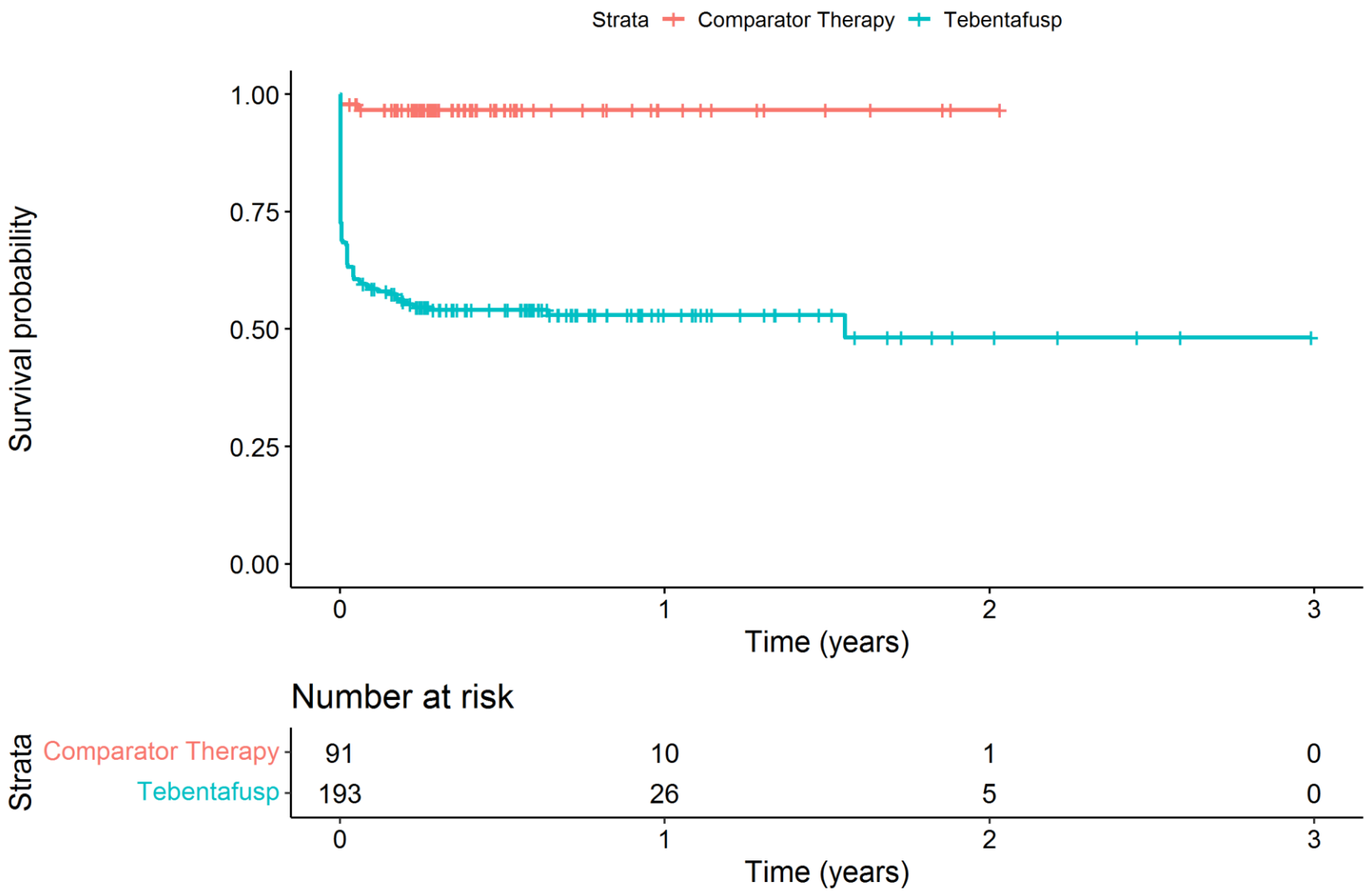
53.177 Schüttelfrost - Nicht-Nordamerika



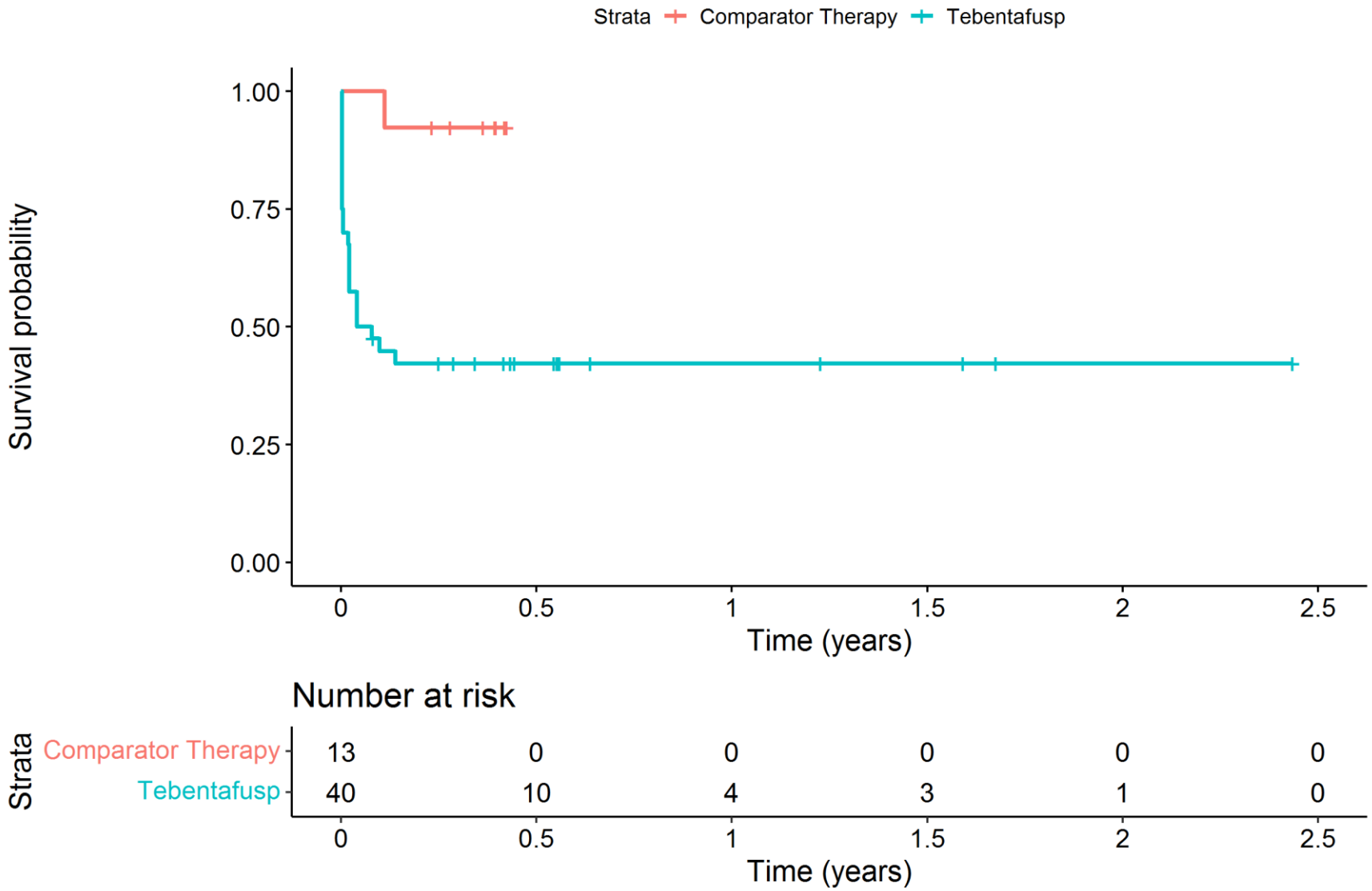
53.178 Schüttelfrost - Dacarbazin



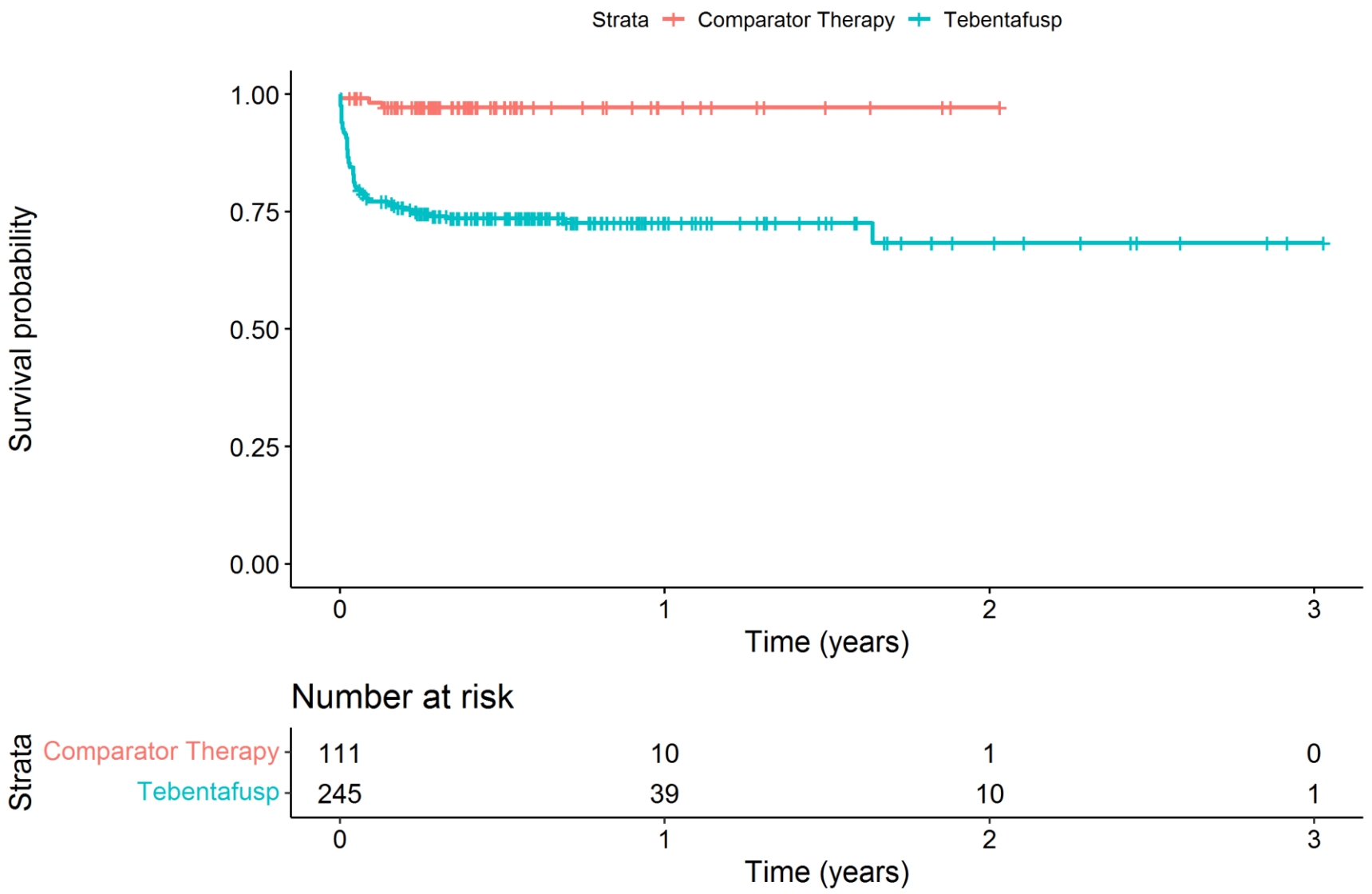
53.179 Schüttelfrost - Pembrolizumab



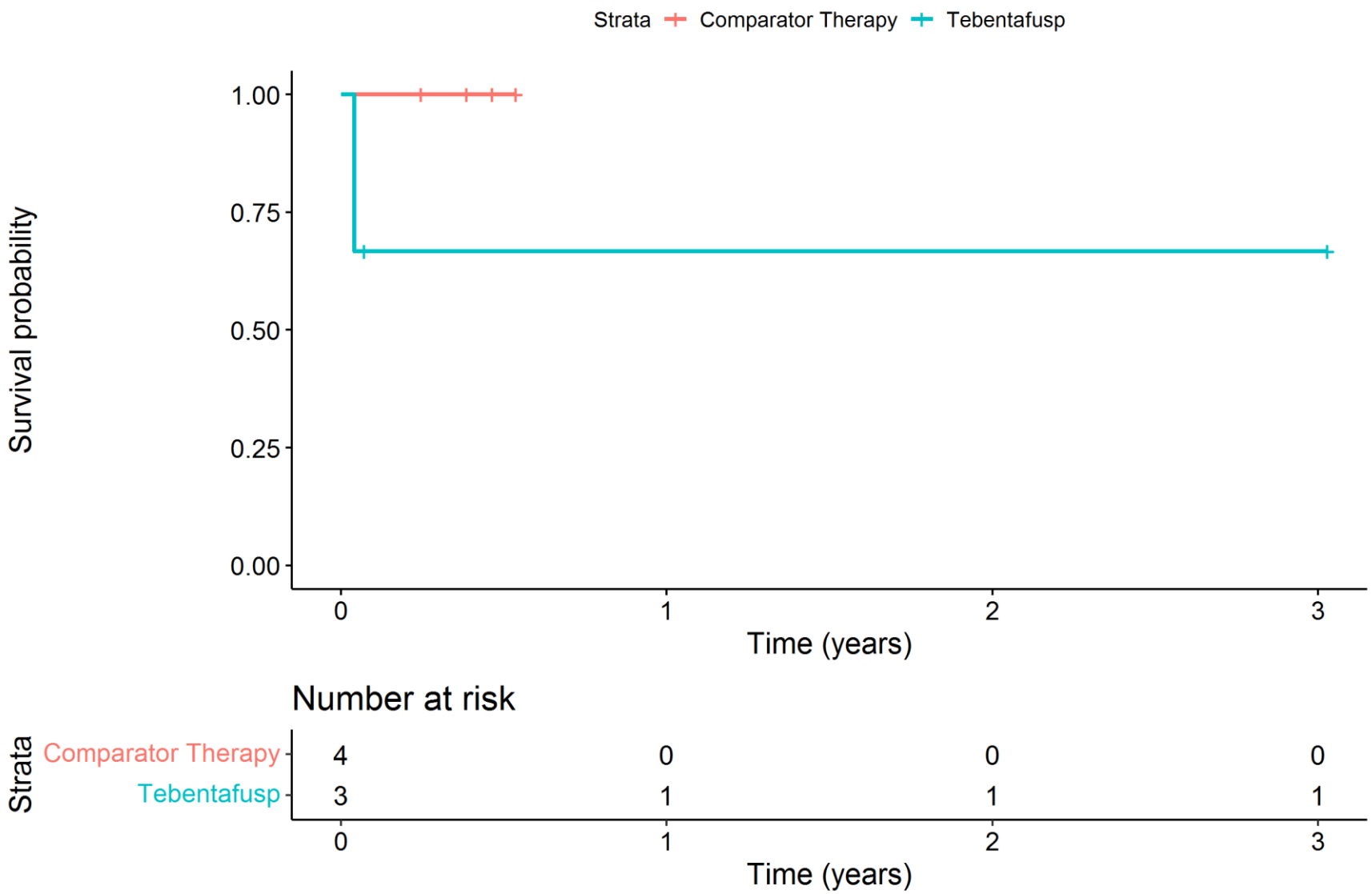
53.180 Schüttelfrost - Ipilimumab



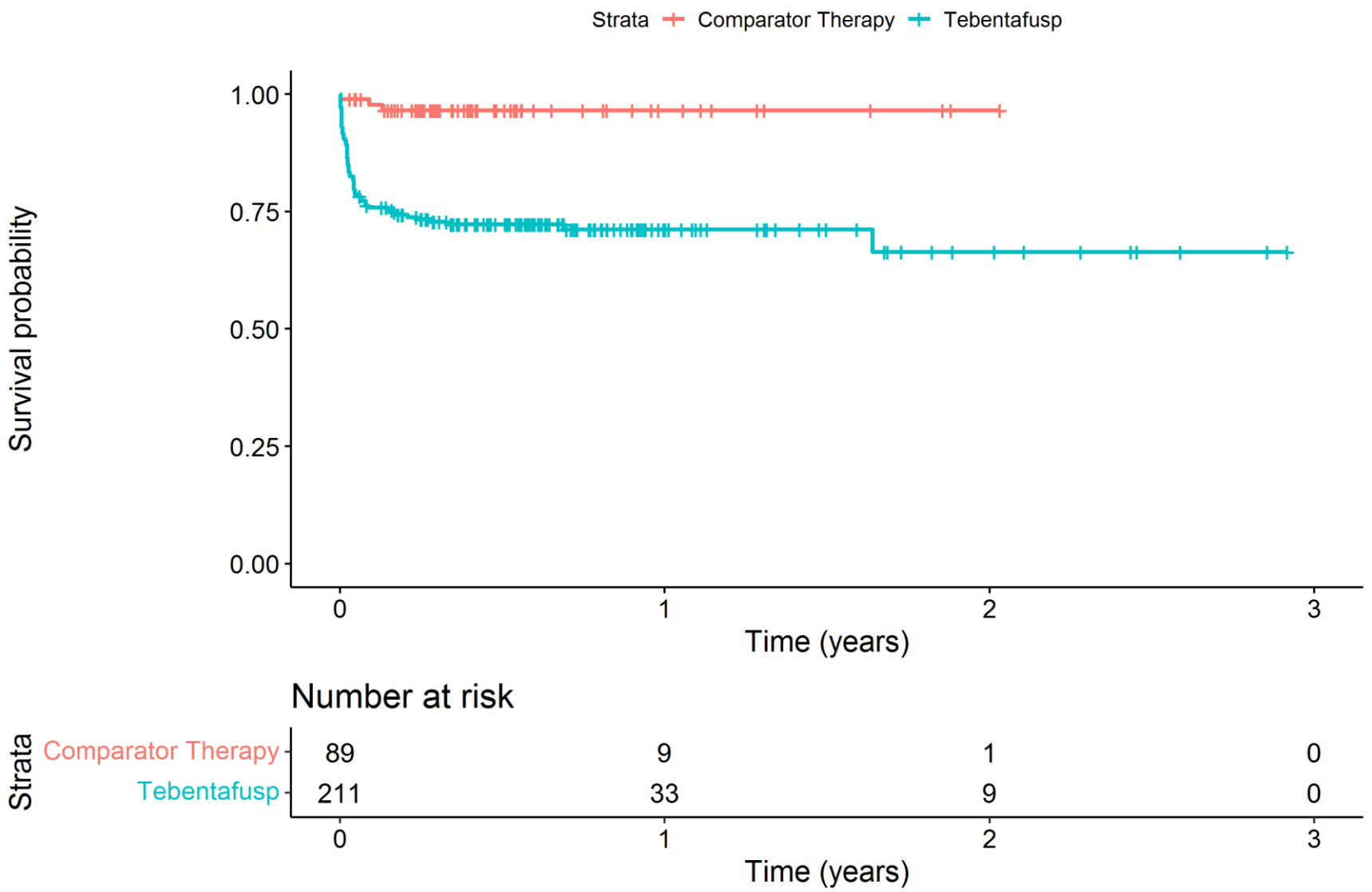
53.181 Periphere Ödeme- Gesamt



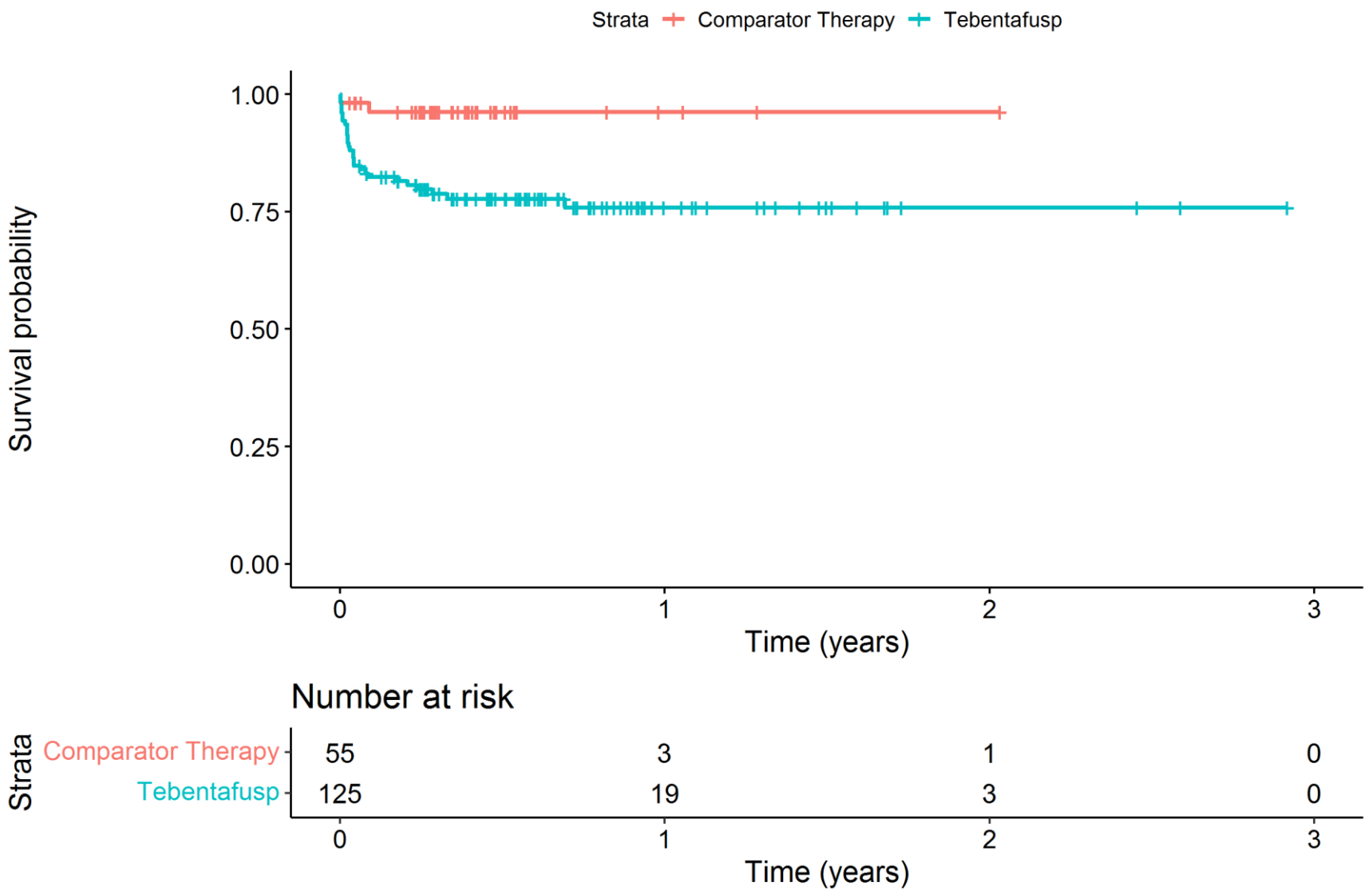
53.182 Periphere Ödeme- Hispanisch



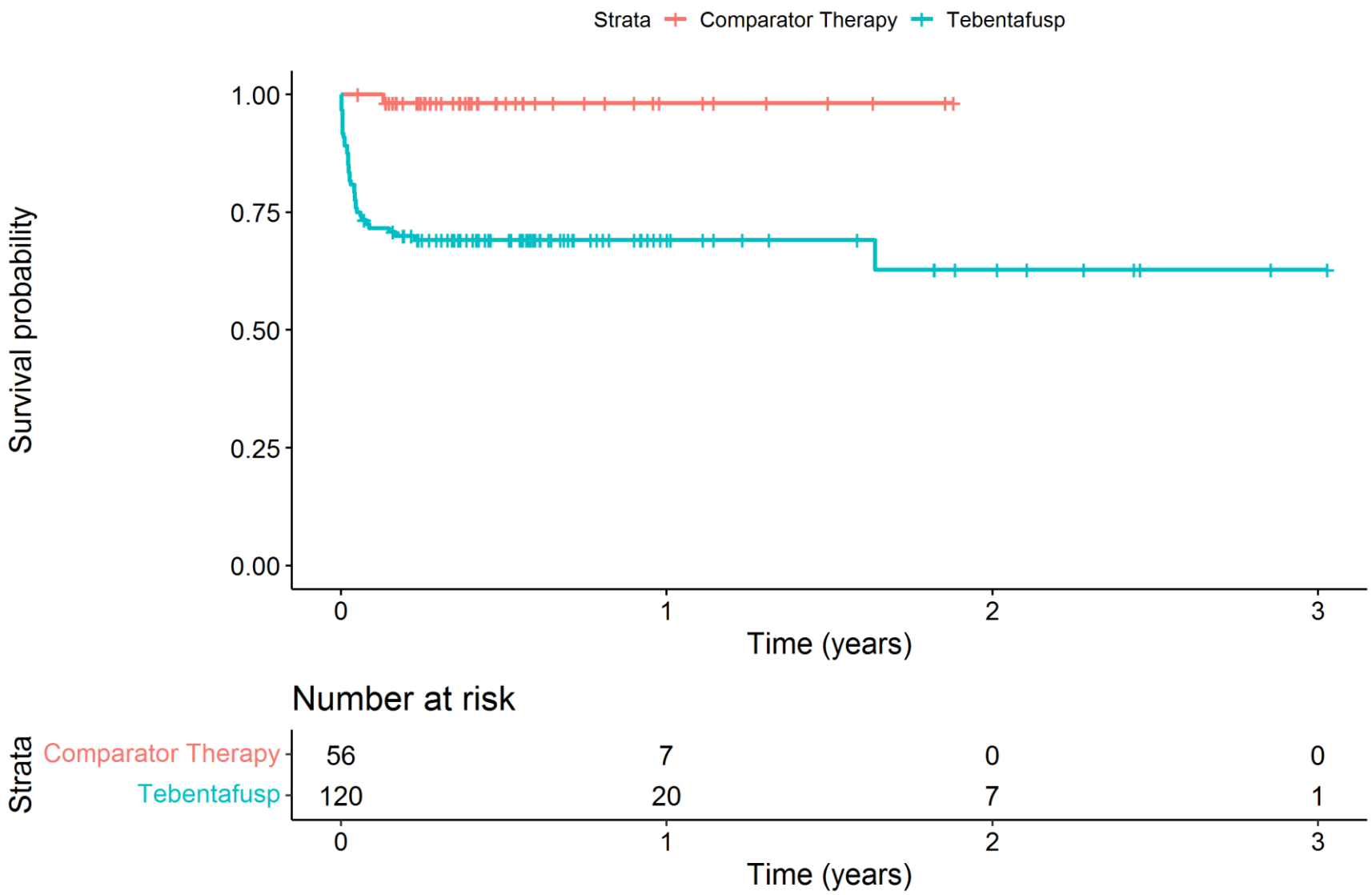
53.183 Periphere Ödeme- Nicht-hispanisch



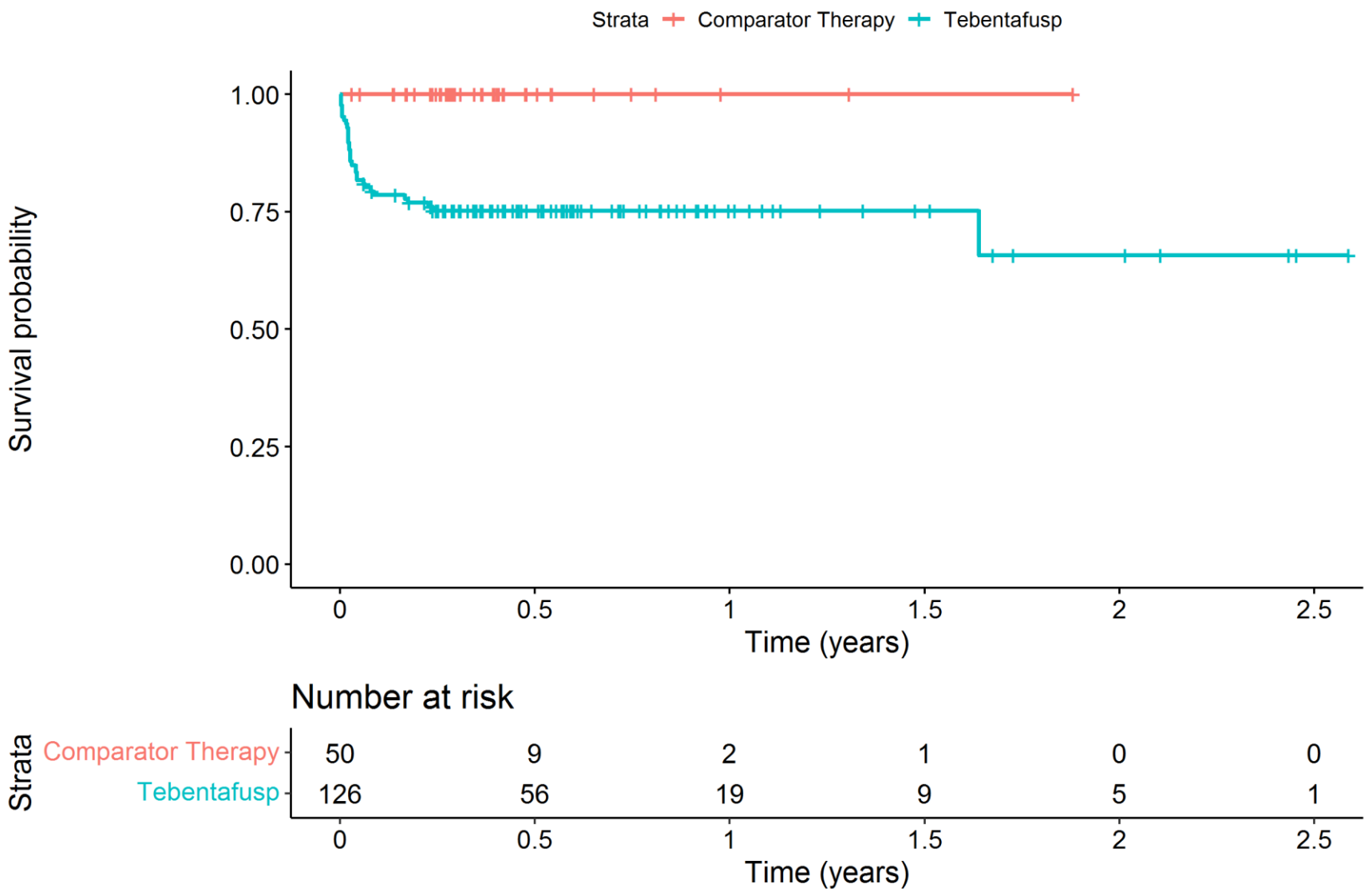
53.184 Periphere Ödeme- Männlich



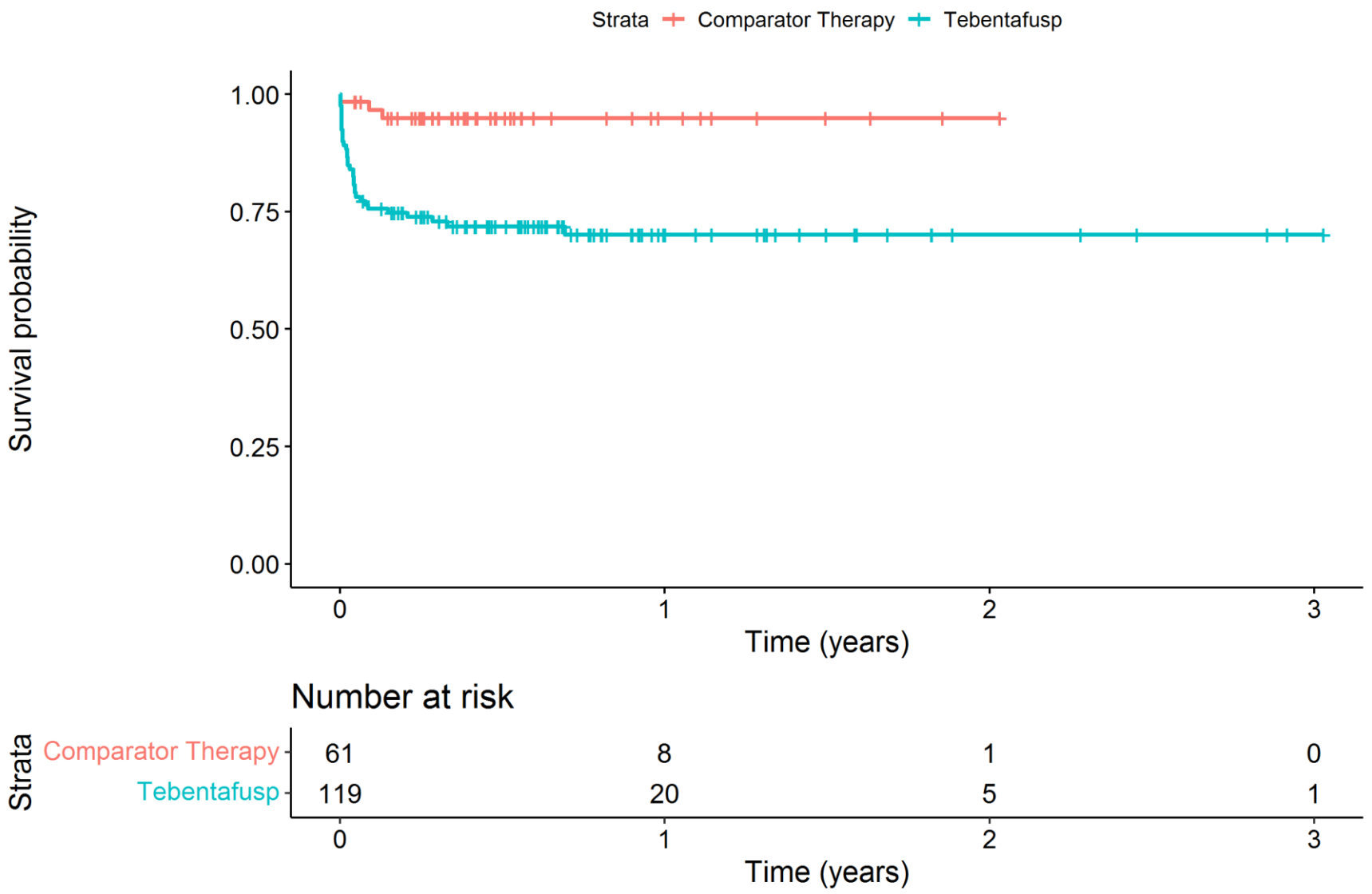
53.185 Periphere Ödeme- Weiblich



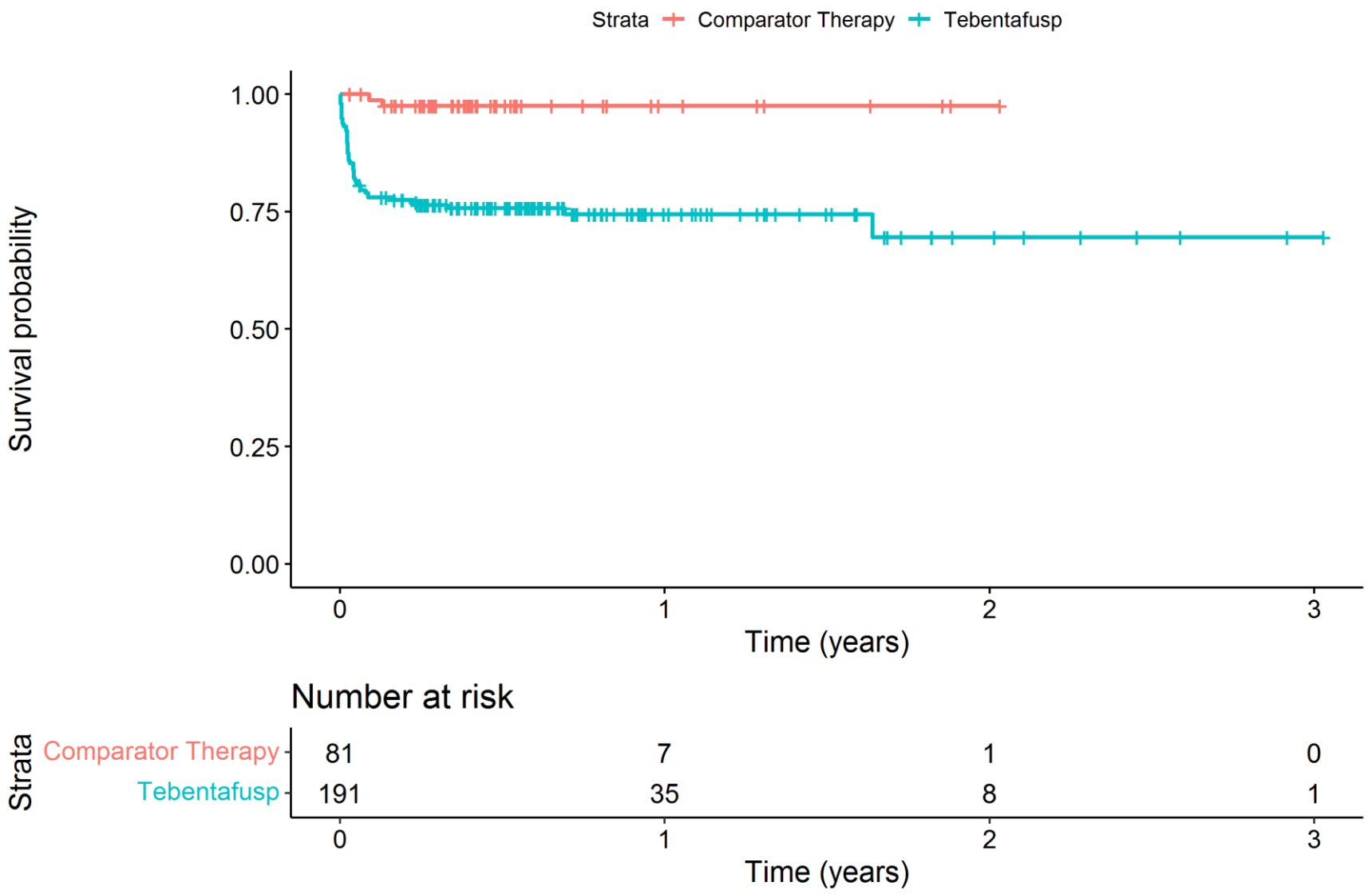
53.186 Periphere Ödeme- <65



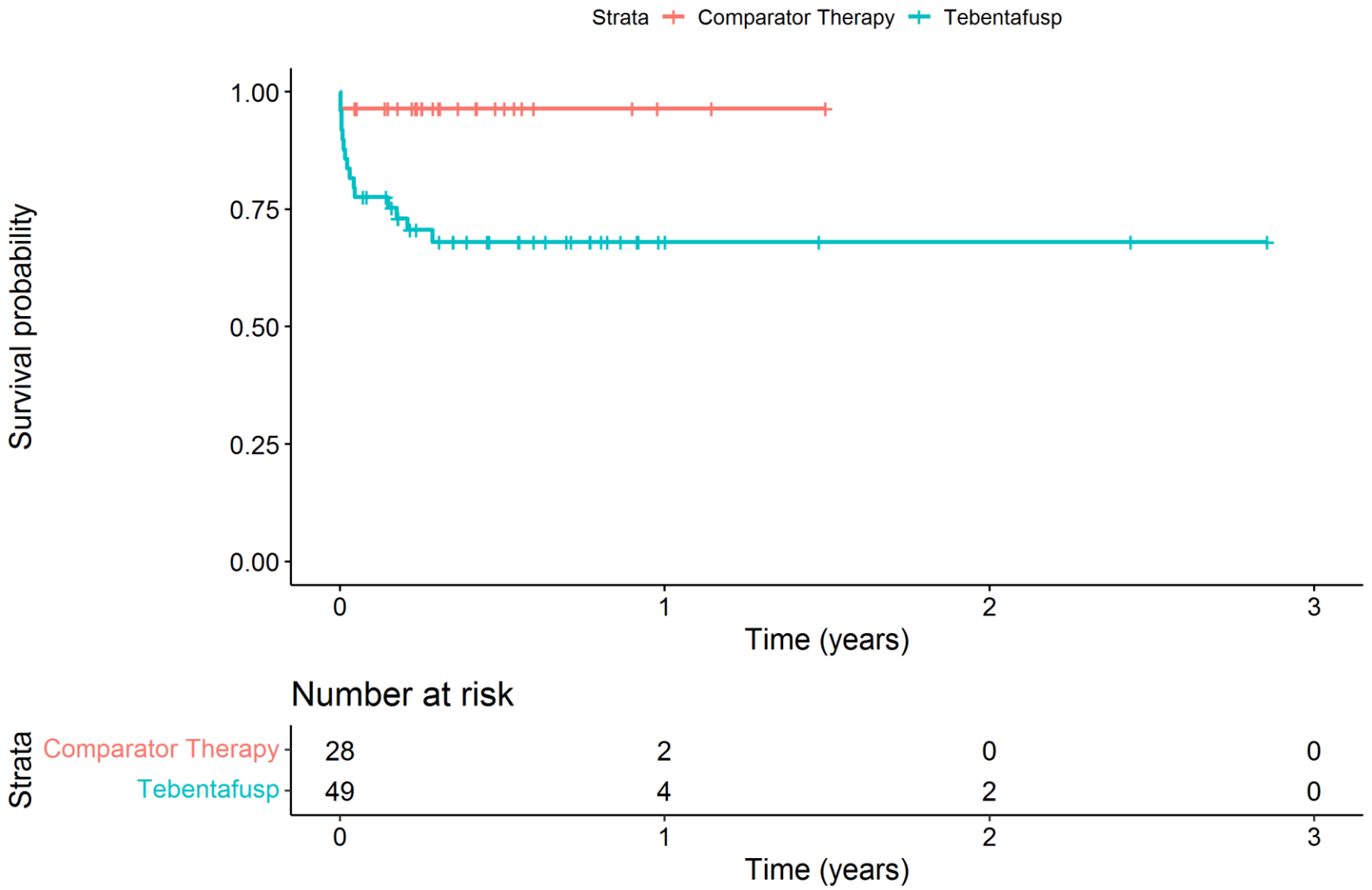
53.187 Periphere Ödeme- ≥65



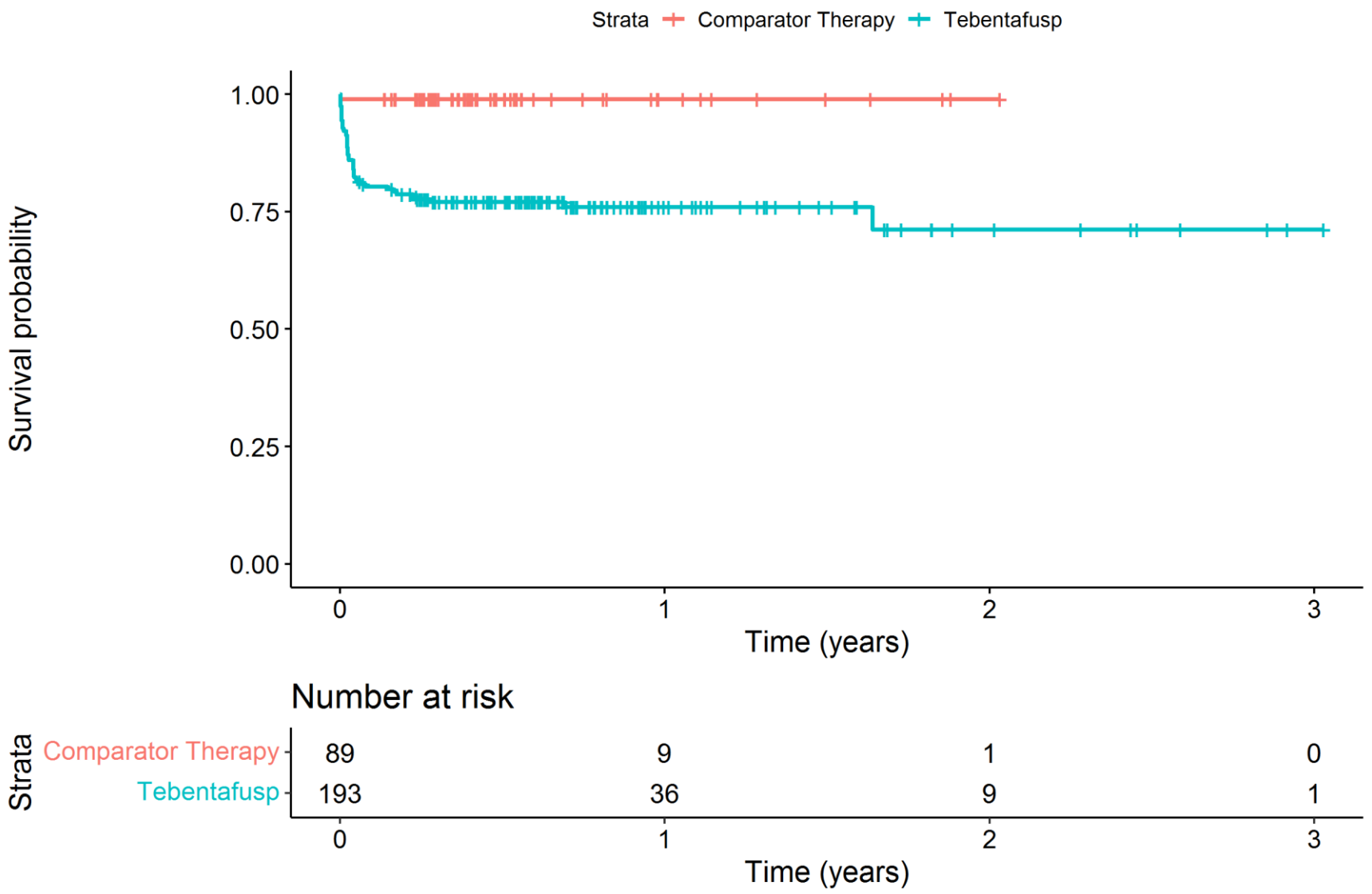
53.188 Periphere Ödeme- ECOG 0



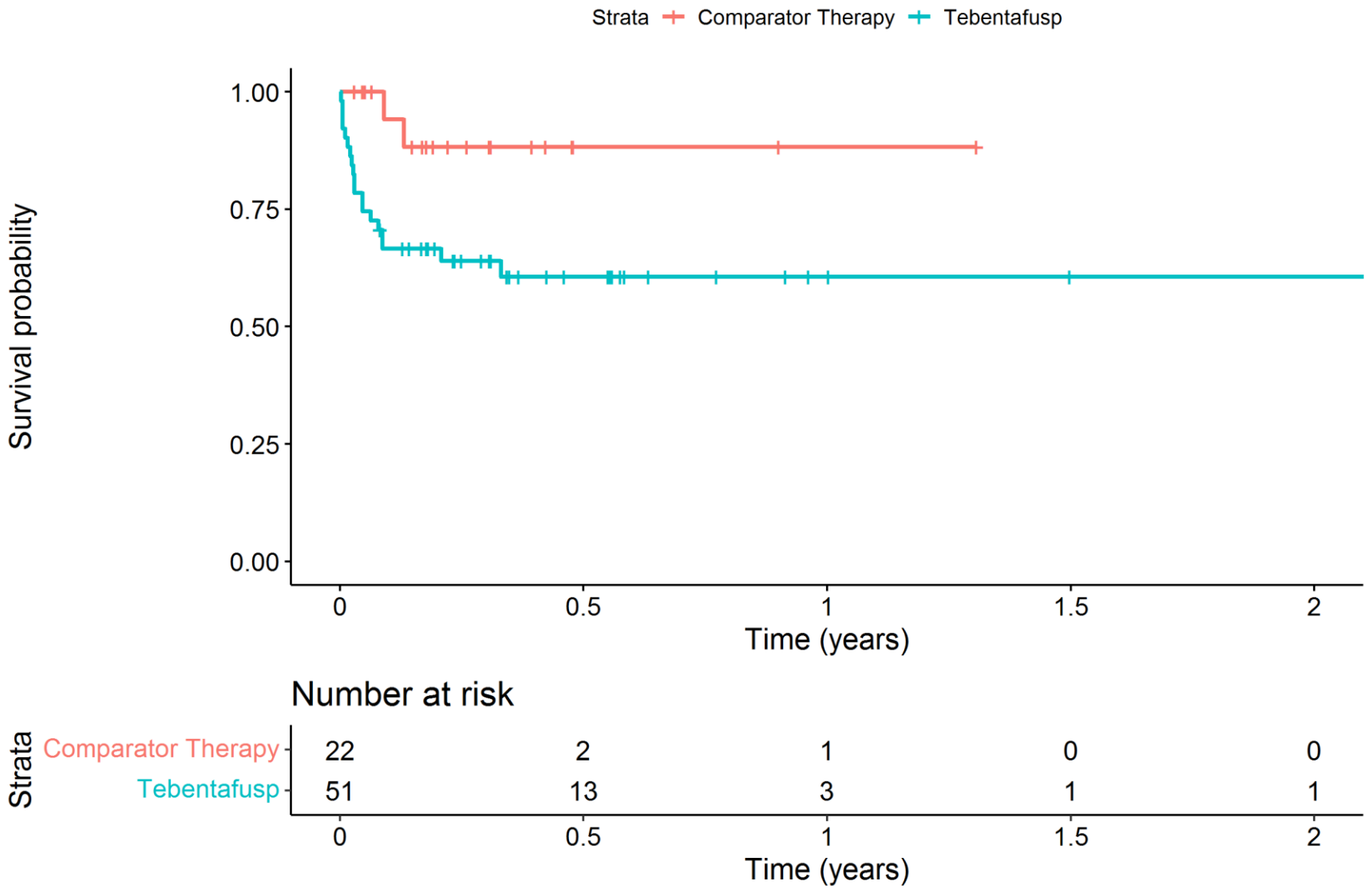
53.189 Periphere Ödeme- ECOG 1



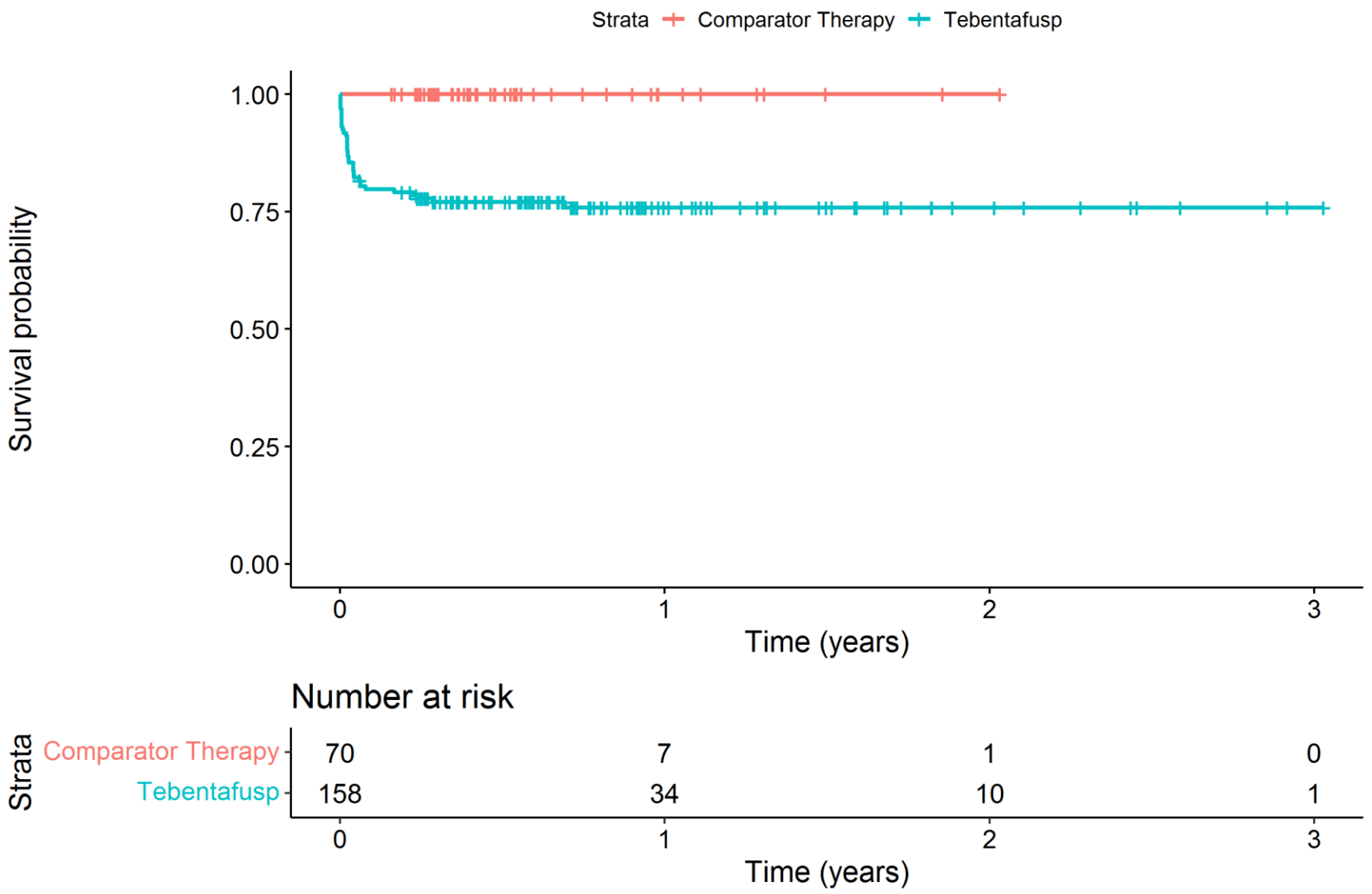
53.190 Periphere Ödeme- ALP ≤ ULN



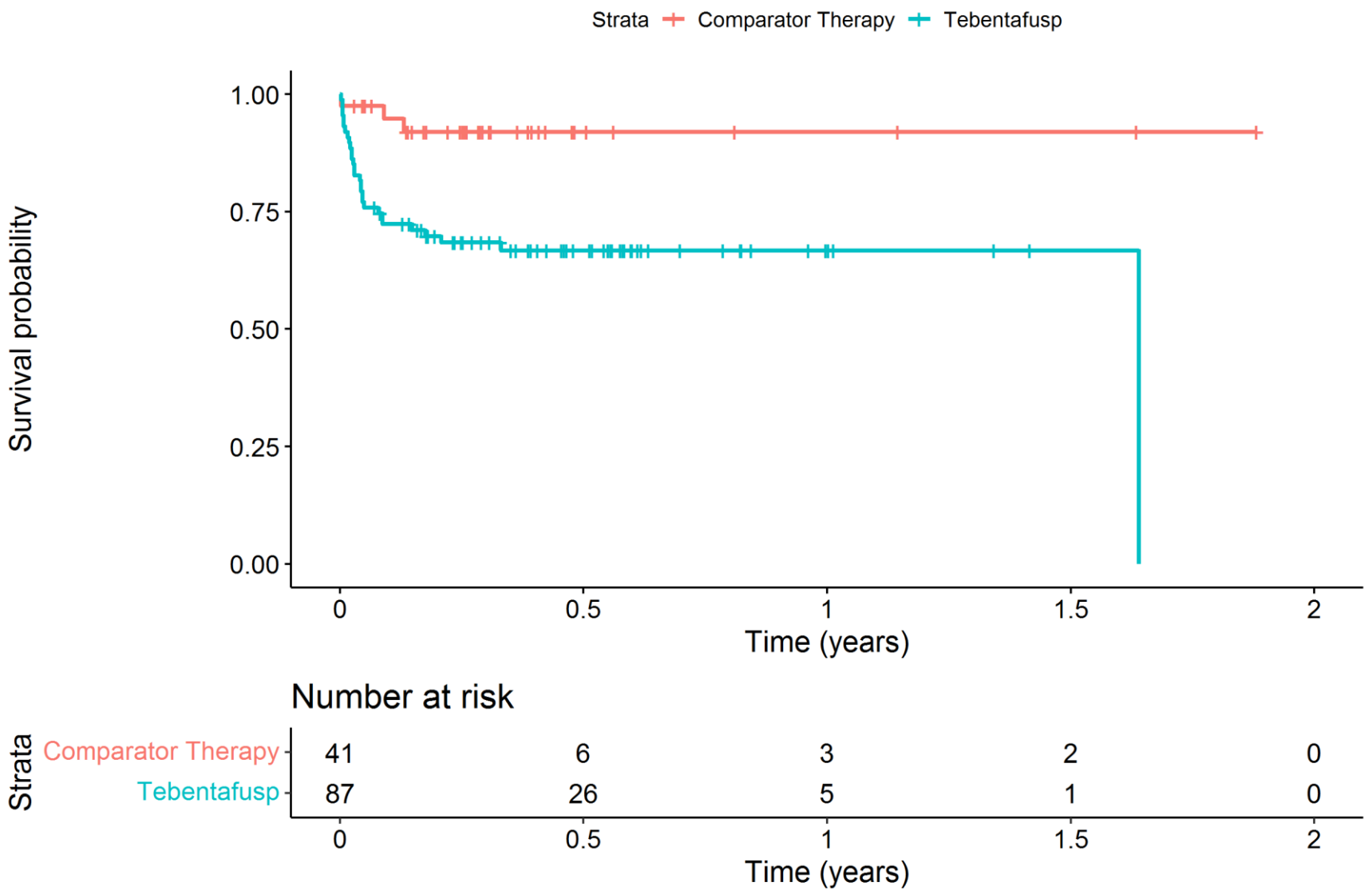
53.191 Periphere Ödeme- ALP > ULN



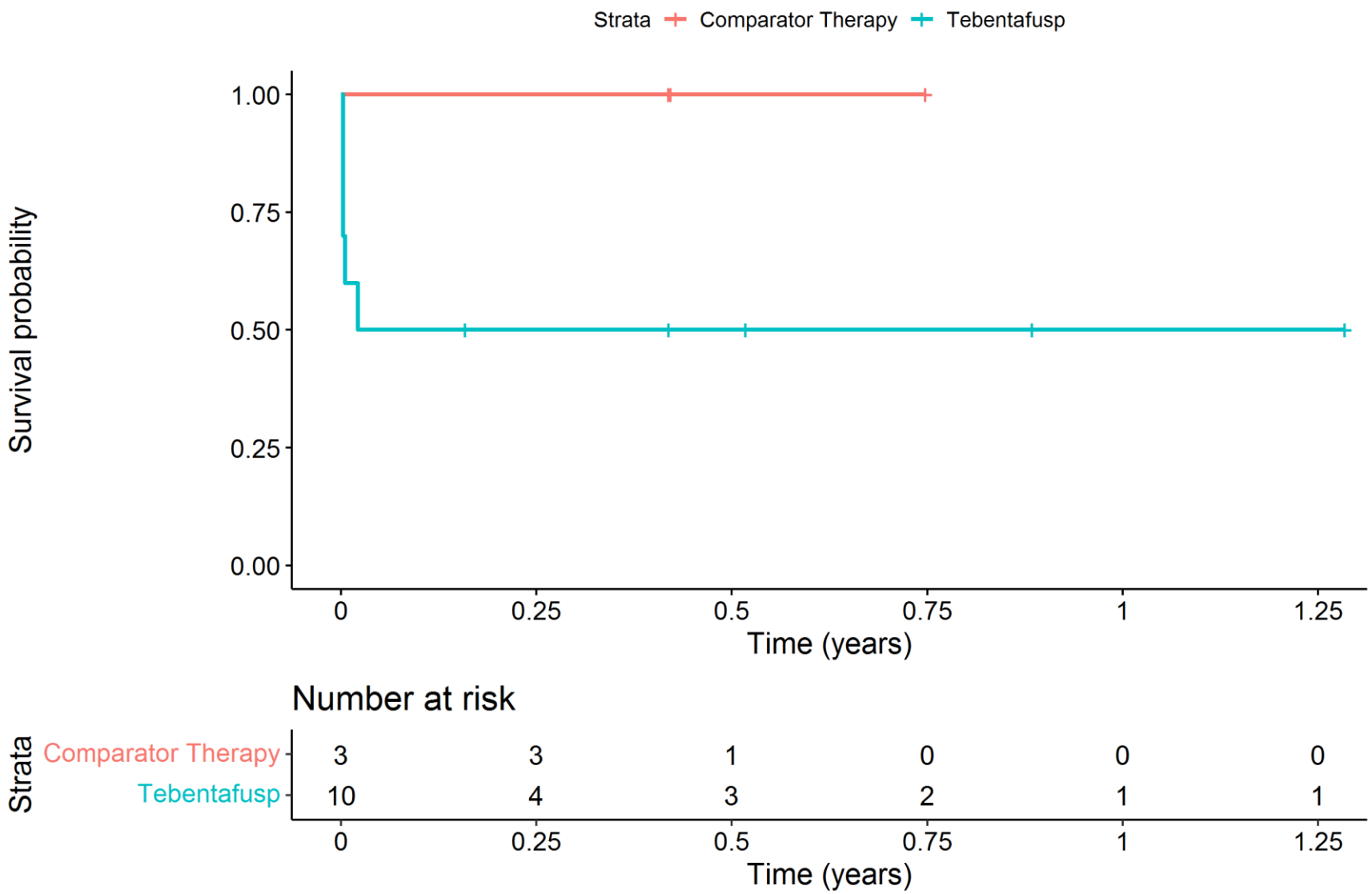
53.192 Periphere Ödeme- LDH =< ULN



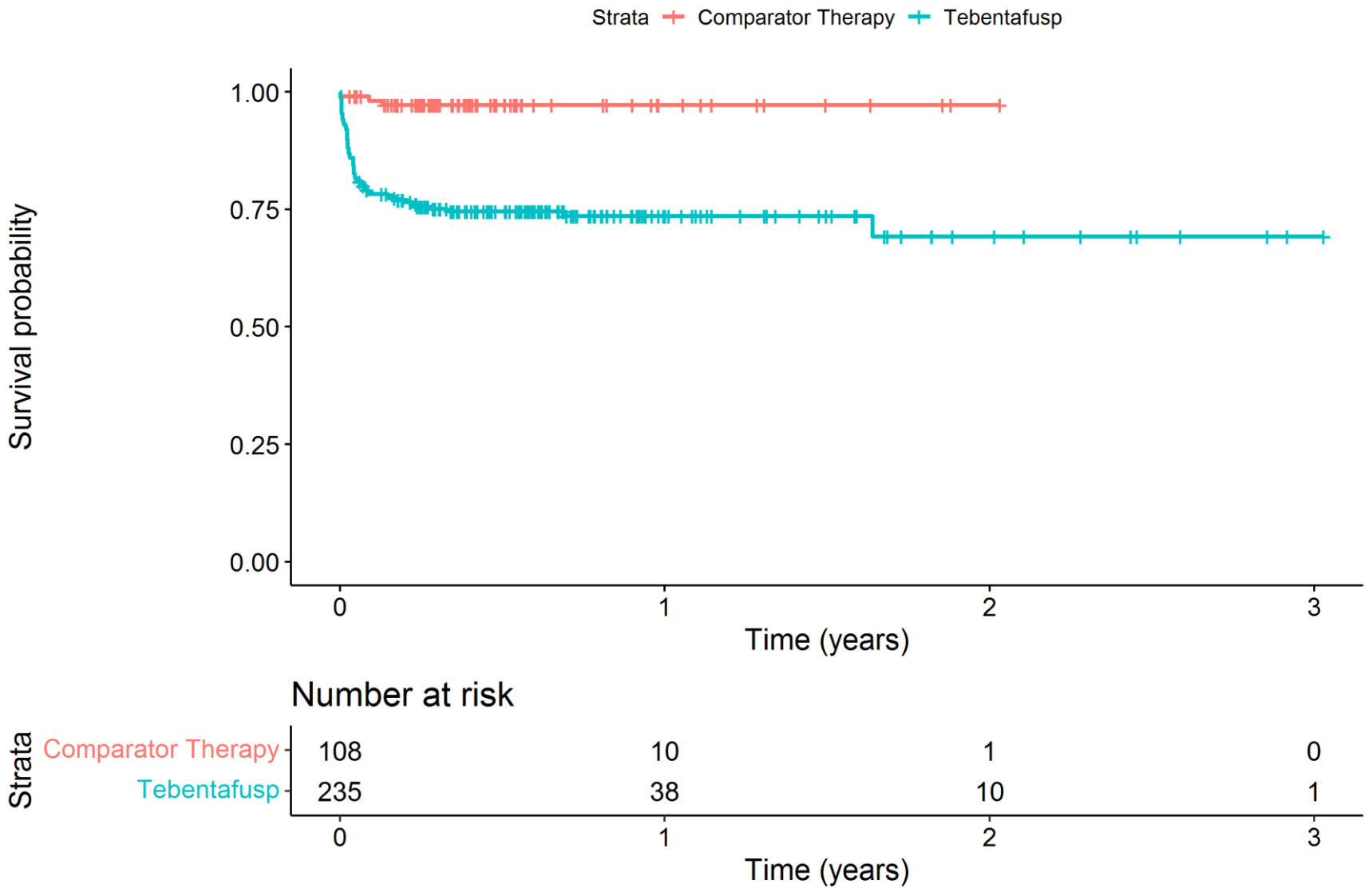
53.193 Periphere Ödeme- LDH > ULN



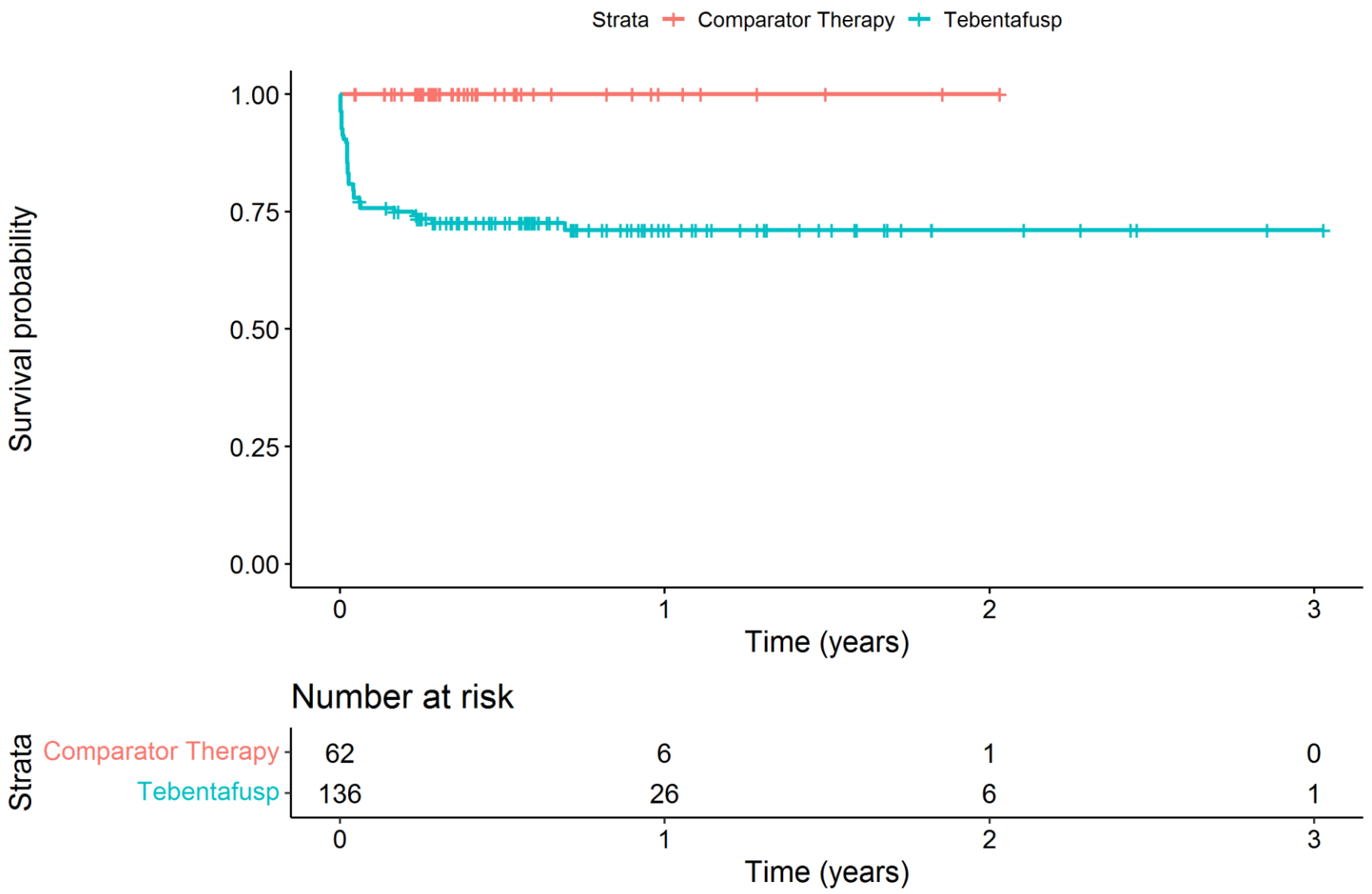
53.194 Periphere Ödeme- Vorherige Therapie adjuvant/neoadjuvant



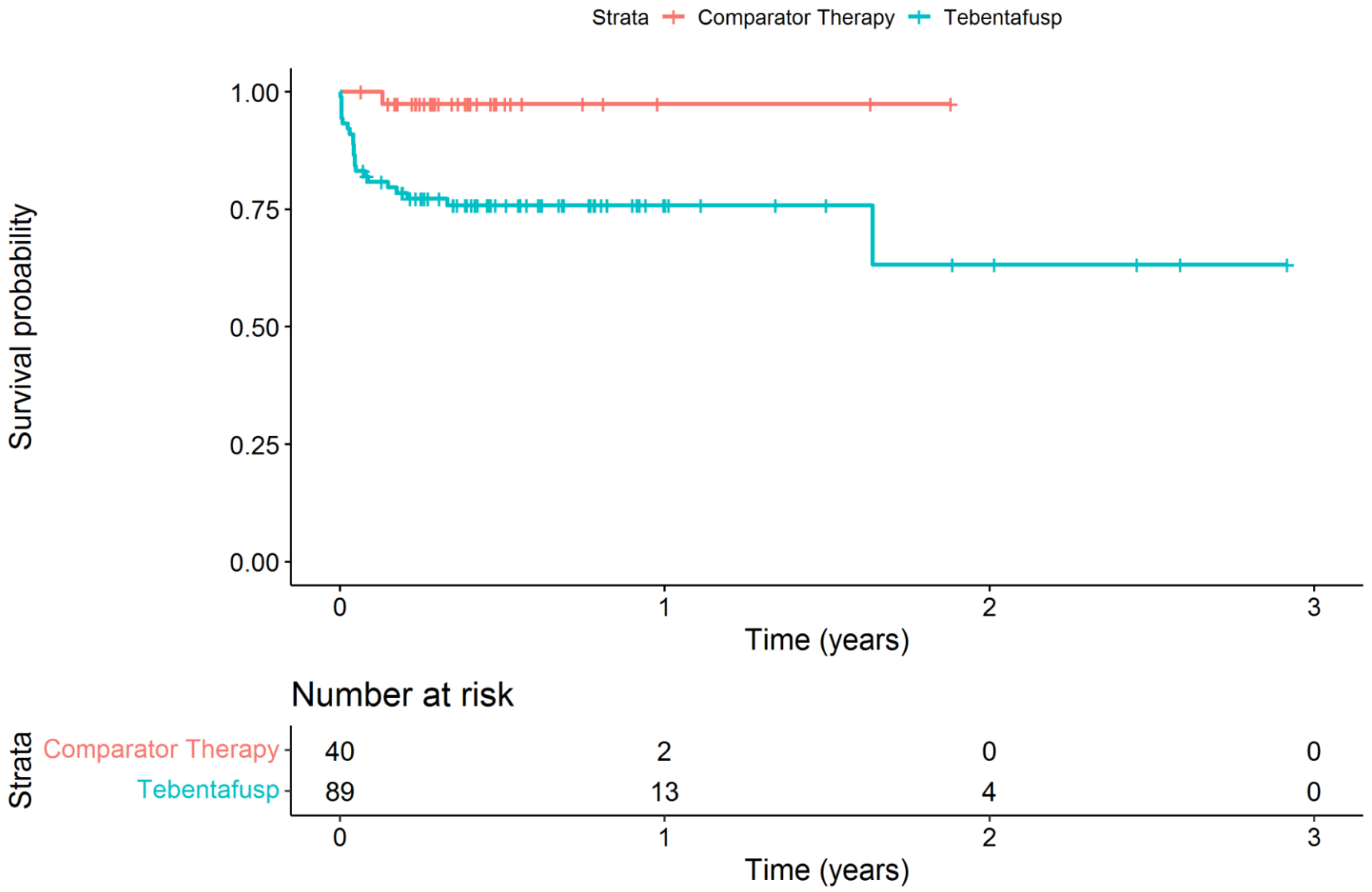
53.195 Periphere Ödeme- Keine vorherige Therapie adjuvant/neoadjuvant



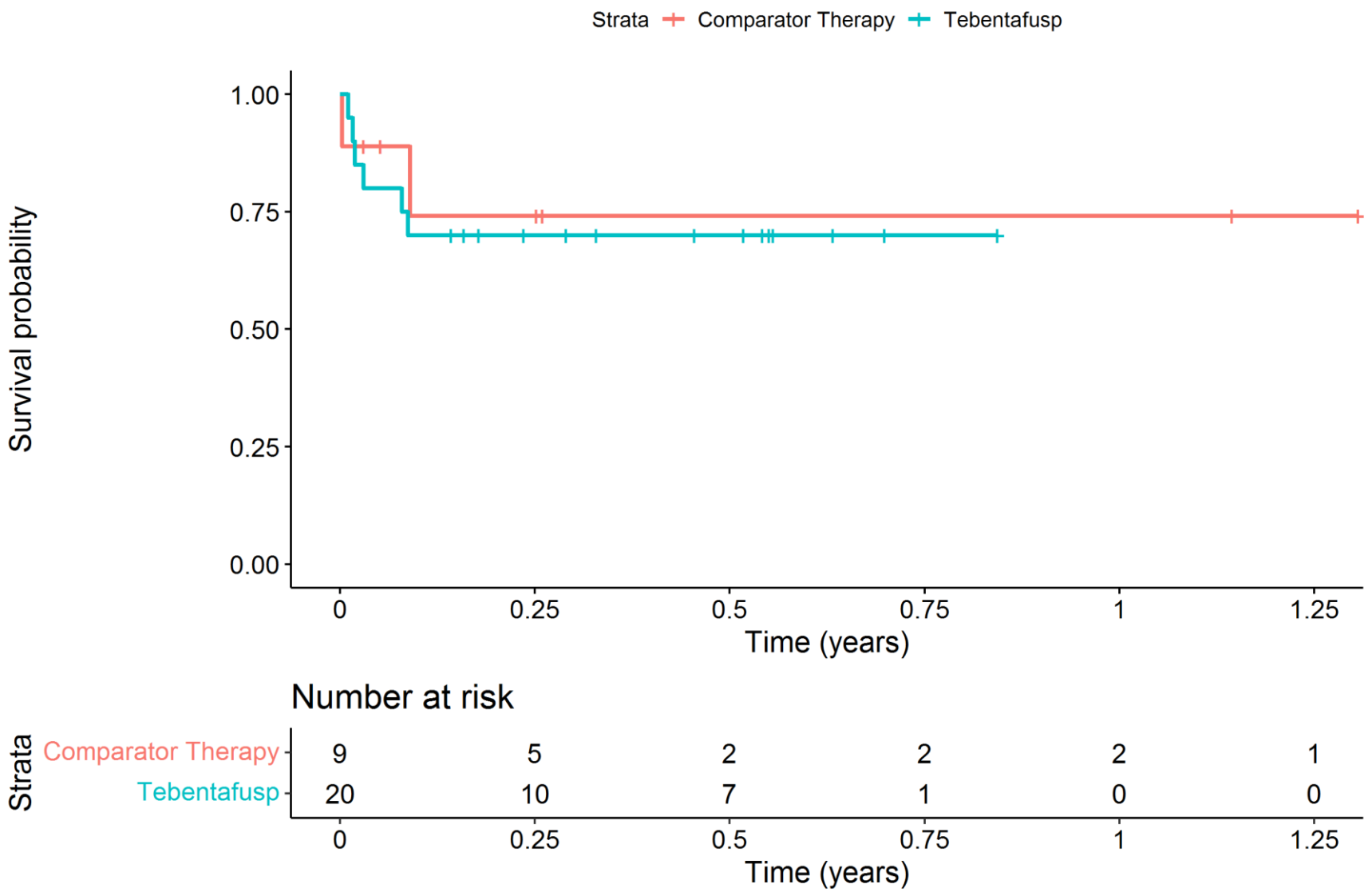
53.196 Periphere Ödeme- Läsion ≤ 3cm



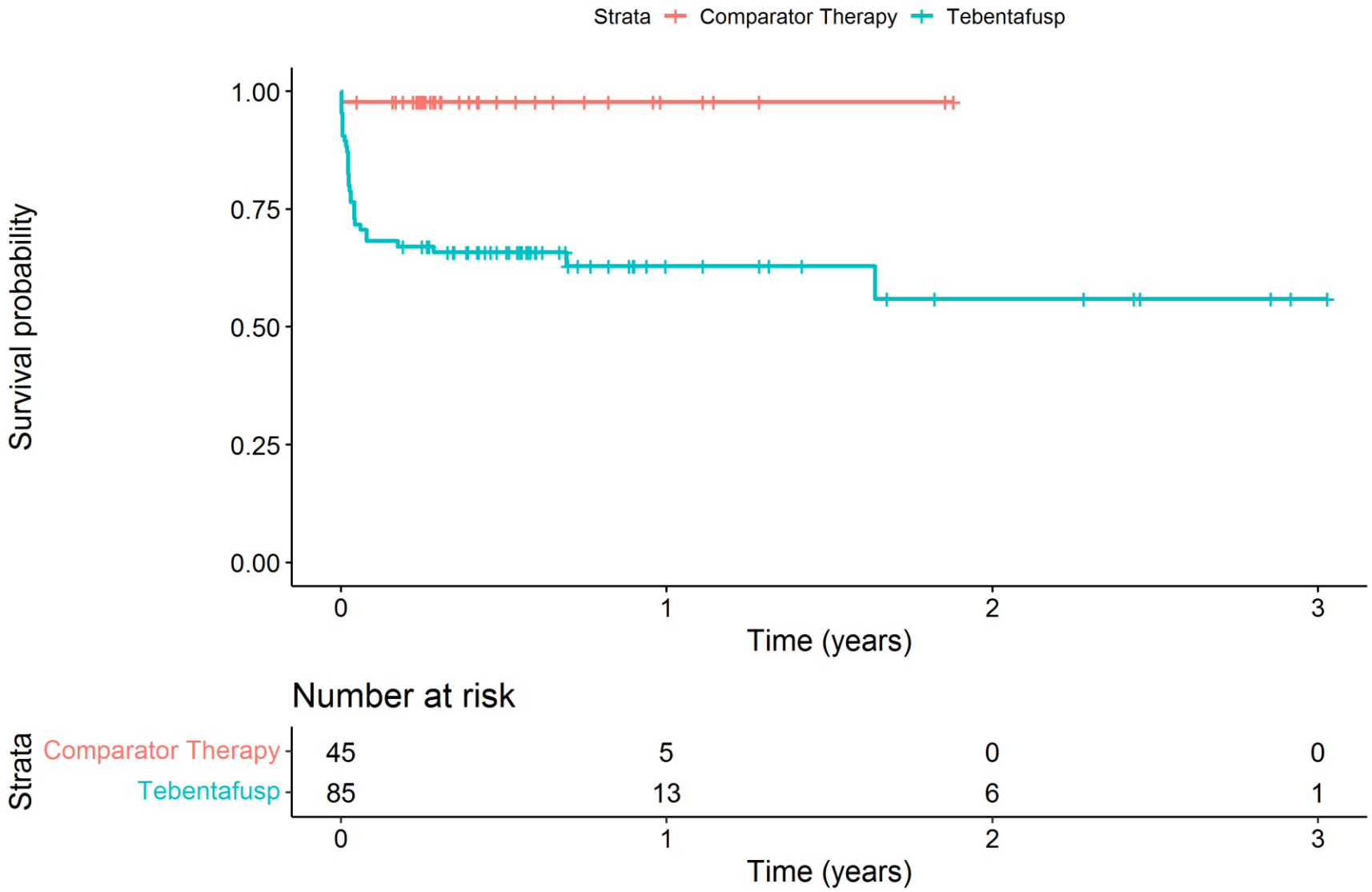
53.197 Periphere Ödeme- Läsion 3,1-8,0 cm



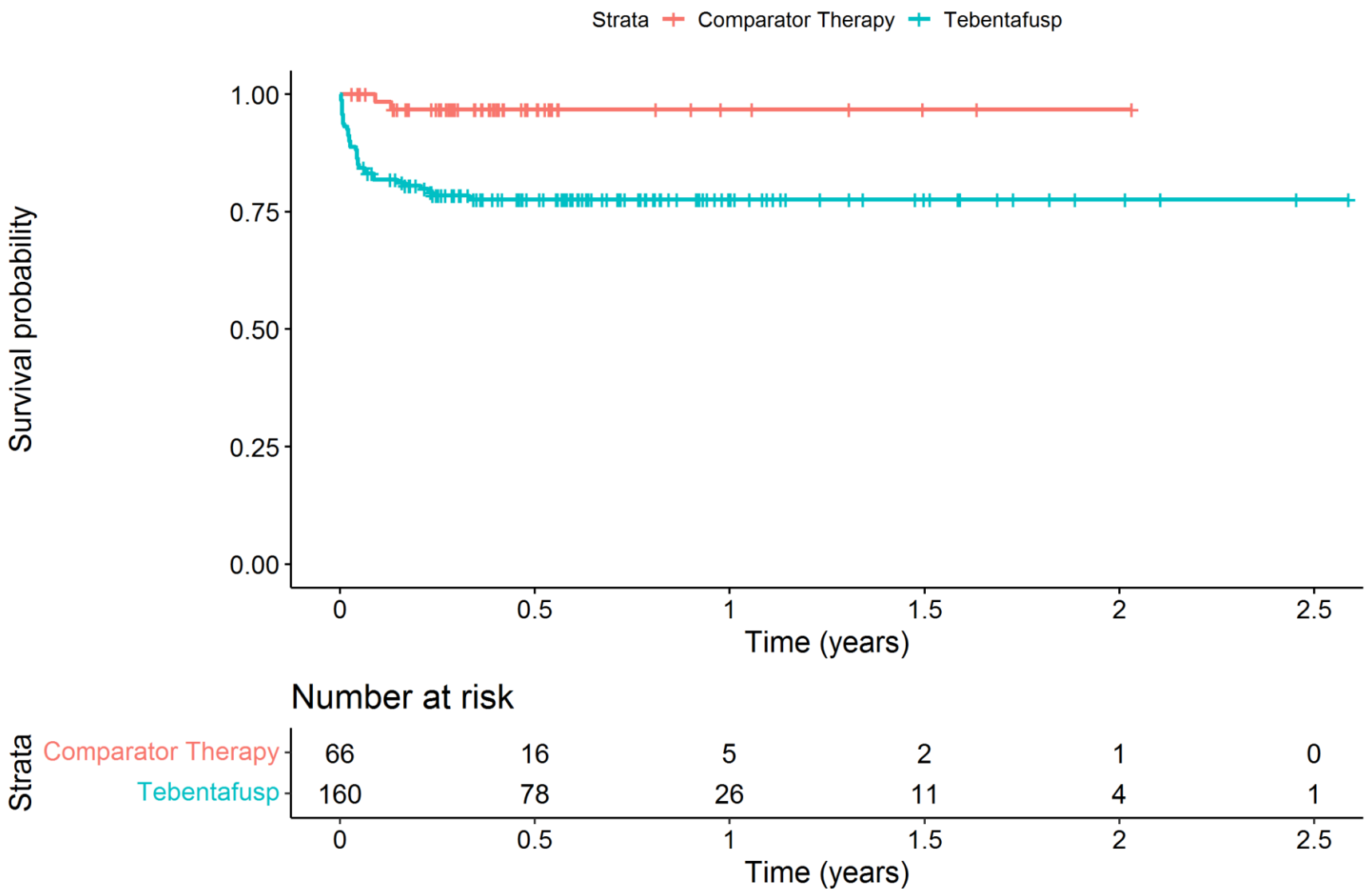
53.198 Periphere Ödeme- Läsion ≥8,1 cm



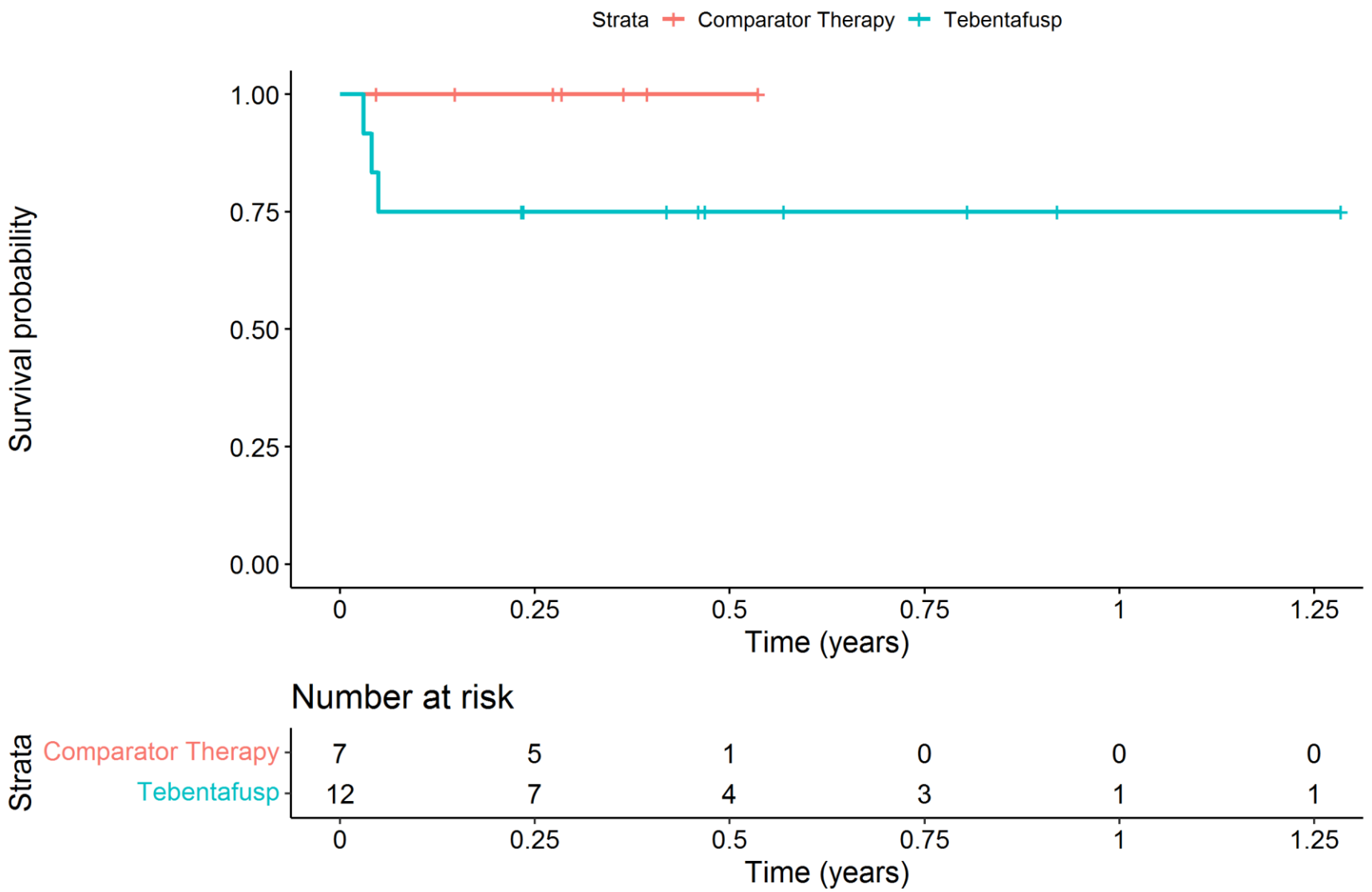
53.199 Periphere Ödeme- Nordamerika



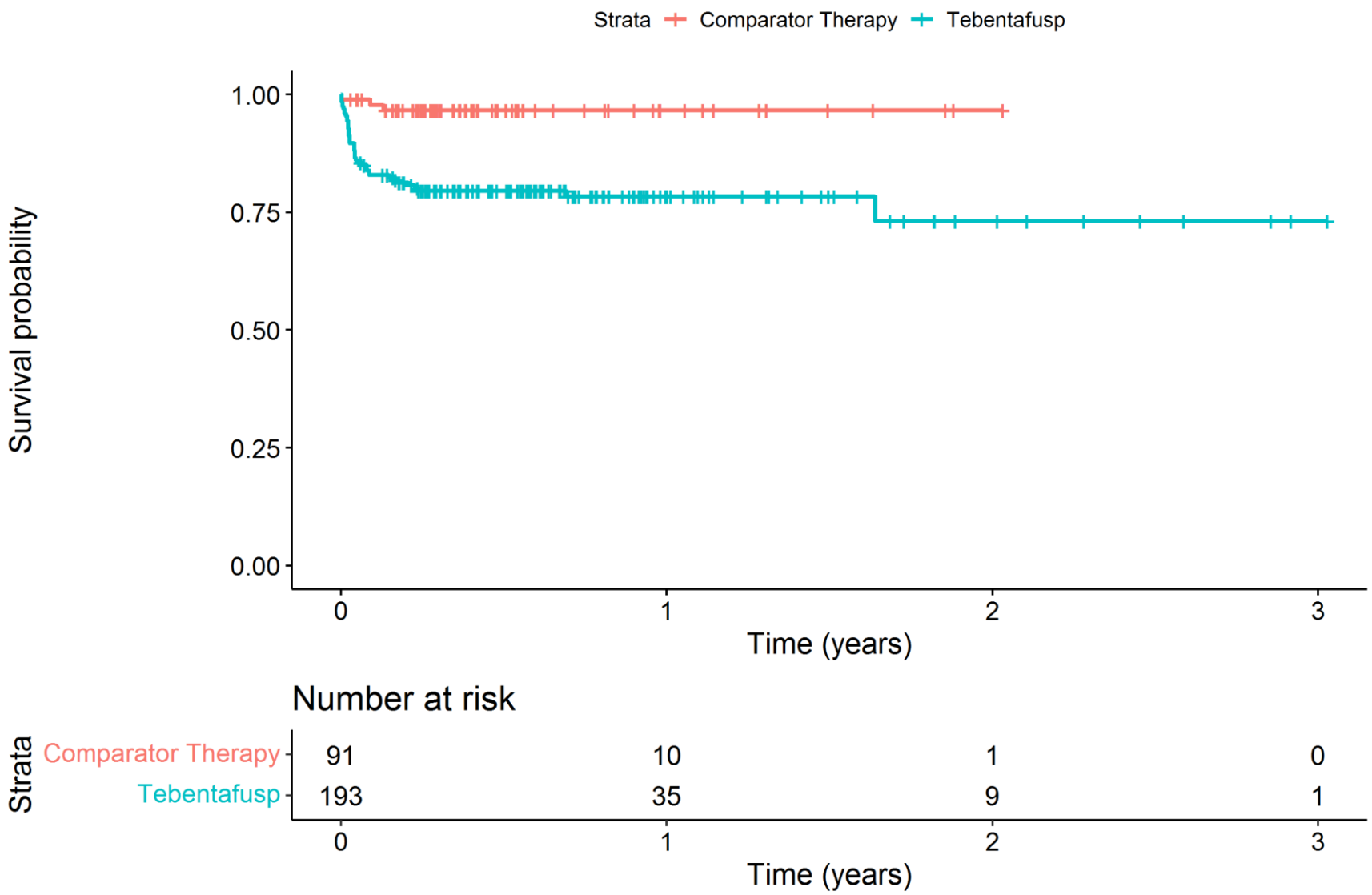
53.200 Periphere Ödeme- Nicht-Nordamerika



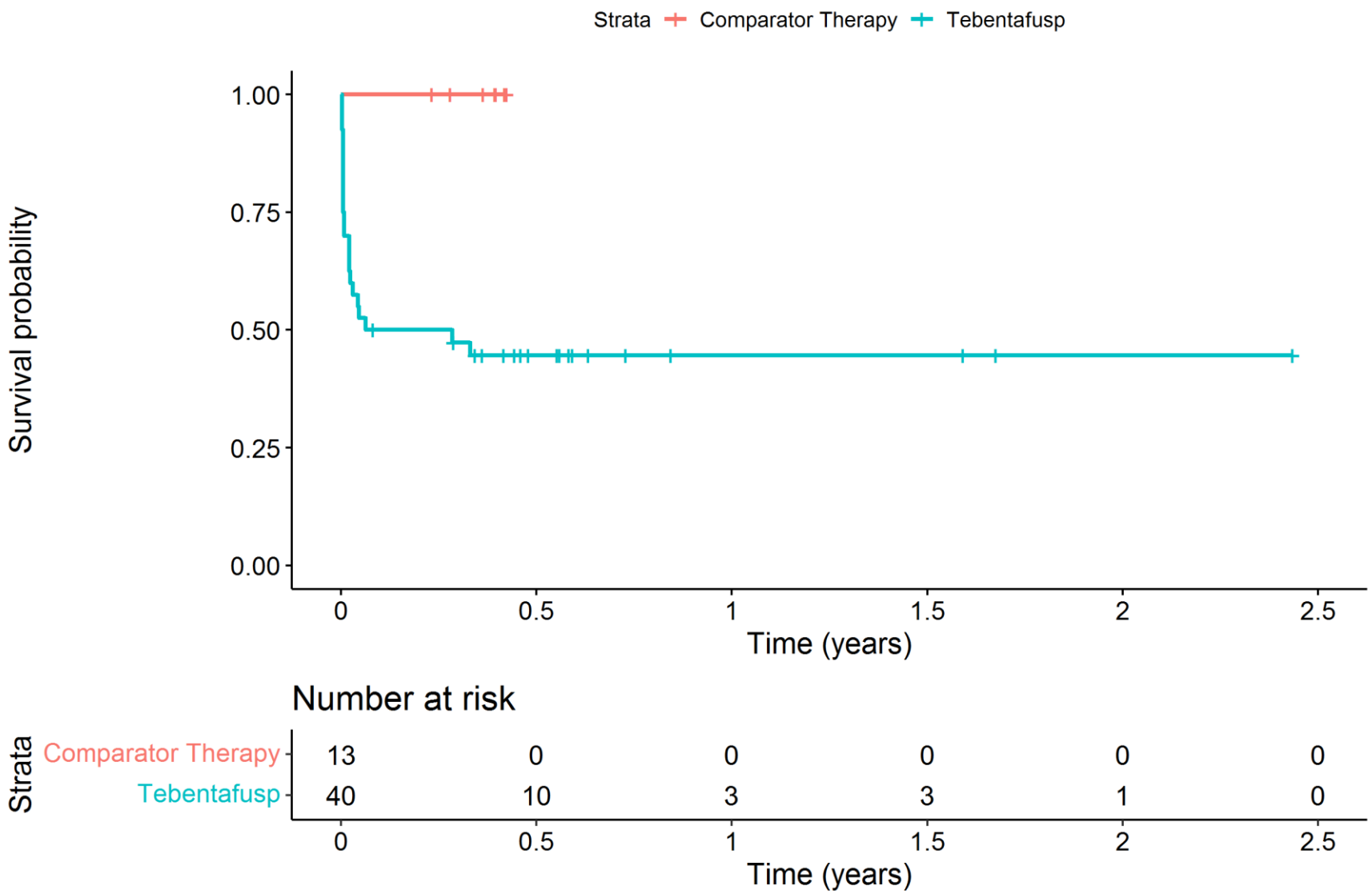
53.201 Periphere Ödeme- Dacarbazin



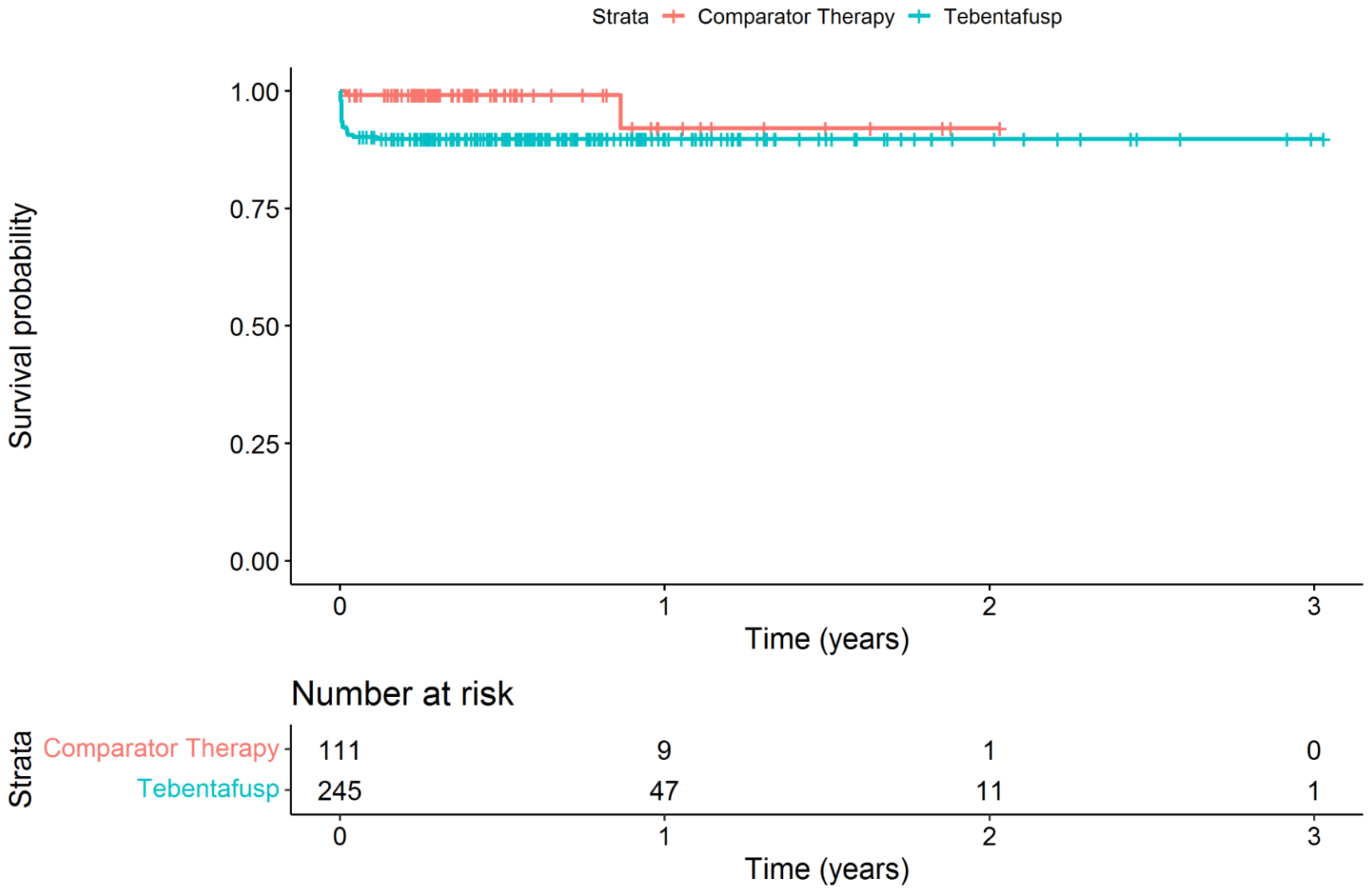
53.202 Periphere Ödeme- Pembrolizumab



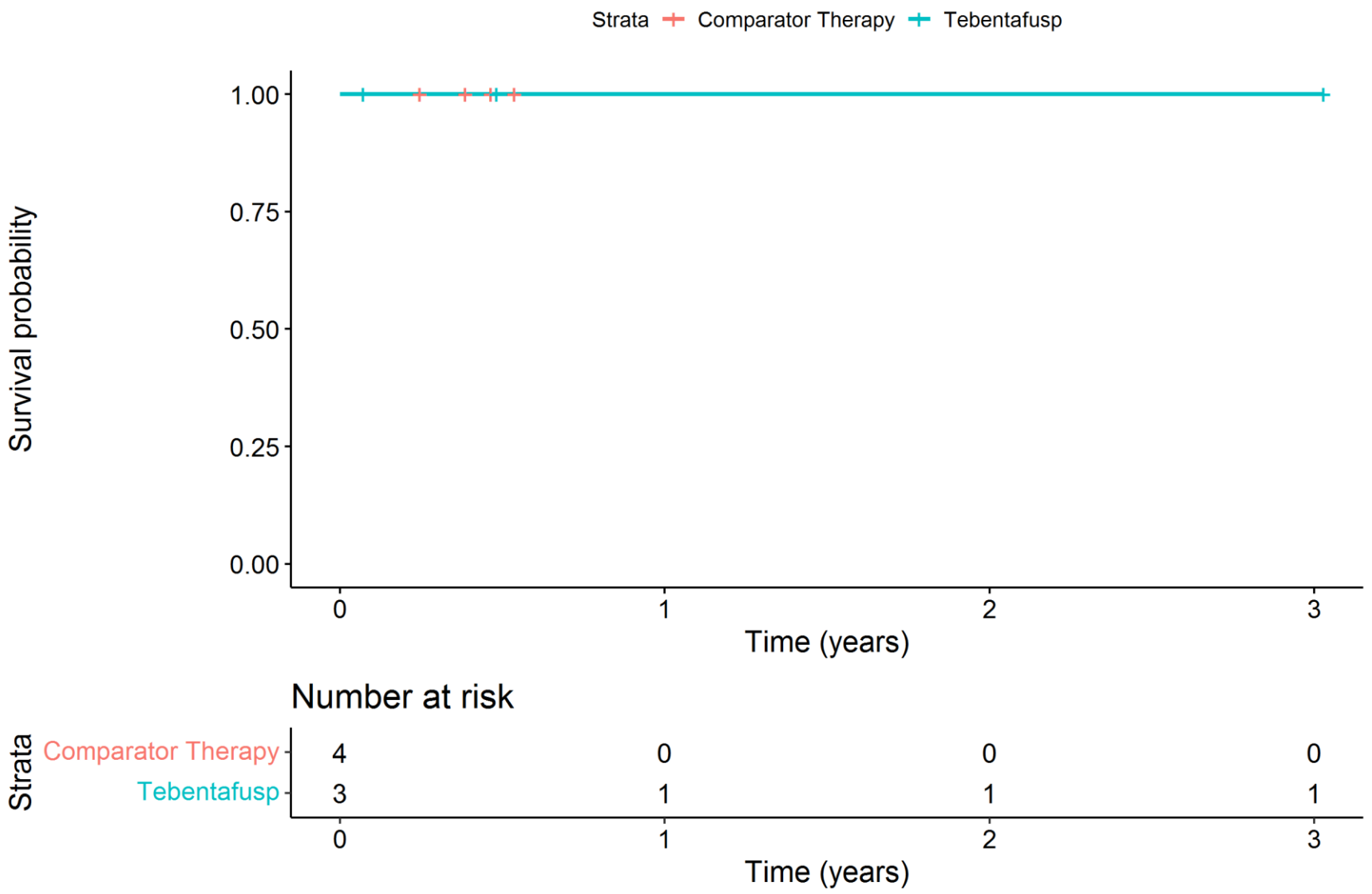
53.203 Periphere Ödeme- Ipilimumab



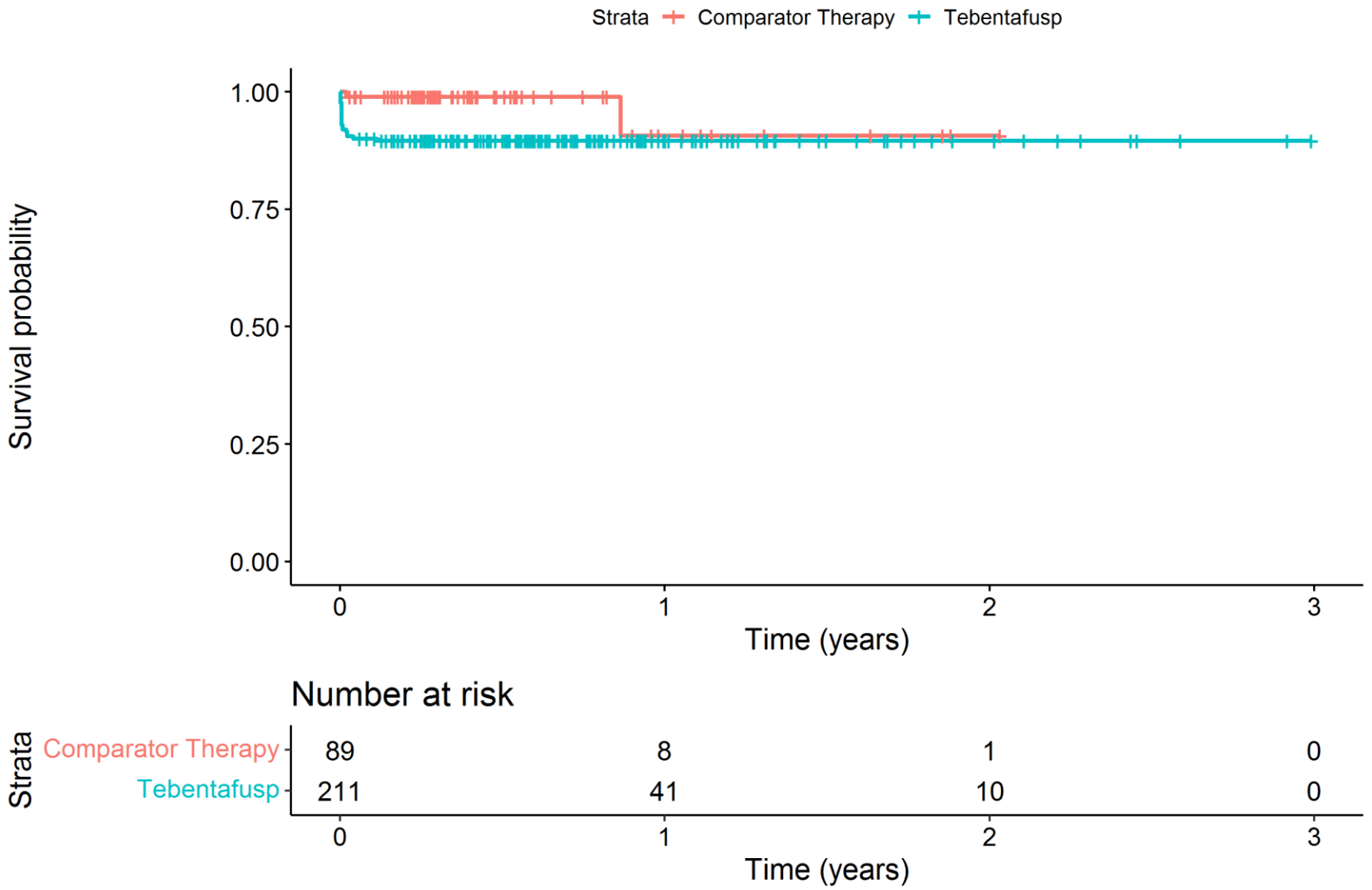
53.204 Gesichtsödeme- Gesamt



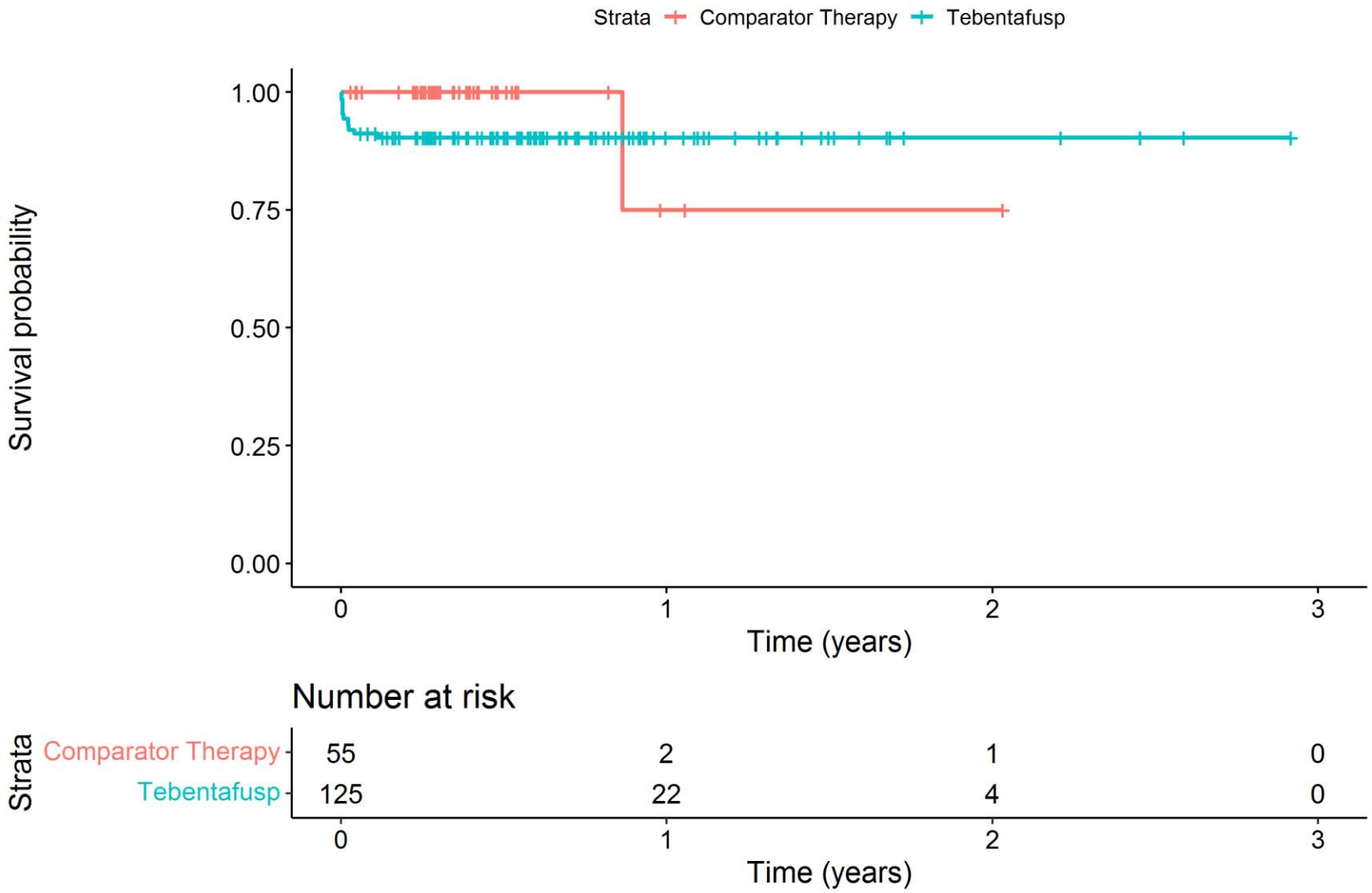
53.205 Gesichtsödeme- Hispanisch



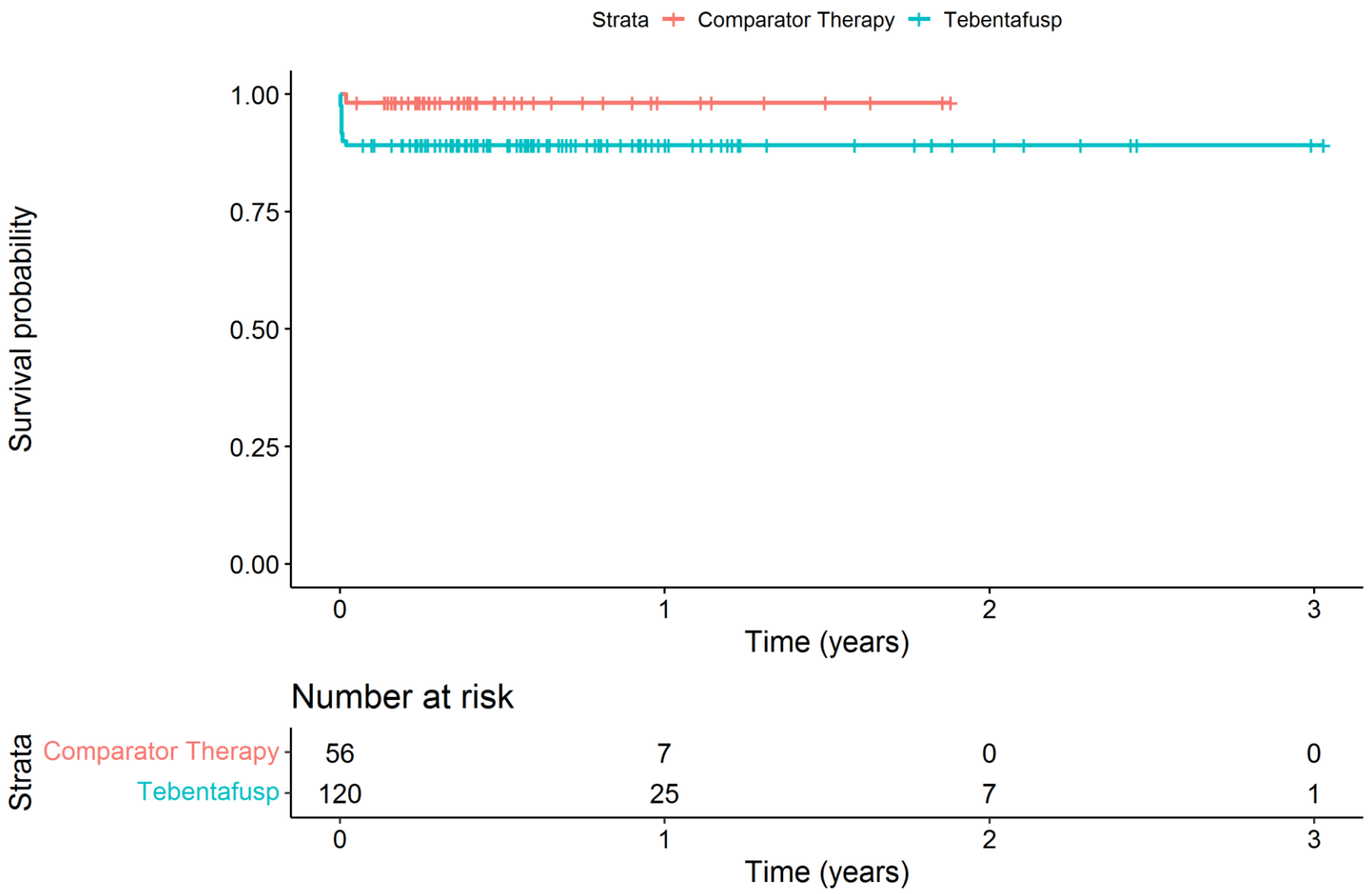
53.206 Gesichtsödeme- Nicht-hispanisch



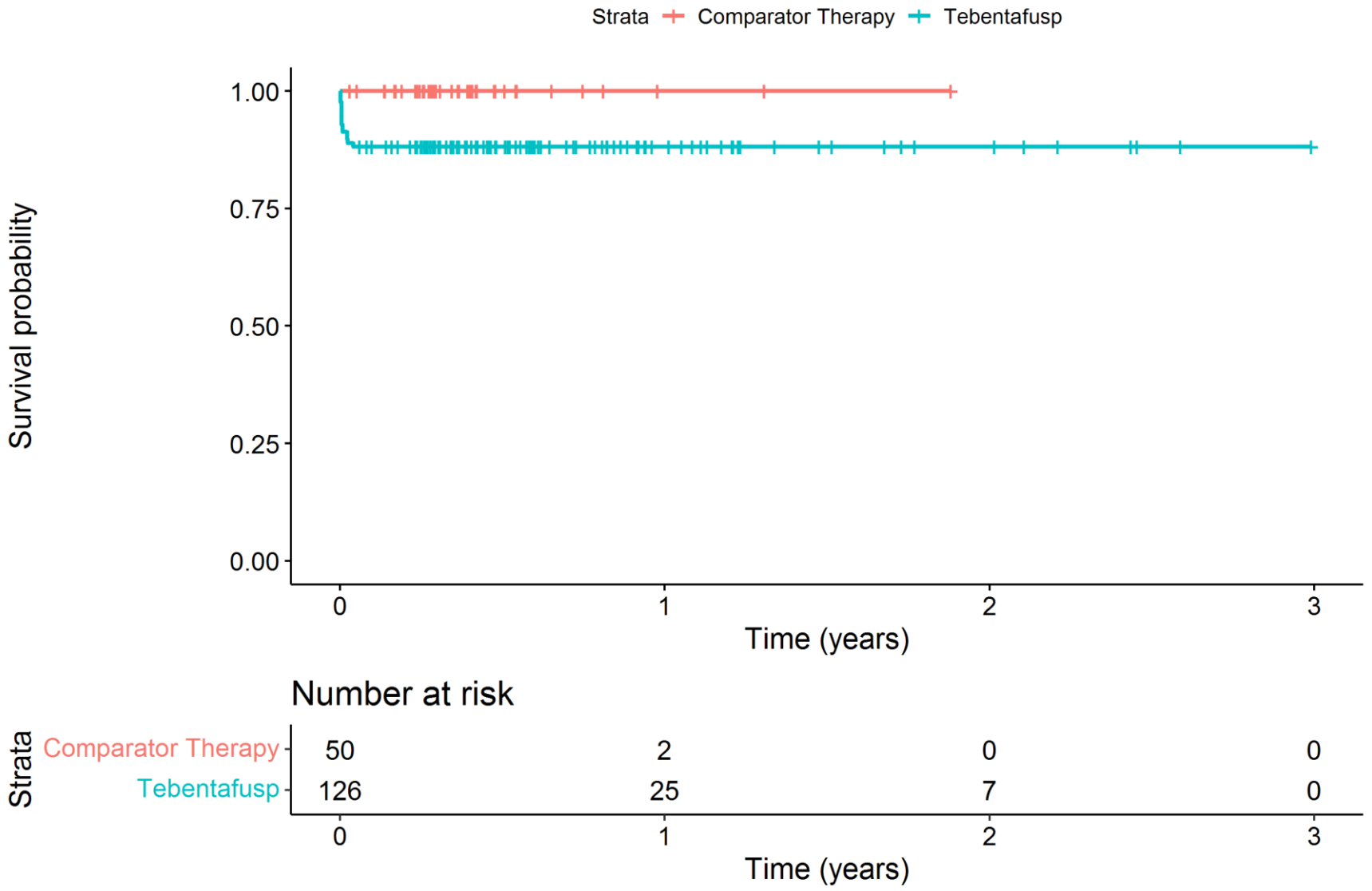
53.207 Gesichtsödeme- Männlich



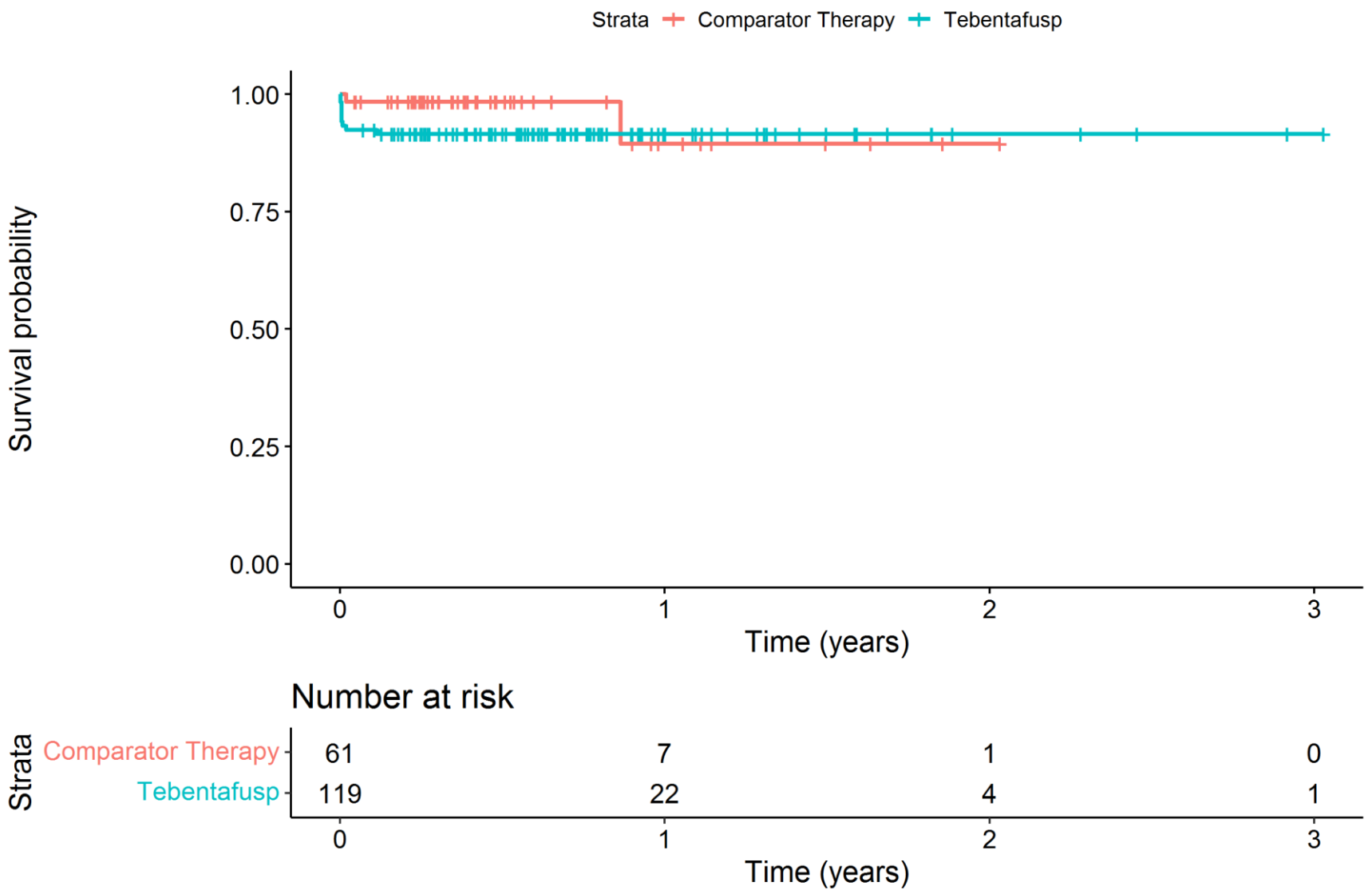
53.208 Gesichtsödeme- Weiblich



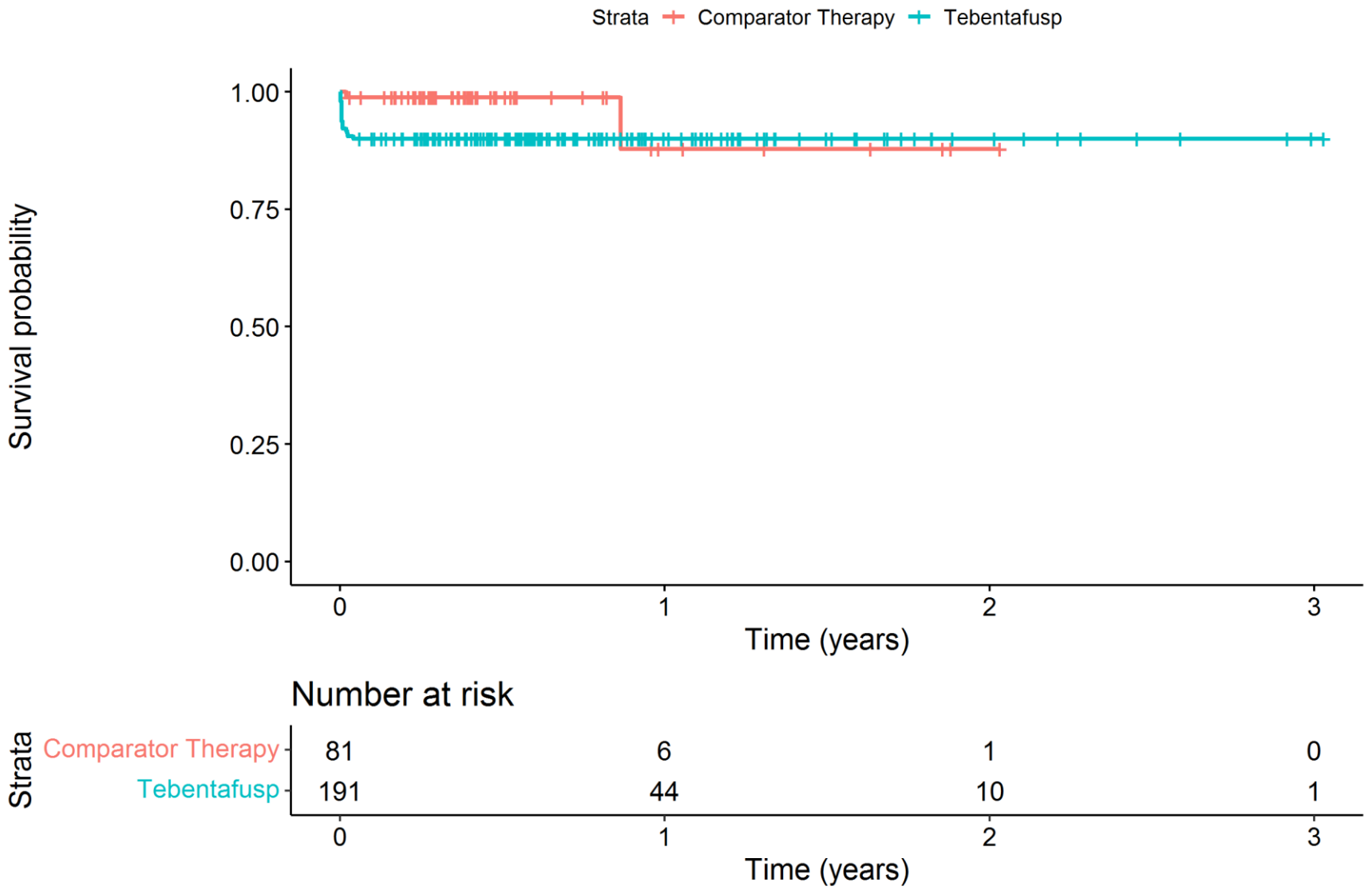
53.209 Gesichtsödeme- <65



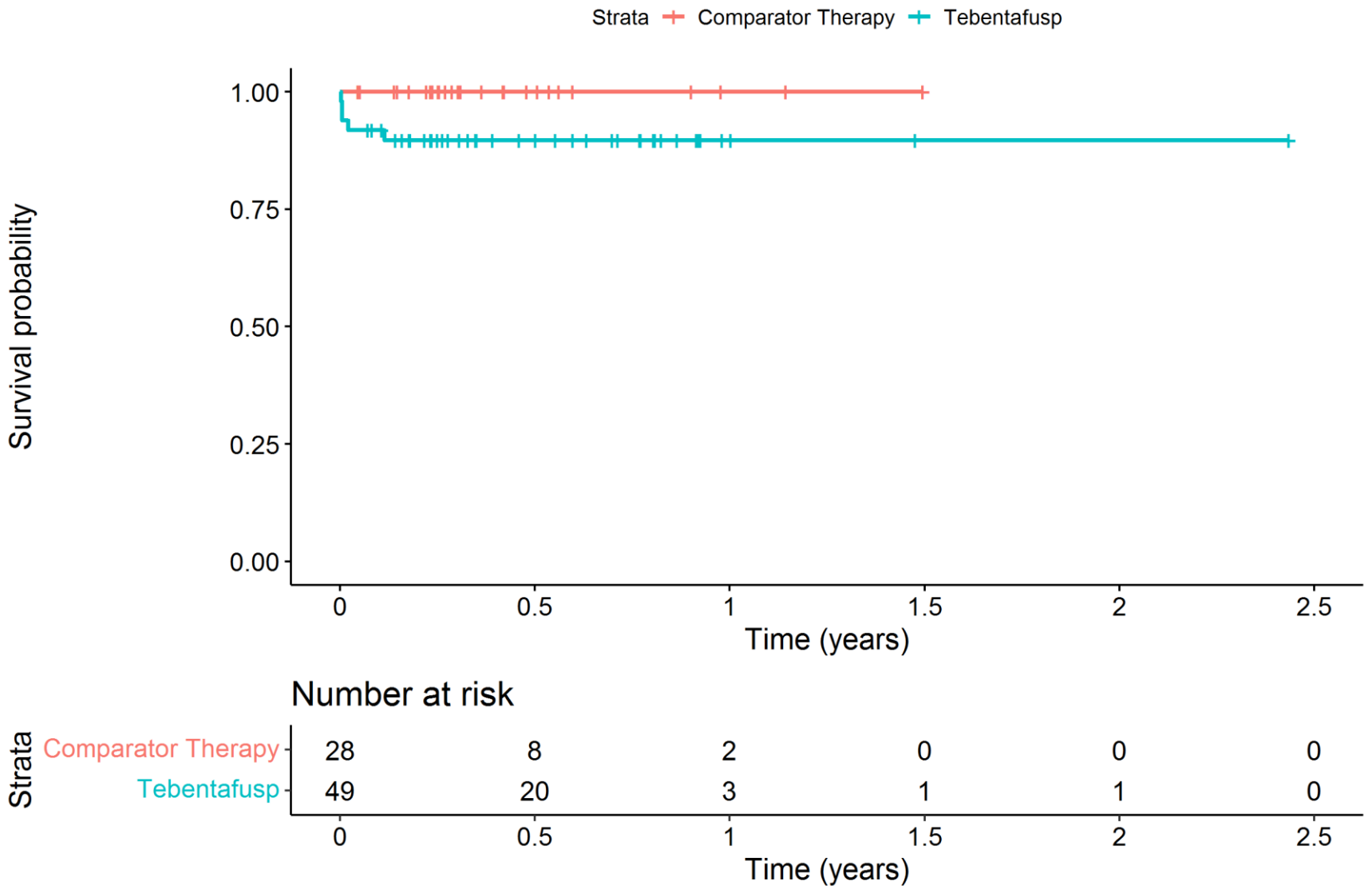
53.210 Gesichtsödeme- ≥65



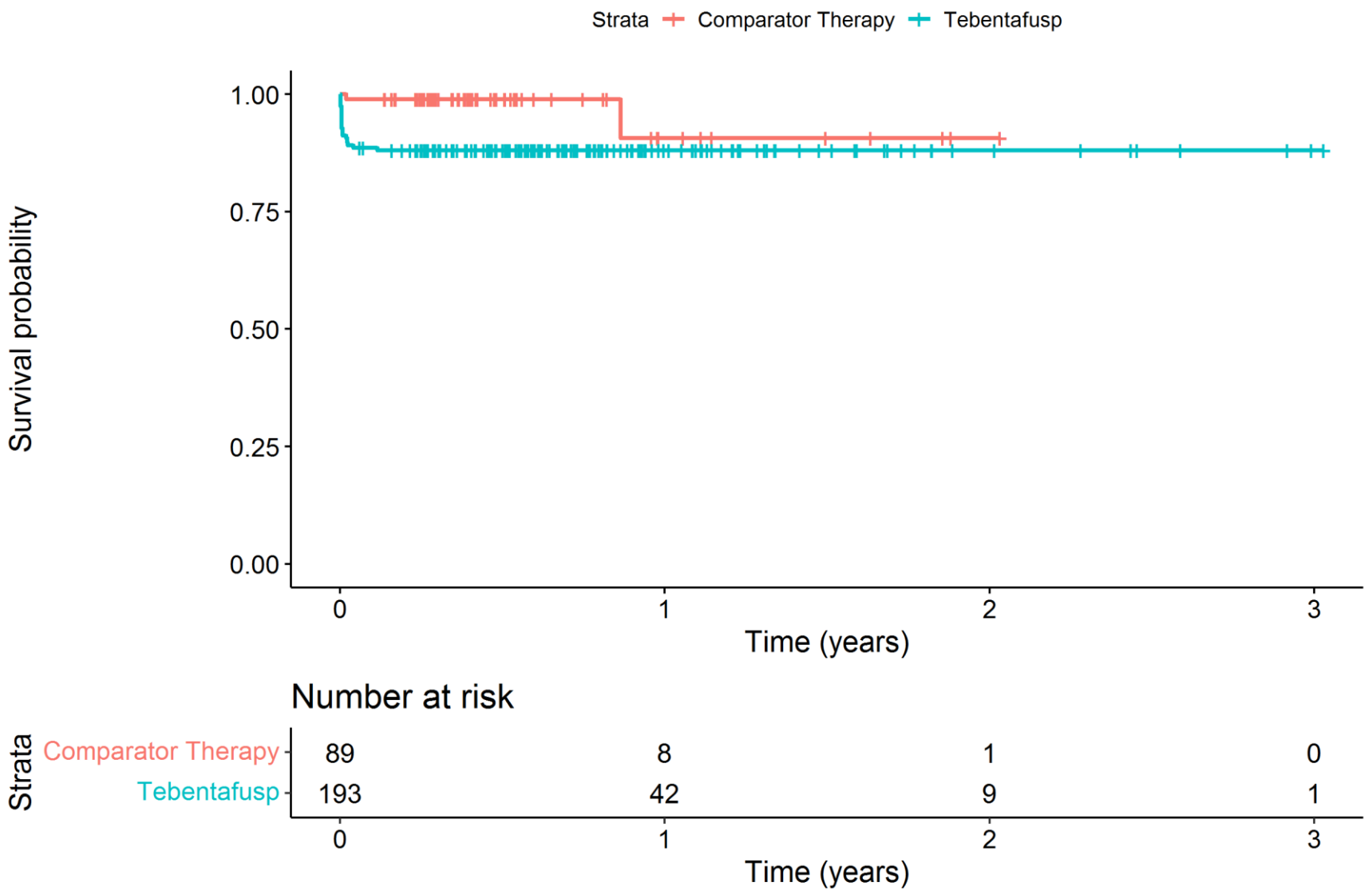
53.211 Gesichtsödeme- ECOG 0



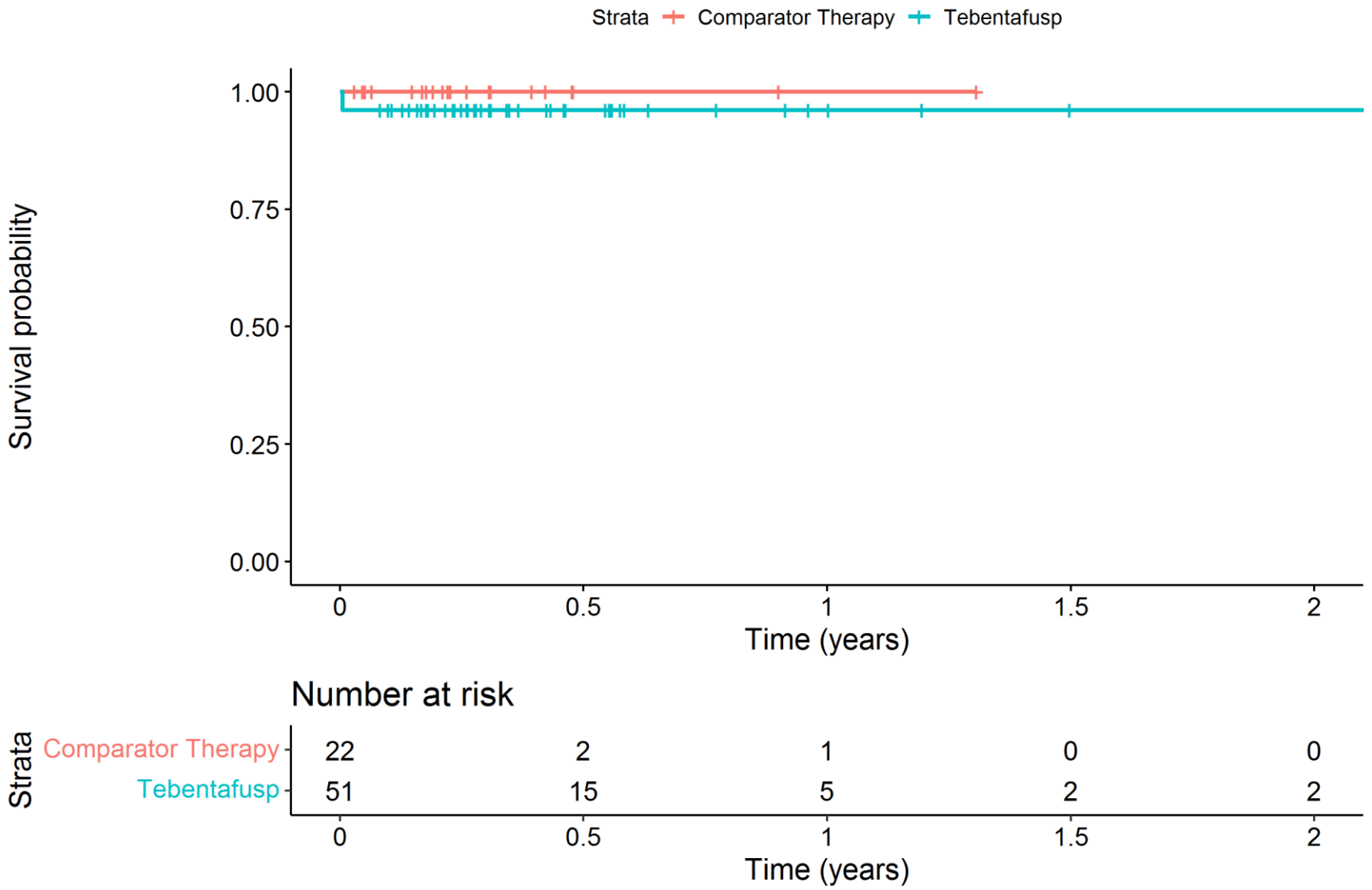
53.212 Gesichtsödeme- ECOG 1



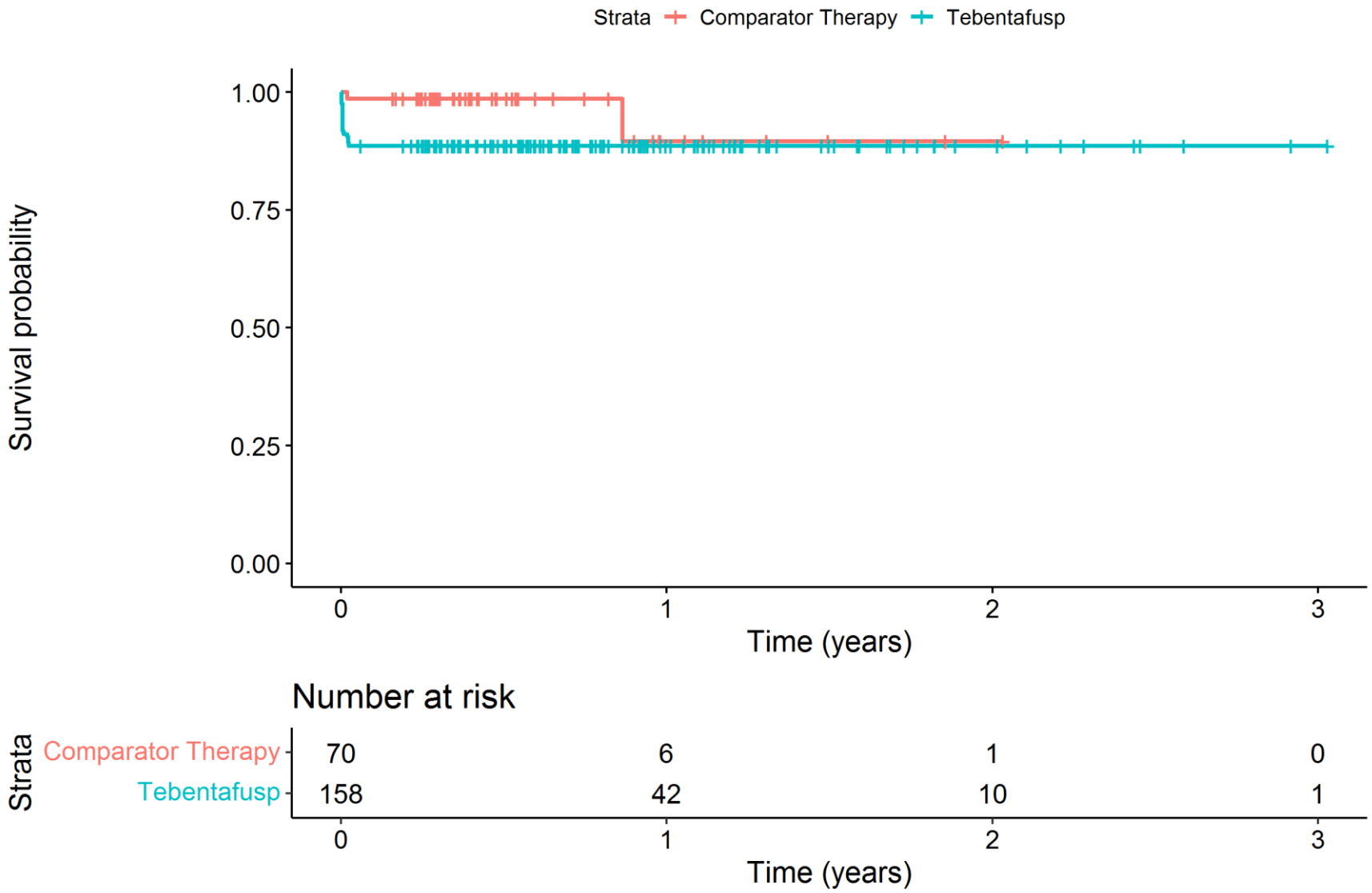
53.213 Gesichtsödeme- ALP ≤ ULN



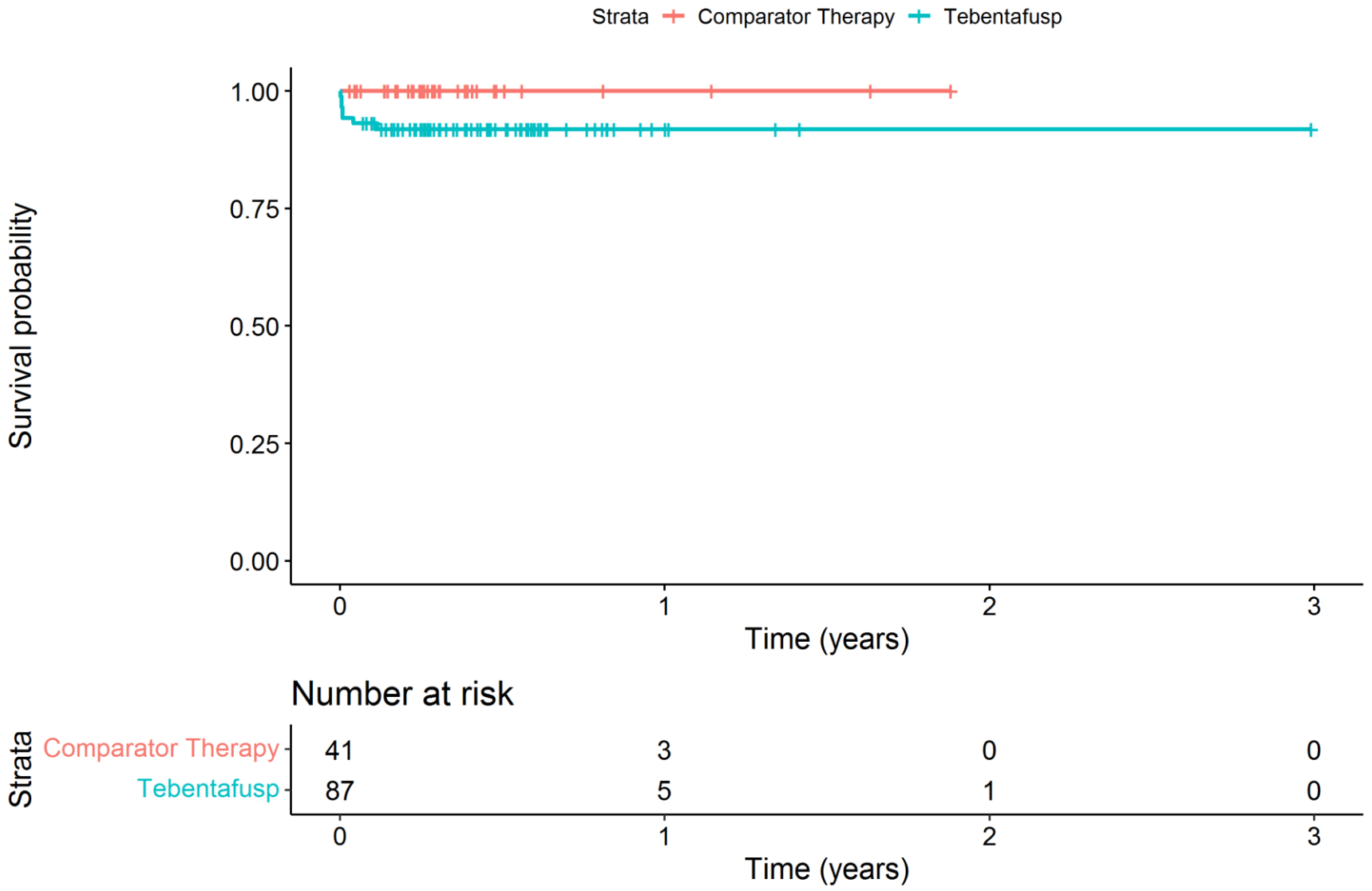
53.214 Gesichtsödeme- ALP > ULN



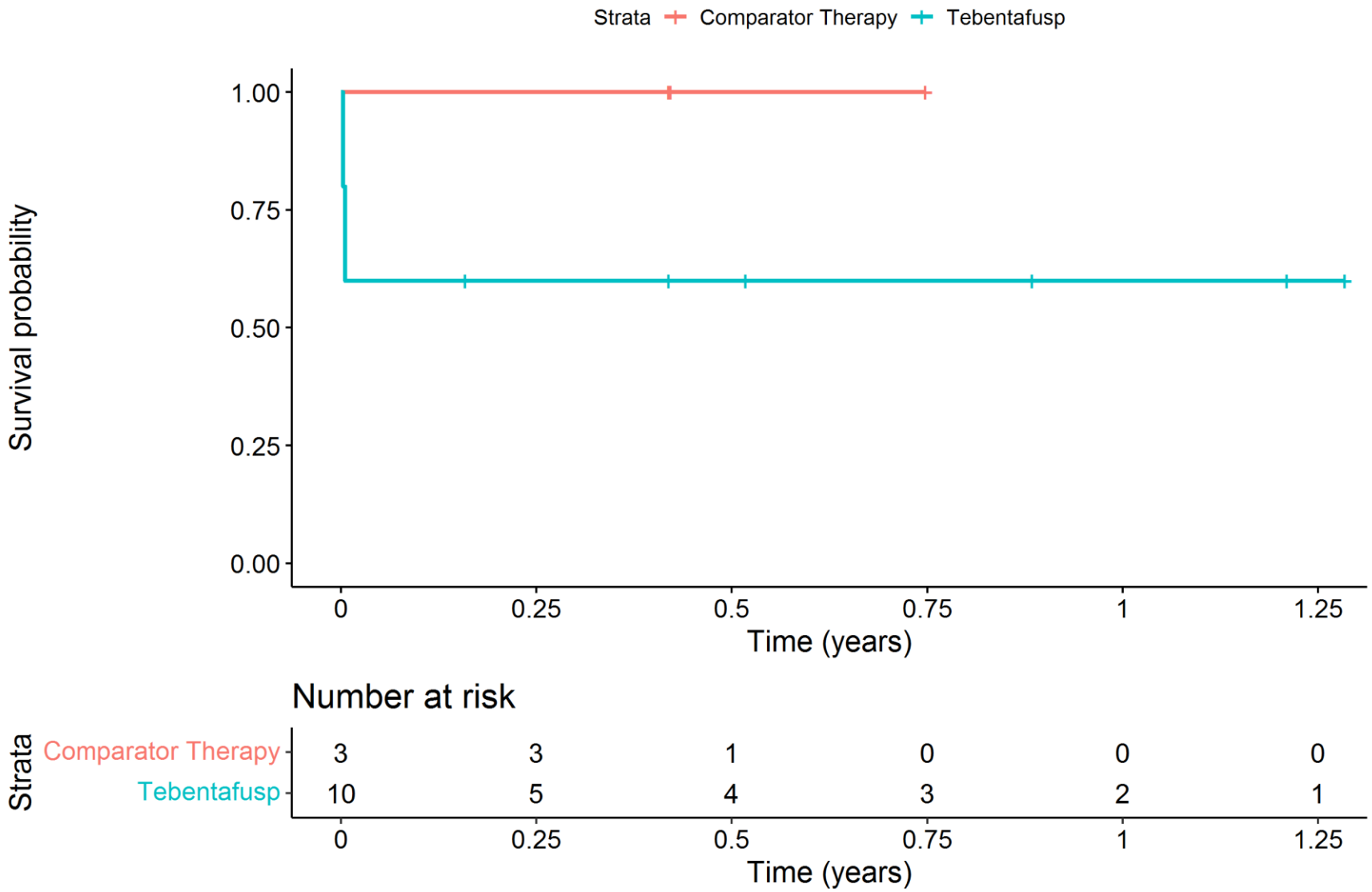
53.215 Gesichtsödeme- LDH =< ULN



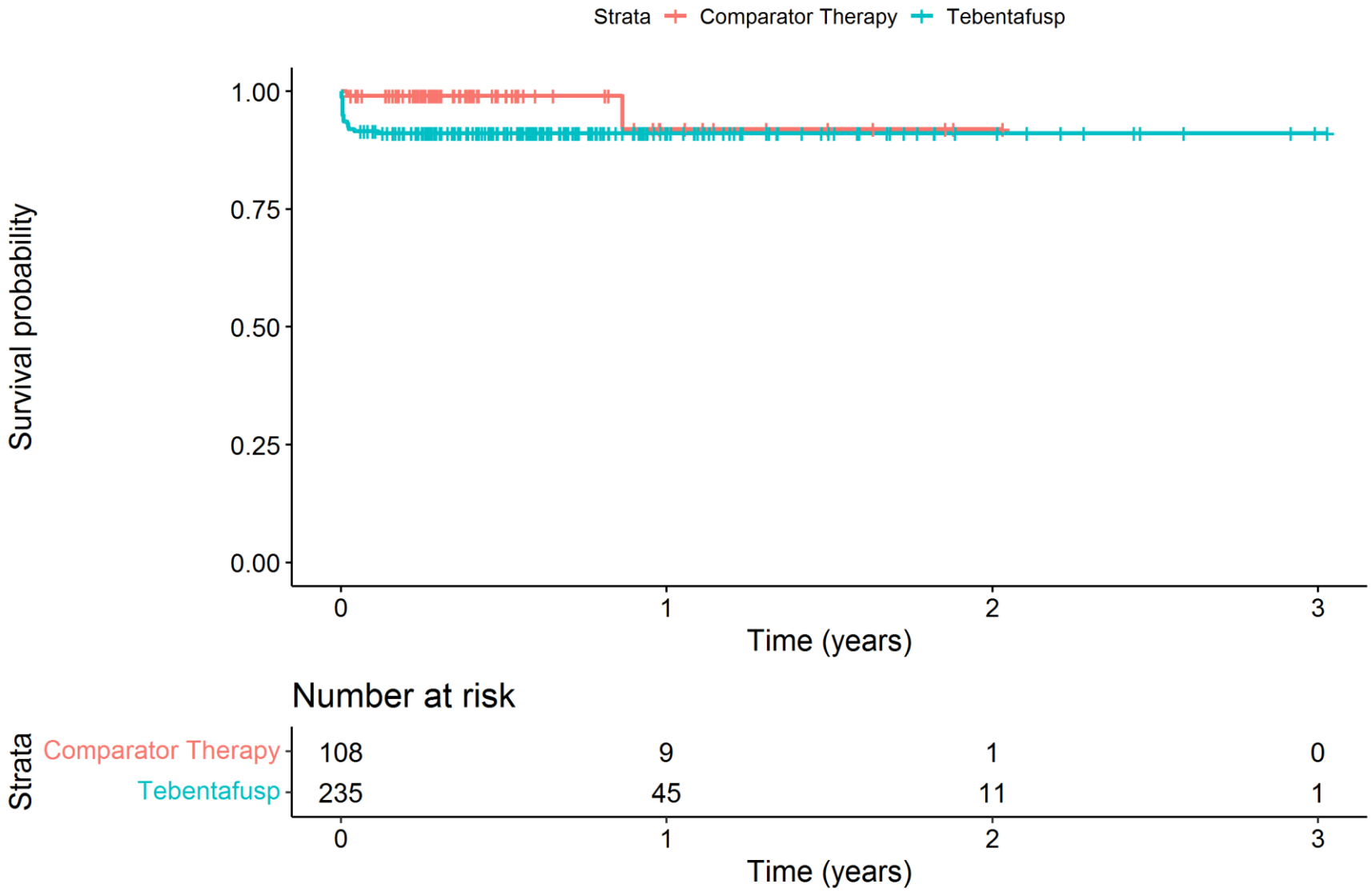
53.216 Gesichtsödeme- LDH > ULN



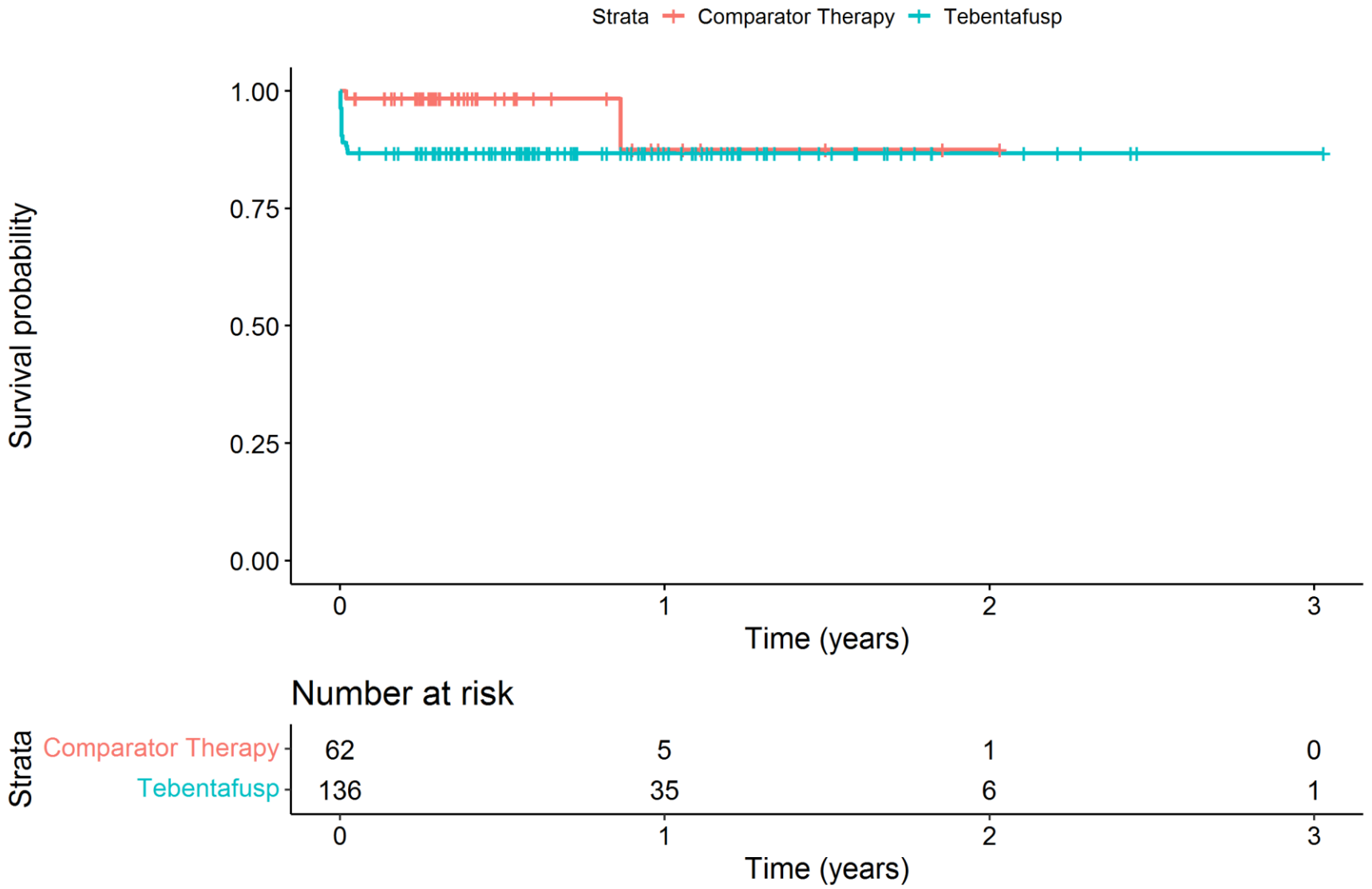
53.217 Gesichtsödeme- Vorherige Therapie adjuvant/neoadjuvant



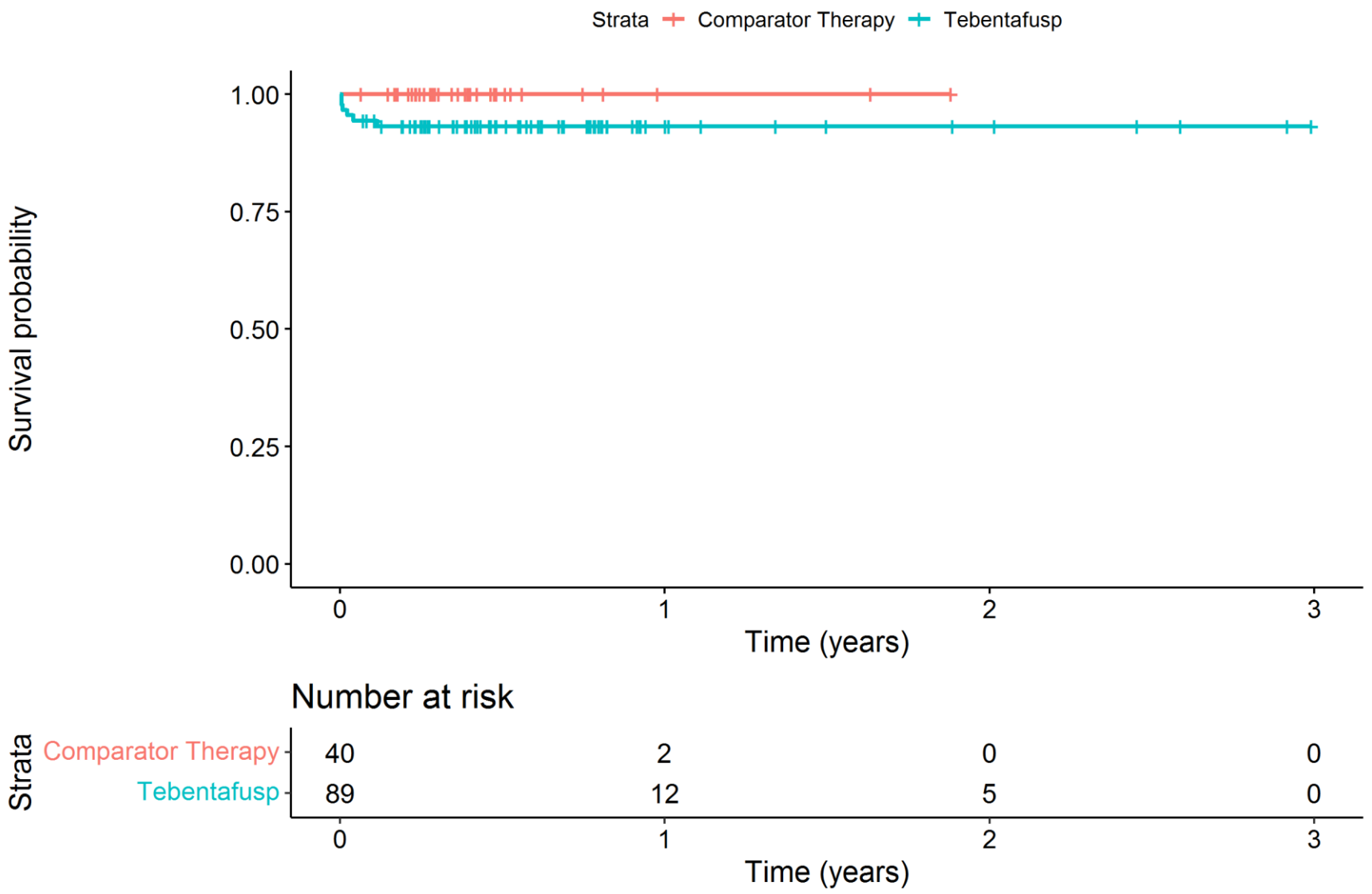
53.218 Gesichtsödeme- Keine vorherige Therapie adjuvant/neoadjuvant



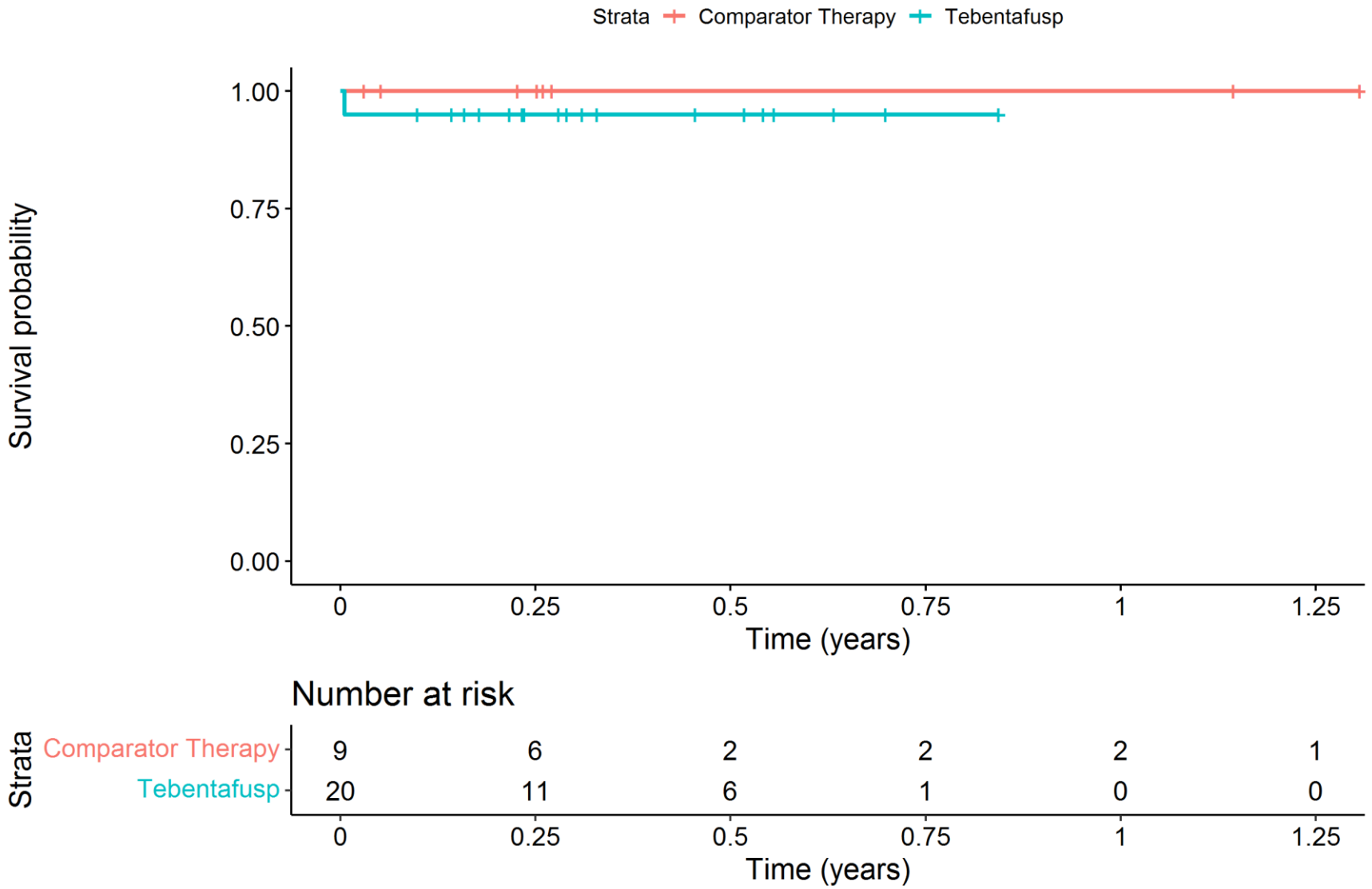
53.219 Gesichtsödeme- Läsion ≤ 3cm



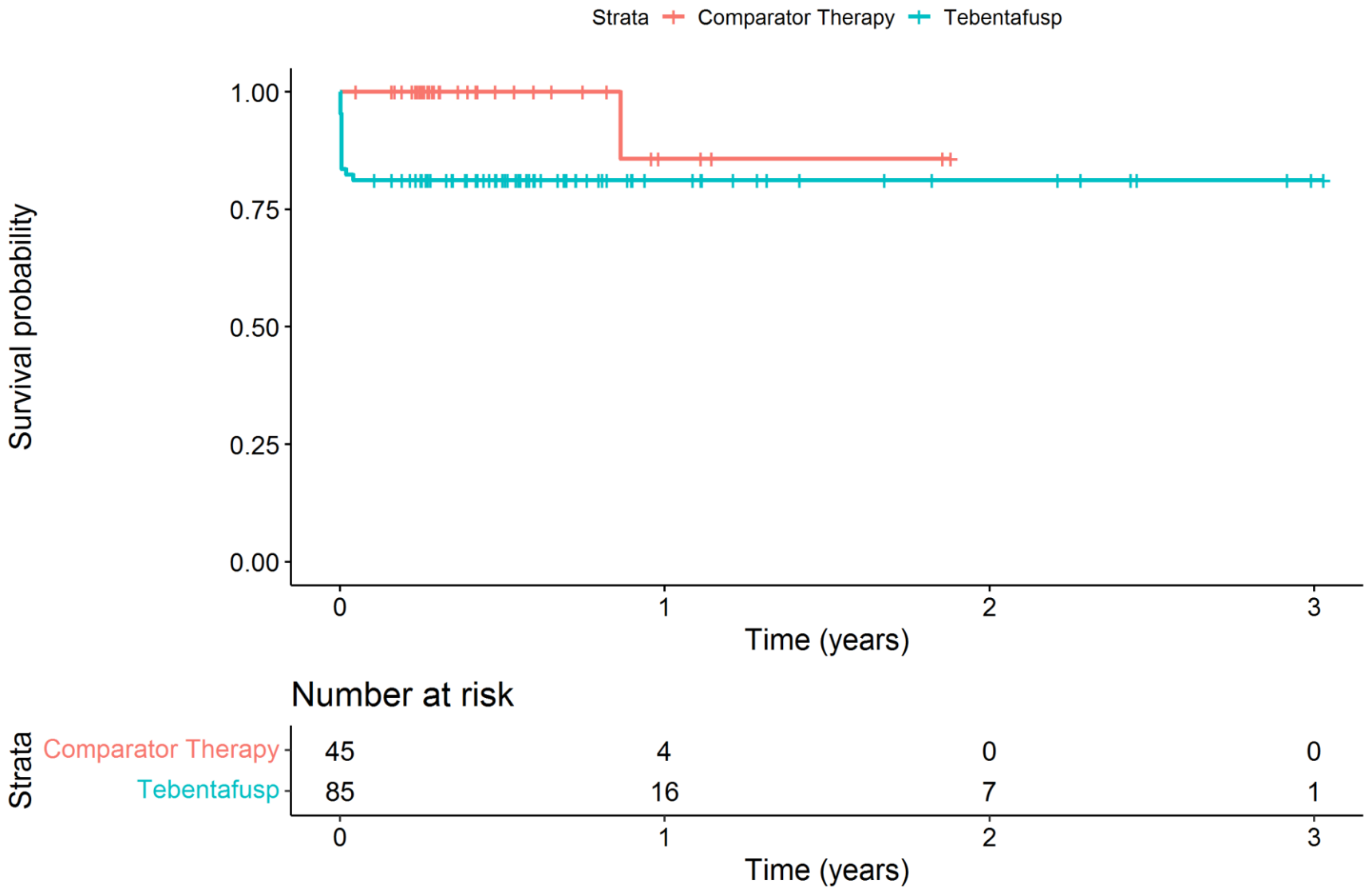
53.220 Gesichtsödeme- Läsion 3,1-8,0 cm



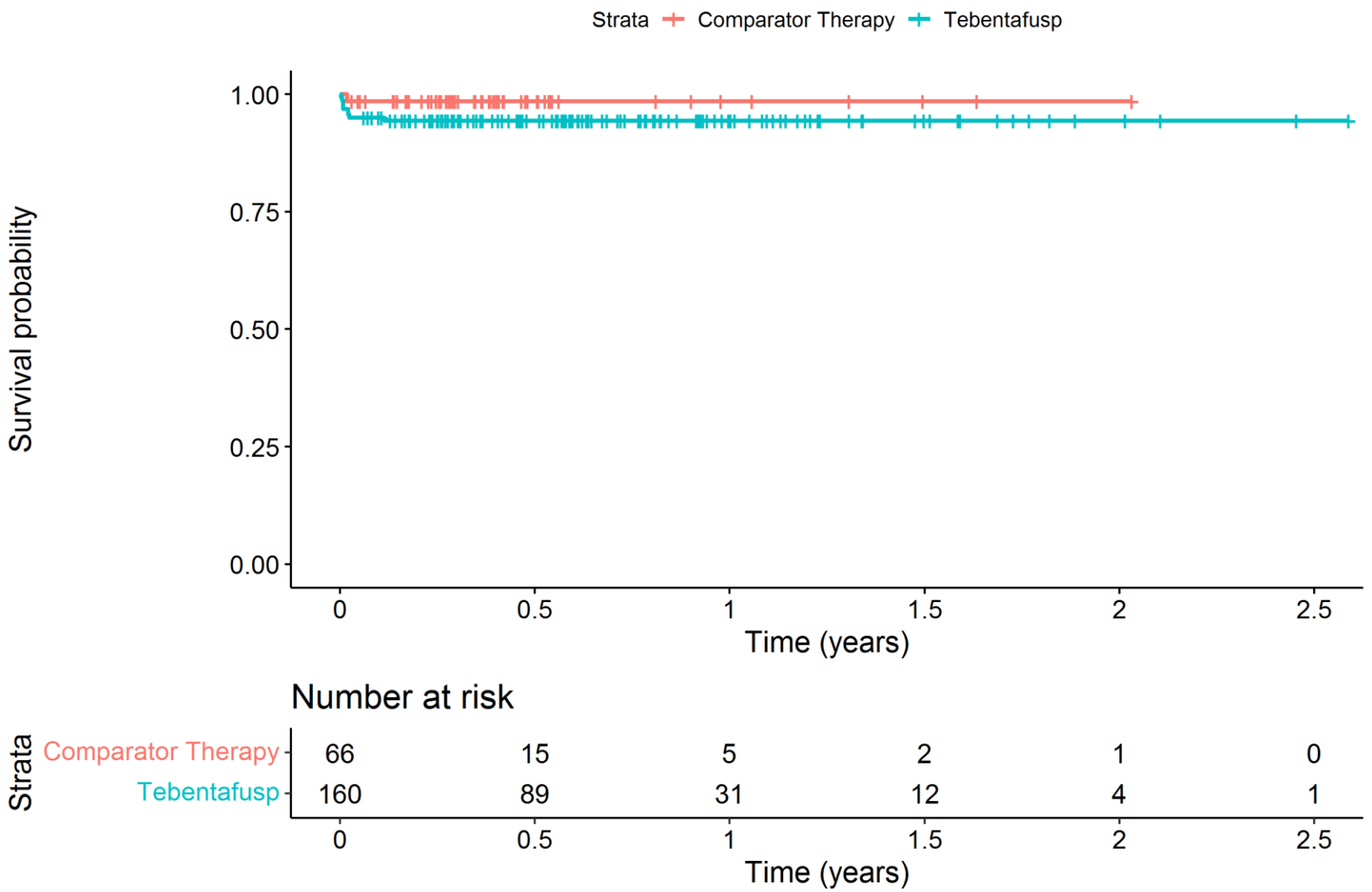
53.221 Gesichtsödeme- Läsion ≥8,1 cm



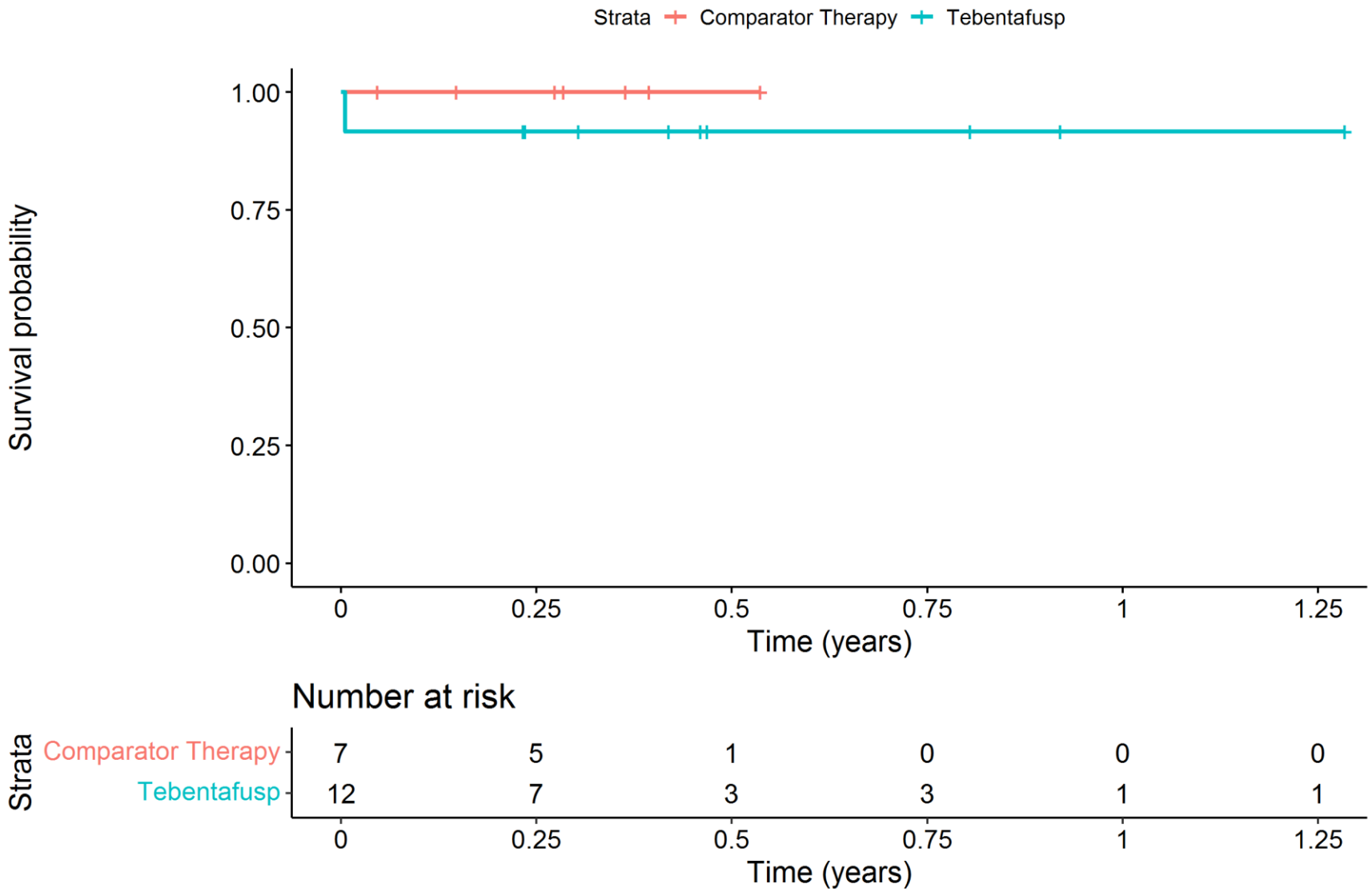
53.222 Gesichtsödeme- Nordamerika



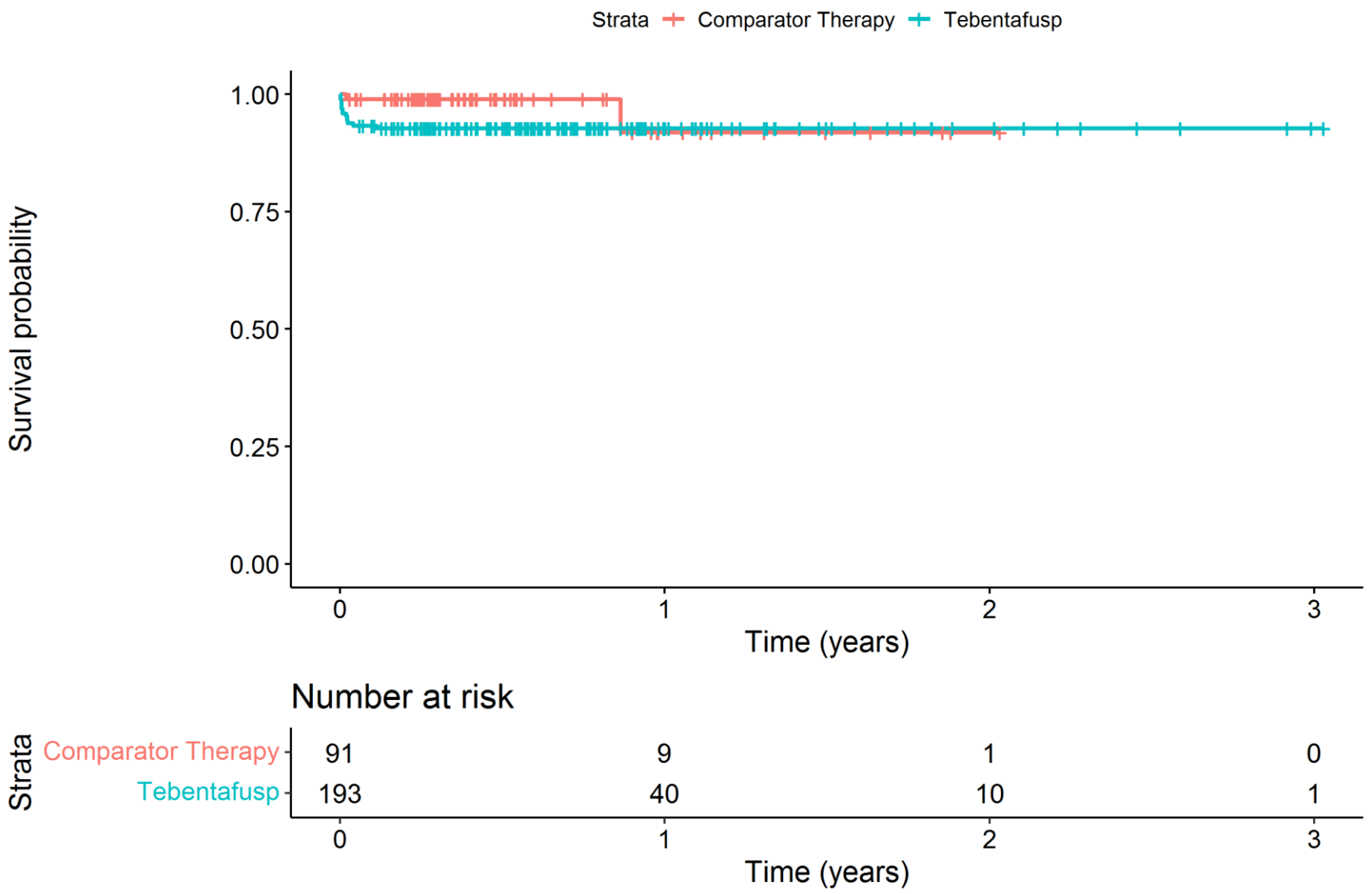
53.223 Gesichtsödeme- Nicht-Nordamerika



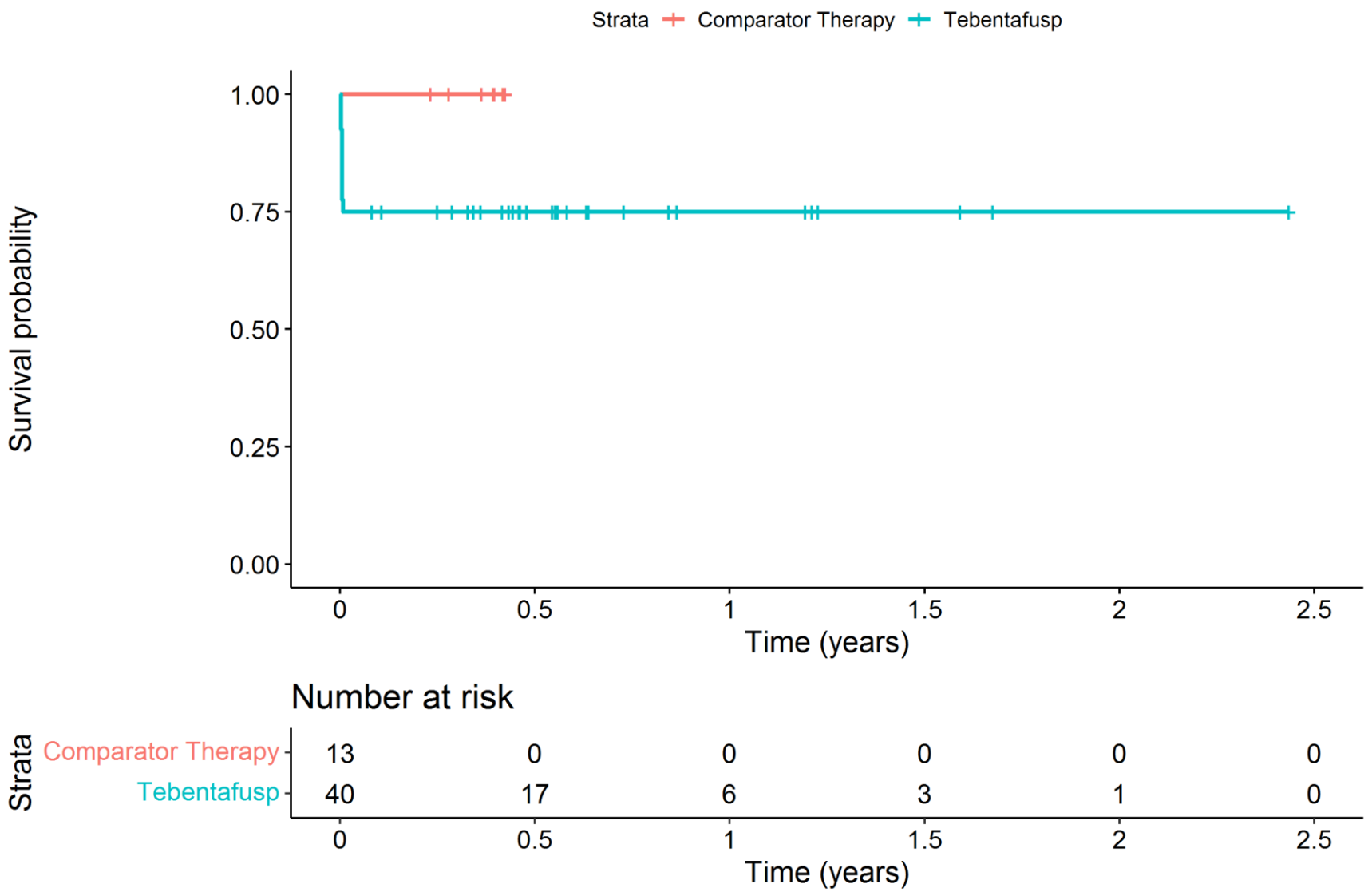
53.224 Gesichtsödeme- Dacarbazin



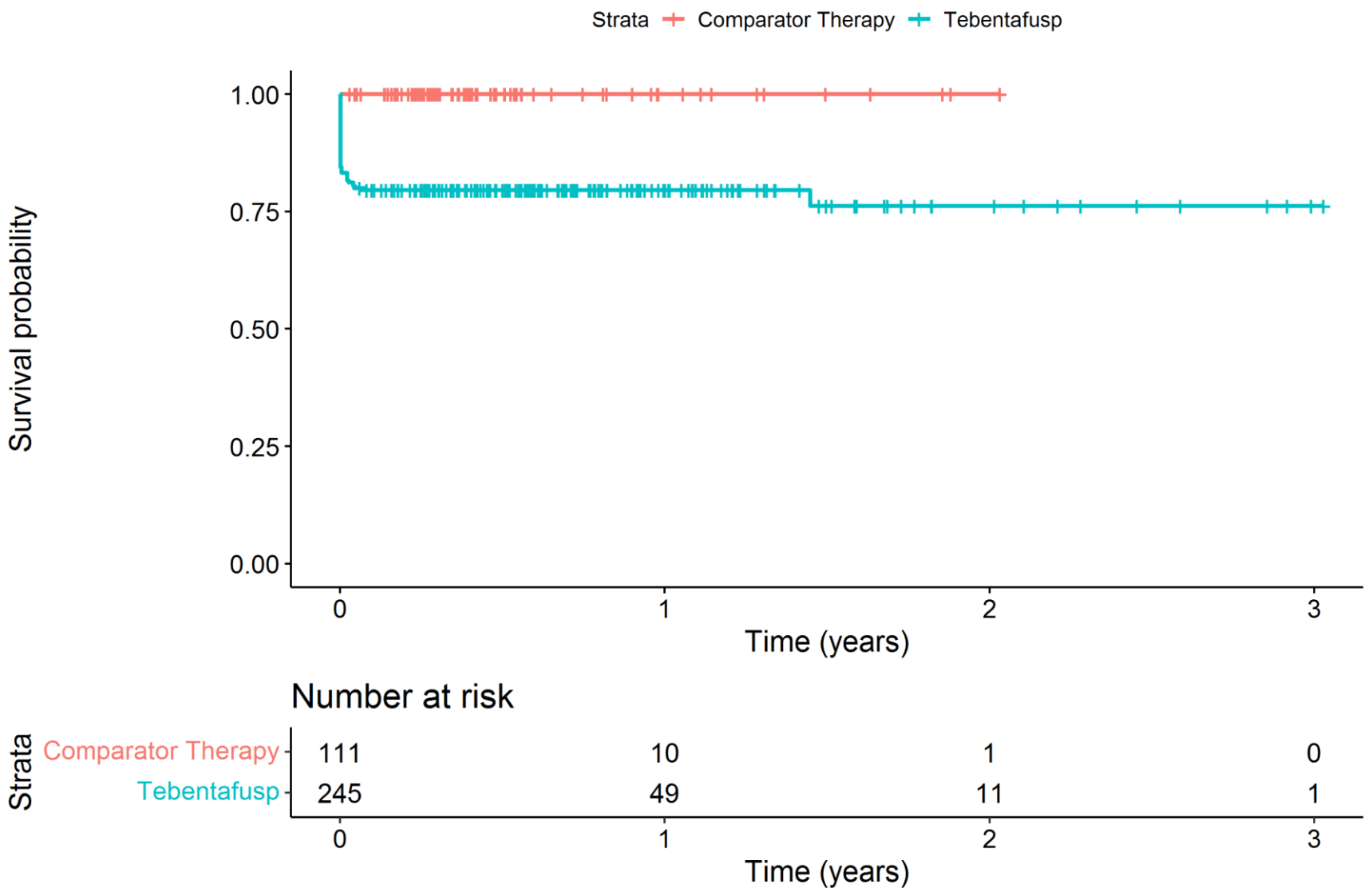
53.225 Gesichtsödeme- Pembrolizumab



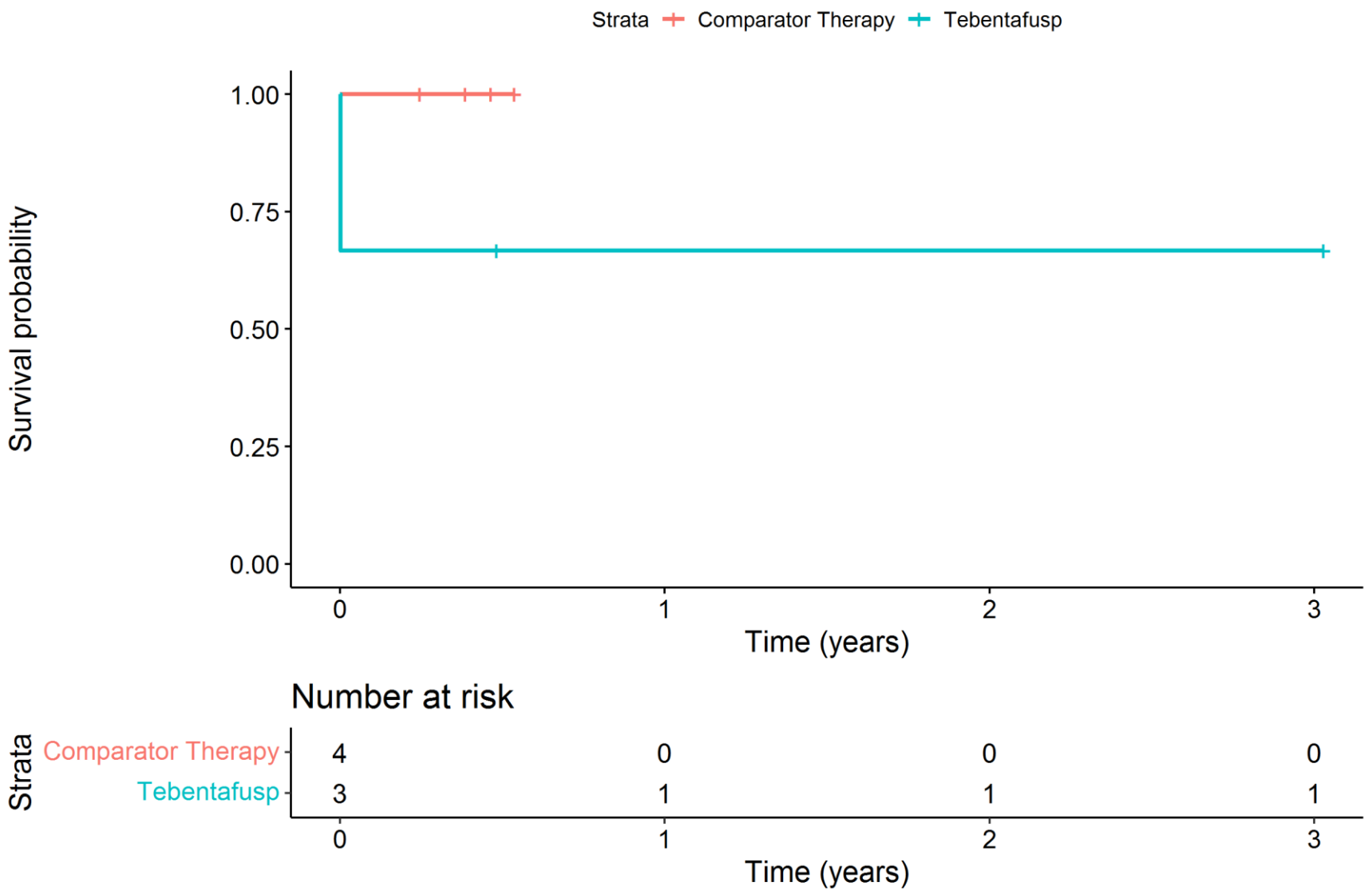
53.226 Gesichtsödeme- Ipilimumab



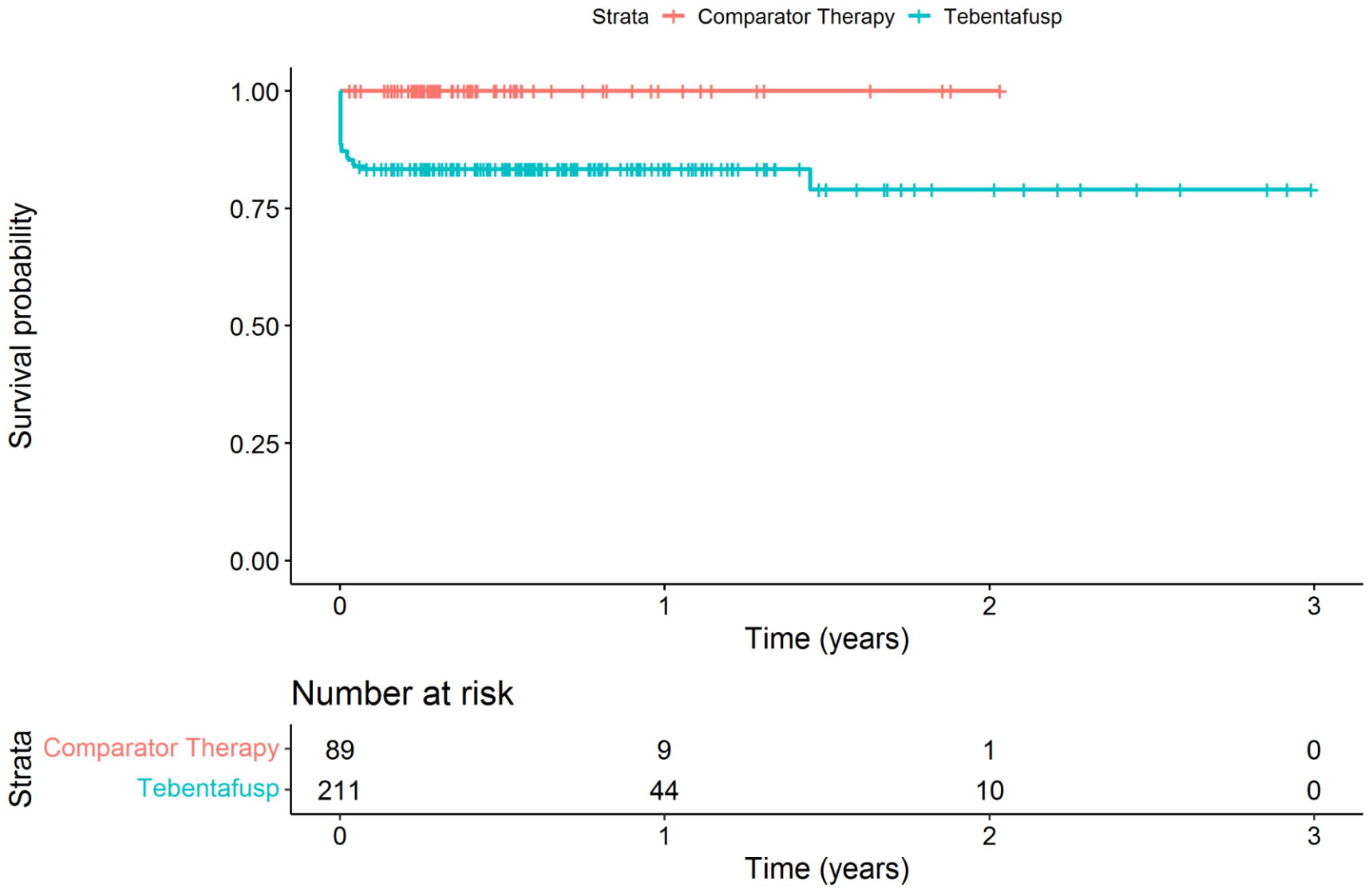
53.227 Zytokin-Freisetzungssyndrom- Gesamt



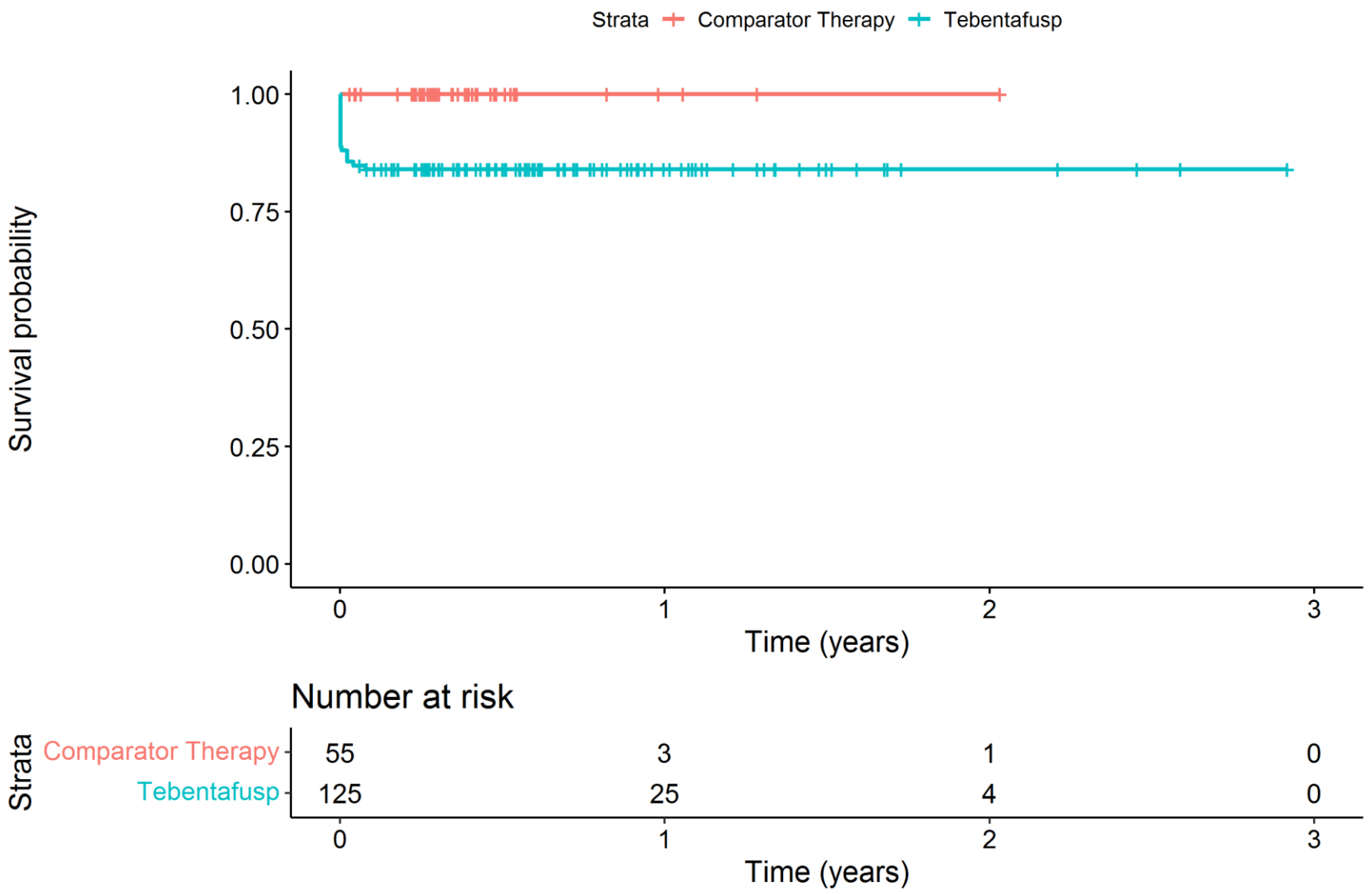
53.228 Zytokin-Freisetzungssyndrom- Hispanisch



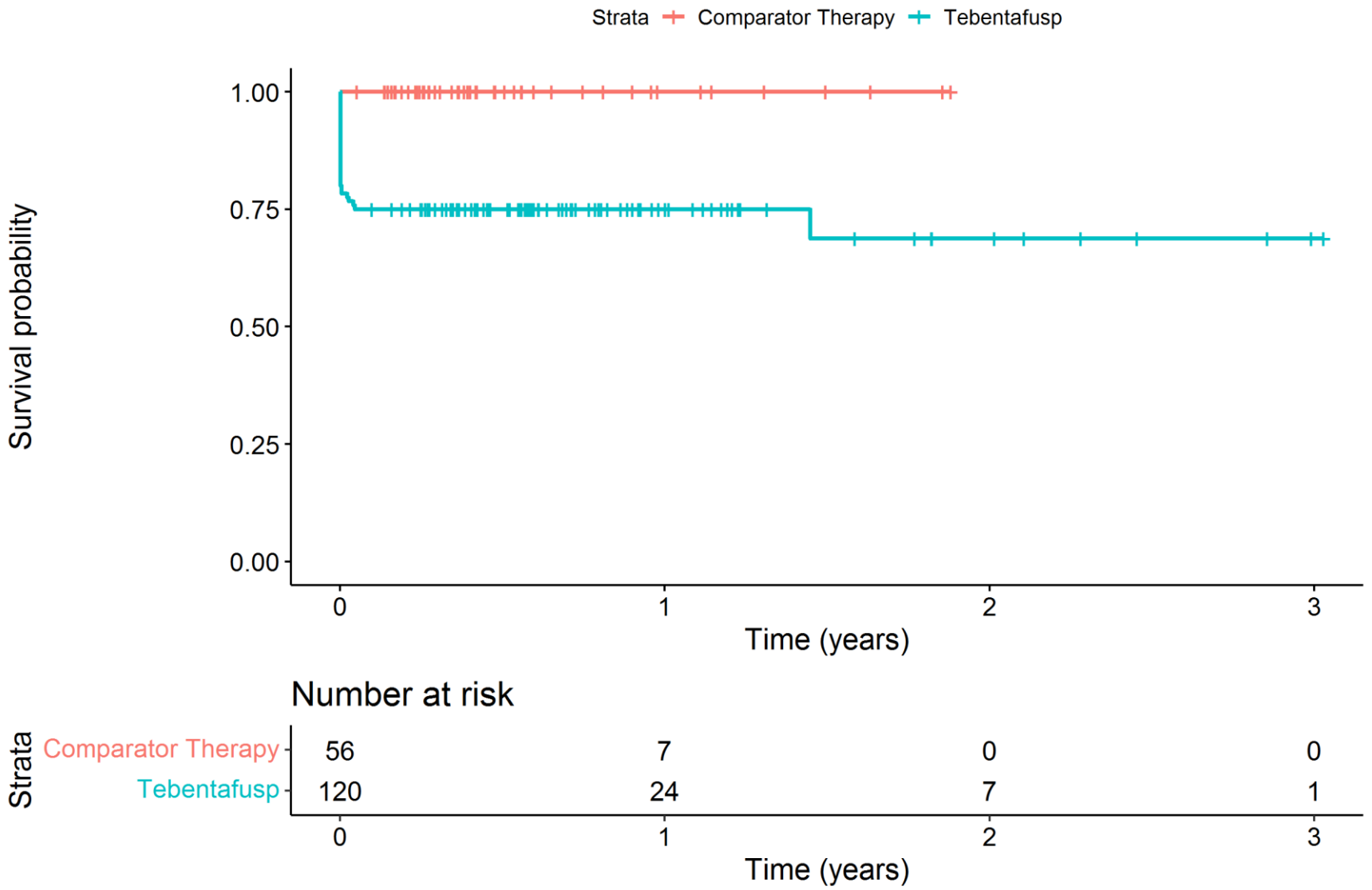
53.229 Zytokin-Freisetzungssyndrom- Nicht-hispanisch



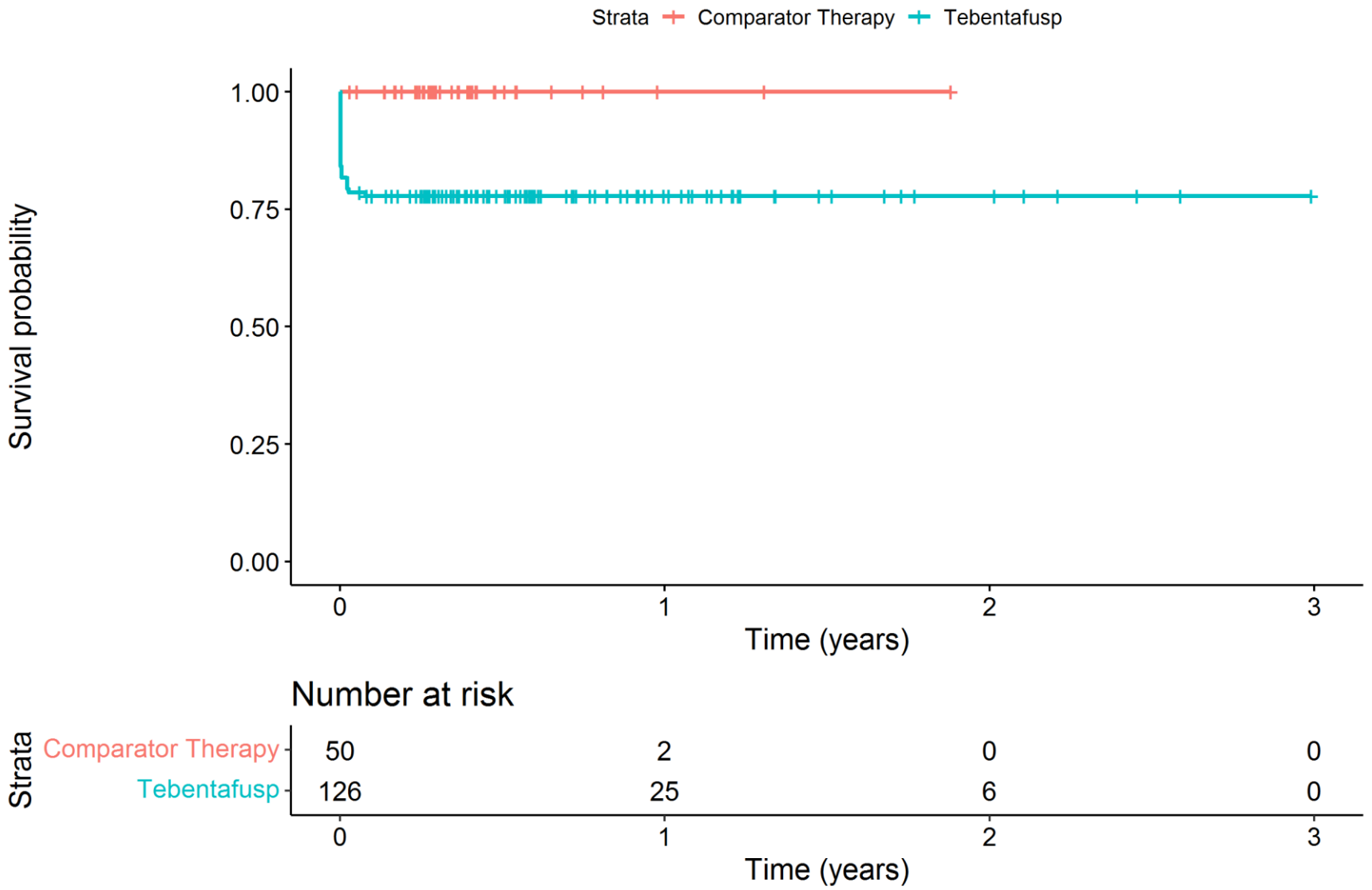
53.230 Zytokin-Freisetzungssyndrom- Männlich



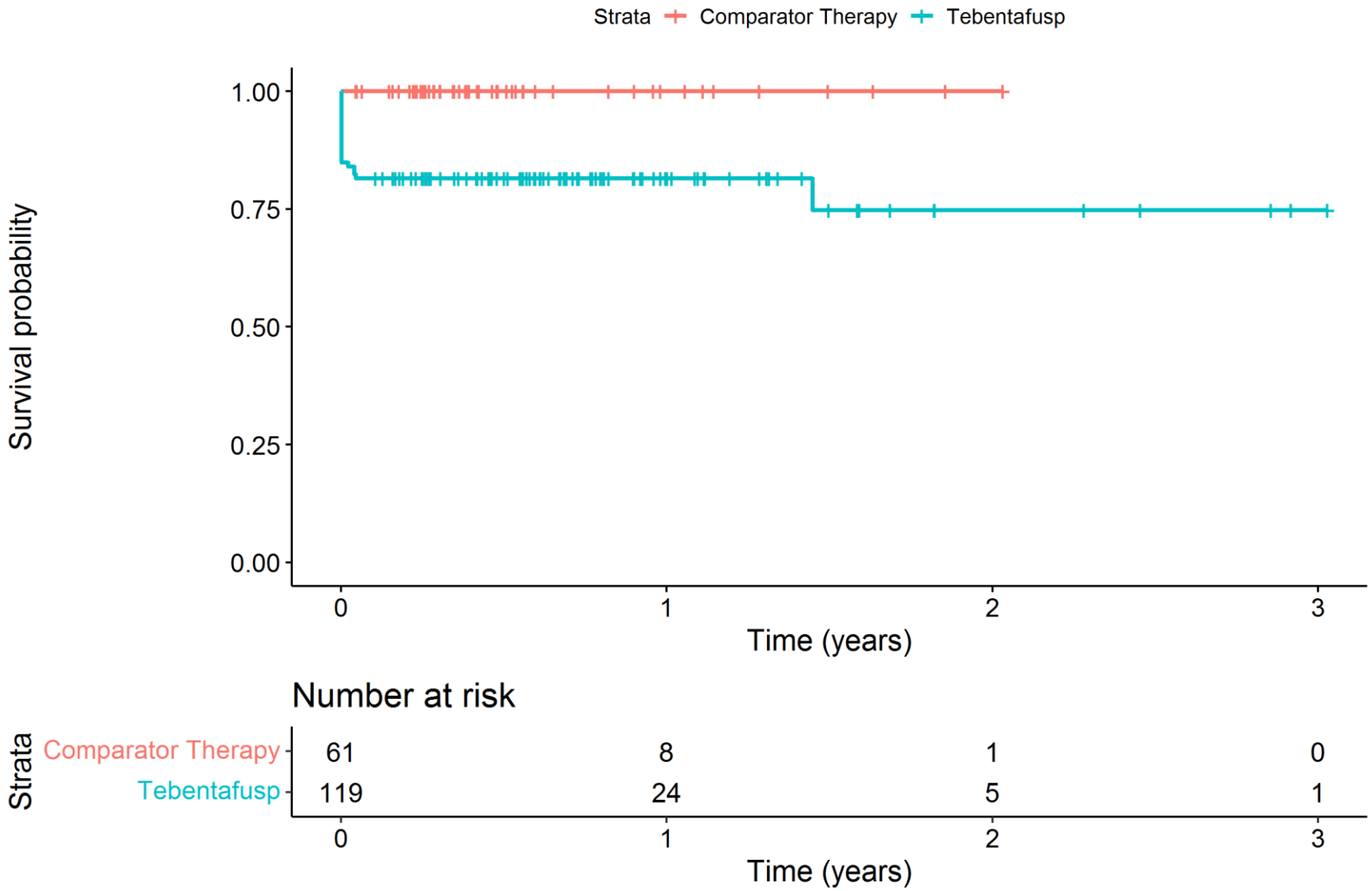
53.231 Zytokin-Freisetzungssyndrom- Weiblich



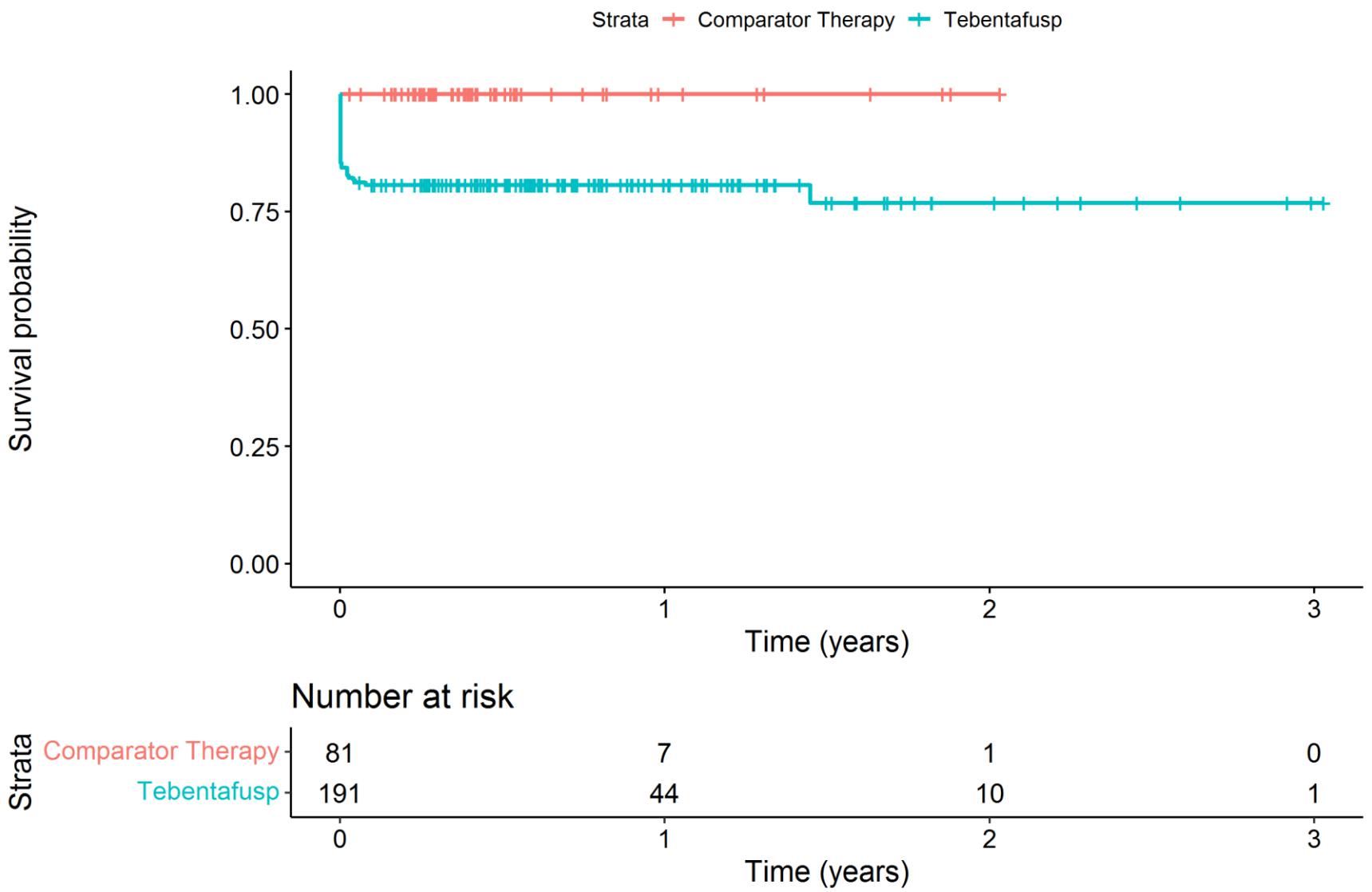
53.232 Zytokin-Freisetzungssyndrom- <65



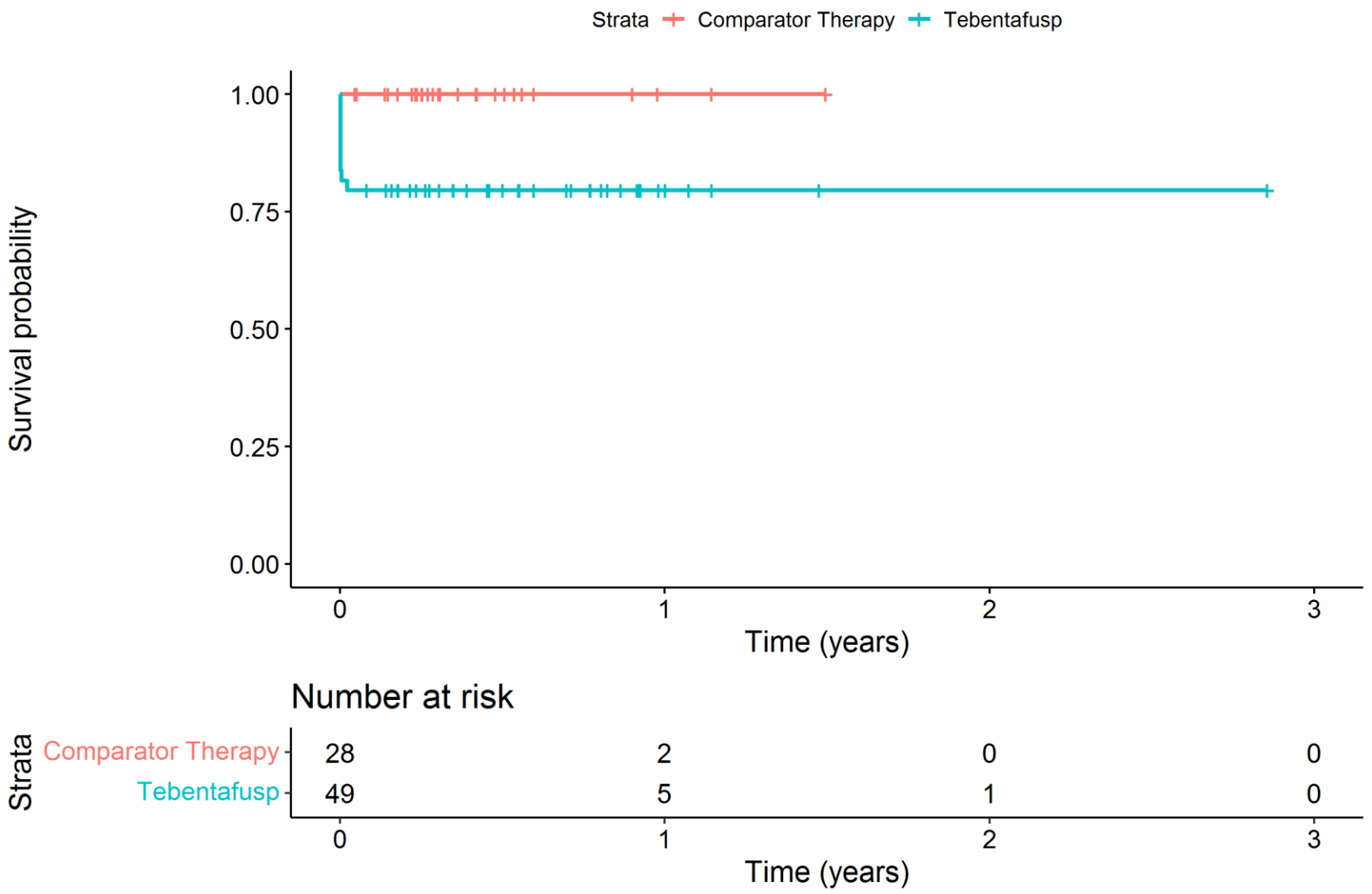
53.233 Zytokin-Freisetzungssyndrom- ≥65



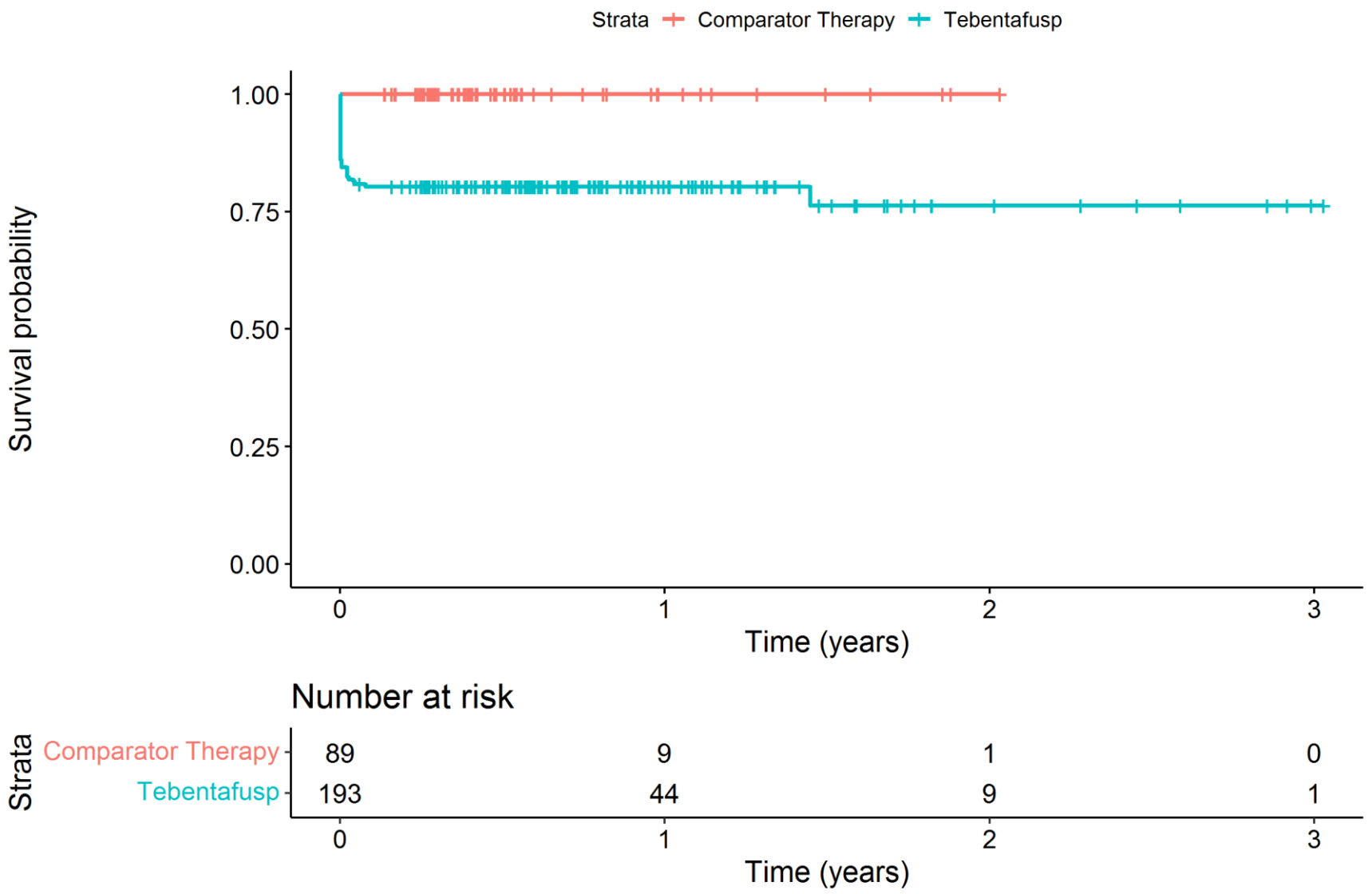
53.234 Zytokin-Freisetzungssyndrom- ECOG 0



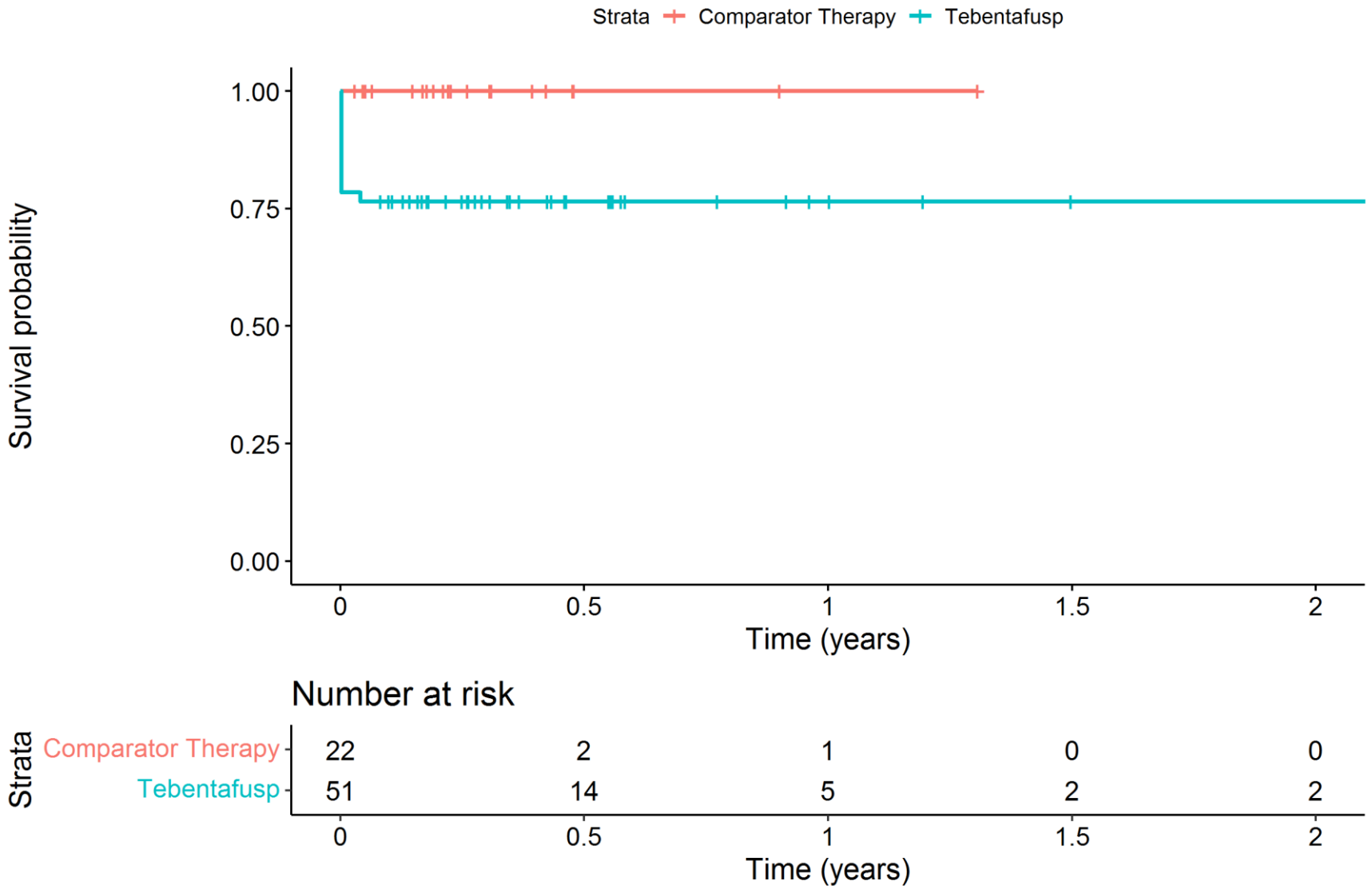
53.235 Zytokin-Freisetzungssyndrom- ECOG 1



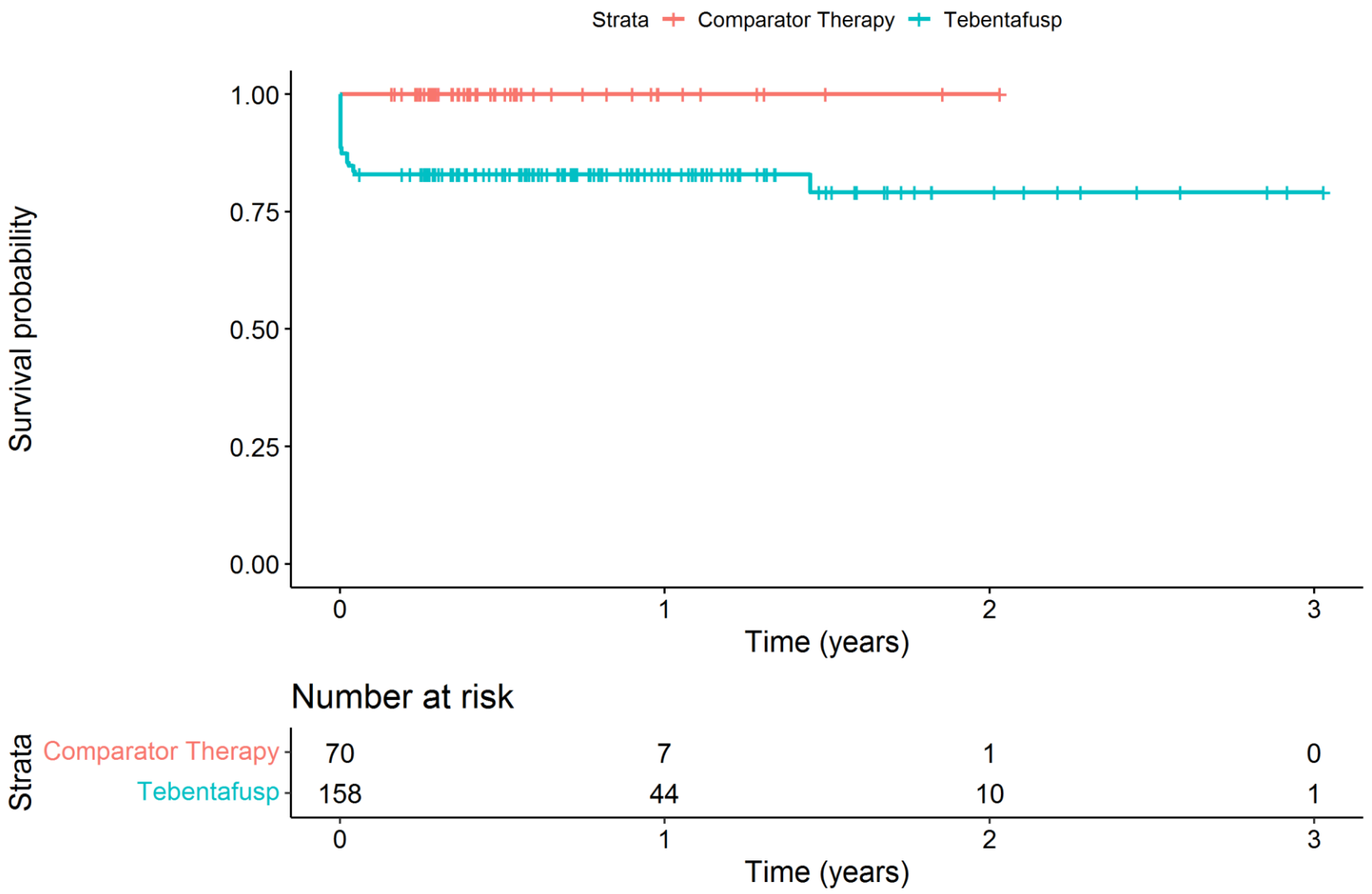
53.236 Zytokin-Freisetzungssyndrom- ALP ≤ ULN



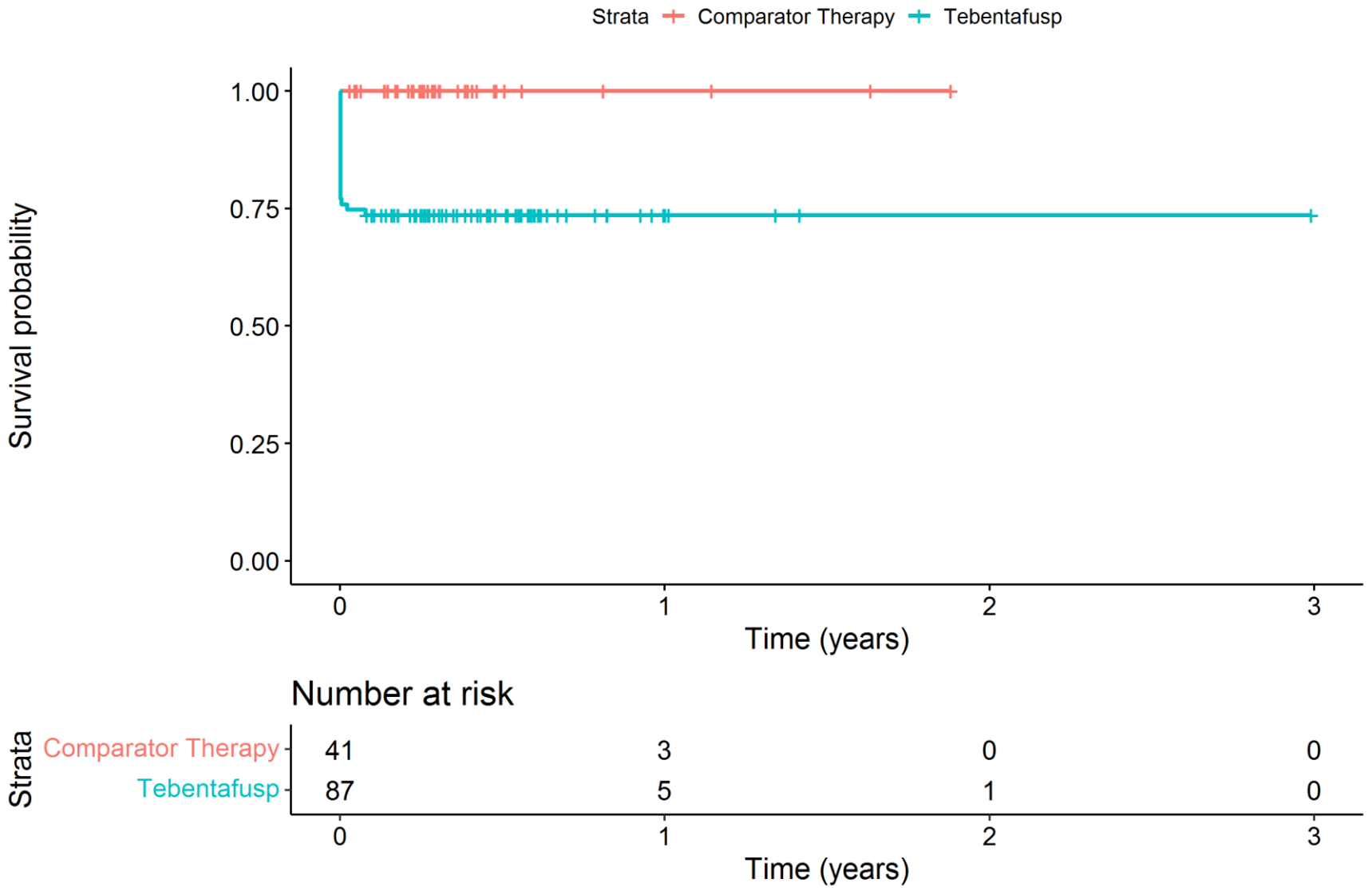
53.237 Zytokin-Freisetzungssyndrom- ALP > ULN



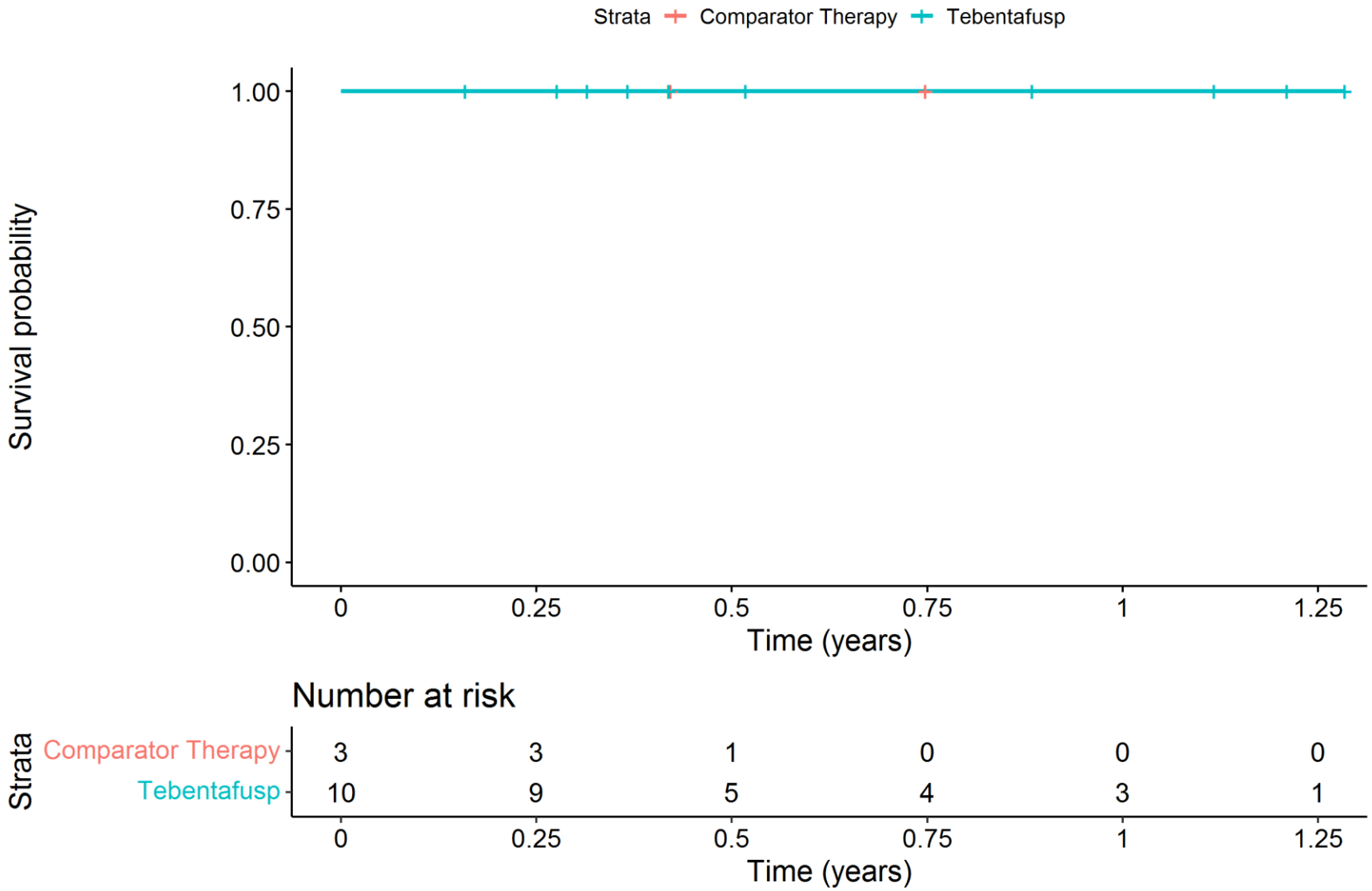
53.238 Zytokin-Freisetzungssyndrom- LDH =< ULN



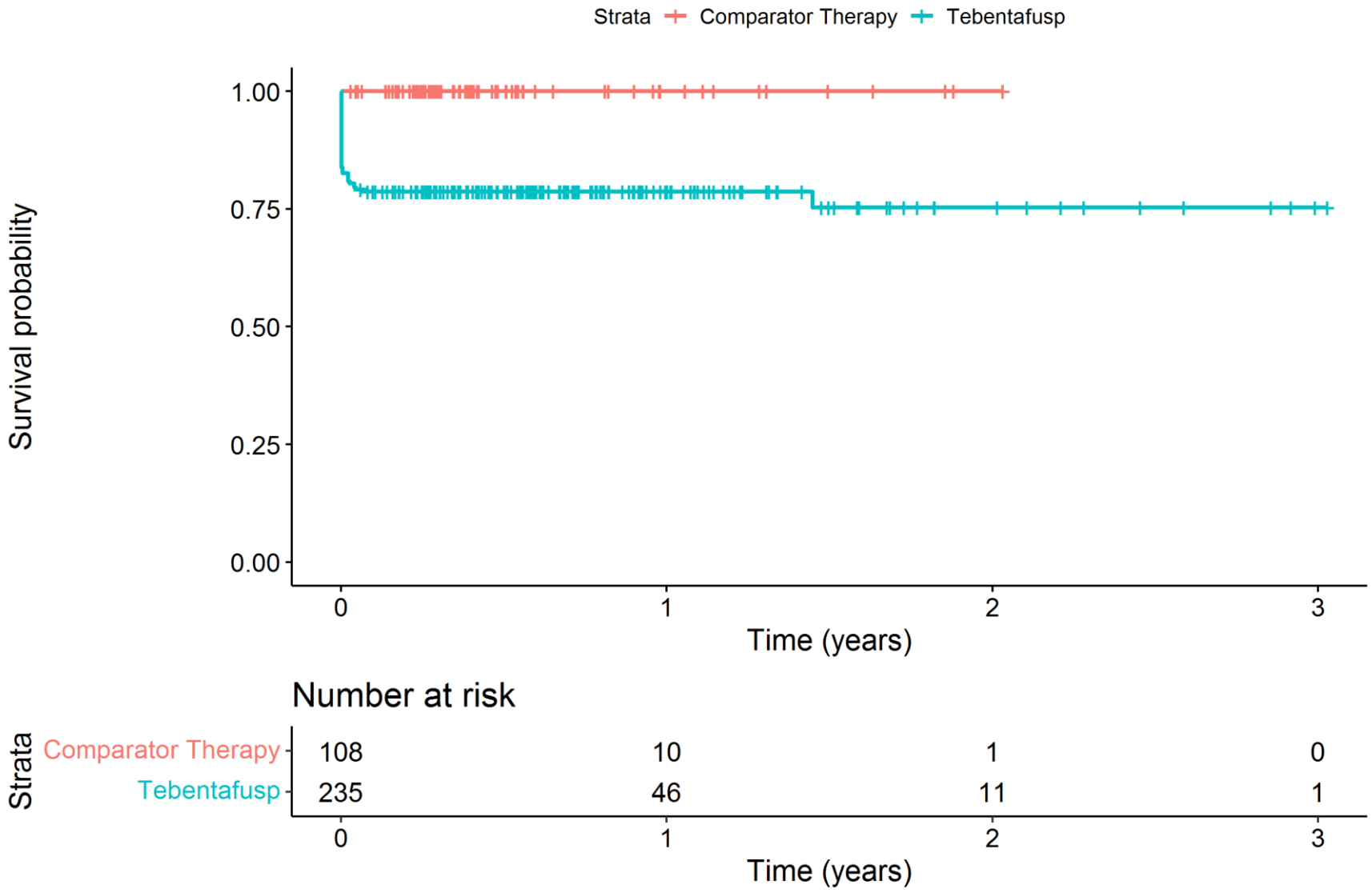
53.239 Zytokin-Freisetzungssyndrom- LDH > ULN



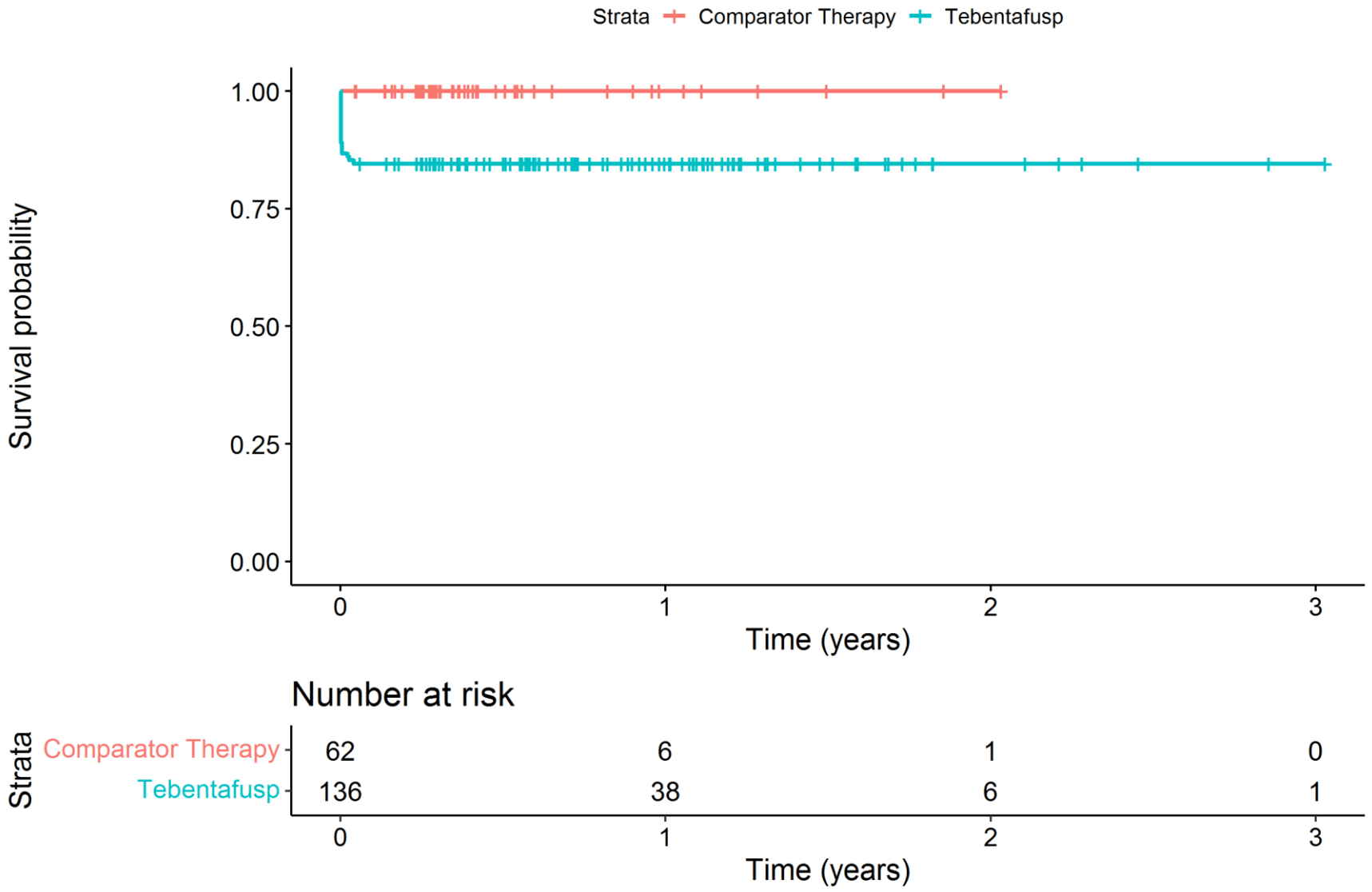
53.240 Zytokin-Freisetzungssyndrom- Vorherige Therapie adjuvant/neoadjuvant



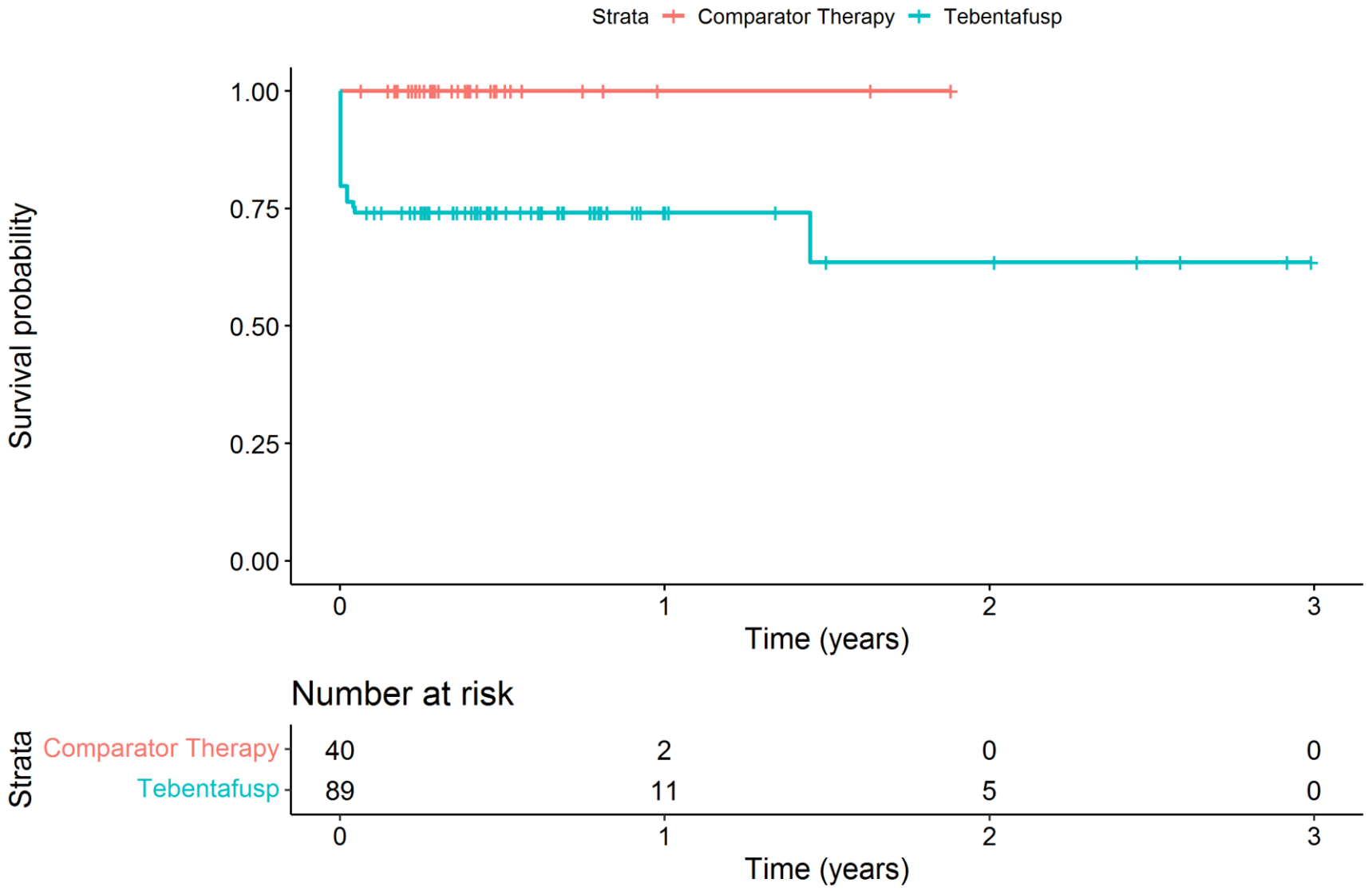
53.241 Zytokin-Freisetzungssyndrom- Keine vorherige Therapie adjuvant/neoadjuvant



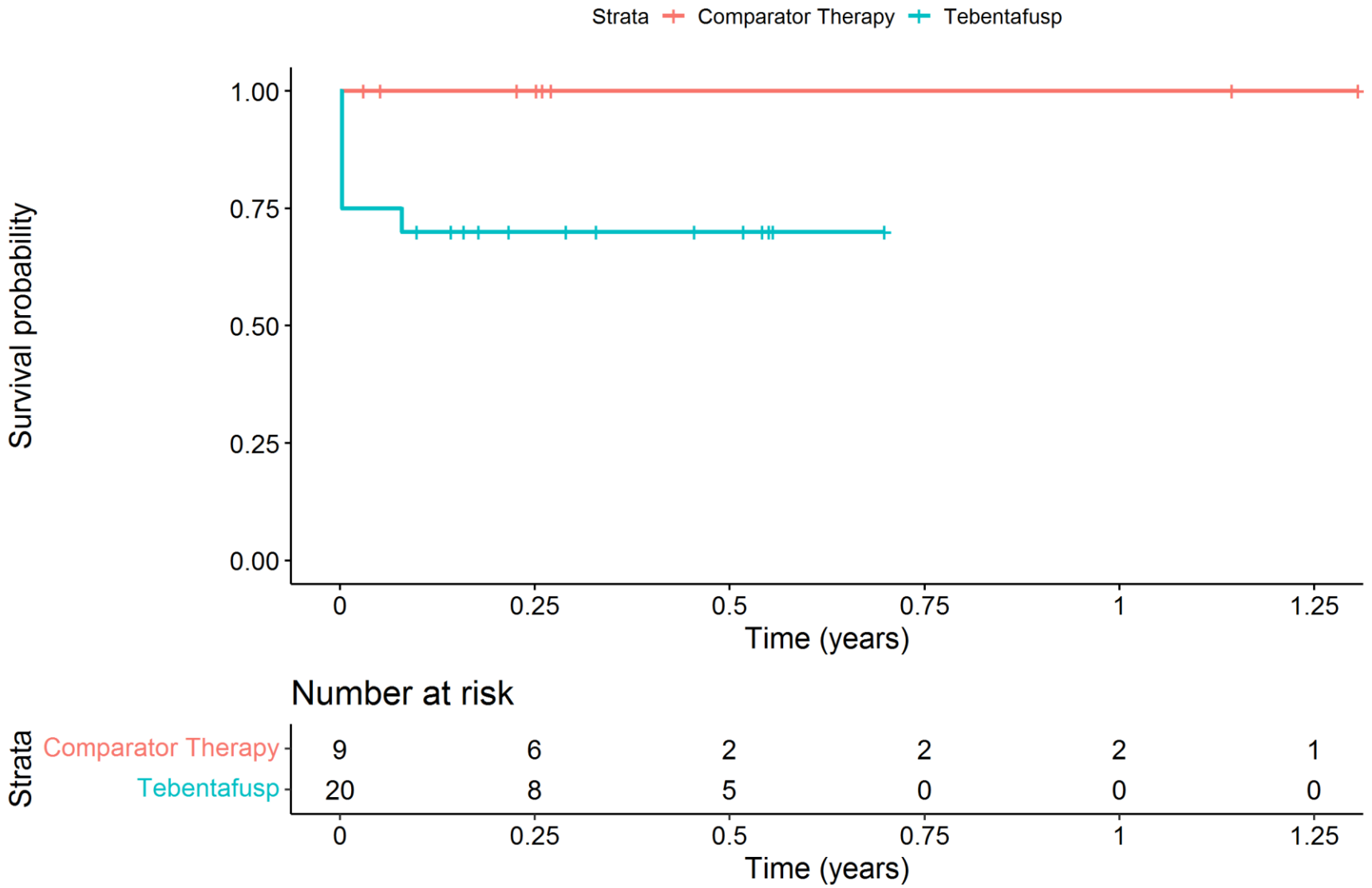
53.242 Zytokin-Freisetzungssyndrom- Läsion ≤ 3cm



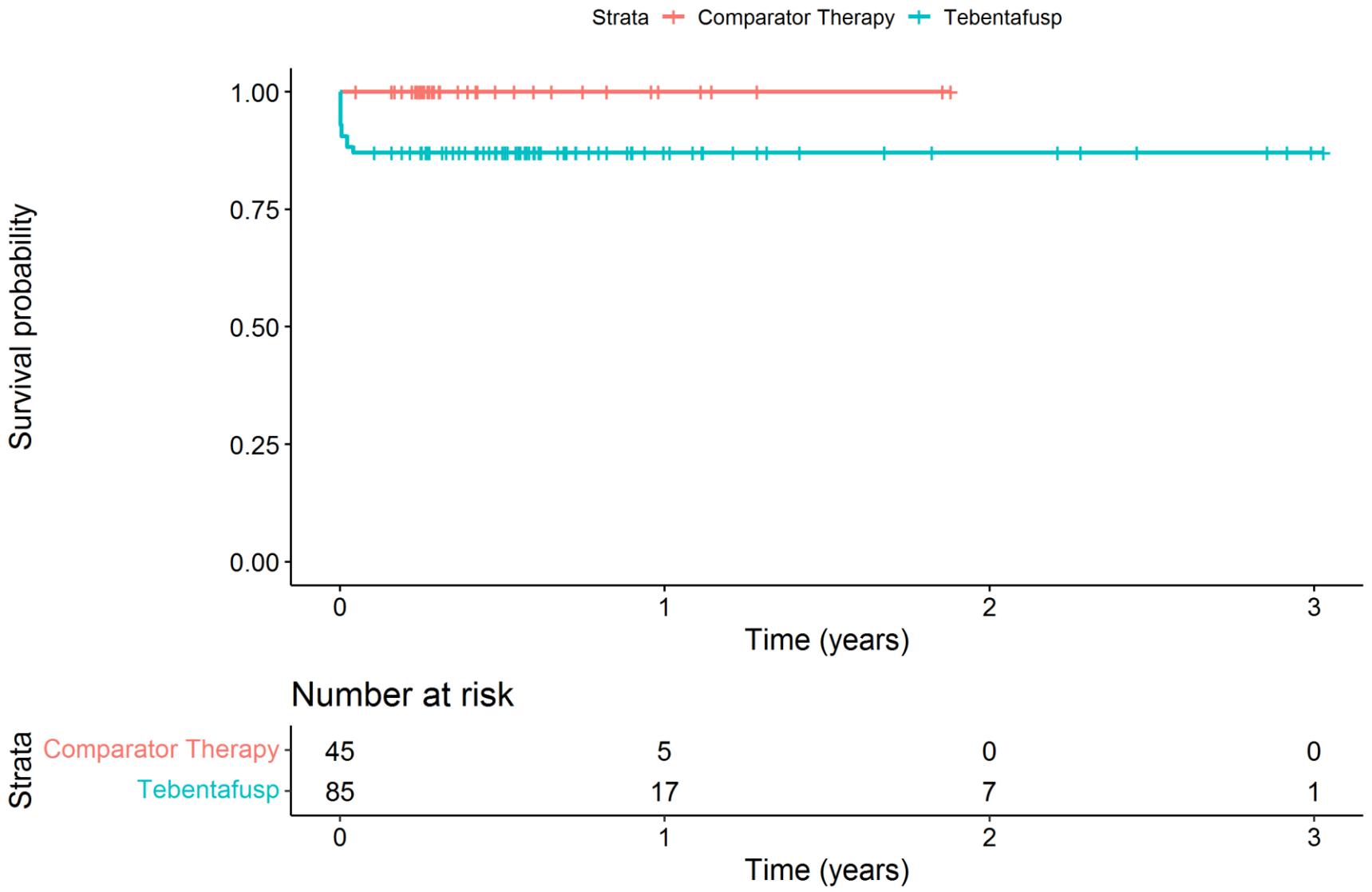
53.243 Zytokin-Freisetzungssyndrom- Läsion 3,1-8,0 cm



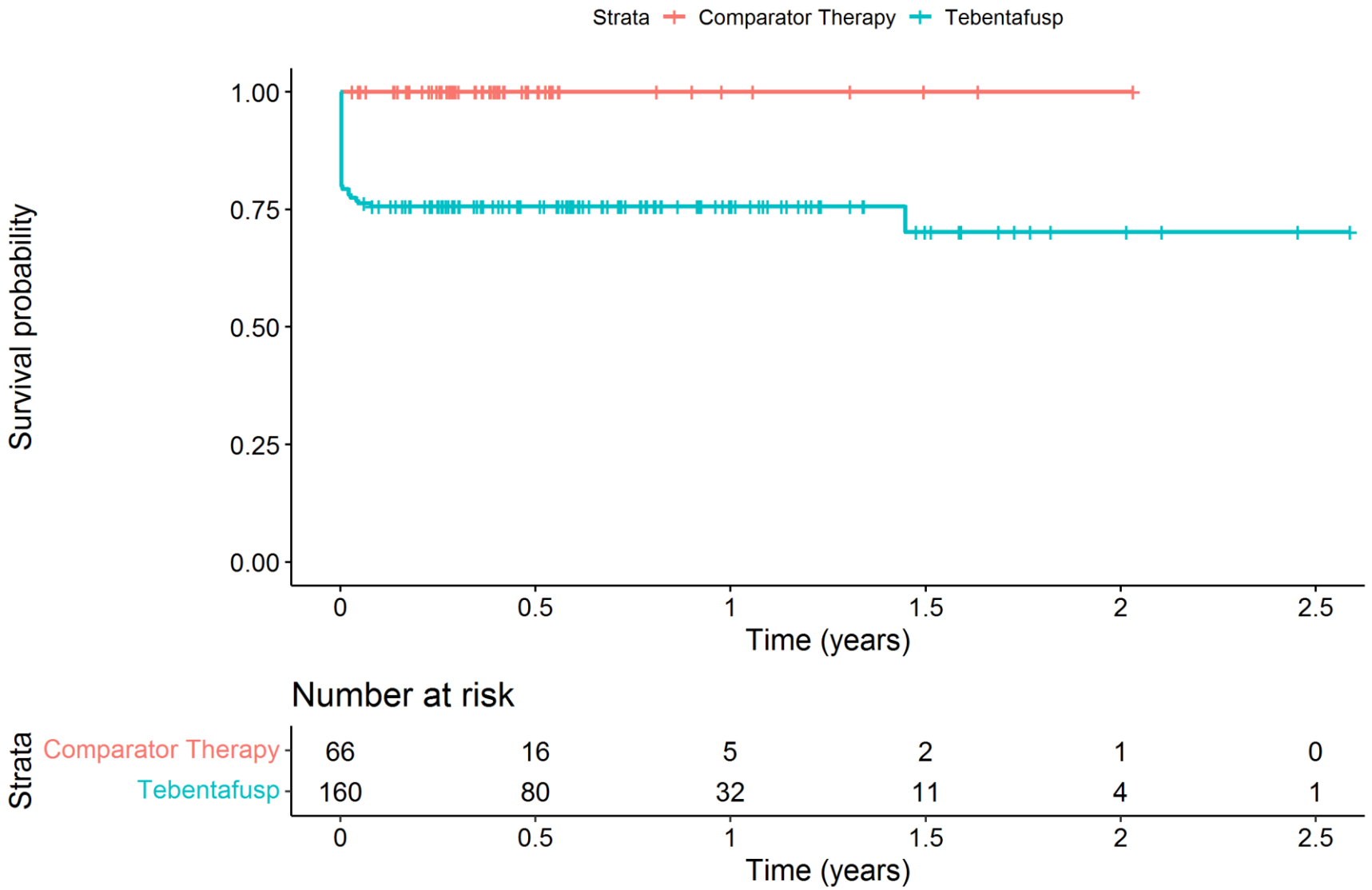
53.244 Zytokin-Freisetzungssyndrom- Läsion ≥8,1 cm



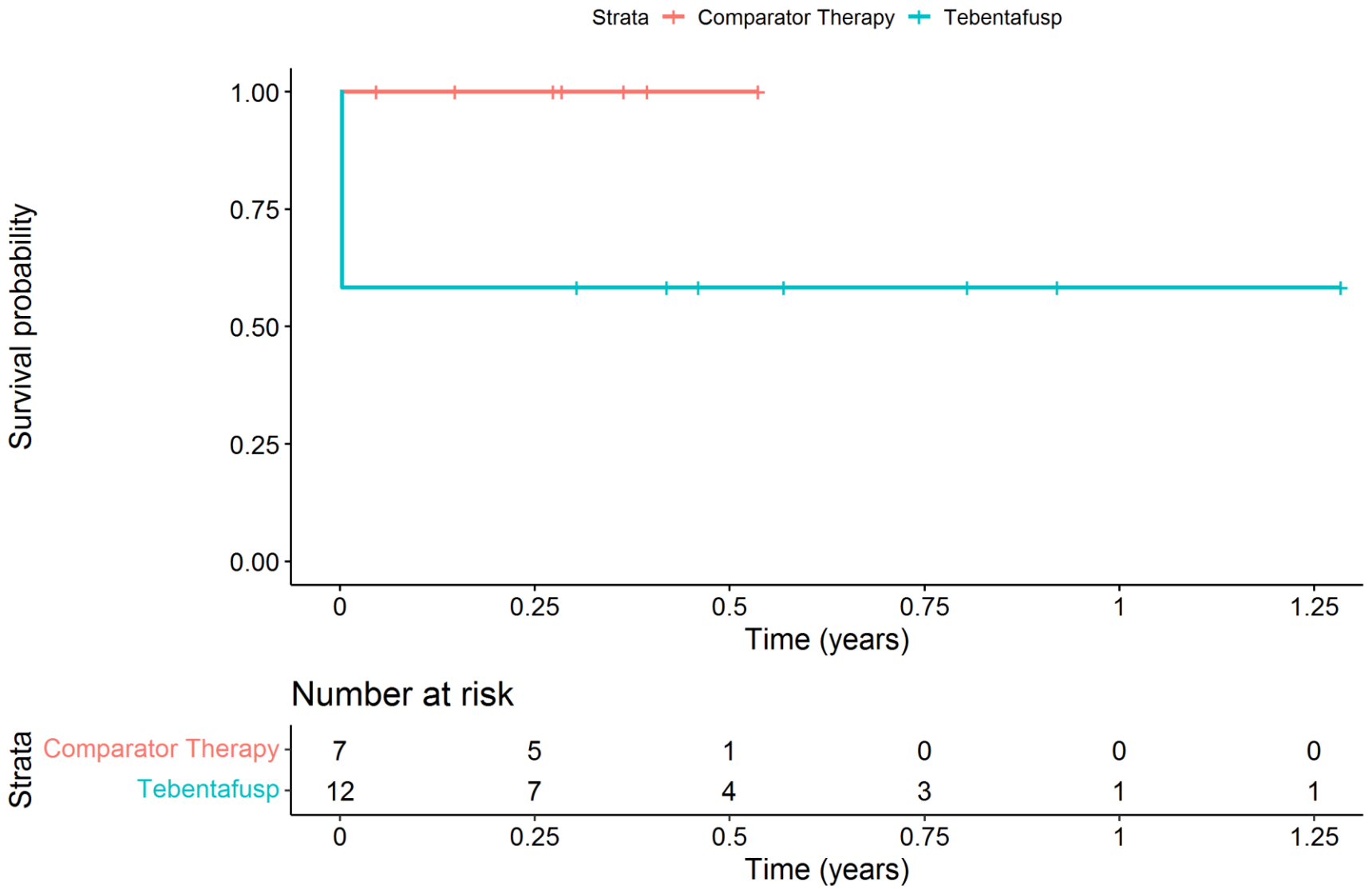
53.245 Zytokin-Freisetzungssyndrom- Nordamerika



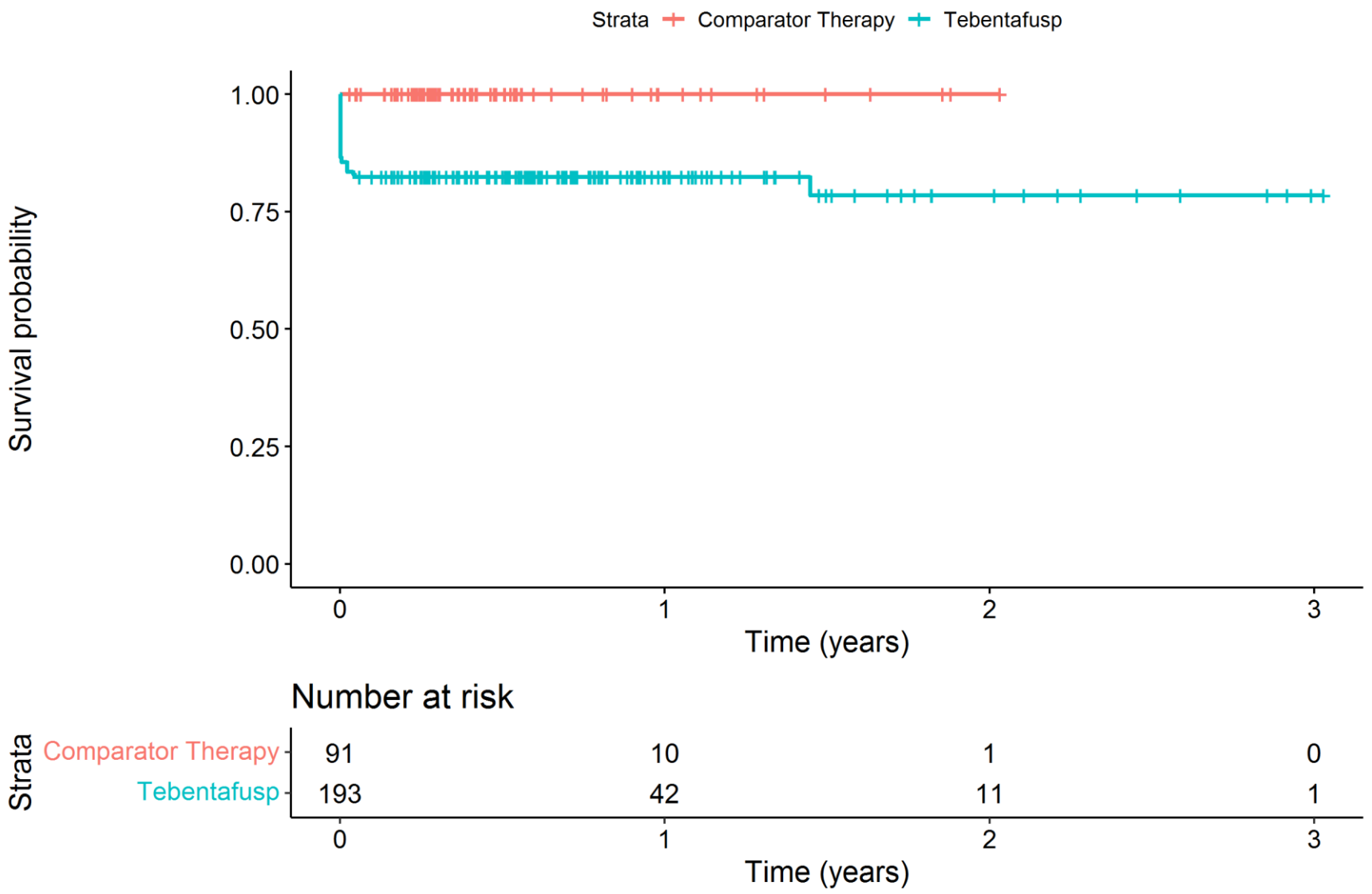
53.246 Zytokin-Freisetzungssyndrom- Nicht-Nordamerika



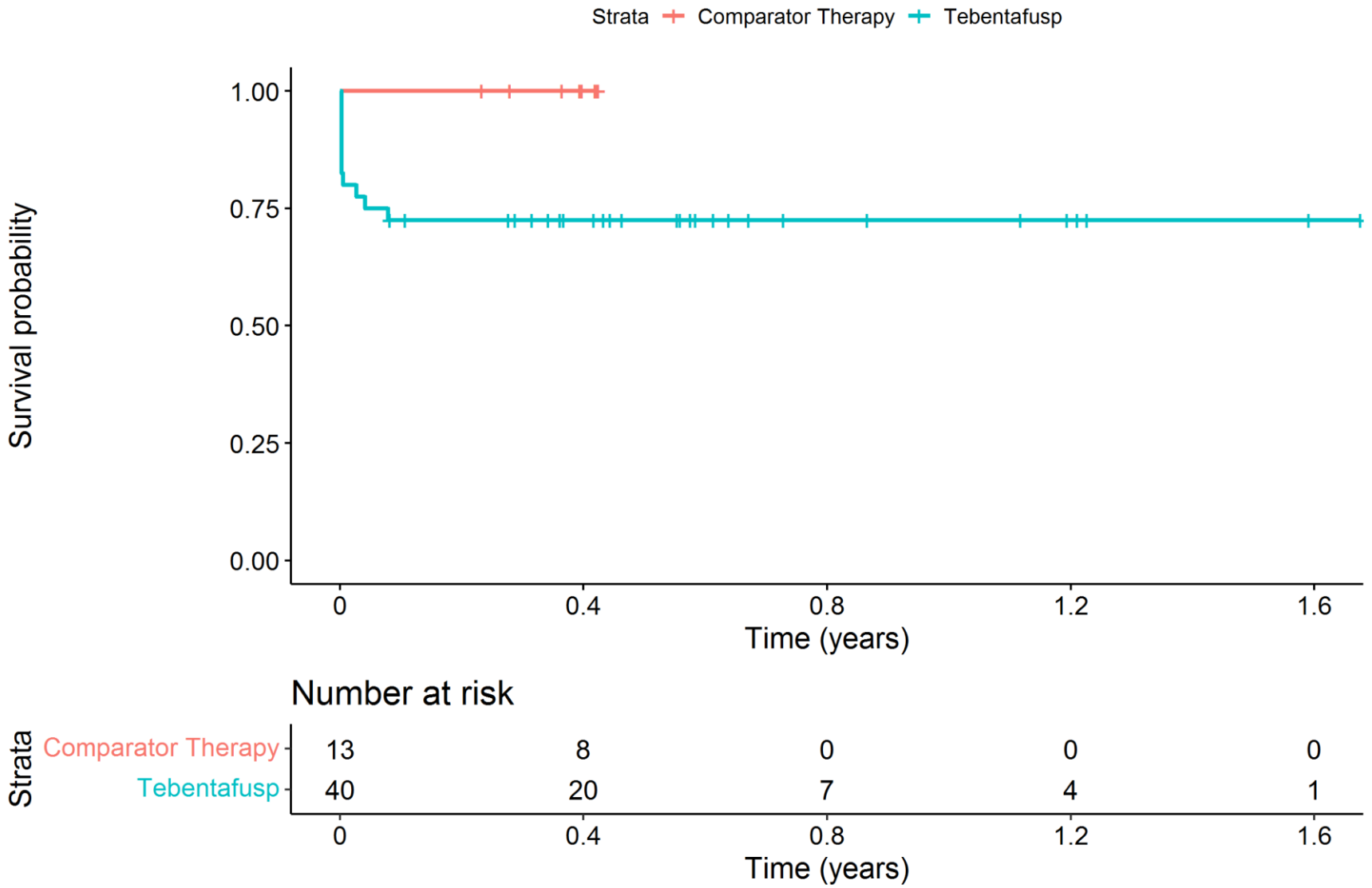
53.247 Zytokin-Freisetzungssyndrom- Dacarbazin



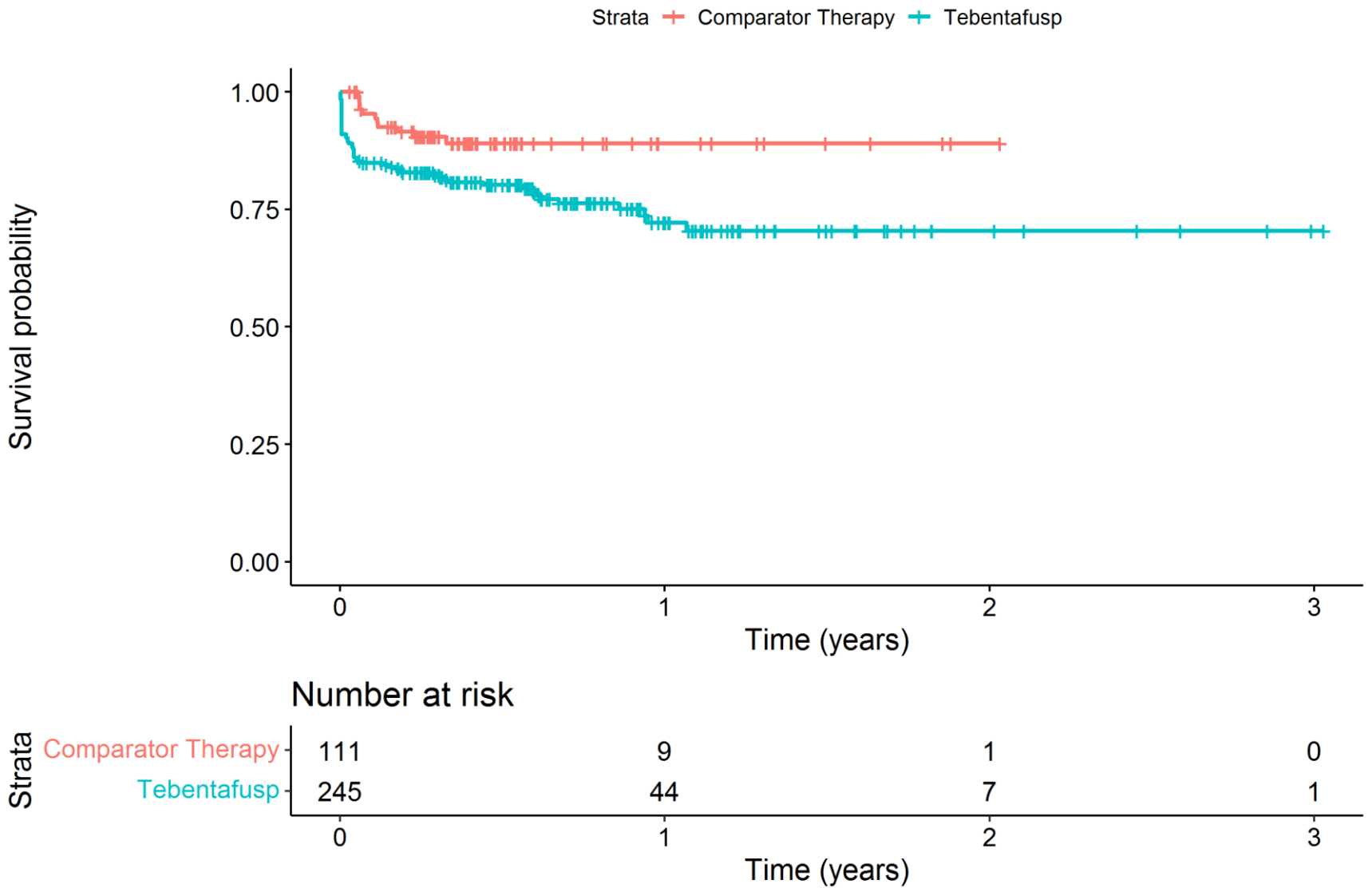
53.248 Zytokin-Freisetzungssyndrom- Pembrolizumab



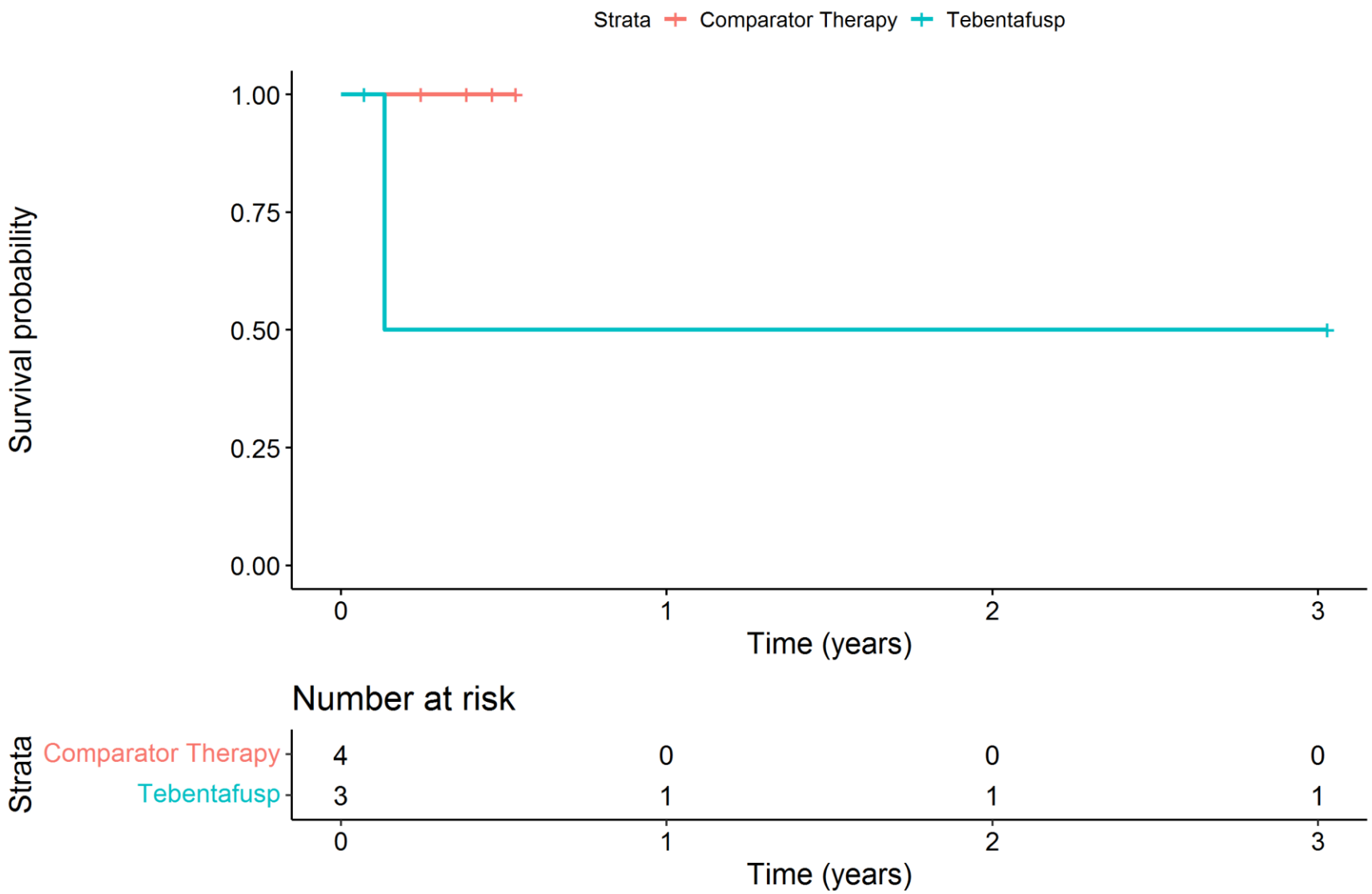
53.249 Zytokin-Freisetzungssyndrom- Ipilimumab



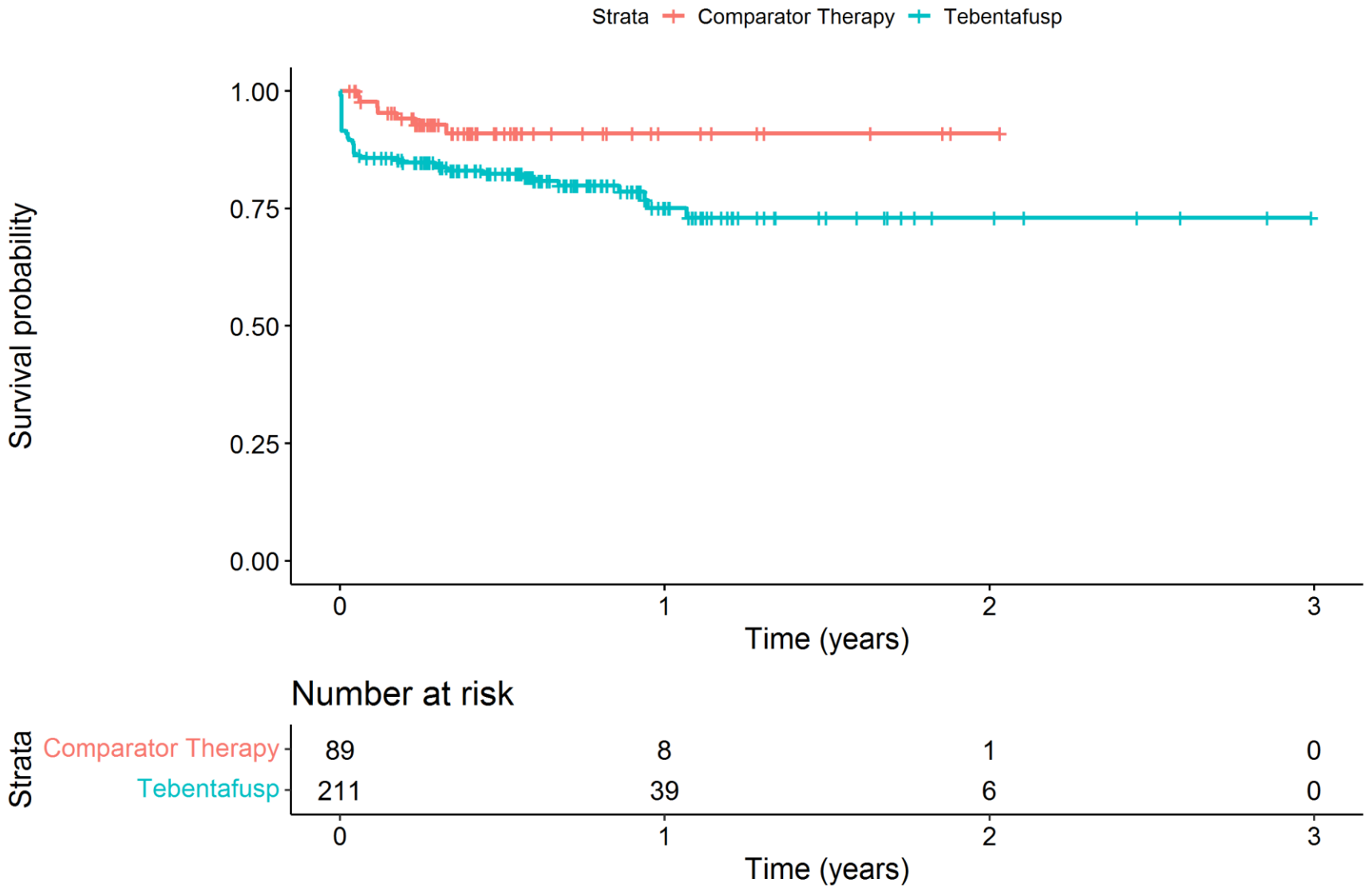
53.250 Erhöhte Aspartat-Aminotransferase - Gesamt



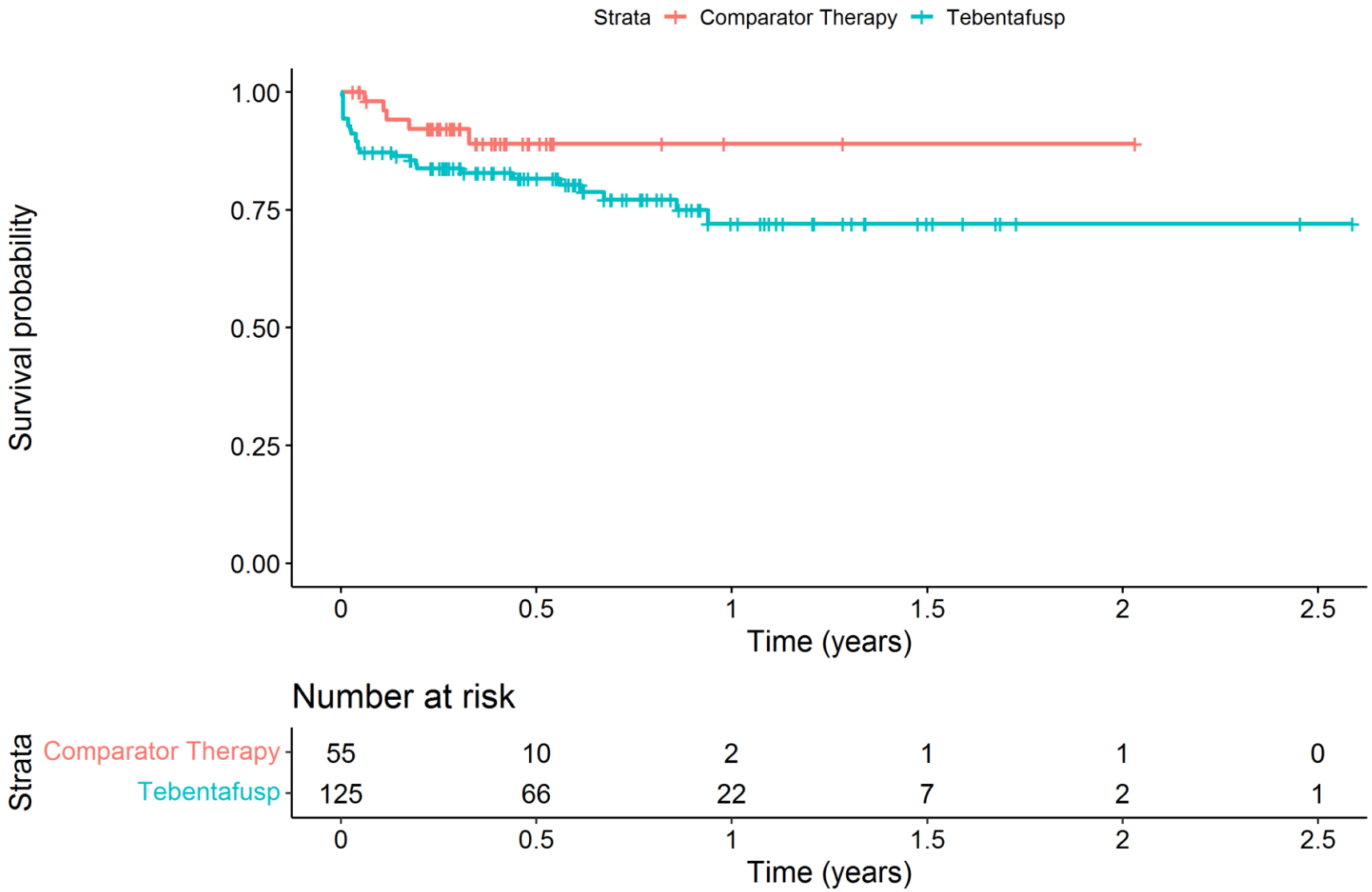
53.251 Erhöhte Aspartat-Aminotransferase - Hispanisch



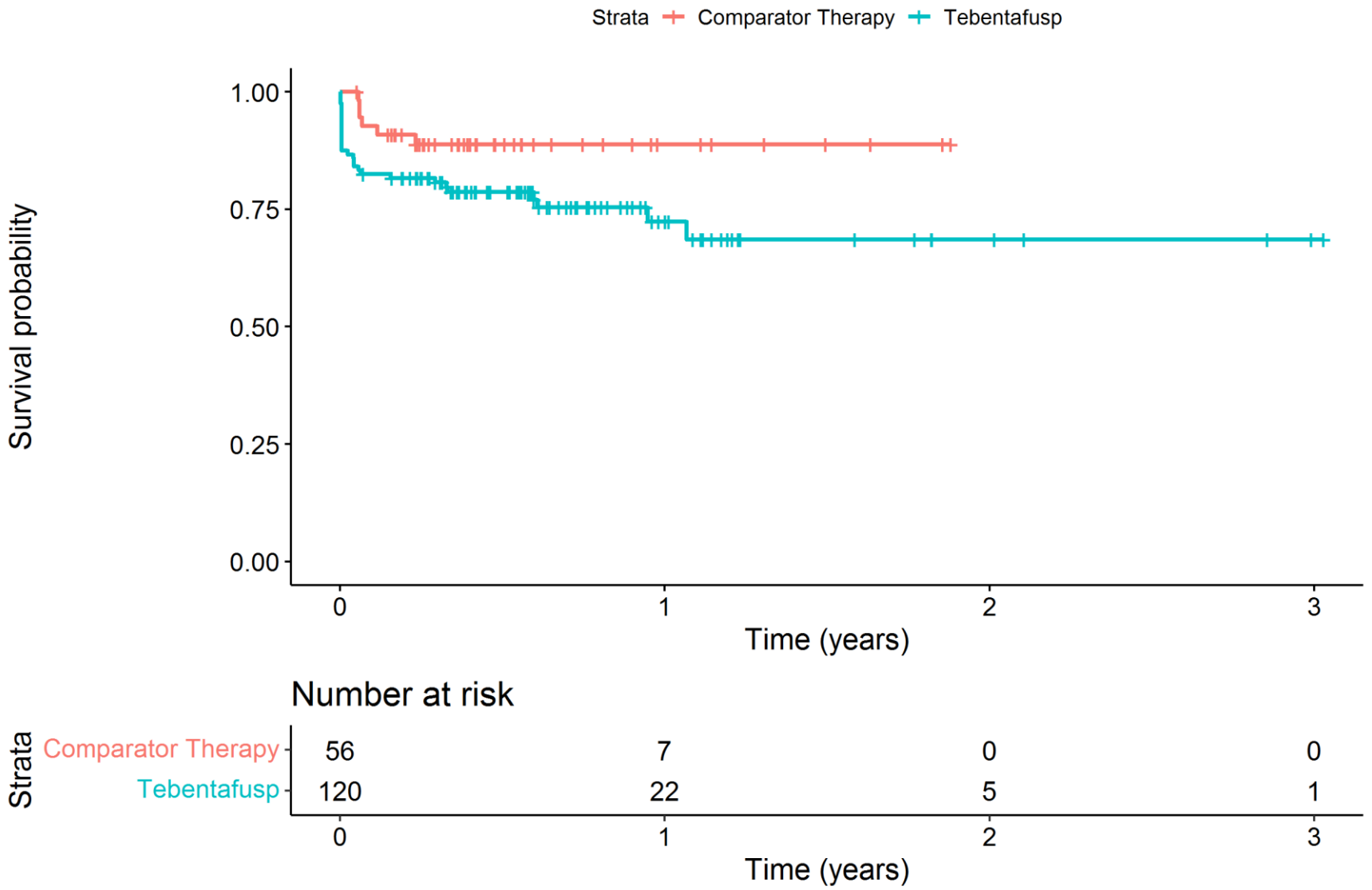
53.252 Erhöhte Aspartat-Aminotransferase - Nicht-hispanisch



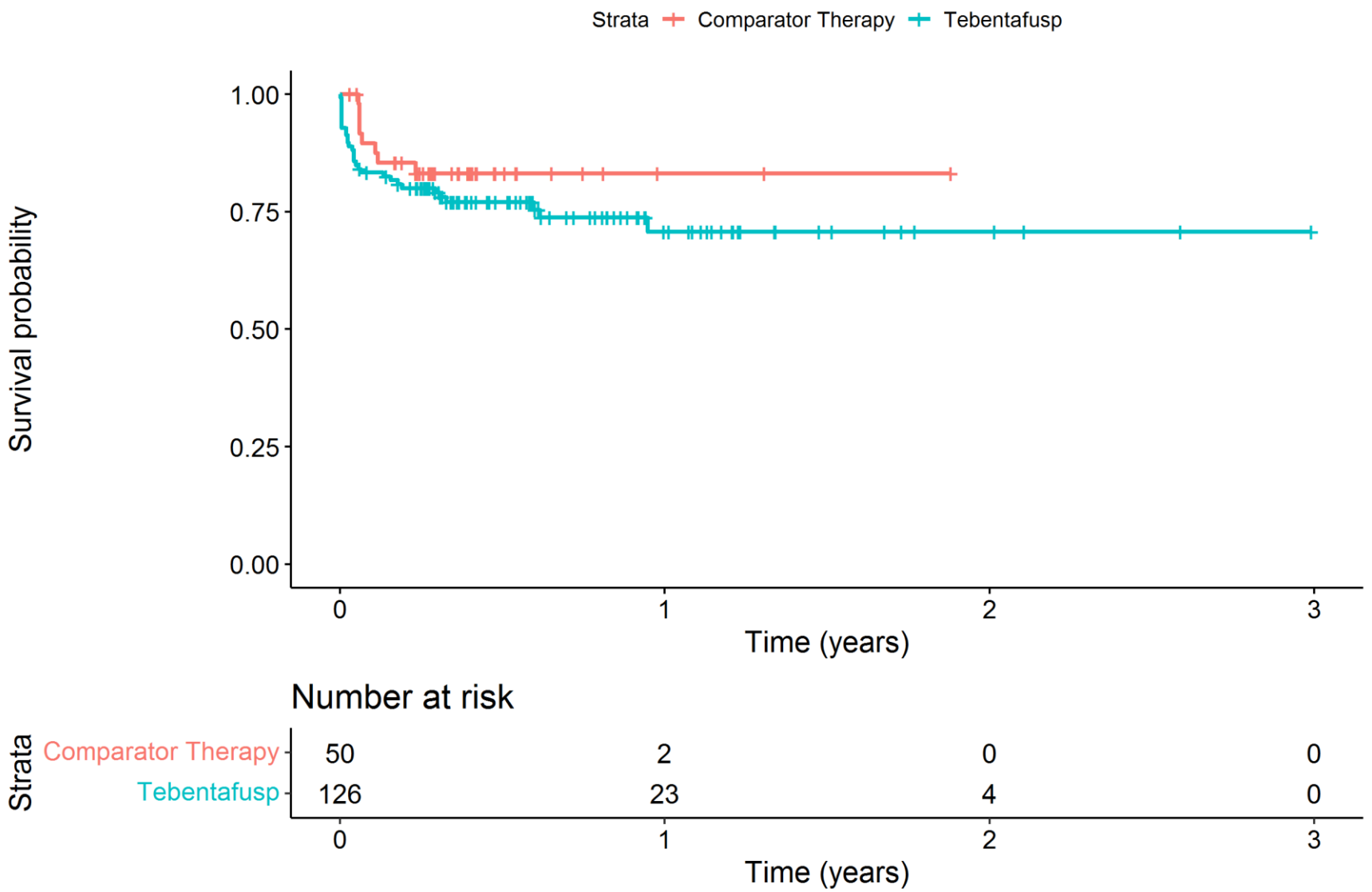
53.253 Erhöhte Aspartat-Aminotransferase - Männlich



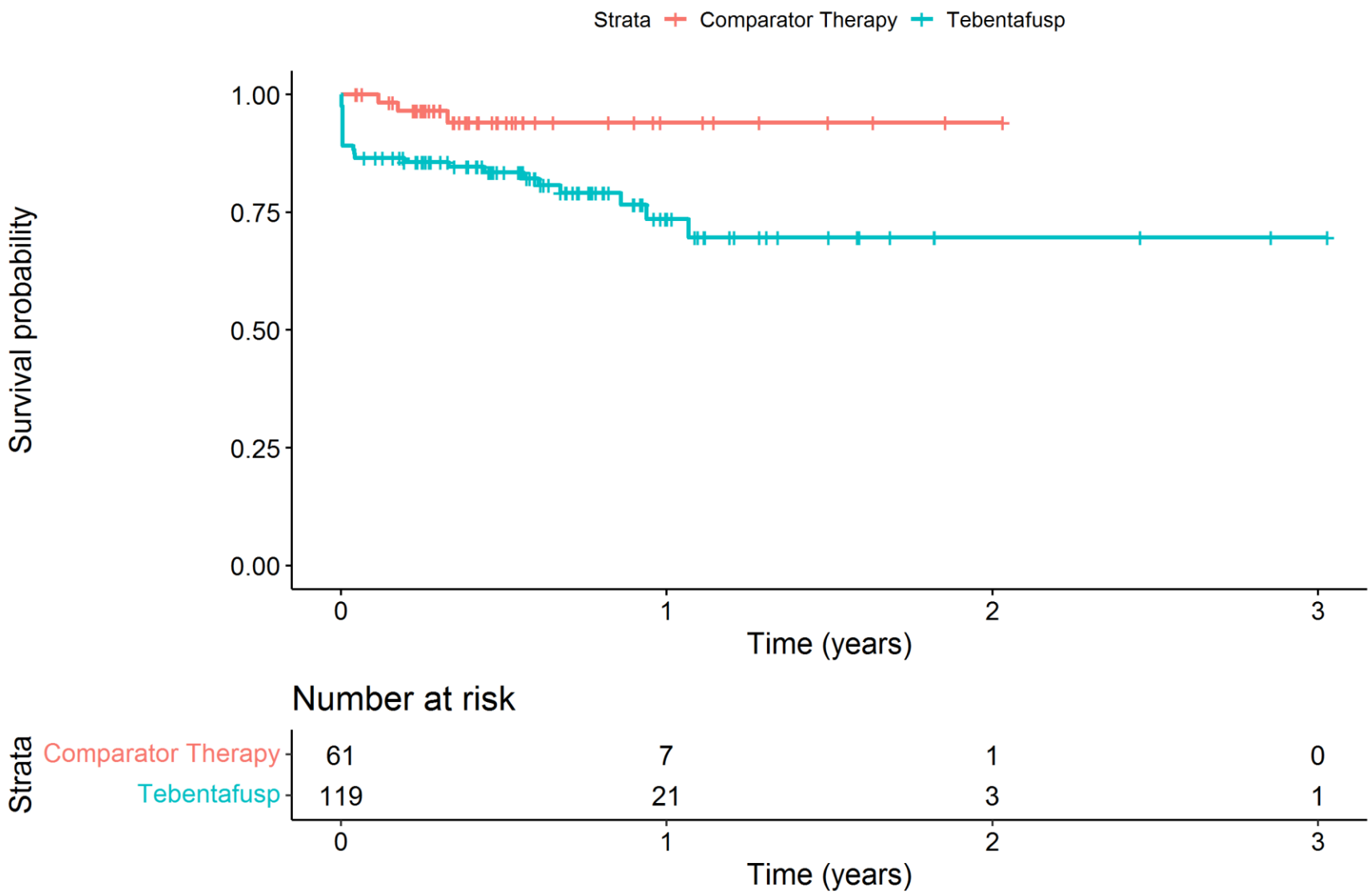
53.254 Erhöhte Aspartat-Aminotransferase - Weiblich



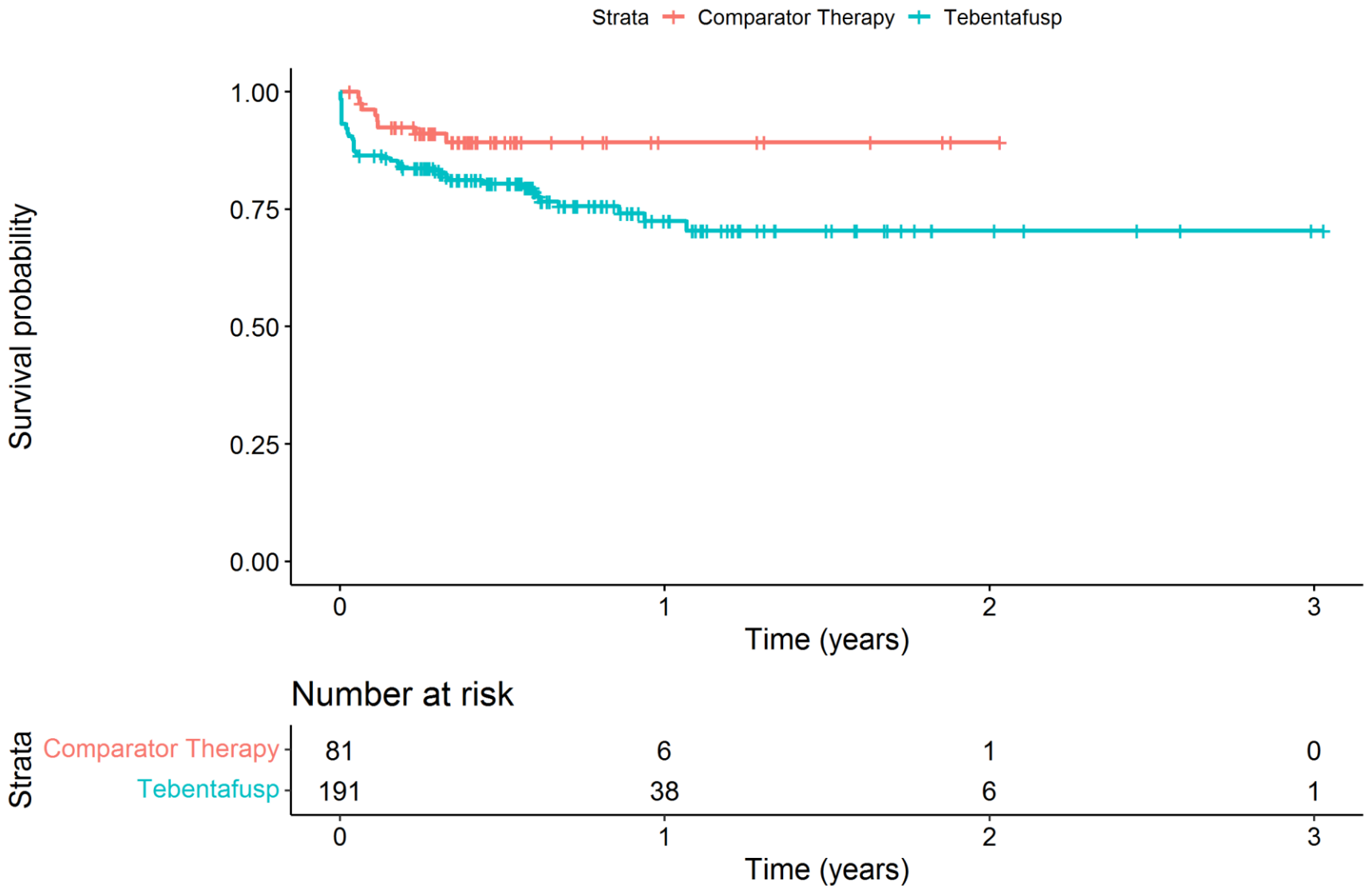
53.255 Erhöhte Aspartat-Aminotransferase - <65



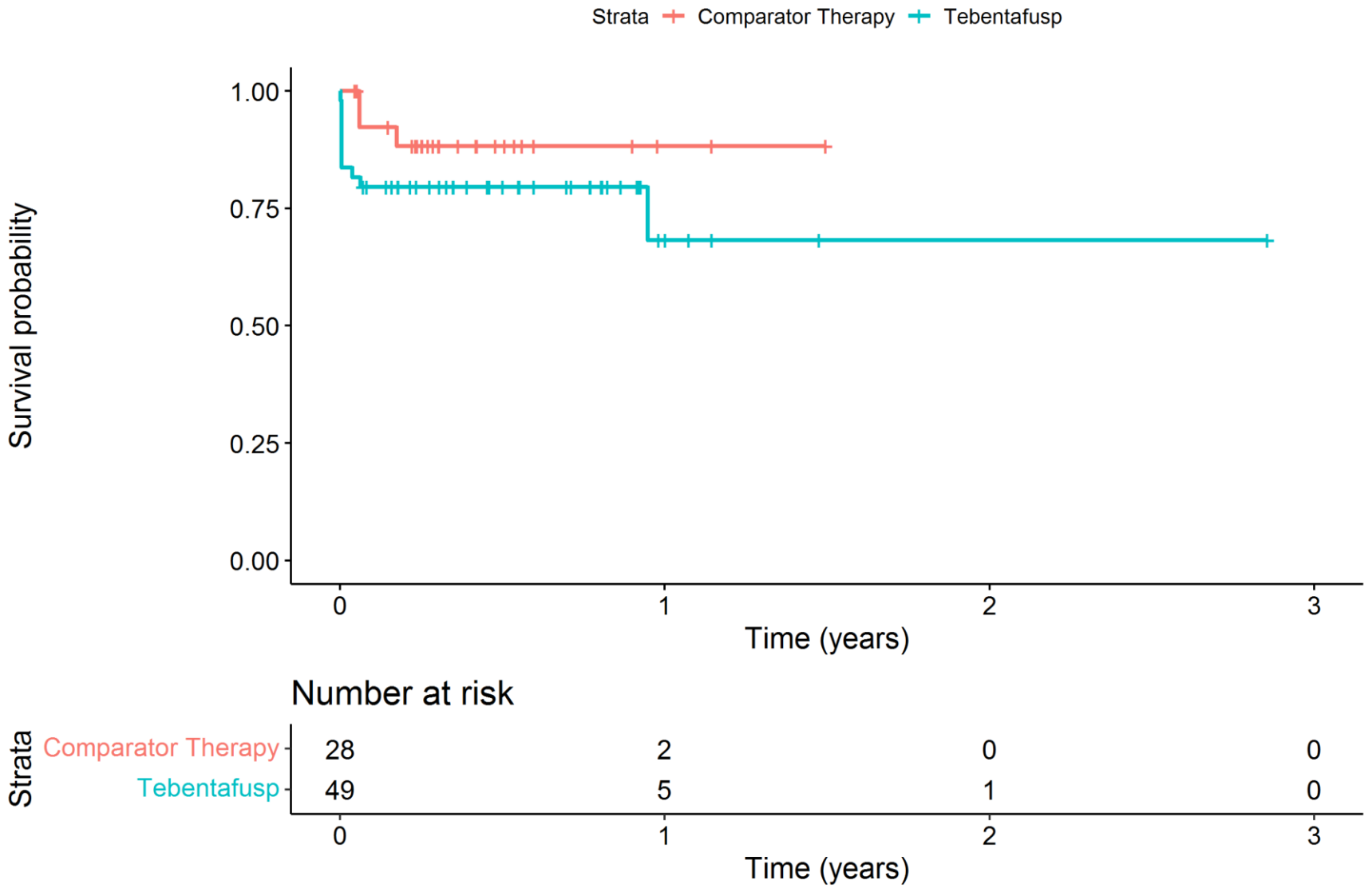
53.256 Erhöhte Aspartat-Aminotransferase - ≥65



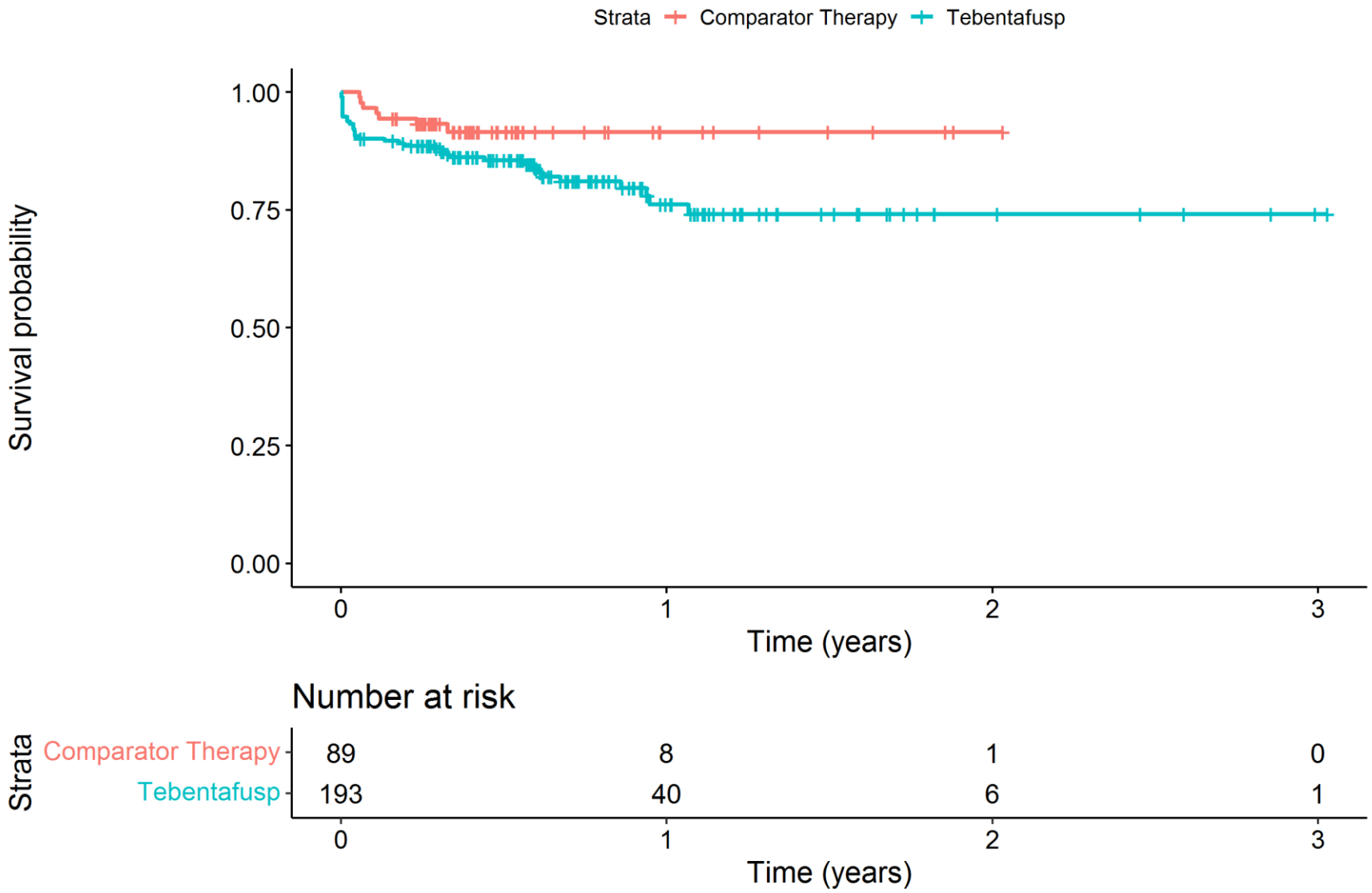
Erhöhte Aspartat-Aminotransferase - ECOG 0



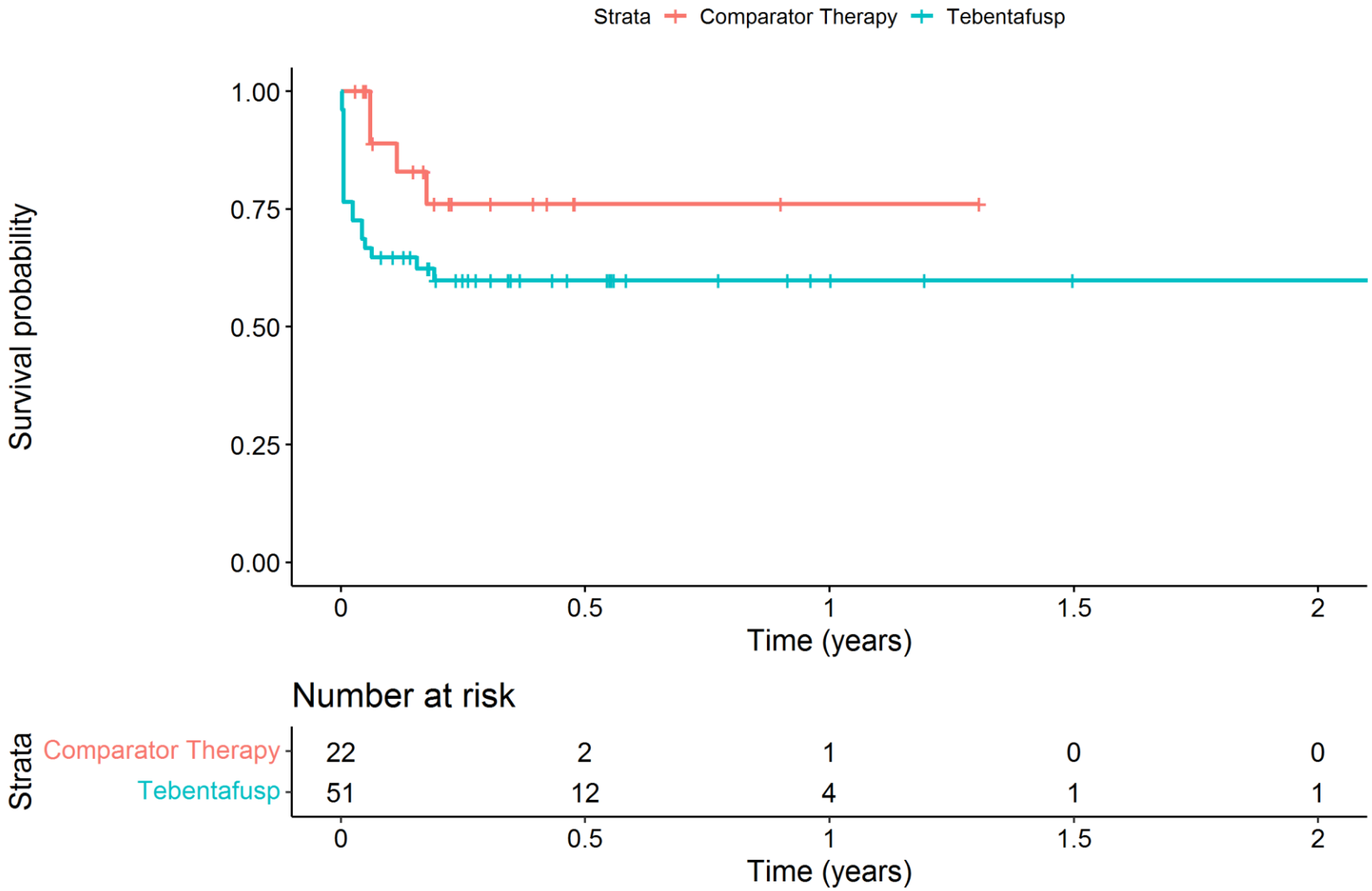
53.257 Erhöhte Aspartat-Aminotransferase - ECOG 1



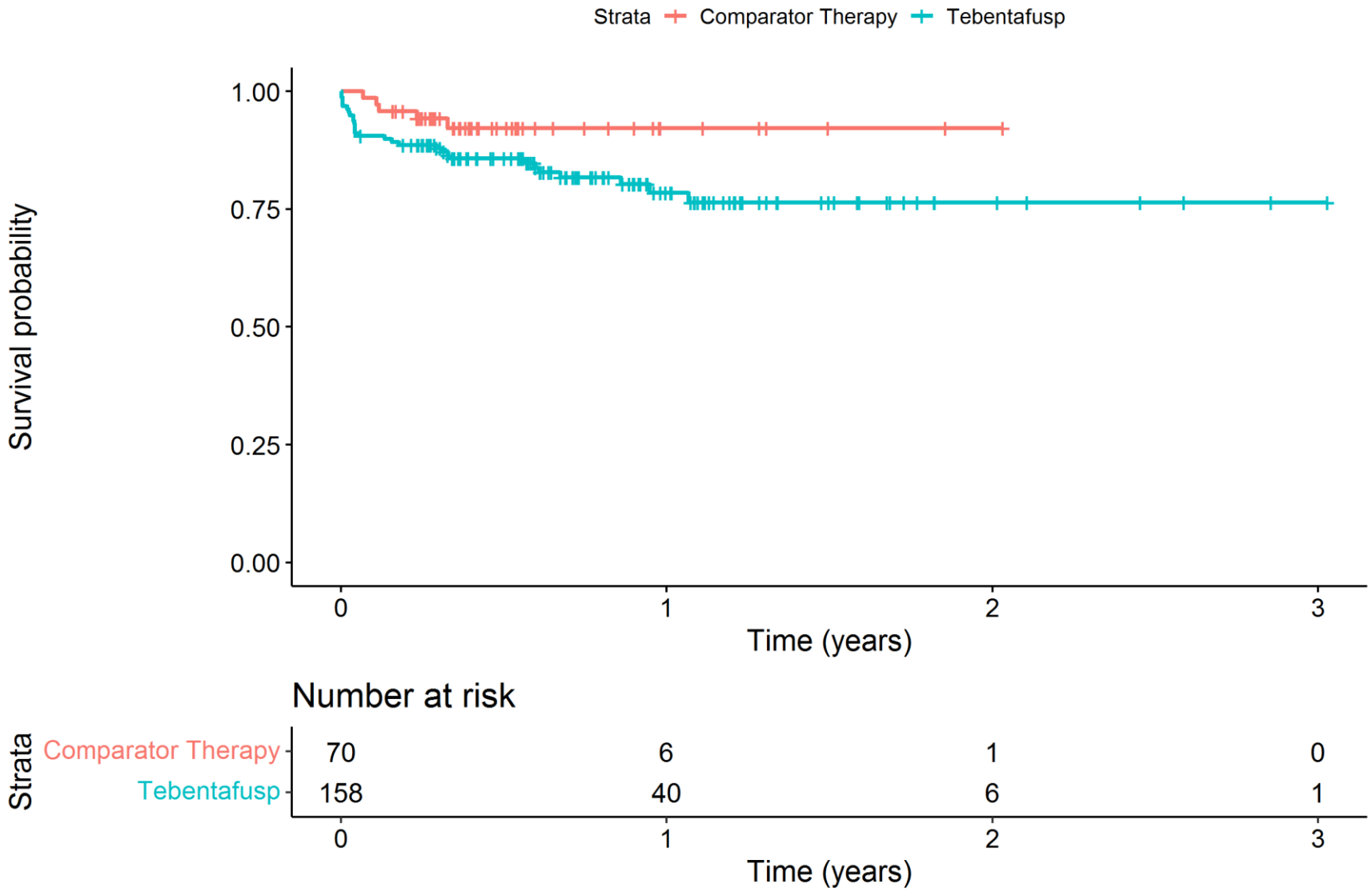
53.258 Erhöhte Aspartat-Aminotransferase - ALP ≤ ULN



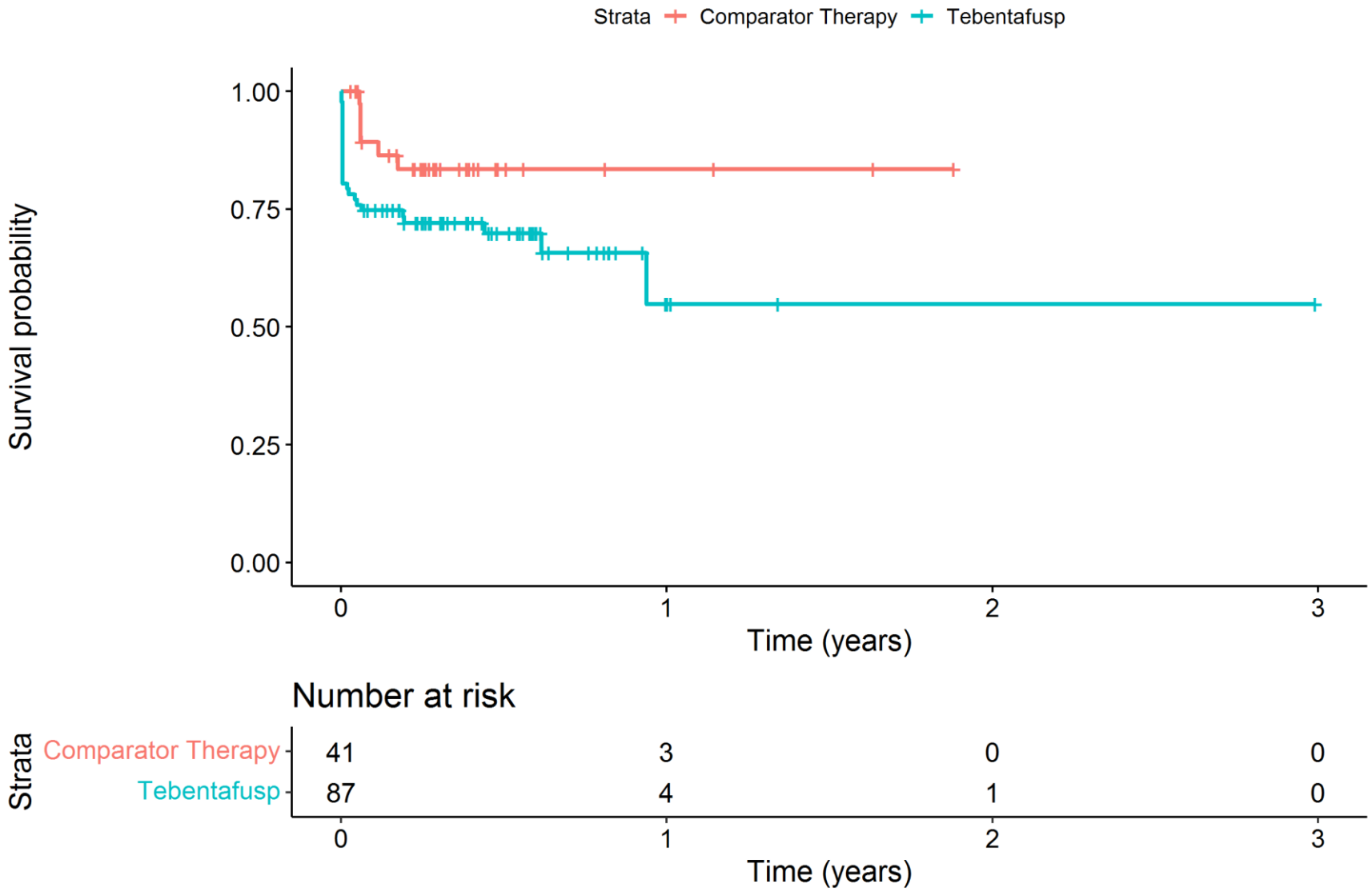
53.259 Erhöhte Aspartat-Aminotransferase - ALP > ULN



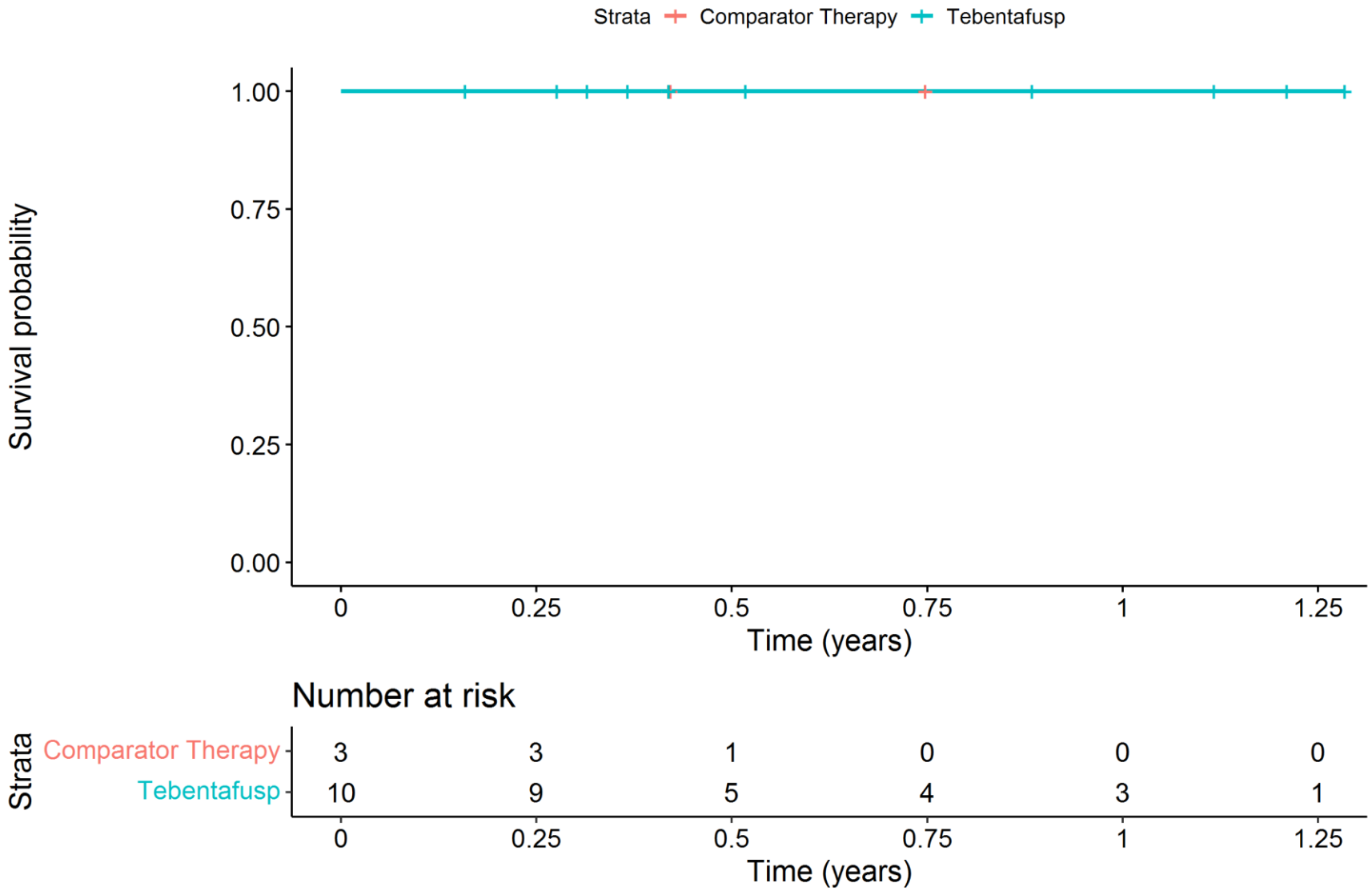
53.260 Erhöhte Aspartat-Aminotransferase - LDH =< ULN



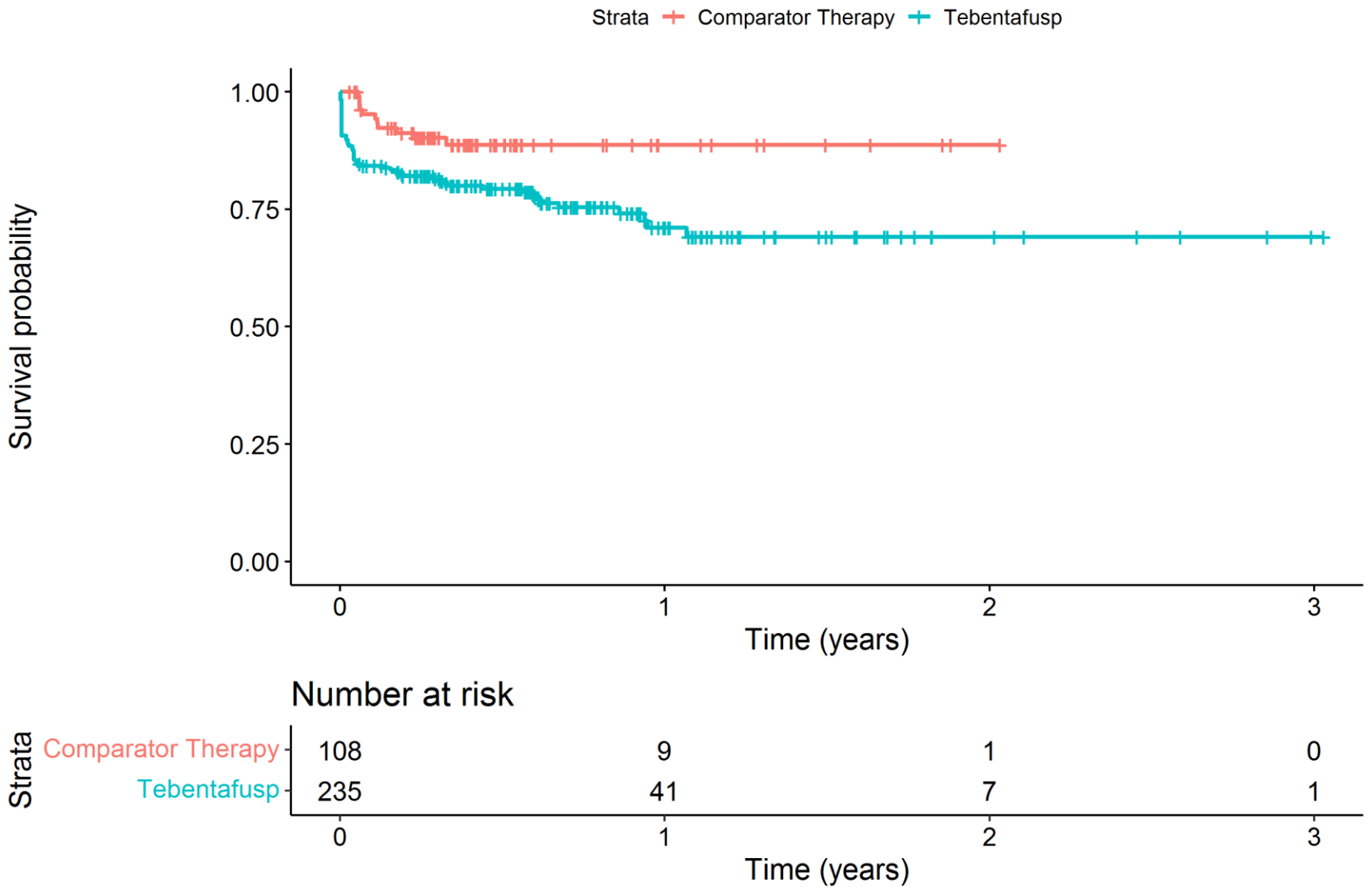
53.261 Erhöhte Aspartat-Aminotransferase - LDH > ULN



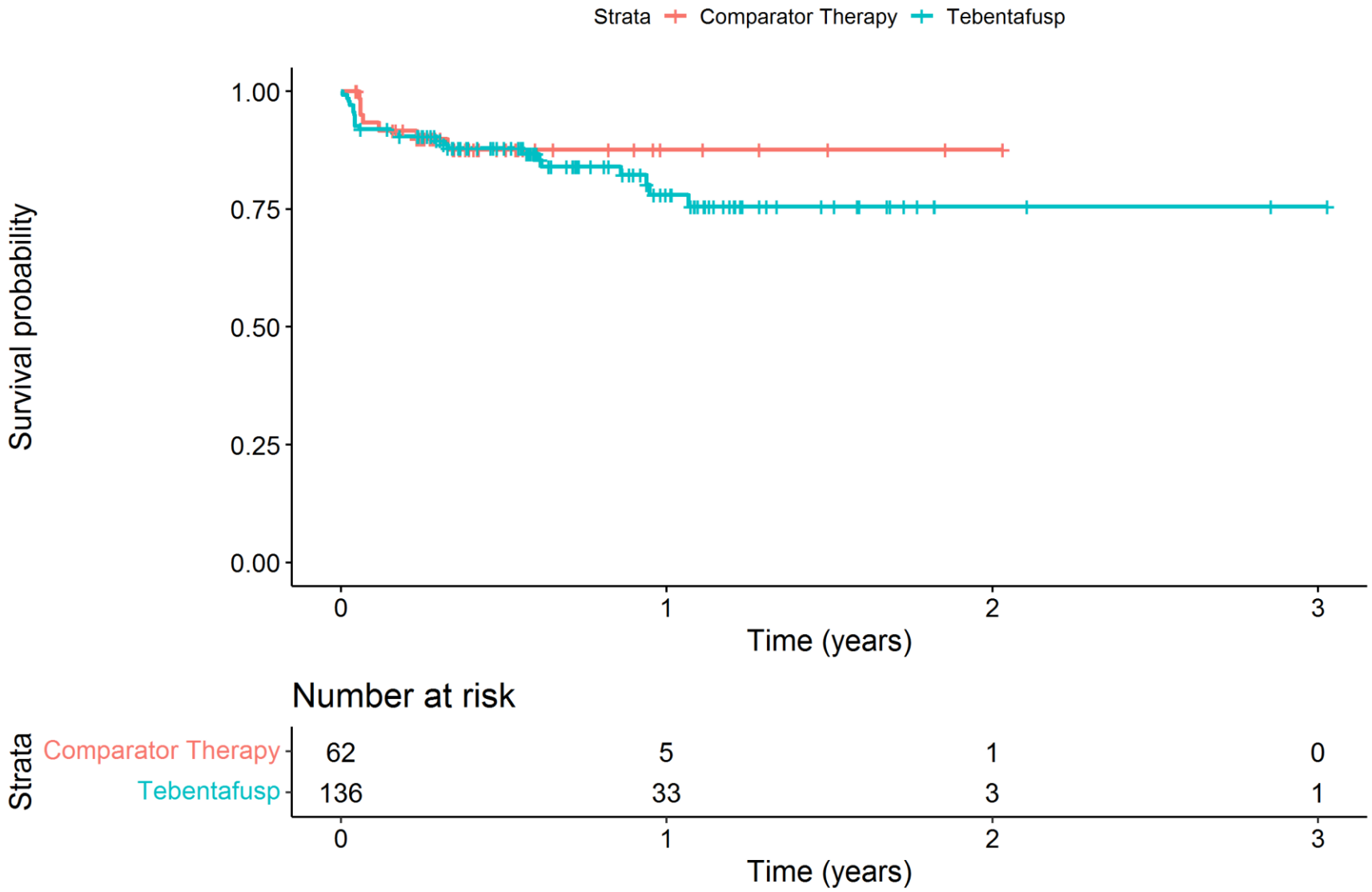
53.262 Erhöhte Aspartat-Aminotransferase - Vorherige Therapie adjuvant/neoadjuvant



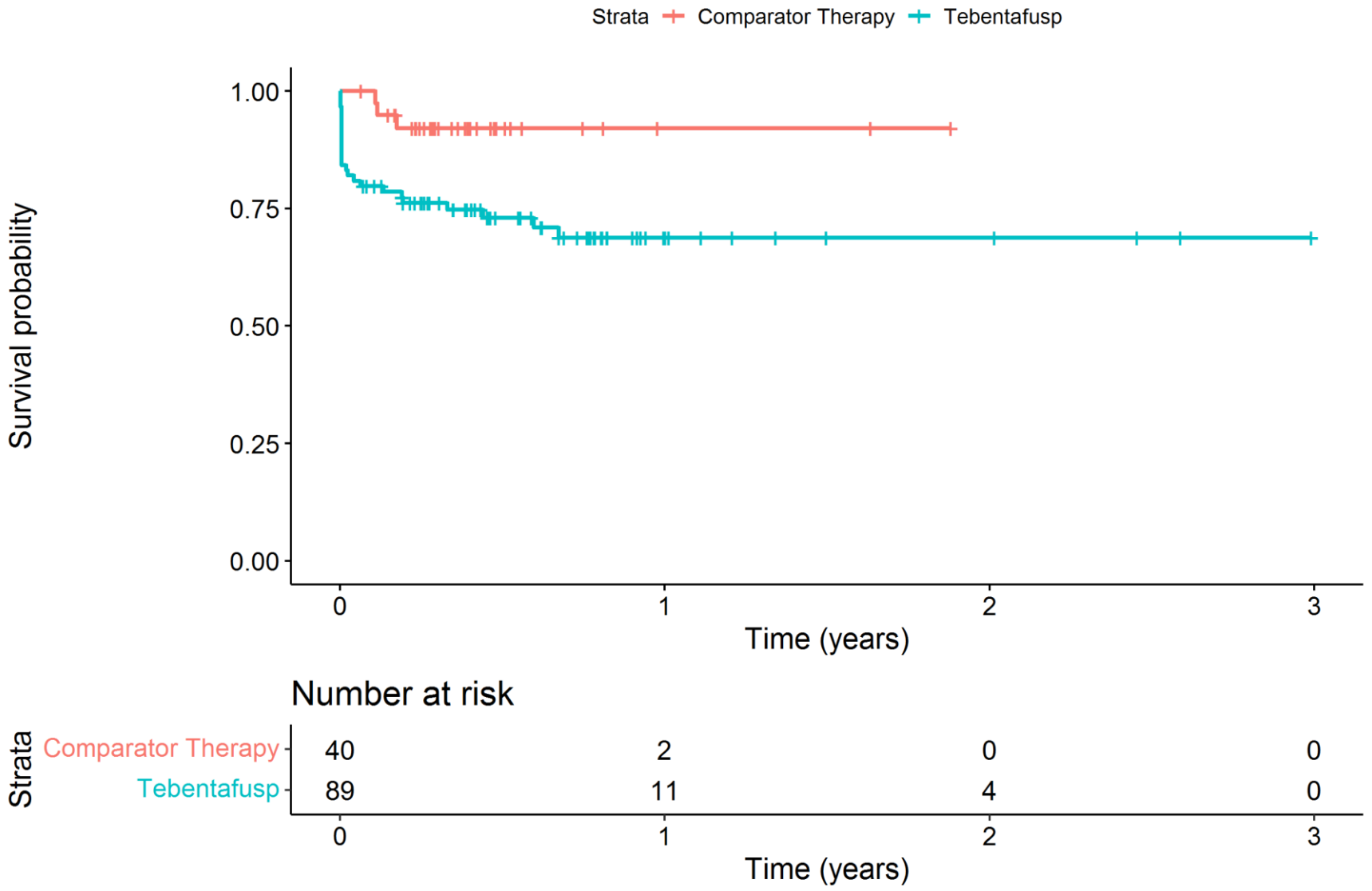
Erhöhte Aspartat-Aminotransferase - Keine vorherige Therapie adjuvant/neoadjuvant



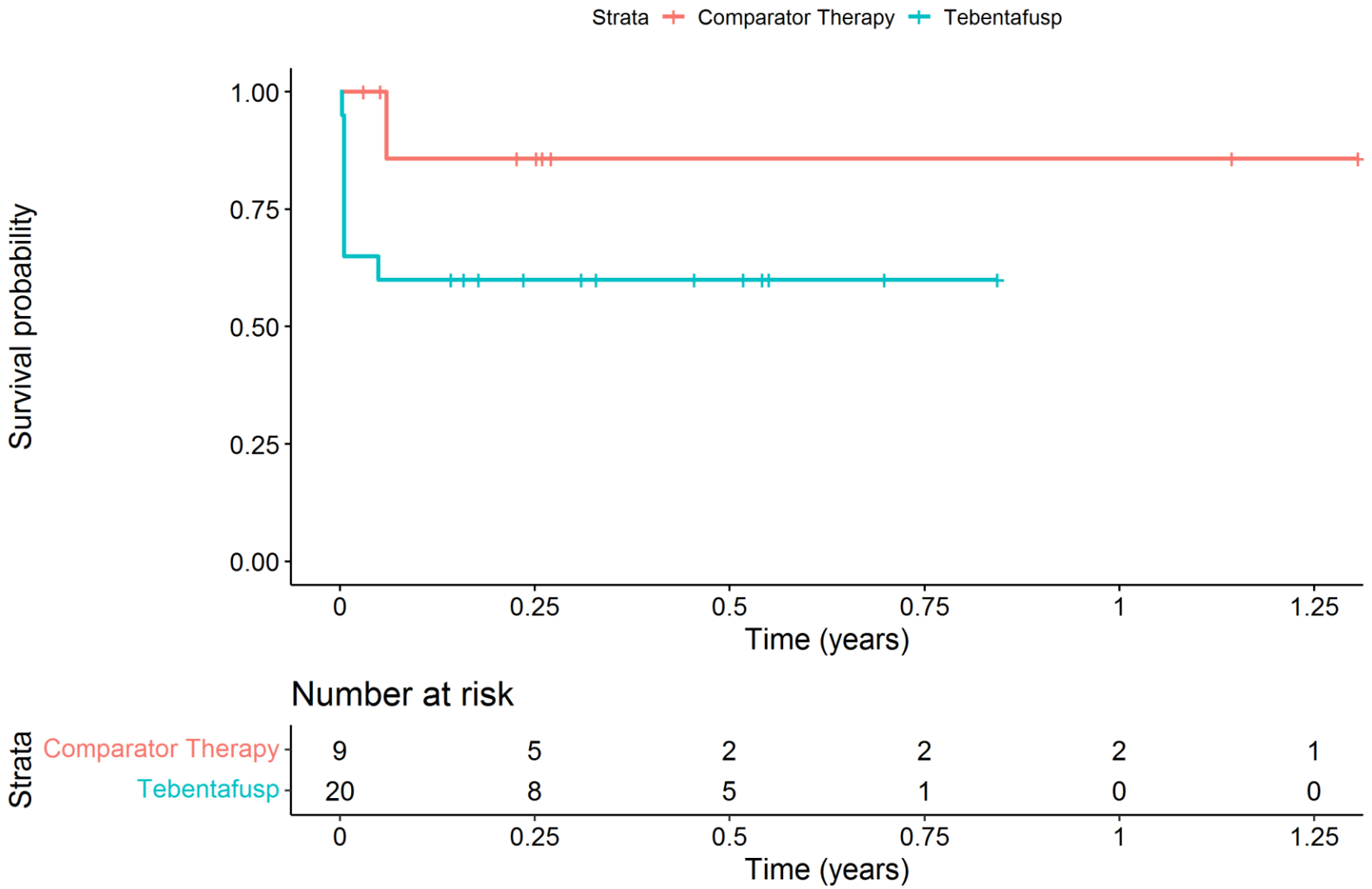
53.263 Erhöhte Aspartat-Aminotransferase - Läsion ≤ 3cm



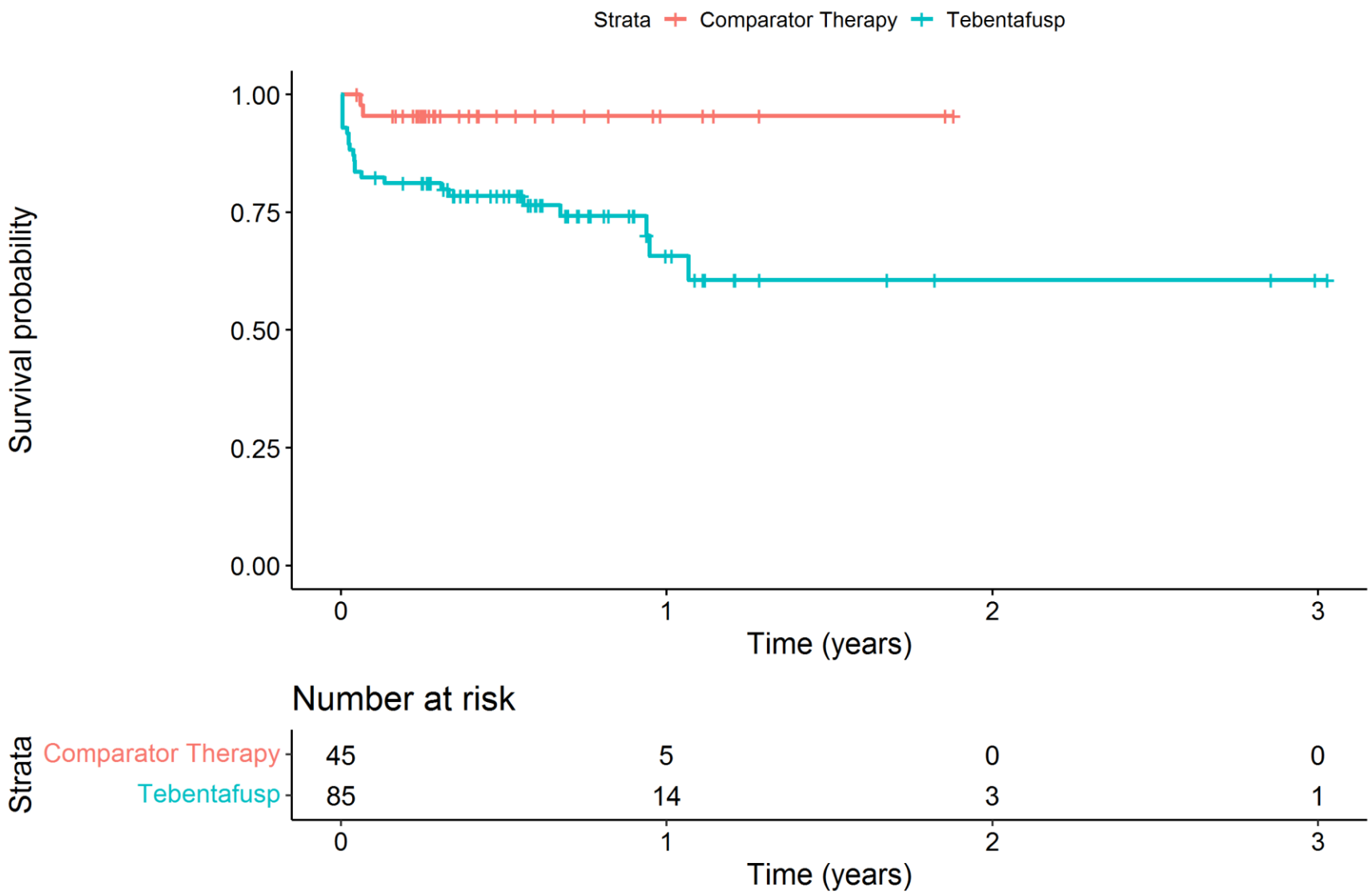
53.264 Erhöhte Aspartat-Aminotransferase - Läsion 3,1-8,0 cm



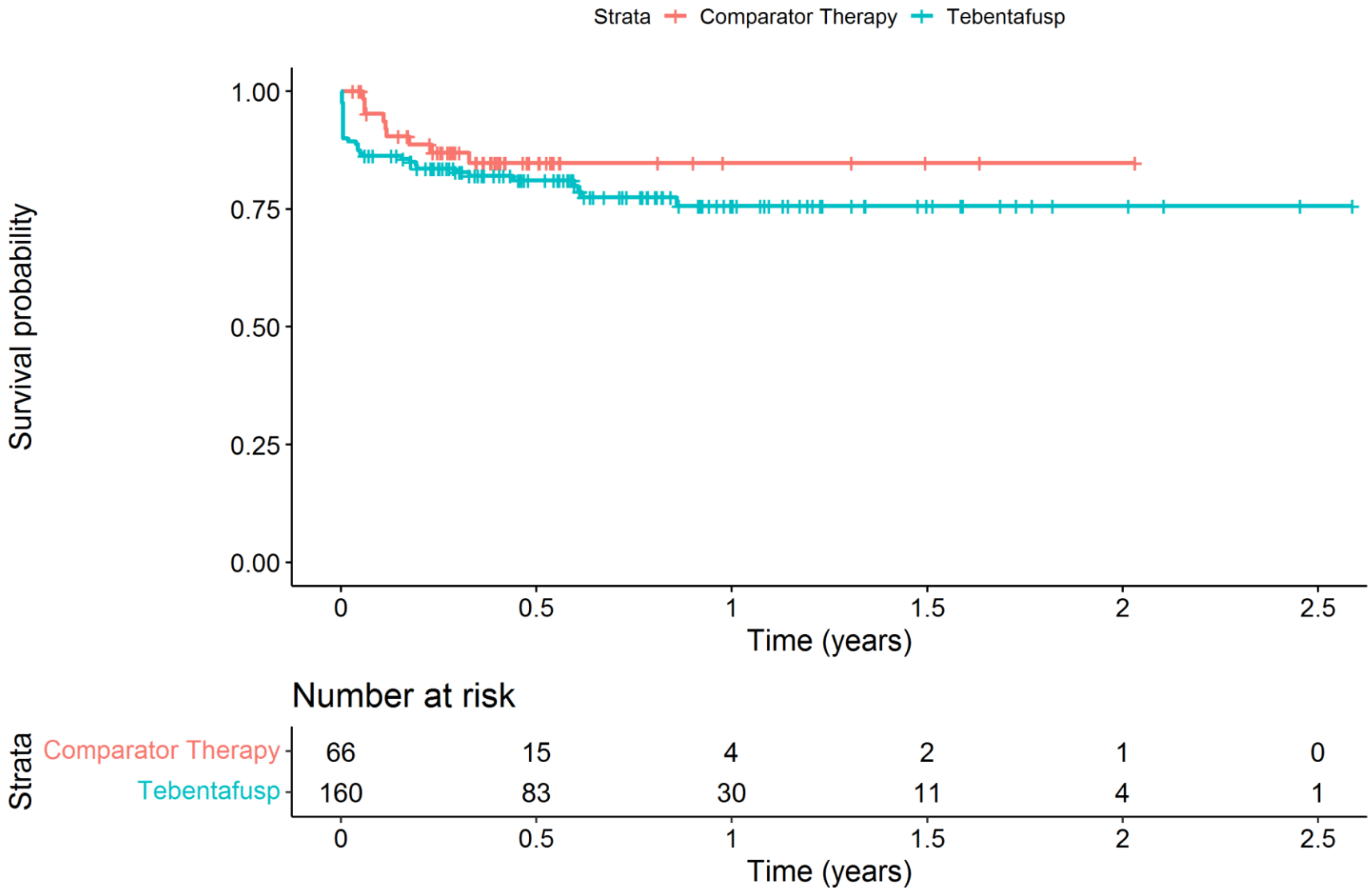
53.265 Erhöhte Aspartat-Aminotransferase - Läsion ≥8,1 cm



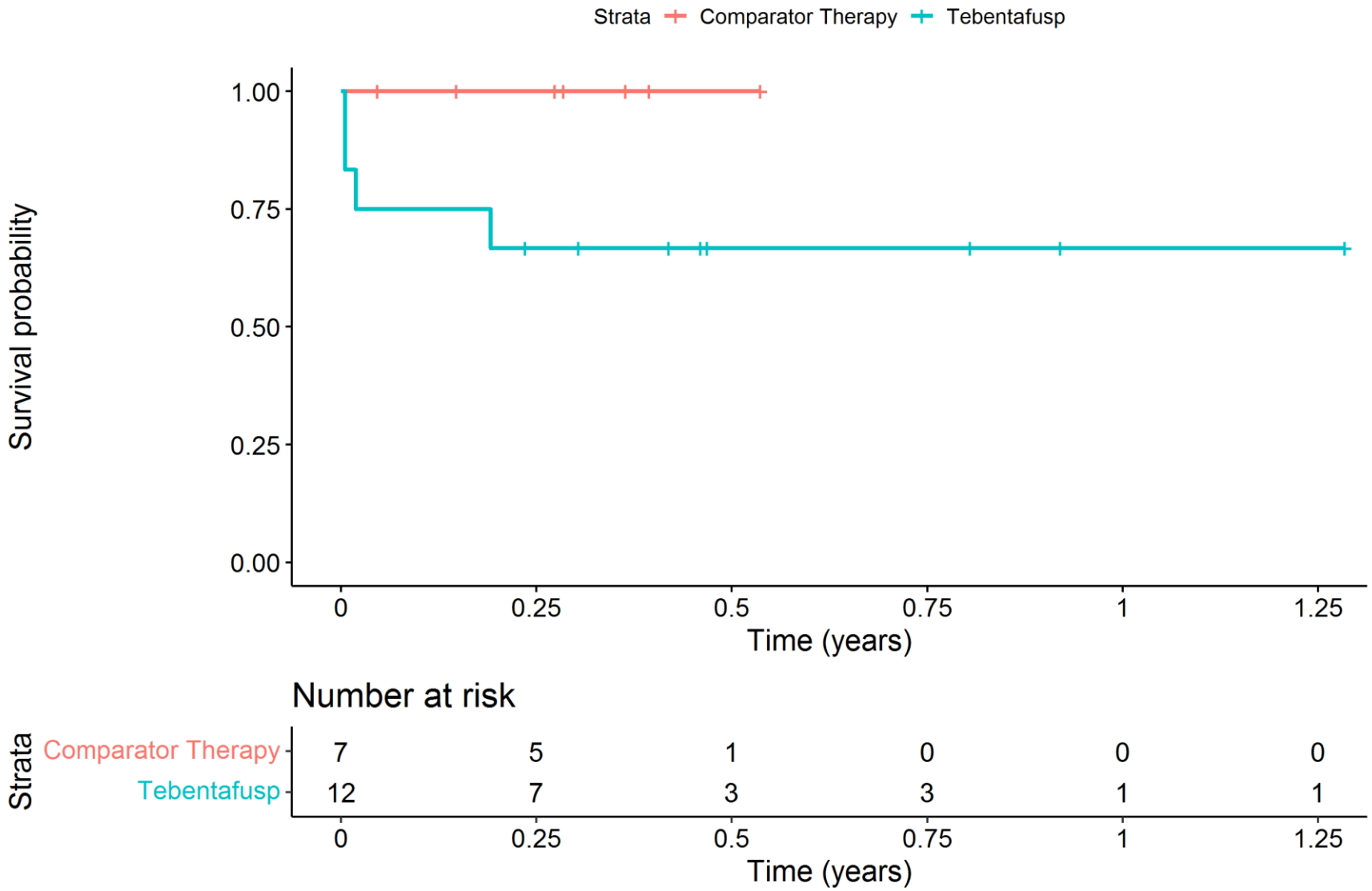
53.266 Erhöhte Aspartat-Aminotransferase - Nordamerika



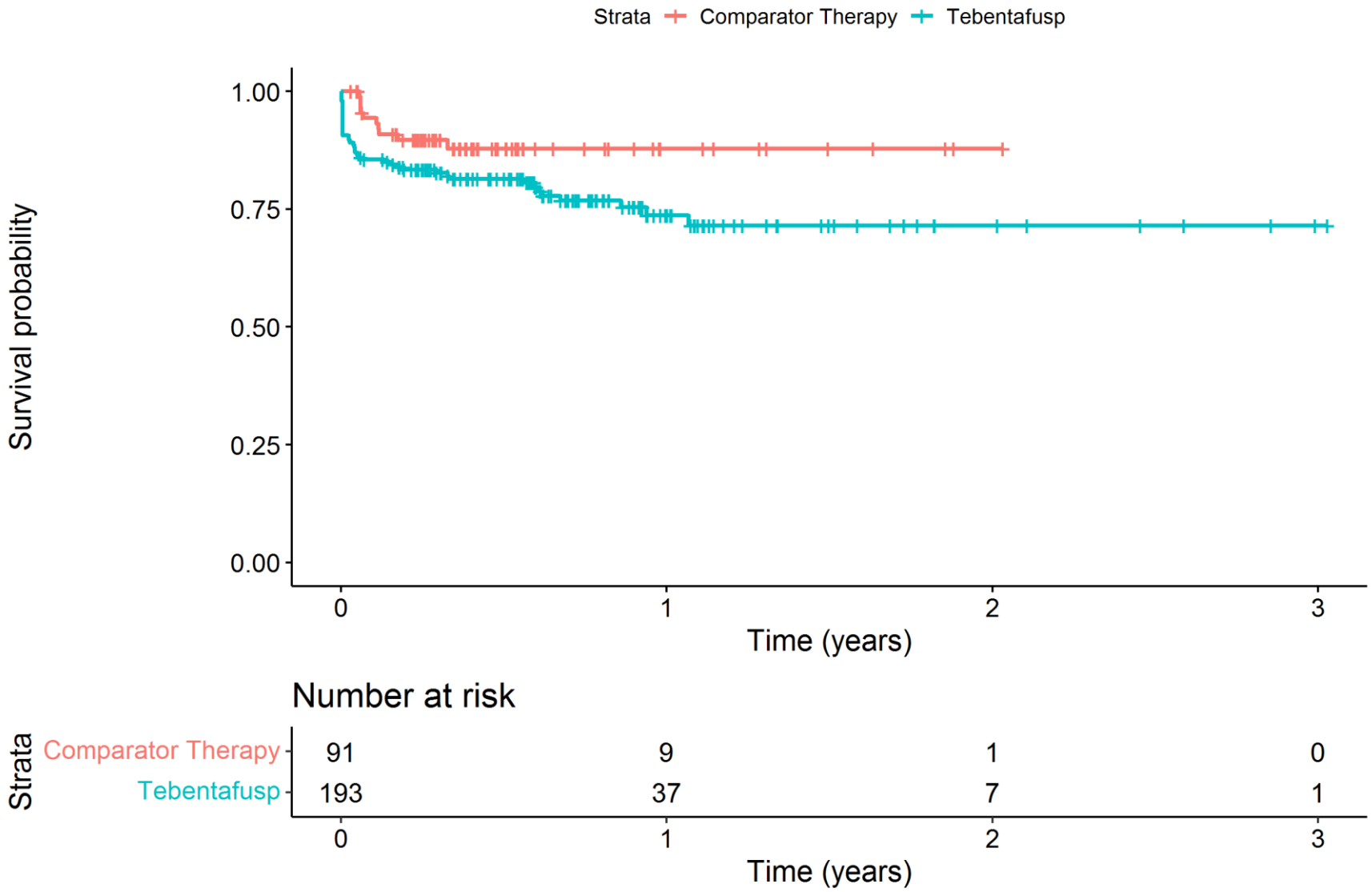
53.267 Erhöhte Aspartat-Aminotransferase - Nicht-Nordamerika



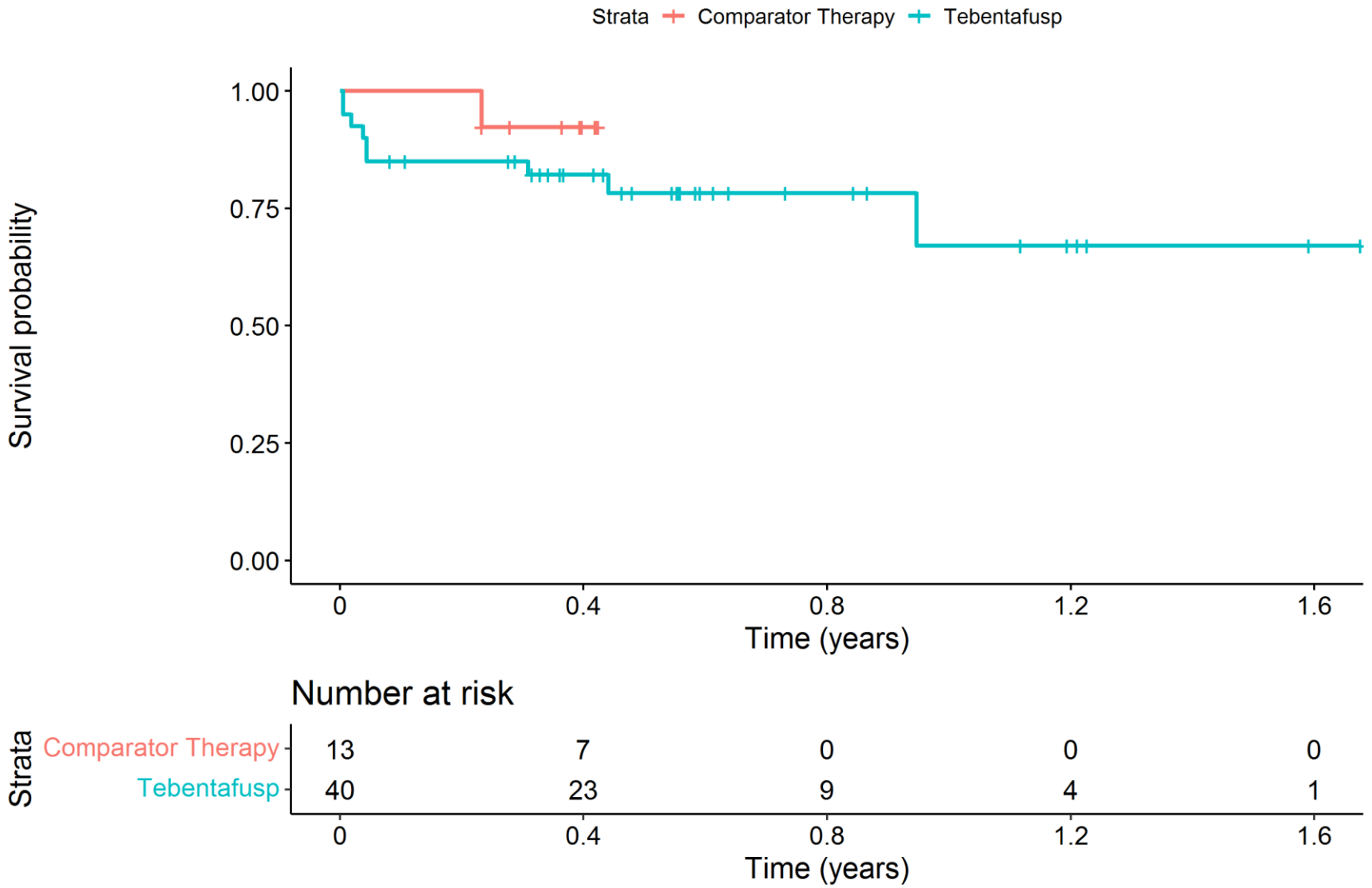
53.268 Erhöhte Aspartat-Aminotransferase - Dacarbazin



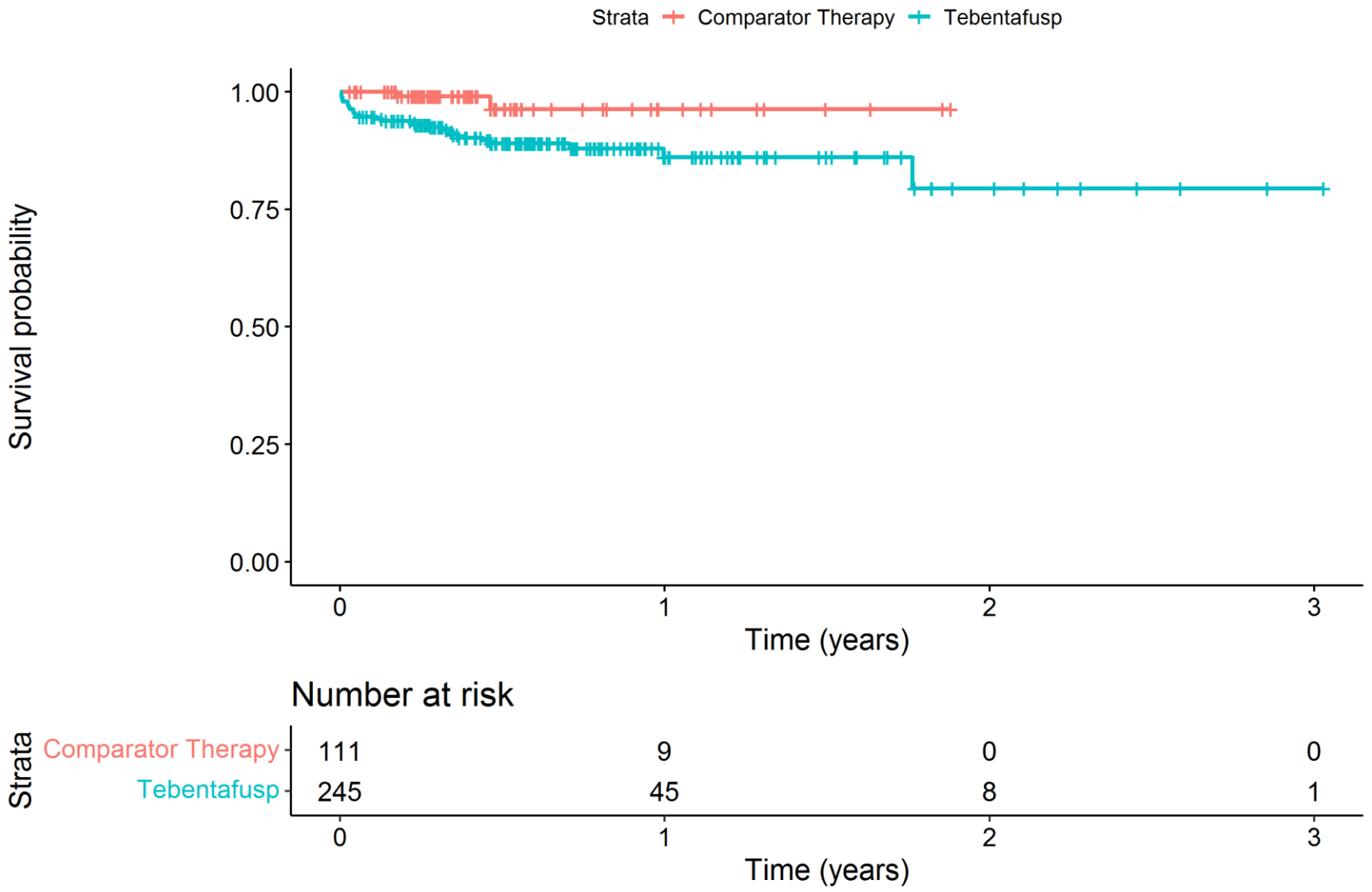
53.269 Erhöhte Aspartat-Aminotransferase - Pembrolizumab



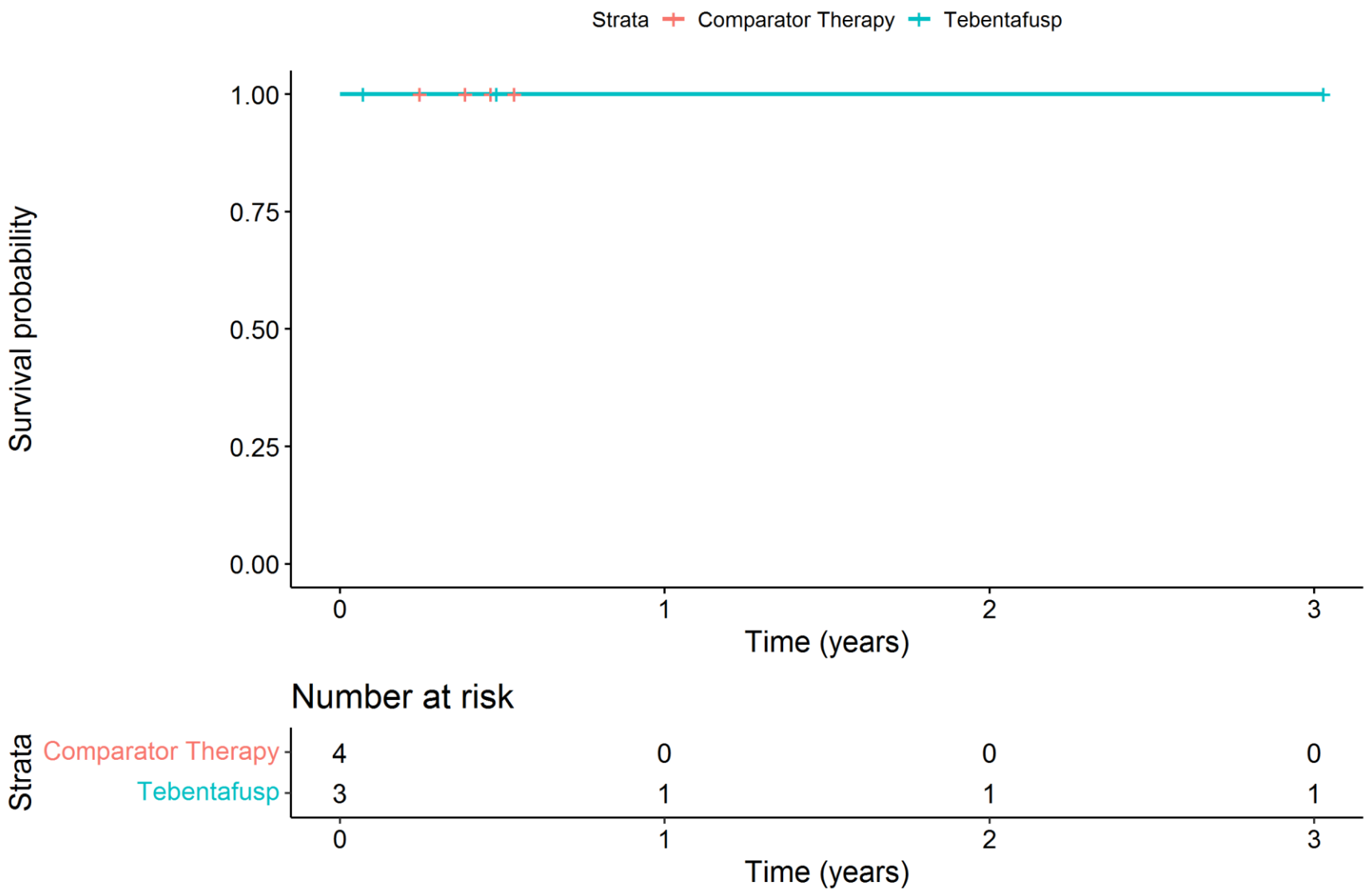
53.270 Erhöhte Aspartat-Aminotransferase - Ipilimumab



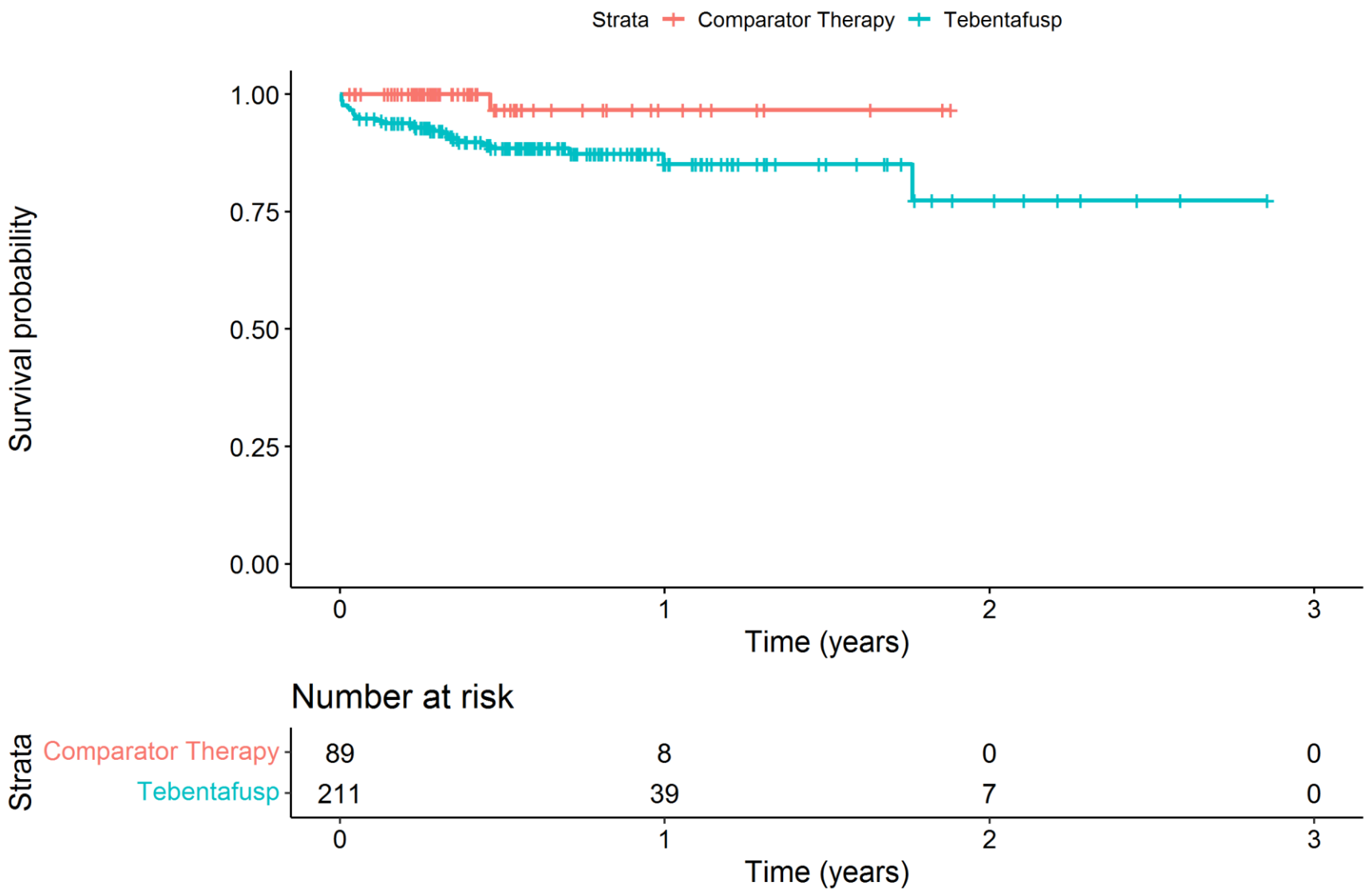
53.271 Hypophosphatämie - Gesamt



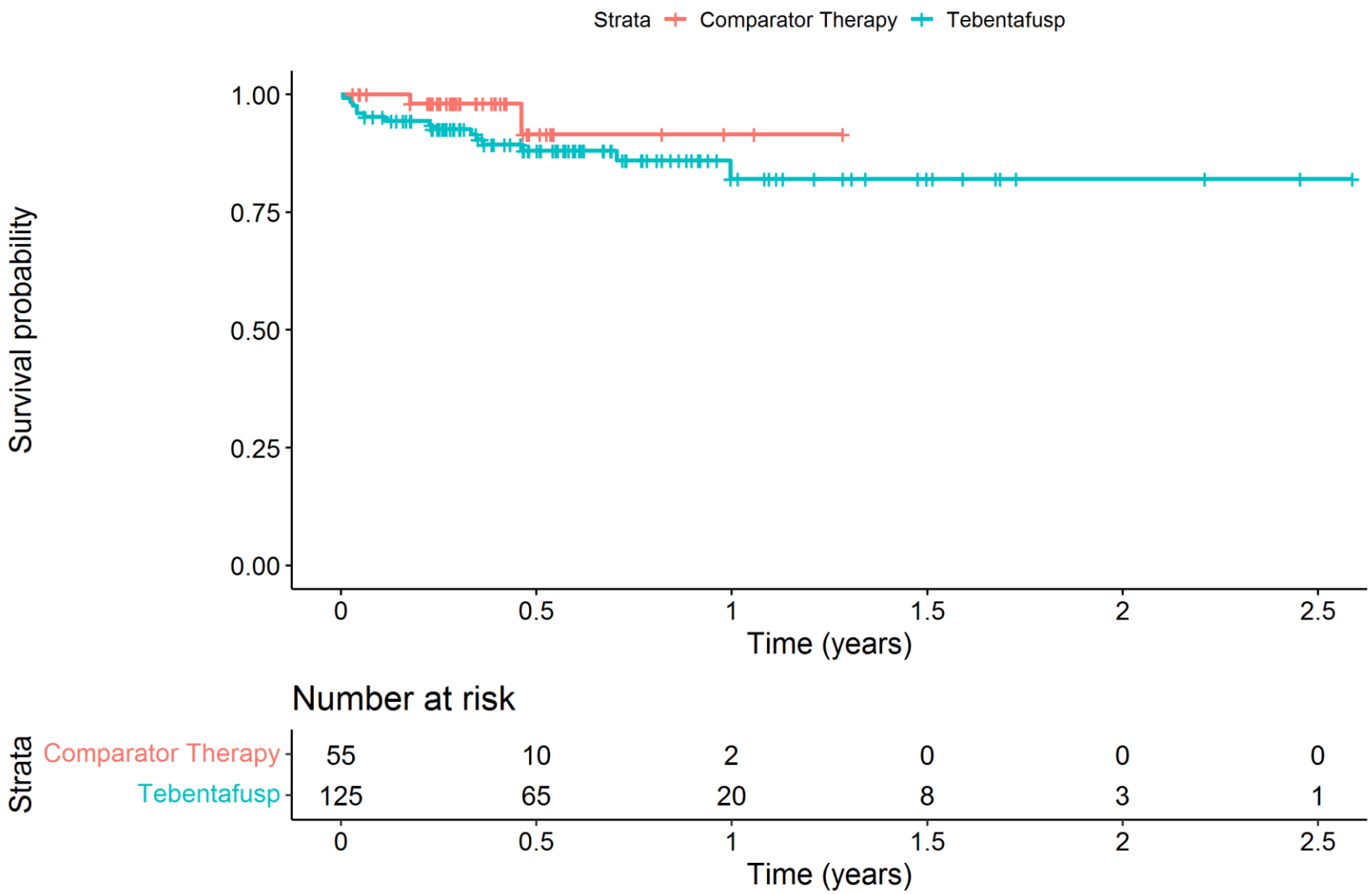
53.272 Hypophosphatämie - Hispanisch



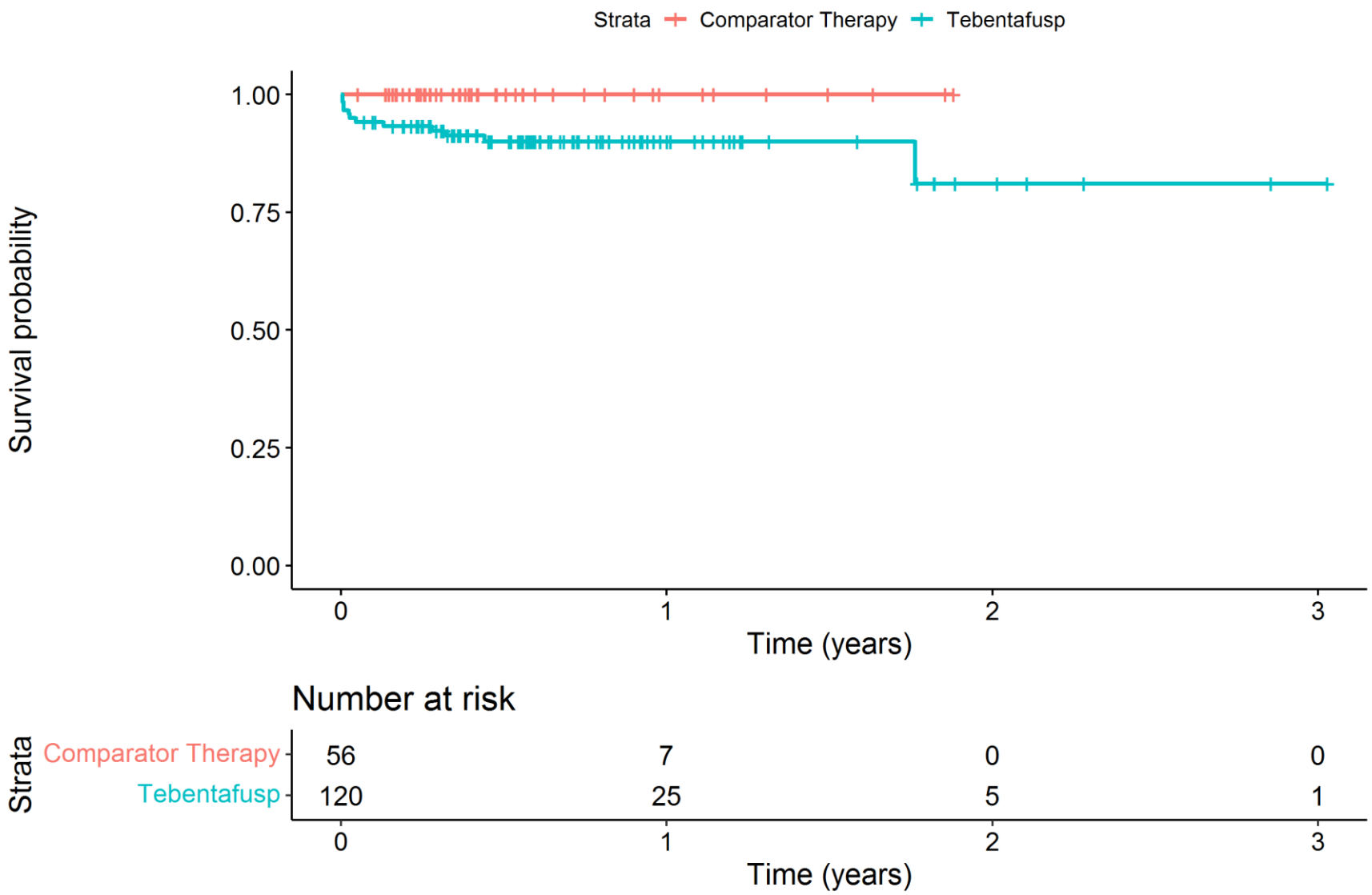
53.273 Hypophosphatämie - Nicht-hispanisch



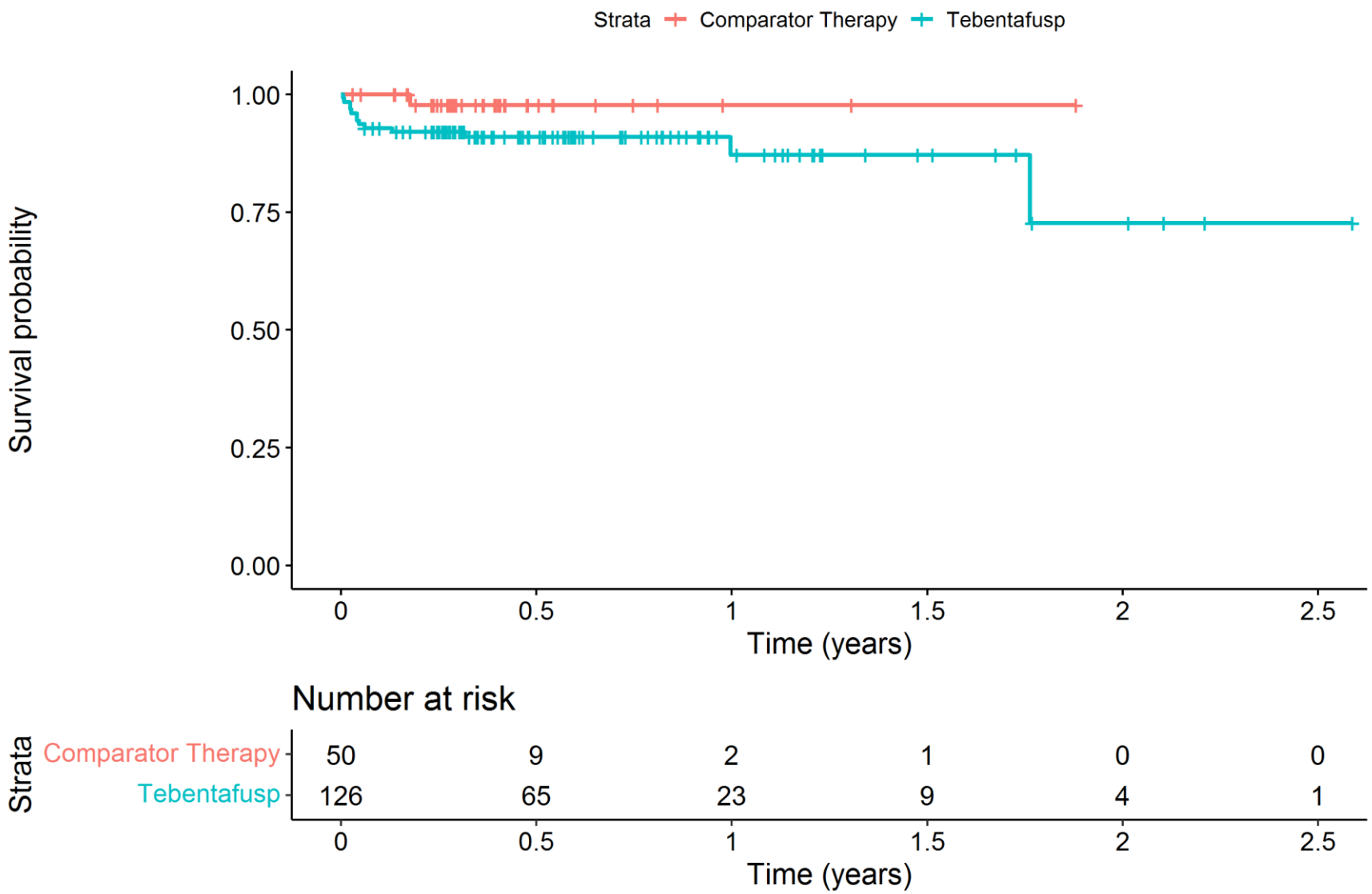
53.274 Hypophosphatämie - Männlich



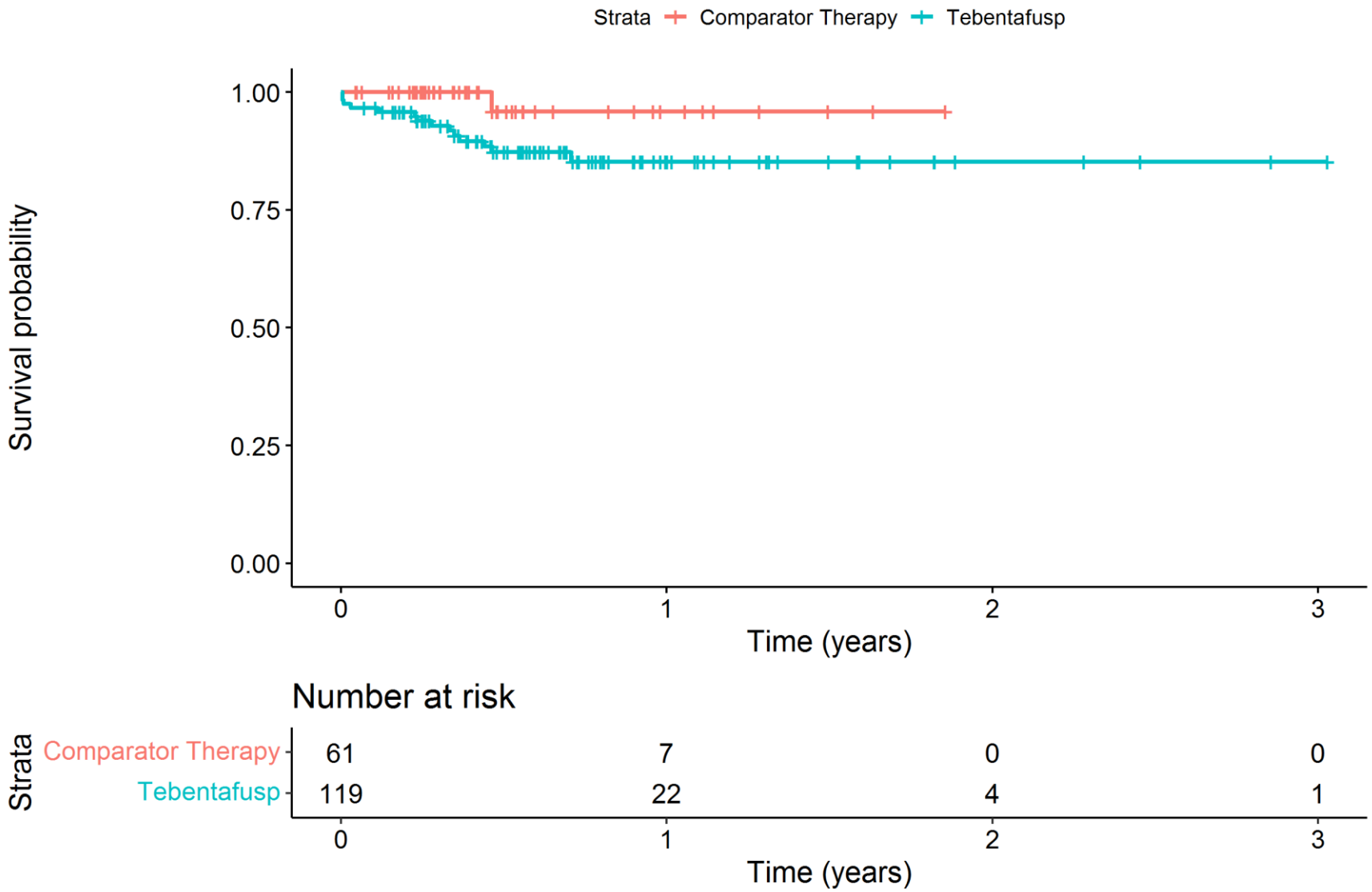
53.275 Hypophosphatämie - Weiblich



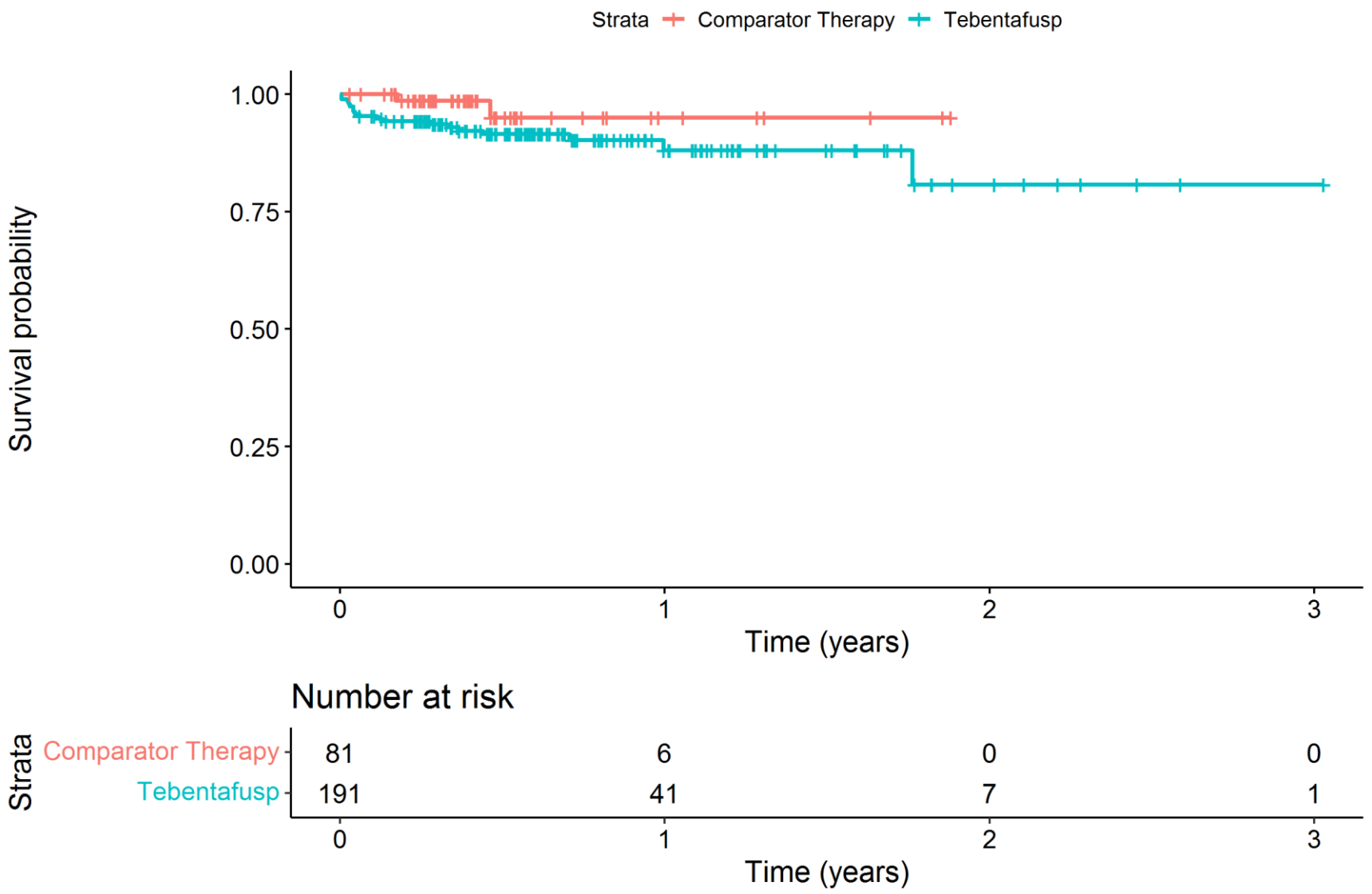
53.276 Hypophosphatämie - <65



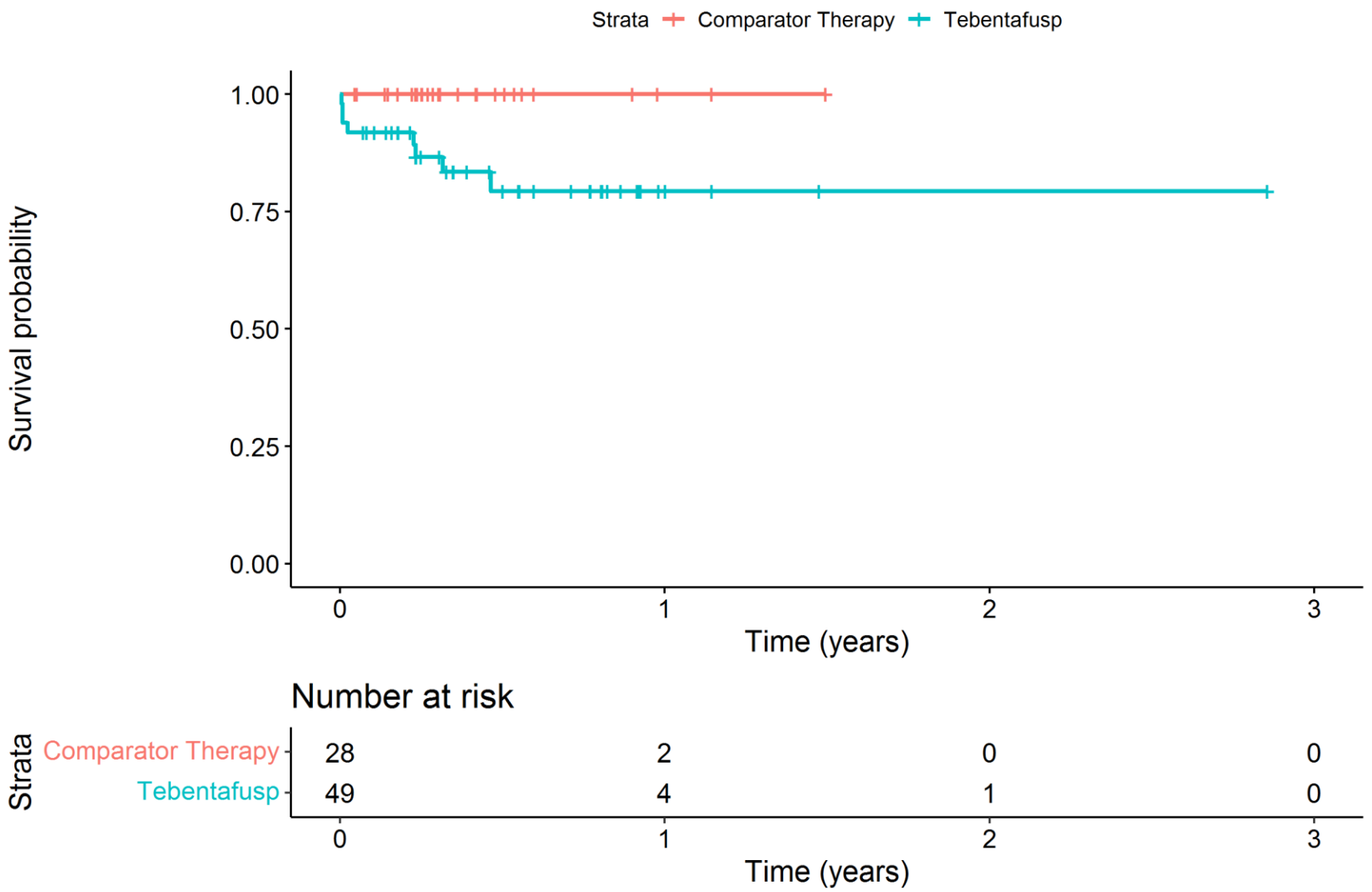
53.277 Hypophosphatämie - ≥65



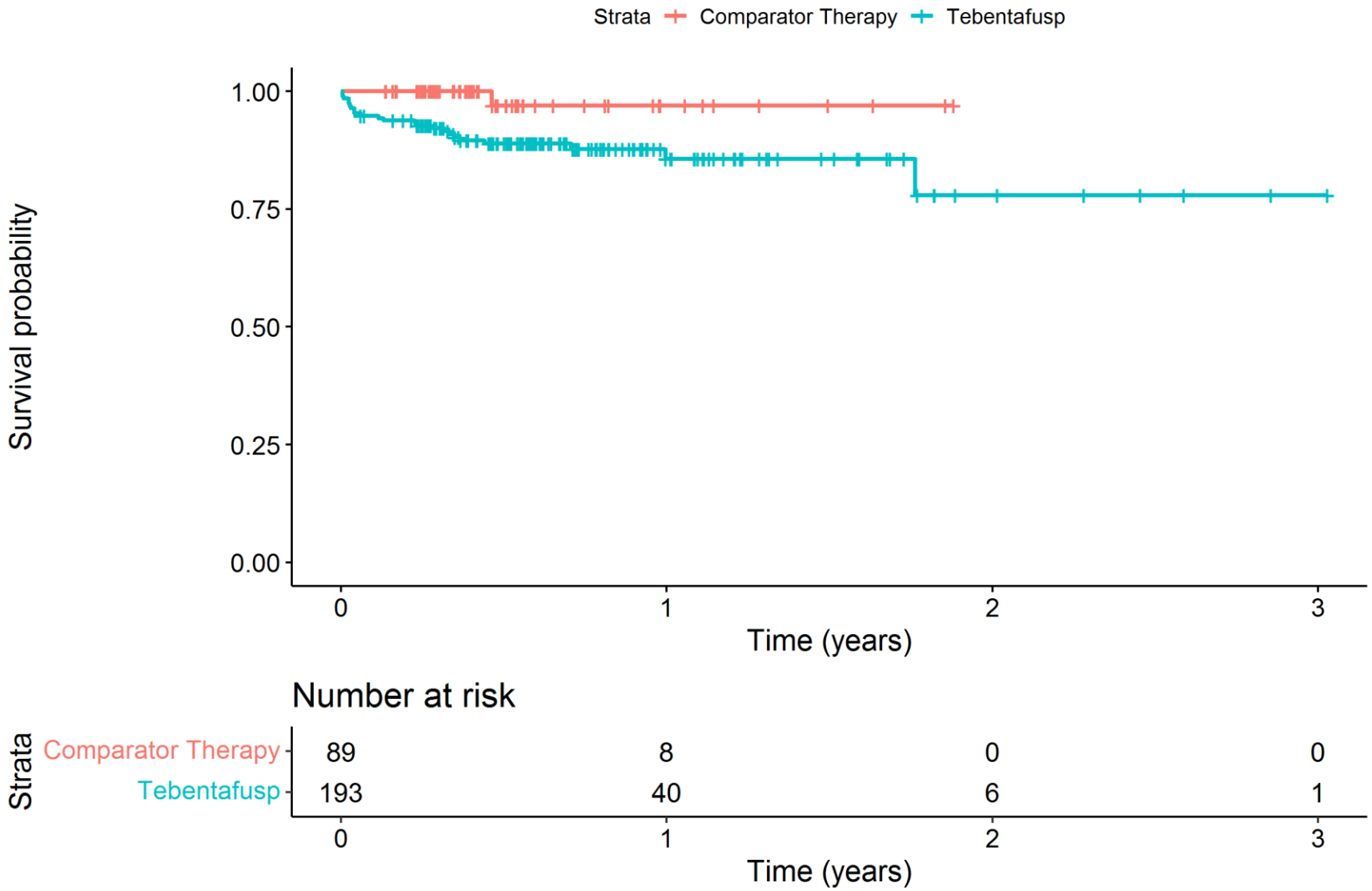
53.278 Hypophosphatämie - ECOG 0



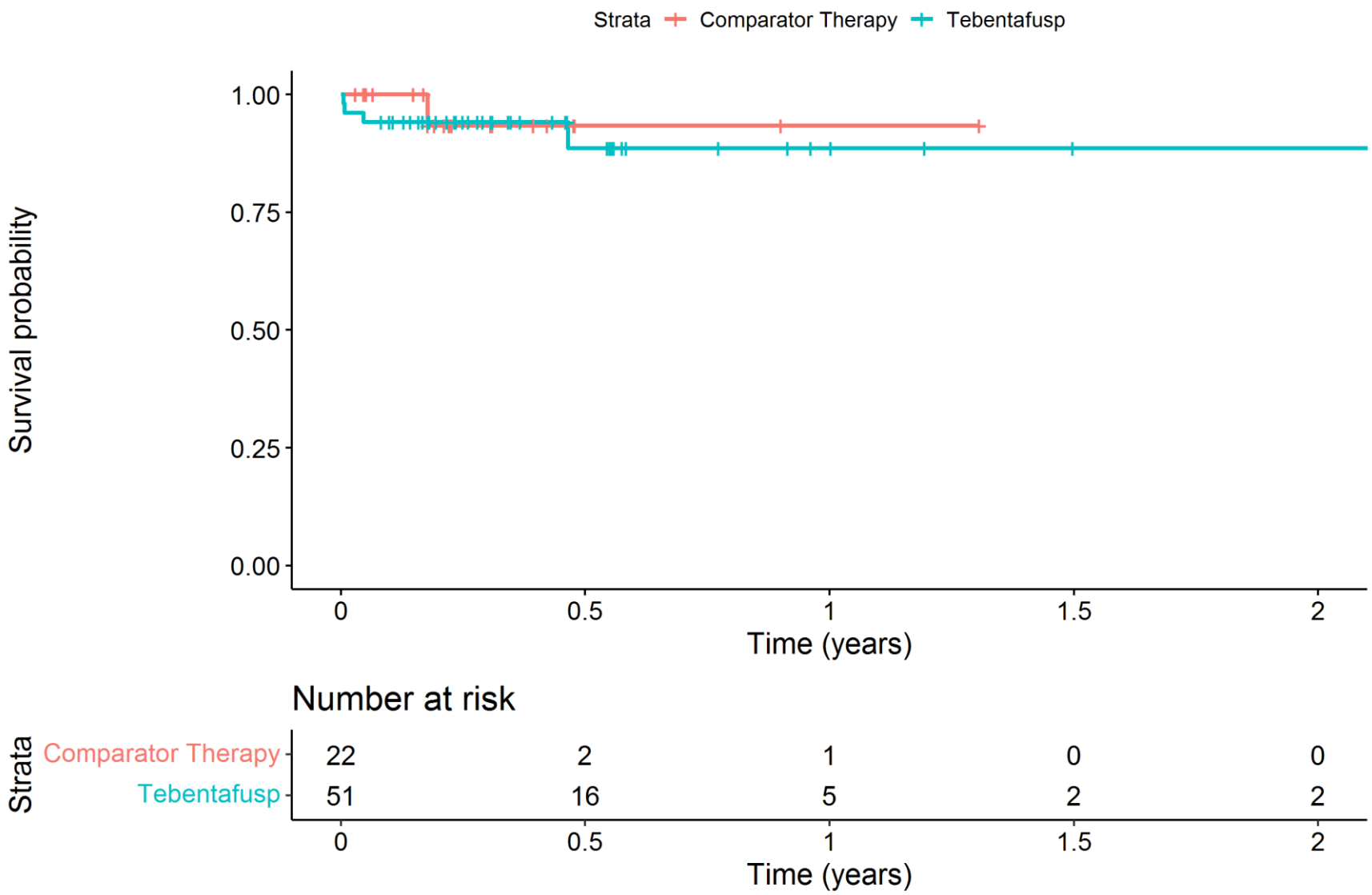
53.279 Hypophosphatämie - ECOG 1



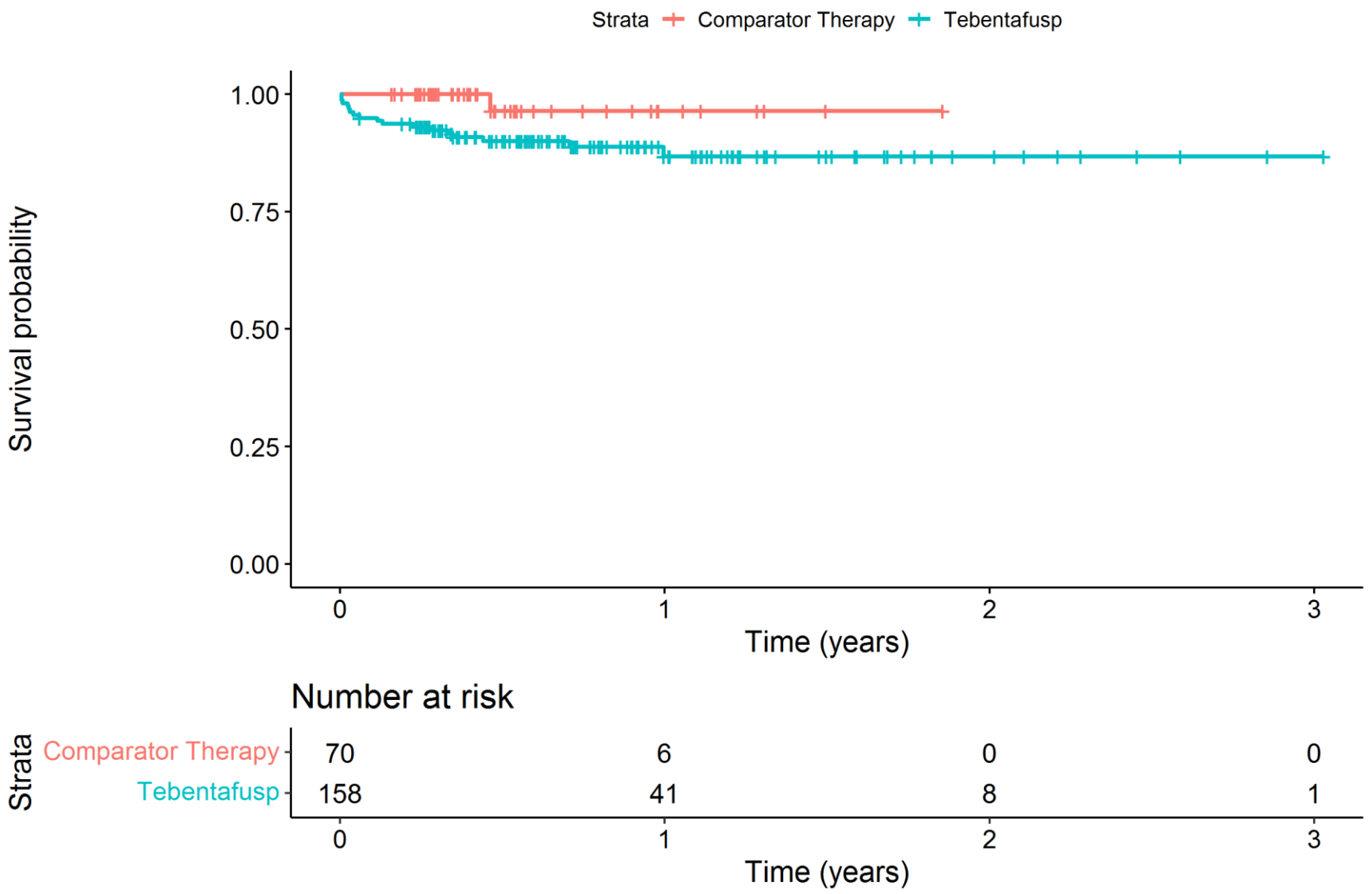
53.280 Hypophosphatämie - ALP ≤ ULN



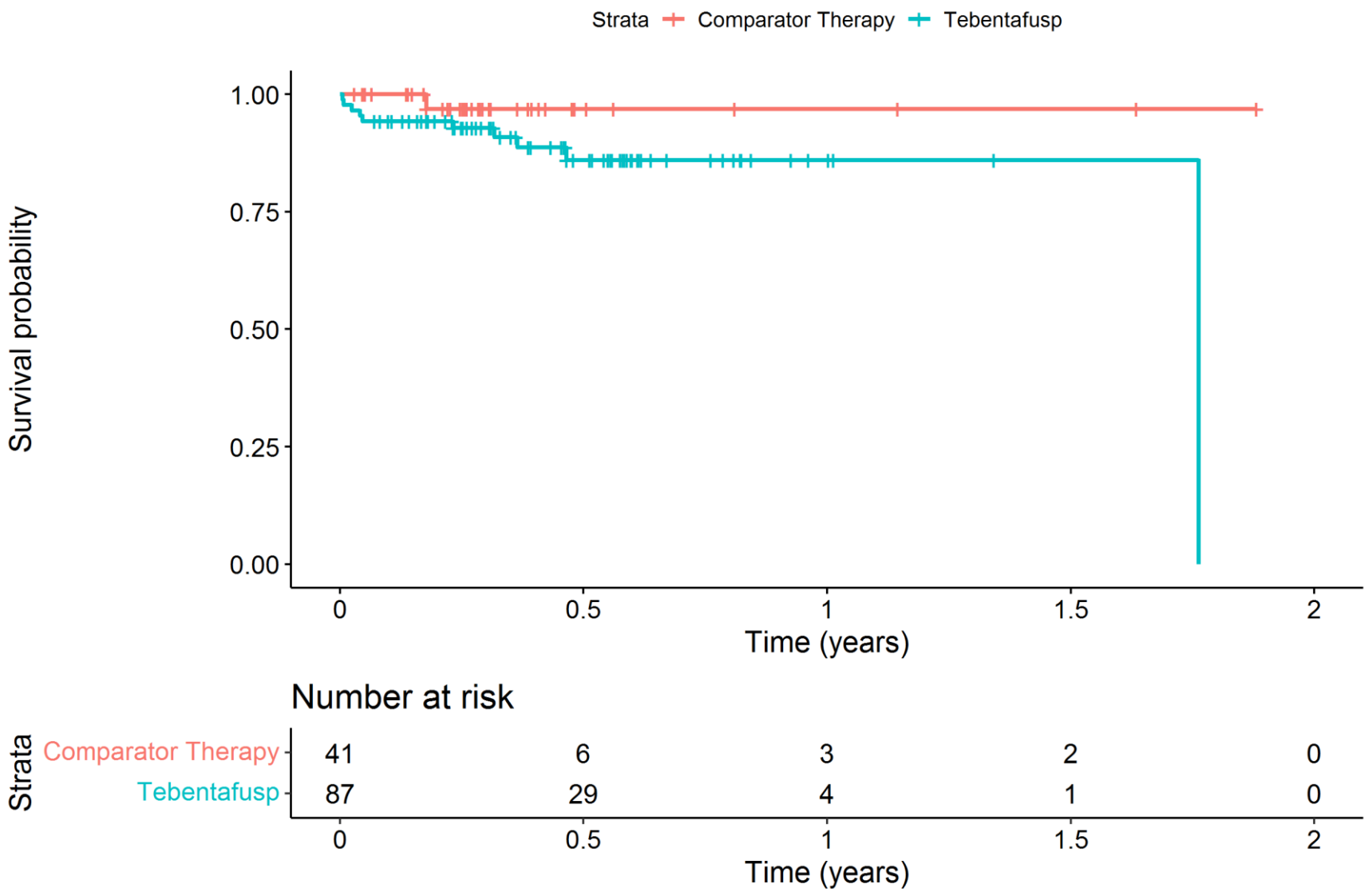
53.281 Hypophosphatämie - ALP > ULN



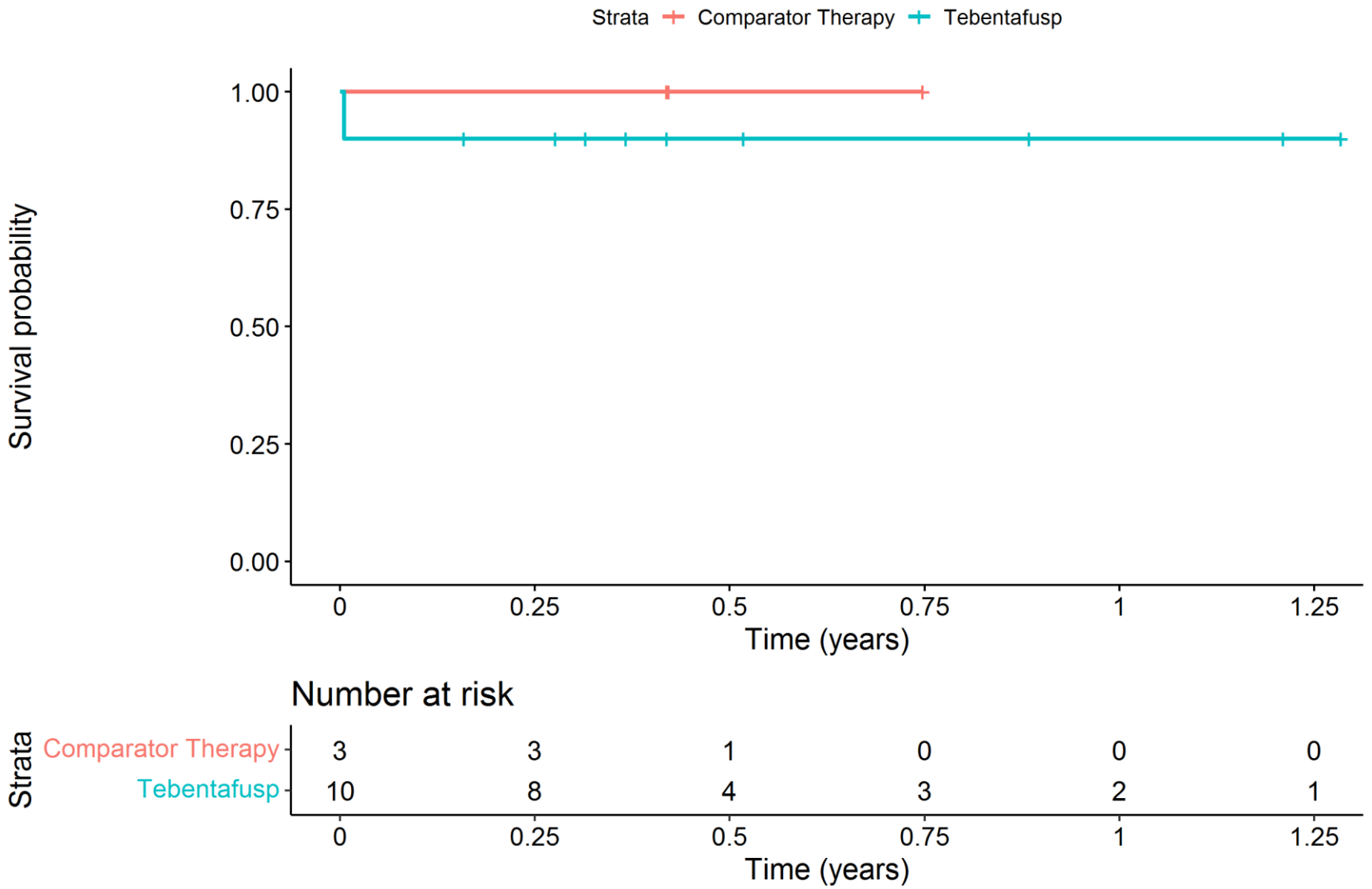
53.282 Hypophosphatämie - LDH =< ULN



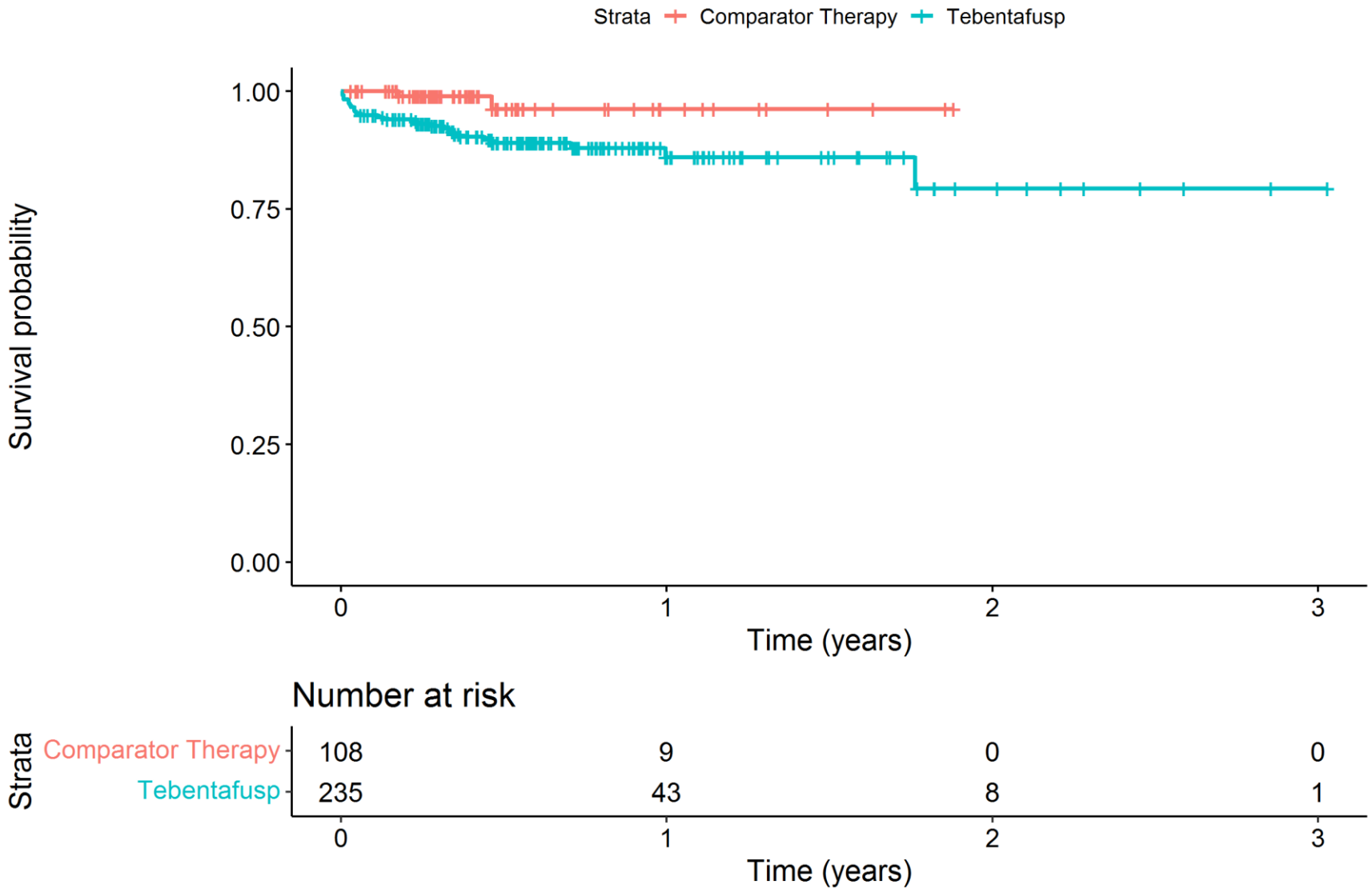
53.283 Hypophosphatämie - LDH > ULN



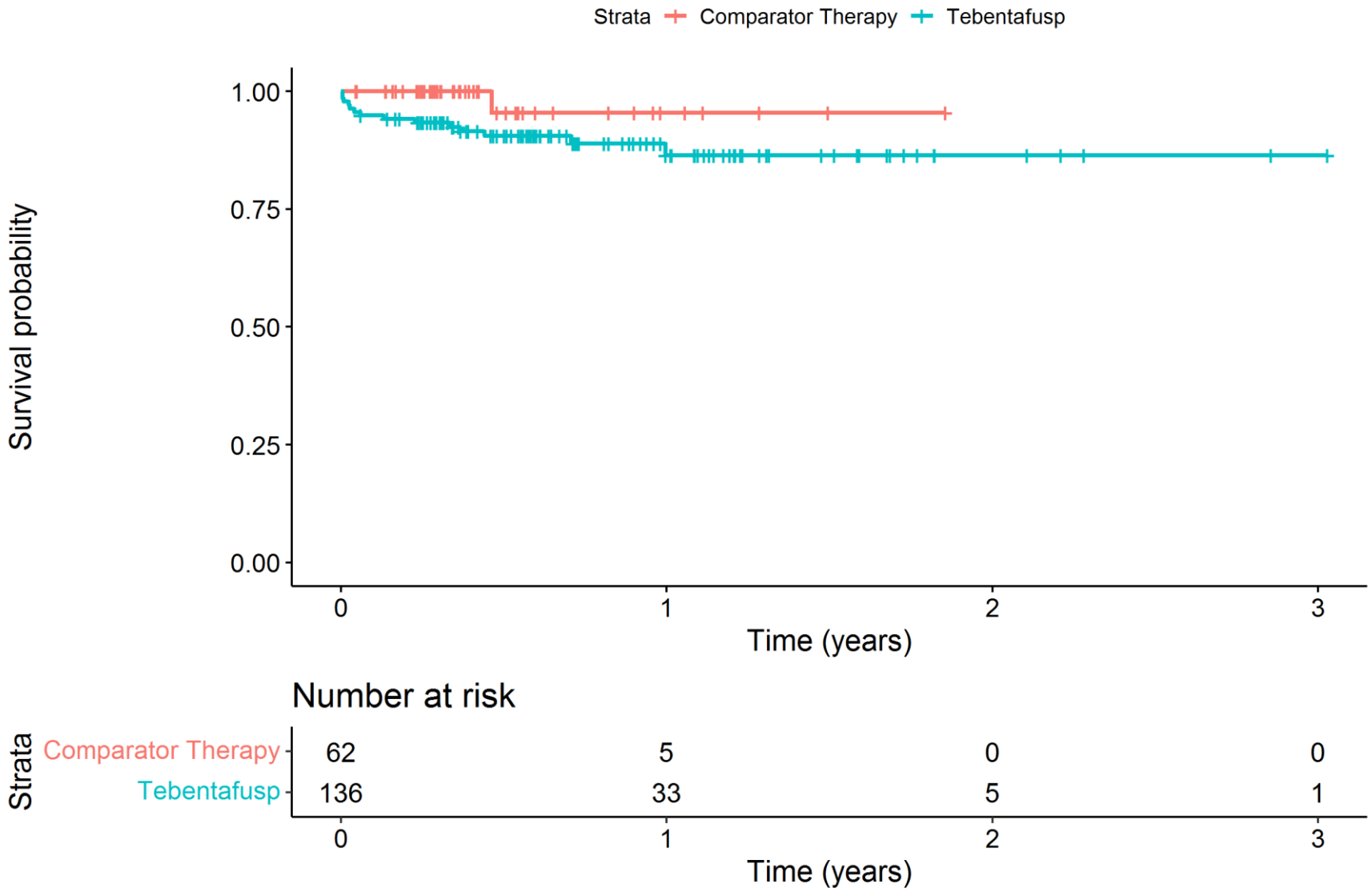
53.284 Hypophosphatämie - Vorherige Therapie adjuvant/neoadjuvant



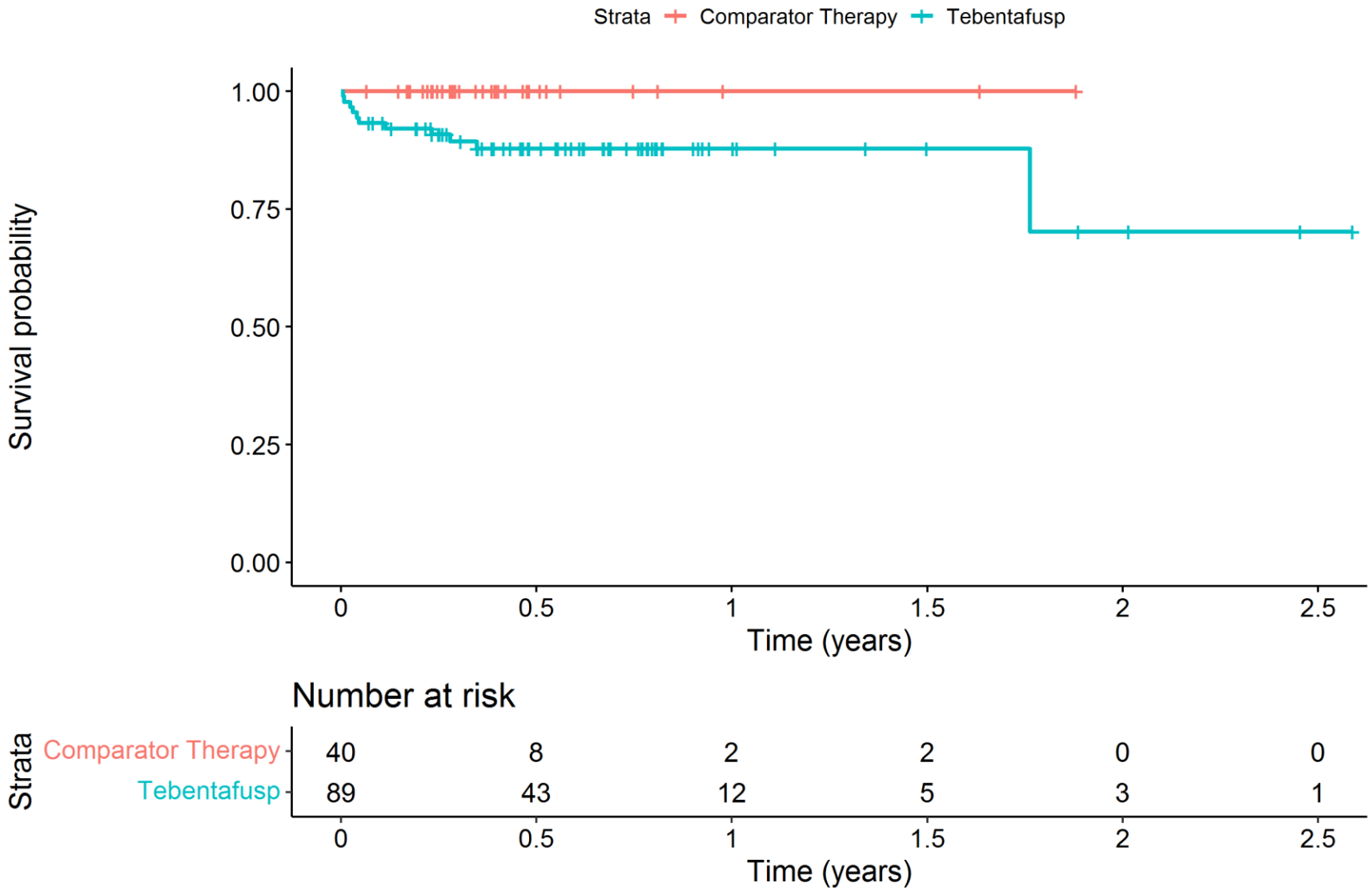
53.285 Hypophosphatämie - Keine vorherige Therapie adjuvant/neoadjuvant



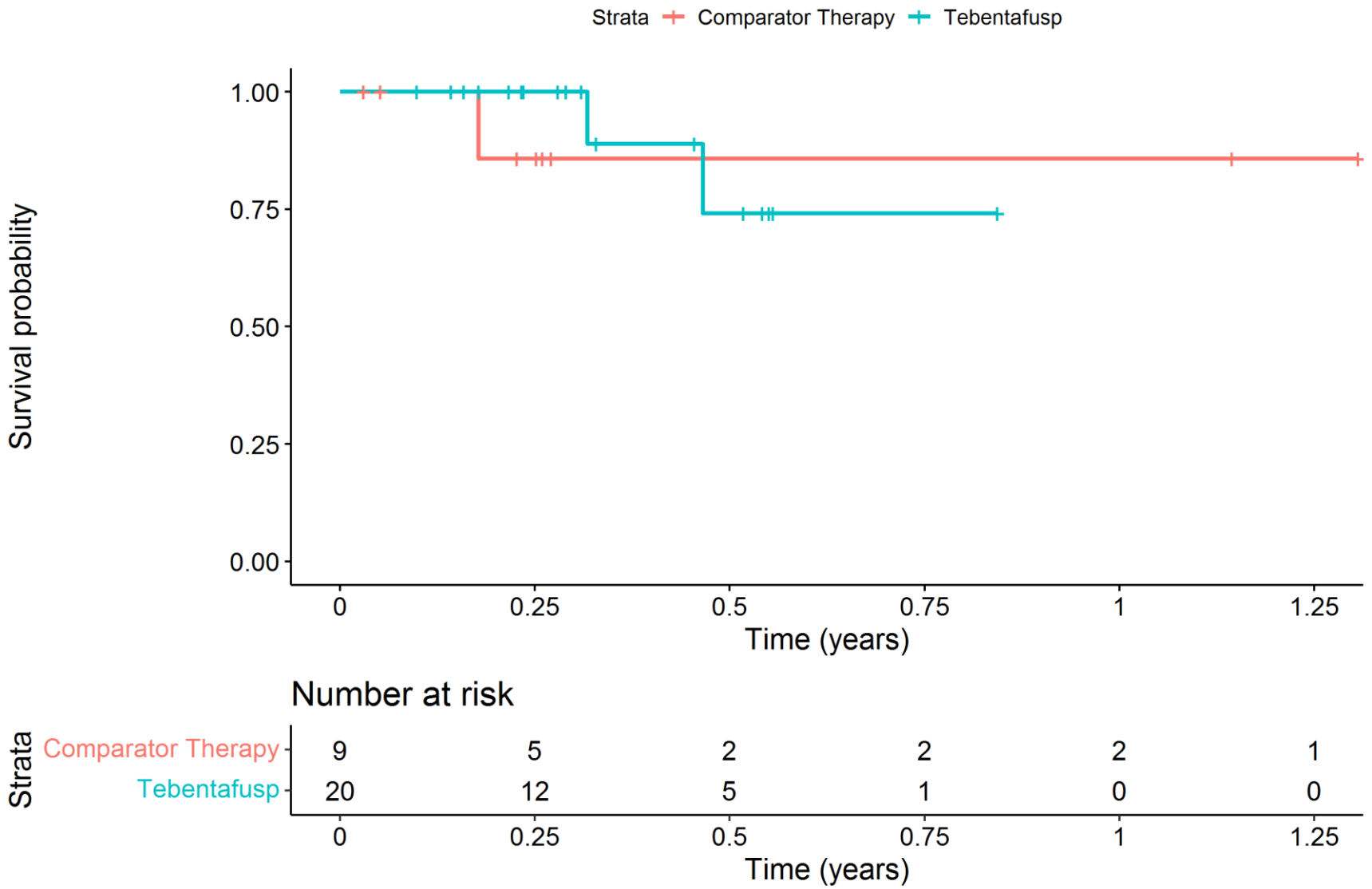
53.286 Hypophosphatämie - Läsion ≤ 3cm



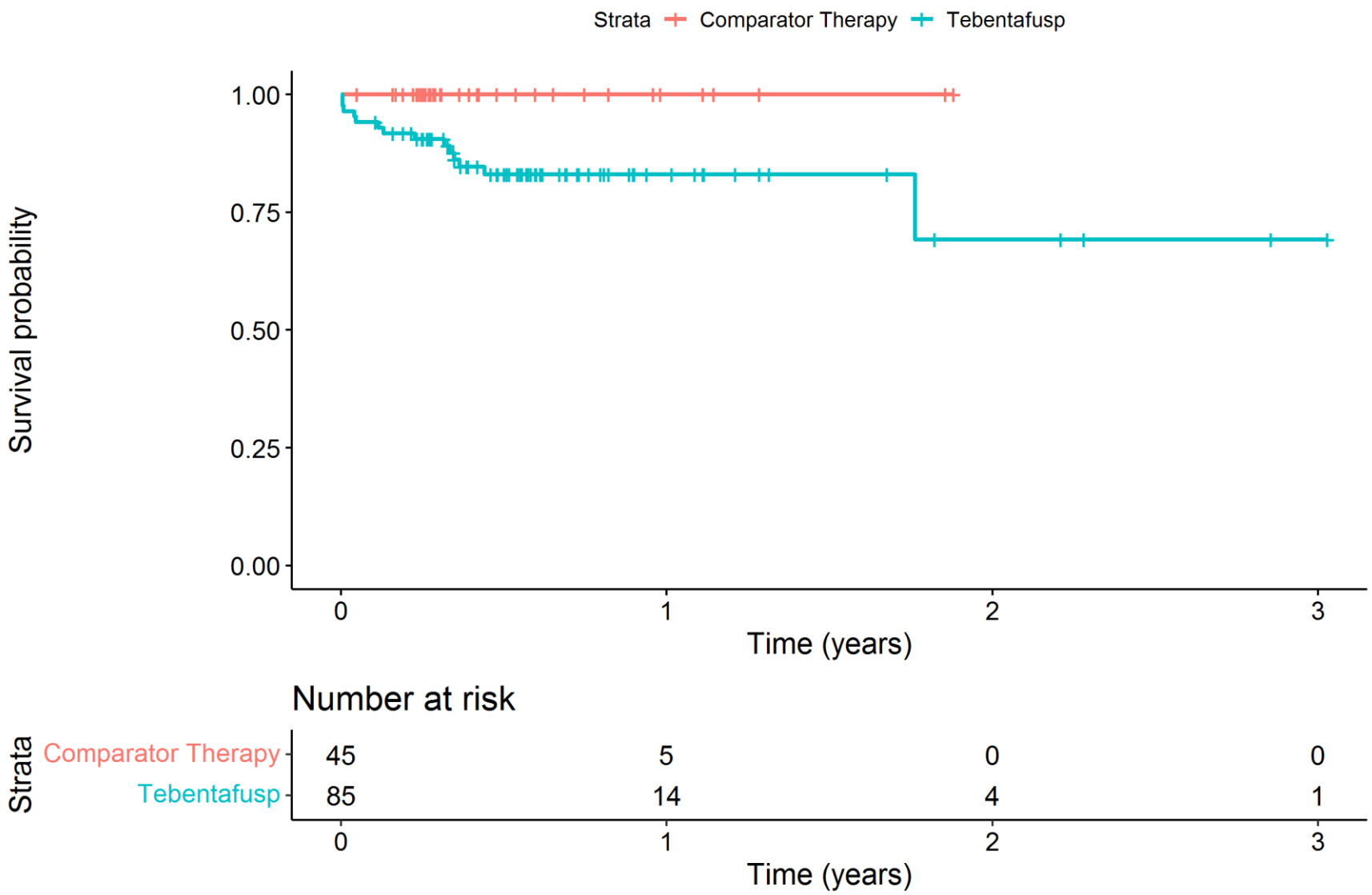
53.287 Hypophosphatämie - Läsion 3,1-8,0 cm



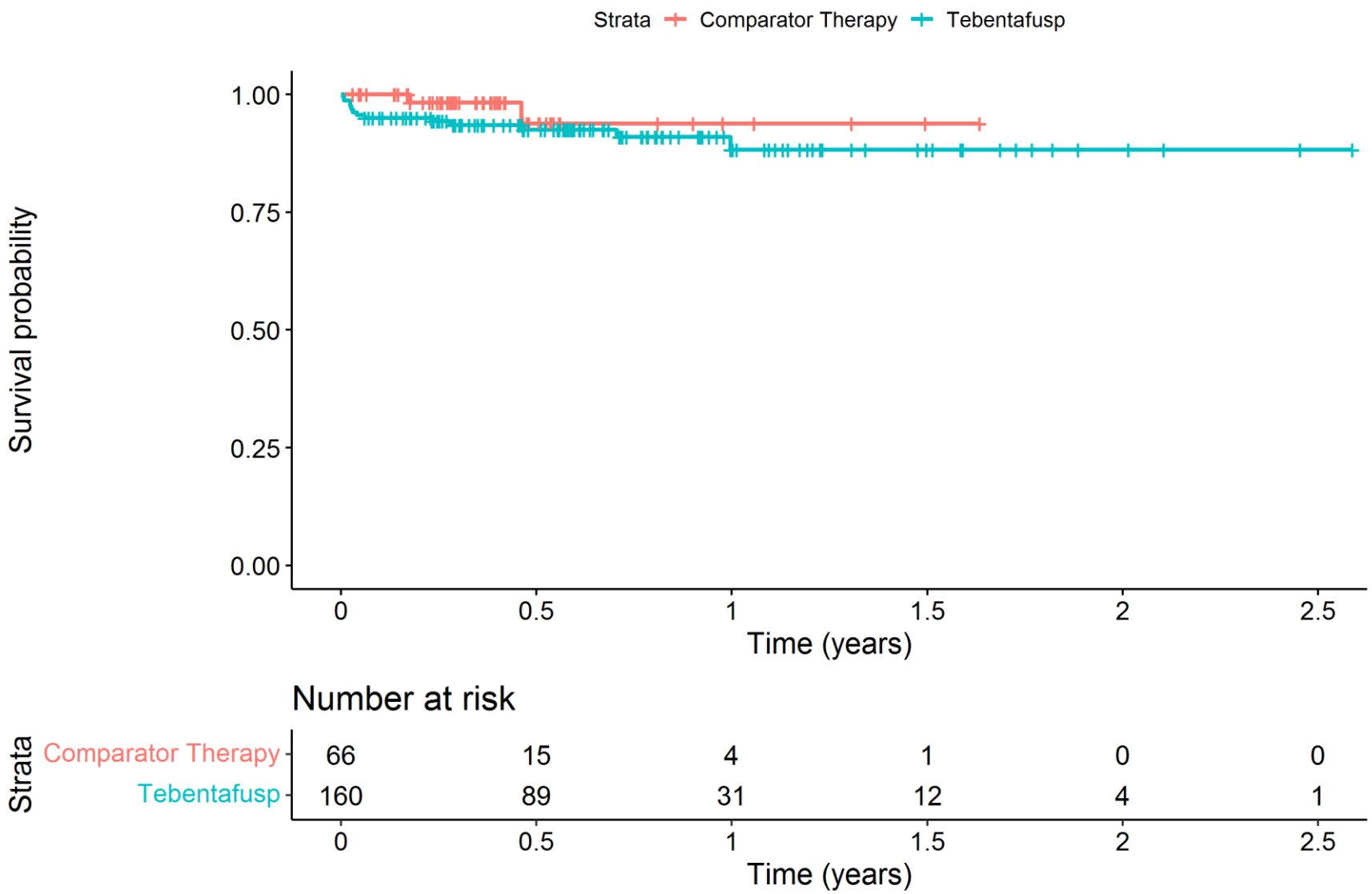
53.288 Hypophosphatämie - Läsion ≥8,1 cm



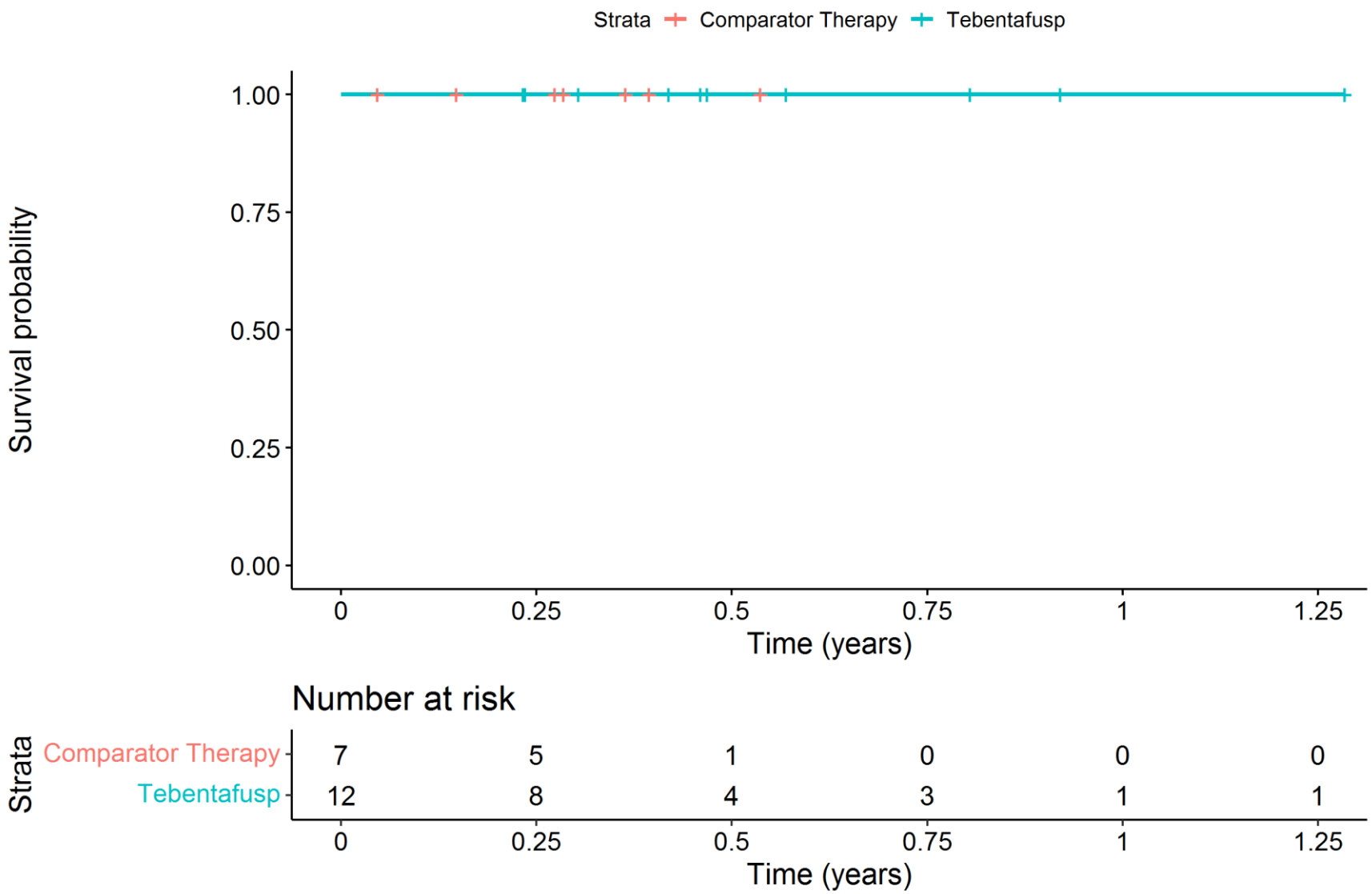
53.289 Hypophosphatämie - Nordamerika



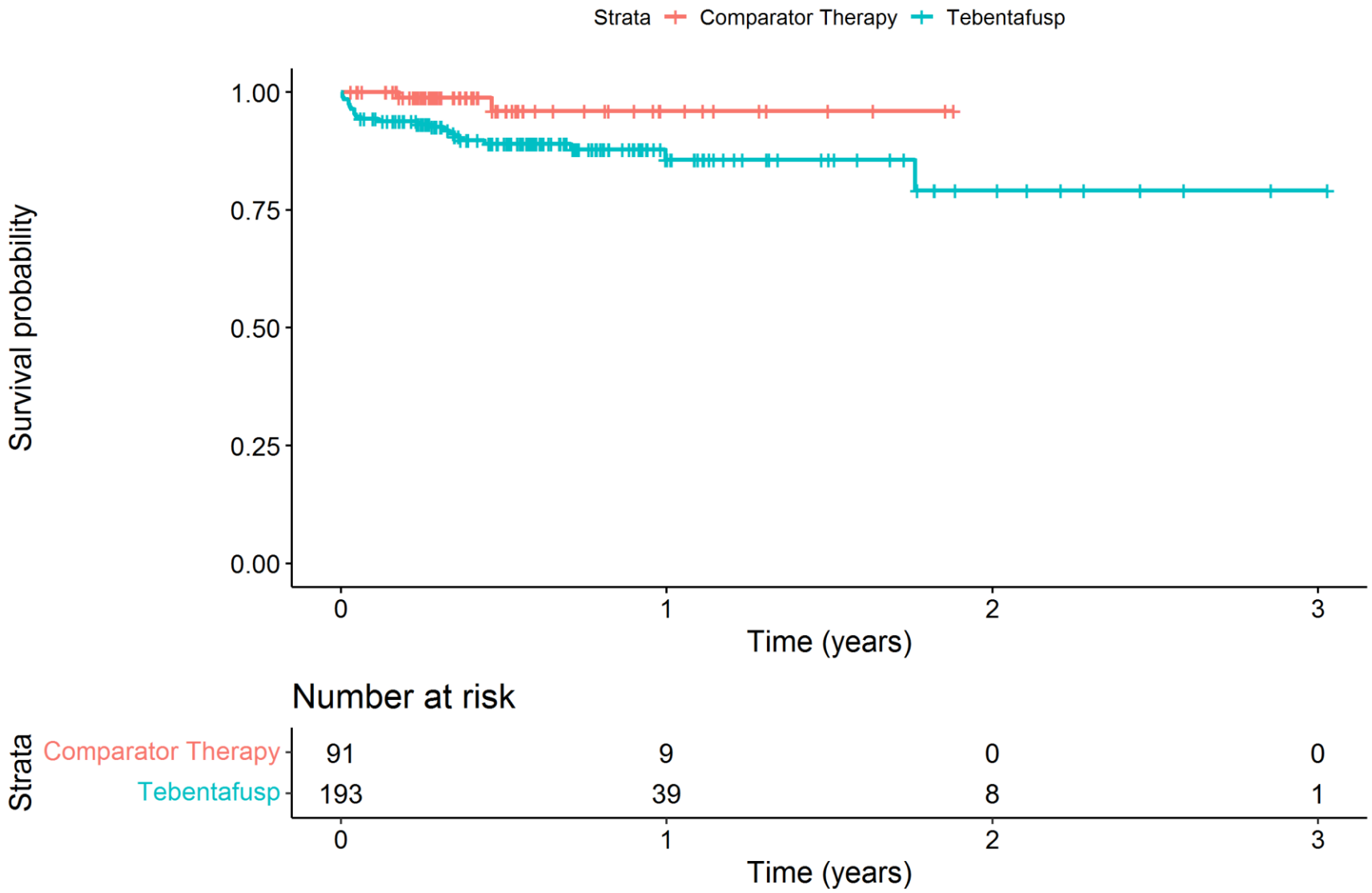
53.290 Hypophosphatämie - Nicht-Nordamerika



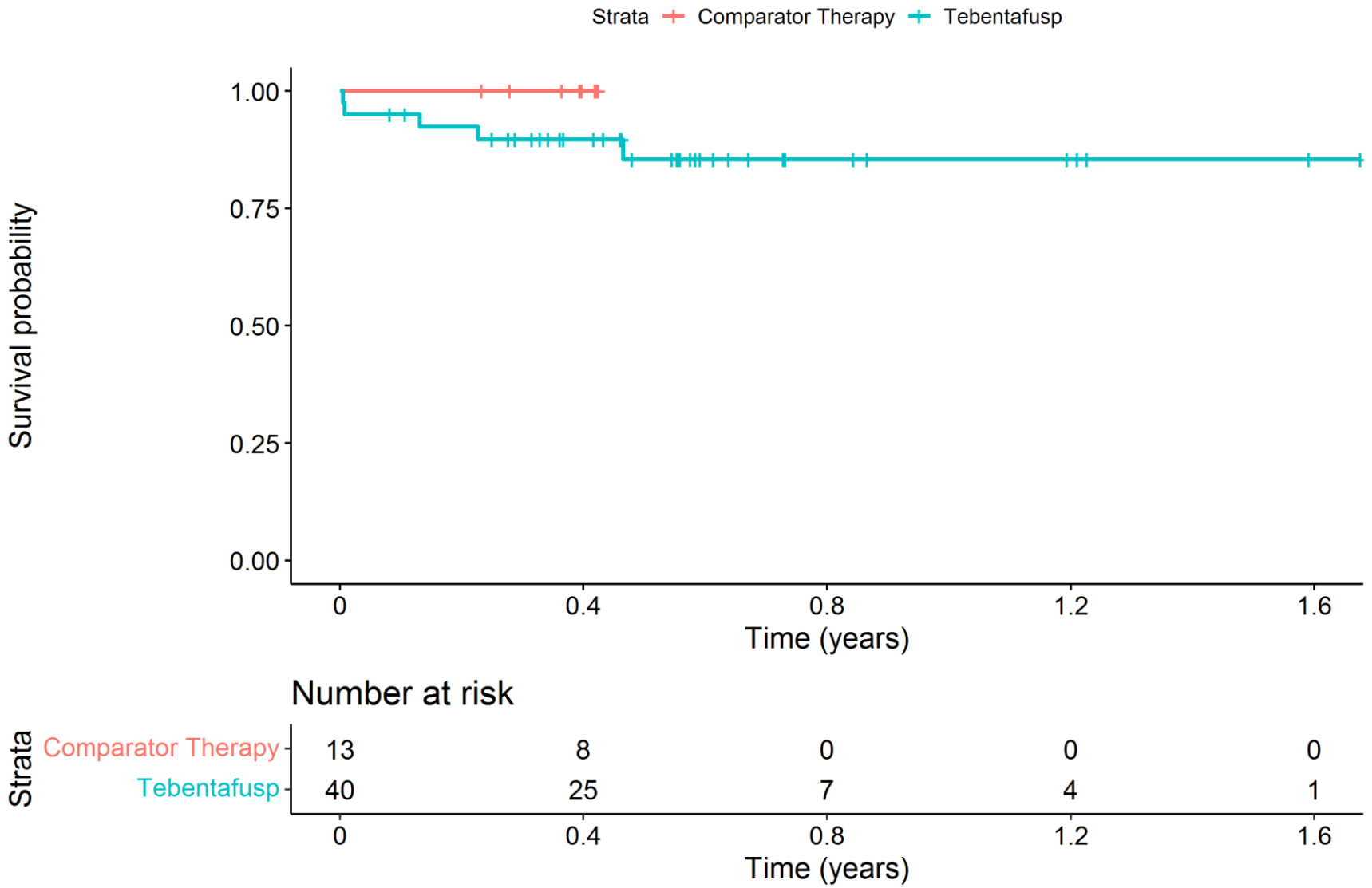
53.291 Hypophosphatämie - Dacarbazin



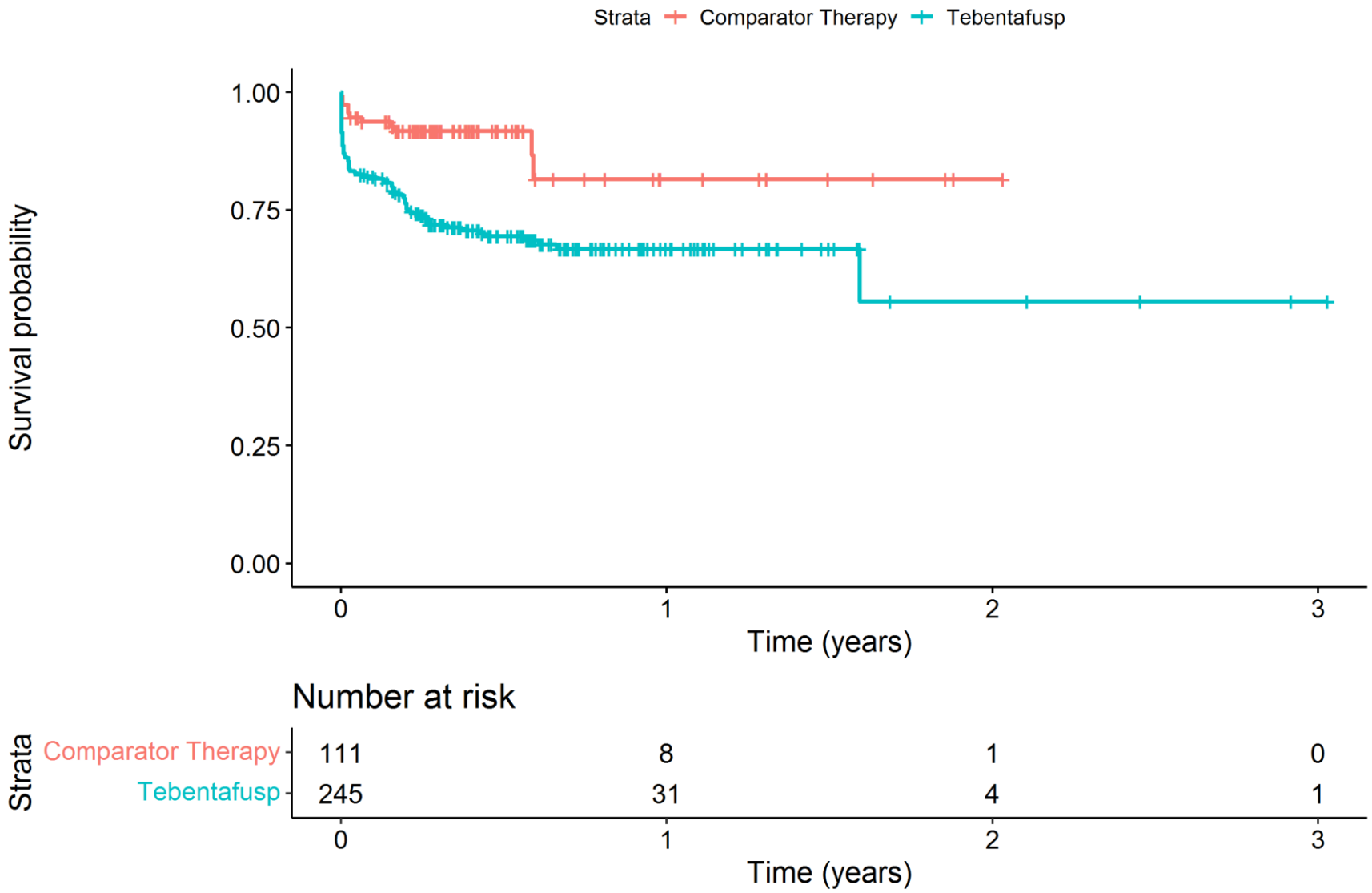
53.292 Hypophosphatämie - Pembrolizumab



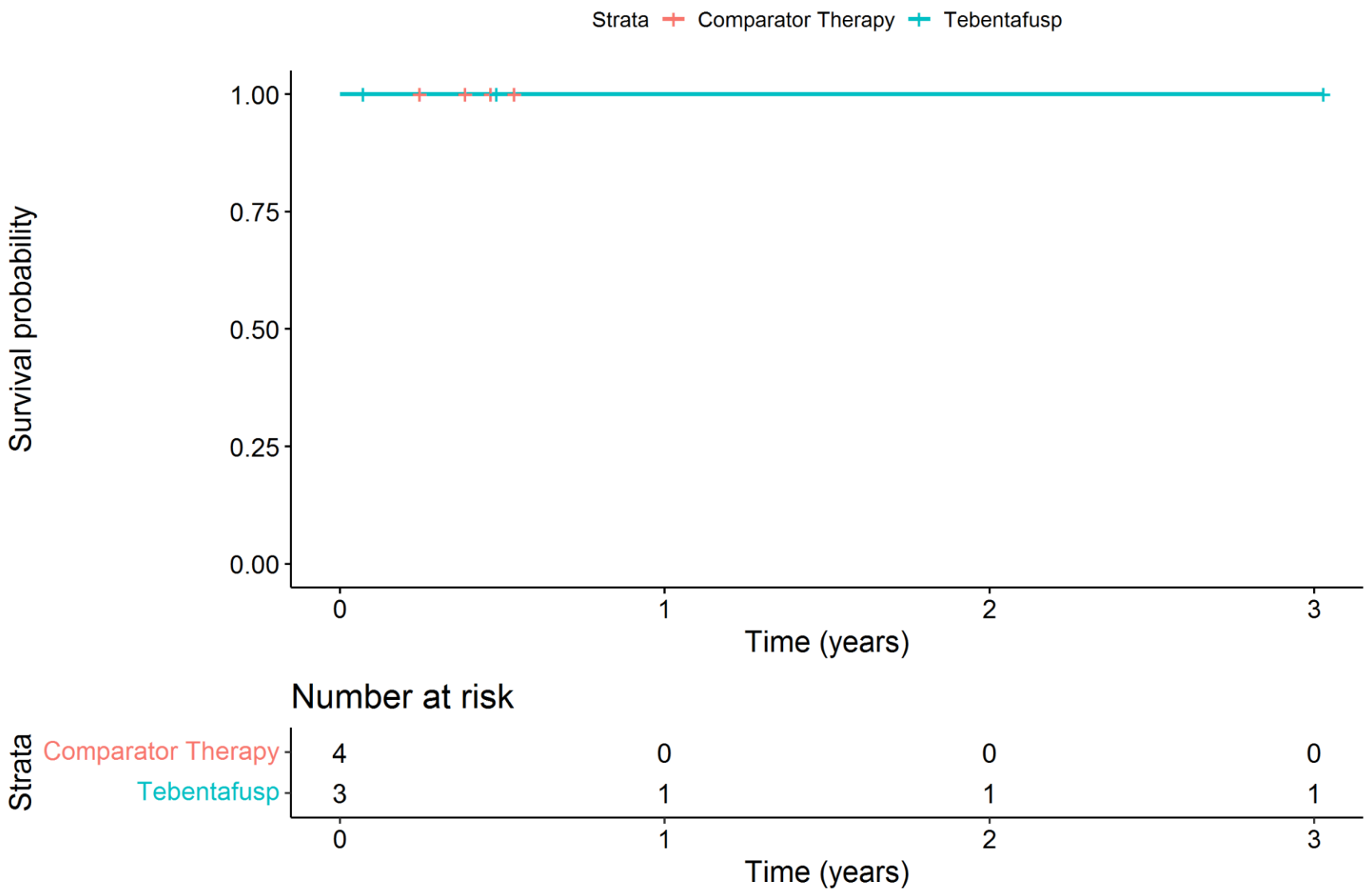
53.293 Hypophosphatämie - Ipilimumab



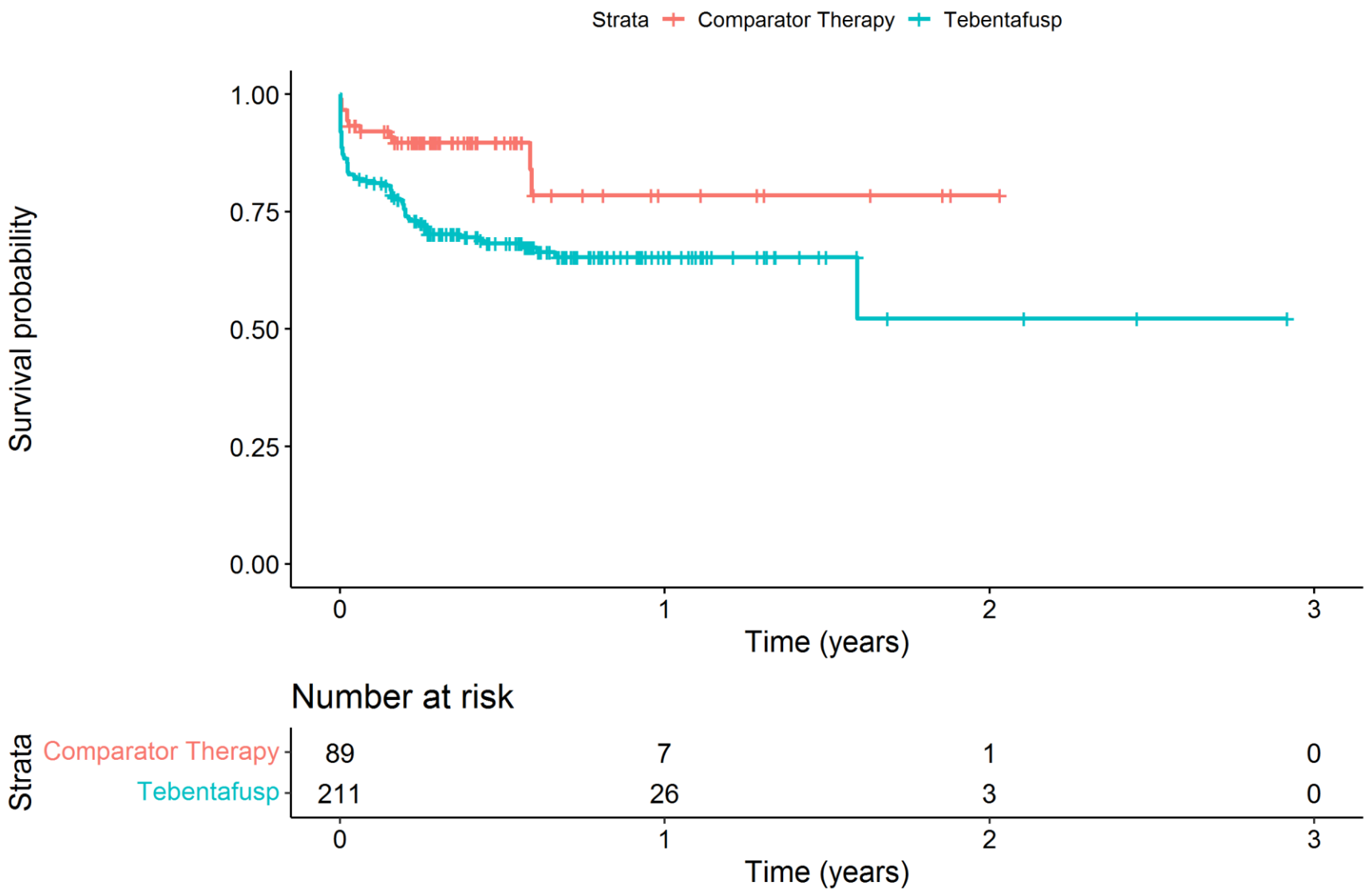
53.294 Kopfschmerzen - Gesamt



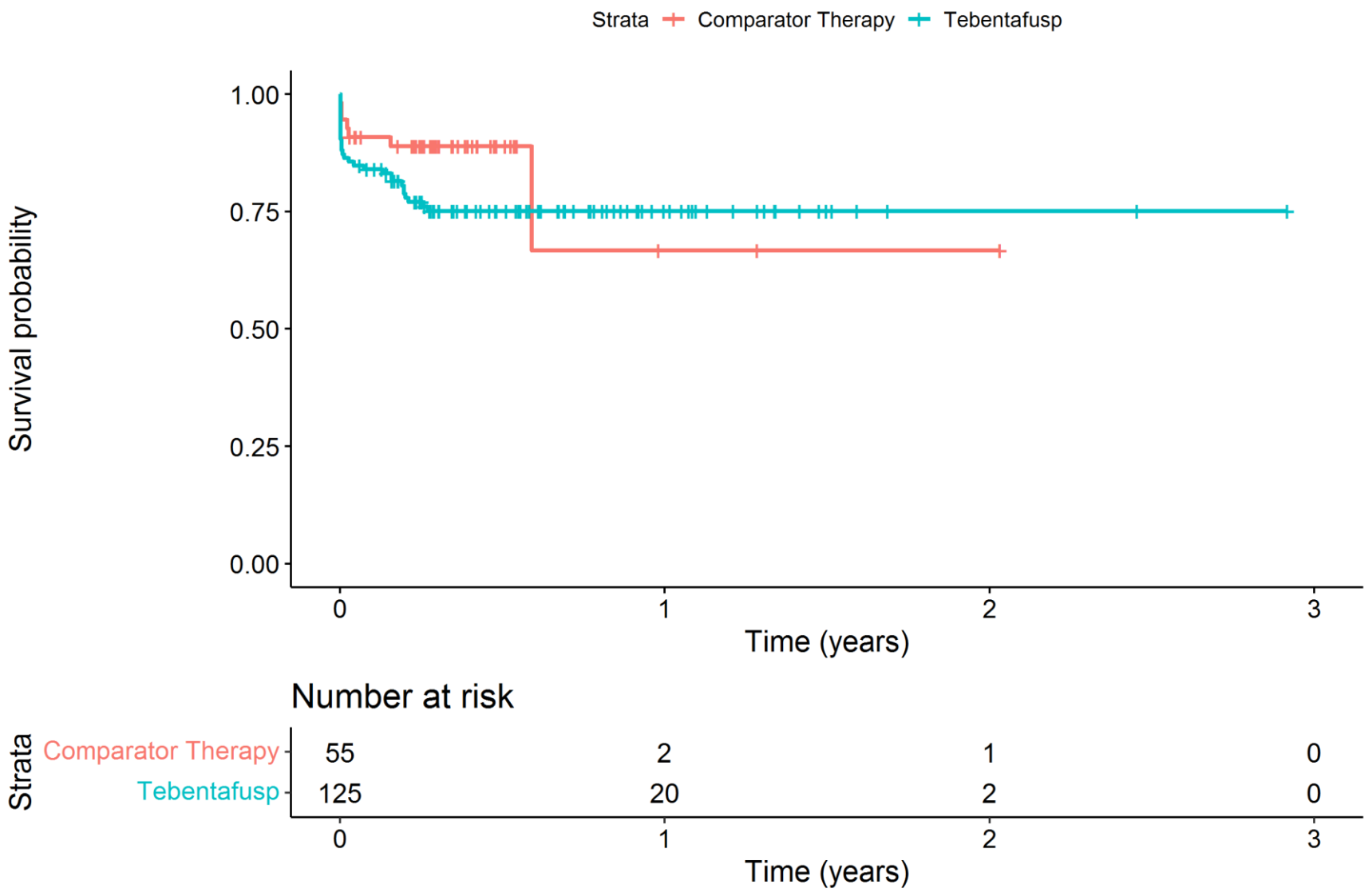
53.295 Kopfschmerzen - Hispanisch



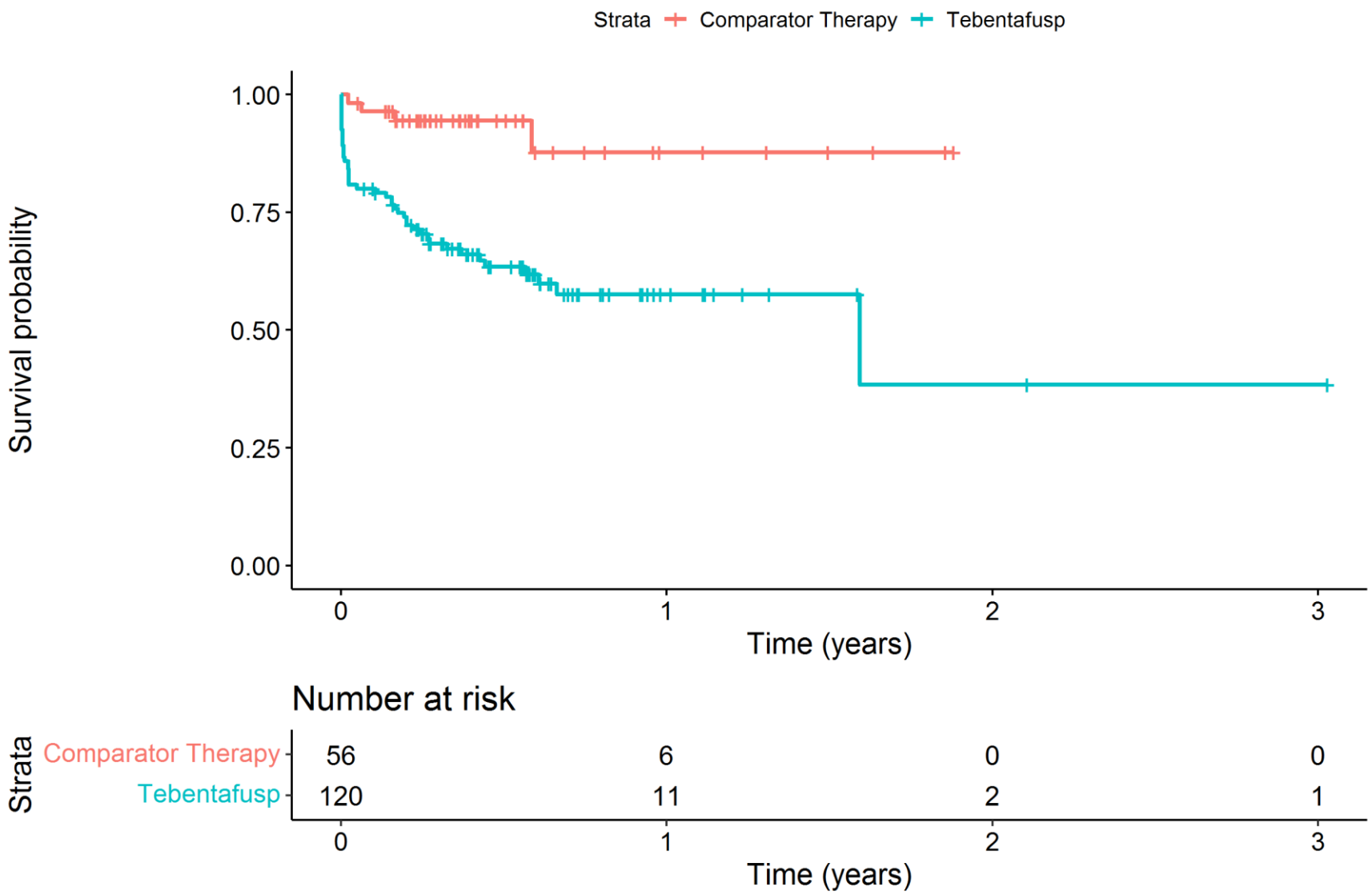
53.296 Kopfschmerzen - Nicht-hispanisch



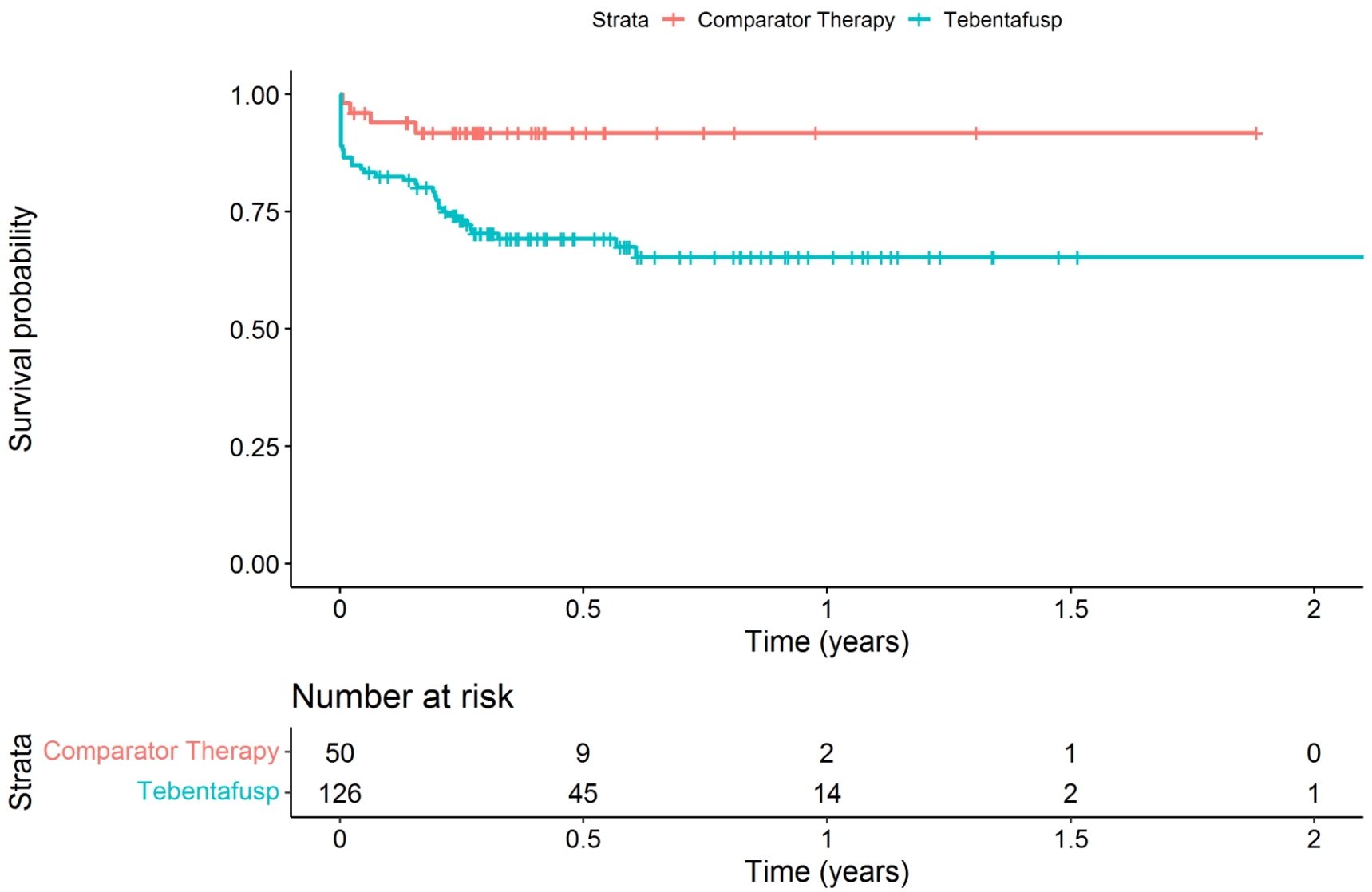
53.297 Kopfschmerzen - Männlich



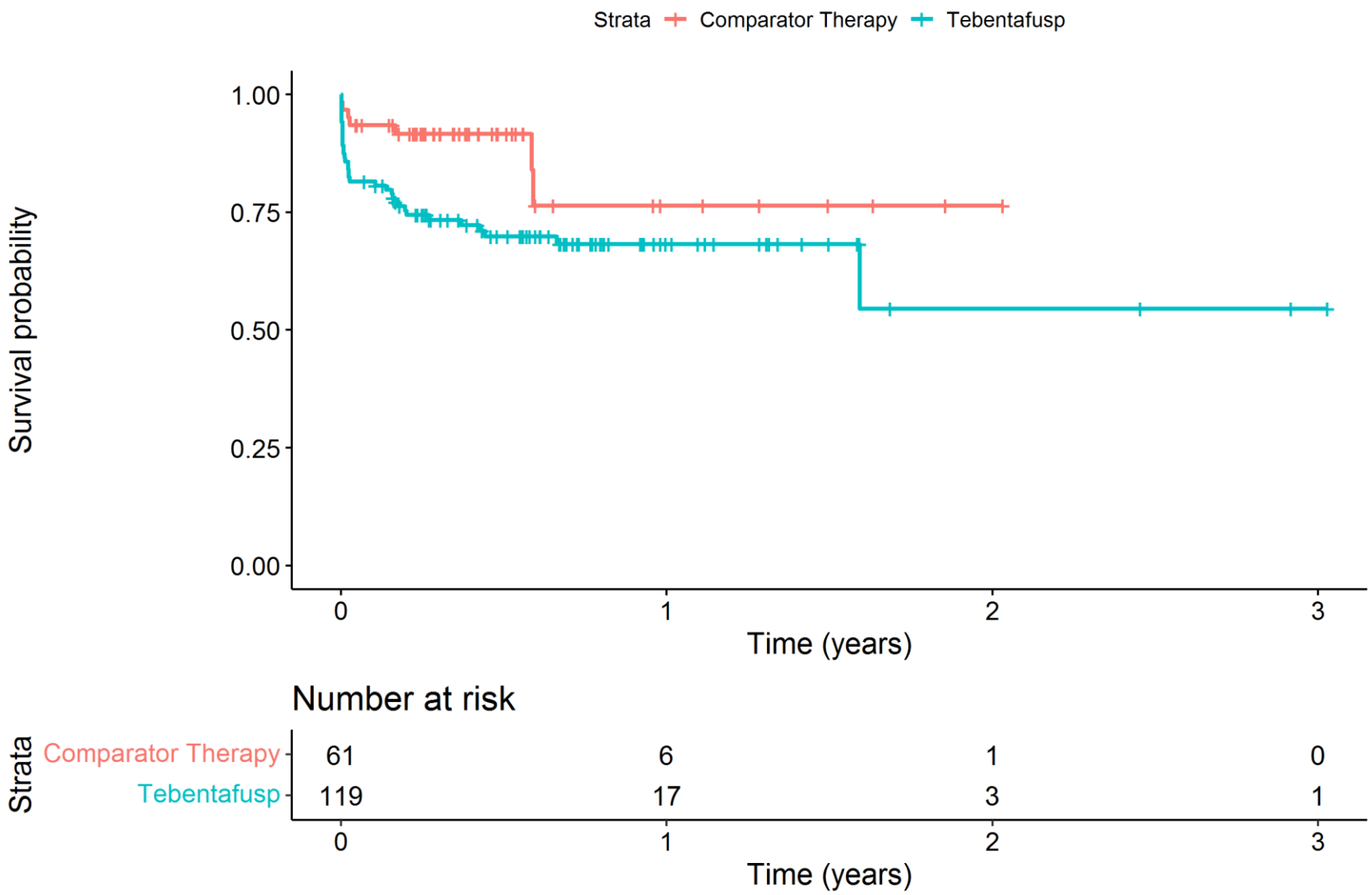
53.298 Kopfschmerzen - Weiblich



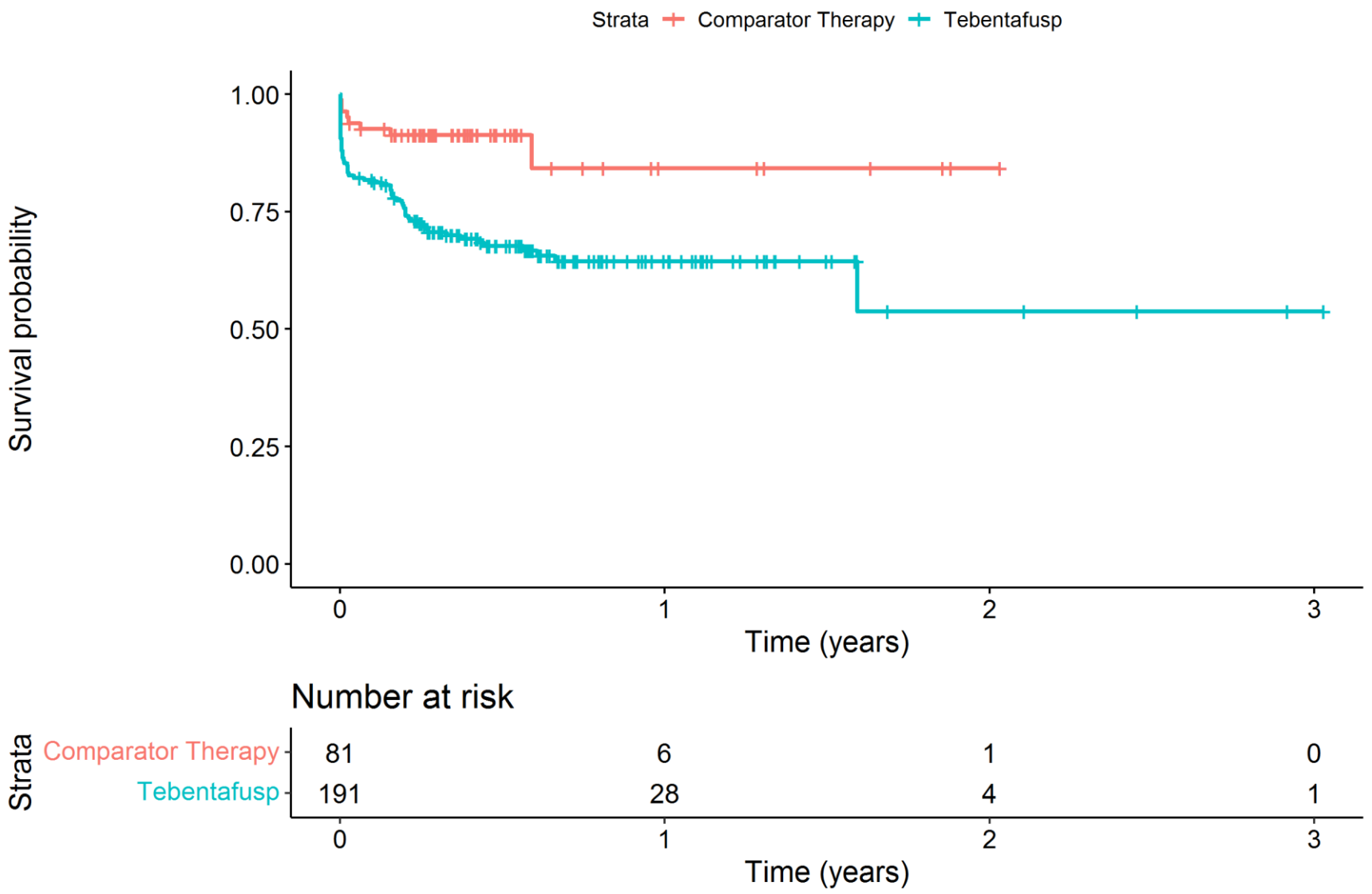
53.299 Kopfschmerzen - <65



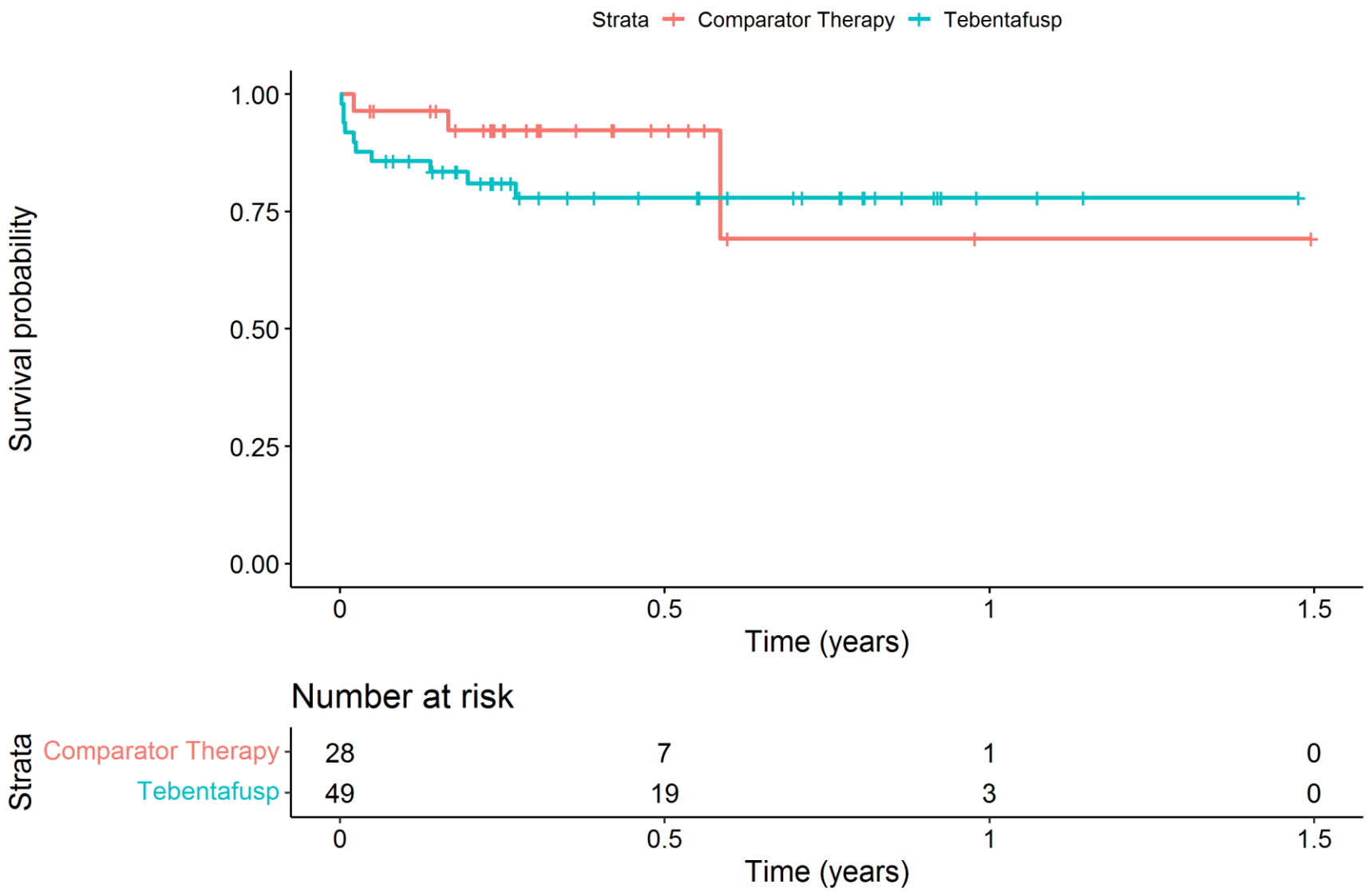
53.300 Kopfschmerzen - ≥65



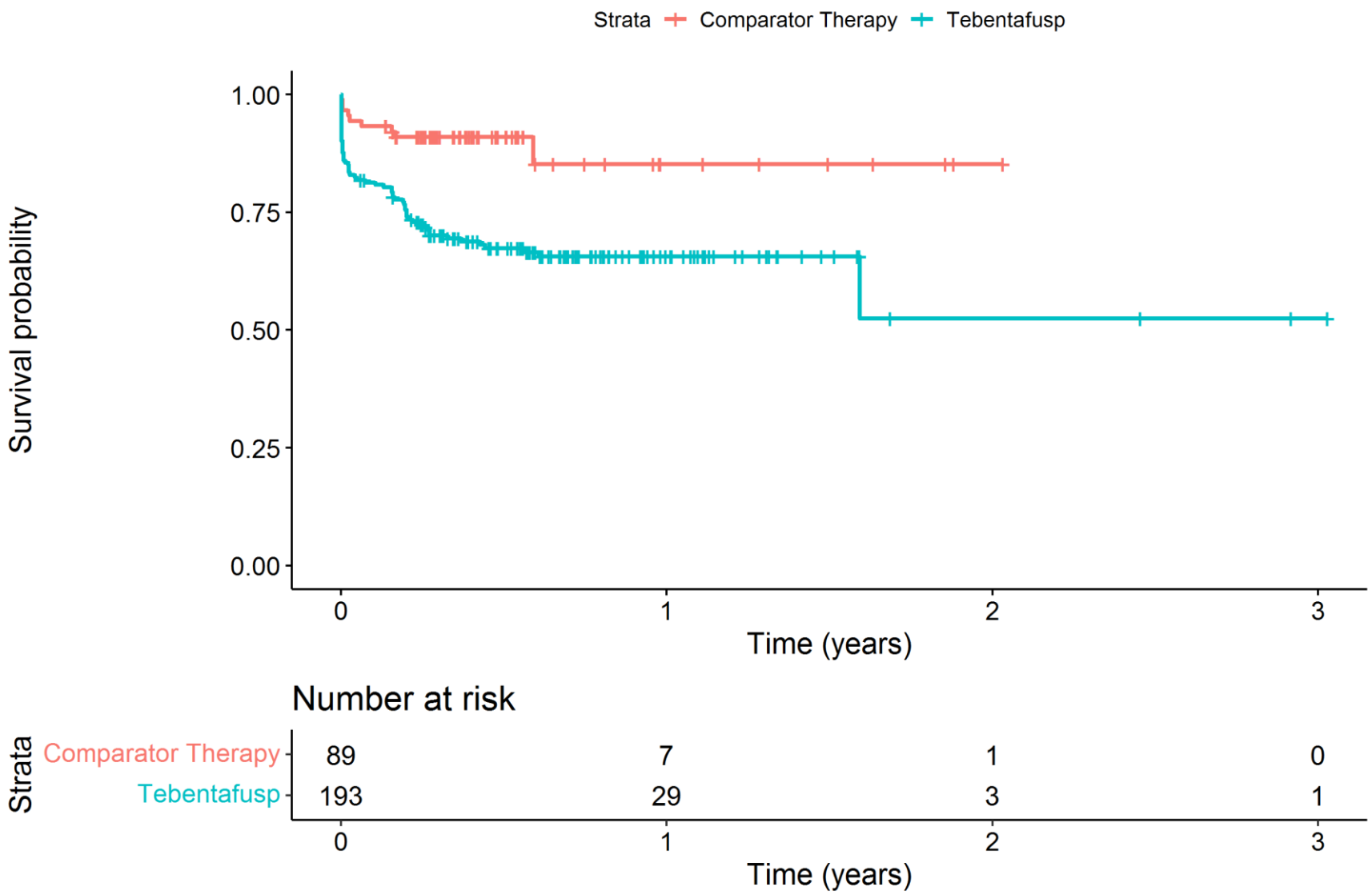
53.301 Kopfschmerzen - ECOG 0



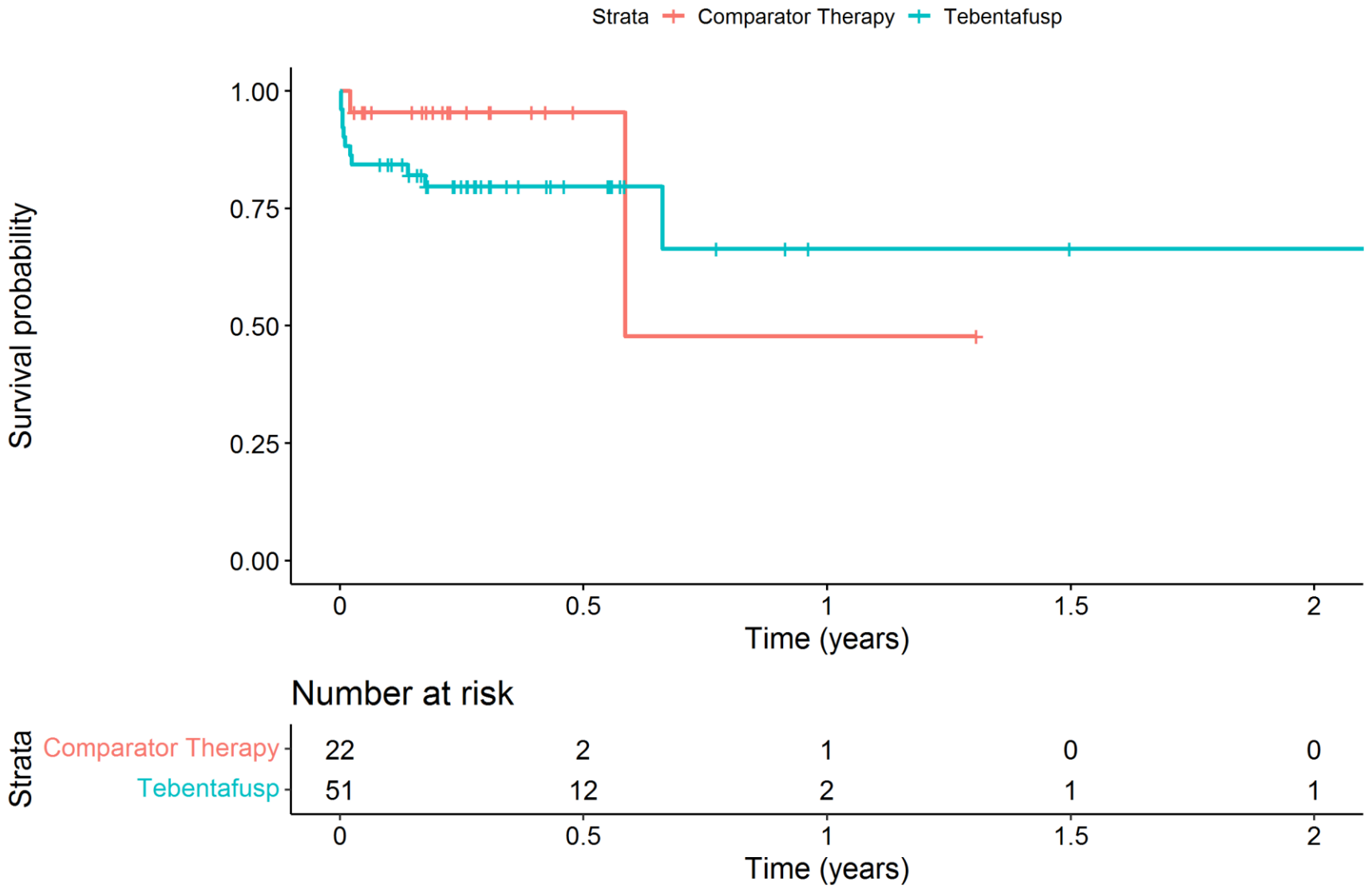
53.302 Kopfschmerzen - ECOG 1



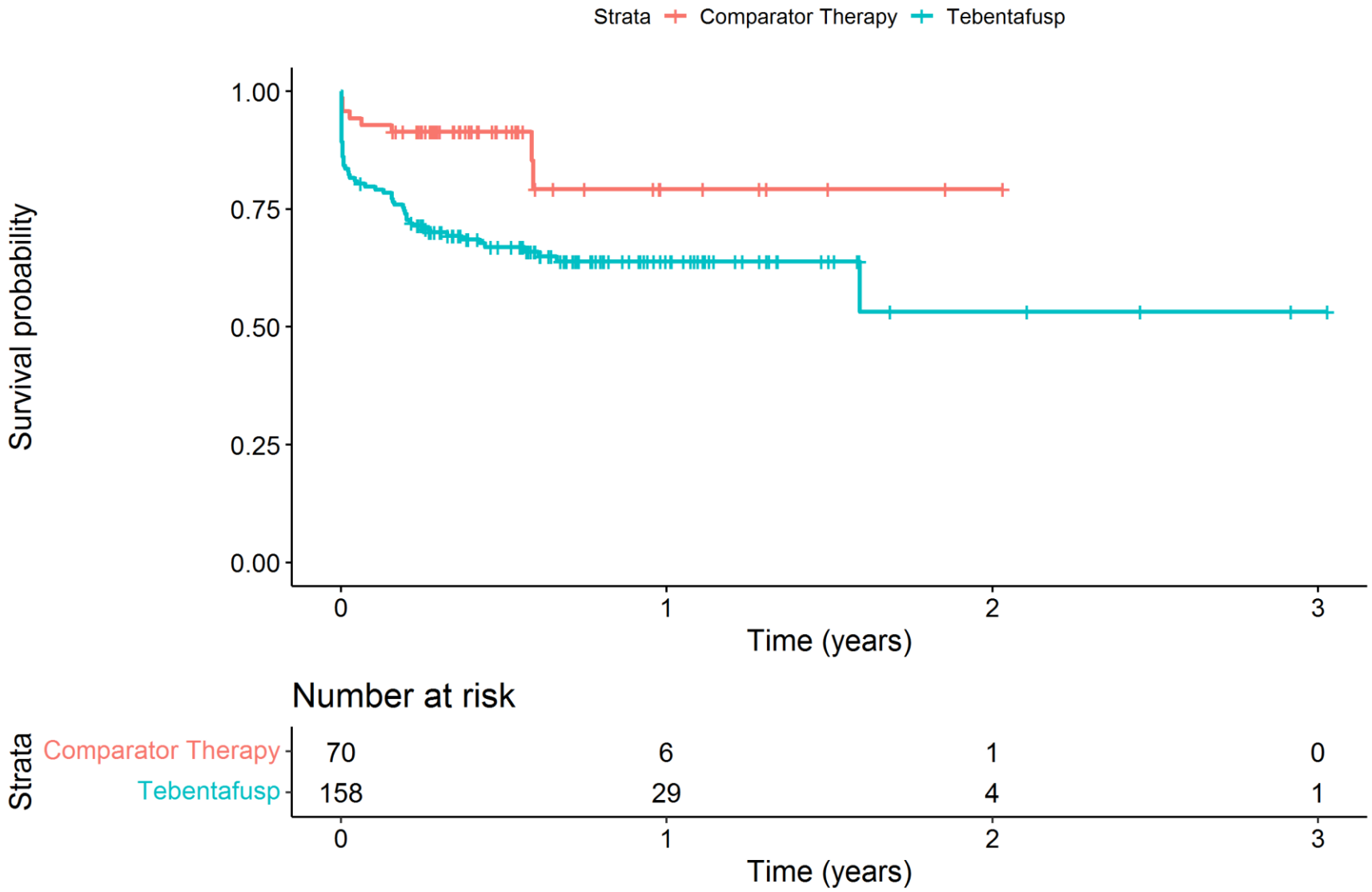
53.303 Kopfschmerzen - ALP ≤ ULN



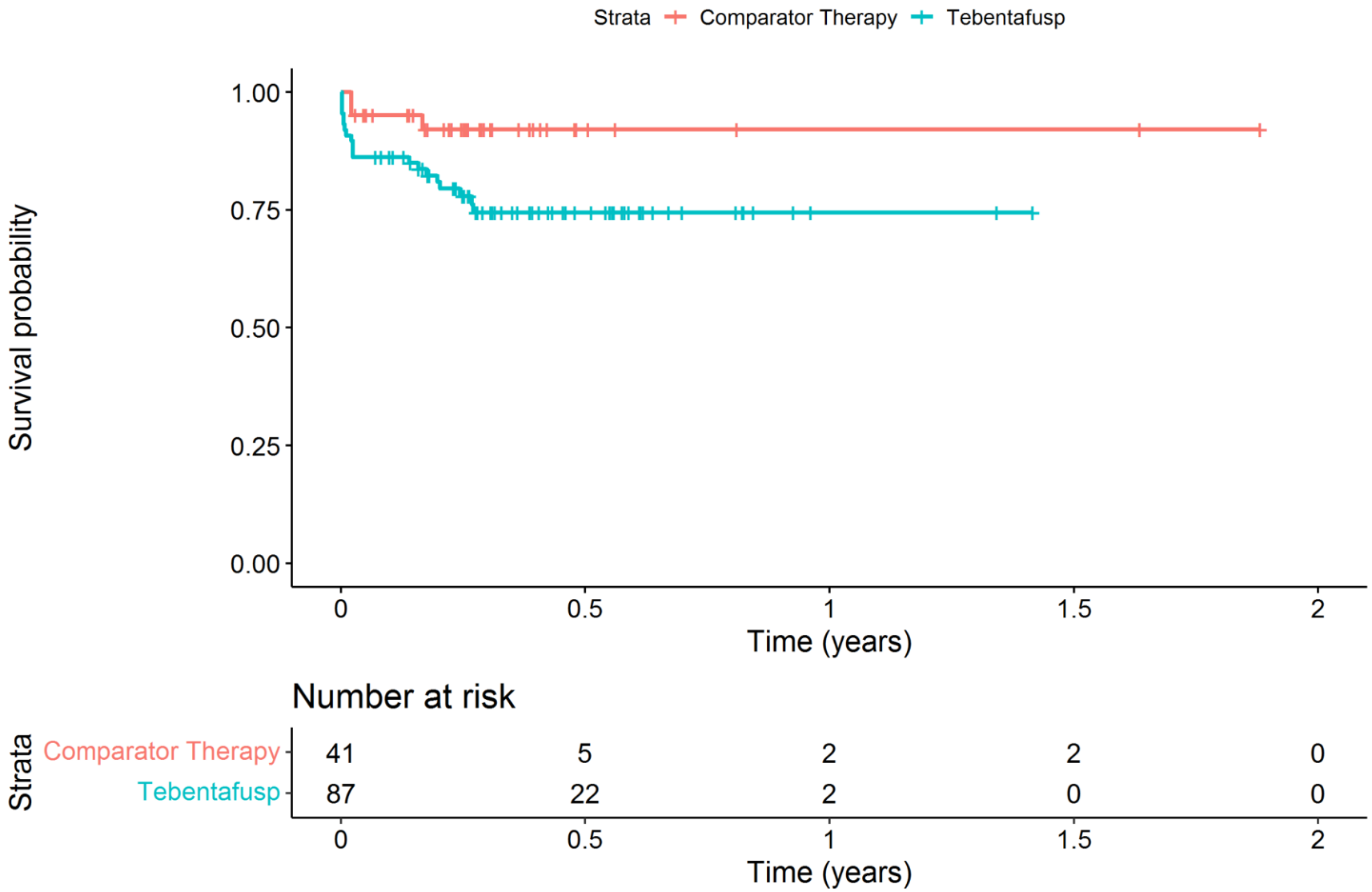
53.304 Kopfschmerzen - ALP > ULN



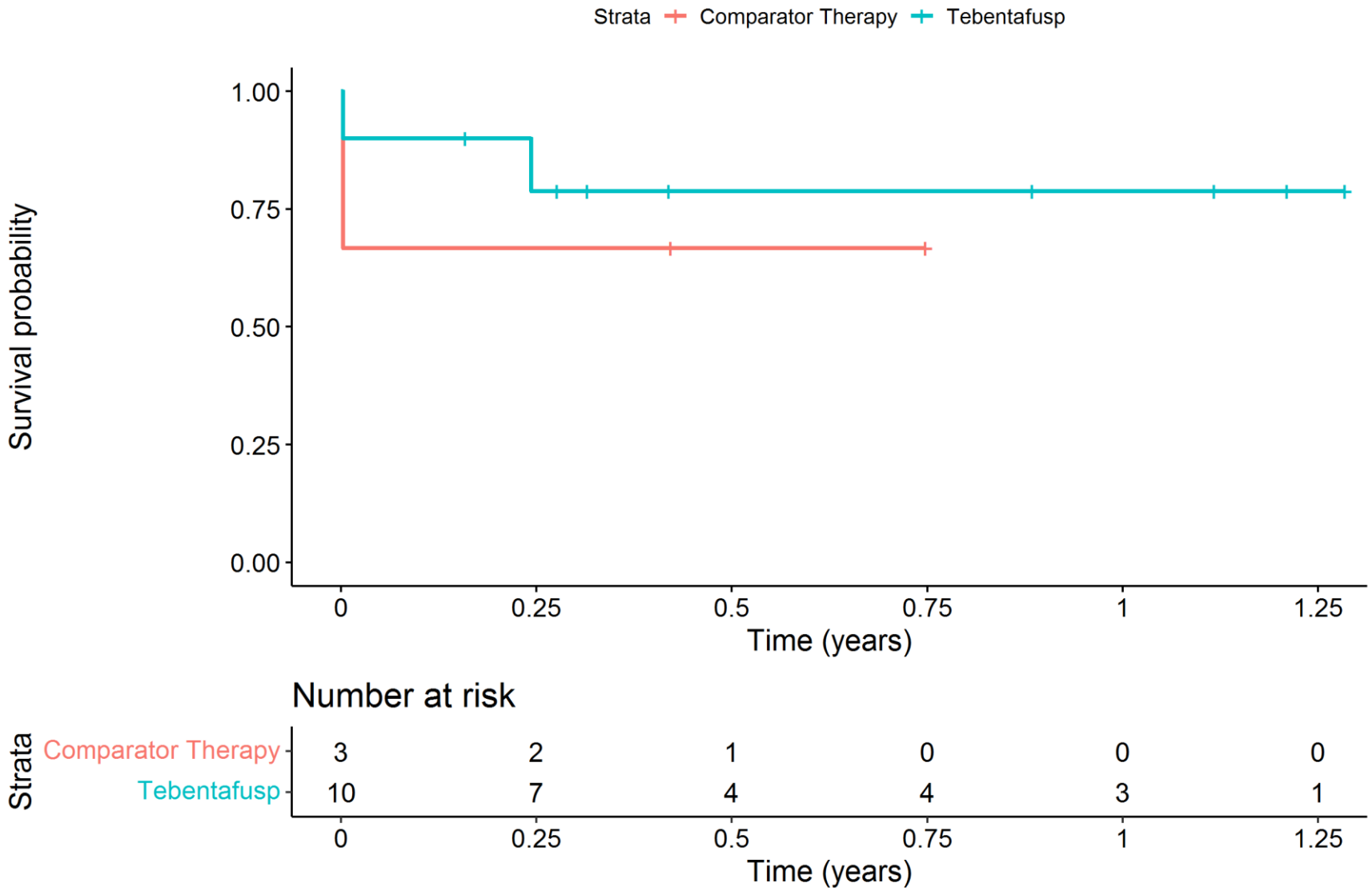
53.305 Kopfschmerzen - LDH =< ULN



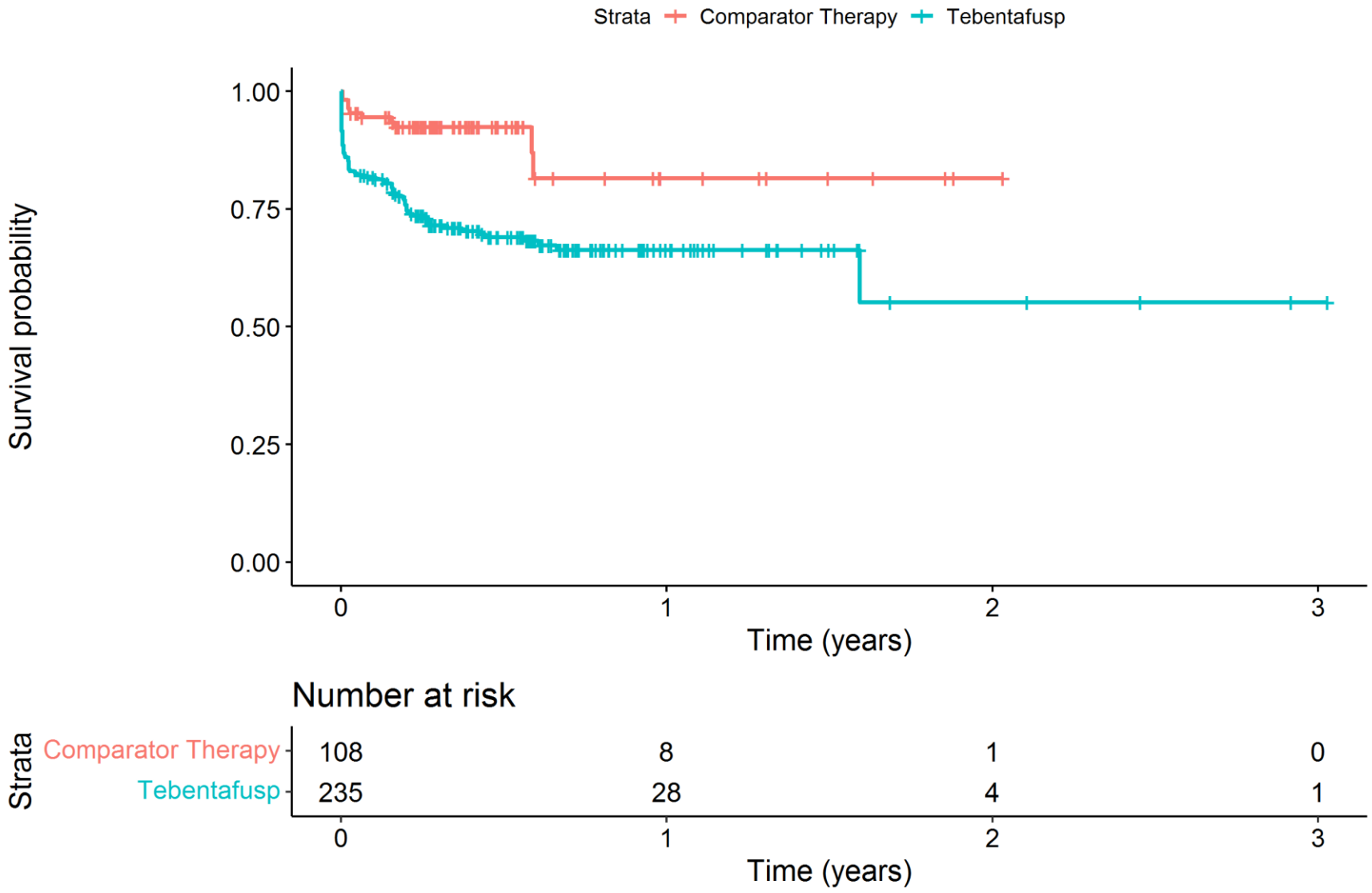
53.306 Kopfschmerzen - LDH > ULN



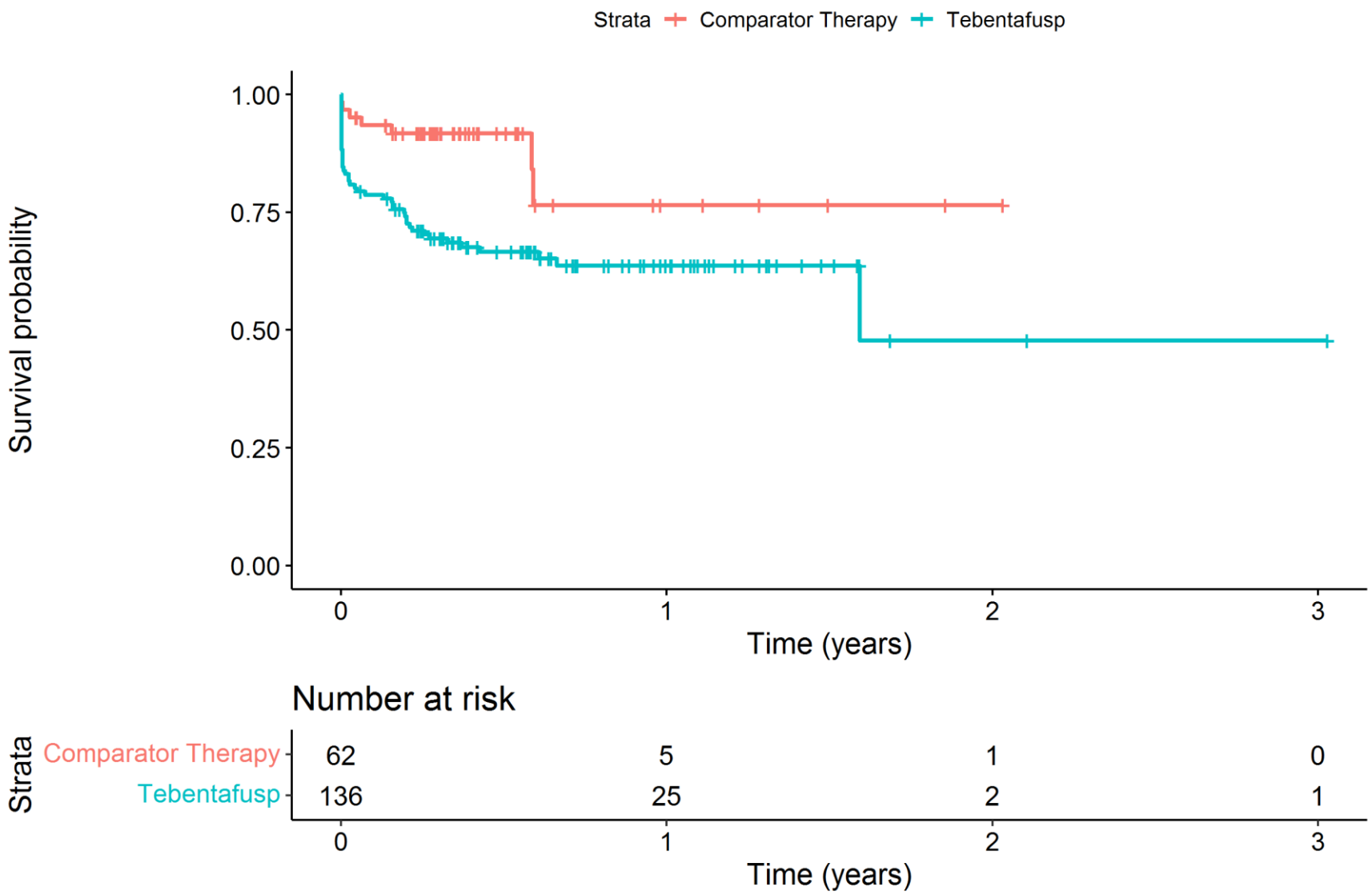
53.307 Kopfschmerzen - Vorherige Therapie adjuvant/neoadjuvant



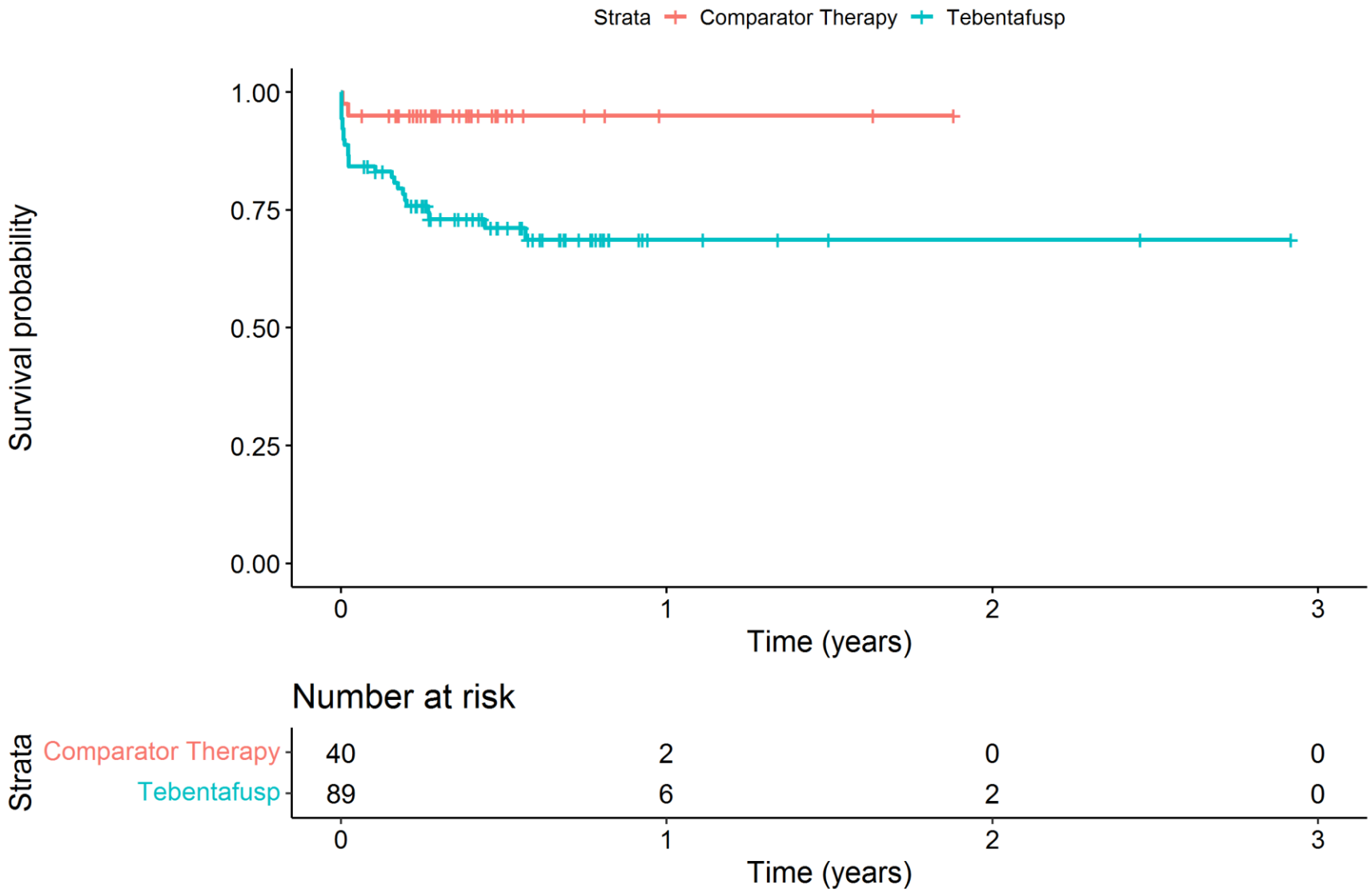
53.308 Kopfschmerzen - Keine vorherige Therapie adjuvant/neoadjuvant



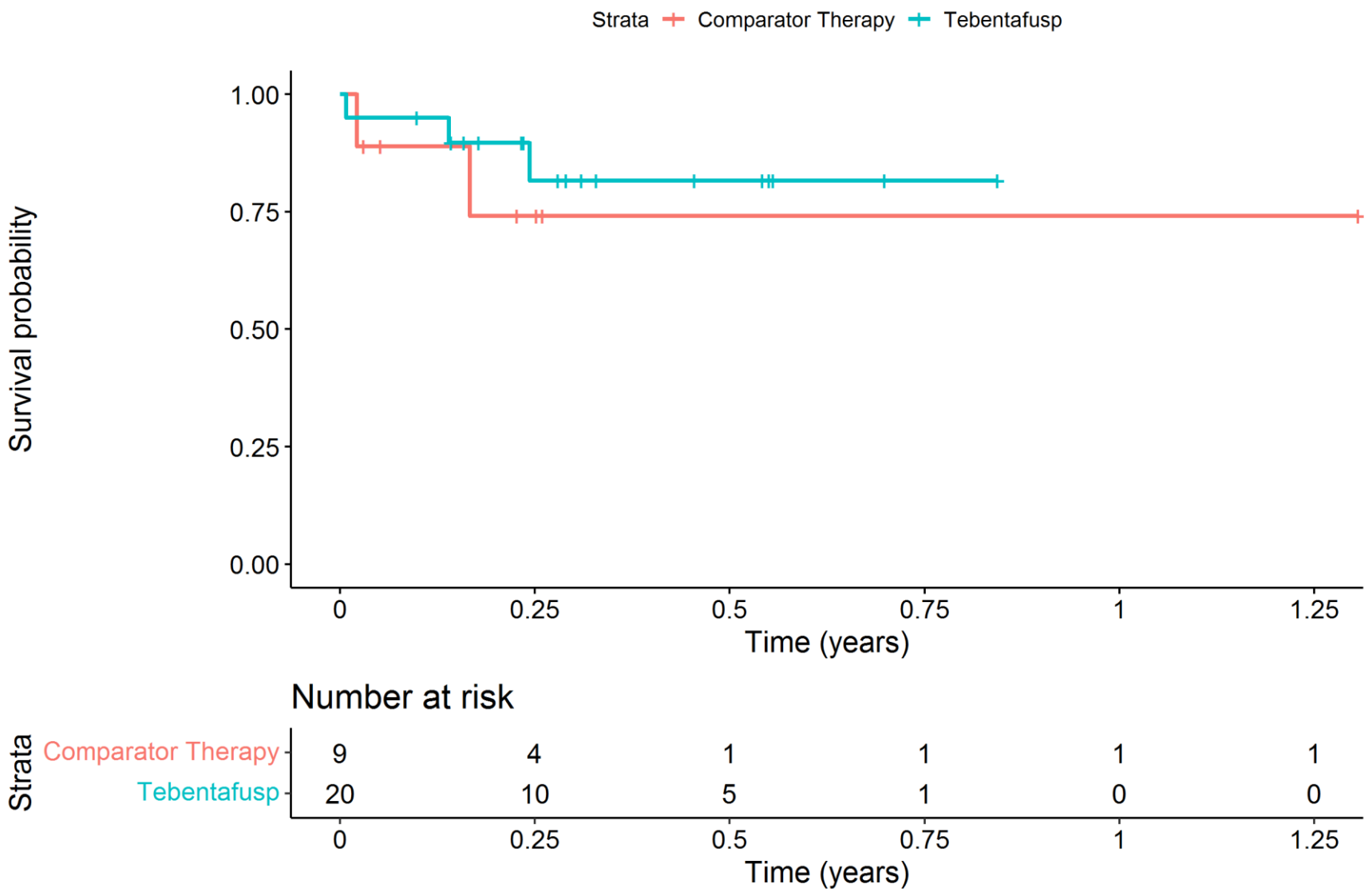
53.309 Kopfschmerzen - Läsion ≤ 3cm



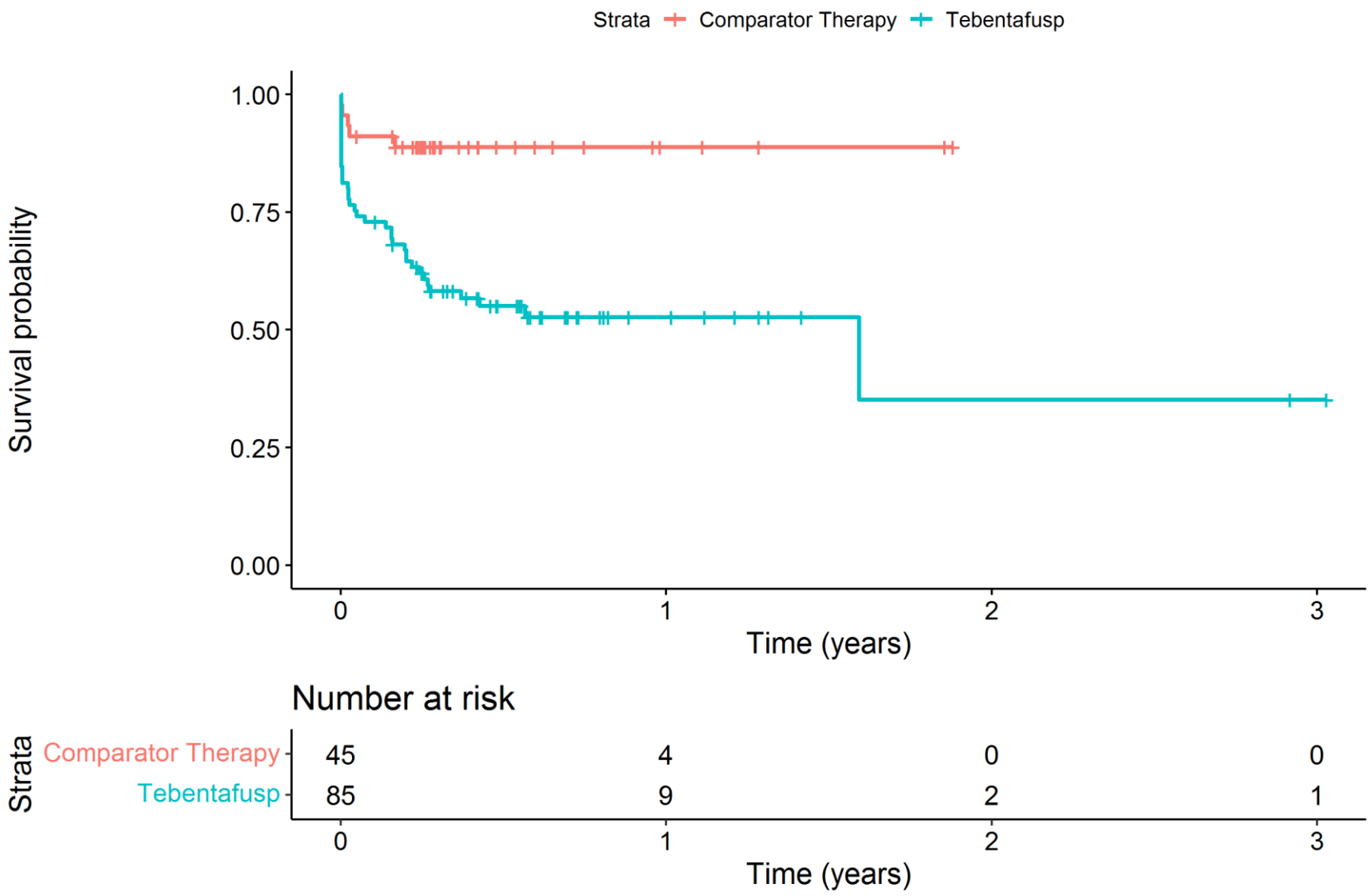
53.310 Kopfschmerzen - Läsion 3,1-8,0 cm



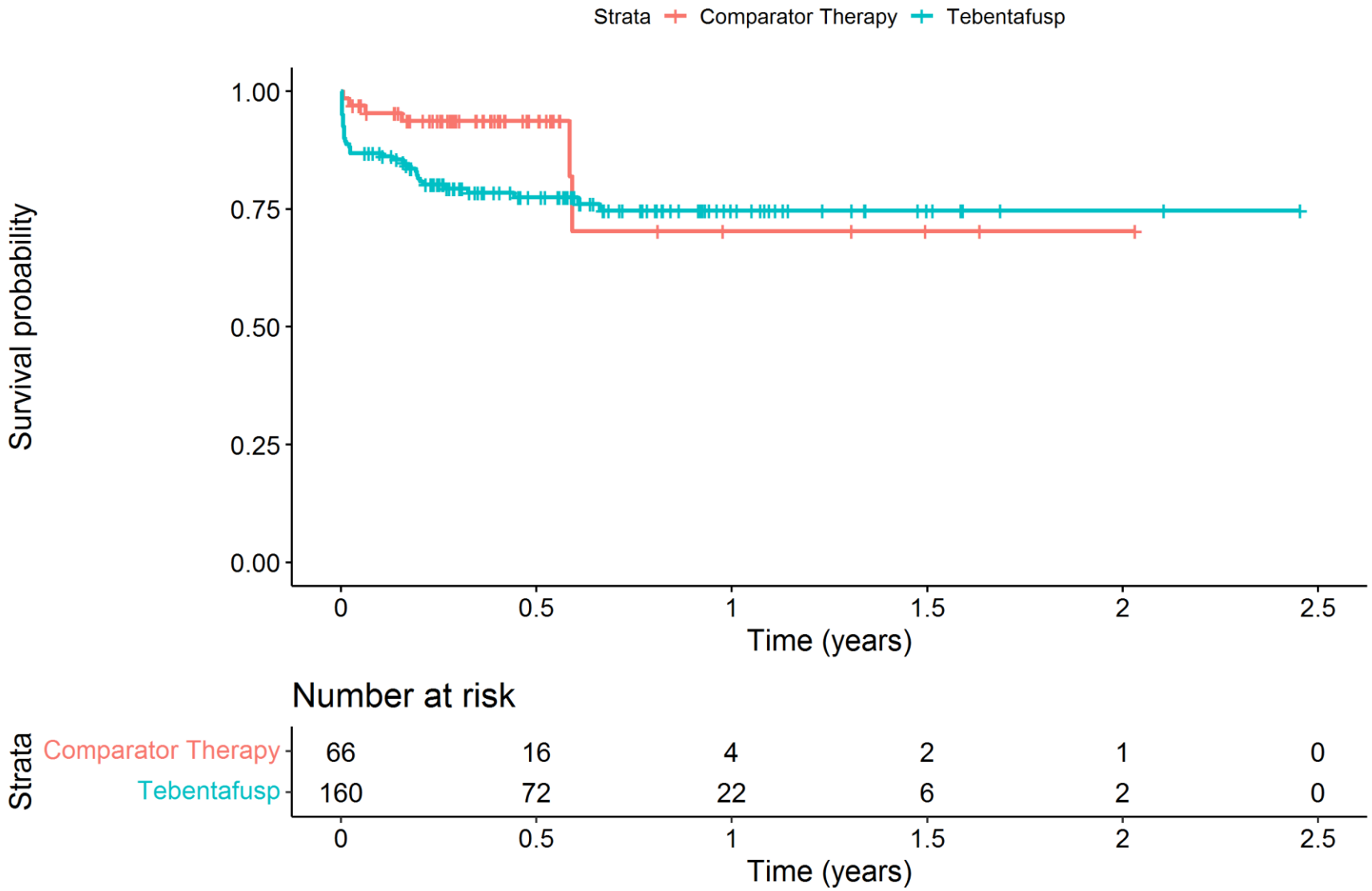
53.311 Kopfschmerzen - Läsion ≥8,1 cm



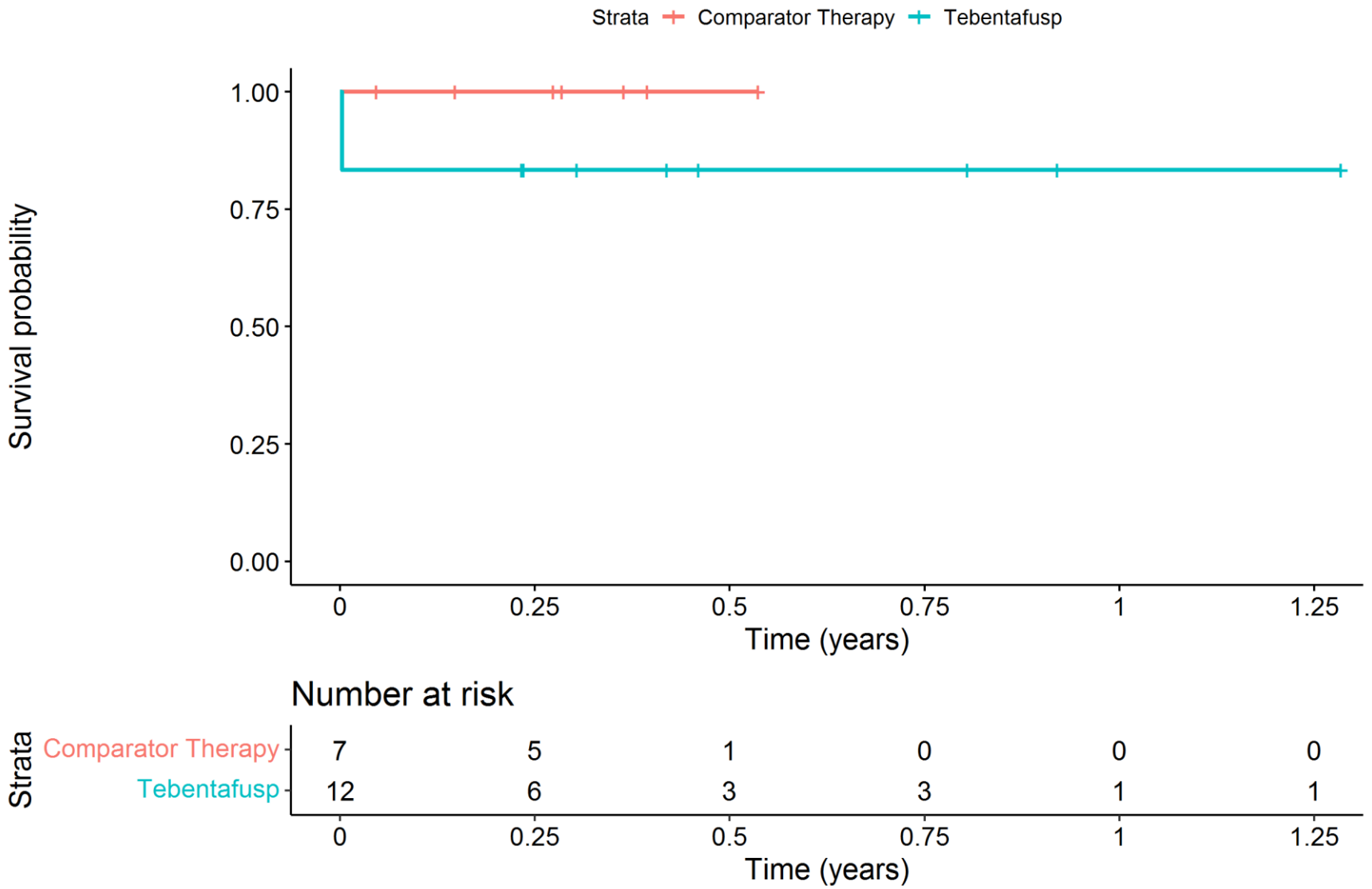
53.312 Kopfschmerzen - Nordamerika



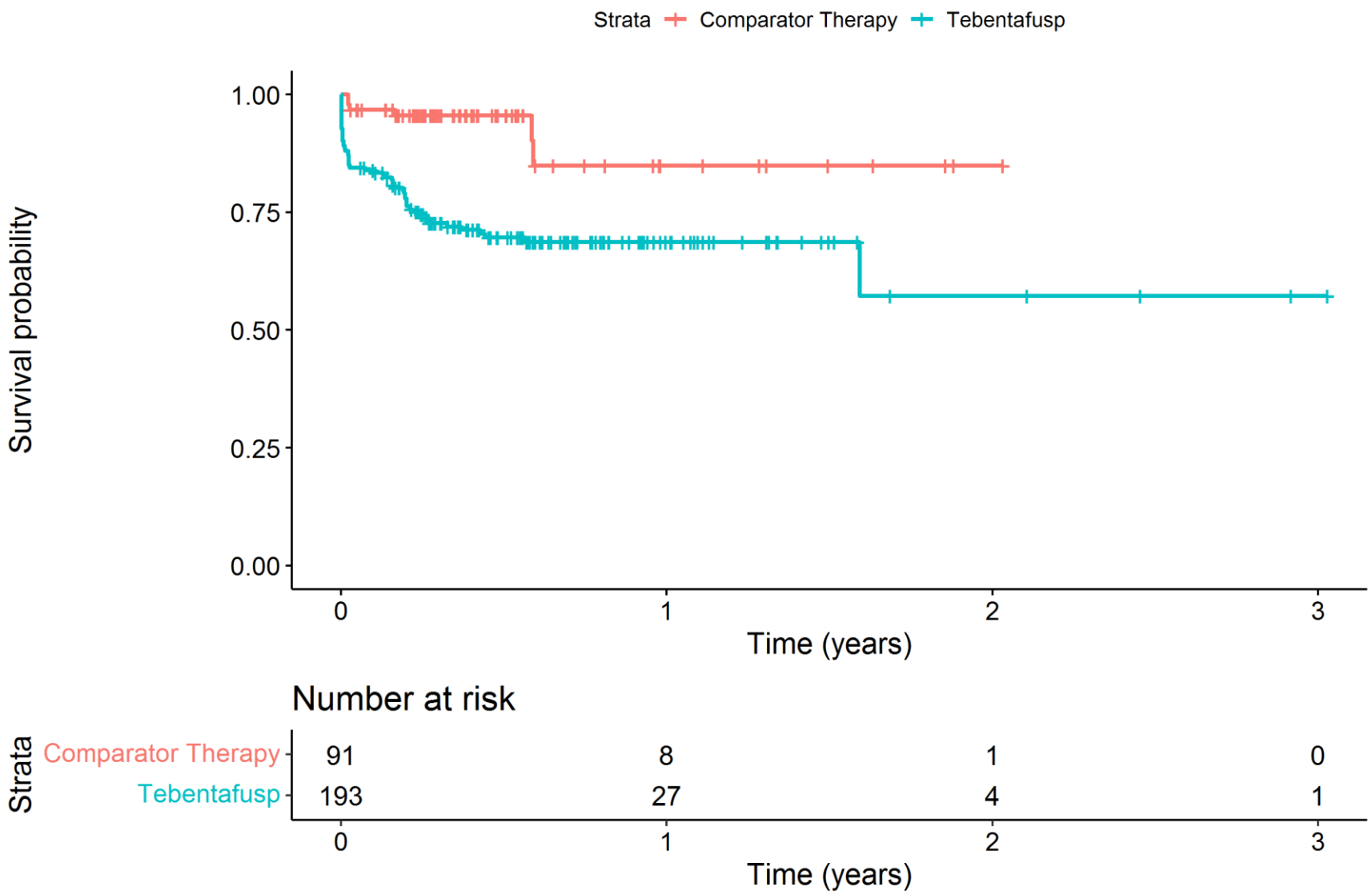
53.313 Kopfschmerzen - Nicht-Nordamerika



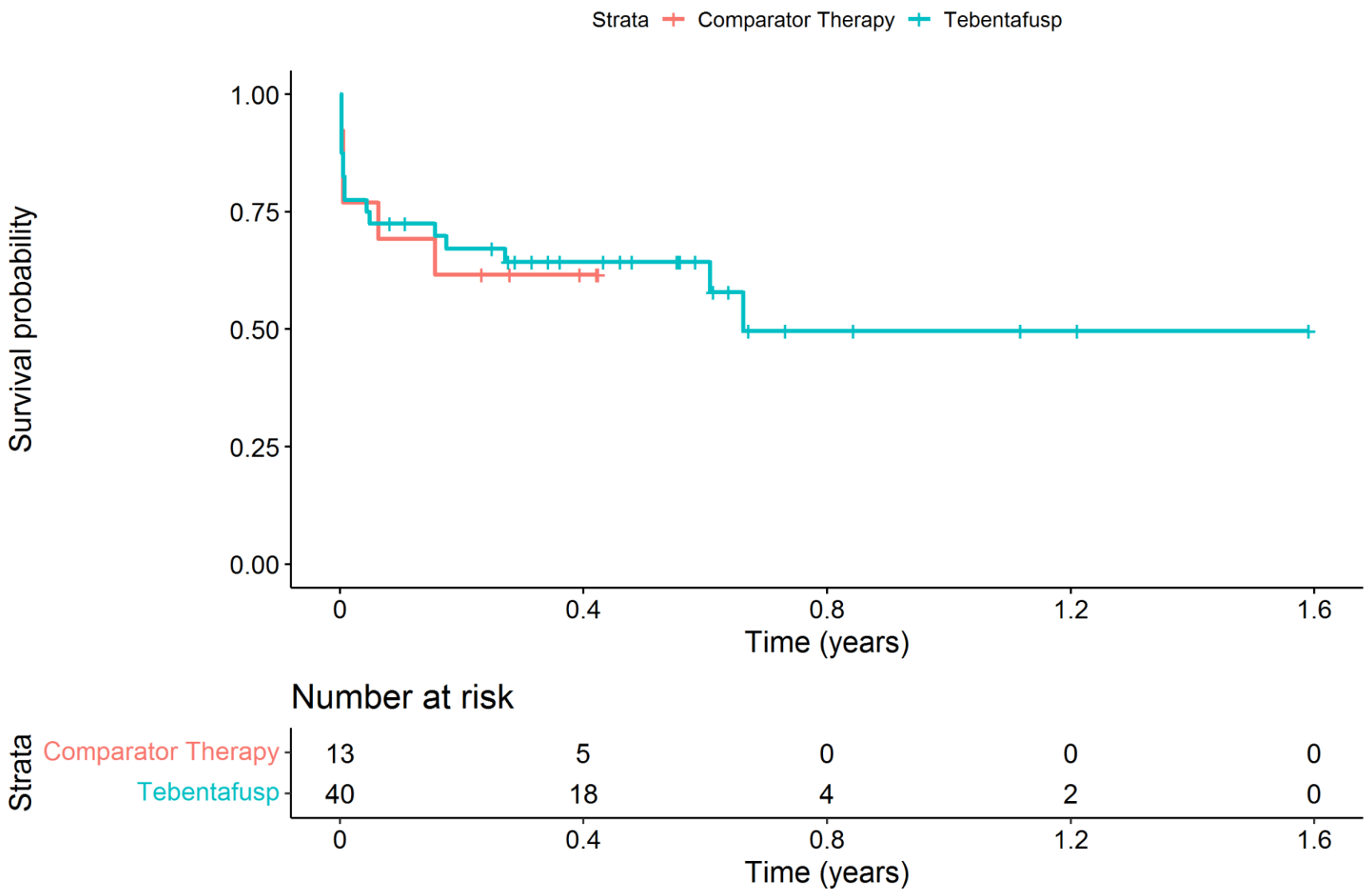
53.314 Kopfschmerzen - Dacarbazin



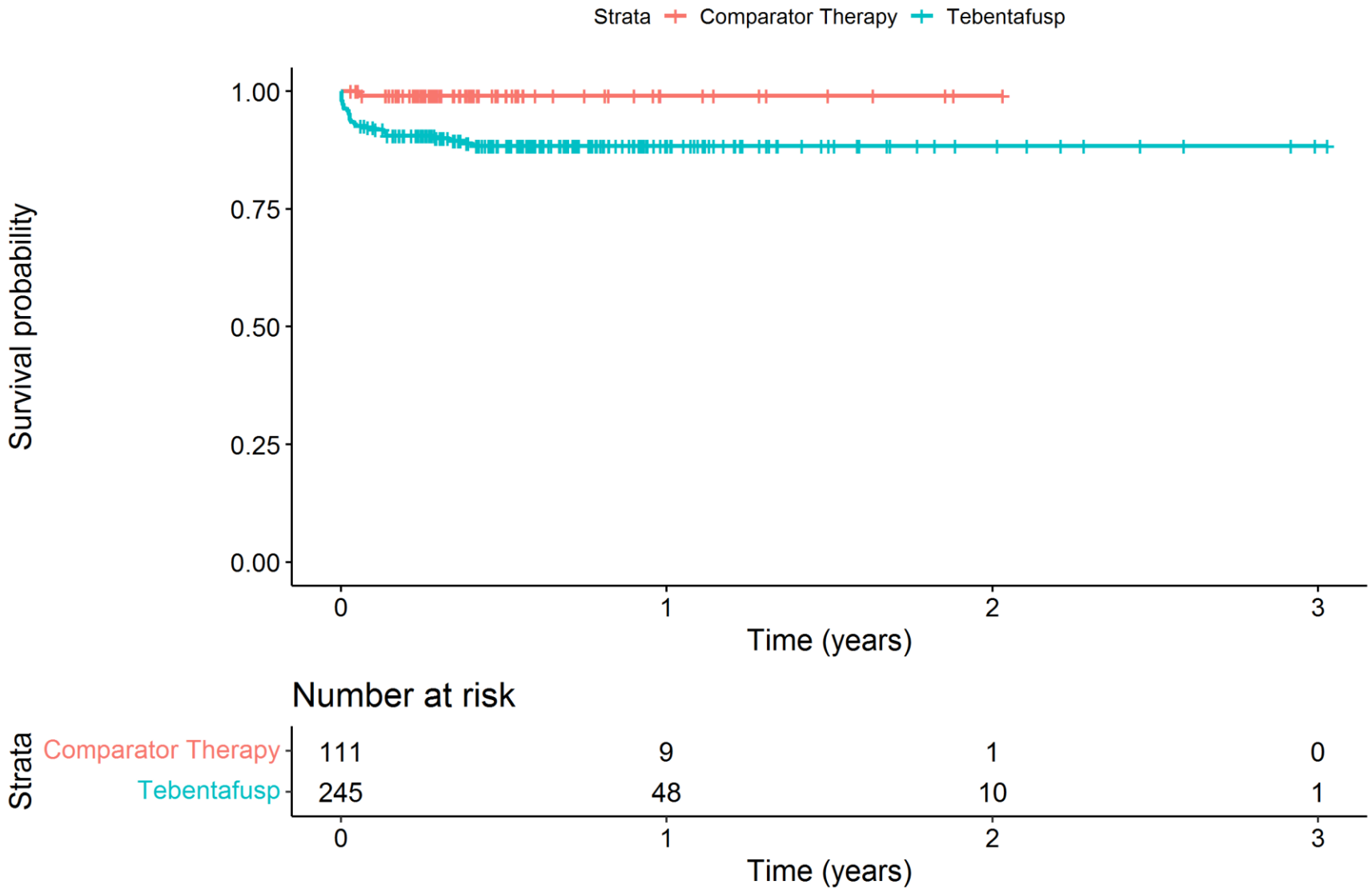
53.315 Kopfschmerzen - Pembrolizumab



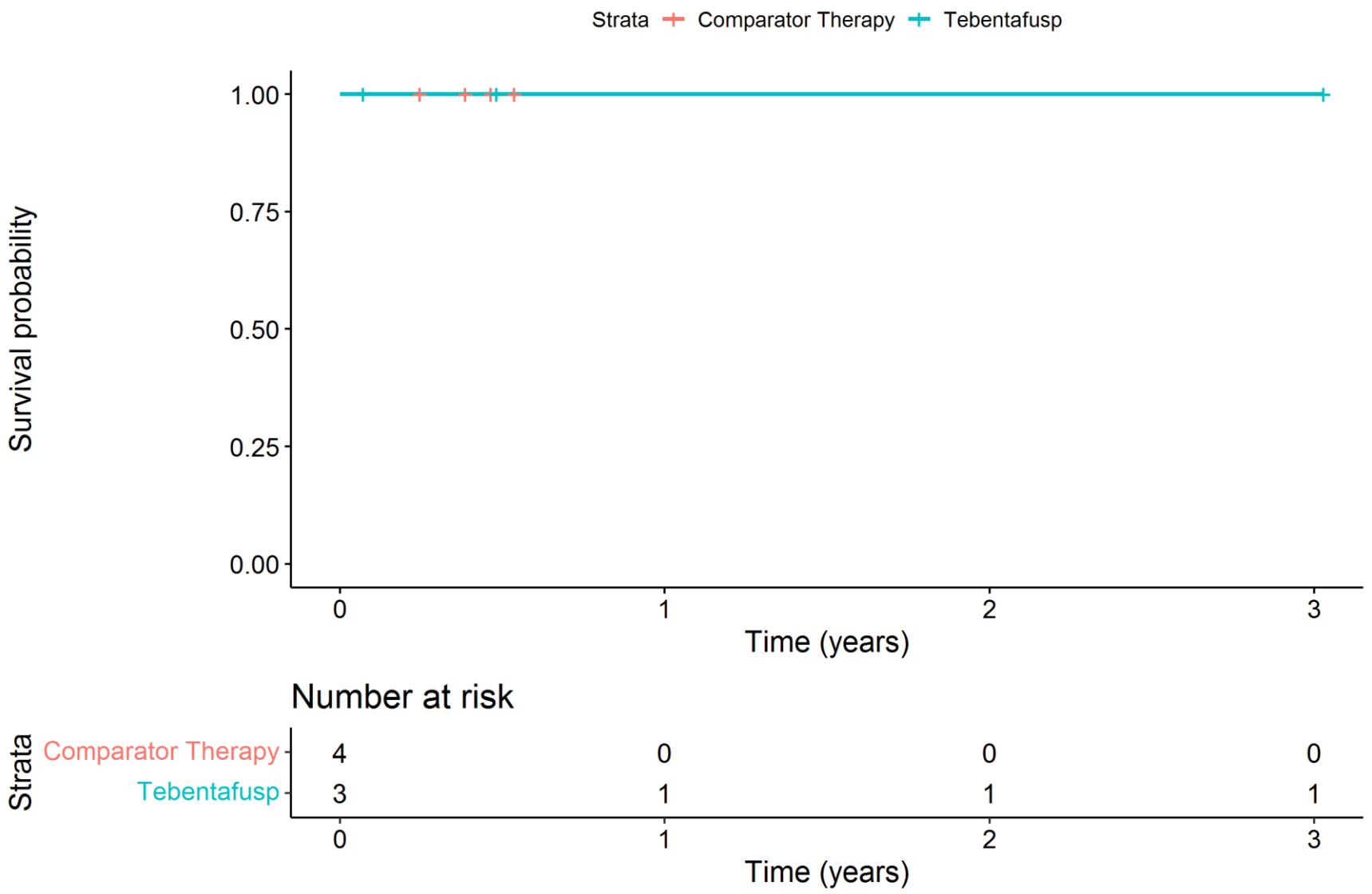
53.316 Kopfschmerzen - Ipilimumab



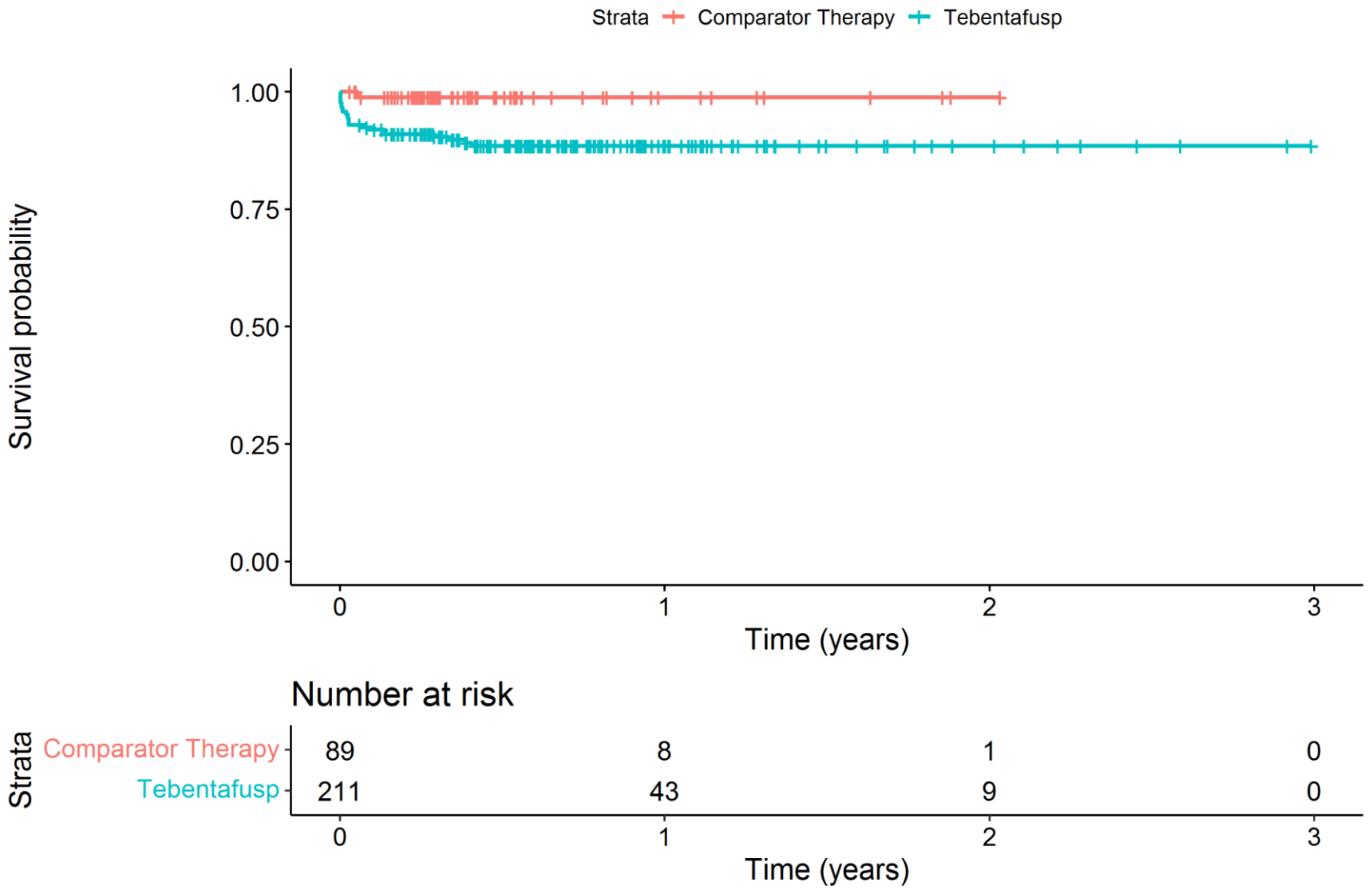
53.317 Parästhesie - Gesamt



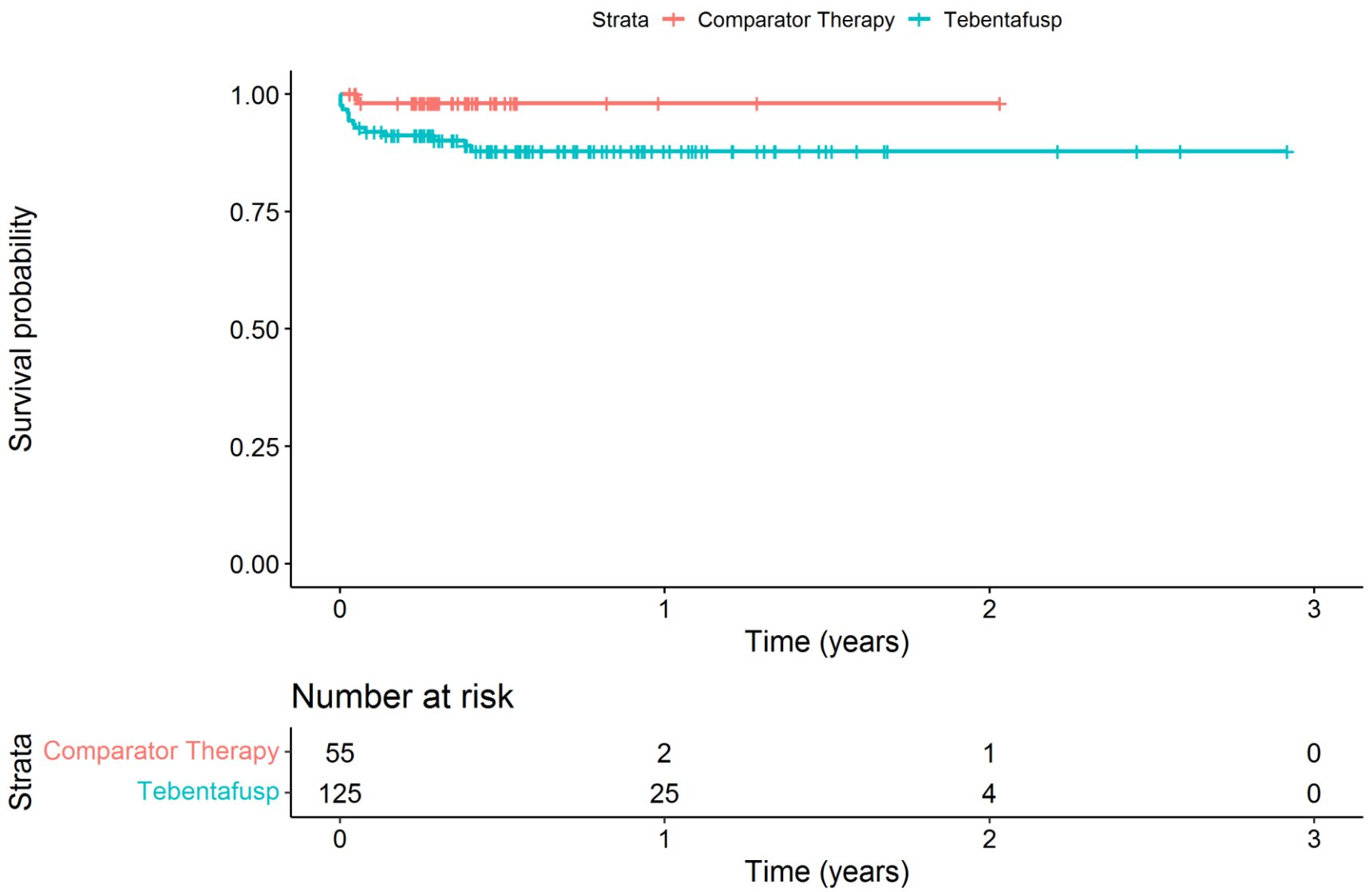
53.318 Parästhesie - Hispanisch



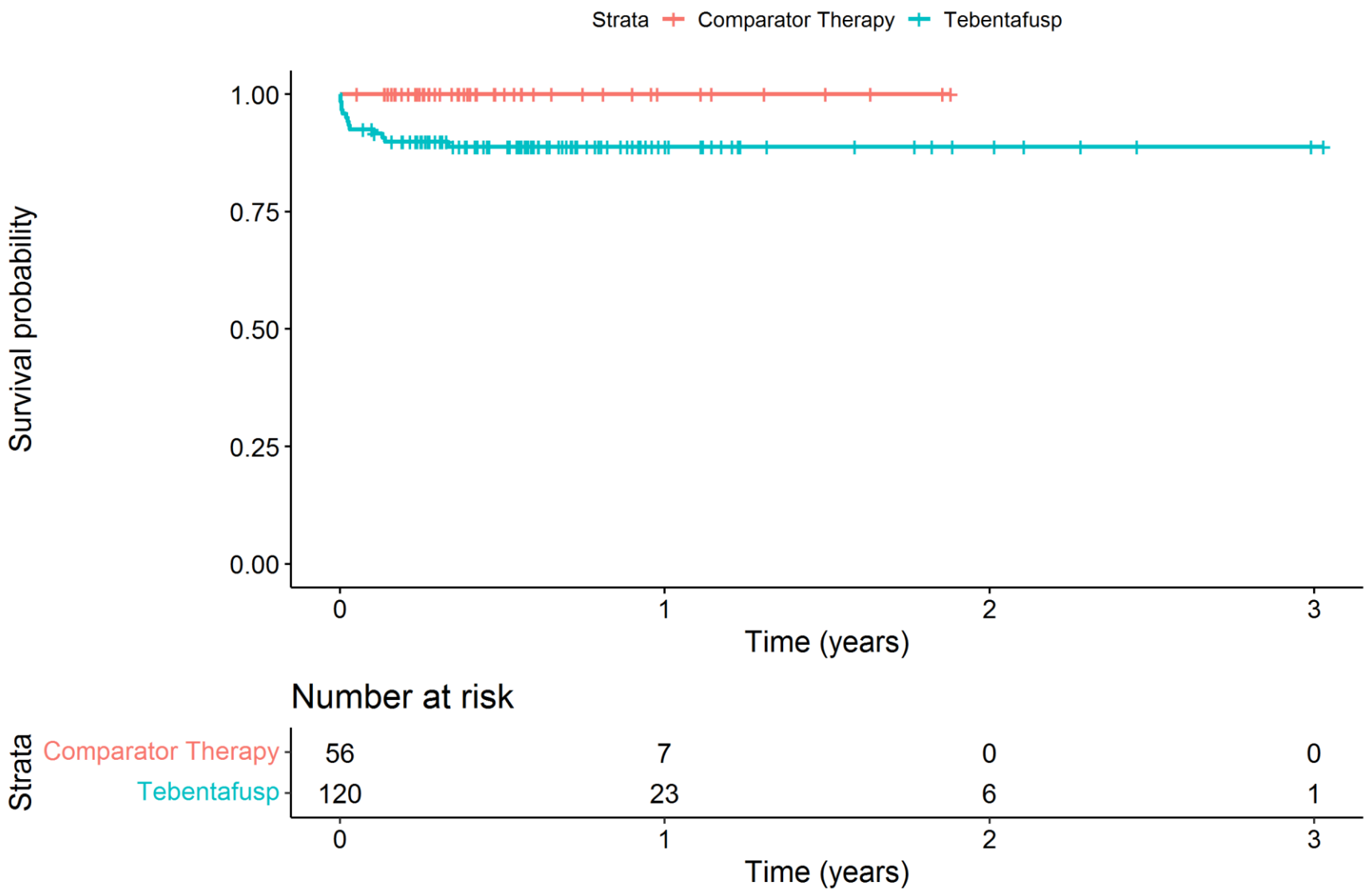
53.319 Parästhesie - Nicht-hispanisch



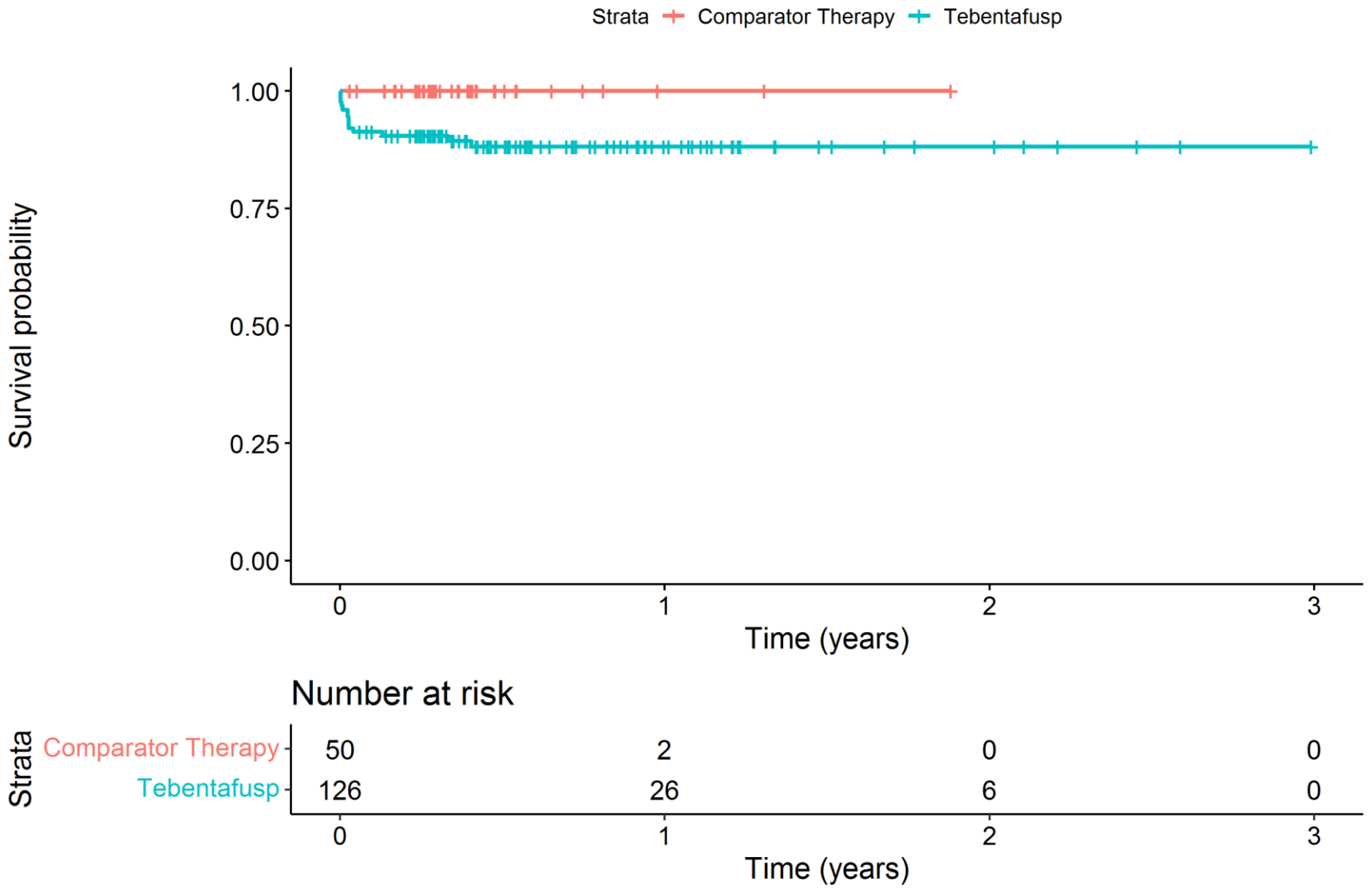
53.320 Parästhesie - Männlich



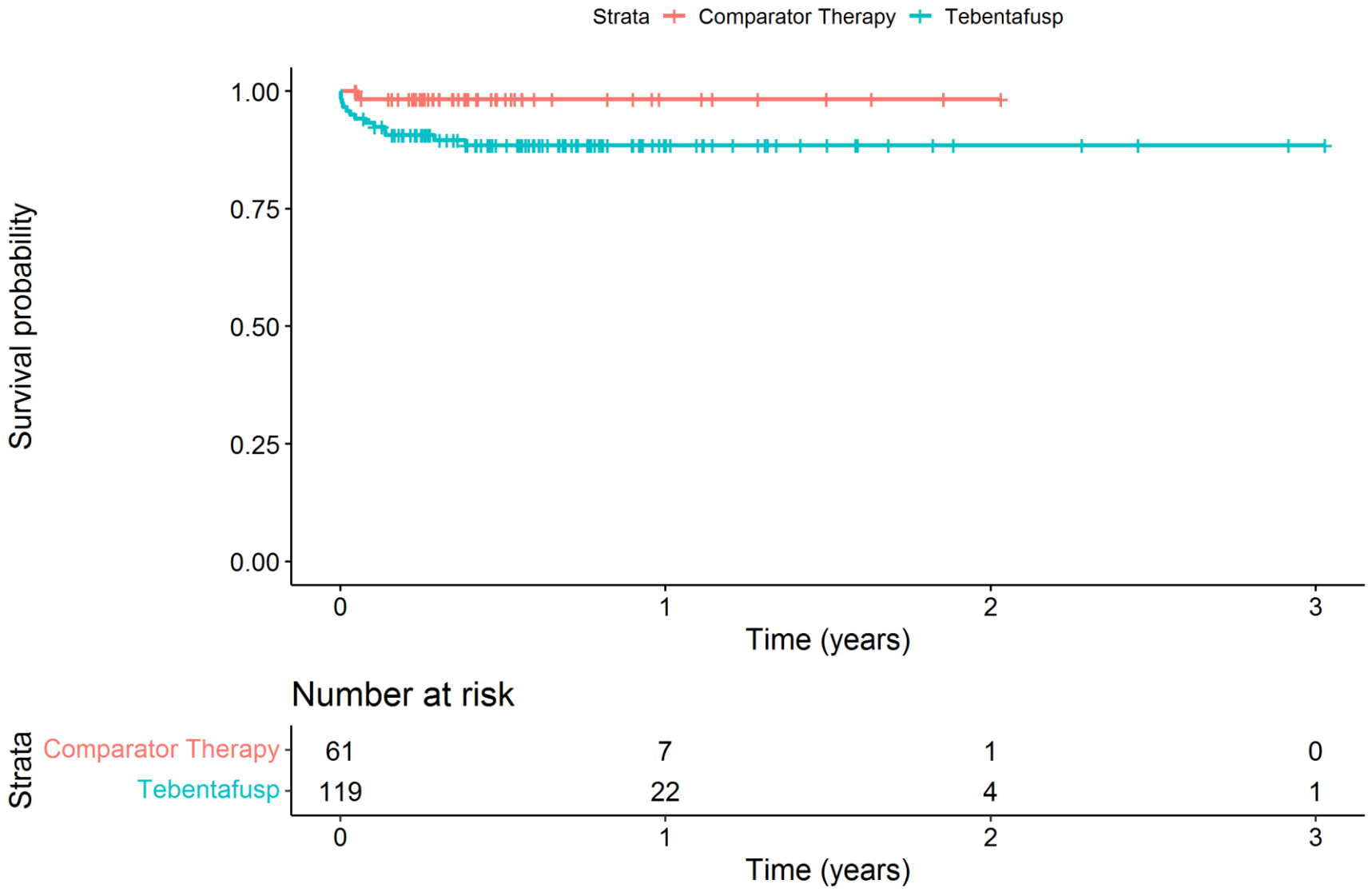
53.321 Parästhesie - Weiblich



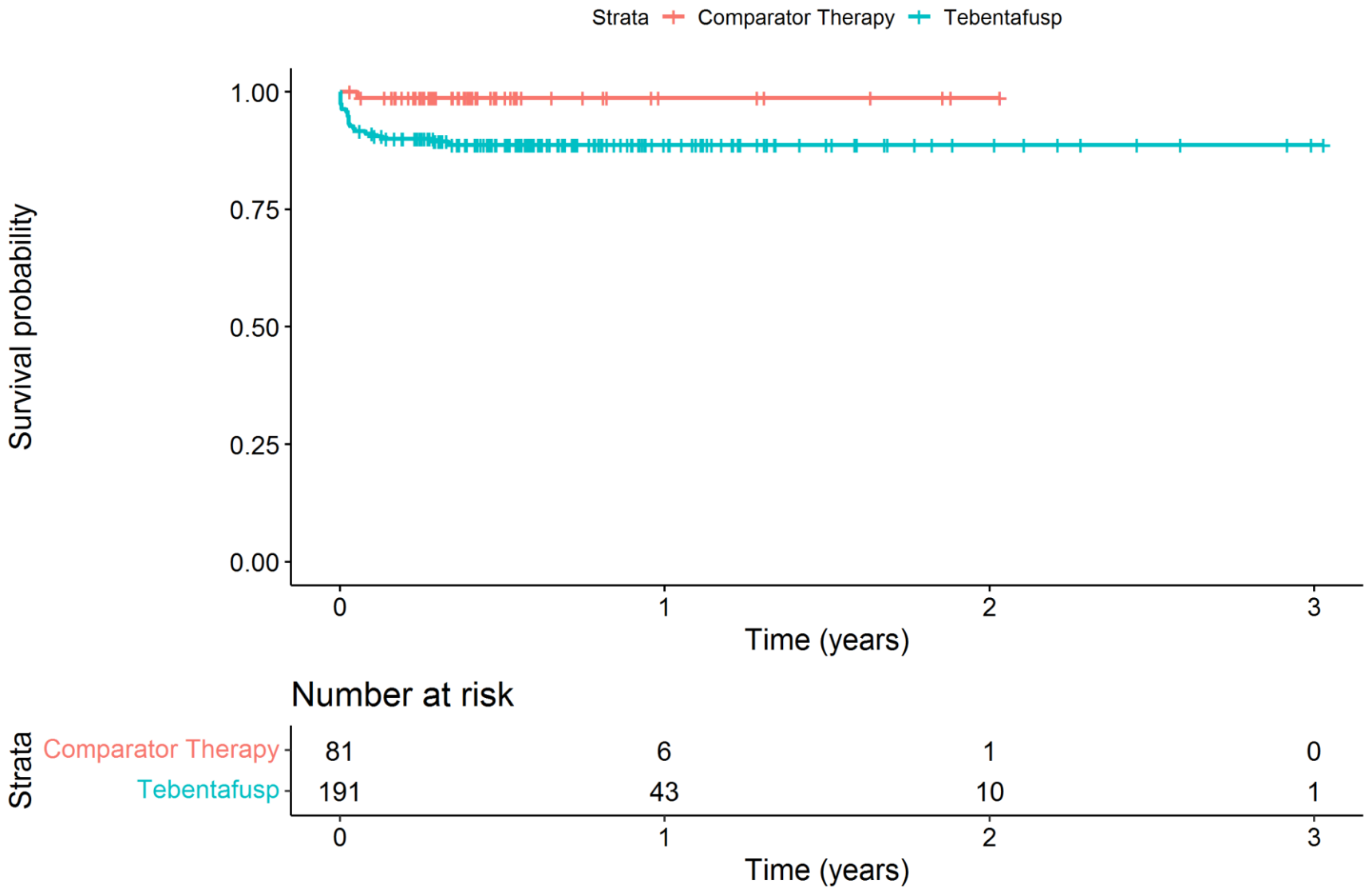
53.322 Parästhesie - <65



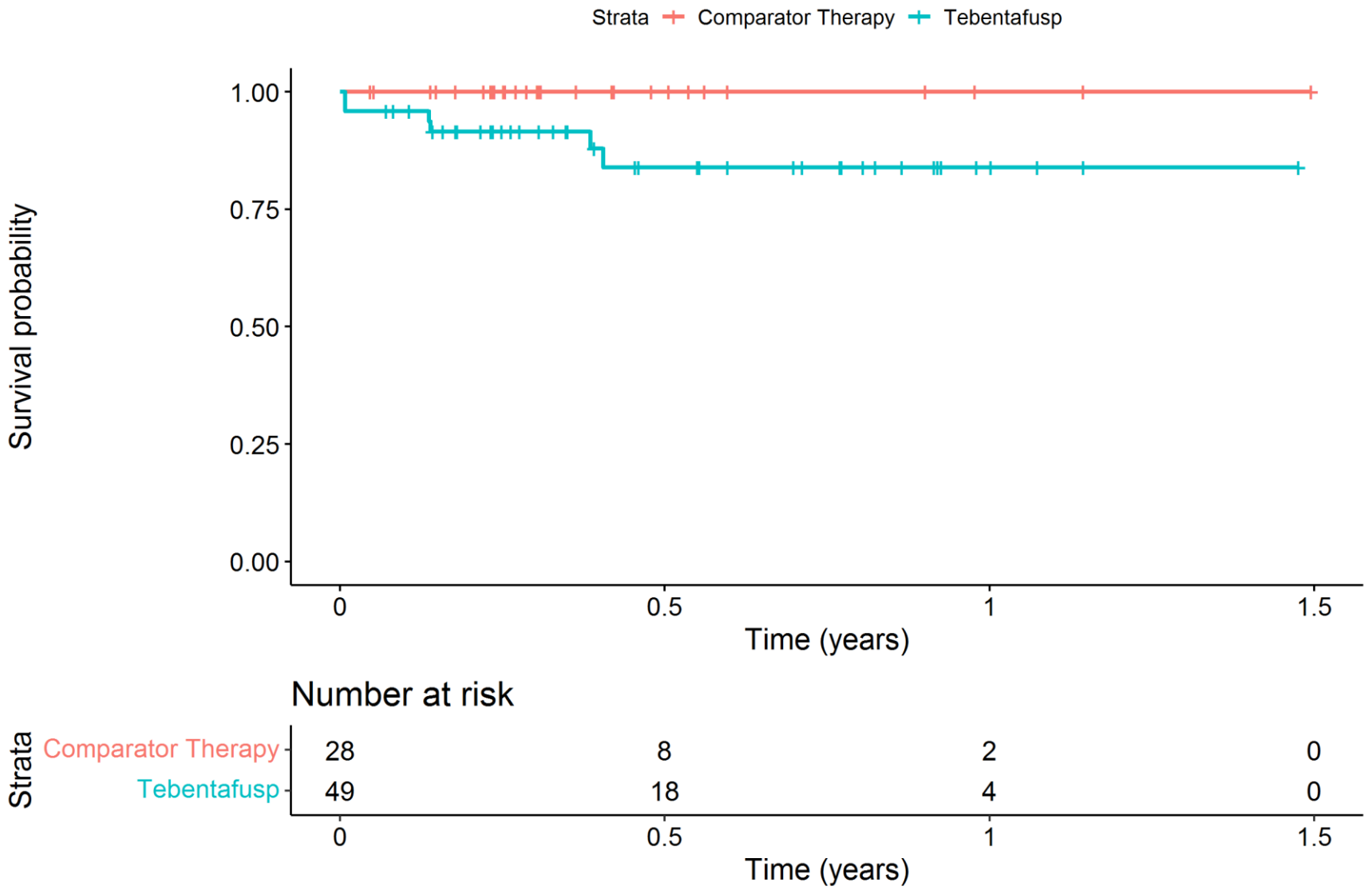
53.323 Parästhesie - ≥65



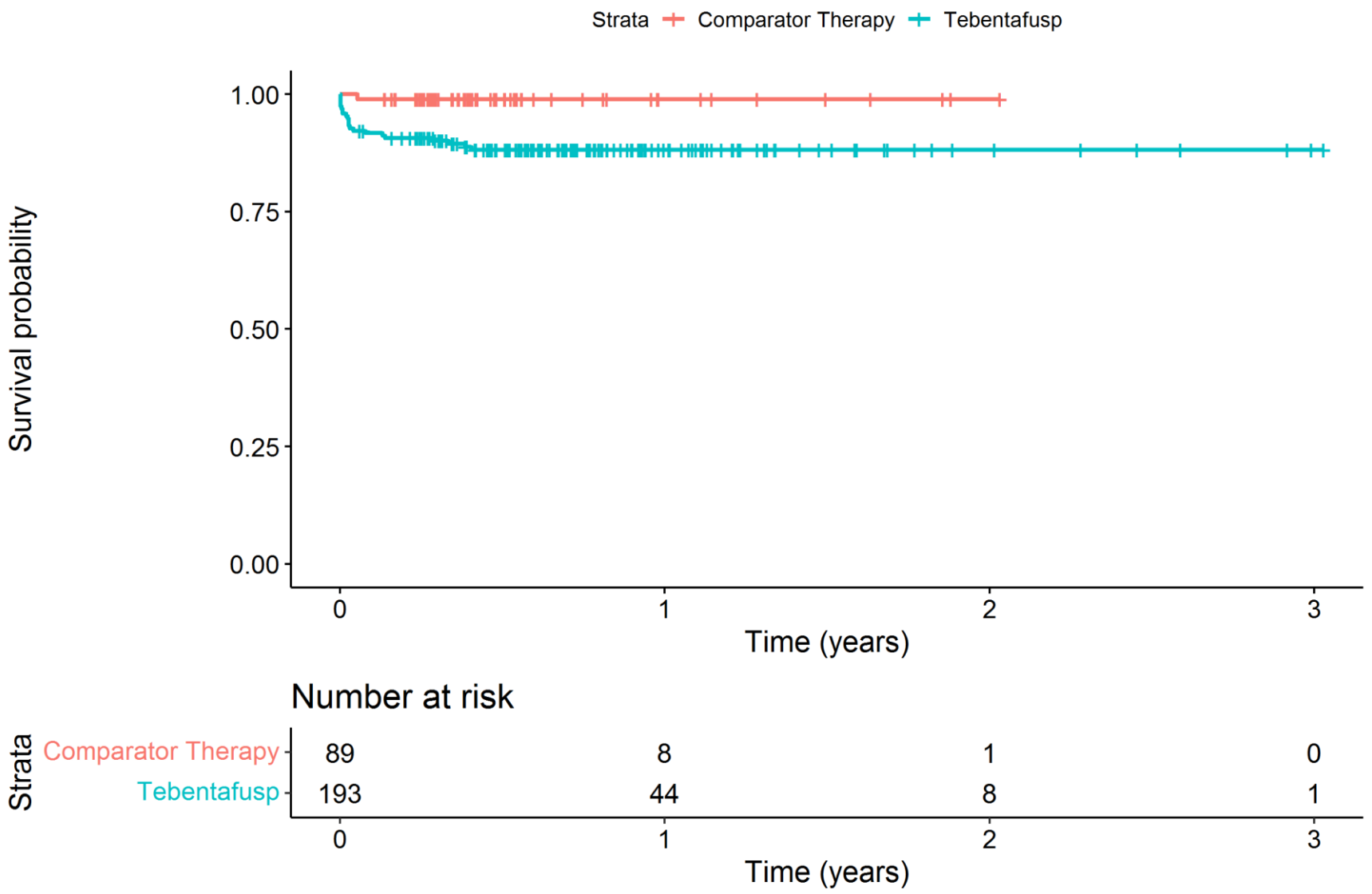
53.324 Parästhesie - ECOG 0



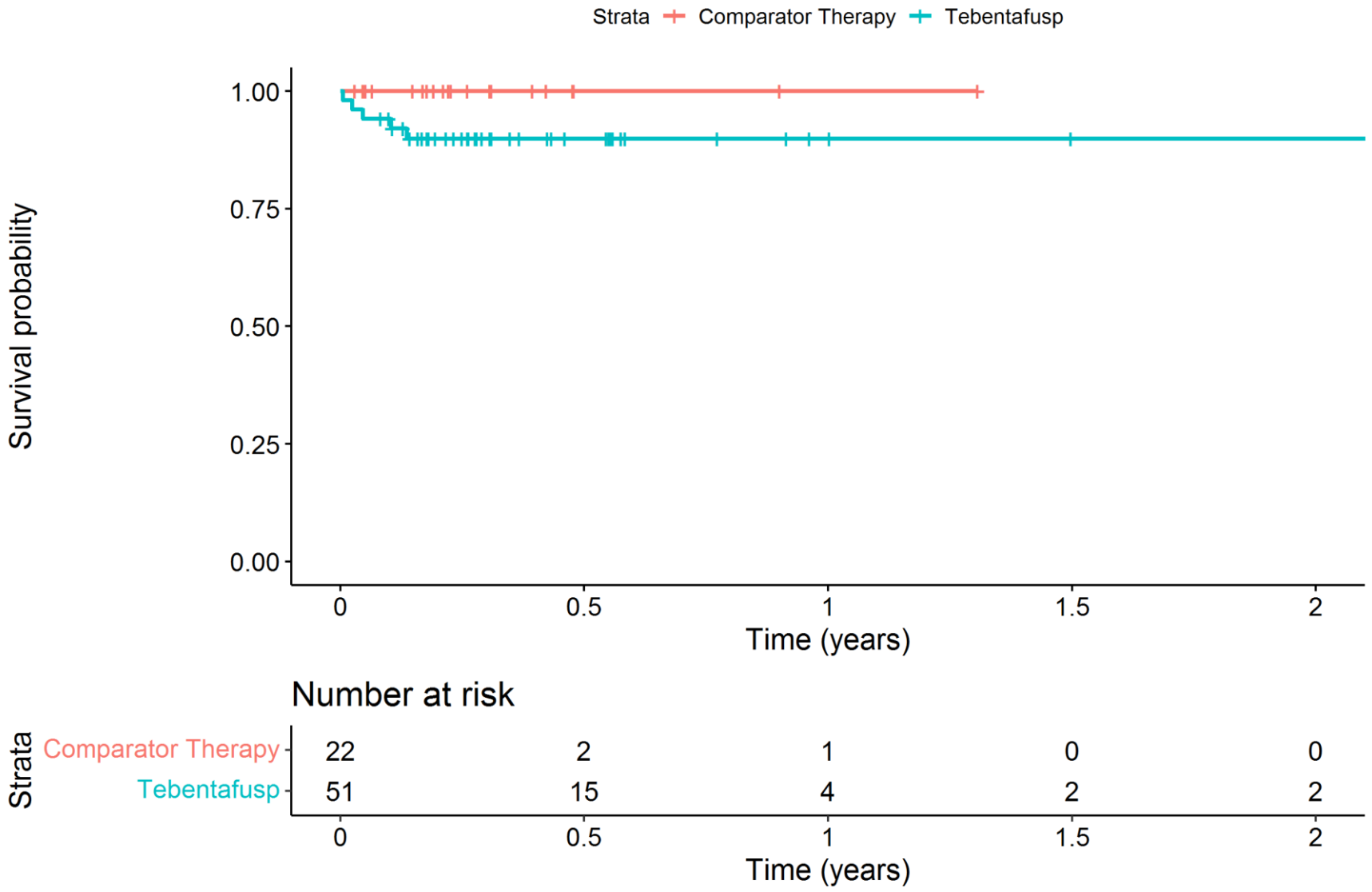
53.325 Parästhesie - ECOG 1



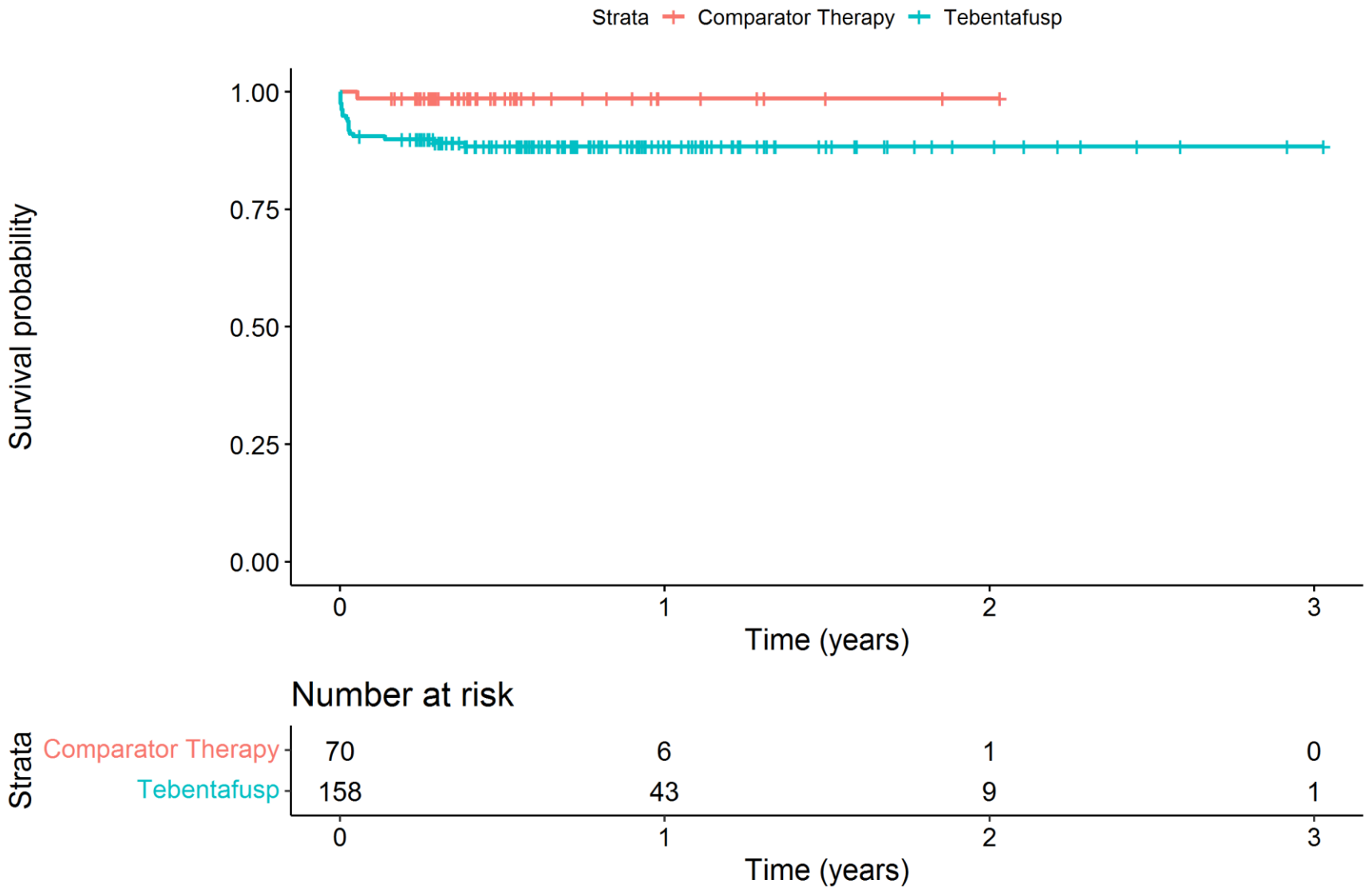
53.326 Parästhesie - ALP ≤ ULN



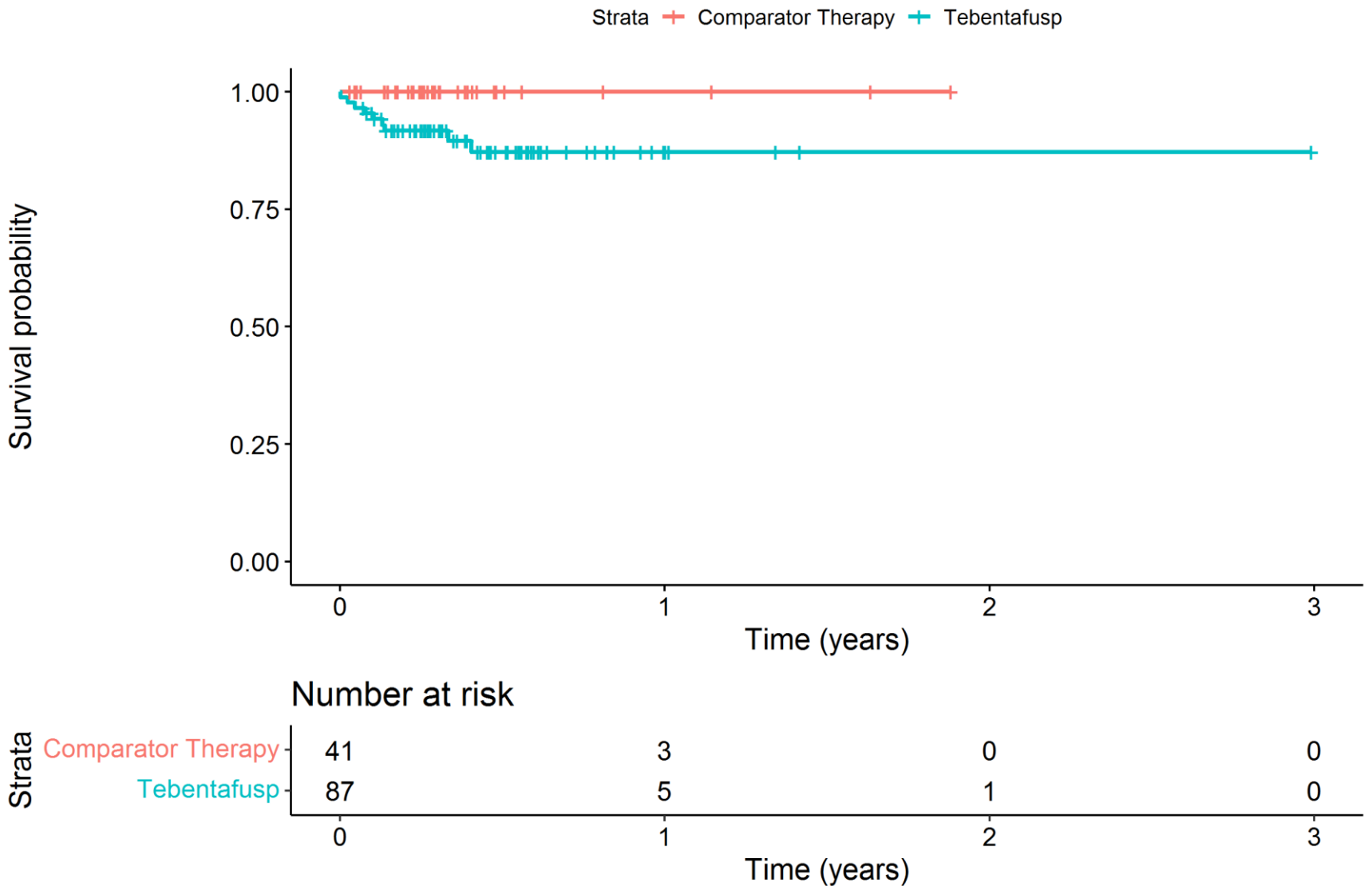
53.327 Parästhesie - ALP > ULN



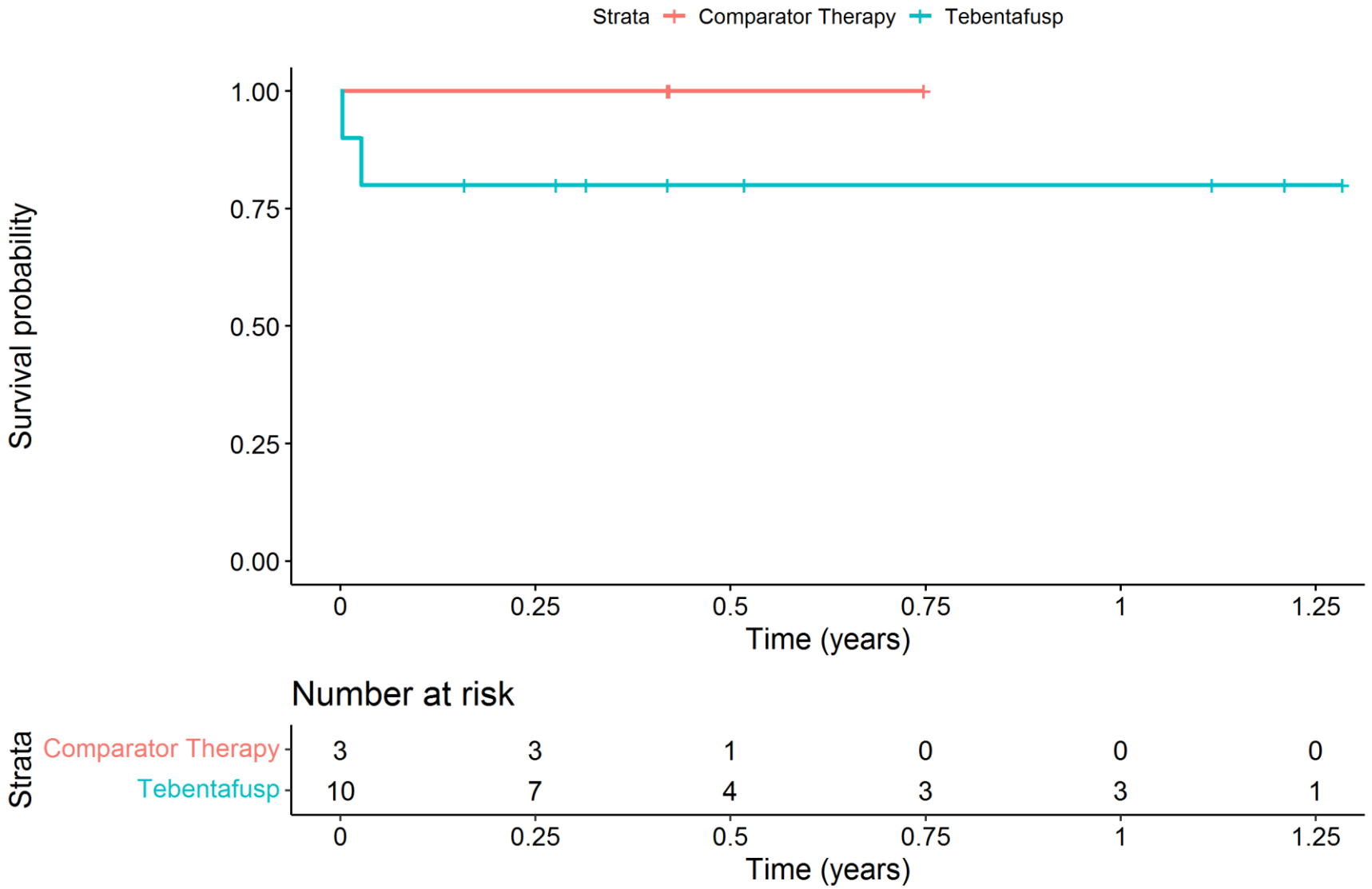
53.328 Parästhesie - LDH =< ULN



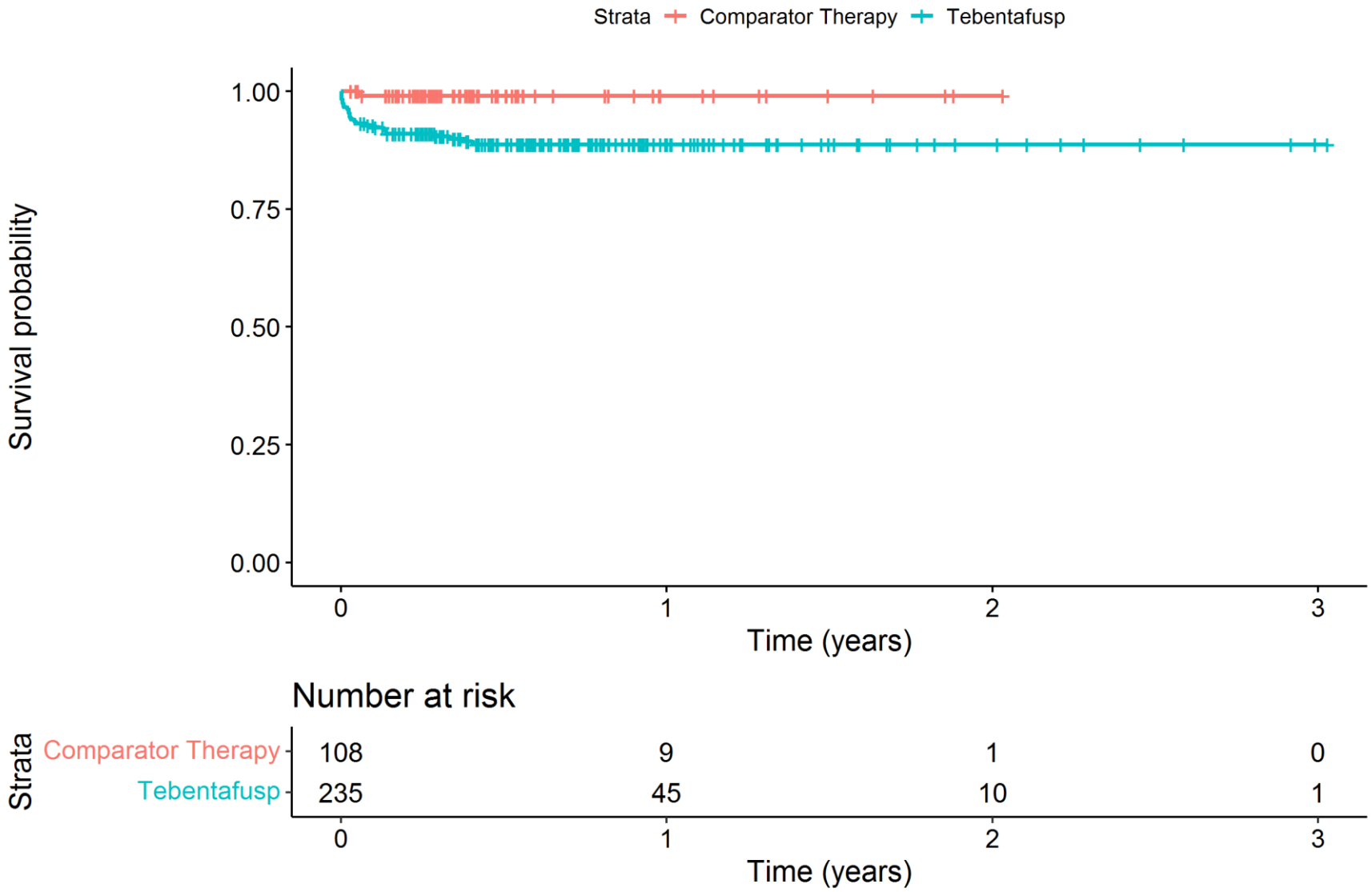
53.329 Parästhesie - LDH > ULN



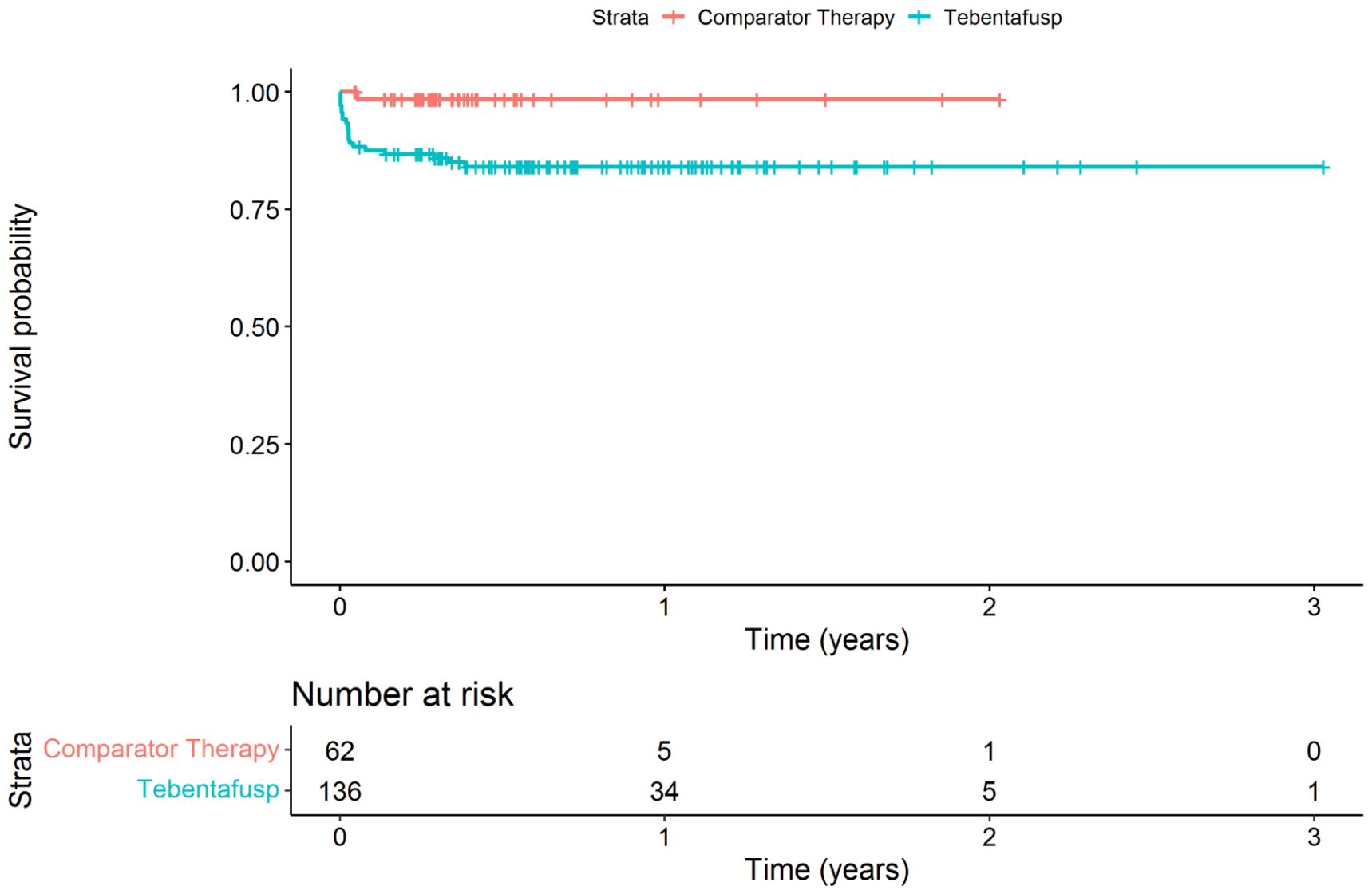
53.330 Parästhesie - Vorherige Therapie adjuvant/neoadjuvant



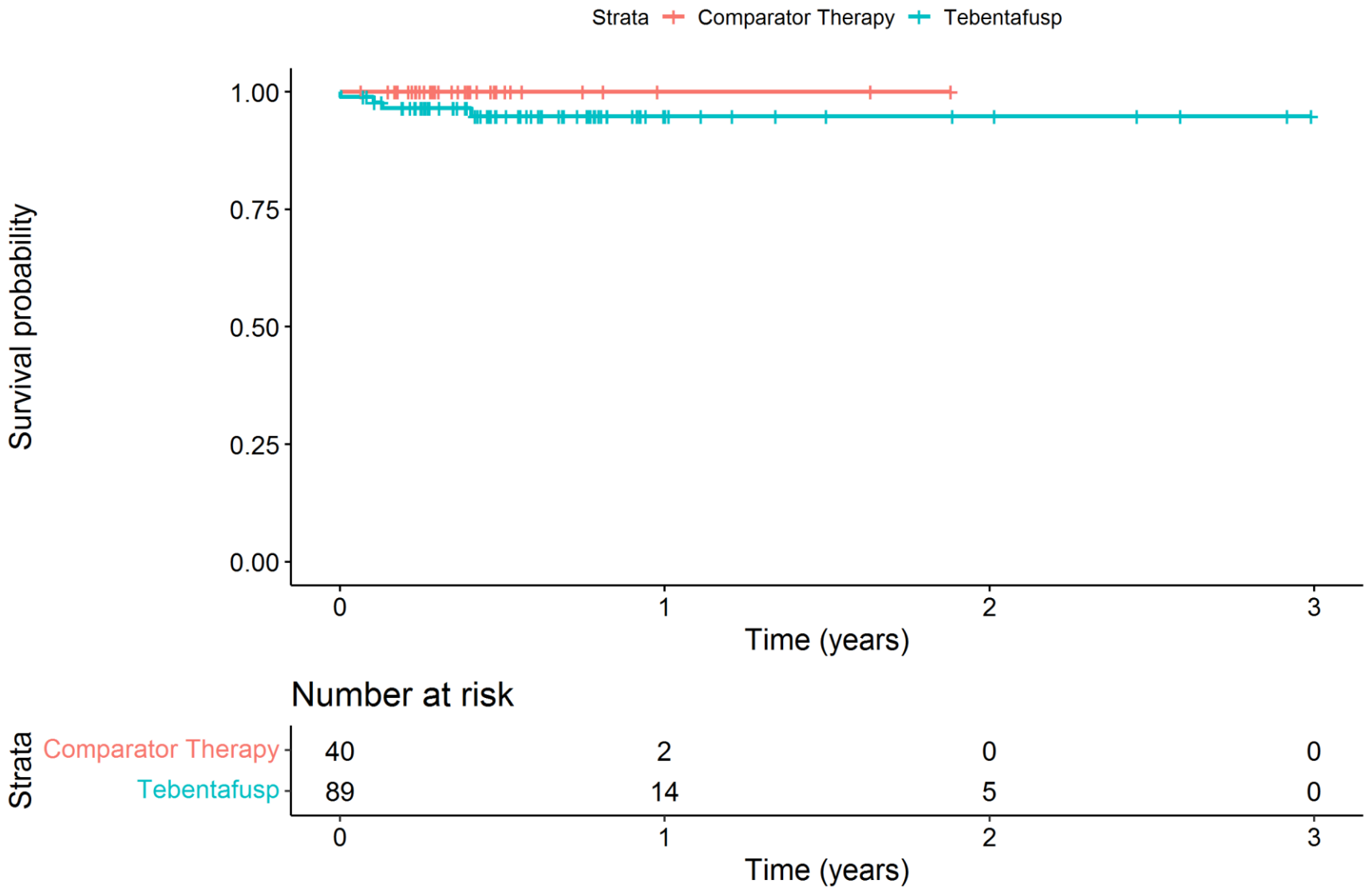
53.331 Parästhesie - Keine vorherige Therapie adjuvant/neoadjuvant



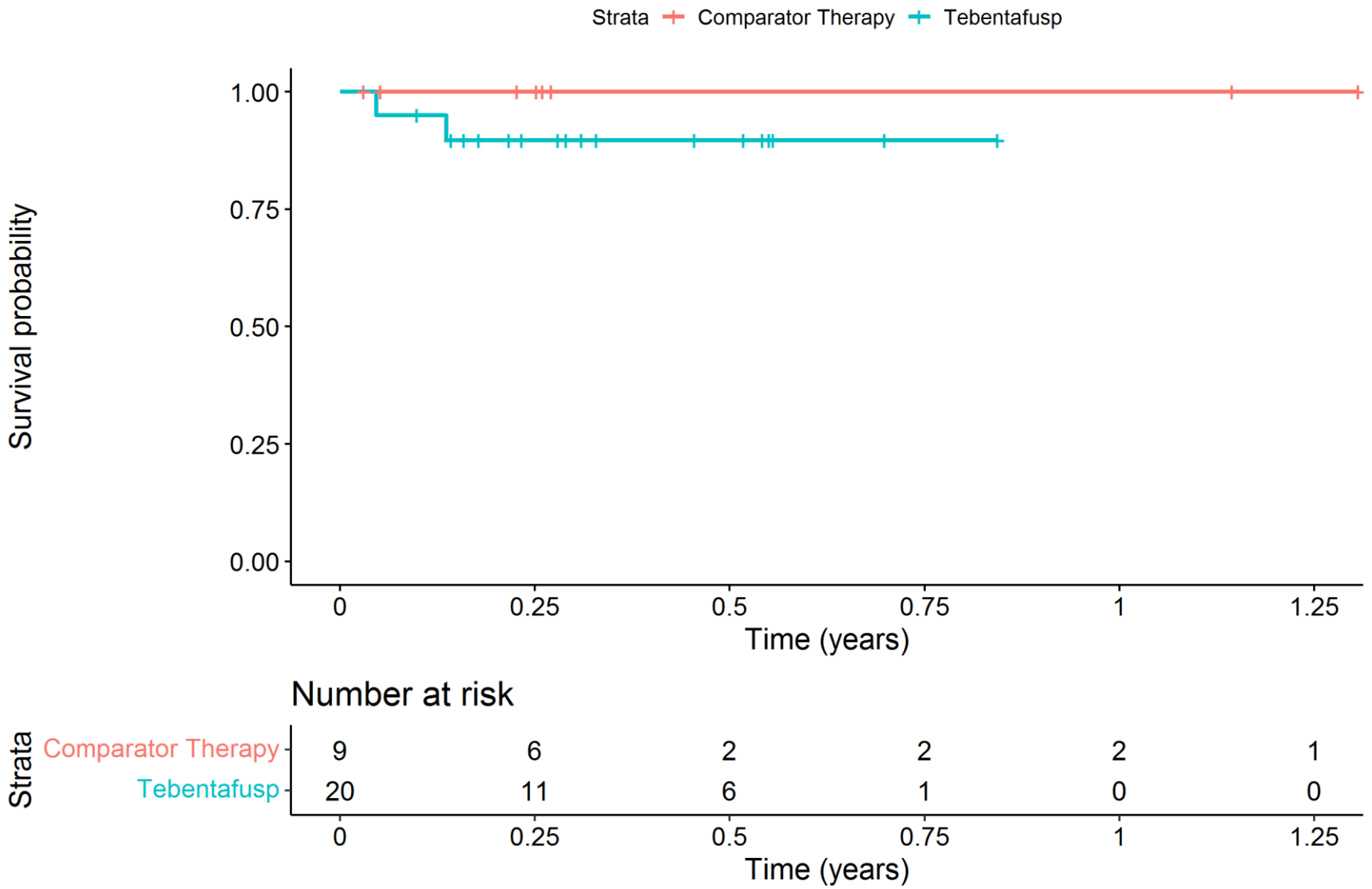
53.332 Parästhesie - Läsion ≤ 3cm



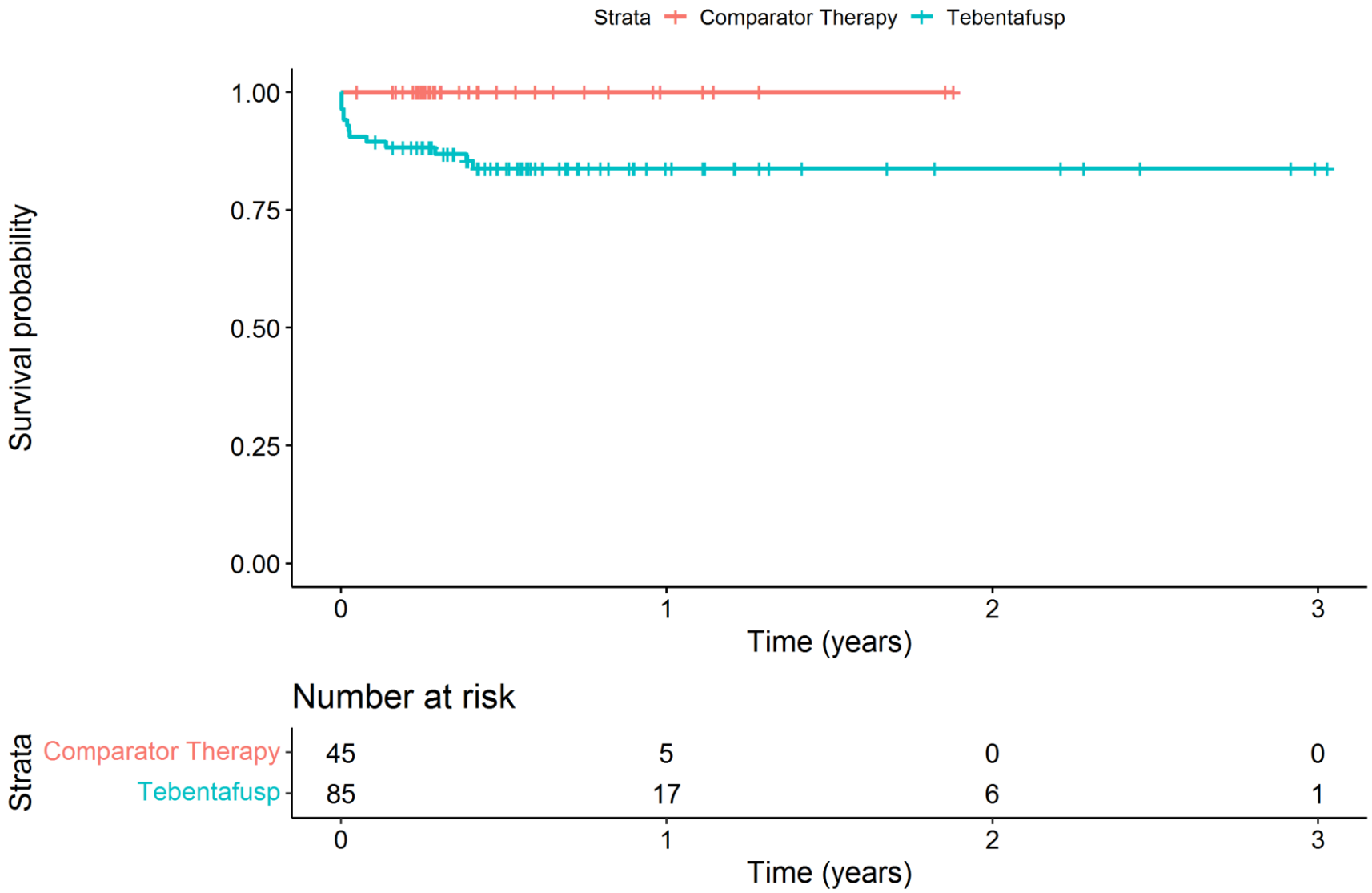
53.333 Parästhesie - Läsion 3,1-8,0 cm



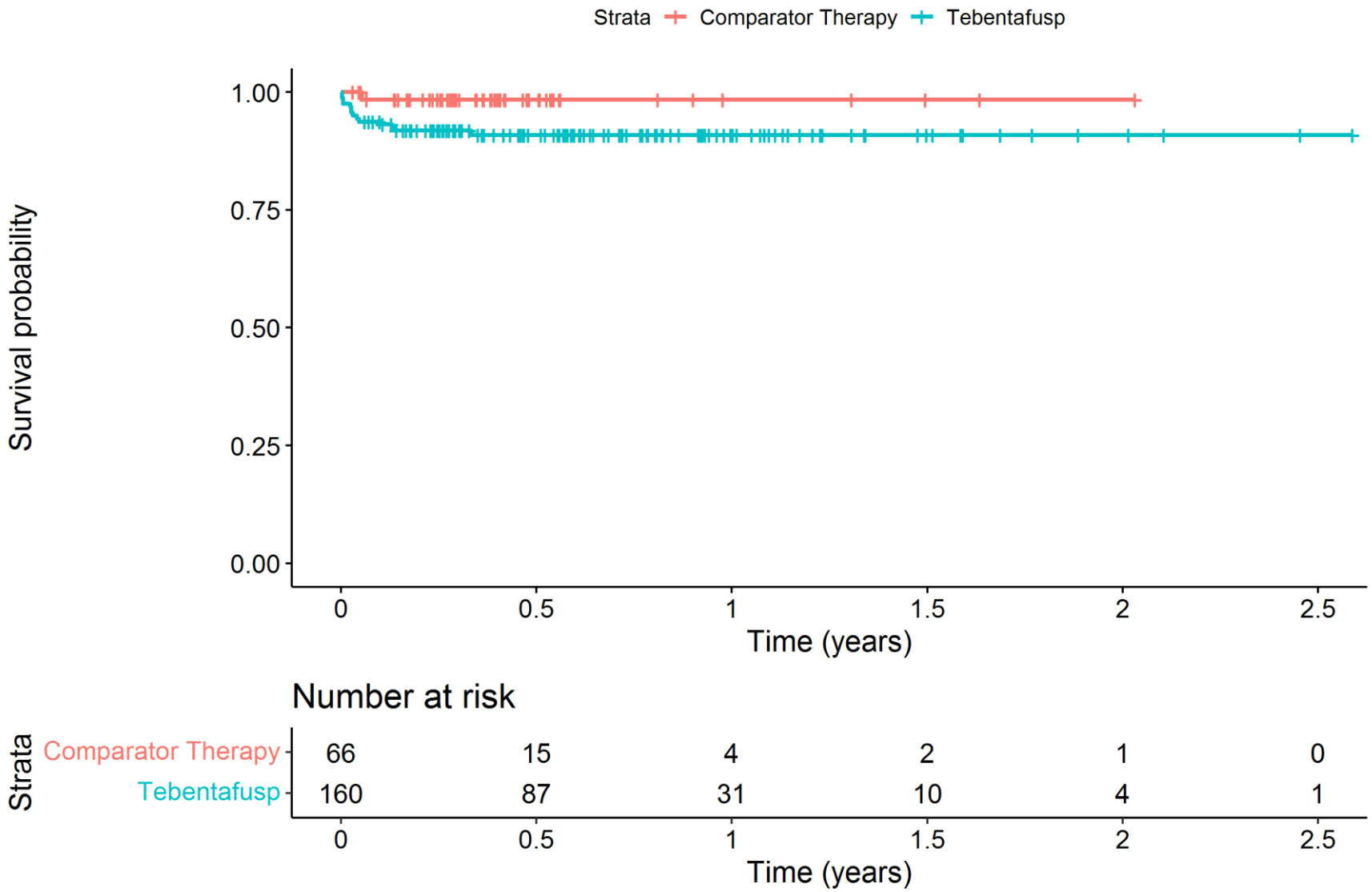
53.334 Parästhesie - Läsion ≥8,1 cm



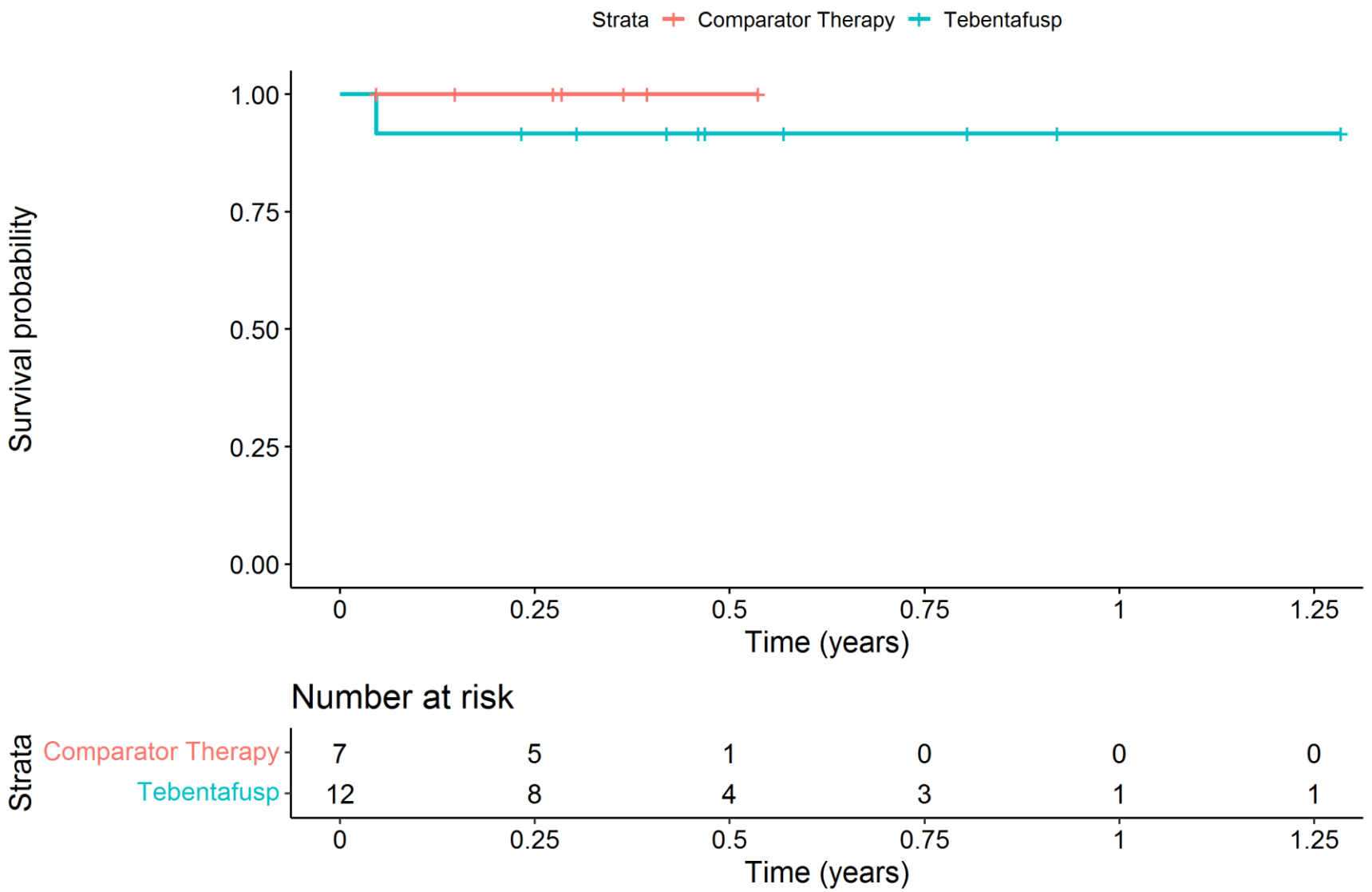
53.335 Parästhesie - Nordamerika



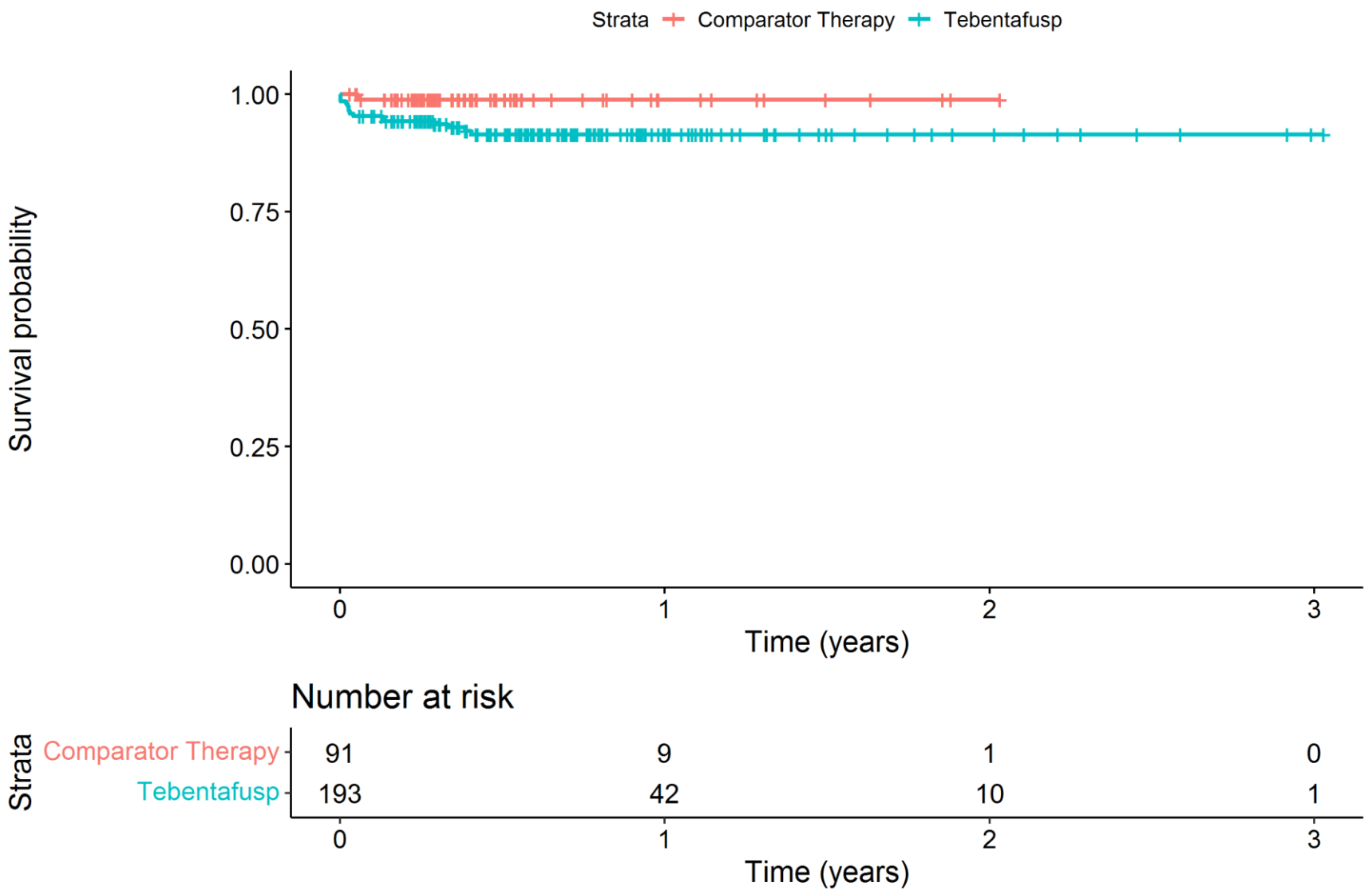
53.336 Parästhesie - Nicht-Nordamerika



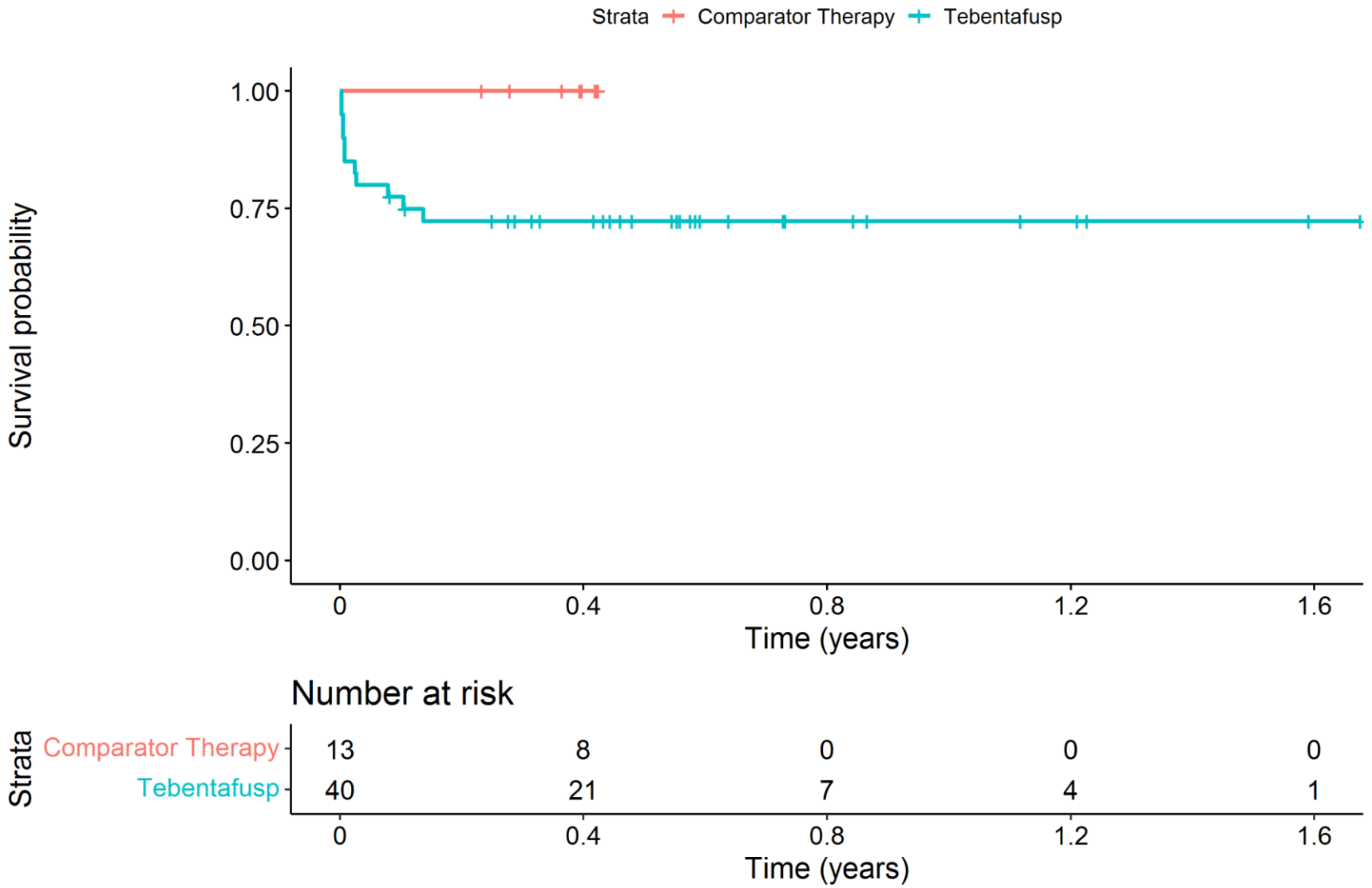
53.337 Parästhesie - Dacarbazin



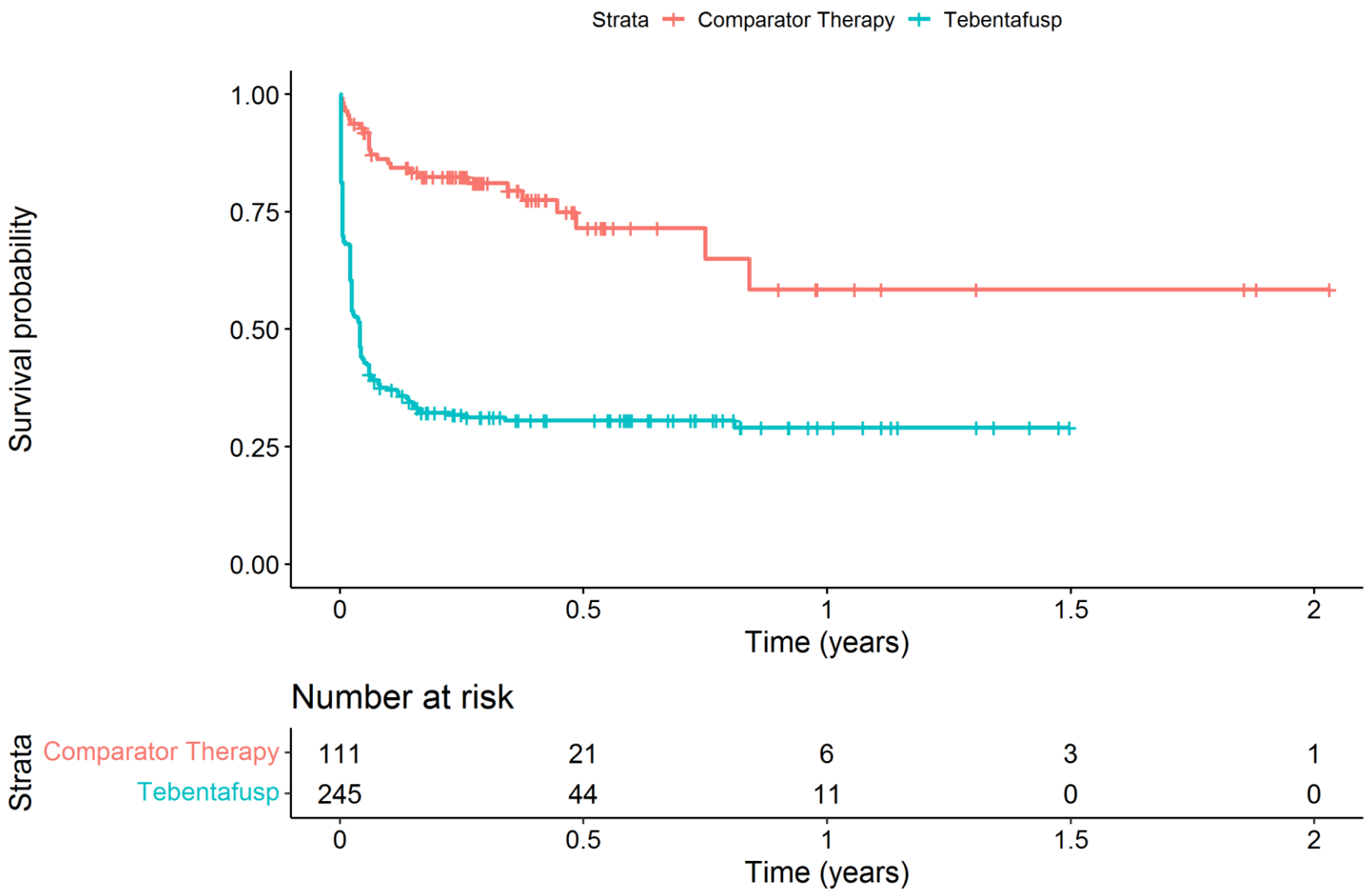
53.338 Parästhesie - Pembrolizumab



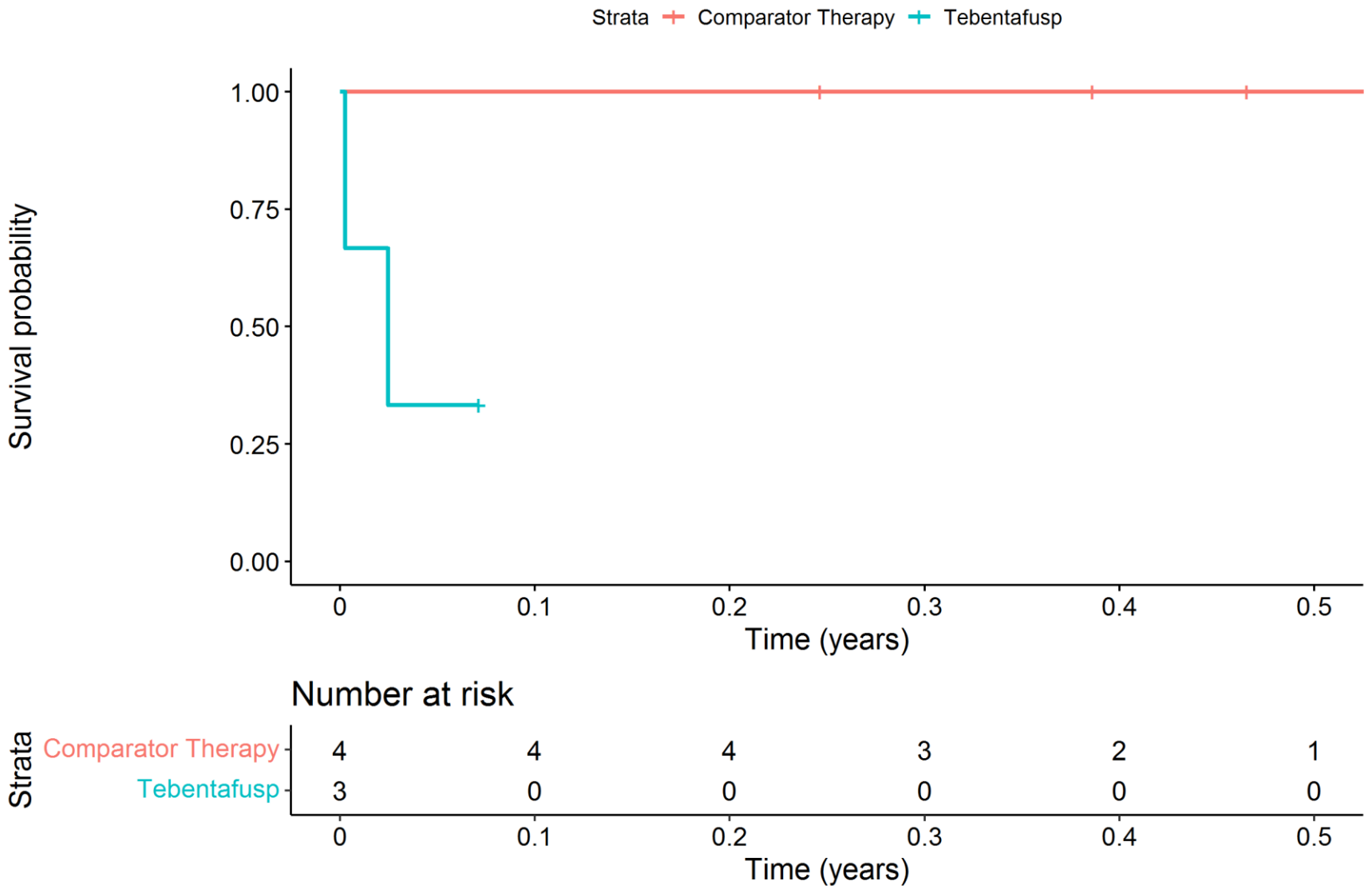
53.339 Parästhesie - Ipilimumab



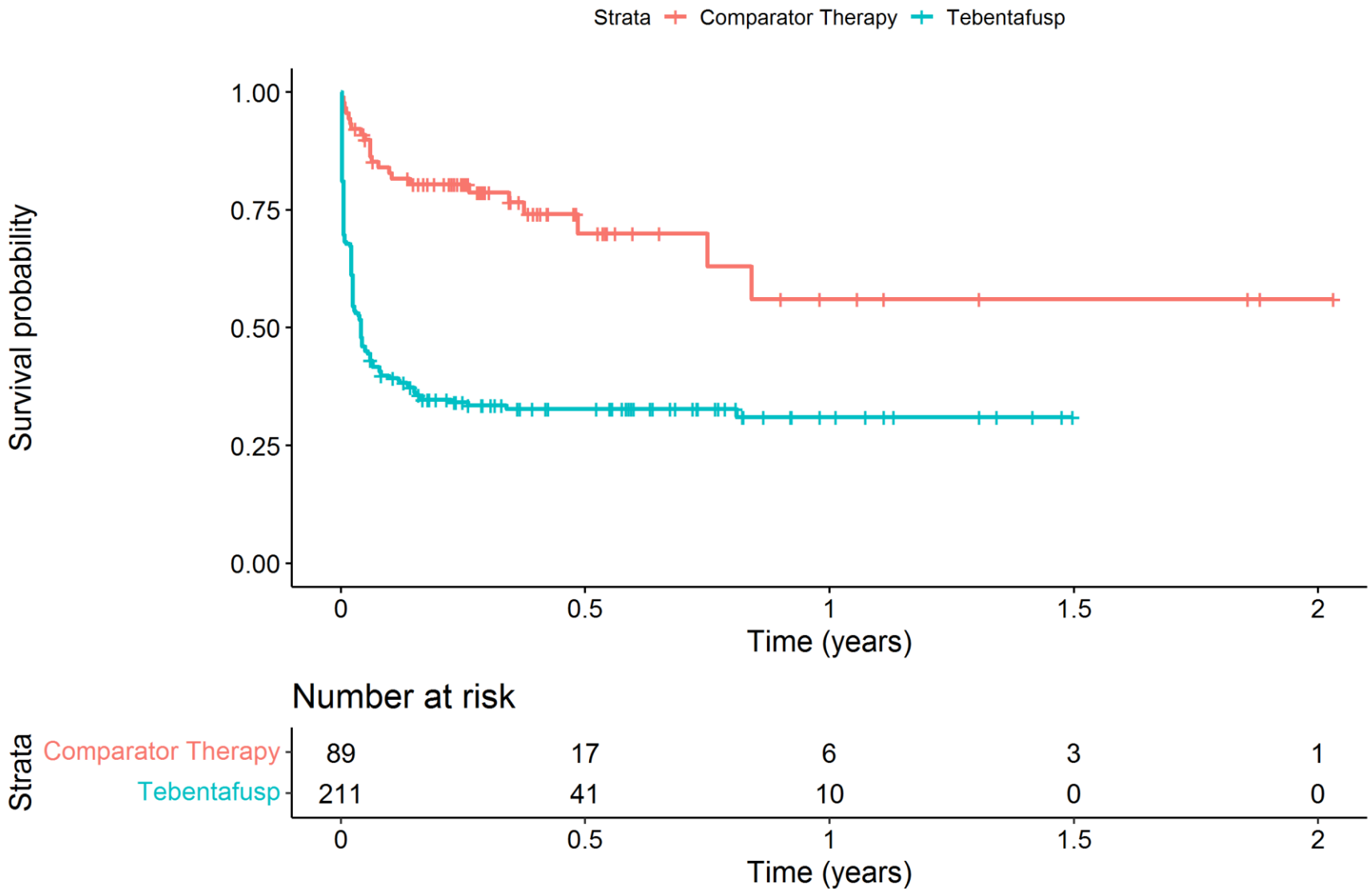
53.340 Pruritus - Gesamt



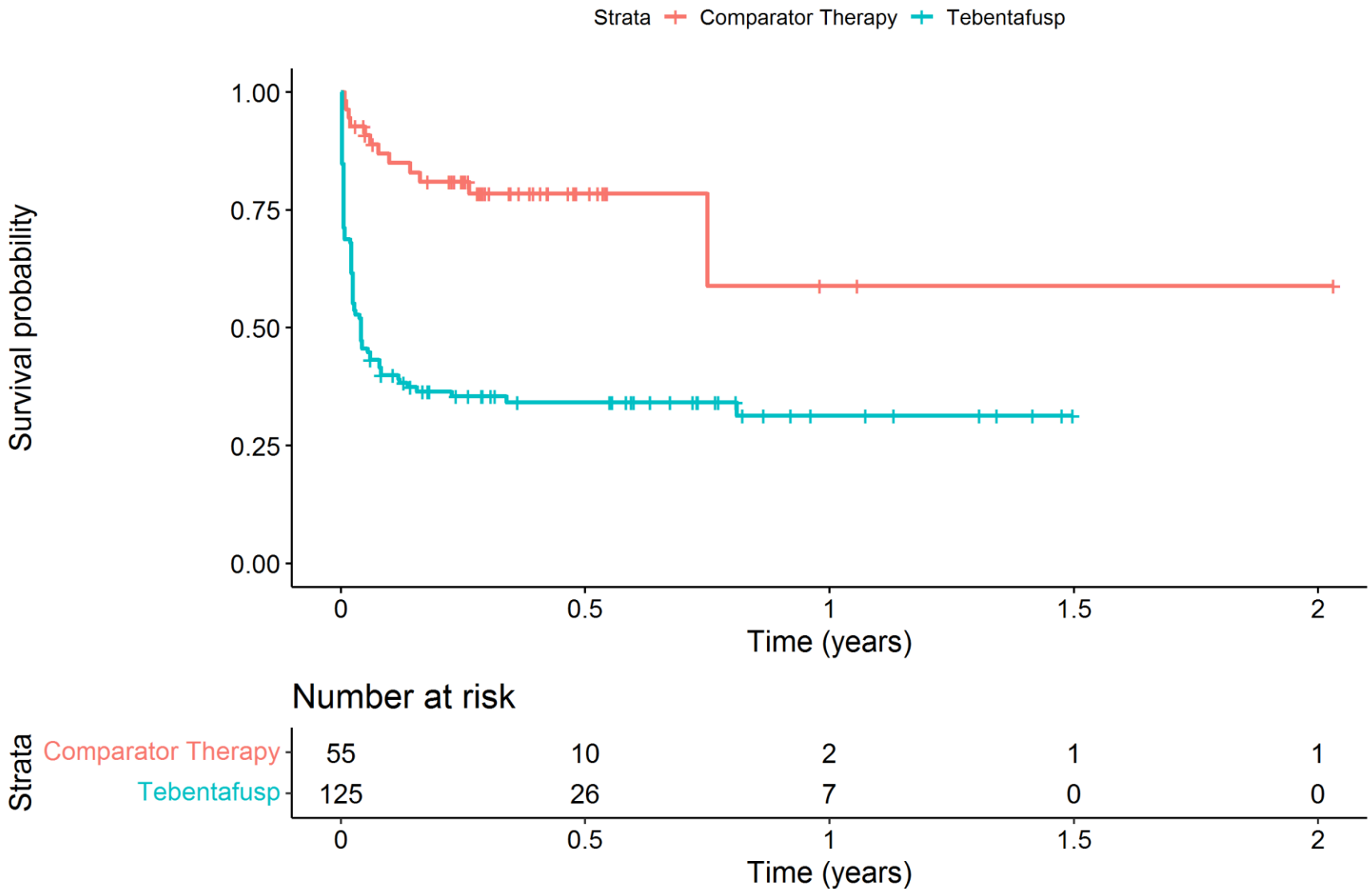
53.341 Pruritus - Hispanisch



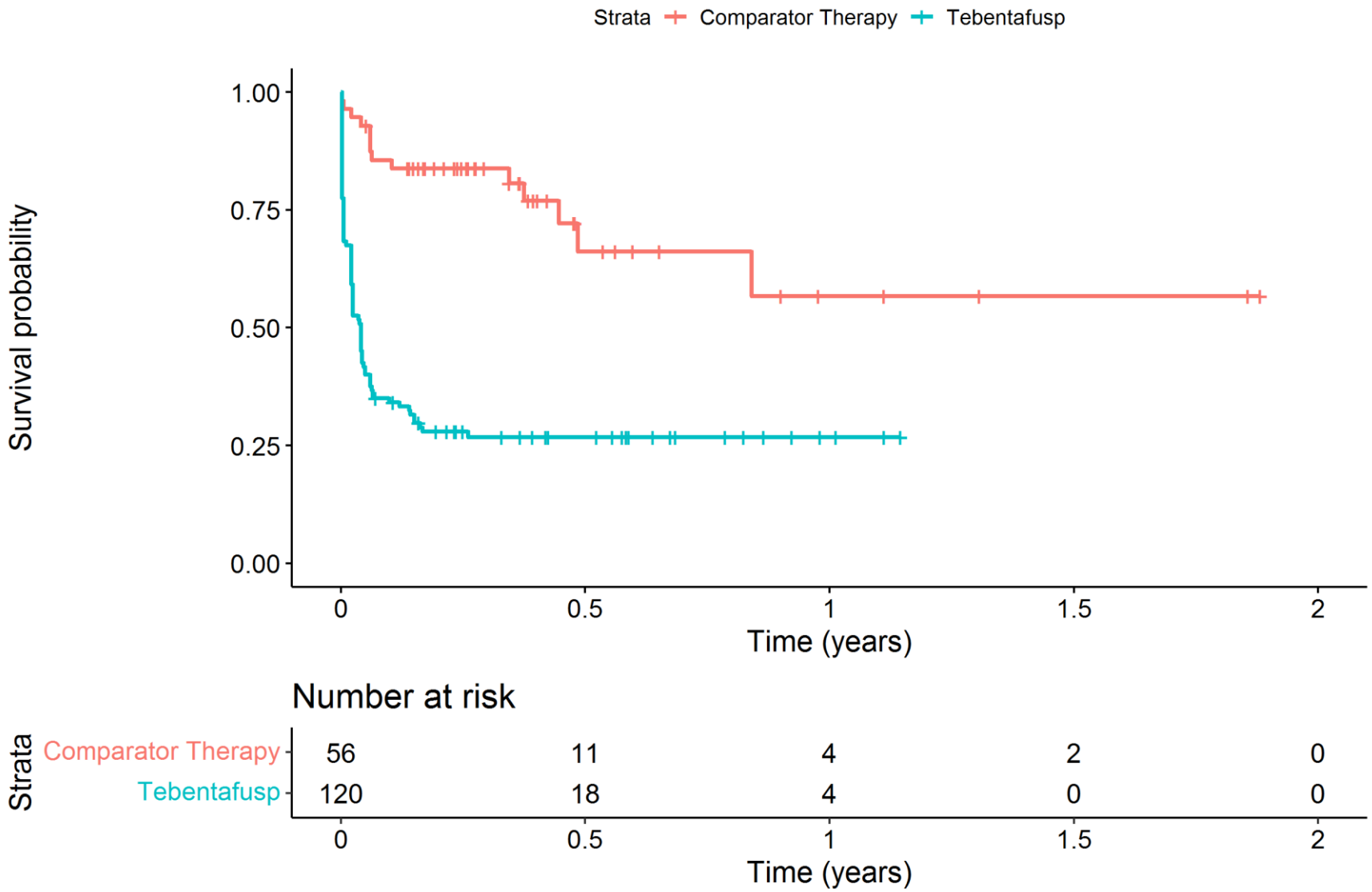
53.342 Pruritus - Nicht-hispanisch



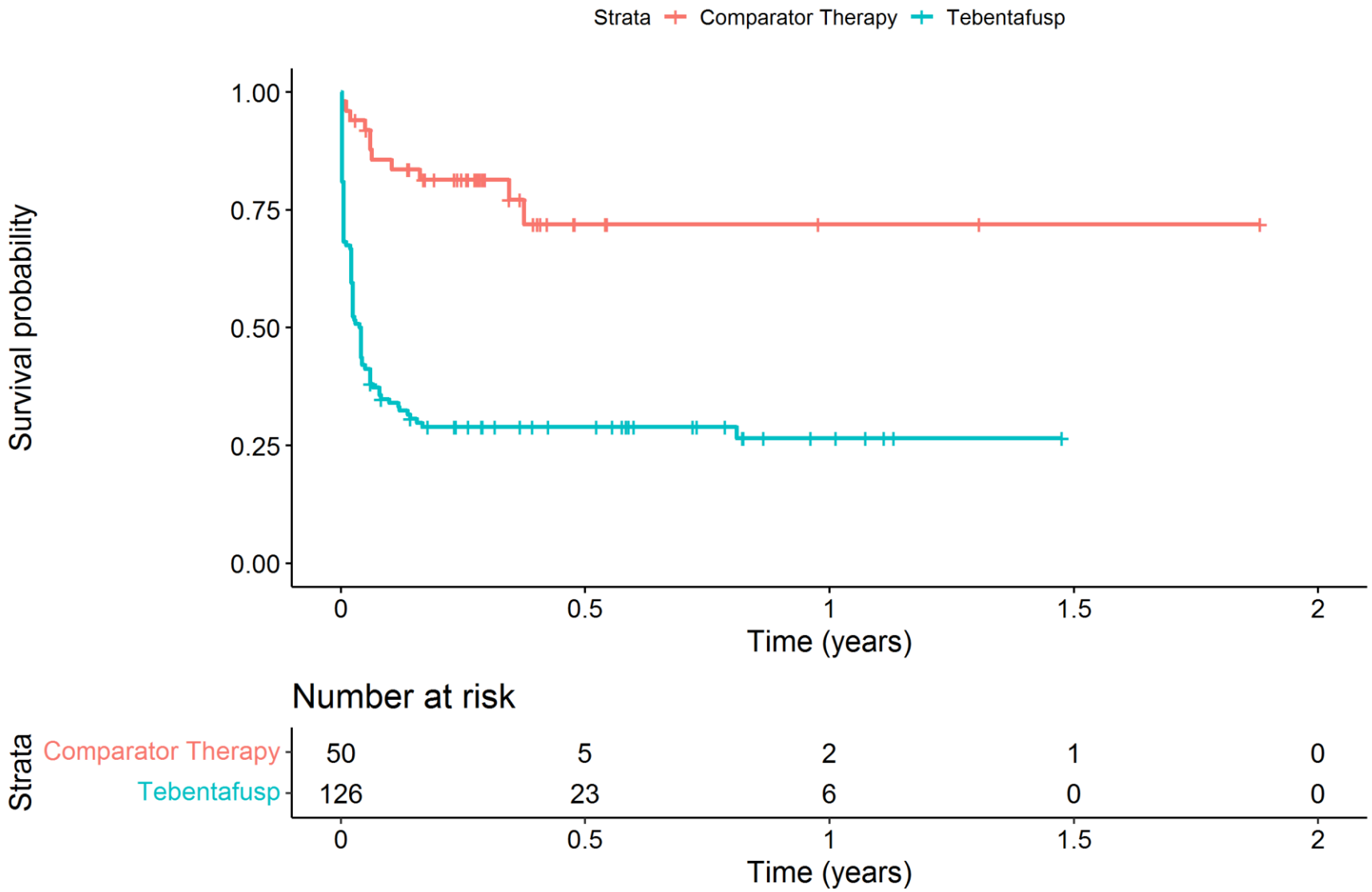
53.343 Pruritus - Männlich



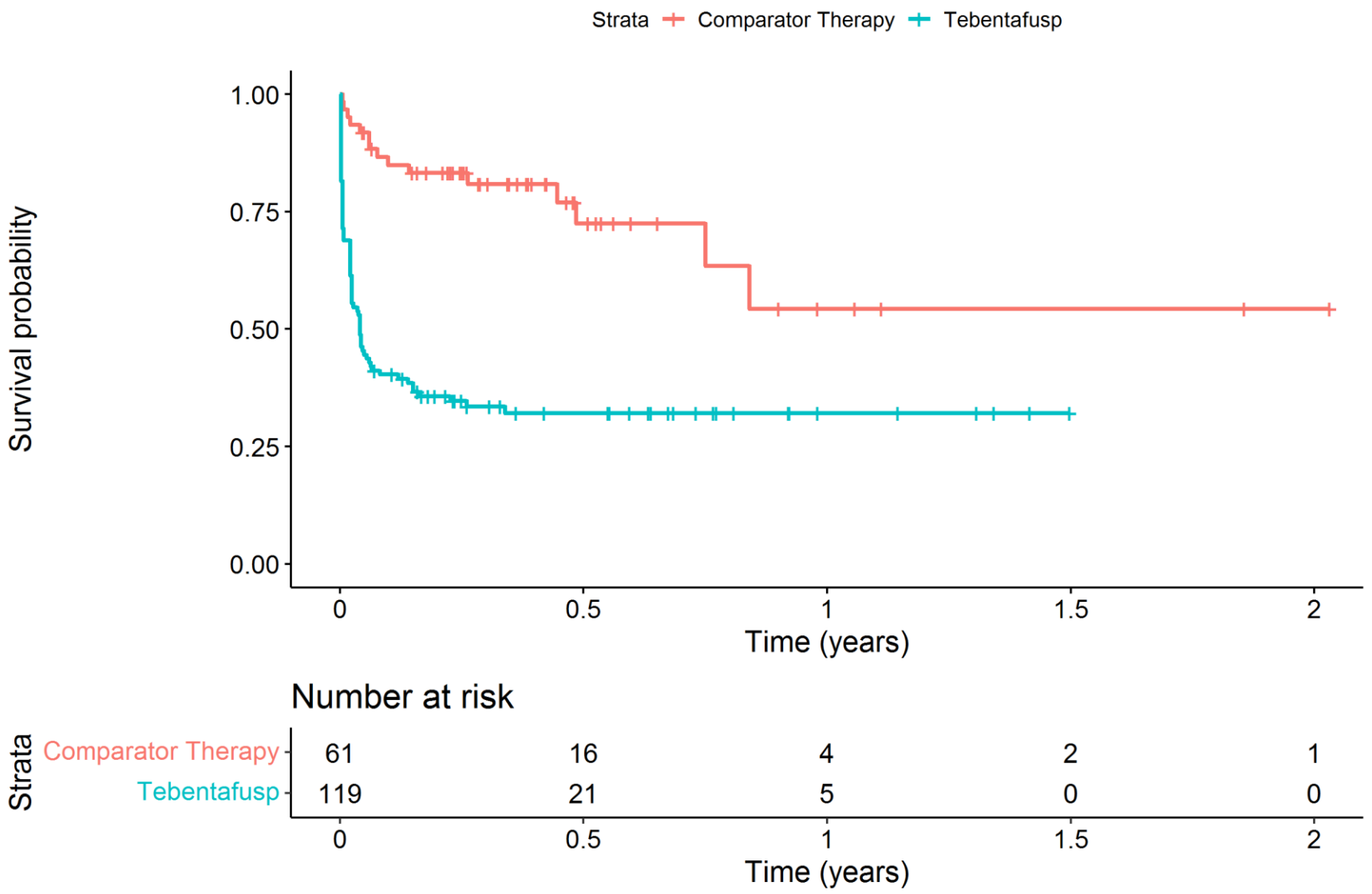
53.344 Pruritus - Weiblich



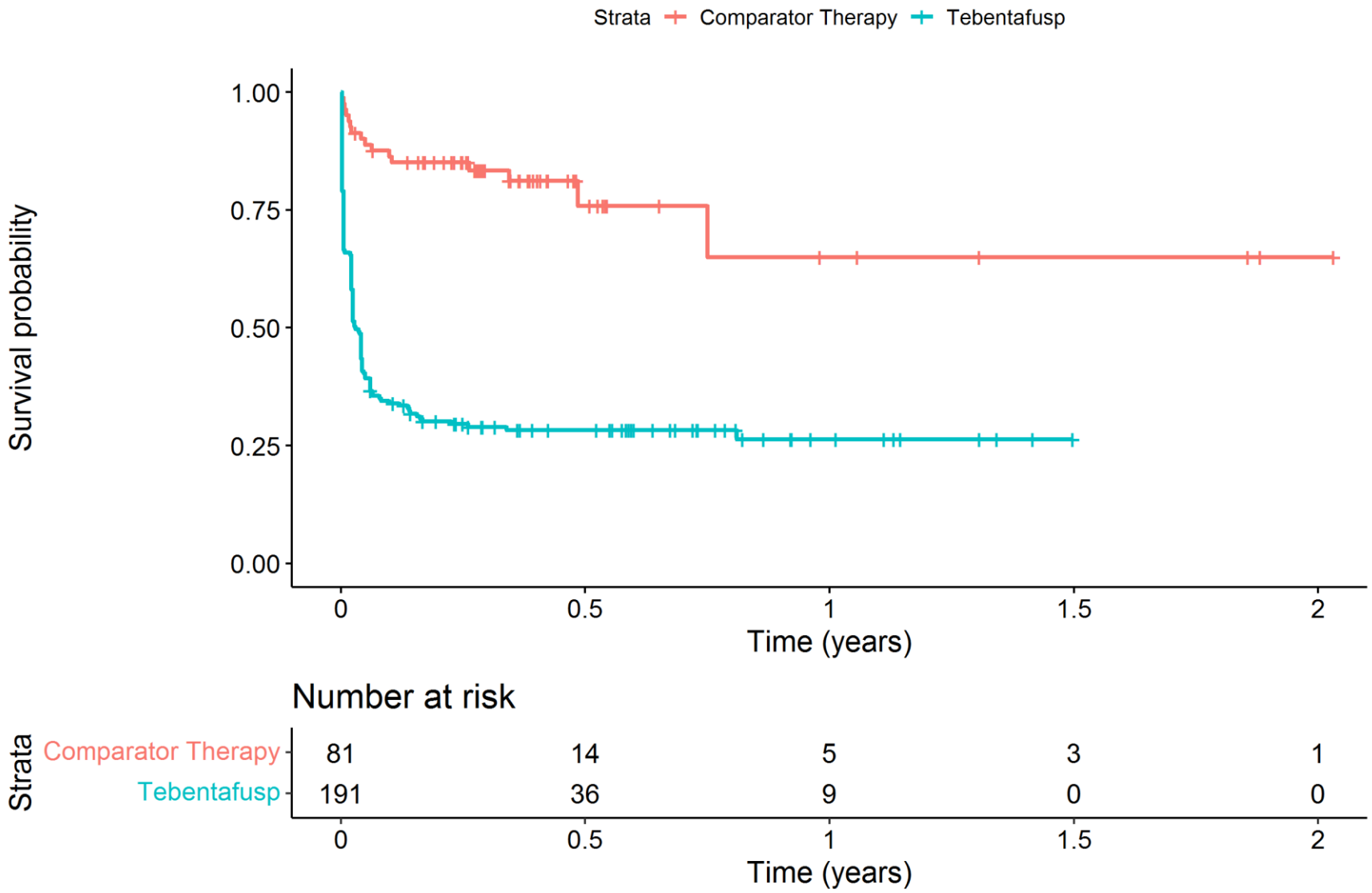
53.345 Pruritus - <65



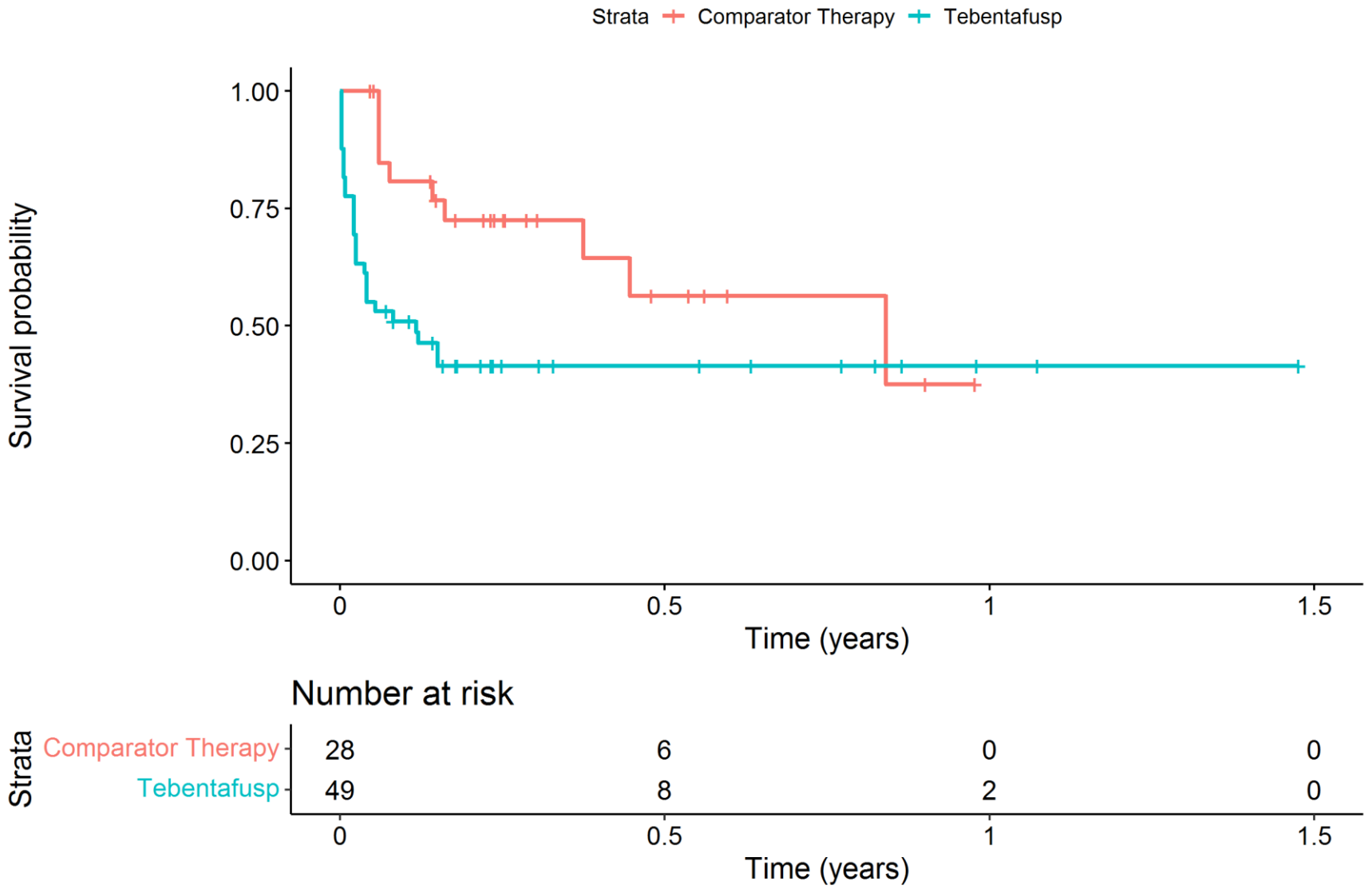
53.346 Pruritus - ≥65



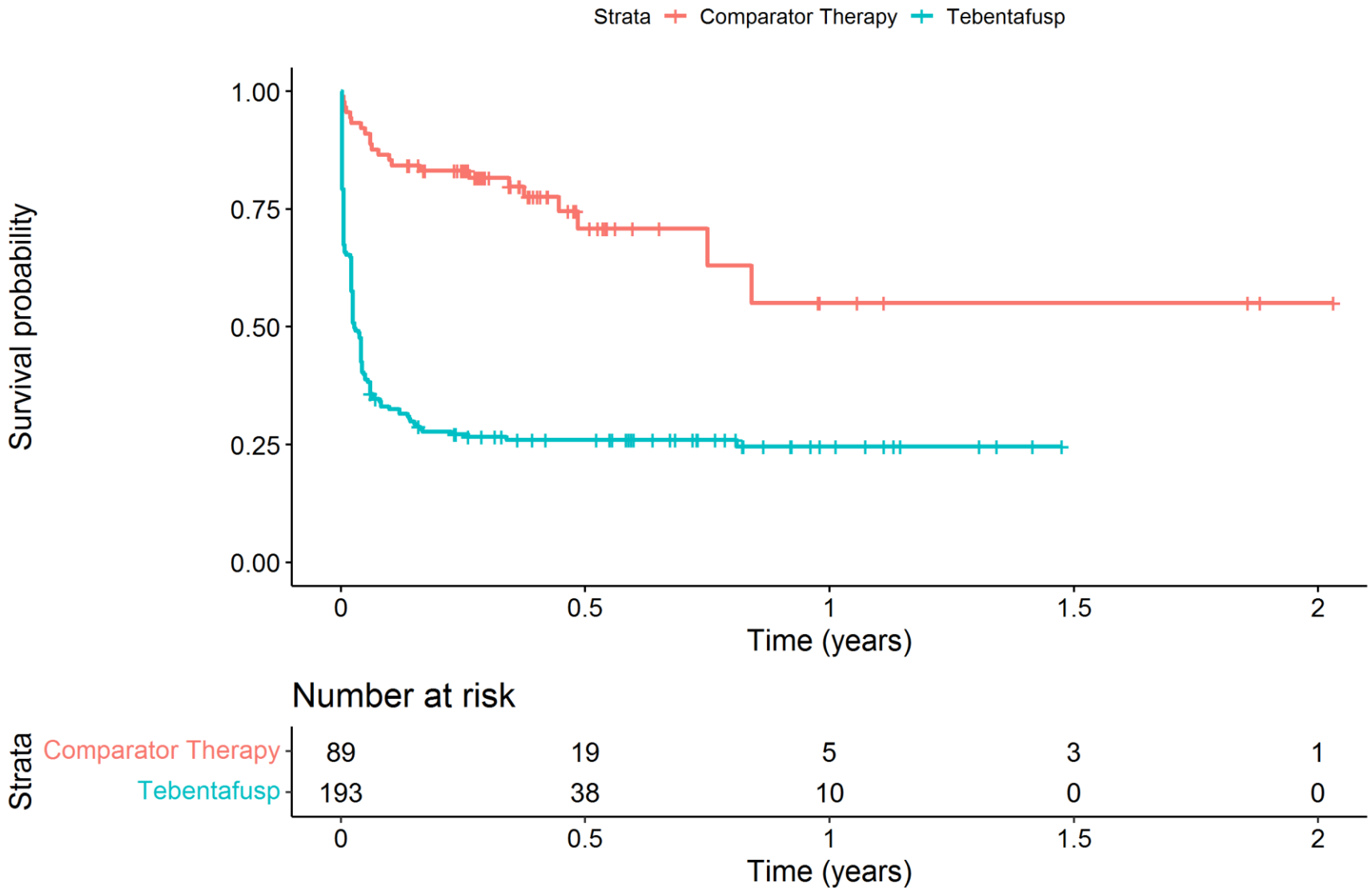
53.347 Pruritus - ECOG 0



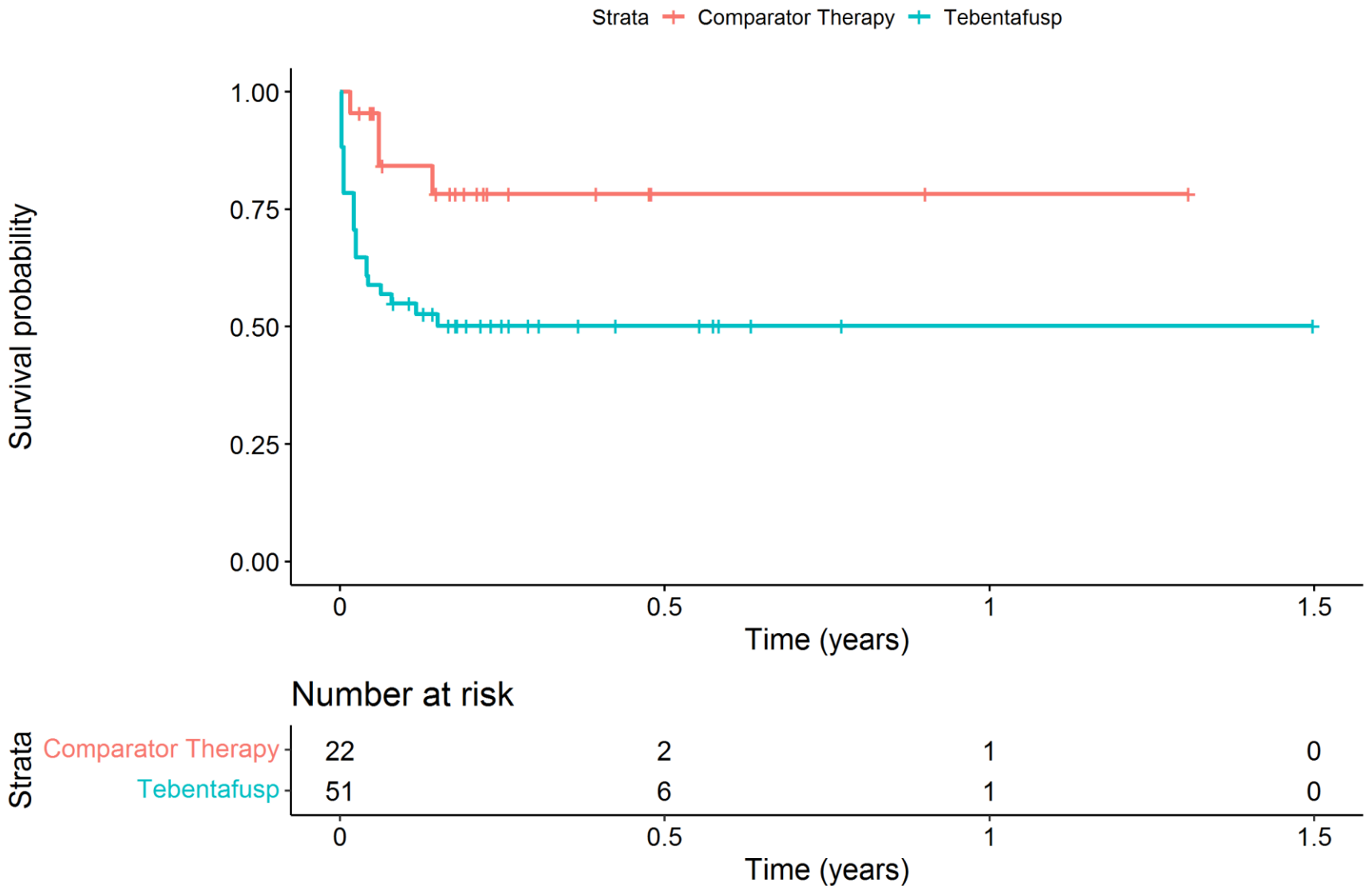
53.348 Pruritus - ECOG 1



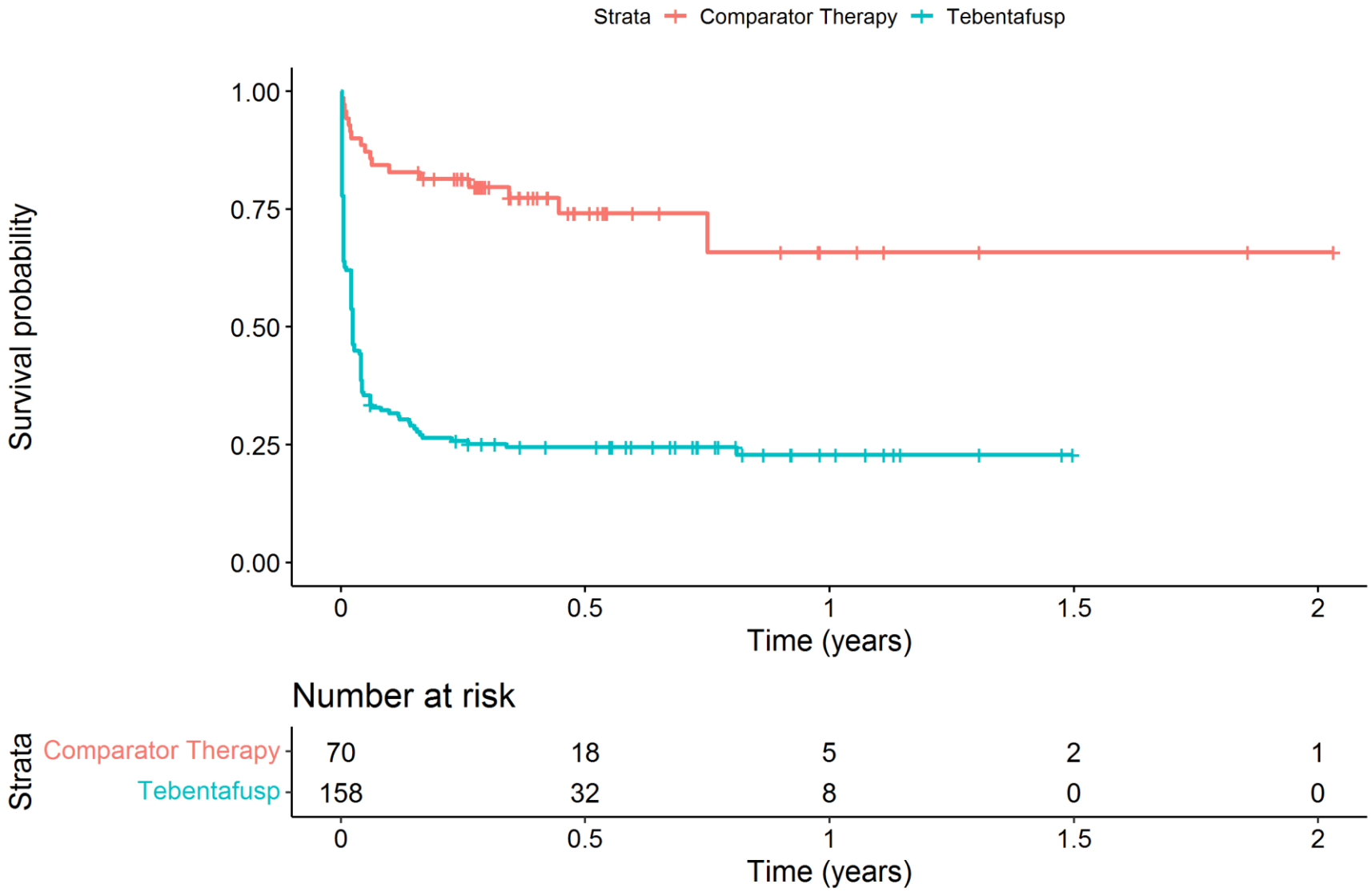
53.349 Pruritus - ALP ≤ ULN



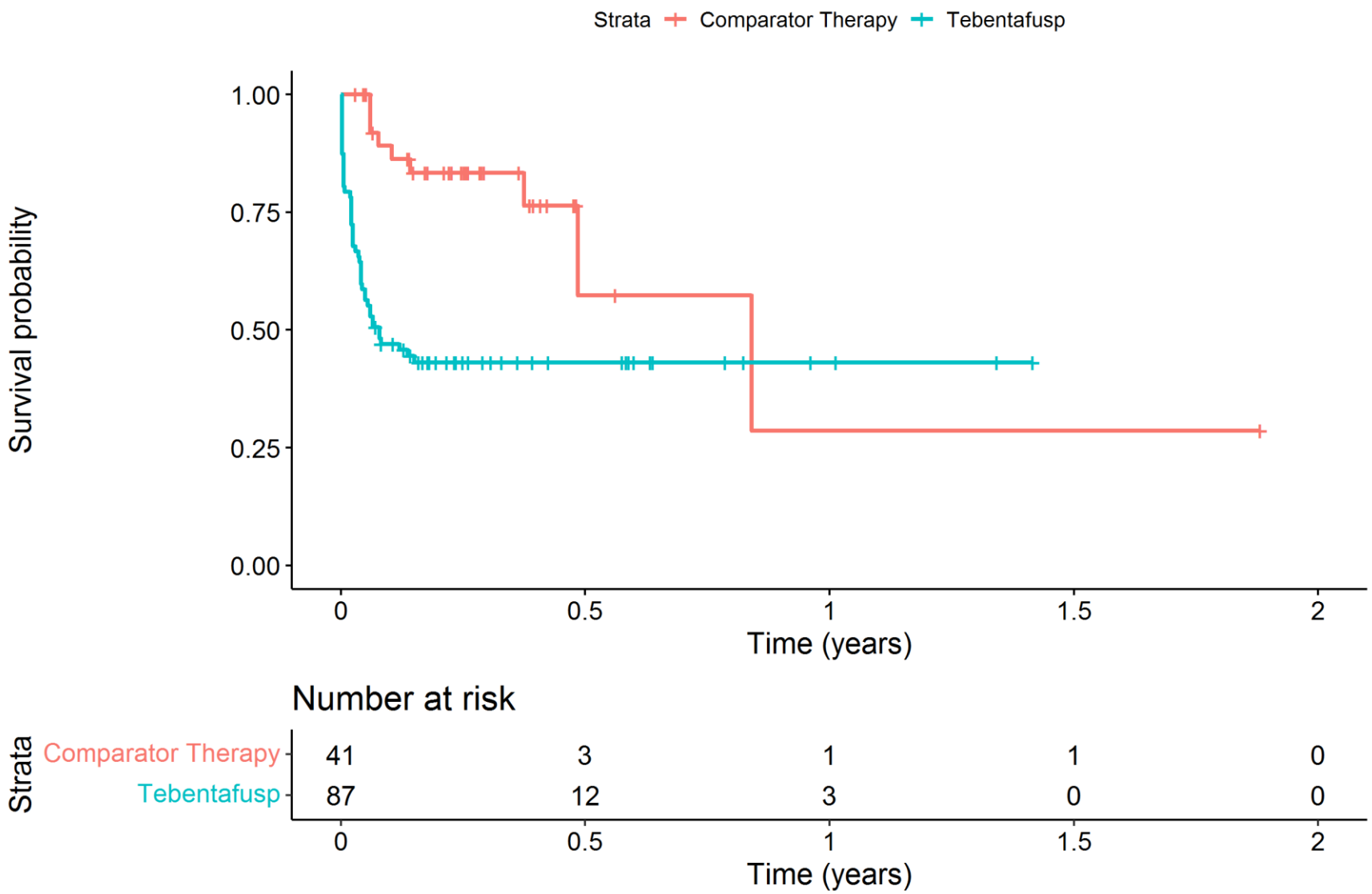
53.350 Pruritus - ALP > ULN



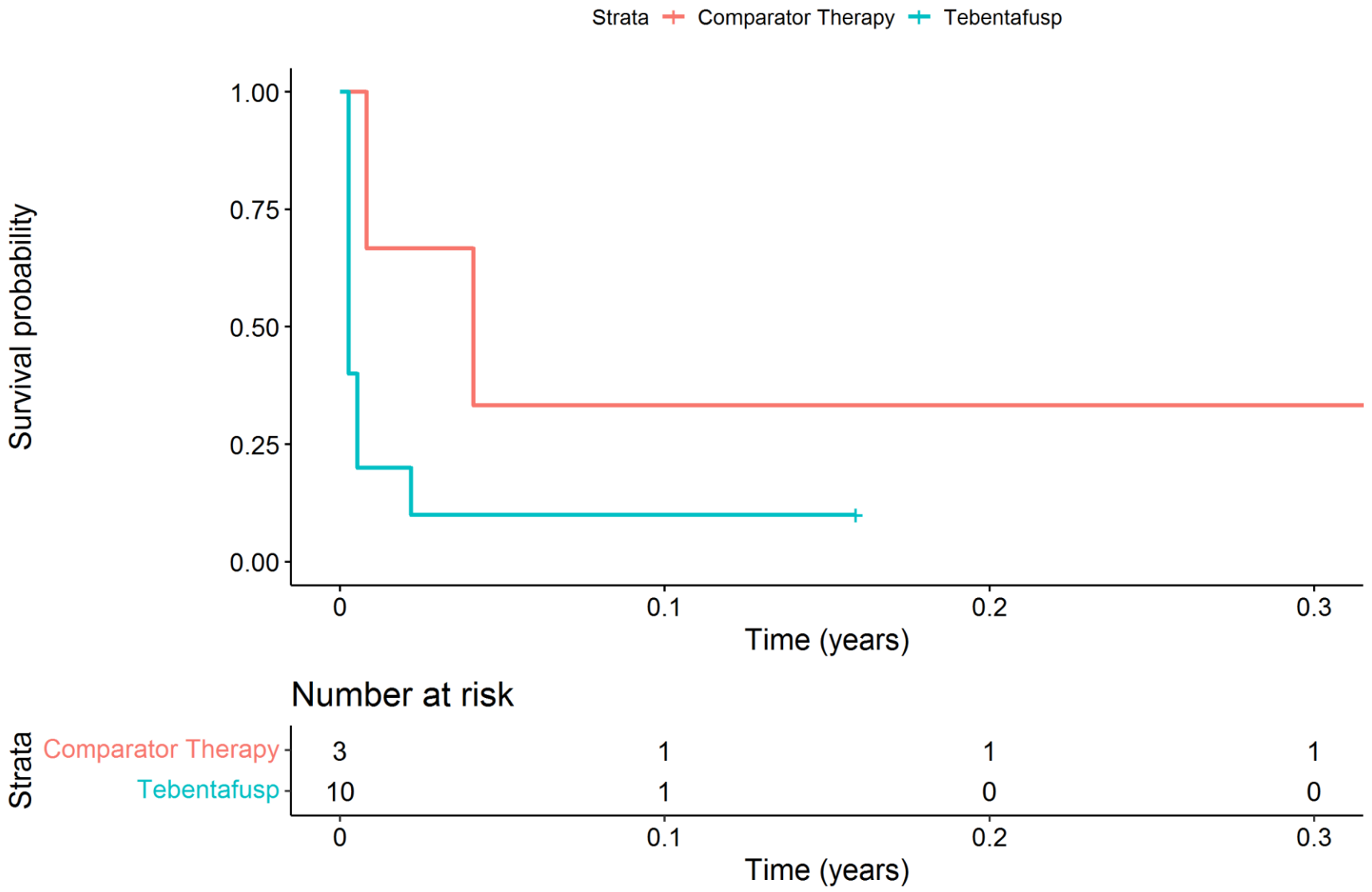
53.351 Pruritus - LDH =< ULN



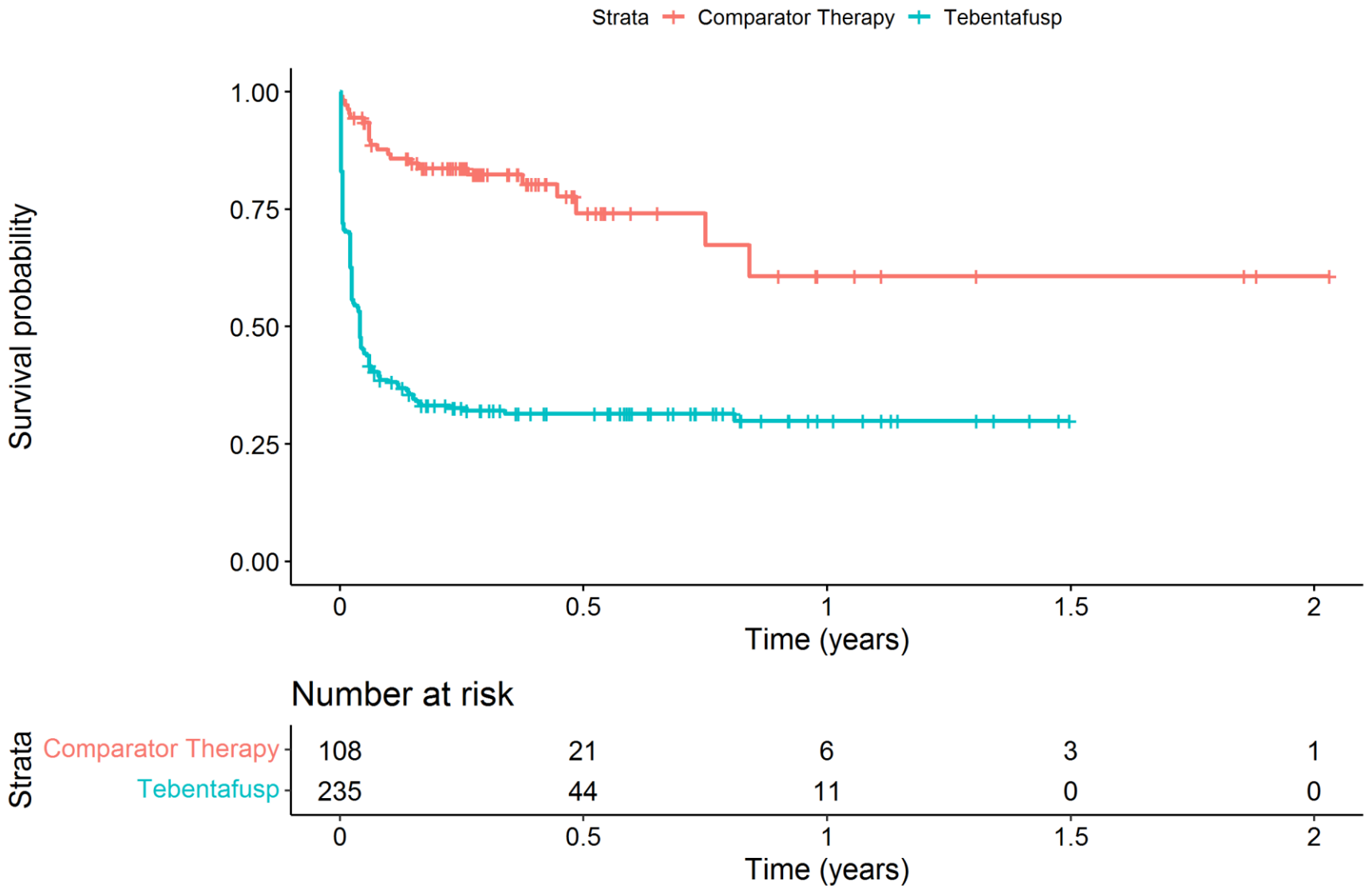
53.352 Pruritus - LDH > ULN



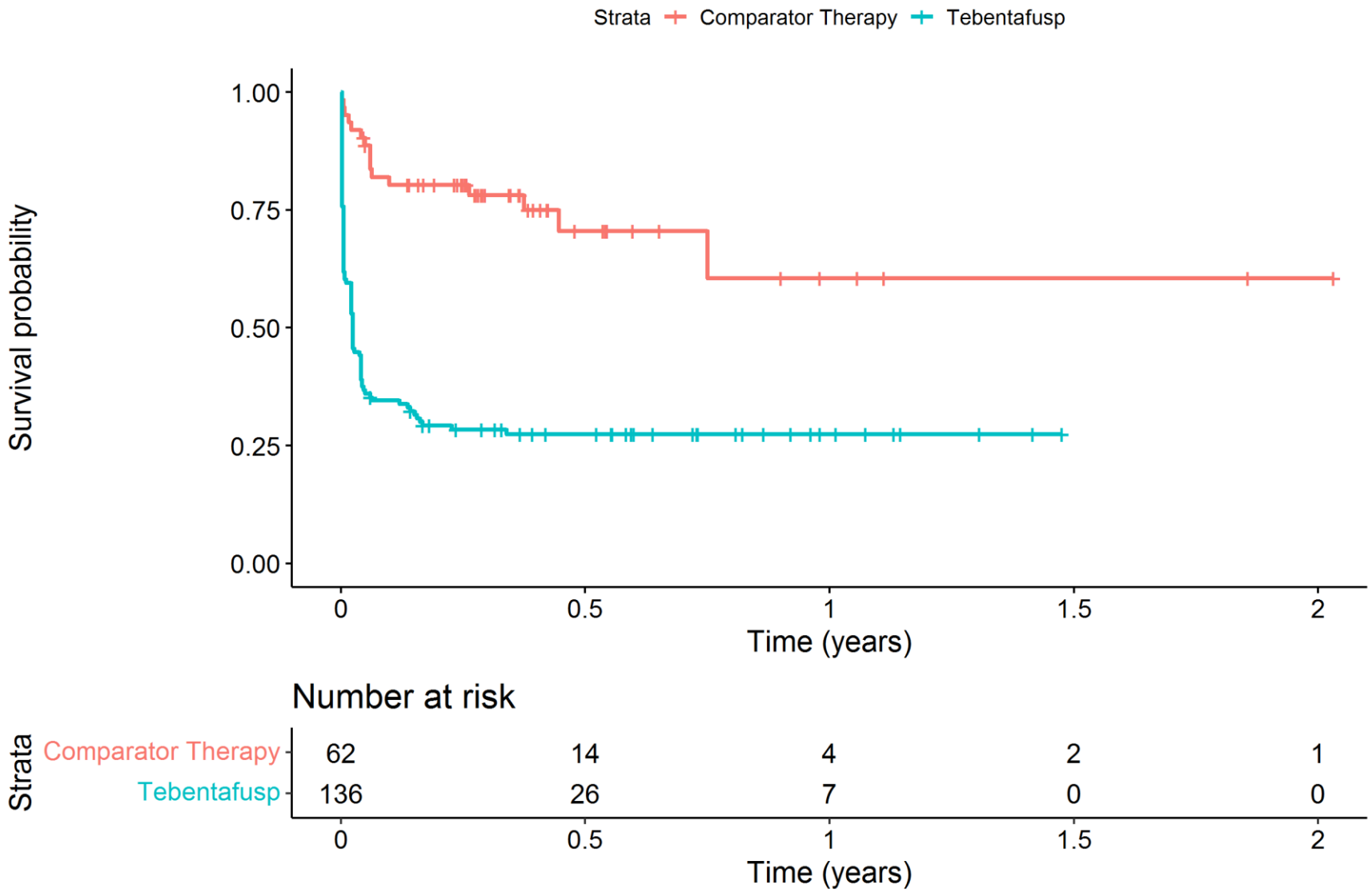
53.353 Pruritus - Vorherige Therapie adjuvant/neoadjuvant



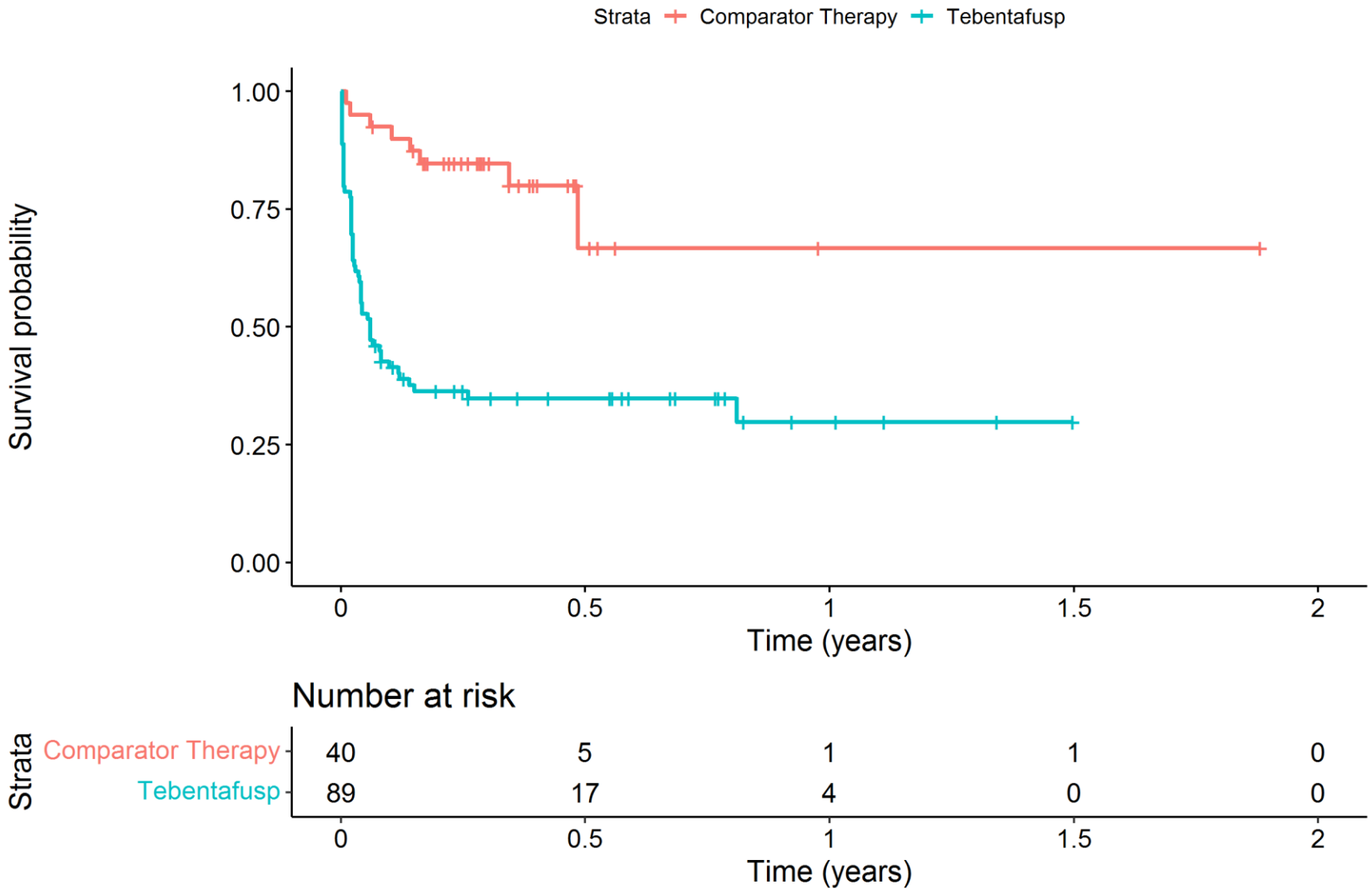
Pruritus - Keine vorherige Therapie adjuvant/neoadjuvant



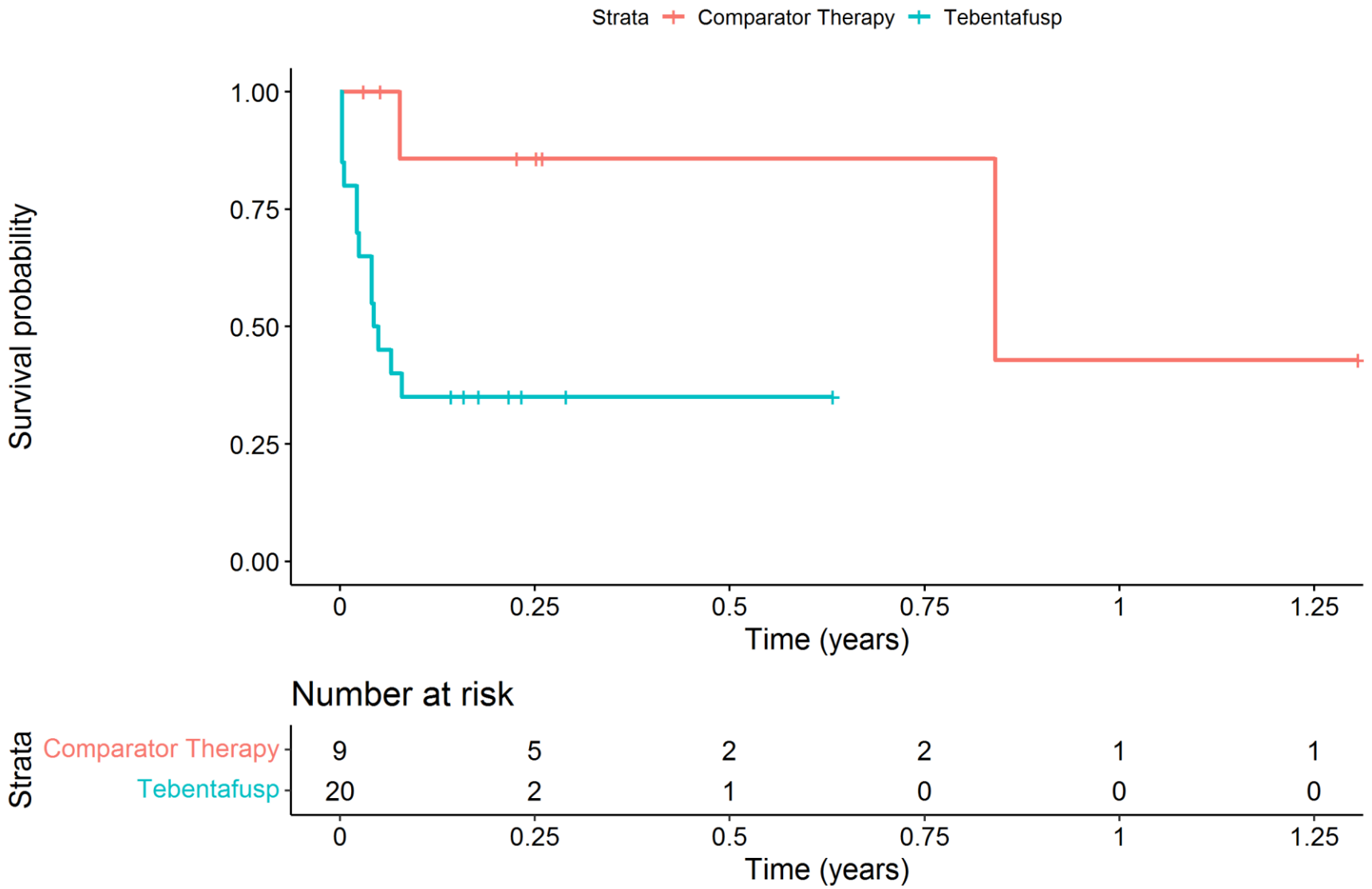
53.354 Pruritus - Läsion ≤ 3cm



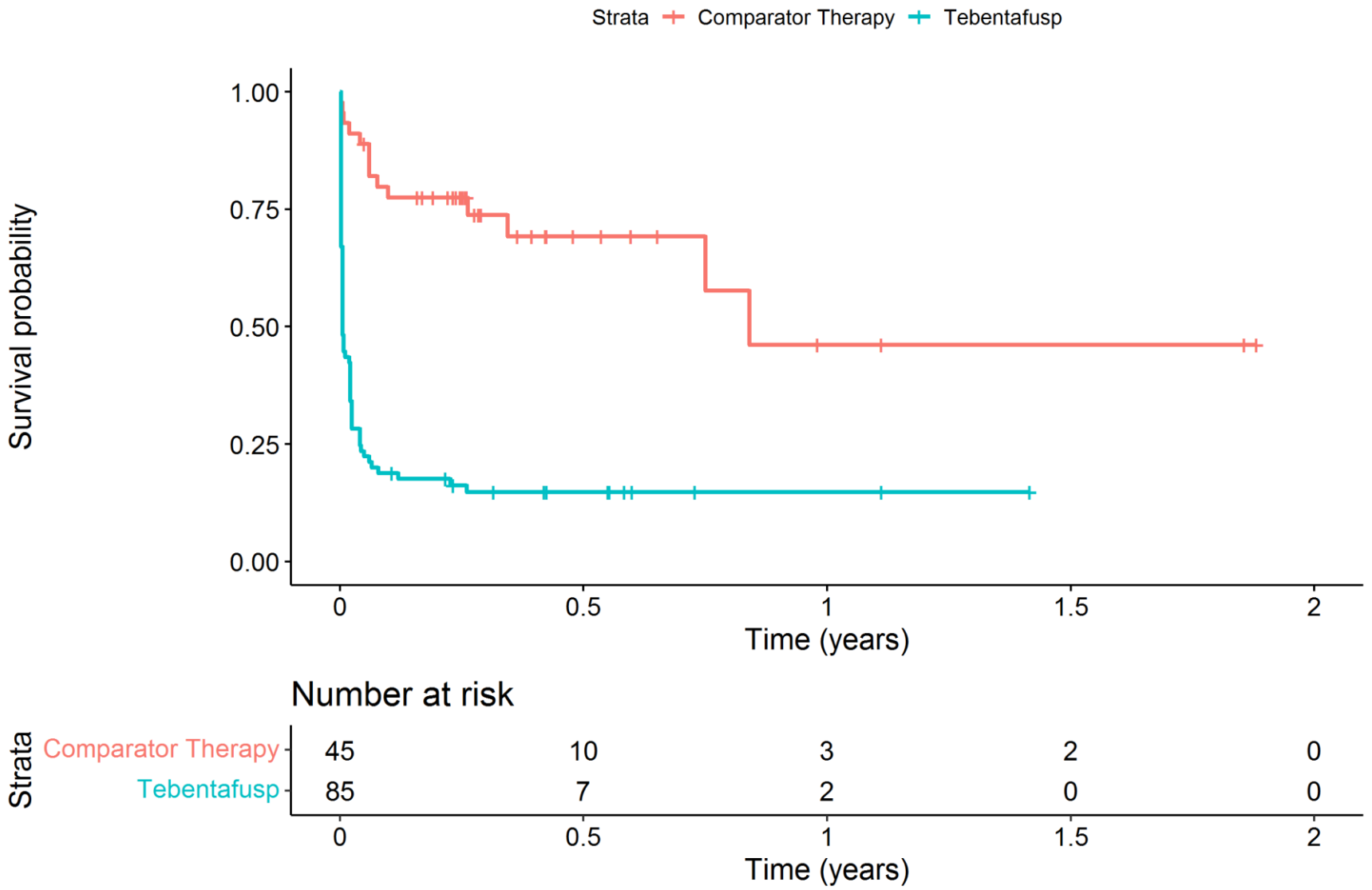
53.355 Pruritus - Läsion 3,1-8,0 cm



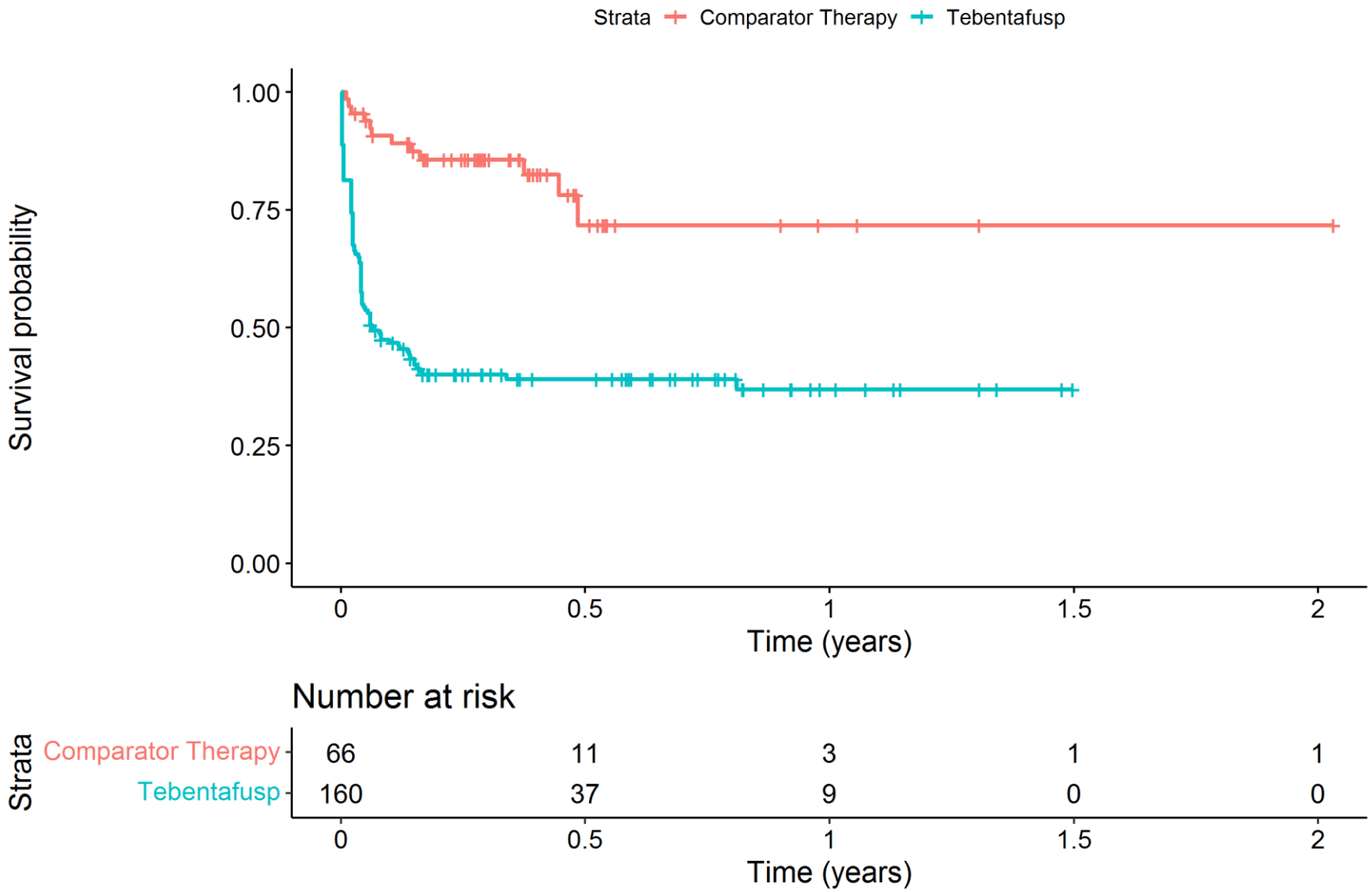
53.356 Pruritus - Läsion ≥8,1 cm



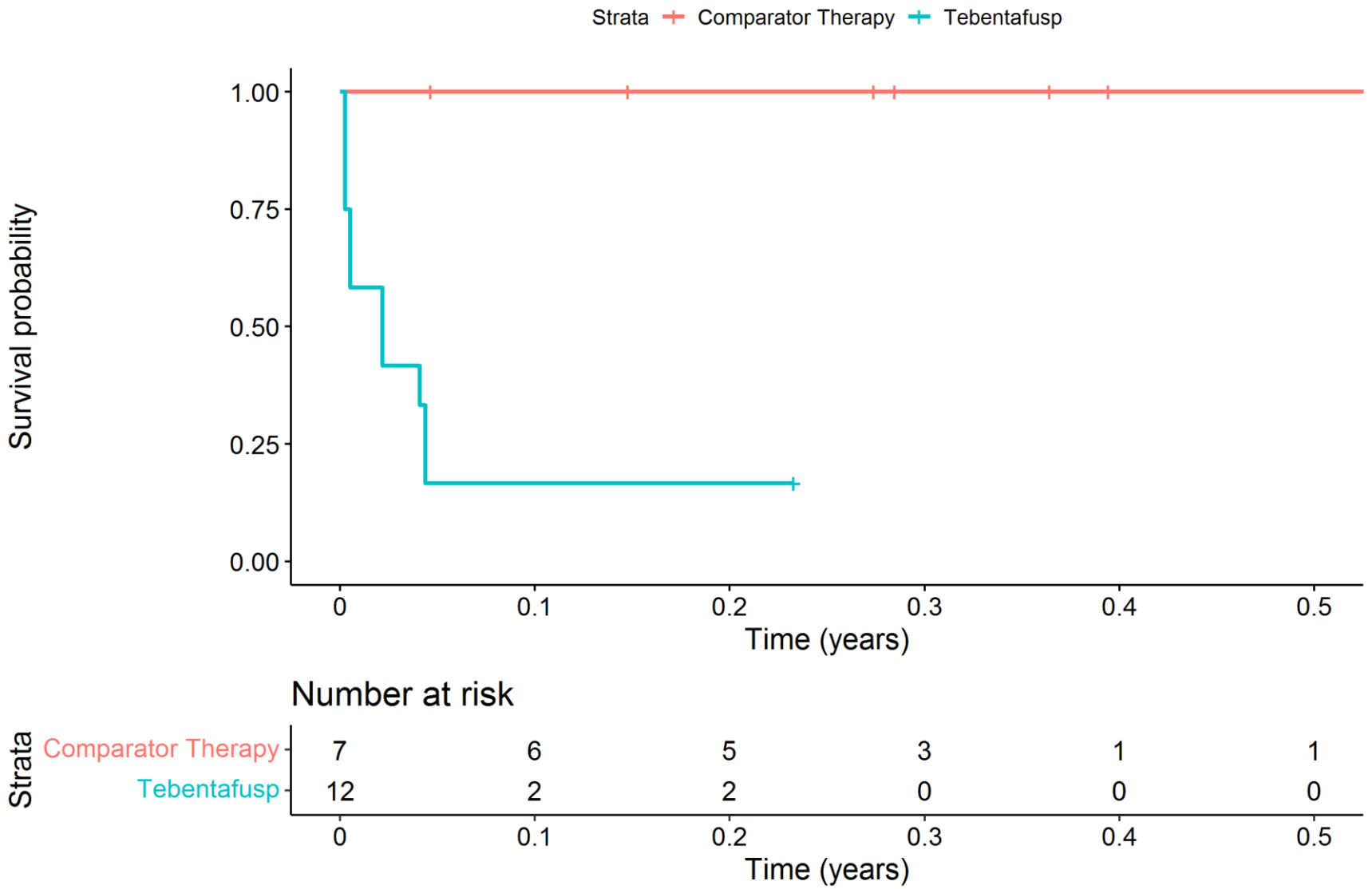
53.357 Pruritus - Nordamerika



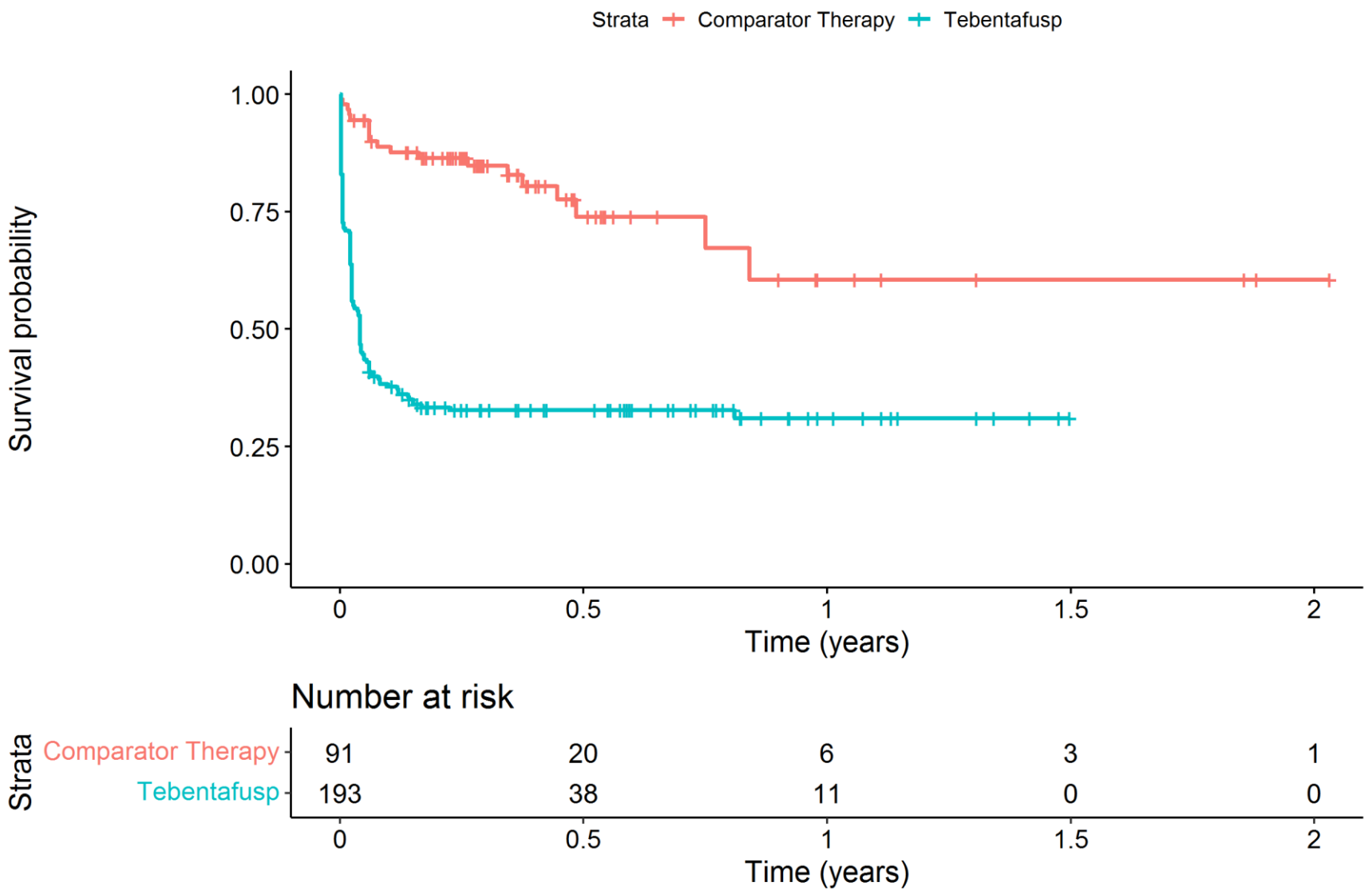
53.358 Pruritus - Nicht-Nordamerika



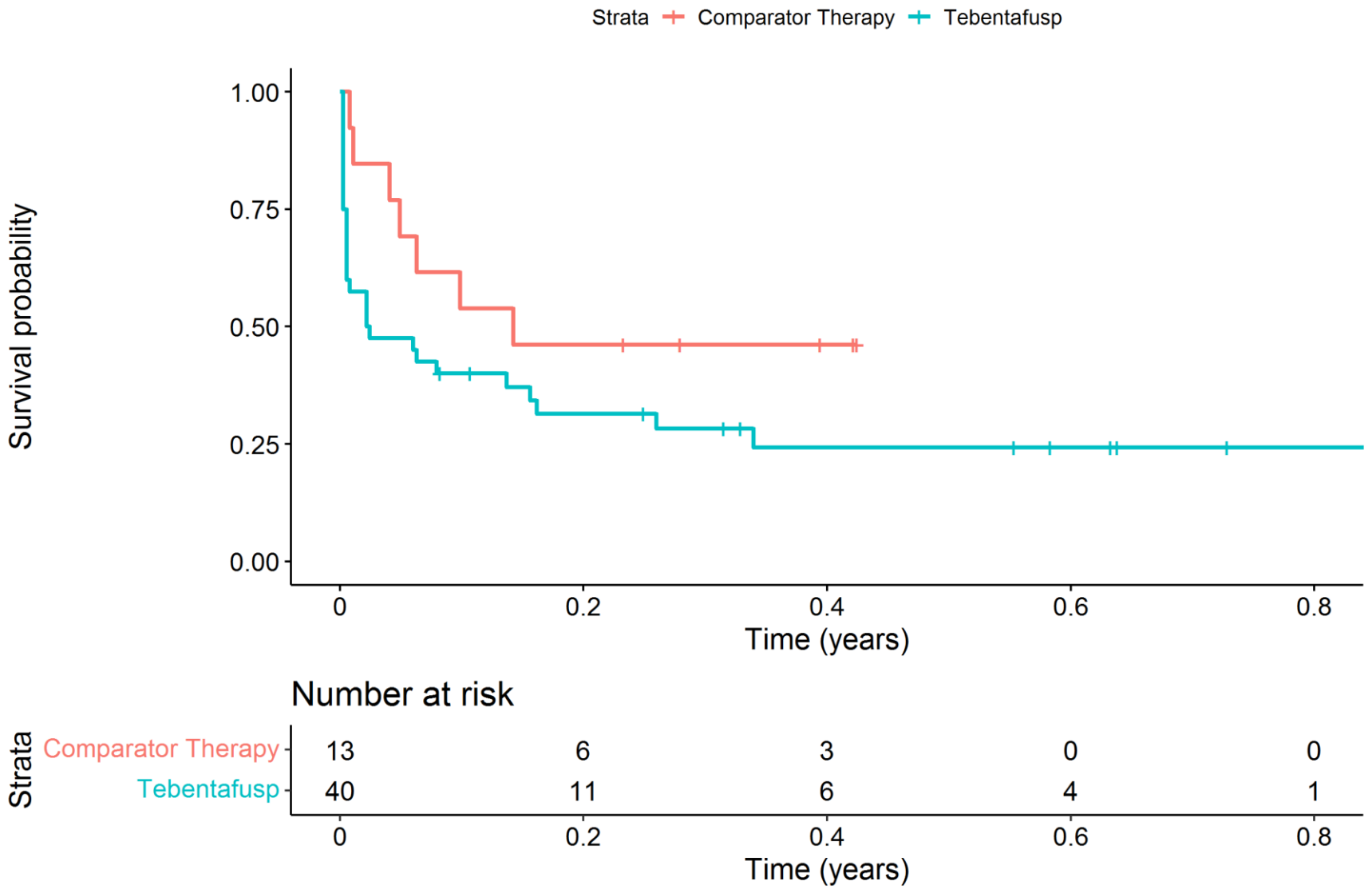
53.359 Pruritus - Dacarbazin



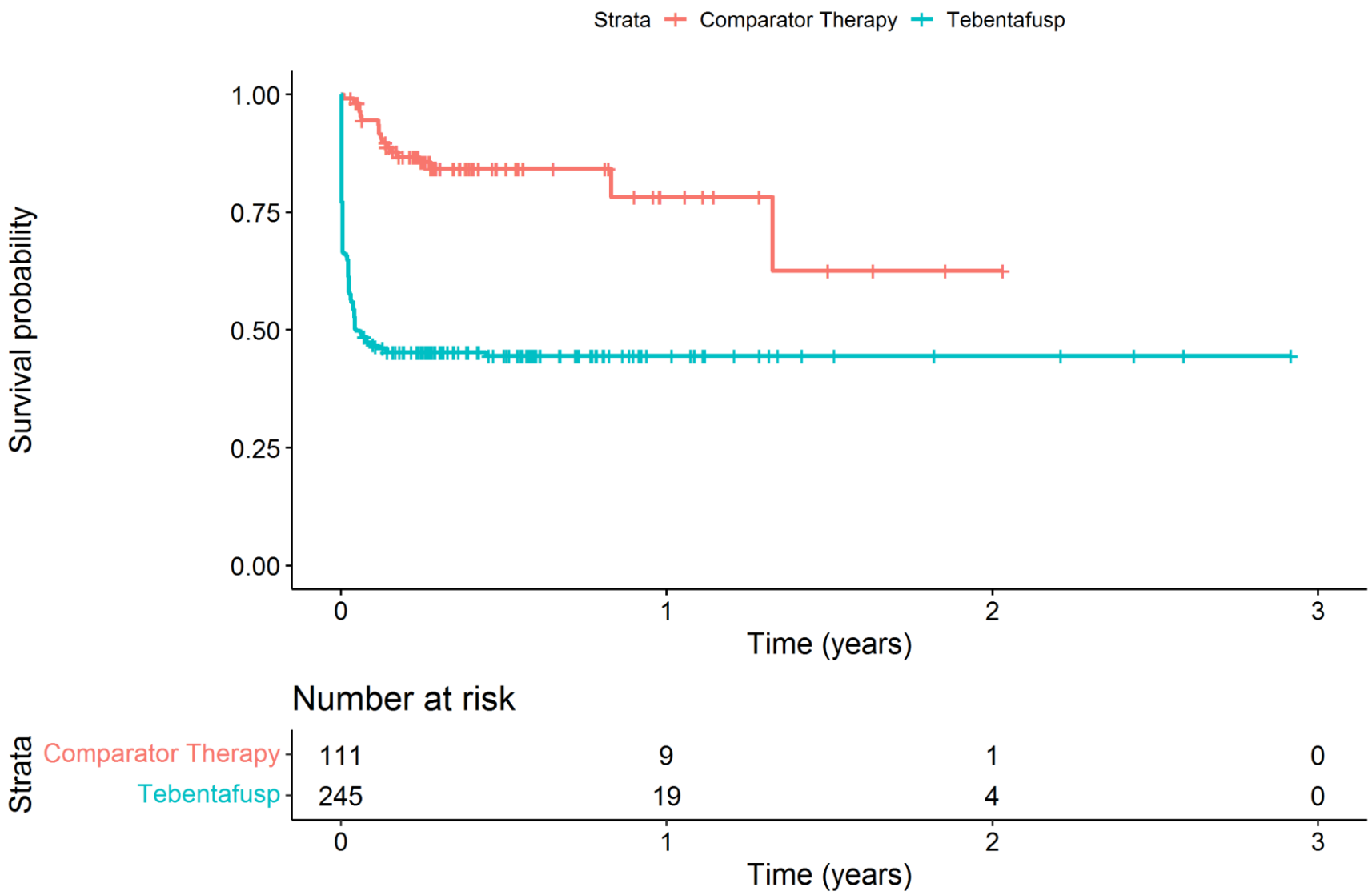
53.360 Pruritus - Pembrolizumab



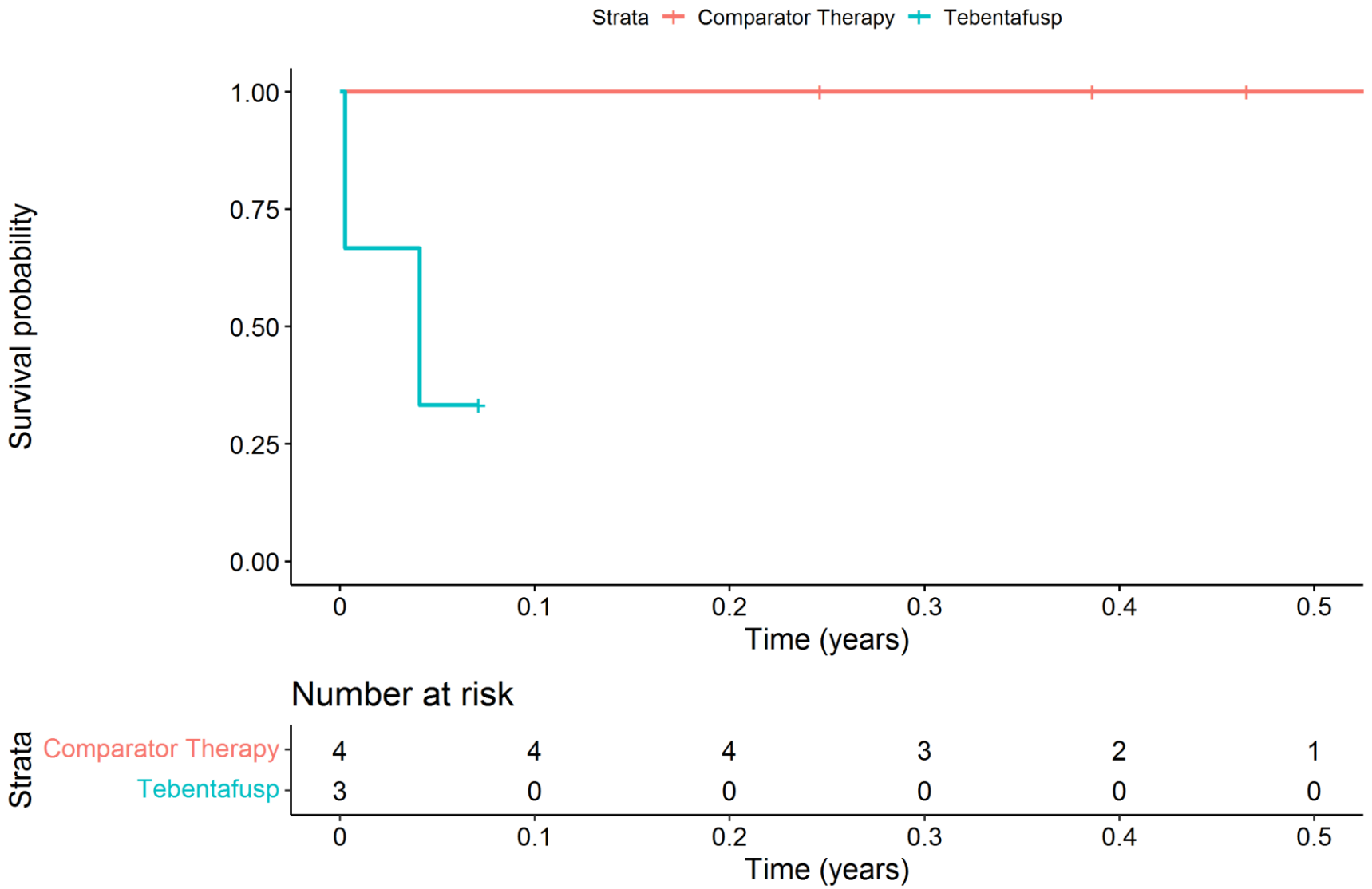
53.361 Pruritus - Ipilimumab



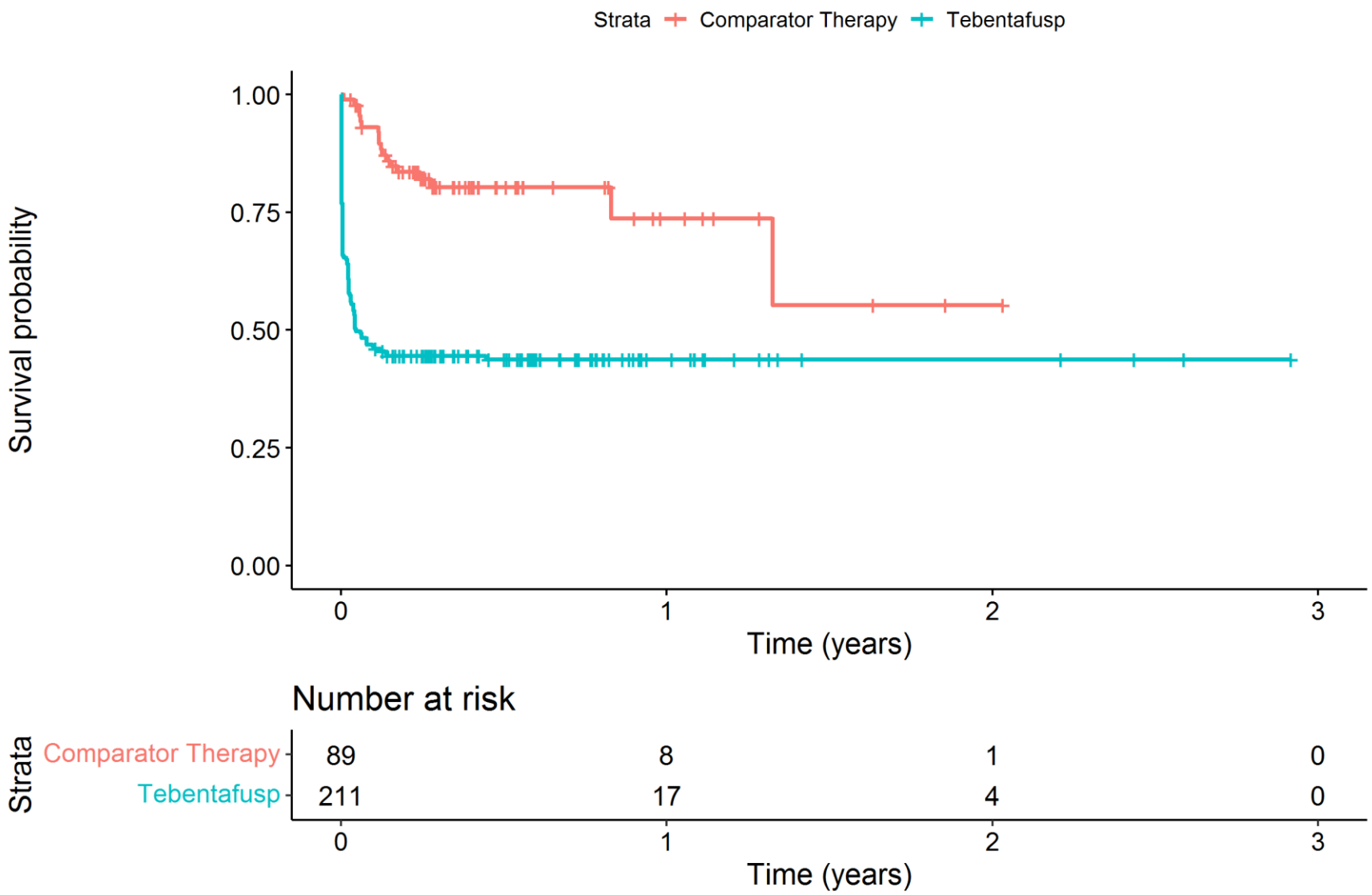
53.362 Hautausschlag - Gesamt



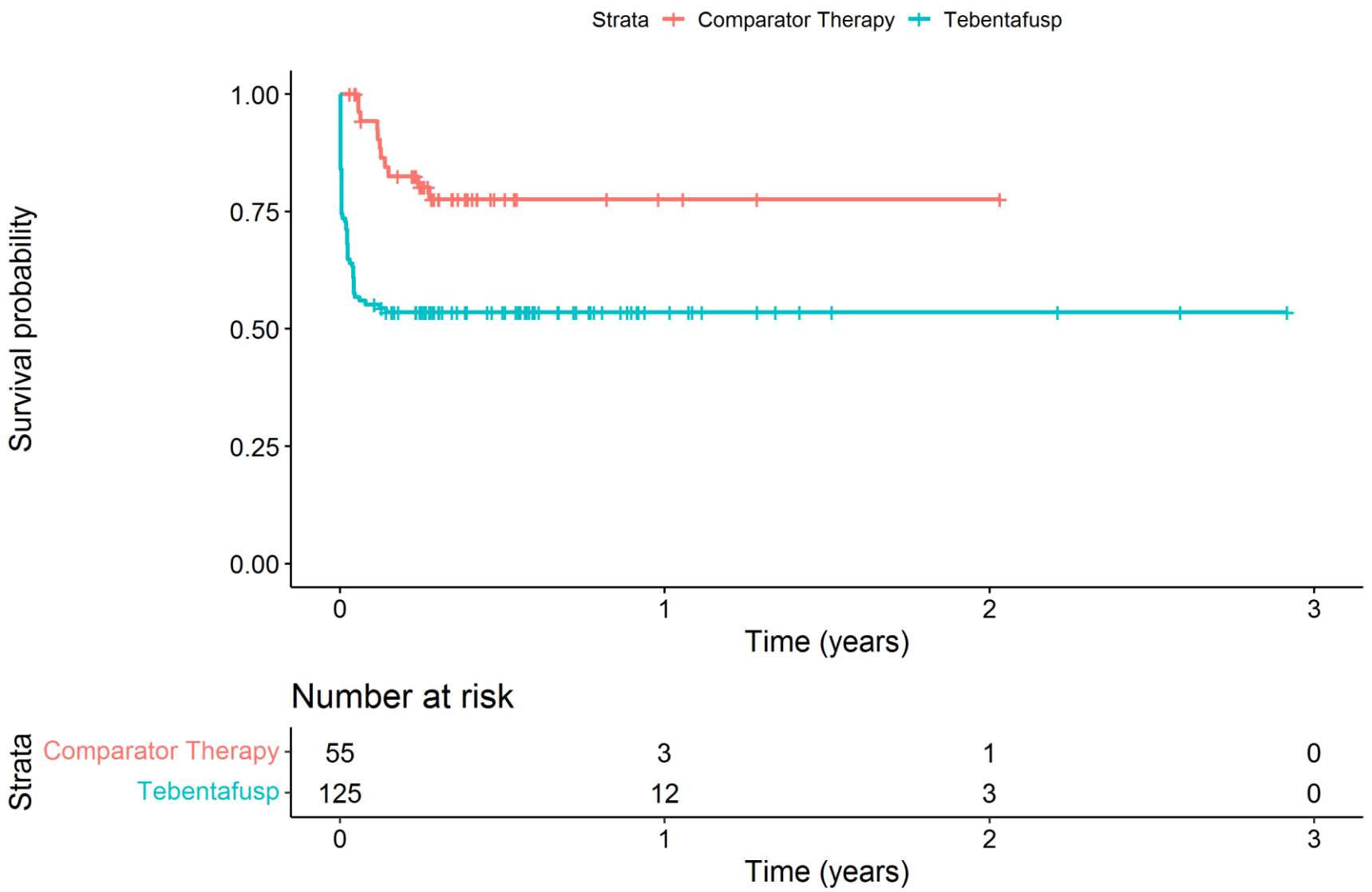
53.363 Hautausschlag - Hispanisch



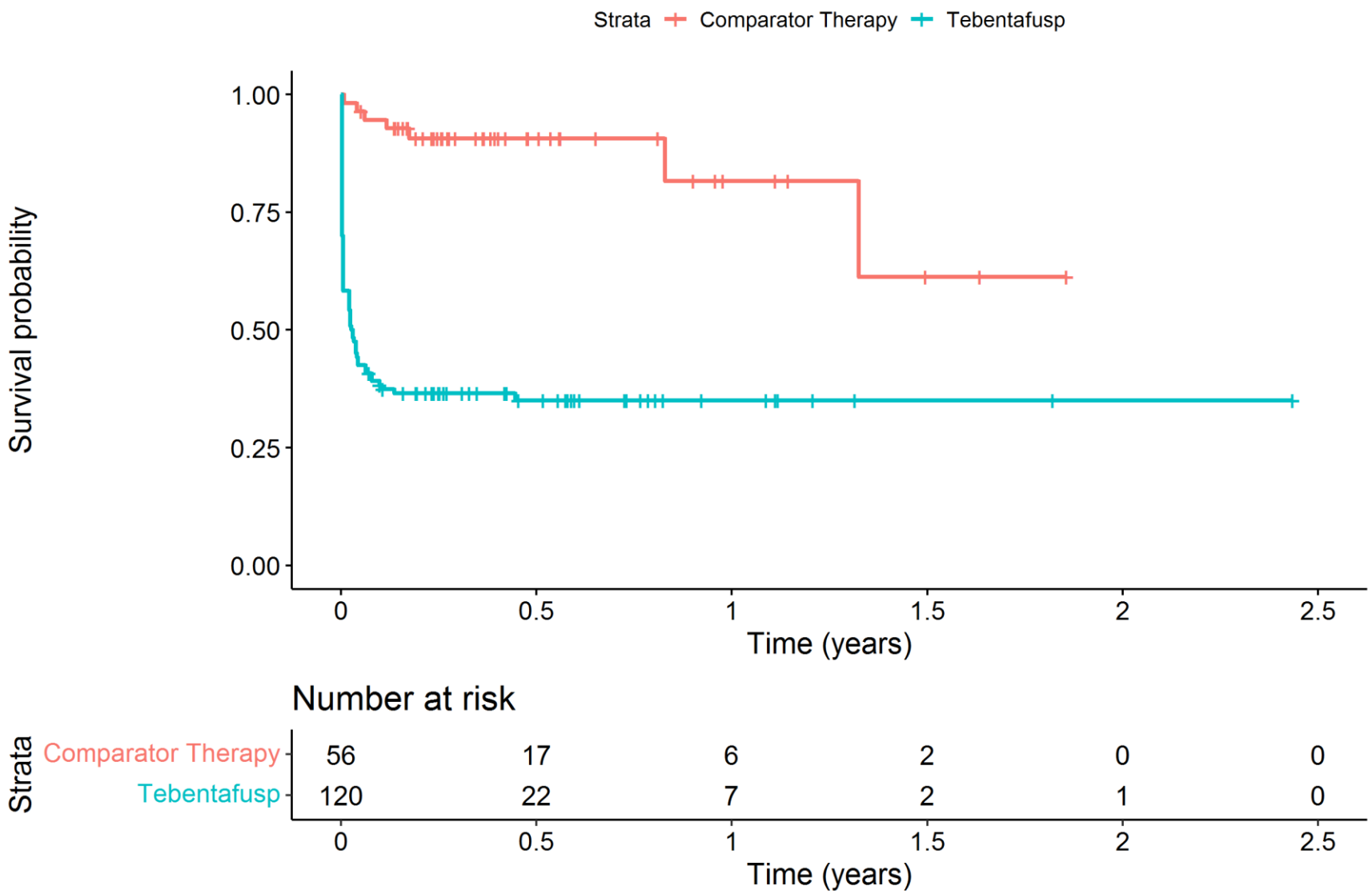
53.364 Hautausschlag - Nicht-hispanisch



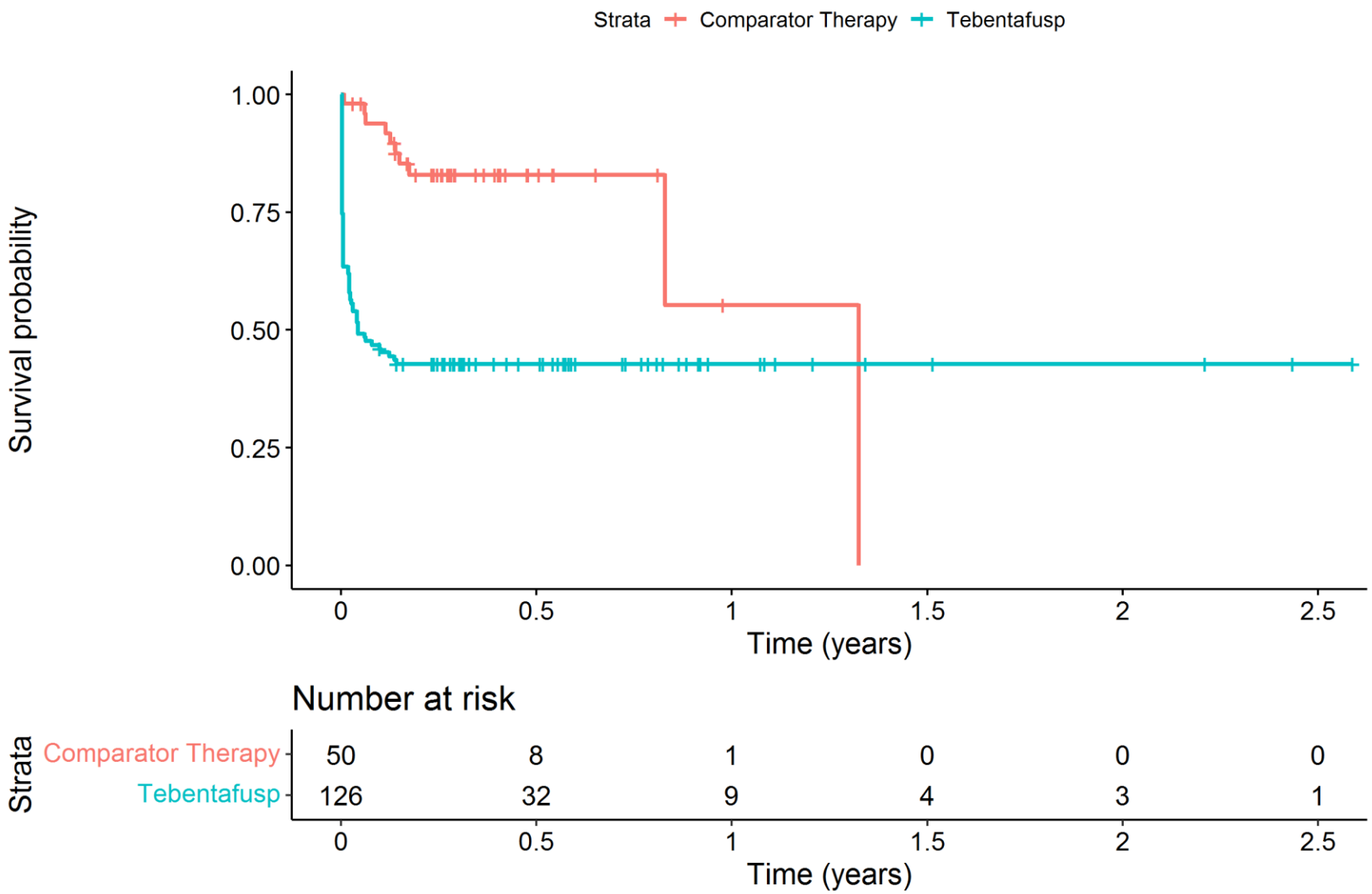
53.365 Hautausschlag - Männlich



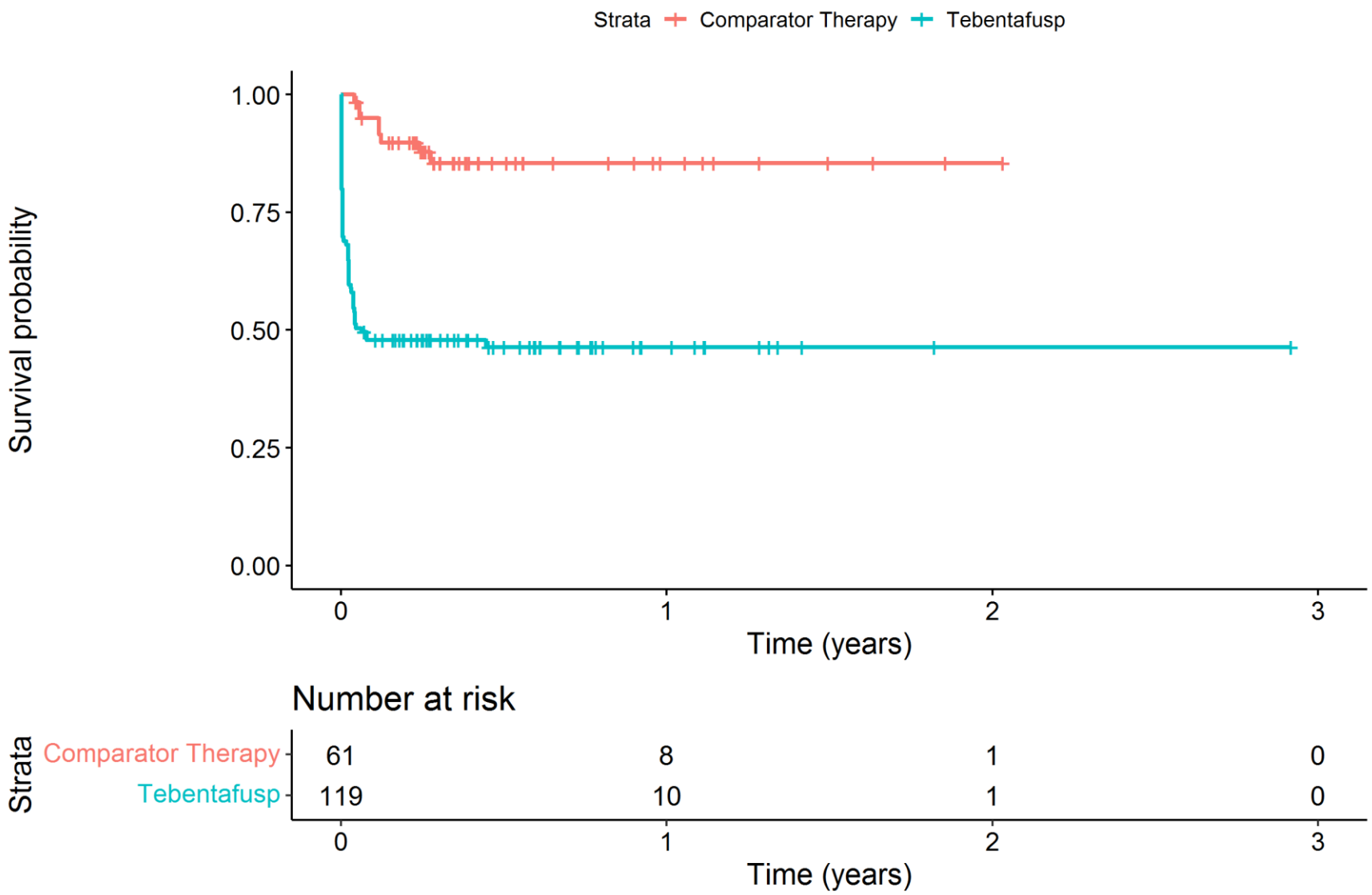
53.366 Hautausschlag - Weiblich



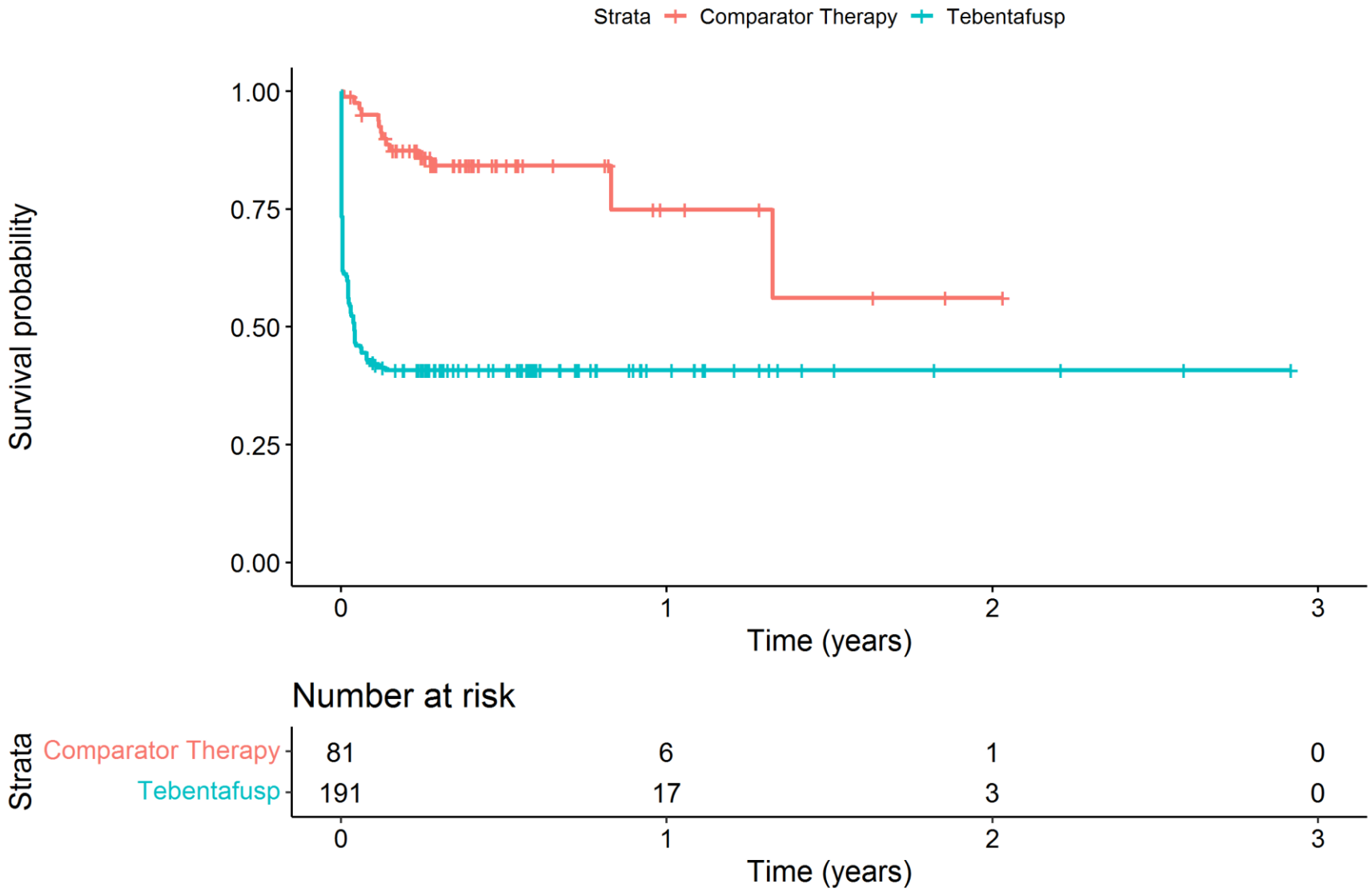
53.367 Hautausschlag - <65



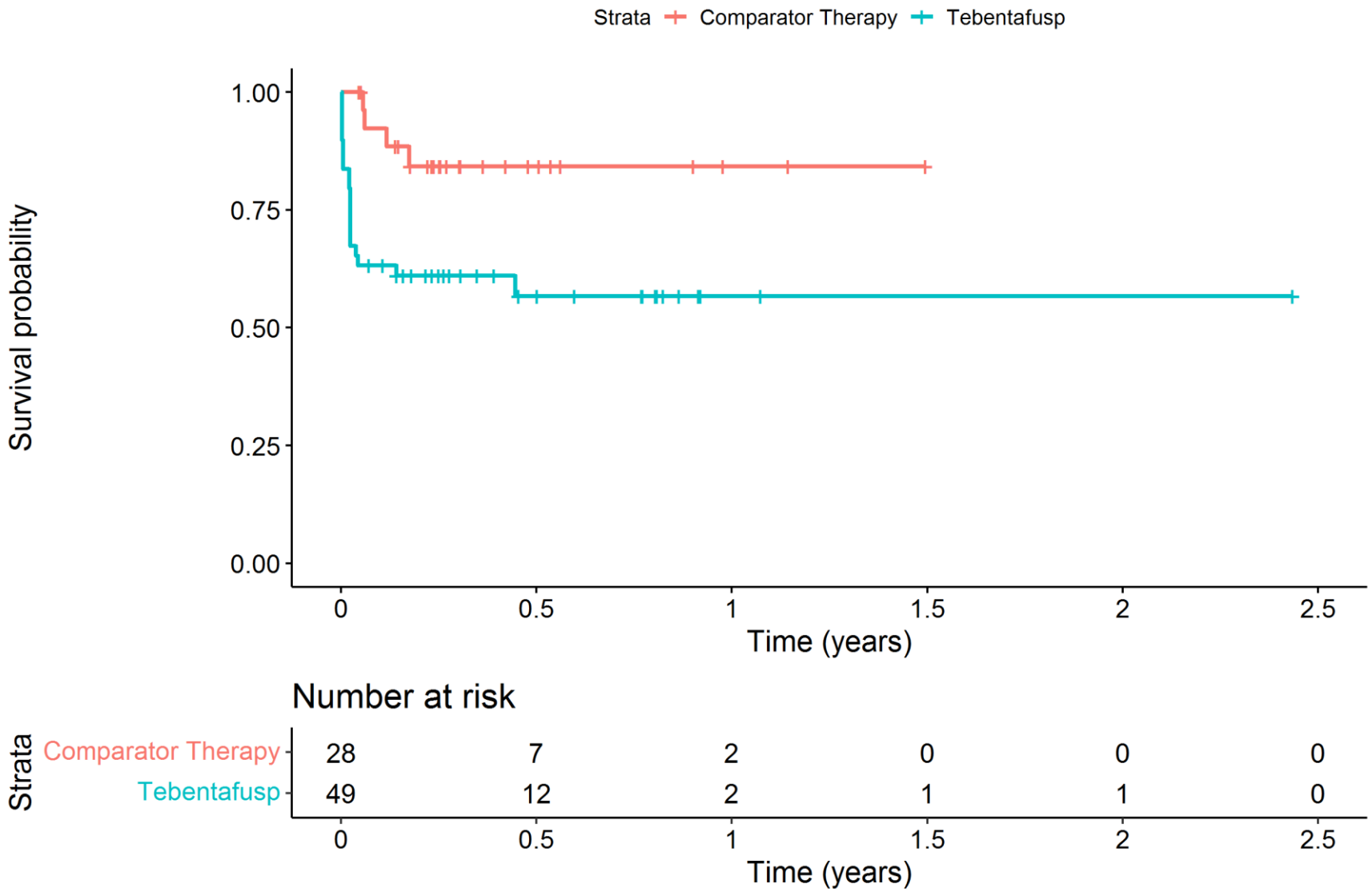
53.368 Hautausschlag - ≥65



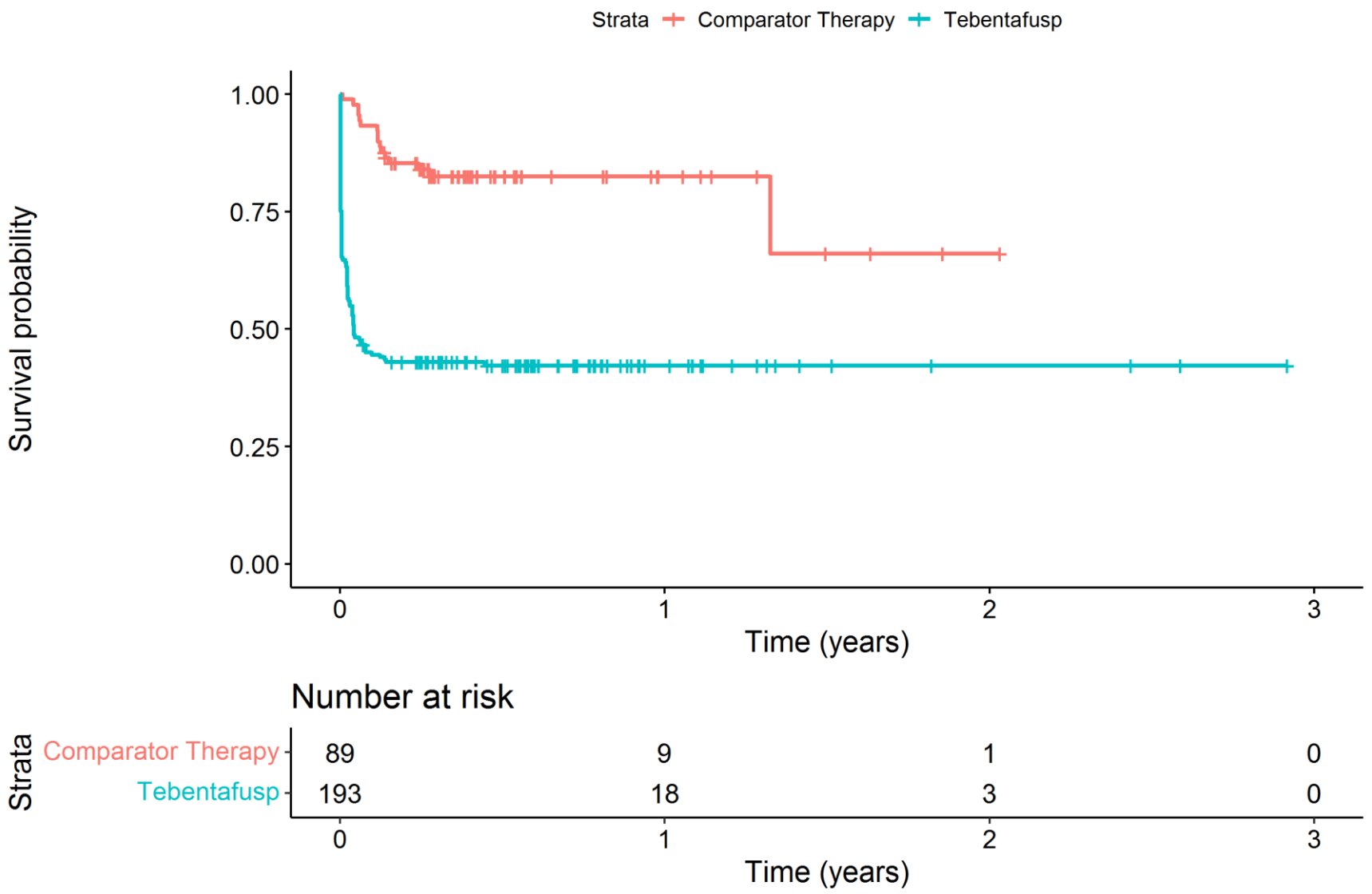
53.369 Hautausschlag - ECOG 0



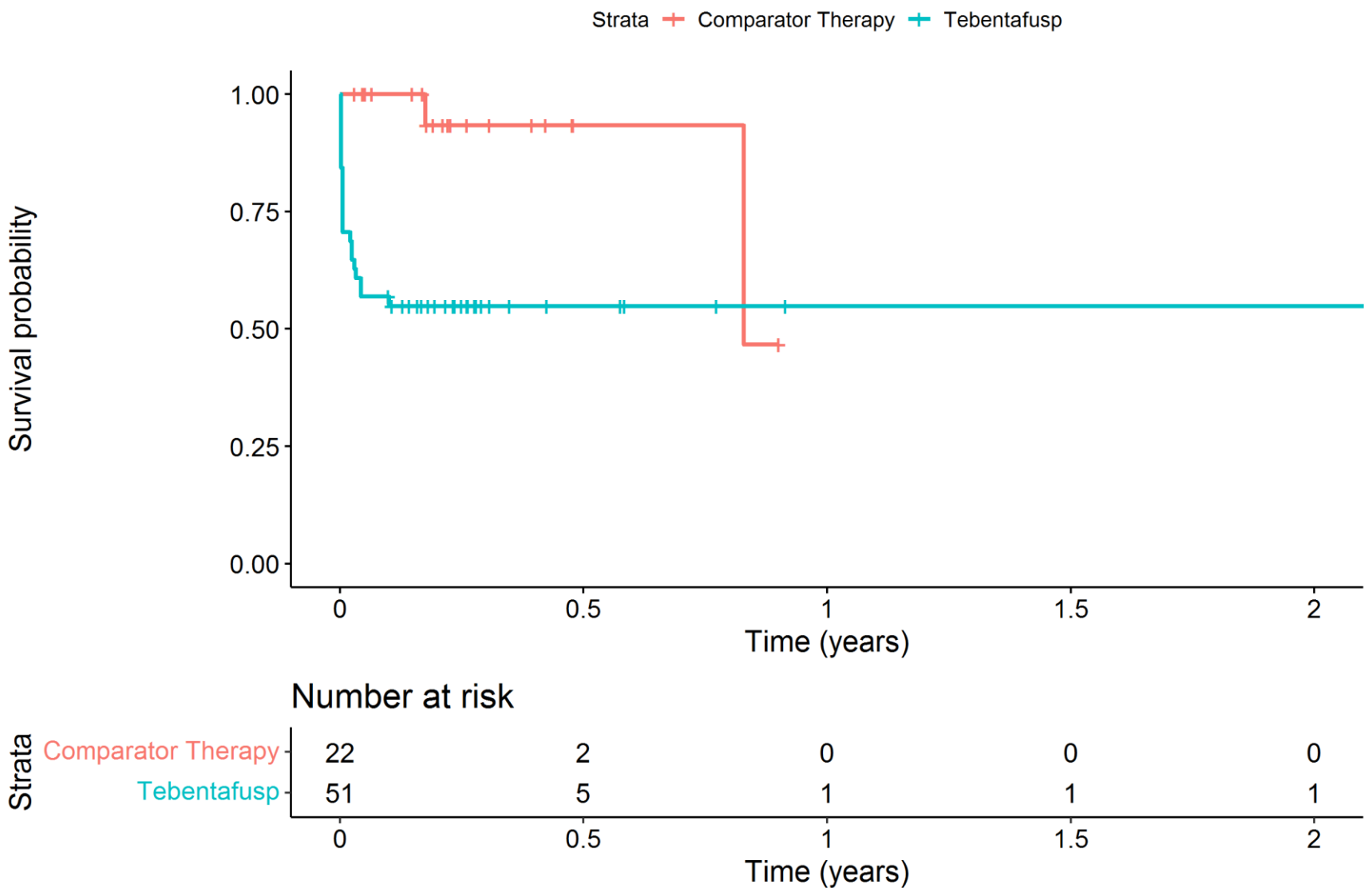
53.370 Hautausschlag - ECOG 1



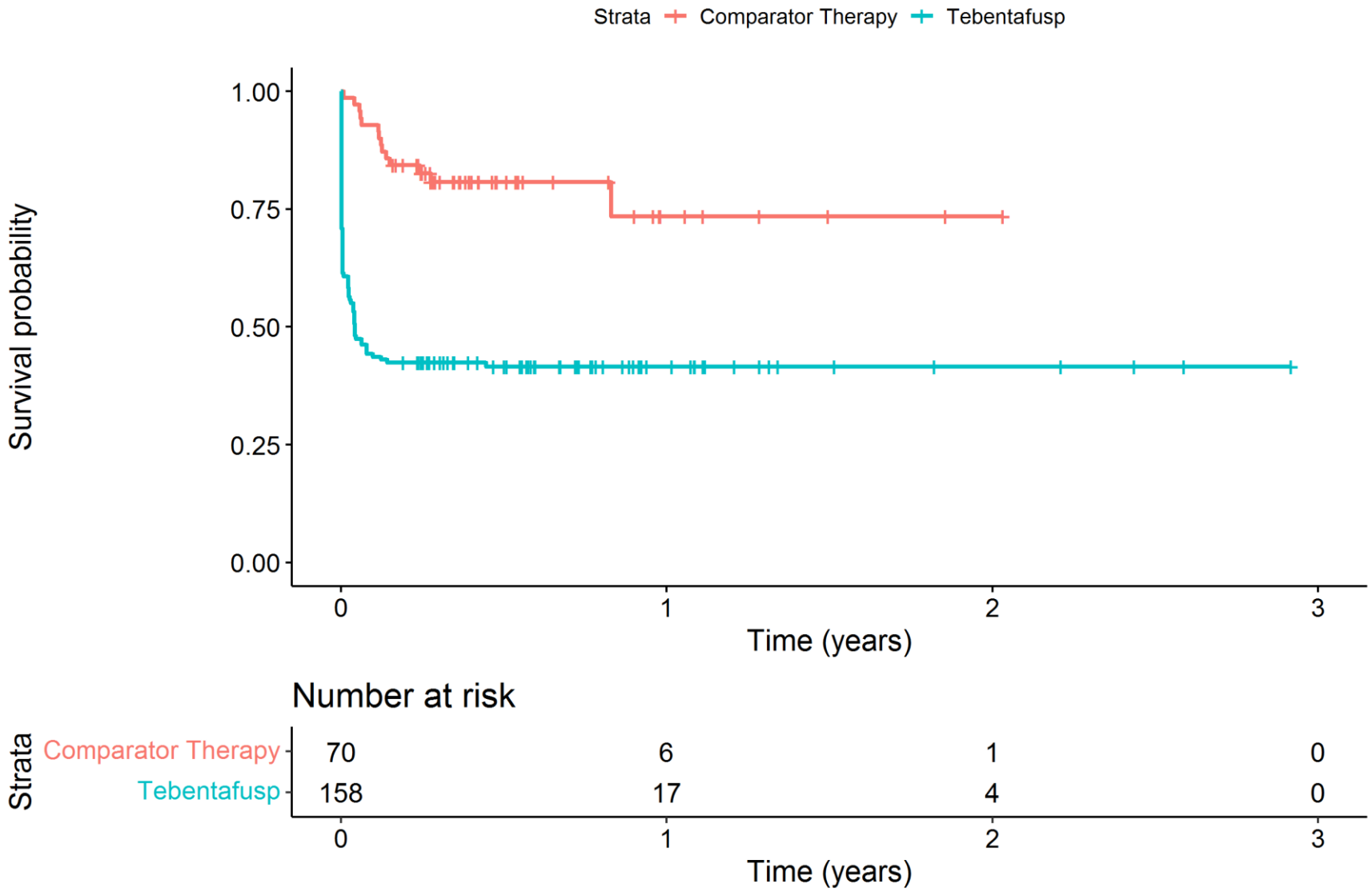
53.371 Hautausschlag - ALP ≤ ULN



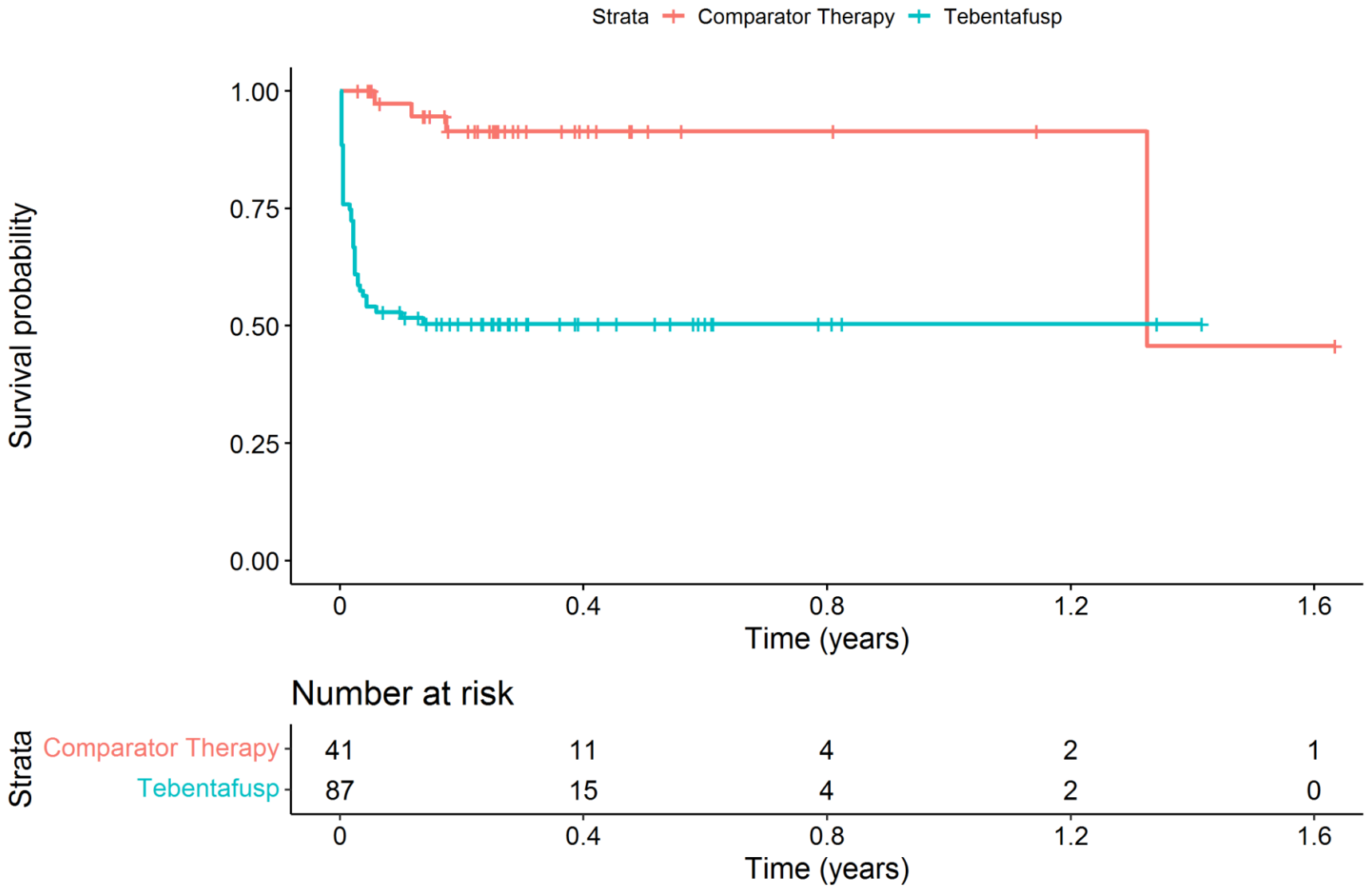
53.372 Hautausschlag - ALP > ULN



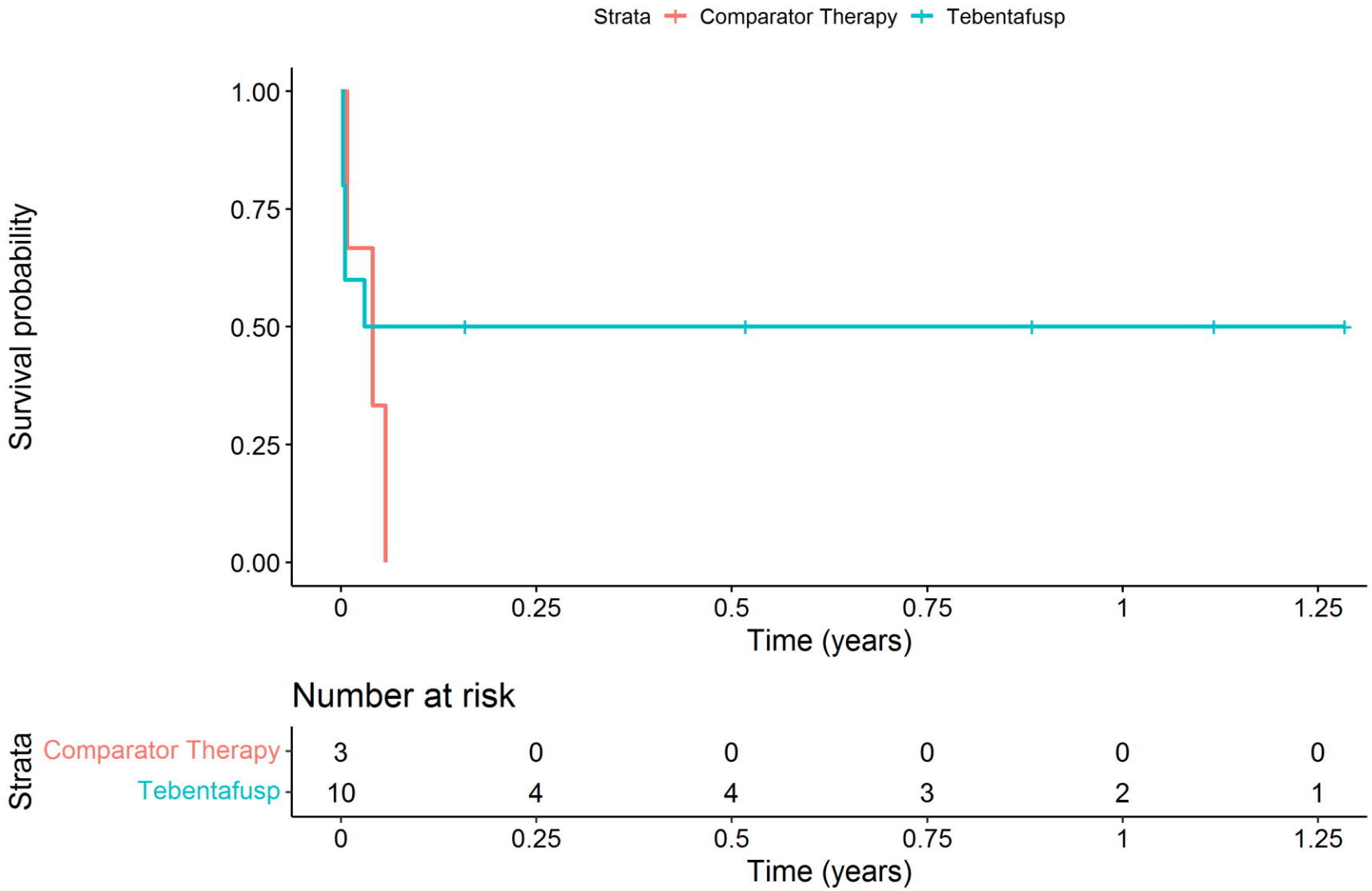
53.373 Hautausschlag - LDH =< ULN



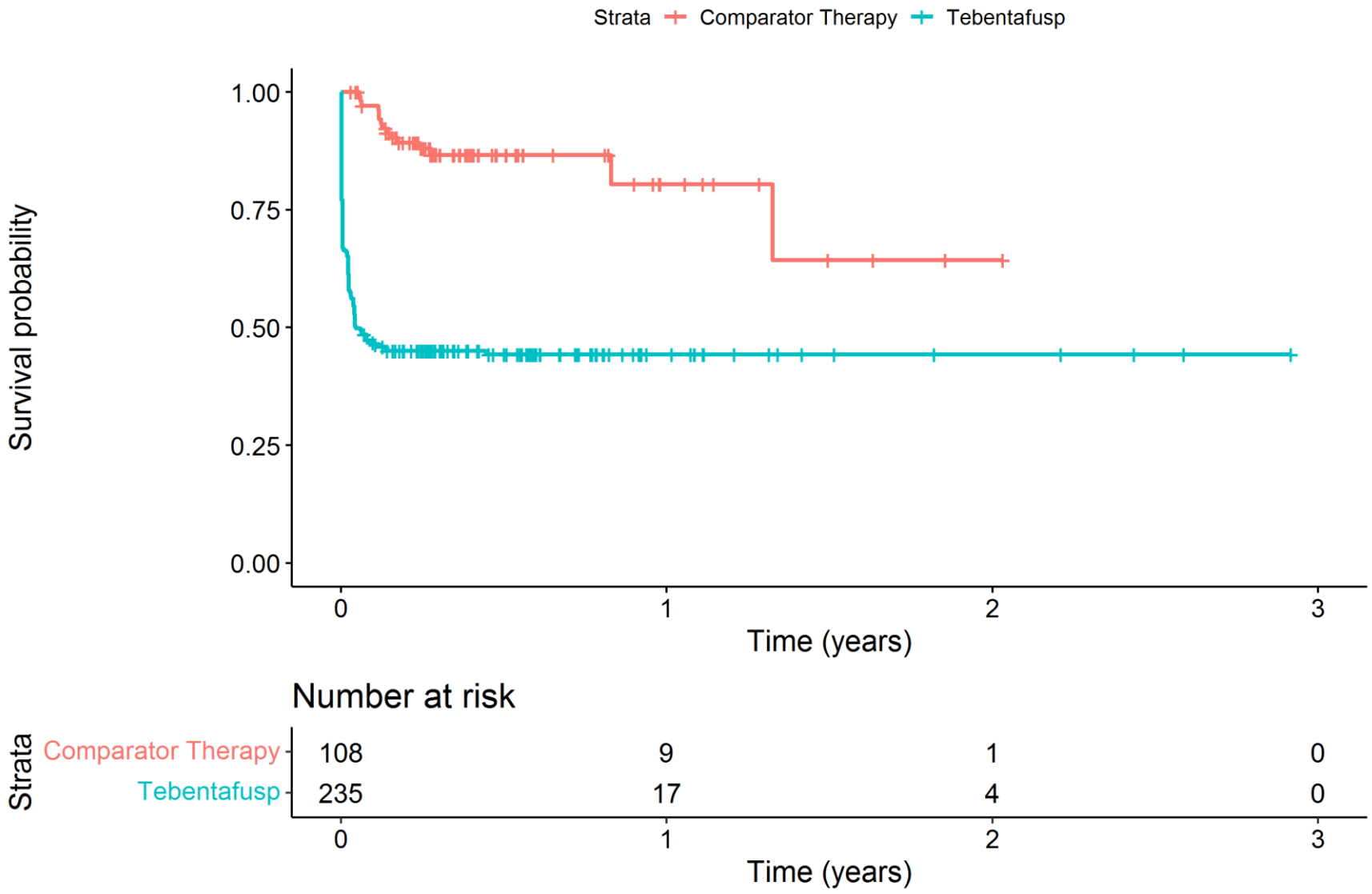
53.374 Hautausschlag - LDH > ULN



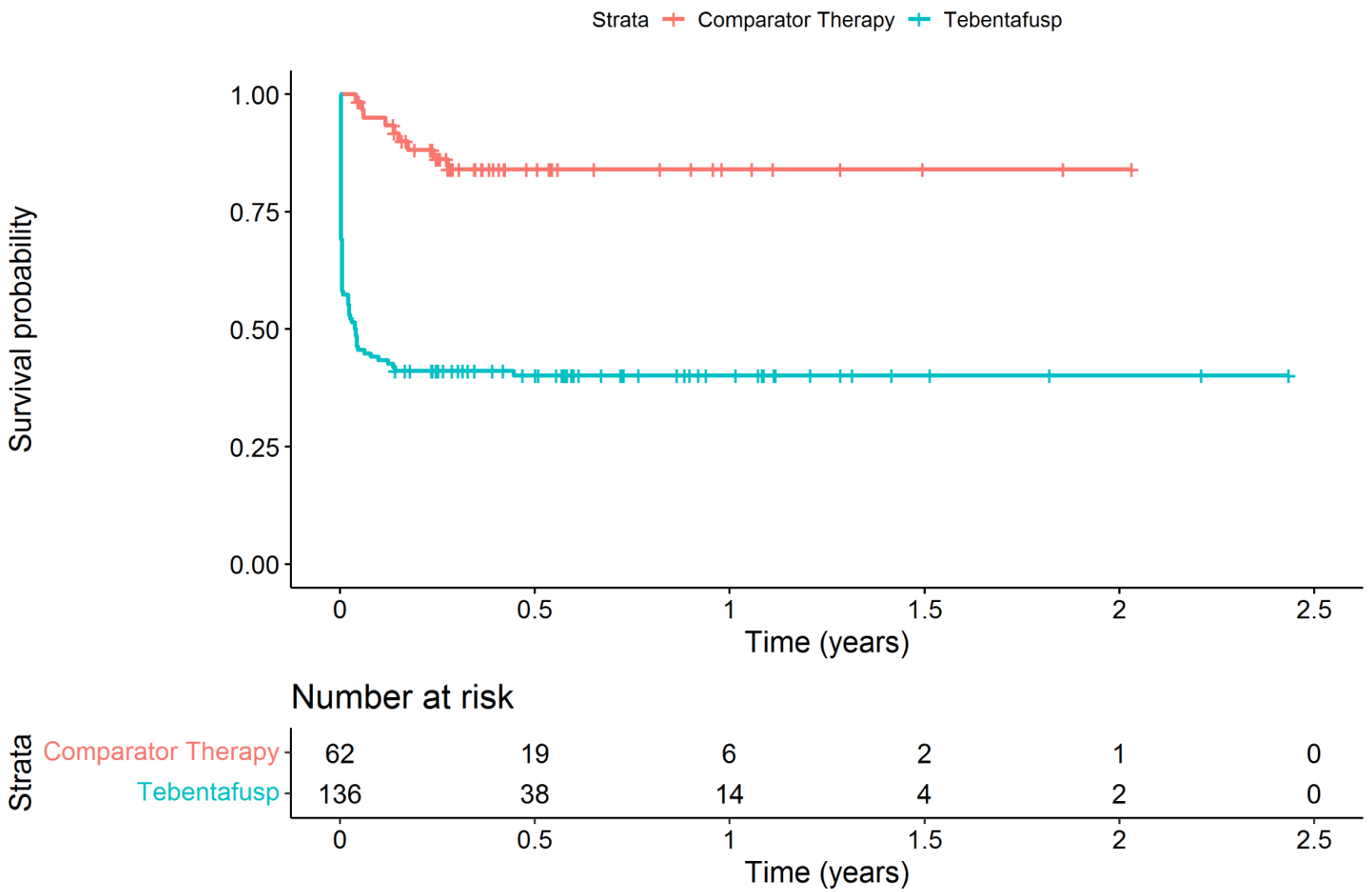
53.375 Hautausschlag - Vorherige Therapie adjuvant/neoadjuvant



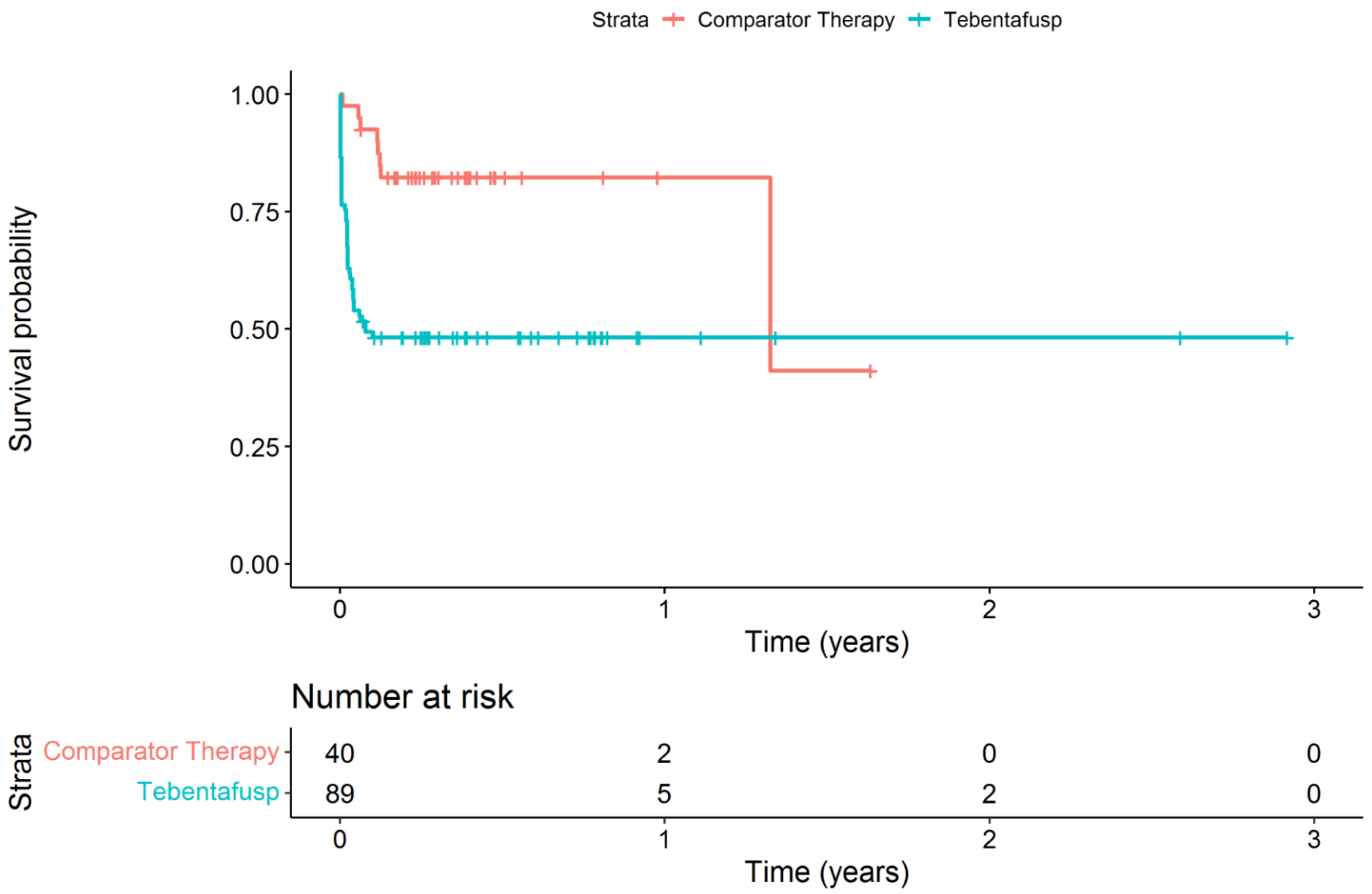
53.376 Hautausschlag - Keine vorherige Therapie adjuvant/neoadjuvant



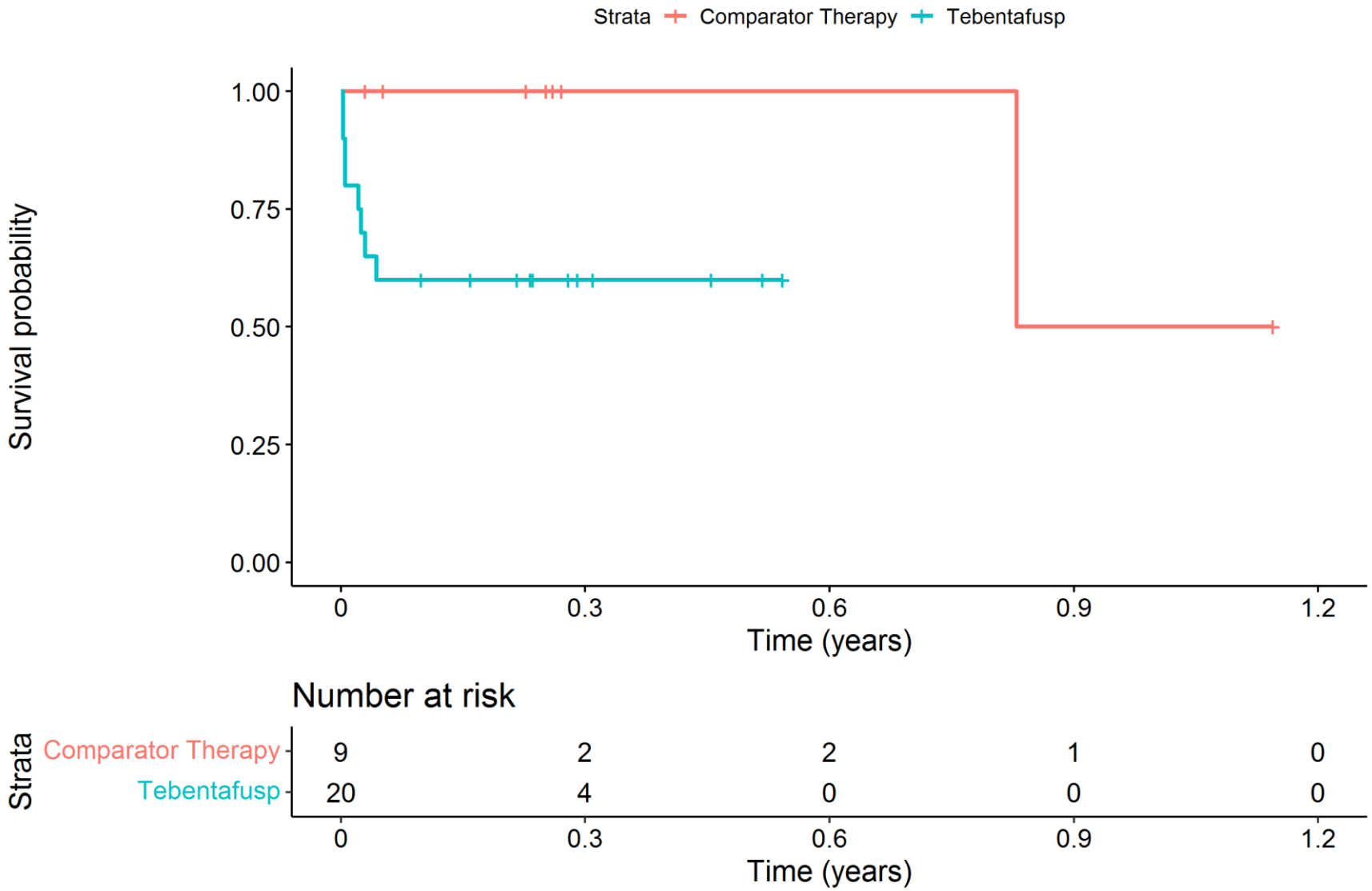
53.377 Hautausschlag - Läsion ≤ 3cm



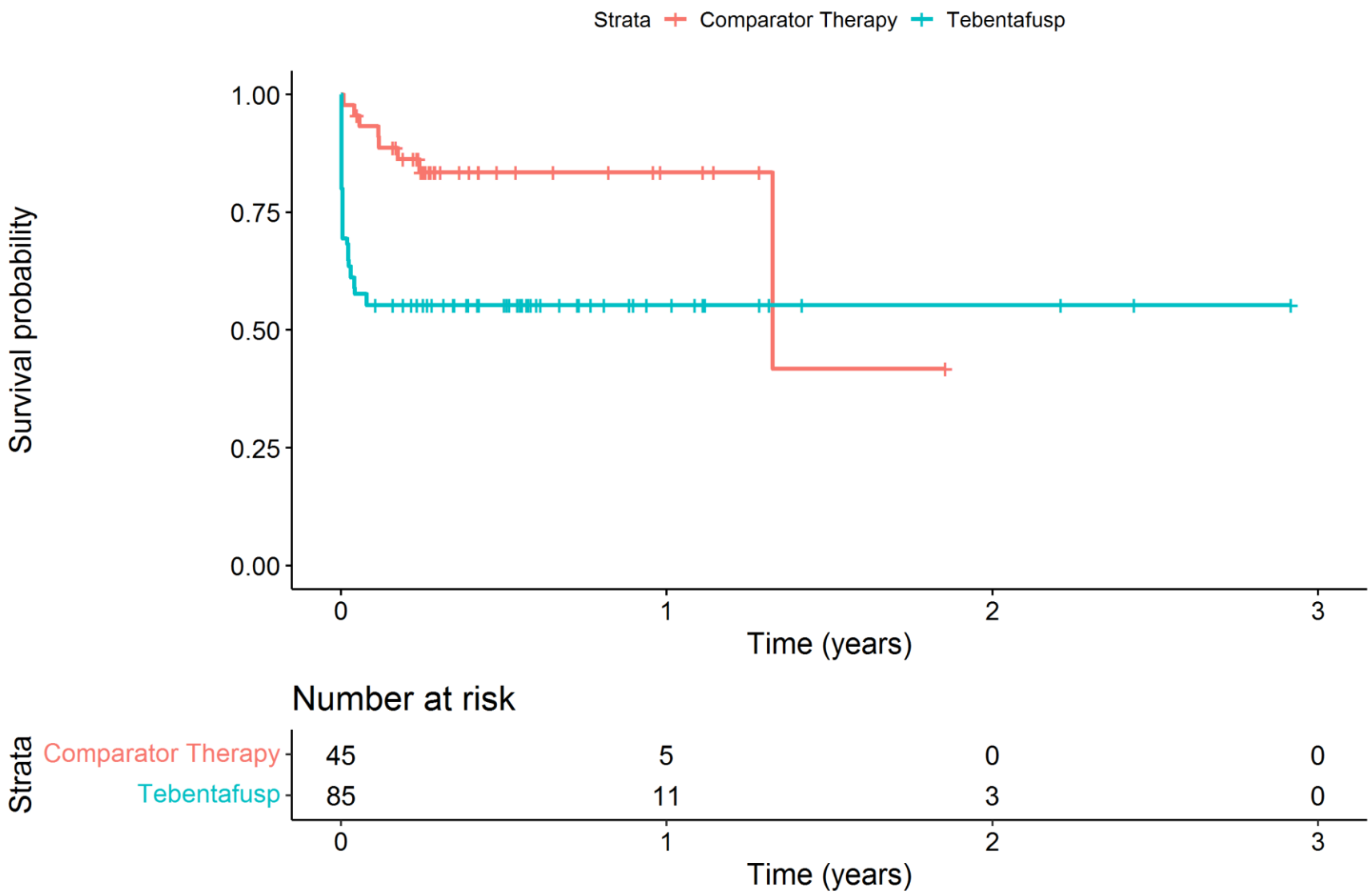
53.378 Hautausschlag - Läsion 3,1-8,0 cm



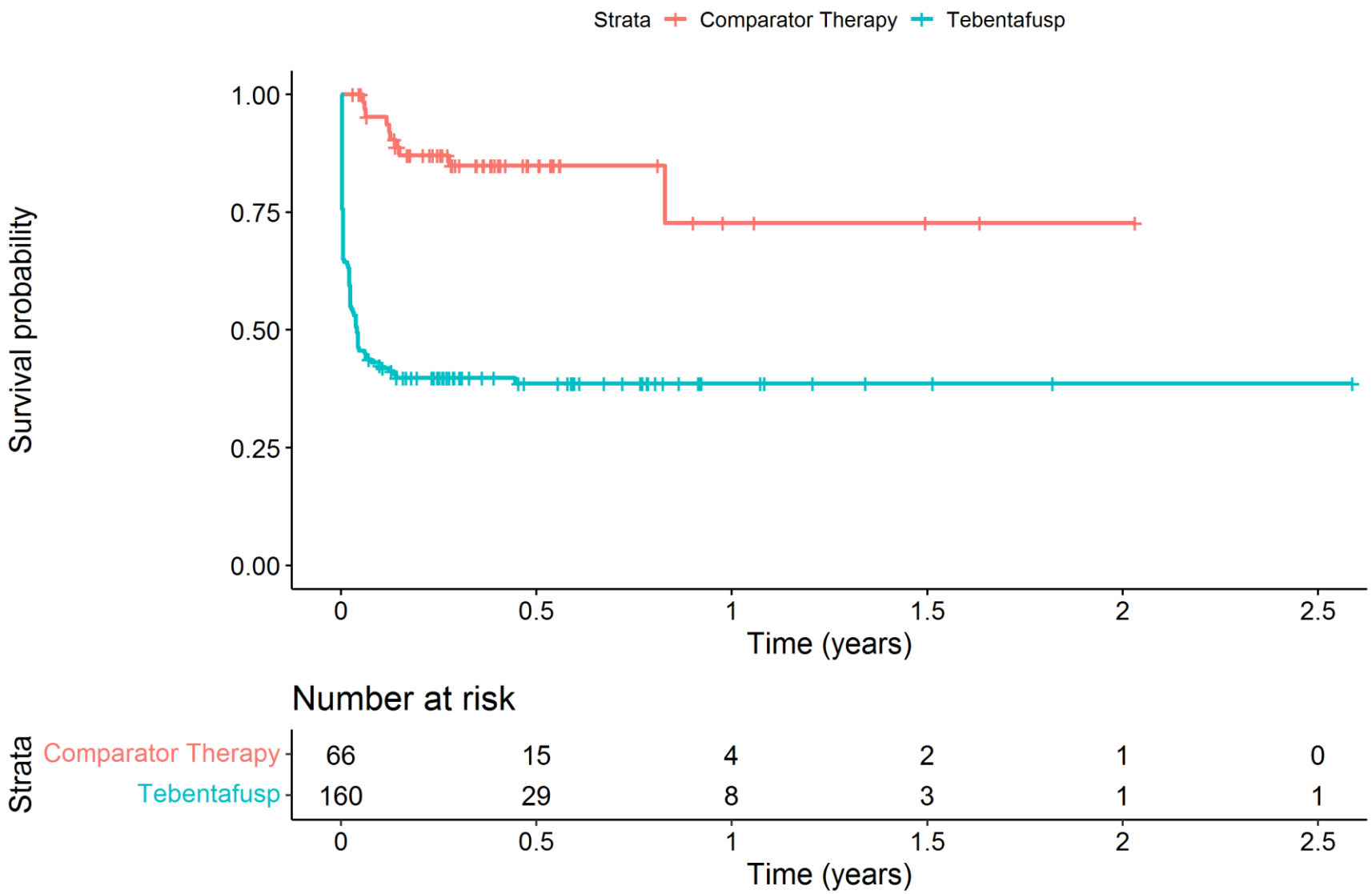
53.379 Hautausschlag - Läsion ≥8,1 cm



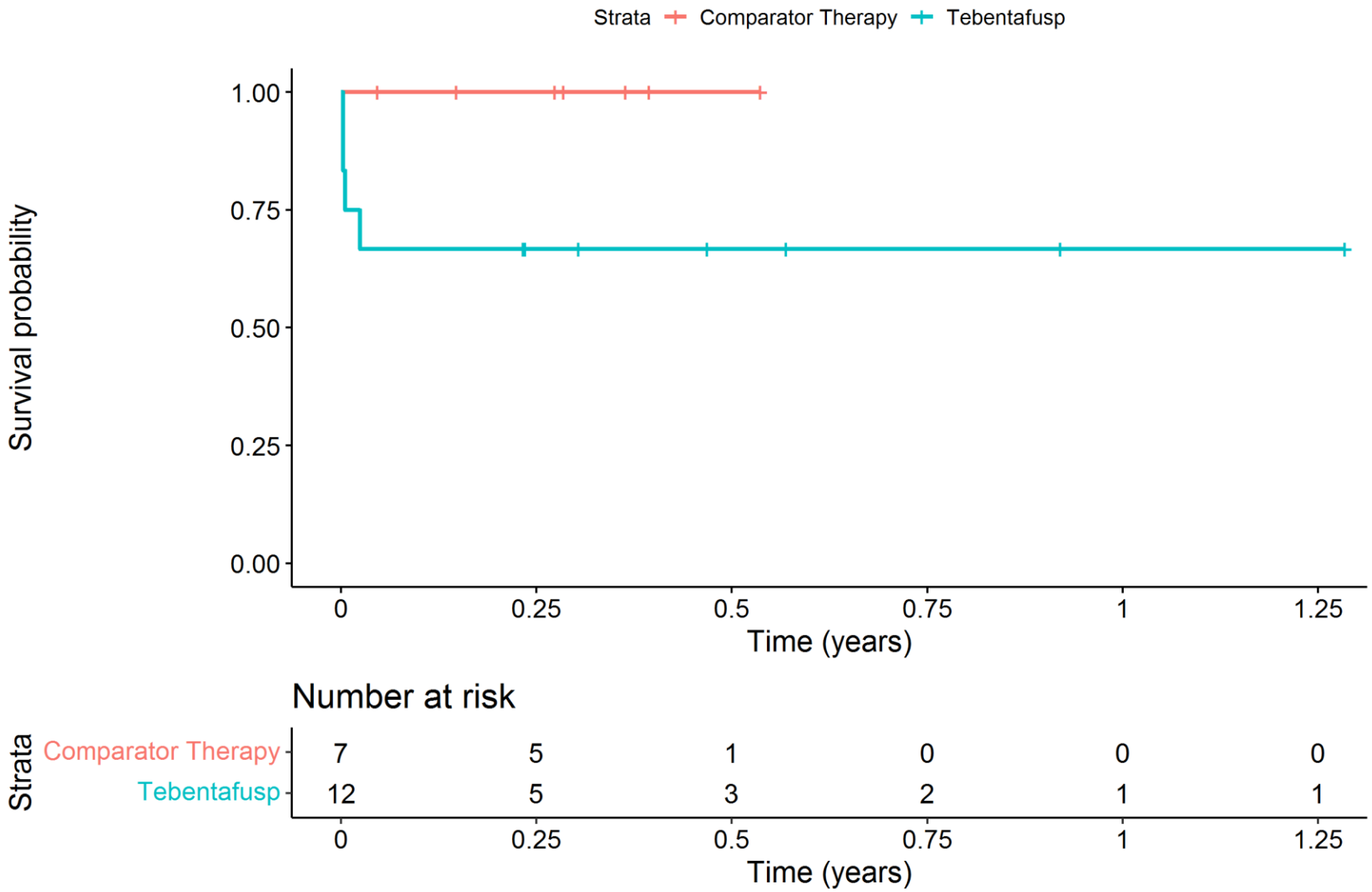
53.380 Hautausschlag - Nordamerika



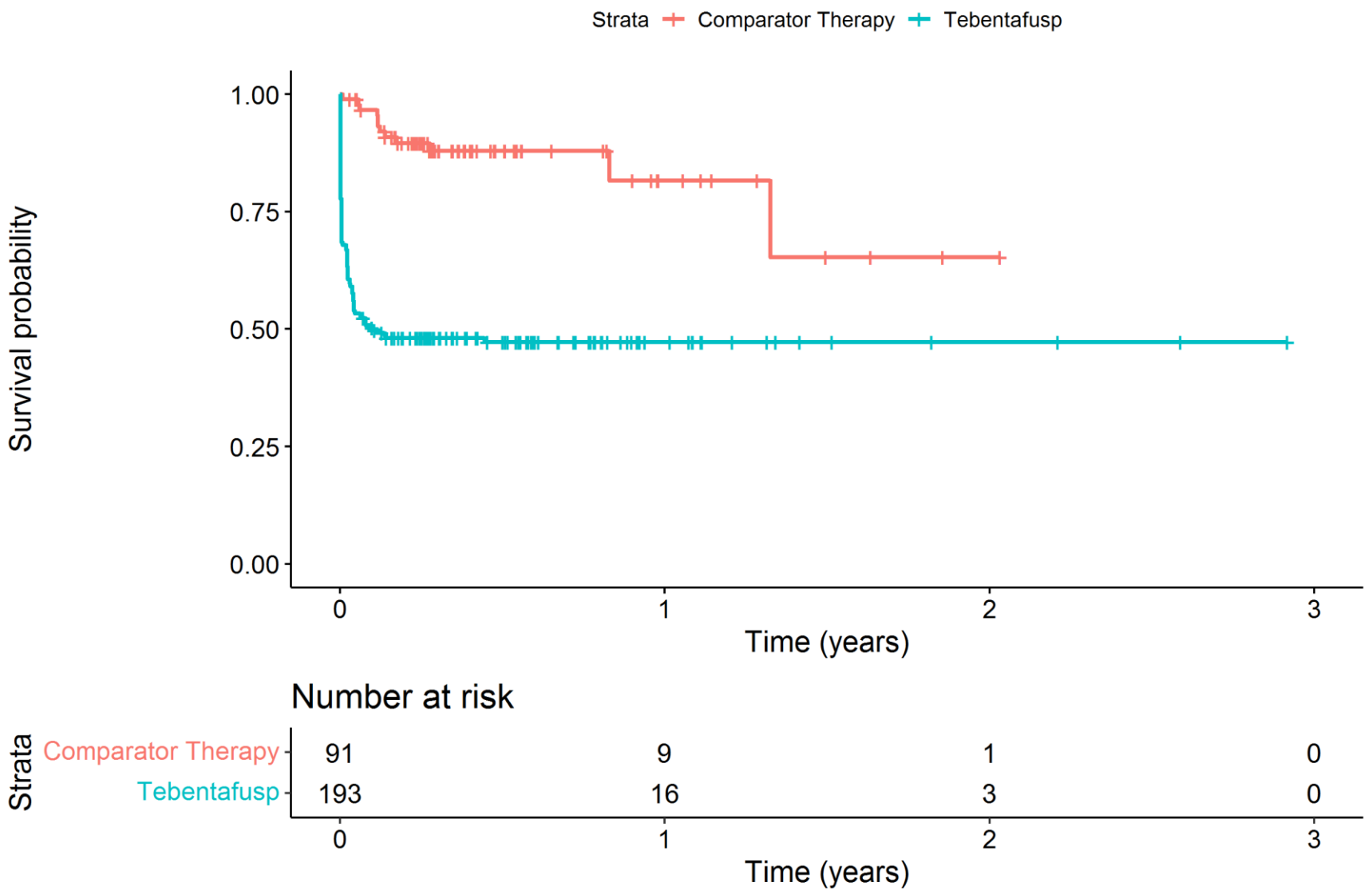
53.381 Hautausschlag - Nicht-Nordamerika



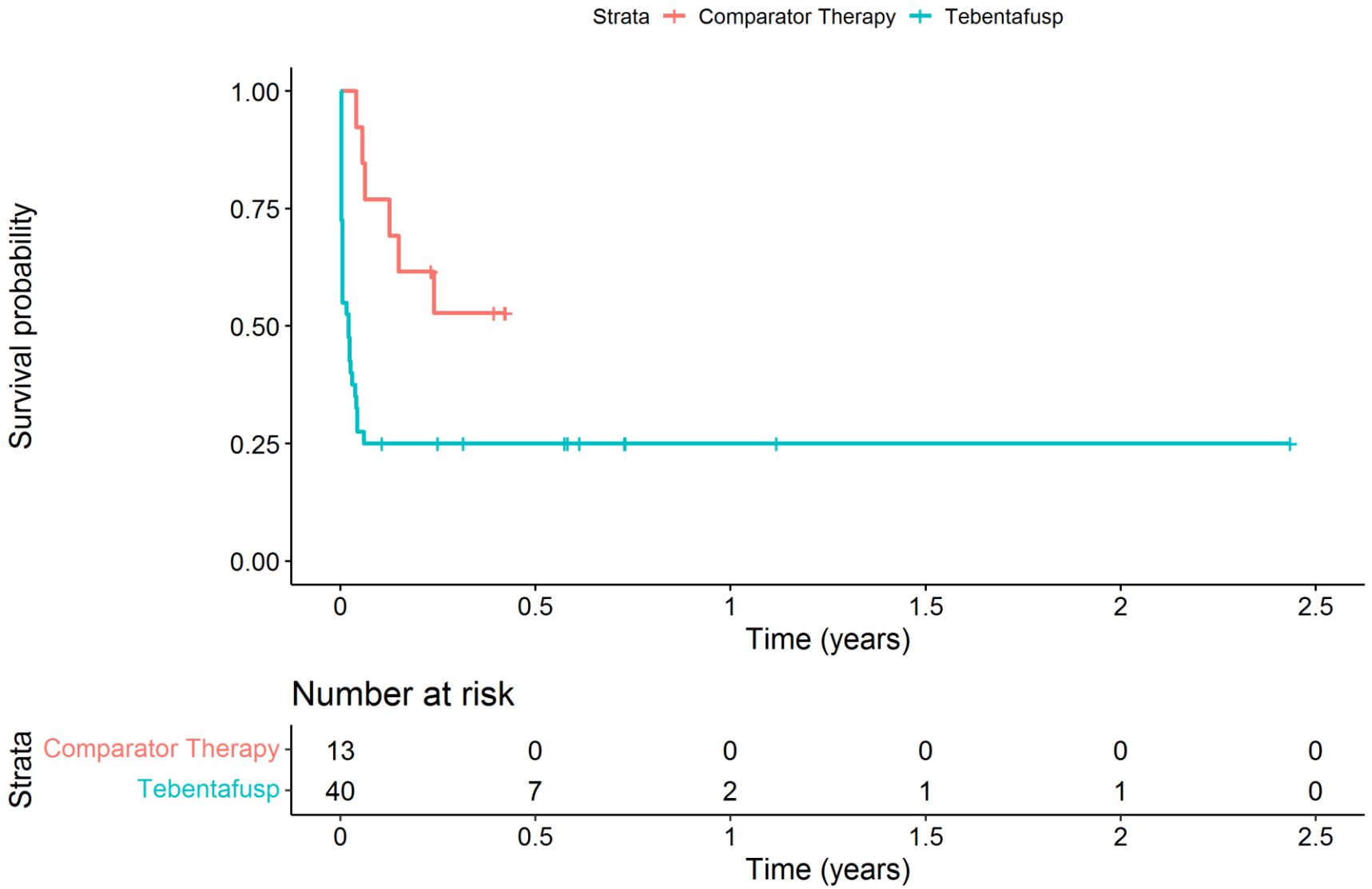
53.382 Hautausschlag - Dacarbazin



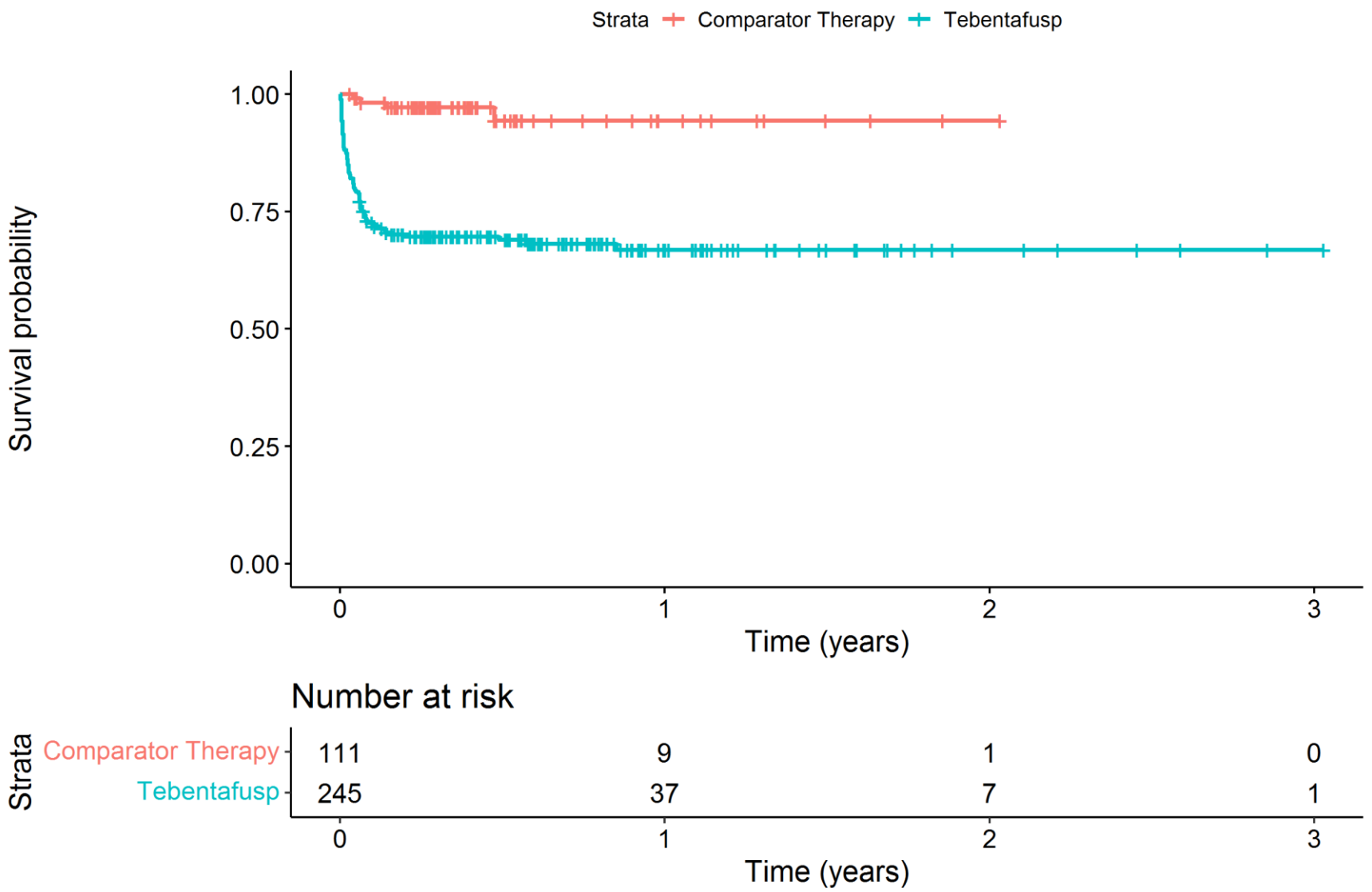
53.383 Hautausschlag - Pembrolizumab



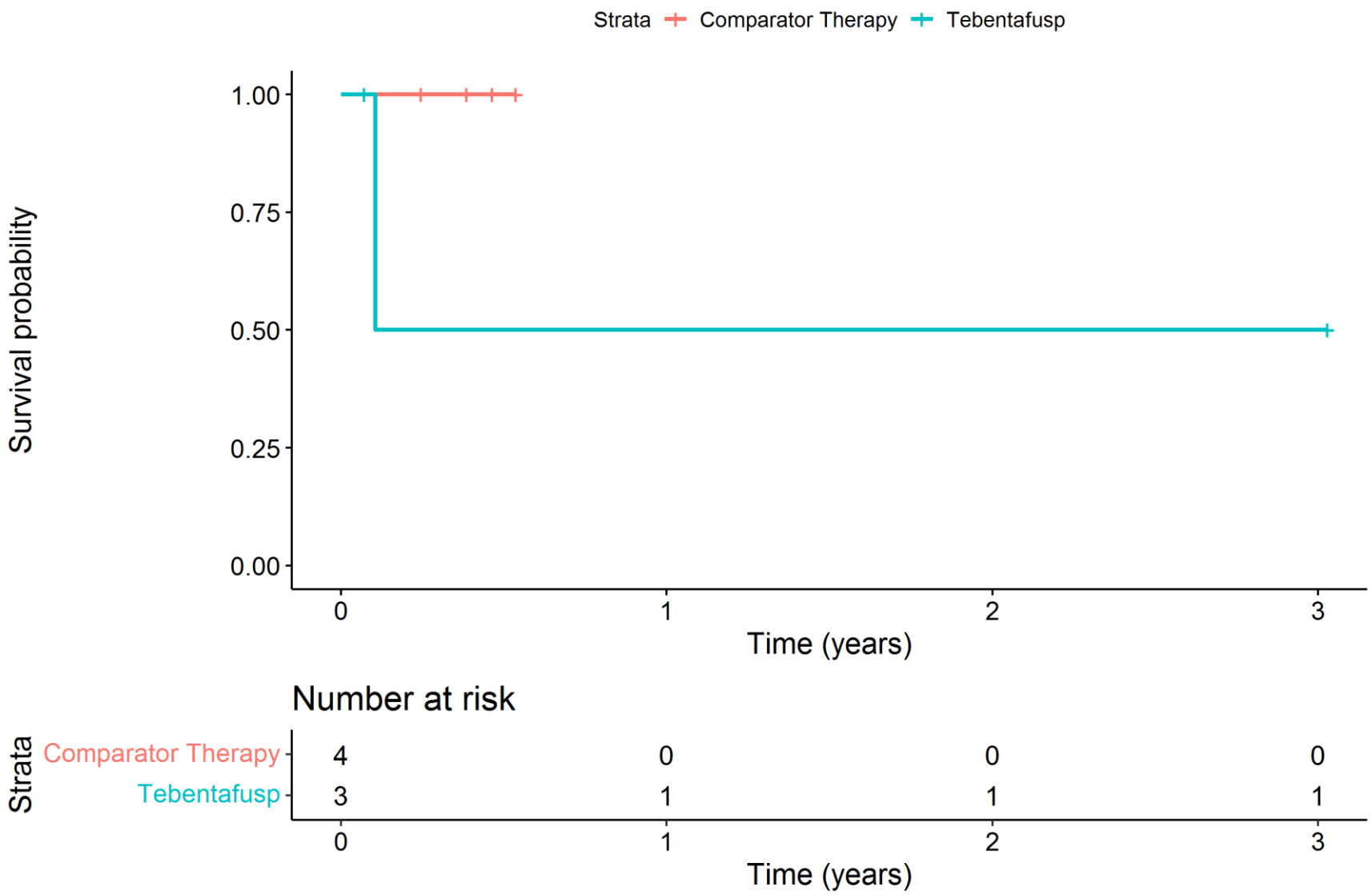
53.384 Hautausschlag - Ipilimumab



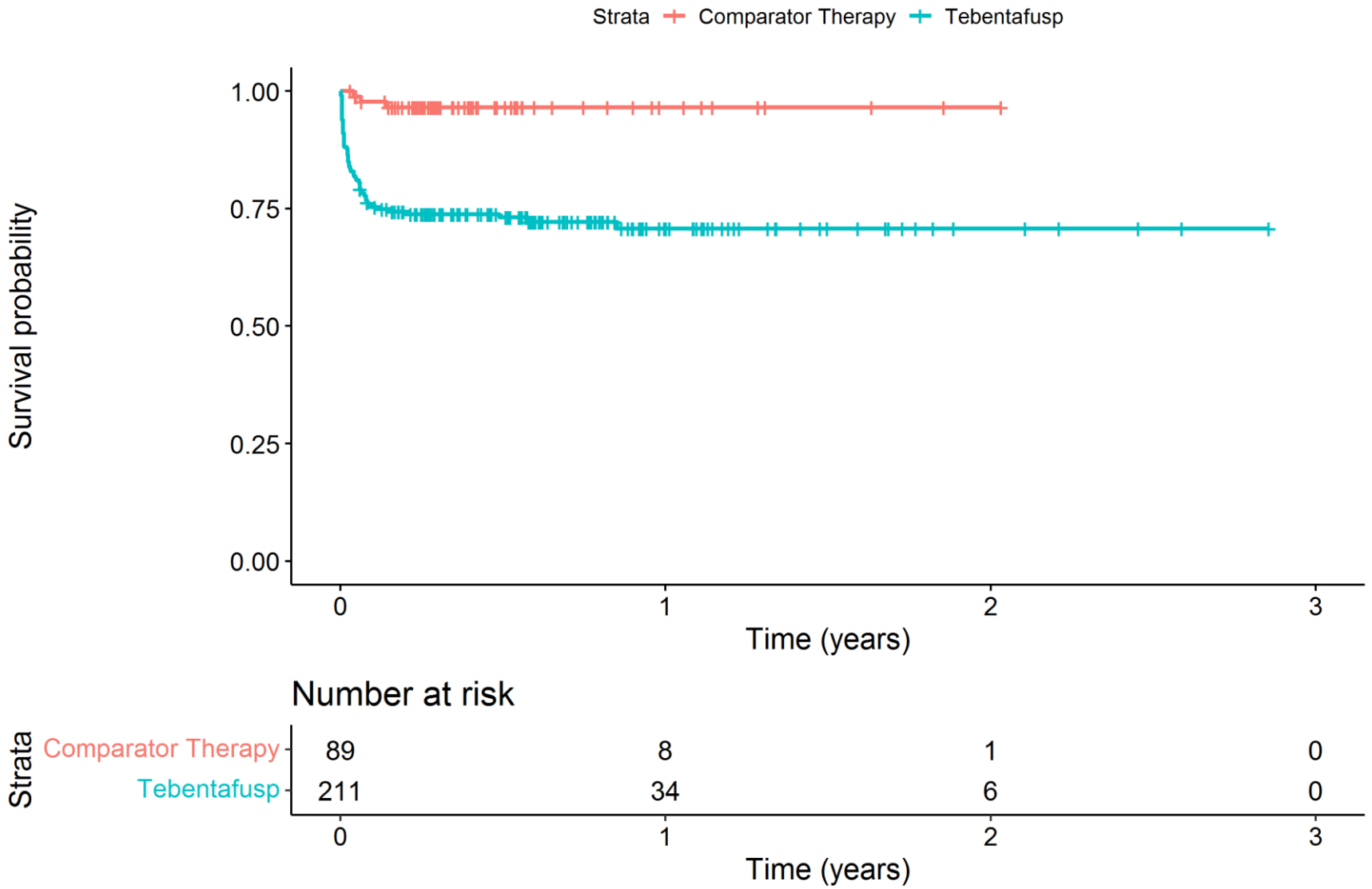
53.385 Trockene Haut - Gesamt



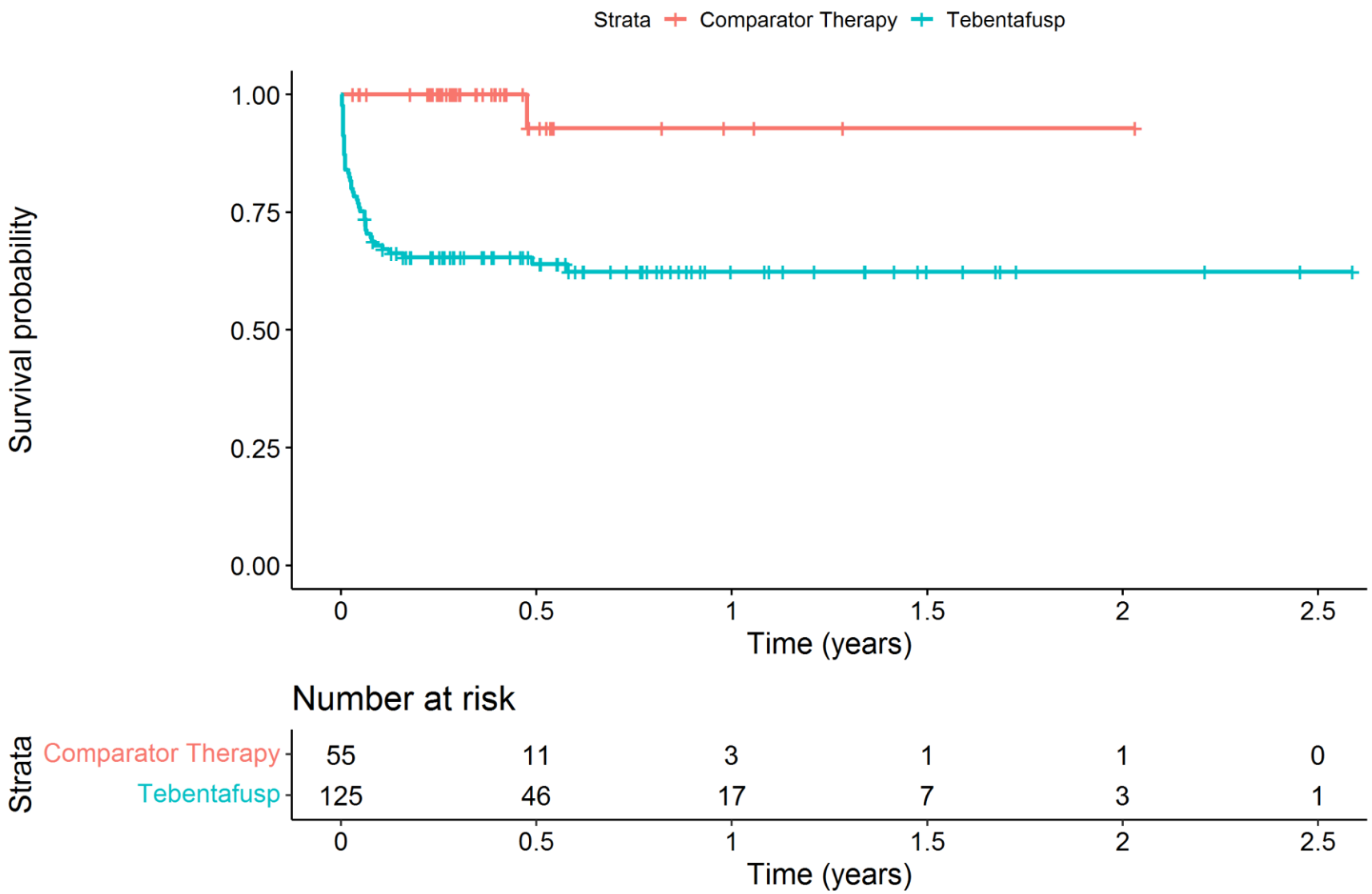
53.386 Trockene Haut - Hispanisch



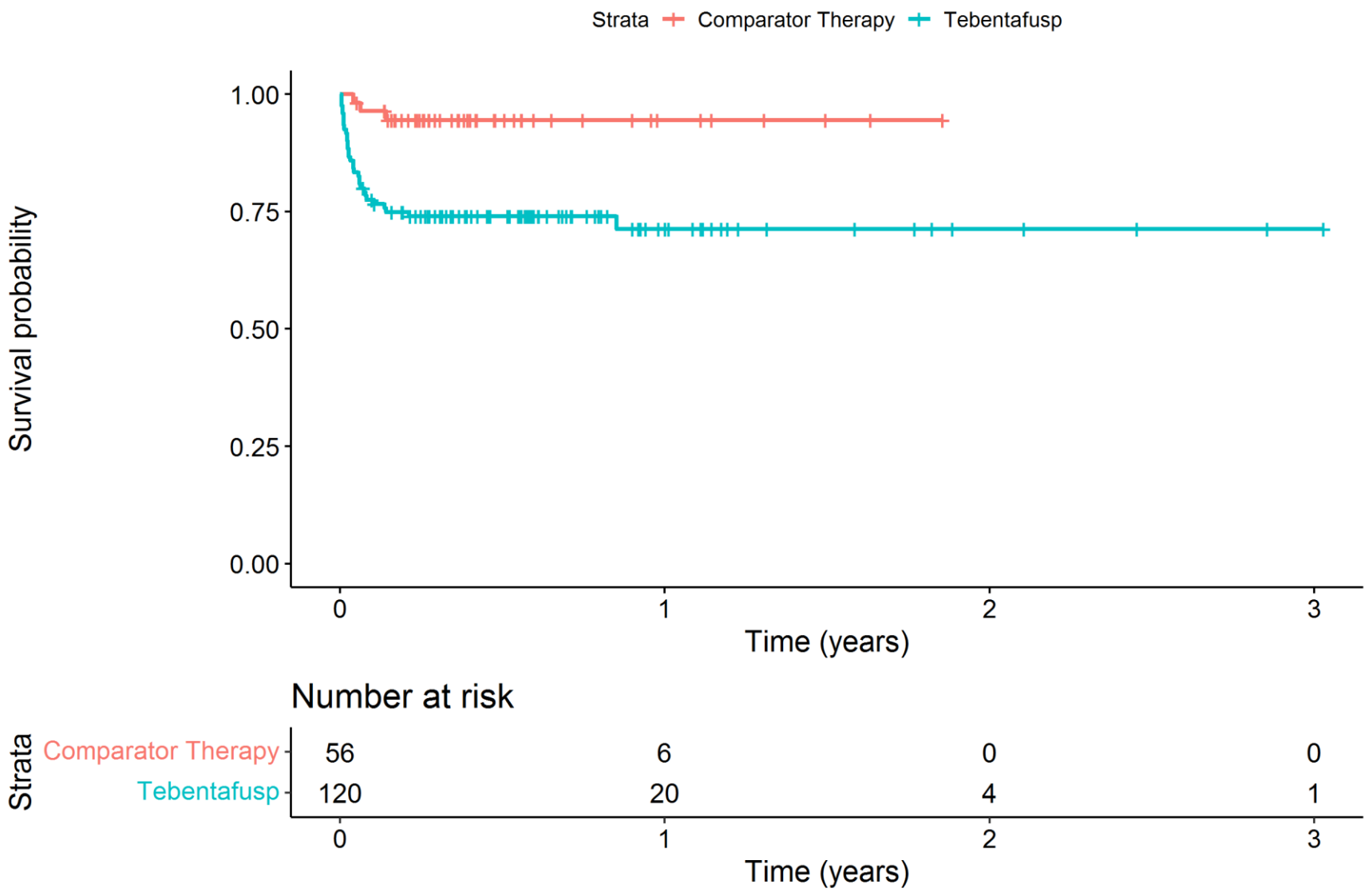
53.387 Trockene Haut - Nicht-hispanisch



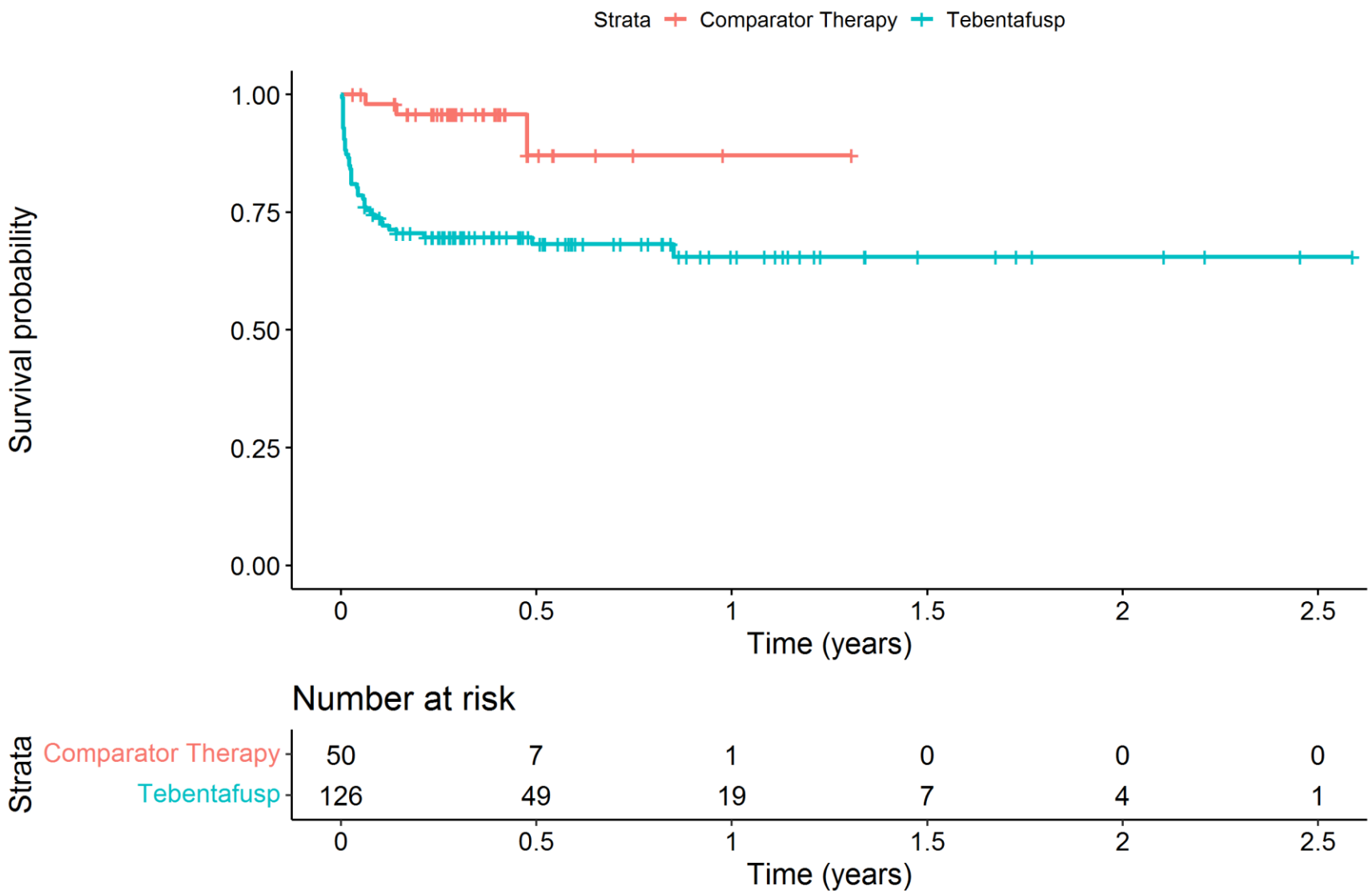
53.388 Trockene Haut - Männlich



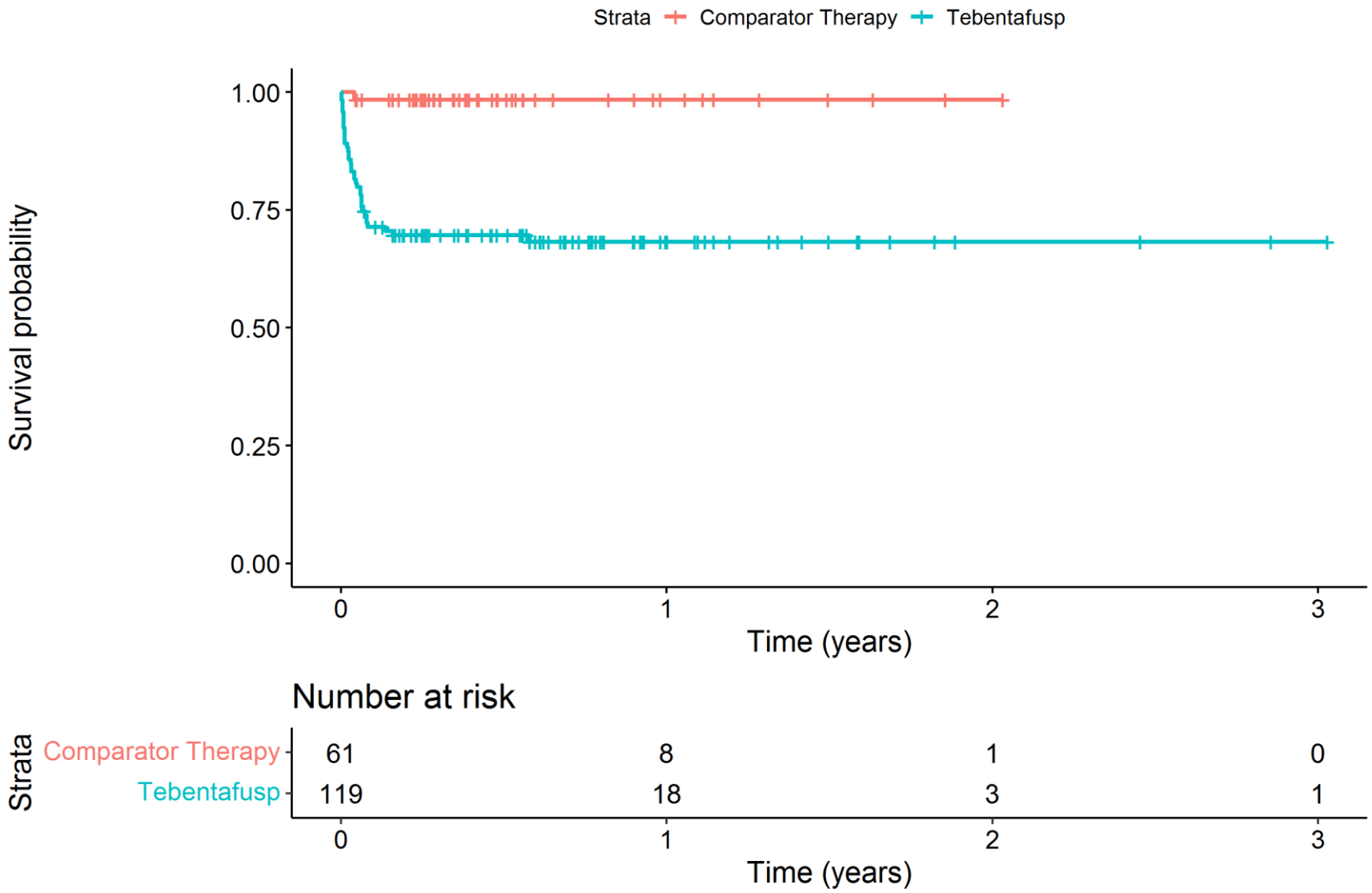
53.389 Trockene Haut - Weiblich



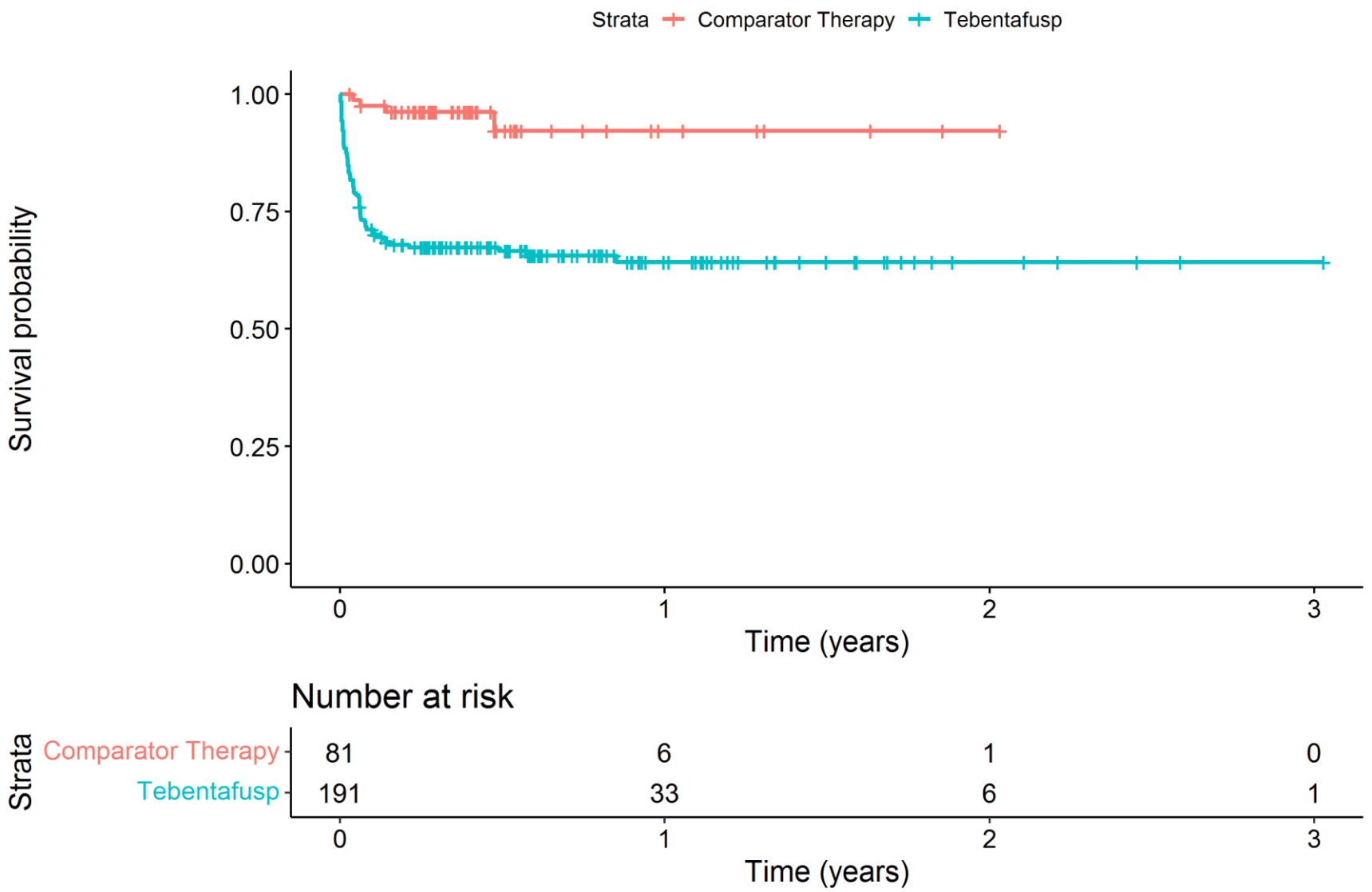
53.390 Trockene Haut - <65



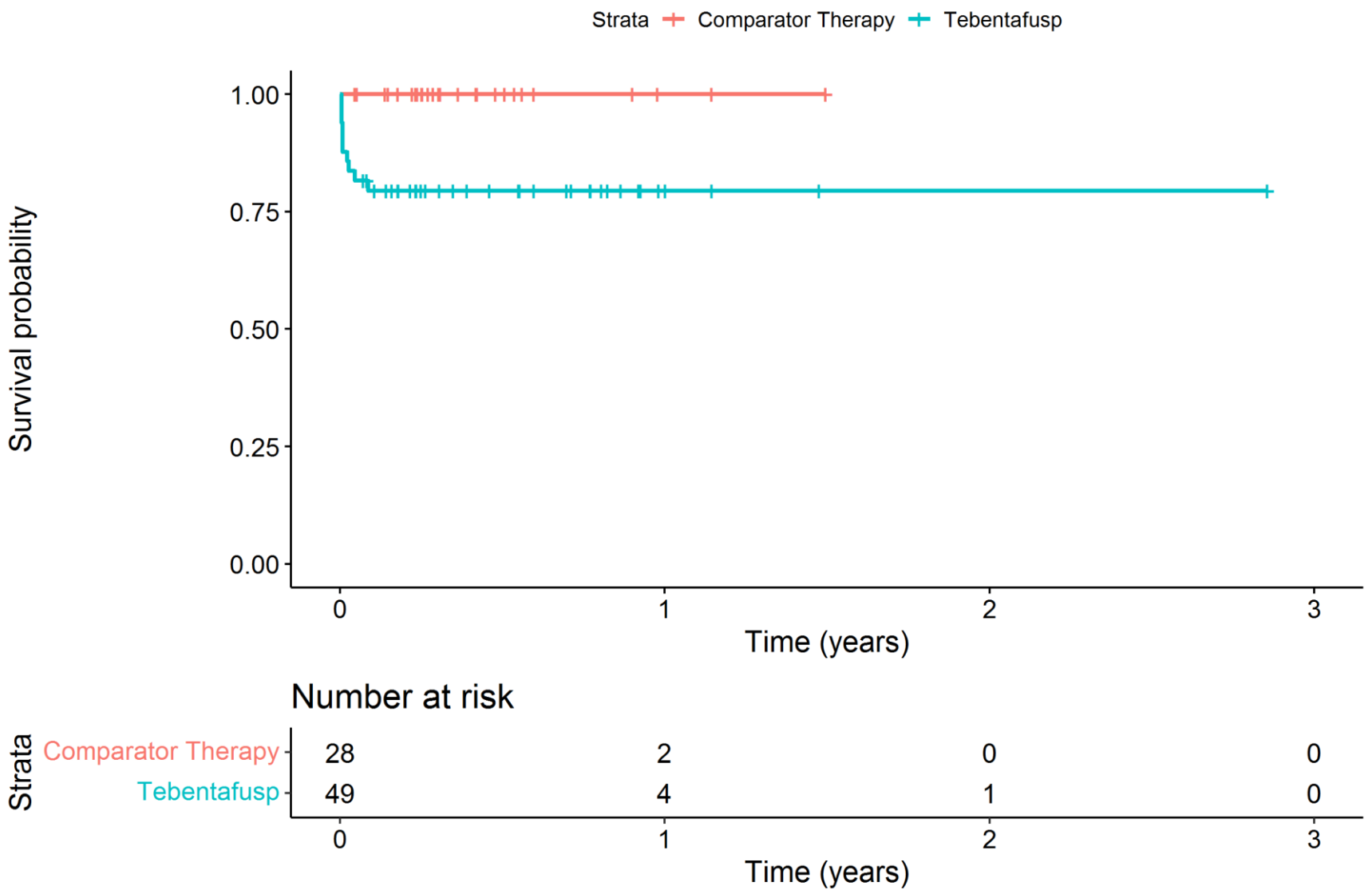
53.391 Trockene Haut - ≥65



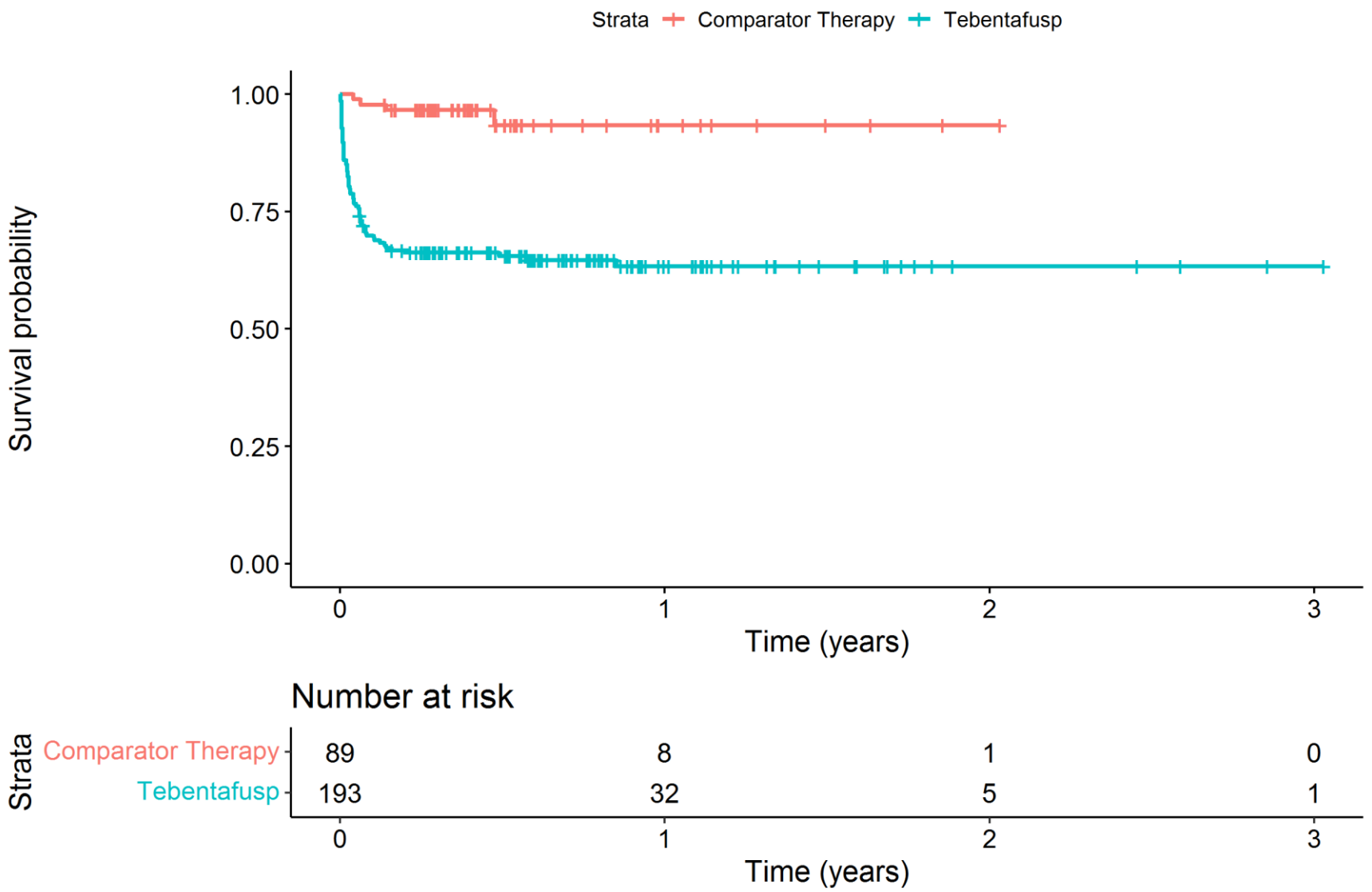
53.392 Trockene Haut - ECOG 0



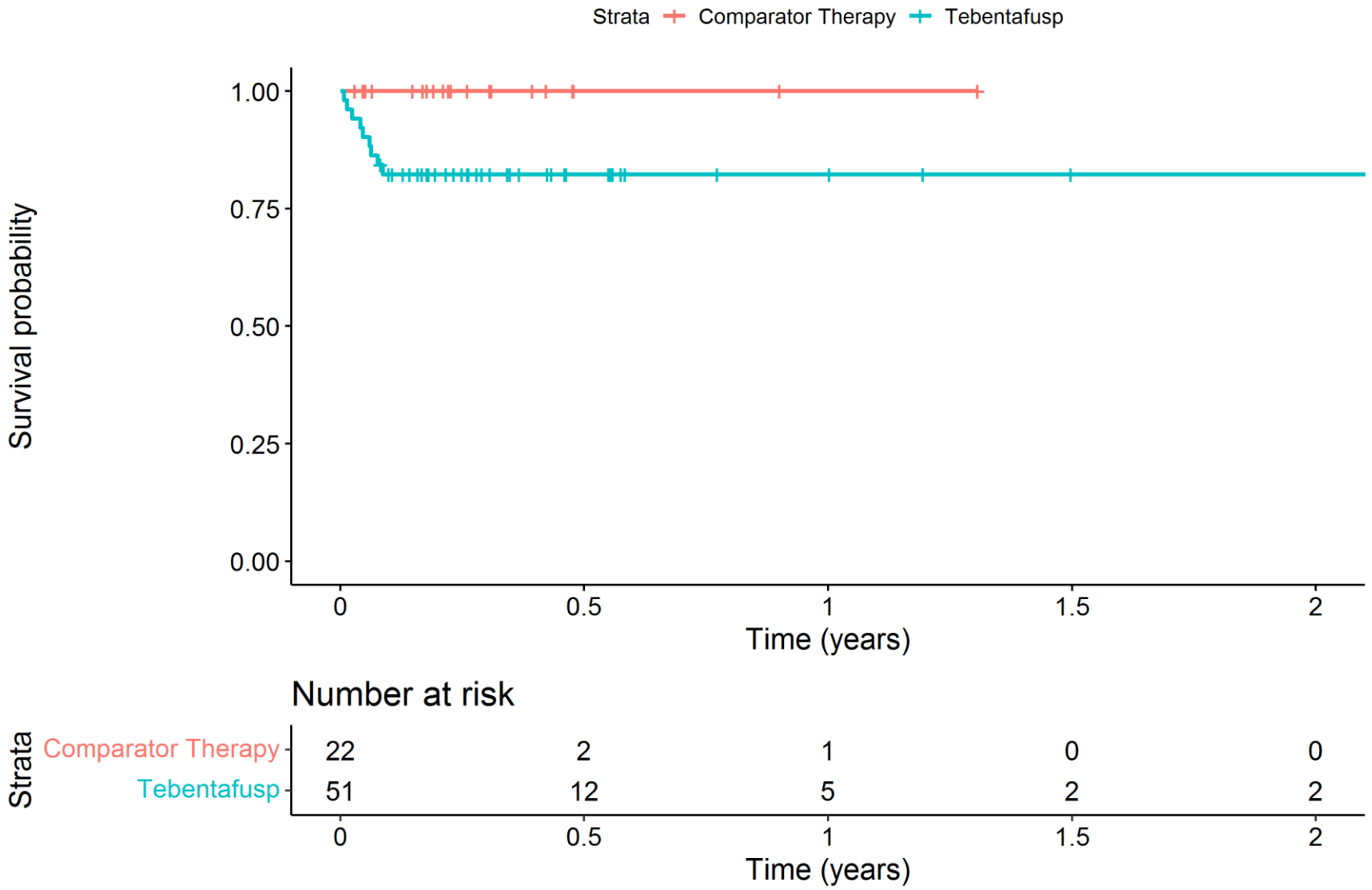
53.393 Trockene Haut - ECOG 1



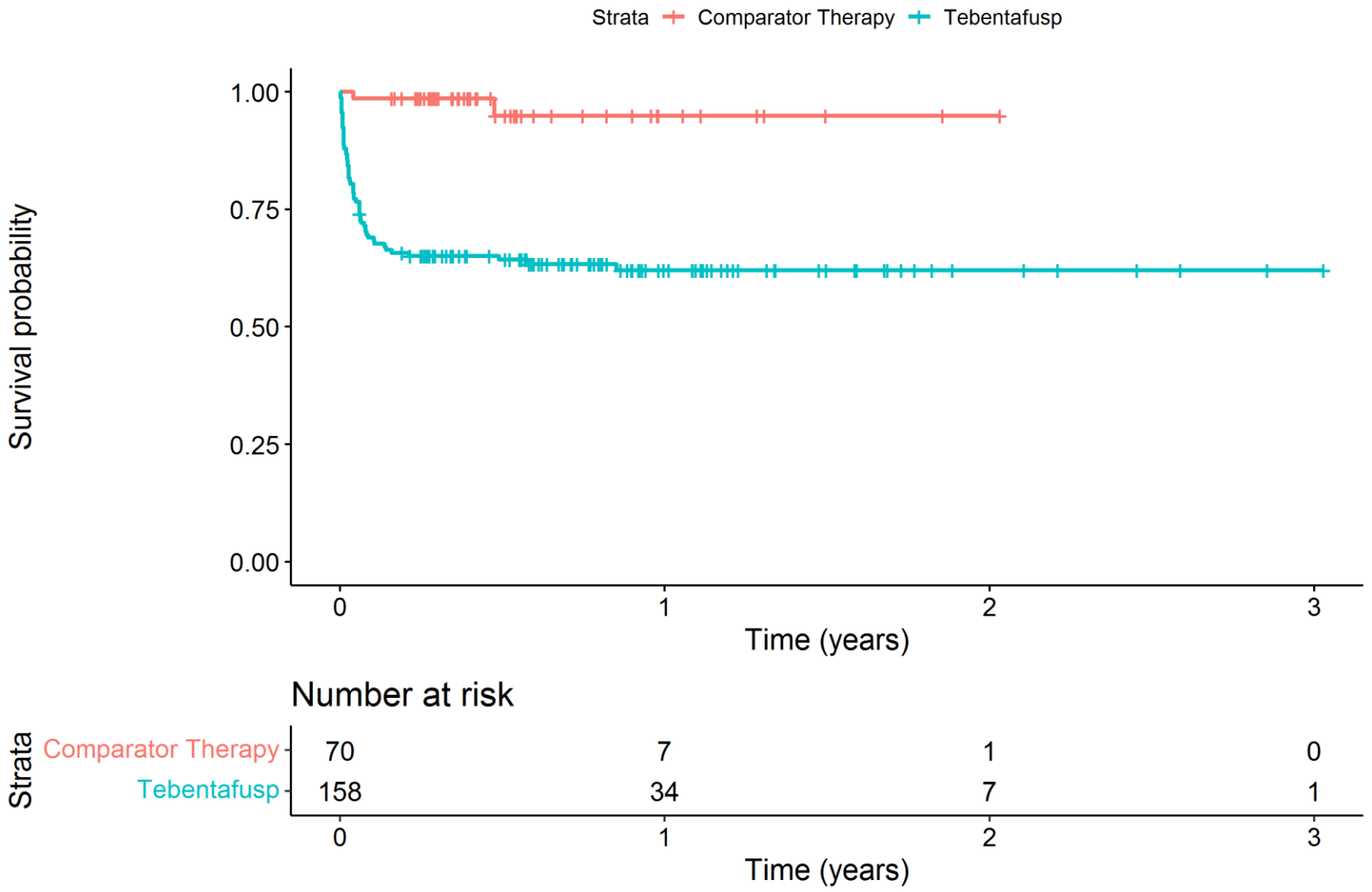
53.394 Trockene Haut - ALP ≤ ULN



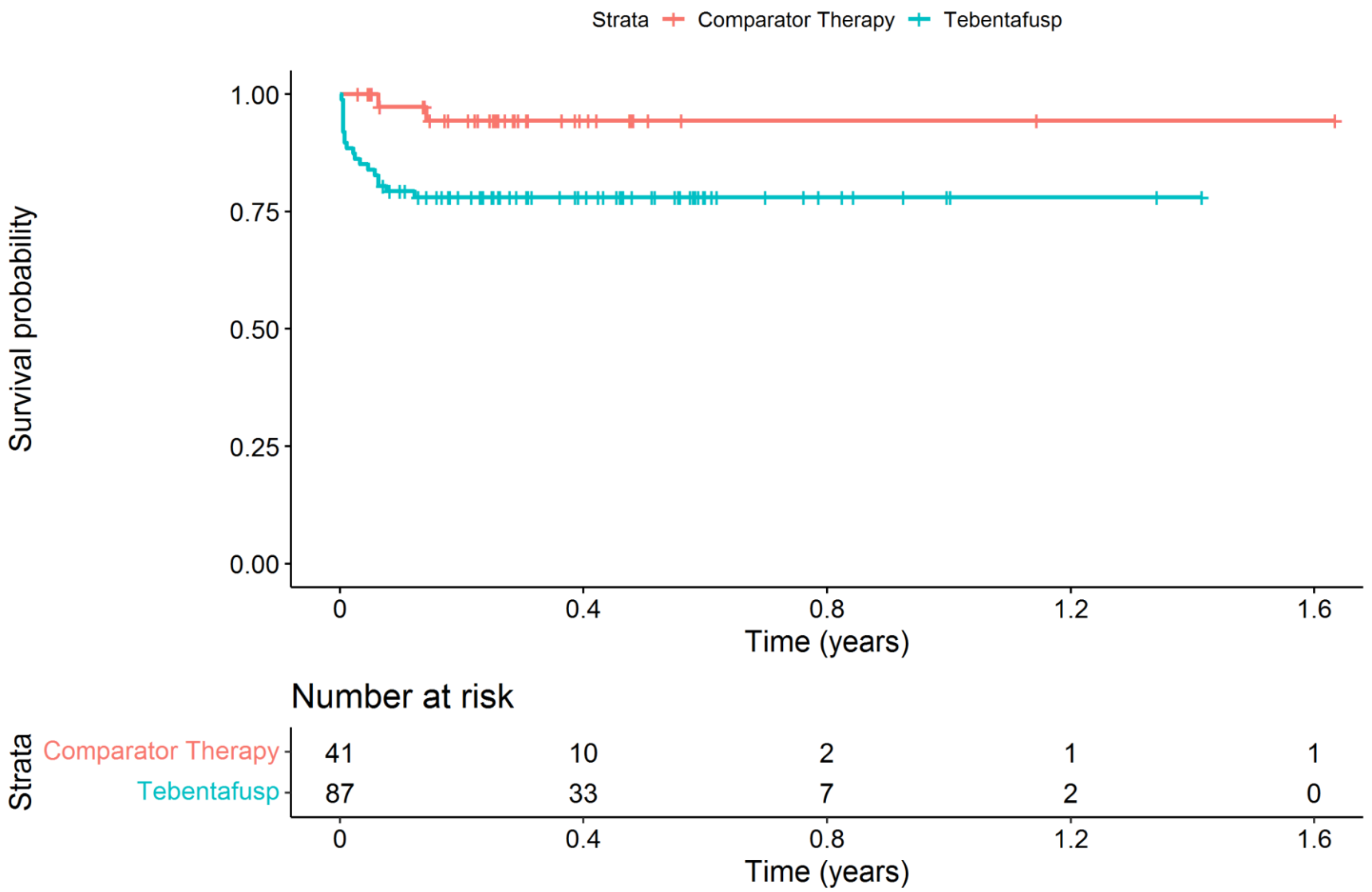
53.395 Trockene Haut - ALP > ULN



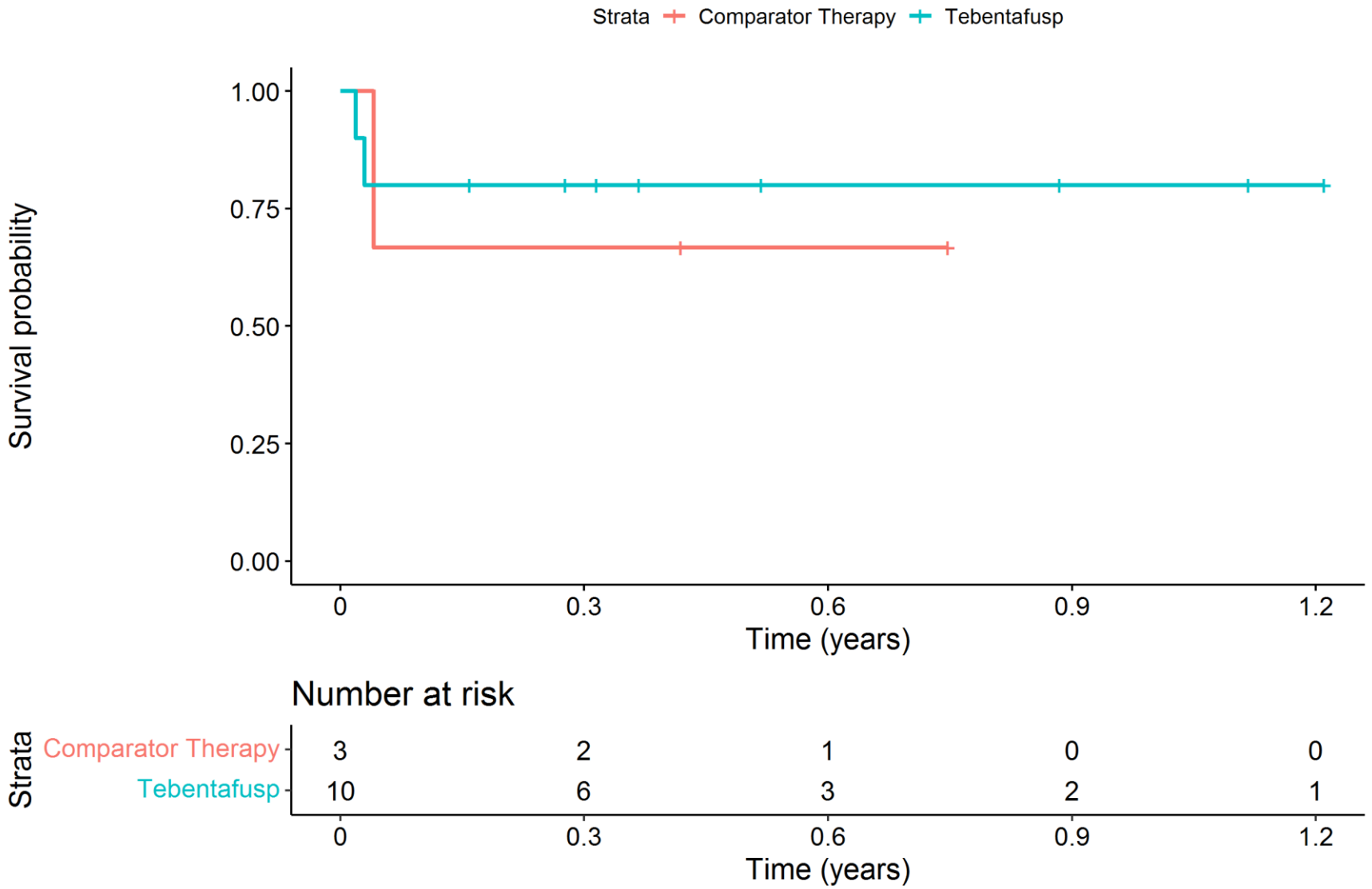
53.396 Trockene Haut - LDH =< ULN



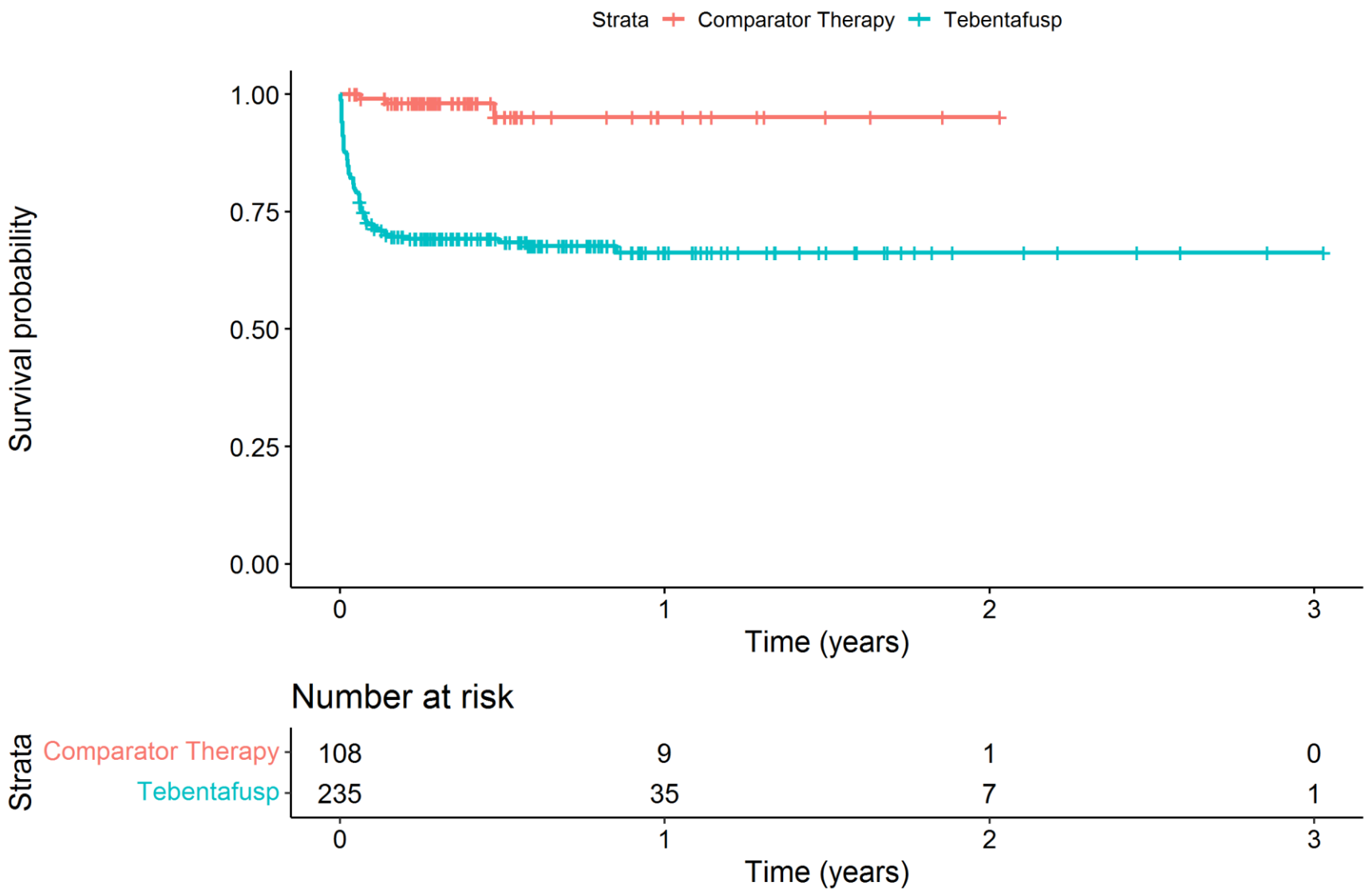
53.397 Trockene Haut - LDH > ULN



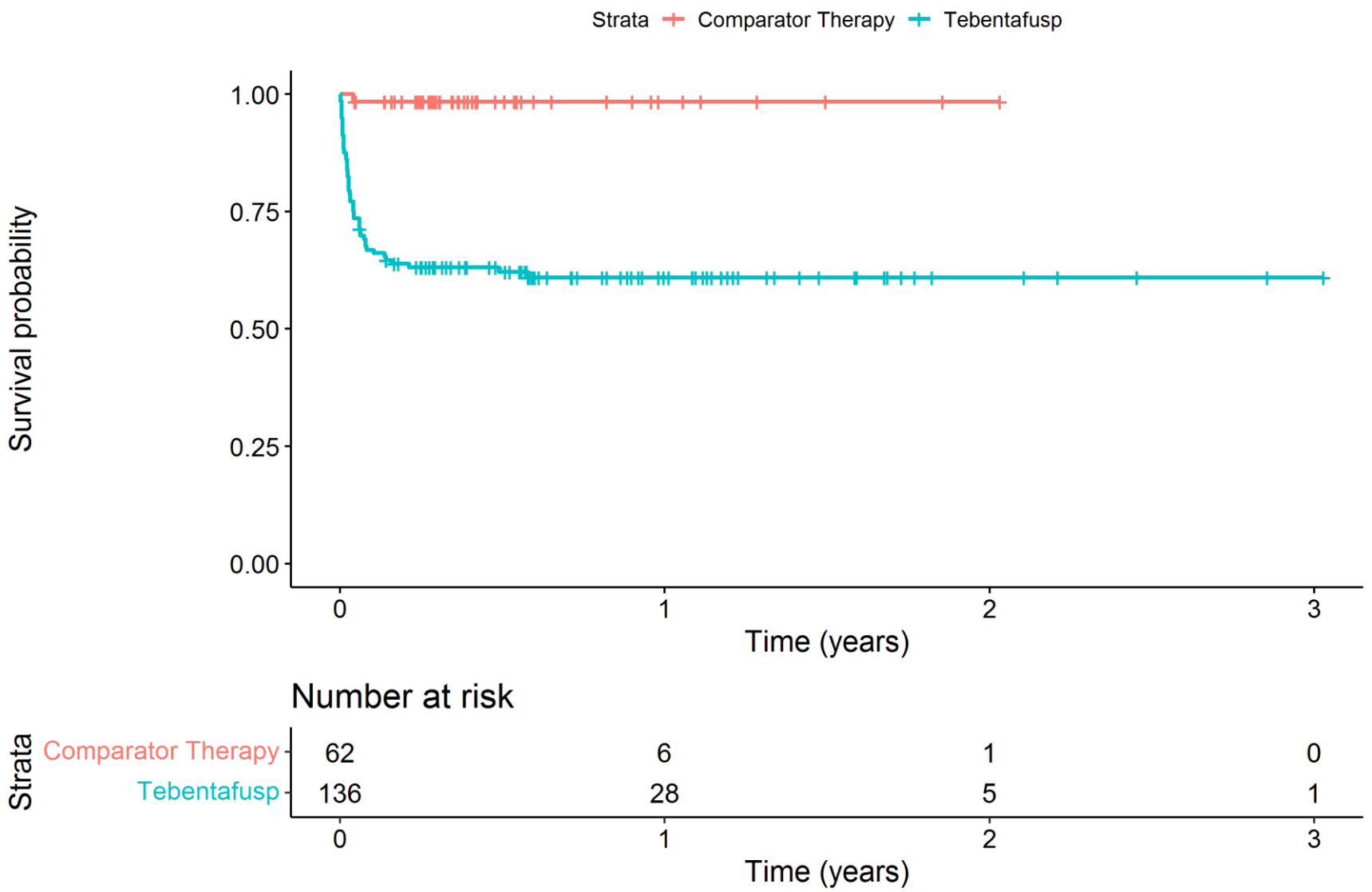
53.398 Trockene Haut - Vorherige Therapie adjuvant/neoadjuvant



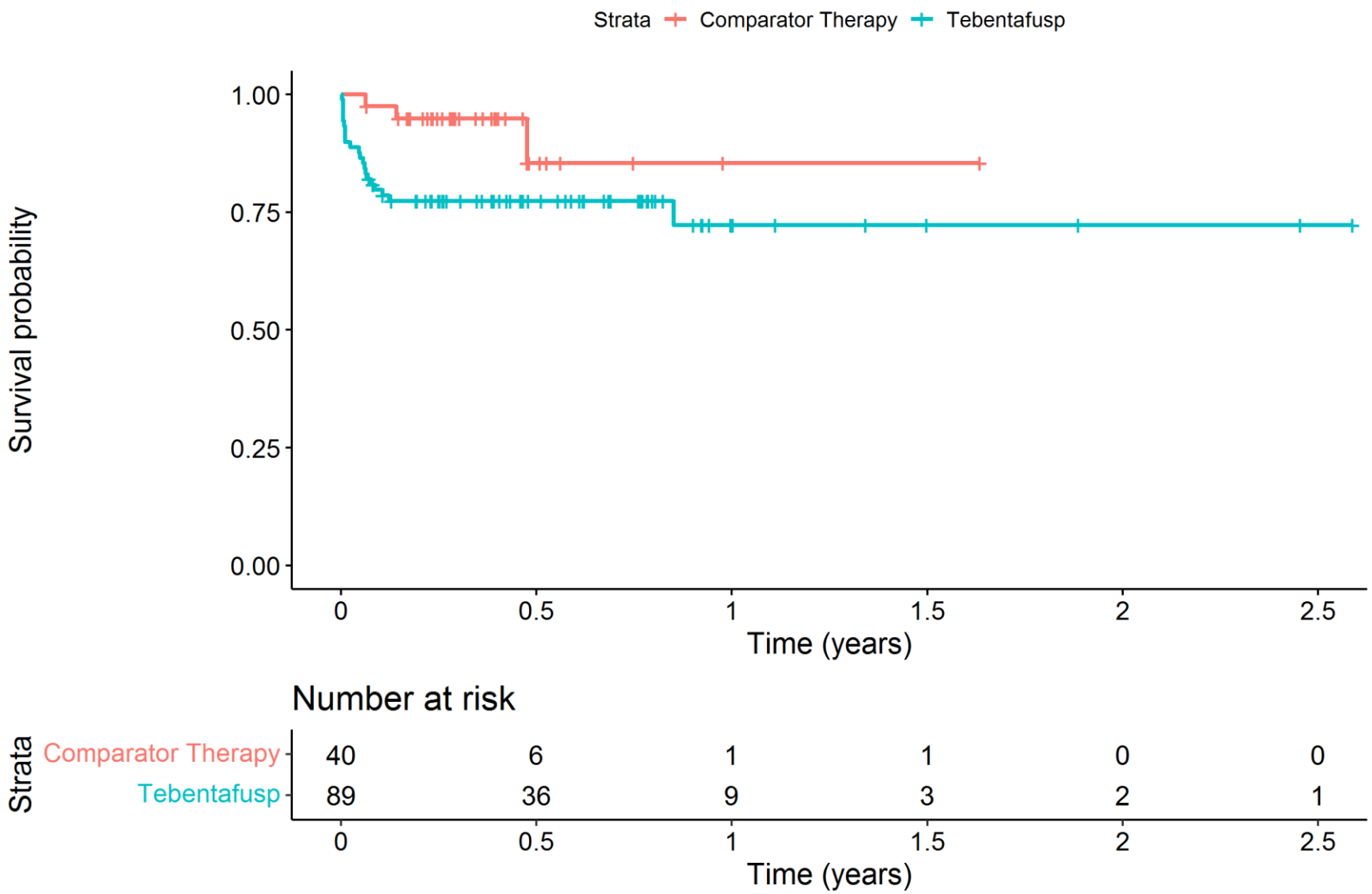
53.399 Trockene Haut - Keine vorherige Therapie adjuvant/neoadjuvant



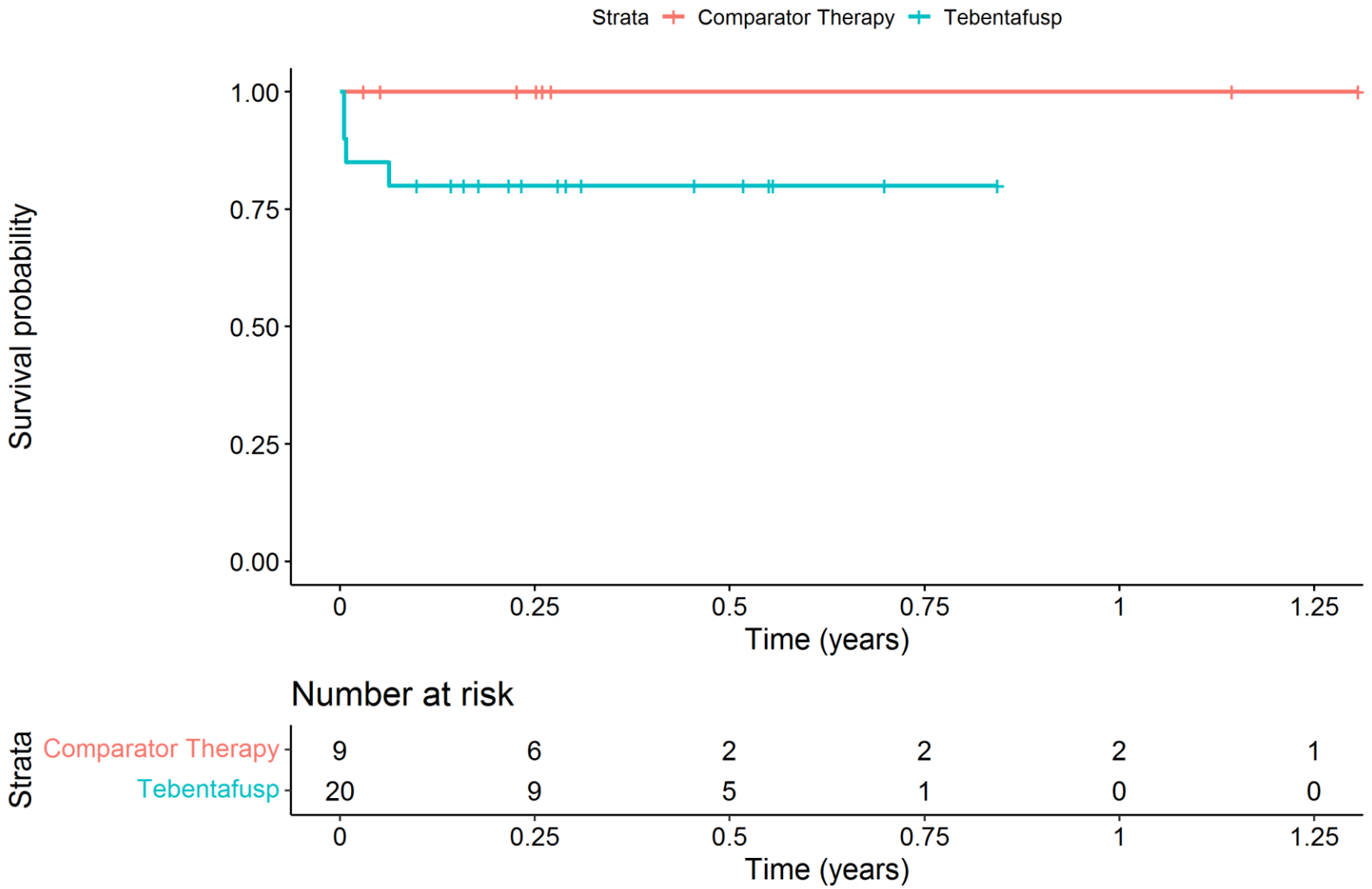
53.400 Trockene Haut - Läsion ≤ 3cm



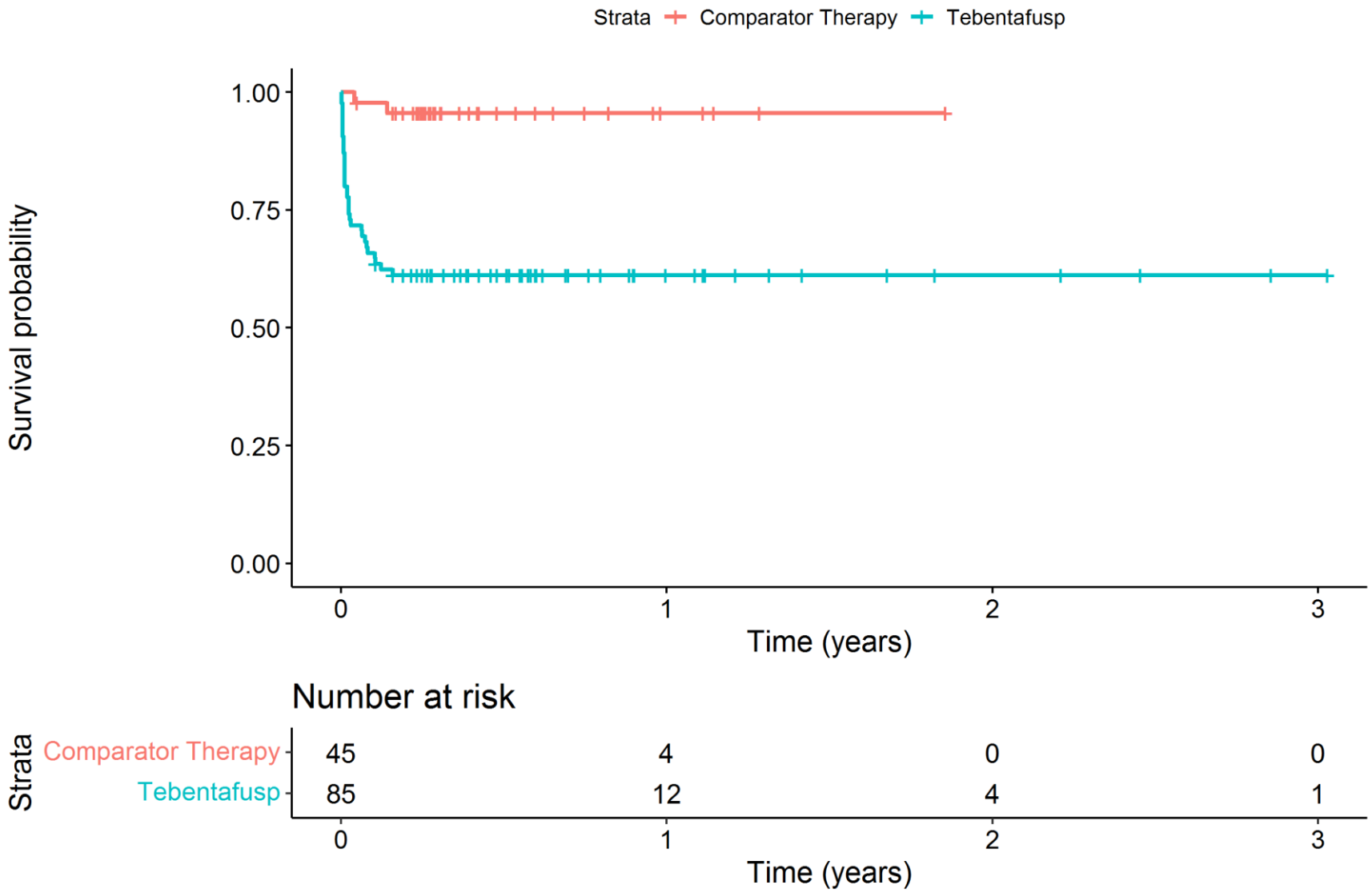
53.401 Trockene Haut - Läsion 3,1-8,0 cm



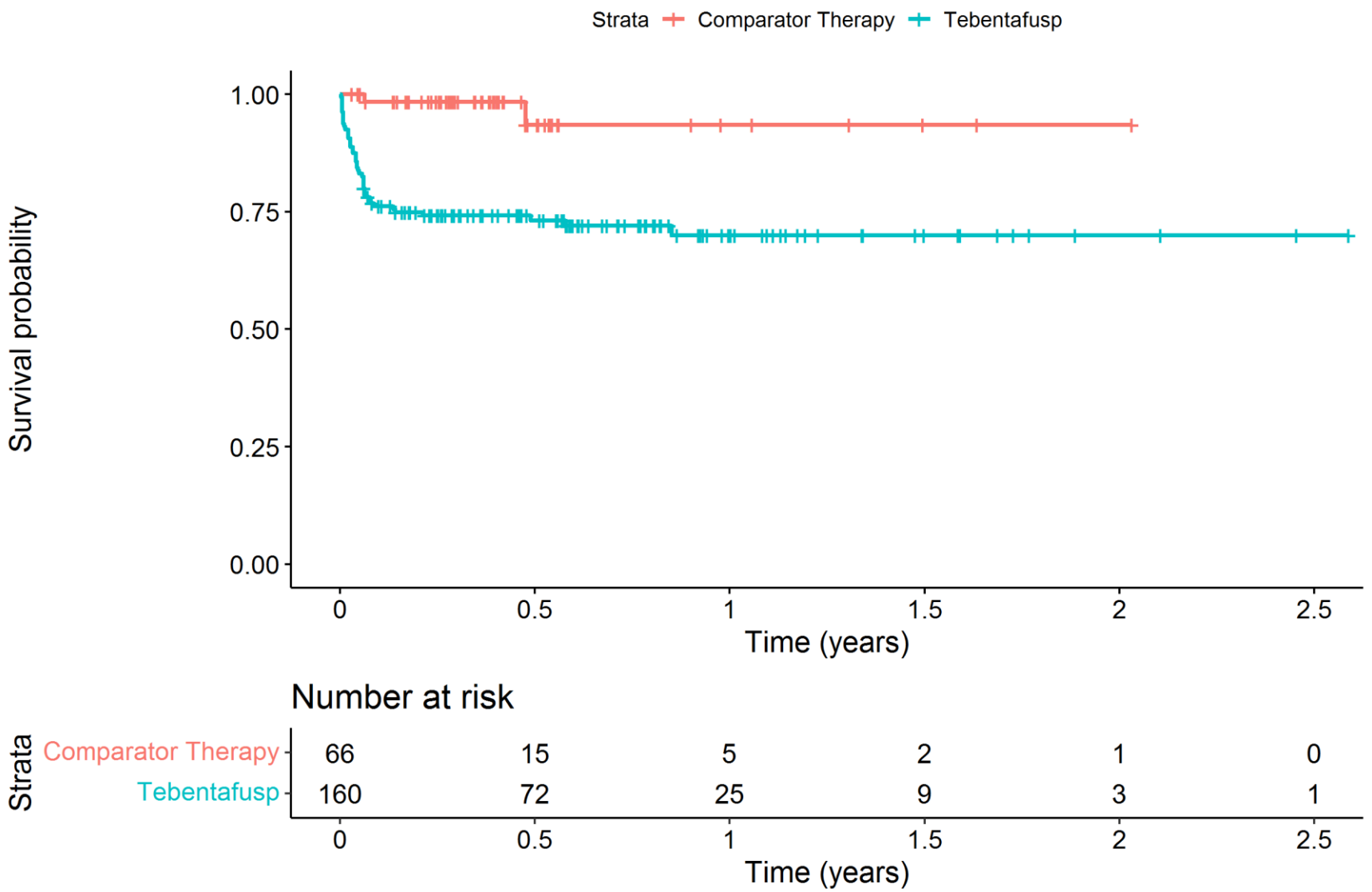
53.402 Trockene Haut - Läsion ≥8,1 cm



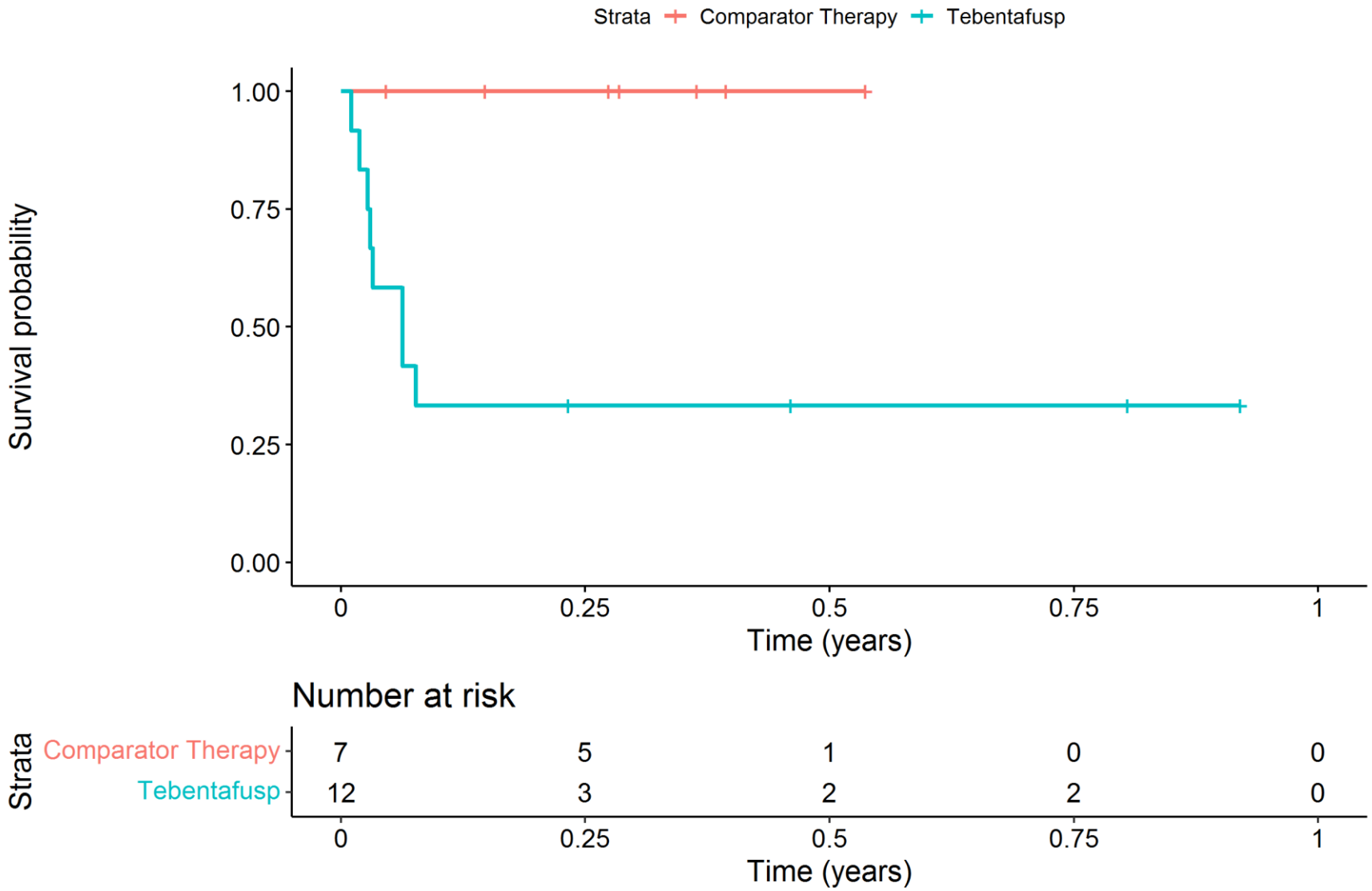
53.403 Trockene Haut - Nordamerika



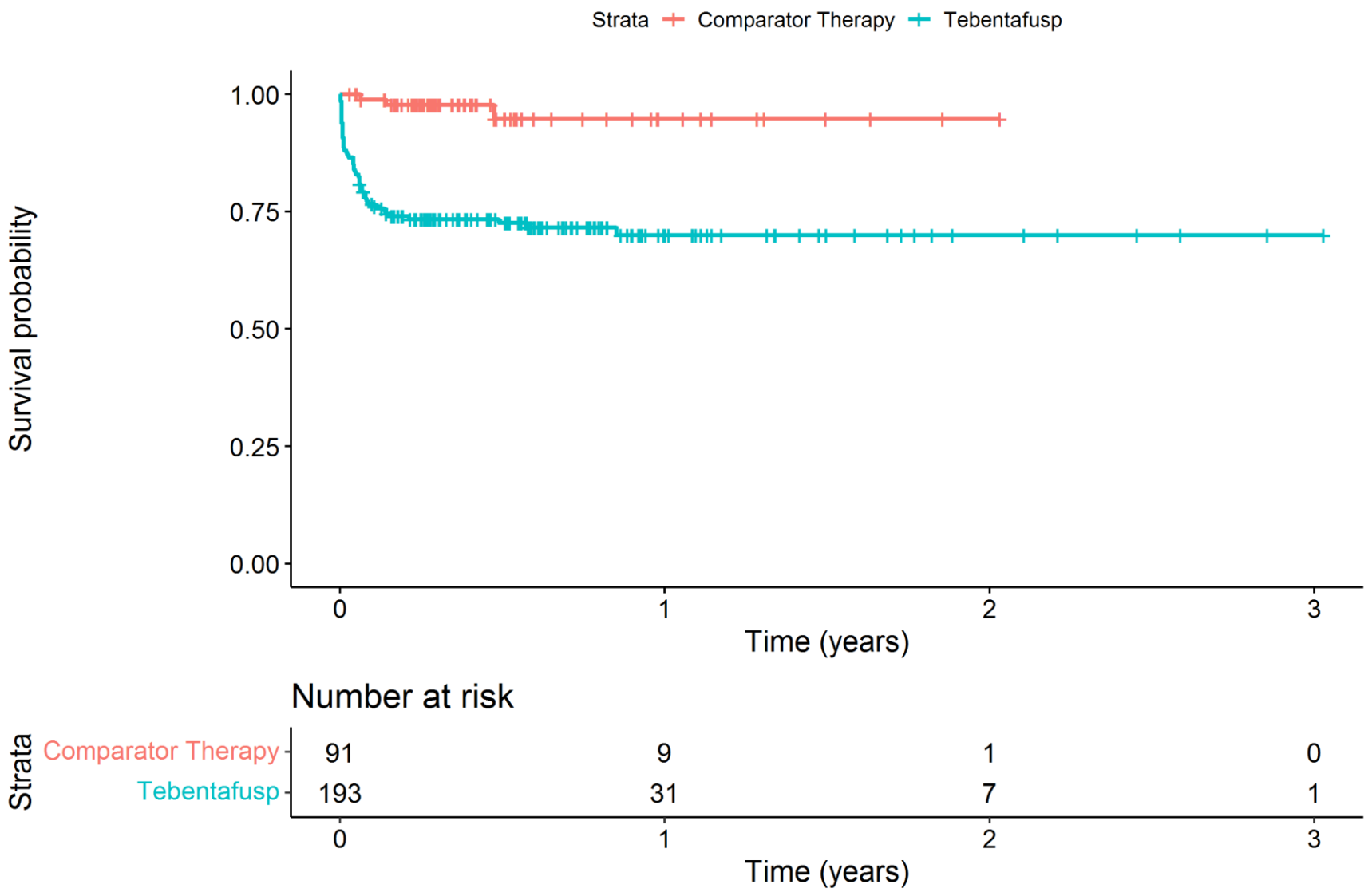
53.404 Trockene Haut - Nicht-Nordamerika



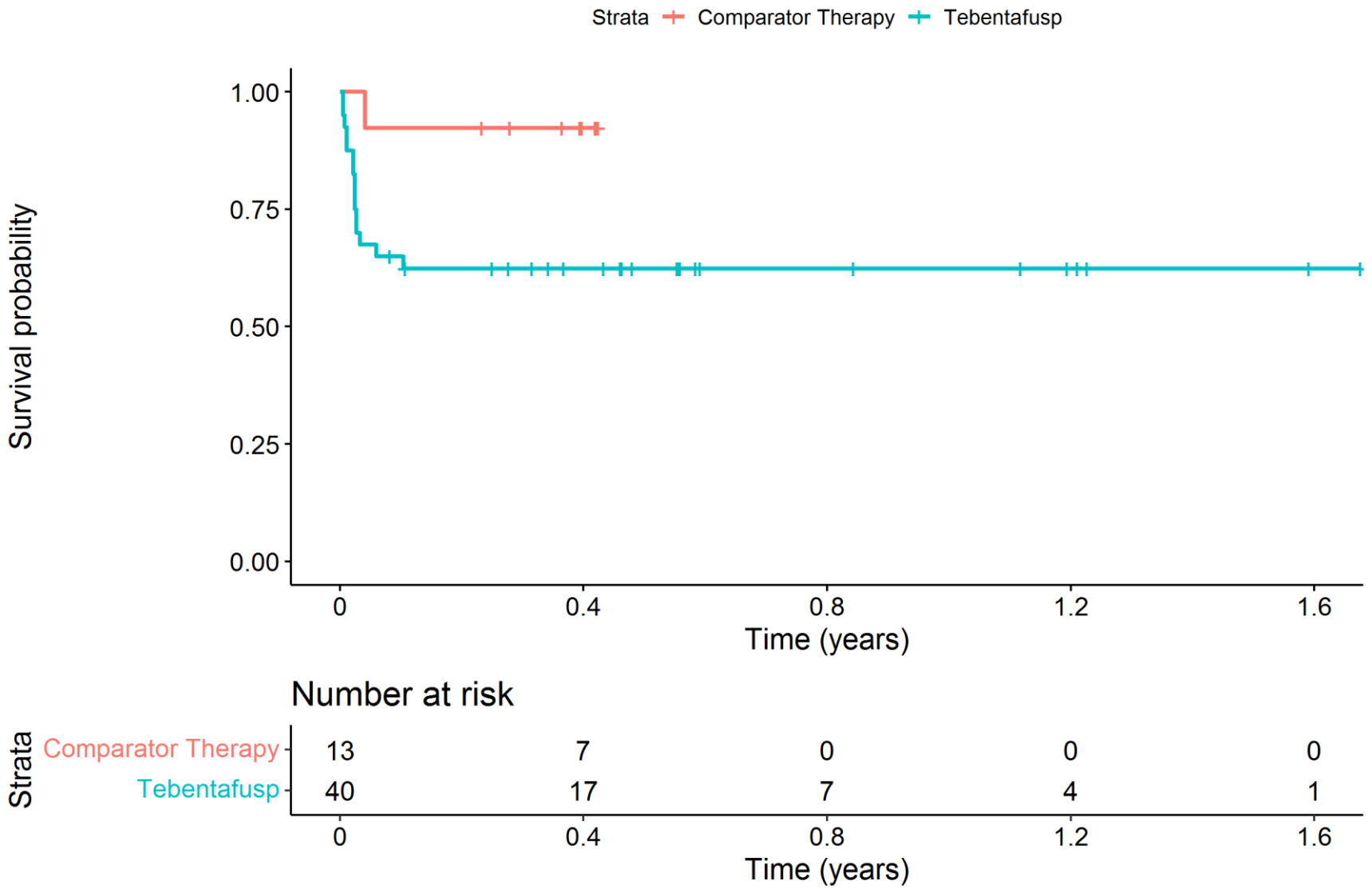
53.405 Trockene Haut - Dacarbazin



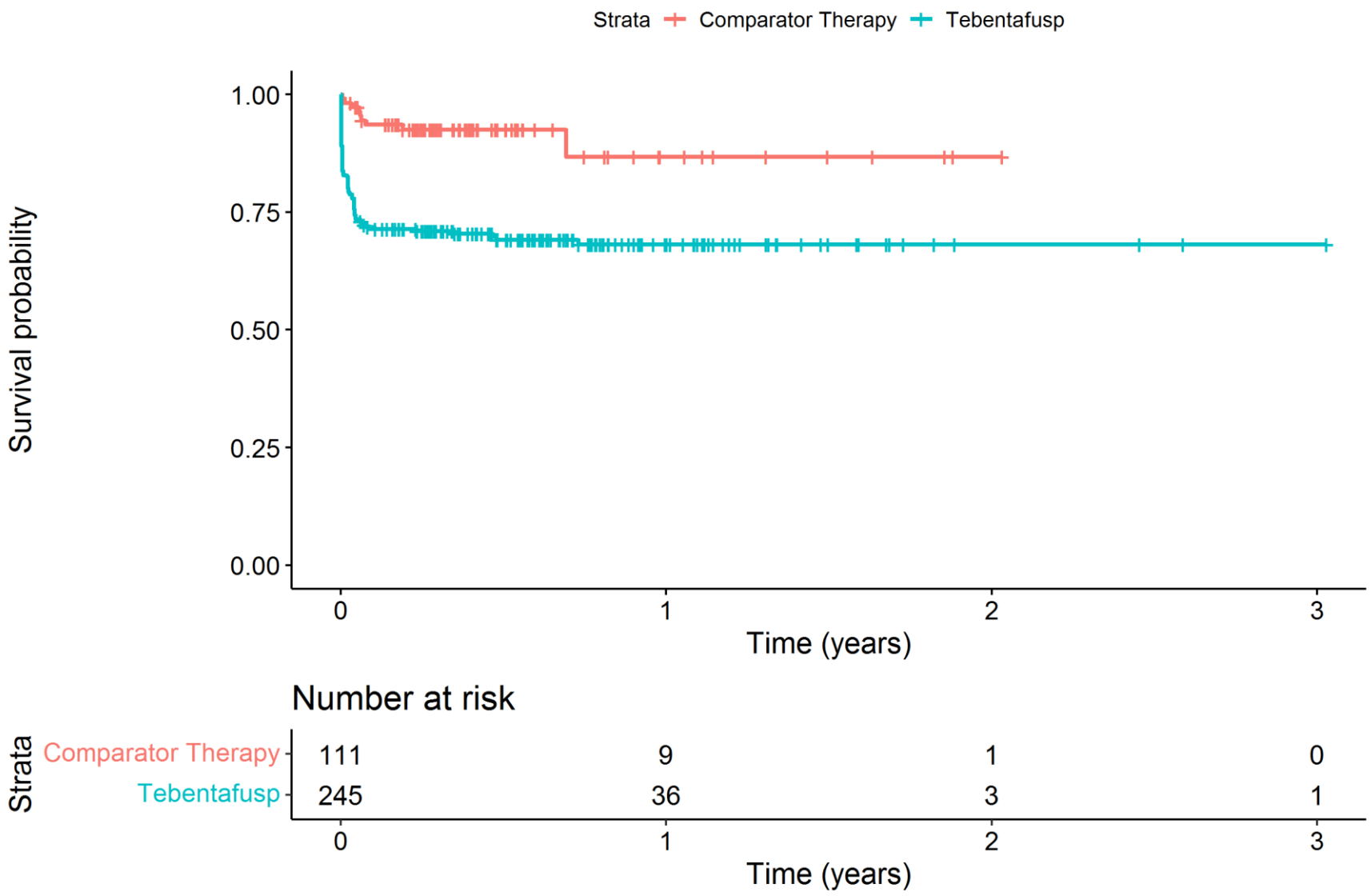
53.406 Trockene Haut - Pembrolizumab



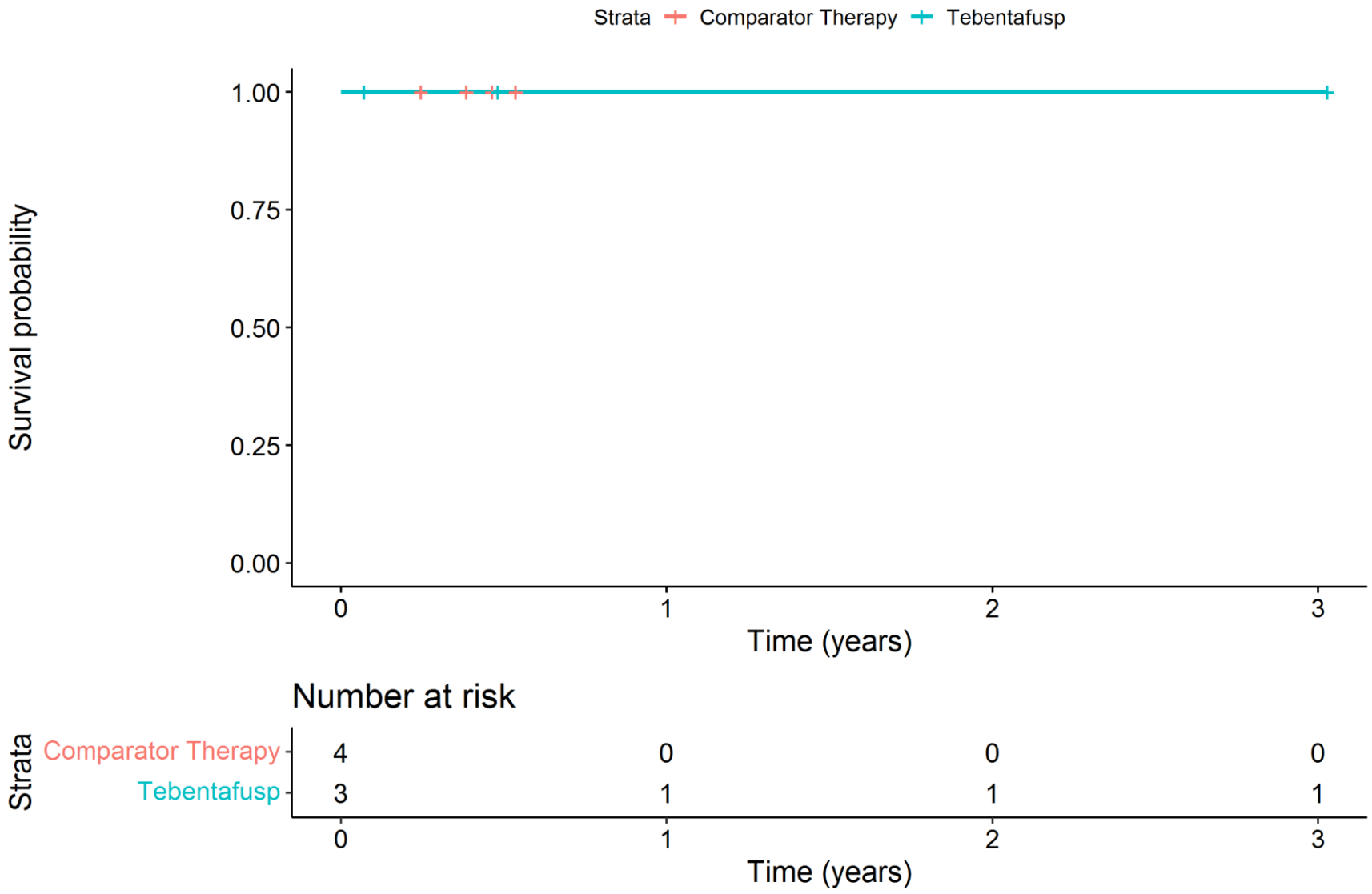
53.407 Trockene Haut - Ipilimumab



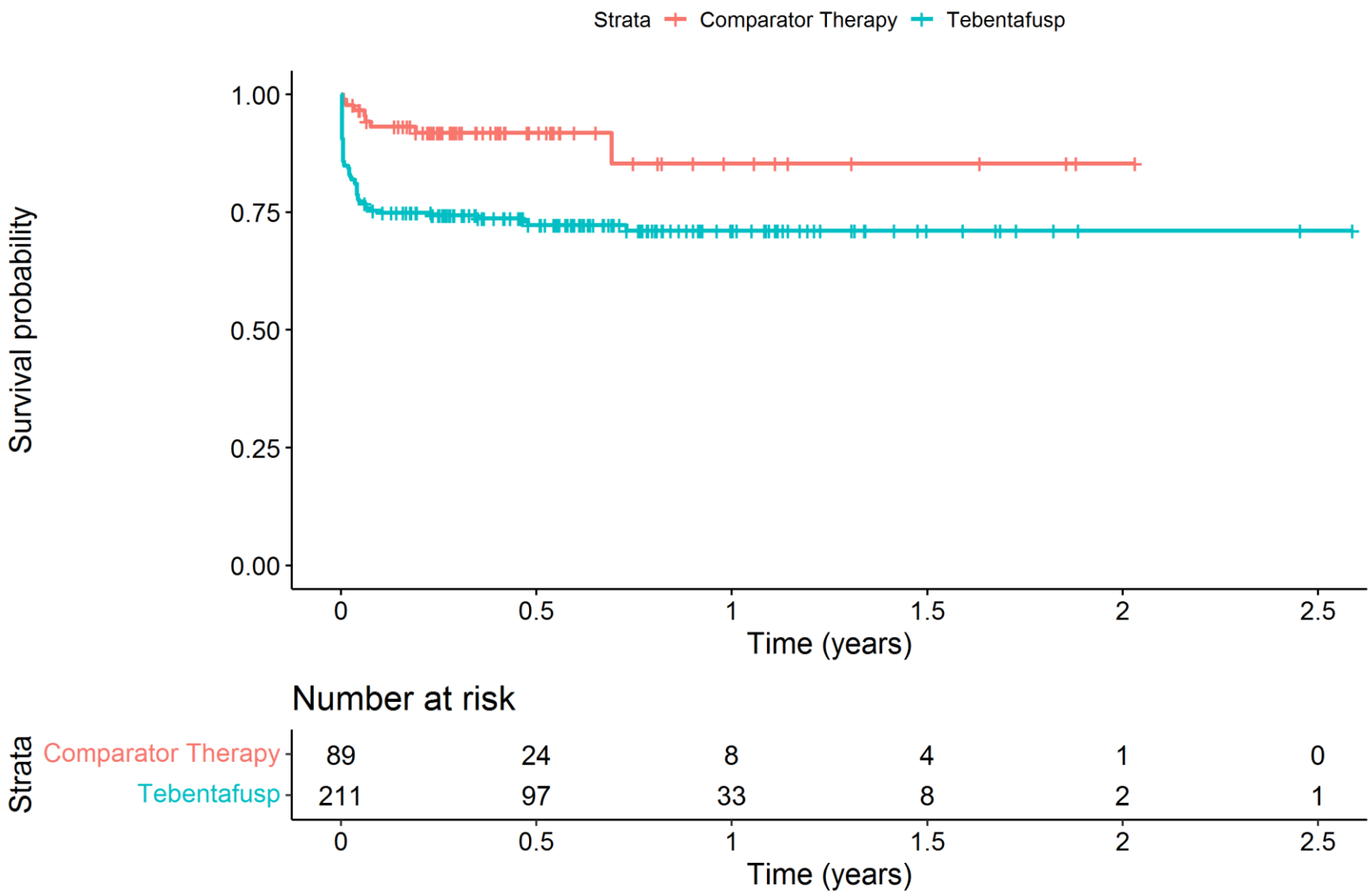
53.408 Makulo-papulöser Hautausschlag - Gesamt



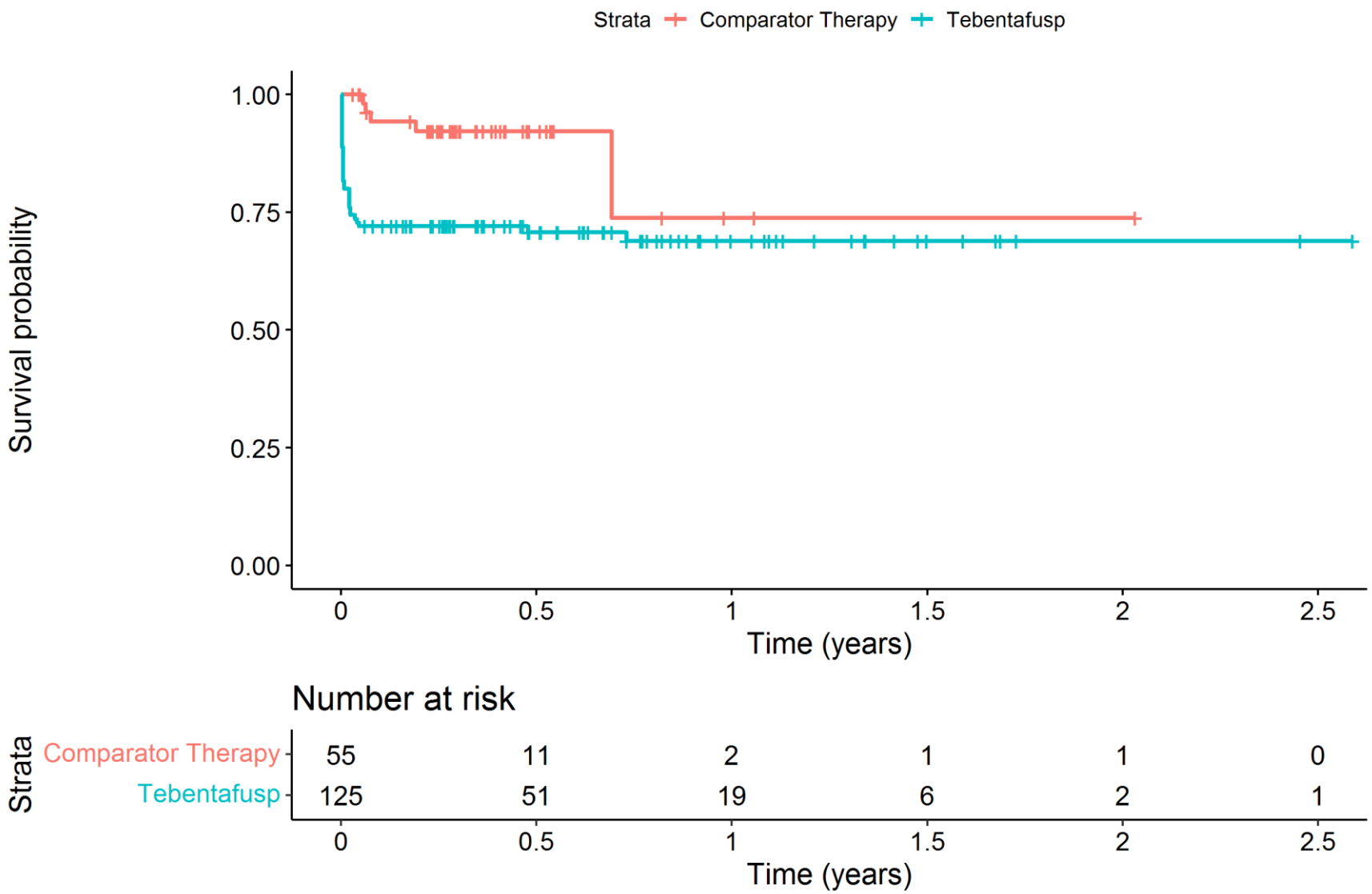
53.409 Makulo-papulöser Hautausschlag - Hispanisch



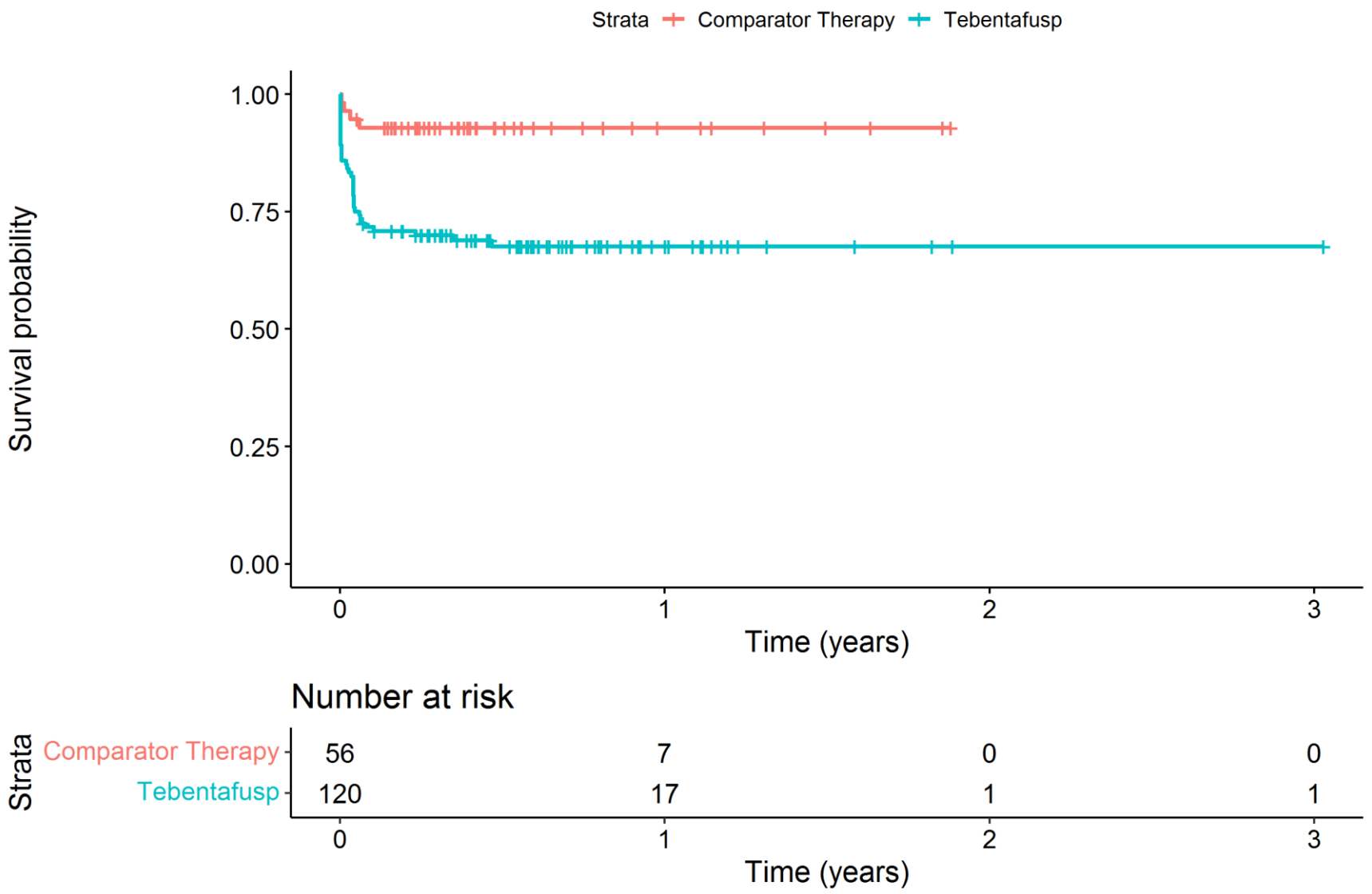
53.410 Makulo-papulöser Hautausschlag - Nicht-hispanisch



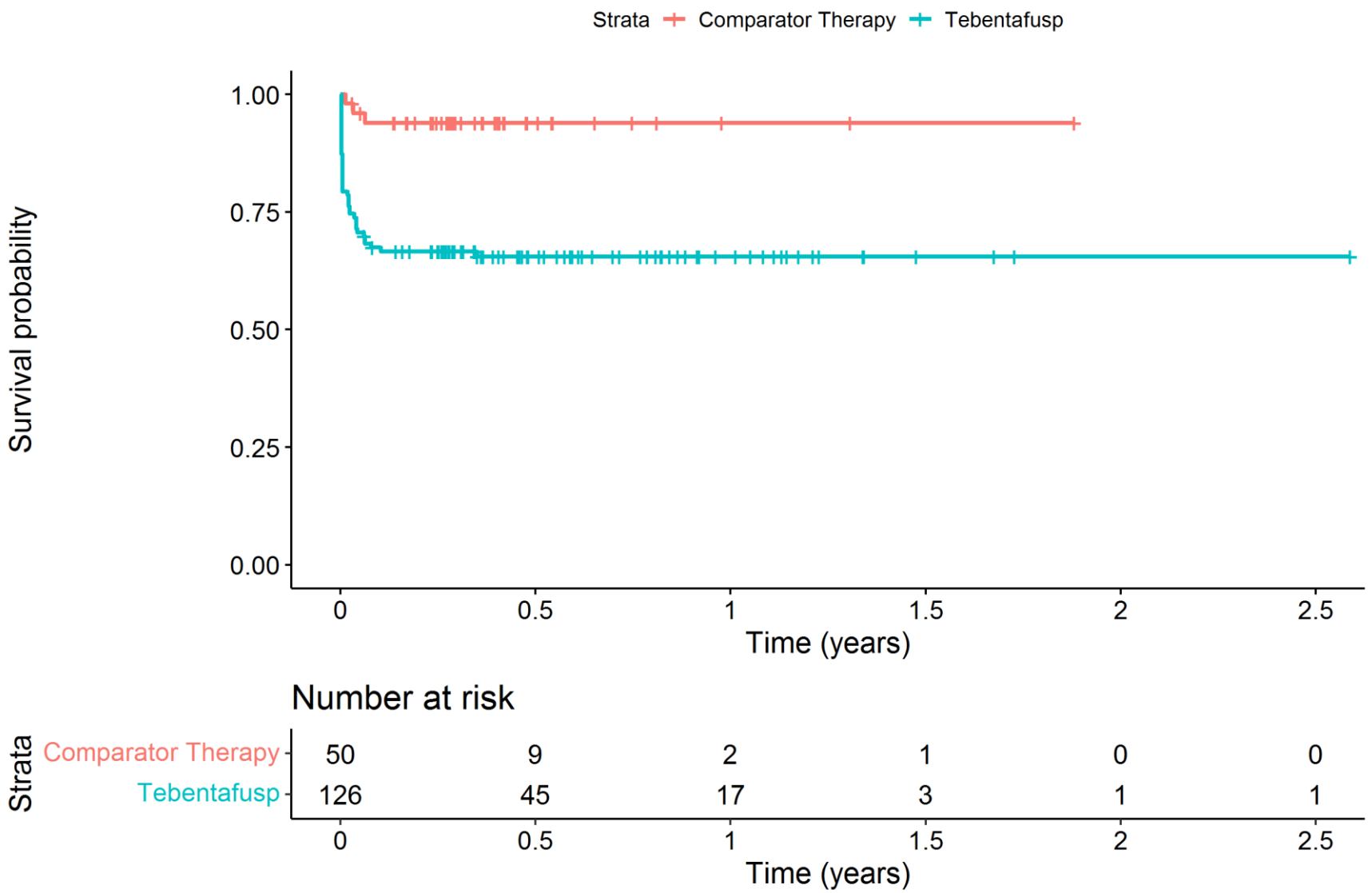
53.411 Makulo-papulöser Hautausschlag - Männlich



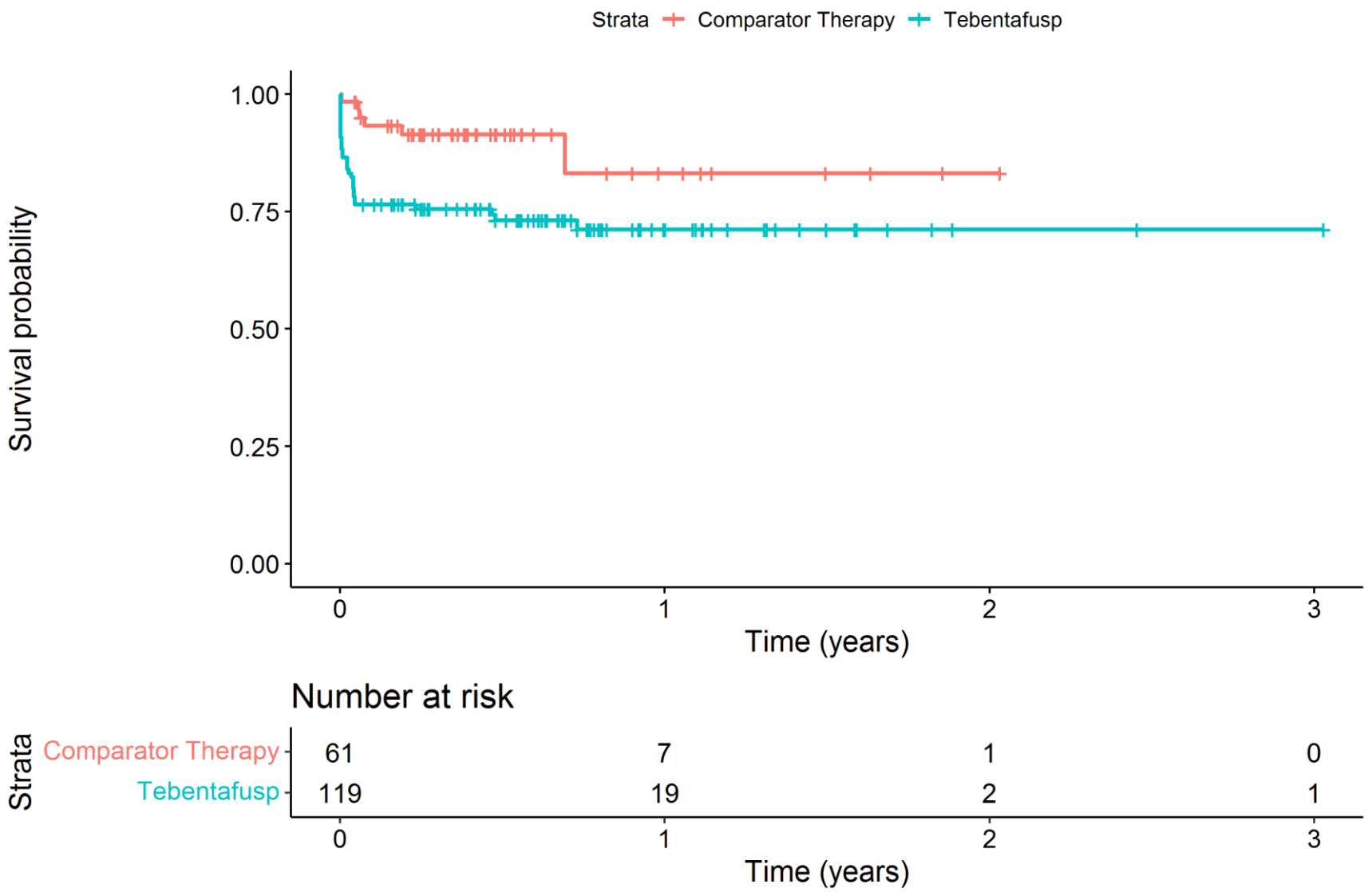
53.412 Makulo-papulöser Hautausschlag - Weiblich



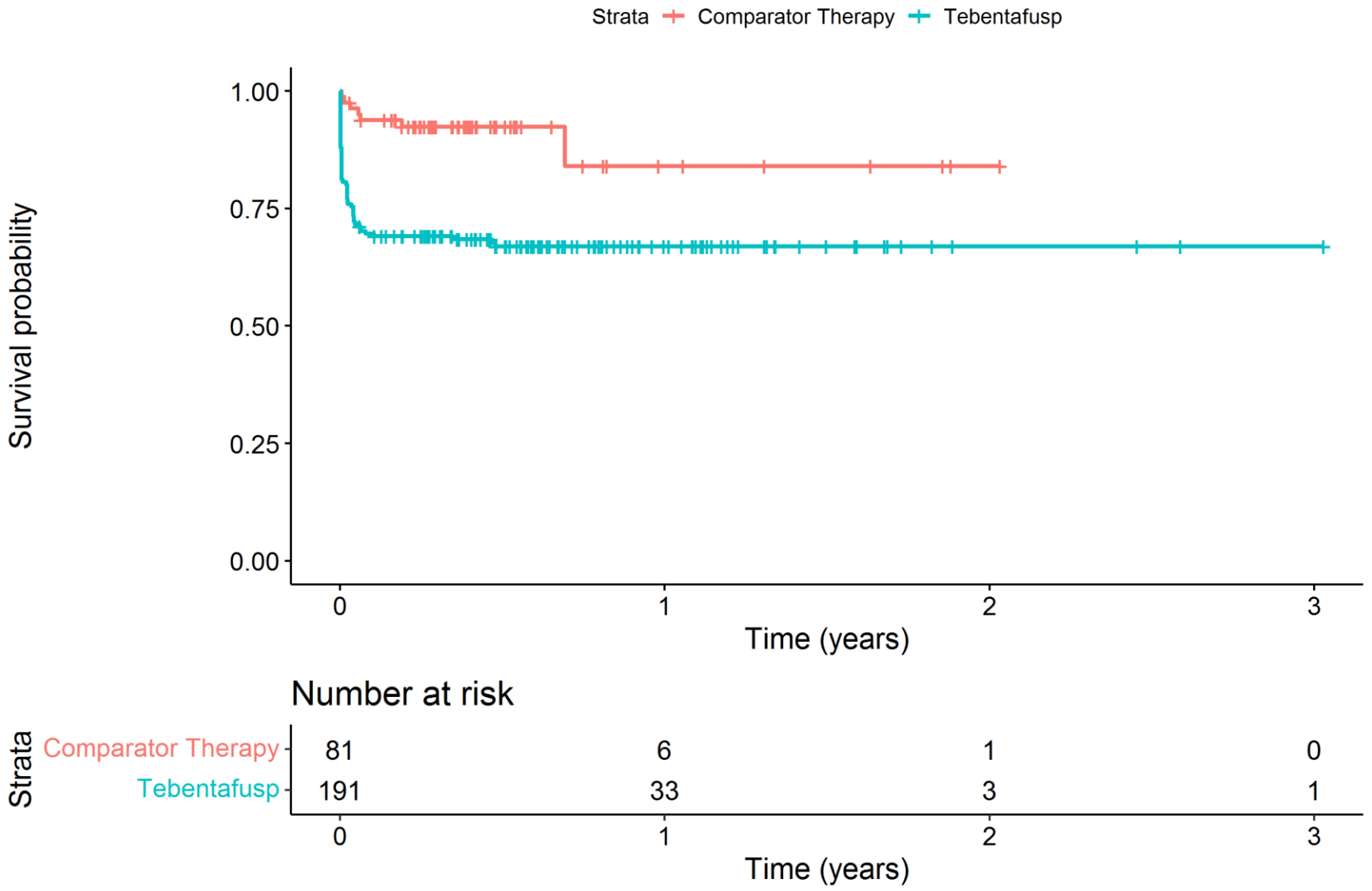
53.413 Makulo-papulöser Hautausschlag - <65



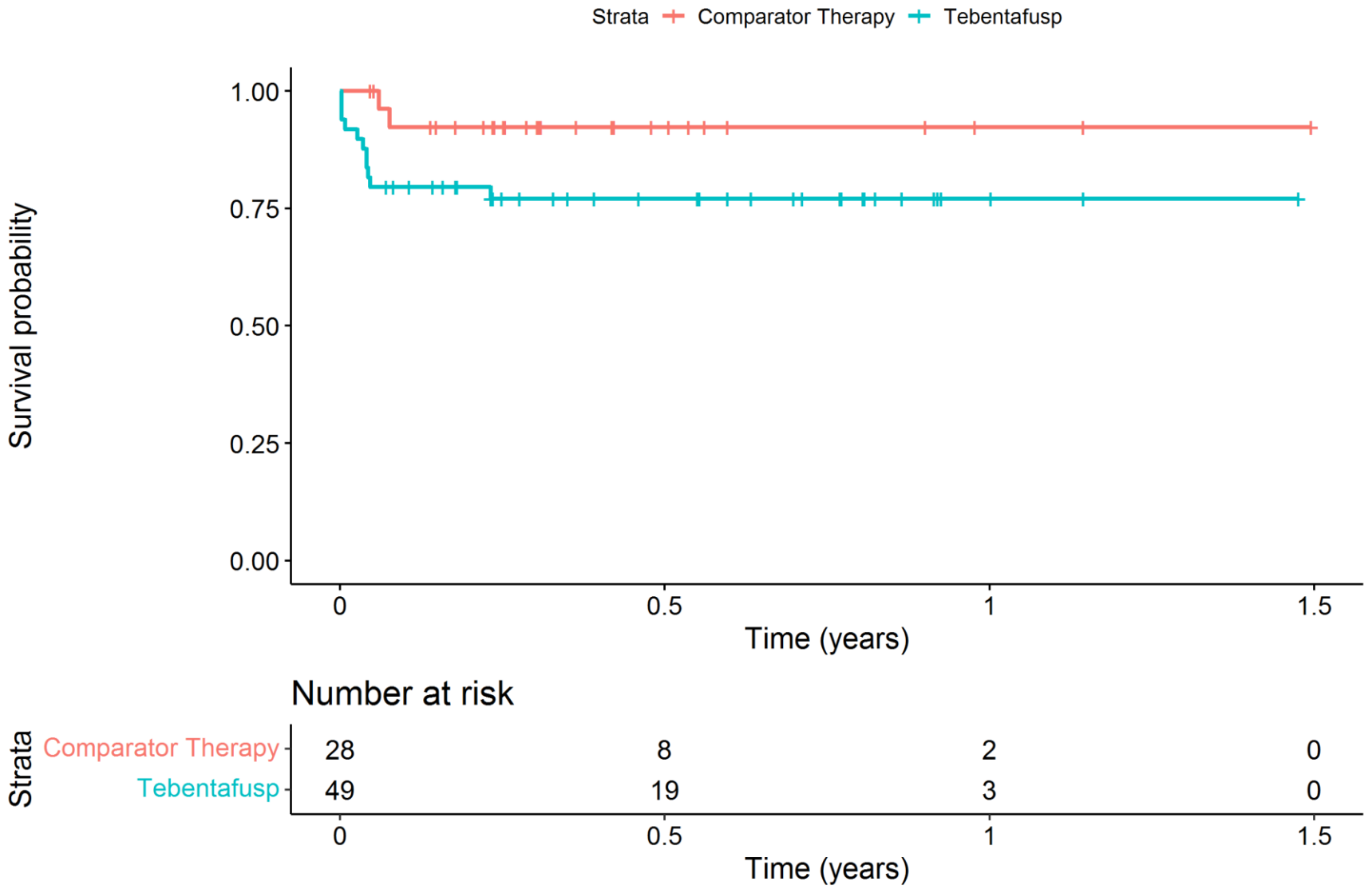
53.414 Makulo-papulöser Hautausschlag - ≥65



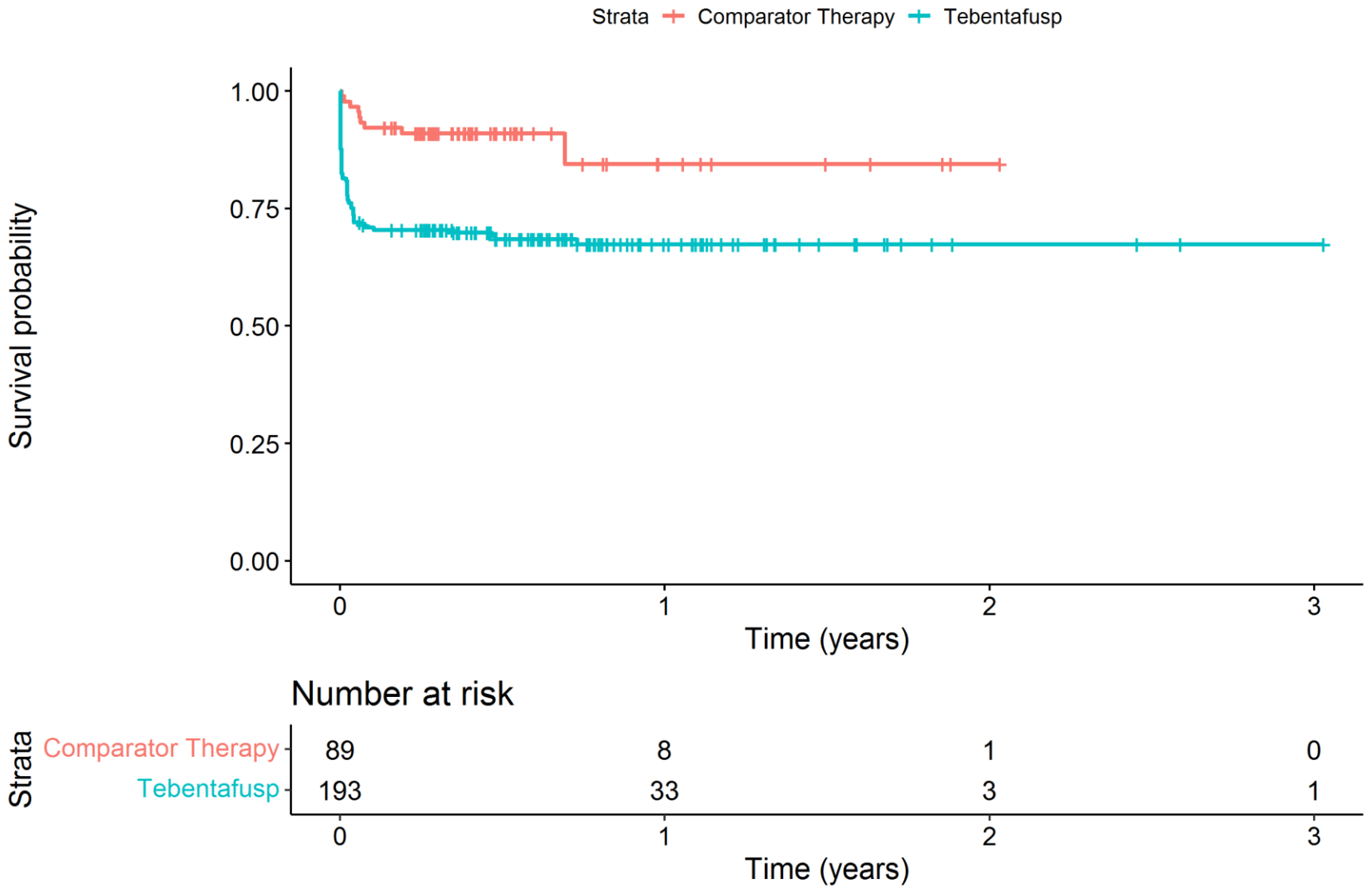
53.415 Makulo-papulöser Hautausschlag - ECOG 0



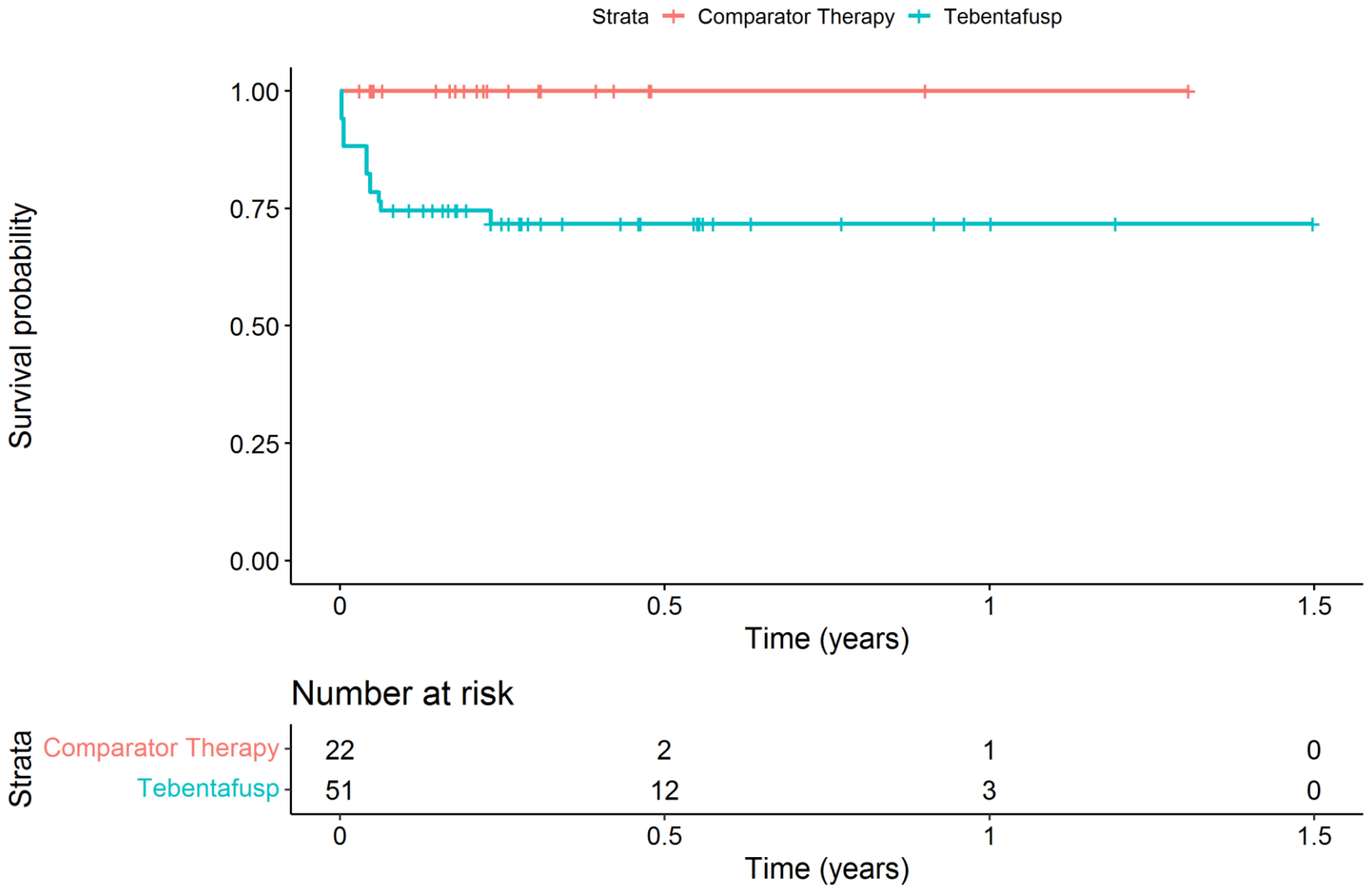
53.416 Makulo-papulöser Hautausschlag - ECOG 1



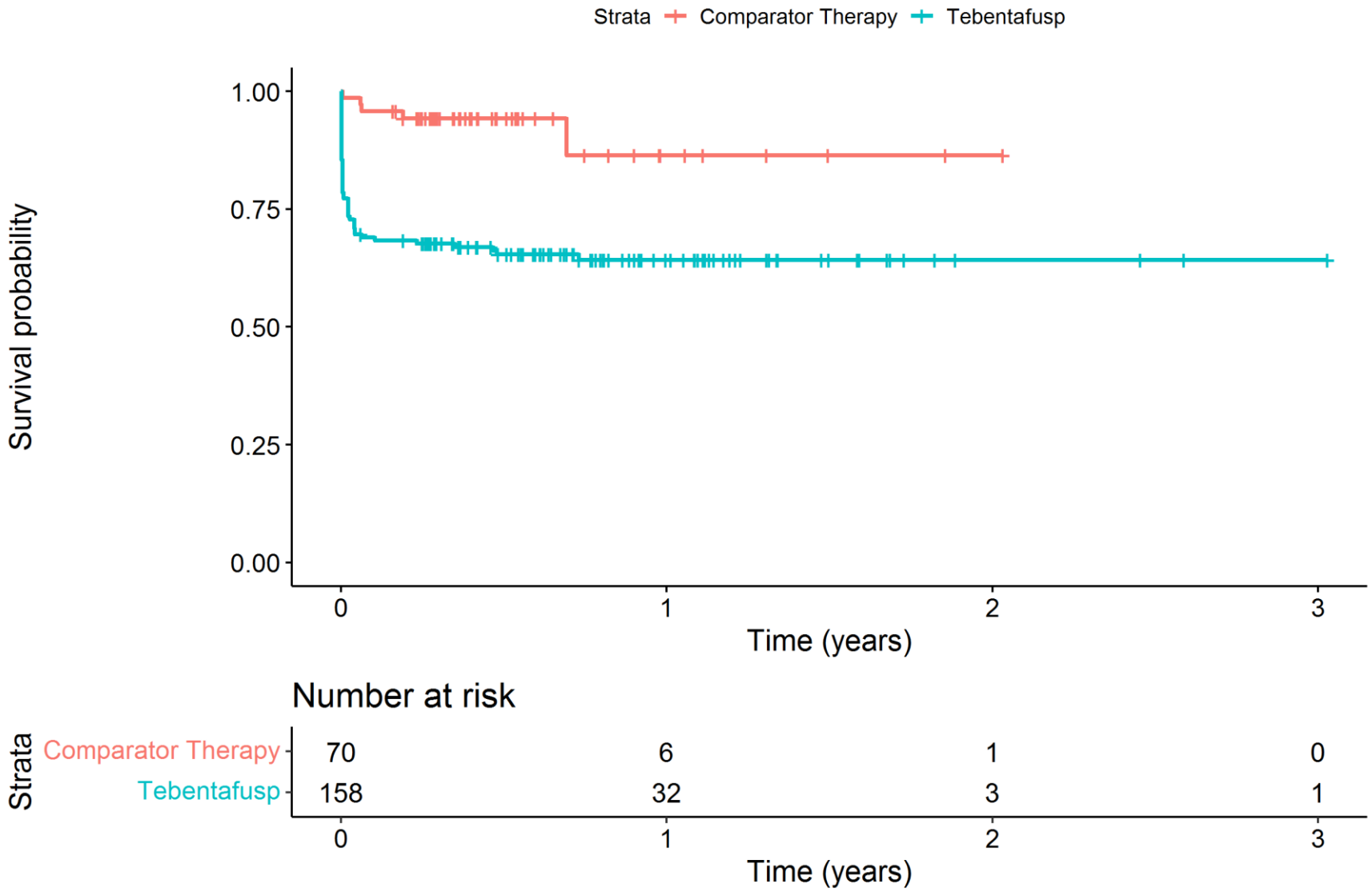
53.417 Makulo-papulöser Hautausschlag - ALP ≤ ULN



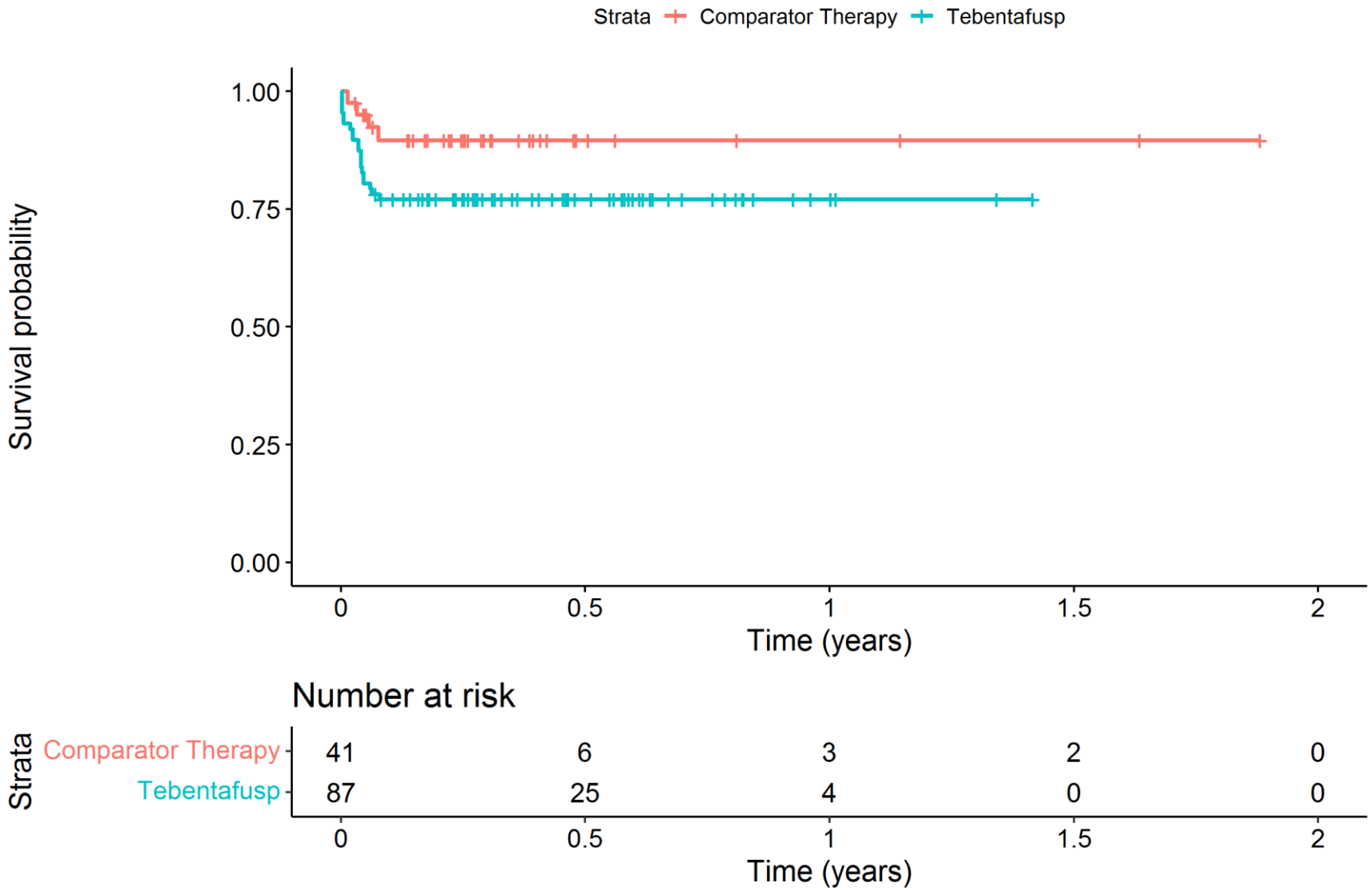
53.418 Makulo-papulöser Hautausschlag - ALP > ULN



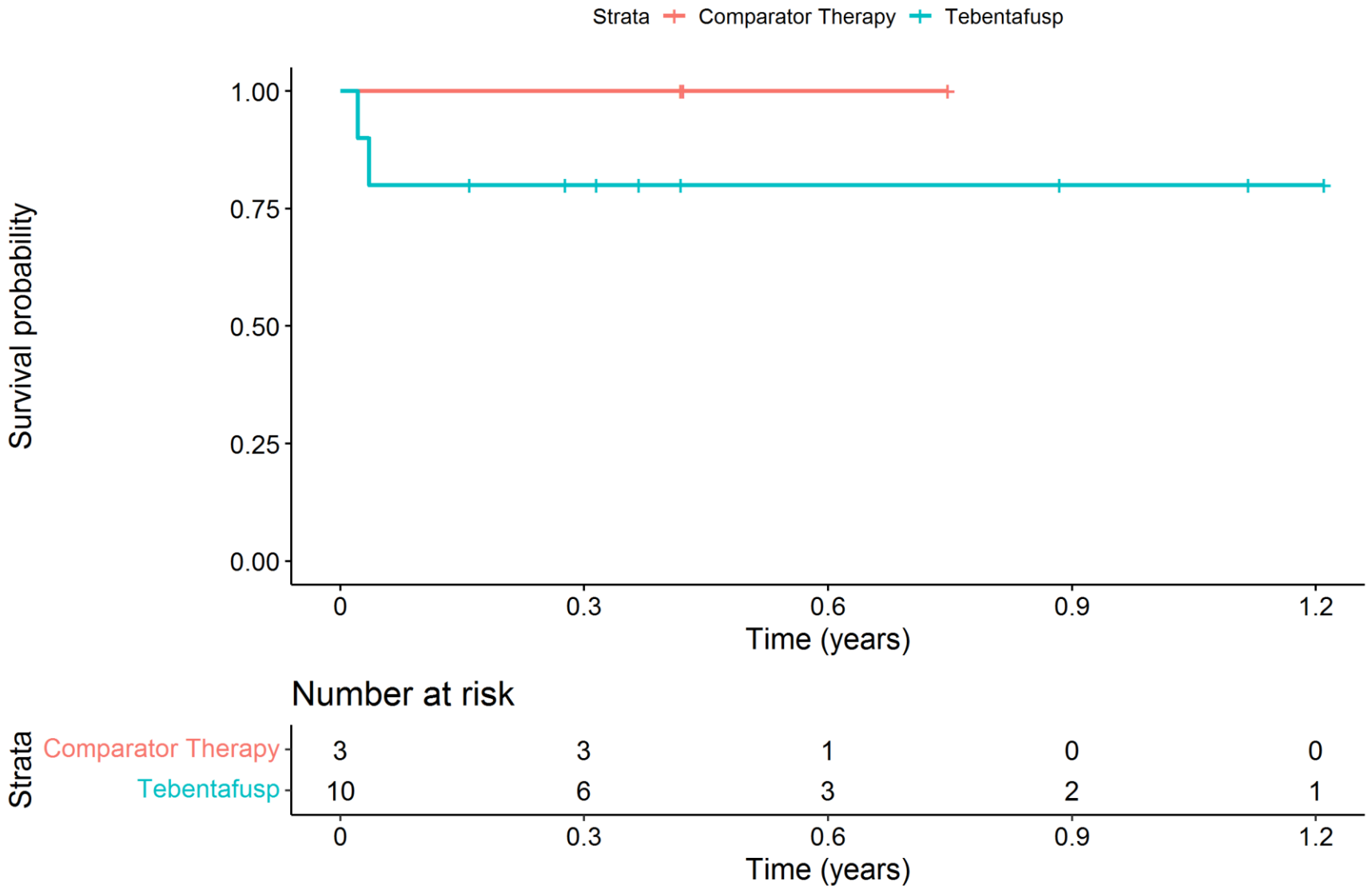
53.419 Makulo-papulöser Hautausschlag - LDH =< ULN



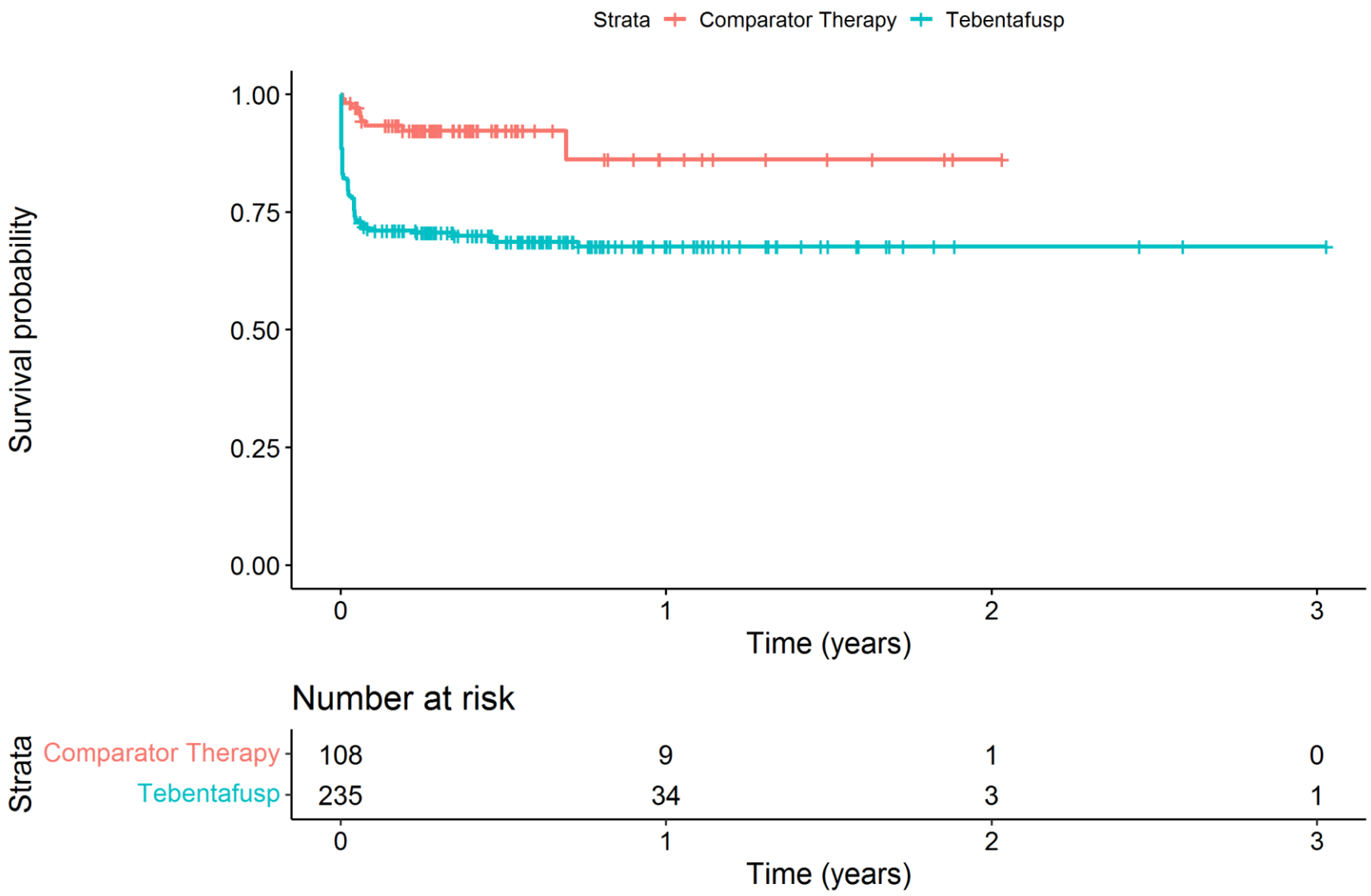
53.420 Makulo-papulöser Hautausschlag - LDH > ULN



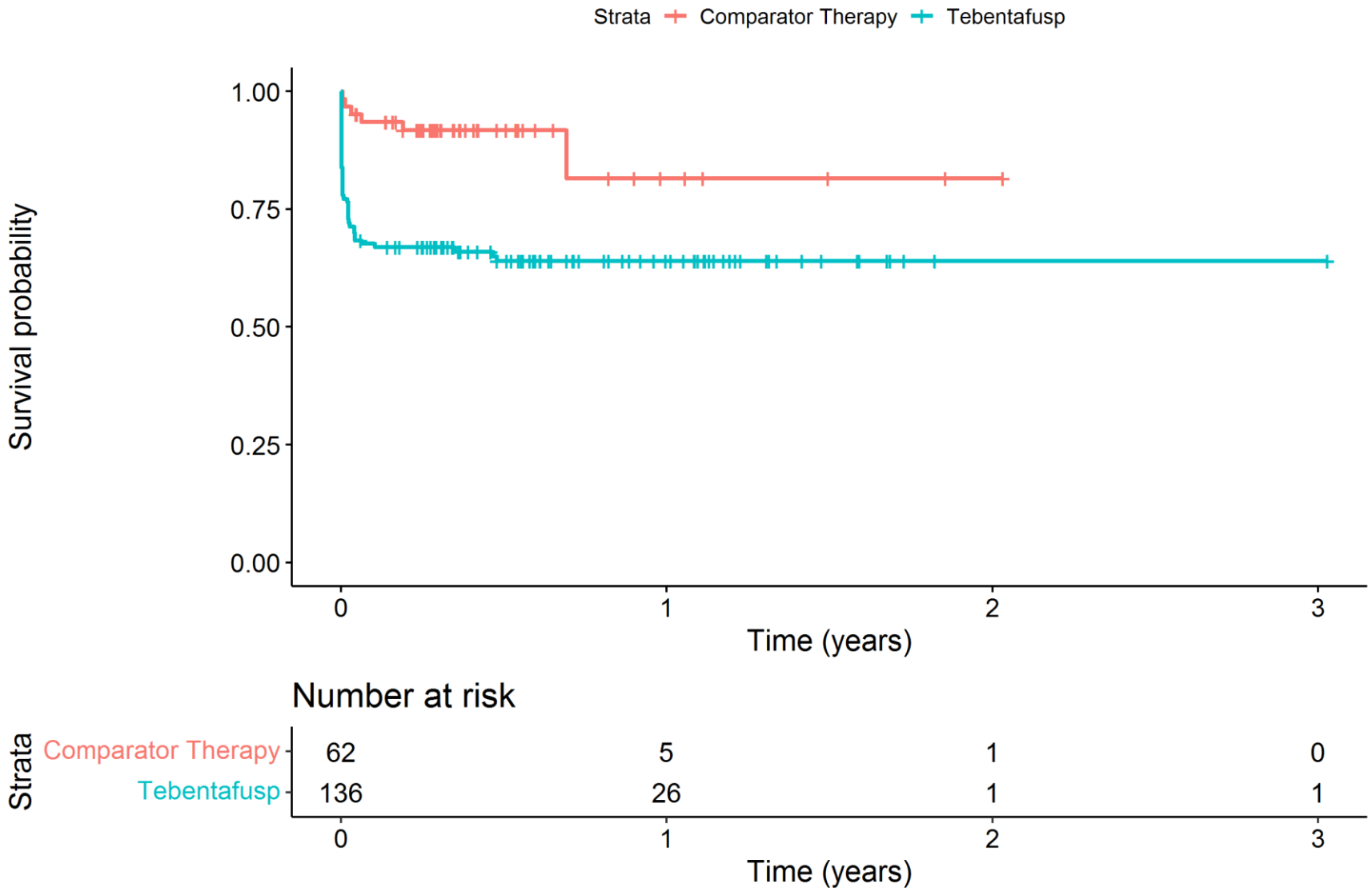
53.421 Makulo-papulöser Hautausschlag - Vorherige Therapie adjuvant/neoadjuvant



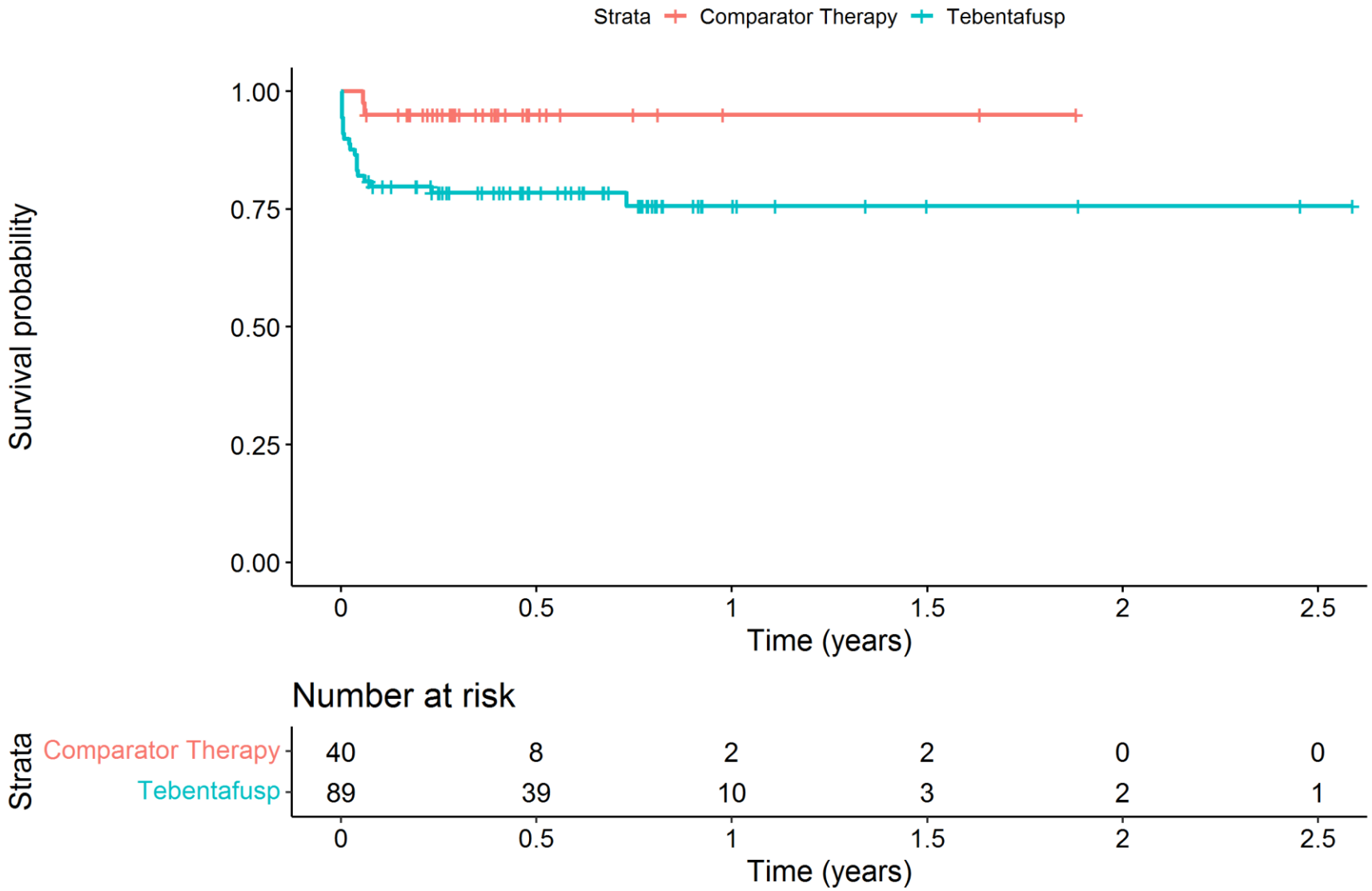
53.422 Makulo-papulöser Hautausschlag - Keine vorherige Therapie adjuvant/neoadjuvant



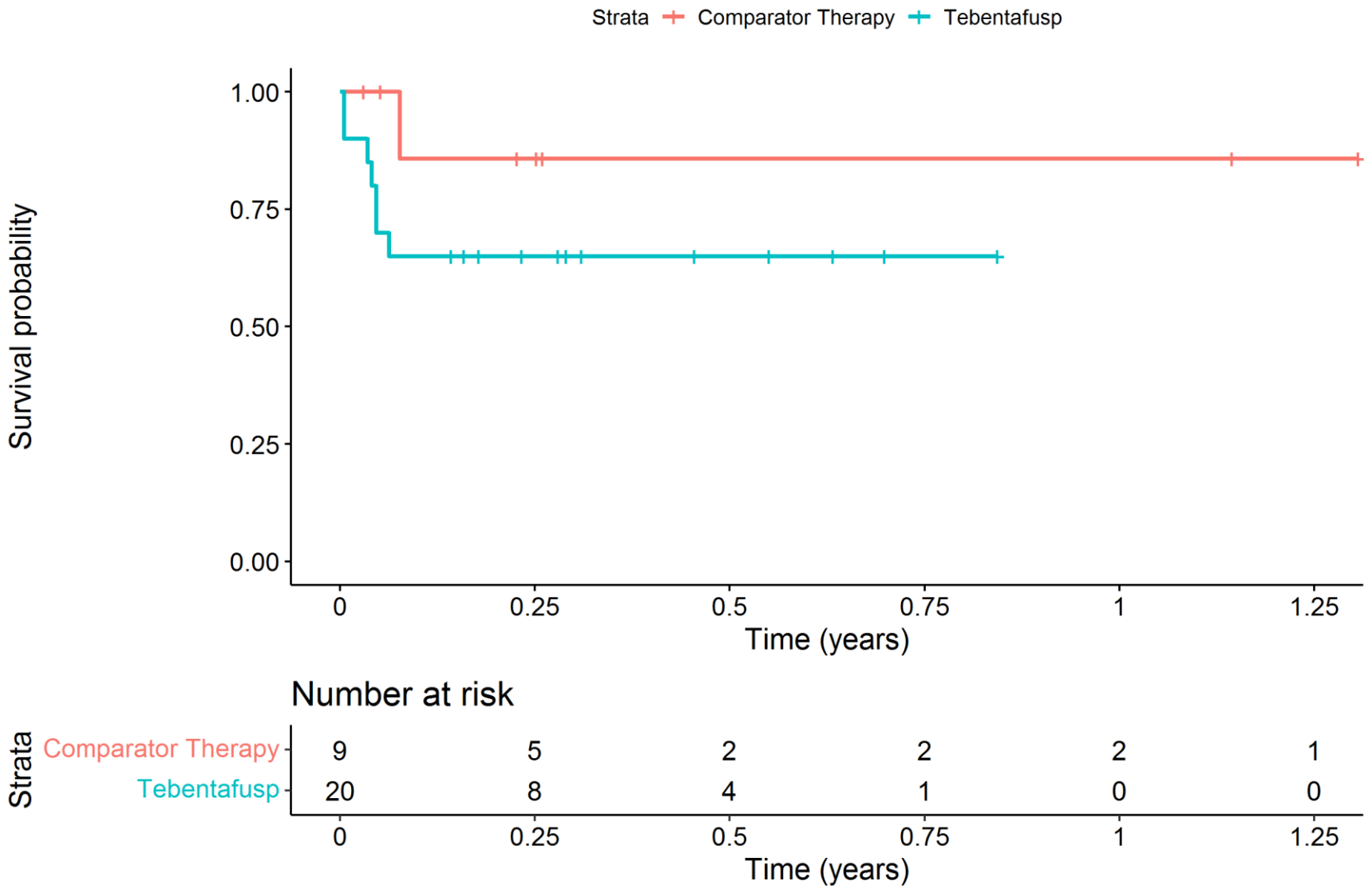
53.423 Makulo-papulöser Hautausschlag - Läsion ≤ 3cm



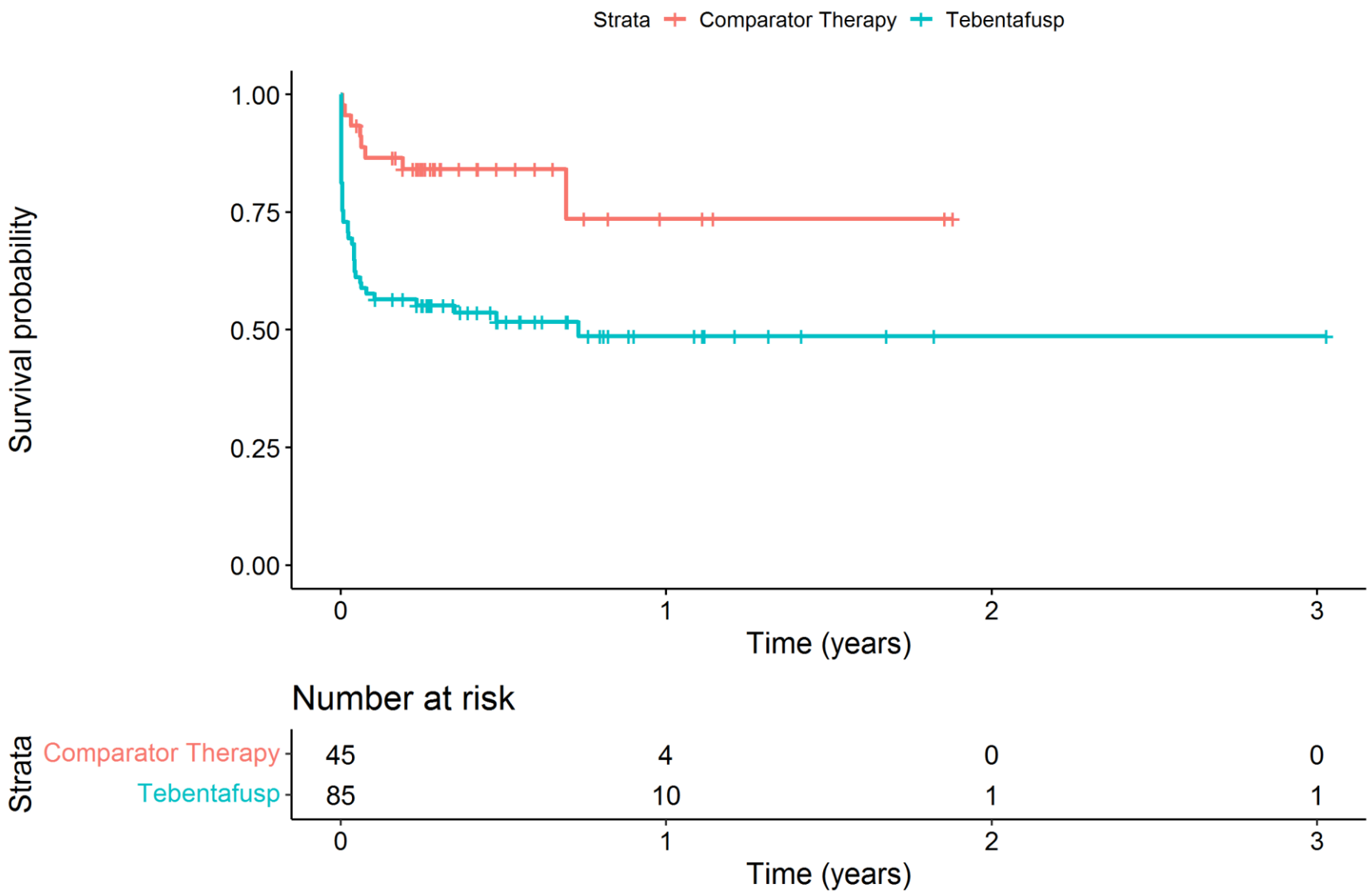
53.424 Makulo-papulöser Hautausschlag - Läsion 3,1-8,0 cm



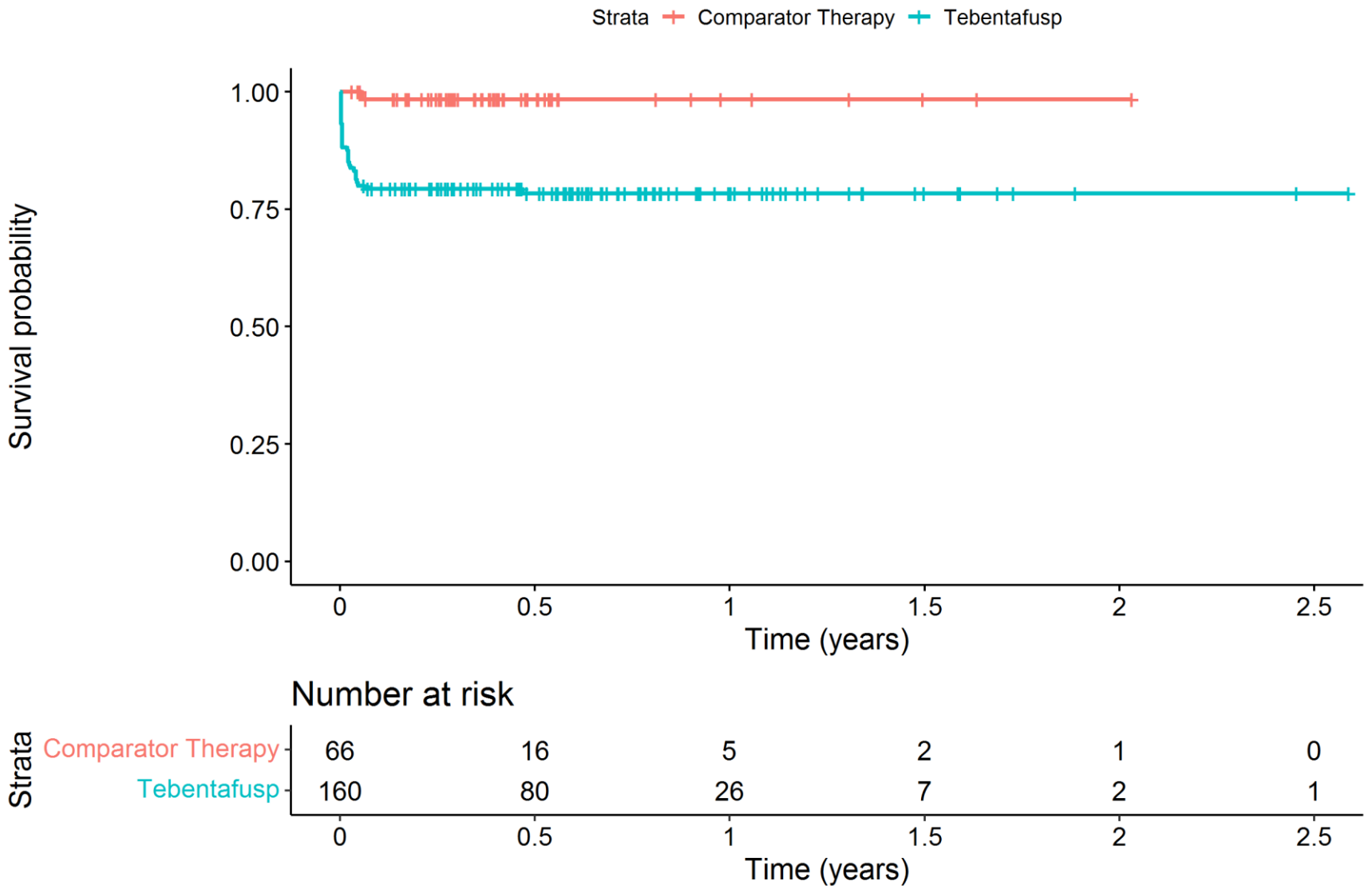
53.425 Makulo-papulöser Hautausschlag - Läsion ≥8,1 cm



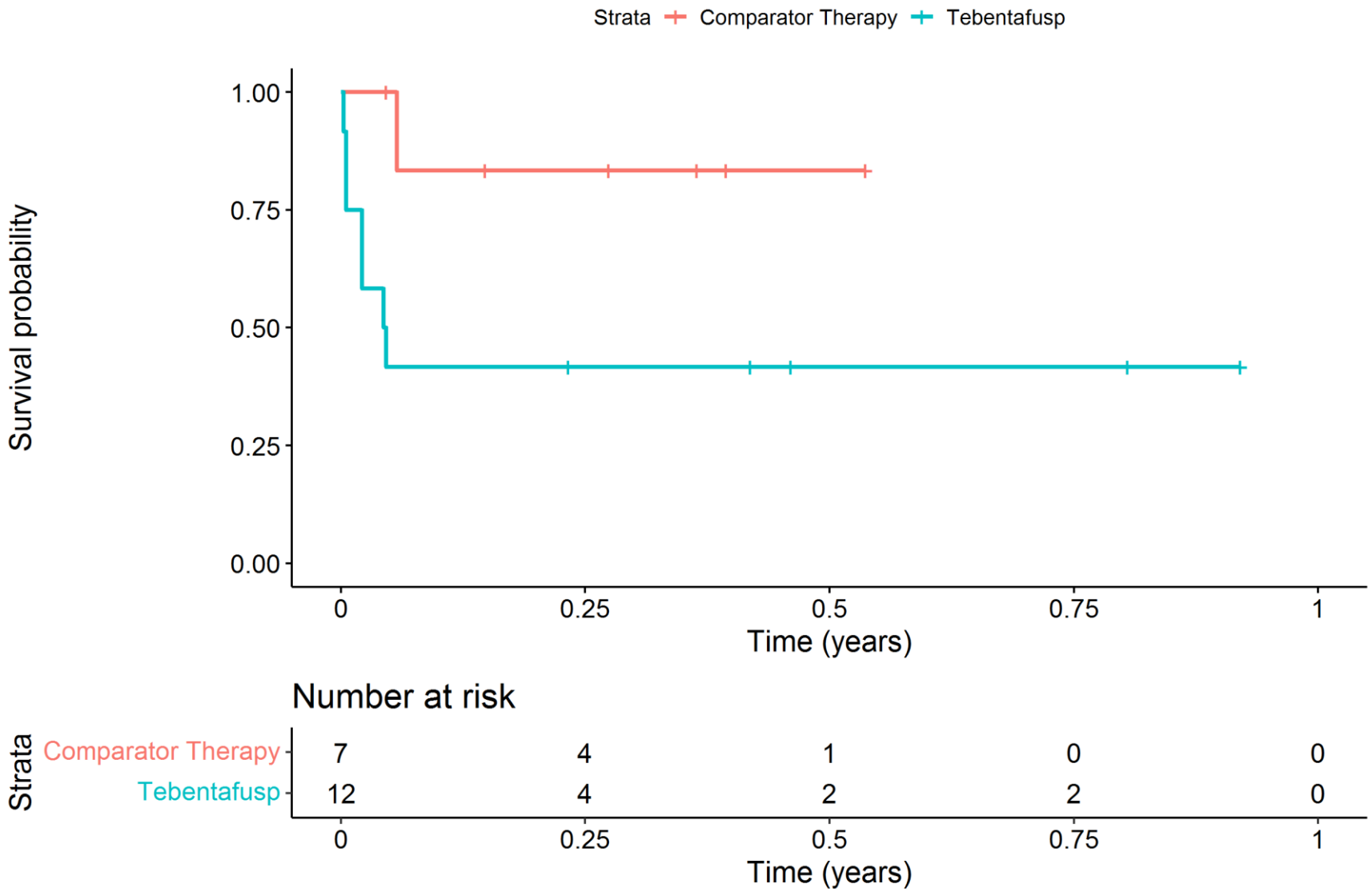
53.426 Makulo-papulöser Hautausschlag - Nordamerika



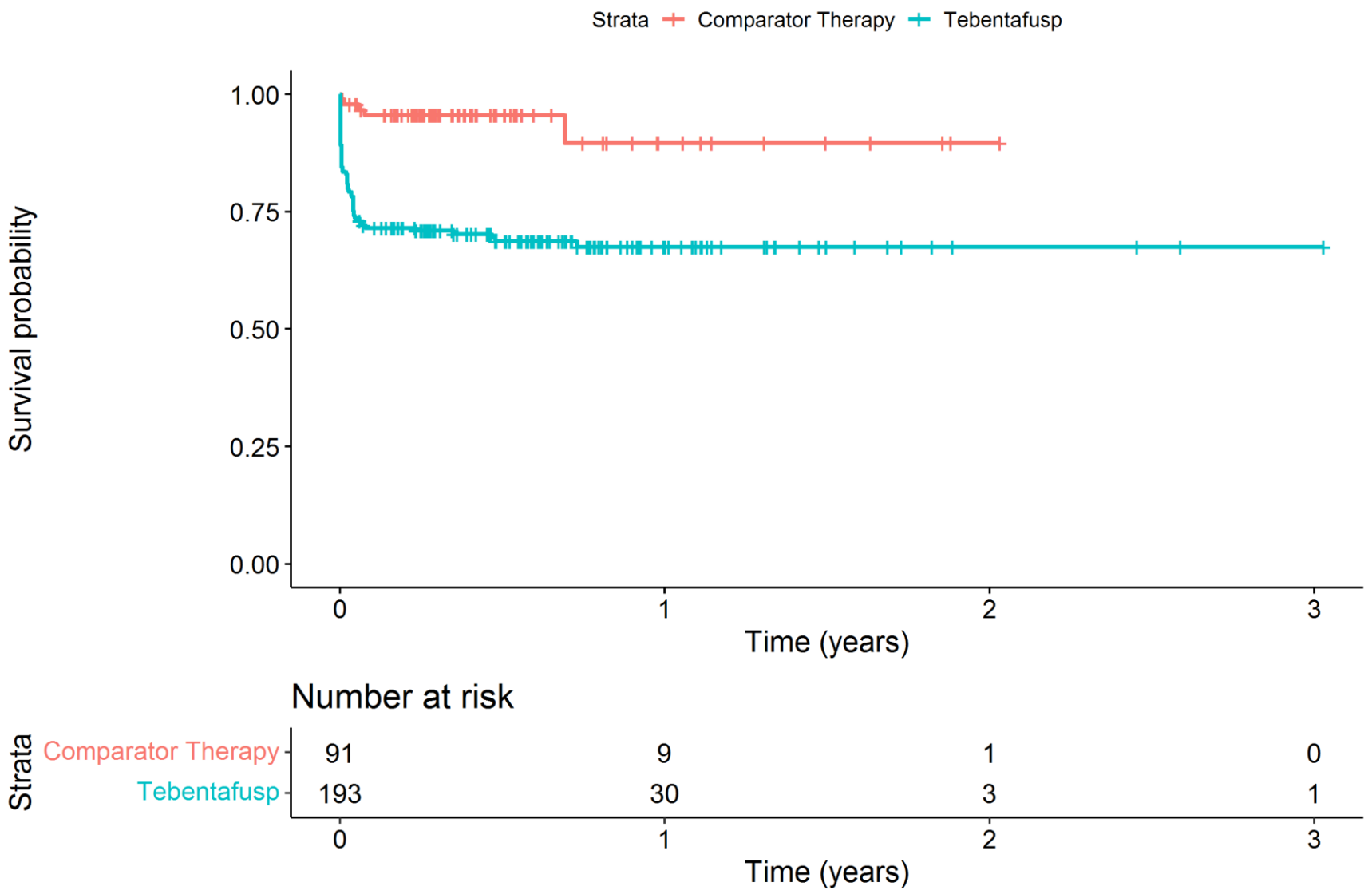
53.427 Makulo-papulöser Hautausschlag - Nicht-Nordamerika



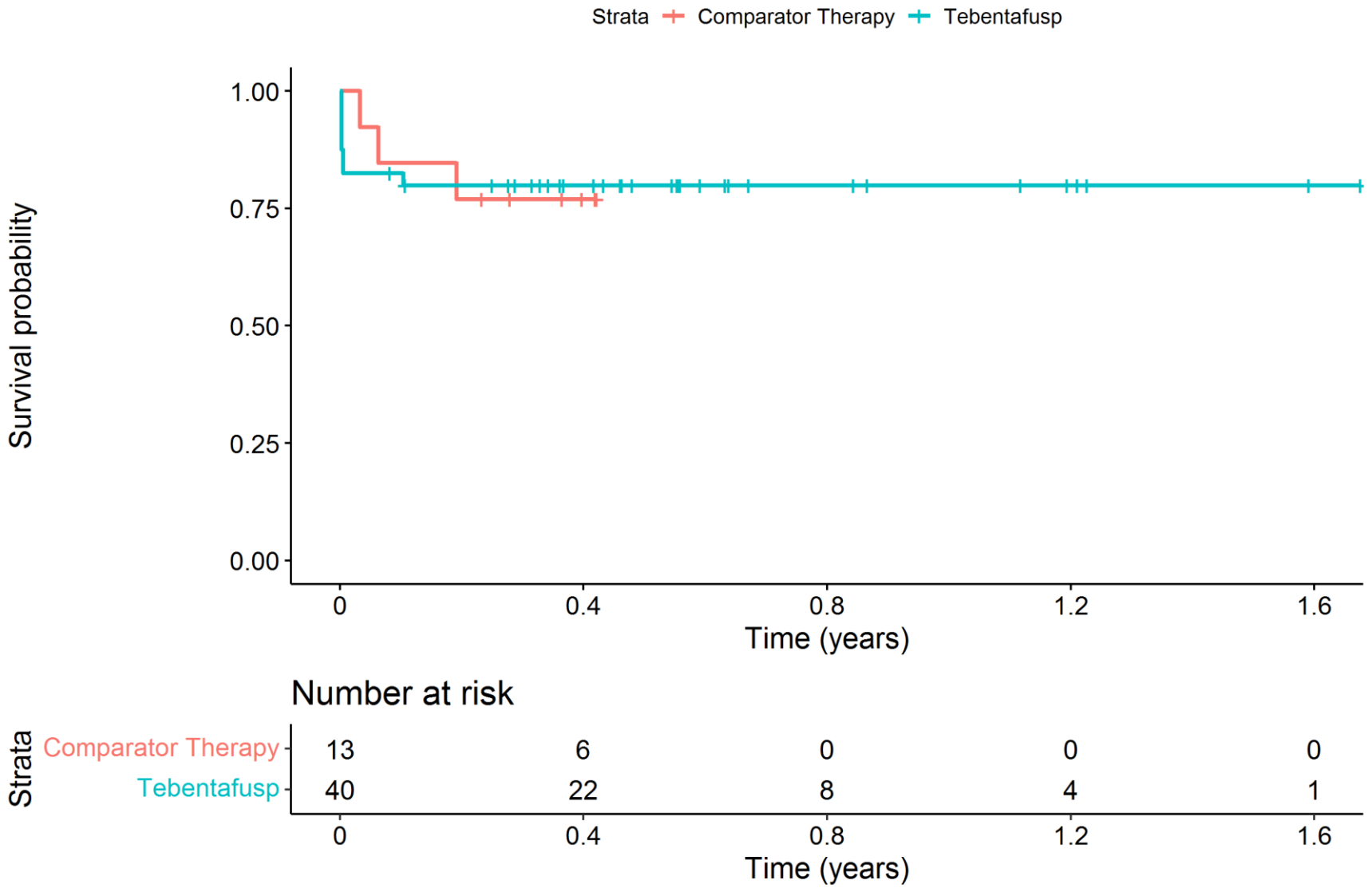
53.428 Makulo-papulöser Hautausschlag - Dacarbazin



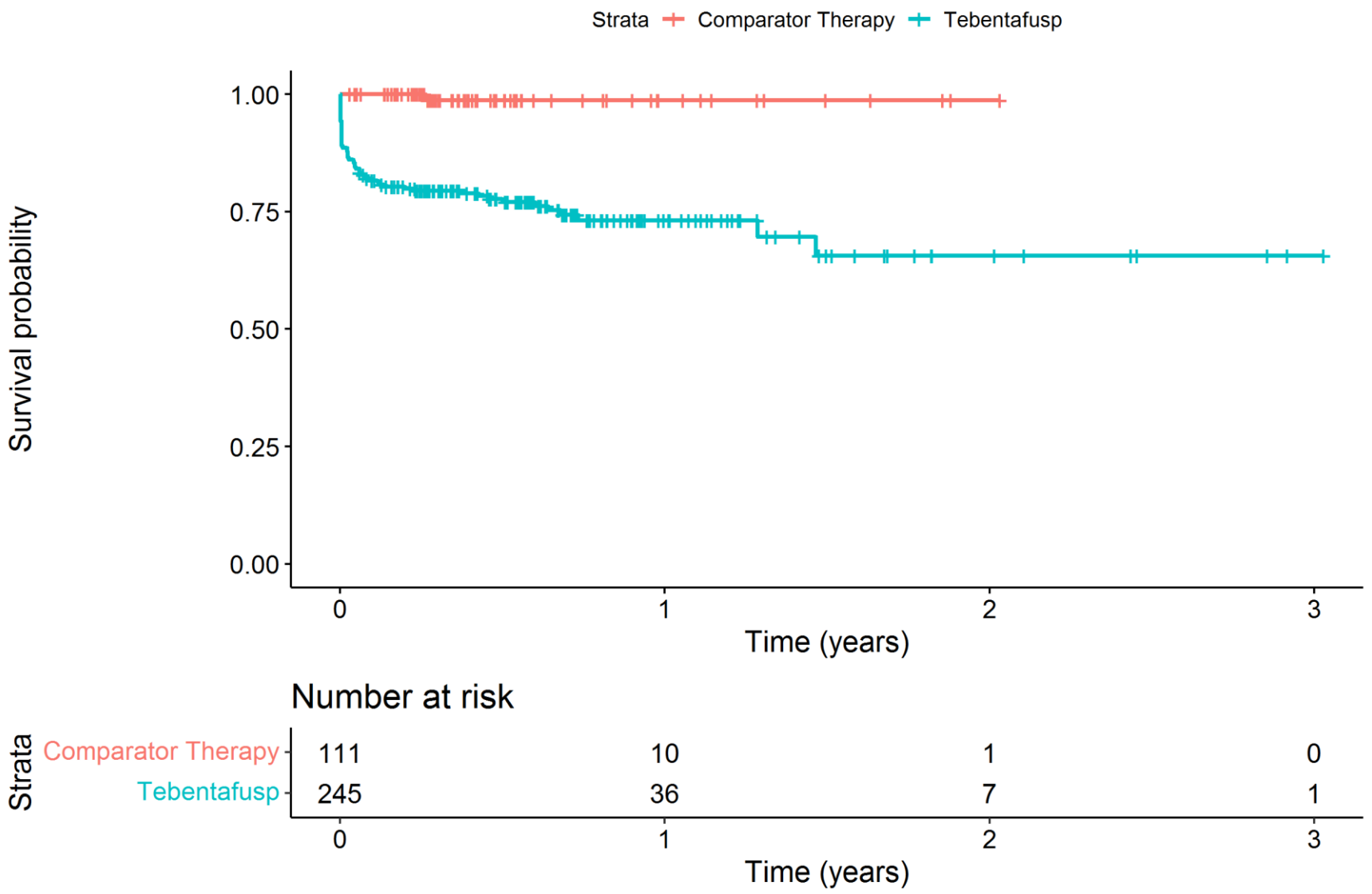
53.429 Makulo-papulöser Hautausschlag - Pembrolizumab



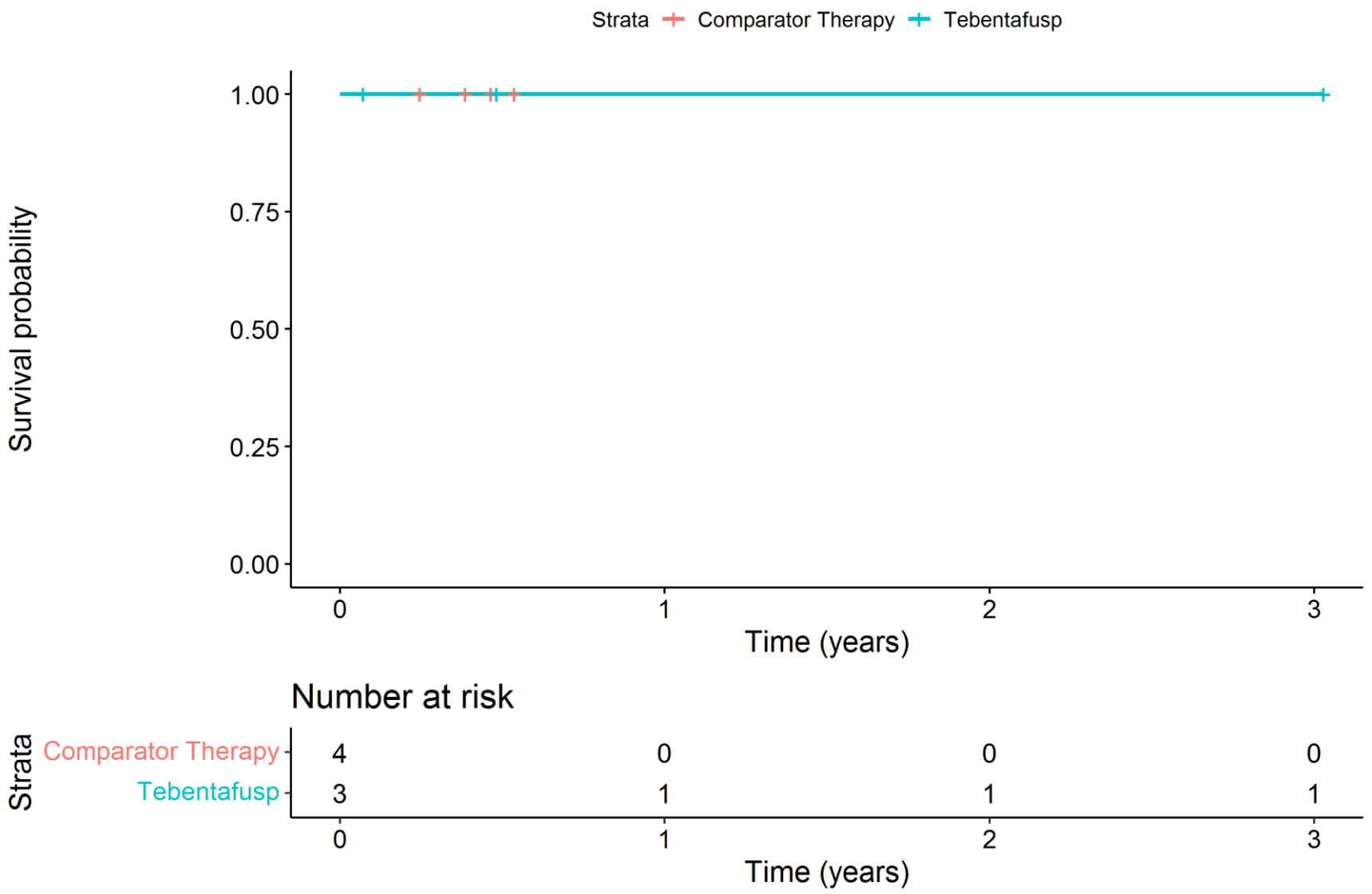
53.430 Makulo-papulöser Hautausschlag - Ipilimumab



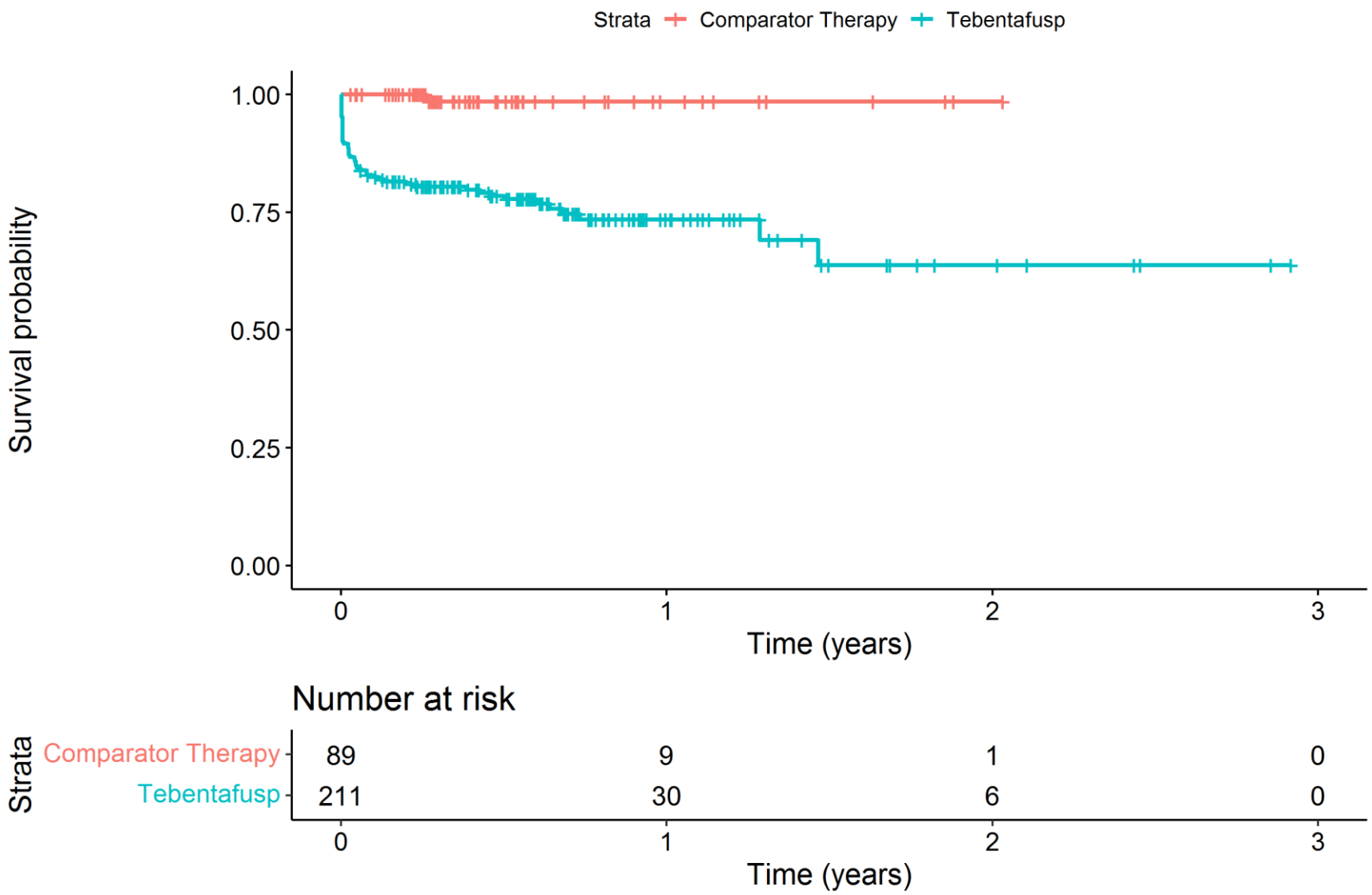
53.431 Erythem - Gesamt



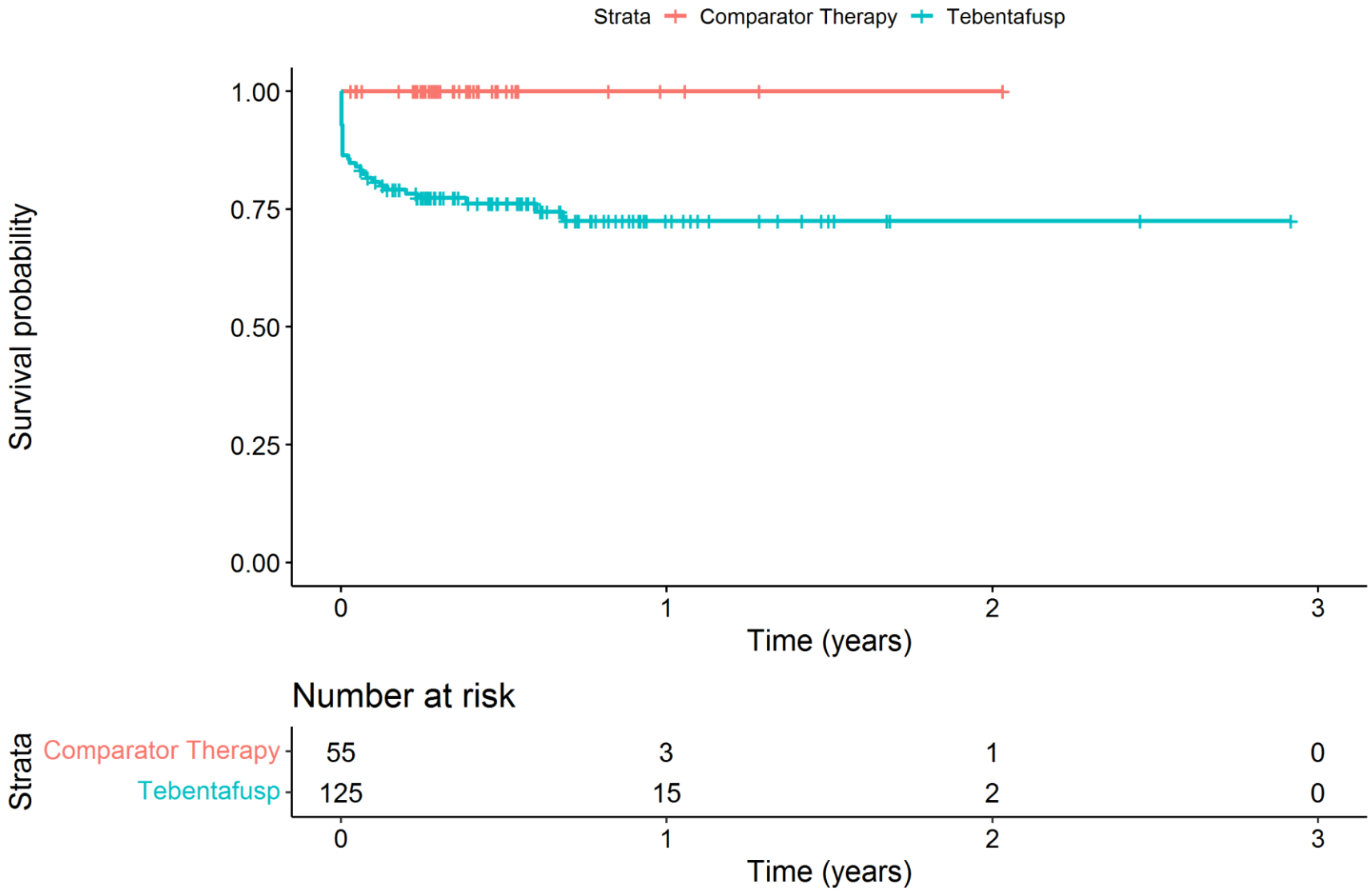
53.432 Erythem - Hispanisch



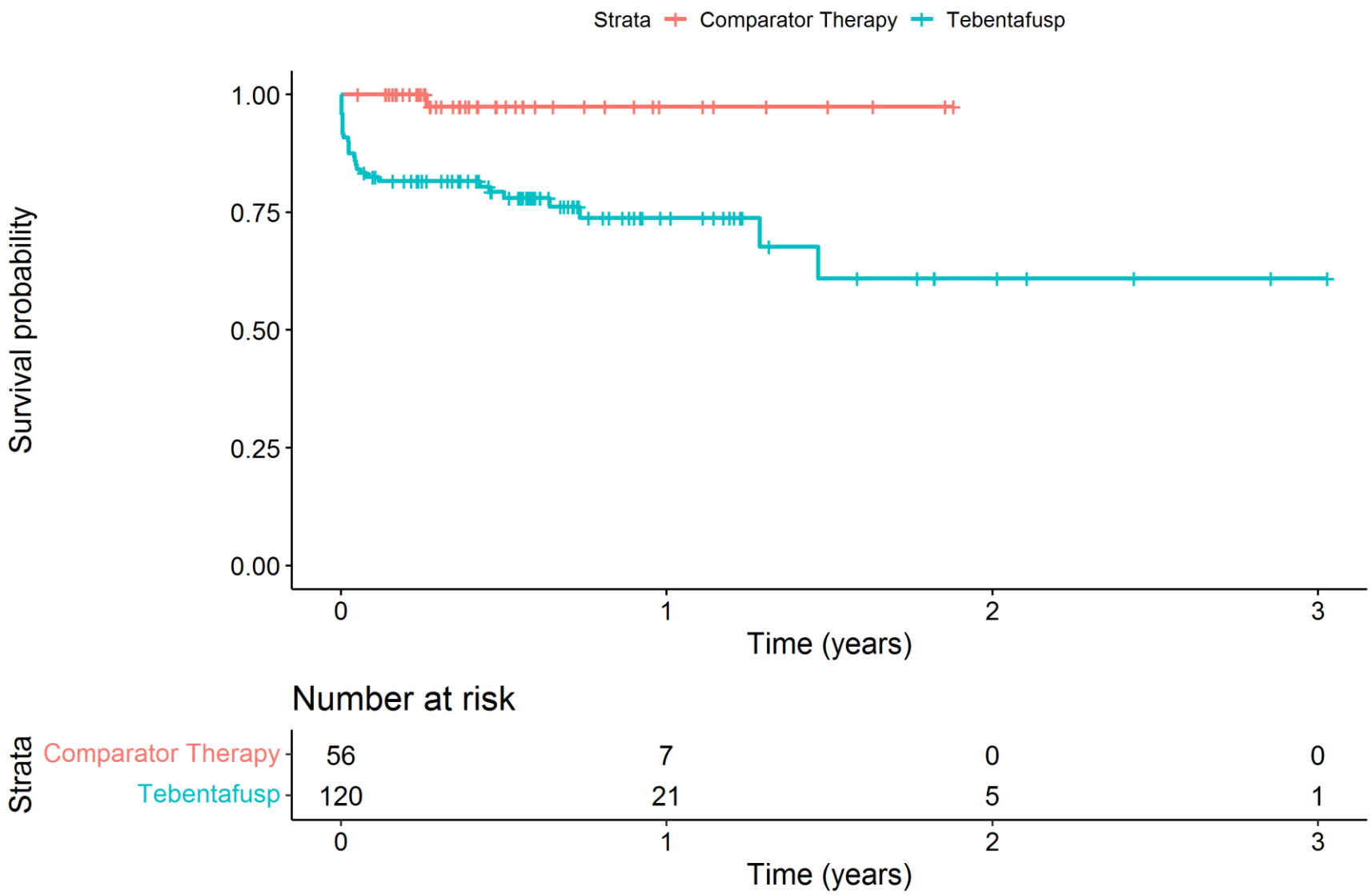
53.433 Erythem - Nicht-hispanisch



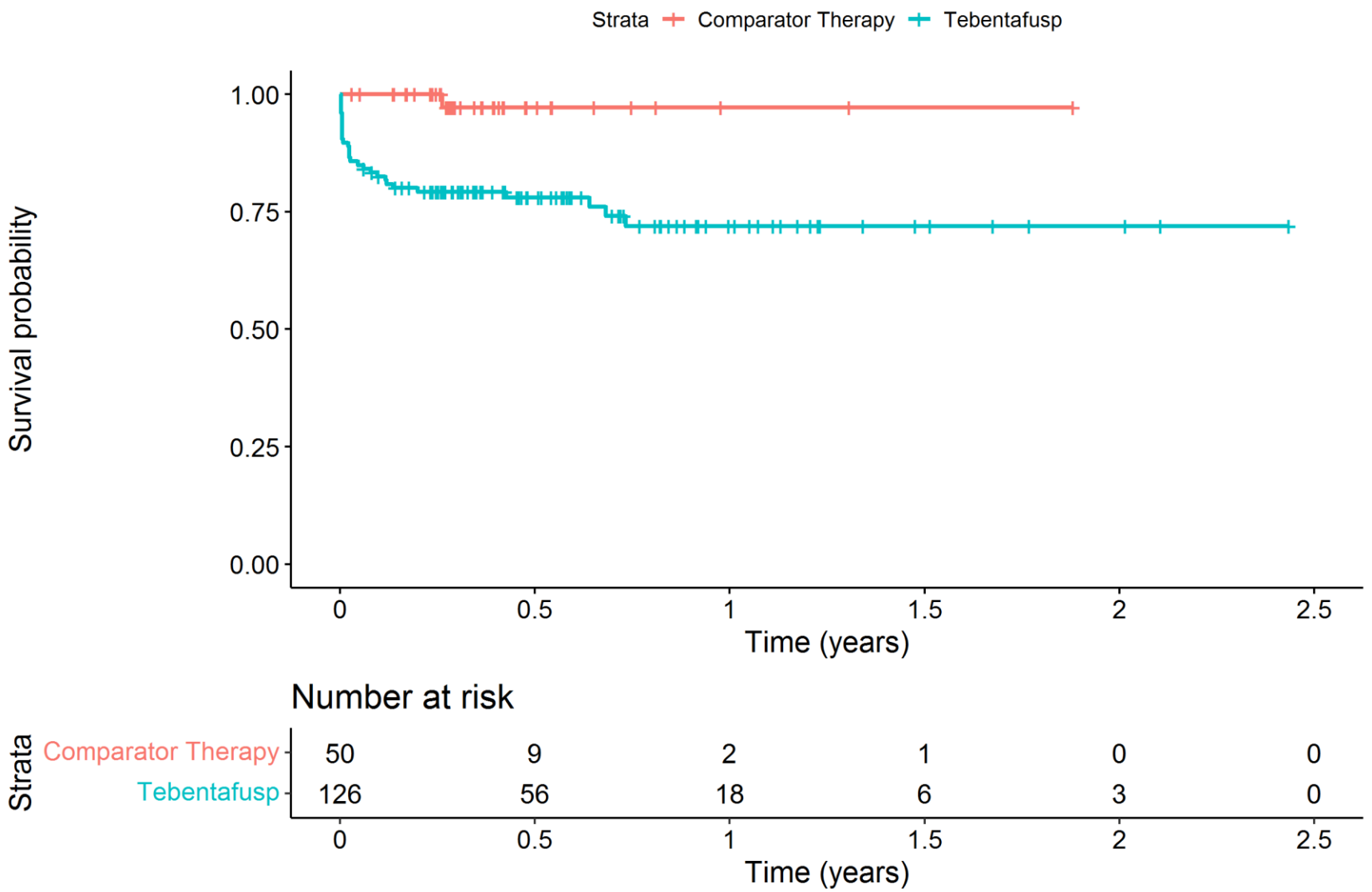
53.434 Erythem - Männlich



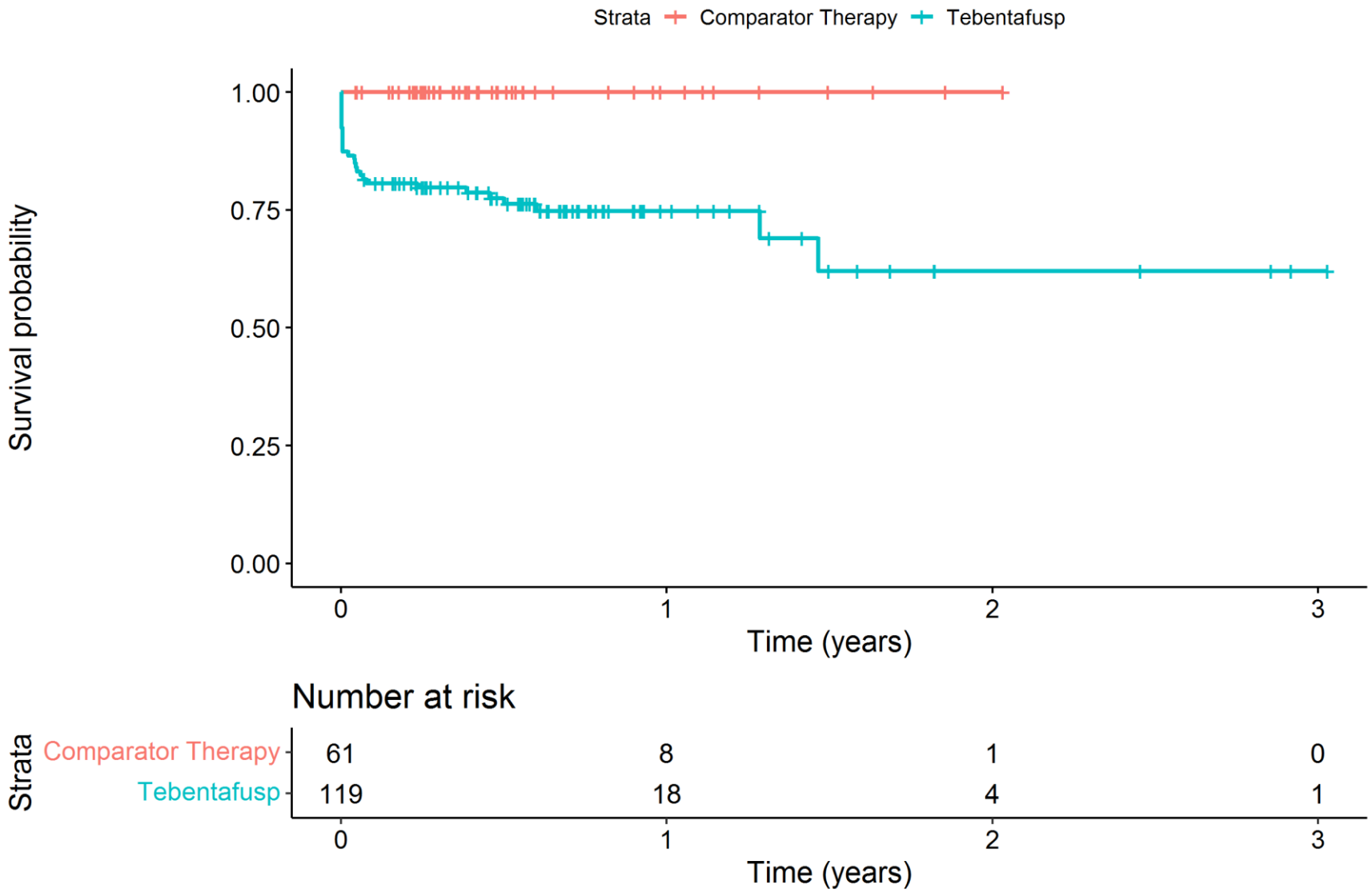
53.435 Erythem - Weiblich



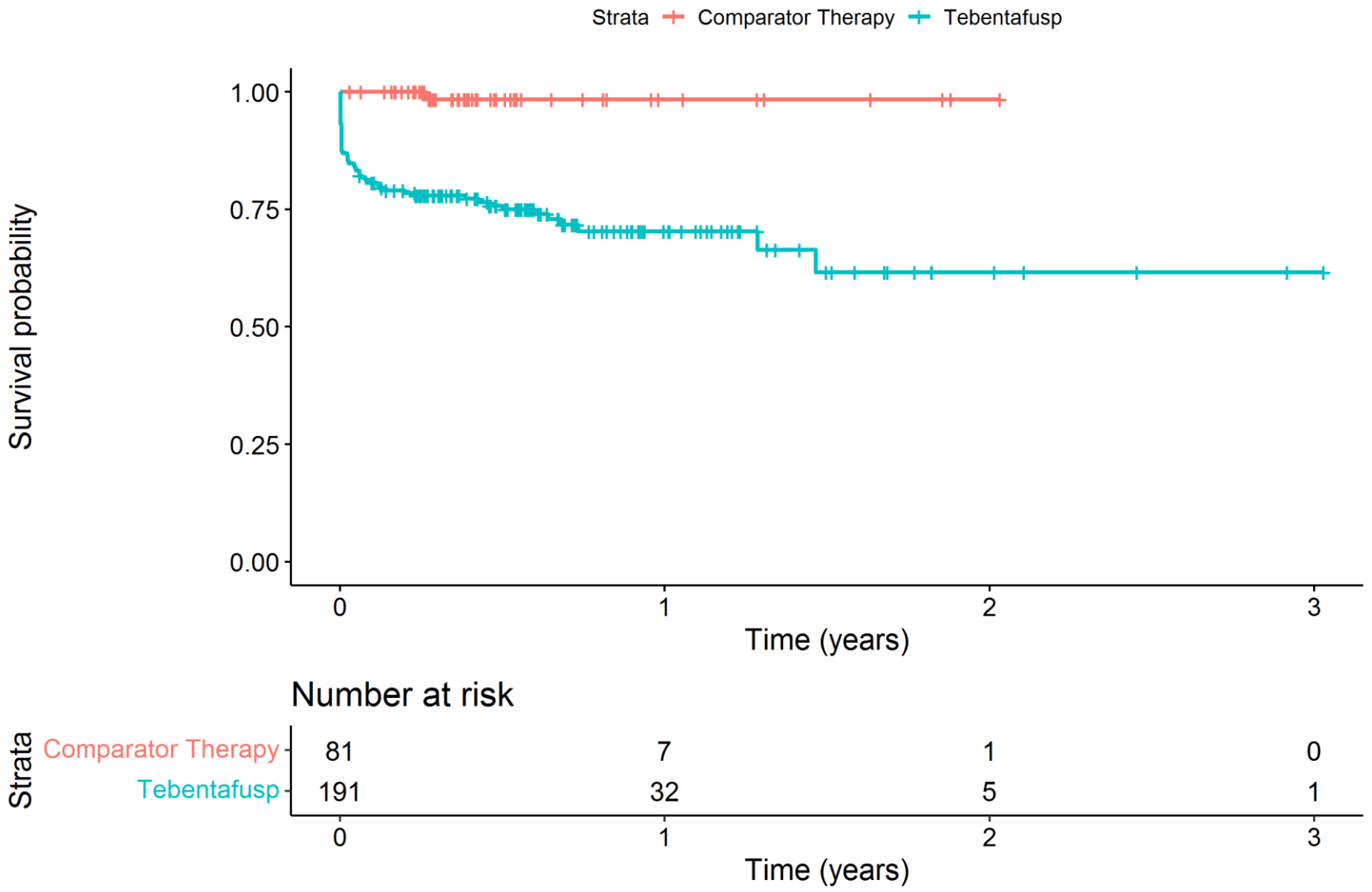
53.436 Erythem - <65



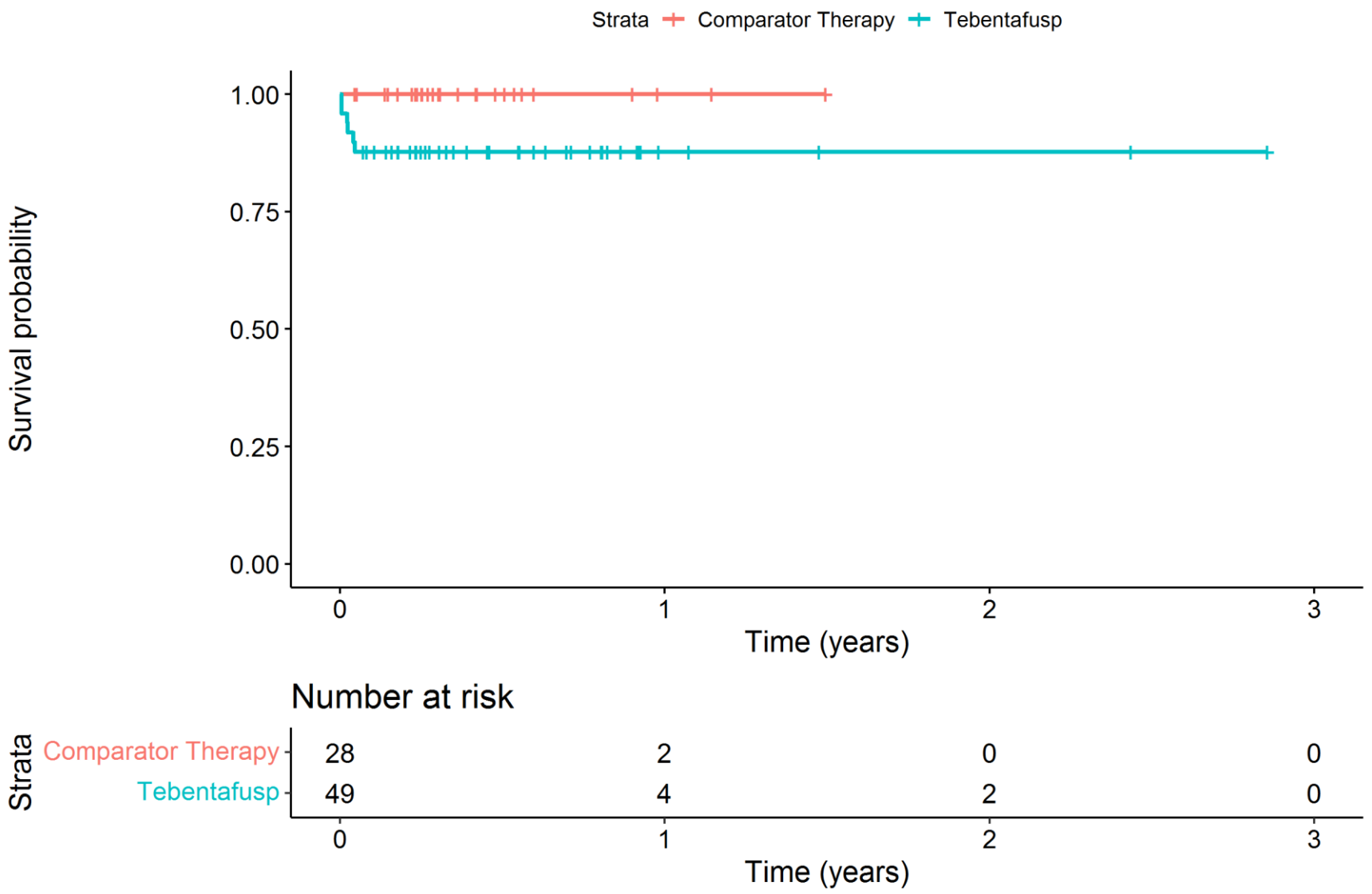
53.437 Erythem - ≥65



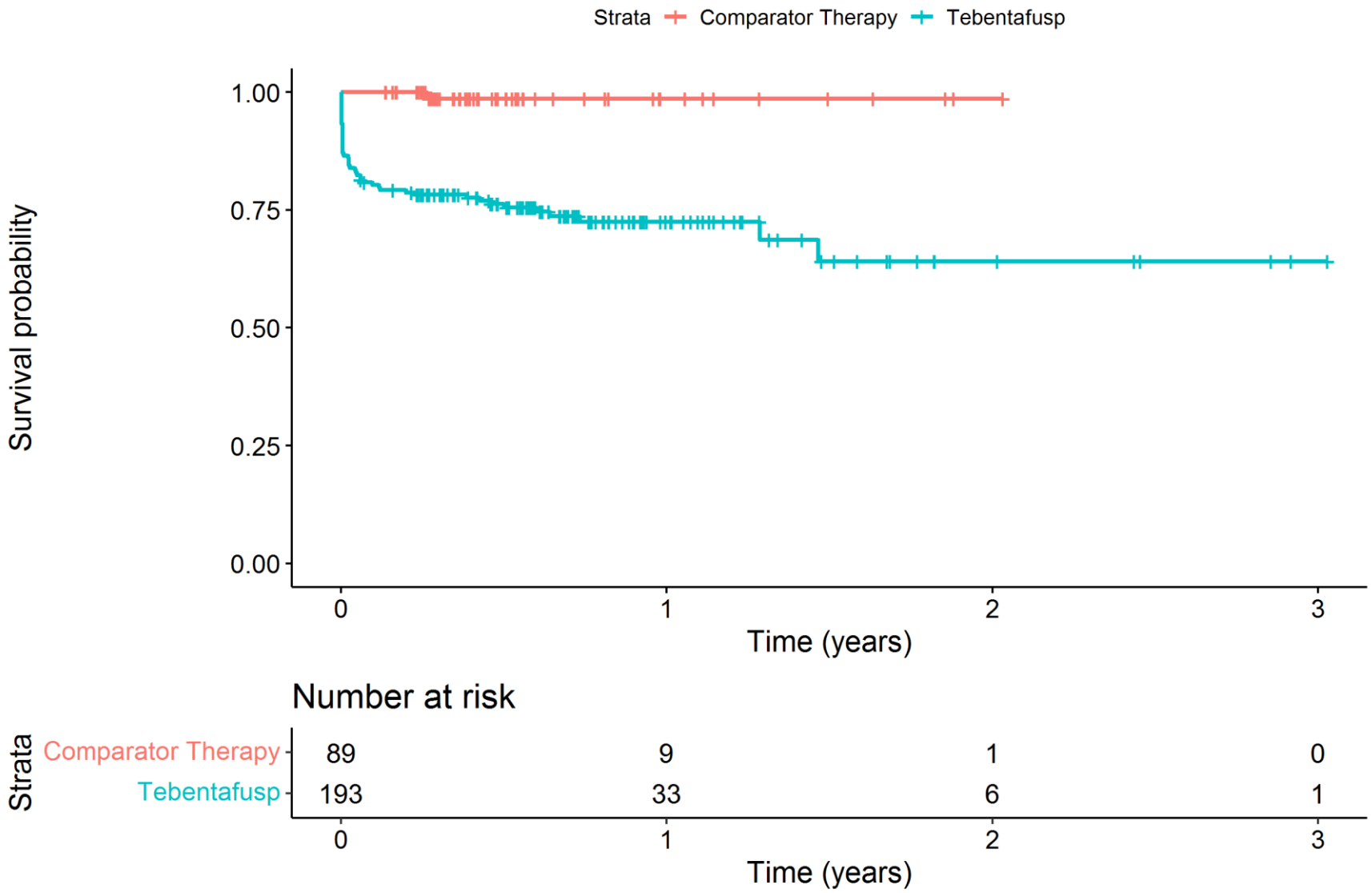
53.438 Erythem - ECOG 0



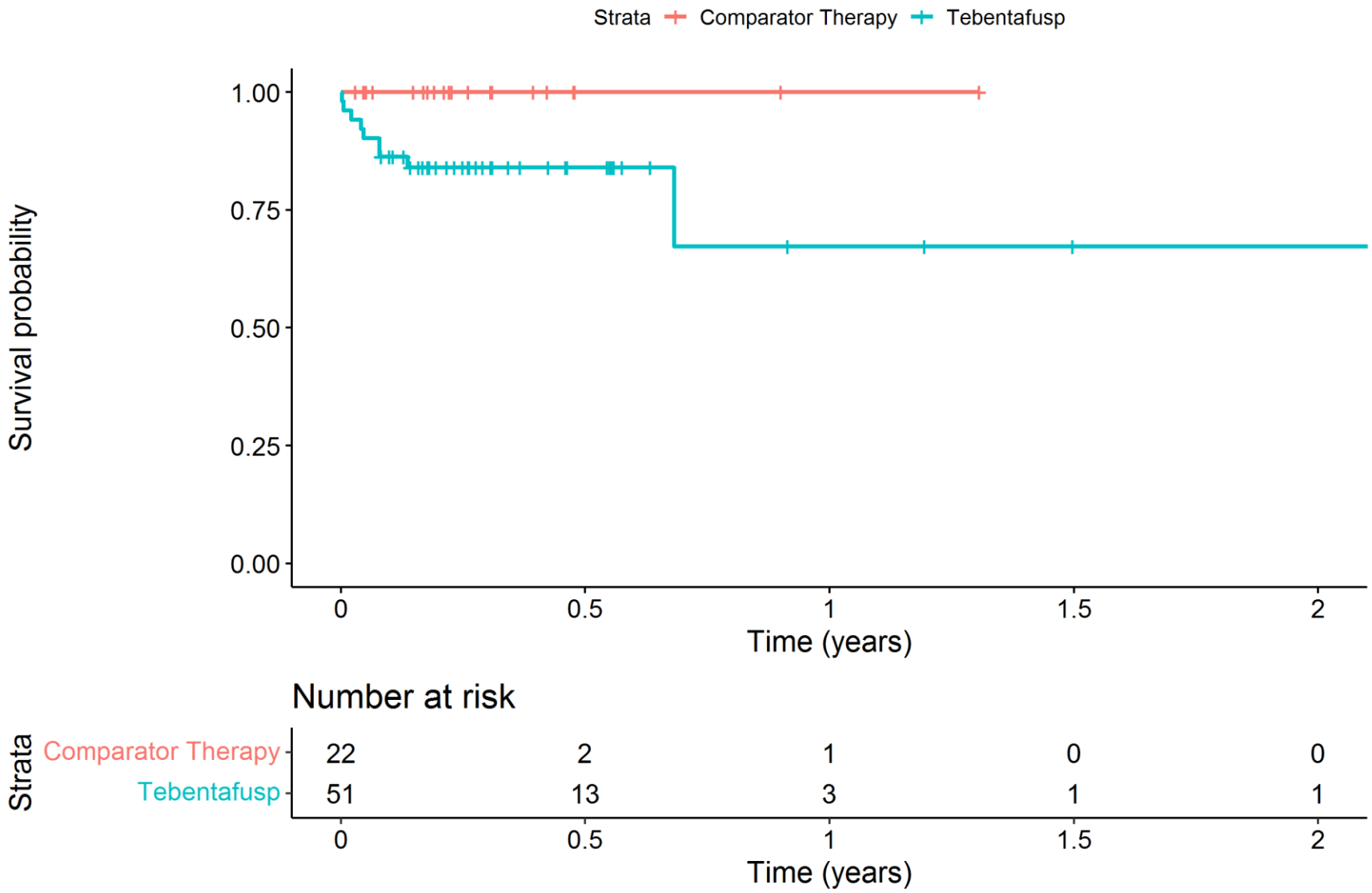
53.439 Erythem - ECOG 1



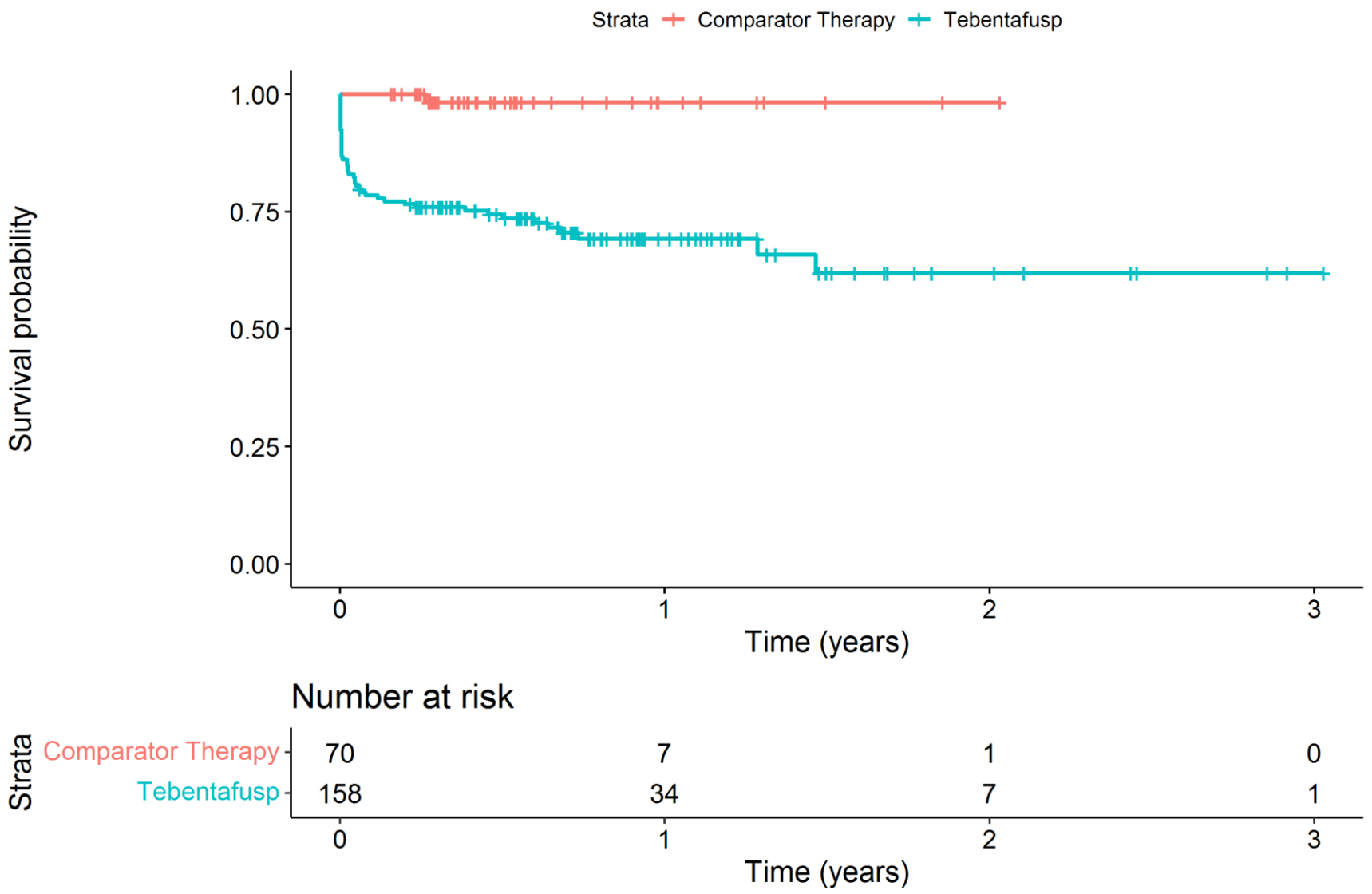
53.440 Erythem - ALP ≤ ULN



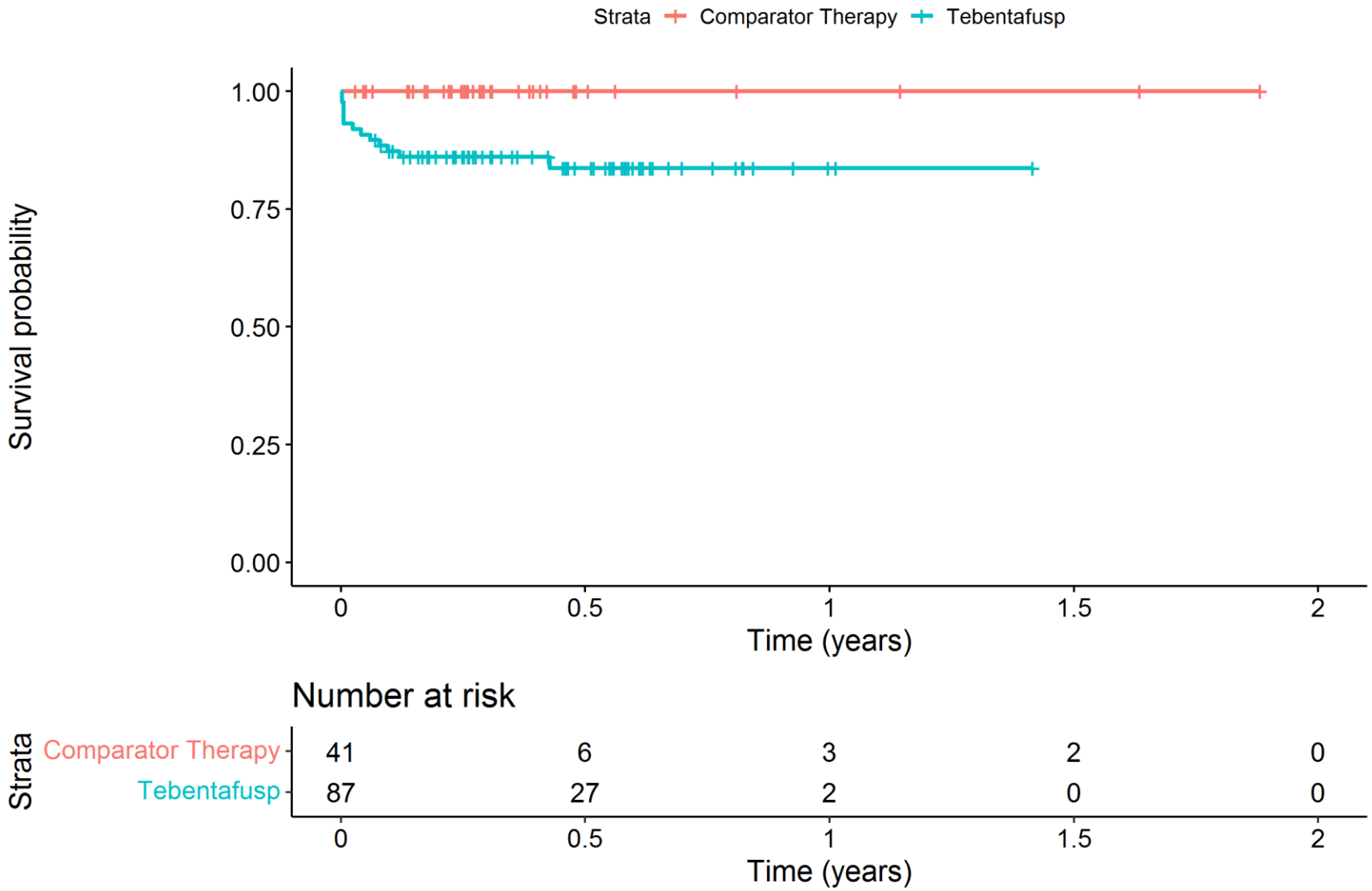
53.441 Erythem - ALP > ULN



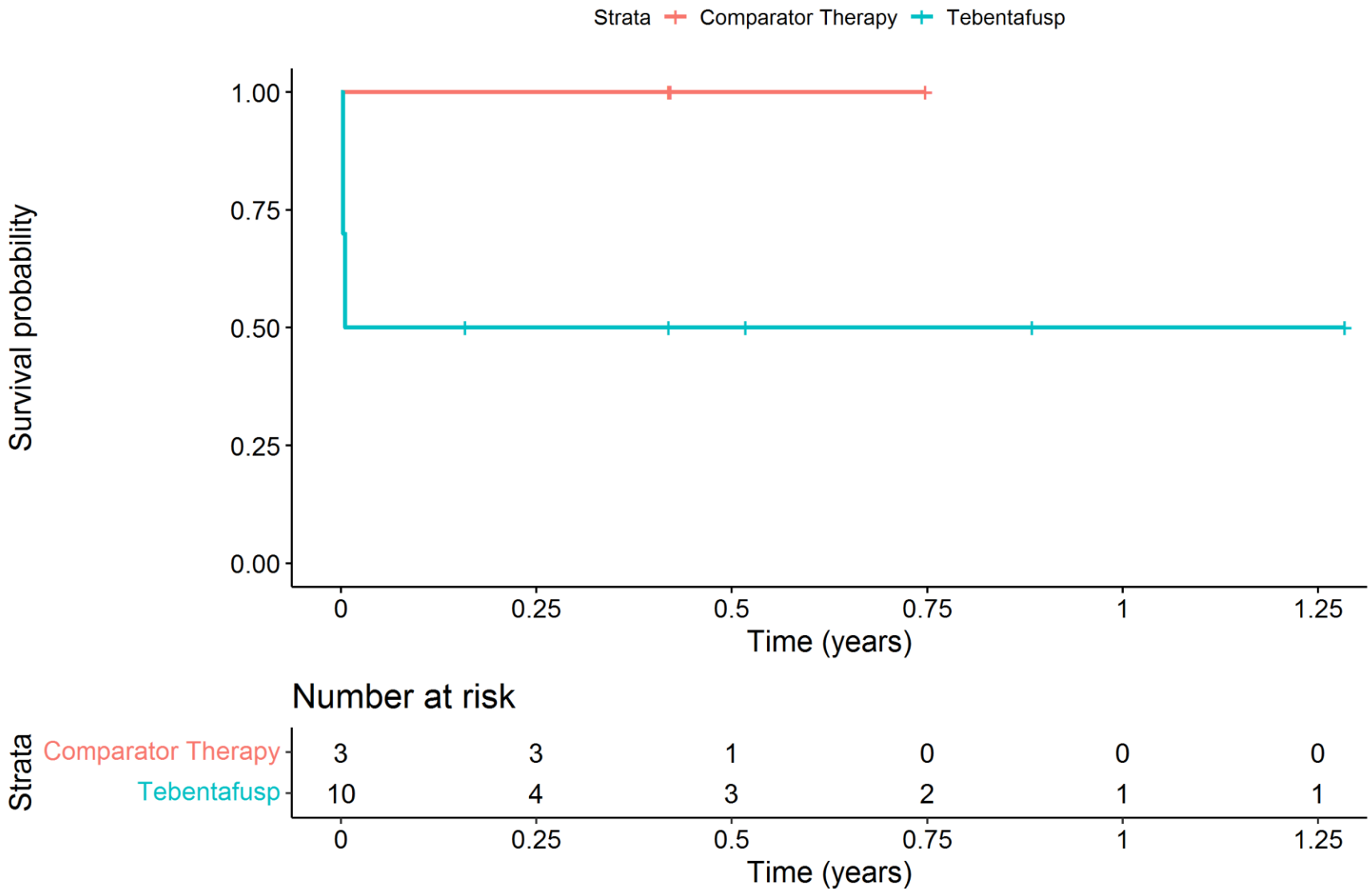
53.442 Erythem - LDH =< ULN



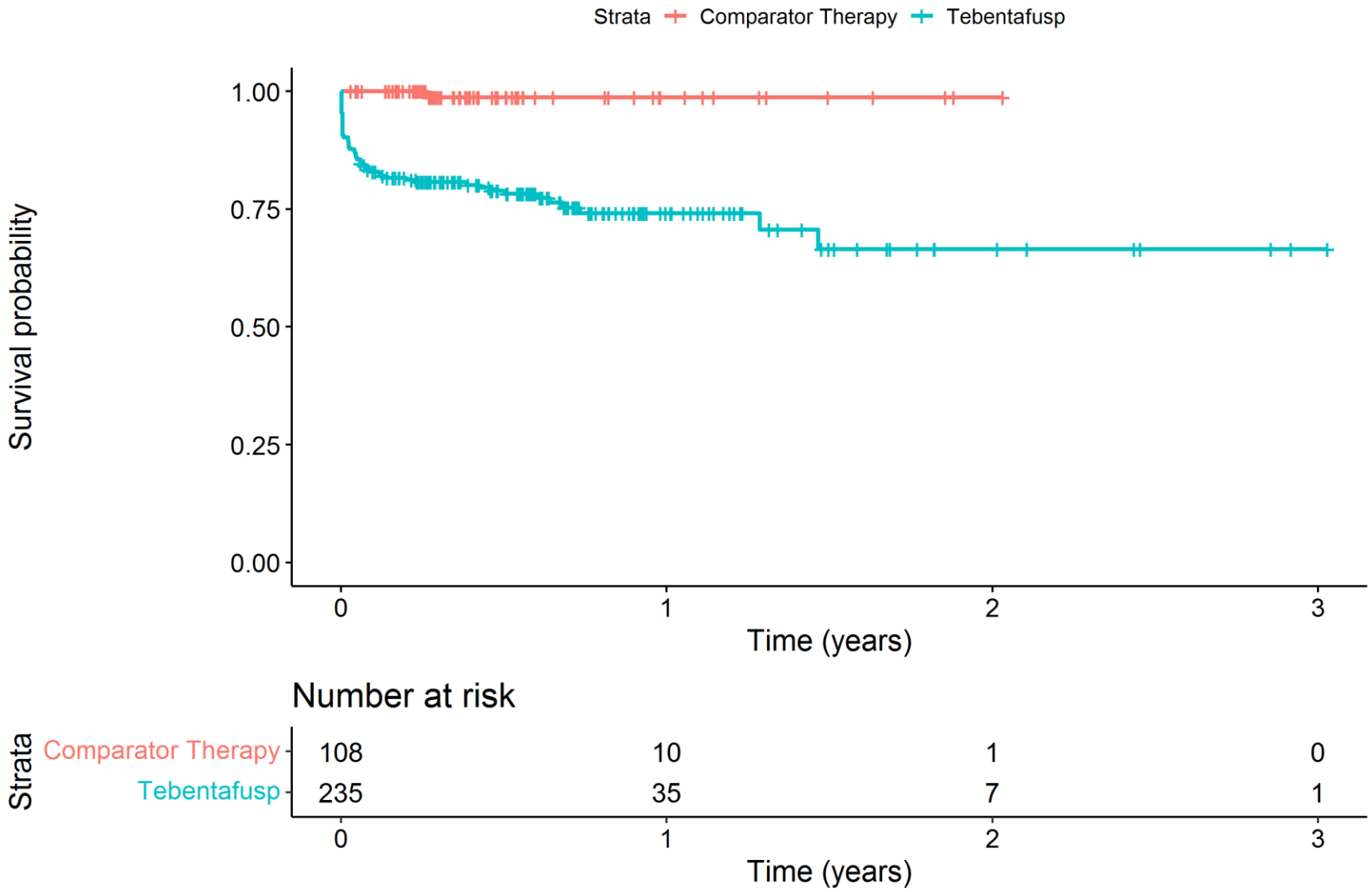
53.443 Erythem - LDH > ULN



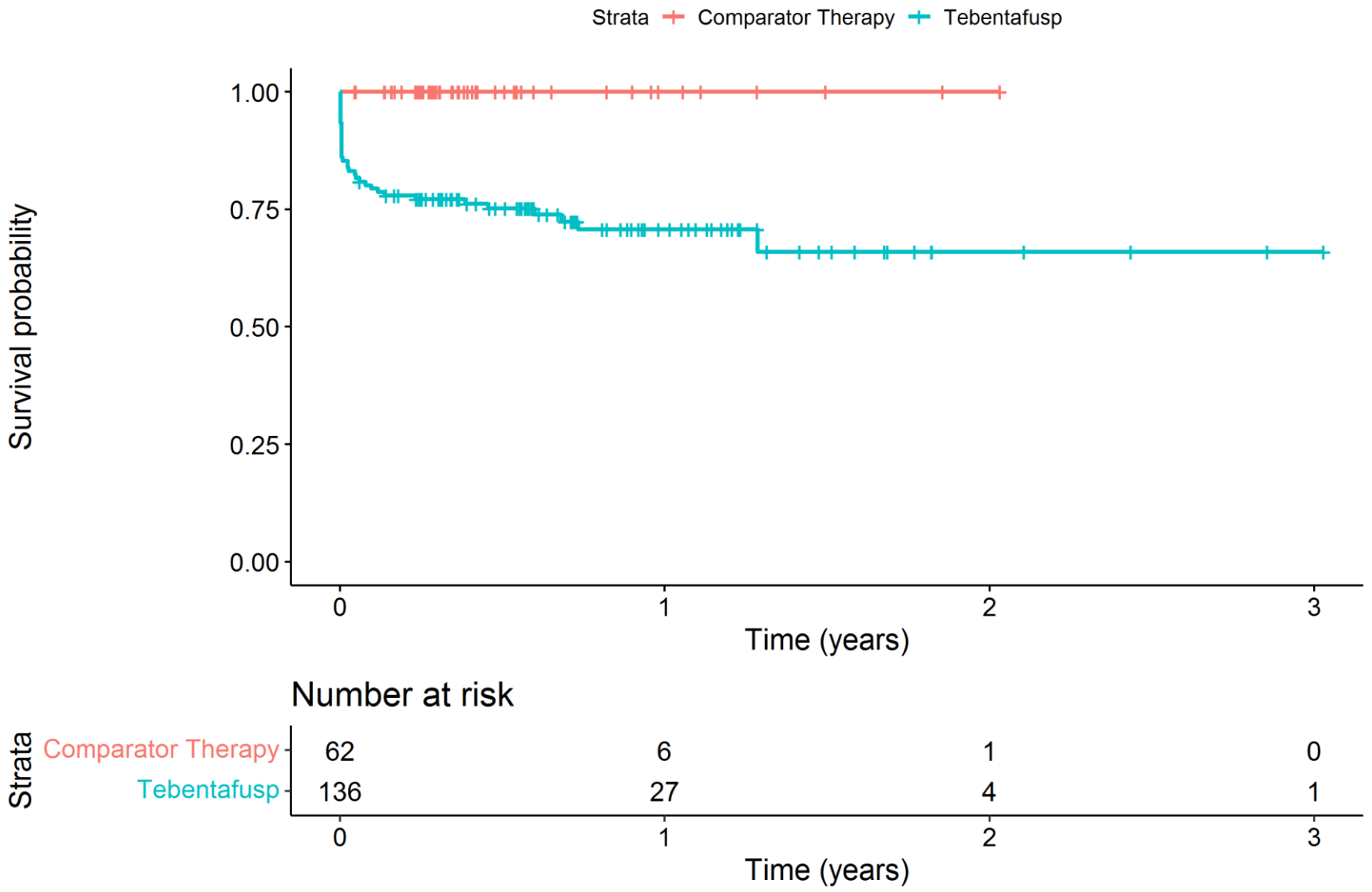
53.444 Erythem - Vorherige Therapie adjuvant/neoadjuvant



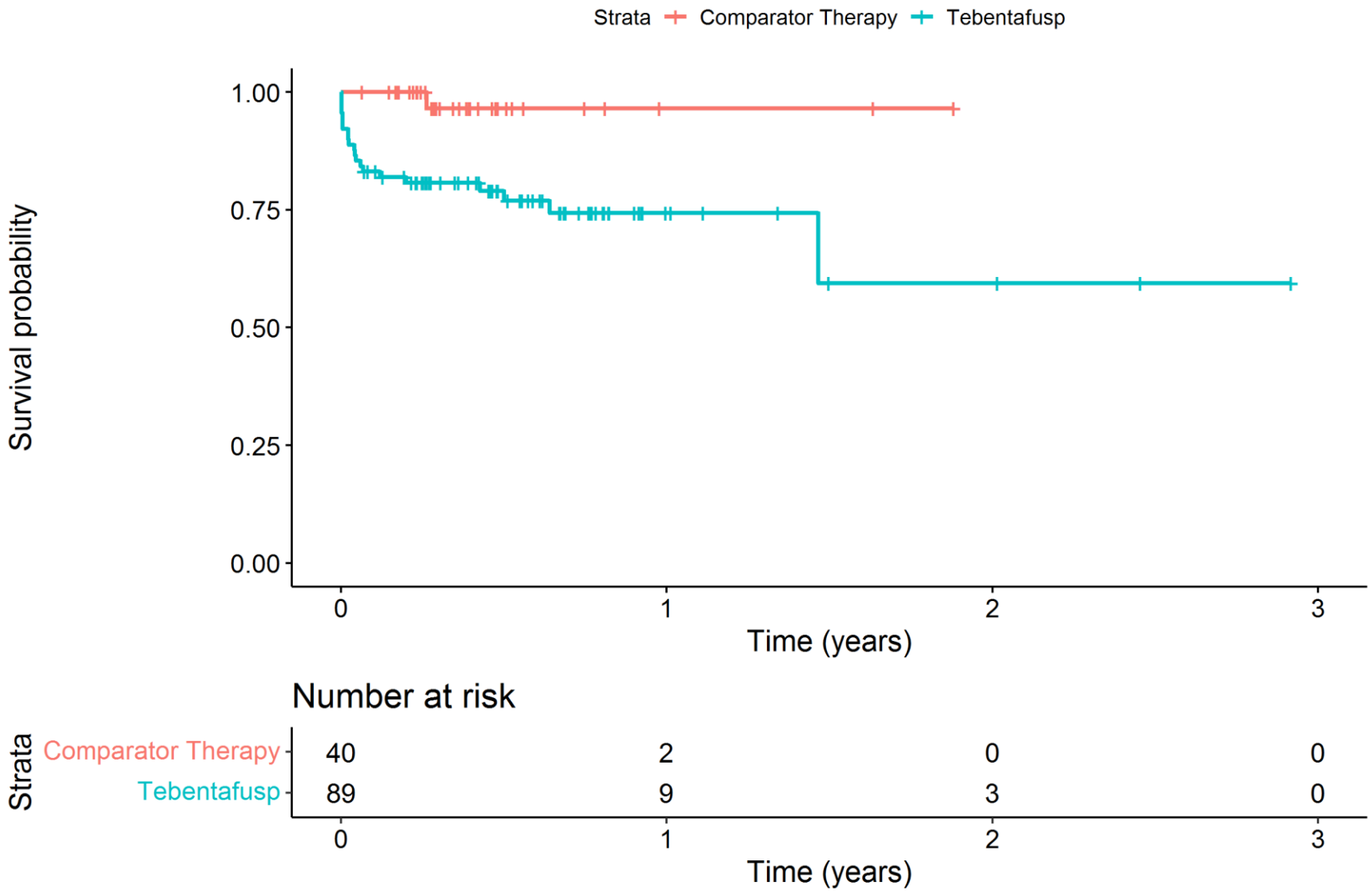
53.445 Erythem - Keine vorherige Therapie adjuvant/neoadjuvant



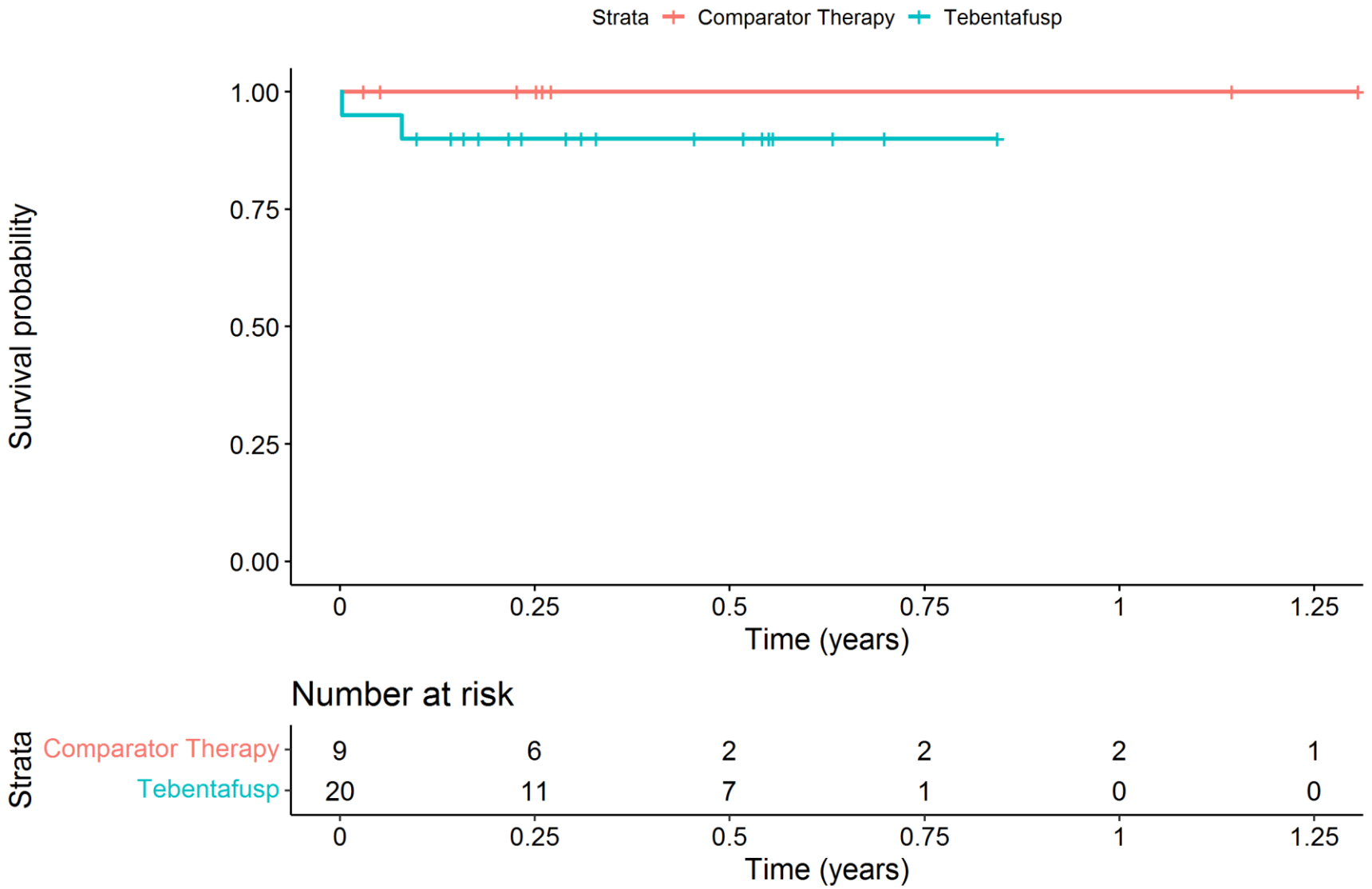
53.446 Erythem - Läsion ≤ 3cm



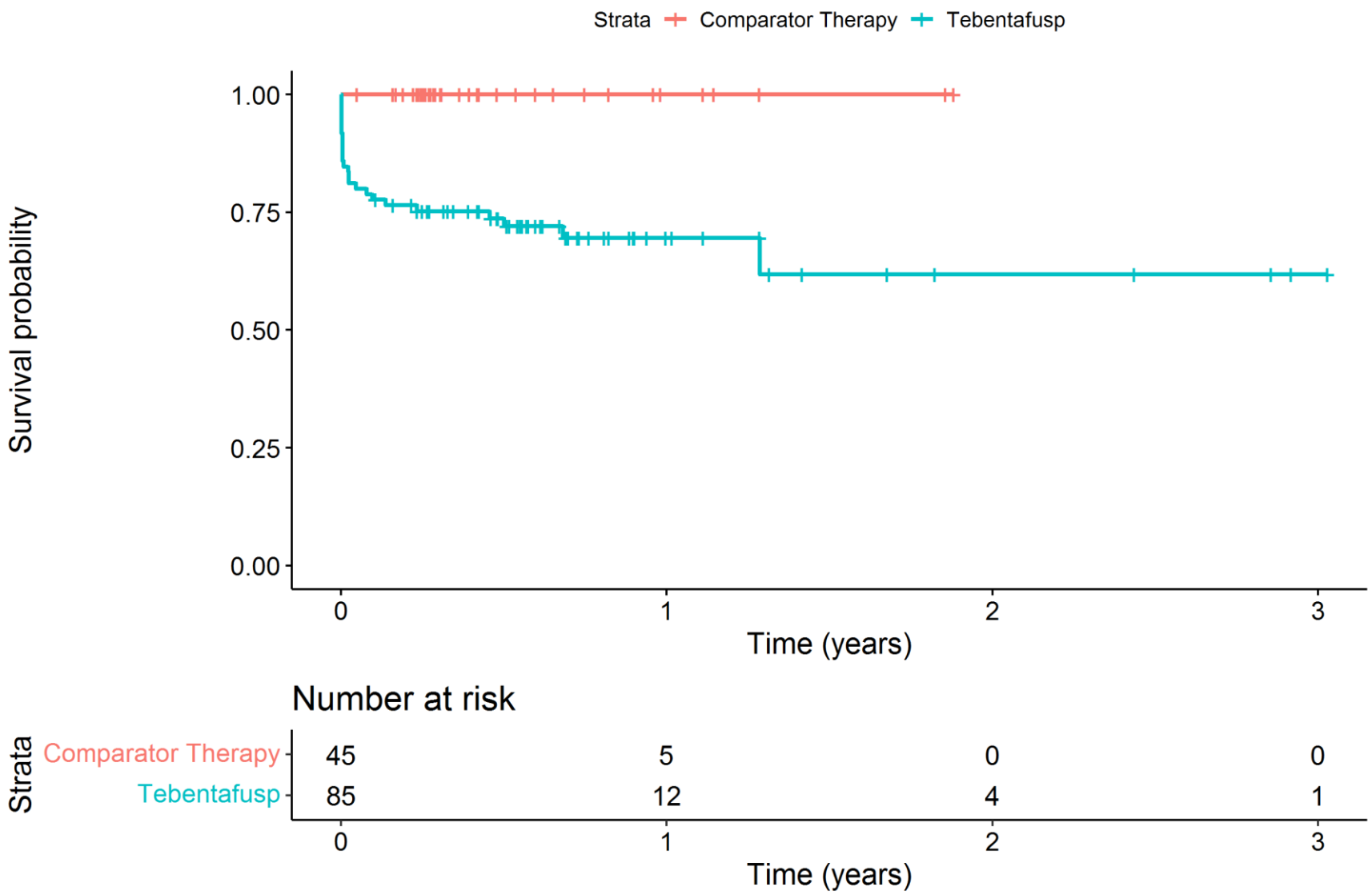
53.447 Erythem - Läsion 3,1-8,0 cm



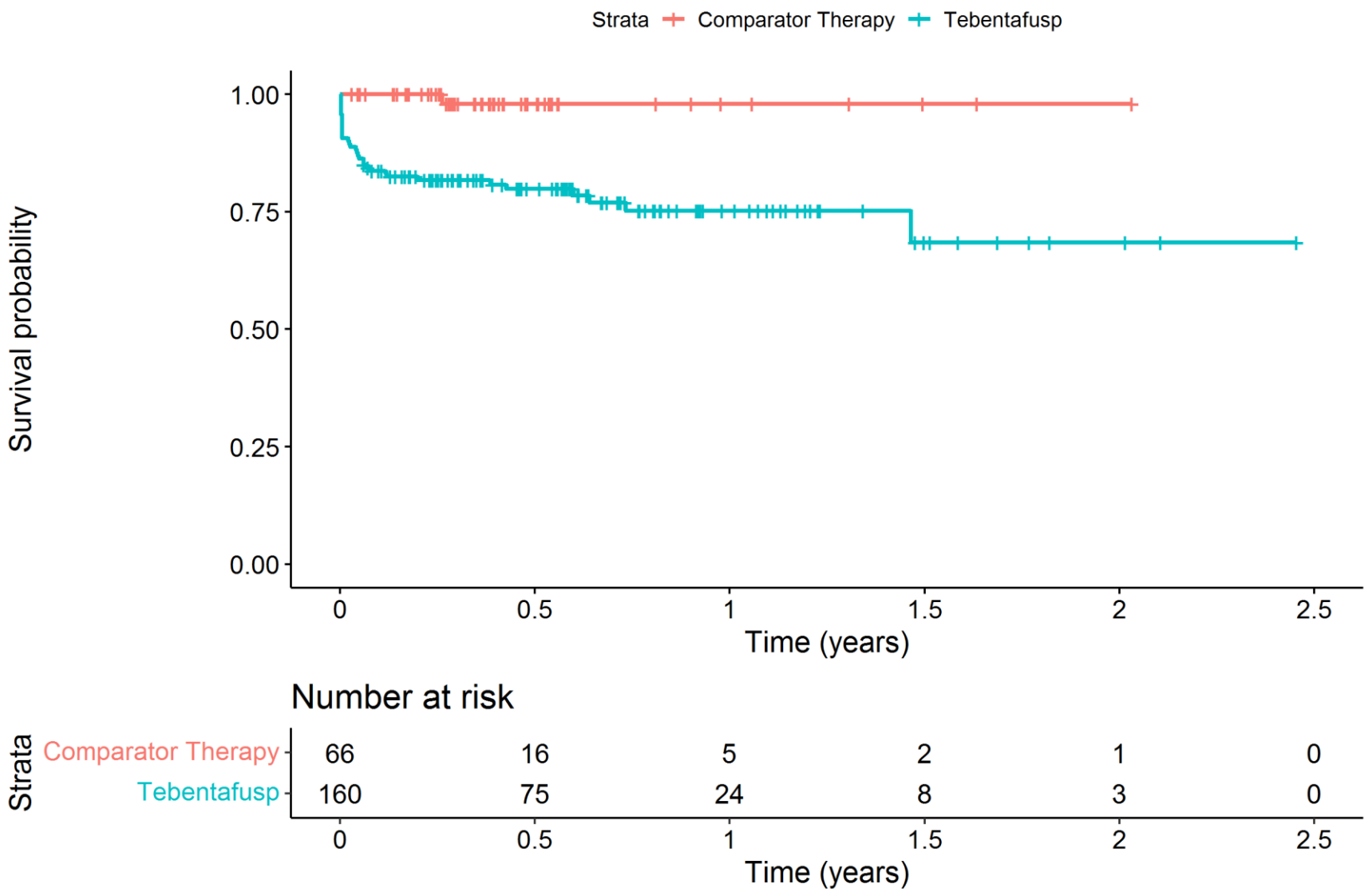
53.448 Erythem - Läsion ≥8,1 cm



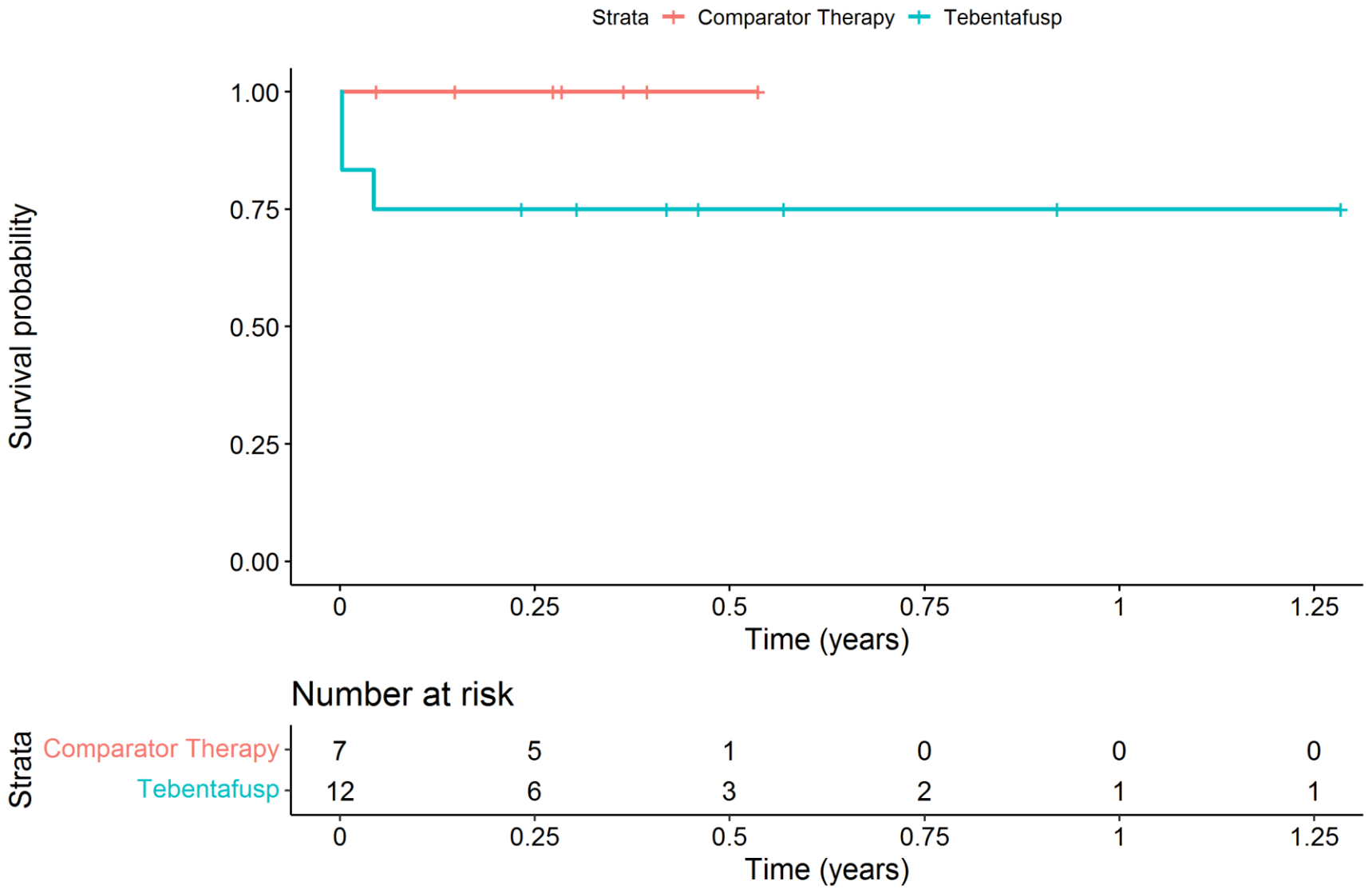
53.449 Erythem - Nordamerika



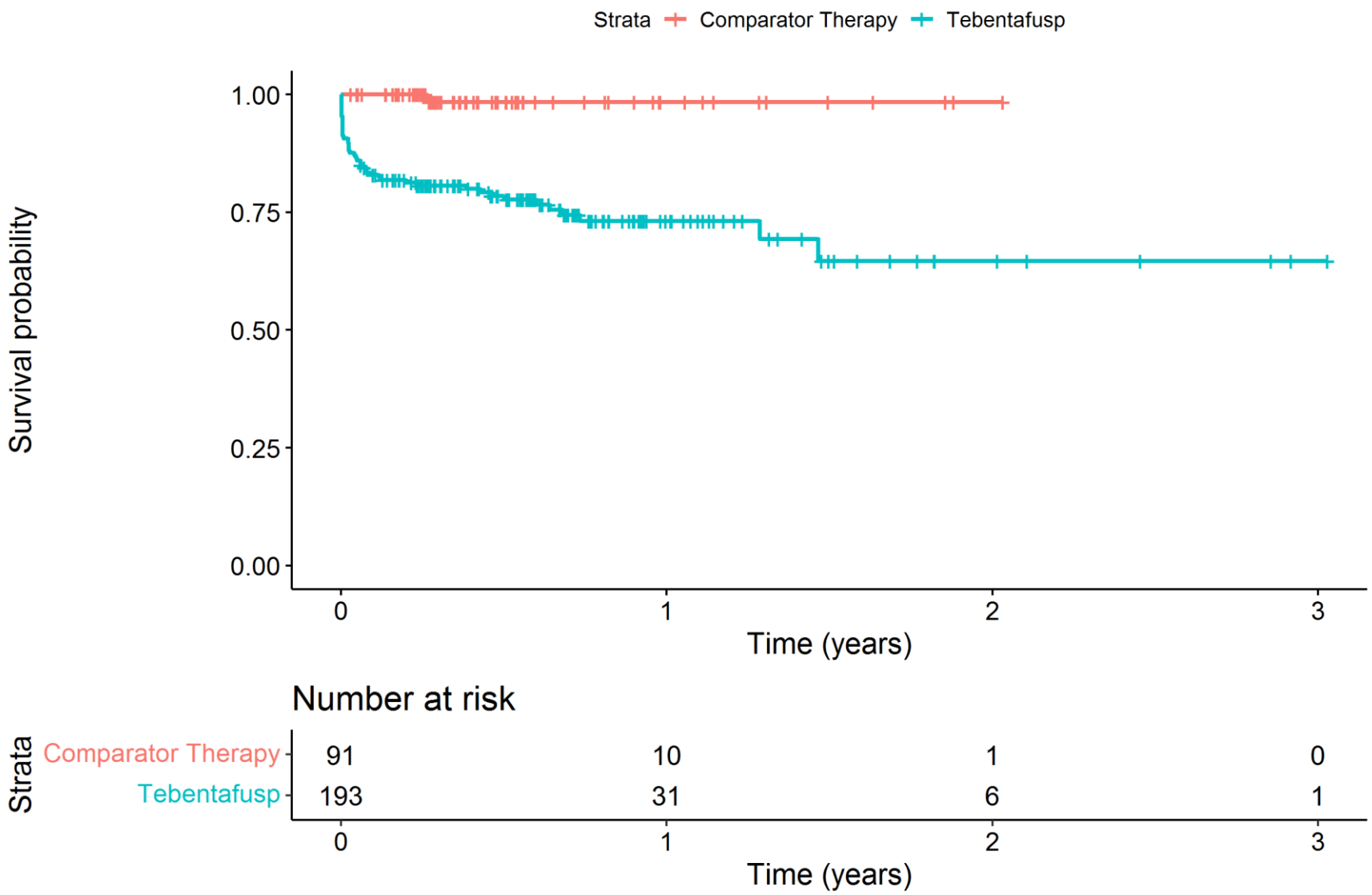
53.450 Erythem - Nicht-Nordamerika



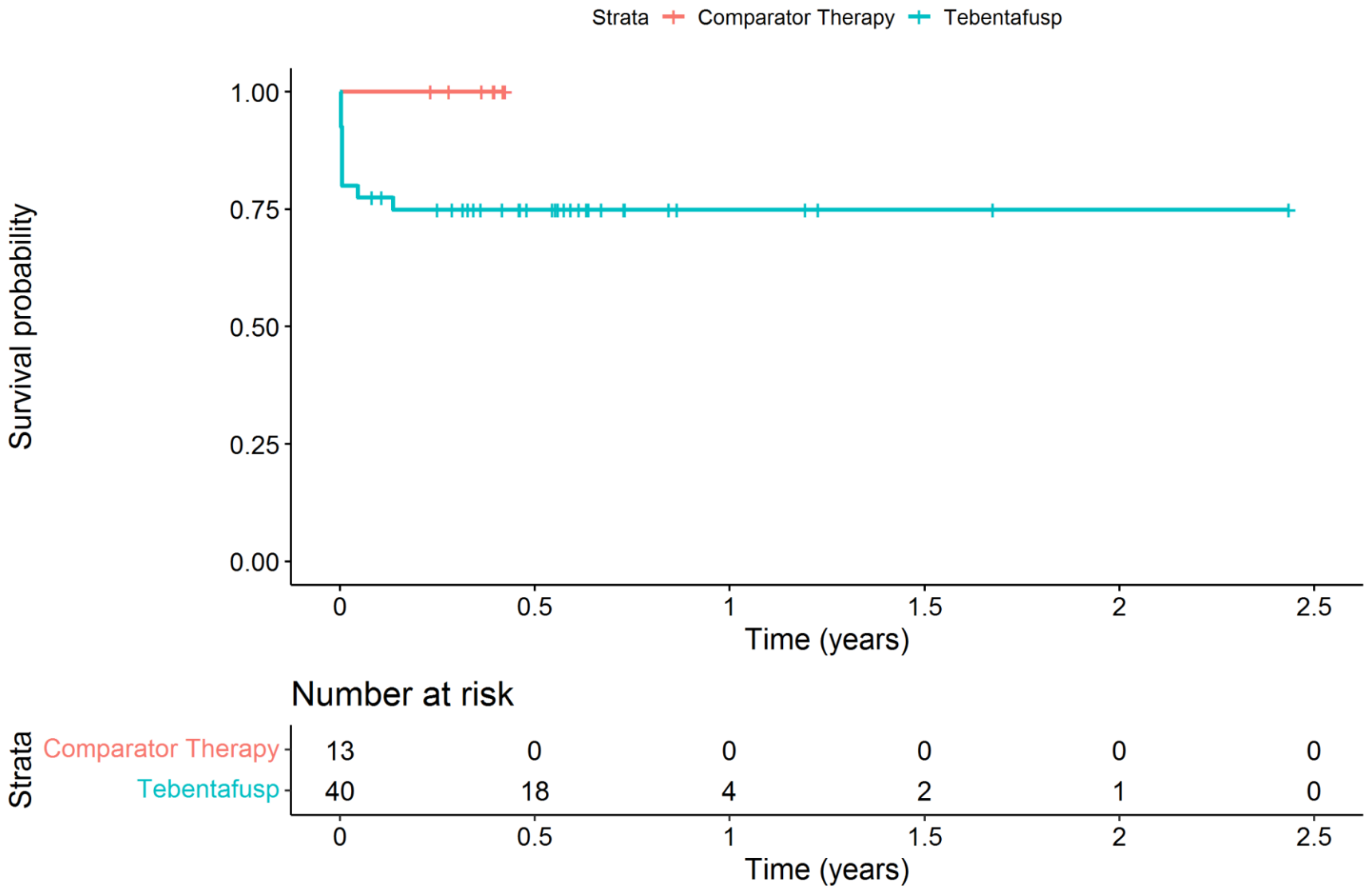
53.451 Erythem - Dacarbazin



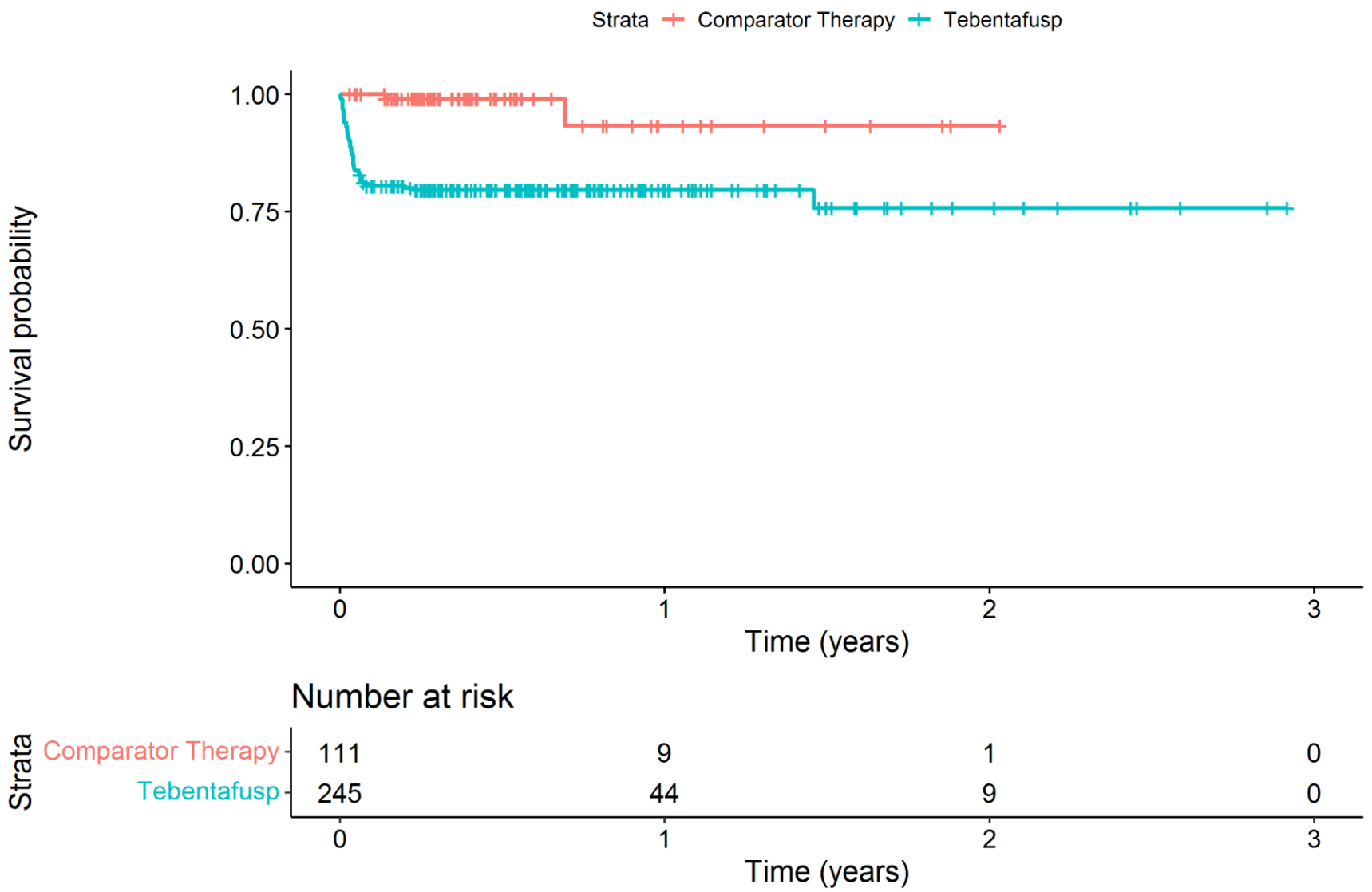
53.452 Erythem - Pembrolizumab



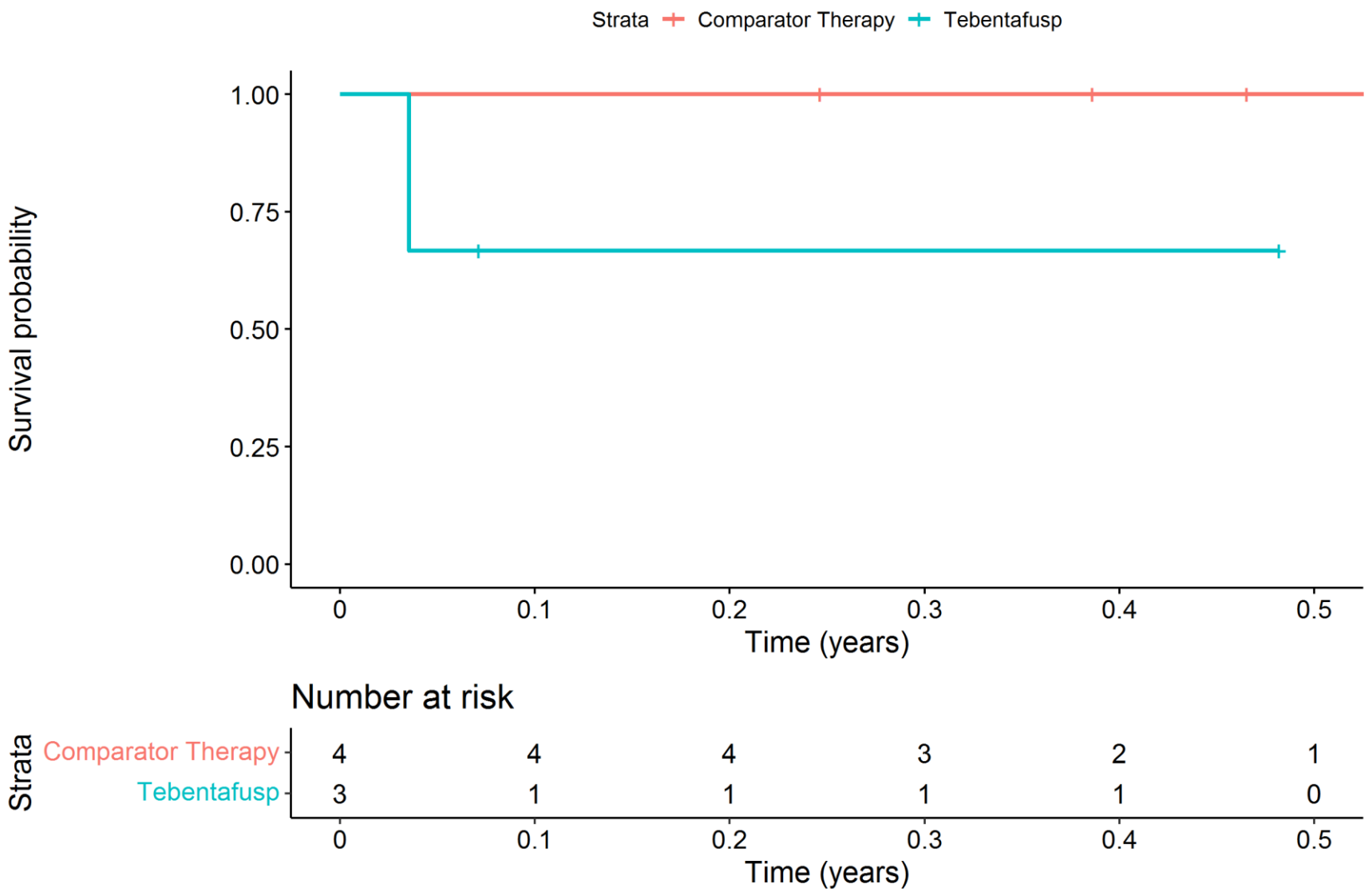
53.453 Erythem - Ipilimumab



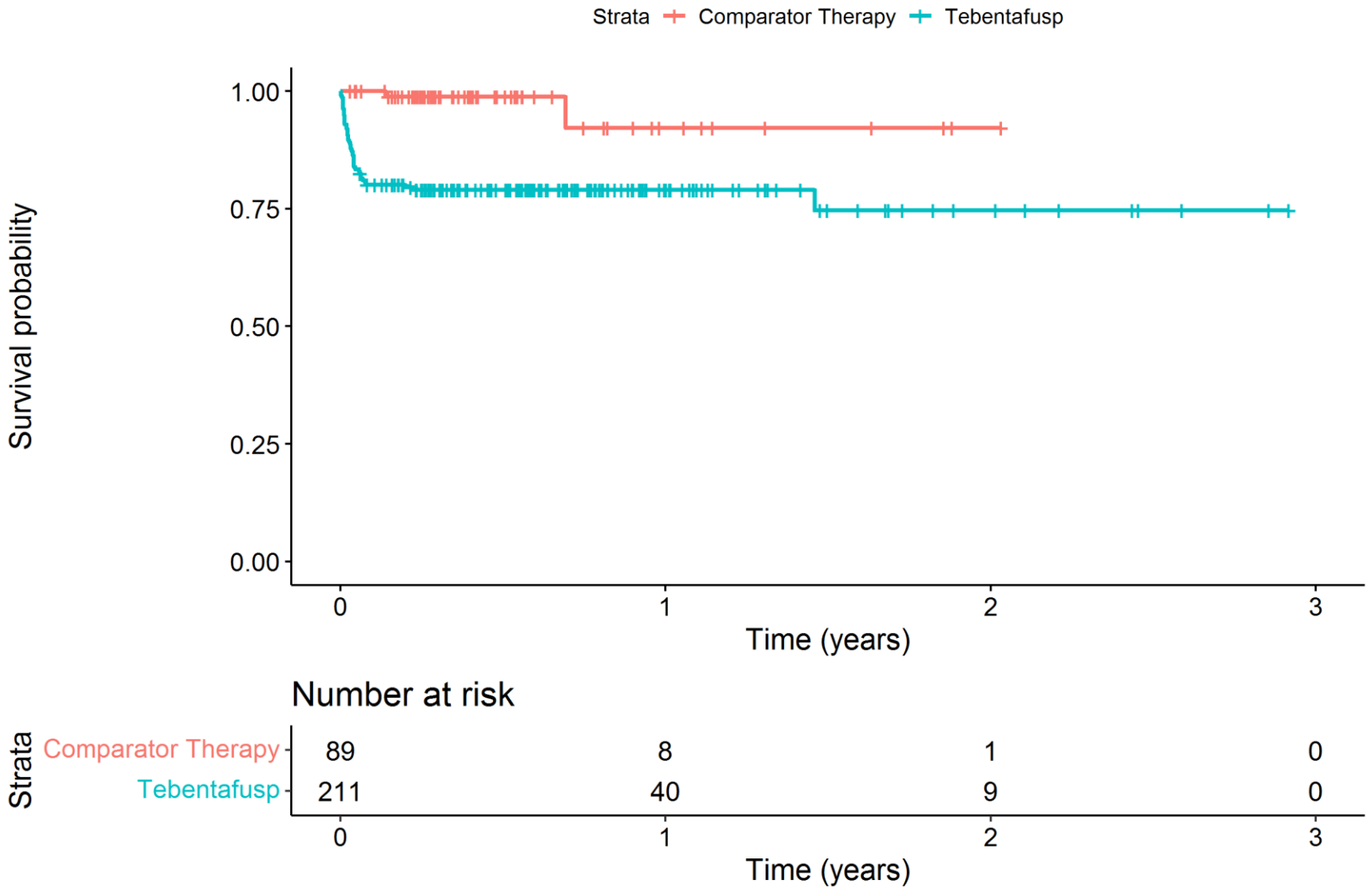
53.454 Hautabschälung - Gesamt



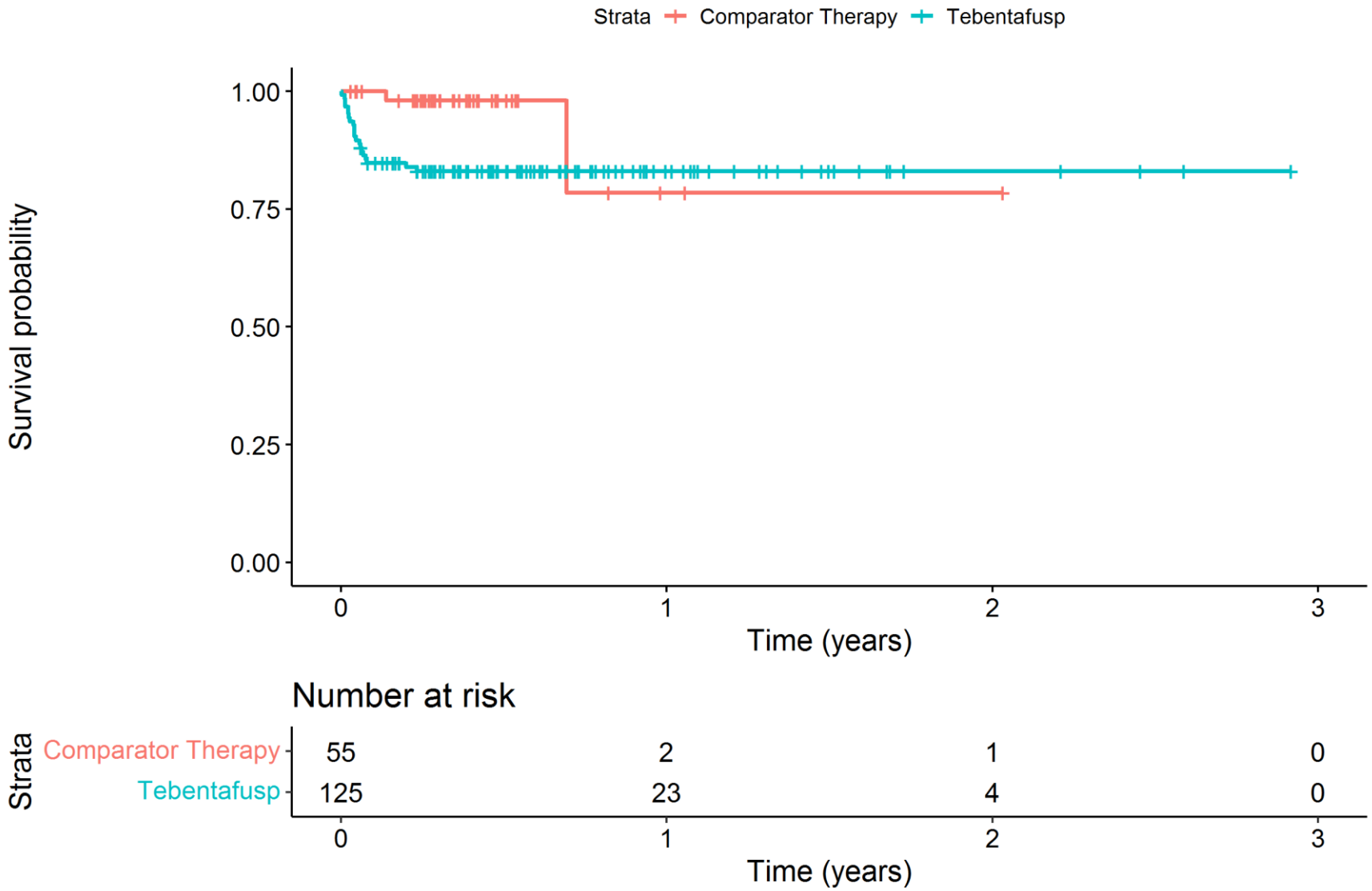
53.455 Hautabschälung - Hispanisch



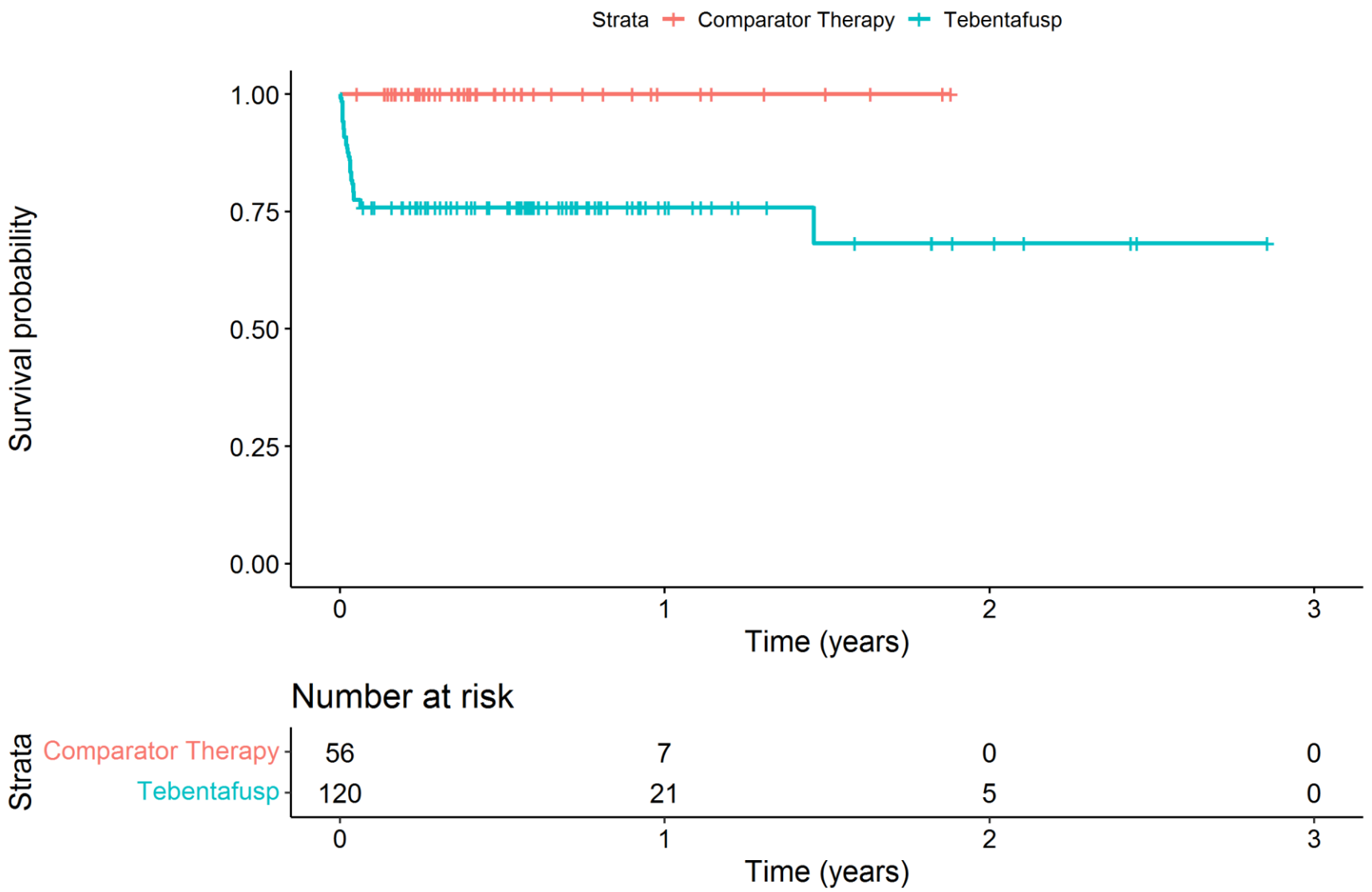
53.456 Hautabschälung - Nicht-hispanisch



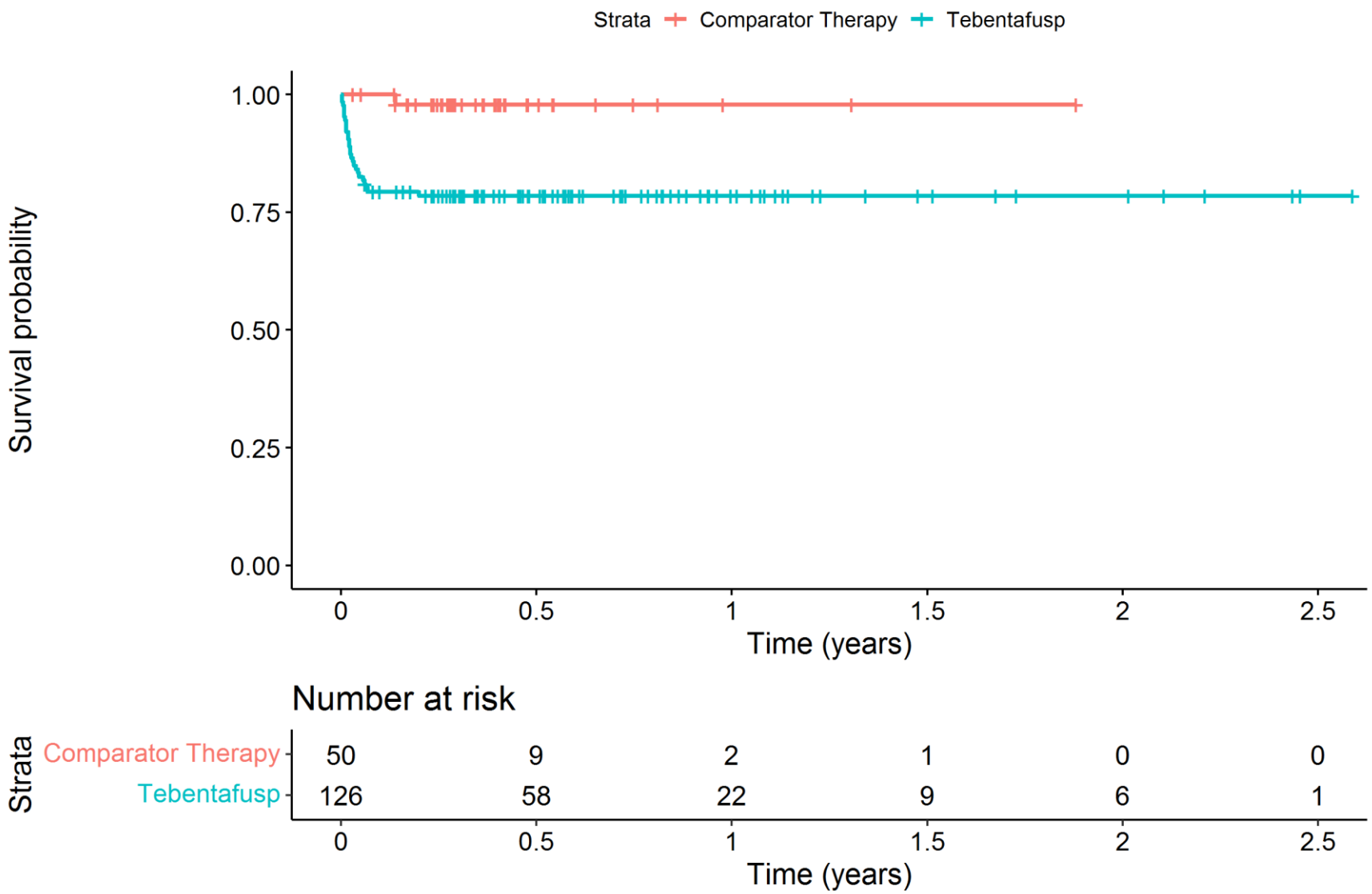
53.457 Hautabschälung - Männlich



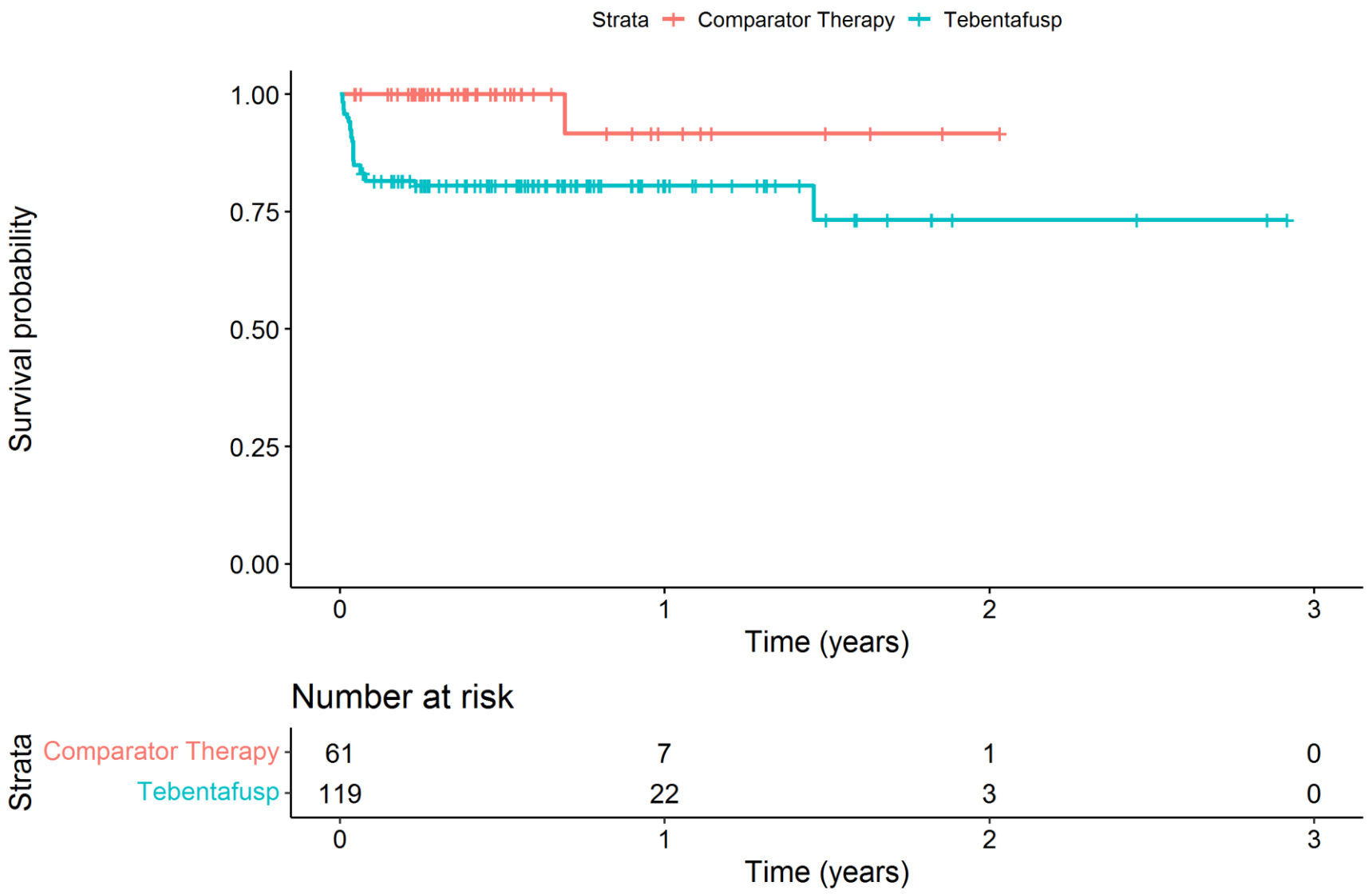
53.458 Hautabschälung - Weiblich



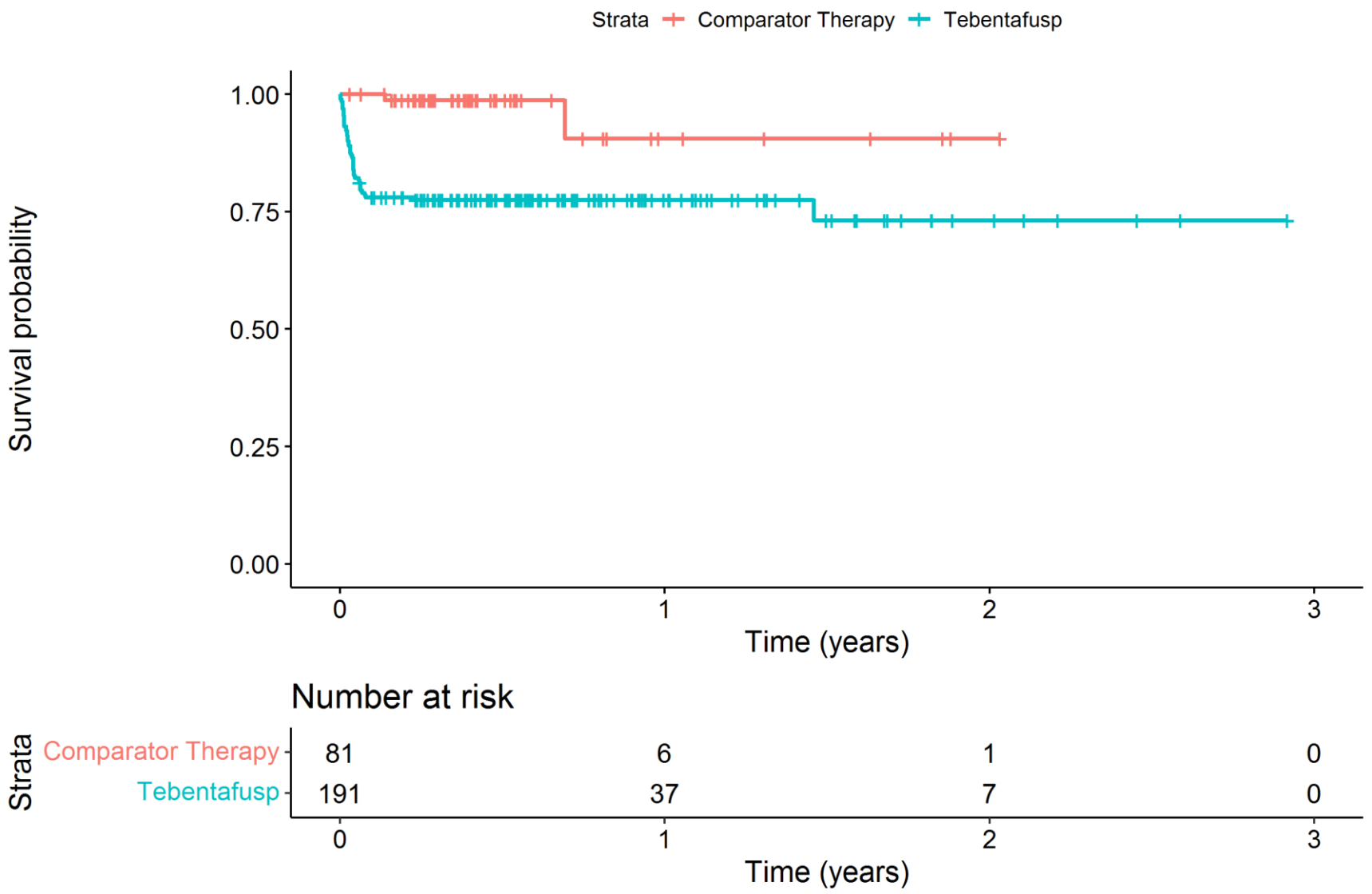
53.459 Hautabschälung - <65



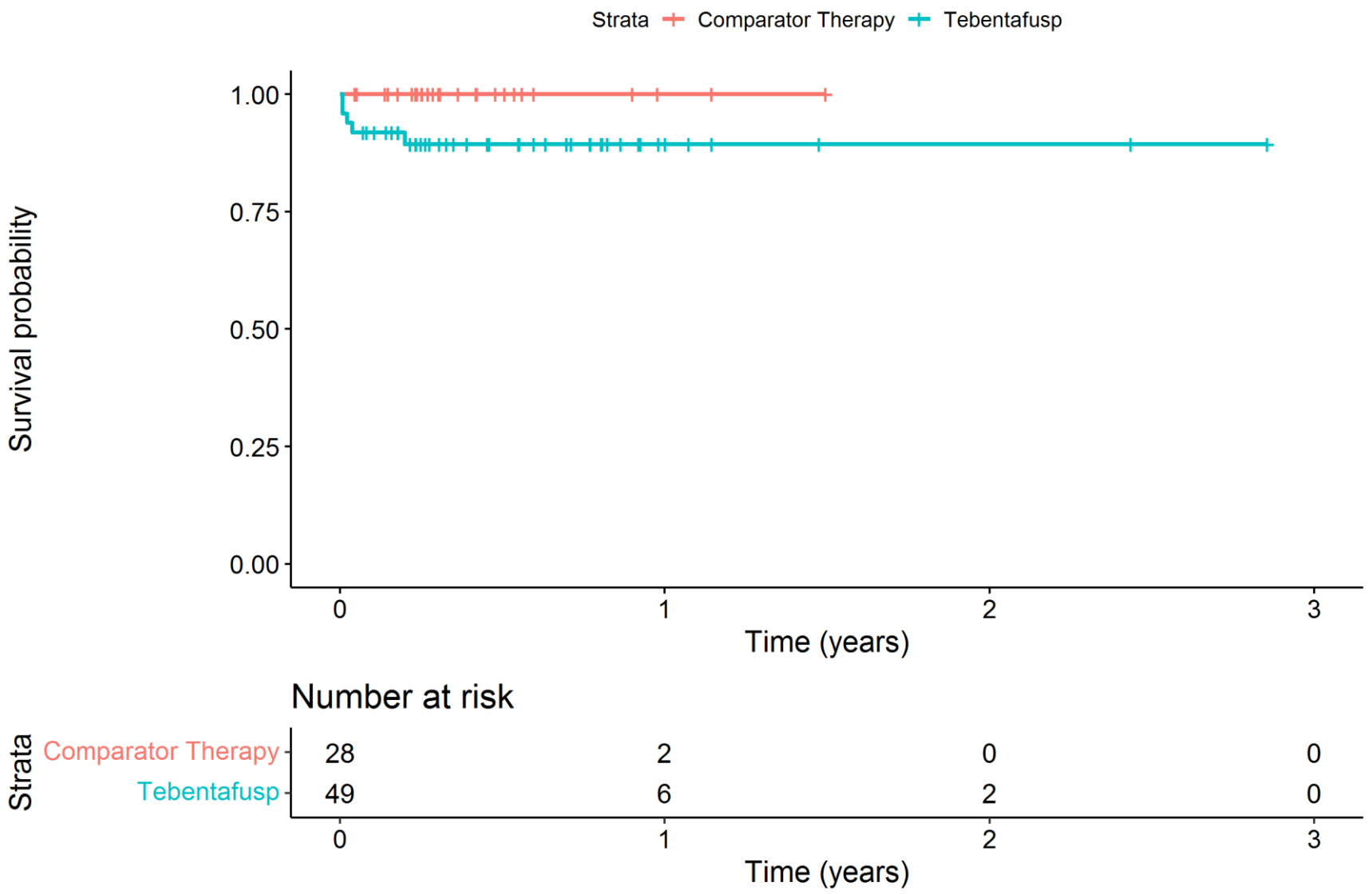
53.460 Hautabschälung - ≥65



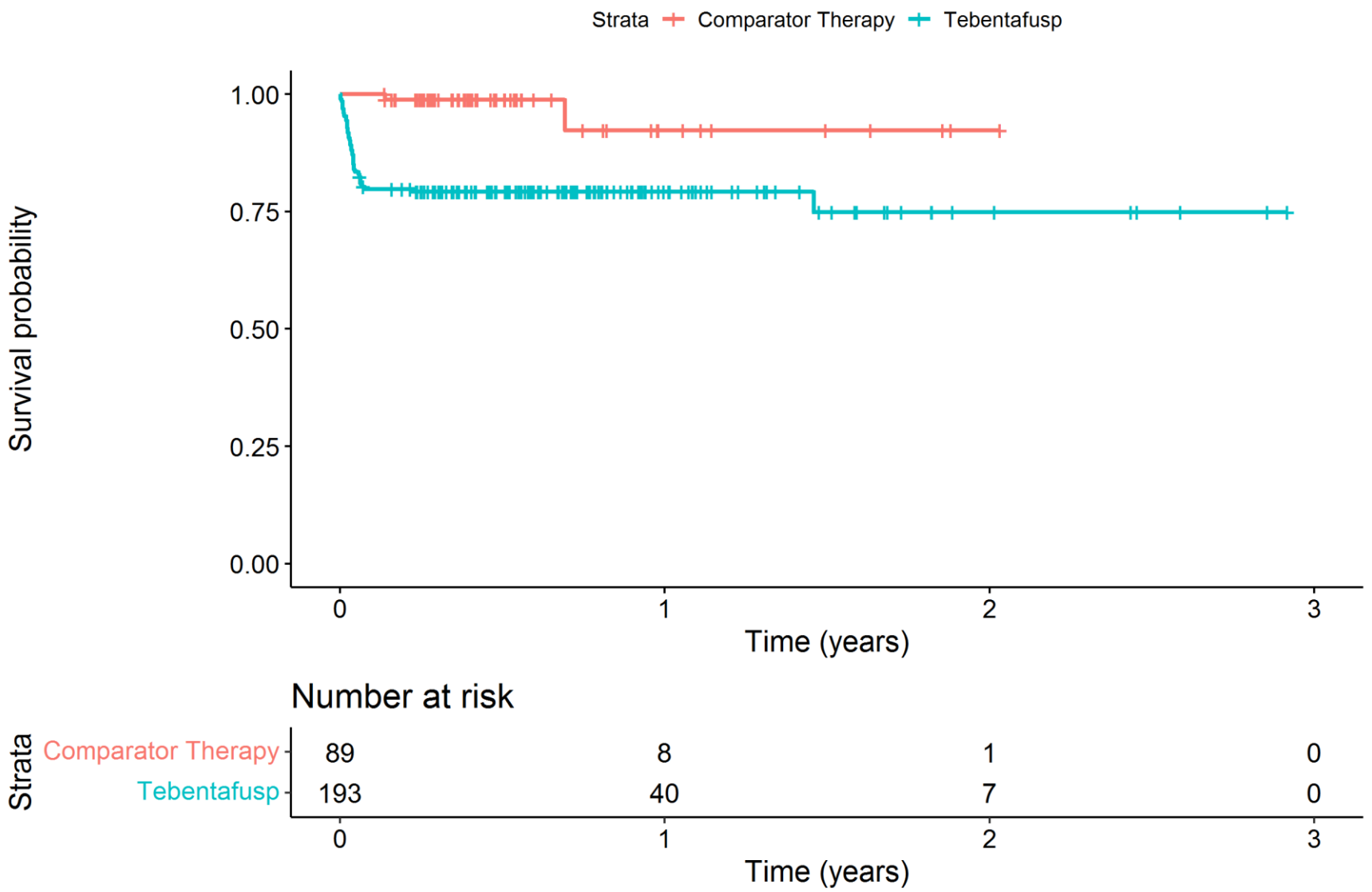
53.461 Hautabschälung - ECOG 0



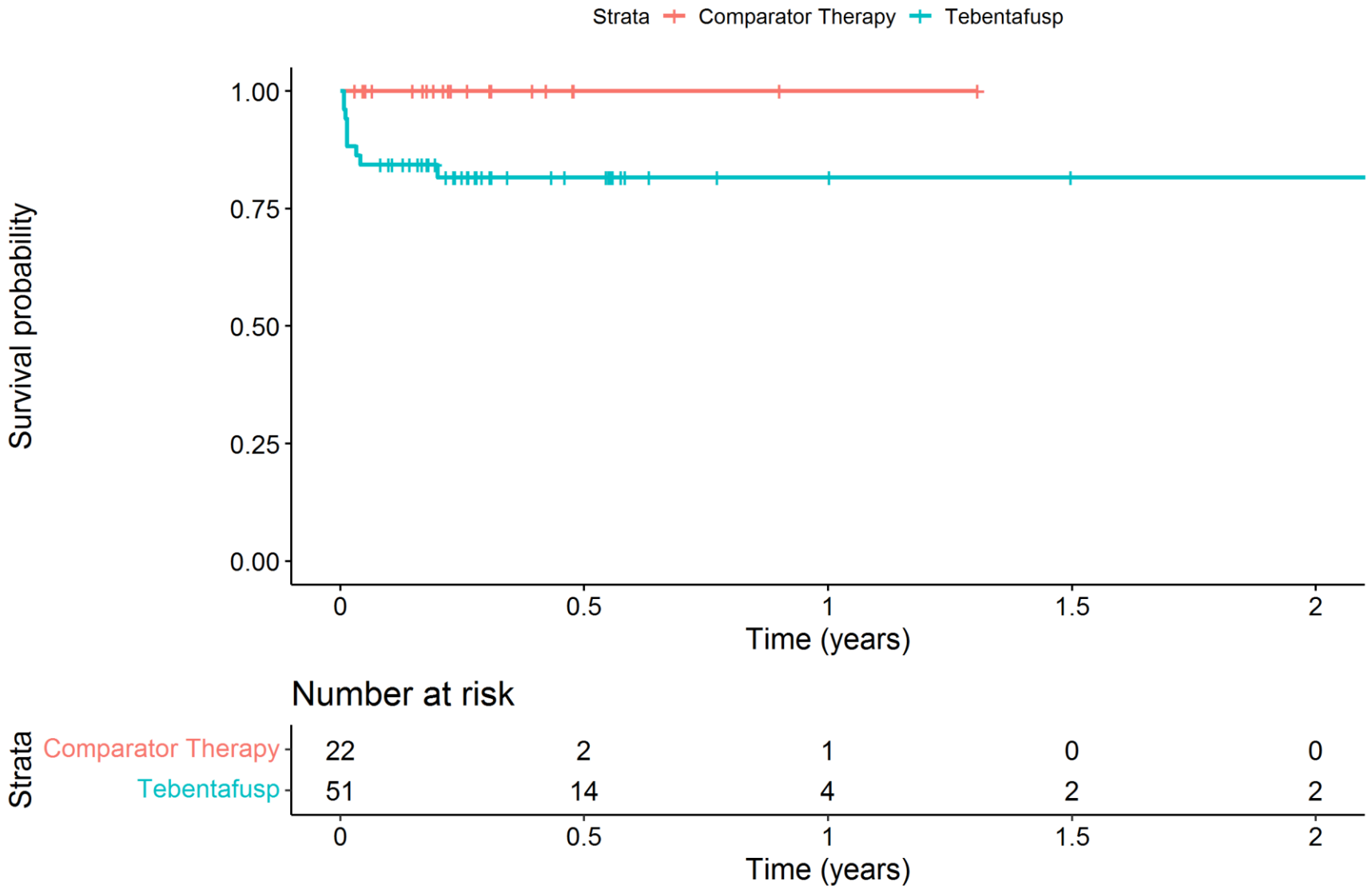
53.462 Hautabschälung - ECOG 1



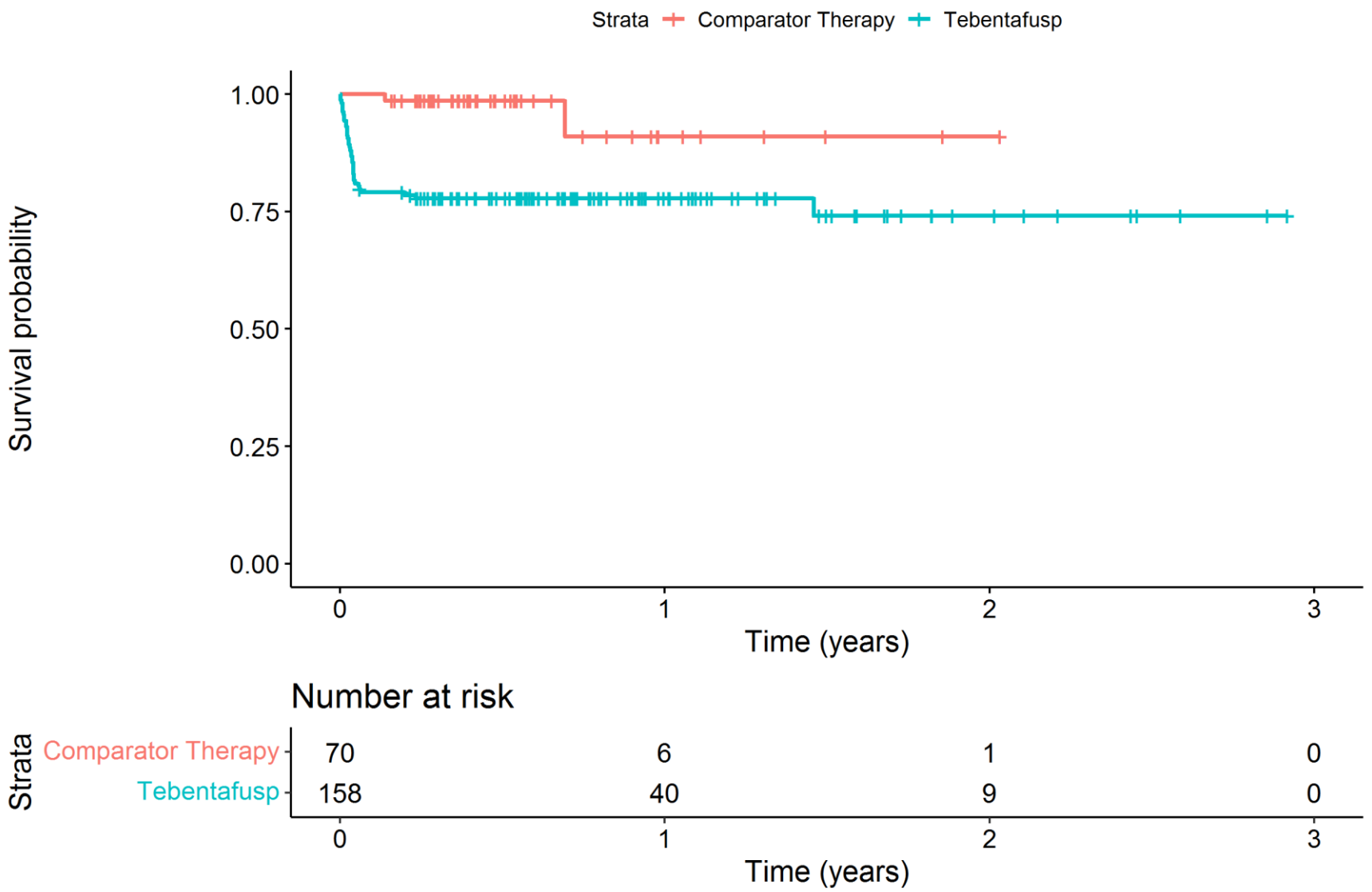
53.463 Hautabschälung - ALP ≤ ULN



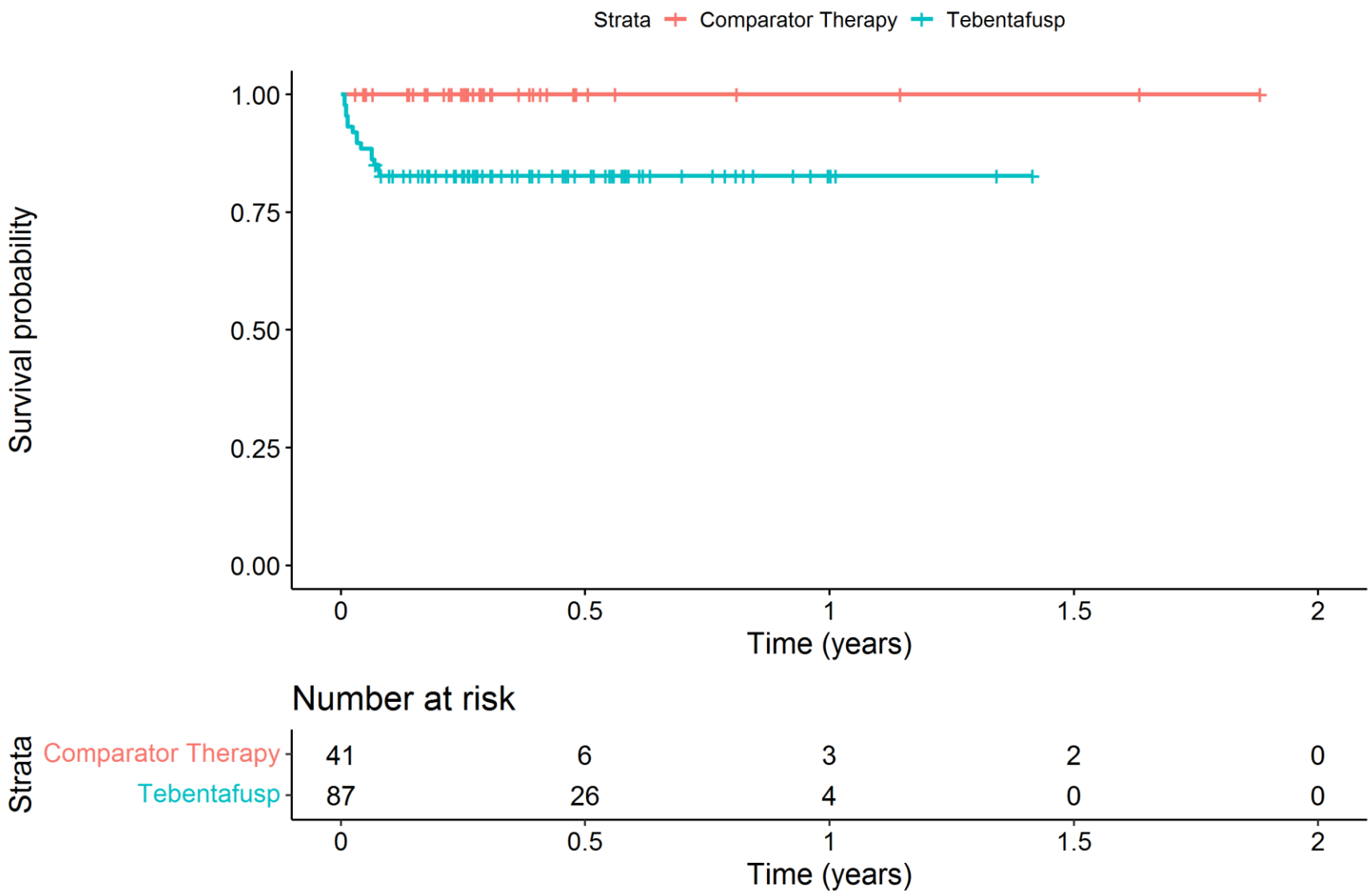
53.464 Hautabschälung - ALP > ULN



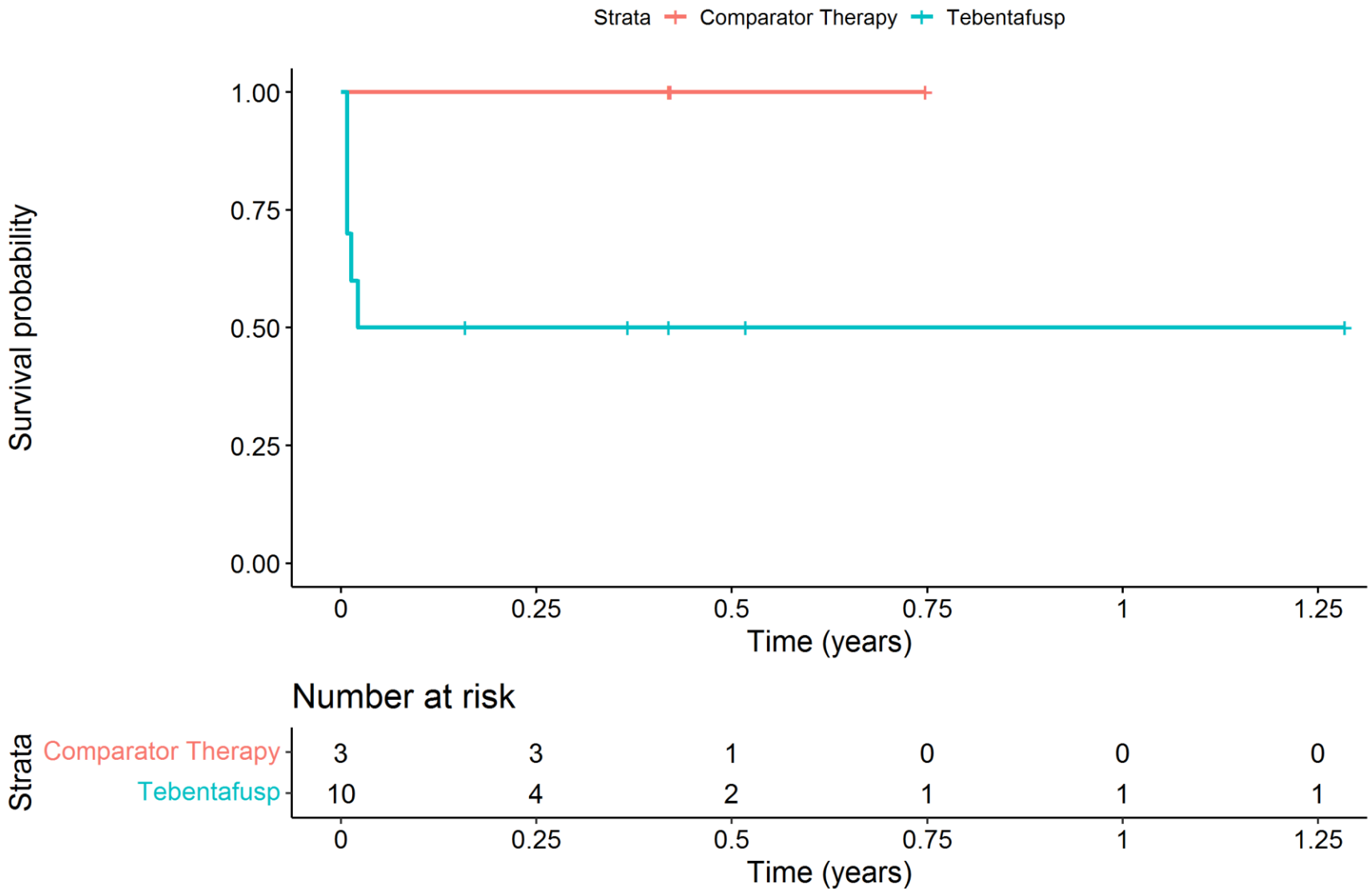
53.465 Hautabschälung - LDH =< ULN



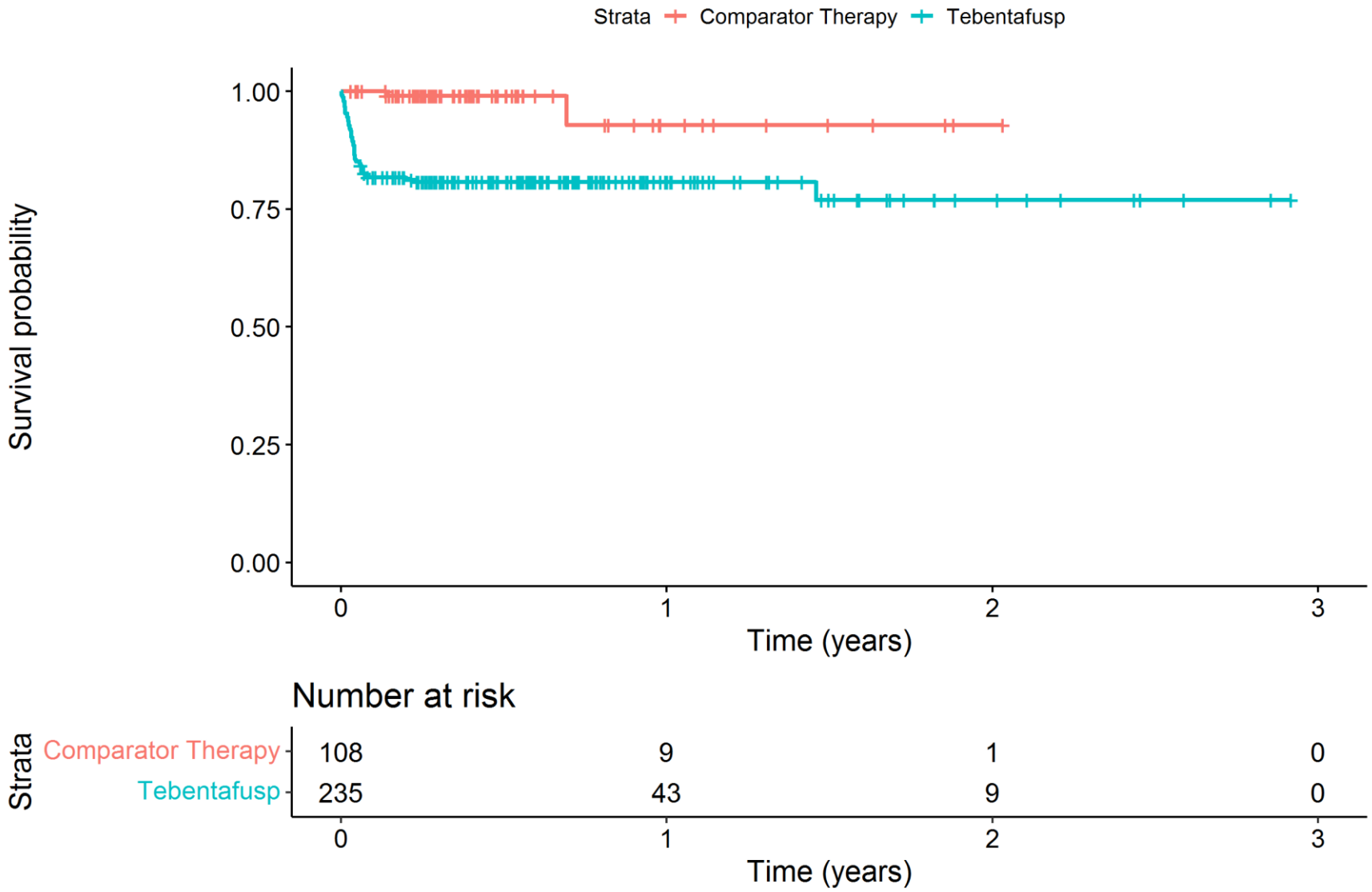
53.466 Hautabschälung - LDH > ULN



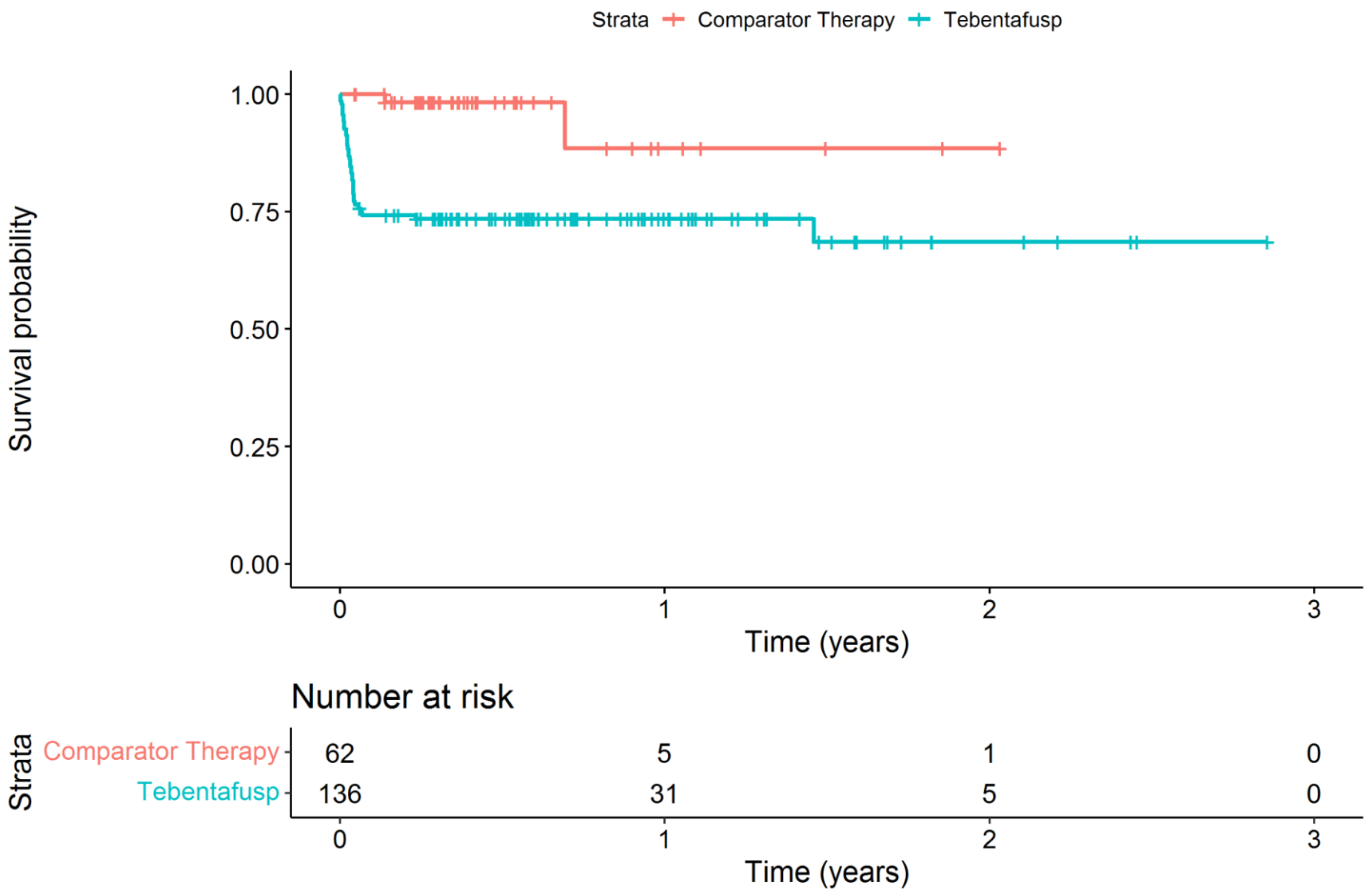
53.467 Hautabschälung - Vorherige Therapie adjuvant/neoadjuvant



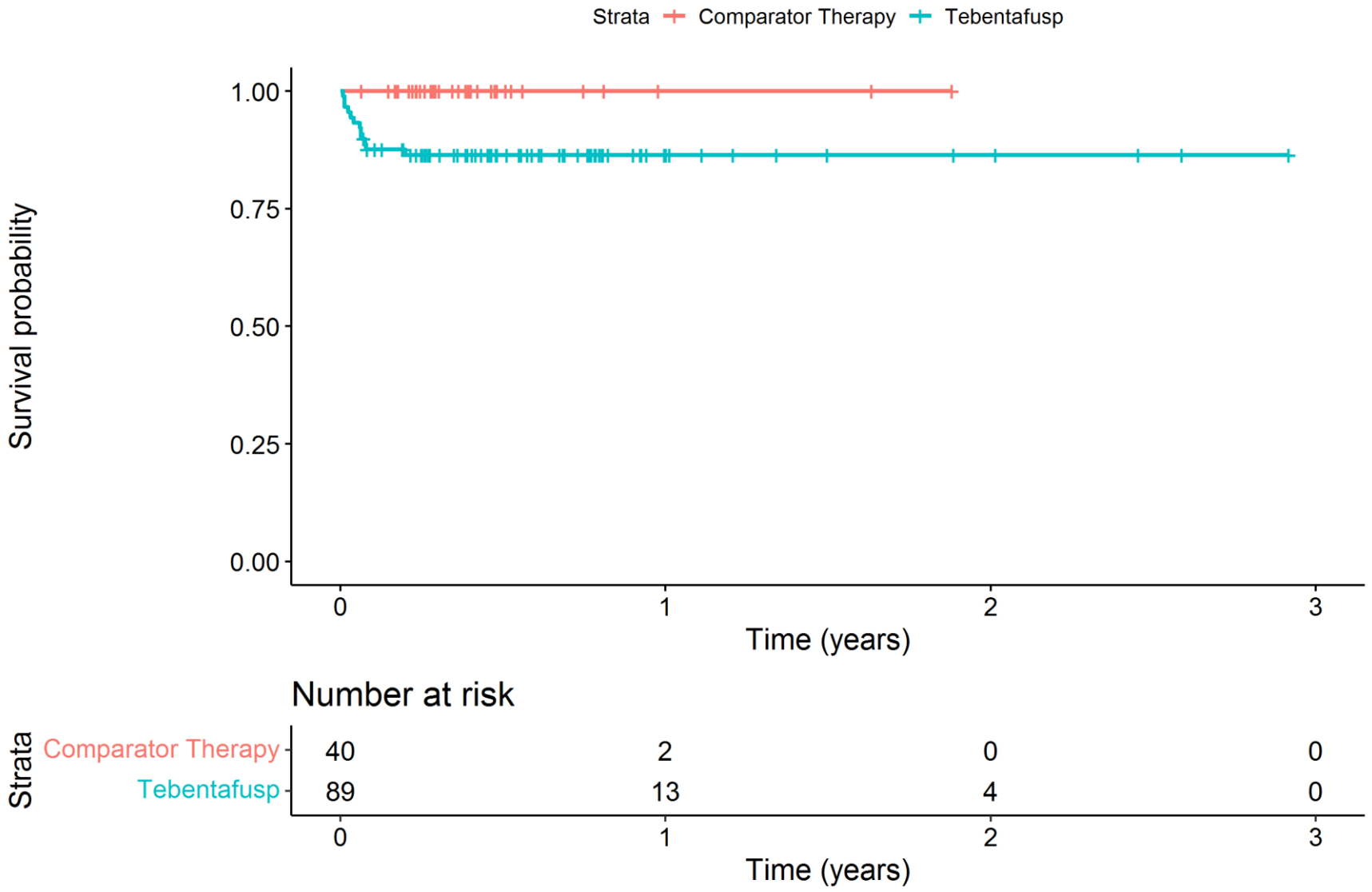
53.468 Hautabschälung - Keine vorherige Therapie adjuvant/neoadjuvant



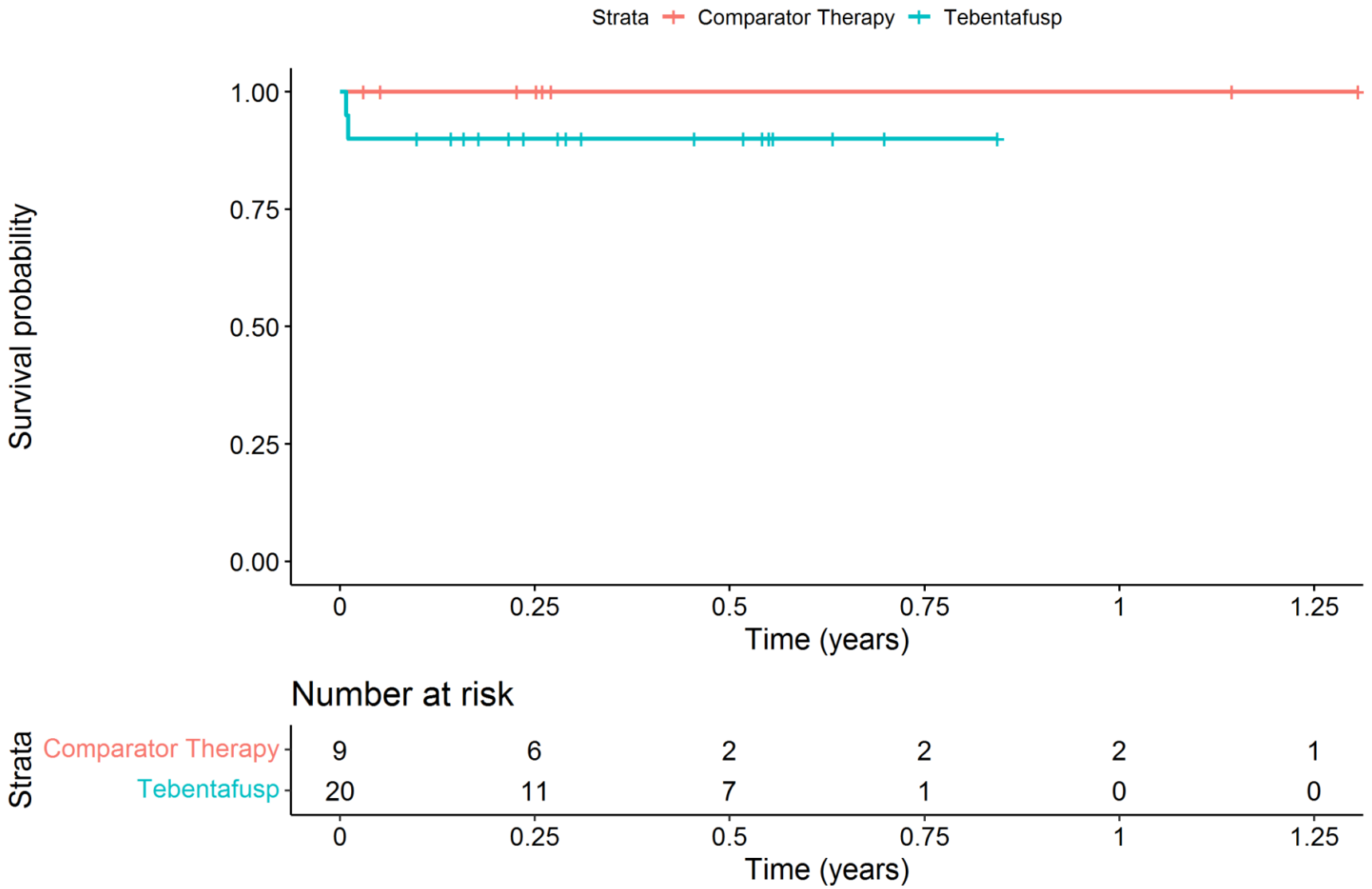
53.469 Hautabschälung - Läsion ≤ 3cm



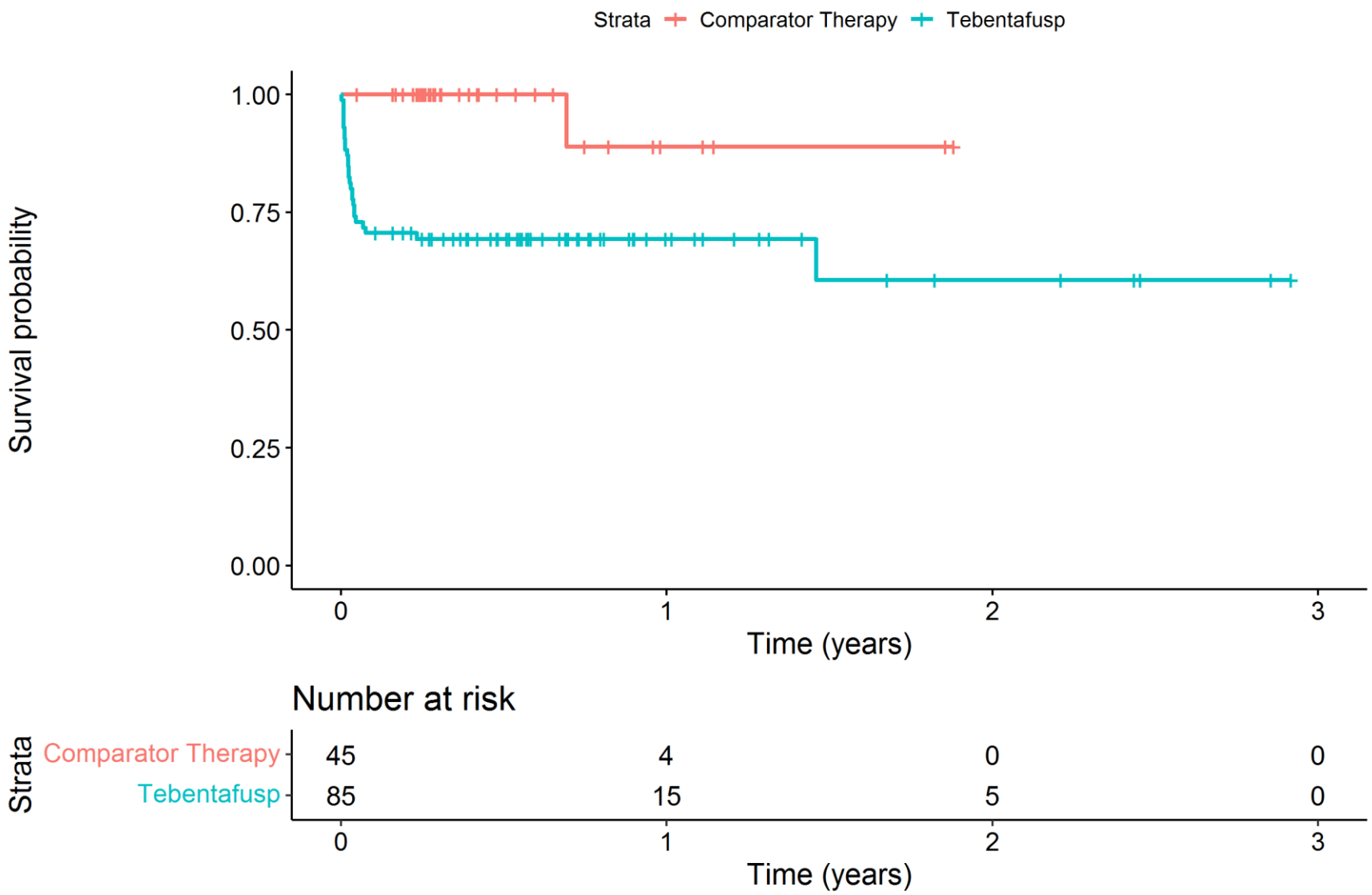
53.470 Hautabschälung - Läsion 3,1-8,0 cm



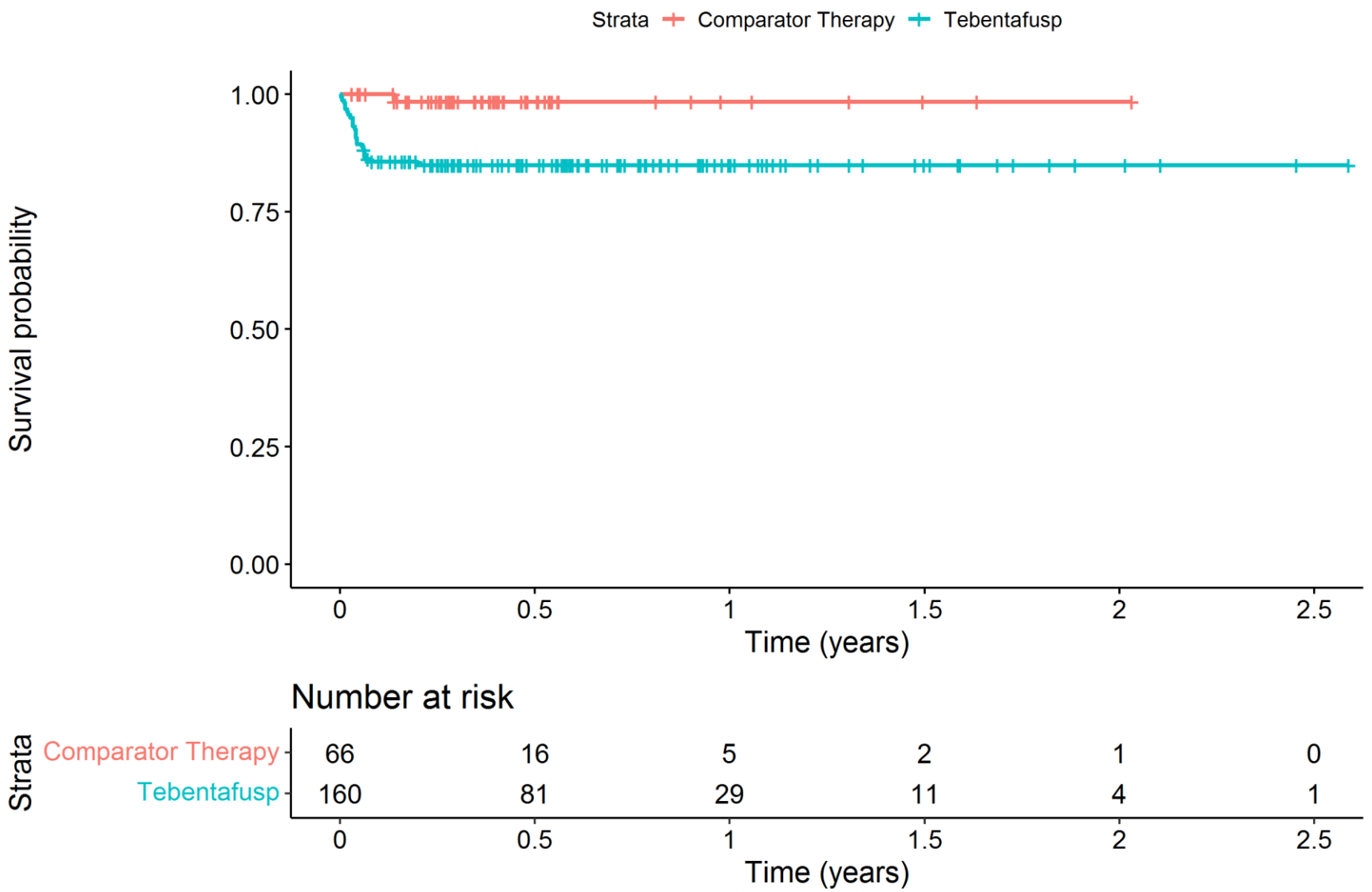
53.471 Hautabschälung - Läsion ≥8,1 cm



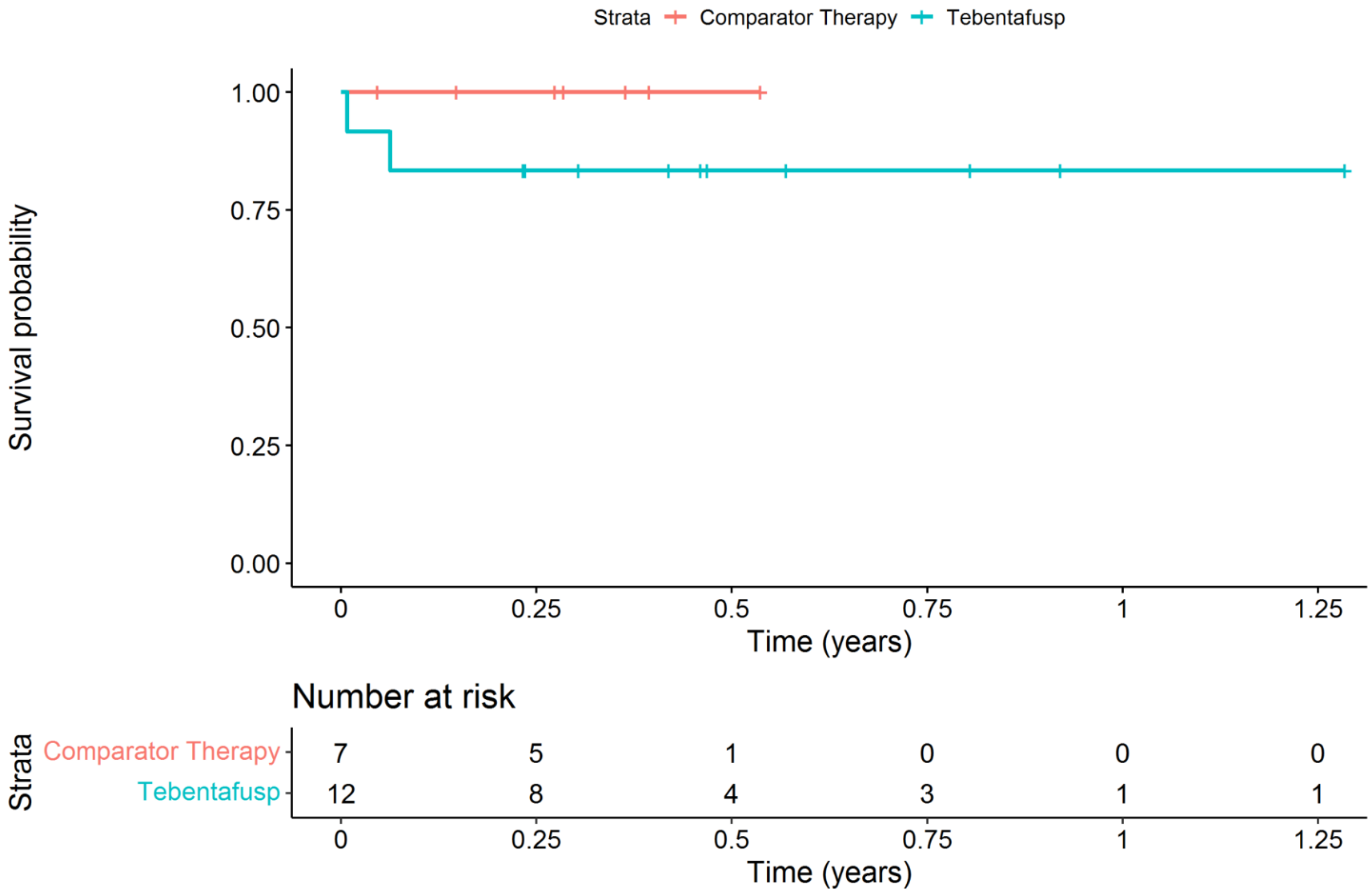
53.472 Hautabschälung - Nordamerika



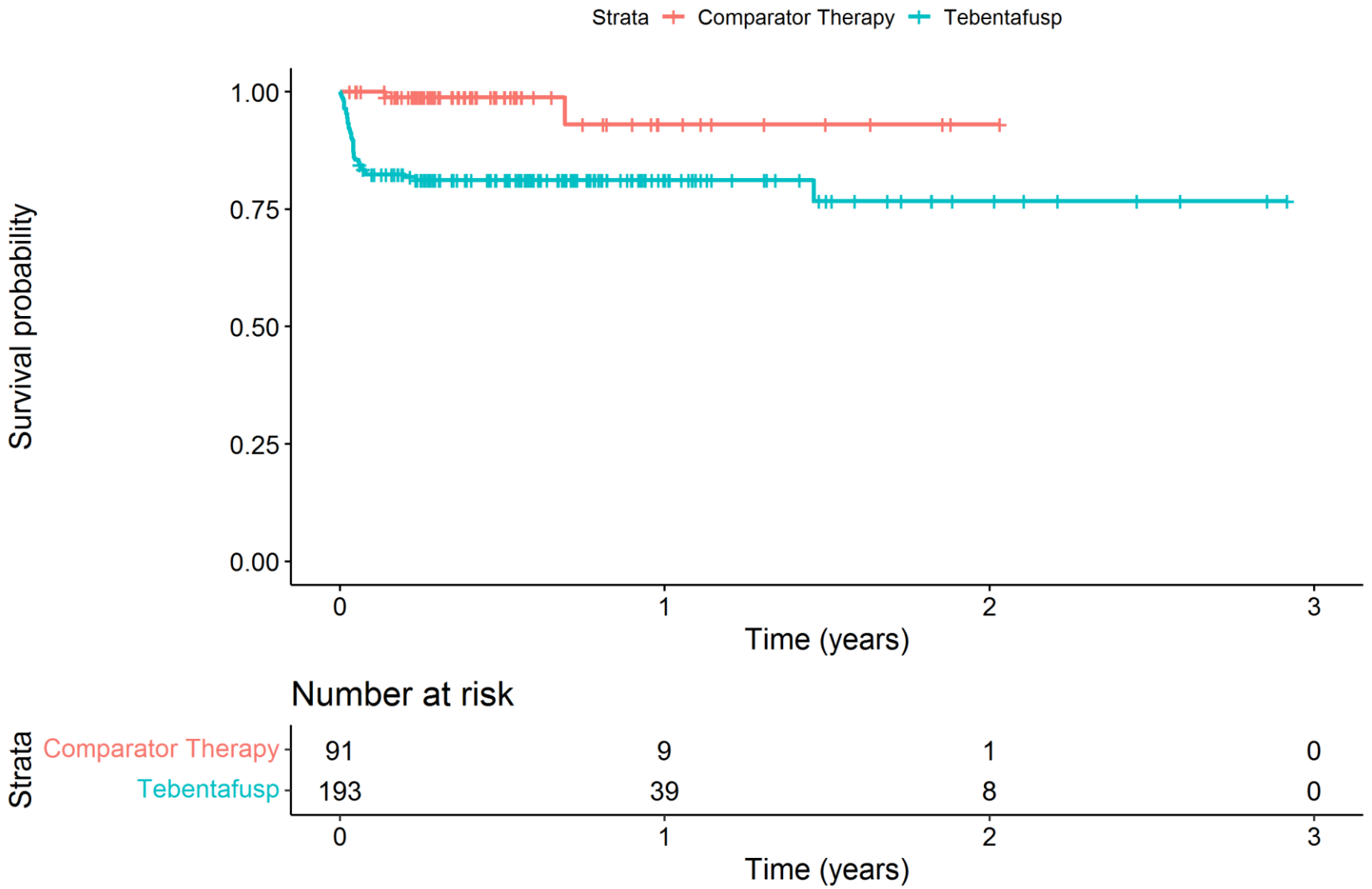
53.473 Hautabschälung - Nicht-Nordamerika



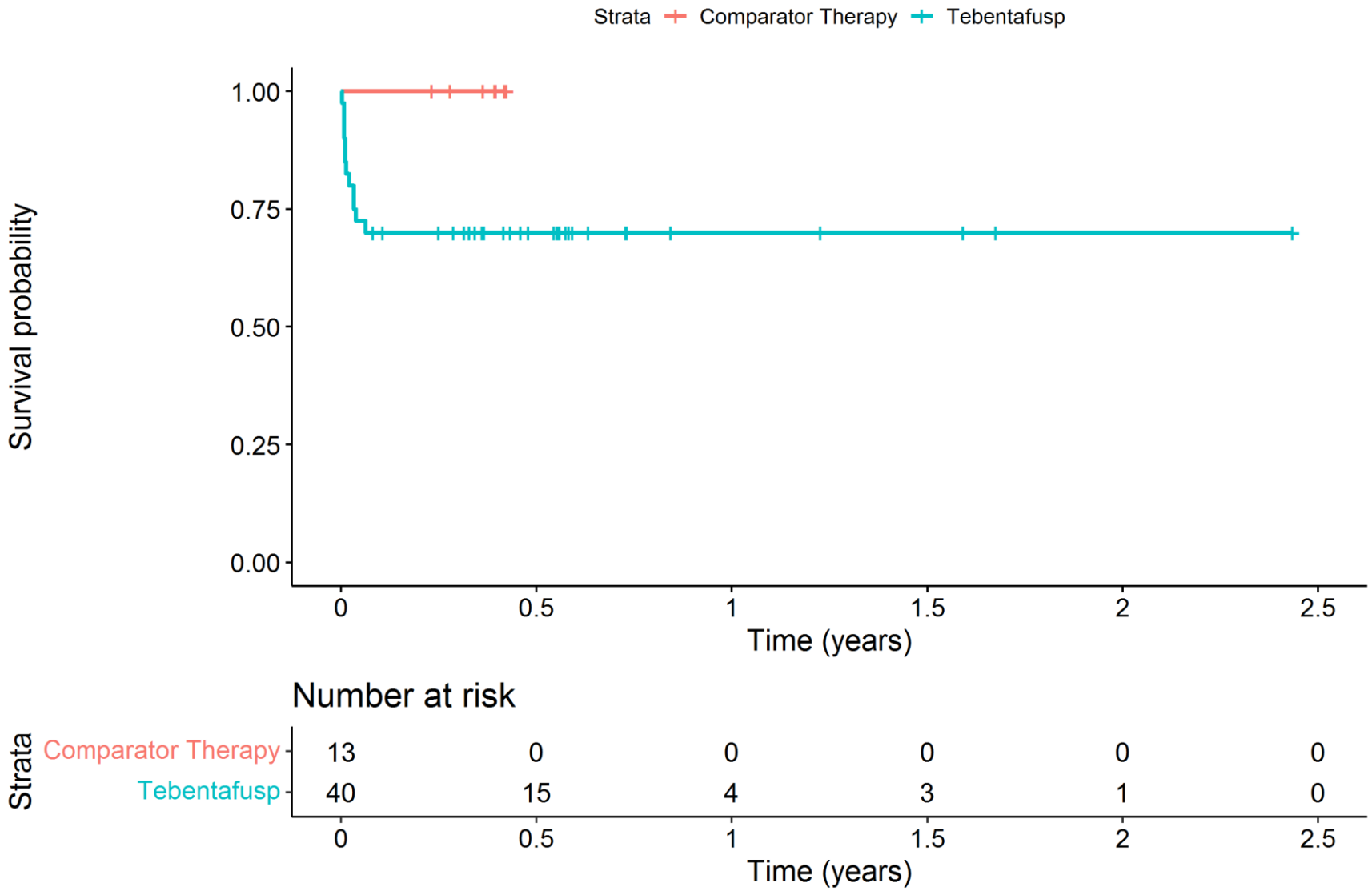
53.474 Hautabschälung - Dacarbazin



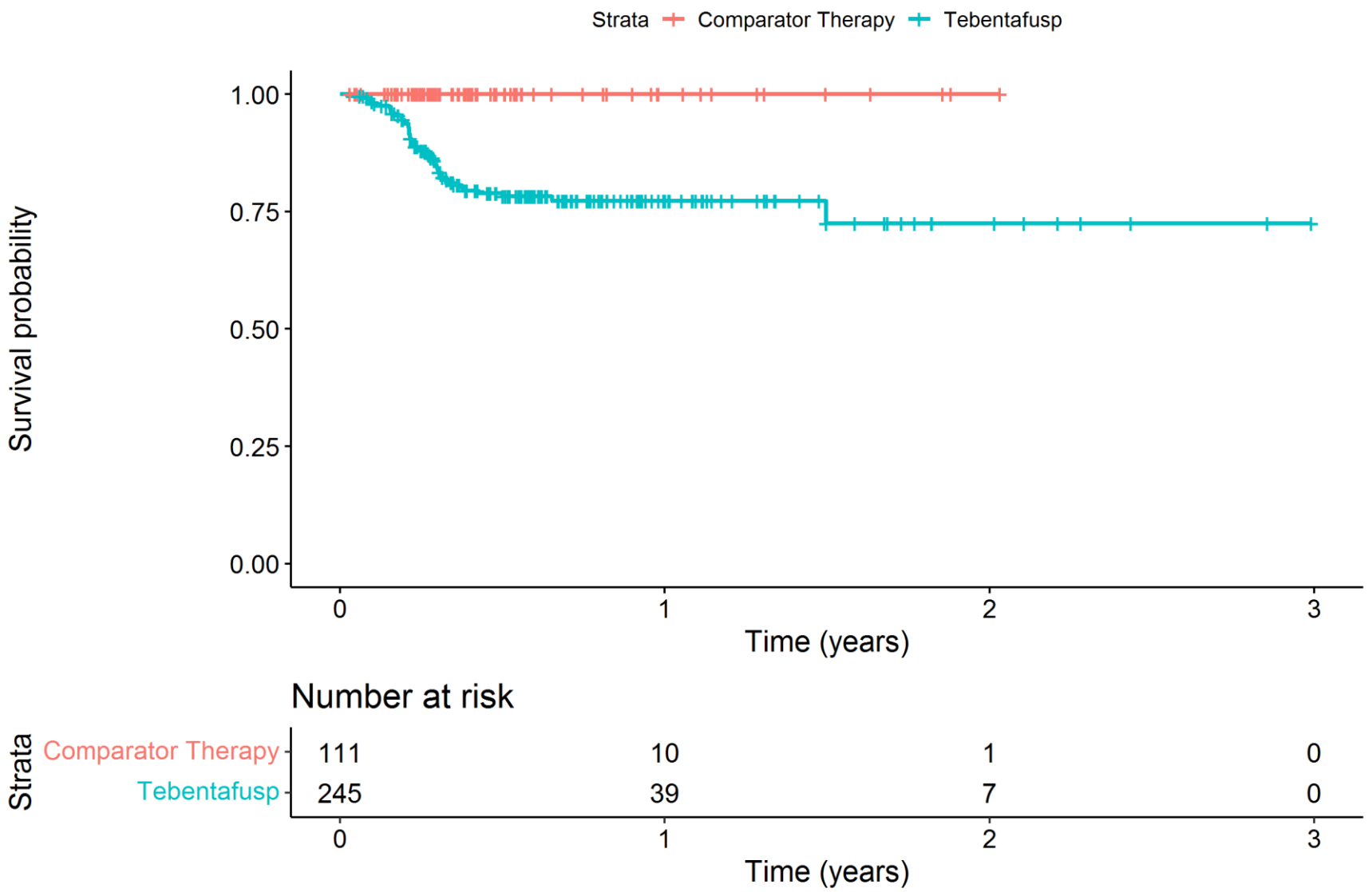
53.475 Hautabschälung - Pembrolizumab



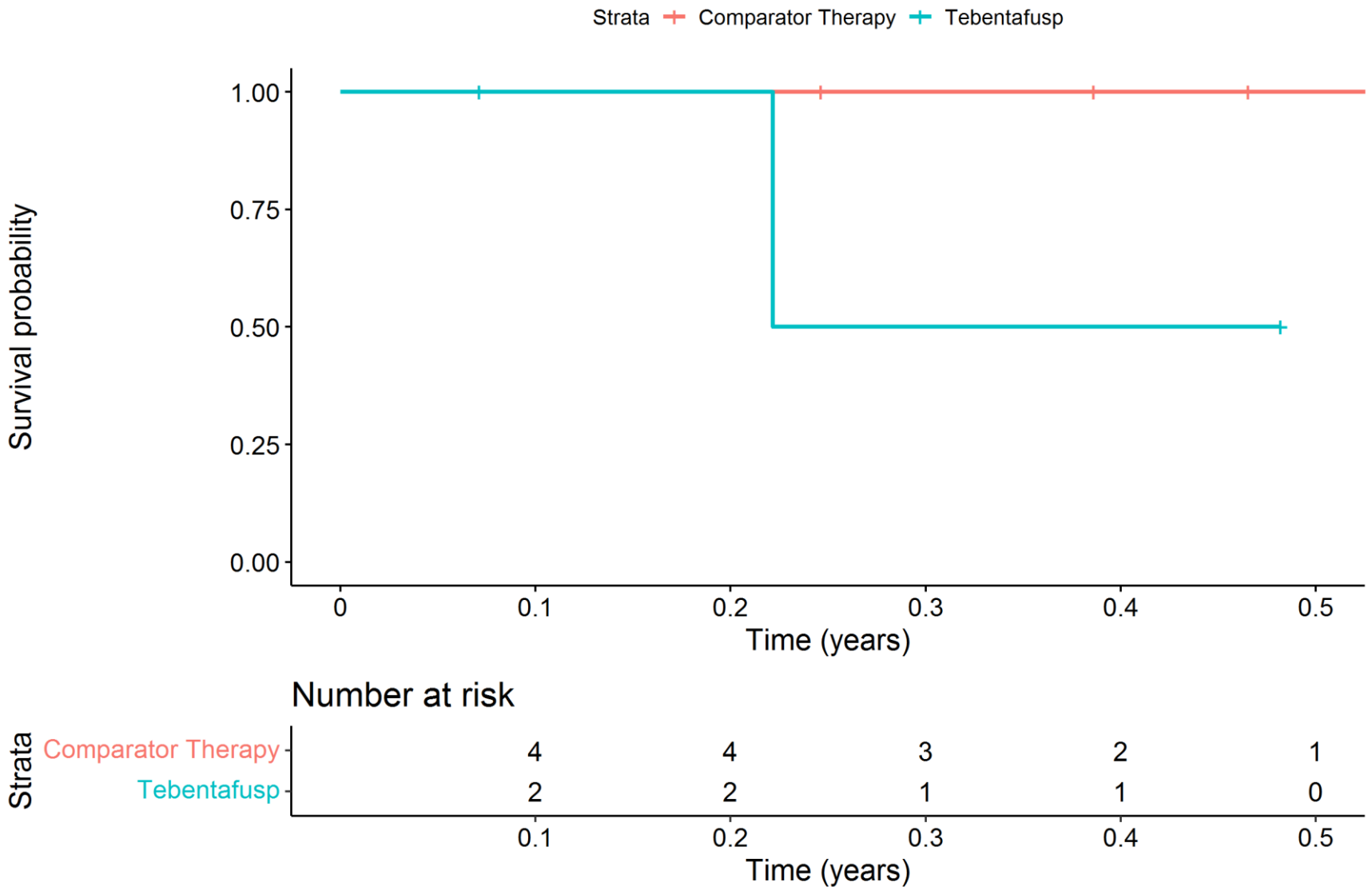
53.476 Hautabschälung - Ipilimumab



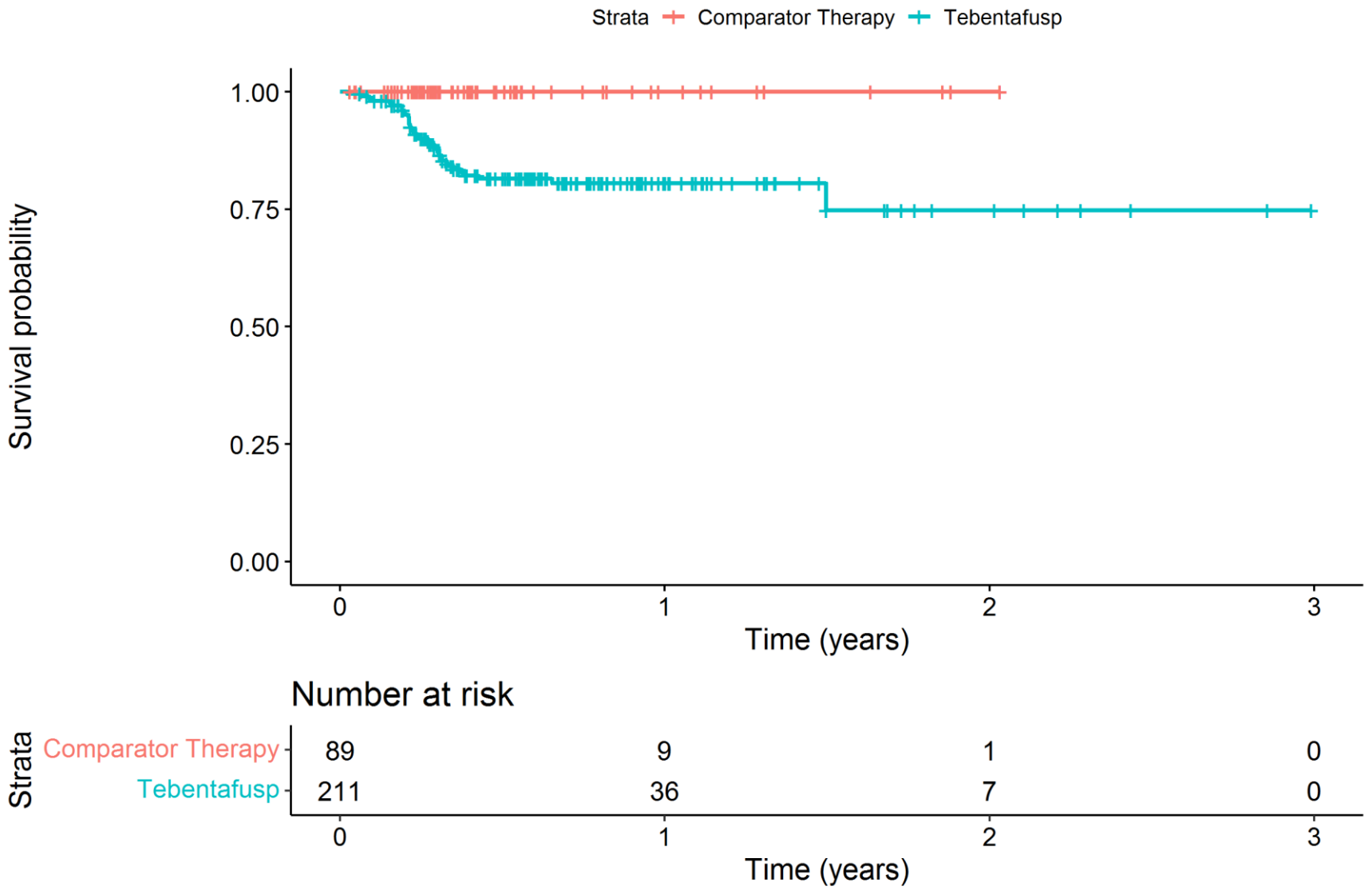
53.477 Veränderung der Haarfarbe - Gesamt



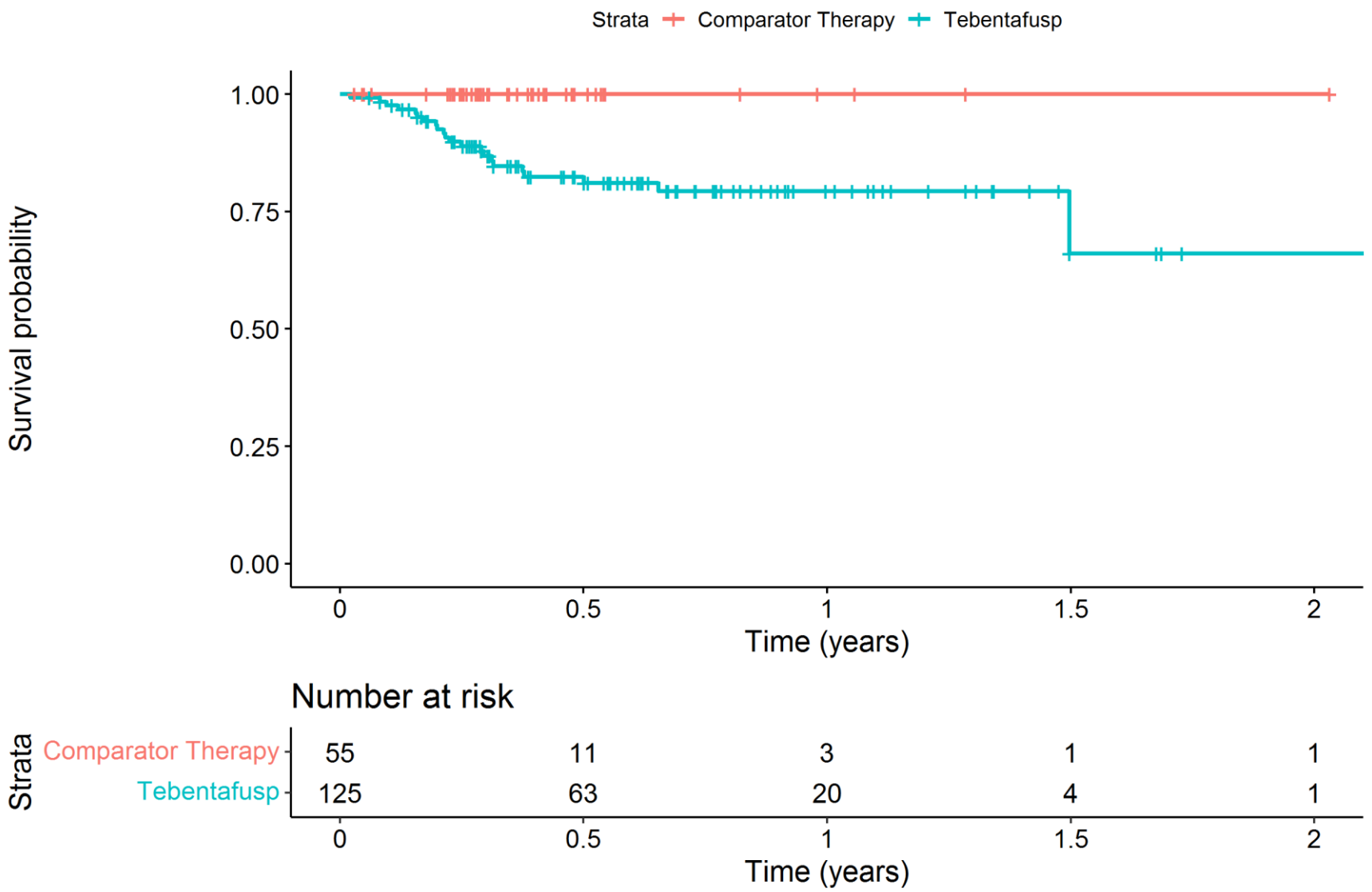
53.478 Veränderung der Haarfarbe - Hispanisch



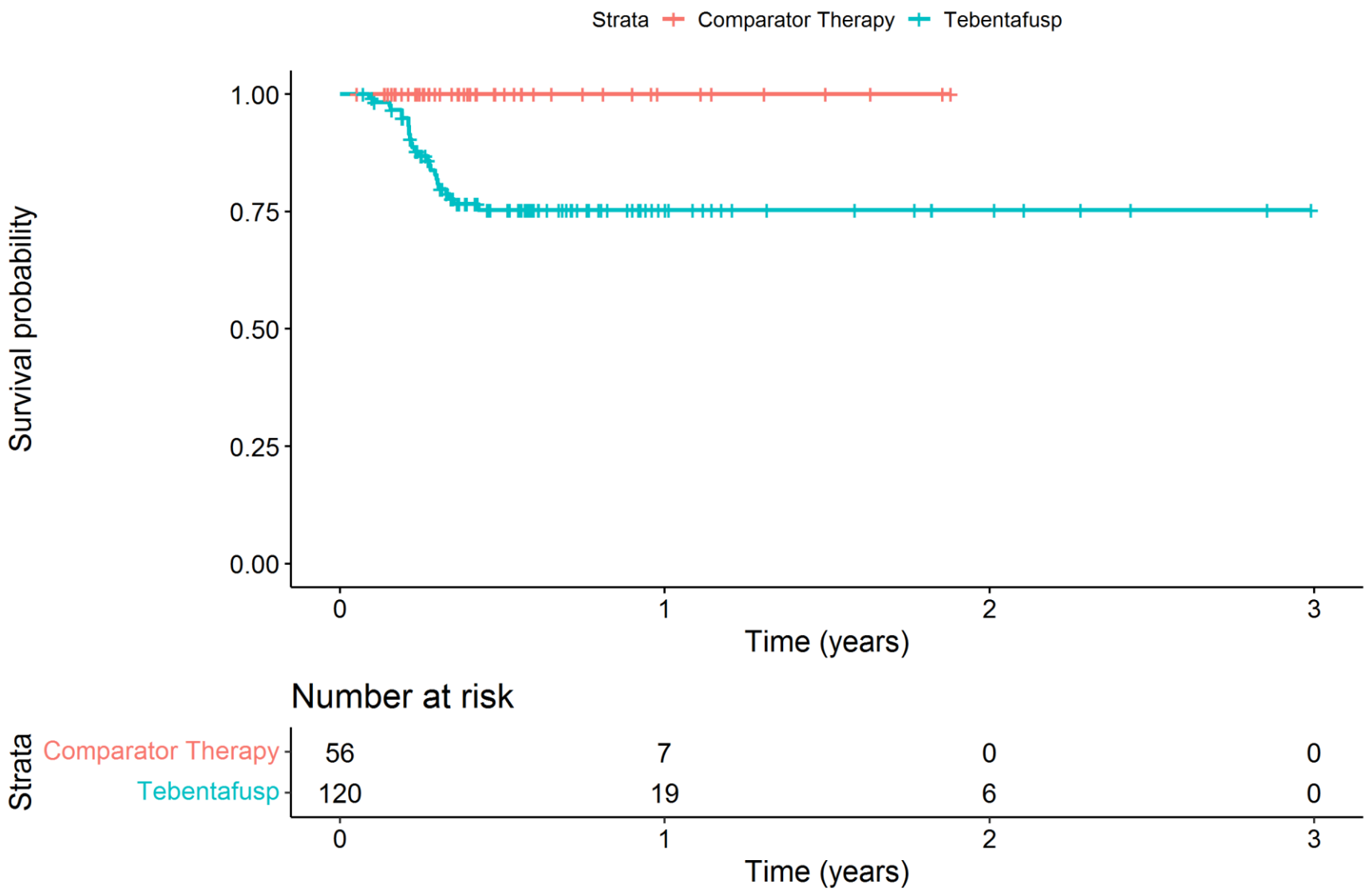
53.479 Veränderung der Haarfarbe - Nicht-hispanisch



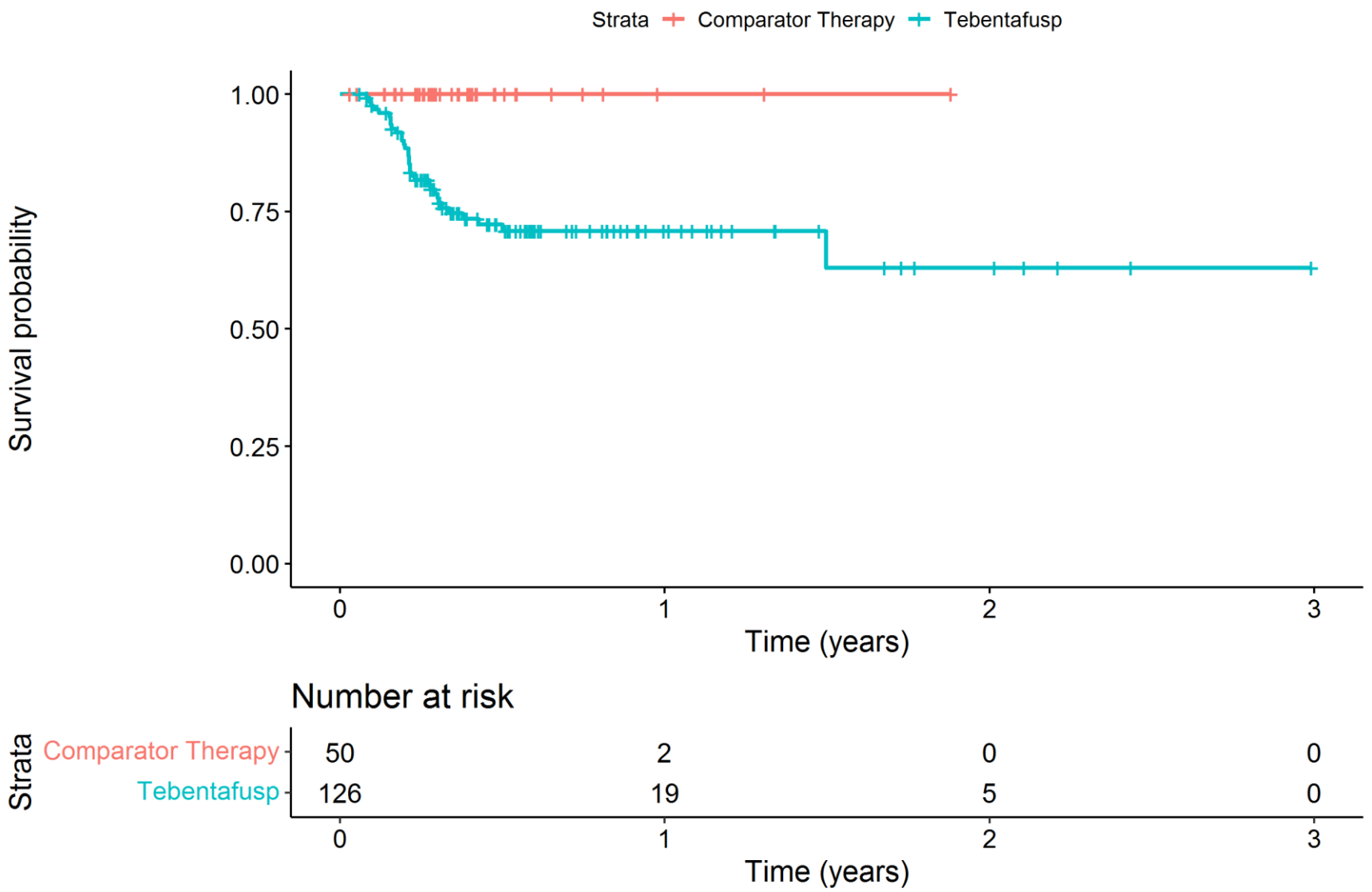
53.480 Veränderung der Haarfarbe - Männlich



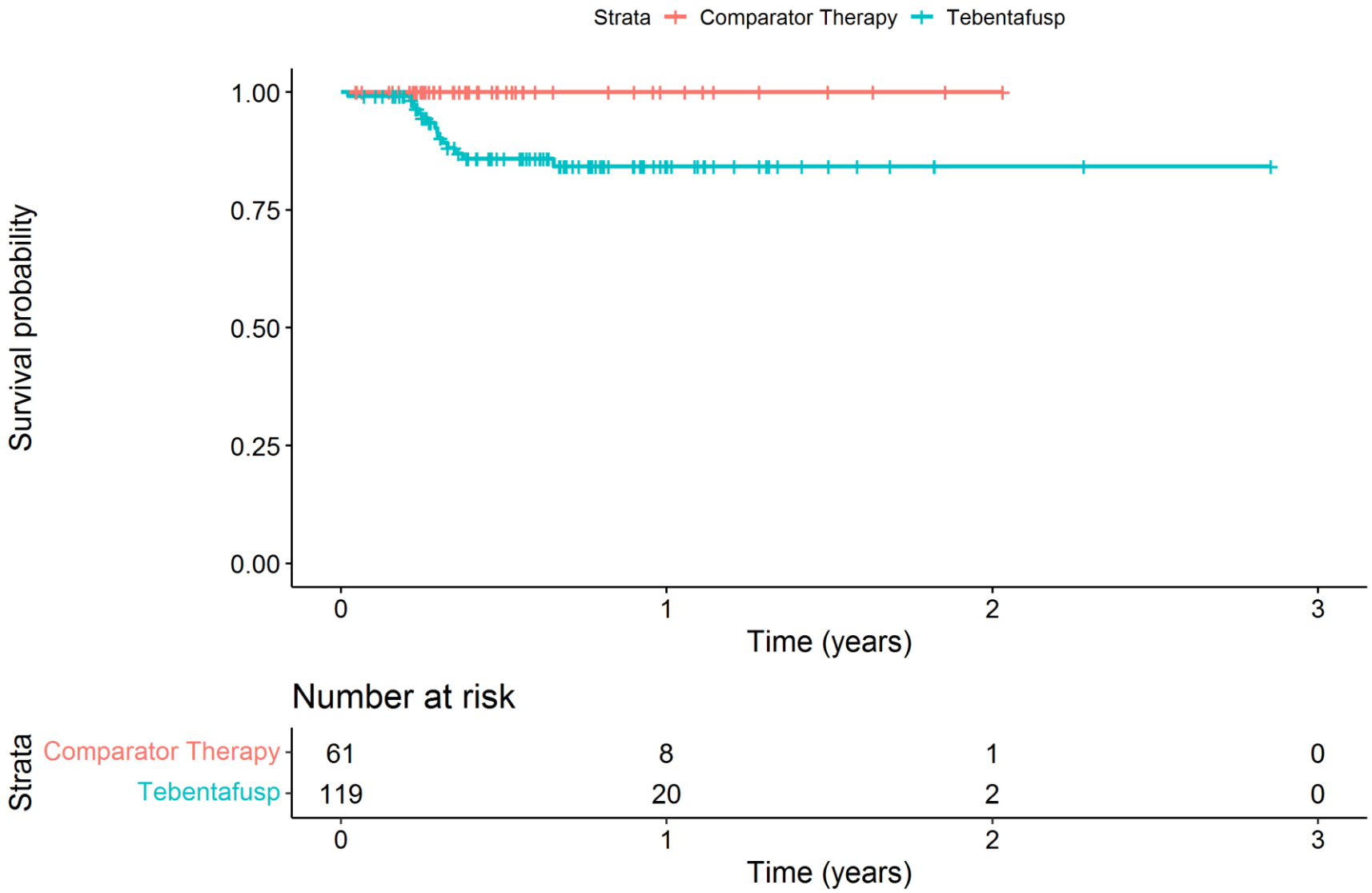
53.481 Veränderung der Haarfarbe - Weiblich



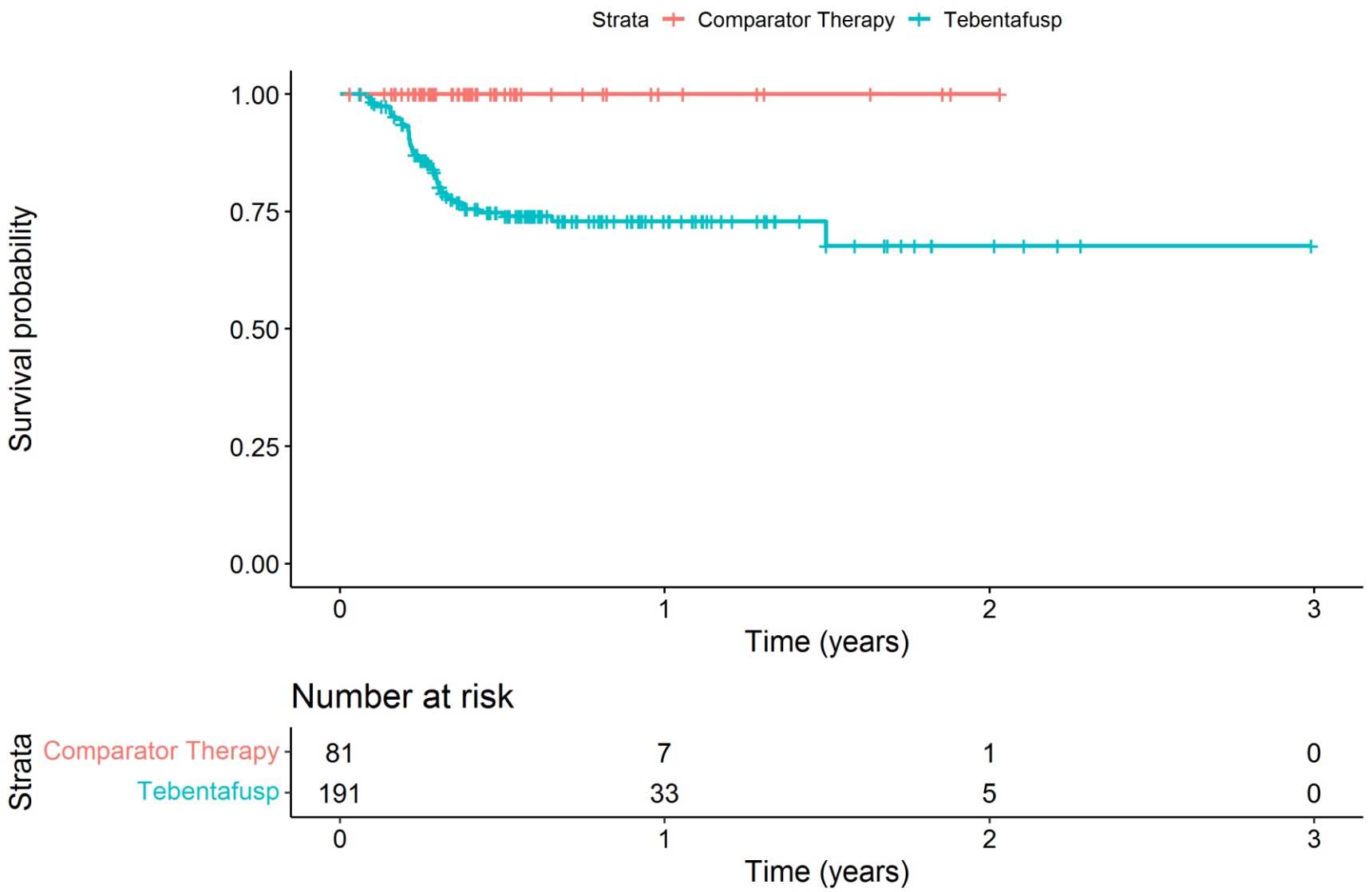
53.482 Veränderung der Haarfarbe - <65



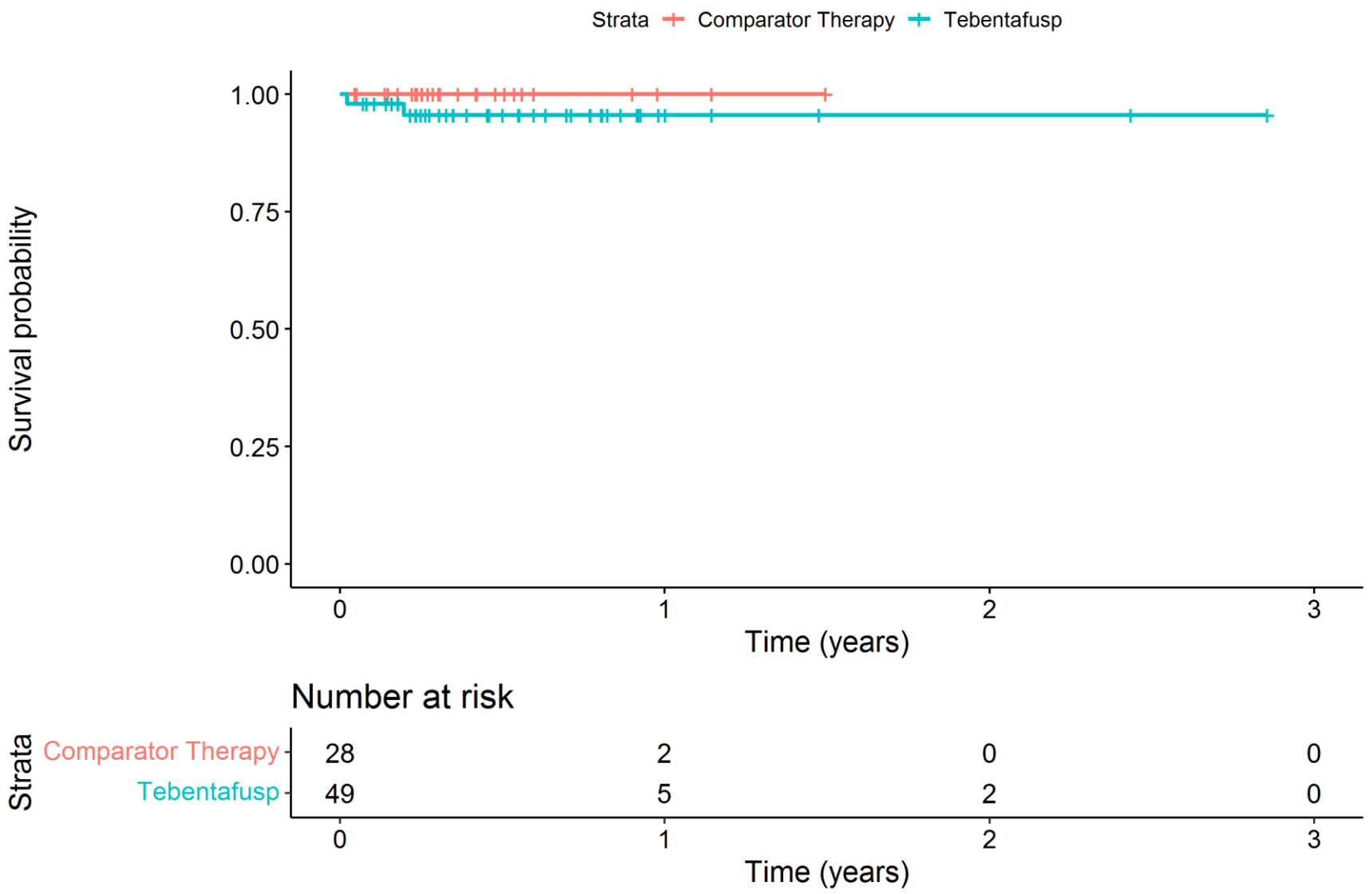
53.483 Veränderung der Haarfarbe - ≥65



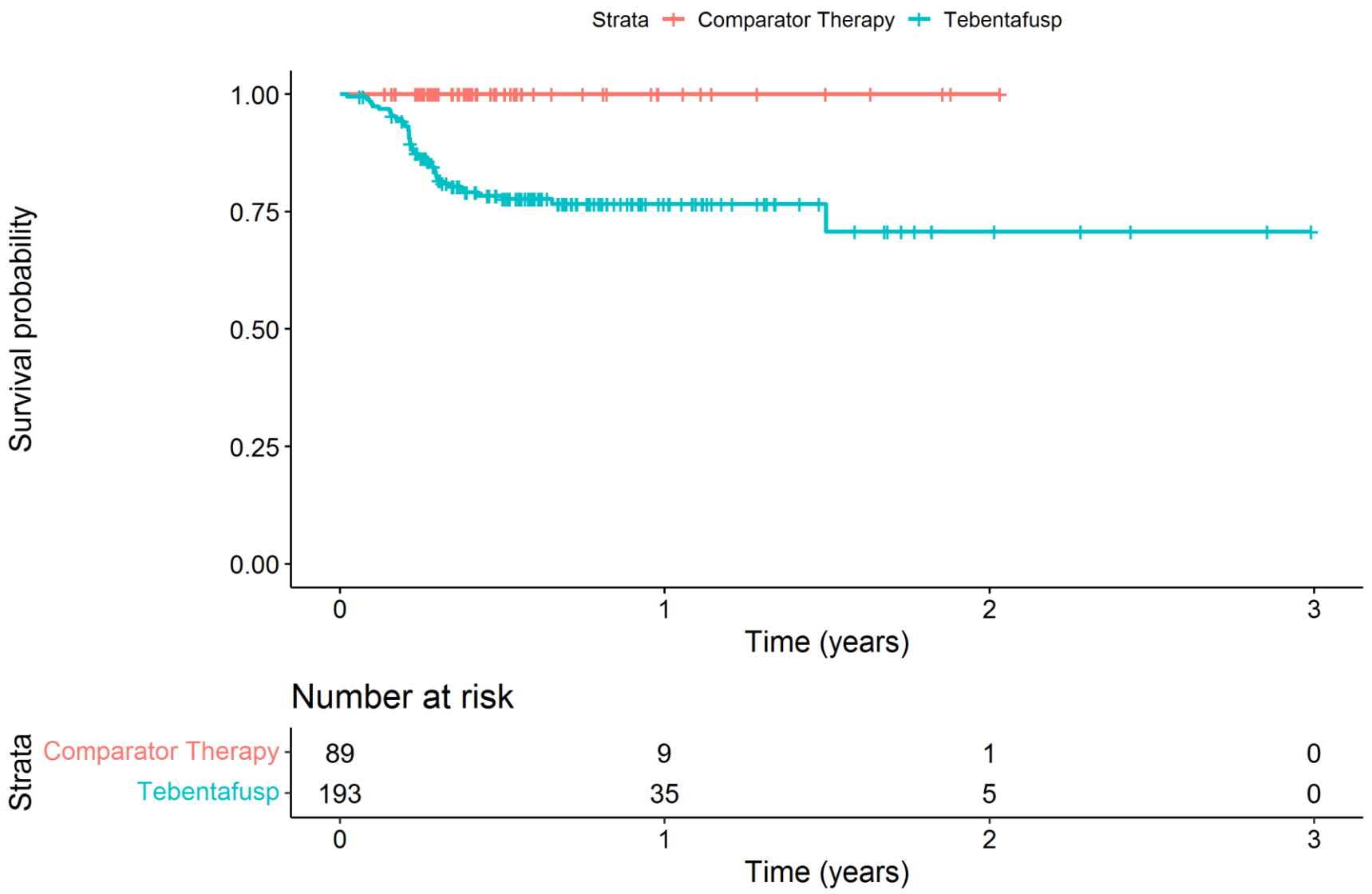
53.484 Veränderung der Haarfarbe - ECOG 0



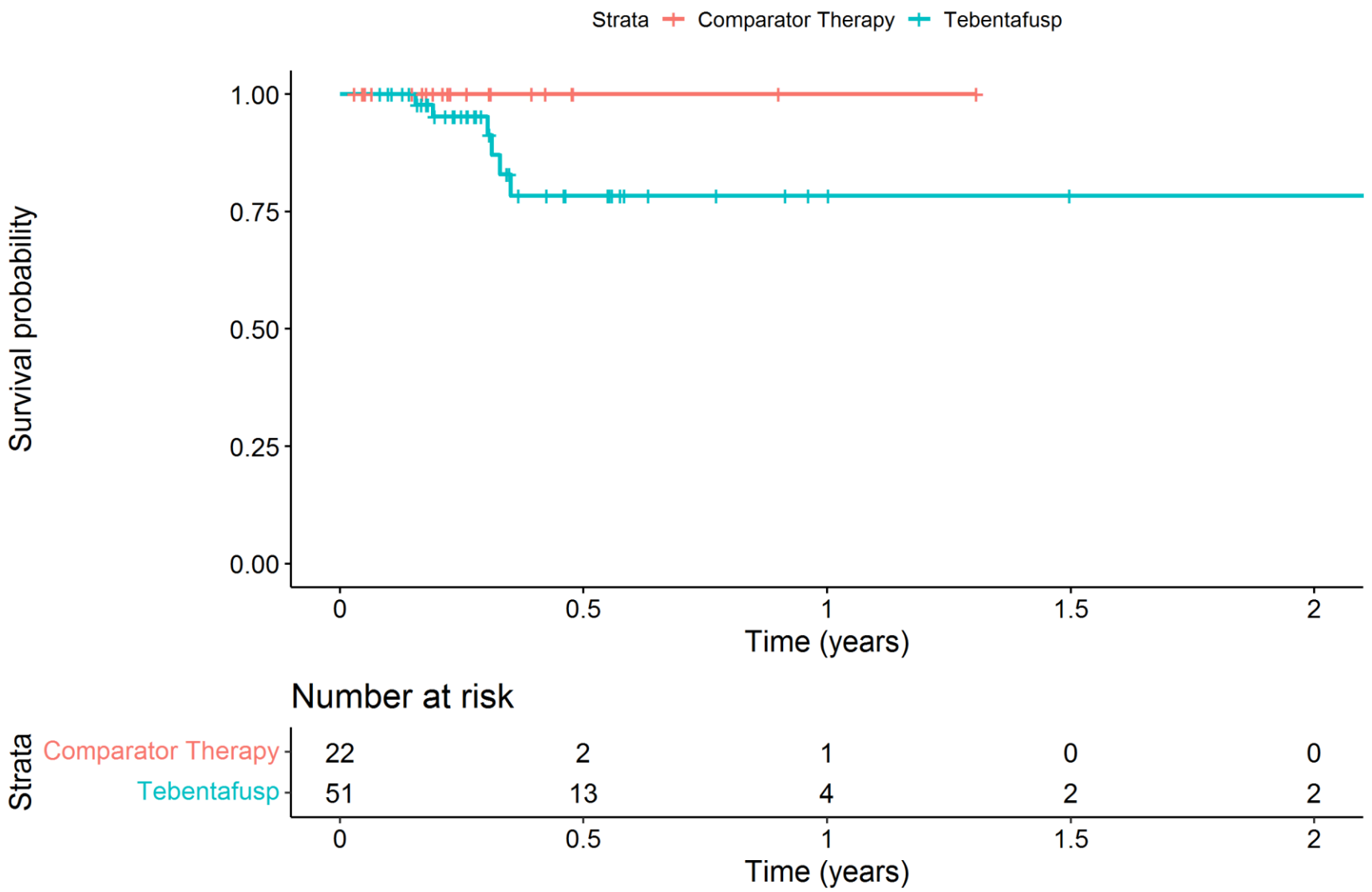
53.485 Veränderung der Haarfarbe - ECOG 1



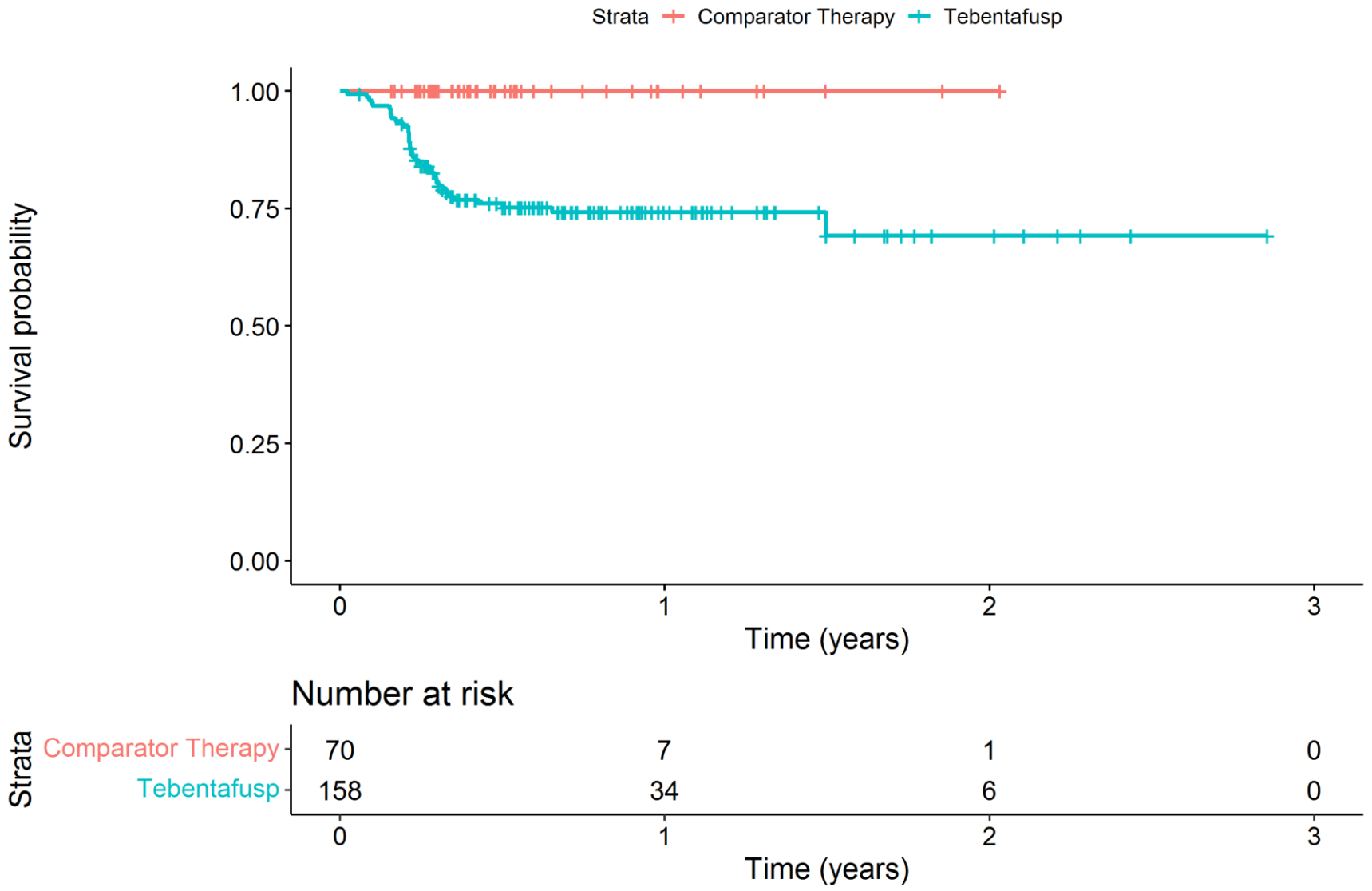
53.486 Veränderung der Haarfarbe - ALP ≤ ULN



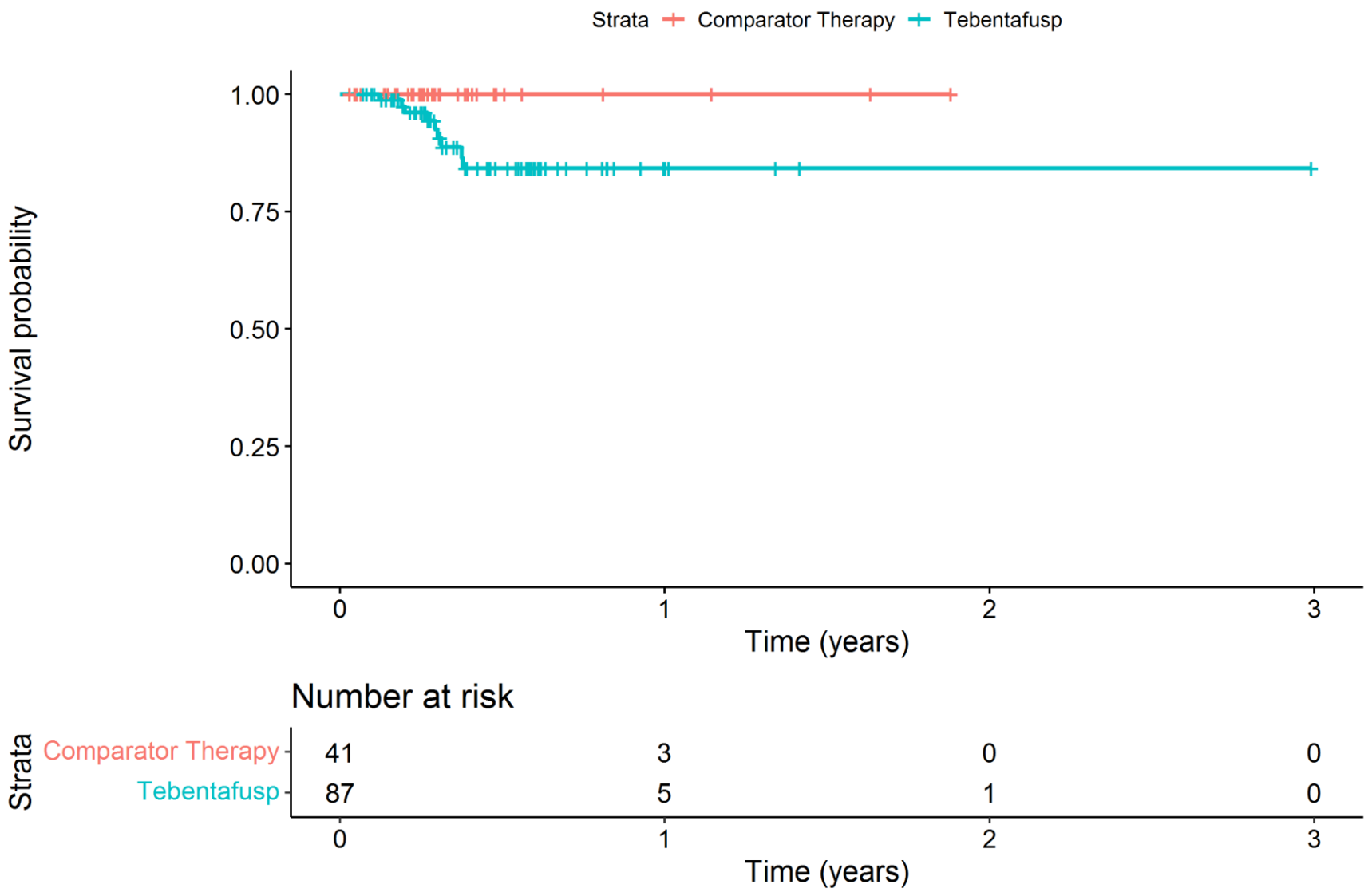
53.487 Veränderung der Haarfarbe - ALP > ULN



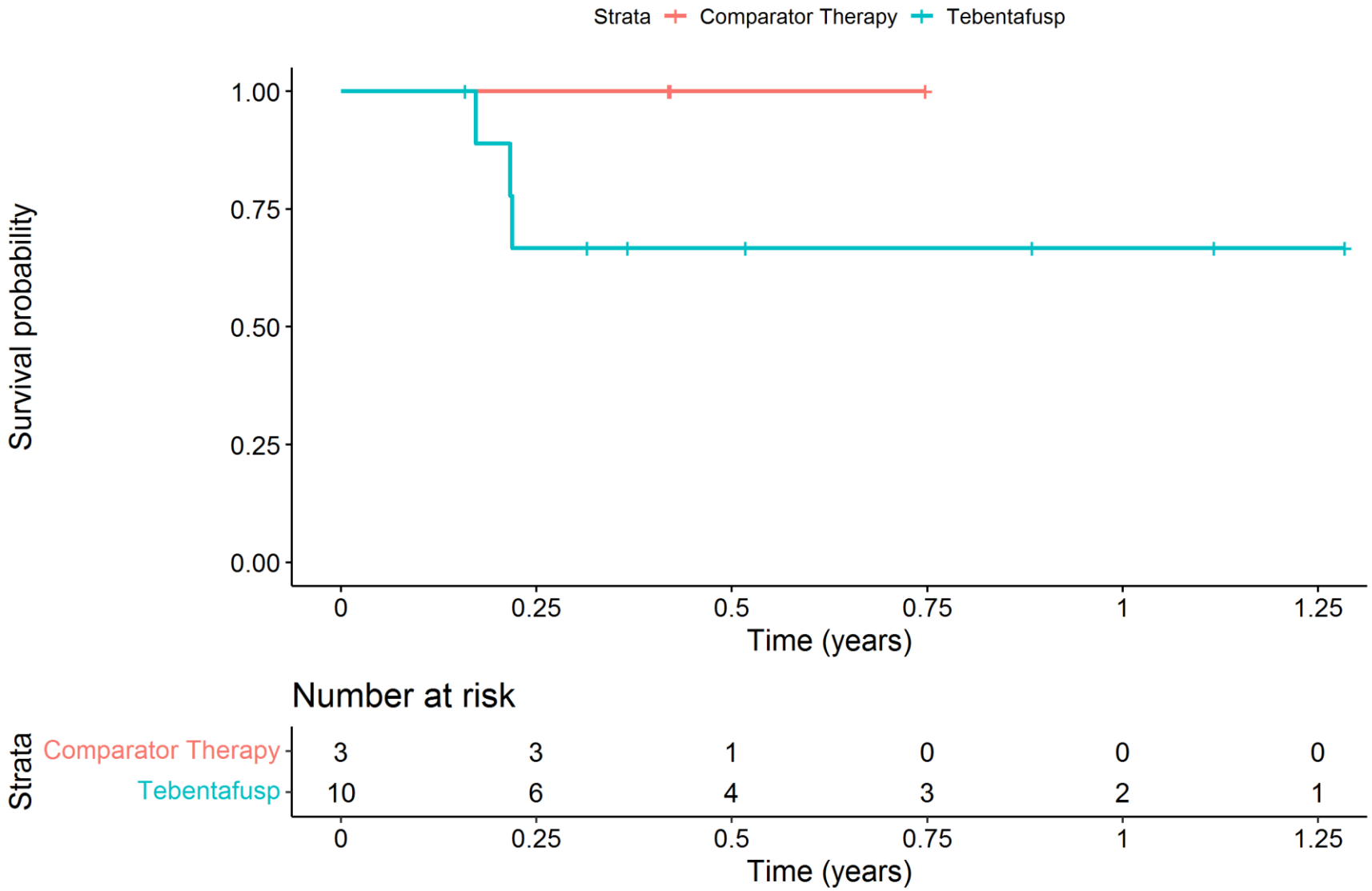
53.488 Veränderung der Haarfarbe - LDH =< ULN



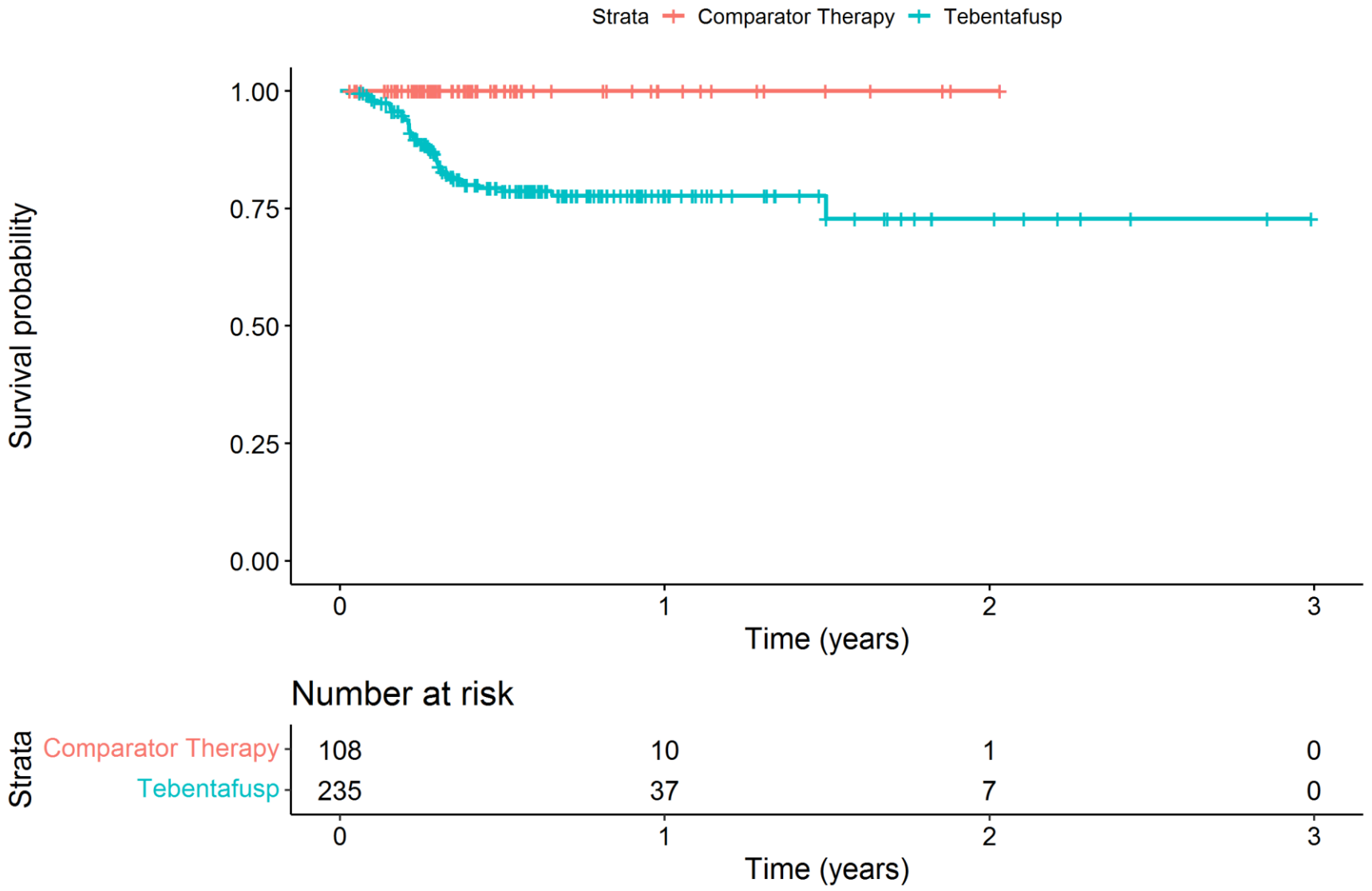
53.489 Veränderung der Haarfarbe - LDH > ULN



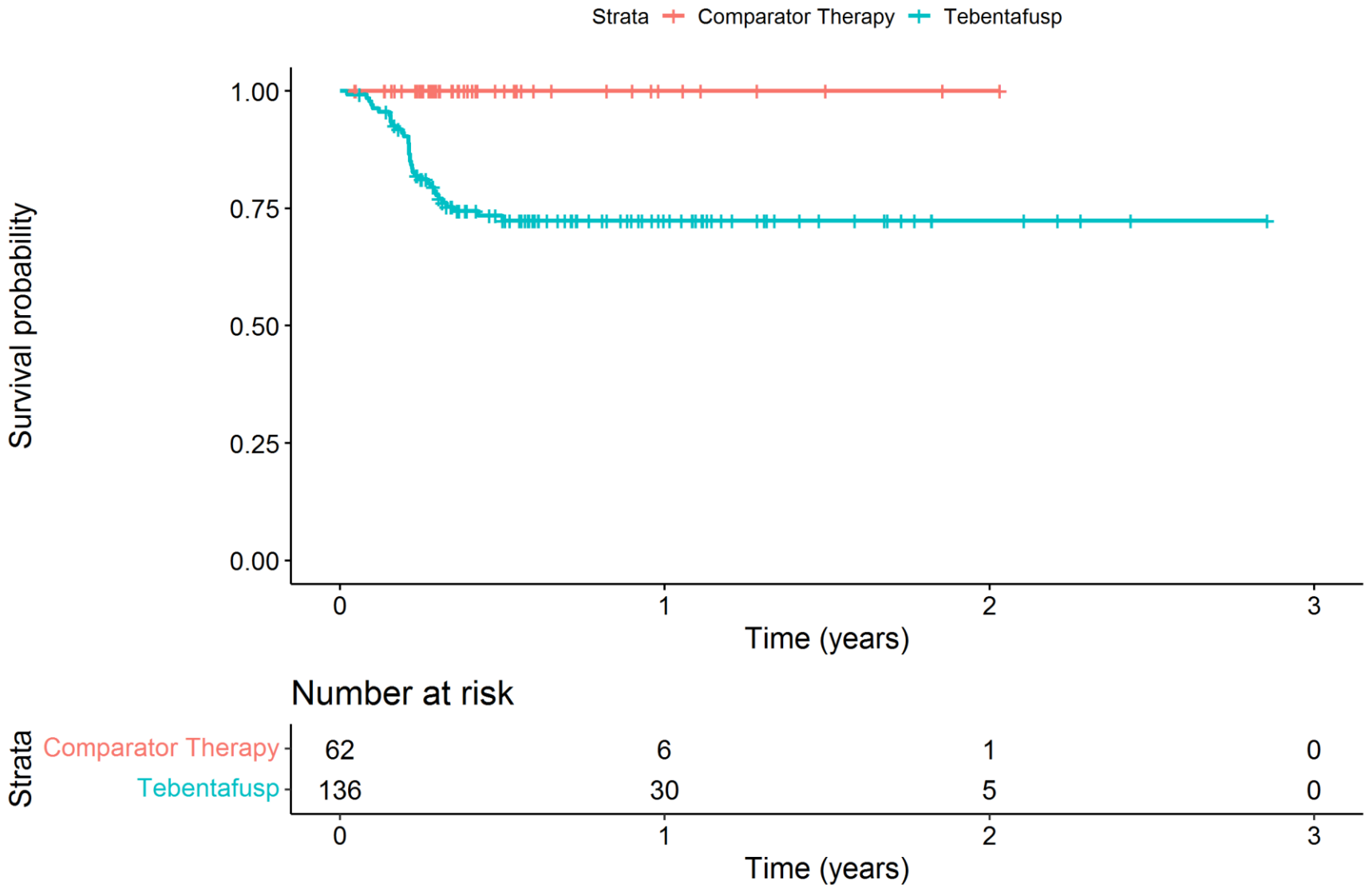
53.490 Veränderung der Haarfarbe - Vorherige Therapie adjuvant/neoadjuvant



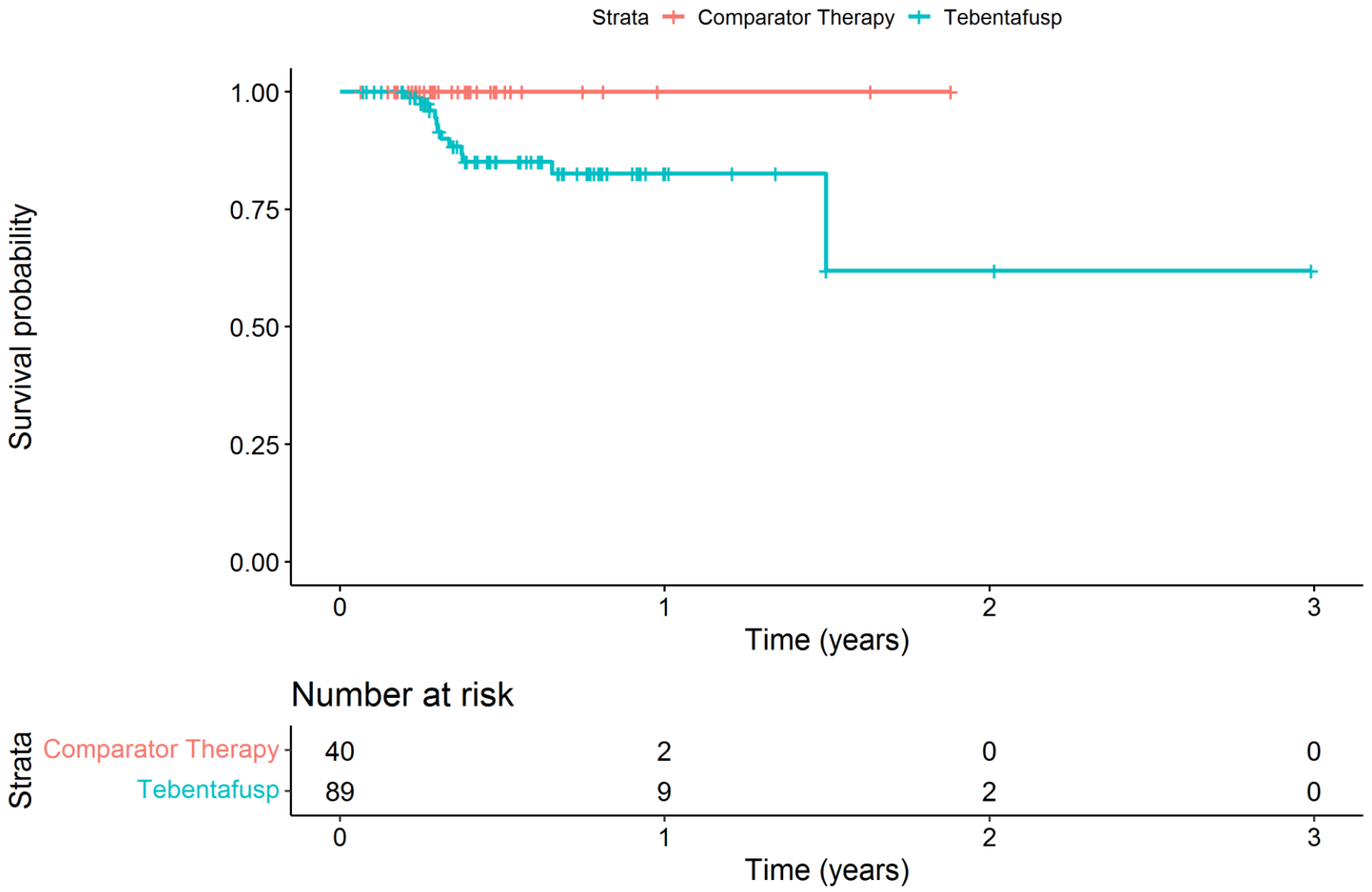
53.491 Veränderung der Haarfarbe - Keine vorherige Therapie adjuvant/neoadjuvant



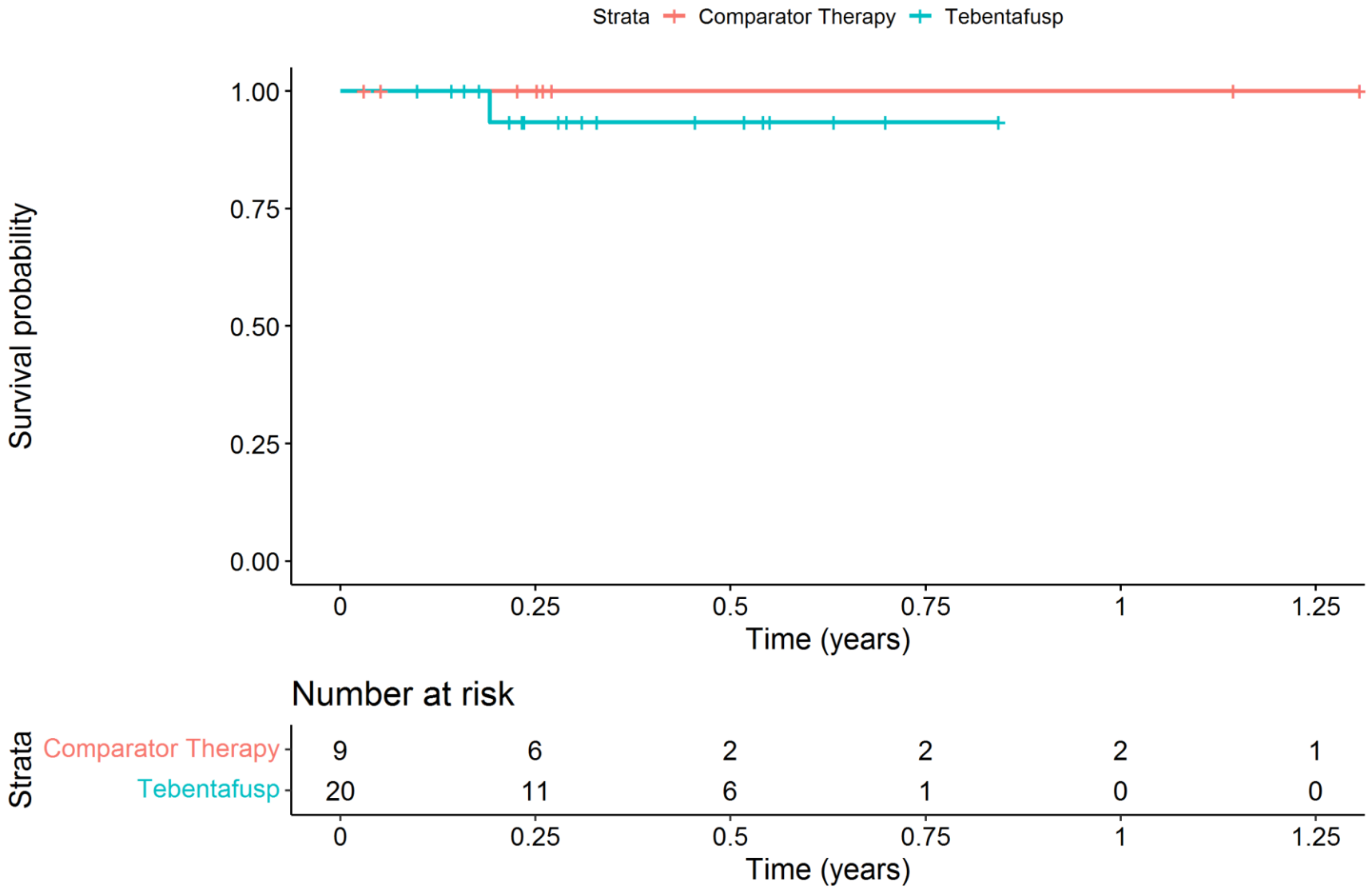
53.492 Veränderung der Haarfarbe - Läsion ≤ 3cm



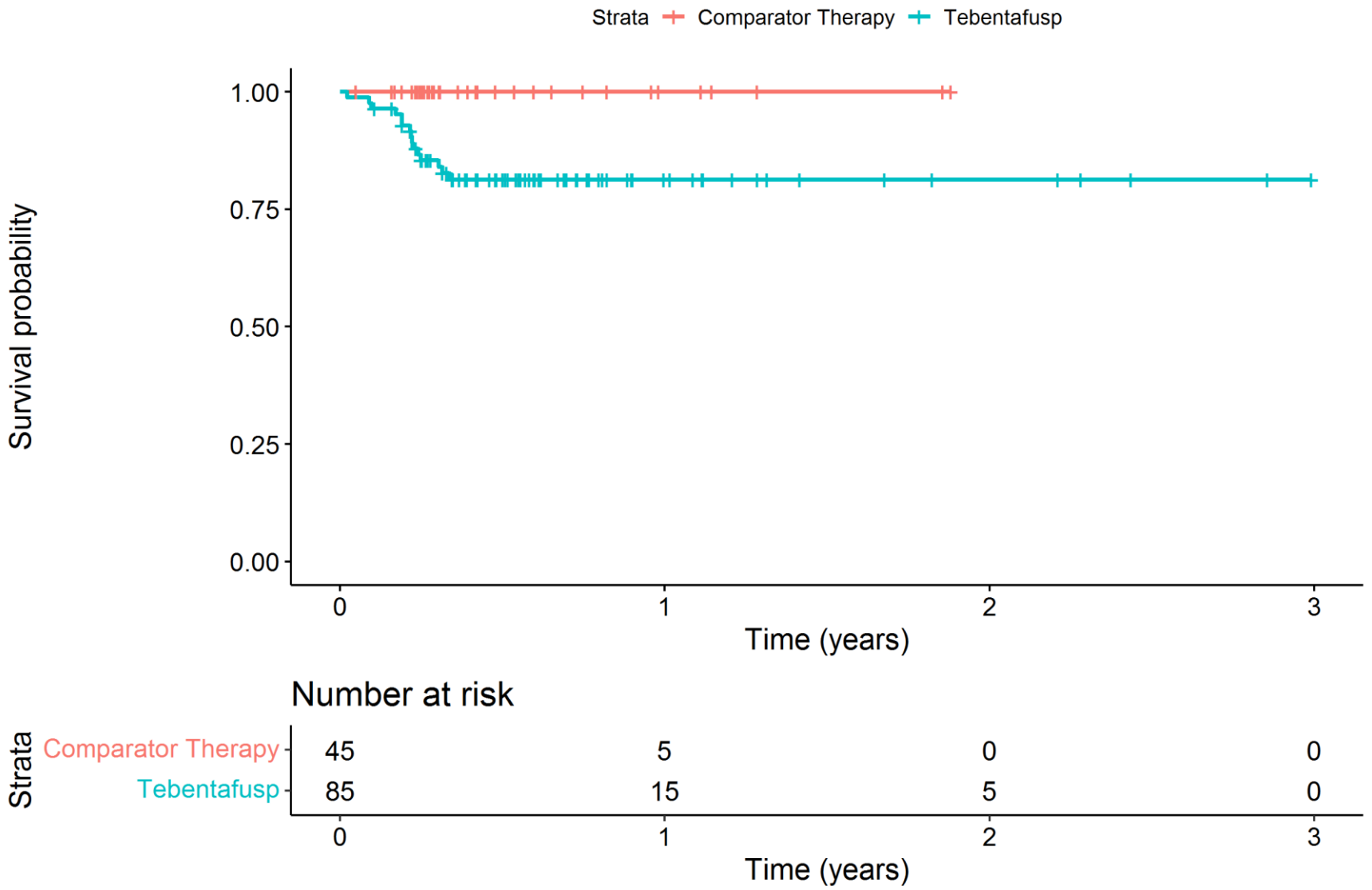
53.493 Veränderung der Haarfarbe - Läsion 3,1-8,0 cm



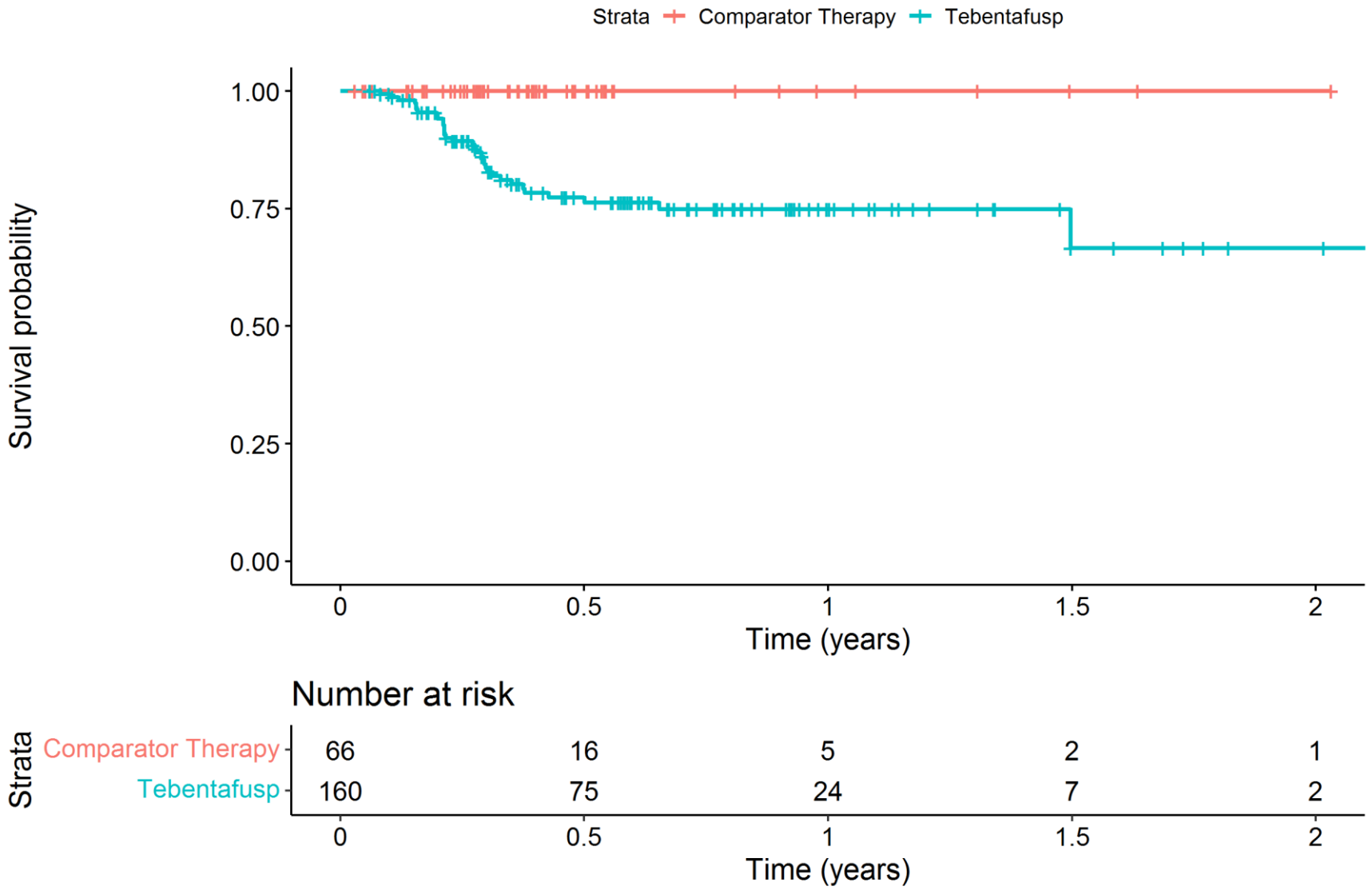
53.494 Veränderung der Haarfarbe - Läsion ≥8,1 cm



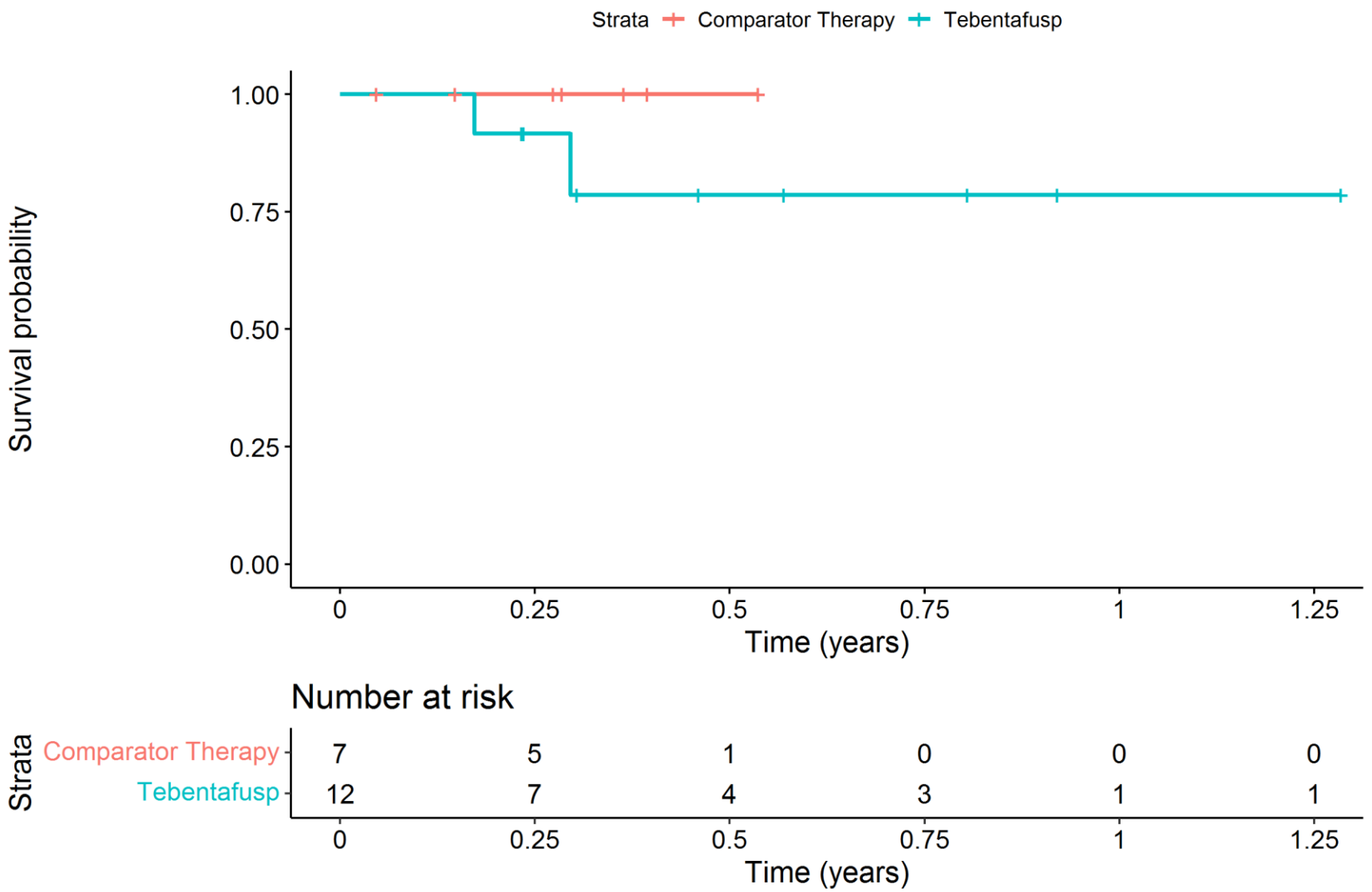
53.495 Veränderung der Haarfarbe - Nordamerika



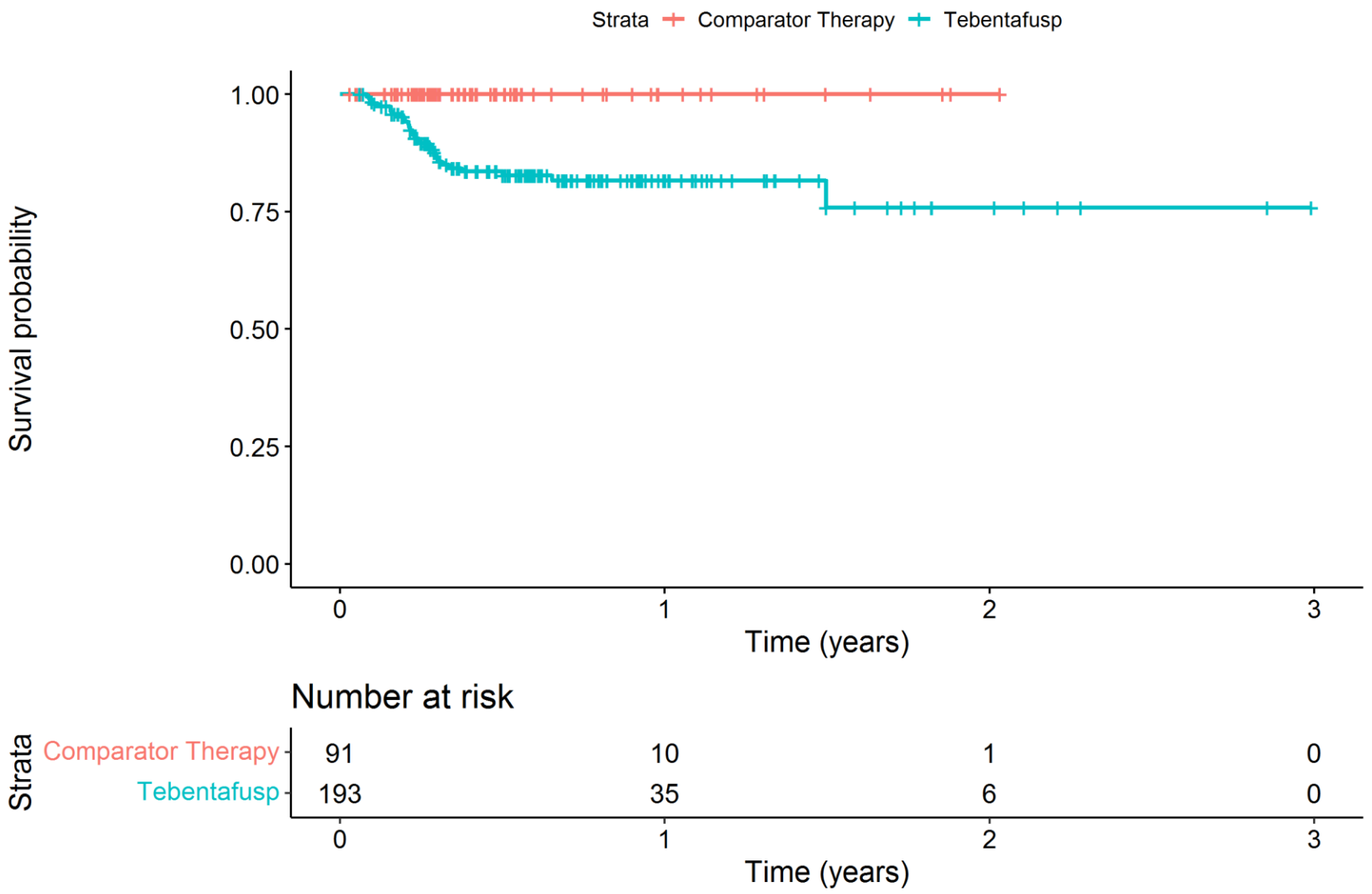
53.496 Veränderung der Haarfarbe - Nicht-Nordamerika



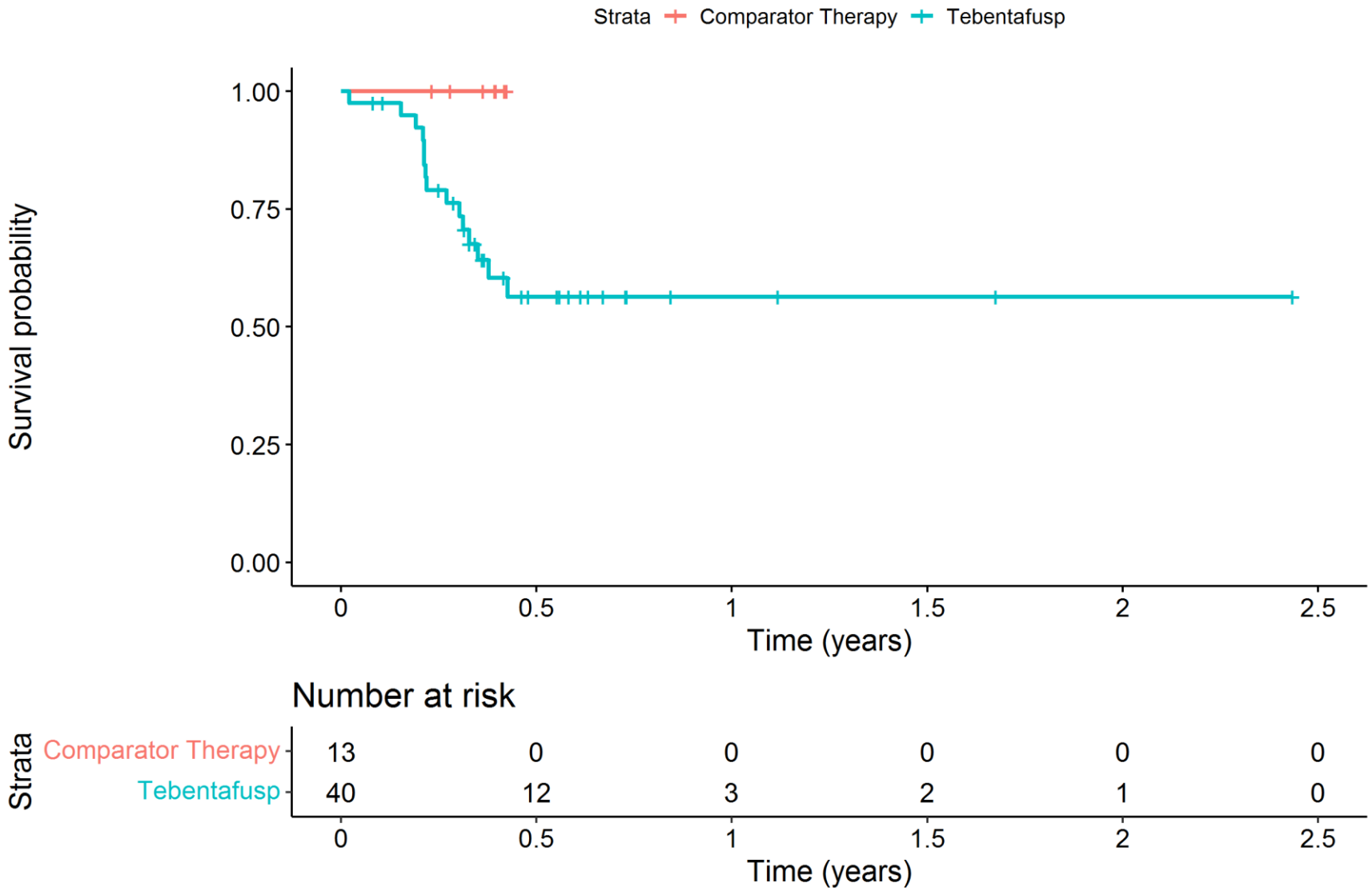
53.497 Veränderung der Haarfarbe - Dacarbazin



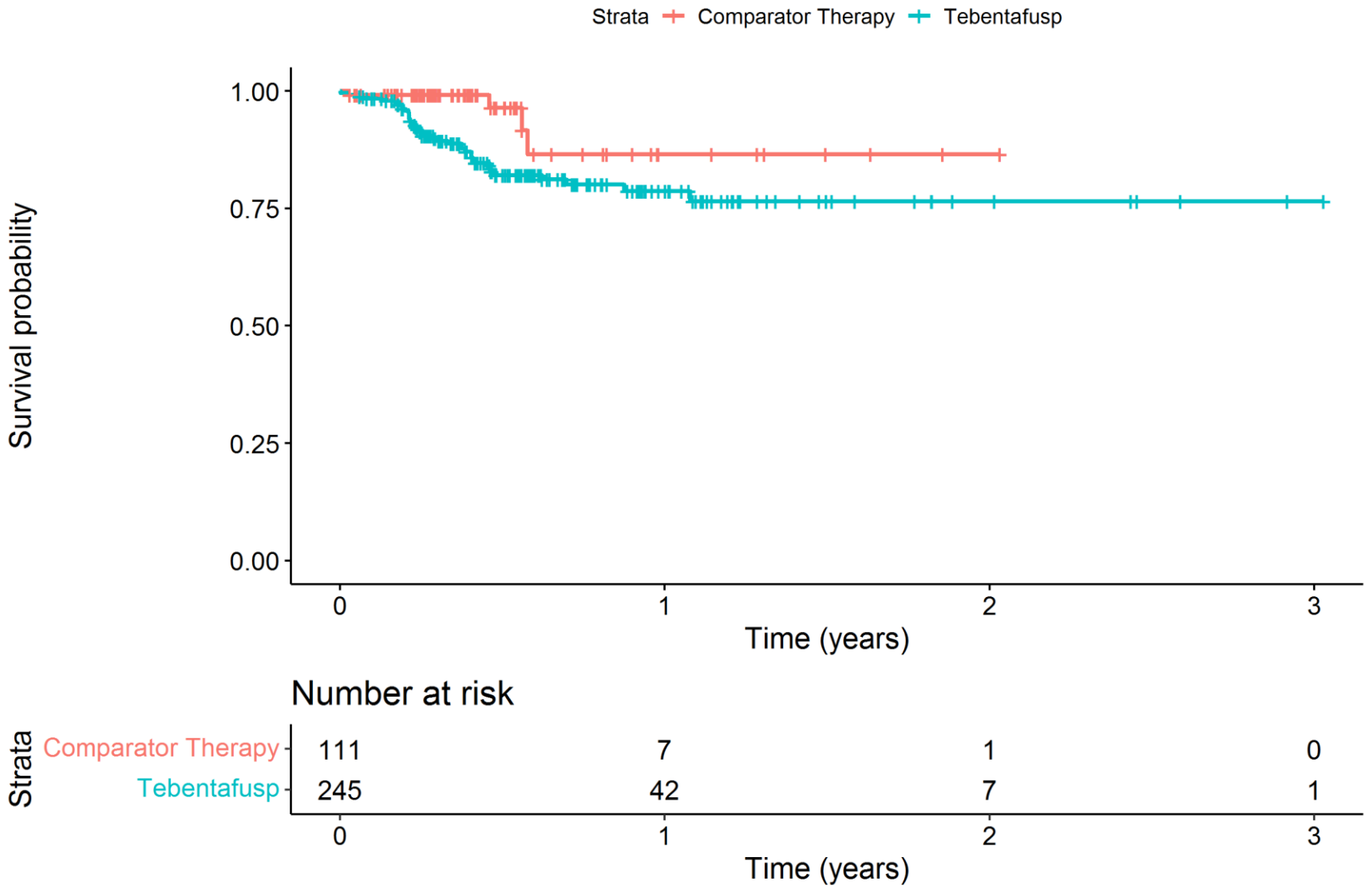
53.498 Veränderung der Haarfarbe - Pembrolizumab



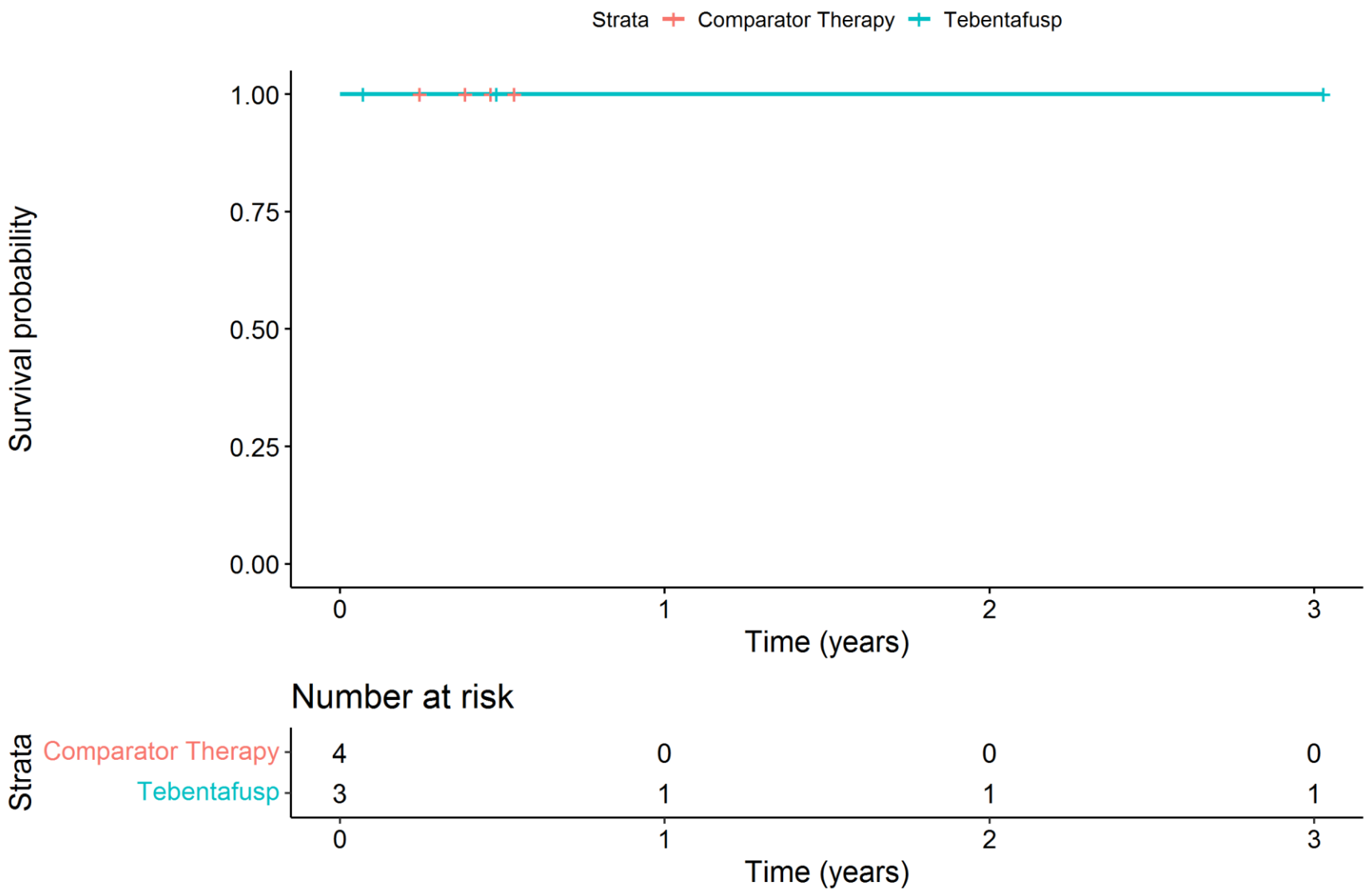
53.499 Veränderung der Haarfarbe - Ipilimumab



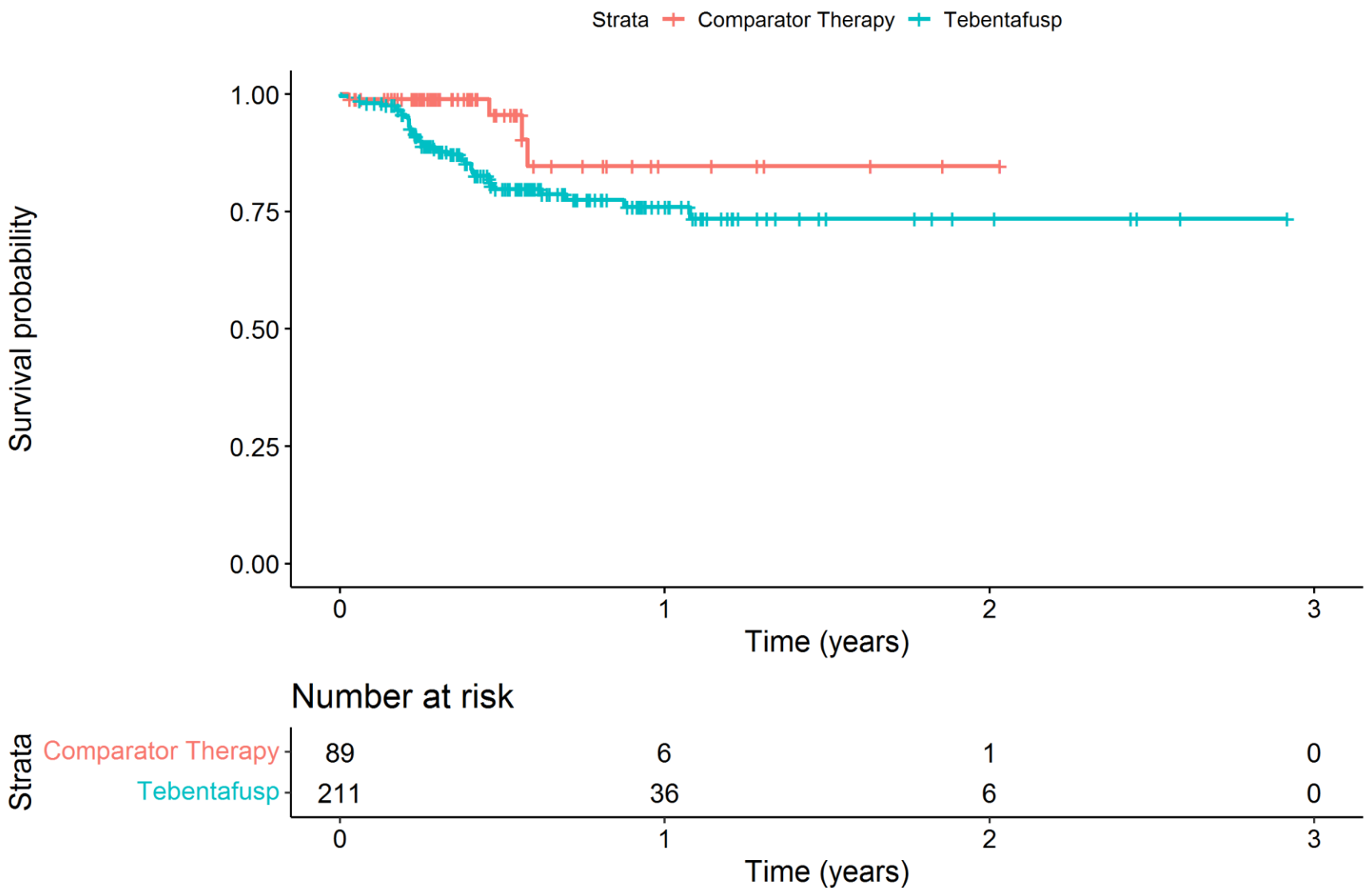
53.500 Vitiligo - Gesamt



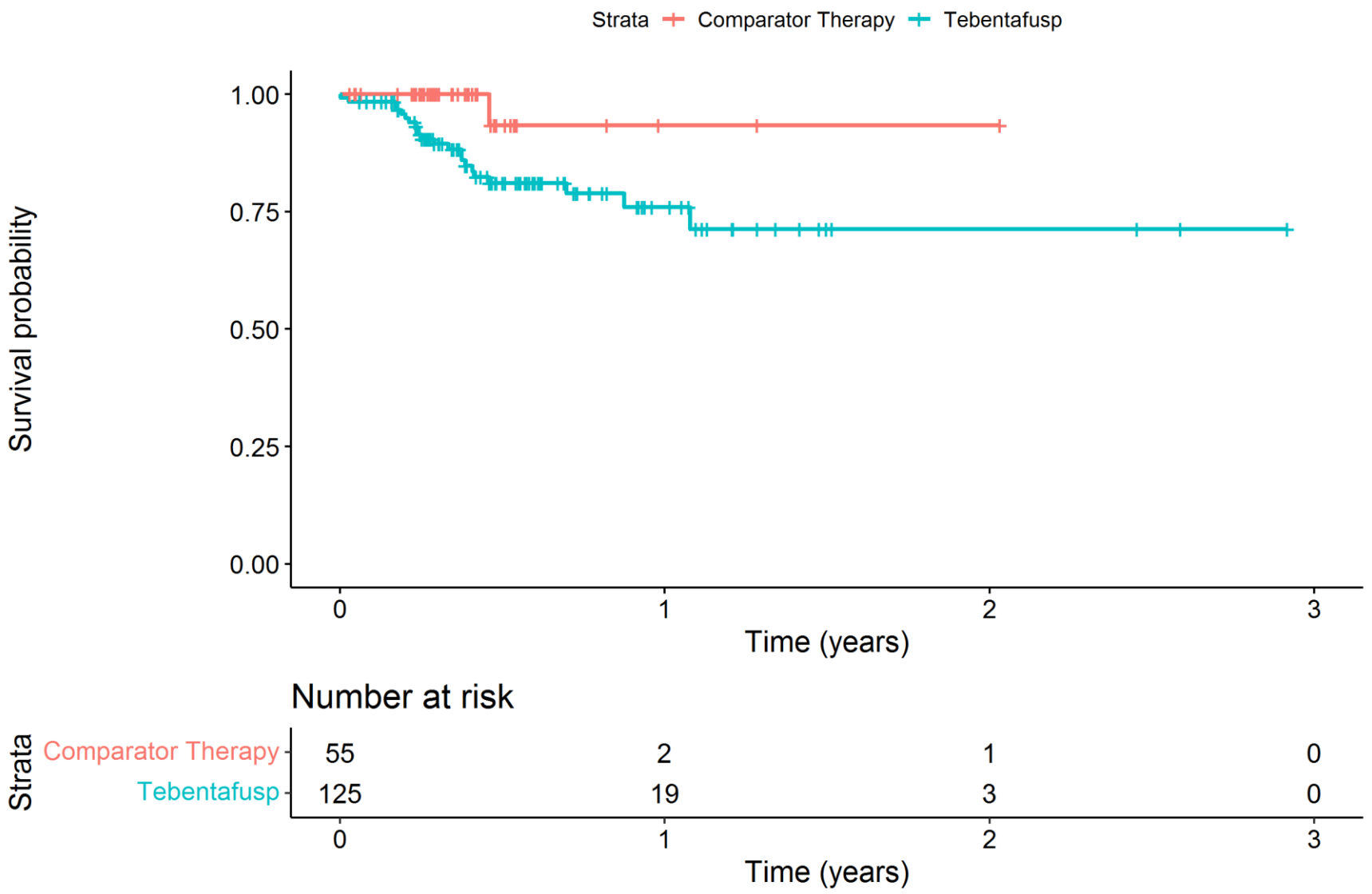
53.501 Vitiligo - Hispanisch



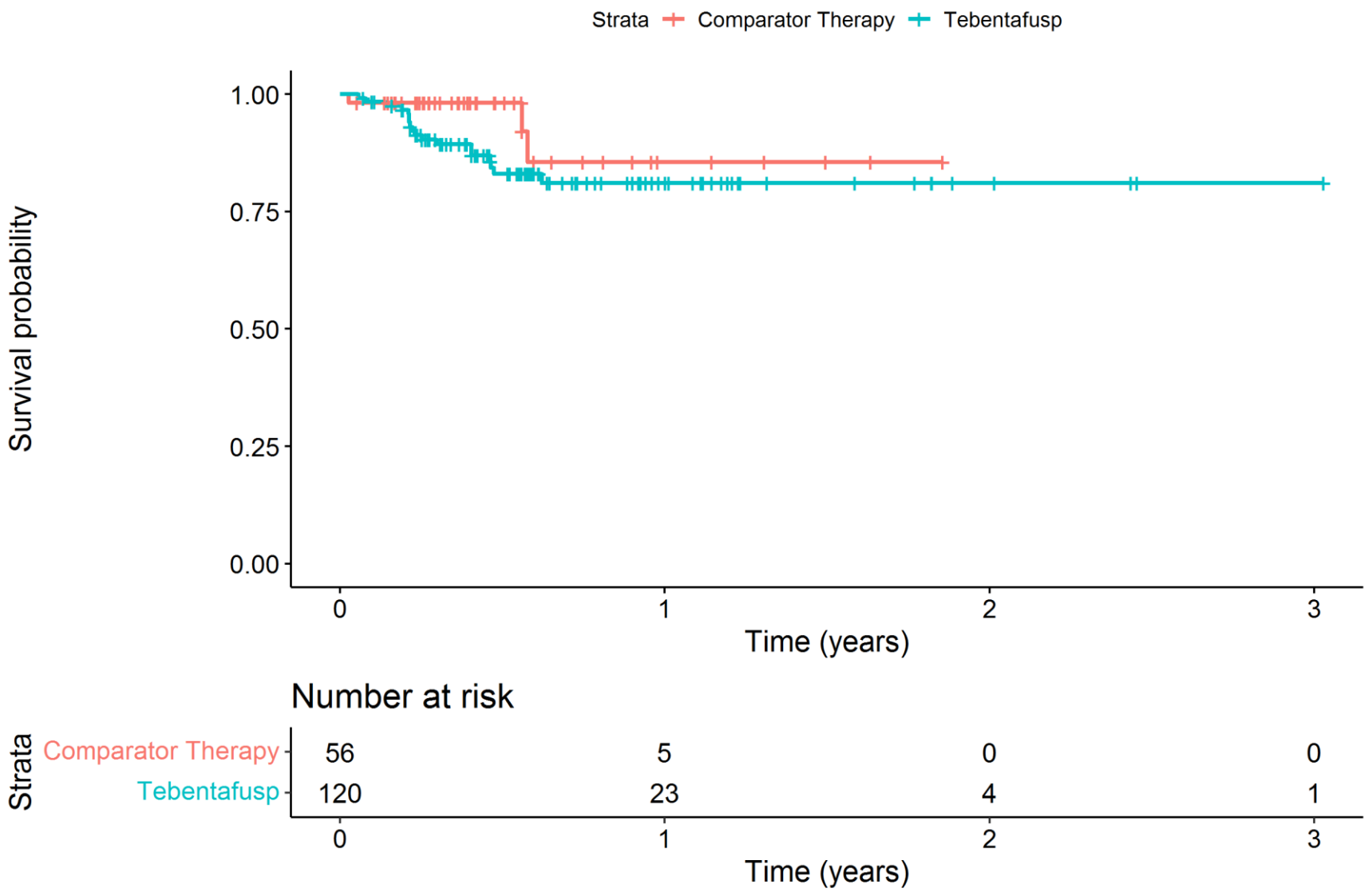
53.502 Vitiligo - Nicht-hispanisch



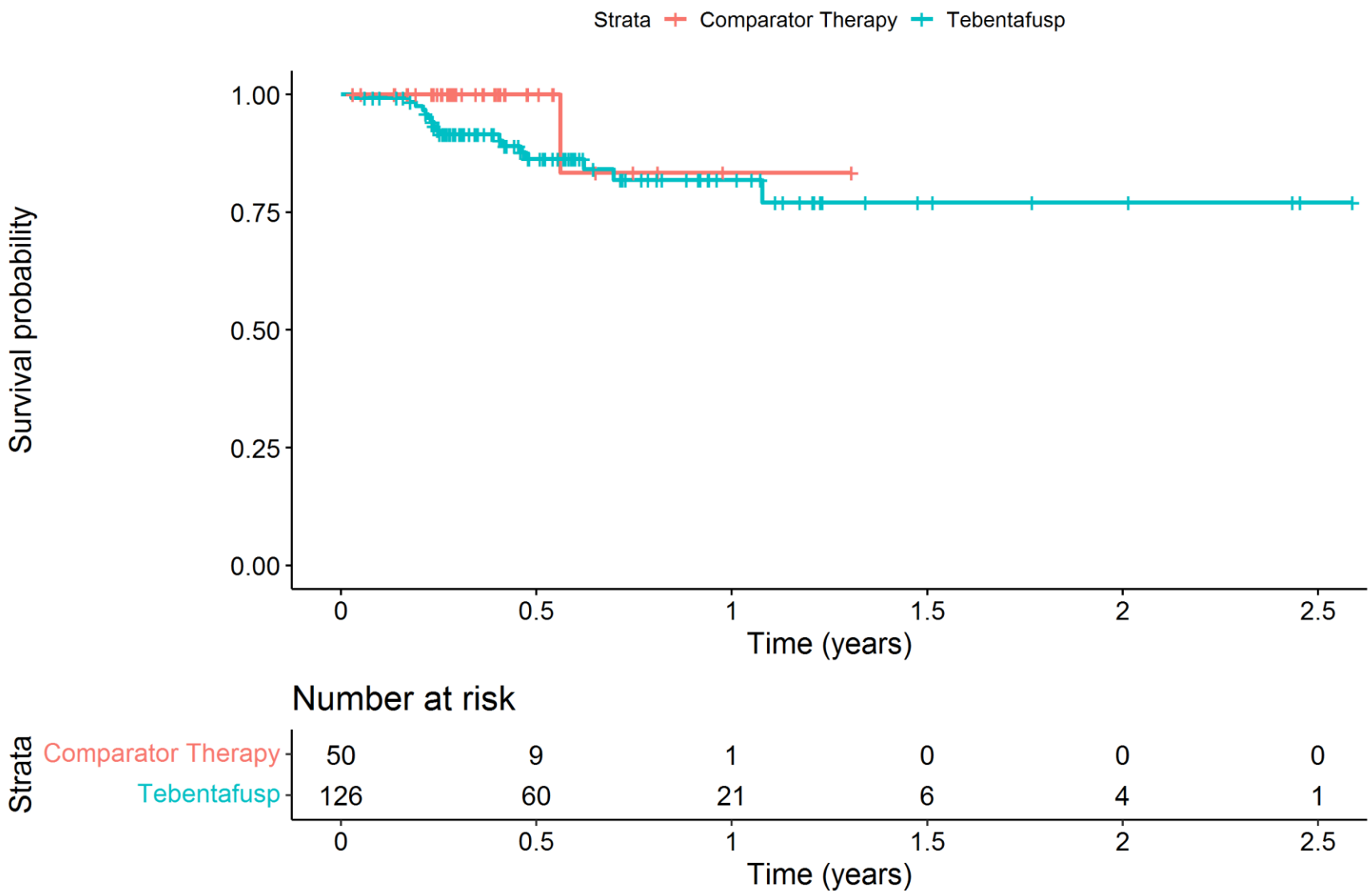
53.503 Vitiligo - Männlich



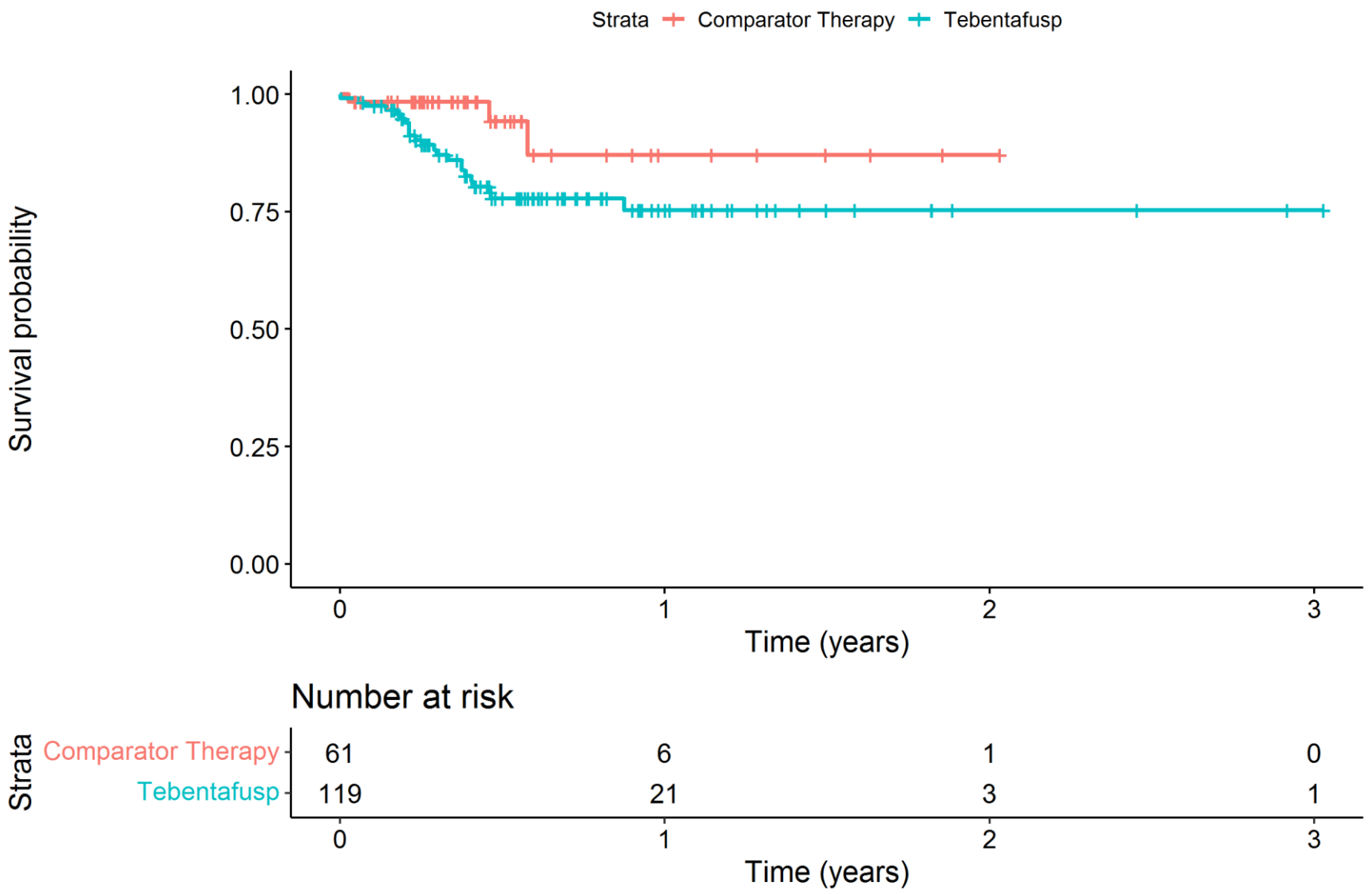
53.504 Vitiligo - Weiblich



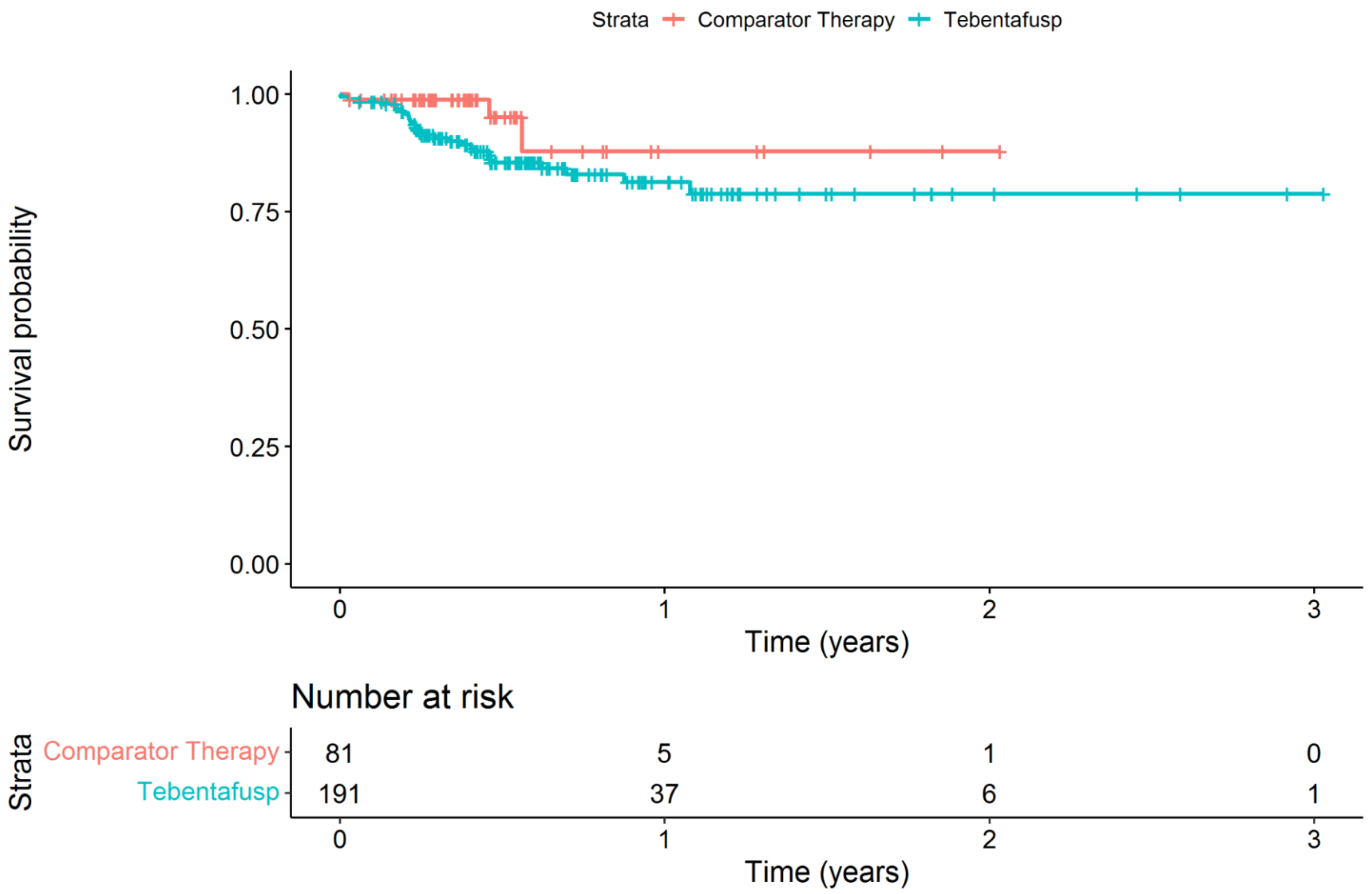
53.505 Vitiligo - <65



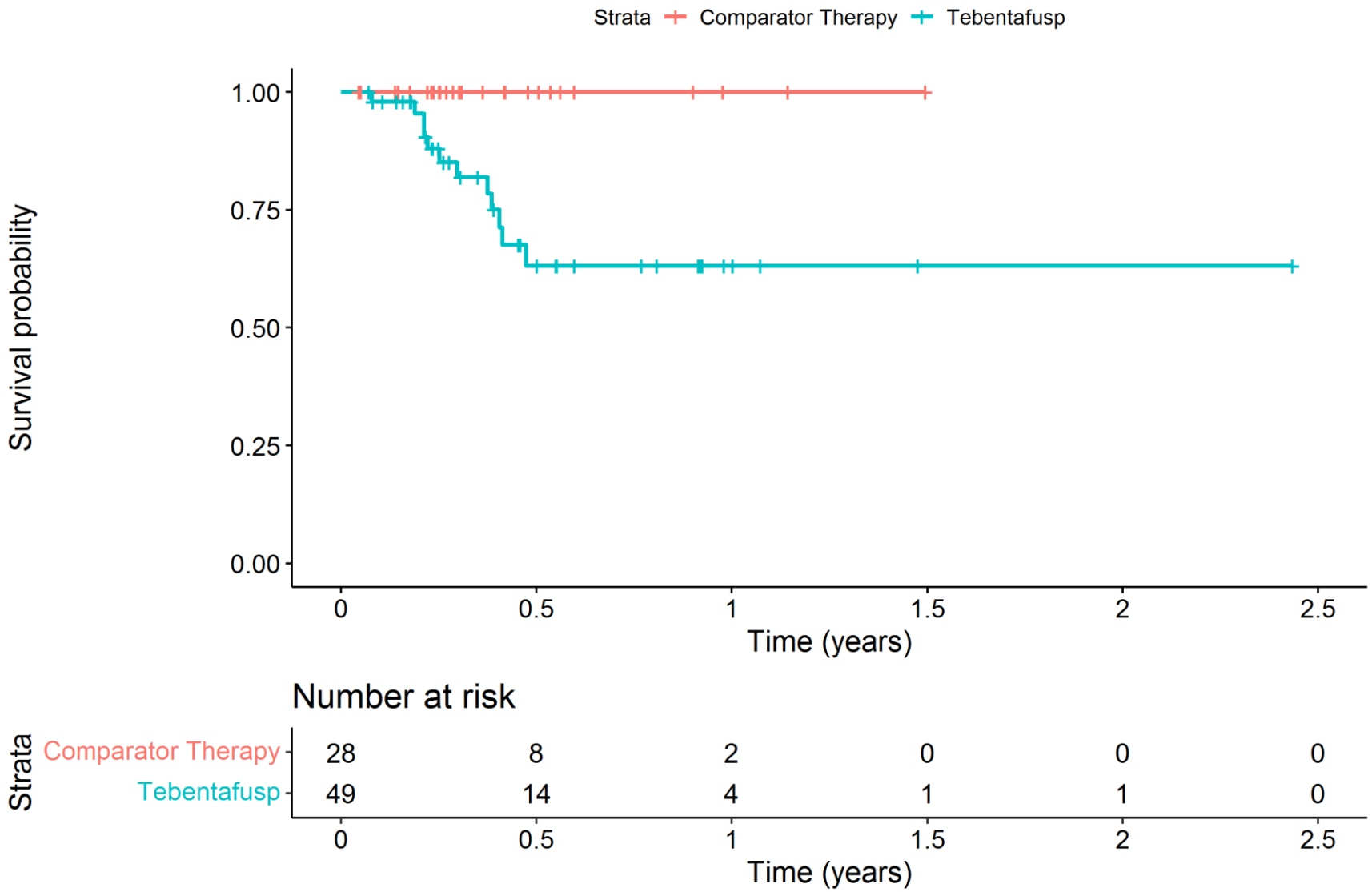
53.506 Vitiligo - ≥65



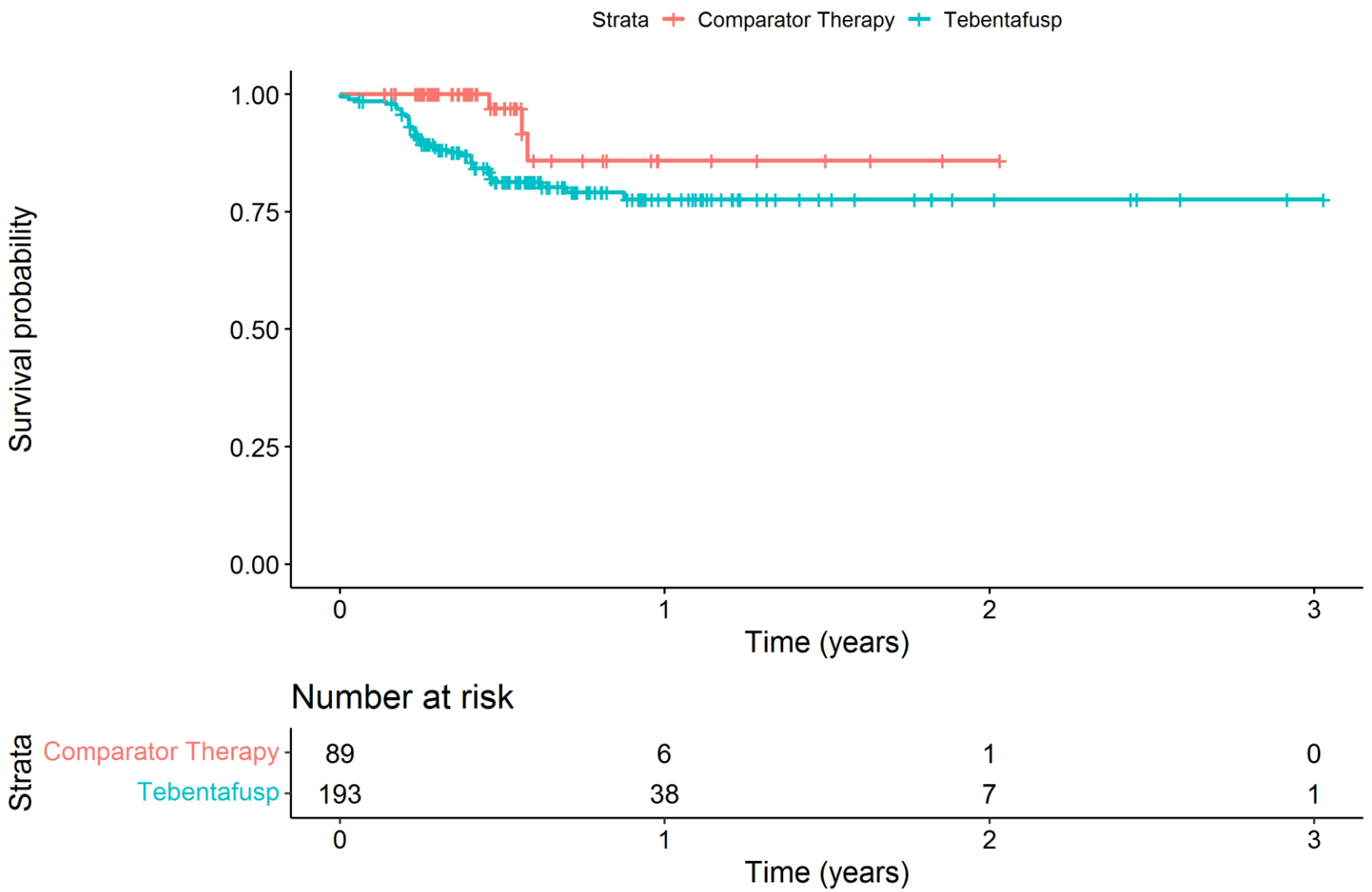
53.507 Vitiligo - ECOG 0



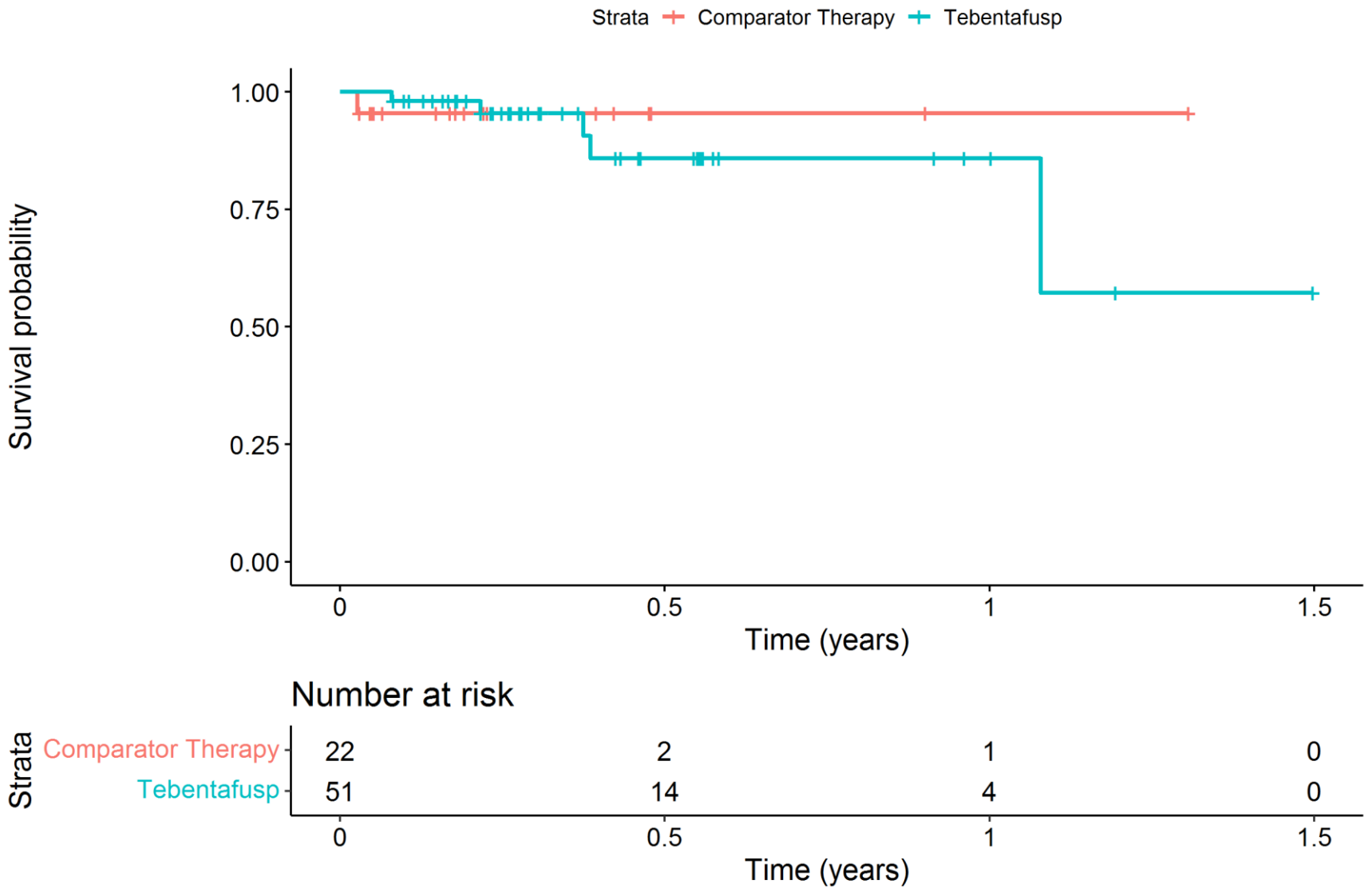
53.508 Vitiligo - ECOG 1



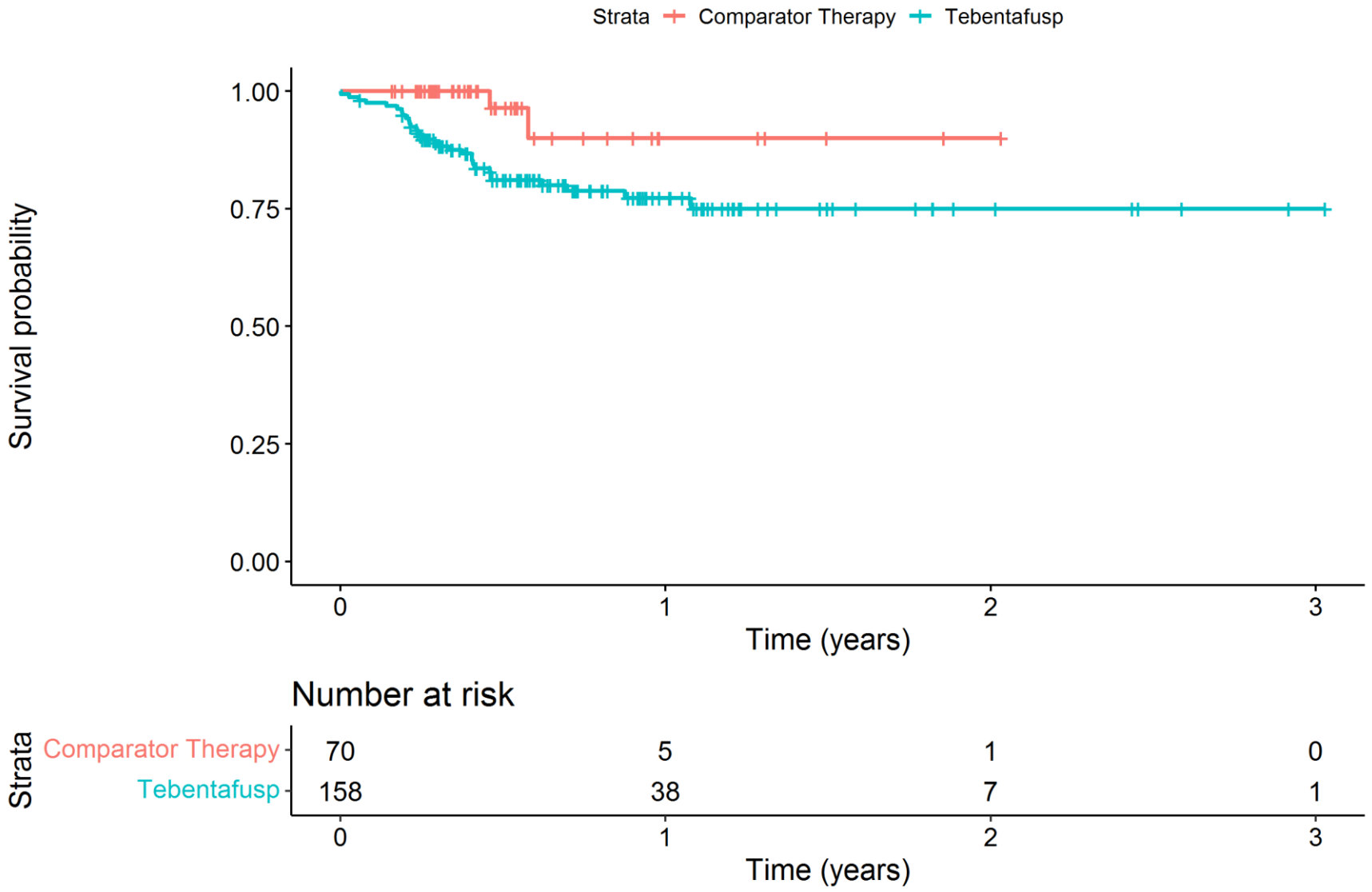
53.509 Vitiligo - ALP ≤ ULN



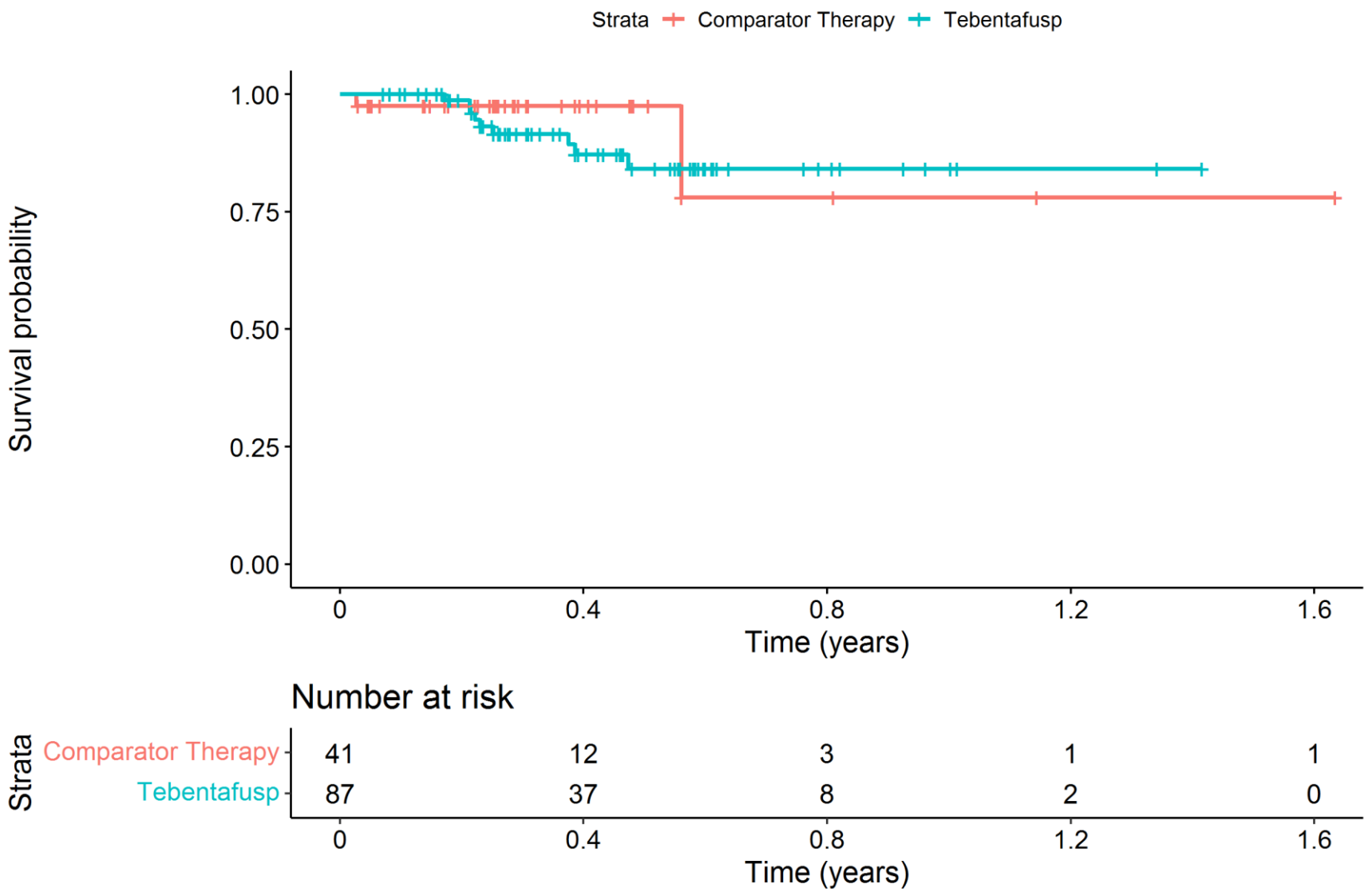
53.510 Vitiligo - ALP > ULN



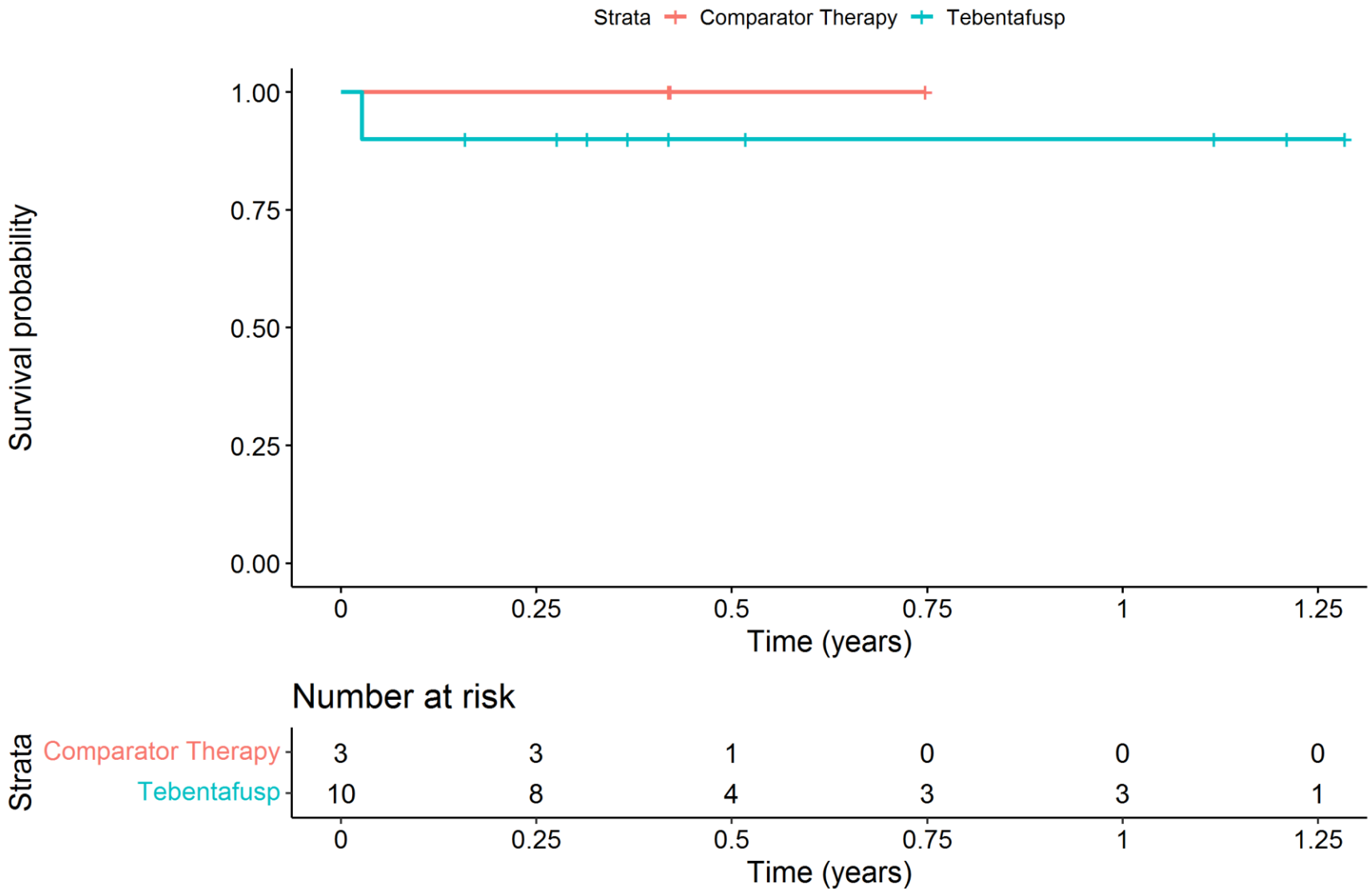
53.511 Vitiligo - LDH =< ULN



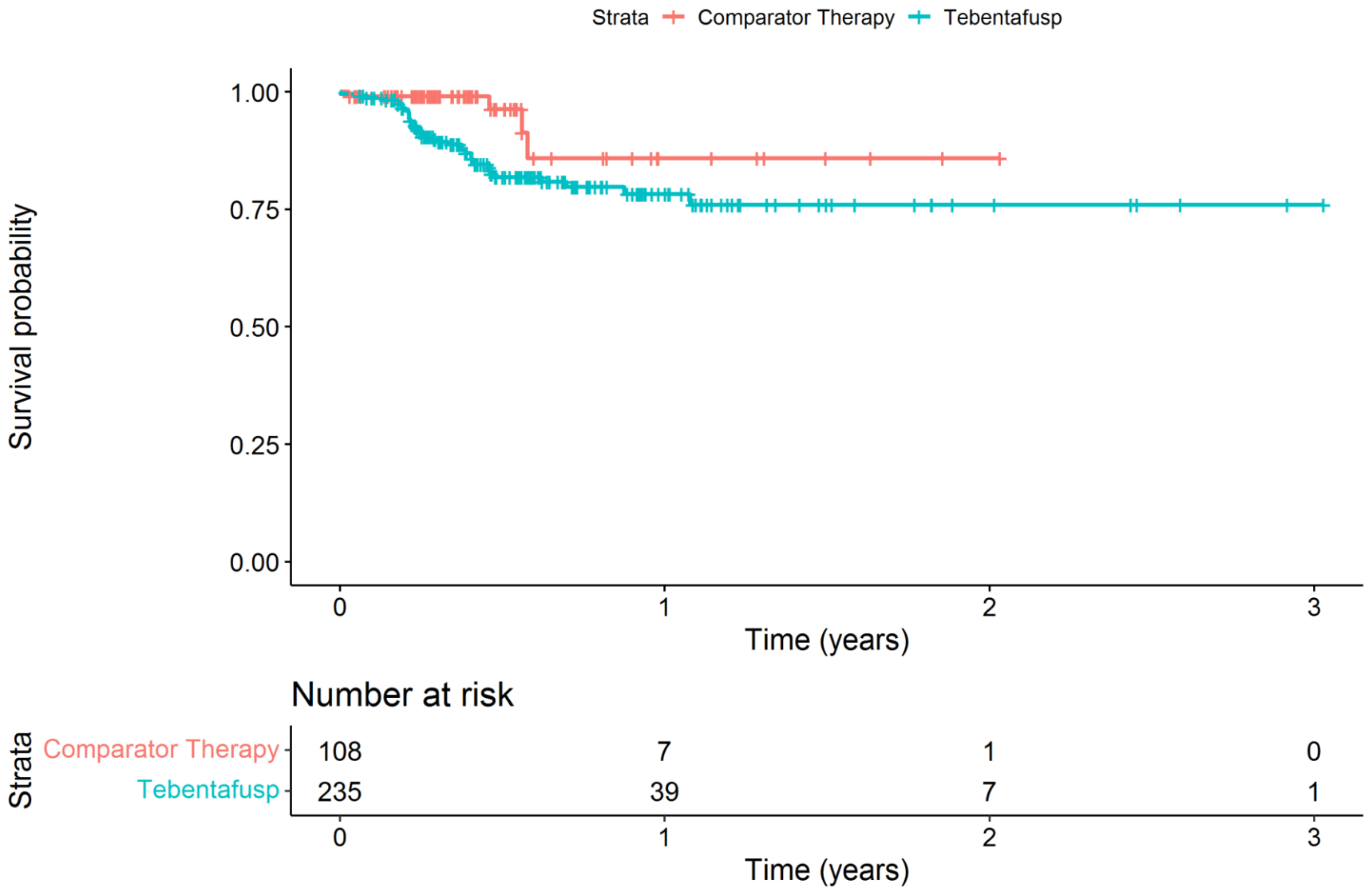
53.512 Vitiligo - LDH > ULN



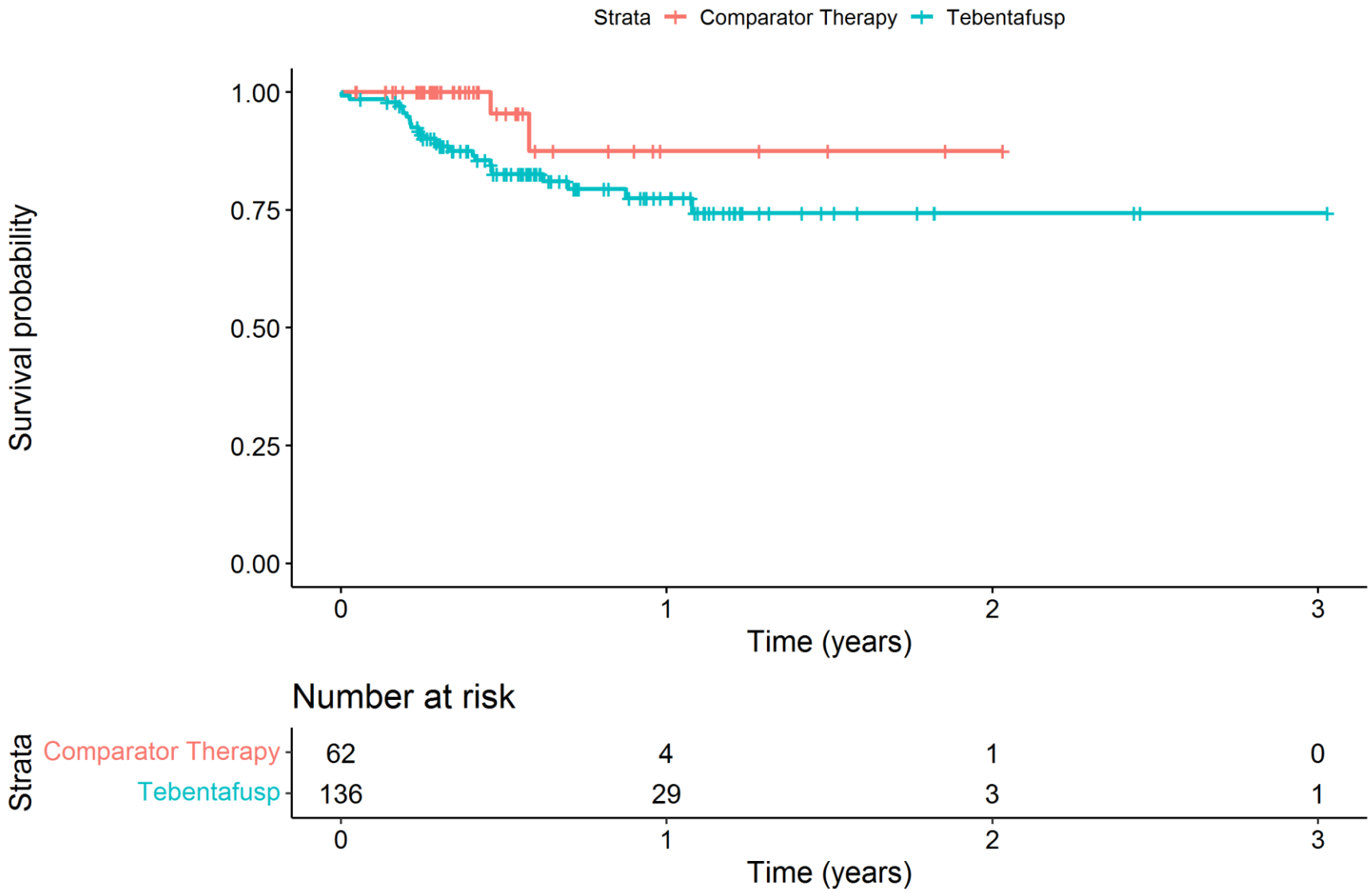
53.513 Vitiligo - Vorherige Therapie adjuvant/neoadjuvant



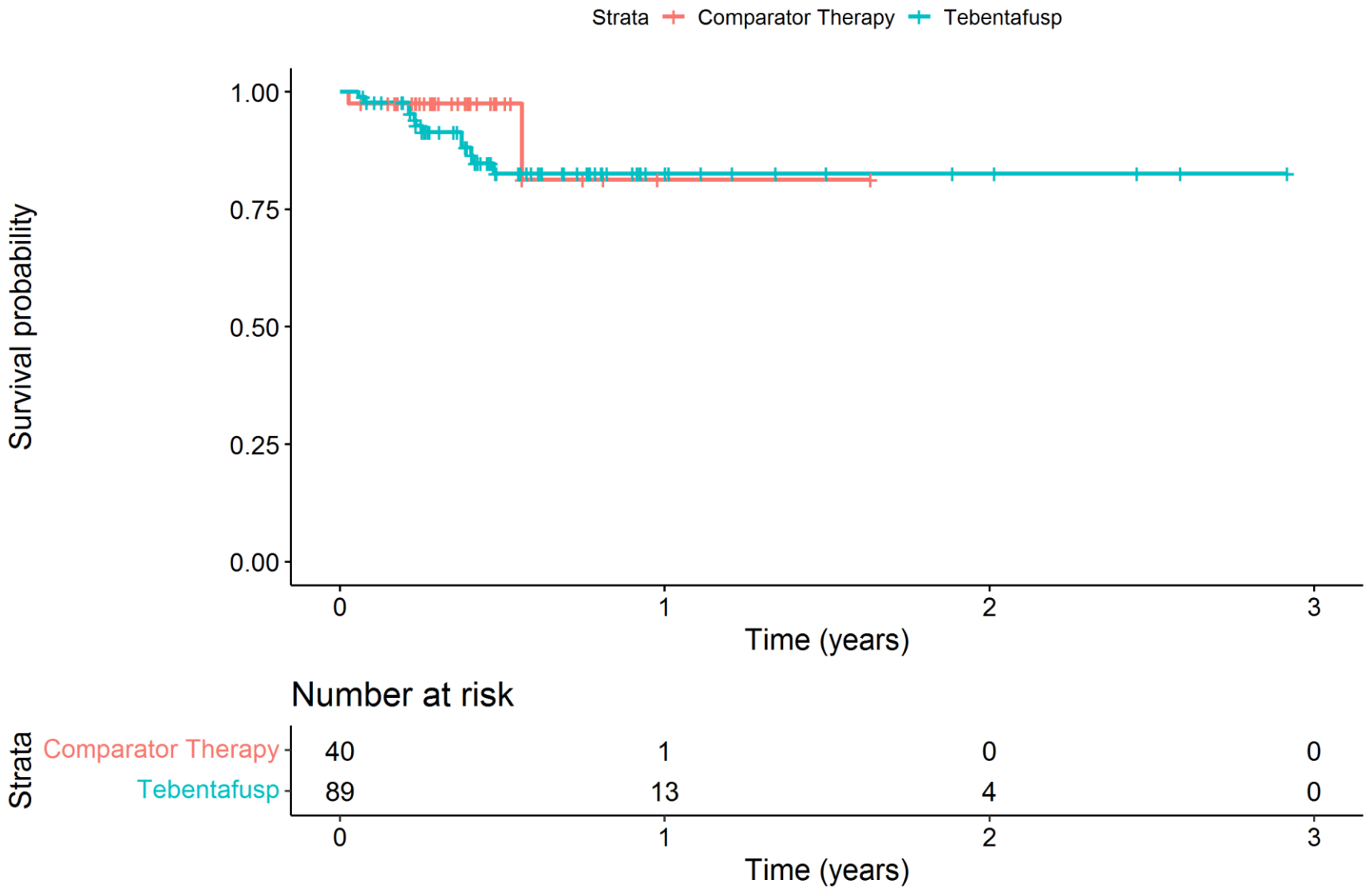
53.514 Vitiligo - Keine vorherige Therapie adjuvant/neoadjuvant



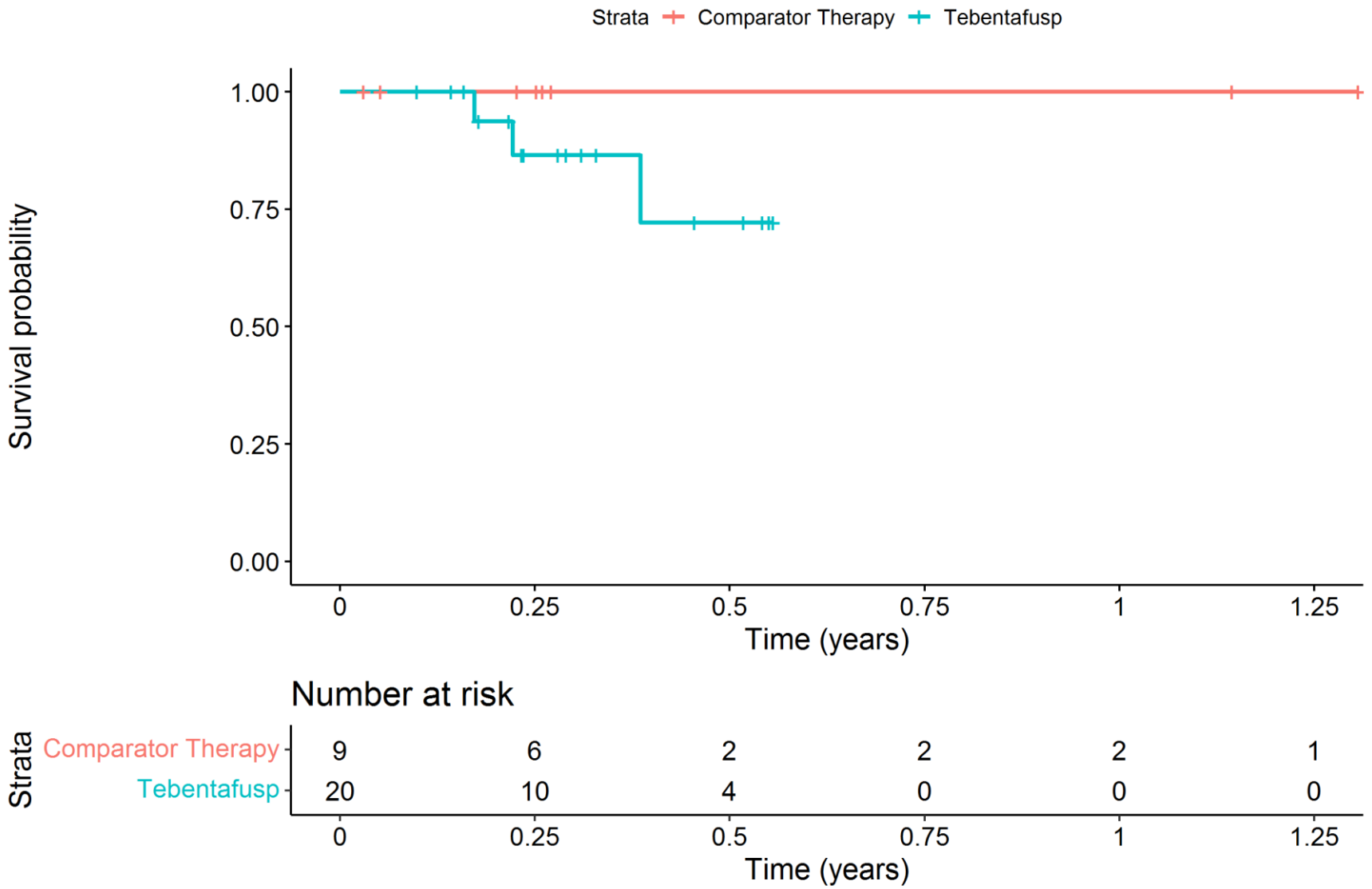
53.515 Vitiligo - Läsion ≤ 3cm



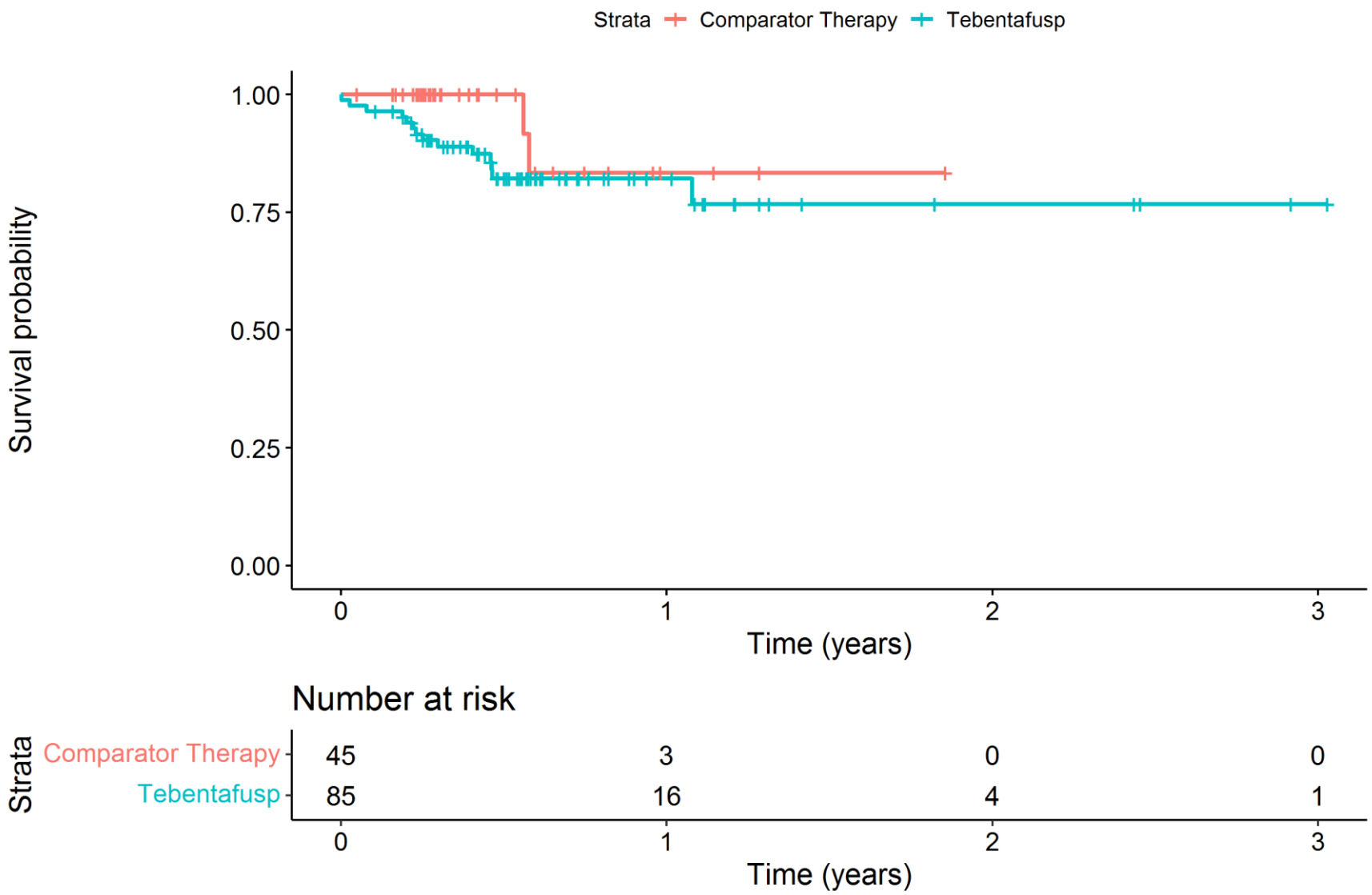
53.516 Vitiligo - Läsion 3,1-8,0 cm



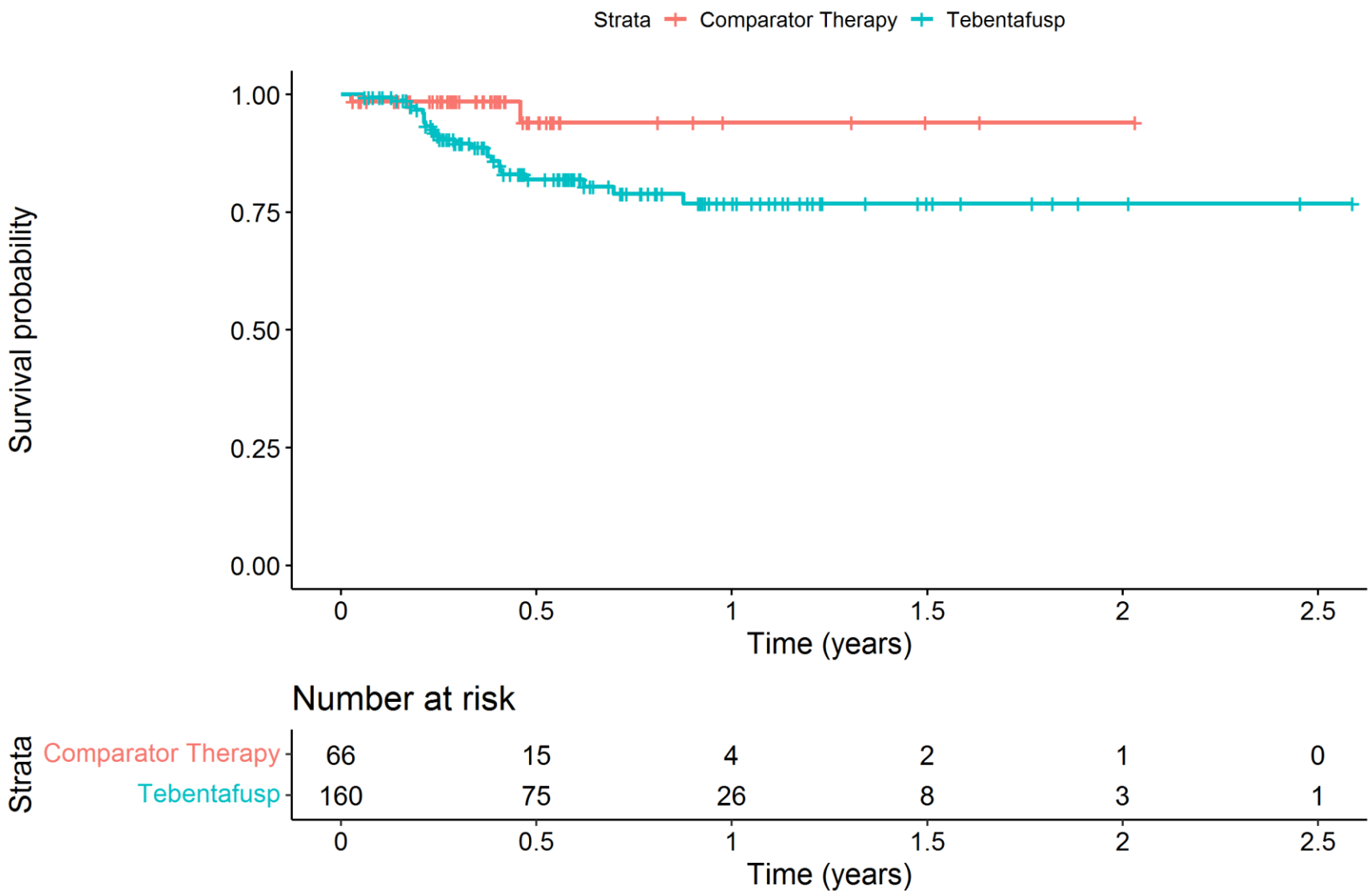
53.517 Vitiligo - Läsion ≥8,1 cm



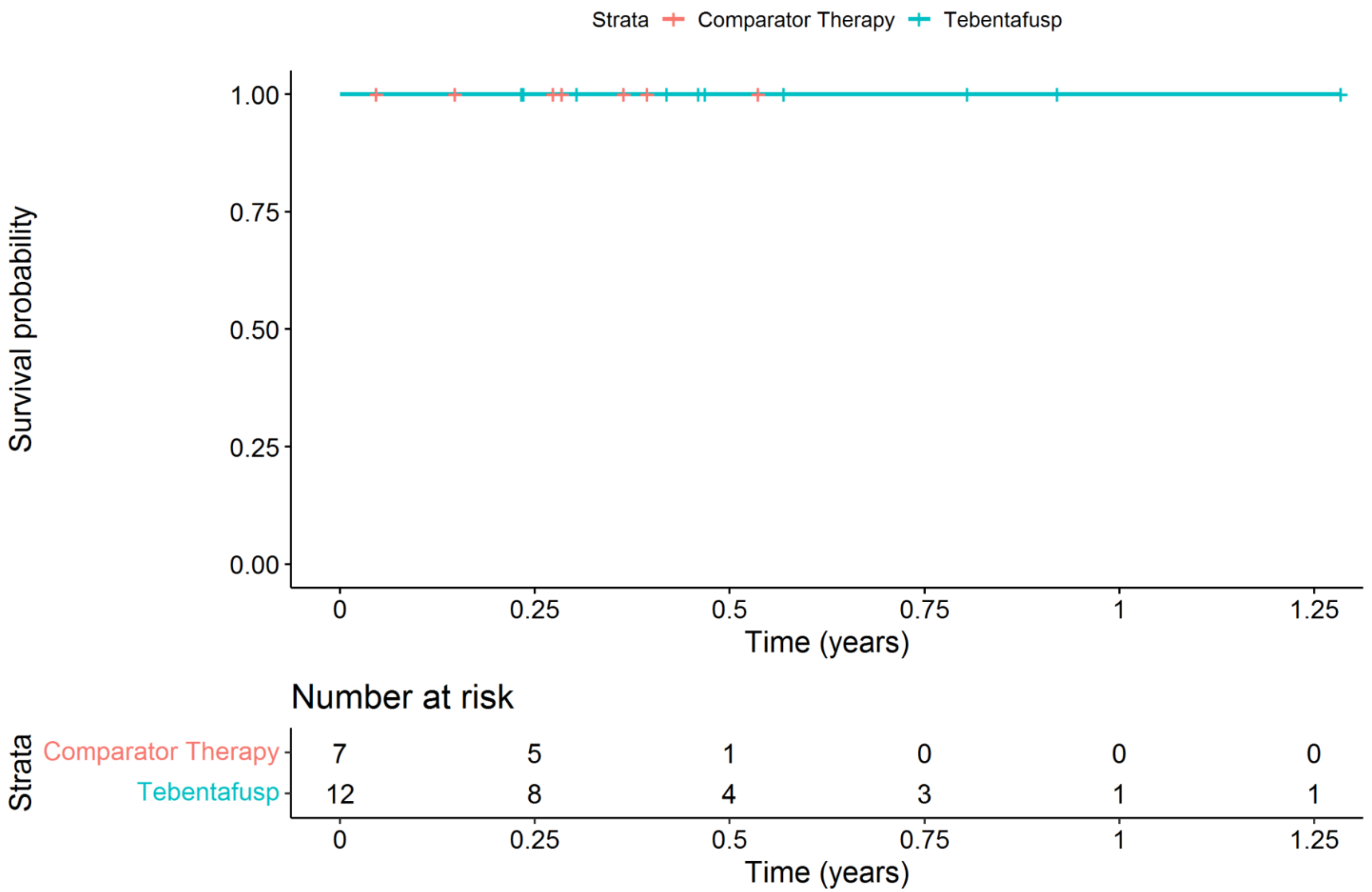
53.518 Vitiligo - Nordamerika



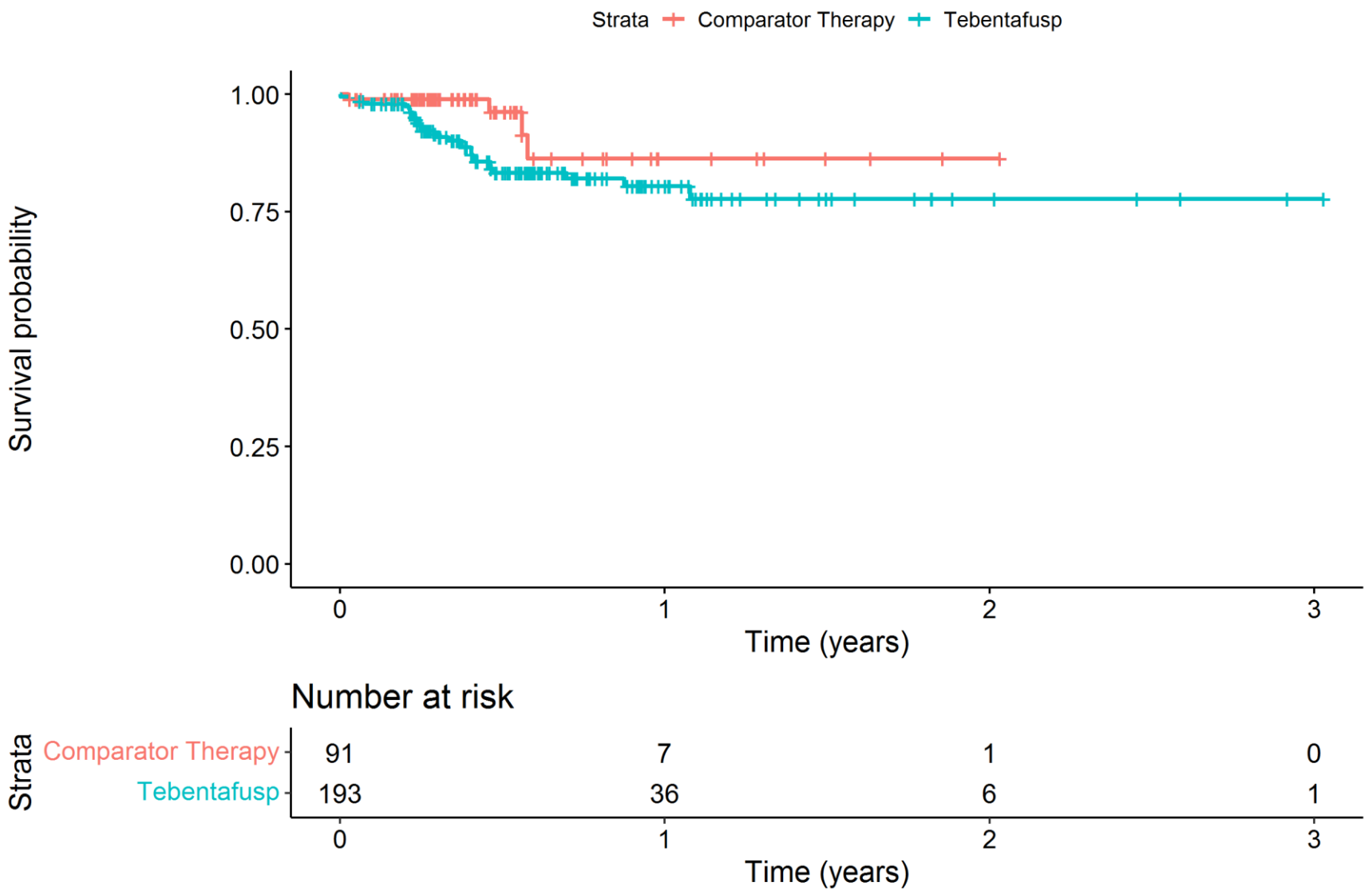
53.519 Vitiligo - Nicht-Nordamerika



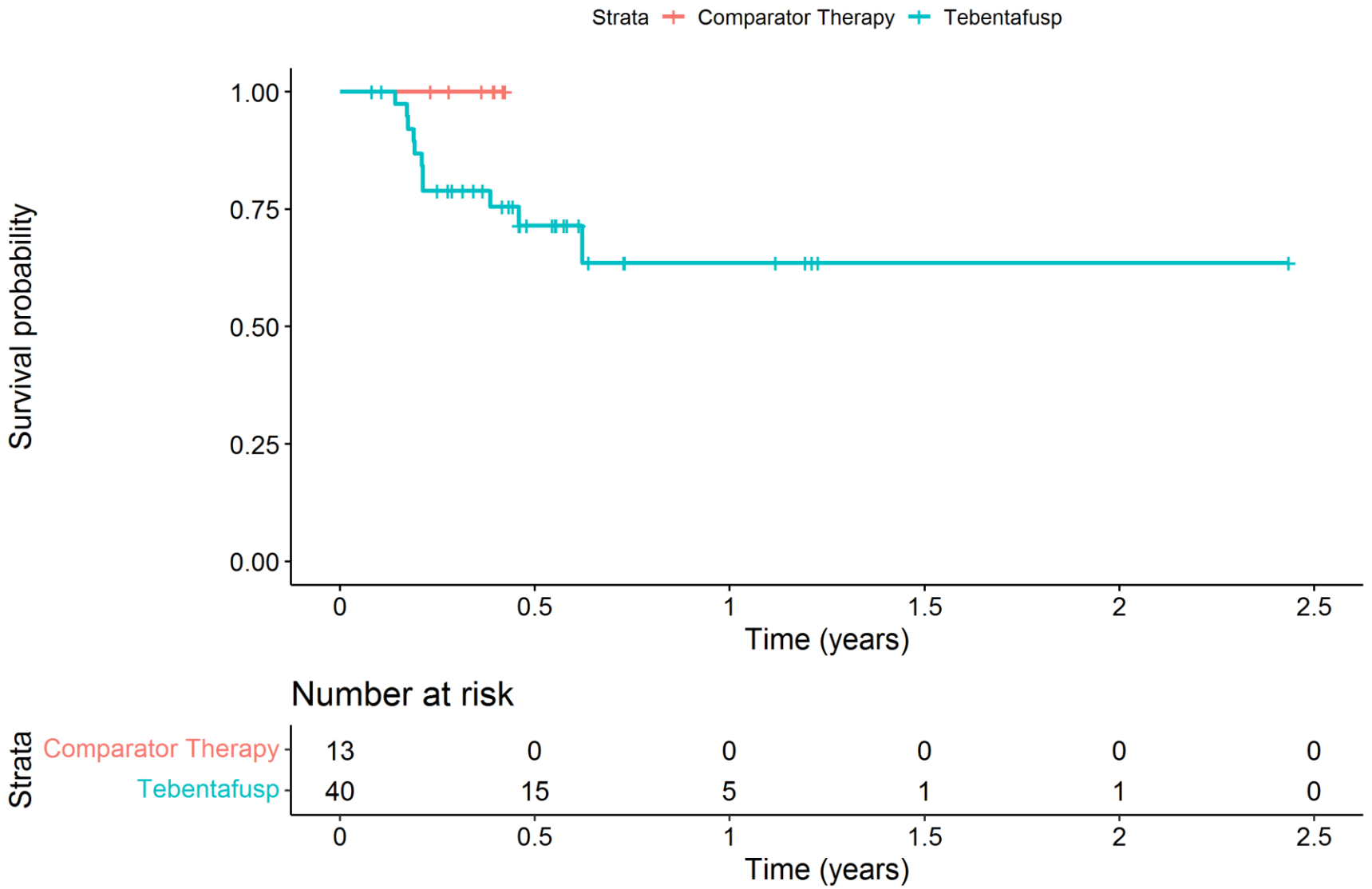
53.520 Vitiligo - Dacarbazin



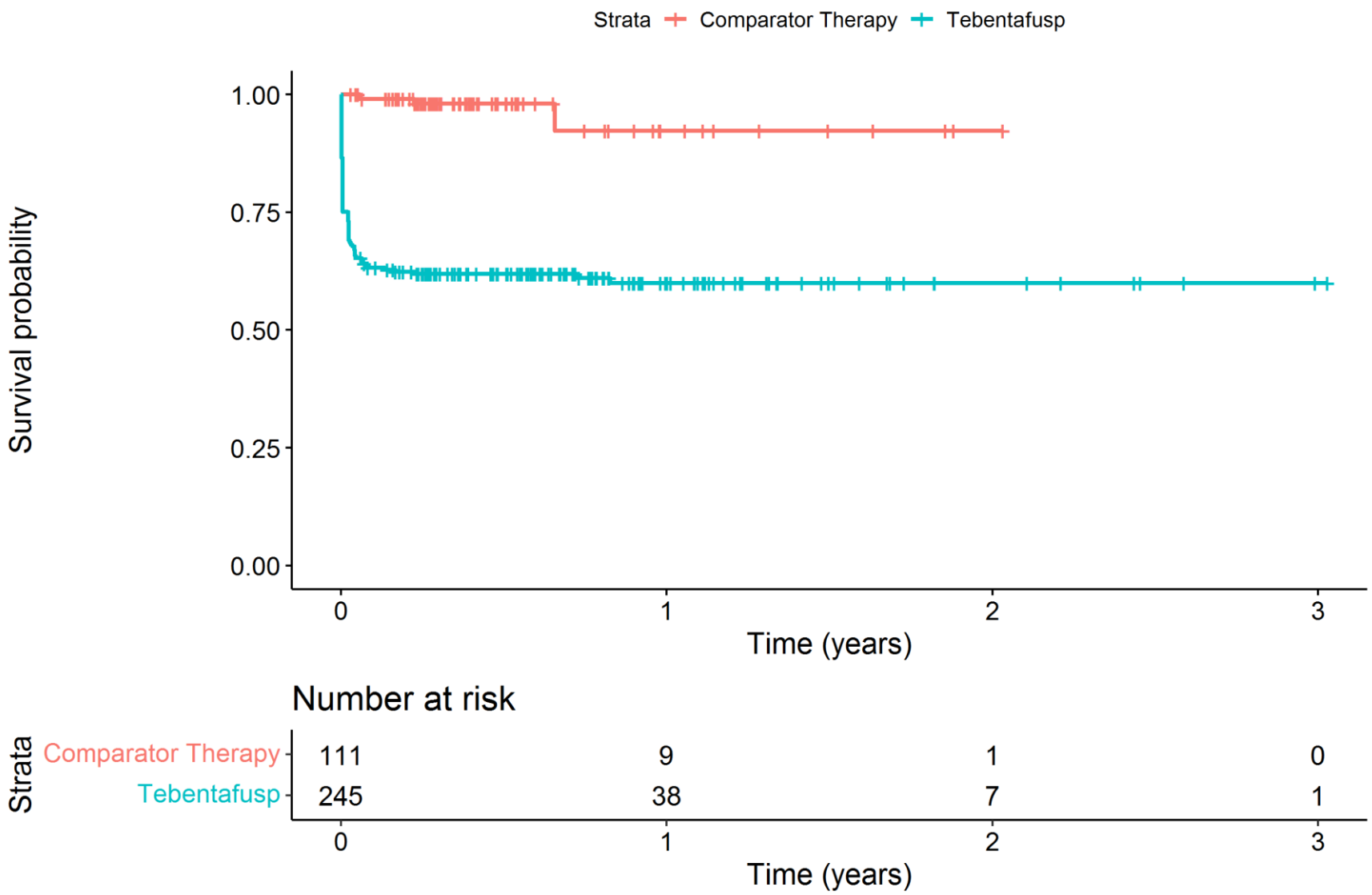
53.521 Vitiligo - Pembrolizumab



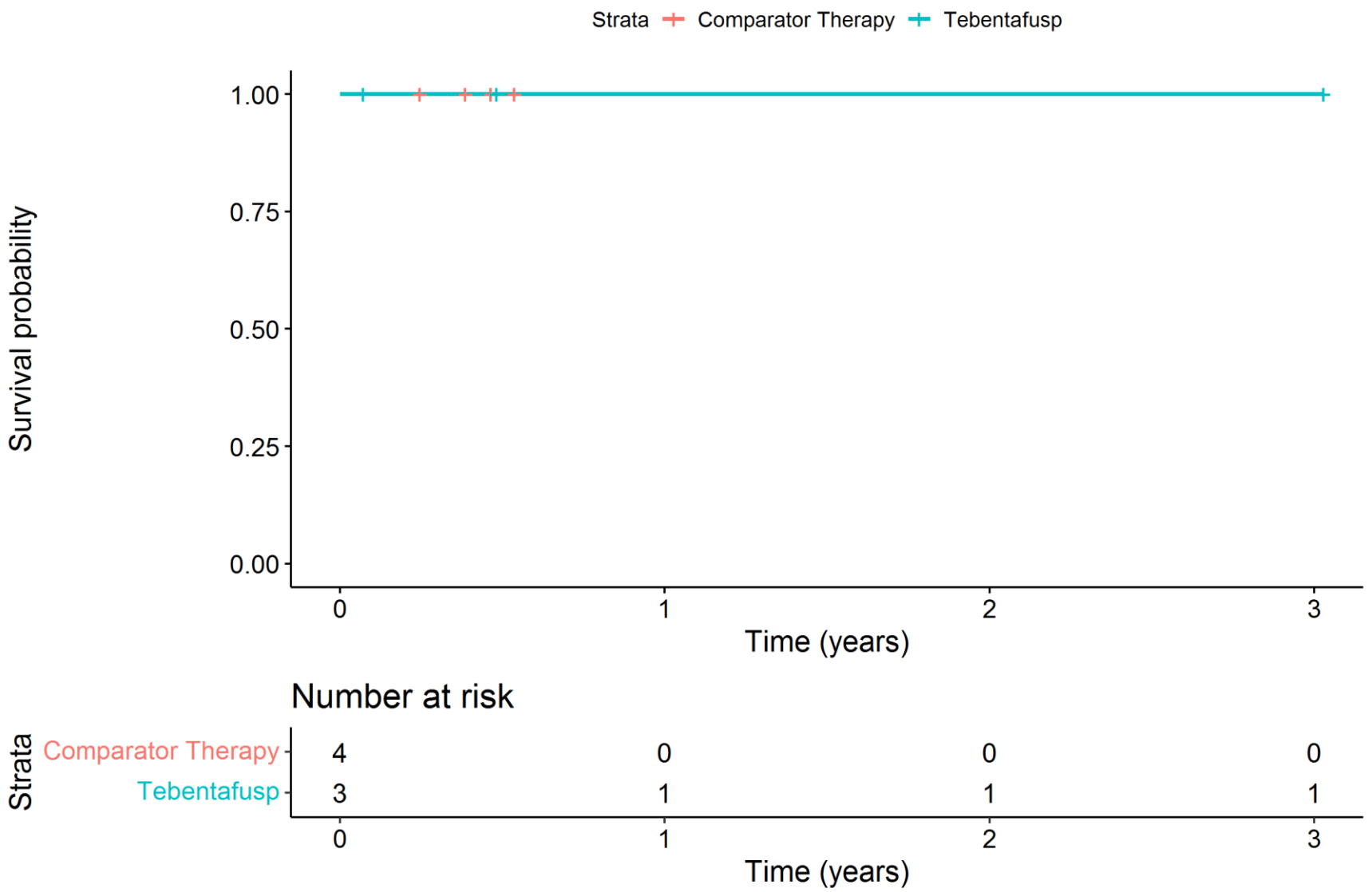
53.522 Vitiligo - Ipilimumab



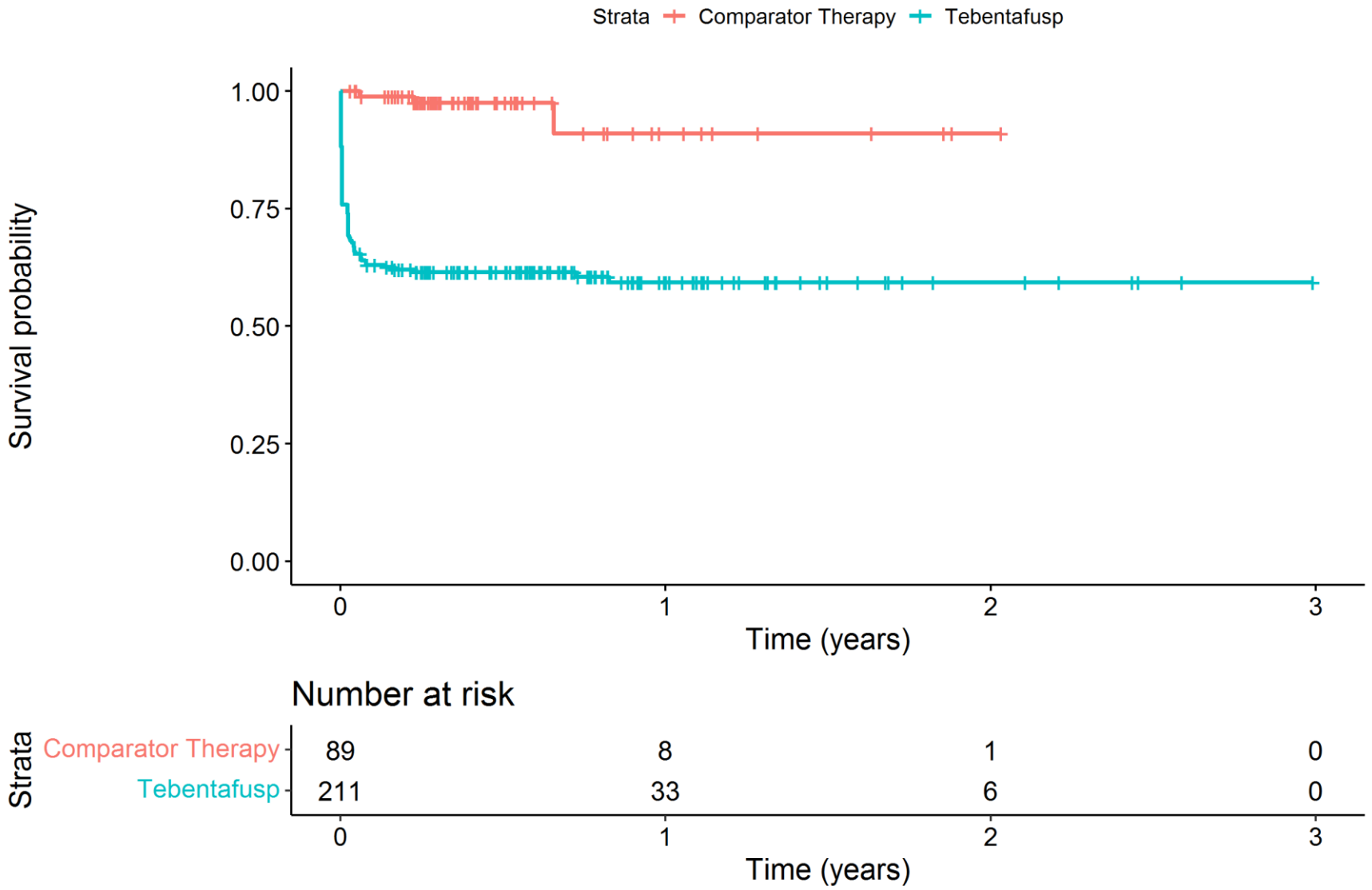
53.523 Hypotonie - Gesamt



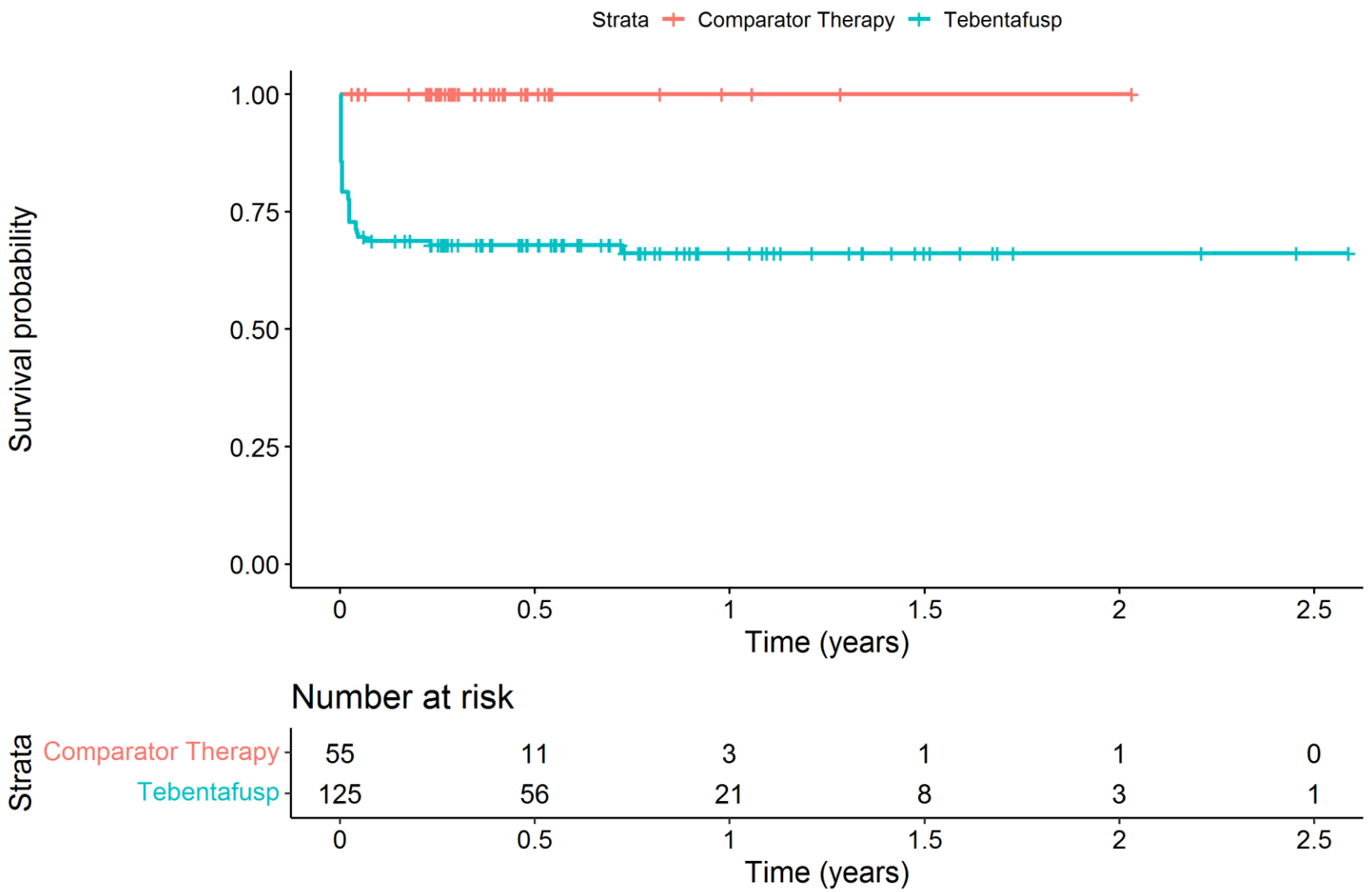
53.524 Hypotonie - Hispanisch



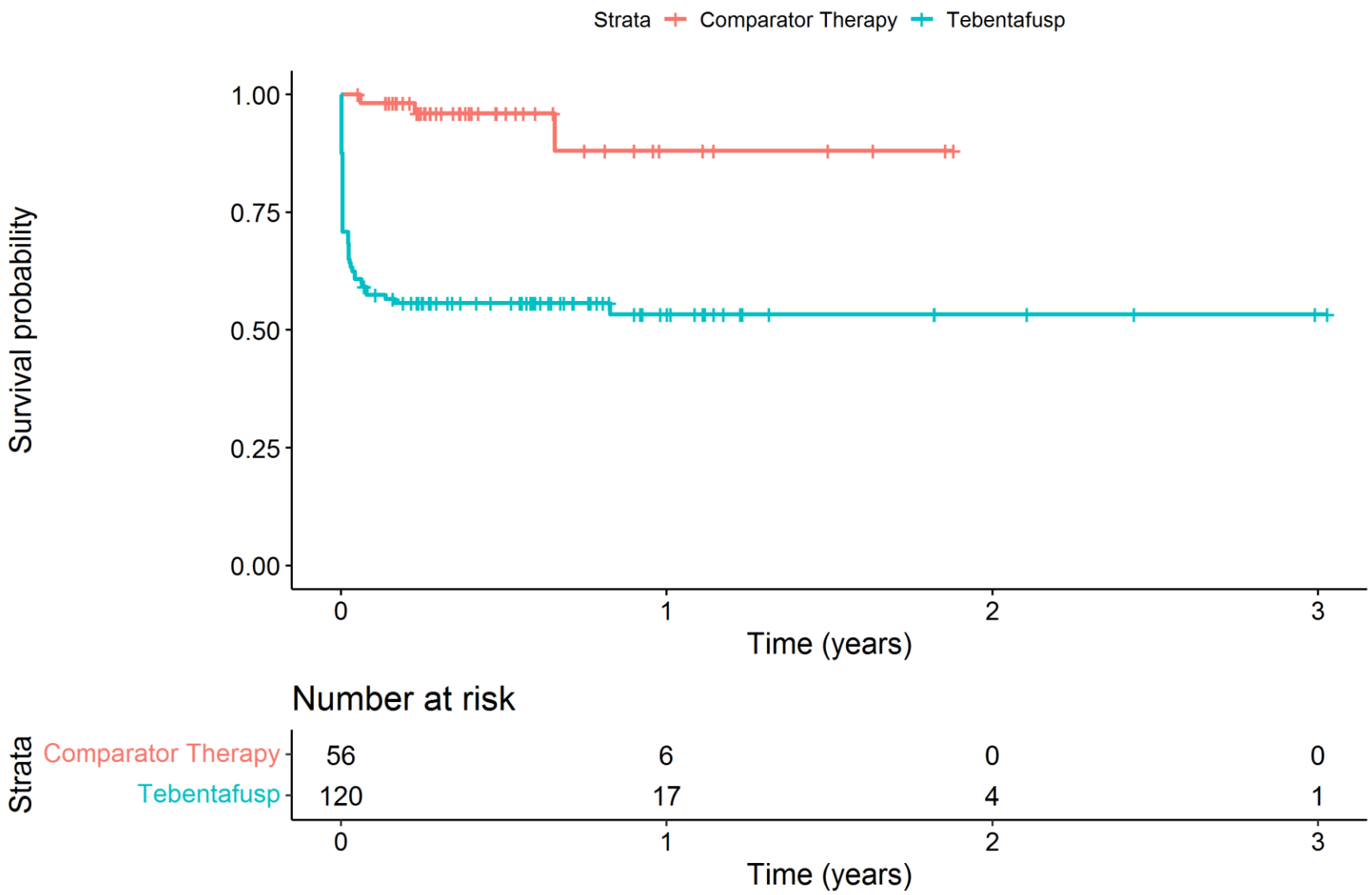
53.525 Hypotonie - Nicht-hispanisch



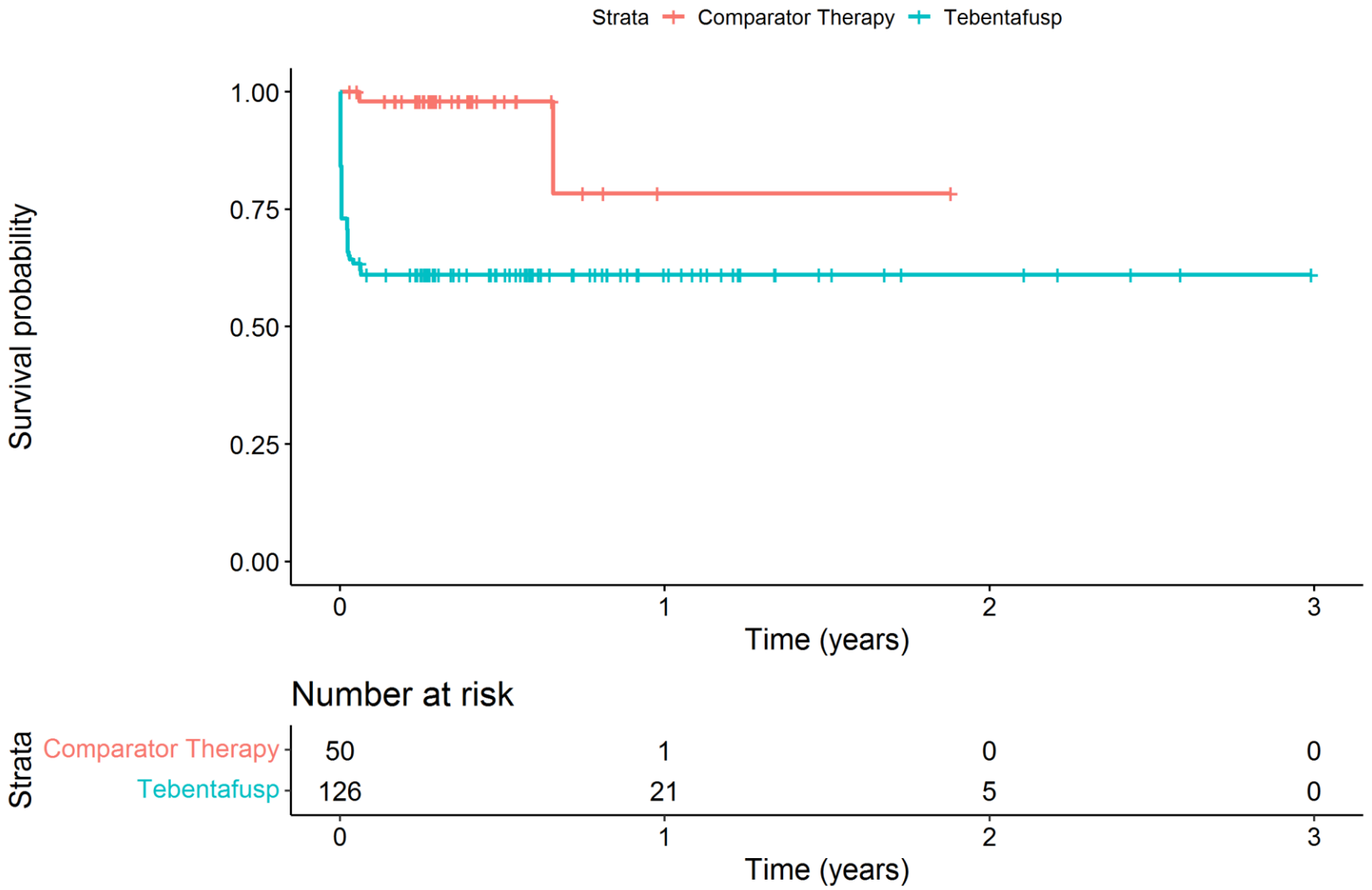
53.526 Hypotonie - Männlich



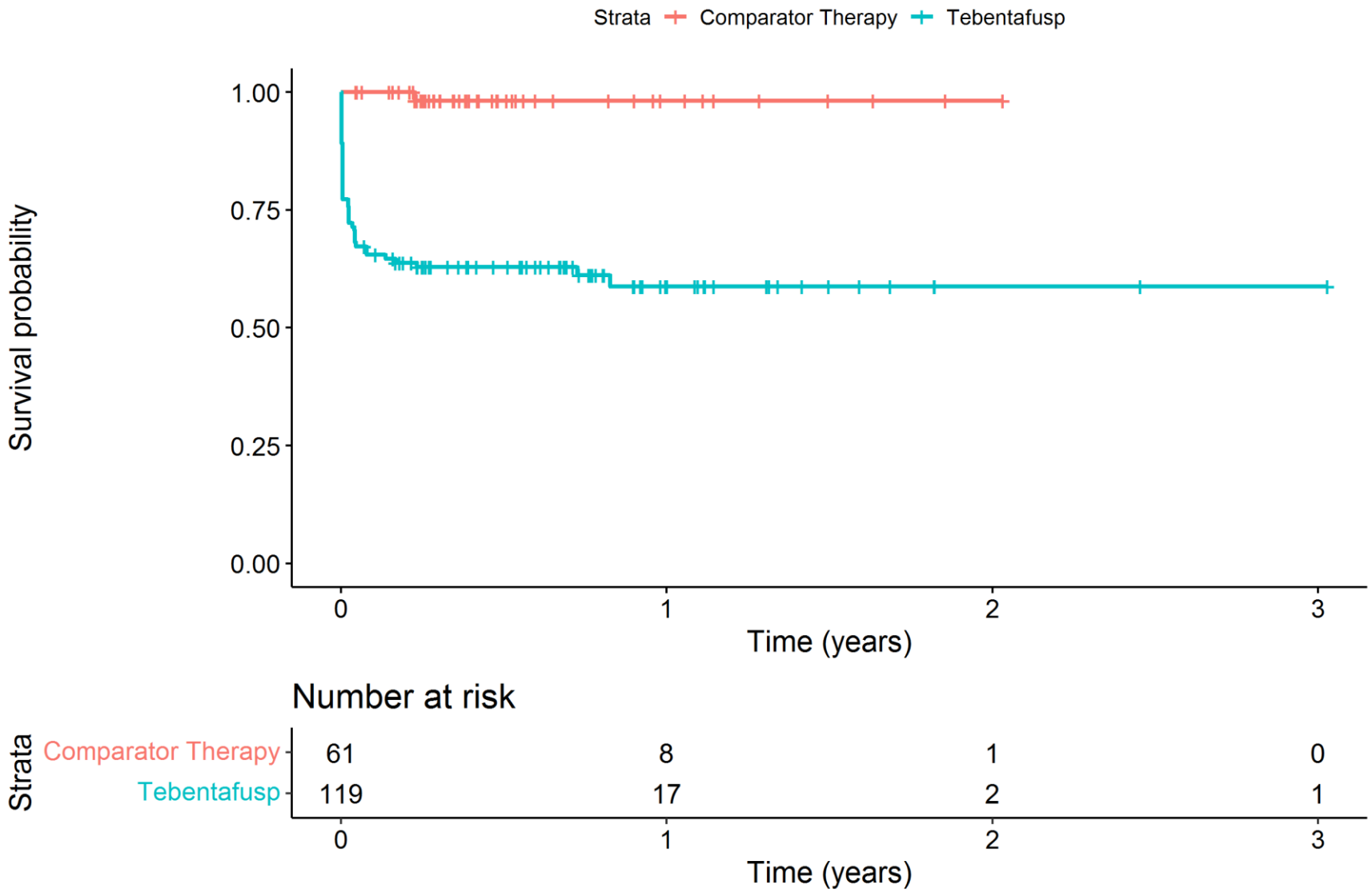
53.527 Hypotonie - Weiblich



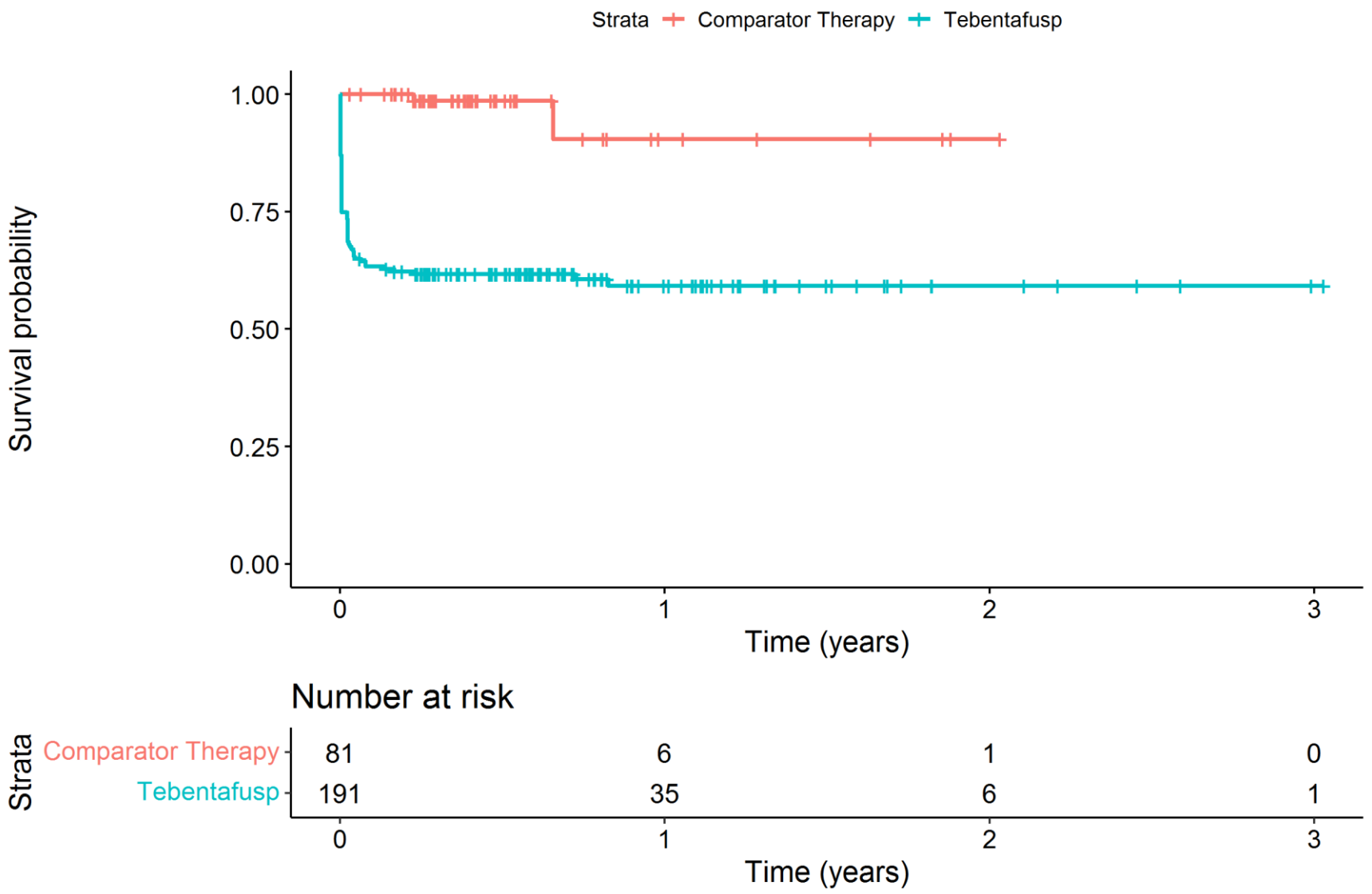
53.528 Hypotonie - <65



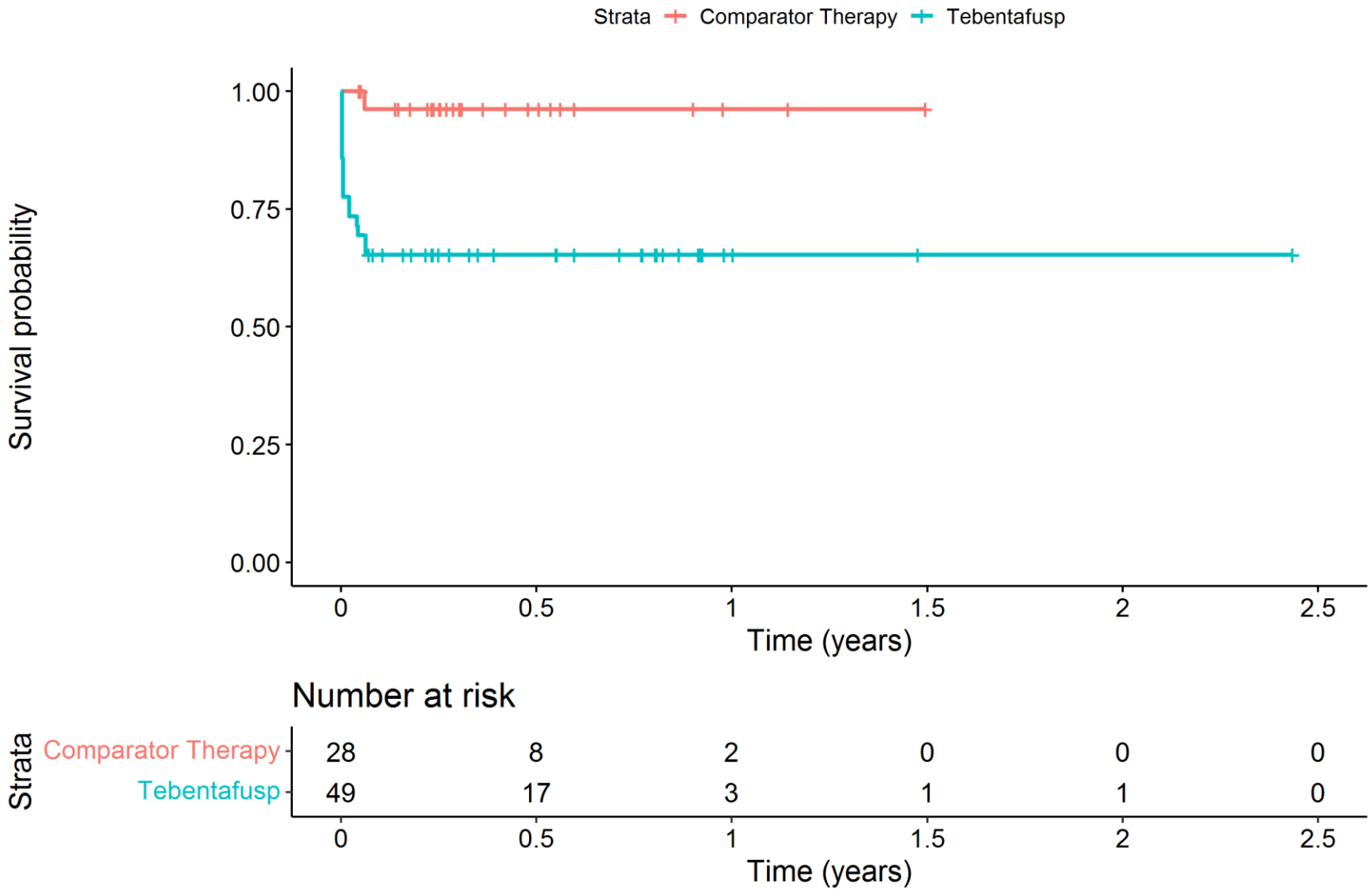
53.529 Hypotonie - ≥65



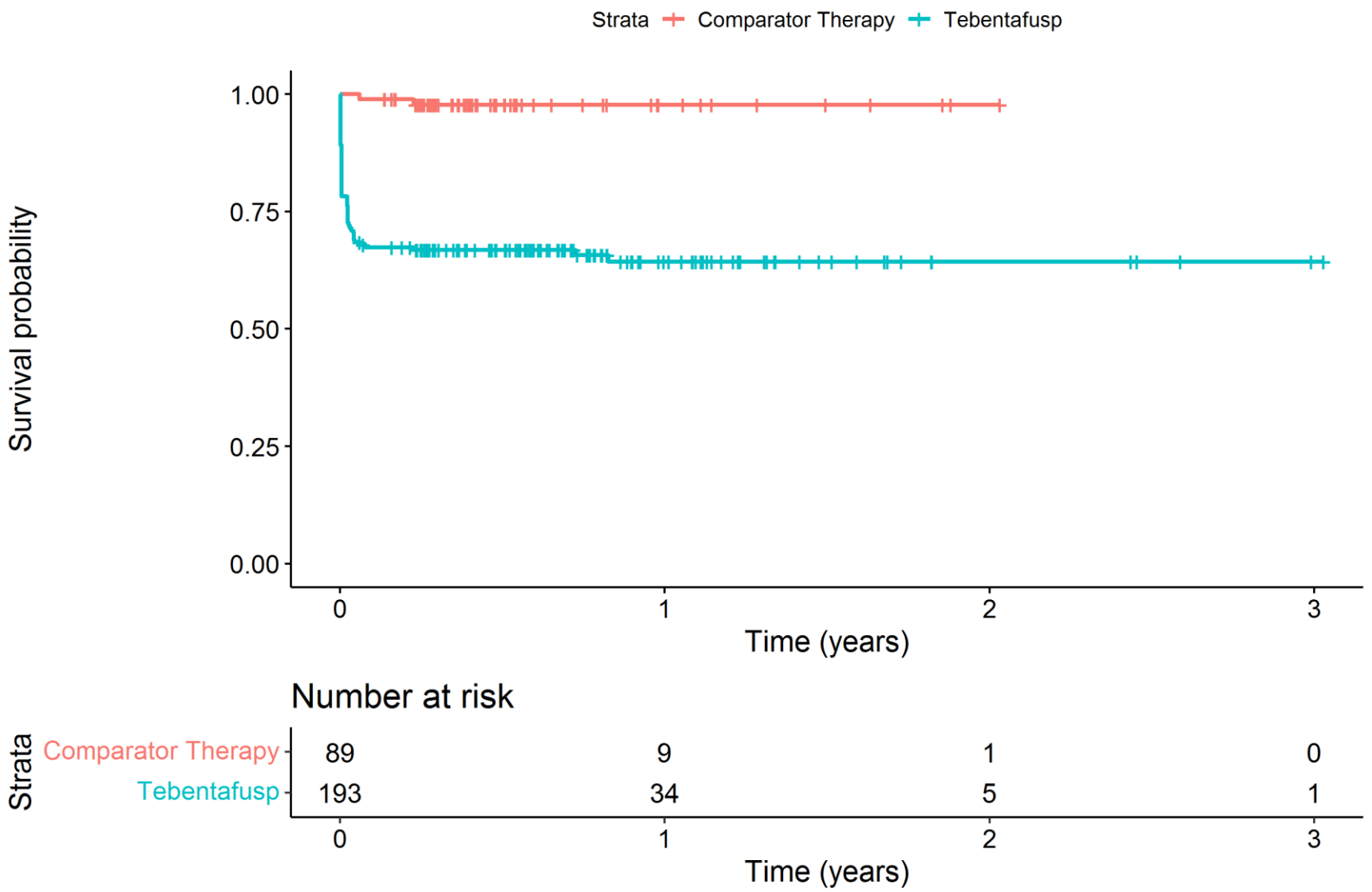
53.530 Hypotonie - ECOG 0



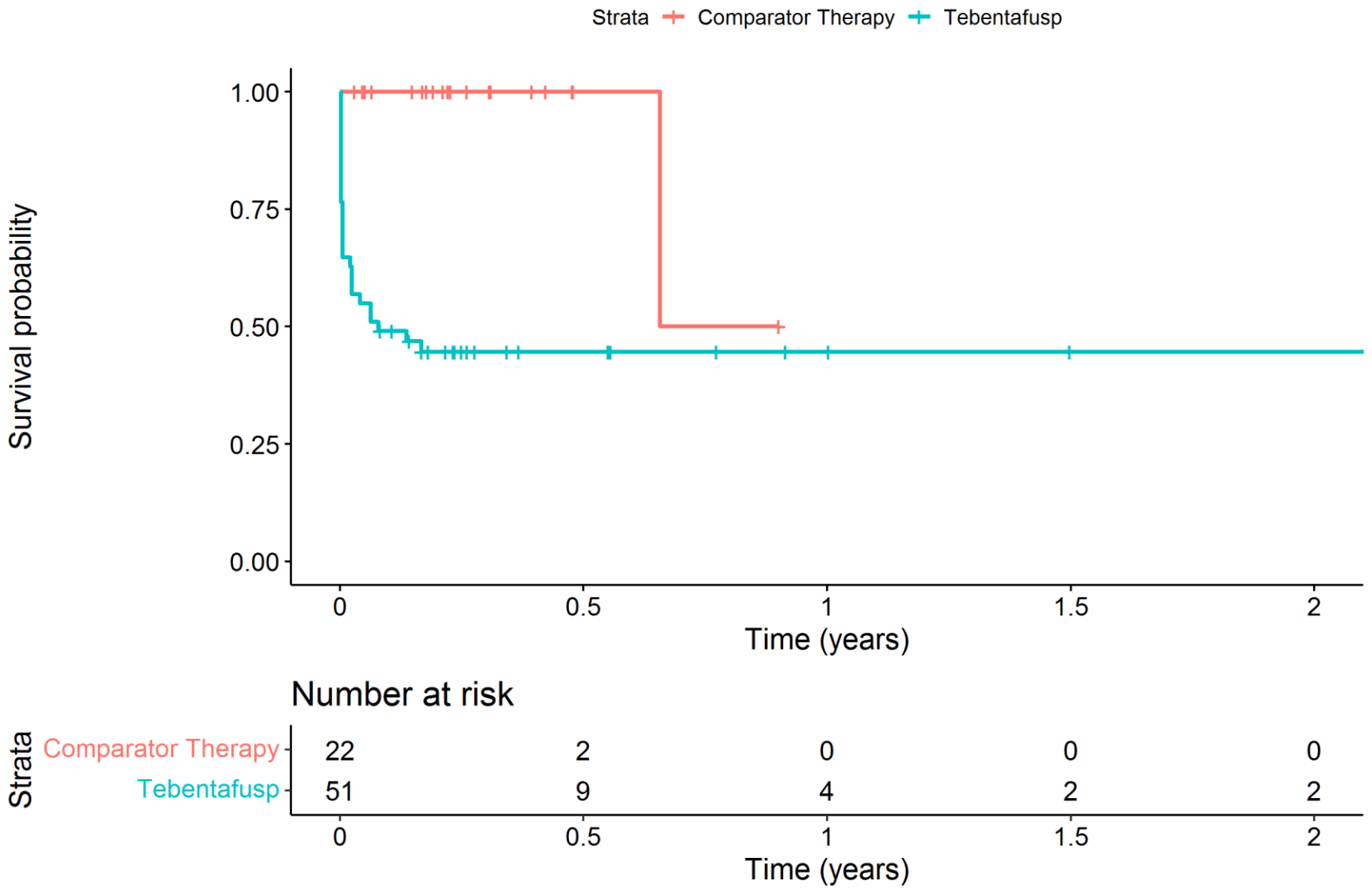
53.531 Hypotonie - ECOG 1



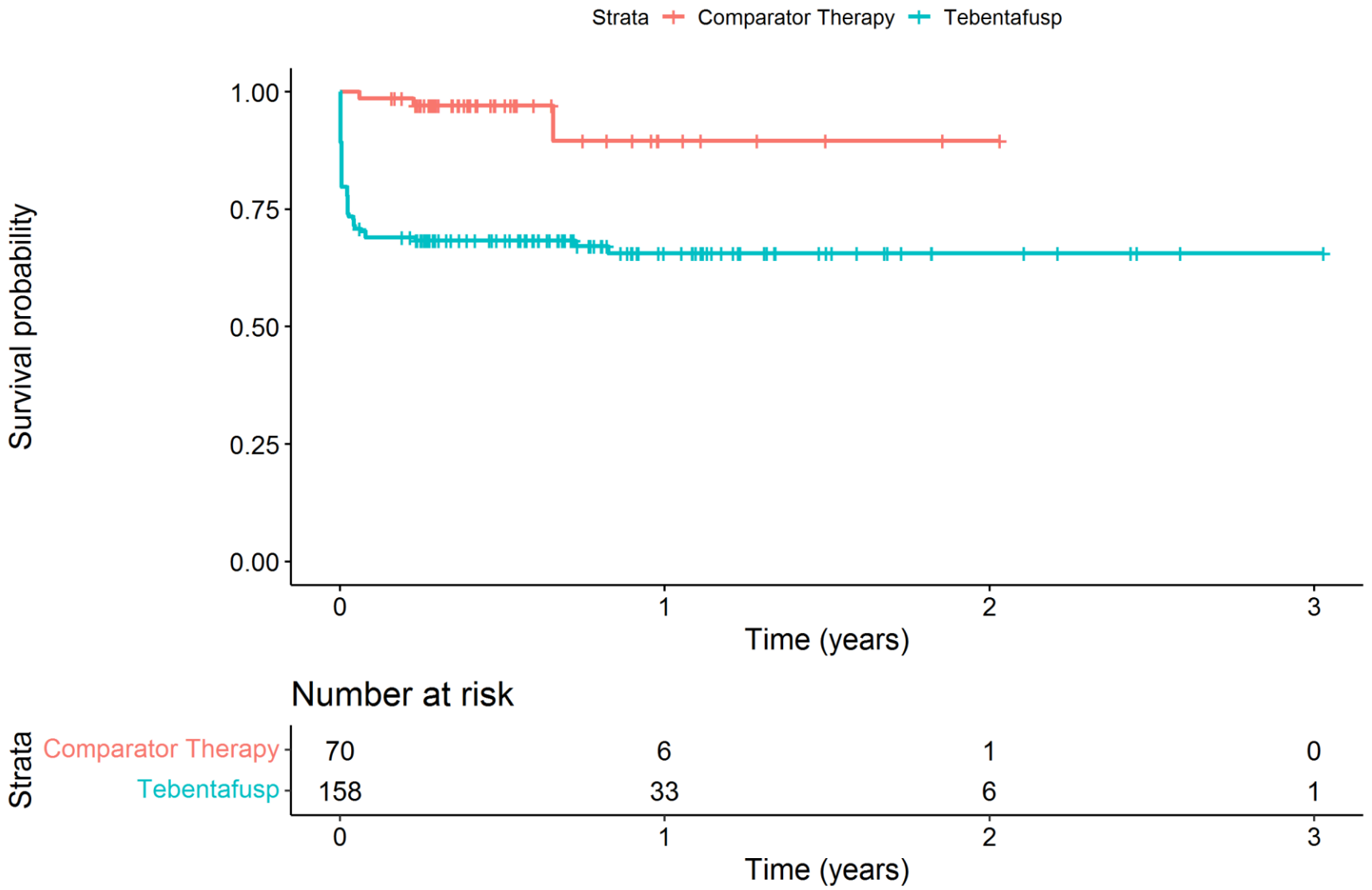
53.532 Hypotonie - ALP ≤ ULN



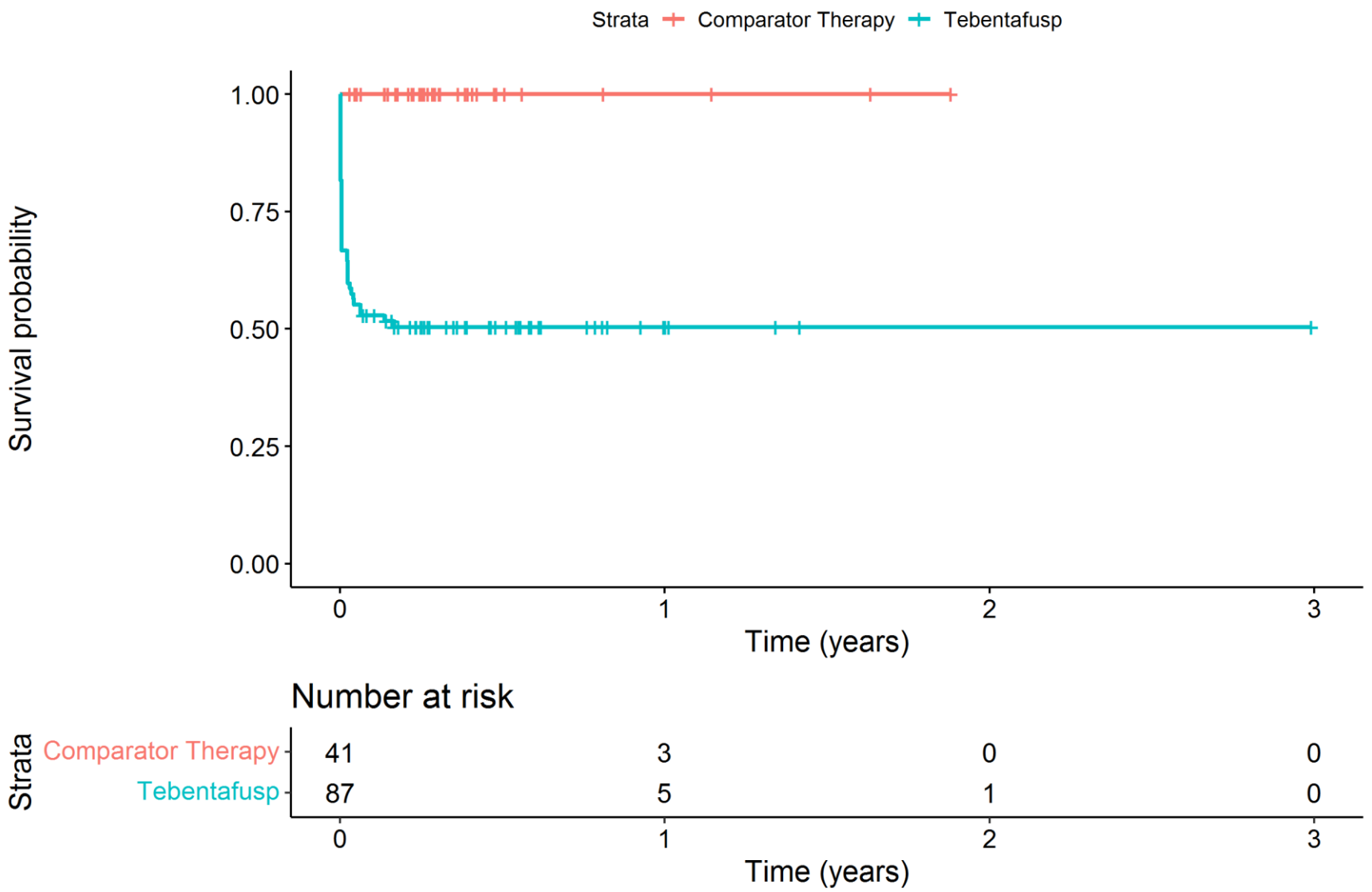
53.533 Hypotonie - ALP > ULN



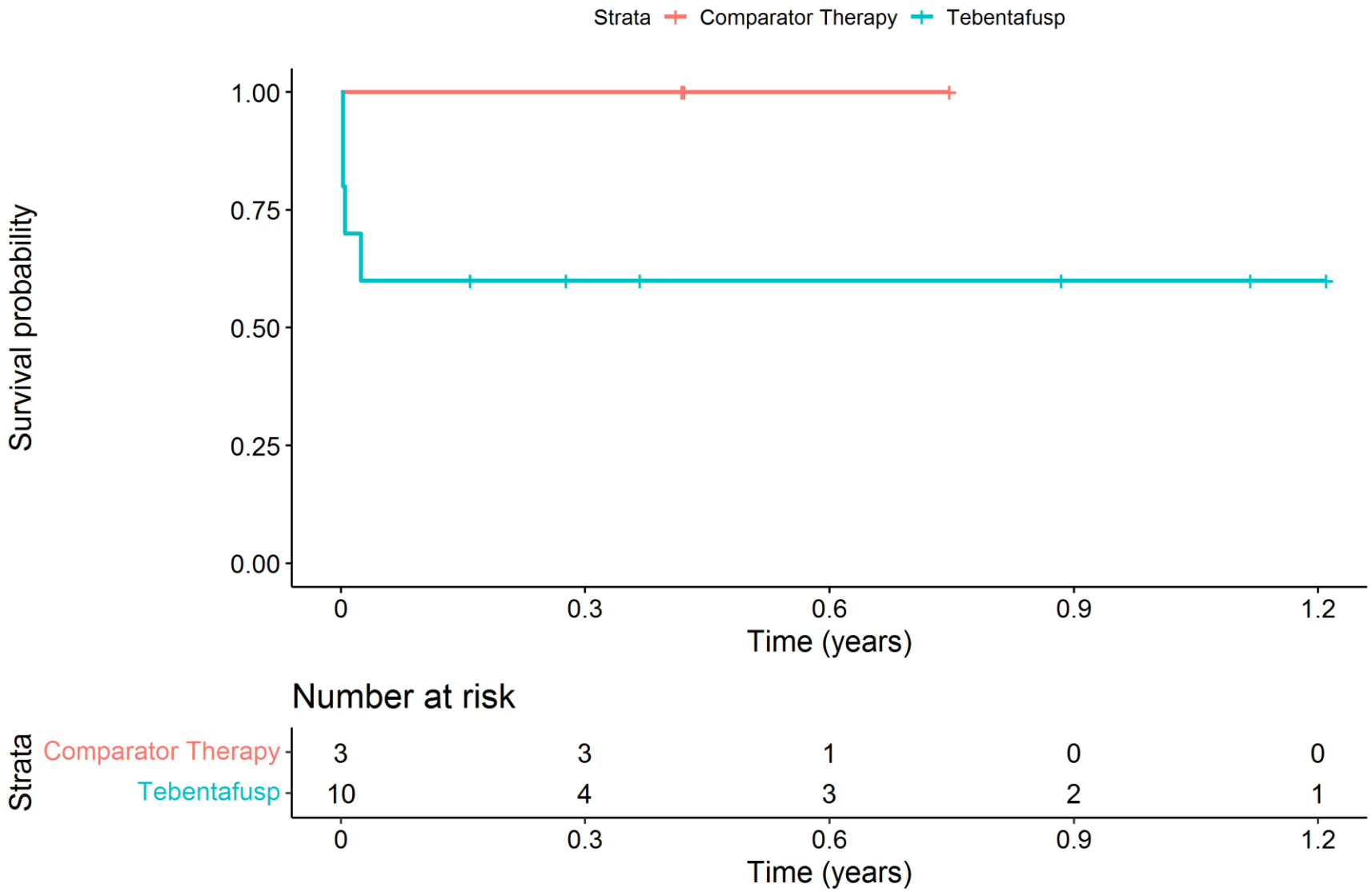
53.534 Hypotonie - LDH =< ULN



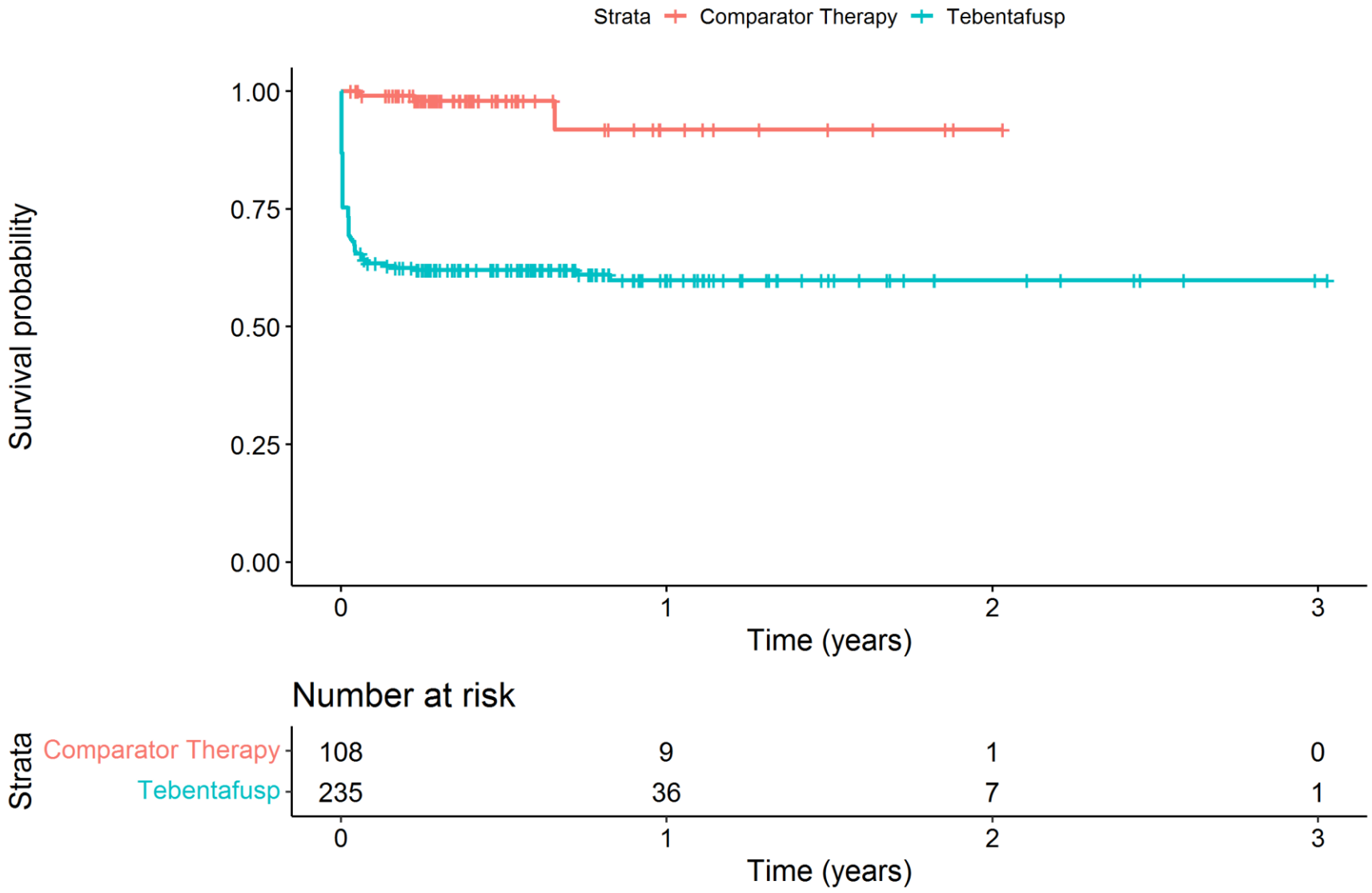
53.535 Hypotonie - LDH > ULN



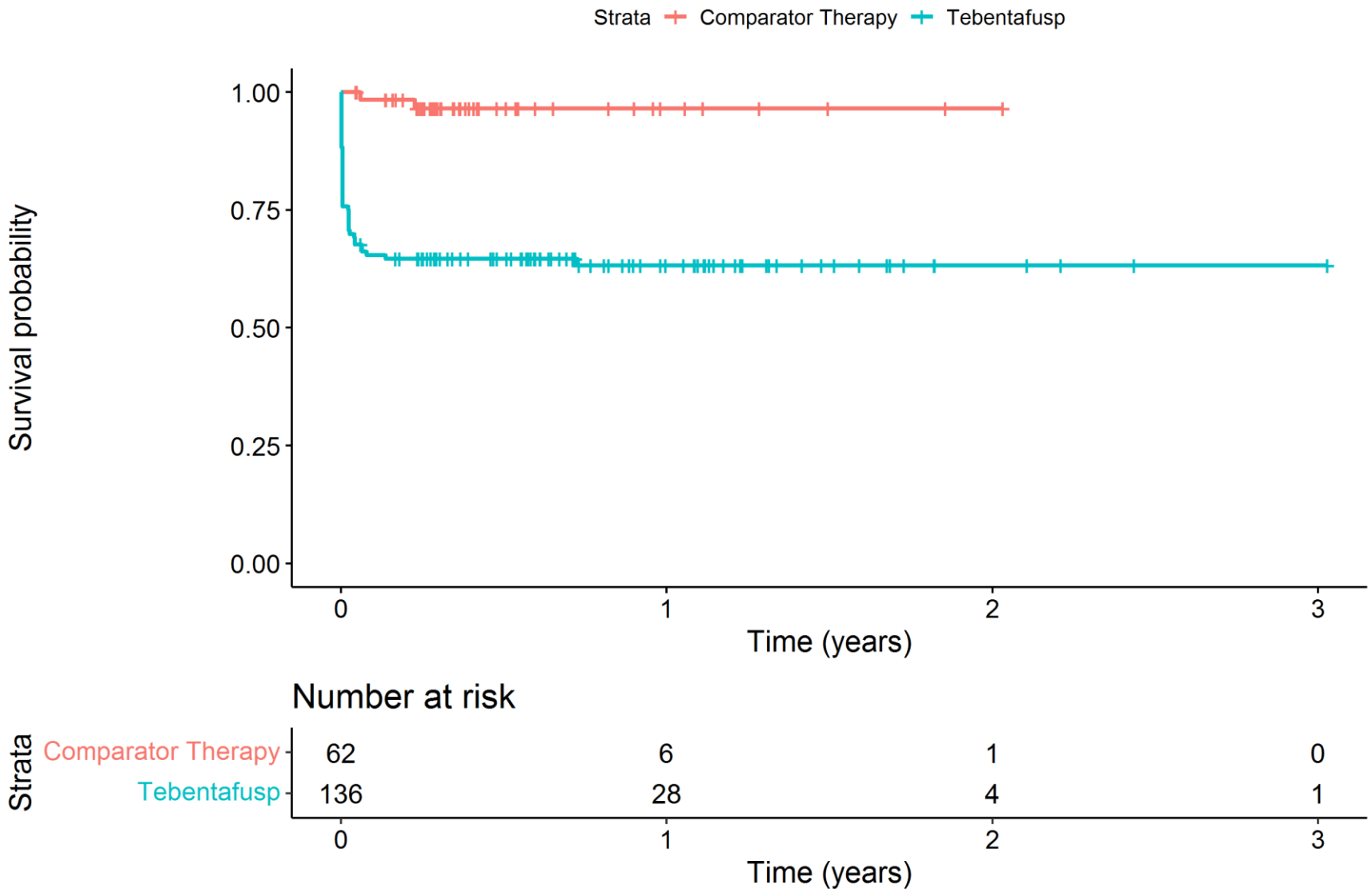
53.536 Hypotonie - Vorherige Therapie adjuvant/neoadjuvant



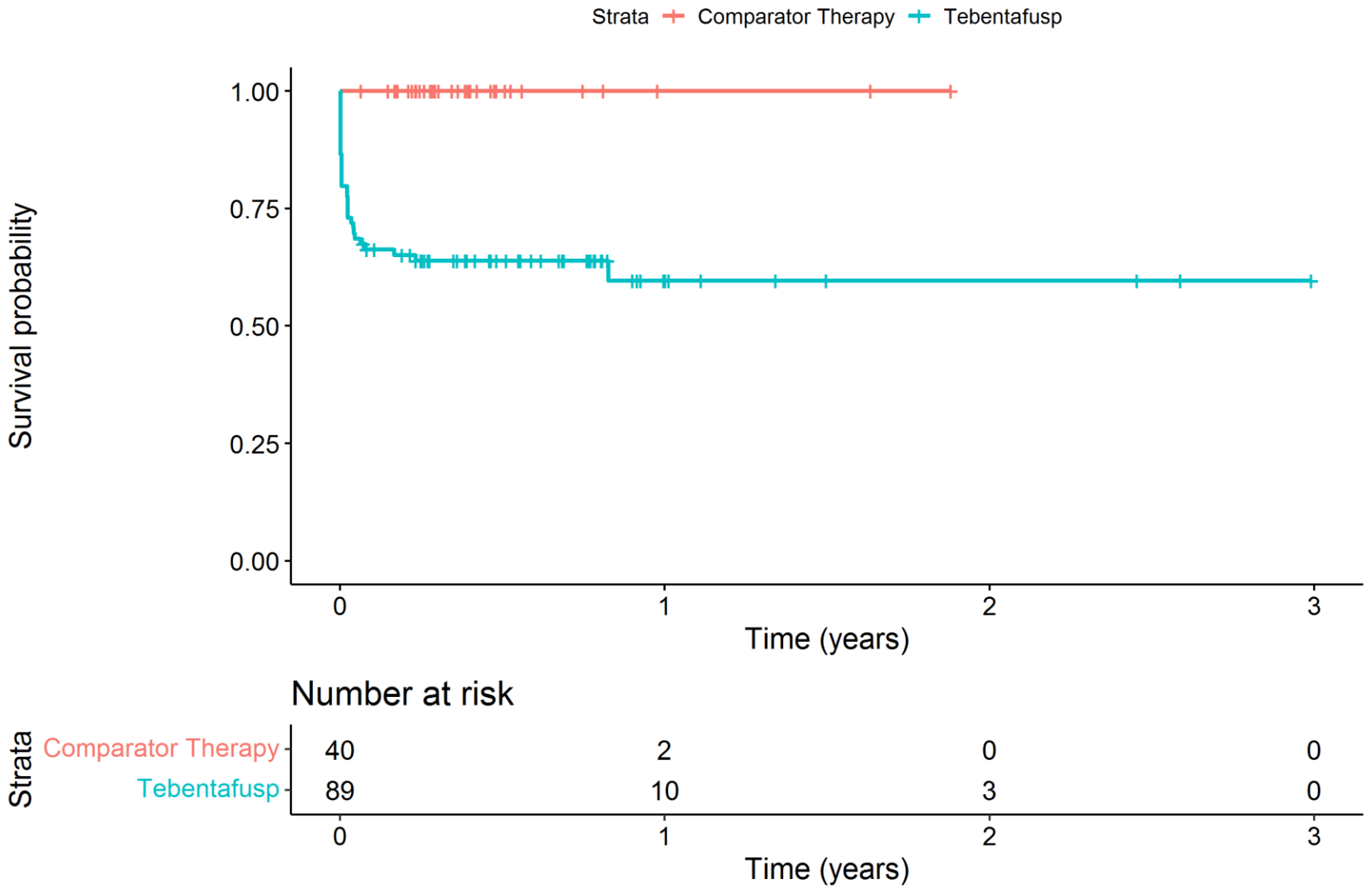
53.537 Hypotonie - Keine vorherige Therapie adjuvant/neoadjuvant



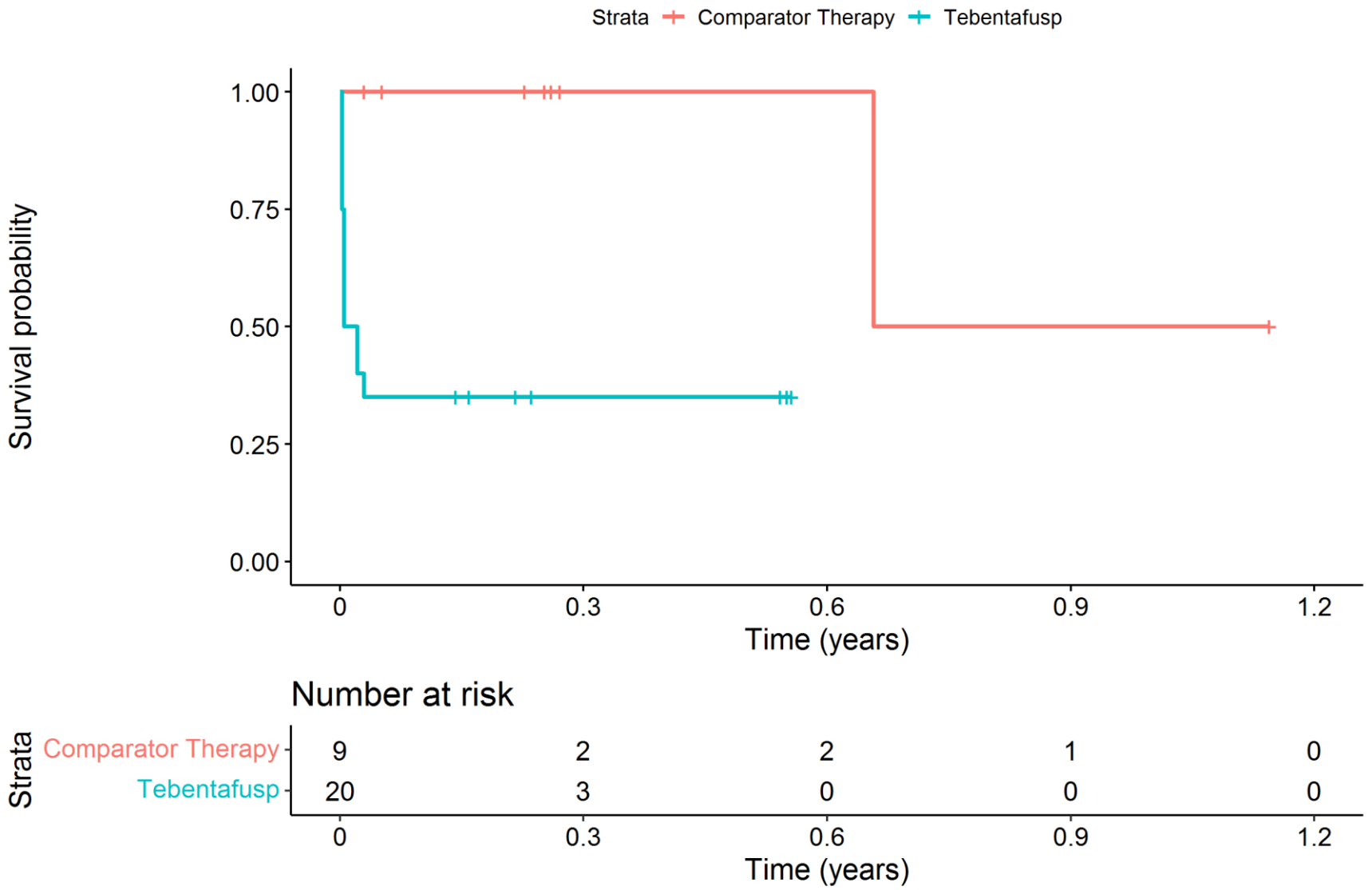
53.538 Hypotonie - Läsion ≤ 3cm



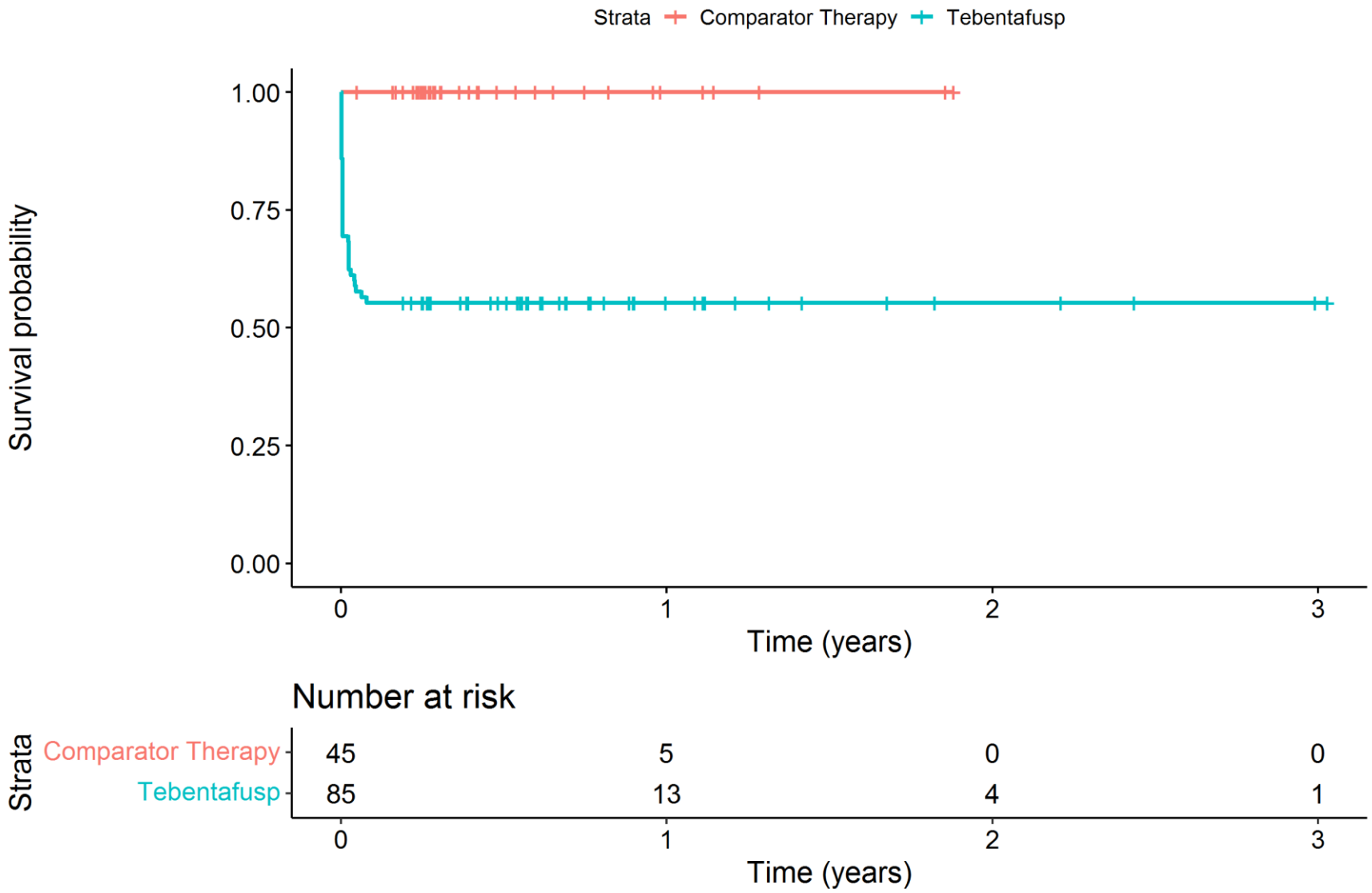
53.539 Hypotonie - Läsion 3,1-8,0 cm



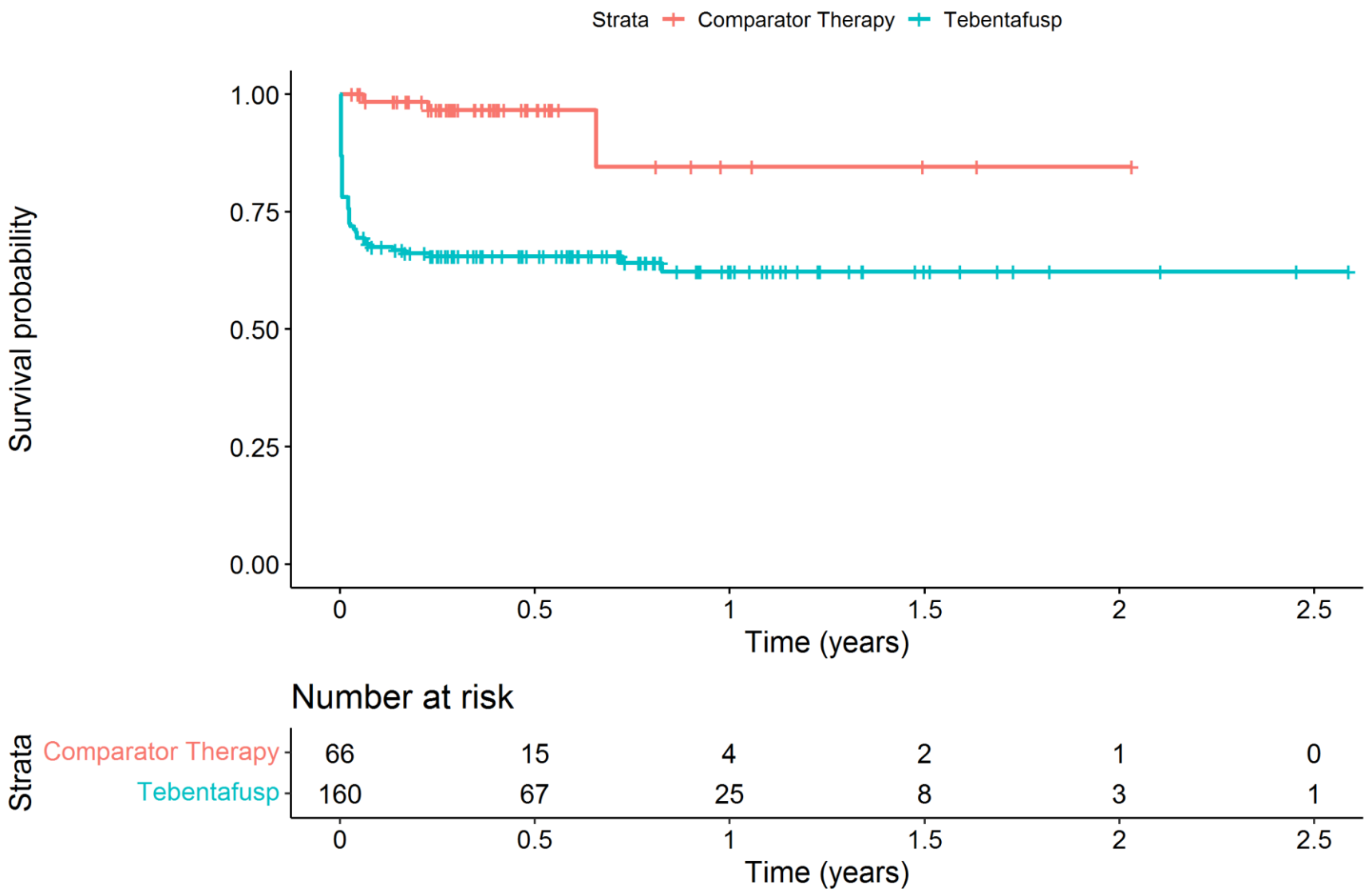
53.540 Hypotonie - Läsion ≥8,1 cm



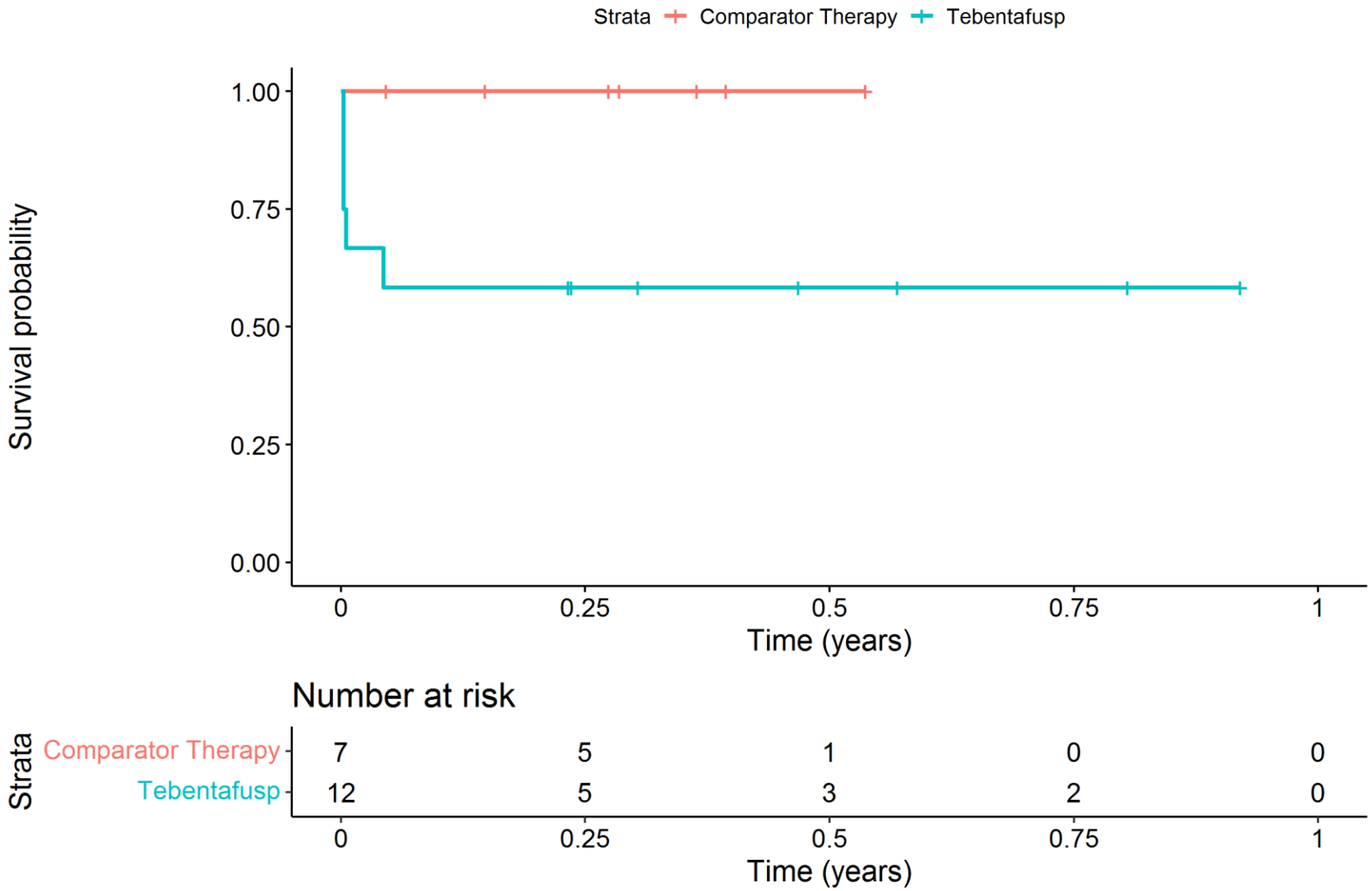
53.541 Hypotonie - Nordamerika



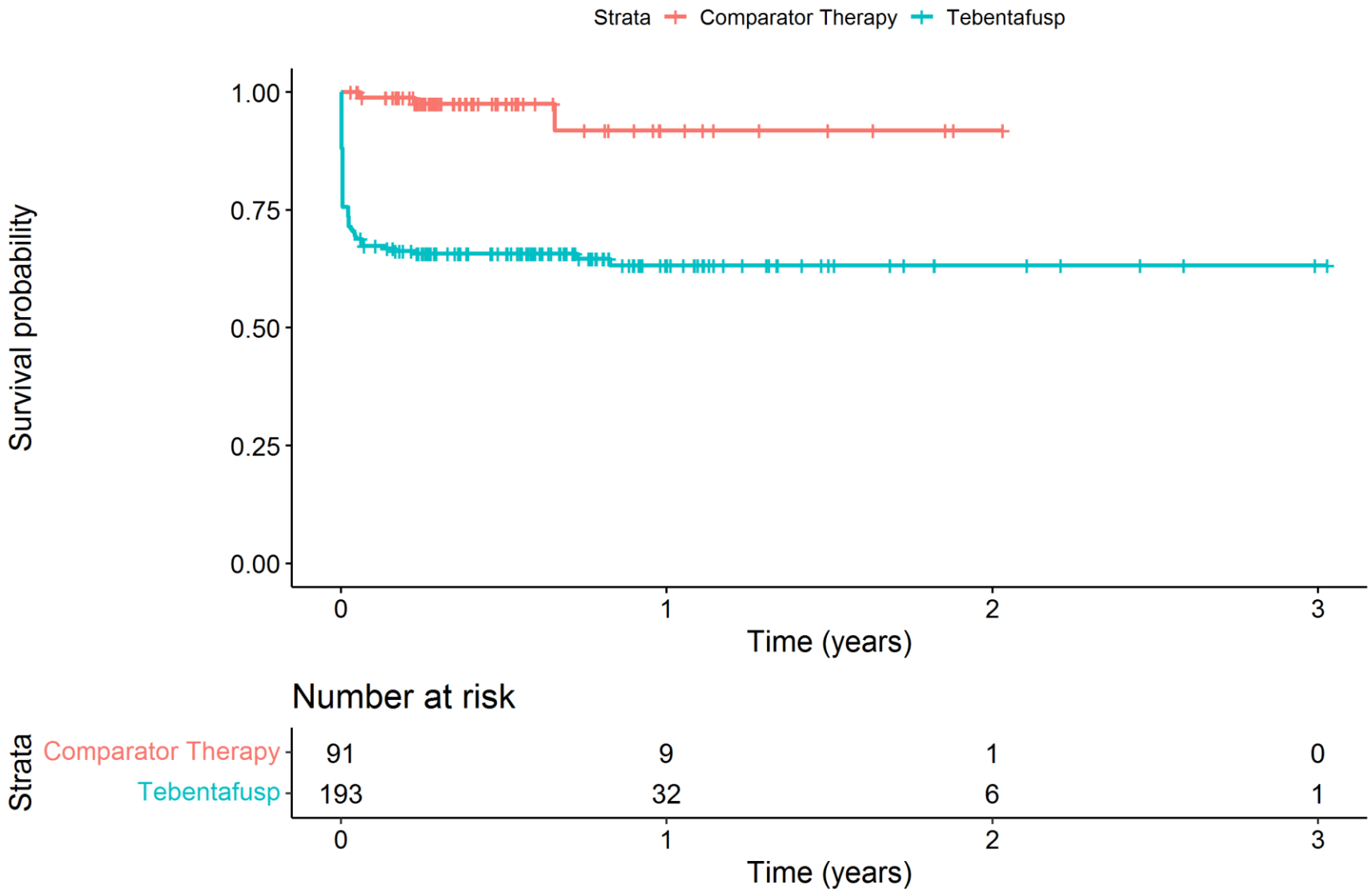
53.542 Hypotonie - Nicht-Nordamerika



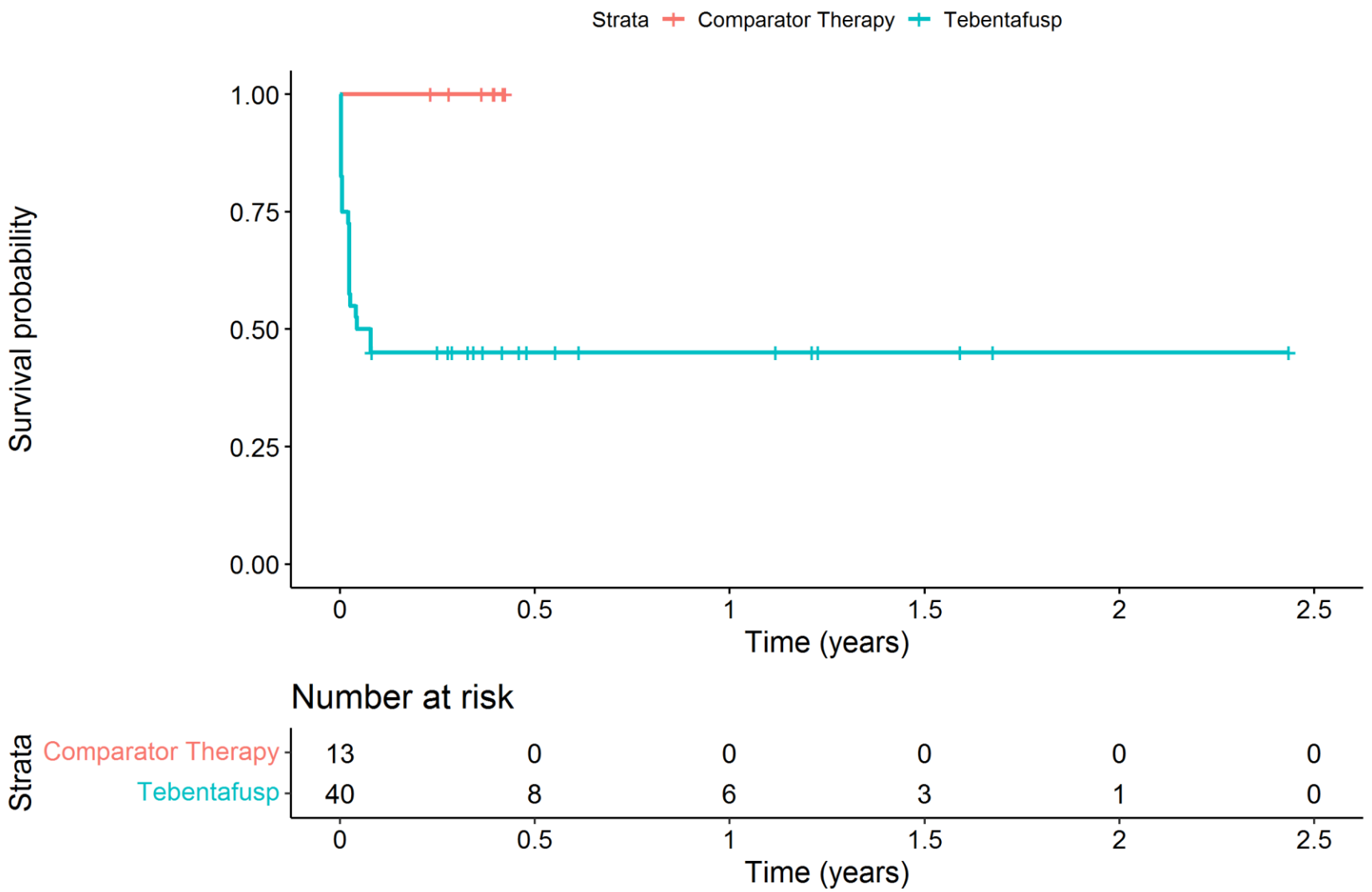
53.543 Hypotonie - Dacarbazin



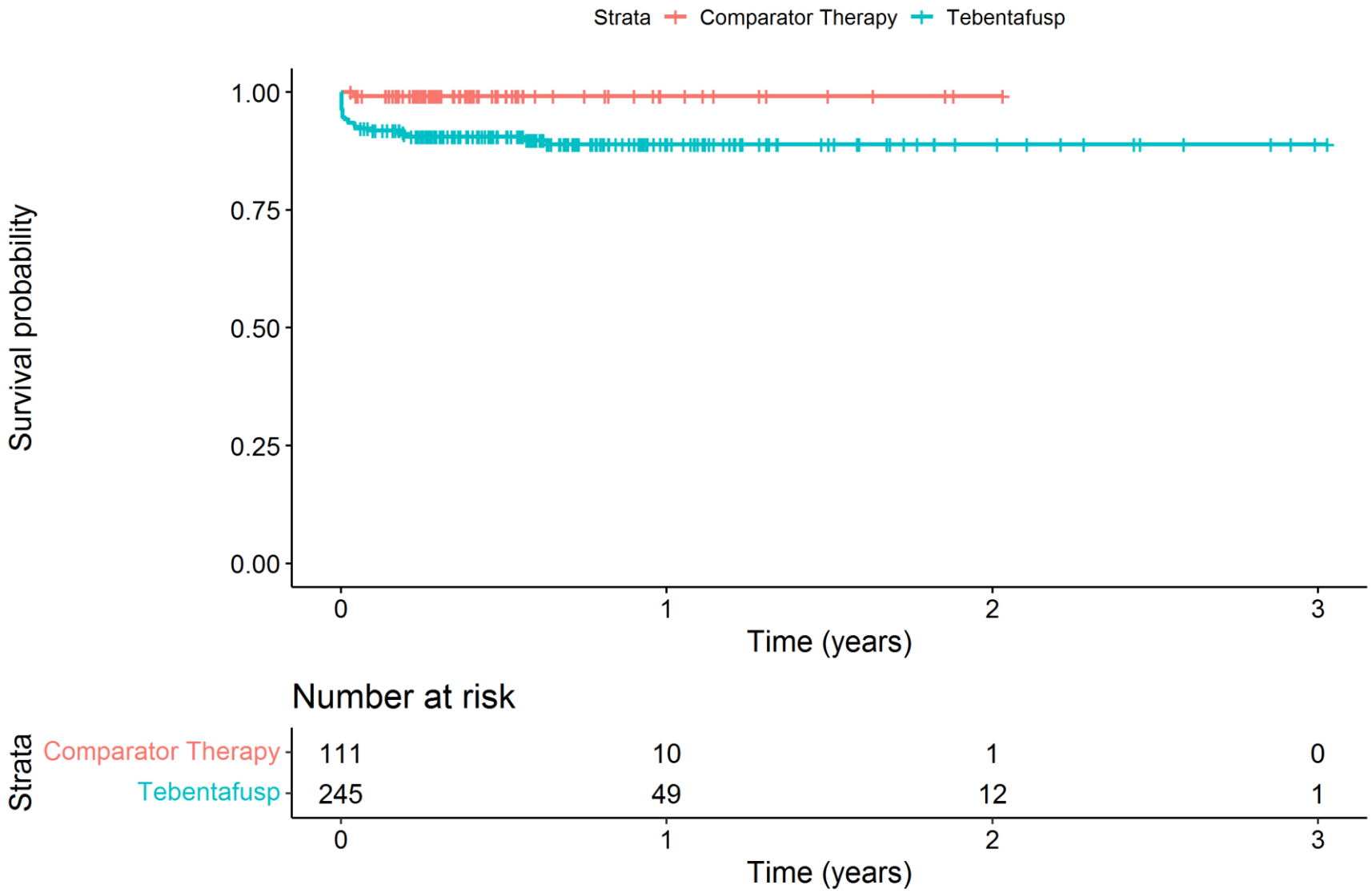
53.544 Hypotonie - Pembrolizumab



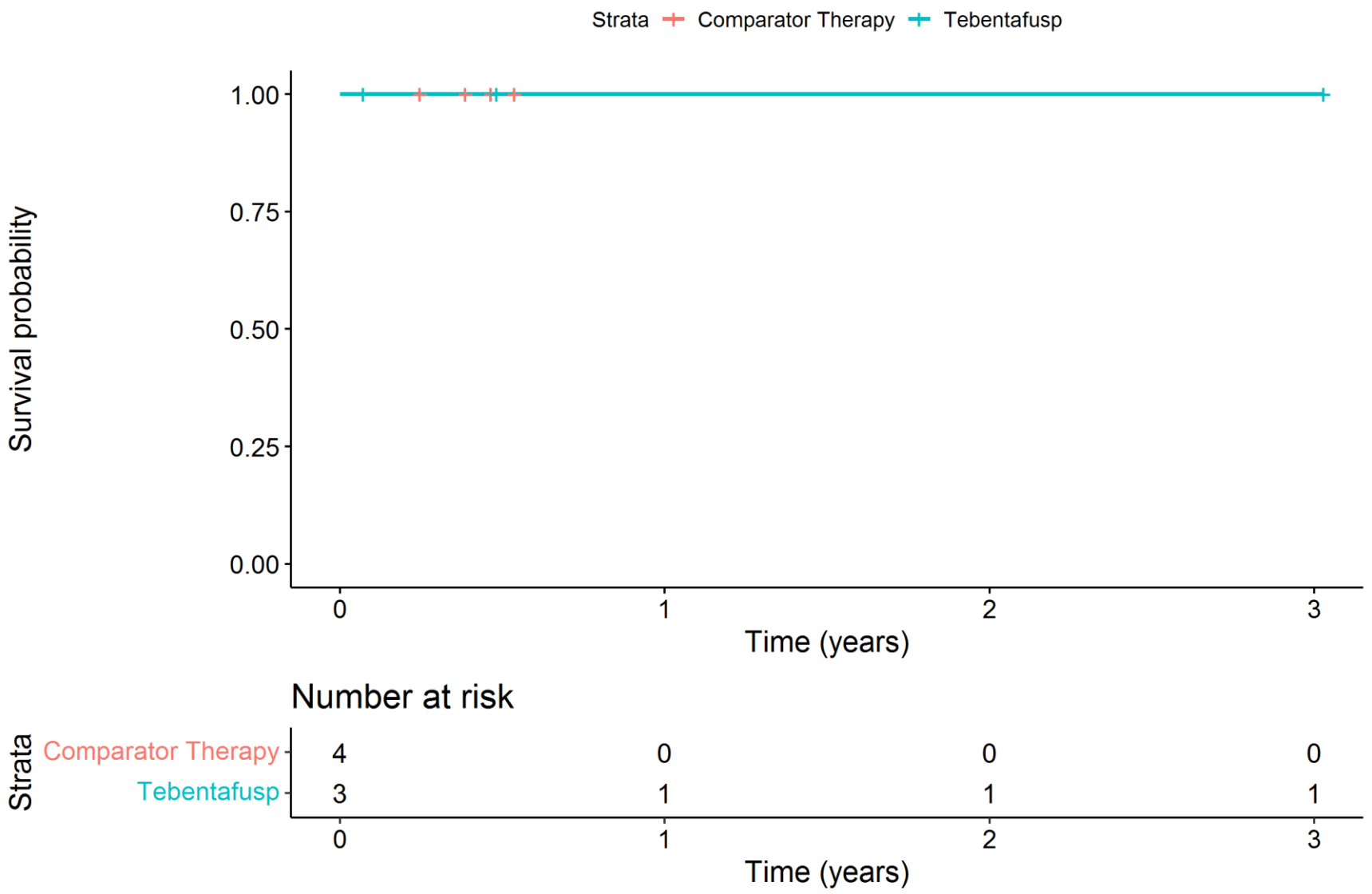
53.545 Hypotonie - Ipilimumab



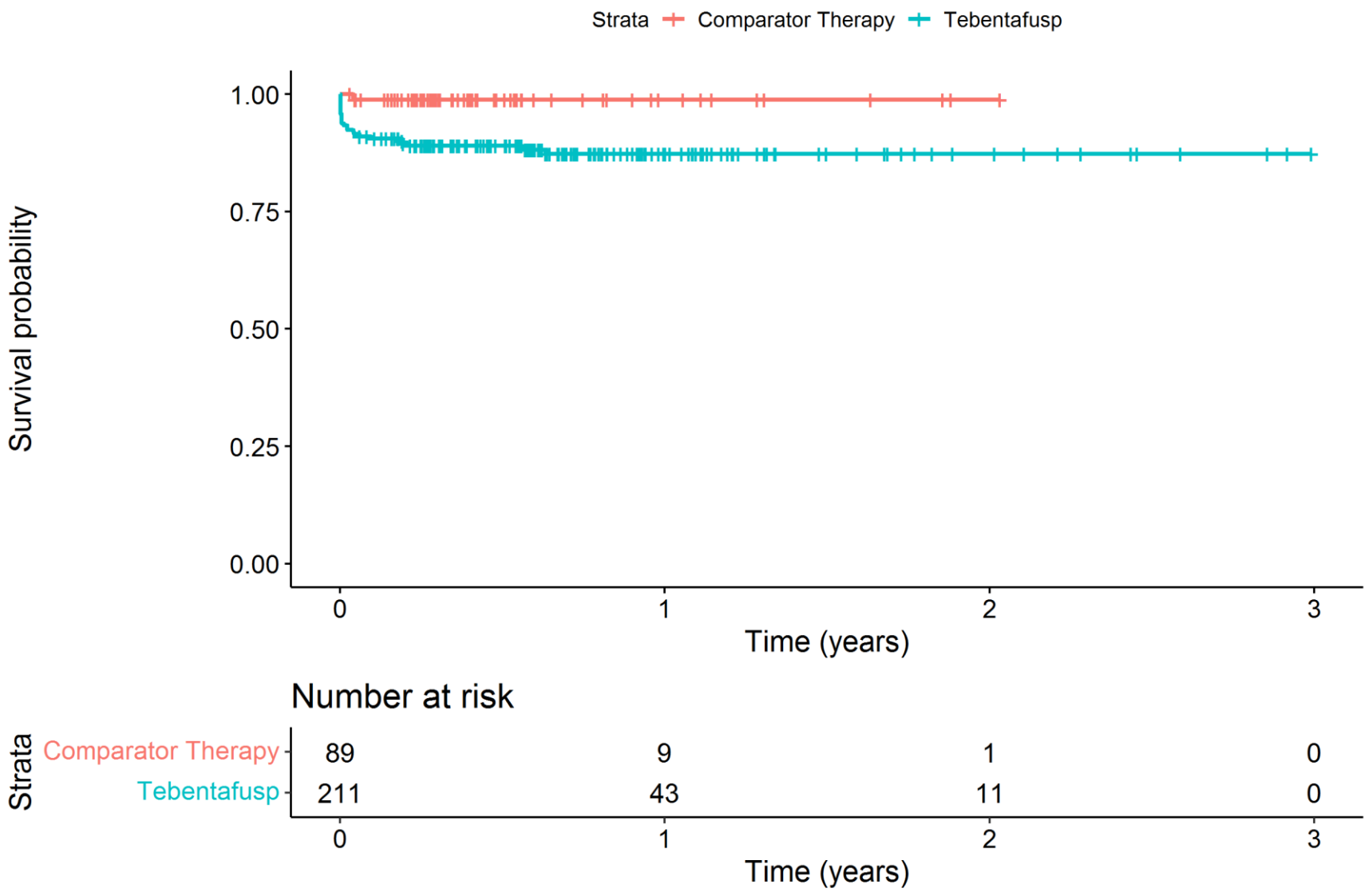
53.546 Hautrötung - Gesamt



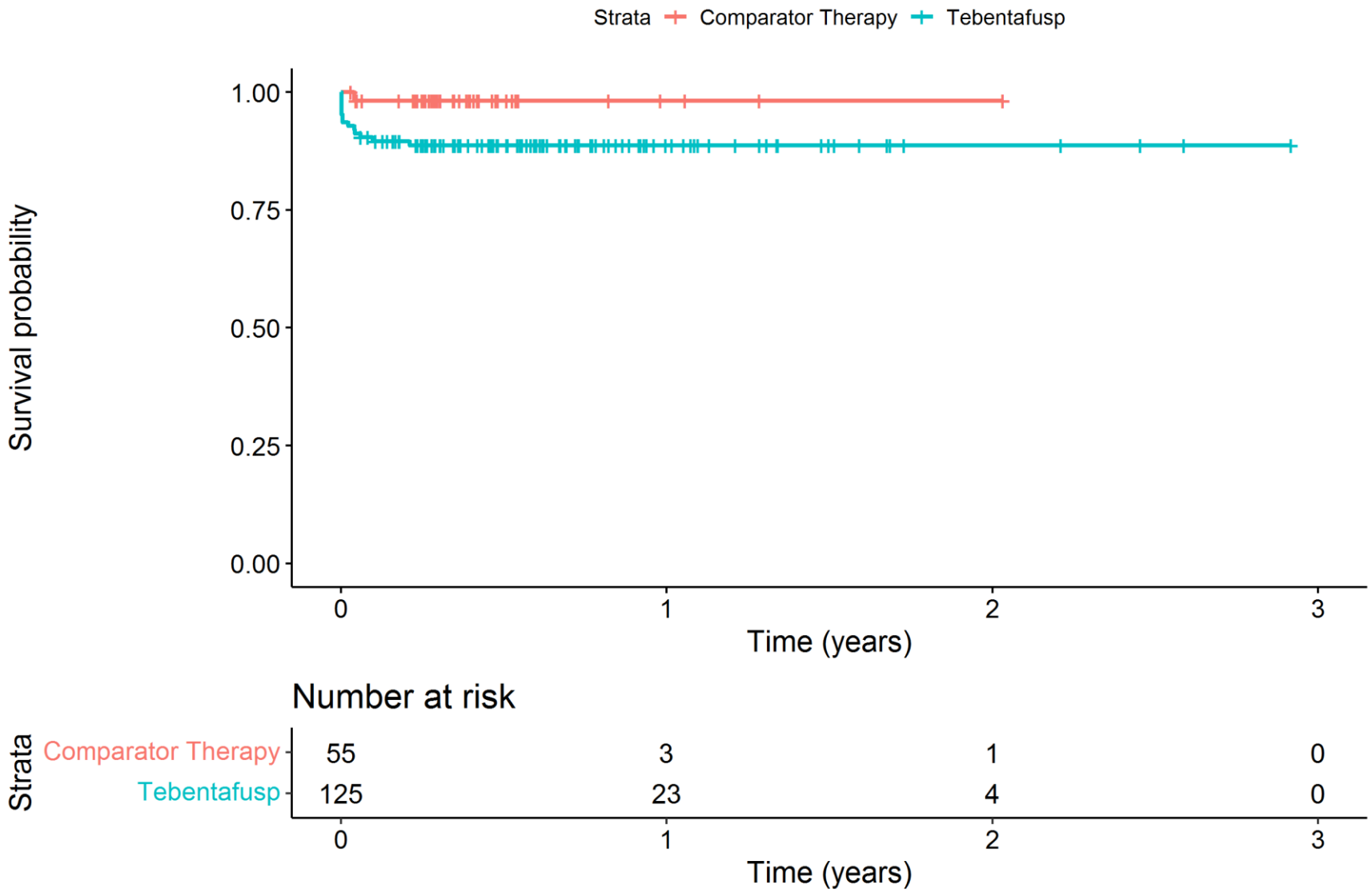
53.547 Hautrötung - Hispanisch



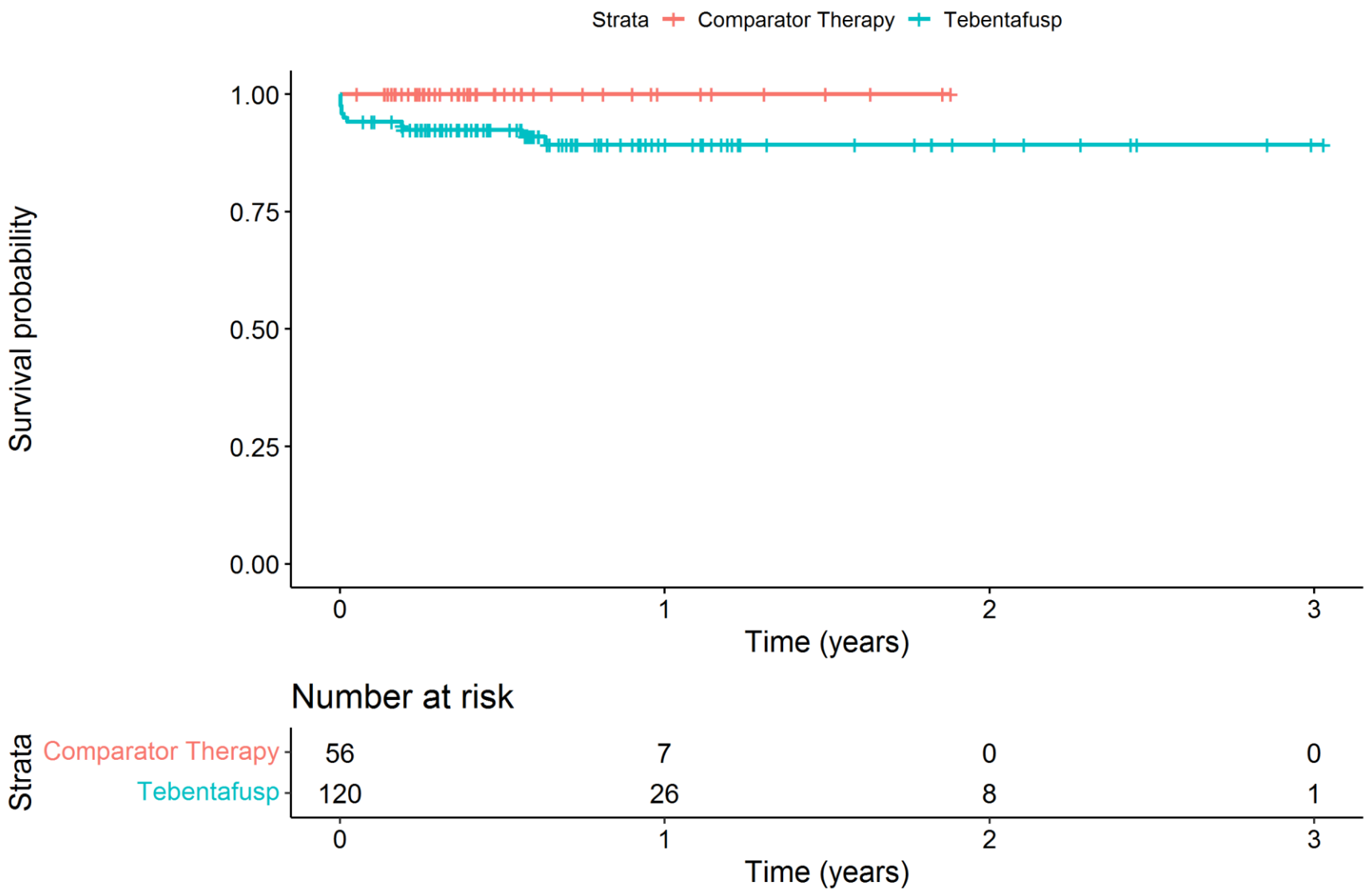
53.548 Hautrötung - Nicht-hispanisch



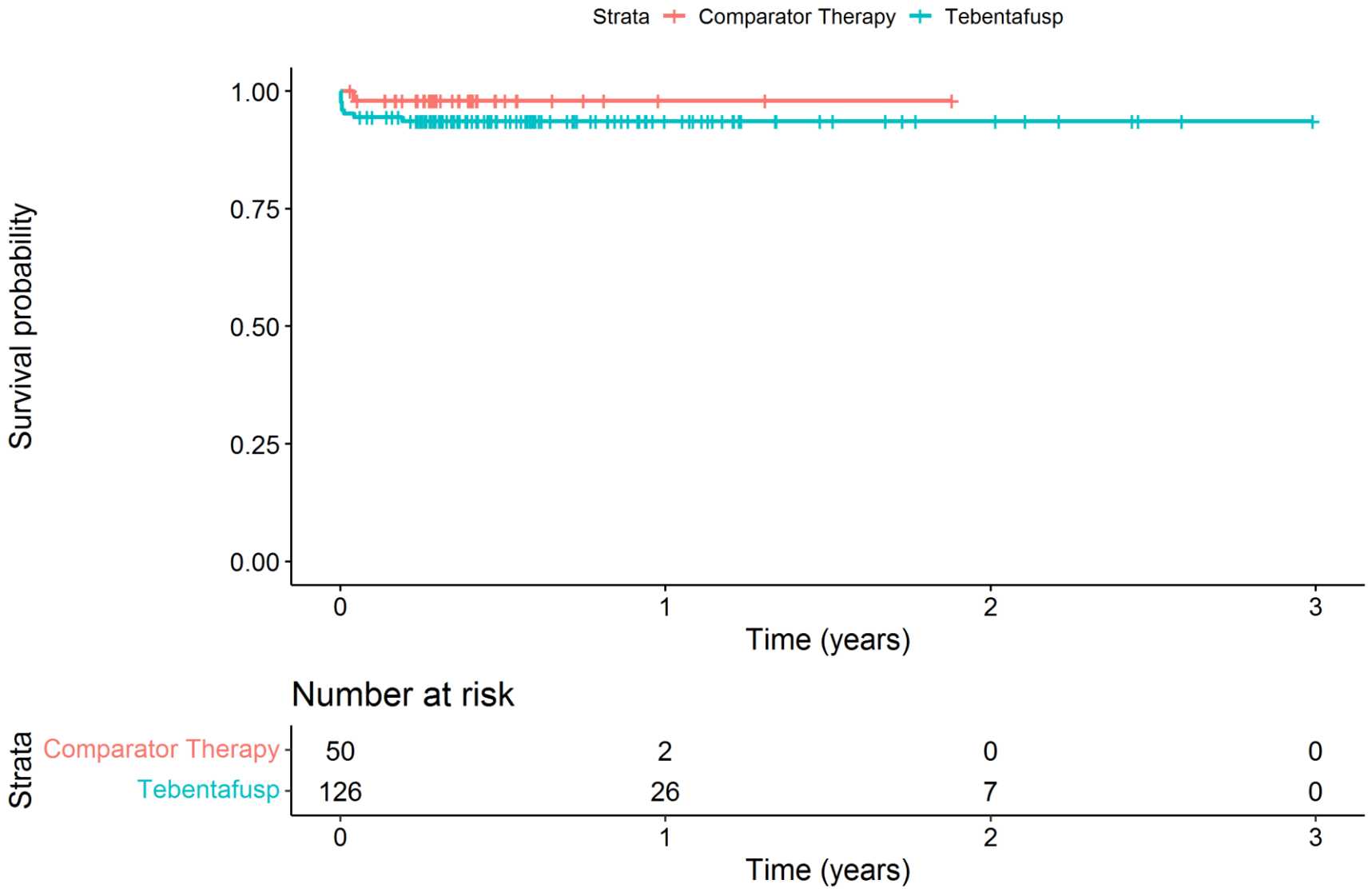
53.549 Hautrötung - Männlich



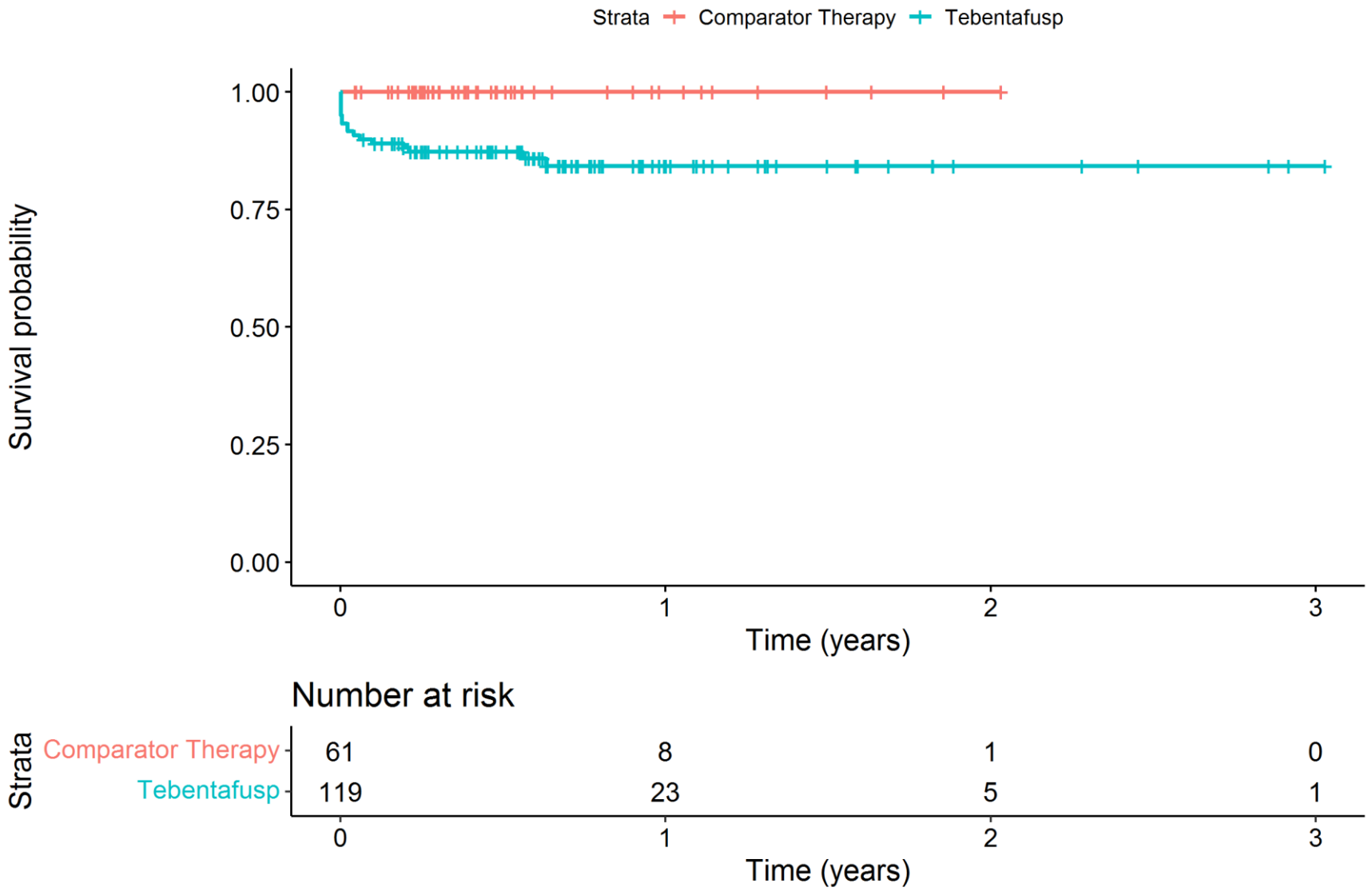
53.550 Hautrötung - Weiblich



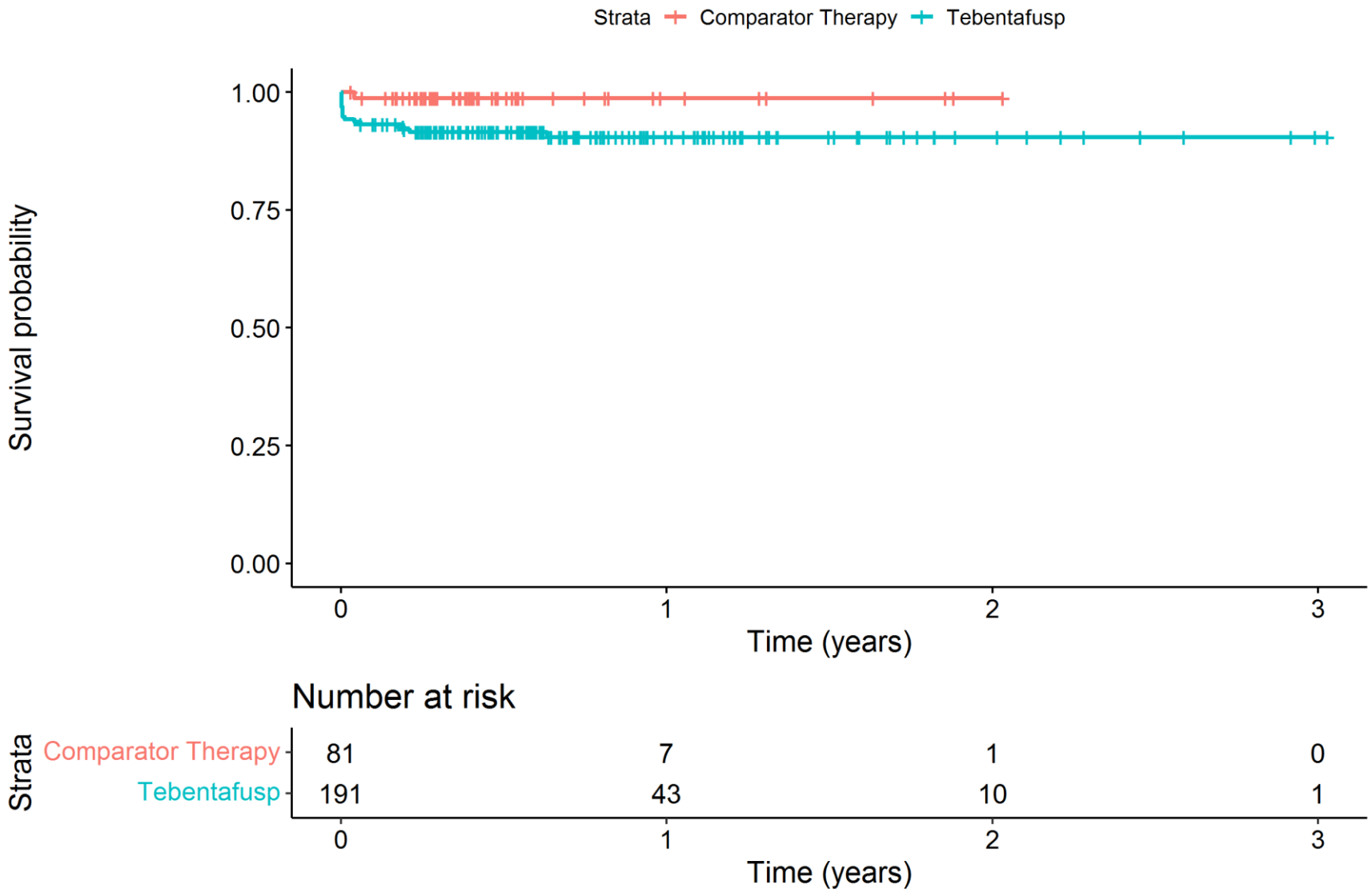
53.551 Hautrötung - <65



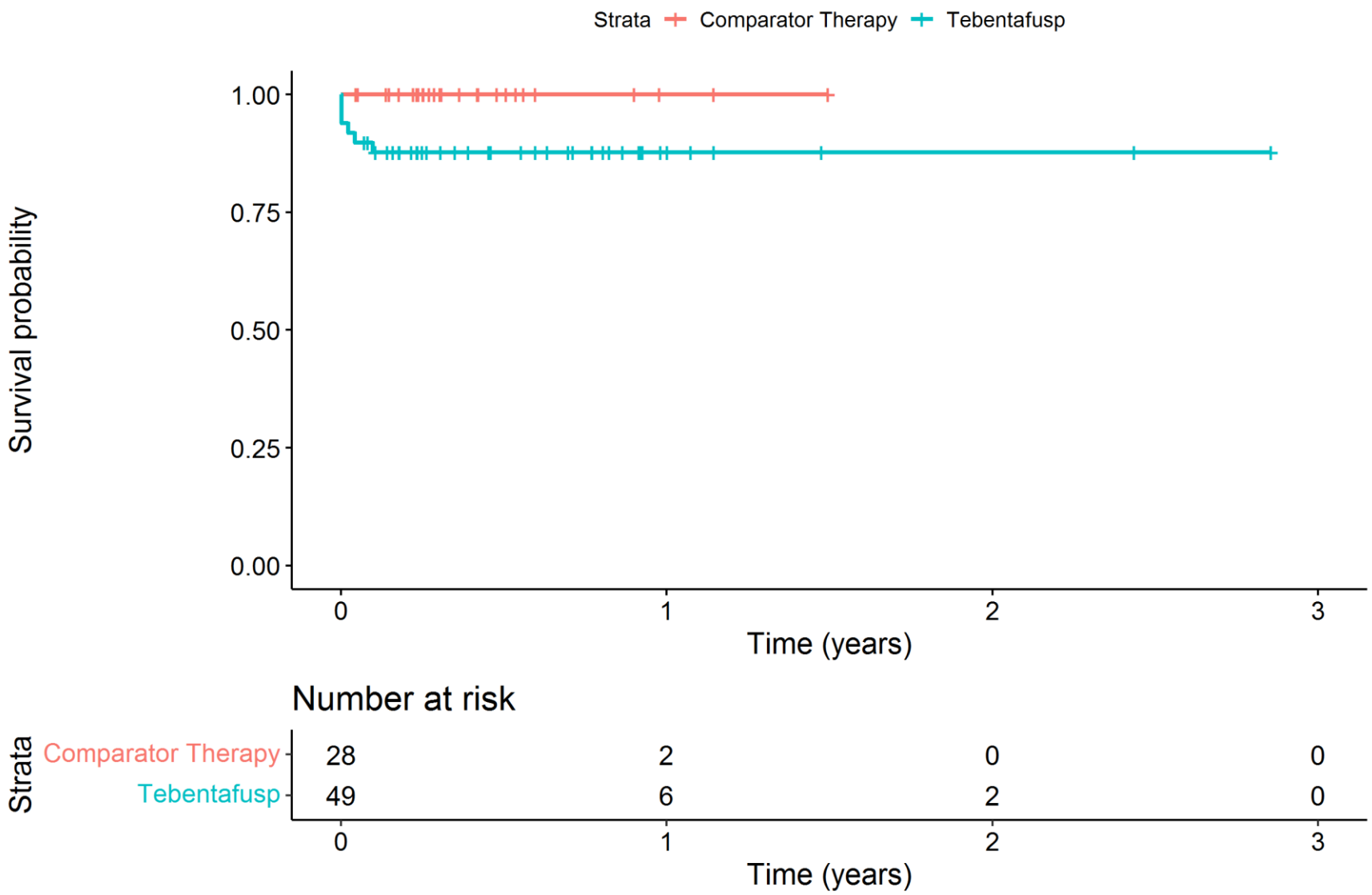
53.552 Hautrötung - ≥65



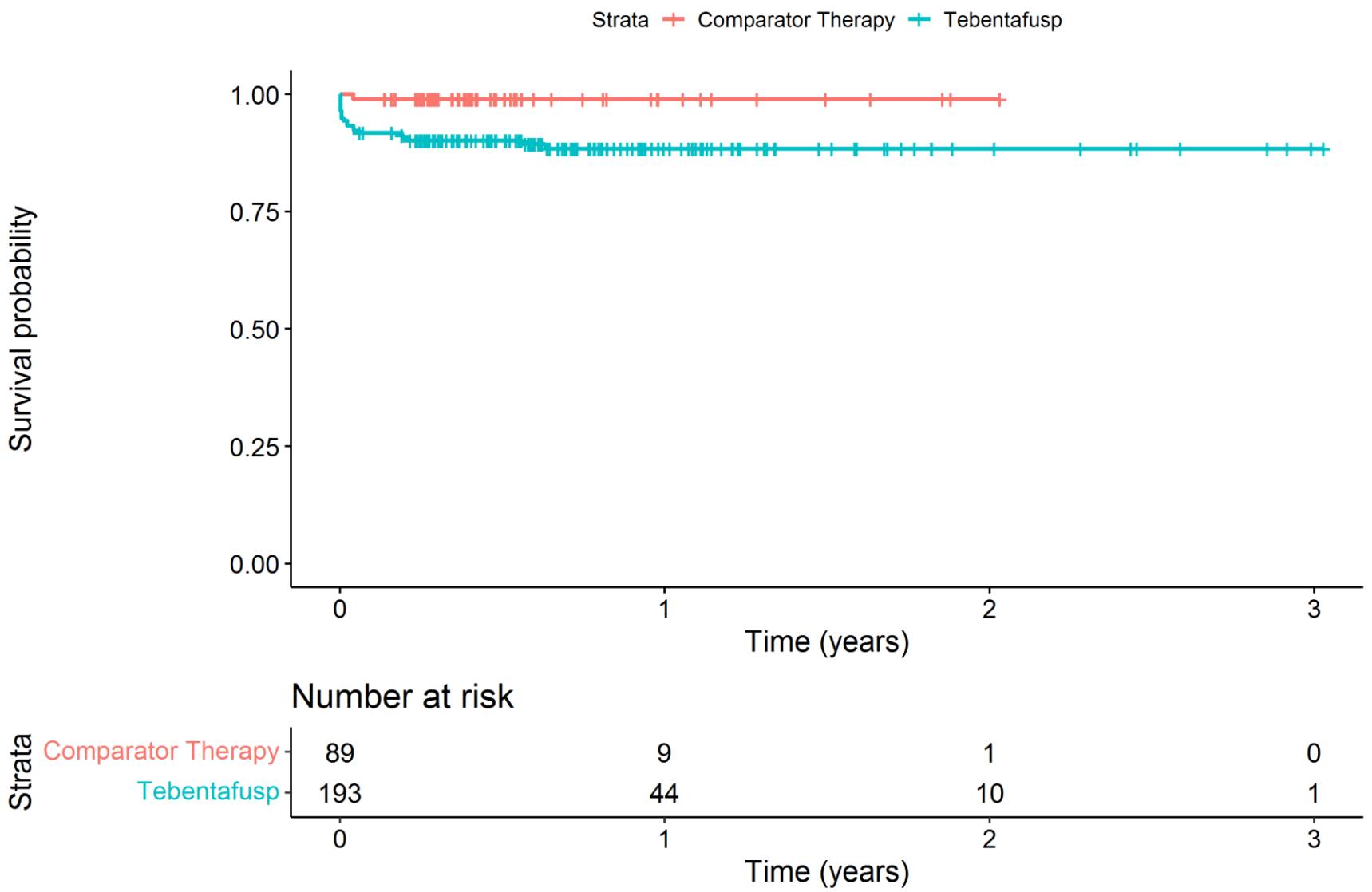
53.553 Hautrötung - ECOG 0



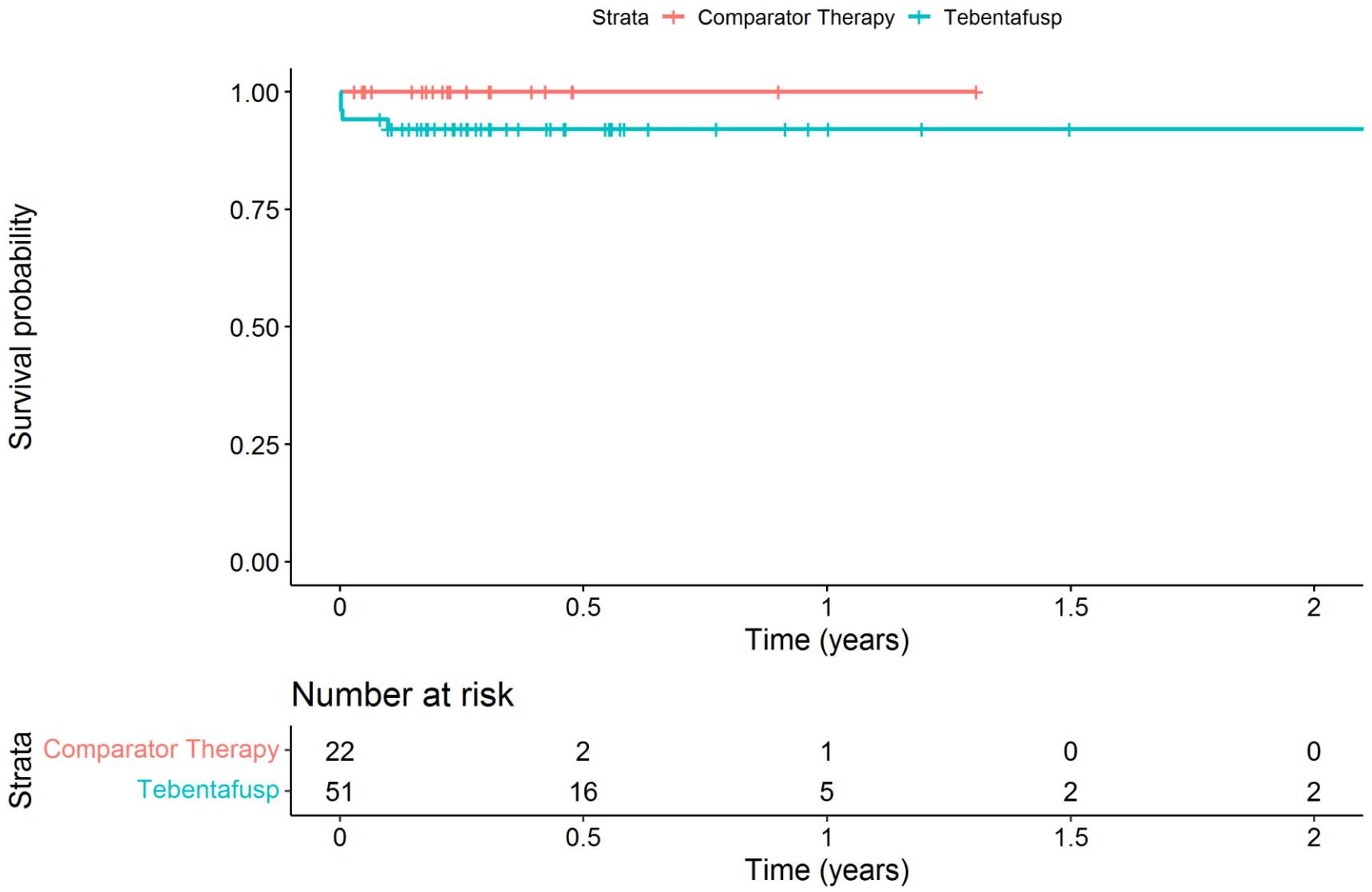
53.554 Hautrötung - ECOG 1



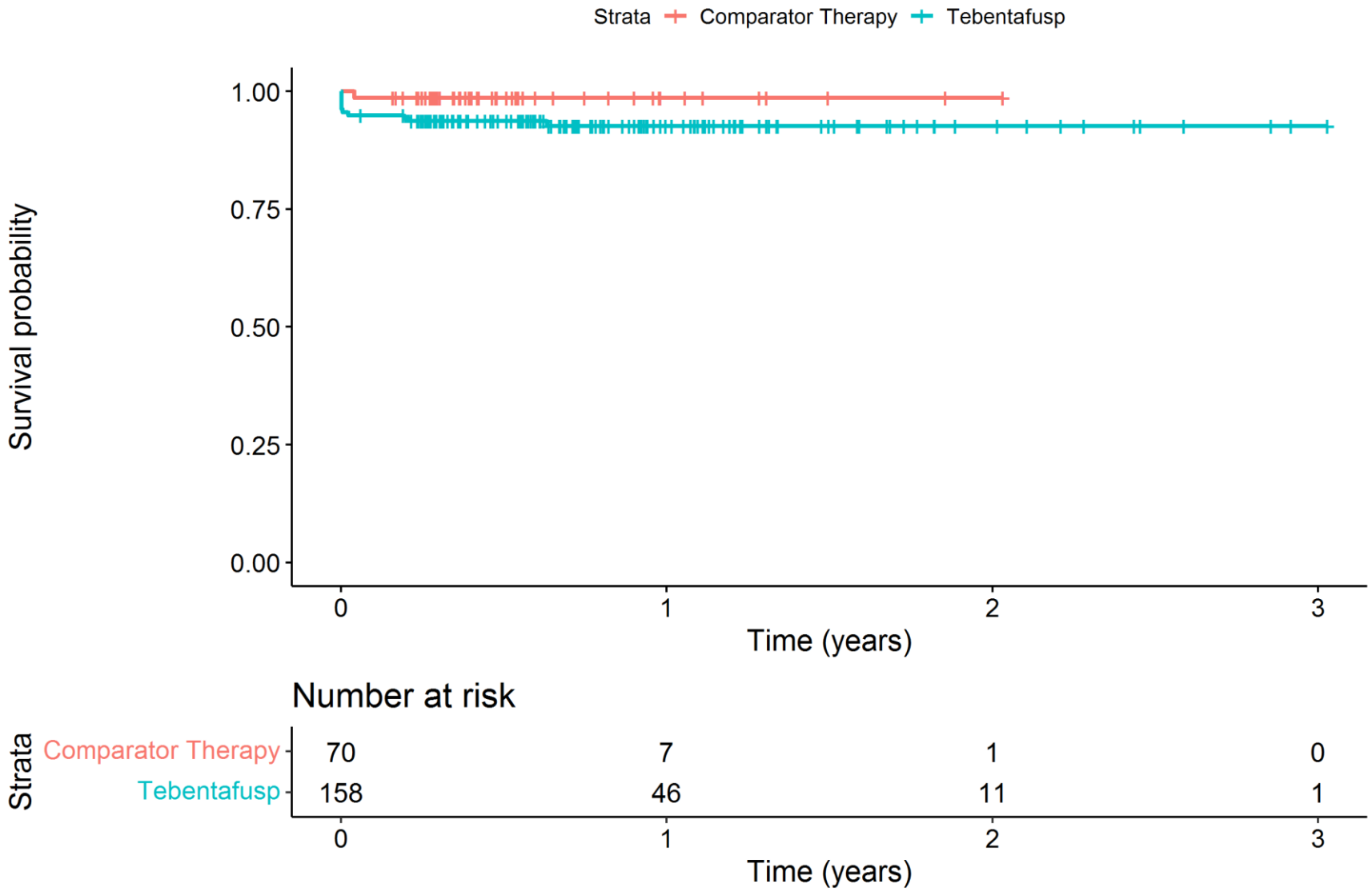
53.555 Hautrötung - ALP ≤ ULN



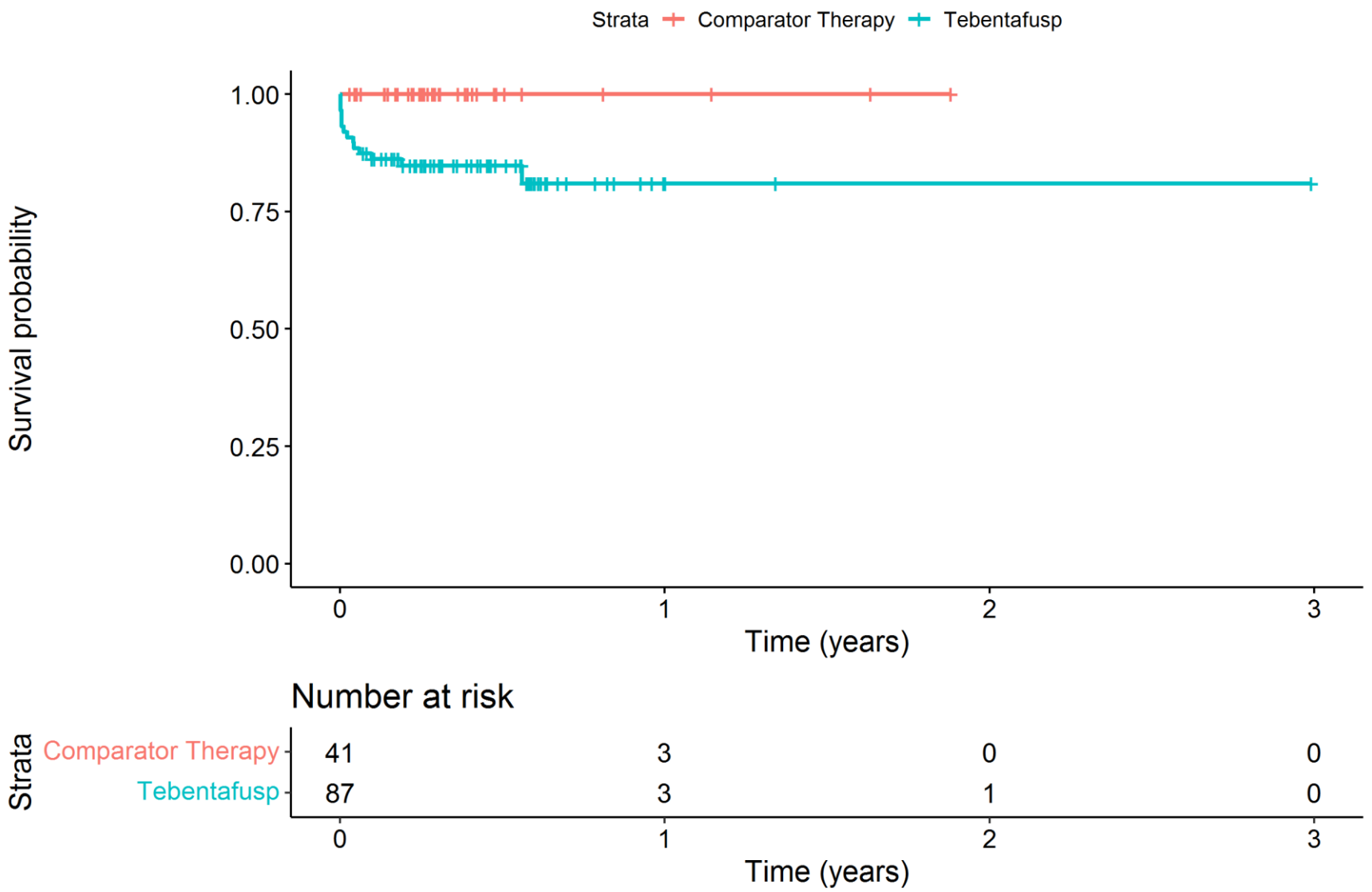
53.556 Hautrötung - ALP > ULN



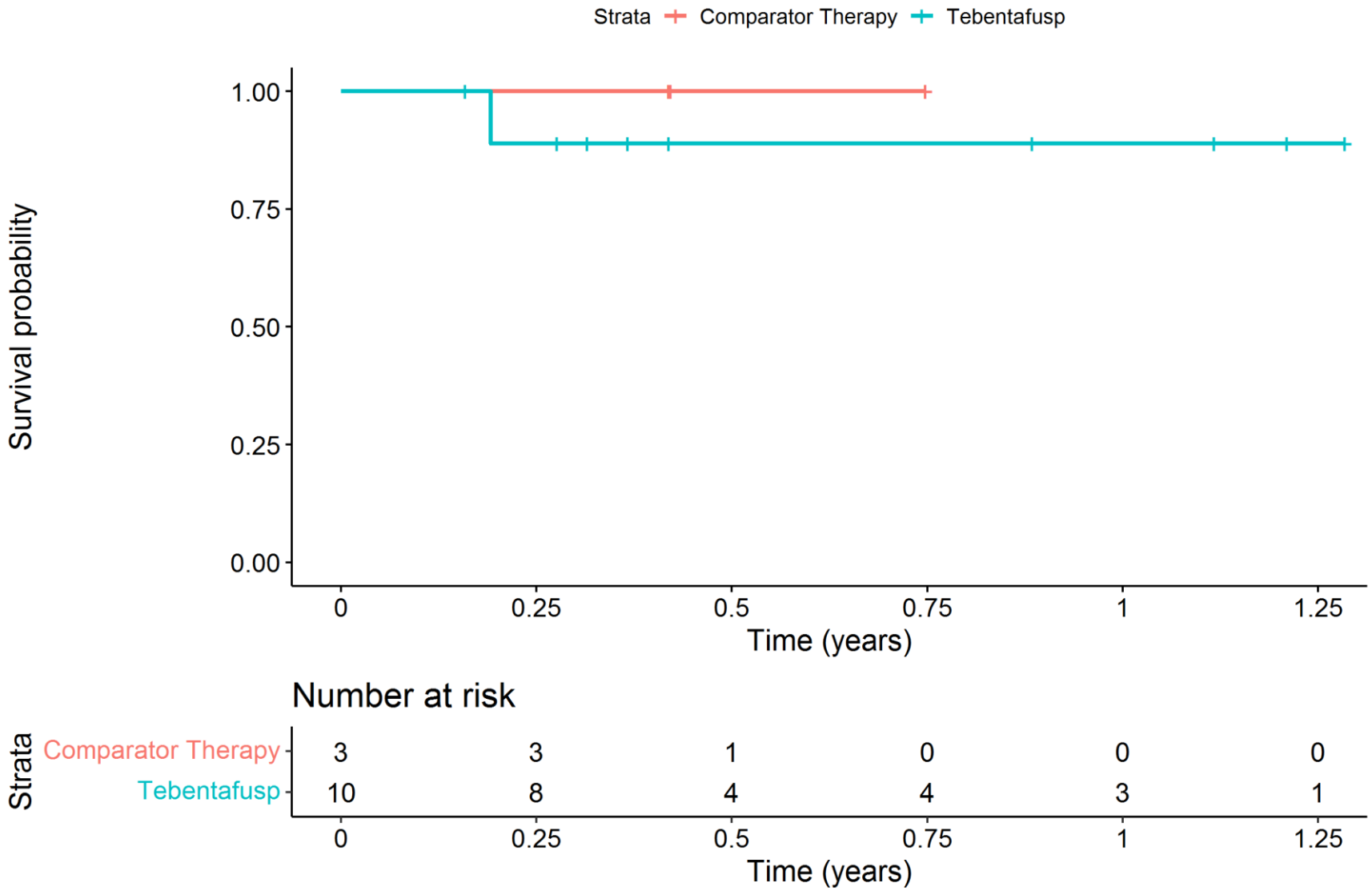
53.557 Hautrötung - LDH =< ULN



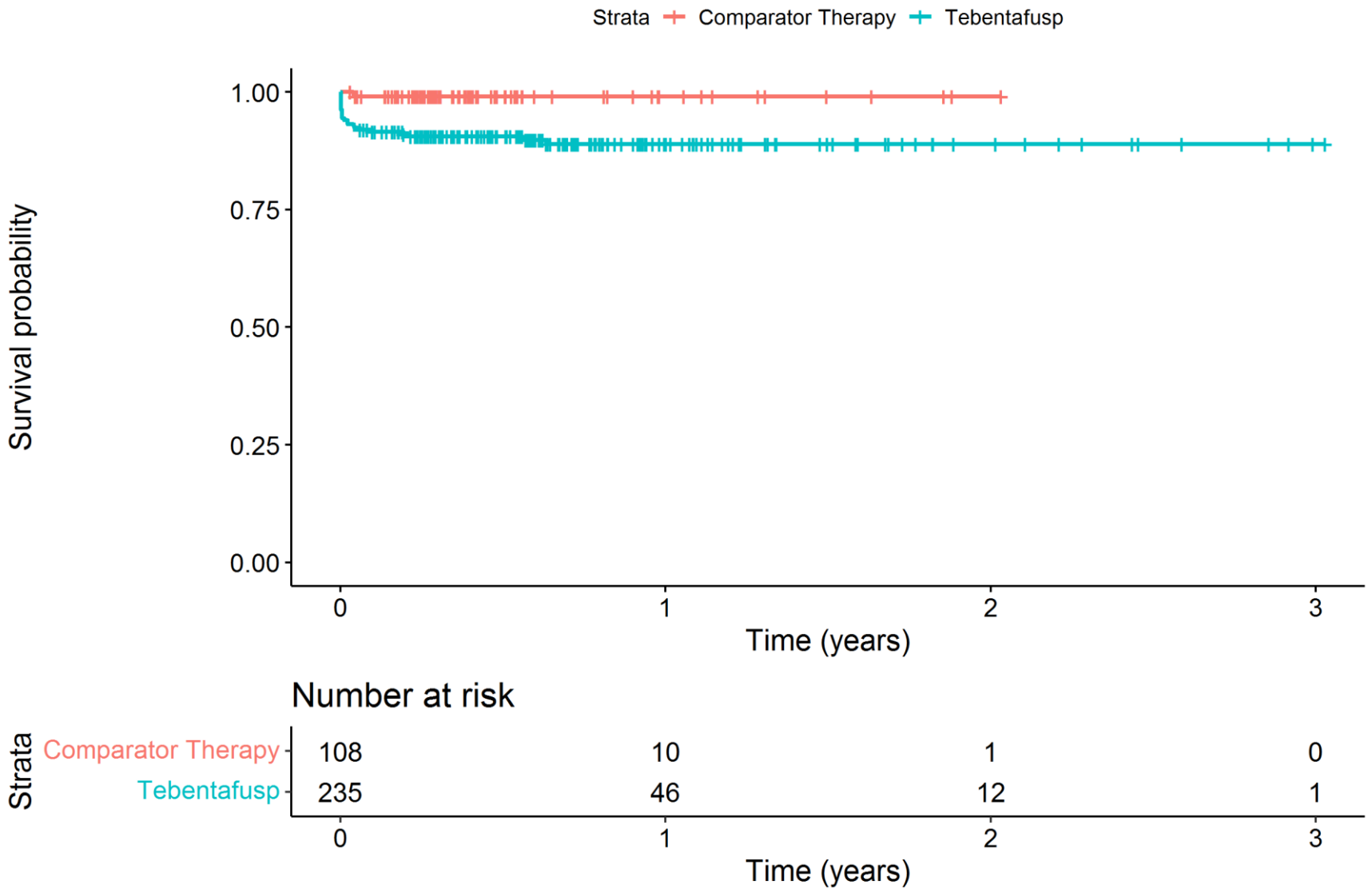
53.558 Hautrötung - LDH > ULN



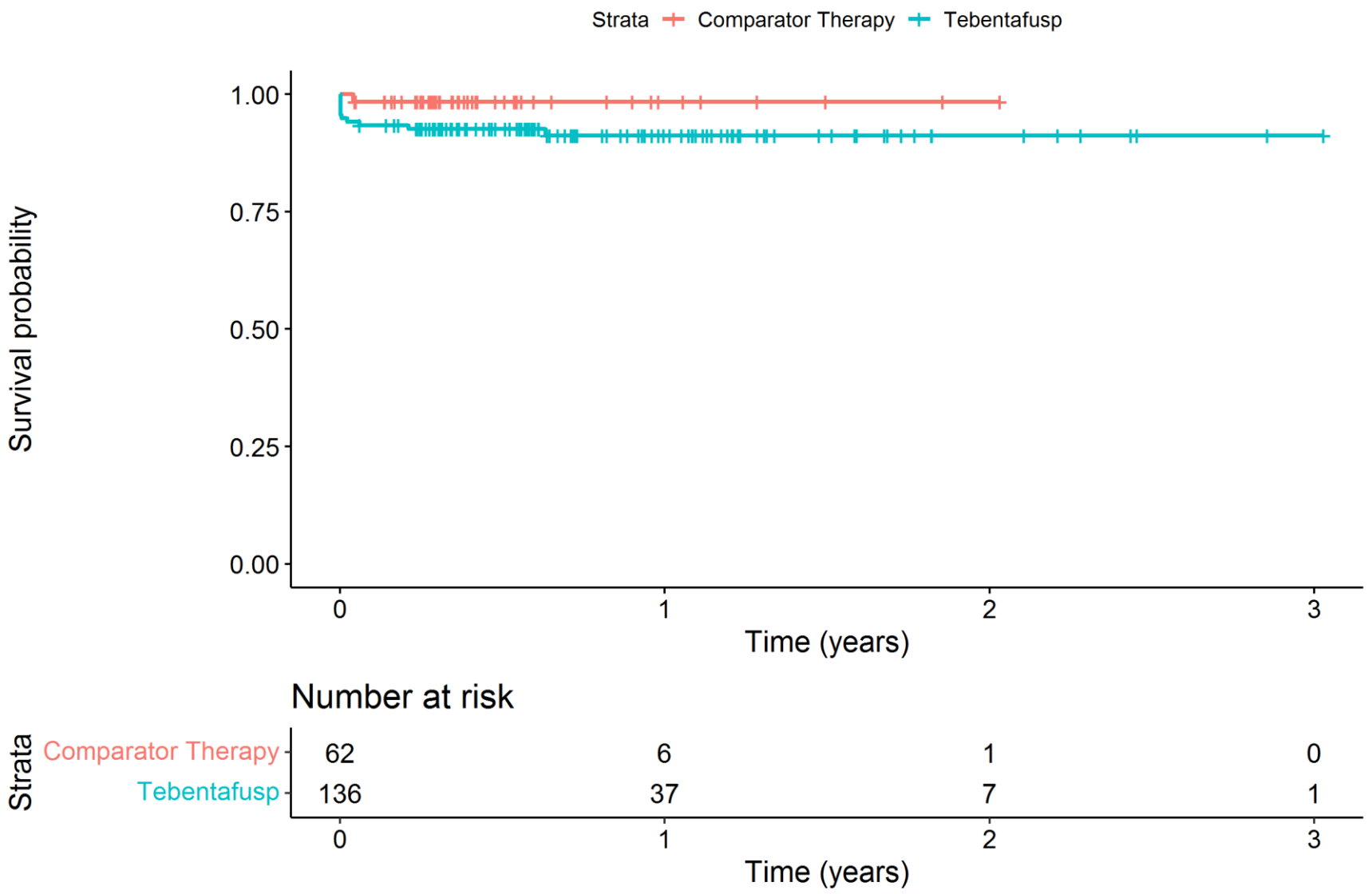
53.559 Hautrötung - Vorherige Therapie adjuvant/neoadjuvant



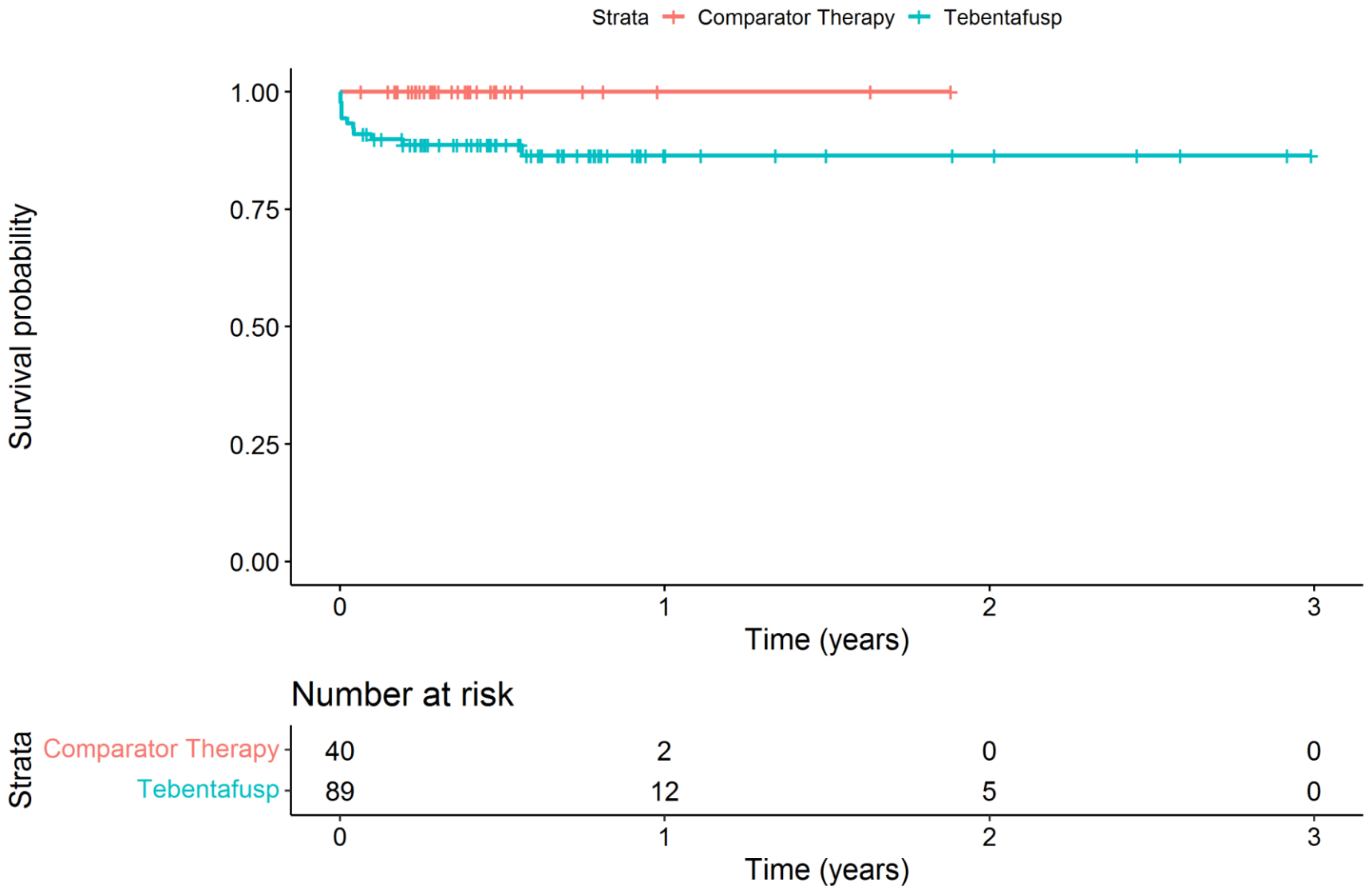
53.560 Hautrötung - Keine vorherige Therapie adjuvant/neoadjuvant



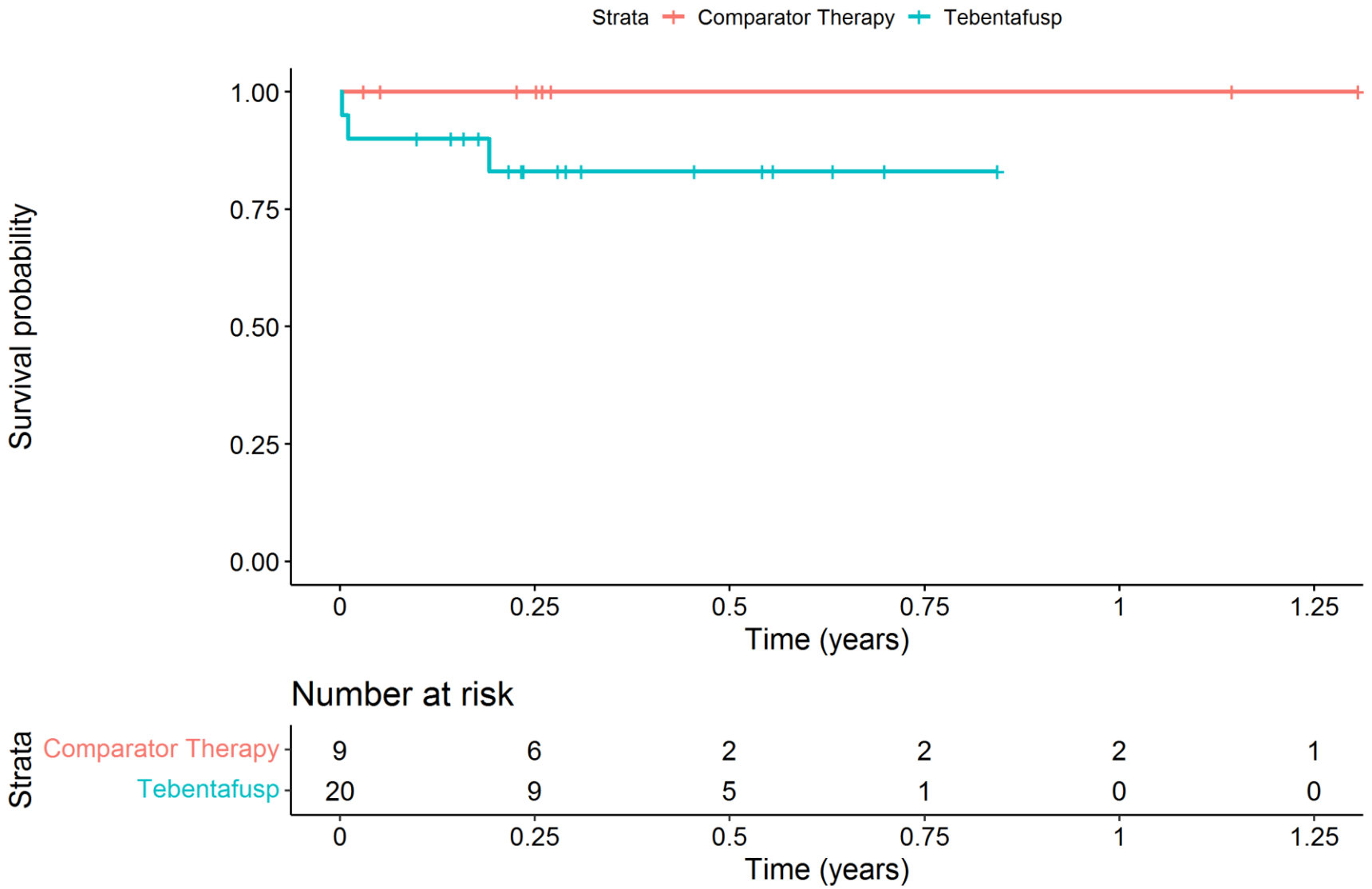
53.561 Hautrötung - Läsion ≤ 3cm



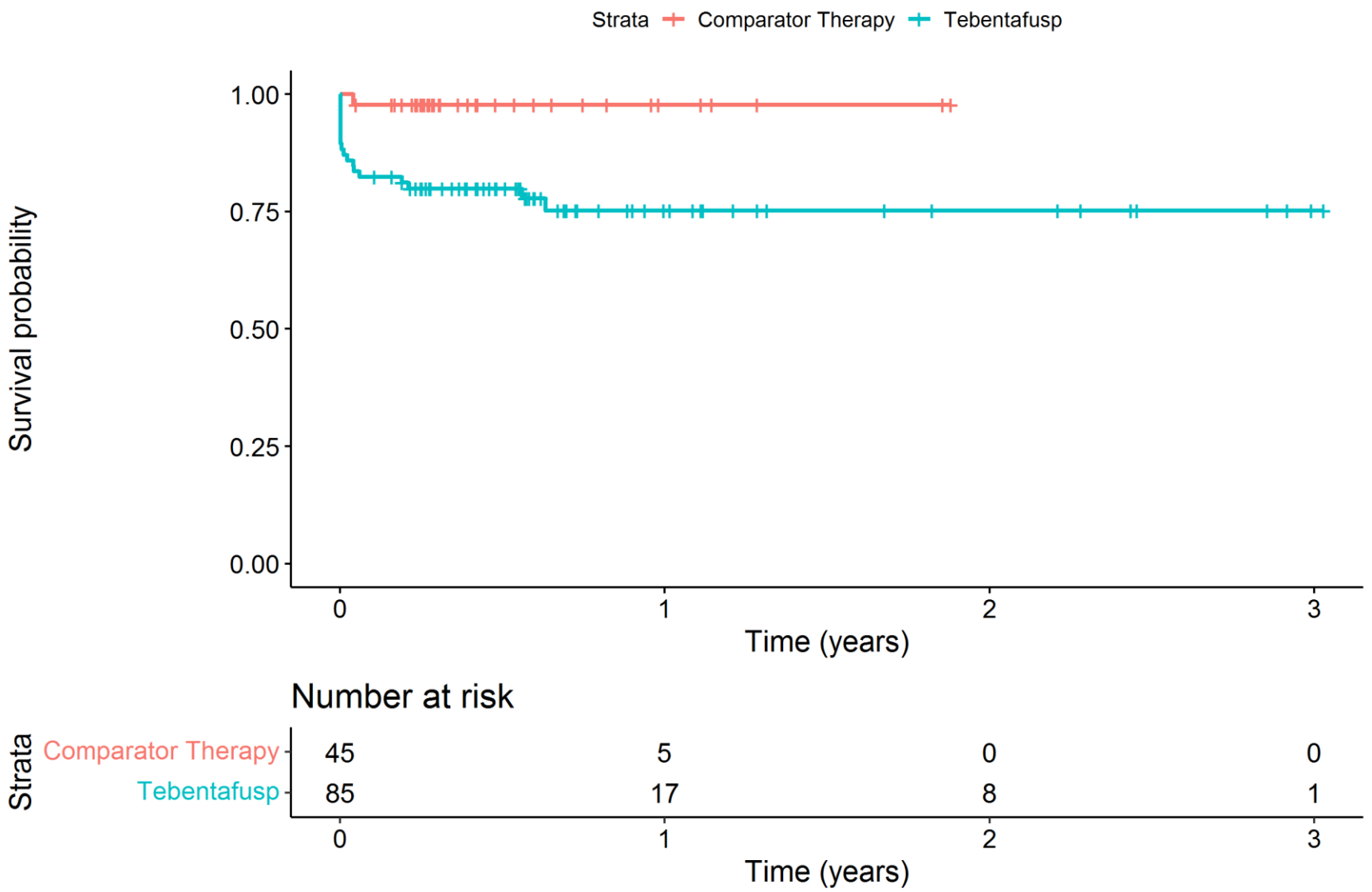
53.562 Hautrötung - Läsion 3,1-8,0 cm



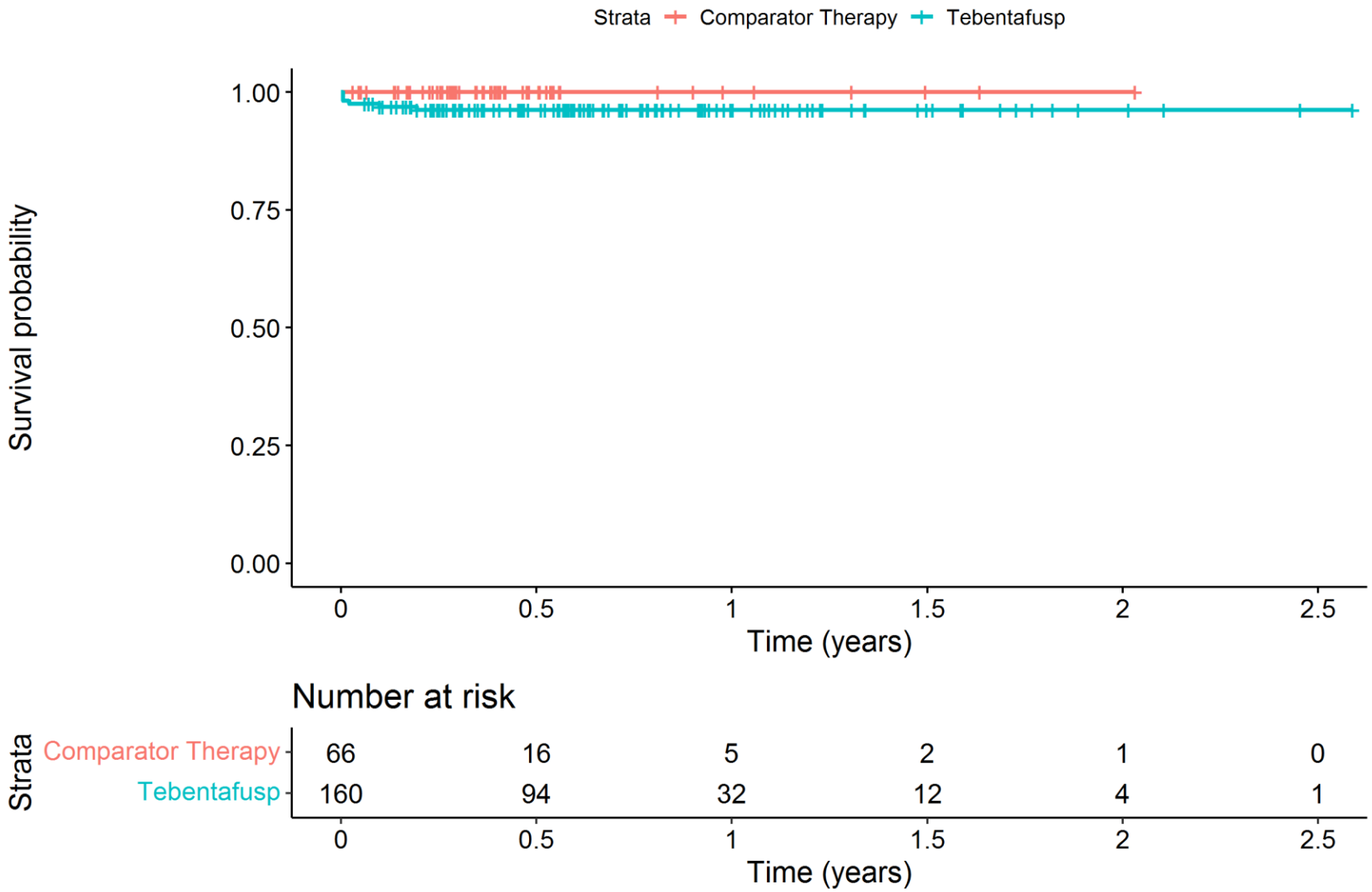
53.563 Hautrötung - Läsion ≥8,1 cm



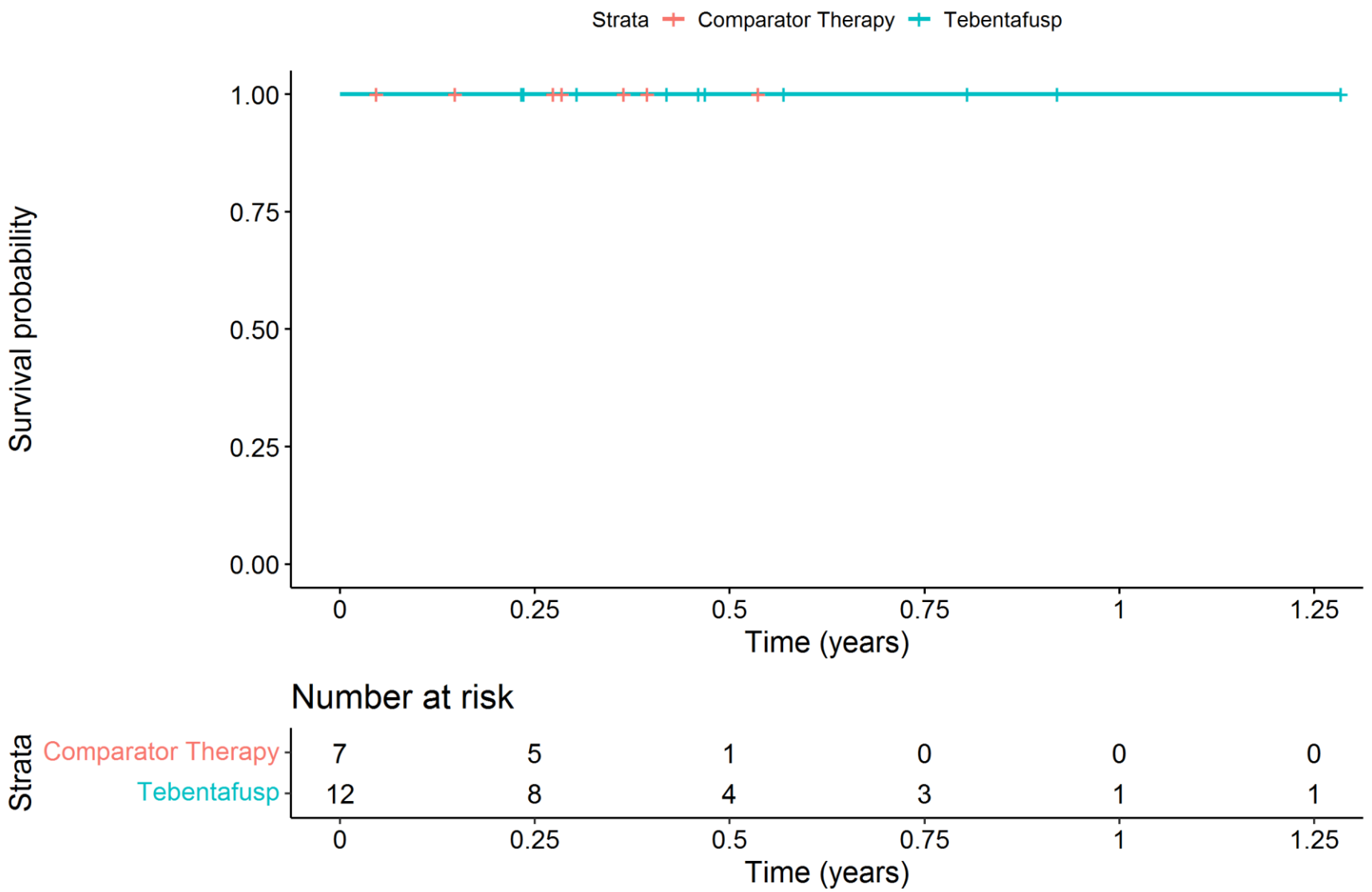
53.564 Hautrötung - Nordamerika



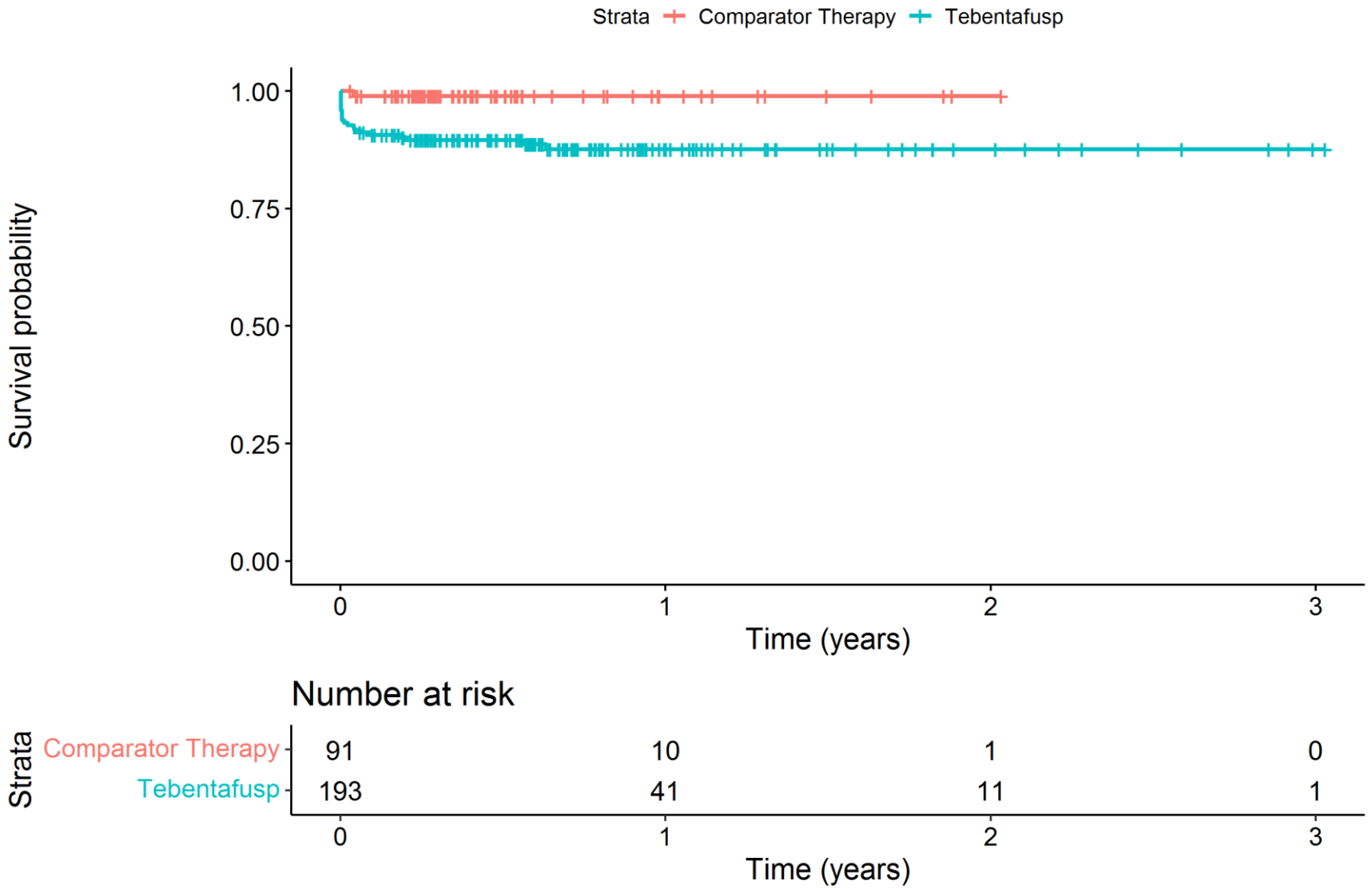
53.565 Hautrötung - Nicht-Nordamerika



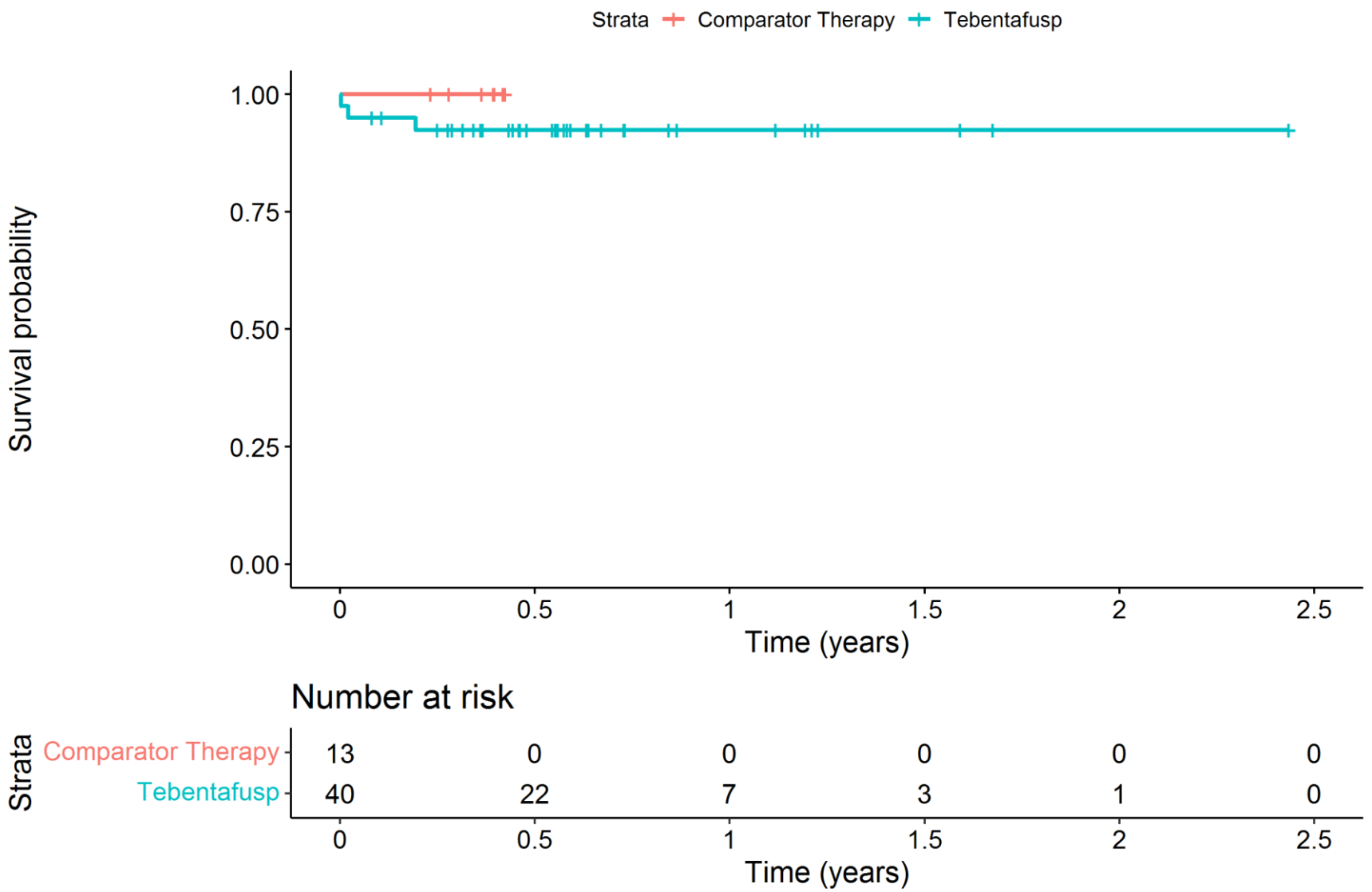
53.566 Hautrötung - Dacarbazin



53.567 Hautrötung - Pembrolizumab

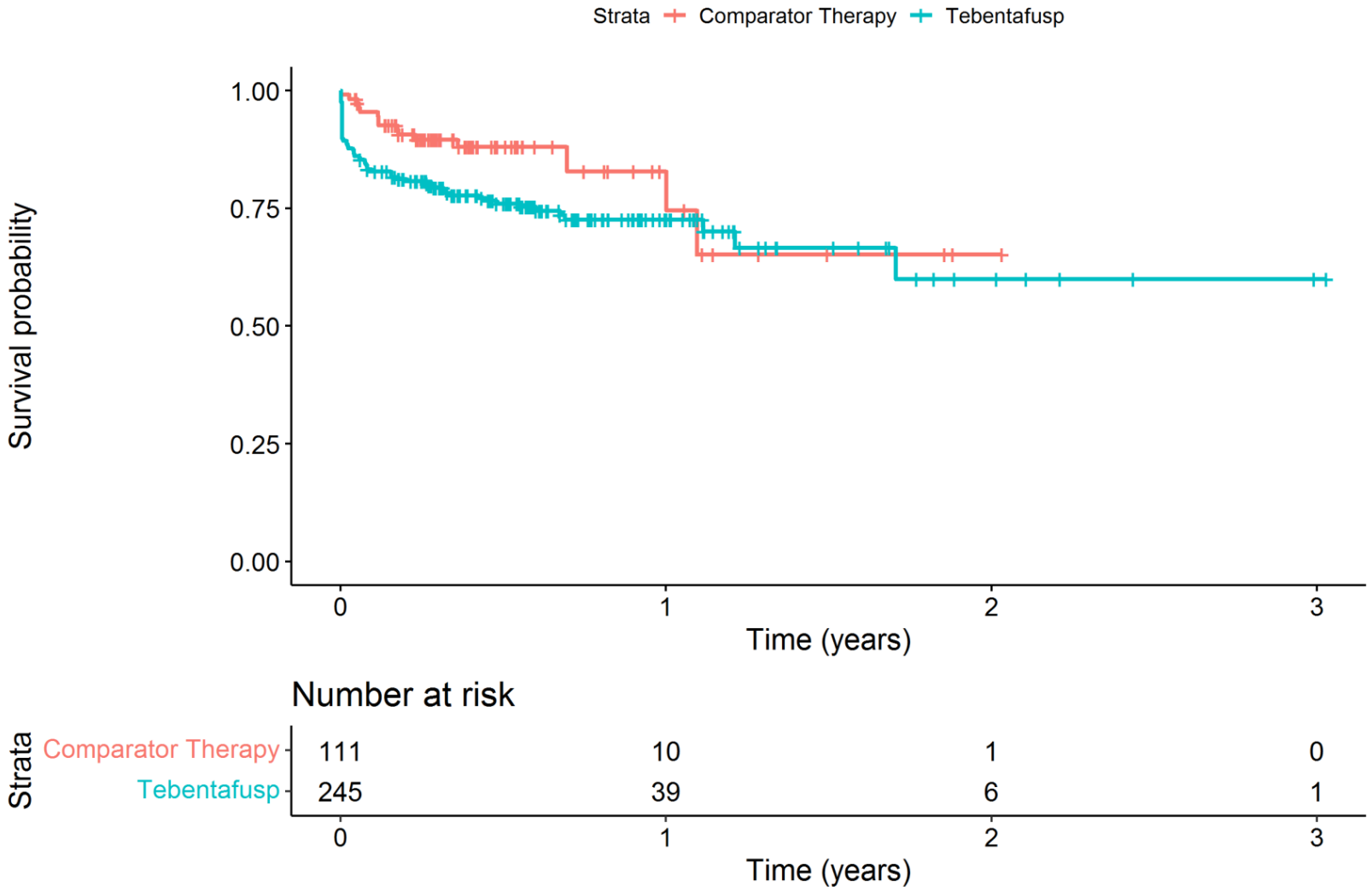


53.568 Hautrötung - Ipilimumab

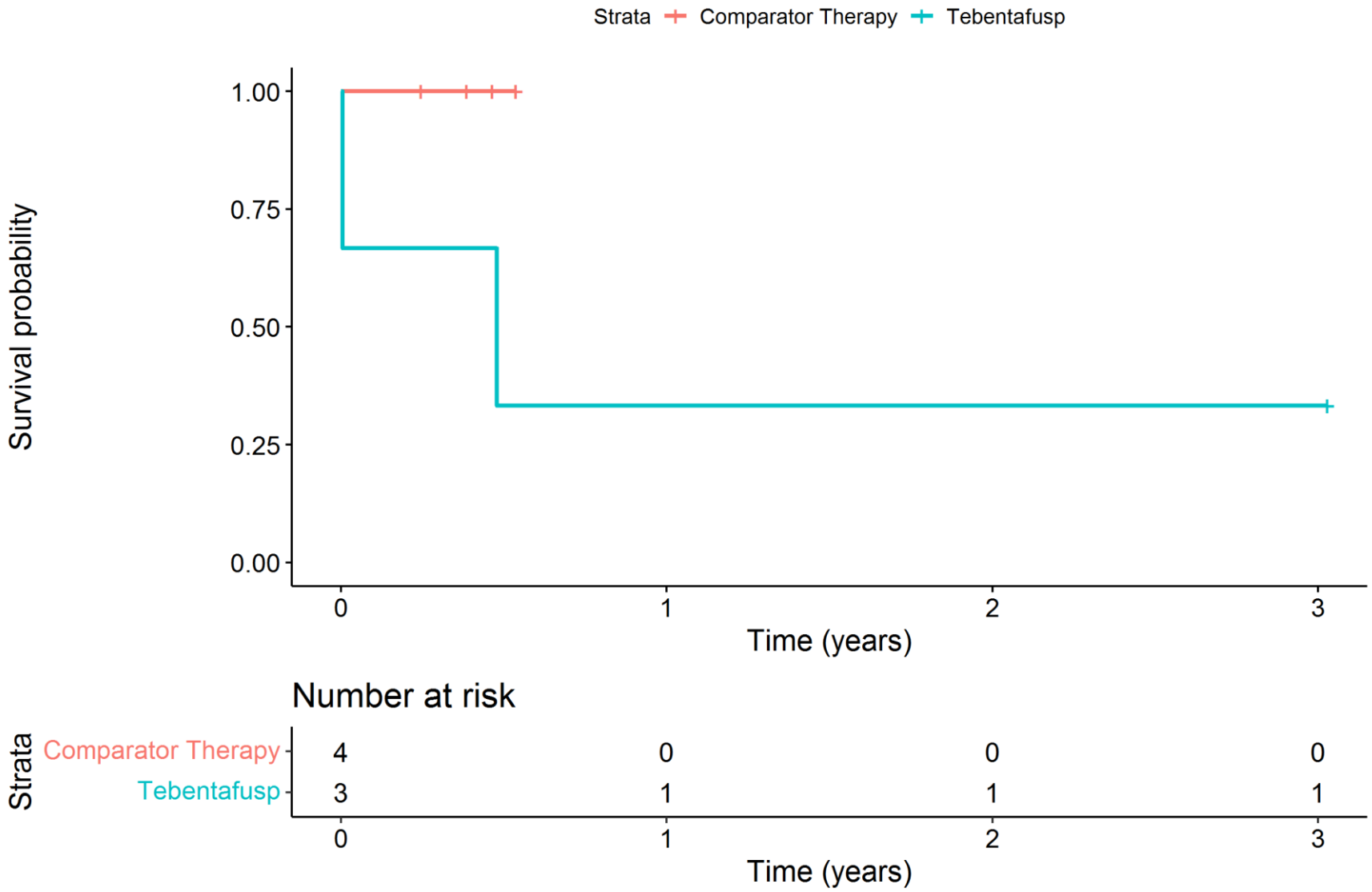


54 UEs (SOC), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-118)

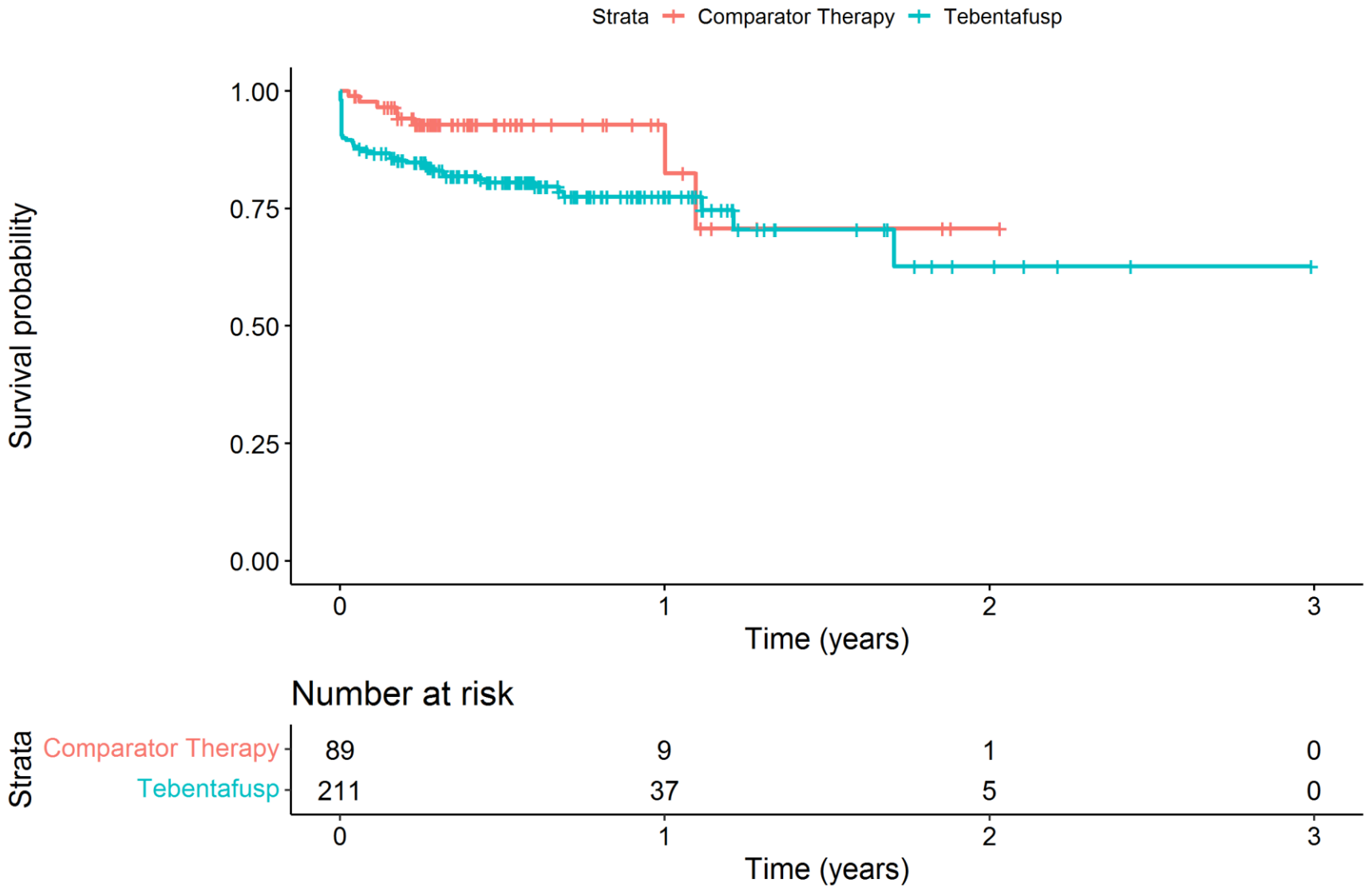
54.1 Erkrankungen des Blutes und des Lymphsystems- Gesamt



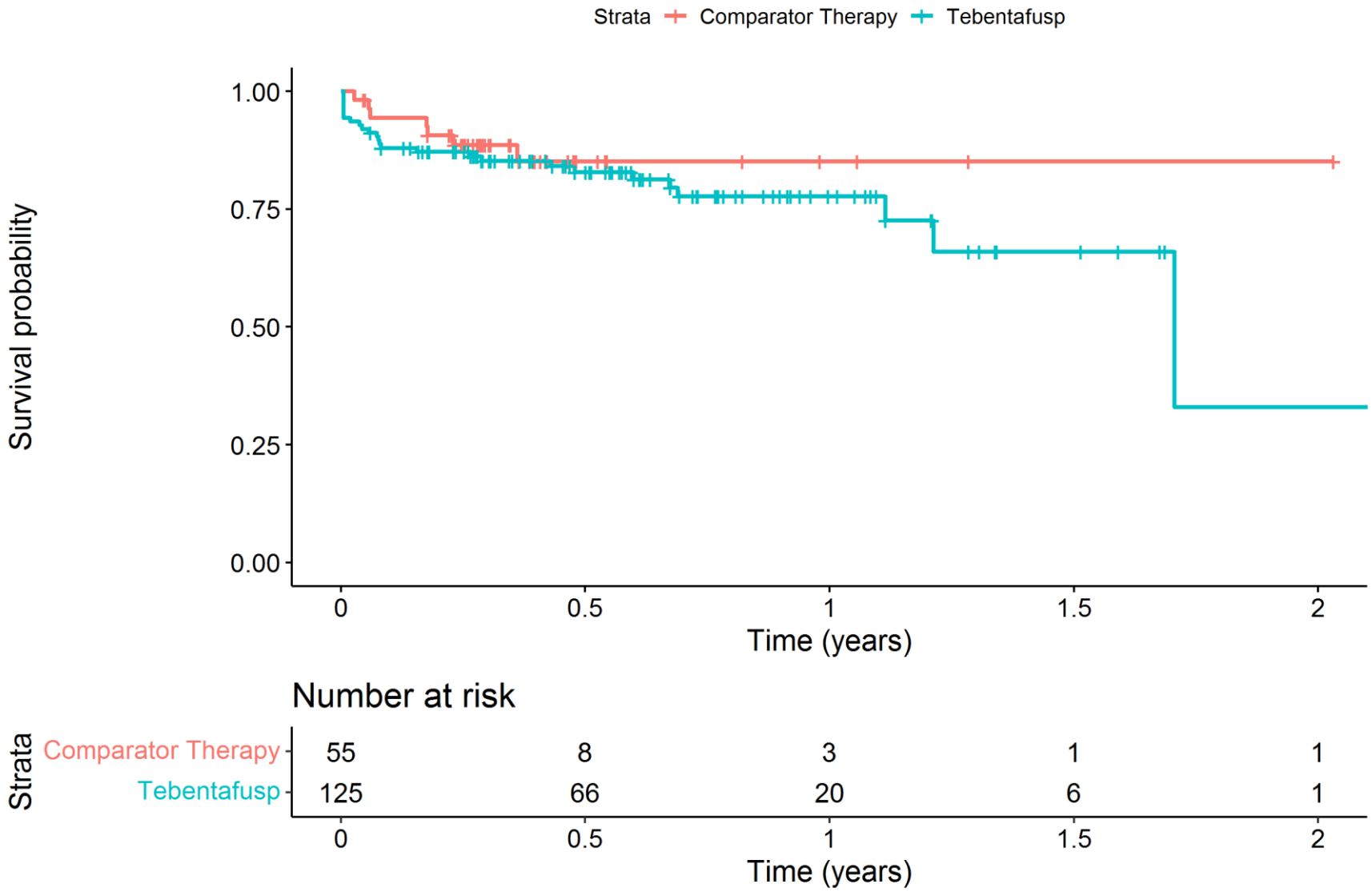
54.2 Erkrankungen des Blutes und des Lymphsystems- Hispanisch



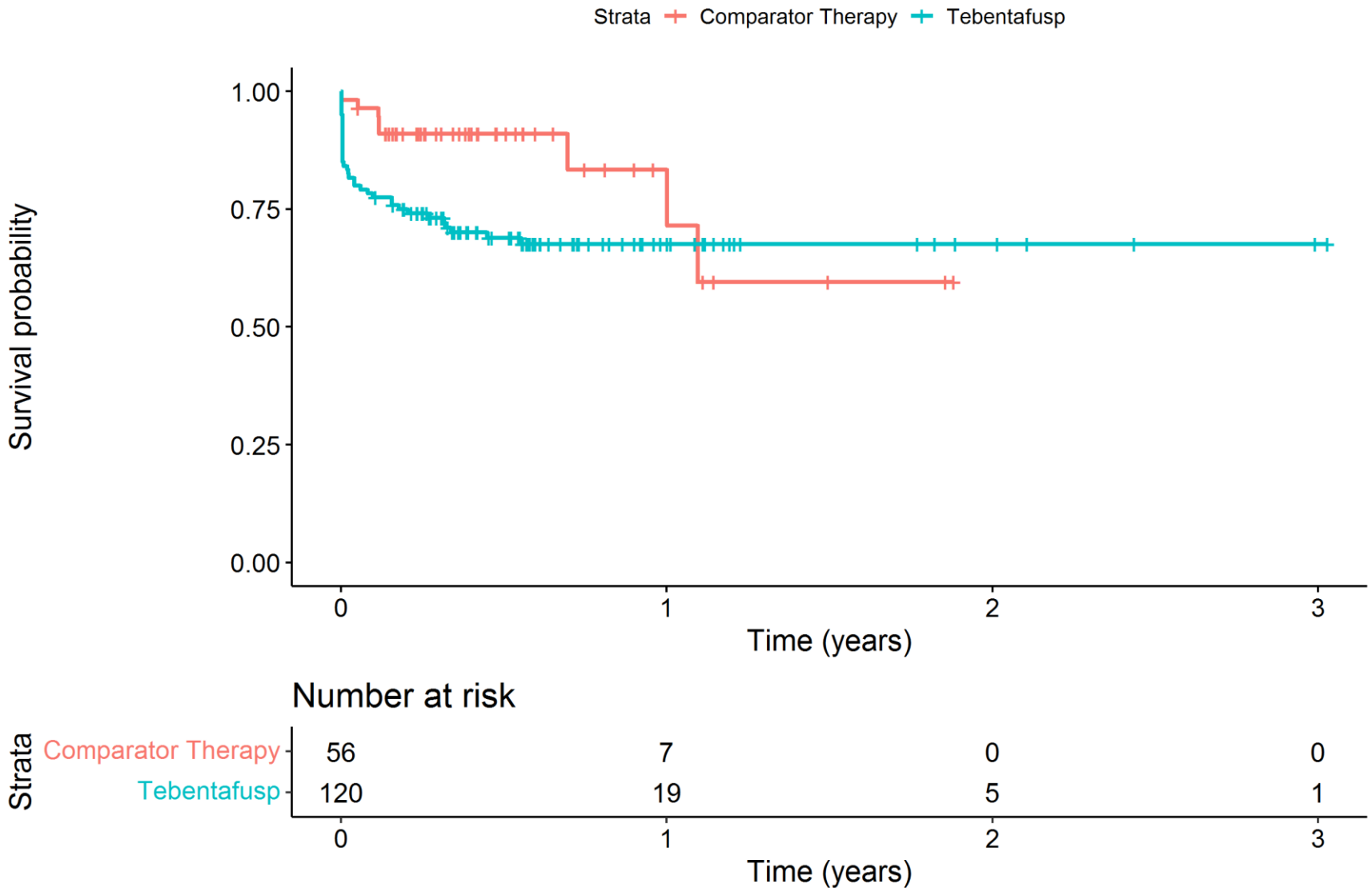
54.3 Erkrankungen des Blutes und des Lymphsystems- Nicht-hispanisch



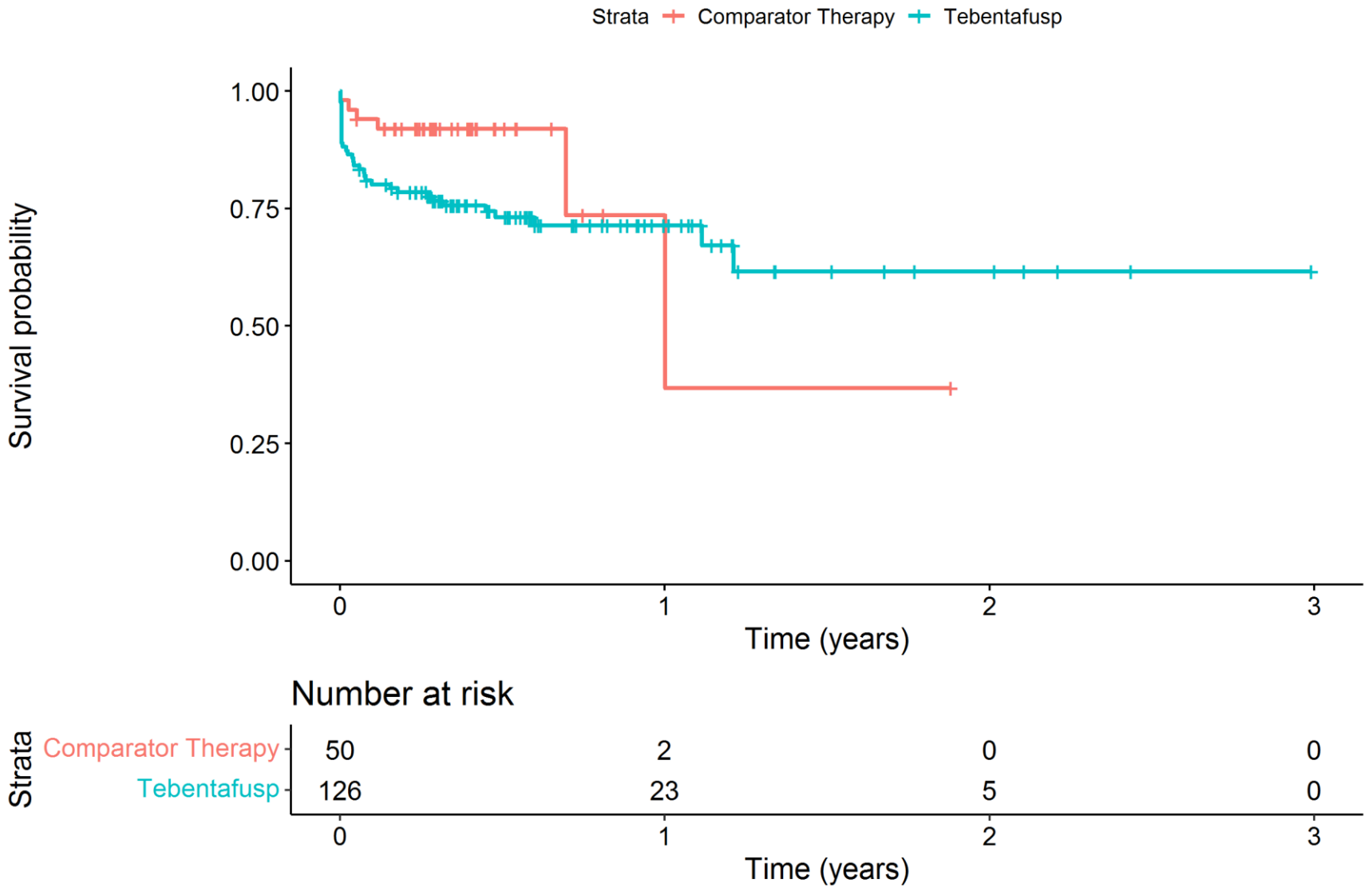
54.4 Erkrankungen des Blutes und des Lymphsystems- Männlich



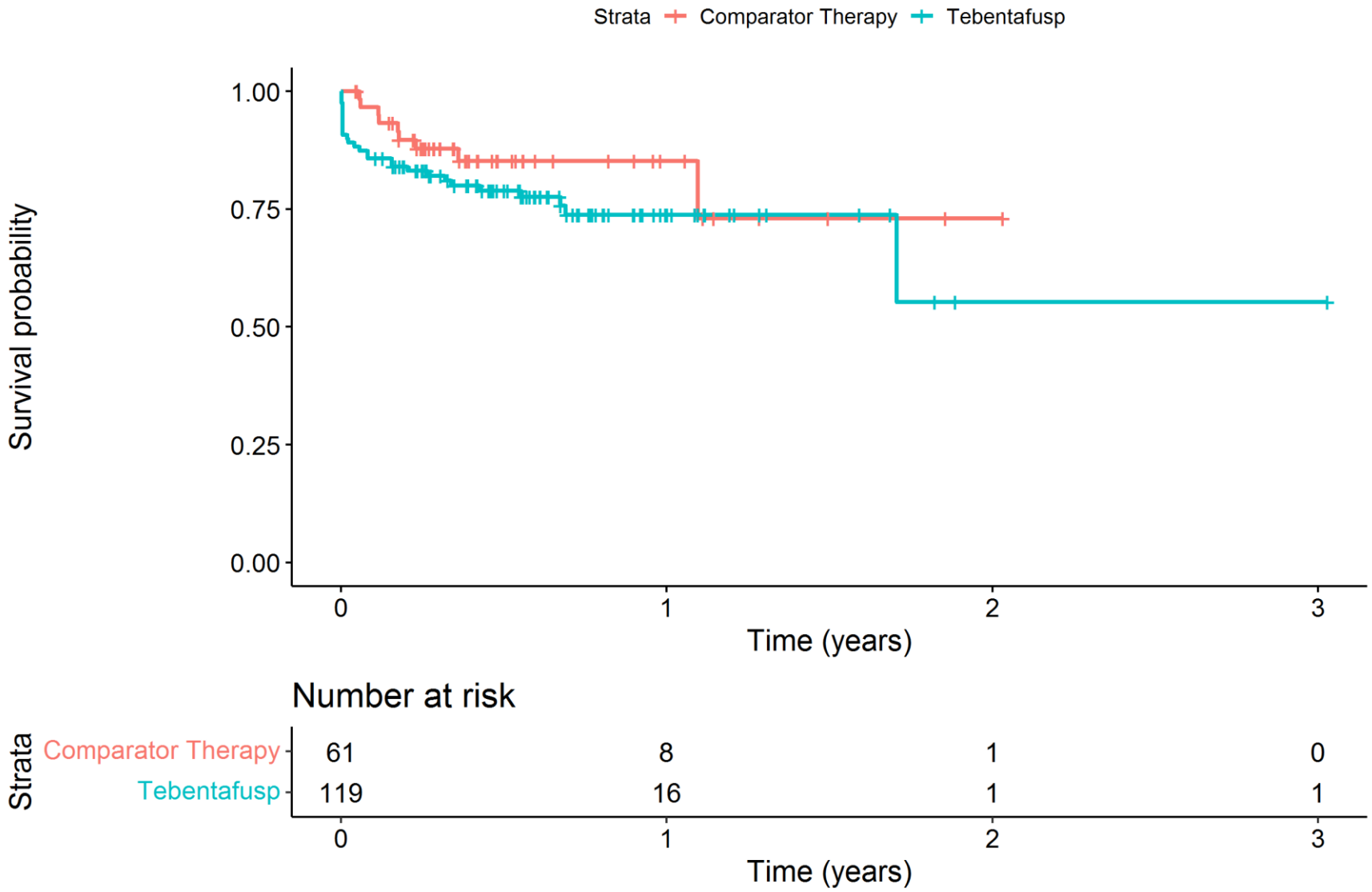
54.5 Erkrankungen des Blutes und des Lymphsystems- Weiblich



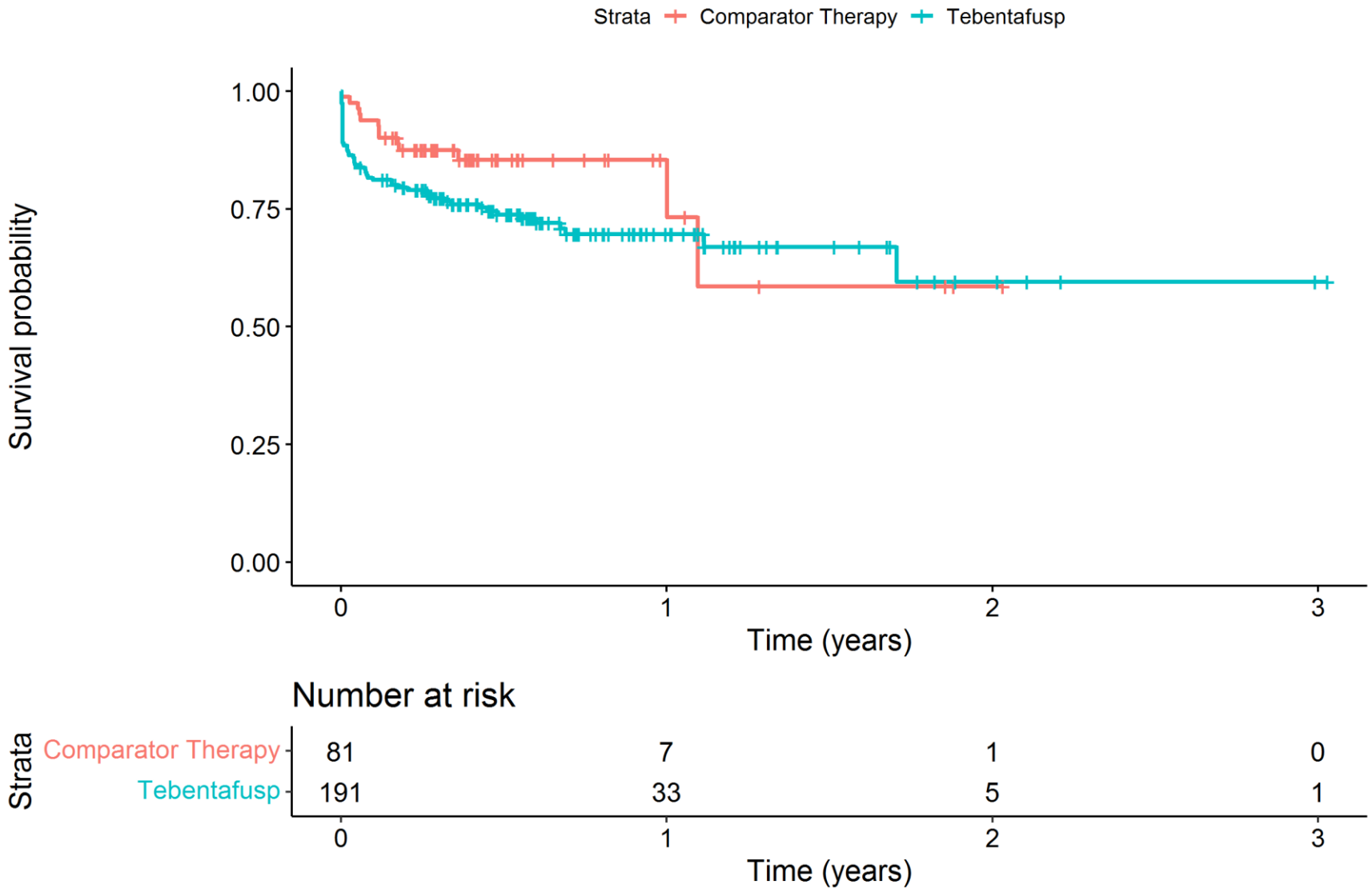
54.6 Erkrankungen des Blutes und des Lymphsystems- <65



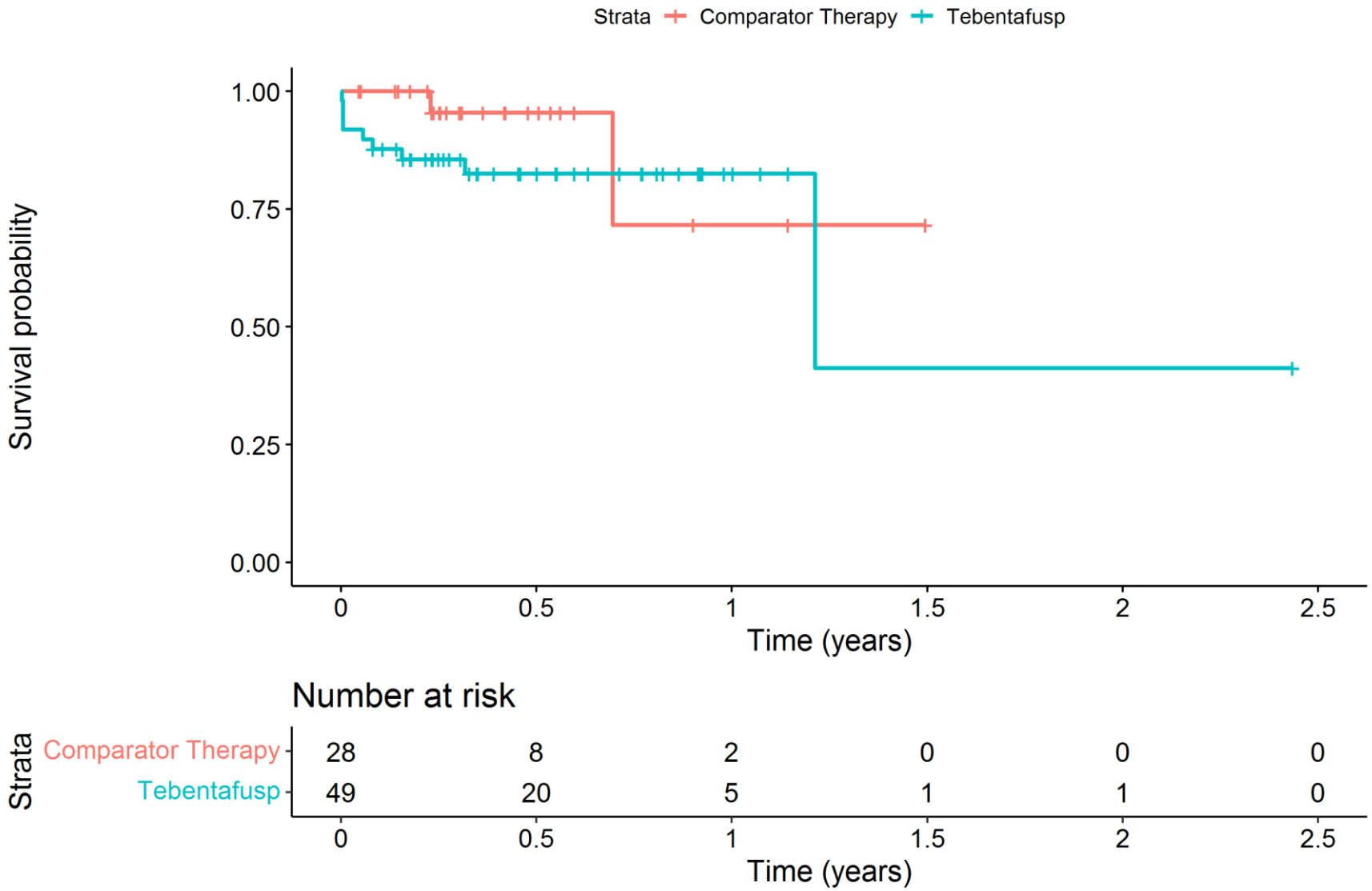
54.7 Erkrankungen des Blutes und des Lymphsystems- ≥65



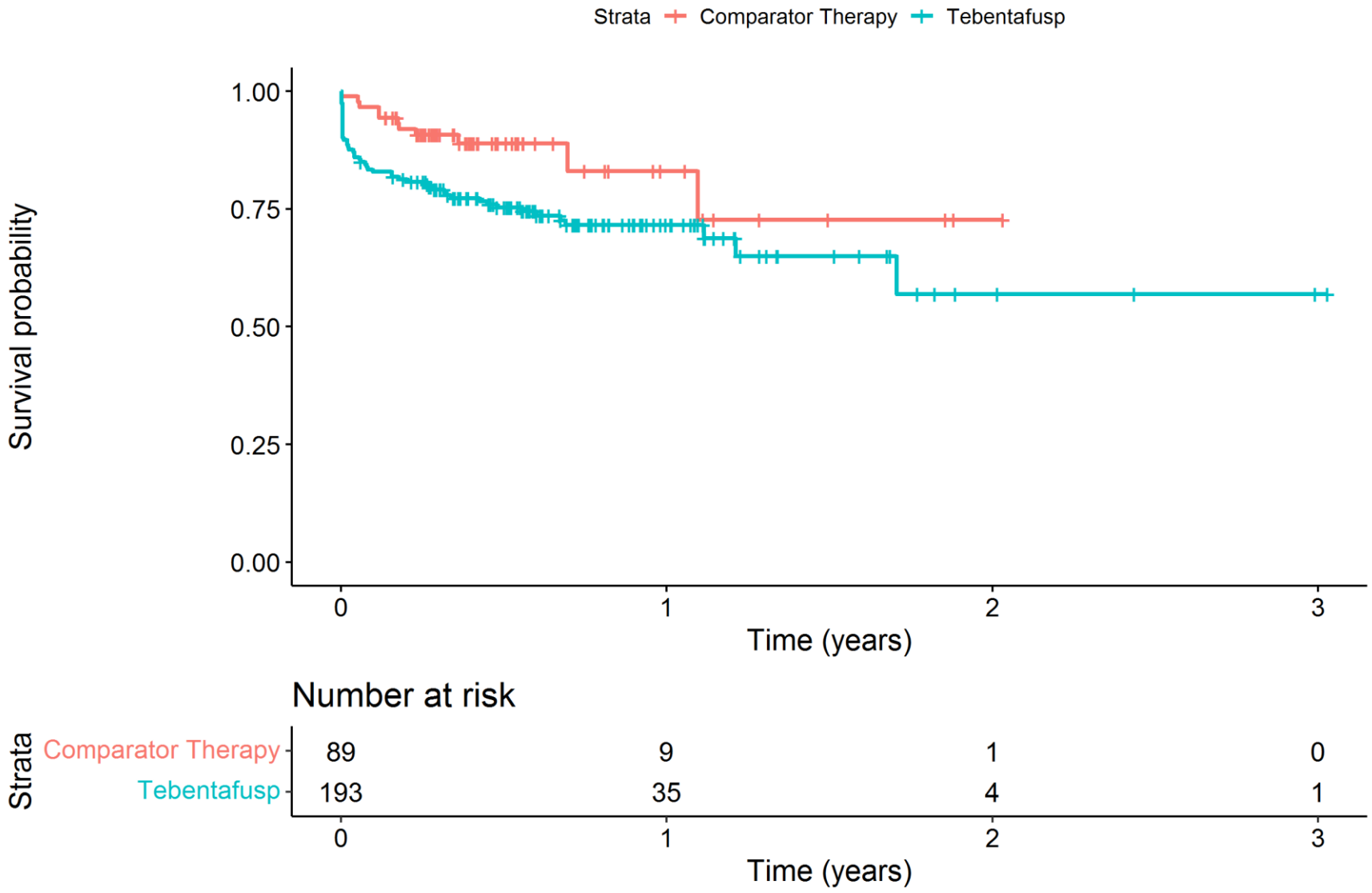
54.8 Erkrankungen des Blutes und des Lymphsystems- ECOG 0



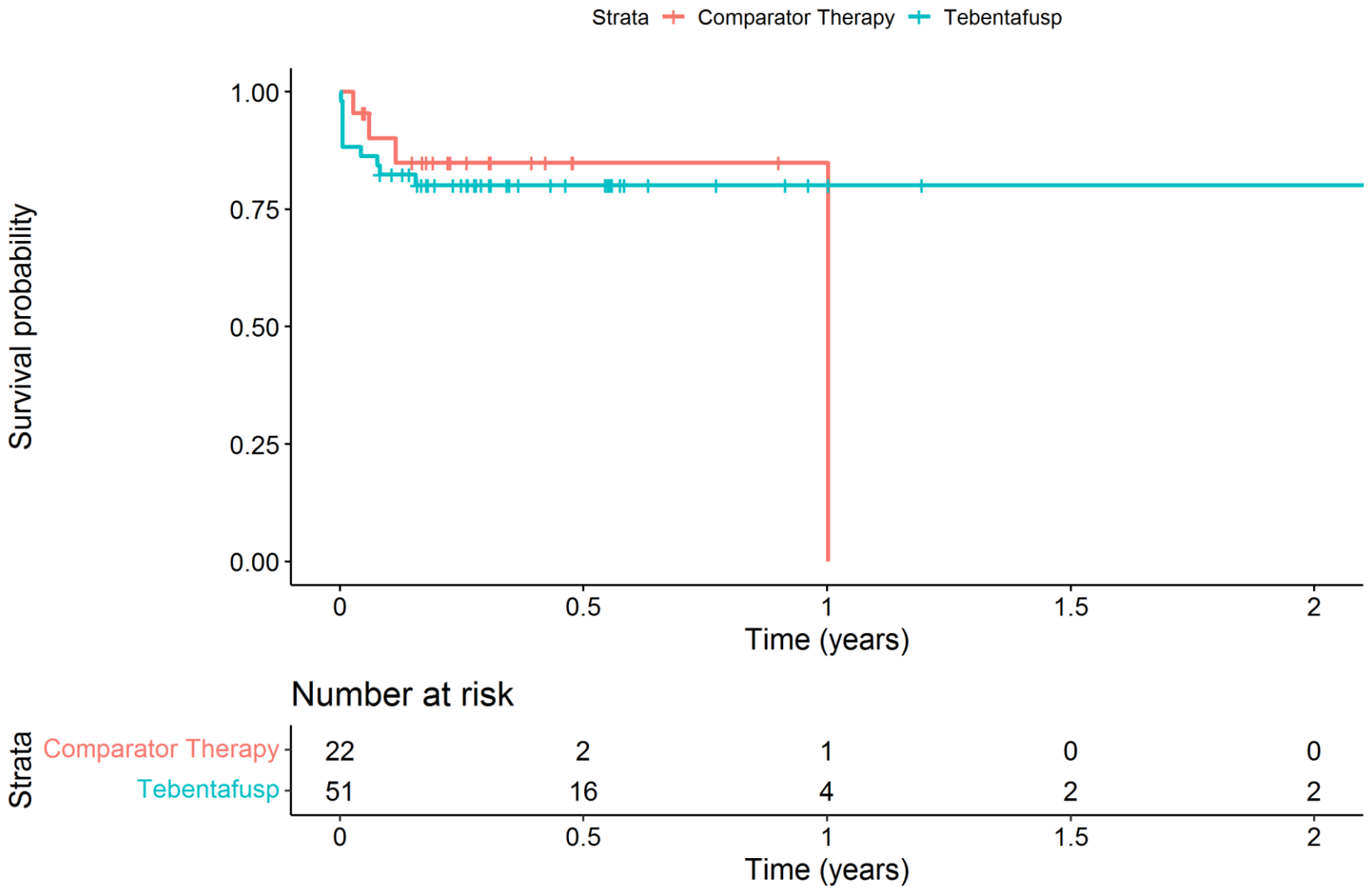
54.9 Erkrankungen des Blutes und des Lymphsystems- ECOG 1



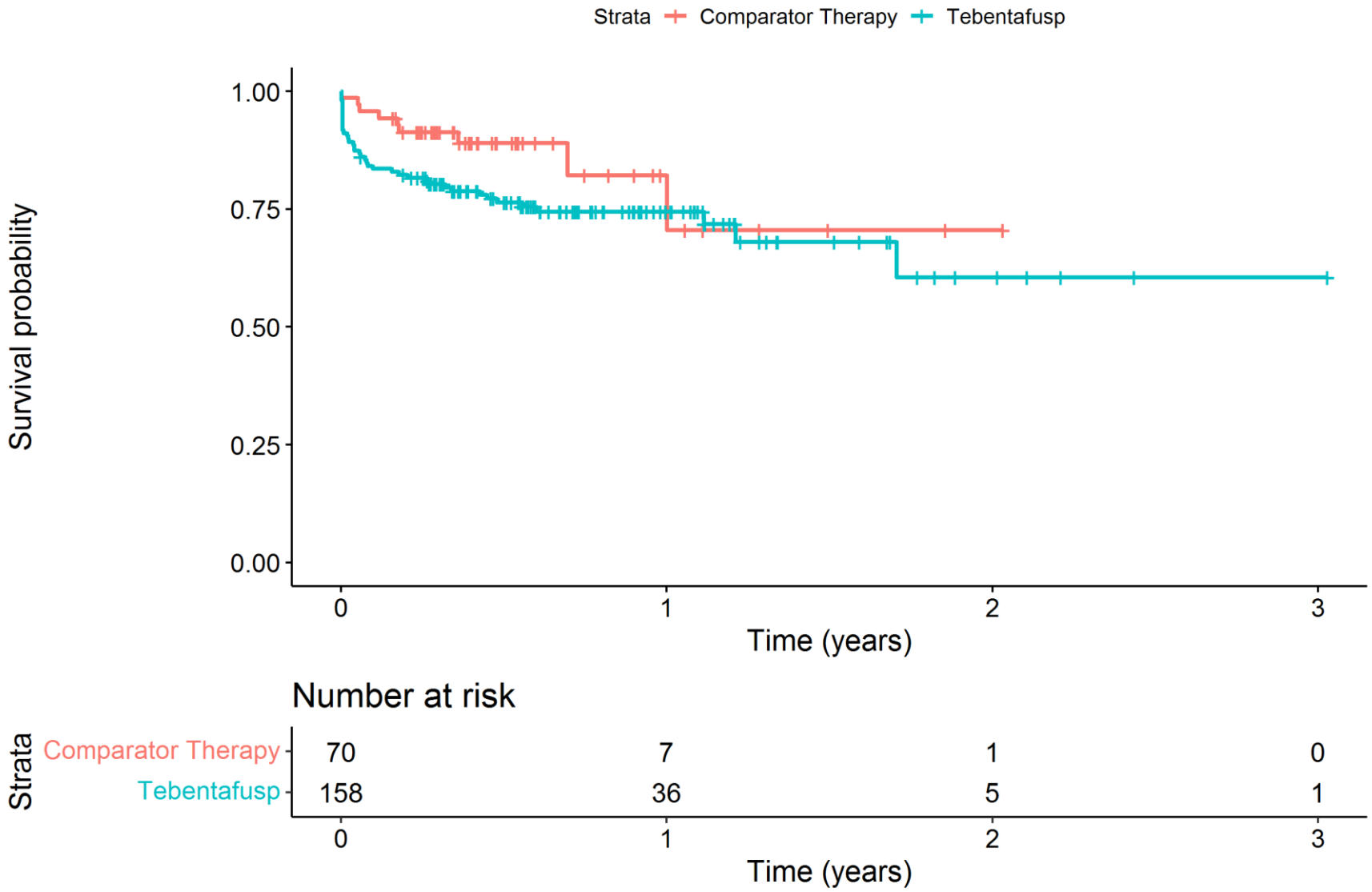
54.10 Erkrankungen des Blutes und des Lymphsystems- ALP ≤ ULN



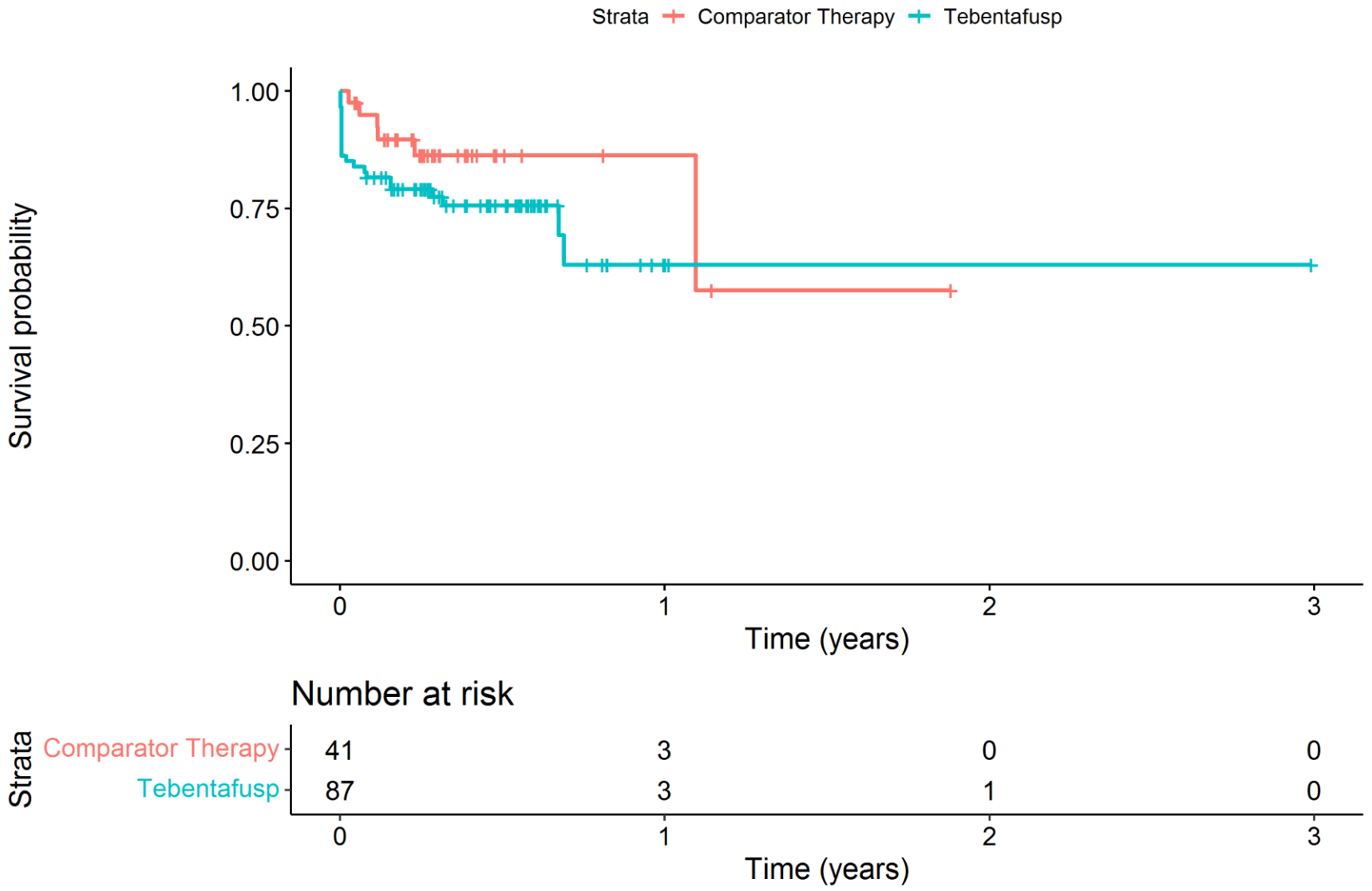
54.11 Erkrankungen des Blutes und des Lymphsystems- ALP > ULN



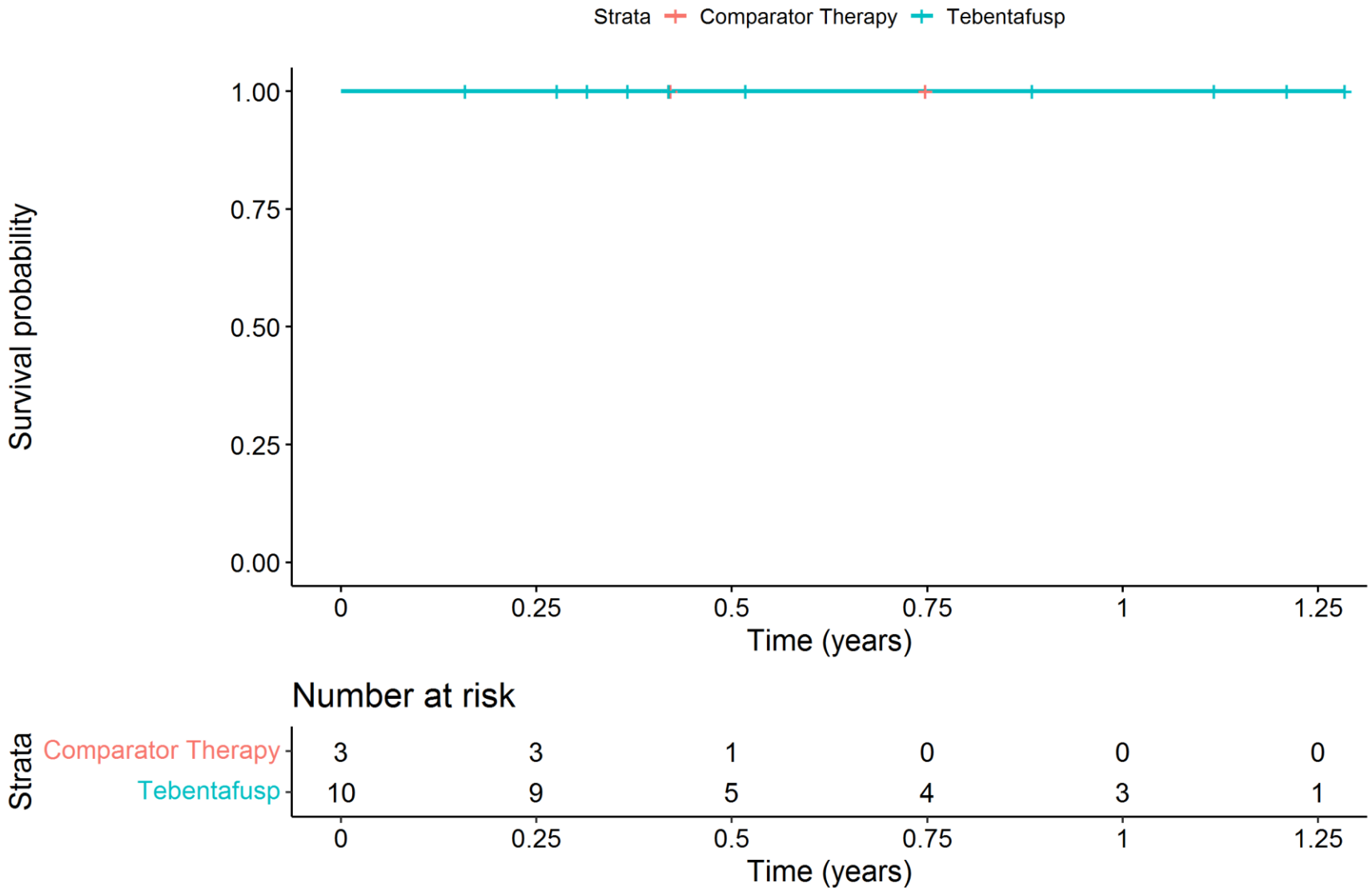
54.12 Erkrankungen des Blutes und des Lymphsystems- LDH =< ULN



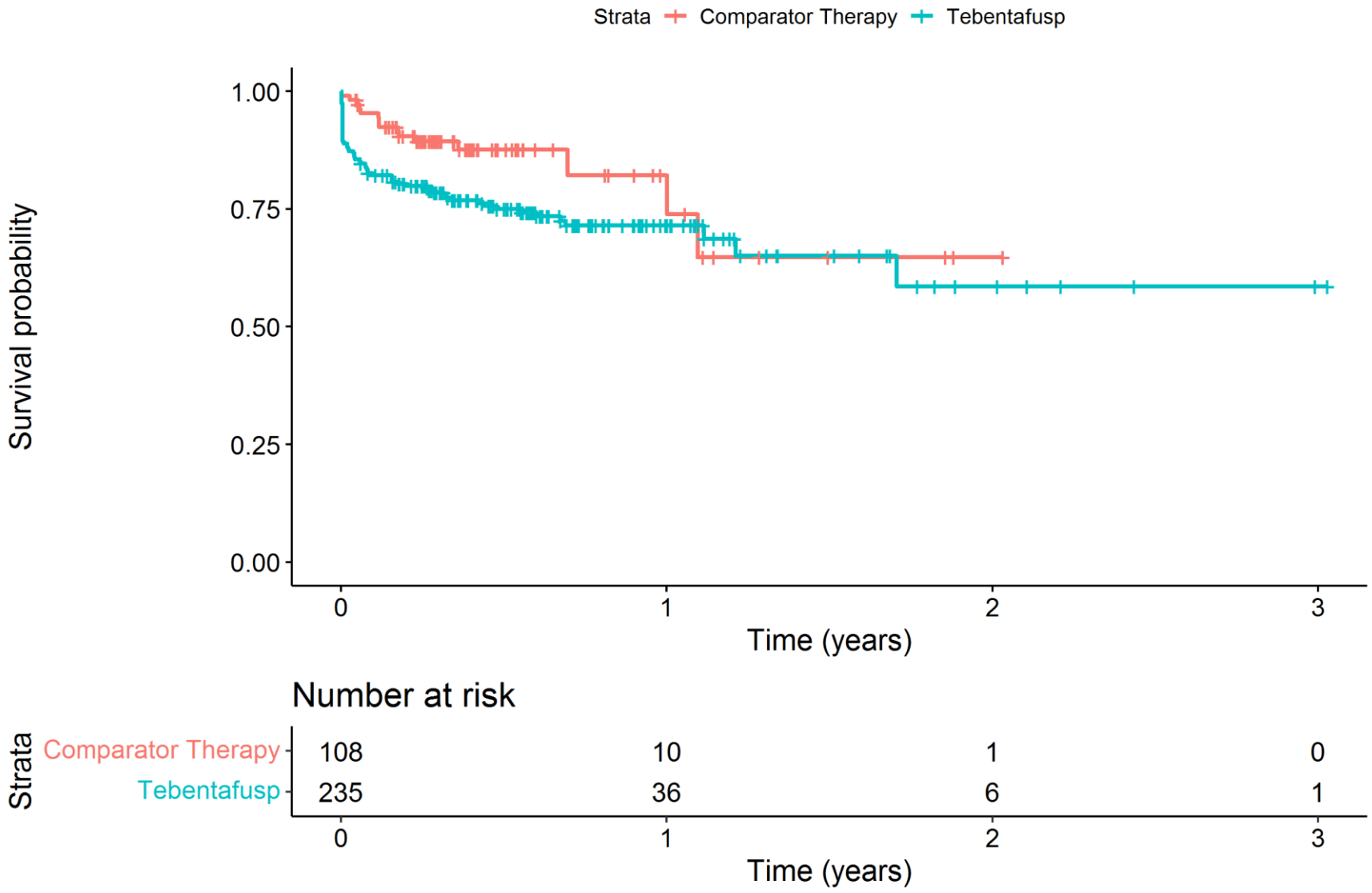
54.13 Erkrankungen des Blutes und des Lymphsystems- LDH > ULN



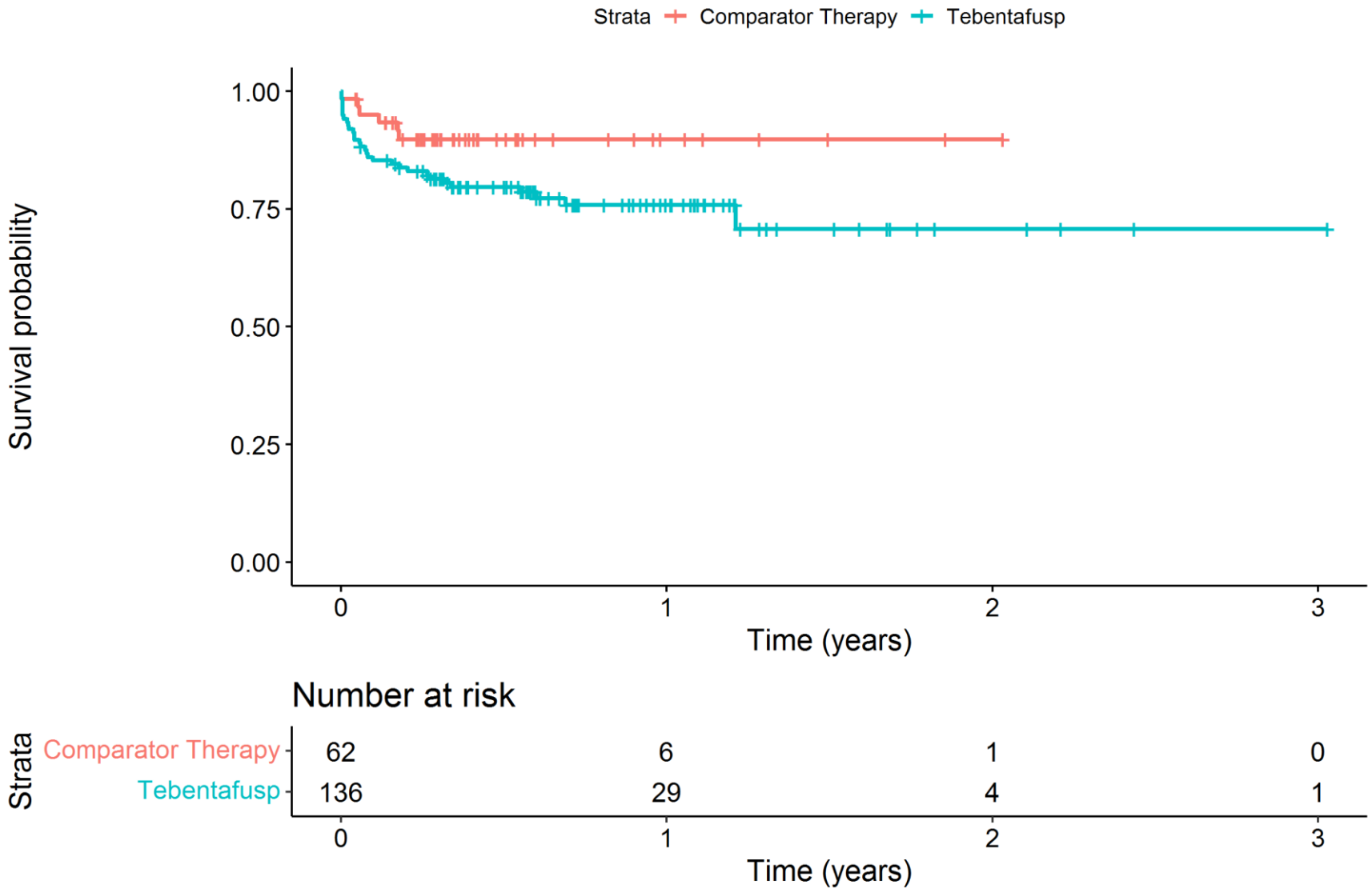
54.14 Erkrankungen des Blutes und des Lymphsystems- Vorherige Therapie adjuvant/neoadjuvant



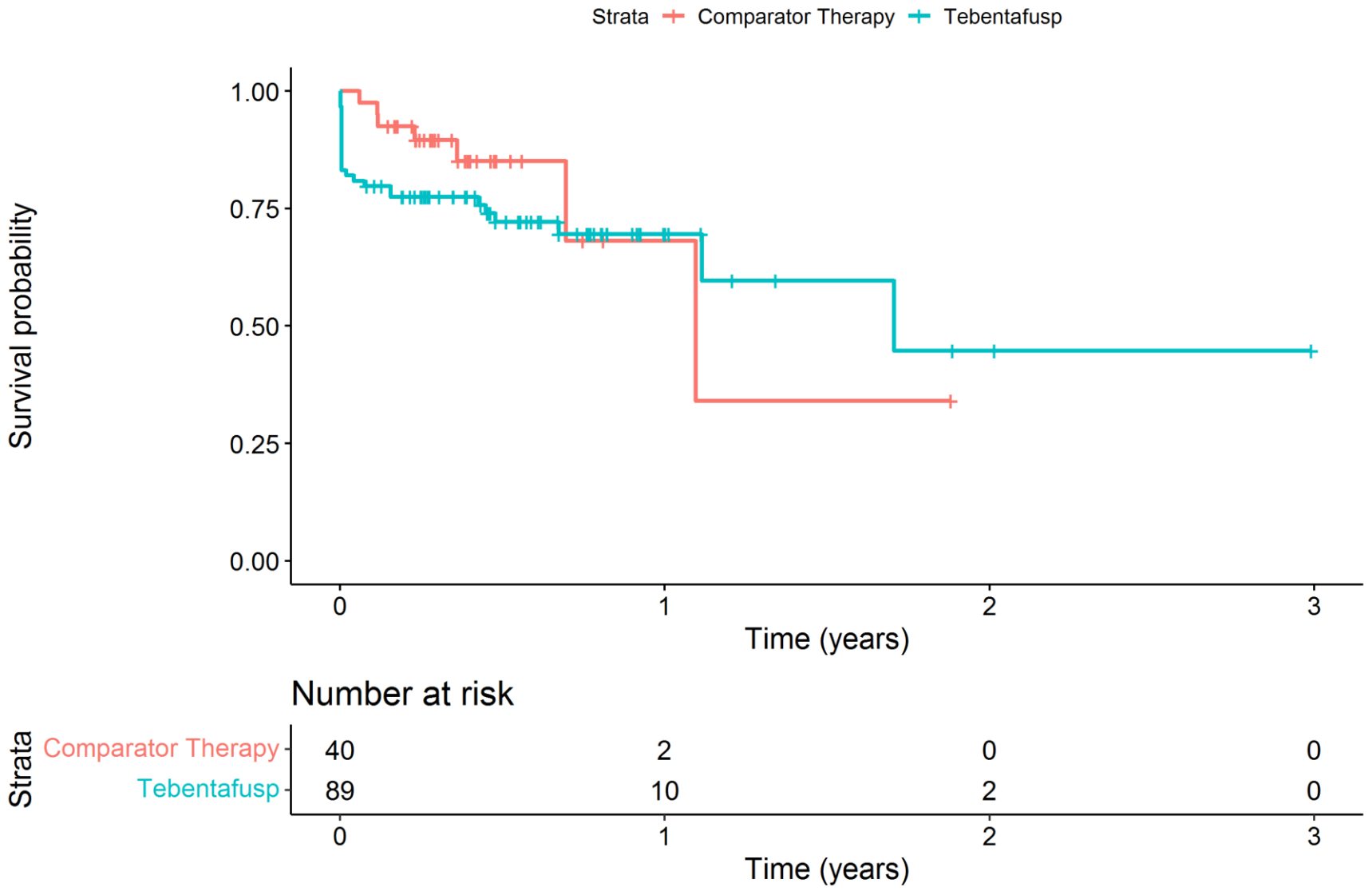
54.15 Erkrankungen des Blutes und des Lymphsystems- Keine vorherige Therapie adjuvant/neoadjuvant



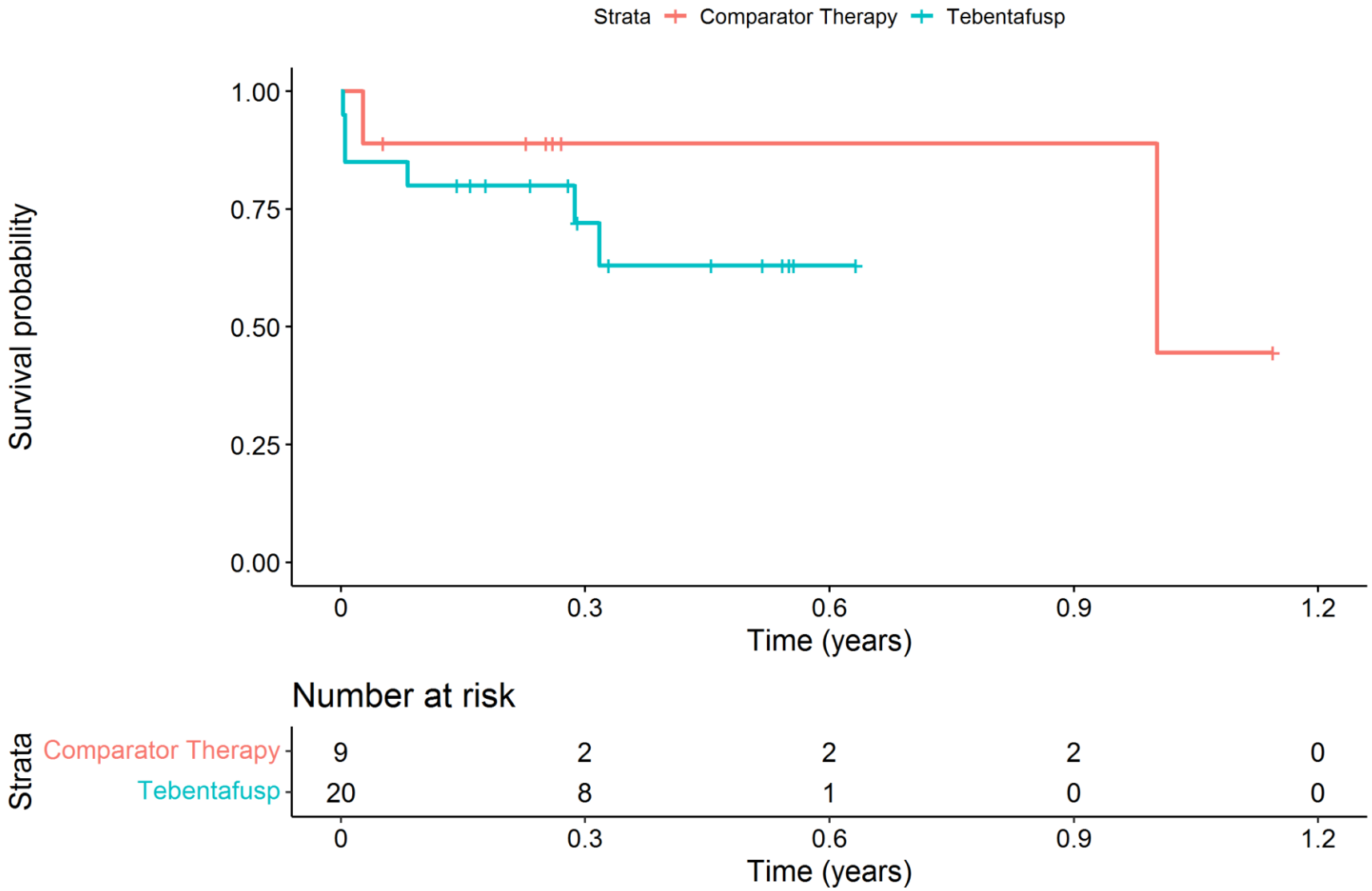
54.16 Erkrankungen des Blutes und des Lymphsystems- Läsion ≤ 3cm



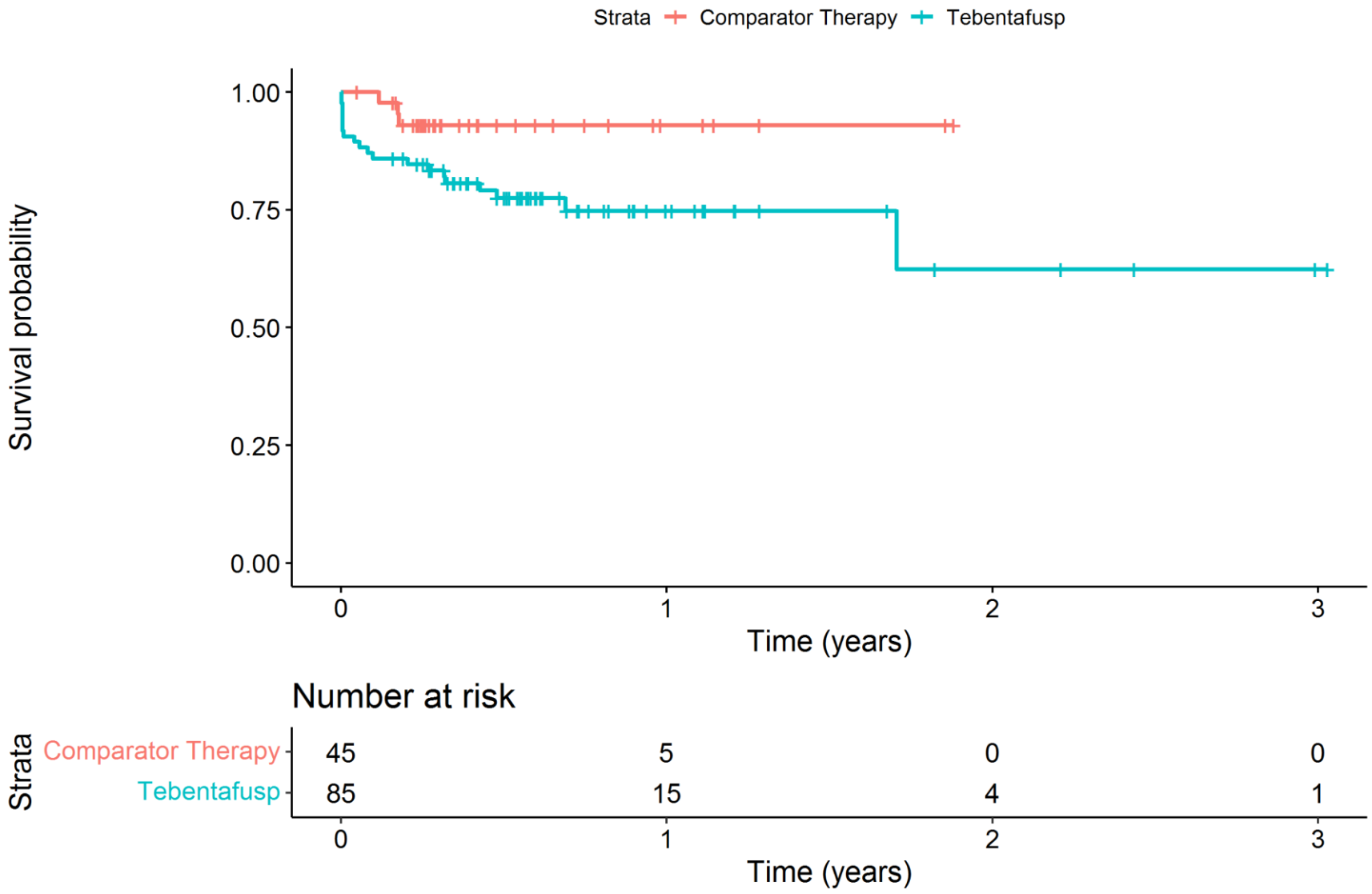
54.17 Erkrankungen des Blutes und des Lymphsystems- Läsion 3,1-8,0 cm



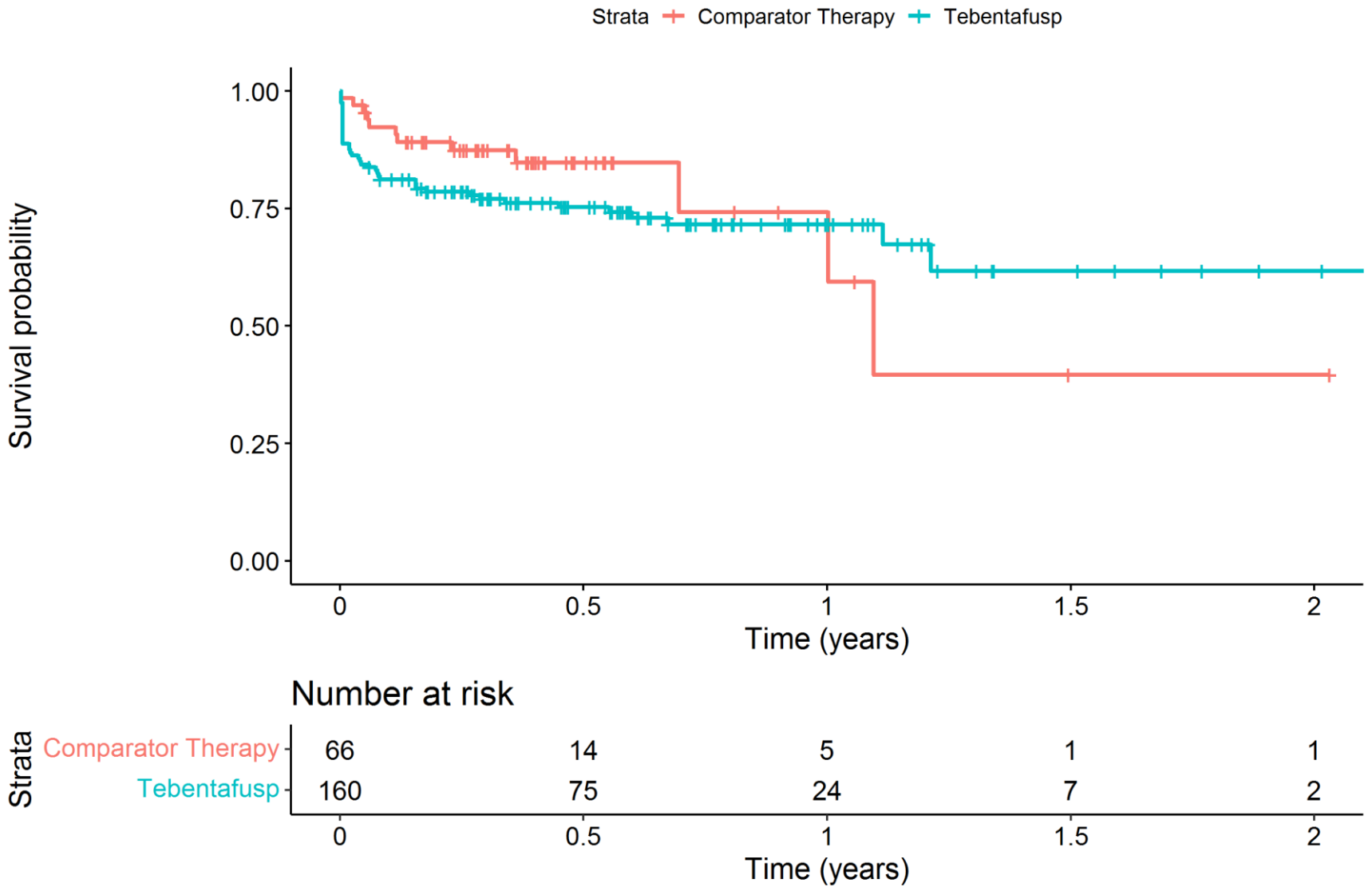
54.18 Erkrankungen des Blutes und des Lymphsystems- Läsion ≥8,1 cm



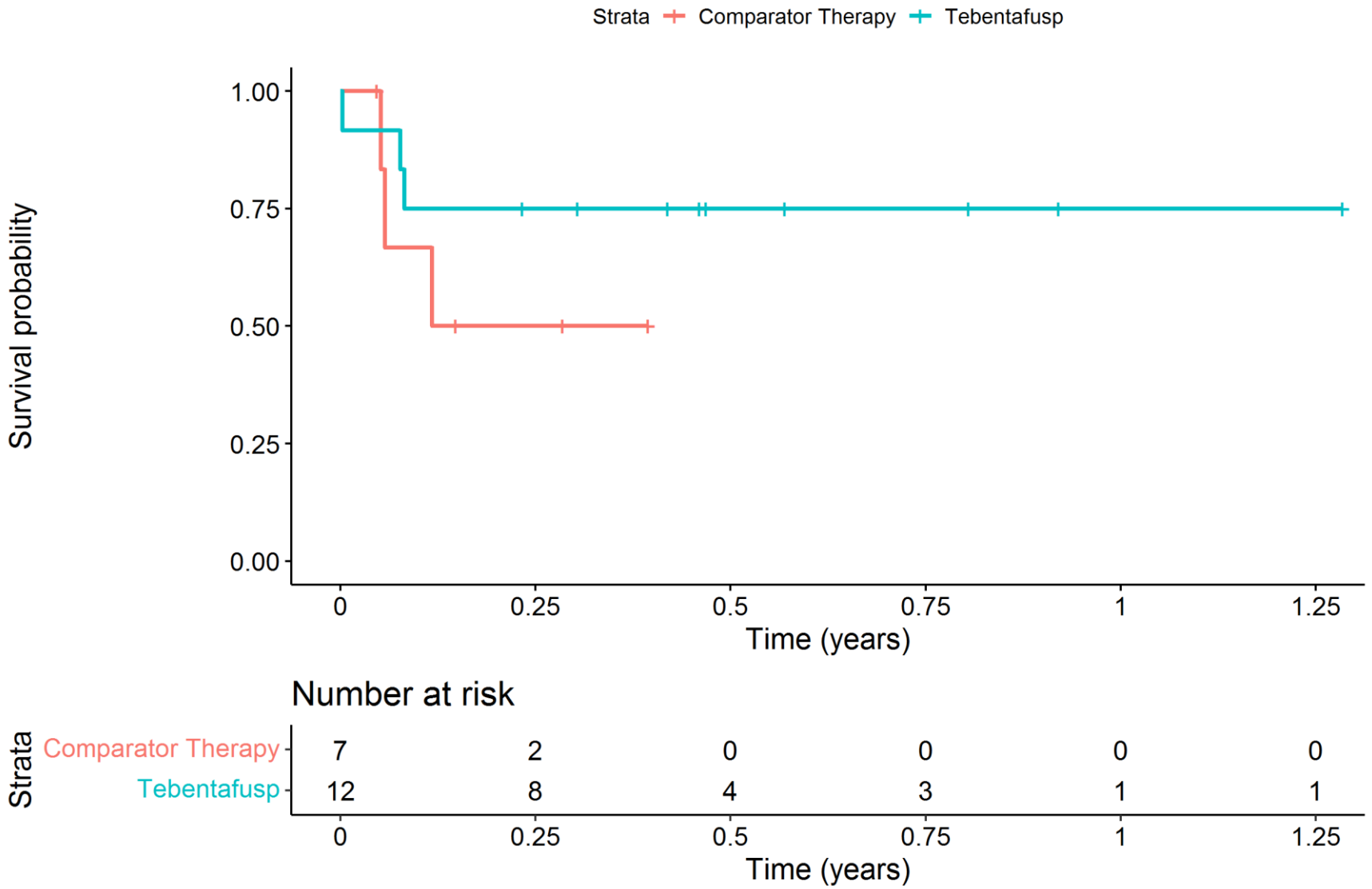
54.19 Erkrankungen des Blutes und des Lymphsystems- Nordamerika



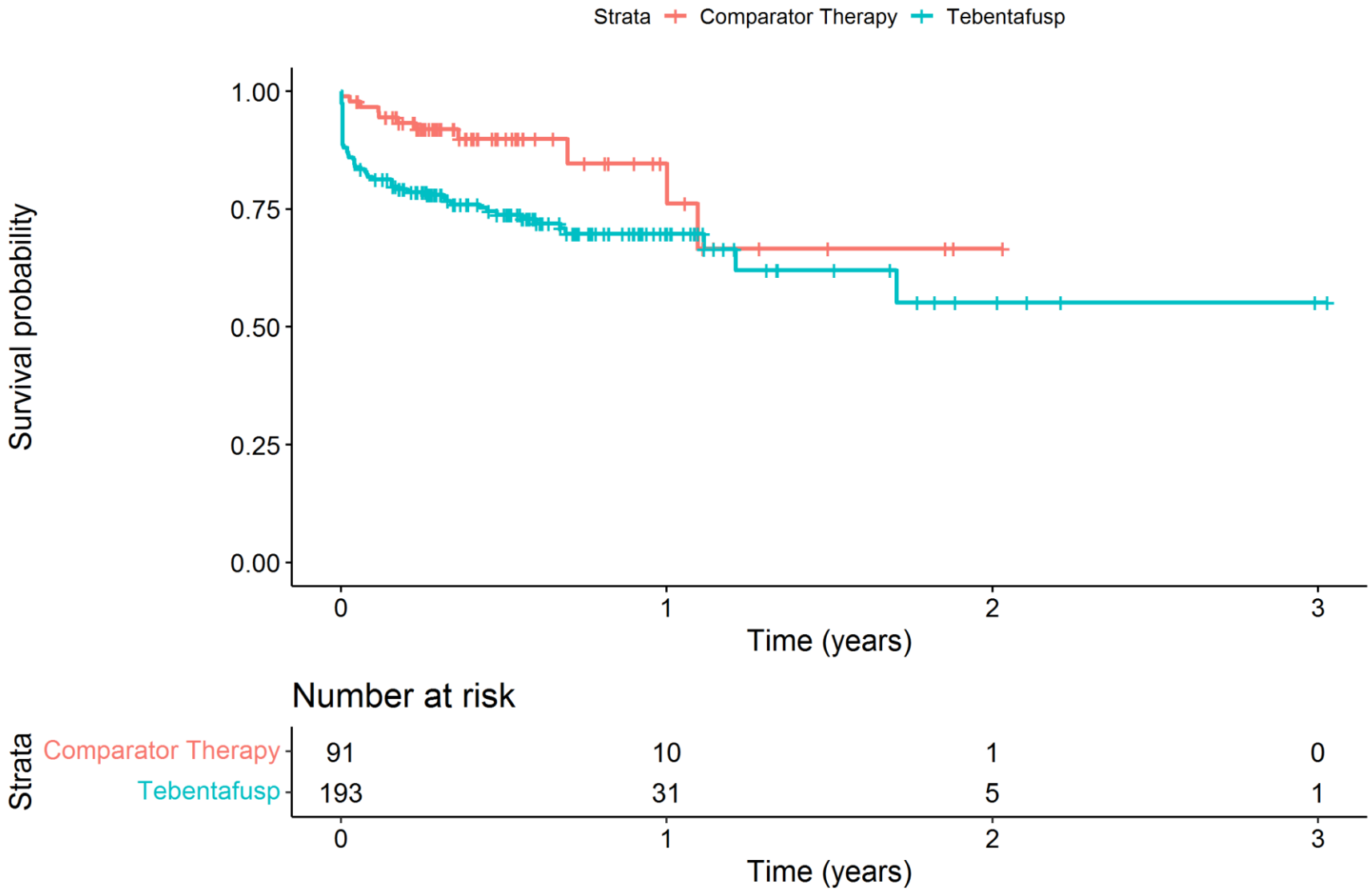
54.20 Erkrankungen des Blutes und des Lymphsystems- Nicht-Nordamerika



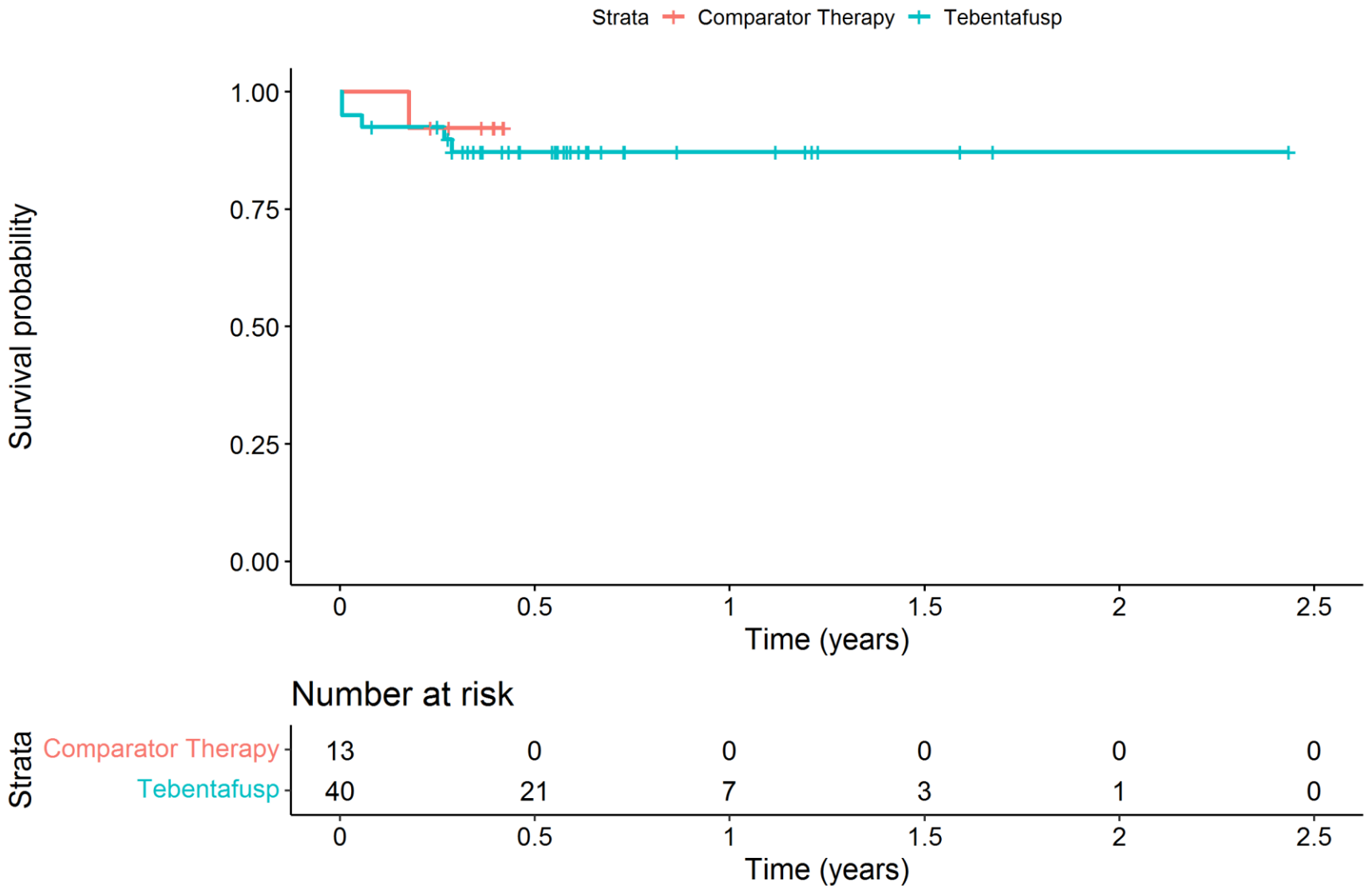
54.21 Erkrankungen des Blutes und des Lymphsystems- Dacarbazin



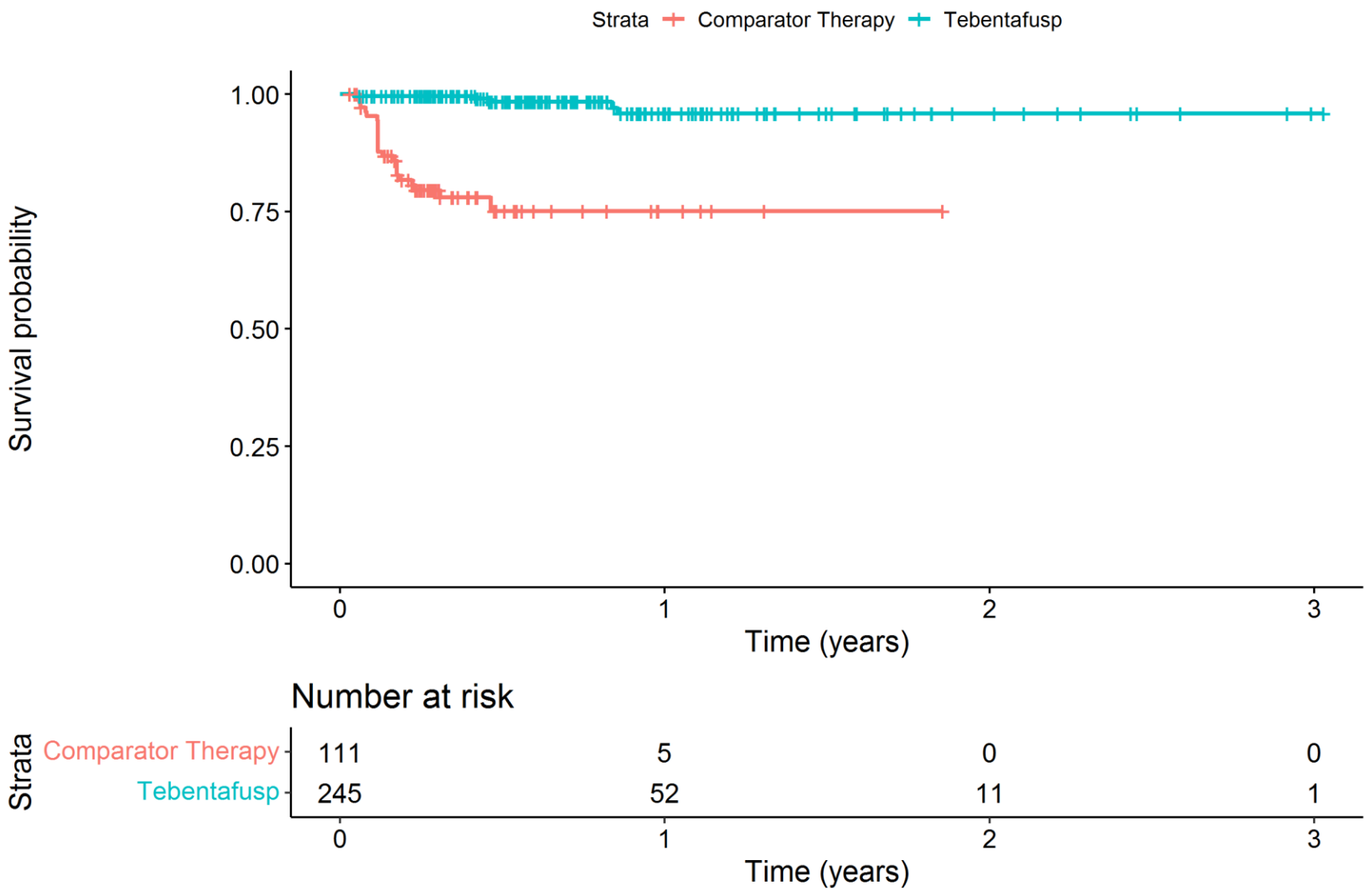
54.22 Erkrankungen des Blutes und des Lymphsystems- Pembrolizumab



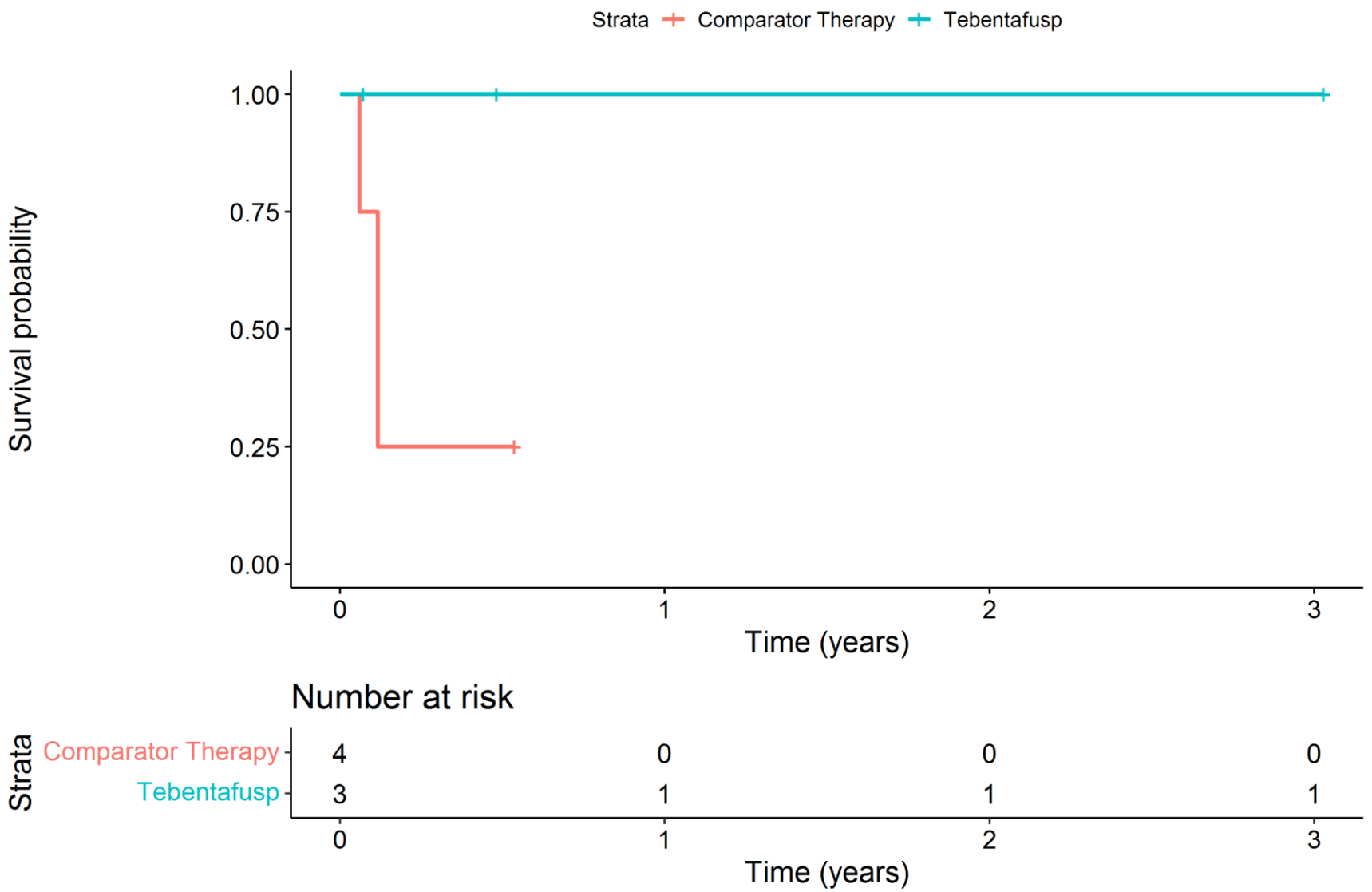
54.23 Erkrankungen des Blutes und des Lymphsystems- Ipilimumab



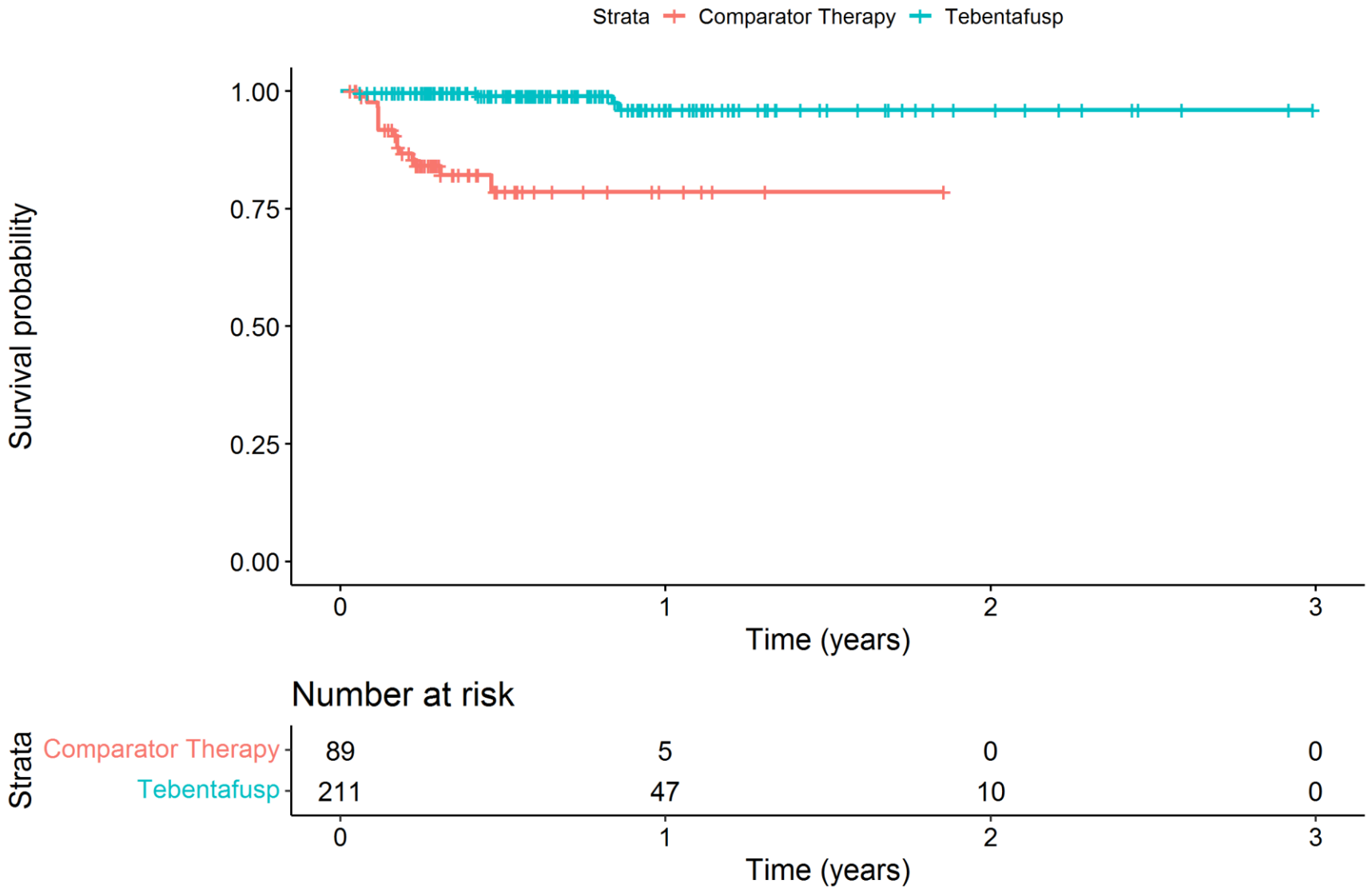
54.24 Endokrine Erkrankungen - Gesamt



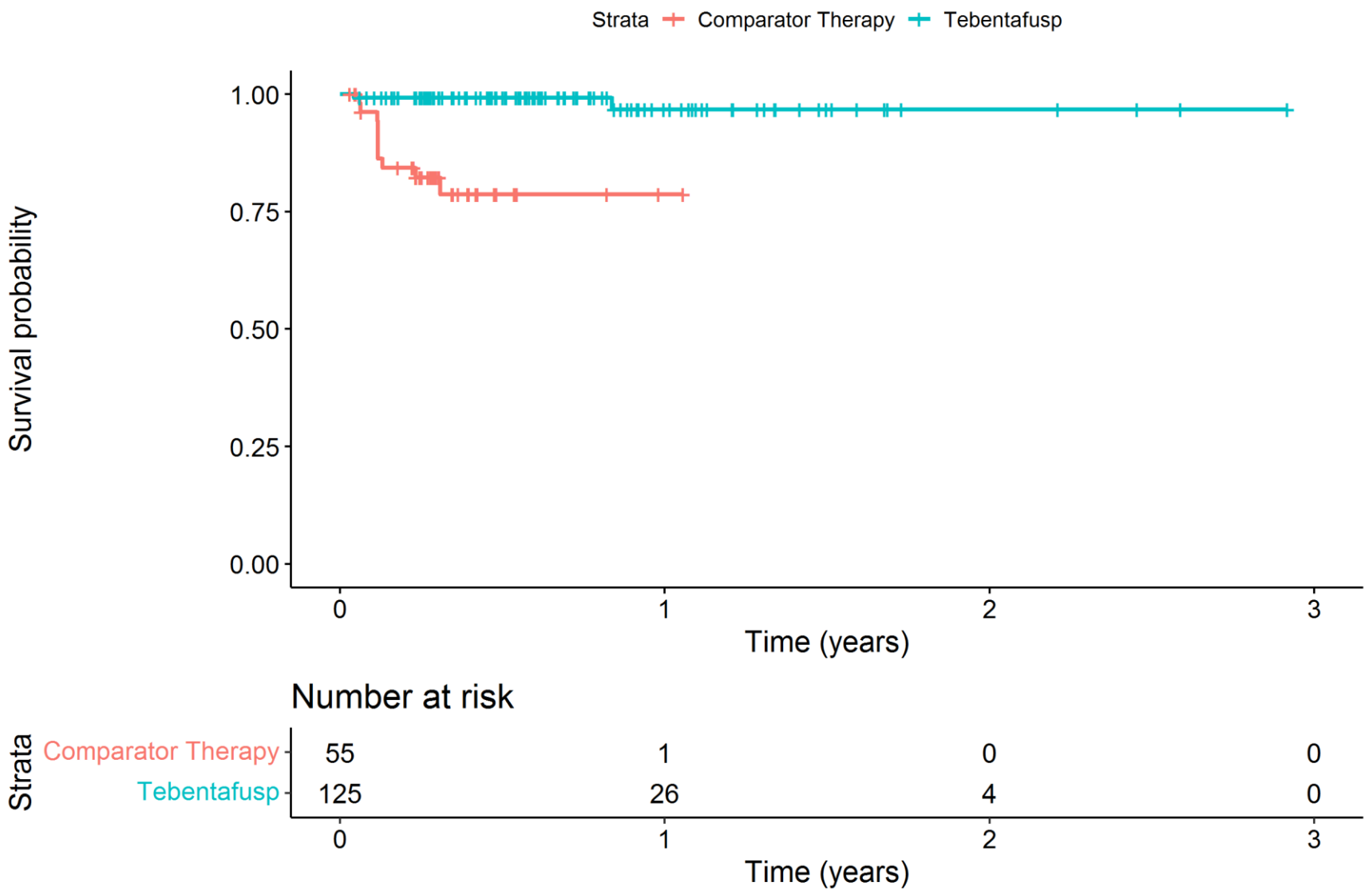
54.25 Endokrine Erkrankungen - Hispanisch



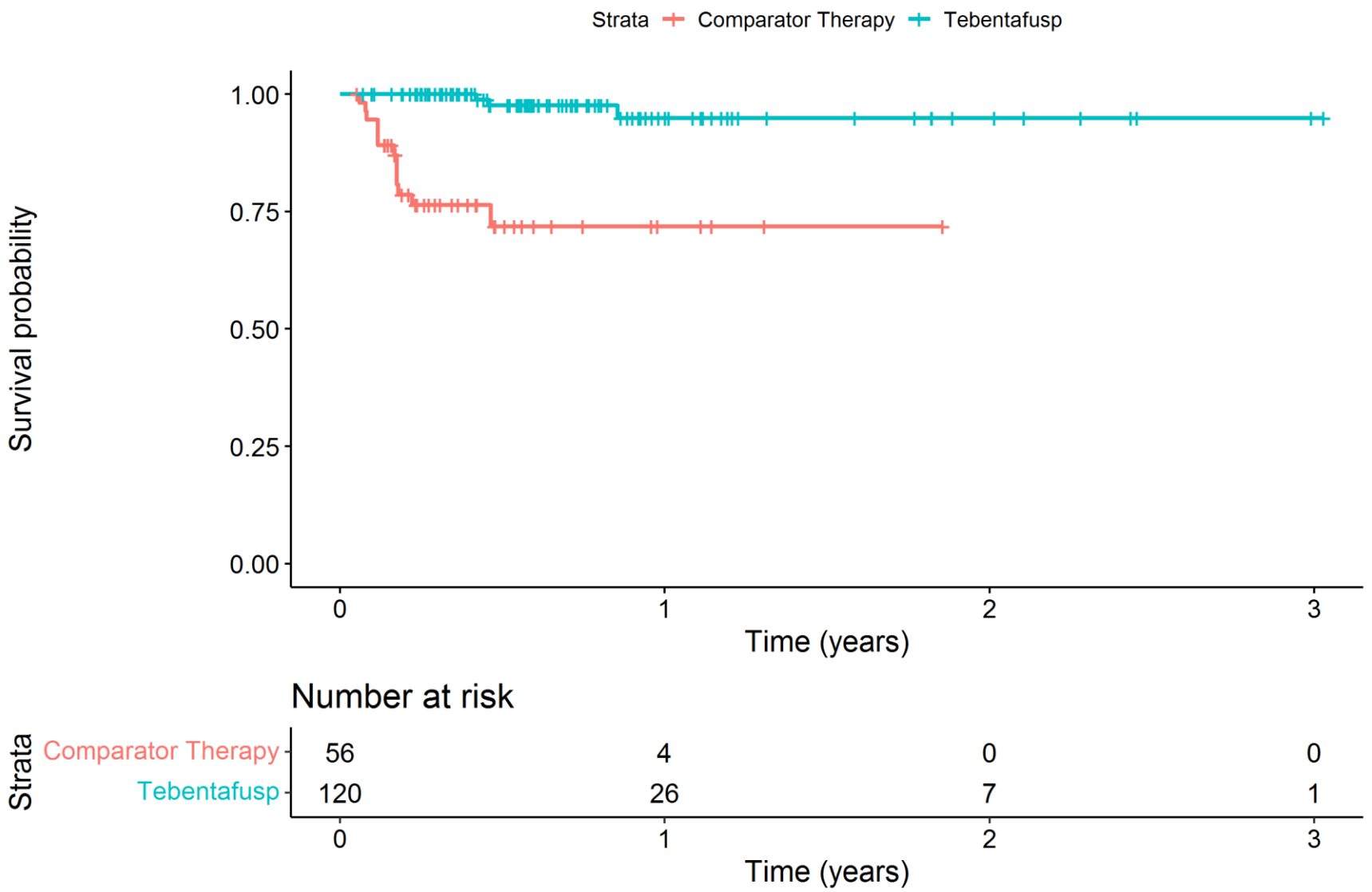
54.26 Endokrine Erkrankungen - Nicht-hispanisch



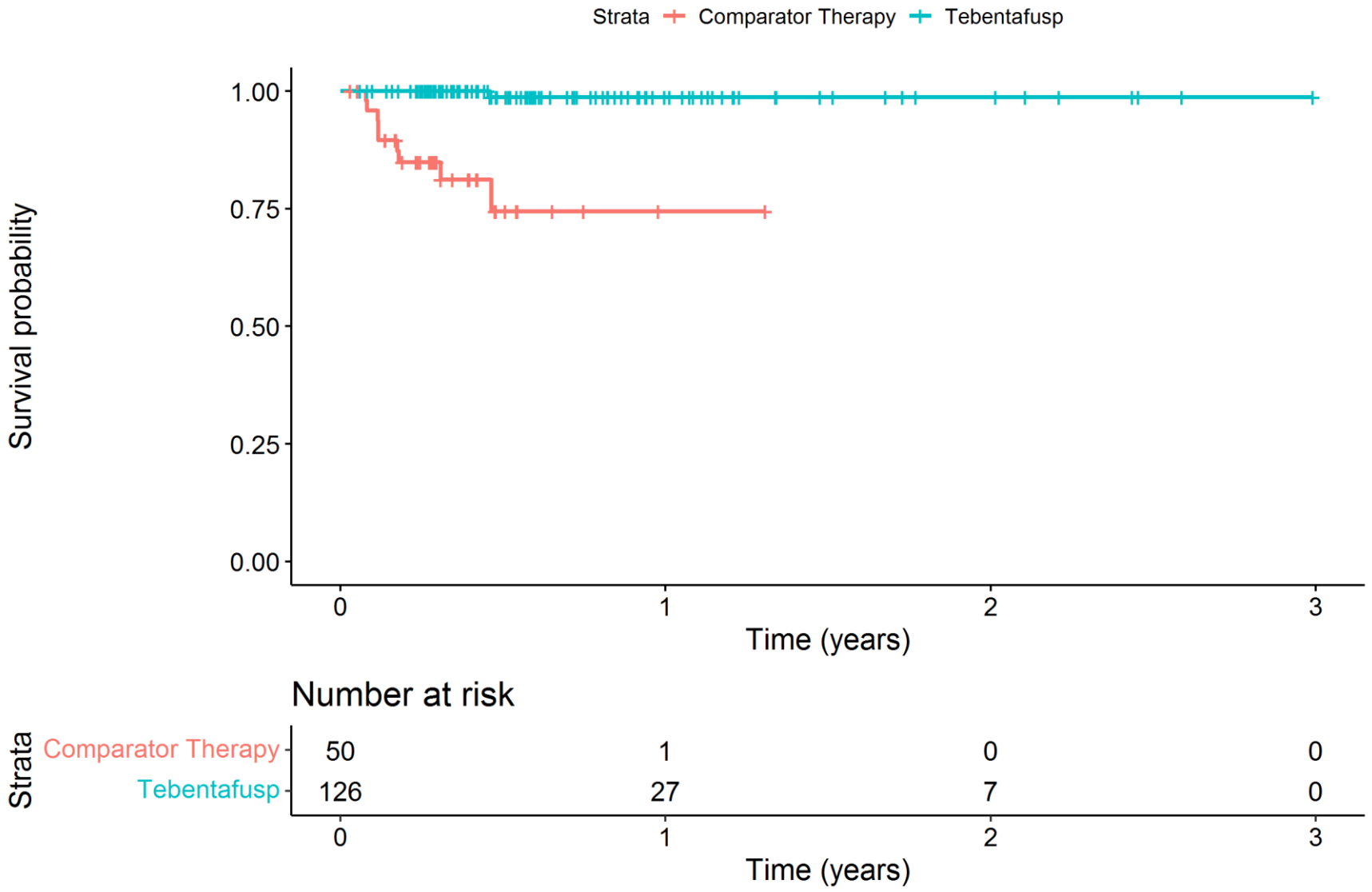
54.27 Endokrine Erkrankungen - Männlich



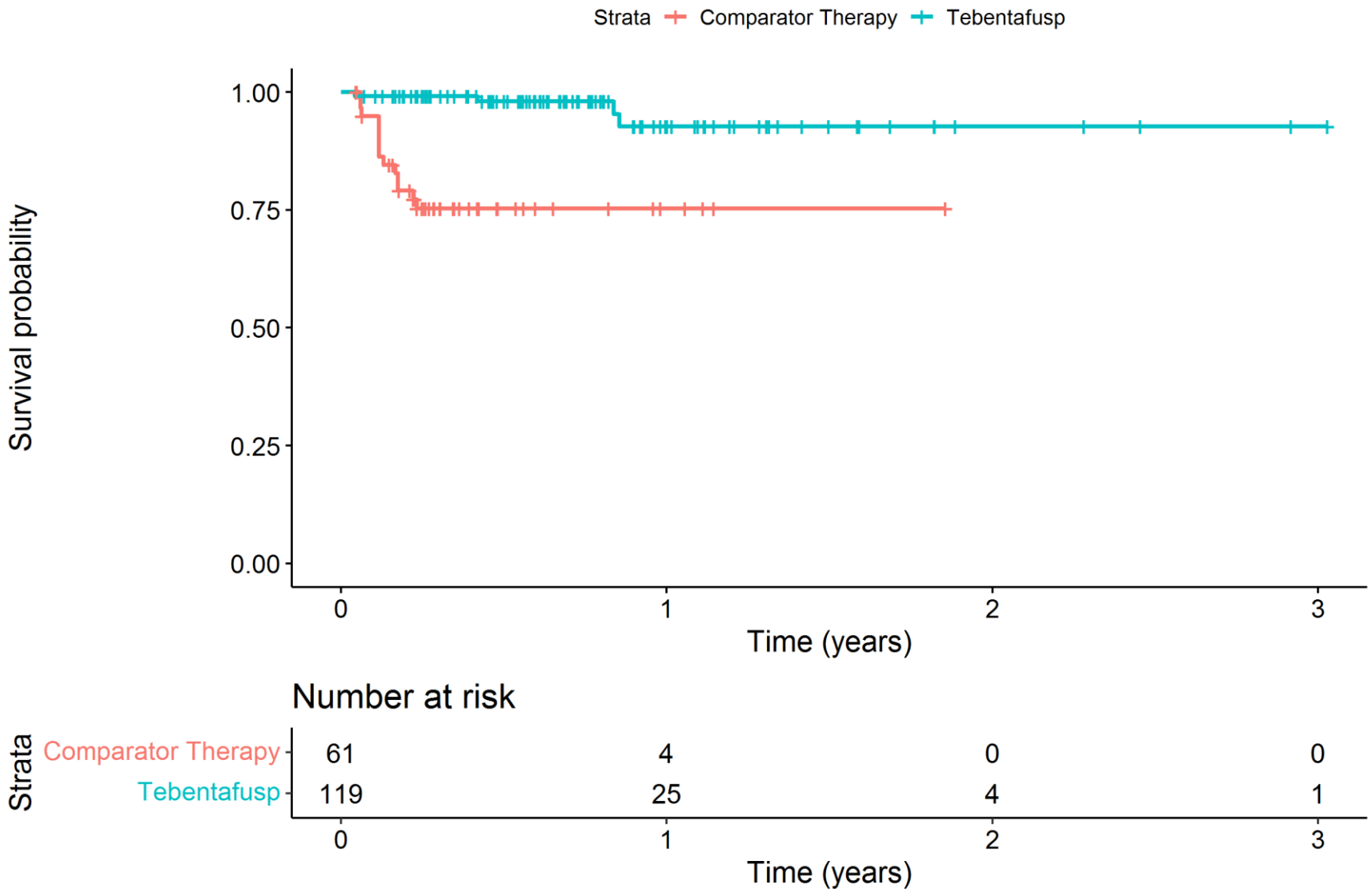
54.28 Endokrine Erkrankungen - Weiblich



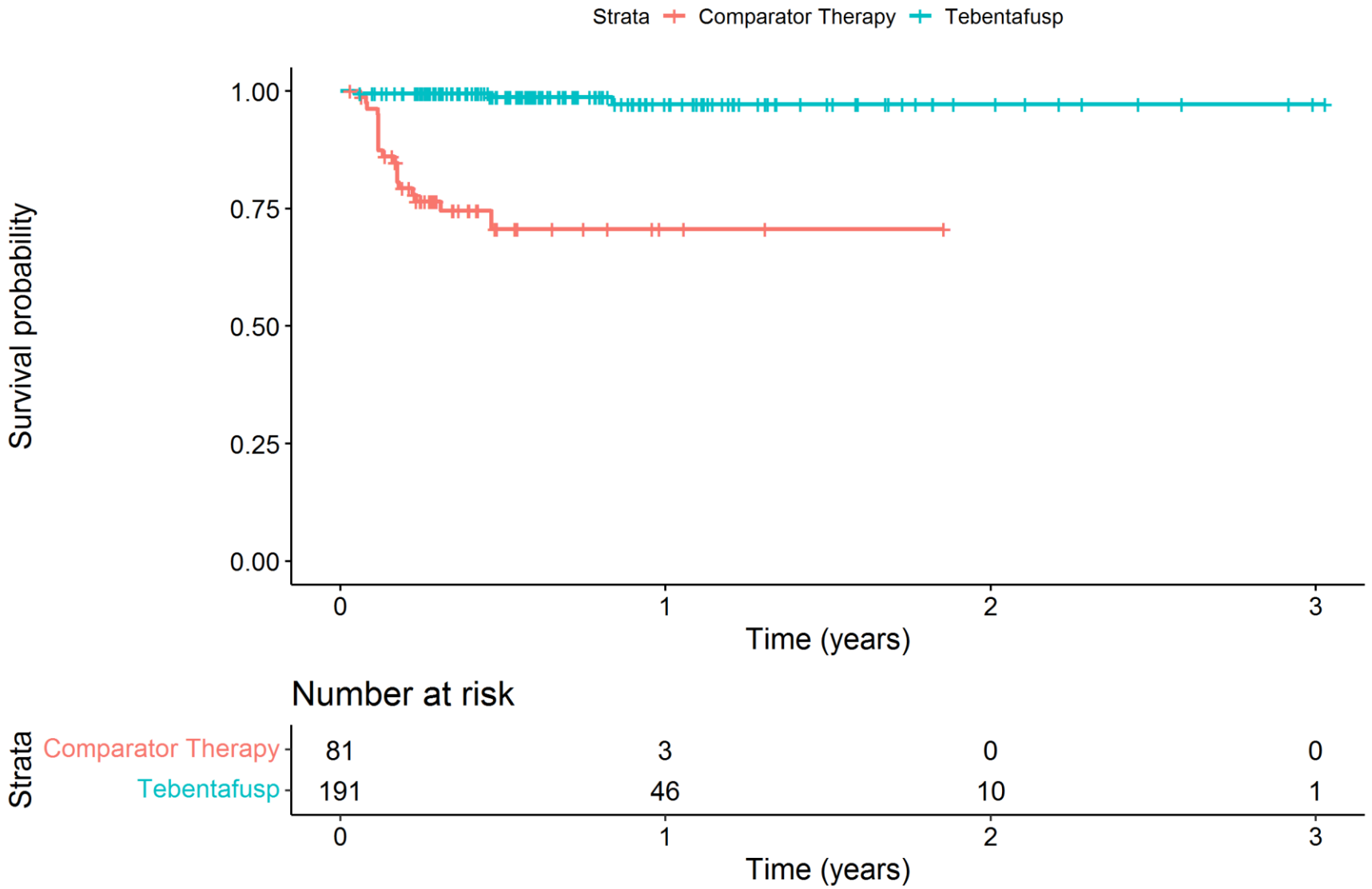
54.29 Endokrine Erkrankungen - <65



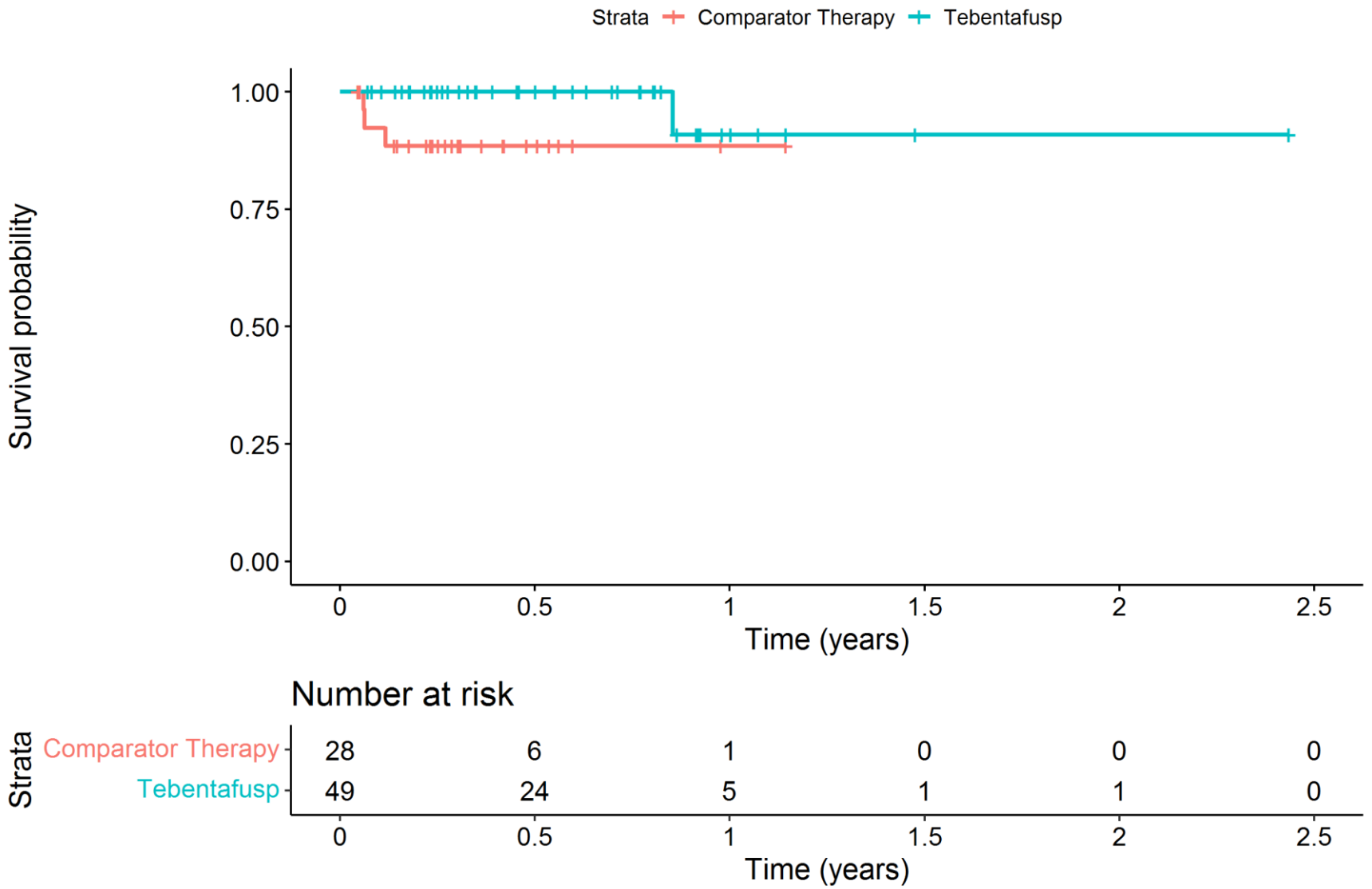
54.30 Endokrine Erkrankungen - ≥65



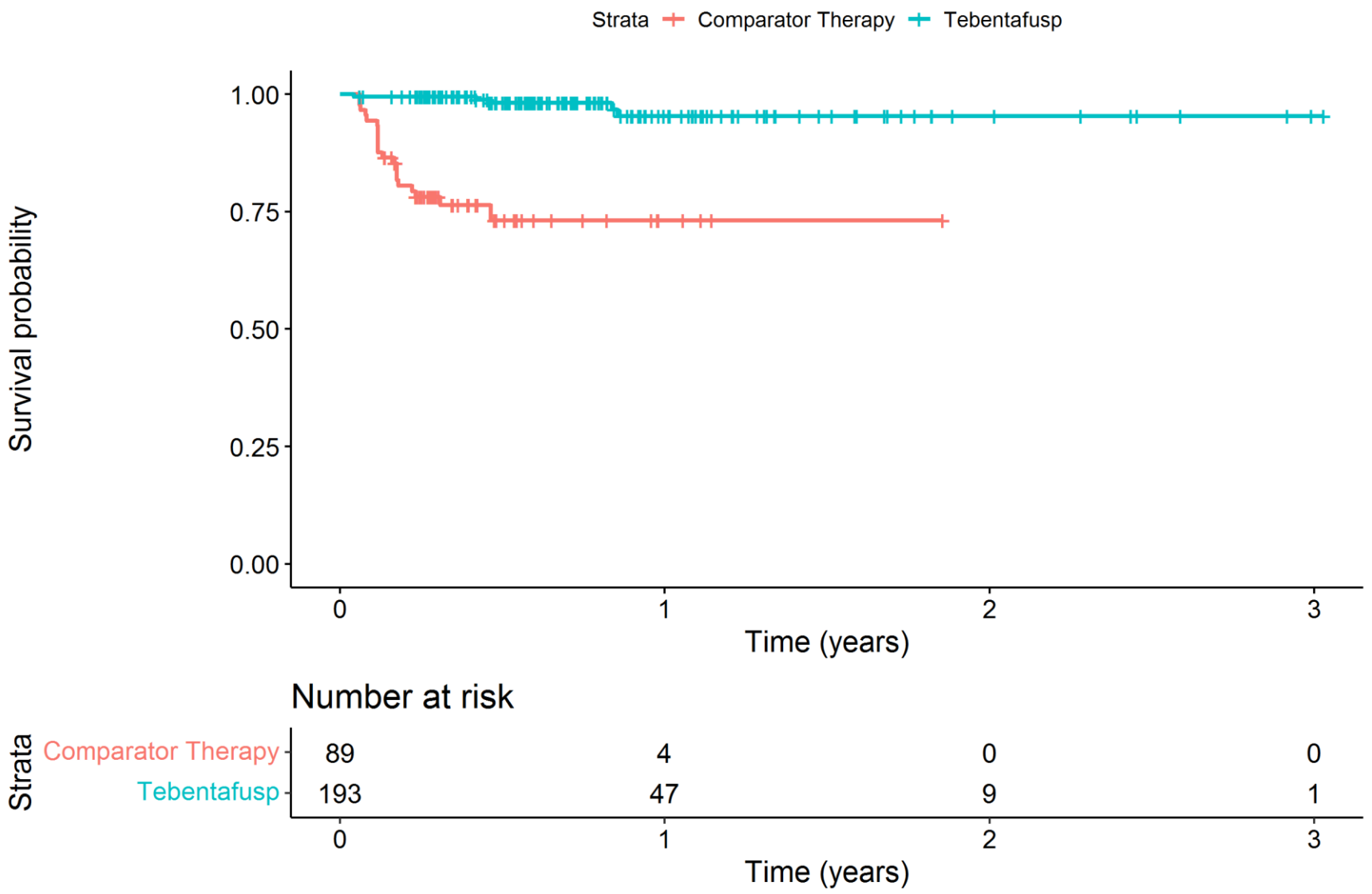
54.31 Endokrine Erkrankungen - ECOG 0



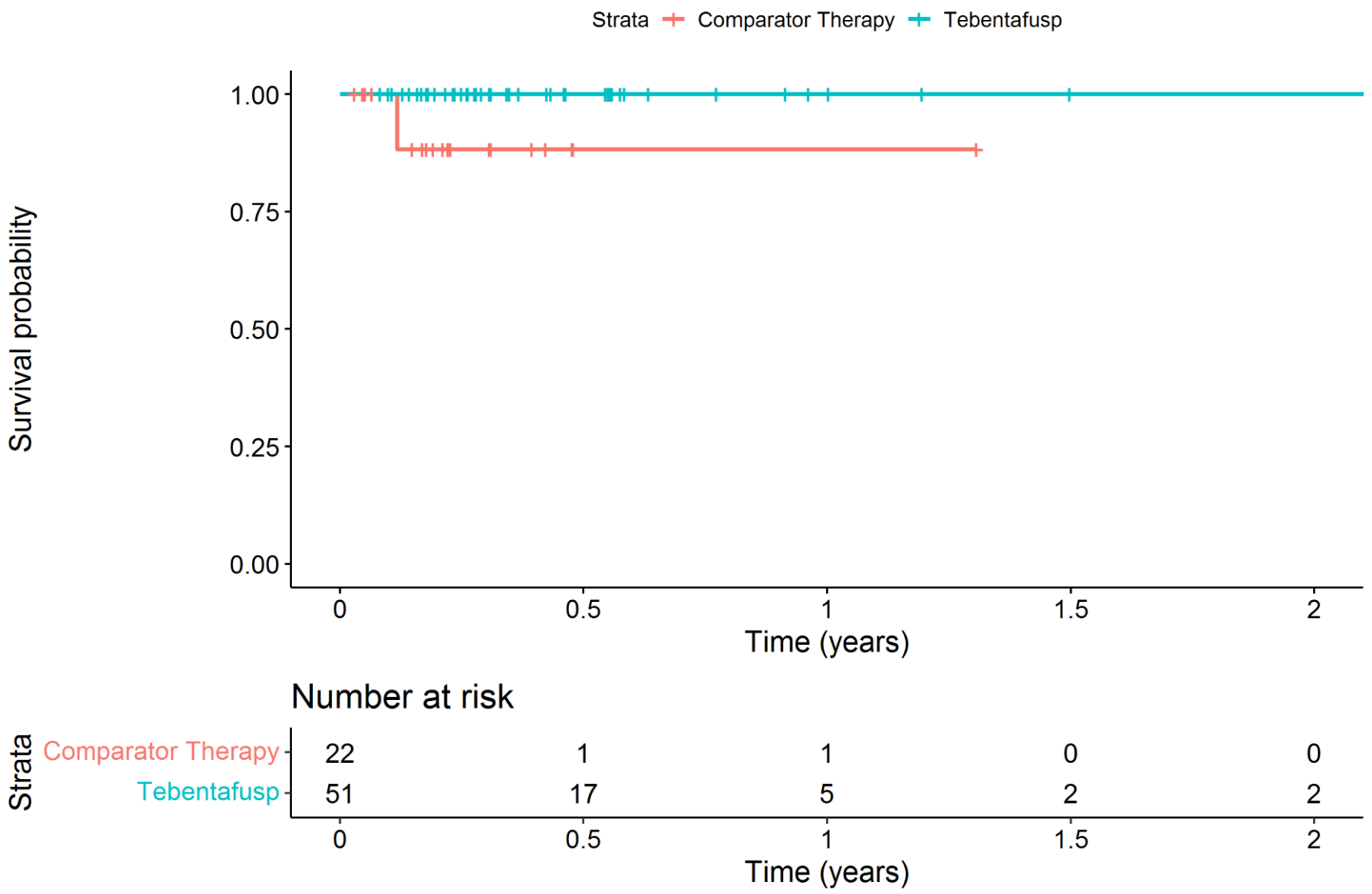
54.32 Endokrine Erkrankungen - ECOG 1



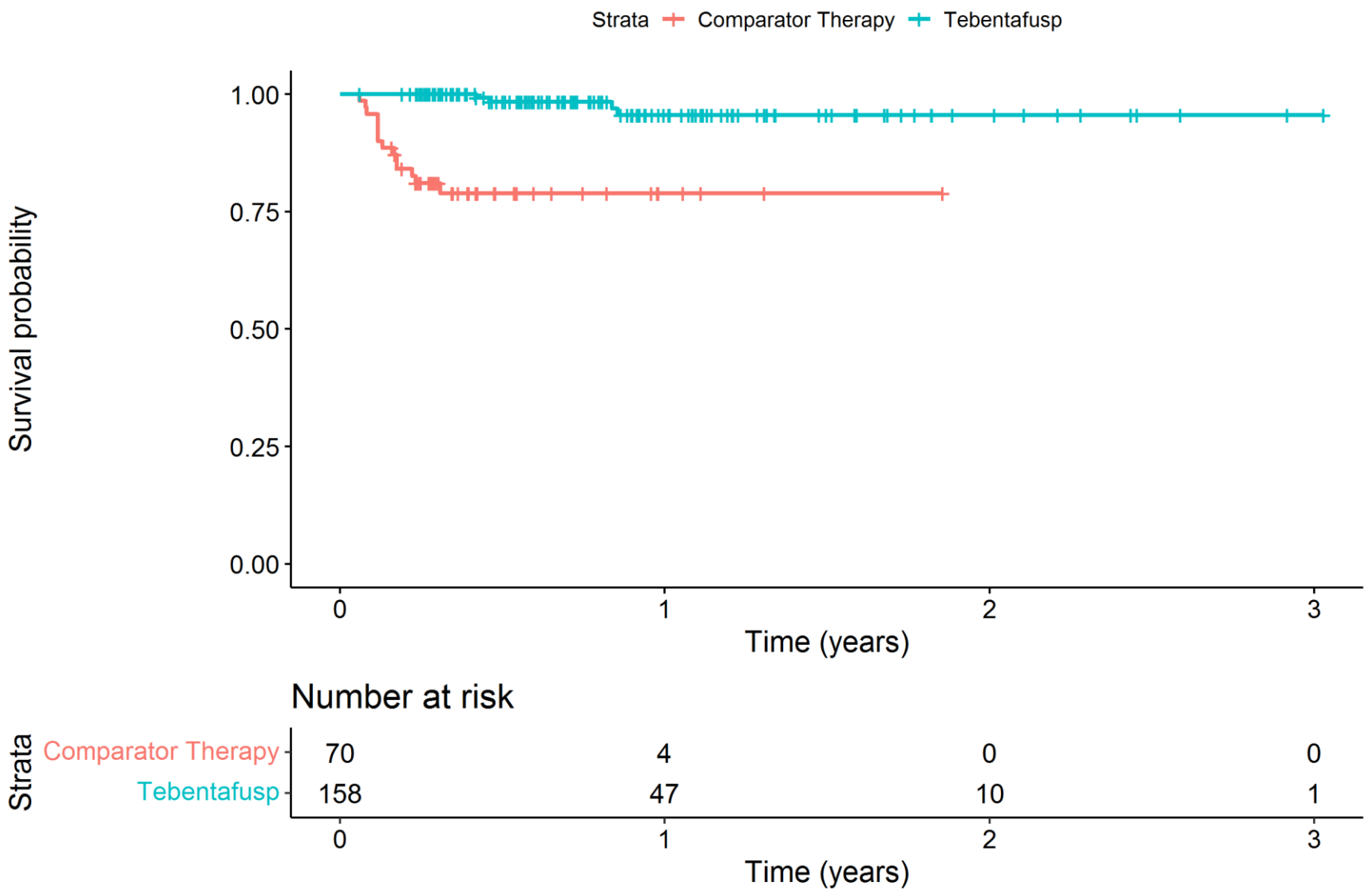
54.33 Endokrine Erkrankungen - ALP ≤ ULN



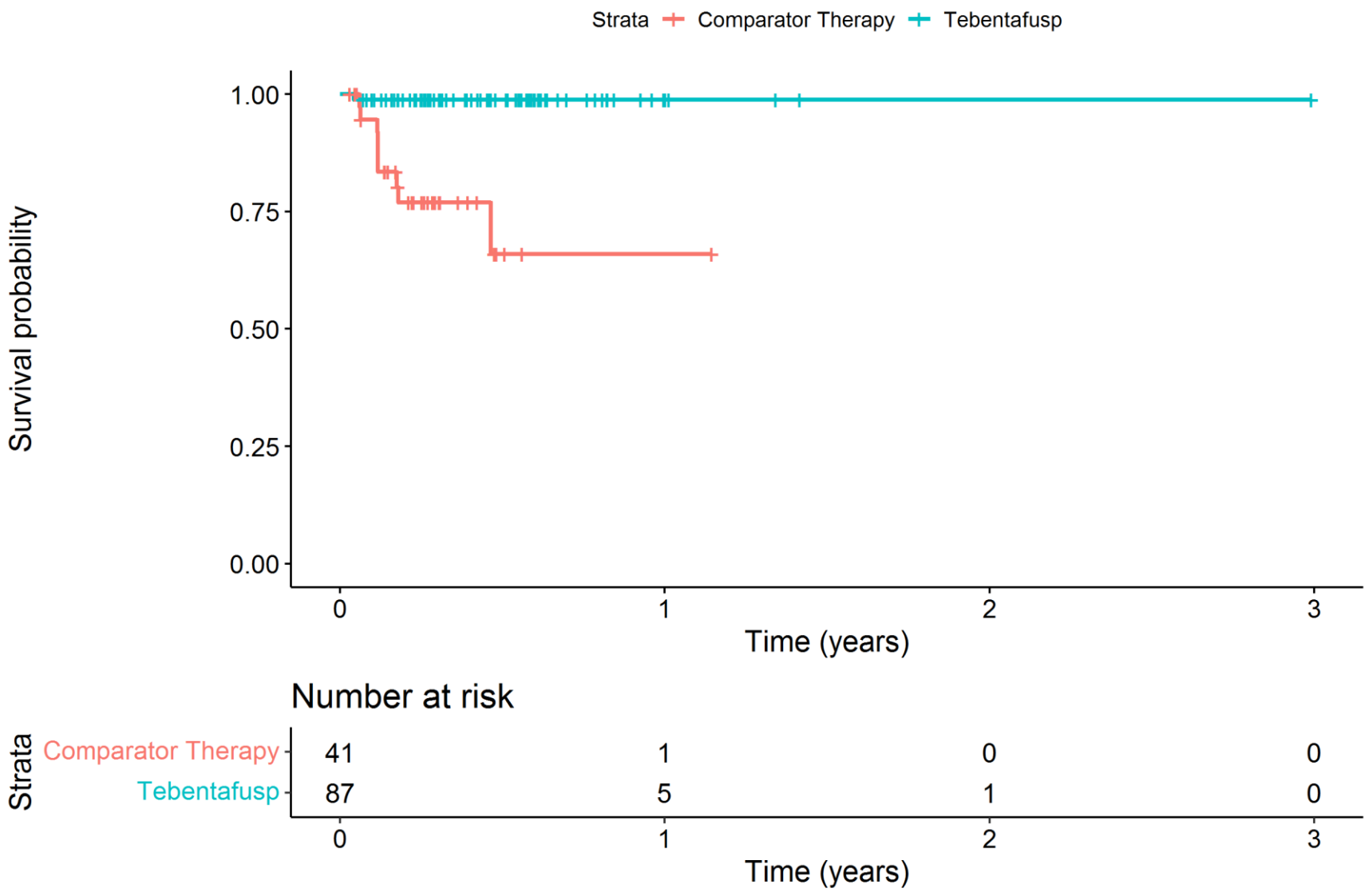
54.34 Endokrine Erkrankungen - ALP > ULN



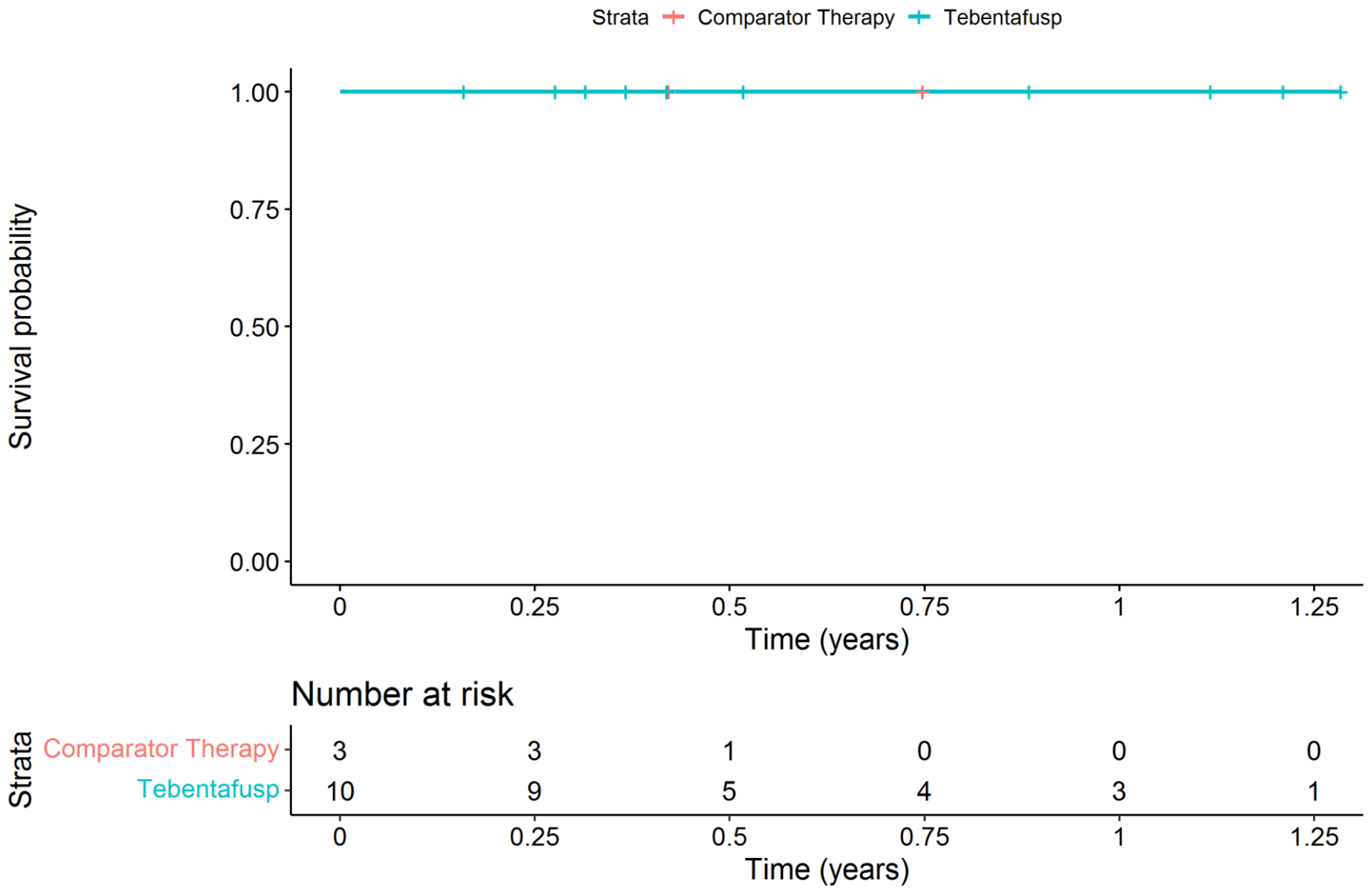
54.35 Endokrine Erkrankungen - LDH =< ULN



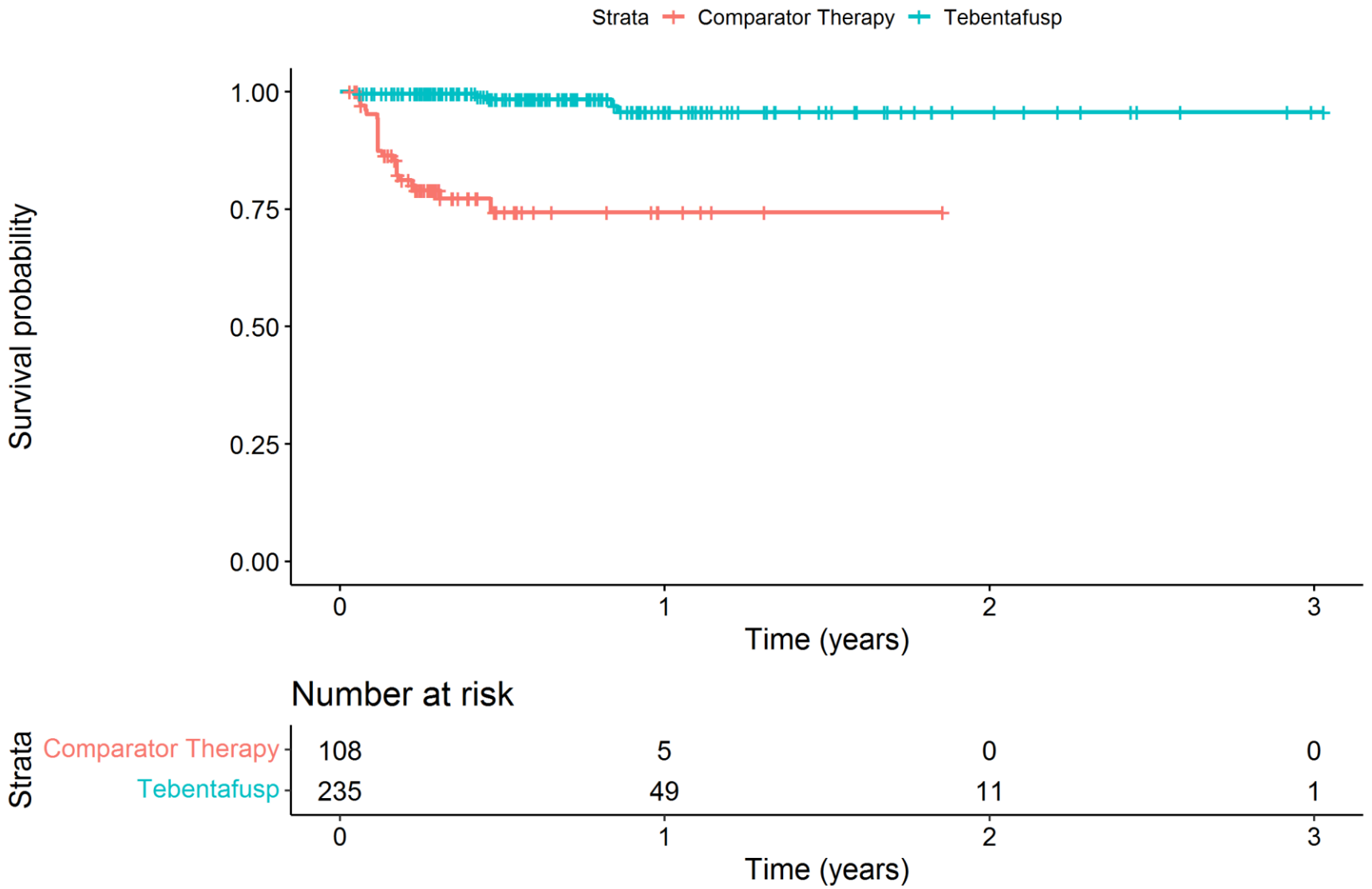
54.36 Endokrine Erkrankungen - LDH > ULN



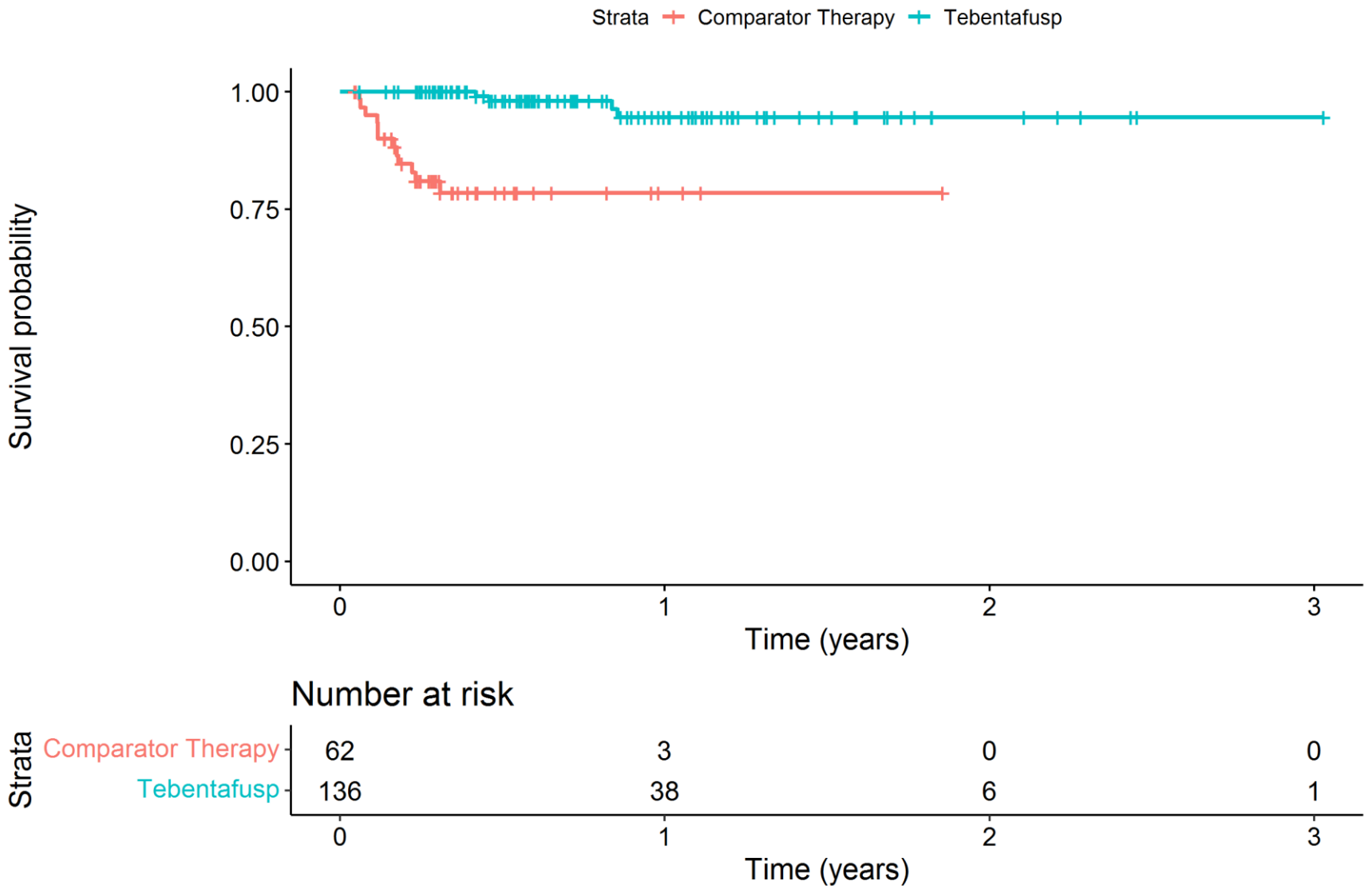
Endokrine Erkrankungen - Vorherige Therapie adjuvant/neoadjuvant



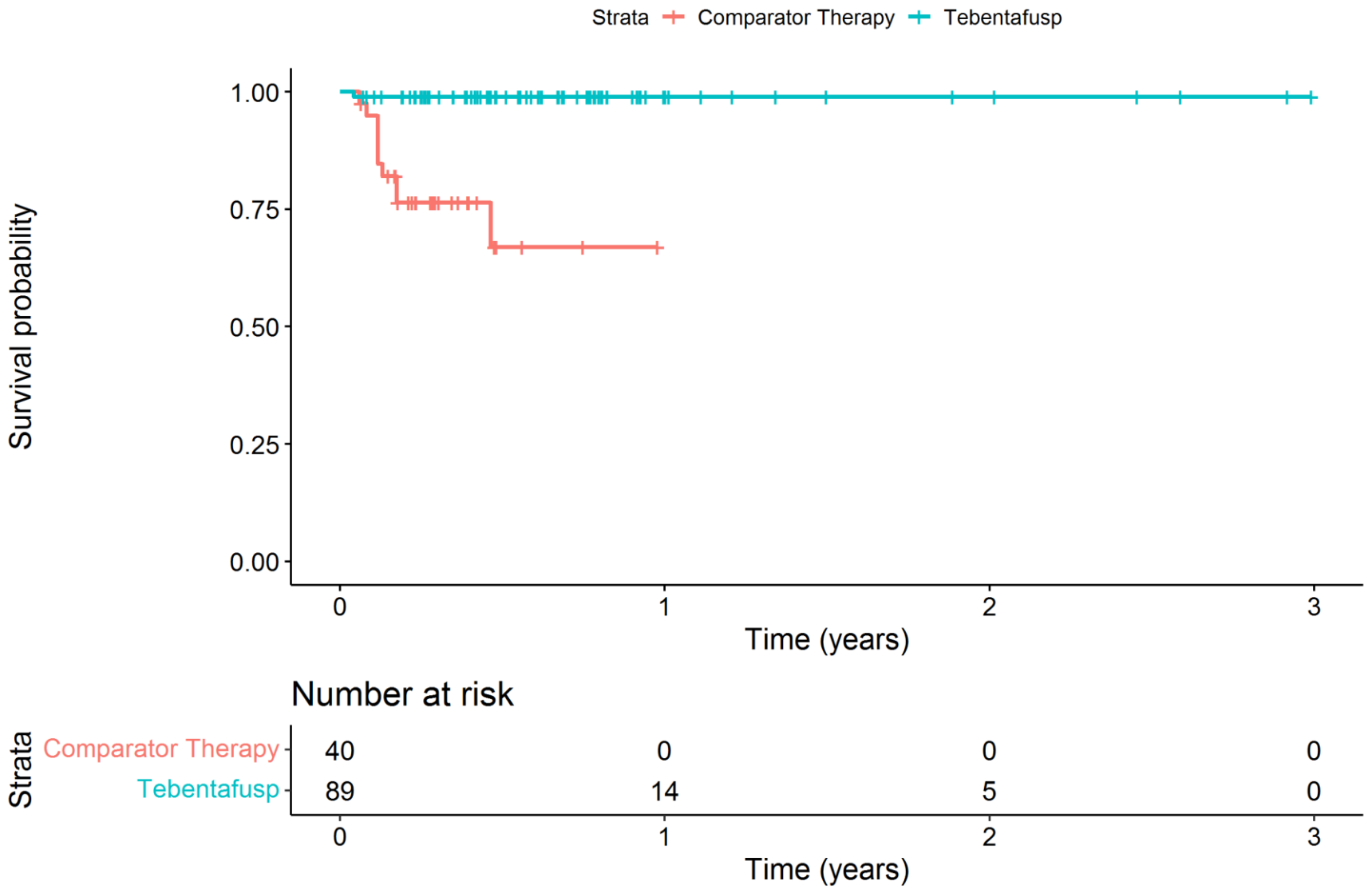
Endokrine Erkrankungen - Keine vorherige Therapie adjuvant/neoadjuvant



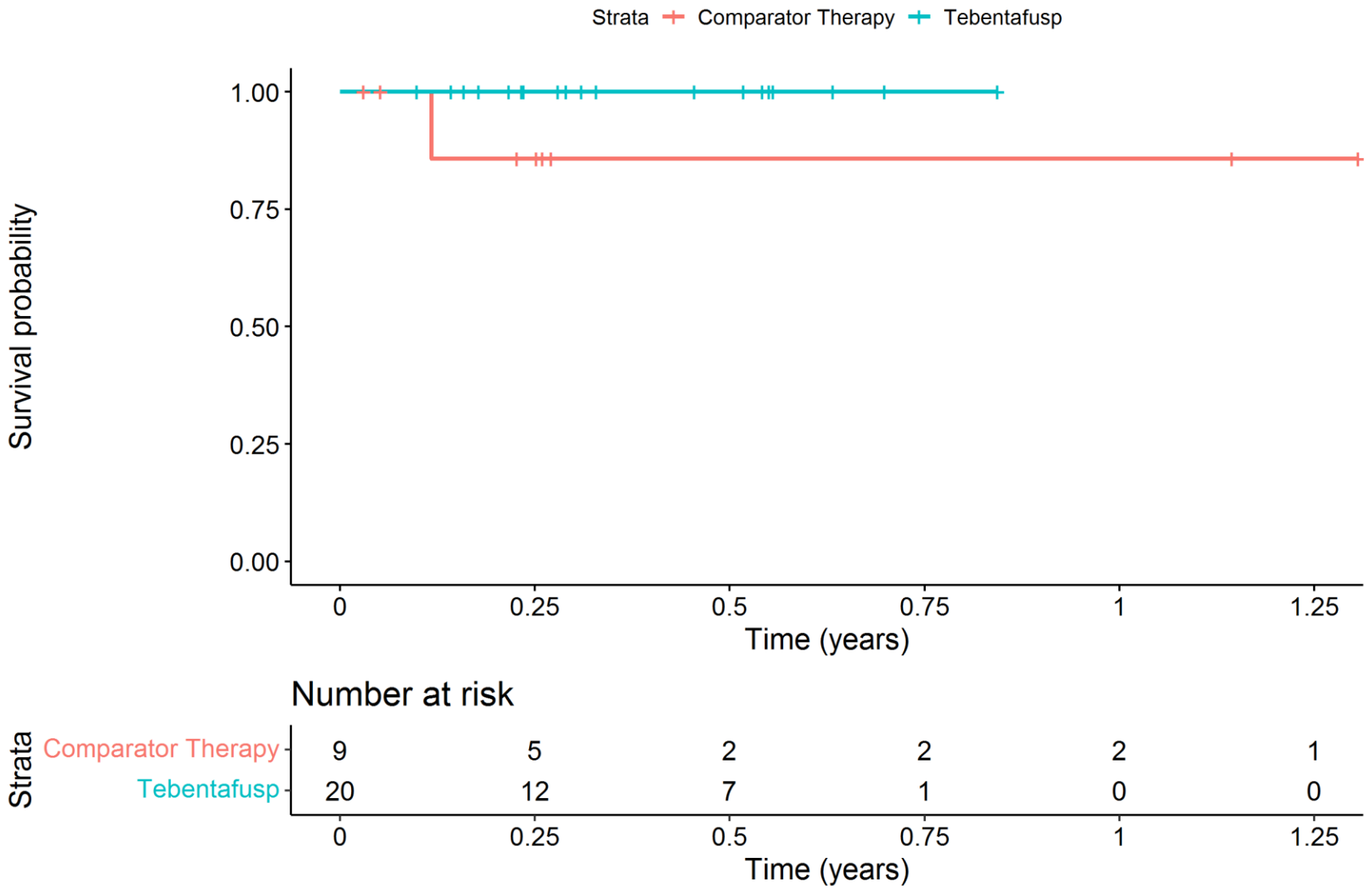
Endokrine Erkrankungen - Läsion ≤ 3cm



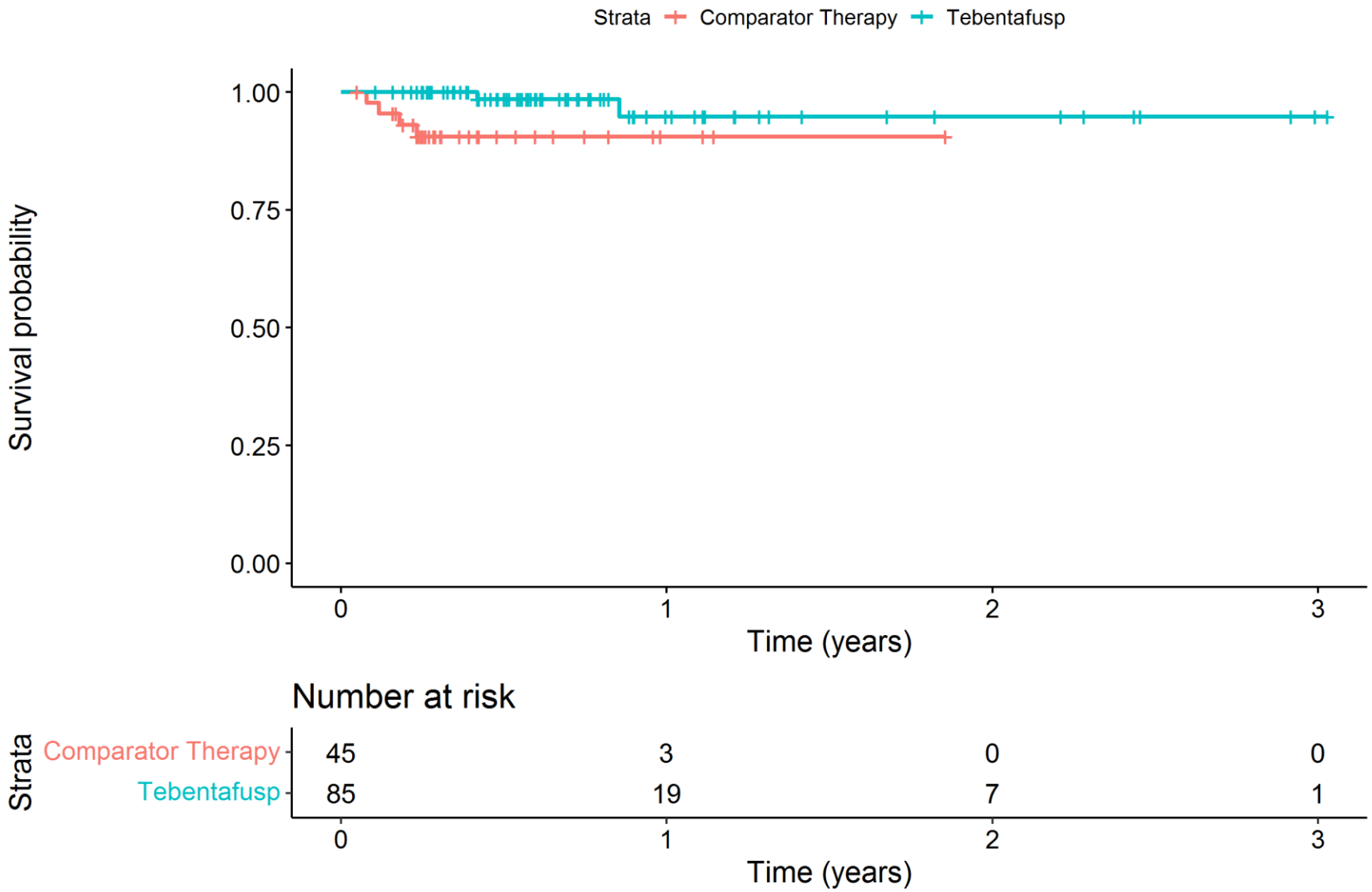
Endokrine Erkrankungen - Läsion 3,1-8,0 cm



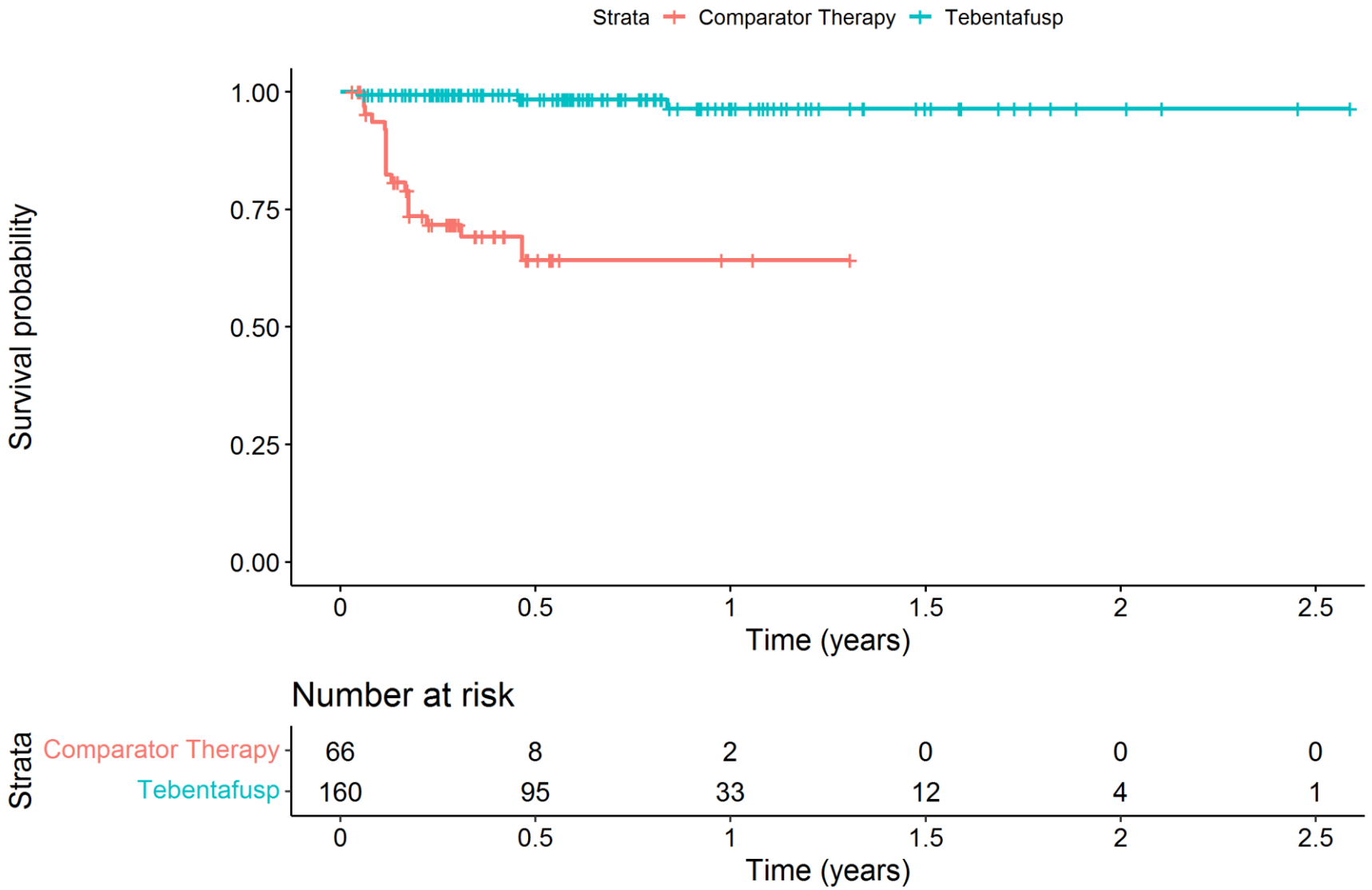
Endokrine Erkrankungen - Läsion ≥8,1 cm



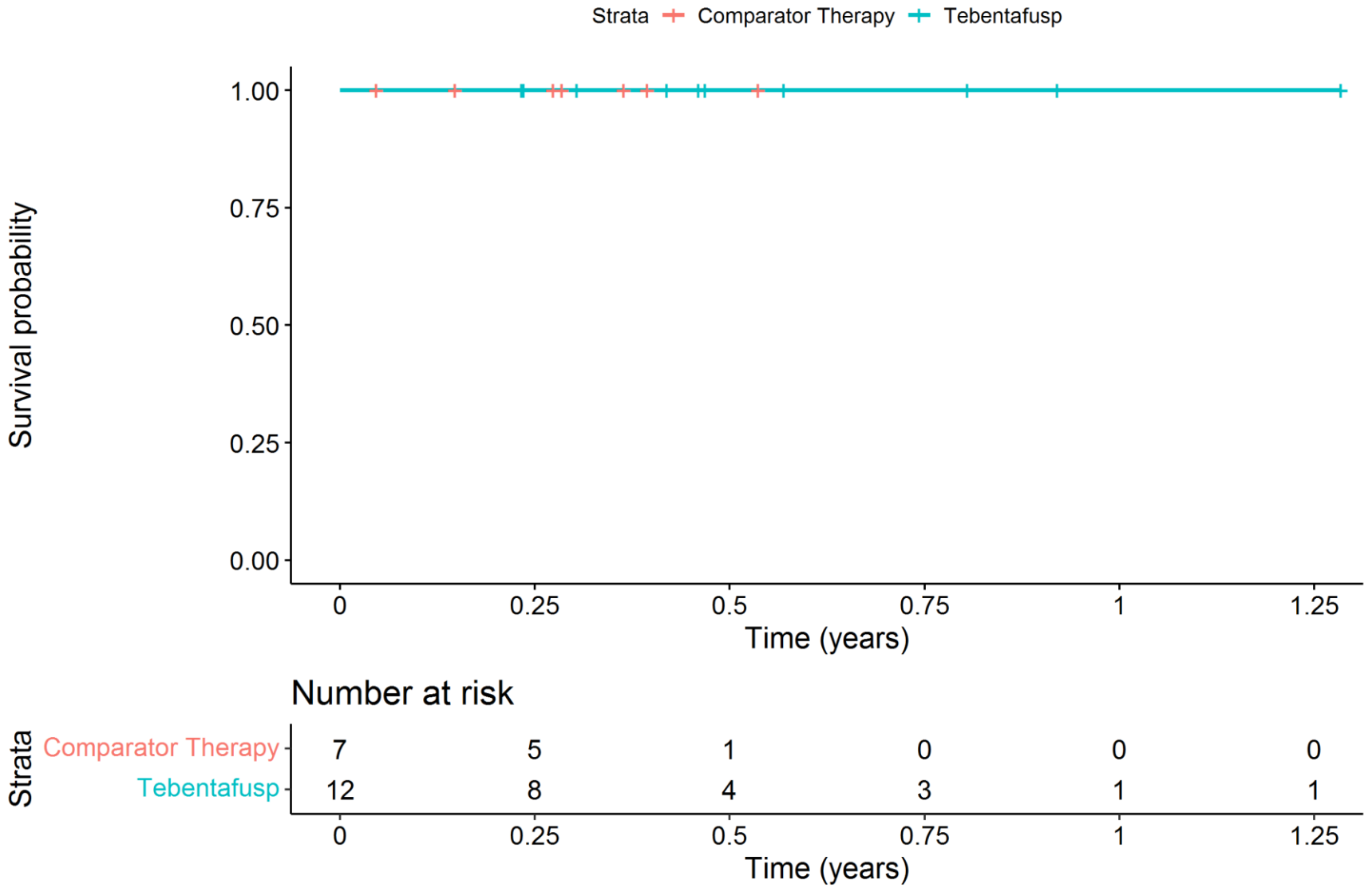
Endokrine Erkrankungen - Nordamerika



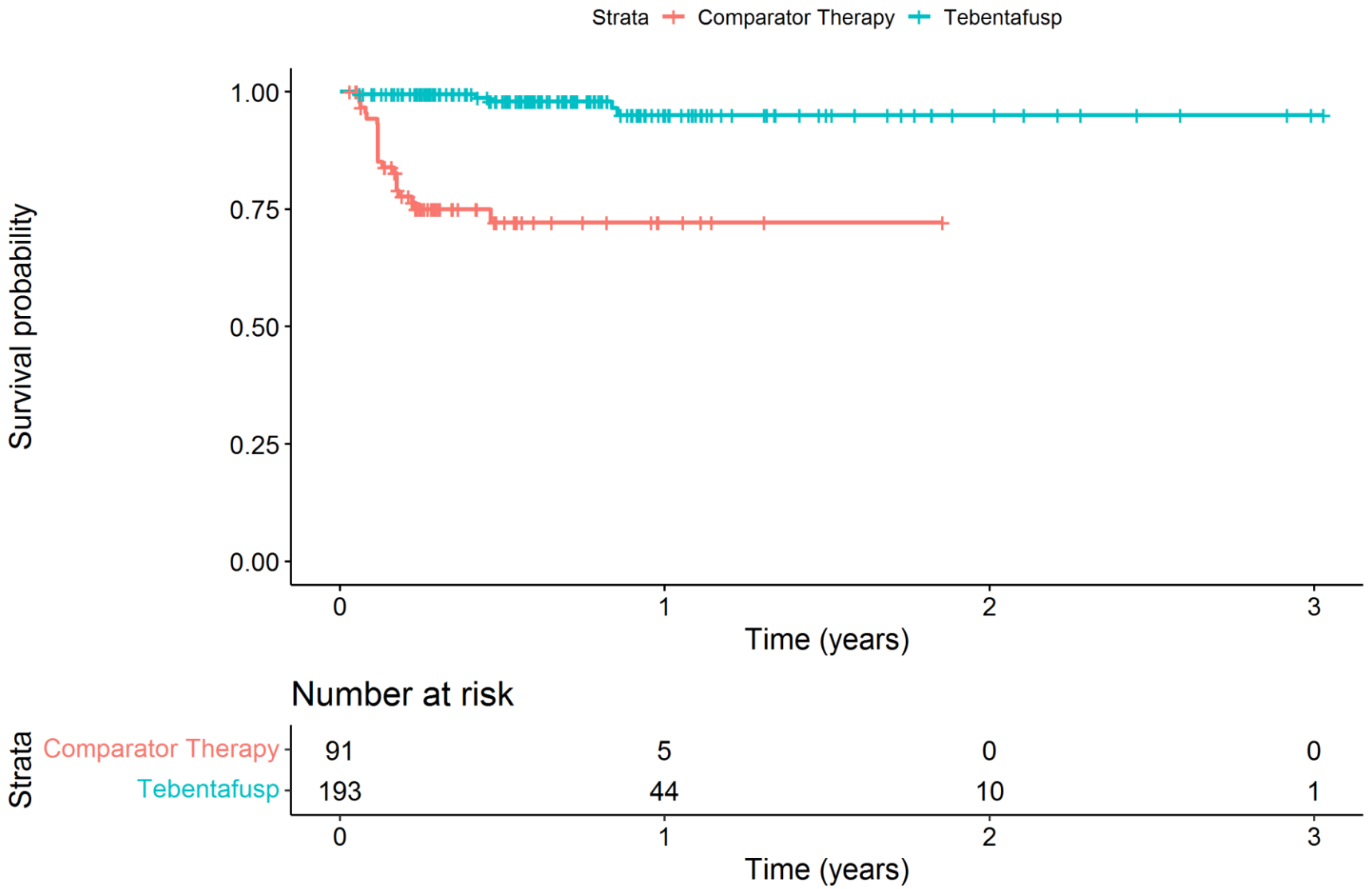
Endokrine Erkrankungen - Nicht-Nordamerika



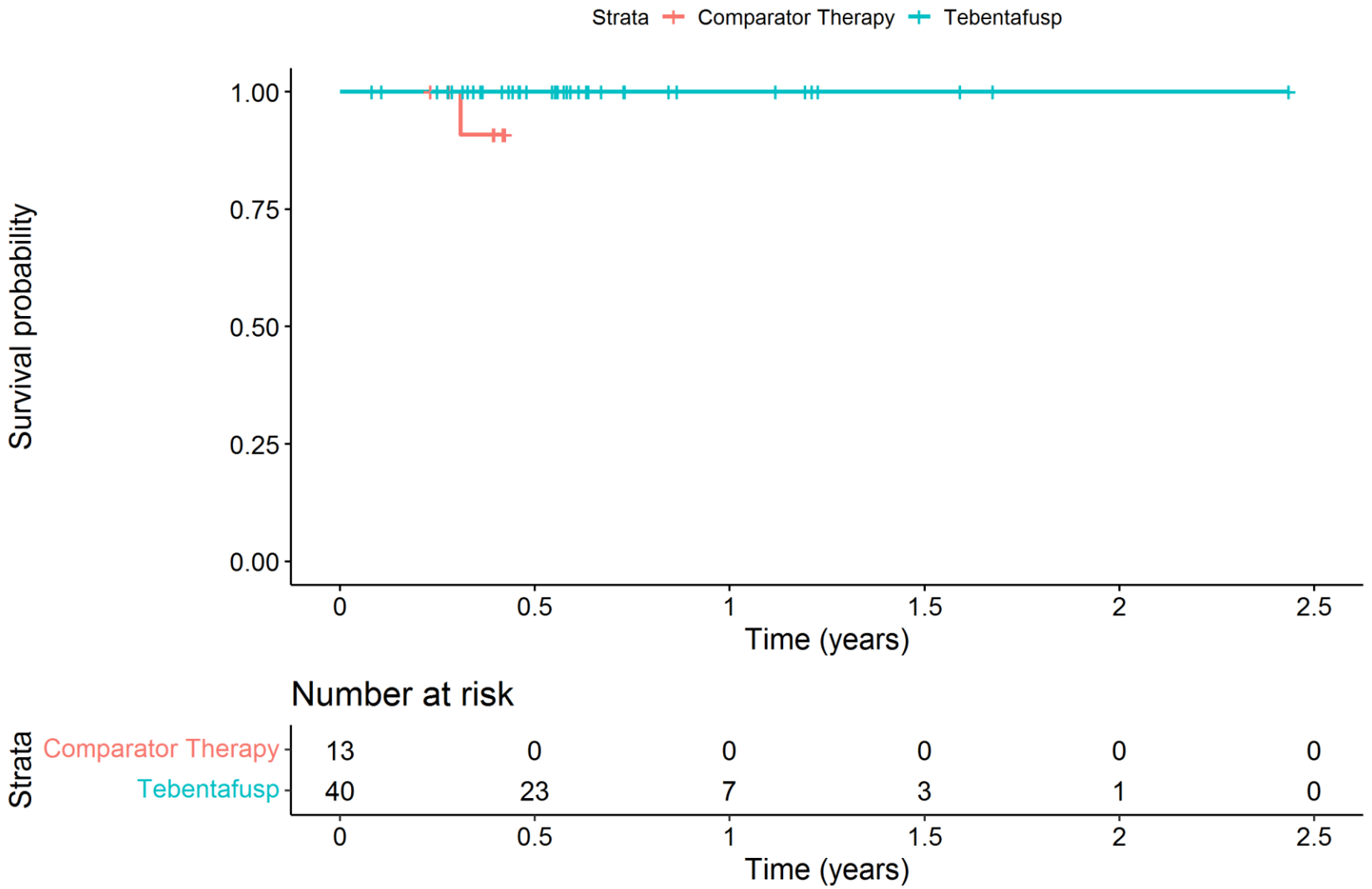
Endokrine Erkrankungen - Dacarbazin



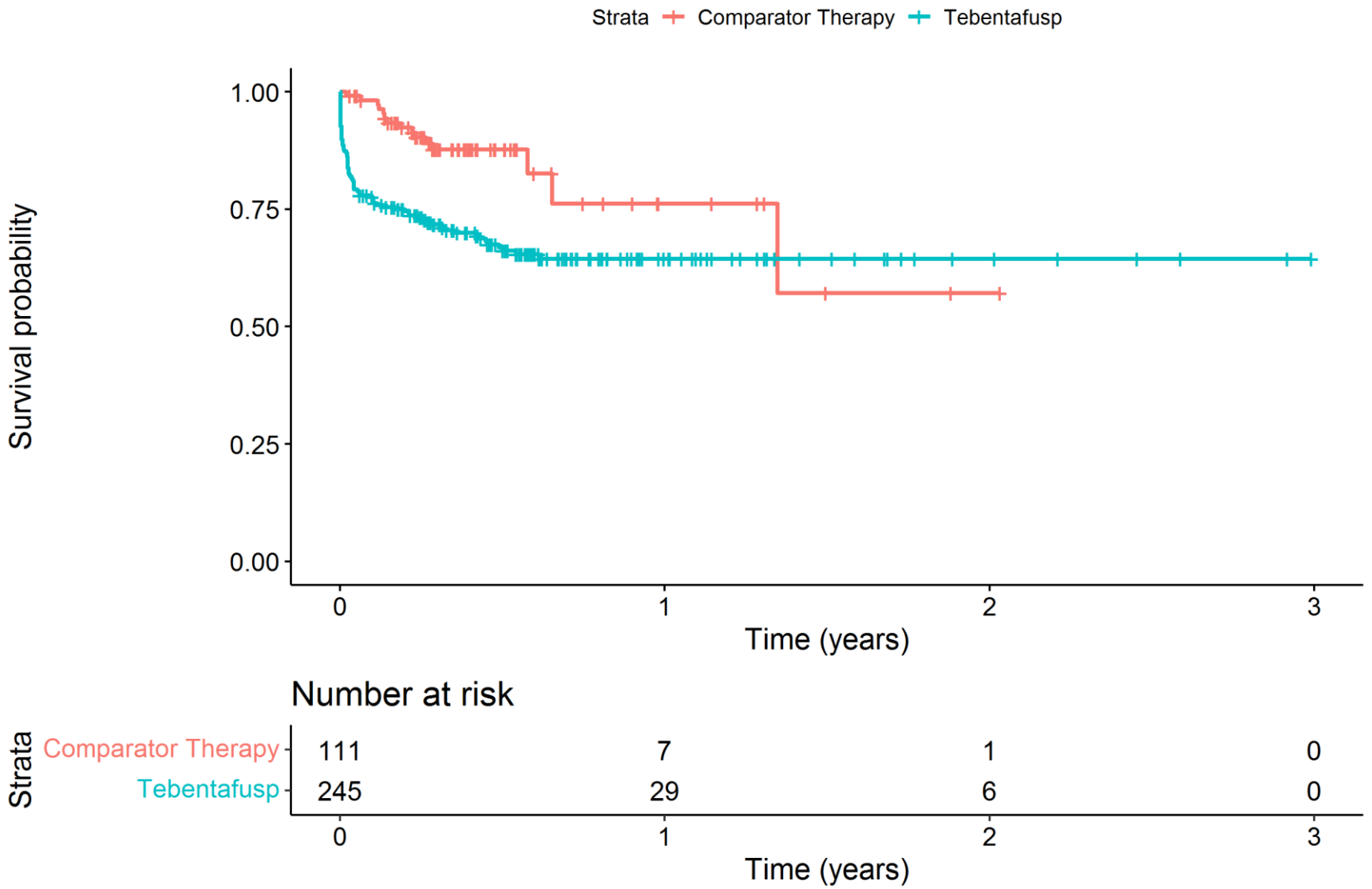
Endokrine Erkrankungen - Pembrolizumab



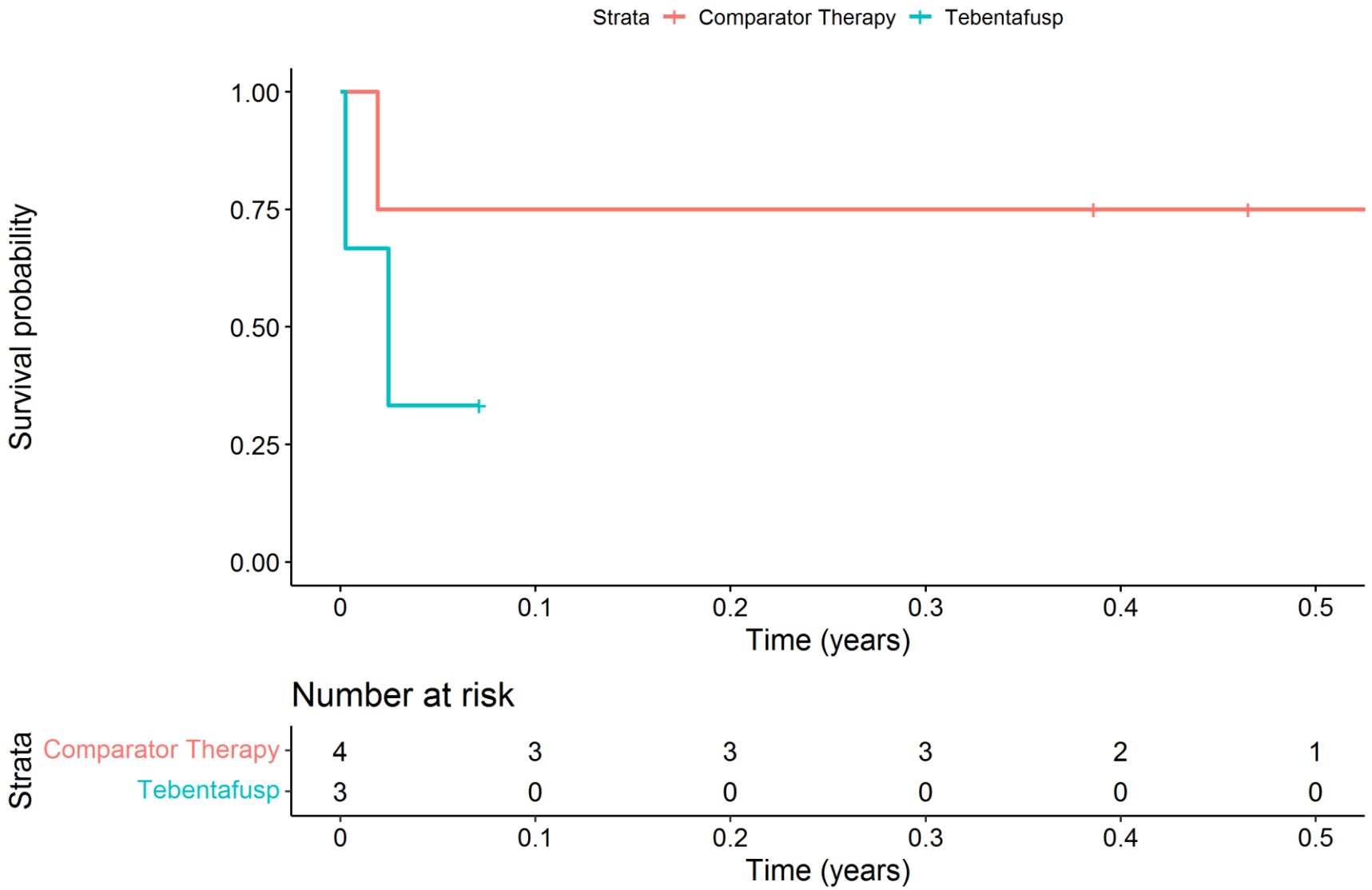
Endokrine Erkrankungen - Ipilimumab



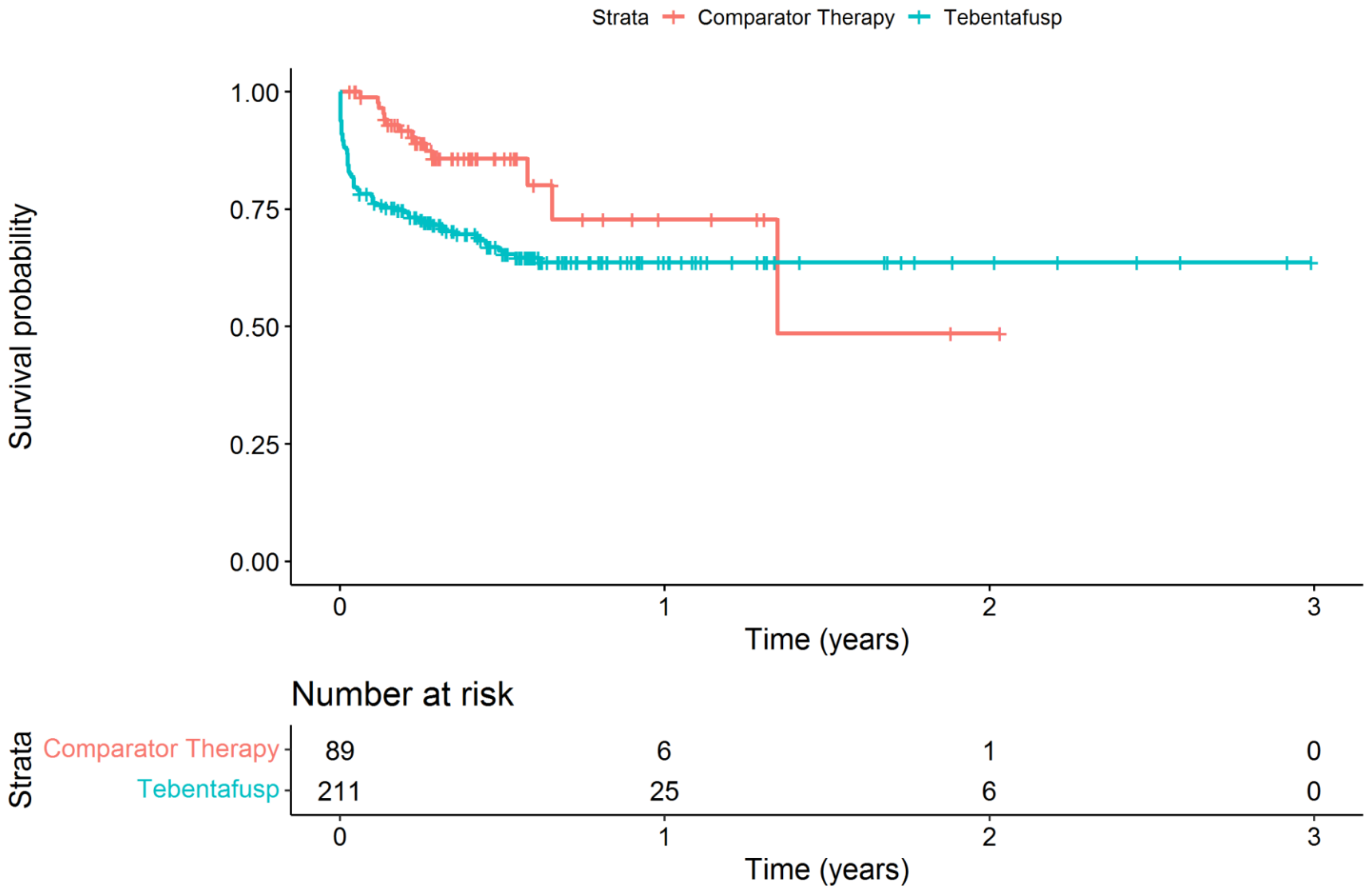
Augenerkrankungen - Gesamt



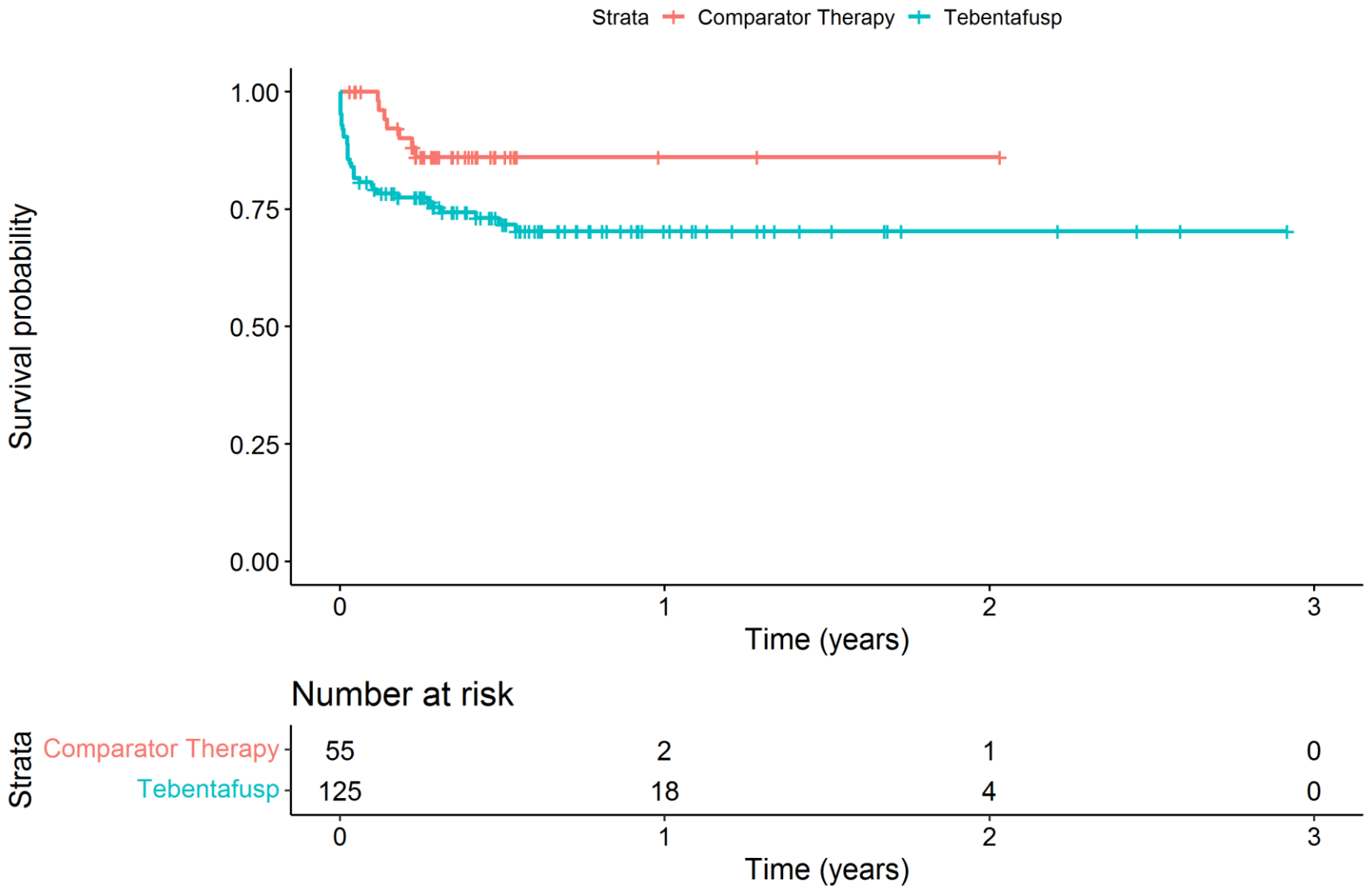
Augenerkrankungen - Hispanisch



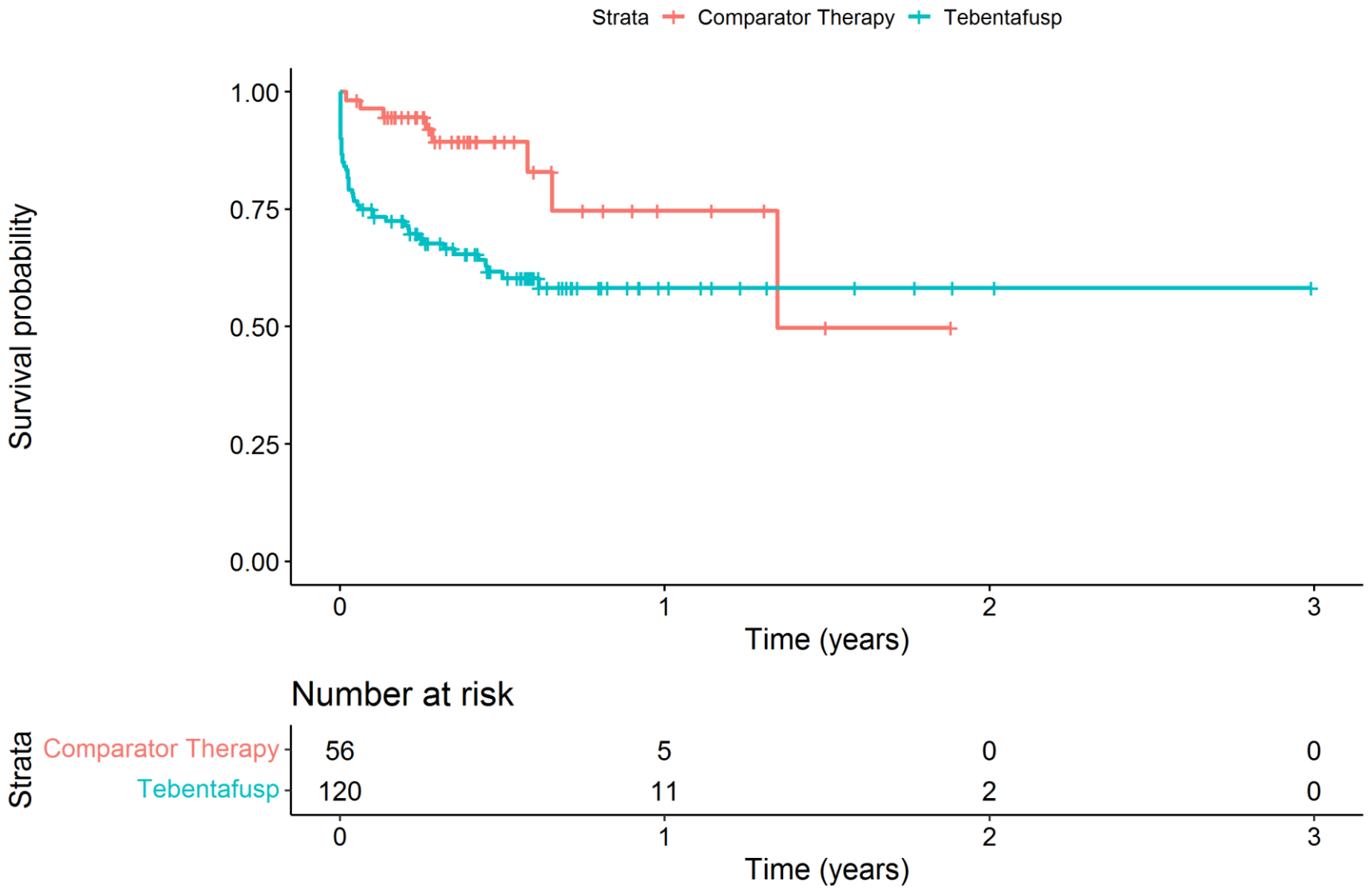
Augenerkrankungen - Nicht-hispanisch



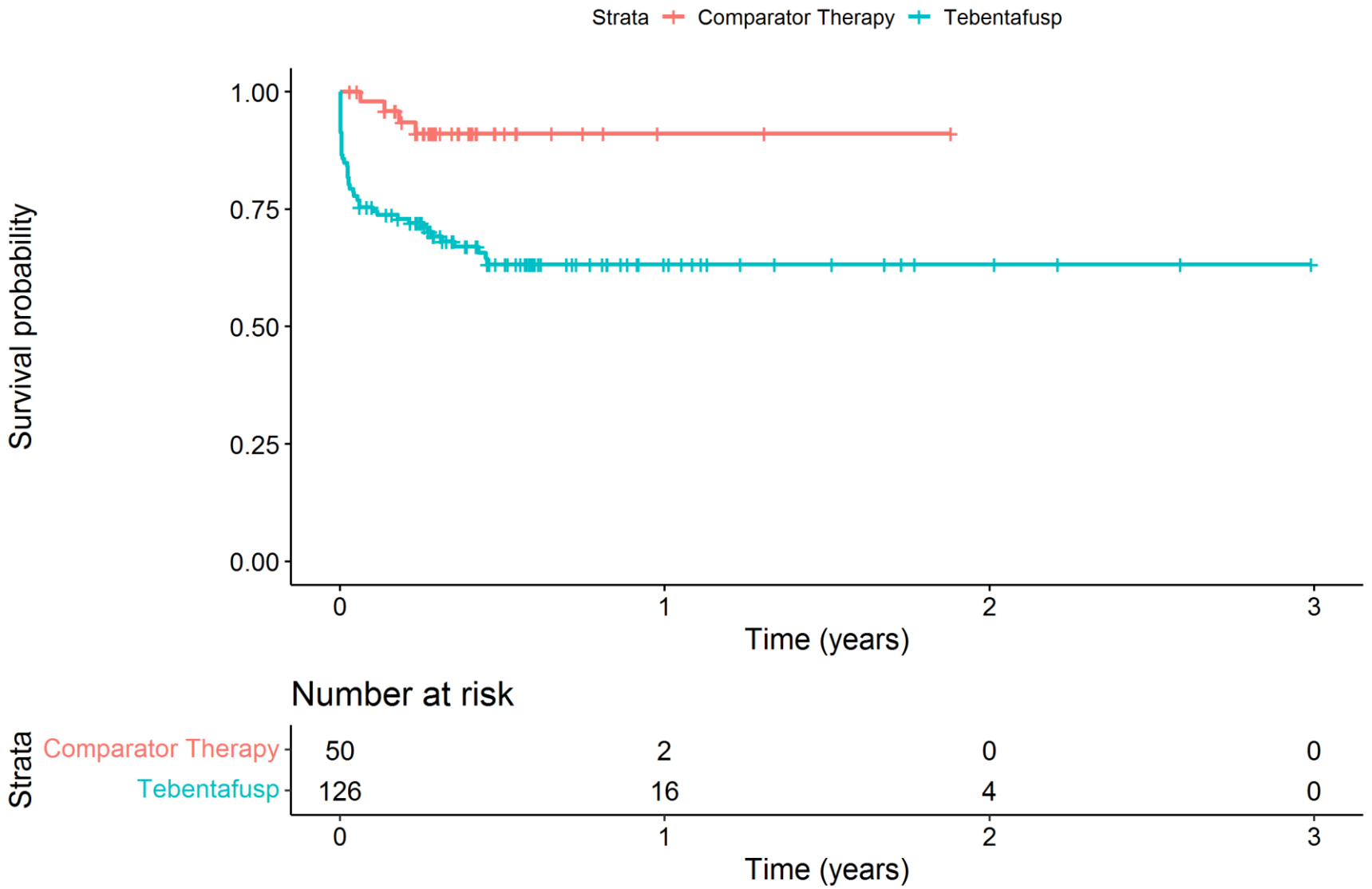
Augenerkrankungen - Männlich



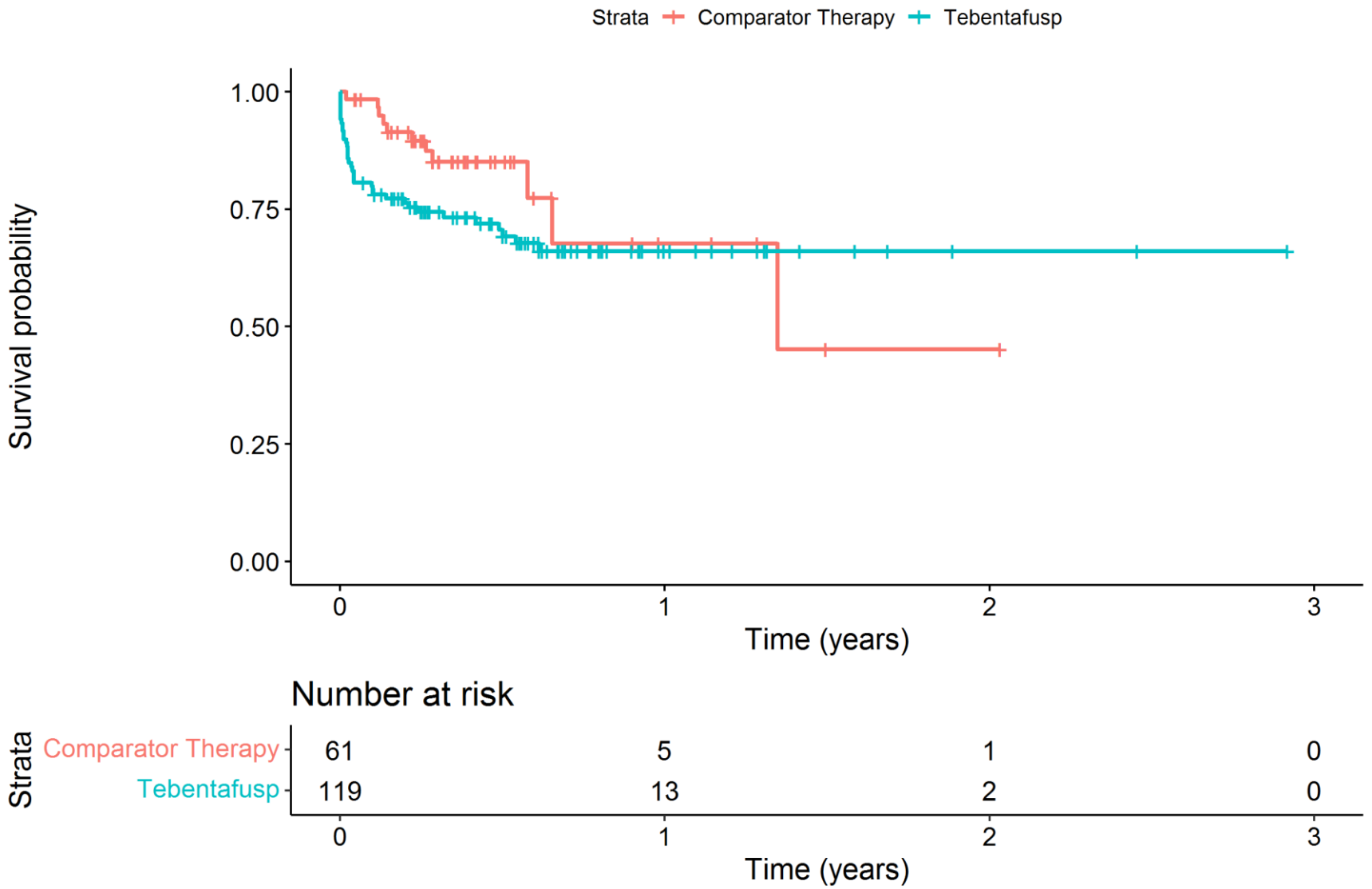
Augenerkrankungen - Weiblich



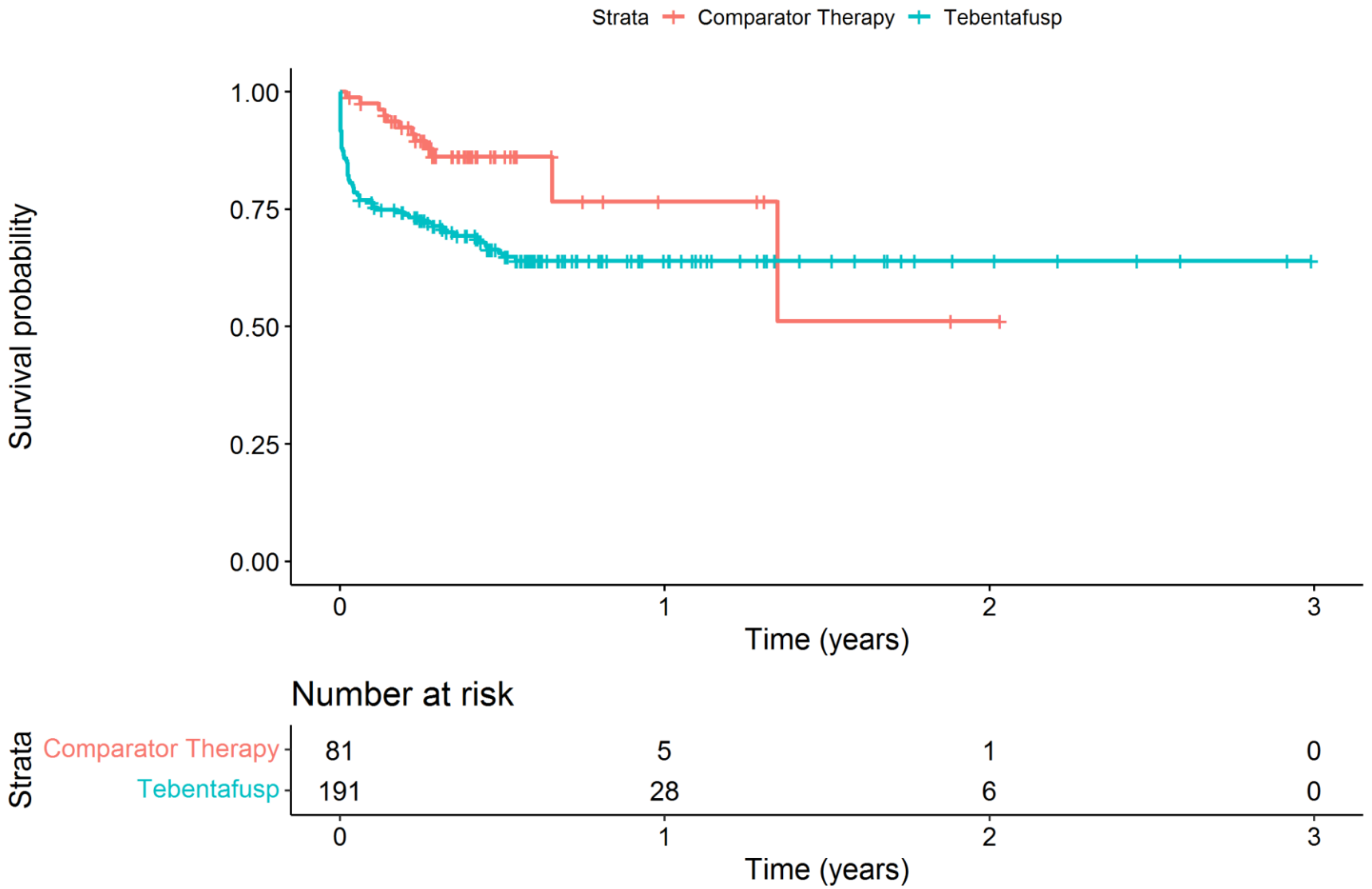
Augenerkrankungen - <65



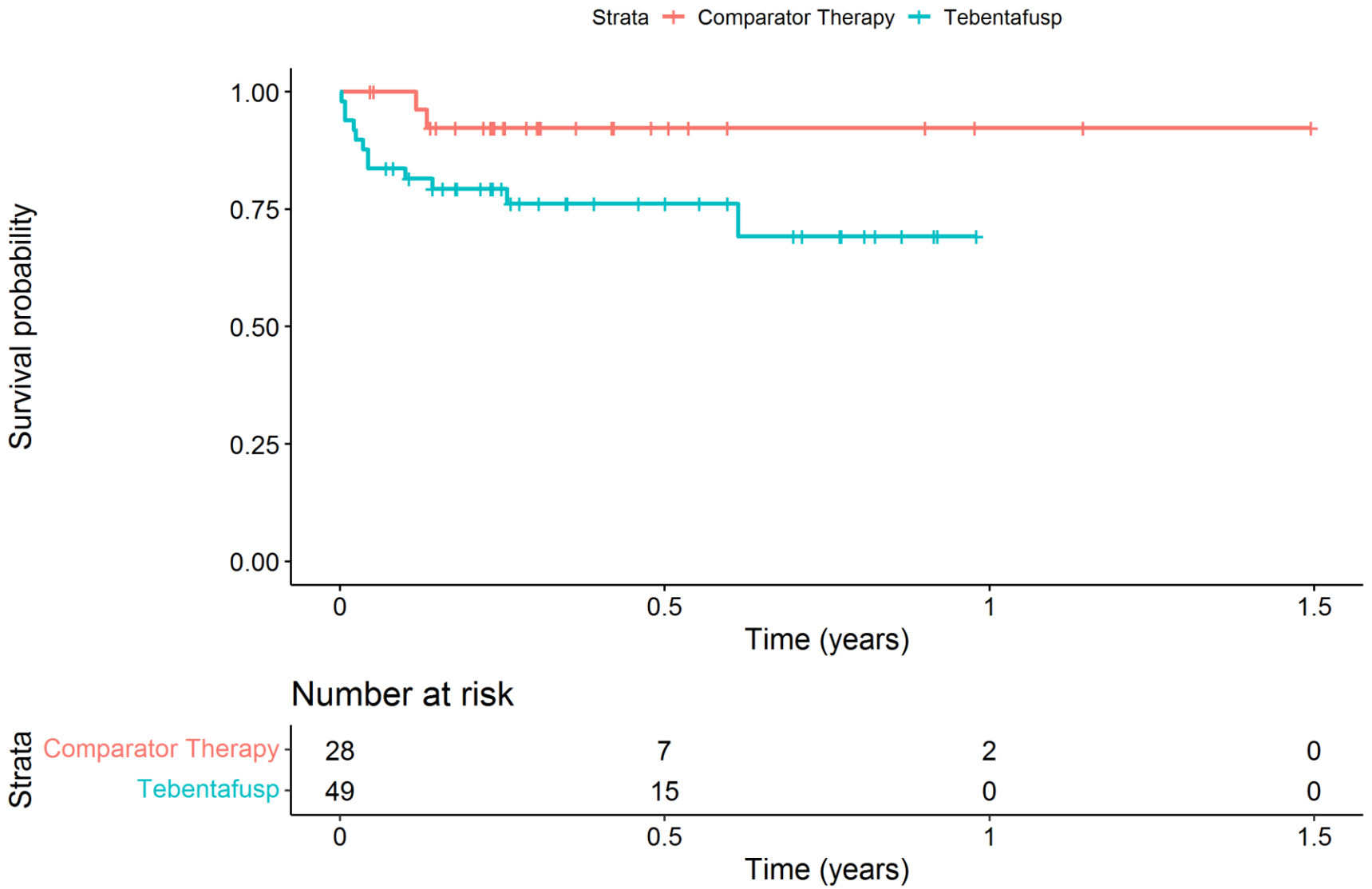
Augenerkrankungen - ≥65



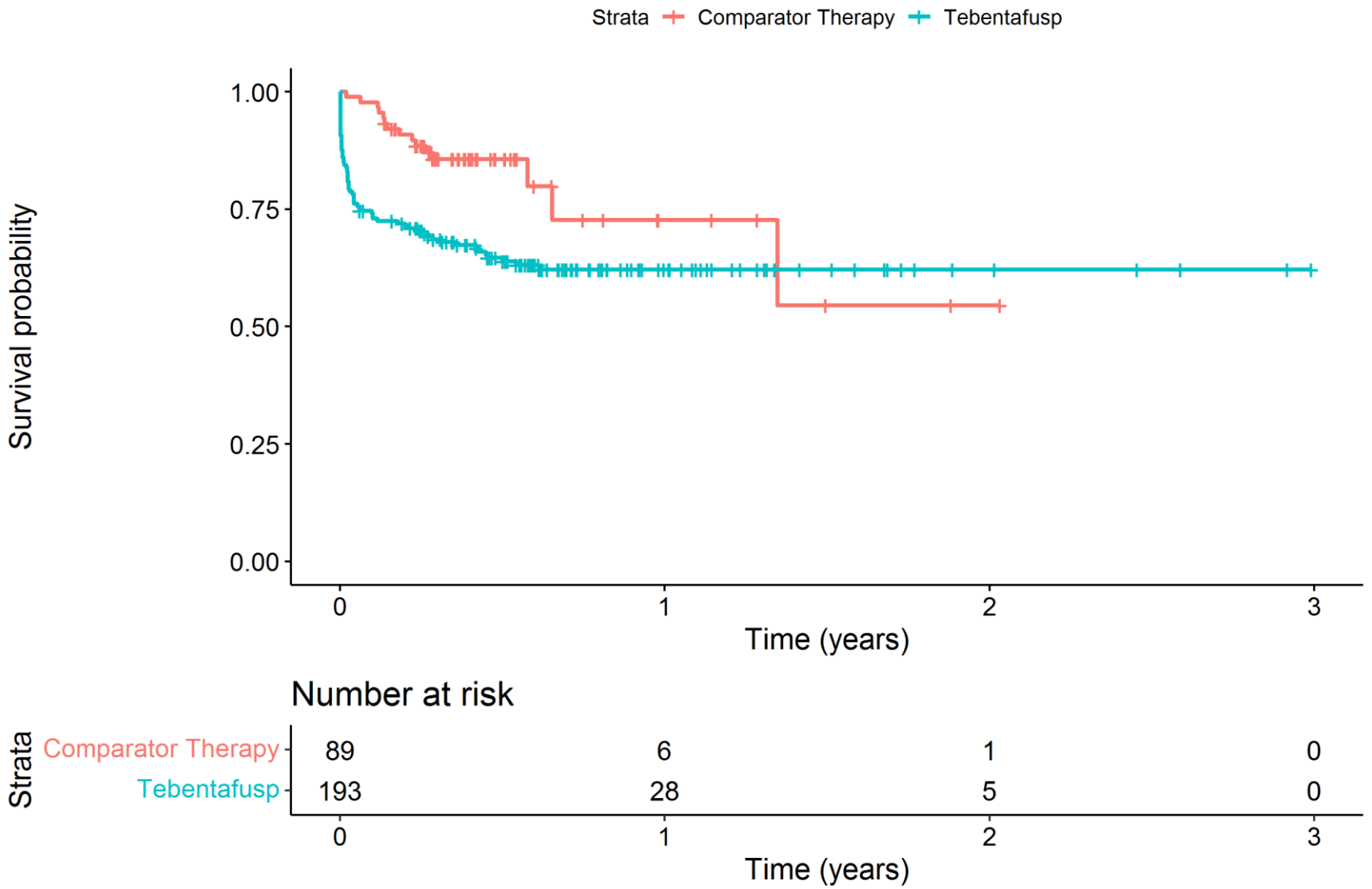
Augenerkrankungen - ECOG 0



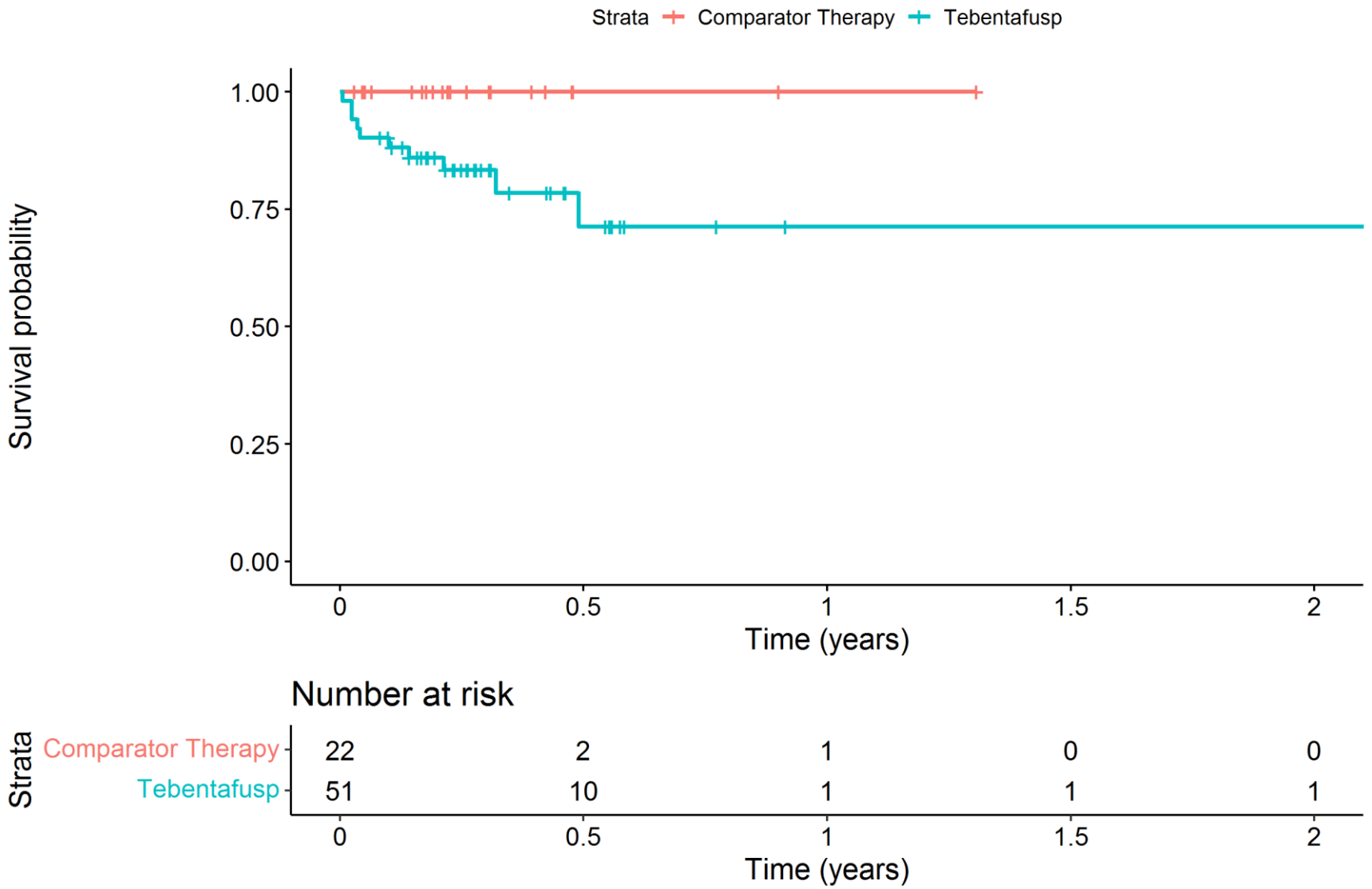
Augenerkrankungen - ECOG 1



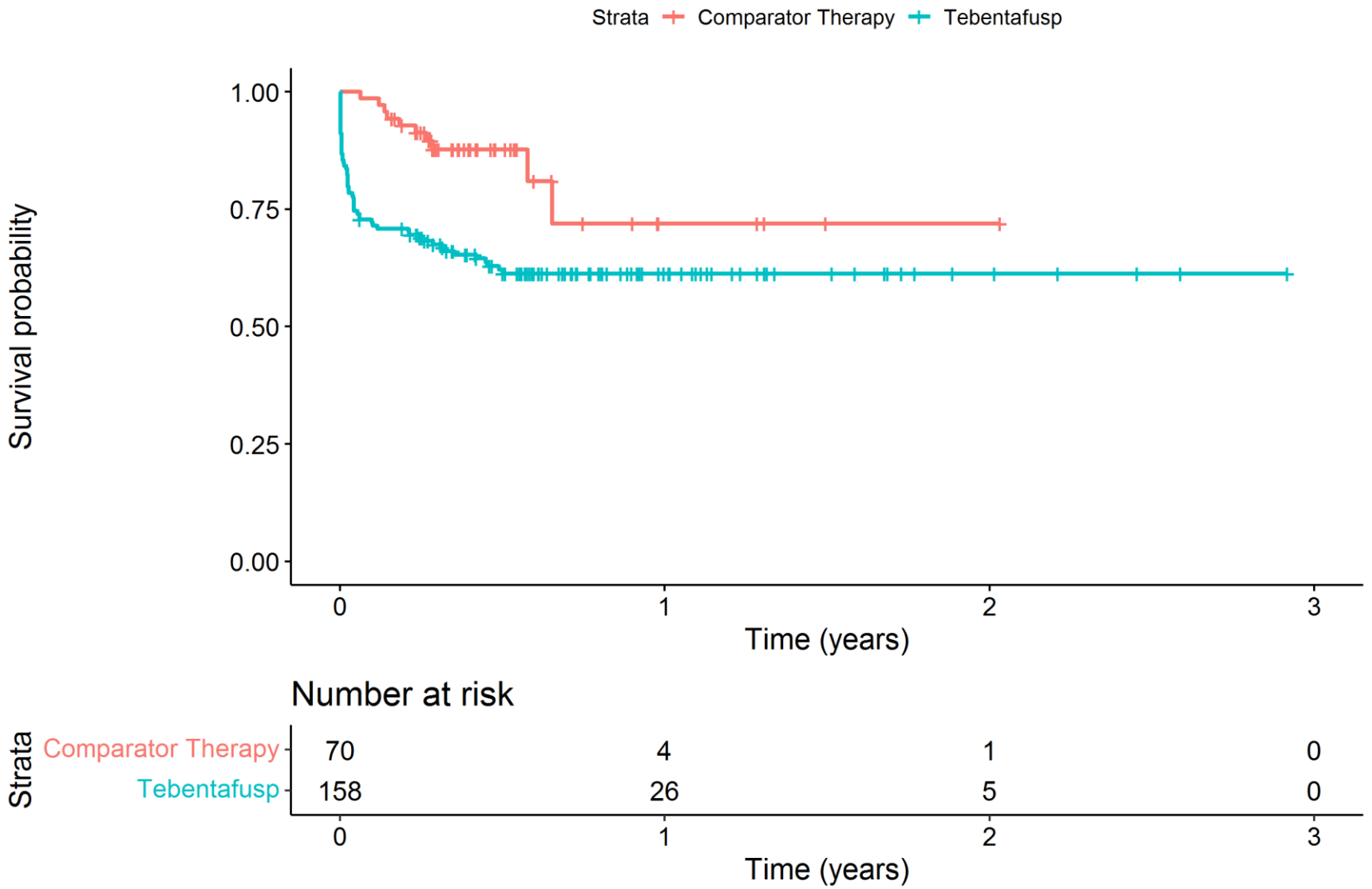
Augenerkrankungen - ALP ≤ ULN



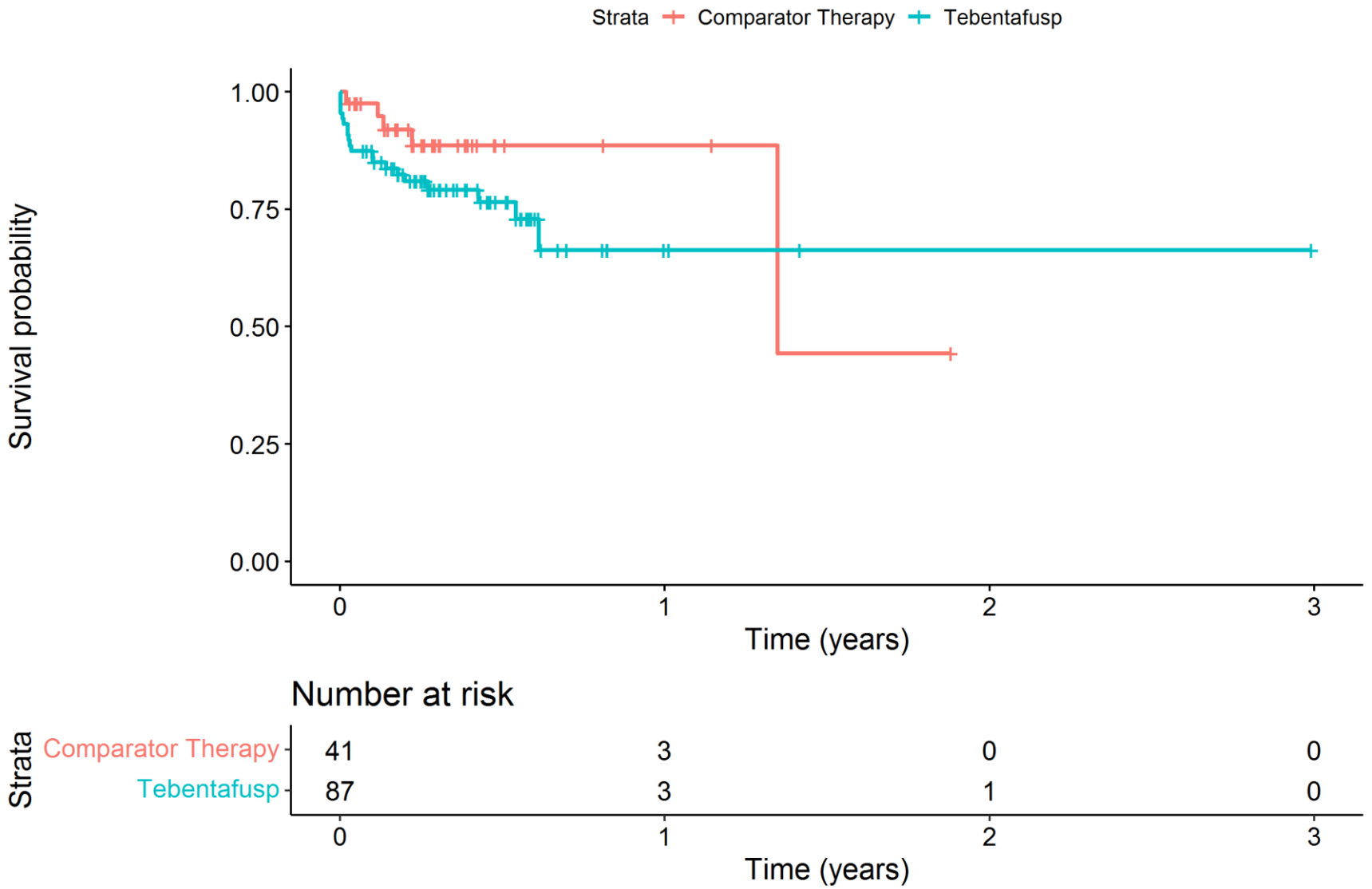
Augenerkrankungen - ALP > ULN



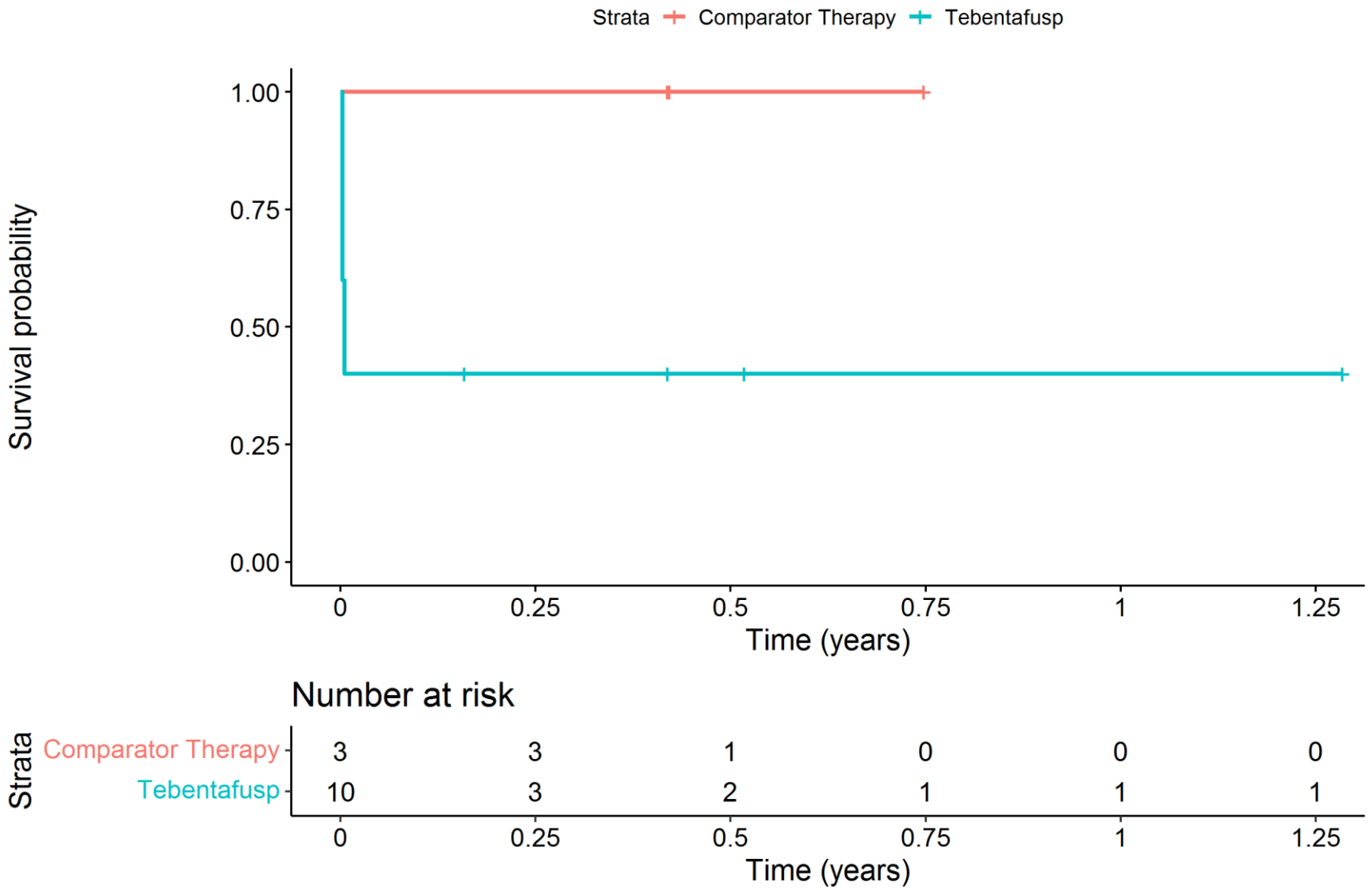
Augenerkrankungen - LDH =< ULN



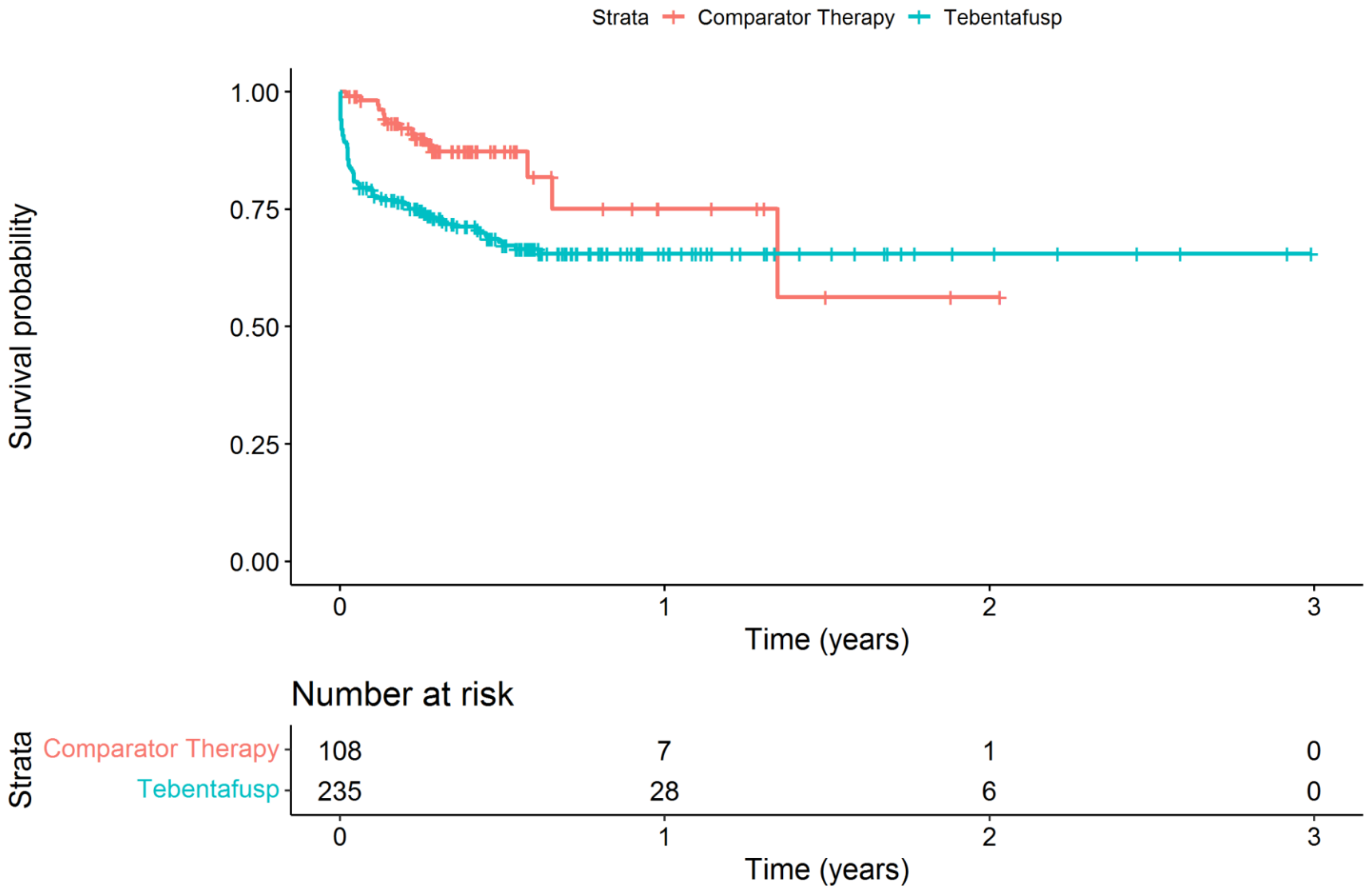
Augenerkrankungen - LDH > ULN



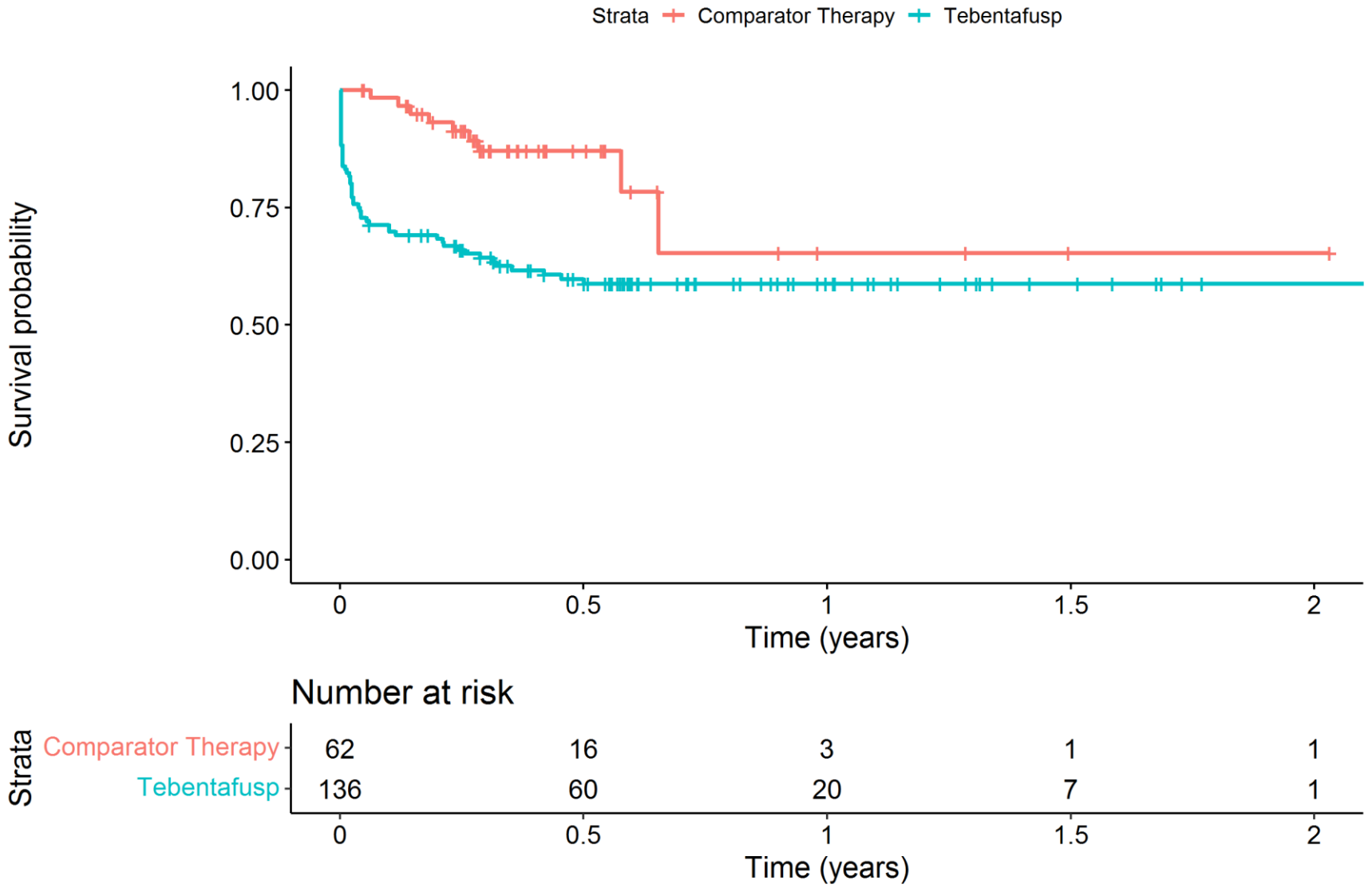
Augenerkrankungen - Vorherige Therapie adjuvant/neoadjuvant



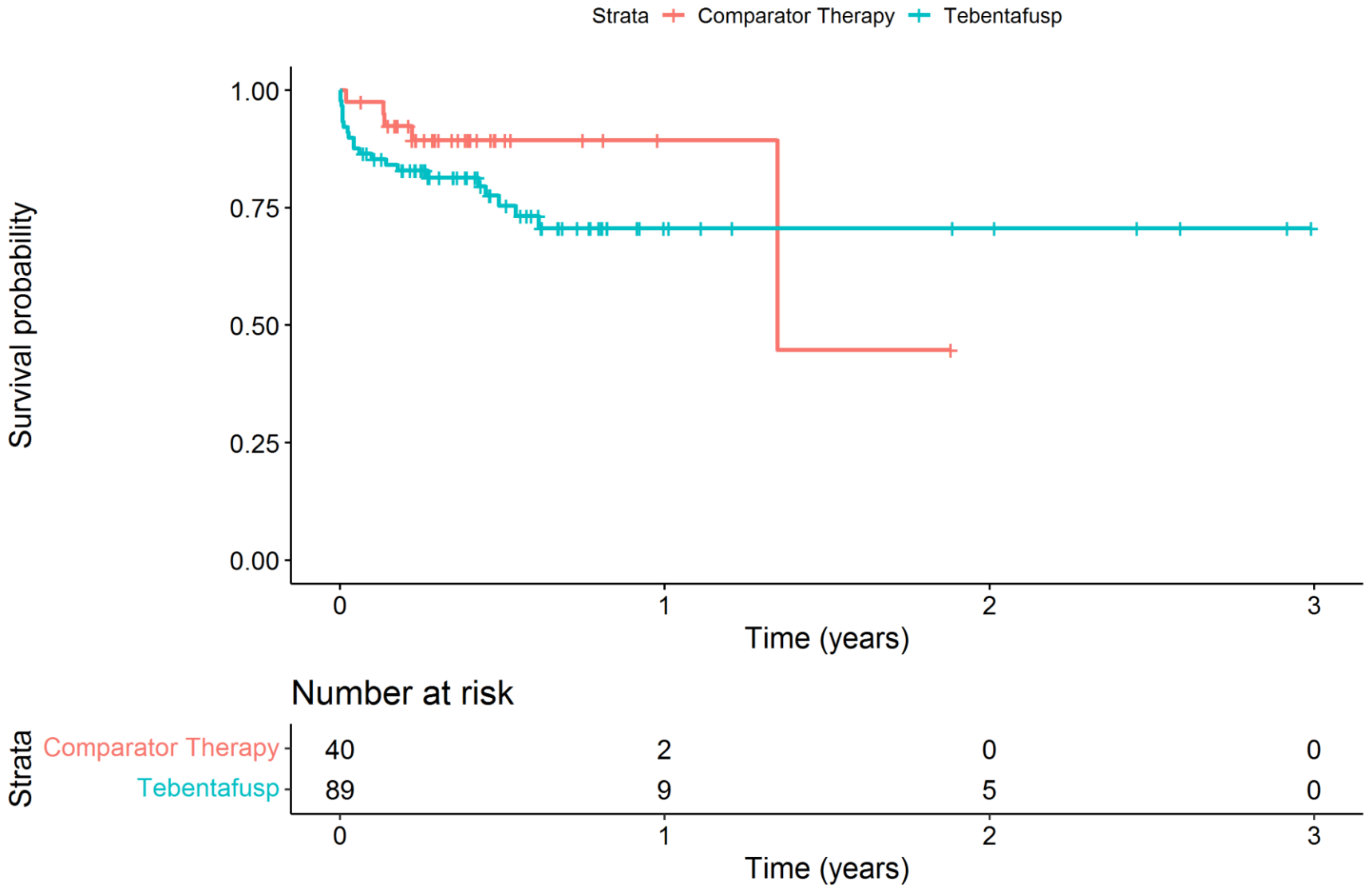
Augenerkrankungen - Keine vorherige Therapie adjuvant/neoadjuvant



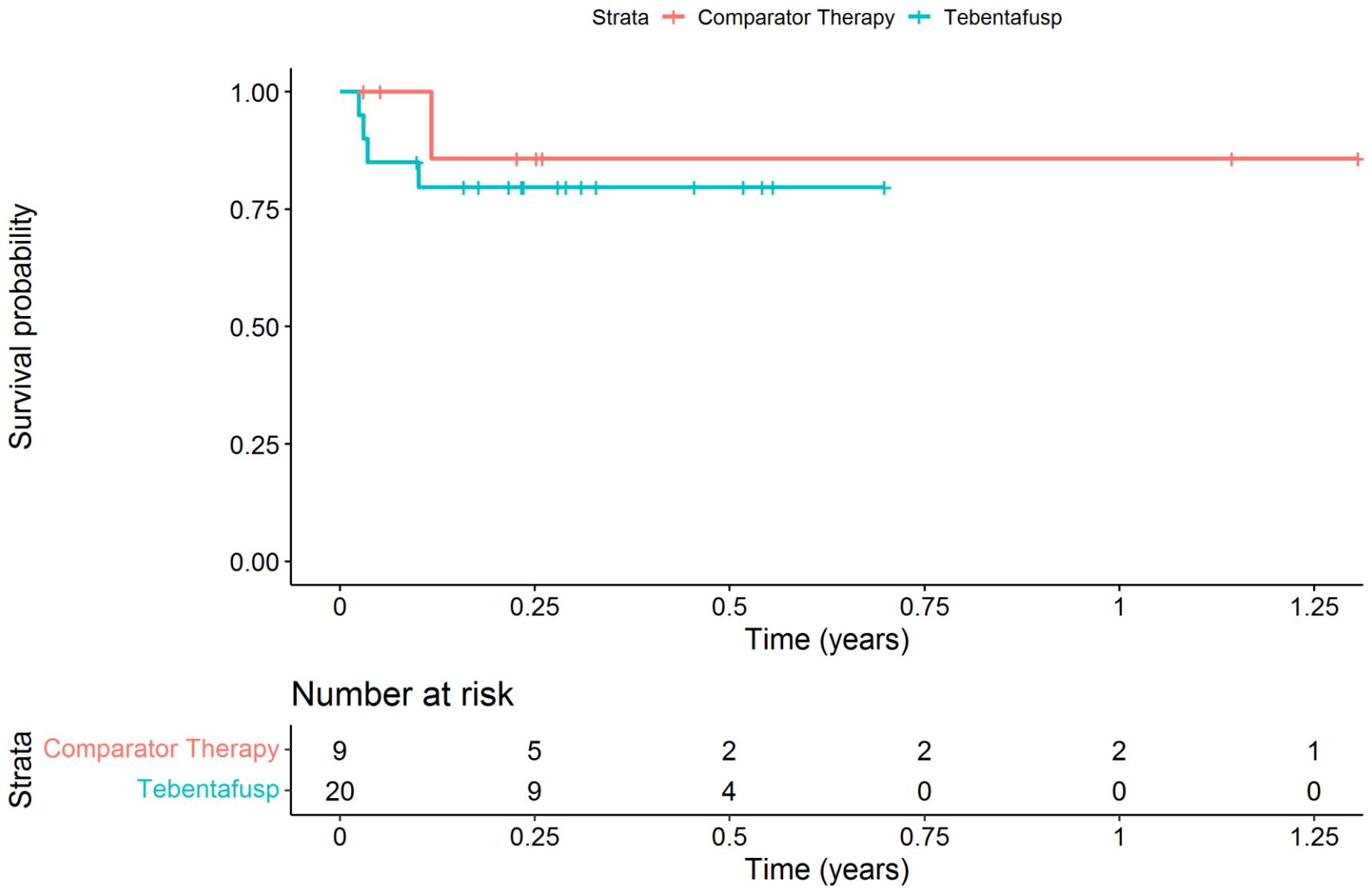
Augenerkrankungen - Läsion ≤ 3cm



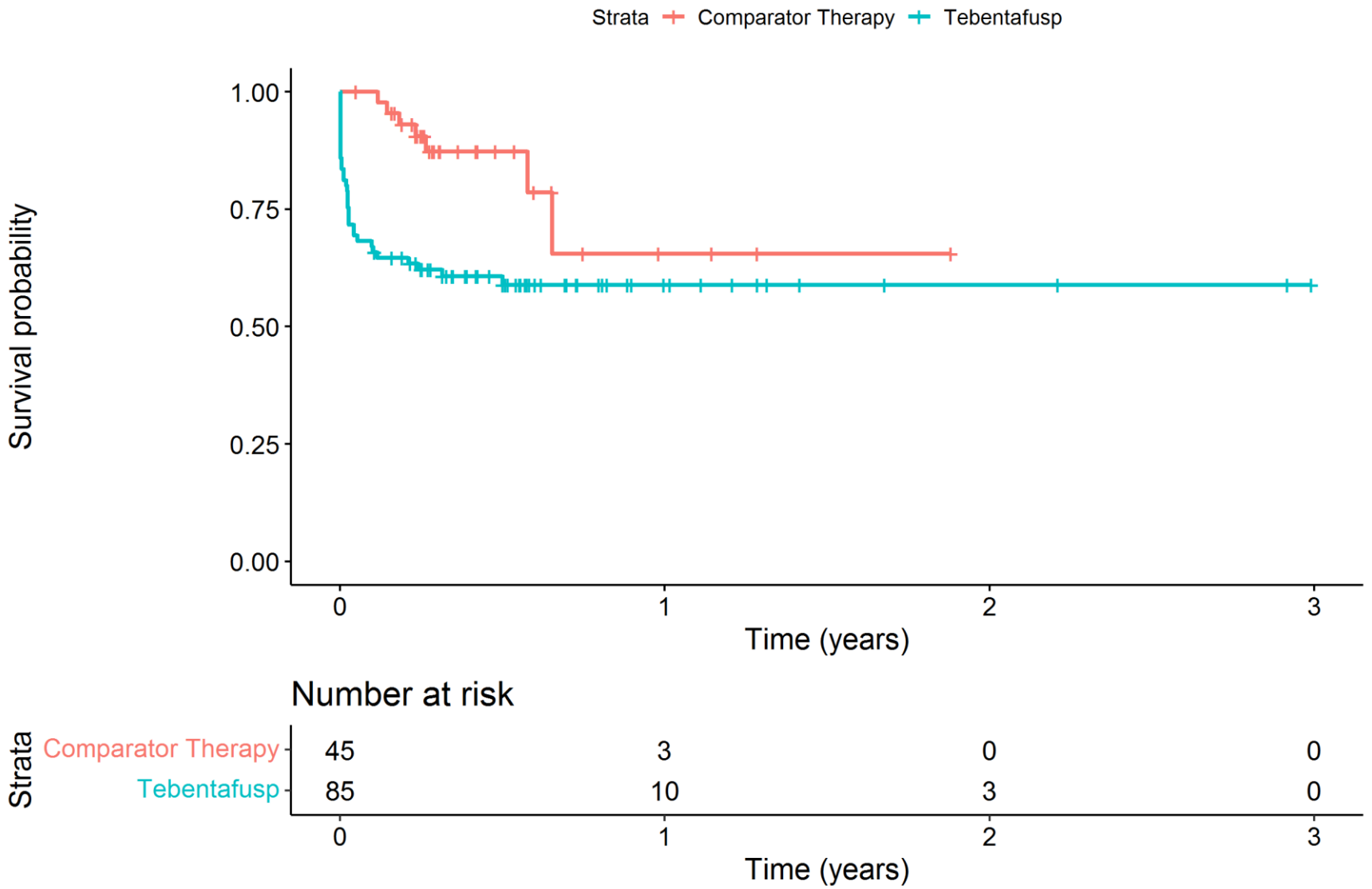
Augenerkrankungen - Läsion 3,1-8,0 cm



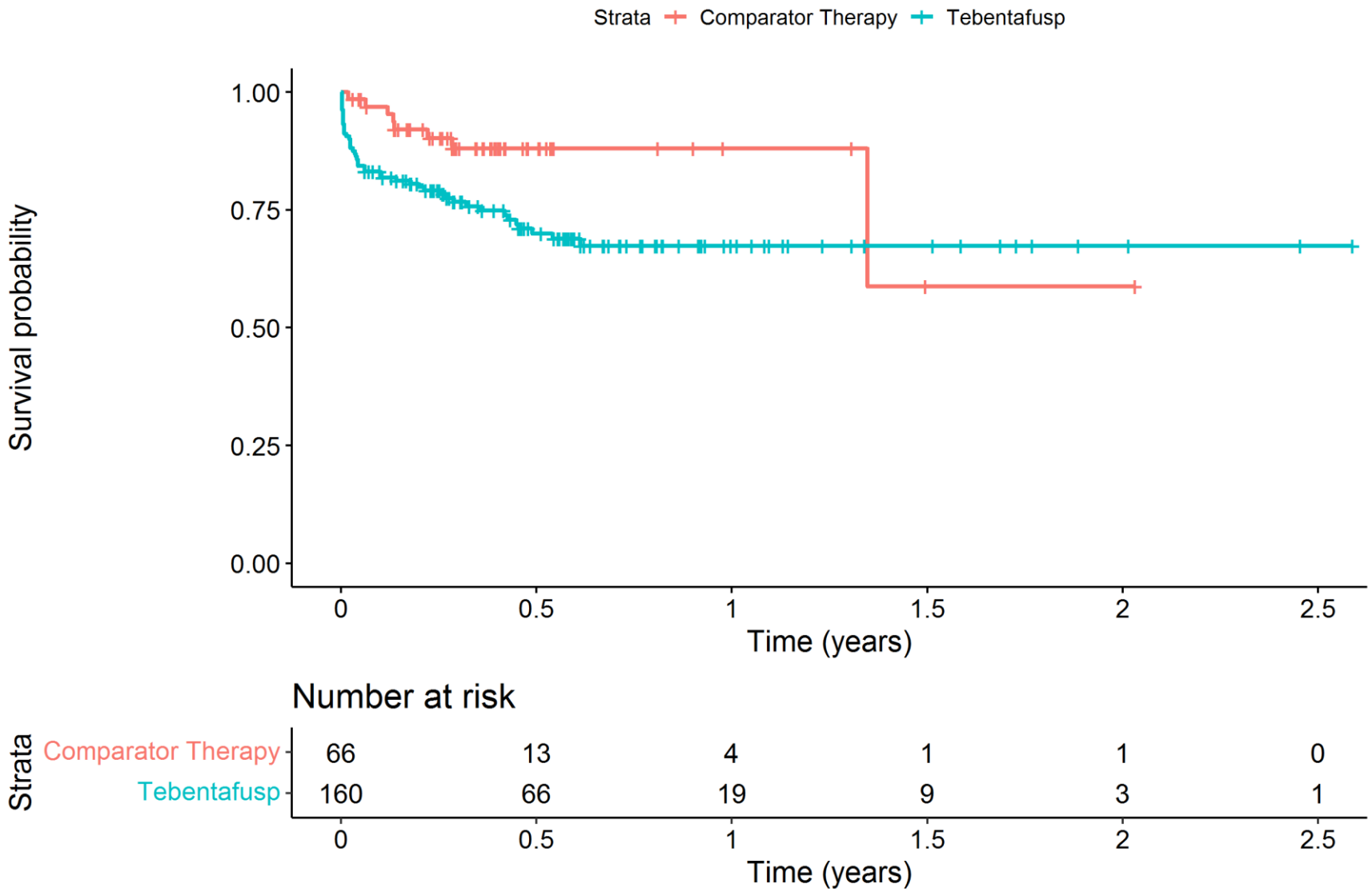
Augenerkrankungen - Läsion ≥8,1 cm



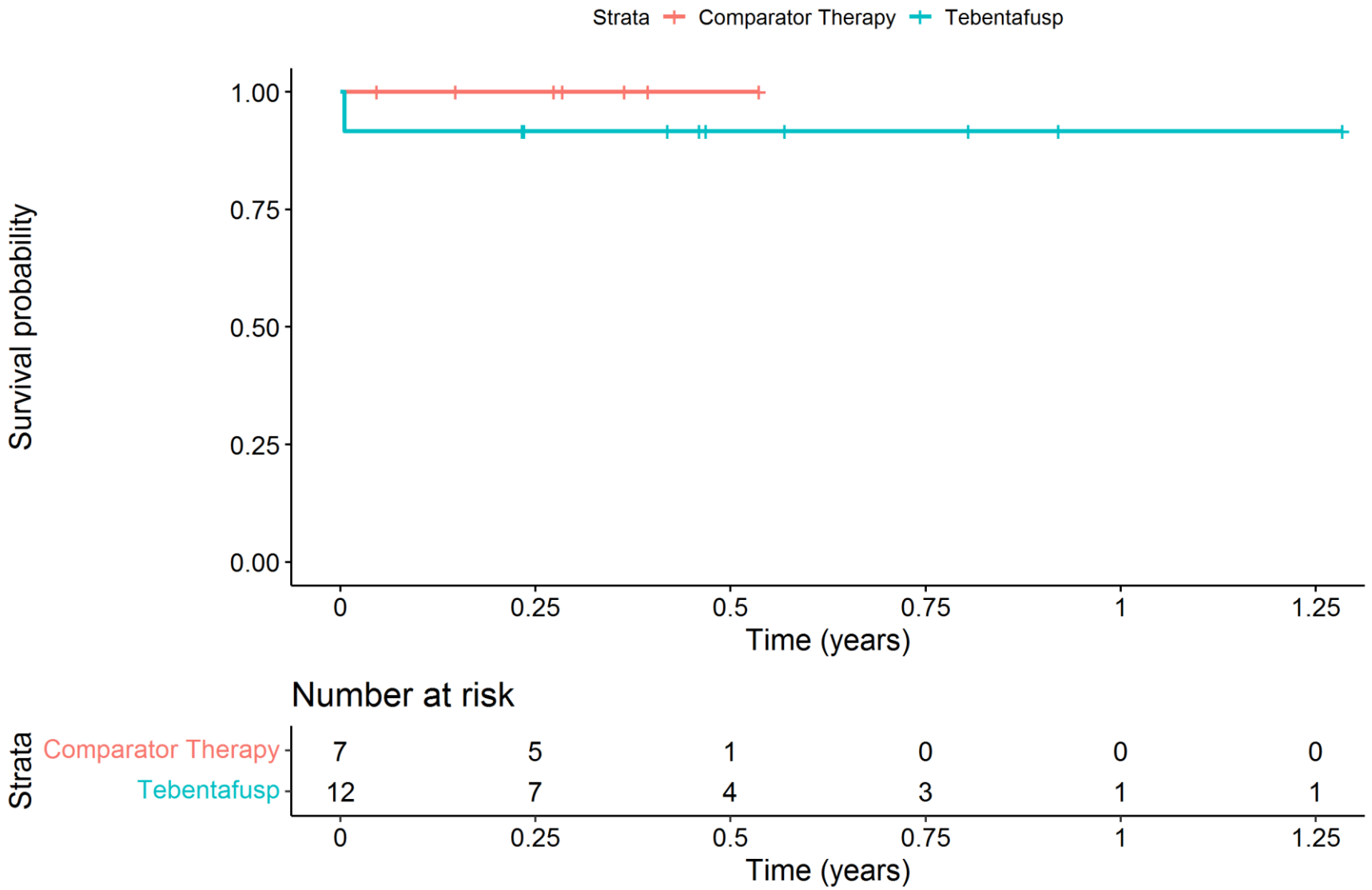
Augenerkrankungen - Nordamerika



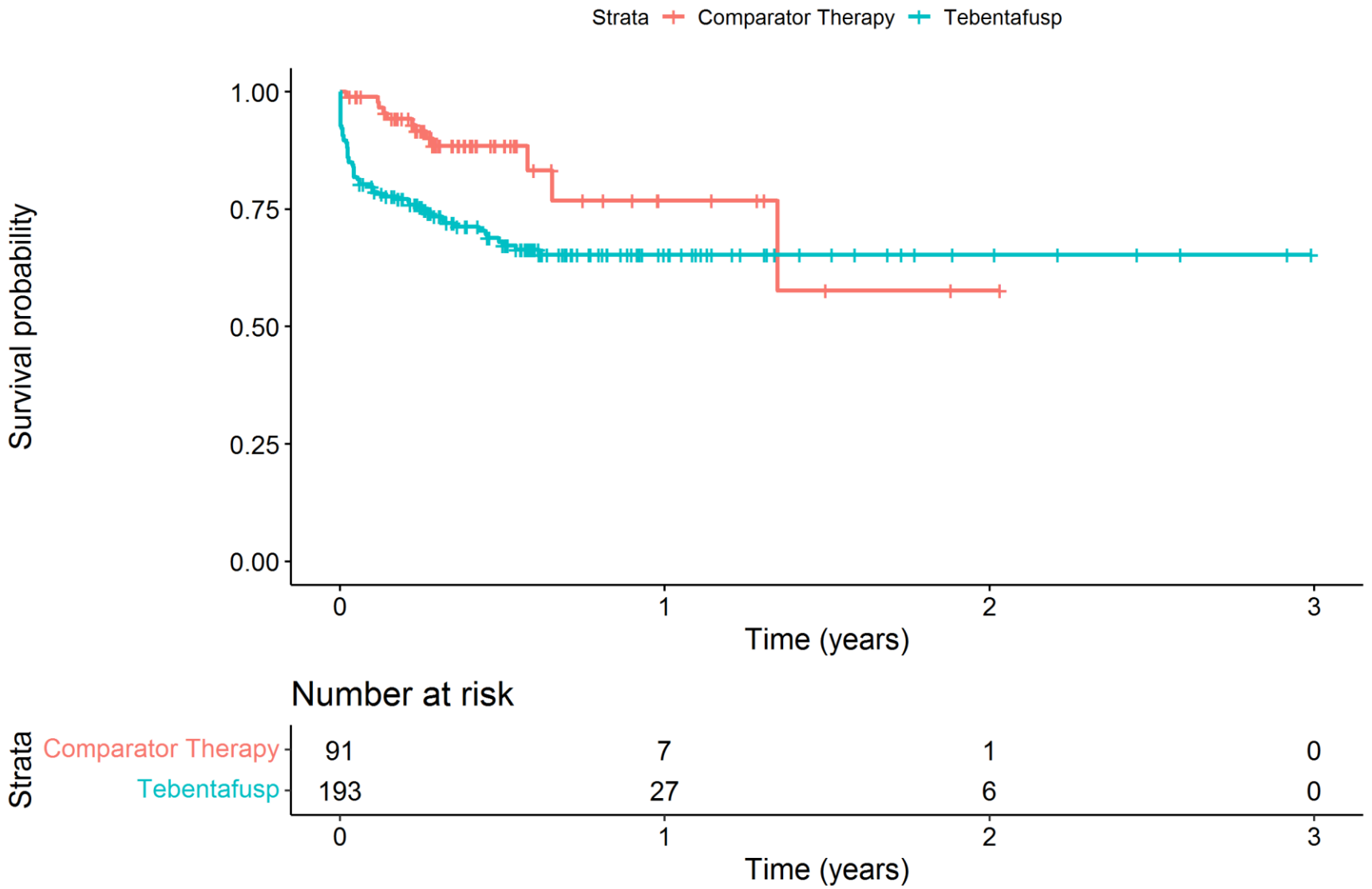
Augenerkrankungen - Nicht-Nordamerika



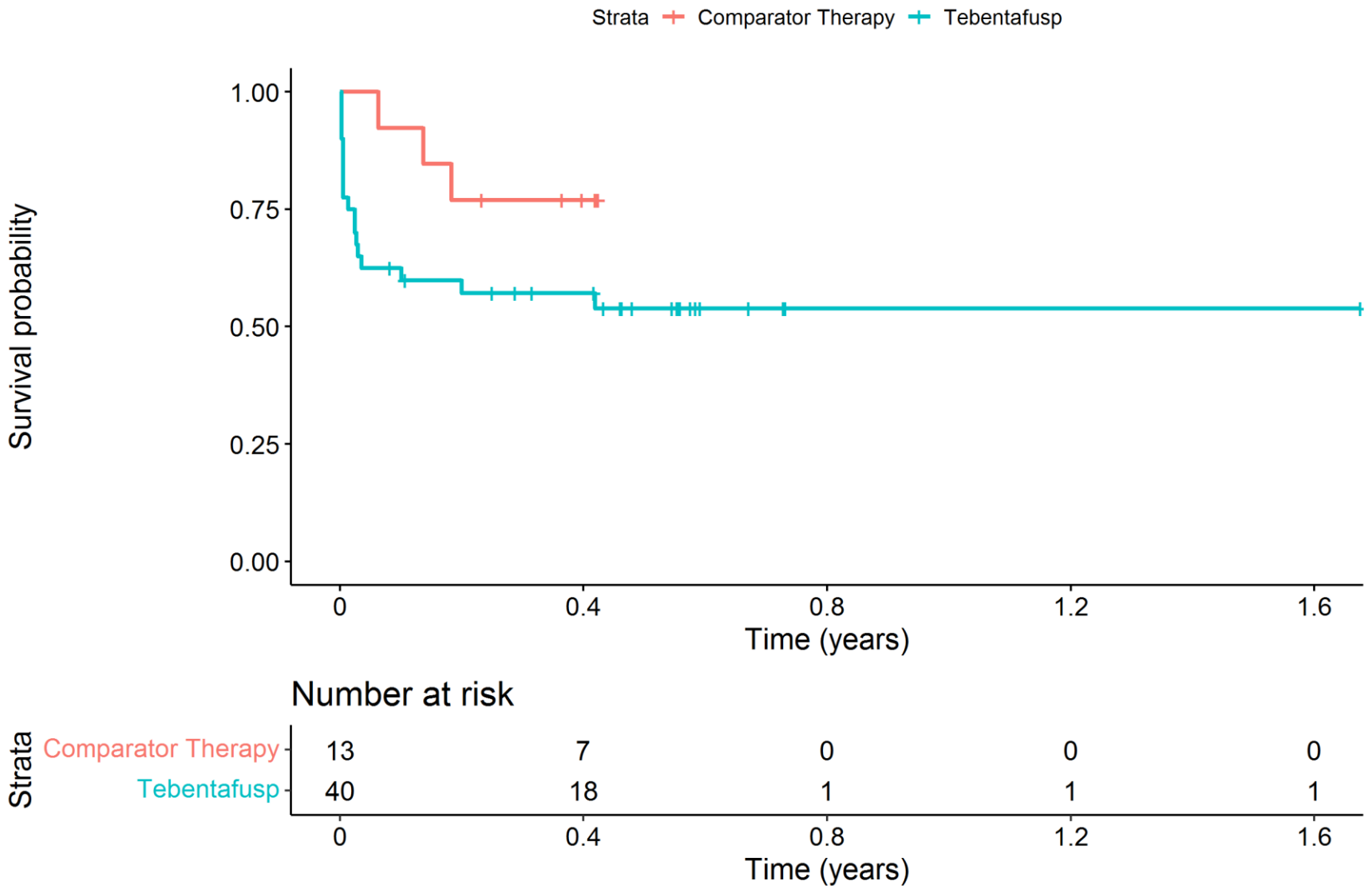
Augenerkrankungen - Dacarbazin



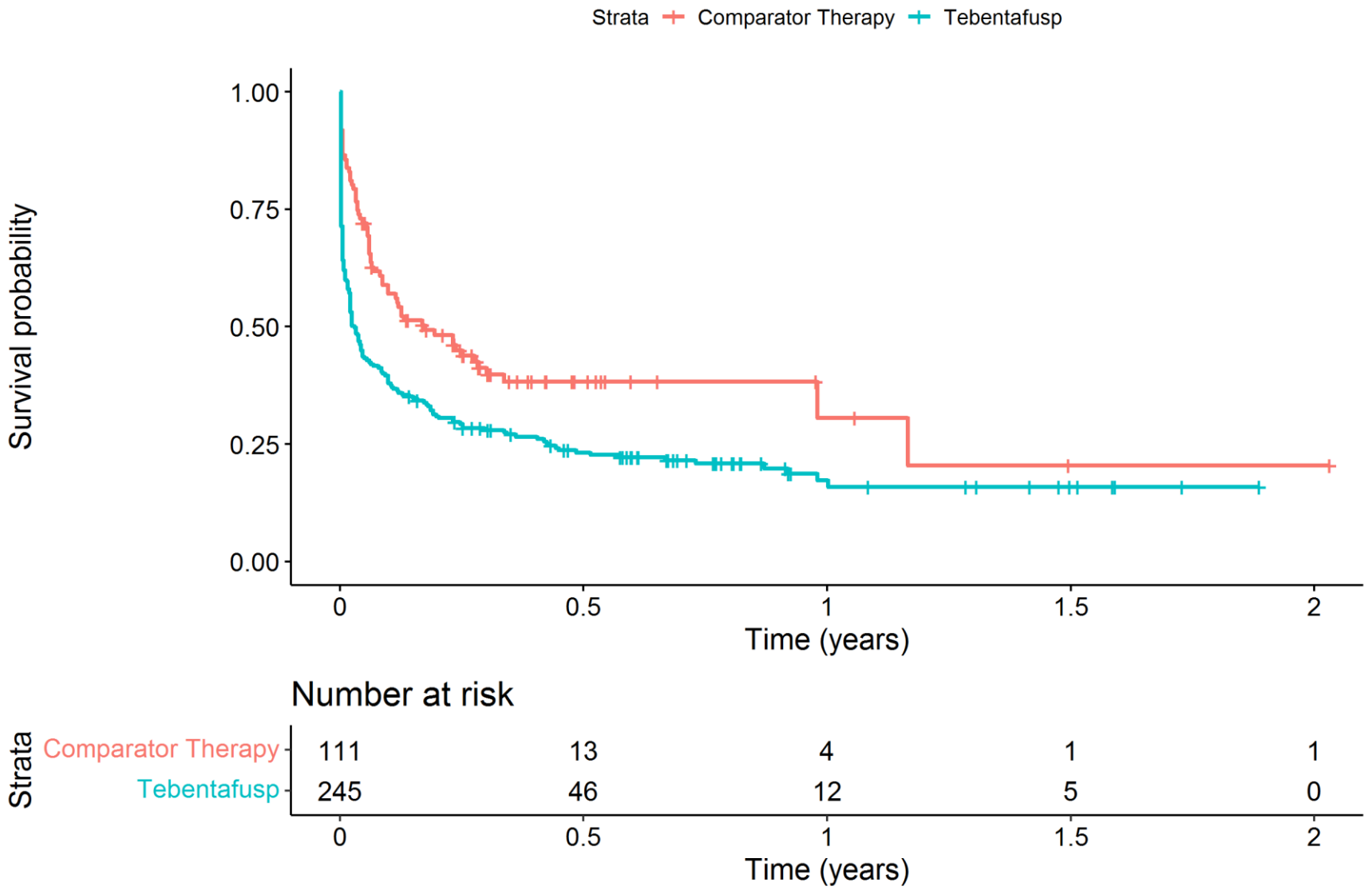
Augenerkrankungen - Pembrolizumab



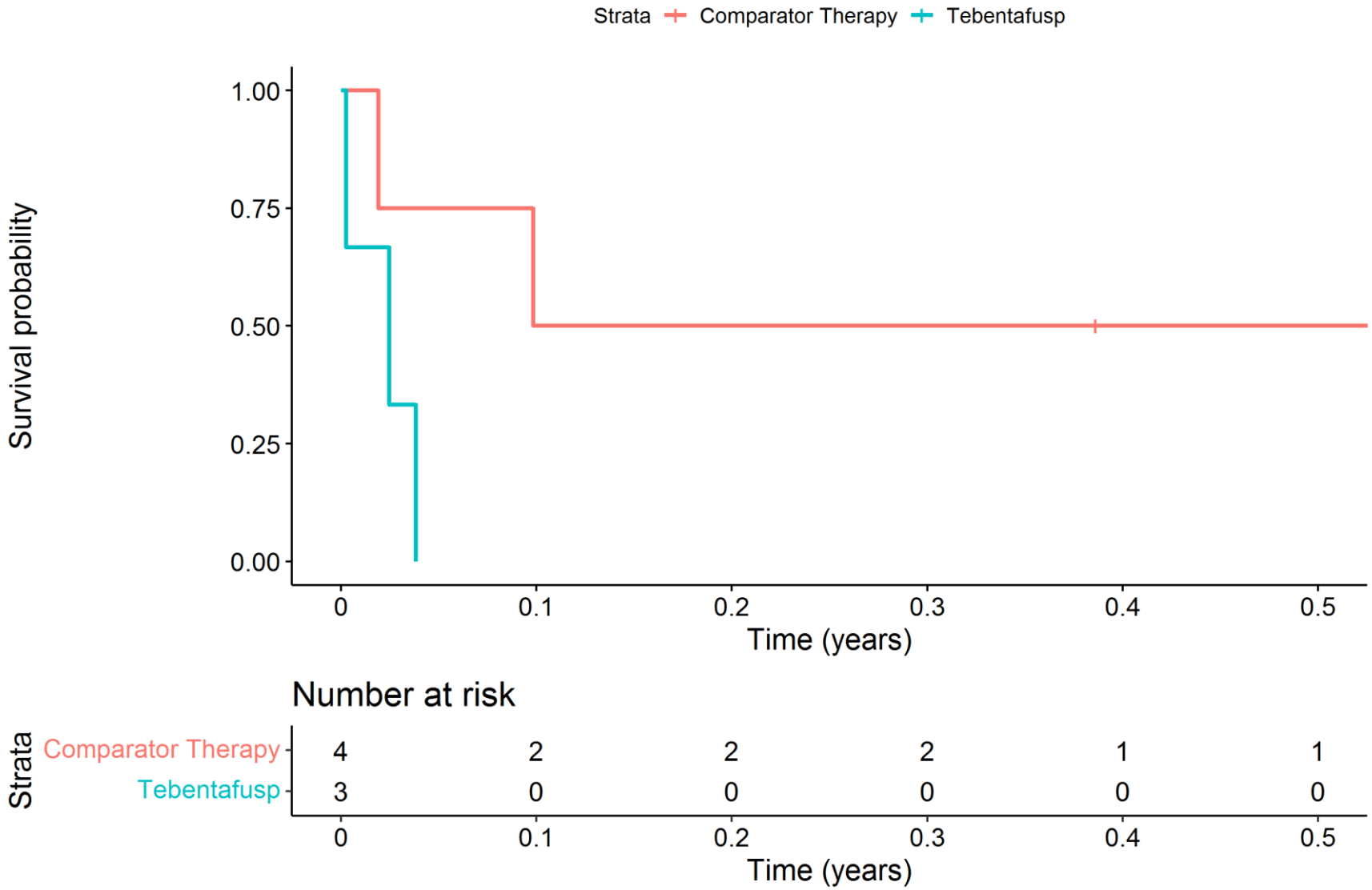
Augenerkrankungen - Ipilimumab



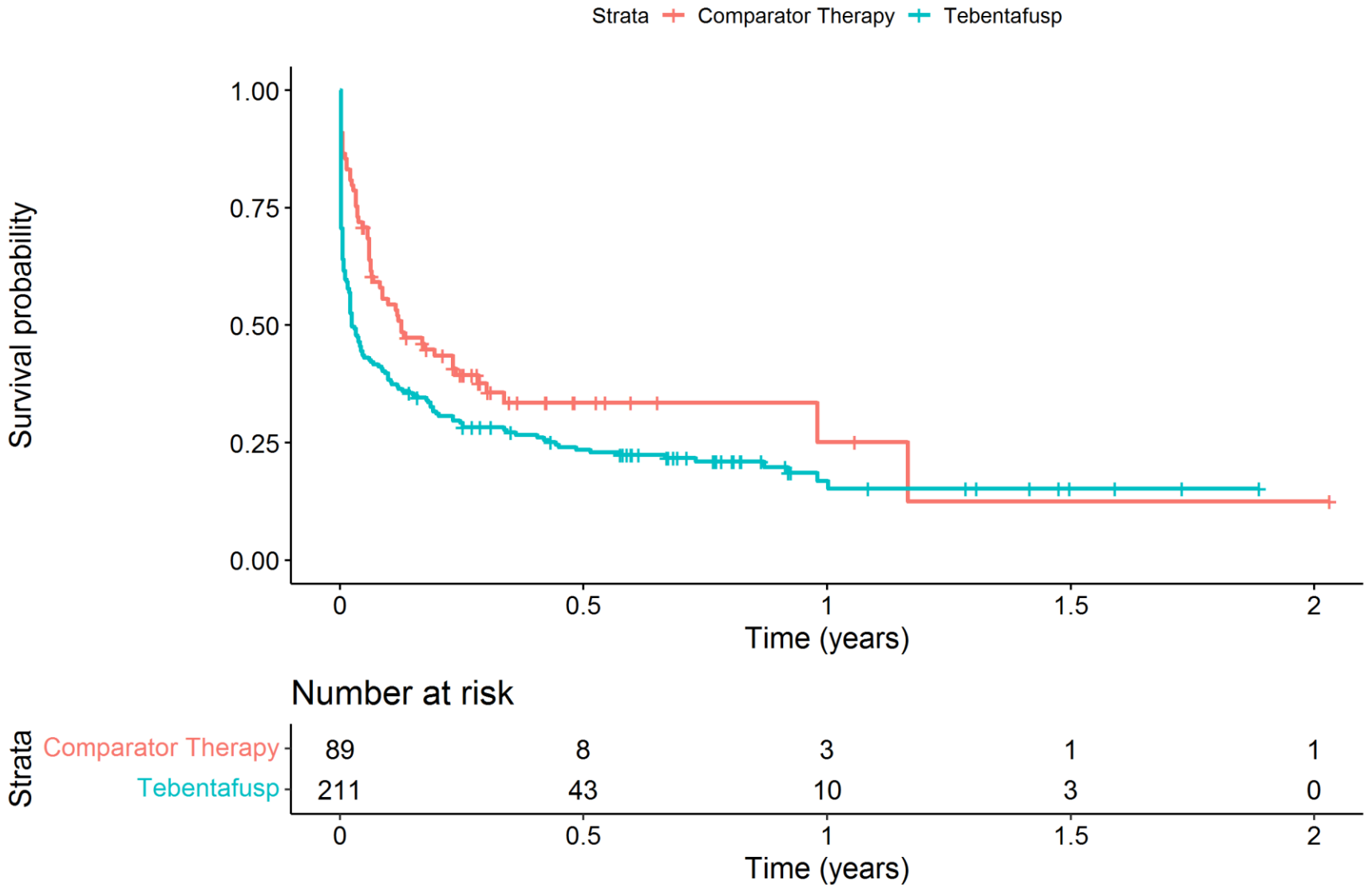
Erkrankungen des Gastrointestinaltrakts - Gesamt



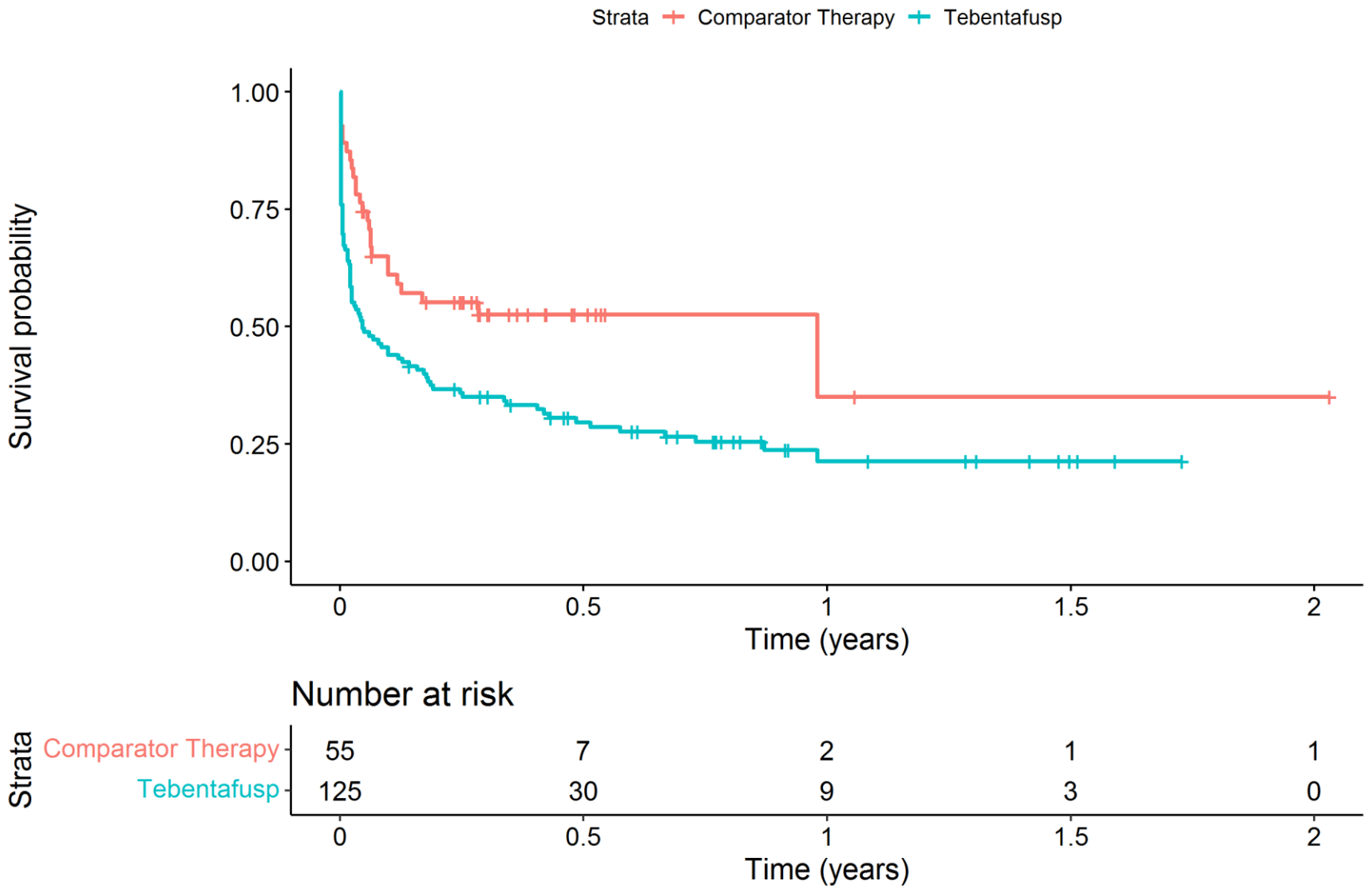
Erkrankungen des Gastrointestinaltrakts - Hispanisch



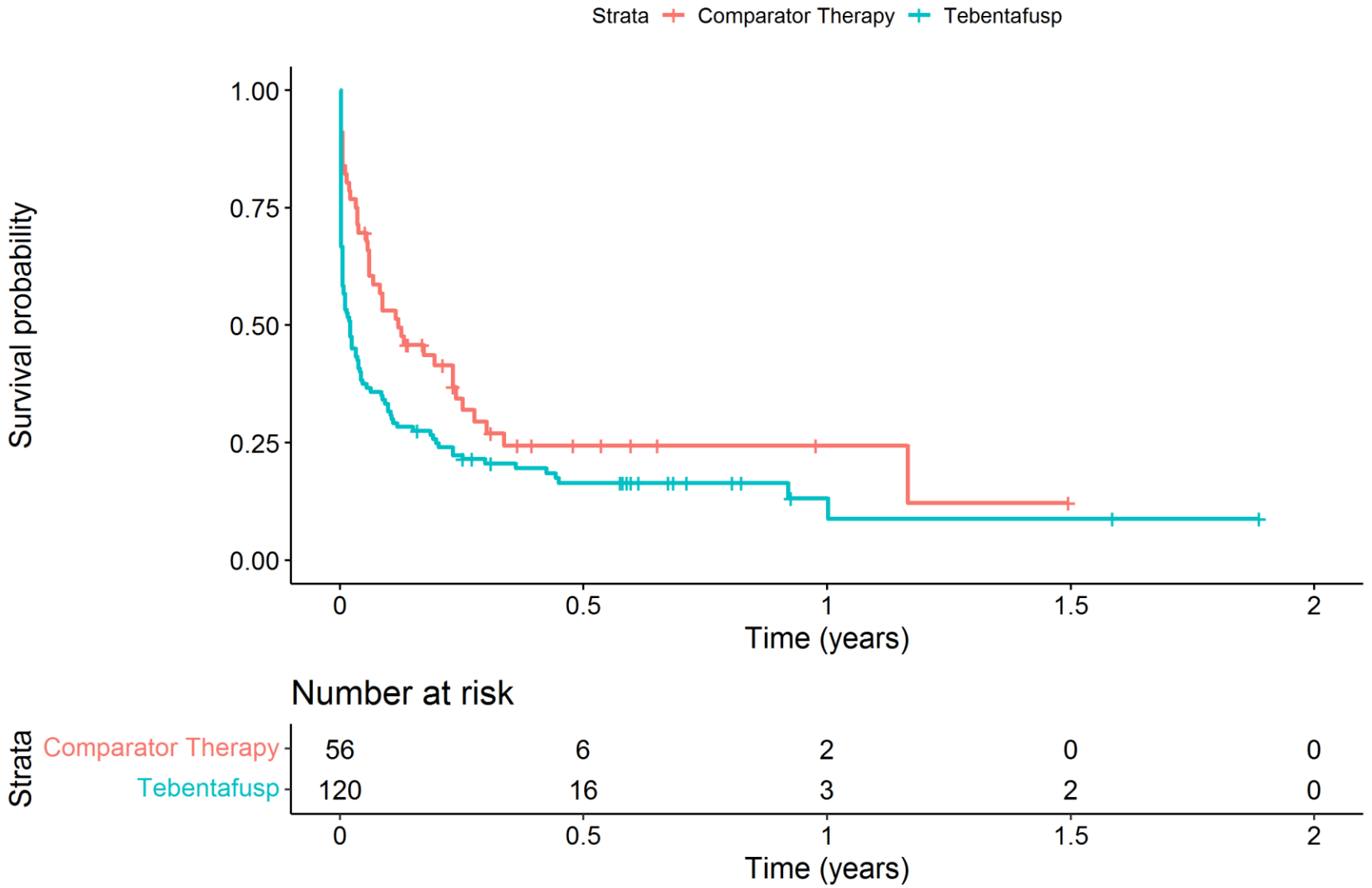
Erkrankungen des Gastrointestinaltrakts - Nicht-hispanisch



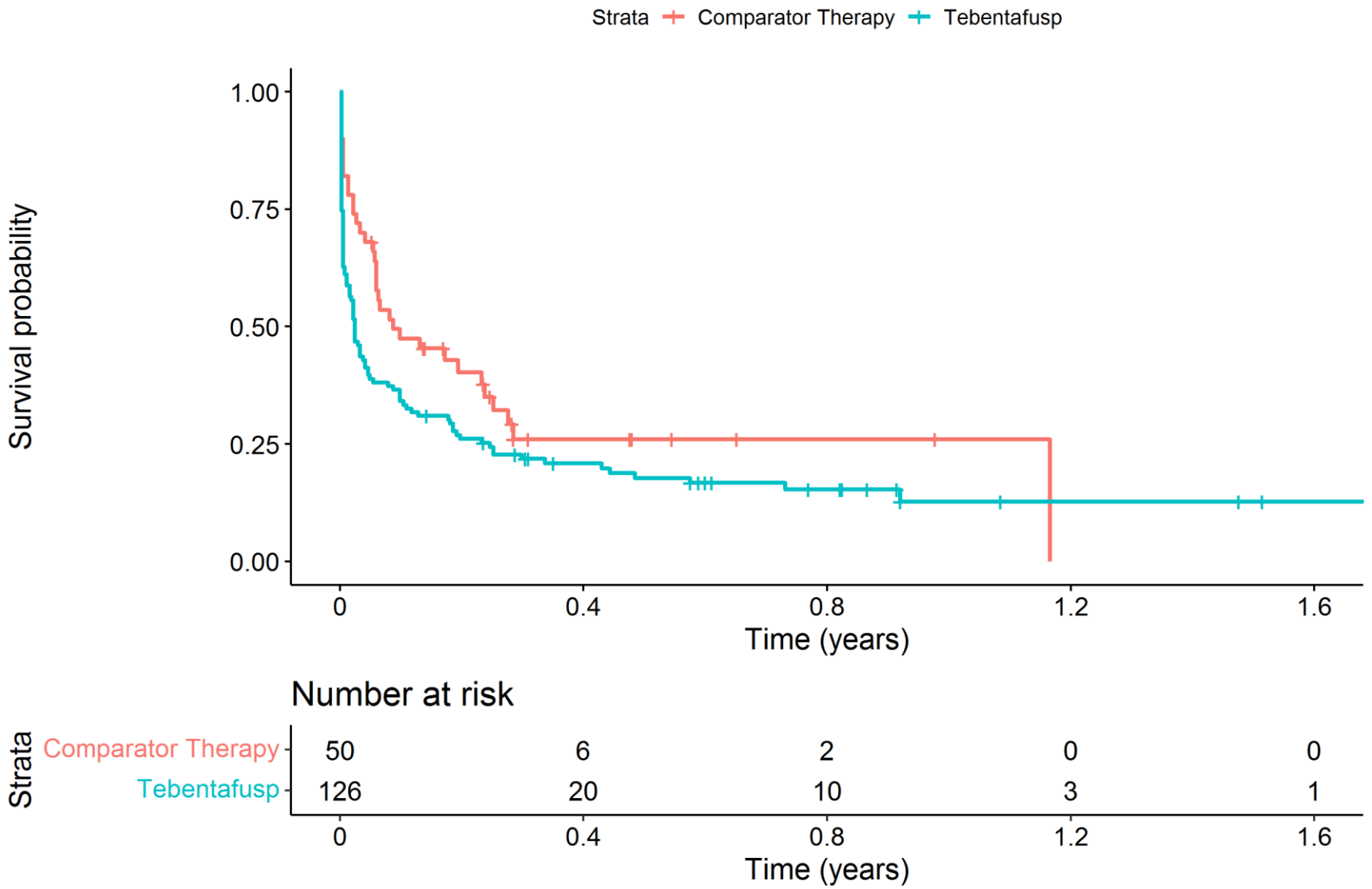
Erkrankungen des Gastrointestinaltrakts - Männlich



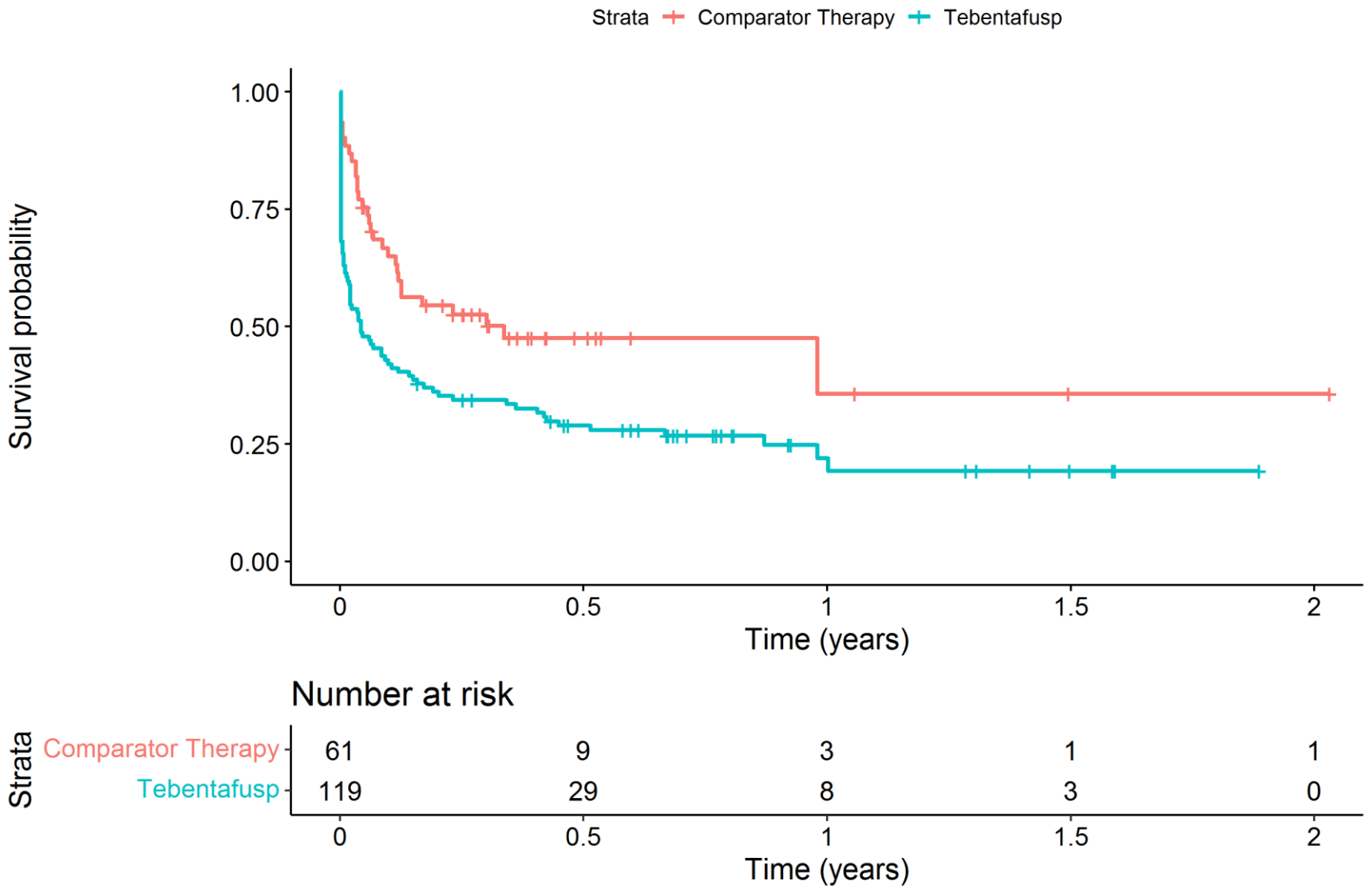
Erkrankungen des Gastrointestinaltrakts - Weiblich



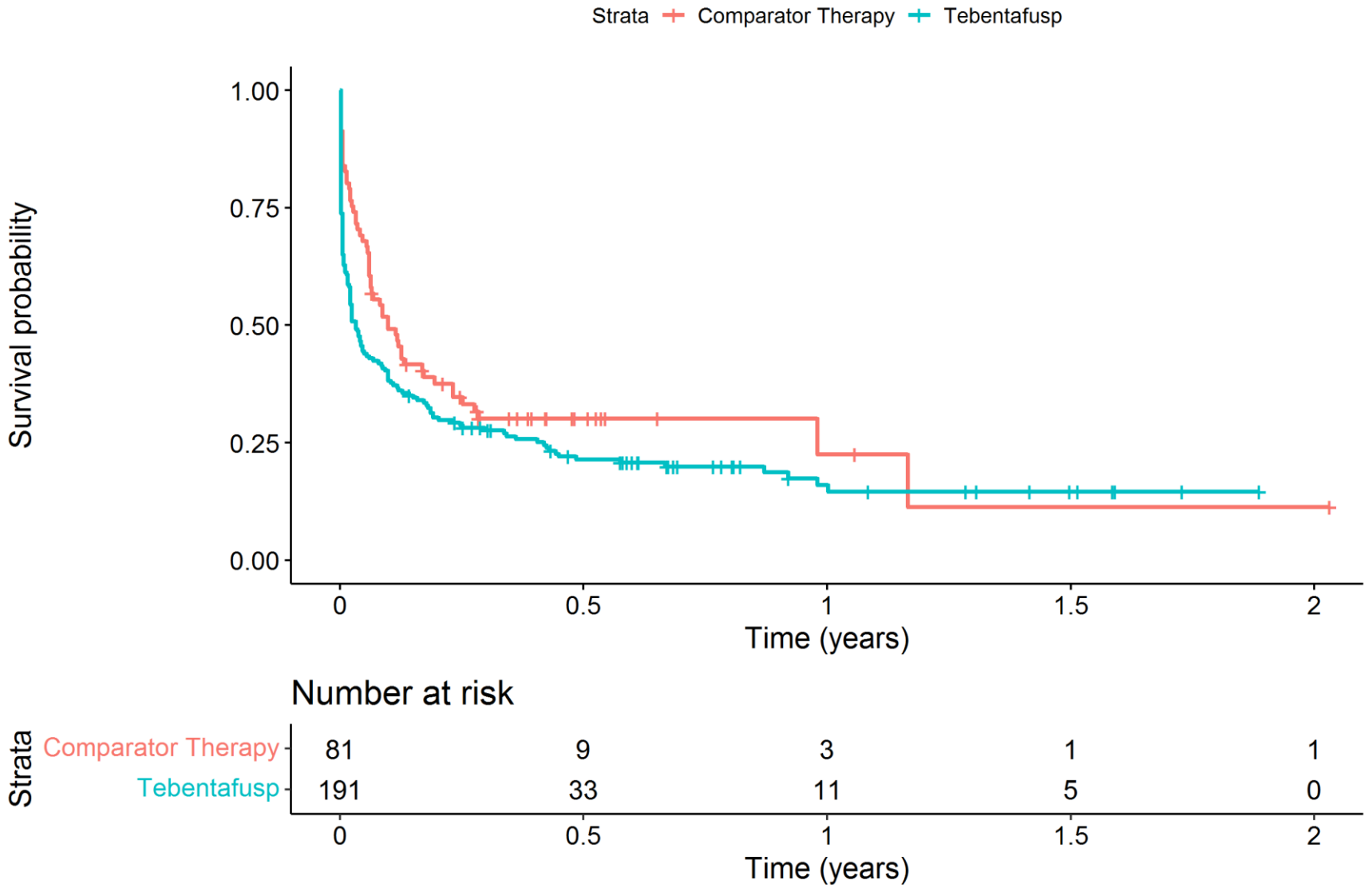
Erkrankungen des Gastrointestinaltrakts - <65



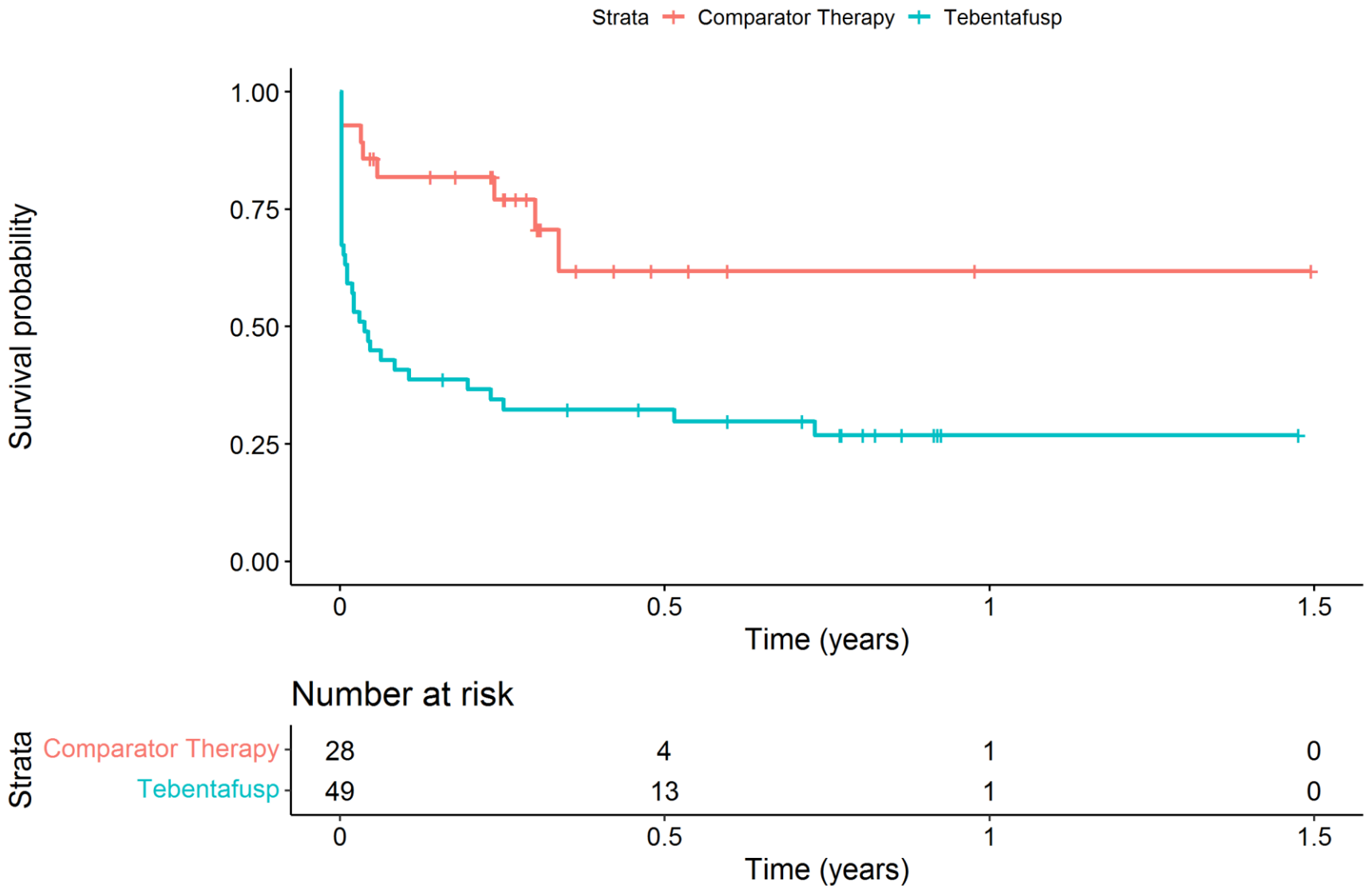
Erkrankungen des Gastrointestinaltrakts - ≥65



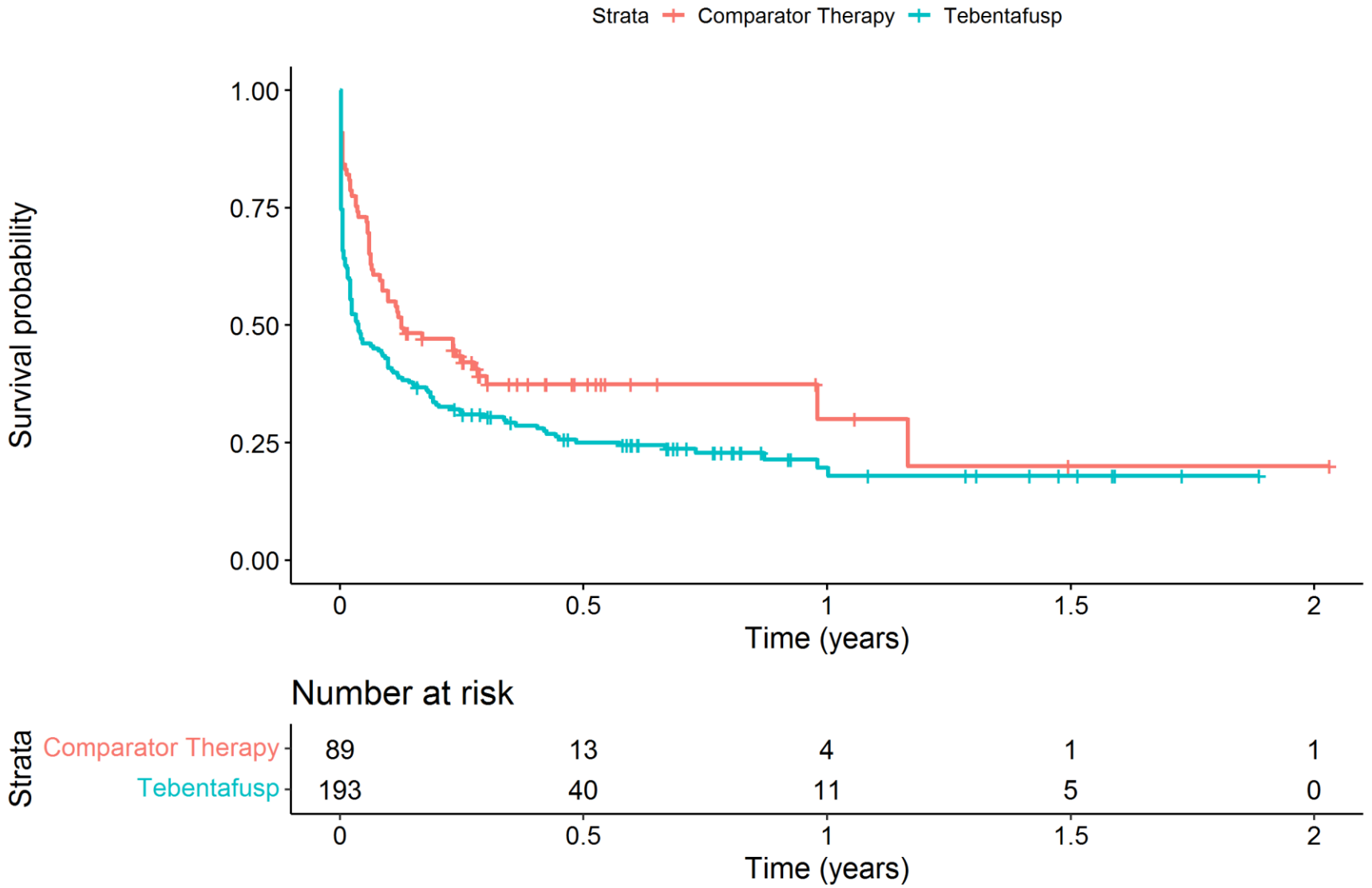
Erkrankungen des Gastrointestinaltrakts - ECOG 0



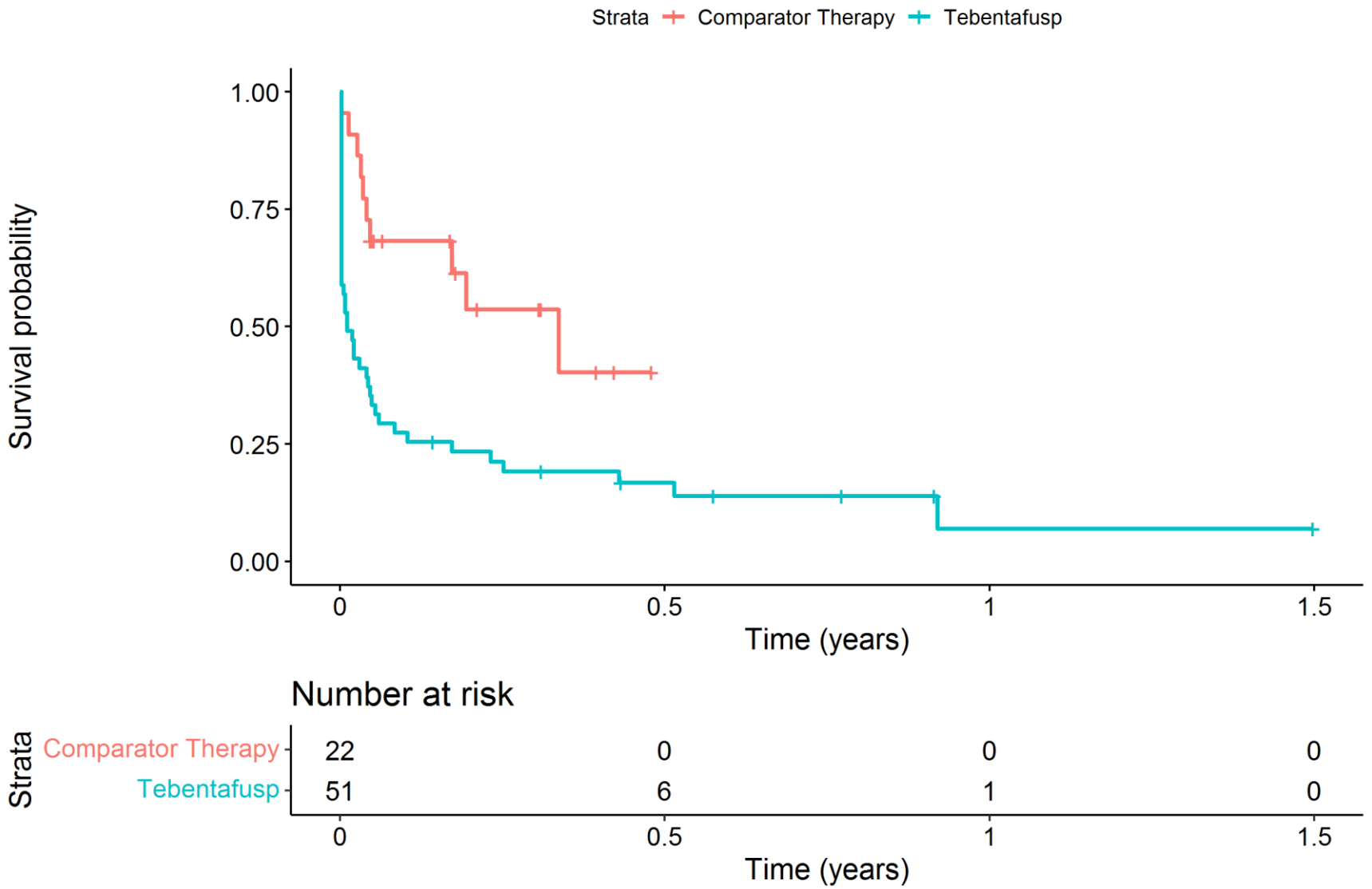
Erkrankungen des Gastrointestinaltrakts - ECOG 1



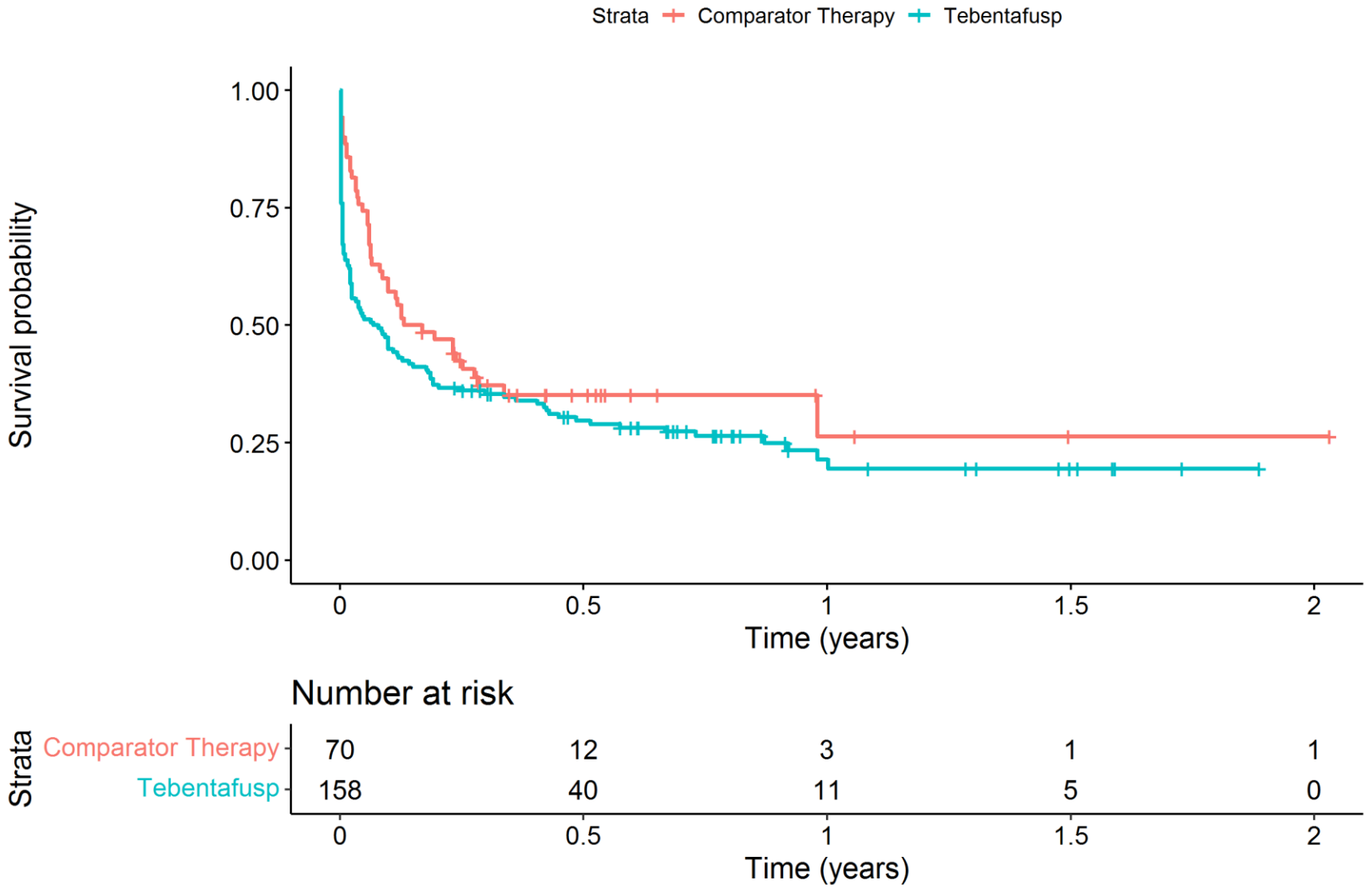
Erkrankungen des Gastrointestinaltrakts - ALP ≤ ULN



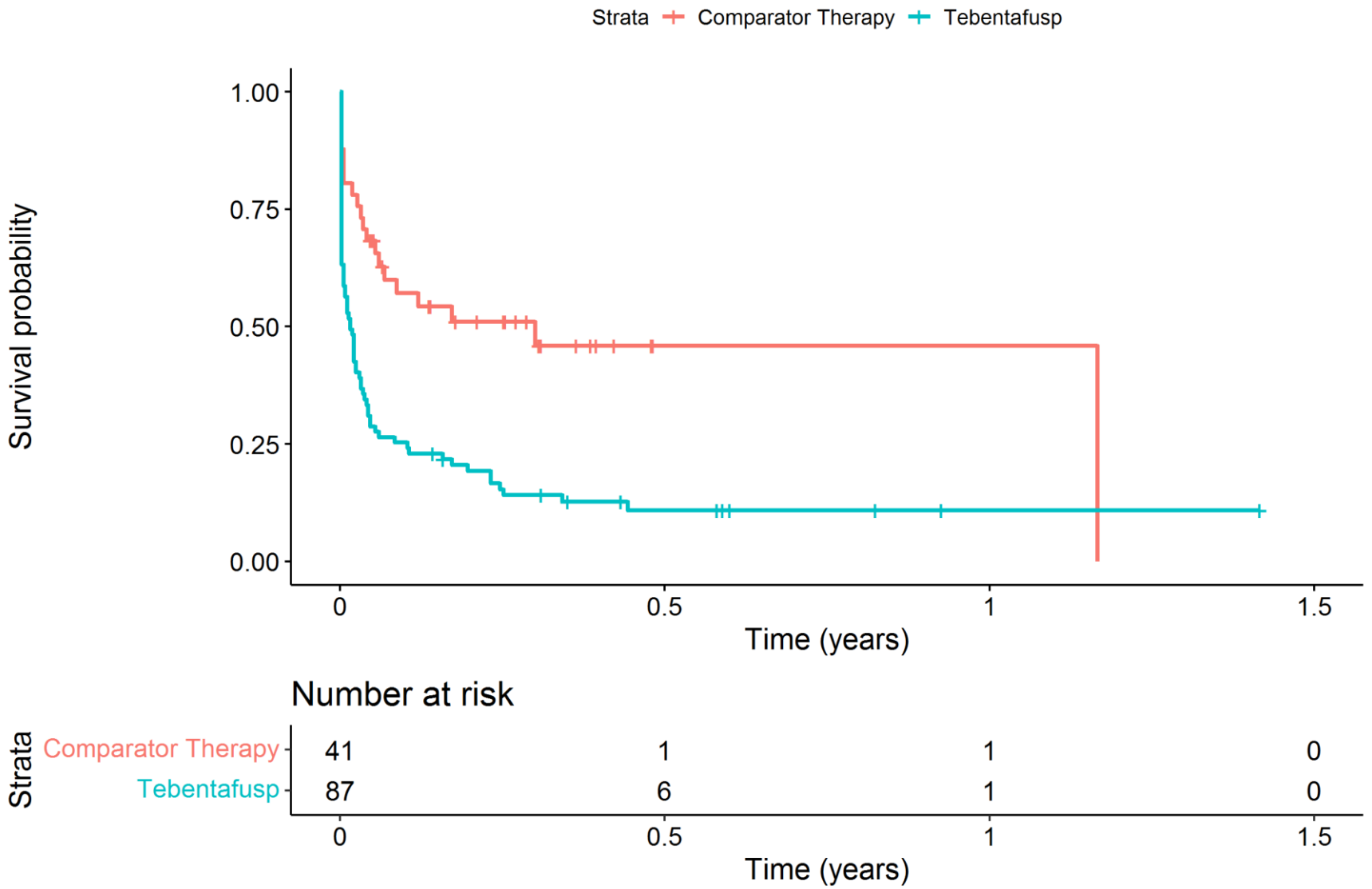
Erkrankungen des Gastrointestinaltrakts - ALP > ULN



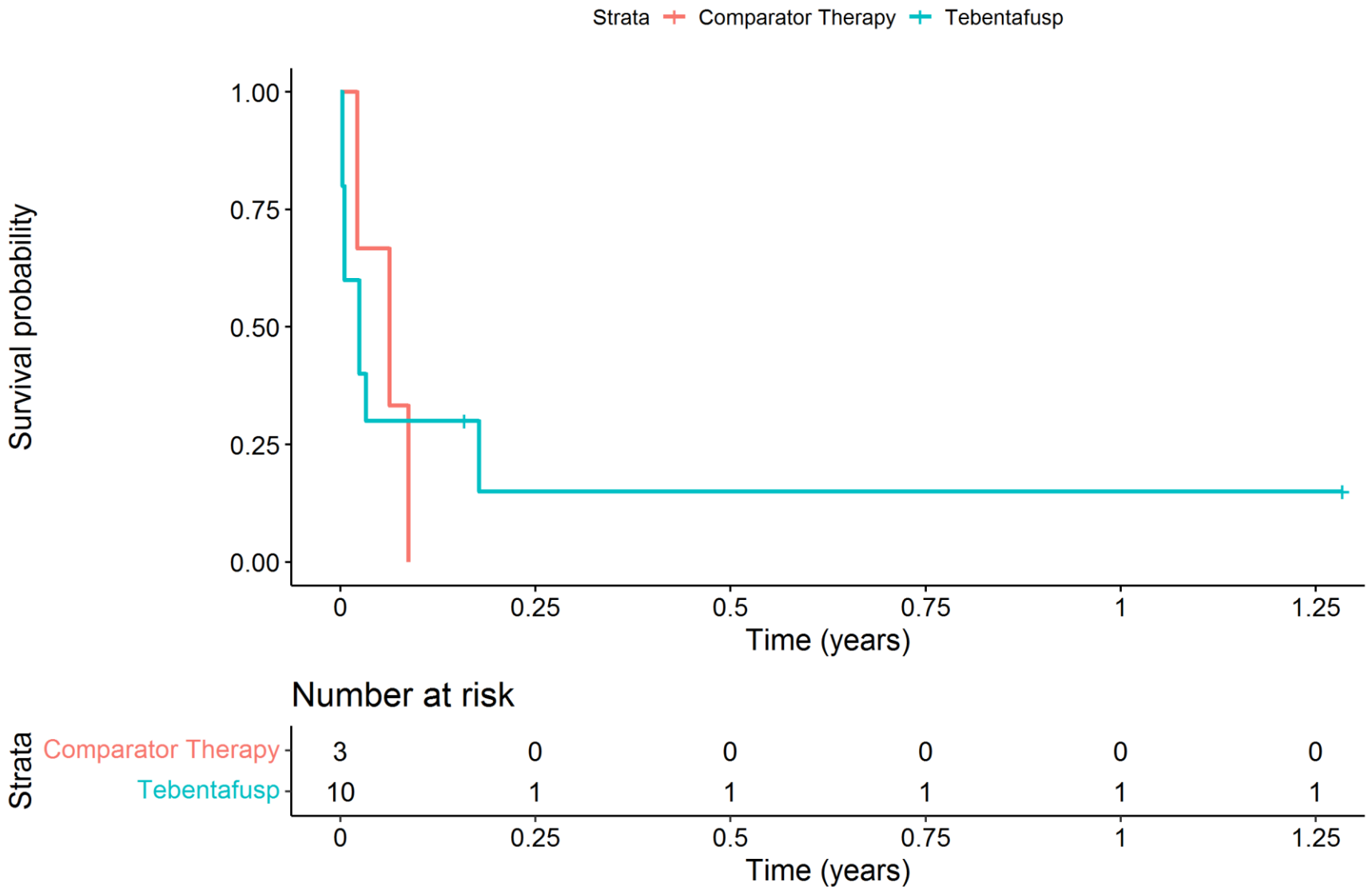
Erkrankungen des Gastrointestinaltrakts - LDH =< ULN



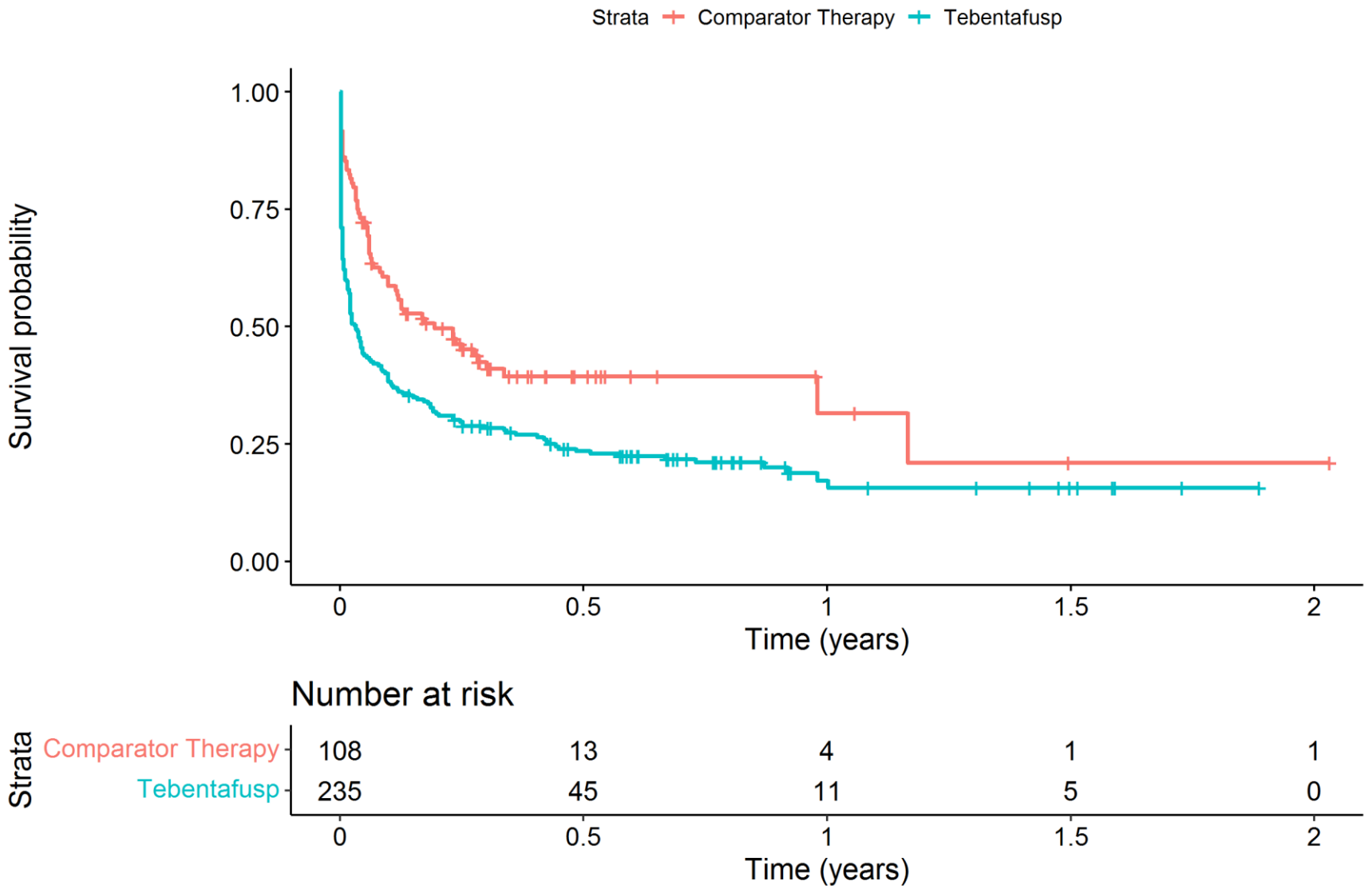
Erkrankungen des Gastrointestinaltrakts - LDH > ULN



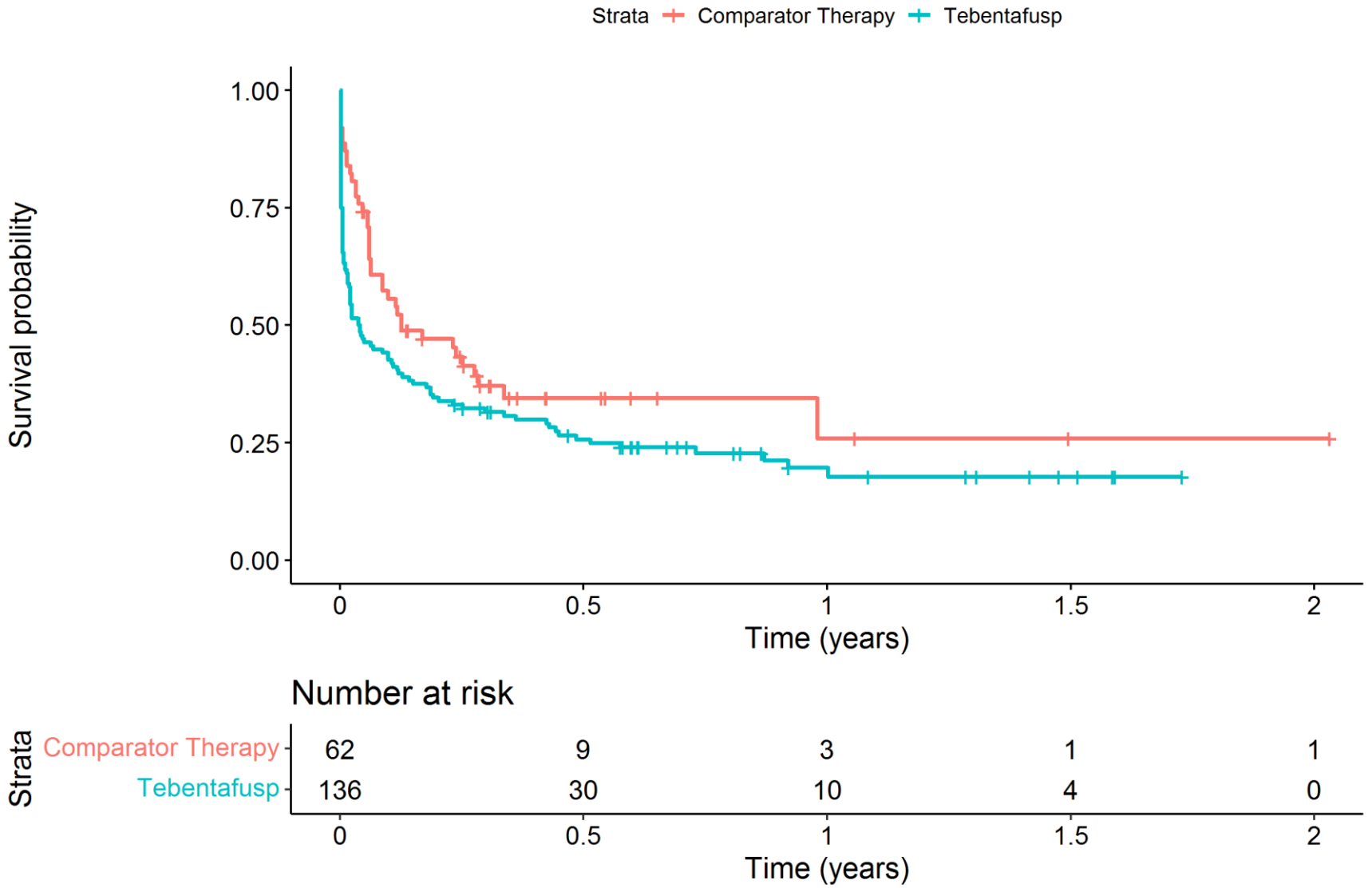
Erkrankungen des Gastrointestinaltrakts - Vorherige Therapie adjuvant/neoadjuvant



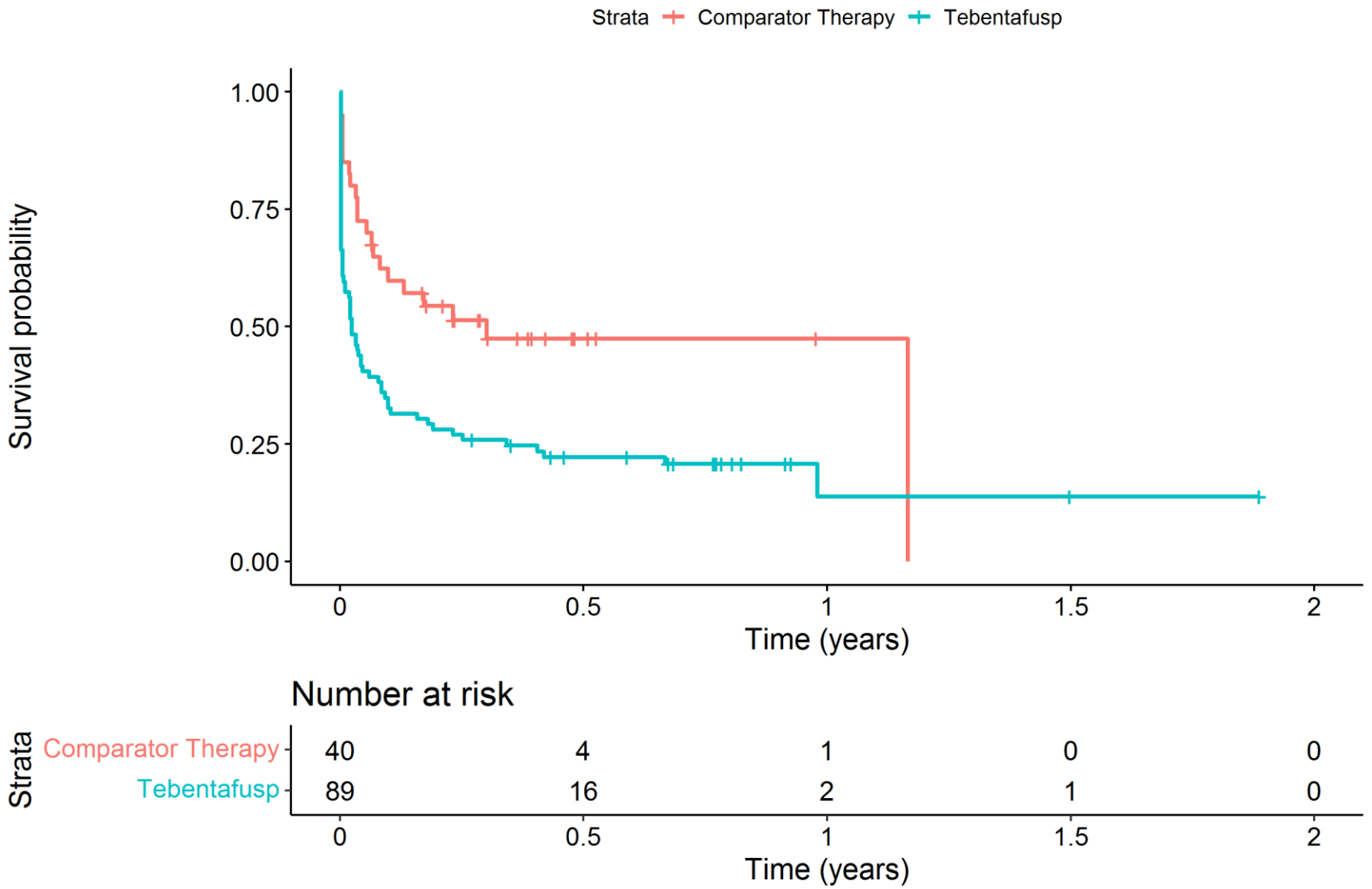
Erkrankungen des Gastrointestinaltrakts - Keine vorherige Therapie adjuvant/neoadjuvant



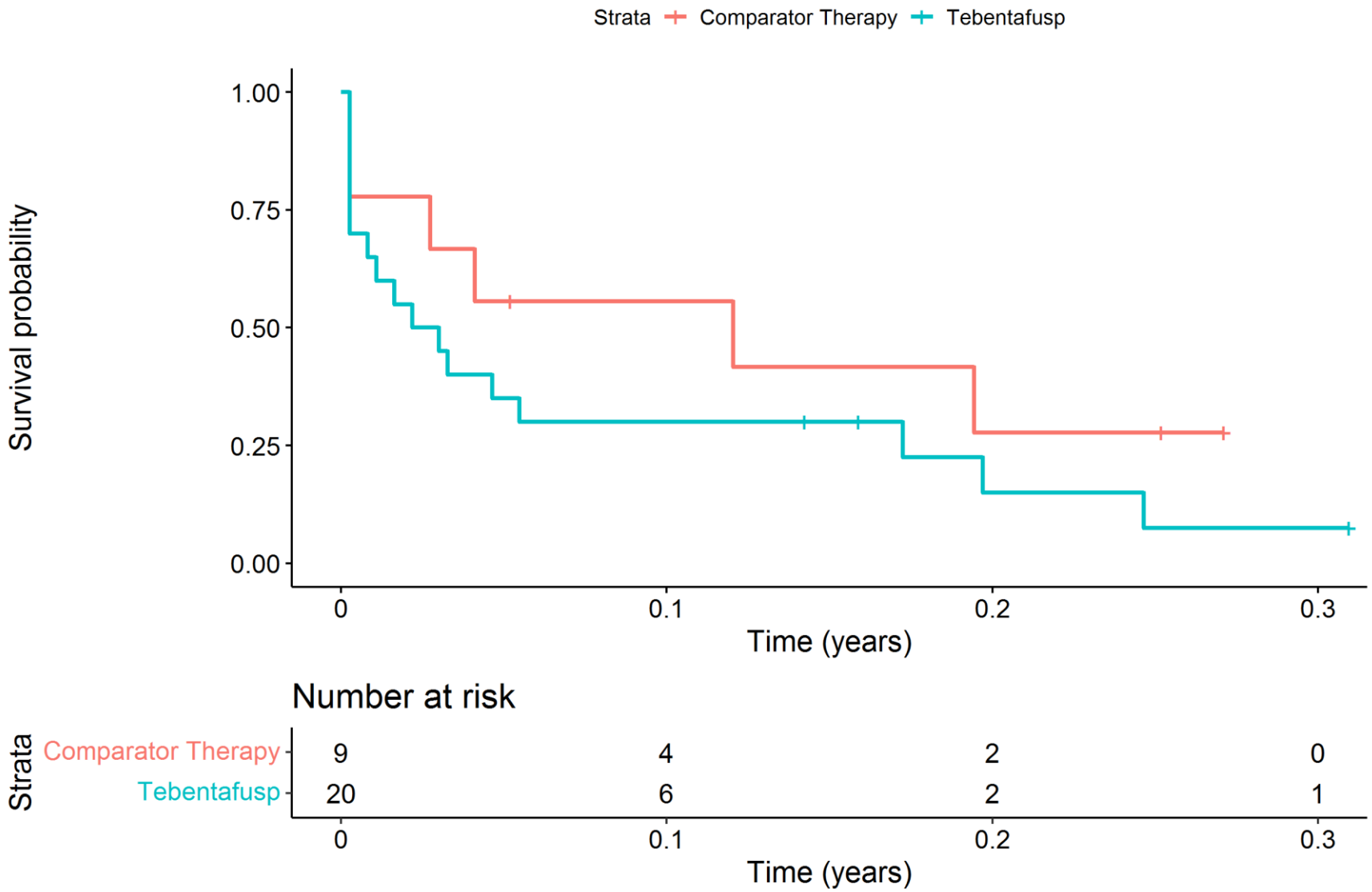
Erkrankungen des Gastrointestinaltrakts - Läsion ≤ 3cm



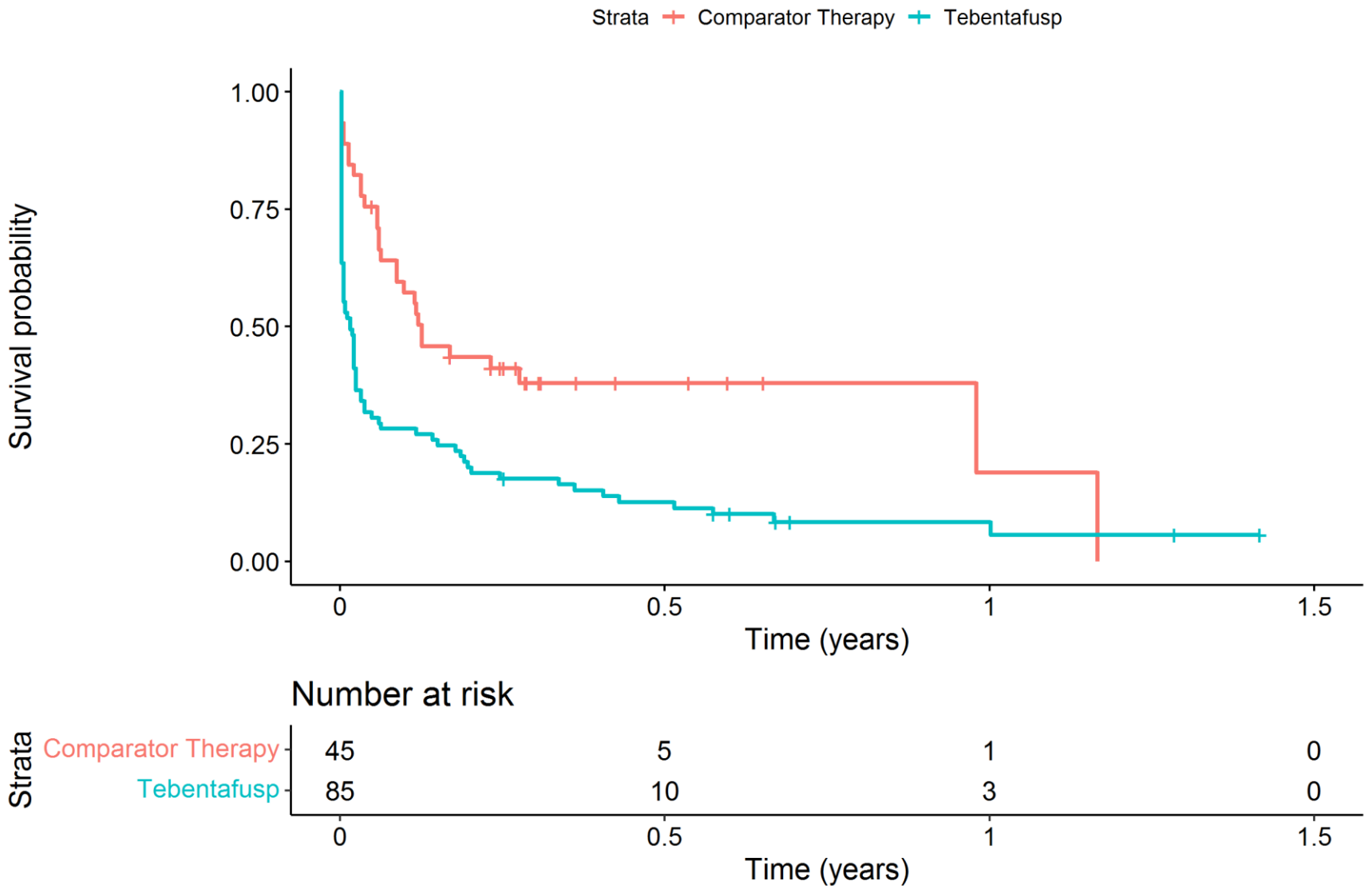
Erkrankungen des Gastrointestinaltrakts - Läsion 3,1-8,0 cm



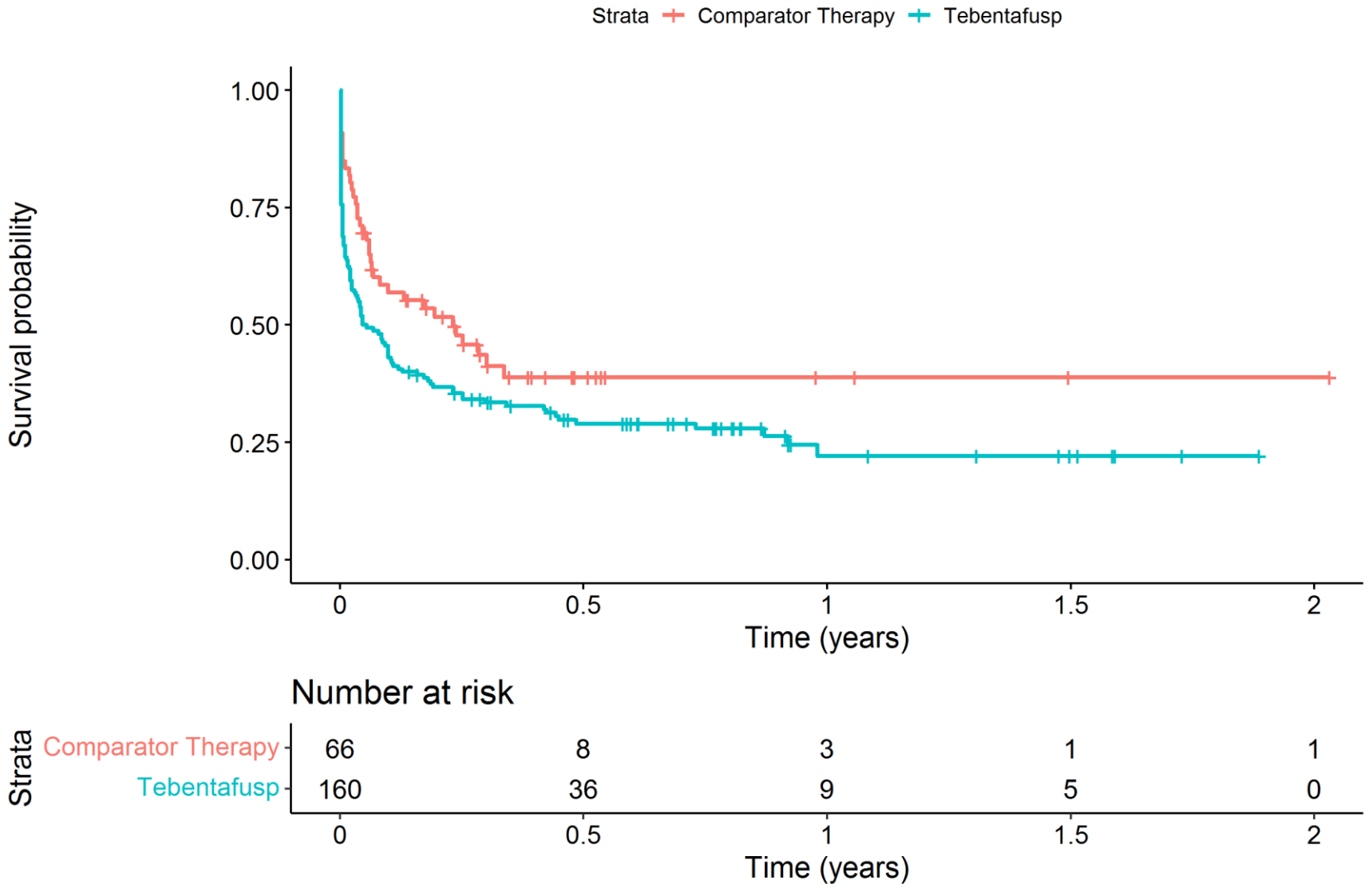
Erkrankungen des Gastrointestinaltrakts - Läsion ≥8,1 cm



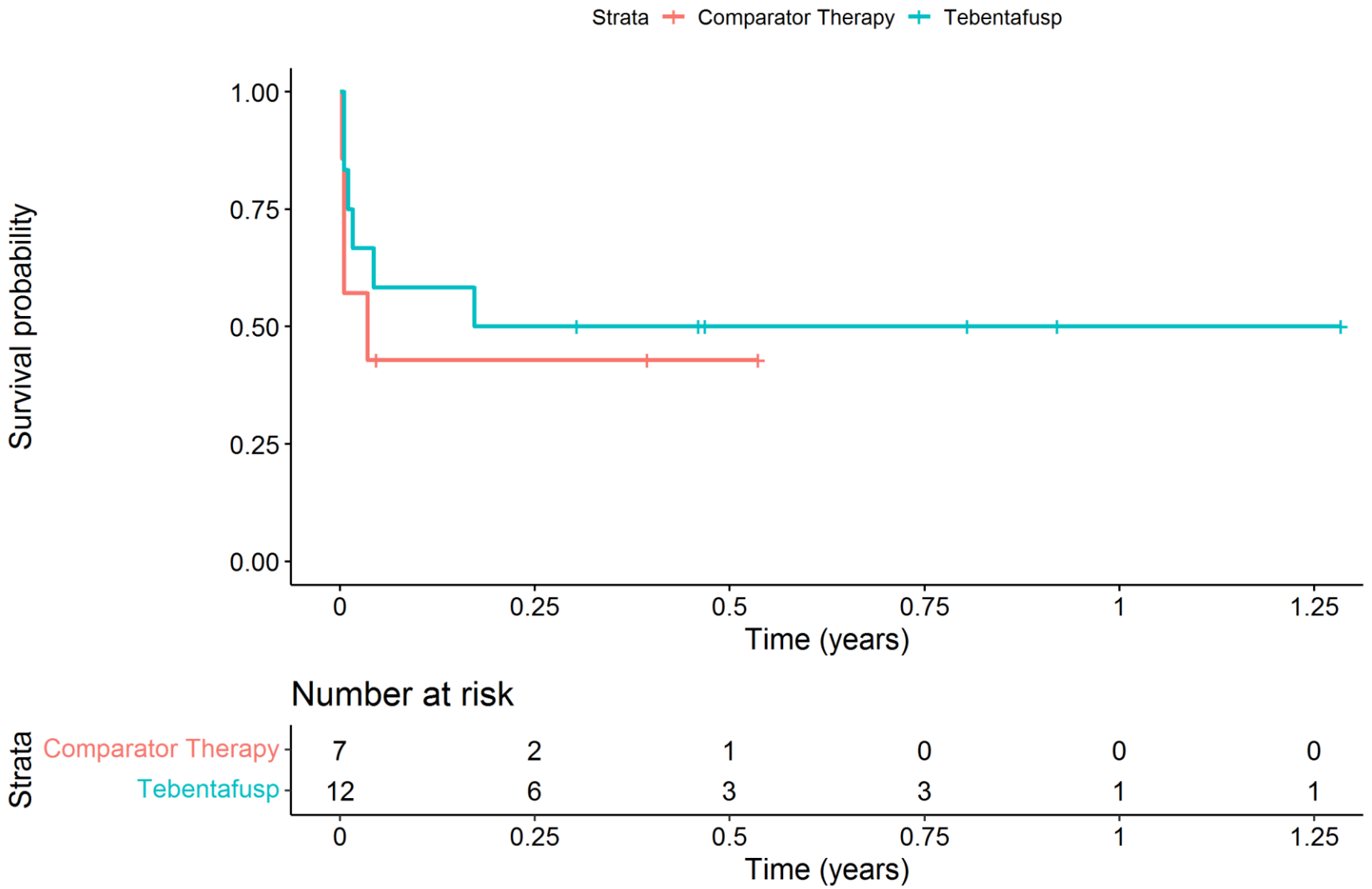
Erkrankungen des Gastrointestinaltrakts - Nordamerika



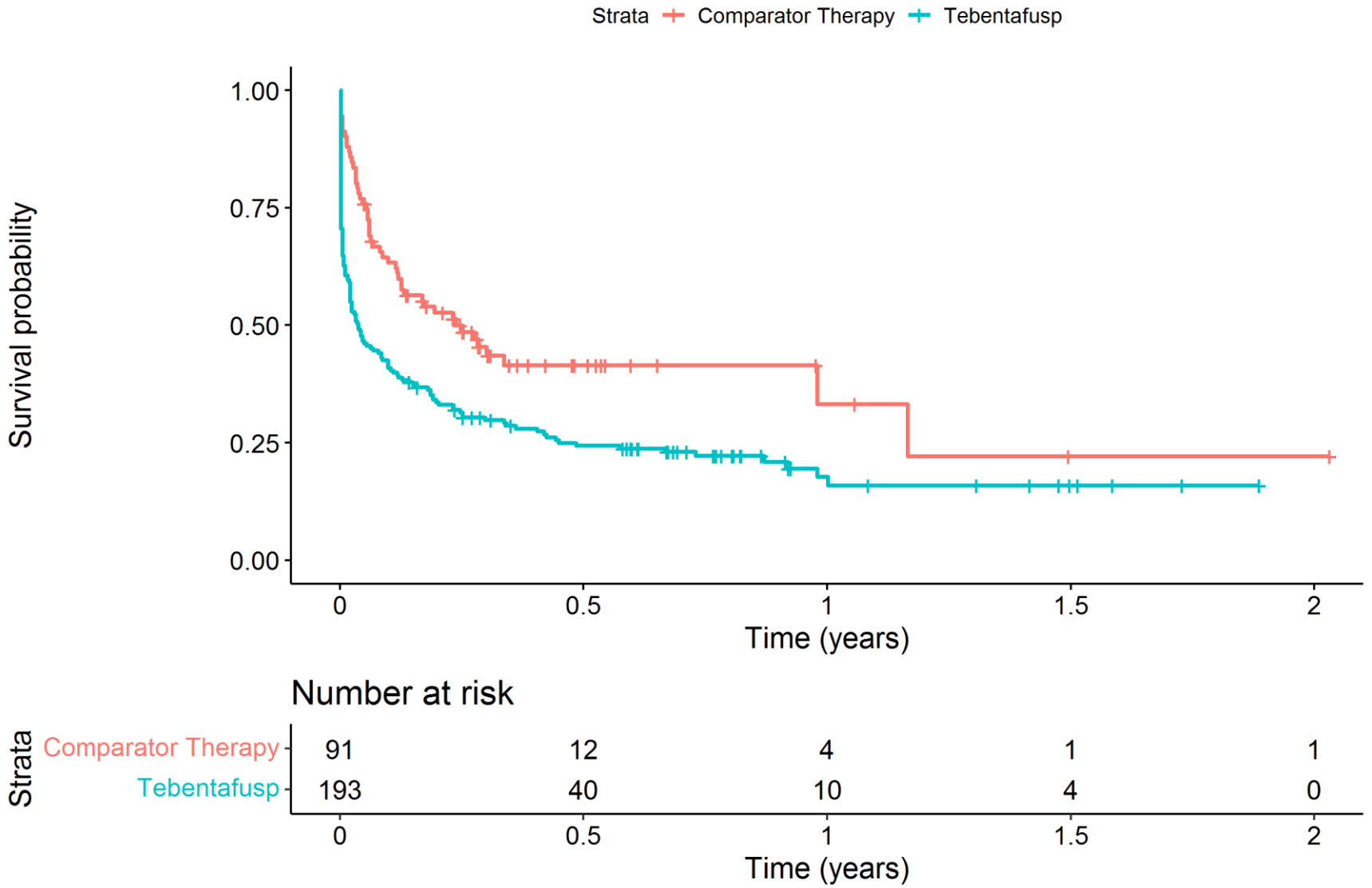
Erkrankungen des Gastrointestinaltrakts - Nicht-Nordamerika



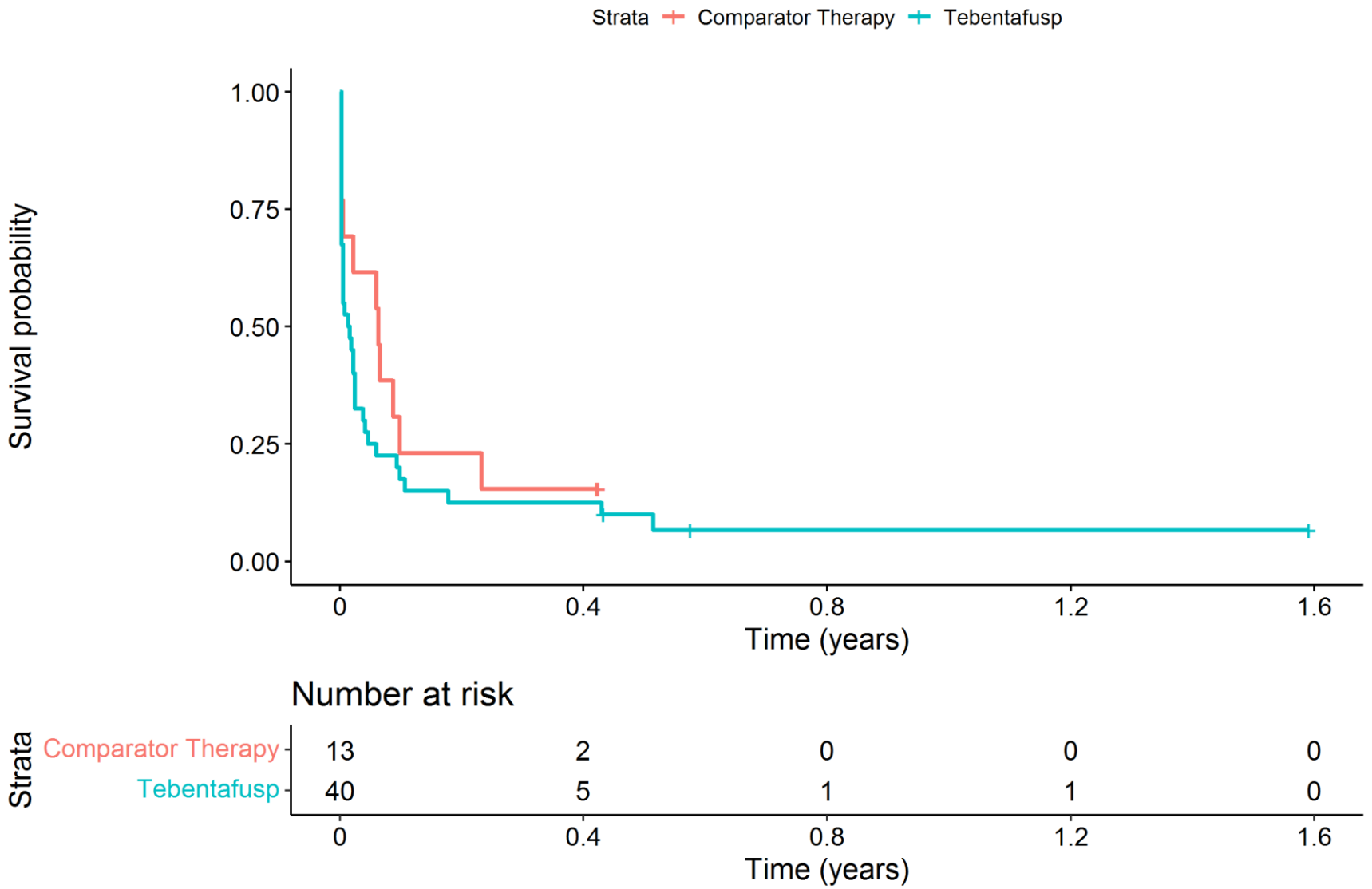
Erkrankungen des Gastrointestinaltrakts - Dacarbazin



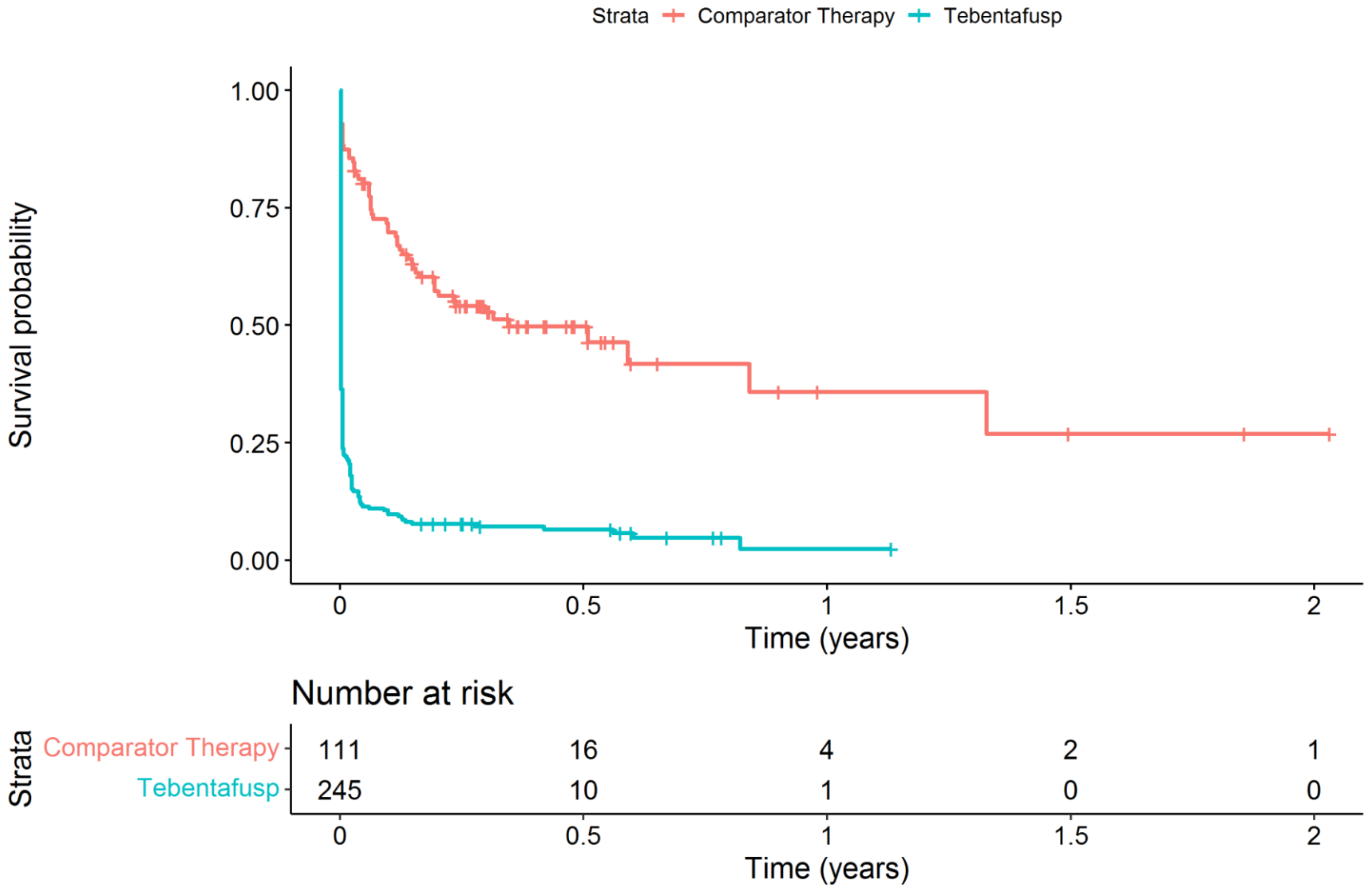
Erkrankungen des Gastrointestinaltrakts - Pembrolizumab



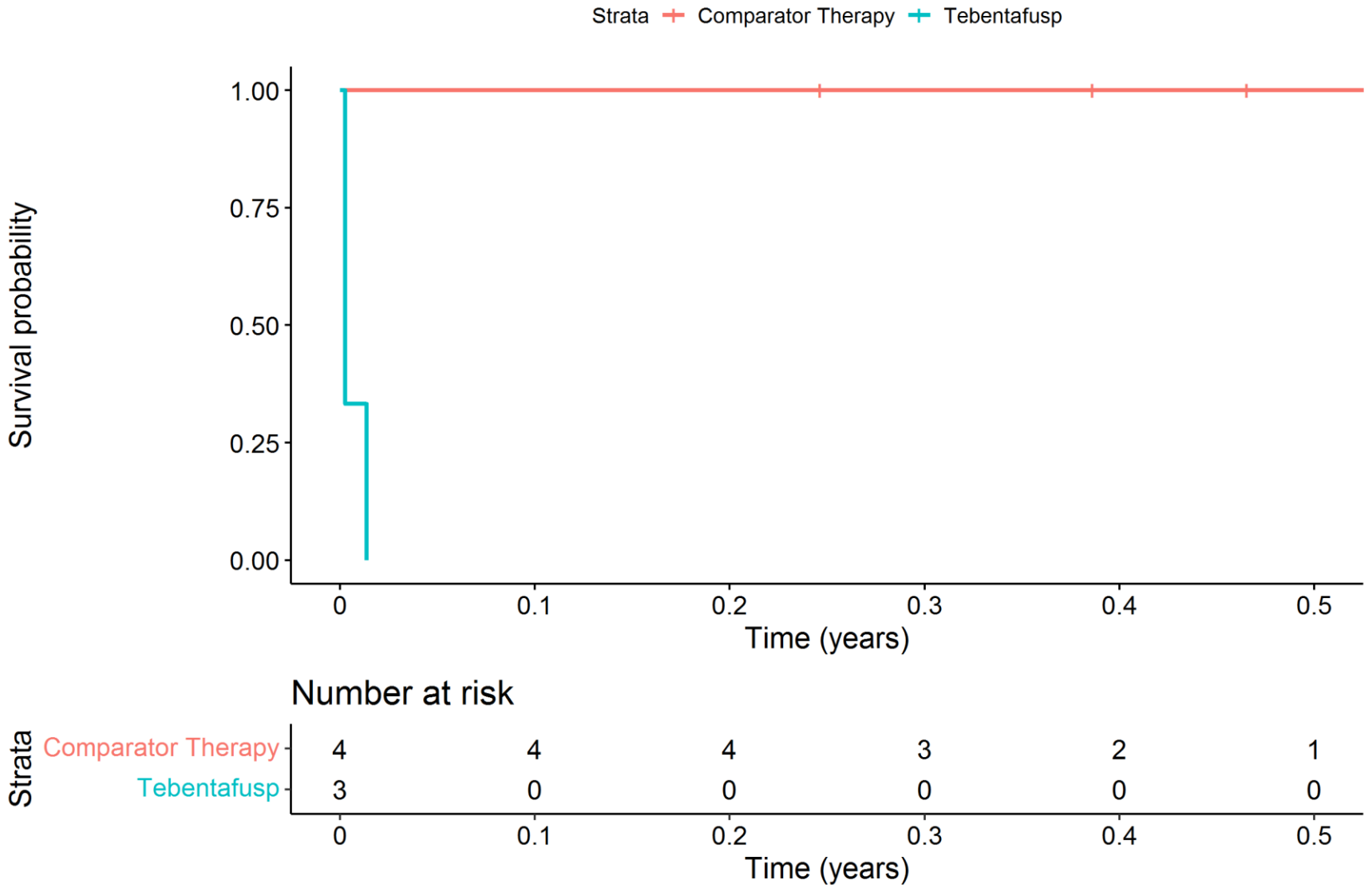
Erkrankungen des Gastrointestinaltrakts - Ipilimumab



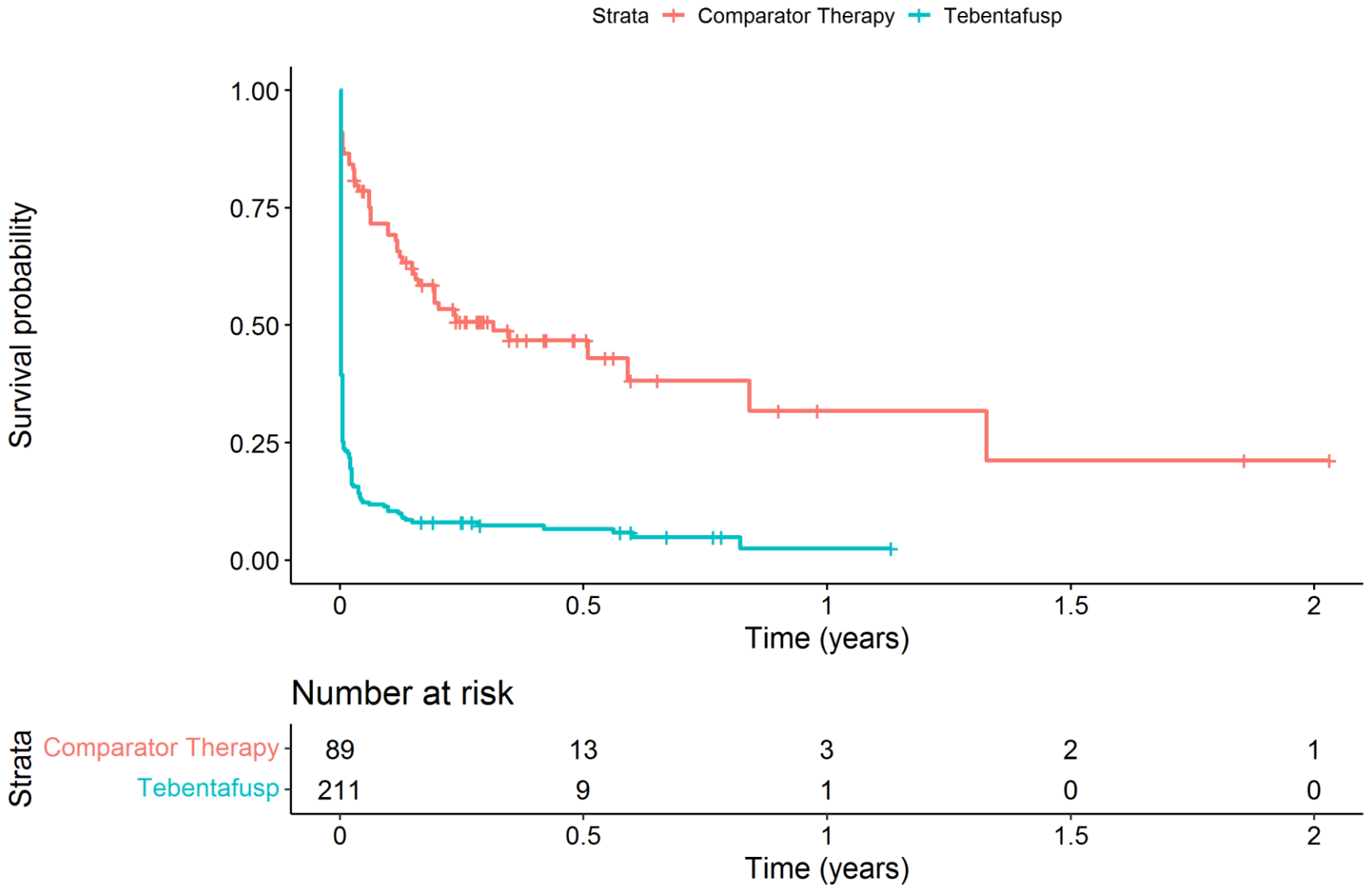
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Gesamt



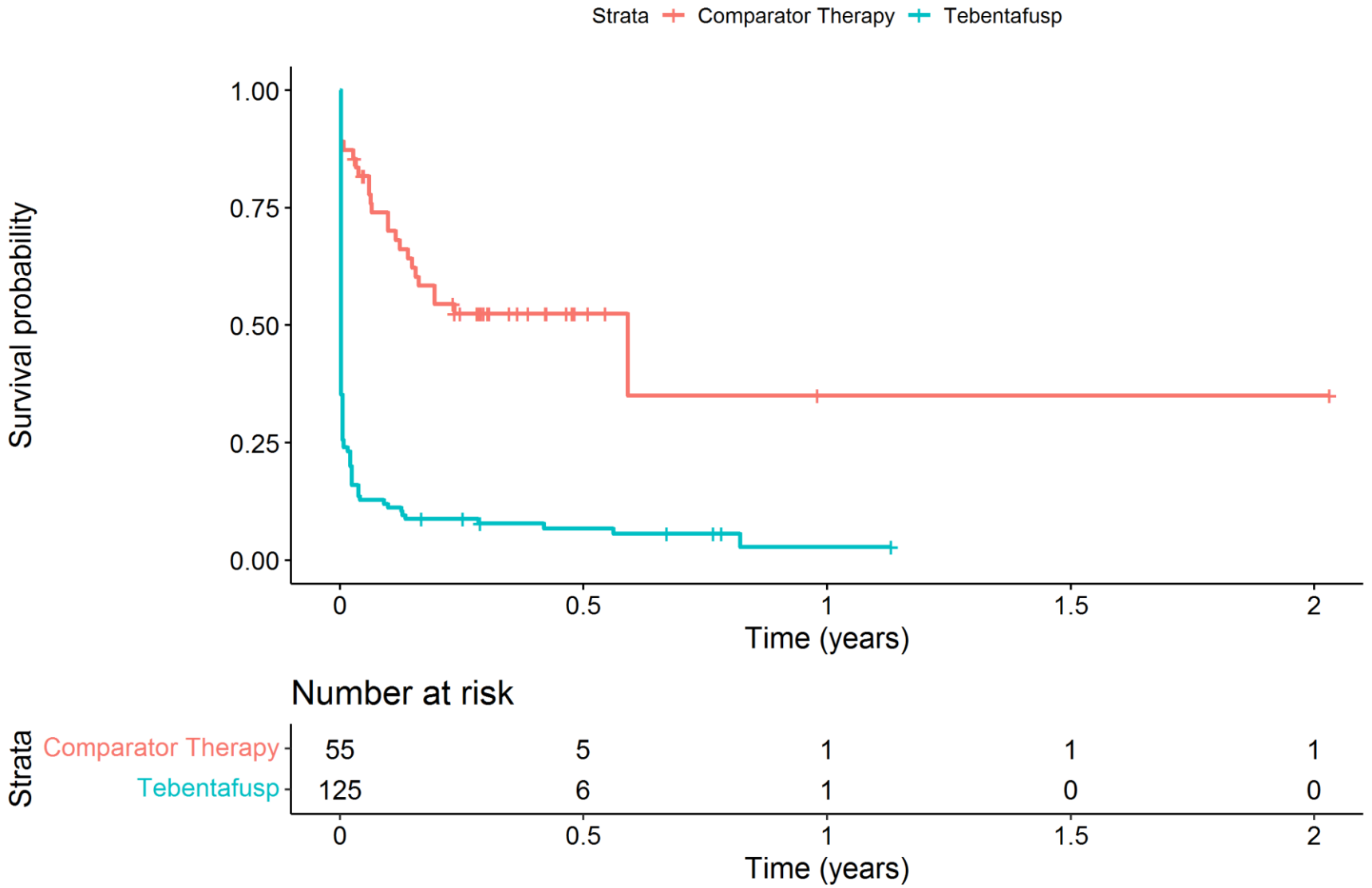
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Hispanisch



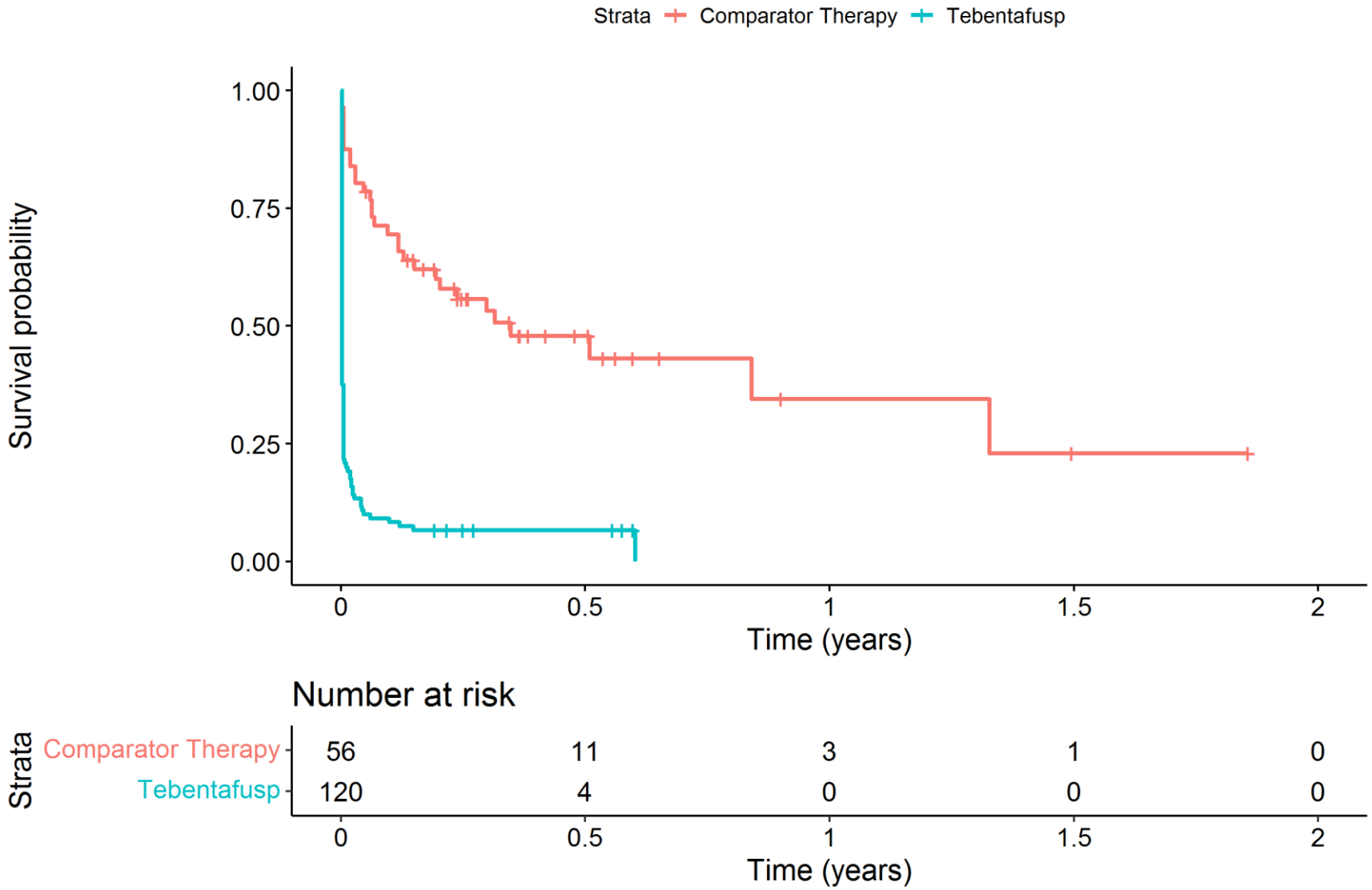
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nicht-hispanisch



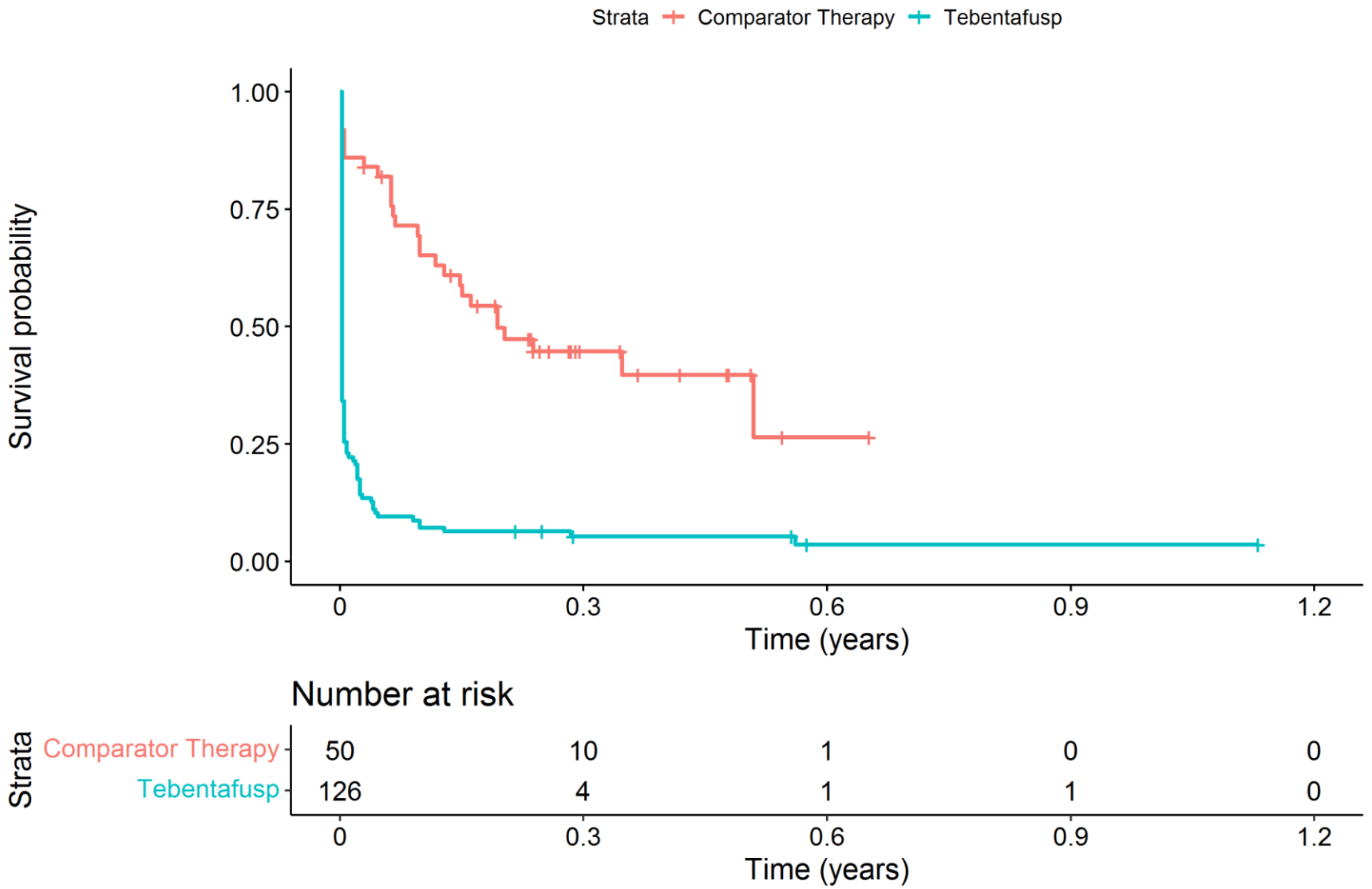
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Männlich



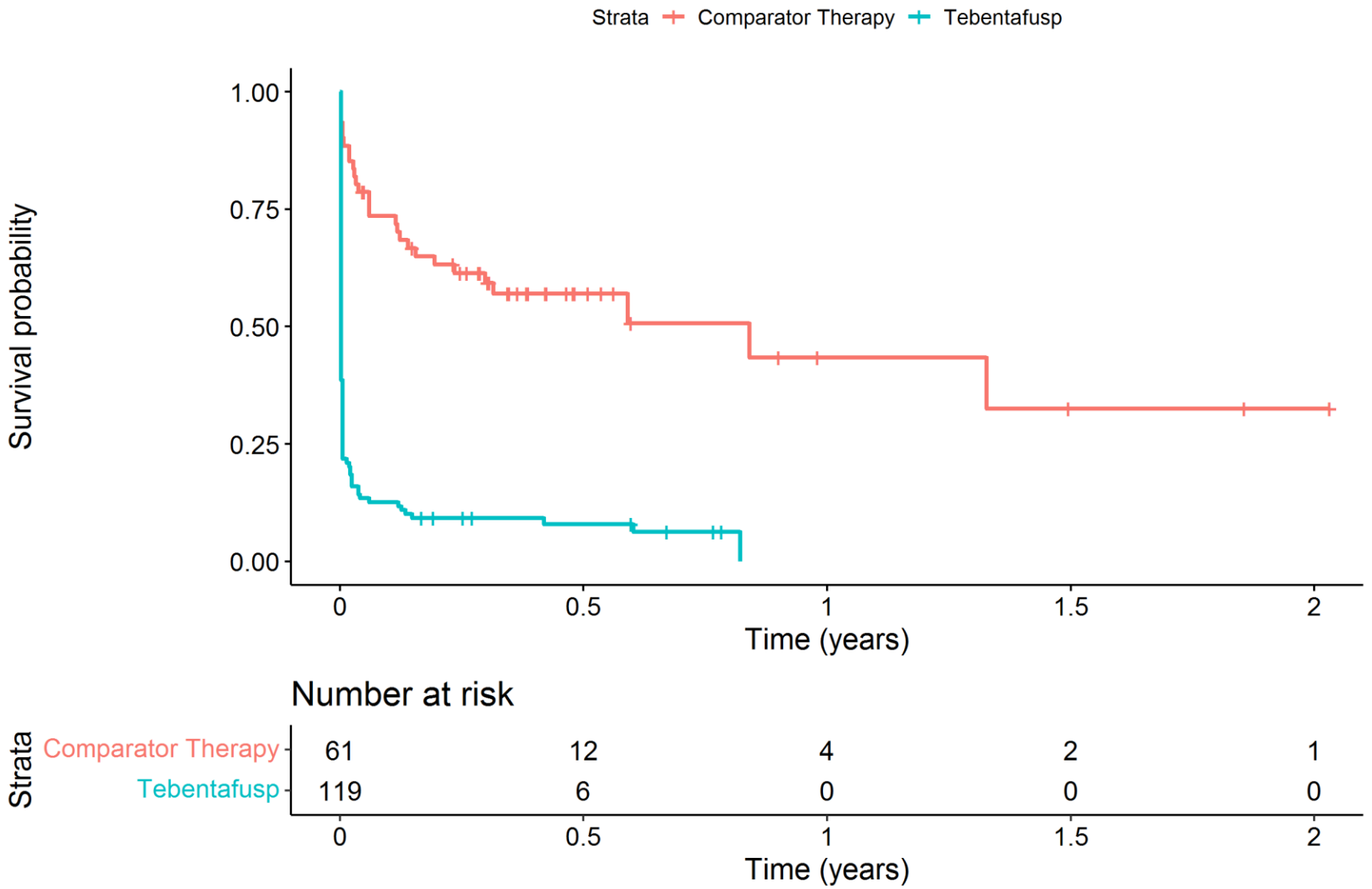
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Weiblich



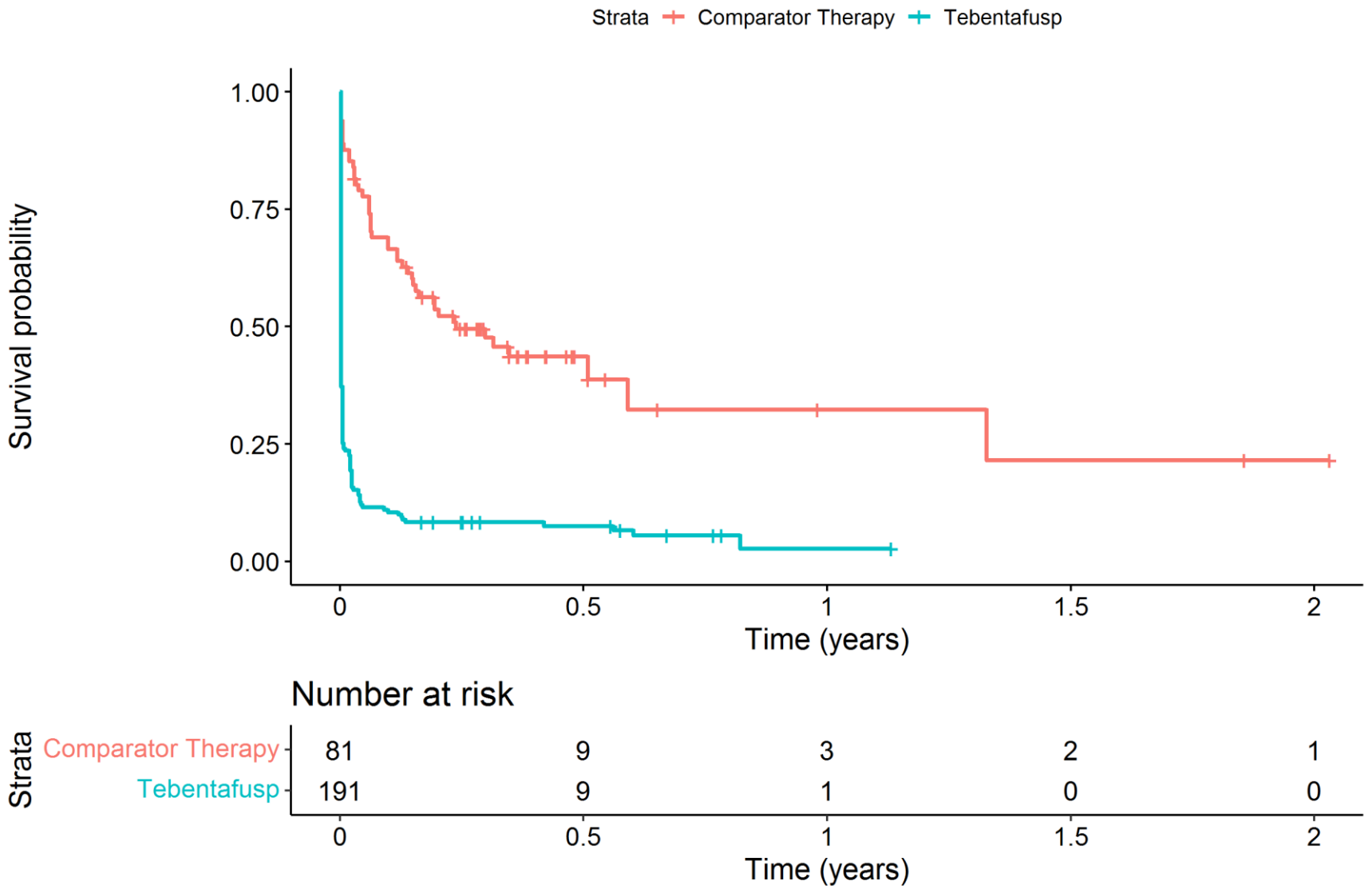
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- <65



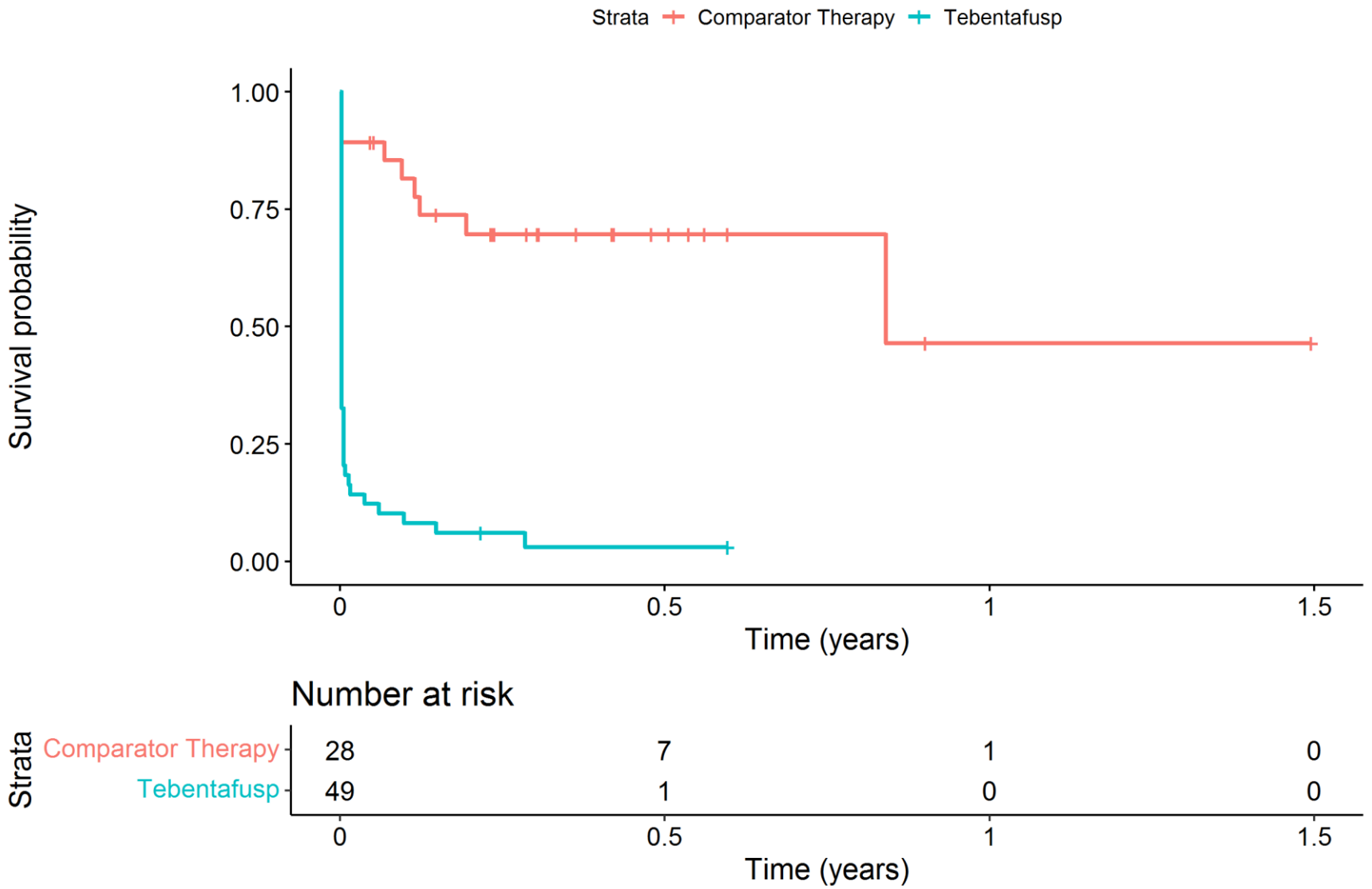
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ≥65



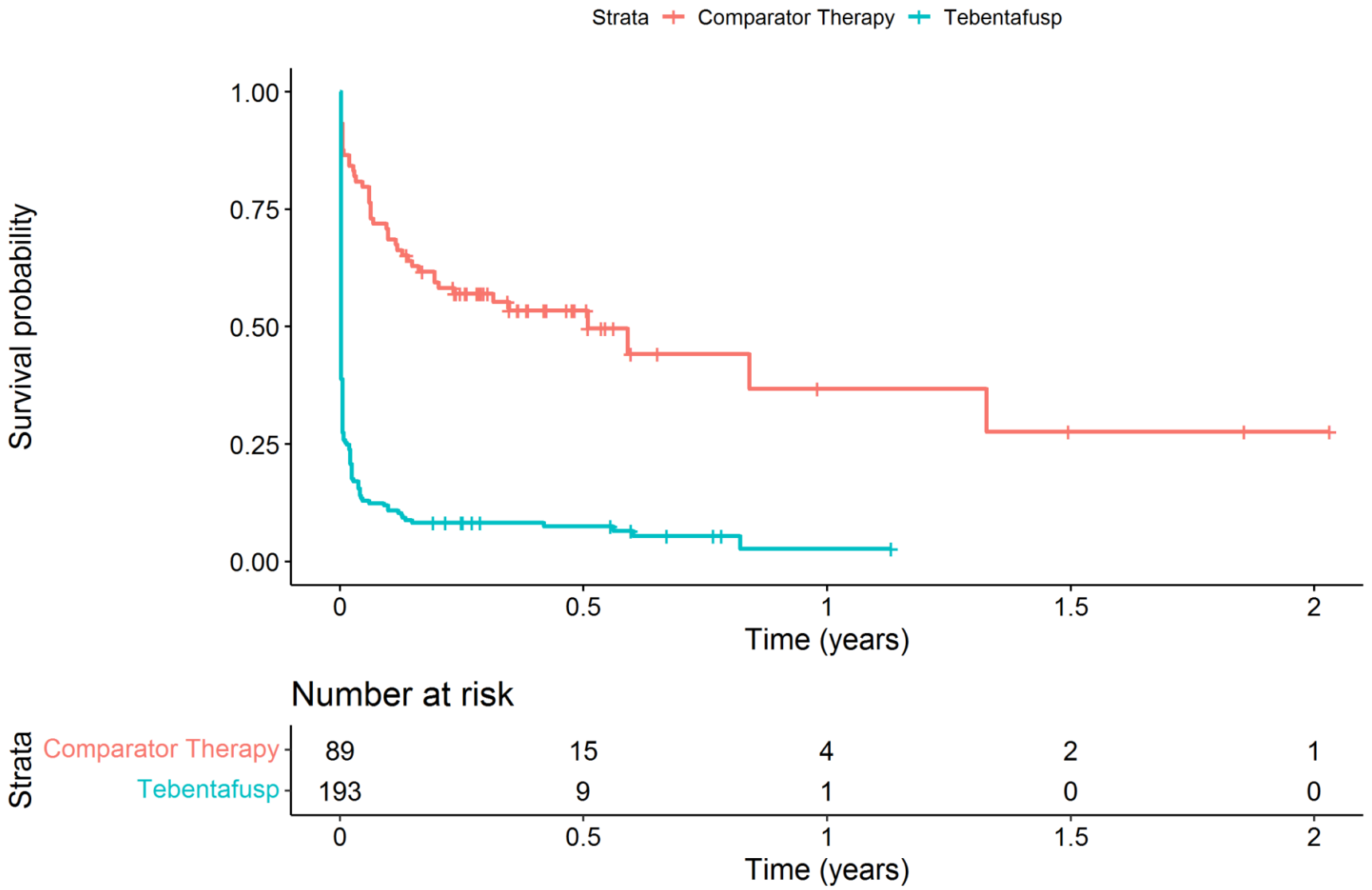
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ECOG 0



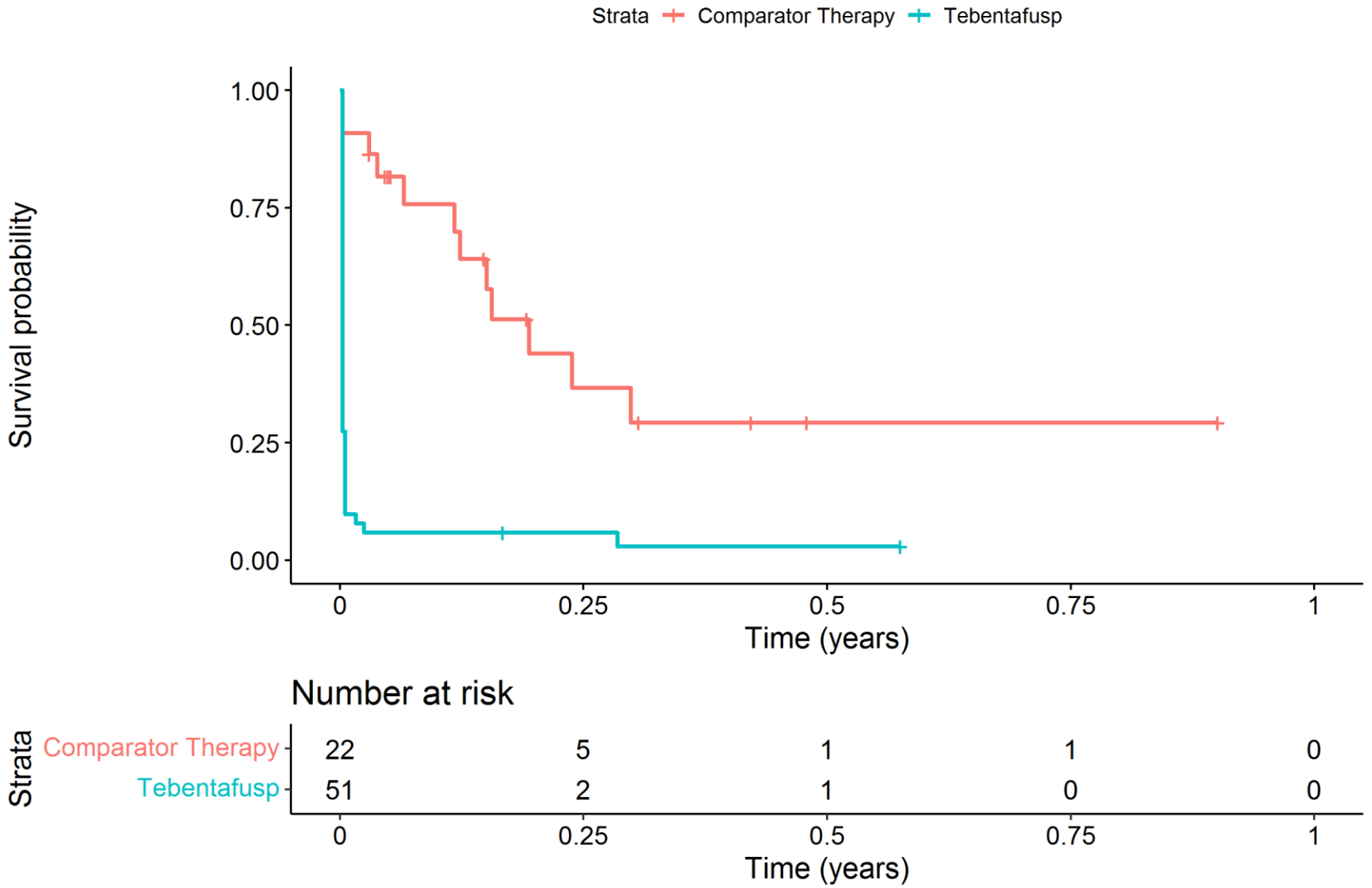
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ECOG 1



Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ALP ≤ ULN



Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ALP > ULN



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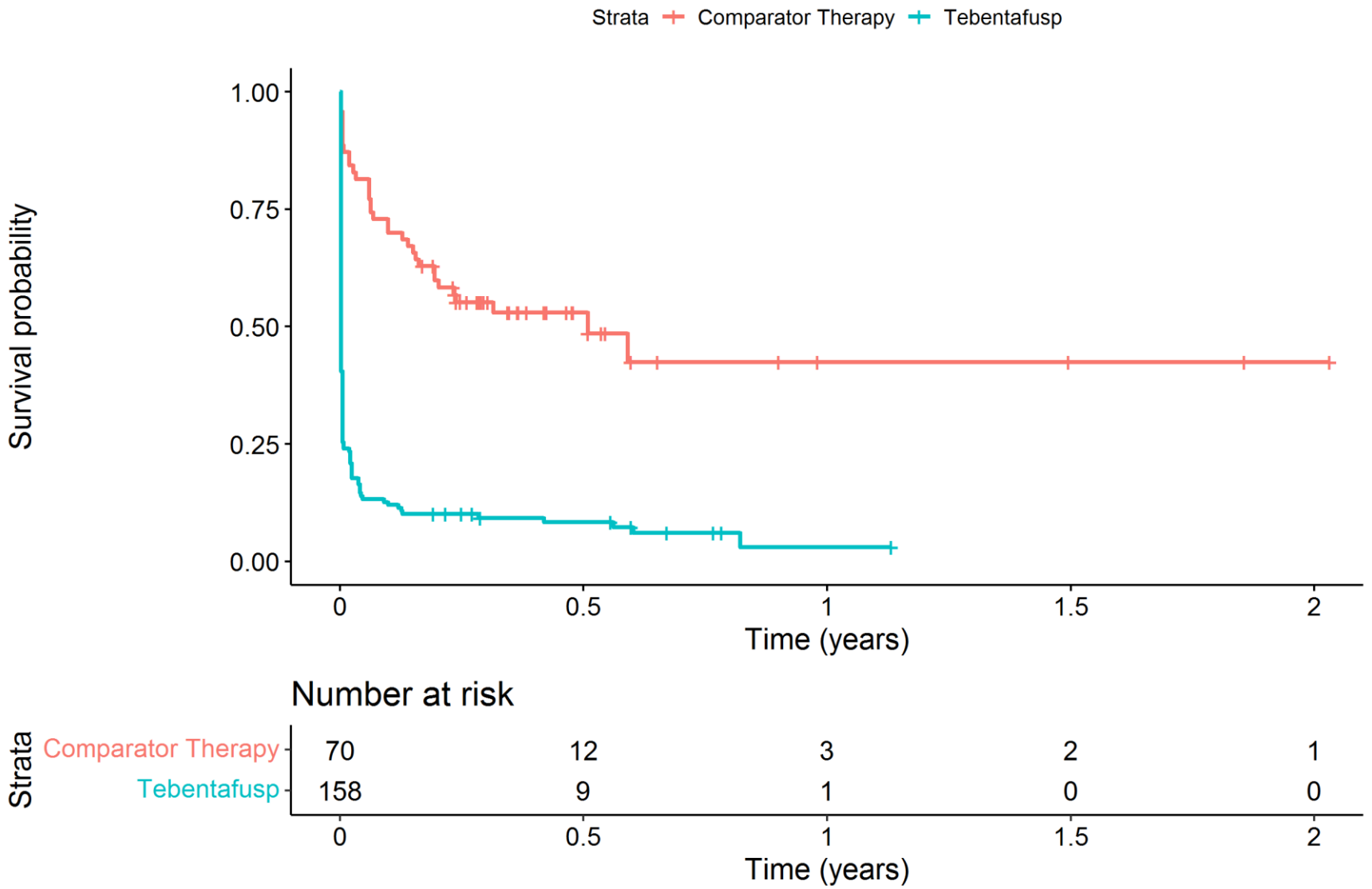
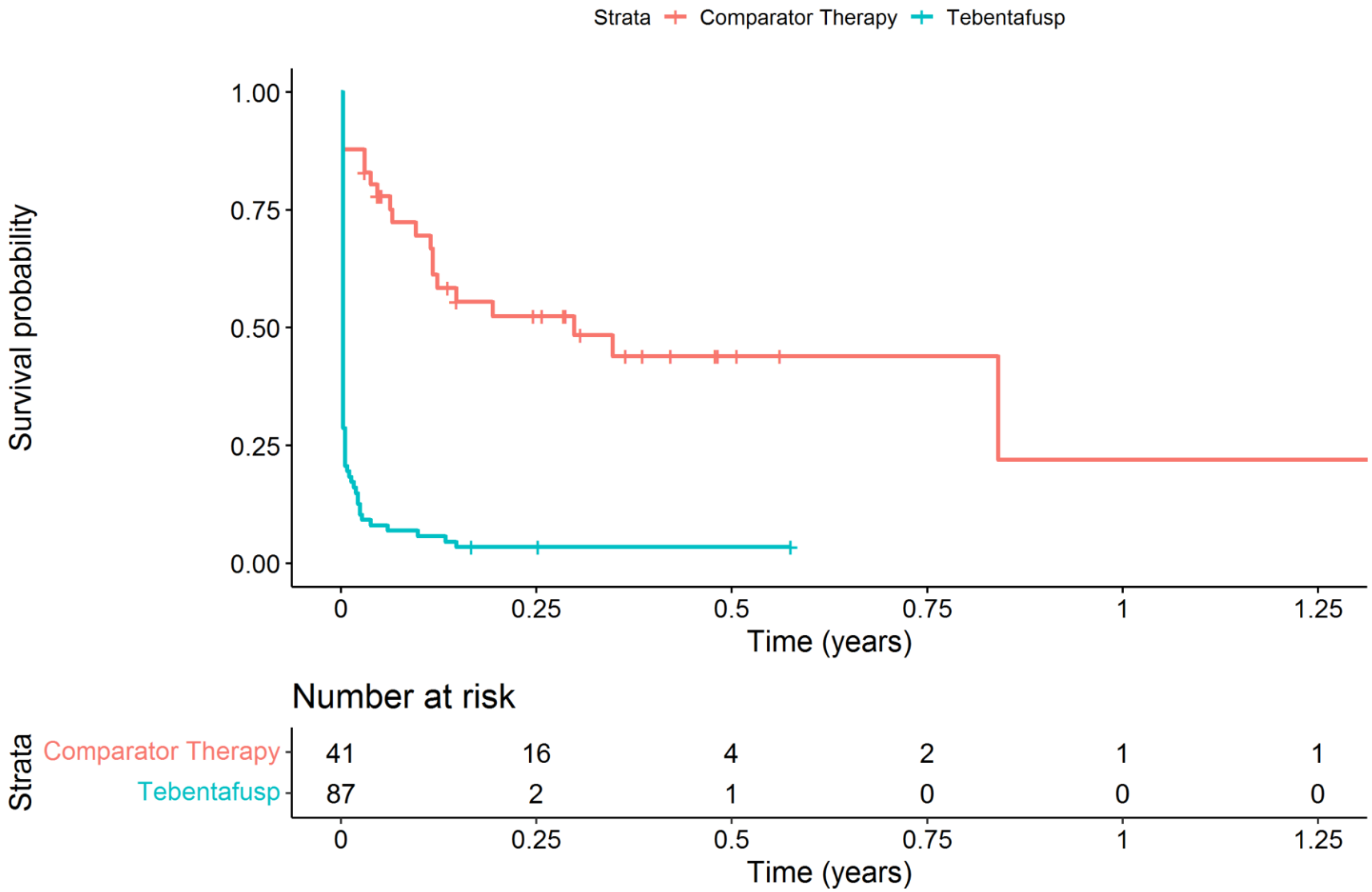
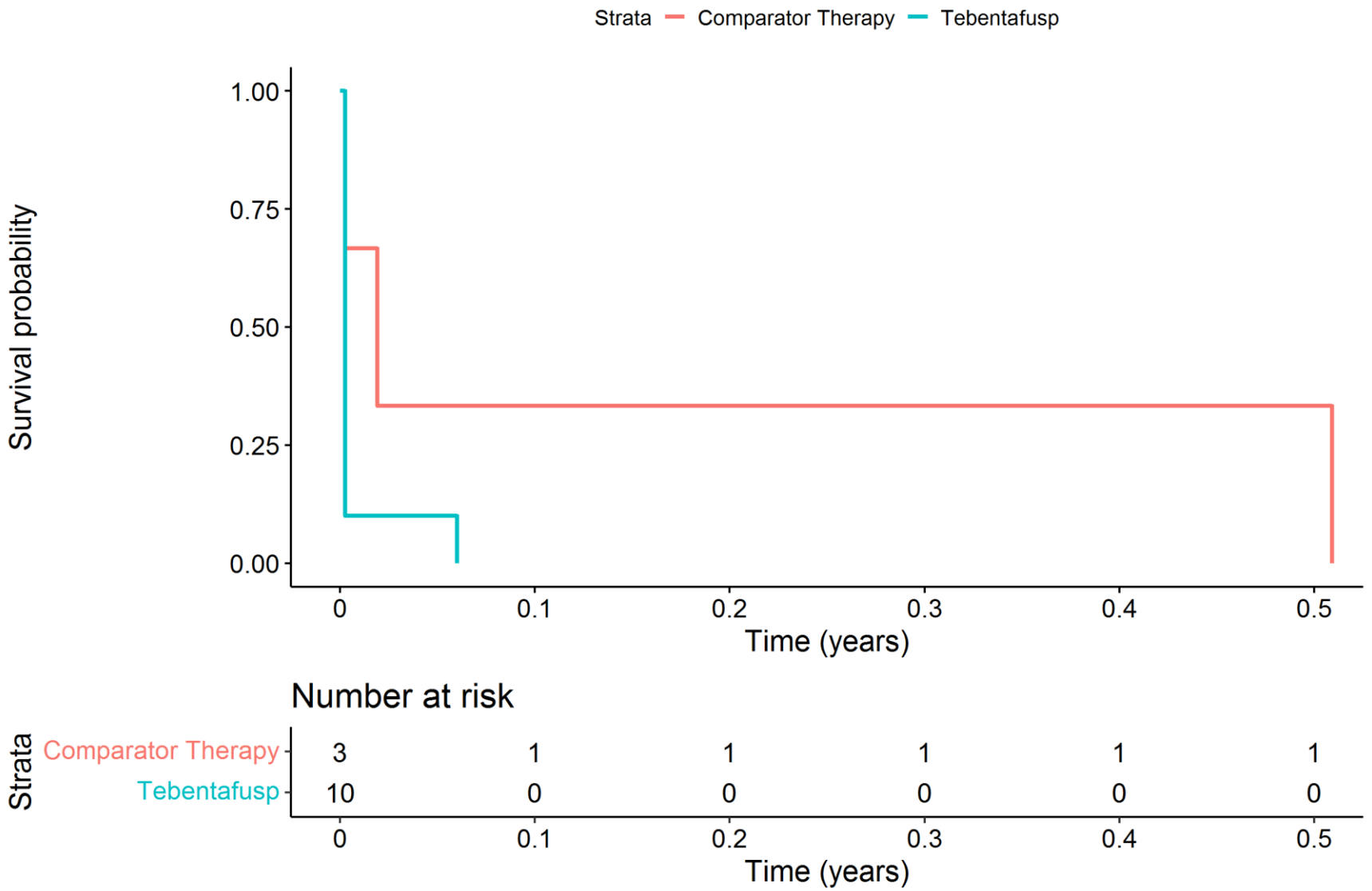


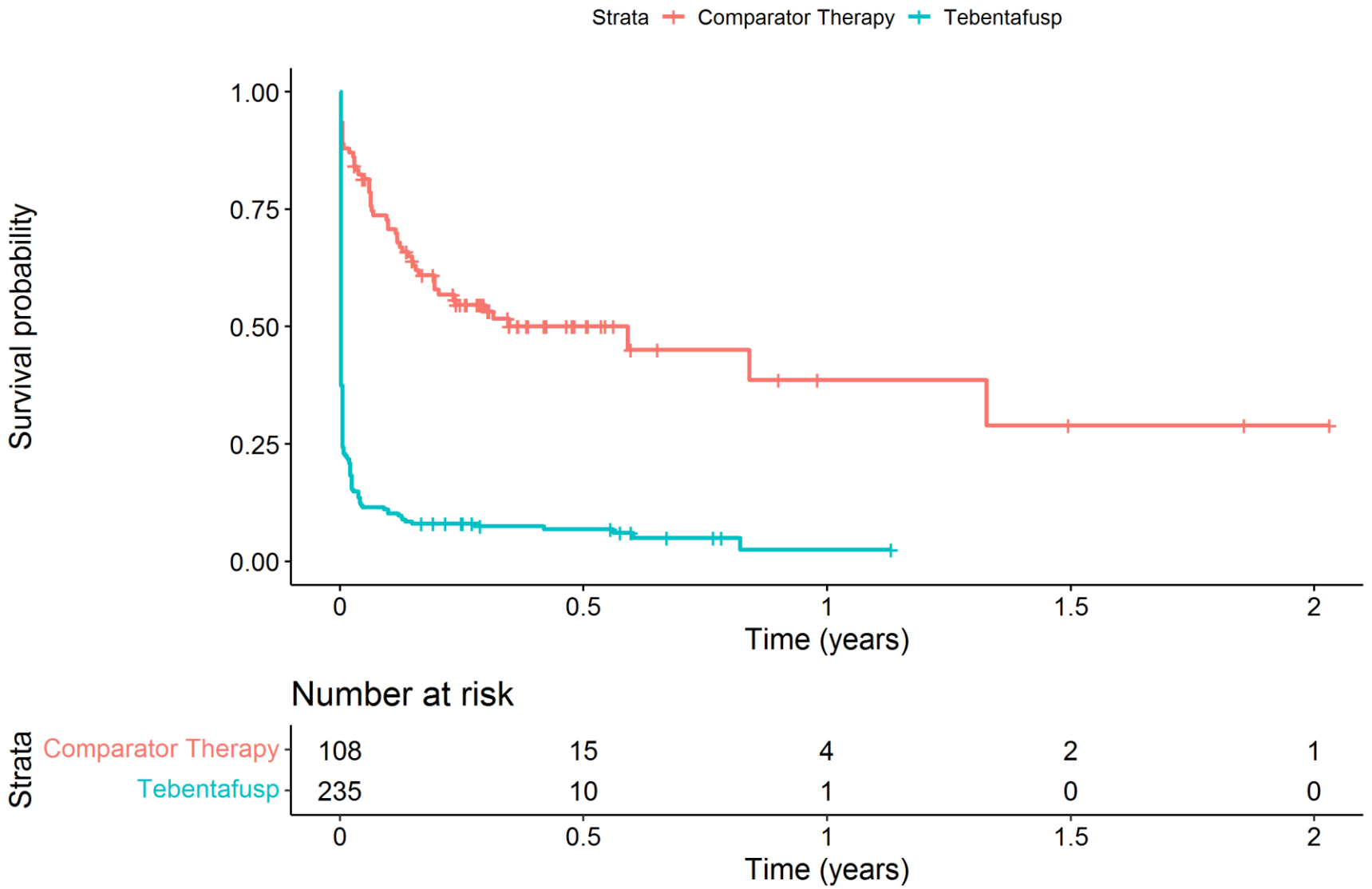
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- LDH > ULN



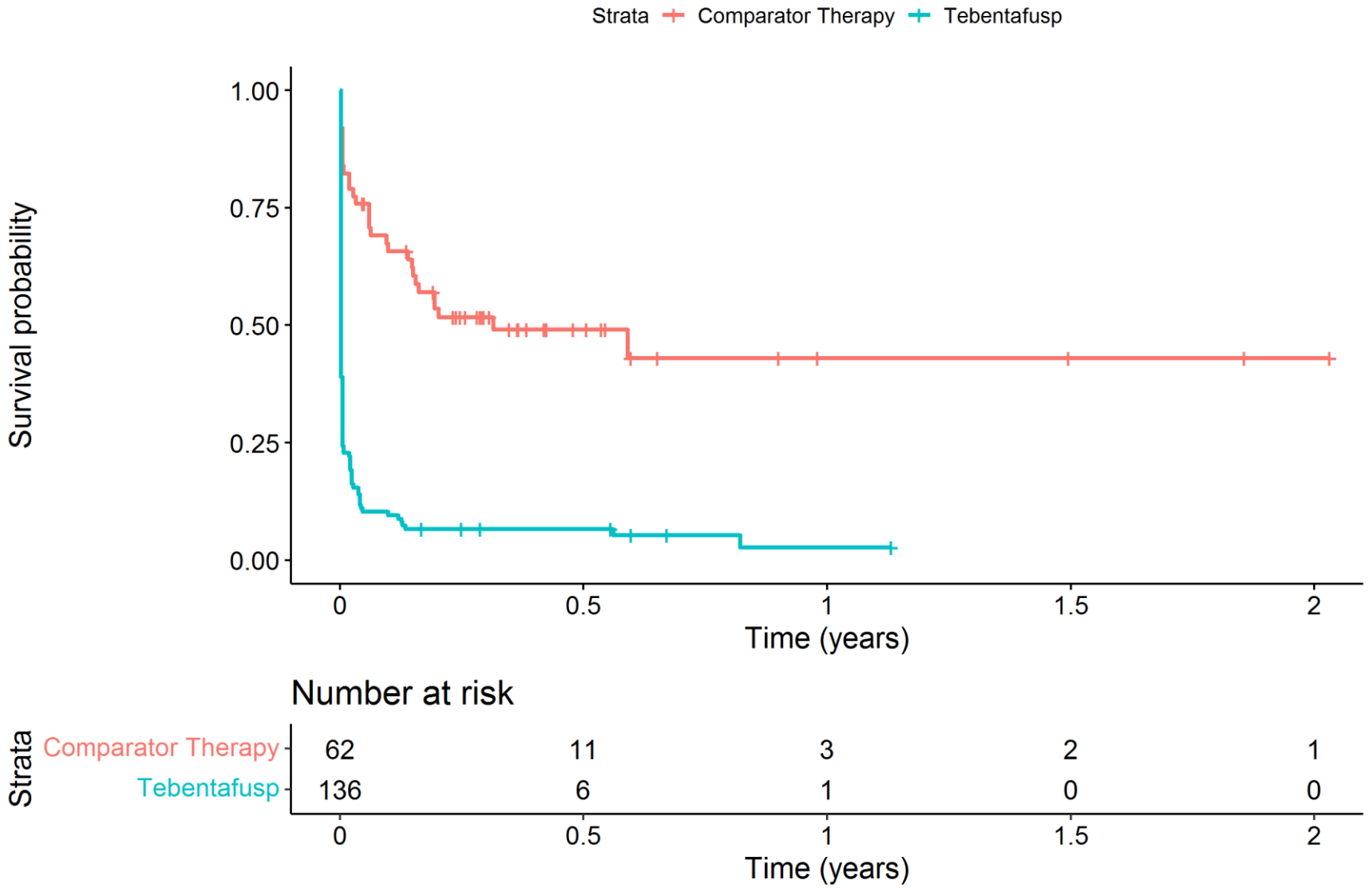
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Vorherige Therapie adjuvant/neoadjuvant



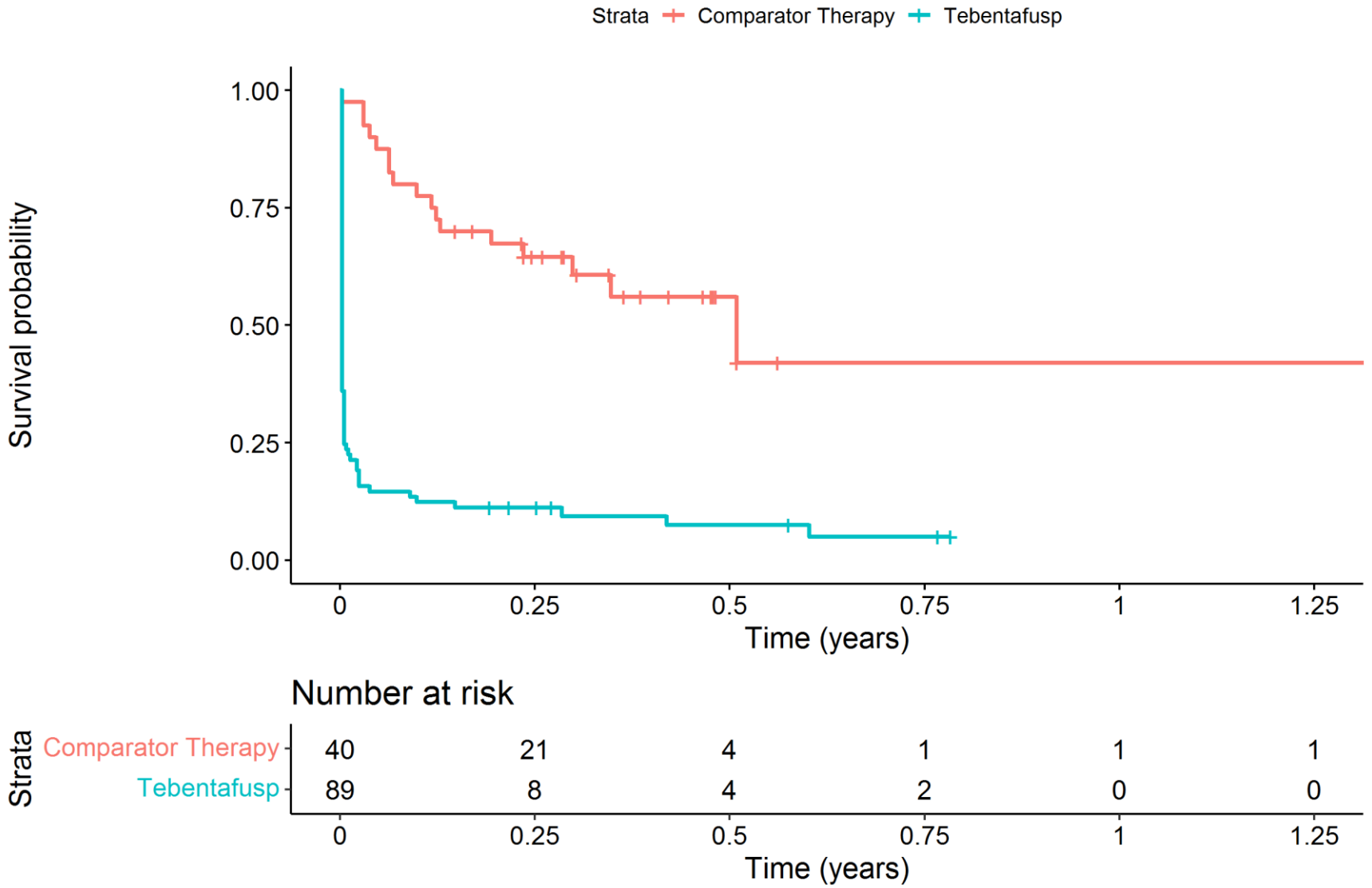
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Keine vorherige Therapie adjuvant/neoadjuvant



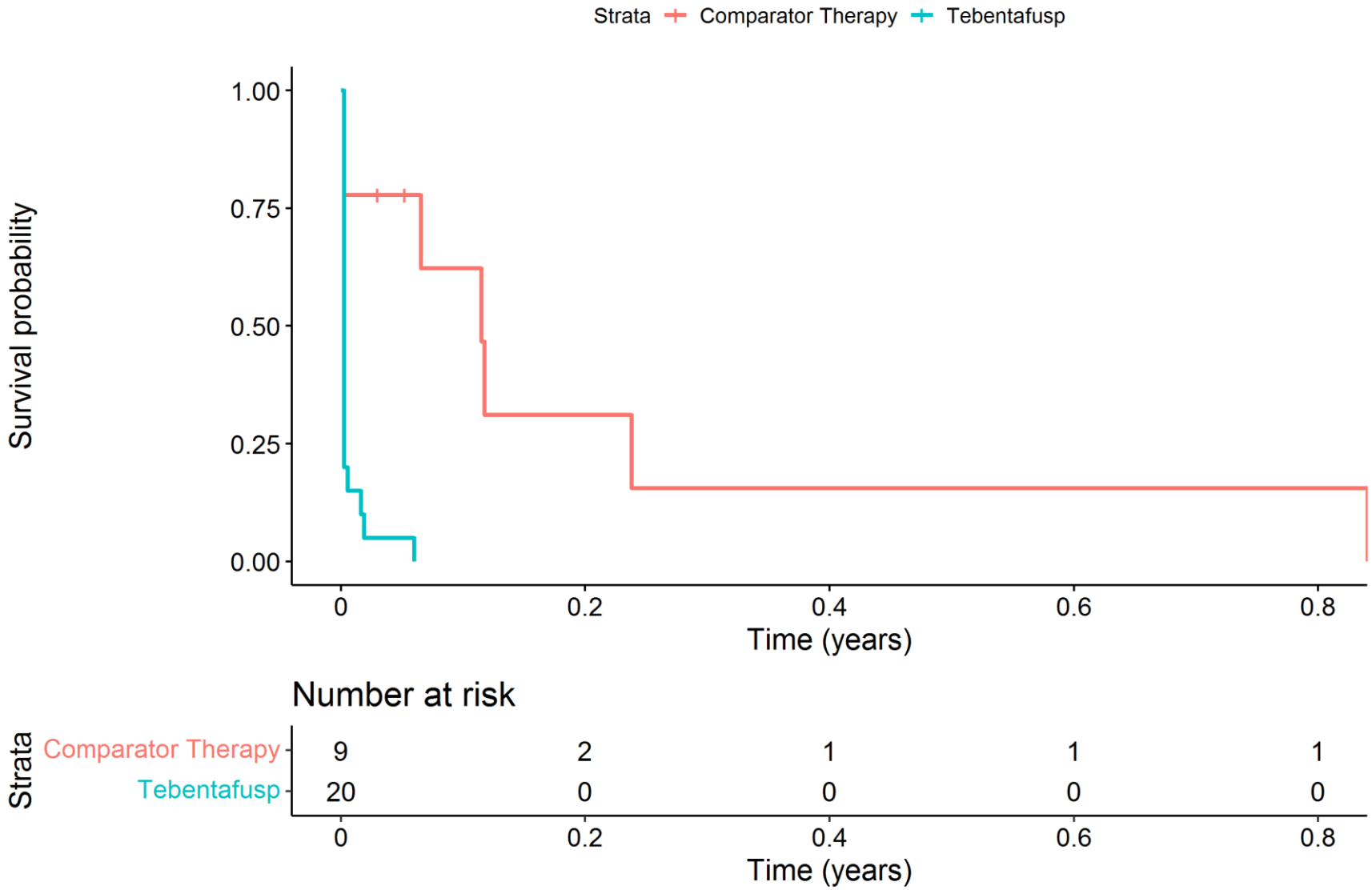
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion ≤ 3cm



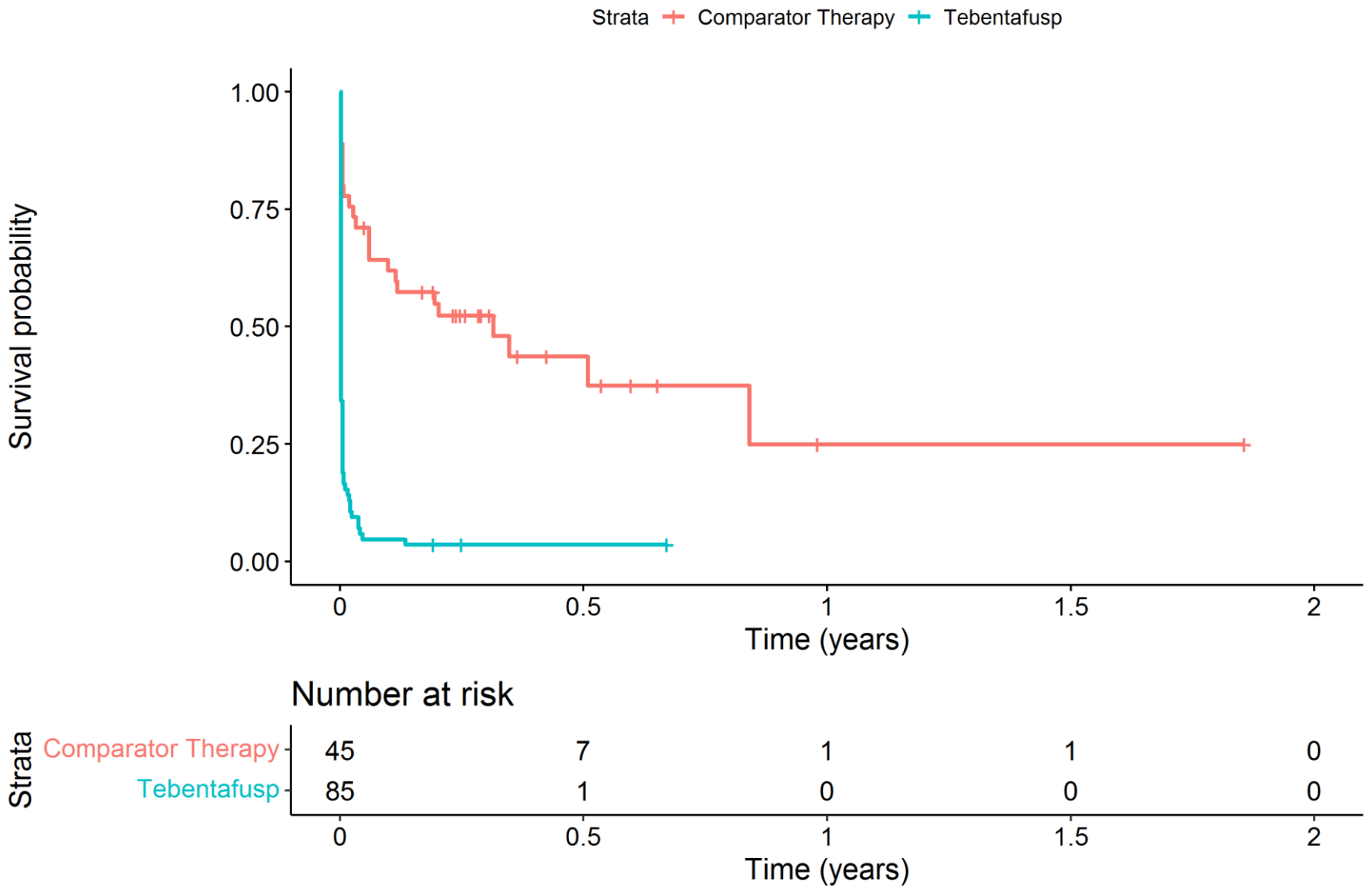
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion 3,1-8,0 cm



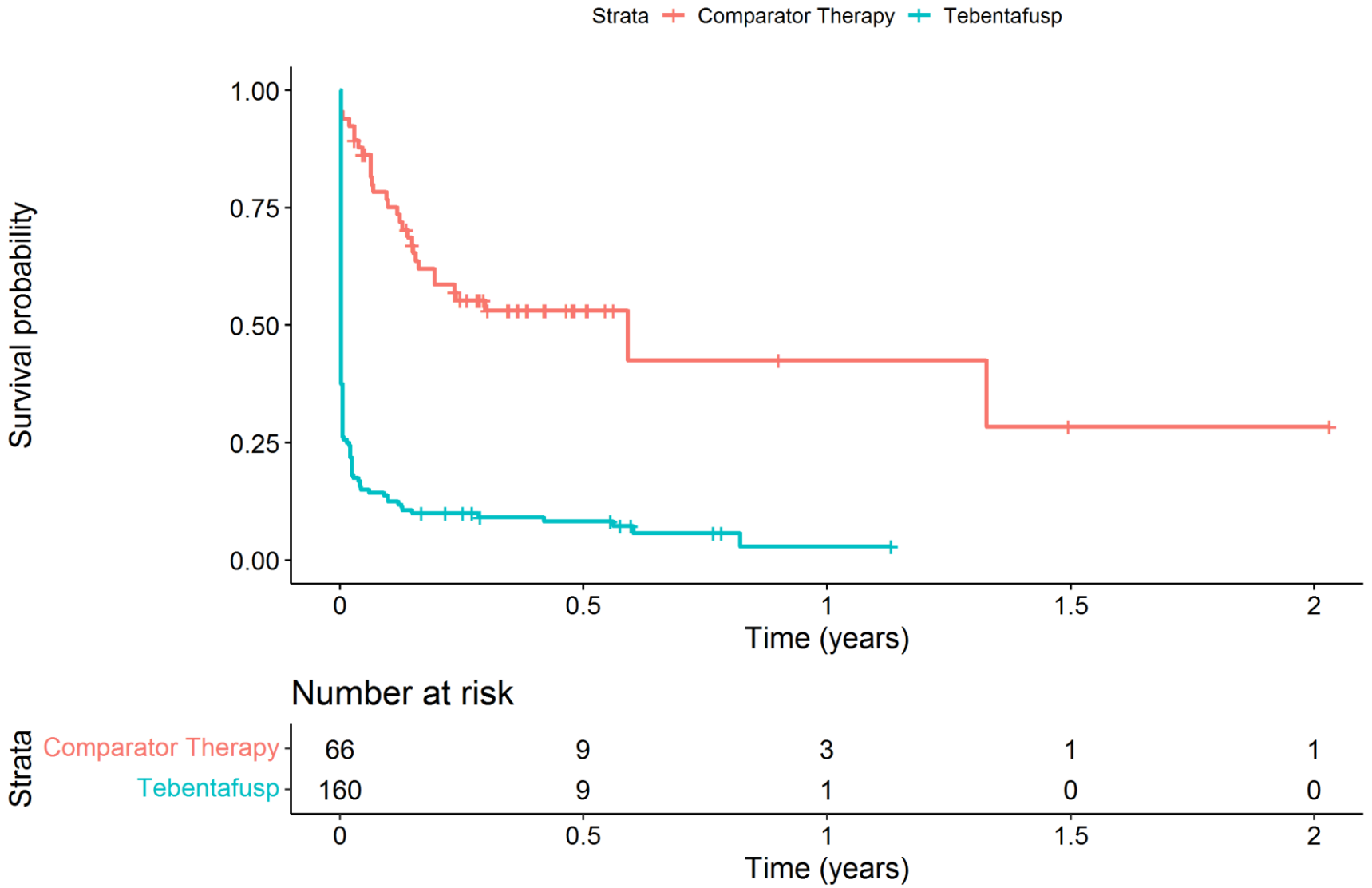
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion ≥8,1 cm



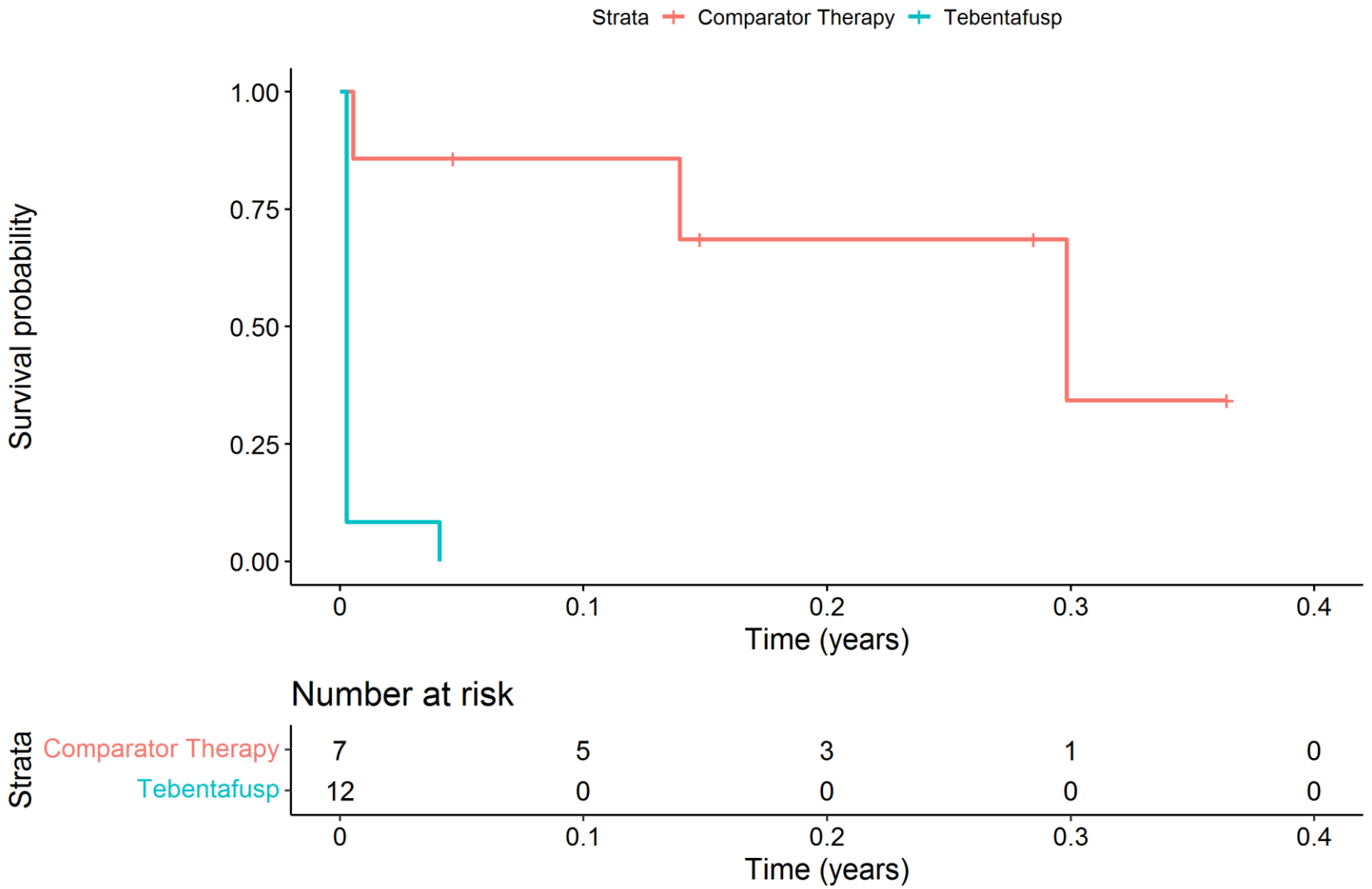
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nordamerika



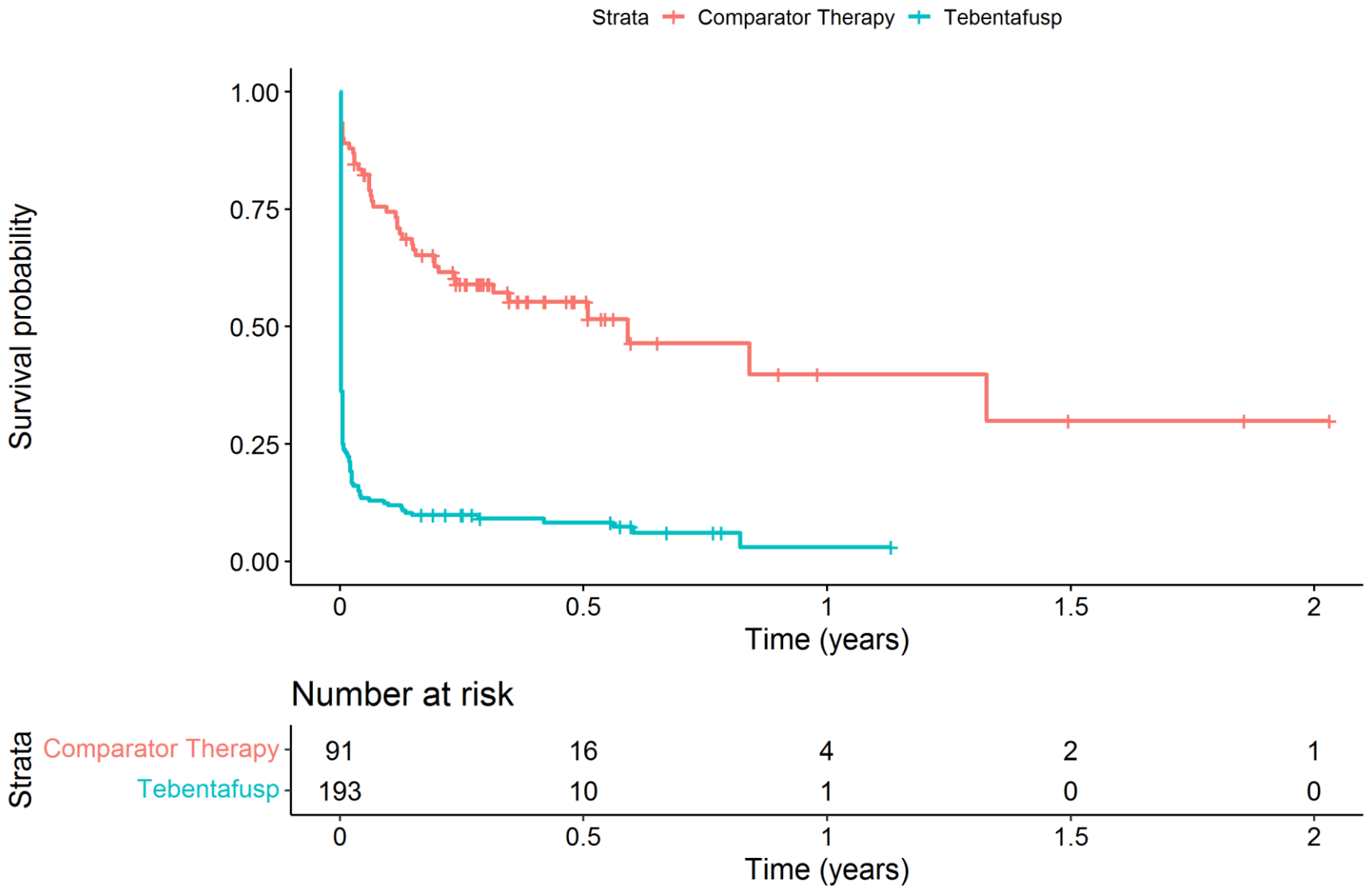
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nicht-Nordamerika



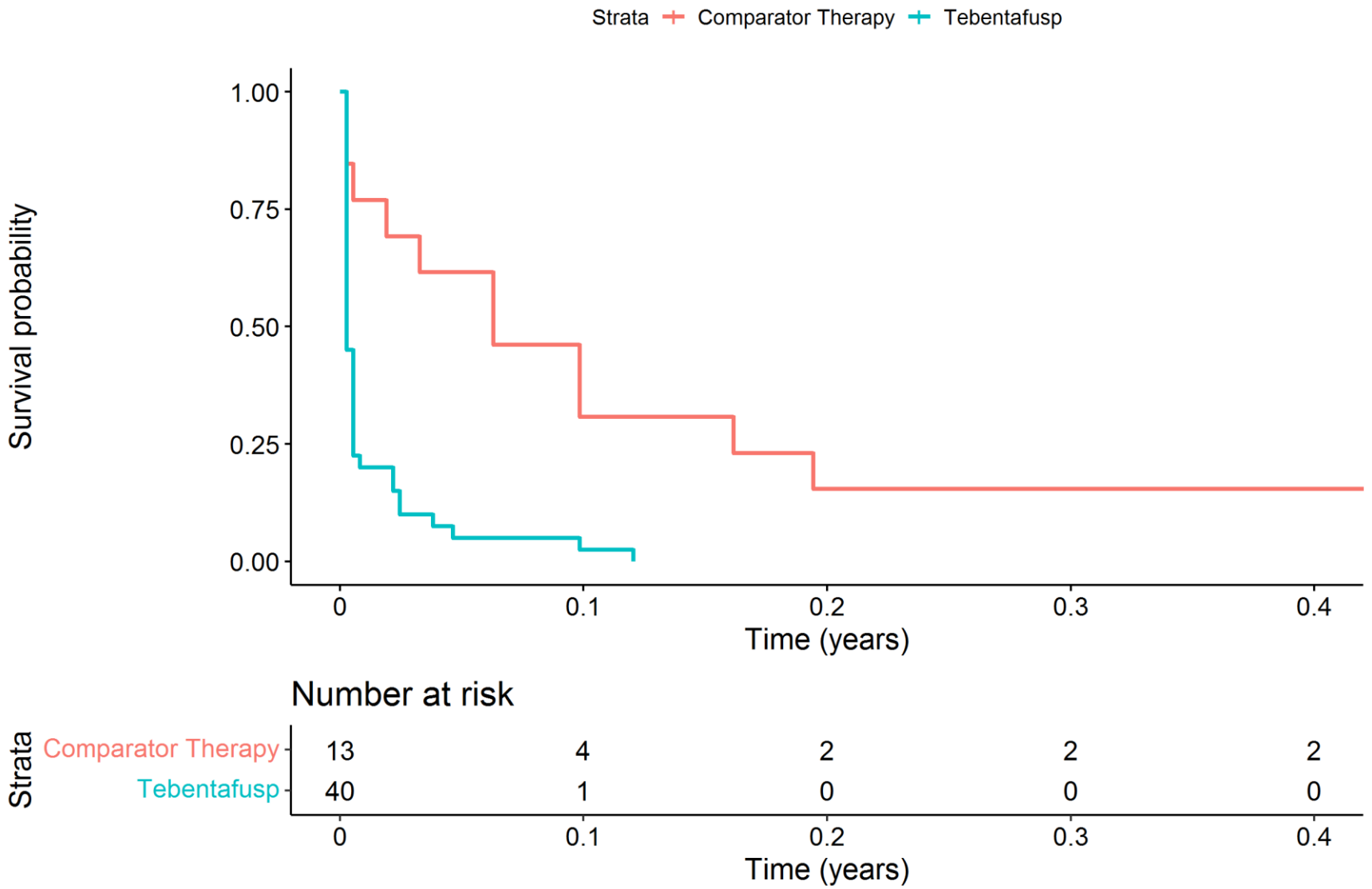
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Dacarbazin



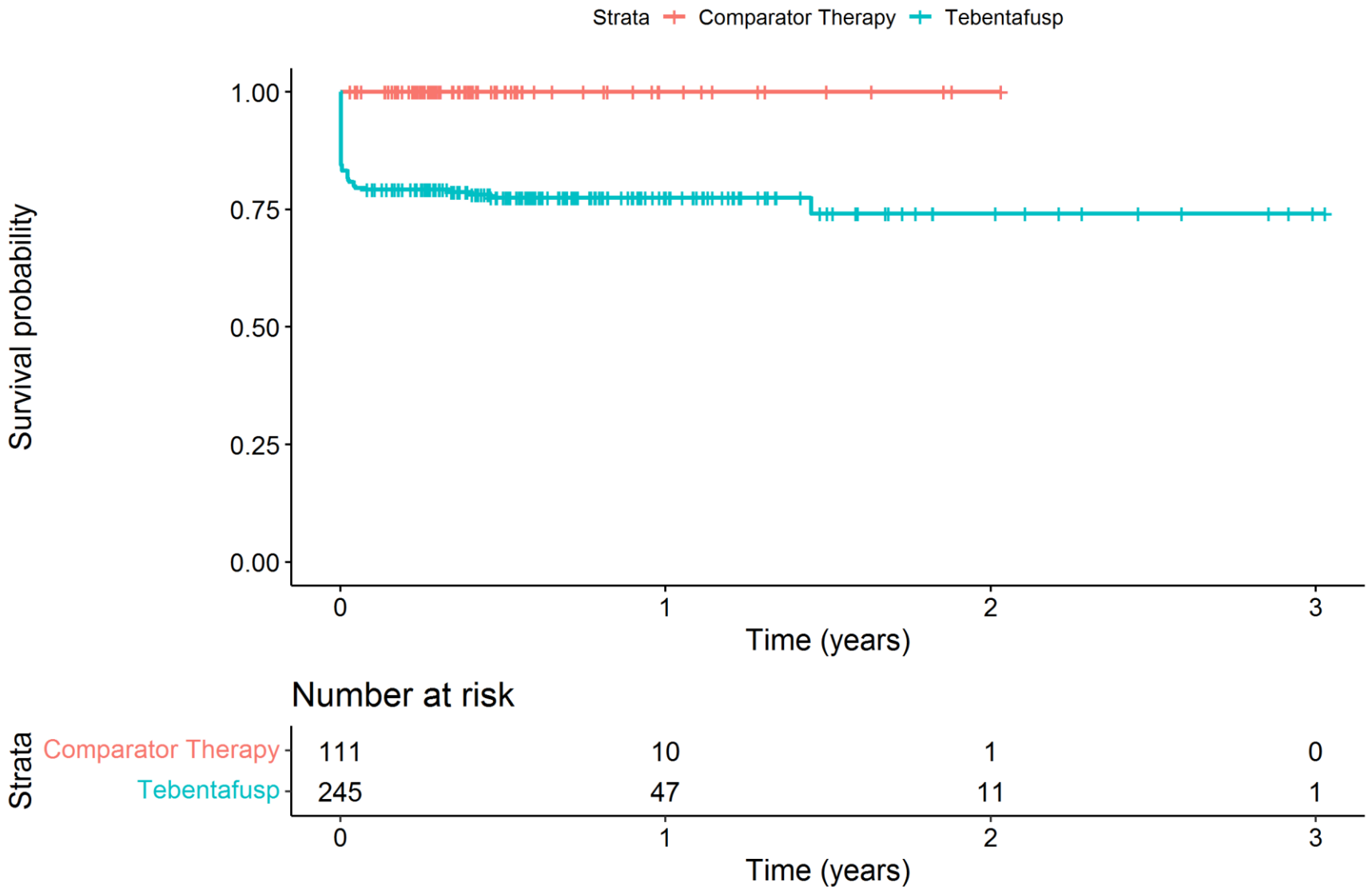
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Pembrolizumab



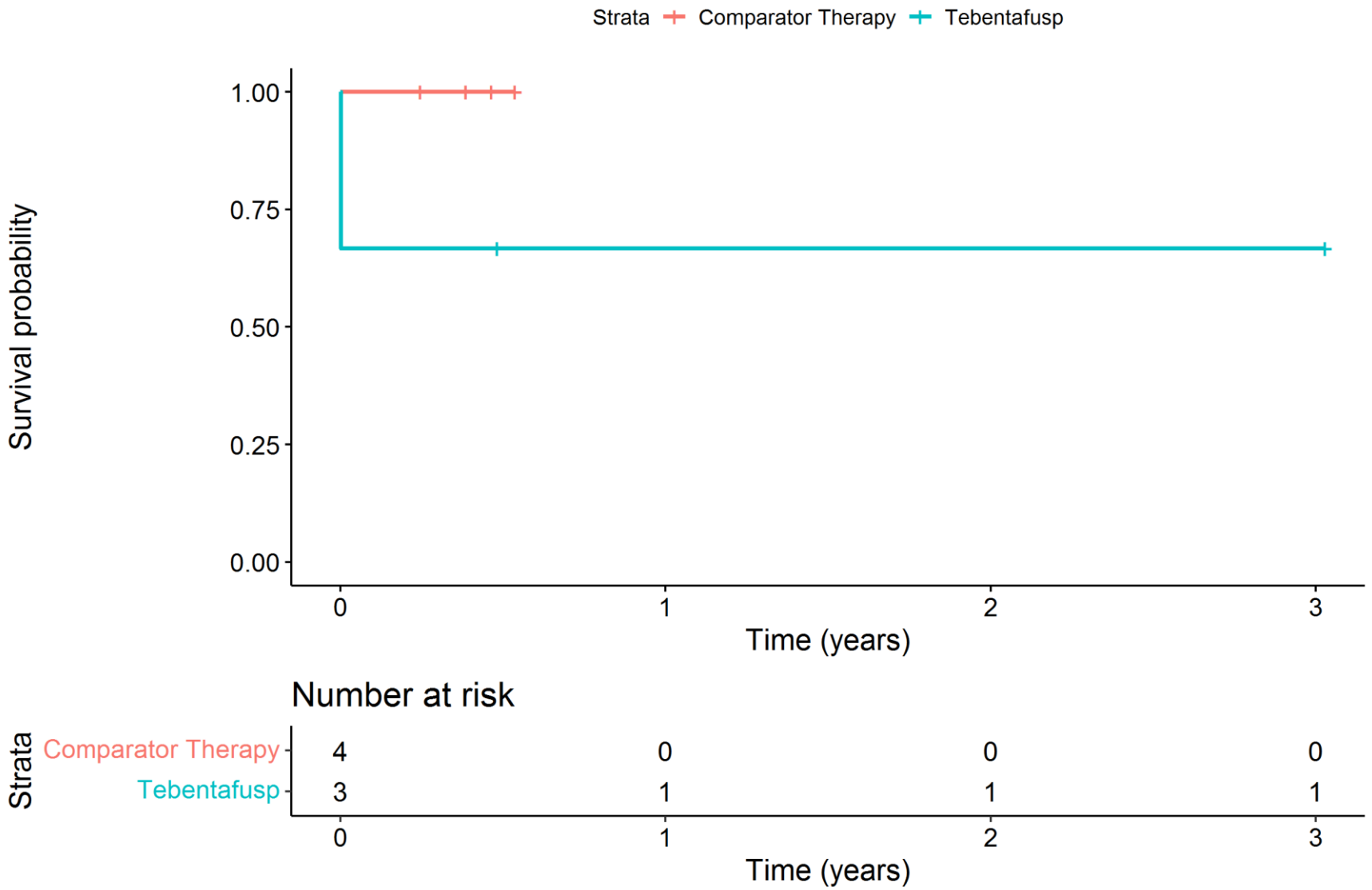
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Ipilimumab



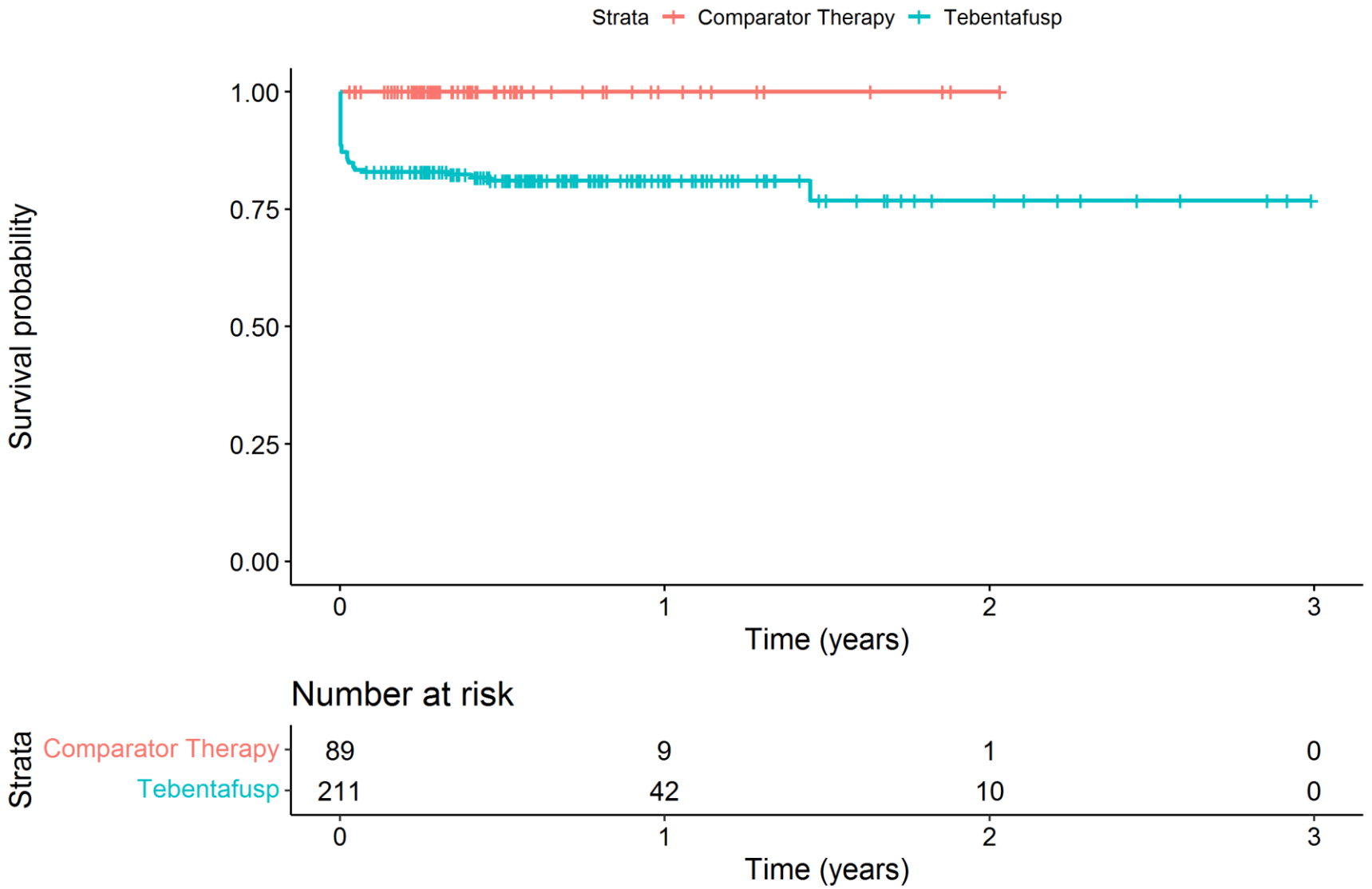
Erkrankungen des Immunsystems - Gesamt



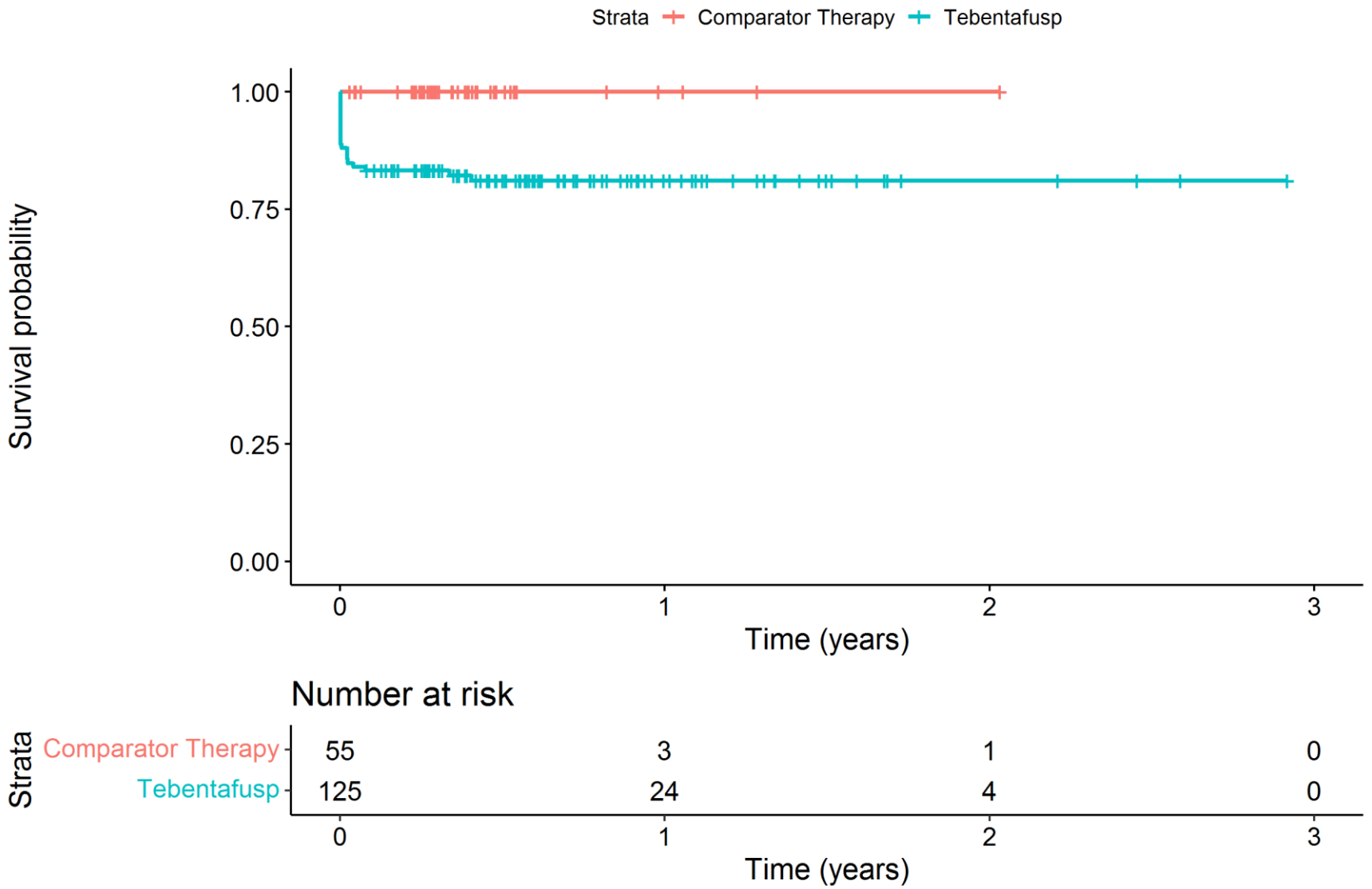
Erkrankungen des Immunsystems - Hispanisch



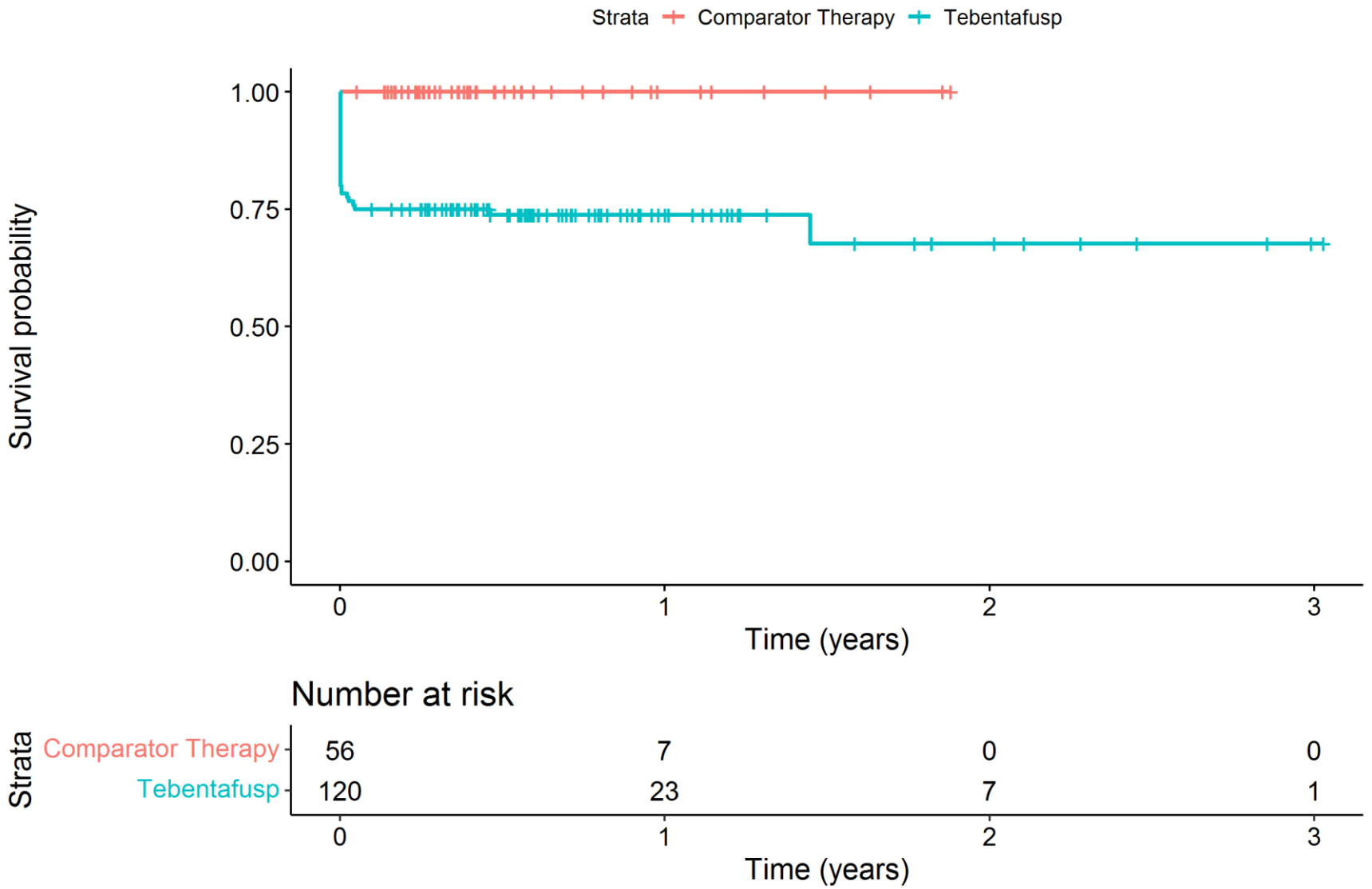
Erkrankungen des Immunsystems - Nicht-hispanisch



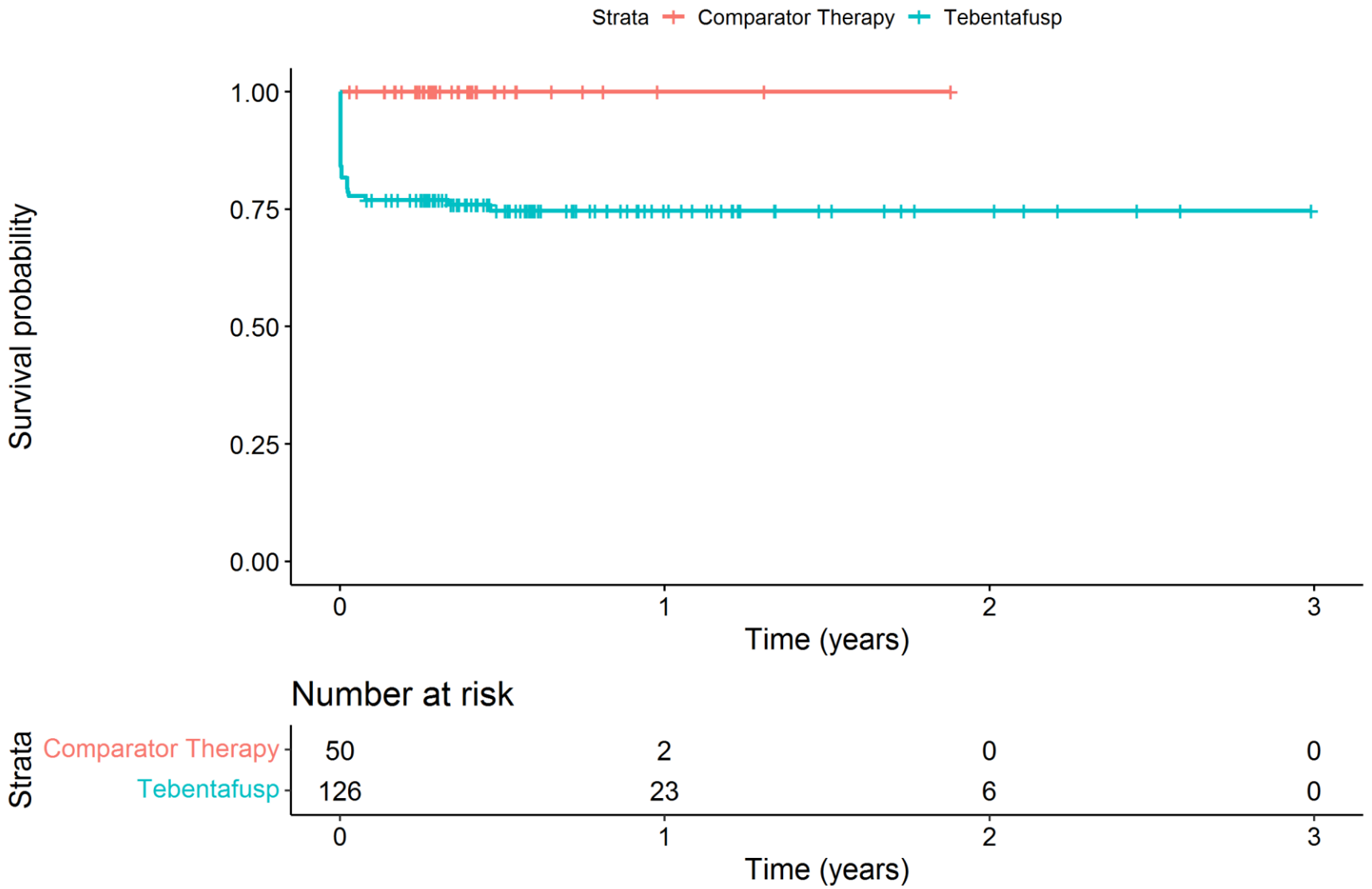
Erkrankungen des Immunsystems - Männlich



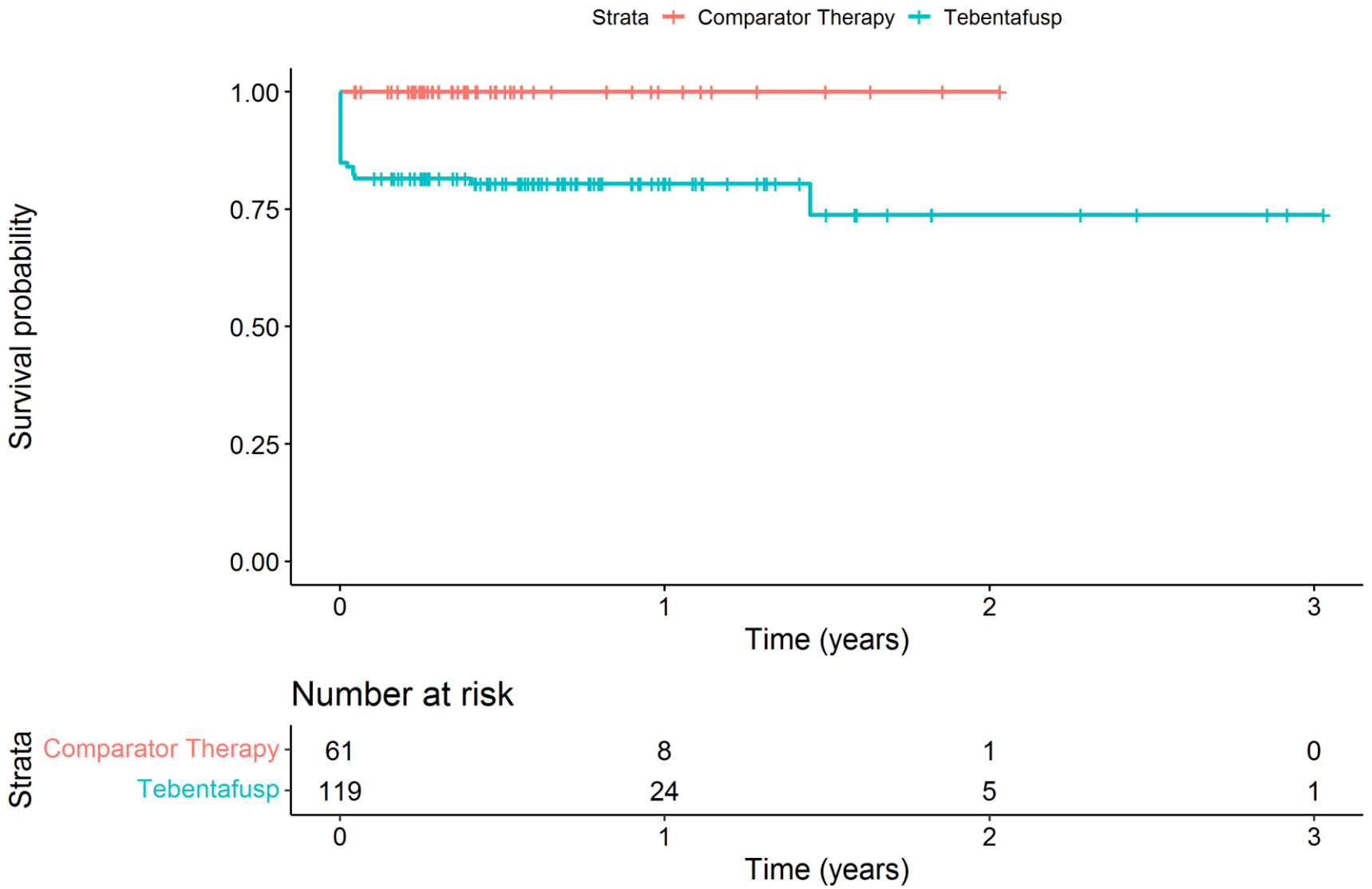
Erkrankungen des Immunsystems - Weiblich



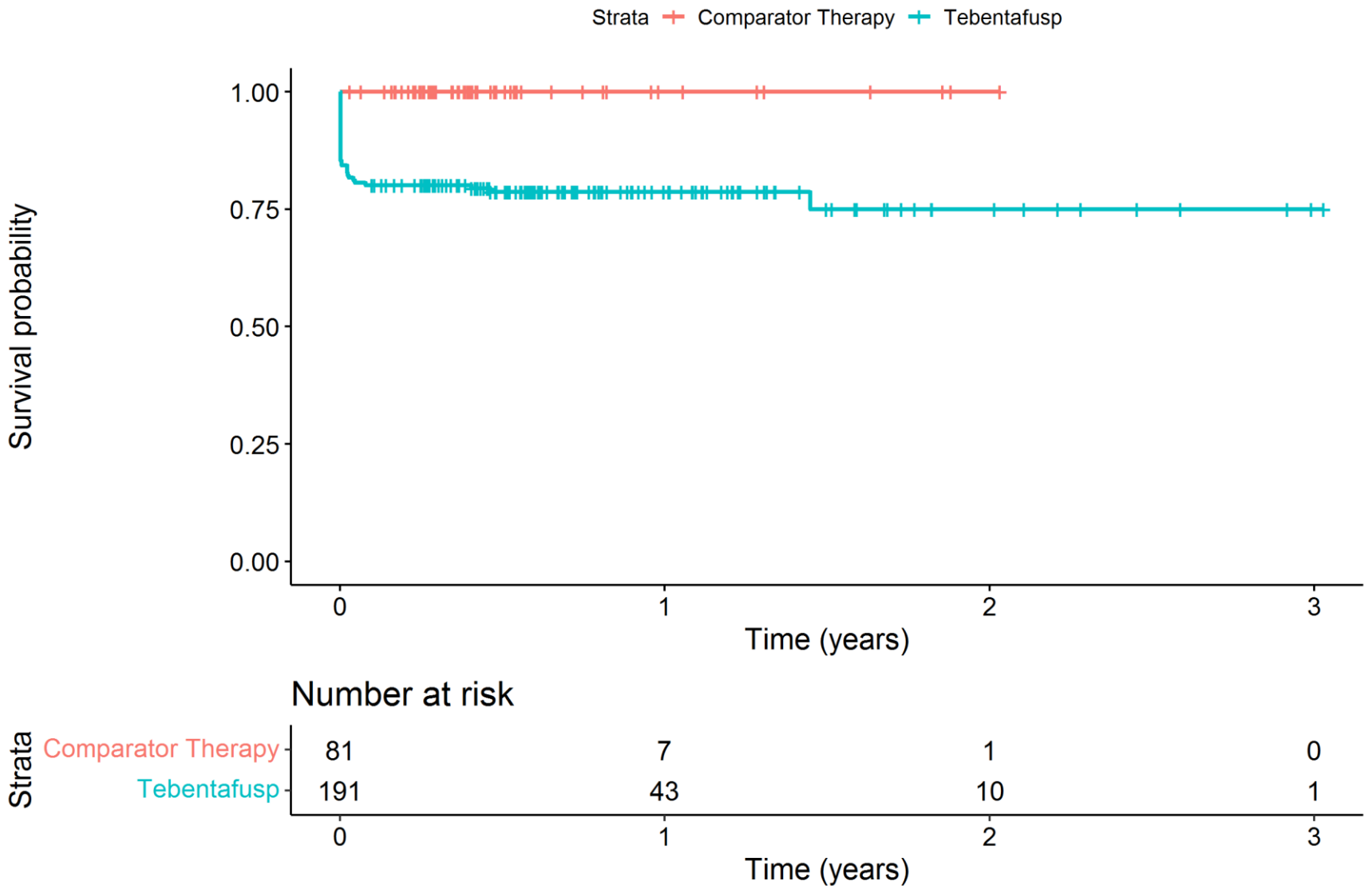
Erkrankungen des Immunsystems - <65



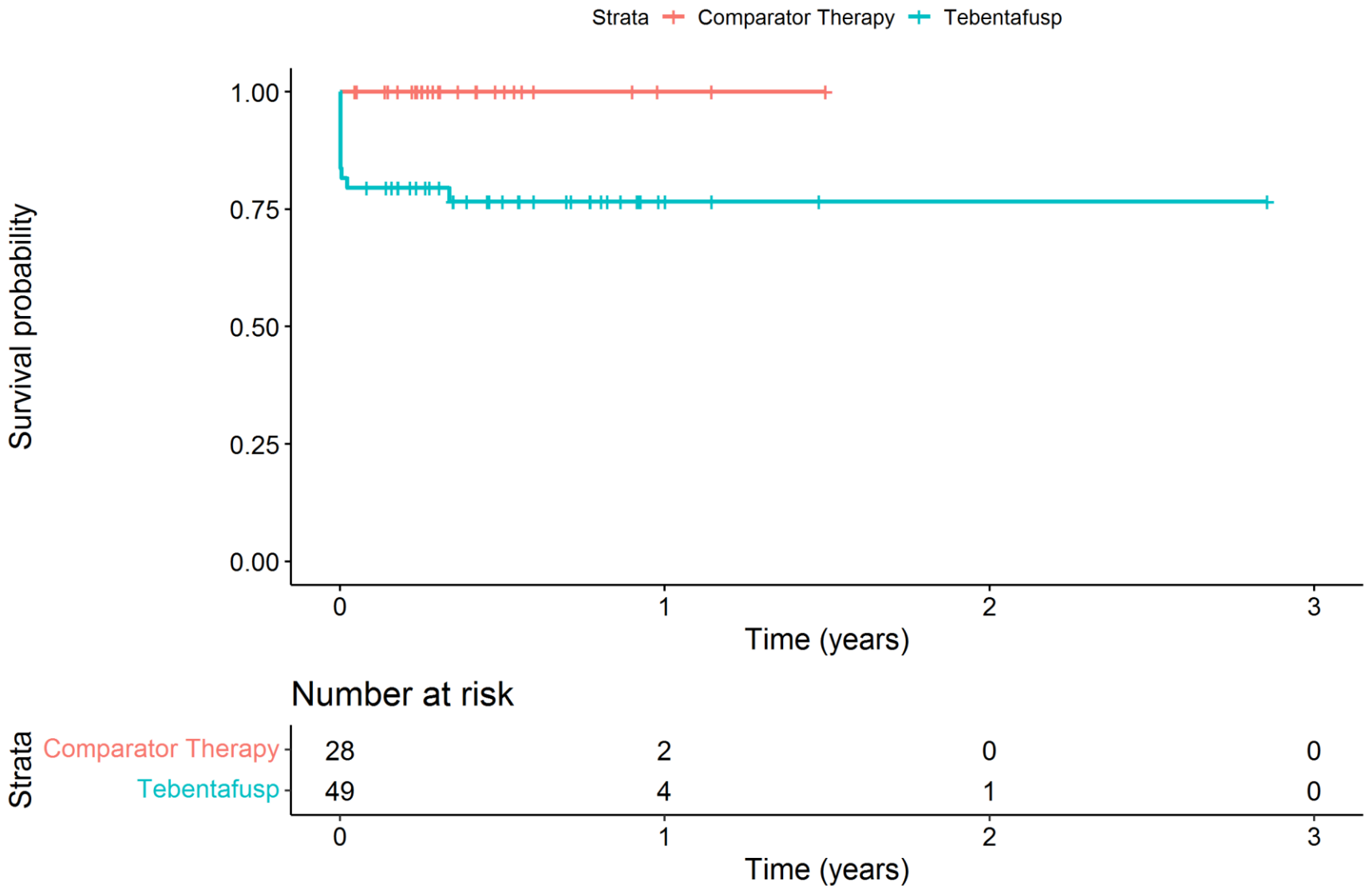
Erkrankungen des Immunsystems - ≥65



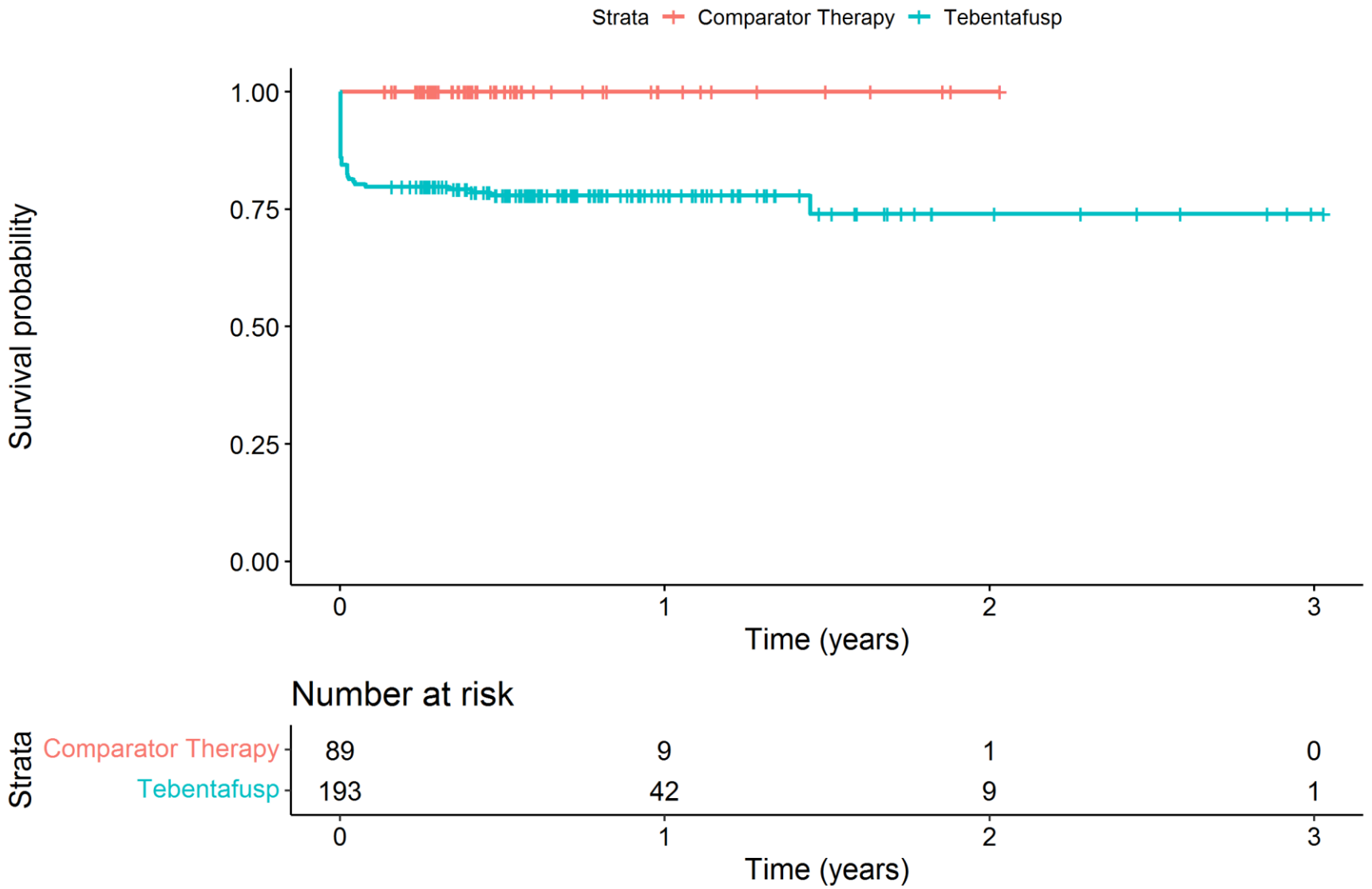
Erkrankungen des Immunsystems - ECOG 0



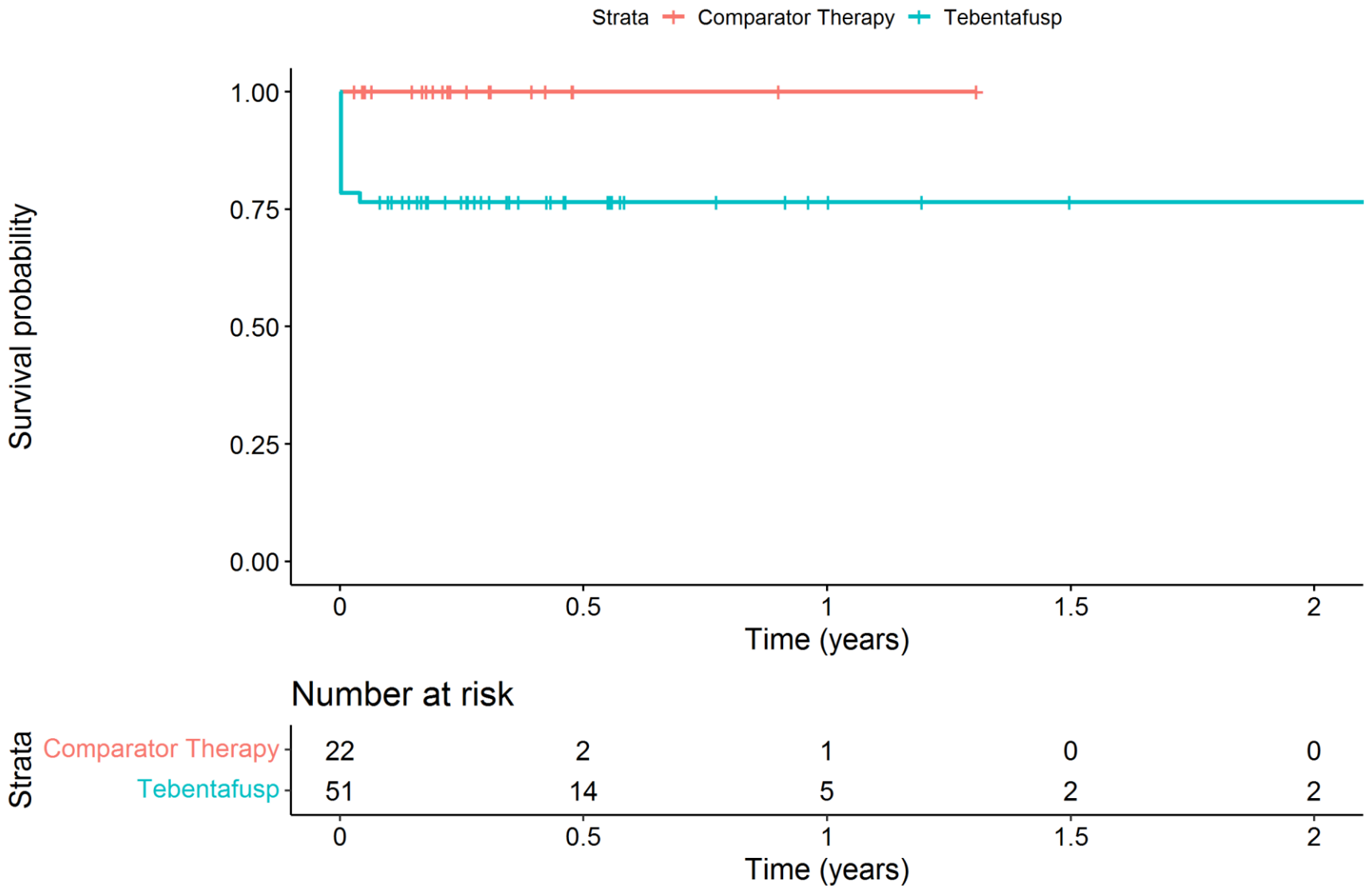
Erkrankungen des Immunsystems - ECOG 1



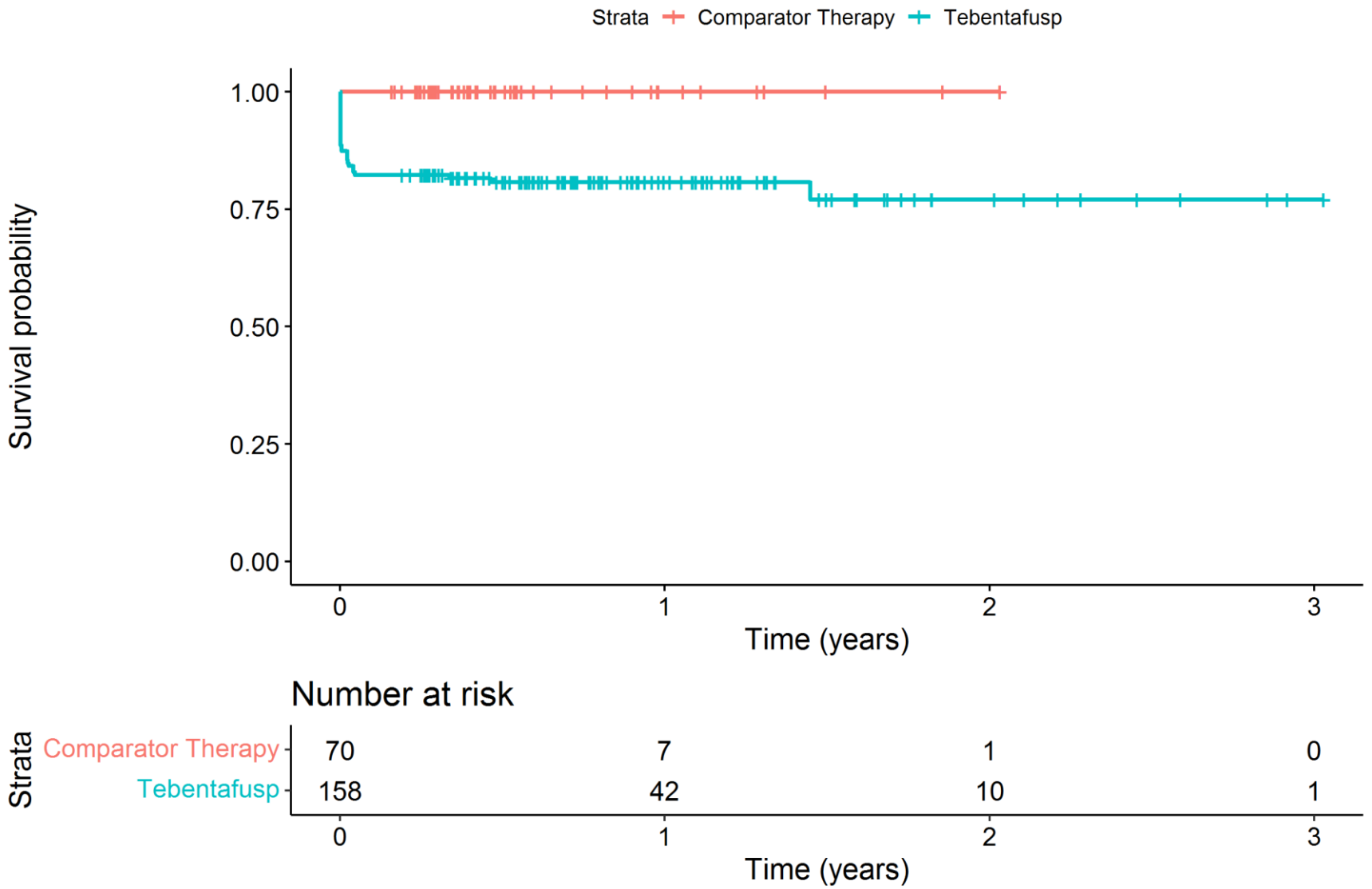
Erkrankungen des Immunsystems - ALP ≤ ULN



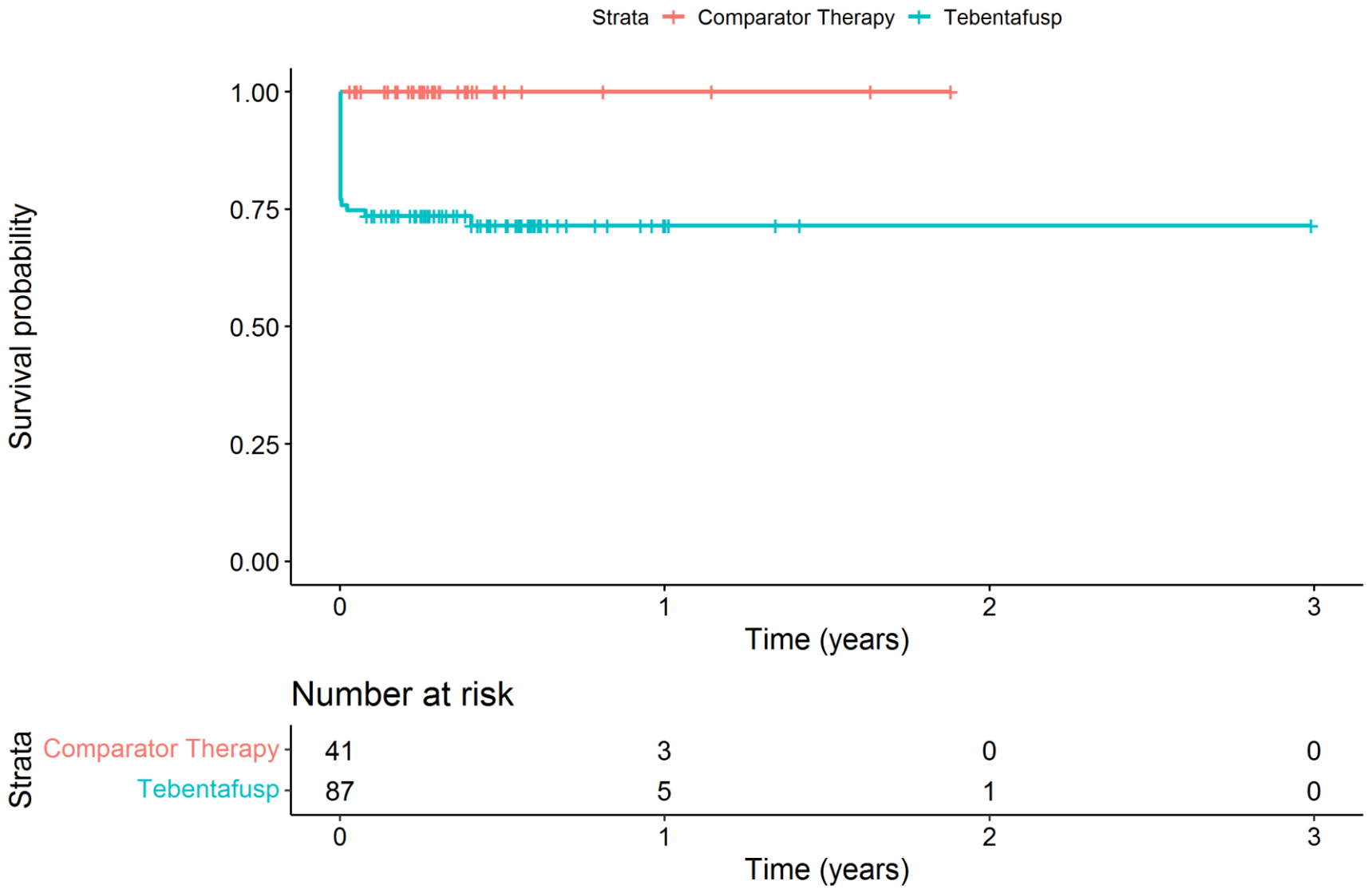
Erkrankungen des Immunsystems - ALP > ULN



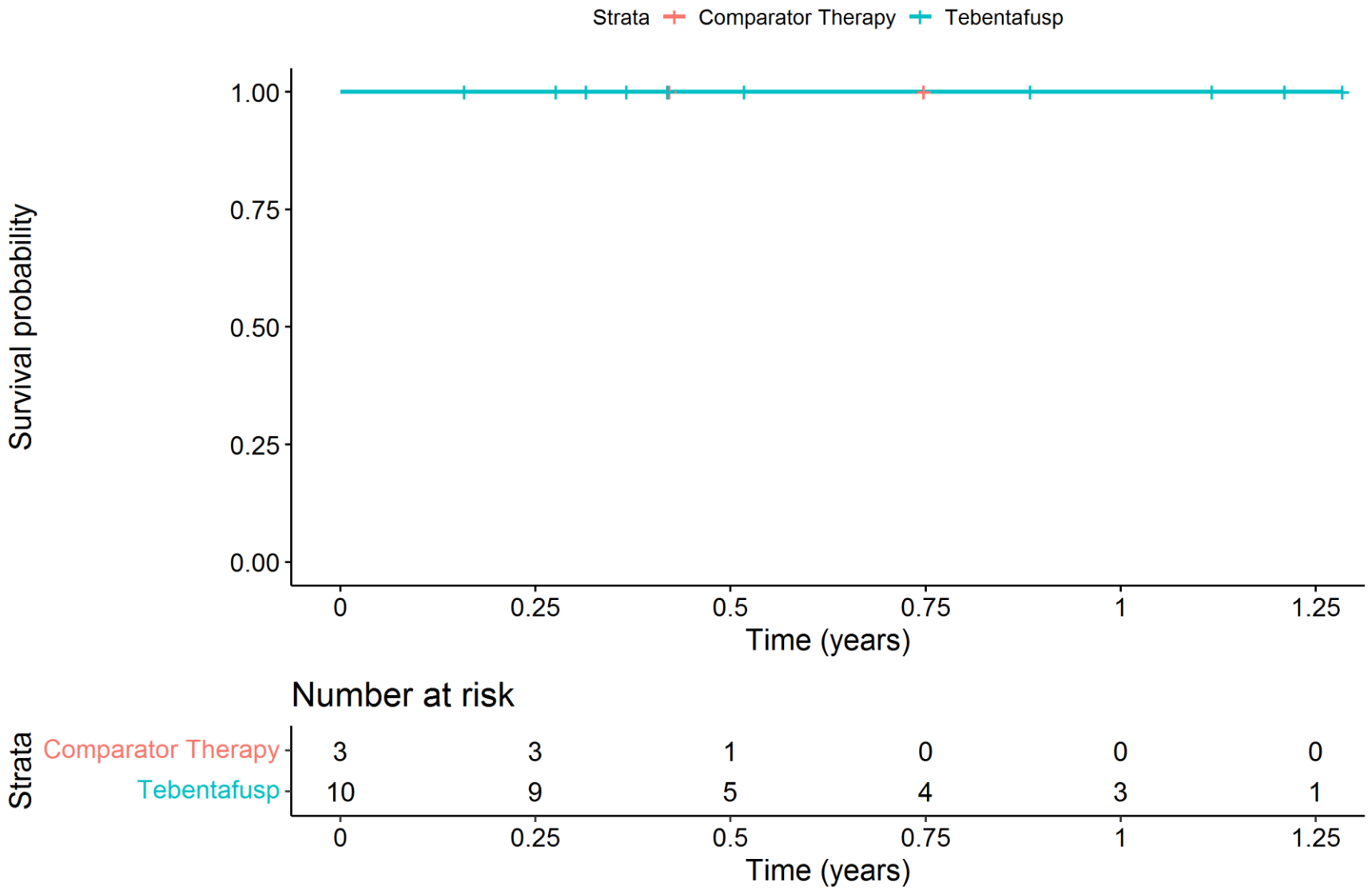
Erkrankungen des Immunsystems - LDH =< ULN



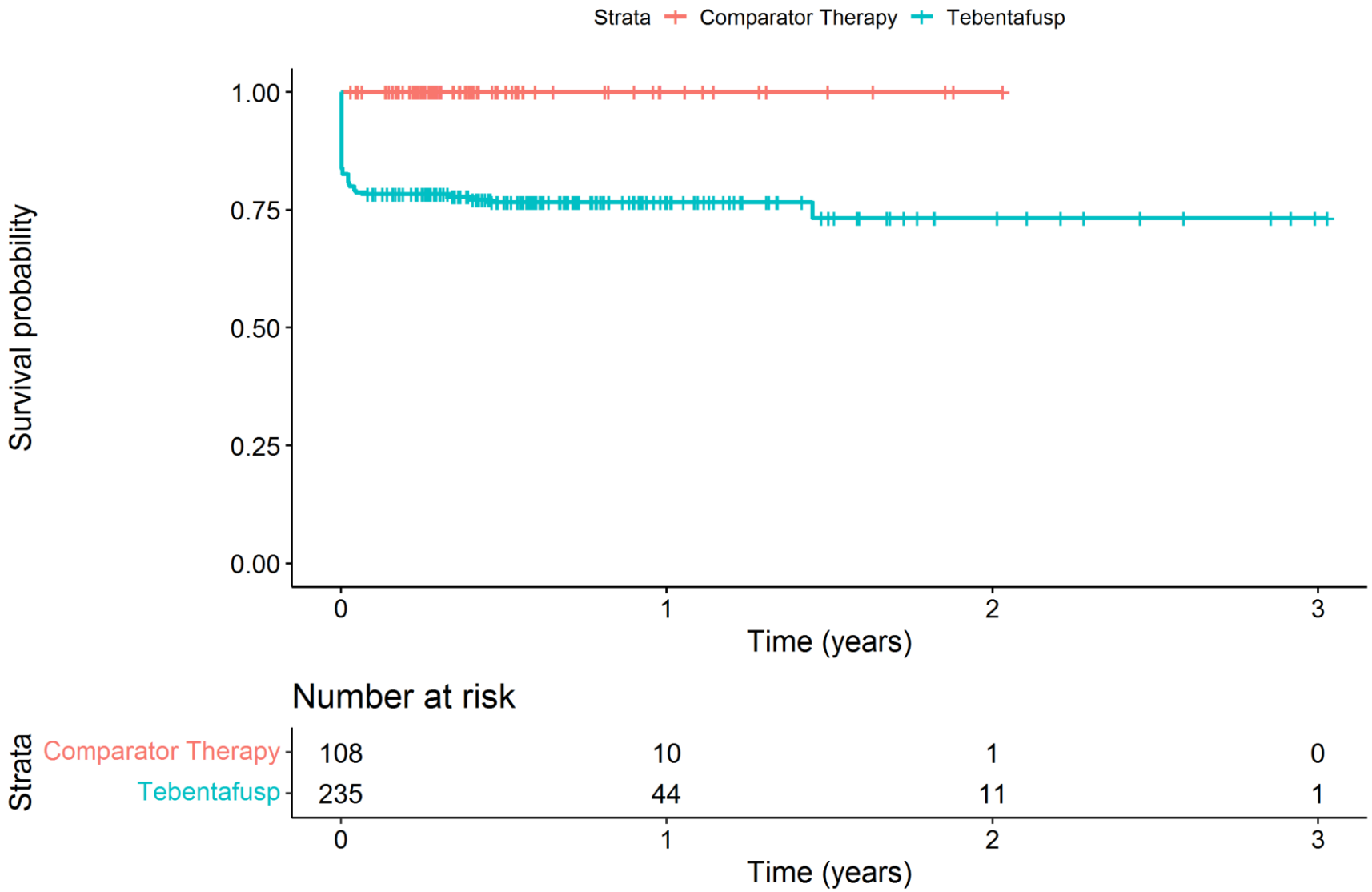
Erkrankungen des Immunsystems - LDH > ULN



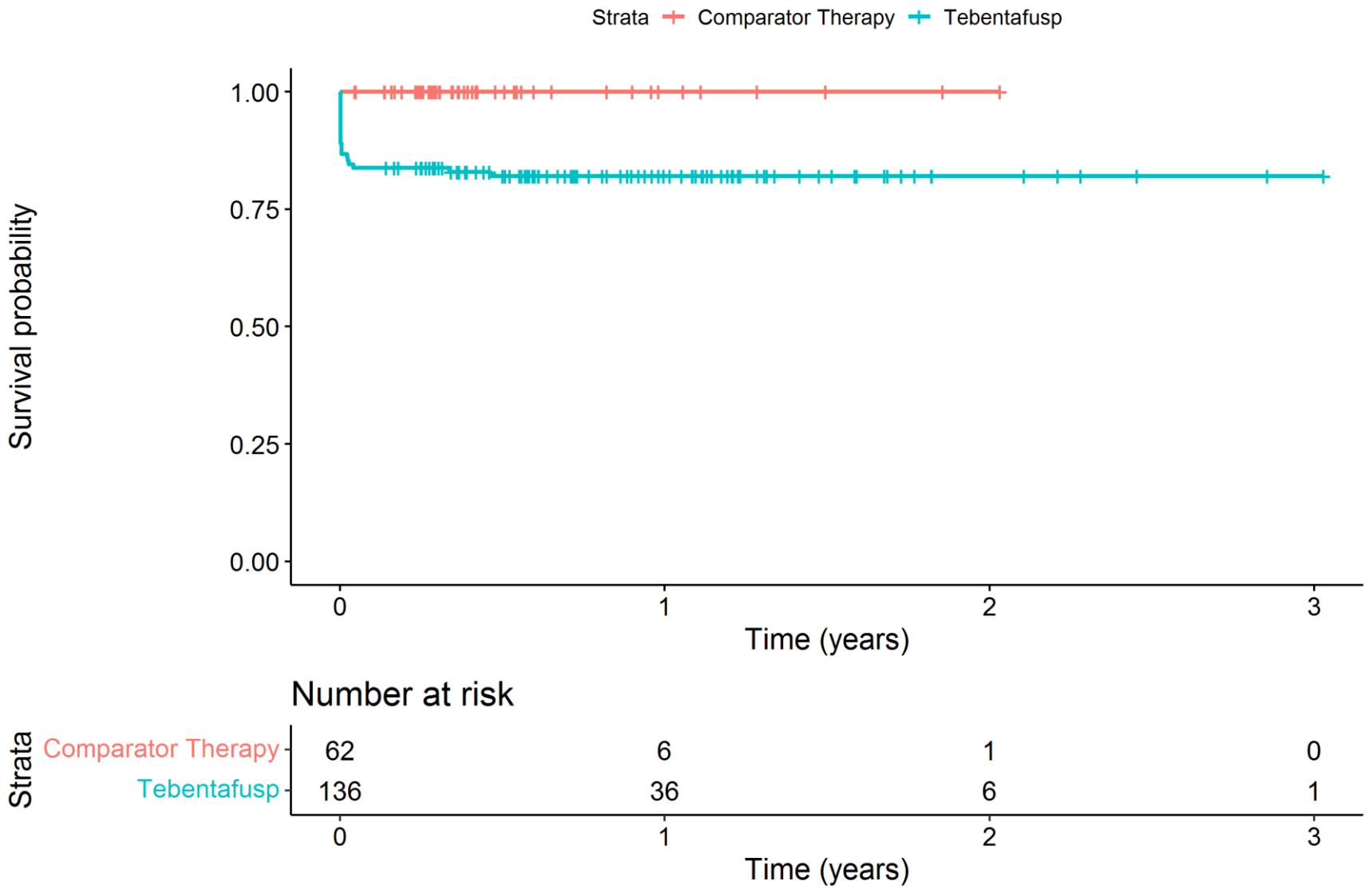
Erkrankungen des Immunsystems - Vorherige Therapie adjuvant/neoadjuvant



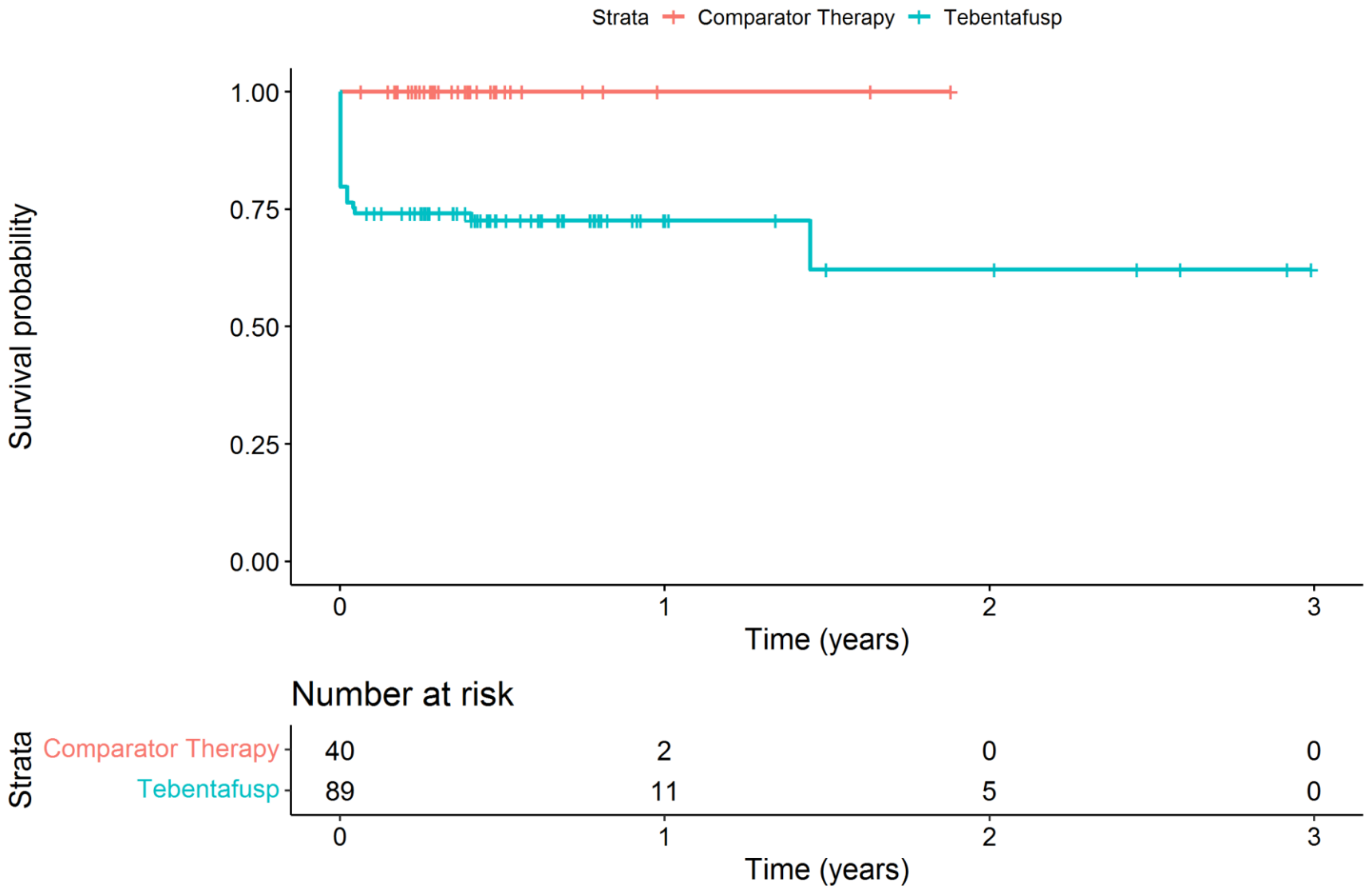
Erkrankungen des Immunsystems - Keine vorherige Therapie adjuvant/neoadjuvant



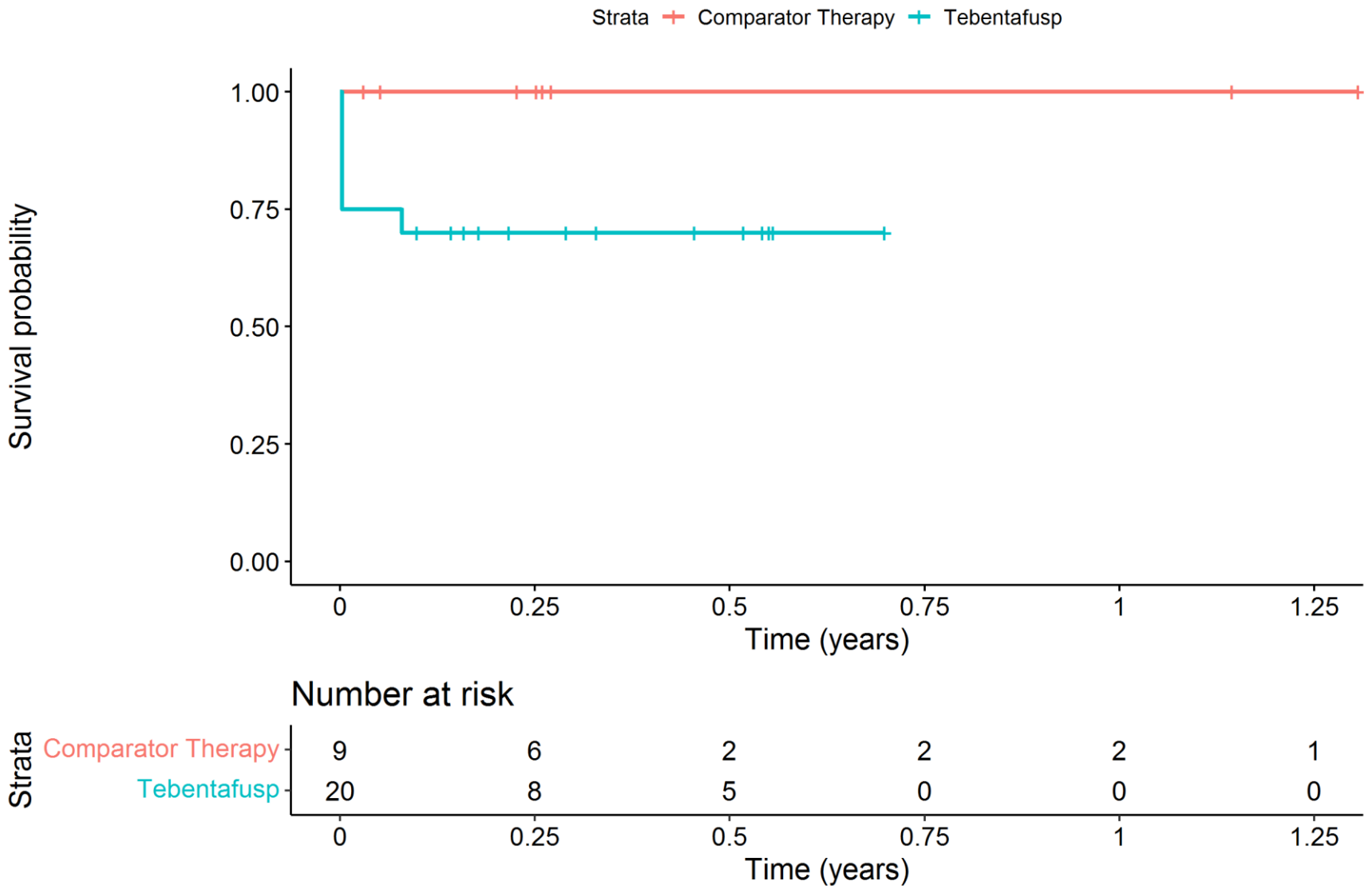
Erkrankungen des Immunsystems - Läsion ≤ 3cm



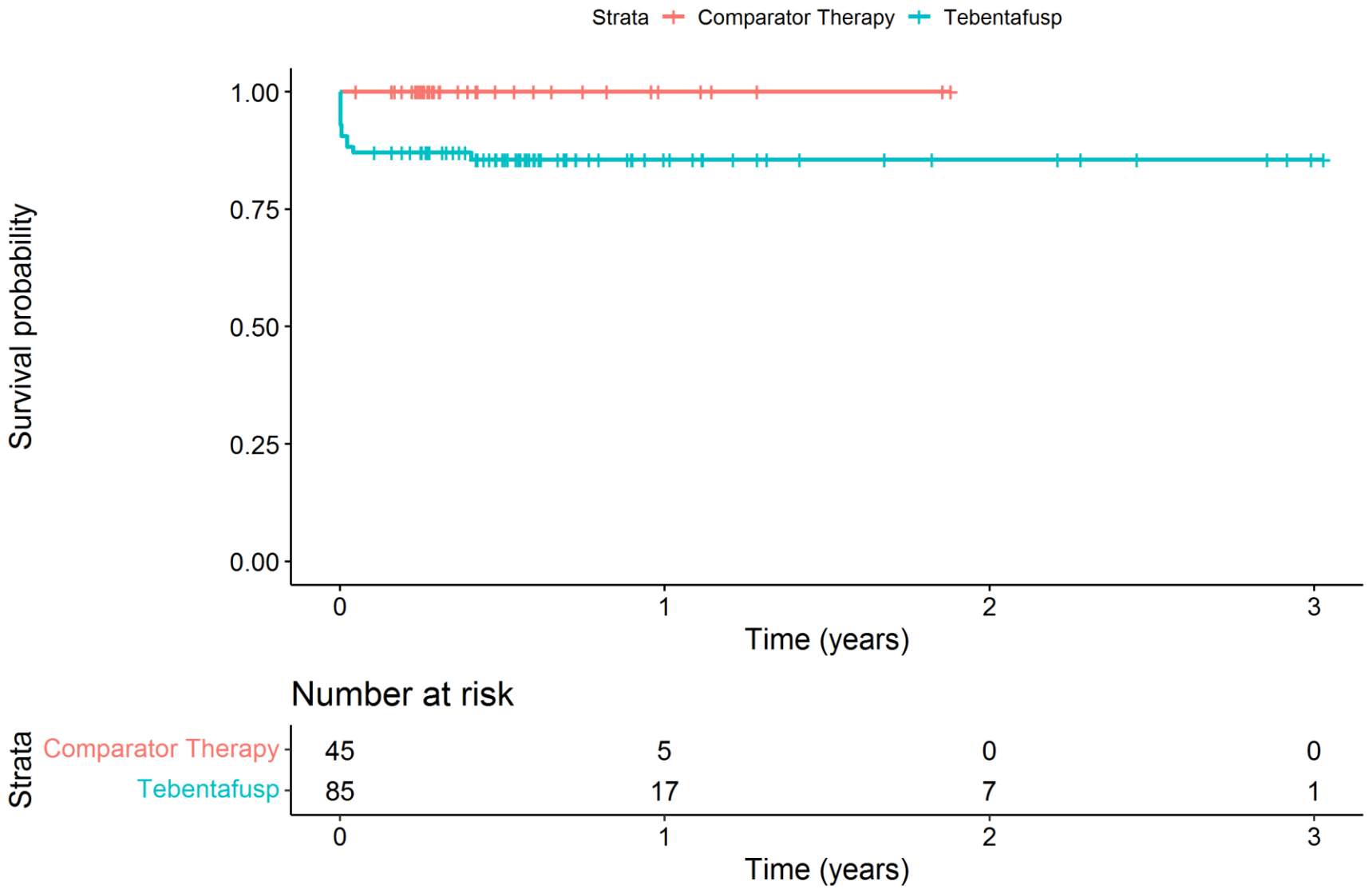
Erkrankungen des Immunsystems - Läsion 3,1-8,0 cm



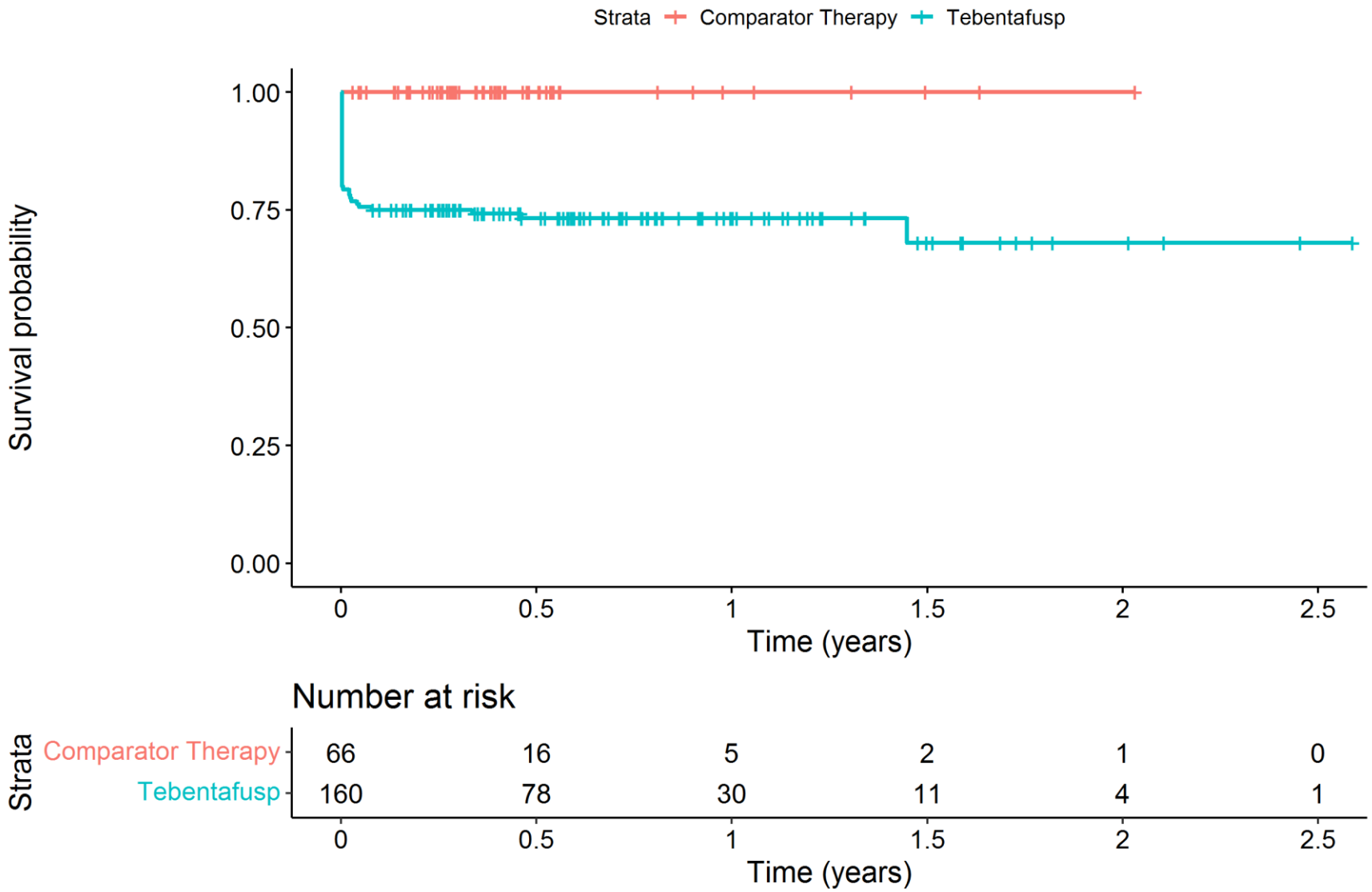
Erkrankungen des Immunsystems - Läsion ≥8,1 cm



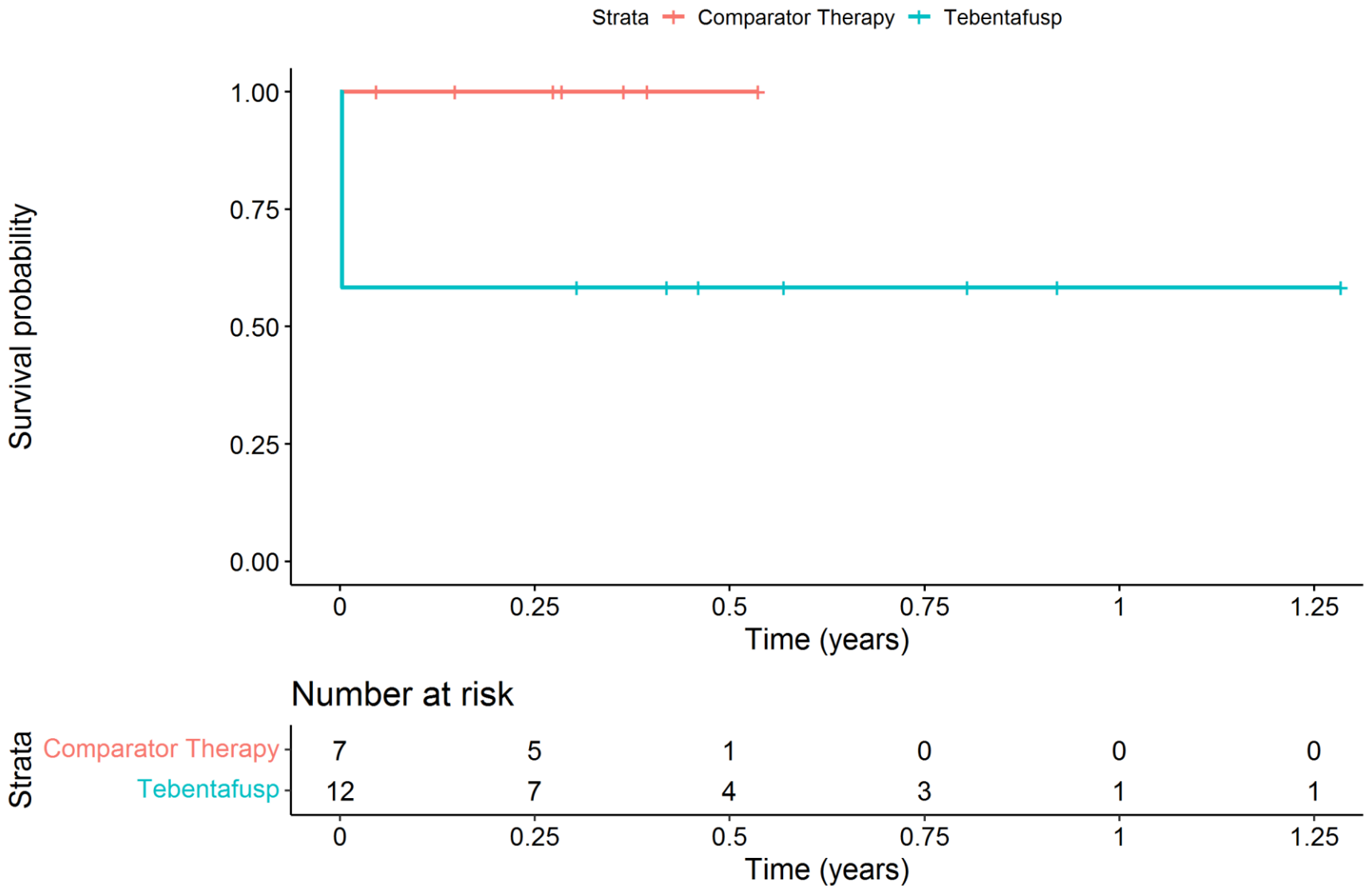
Erkrankungen des Immunsystems - Nordamerika



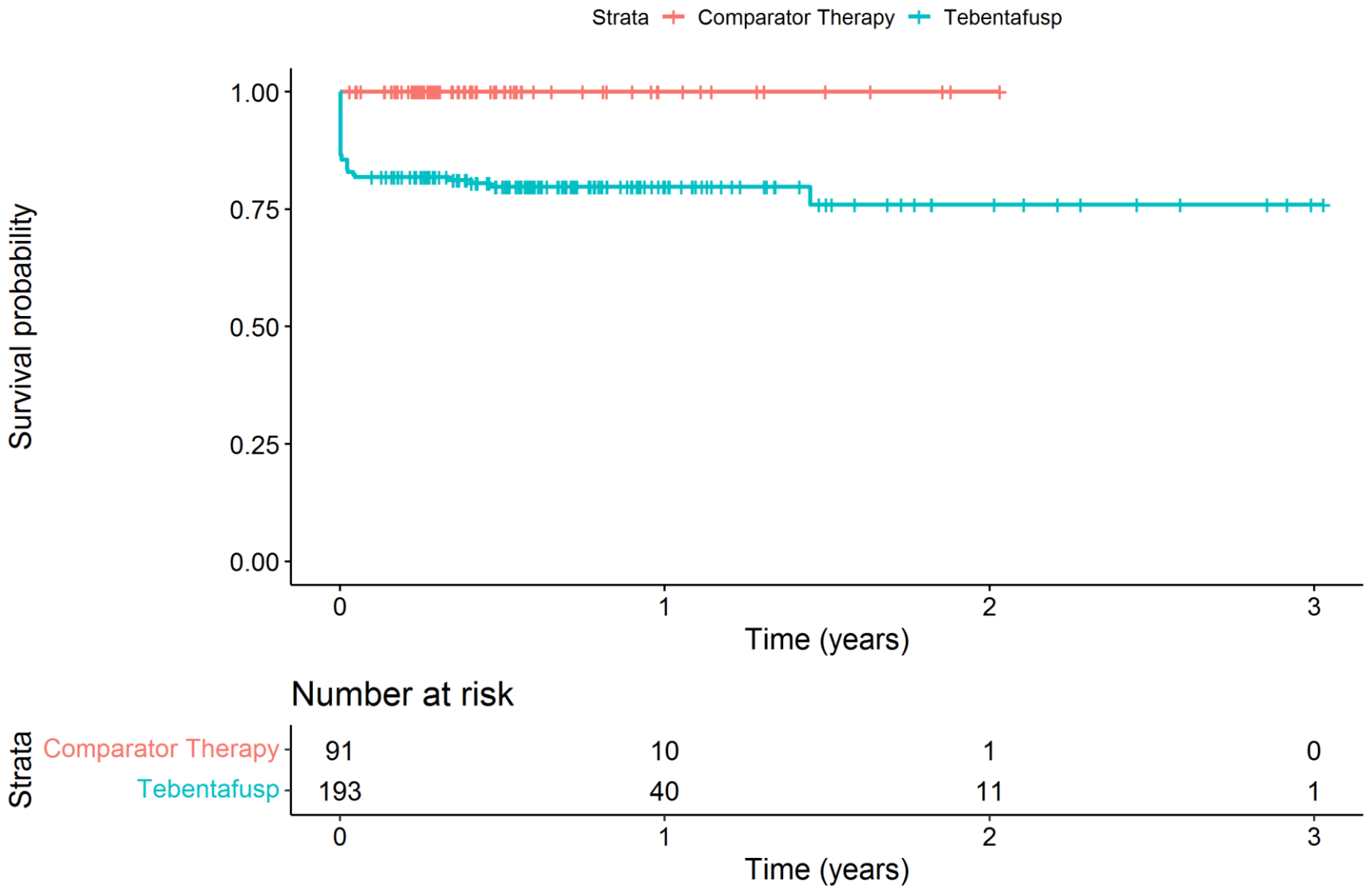
Erkrankungen des Immunsystems - Nicht-Nordamerika



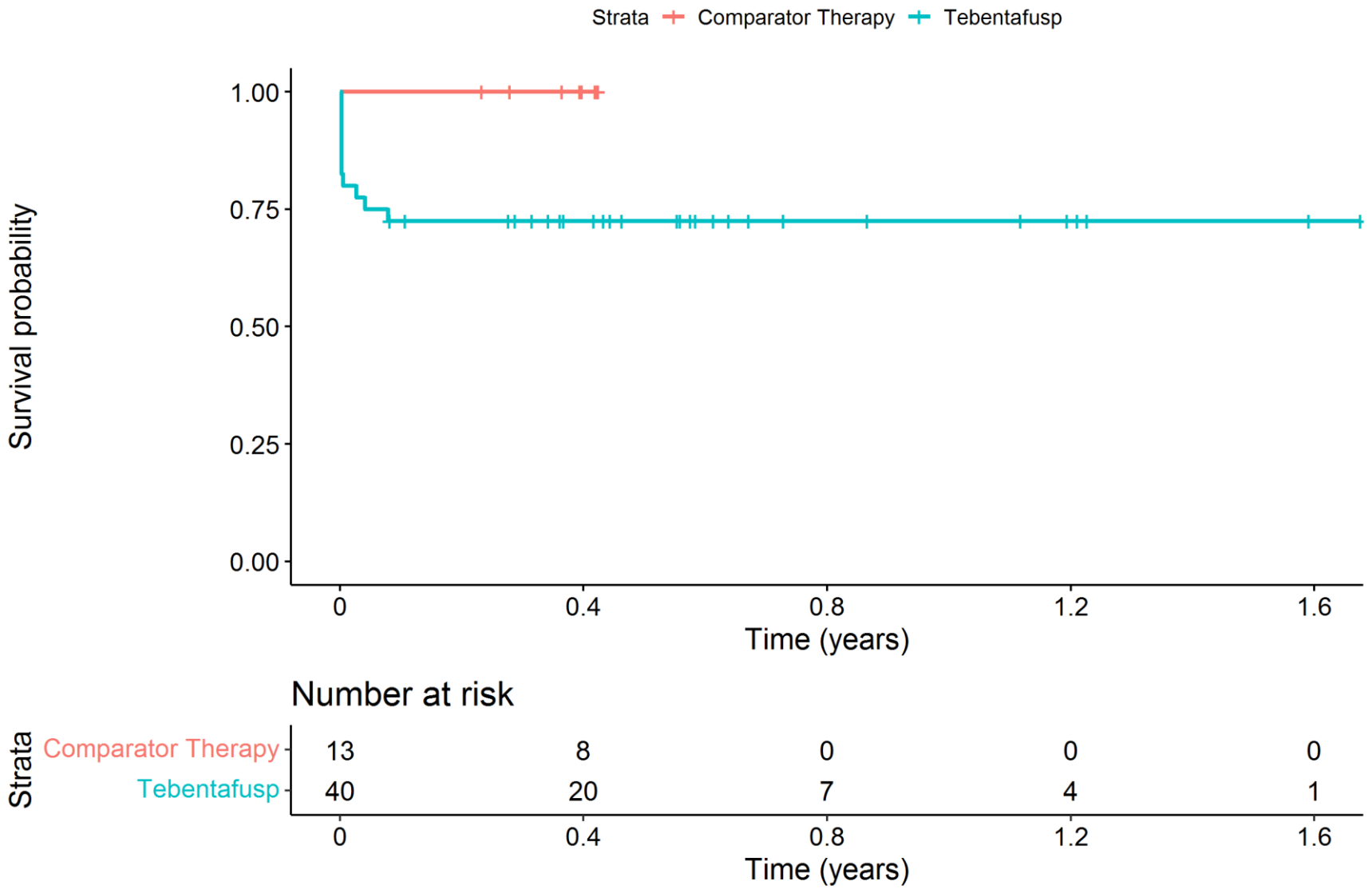
Erkrankungen des Immunsystems - Dacarbazin



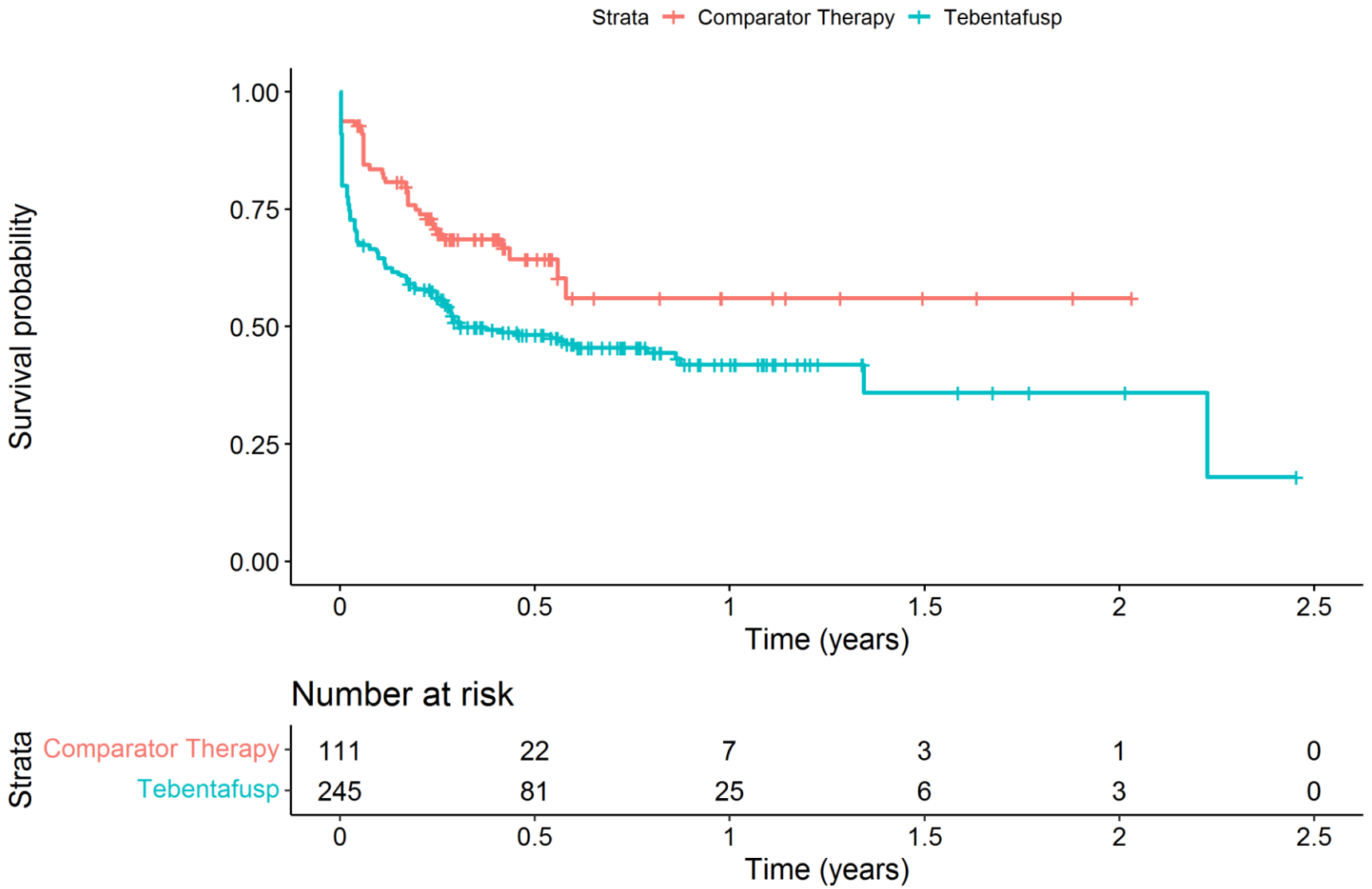
Erkrankungen des Immunsystems - Pembrolizumab



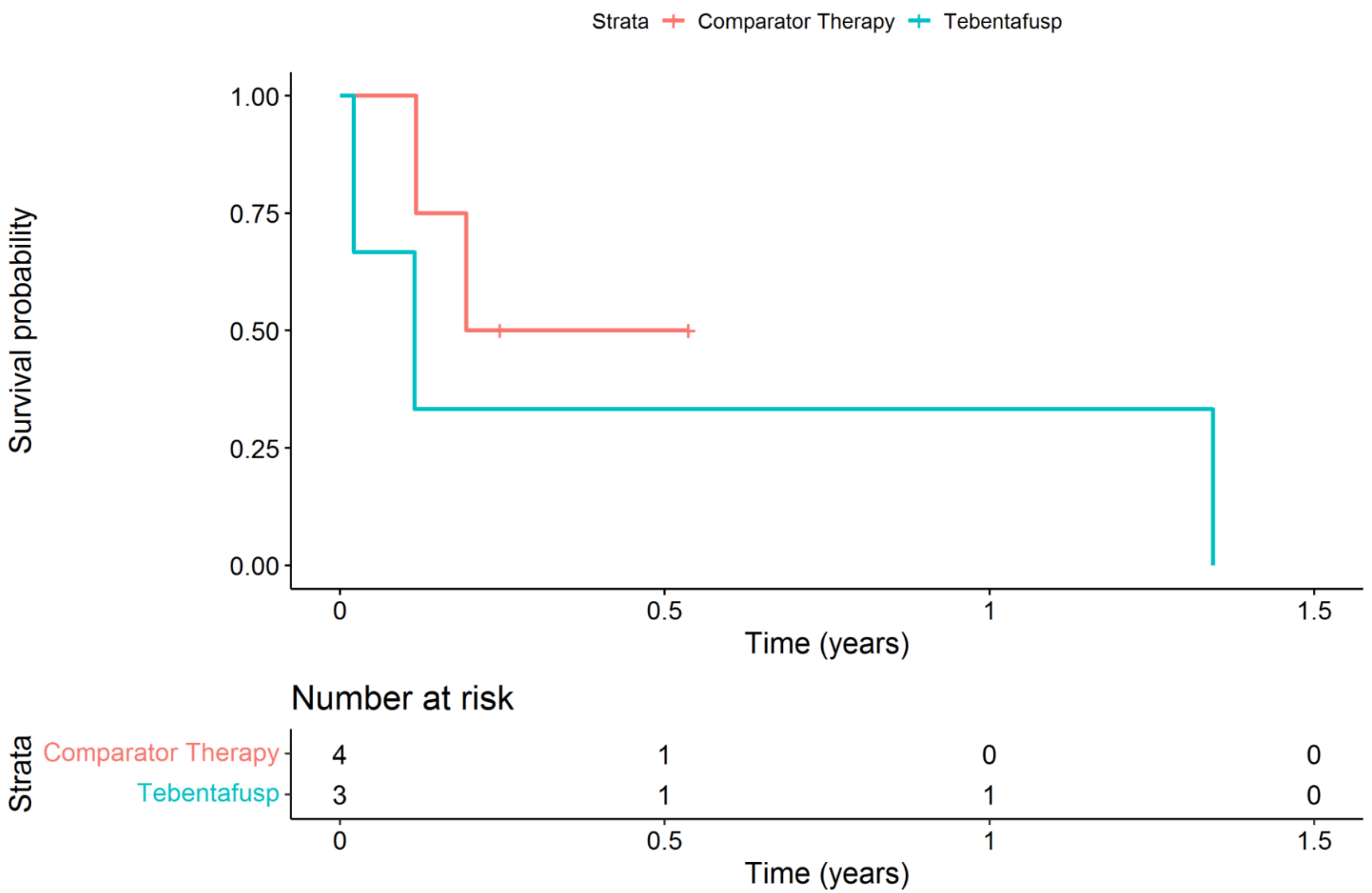
Erkrankungen des Immunsystems - Ipilimumab



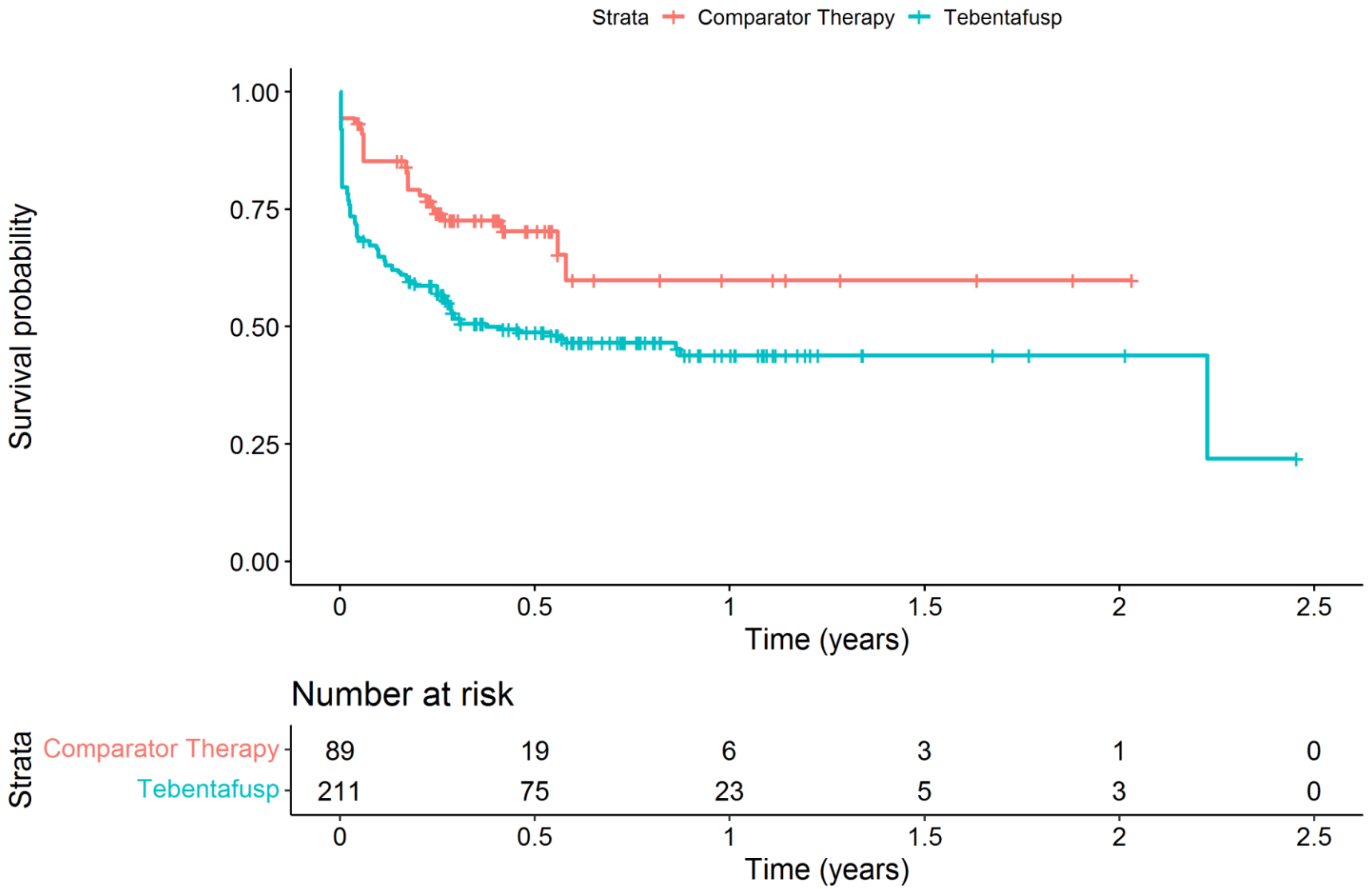
Untersuchungen - Gesamt



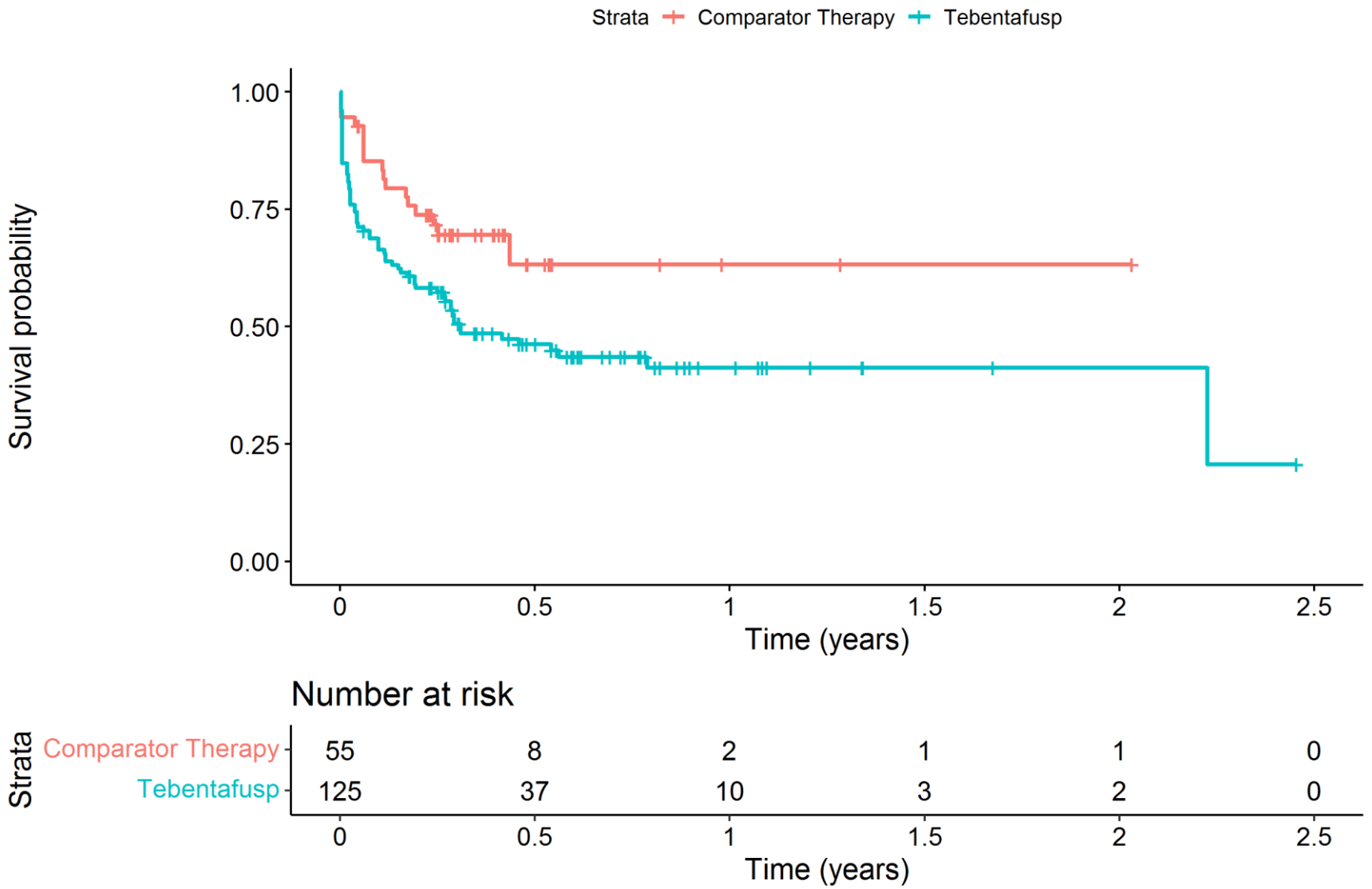
Untersuchungen - Hispanisch



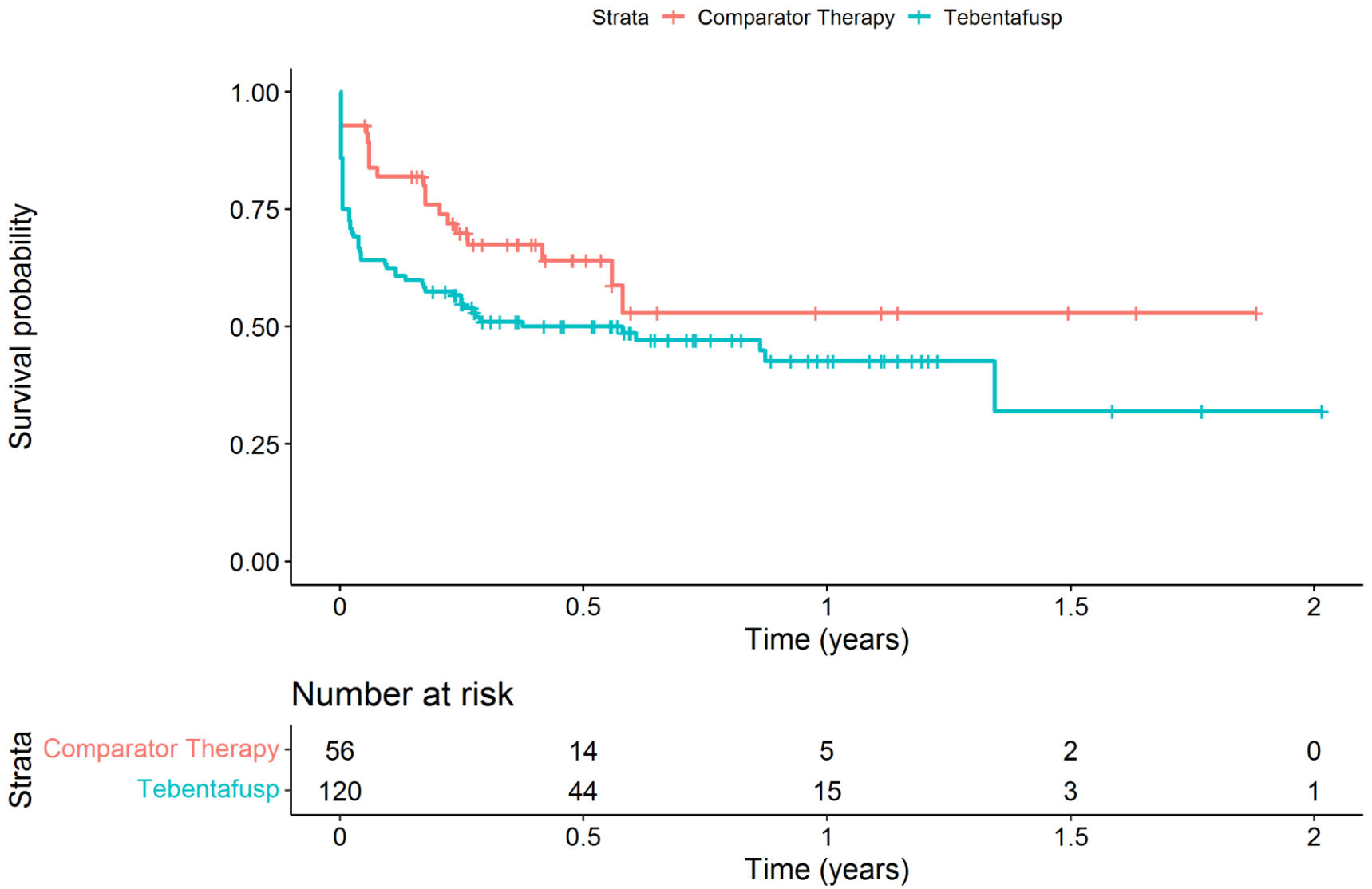
Untersuchungen - Nicht-hispanisch



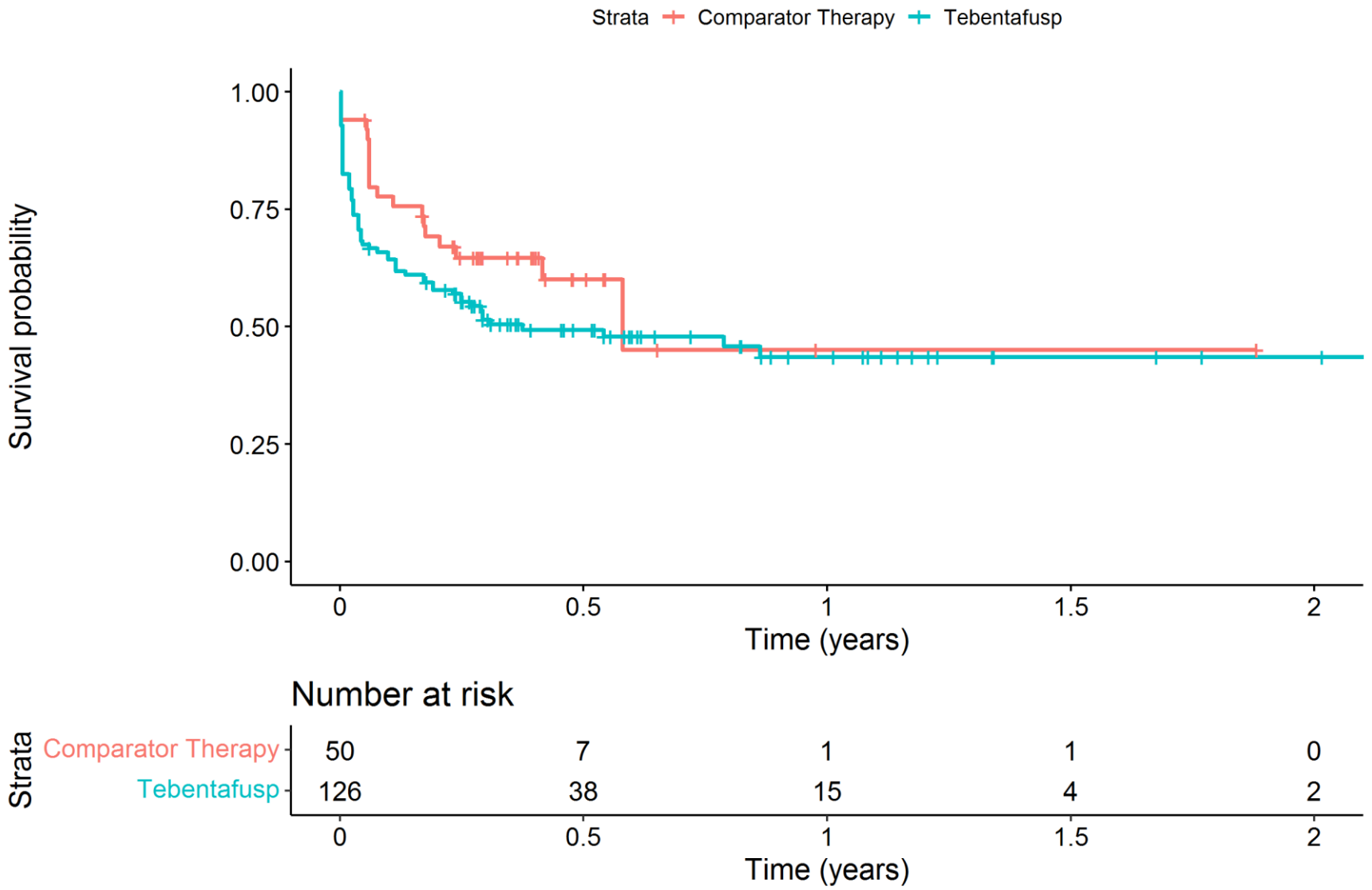
Untersuchungen - Männlich



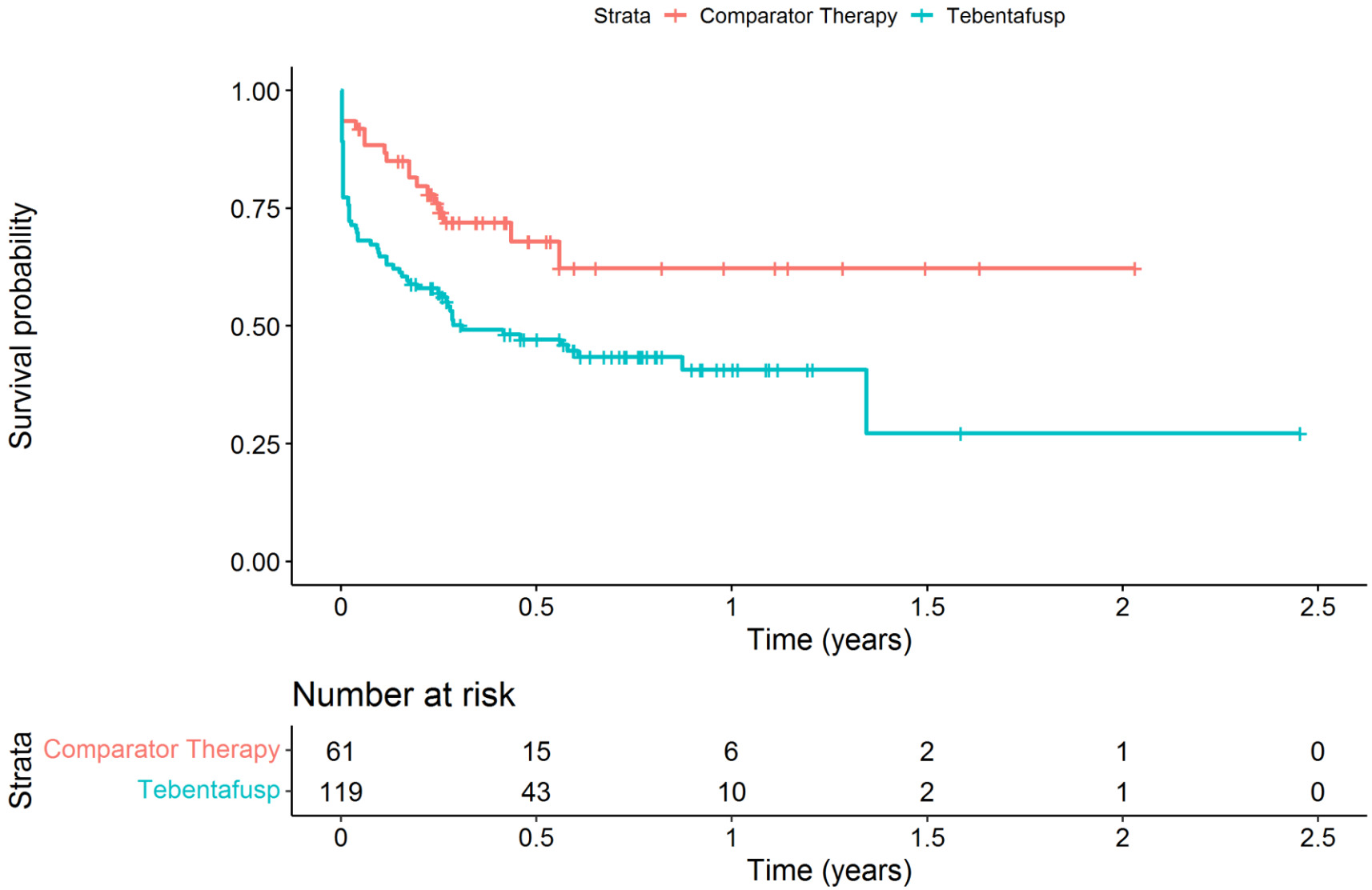
Untersuchungen - Weiblich



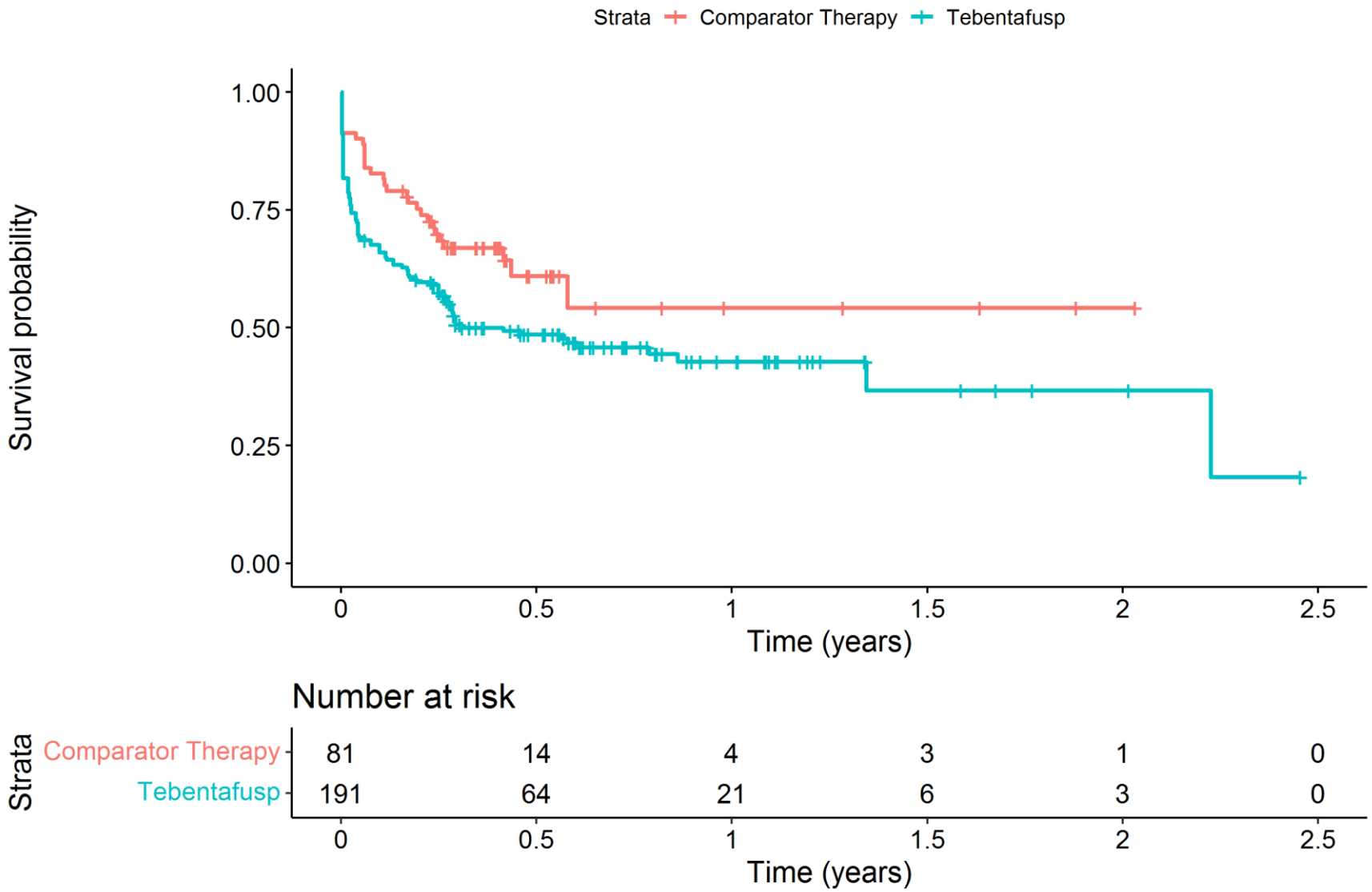
Untersuchungen - <65



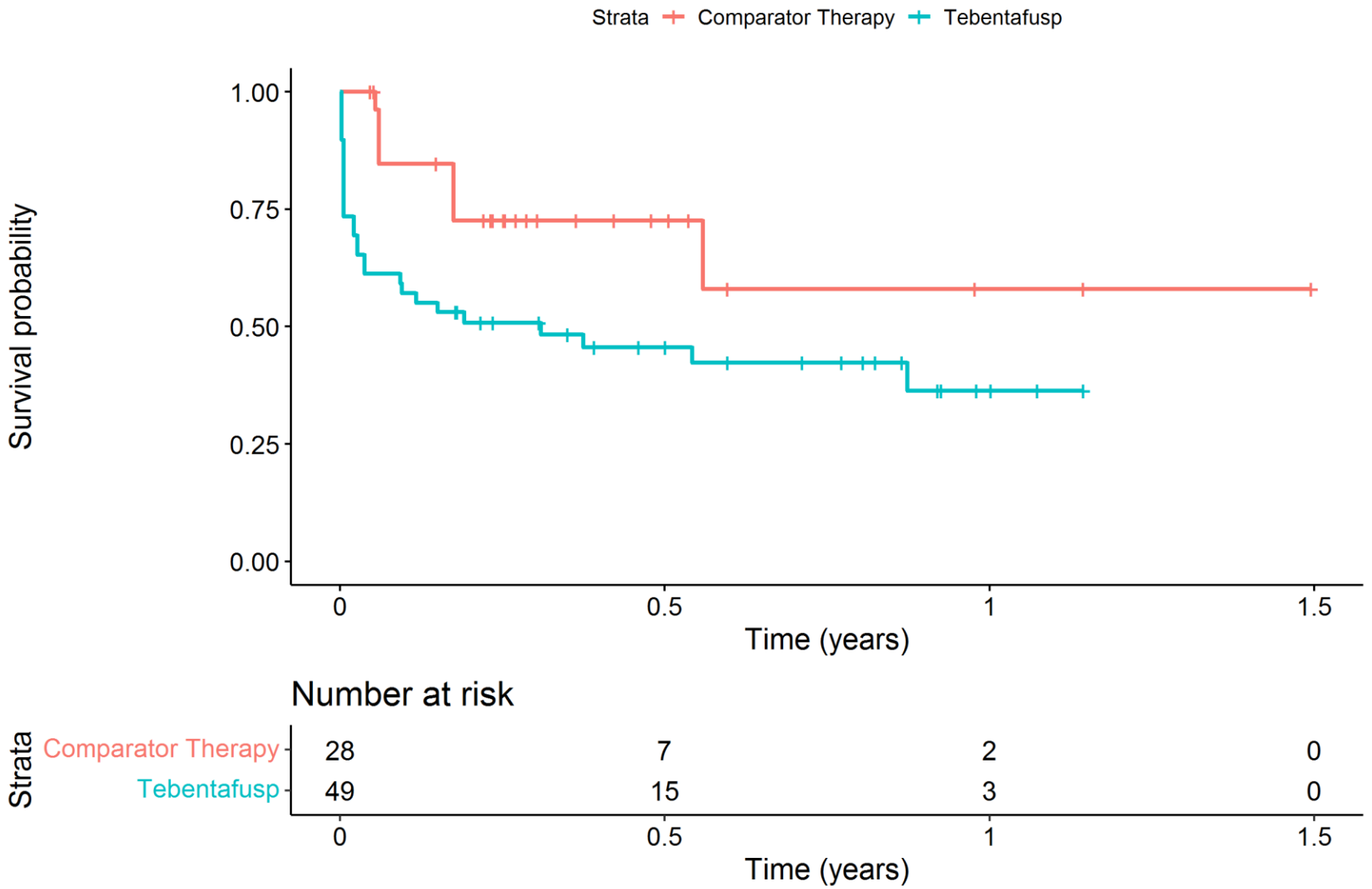
Untersuchungen - ≥65



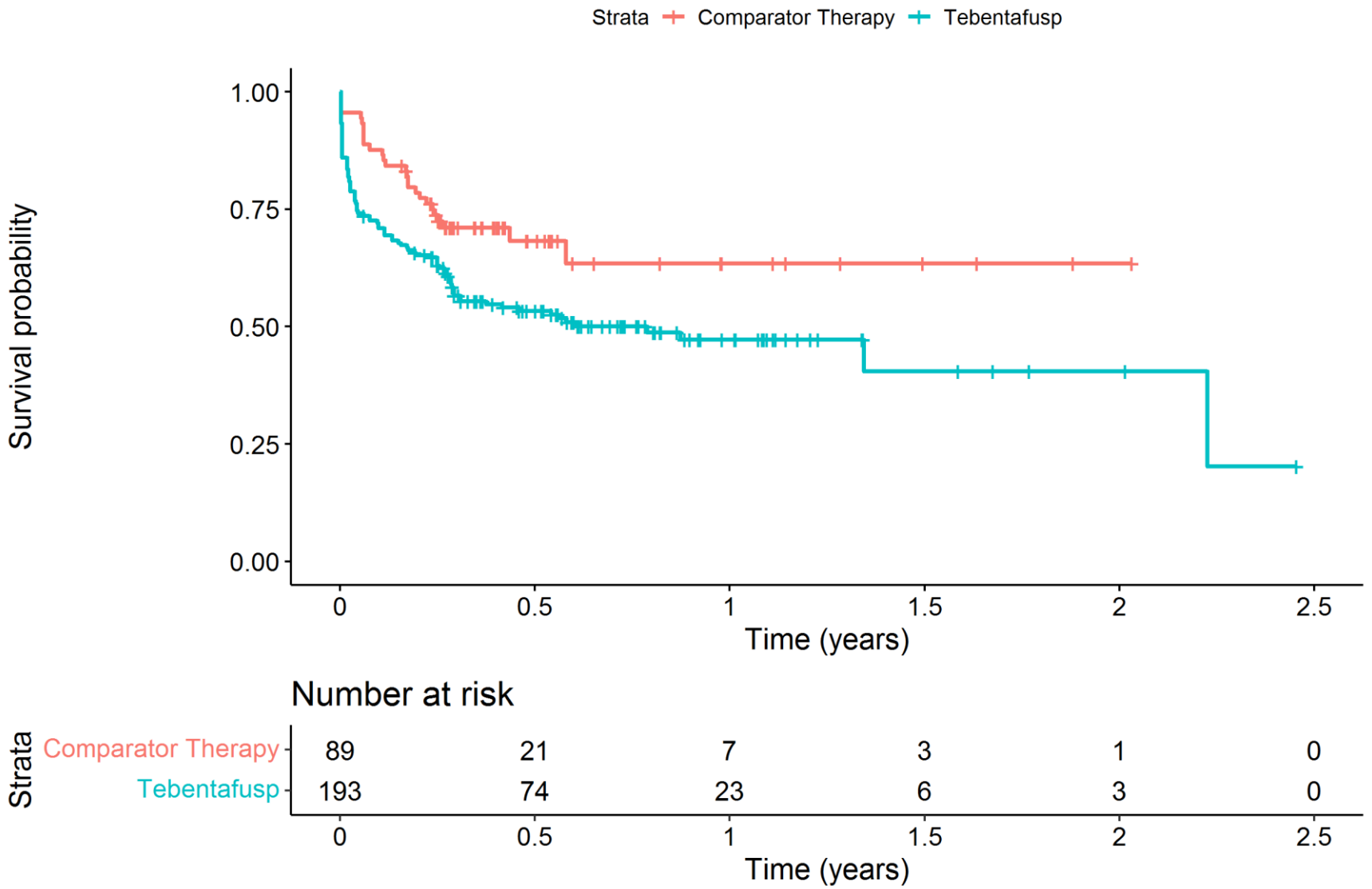
Untersuchungen - ECOG 0



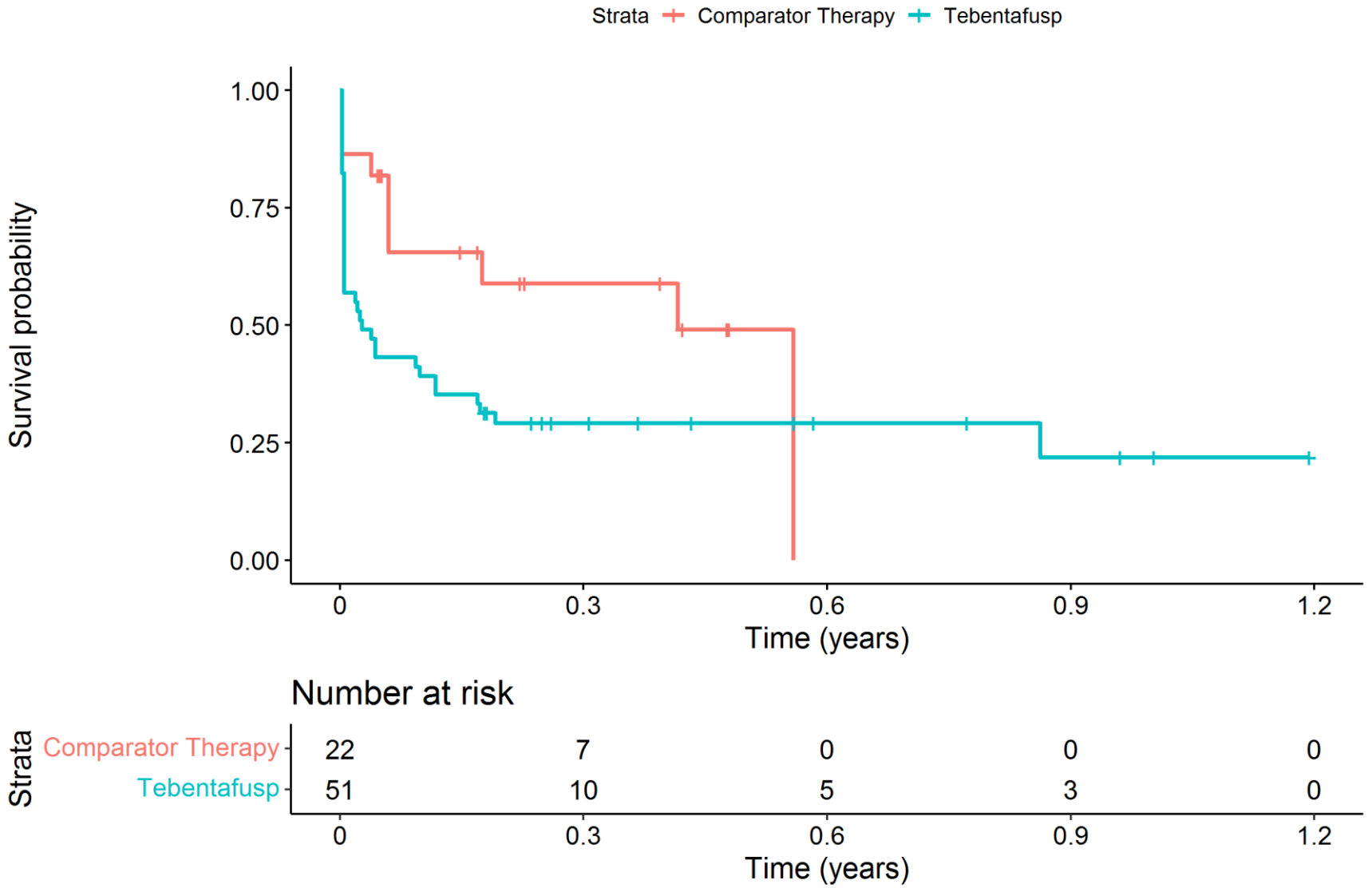
Untersuchungen - ECOG 1



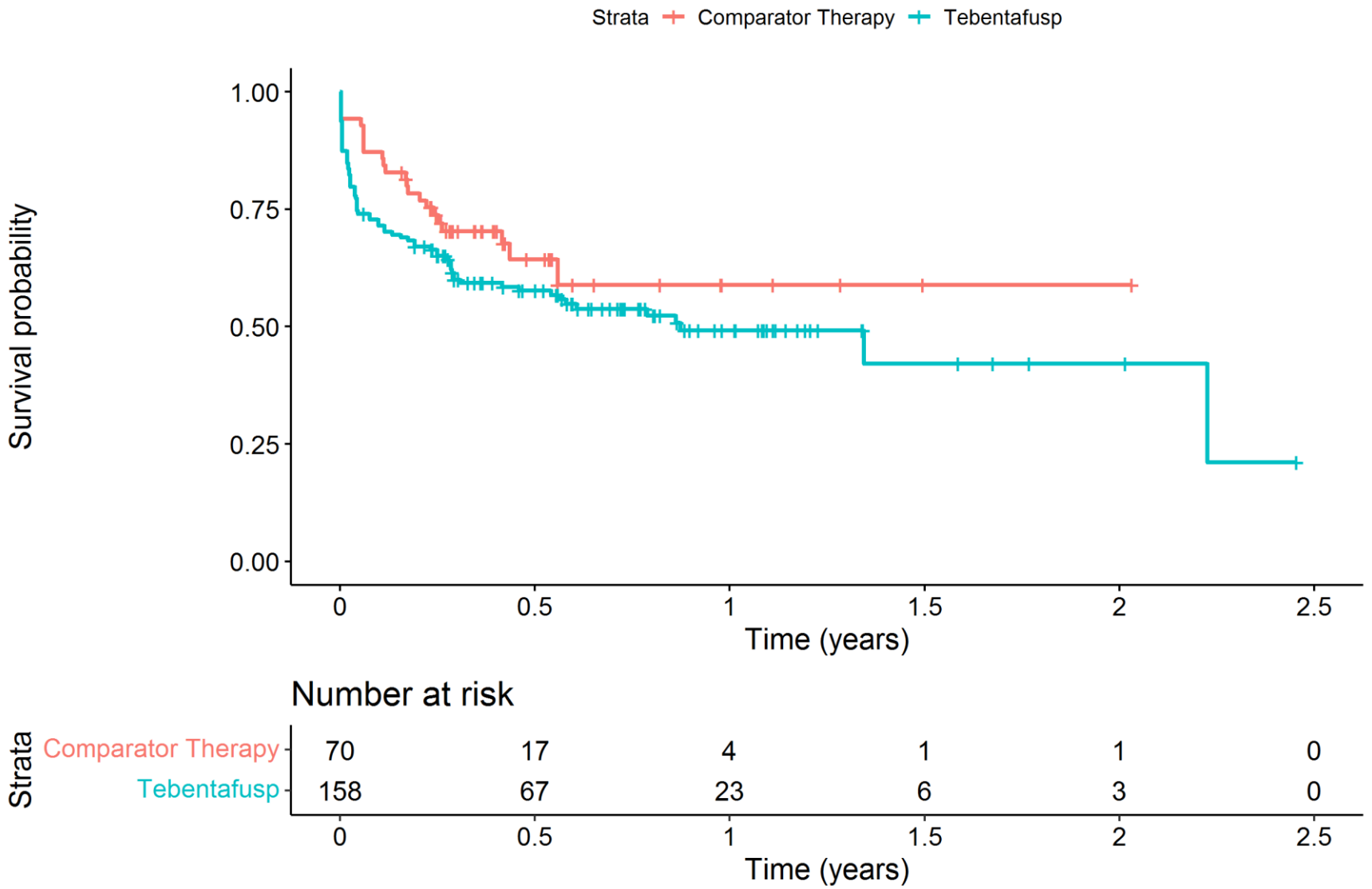
Untersuchungen - ALP ≤ ULN



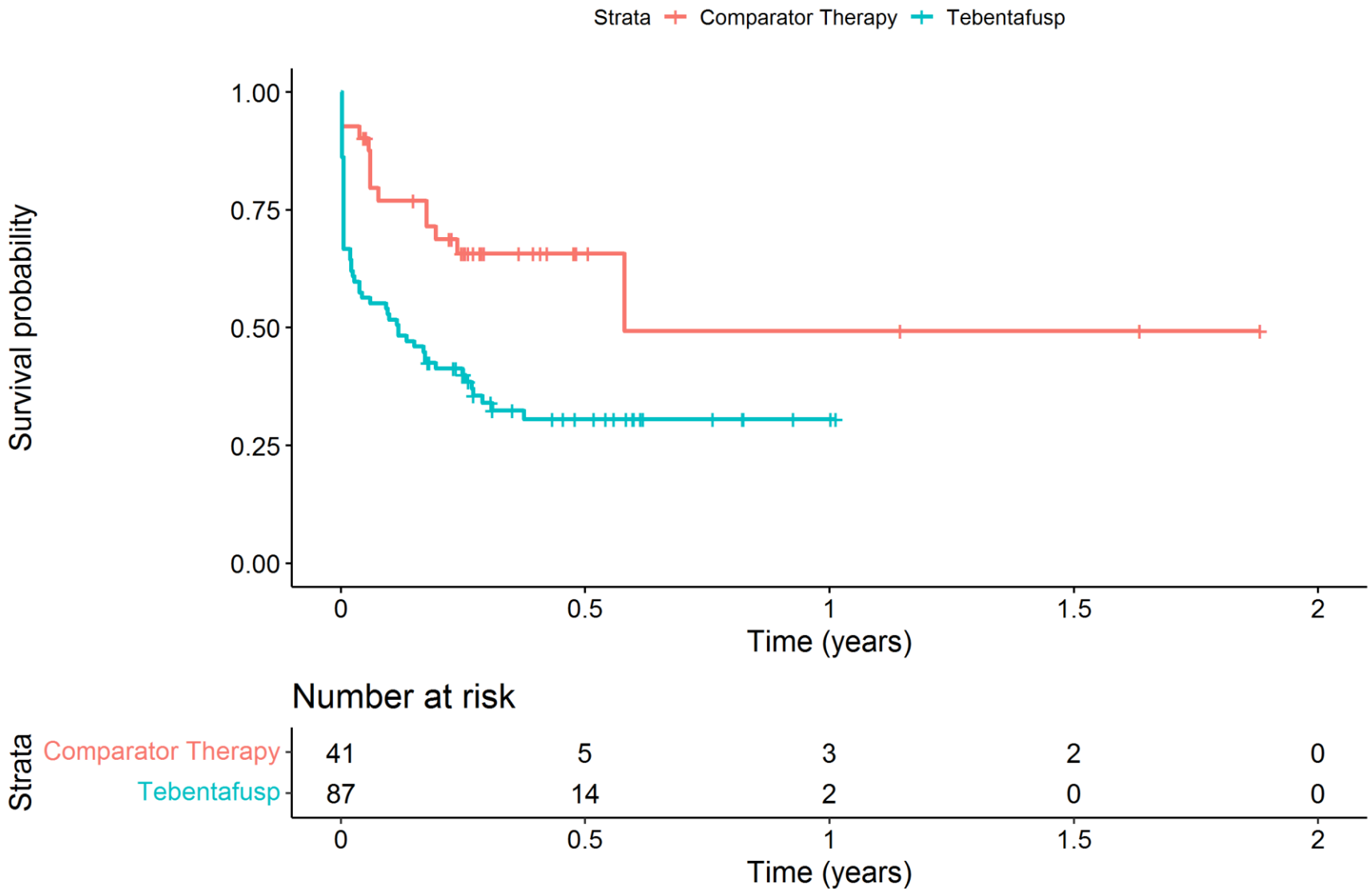
Untersuchungen - ALP > ULN



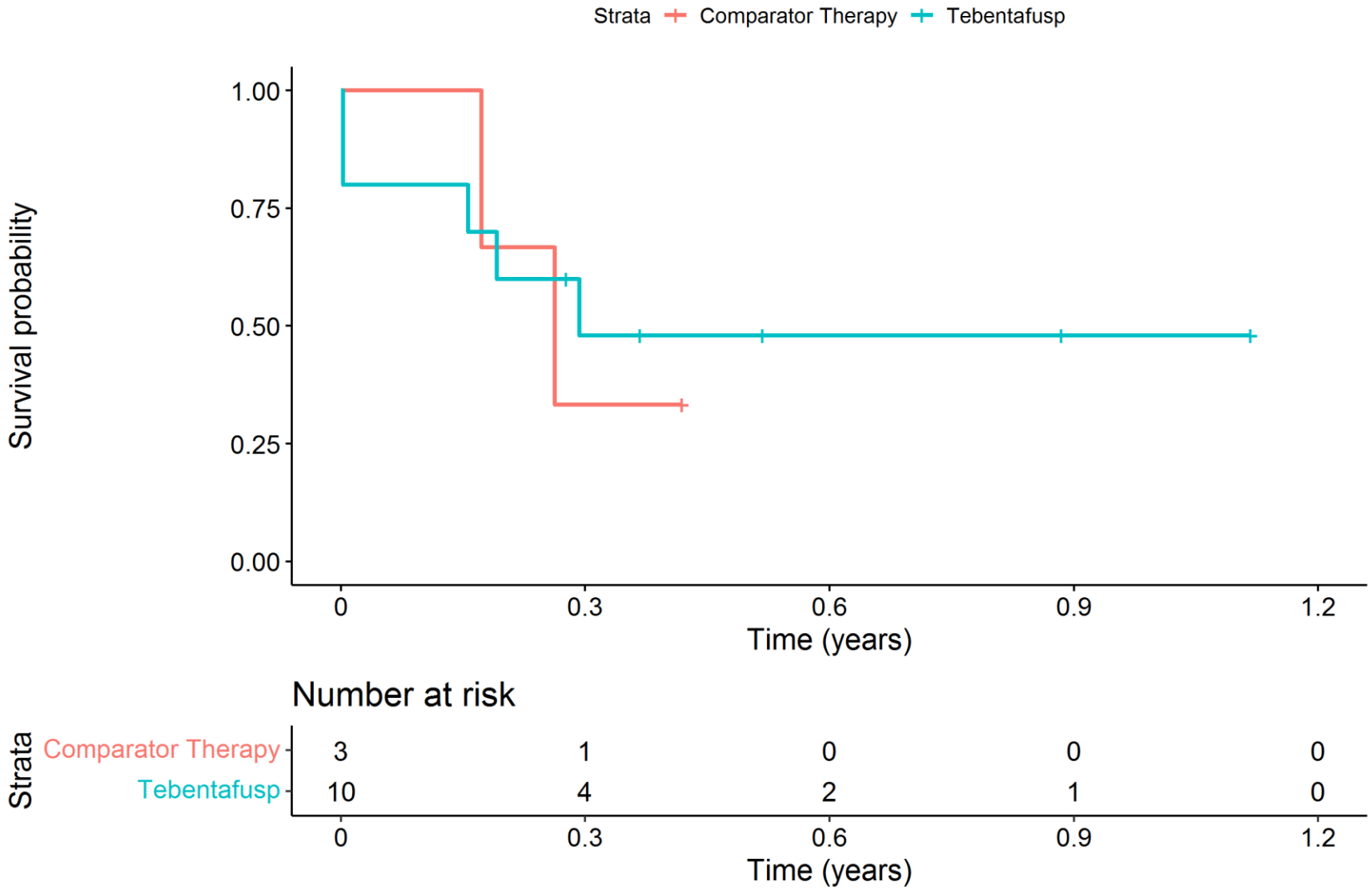
Untersuchungen - LDH =< ULN



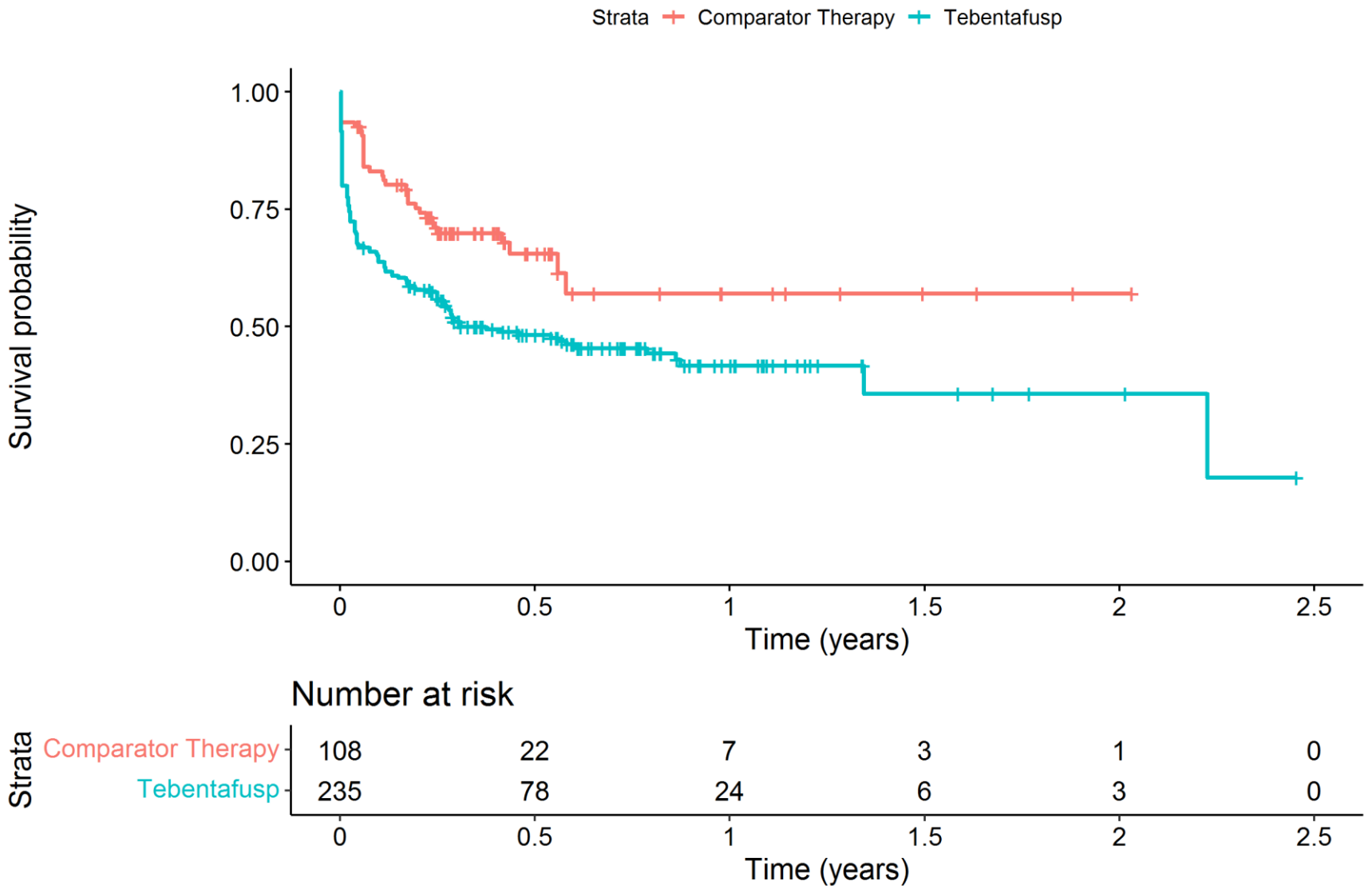
Untersuchungen - LDH > ULN



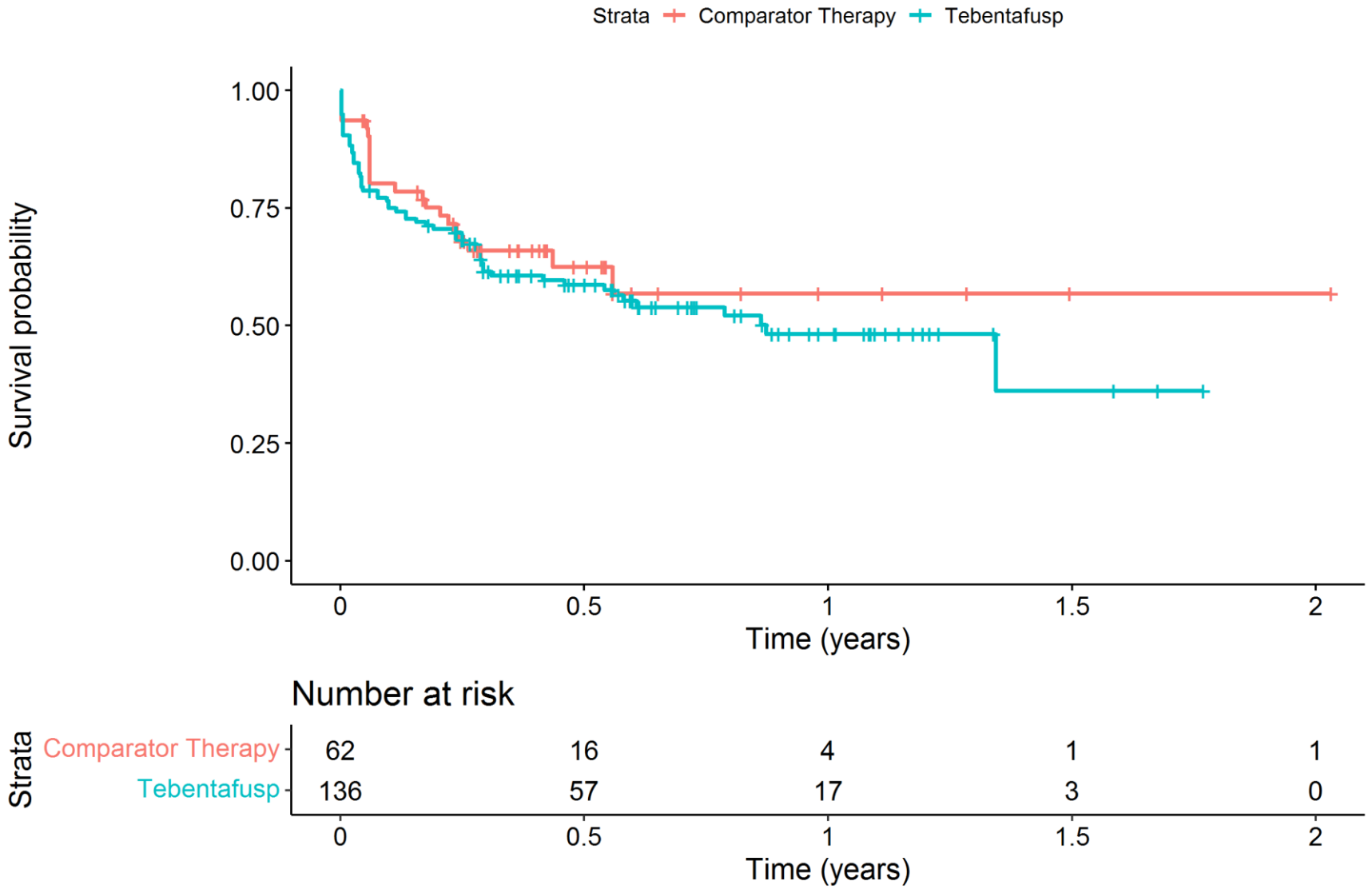
Untersuchungen - Vorherige Therapie adjuvant/neoadjuvant



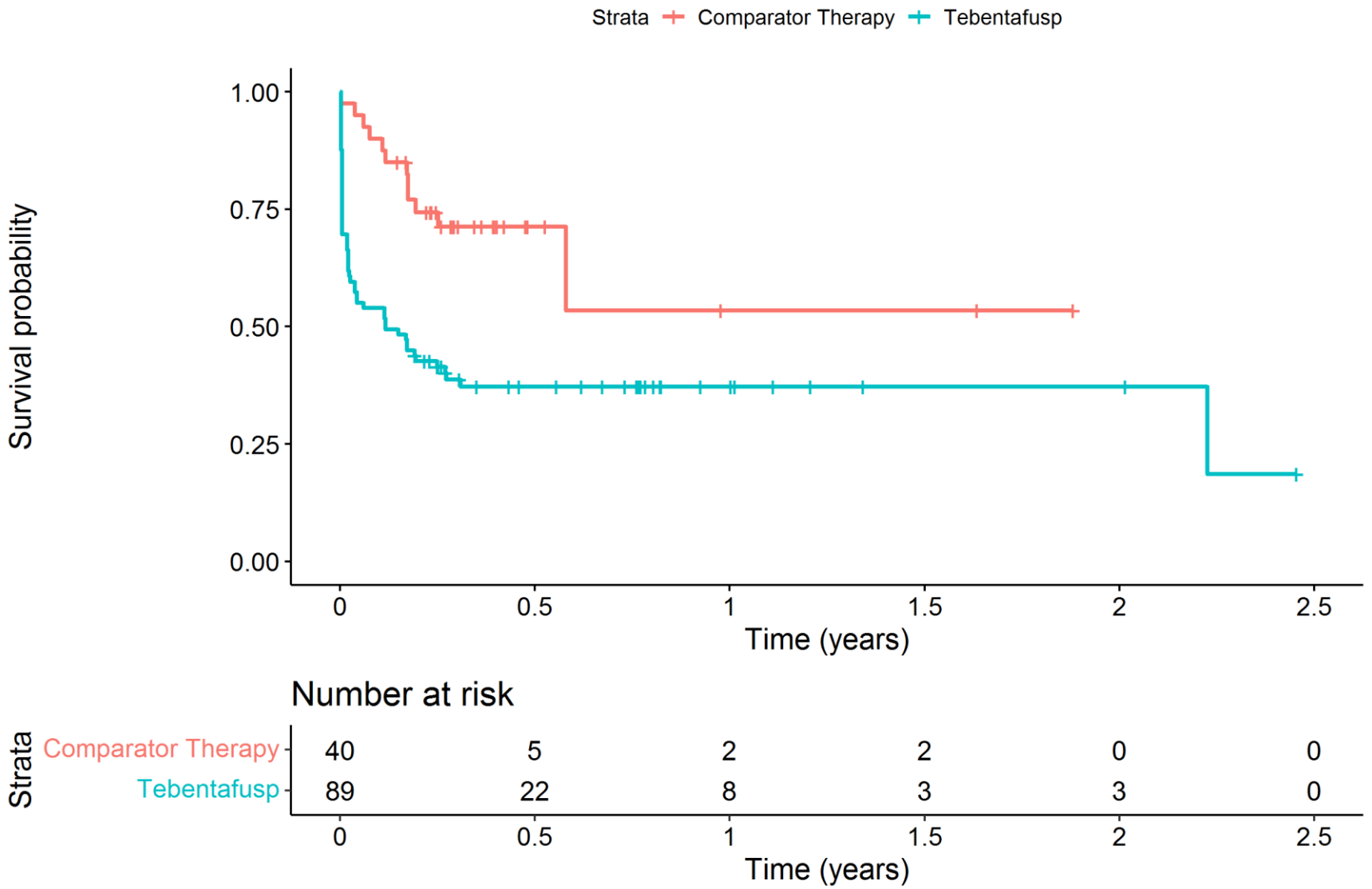
Untersuchungen - Keine vorherige Therapie adjuvant/neoadjuvant



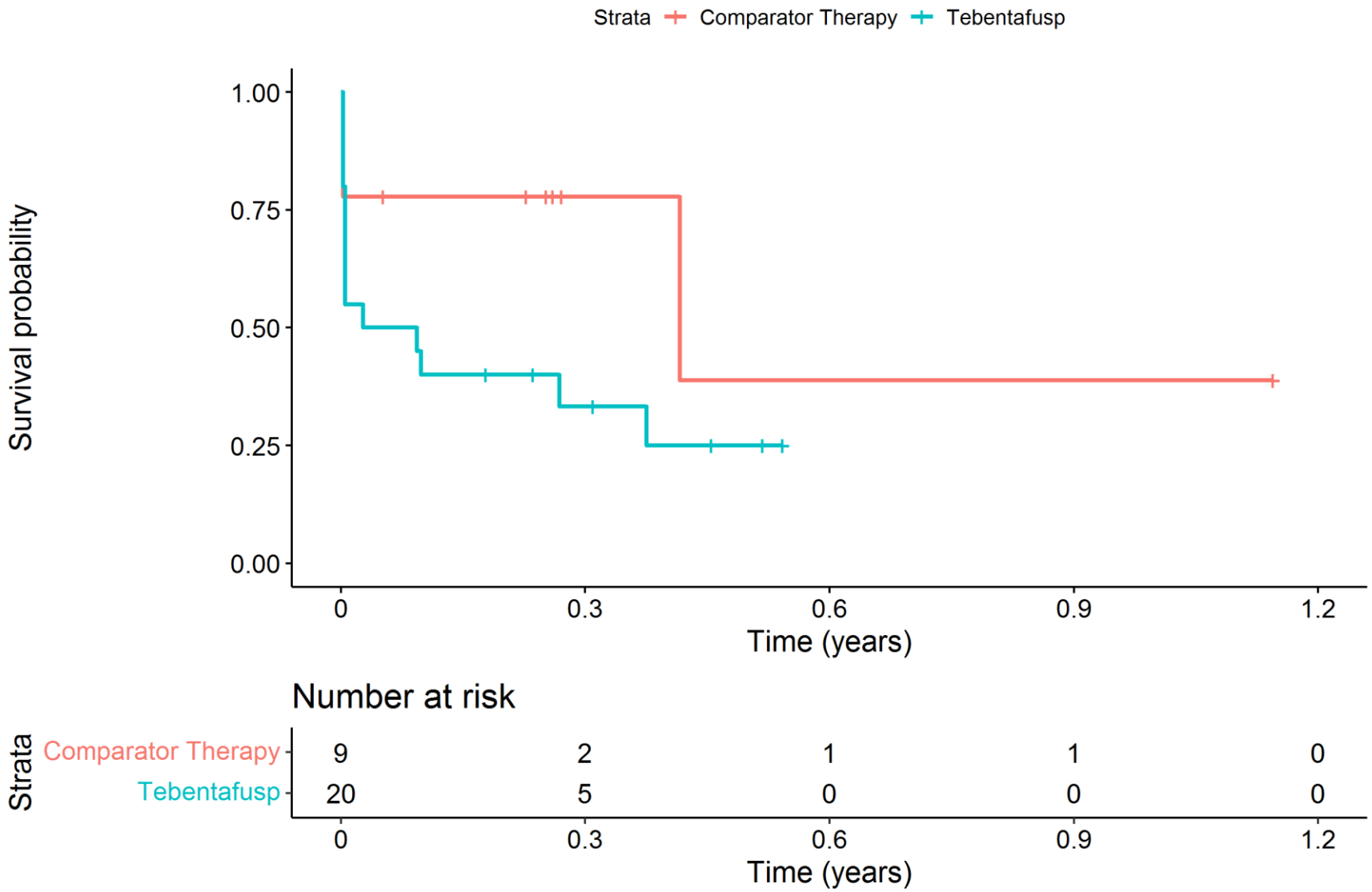
Untersuchungen - Läsion ≤ 3cm



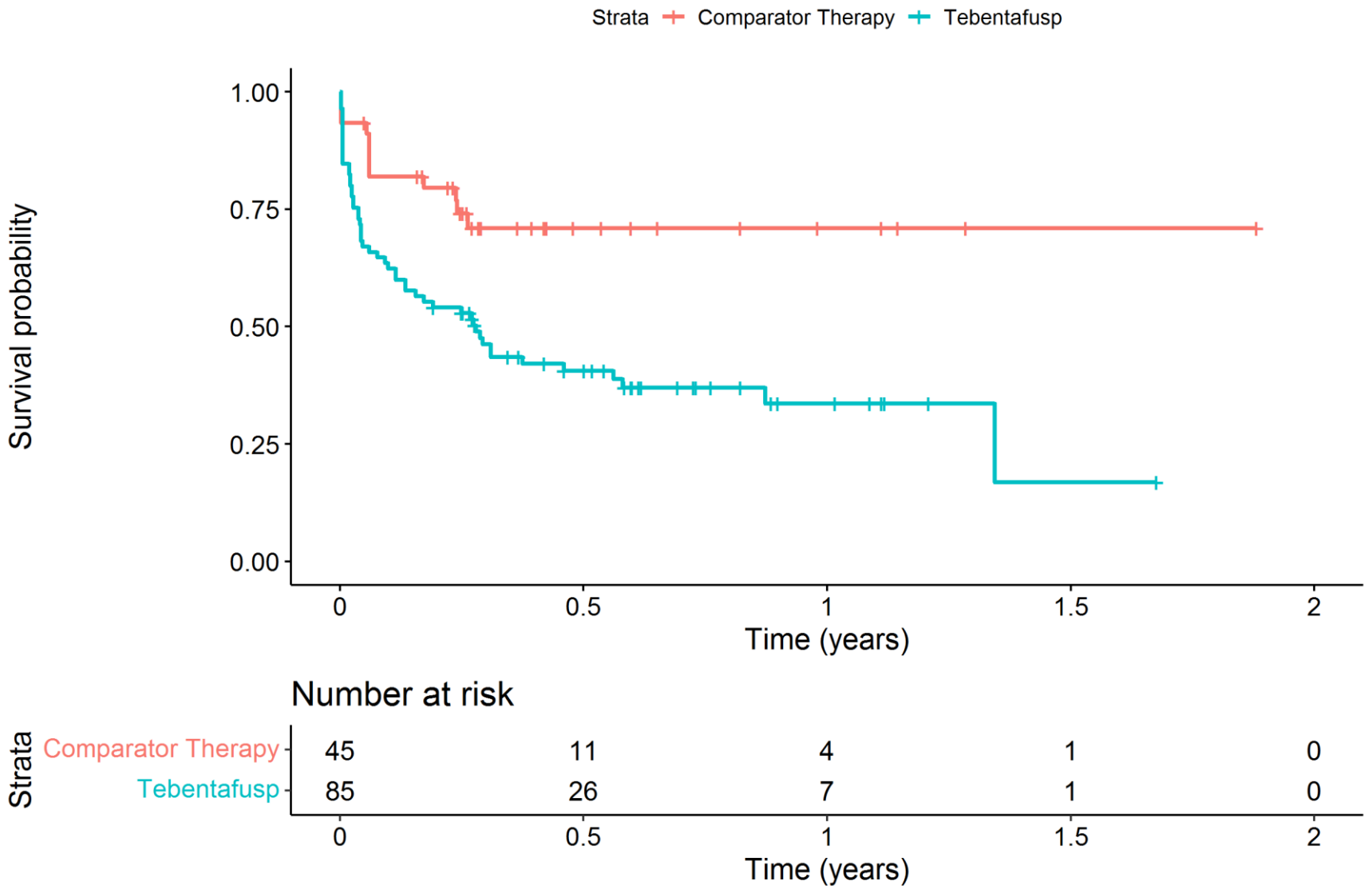
Untersuchungen - Läsion 3,1-8,0 cm



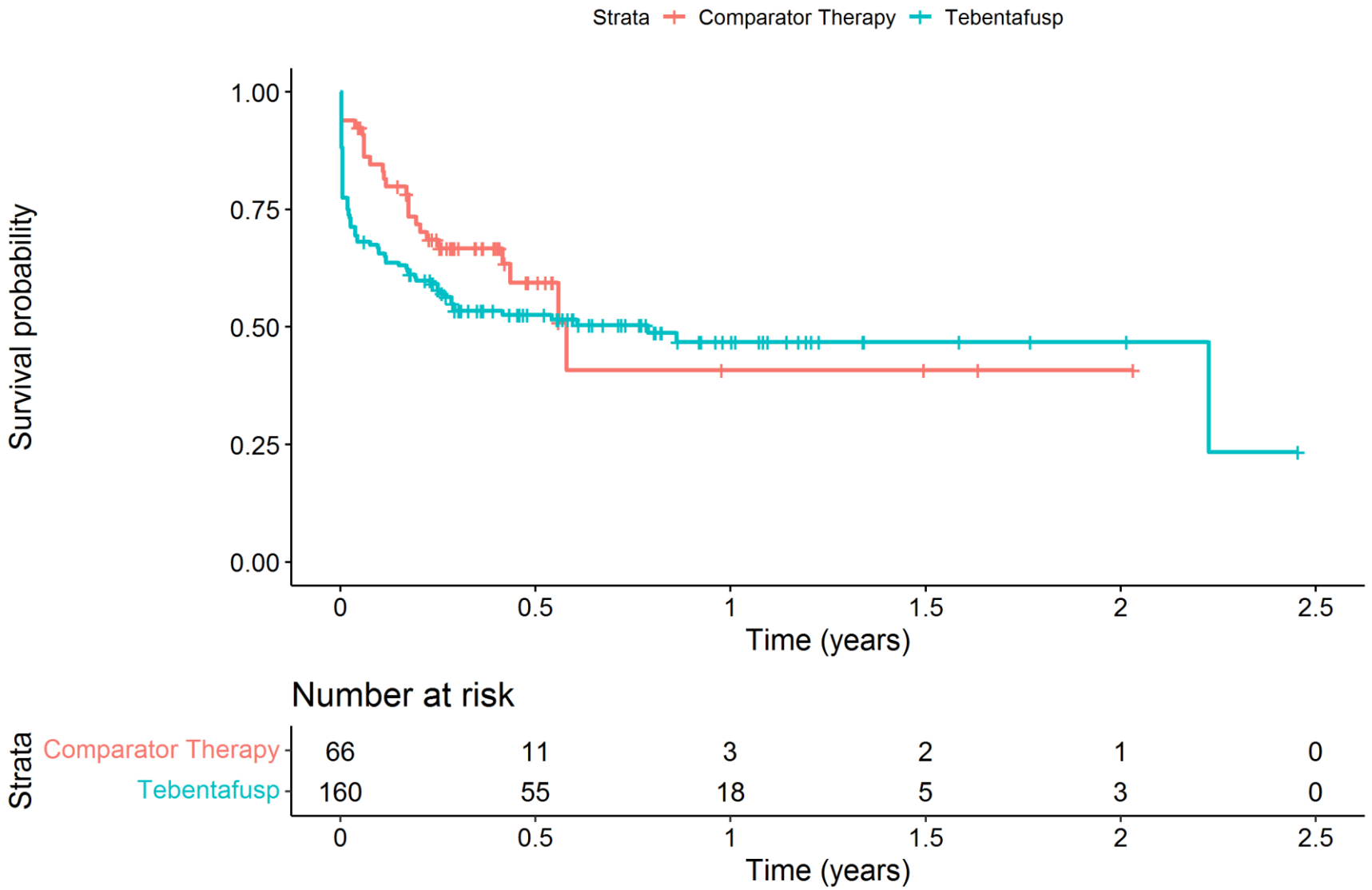
Untersuchungen - Läsion ≥8,1 cm



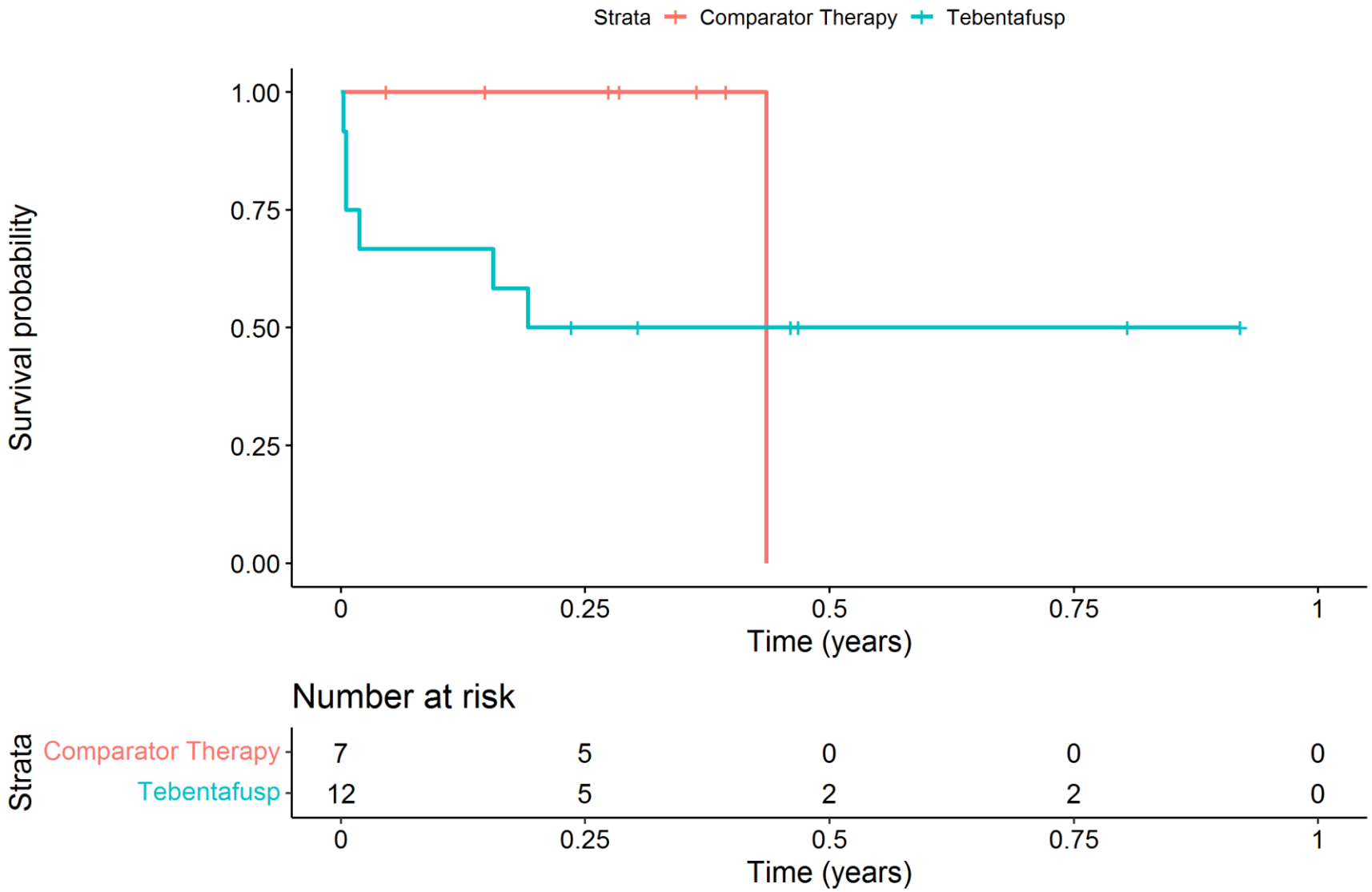
Untersuchungen - Nordamerika



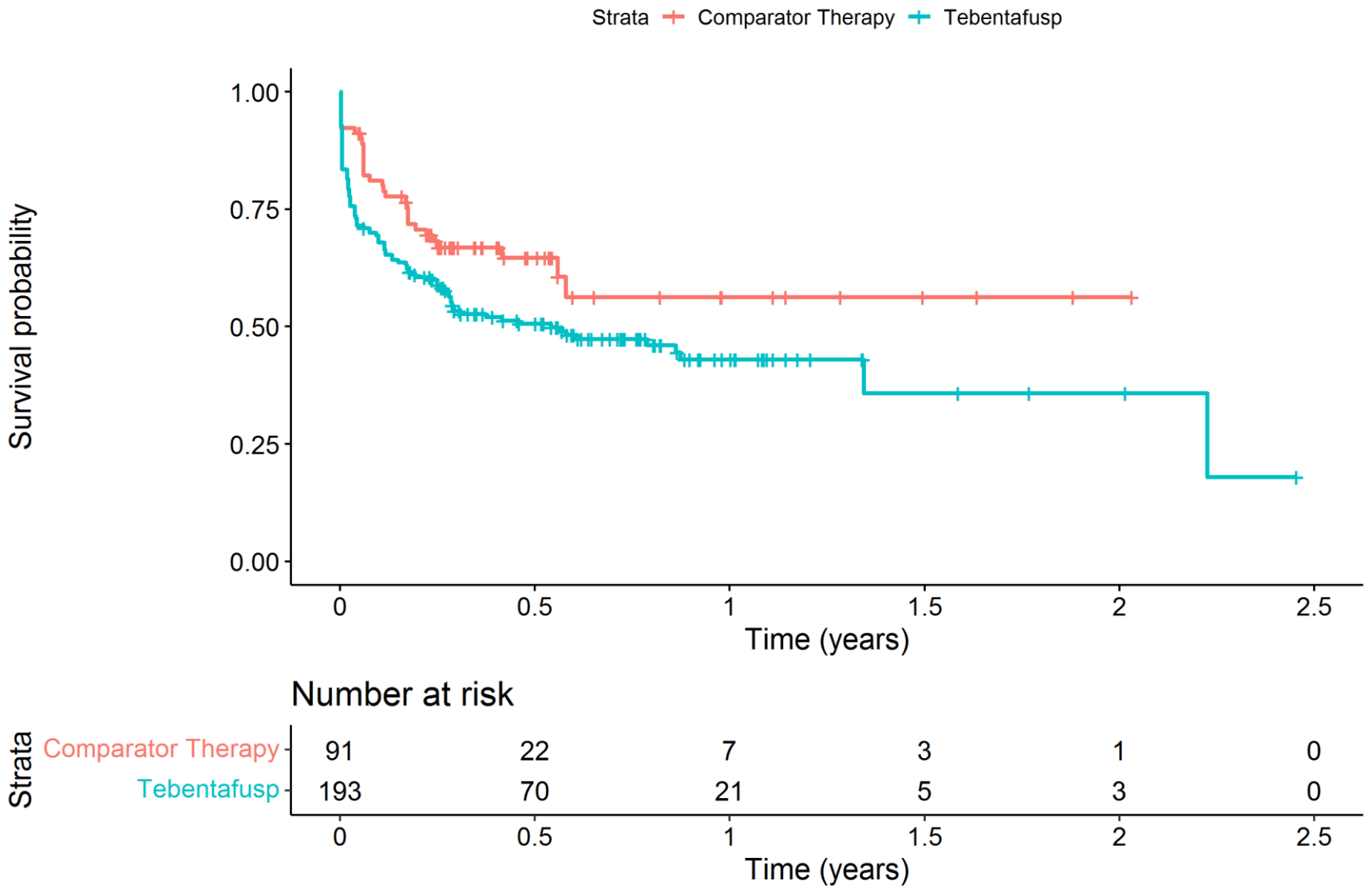
Untersuchungen - Nicht-Nordamerika



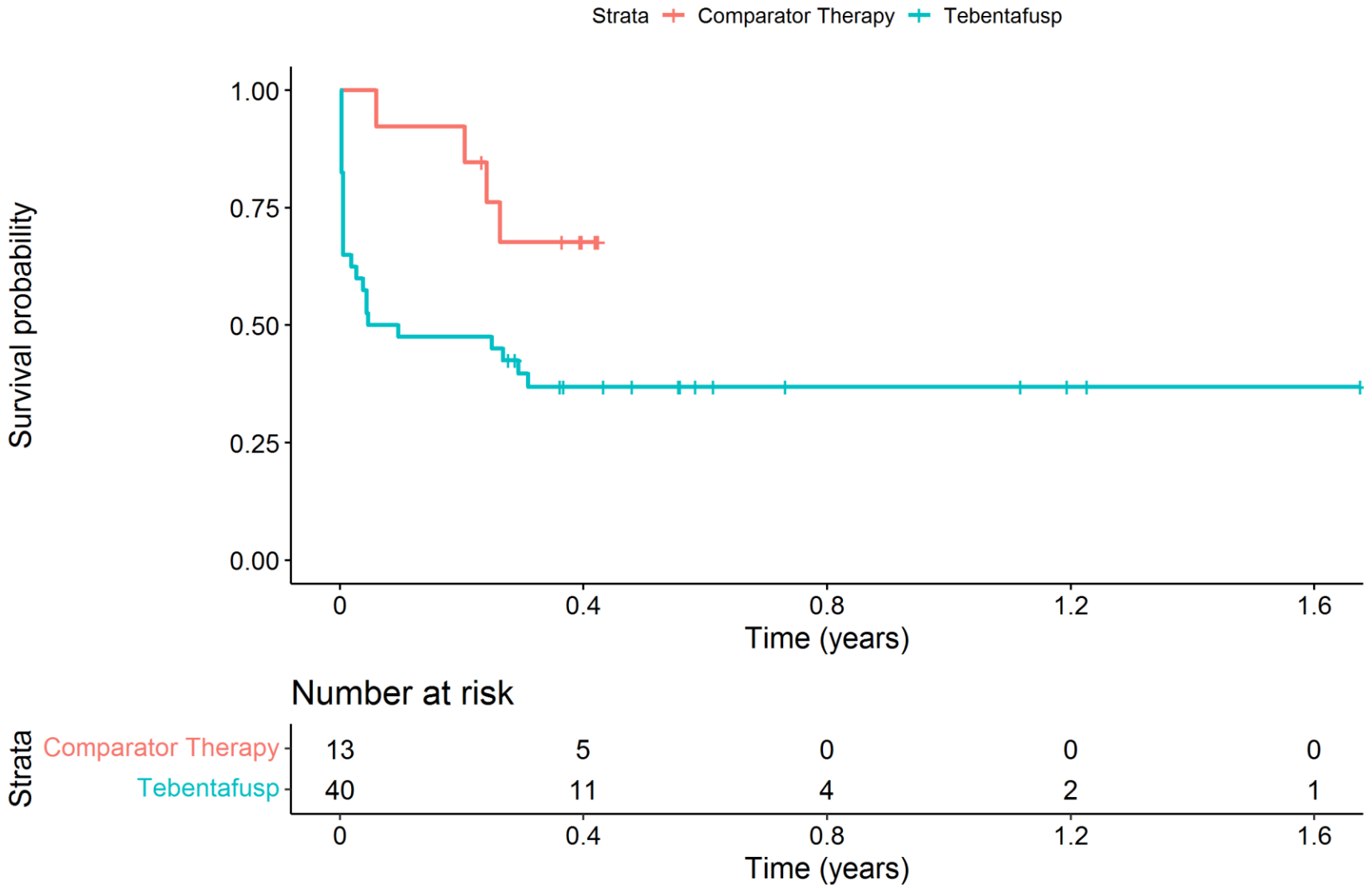
Untersuchungen - Dacarbazin



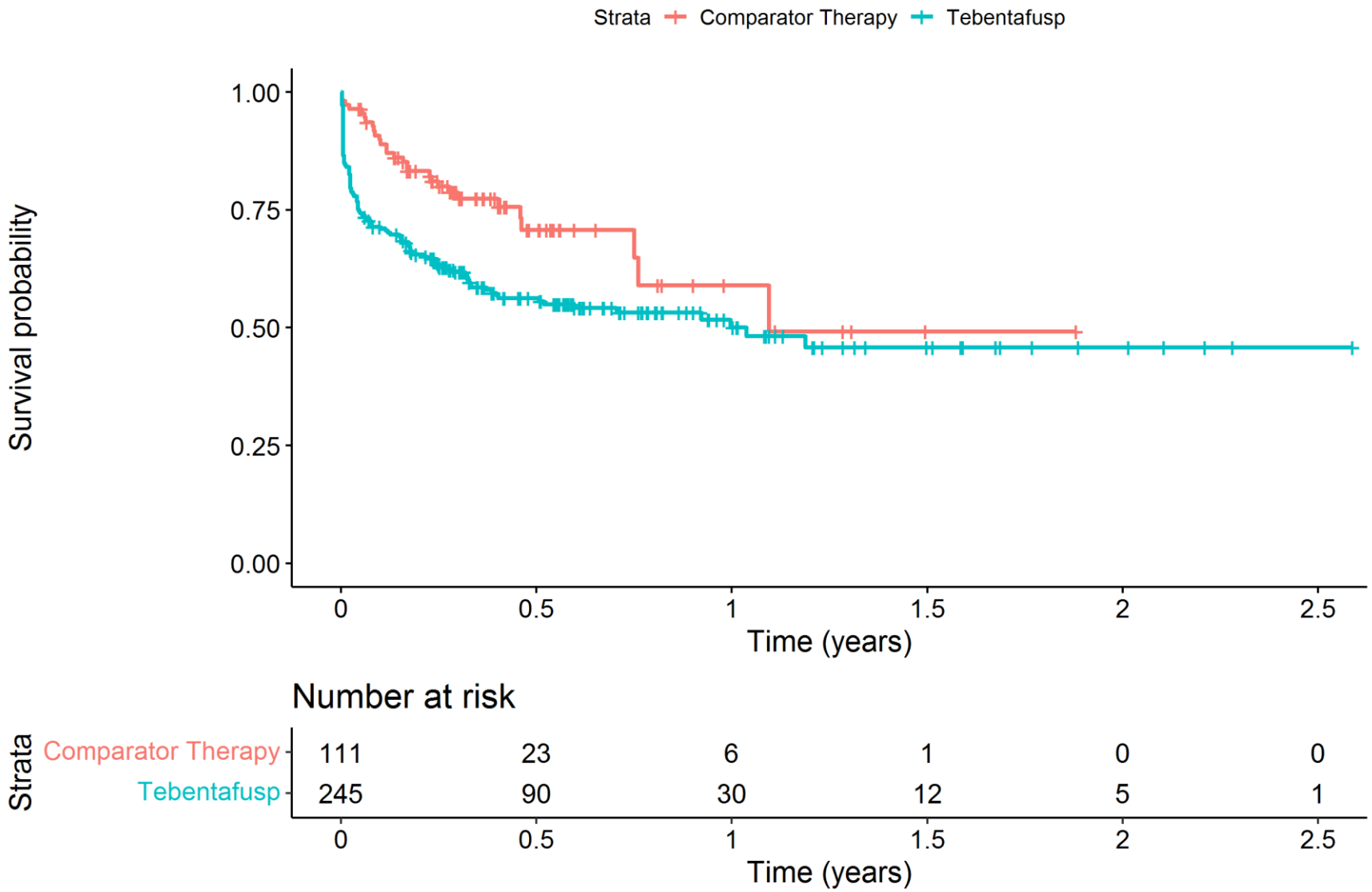
Untersuchungen - Pembrolizumab



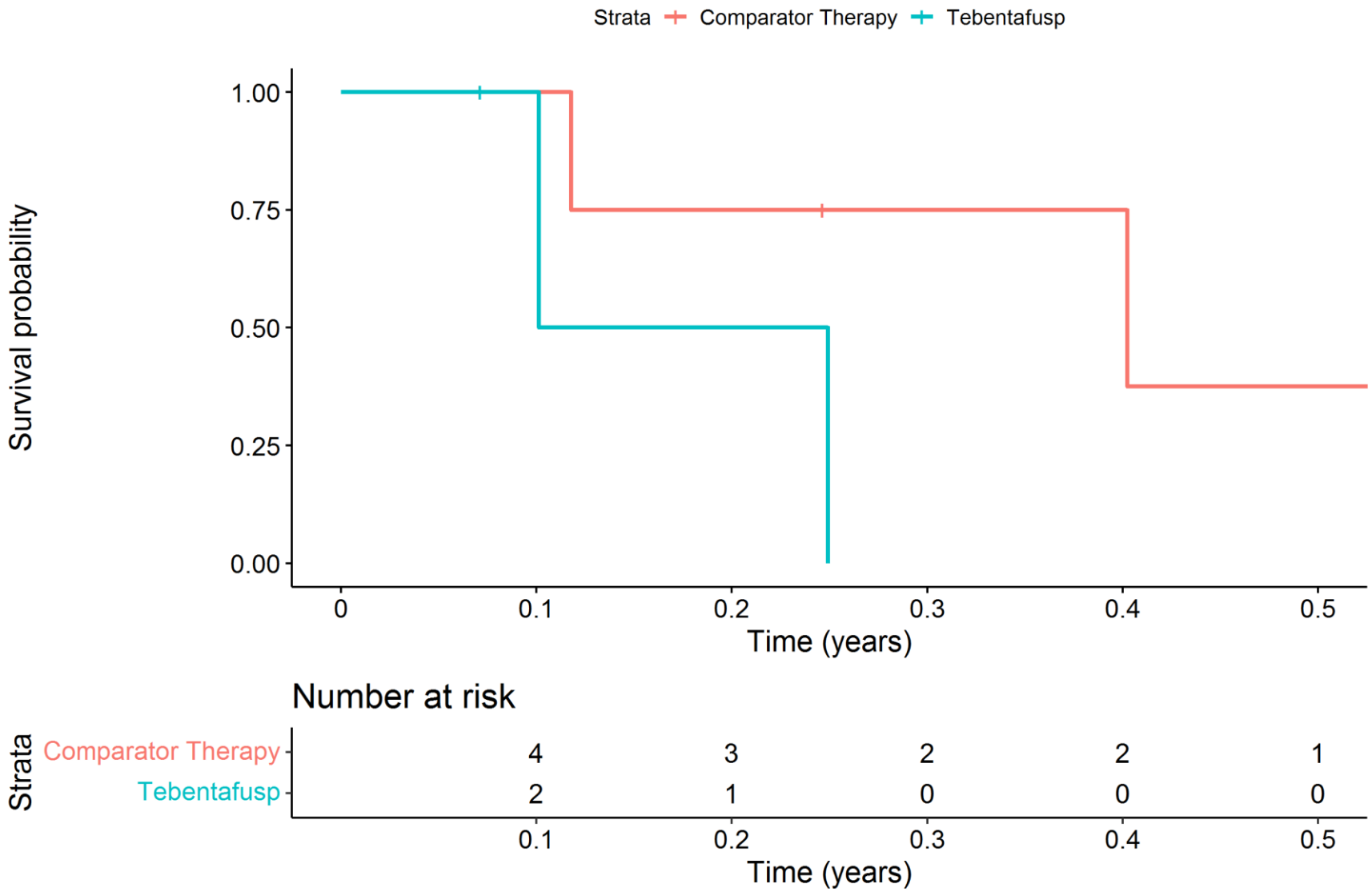
Untersuchungen - Ipilimumab



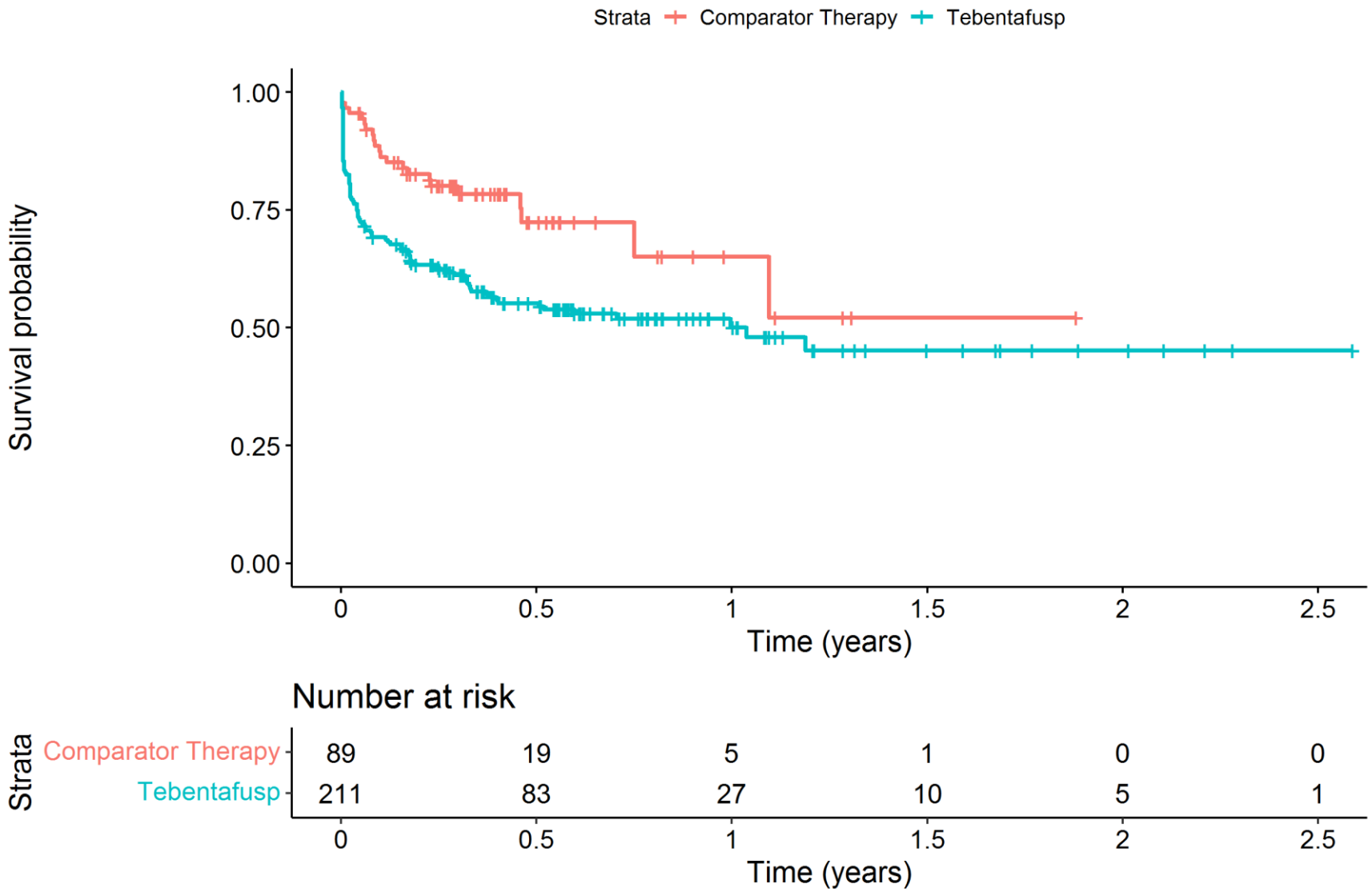
Stoffwechsel- und Ernährungsstörungen- Gesamt



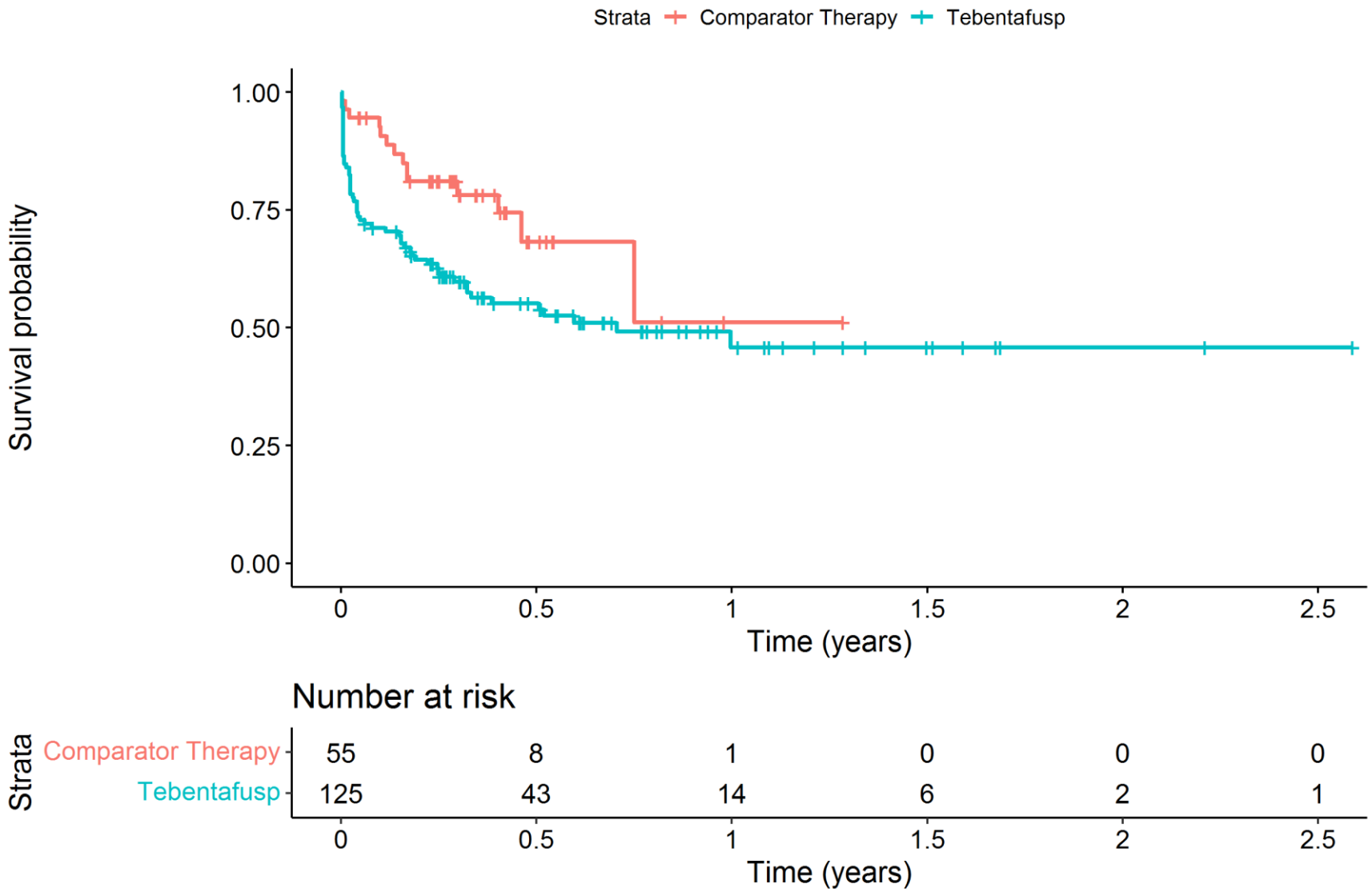
Stoffwechsel- und Ernährungsstörungen- Hispanisch



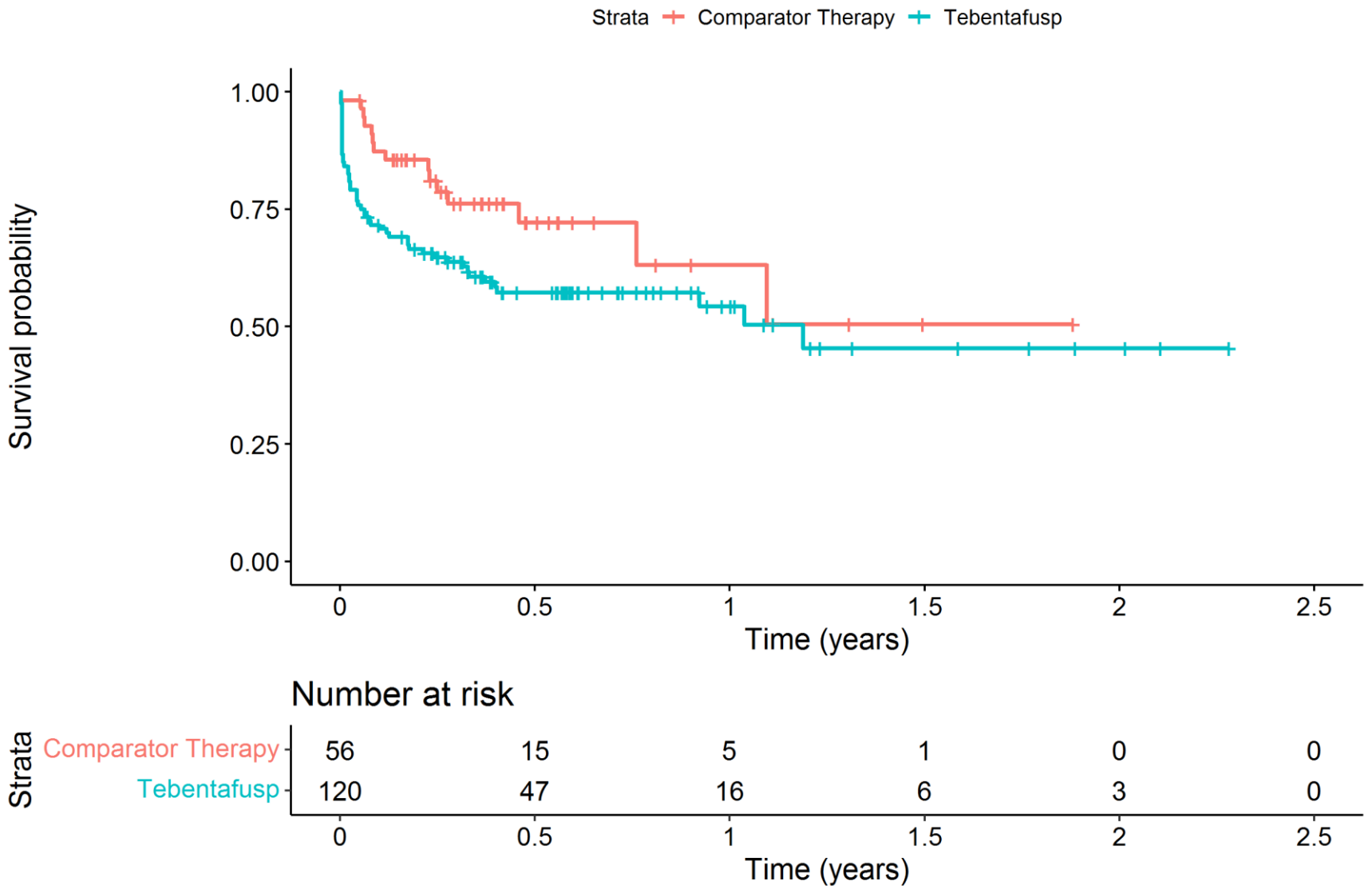
Stoffwechsel- und Ernährungsstörungen- Nicht-hispanisch



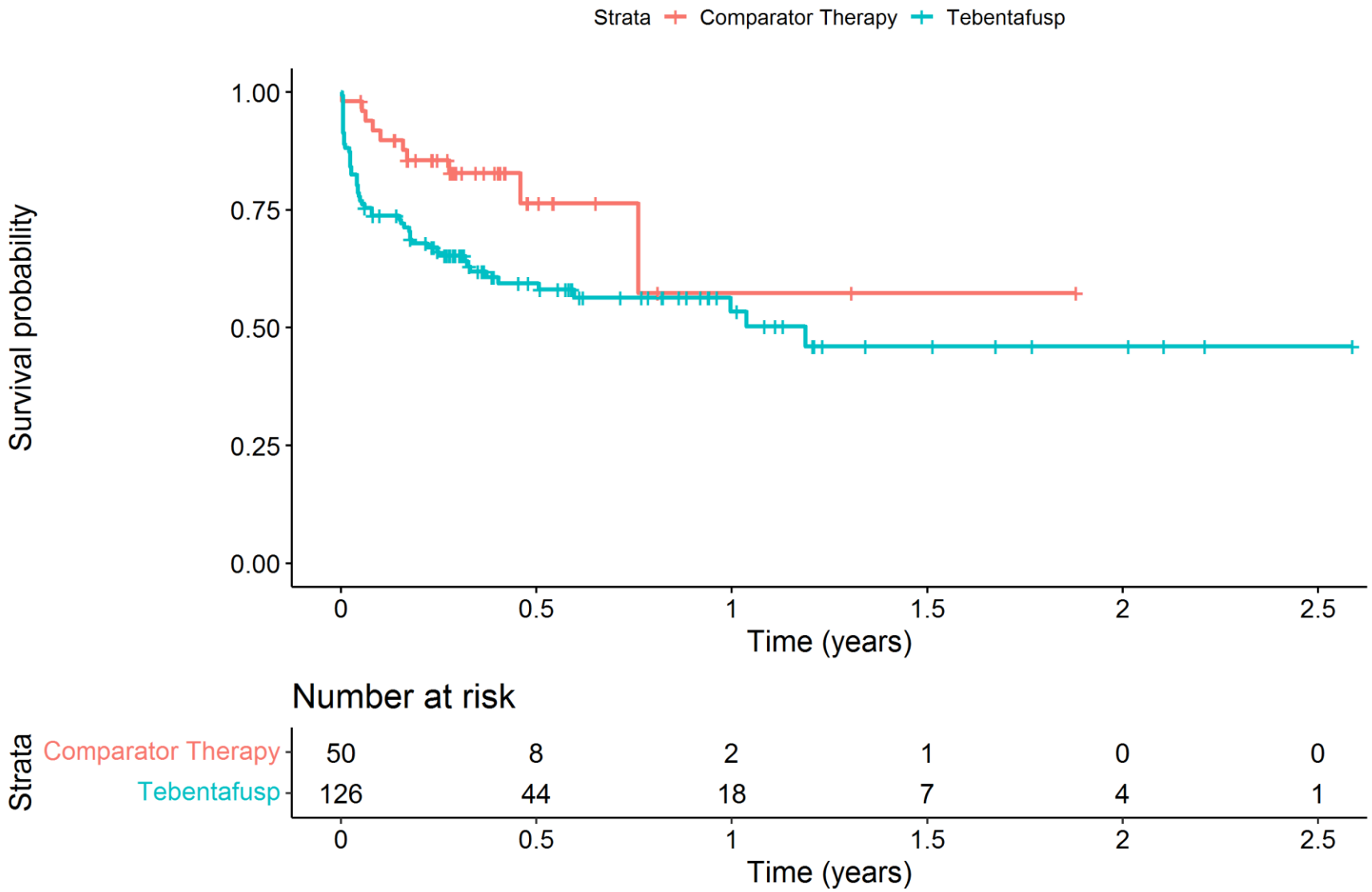
Stoffwechsel- und Ernährungsstörungen- Männlich



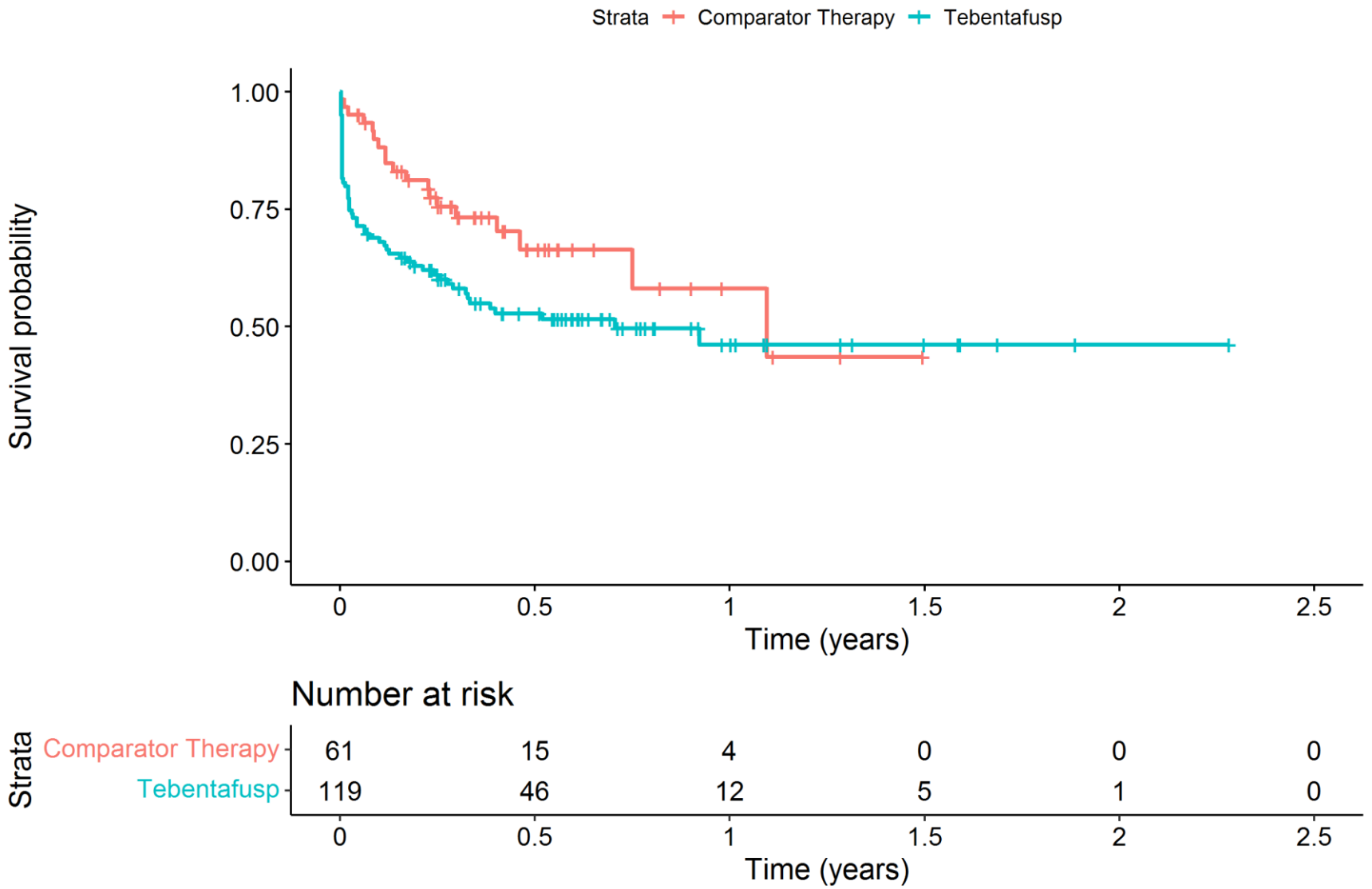
Stoffwechsel- und Ernährungsstörungen- Weiblich



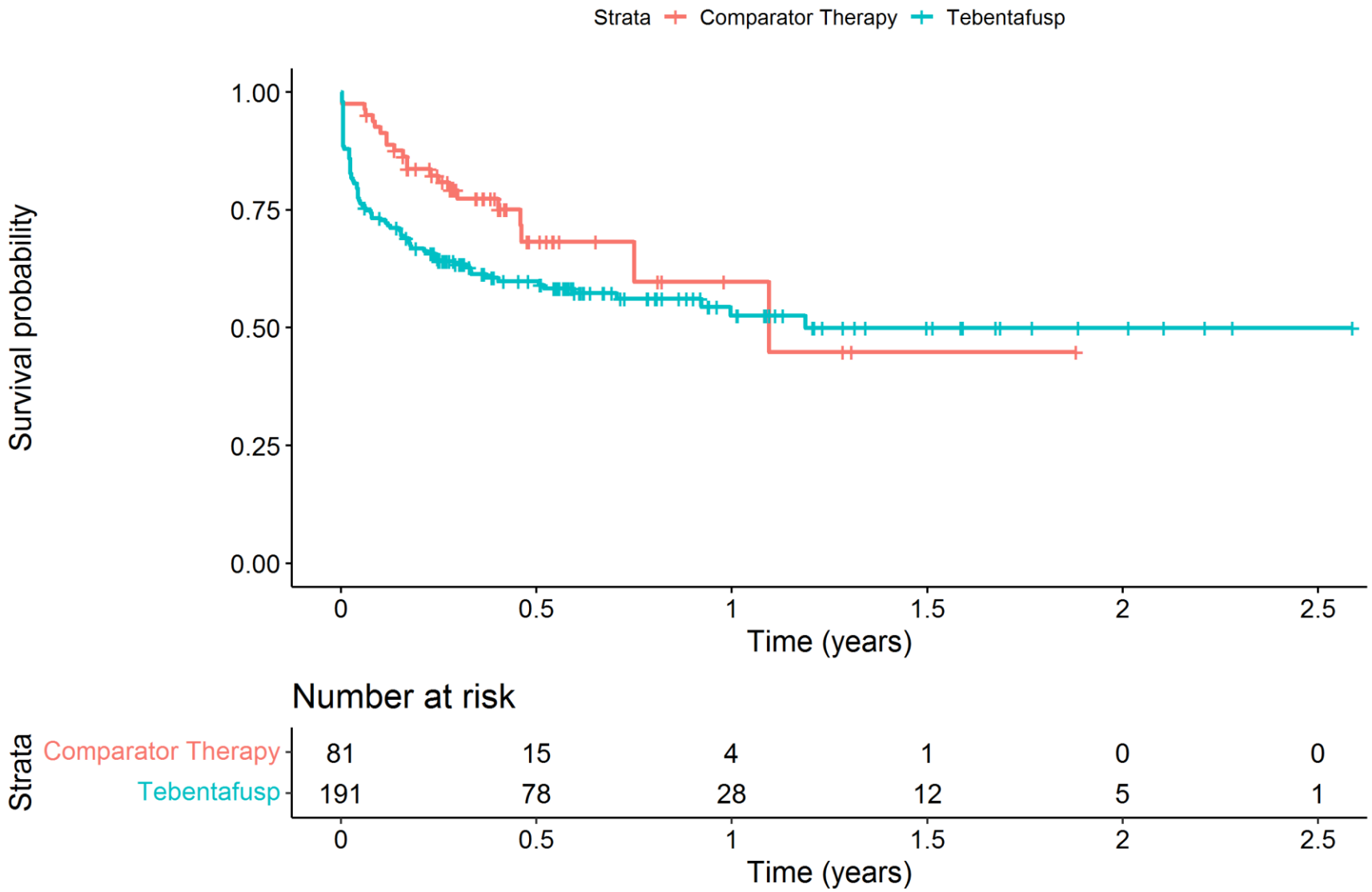
Stoffwechsel- und Ernährungsstörungen- <65



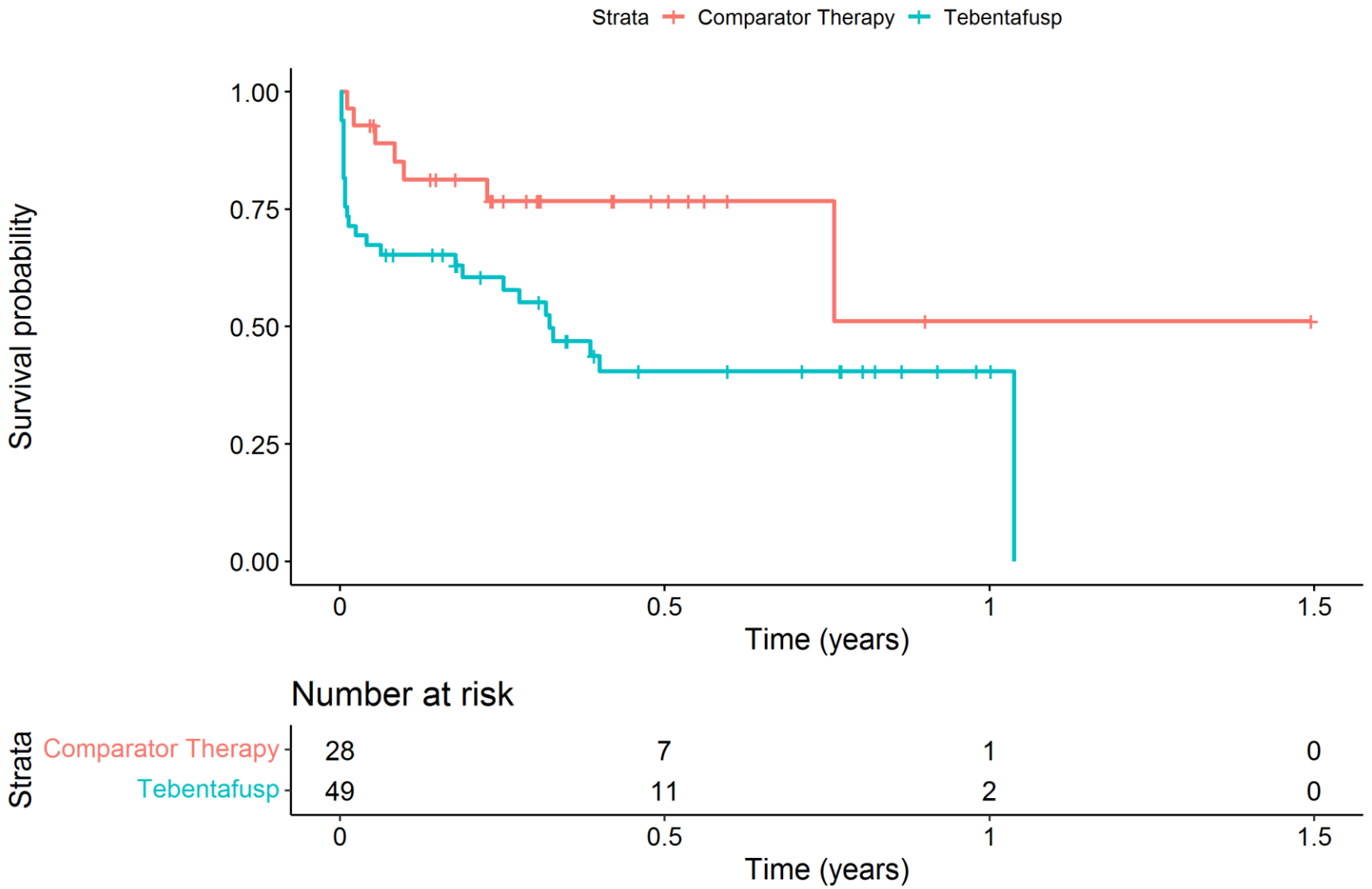
Stoffwechsel- und Ernährungsstörungen- ≥65



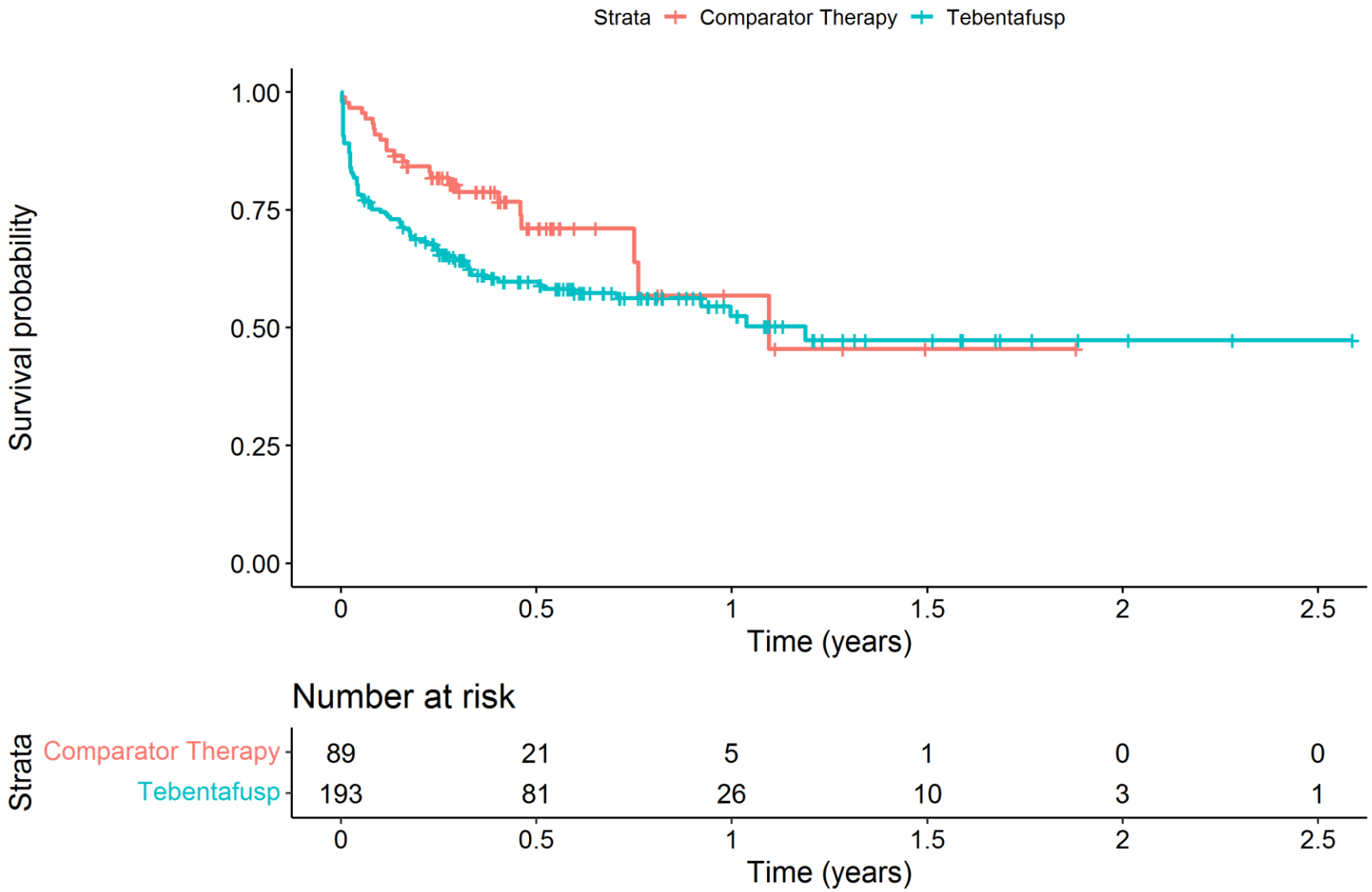
Stoffwechsel- und Ernährungsstörungen- ECOG 0



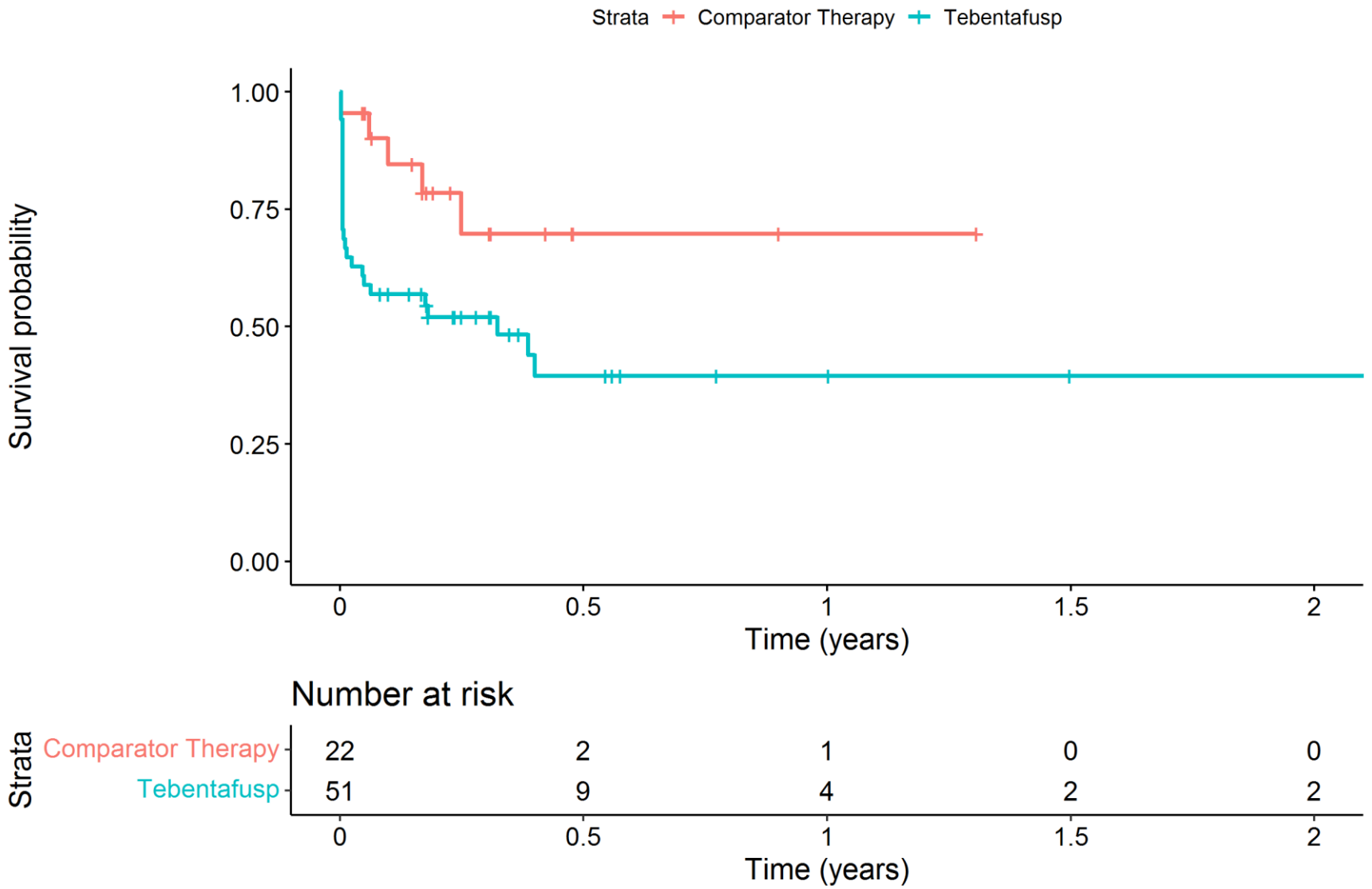
Stoffwechsel- und Ernährungsstörungen- ECOG 1



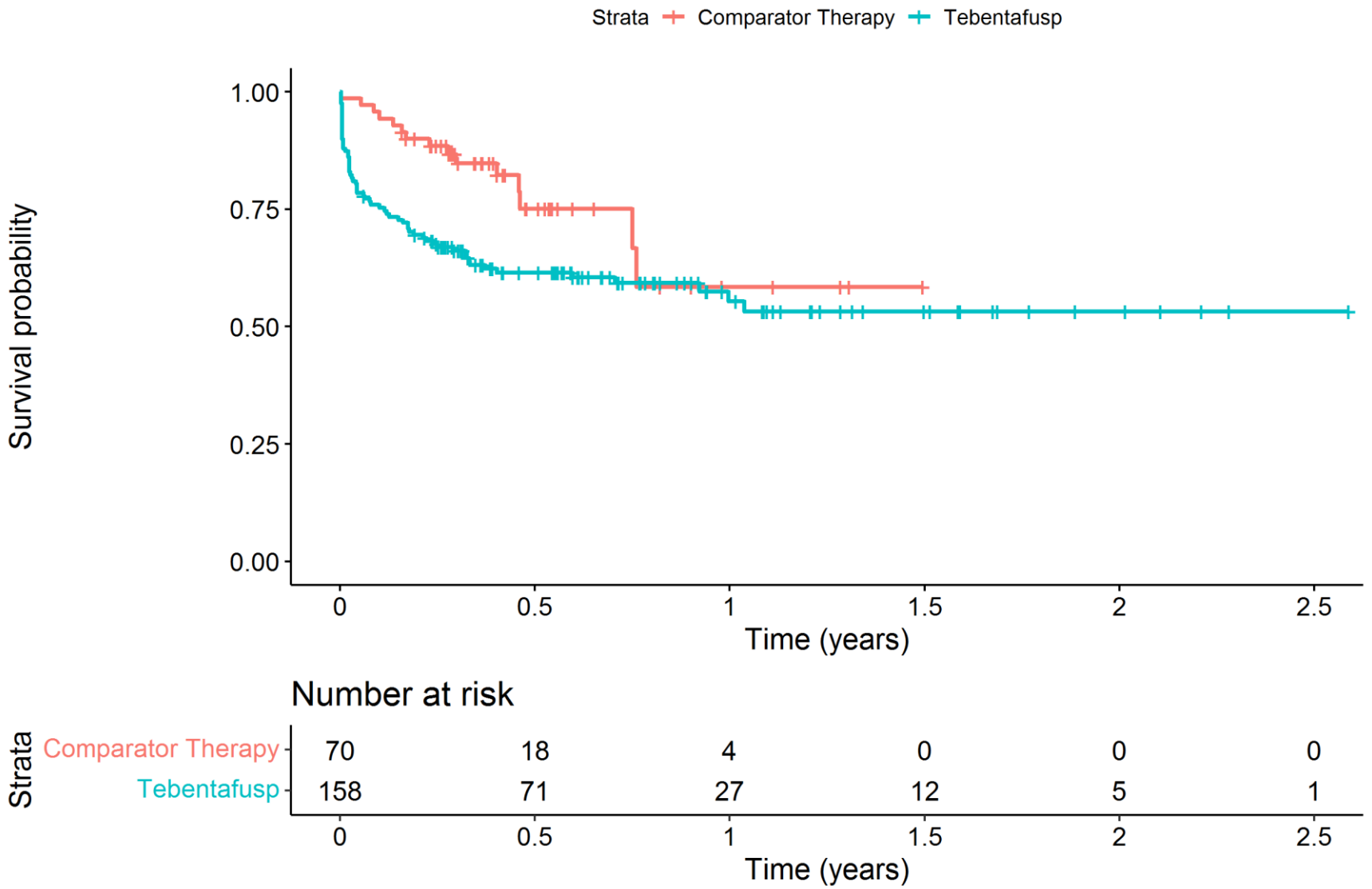
Stoffwechsel- und Ernährungsstörungen- ALP ≤ ULN



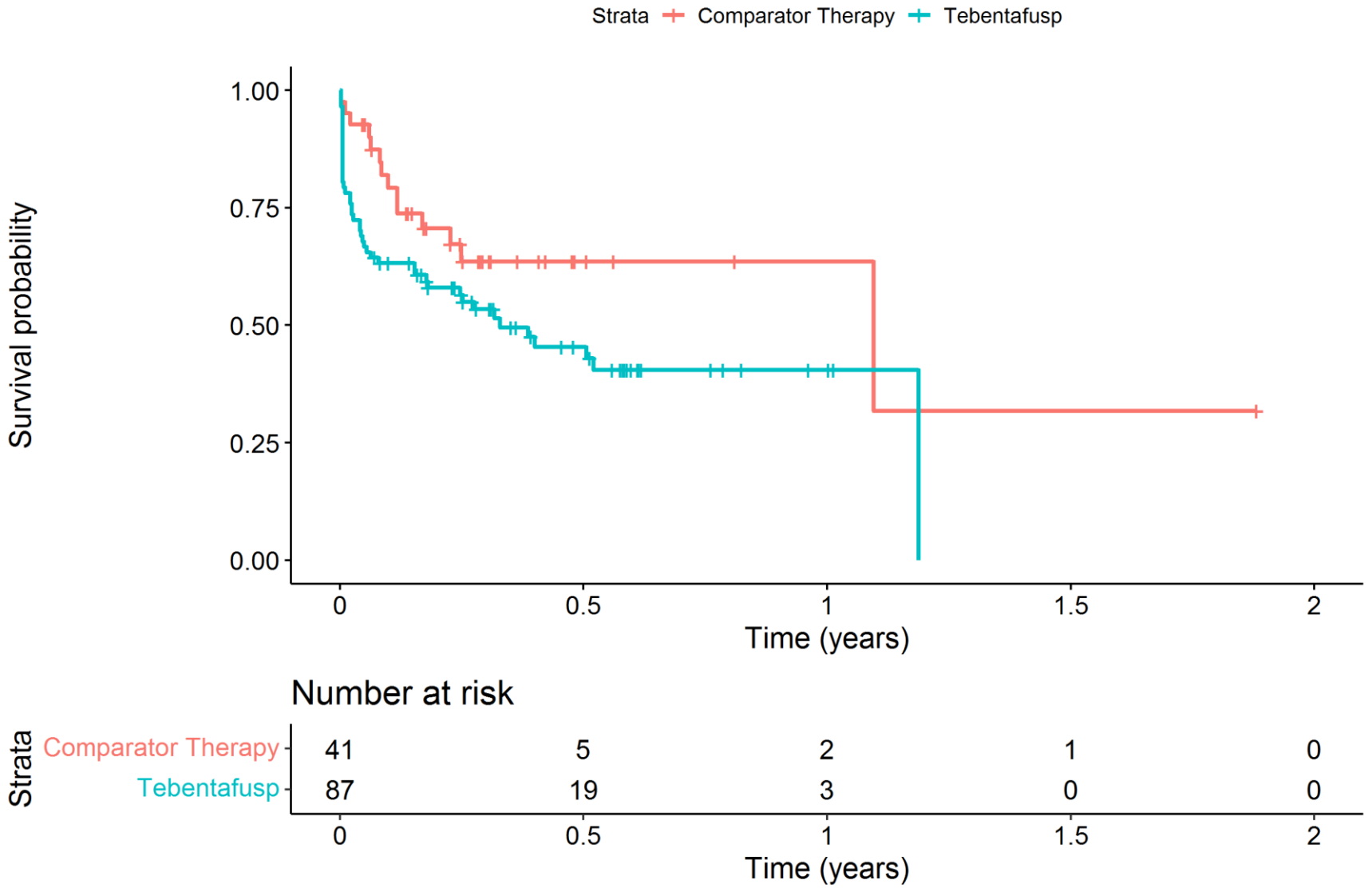
Stoffwechsel- und Ernährungsstörungen- ALP > ULN



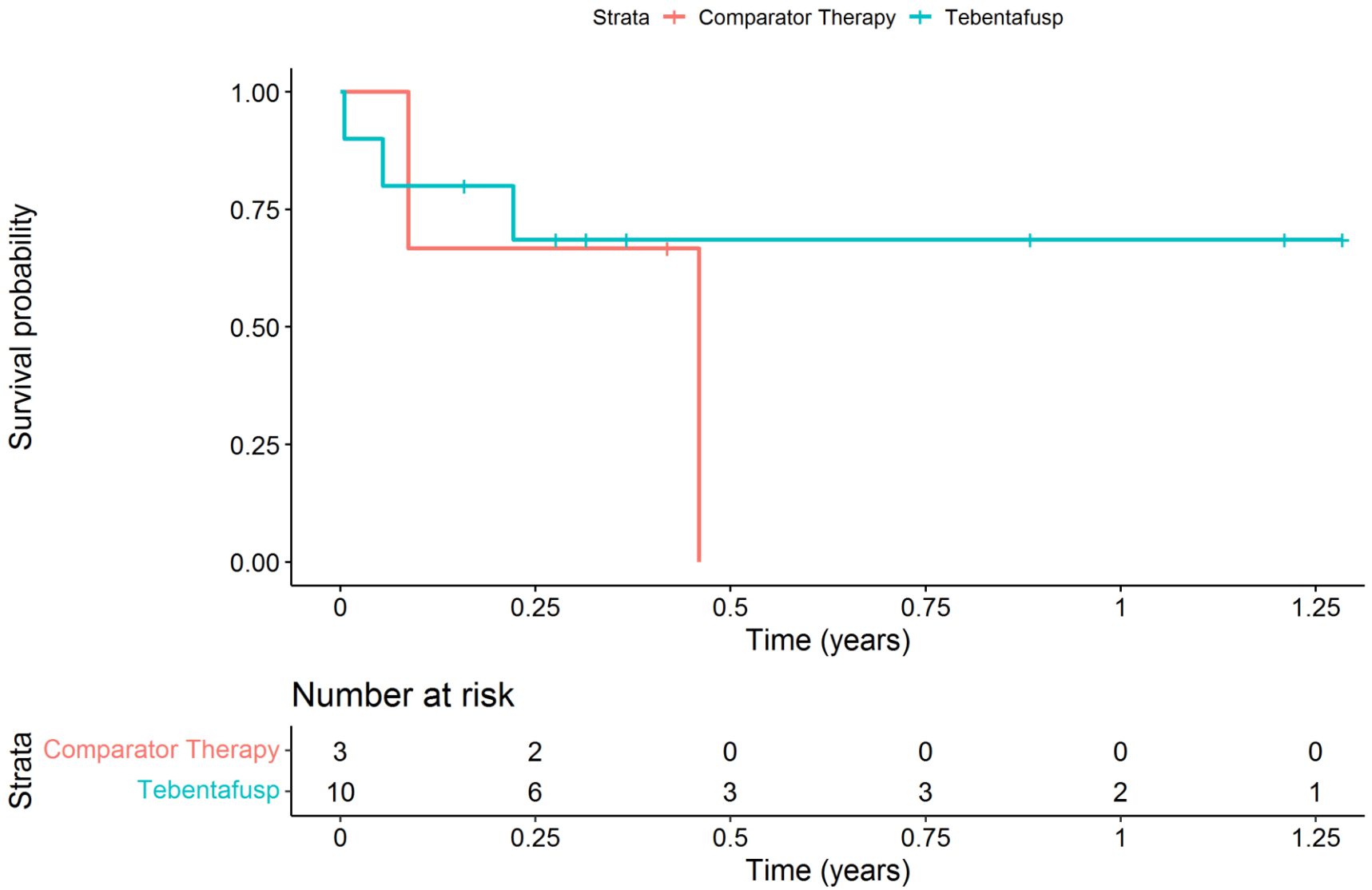
Stoffwechsel- und Ernährungsstörungen- LDH =< ULN



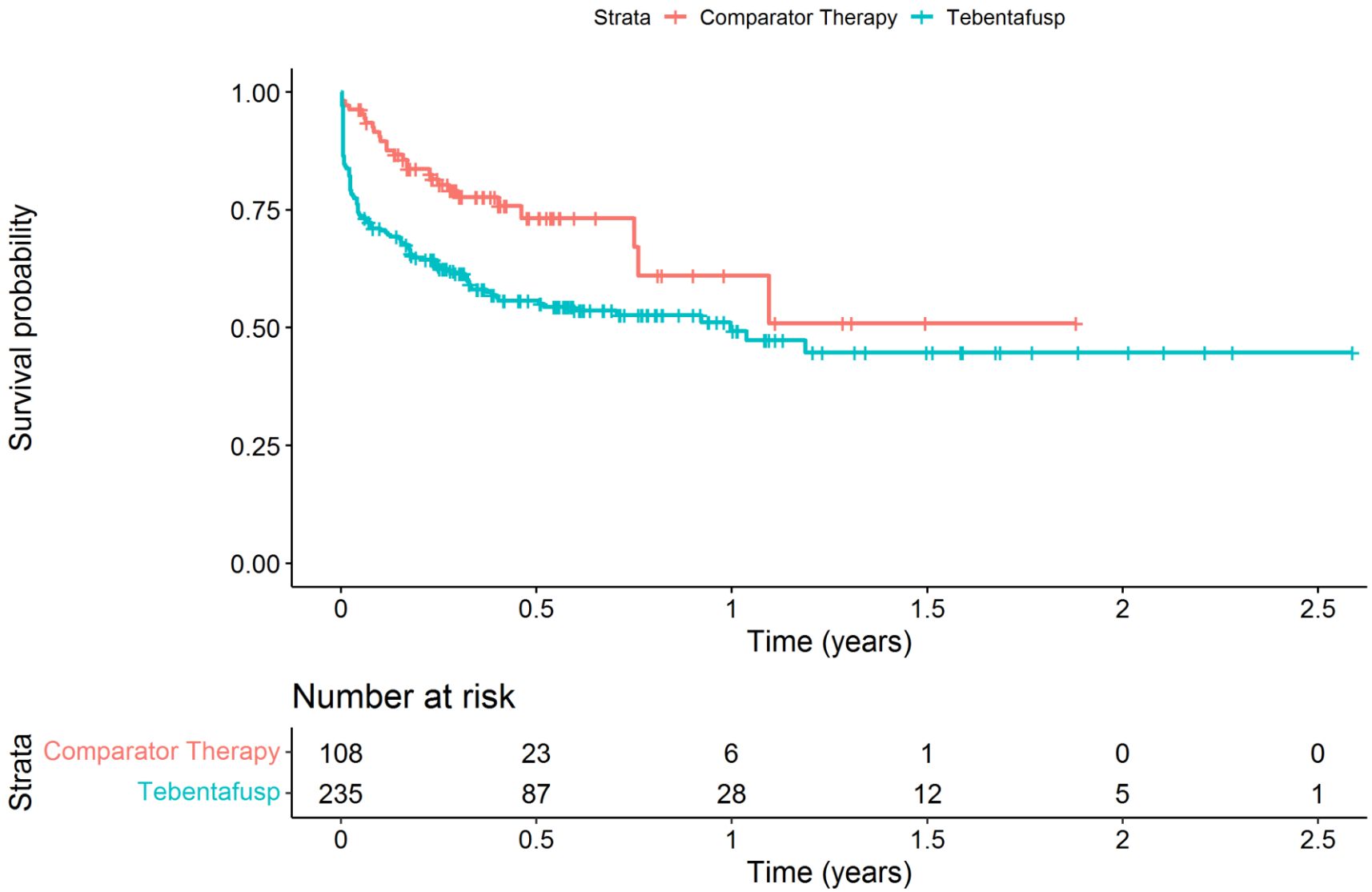
Stoffwechsel- und Ernährungsstörungen- LDH > ULN



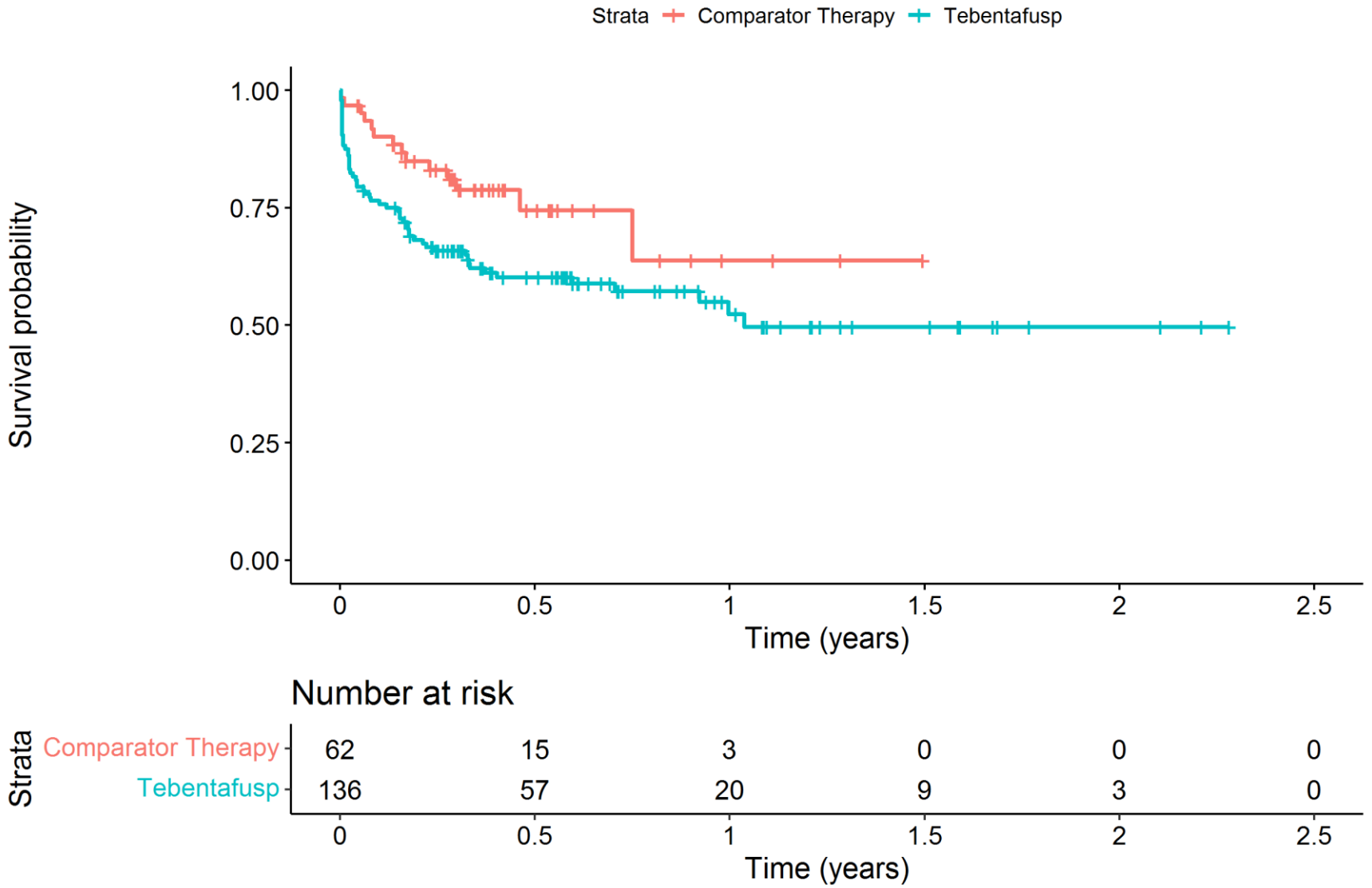
Stoffwechsel- und Ernährungsstörungen- Vorherige Therapie adjuvant/neoadjuvant



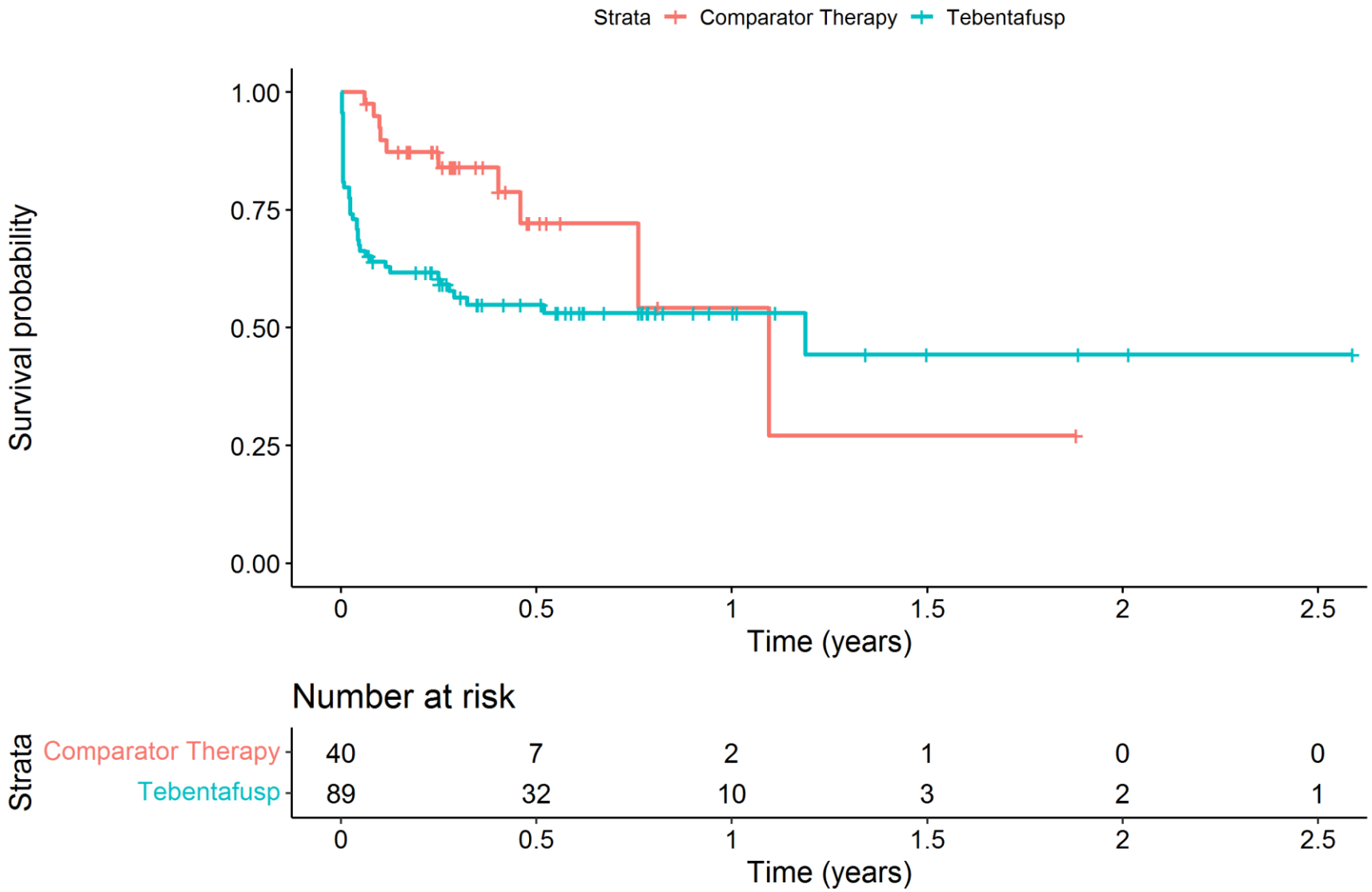
Stoffwechsel- und Ernährungsstörungen- Keine vorherige Therapie adjuvant/neoadjuvant



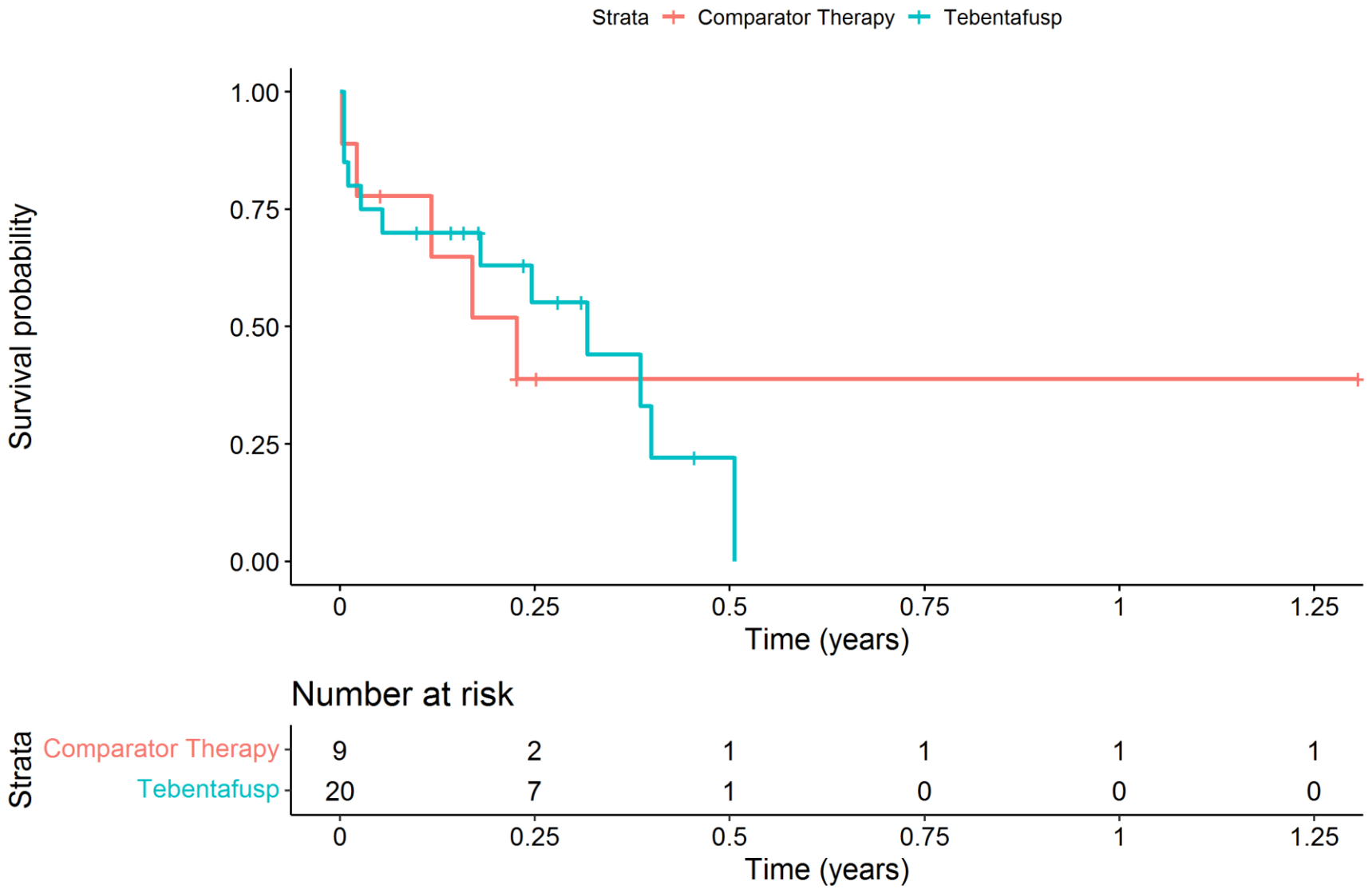
Stoffwechsel- und Ernährungsstörungen- Läsion ≤ 3cm



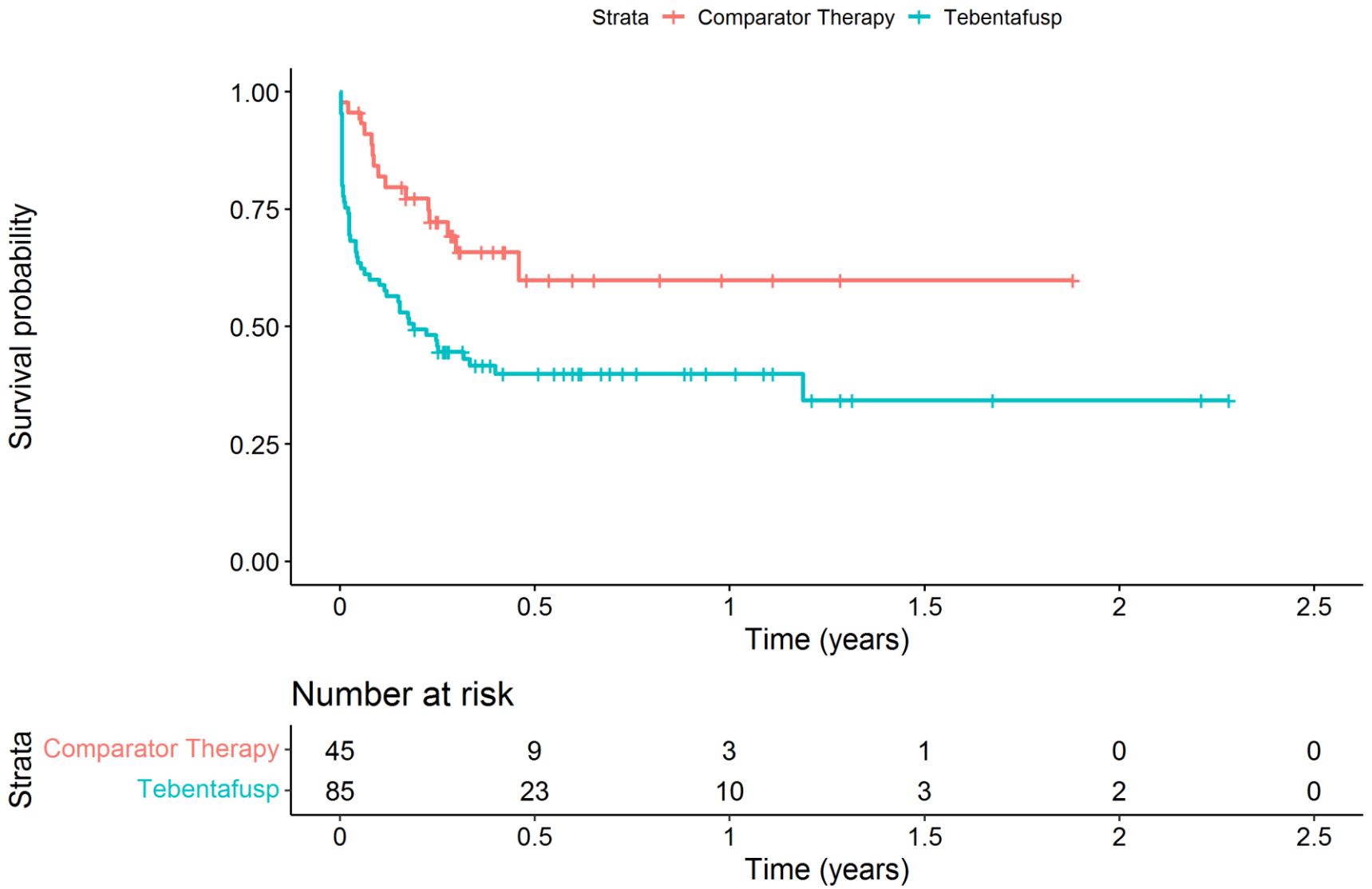
Stoffwechsel- und Ernährungsstörungen- Läsion 3,1-8,0 cm



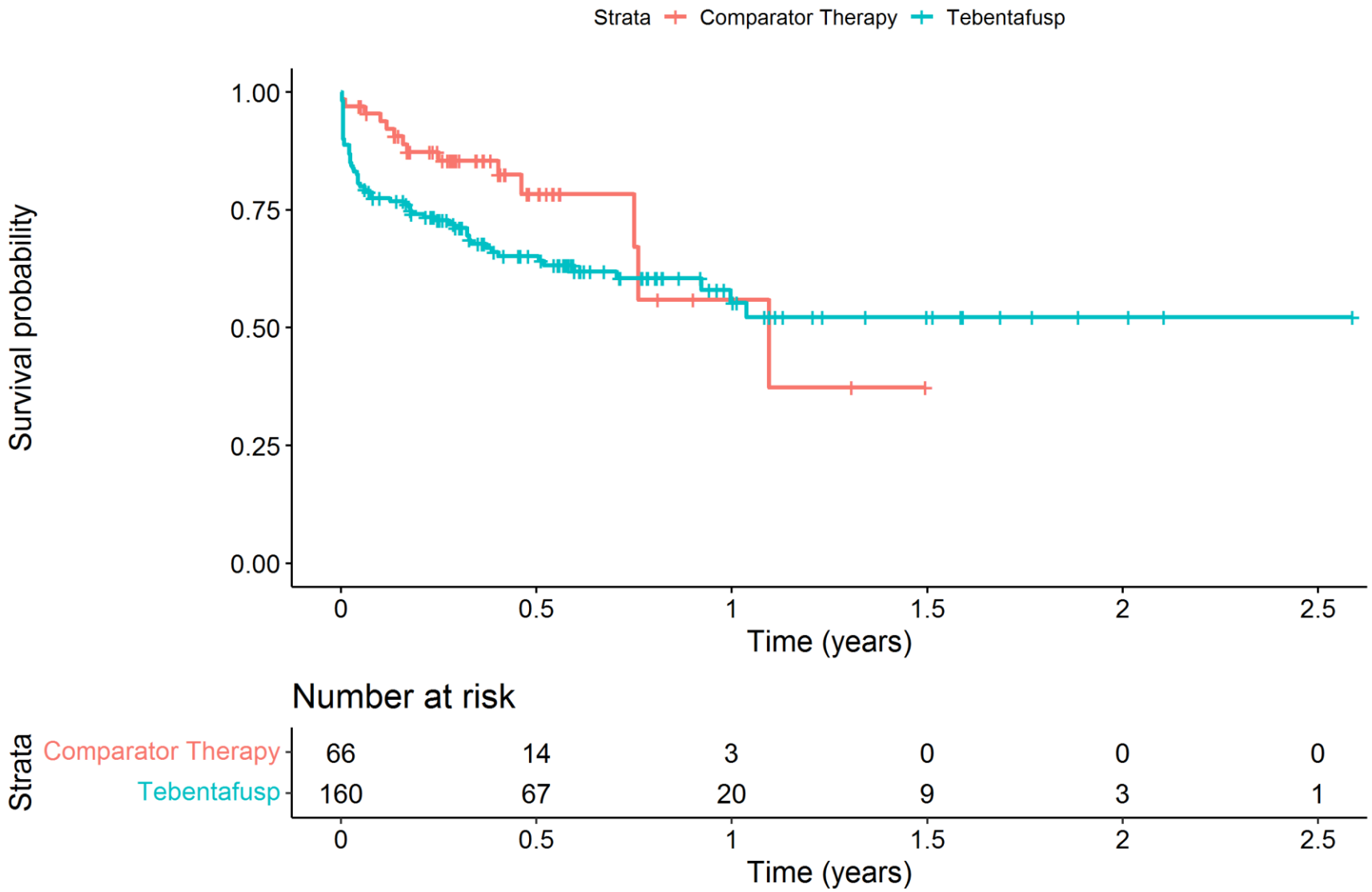
Stoffwechsel- und Ernährungsstörungen- Läsion ≥8,1 cm



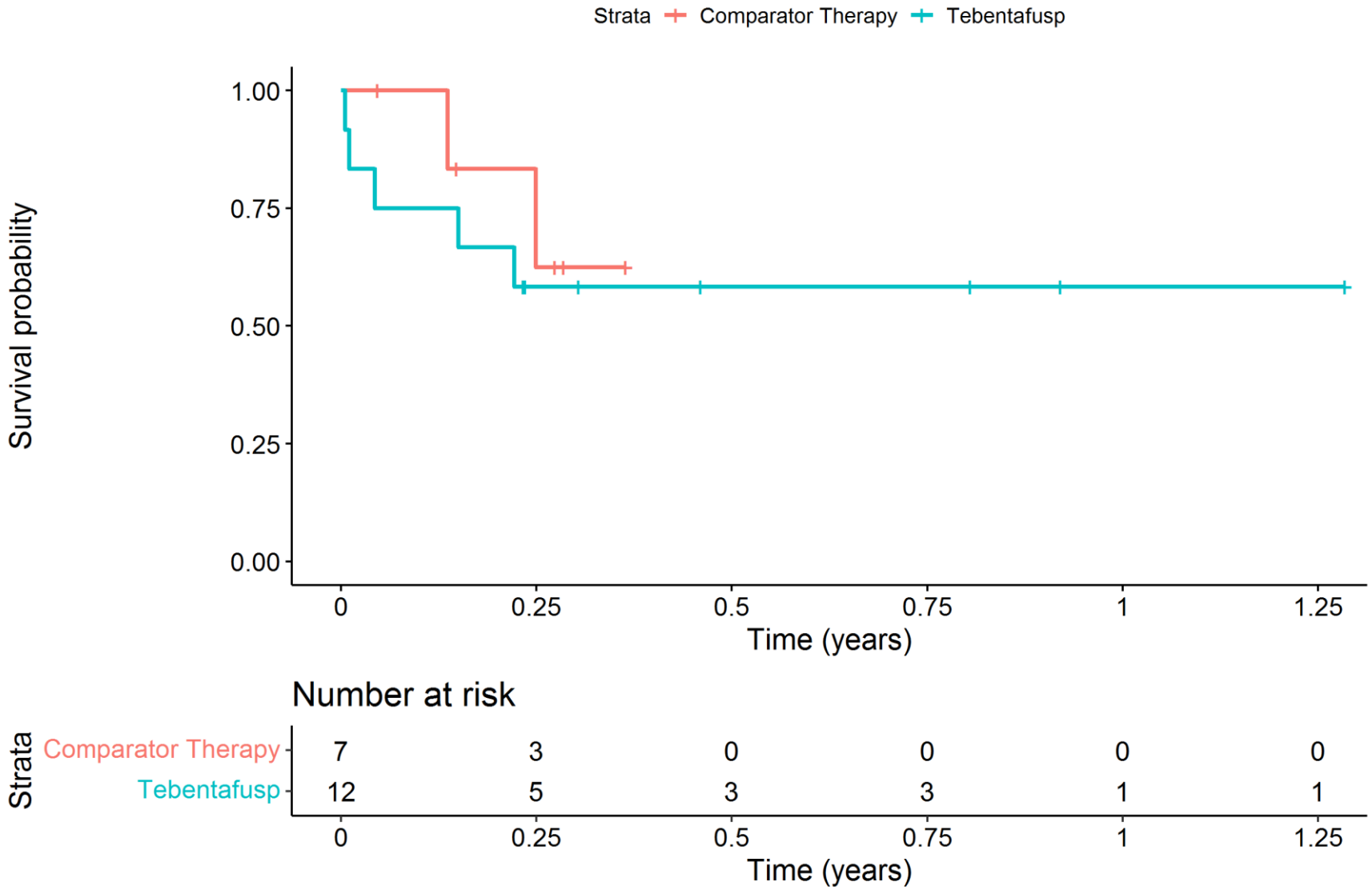
Stoffwechsel- und Ernährungsstörungen- Nordamerika



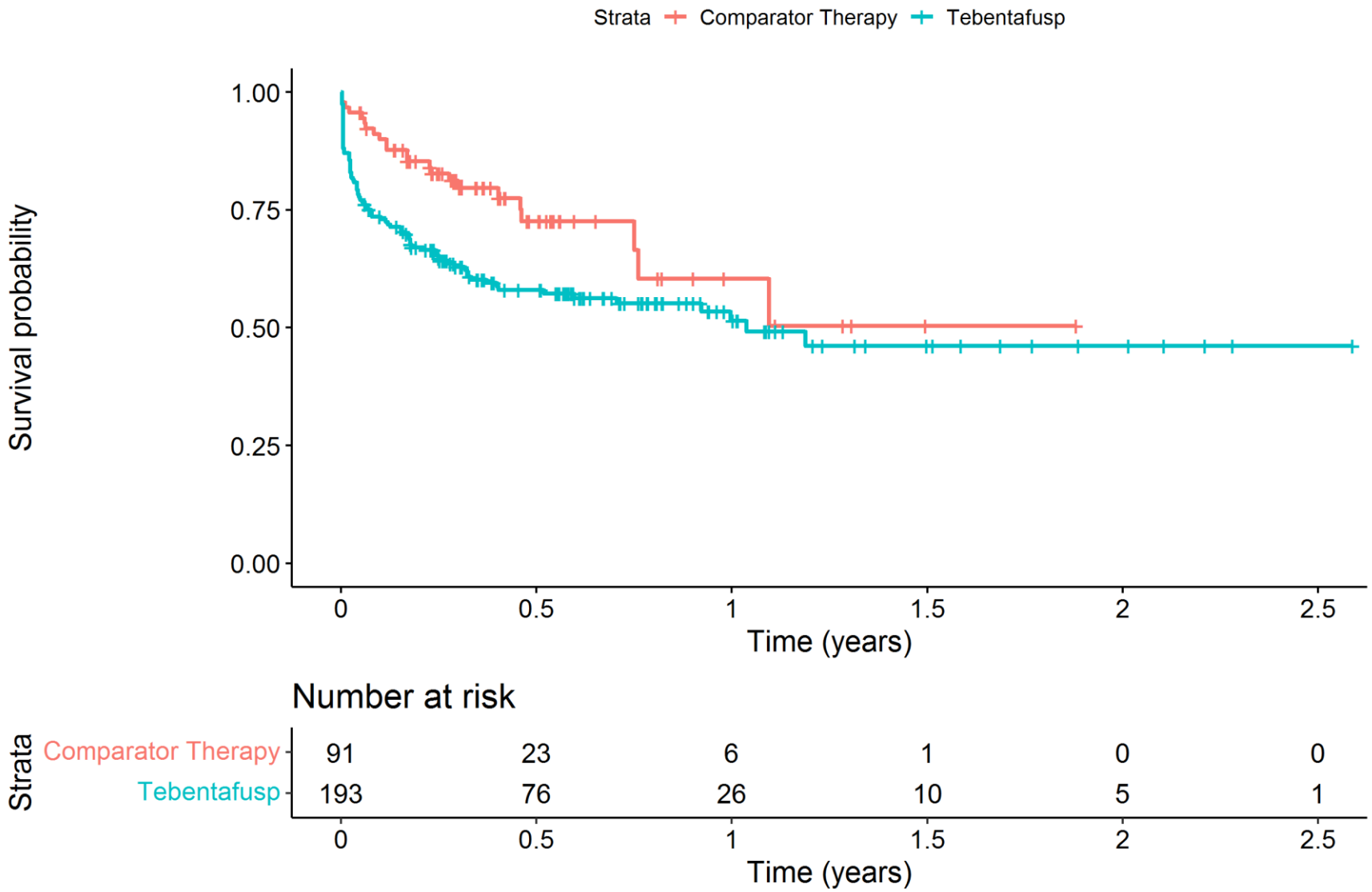
Stoffwechsel- und Ernährungsstörungen- Nicht-Nordamerika



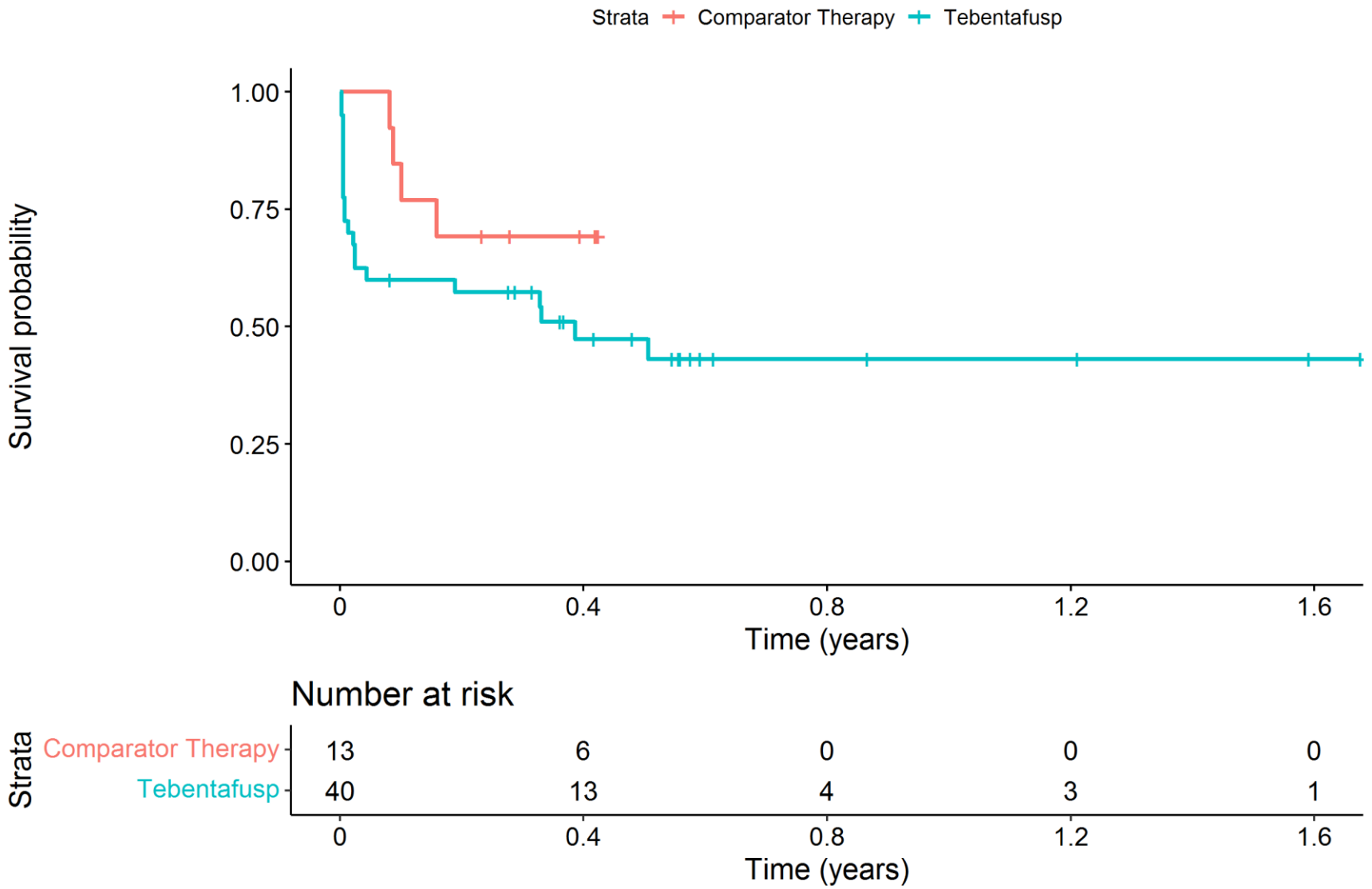
Stoffwechsel- und Ernährungsstörungen- Dacarbazin



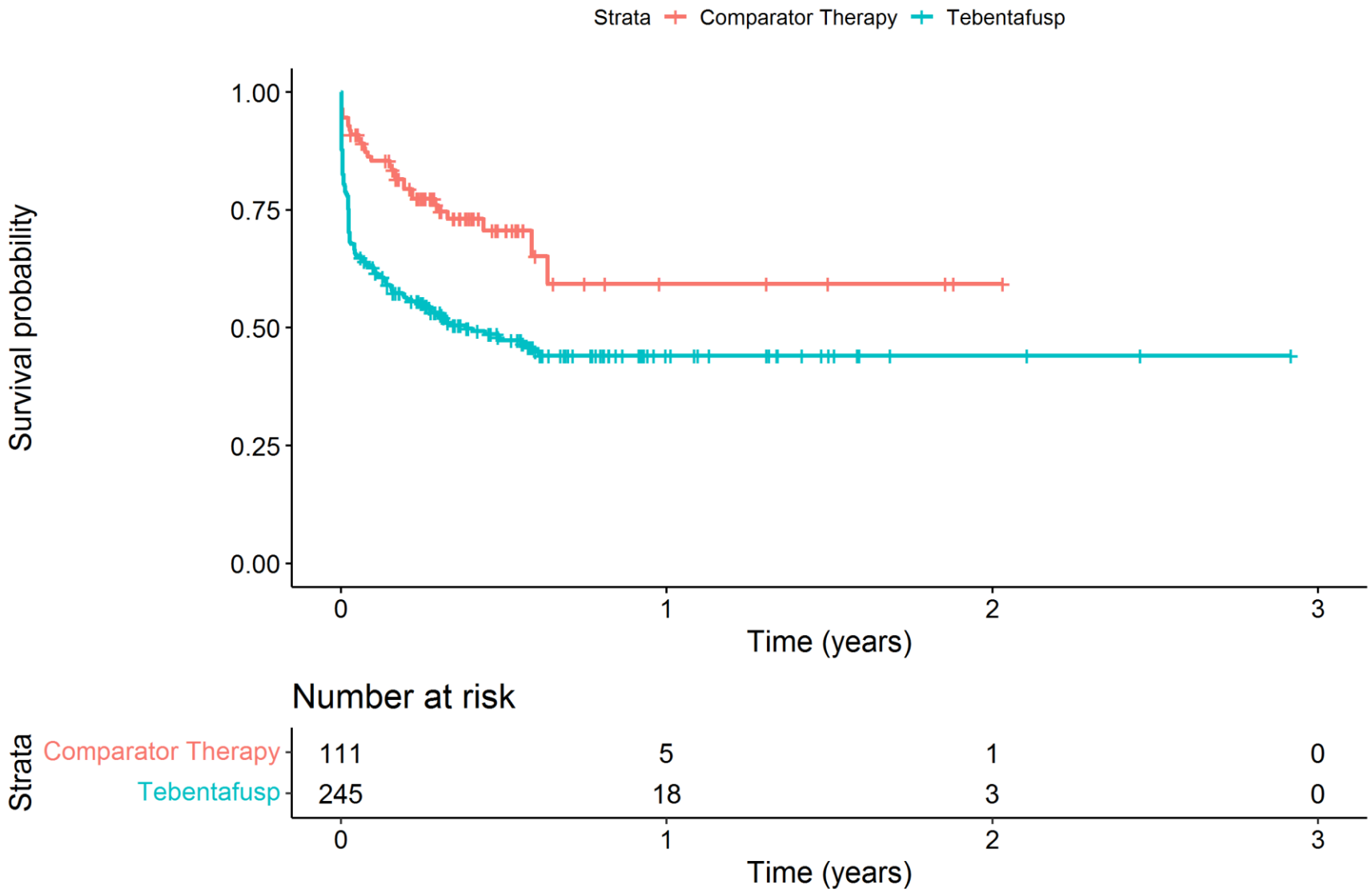
Stoffwechsel- und Ernährungsstörungen- Pembrolizumab



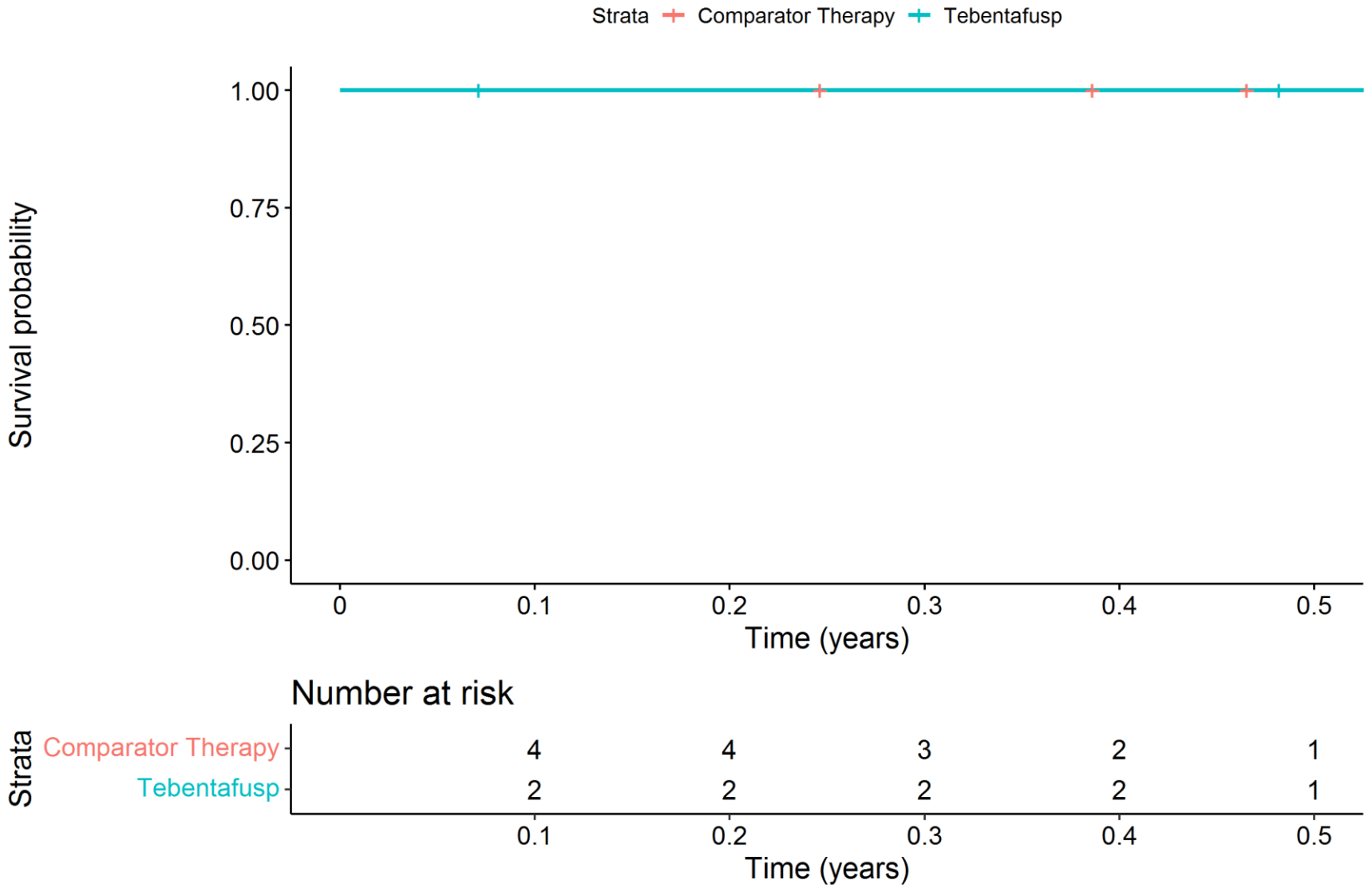
Stoffwechsel- und Ernährungsstörungen- Ipilimumab



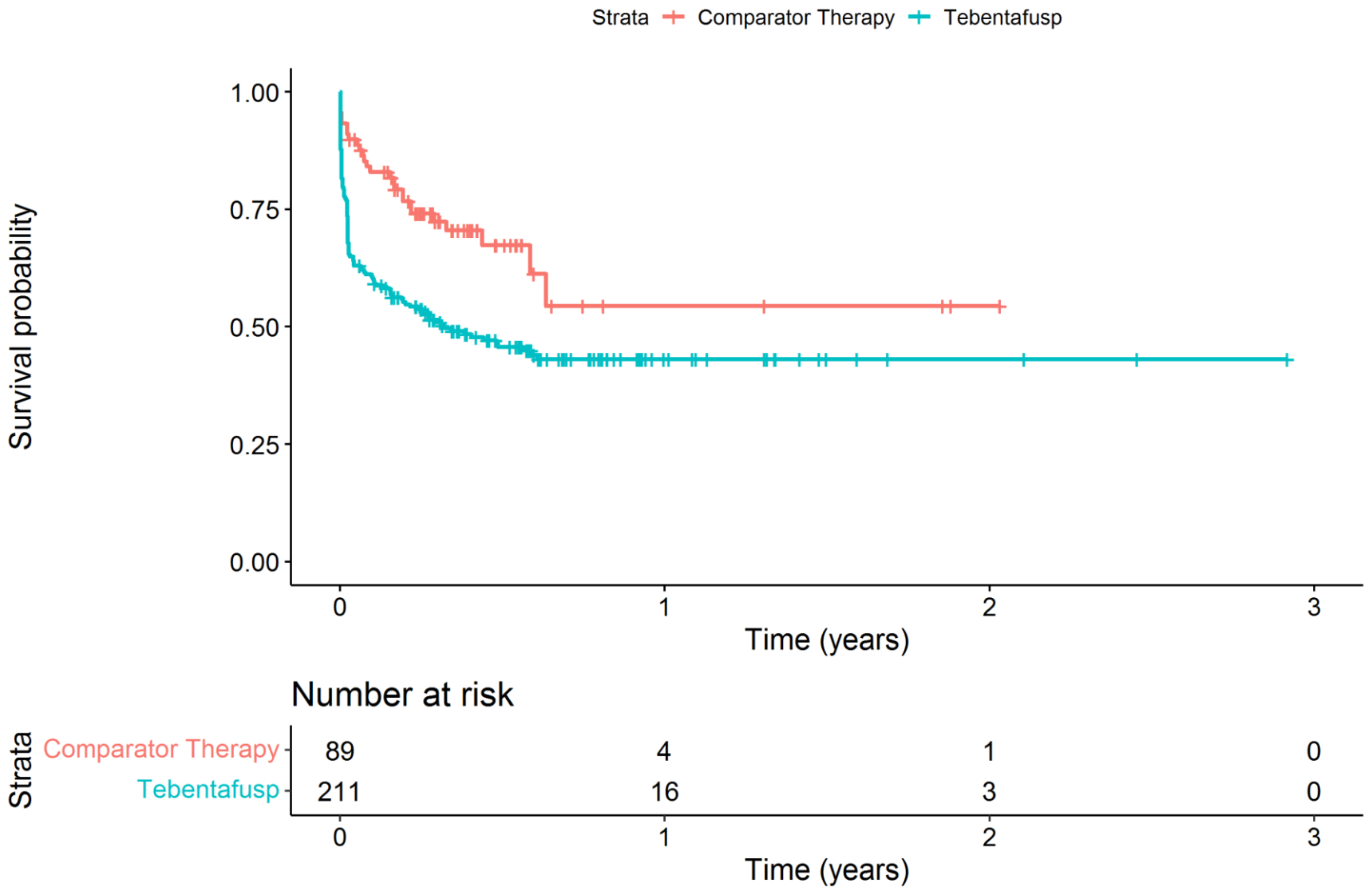
54.37 Erkrankungen des Nervensystems- Gesamt



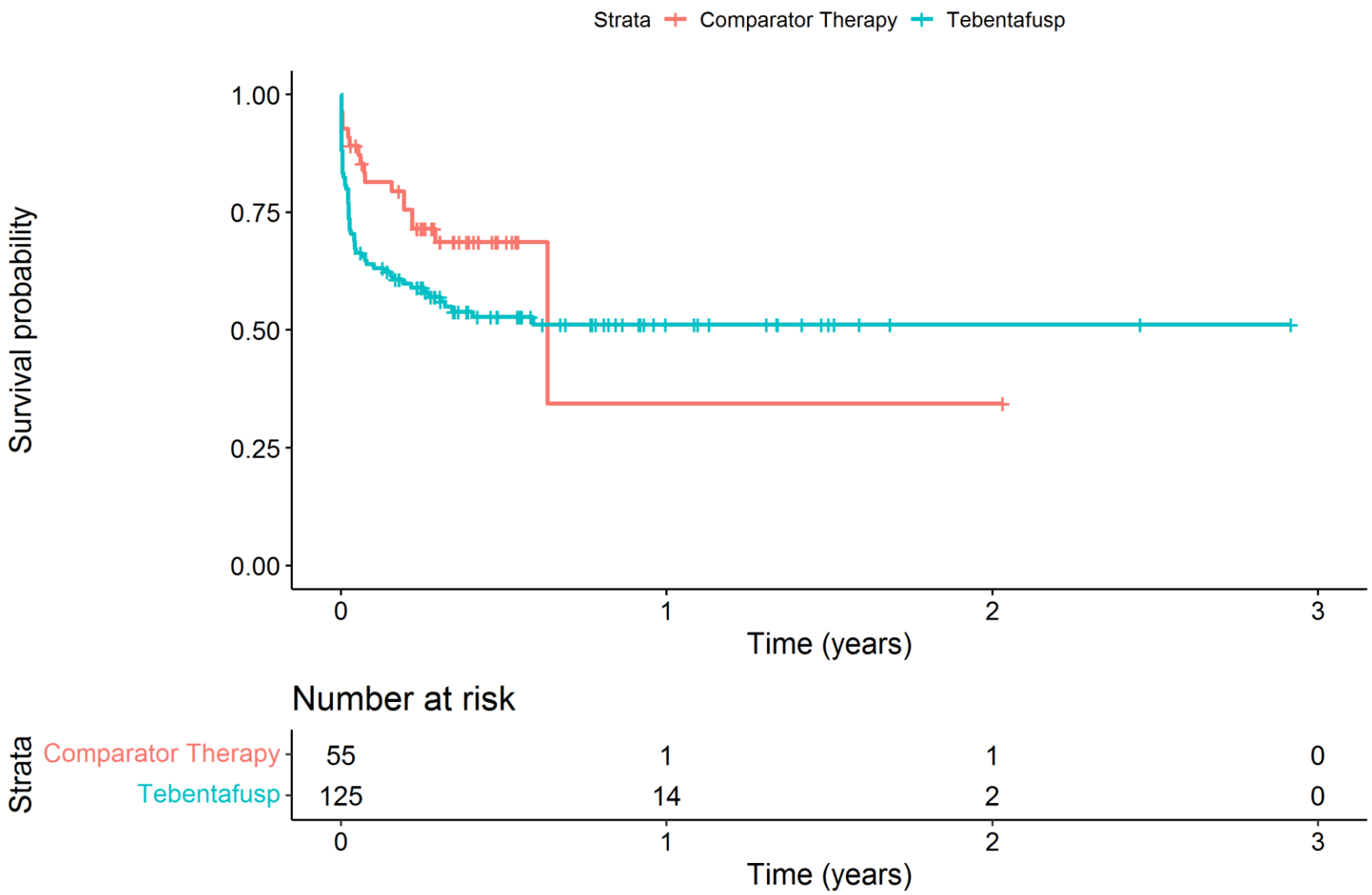
Erkrankungen des Nervensystems- Hispanisch



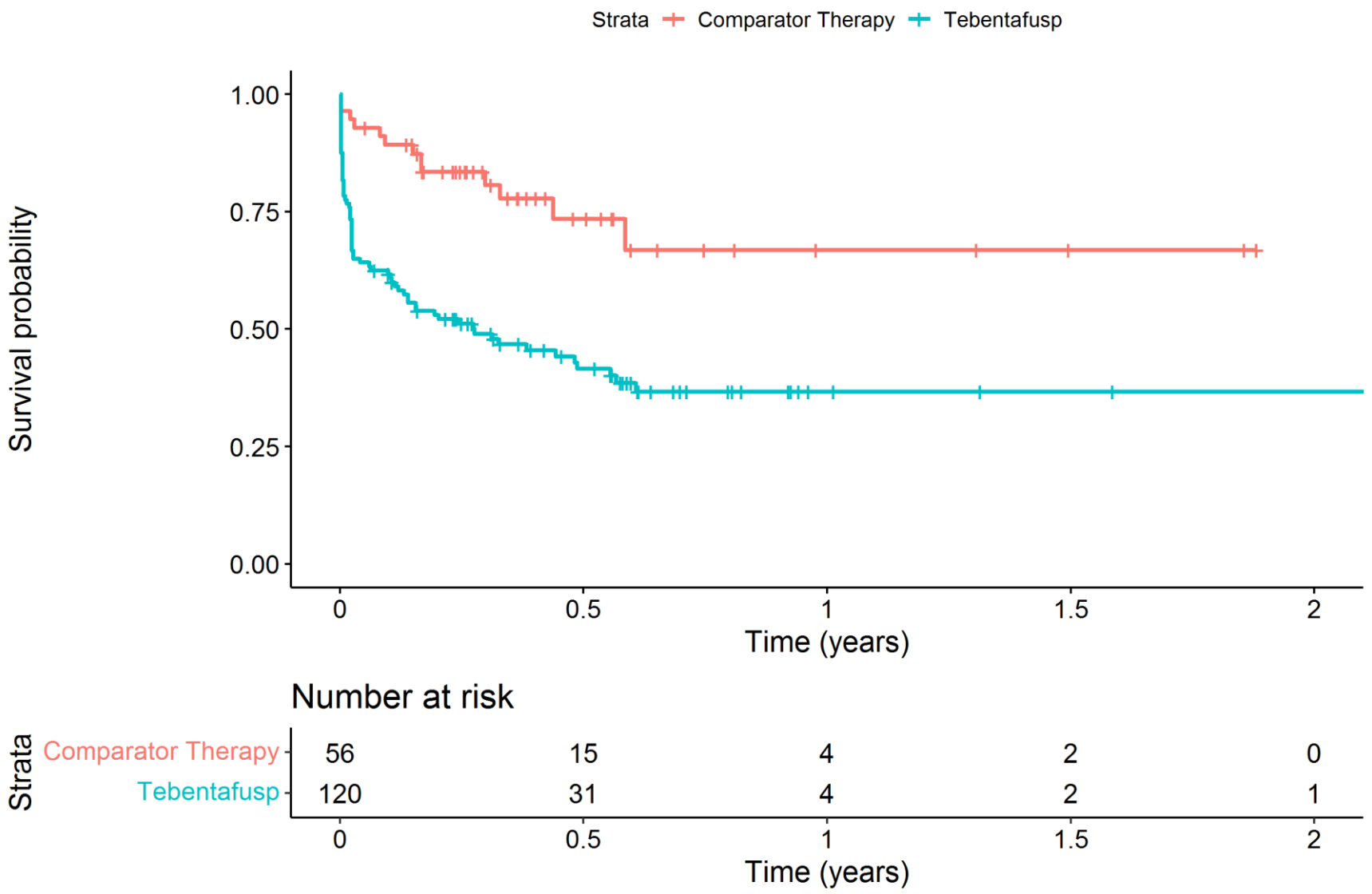
Erkrankungen des Nervensystems- Nicht-hispanisch


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
89
4
1
0
211
16
3
0
0
1
2
3
Time (years)

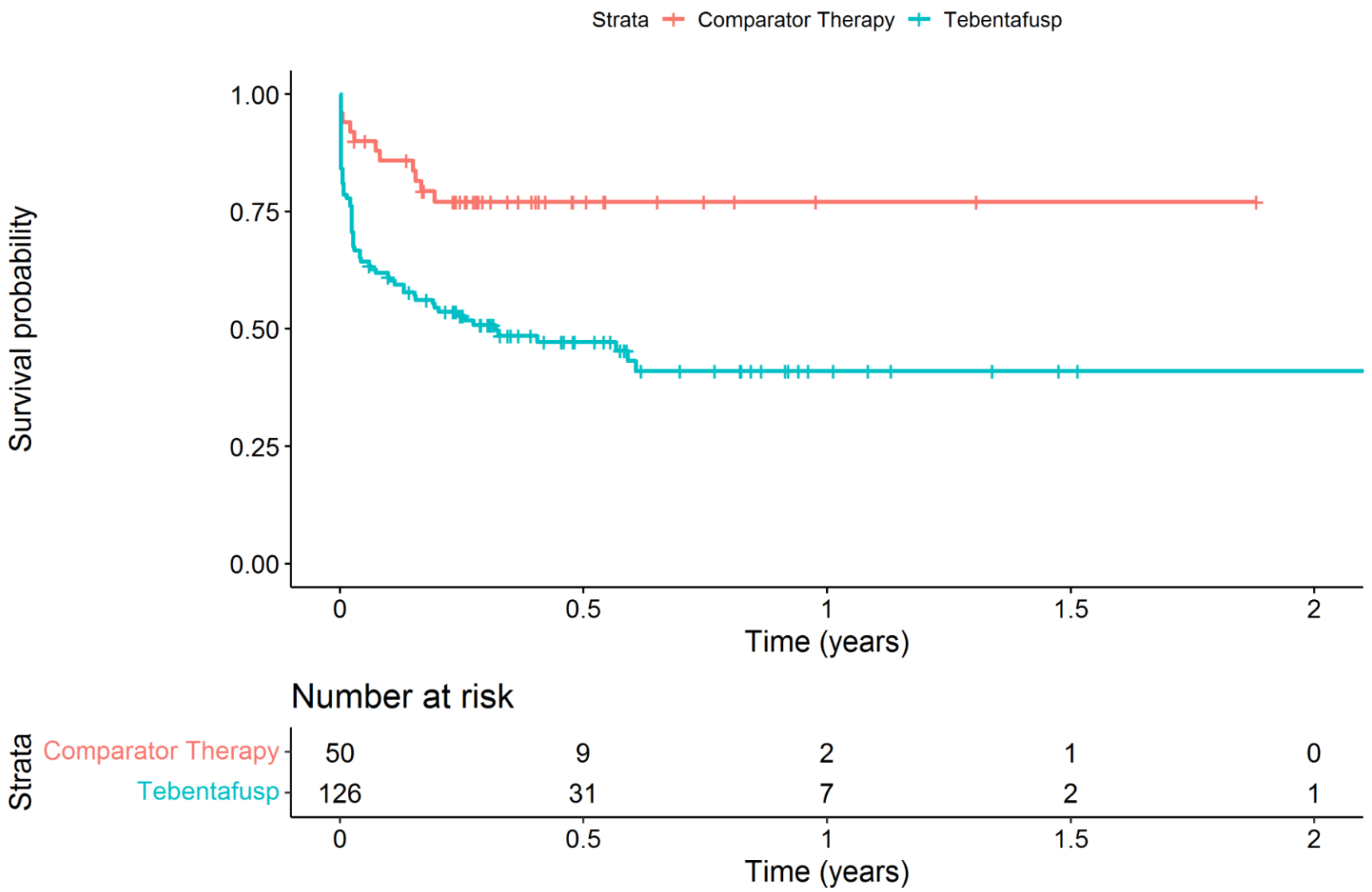
54.38 Erkrankungen des Nervensystems- Männlich



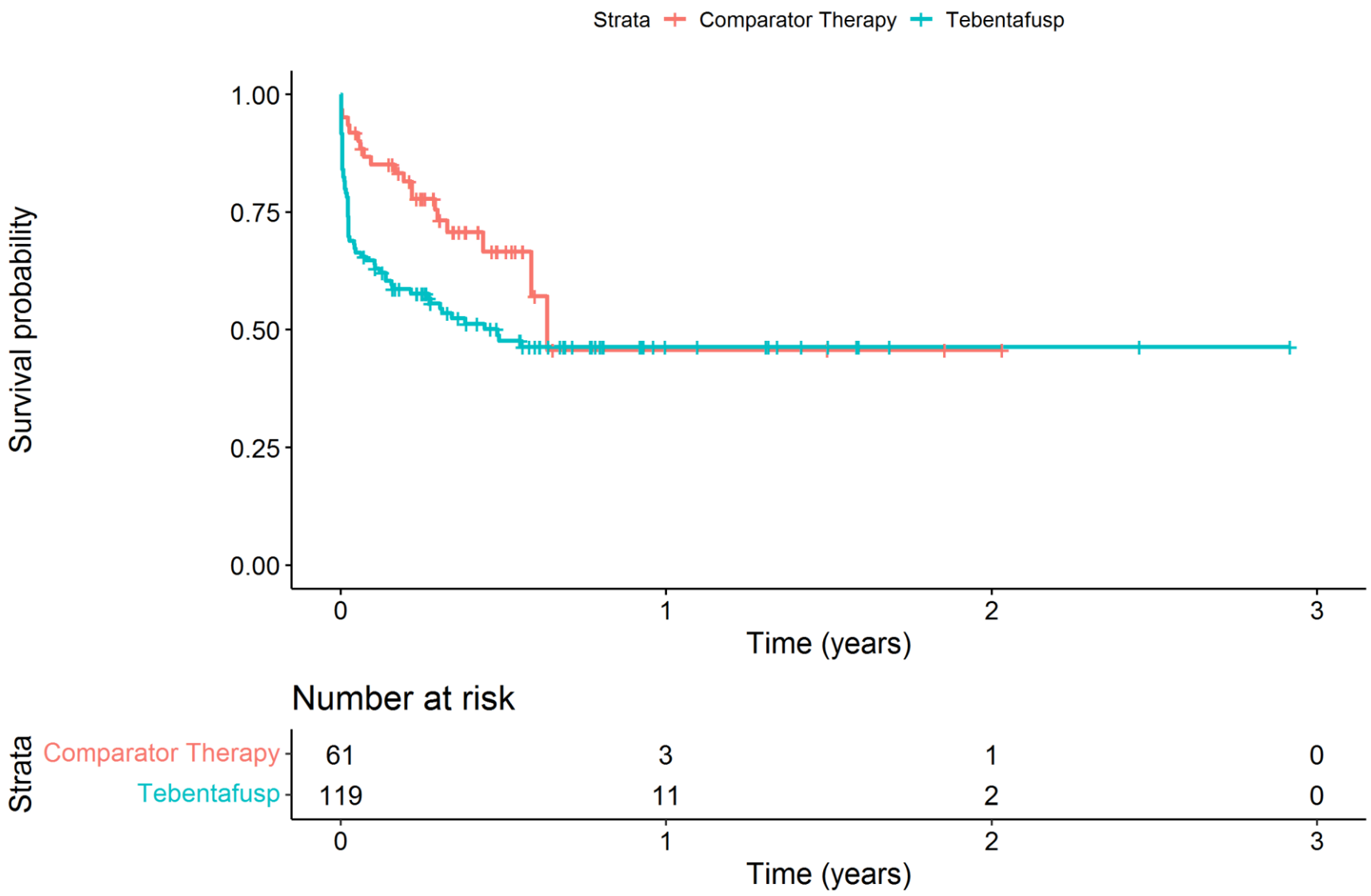
54.39 Erkrankungen des Nervensystems- Weiblich



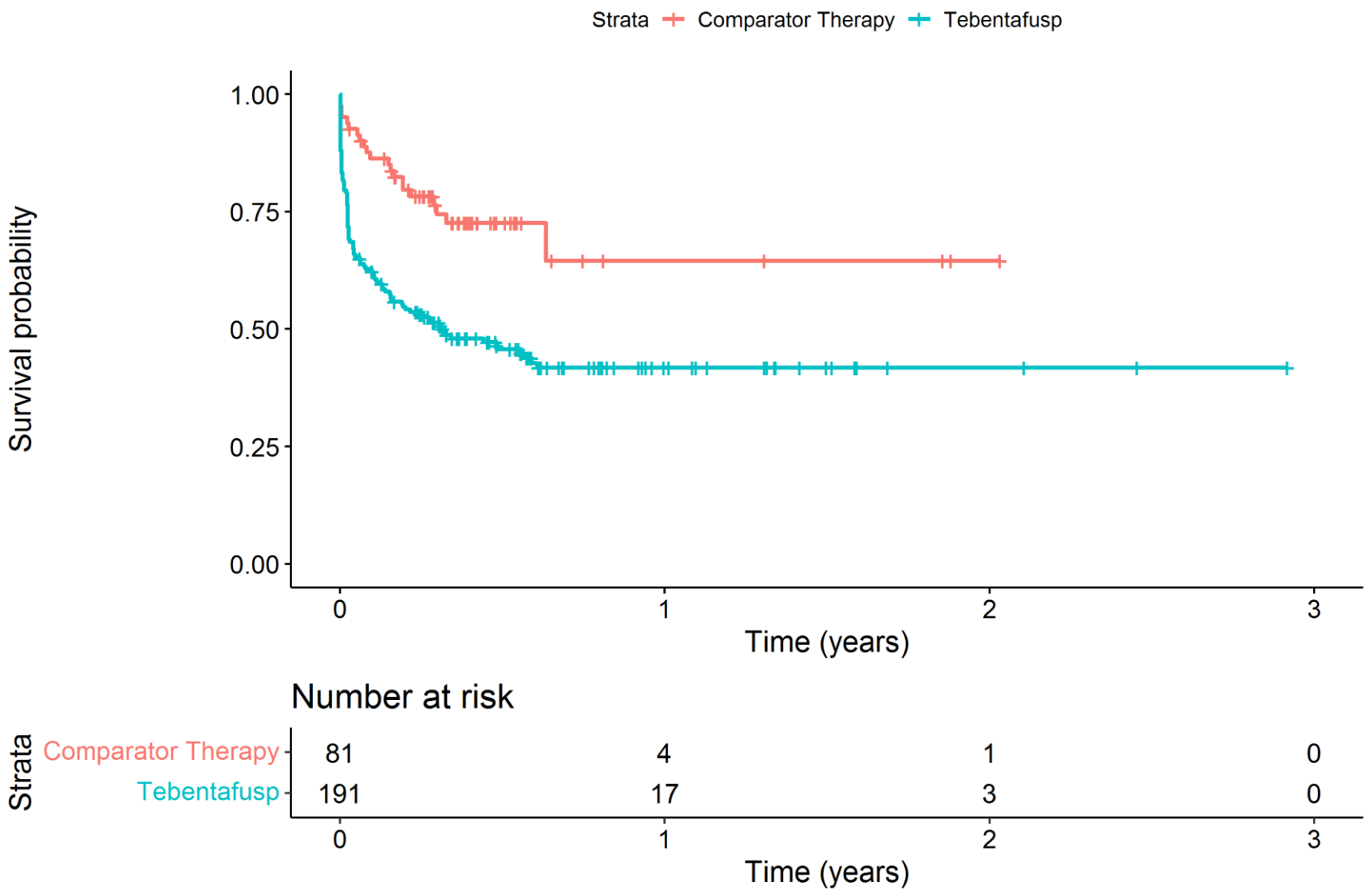
54.40 Erkrankungen des Nervensystems- <65



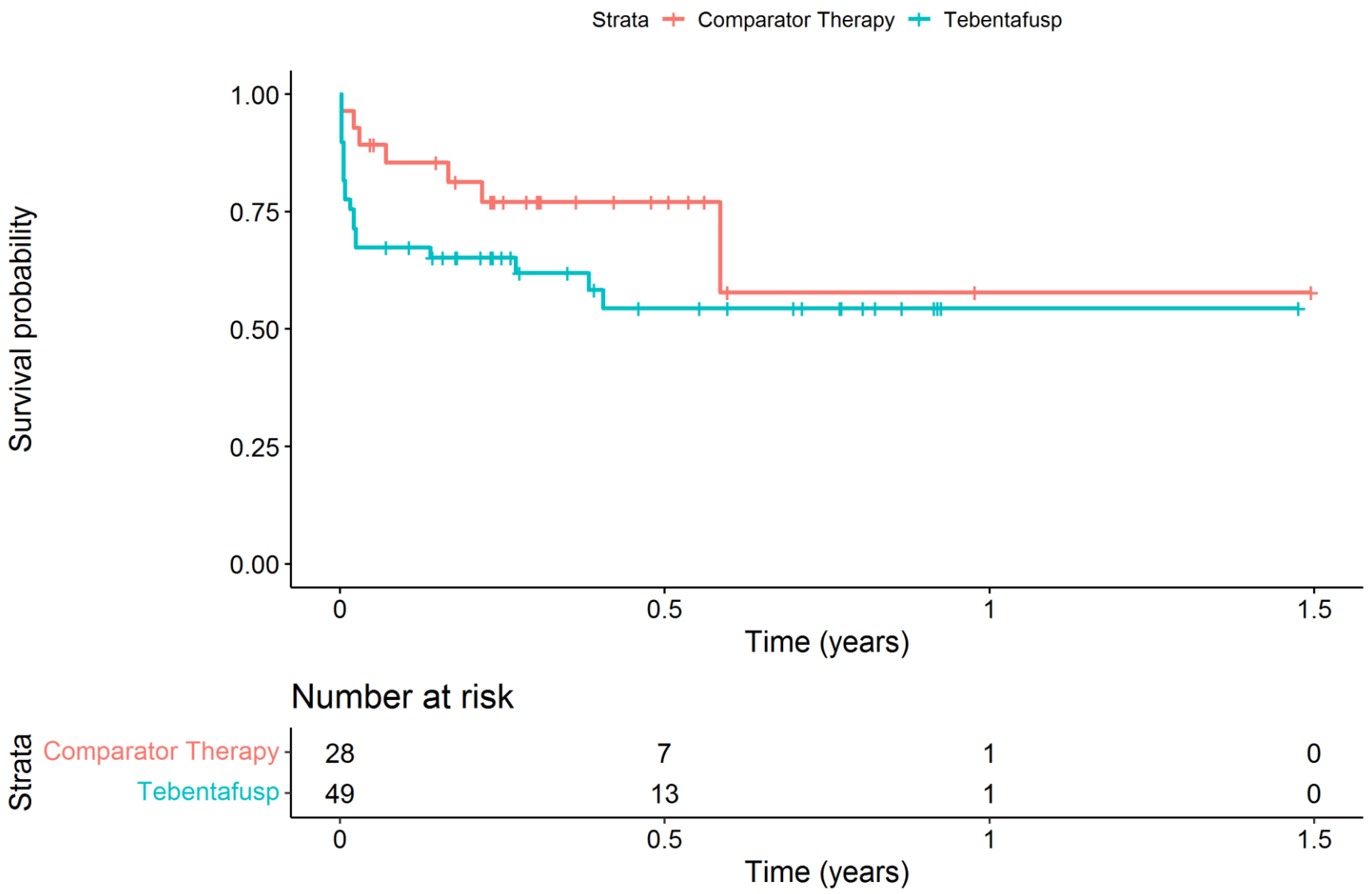
54.41 Erkrankungen des Nervensystems- ≥65



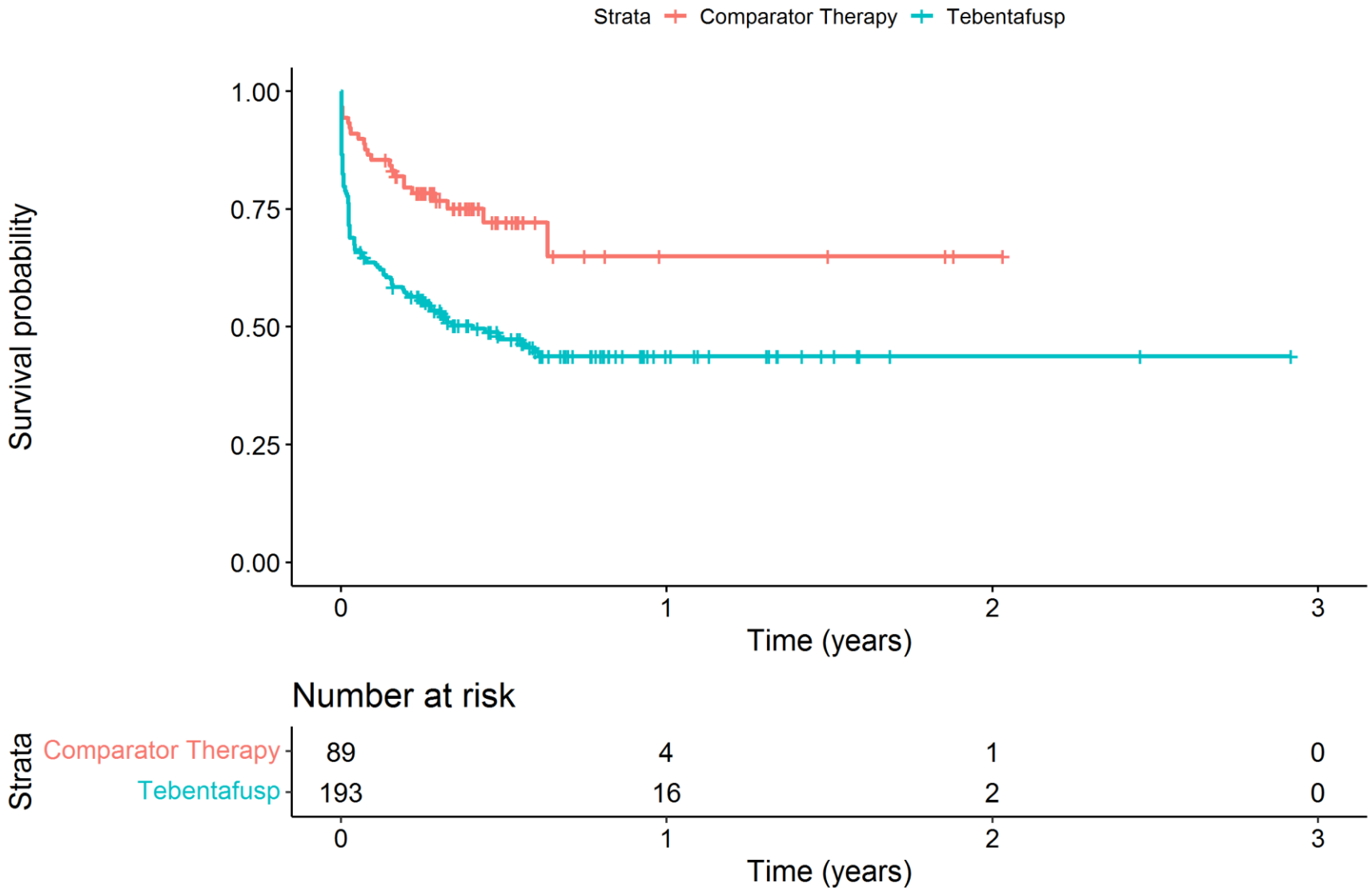
54.42 Erkrankungen des Nervensystems- ECOG 0



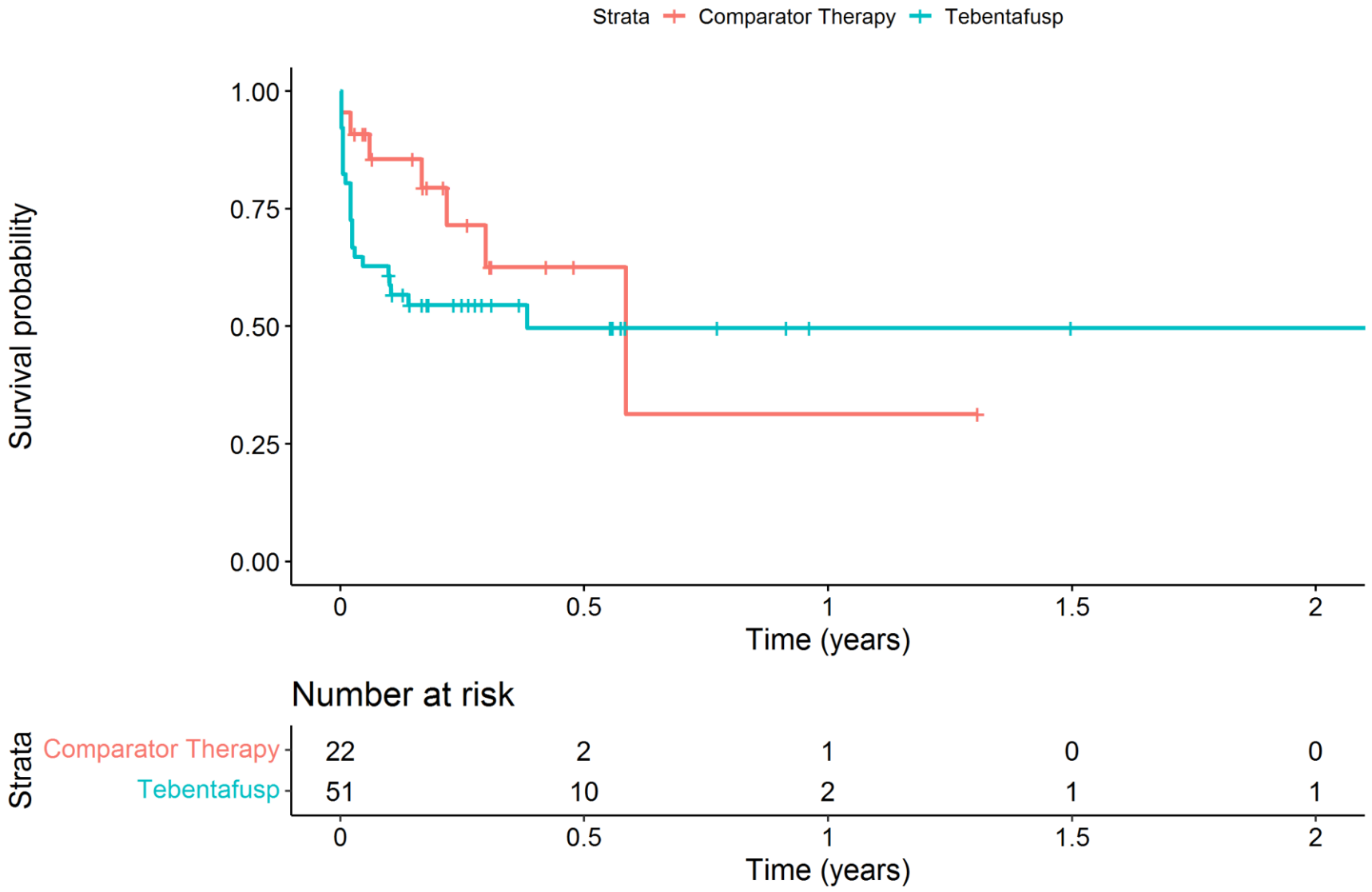
54.43 Erkrankungen des Nervensystems- ECOG 1



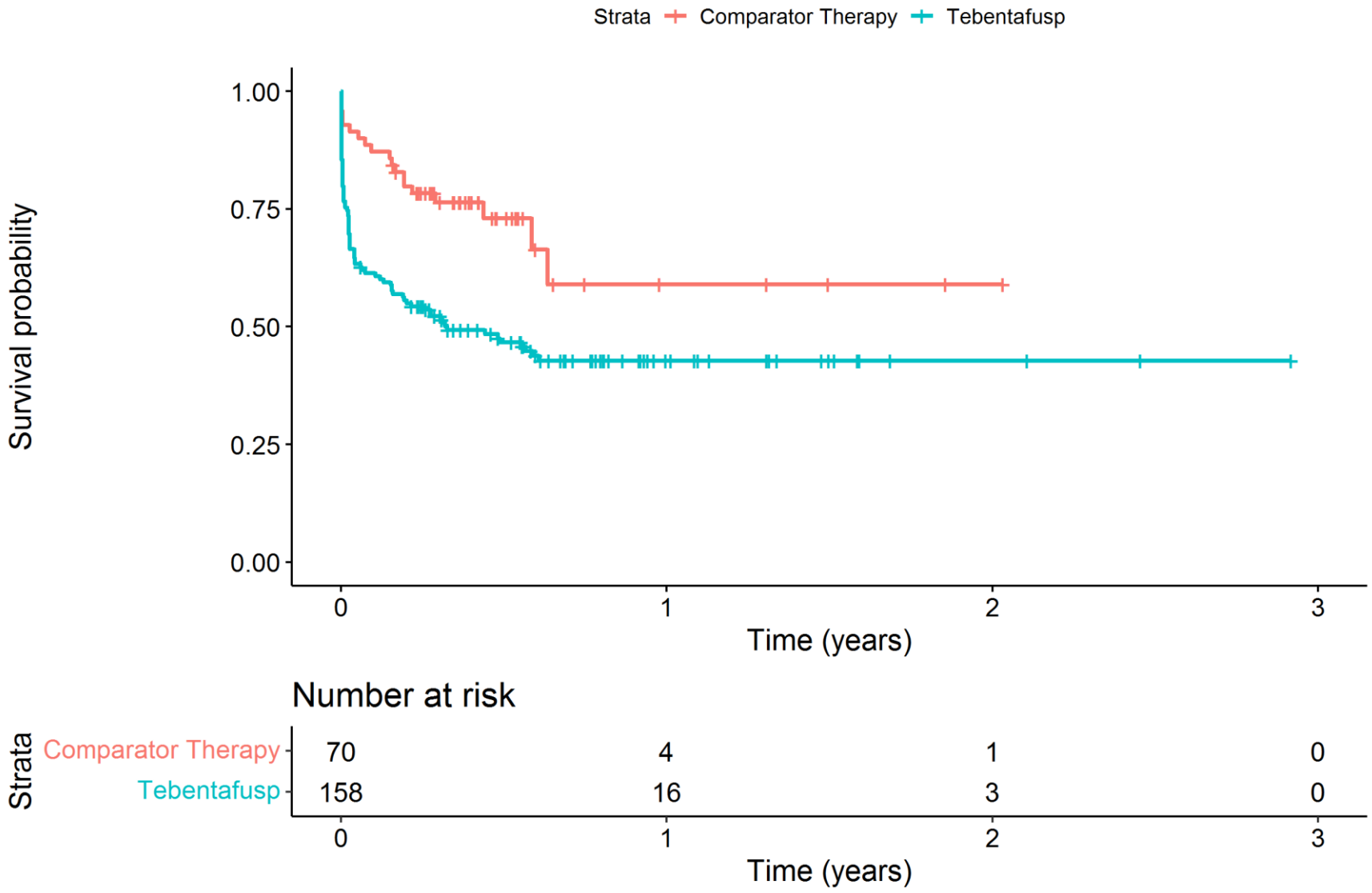
54.44 Erkrankungen des Nervensystems- ALP ≤ ULN



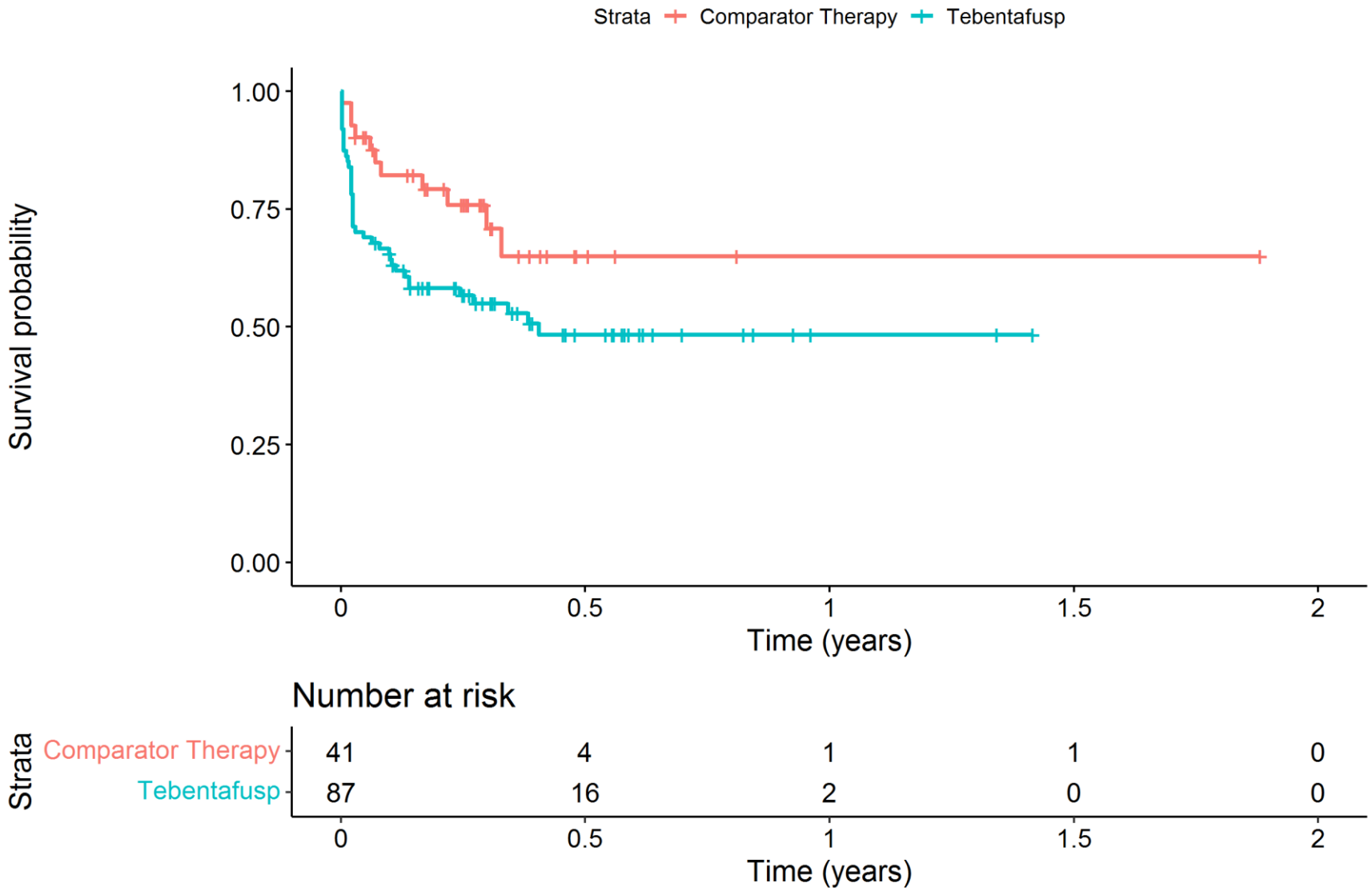
54.45 Erkrankungen des Nervensystems- ALP > ULN



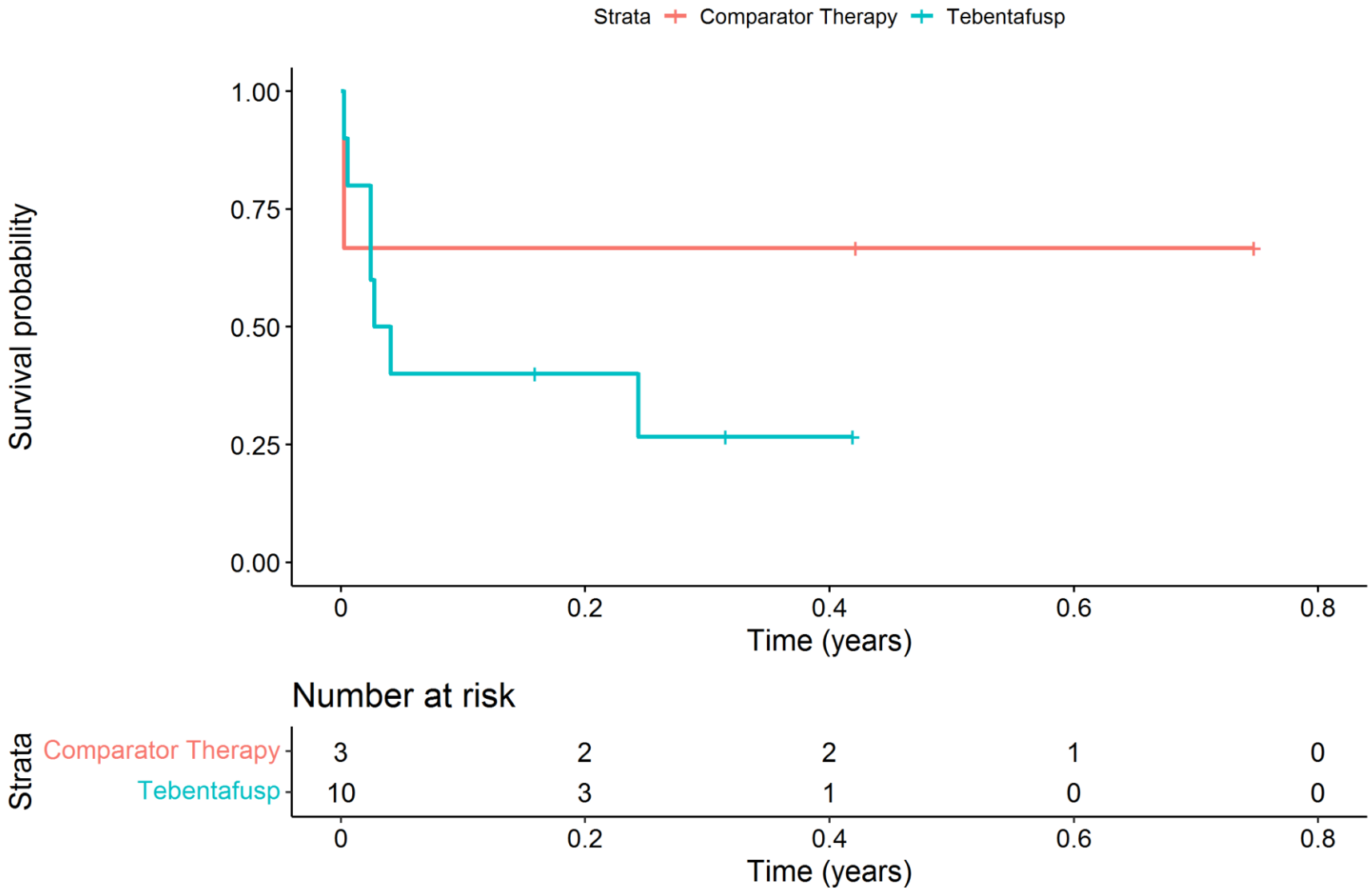
54.46 Erkrankungen des Nervensystems- LDH =< ULN



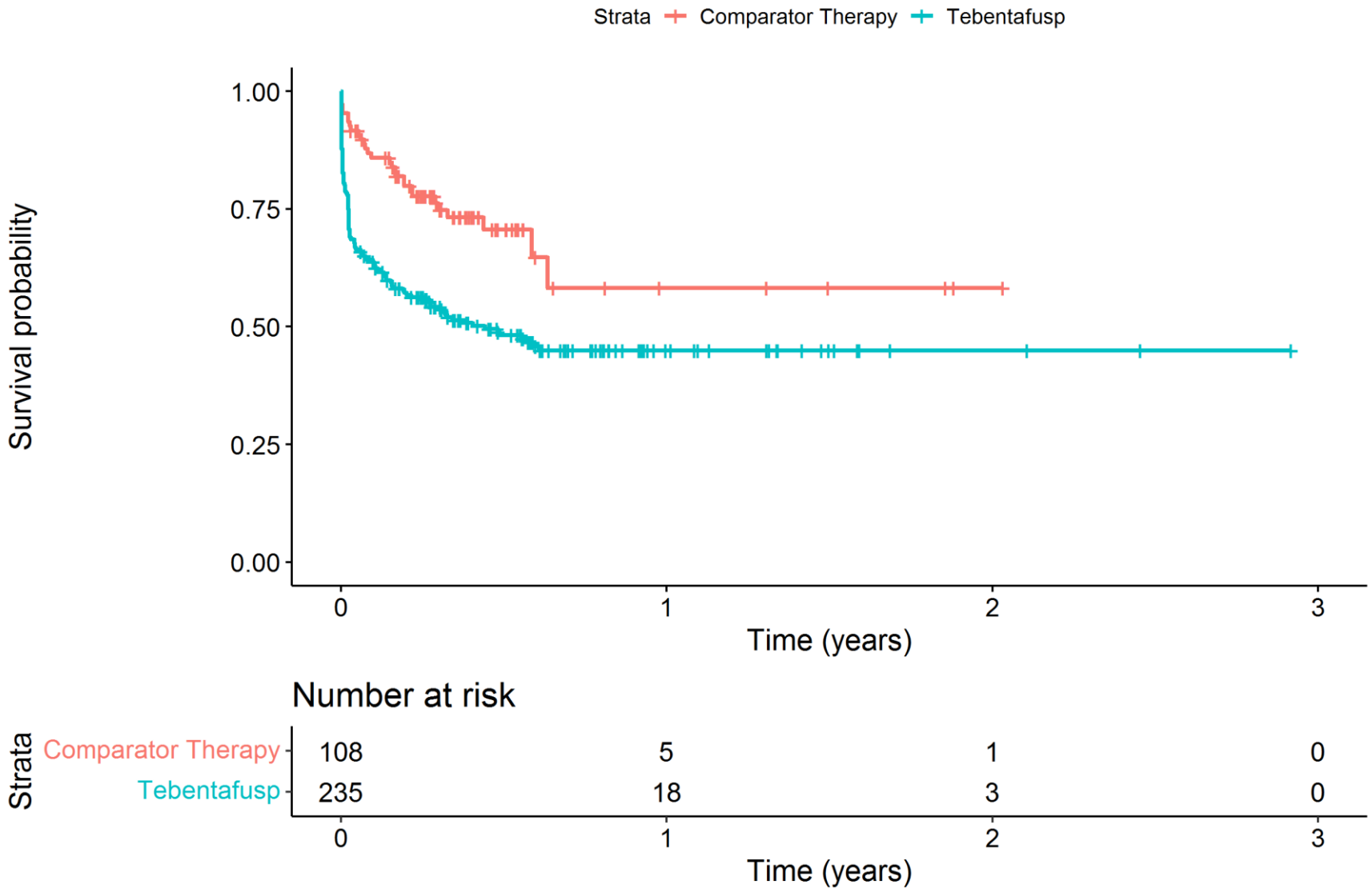
54.47 Erkrankungen des Nervensystems- LDH > ULN



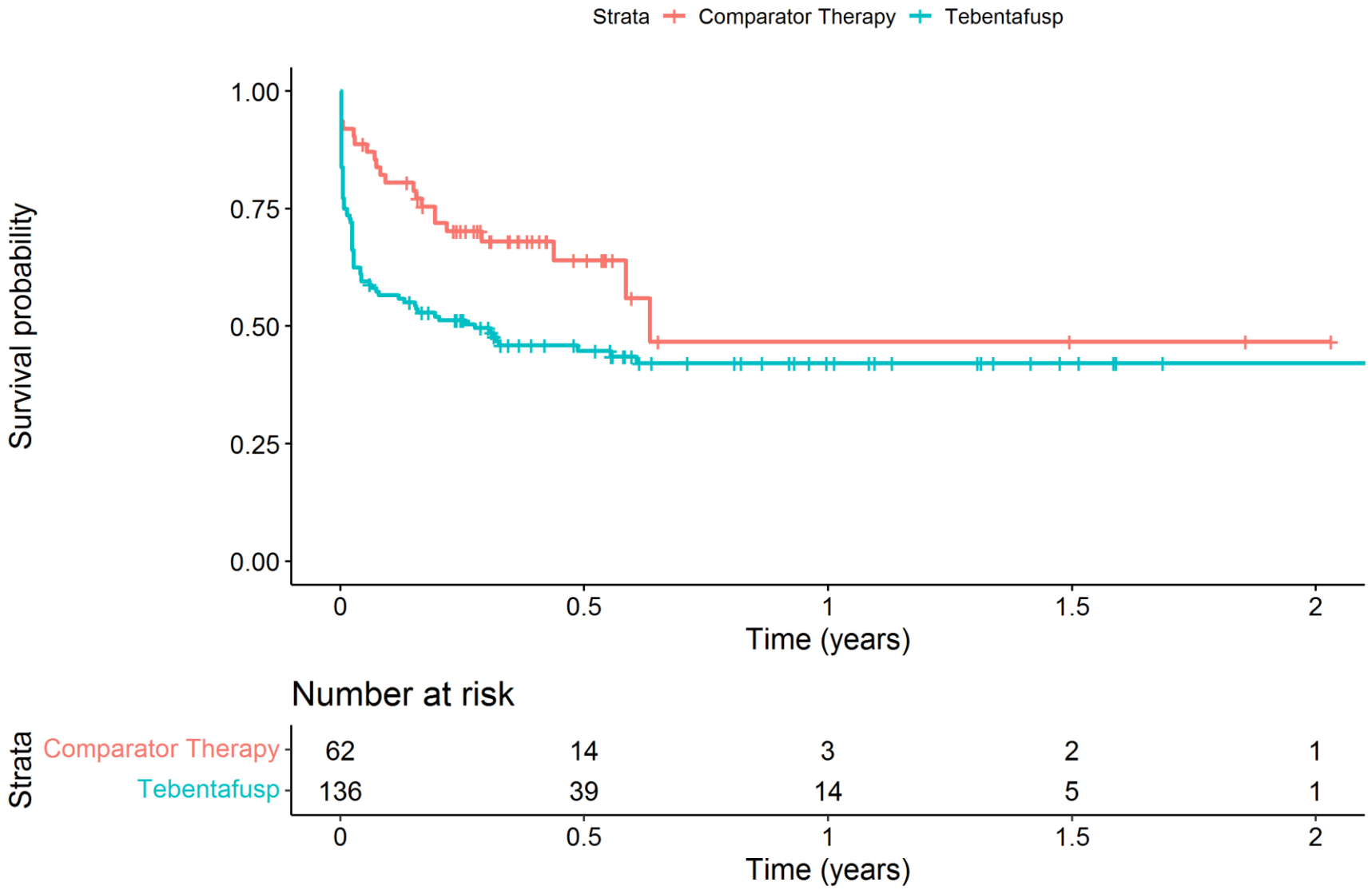
54.48 Erkrankungen des Nervensystems- Vorherige Therapie adjuvant/neoadjuvant



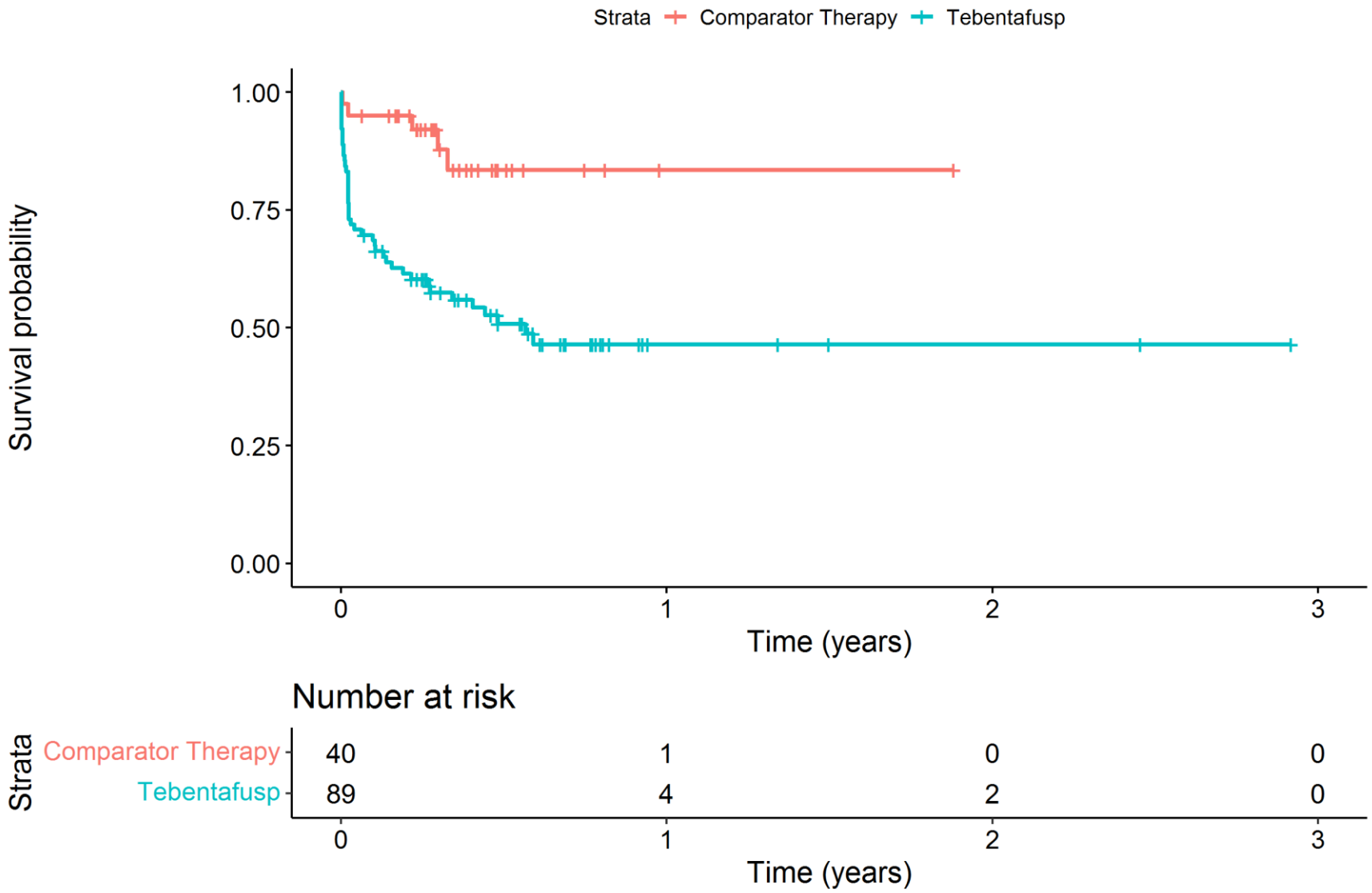
54.49 Erkrankungen des Nervensystems- Keine vorherige Therapie adjuvant/neoadjuvant



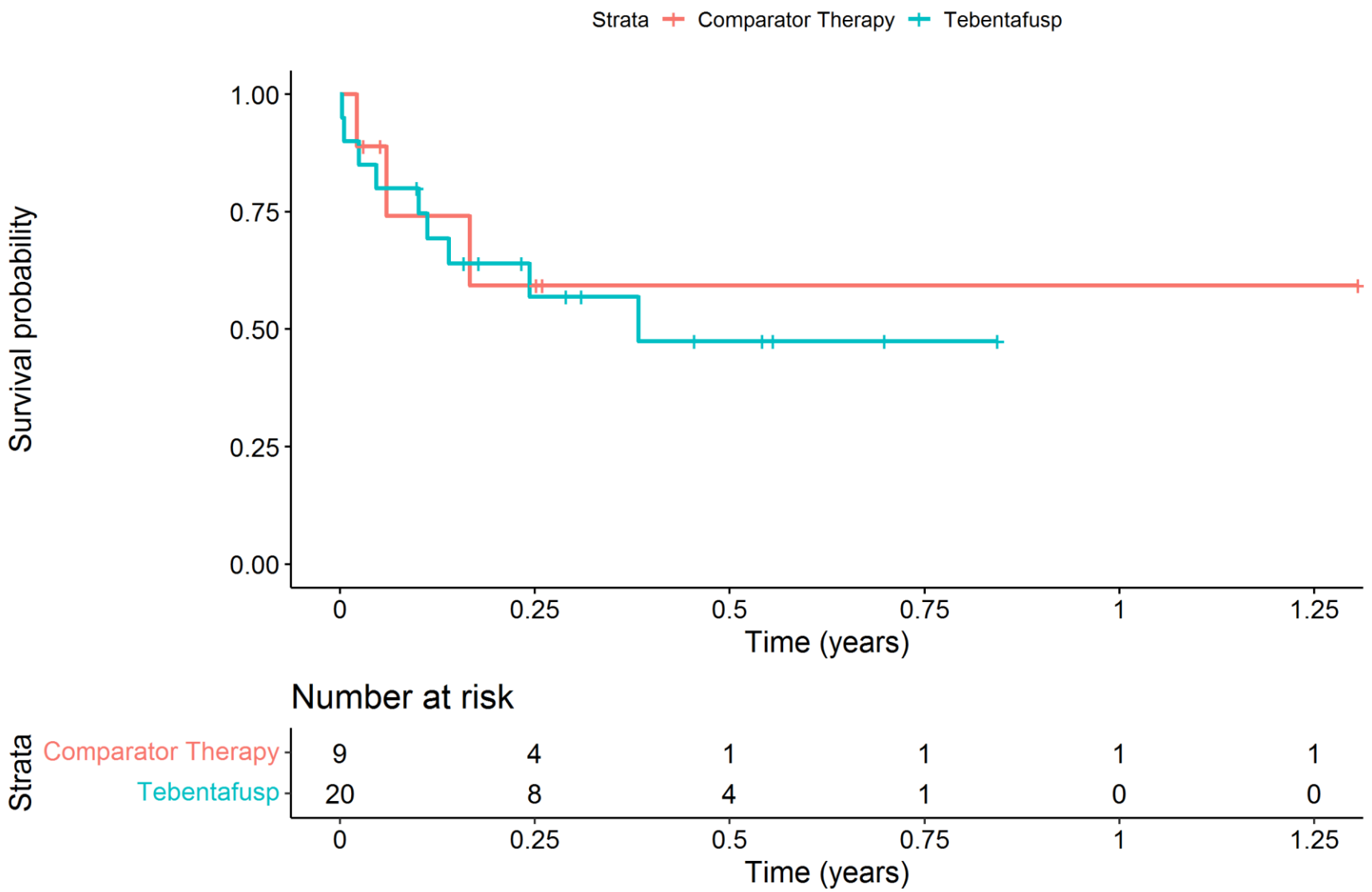
54.50 Erkrankungen des Nervensystems- Läsion ≤ 3cm



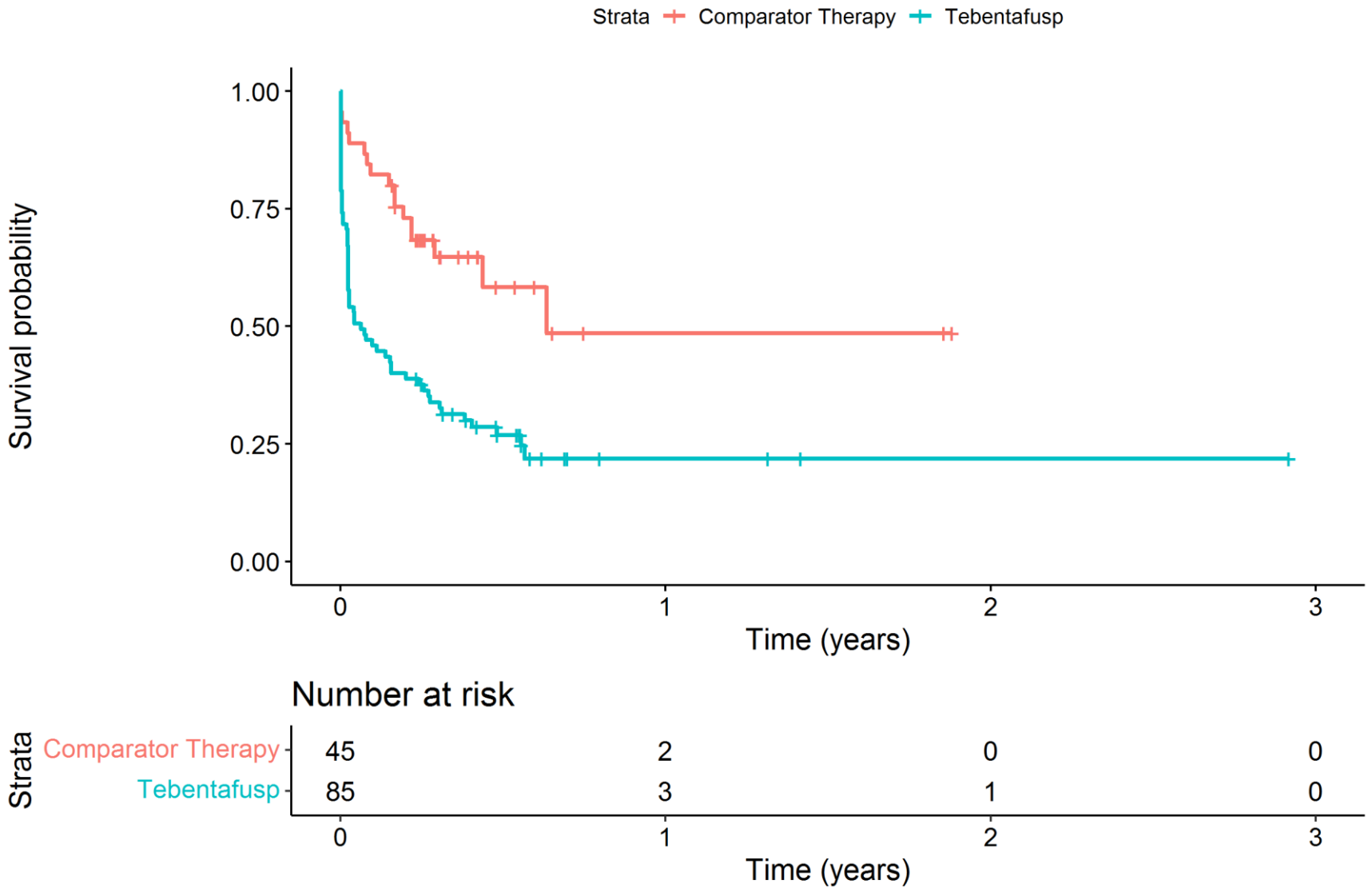
54.51 Erkrankungen des Nervensystems- Läsion 3,1-8,0 cm



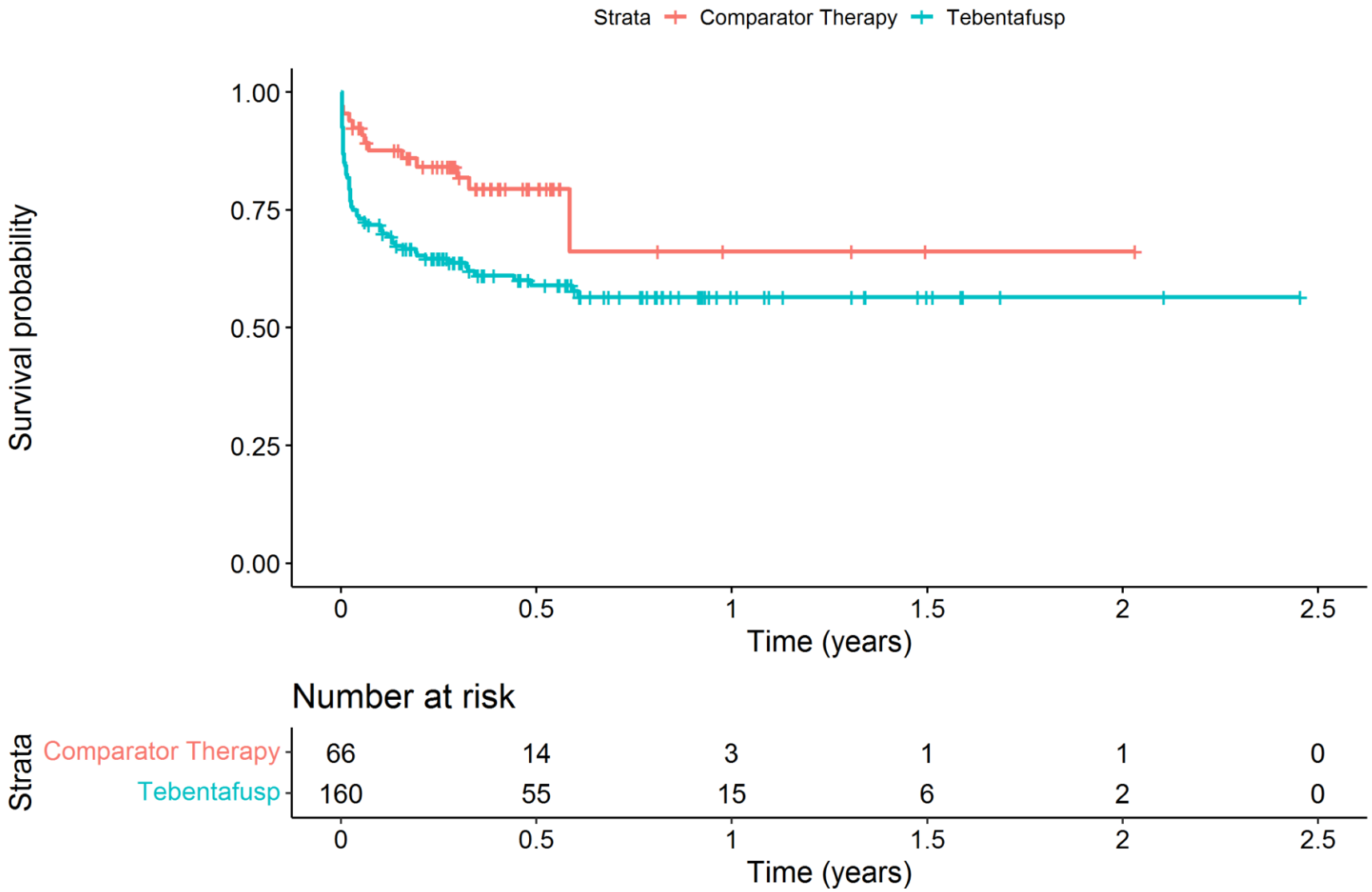
54.52 Erkrankungen des Nervensystems- Läsion ≥8,1 cm



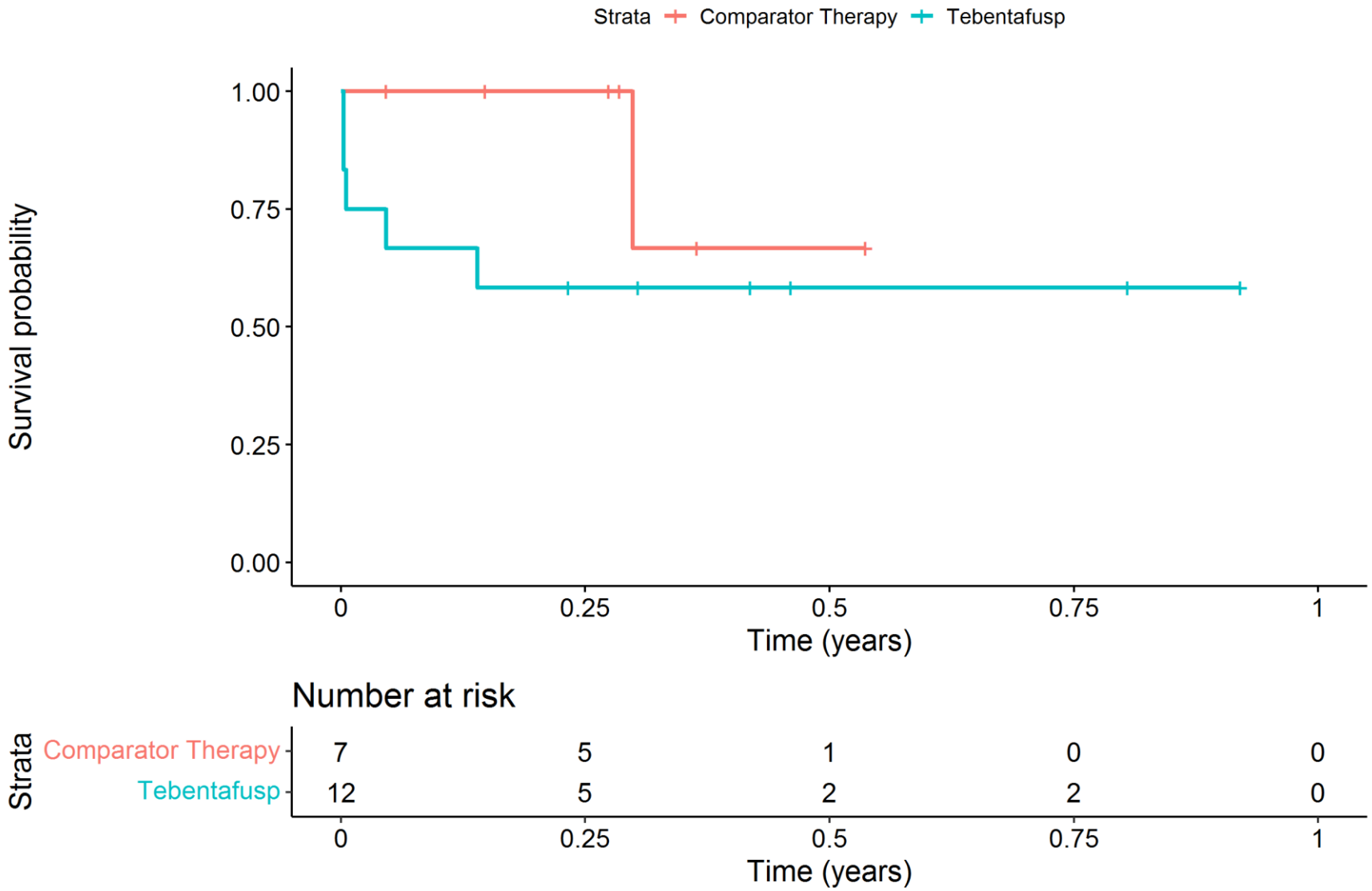
54.53 Erkrankungen des Nervensystems- Nordamerika



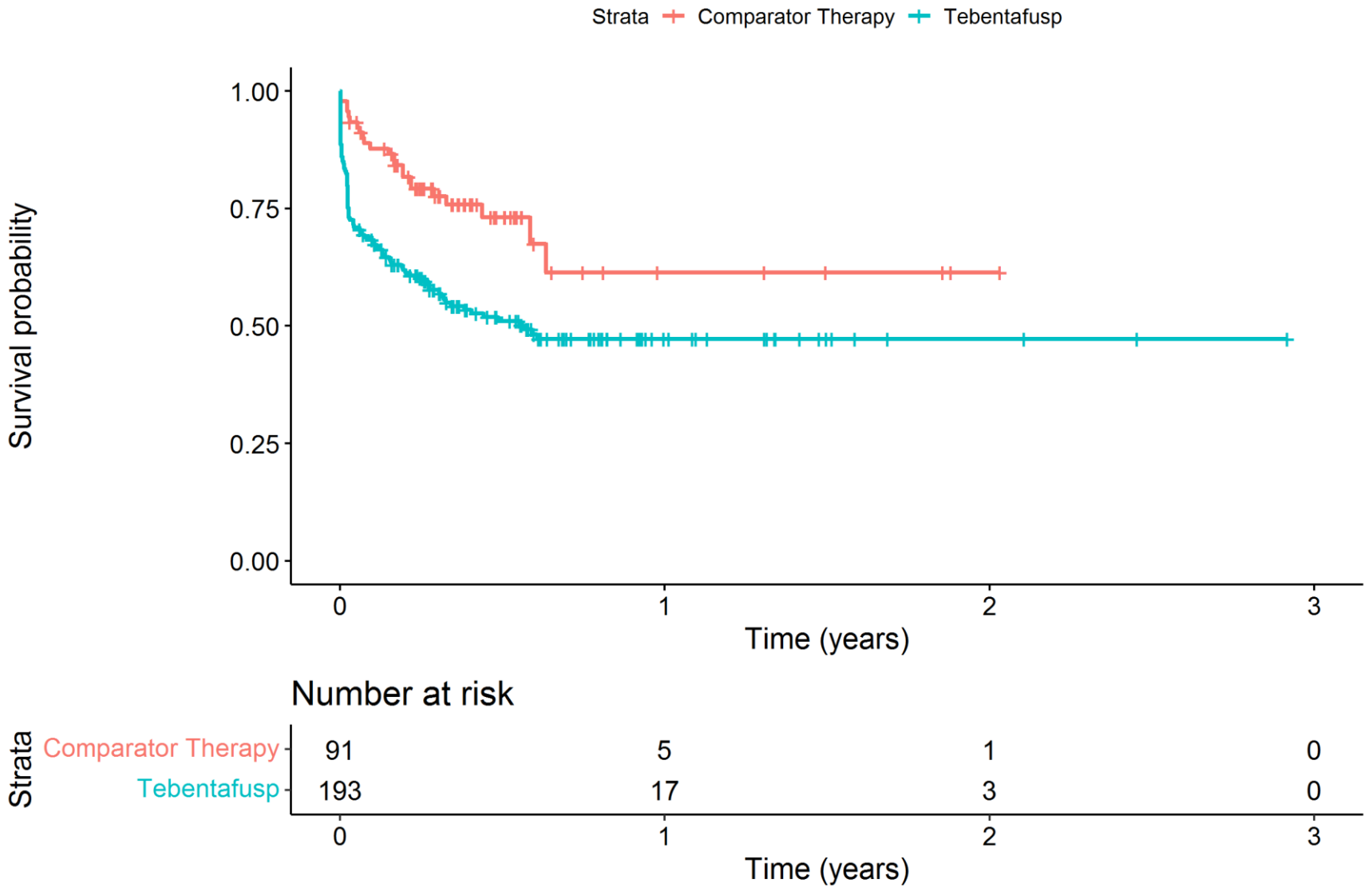
54.54 Erkrankungen des Nervensystems- Nicht-Nordamerika



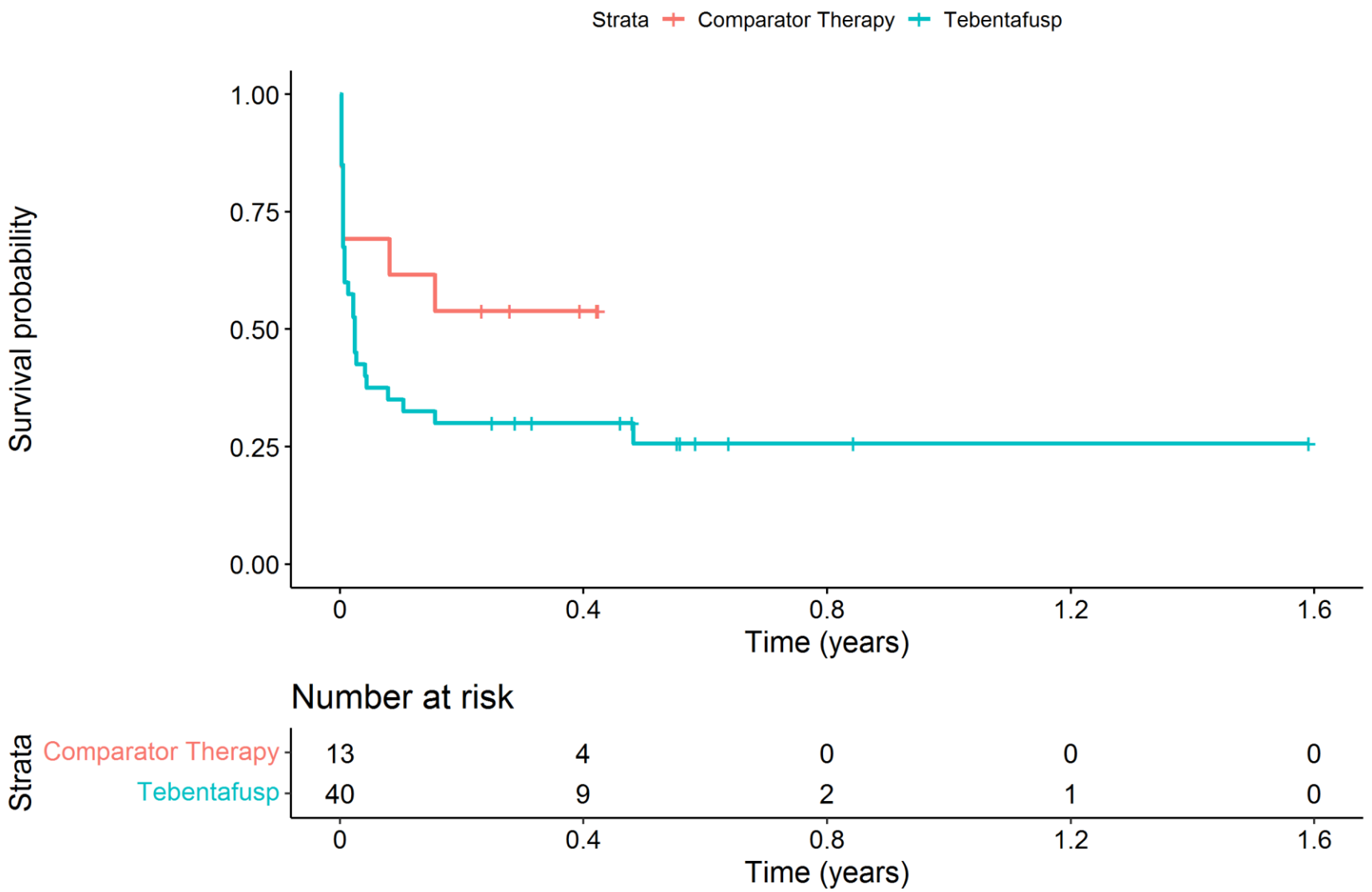
54.55 Erkrankungen des Nervensystems- Dacarbazin



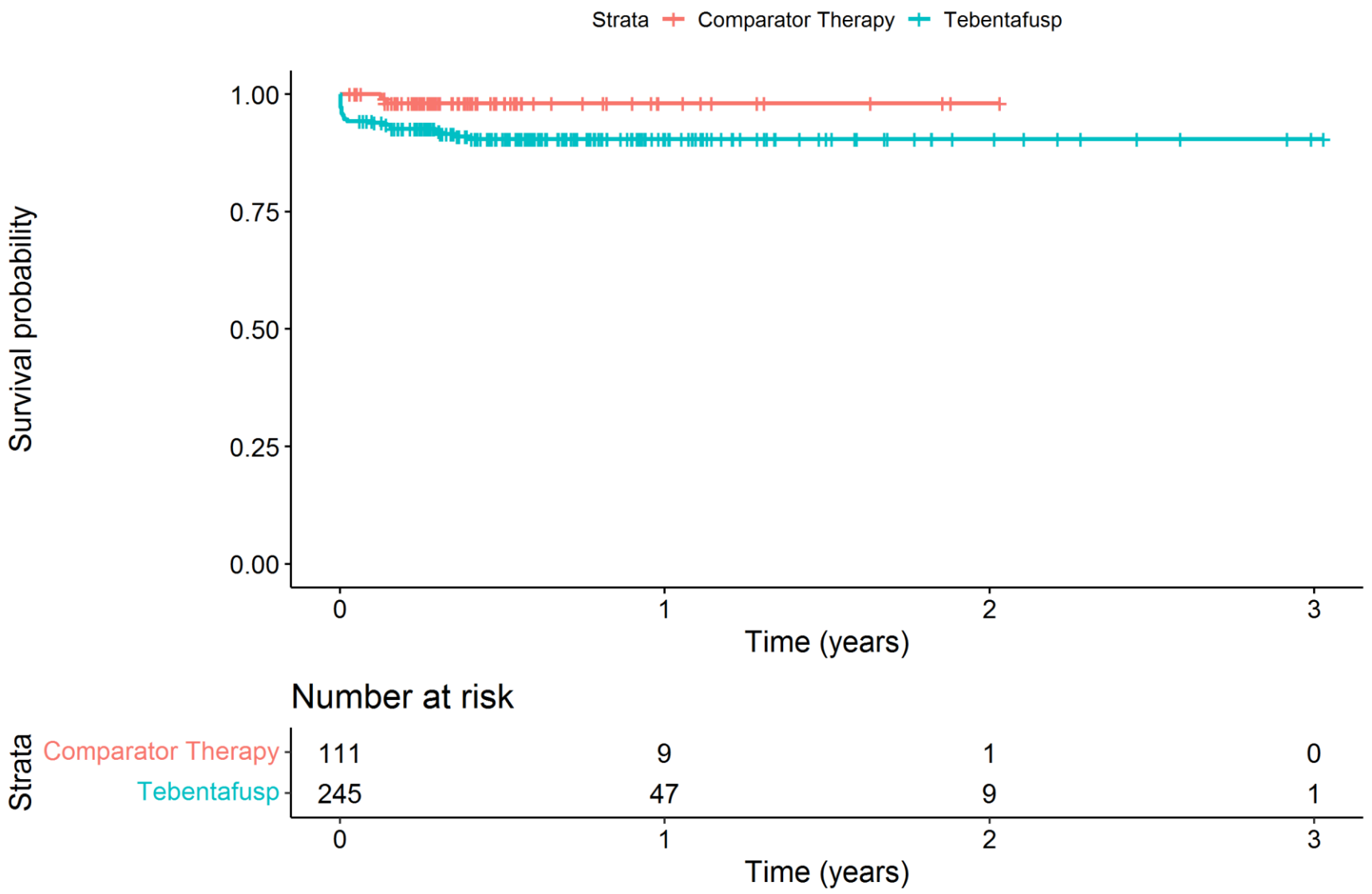
54.56 Erkrankungen des Nervensystems- Pembrolizumab



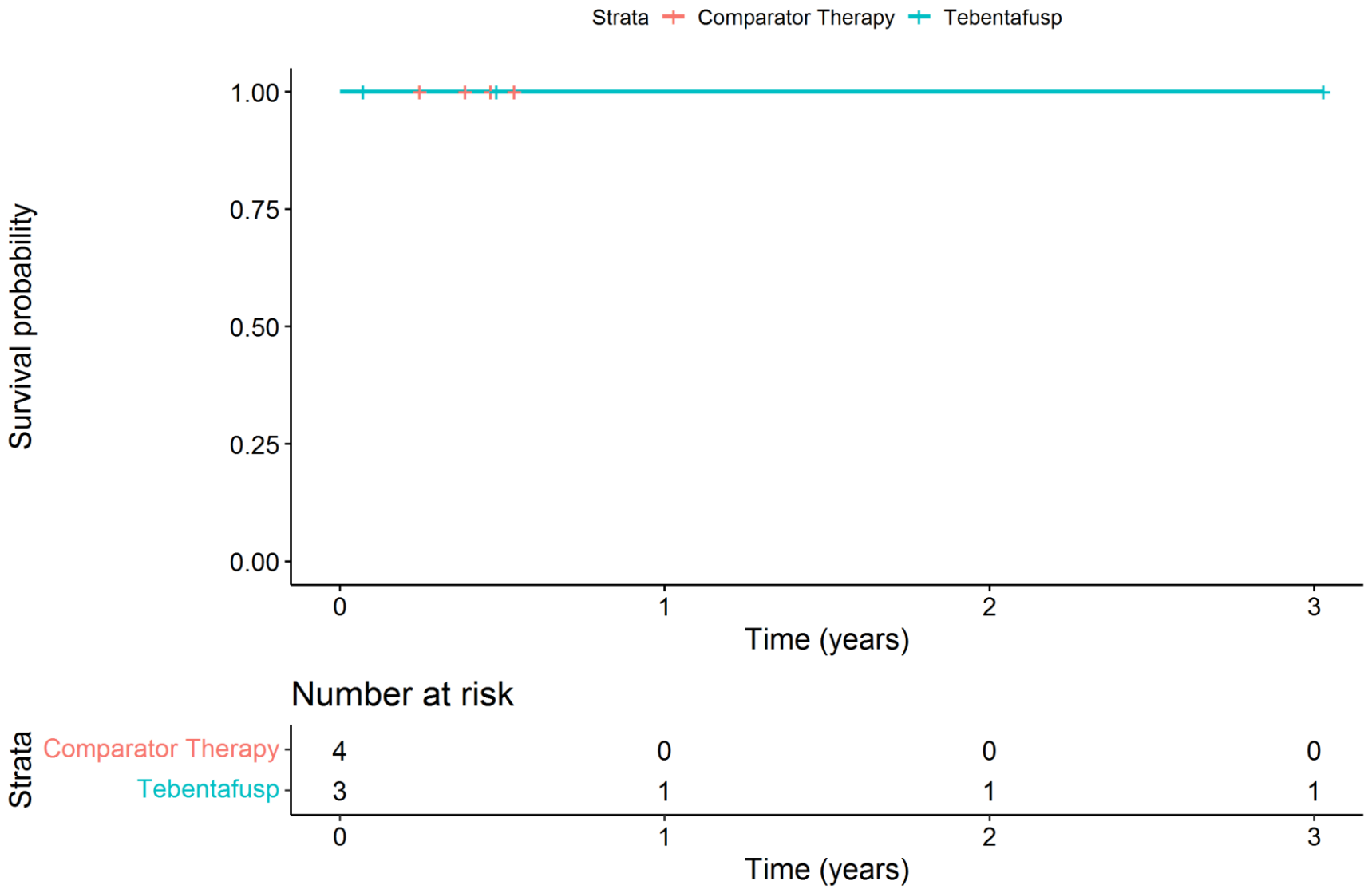
54.57 Erkrankungen des Nervensystems- Ipilimumab



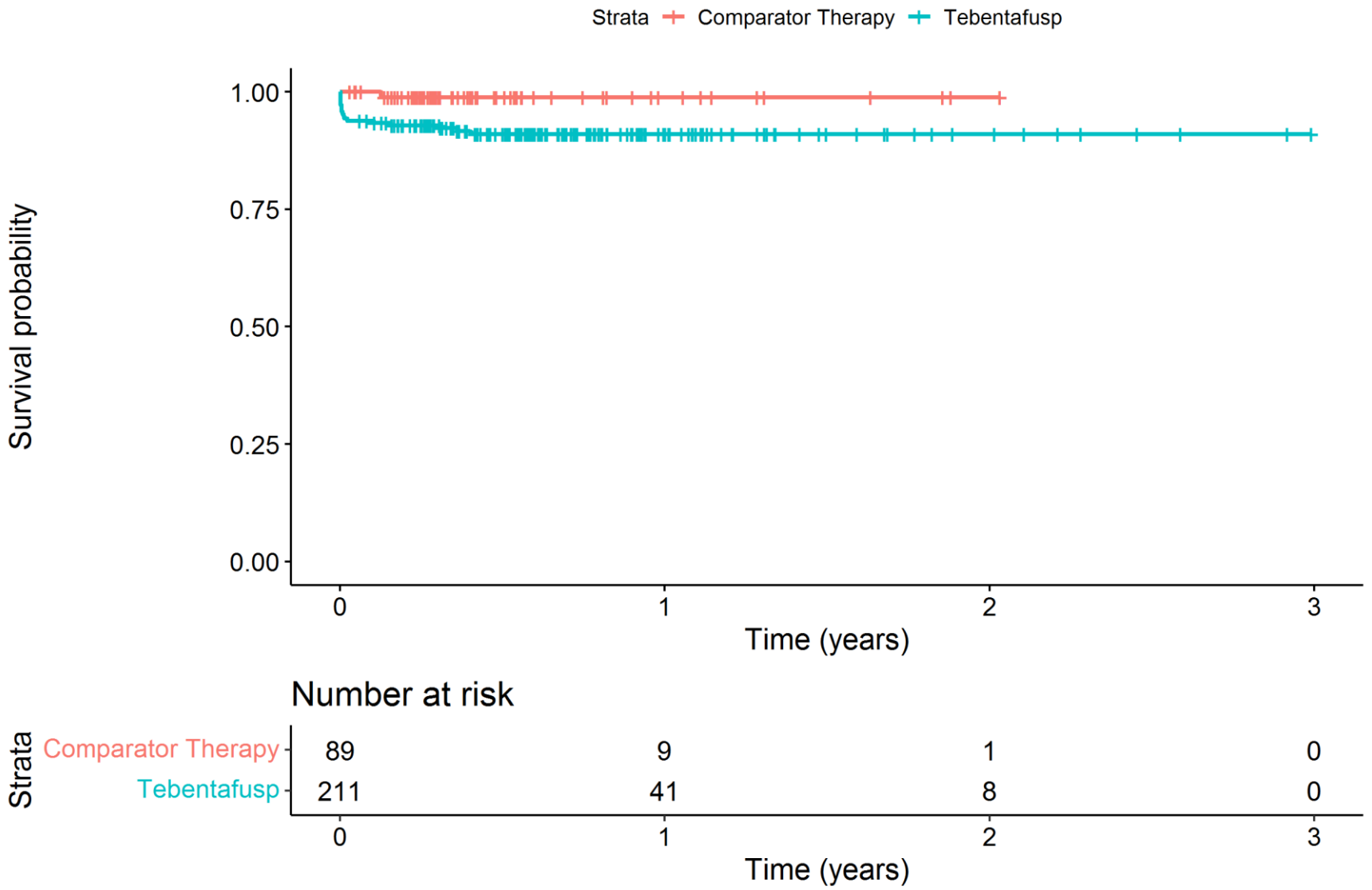
54.58 Erkrankungen der Geschlechtsorgane und der Brustdruese- Gesamt



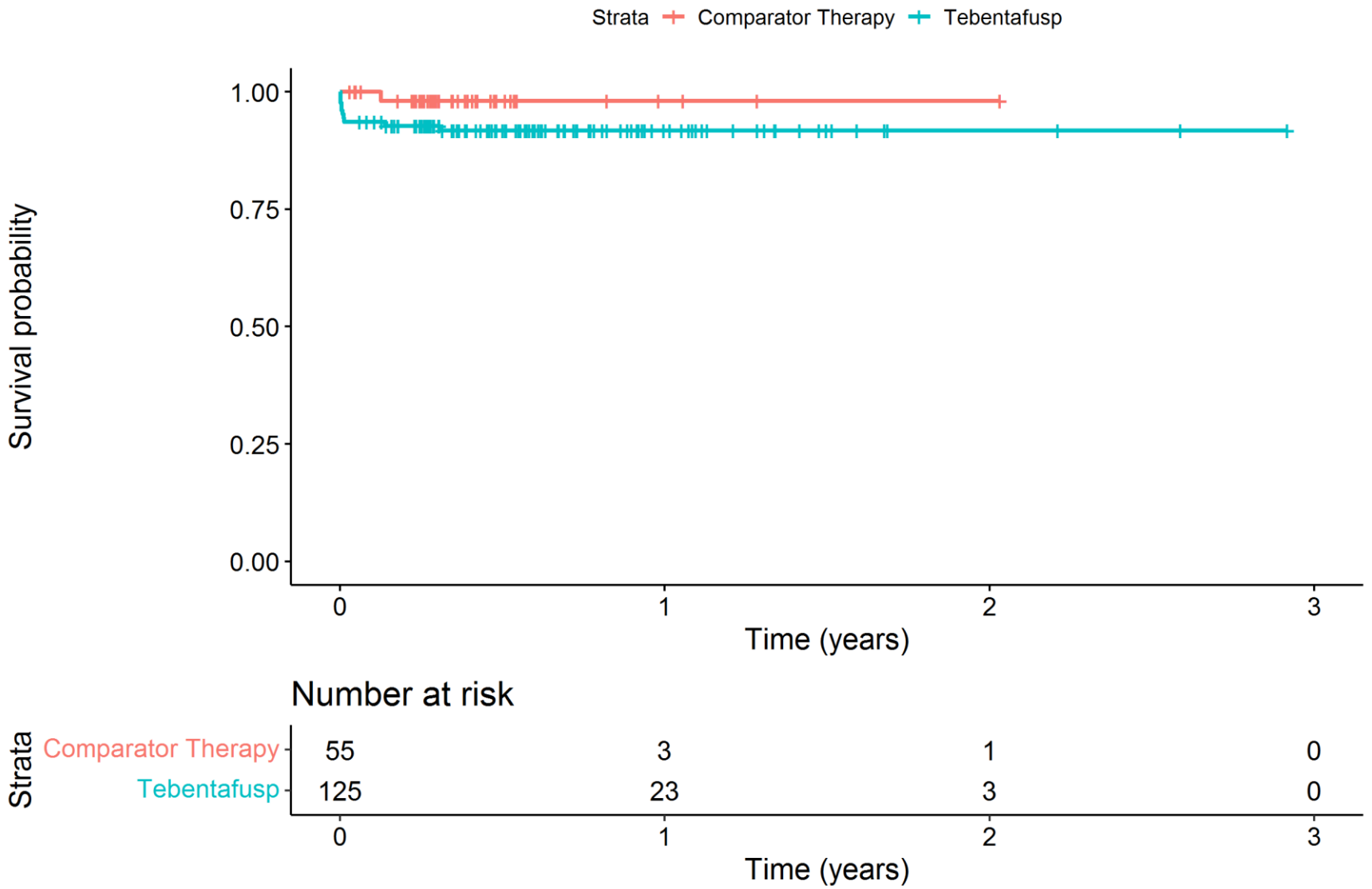
Erkrankungen der Geschlechtsorgane und der Brustdruese- Hispanisch



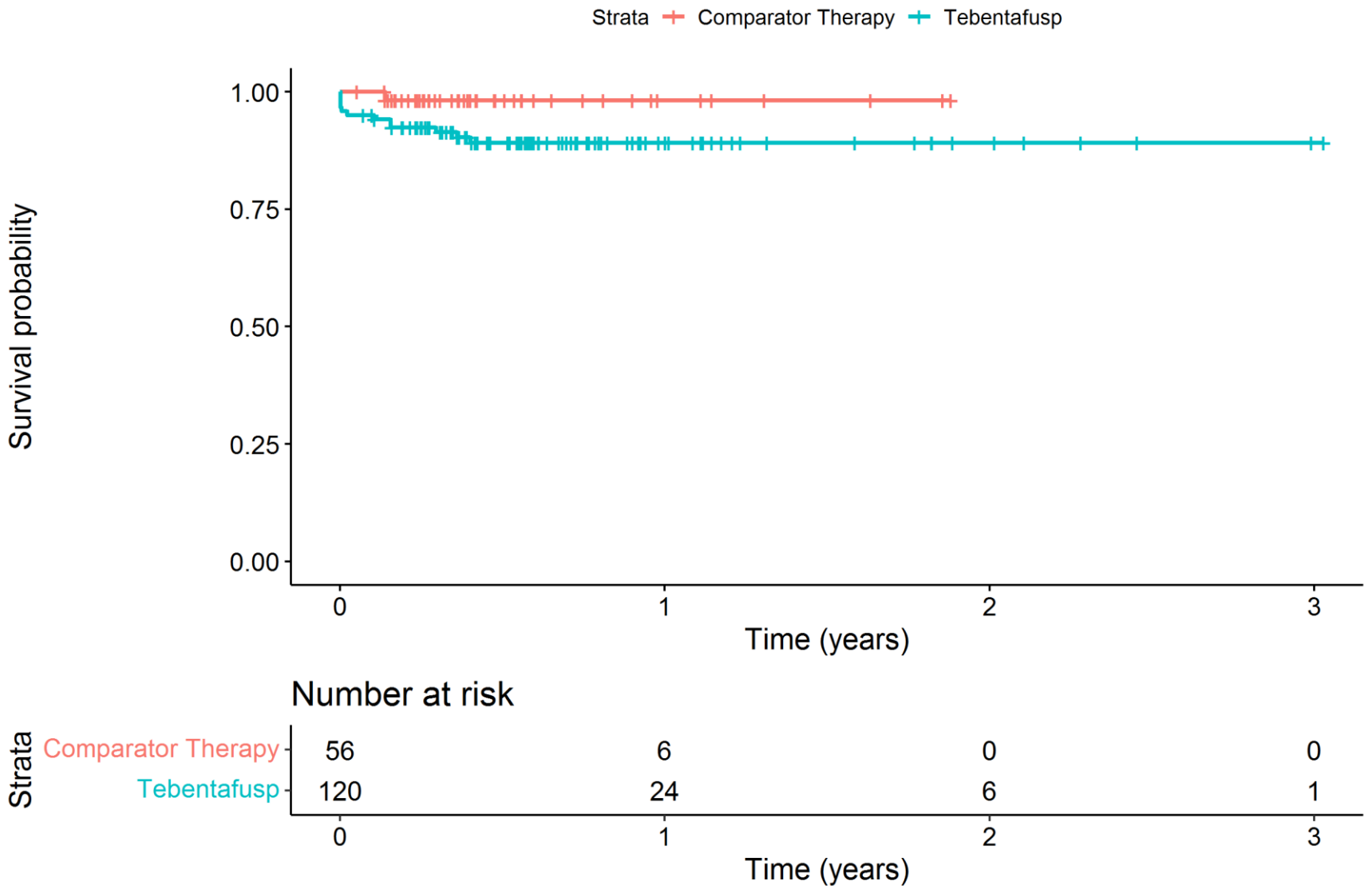
Erkrankungen der Geschlechtsorgane und der Brustdruese- Nicht-hispanisch



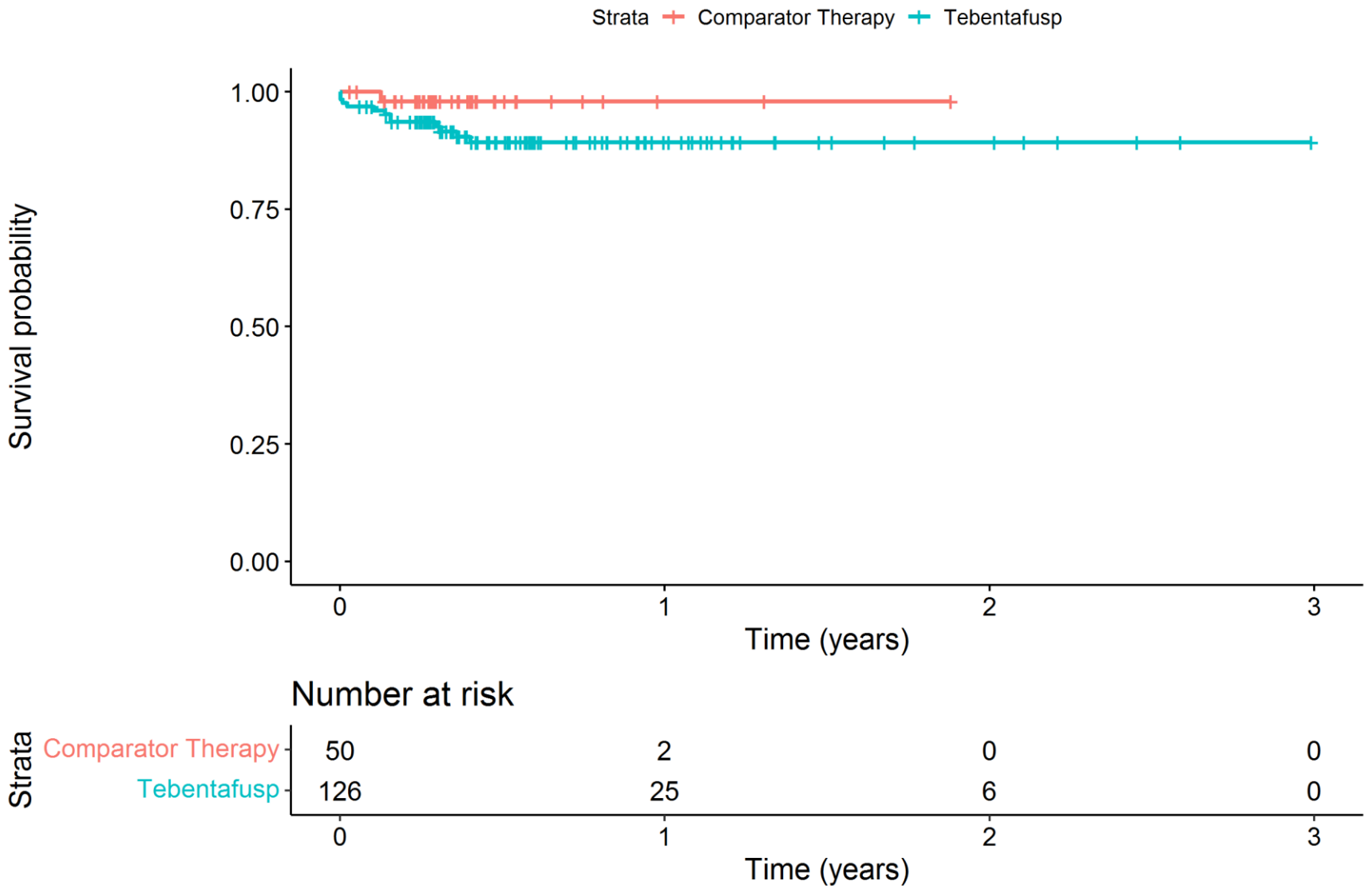
Erkrankungen der Geschlechtsorgane und der Brustdruese- Männlich



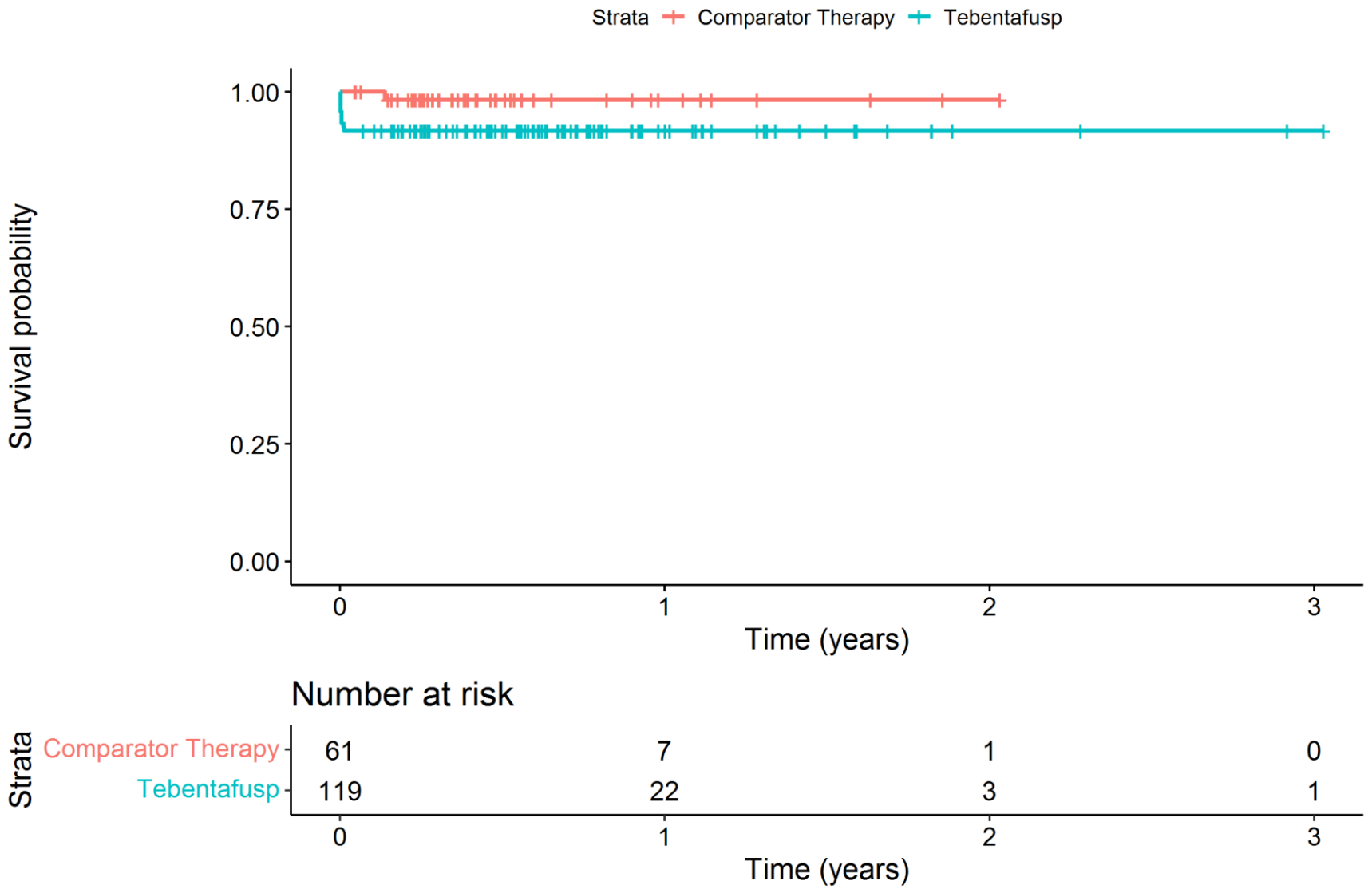
Erkrankungen der Geschlechtsorgane und der Brustdruese- Weiblich



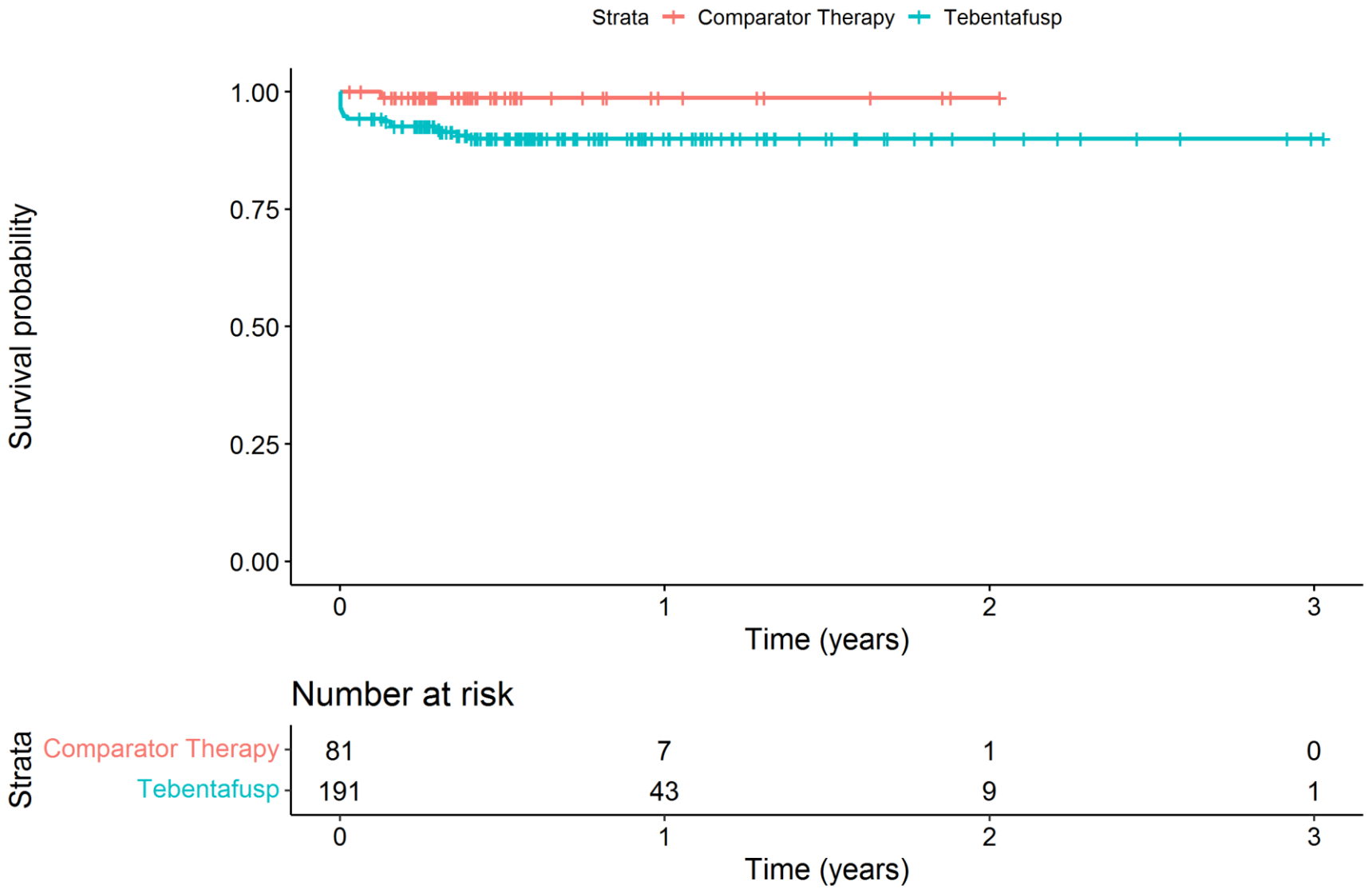
Erkrankungen der Geschlechtsorgane und der Brustdruese- <65



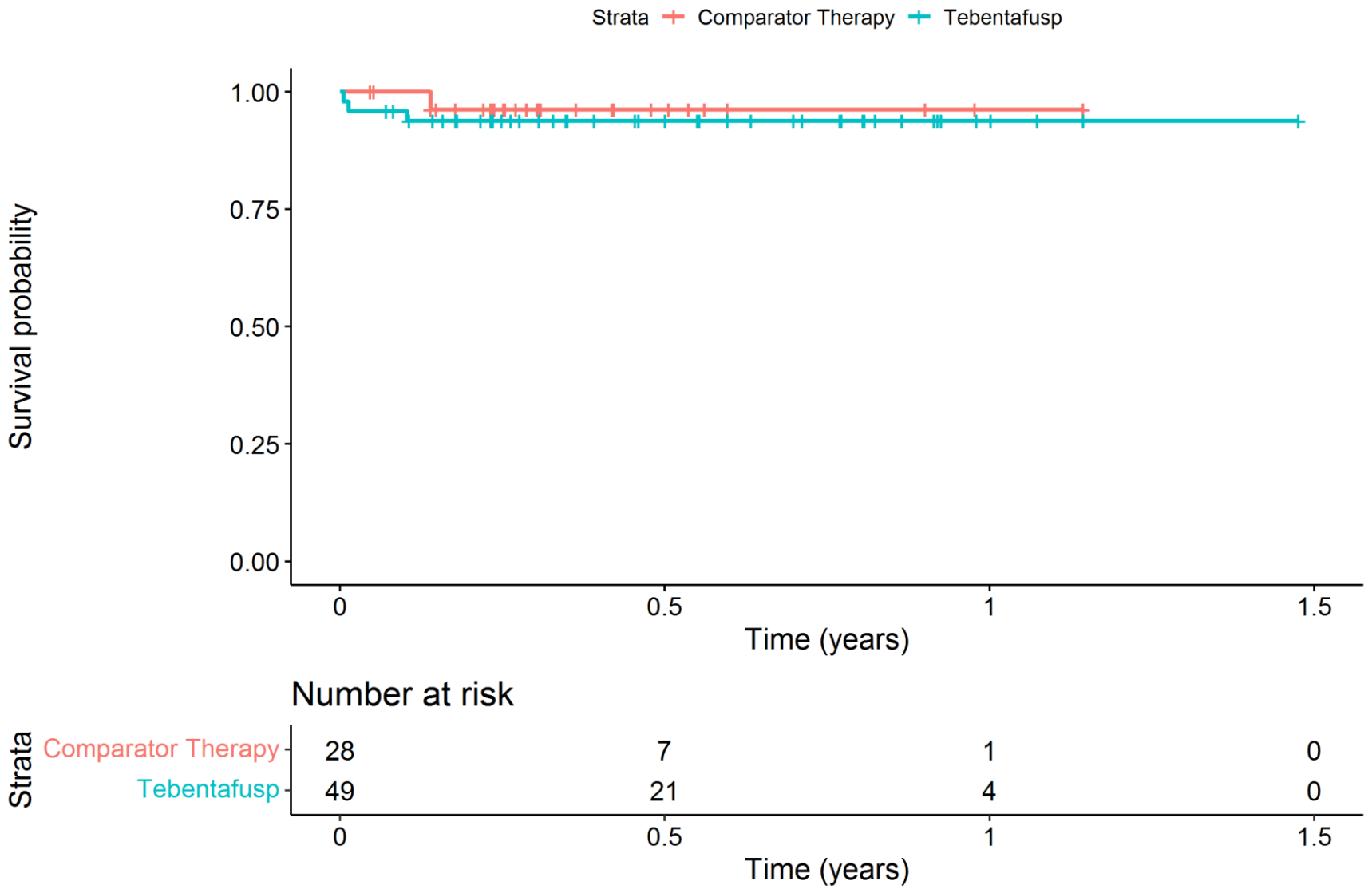
Erkrankungen der Geschlechtsorgane und der Brustdruese- ≥65



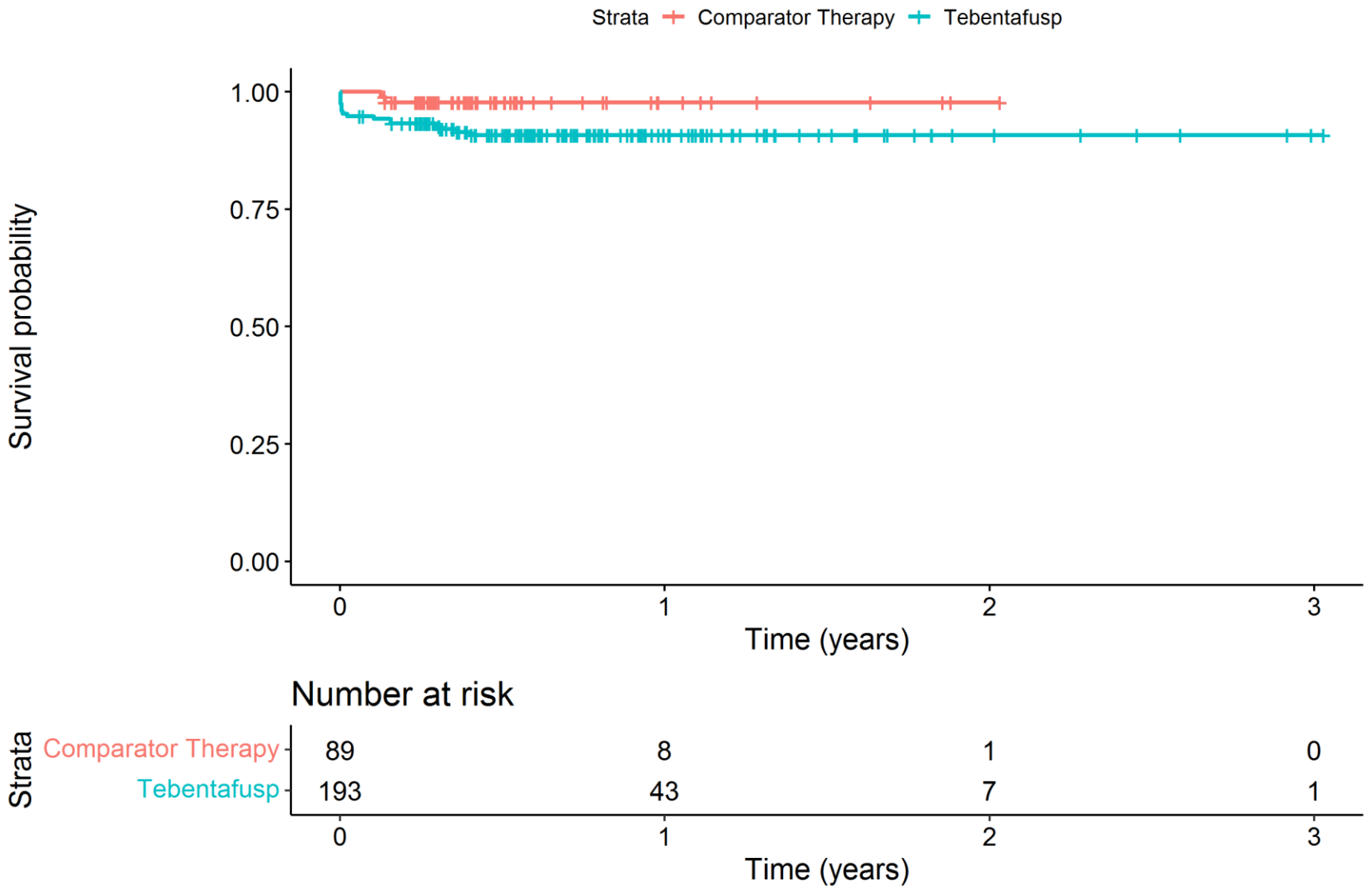
Erkrankungen der Geschlechtsorgane und der Brustdruese- ECOG 0



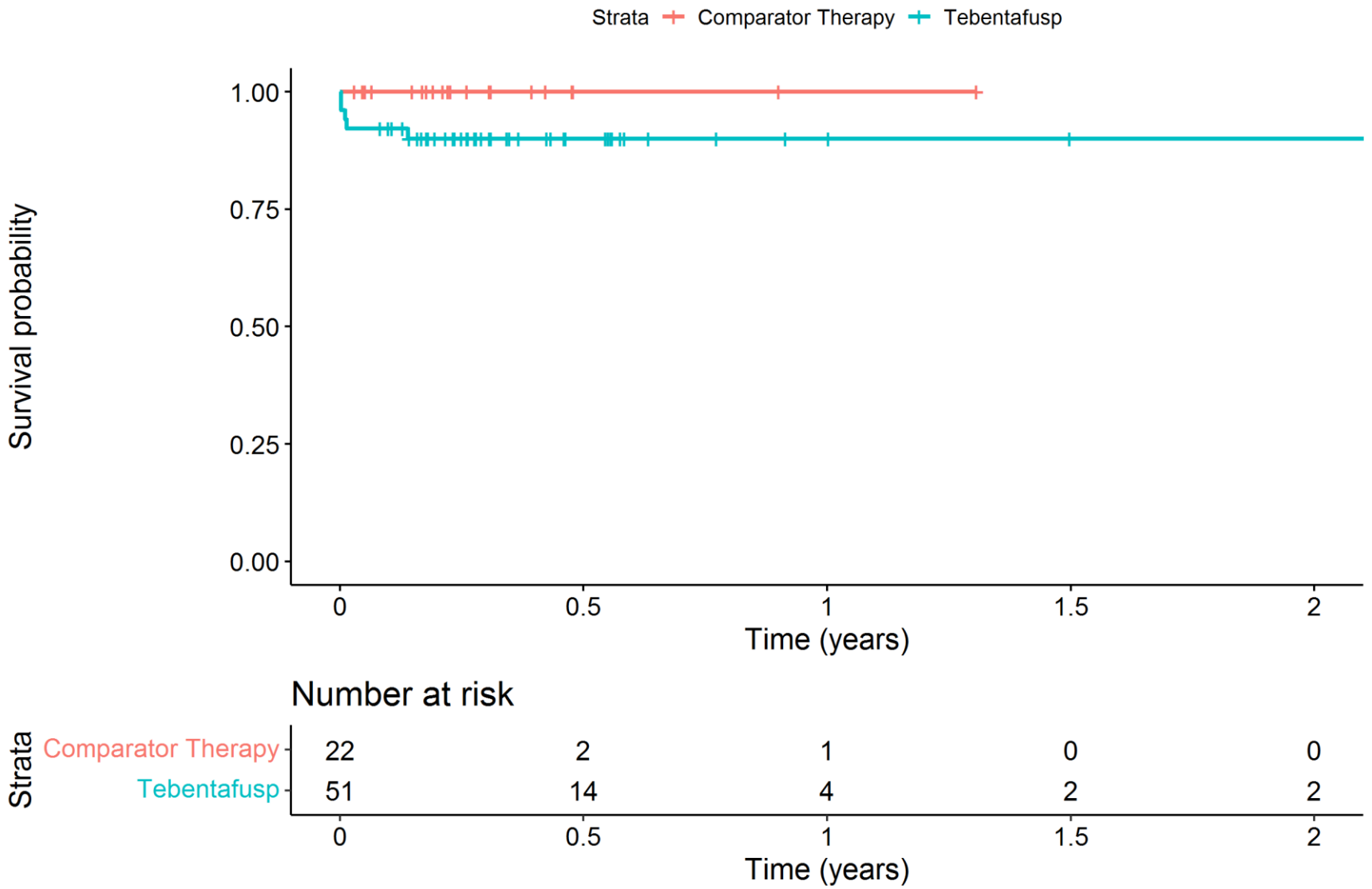
Erkrankungen der Geschlechtsorgane und der Brustdruese- ECOG 1



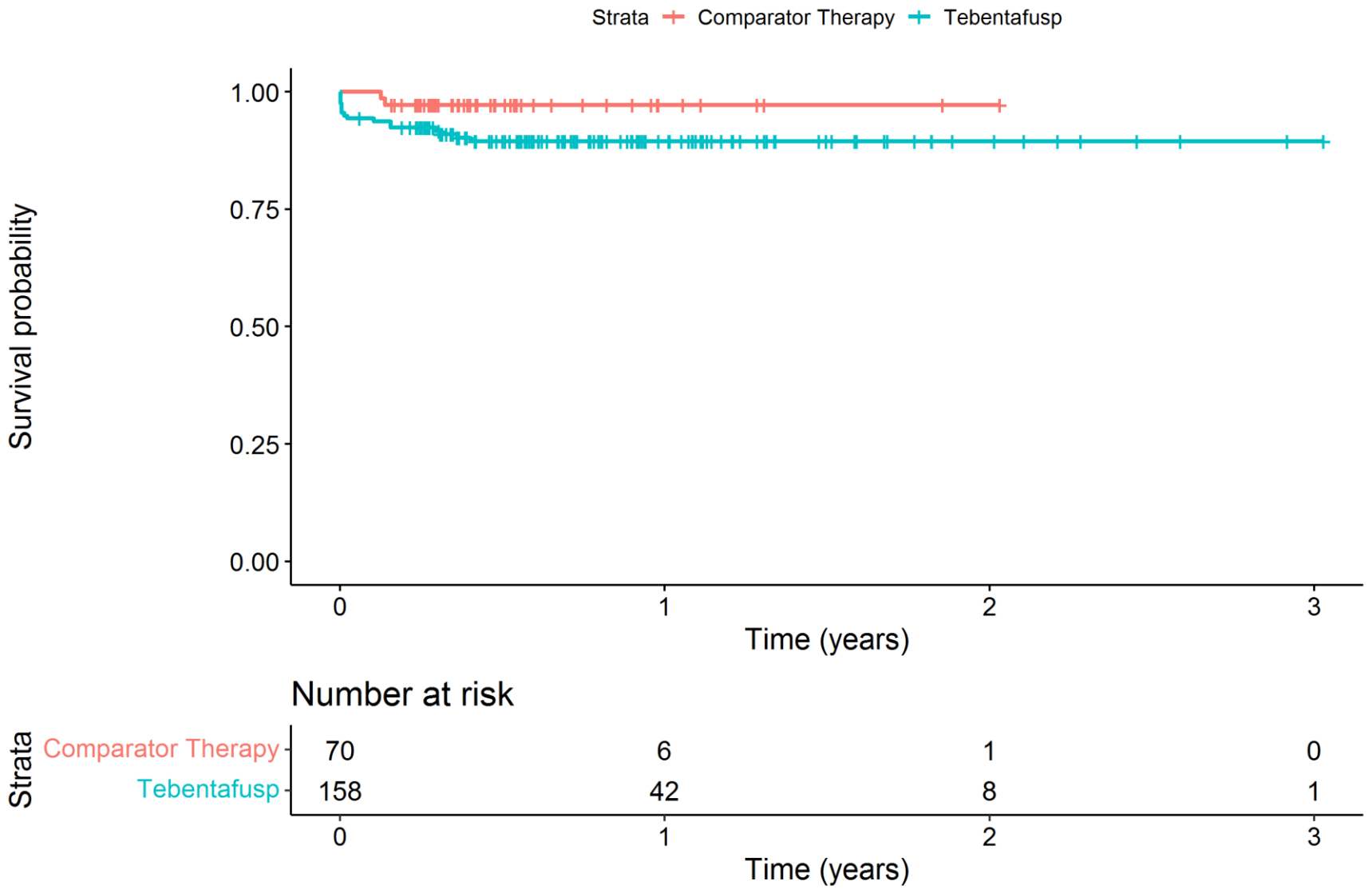
Erkrankungen der Geschlechtsorgane und der Brustdruese- ALP ≤ ULN



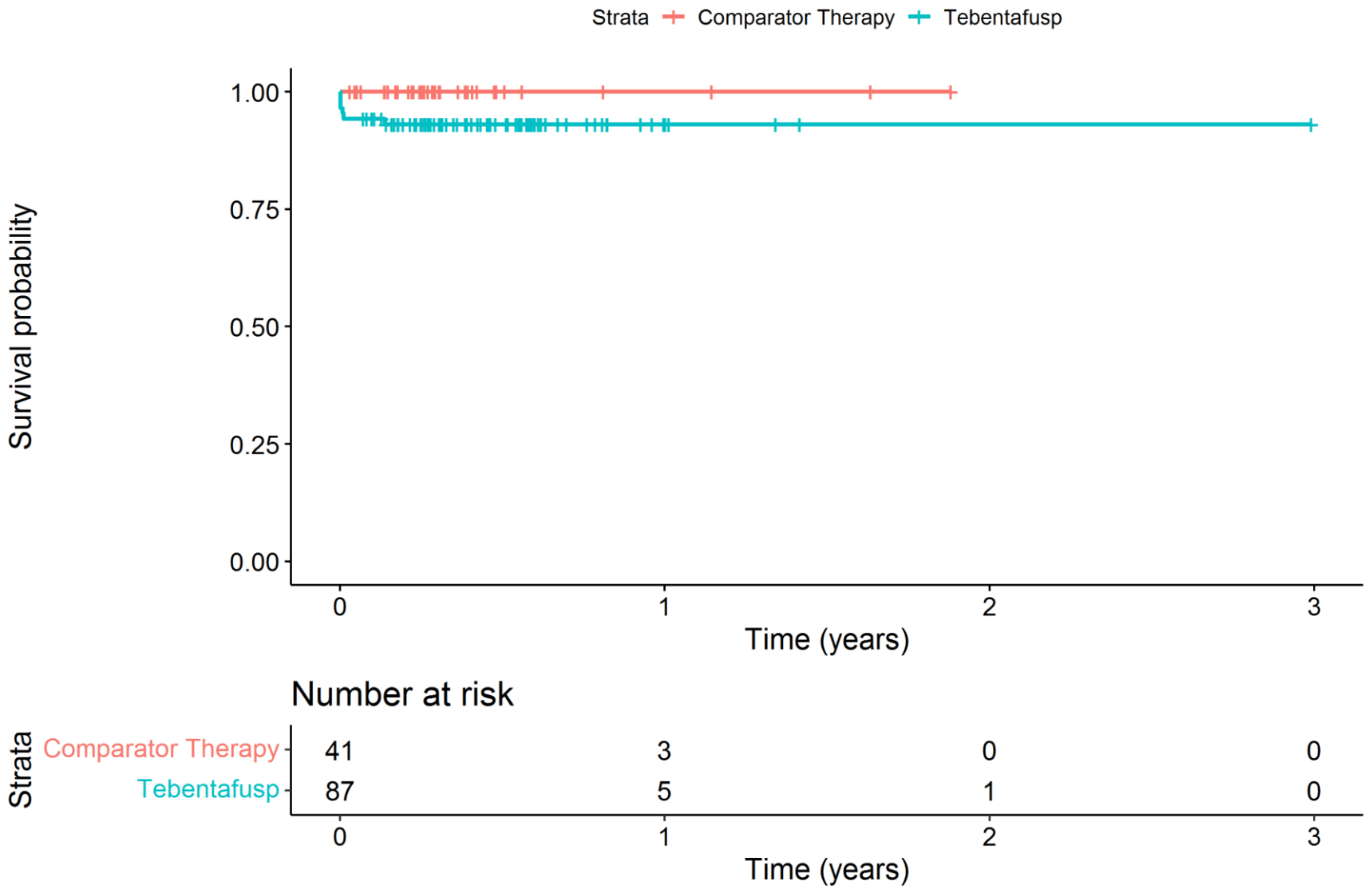
Erkrankungen der Geschlechtsorgane und der Brustdruese- ALP > ULN



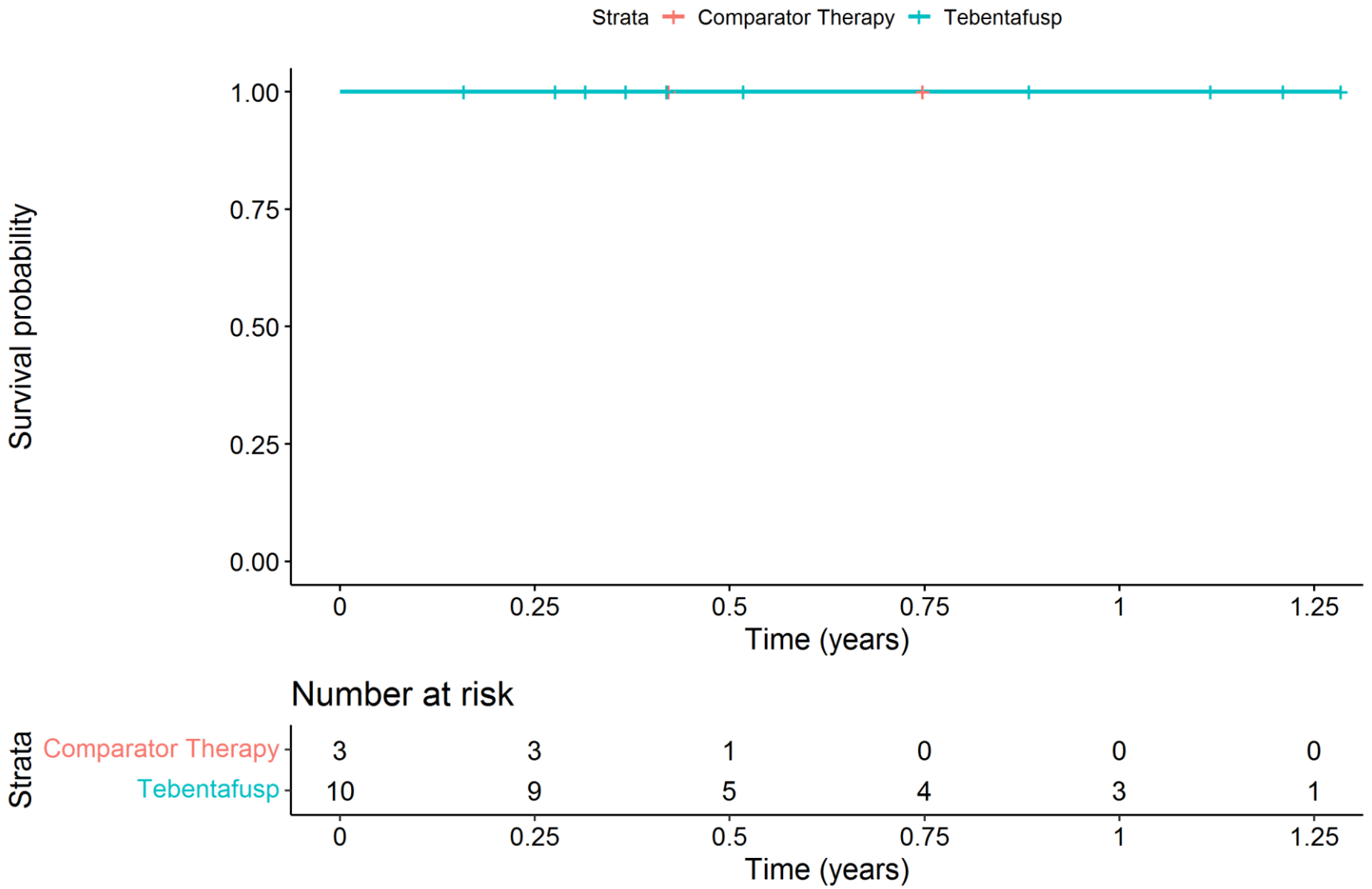
Erkrankungen der Geschlechtsorgane und der Brustdruese- LDH =< ULN



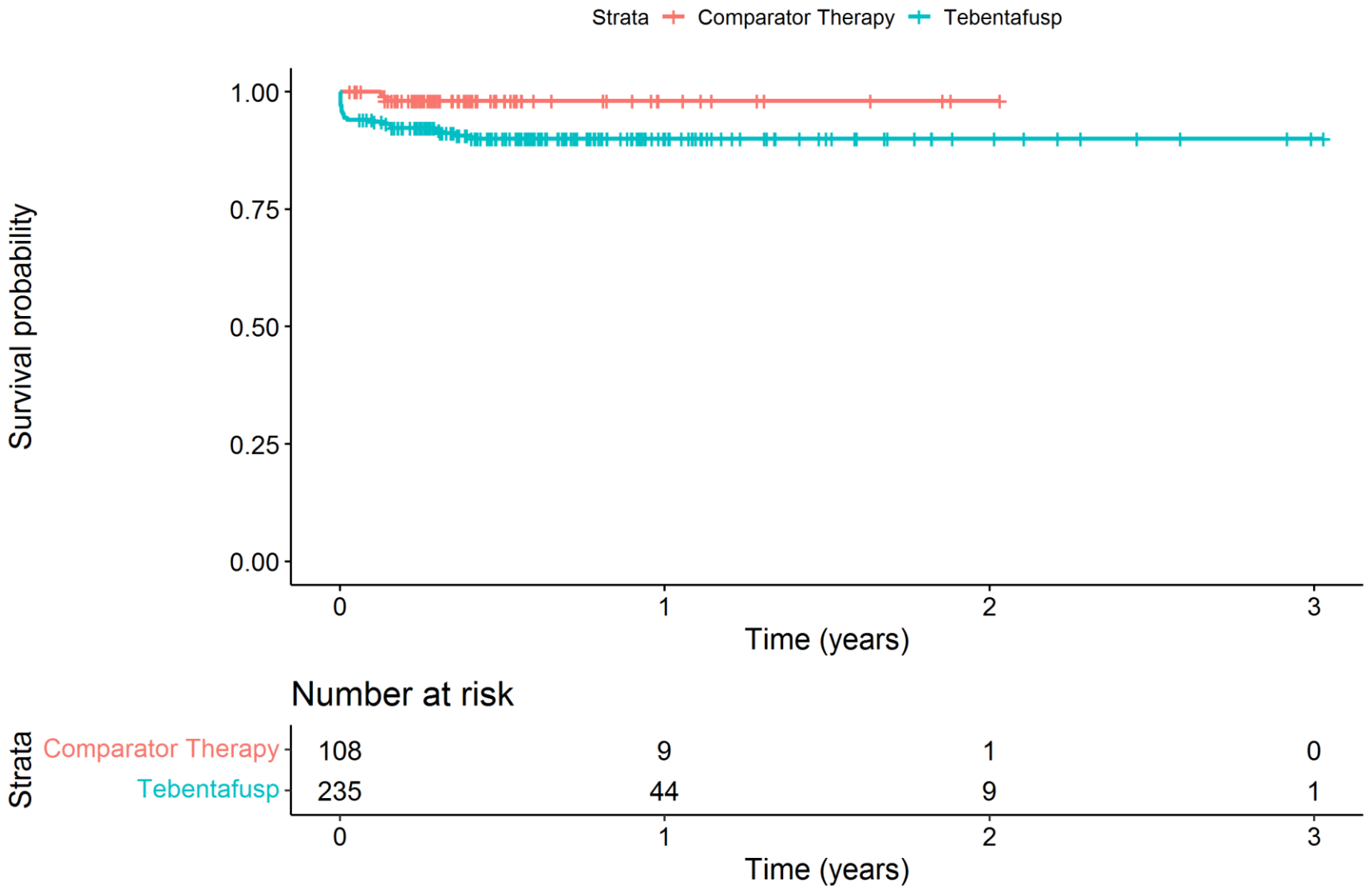
Erkrankungen der Geschlechtsorgane und der Brustdruese- LDH > ULN



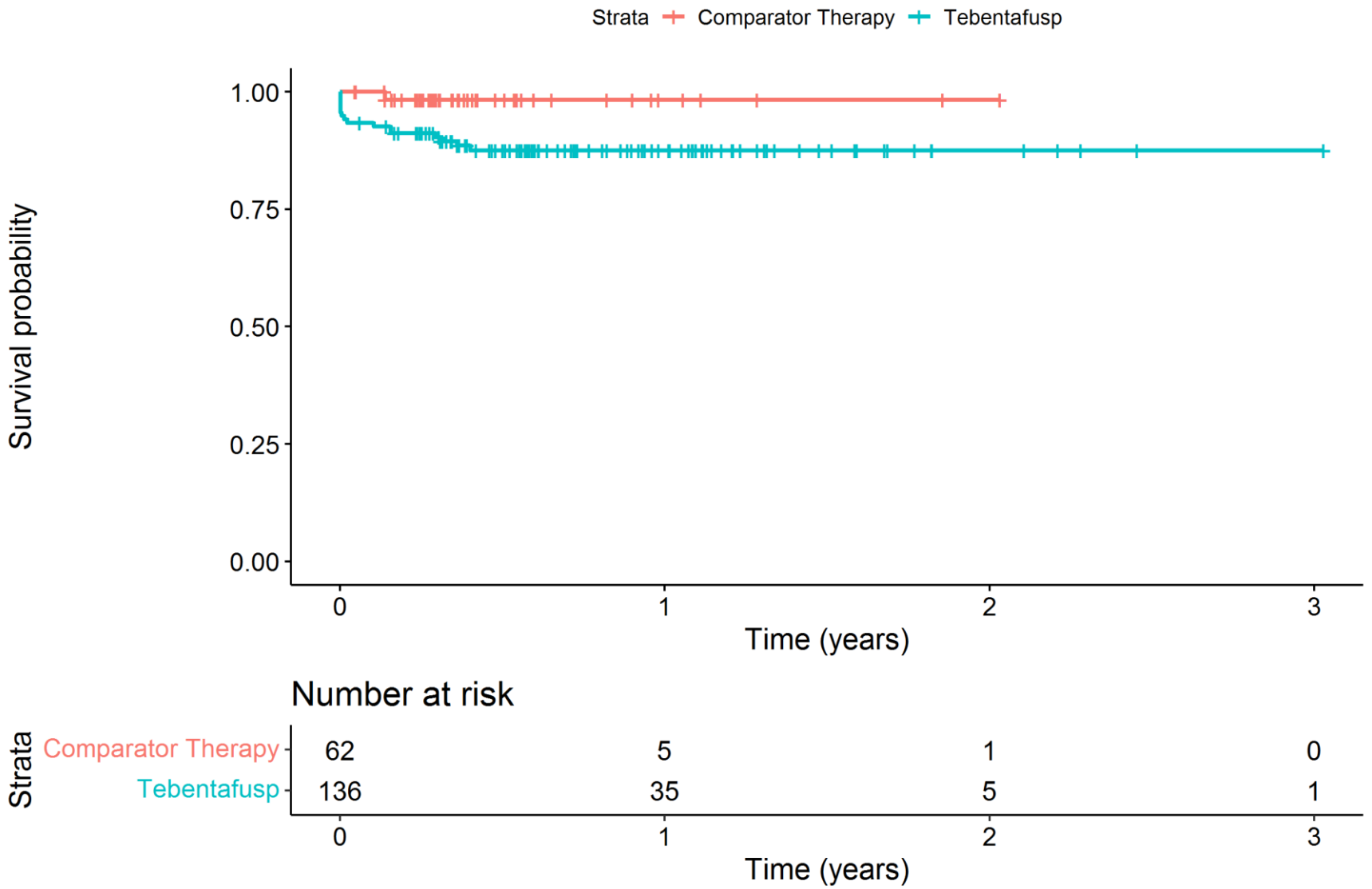
Erkrankungen der Geschlechtsorgane und der Brustdruese- Vorherige Therapie adjuvant/neoadjuvant



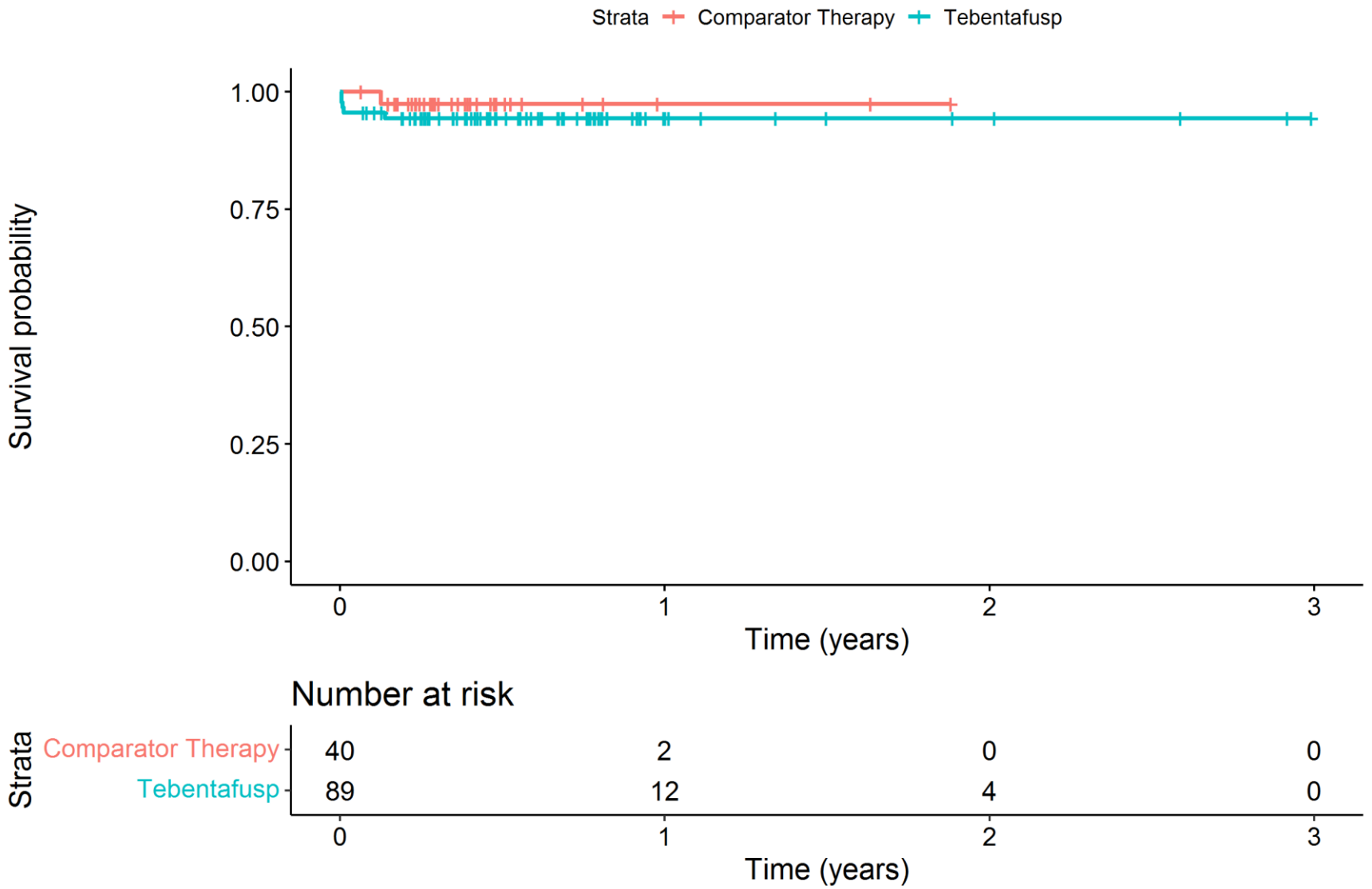
Erkrankungen der Geschlechtsorgane und der Brustdruese- Keine vorherige Therapie adjuvant/neoadjuvant



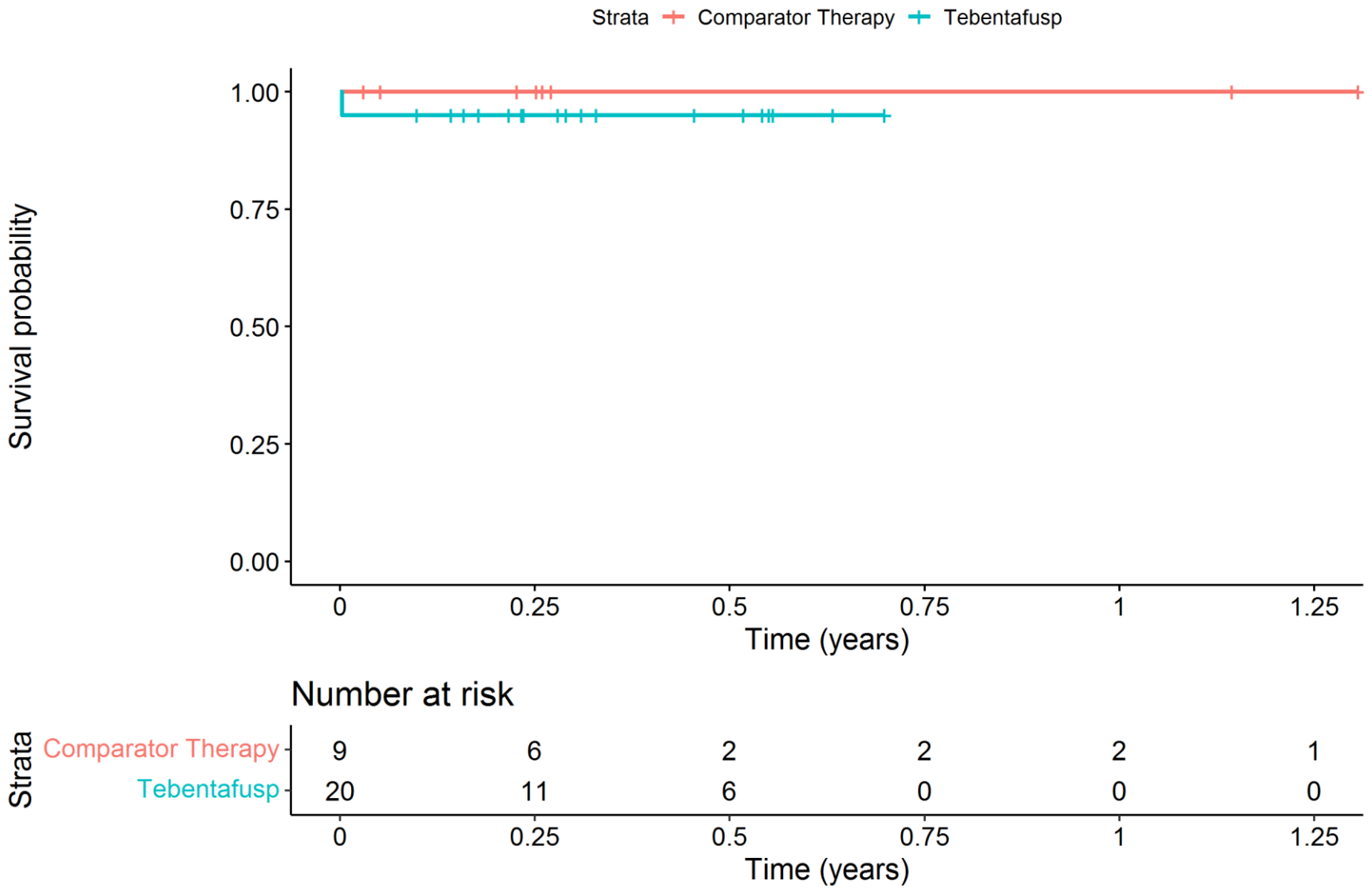
Erkrankungen der Geschlechtsorgane und der Brustdruese- Läsion ≤ 3cm



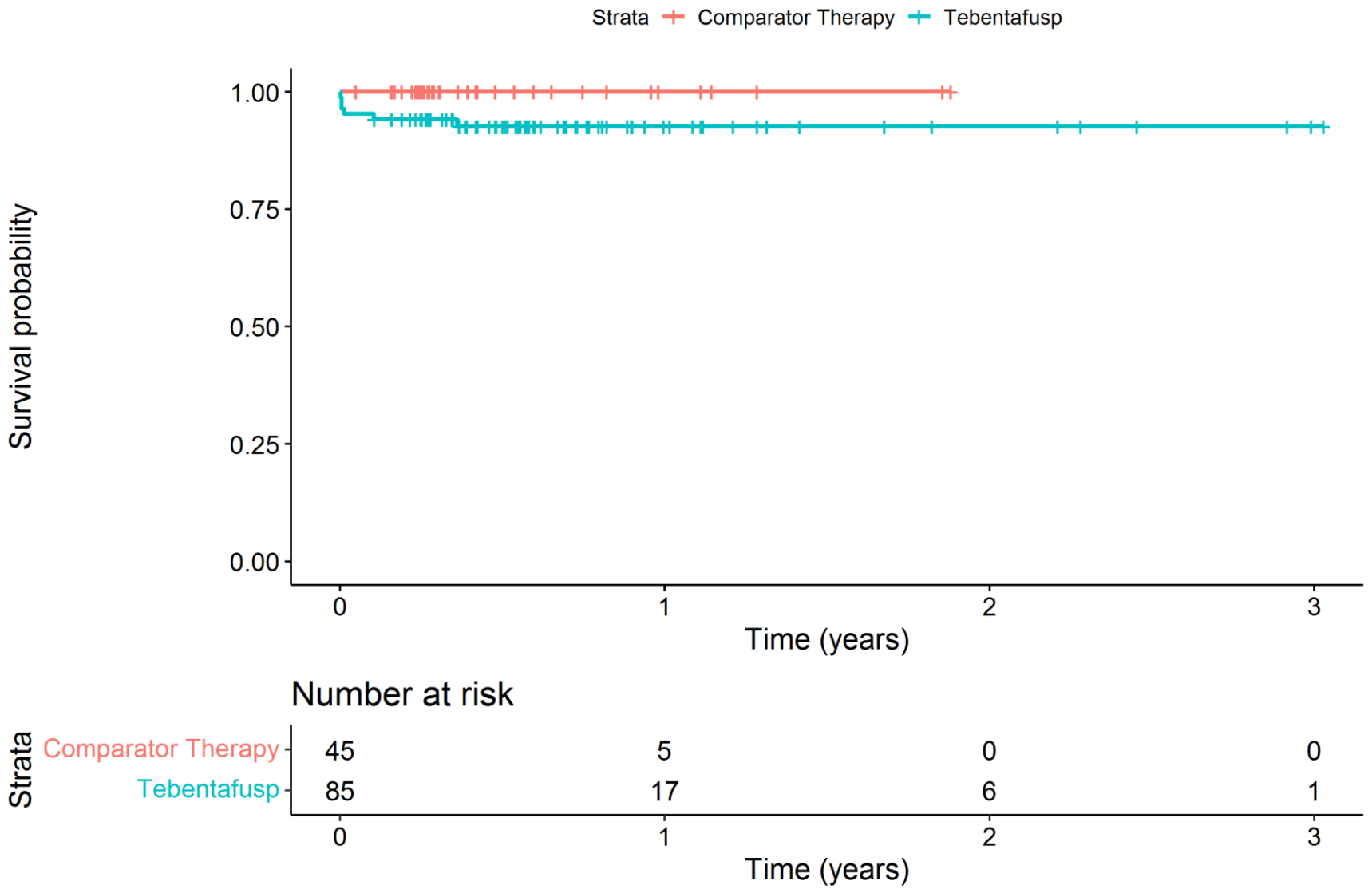
Erkrankungen der Geschlechtsorgane und der Brustdruese- Läsion 3,1-8,0 cm



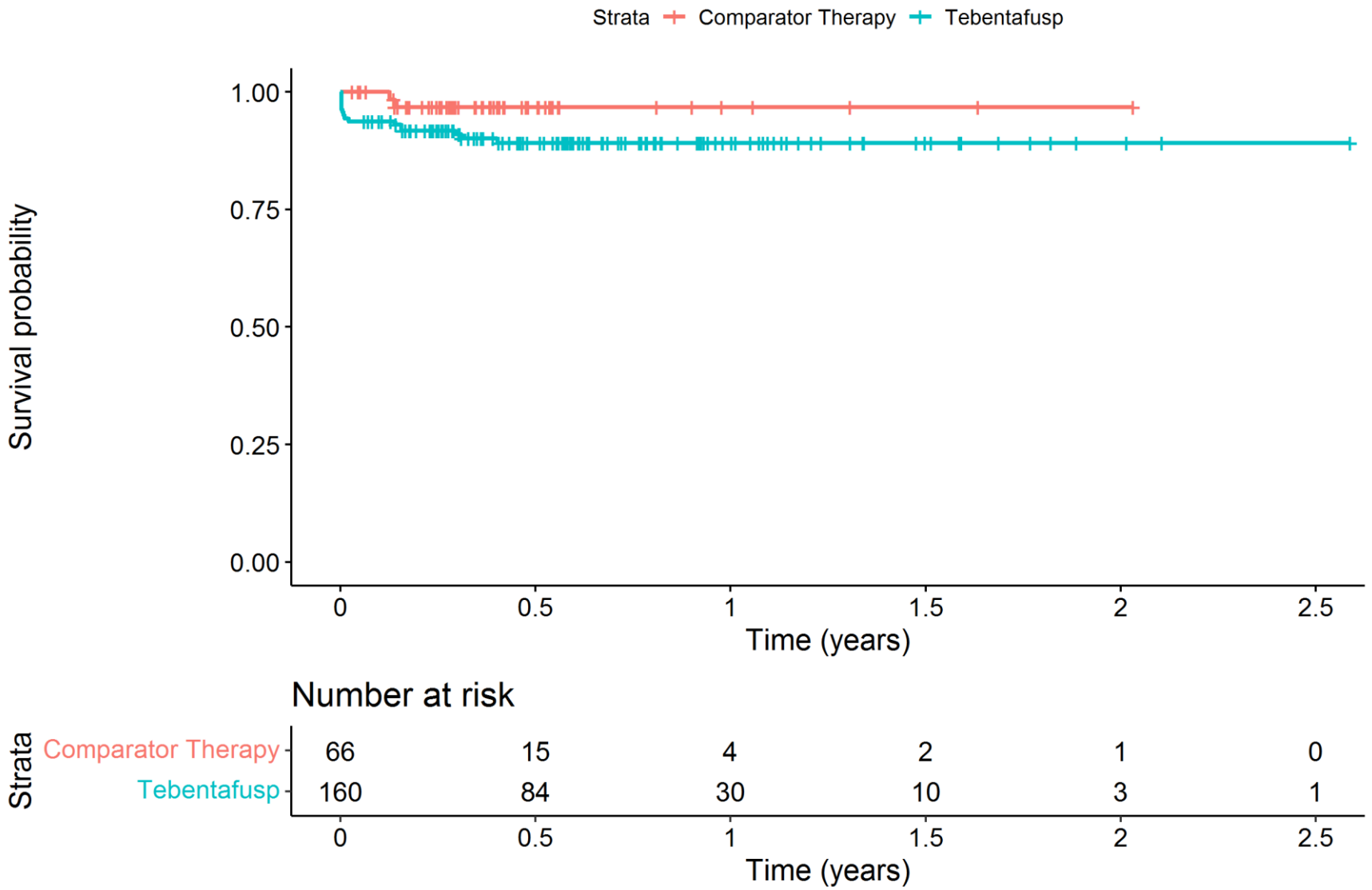
Erkrankungen der Geschlechtsorgane und der Brustdruese- Läsion ≥8,1 cm



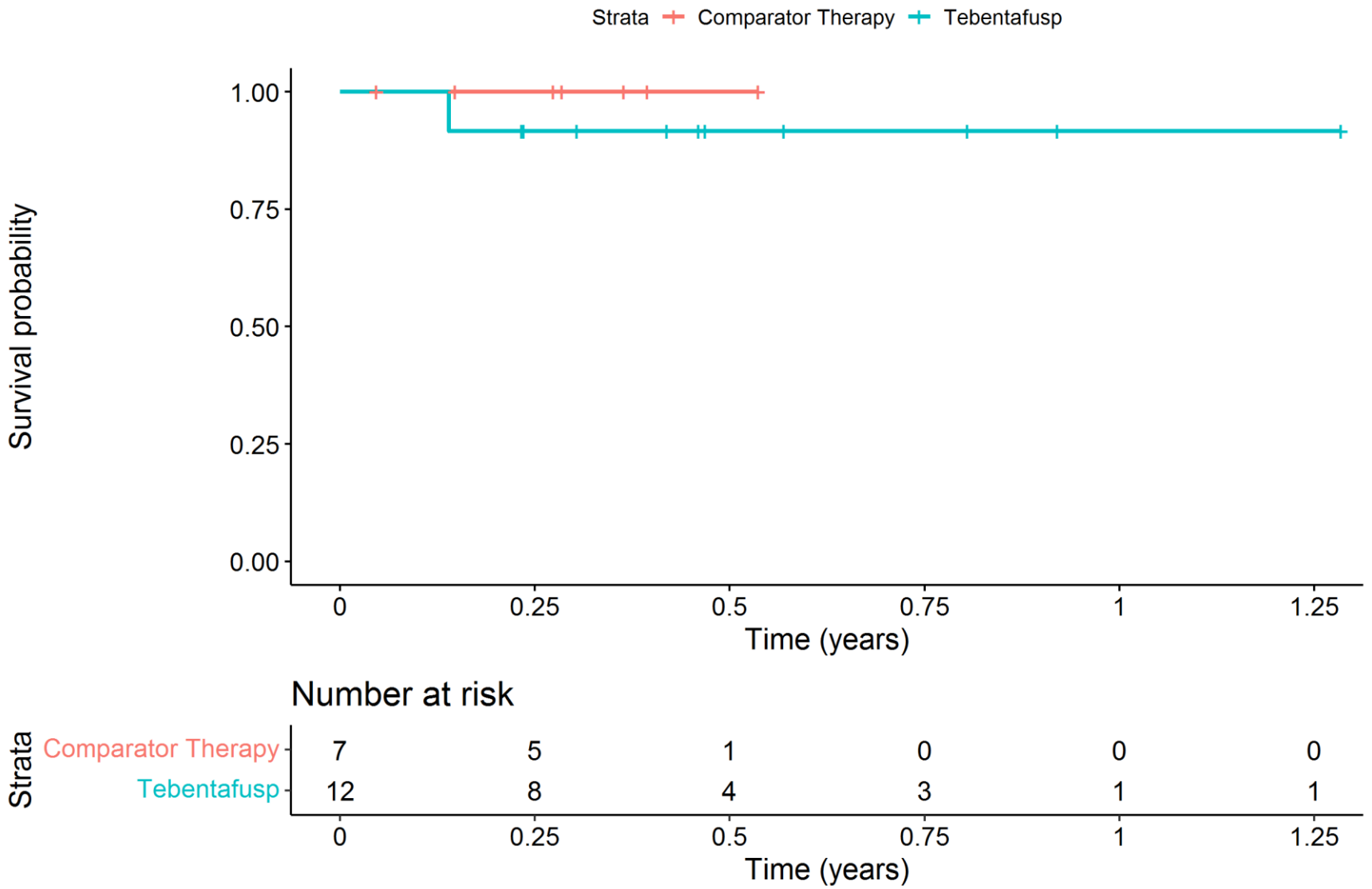
Erkrankungen der Geschlechtsorgane und der Brustdruese- Nordamerika



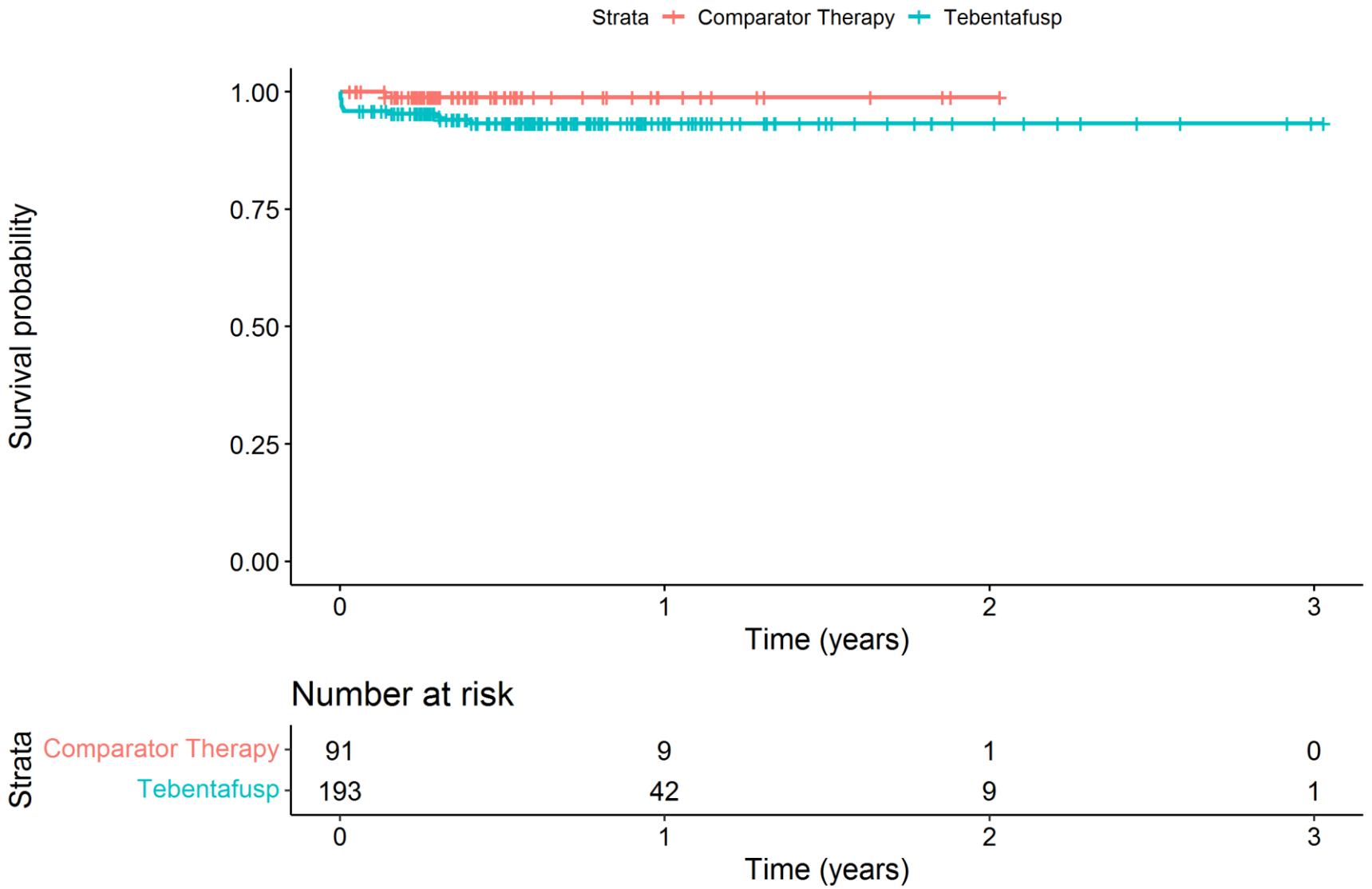
Erkrankungen der Geschlechtsorgane und der Brustdruese- Nicht-Nordamerika



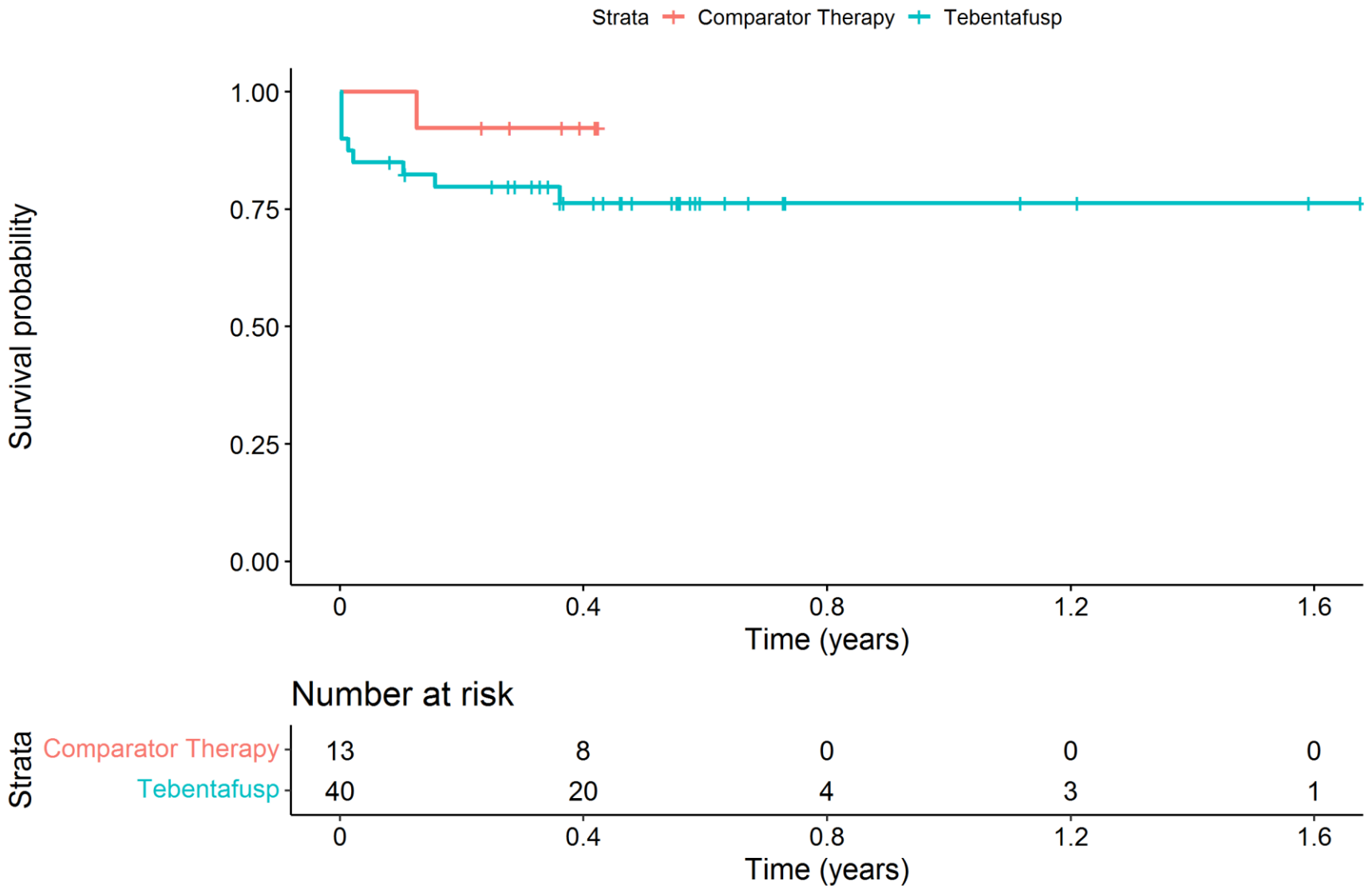
Erkrankungen der Geschlechtsorgane und der Brustdruese- Dacarbazin



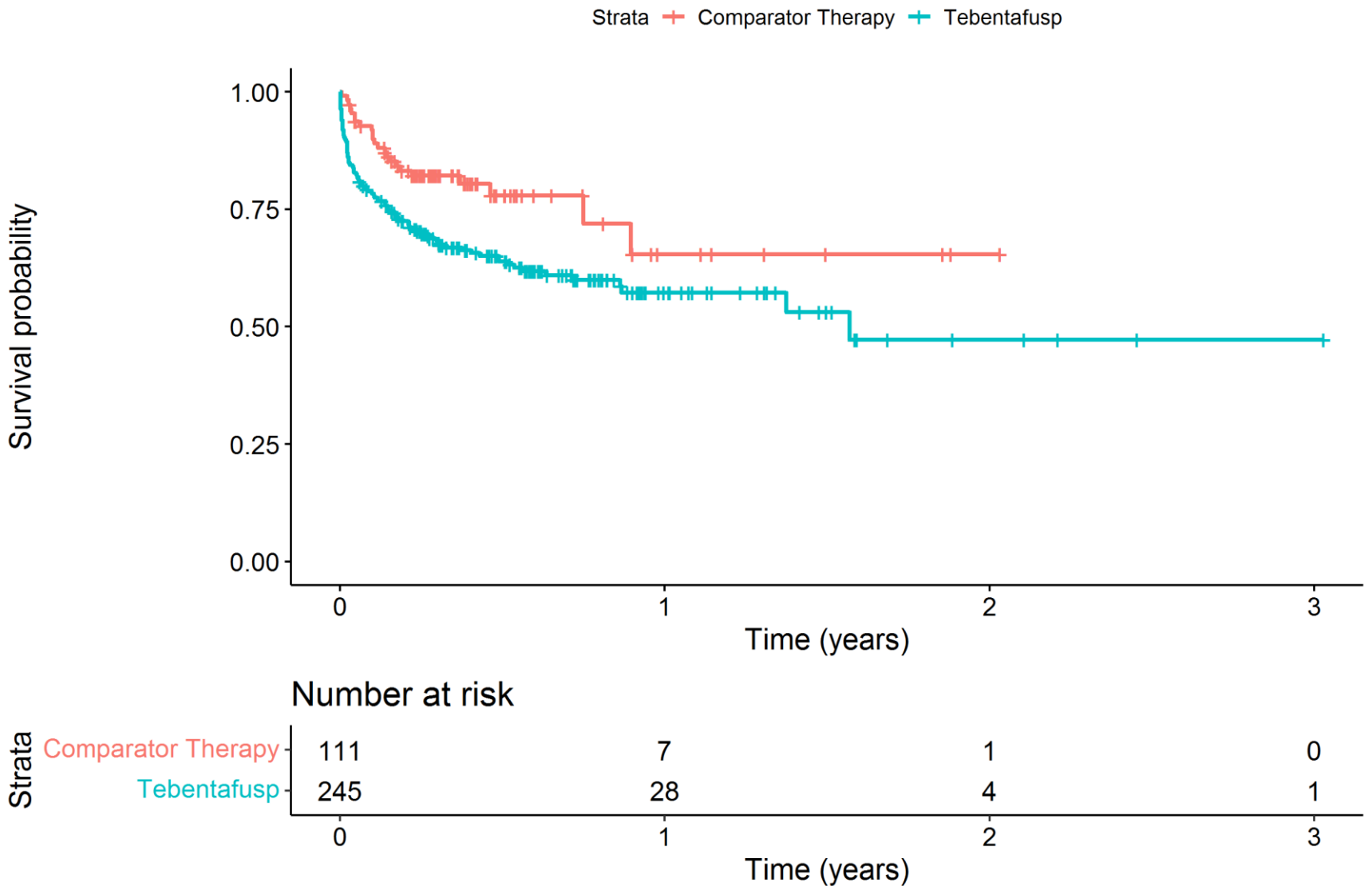
Erkrankungen der Geschlechtsorgane und der Brustdruese- Pembrolizumab



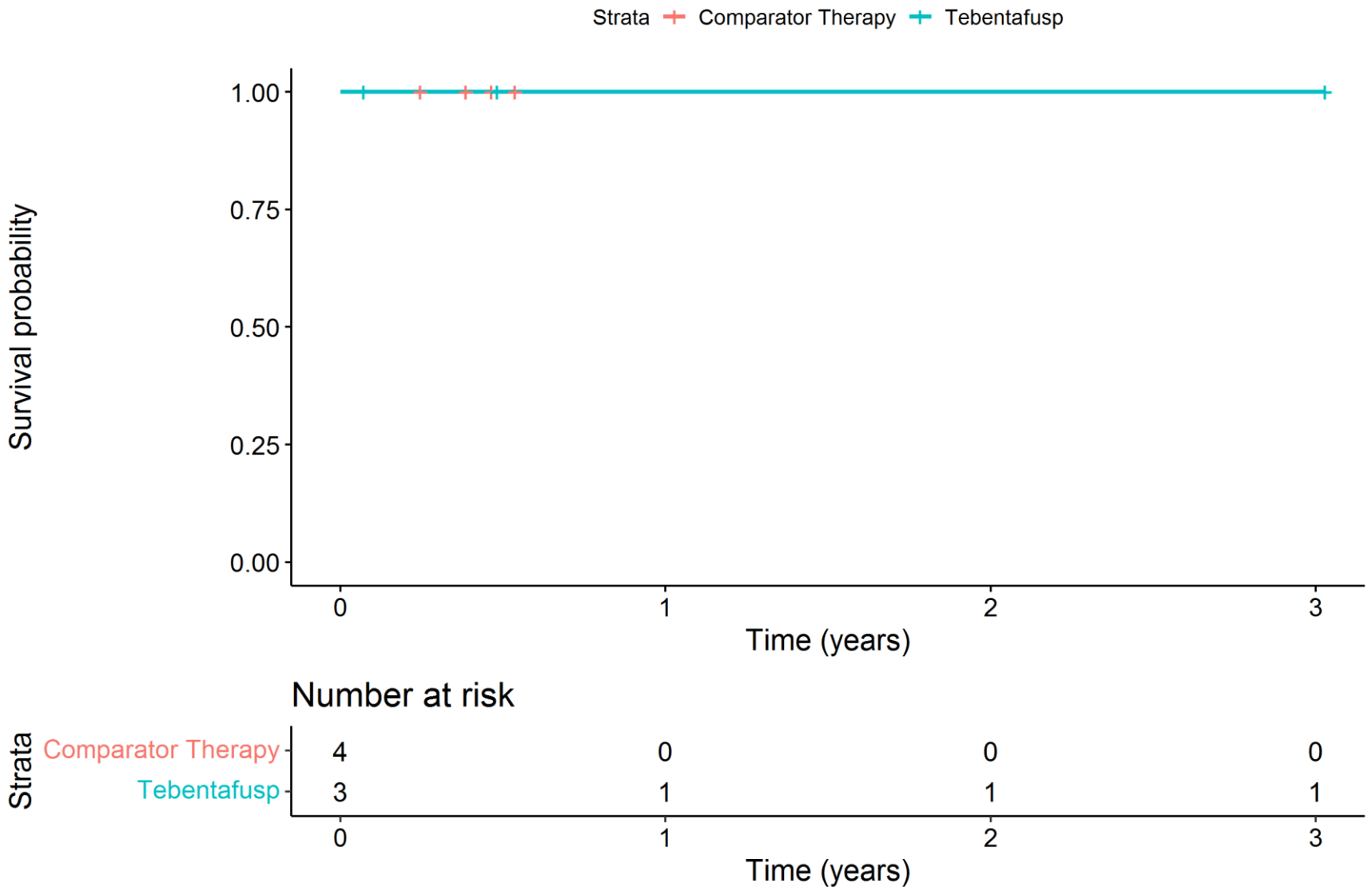
Erkrankungen der Geschlechtsorgane und der Brustdruese- Ipilimumab



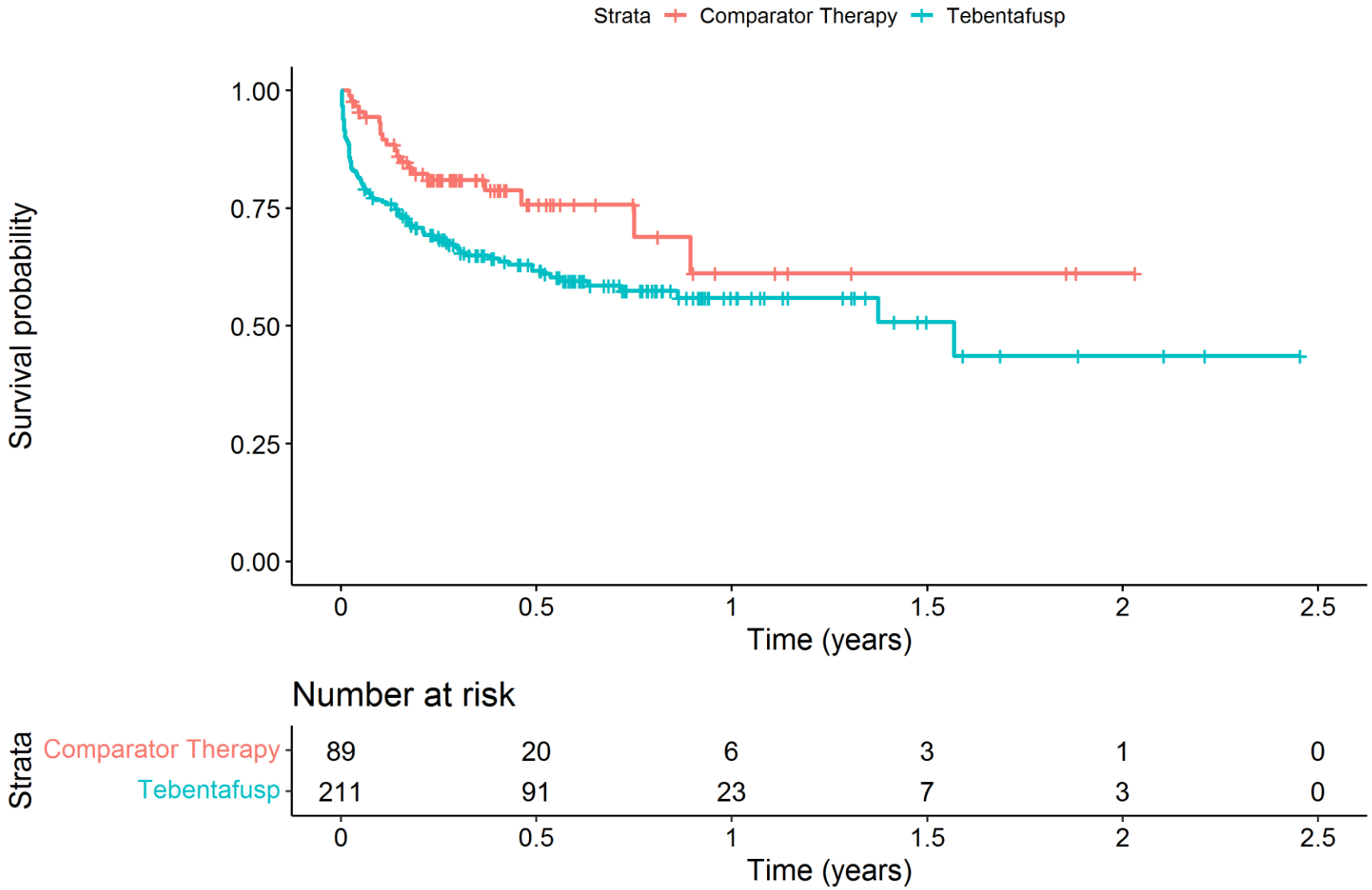
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Gesamt



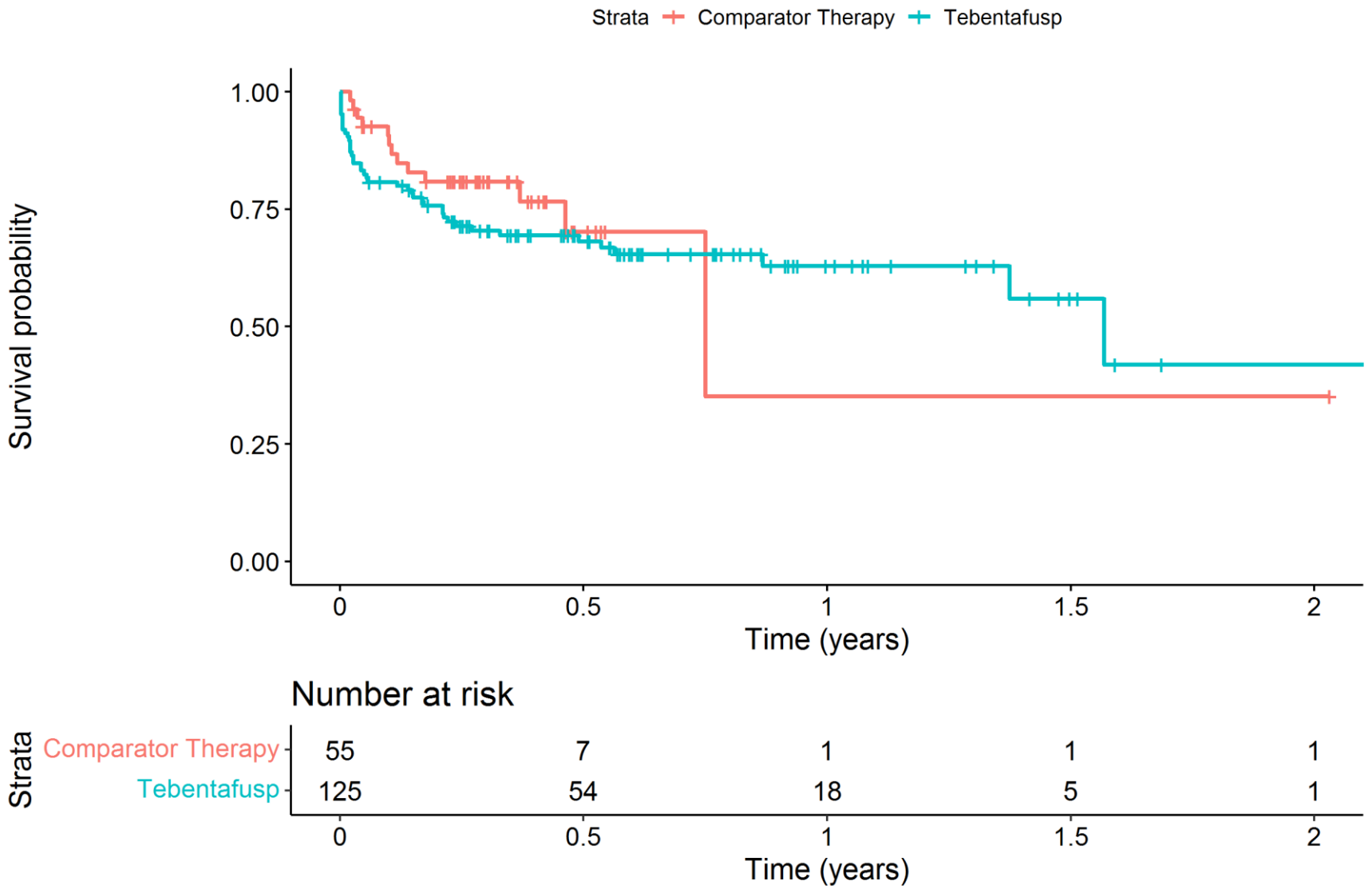
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Hispanisch



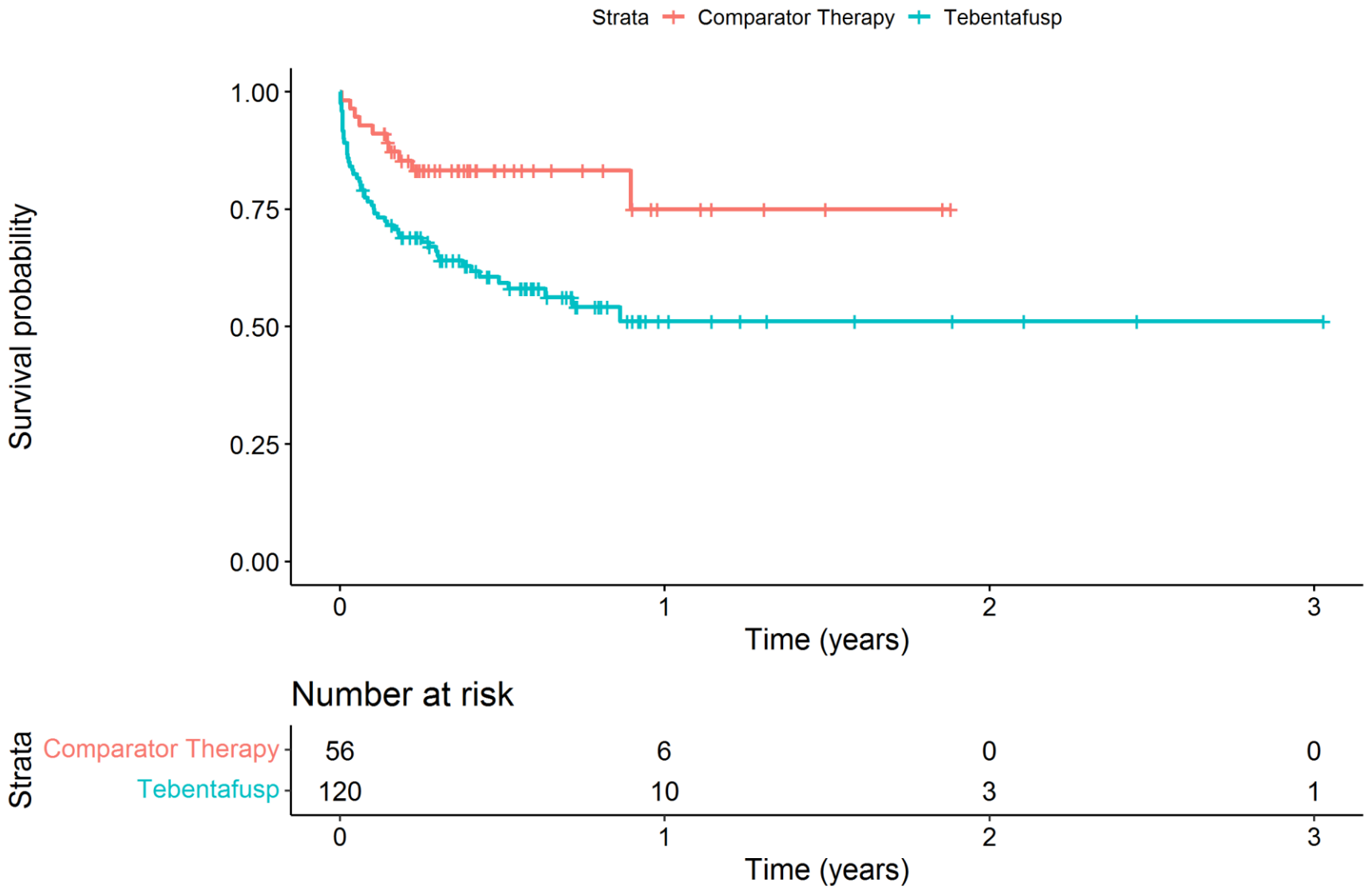
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nicht-hispanisch



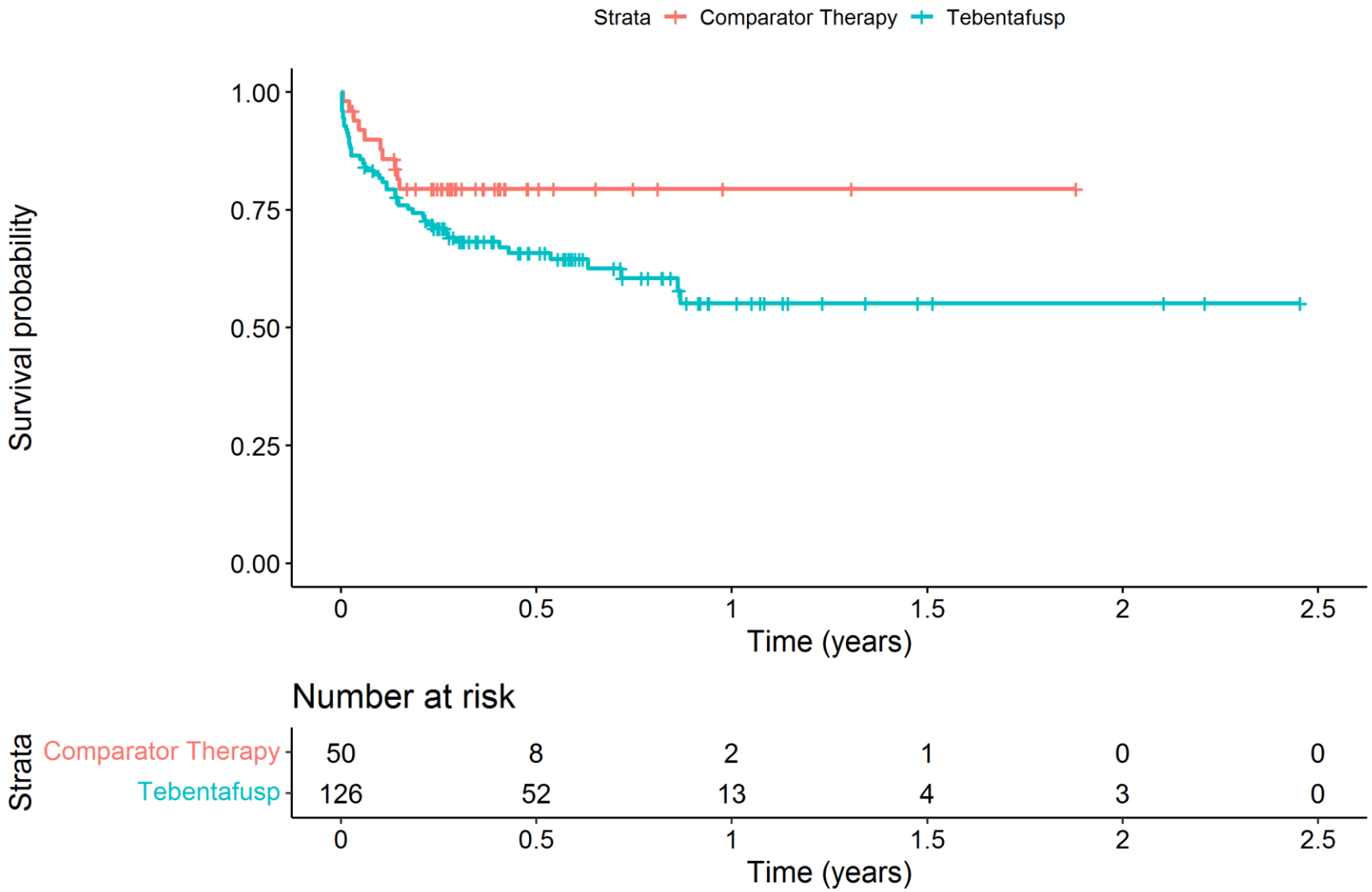
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Männlich



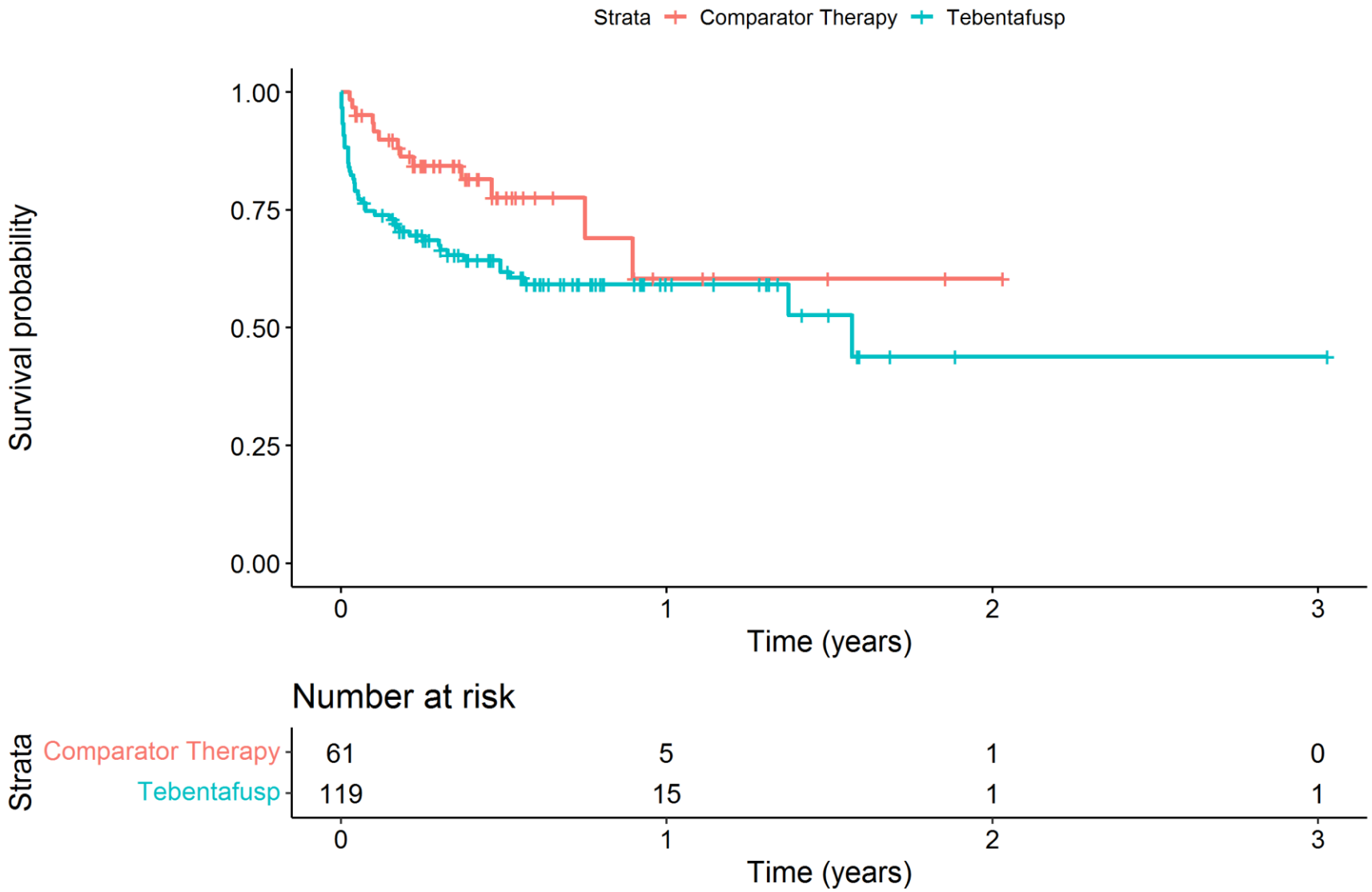
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Weiblich



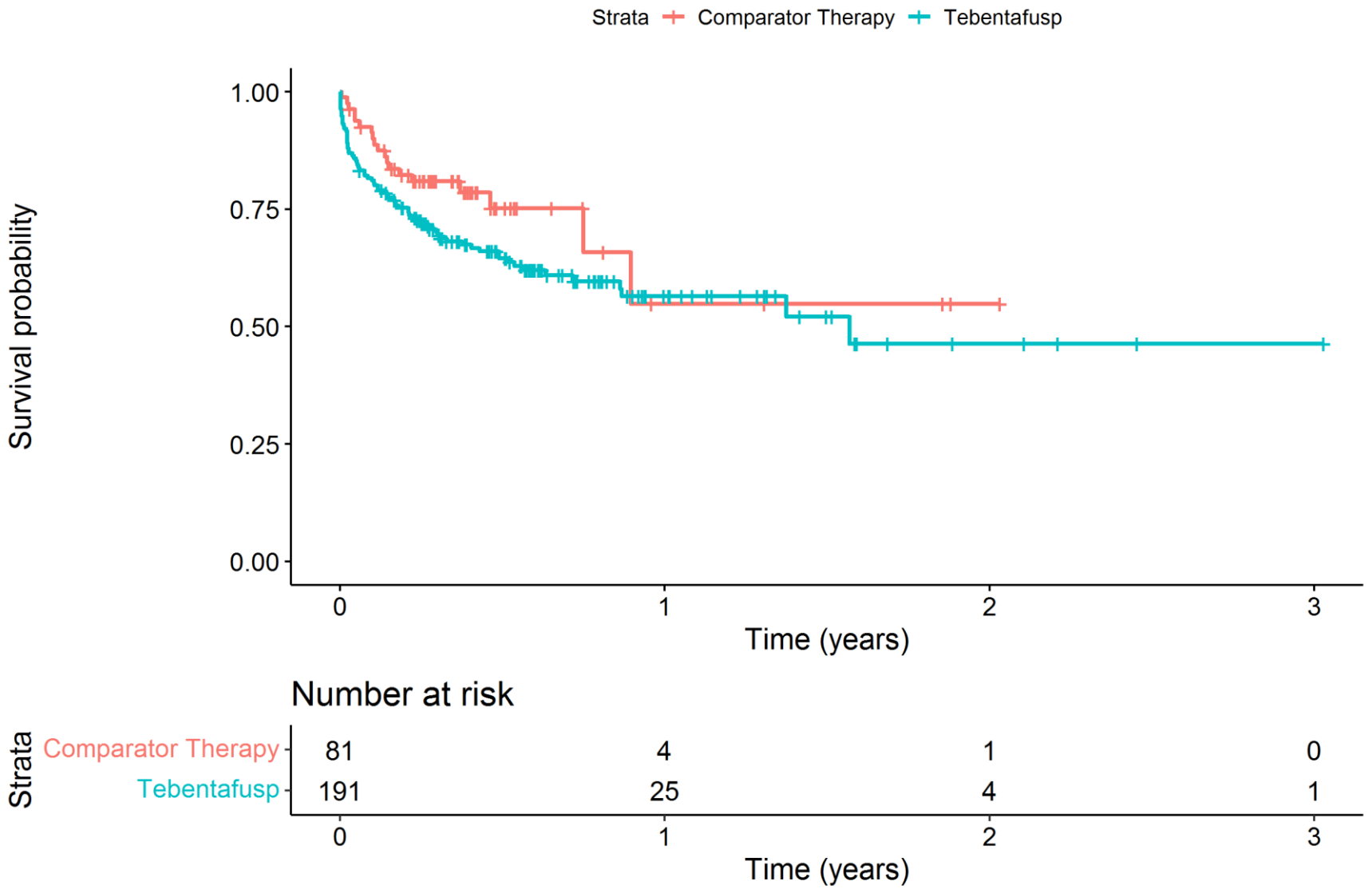
Erkrankungen der Atemwege, des Brustraums und Mediastinums- <65



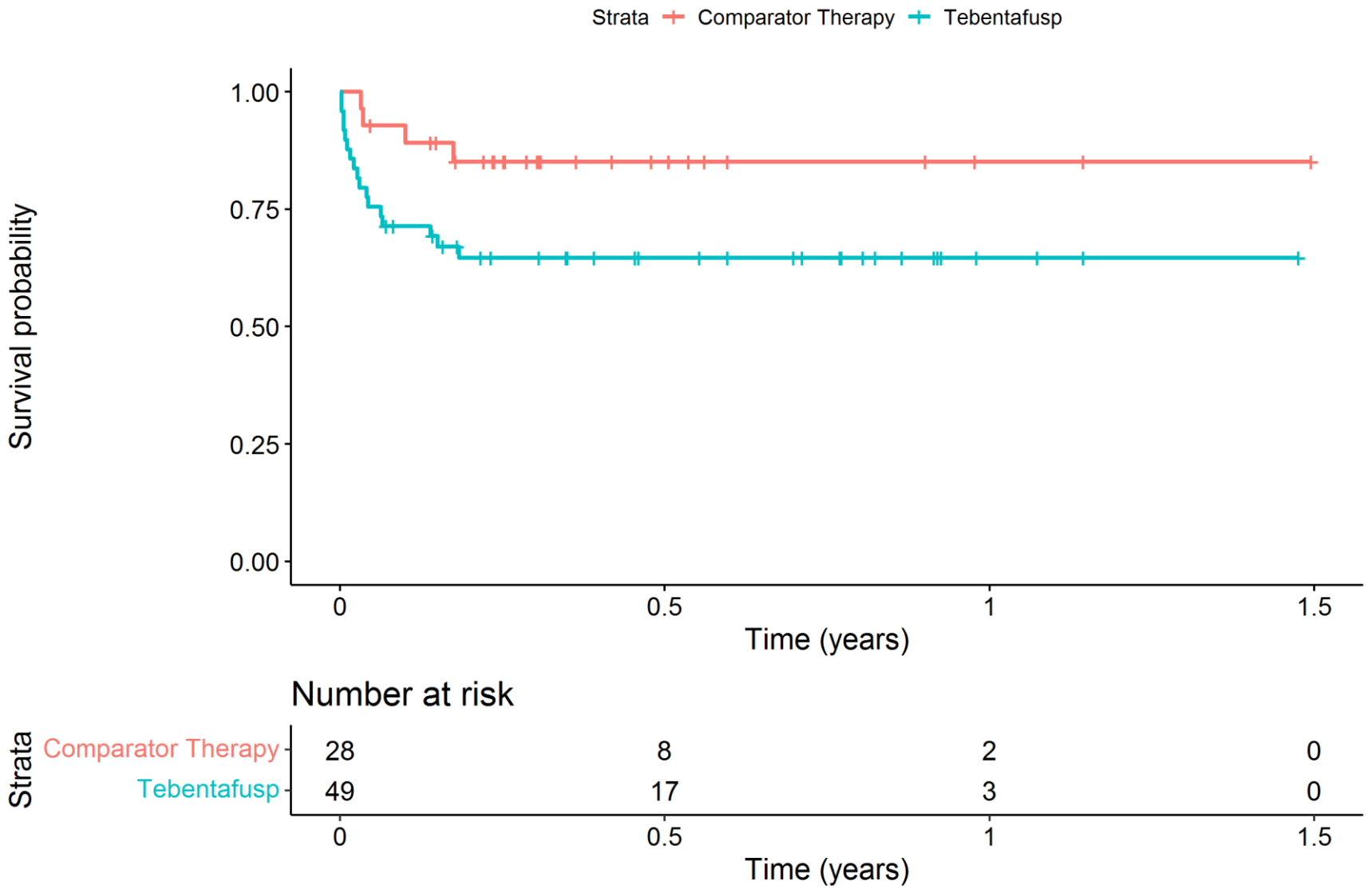
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ≥65



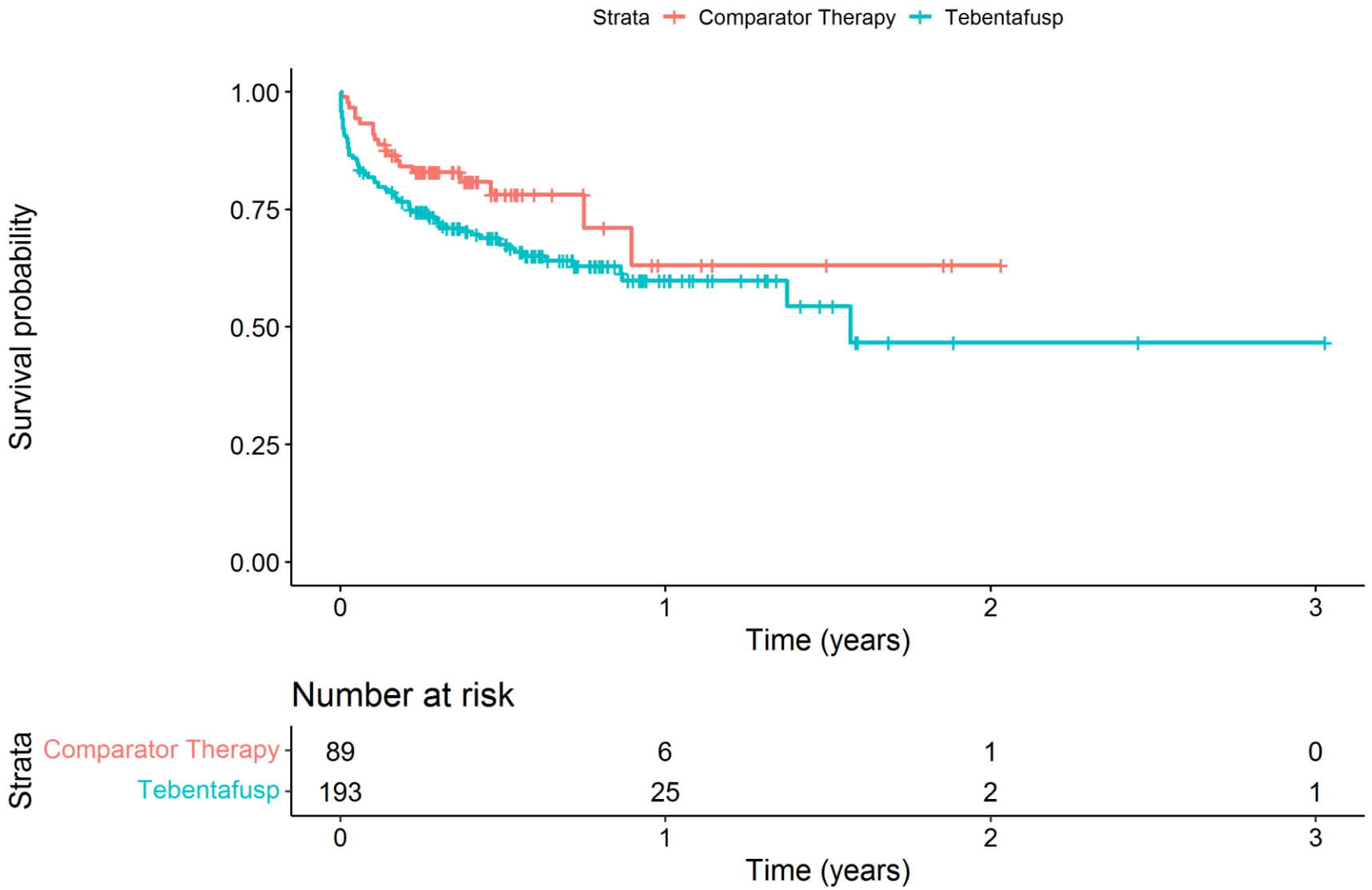
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 0



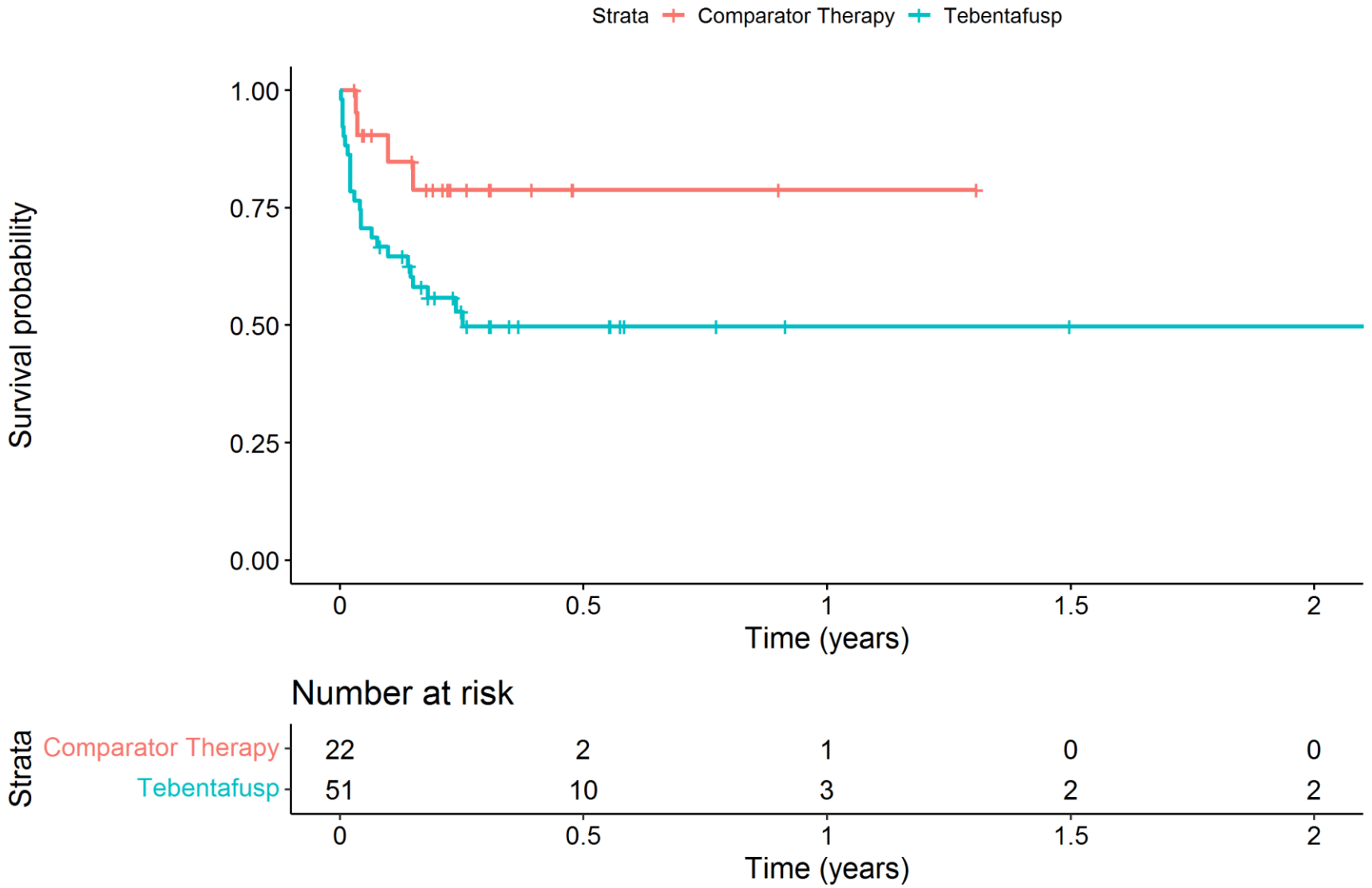
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 1



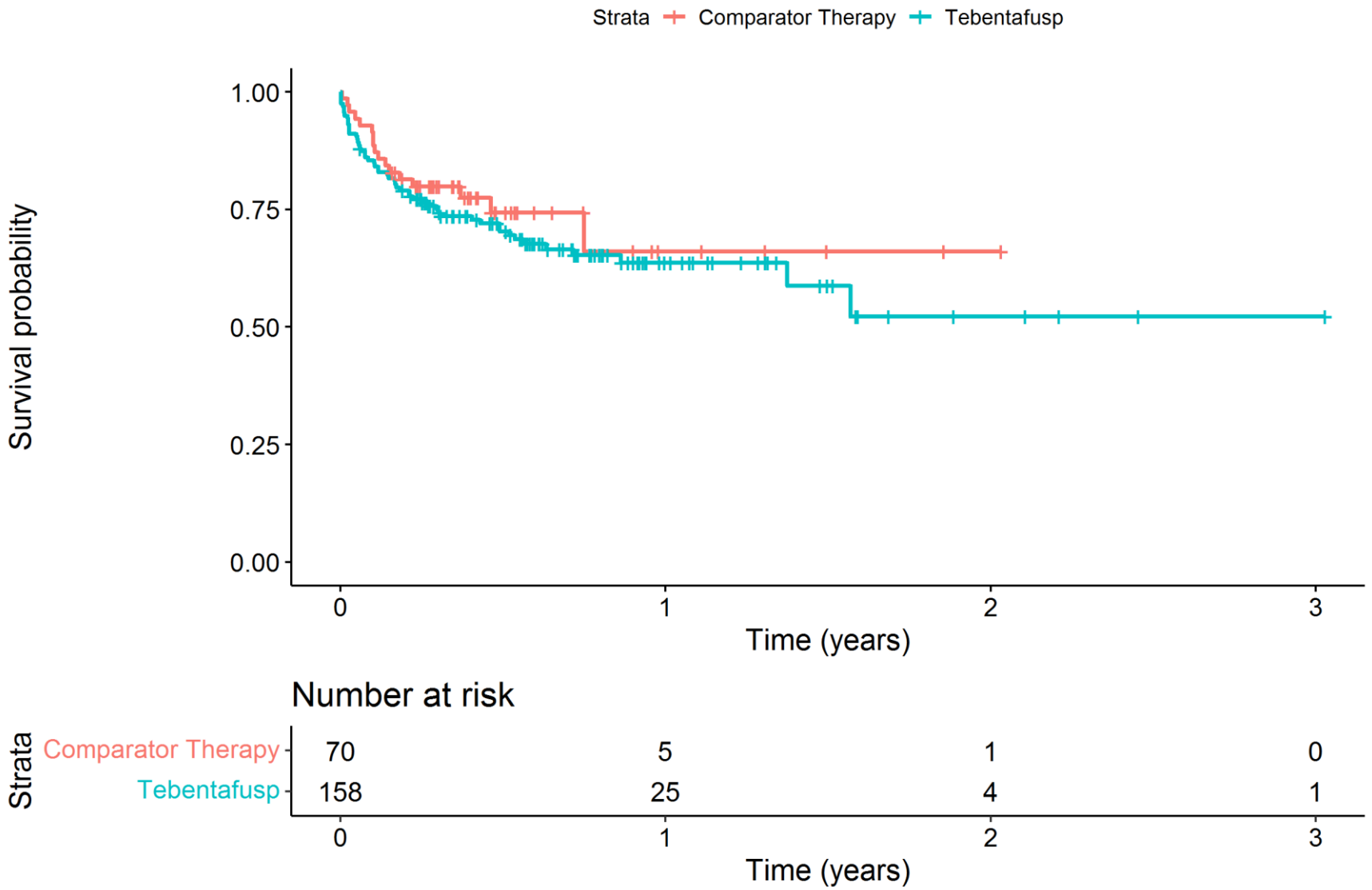
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ALP ≤ ULN



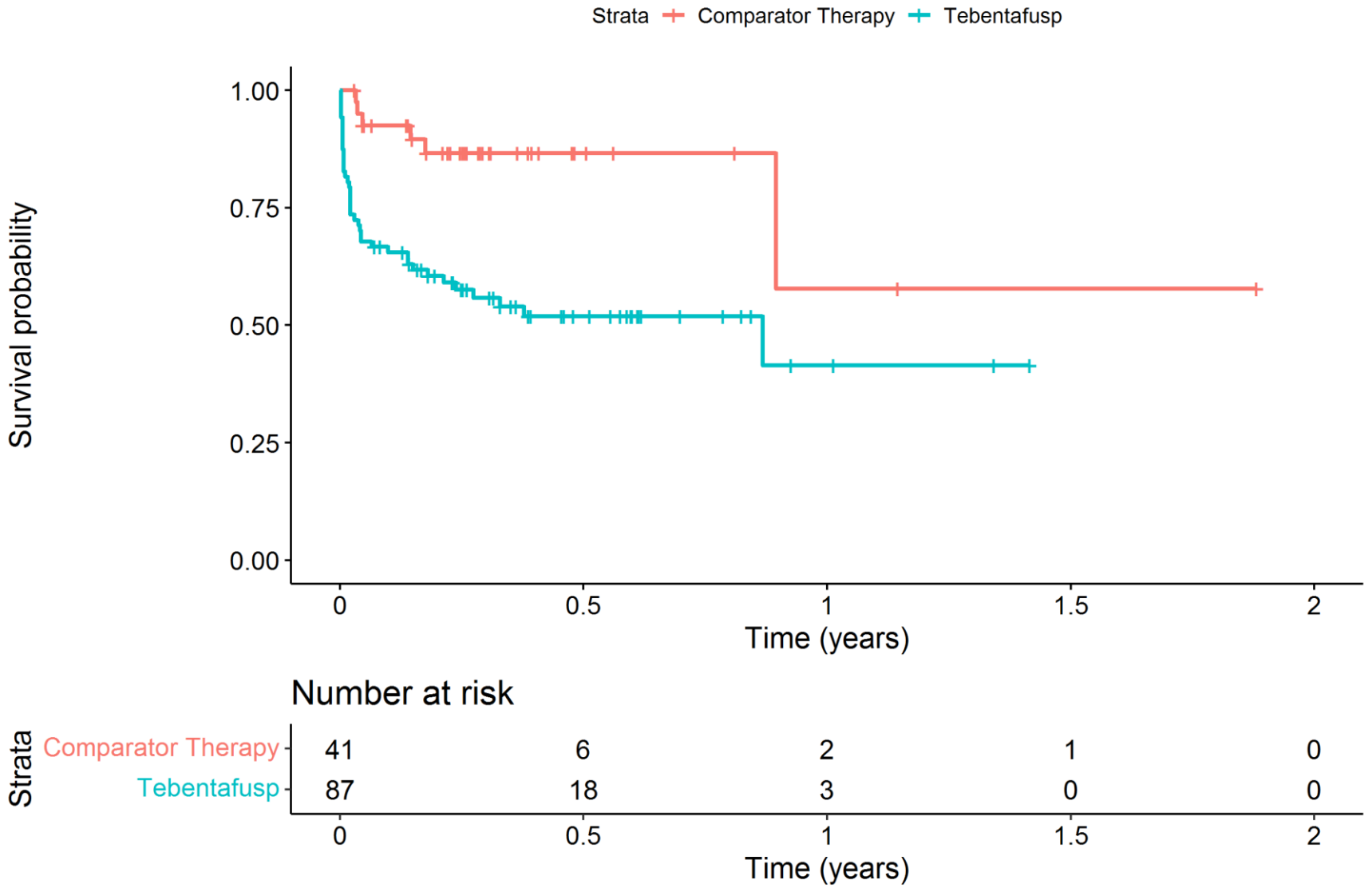
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ALP > ULN



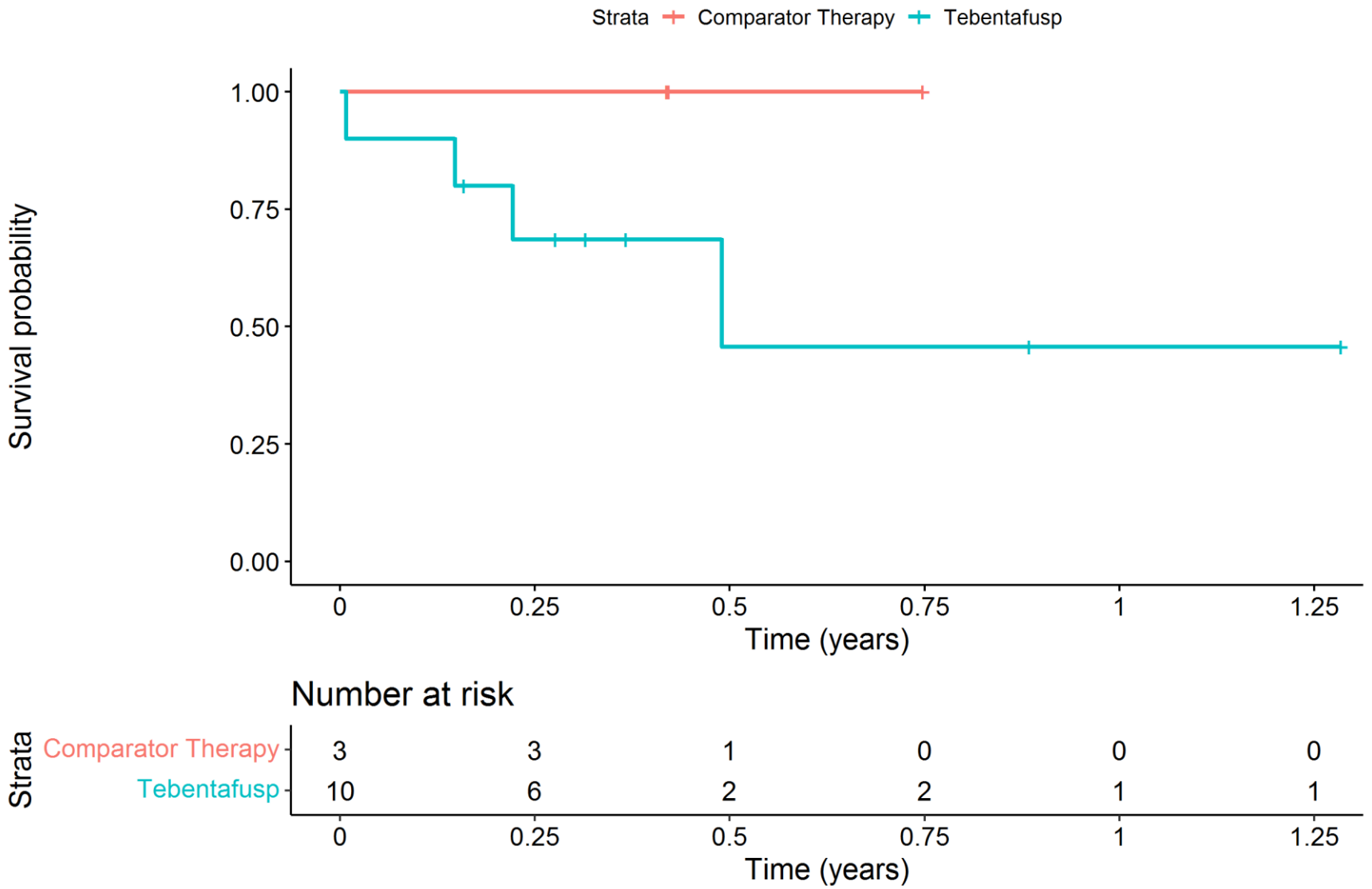
Erkrankungen der Atemwege, des Brustraums und Mediastinums- LDH =< ULN



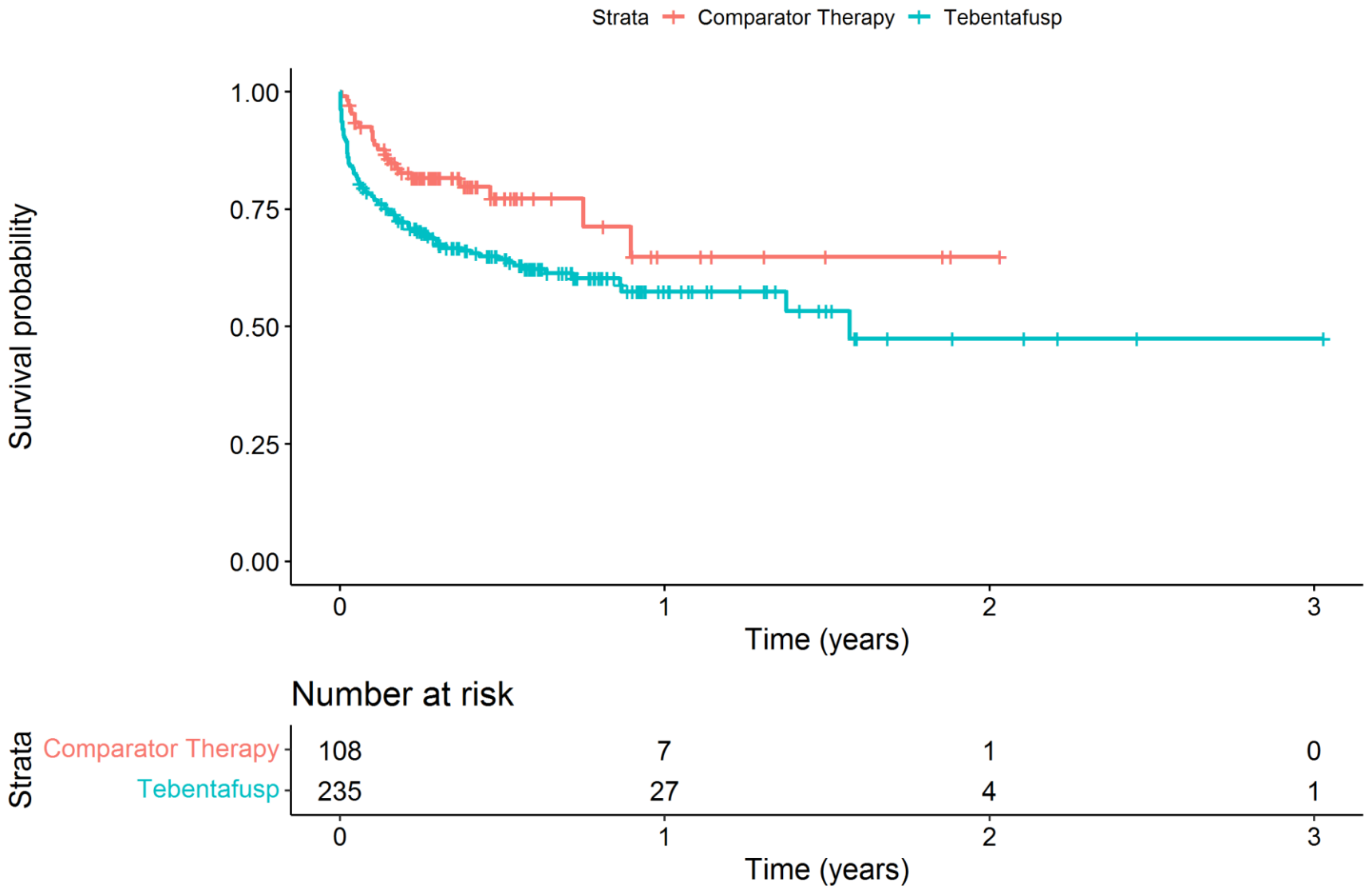
Erkrankungen der Atemwege, des Brustraums und Mediastinums- LDH > ULN



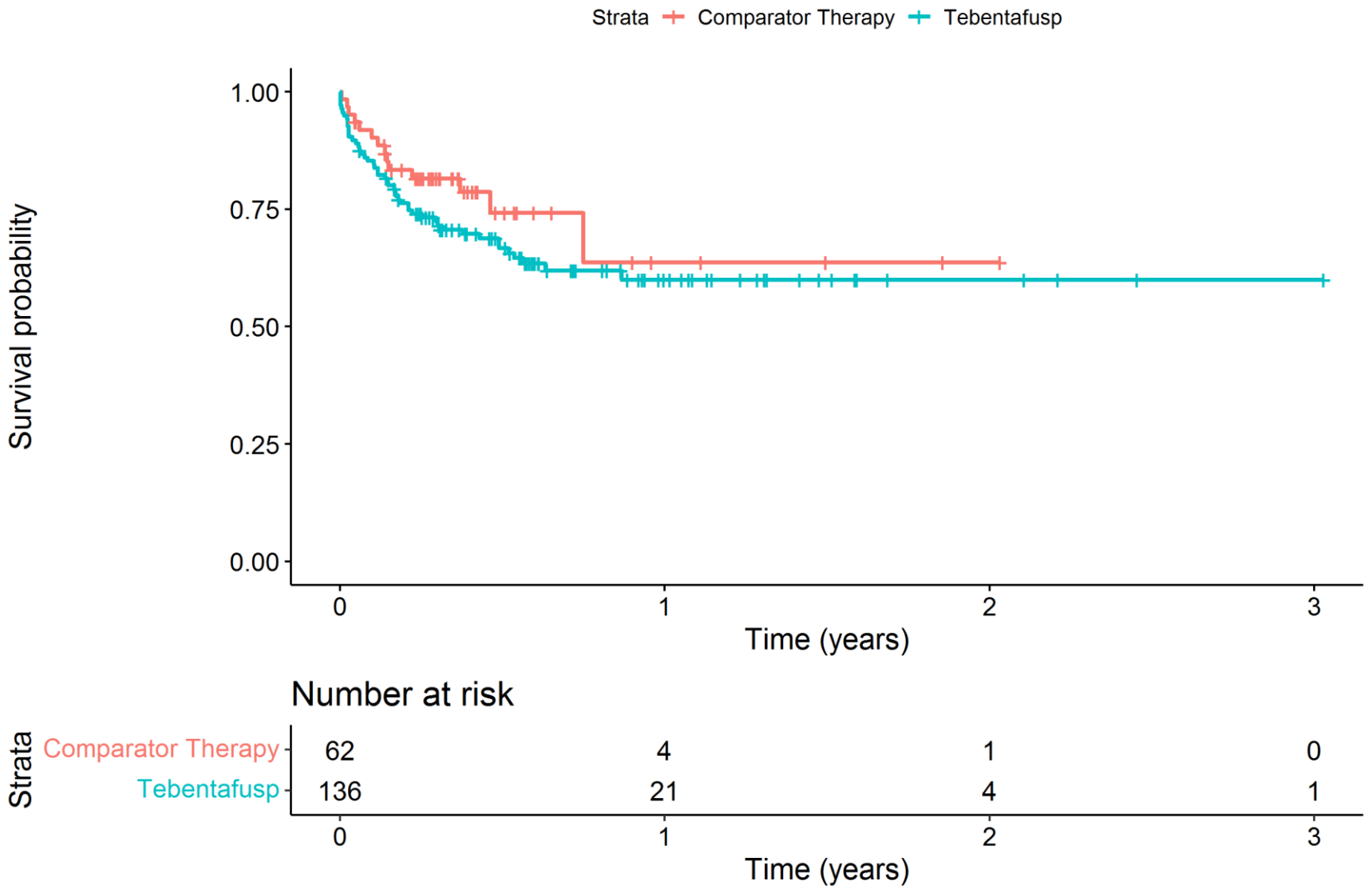
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Vorherige Therapie adjuvant/neoadjuvant



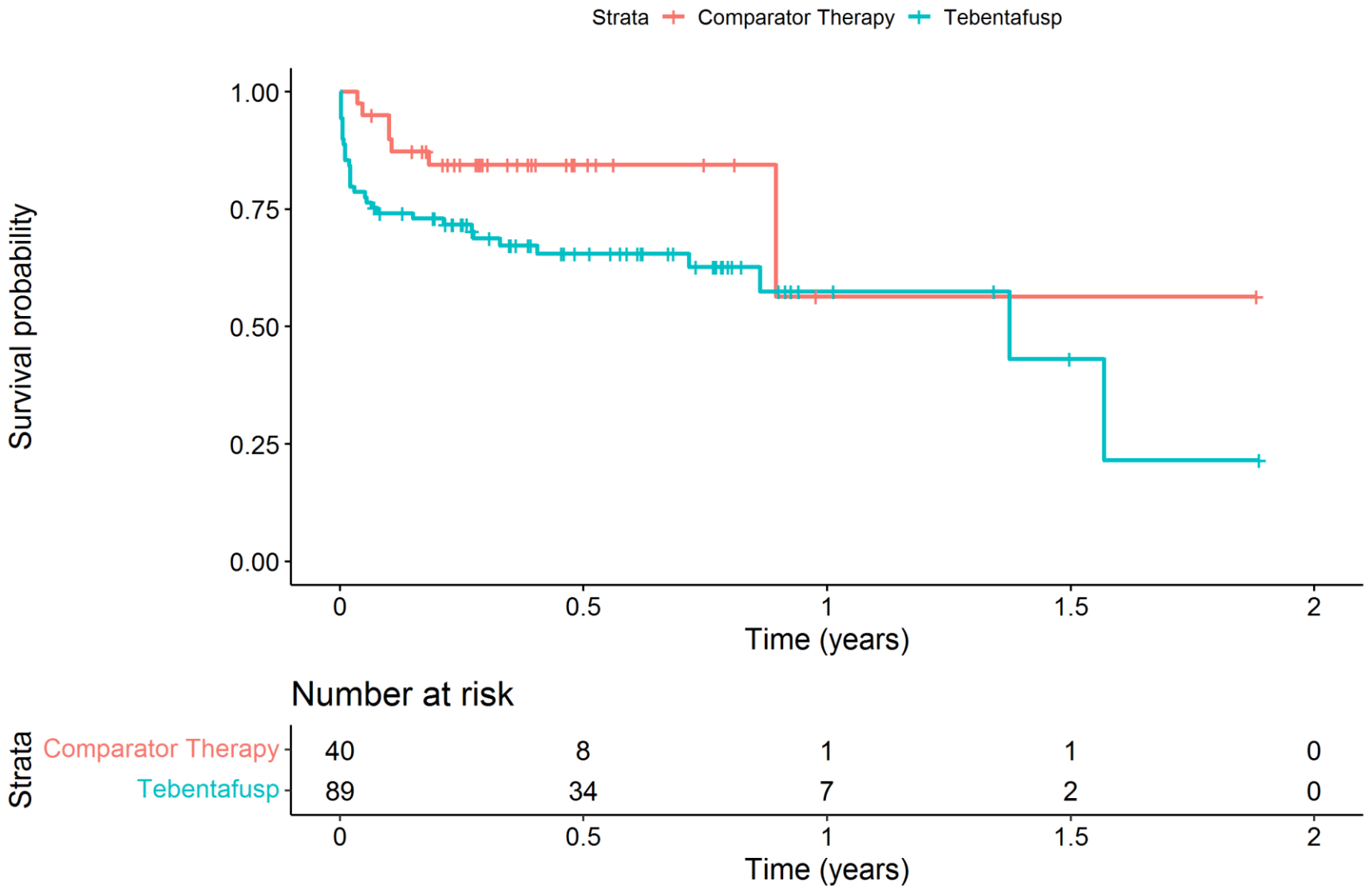
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Keine vorherige Therapie adjuvant/neoadjuvant



Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion ≤ 3cm



Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion 3,1-8,0 cm



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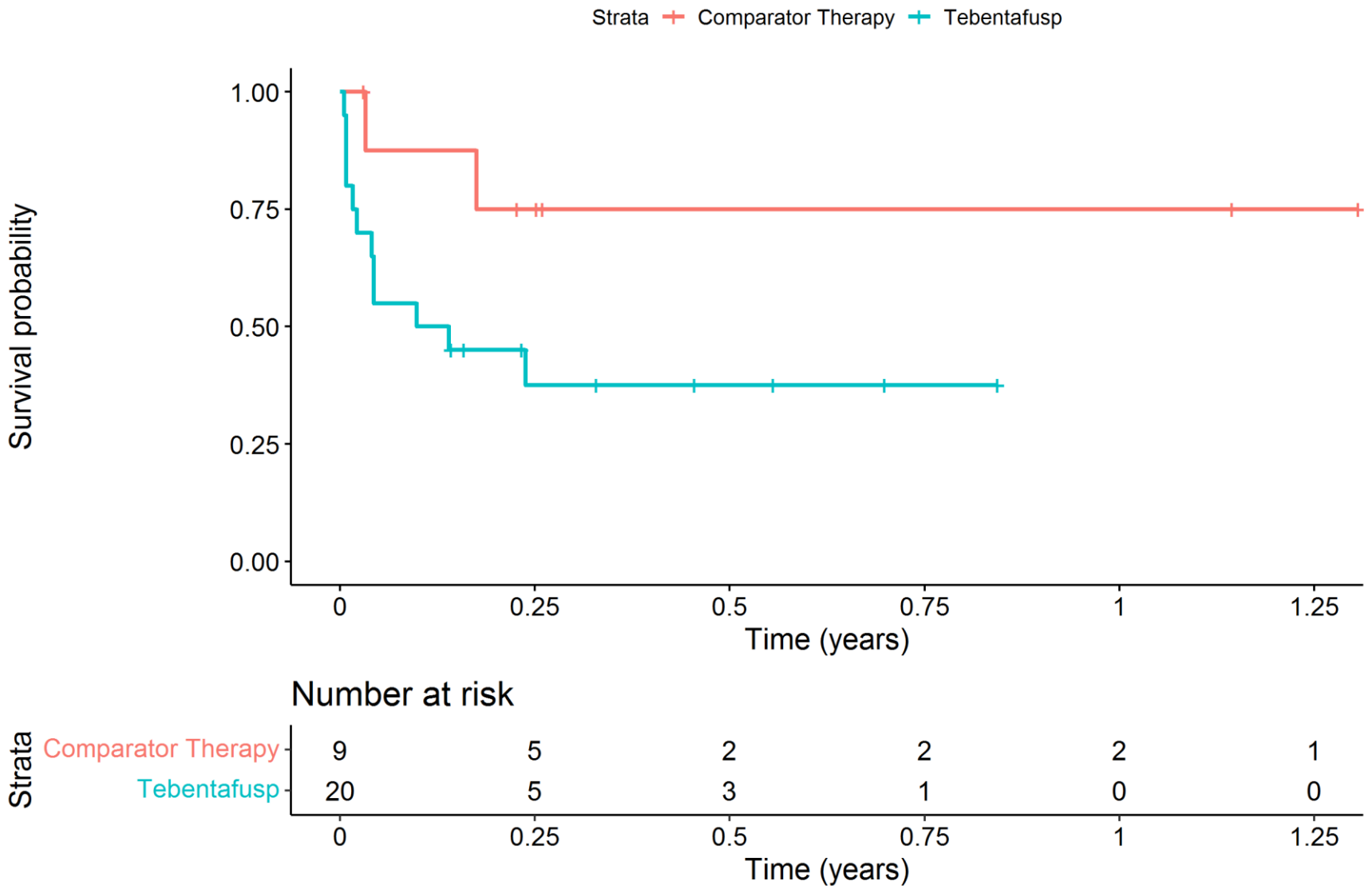
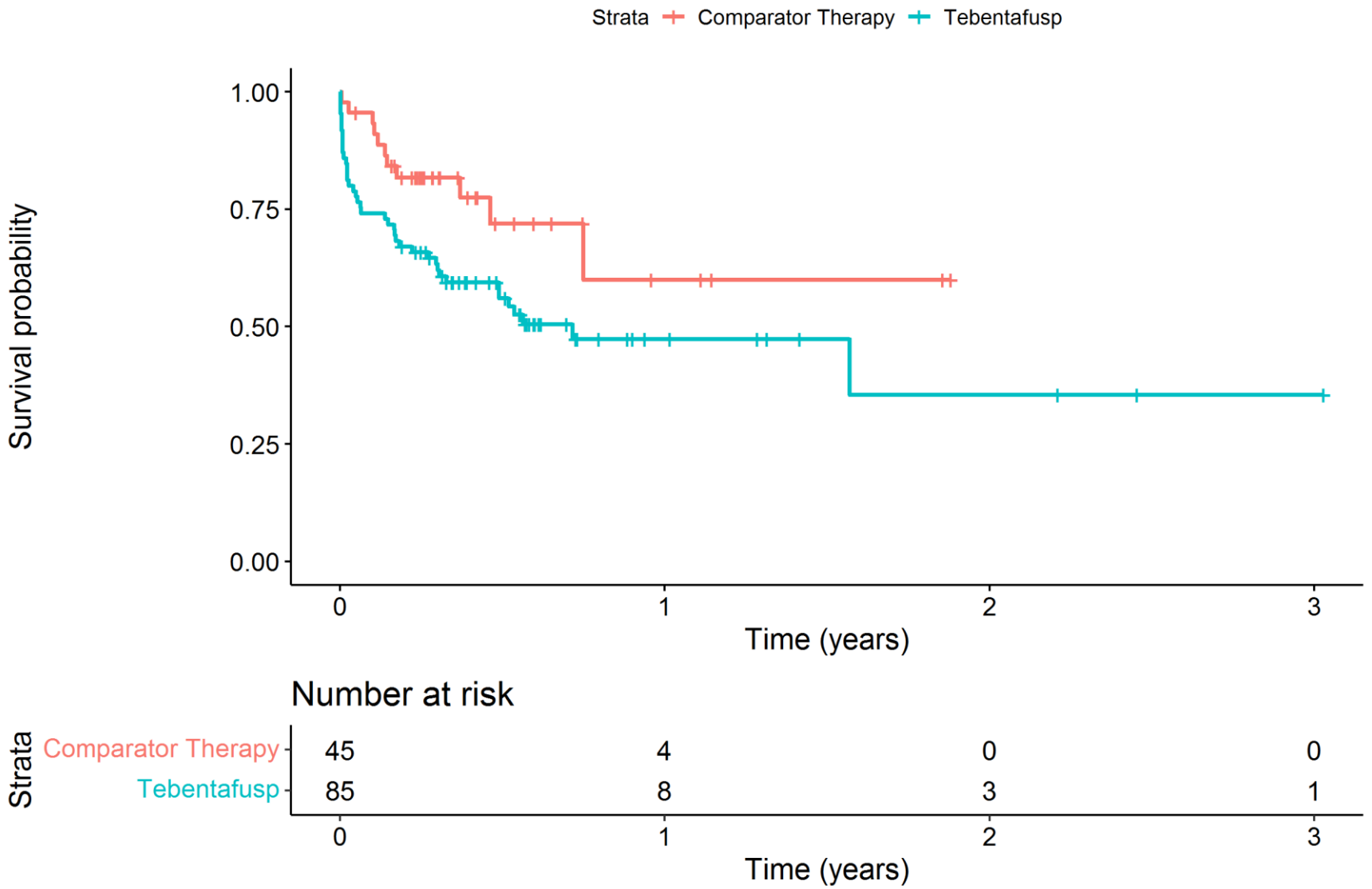
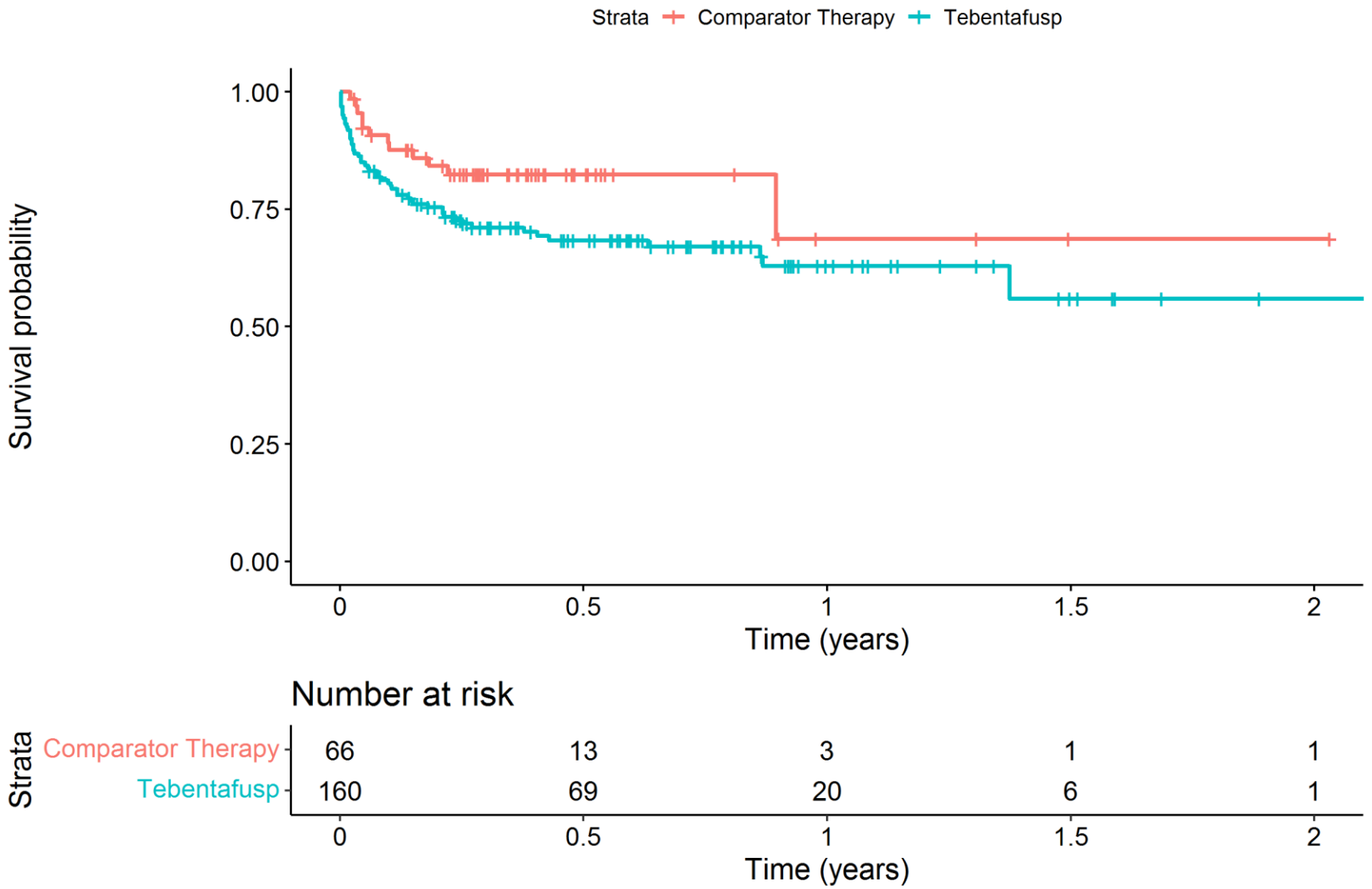


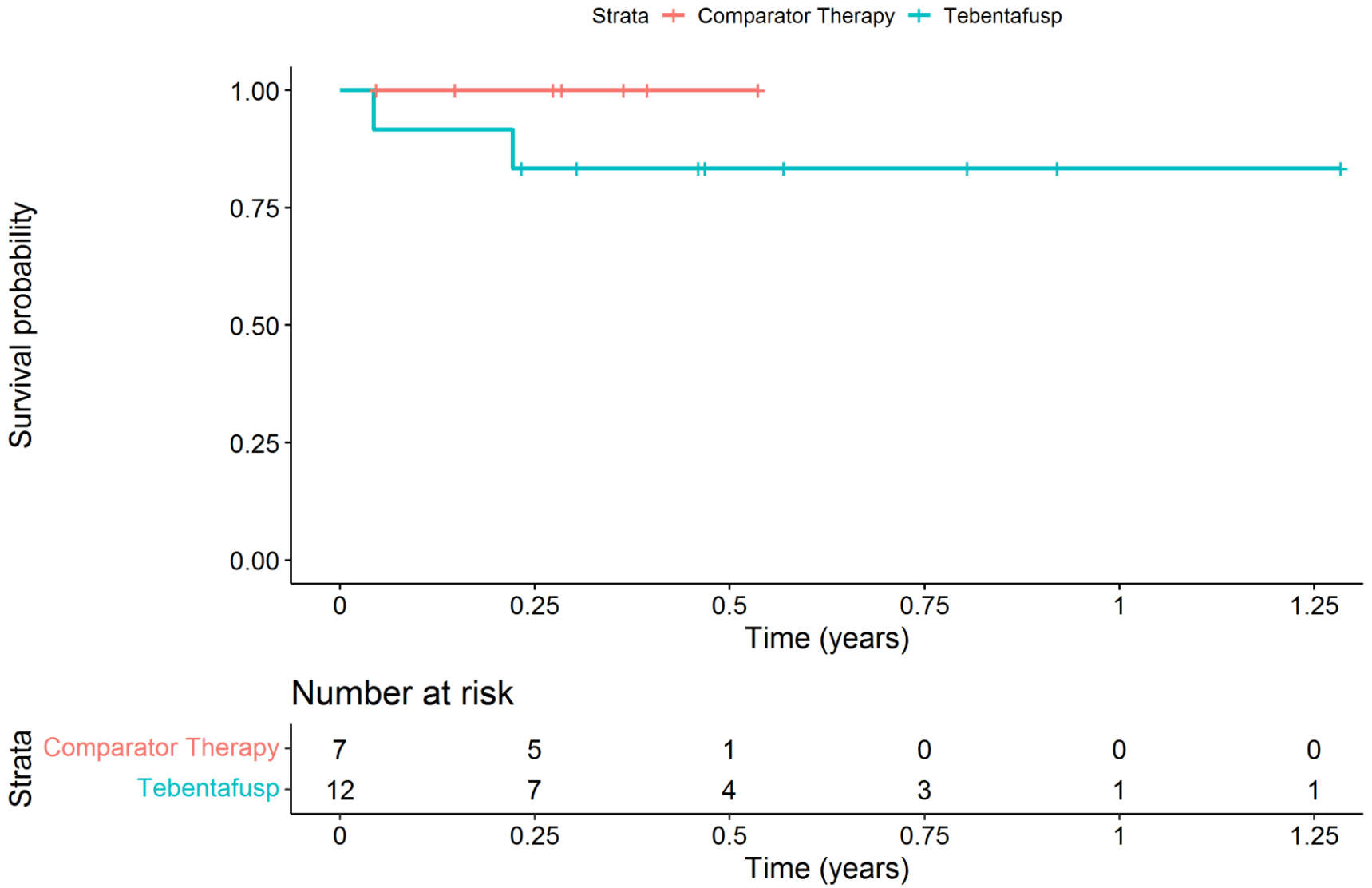
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nordamerika



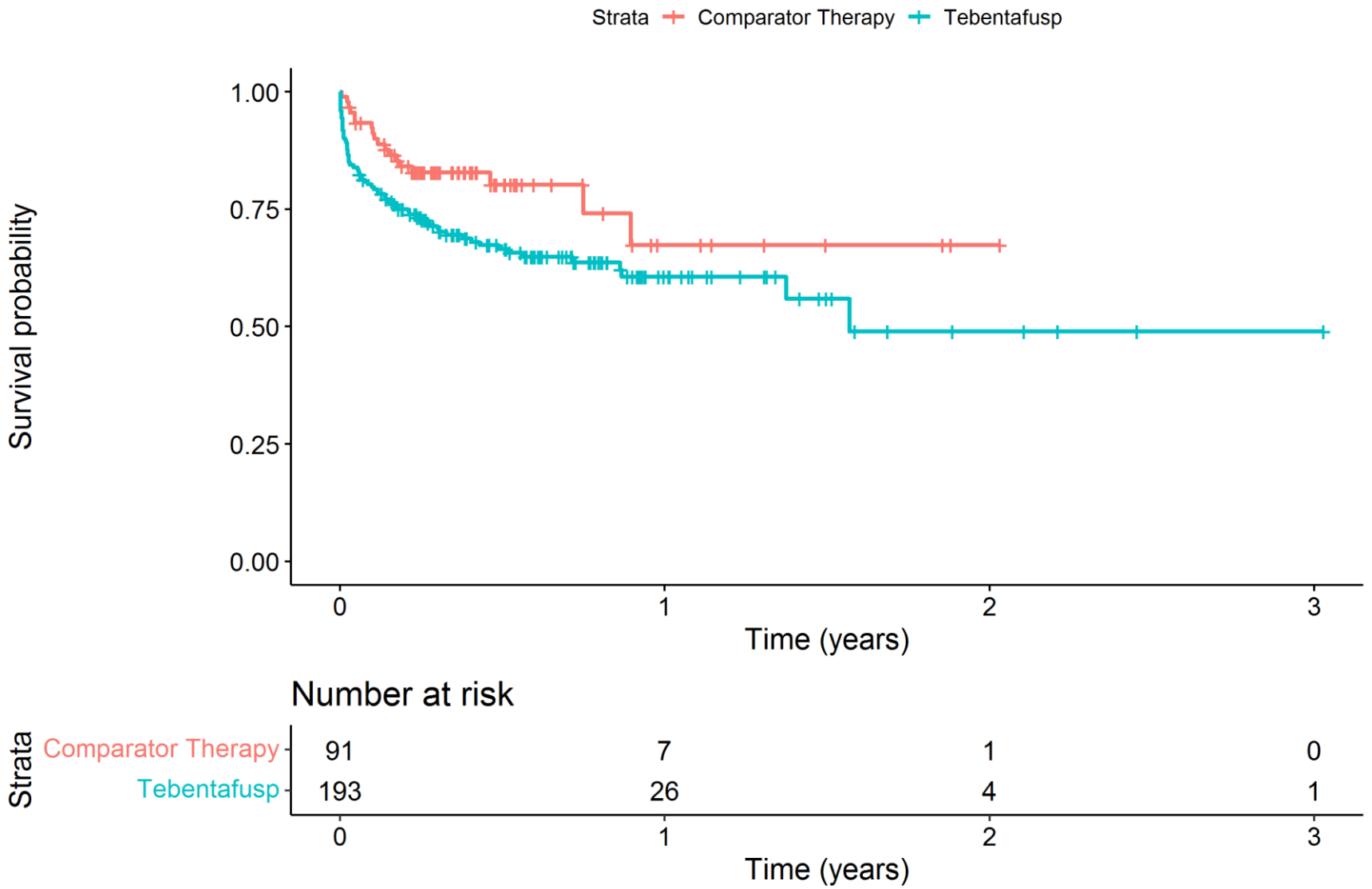
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nicht-Nordamerika



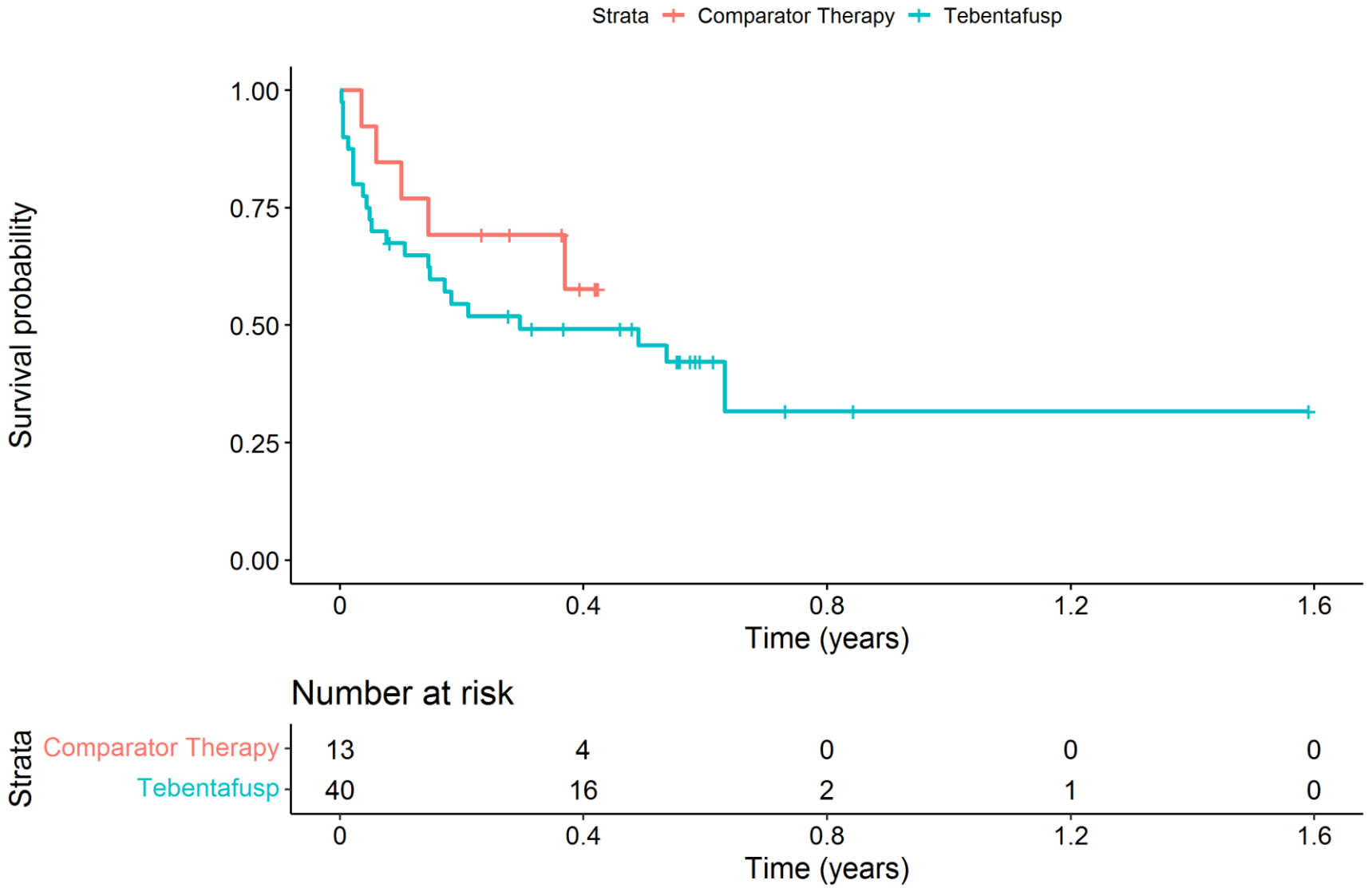
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Dacarbazin



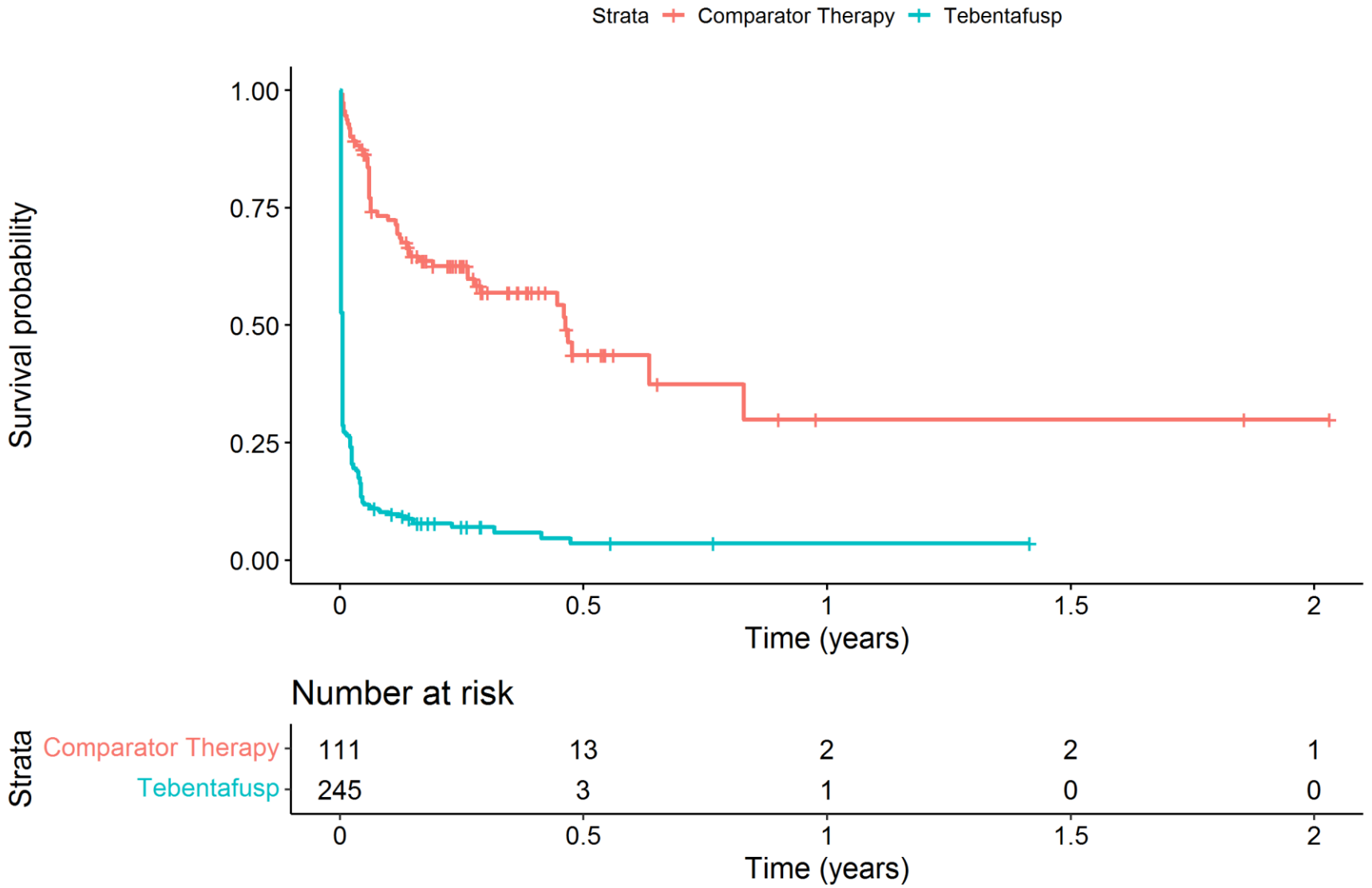
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Pembrolizumab



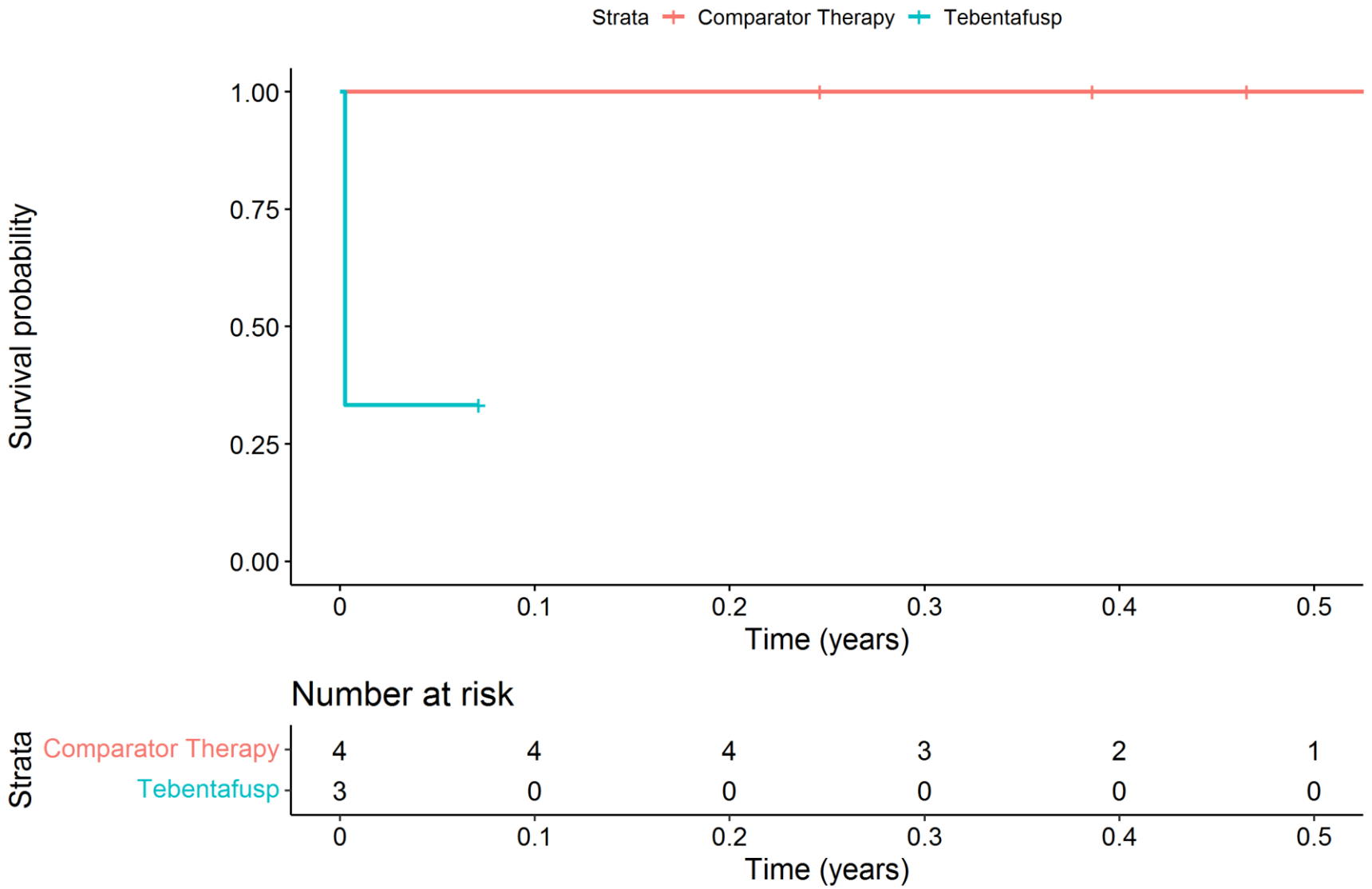
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Ipilimumab



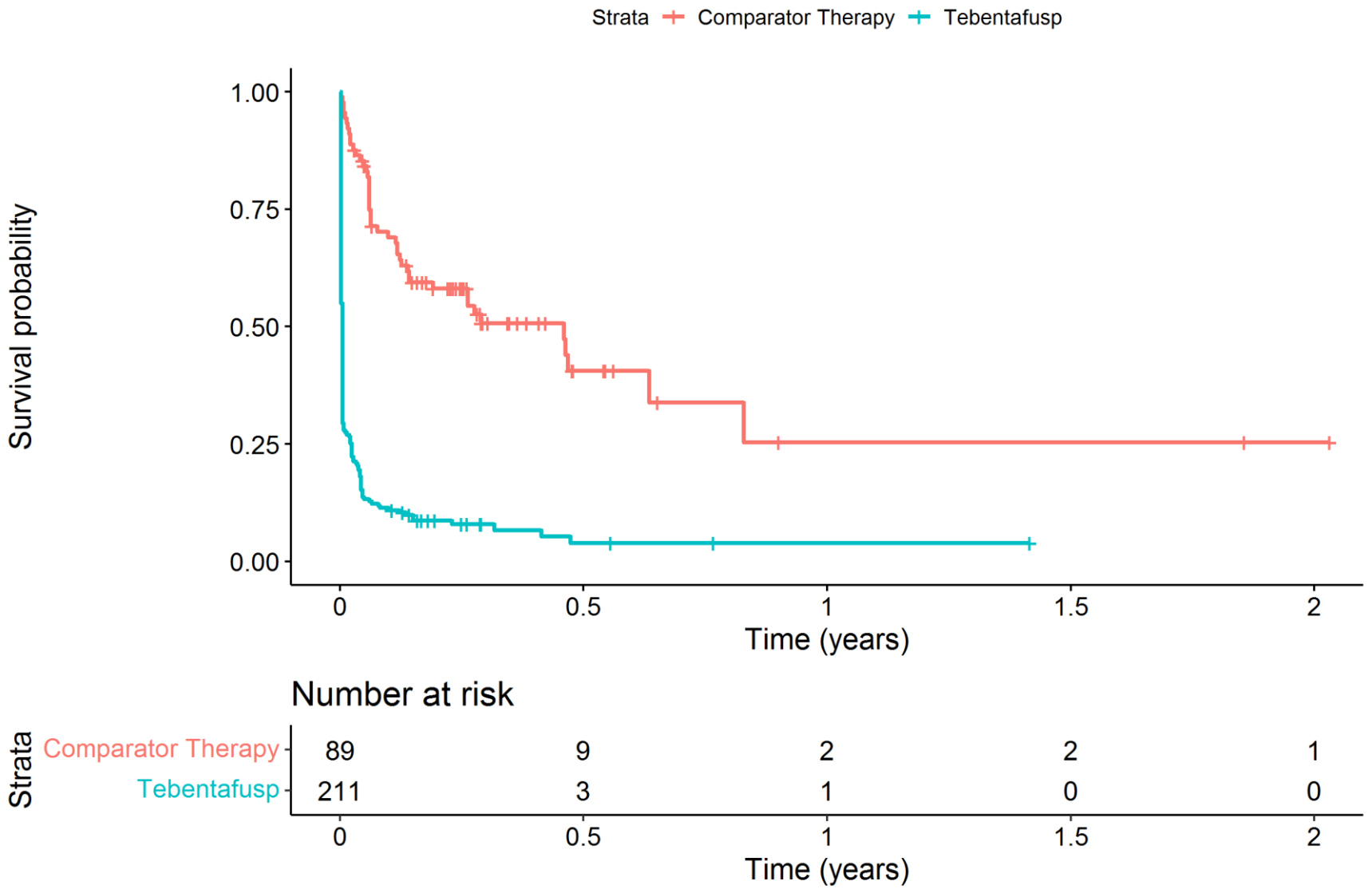
Erkrankungen der Haut und des Unterhautgewebes - Gesamt



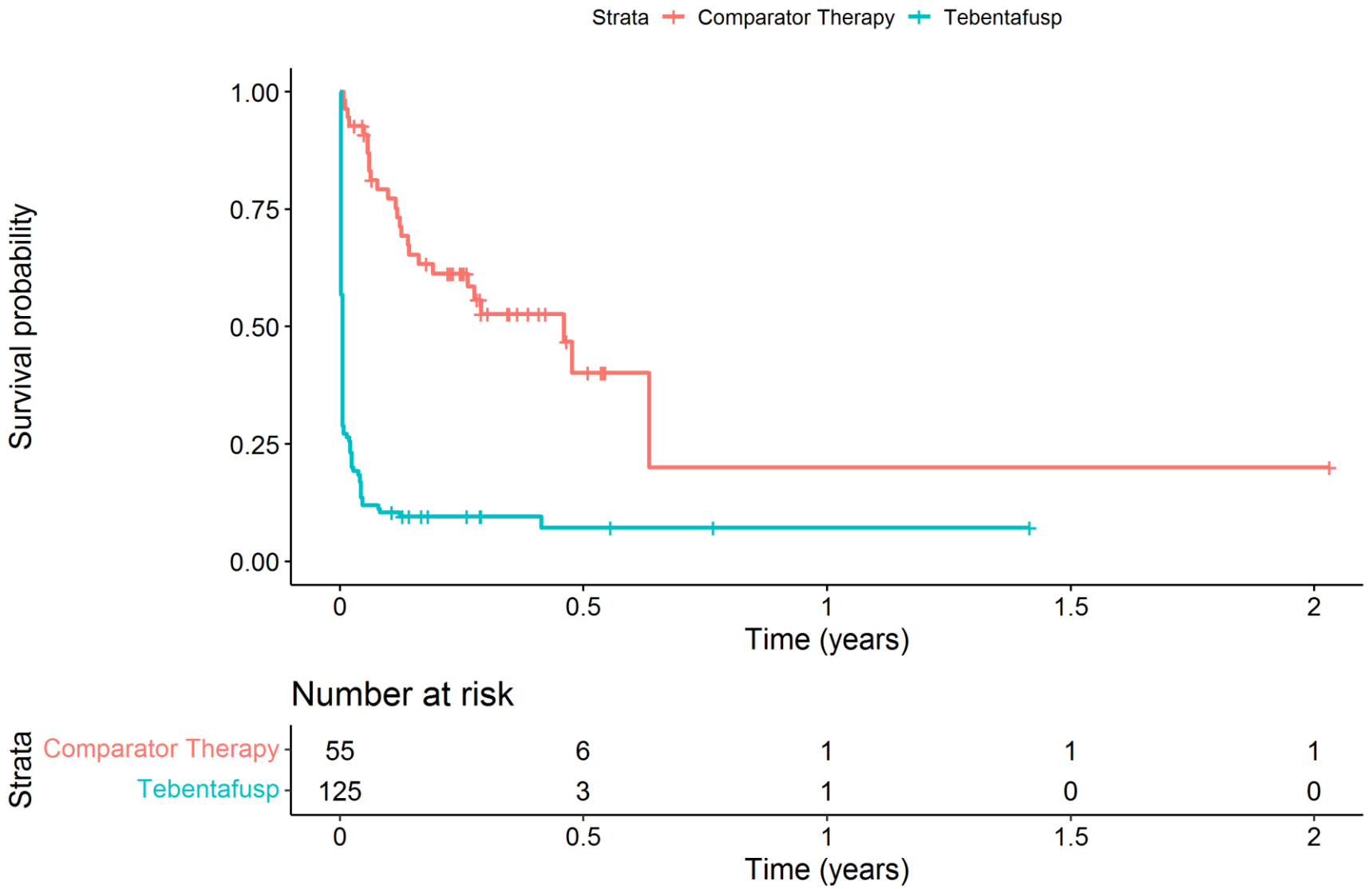
Erkrankungen der Haut und des Unterhautgewebes - Hispanisch



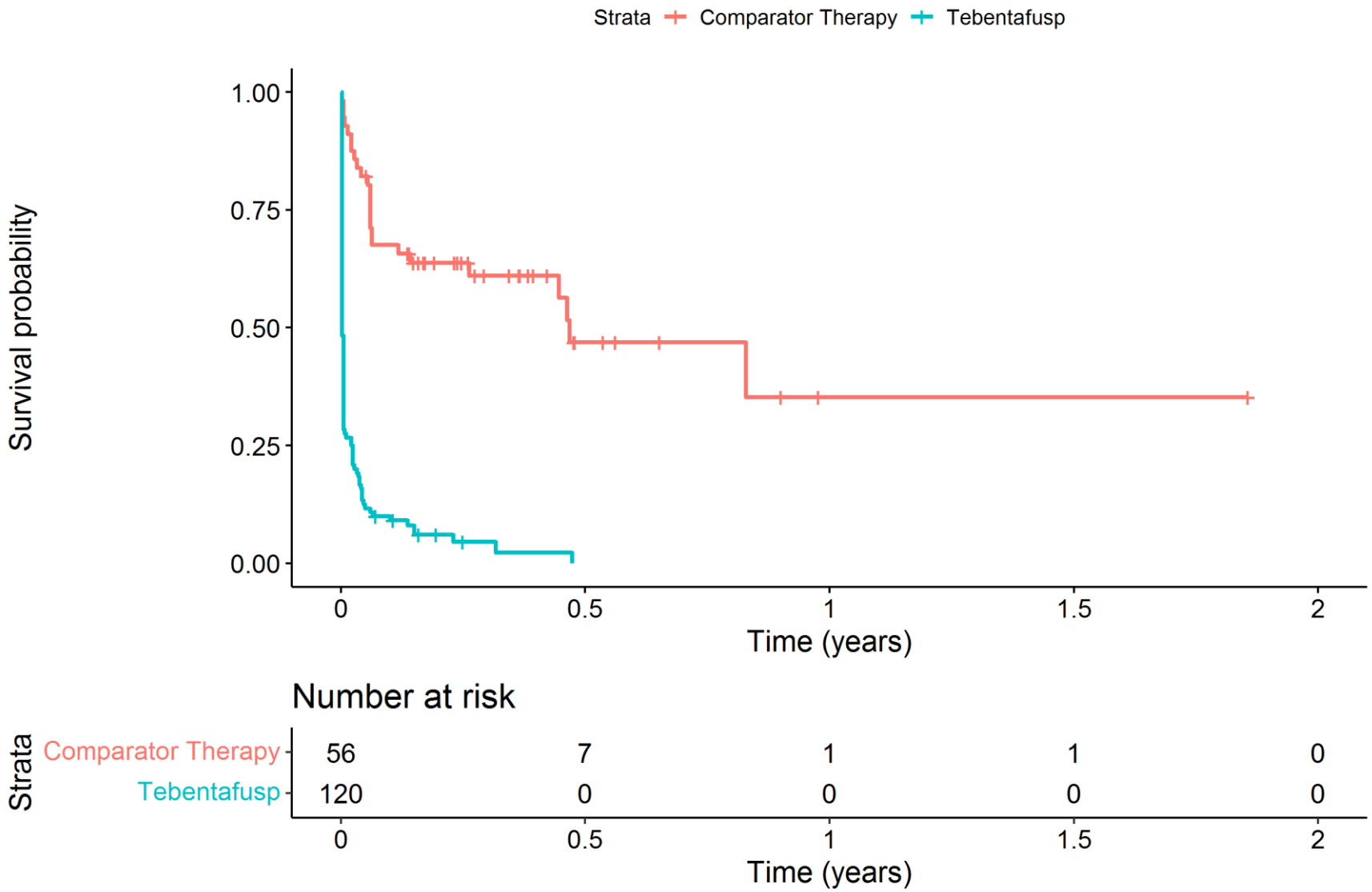
Erkrankungen der Haut und des Unterhautgewebes - Nicht-hispanisch



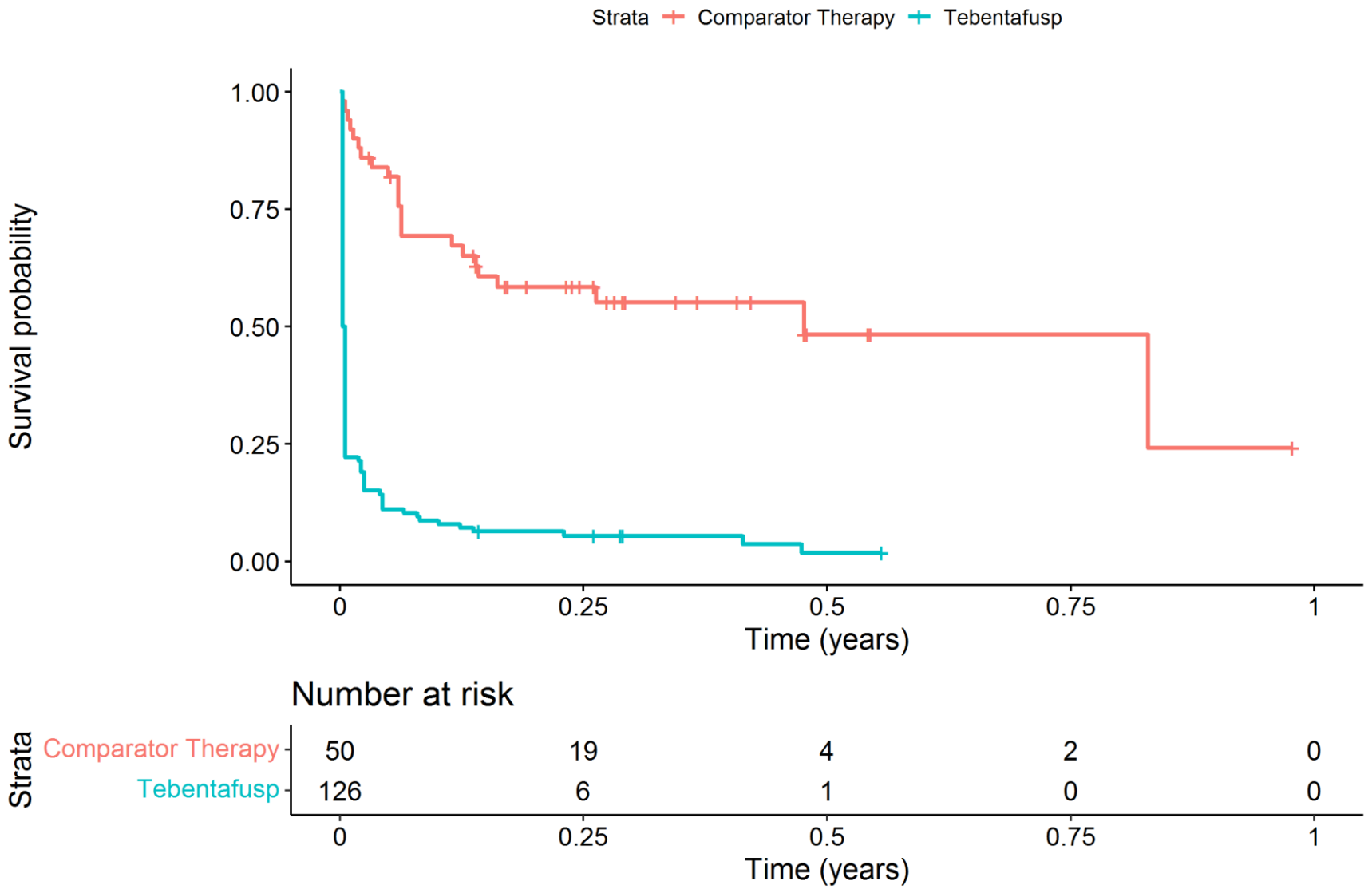
Erkrankungen der Haut und des Unterhautgewebes - Männlich



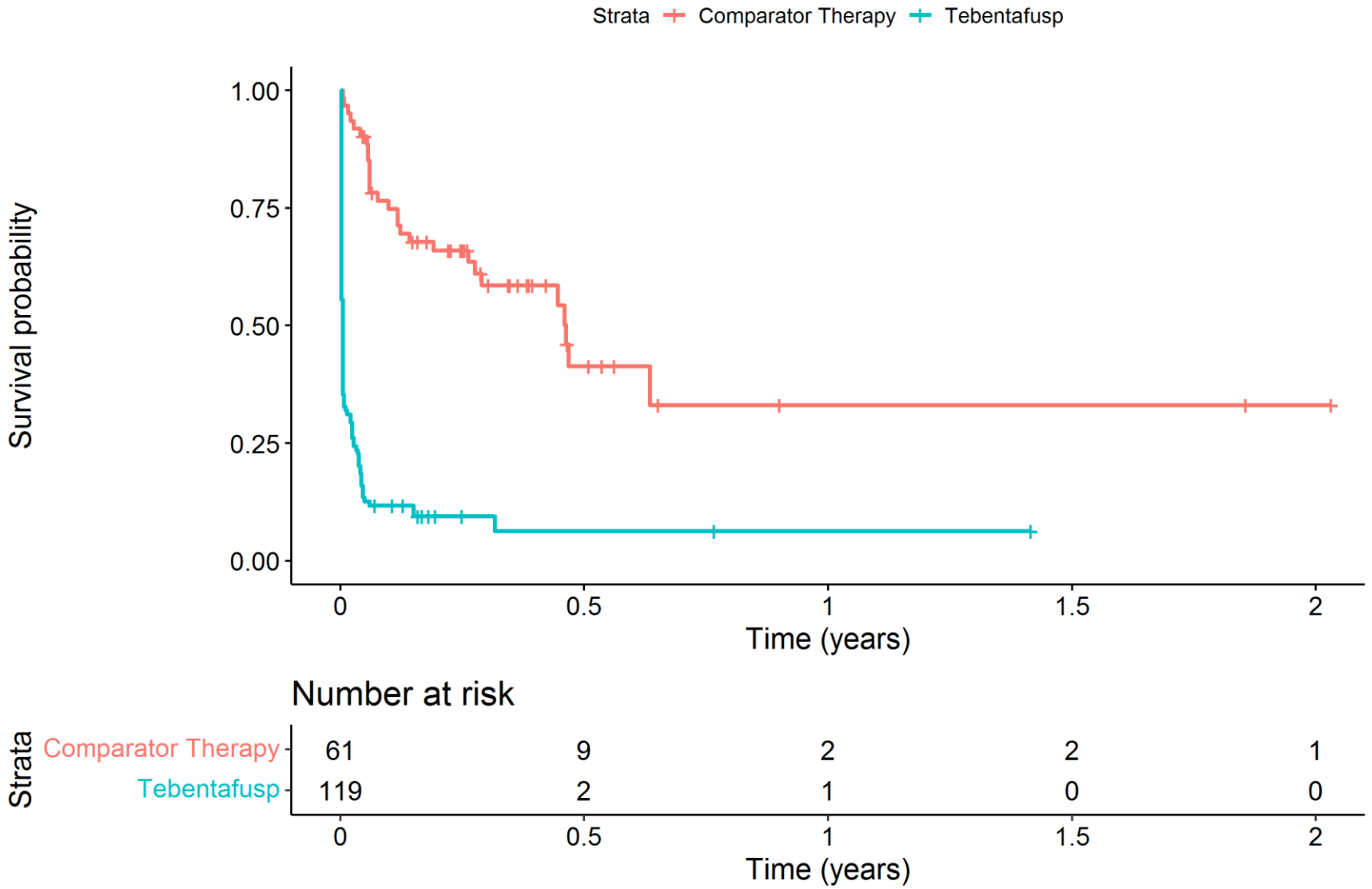
Erkrankungen der Haut und des Unterhautgewebes - Weiblich



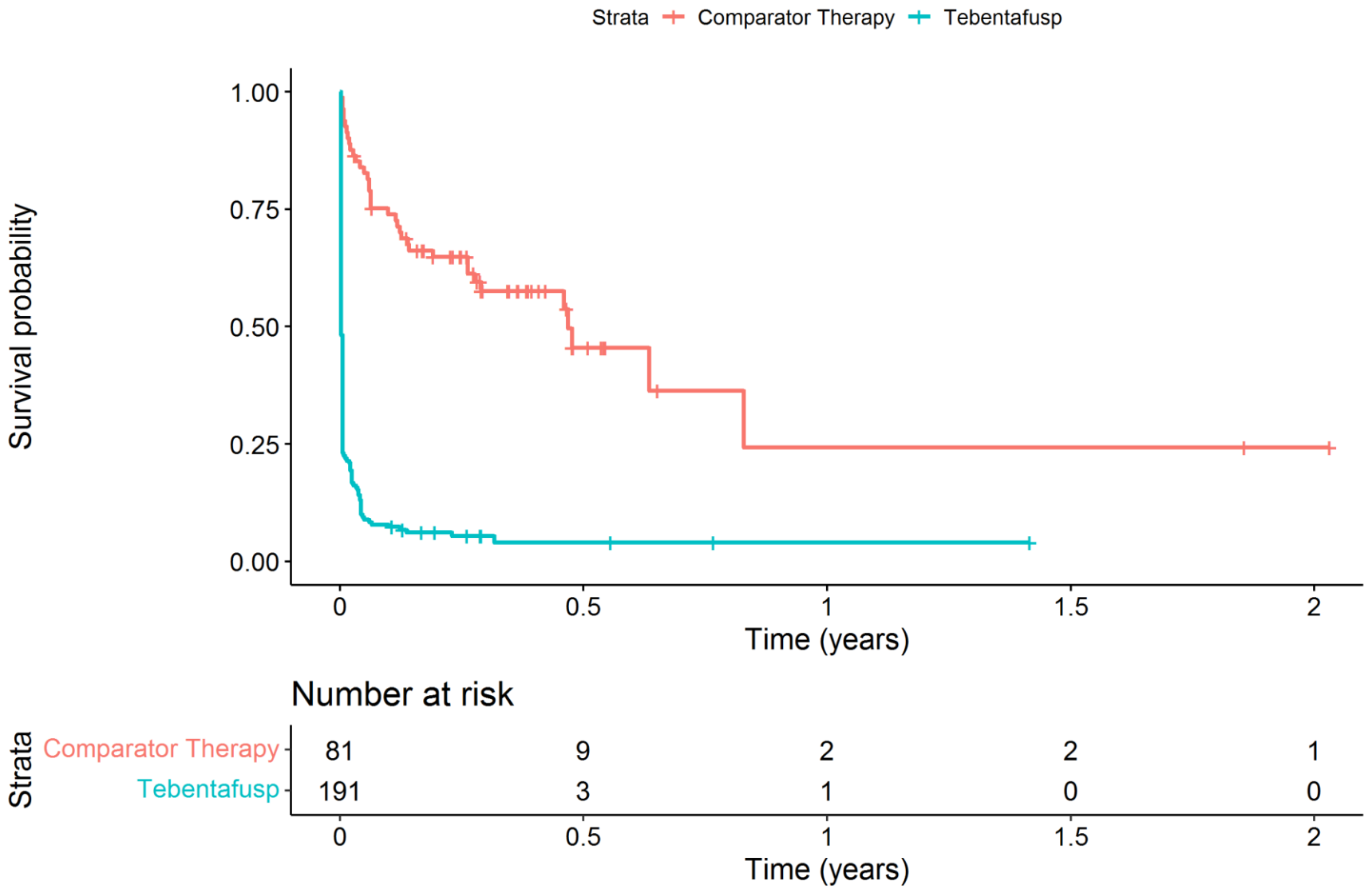
Erkrankungen der Haut und des Unterhautgewebes - <65



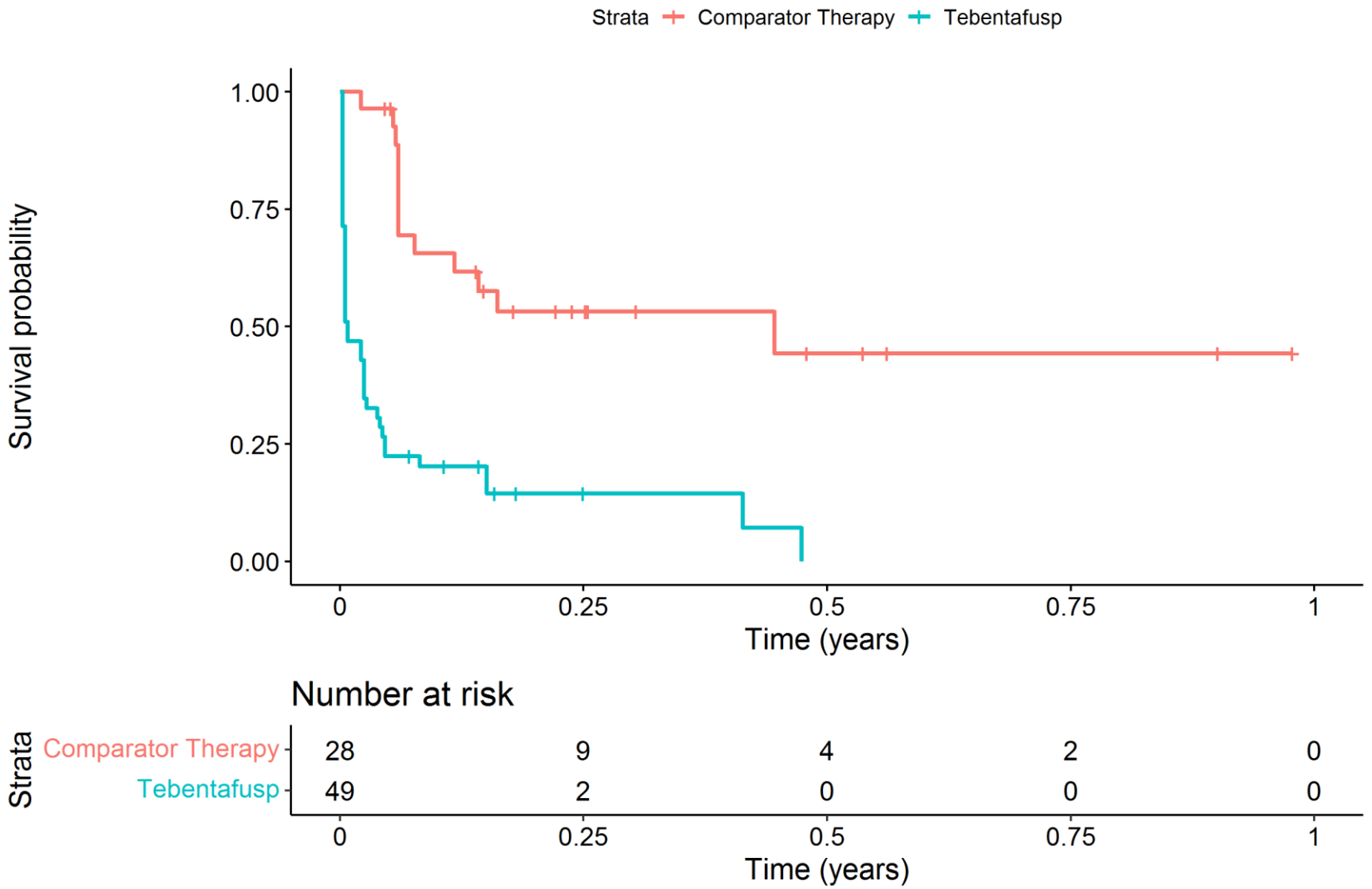
Erkrankungen der Haut und des Unterhautgewebes - ≥65



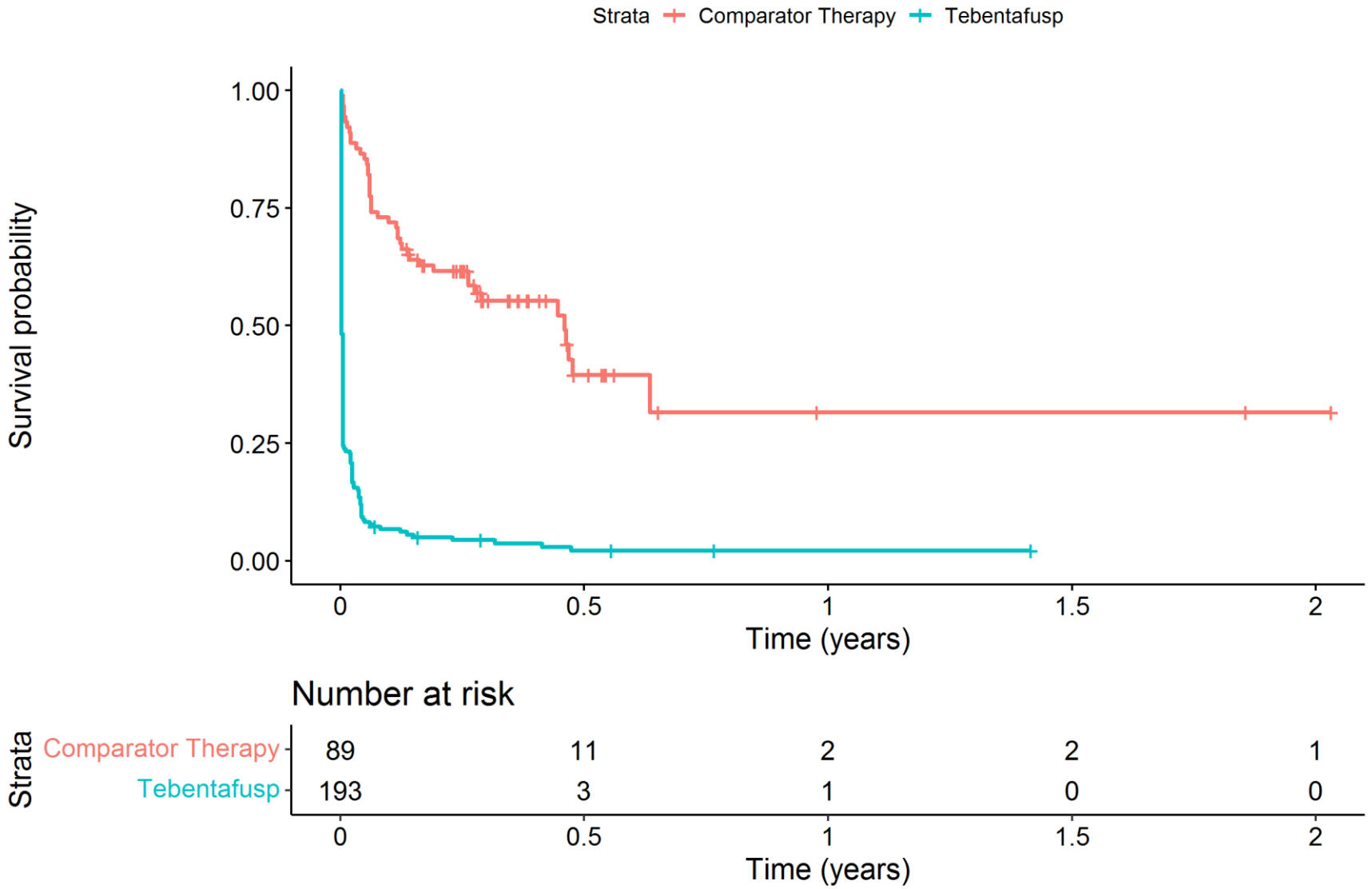
Erkrankungen der Haut und des Unterhautgewebes - ECOG 0



Erkrankungen der Haut und des Unterhautgewebes - ECOG 1



Erkrankungen der Haut und des Unterhautgewebes - ALP ≤ ULN



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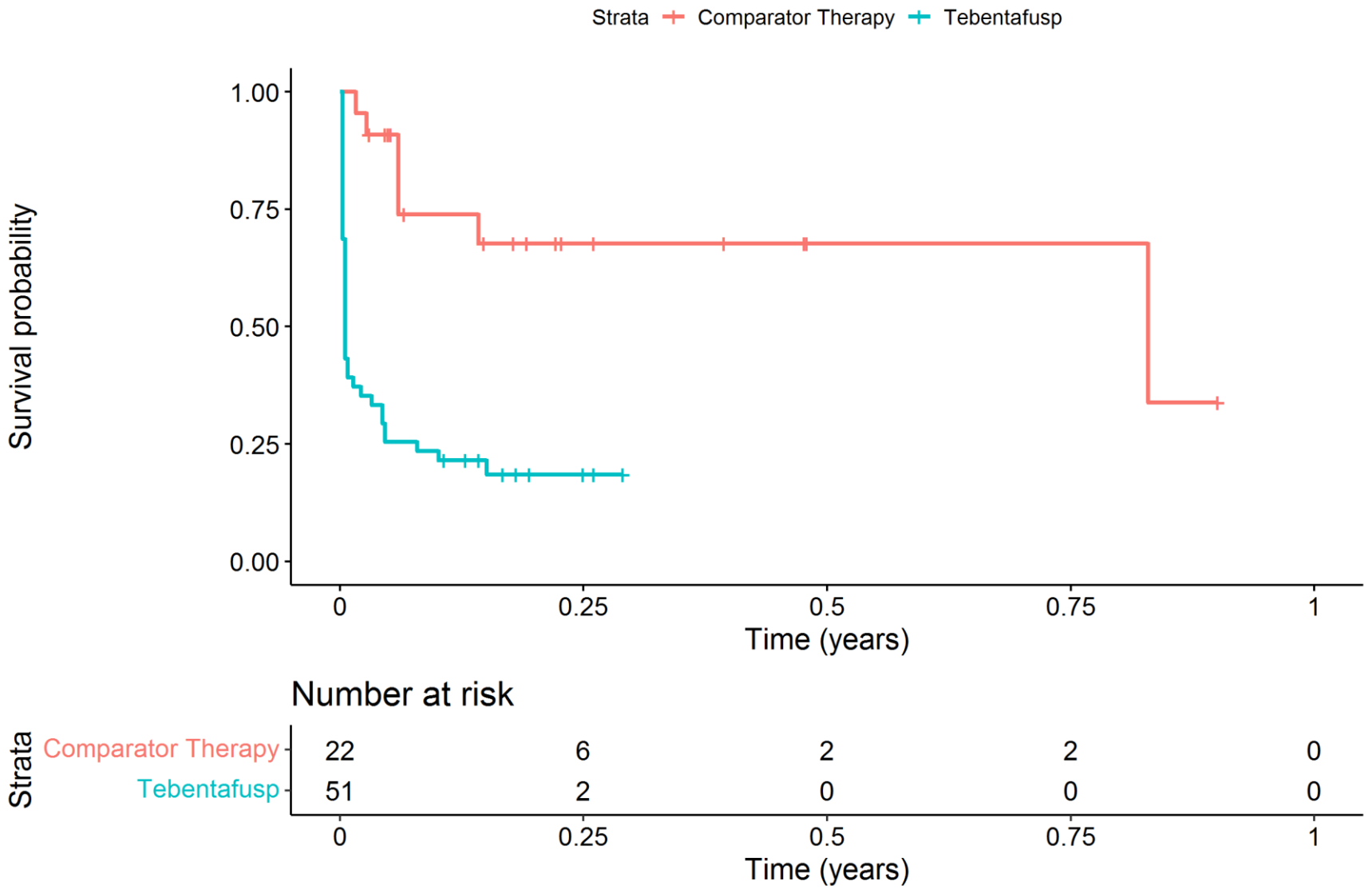

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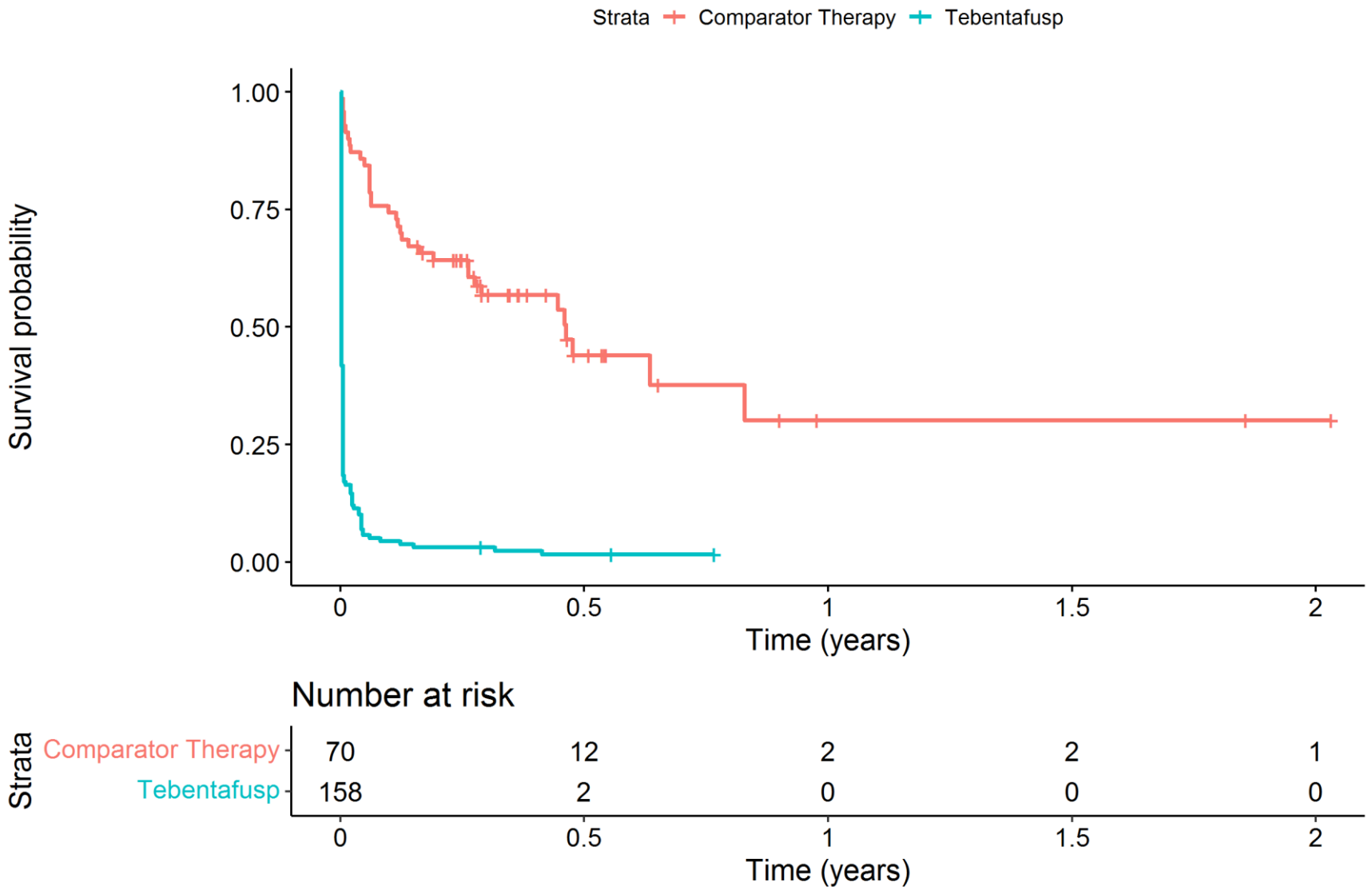
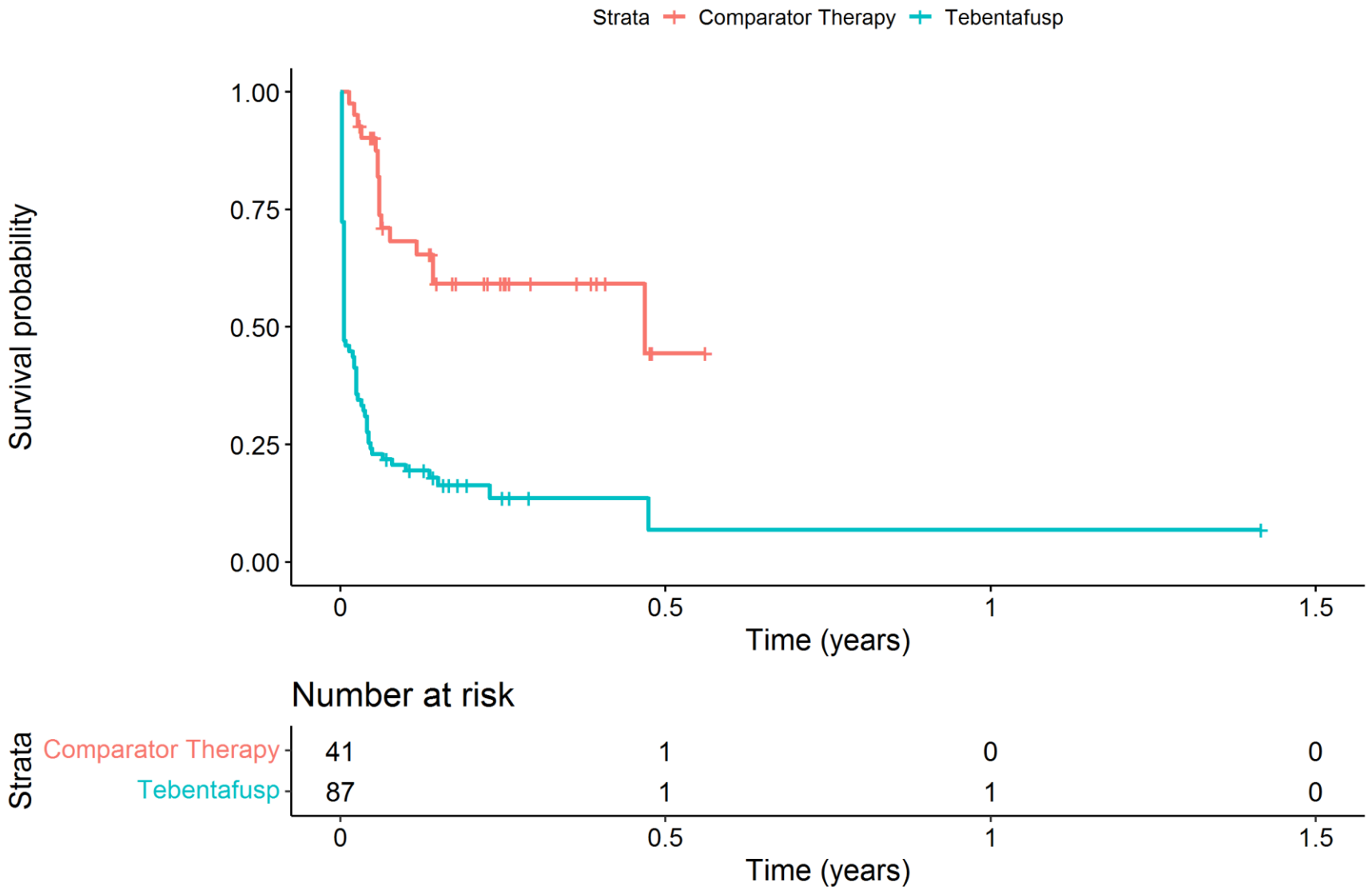
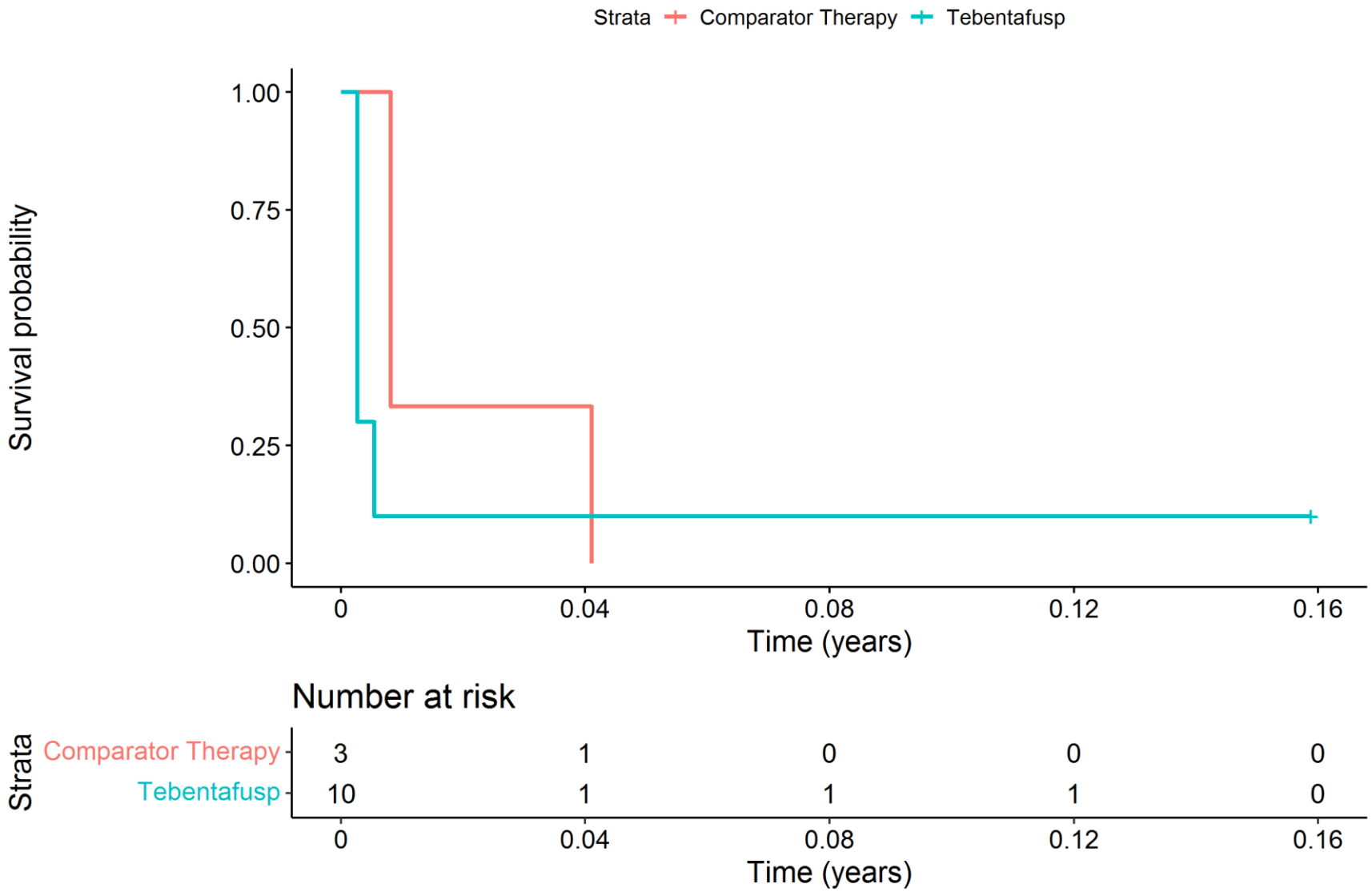


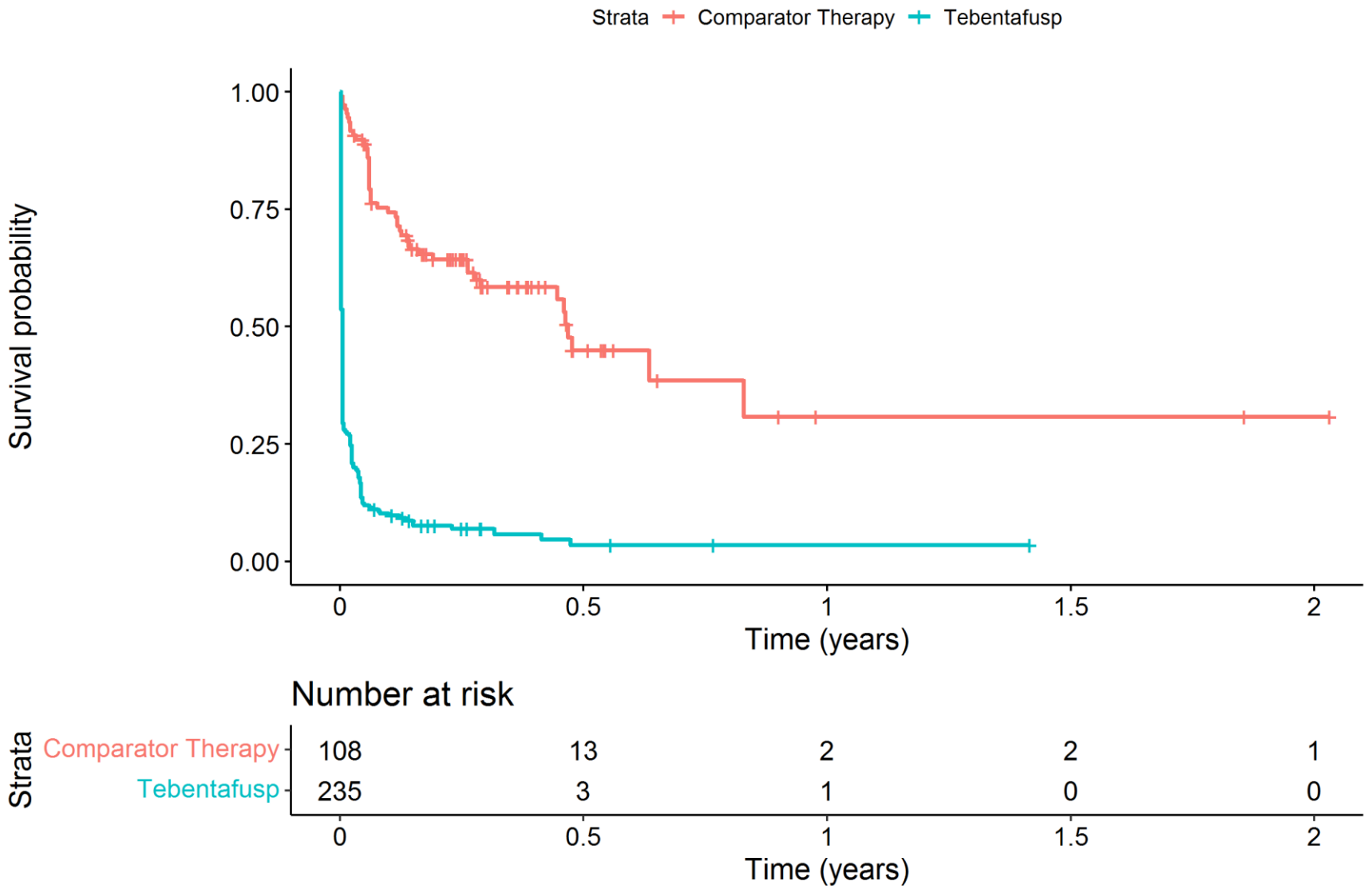
Erkrankungen der Haut und des Unterhautgewebes - LDH > ULN



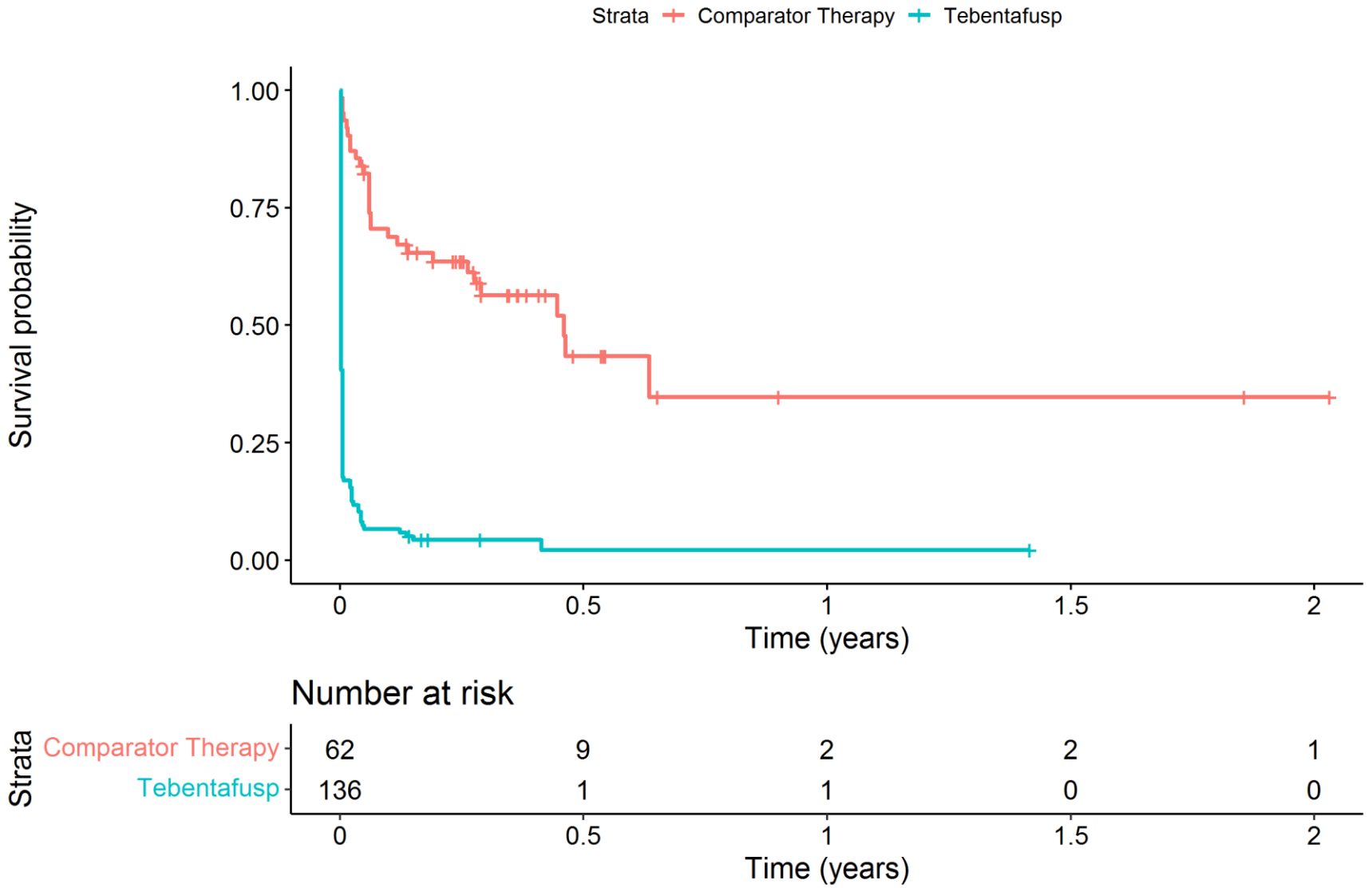
Erkrankungen der Haut und des Unterhautgewebes - Vorherige Therapie adjuvant/neoadjuvant



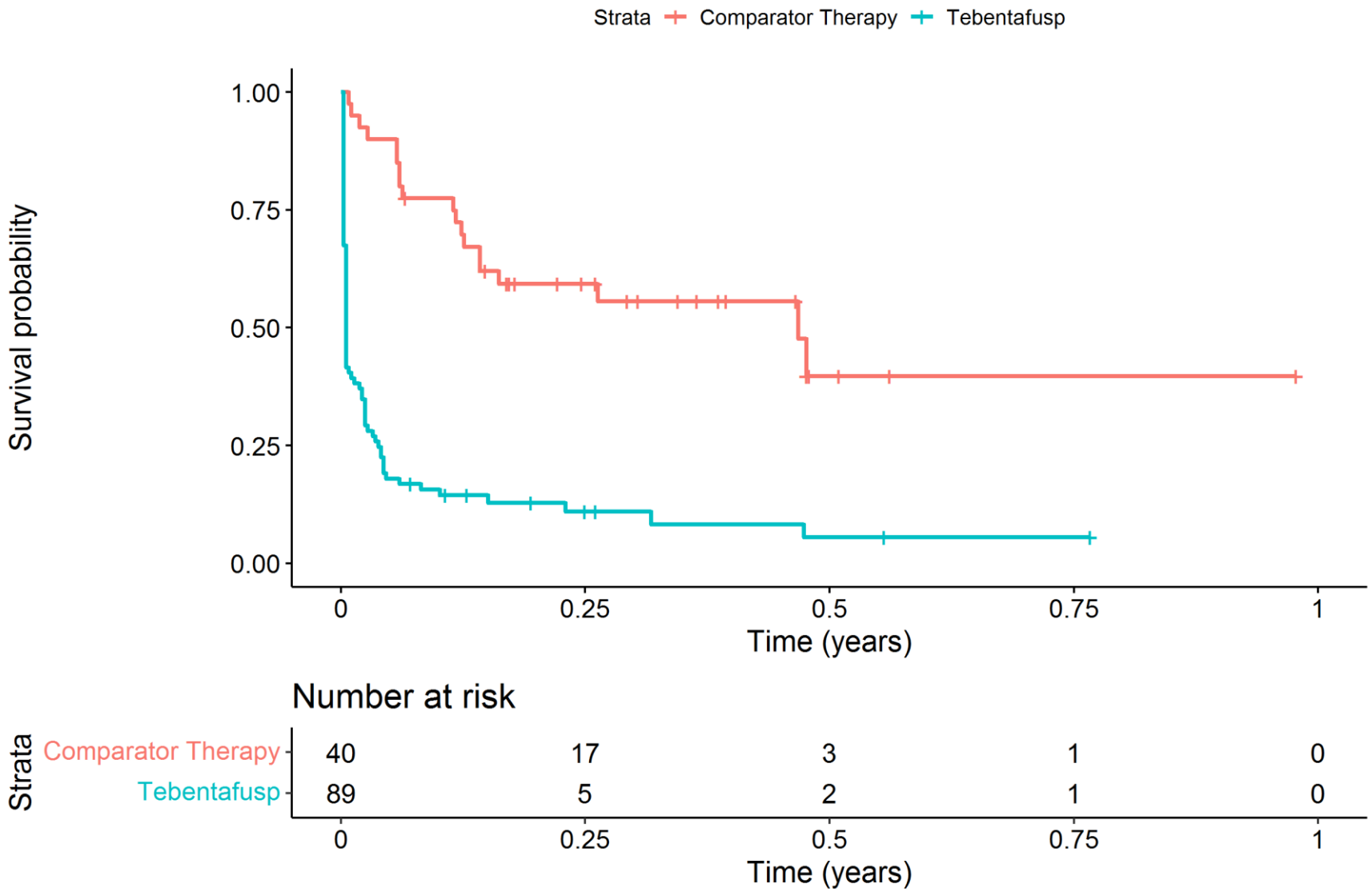
Erkrankungen der Haut und des Unterhautgewebes - Keine vorherige Therapie adjuvant/neoadjuvant



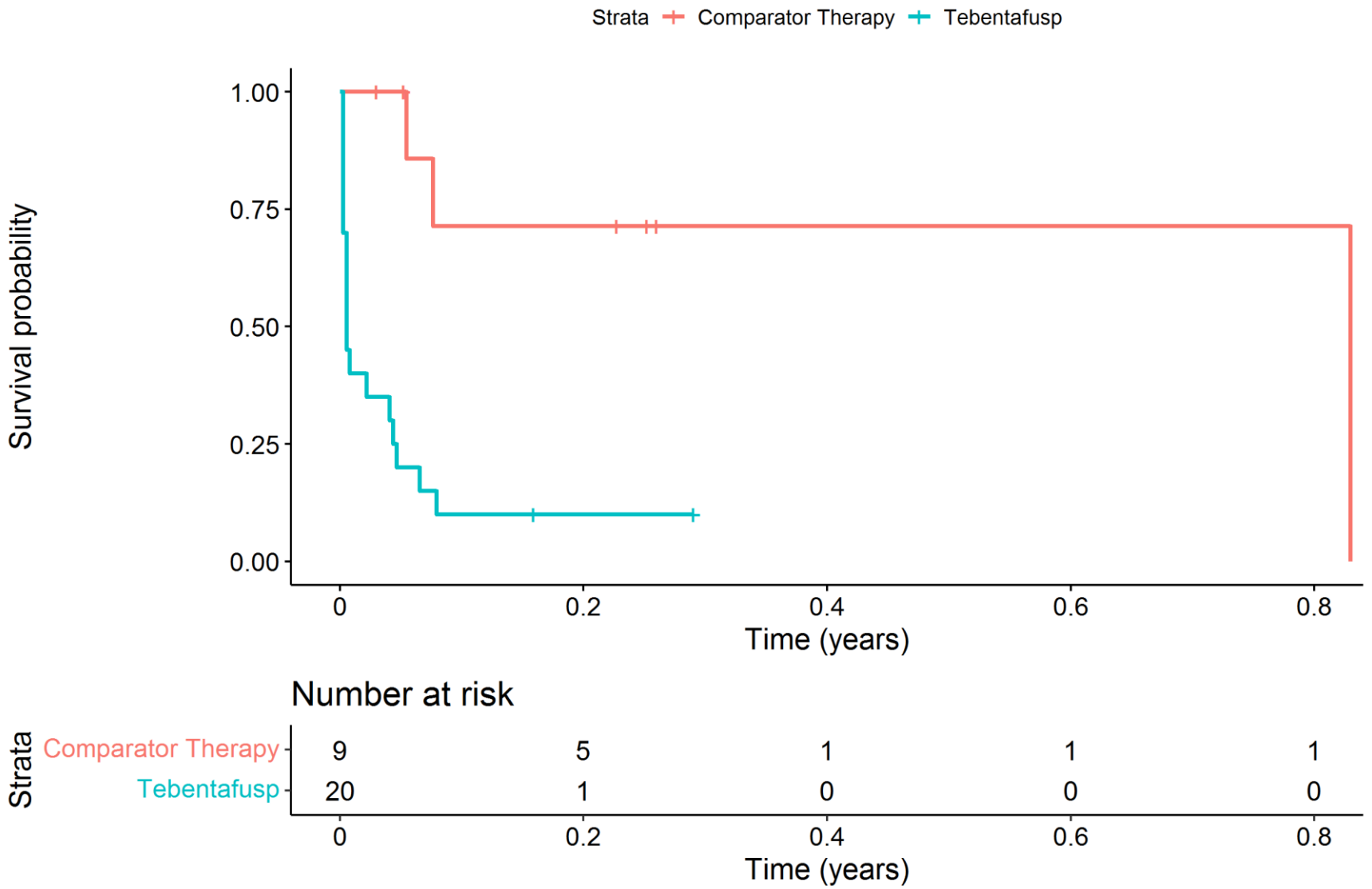
Erkrankungen der Haut und des Unterhautgewebes - Läsion ≤ 3cm



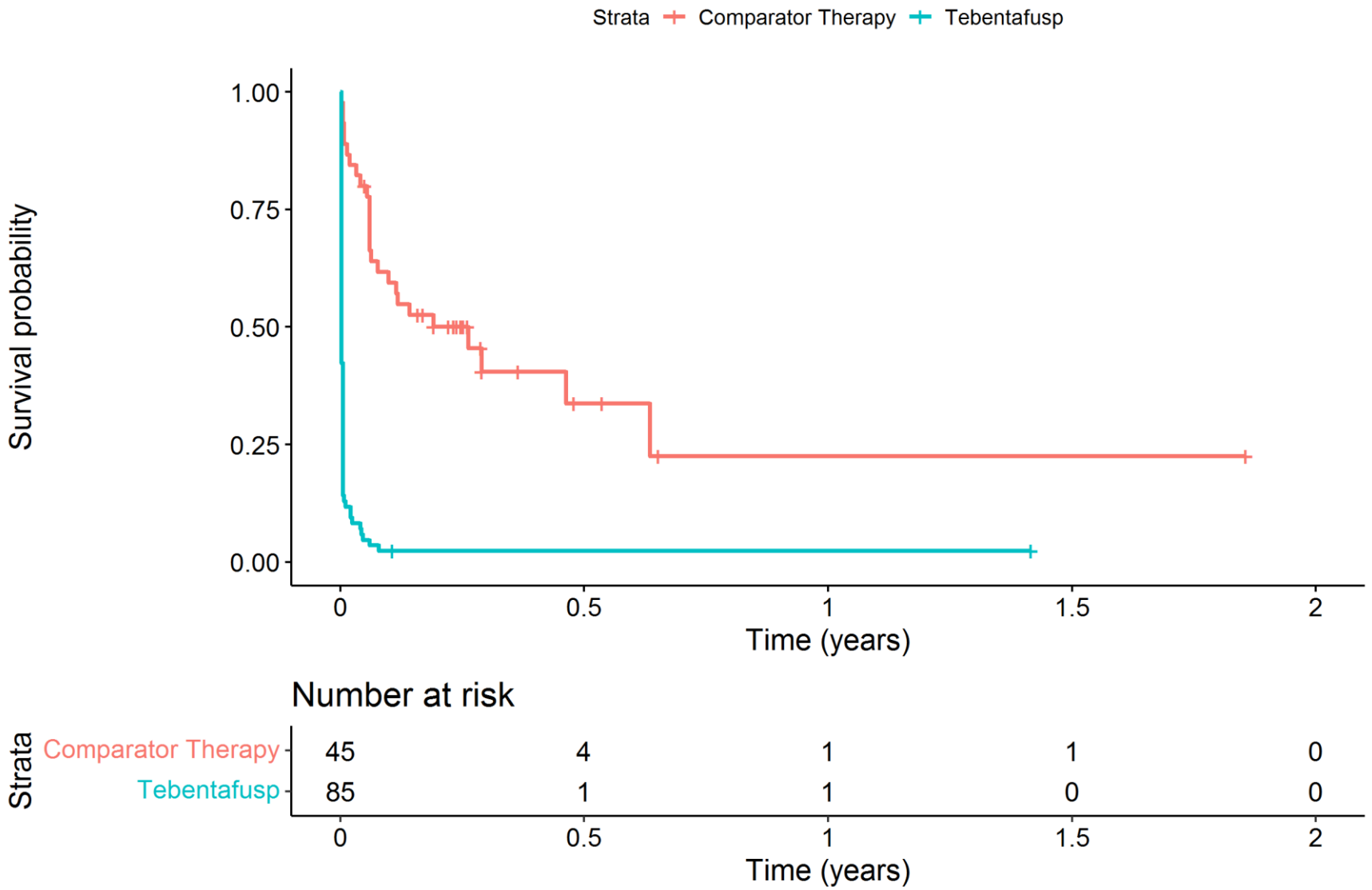
Erkrankungen der Haut und des Unterhautgewebes - Läsion 3,1-8,0 cm



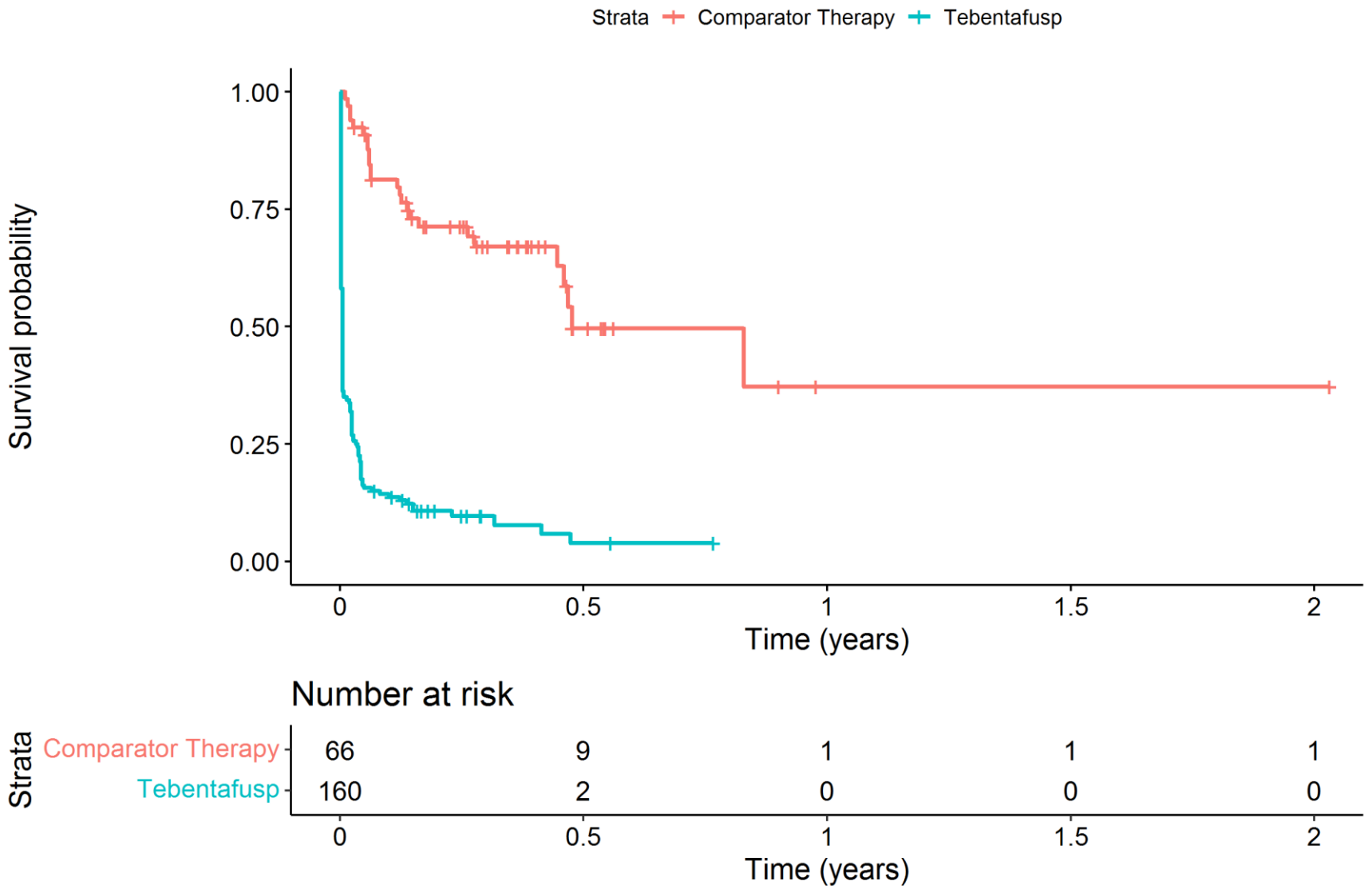
Erkrankungen der Haut und des Unterhautgewebes - Läsion ≥8,1 cm



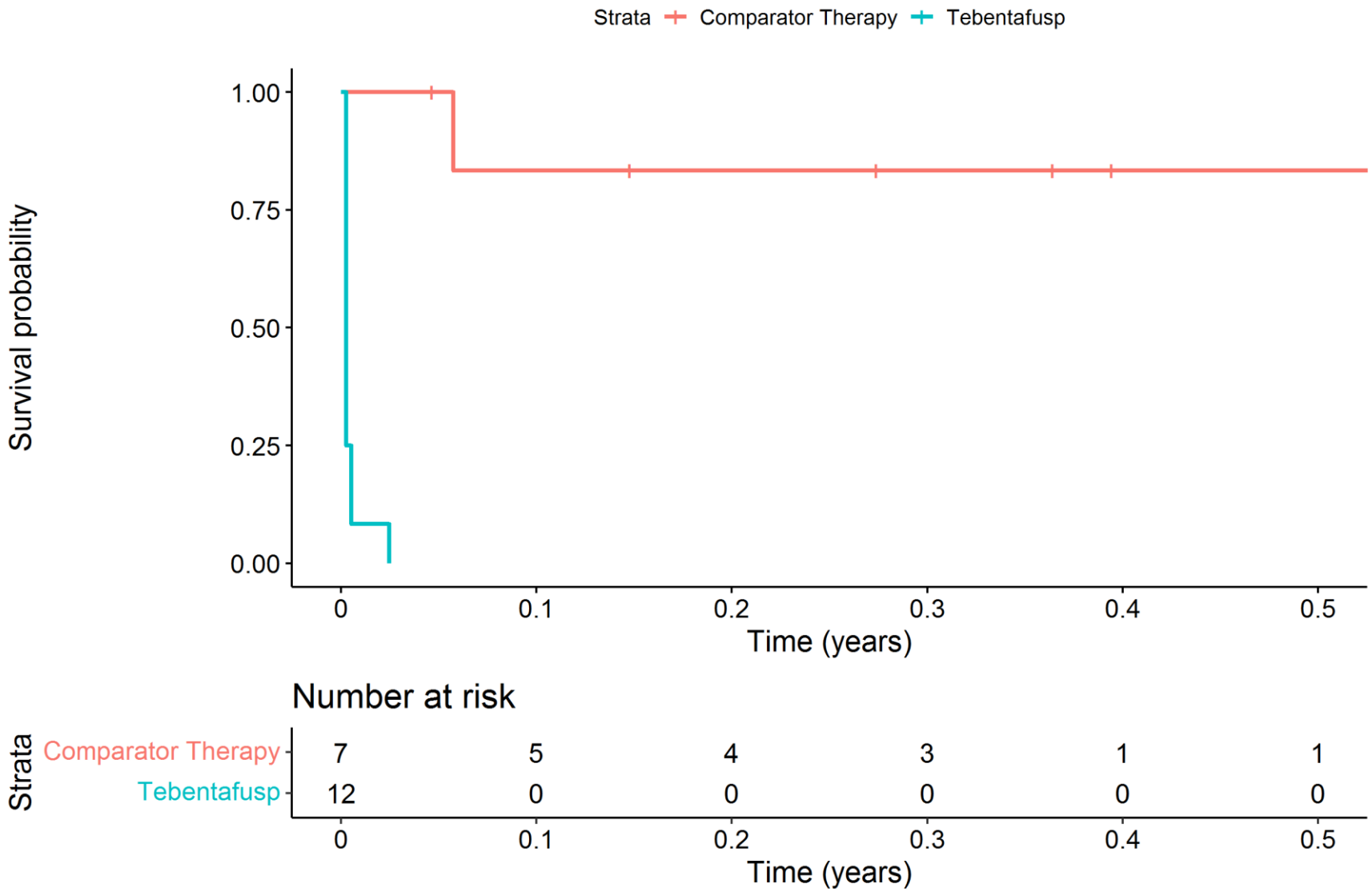
Erkrankungen der Haut und des Unterhautgewebes - Nordamerika



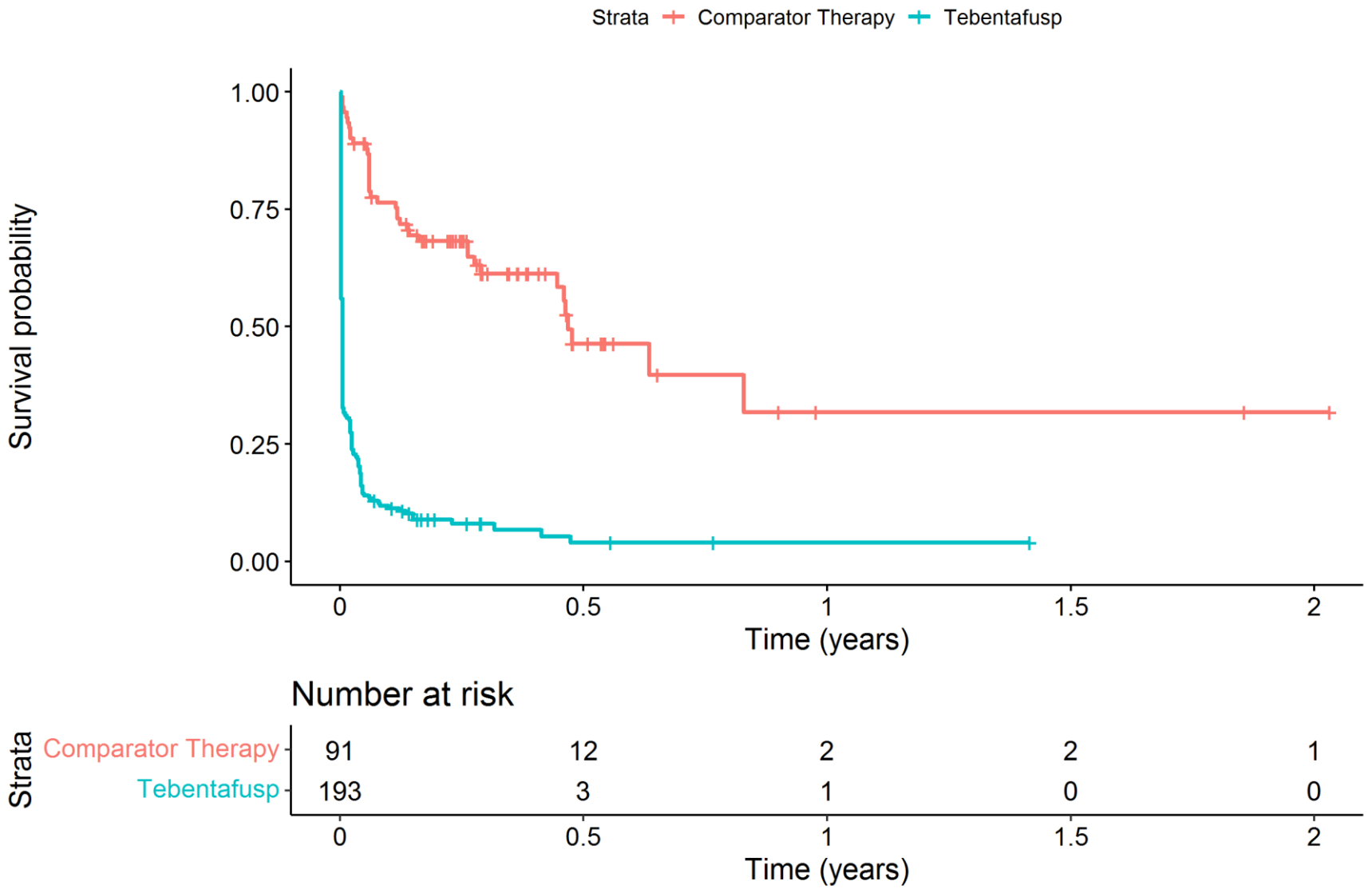
Erkrankungen der Haut und des Unterhautgewebes - Nicht-Nordamerika



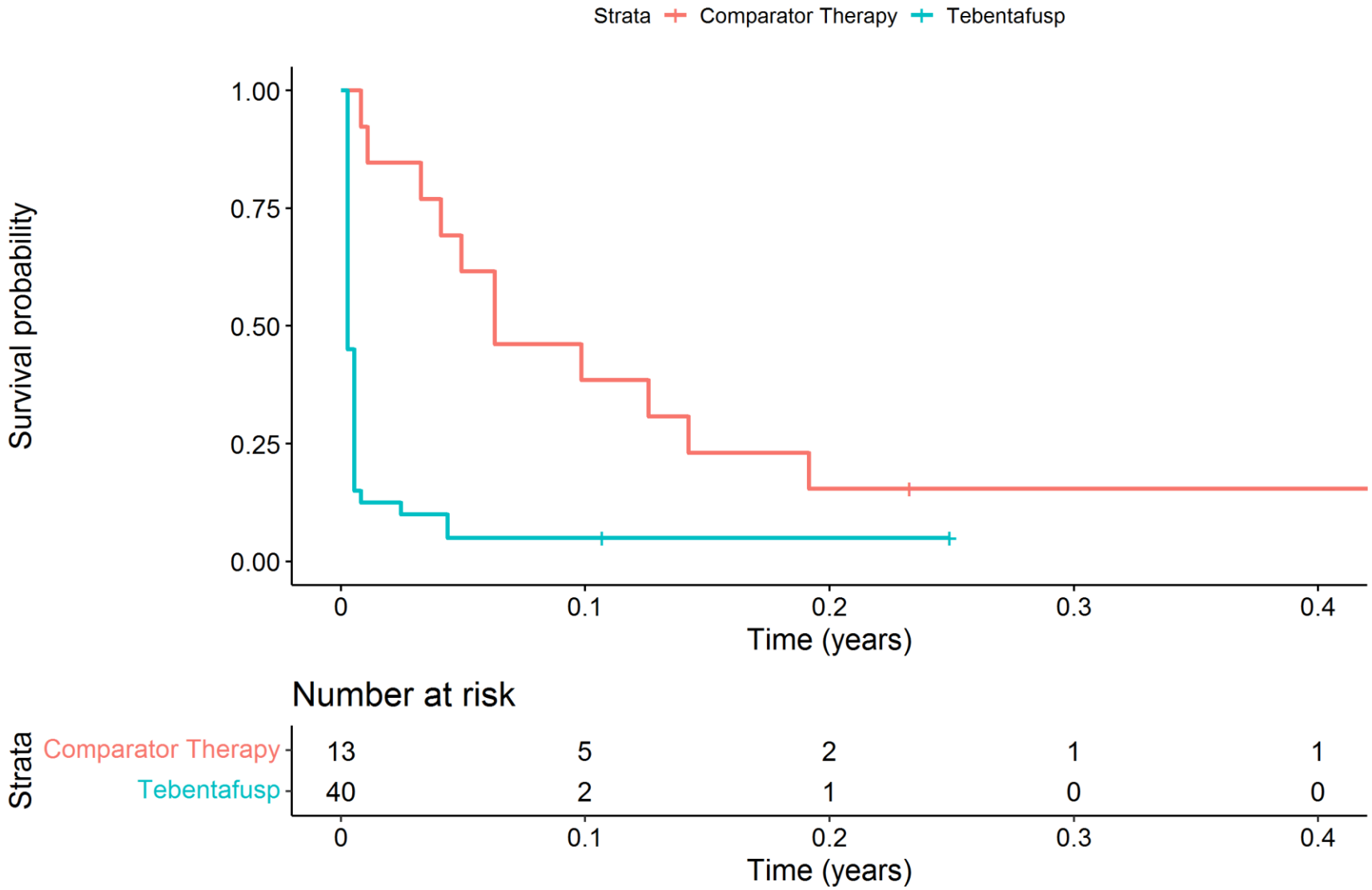
Erkrankungen der Haut und des Unterhautgewebes - Dacarbazin



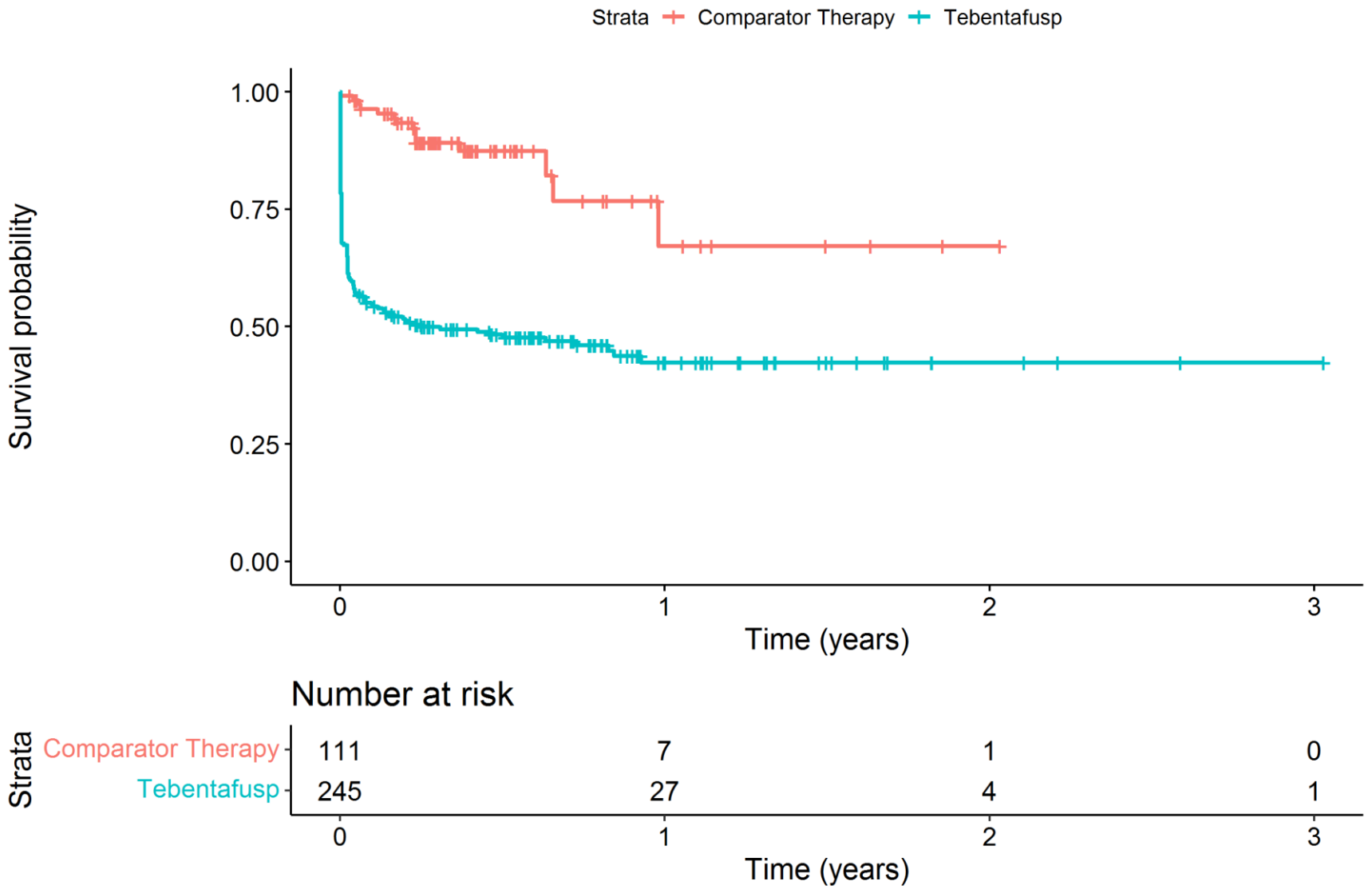
Erkrankungen der Haut und des Unterhautgewebes - Pembrolizumab



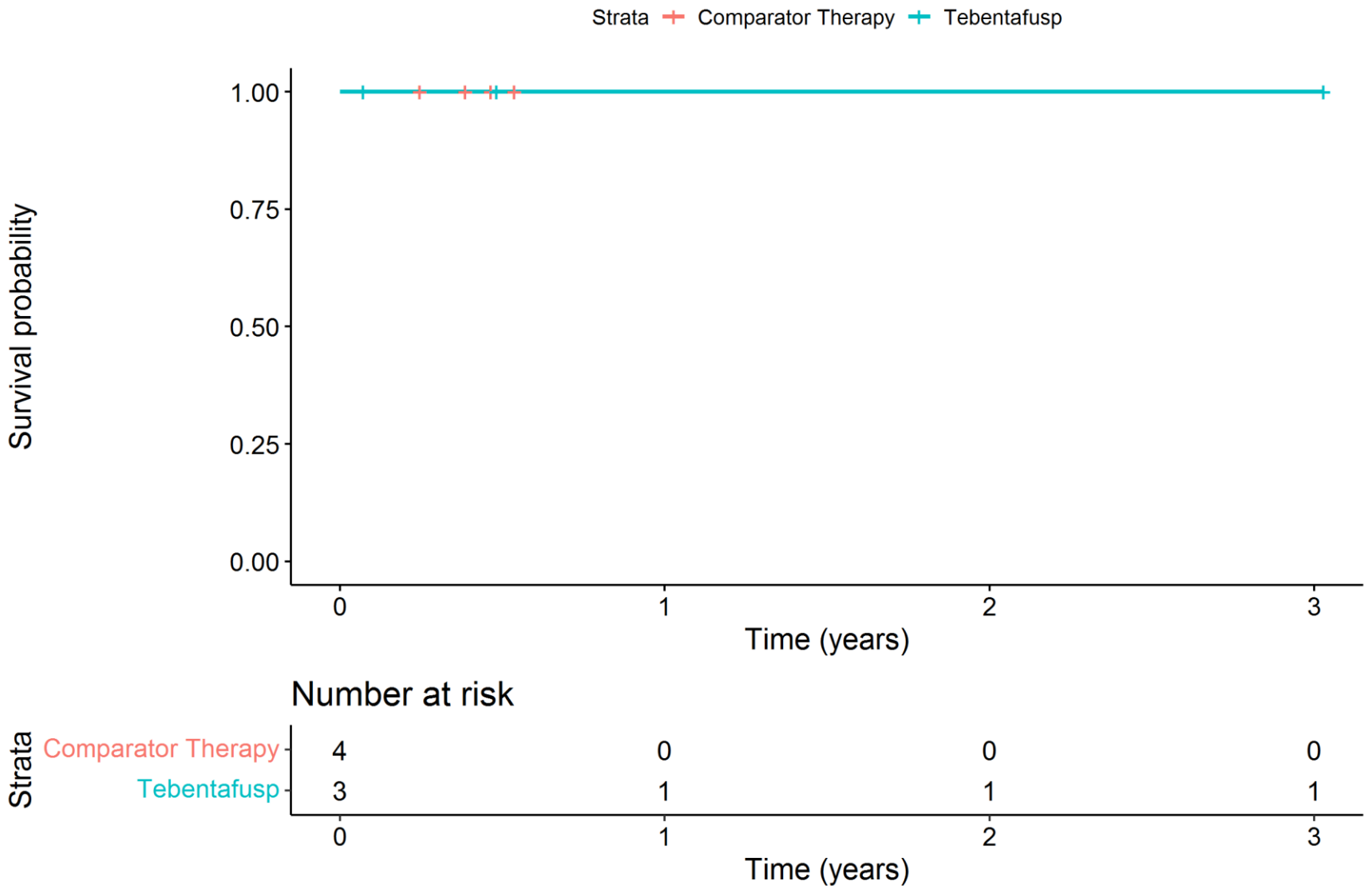
Erkrankungen der Haut und des Unterhautgewebes - Ipilimumab



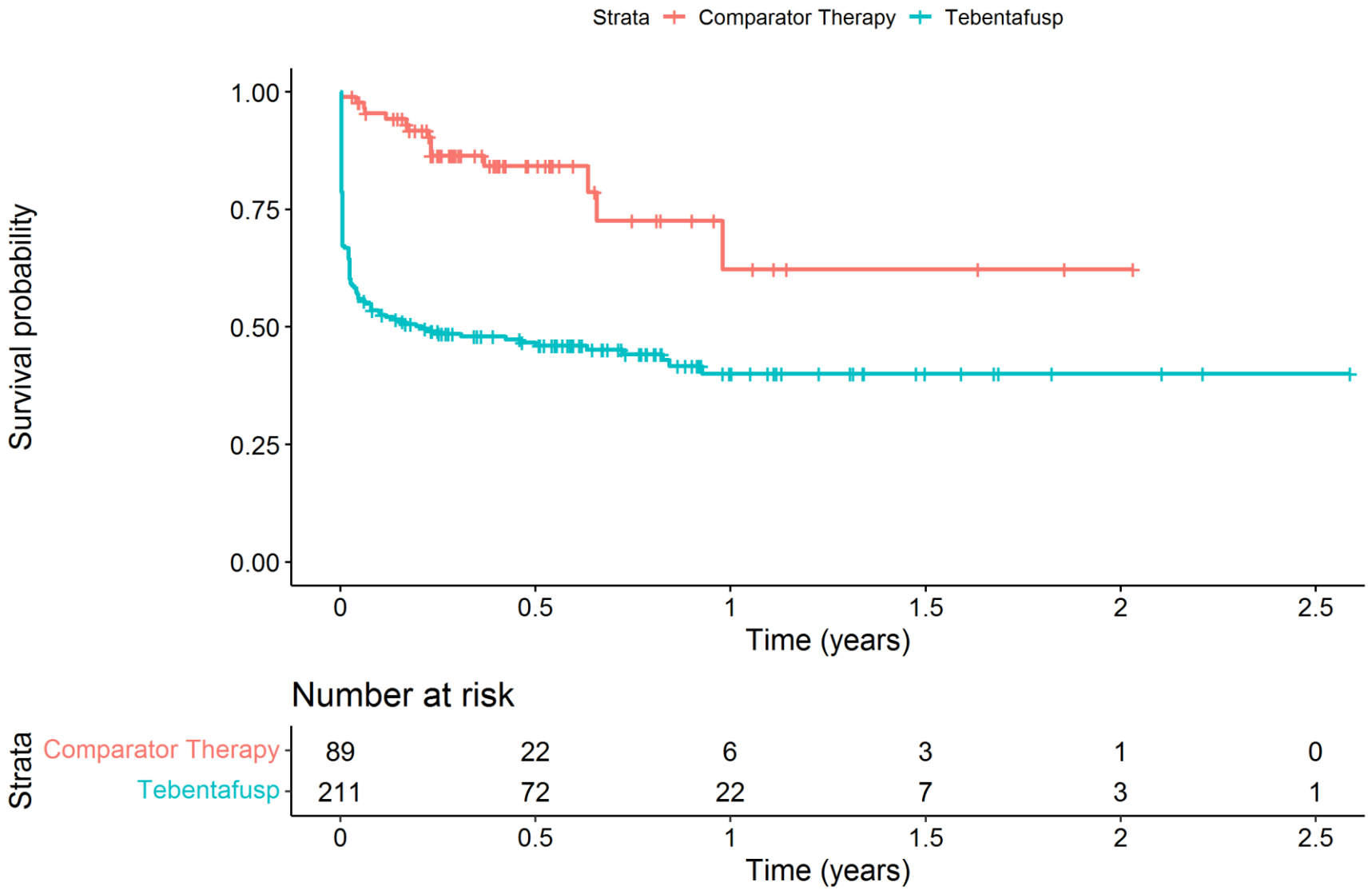
Gefäßerkrankungen - Gesamt



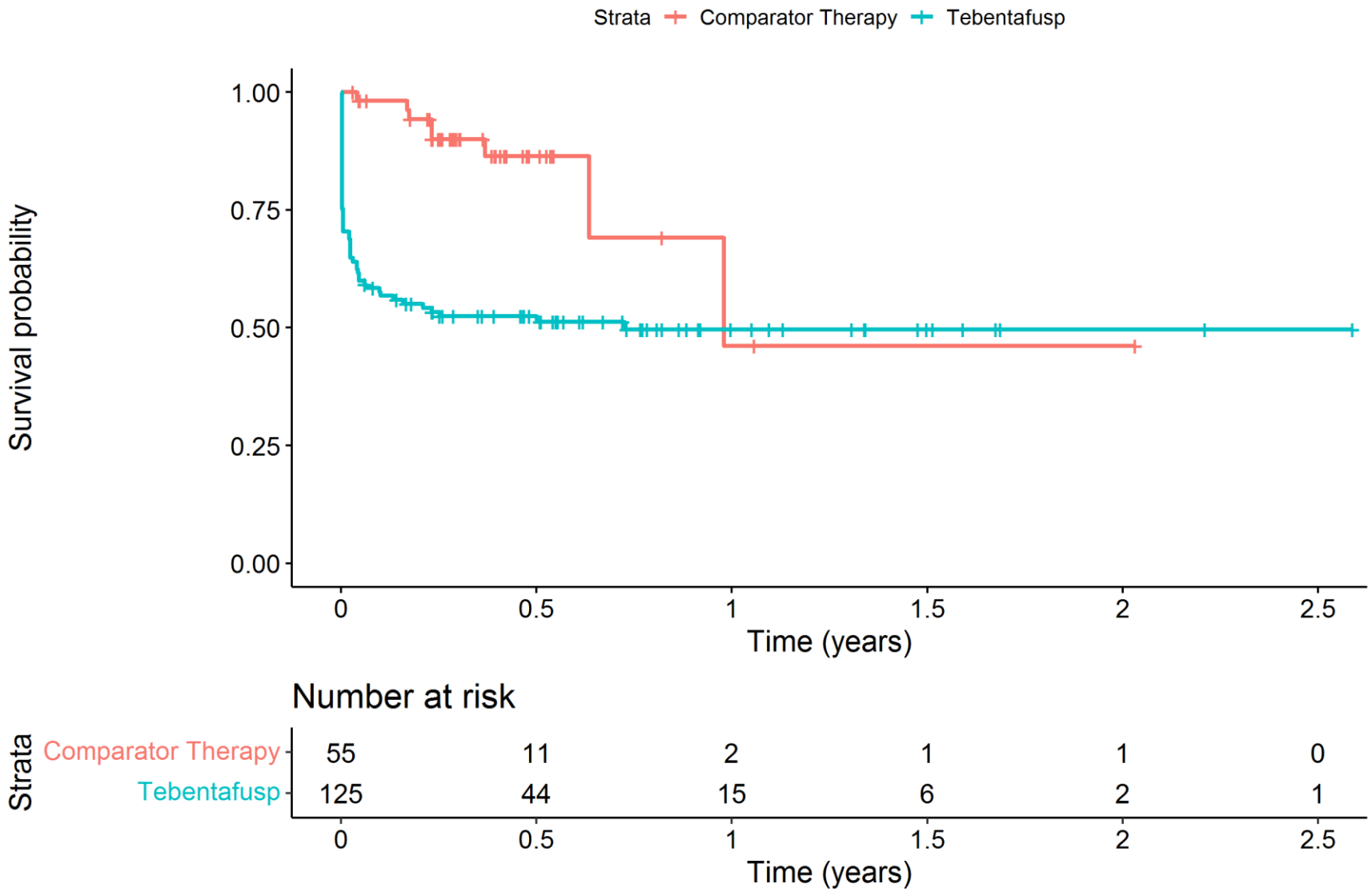
Gefäßerkrankungen - Hispanisch



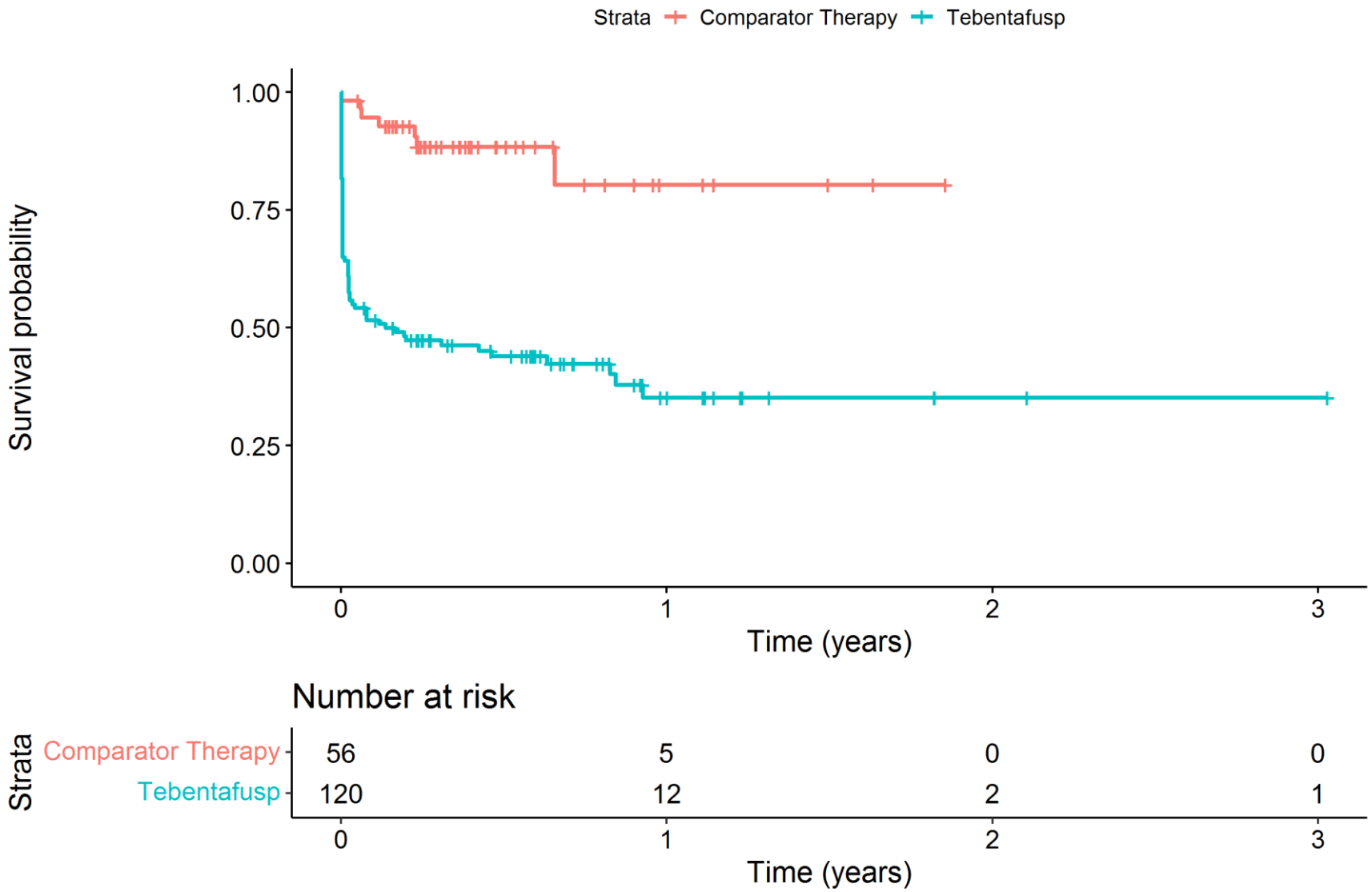
Gefäßerkrankungen - Nicht-hispanisch



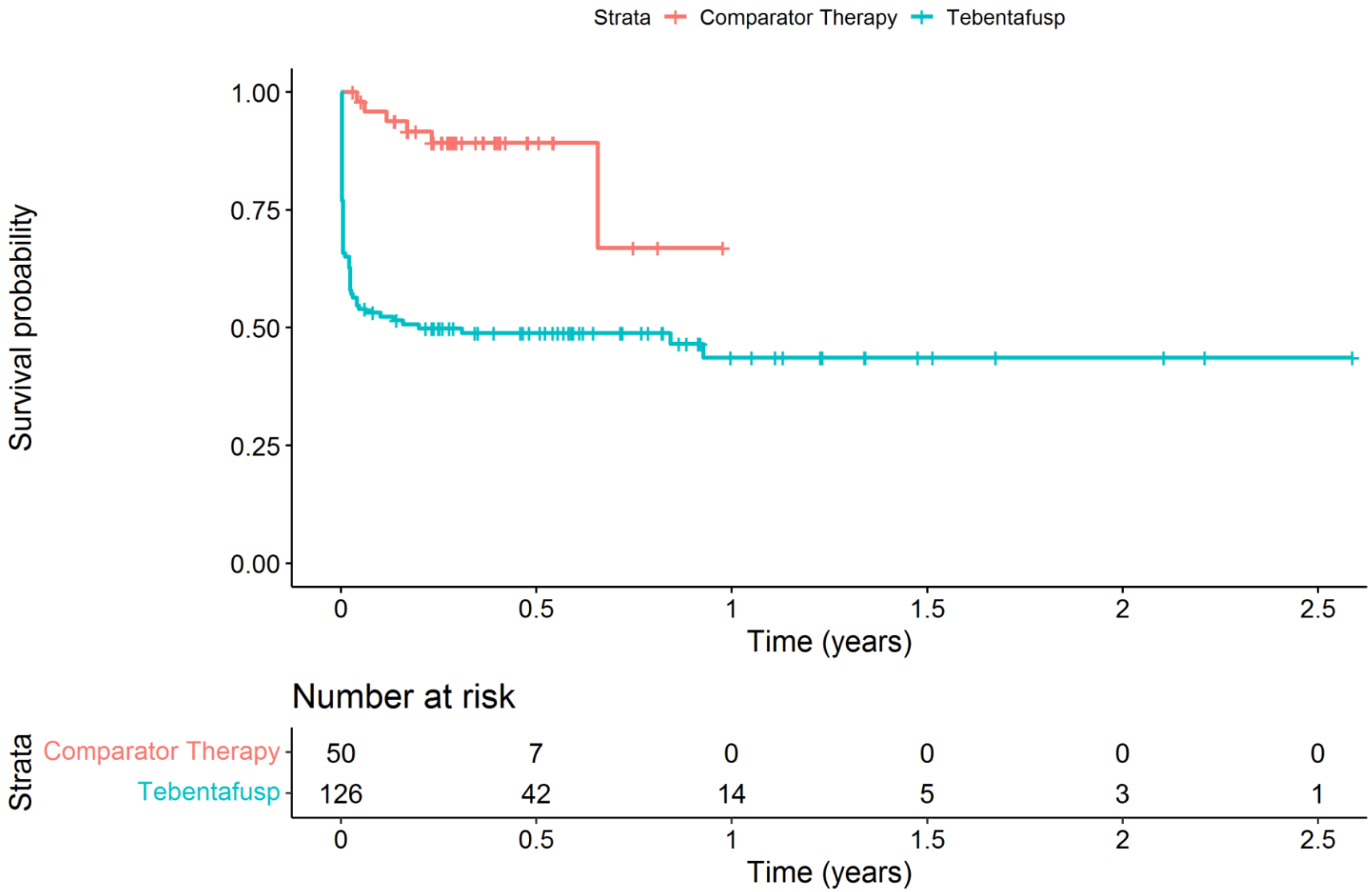
Gefäßerkrankungen - Männlich



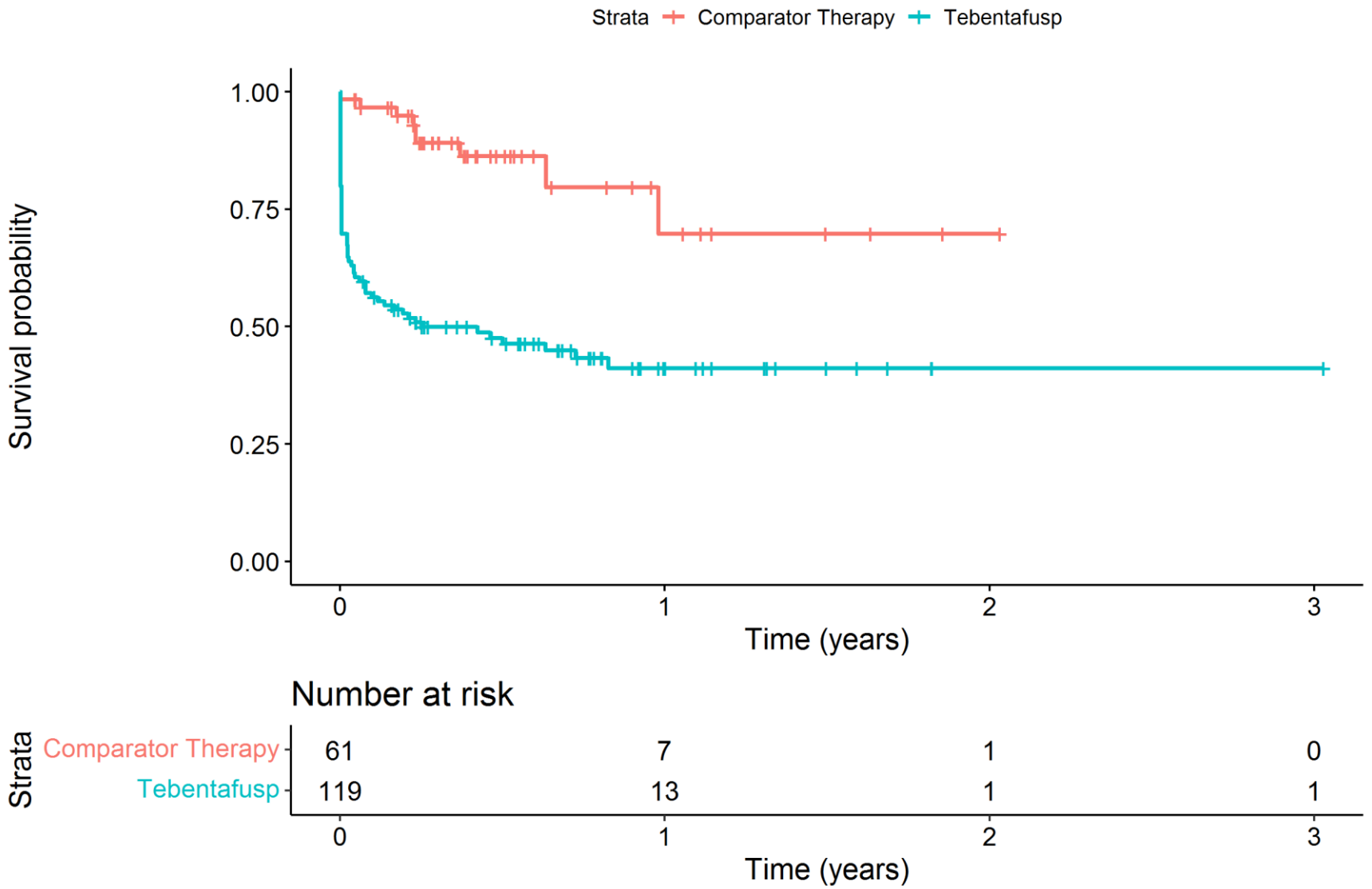
Gefäßerkrankungen - Weiblich



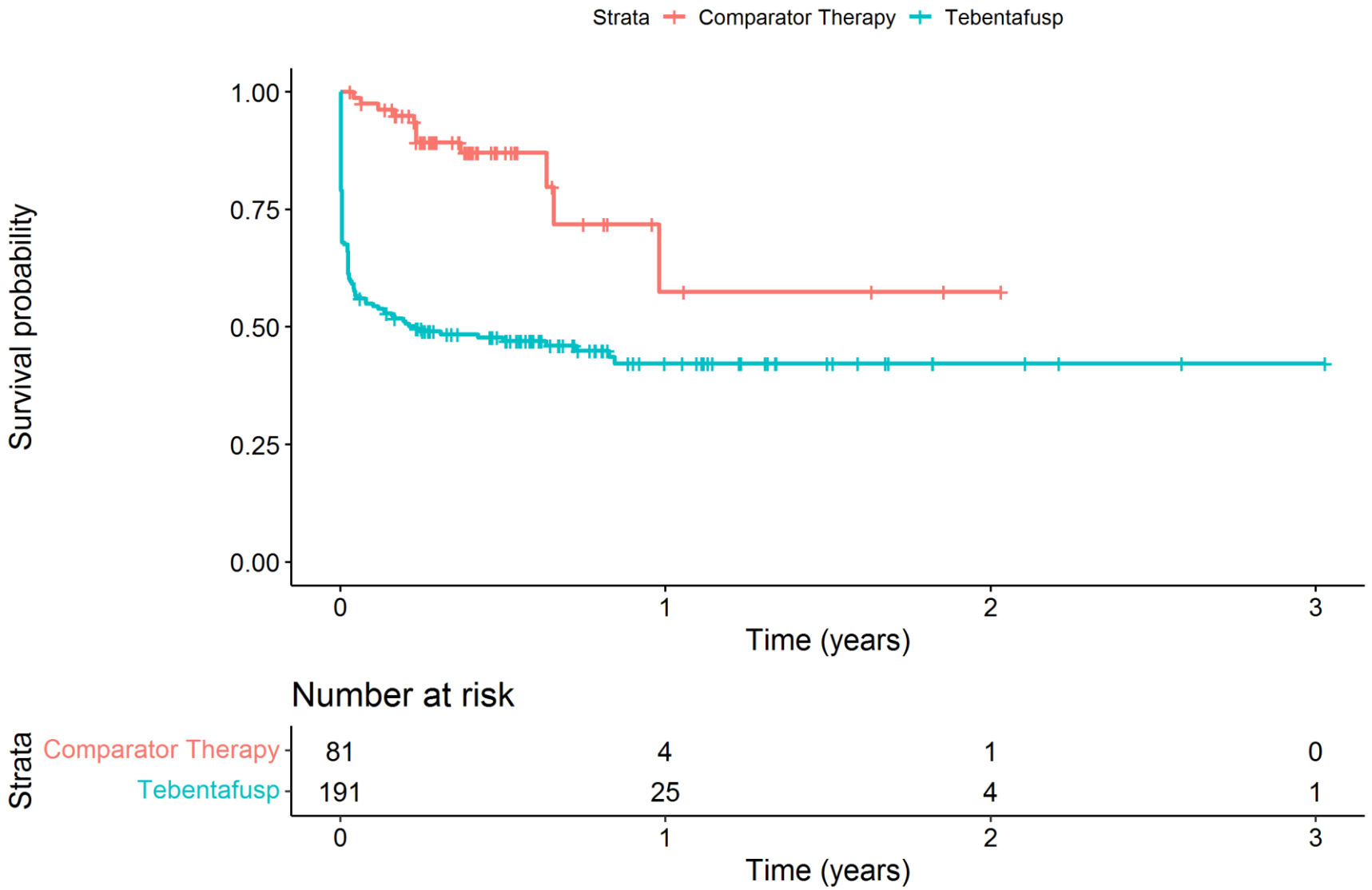
Gefäßerkrankungen - <65



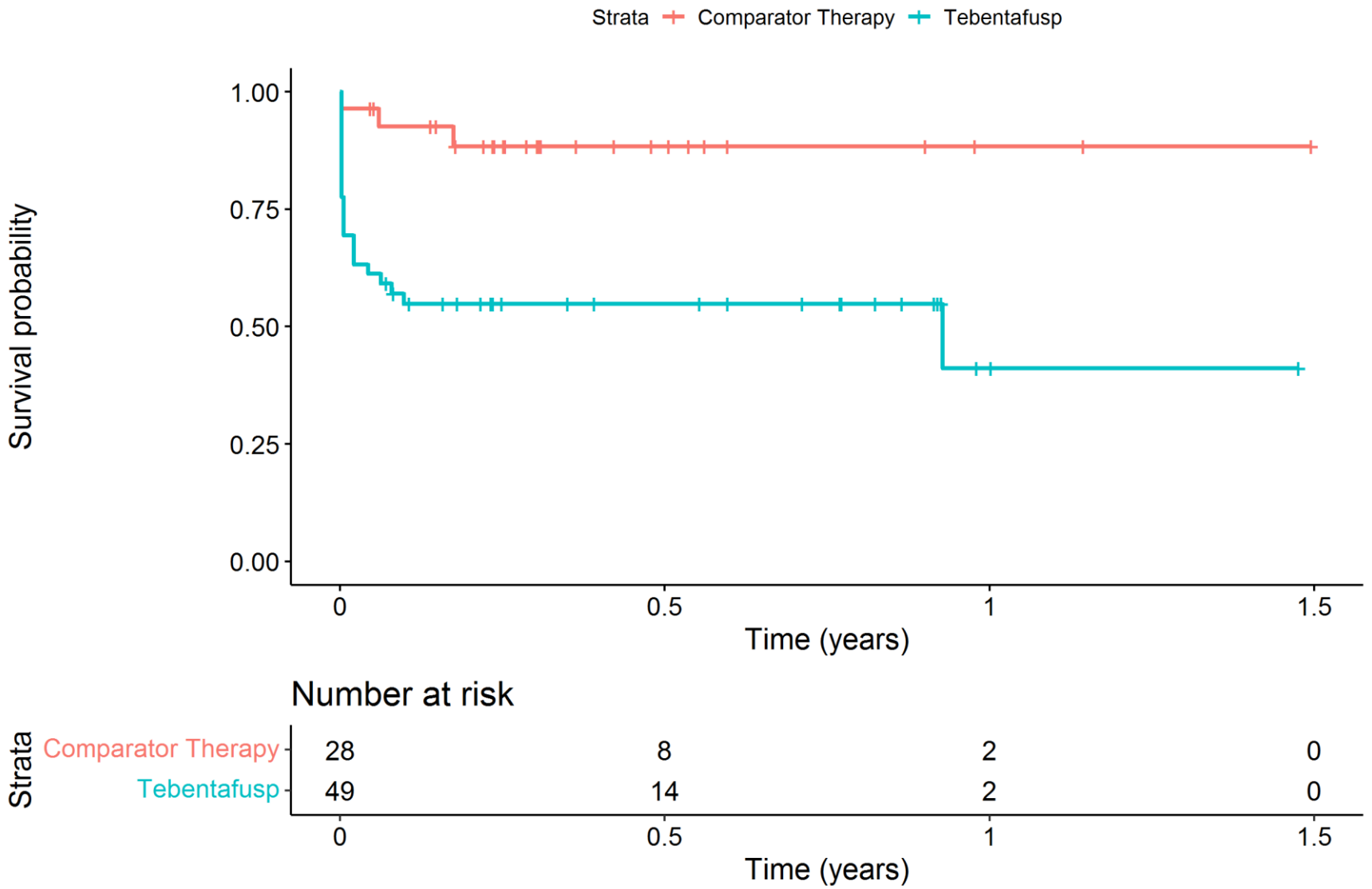
Gefäßerkrankungen - ≥65



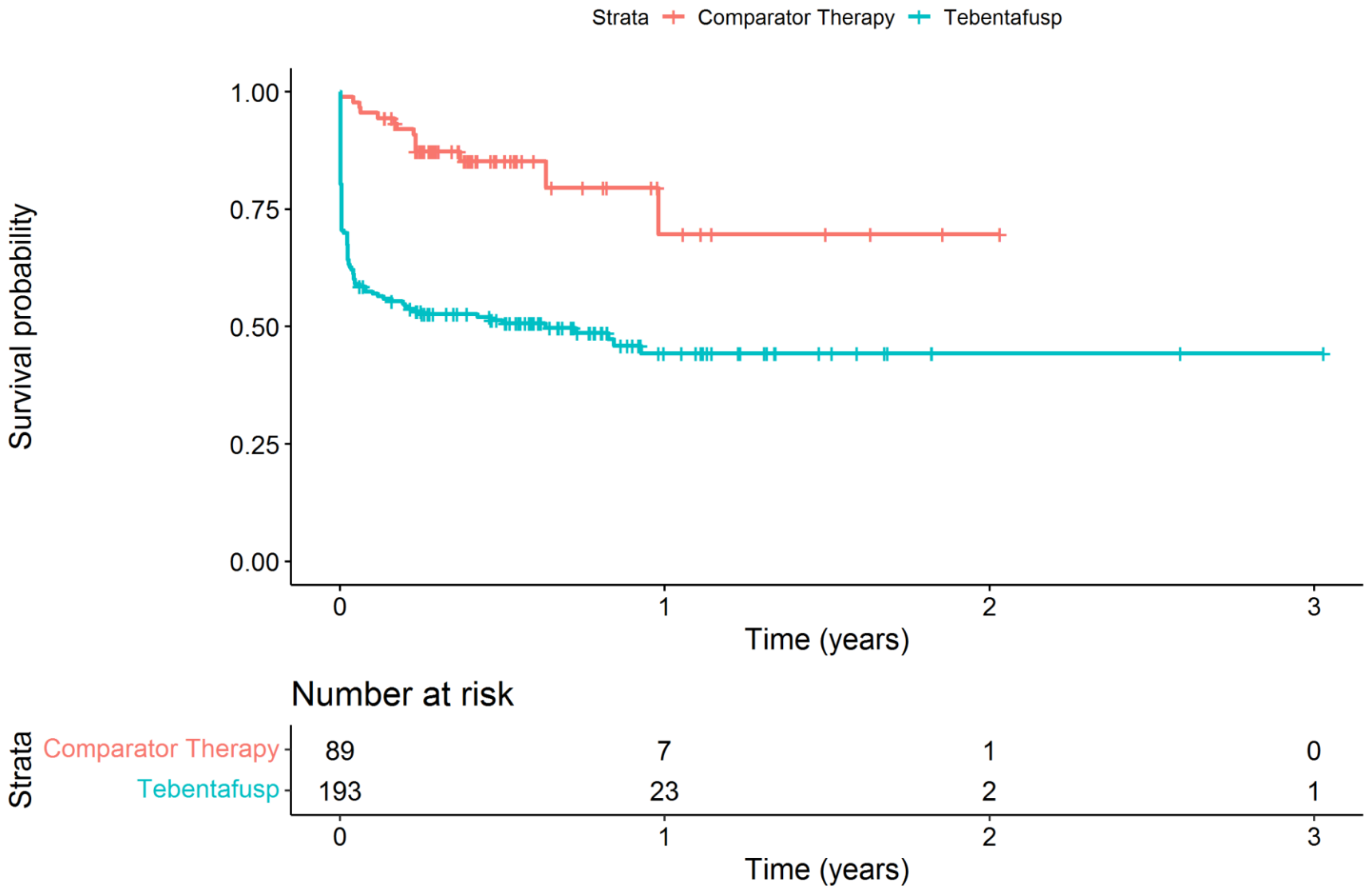
Gefäßerkrankungen - ECOG 0



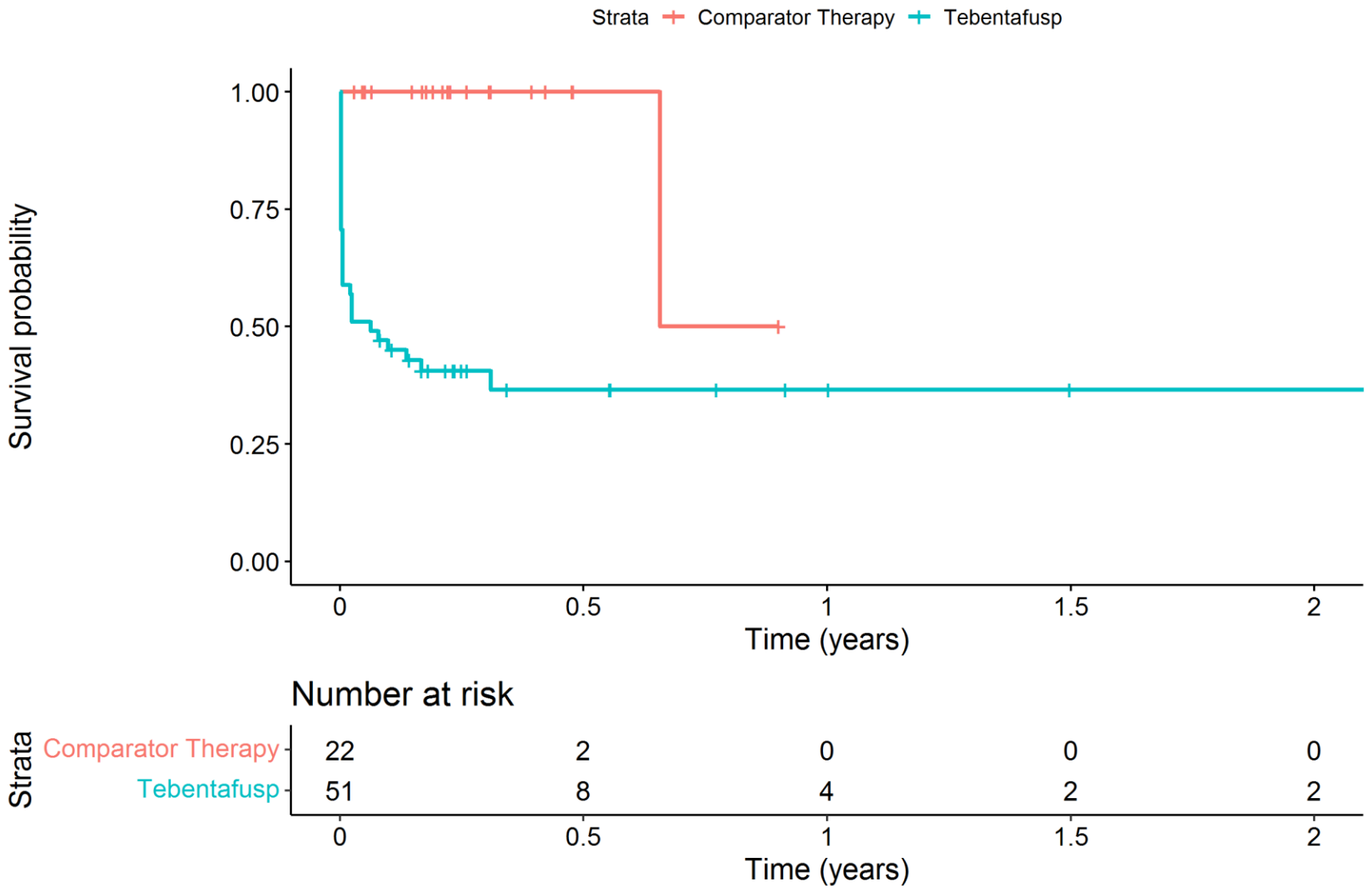
Gefäßerkrankungen - ECOG 1



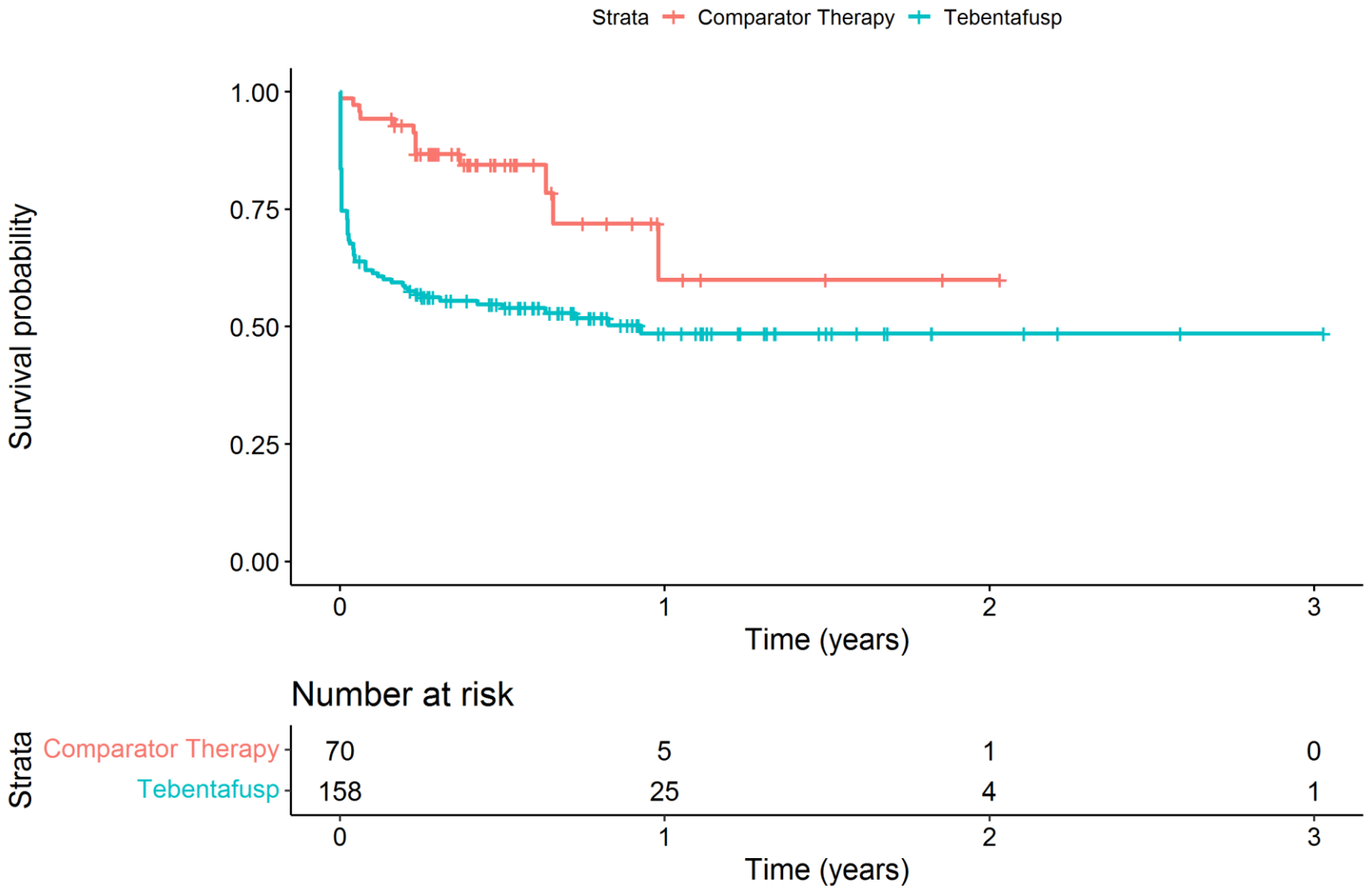
Gefäßerkrankungen - ALP ≤ ULN



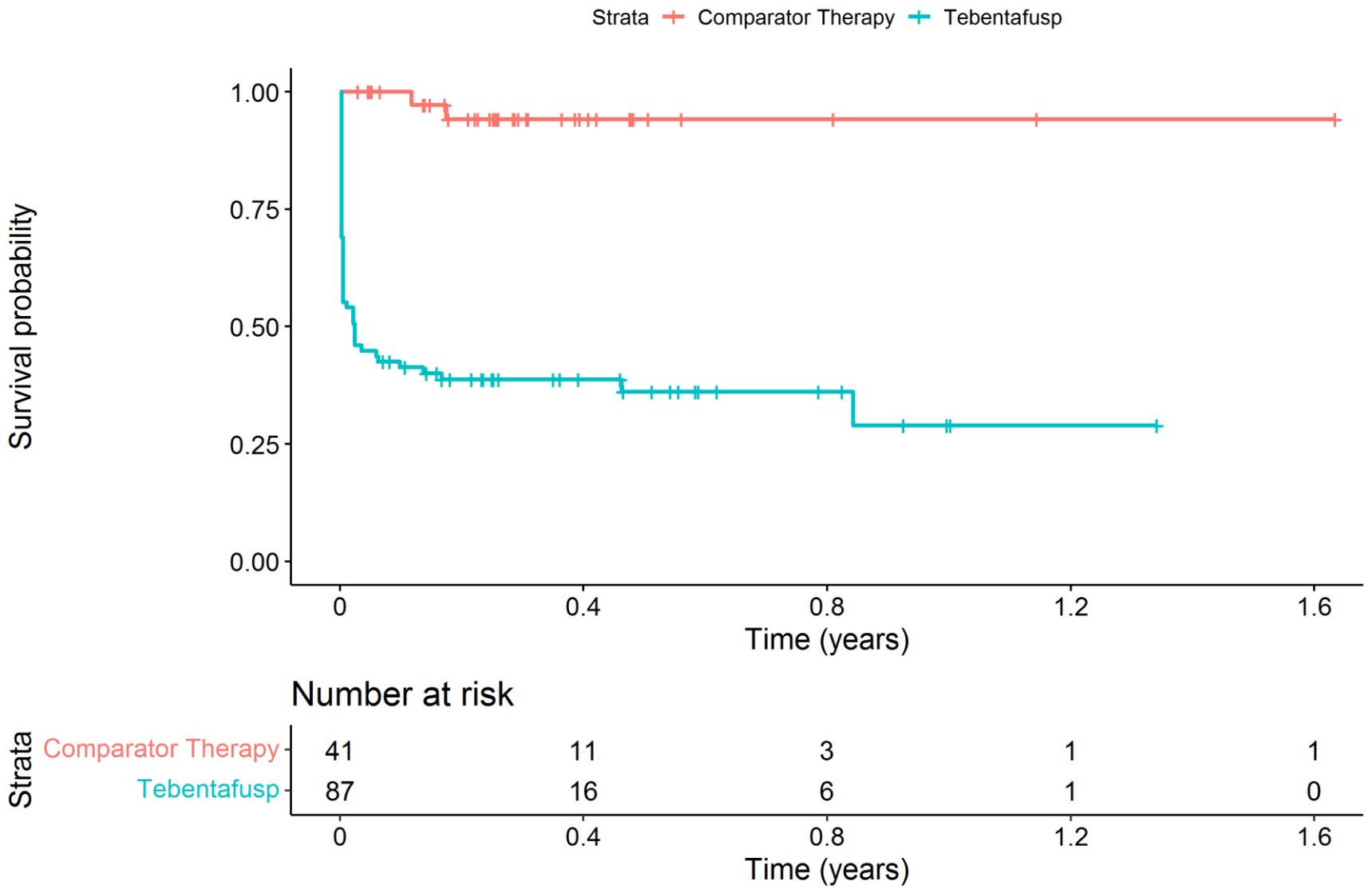
Gefäßerkrankungen - ALP > ULN



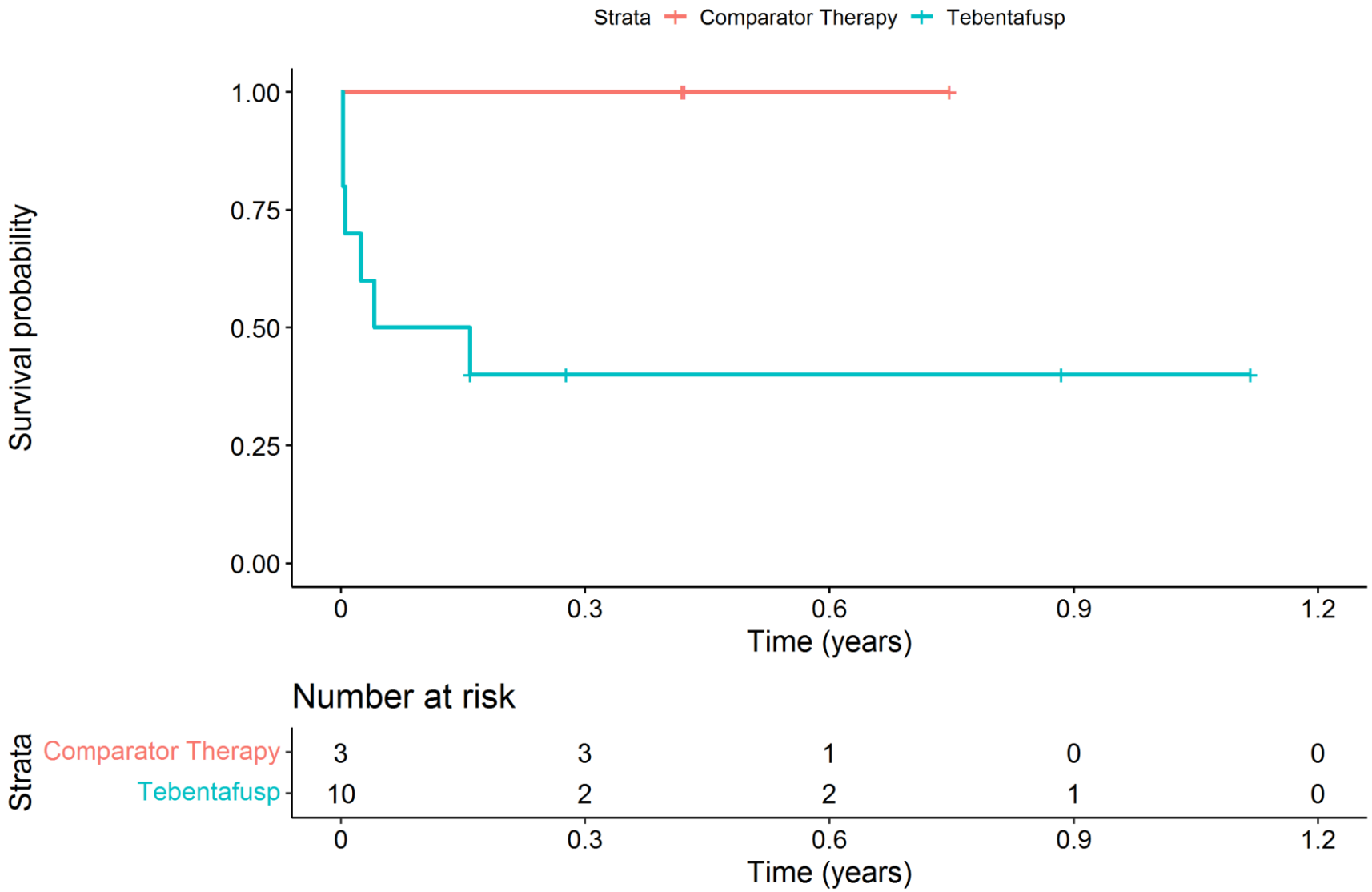
Gefäßerkrankungen - LDH =< ULN



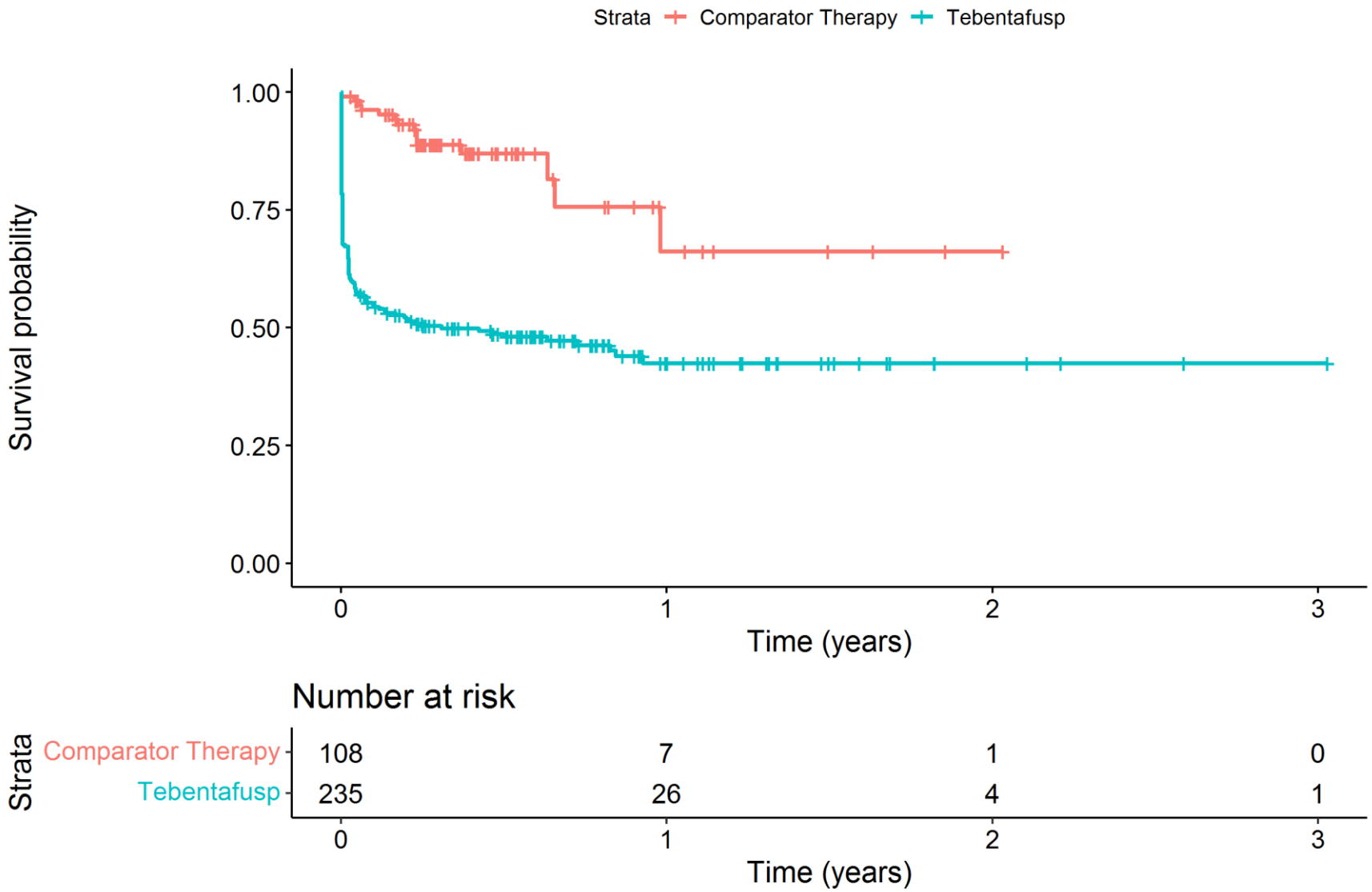
Gefäßerkrankungen - LDH > ULN



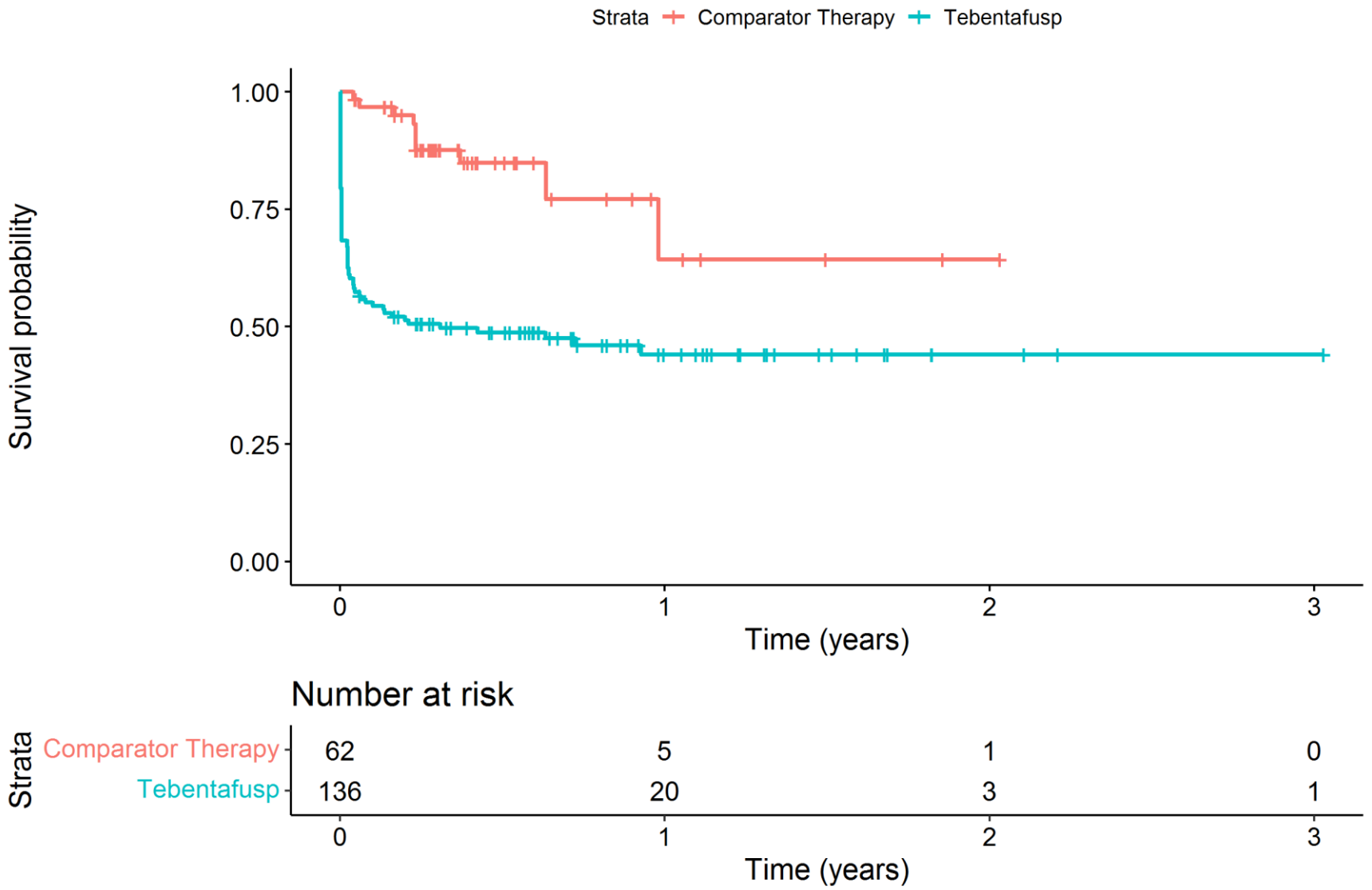
Gefäßerkrankungen - Vorherige Therapie adjuvant/neoadjuvant



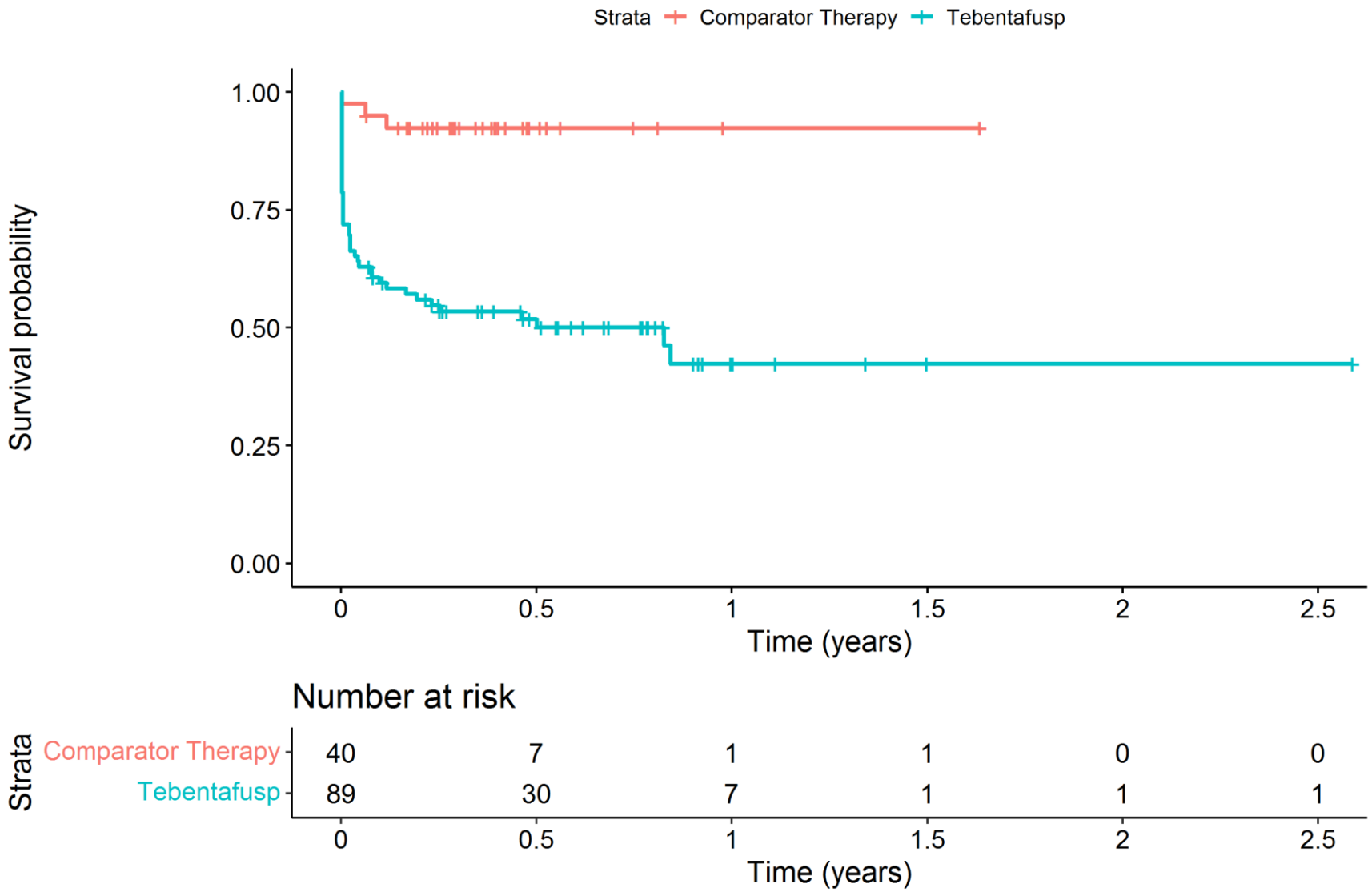
Gefäßerkrankungen - Keine vorherige Therapie adjuvant/neoadjuvant



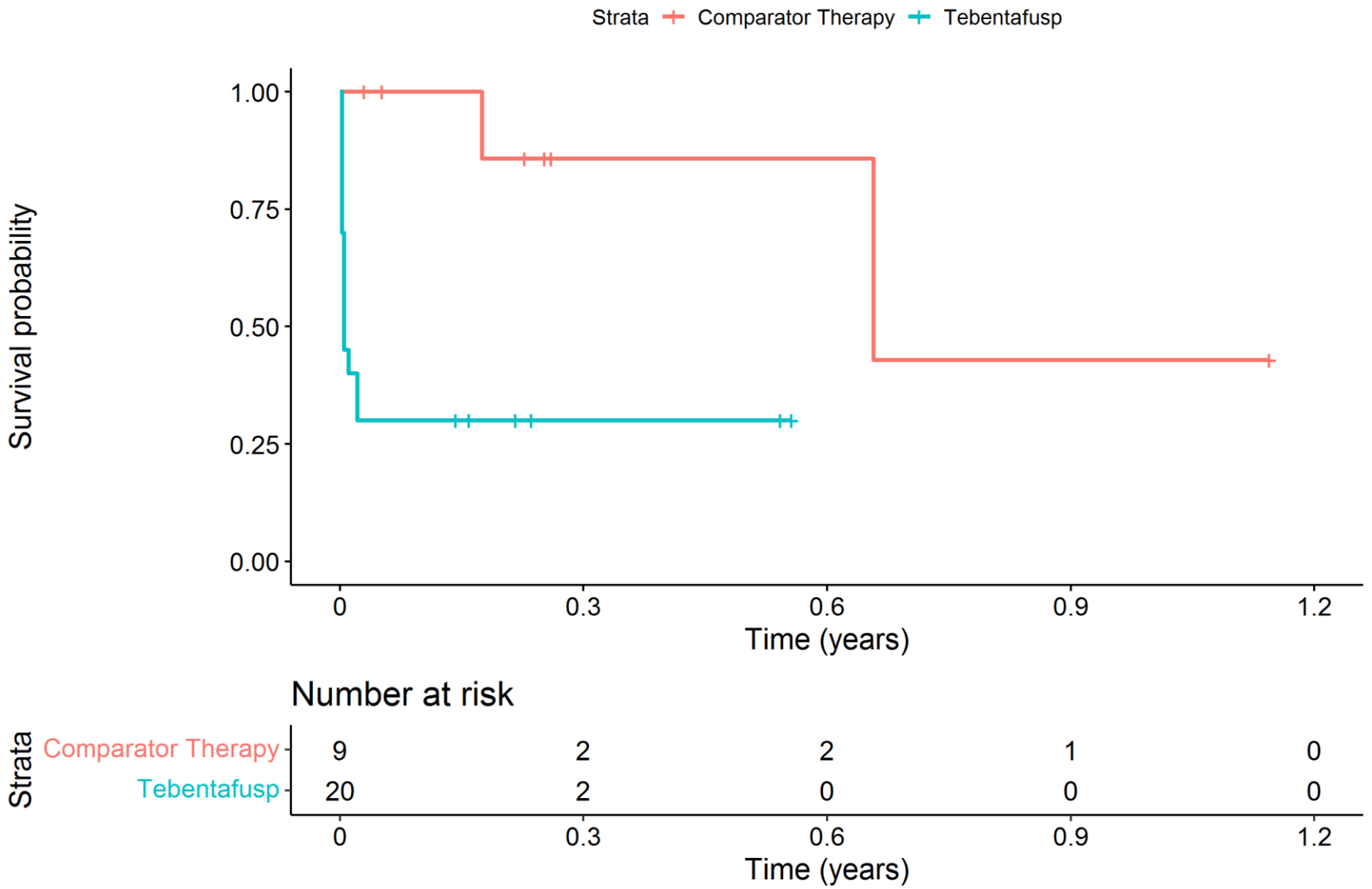
Gefäßerkrankungen - Läsion ≤ 3cm



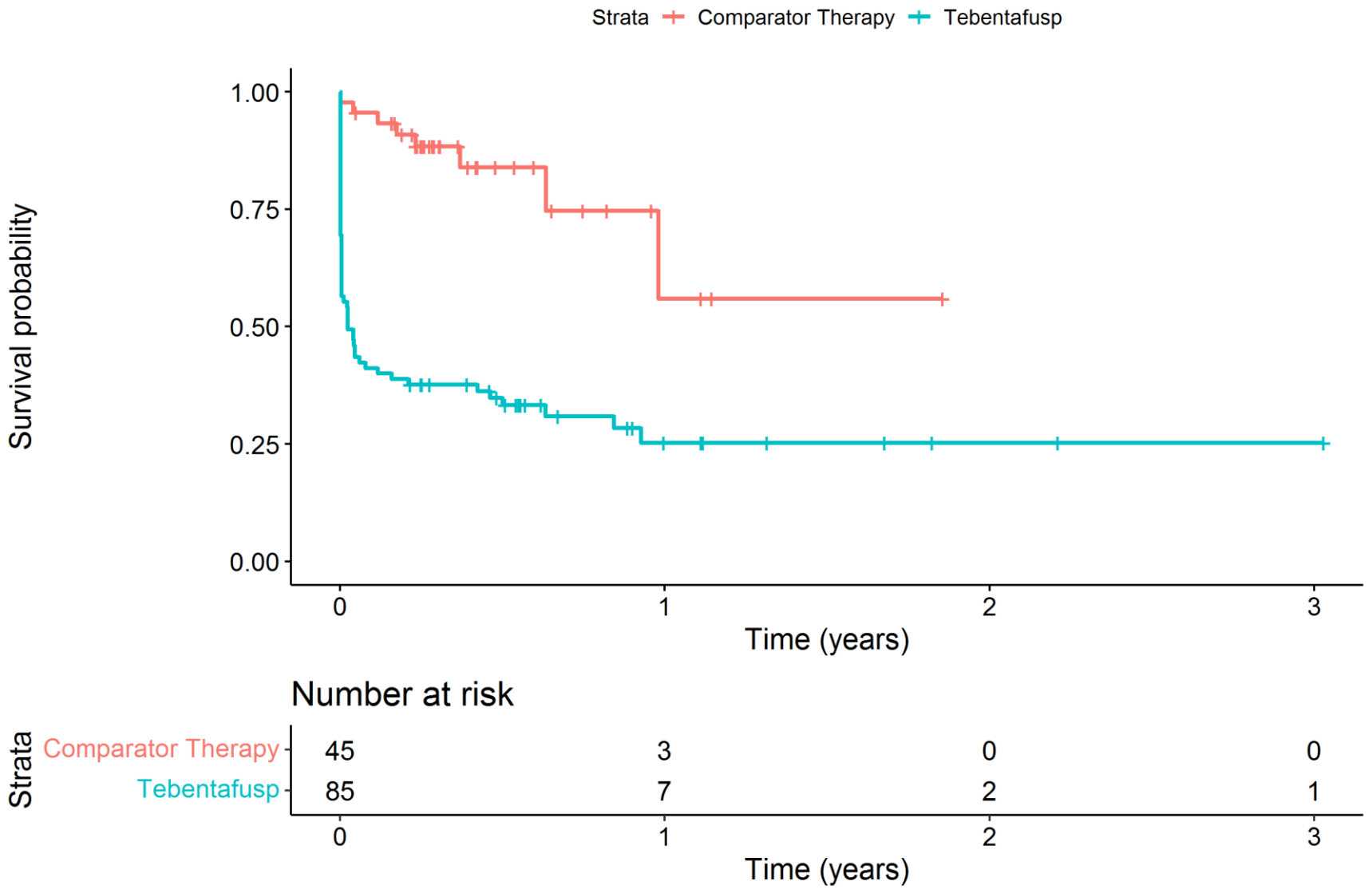
Gefäßerkrankungen - Läsion 3,1-8,0 cm



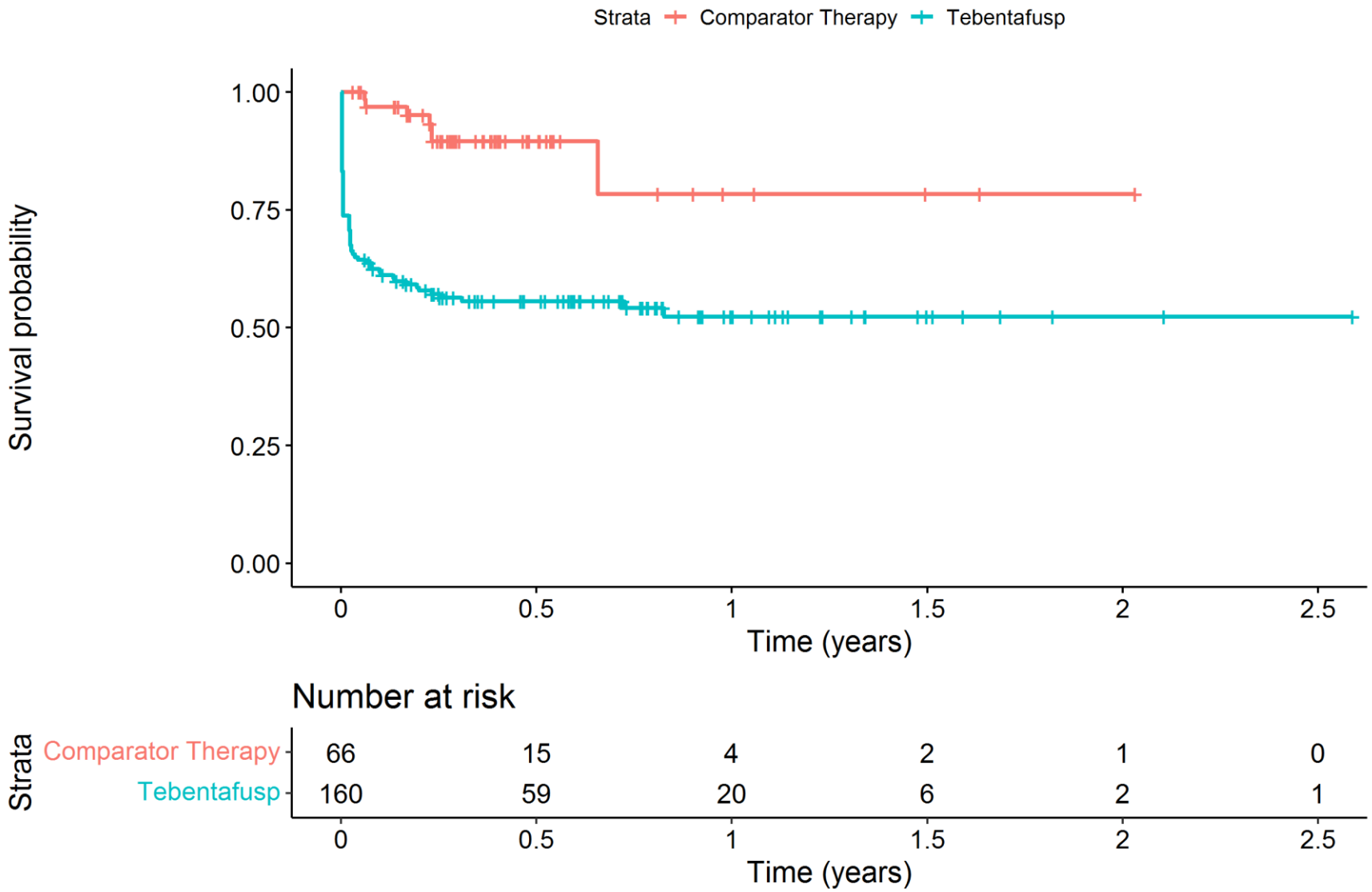
Gefäßerkrankungen - Läsion ≥8,1 cm



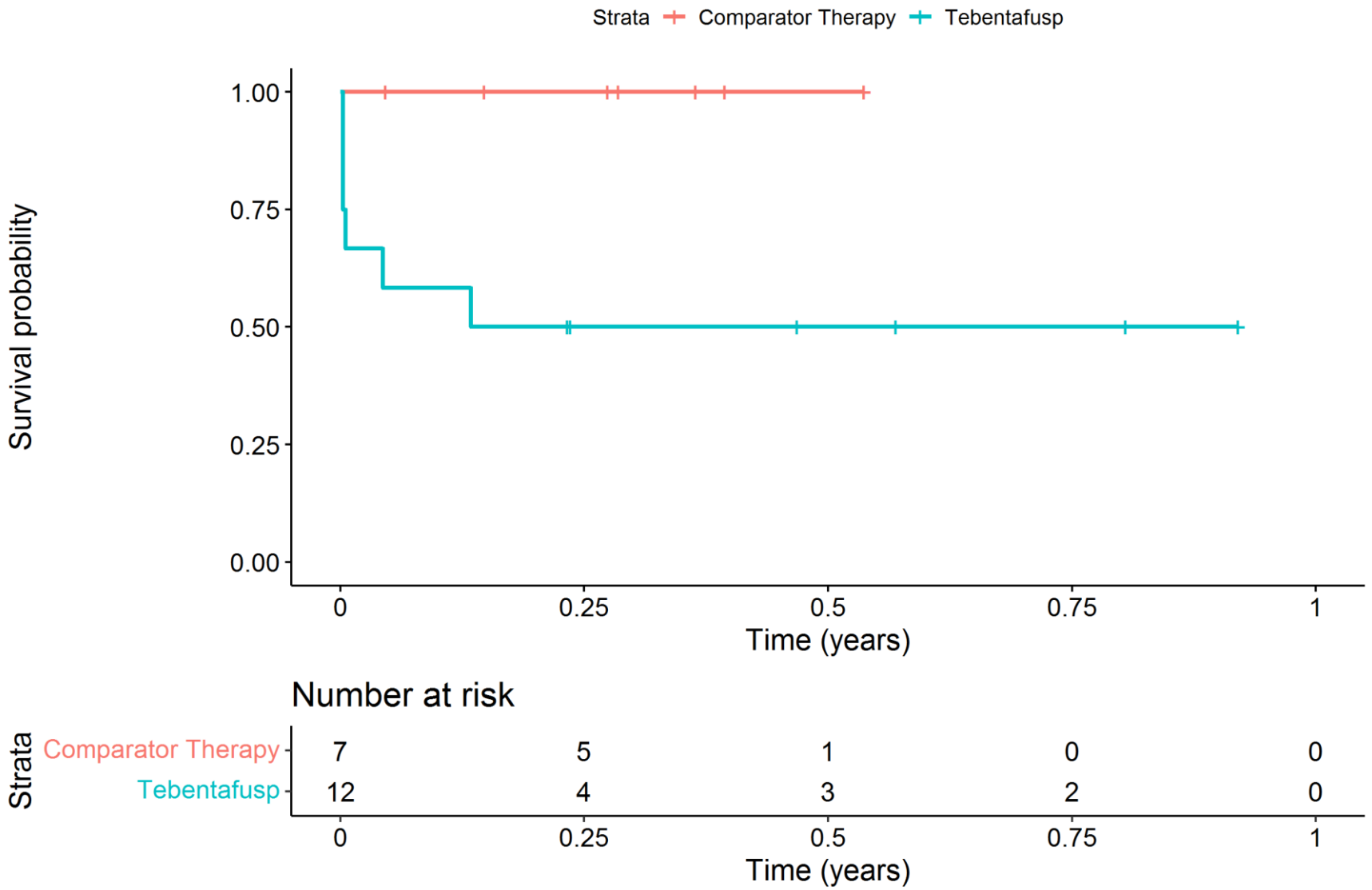
Gefäßerkrankungen - Nordamerika



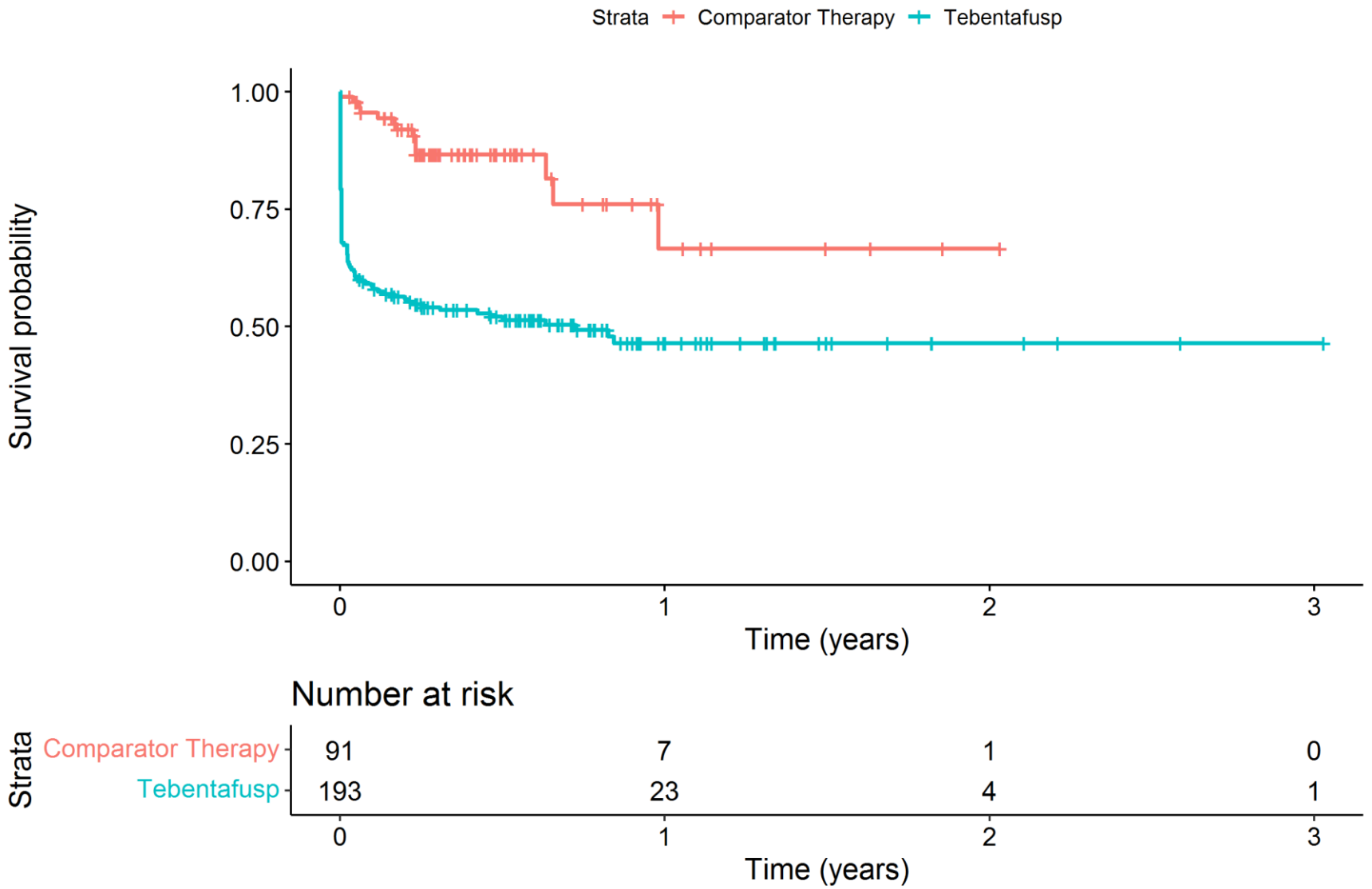
Gefäßerkrankungen - Nicht-Nordamerika



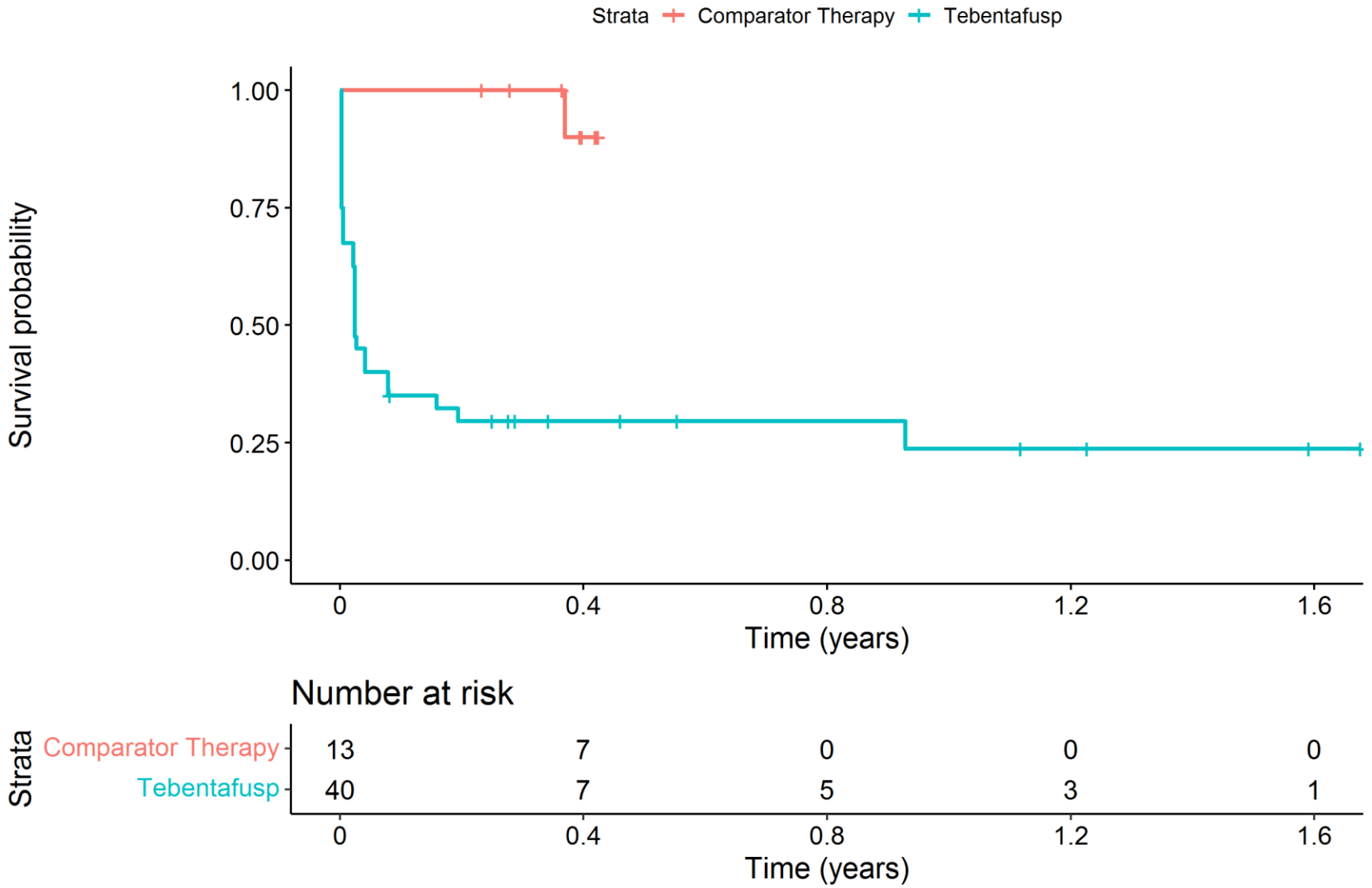
Gefäßerkrankungen - Dacarbazin



Gefäßerkrankungen - Pembrolizumab

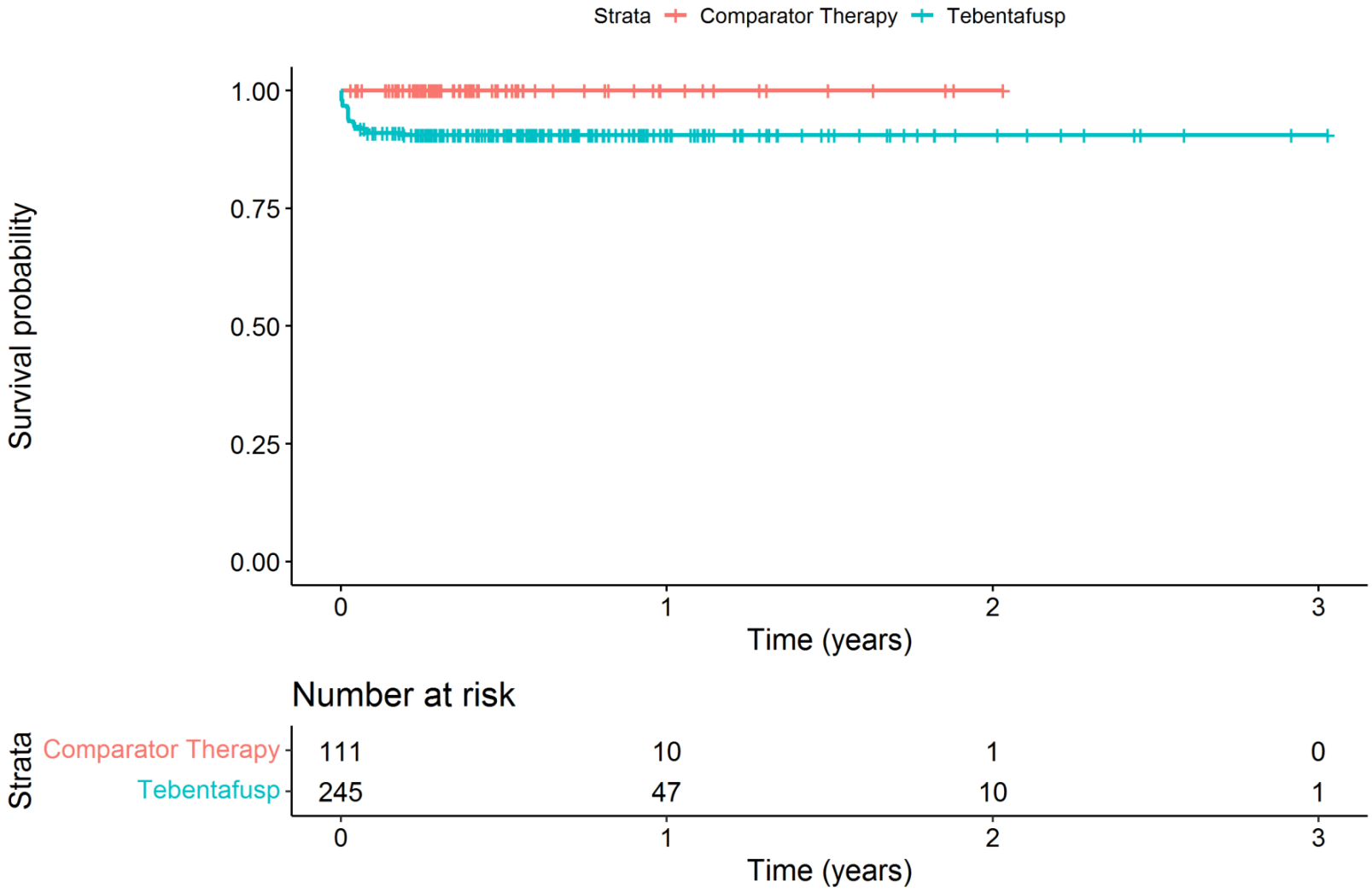


Gefäßerkrankungen - Ipilimumab

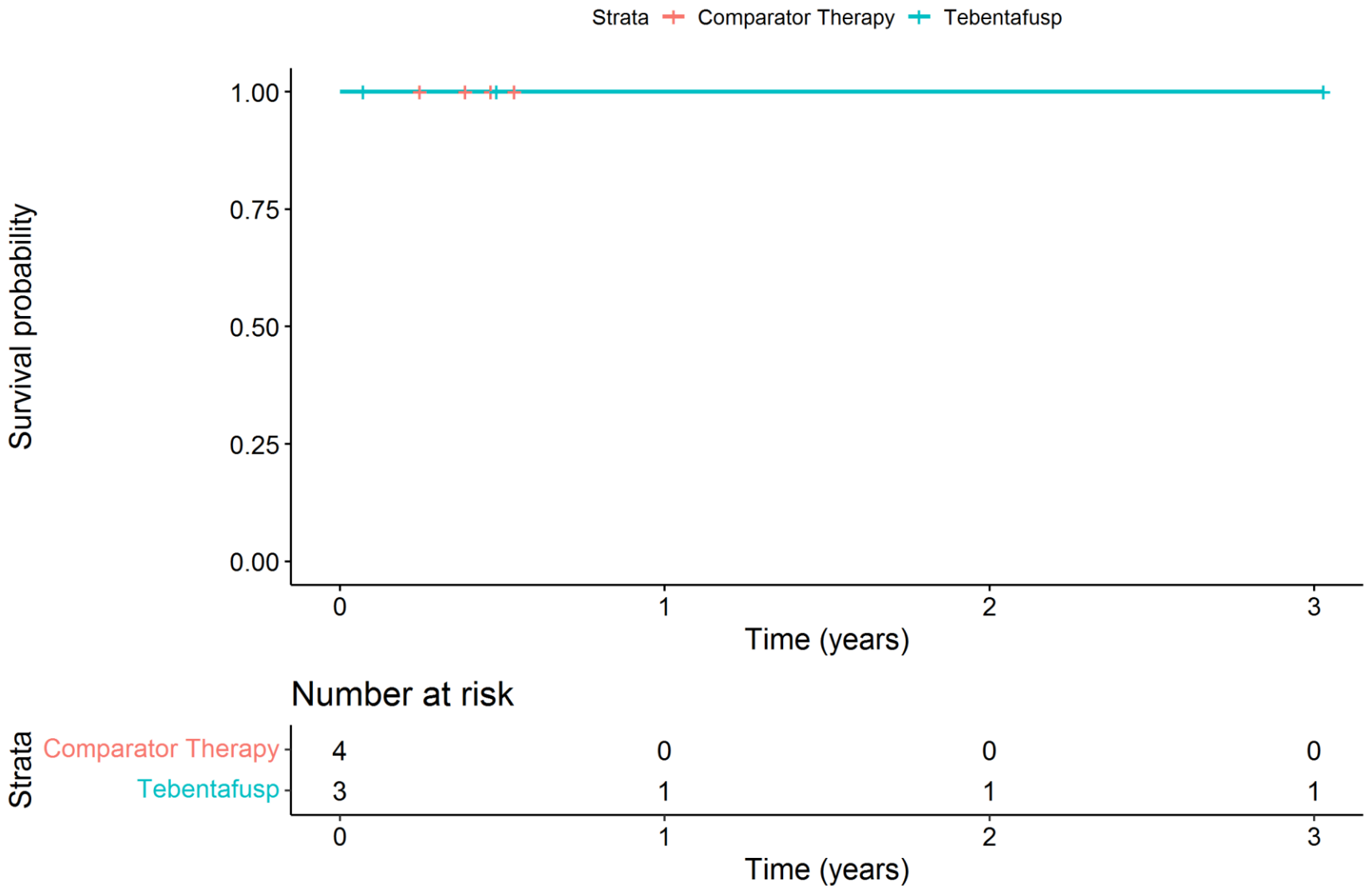


55 UEs (PT) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-194)

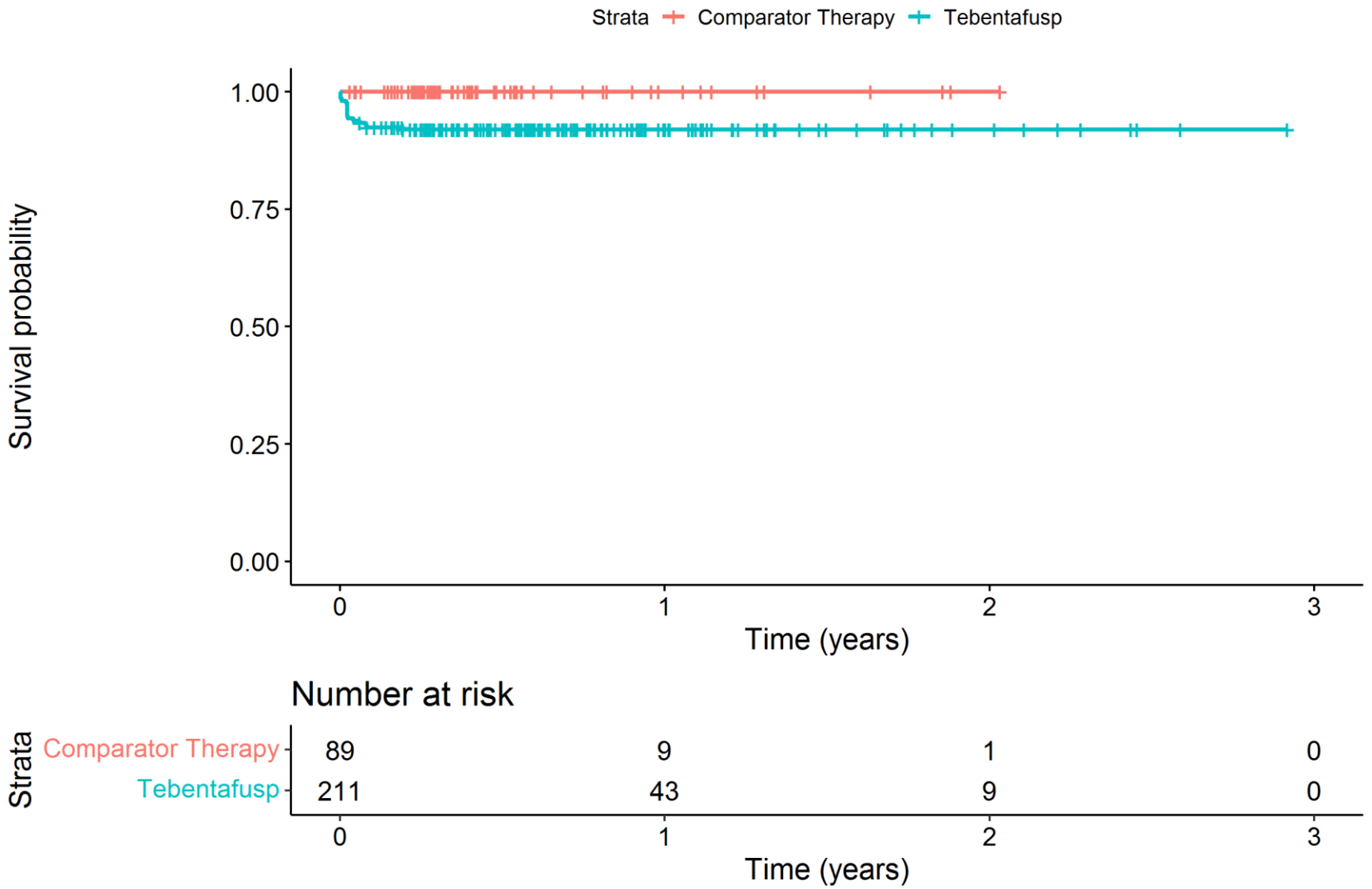
Hautausschlag - Gesamt



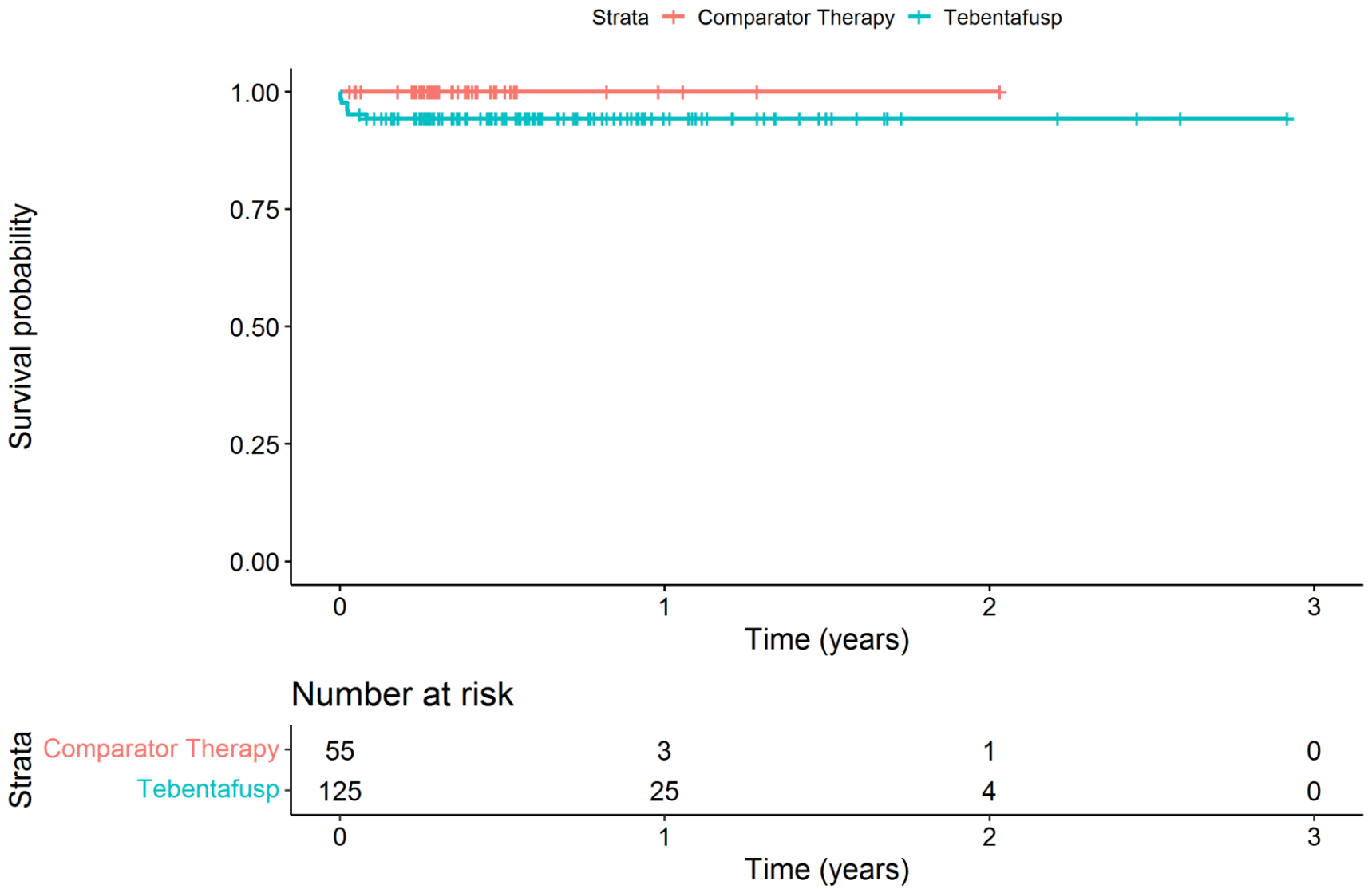
Hautausschlag - Hispanisch



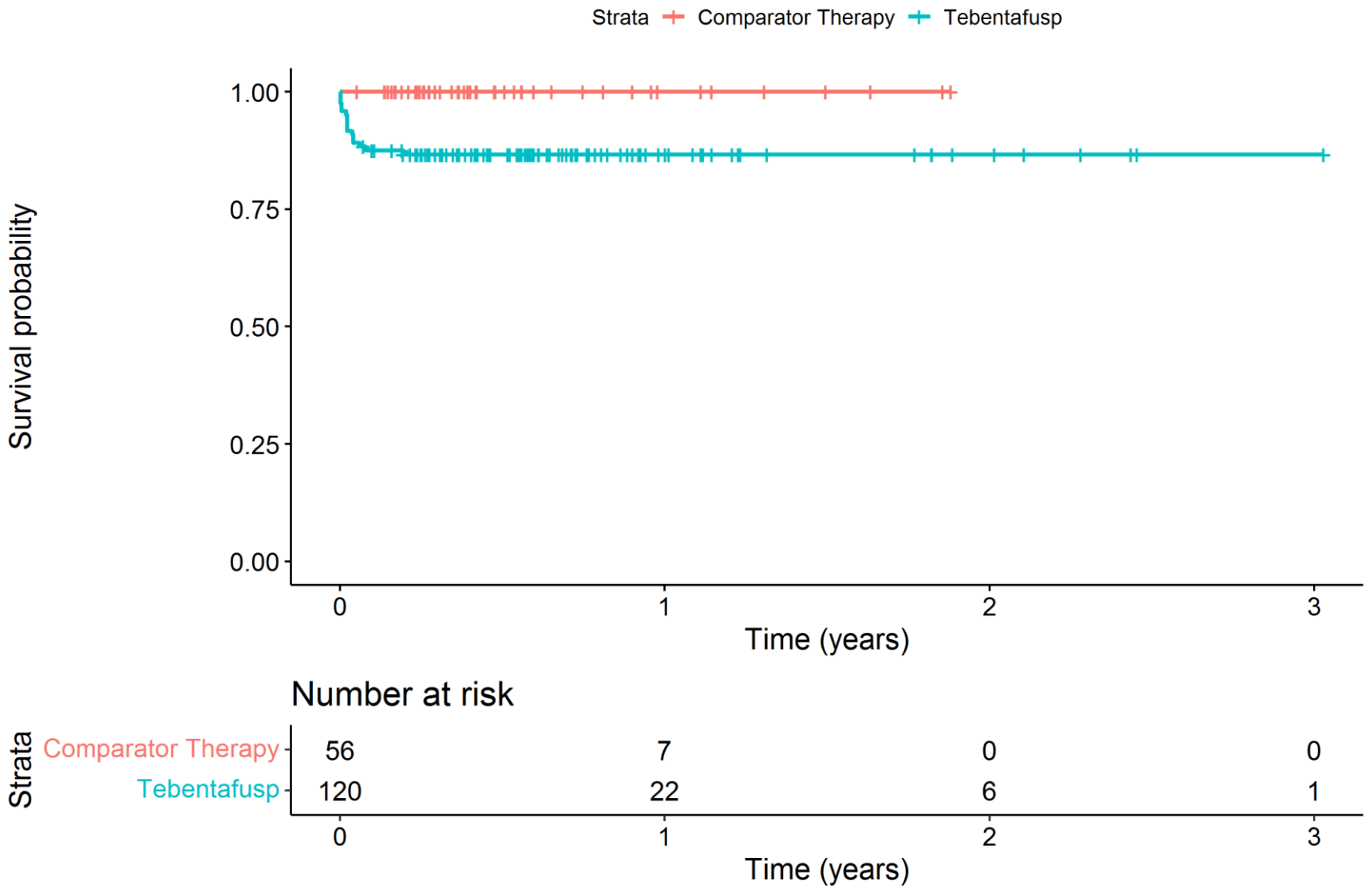
Hautausschlag - Nicht-hispanisch



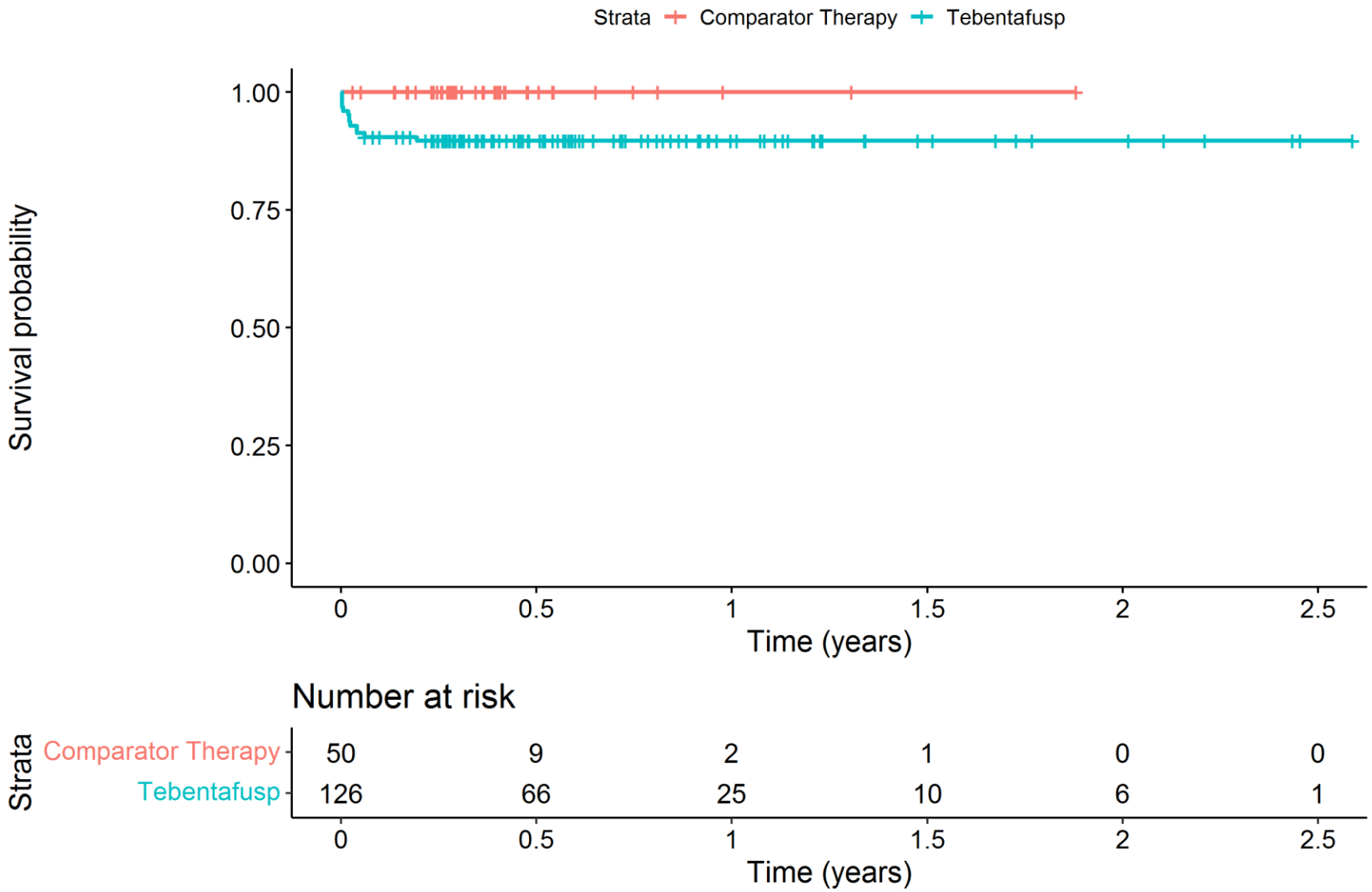
Hautausschlag - Männlich



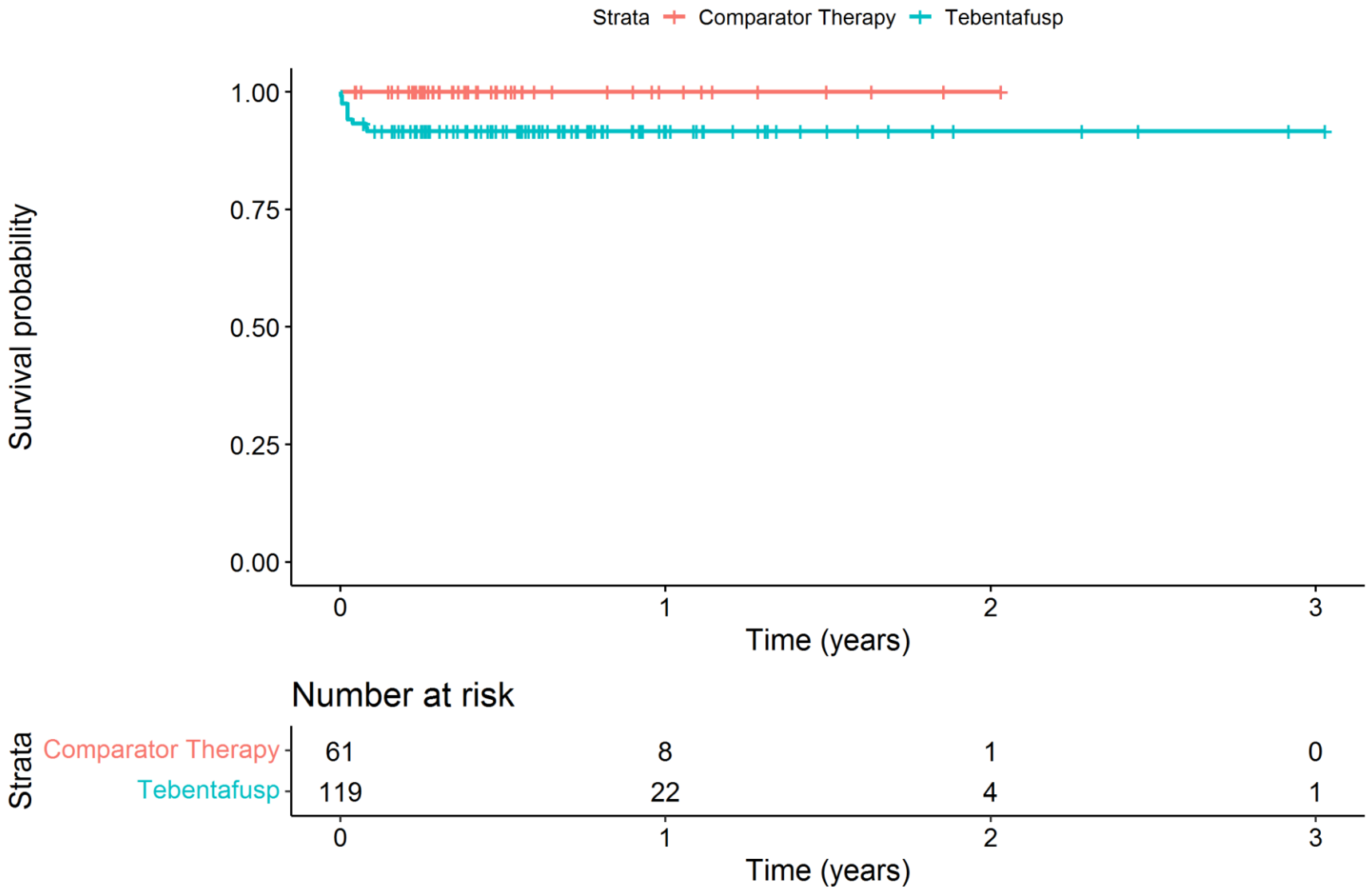
Hautausschlag - Weiblich



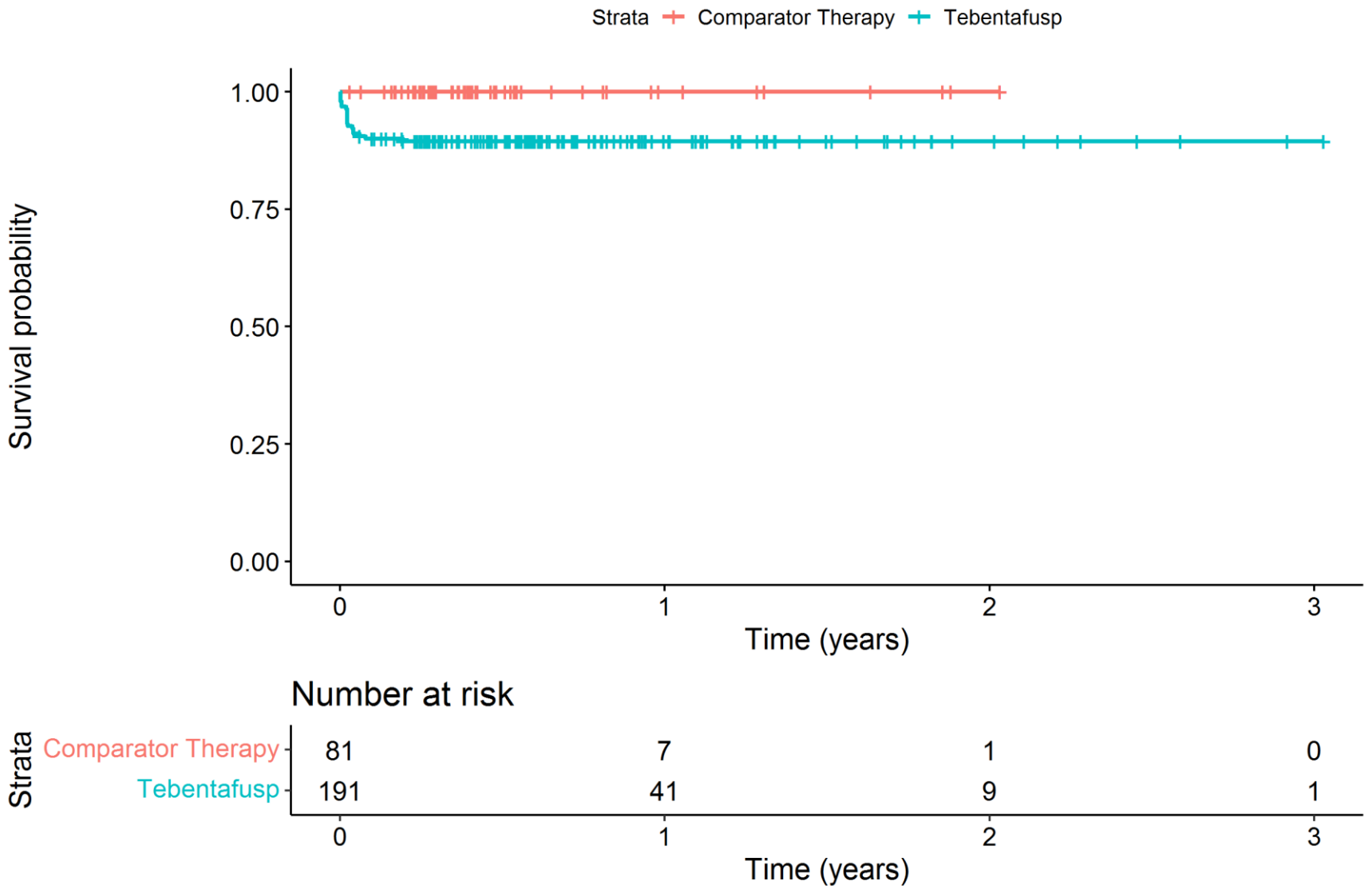
Hautausschlag - <65



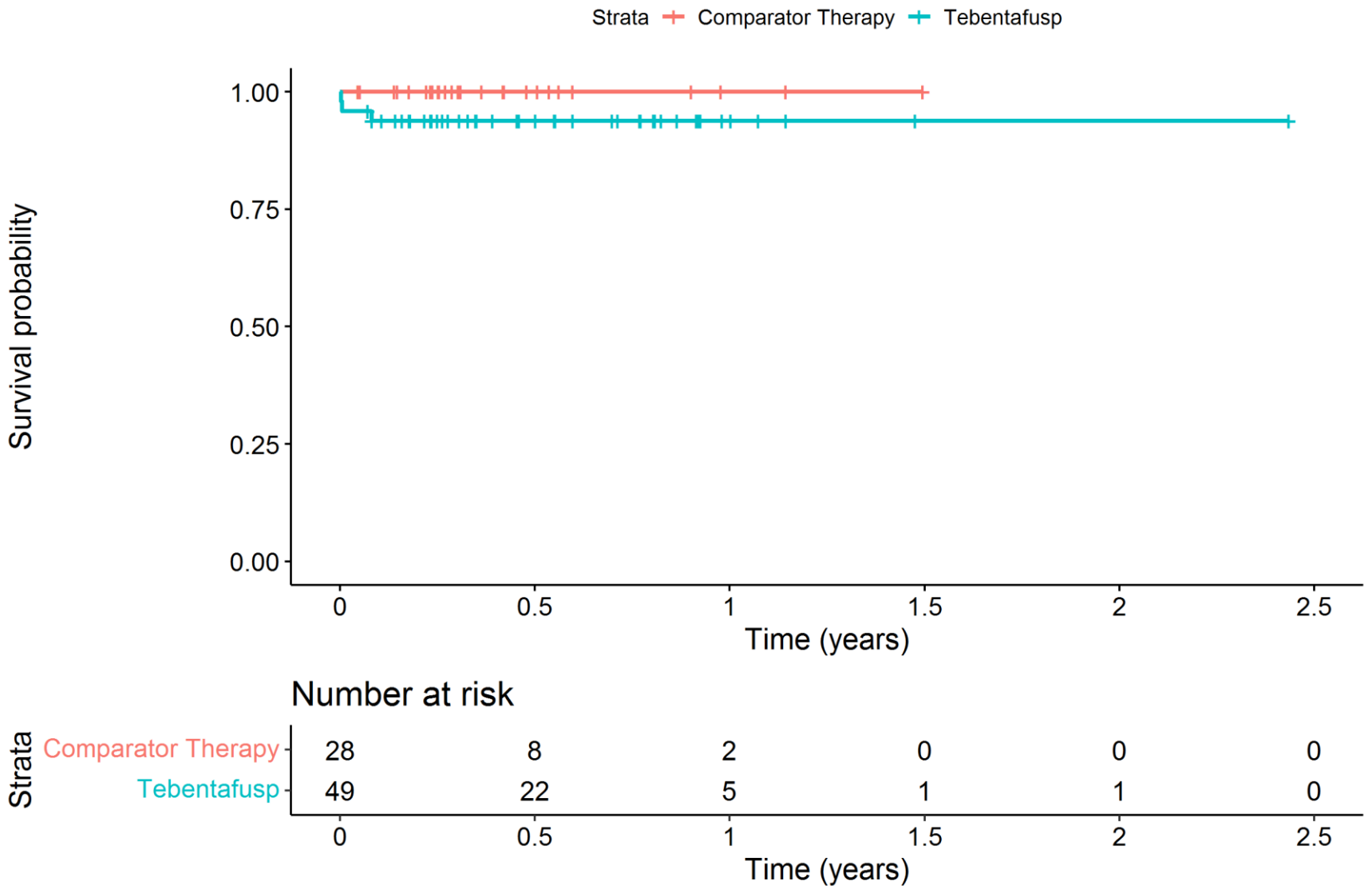
Hautausschlag - ≥65



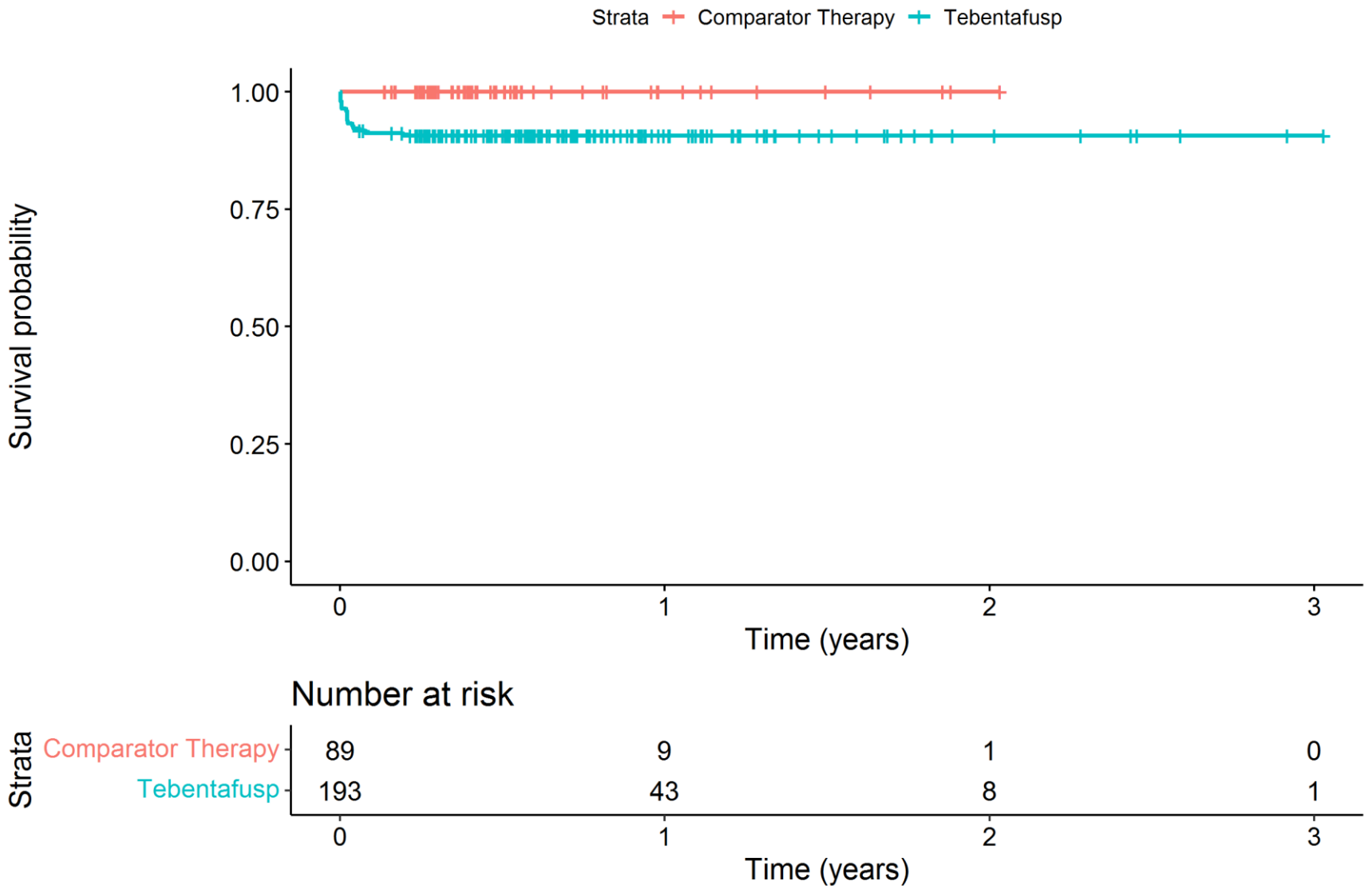
Hautausschlag - ECOG 0



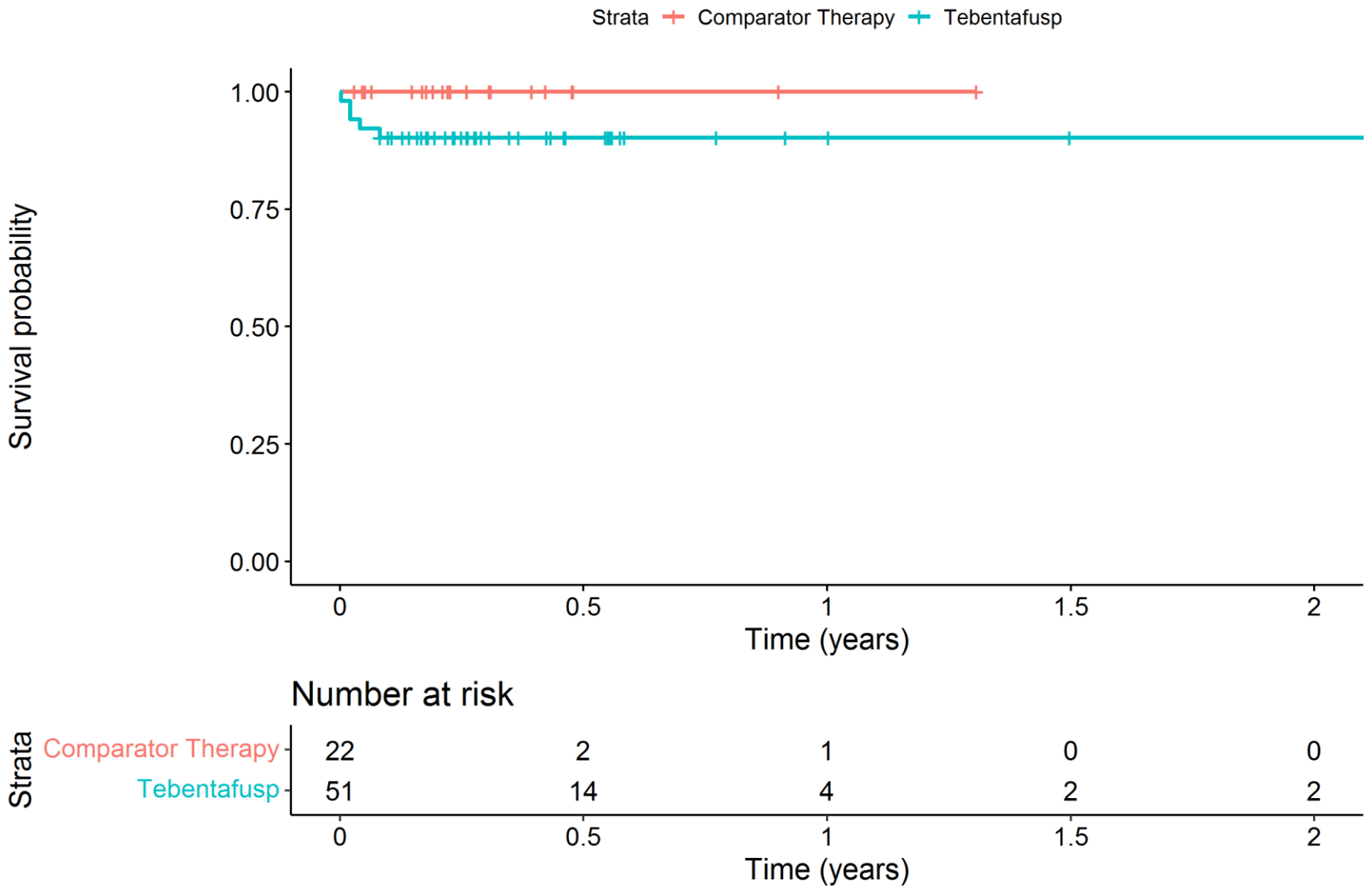
Hautausschlag - ECOG 1



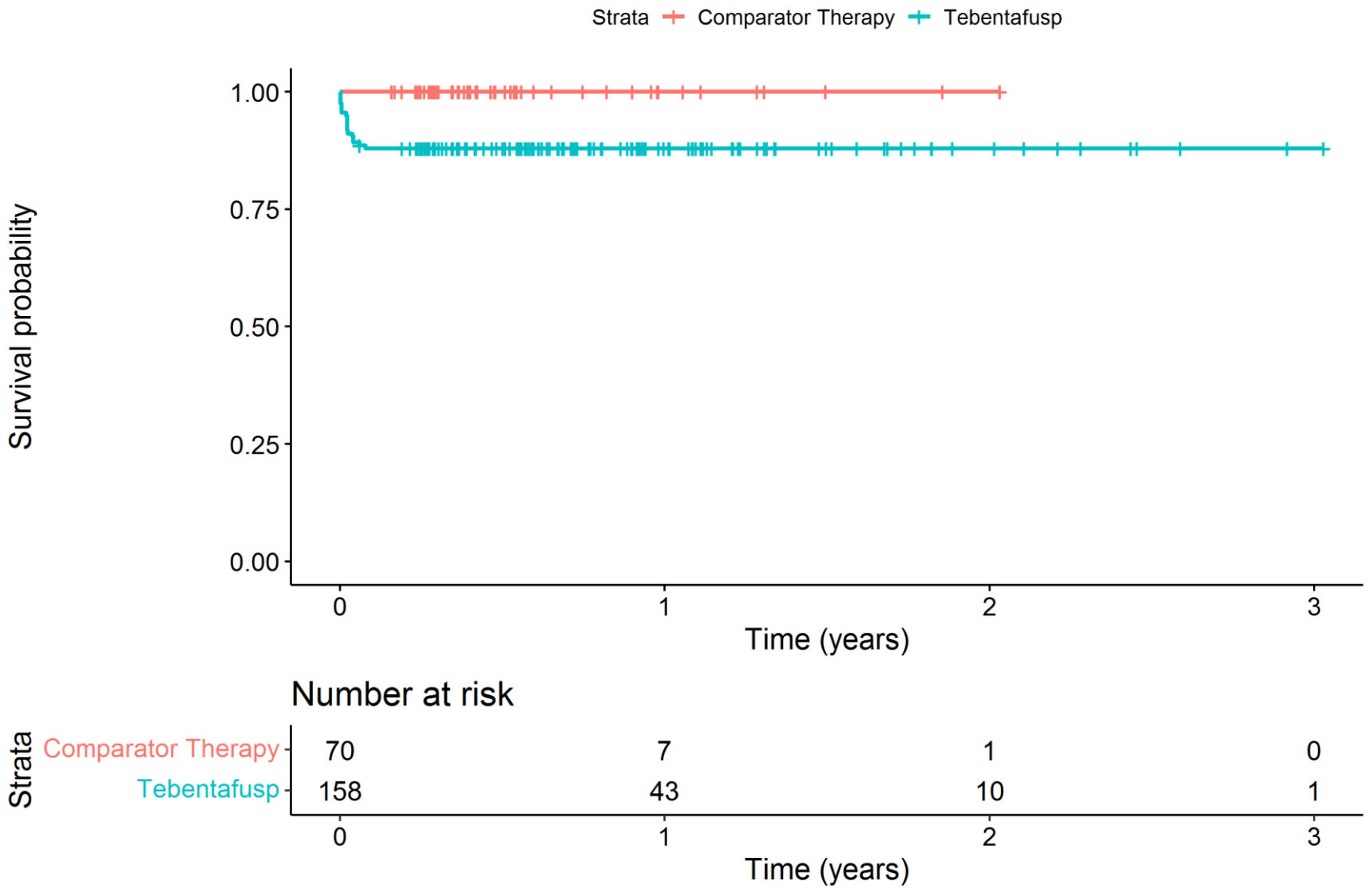
Hautausschlag - ALP ≤ ULN



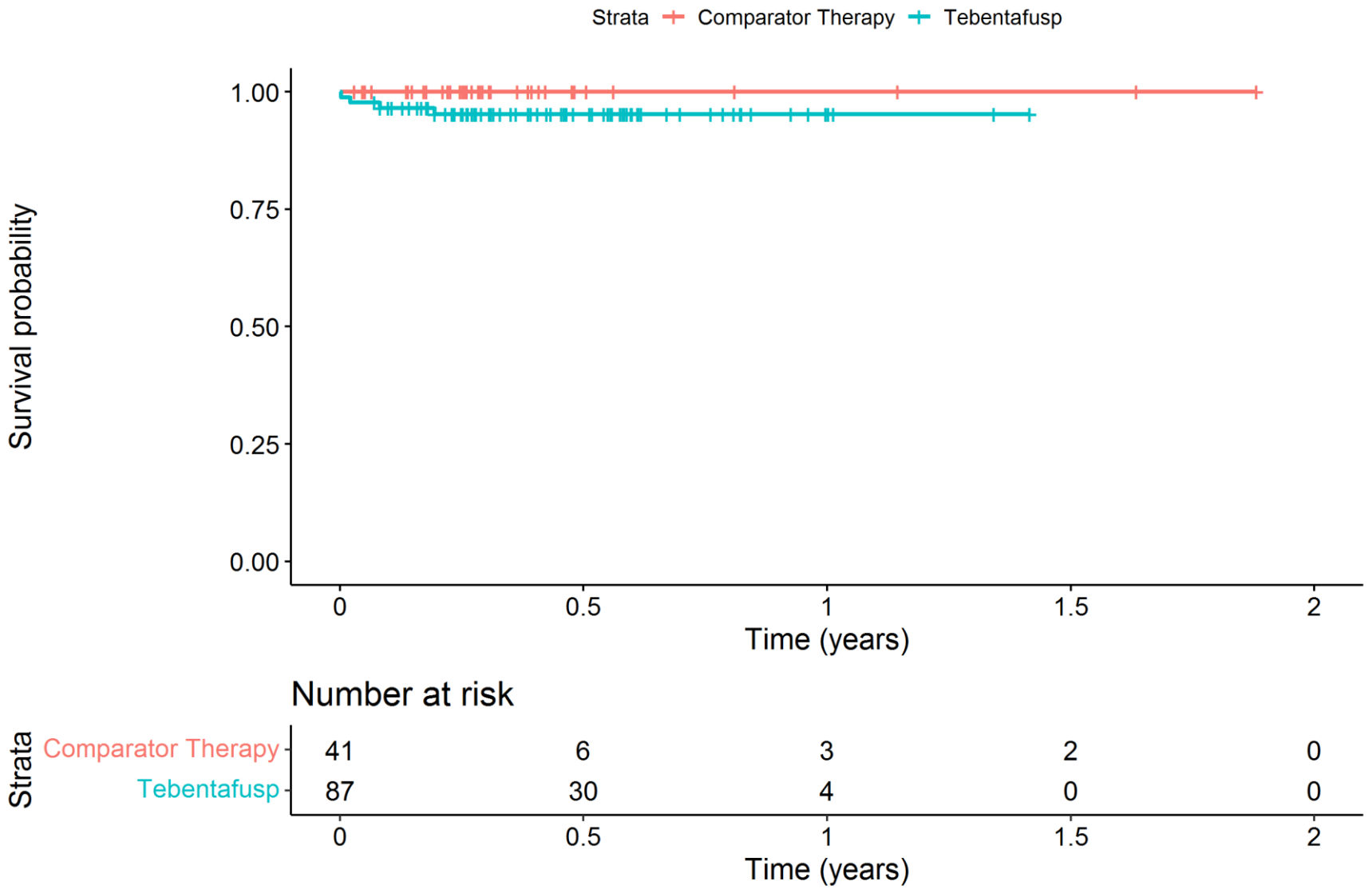
Hautausschlag - ALP > ULN



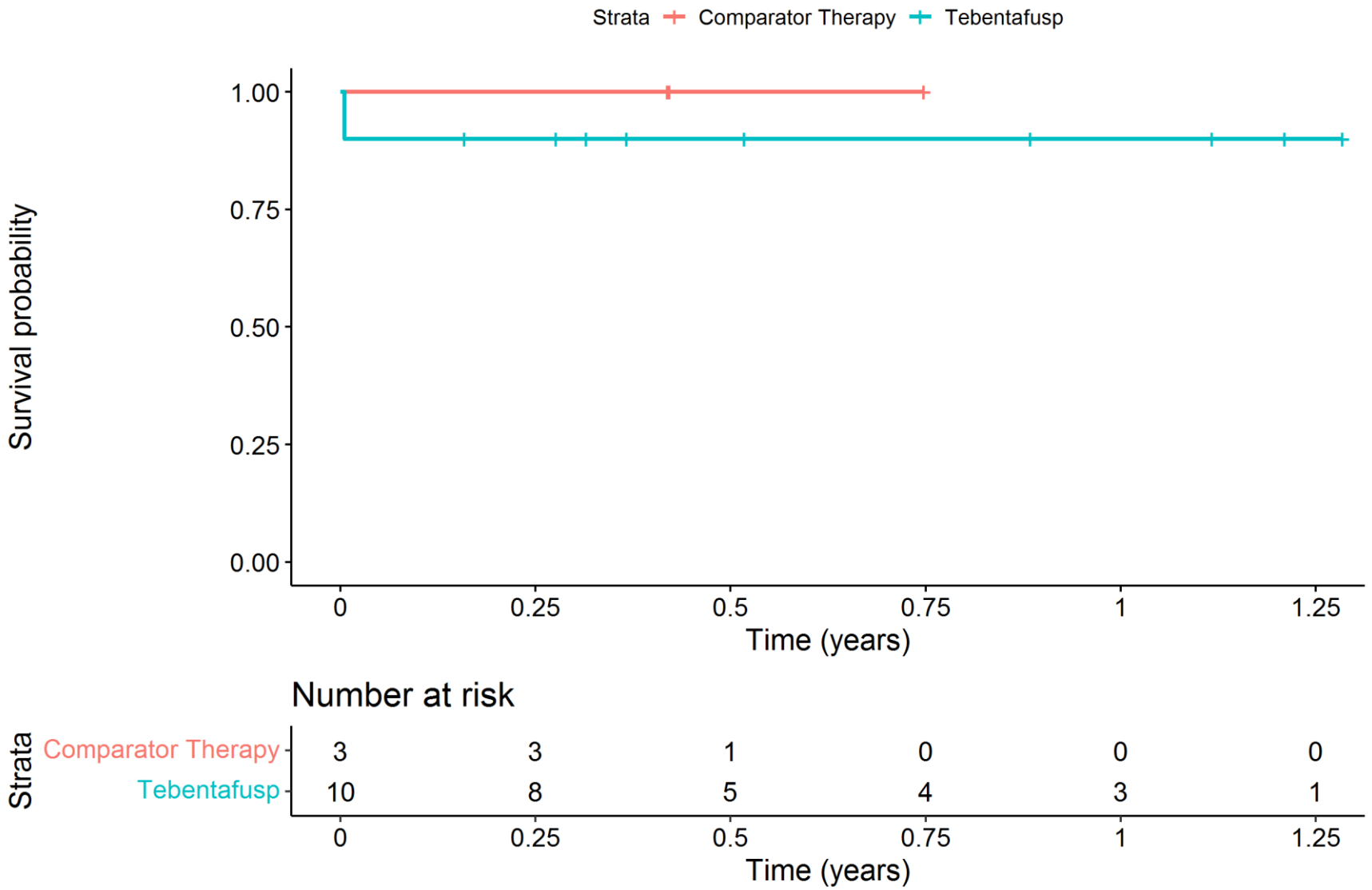
Hautausschlag - LDH =< ULN



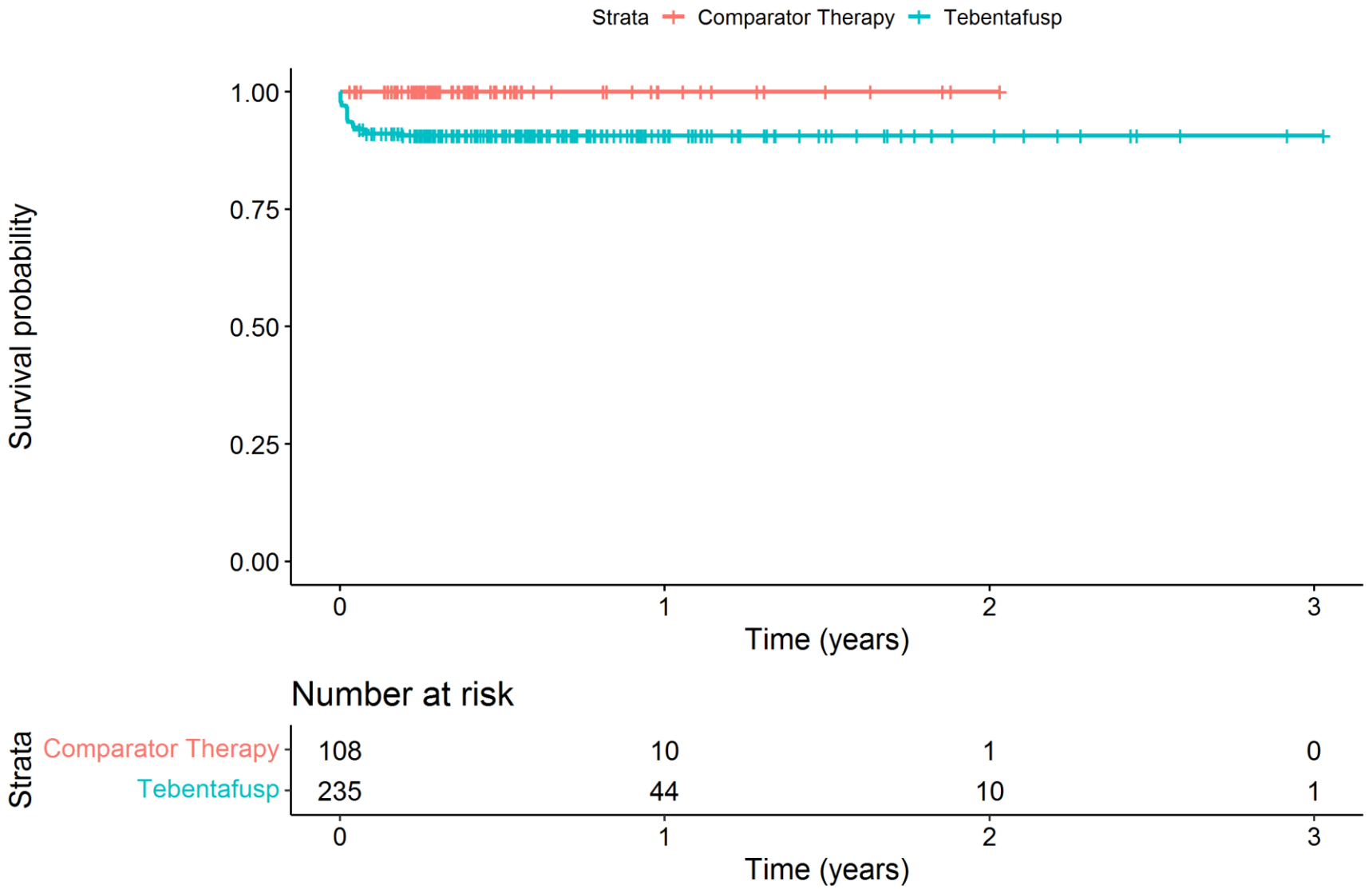
Hautausschlag - LDH > ULN



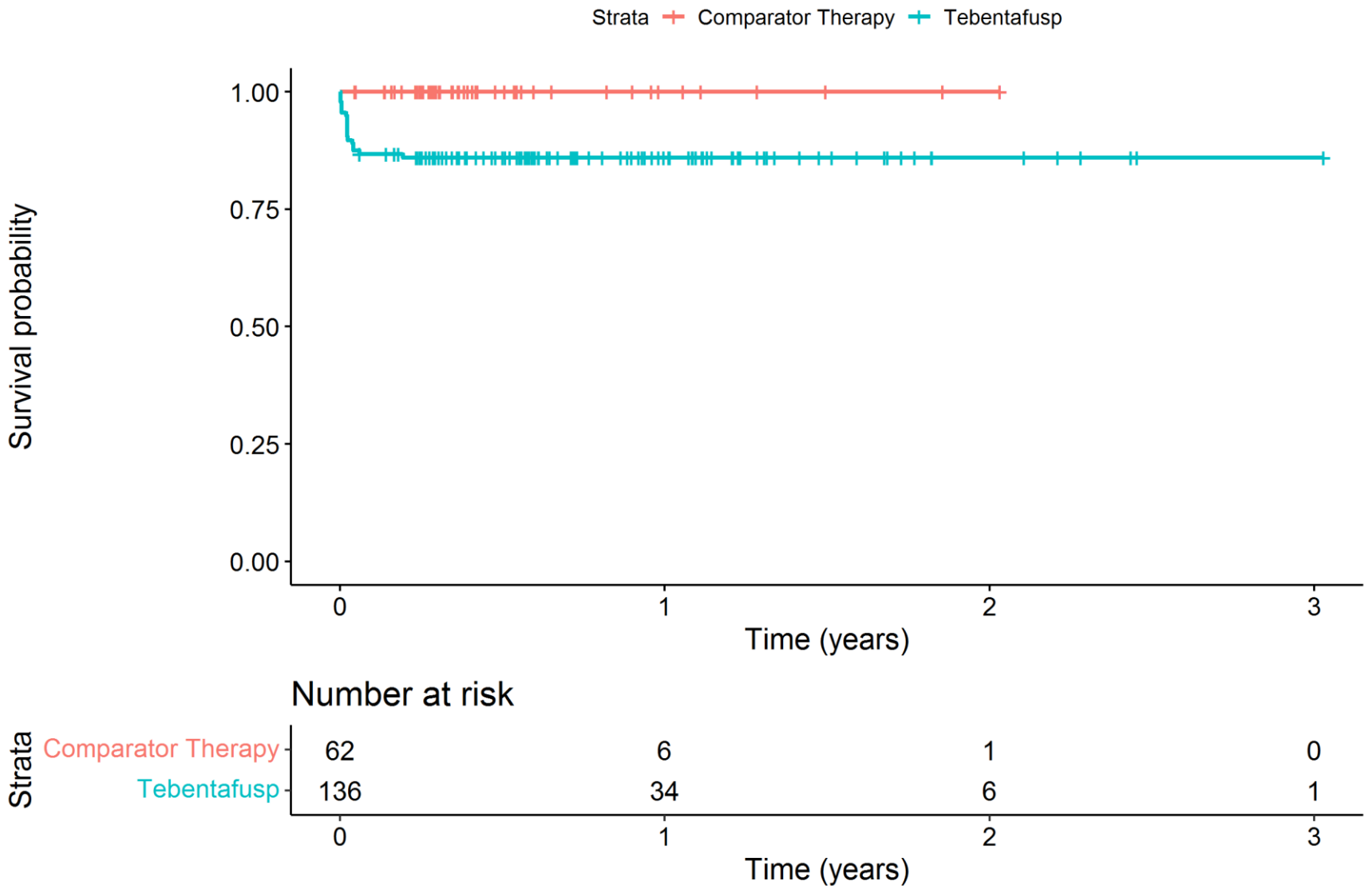
Hautausschlag - Vorherige Therapie adjuvant/neoadjuvant



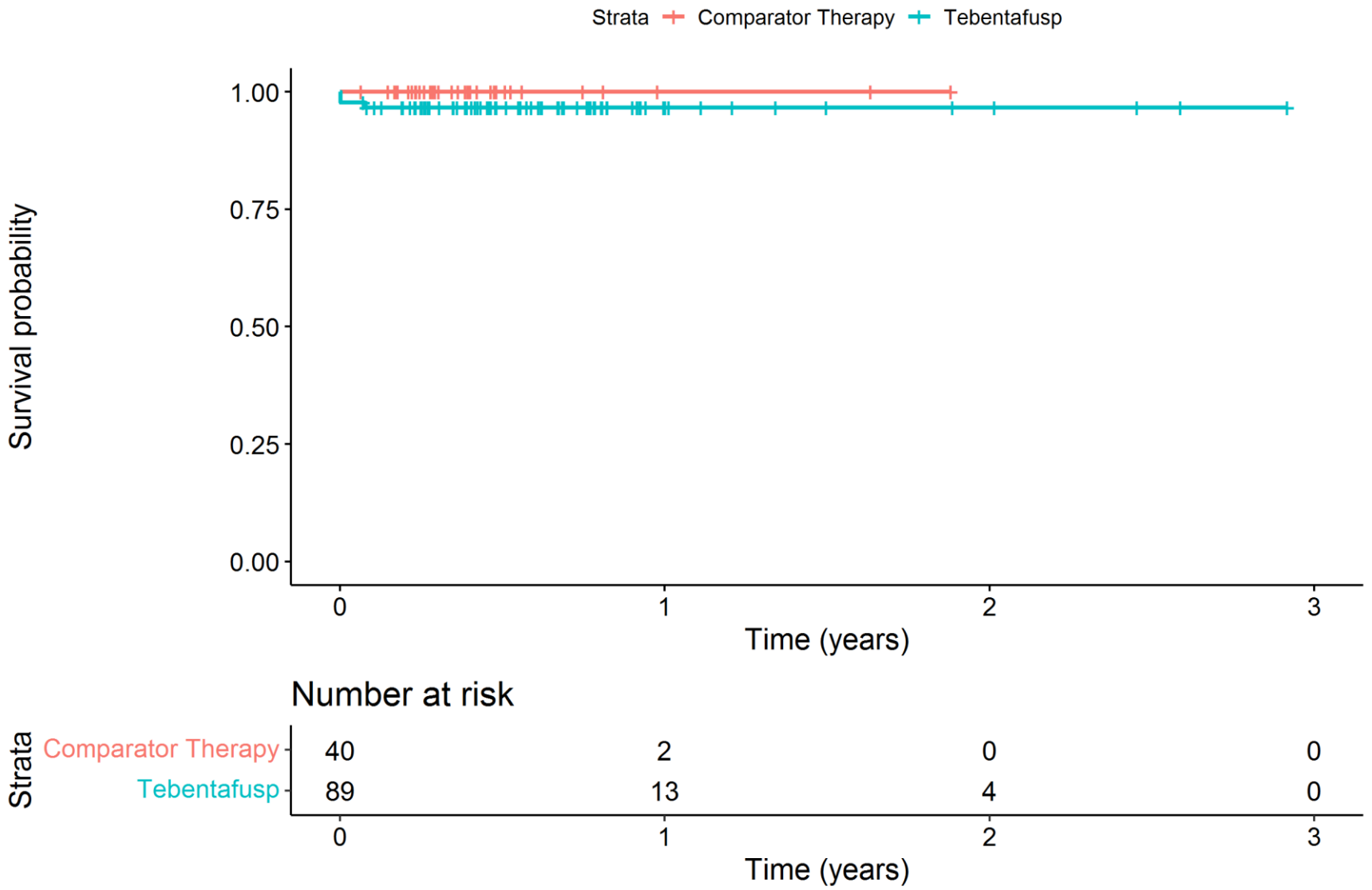
Hautausschlag - Keine vorherige Therapie adjuvant/neoadjuvant



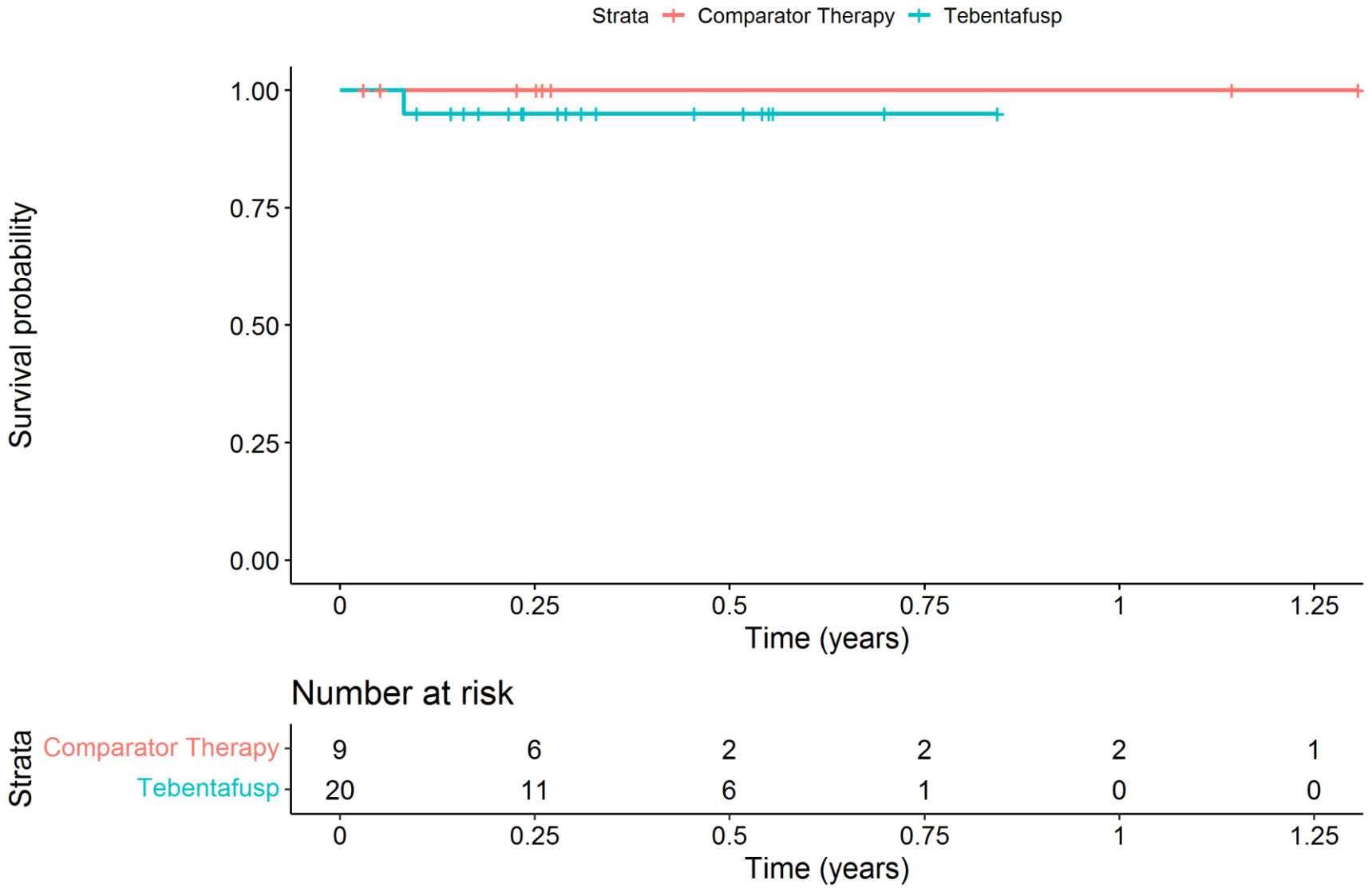
Hautausschlag - Läsion ≤ 3cm



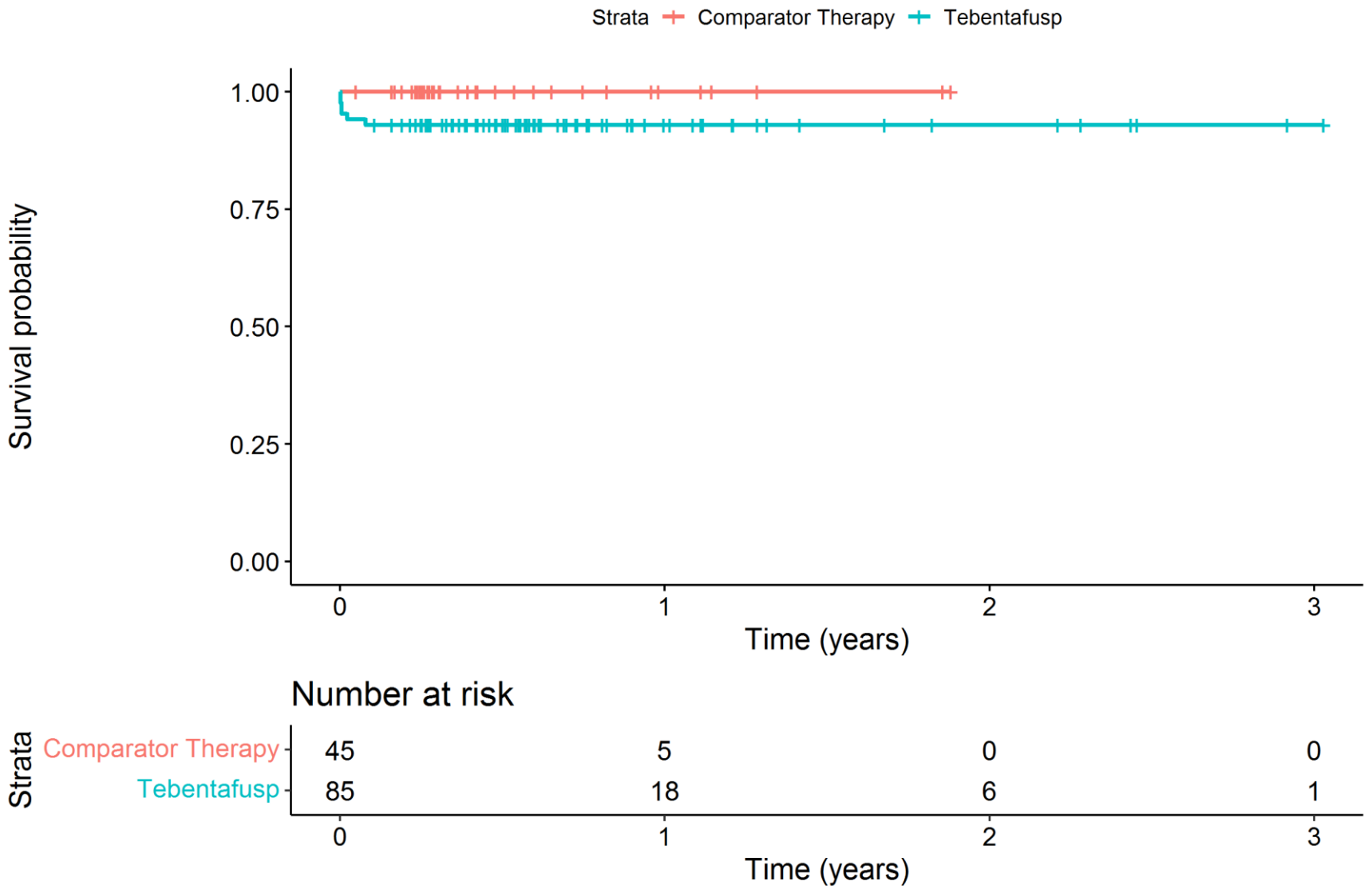
Hautausschlag - Läsion 3,1-8,0 cm



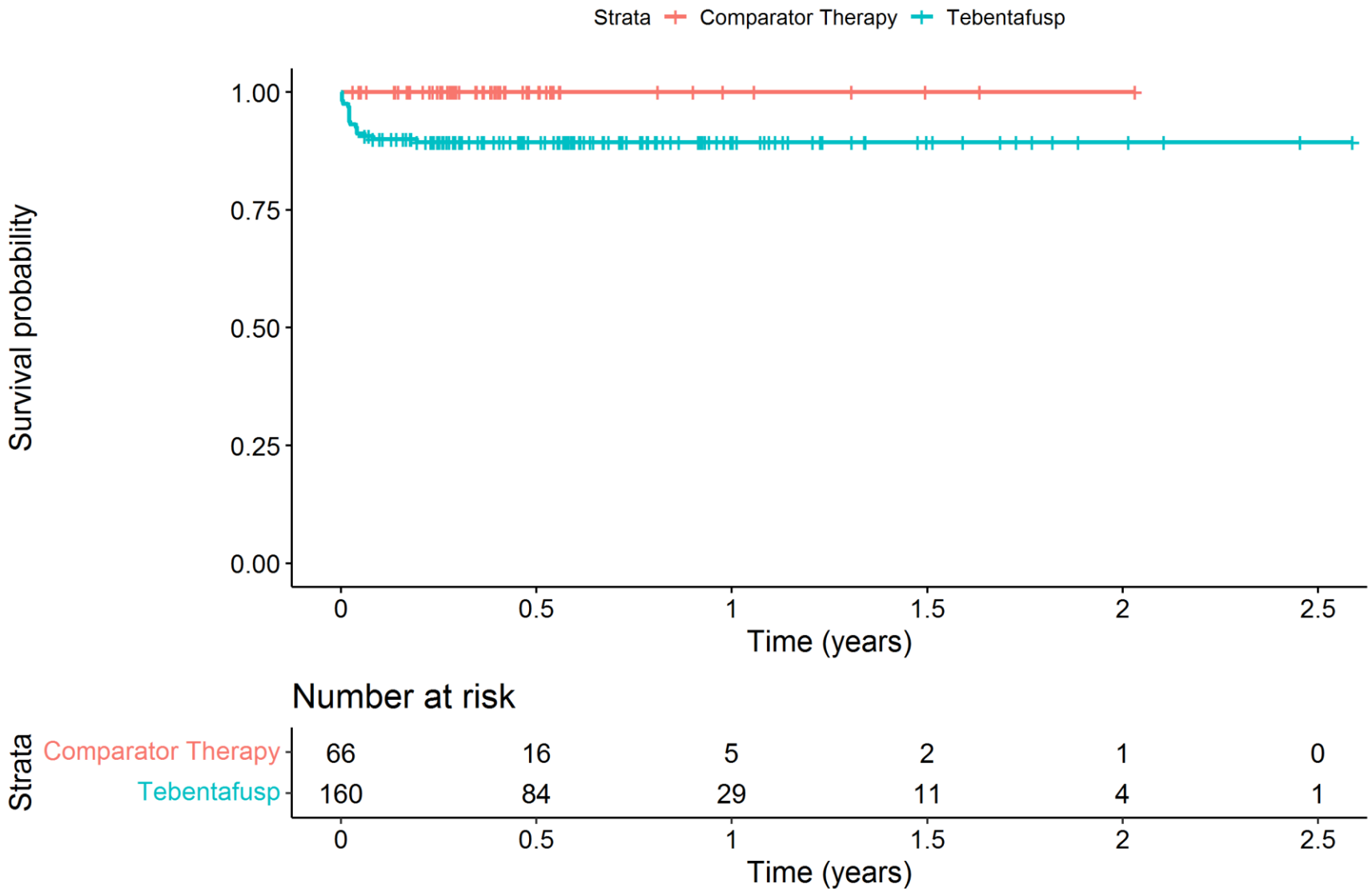
Hautausschlag - Läsion ≥8,1 cm



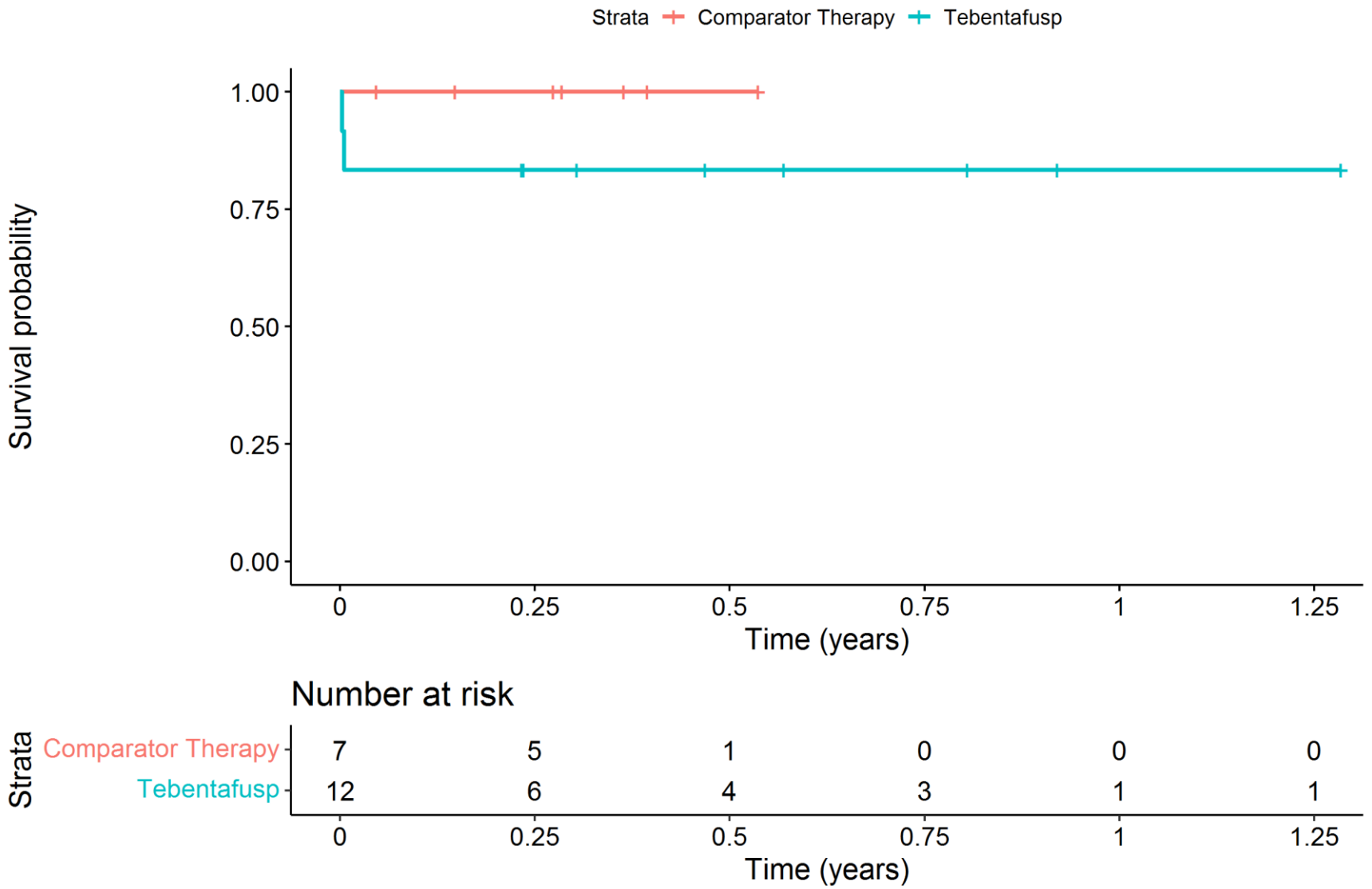
Hautausschlag - Nordamerika



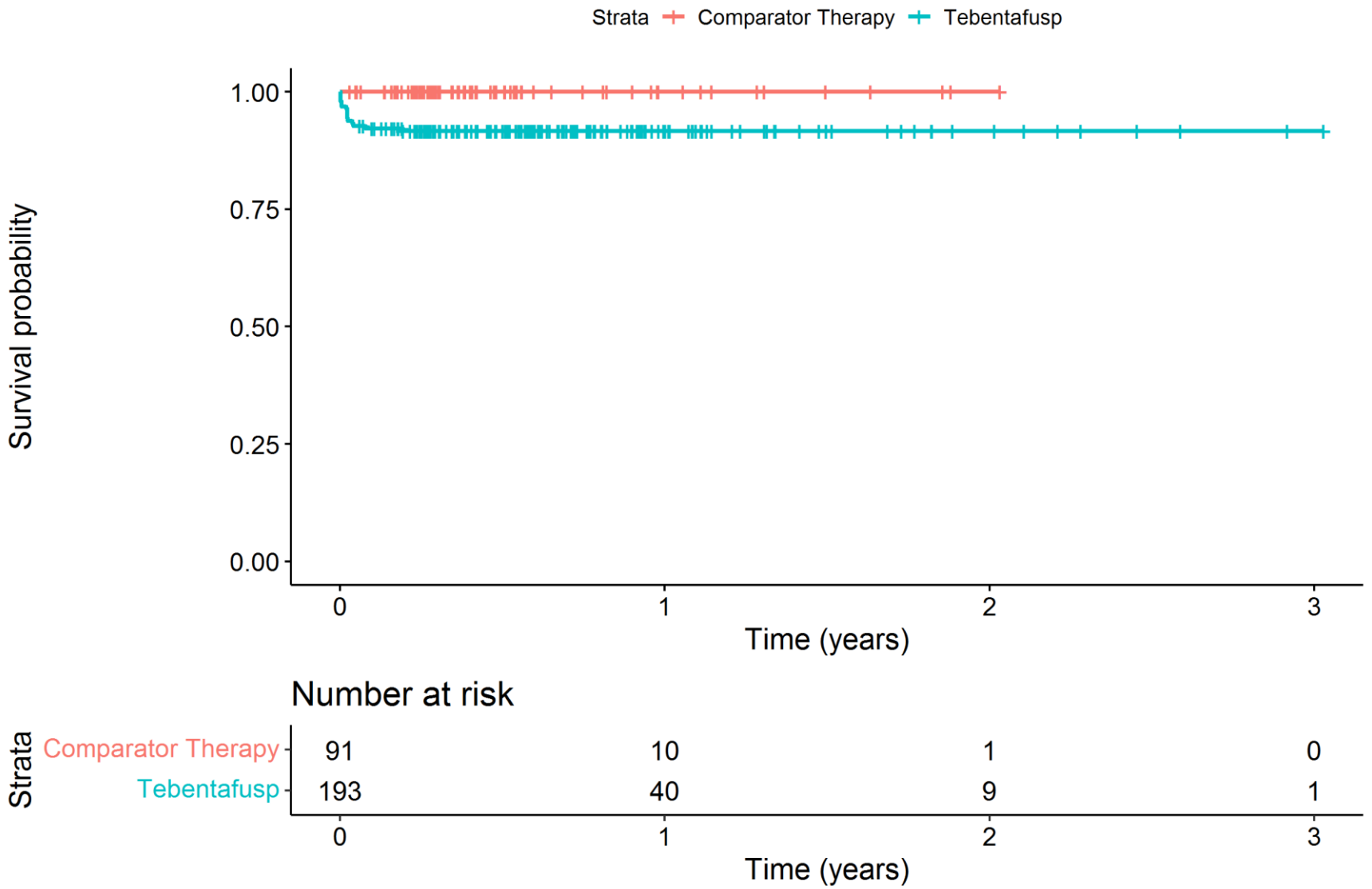
Hautausschlag - Nicht-Nordamerika



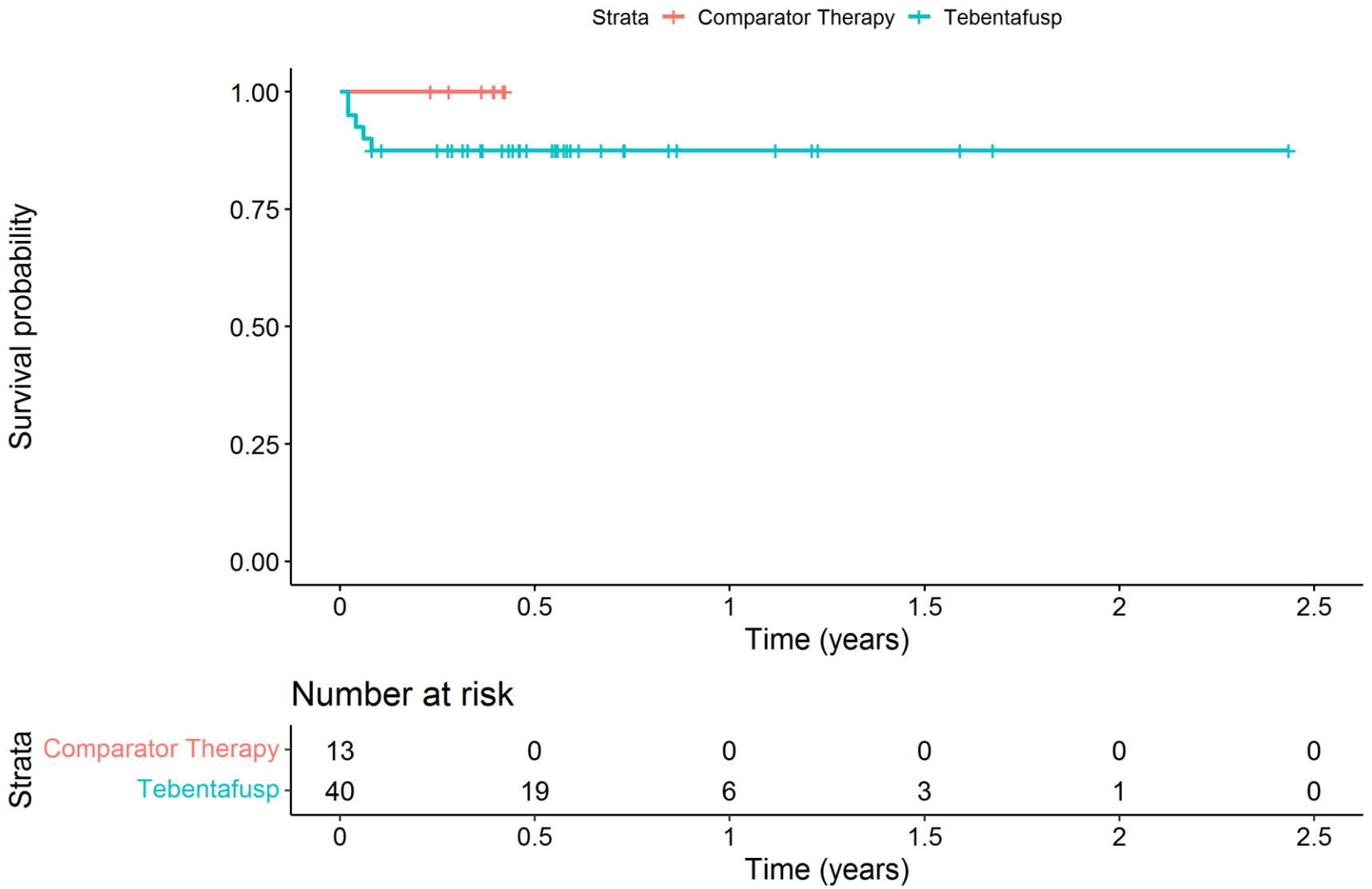
Hautausschlag - Dacarbazin



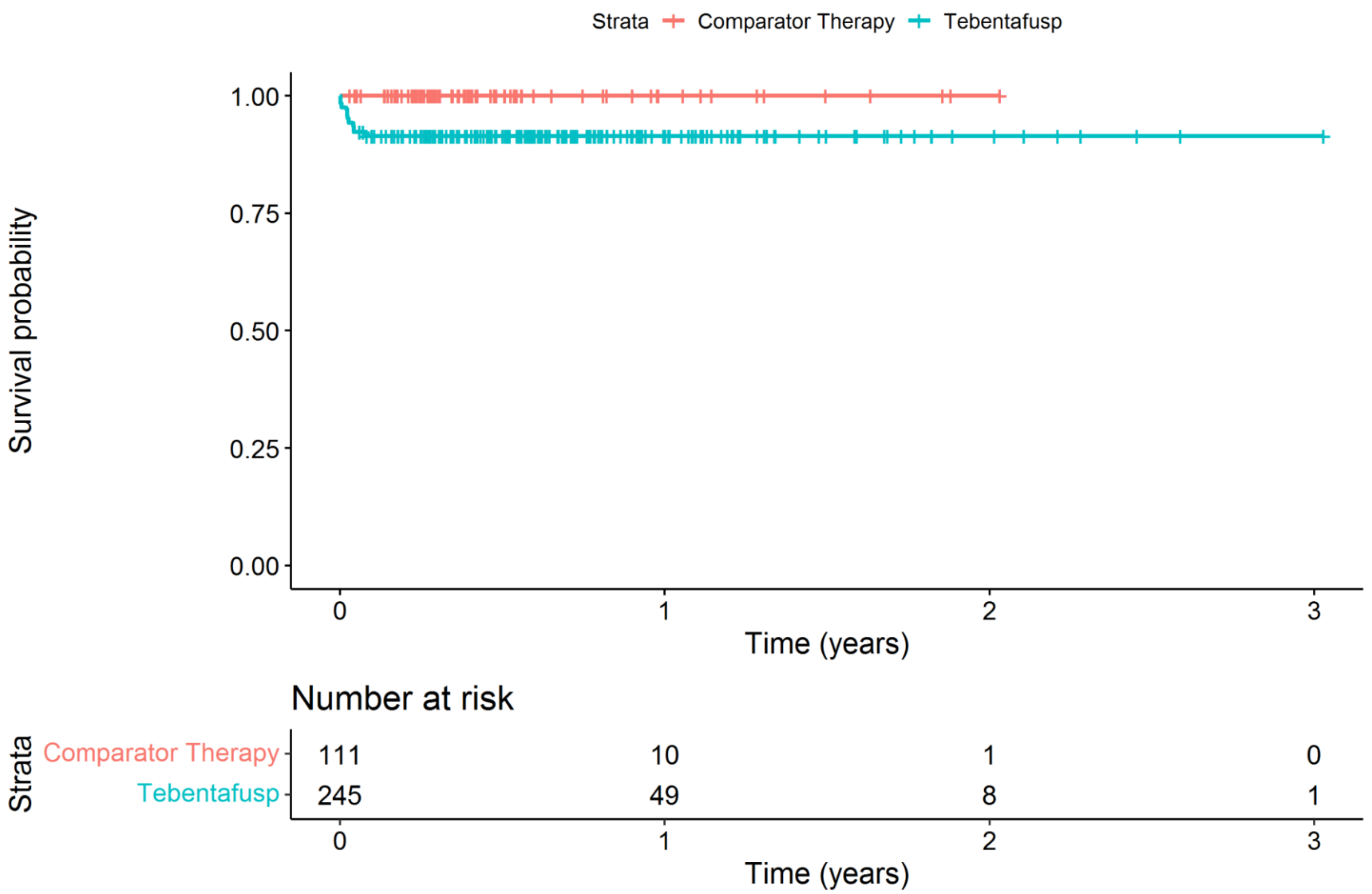
Hautausschlag - Pembrolizumab



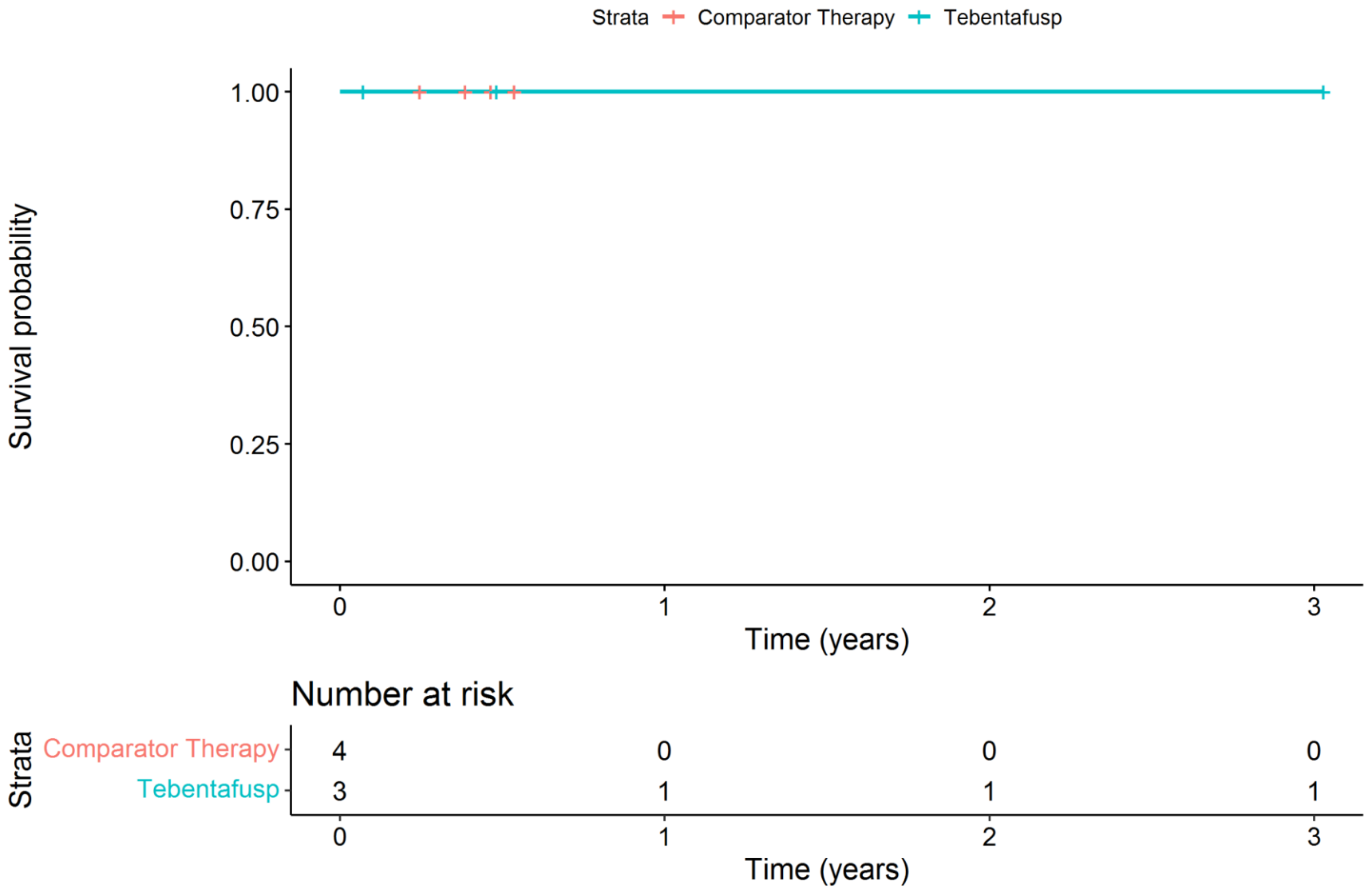
Hautausschlag - Ipilimumab



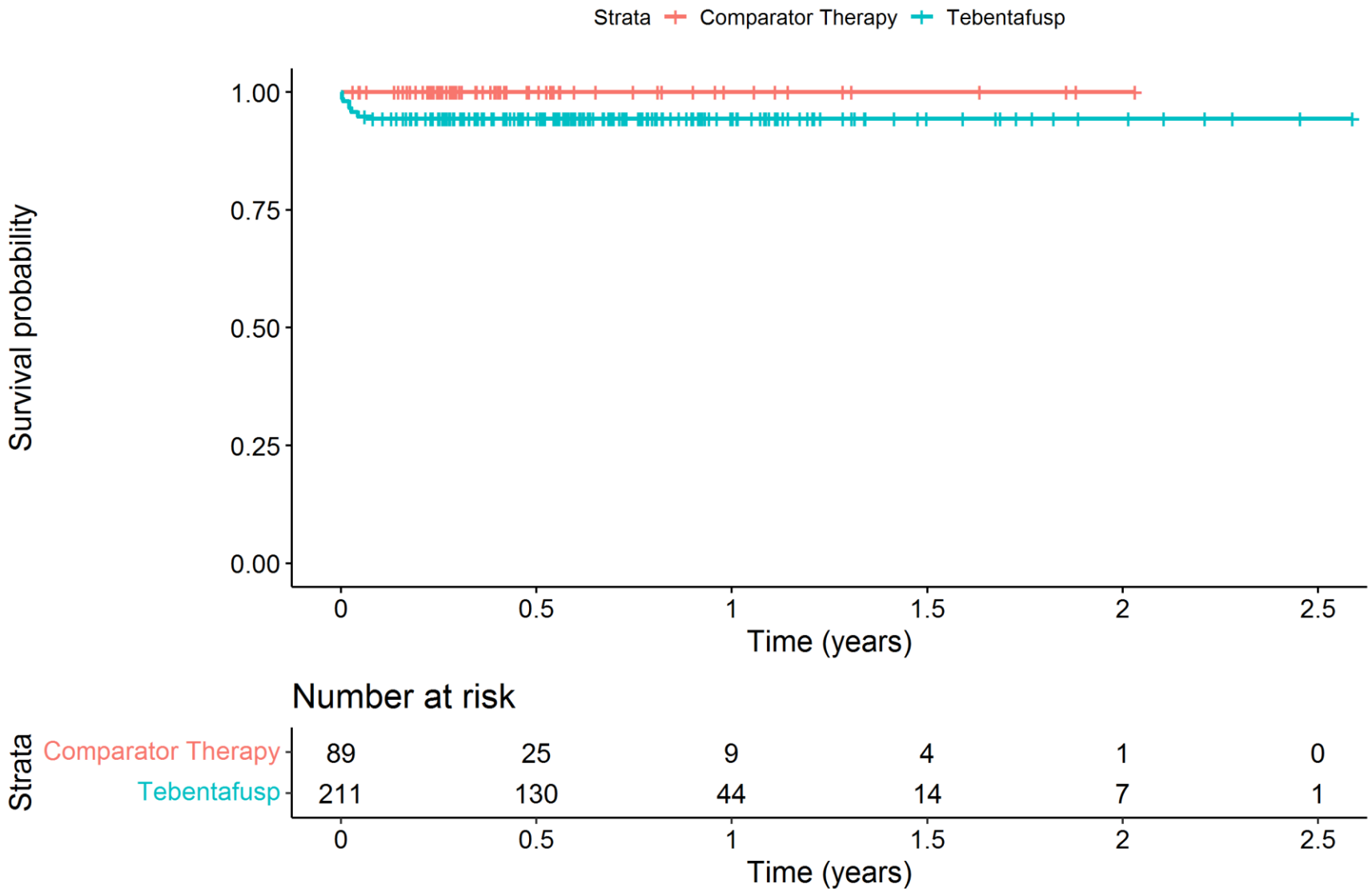
Makulo-papulöser Hautausschlag - Gesamt



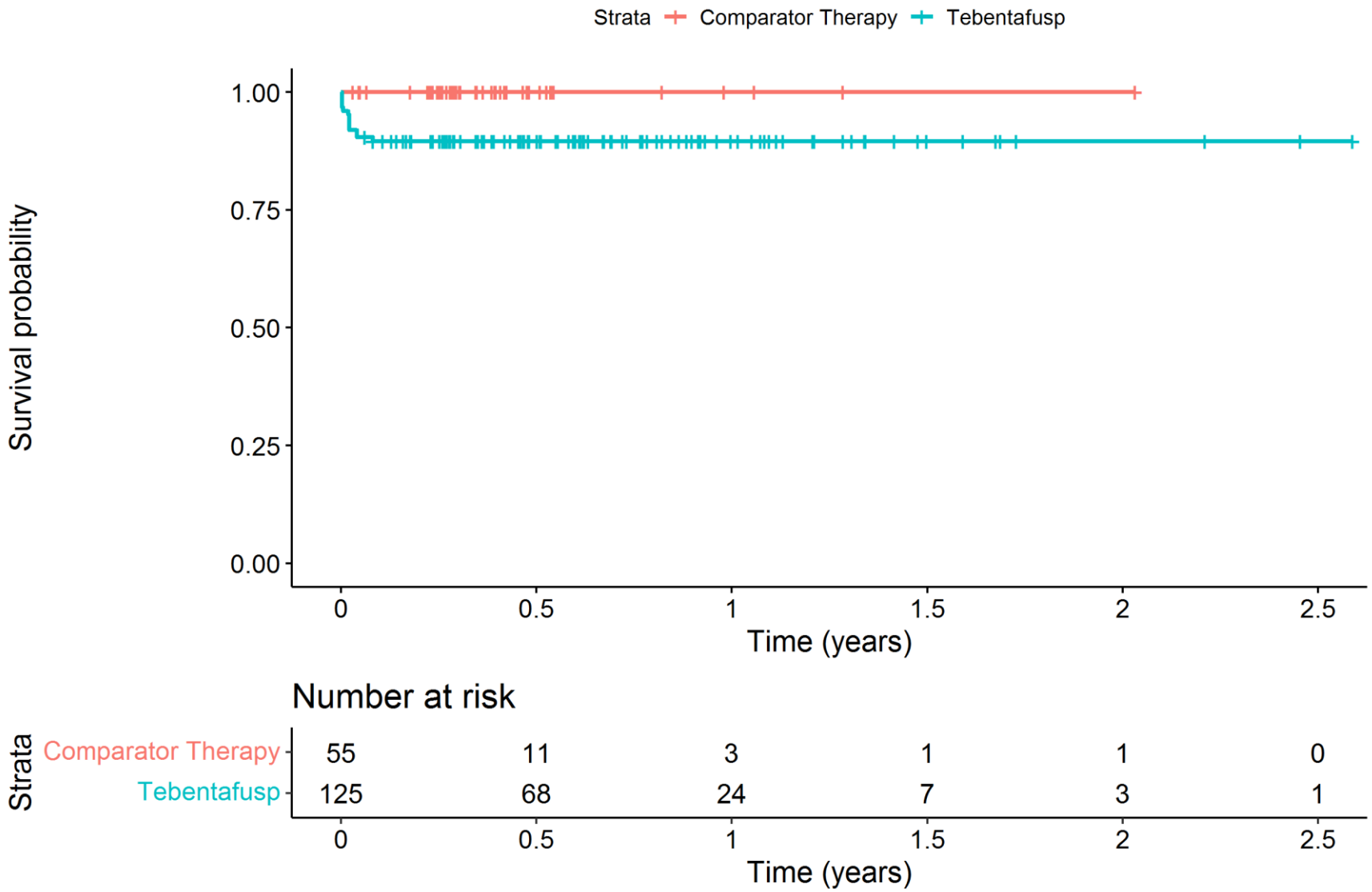
Makulo-papulöser Hautausschlag - Hispanisch



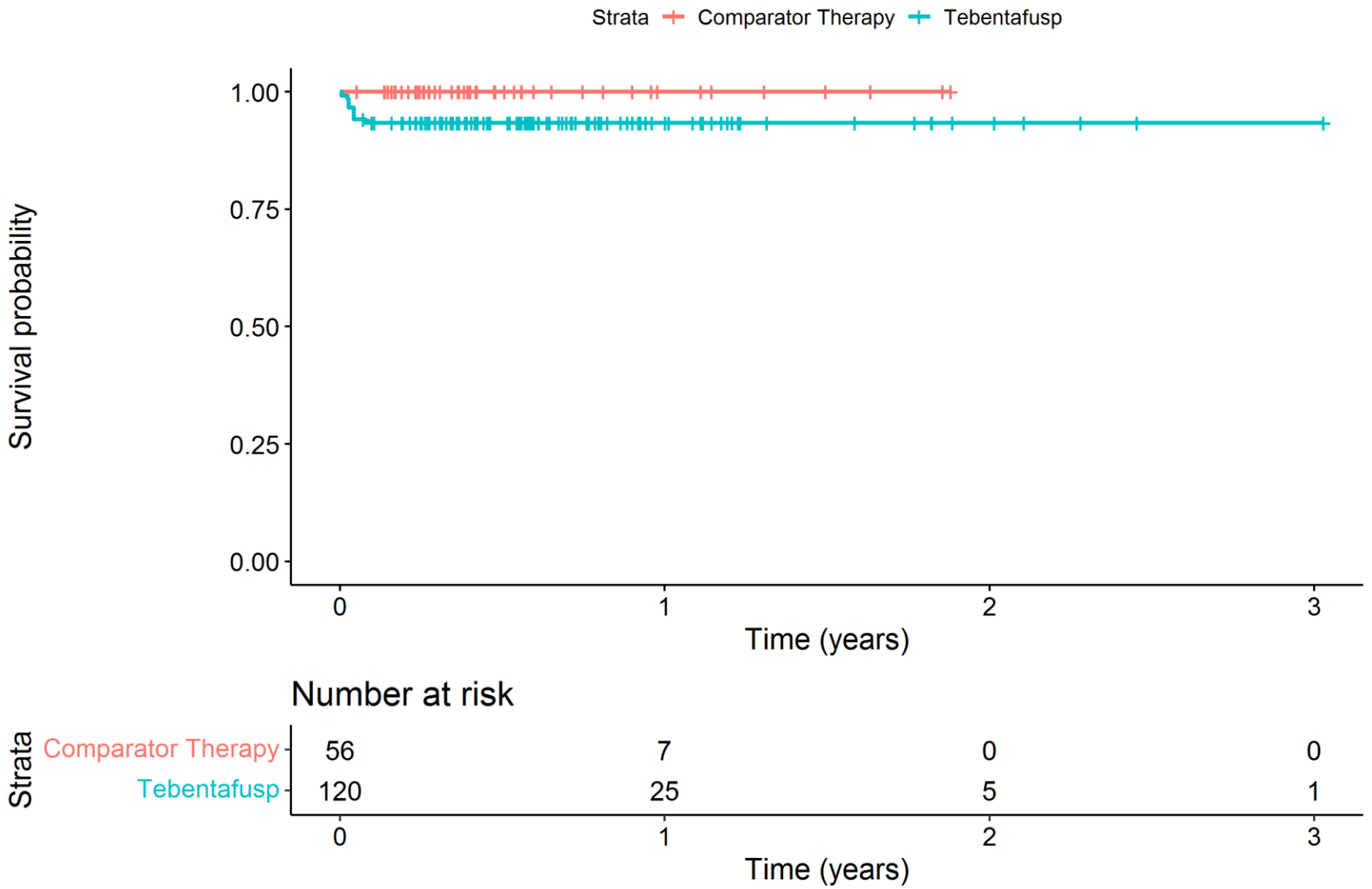
Makulo-papulöser Hautausschlag - Nicht-hispanisch



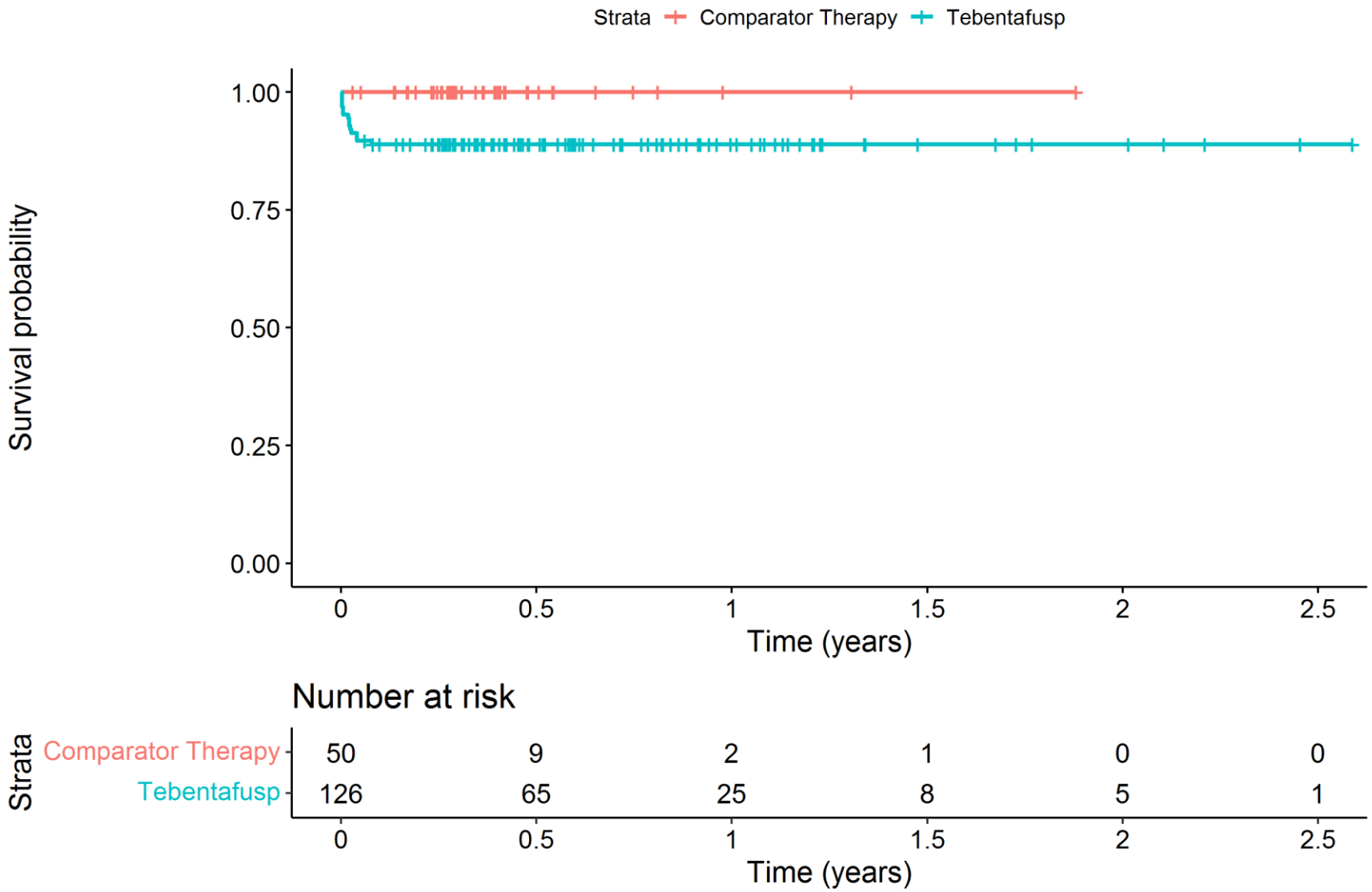
Makulo-papulöser Hautausschlag - Männlich



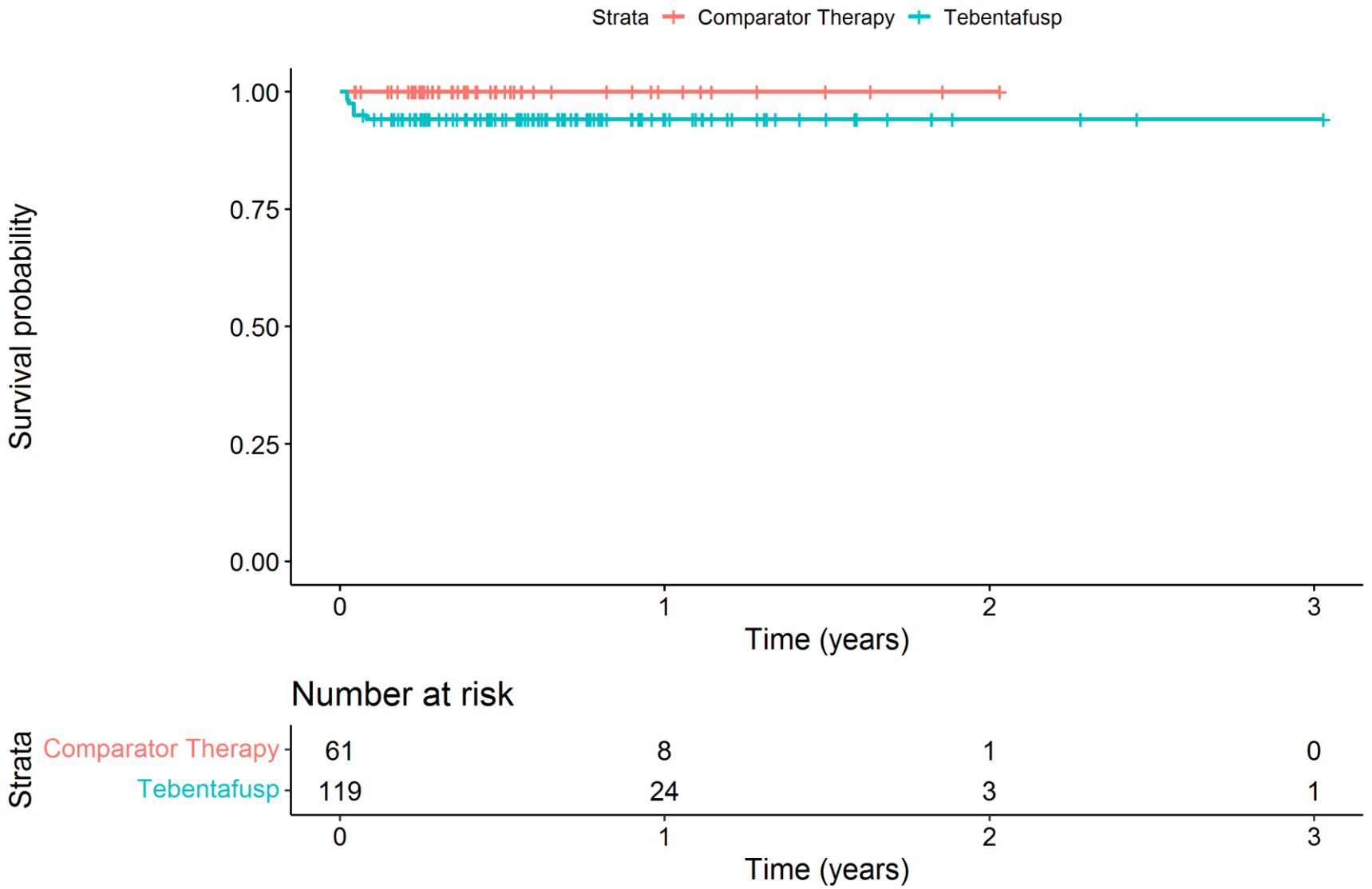
Makulo-papulöser Hautausschlag - Weiblich



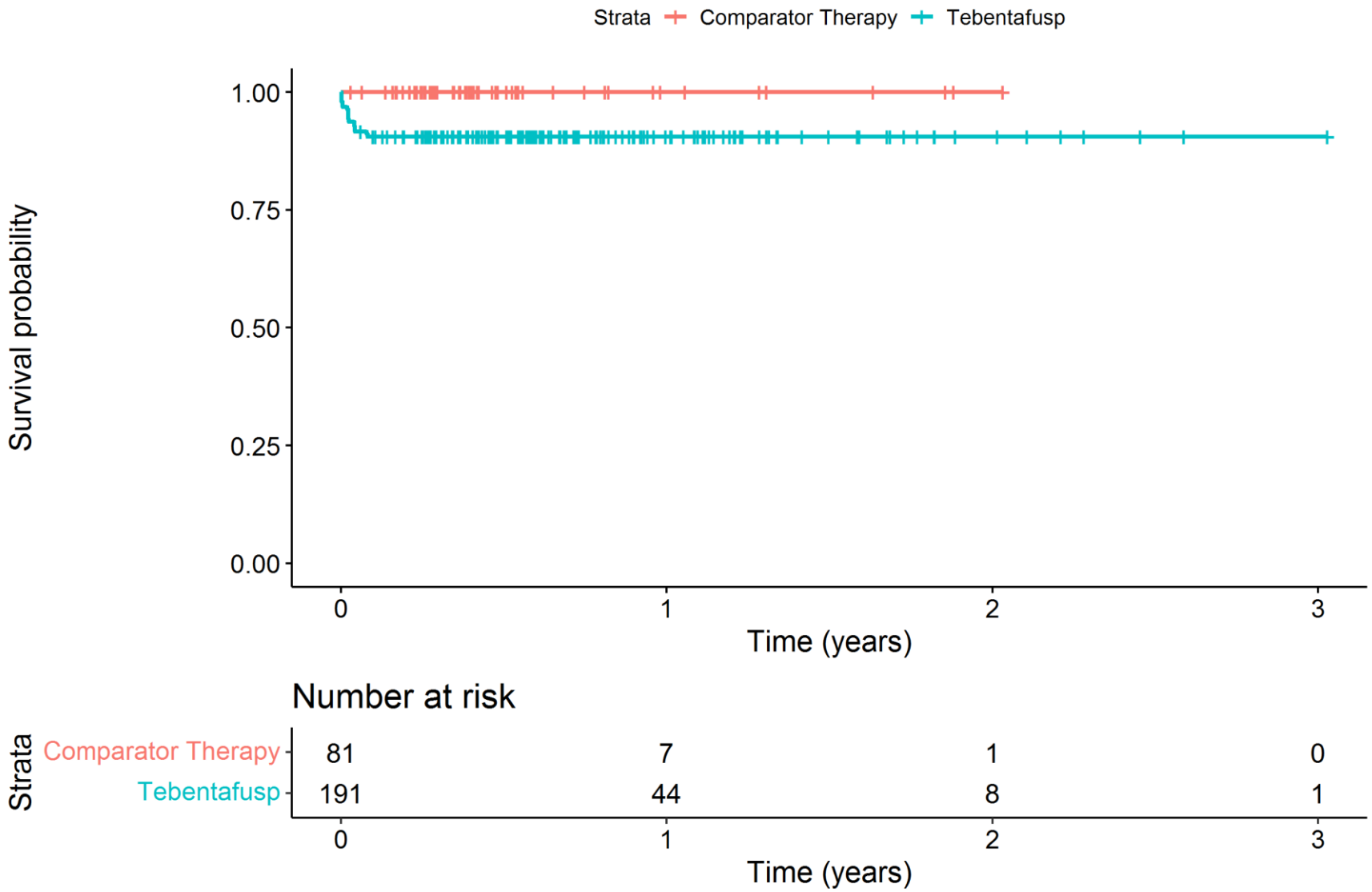
Makulo-papulöser Hautausschlag - <65



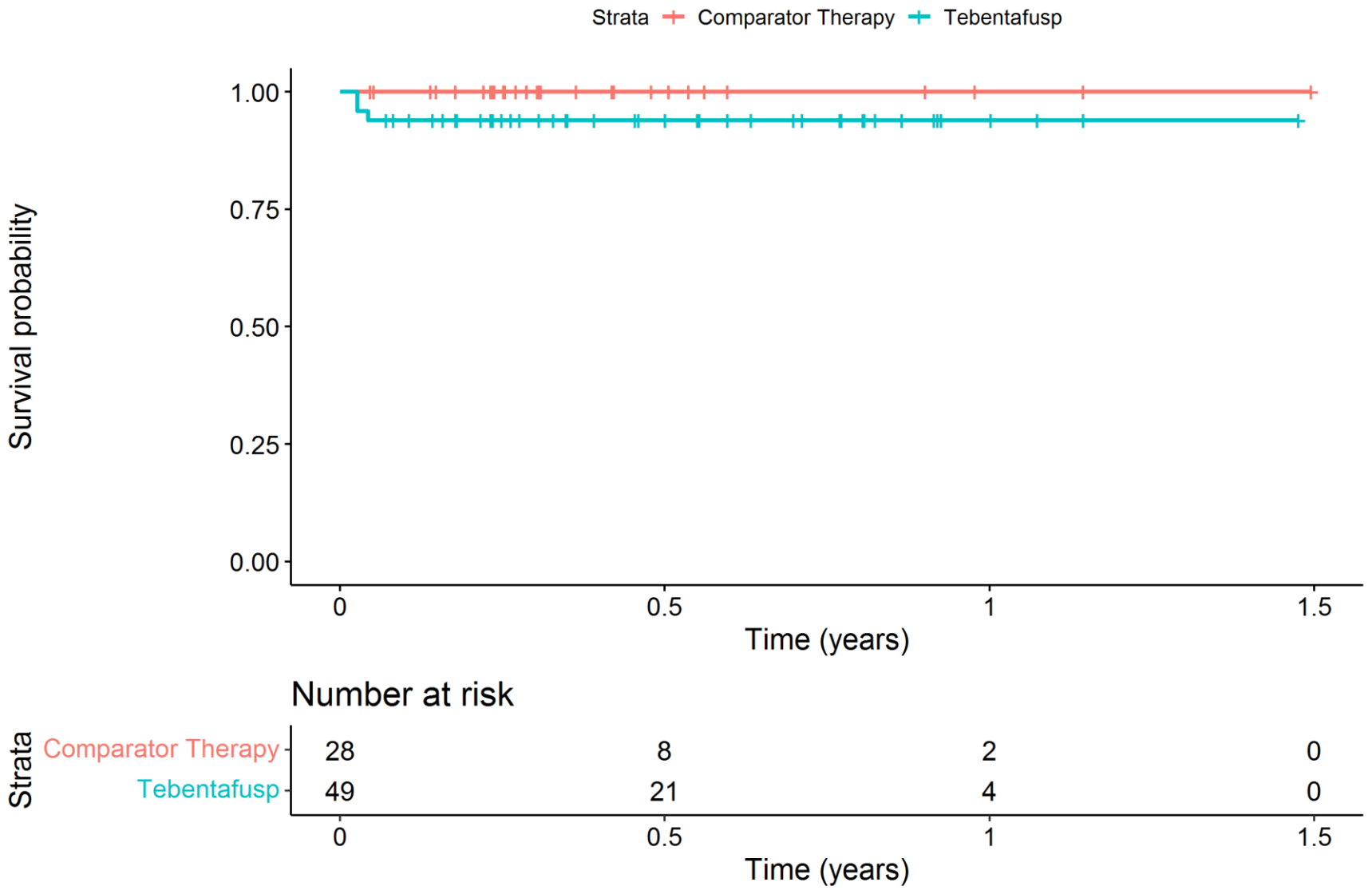
Makulo-papulöser Hautausschlag - ≥65



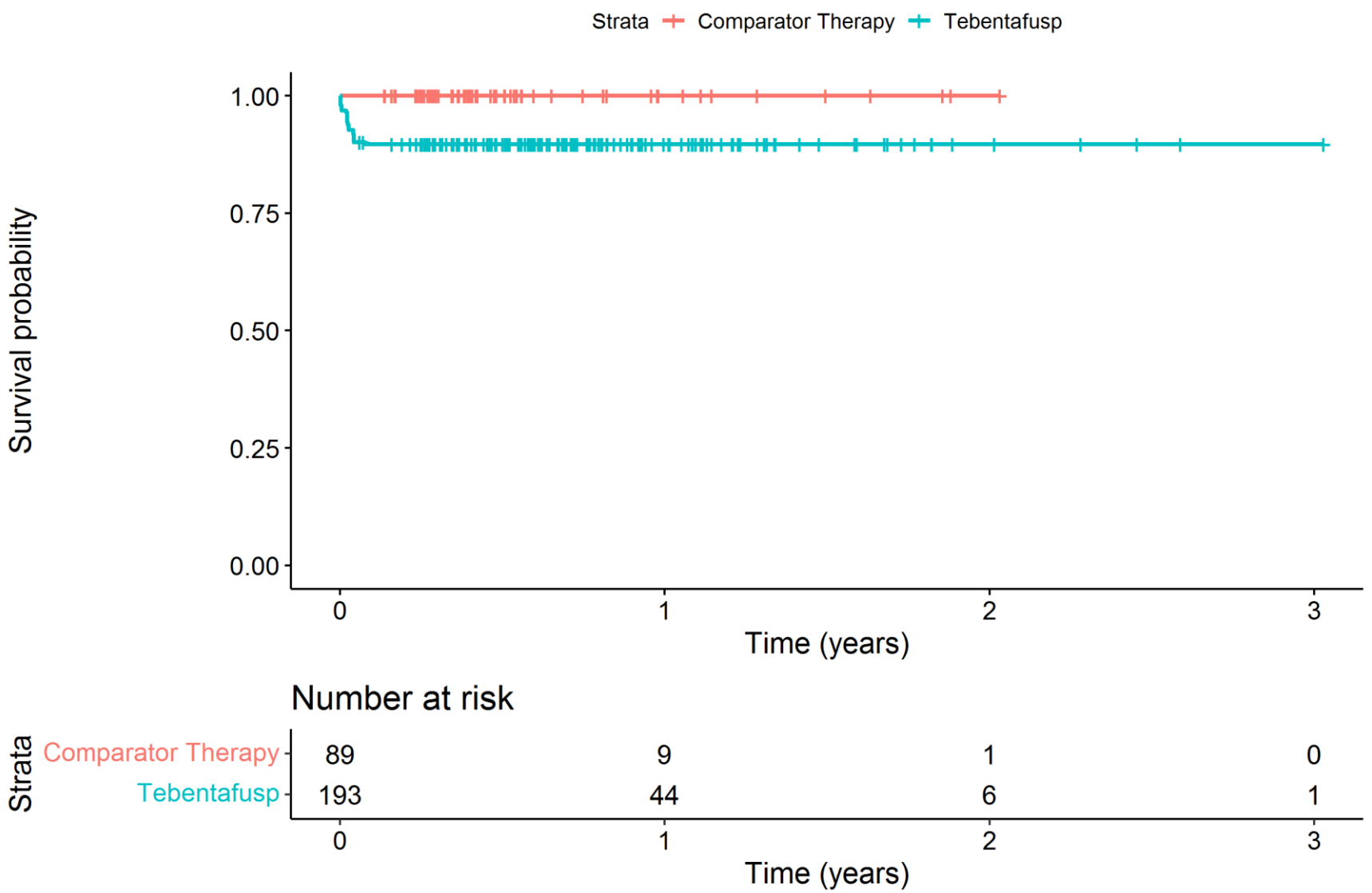
Makulo-papulöser Hautausschlag - ECOG 0



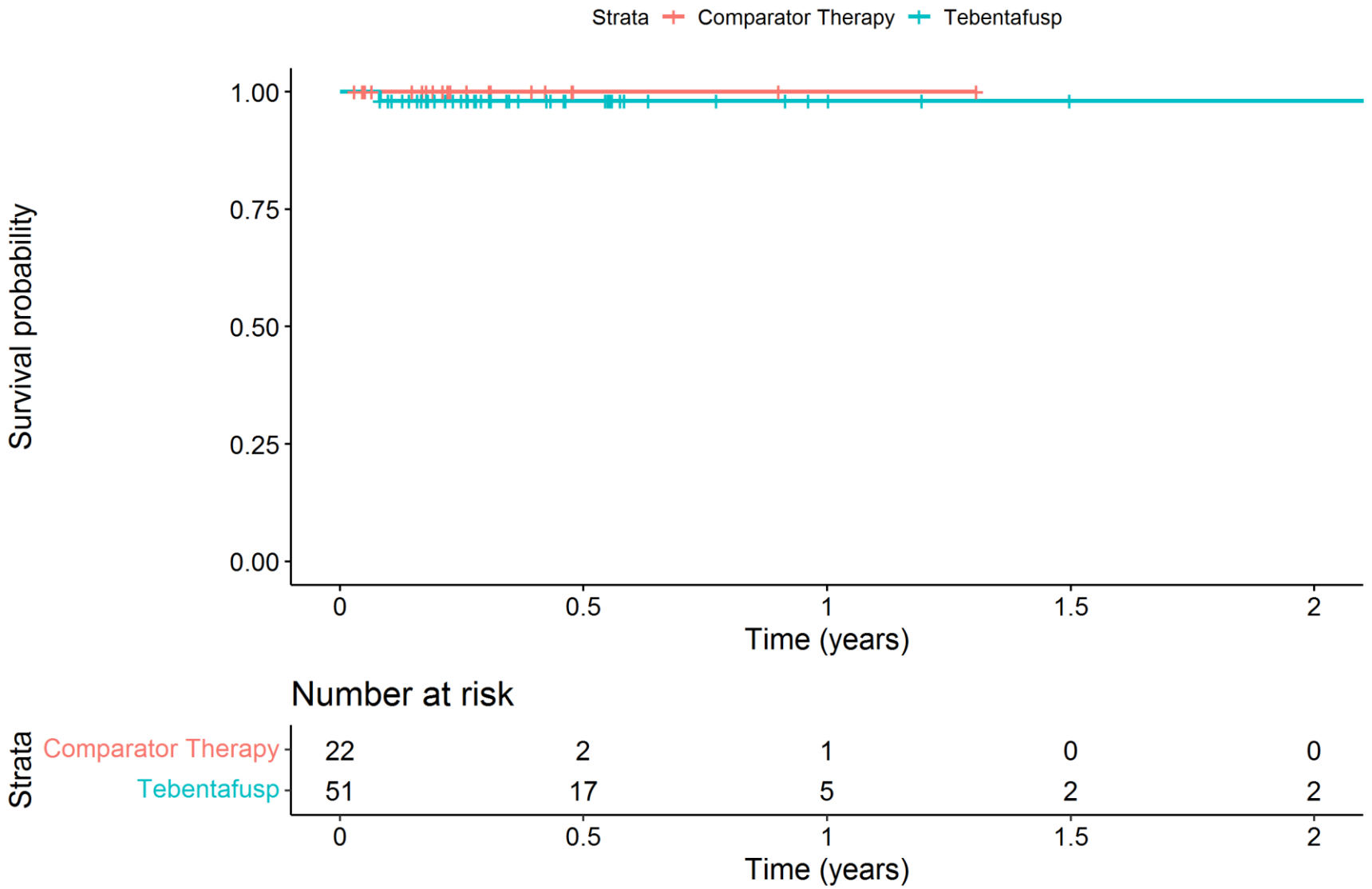
Makulo-papulöser Hautausschlag - ECOG 1



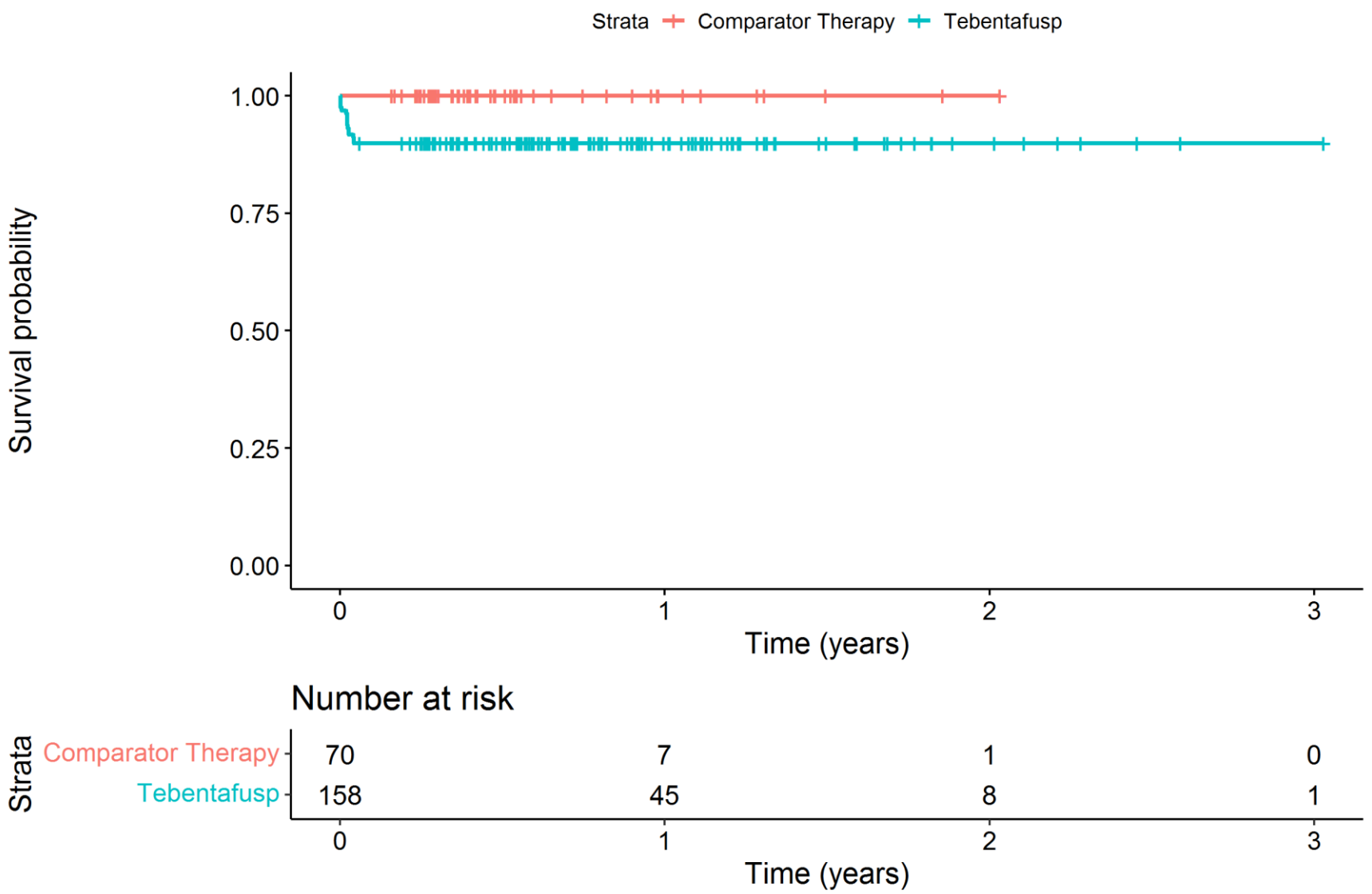
Makulo-papulöser Hautausschlag - ALP ≤ ULN



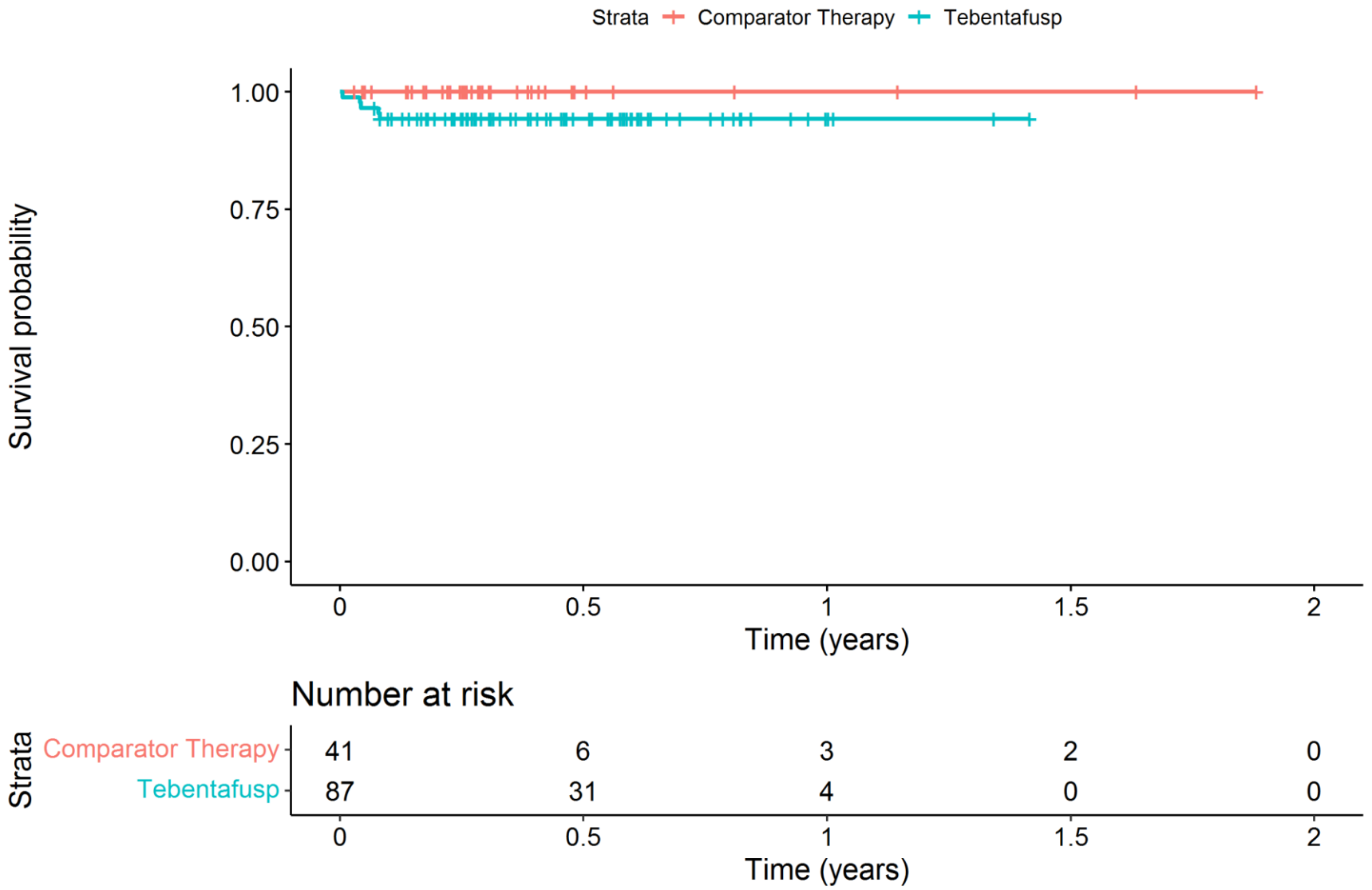
Makulo-papulöser Hautausschlag - ALP > ULN



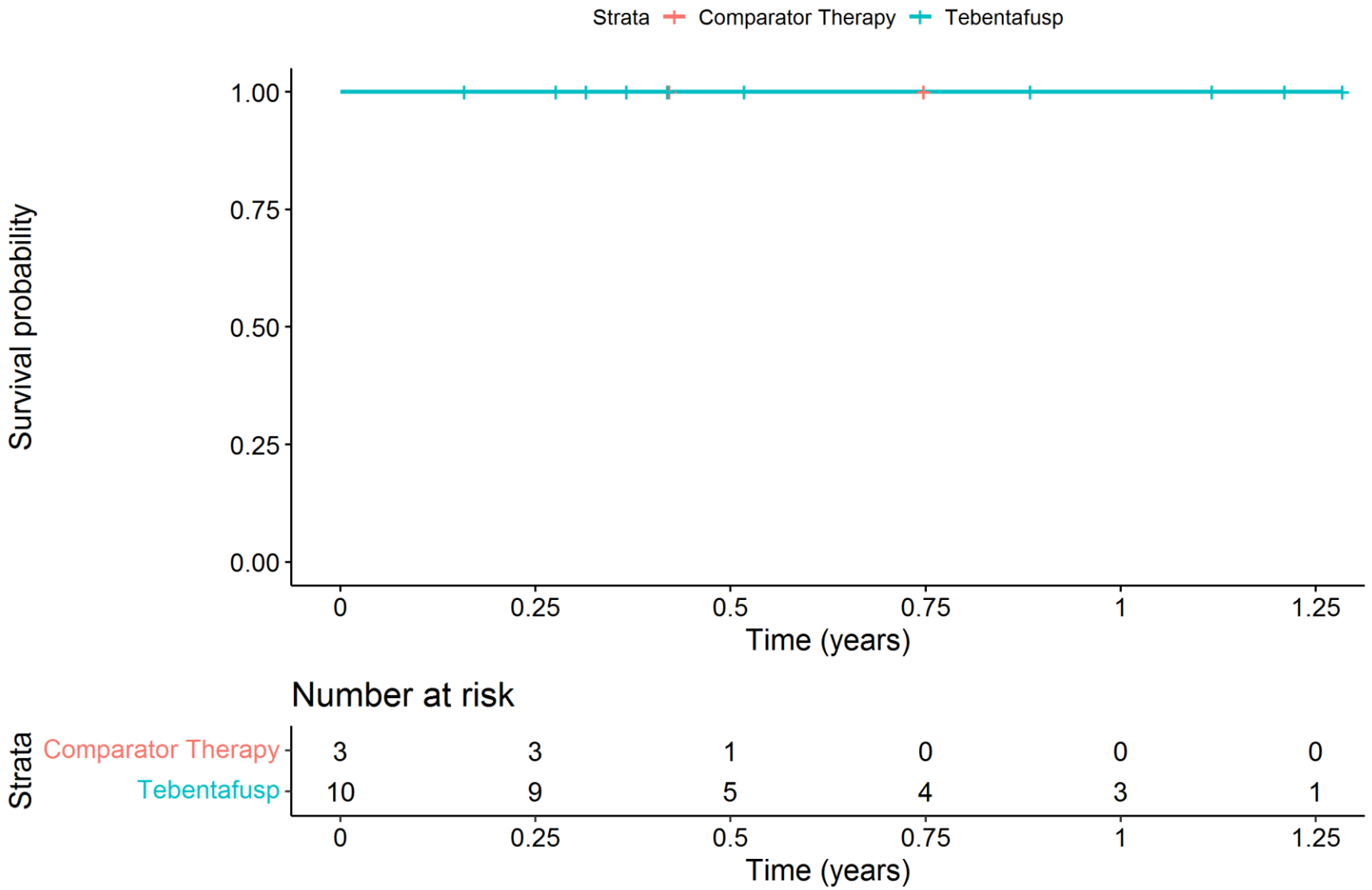
Makulo-papulöser Hautausschlag - LDH =< ULN



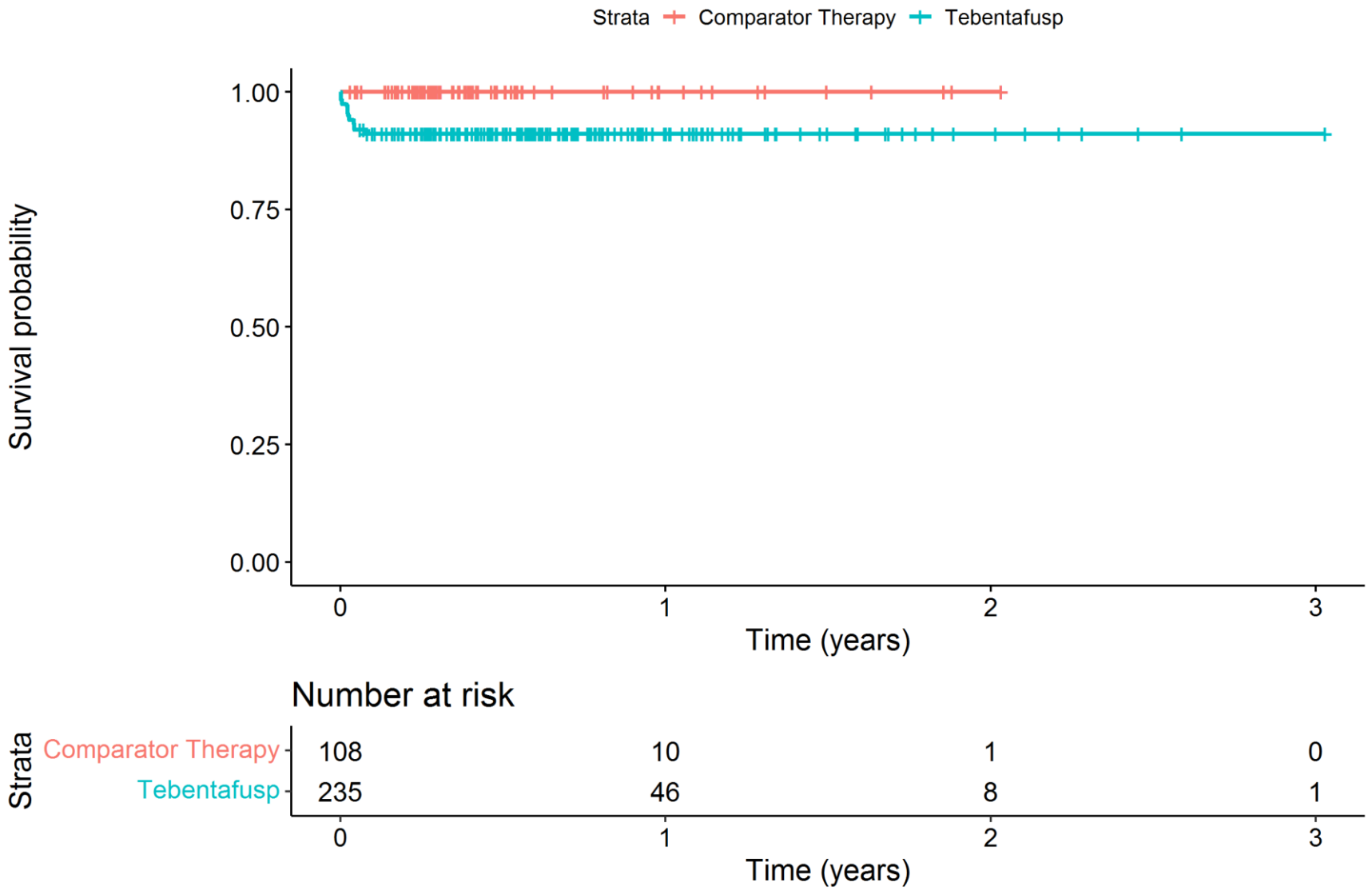
Makulo-papulöser Hautausschlag - LDH > ULN



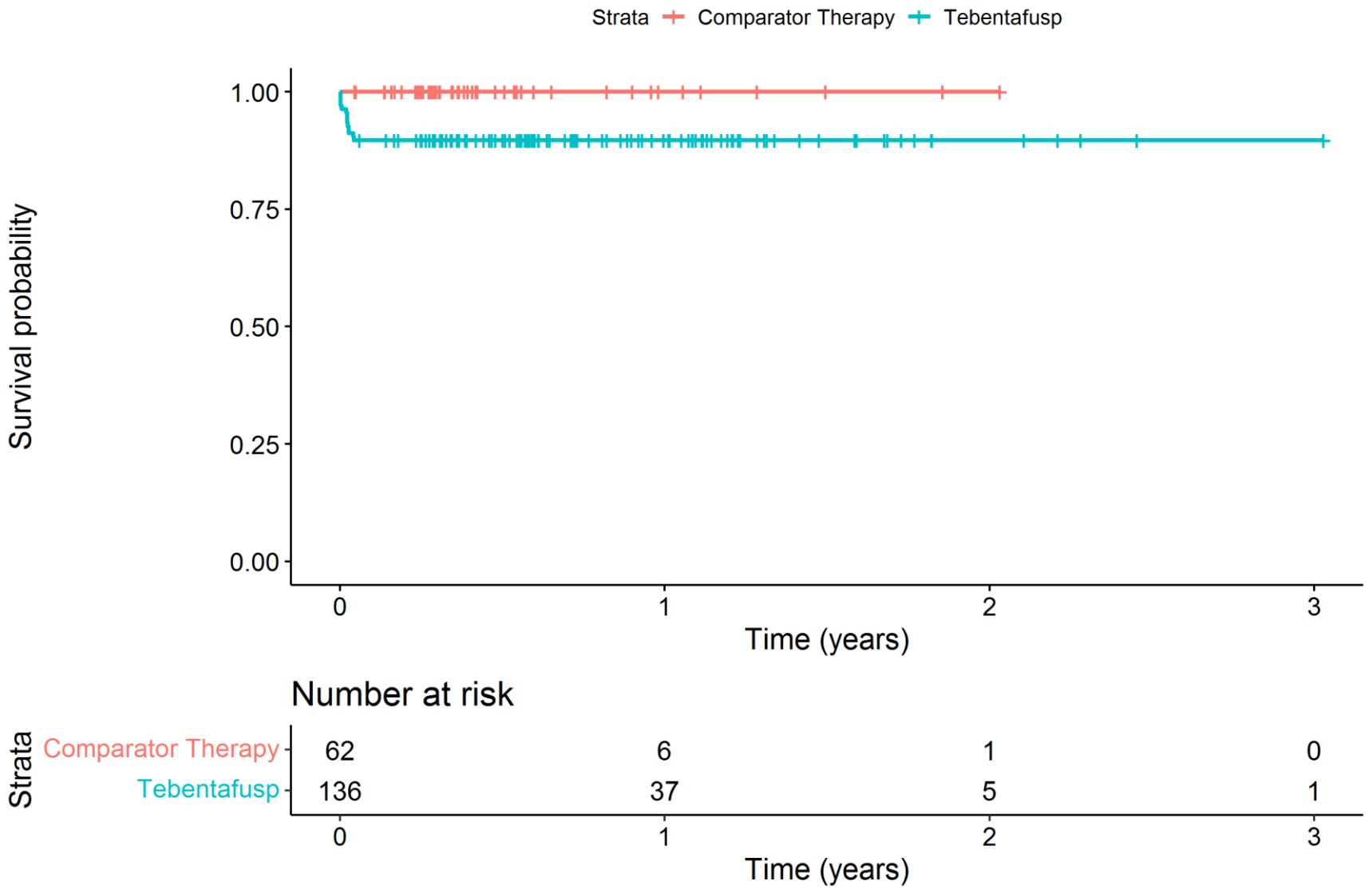
Makulo-papulöser Hautausschlag - Vorherige Therapie adjuvant/neoadjuvant



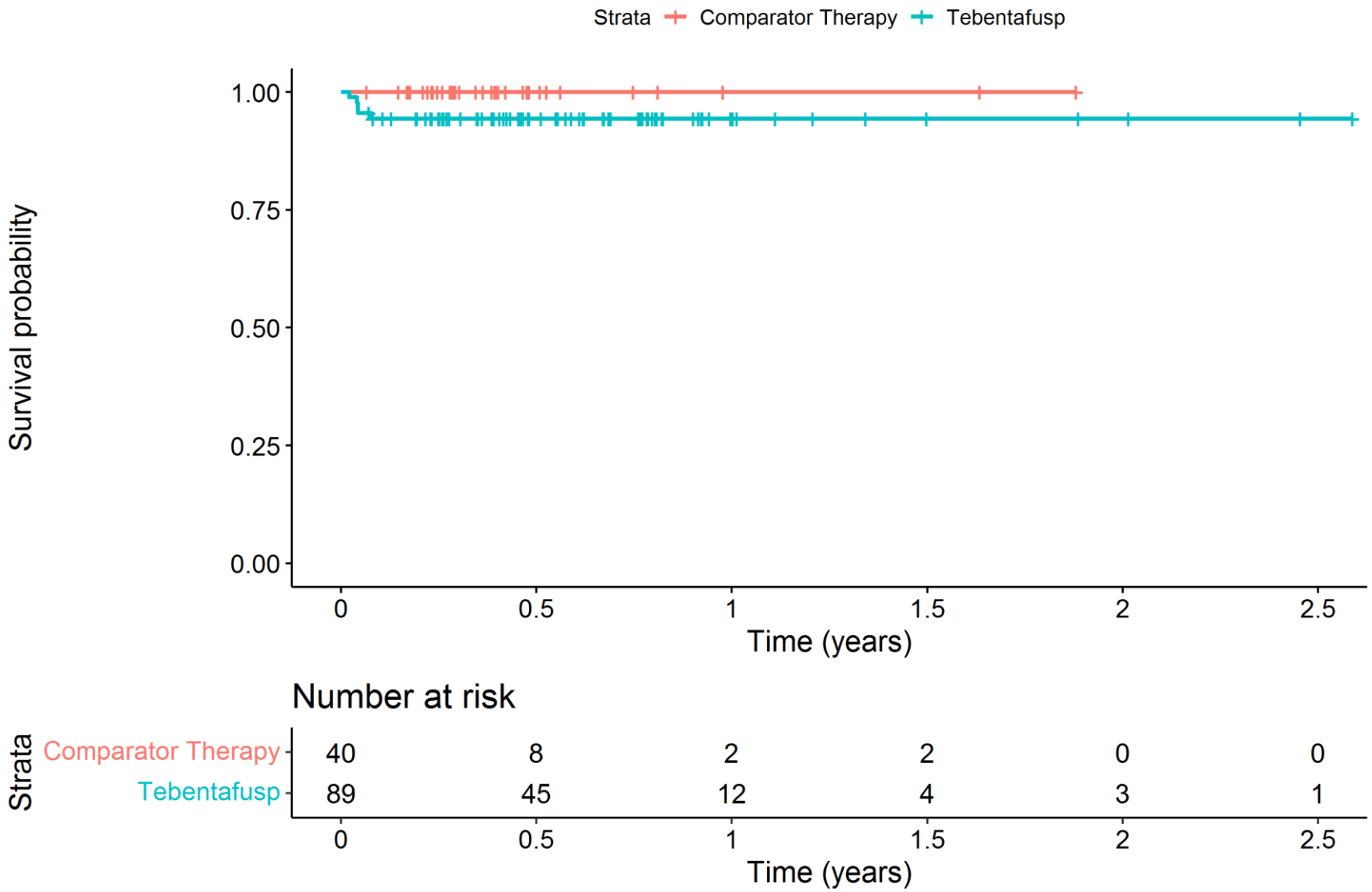
Makulo-papulöser Hautausschlag - Keine vorherige Therapie adjuvant/neoadjuvant



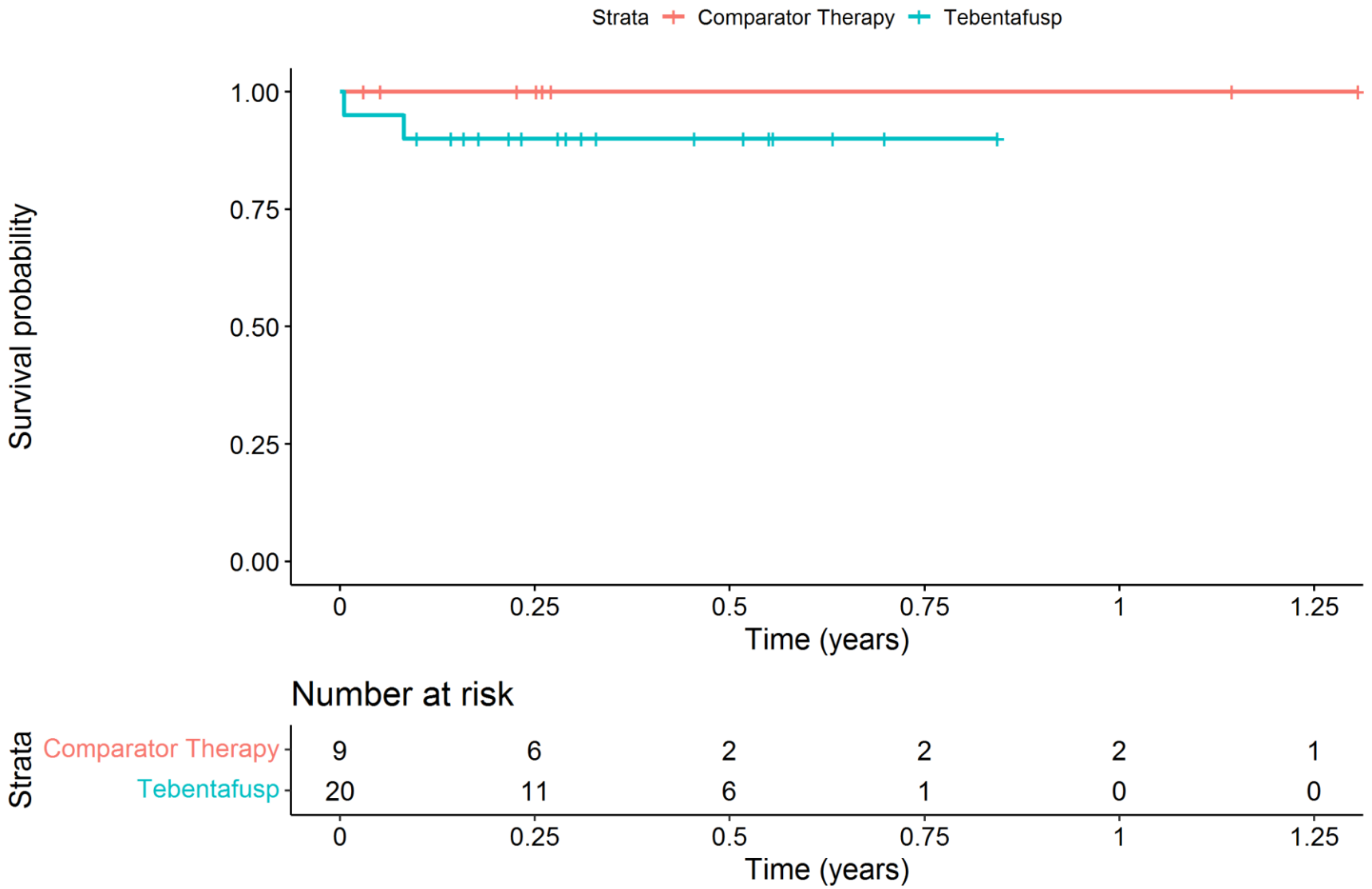
Makulo-papulöser Hautausschlag - Läsion ≤ 3cm



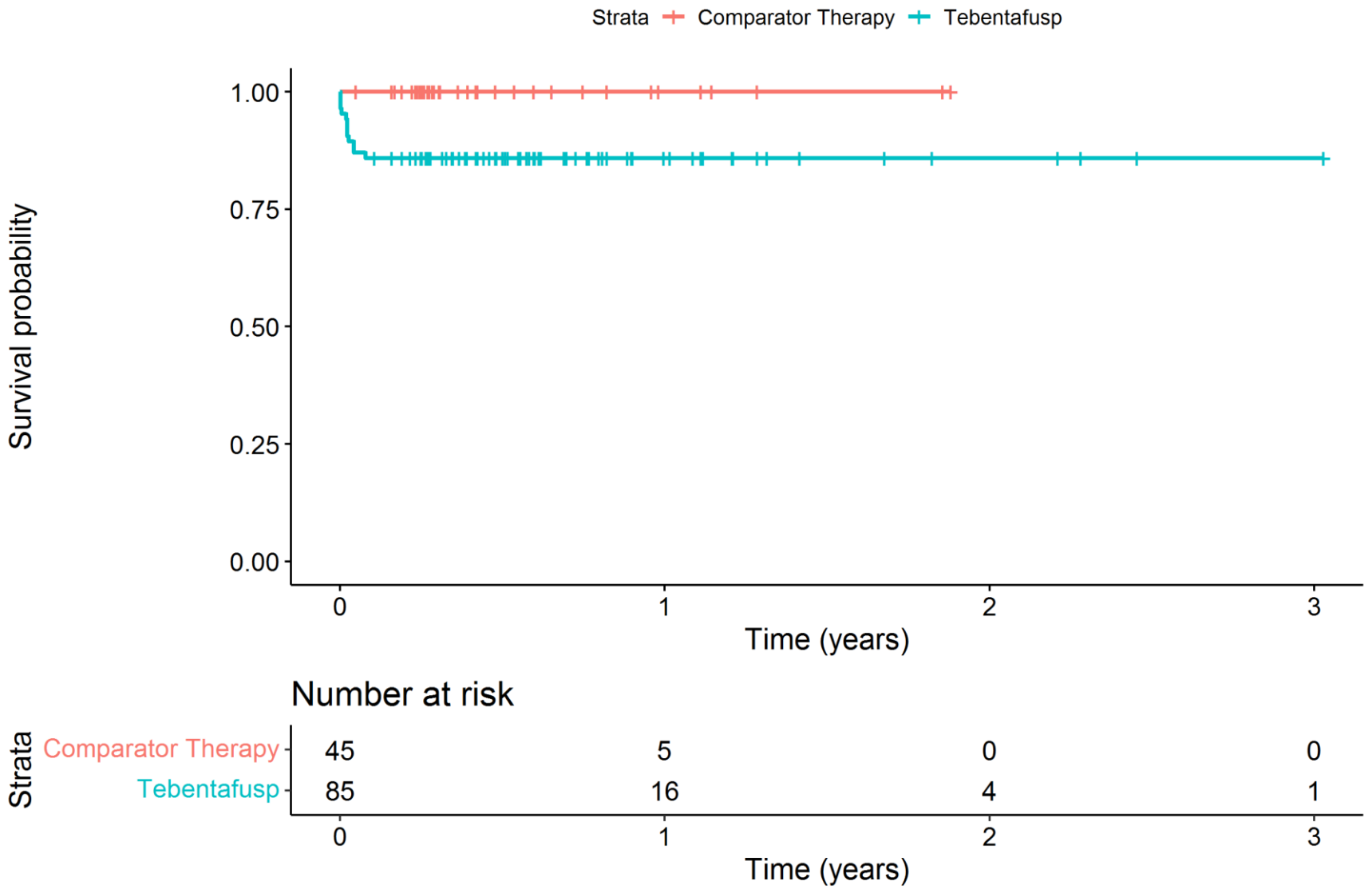
Makulo-papulöser Hautausschlag - Läsion 3,1-8,0 cm



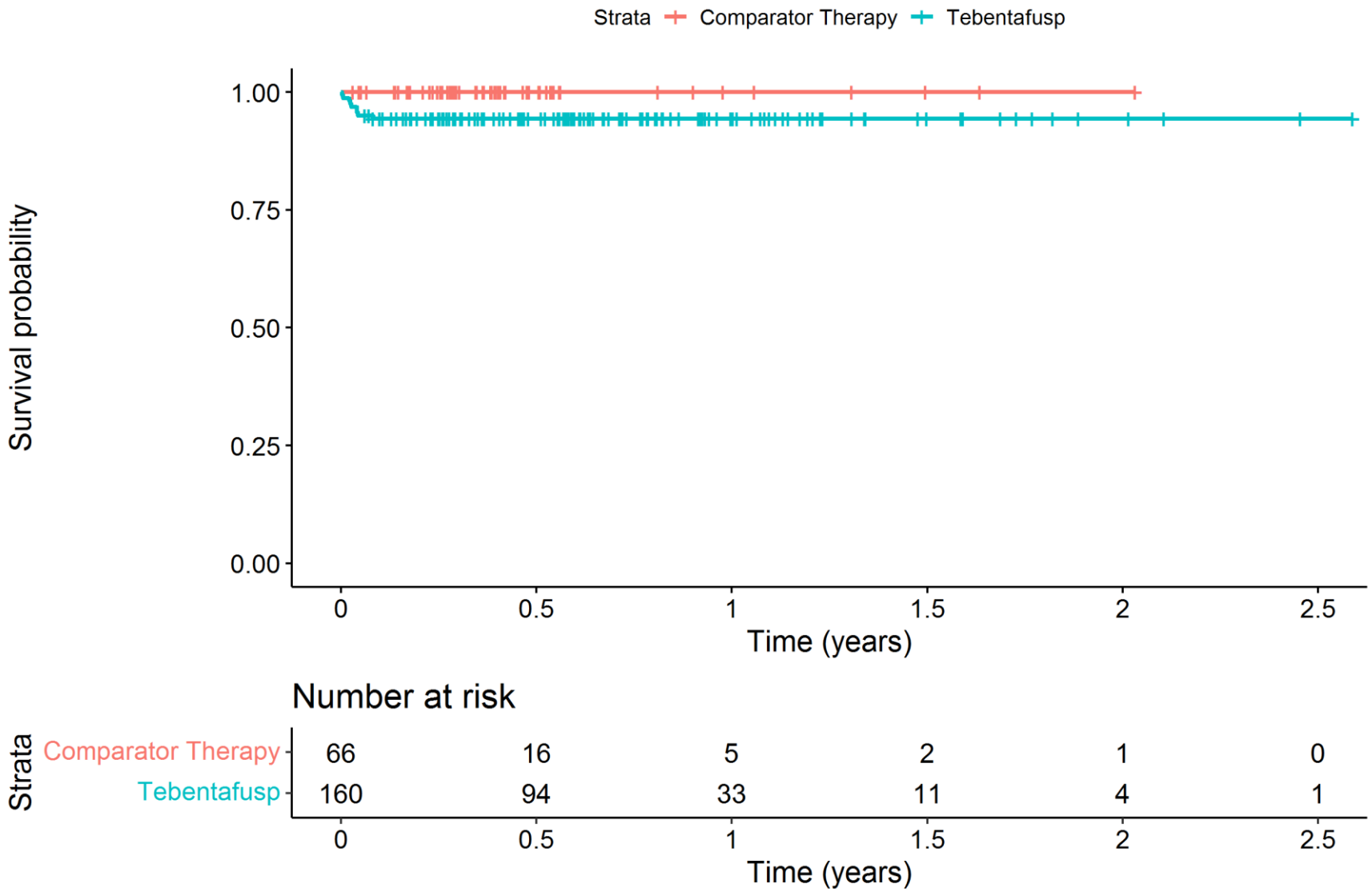
Makulo-papulöser Hautausschlag - Läsion ≥8,1 cm



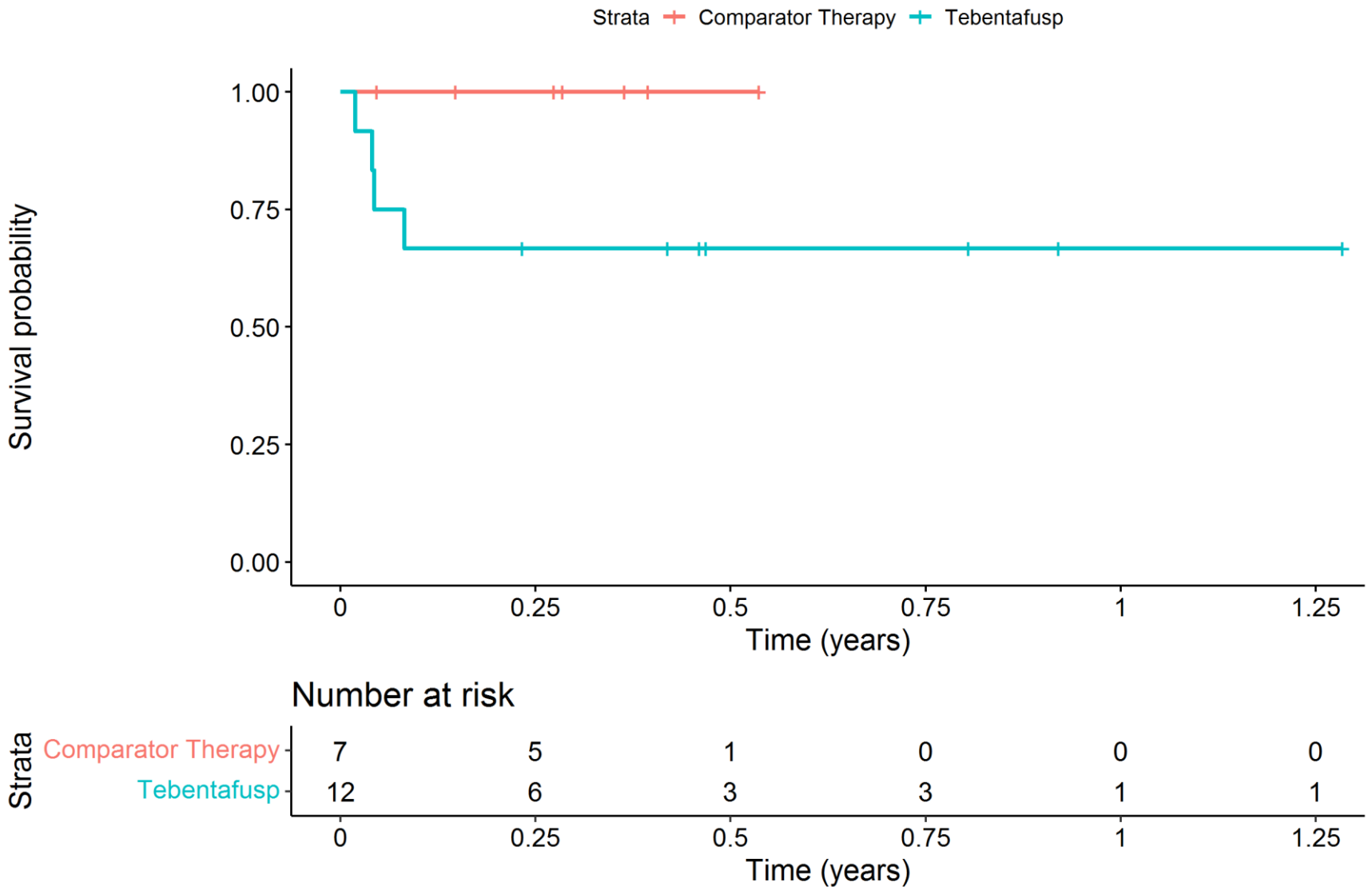
Makulo-papulöser Hautausschlag - Nordamerika



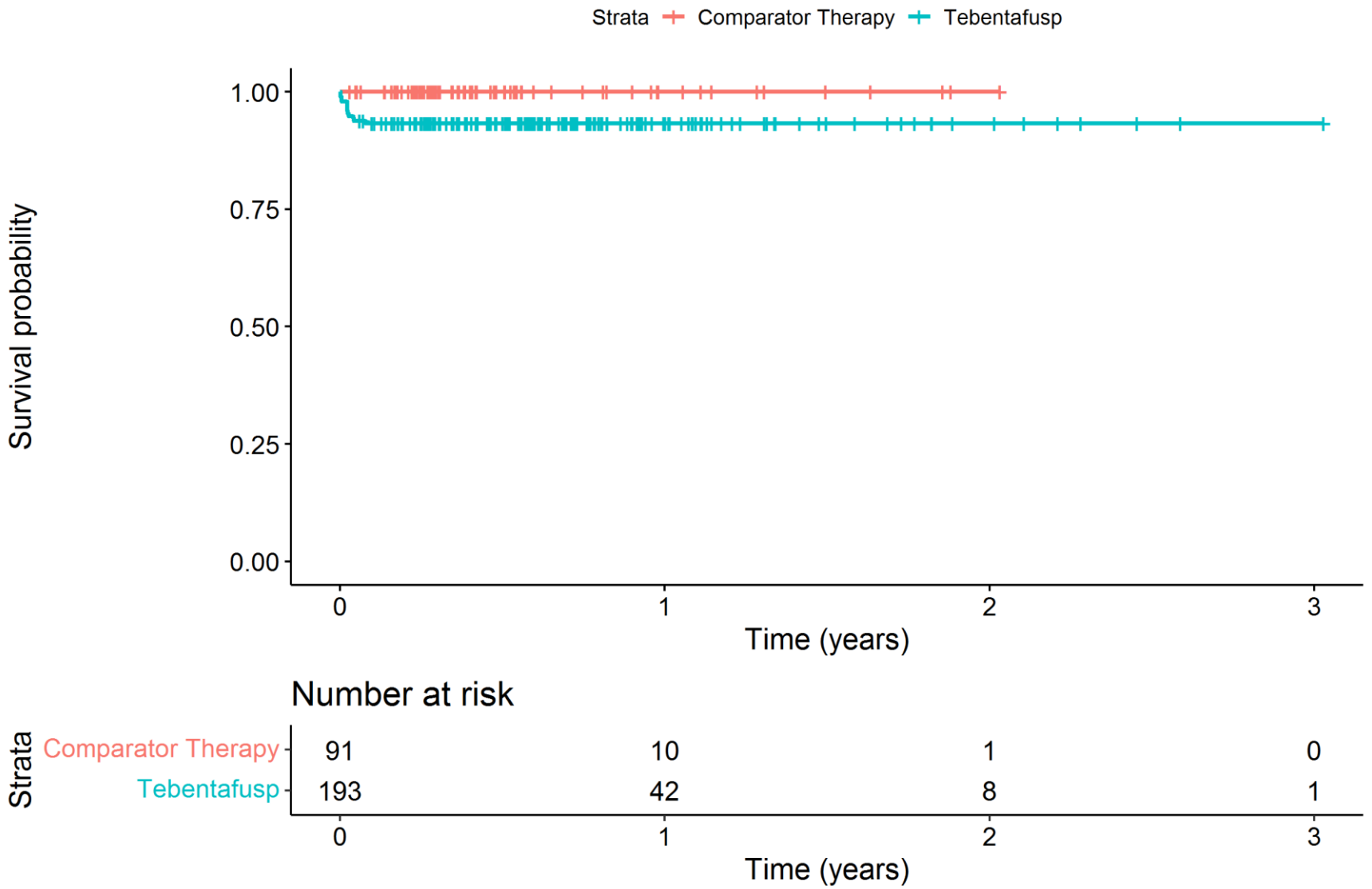
Makulo-papulöser Hautausschlag - Nicht-Nordamerika



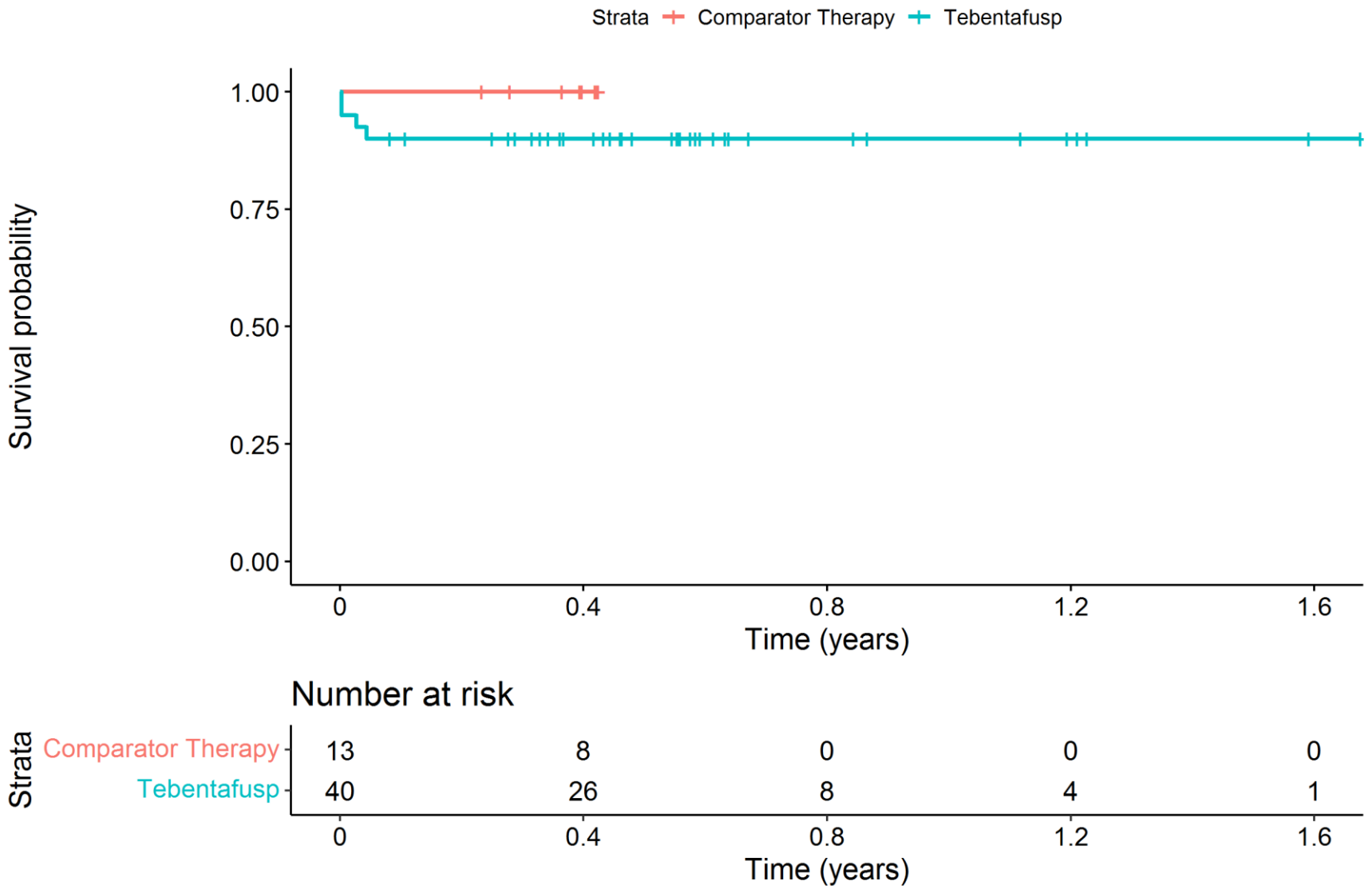
Makulo-papulöser Hautausschlag - Dacarbazin



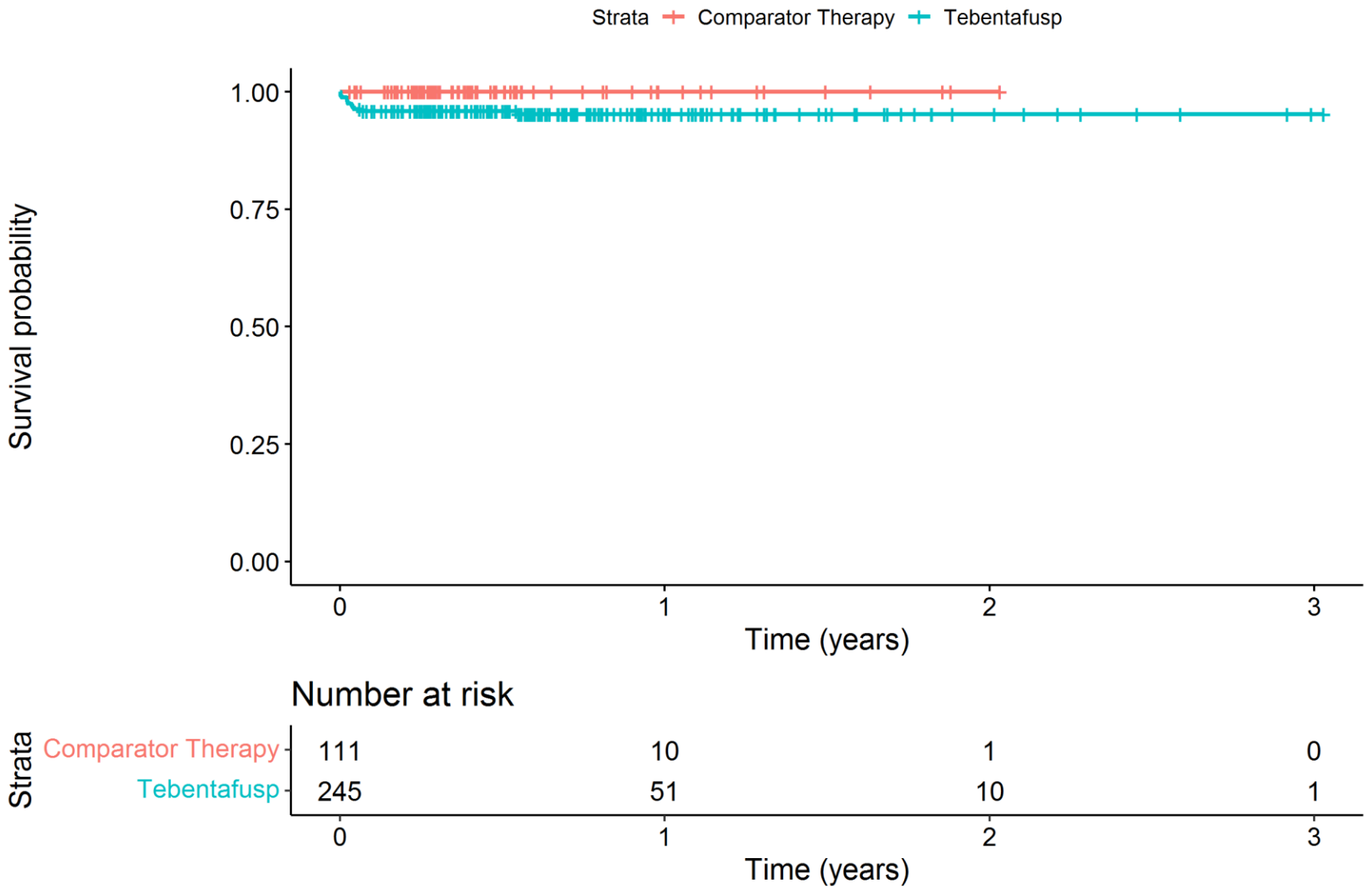
Makulo-papulöser Hautausschlag - Pembrolizumab



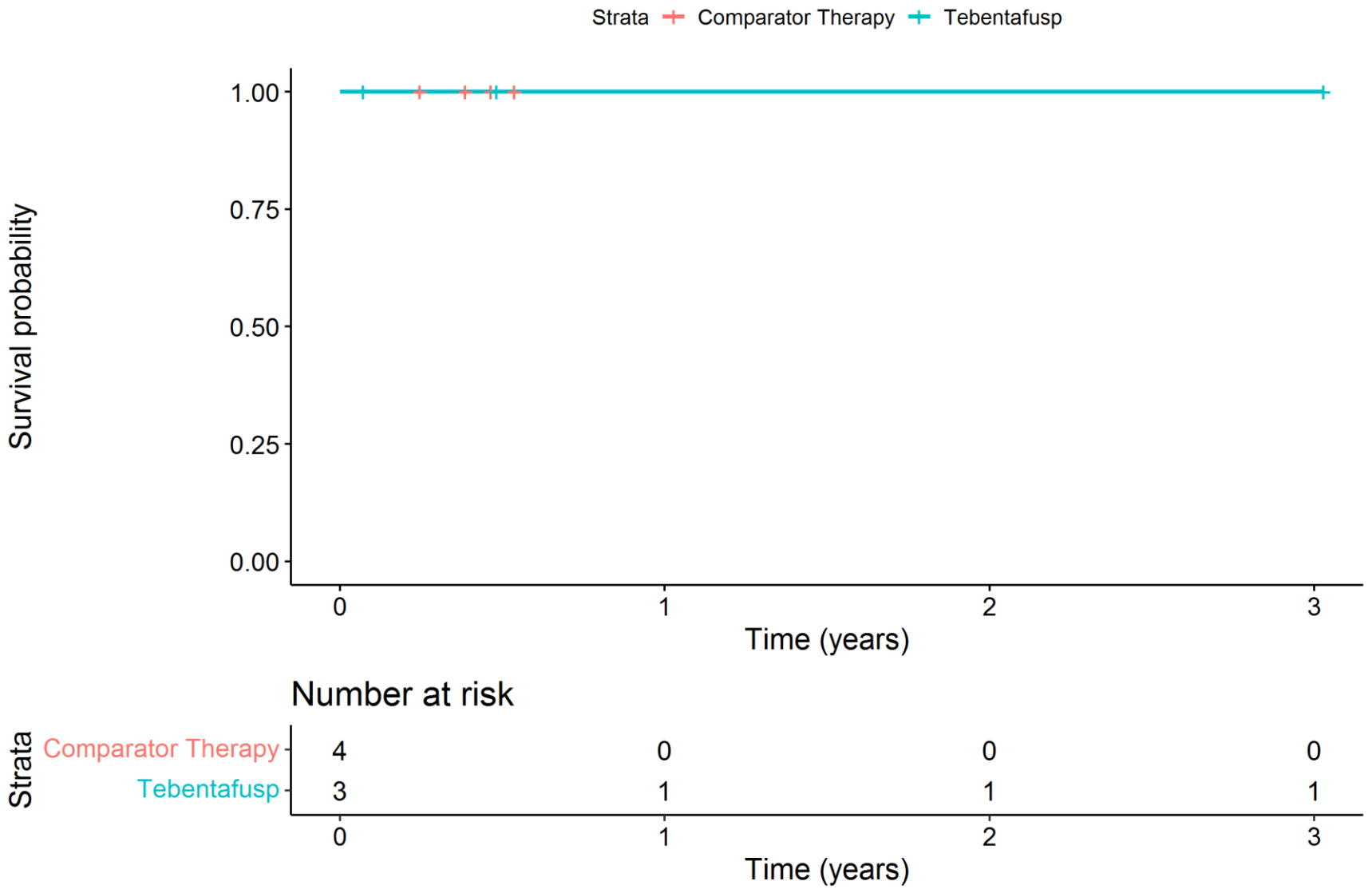
Makulo-papulöser Hautausschlag - Ipilimumab



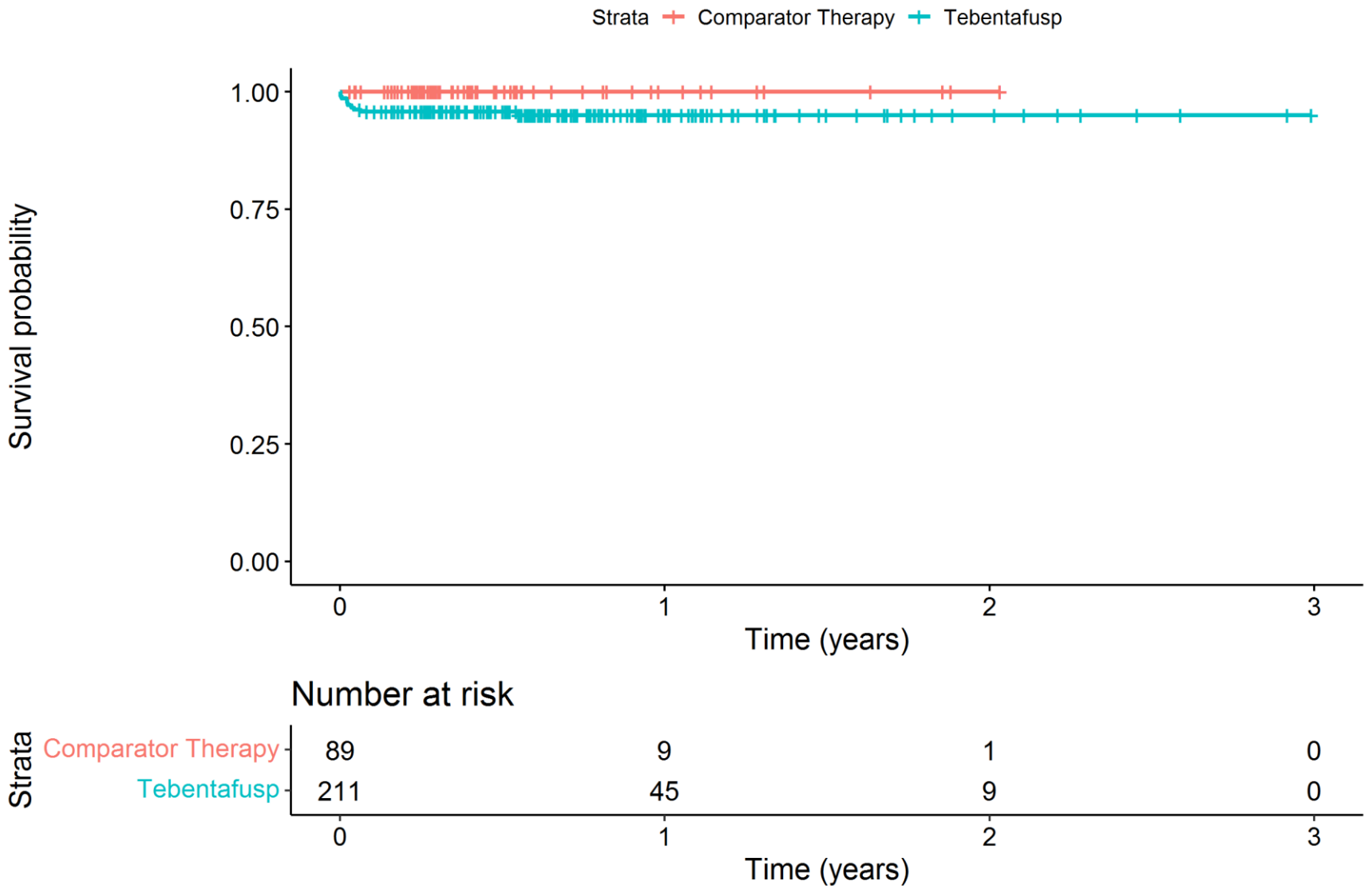
Pruritus - Gesamt



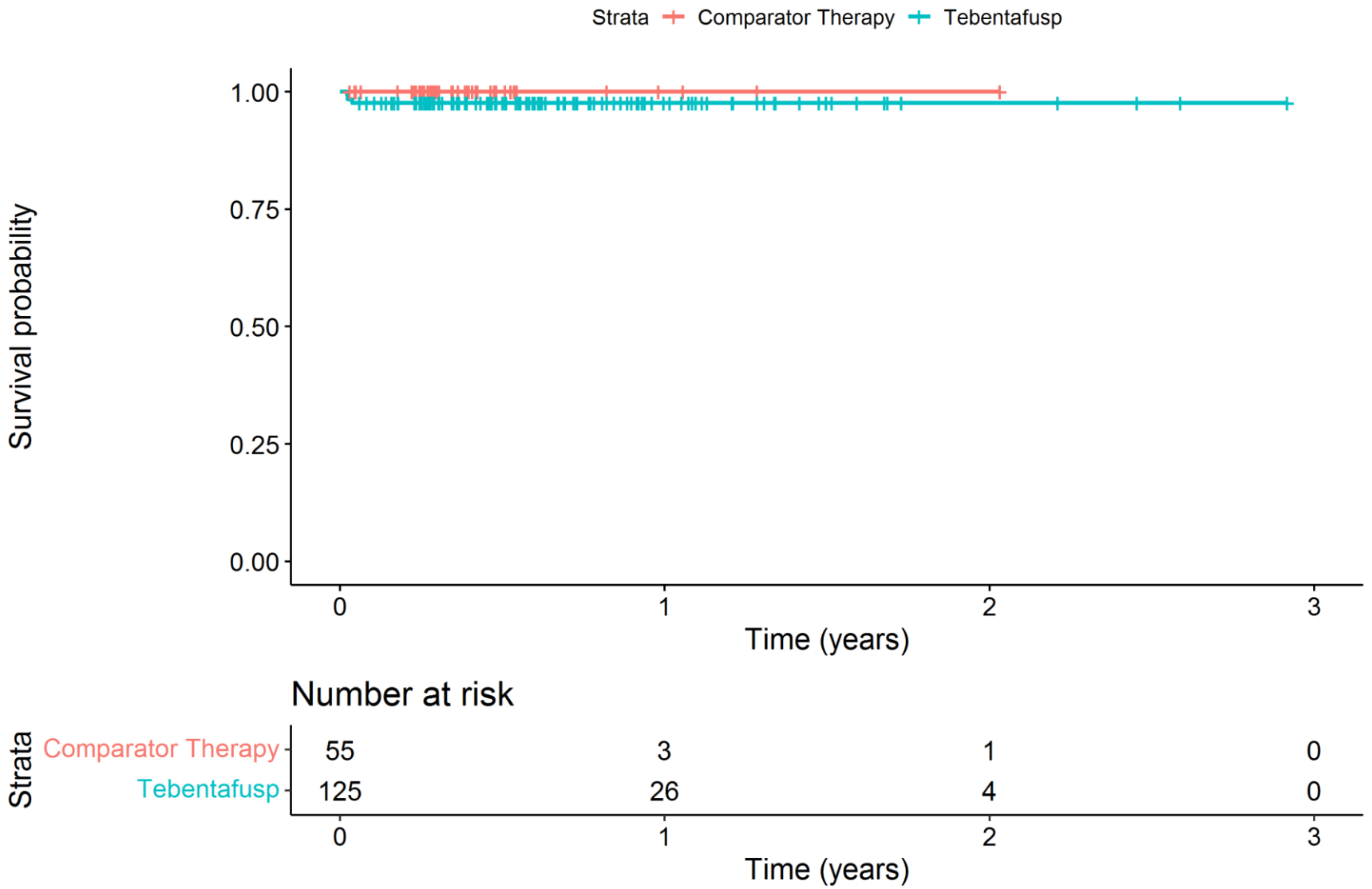
Pruritus - Hispanisch



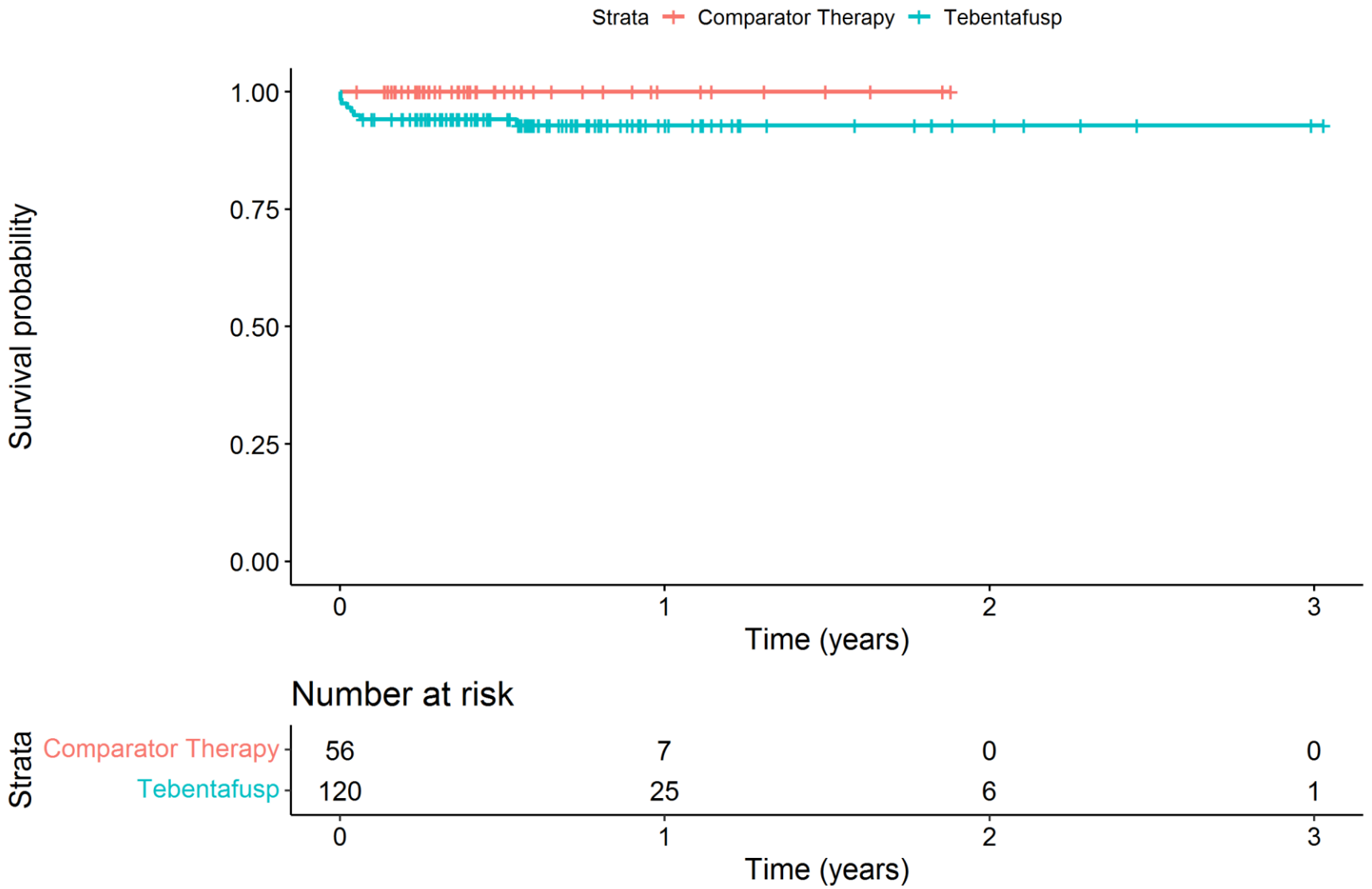
Pruritus - Nicht-hispanisch



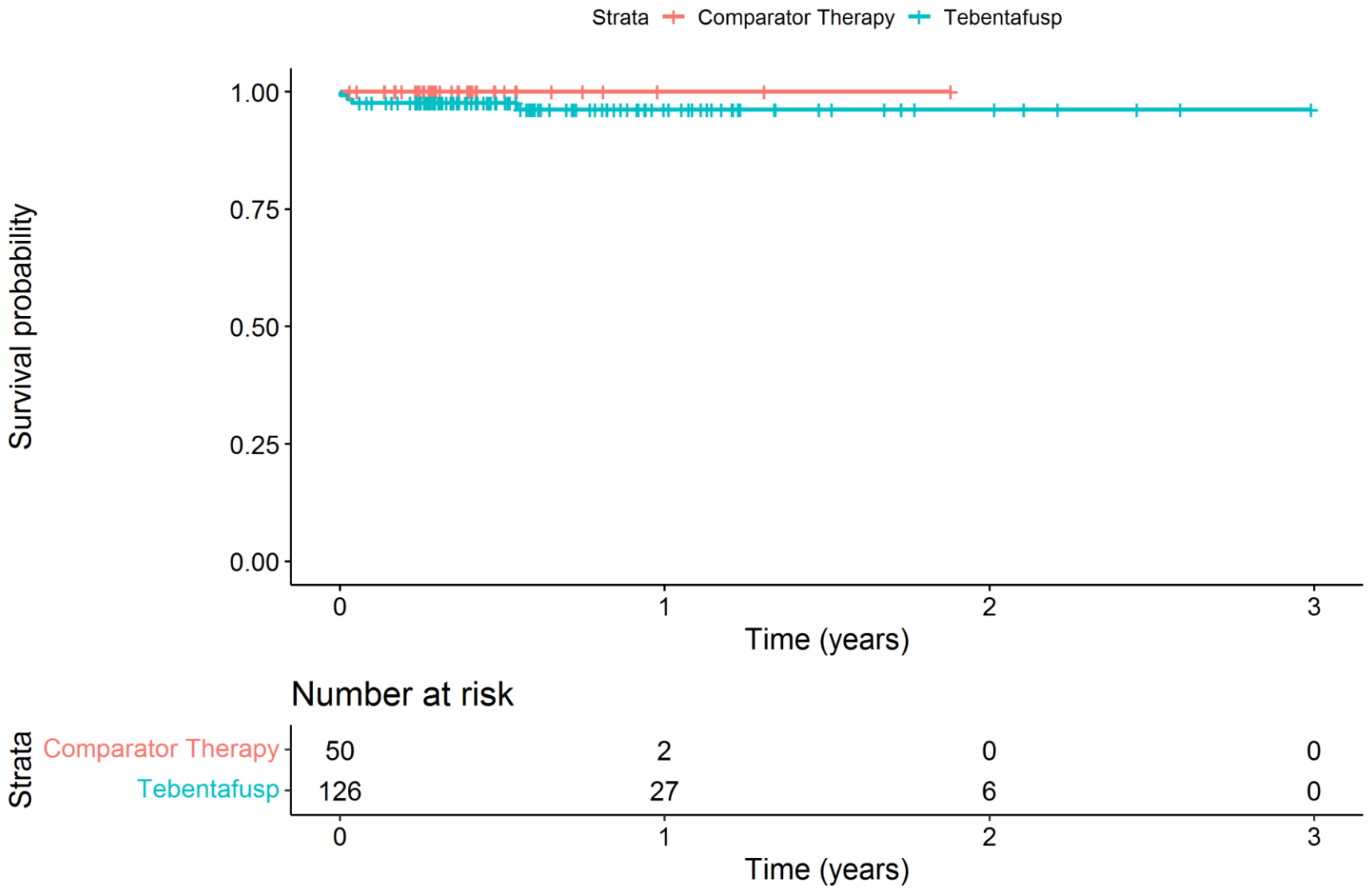
Pruritus - Männlich



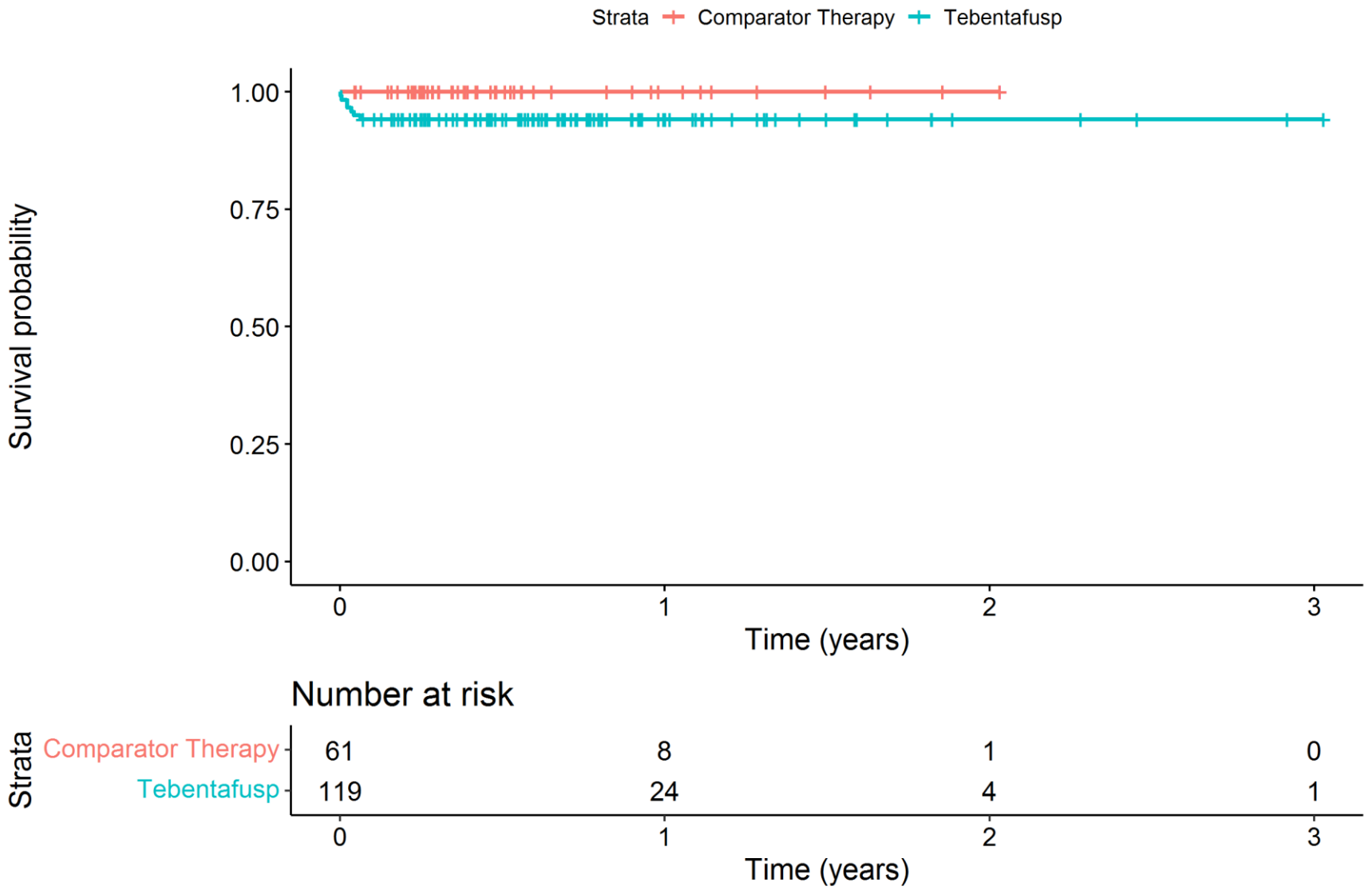
Pruritus - Weiblich



Pruritus - <65


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
50
2
0
0
126
27
6
0
0
1
2
3
Time (years)

Pruritus - ≥65


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
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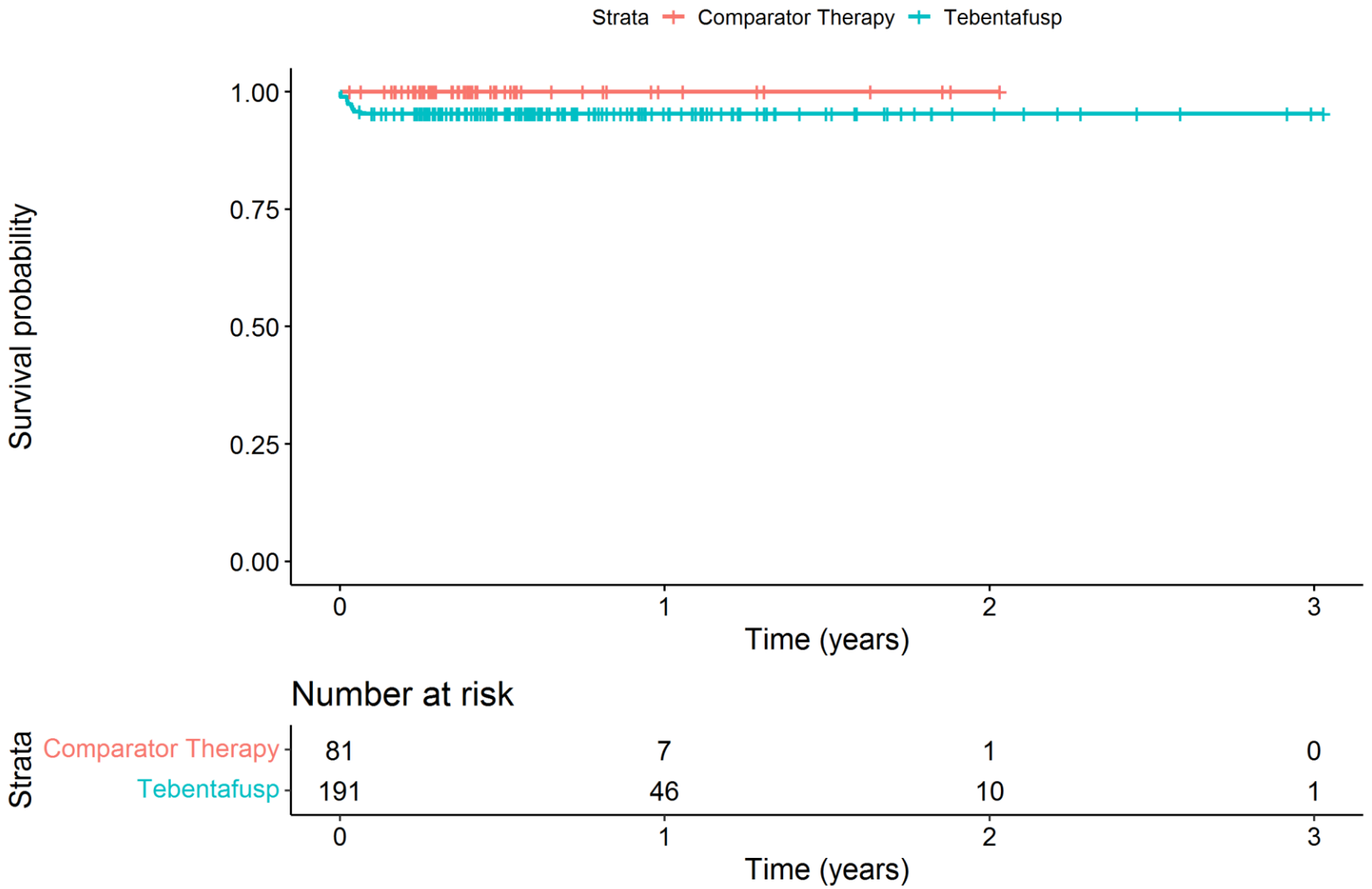
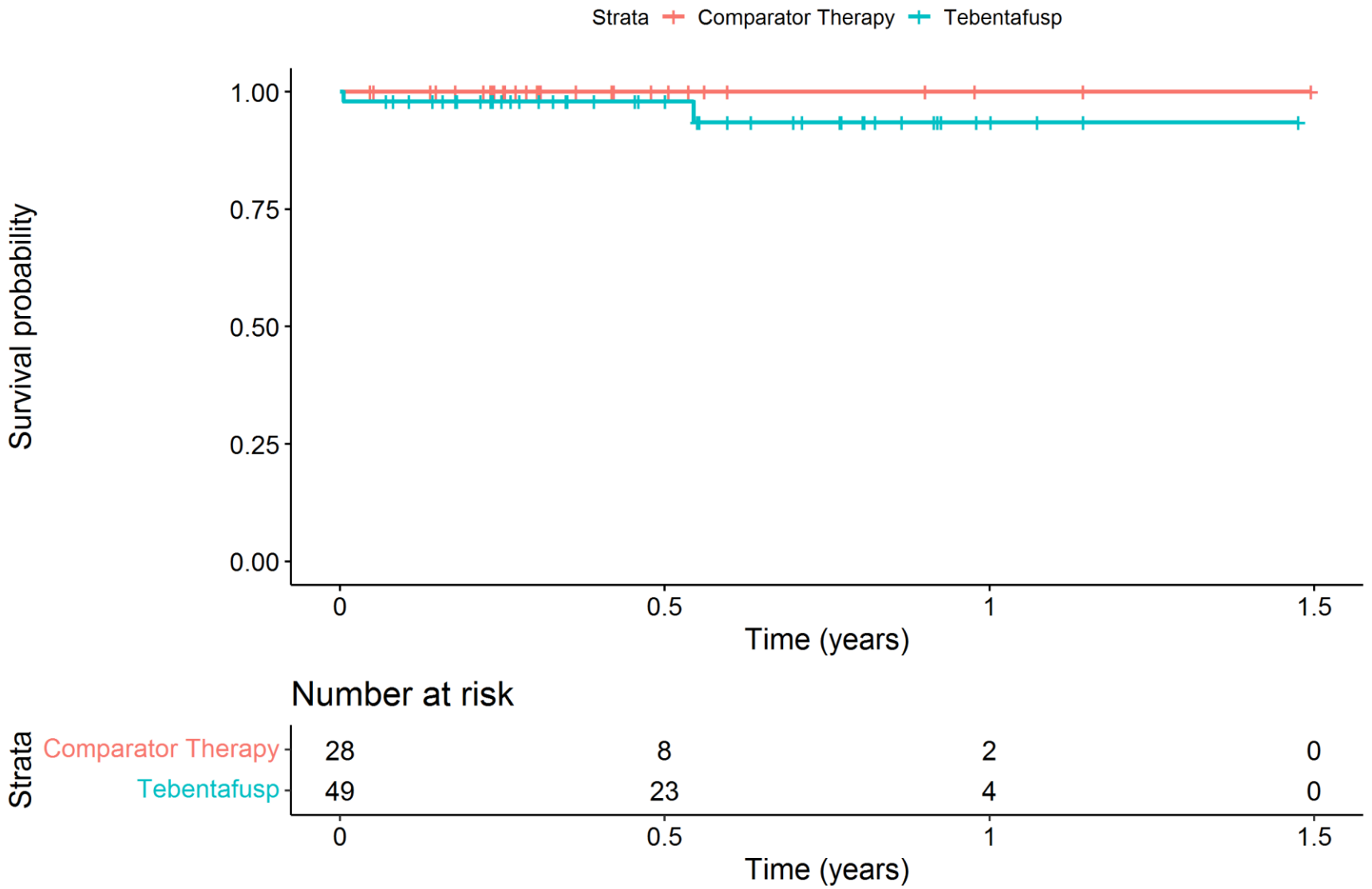
8
1
0
119
24
4
1
0
1
2
3
Time (years)

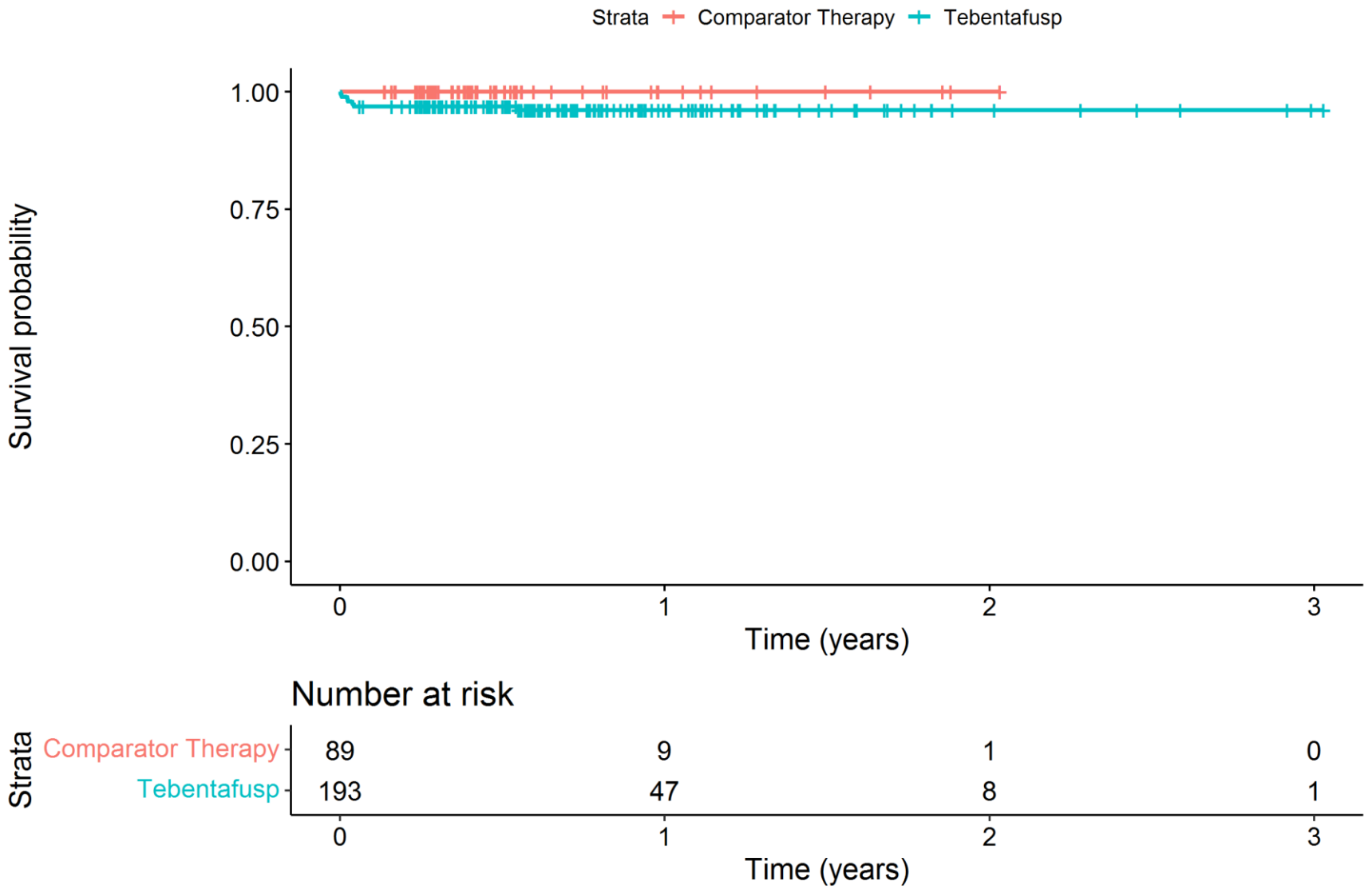
Pruritus - ECOG 0



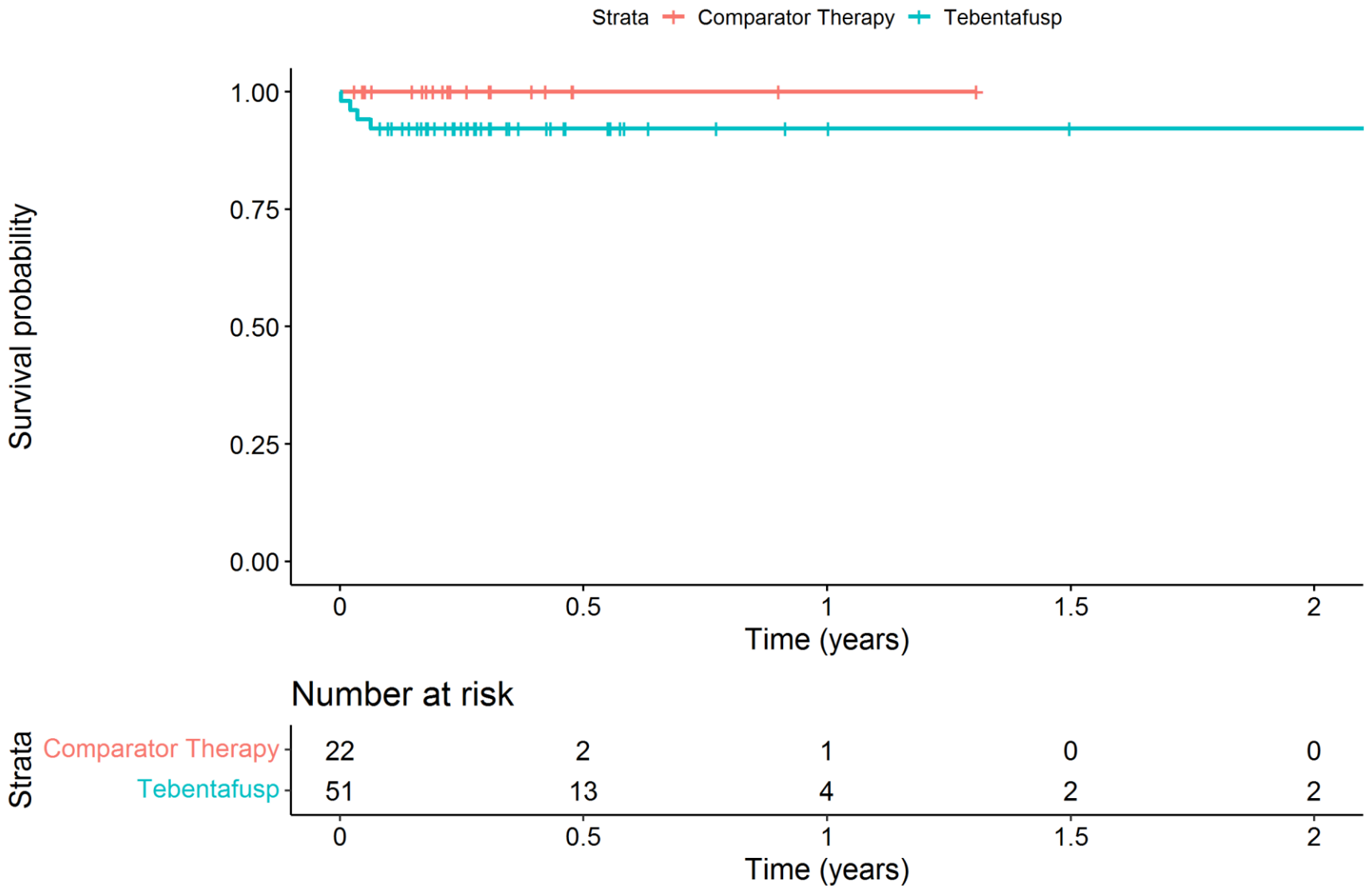
Pruritus - ECOG 1



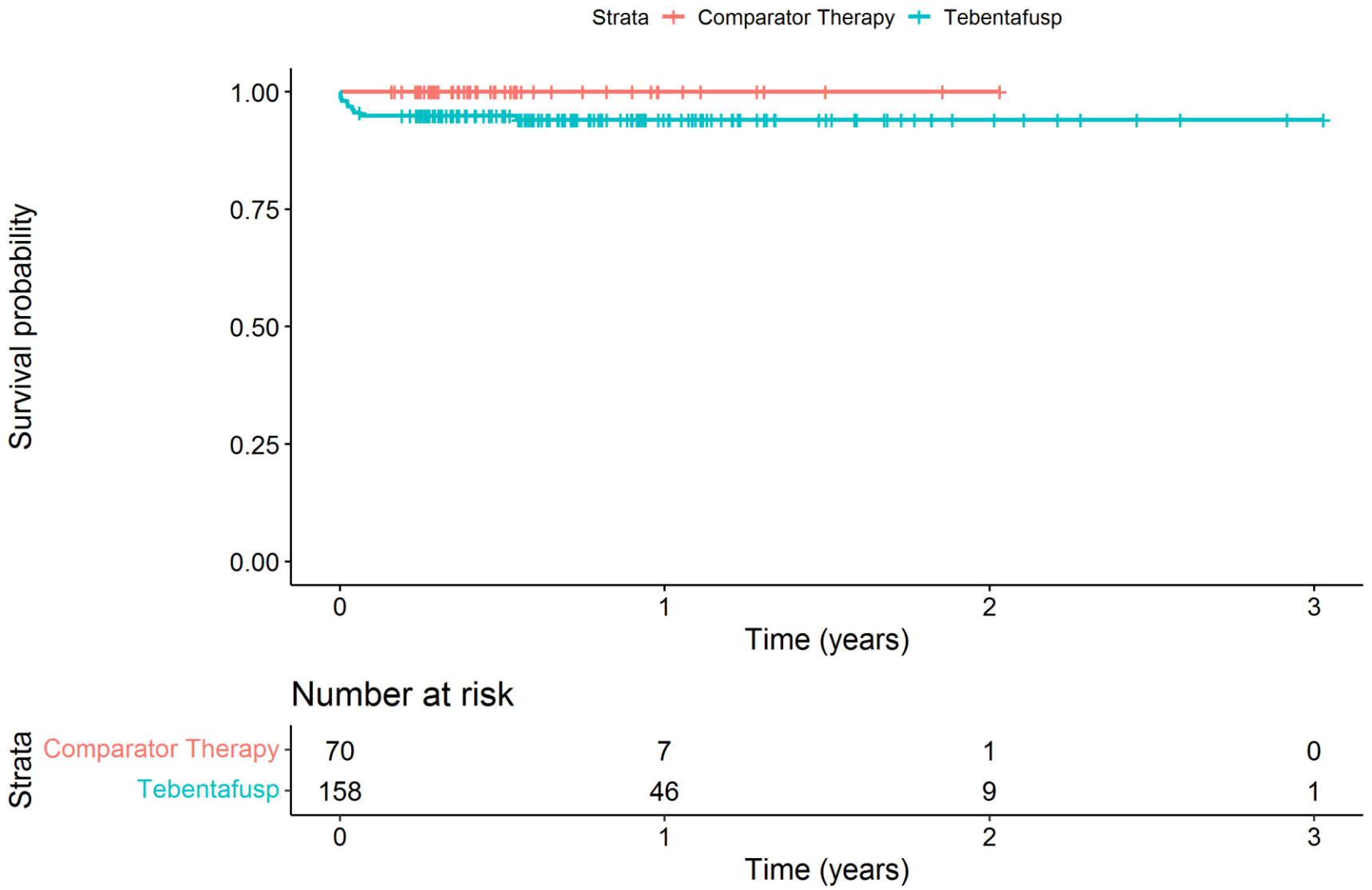
Pruritus - ALP ≤ ULN



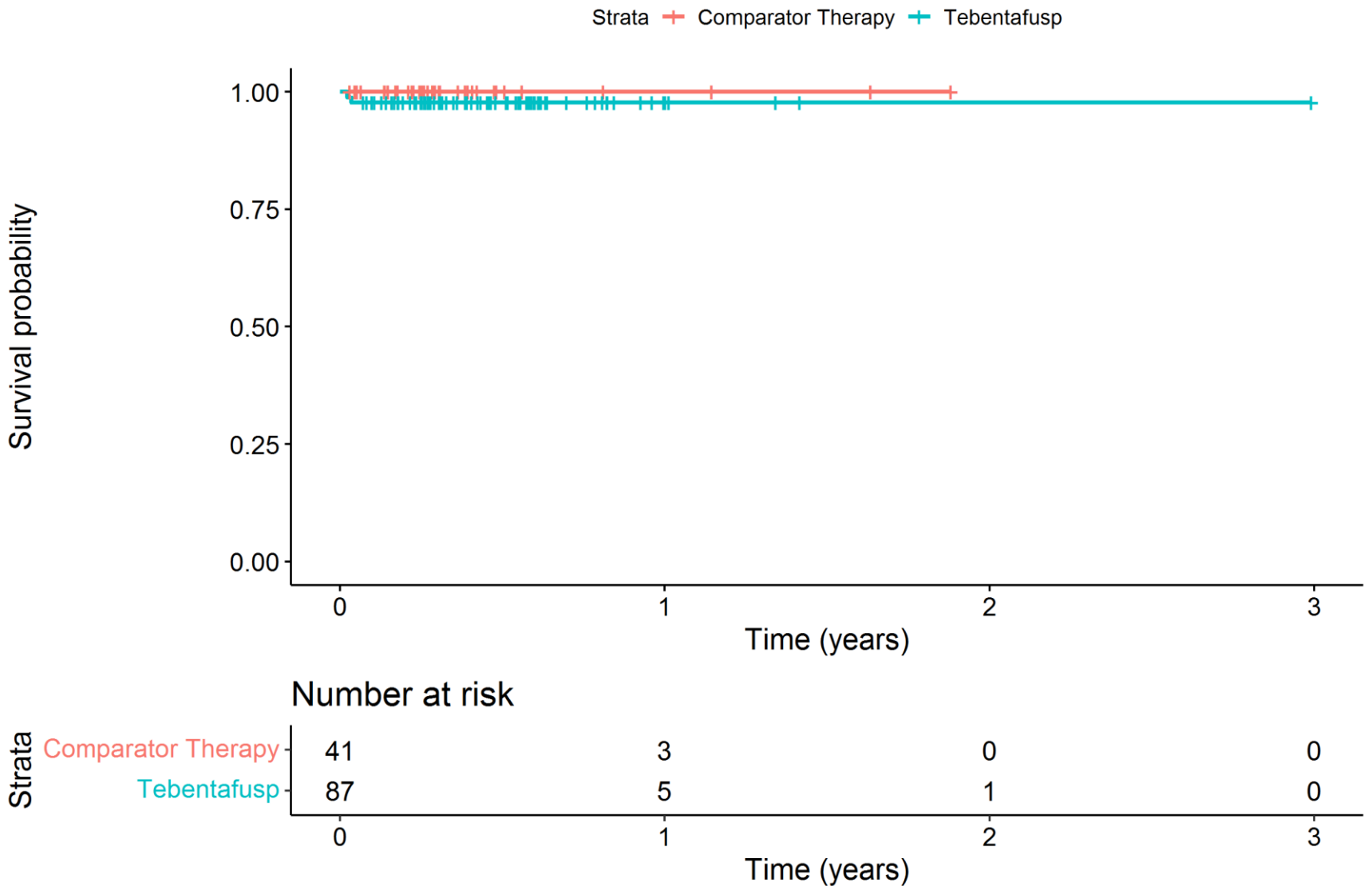
Pruritus - ALP > ULN



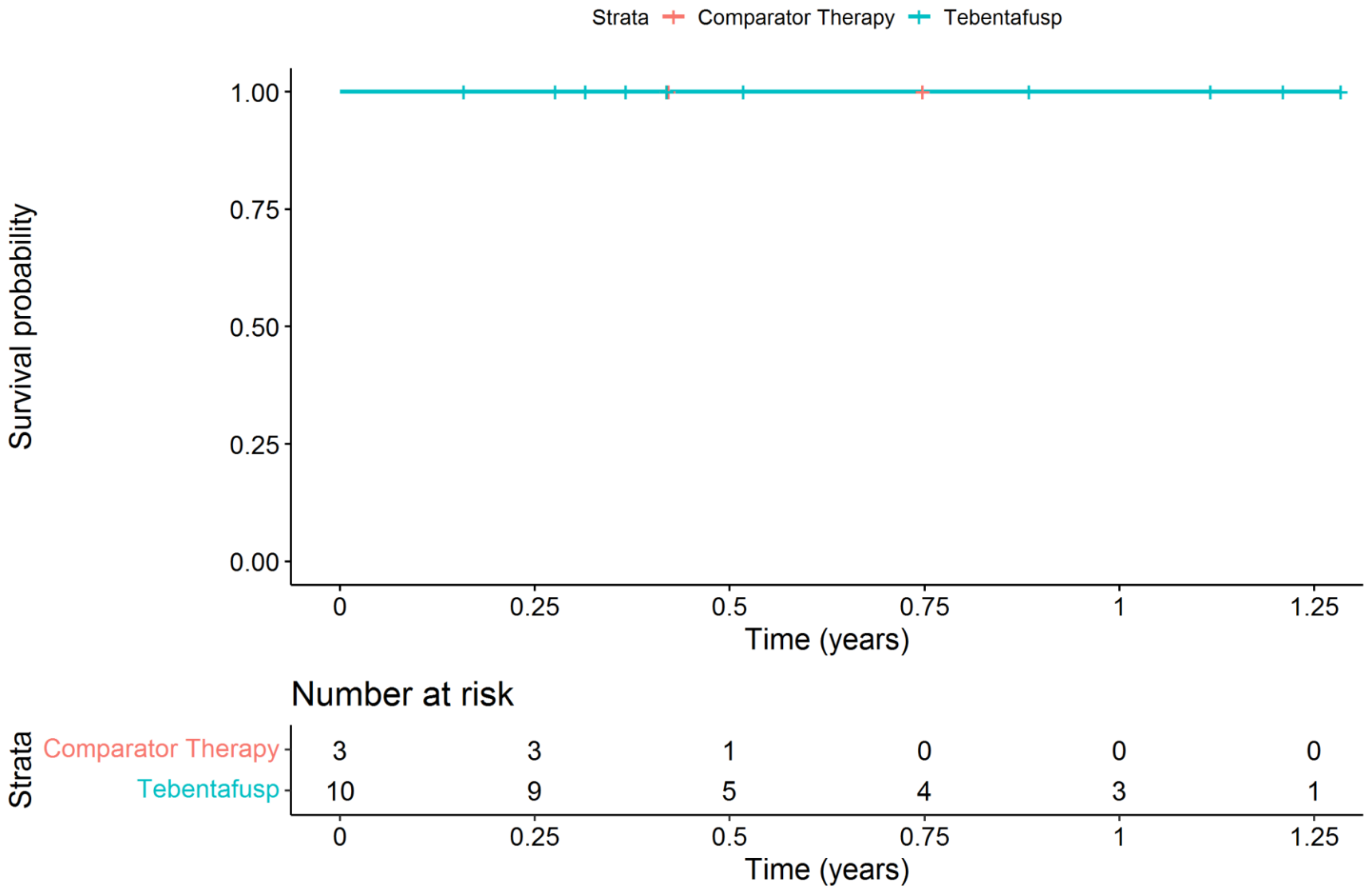
Pruritus - LDH =< ULN



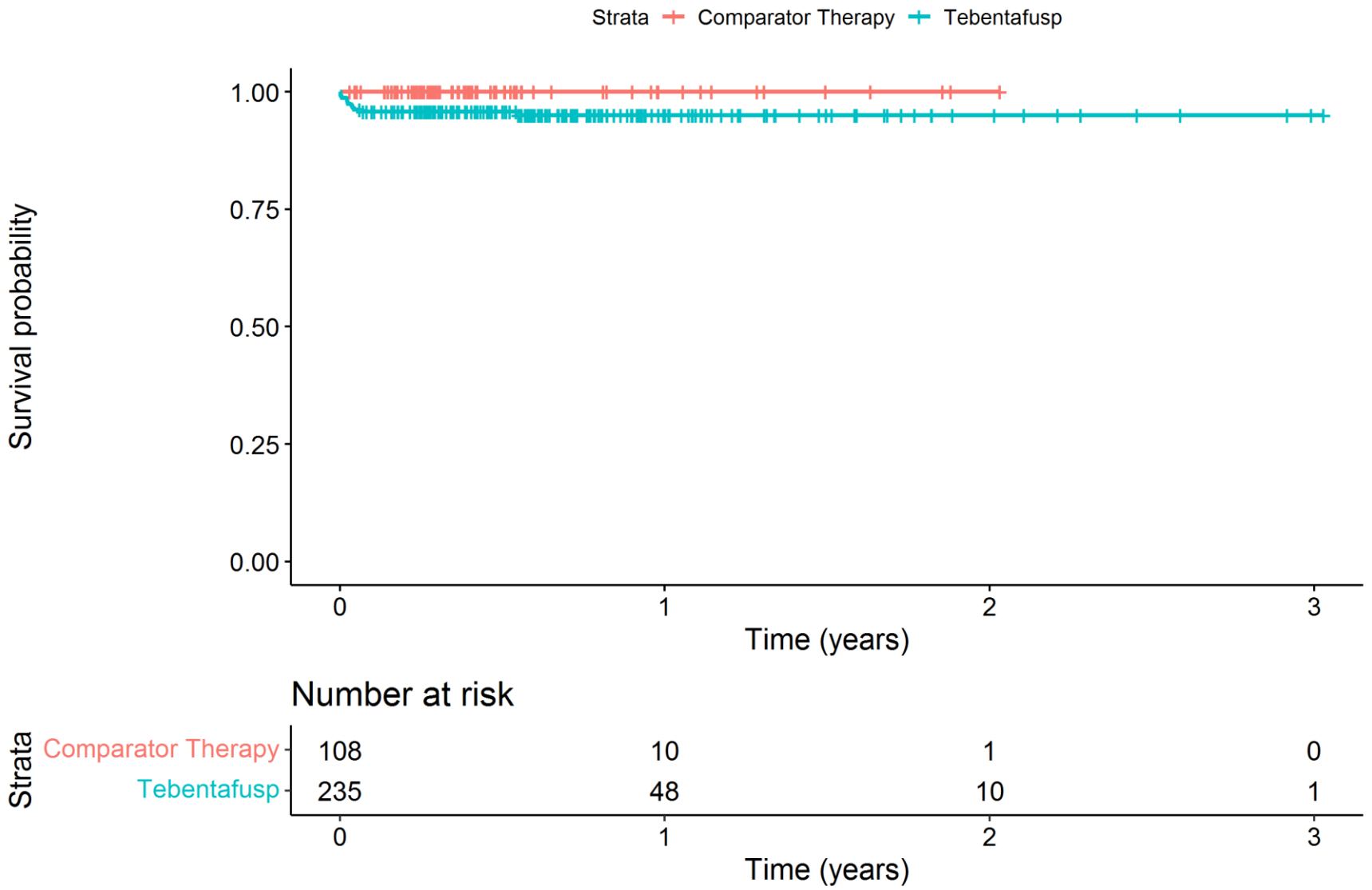
Pruritus - LDH > ULN



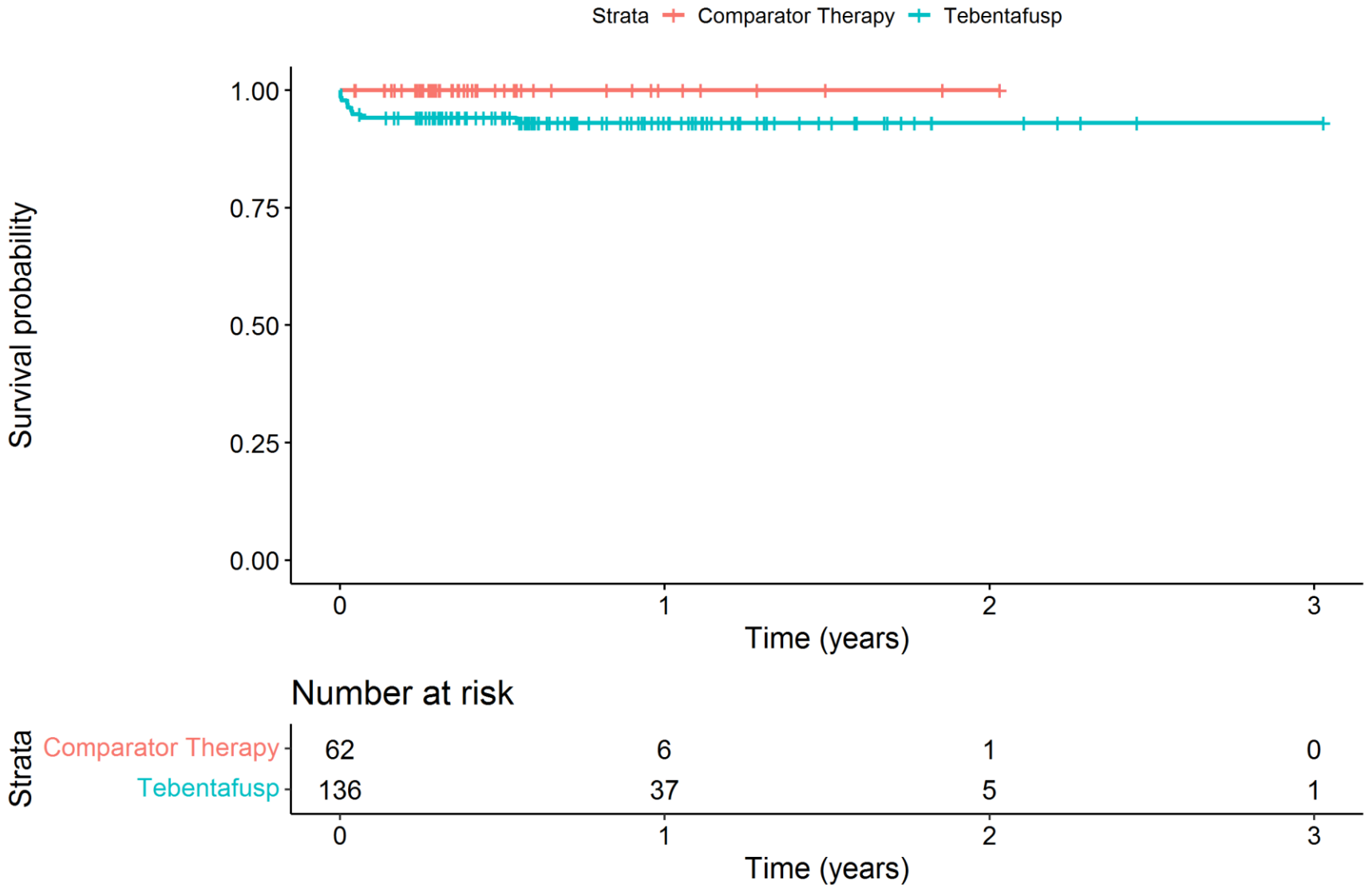
Pruritus - Vorherige Therapie adjuvant/neoadjuvant



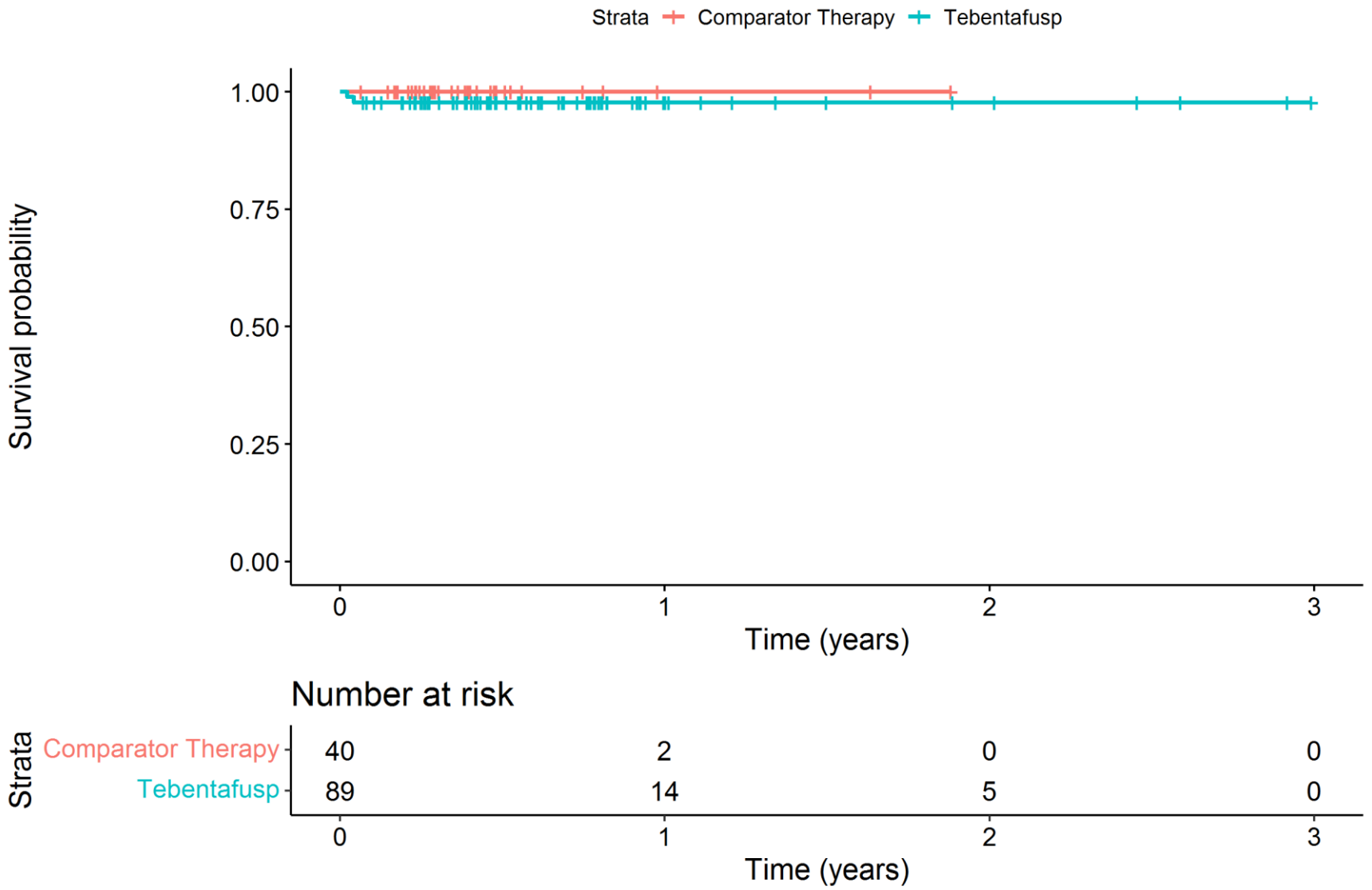
Pruritus - Keine vorherige Therapie adjuvant/neoadjuvant



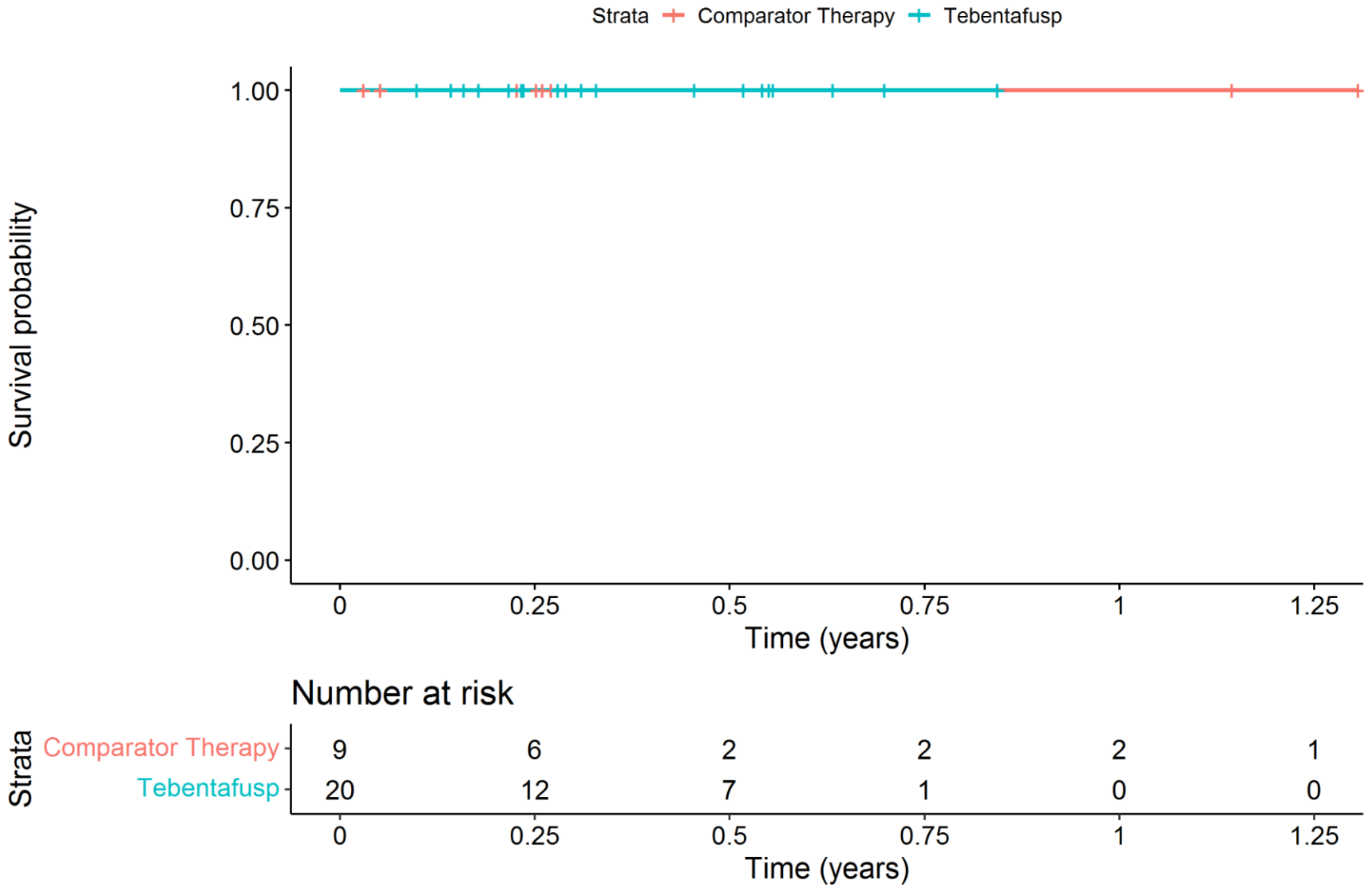
Pruritus - Läsion ≤ 3cm



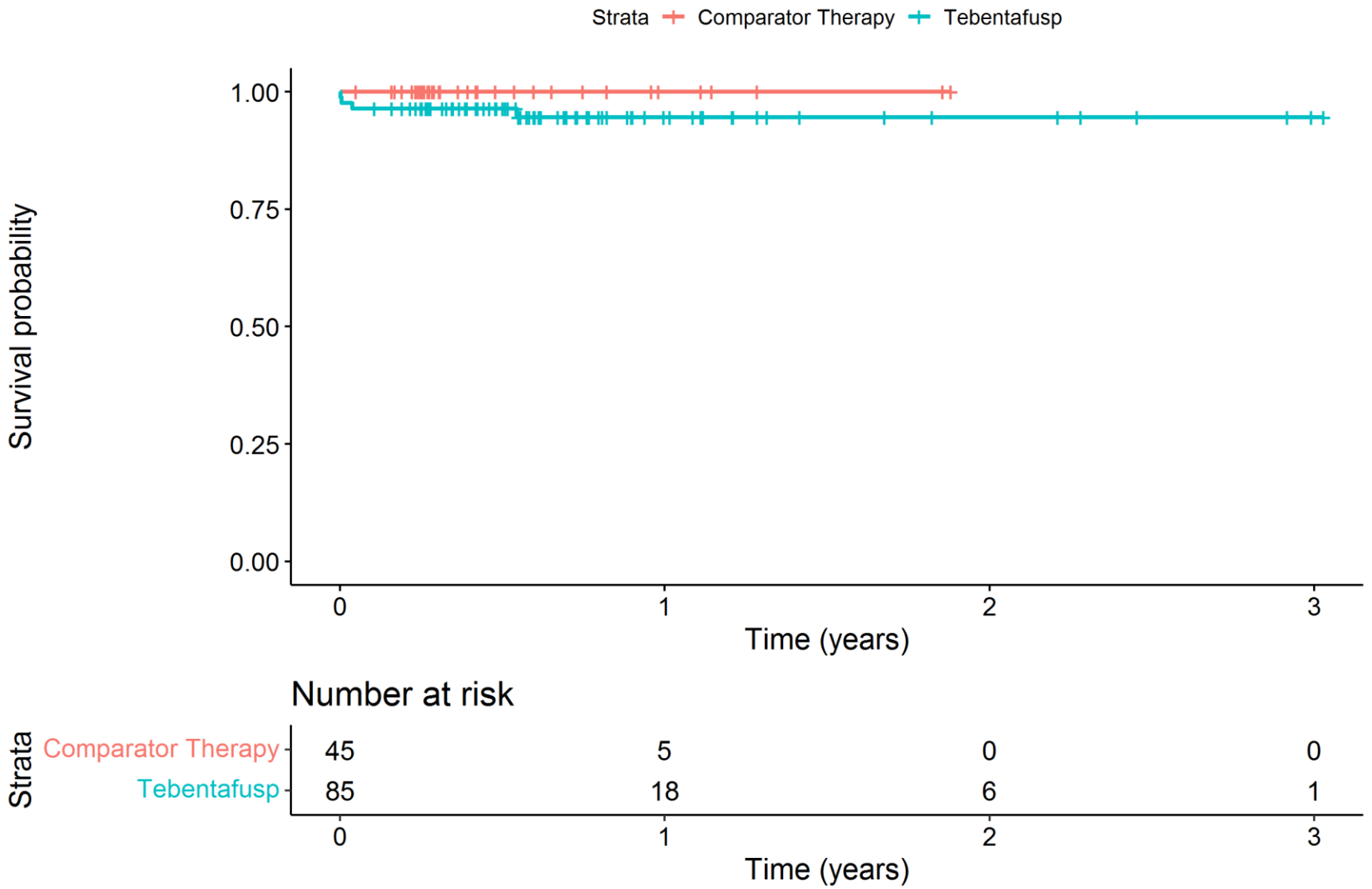
Pruritus - Läsion 3,1-8,0 cm



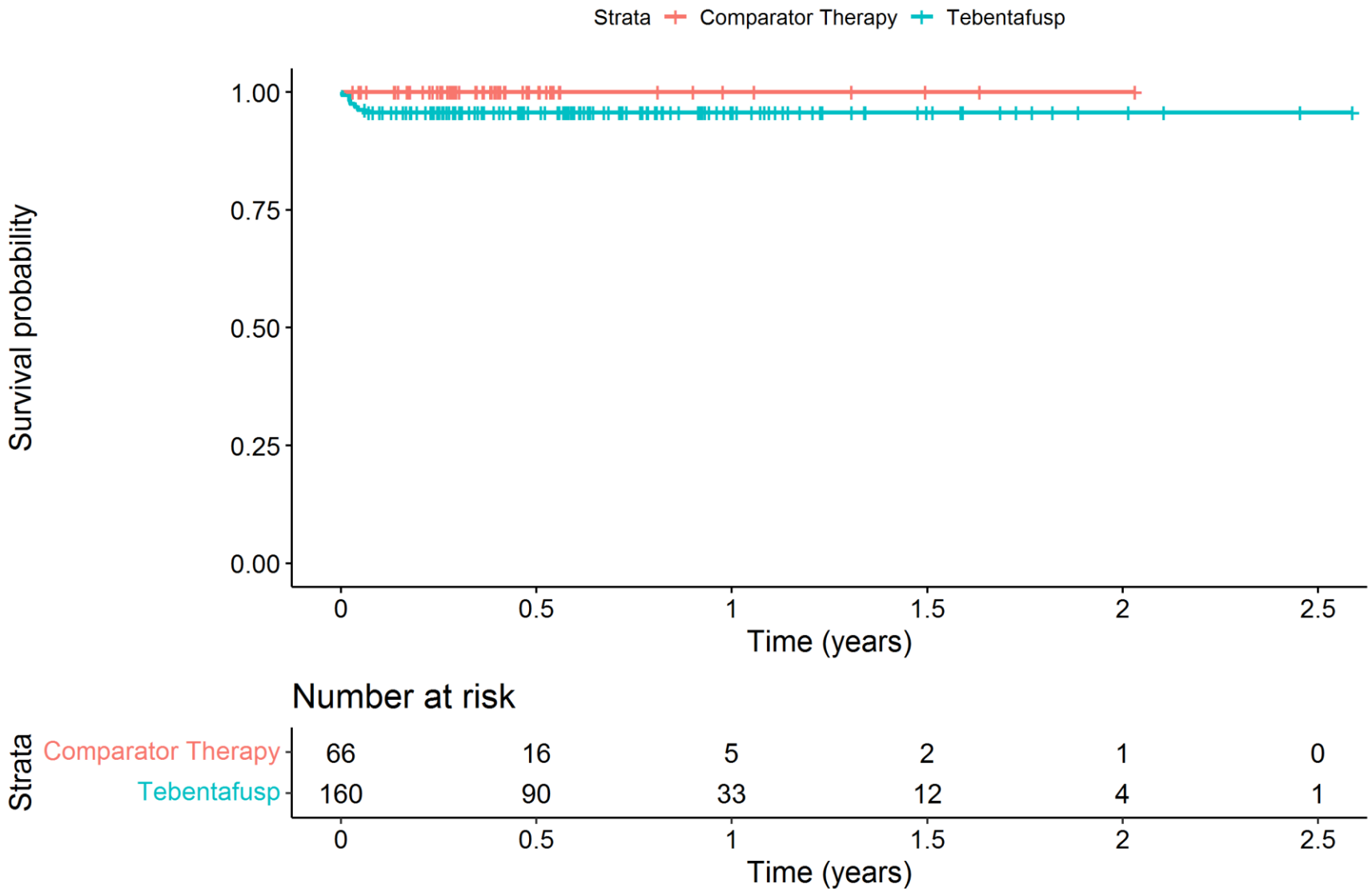
Pruritus - Läsion ≥8,1 cm



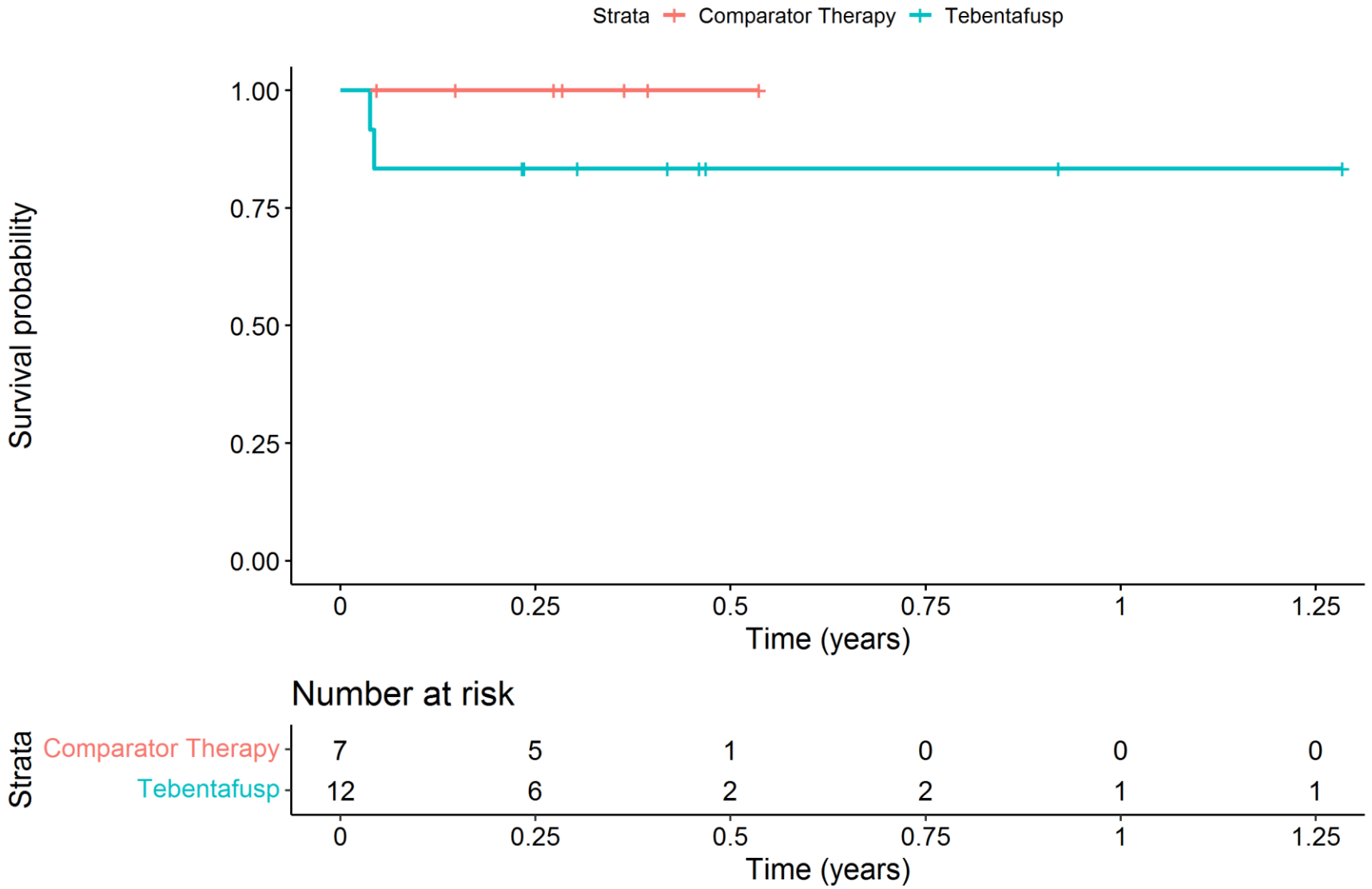
Pruritus - Nordamerika



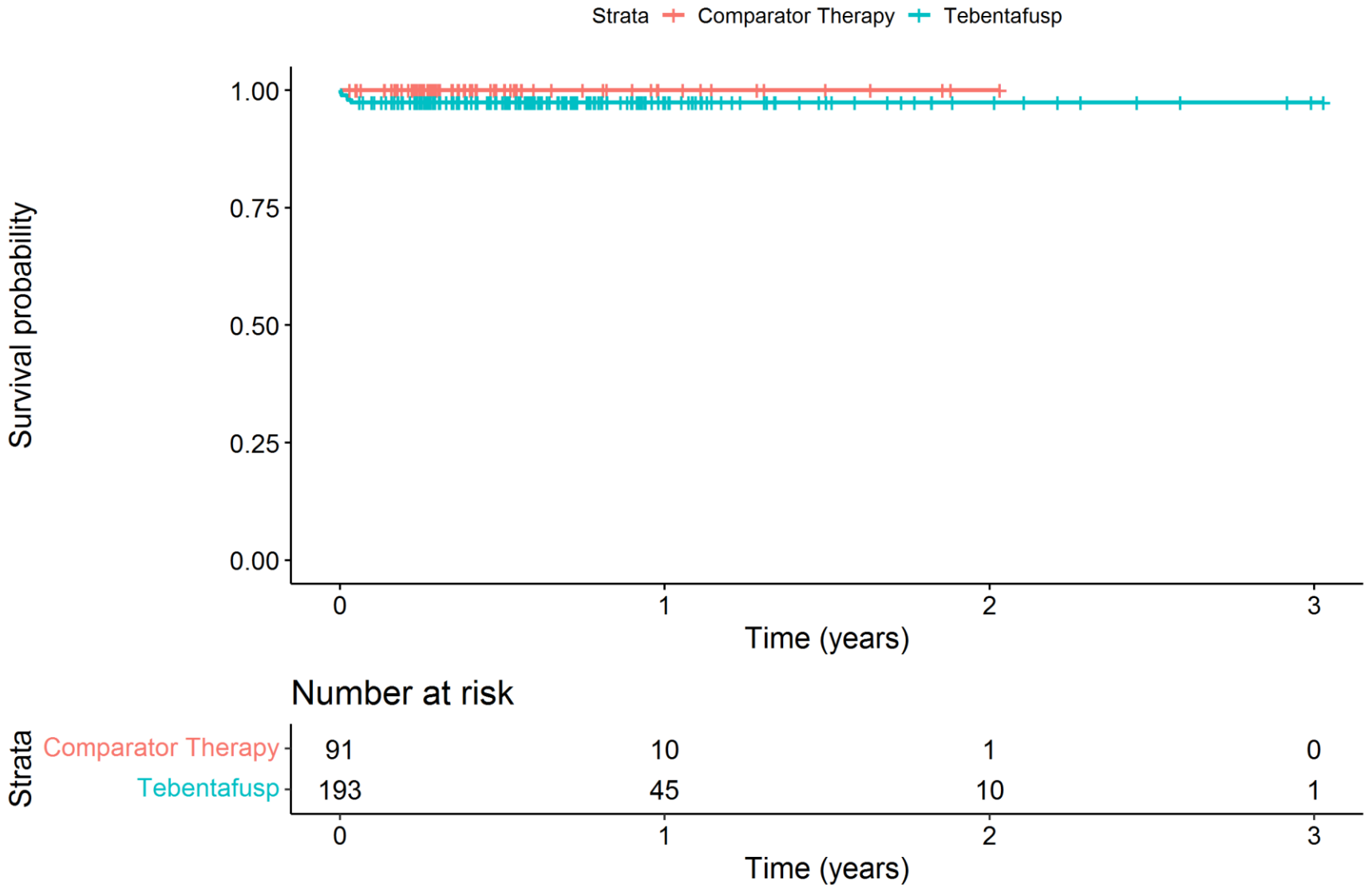
Pruritus - Nicht-Nordamerika



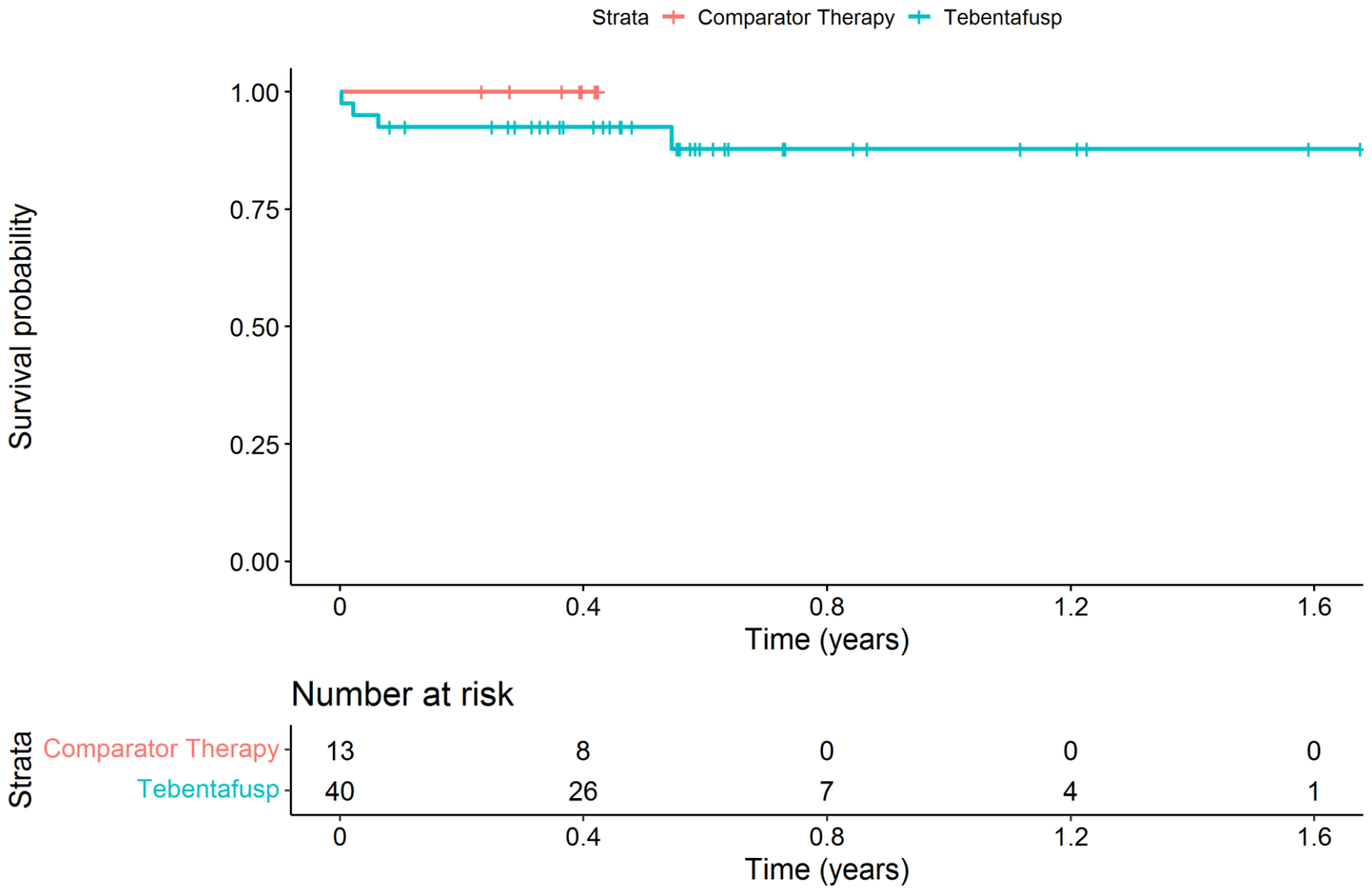
Pruritus - Dacarbazin



Pruritus - Pembrolizumab

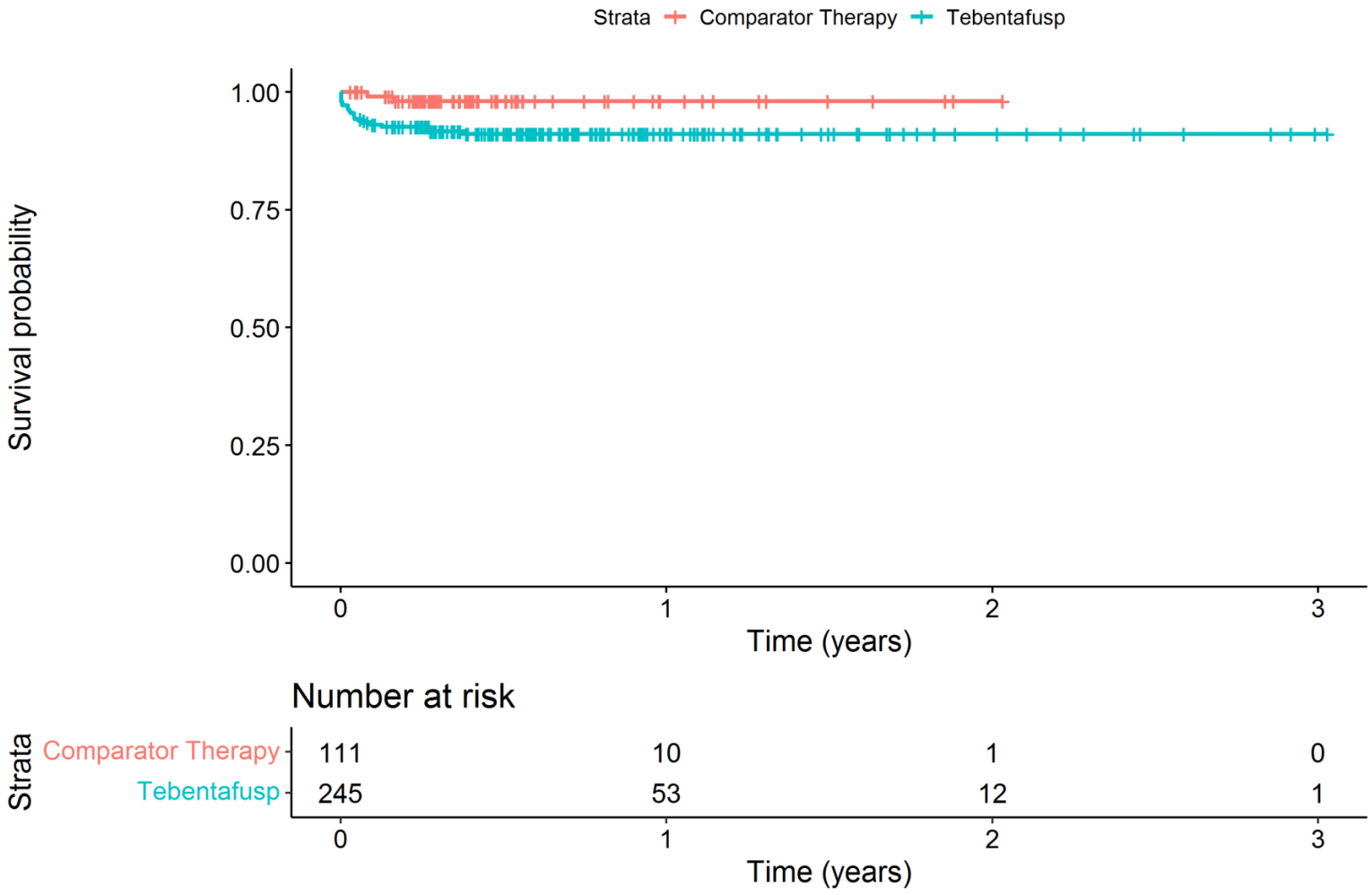


Pruritus - Ipilimumab

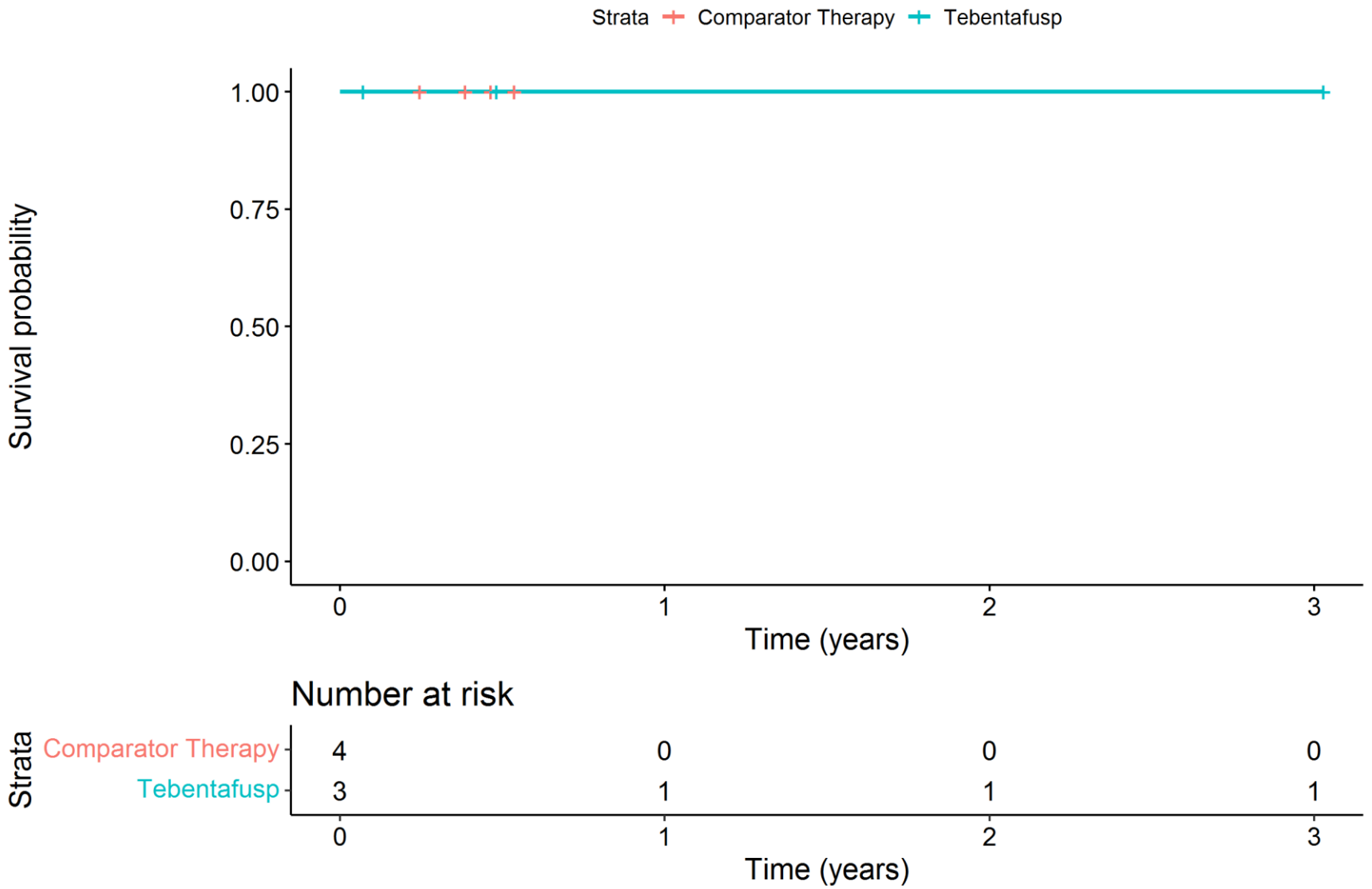


56 UEs (SOC) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-194)

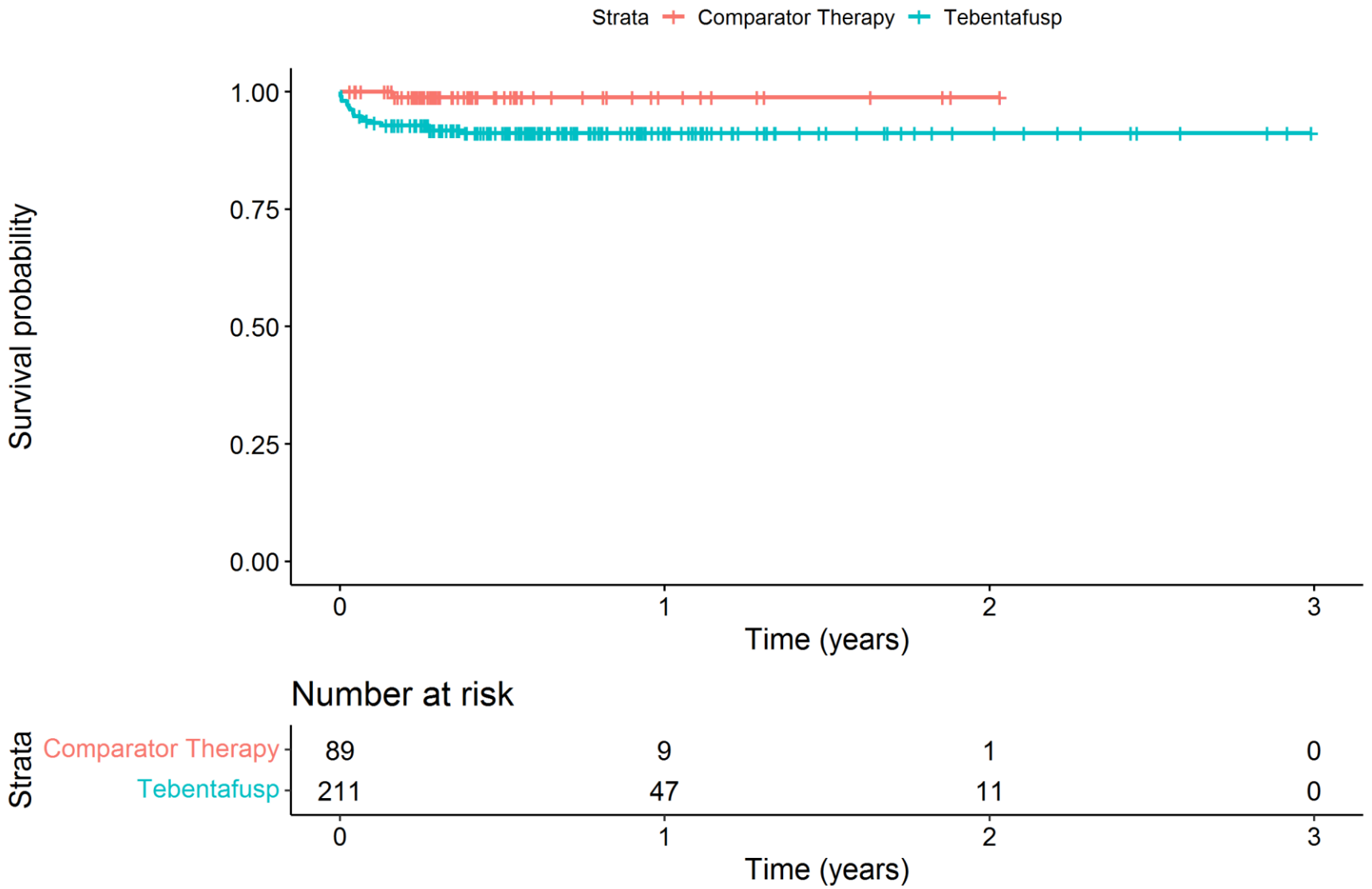
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Gesamt



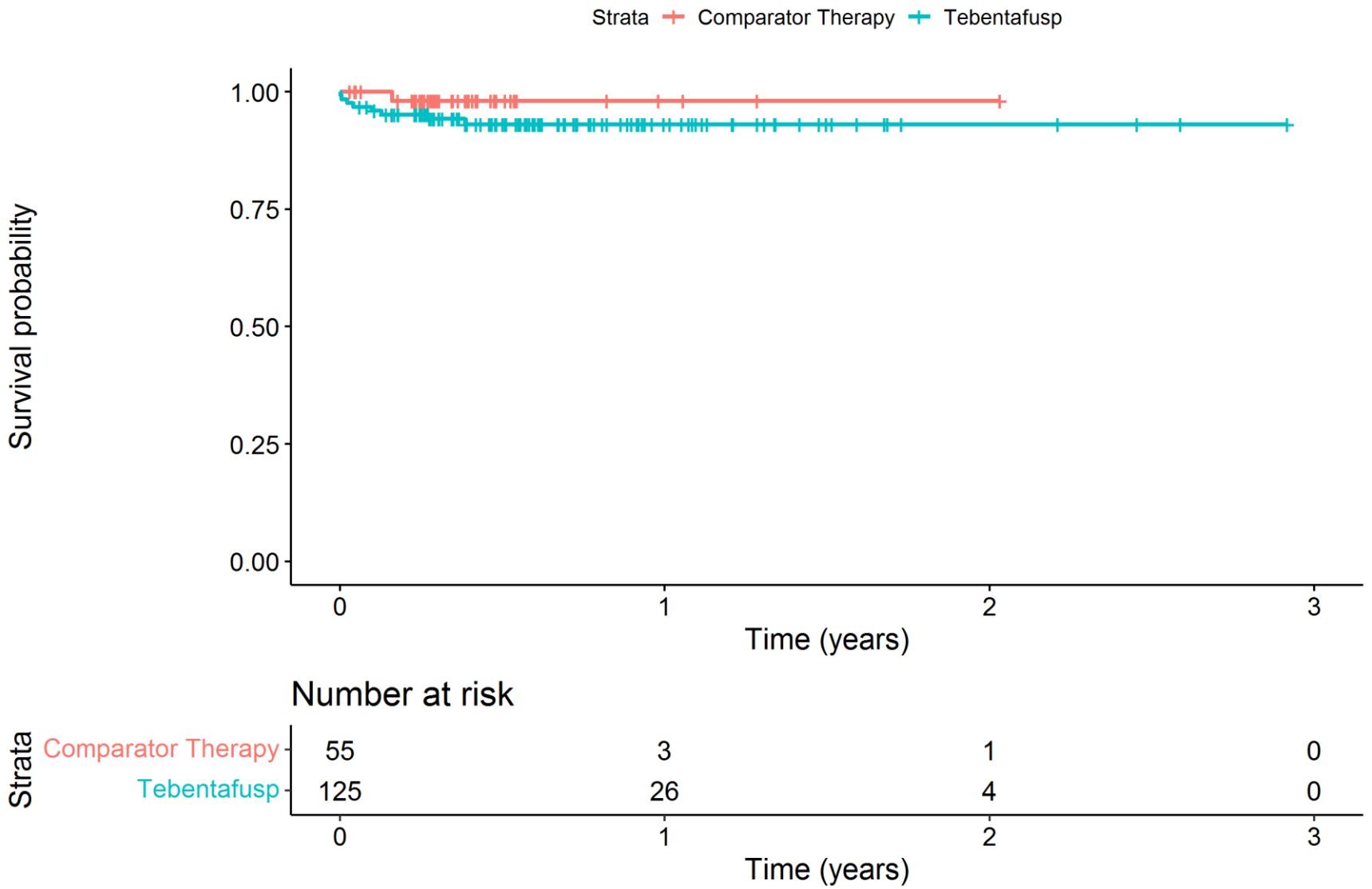
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Hispanisch



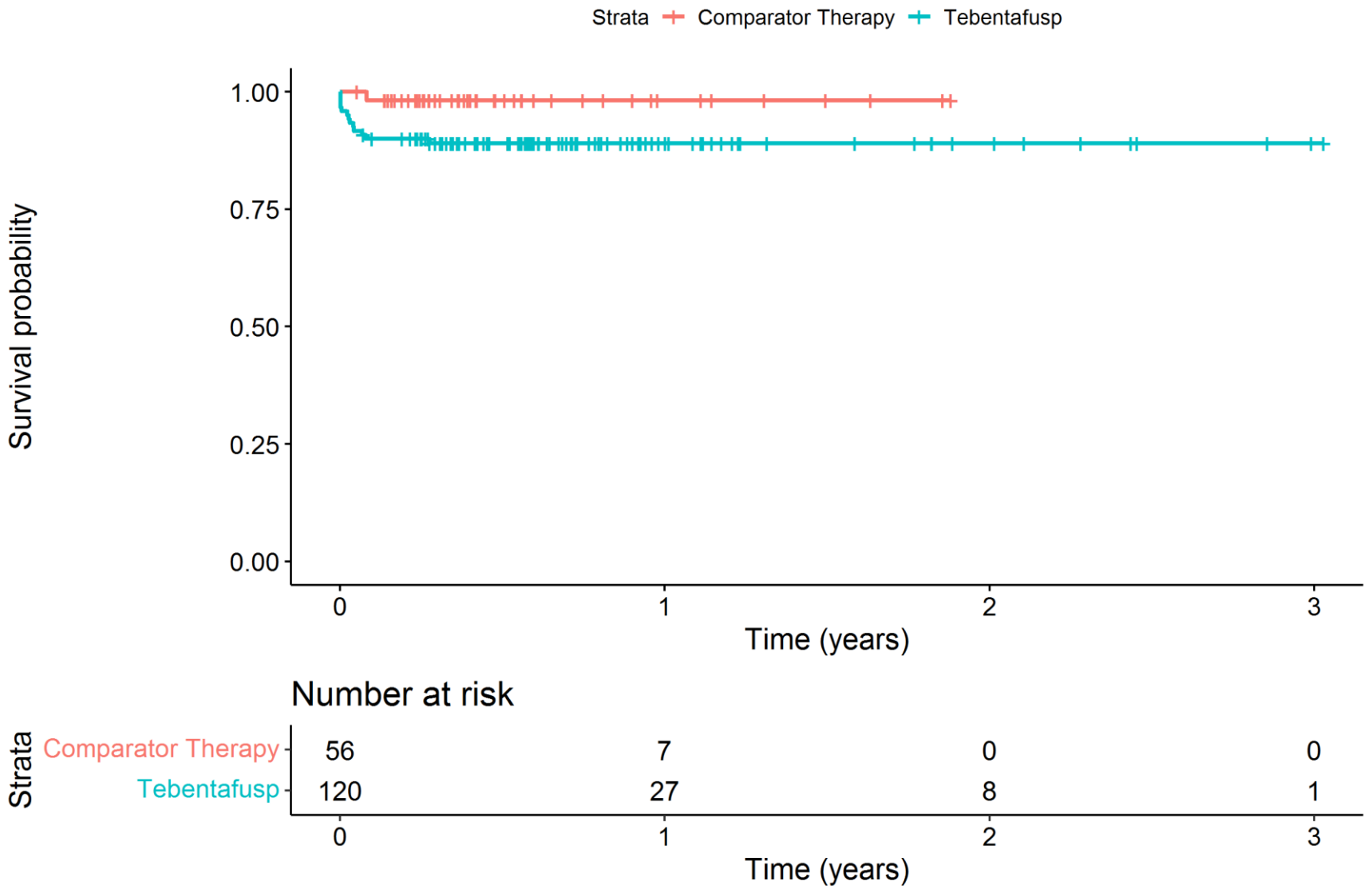
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nicht-hispanisch



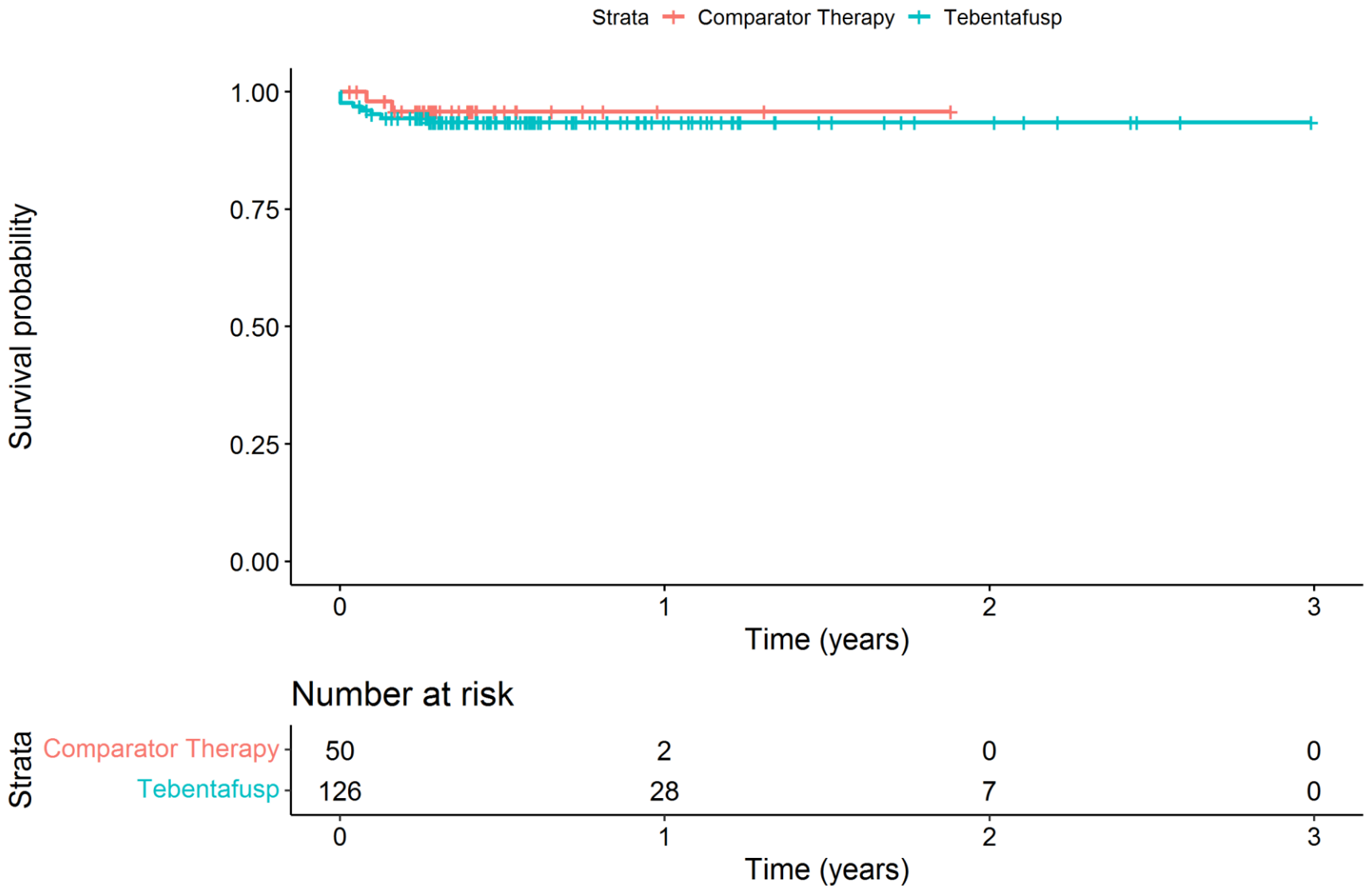
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Männlich



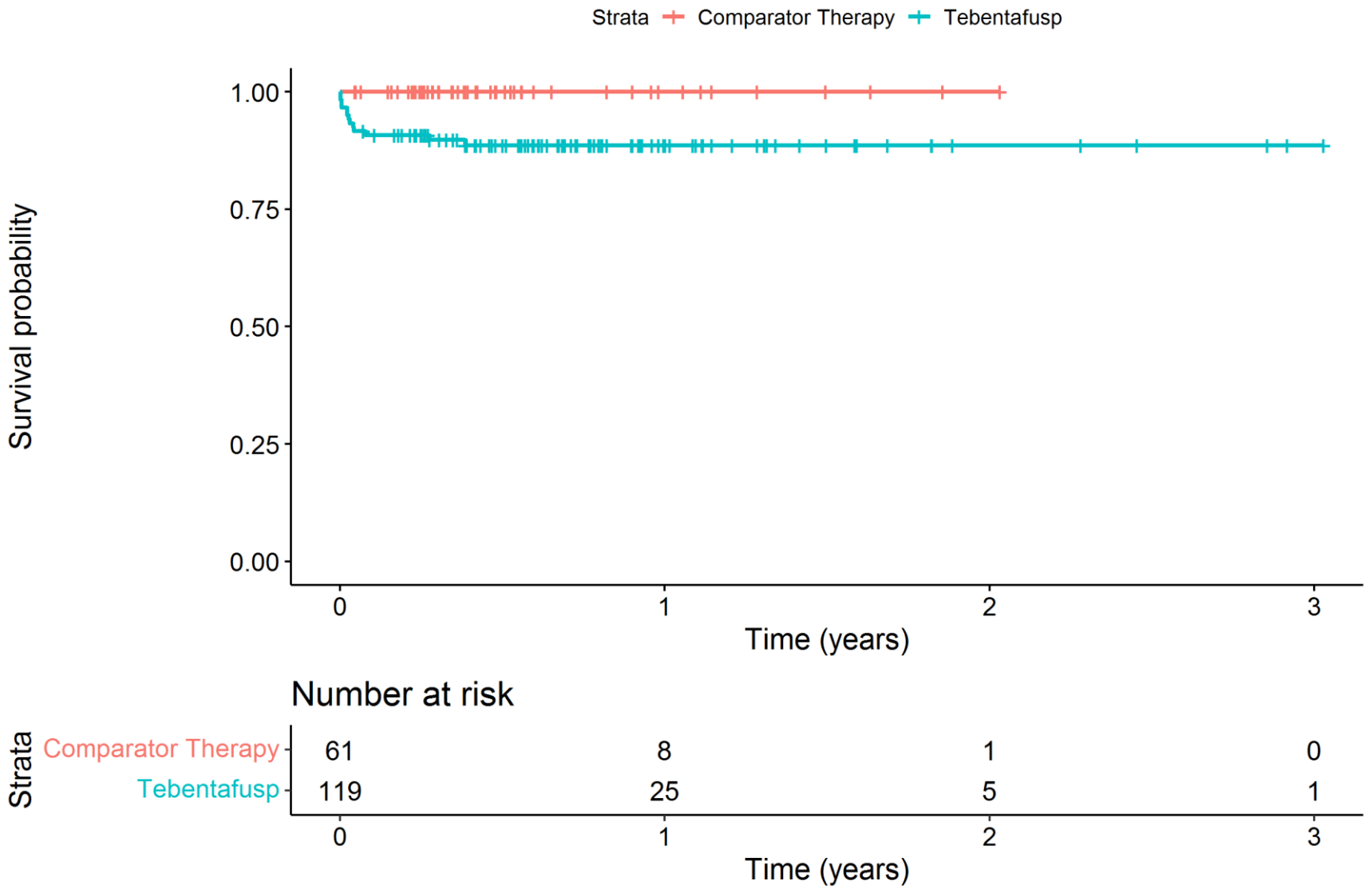
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Weiblich



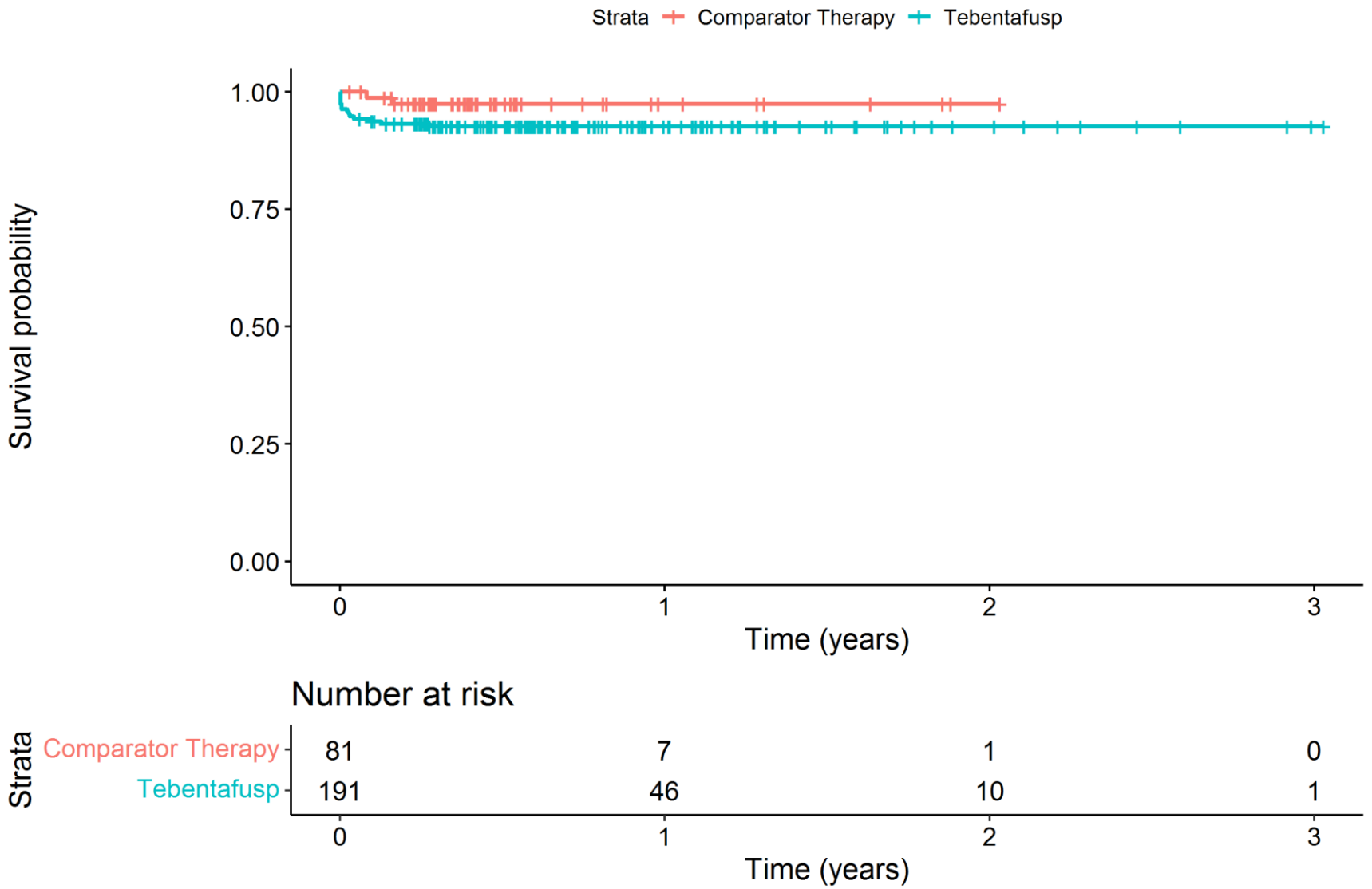
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- <65



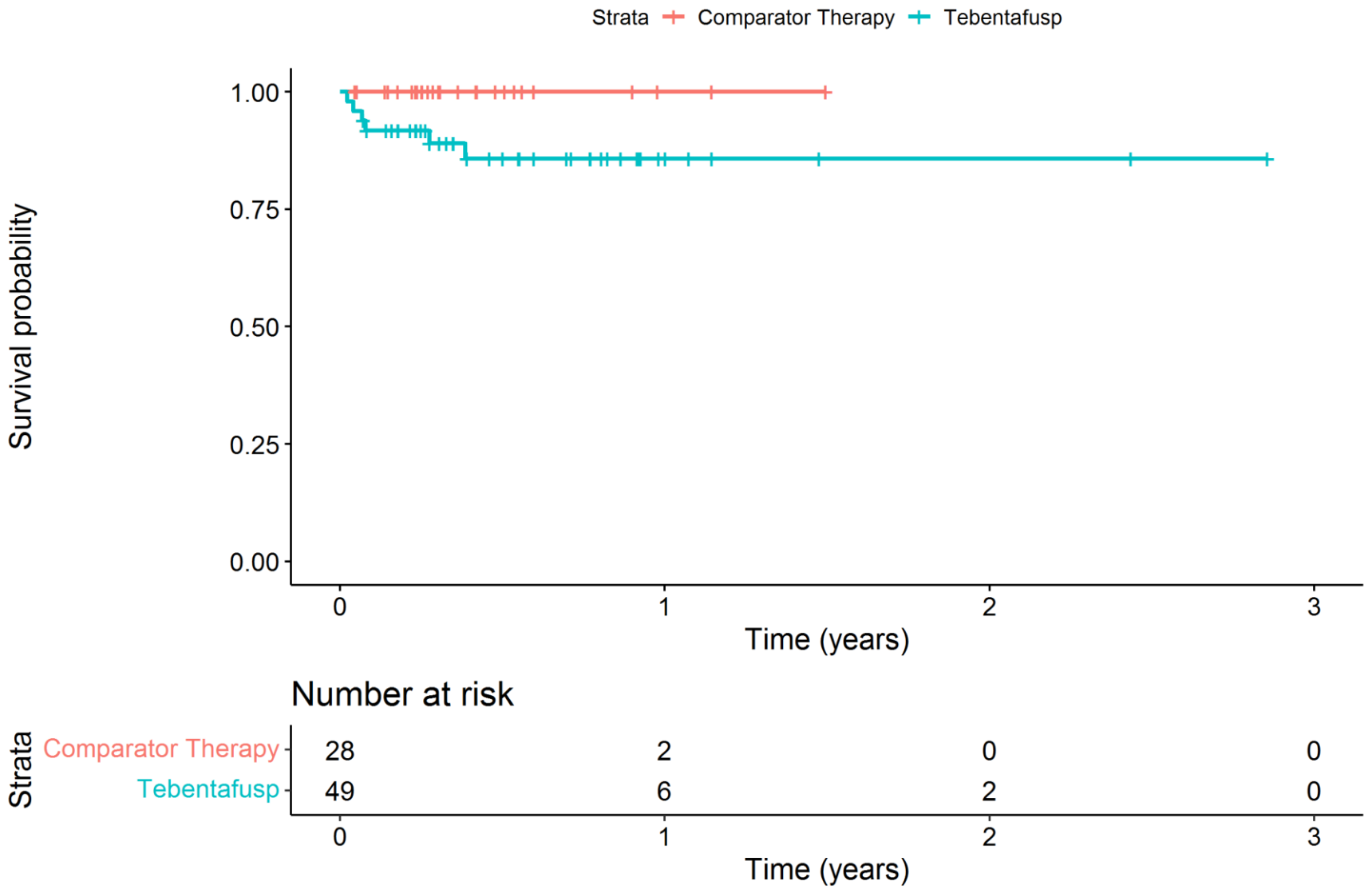
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ≥65



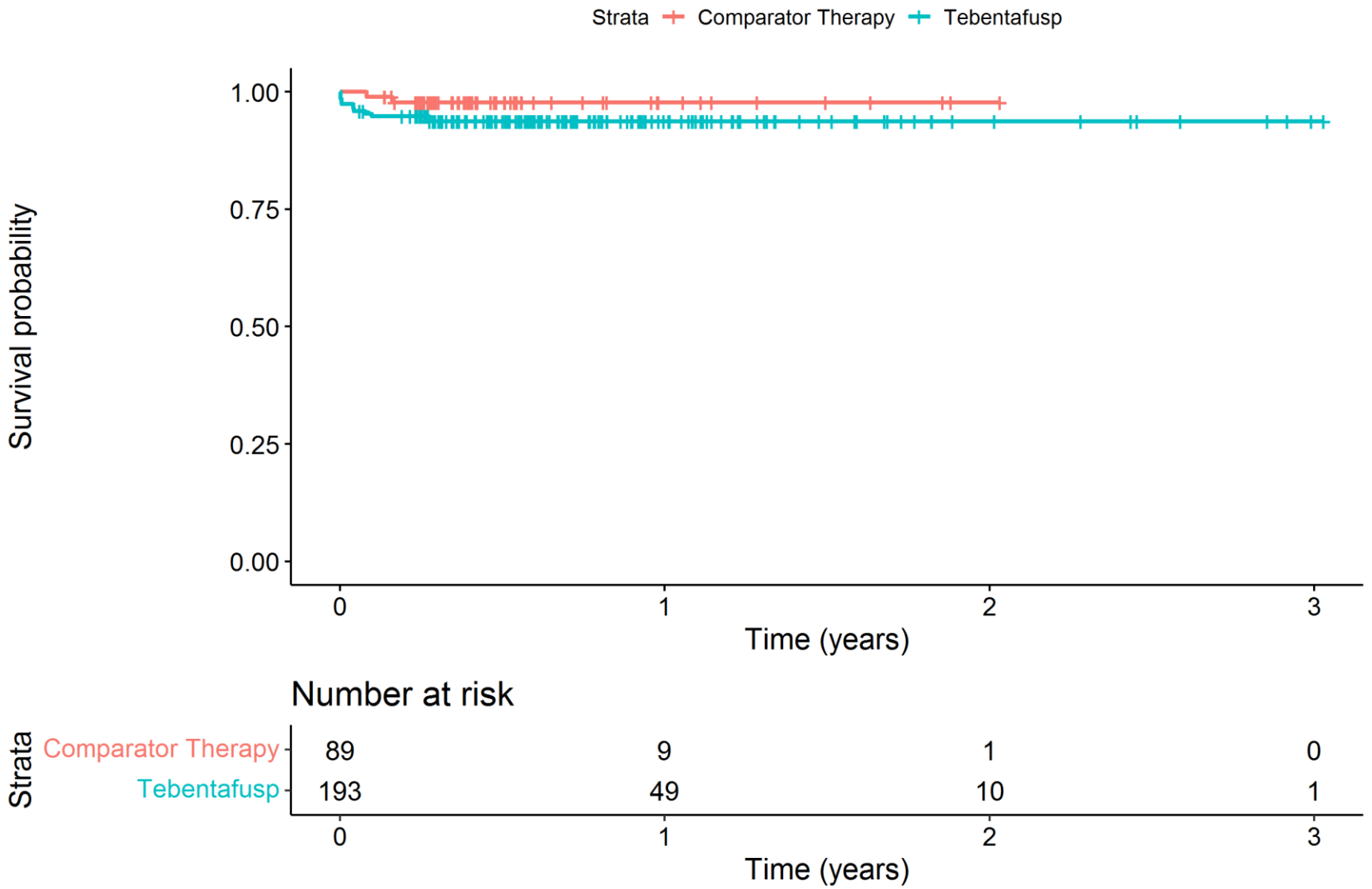
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ECOG 0



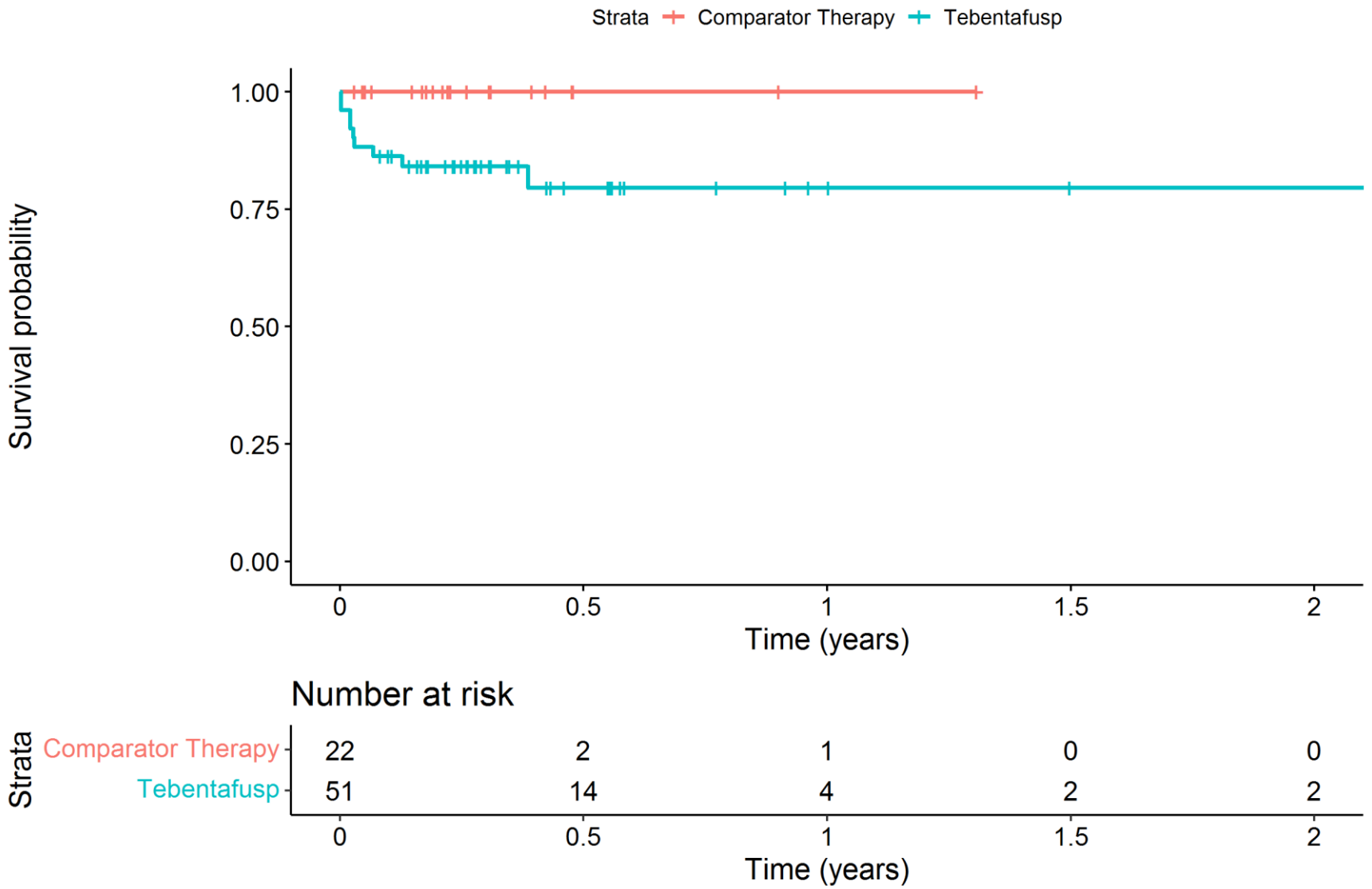
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ECOG 1



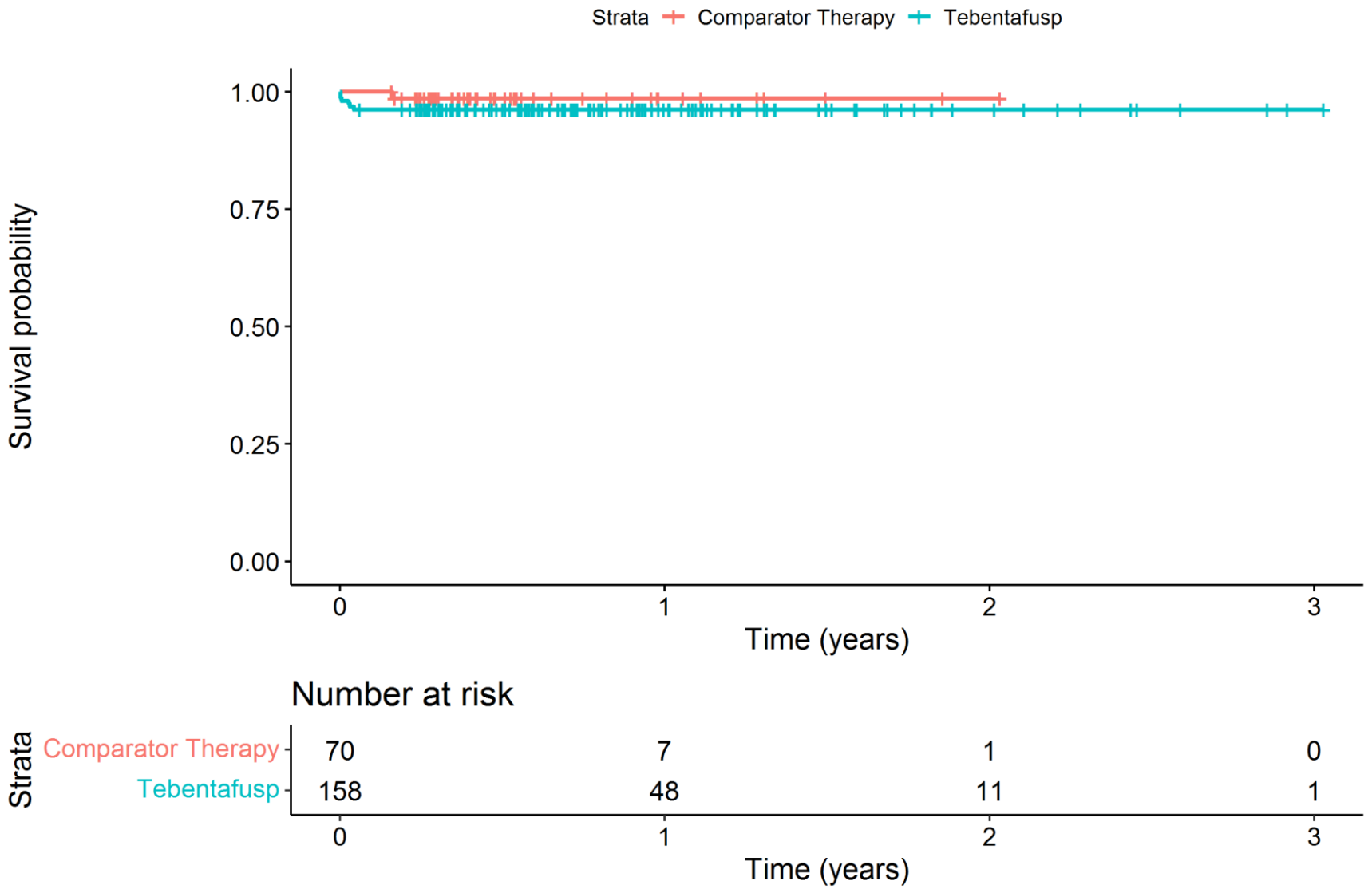
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ALP ≤ ULN



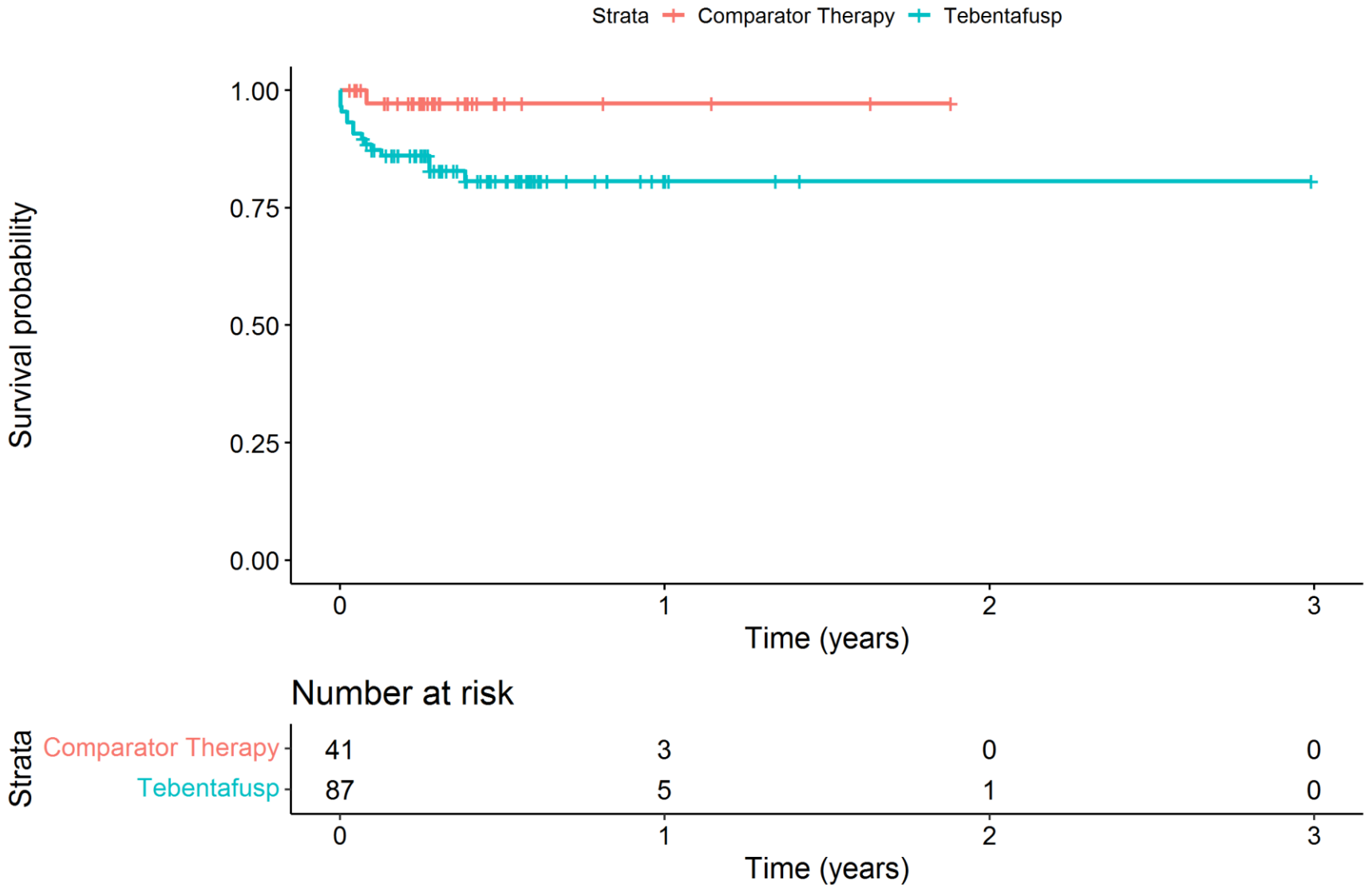
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ALP > ULN



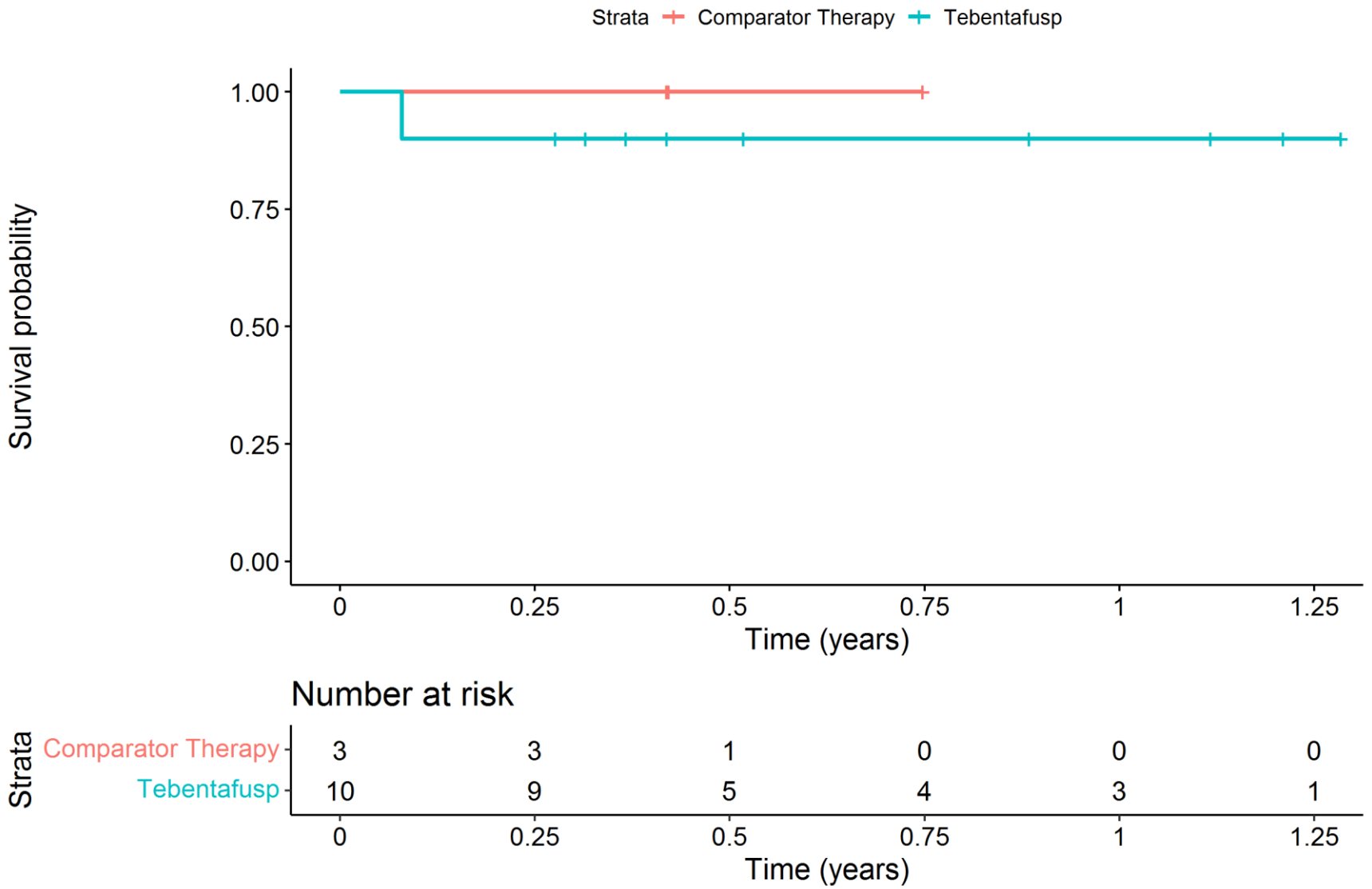
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- LDH =< ULN



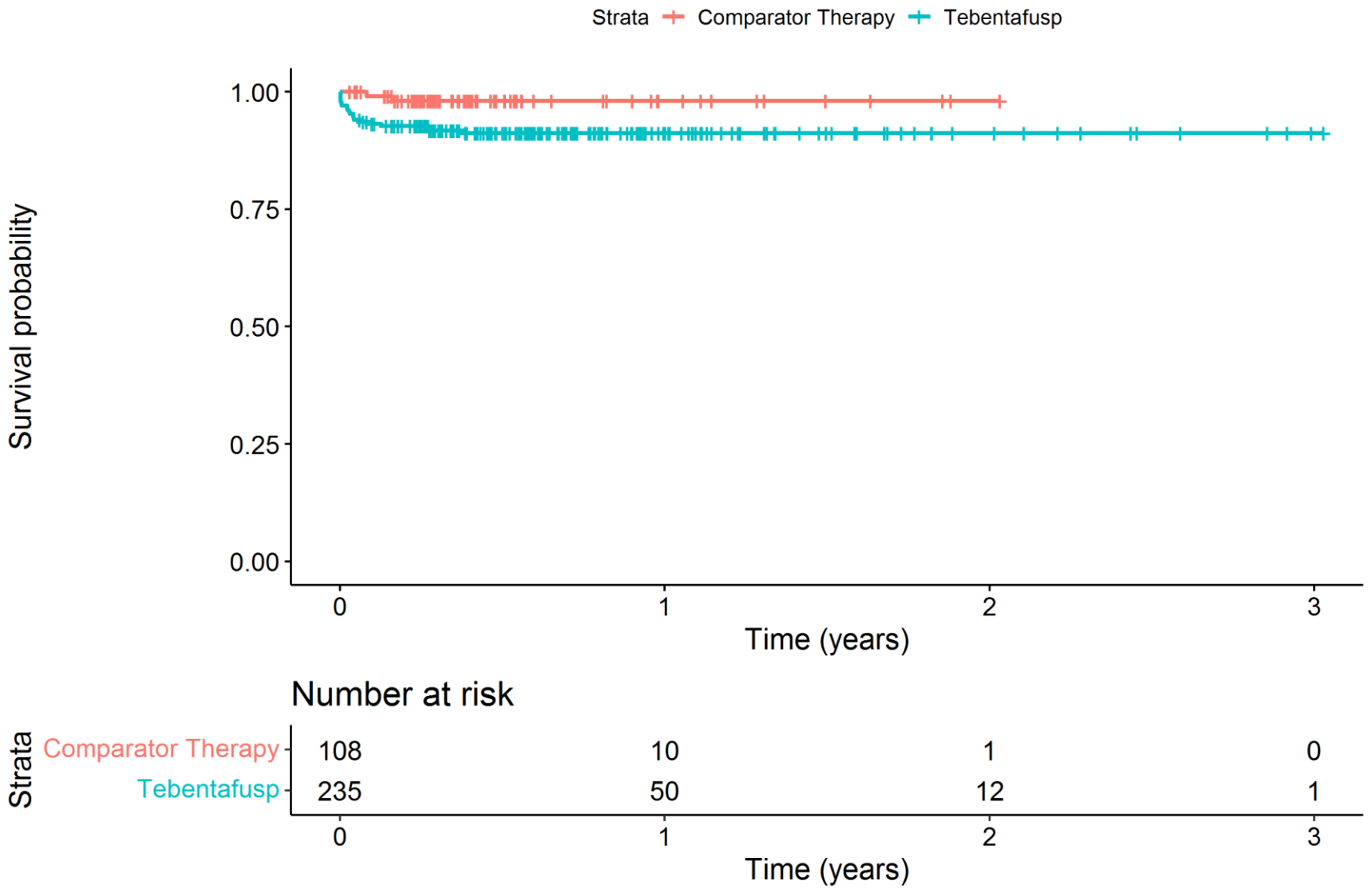
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- LDH > ULN



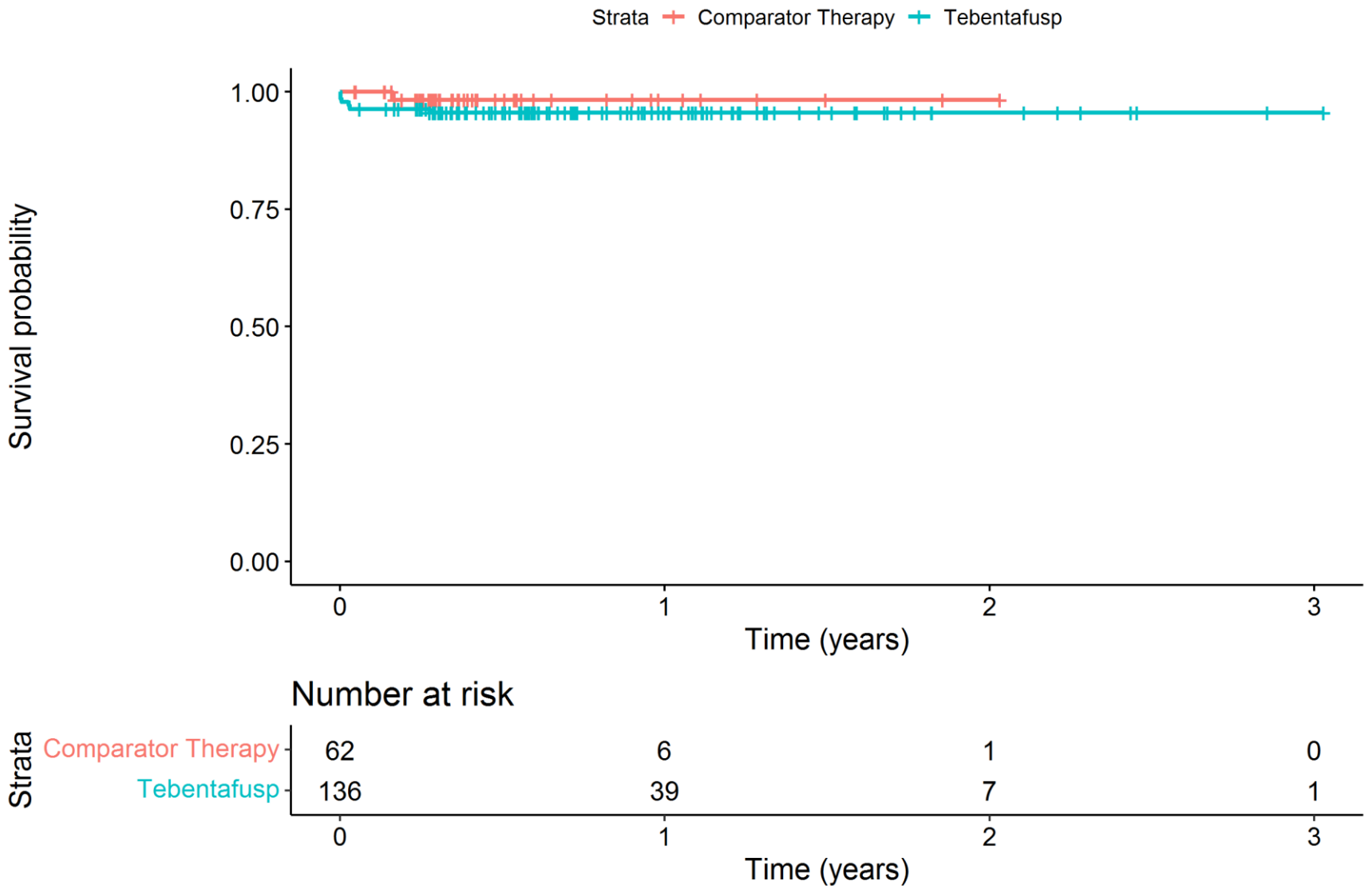
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Vorherige Therapie adjuvant/neoadjuvant



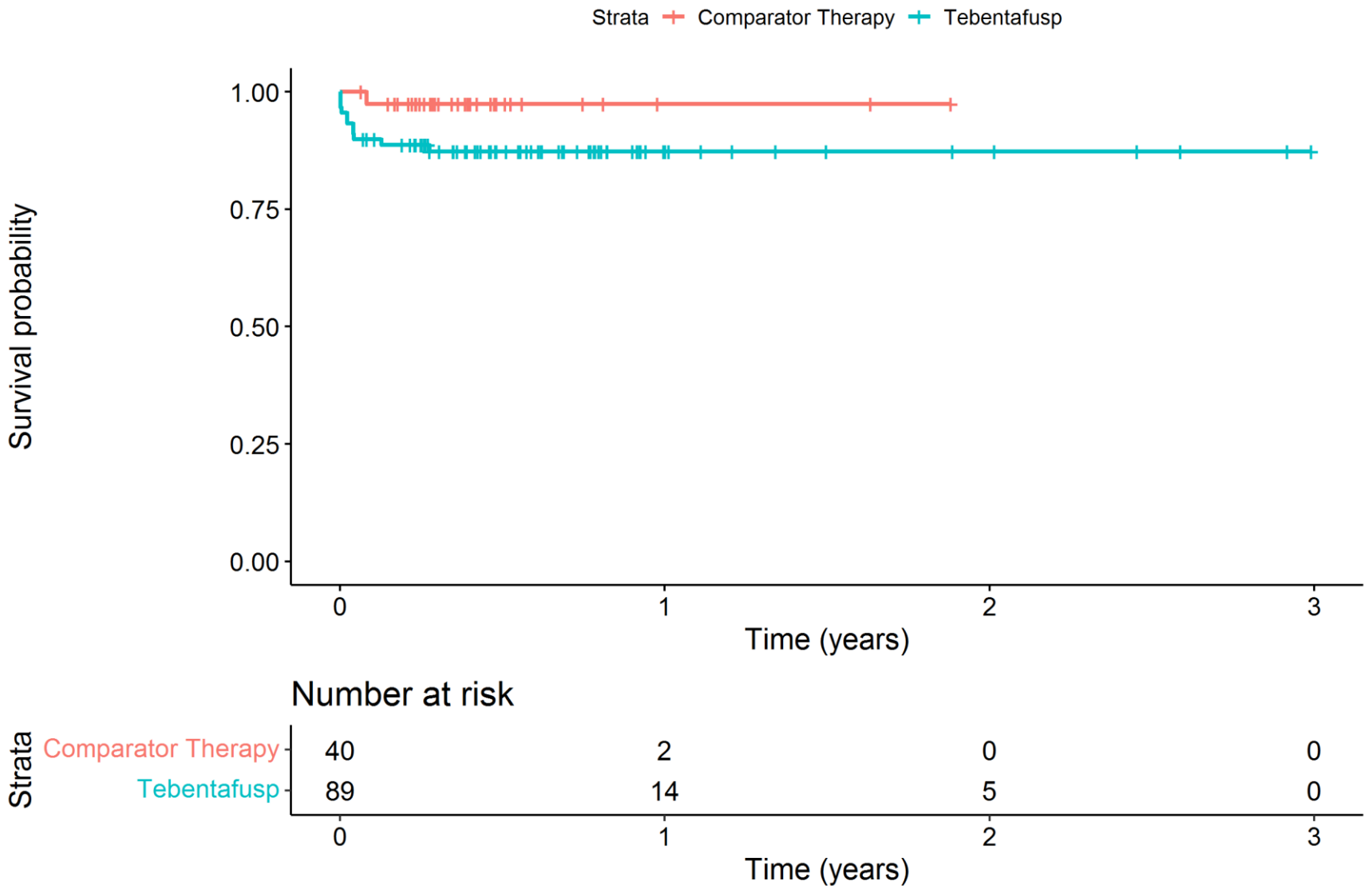
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Keine vorherige Therapie adjuvant/neoadjuvant



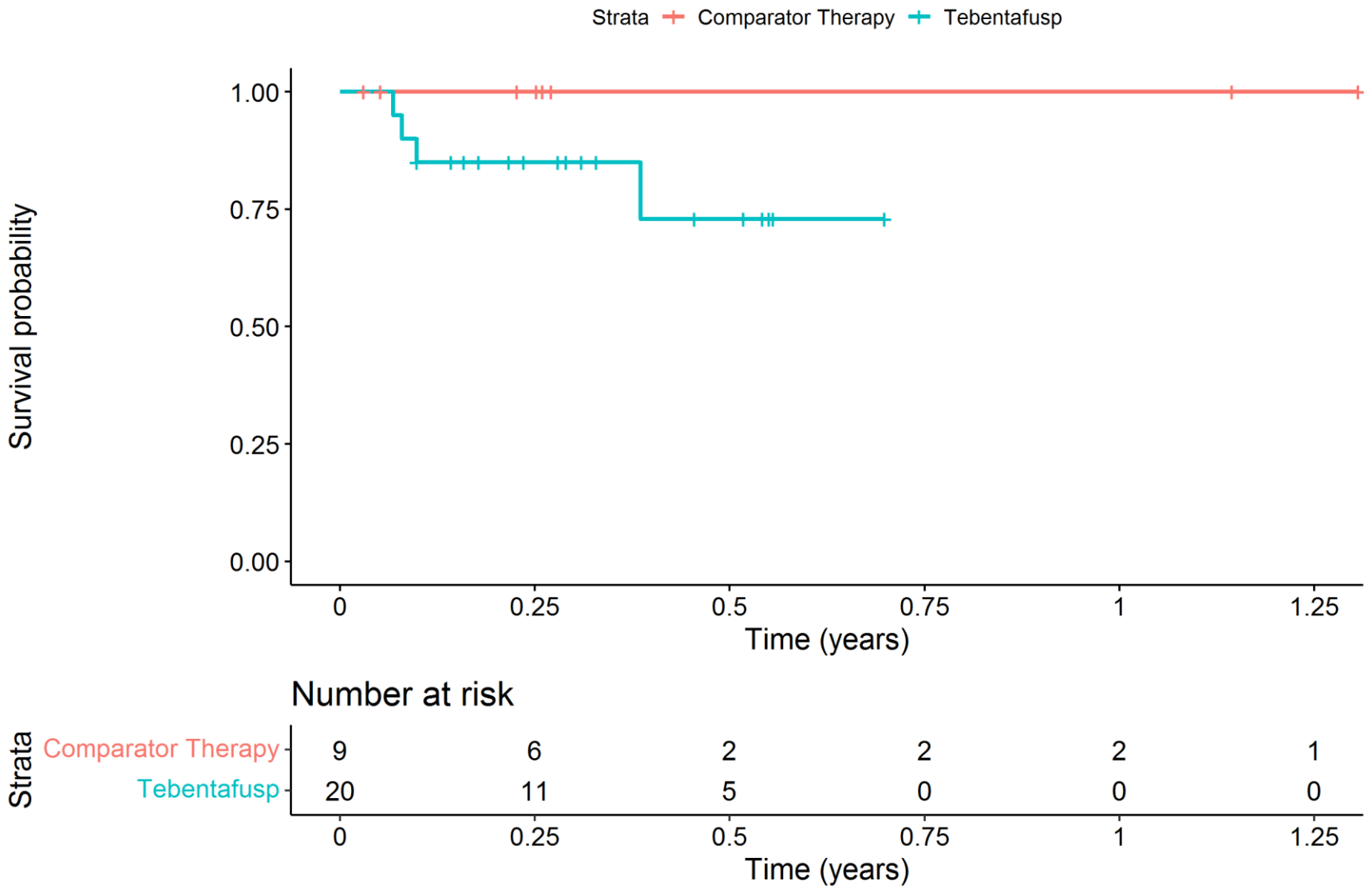
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion ≤ 3cm



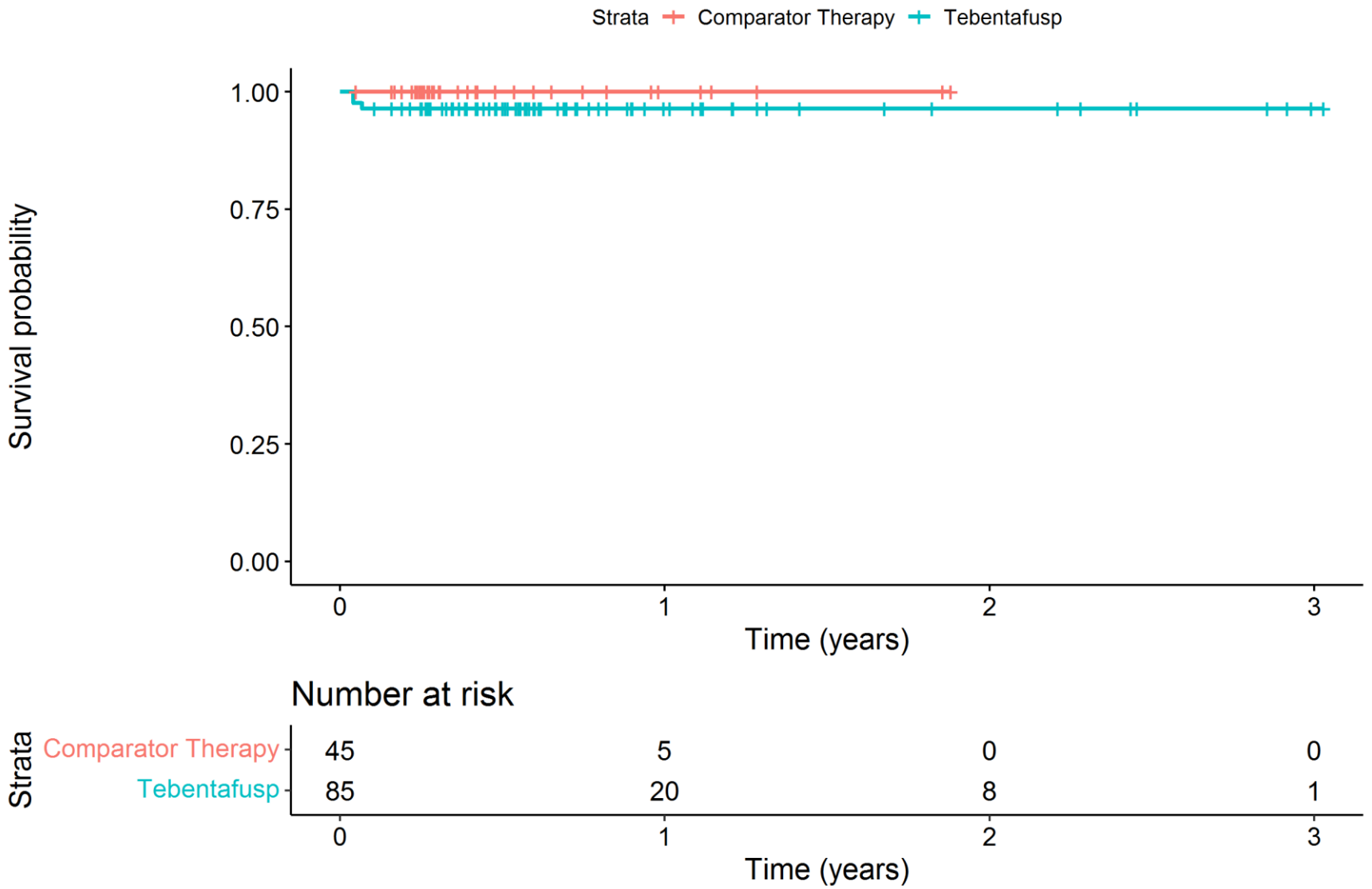
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion 3,1-8,0 cm



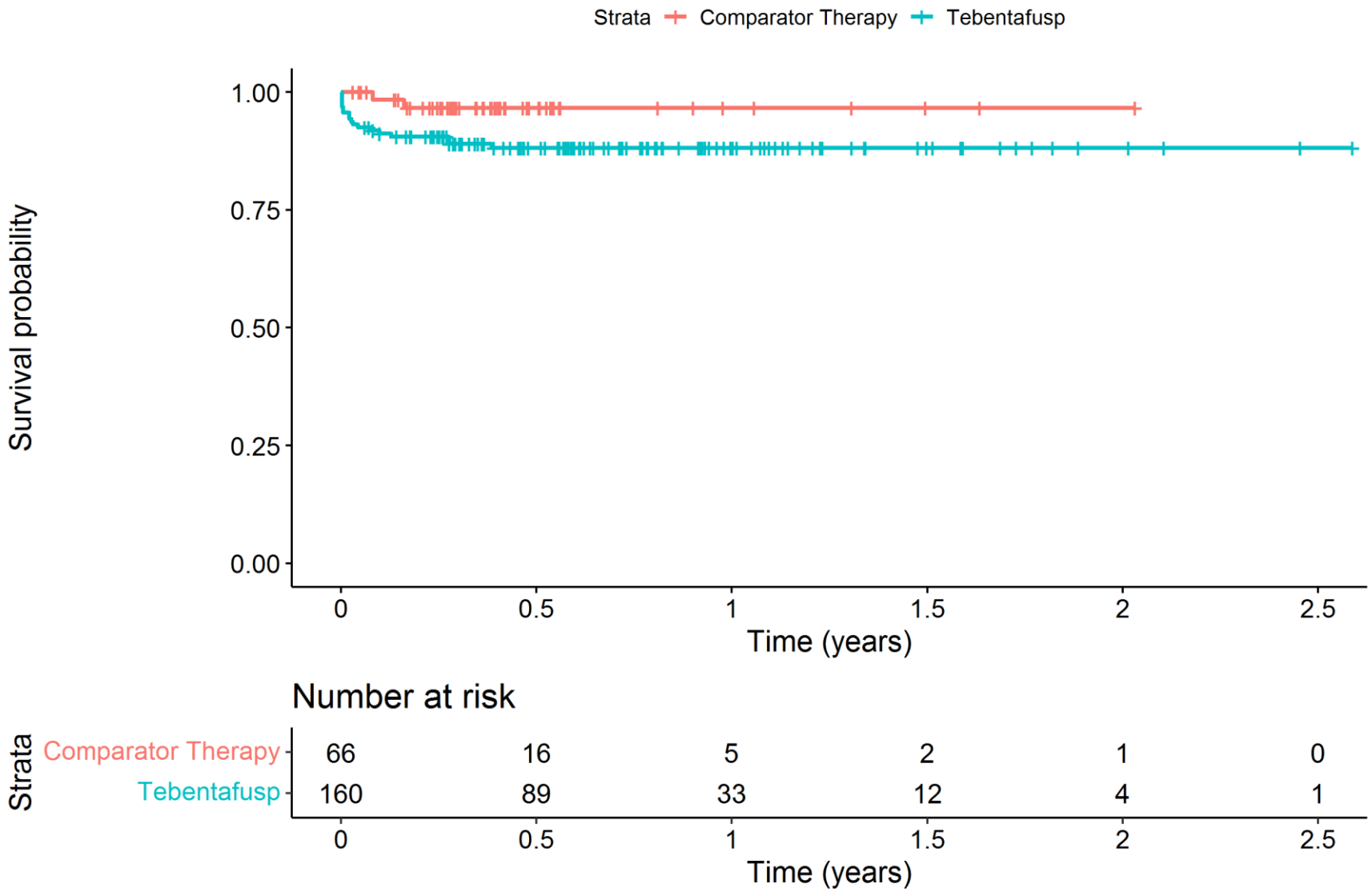
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion ≥8,1 cm



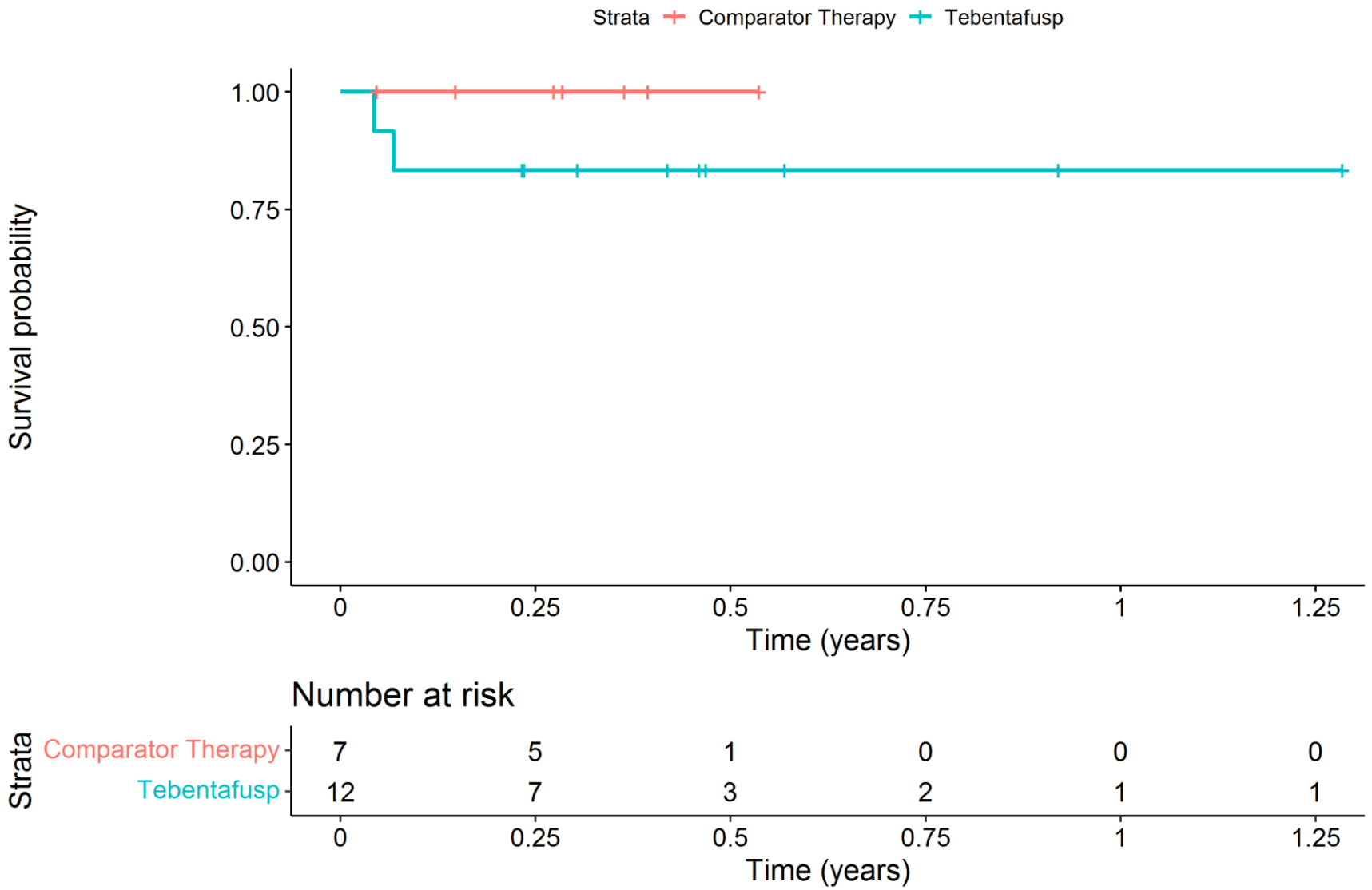
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nordamerika



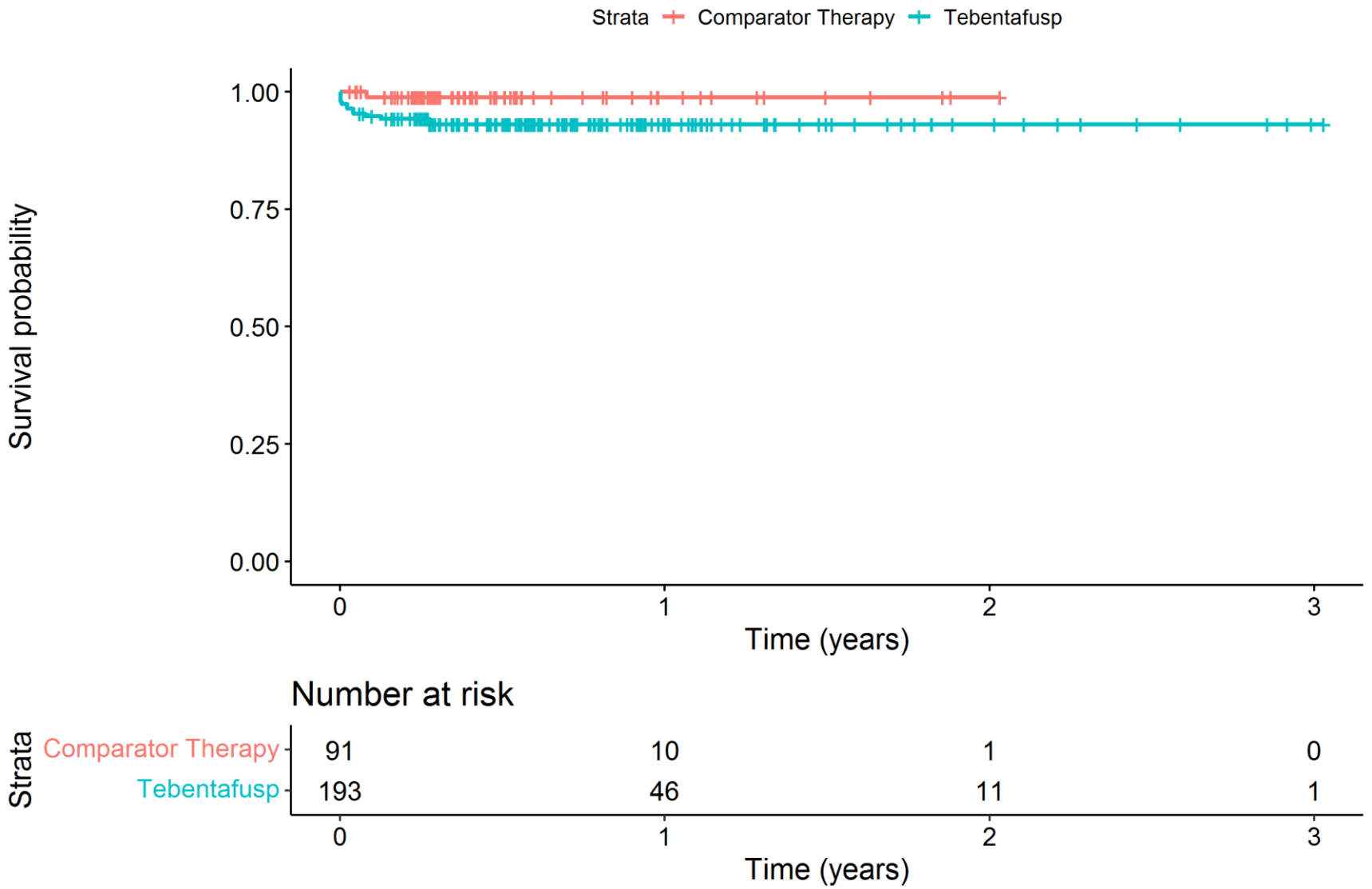
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nicht-Nordamerika



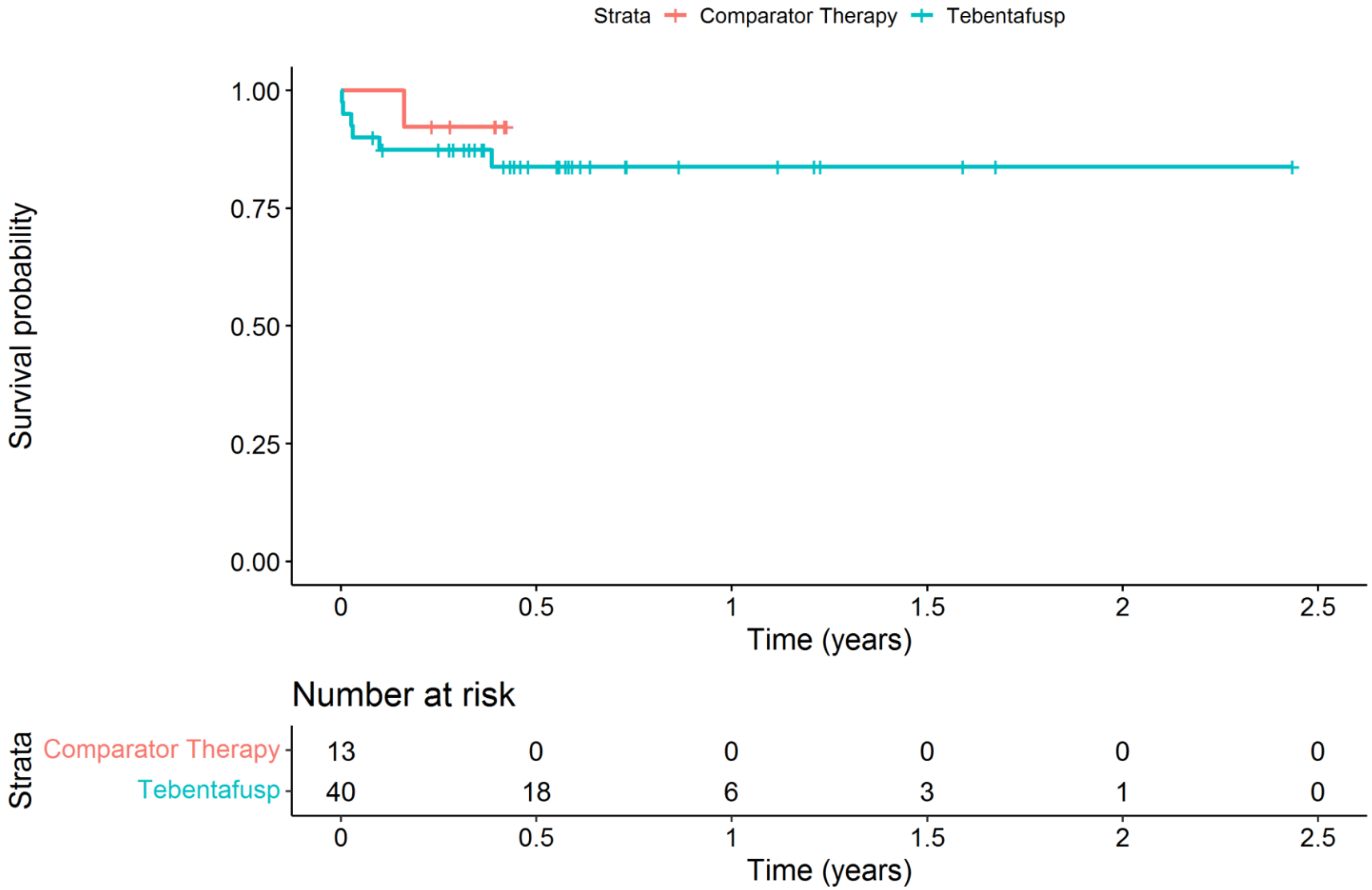
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Dacarbazin



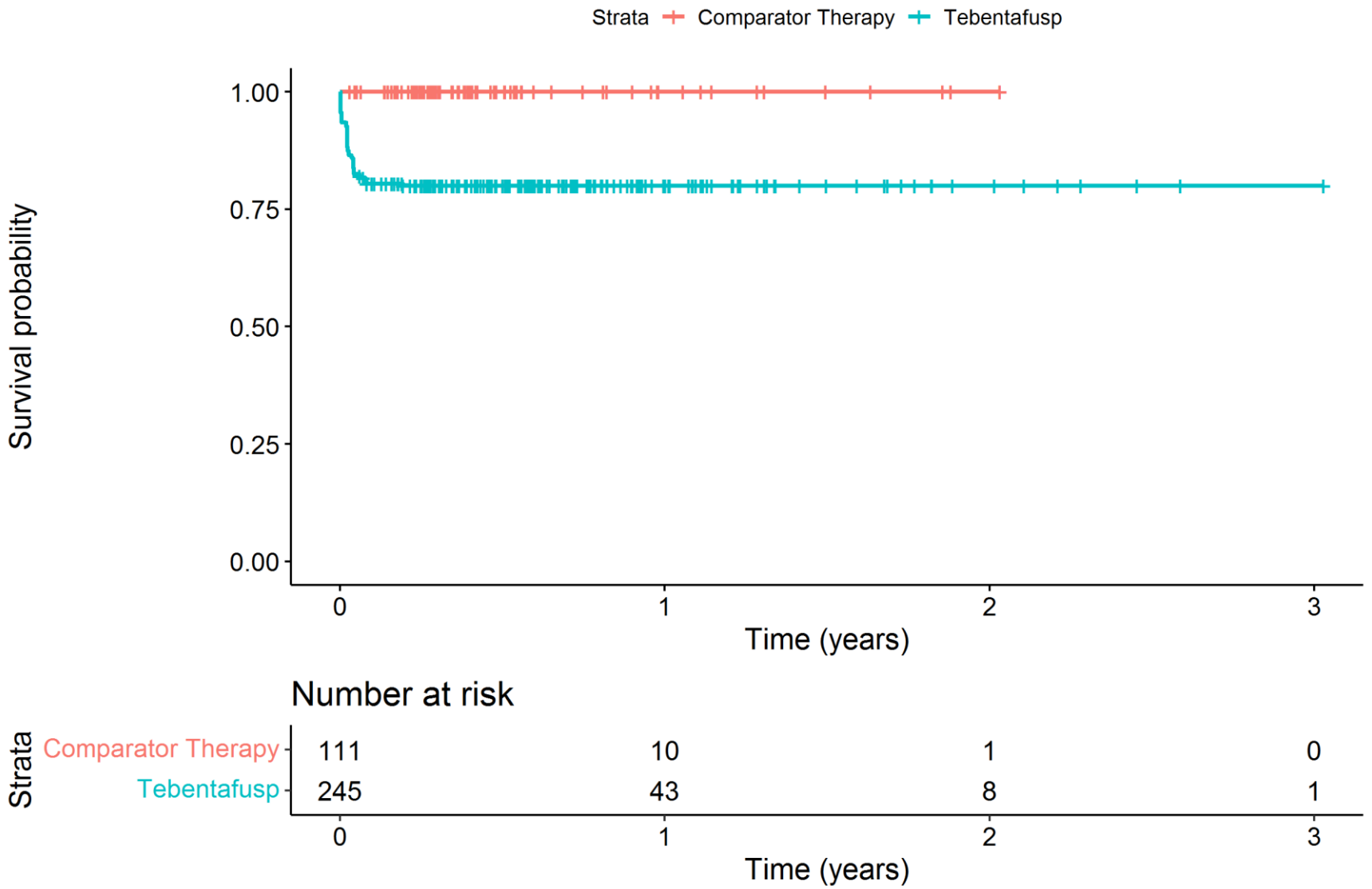
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Pembrolizumab



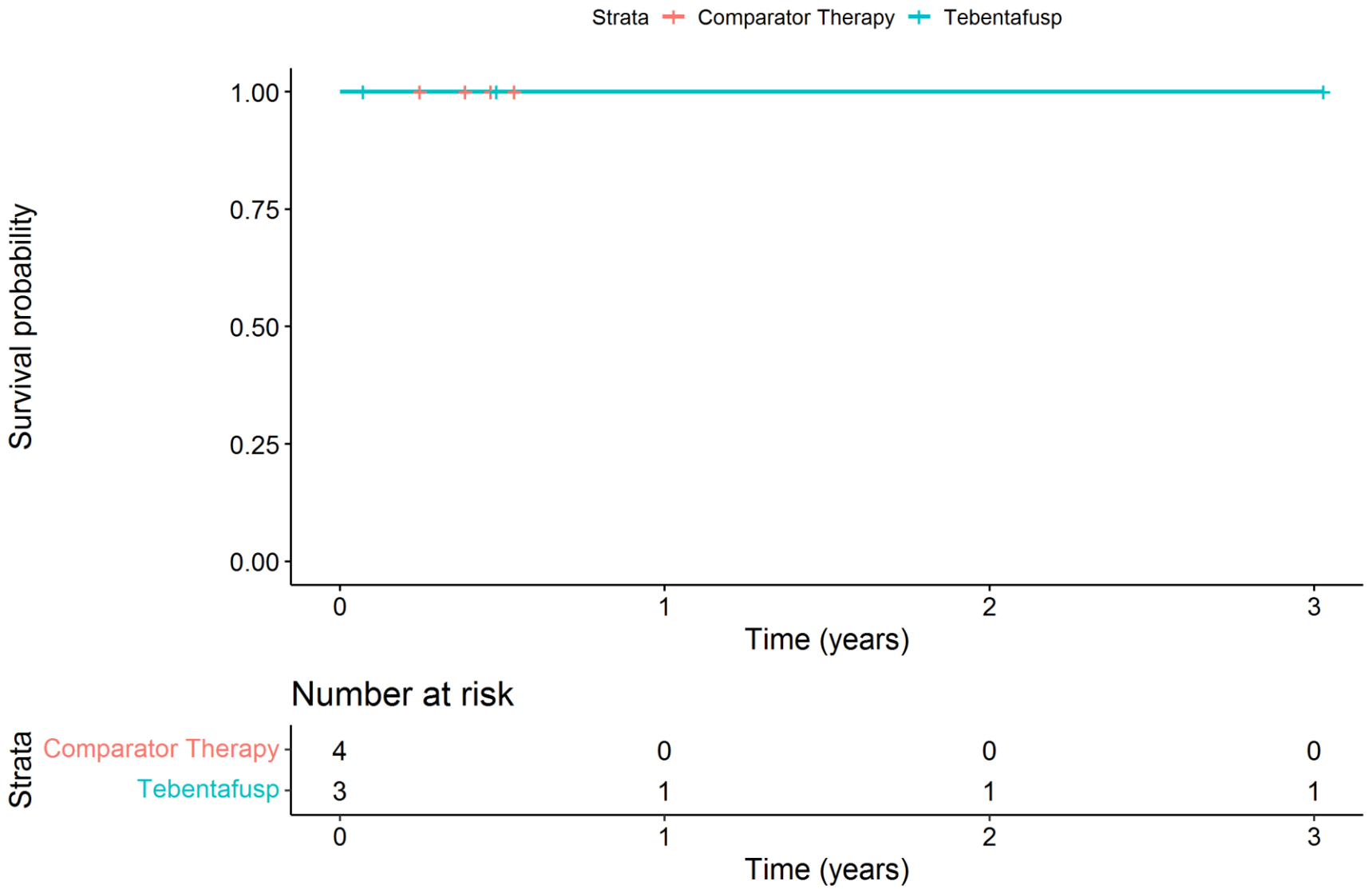
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Ipilimumab



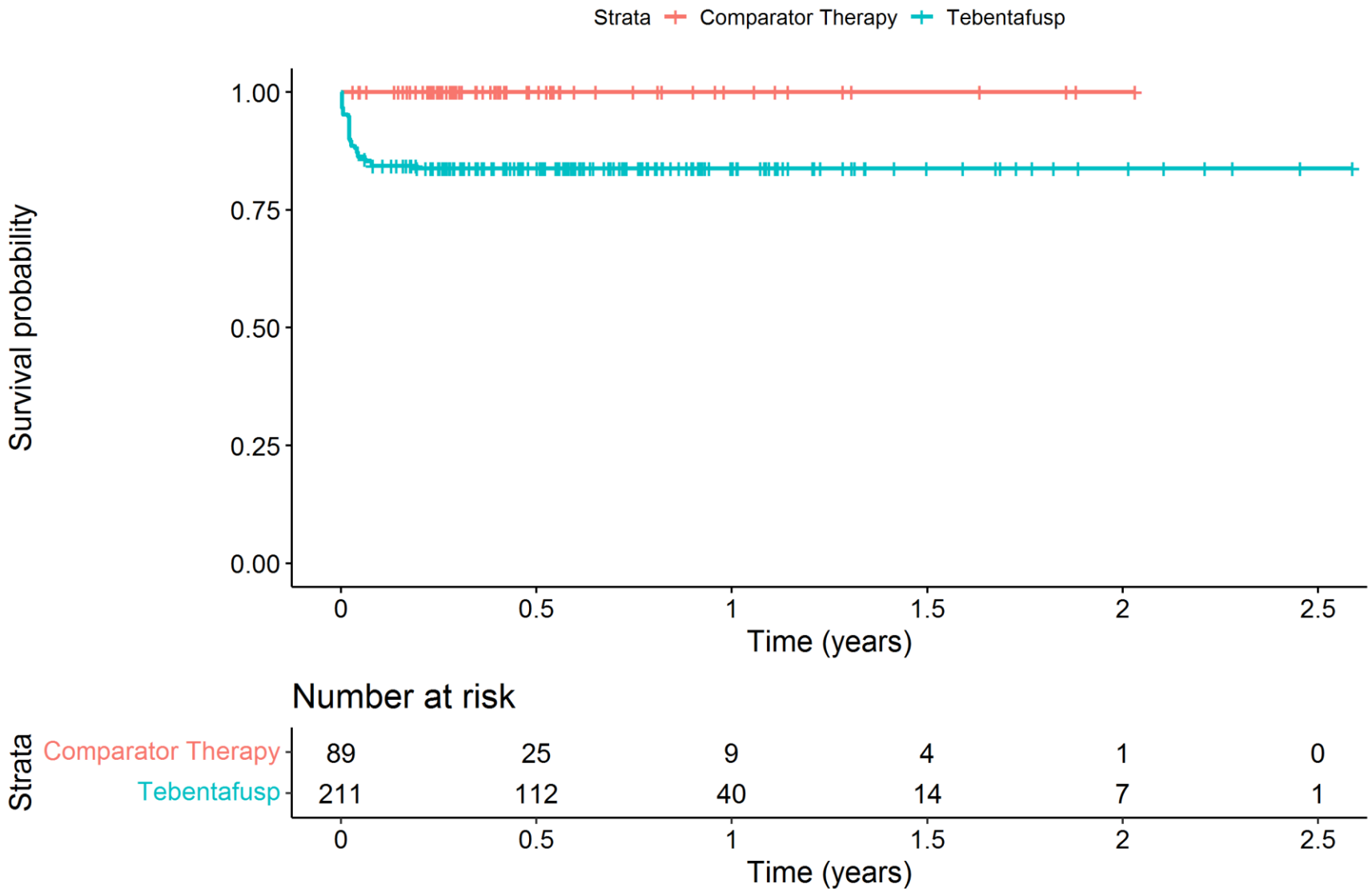
Erkrankungen der Haut und des Unterhautgewebes - Gesamt



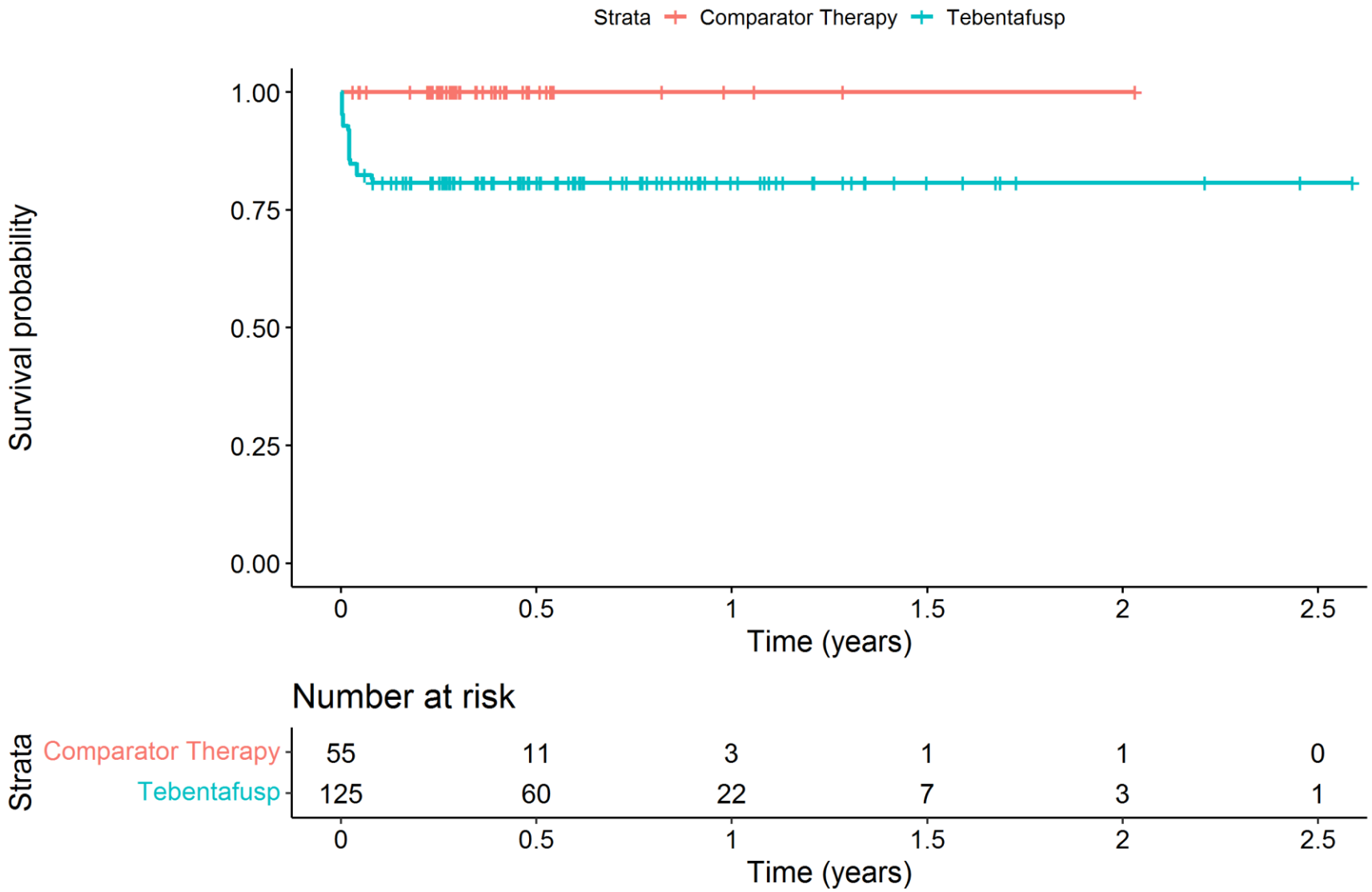
Erkrankungen der Haut und des Unterhautgewebes - Hispanisch



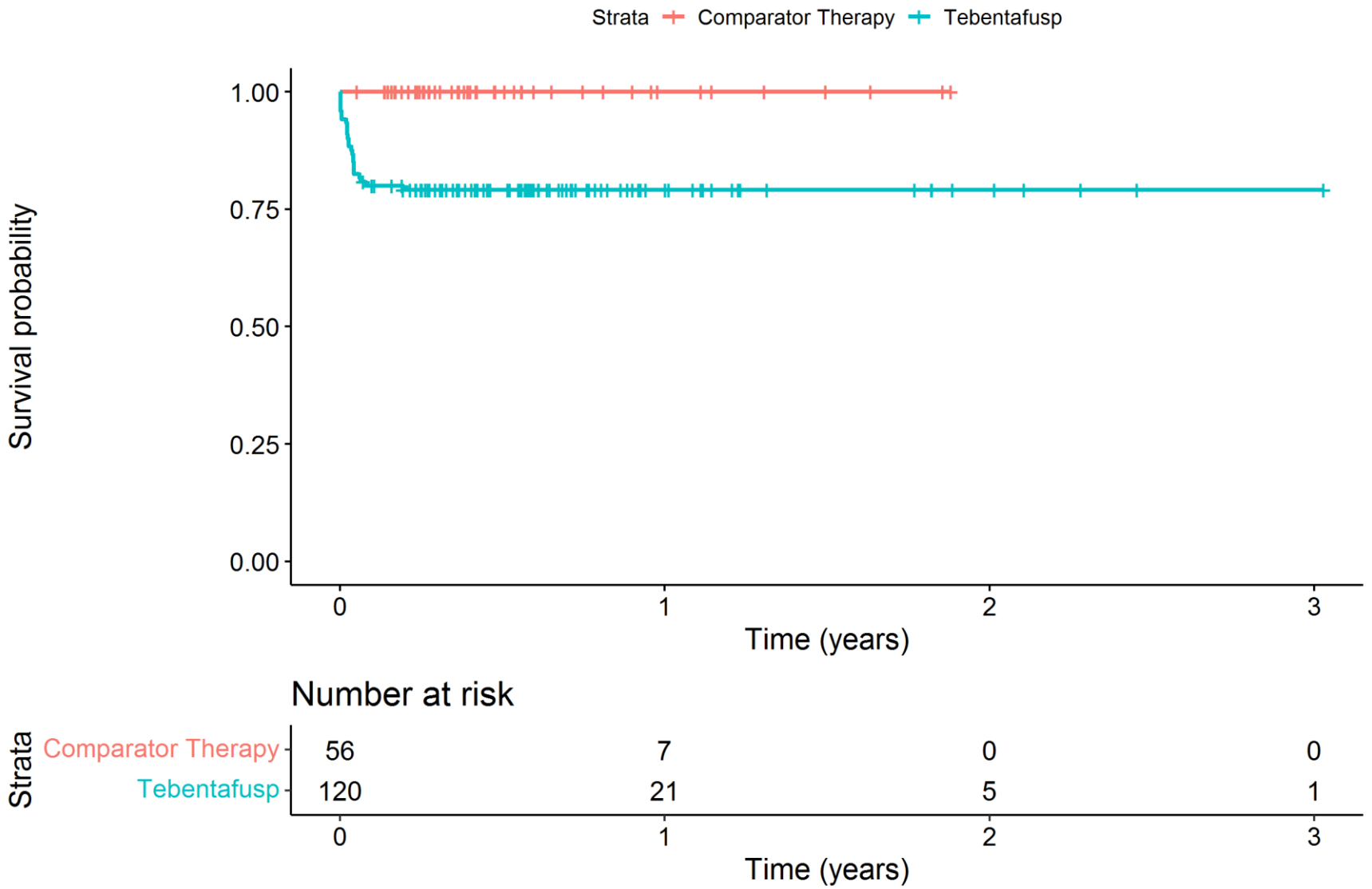
Erkrankungen der Haut und des Unterhautgewebes - Nicht-hispanisch



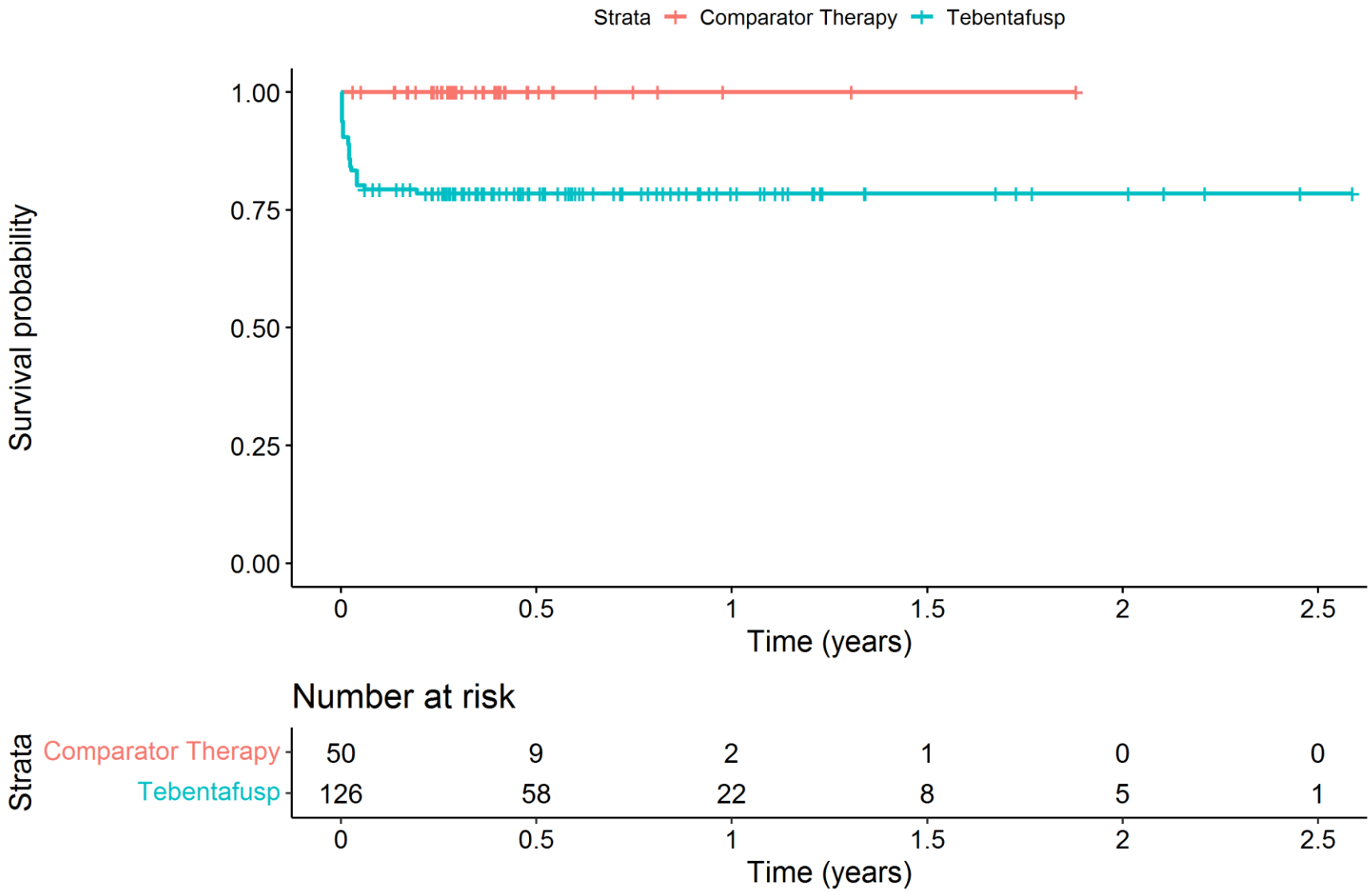
Erkrankungen der Haut und des Unterhautgewebes - Männlich



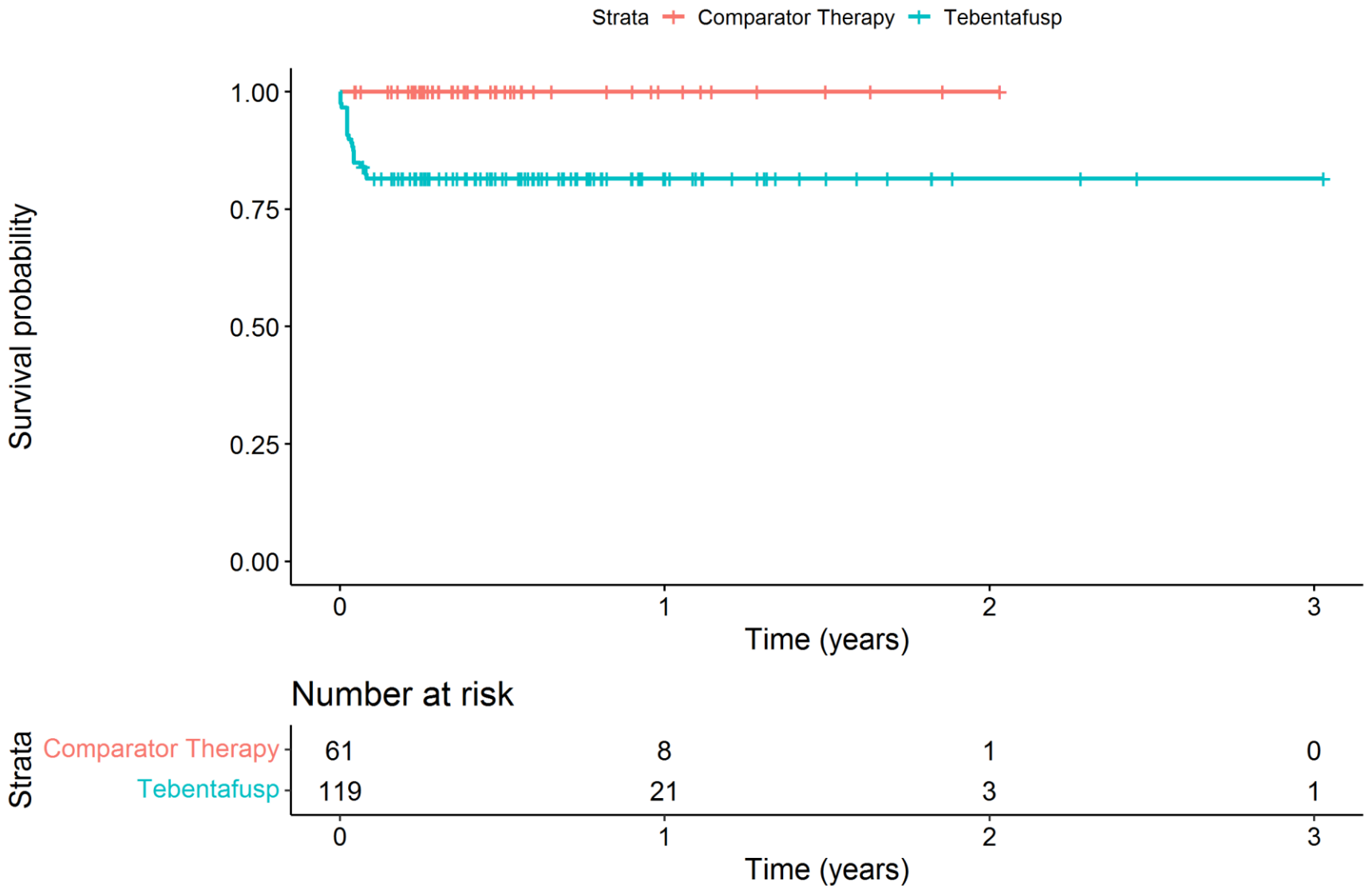
Erkrankungen der Haut und des Unterhautgewebes - Weiblich



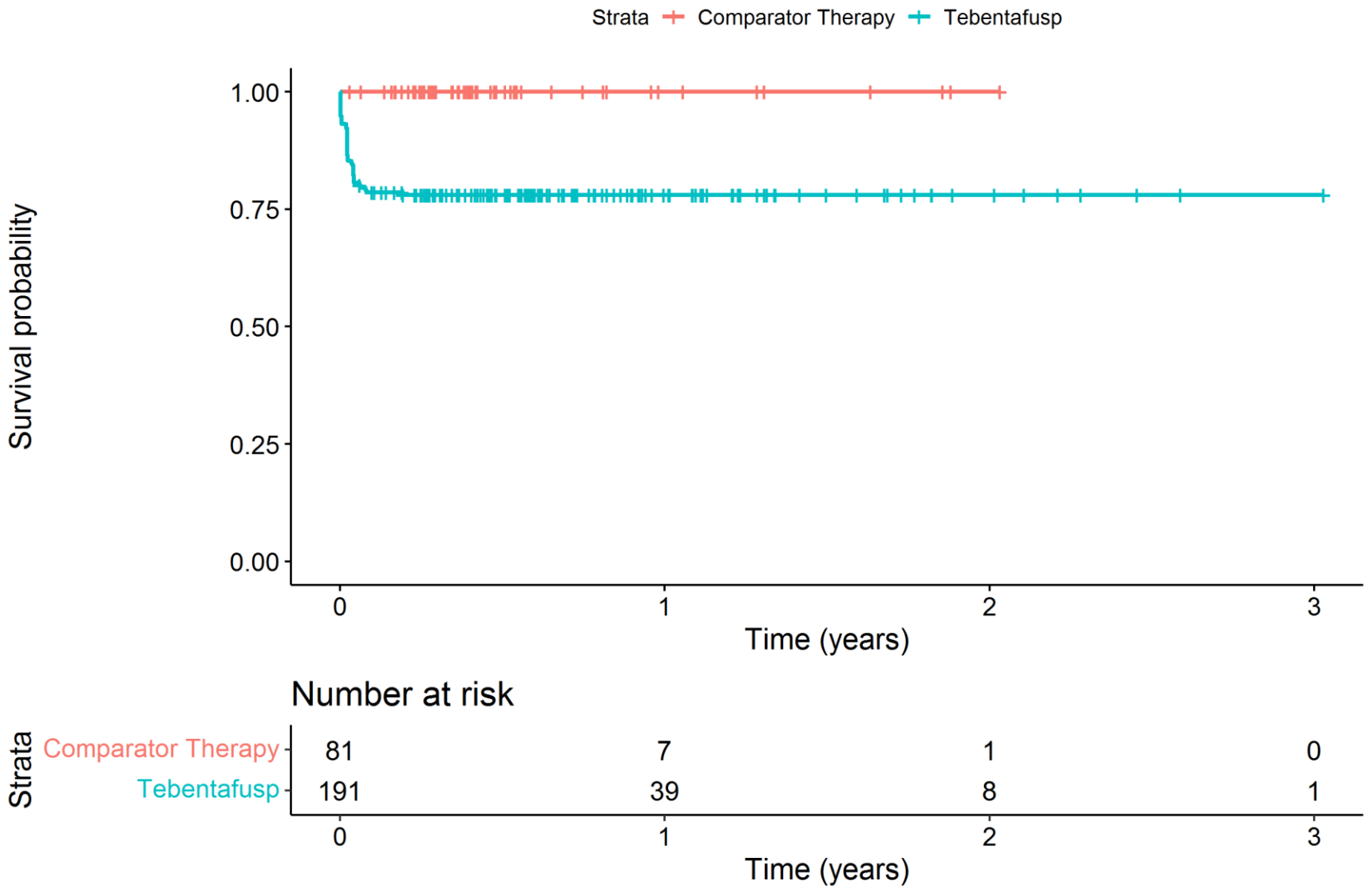
Erkrankungen der Haut und des Unterhautgewebes - <65



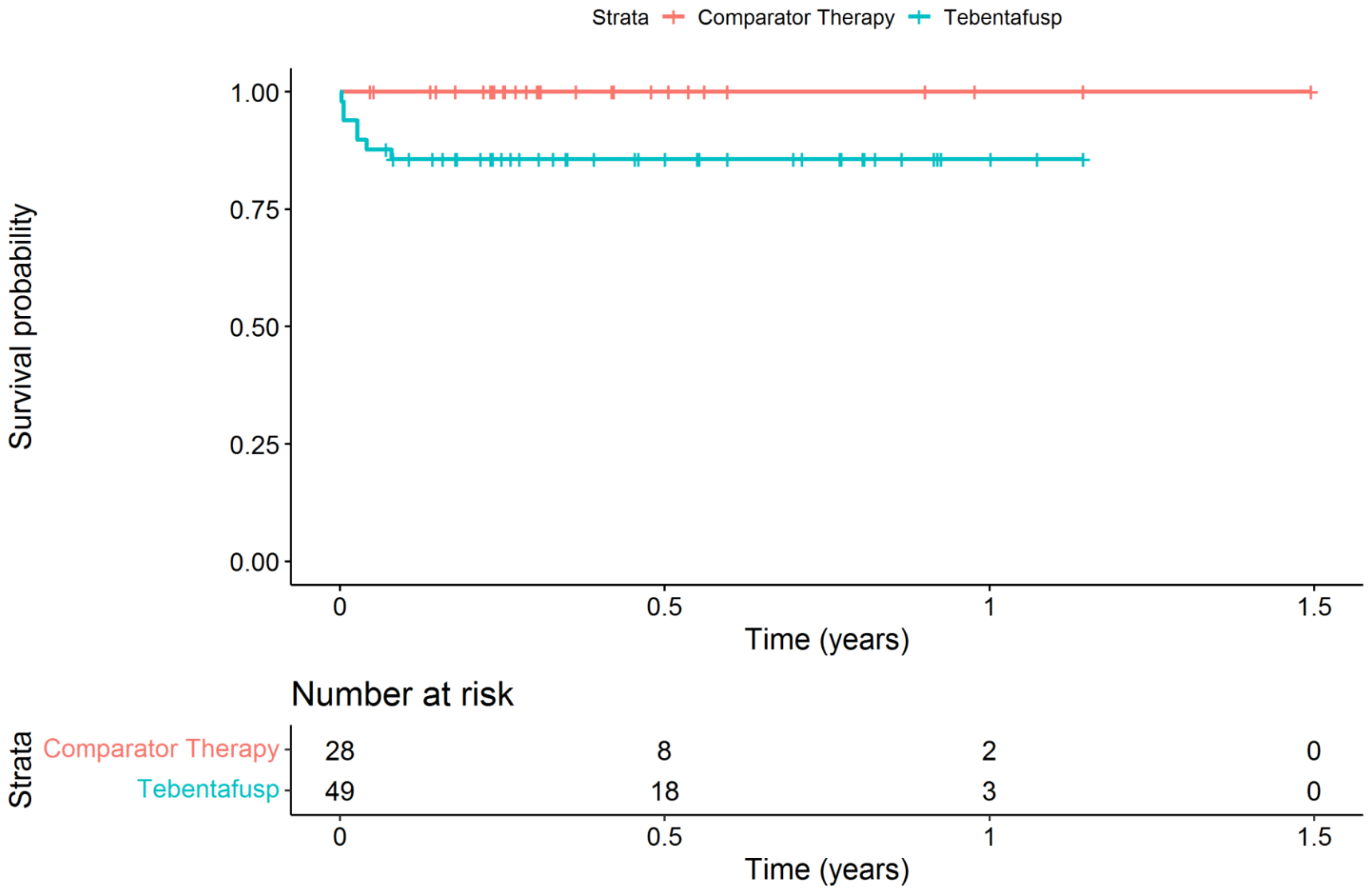
Erkrankungen der Haut und des Unterhautgewebes - ≥65



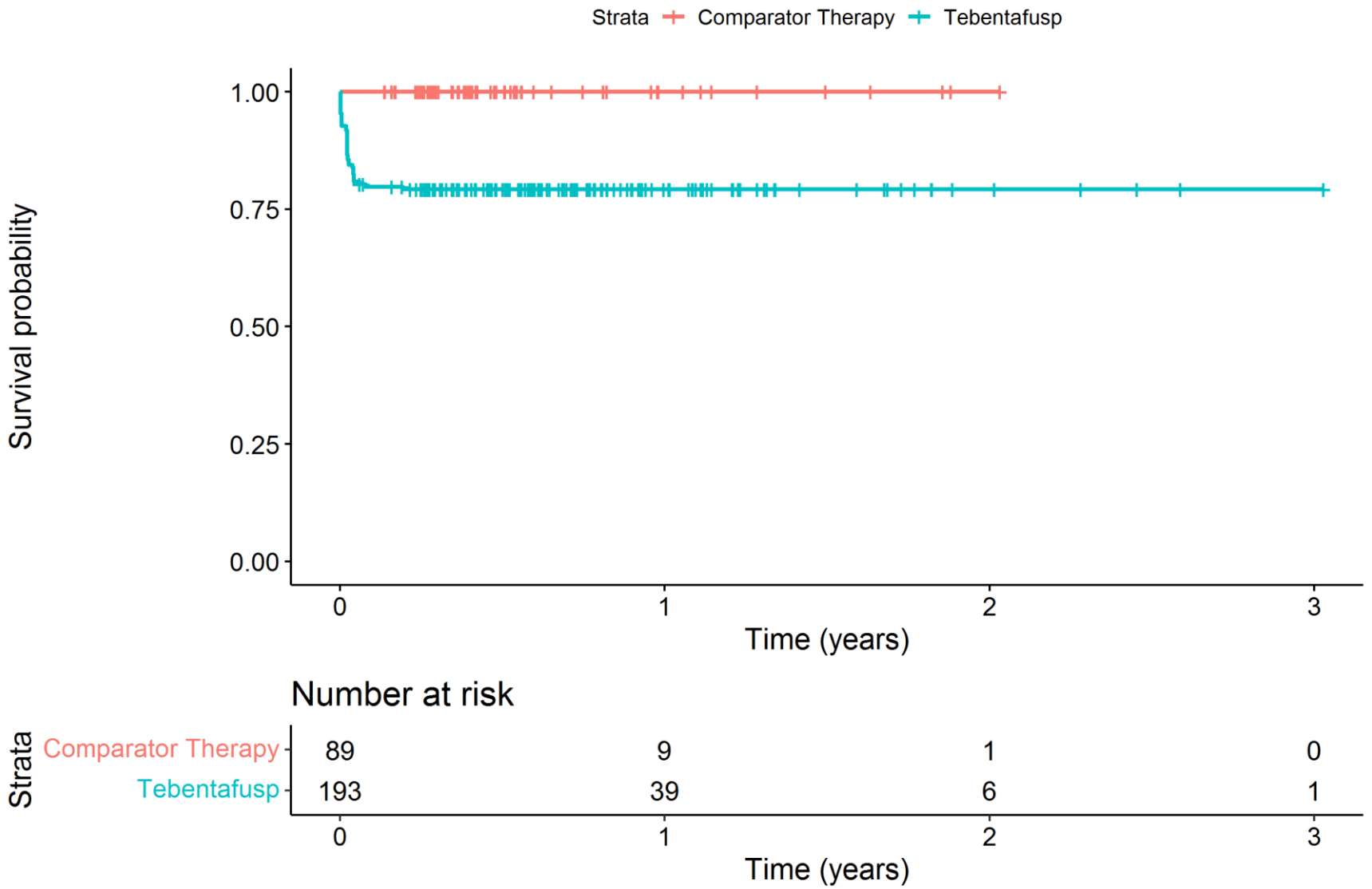
Erkrankungen der Haut und des Unterhautgewebes - ECOG 0



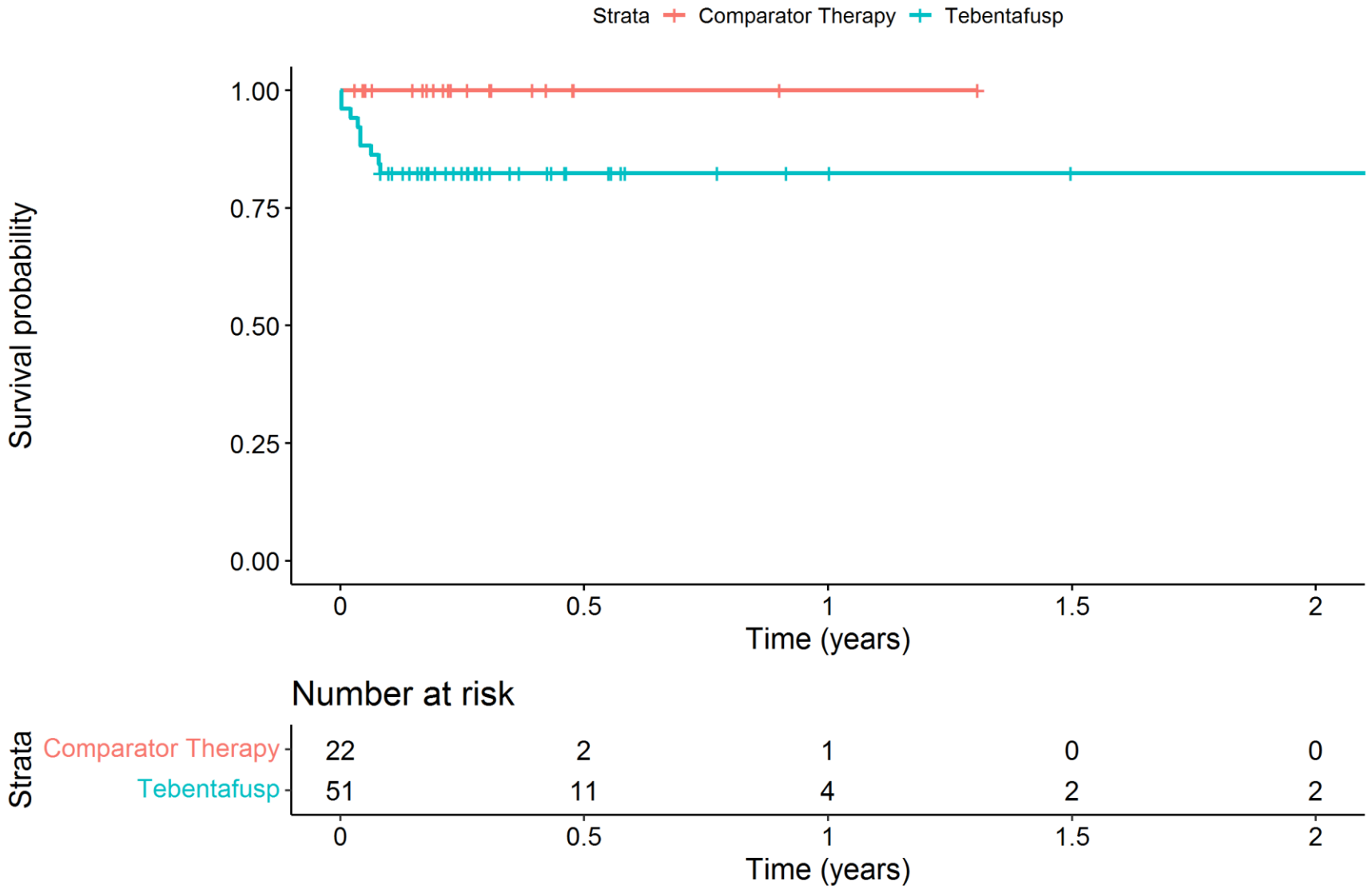
Erkrankungen der Haut und des Unterhautgewebes - ECOG 1



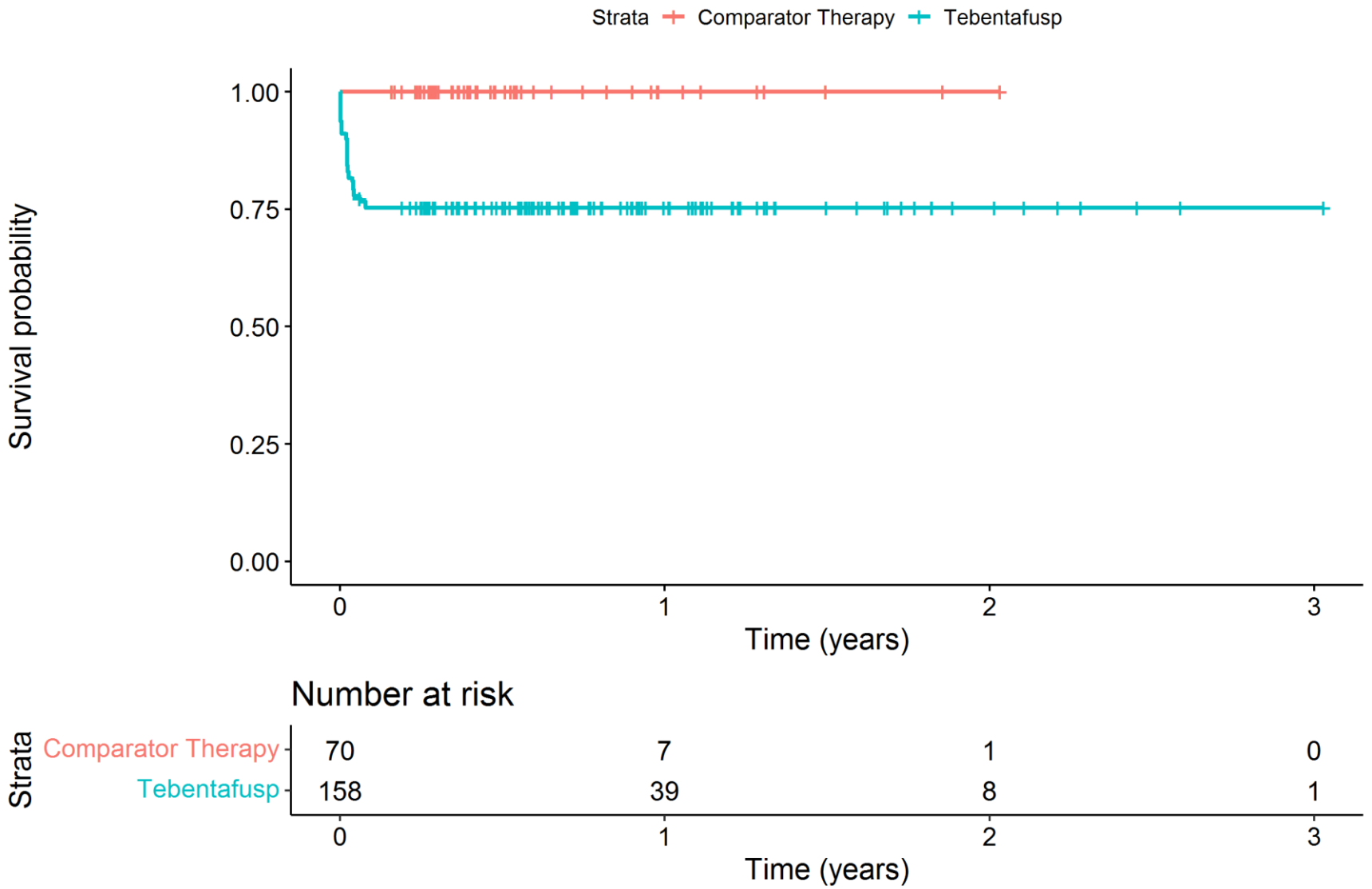
Erkrankungen der Haut und des Unterhautgewebes - ALP ≤ ULN



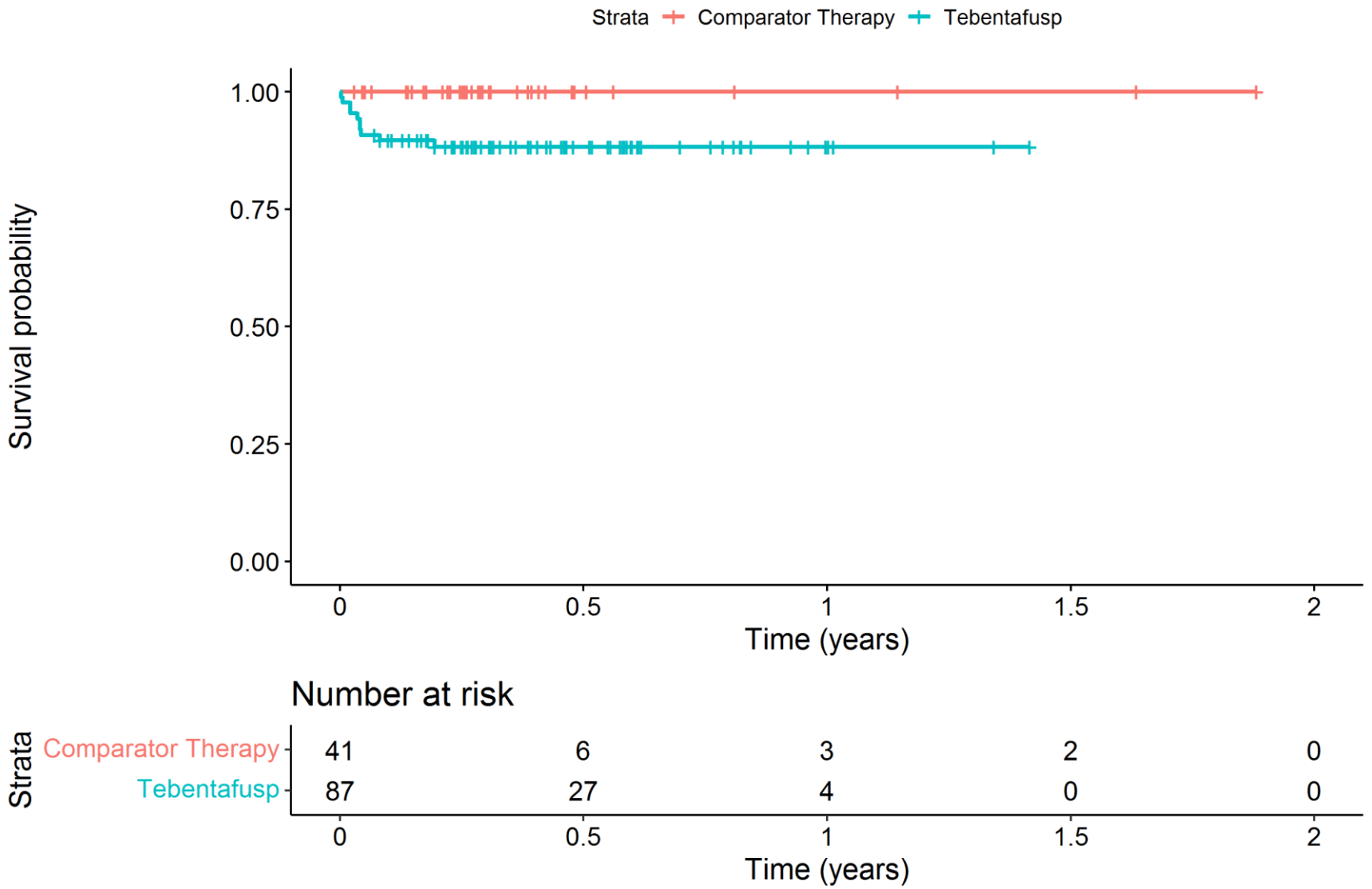
Erkrankungen der Haut und des Unterhautgewebes - ALP > ULN



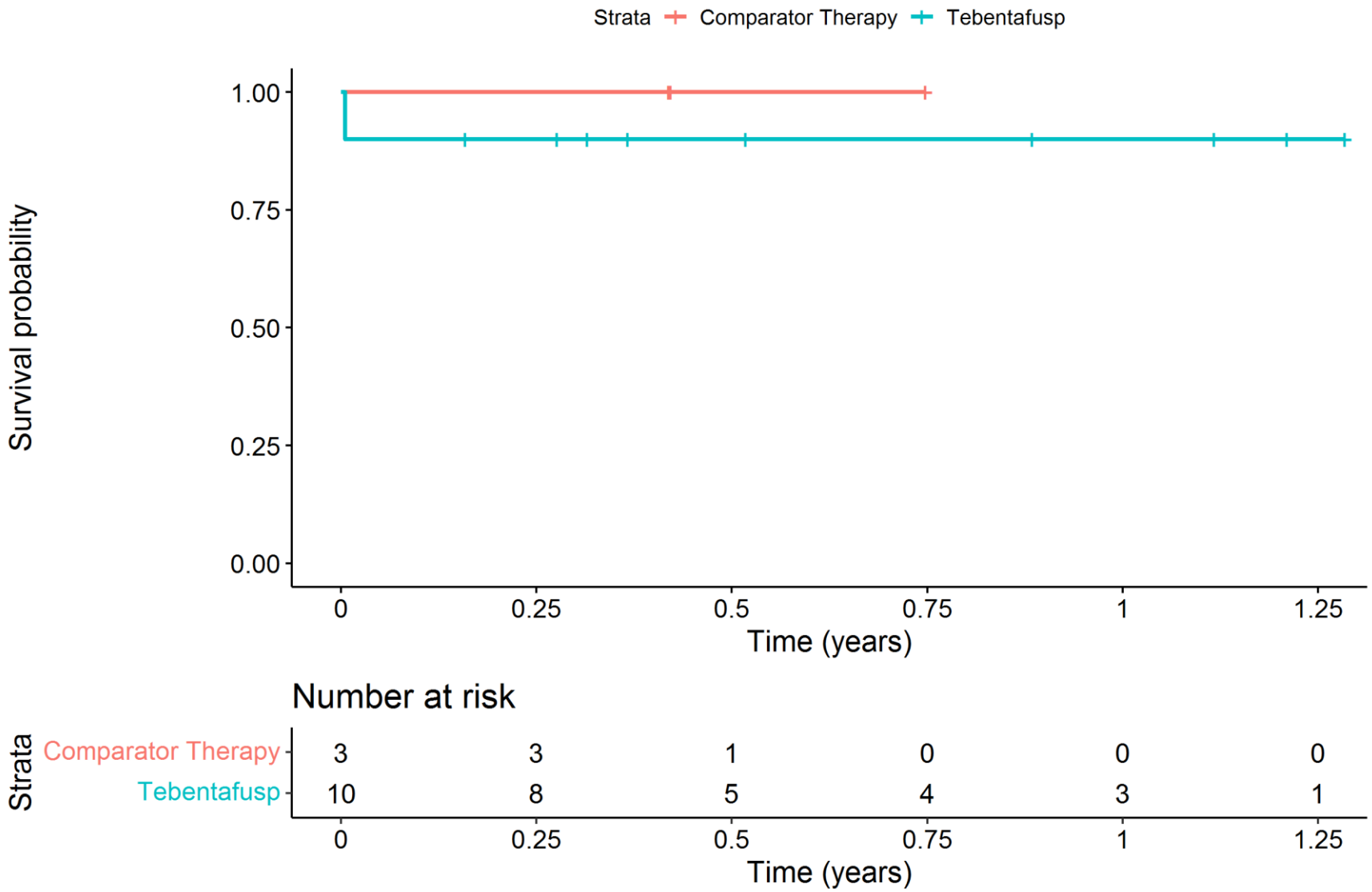
Erkrankungen der Haut und des Unterhautgewebes - LDH =< ULN



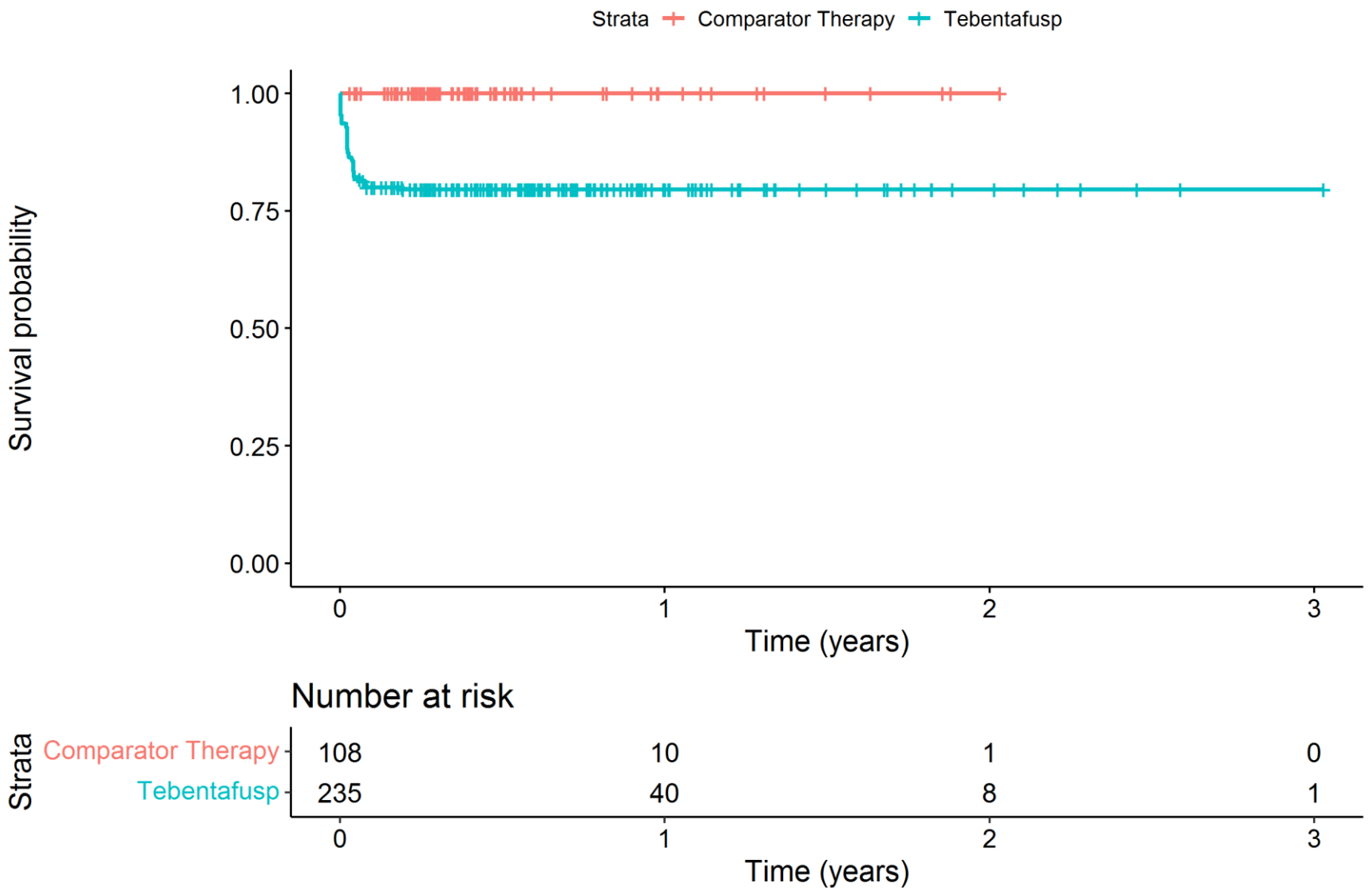
Erkrankungen der Haut und des Unterhautgewebes - LDH > ULN



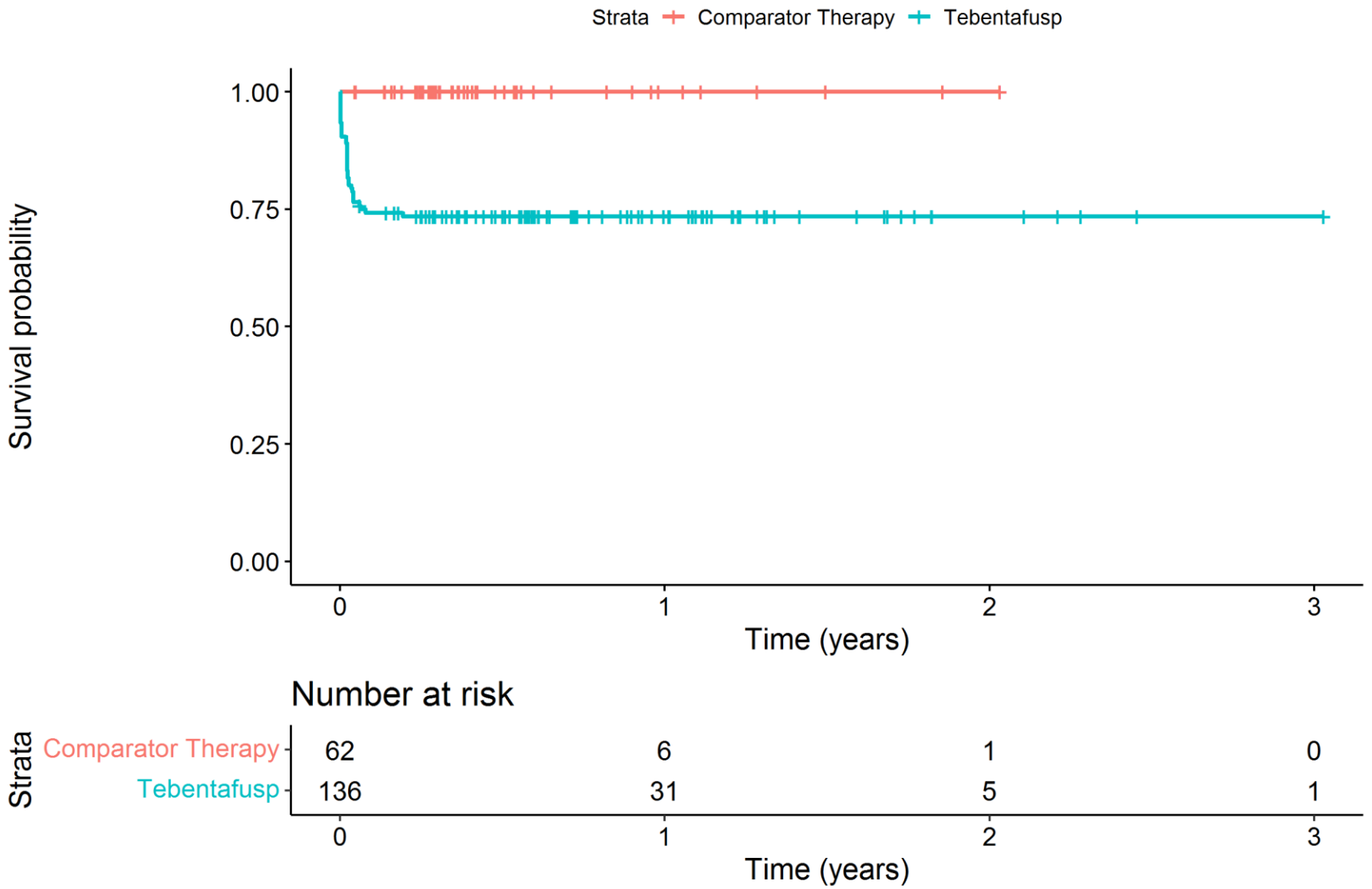
Erkrankungen der Haut und des Unterhautgewebes - Vorherige Therapie adjuvant/neoadjuvant



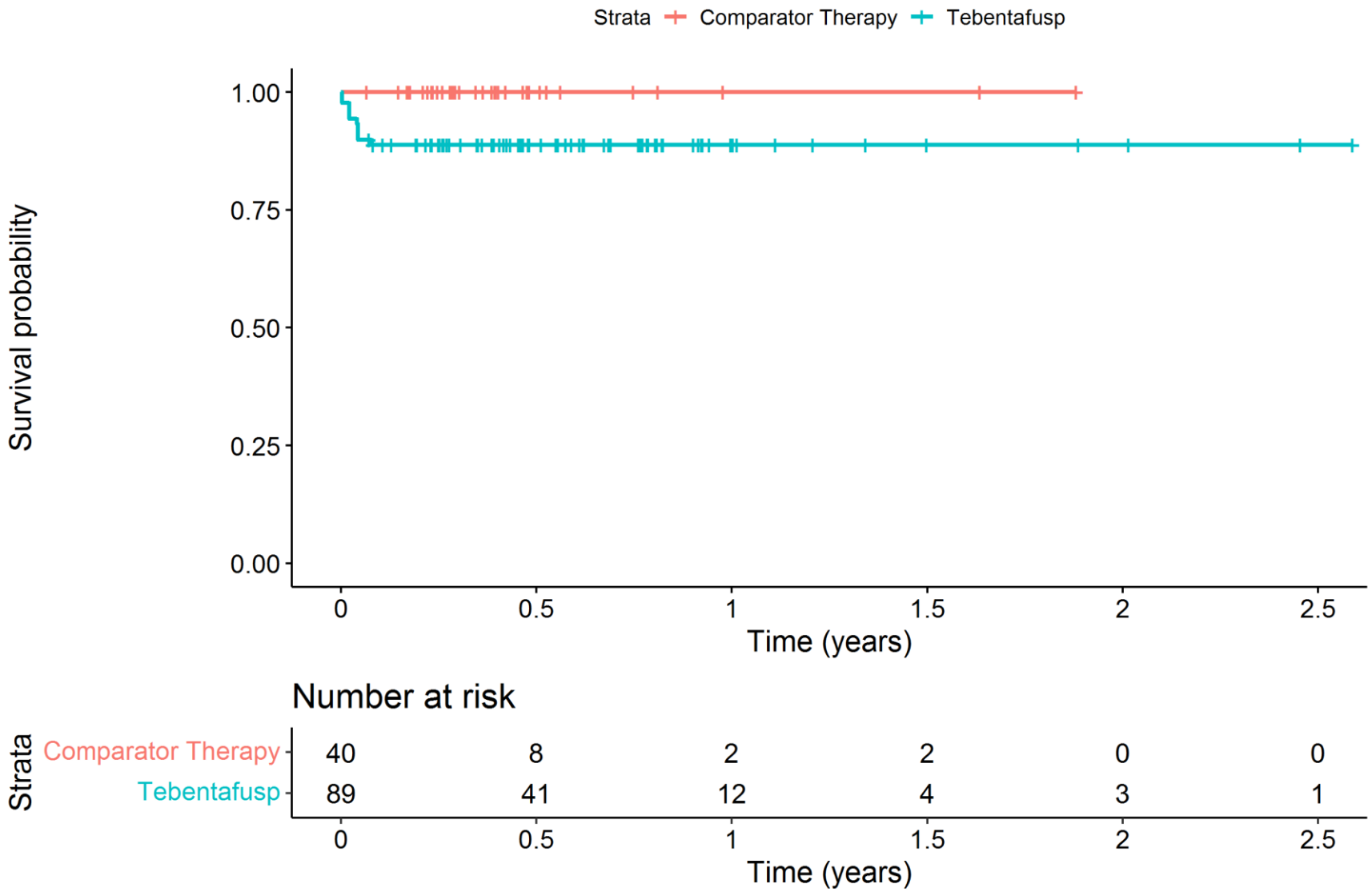
Erkrankungen der Haut und des Unterhautgewebes - Keine vorherige Therapie adjuvant/neoadjuvant



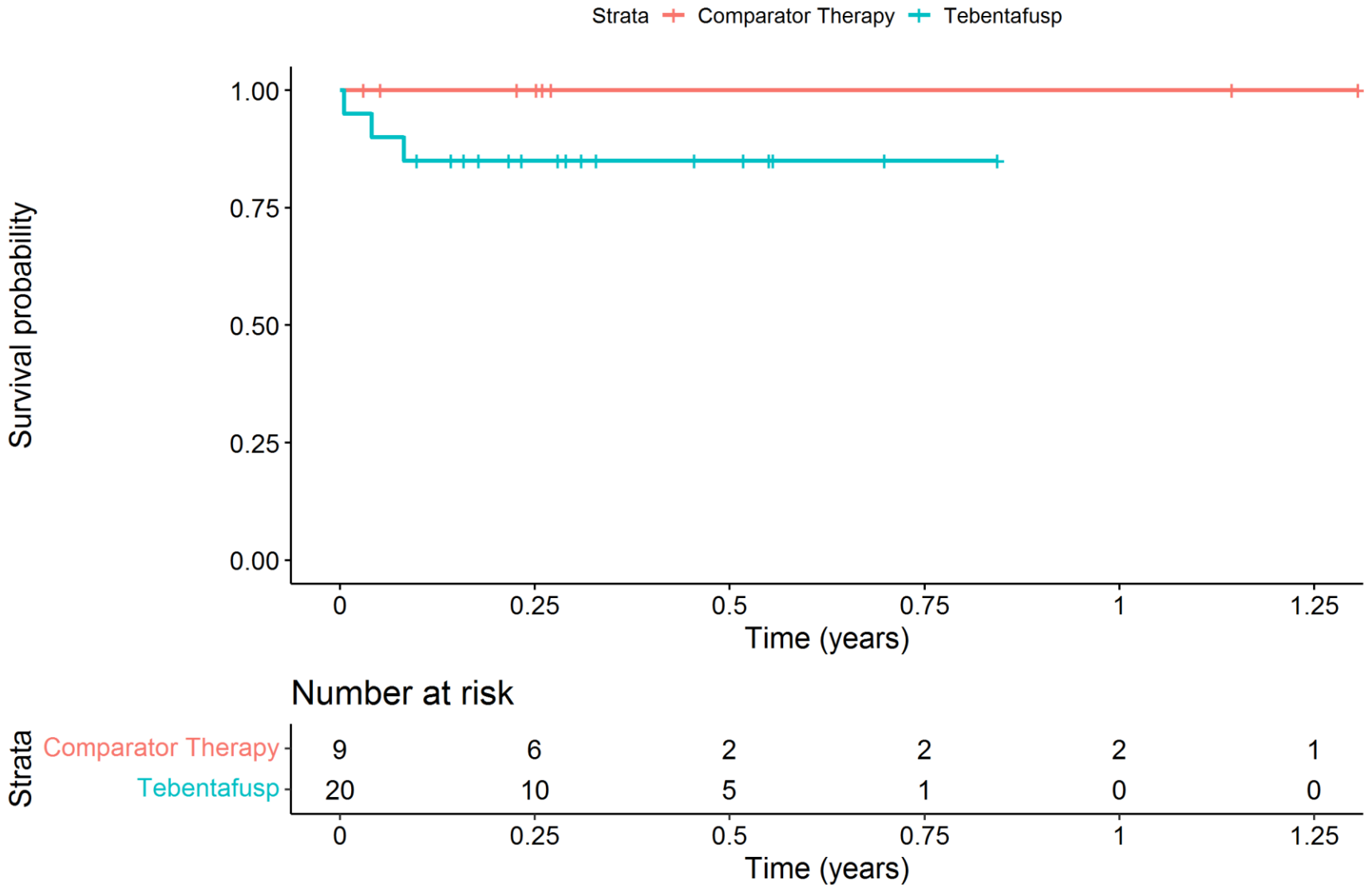
Erkrankungen der Haut und des Unterhautgewebes - Läsion ≤ 3cm



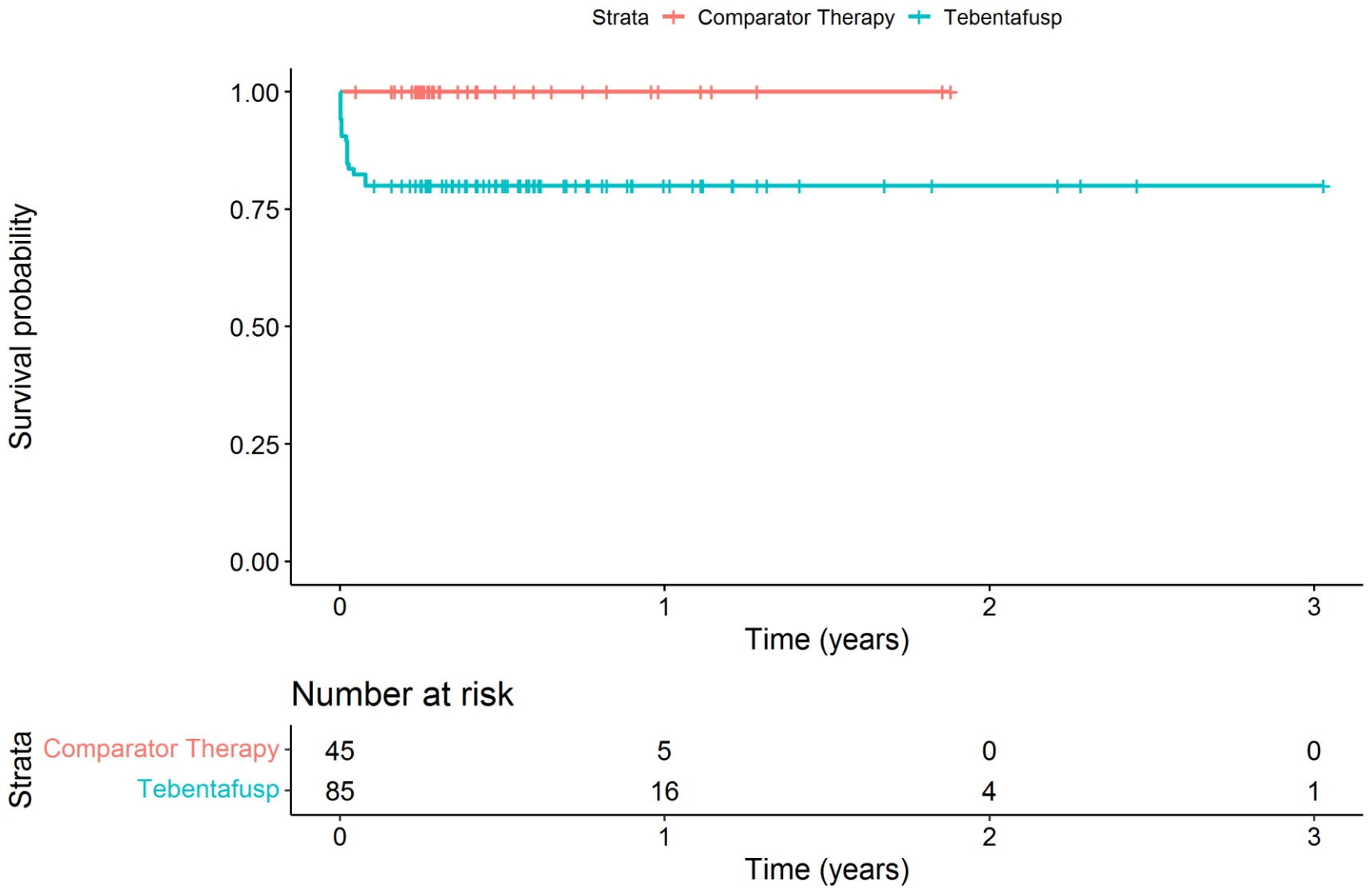
Erkrankungen der Haut und des Unterhautgewebes - Läsion 3,1-8,0 cm



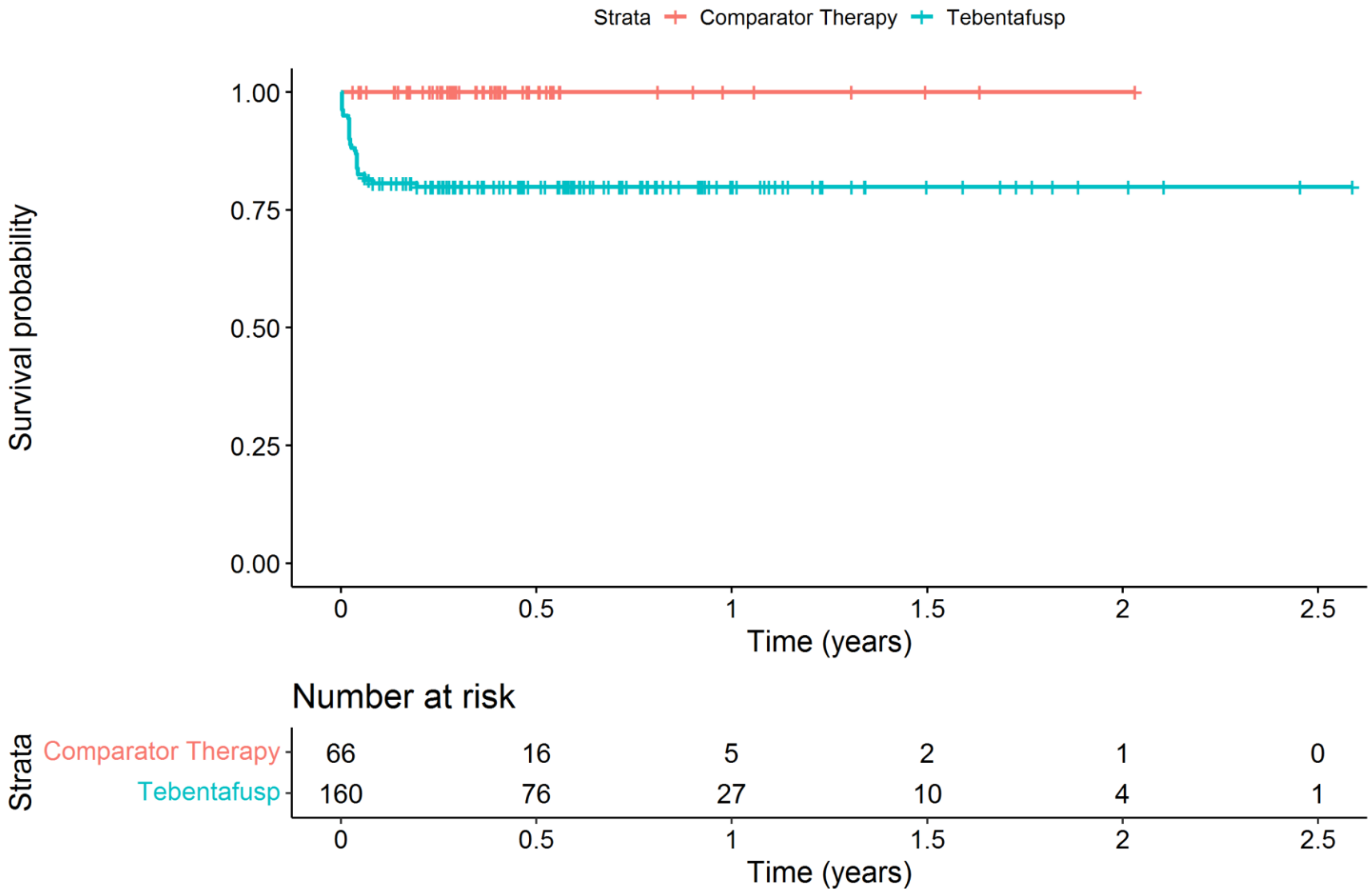
Erkrankungen der Haut und des Unterhautgewebes - Läsion ≥8,1 cm



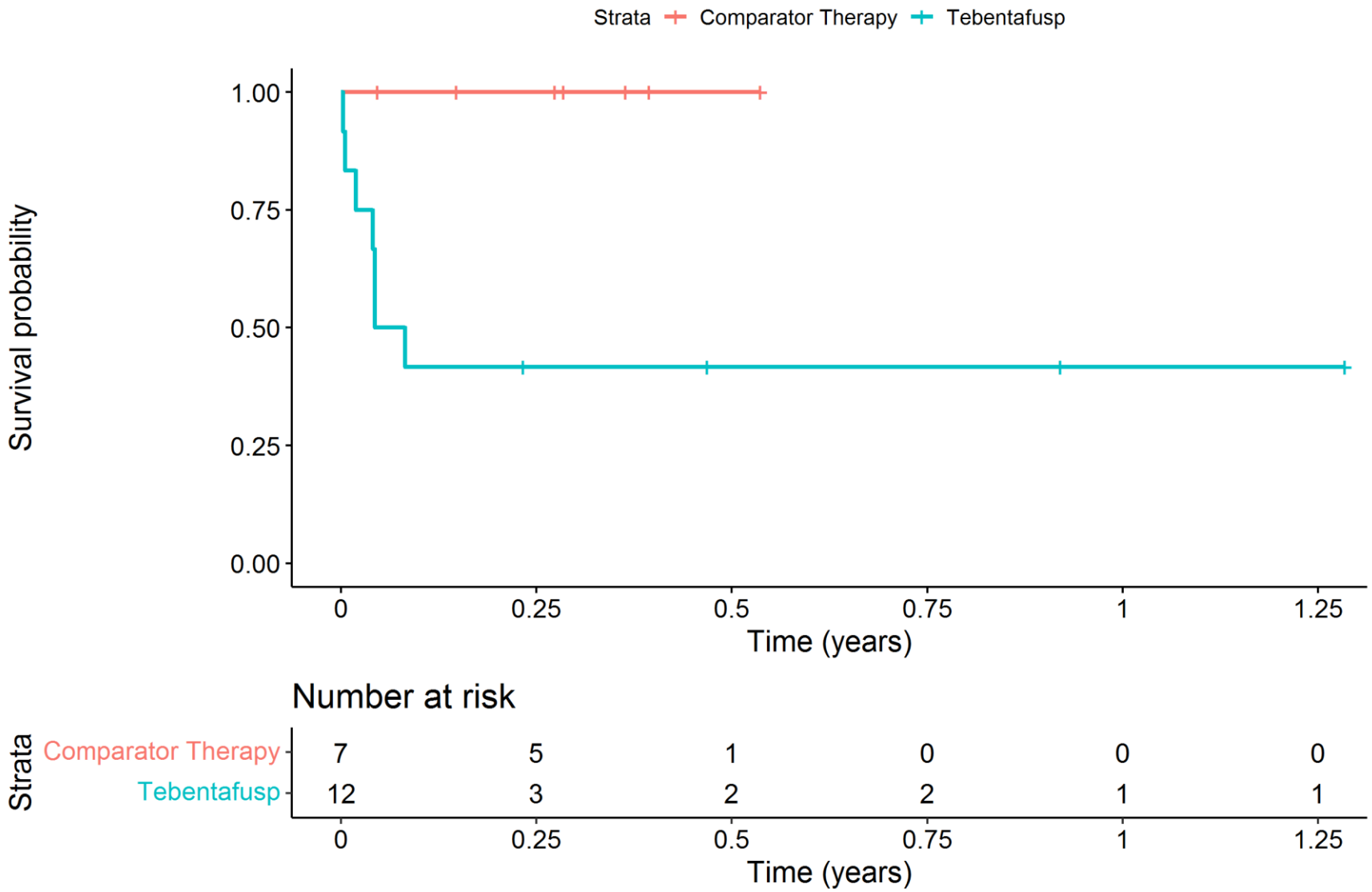
Erkrankungen der Haut und des Unterhautgewebes - Nordamerika



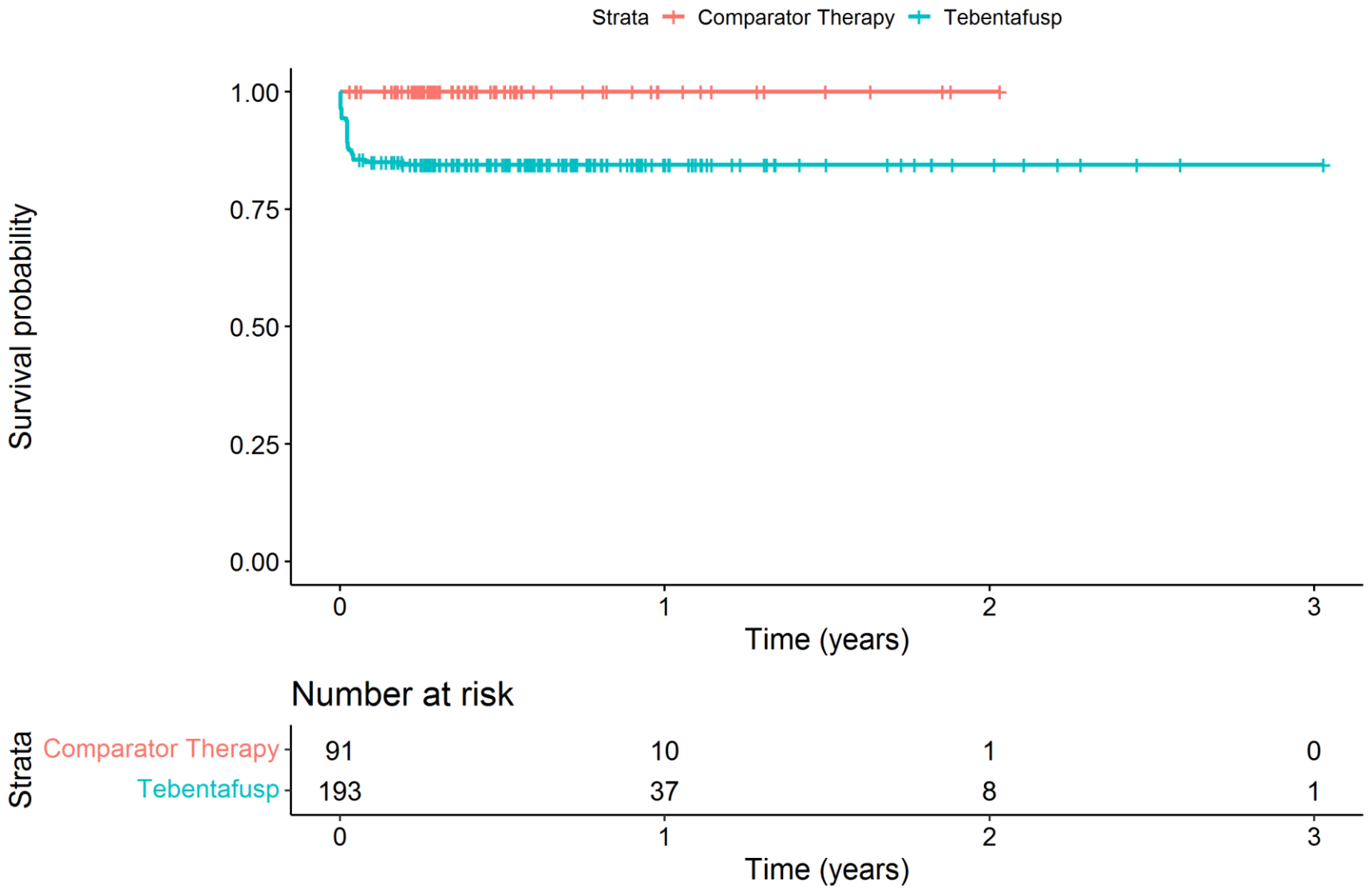
Erkrankungen der Haut und des Unterhautgewebes - Nicht-Nordamerika



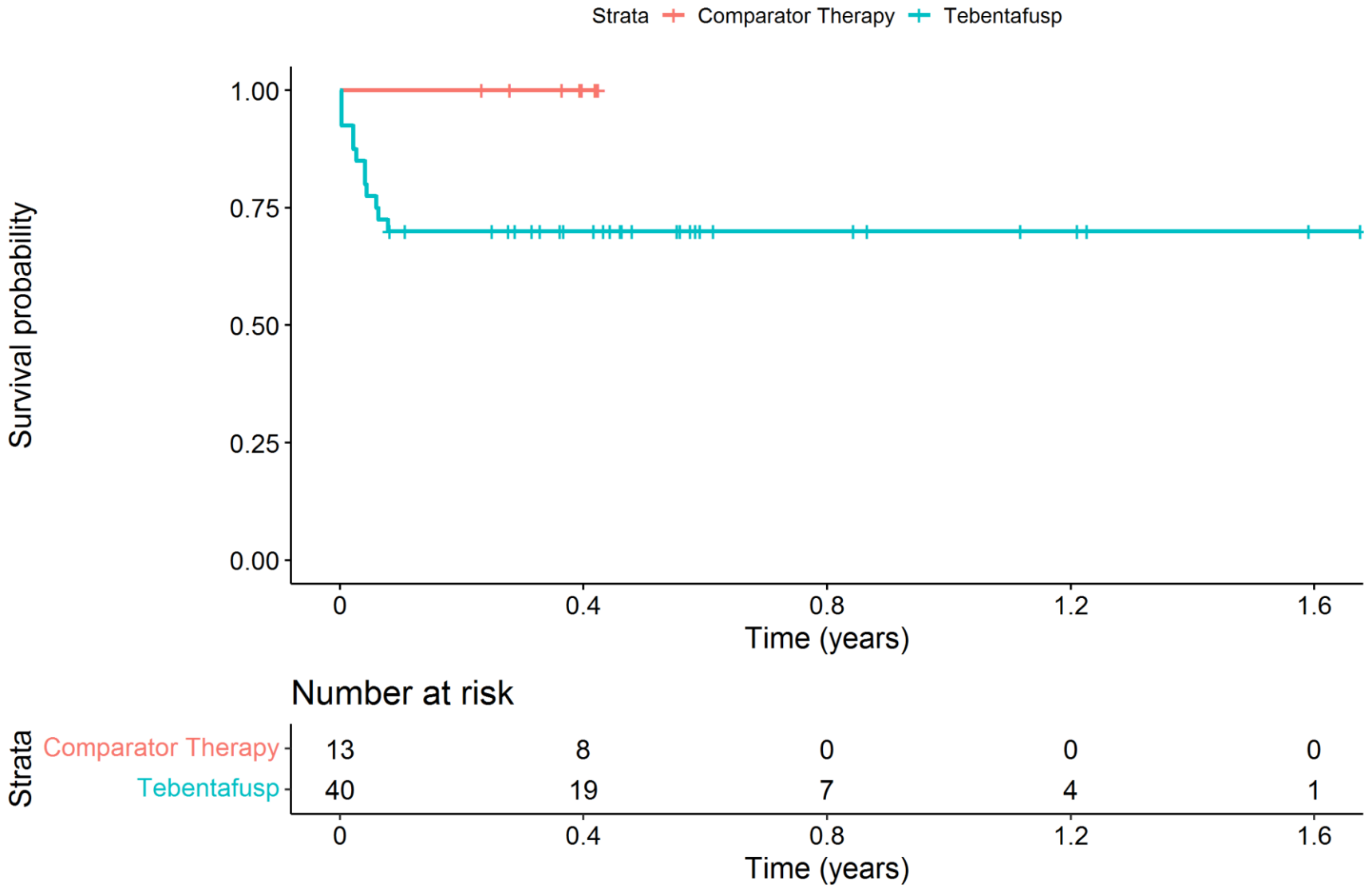
Erkrankungen der Haut und des Unterhautgewebes - Dacarbazin



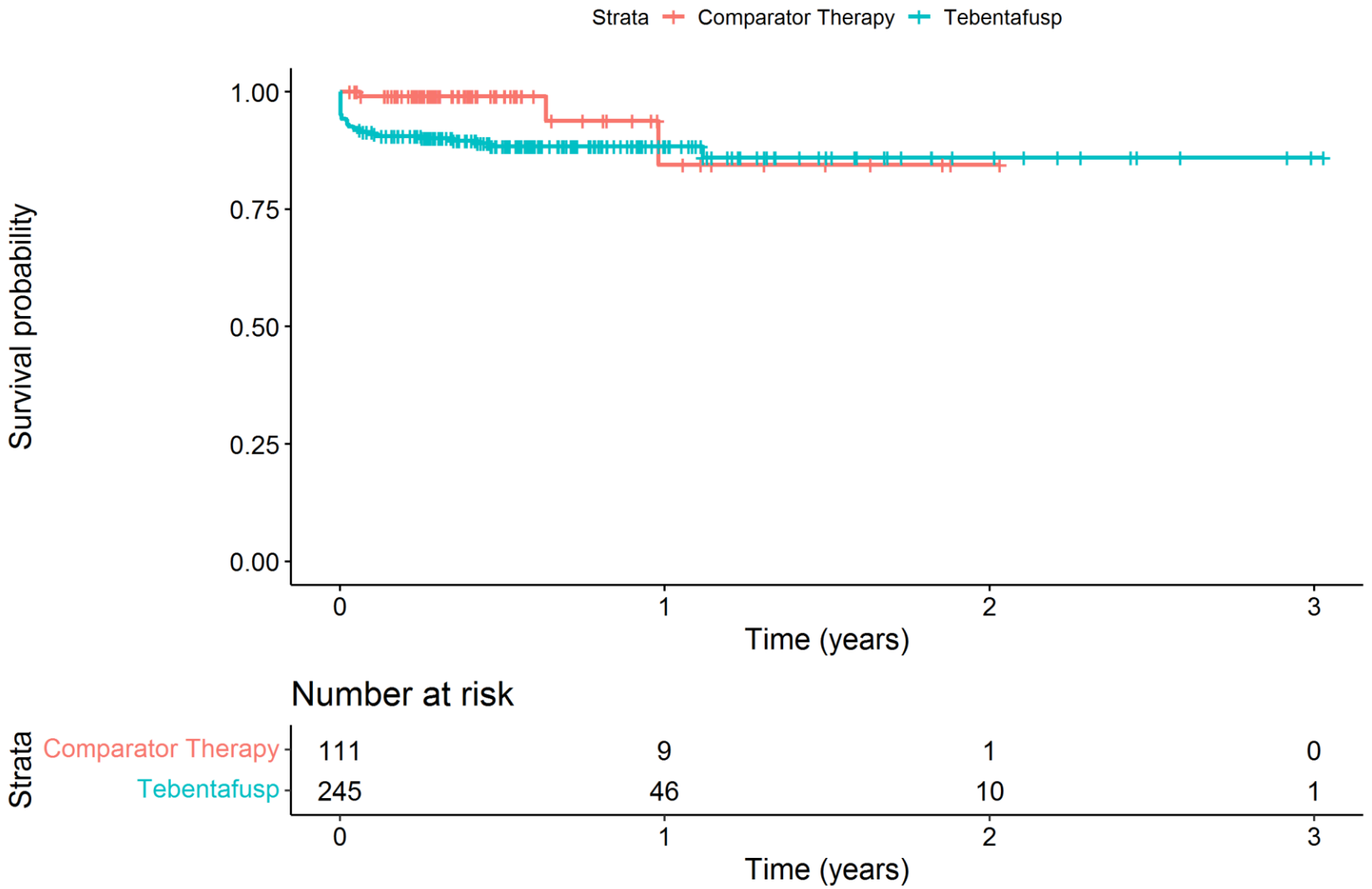
Erkrankungen der Haut und des Unterhautgewebes - Pembrolizumab



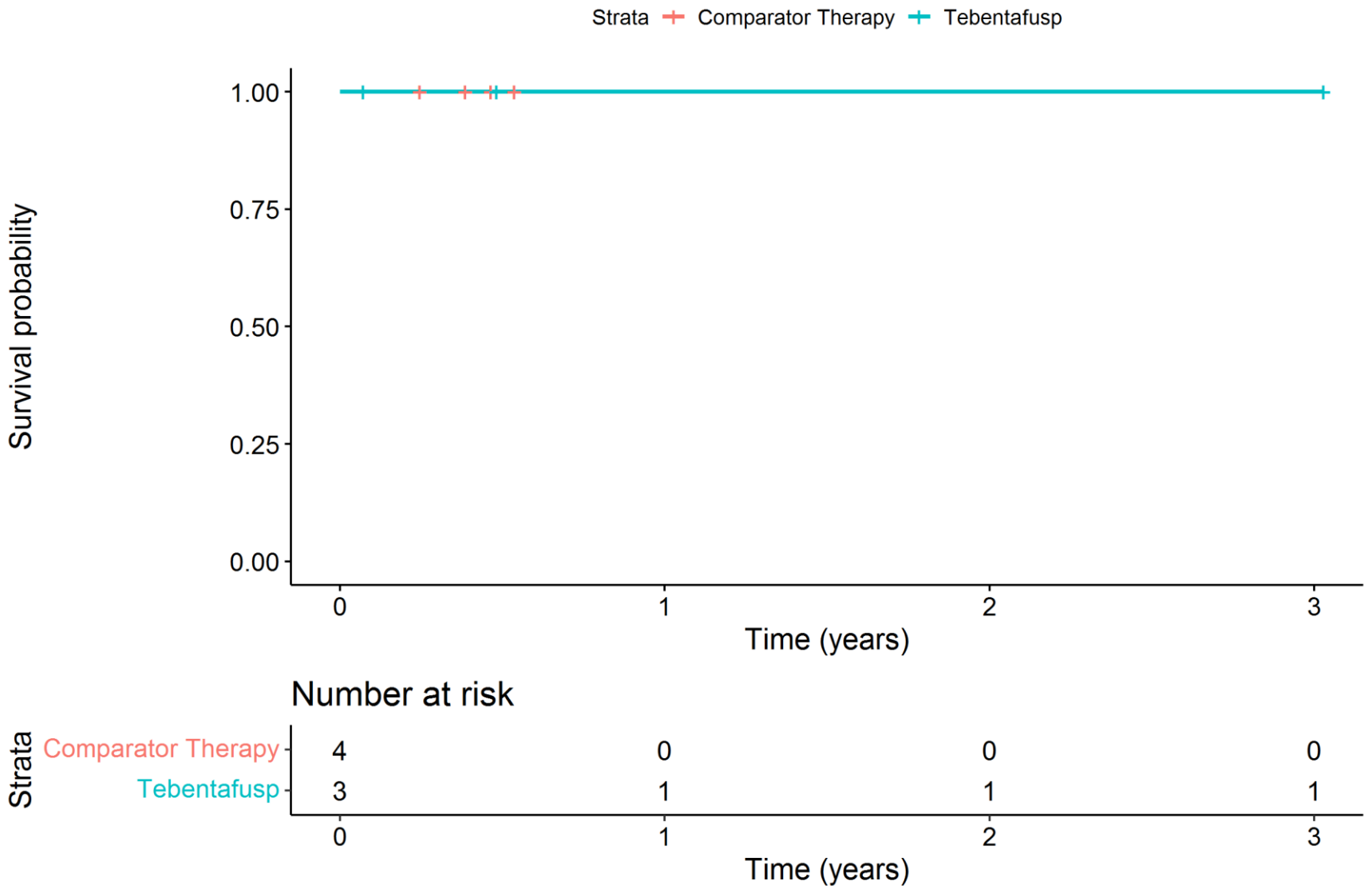
Erkrankungen der Haut und des Unterhautgewebes - Ipilimumab



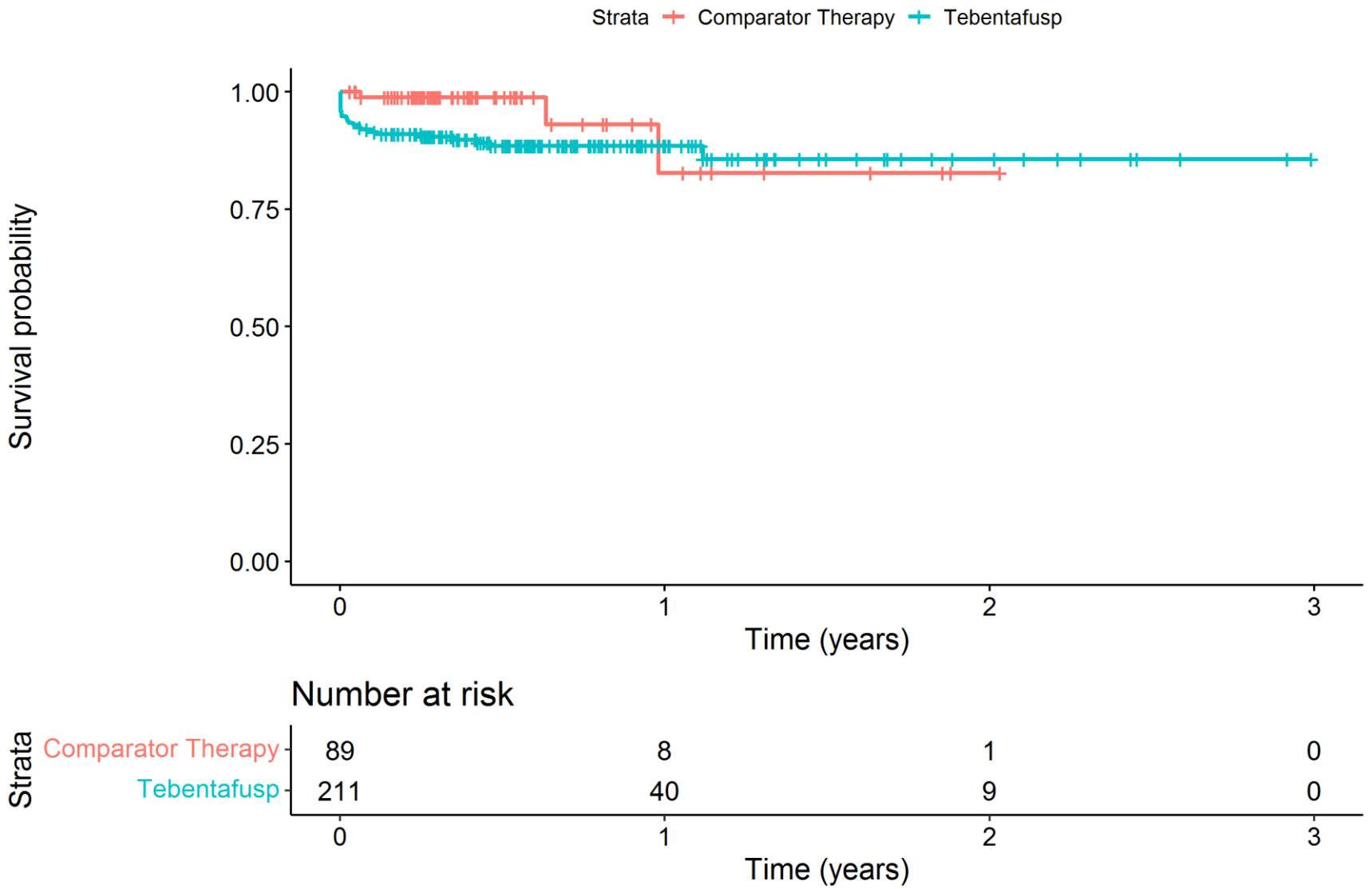
Gefäßerkrankungen - Gesamt



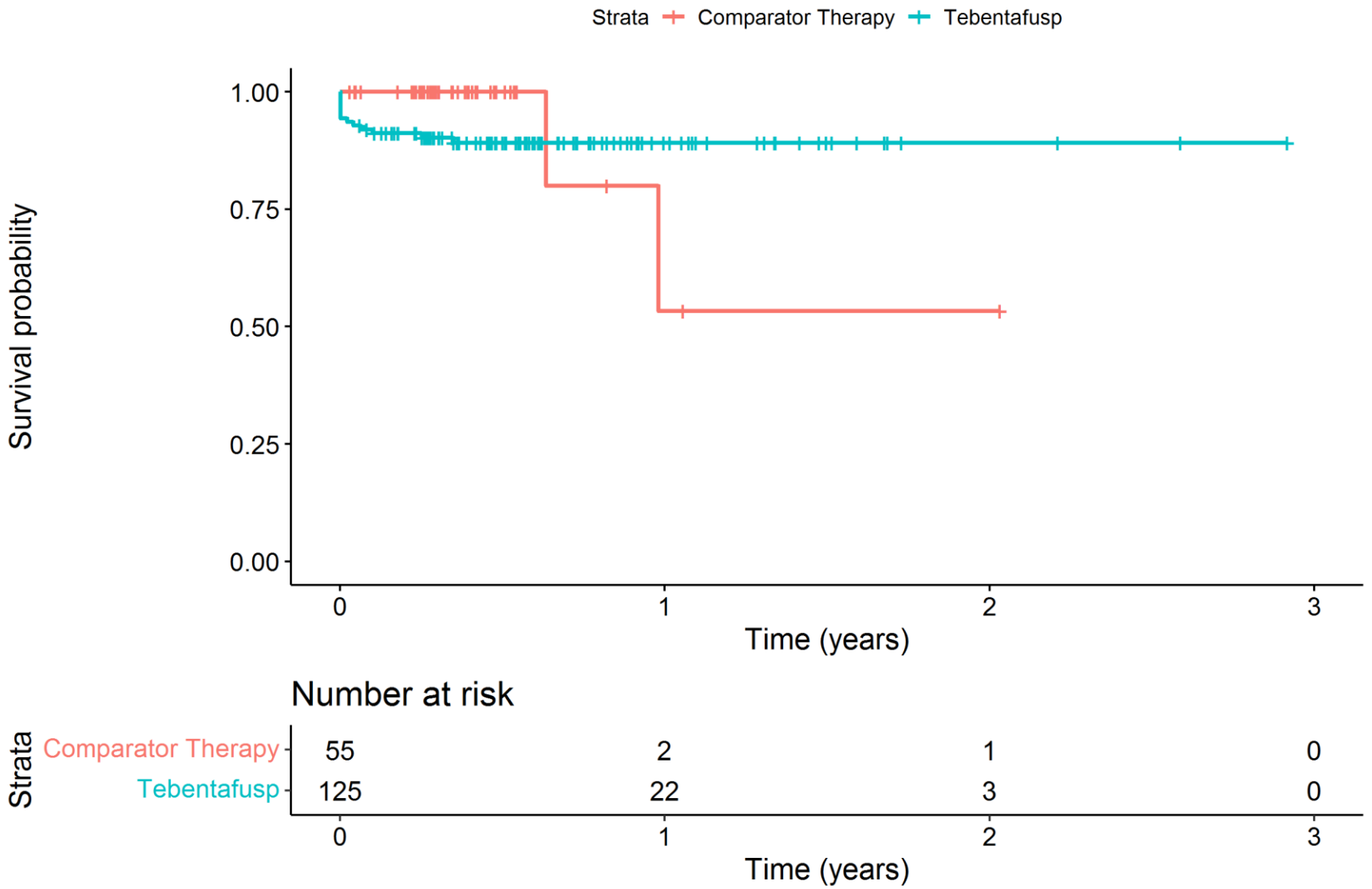
Gefäßerkrankungen - Hispanisch



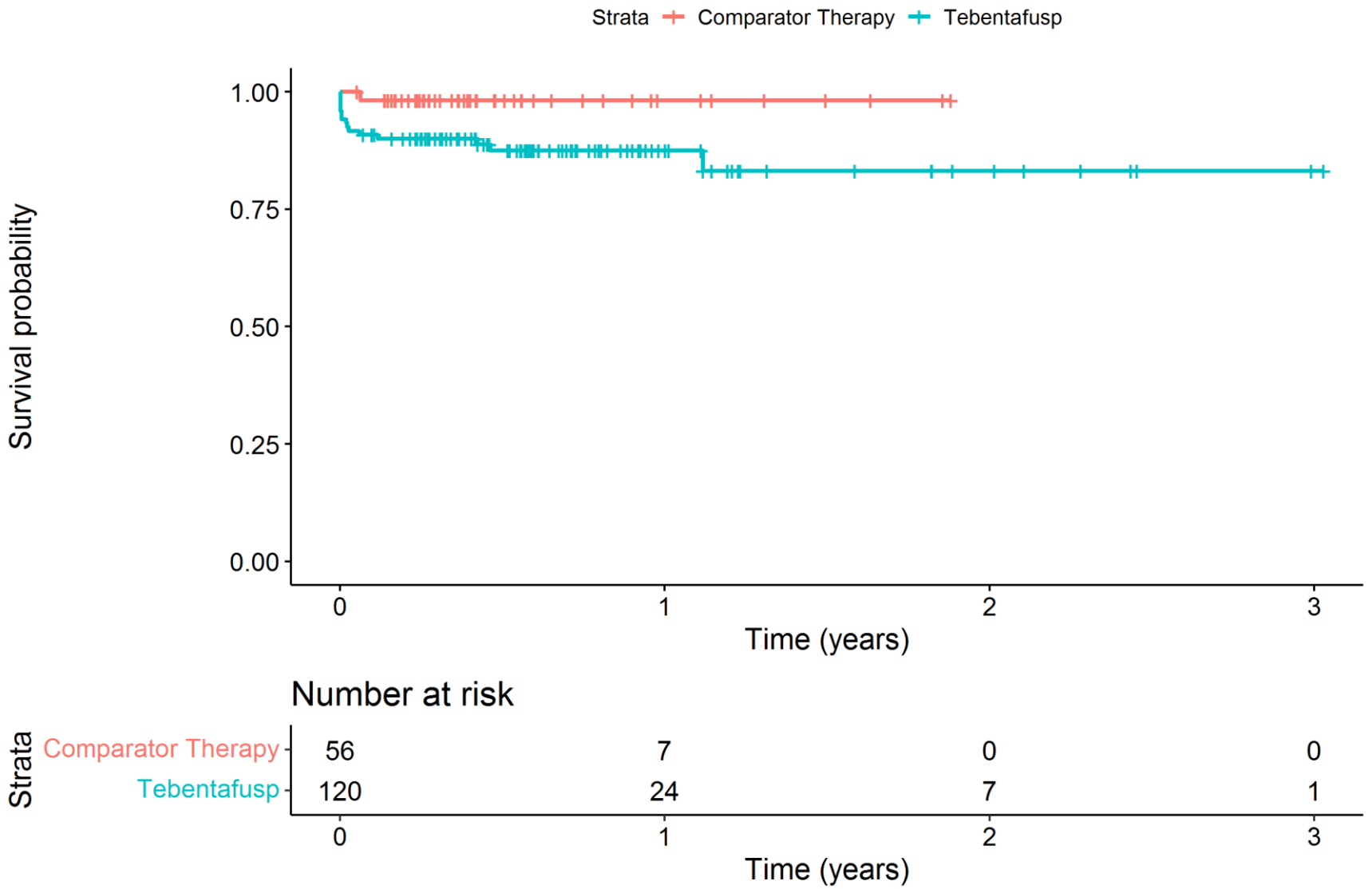
Gefäßerkrankungen - Nicht-hispanisch



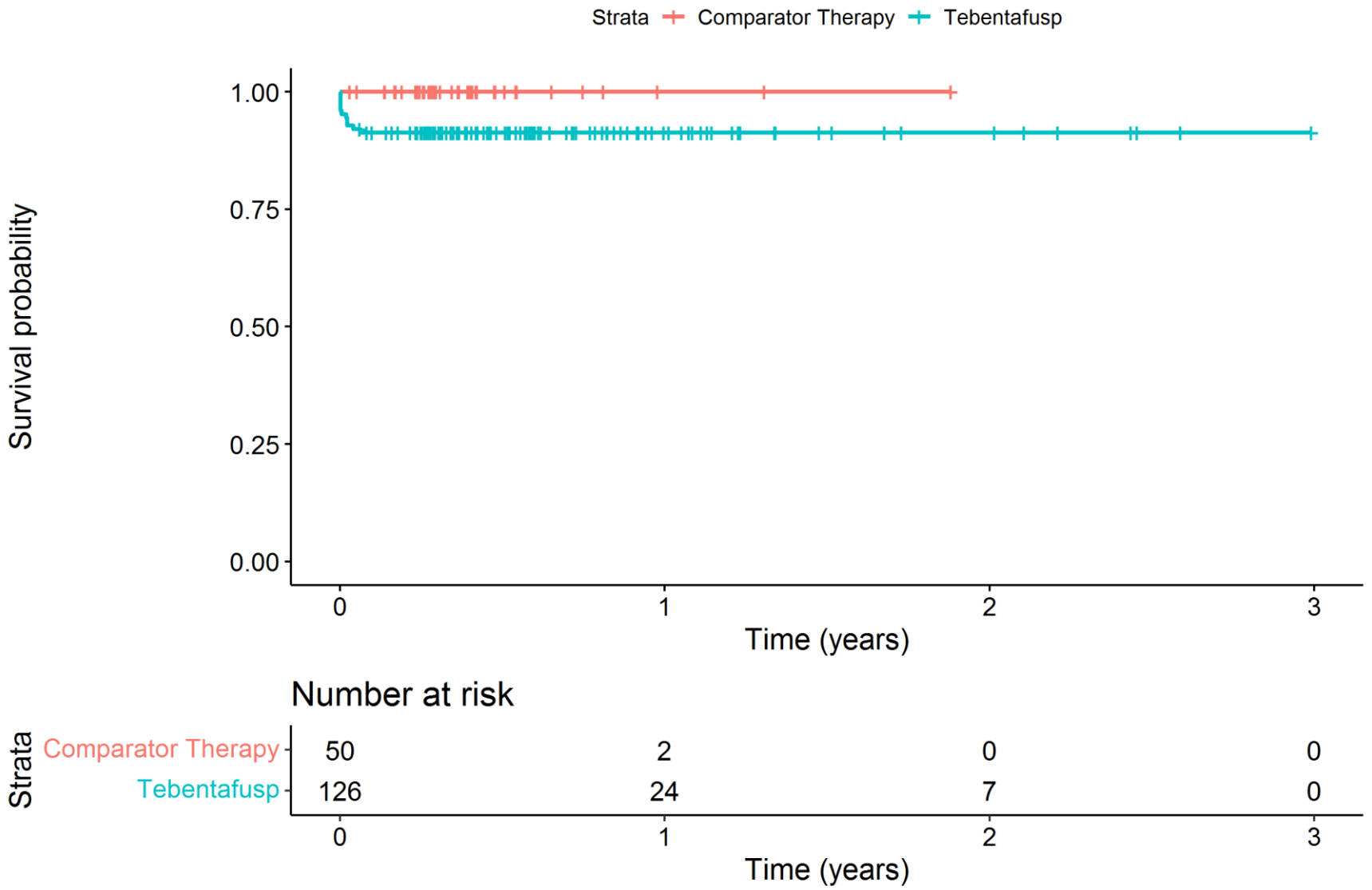
Gefäßerkrankungen - Männlich



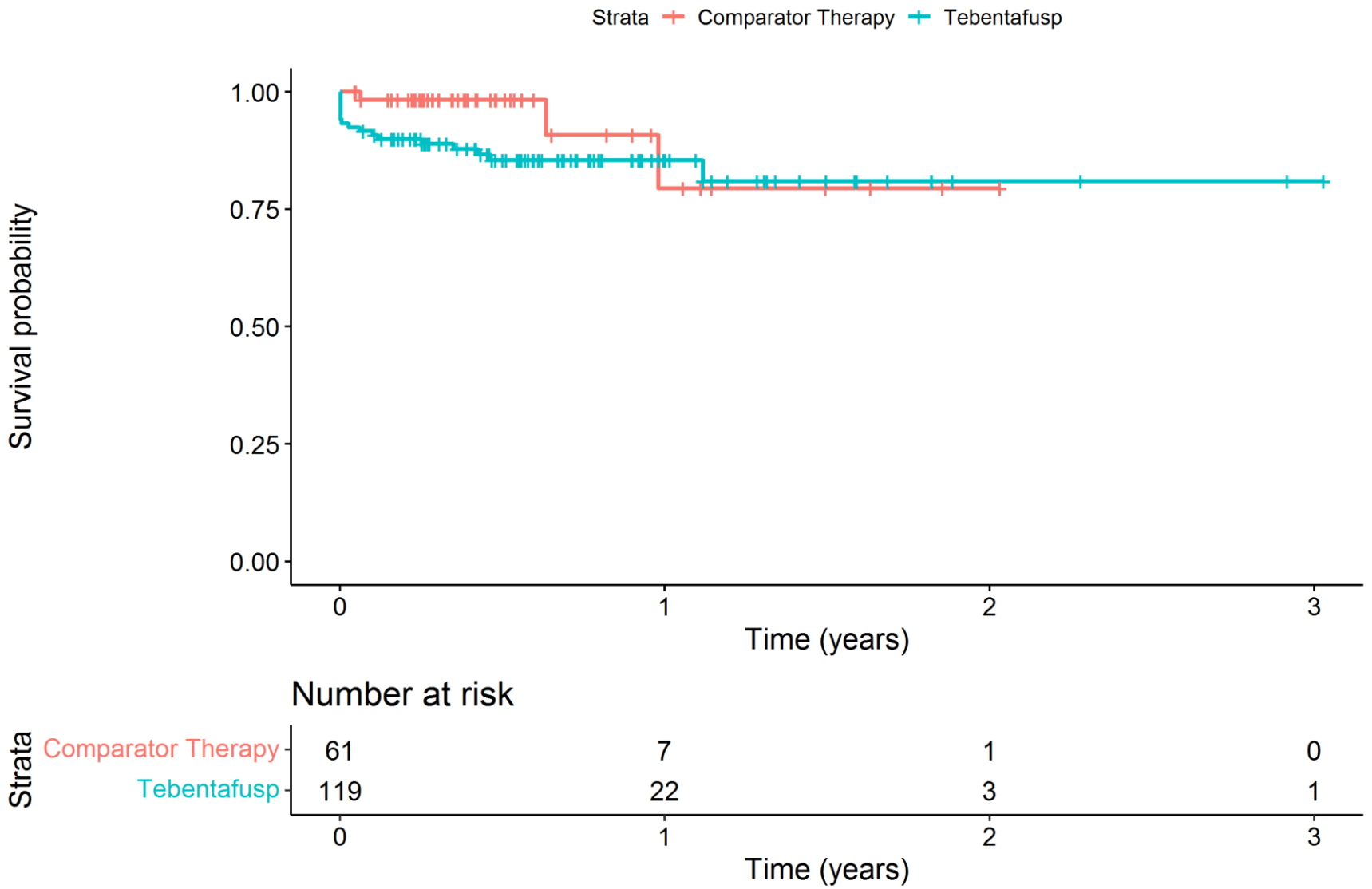
Gefäßerkrankungen - Weiblich



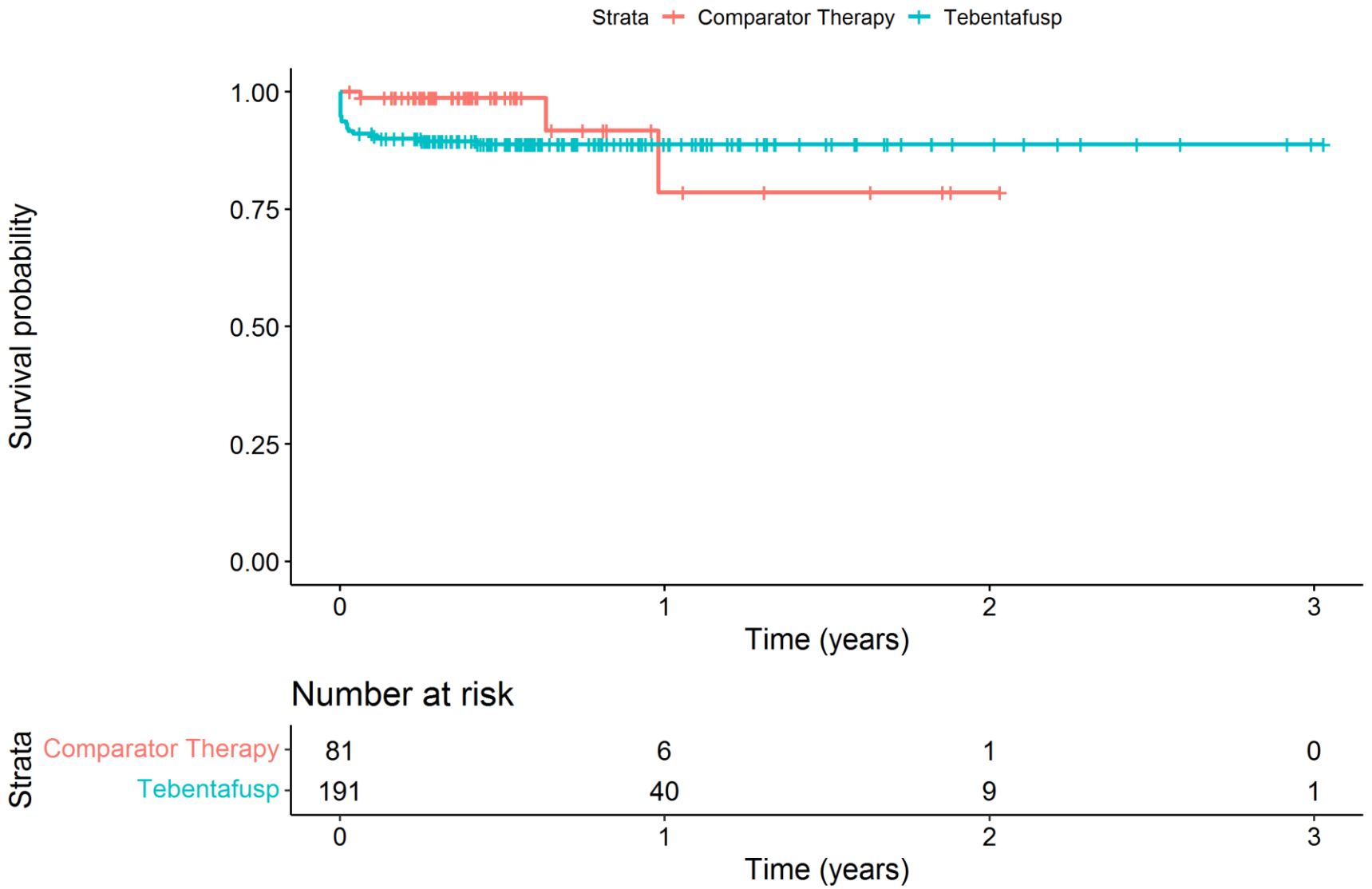
Gefäßerkrankungen - <65



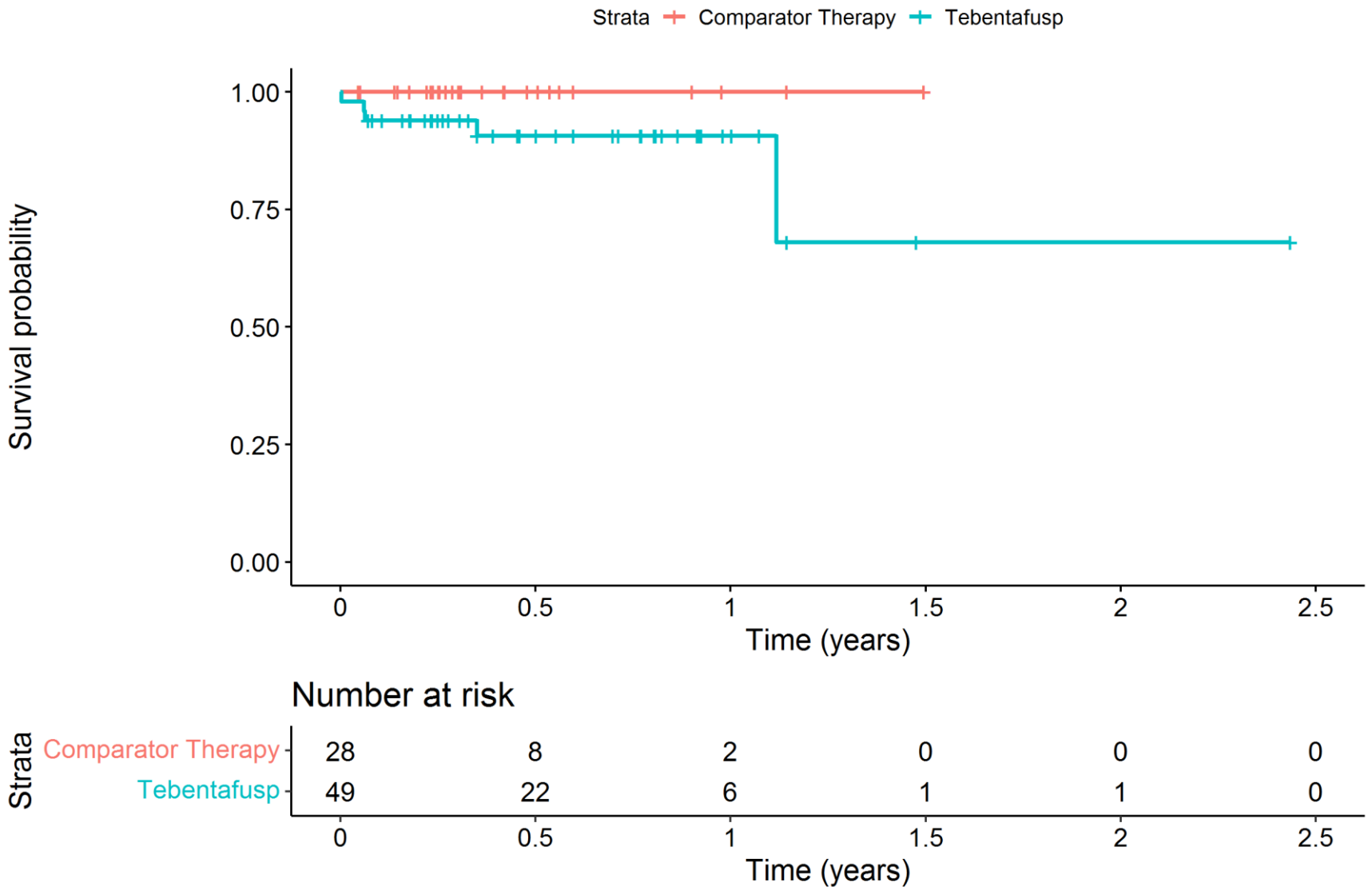
Gefäßerkrankungen - ≥65



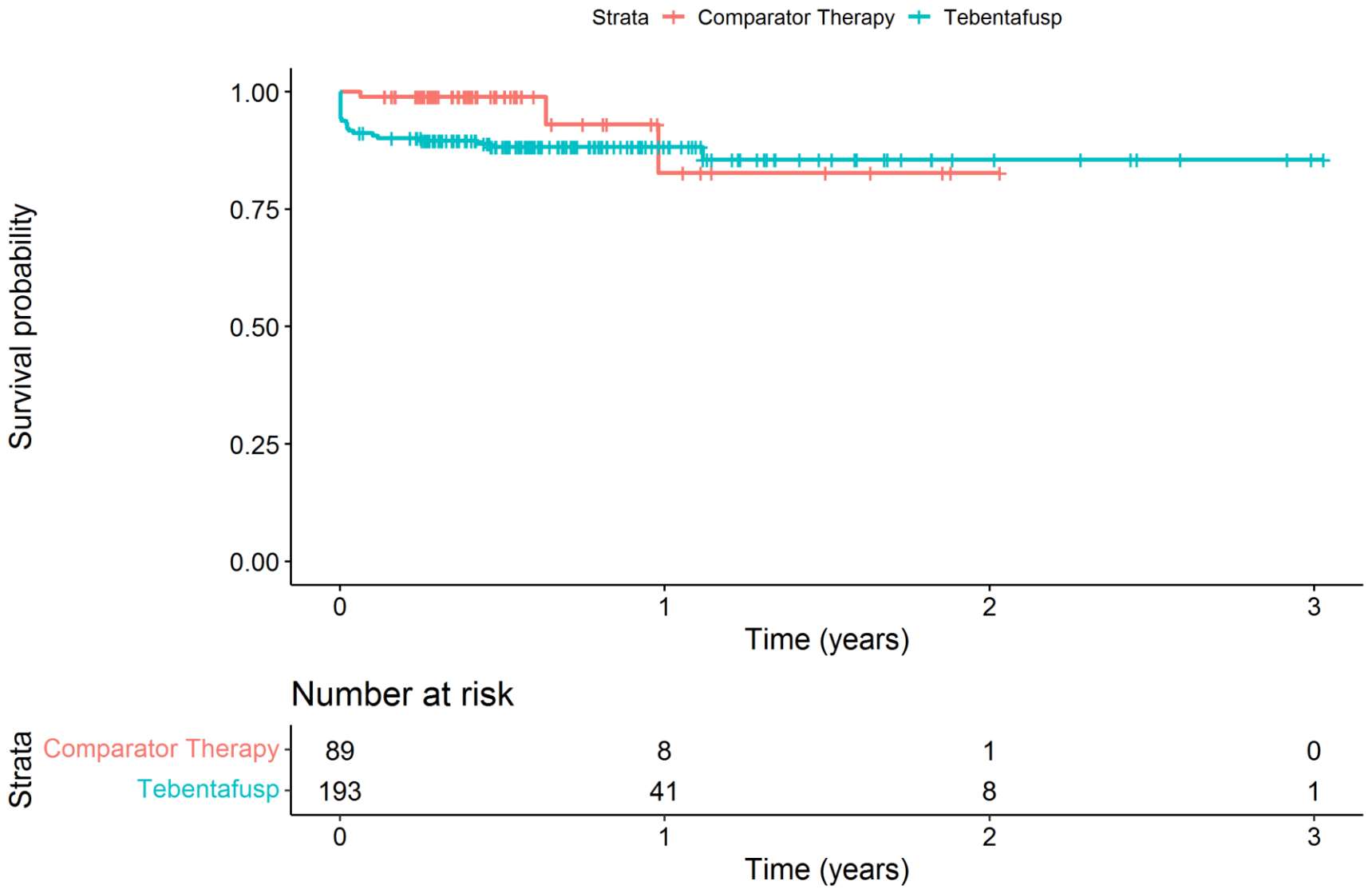
Gefäßerkrankungen - ECOG 0



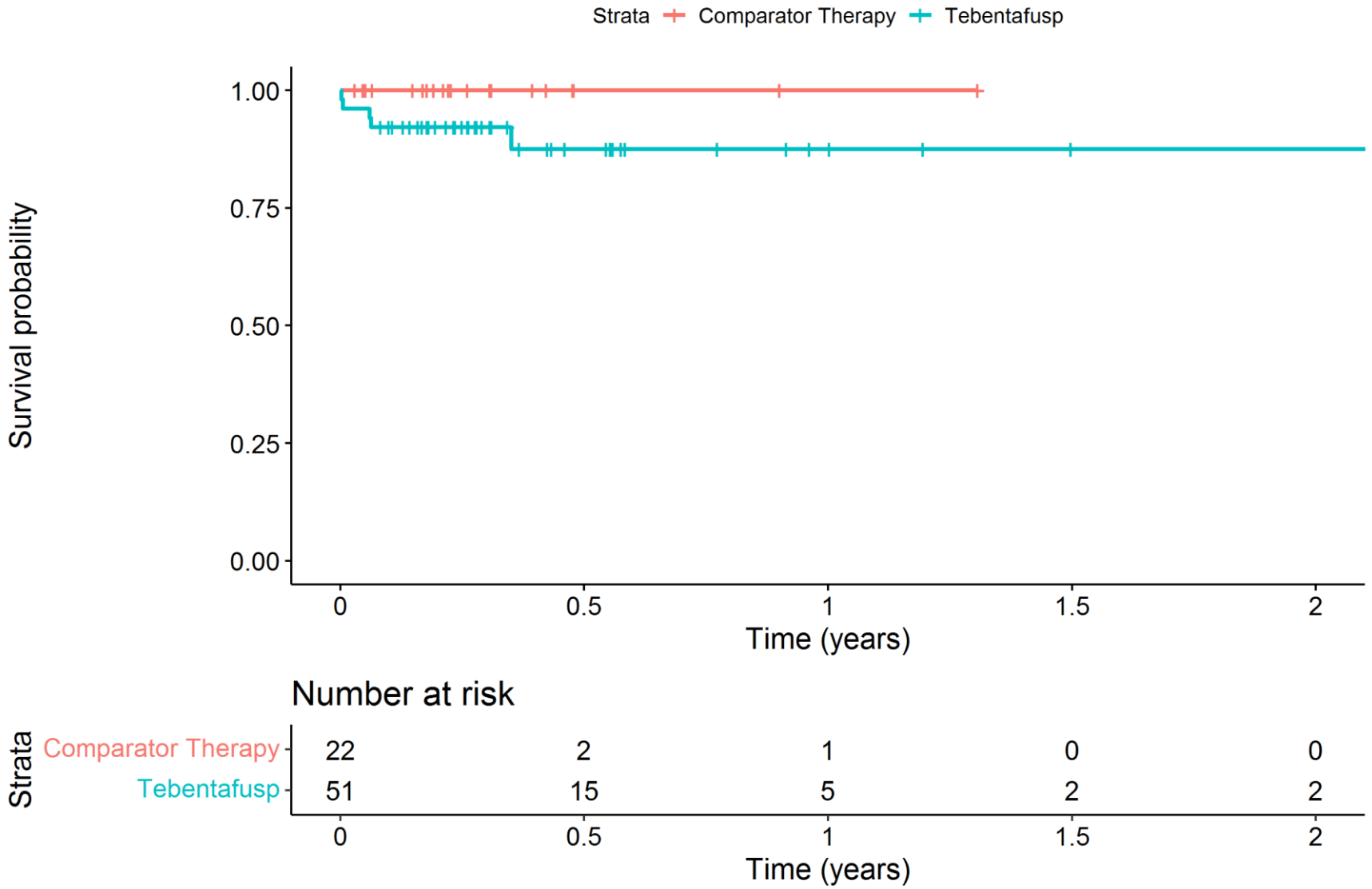
Gefäßerkrankungen - ECOG 1



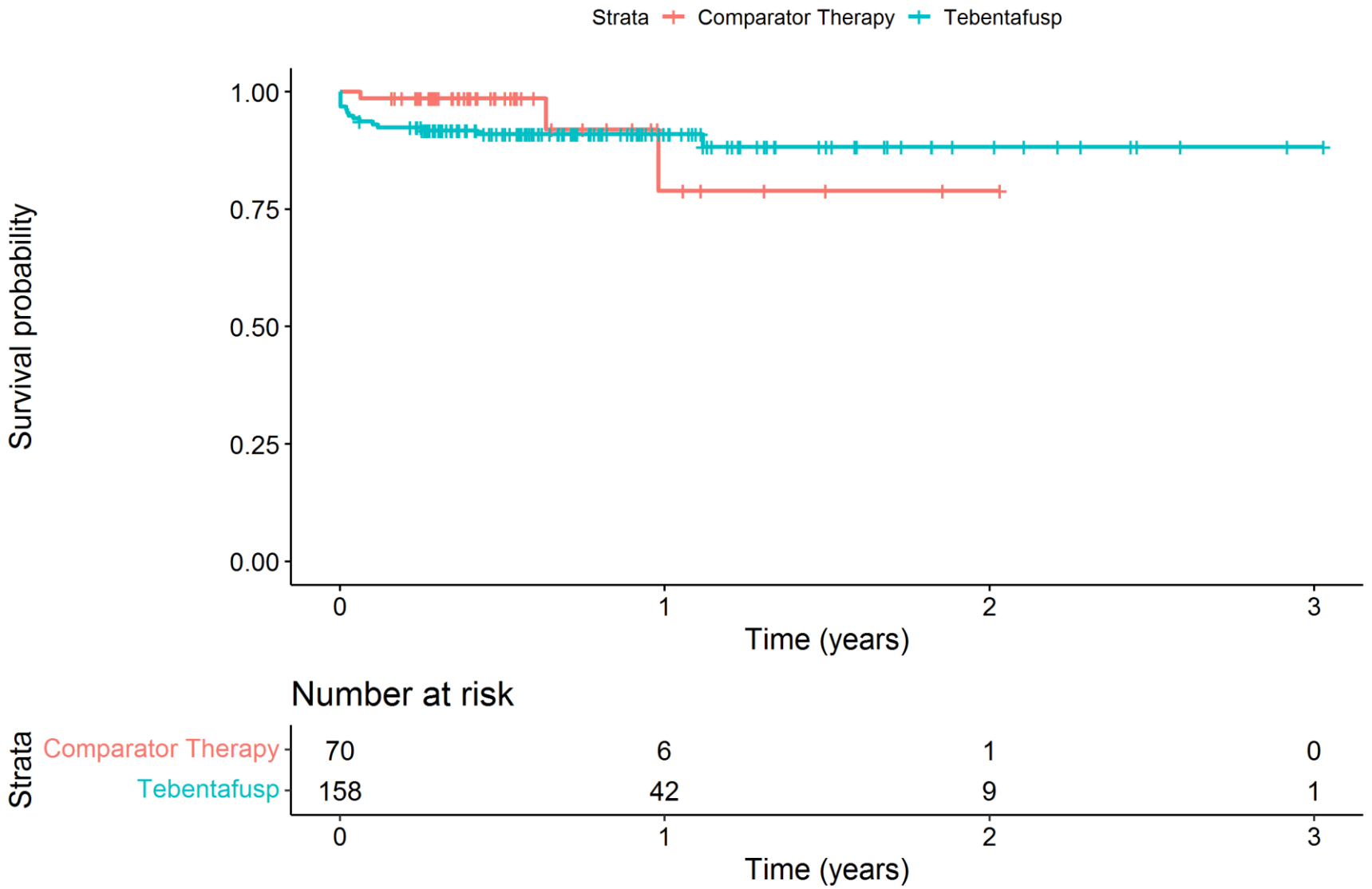
Gefäßerkrankungen - ALP ≤ ULN



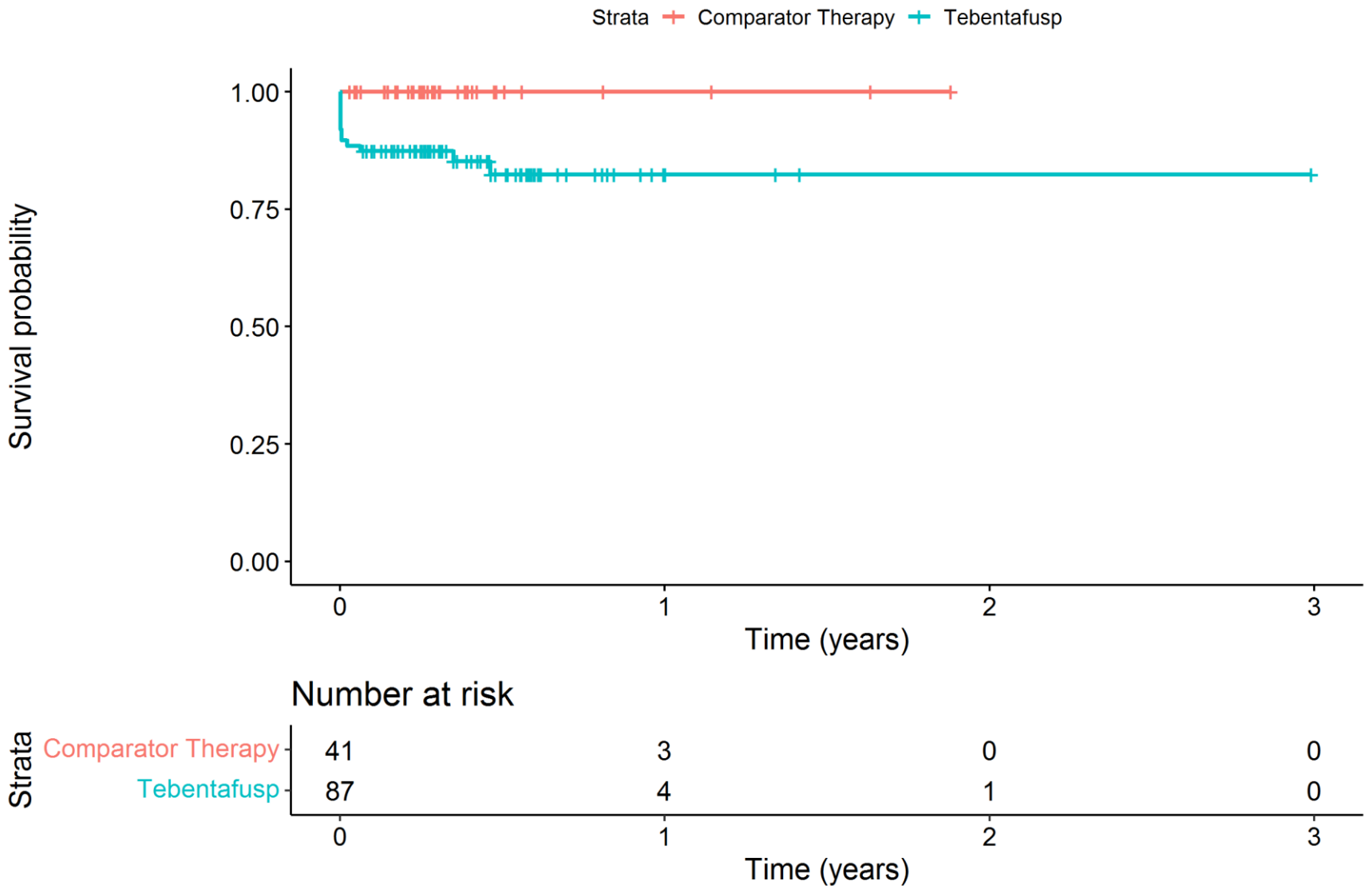
Gefäßerkrankungen - ALP > ULN



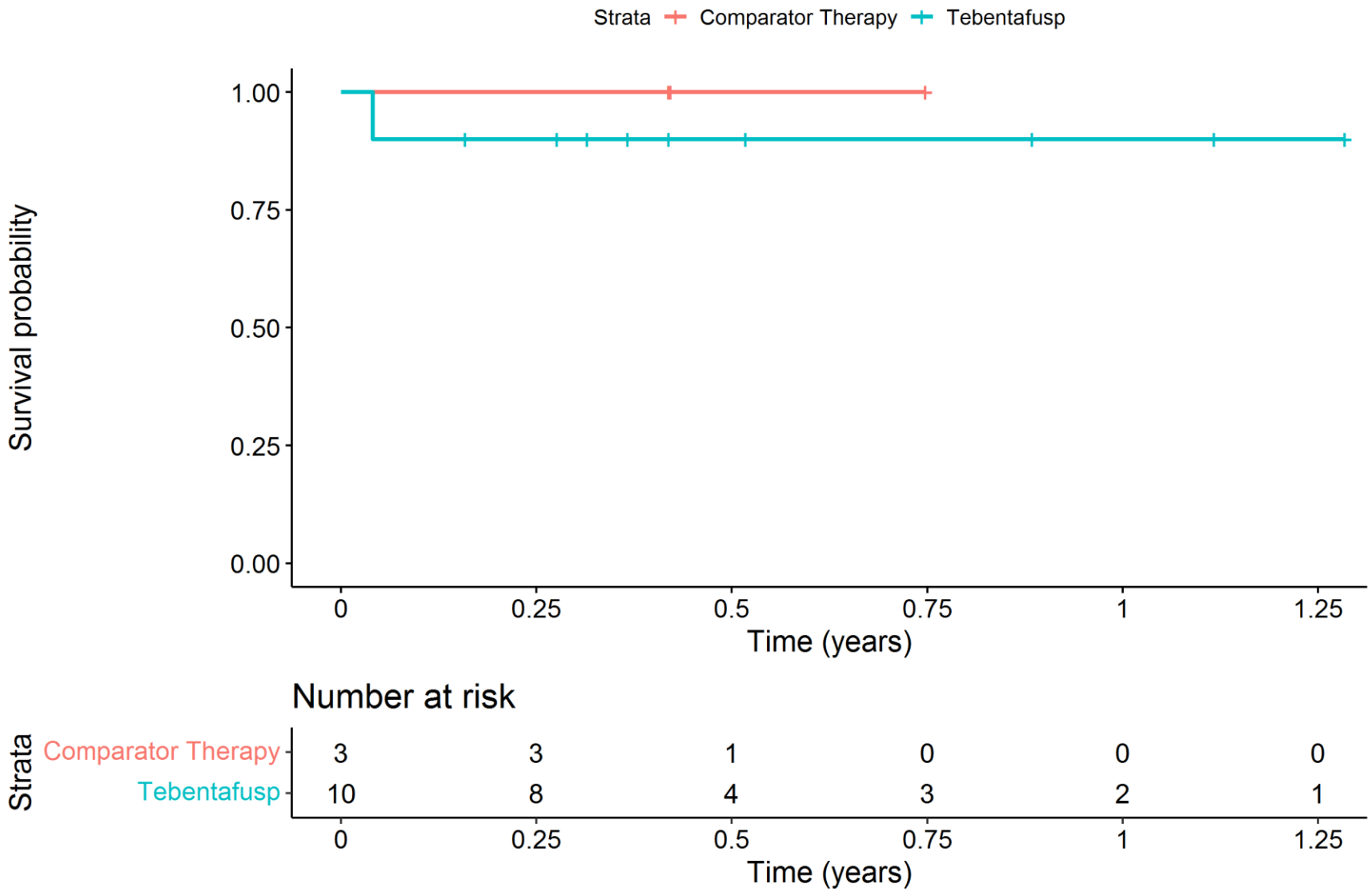
Gefäßerkrankungen - LDH =< ULN



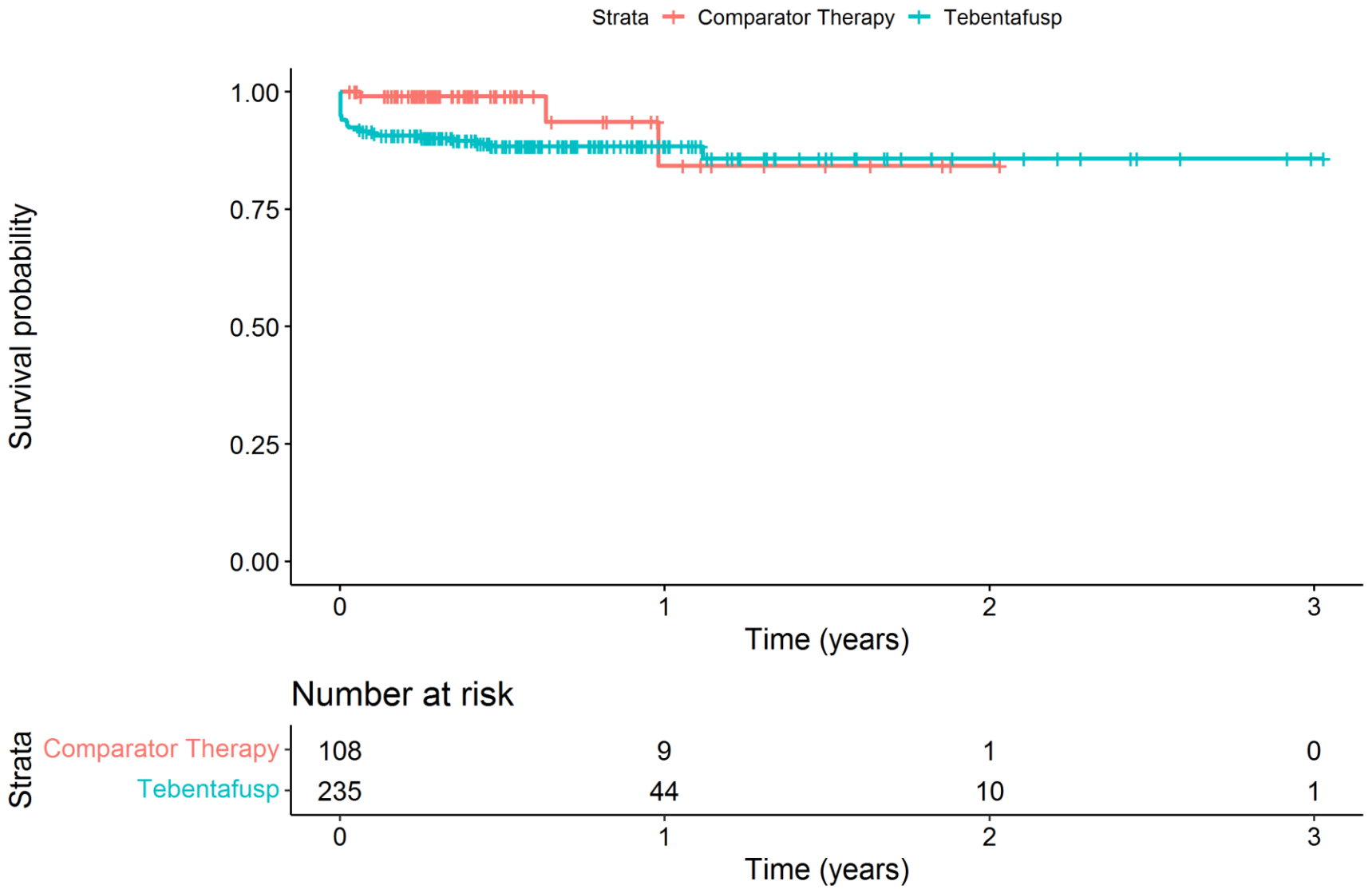
Gefäßerkrankungen - LDH > ULN



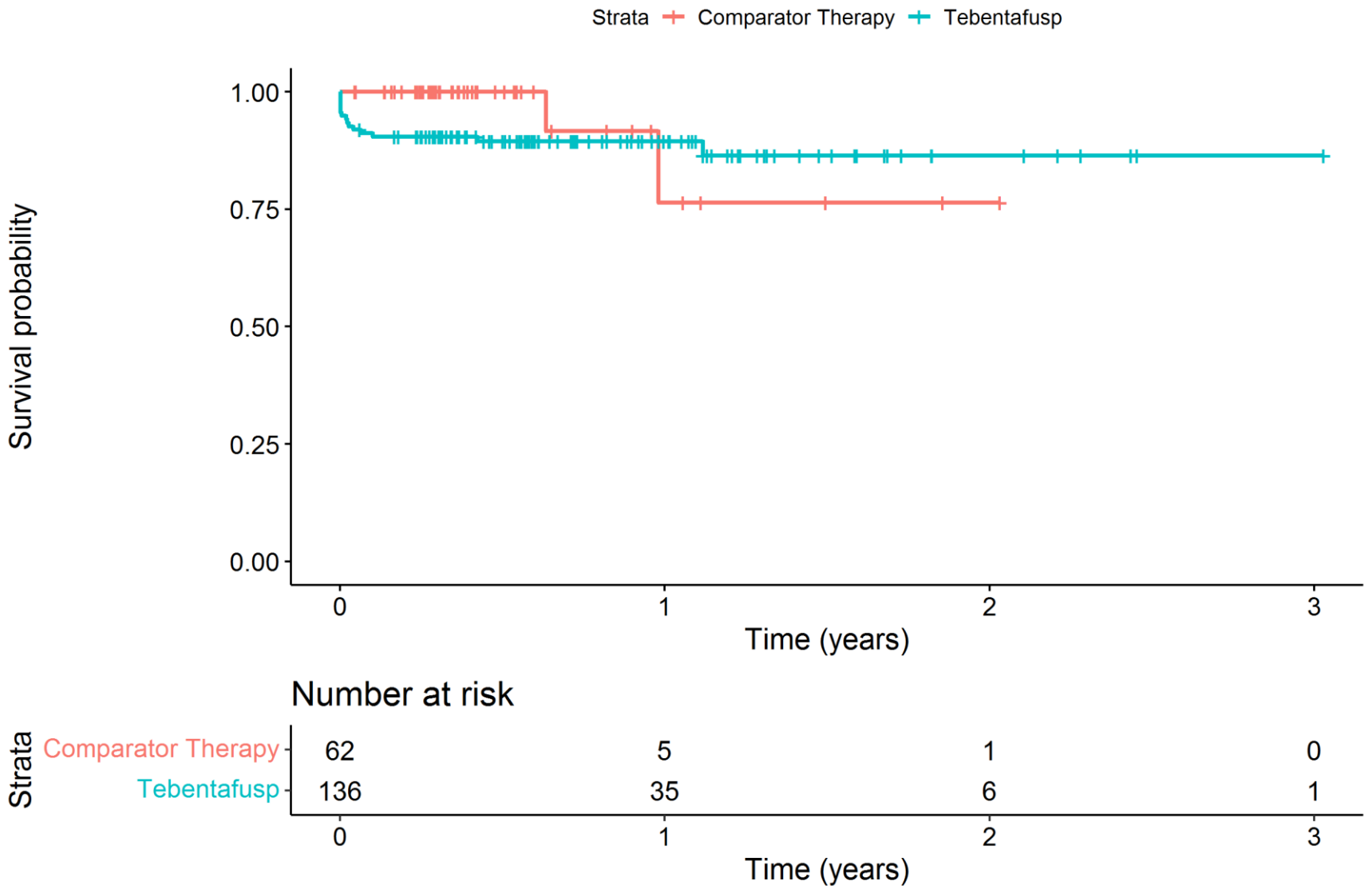
Gefäßerkrankungen - Vorherige Therapie adjuvant/neoadjuvant



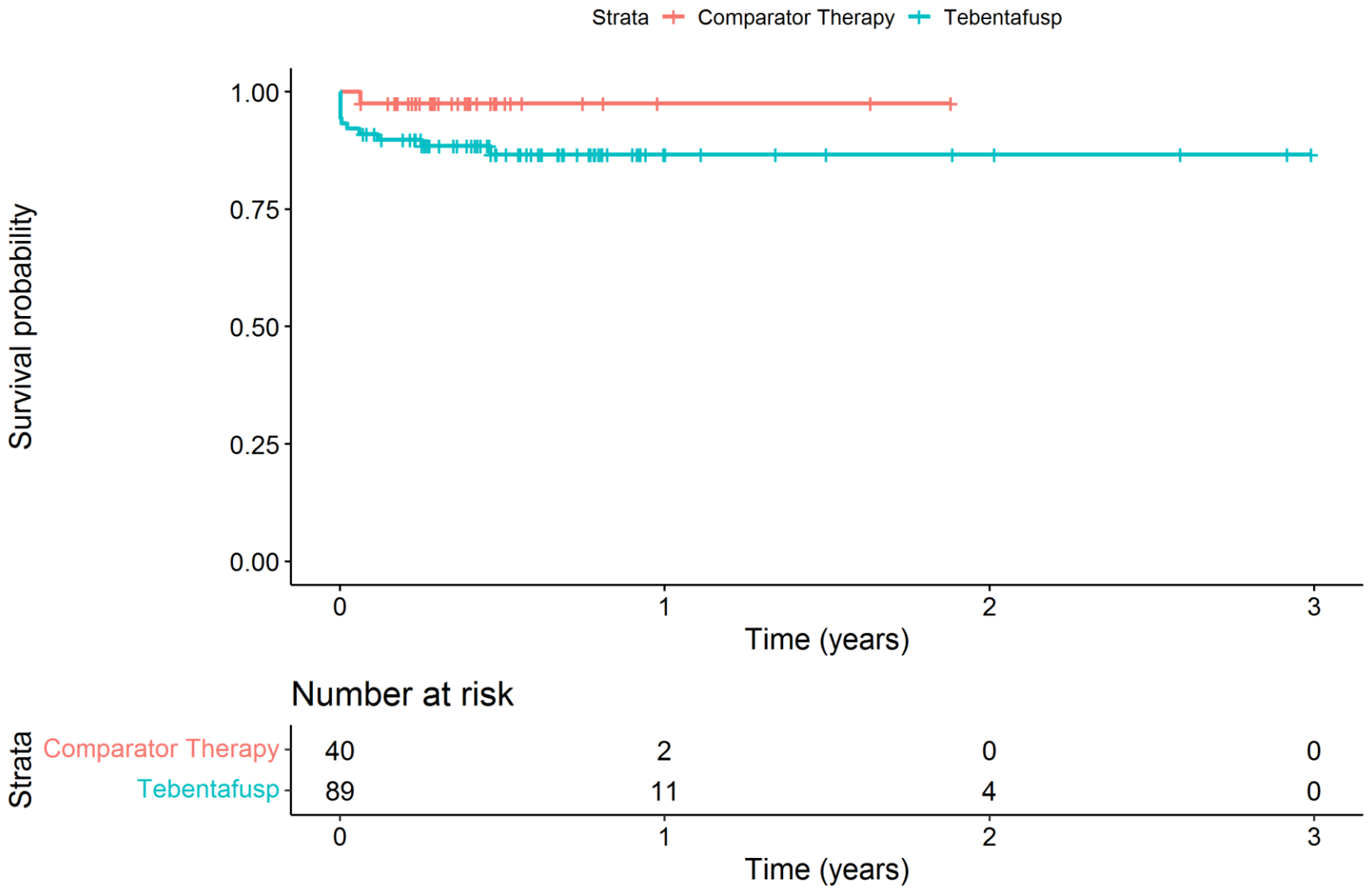
Gefäßerkrankungen - Keine vorherige Therapie adjuvant/neoadjuvant



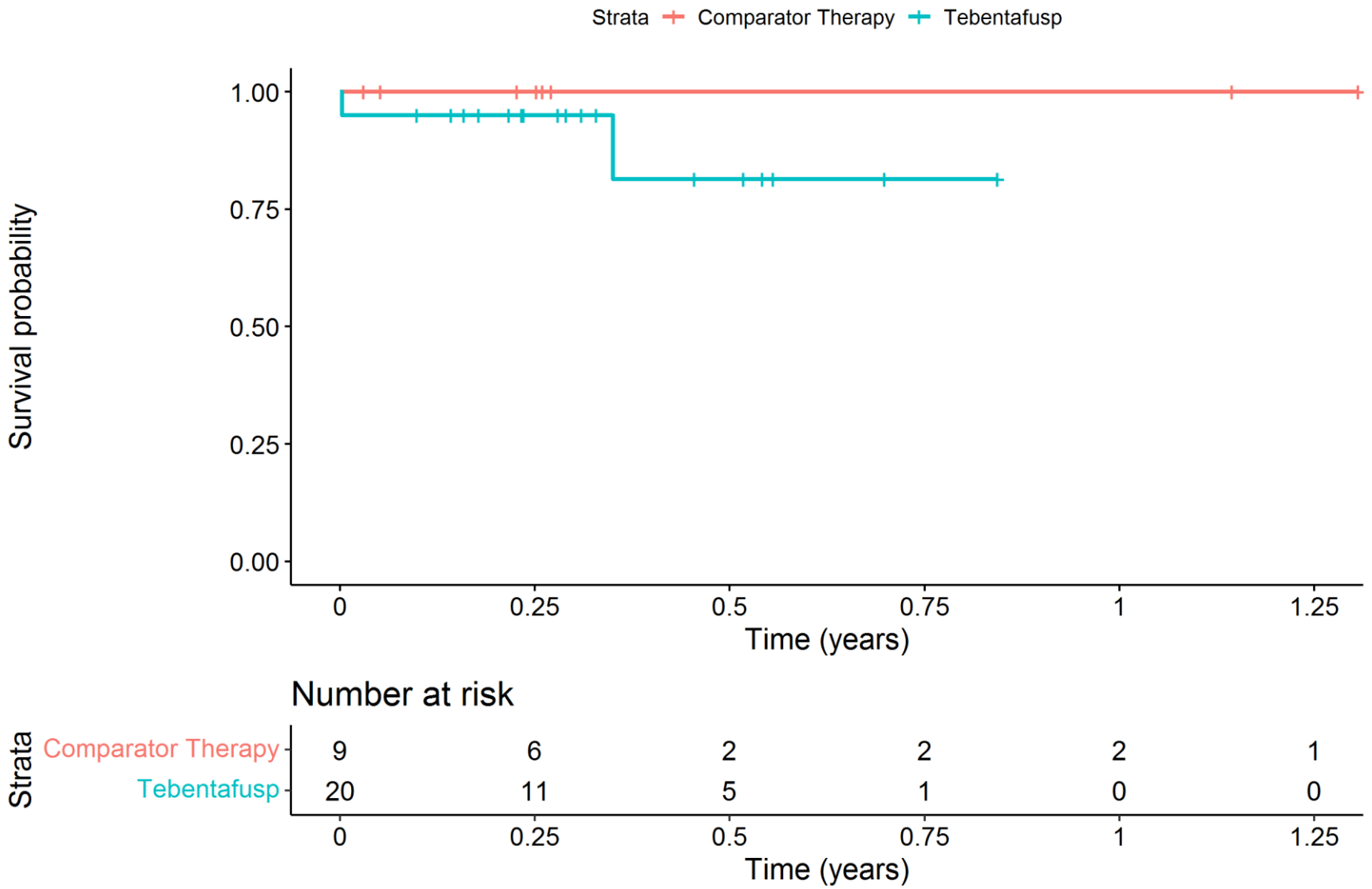
Gefäßerkrankungen - Läsion ≤ 3cm



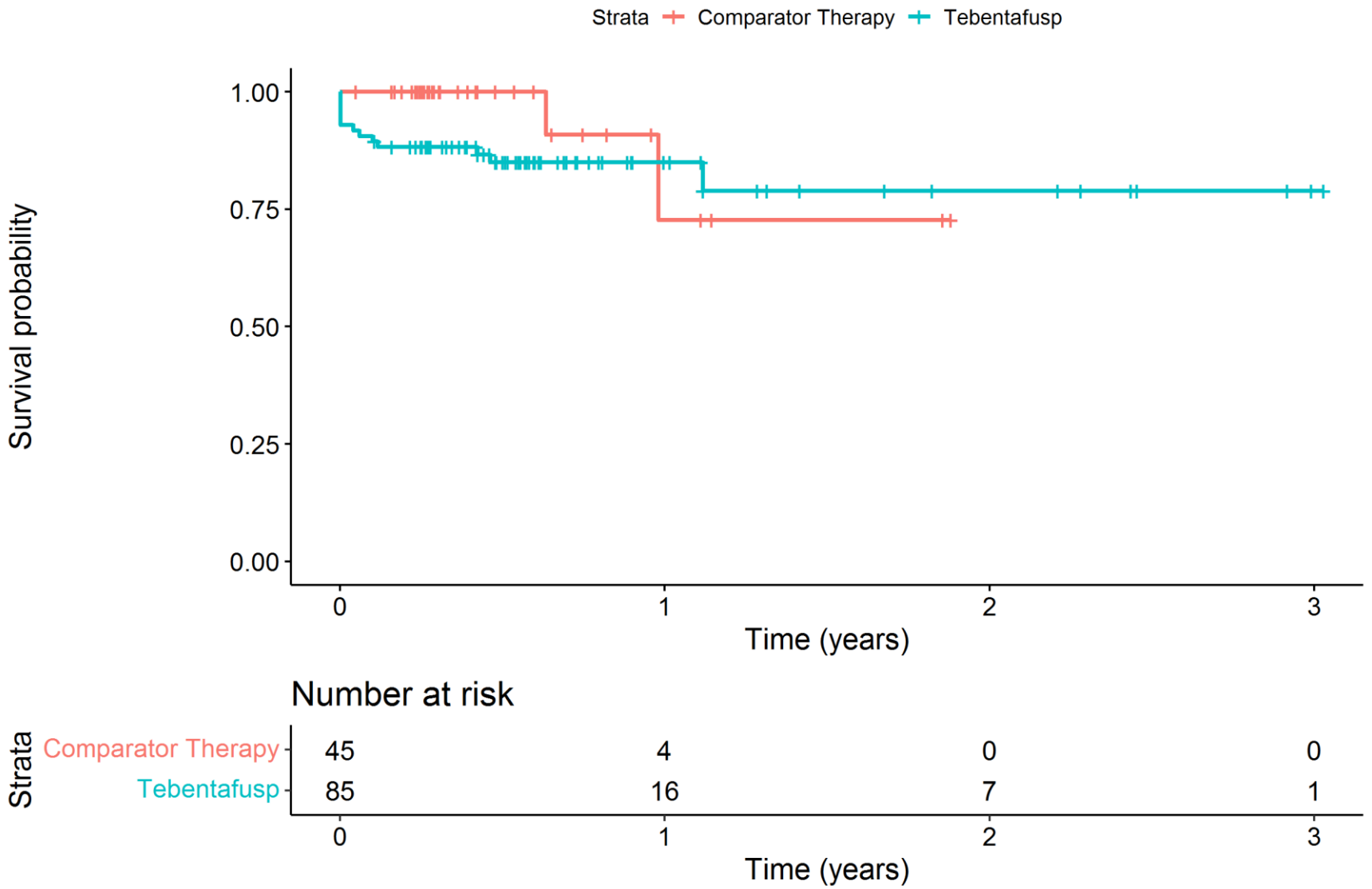
Gefäßerkrankungen - Läsion 3,1-8,0 cm



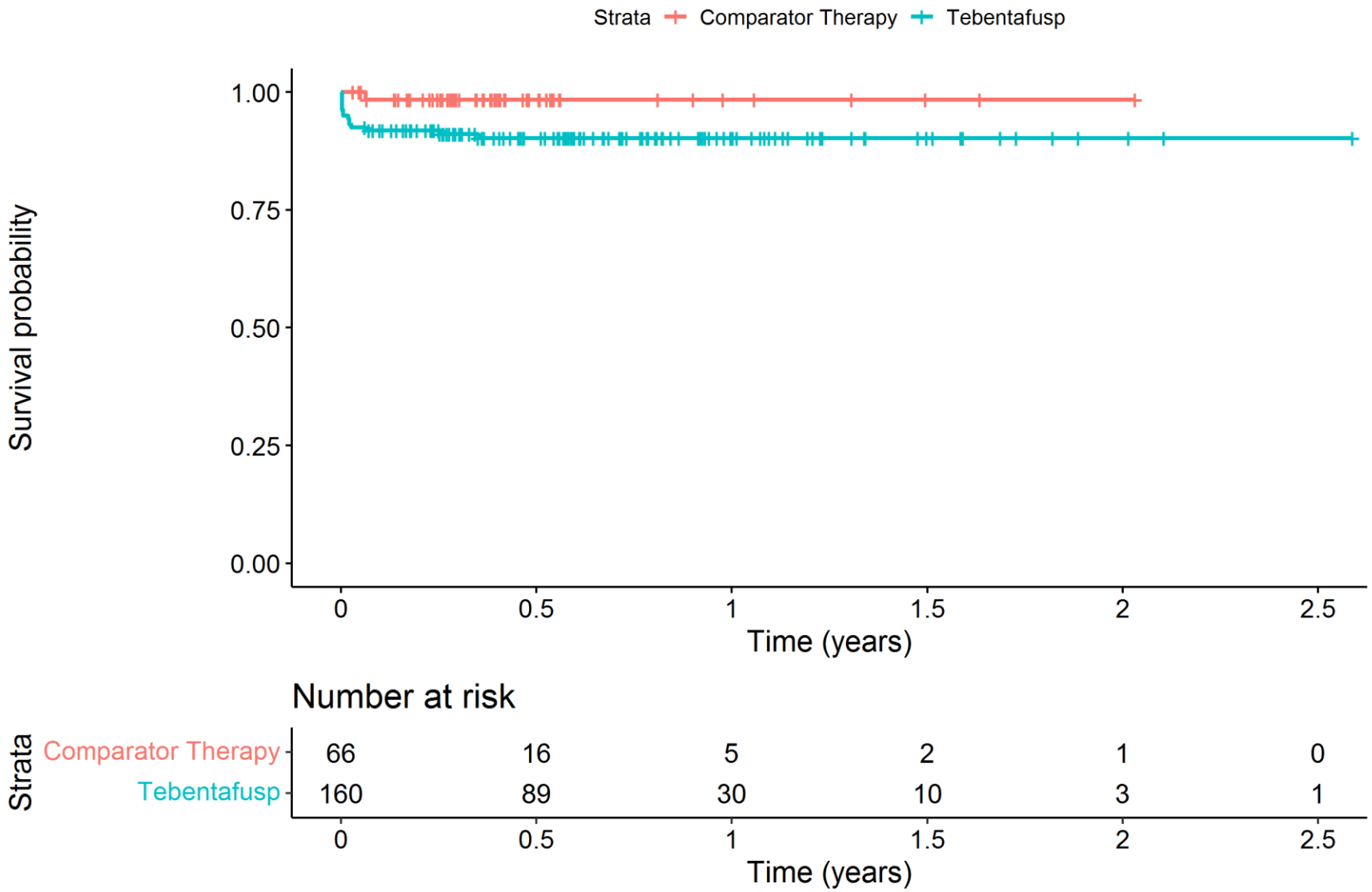
Gefäßerkrankungen - Läsion ≥8,1 cm



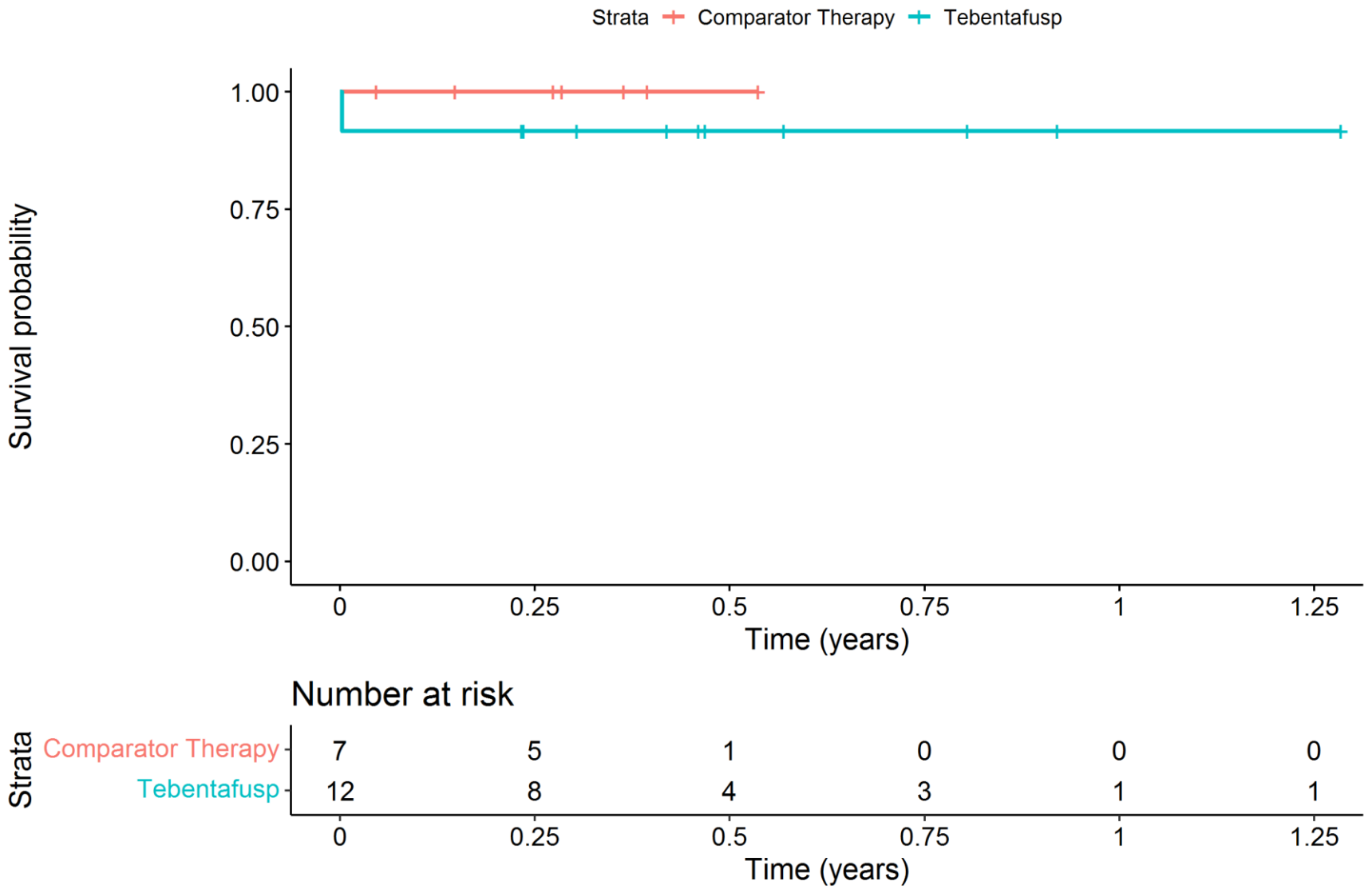
Gefäßerkrankungen - Nordamerika



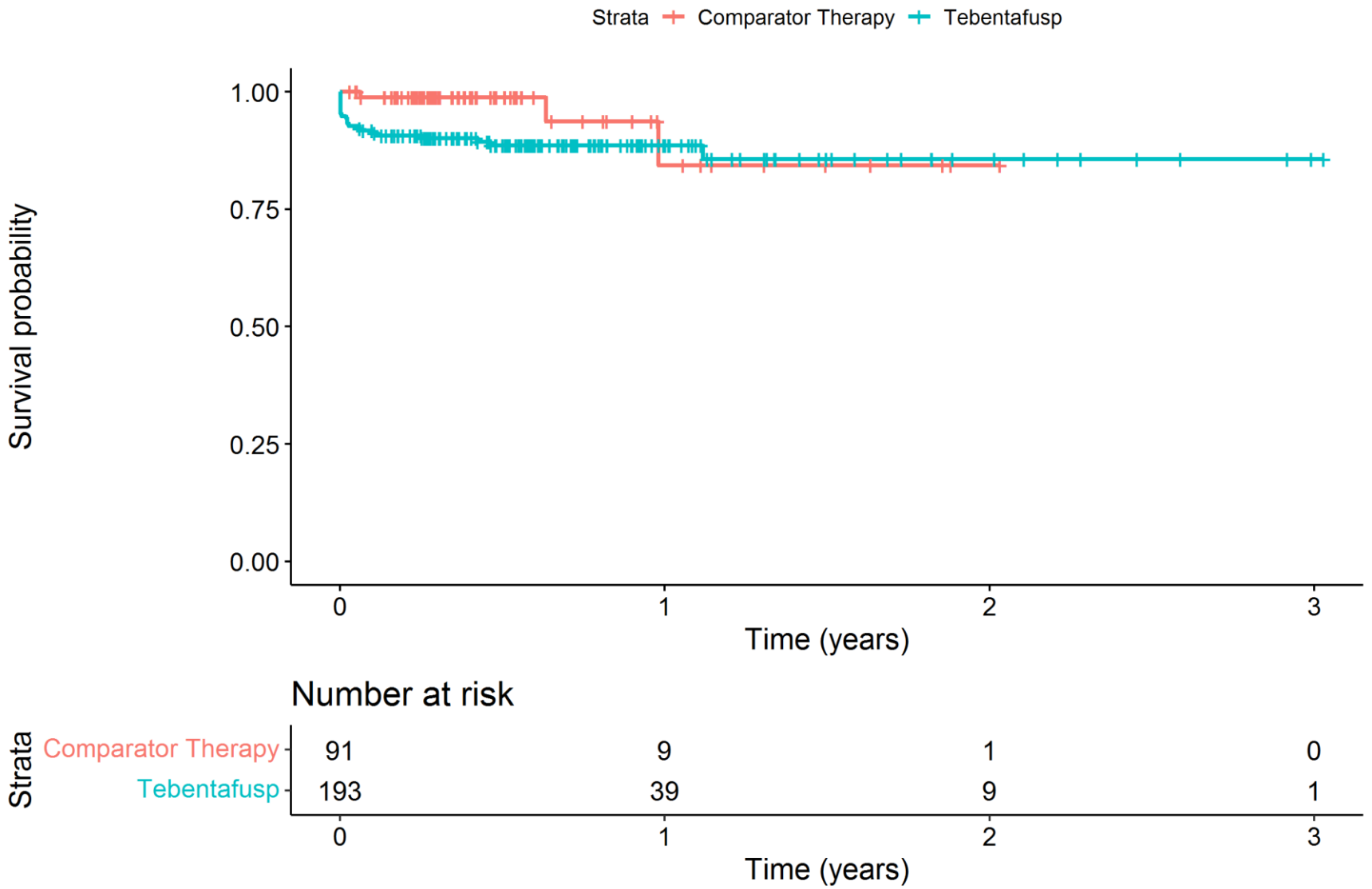
Gefäßerkrankungen - Nicht-Nordamerika



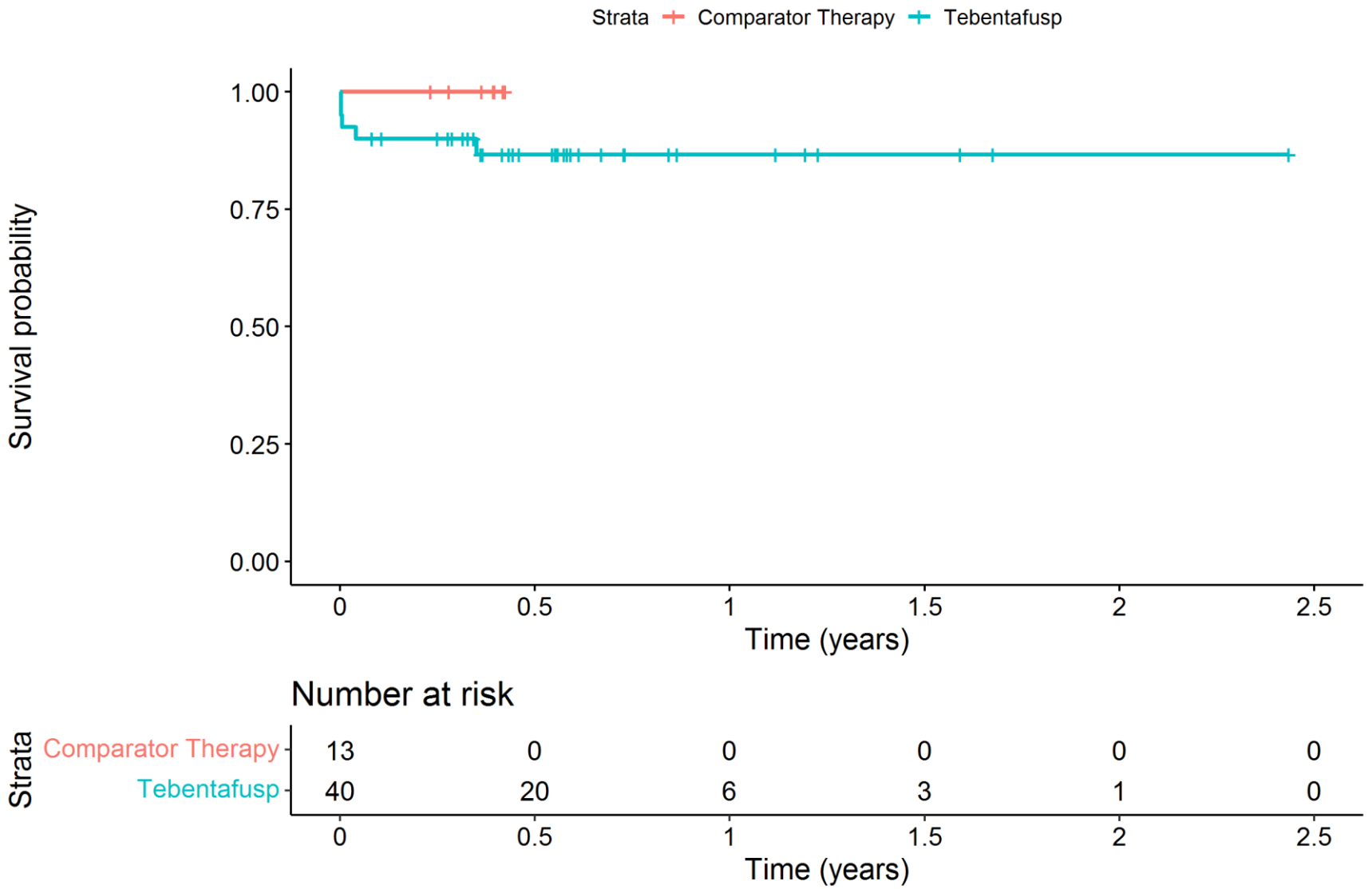
Gefäßerkrankungen - Dacarbazin



Gefäßerkrankungen - Pembrolizumab

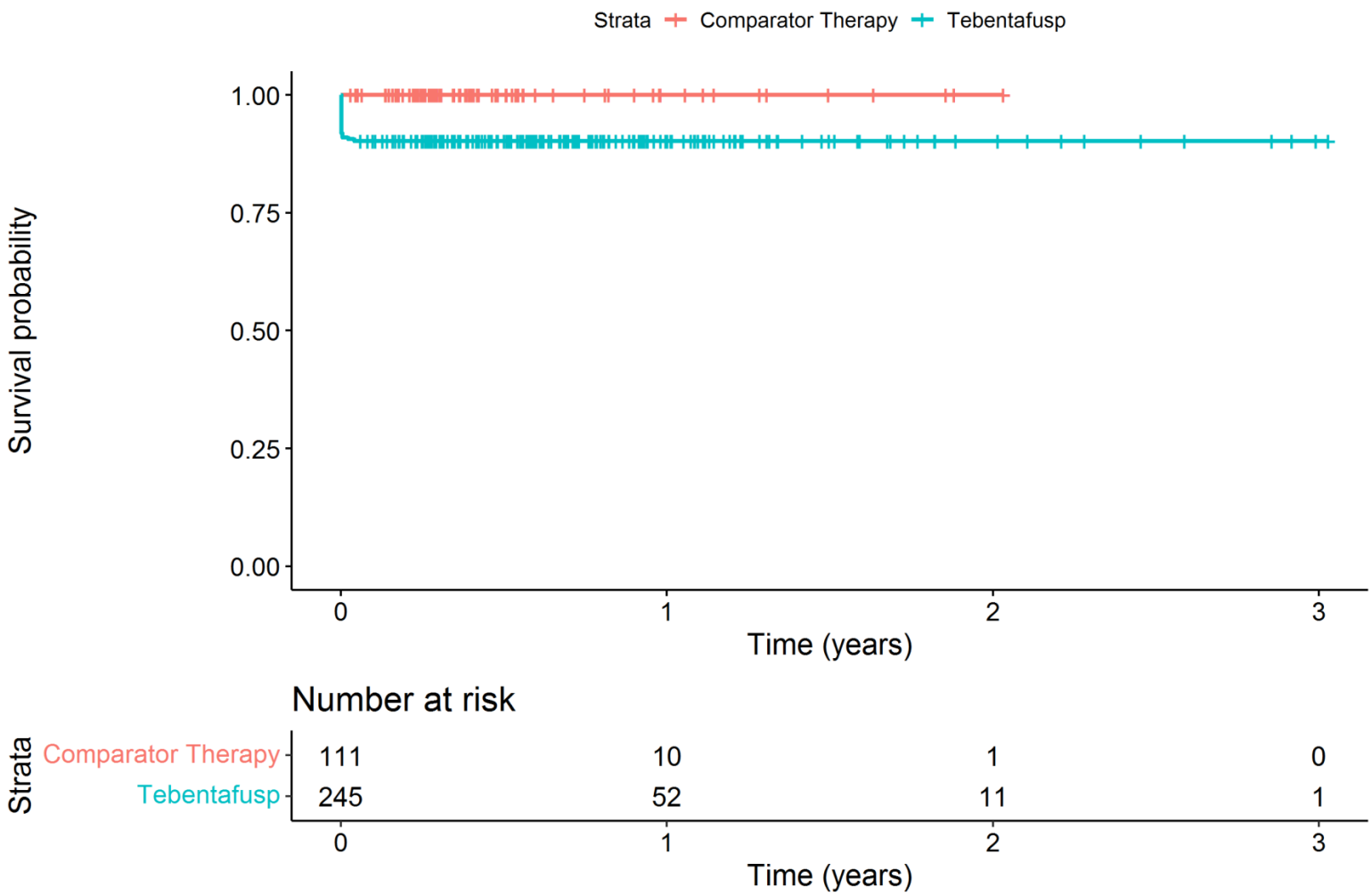


Gefäßerkrankungen - Ipilimumab

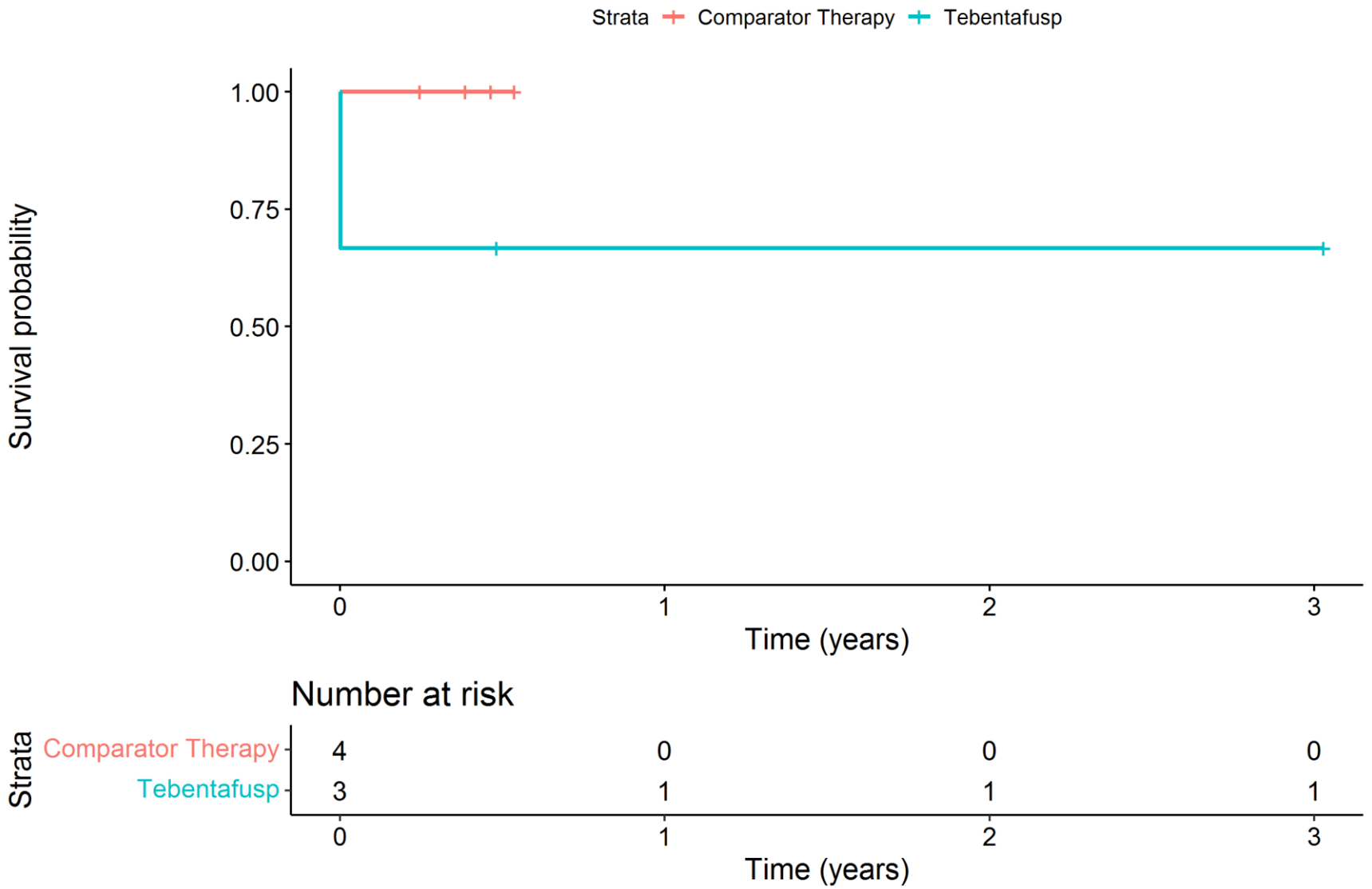


57 SUEs (PT) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-206)

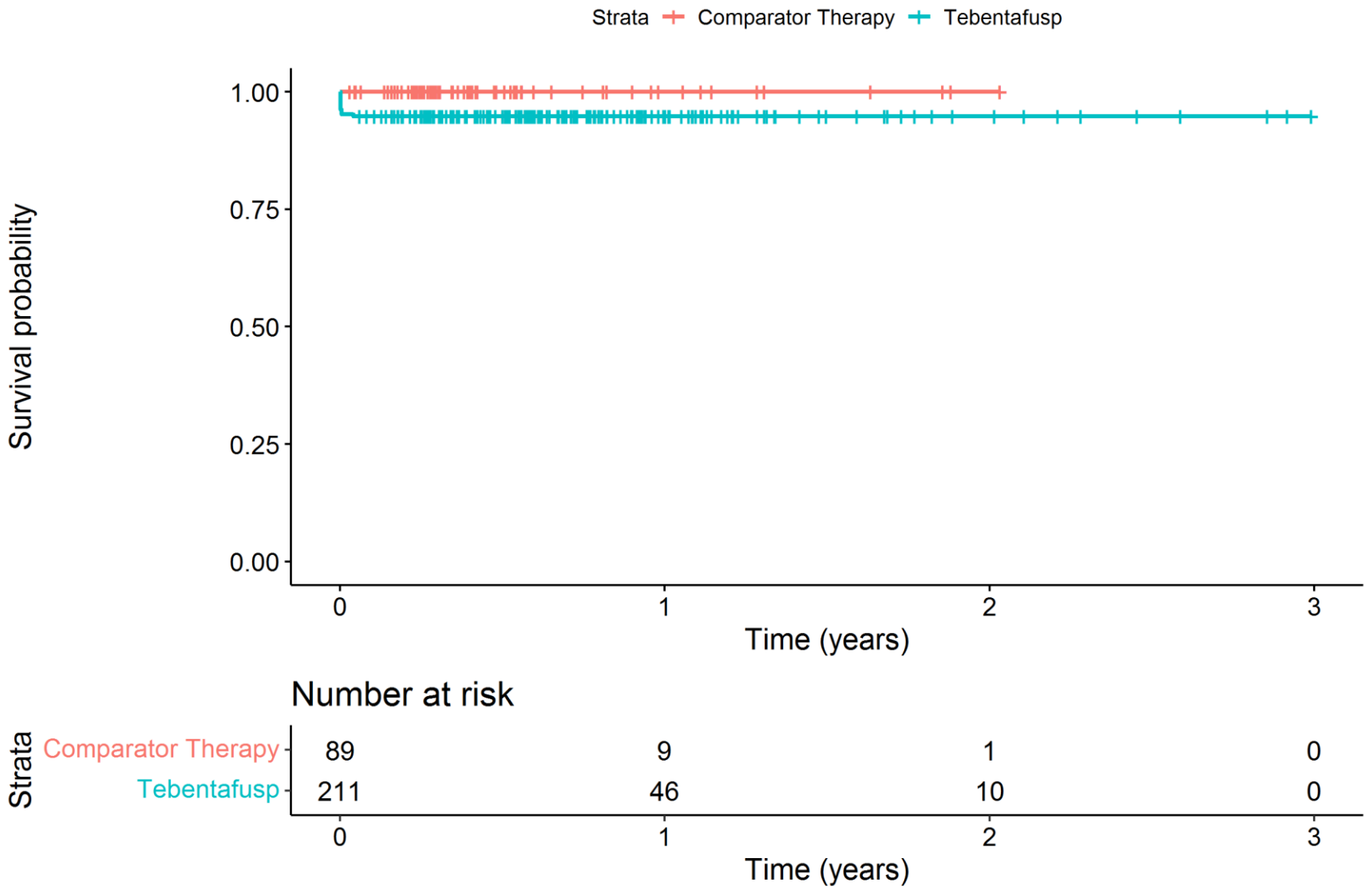
Zytokin-Freisetzungssyndrom- Gesamt



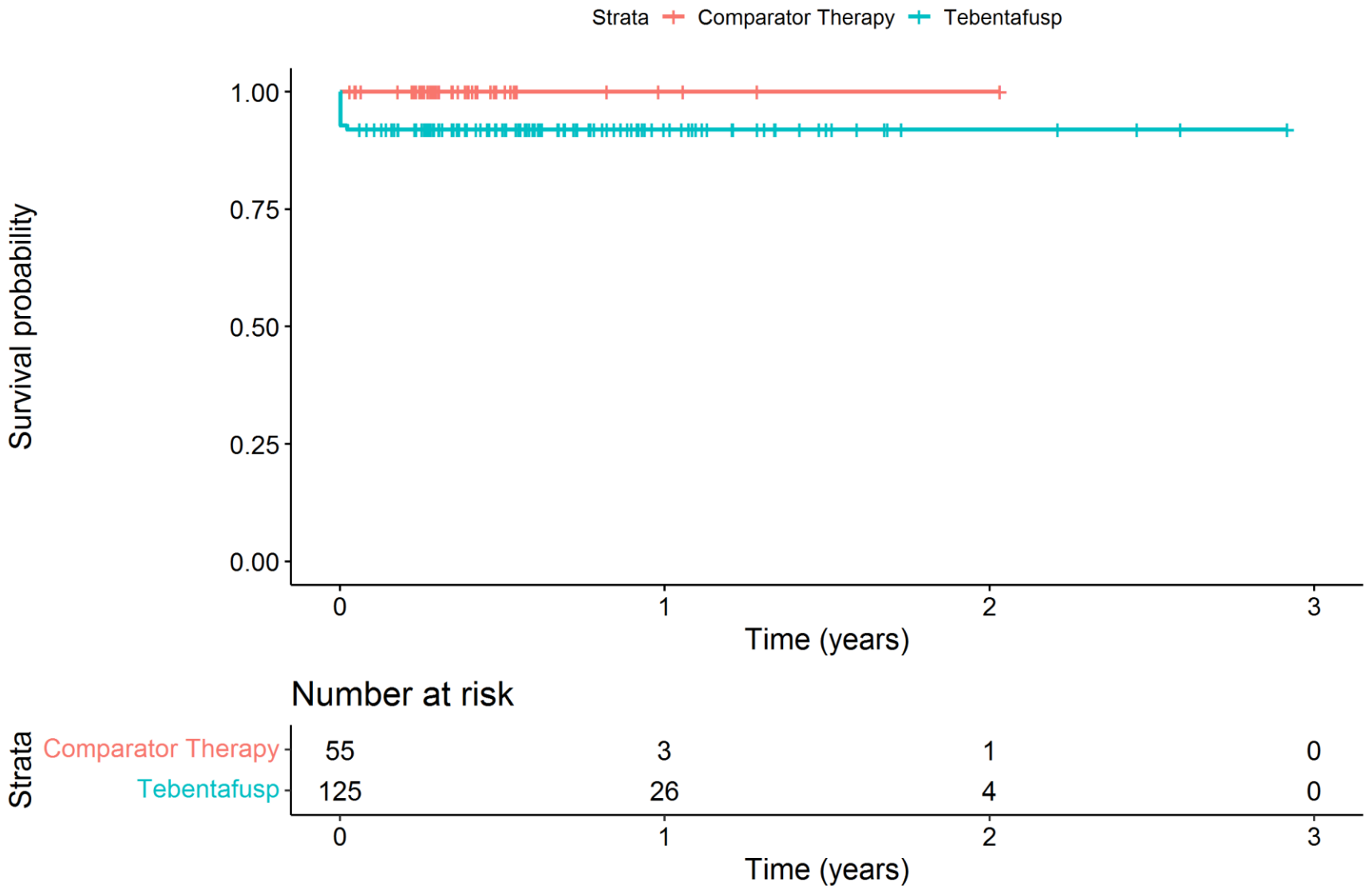
Zytokin-Freisetzungssyndrom- Hispanisch



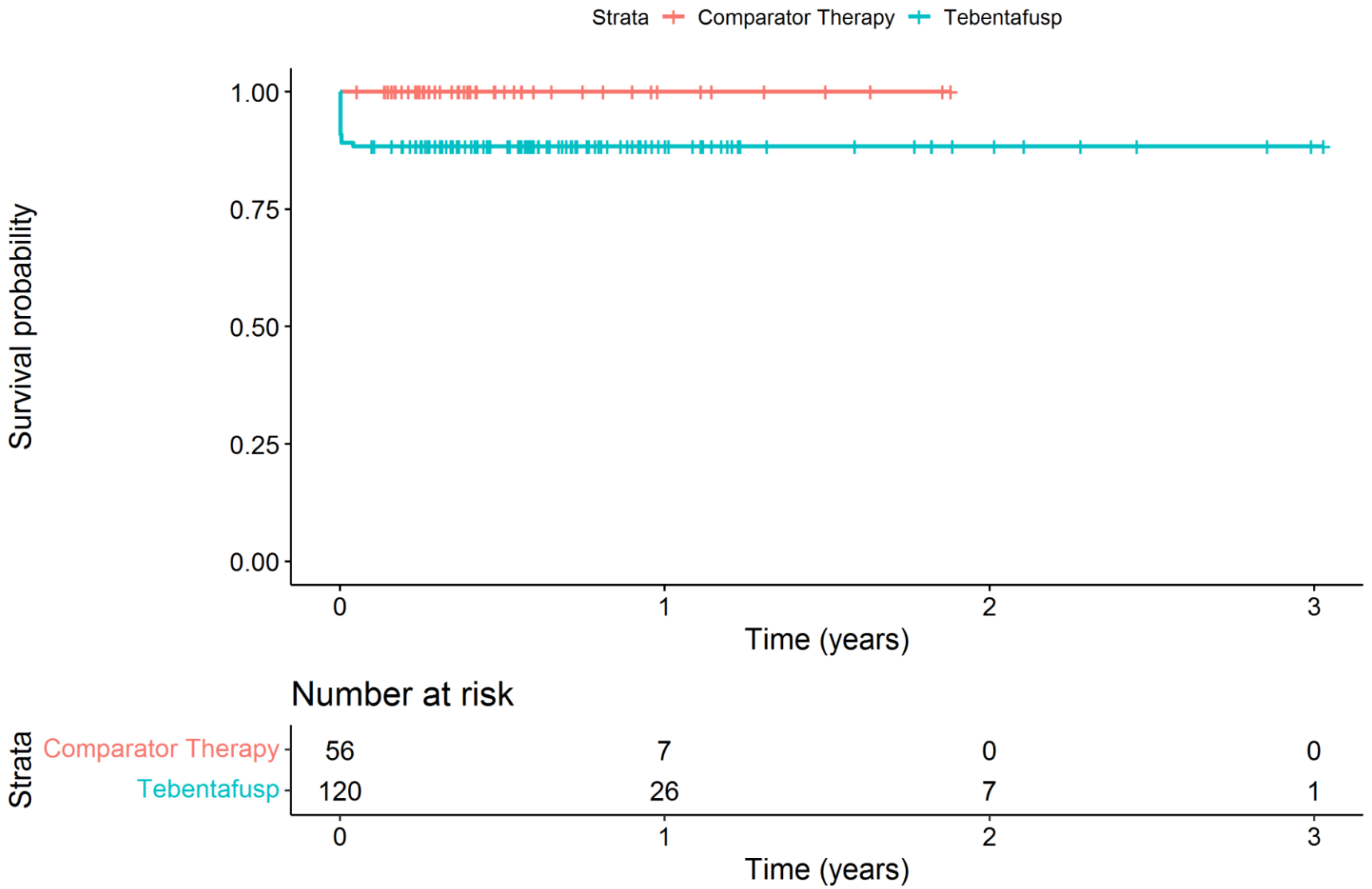
Zytokin-Freisetzungssyndrom- Nicht-hispanisch



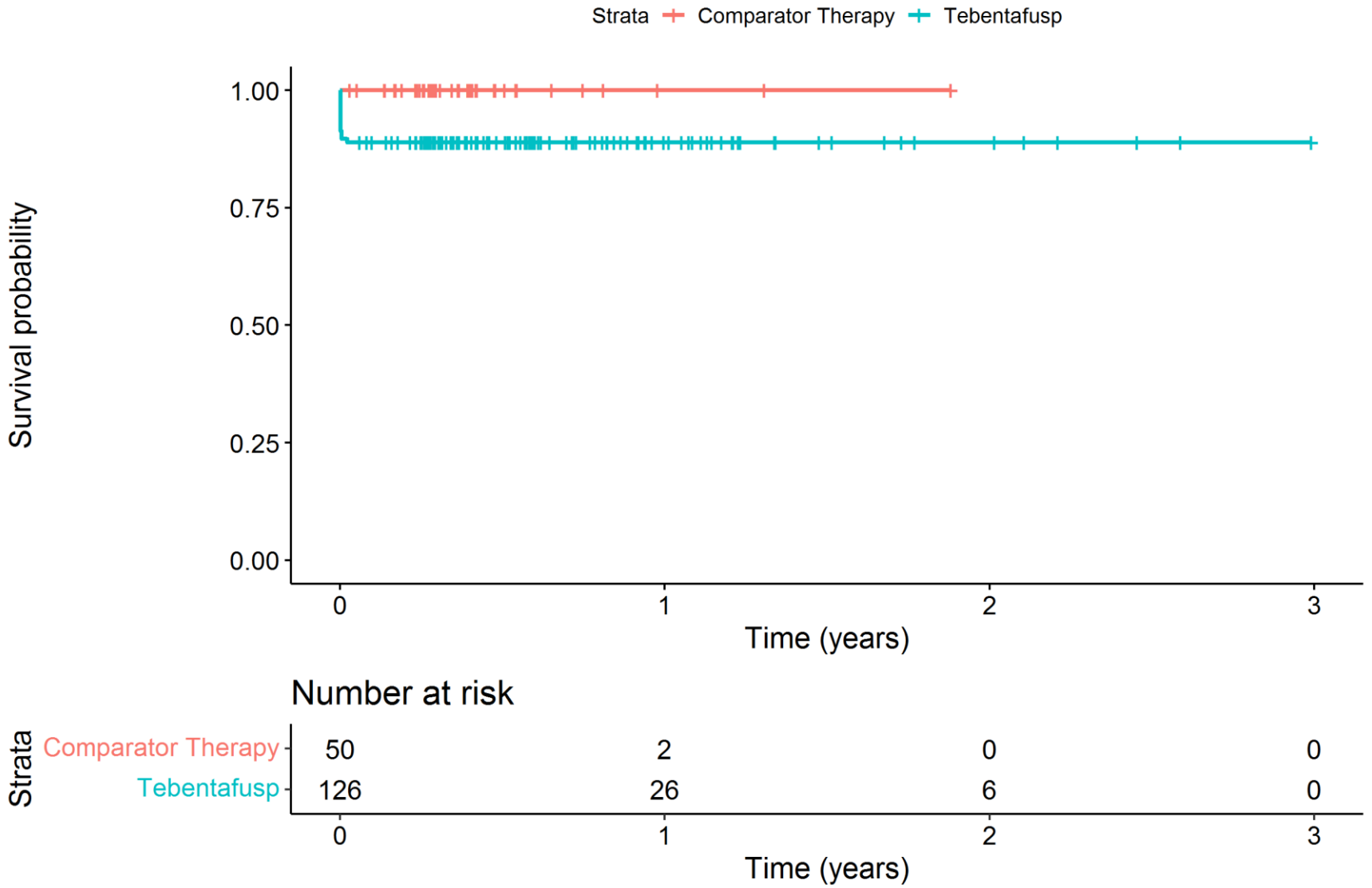
Zytokin-Freisetzungssyndrom- Männlich



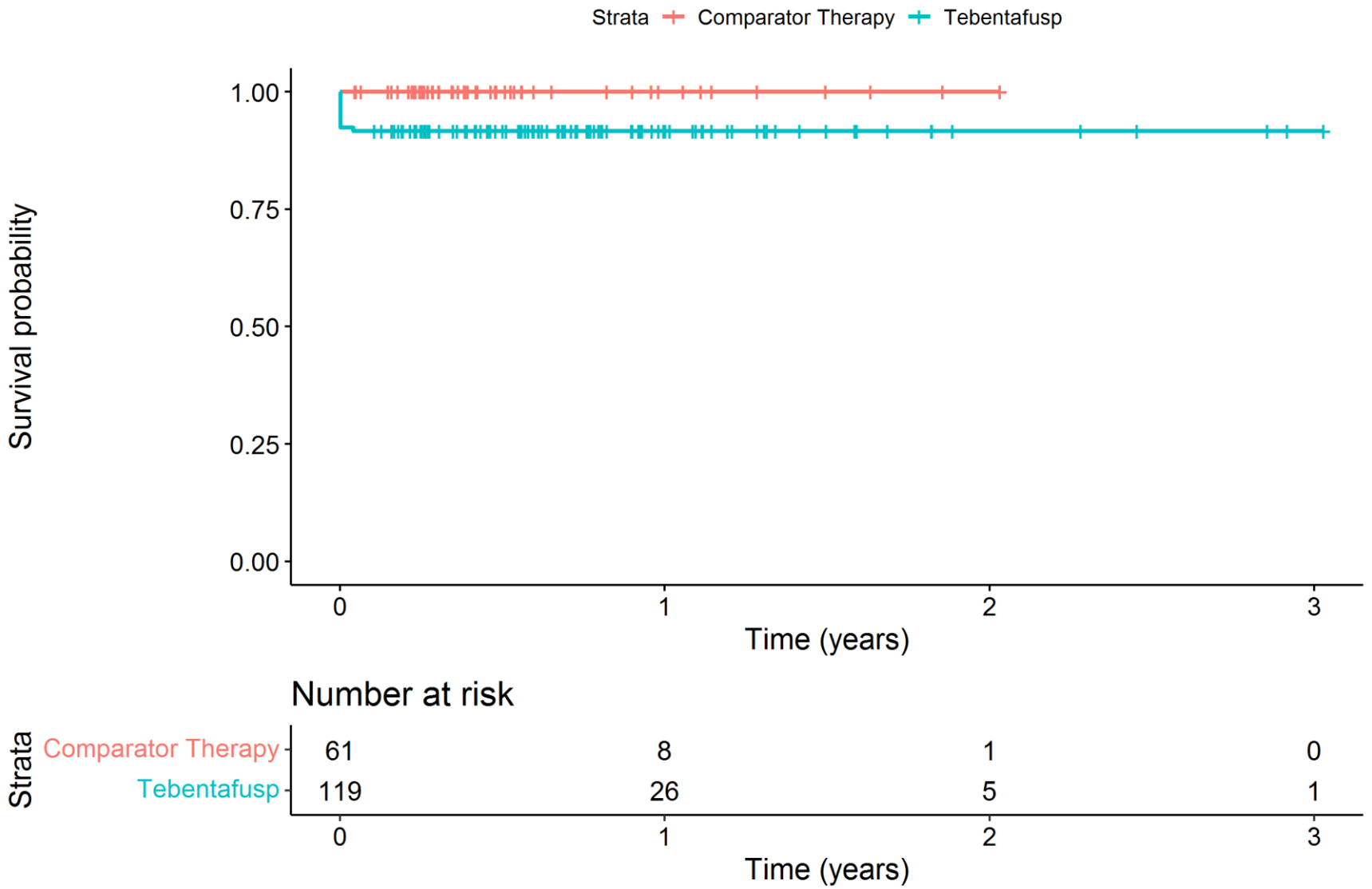
Zytokin-Freisetzungssyndrom- Weiblich



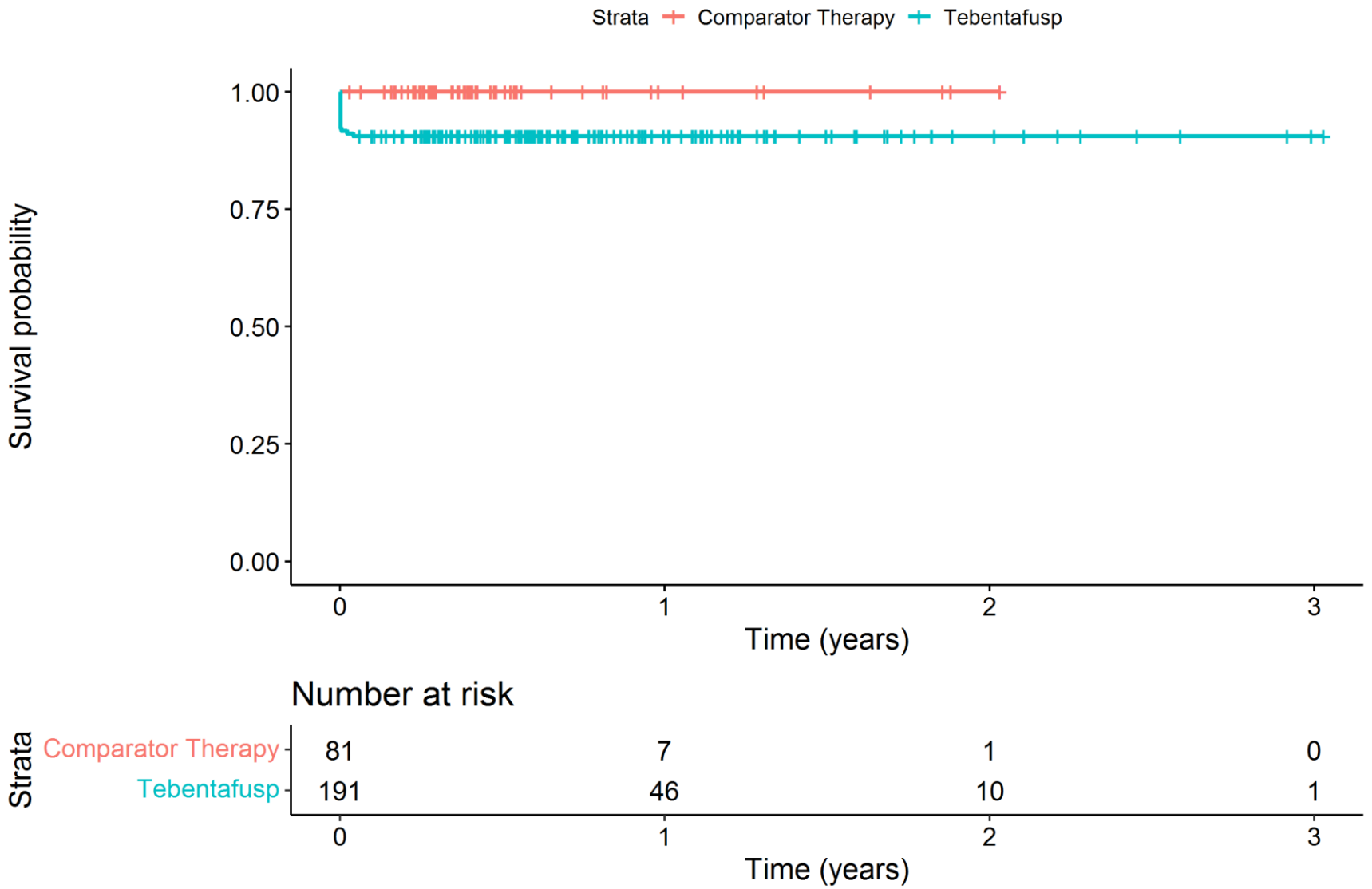
Zytokin-Freisetzungssyndrom- <65



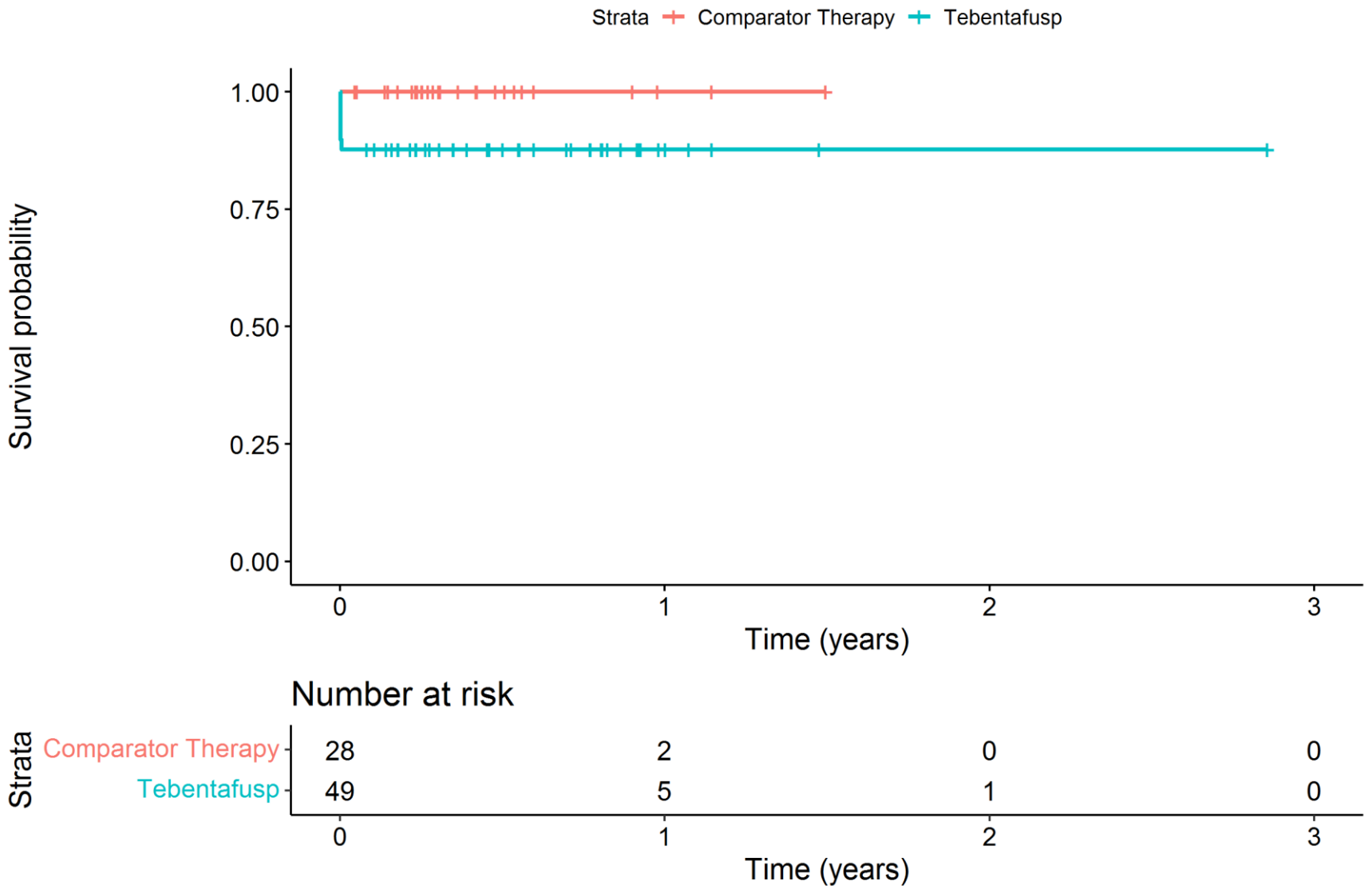
Zytokin-Freisetzungssyndrom- ≥65



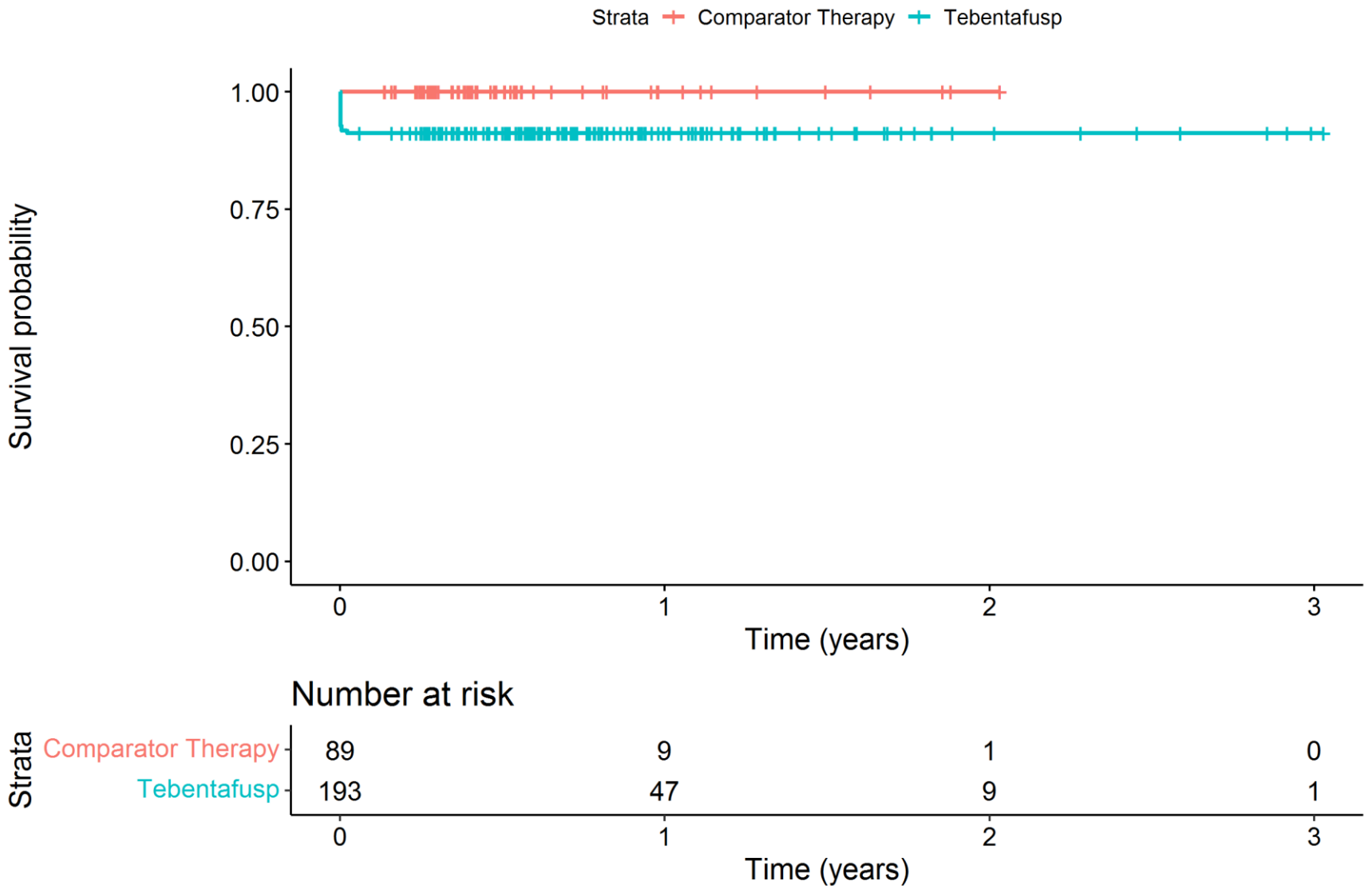
Zytokin-Freisetzungssyndrom- ECOG 0



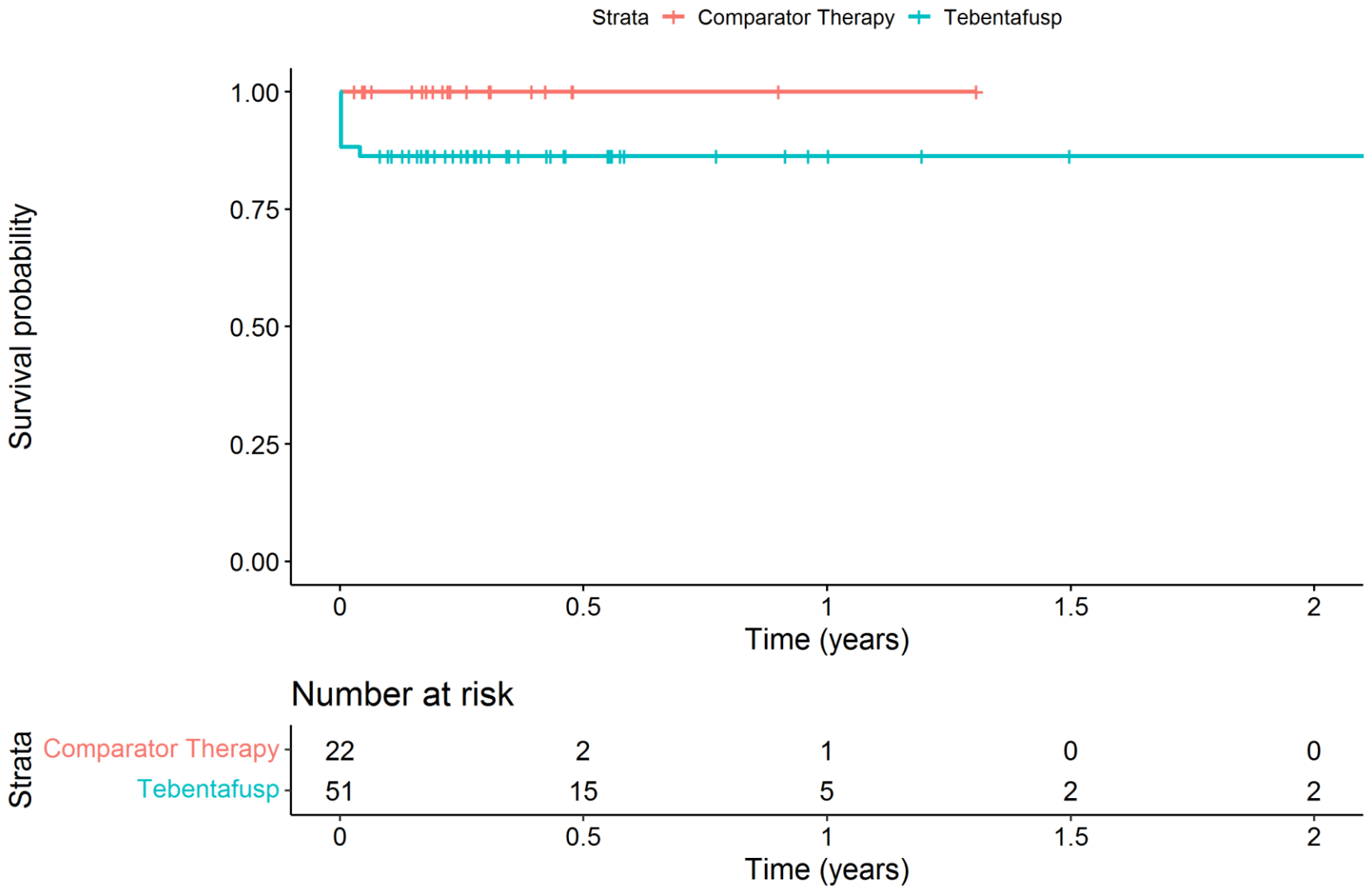
Zytokin-Freisetzungssyndrom- ECOG 1



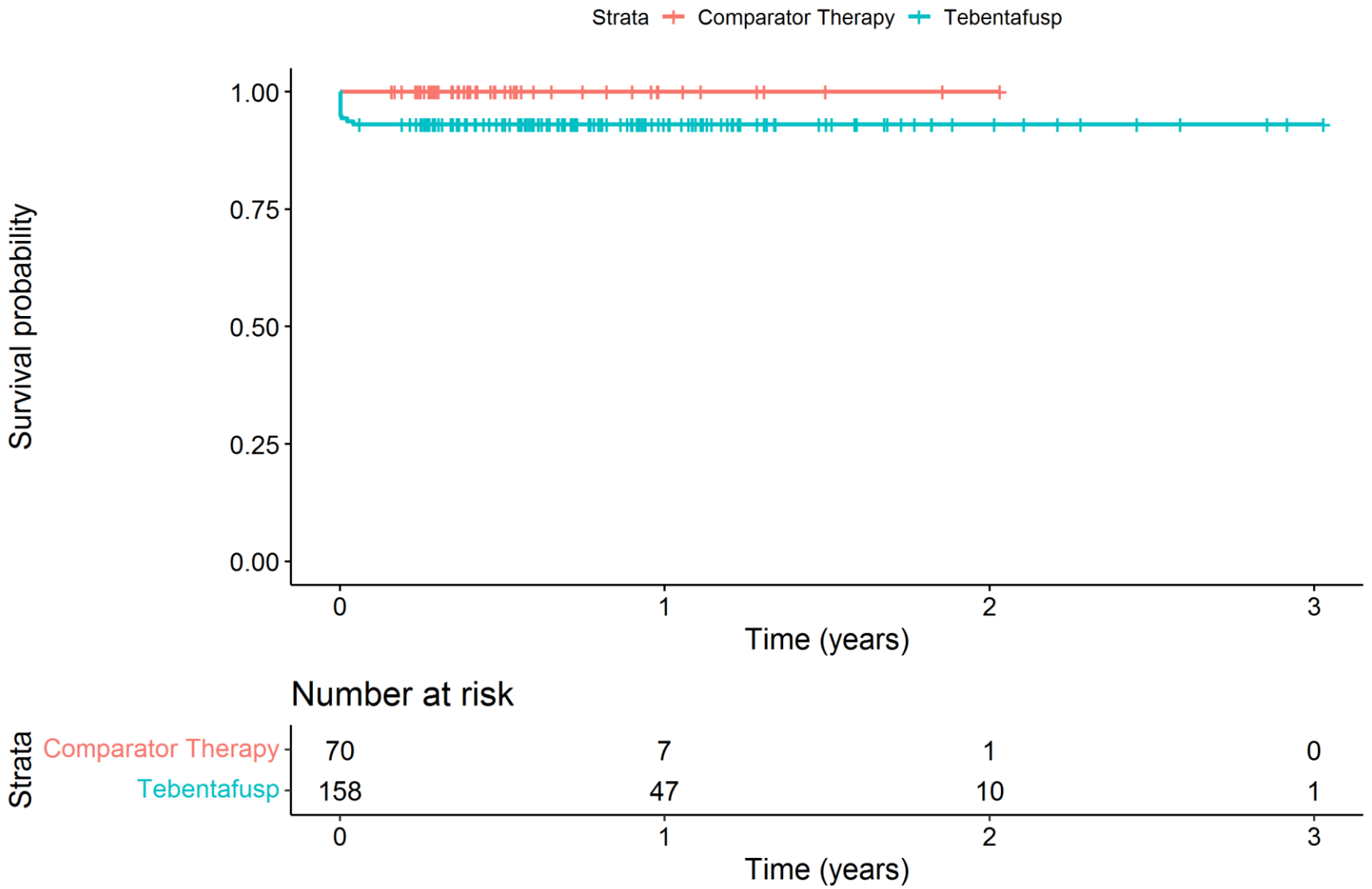
Zytokin-Freisetzungssyndrom- ALP ≤ ULN



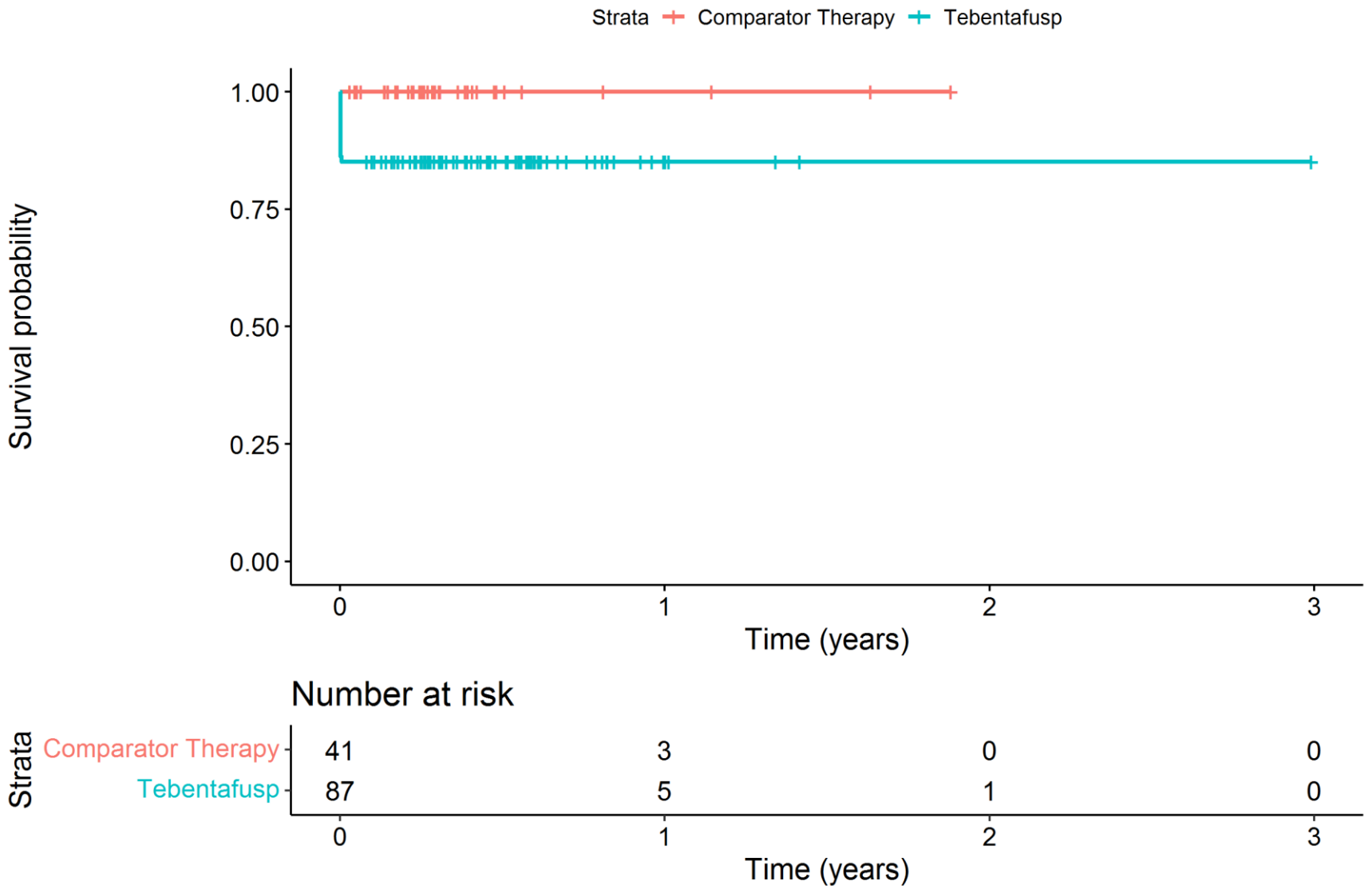
Zytokin-Freisetzungssyndrom- ALP > ULN



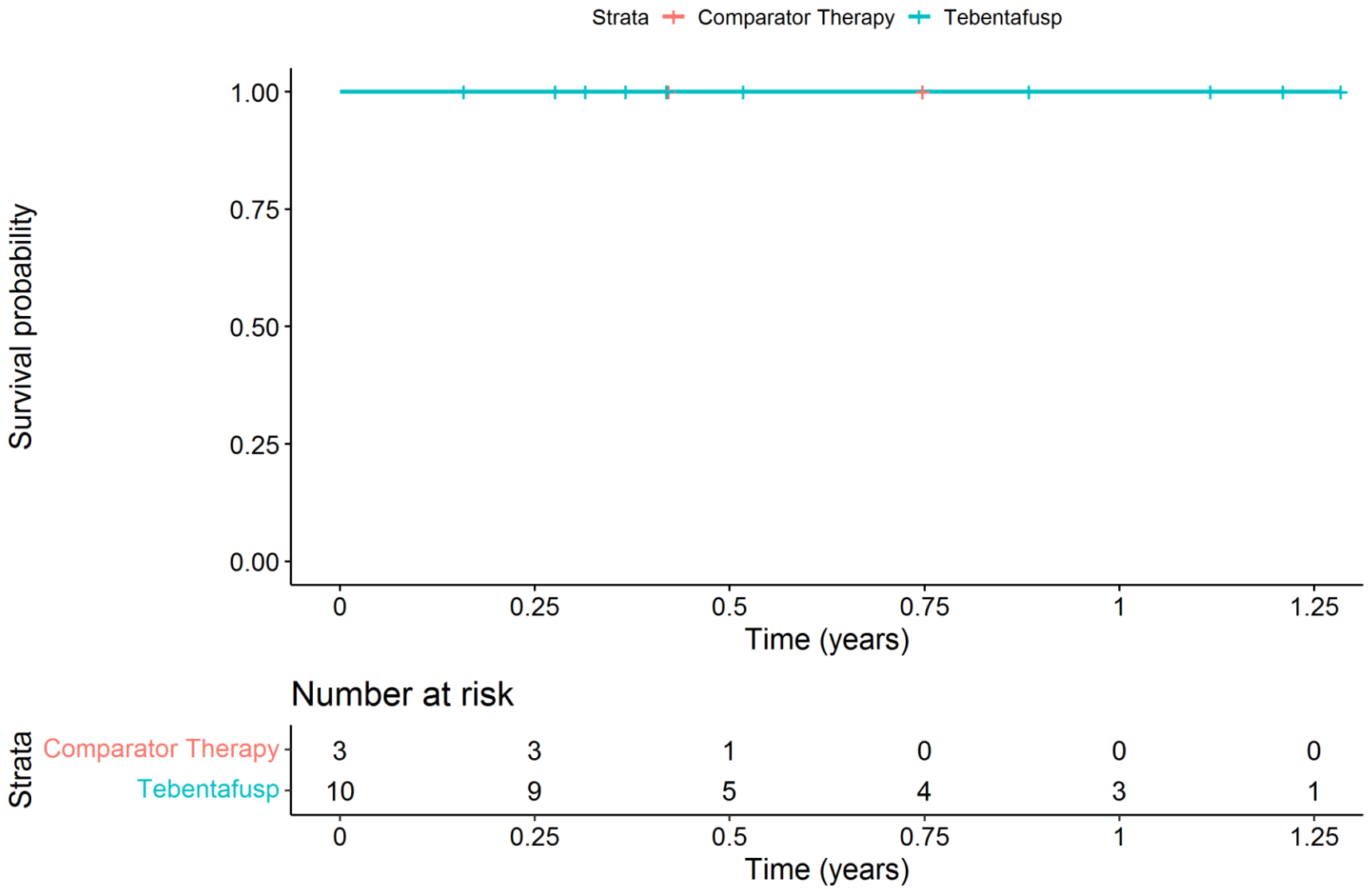
Zytokin-Freisetzungssyndrom- LDH =< ULN



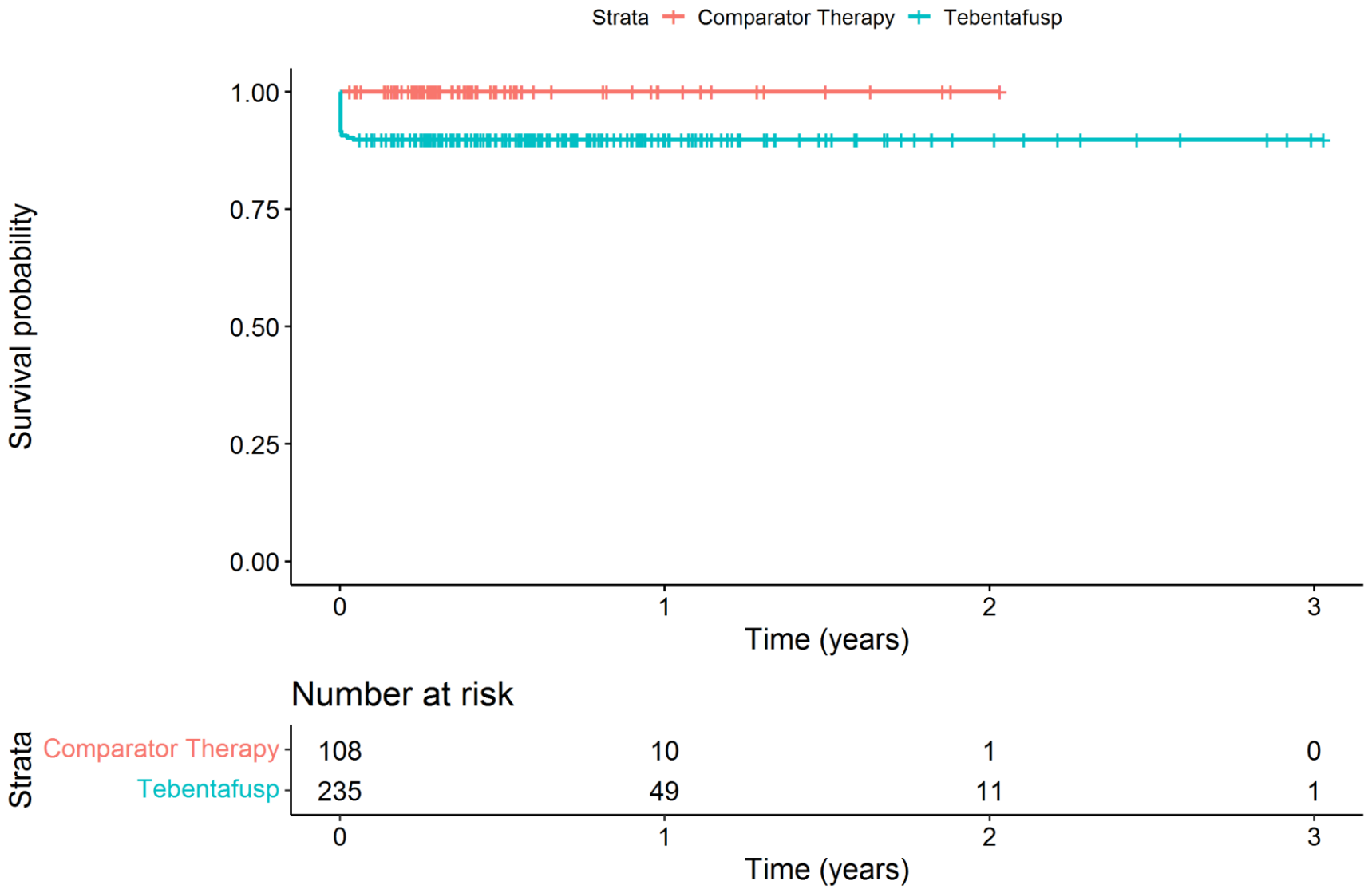
Zytokin-Freisetzungssyndrom- LDH > ULN



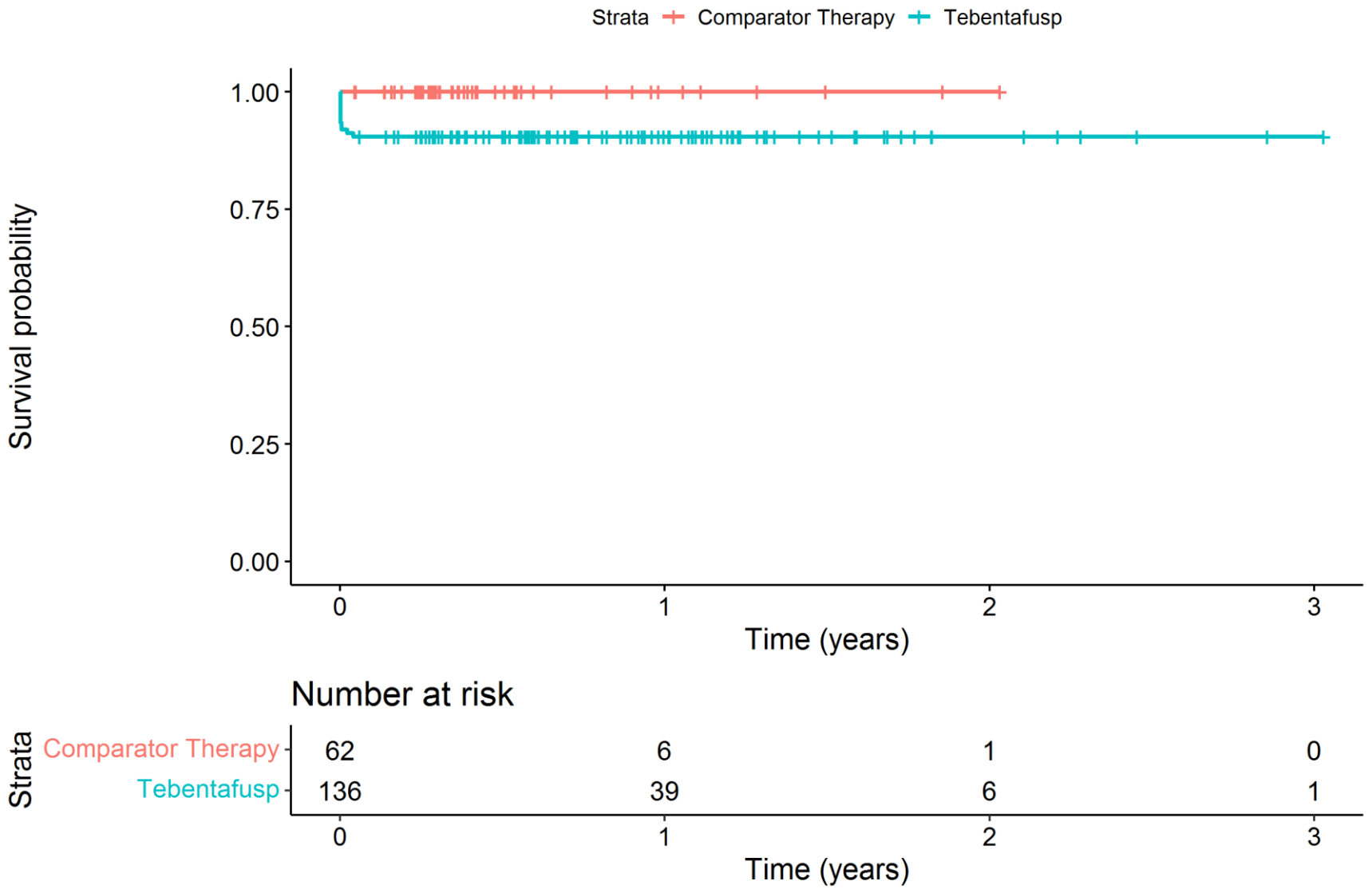
Zytokin-Freisetzungssyndrom- Vorherige Therapie adjuvant/neoadjuvant



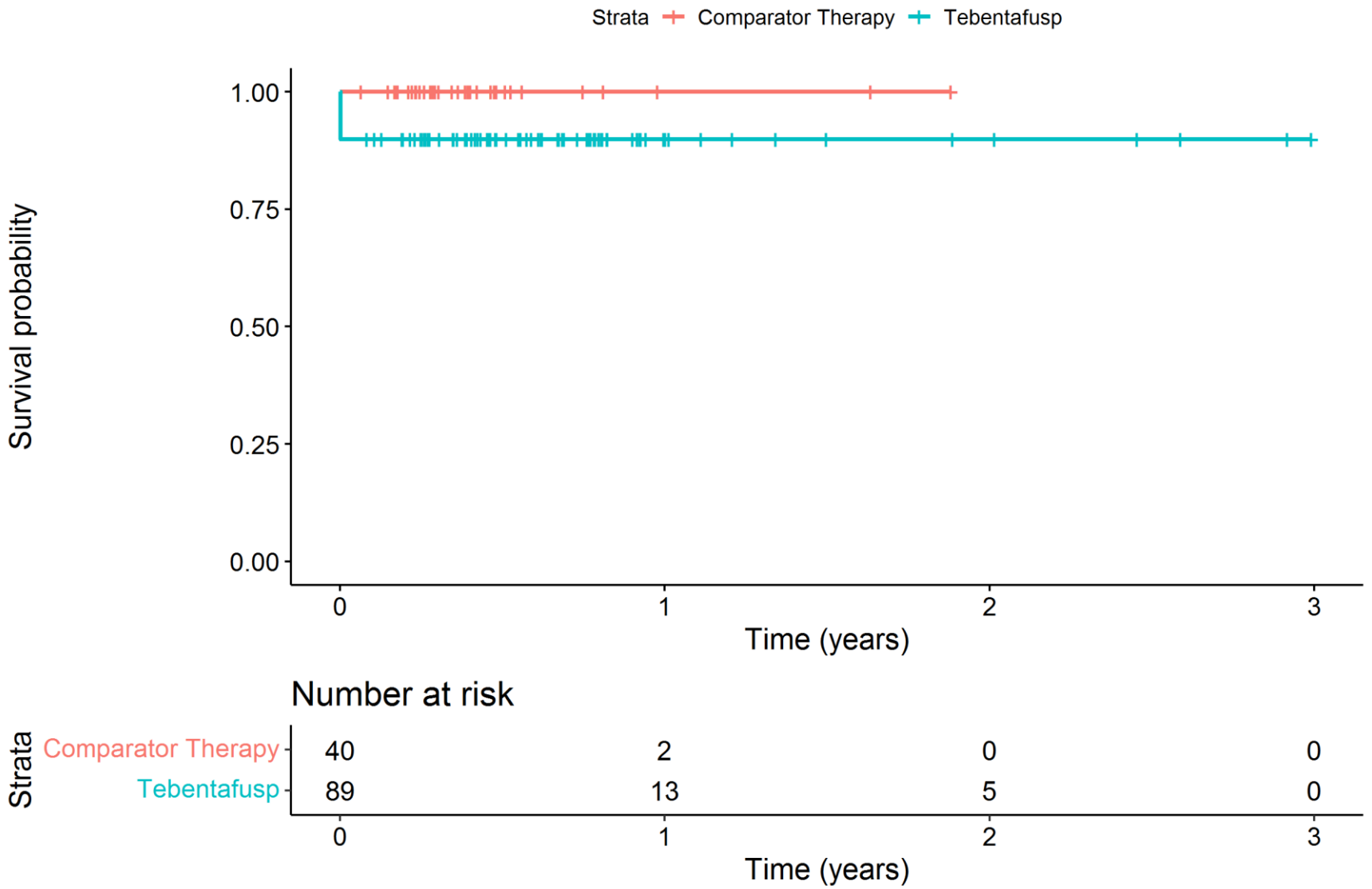
Zytokin-Freisetzungssyndrom- Keine vorherige Therapie adjuvant/neoadjuvant



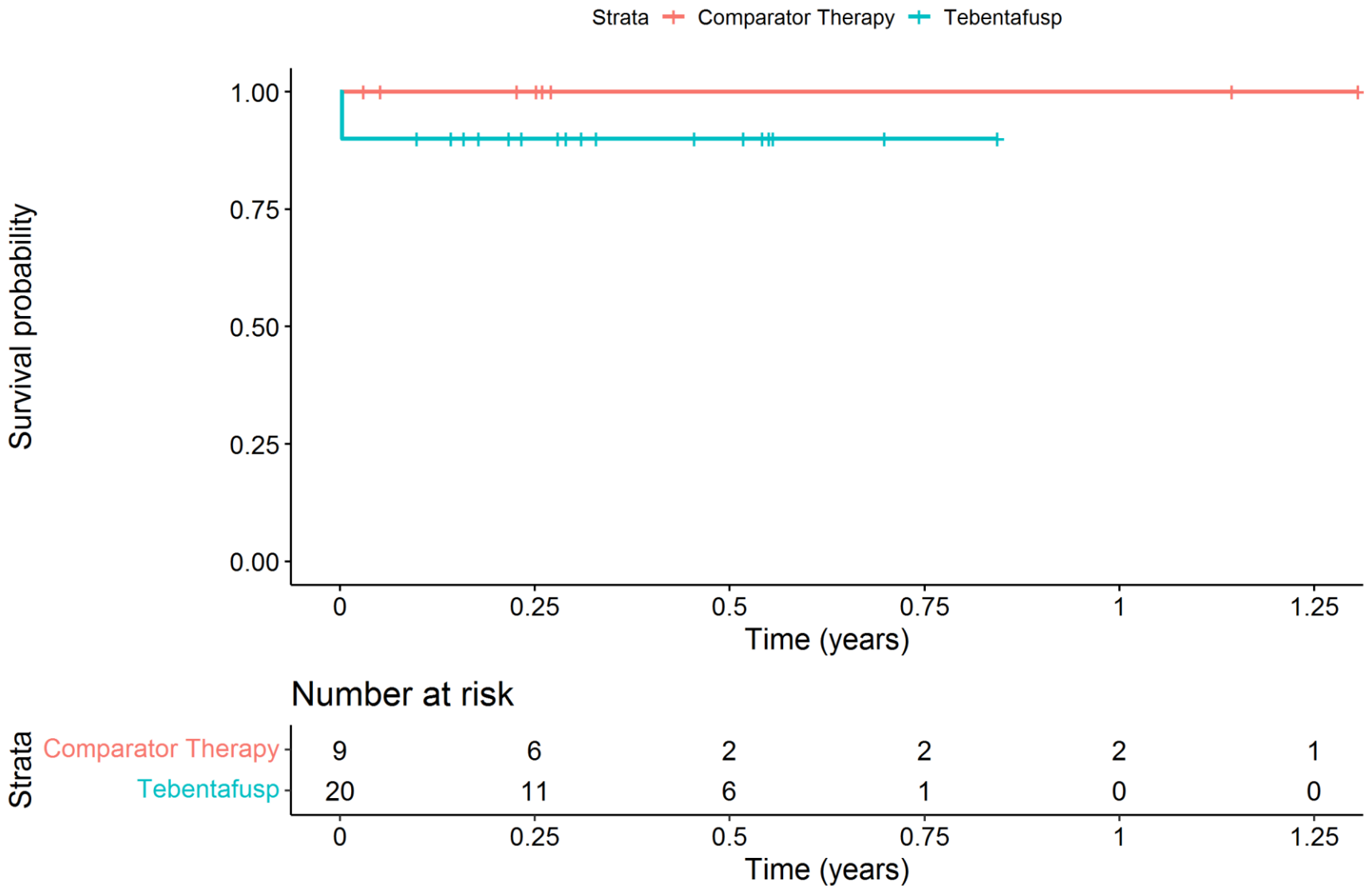
Zytokin-Freisetzungssyndrom- Läsion ≤ 3cm



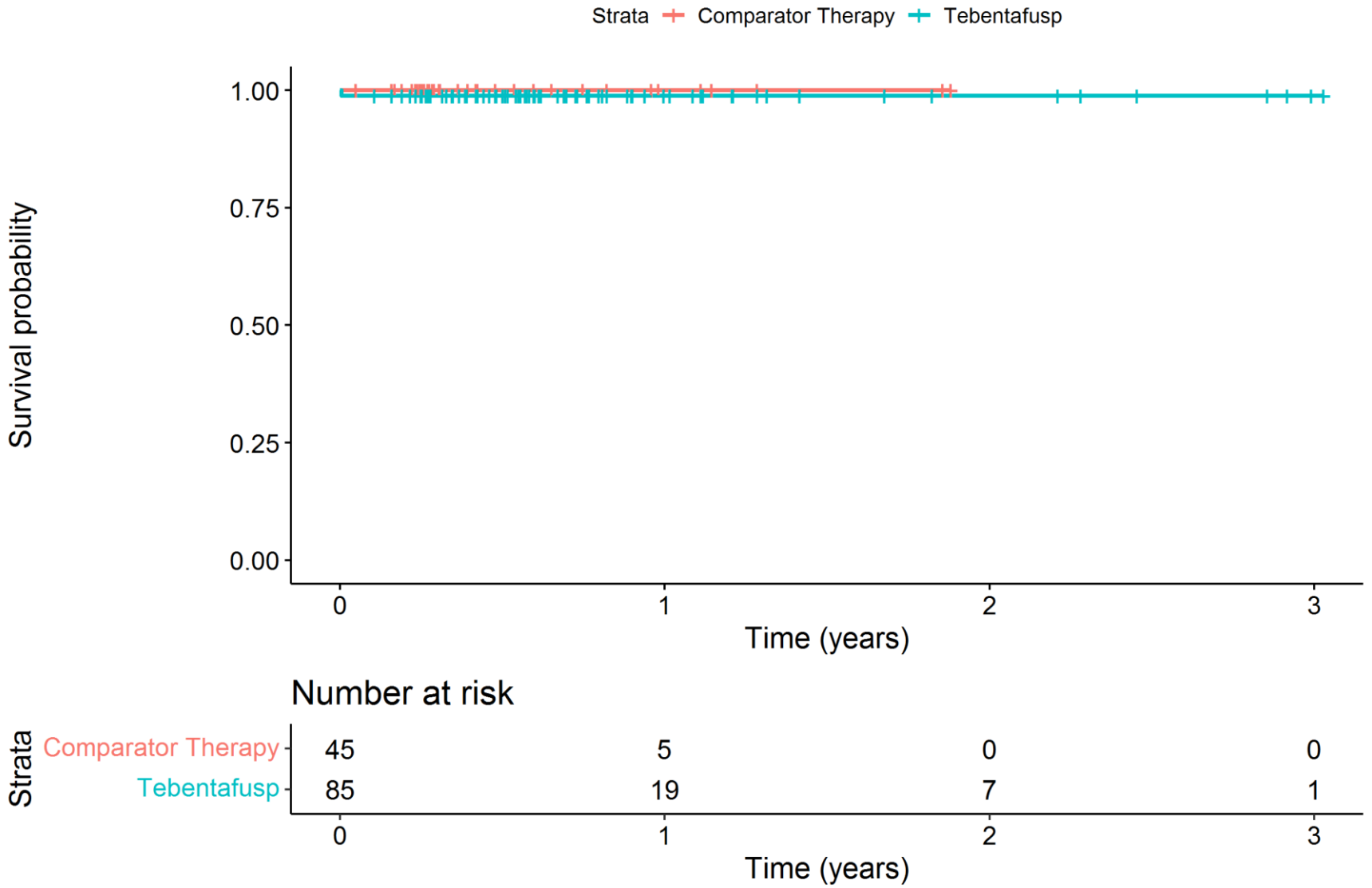
Zytokin-Freisetzungssyndrom- Läsion 3,1-8,0 cm



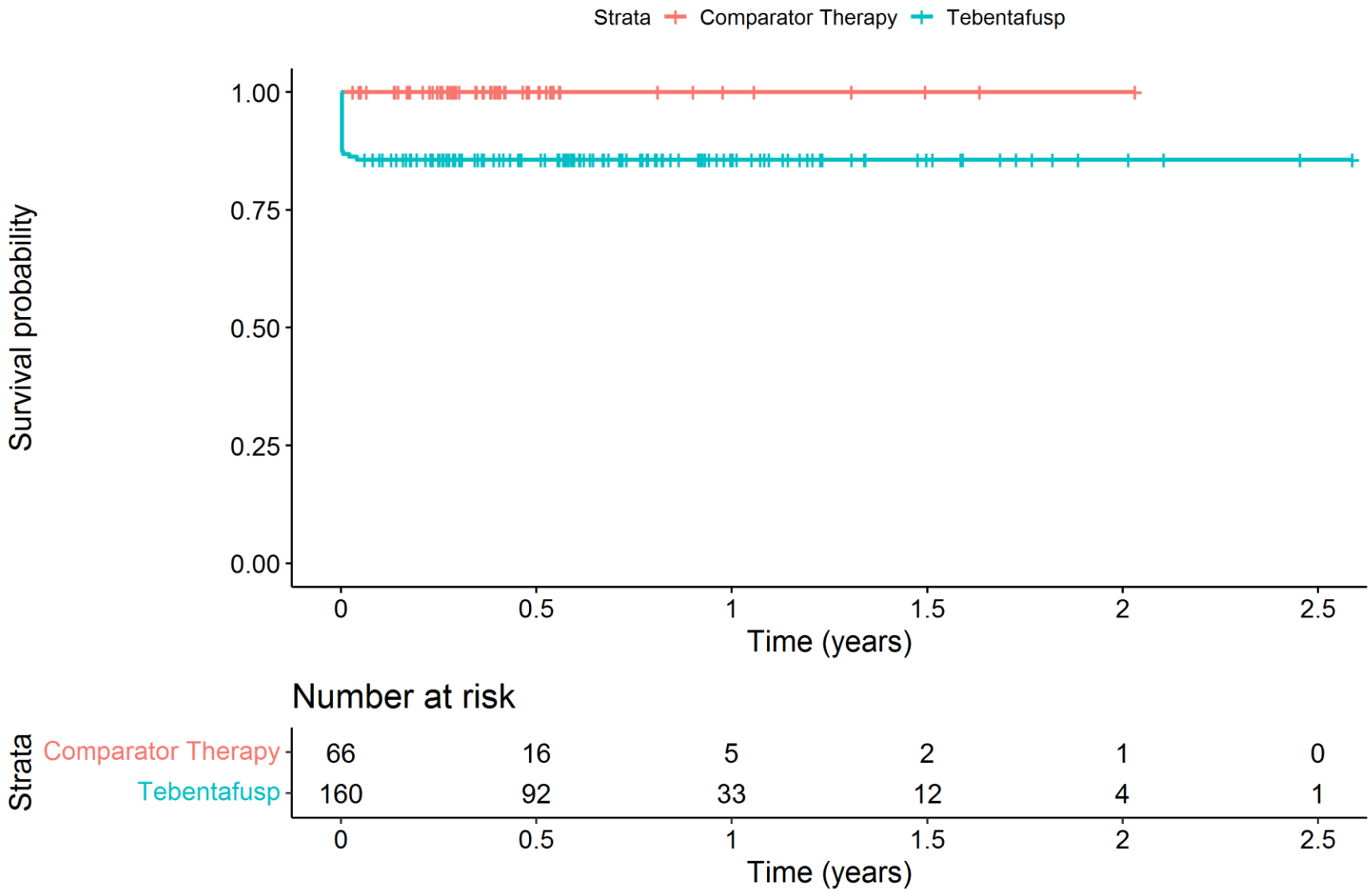
Zytokin-Freisetzungssyndrom- Läsion ≥8,1 cm



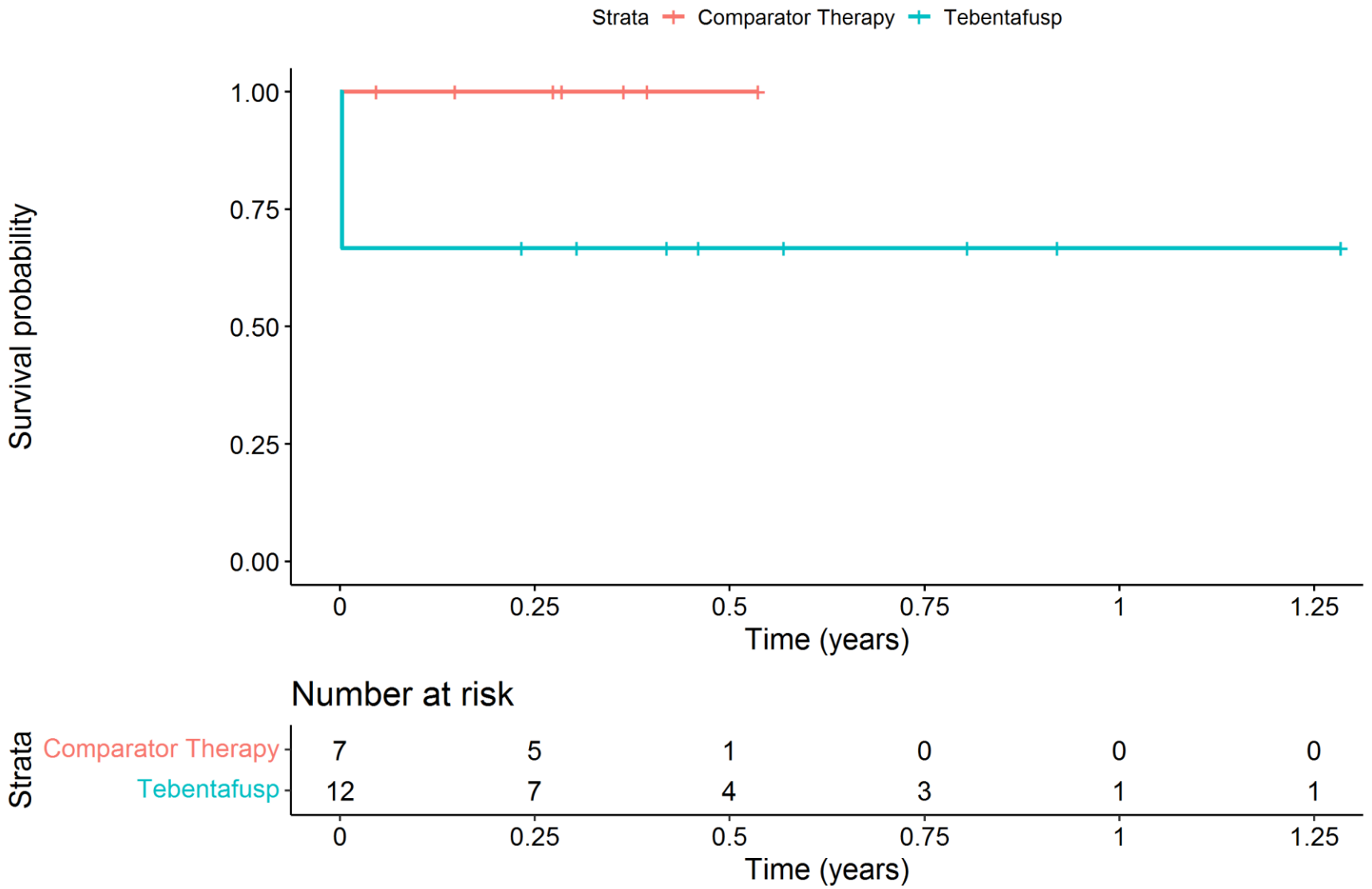
Zytokin-Freisetzungssyndrom- Nordamerika



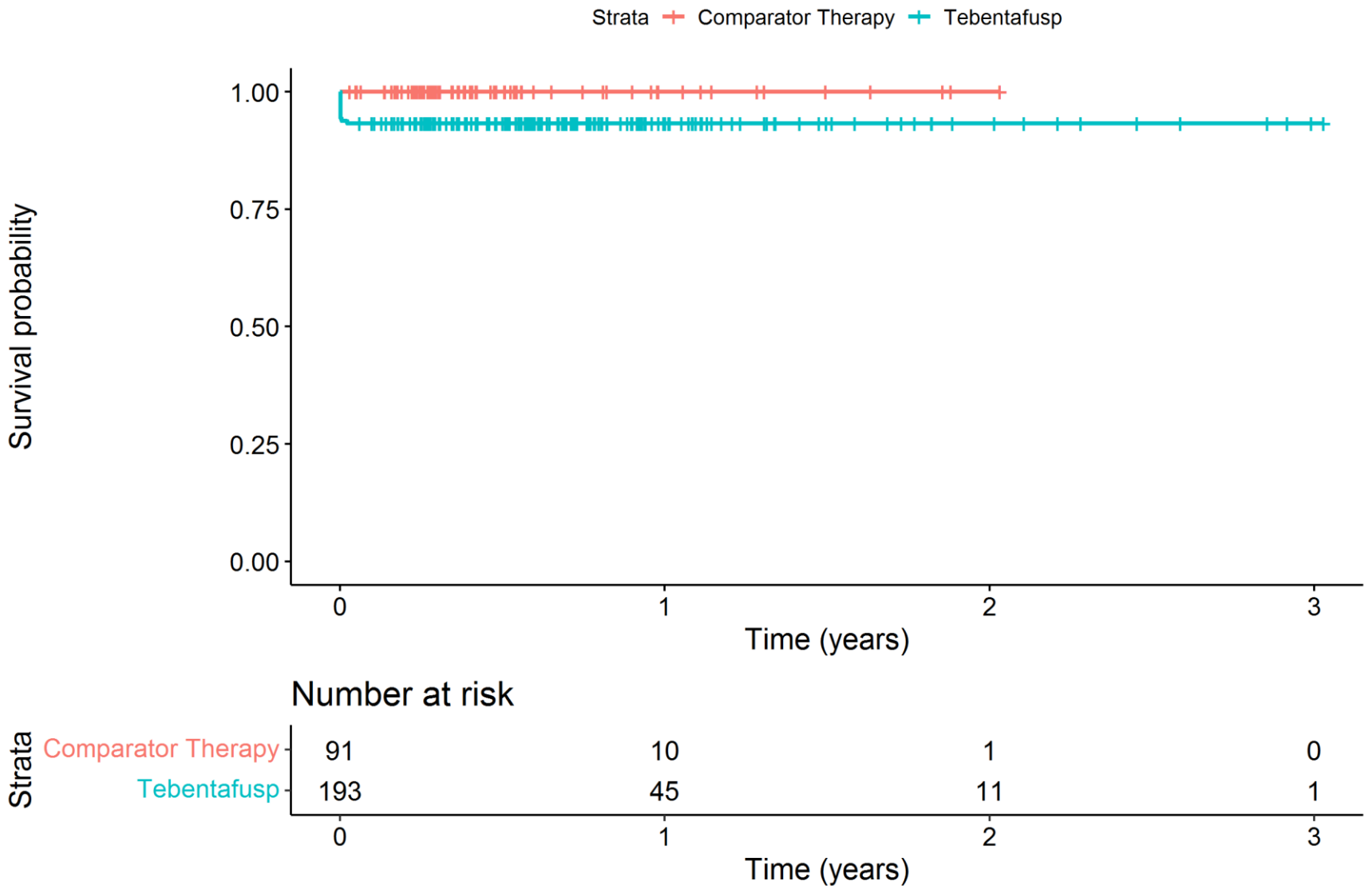
Zytokin-Freisetzungssyndrom- Nicht-Nordamerika



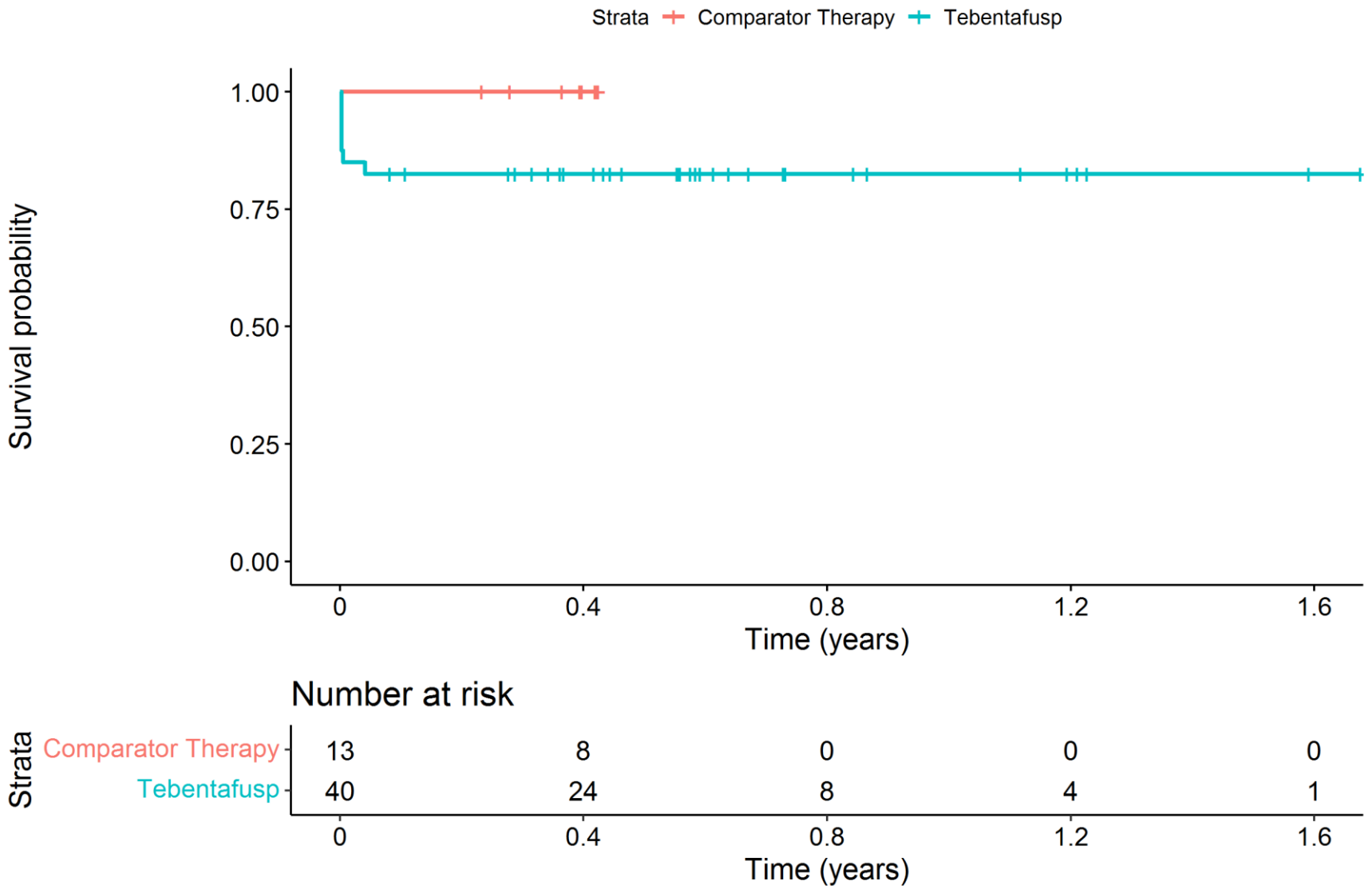
Zytokin-Freisetzungssyndrom- Dacarbazin



Zytokin-Freisetzungssyndrom- Pembrolizumab

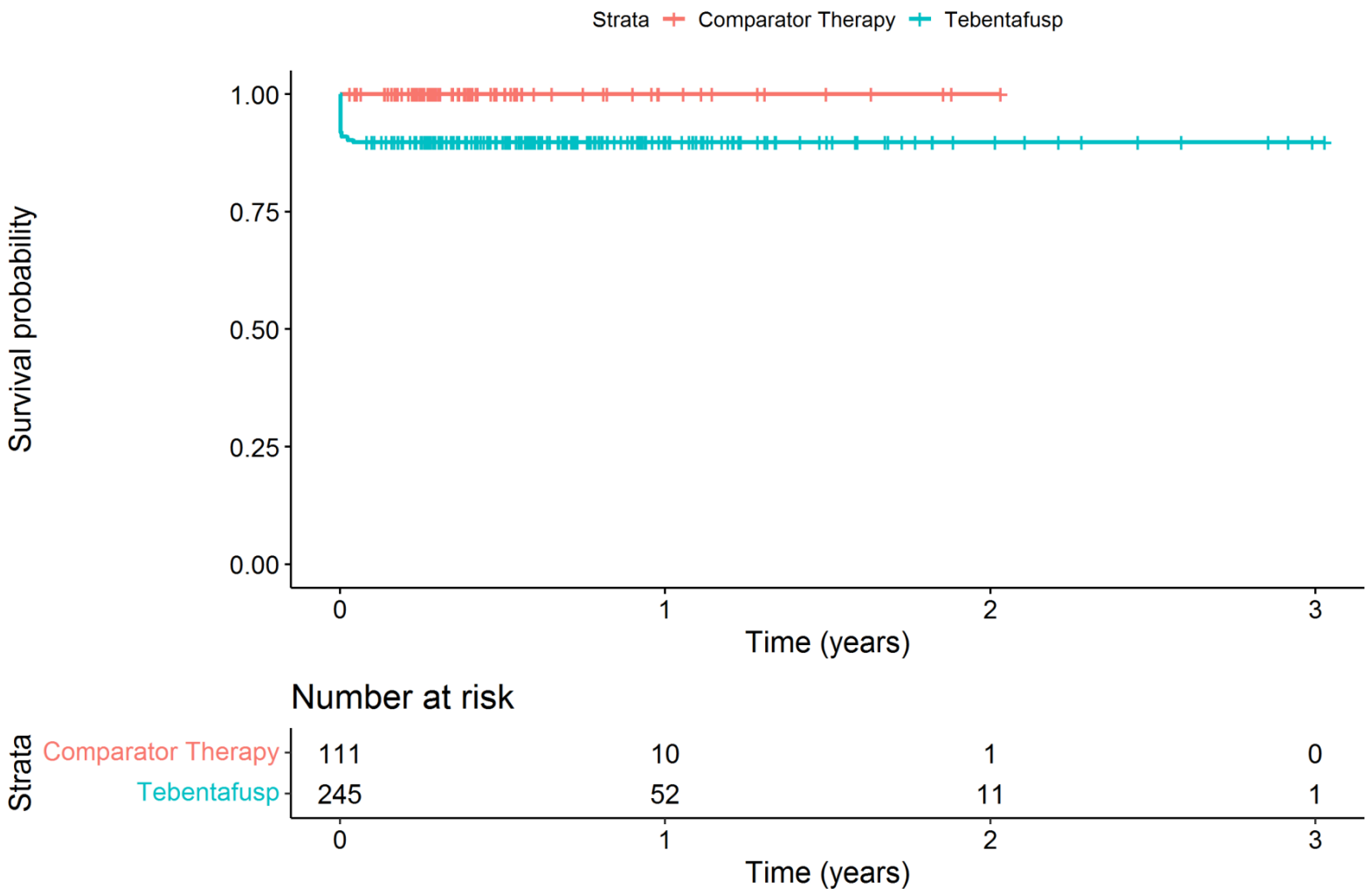


Zytokin-Freisetzungssyndrom- Ipilimumab

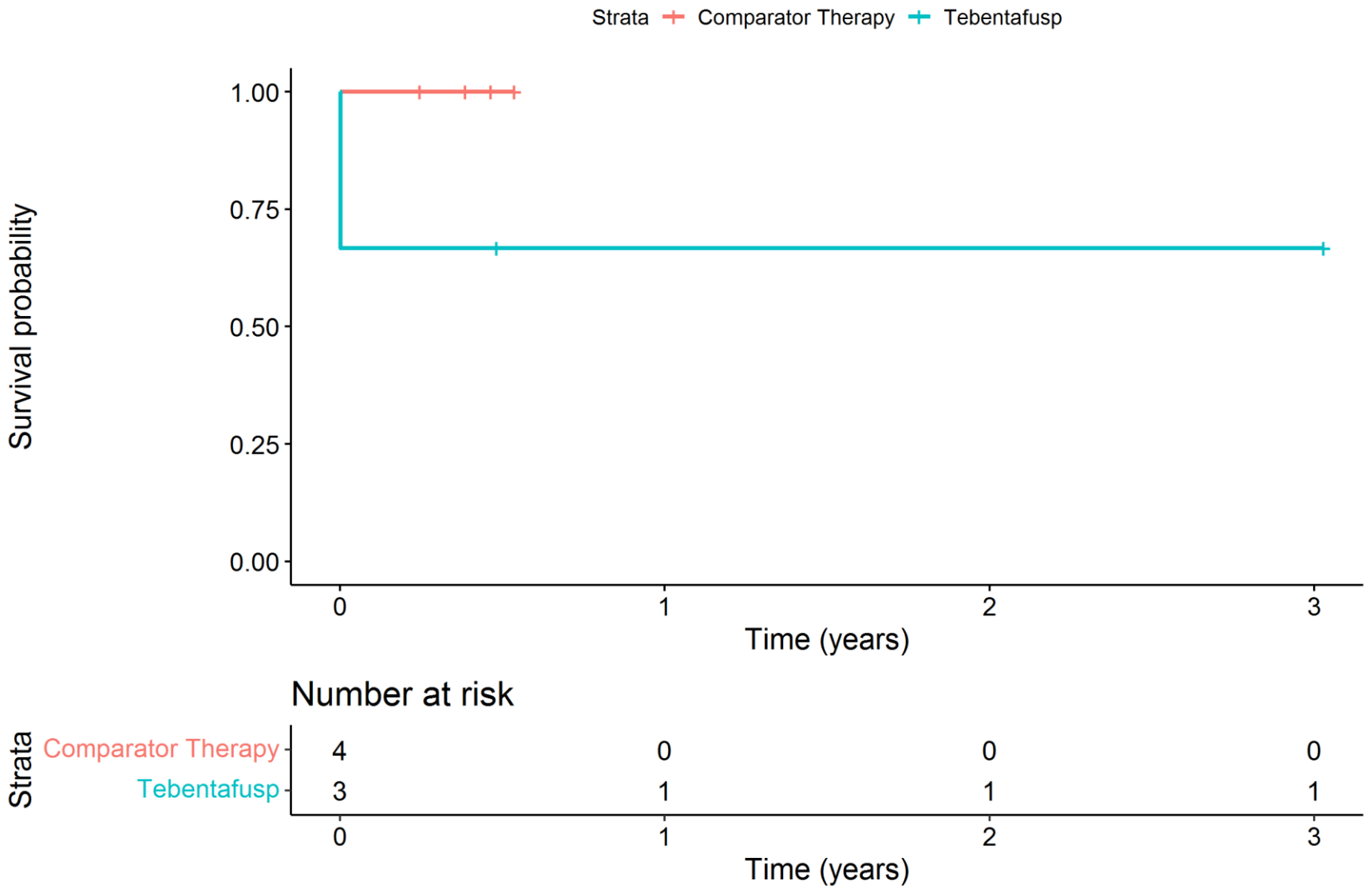


58 SUEs (SOC) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-206)

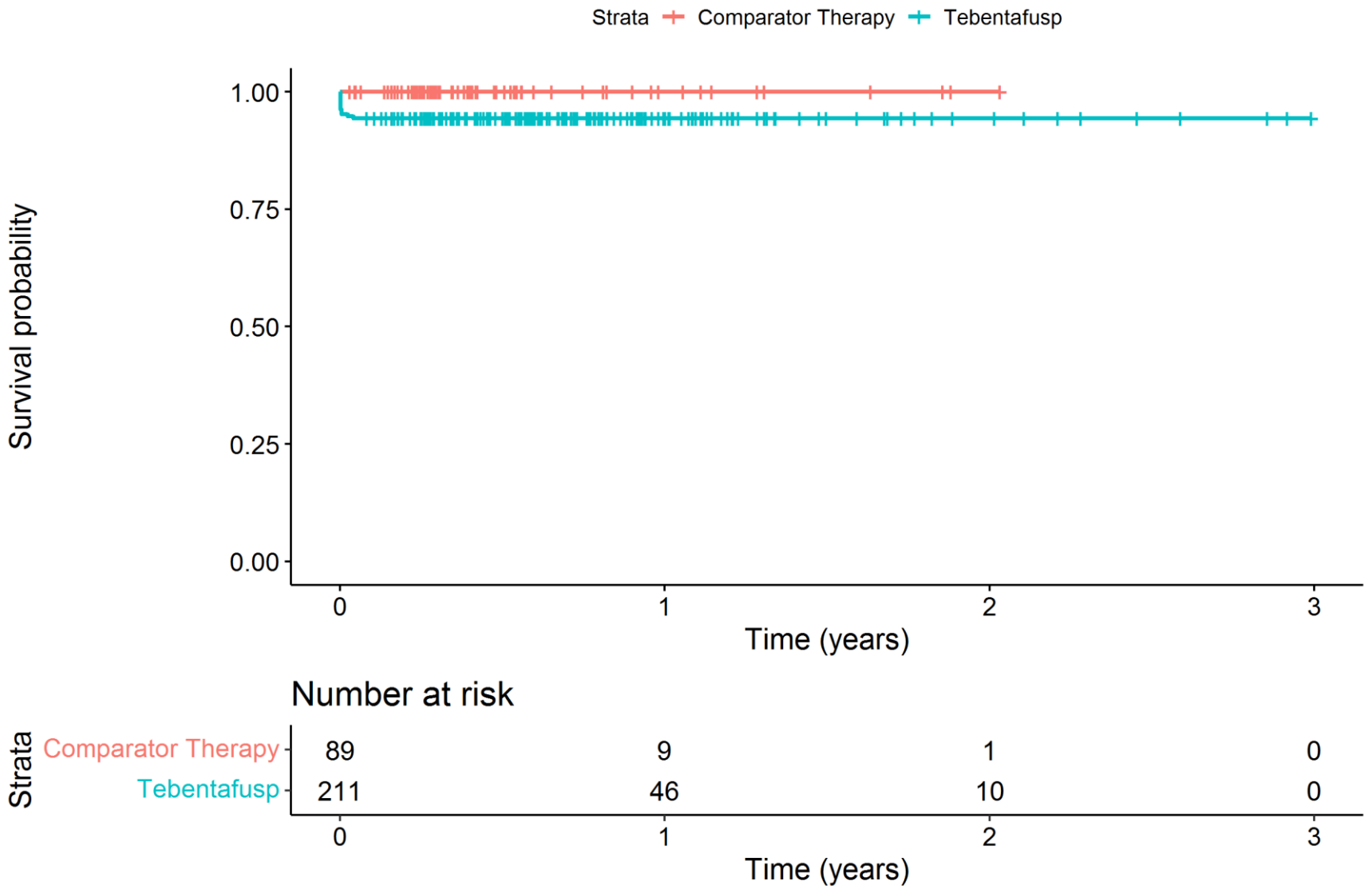
Erkrankungen des Immunsystems - Gesamt



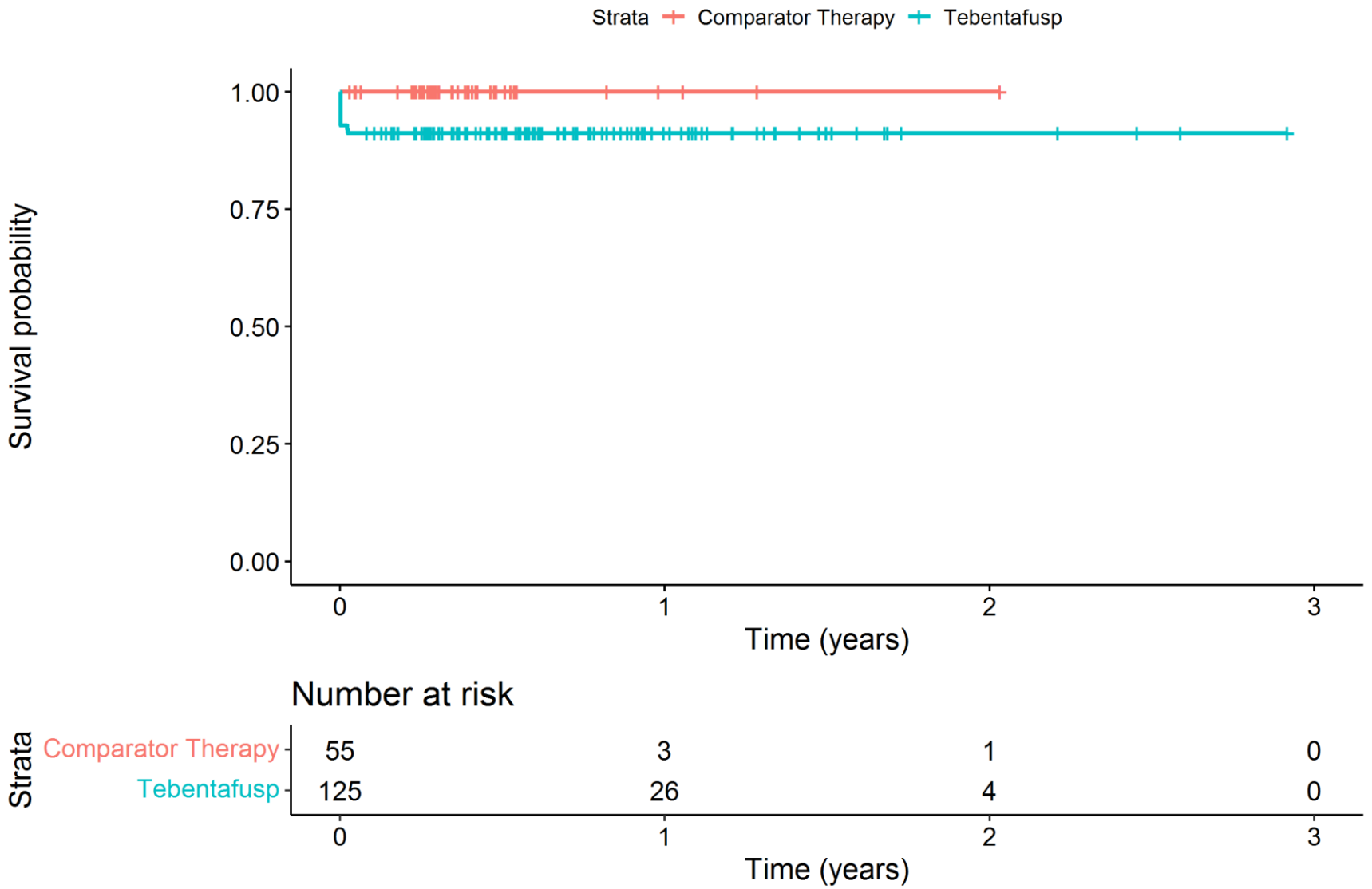
Erkrankungen des Immunsystems - Hispanisch



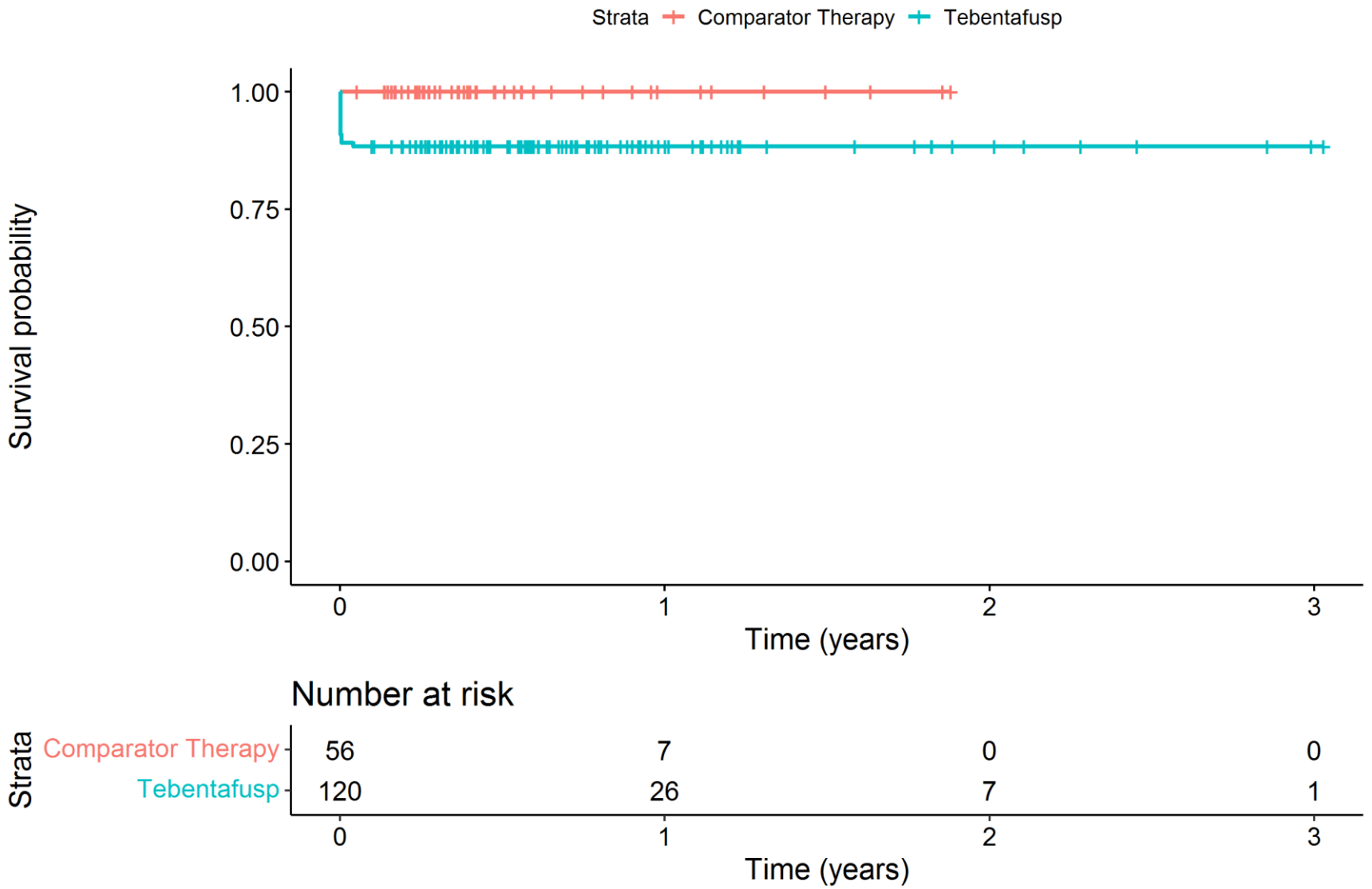
Erkrankungen des Immunsystems - Nicht-hispanisch



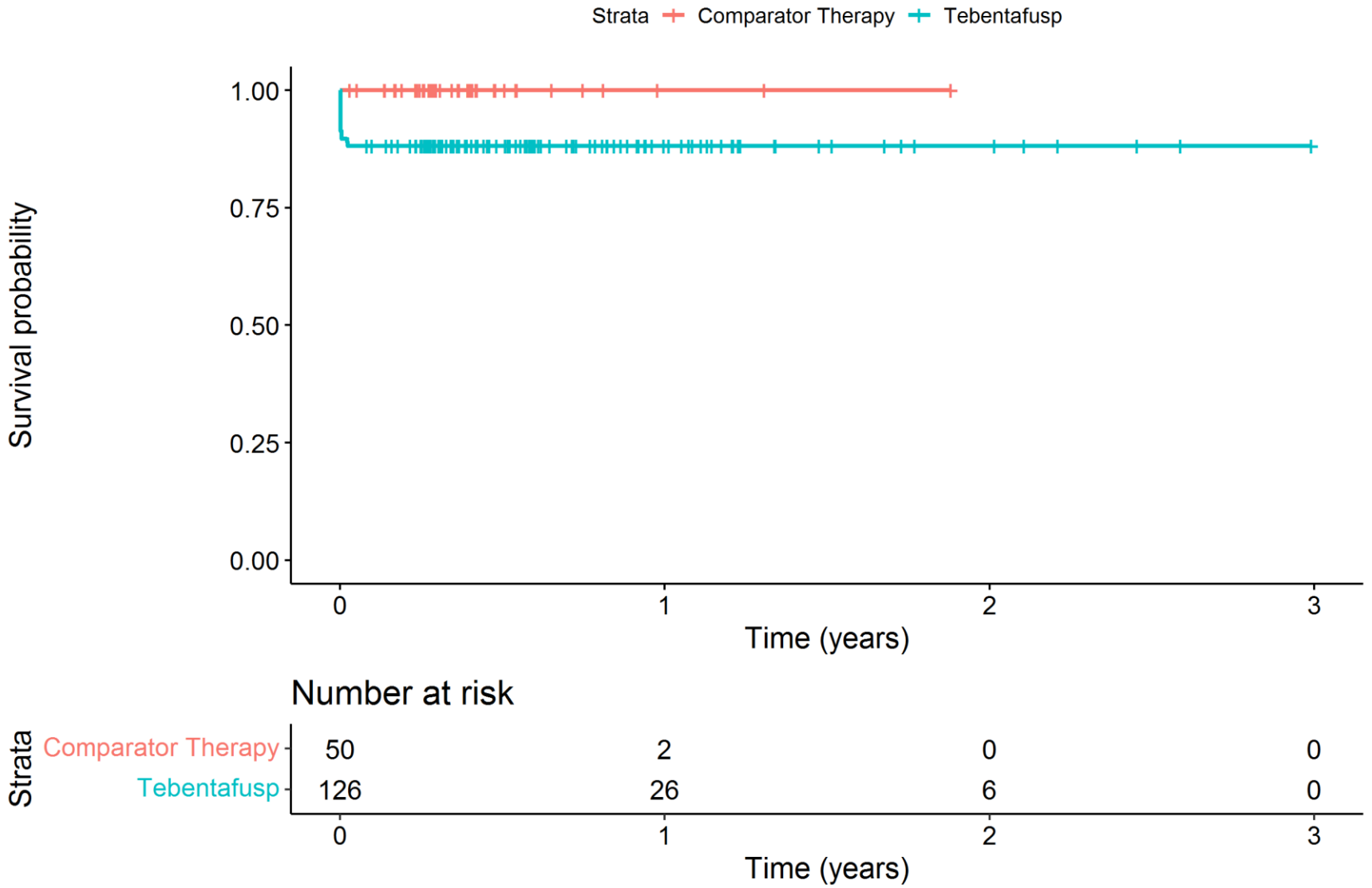
Erkrankungen des Immunsystems - Männlich



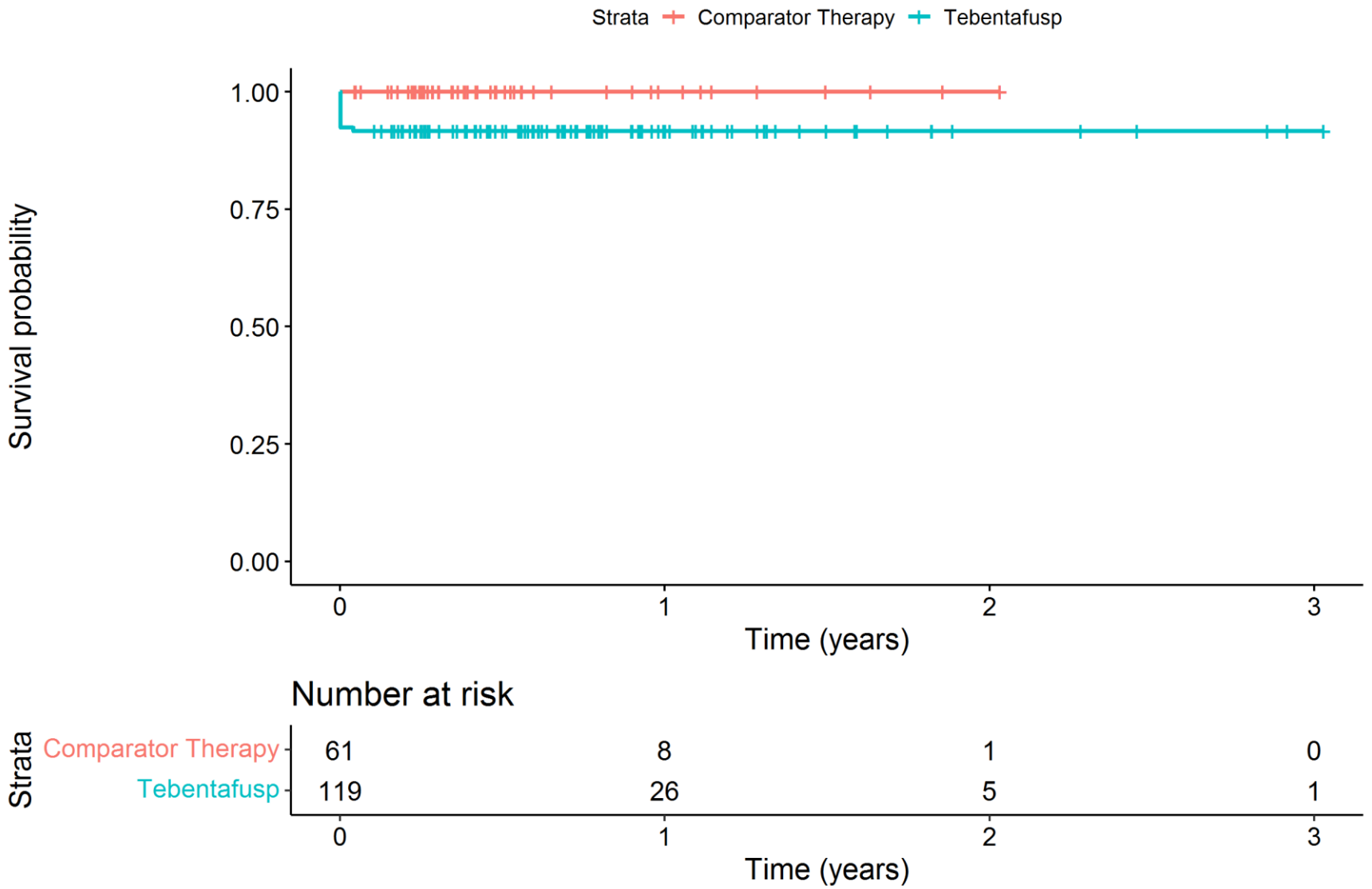
Erkrankungen des Immunsystems - Weiblich



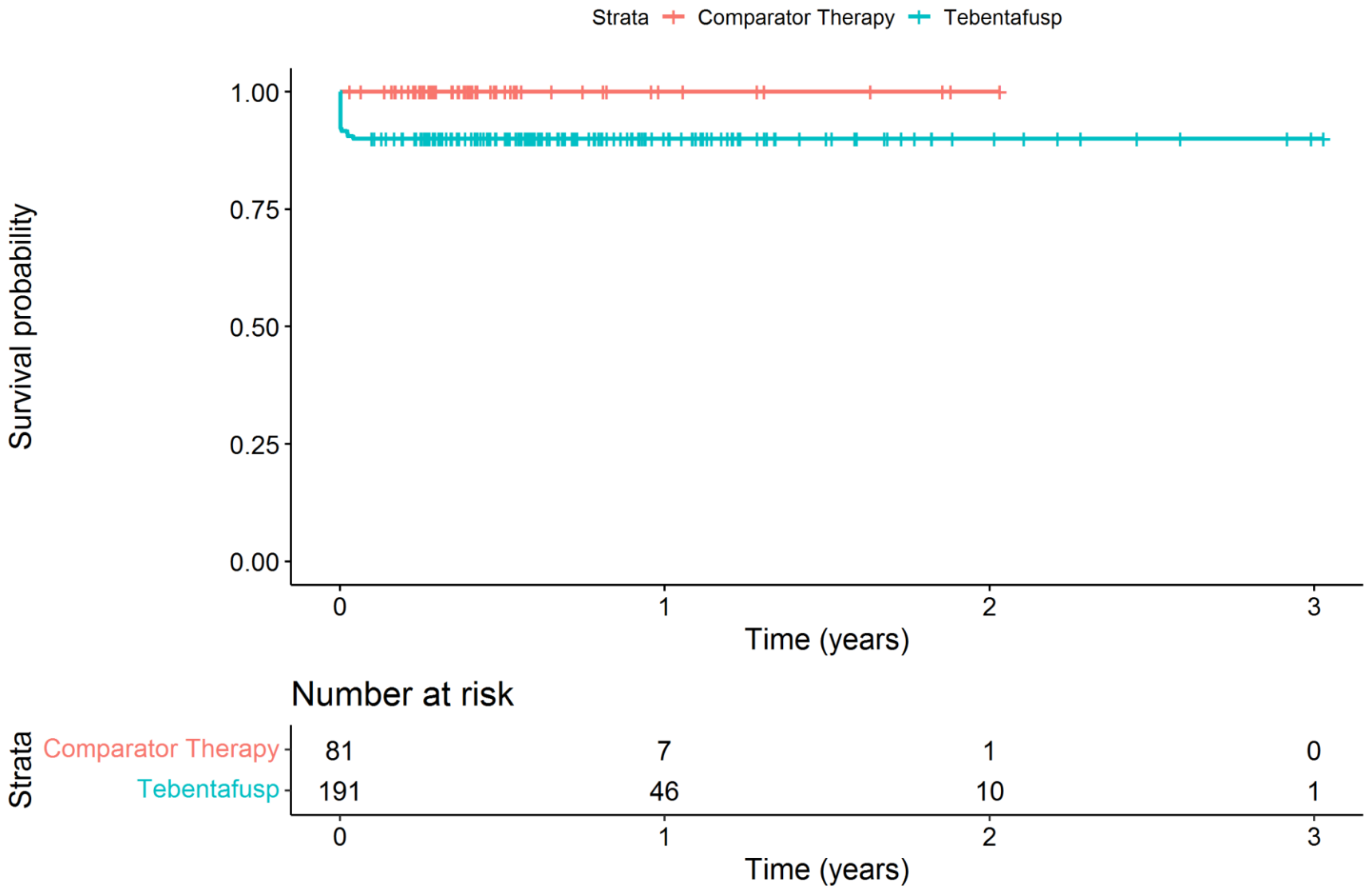
Erkrankungen des Immunsystems - <65



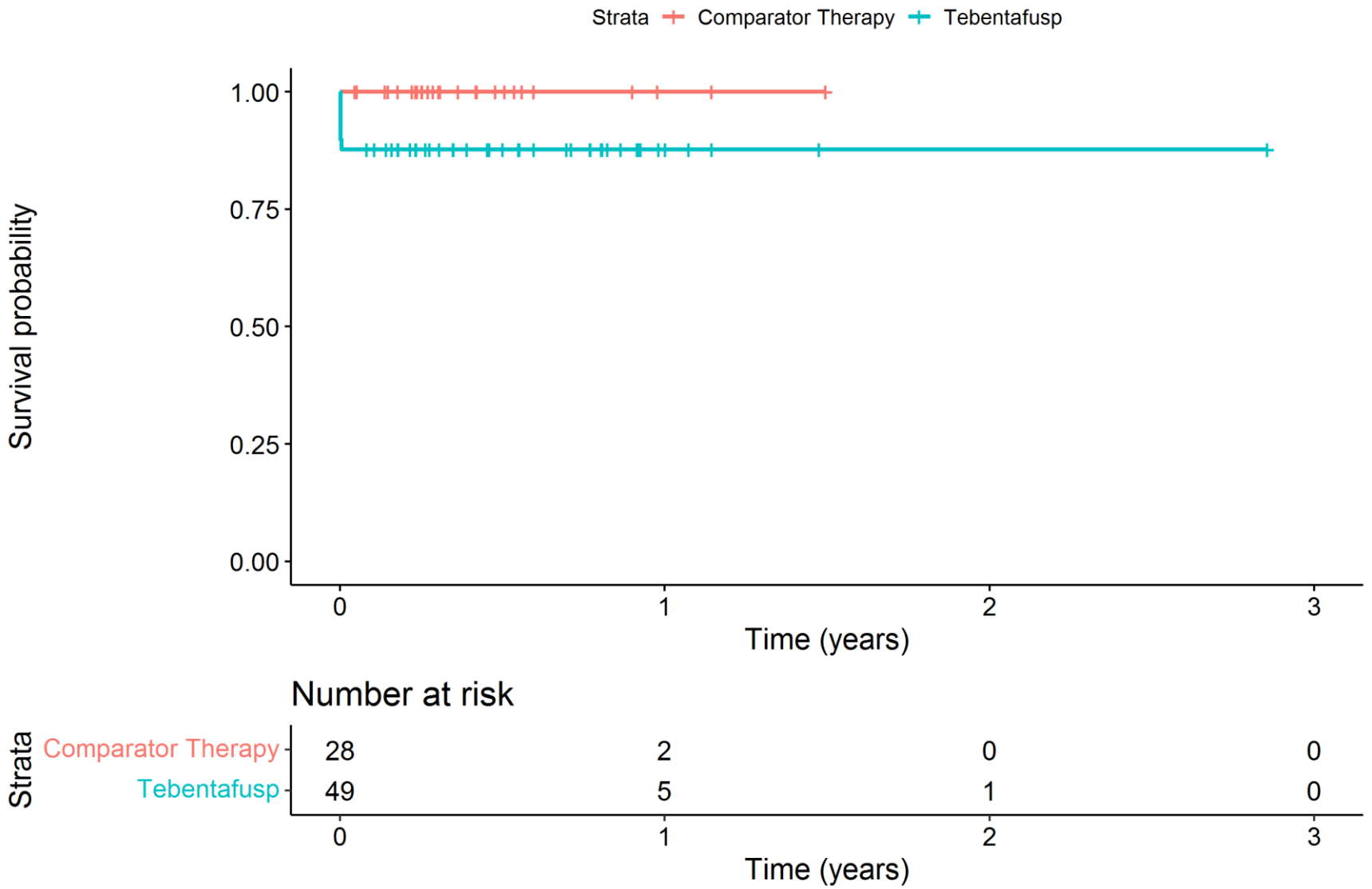
Erkrankungen des Immunsystems - ≥65



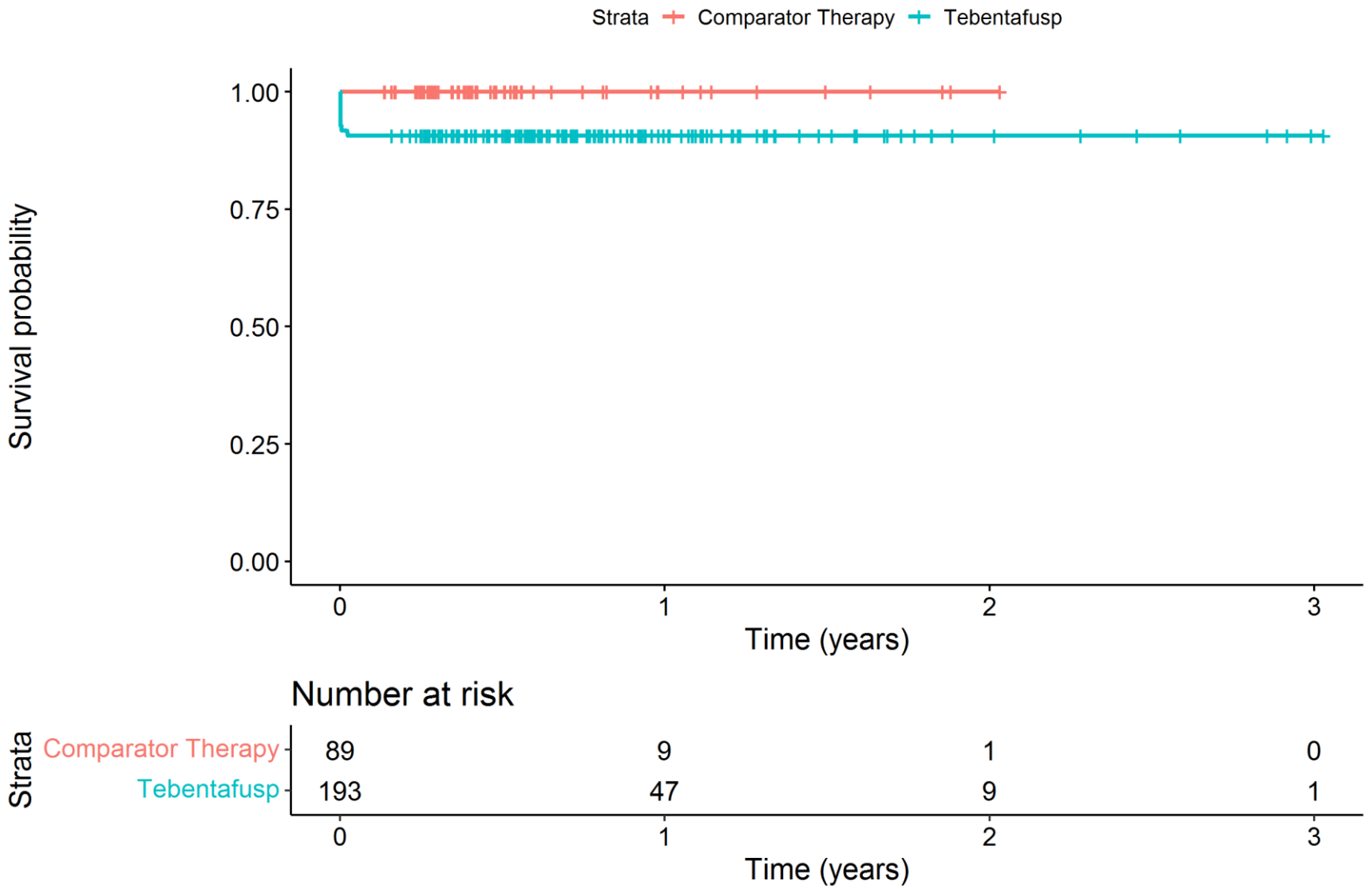
Erkrankungen des Immunsystems - ECOG 0



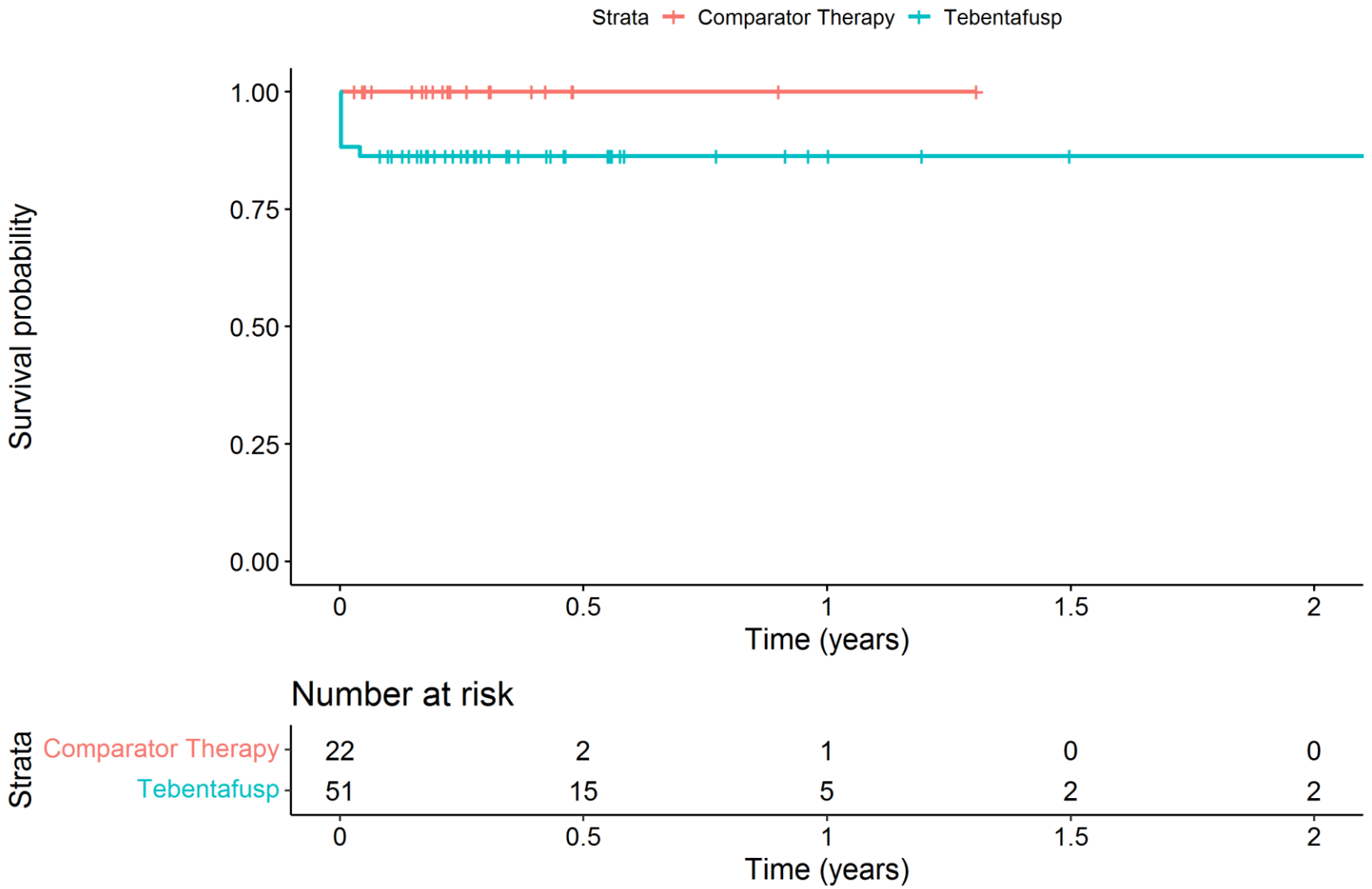
Erkrankungen des Immunsystems - ECOG 1



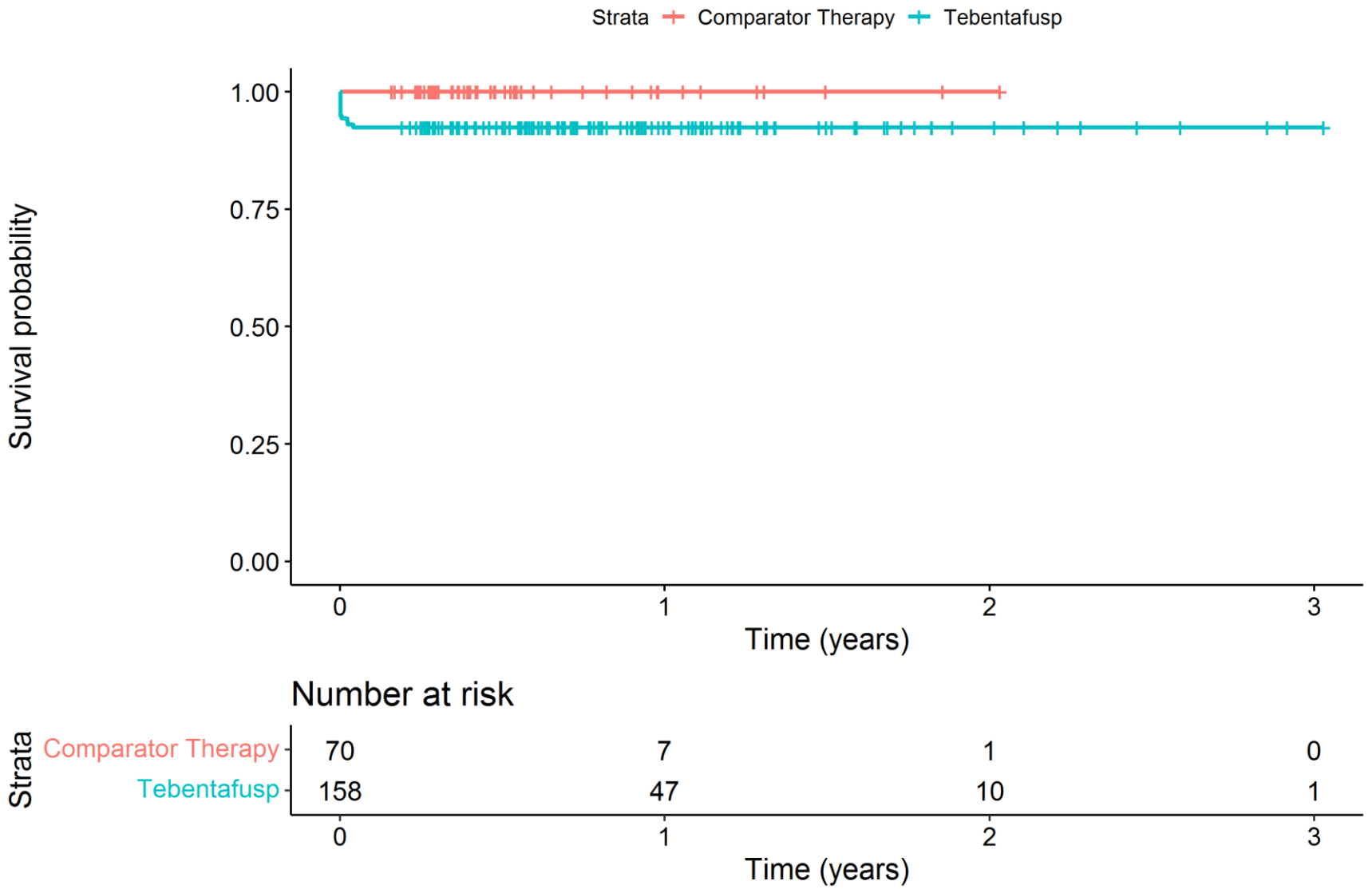
Erkrankungen des Immunsystems - ALP ≤ ULN



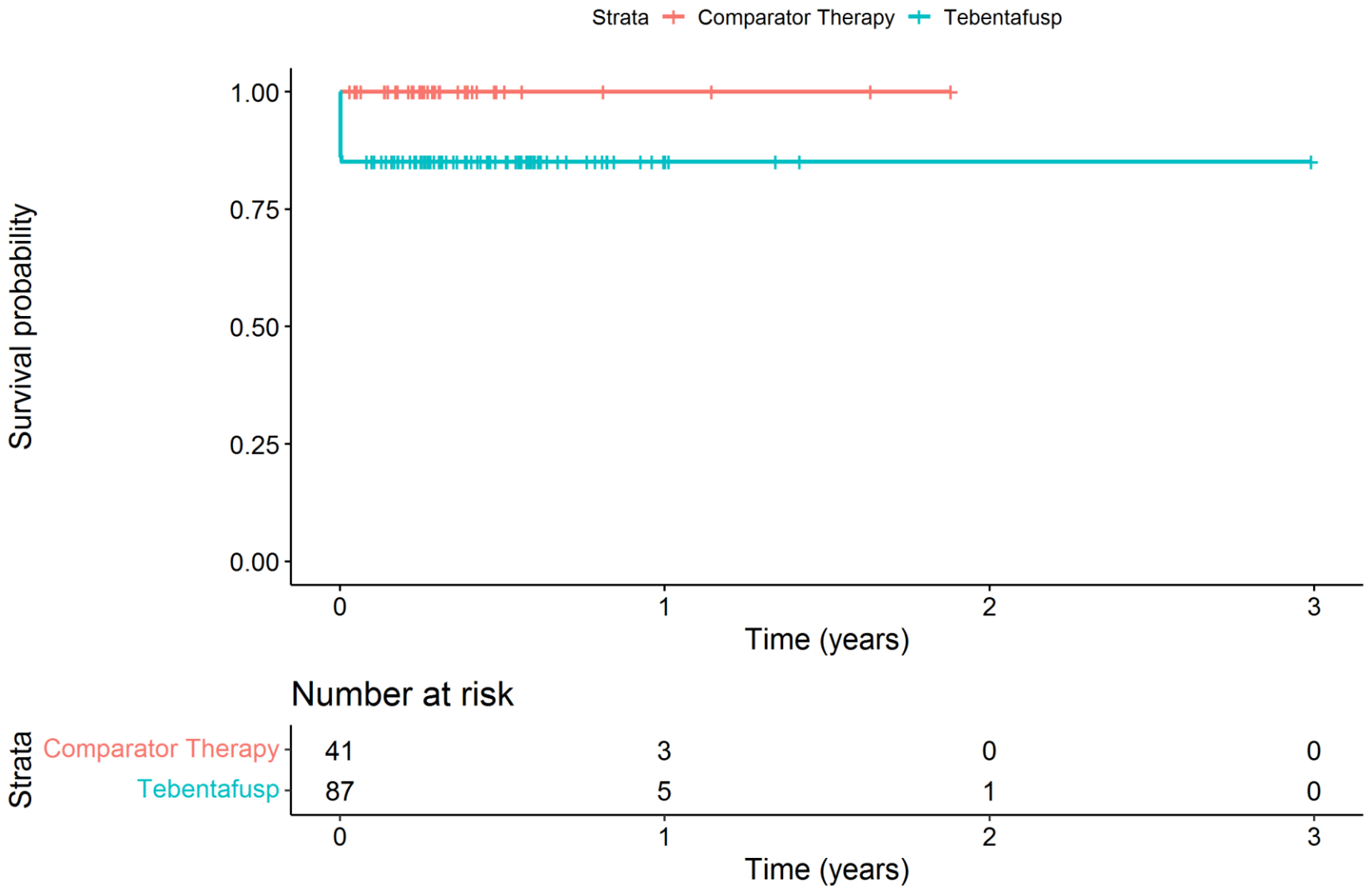
Erkrankungen des Immunsystems - ALP > ULN



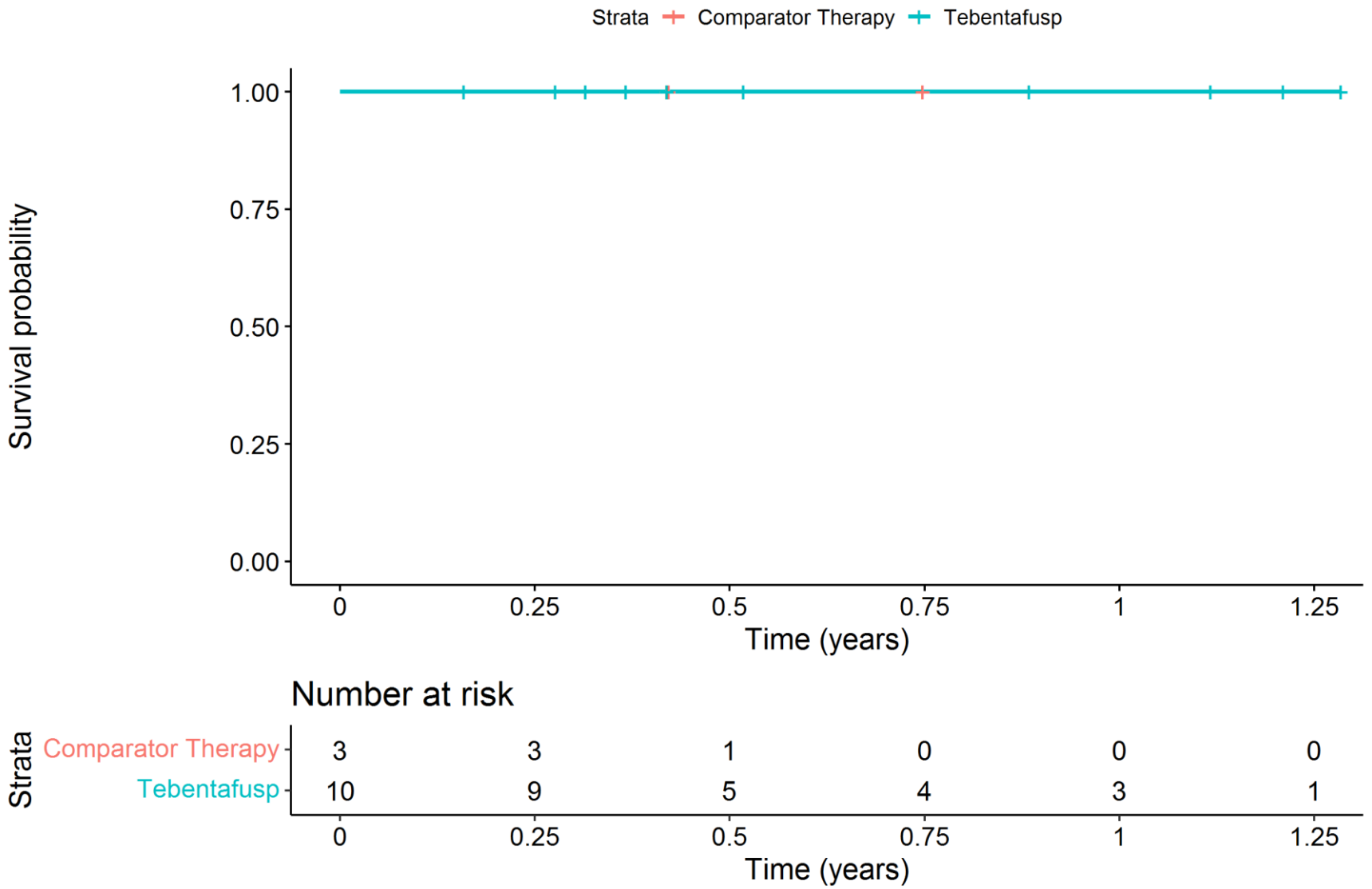
Erkrankungen des Immunsystems - LDH =< ULN



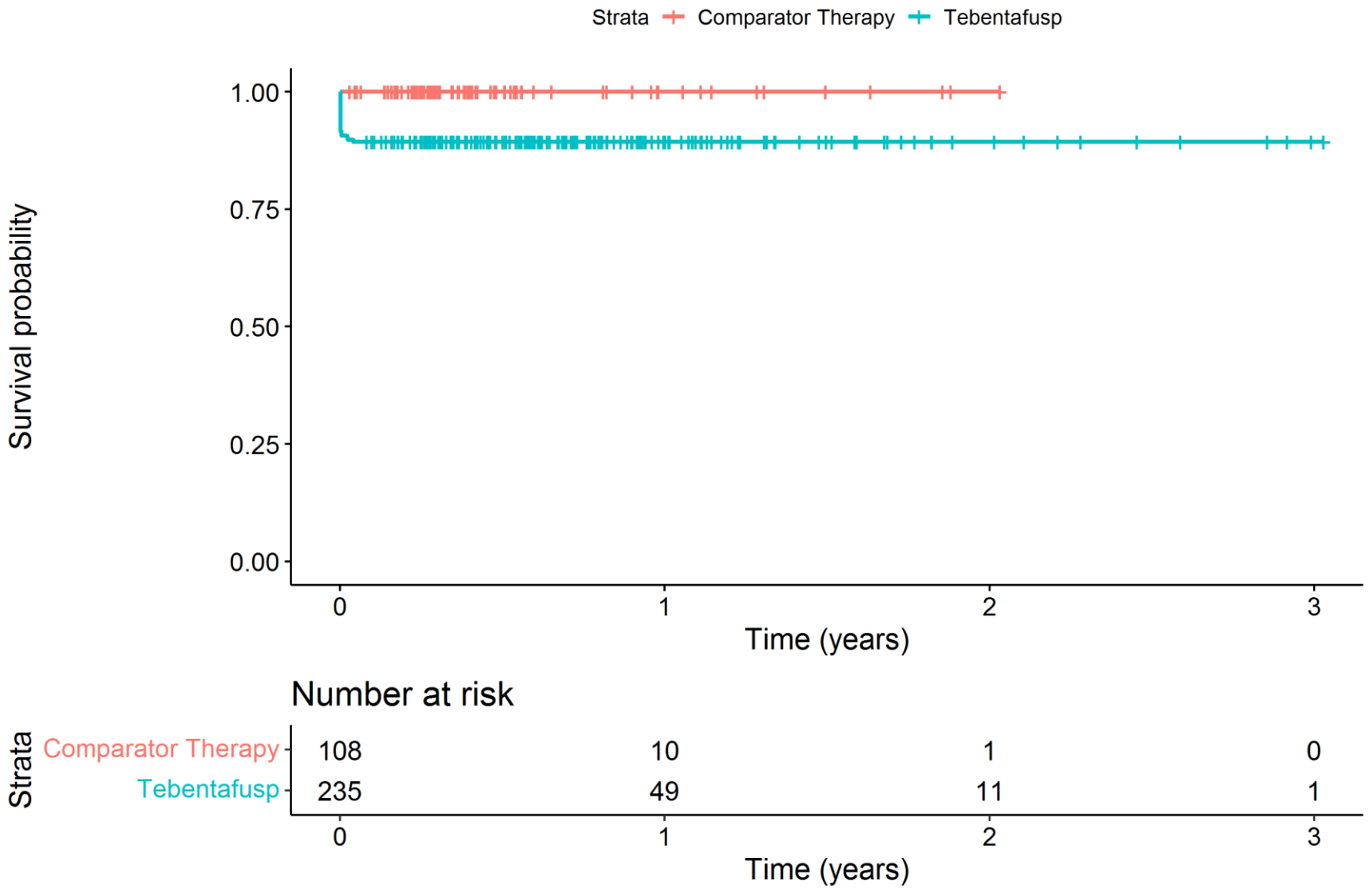
Erkrankungen des Immunsystems - LDH > ULN



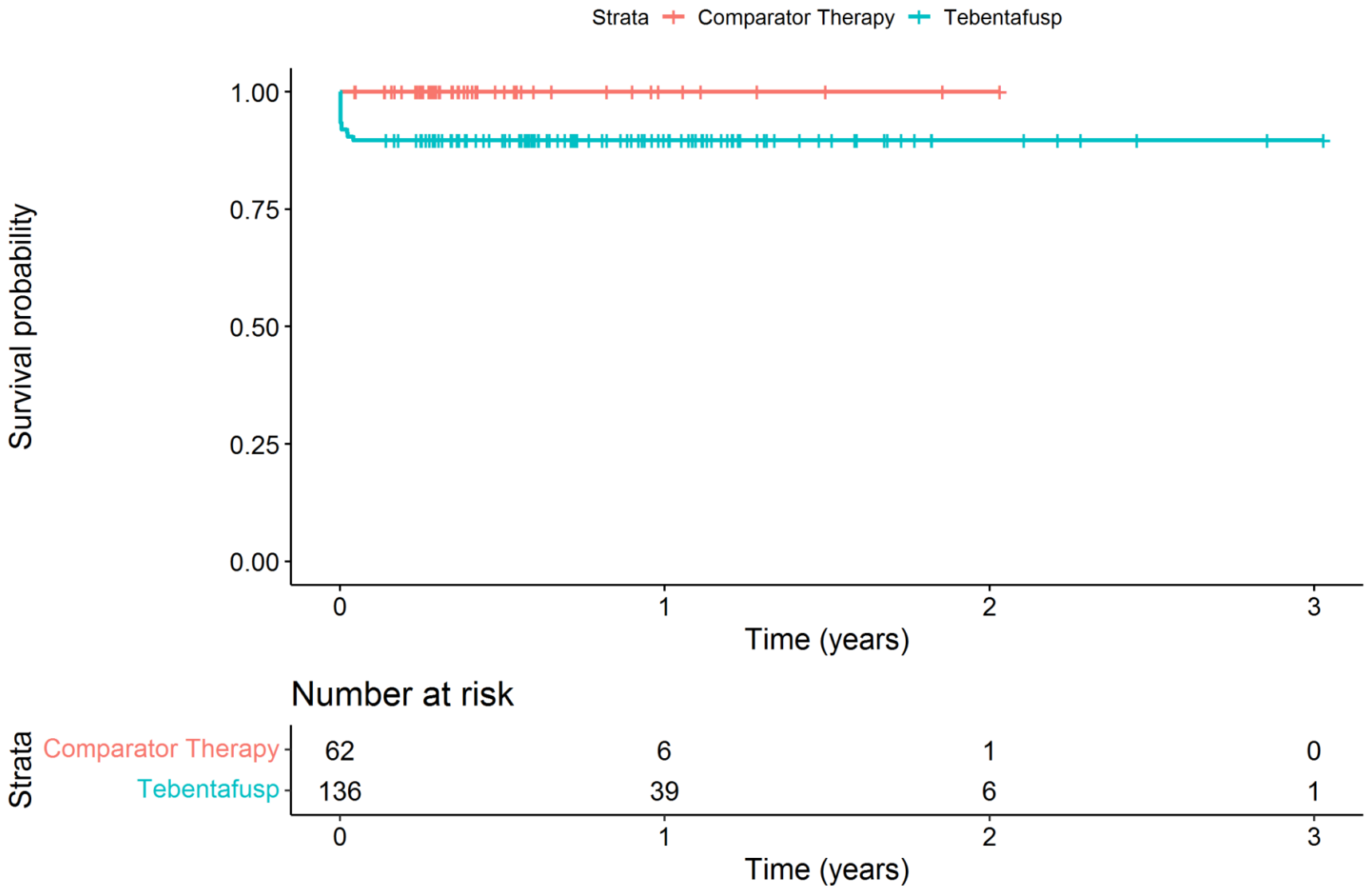
Erkrankungen des Immunsystems - Vorherige Therapie adjuvant/neoadjuvant



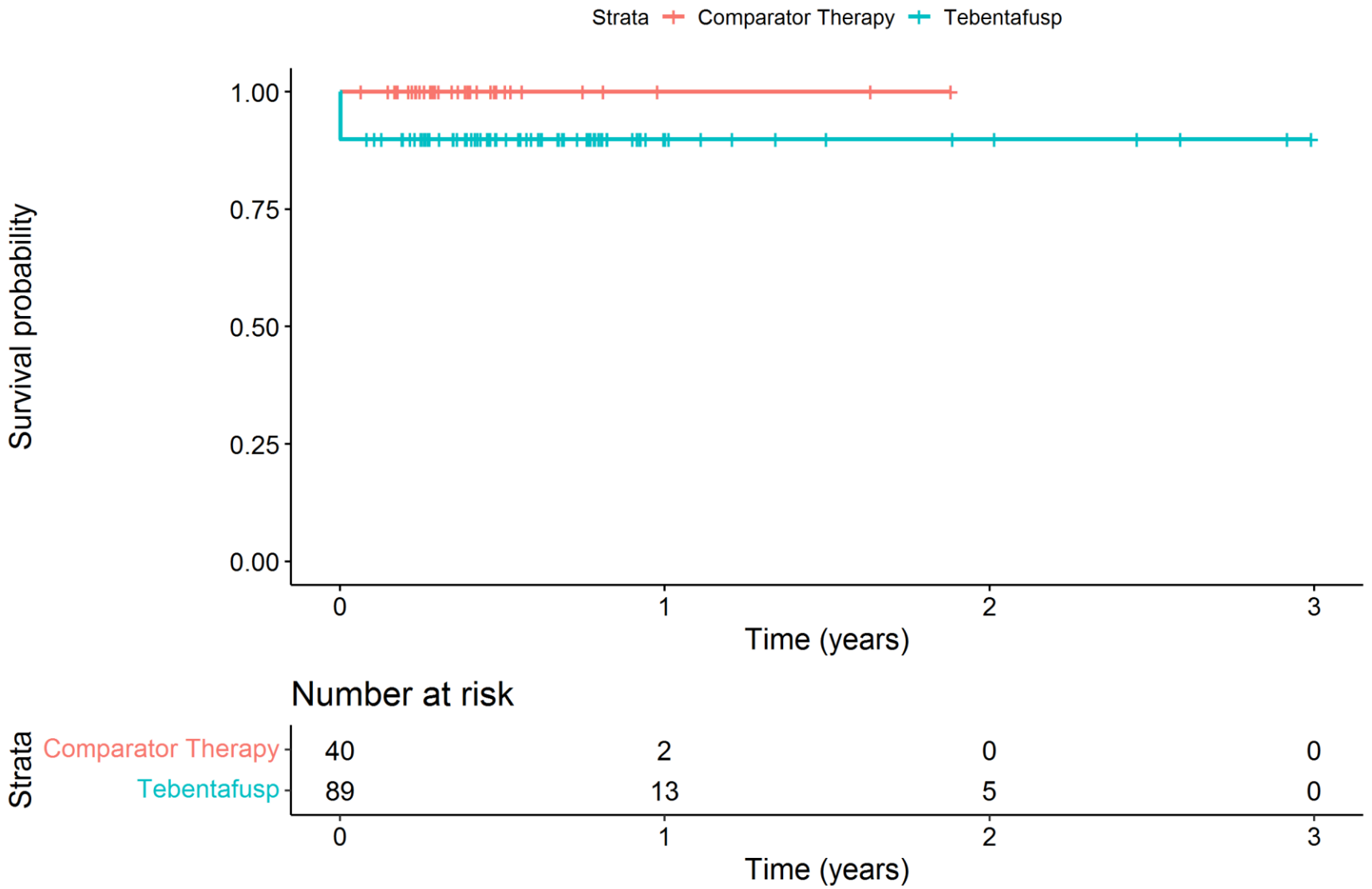
Erkrankungen des Immunsystems - Keine vorherige Therapie adjuvant/neoadjuvant



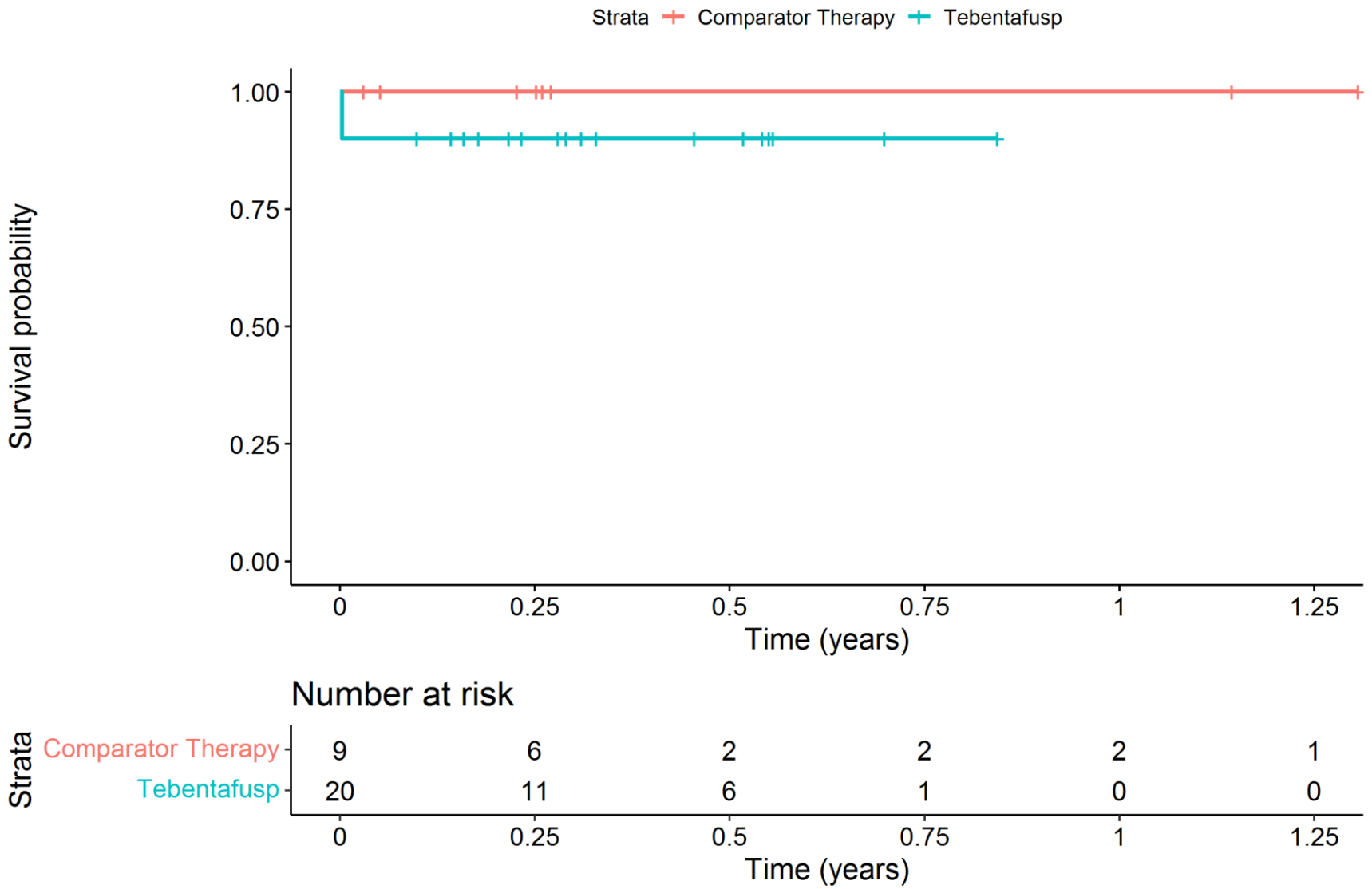
Erkrankungen des Immunsystems - Läsion ≤ 3cm



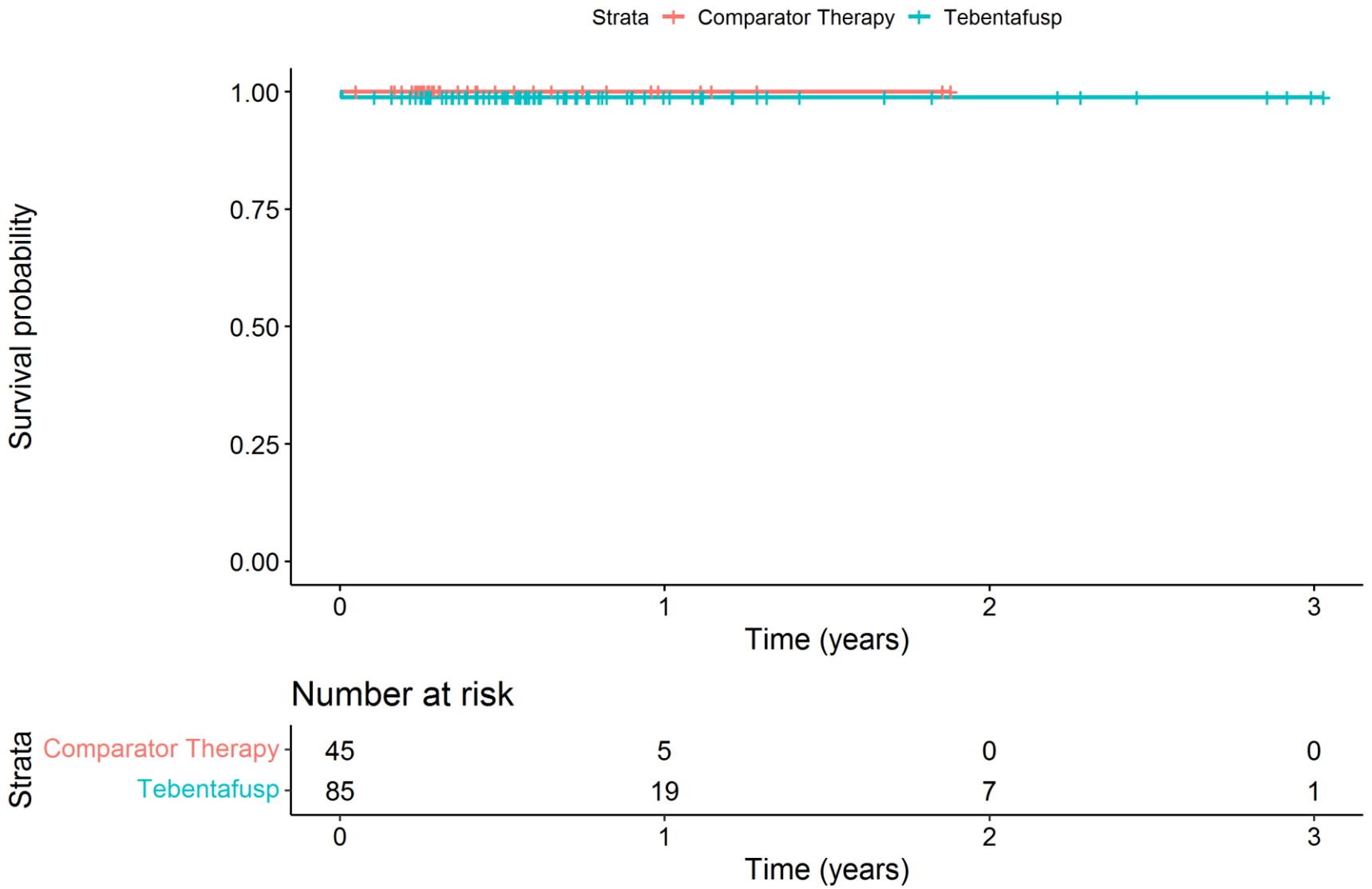
Erkrankungen des Immunsystems - Läsion 3,1-8,0 cm



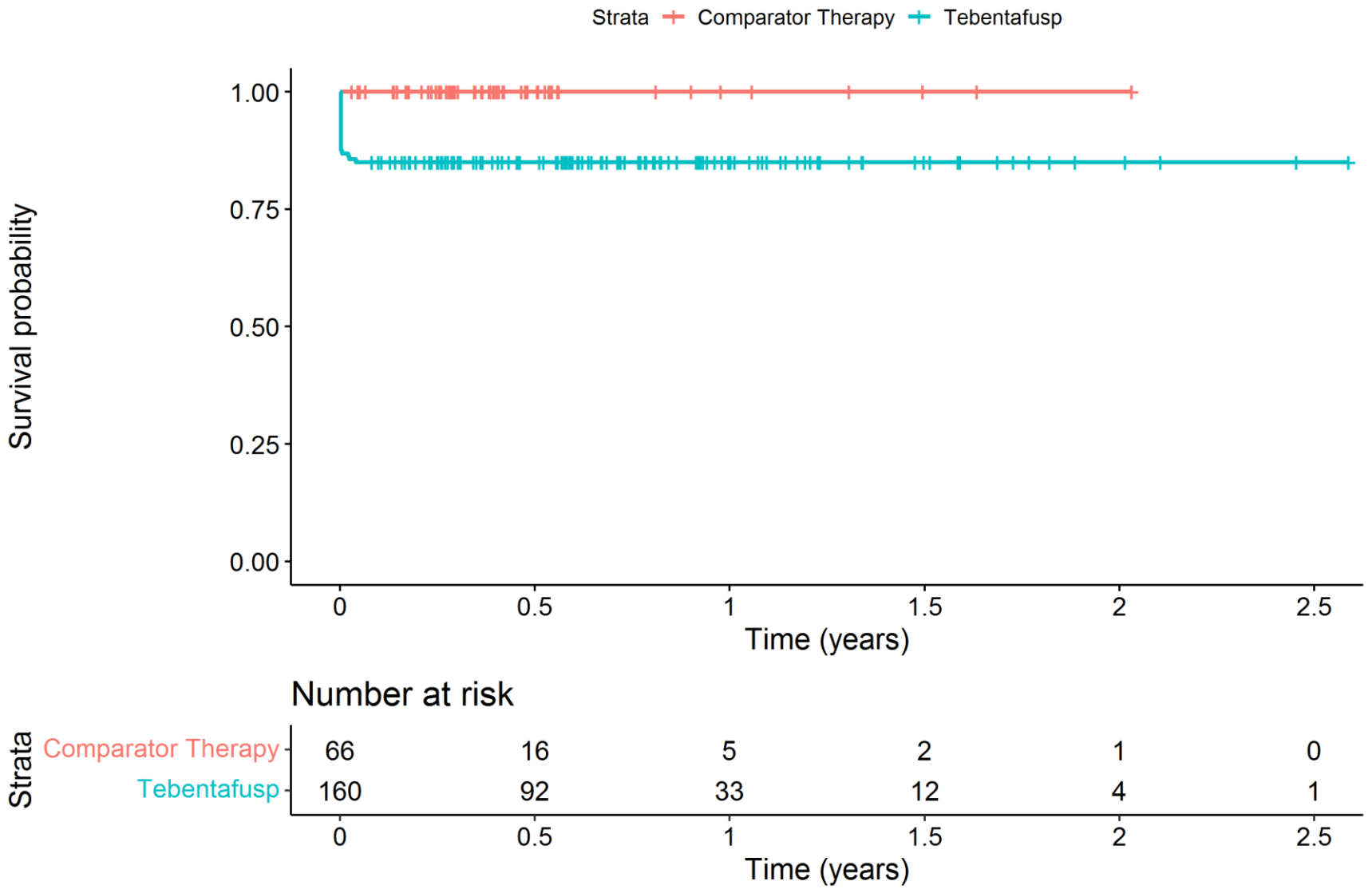
Erkrankungen des Immunsystems - Läsion ≥8,1 cm



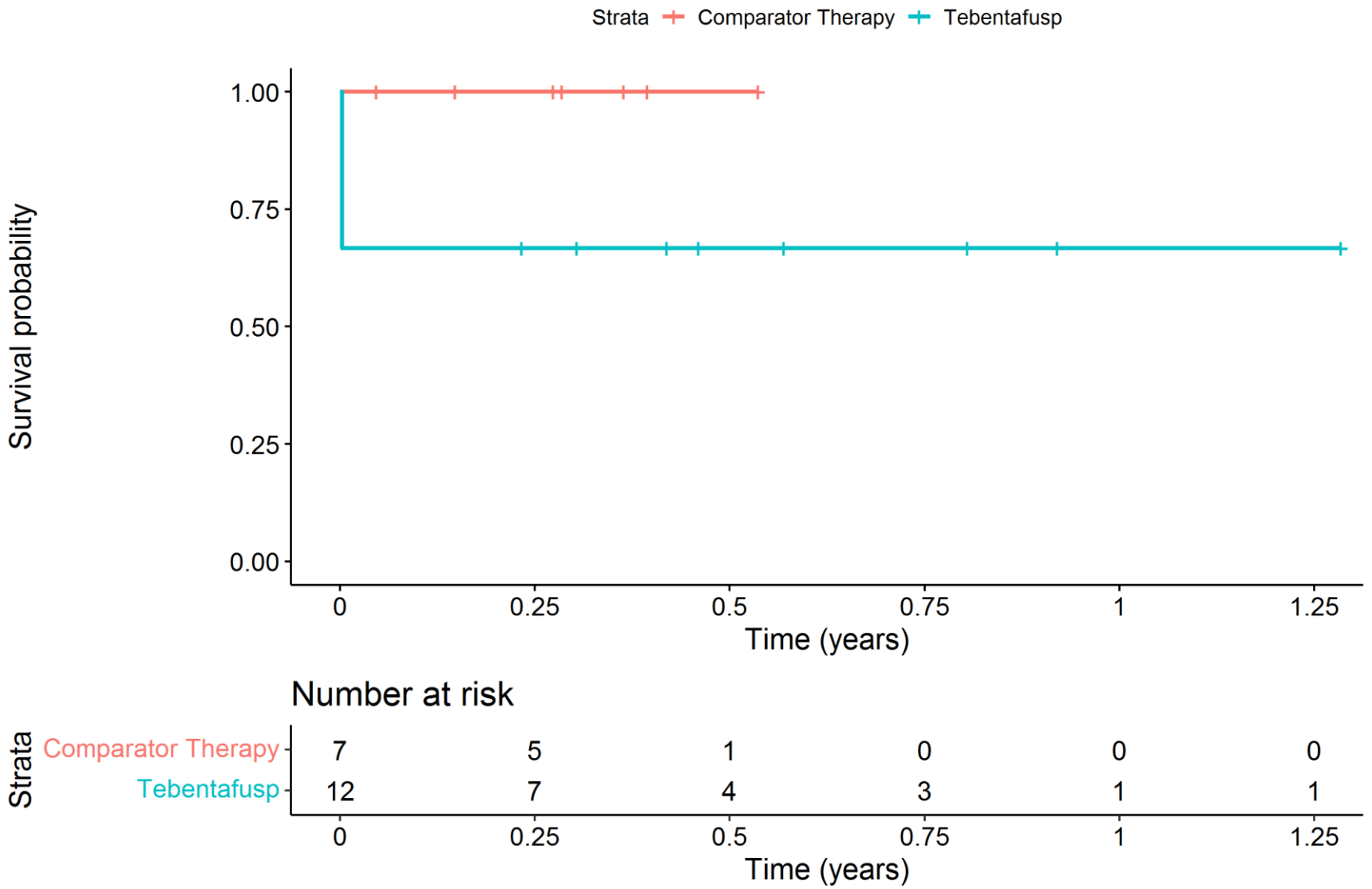
Erkrankungen des Immunsystems - Nordamerika



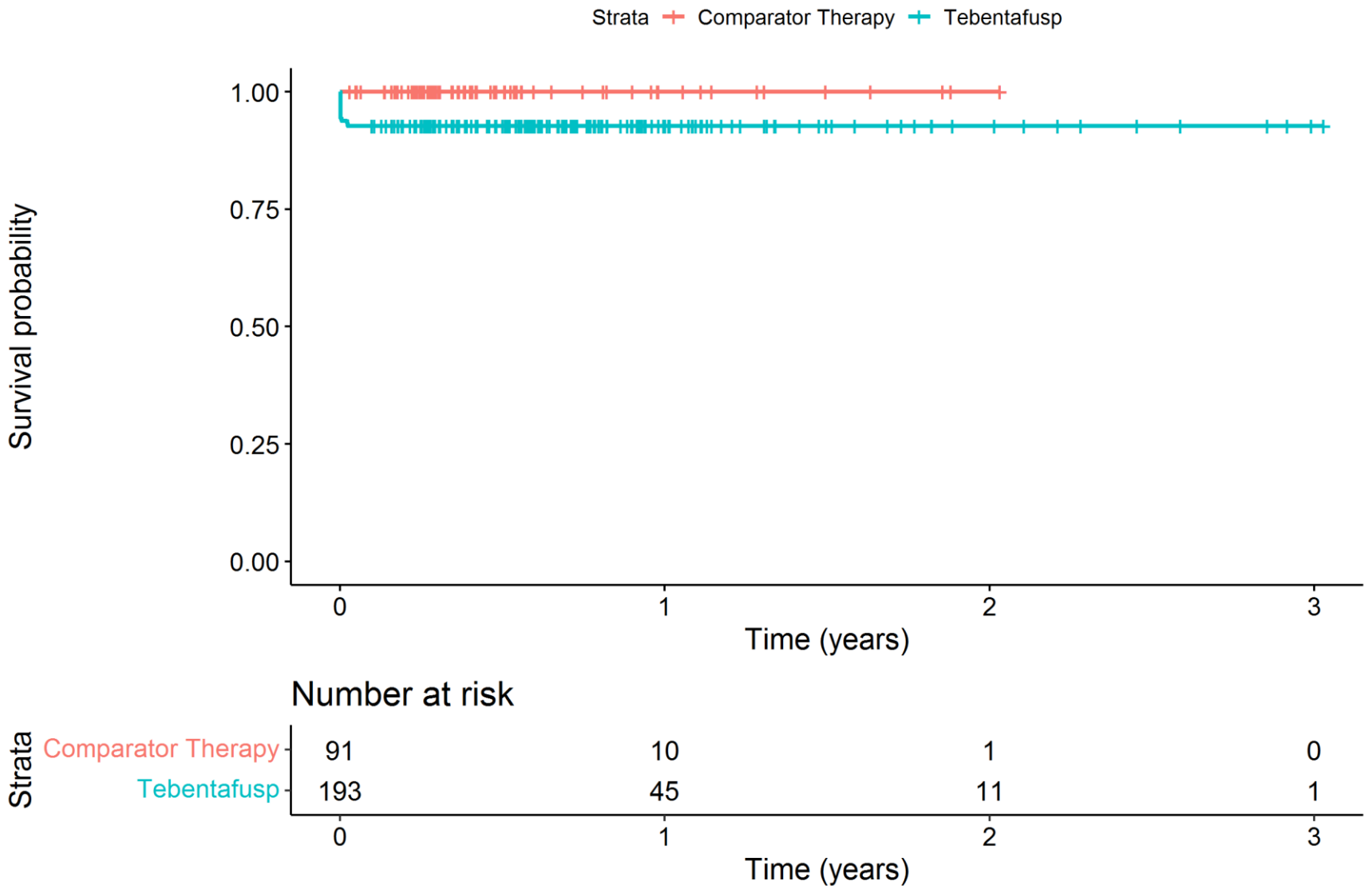
Erkrankungen des Immunsystems - Nicht-Nordamerika



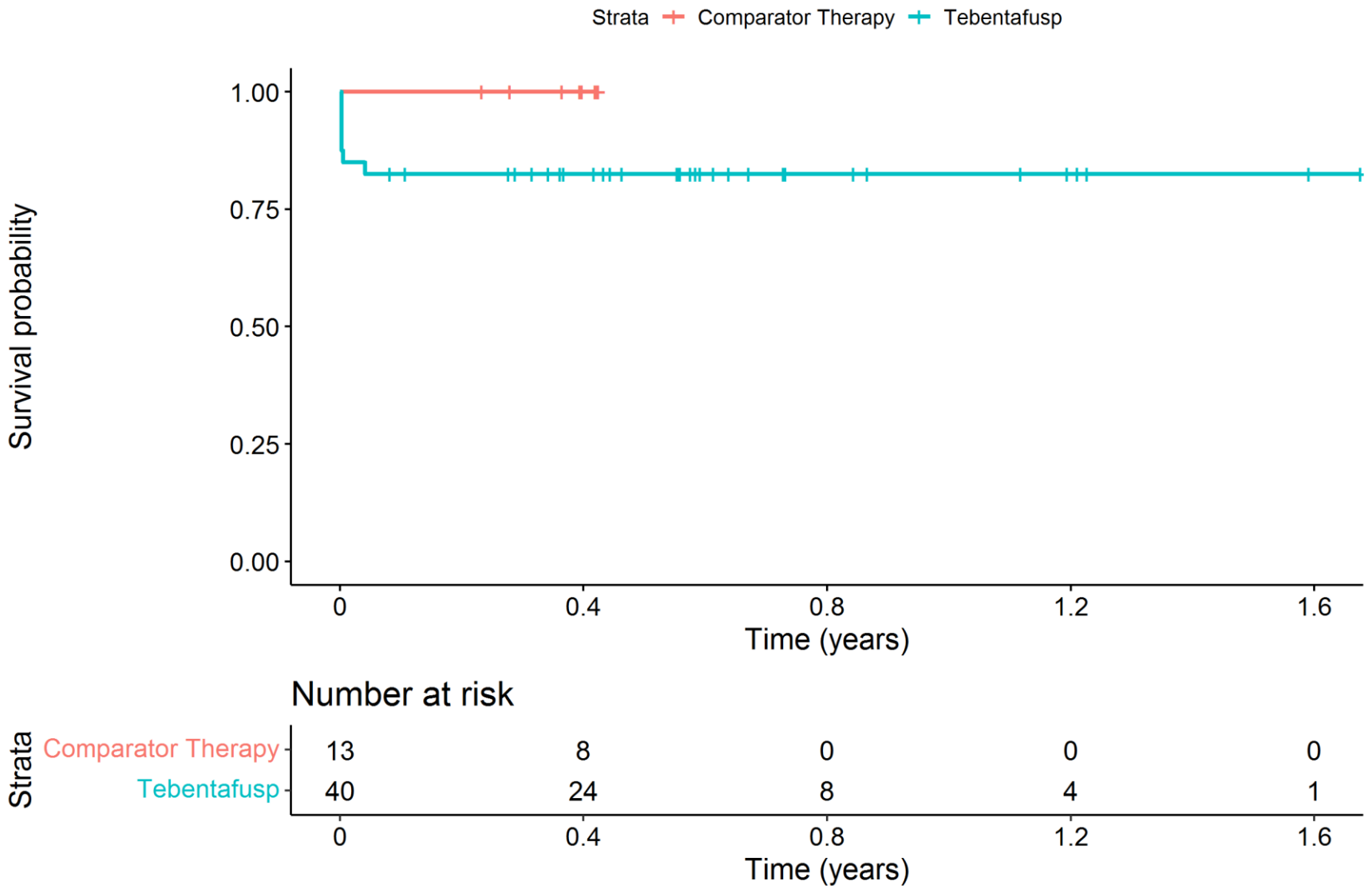
Erkrankungen des Immunsystems - Dacarbazin



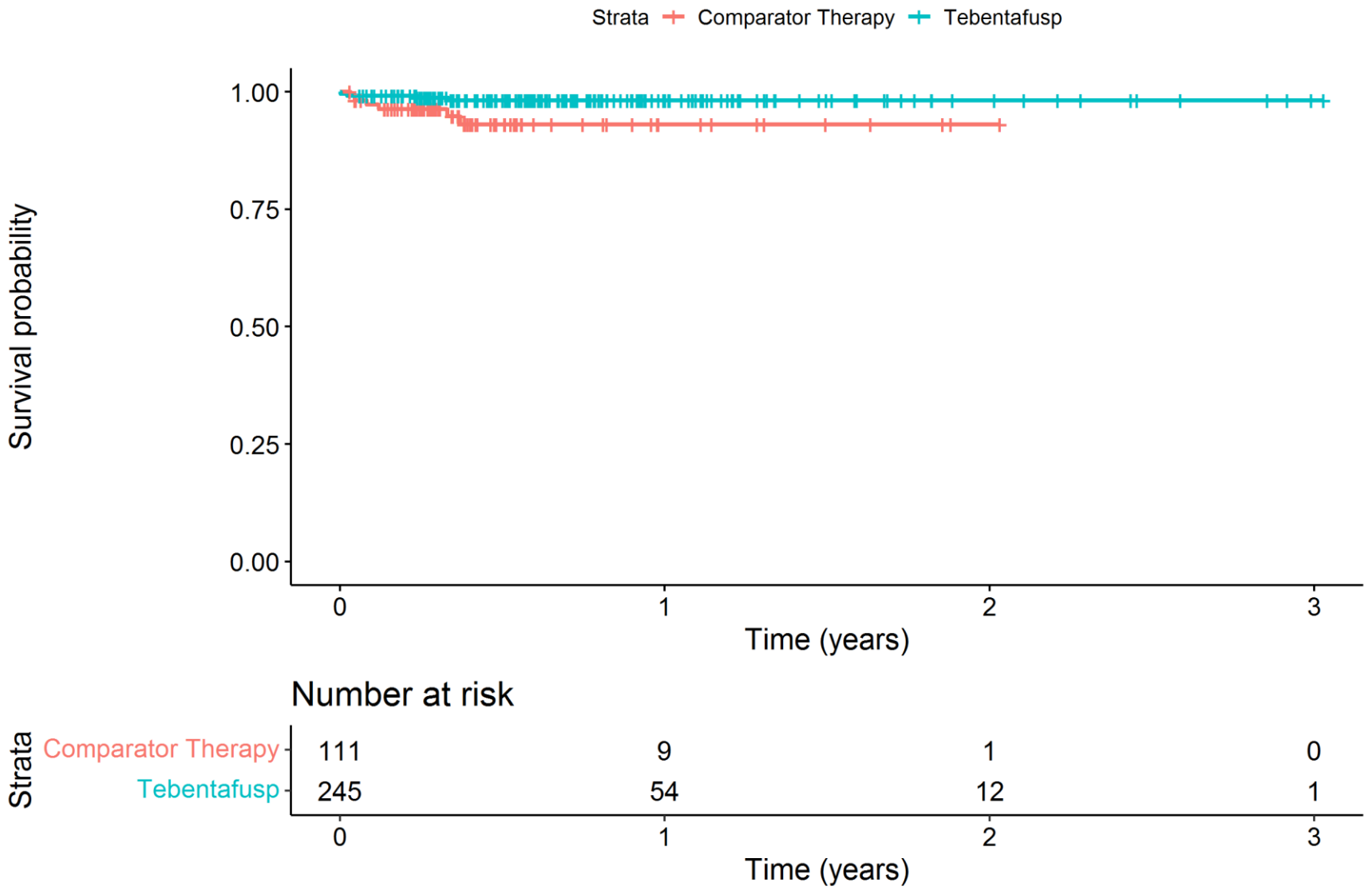
Erkrankungen des Immunsystems - Pembrolizumab



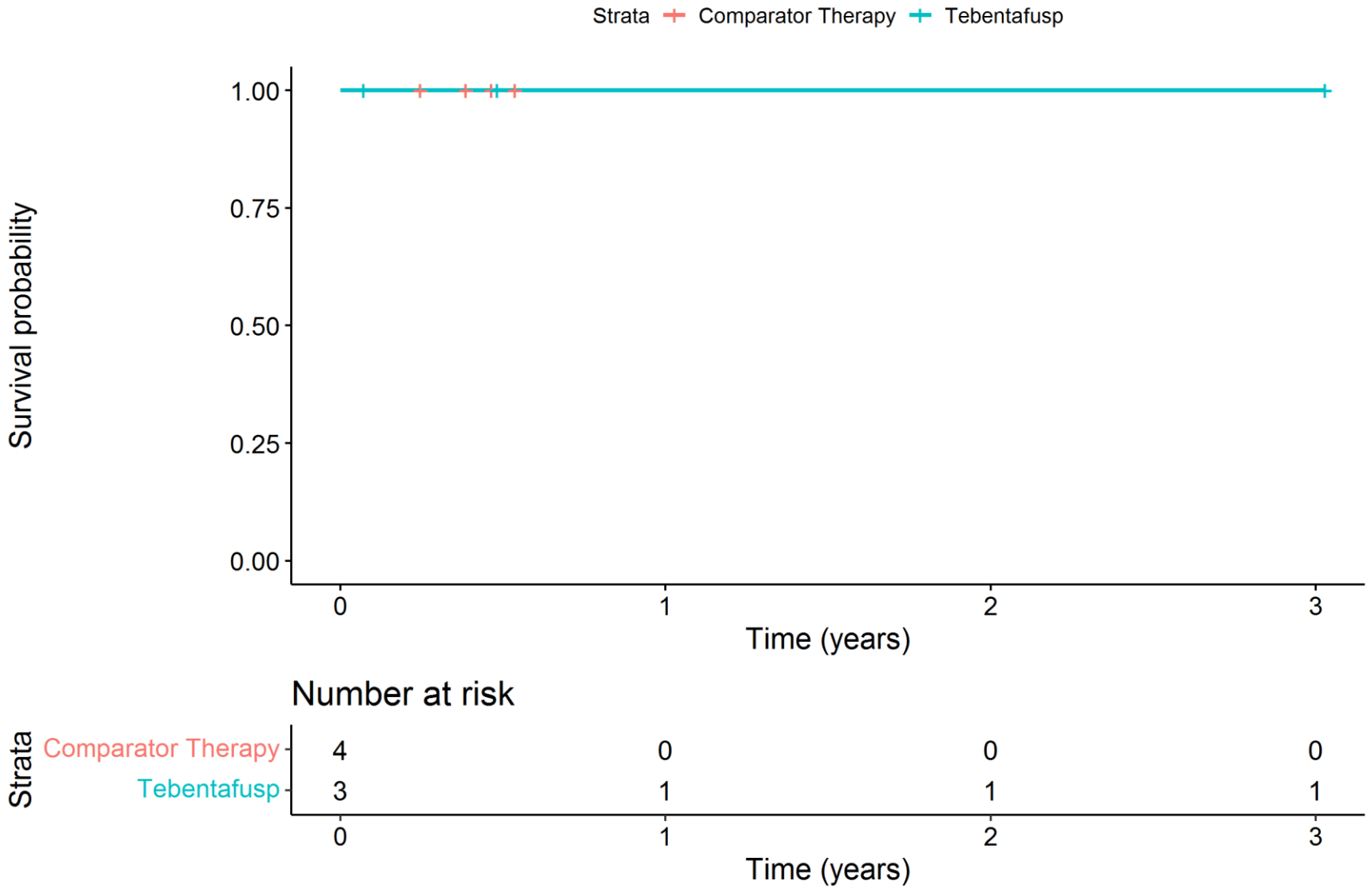
Erkrankungen des Immunsystems - Ipilimumab



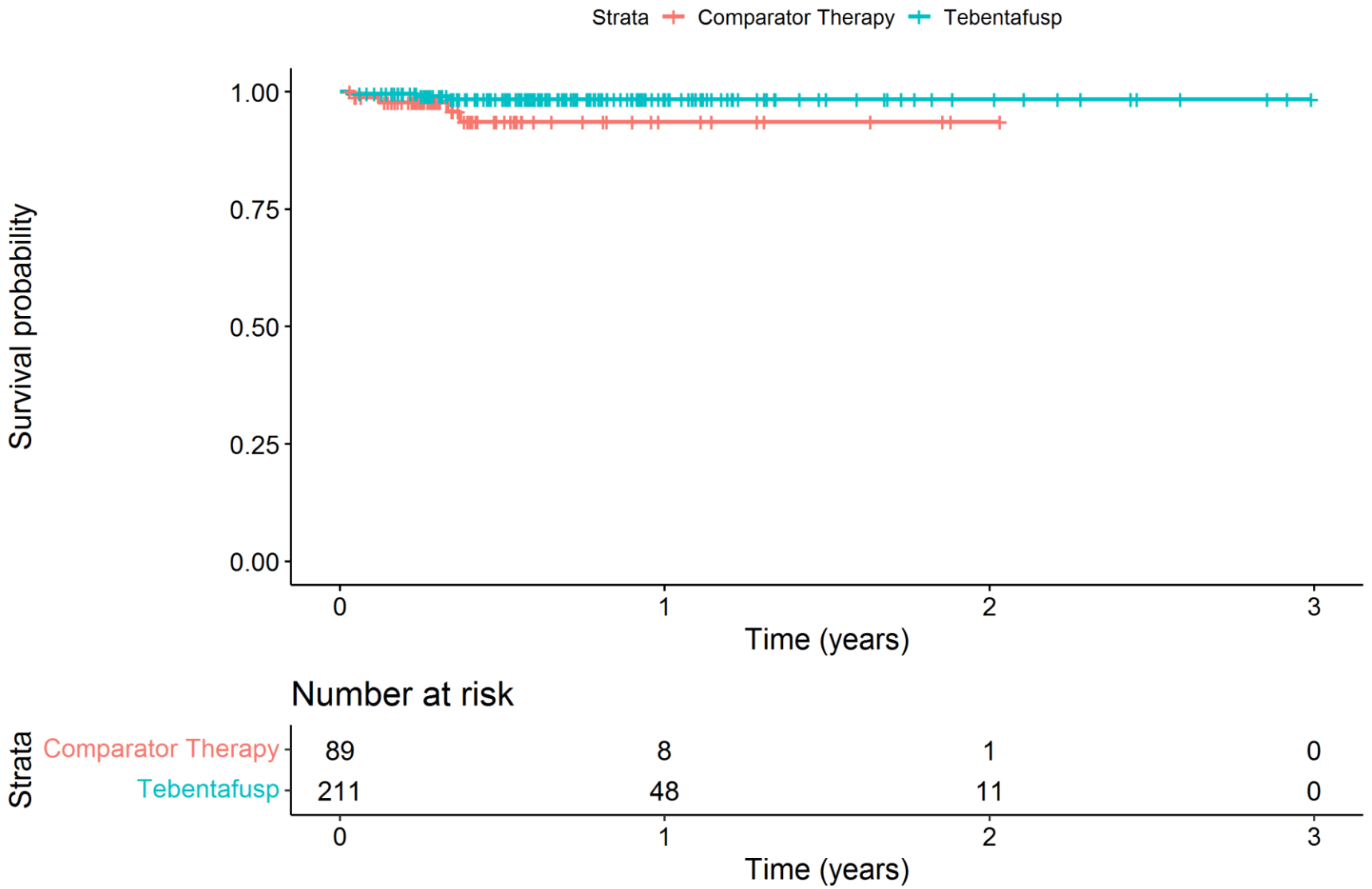
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Gesamt



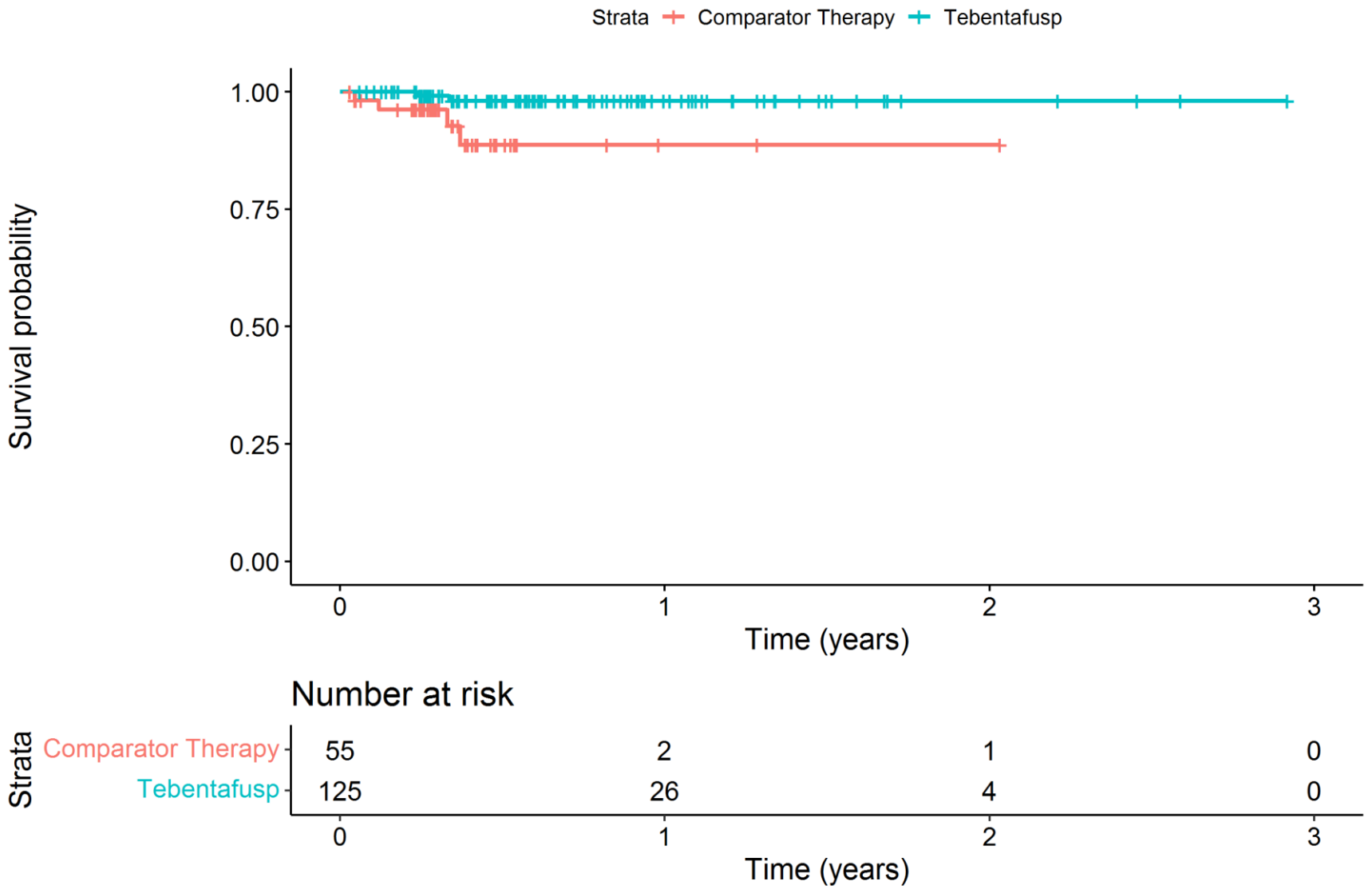
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Hispanisch



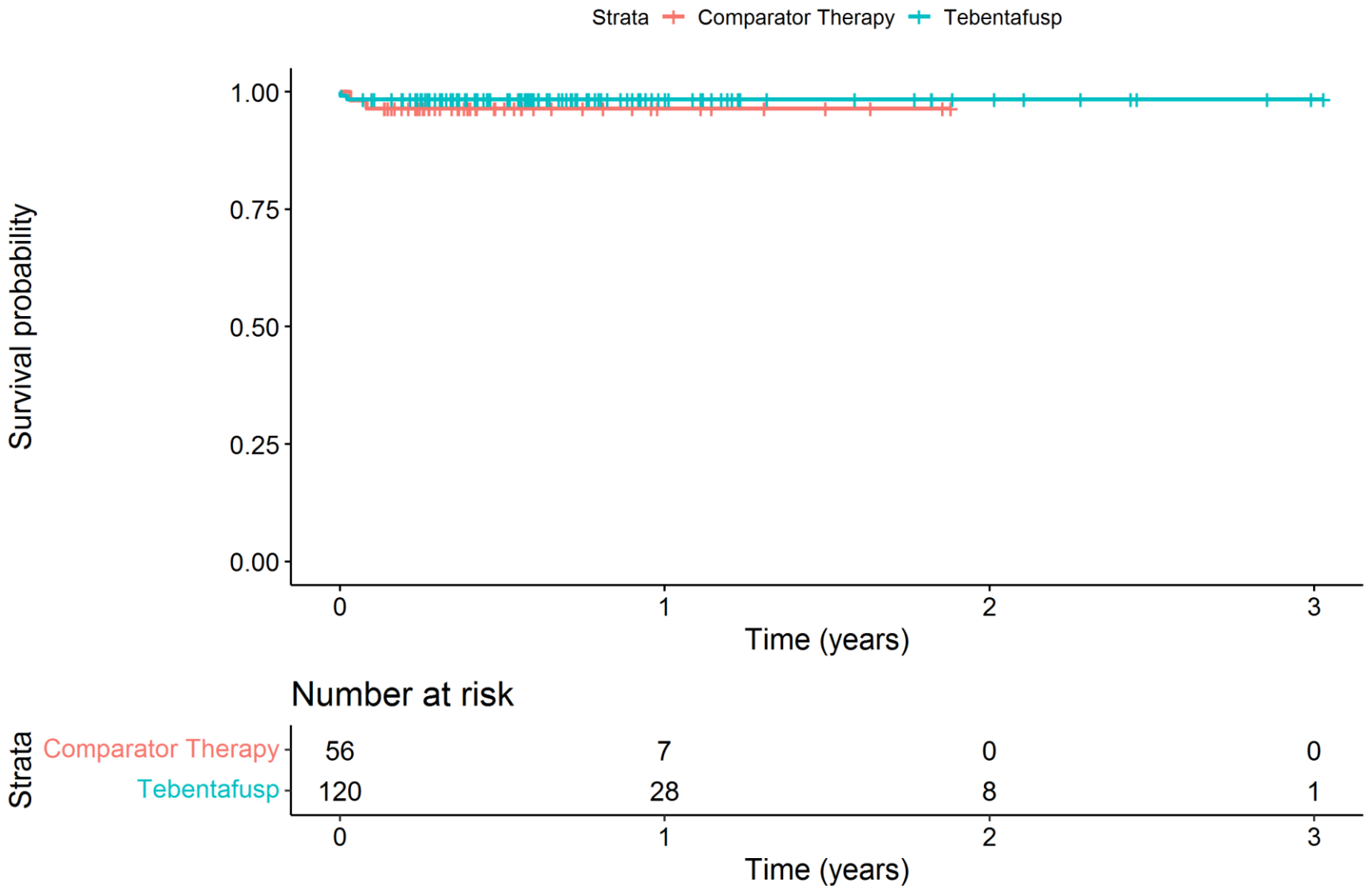
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nicht-hispanisch



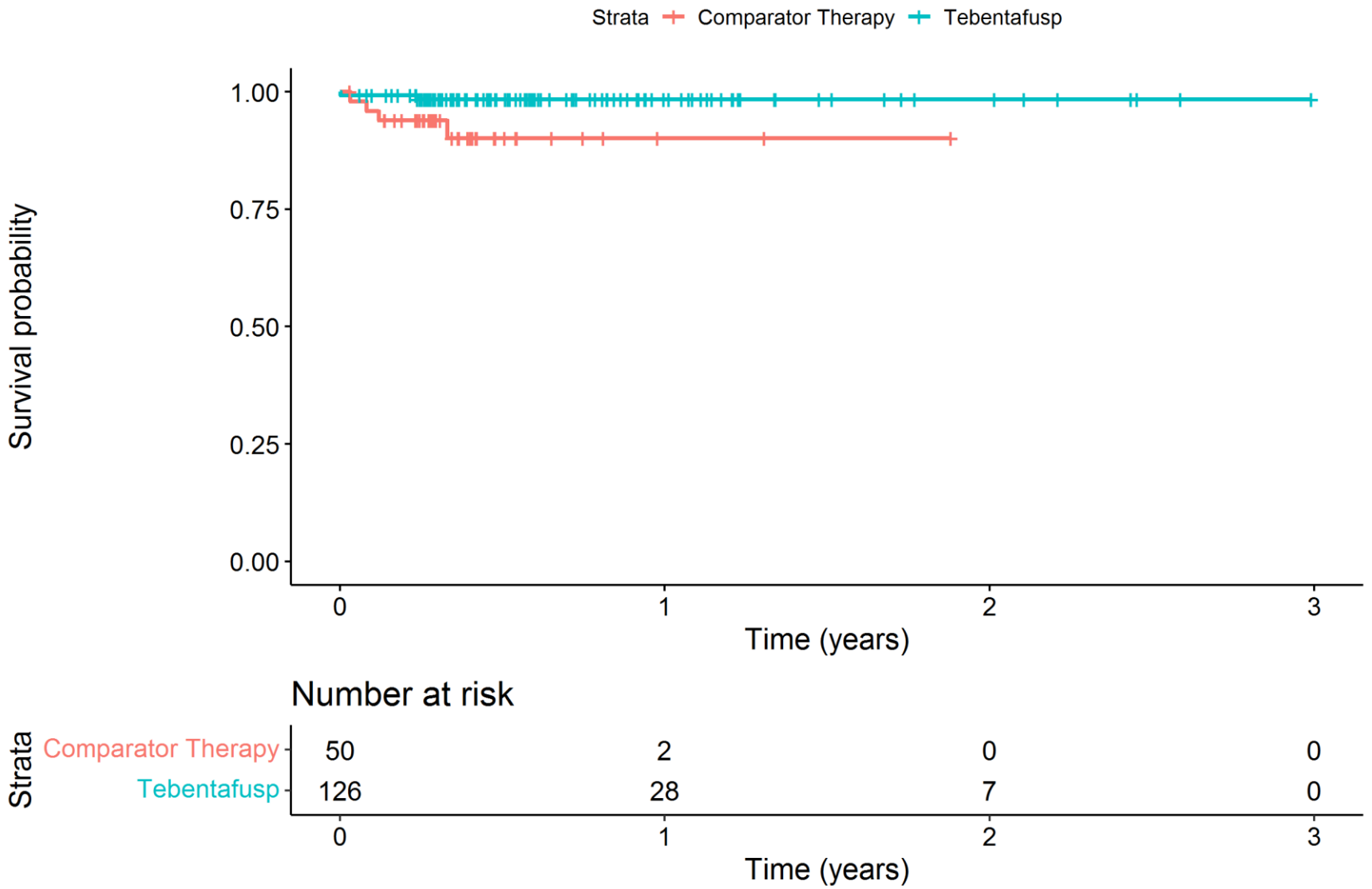
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Männlich



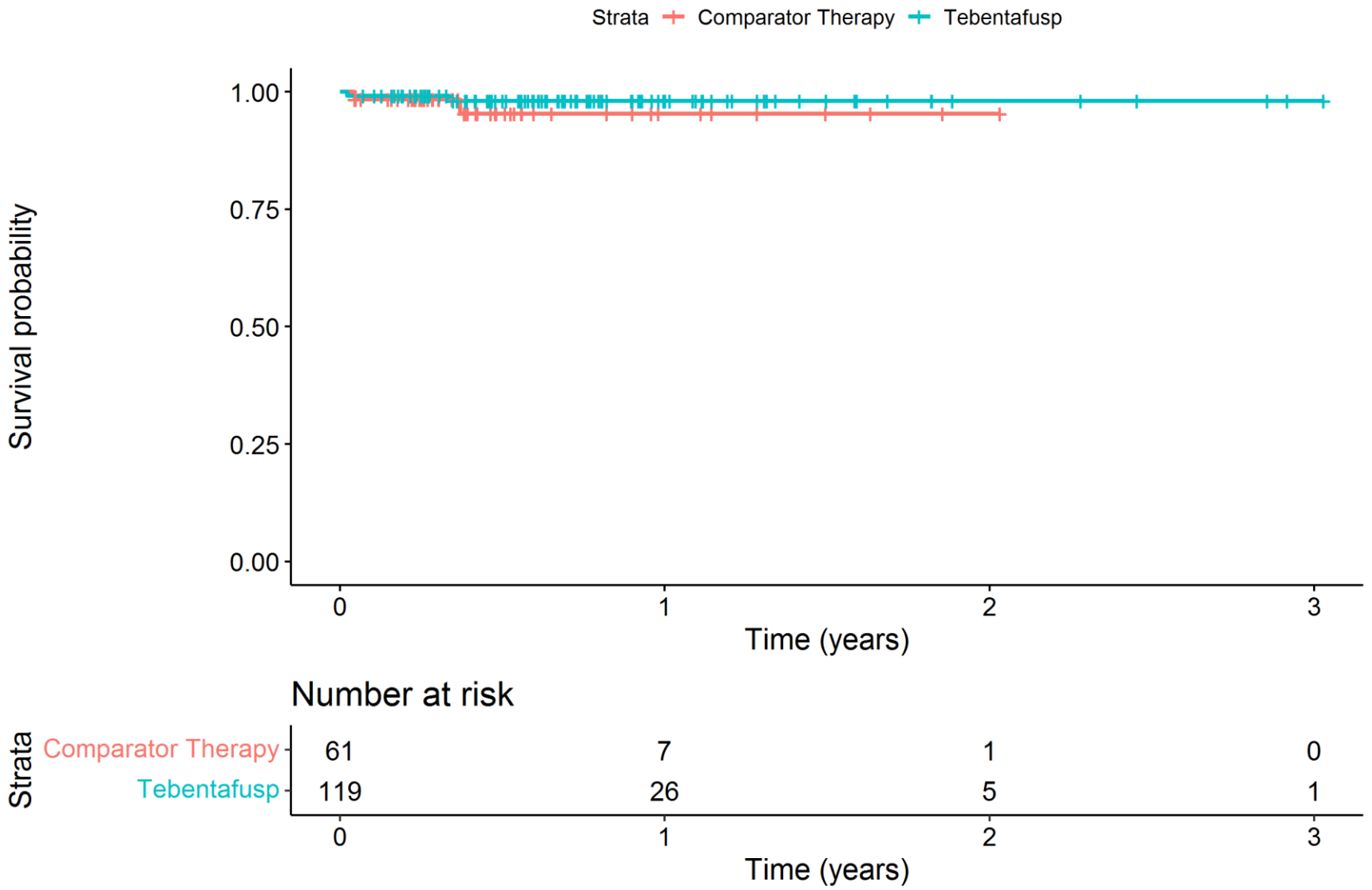
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Weiblich



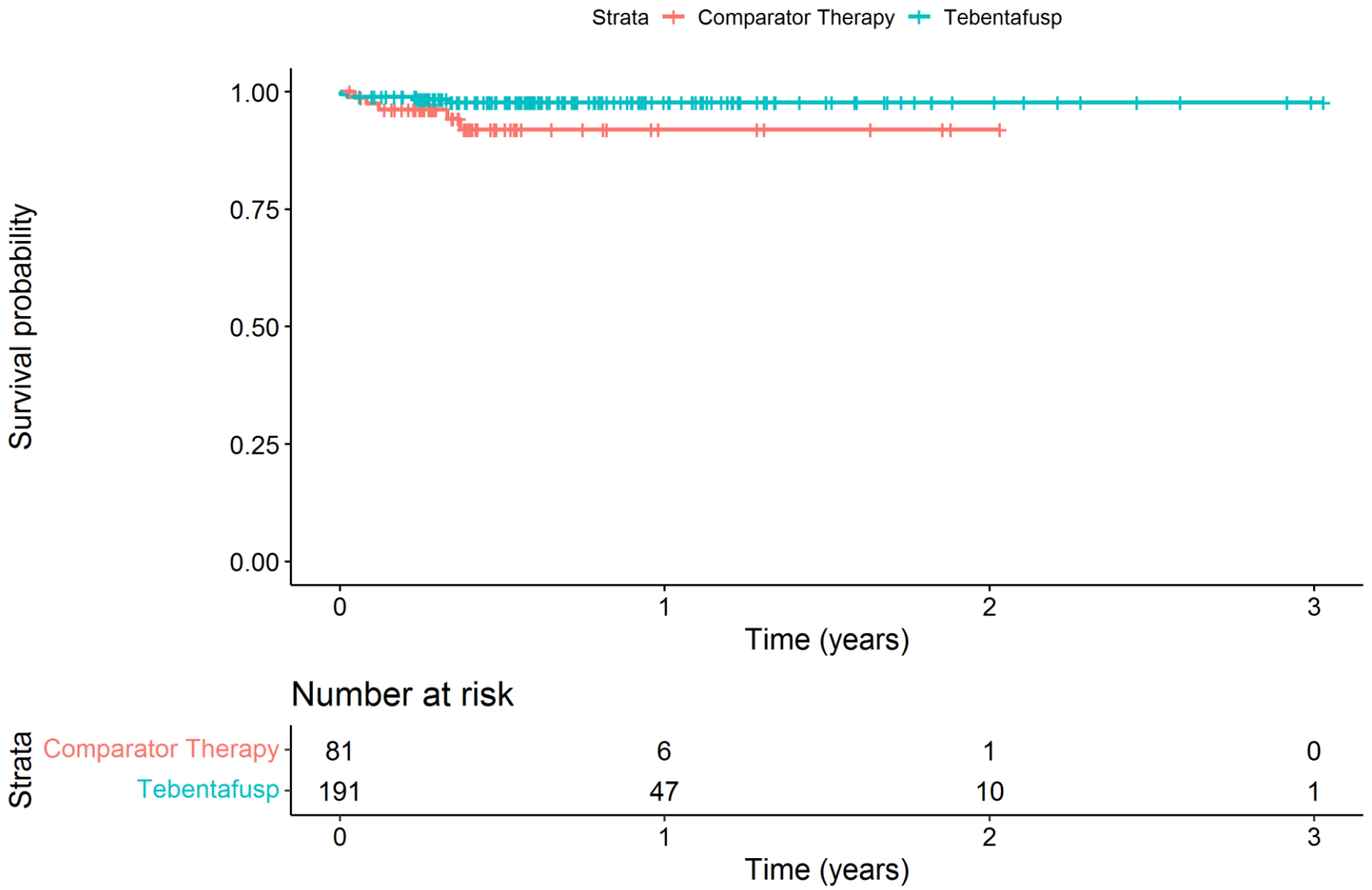
Erkrankungen der Atemwege, des Brustraums und Mediastinums- <65



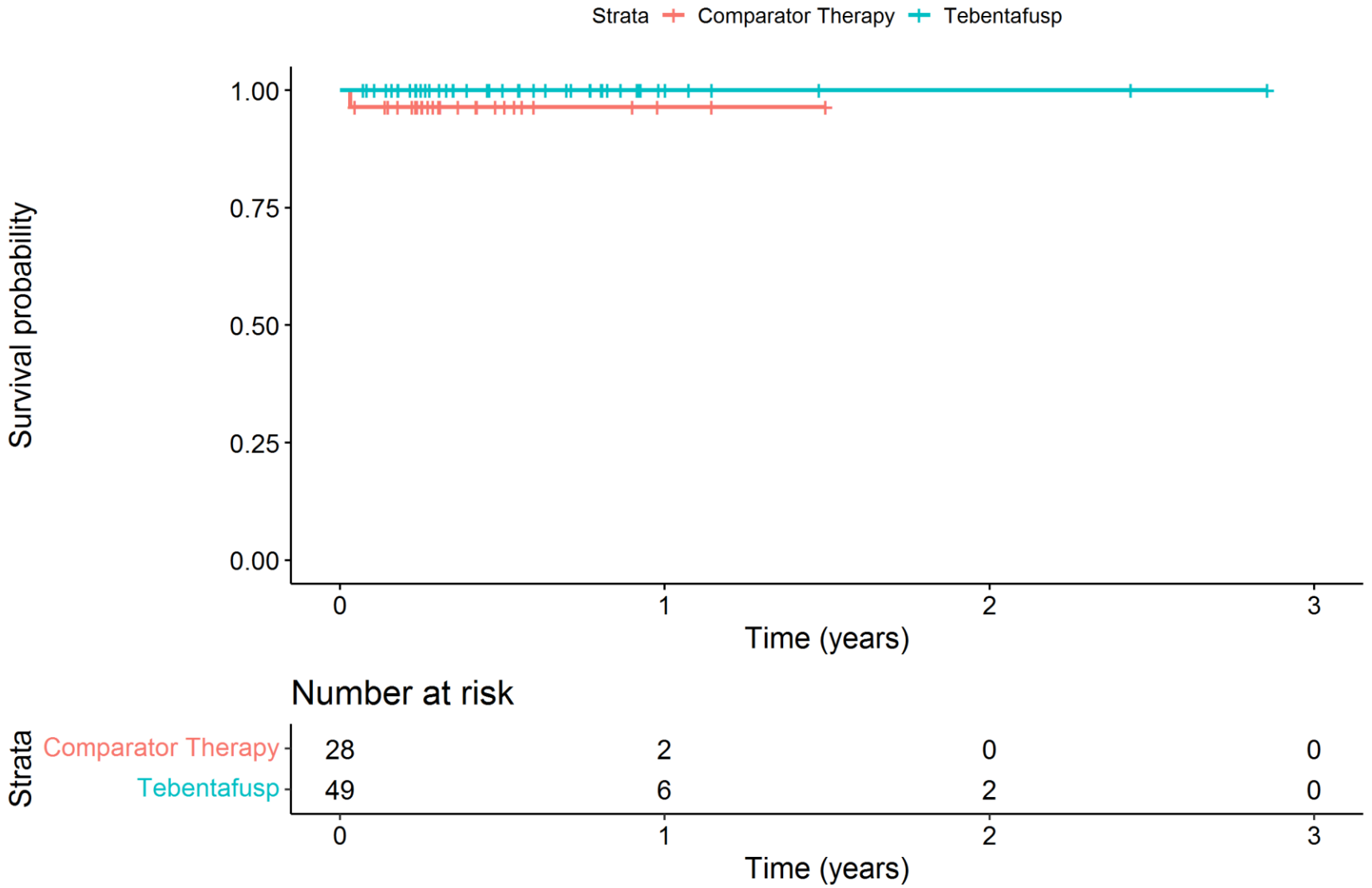
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ≥65



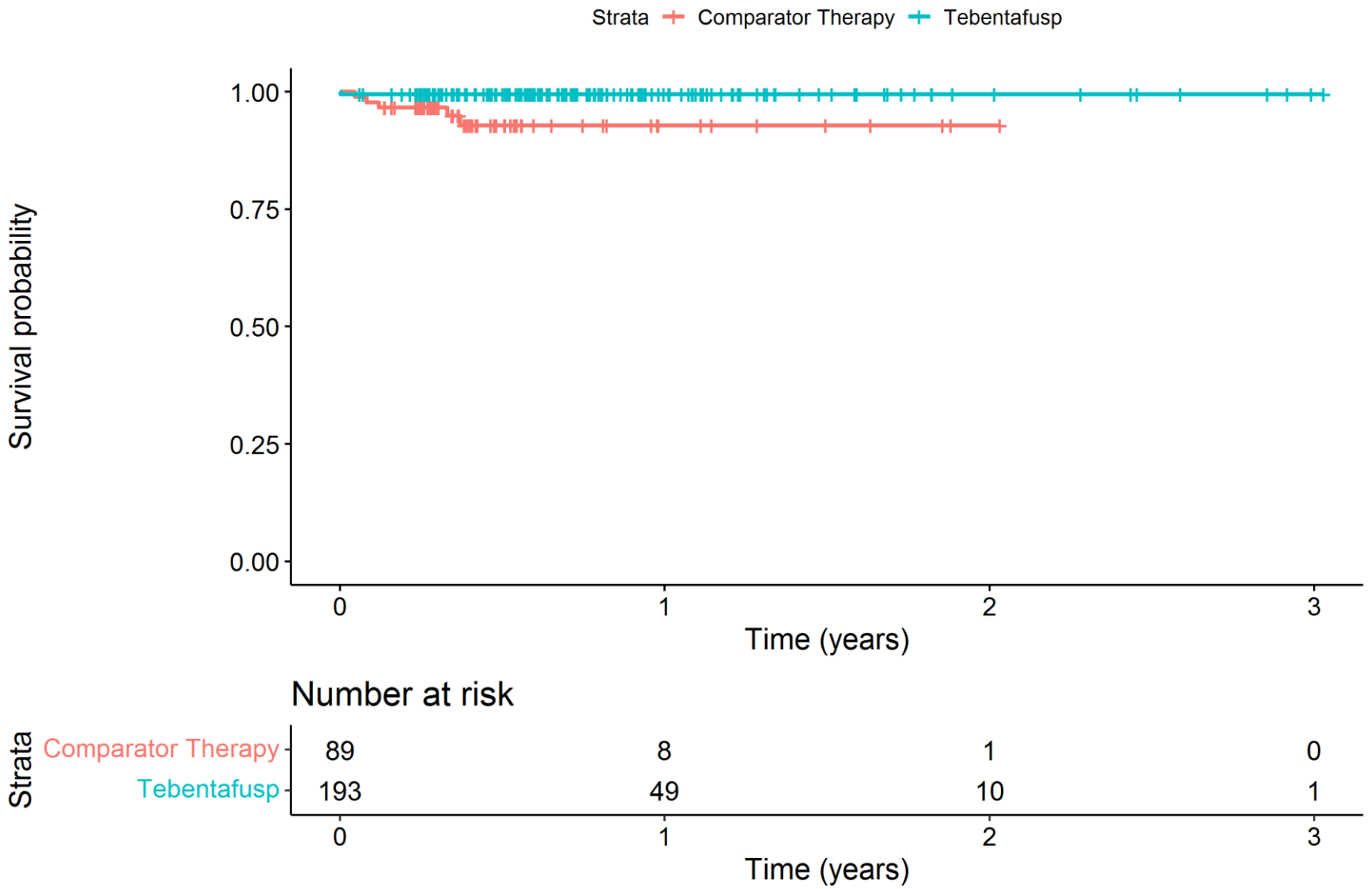
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 0



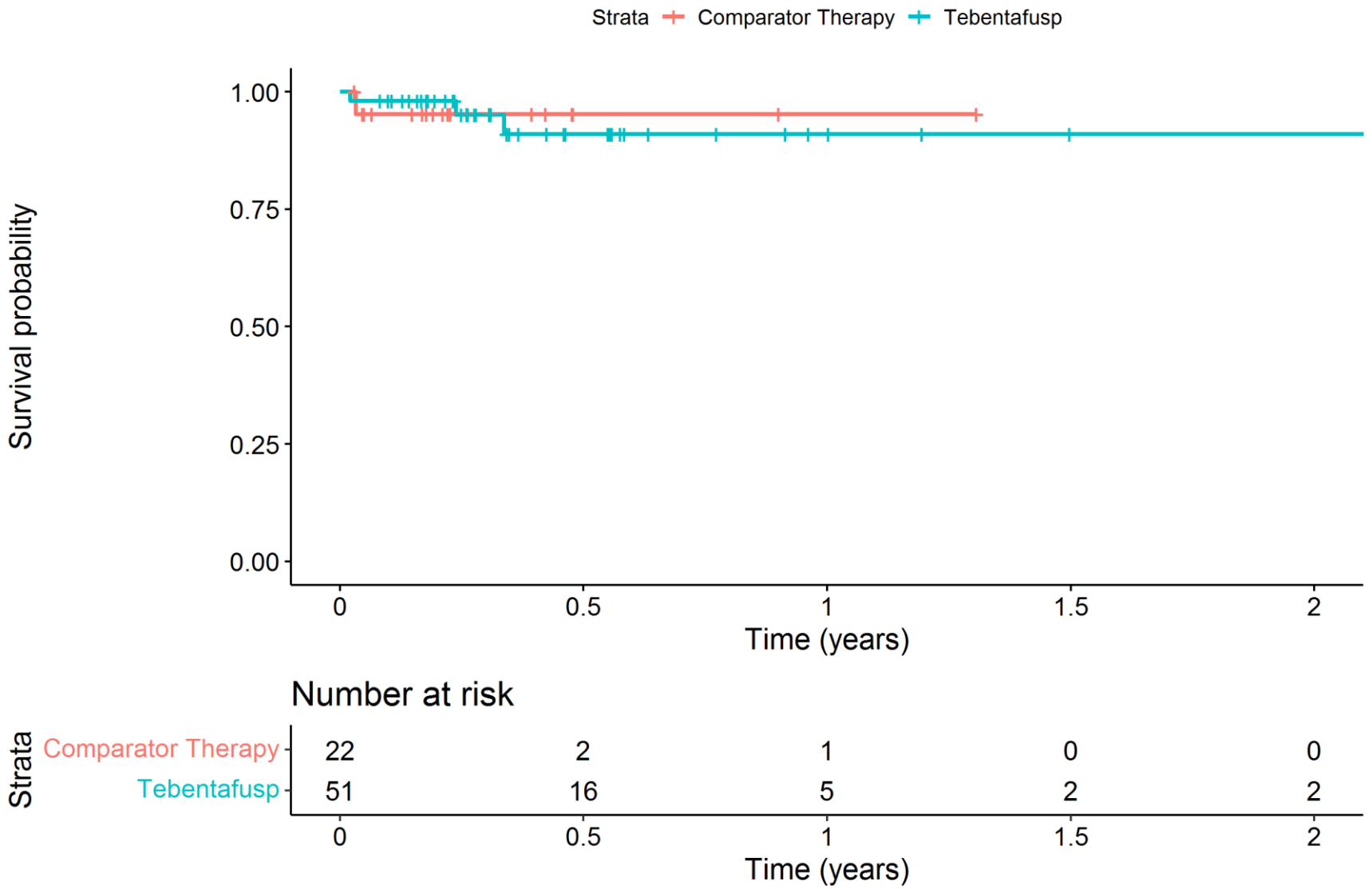
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 1



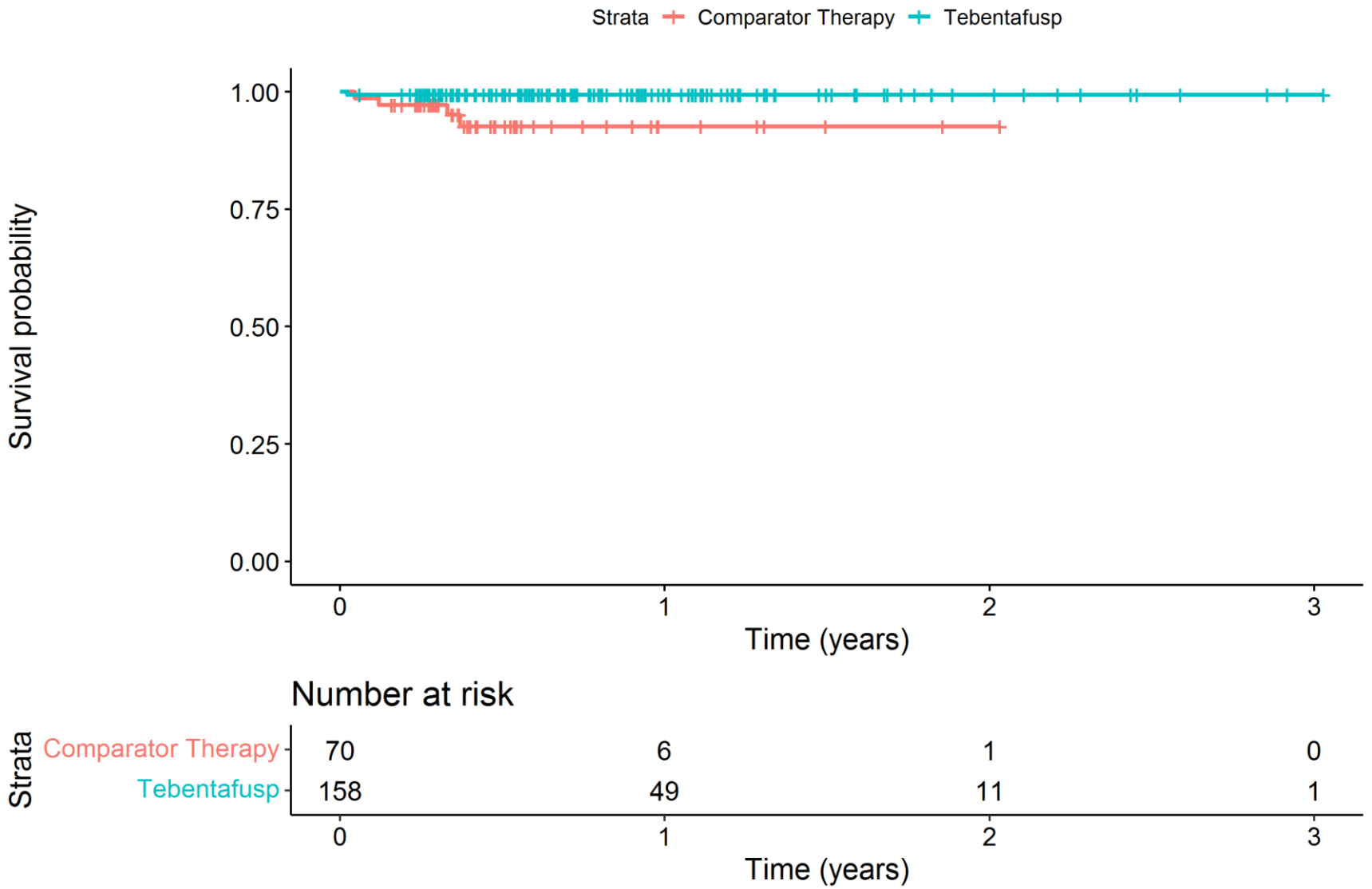
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ALP ≤ ULN



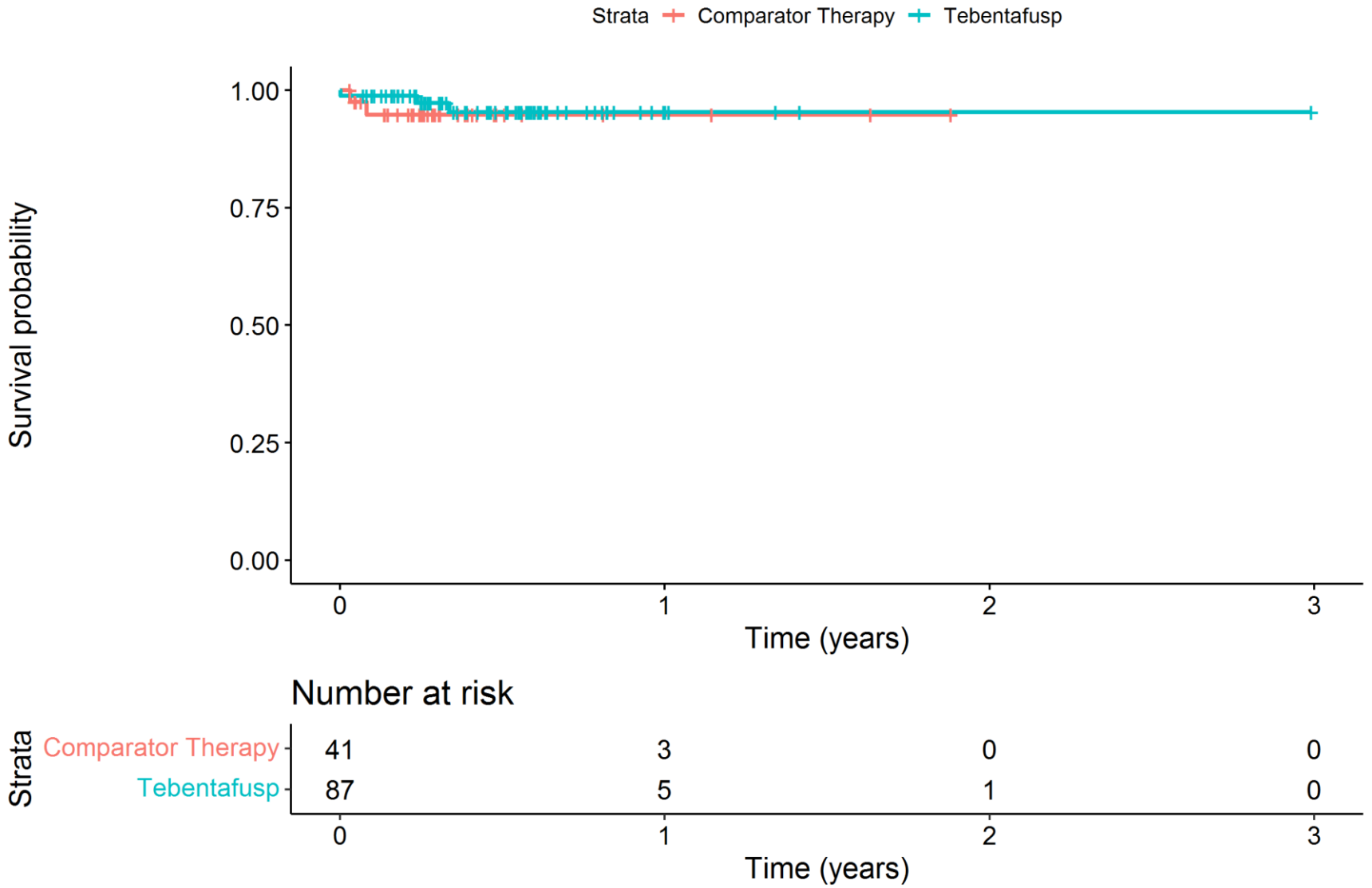
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ALP > ULN



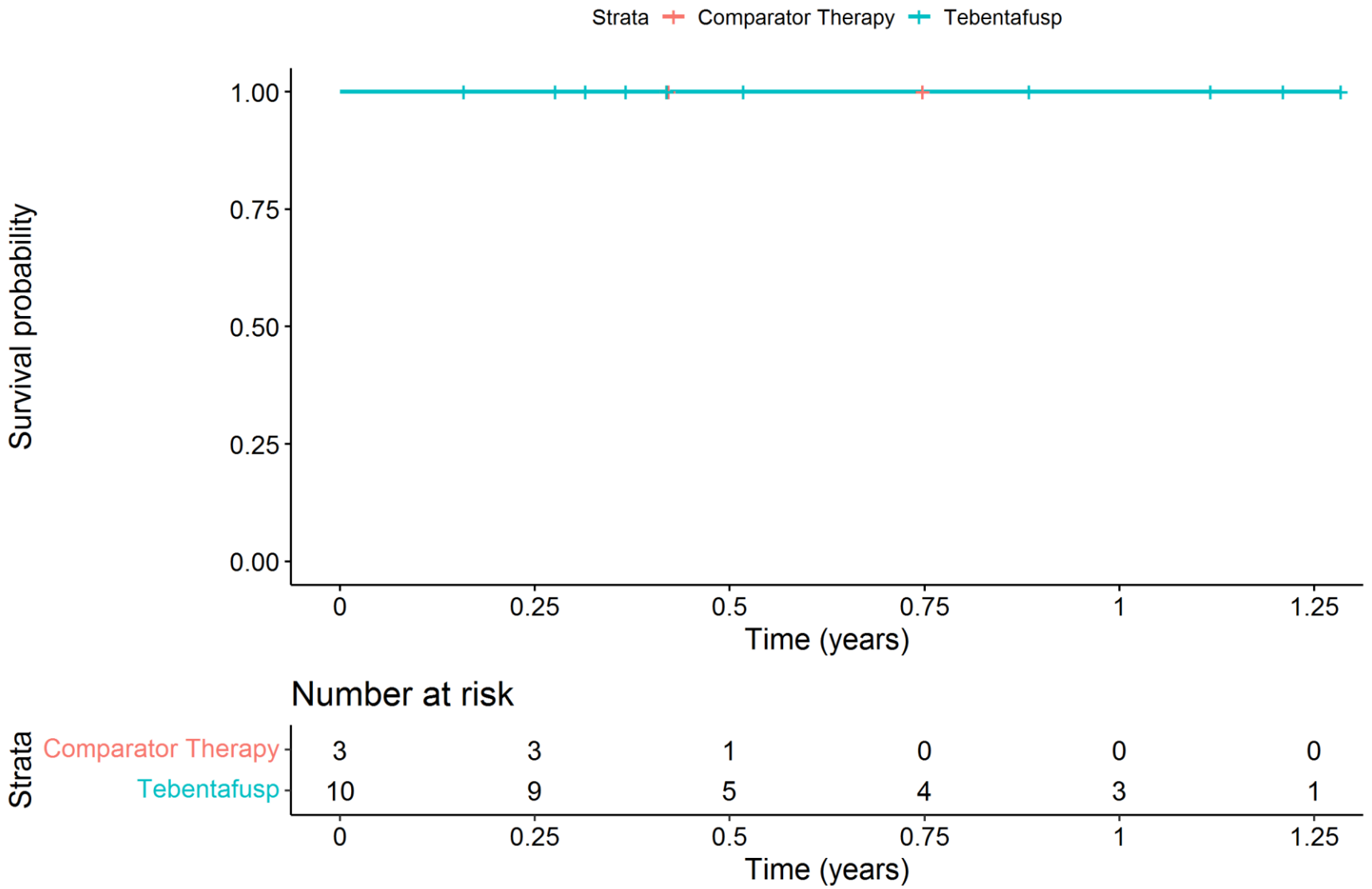
Erkrankungen der Atemwege, des Brustraums und Mediastinums- LDH =< ULN



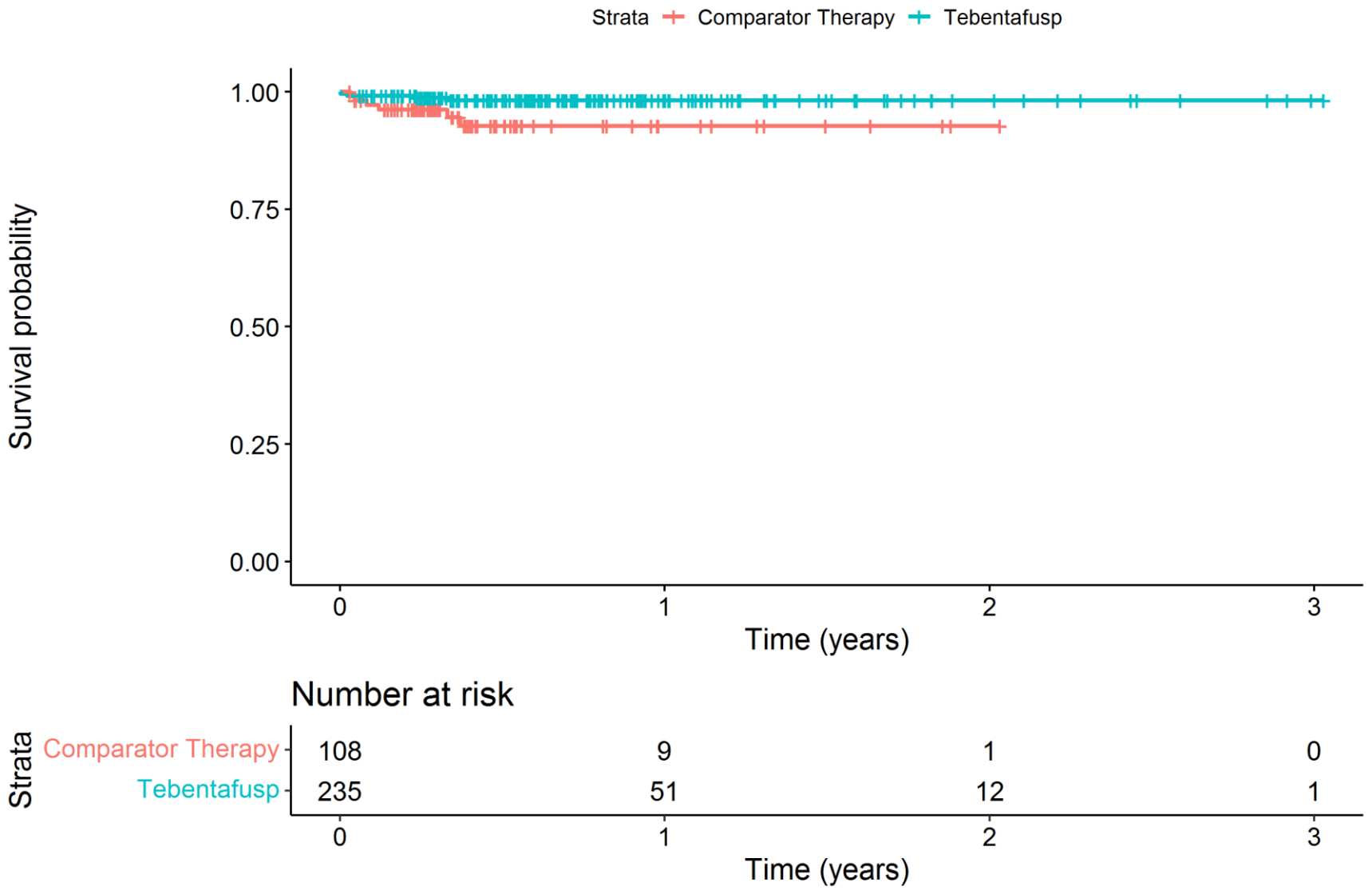
Erkrankungen der Atemwege, des Brustraums und Mediastinums- LDH > ULN



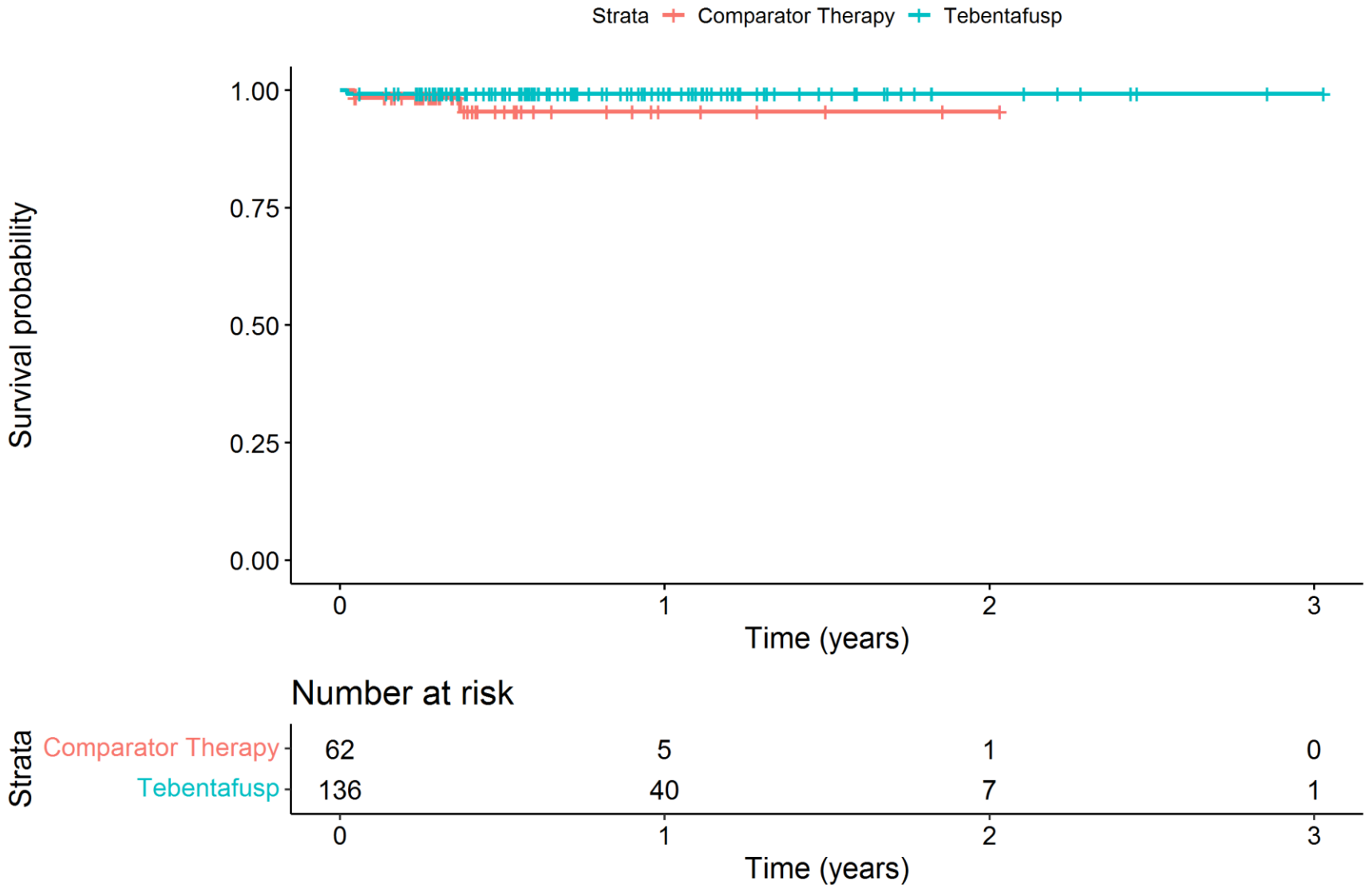
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Vorherige Therapie adjuvant/neoadjuvant



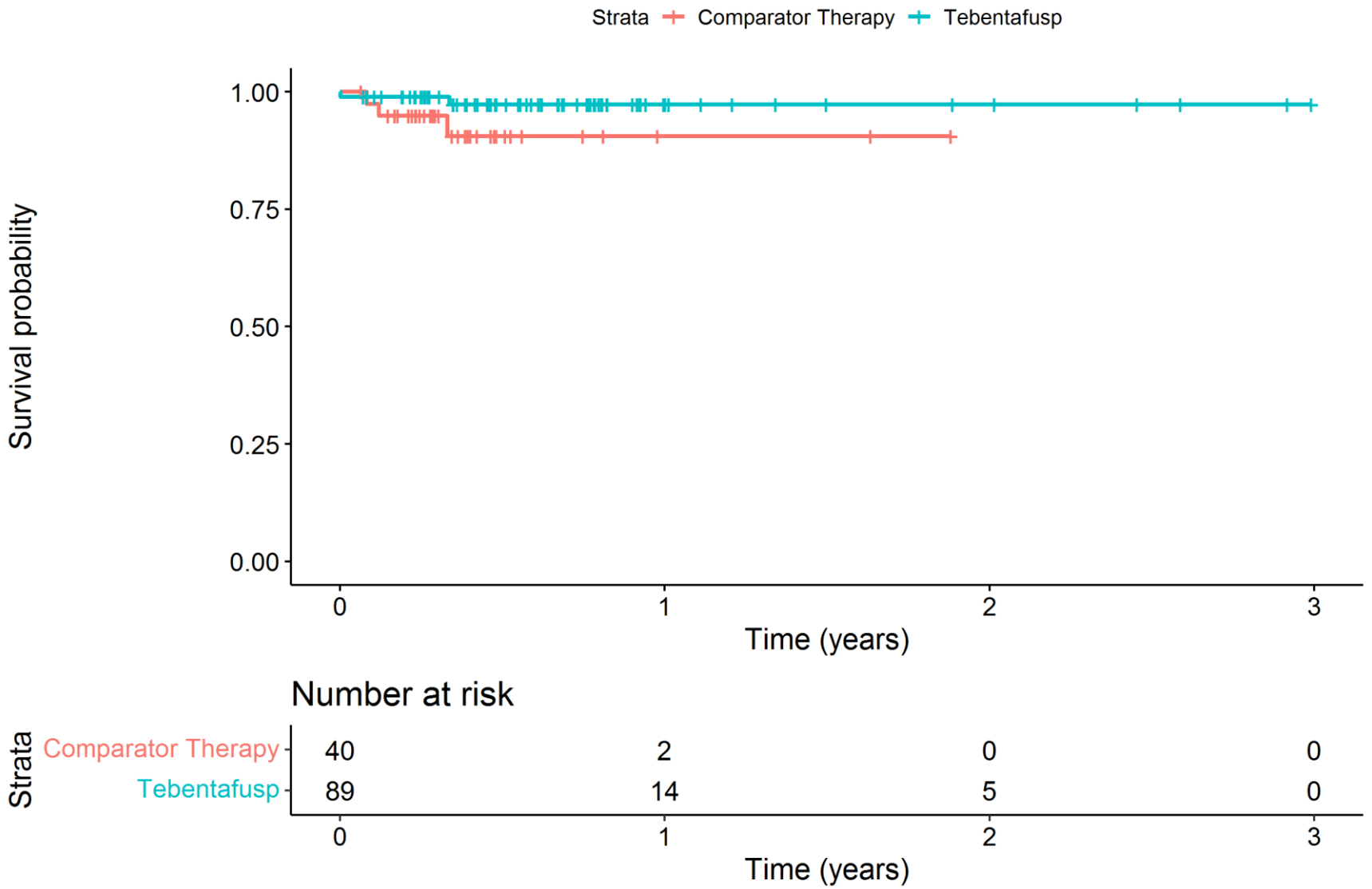
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Keine vorherige Therapie adjuvant/neoadjuvant



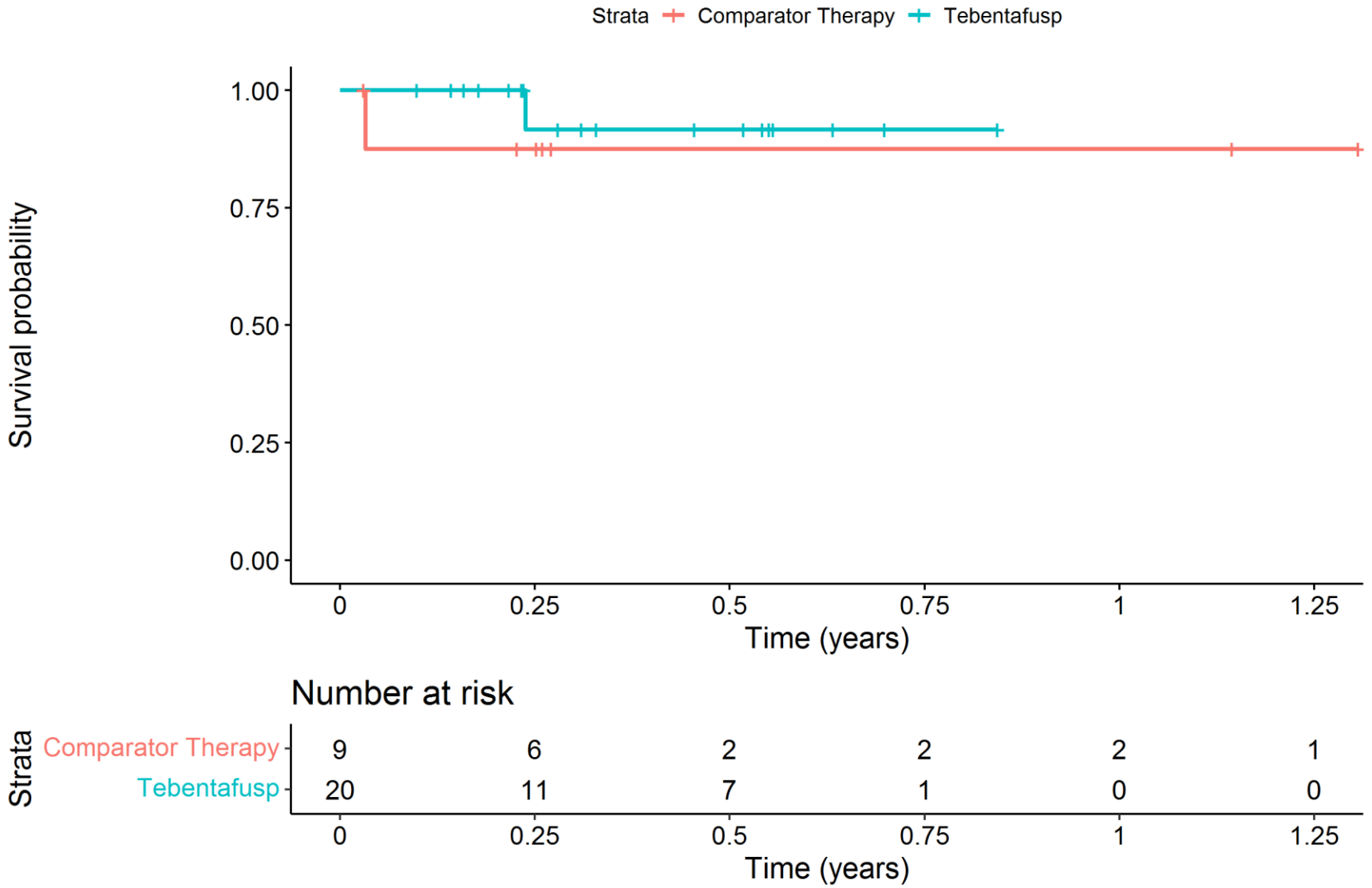
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion ≤ 3cm



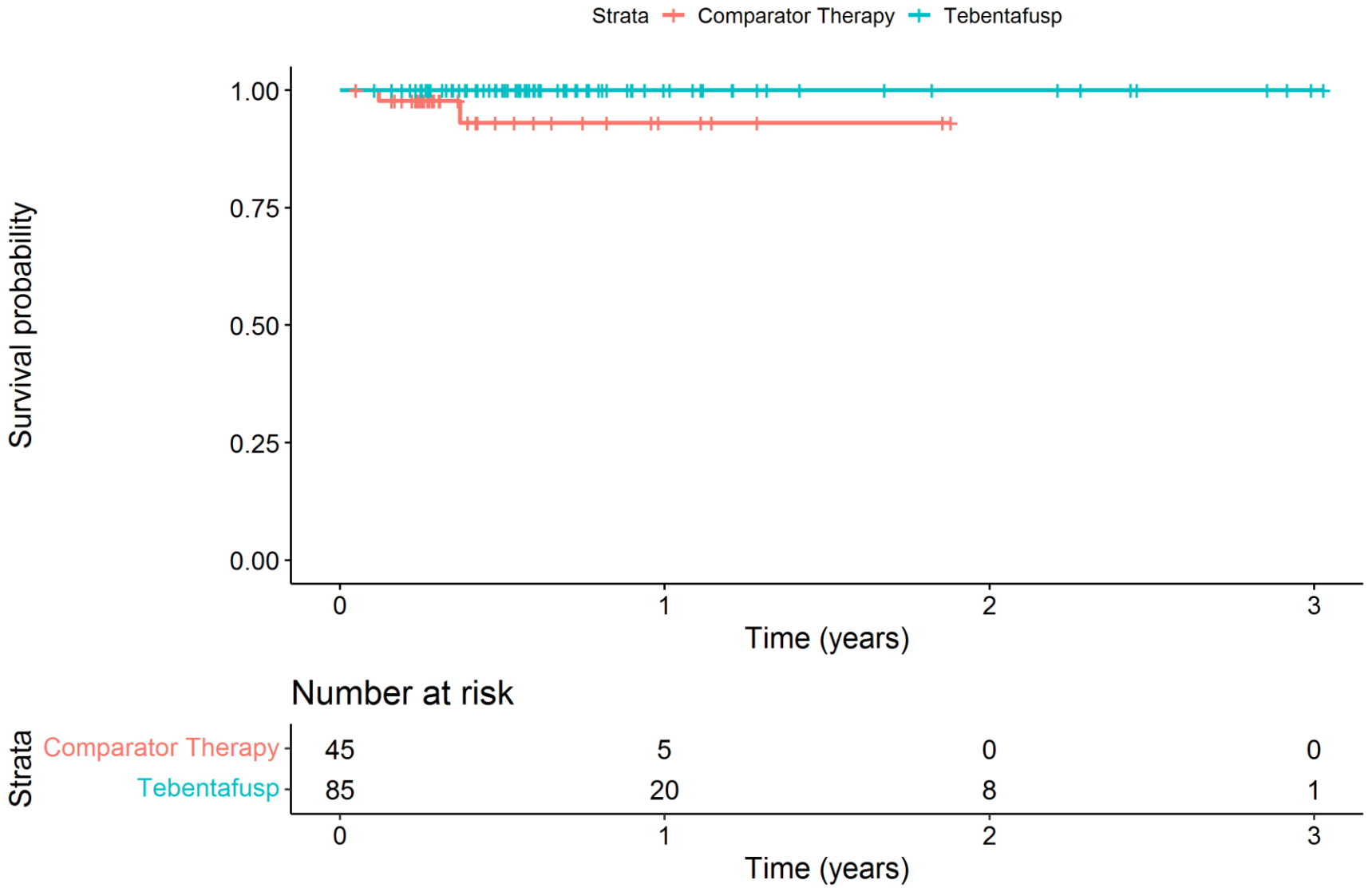
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion 3,1-8,0 cm



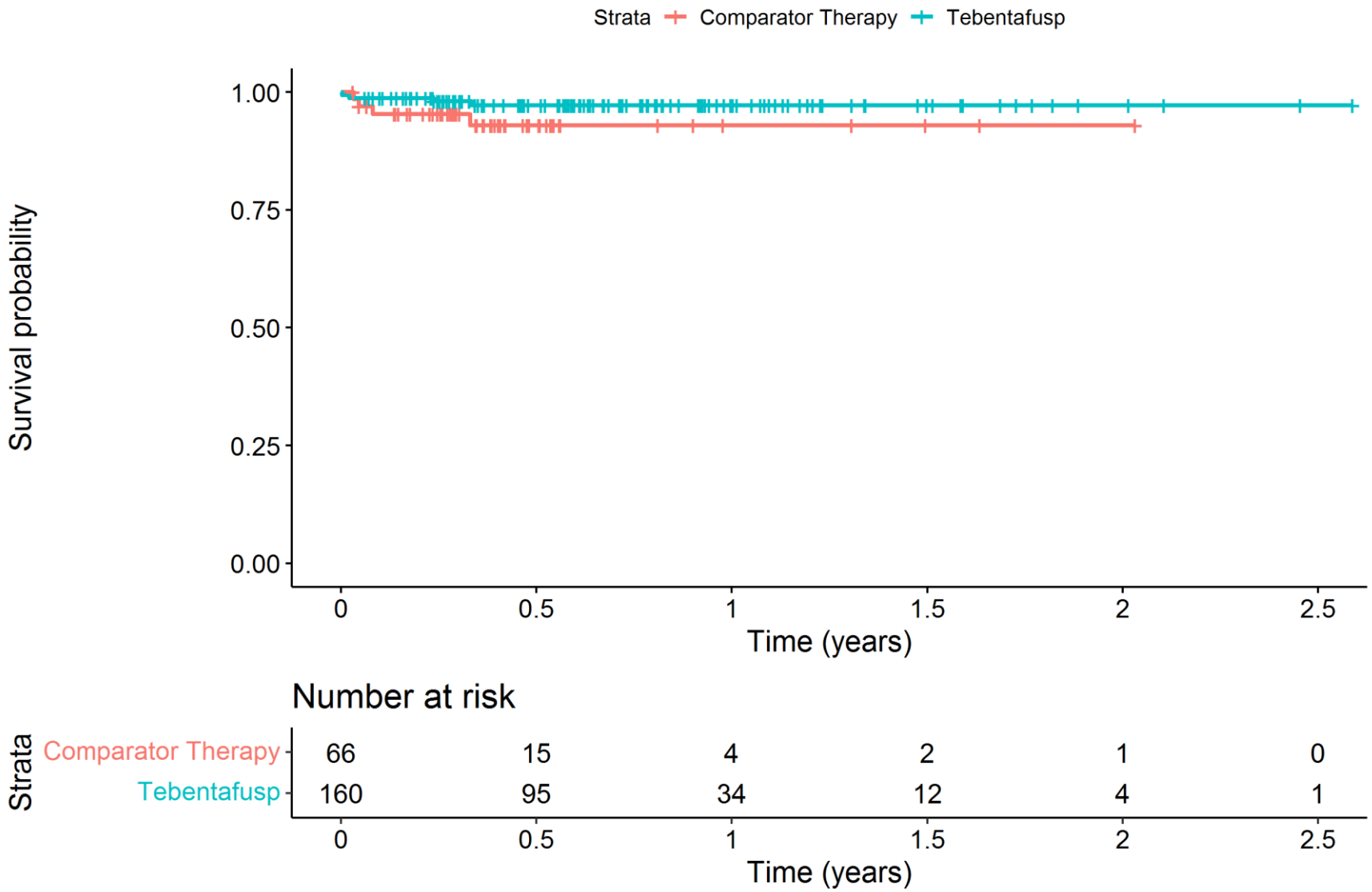
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion ≥8,1 cm



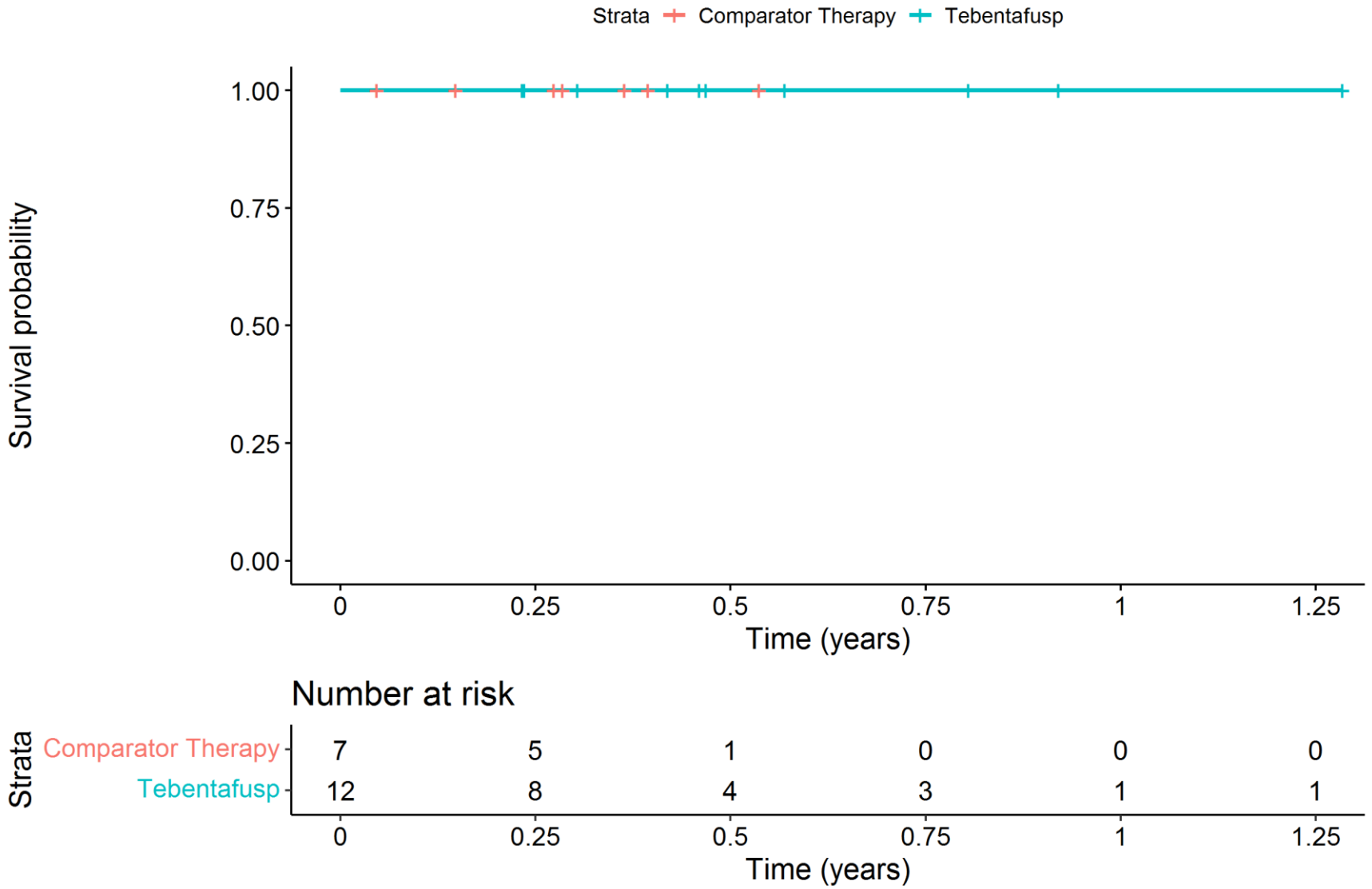
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nordamerika



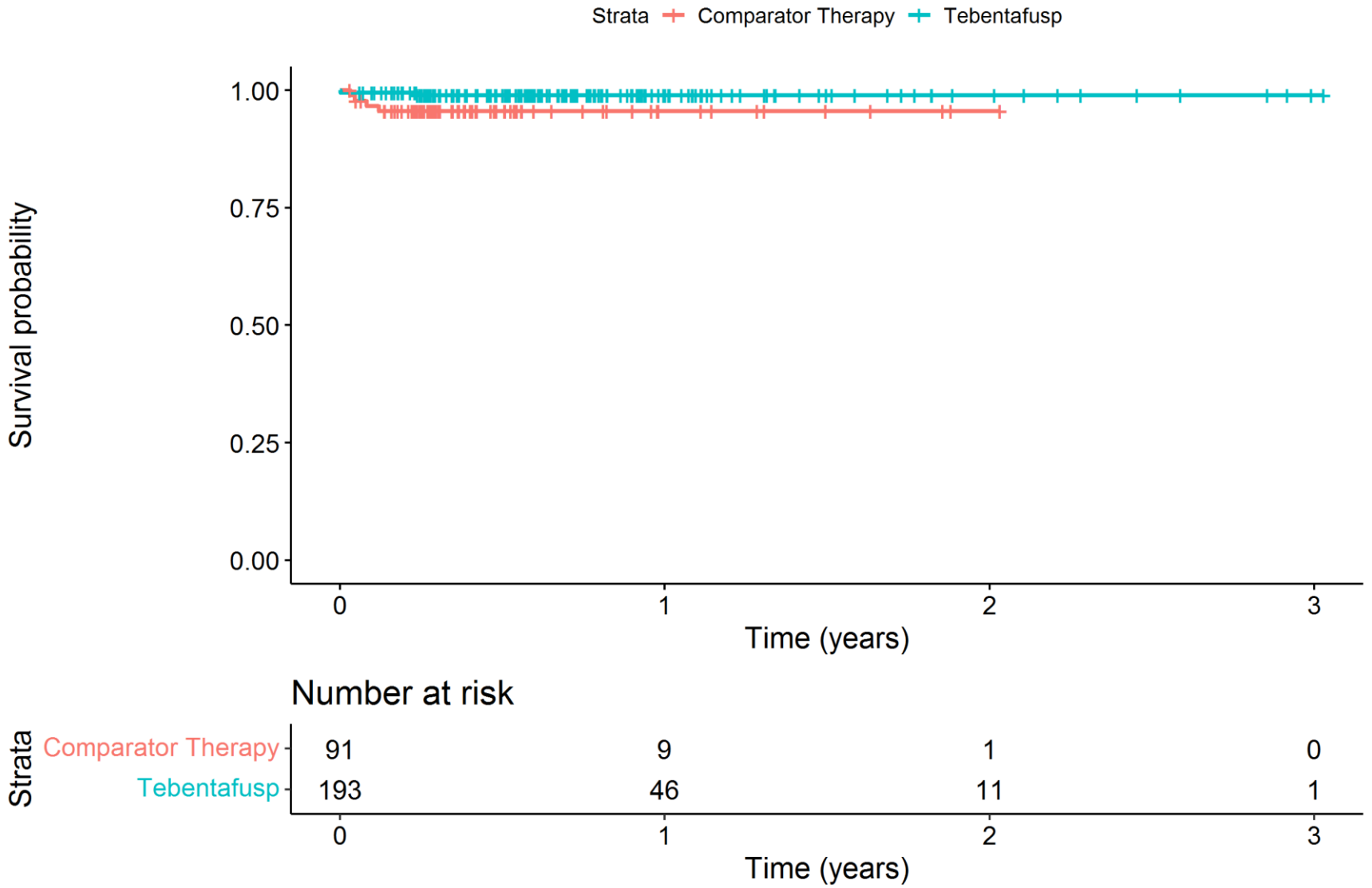
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nicht-Nordamerika



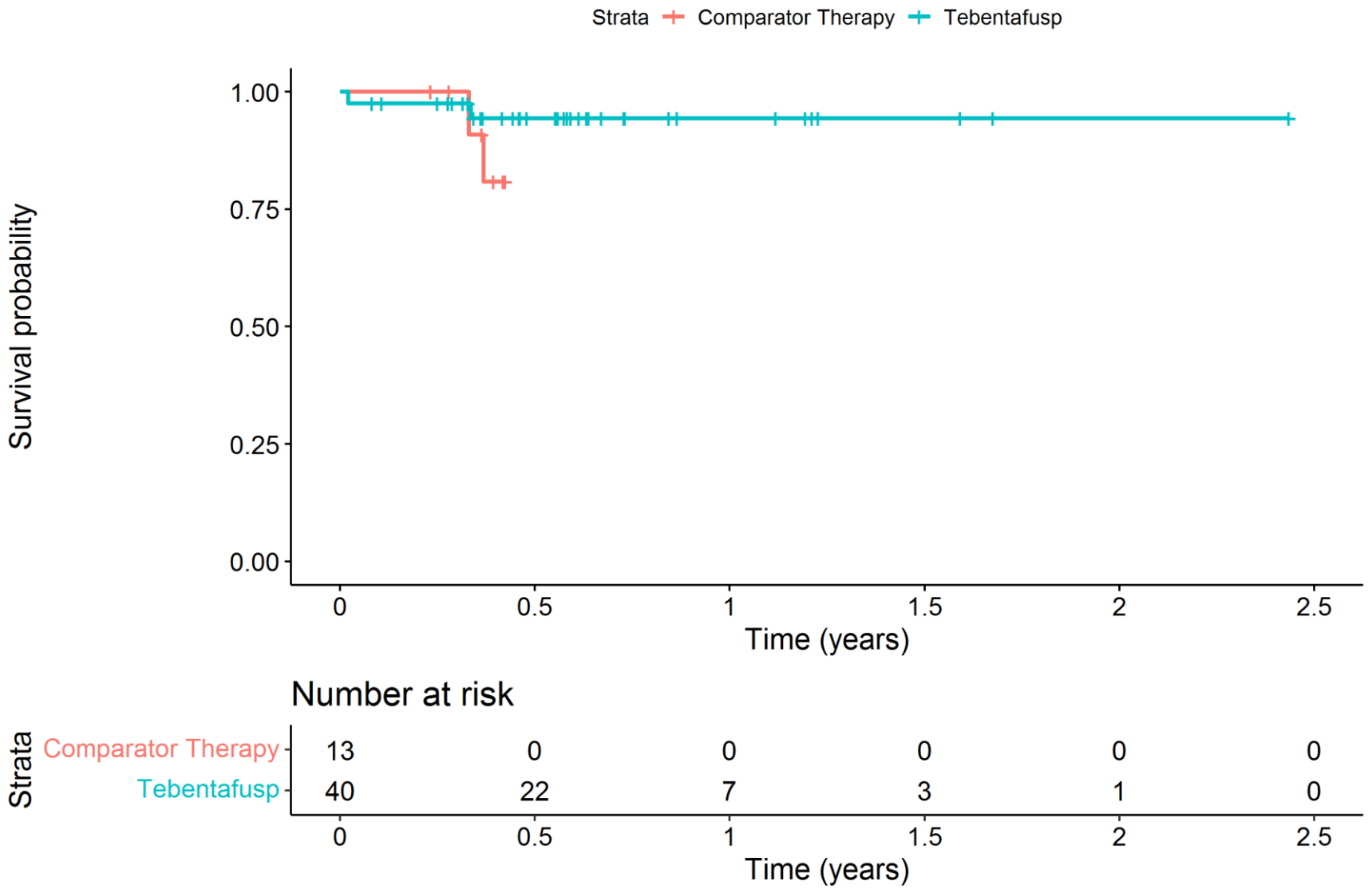
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Dacarbazin



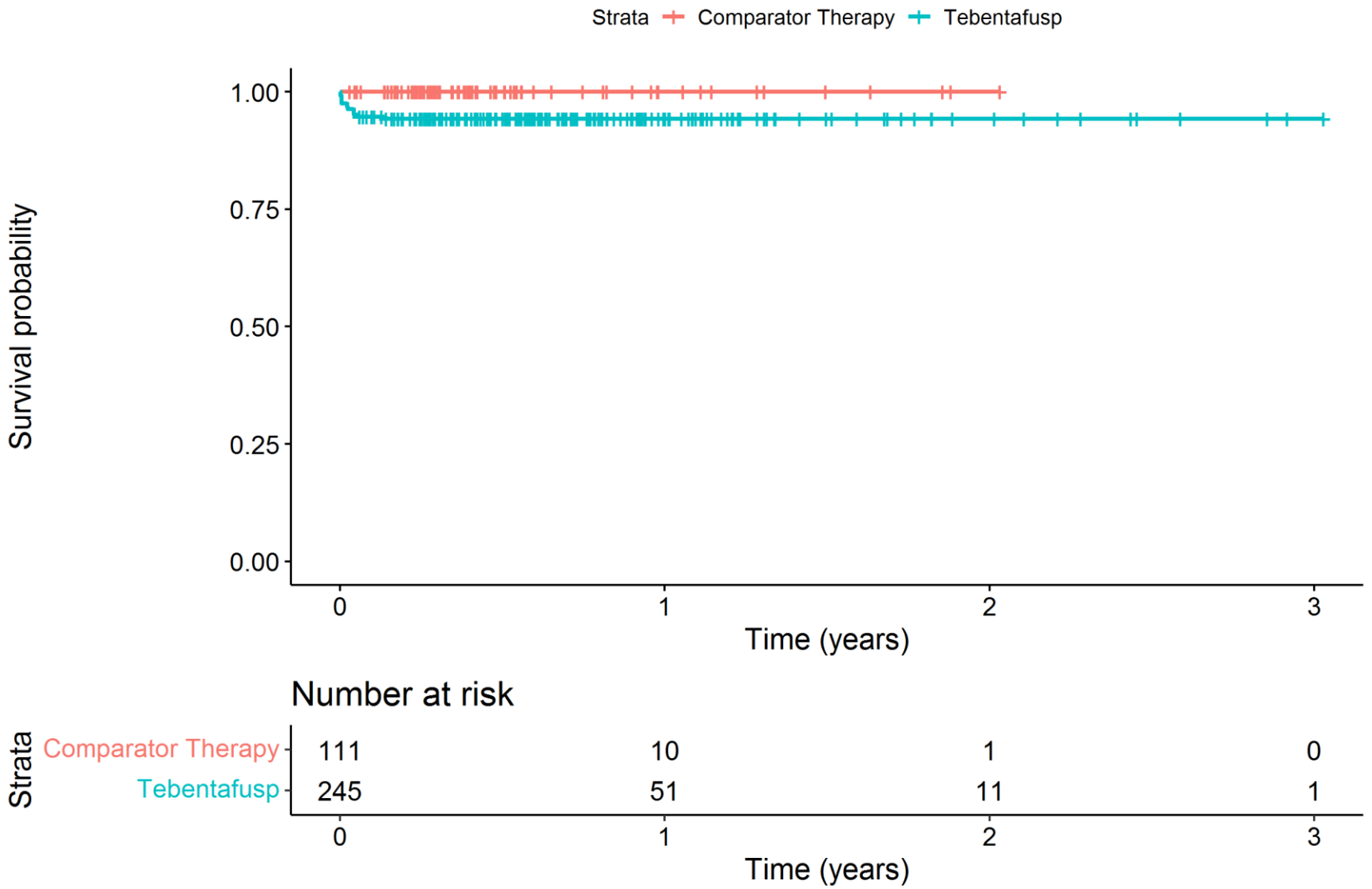
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Pembrolizumab



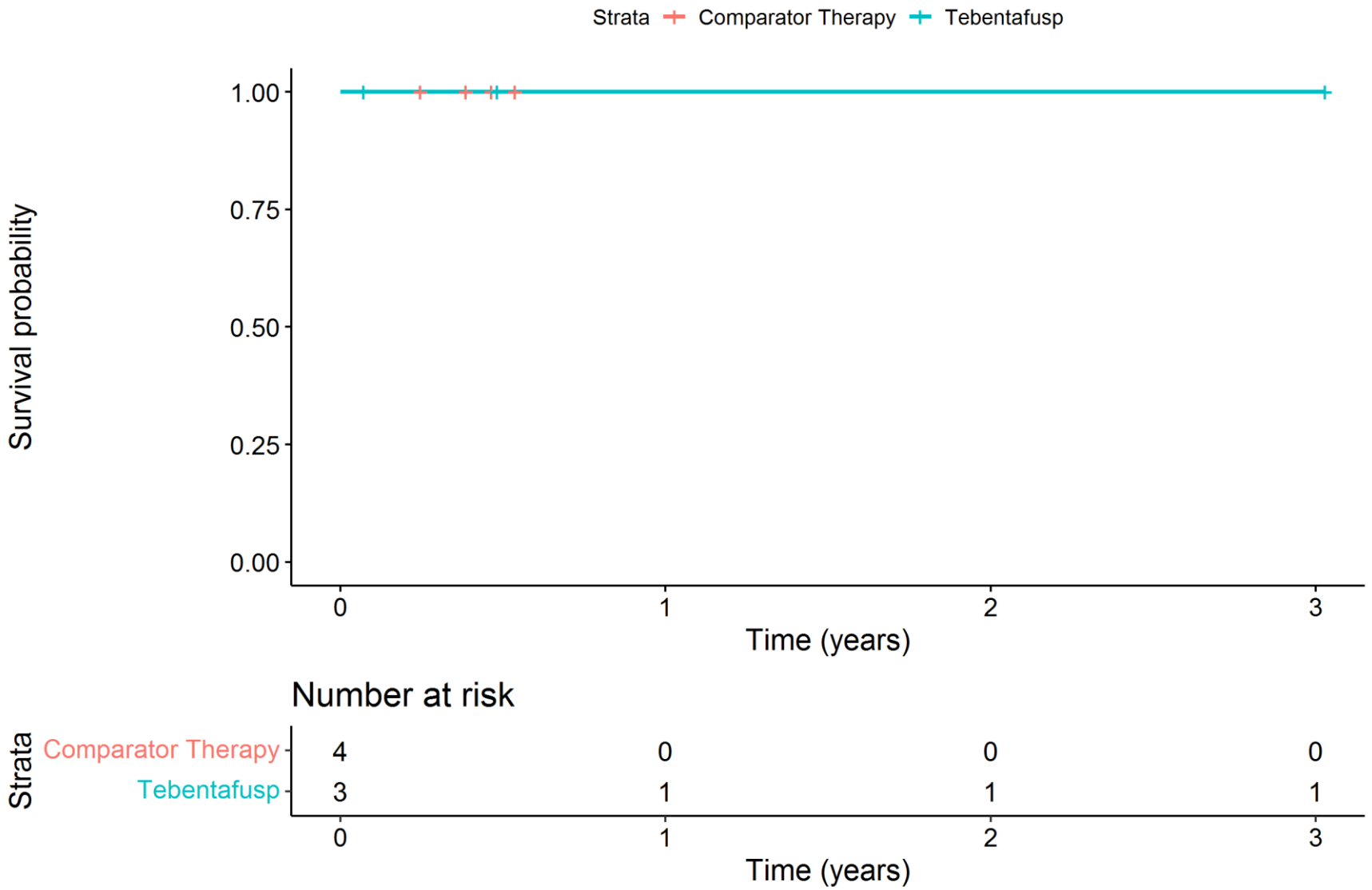
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Ipilimumab



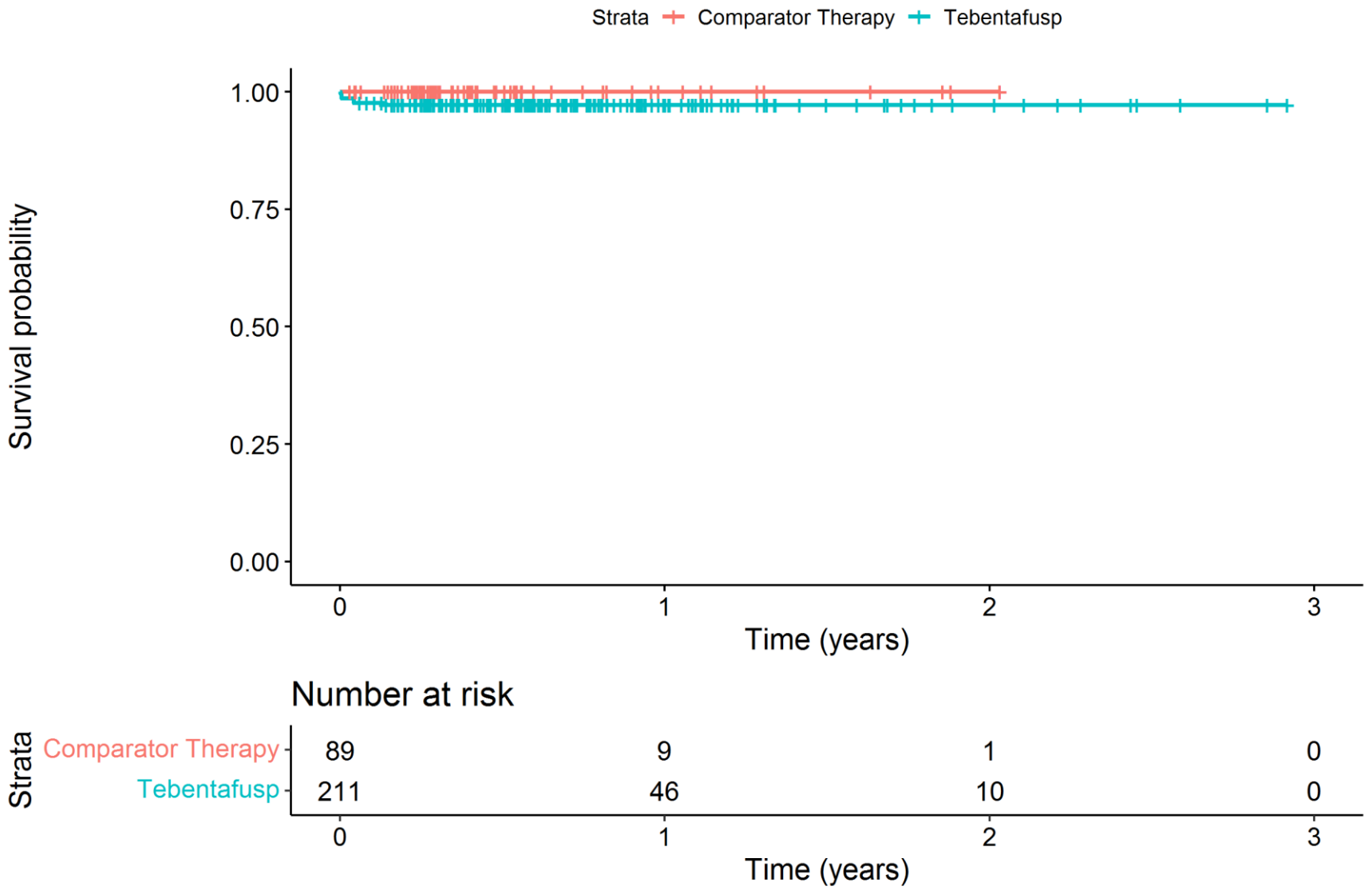
Erkrankungen der Haut und des Unterhautgewebes - Gesamt



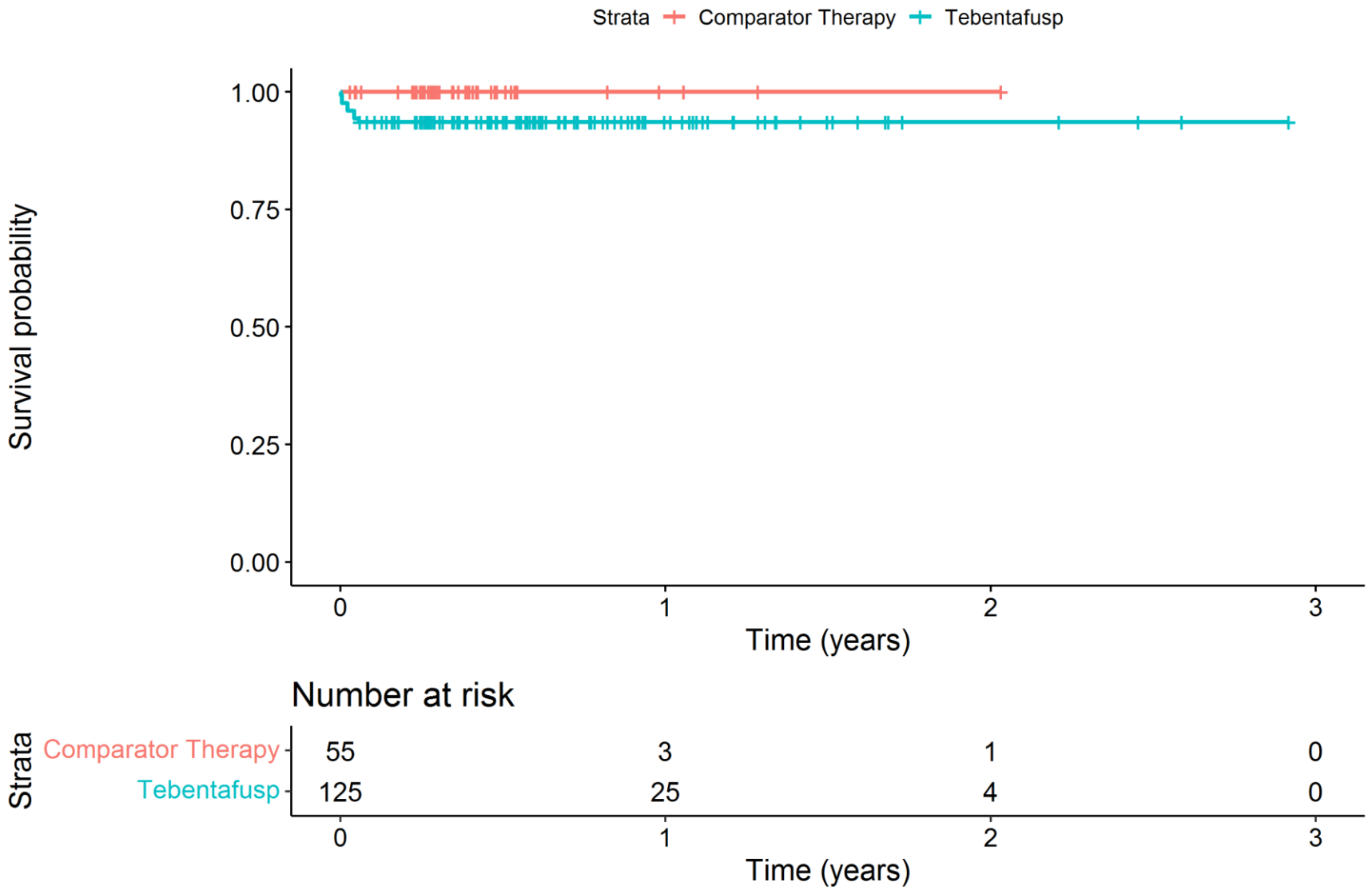
Erkrankungen der Haut und des Unterhautgewebes - Hispanisch



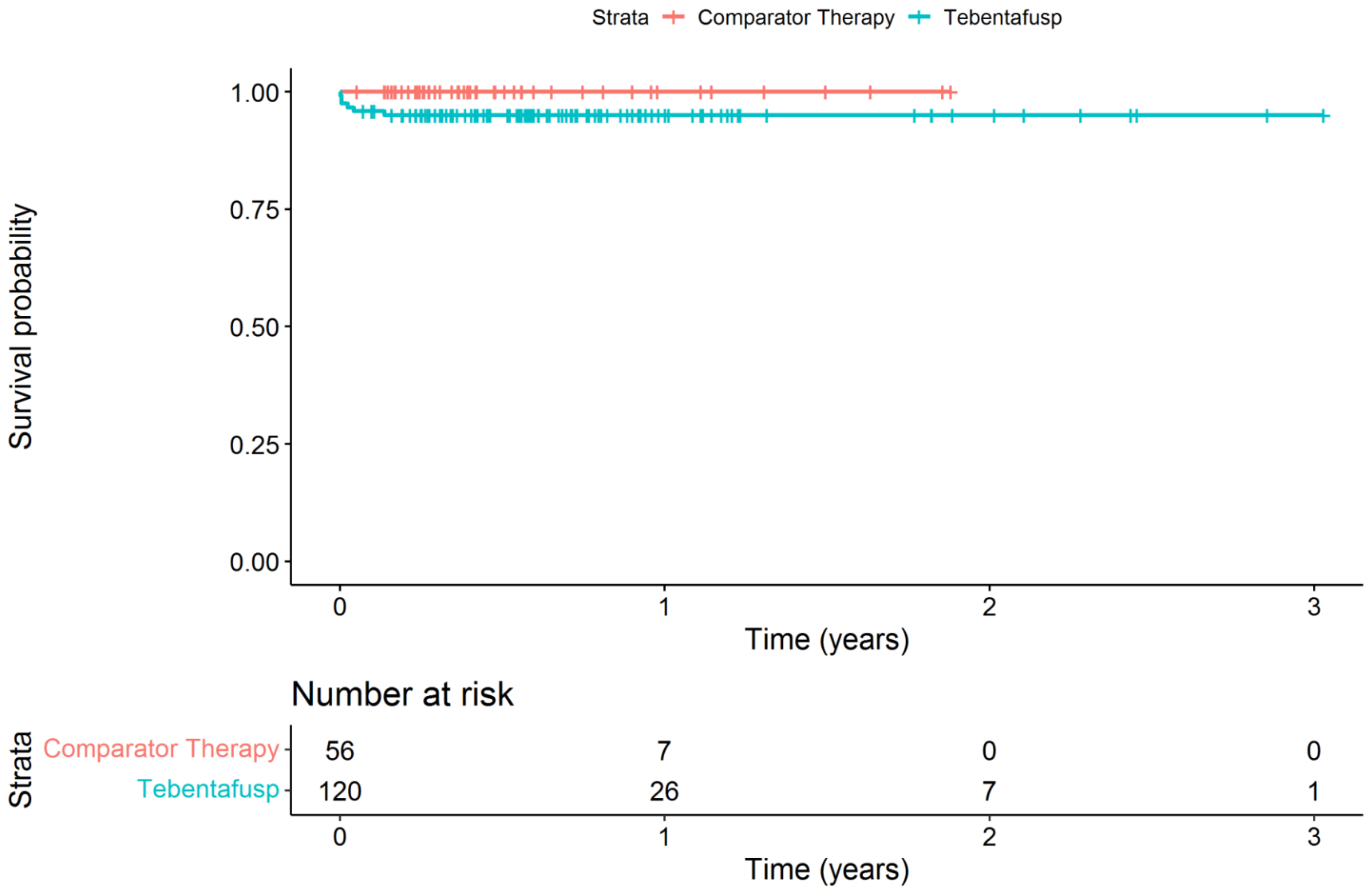
Erkrankungen der Haut und des Unterhautgewebes - Nicht-hispanisch



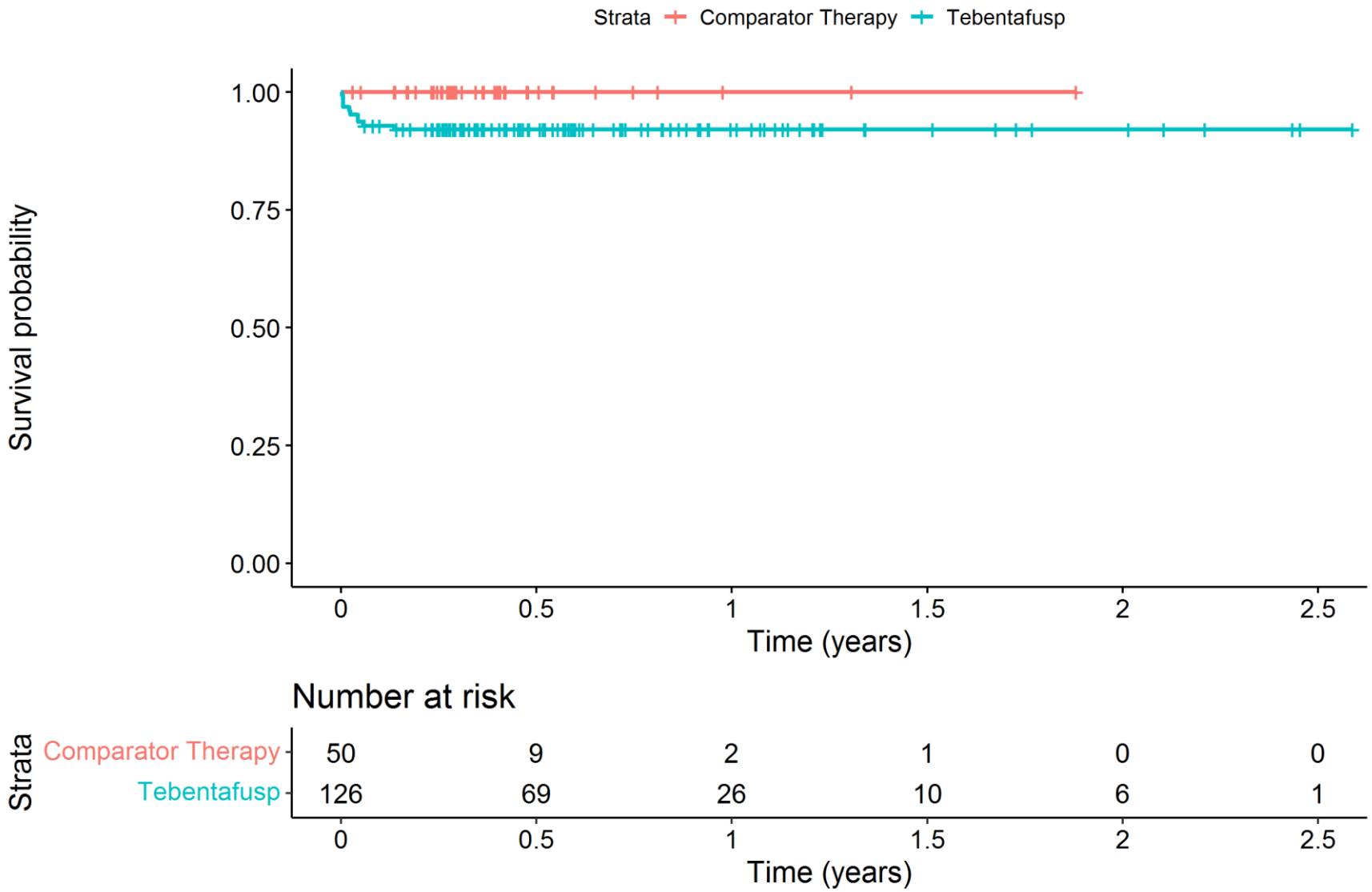
Erkrankungen der Haut und des Unterhautgewebes - Männlich



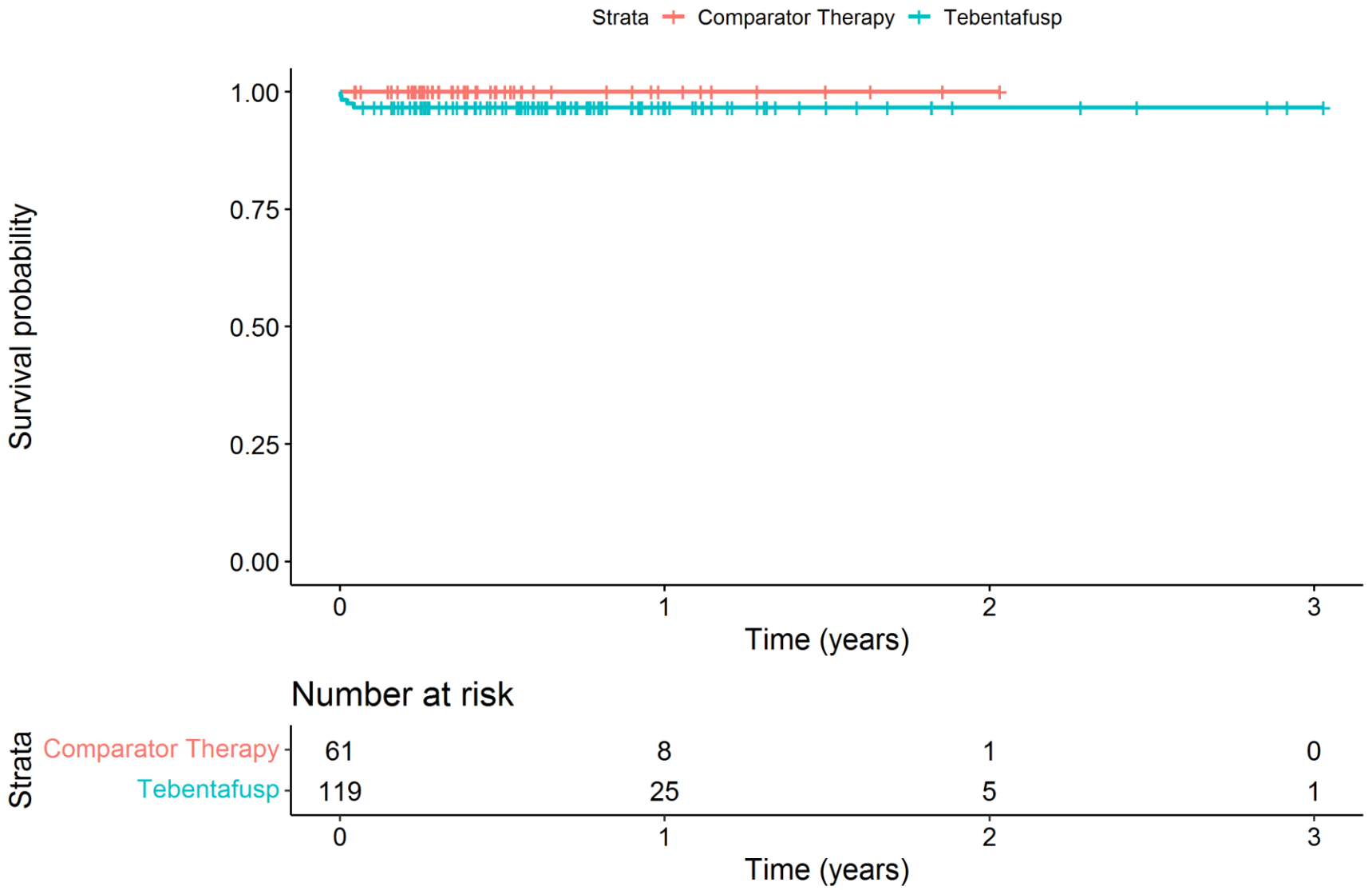
Erkrankungen der Haut und des Unterhautgewebes - Weiblich



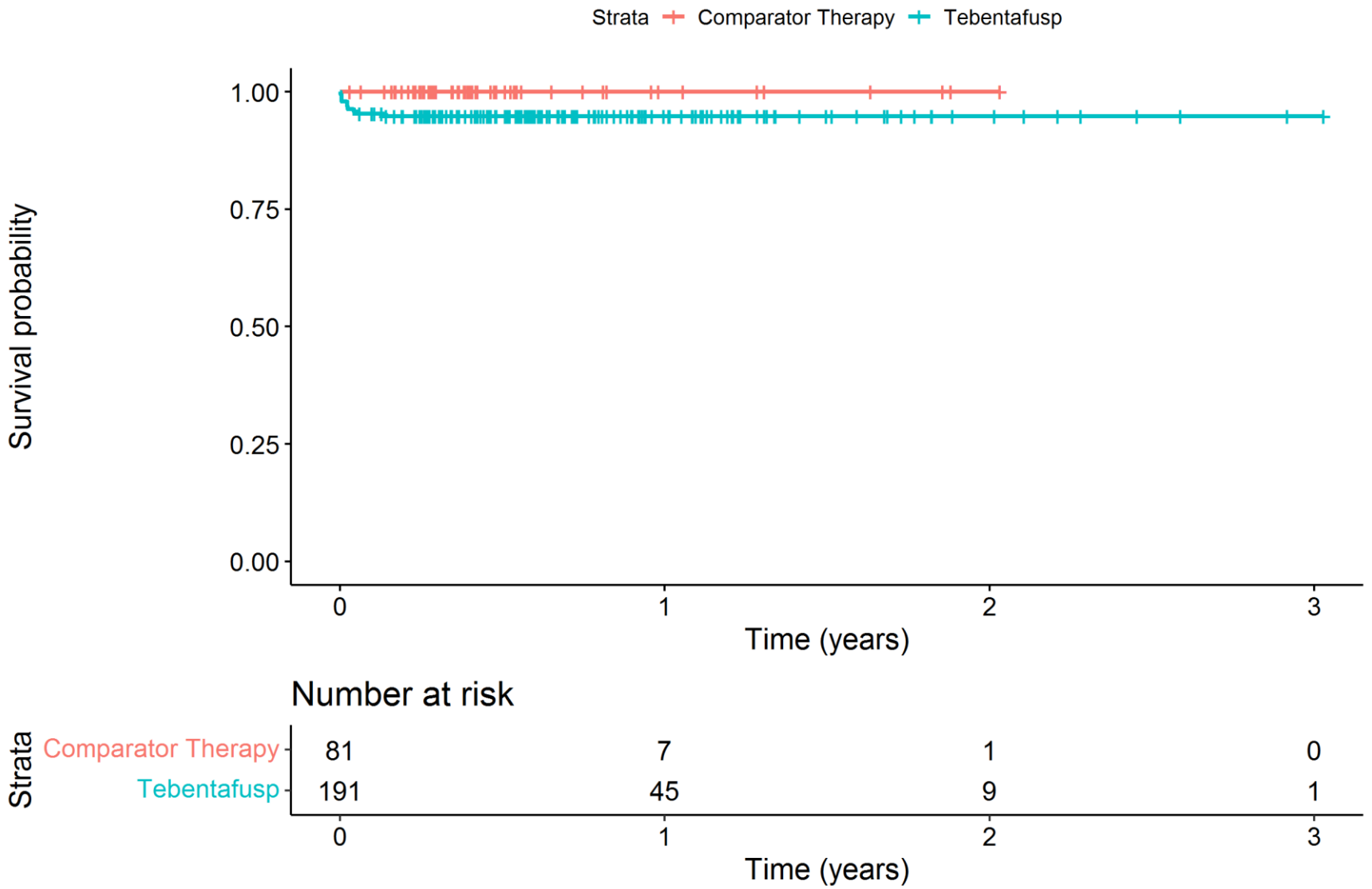
Erkrankungen der Haut und des Unterhautgewebes - <65



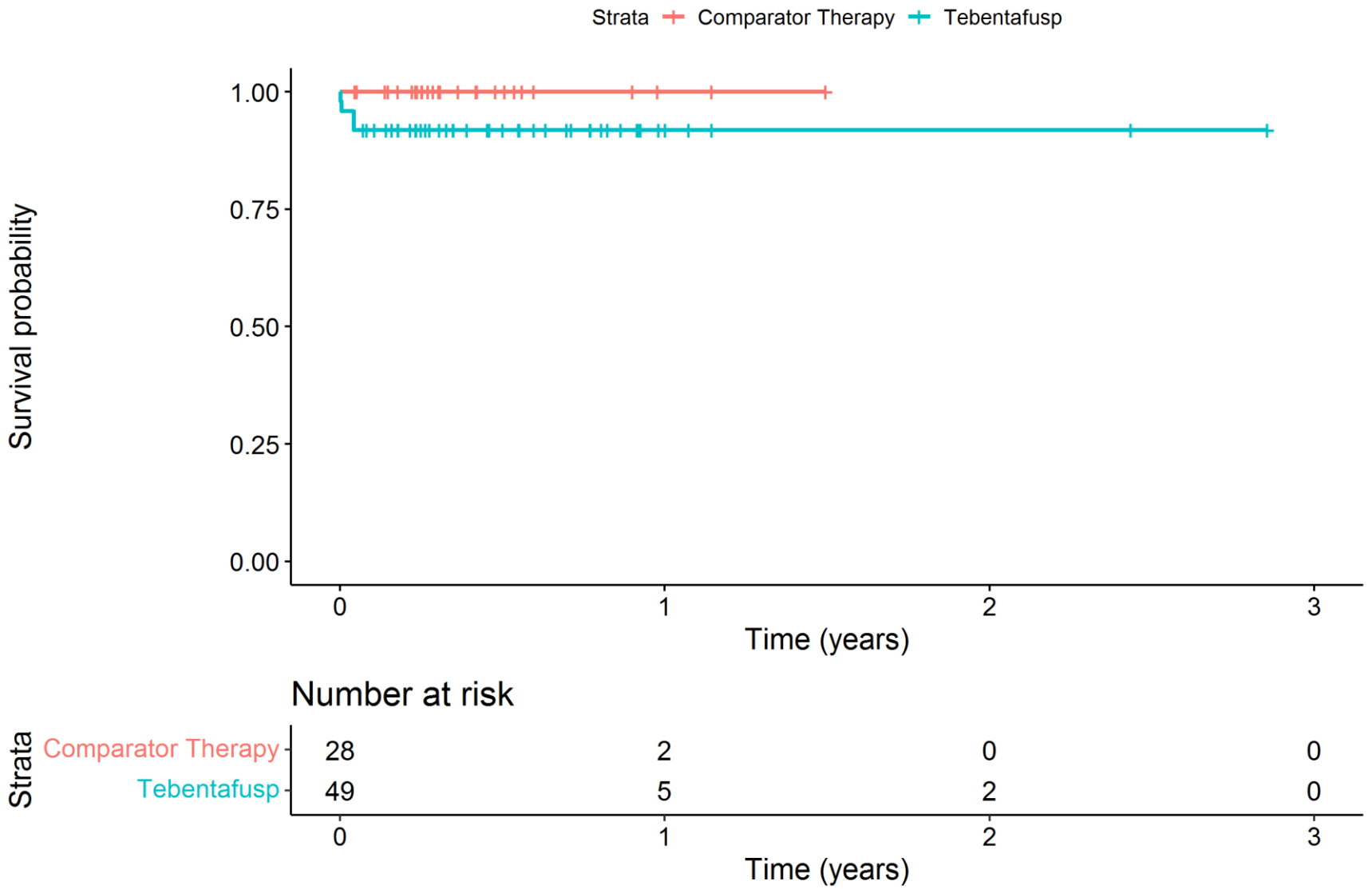
Erkrankungen der Haut und des Unterhautgewebes - ≥65



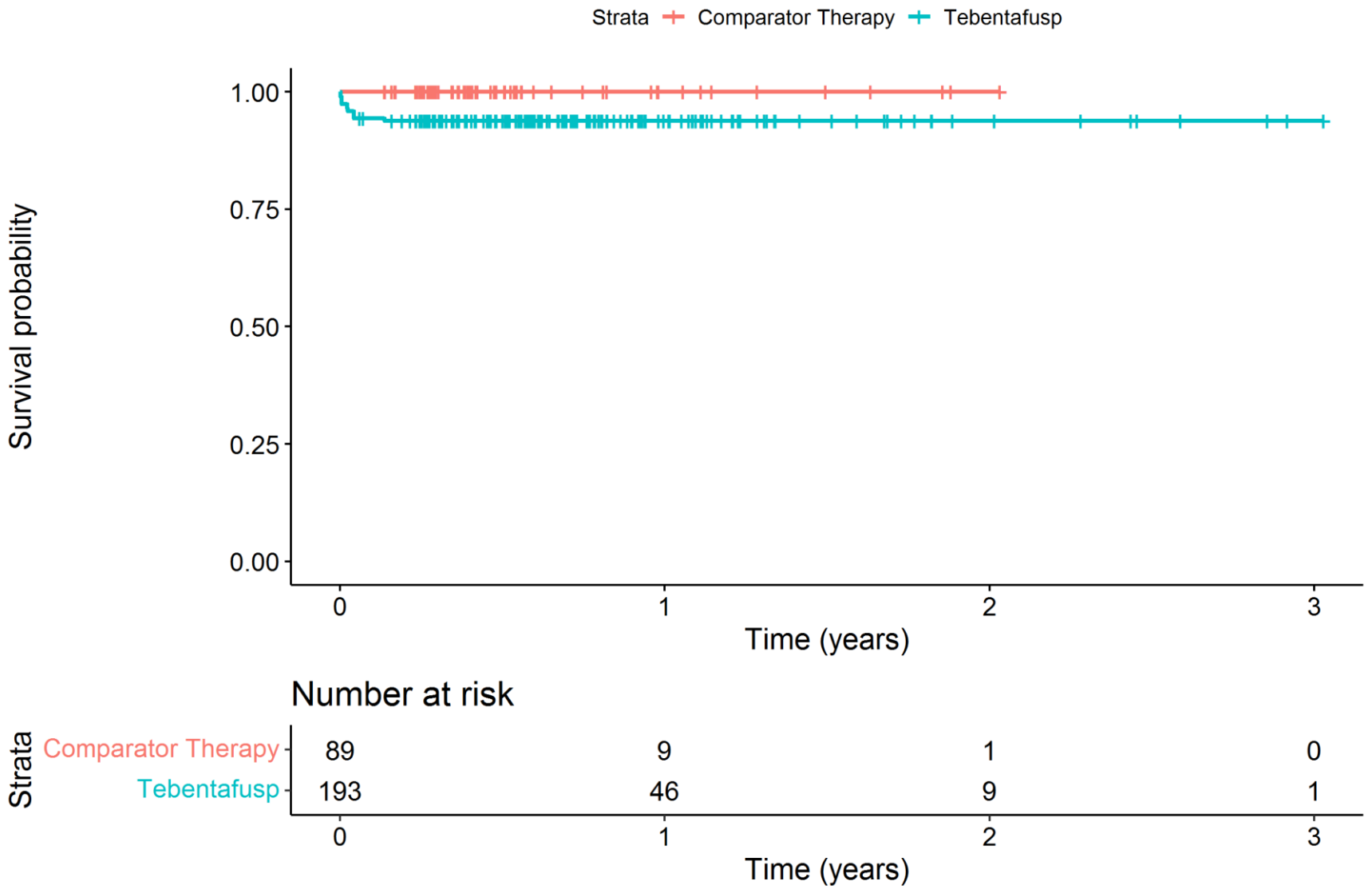
Erkrankungen der Haut und des Unterhautgewebes - ECOG 0



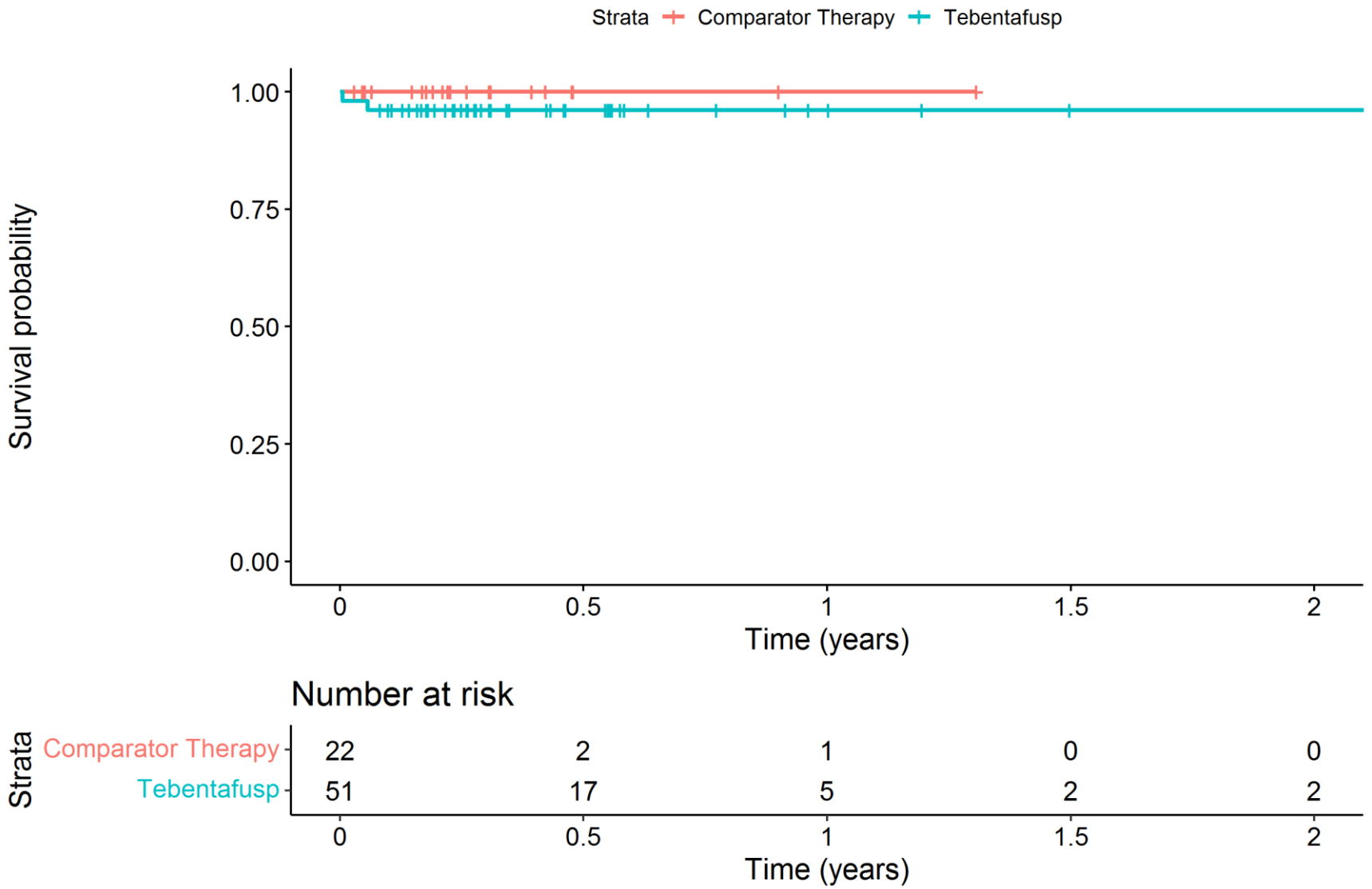
Erkrankungen der Haut und des Unterhautgewebes - ECOG 1



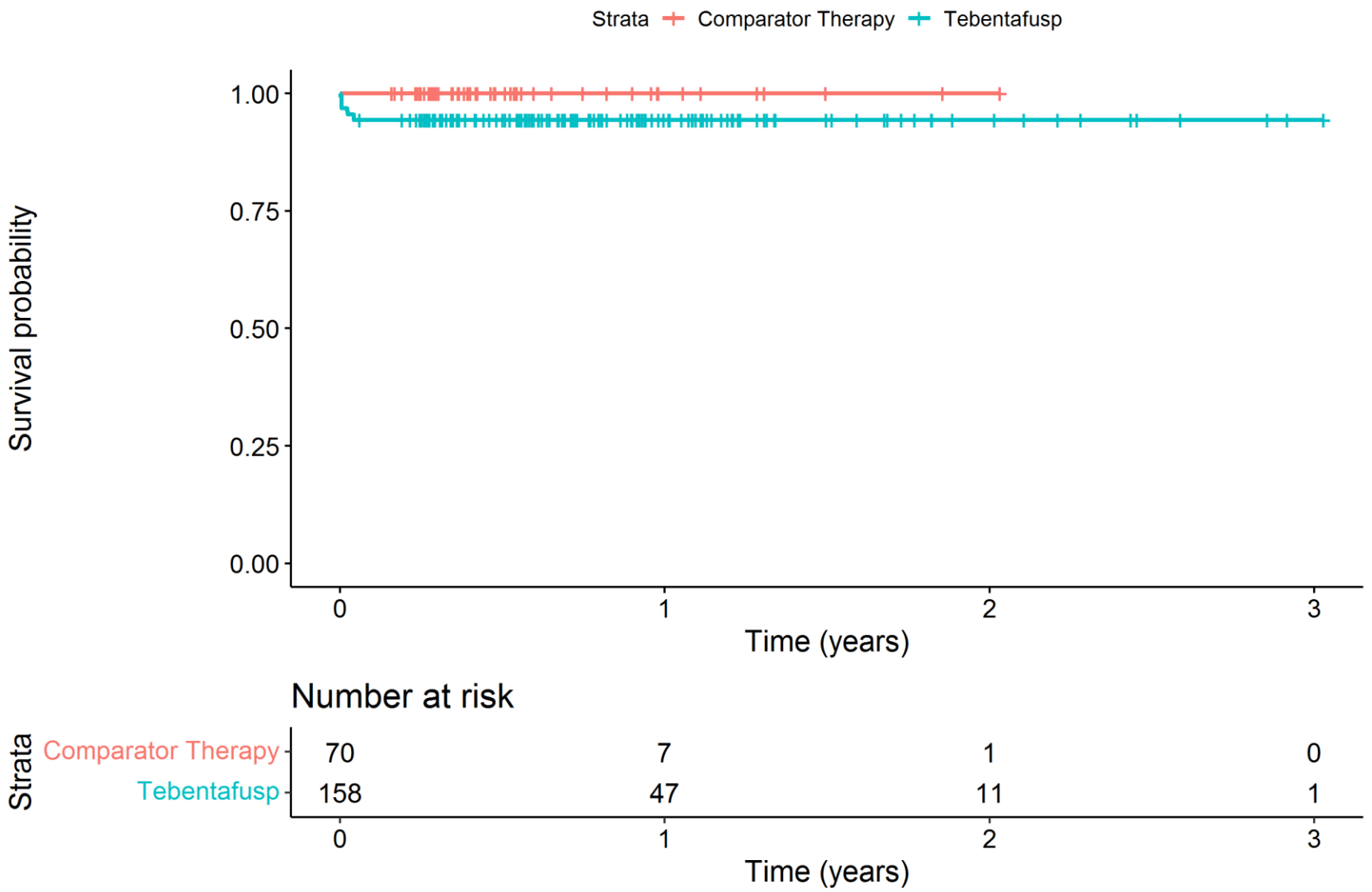
Erkrankungen der Haut und des Unterhautgewebes - ALP ≤ ULN



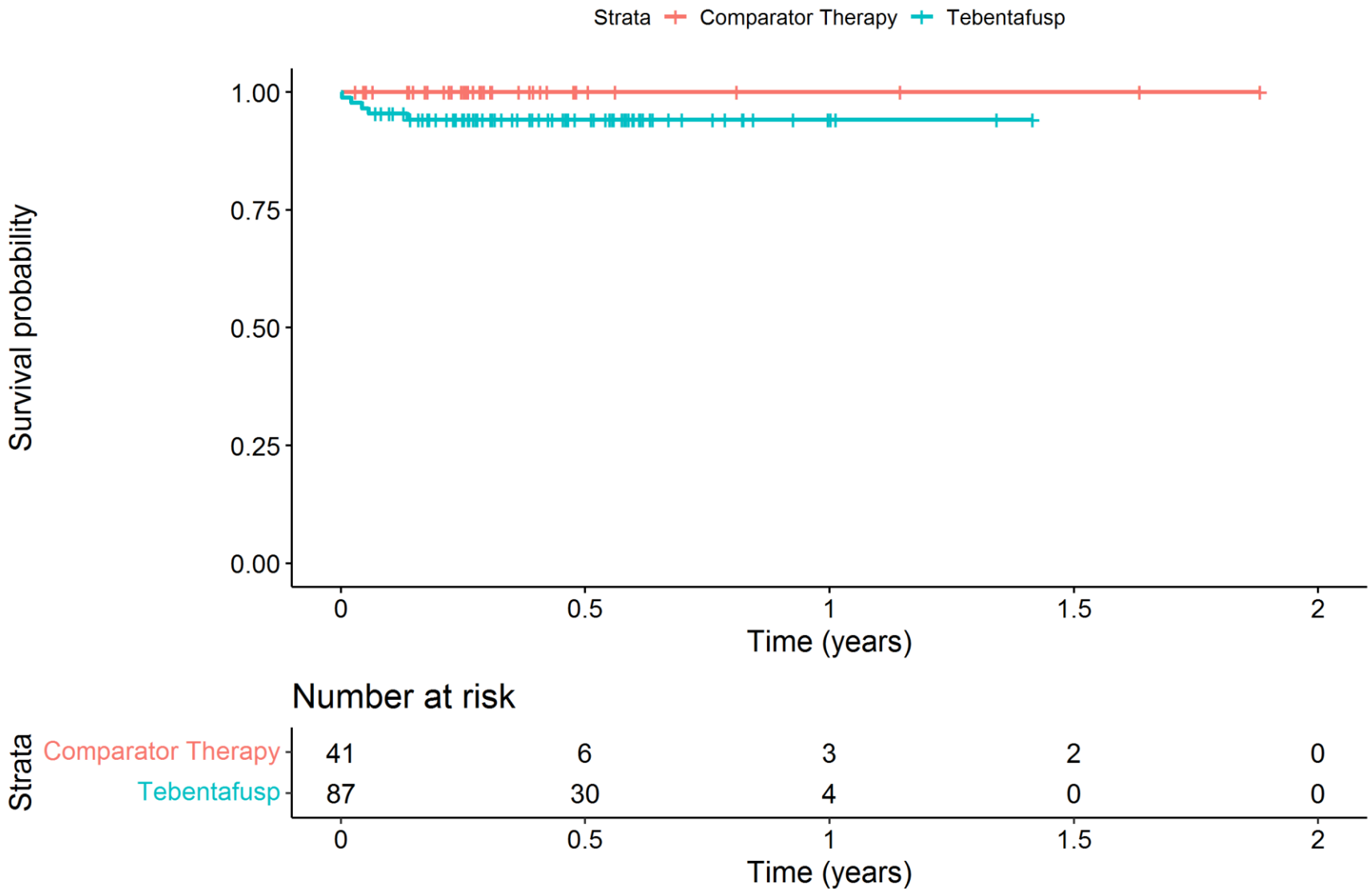
Erkrankungen der Haut und des Unterhautgewebes - ALP > ULN



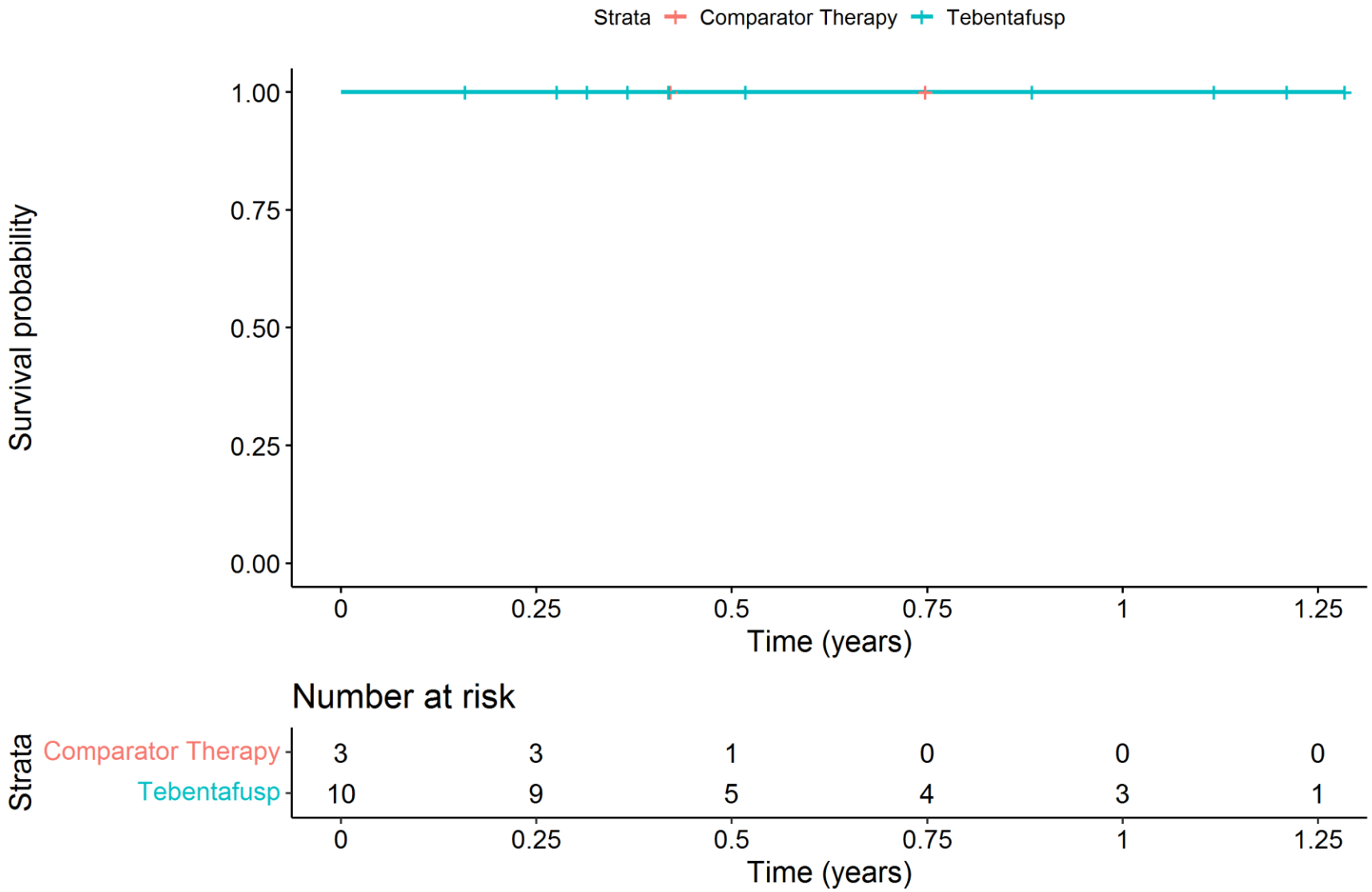
Erkrankungen der Haut und des Unterhautgewebes - LDH =< ULN



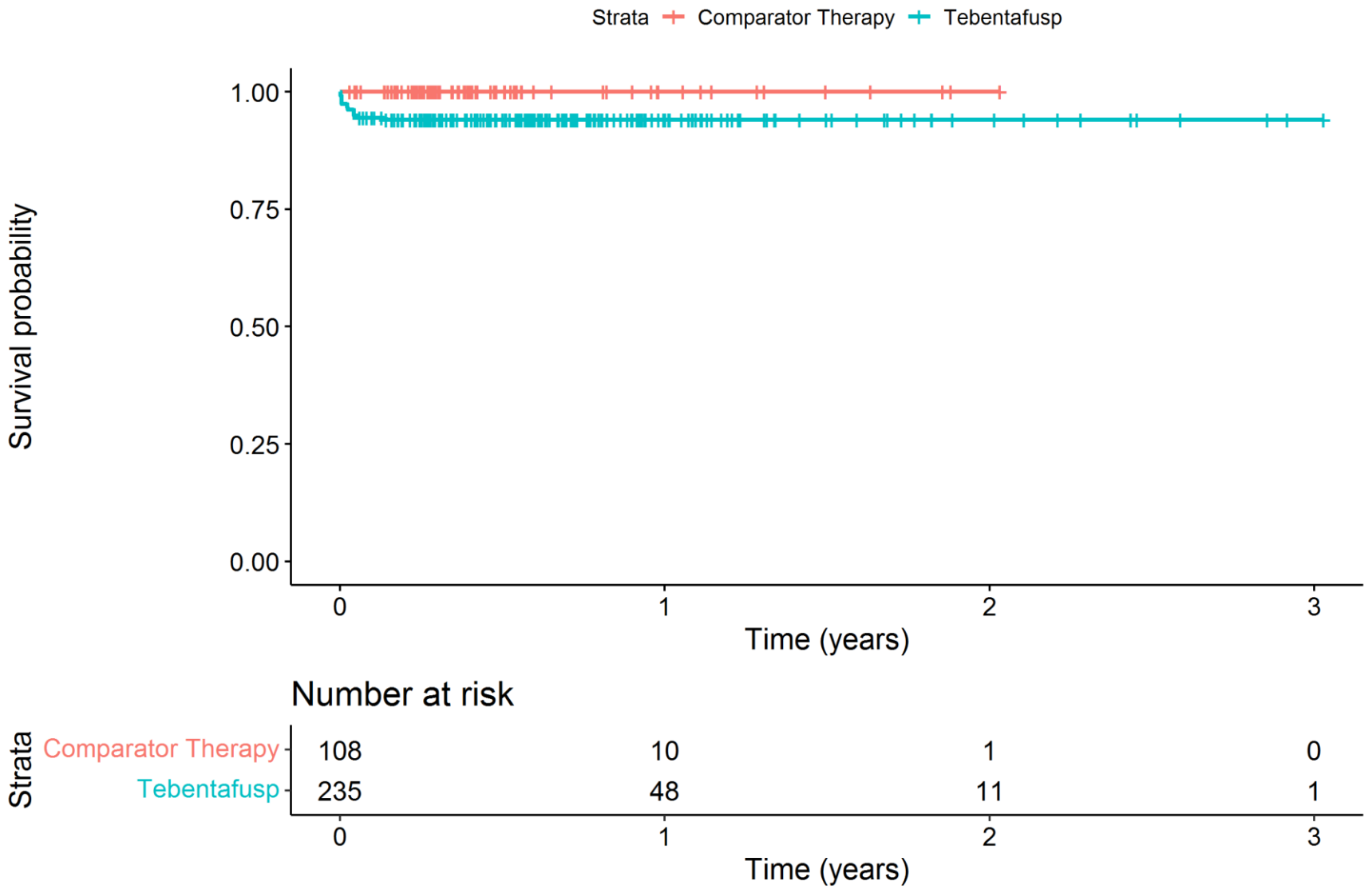
Erkrankungen der Haut und des Unterhautgewebes - LDH > ULN



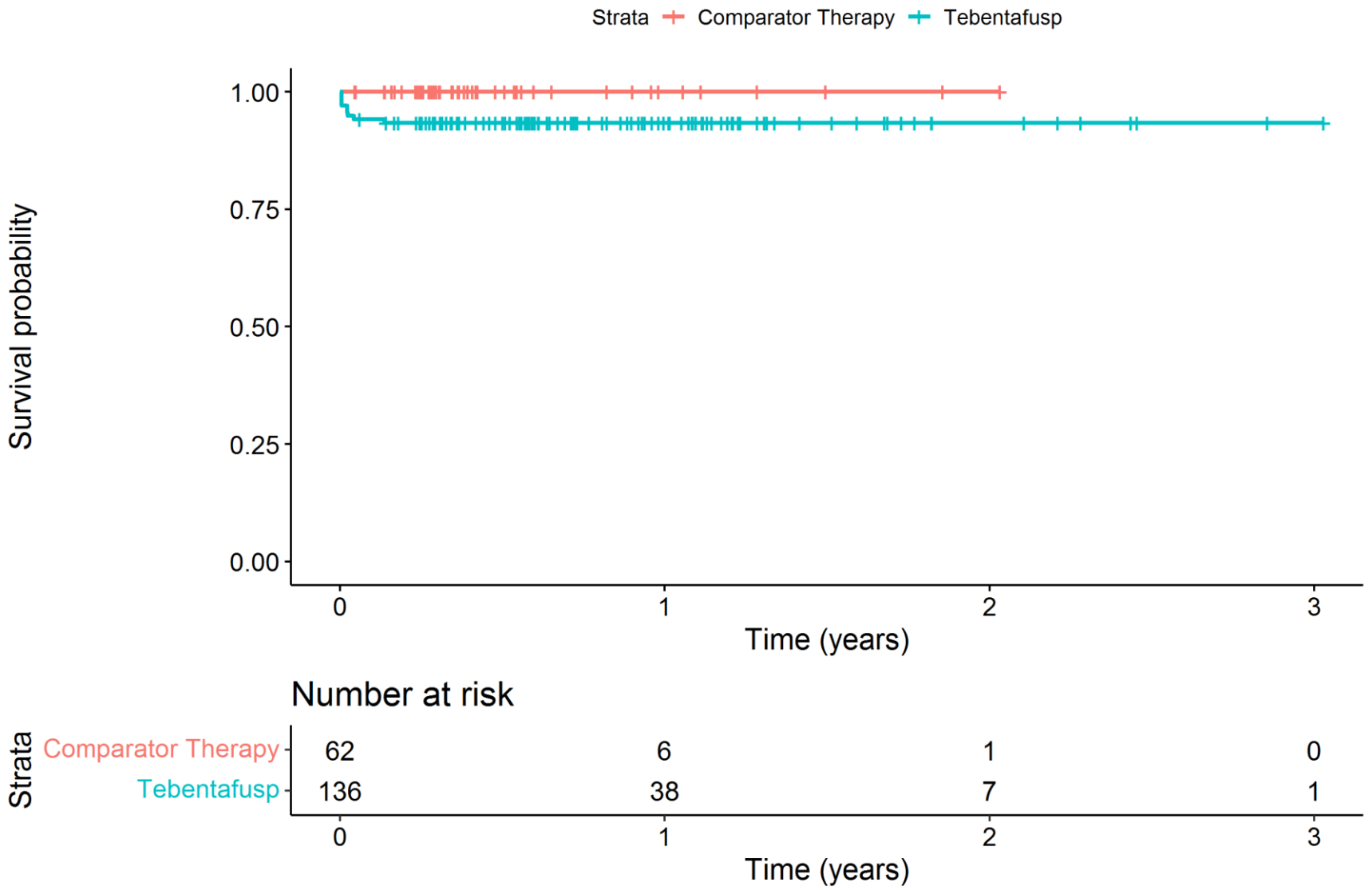
Erkrankungen der Haut und des Unterhautgewebes - Vorherige Therapie adjuvant/neoadjuvant



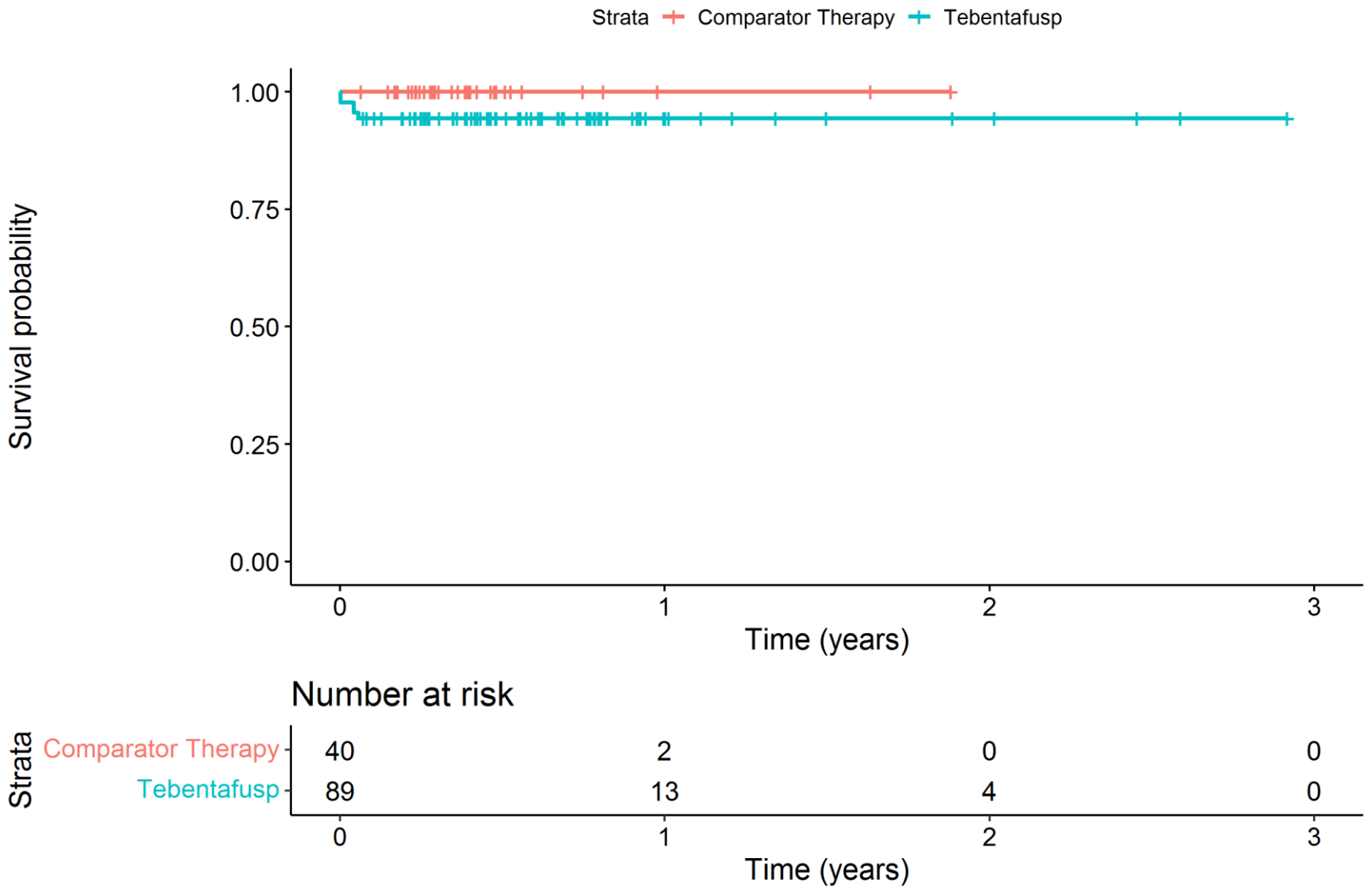
Erkrankungen der Haut und des Unterhautgewebes - Keine vorherige Therapie adjuvant/neoadjuvant



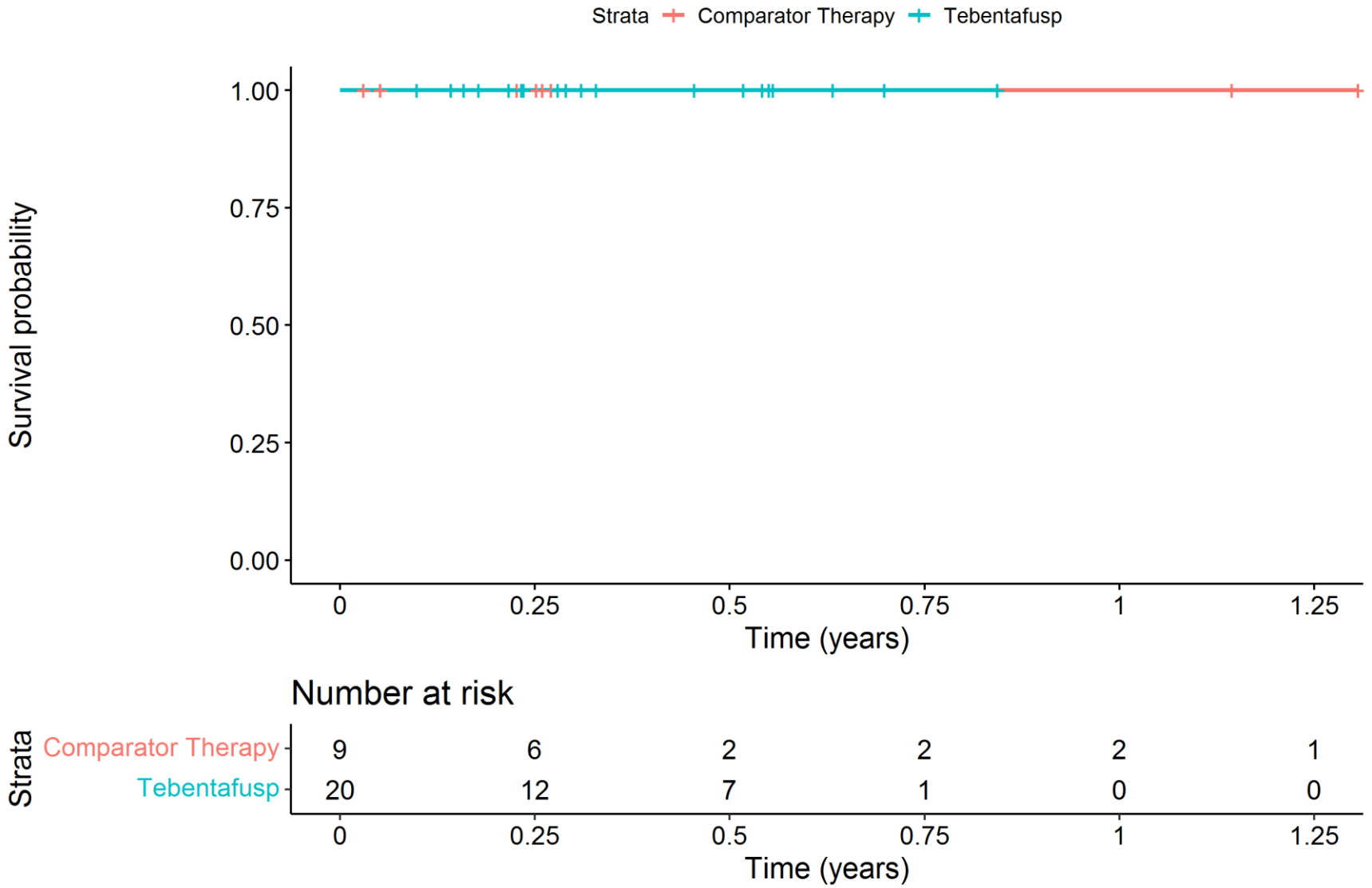
Erkrankungen der Haut und des Unterhautgewebes - Läsion ≤ 3cm



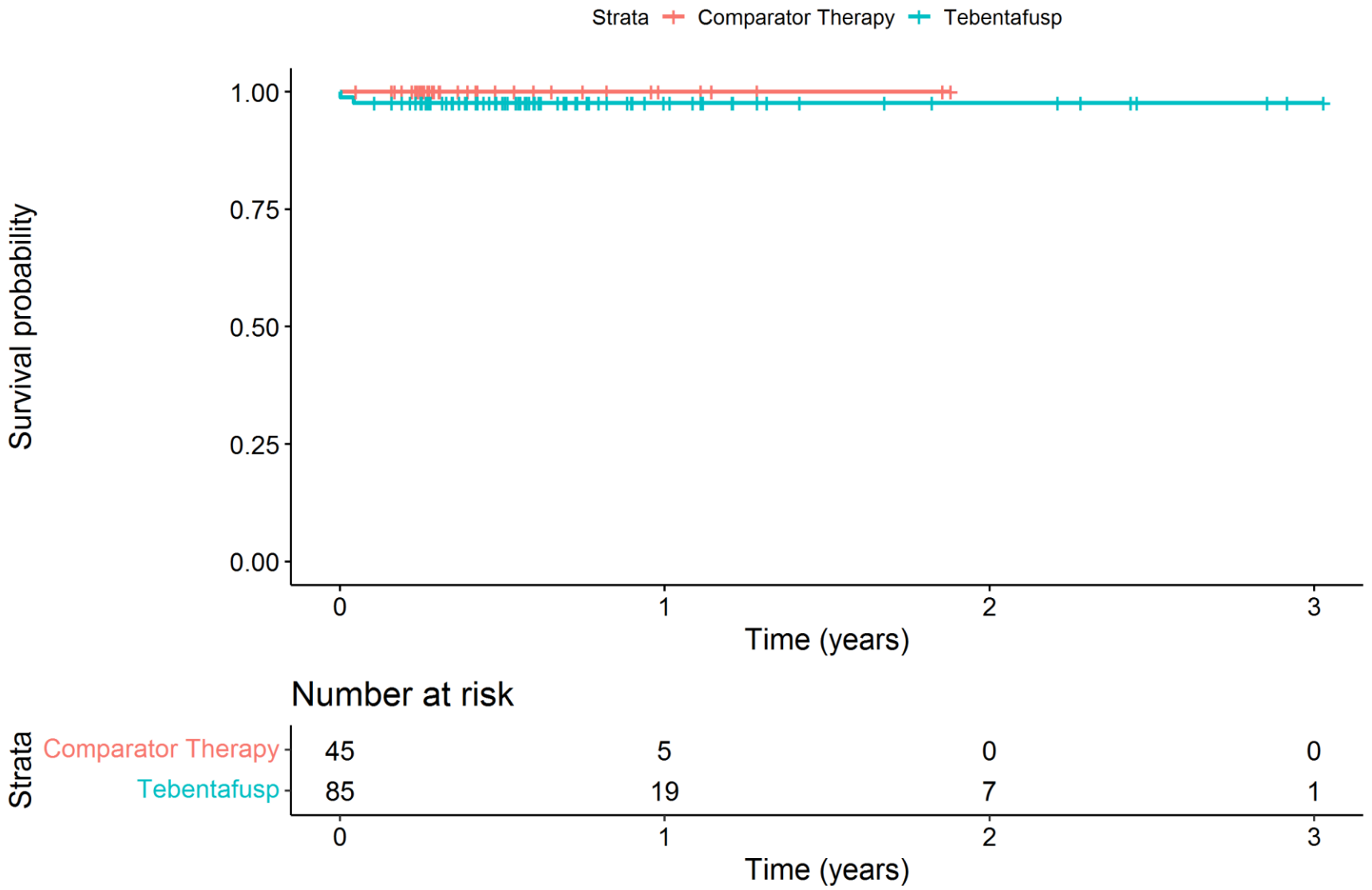
Erkrankungen der Haut und des Unterhautgewebes - Läsion 3,1-8,0 cm



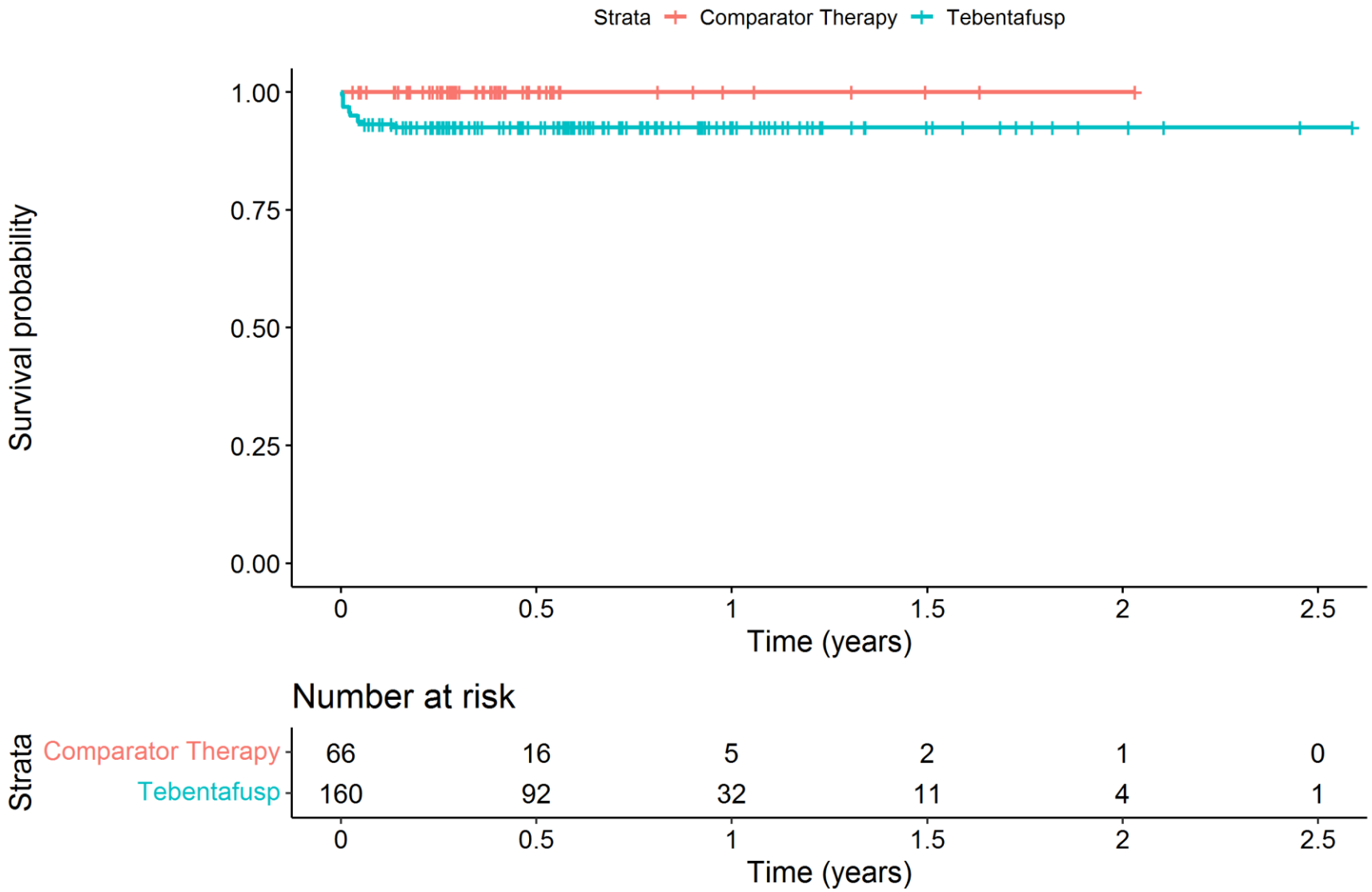
Erkrankungen der Haut und des Unterhautgewebes - Läsion ≥8,1 cm



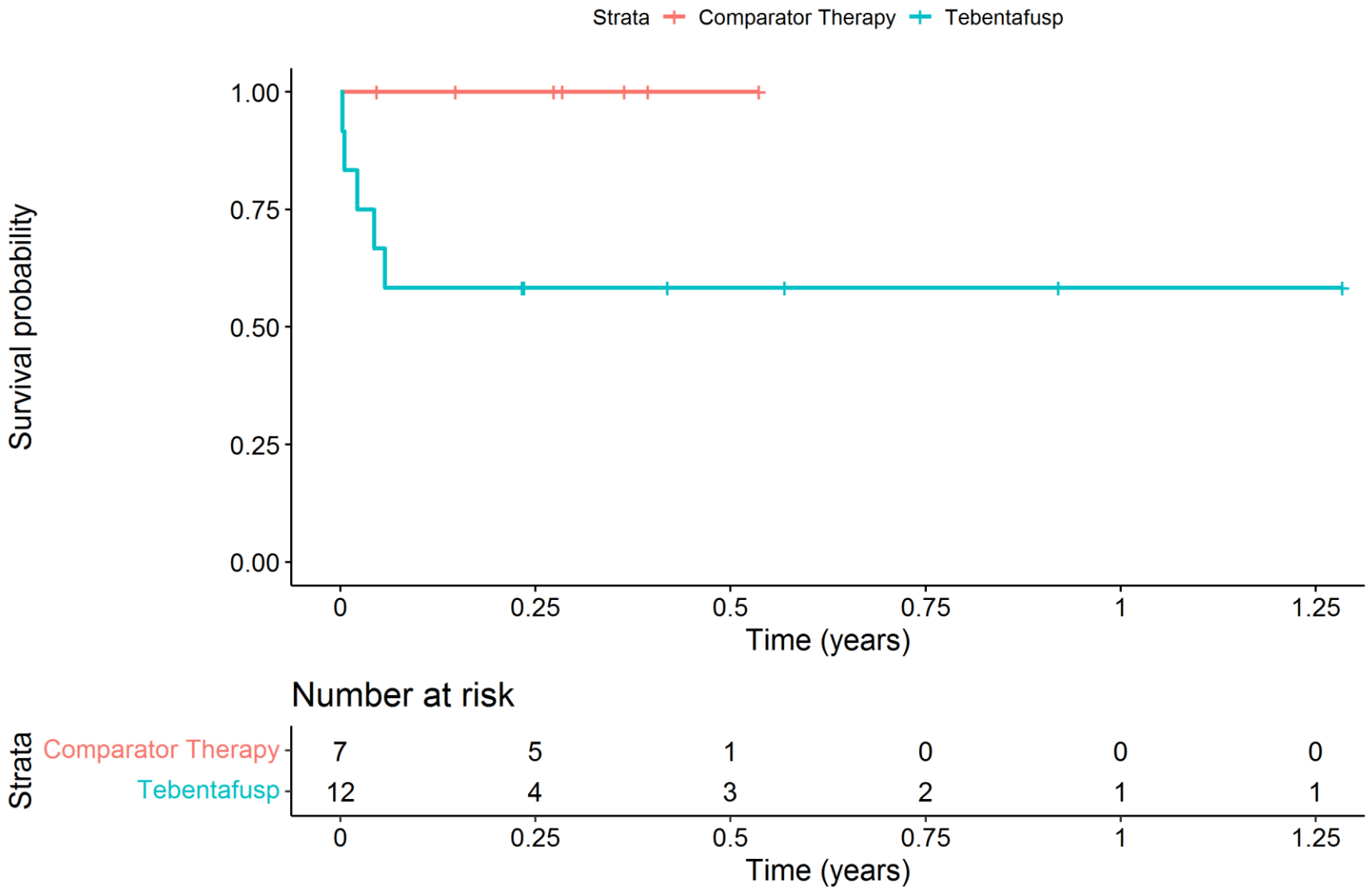
Erkrankungen der Haut und des Unterhautgewebes - Nordamerika



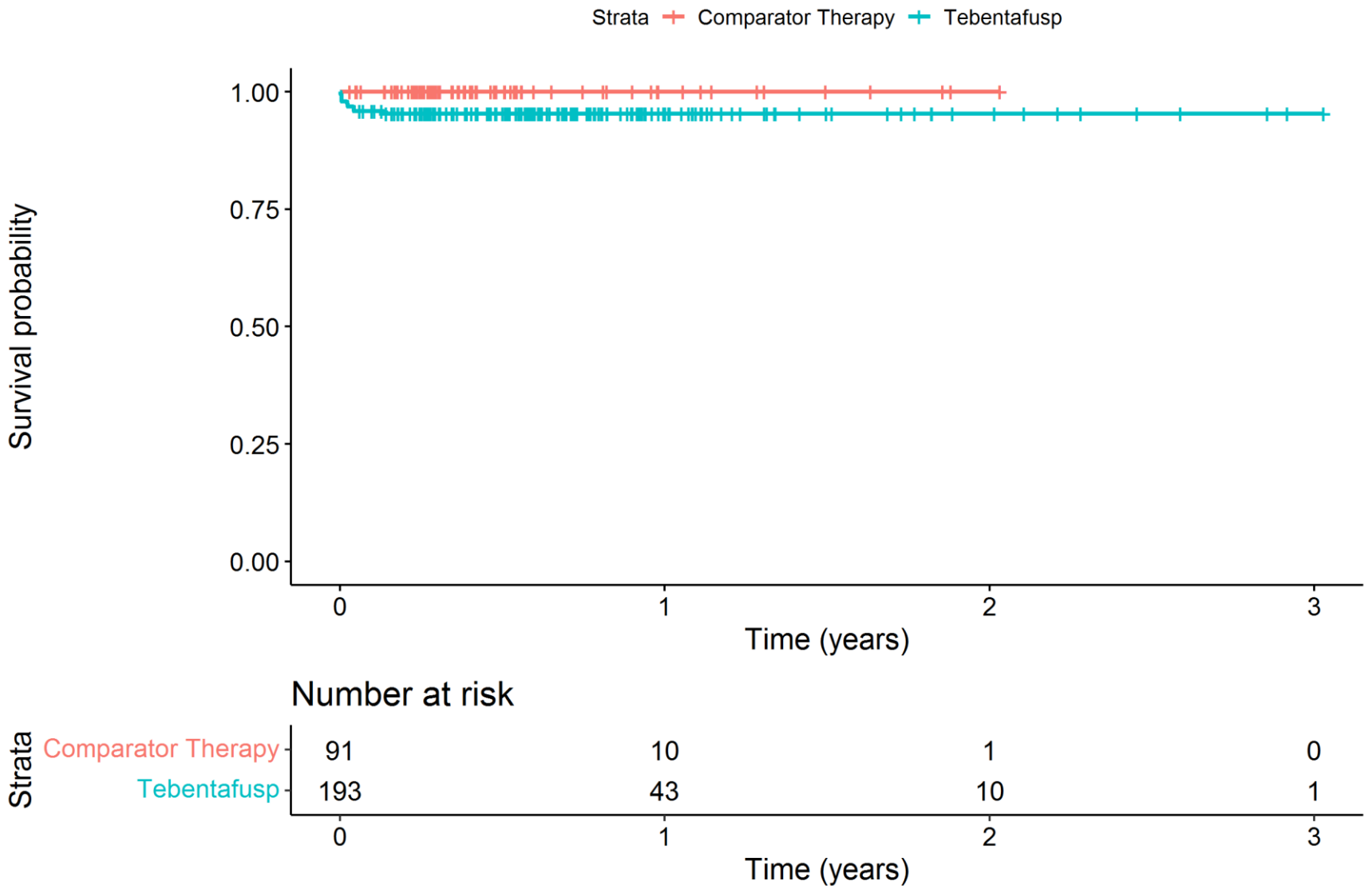
Erkrankungen der Haut und des Unterhautgewebes - Nicht-Nordamerika



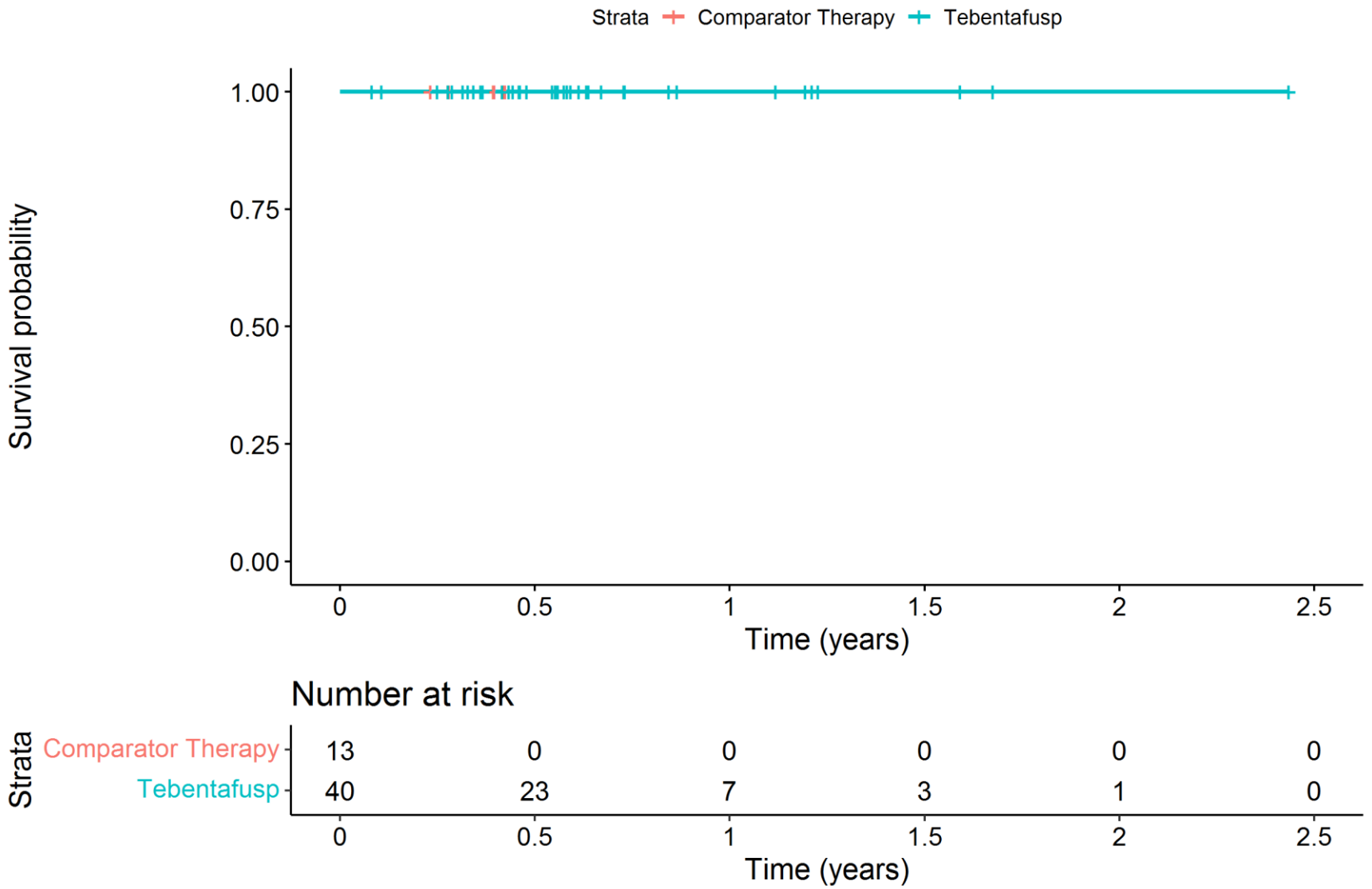
Erkrankungen der Haut und des Unterhautgewebes - Dacarbazin



Erkrankungen der Haut und des Unterhautgewebes - Pembrolizumab



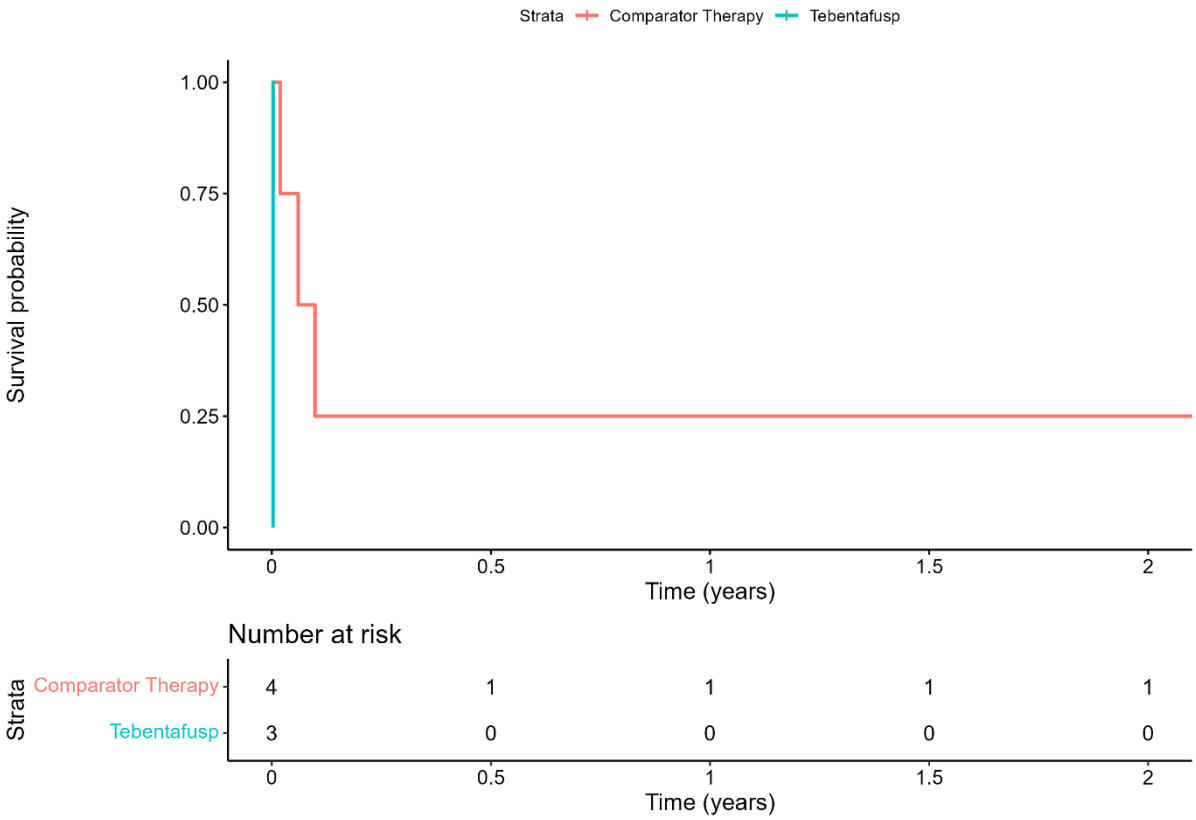
Erkrankungen der Haut und des Unterhautgewebes - Ipilimumab



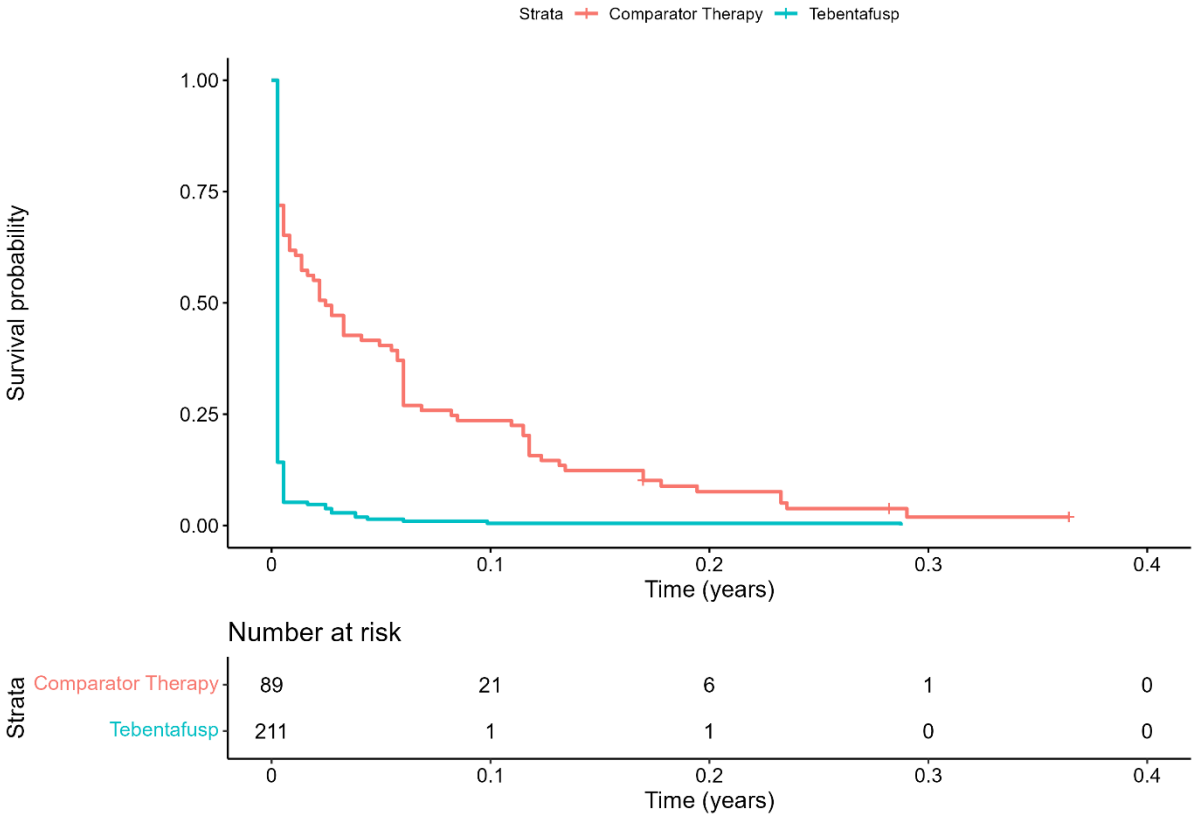
59 3-Jahres-Analyse (Juni 2023)

59.1 Jegliches UE (Tabelle 4-214)

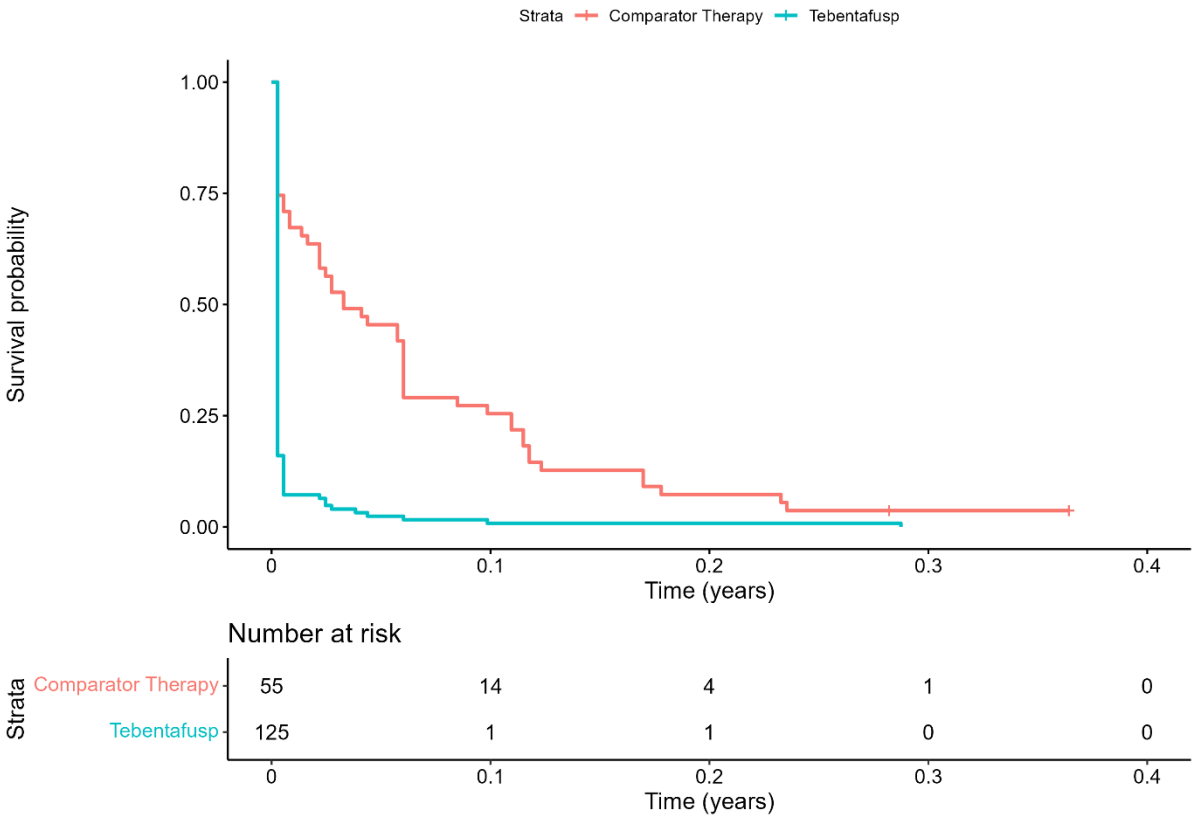
Herkunft: Hispanisch



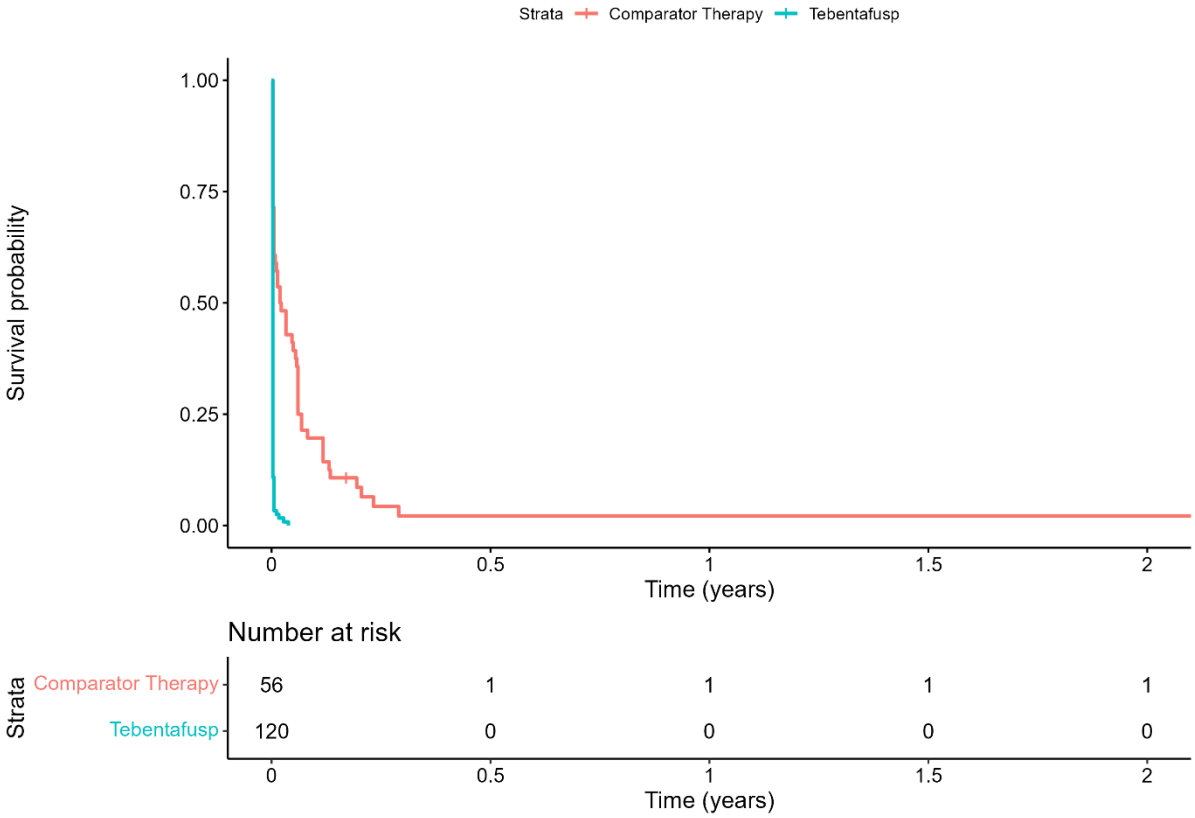
Herkunft: Nicht-hispanisch



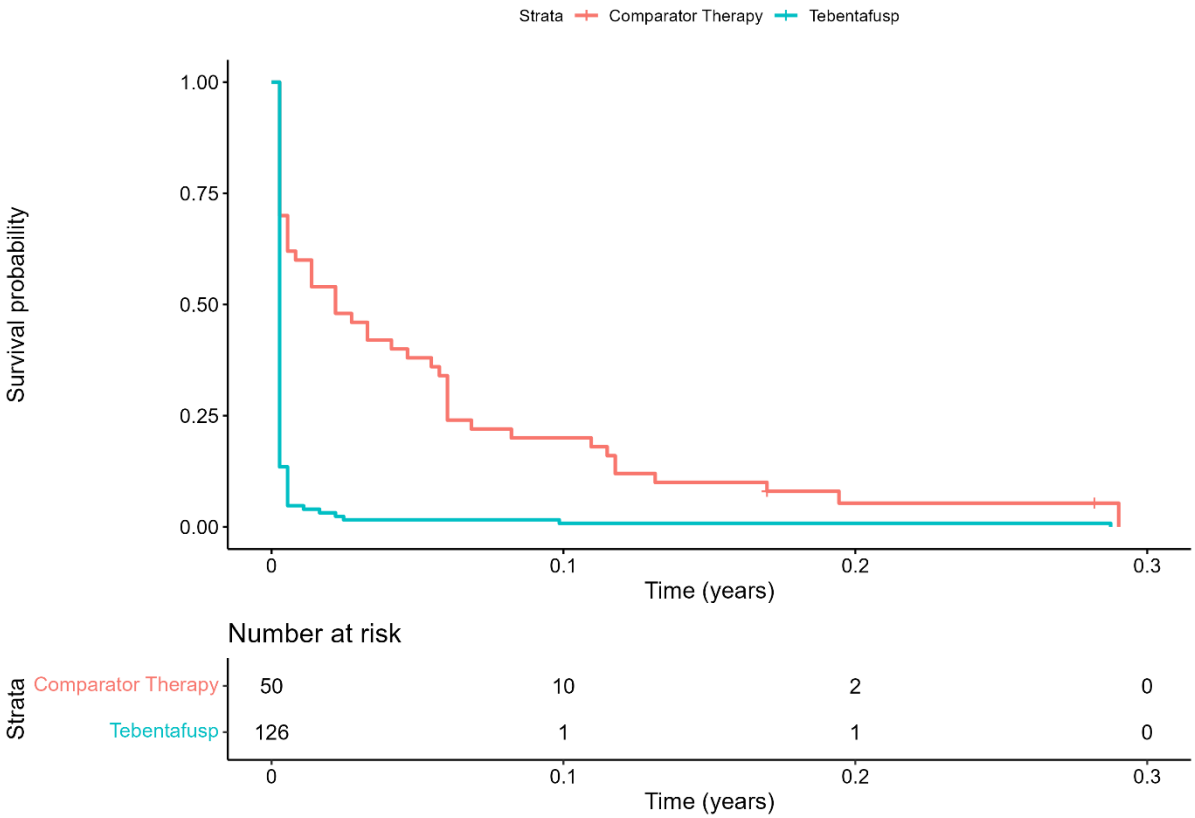
Geschlecht: Männlich



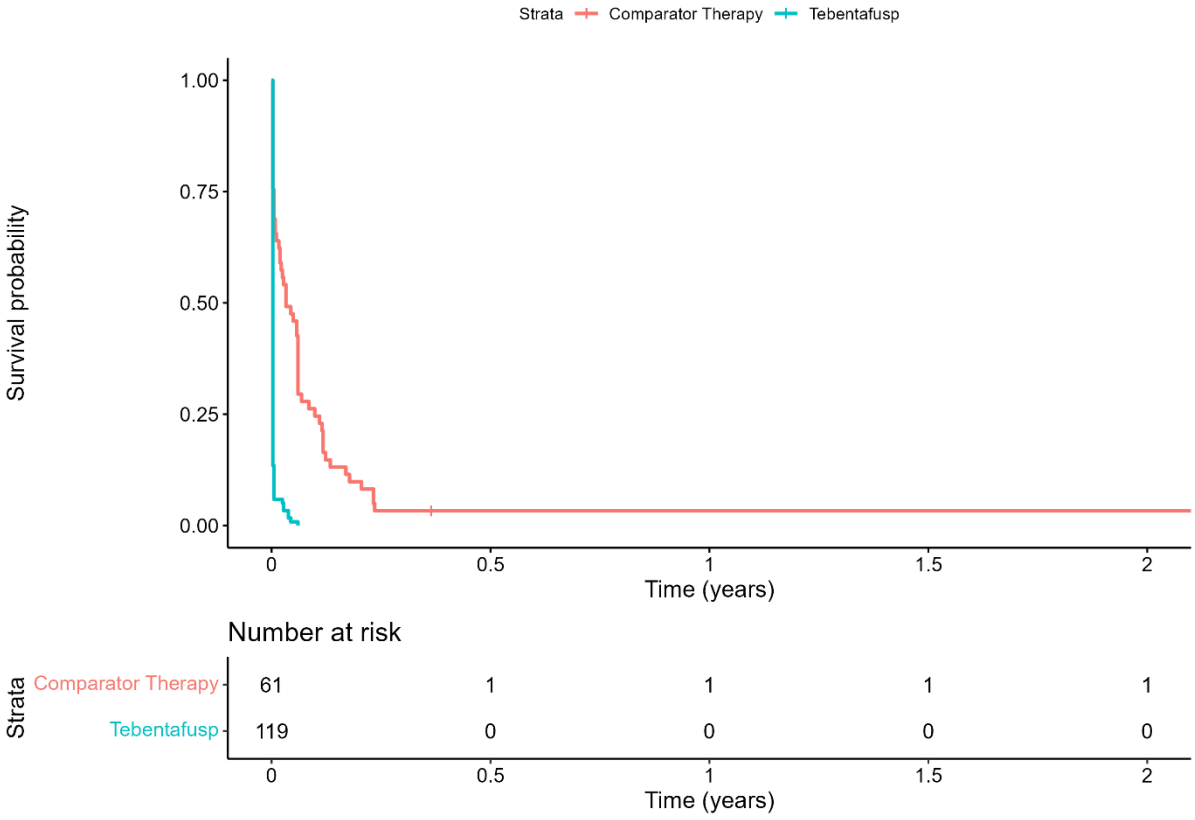
Geschlecht: Weiblich



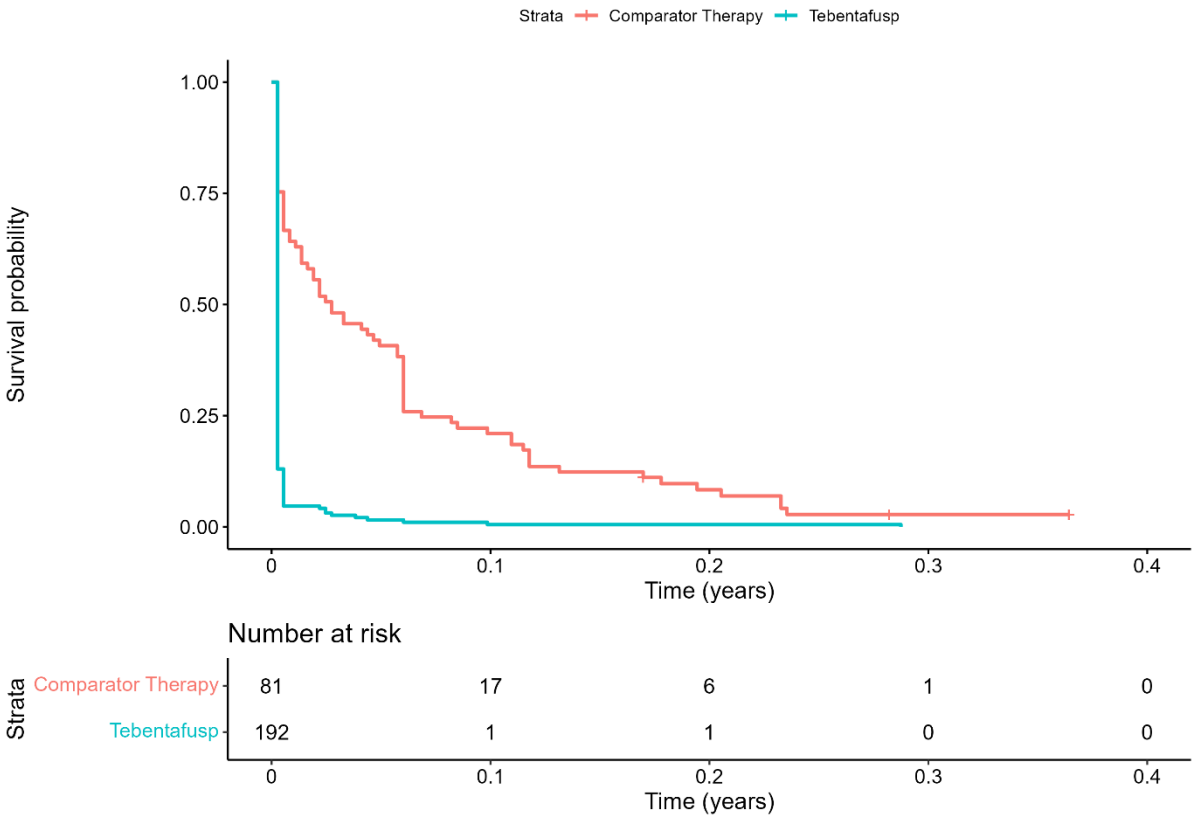
Alter: <65 Jahre



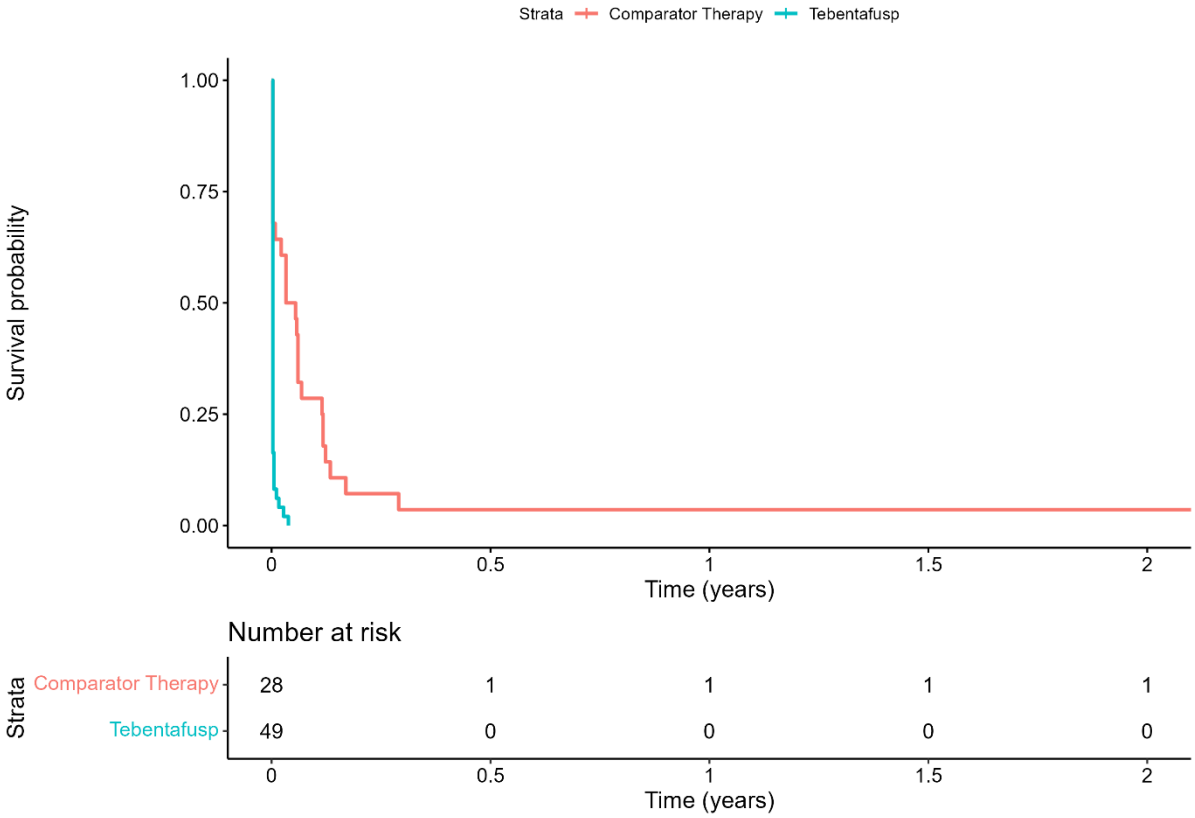
Alter: ≥65 Jahre



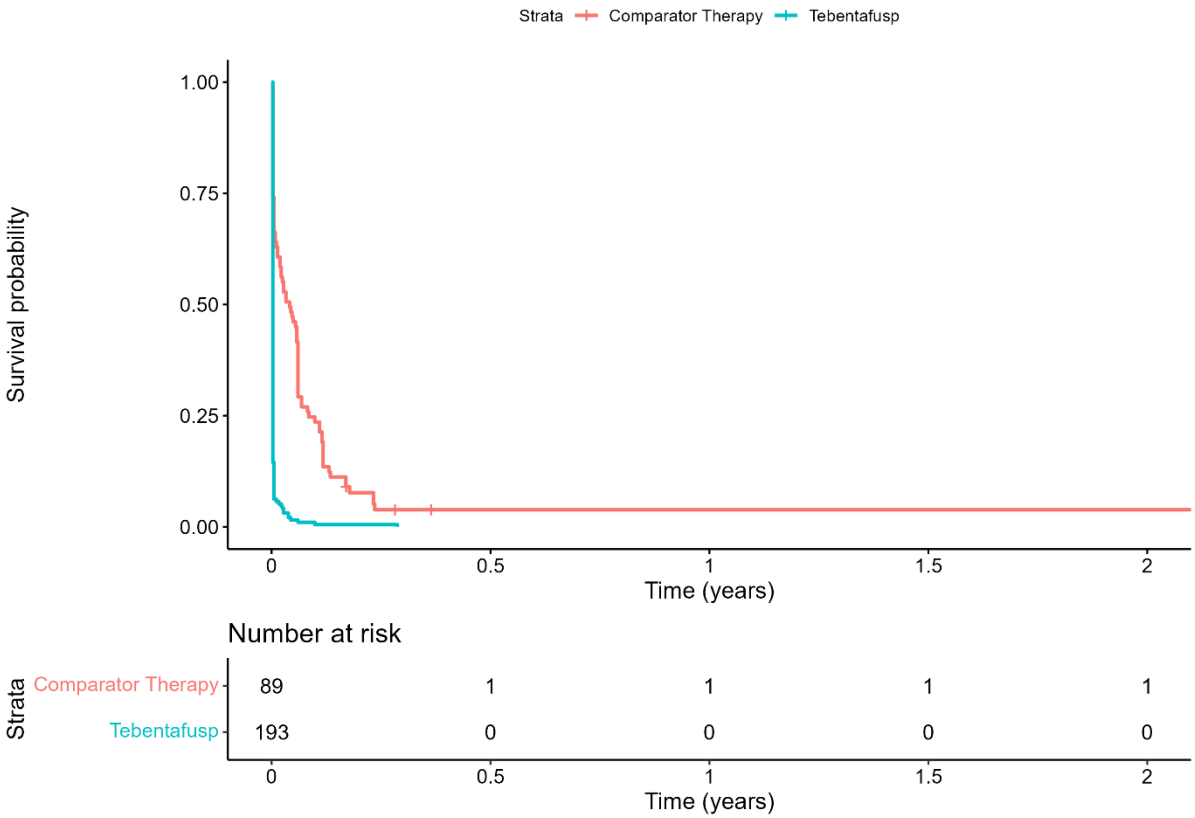
ECOG-Performance-Status: 0



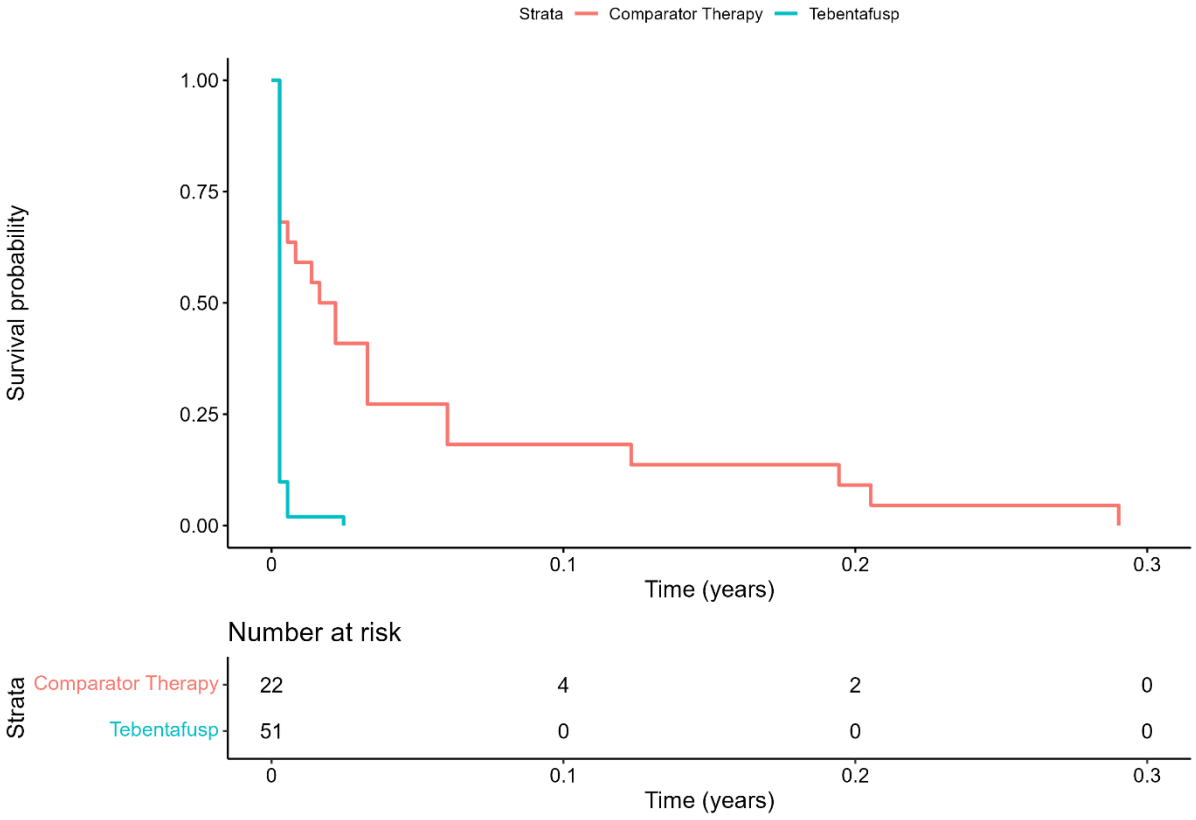
ECOG-Performance-Status: 1



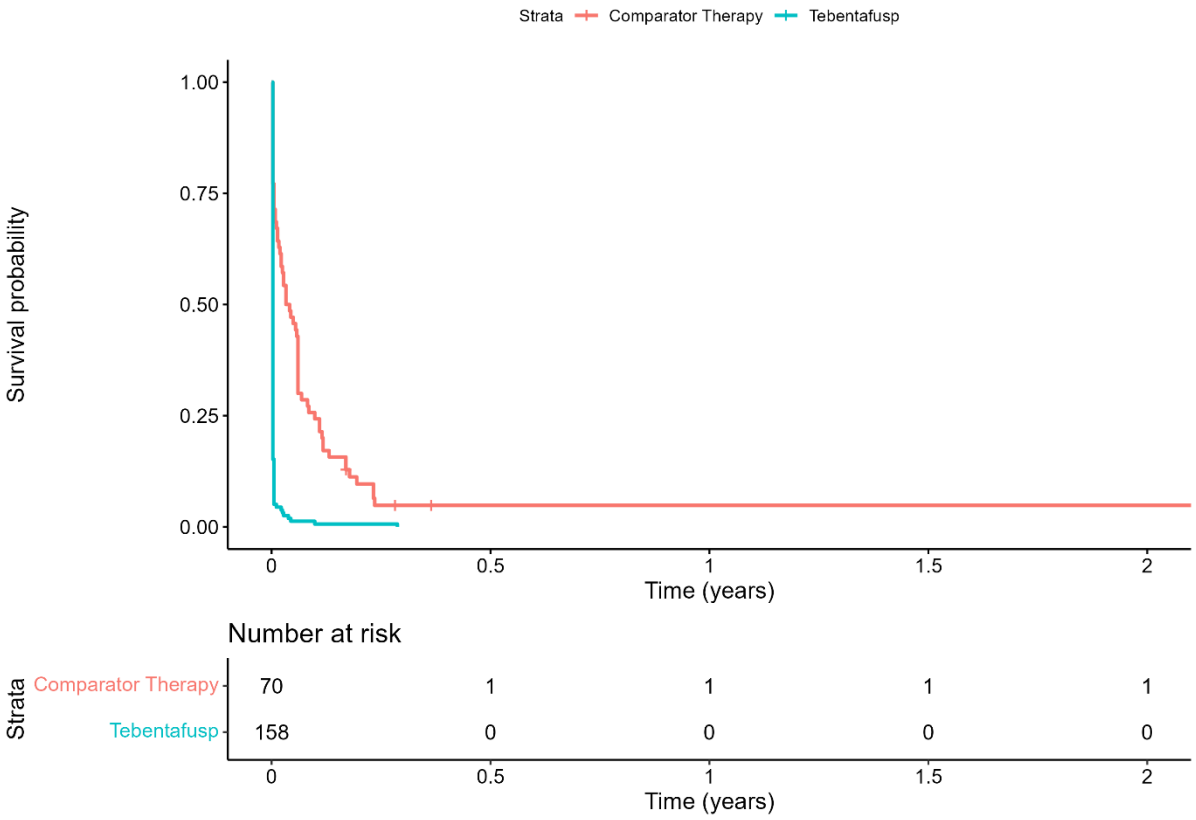
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



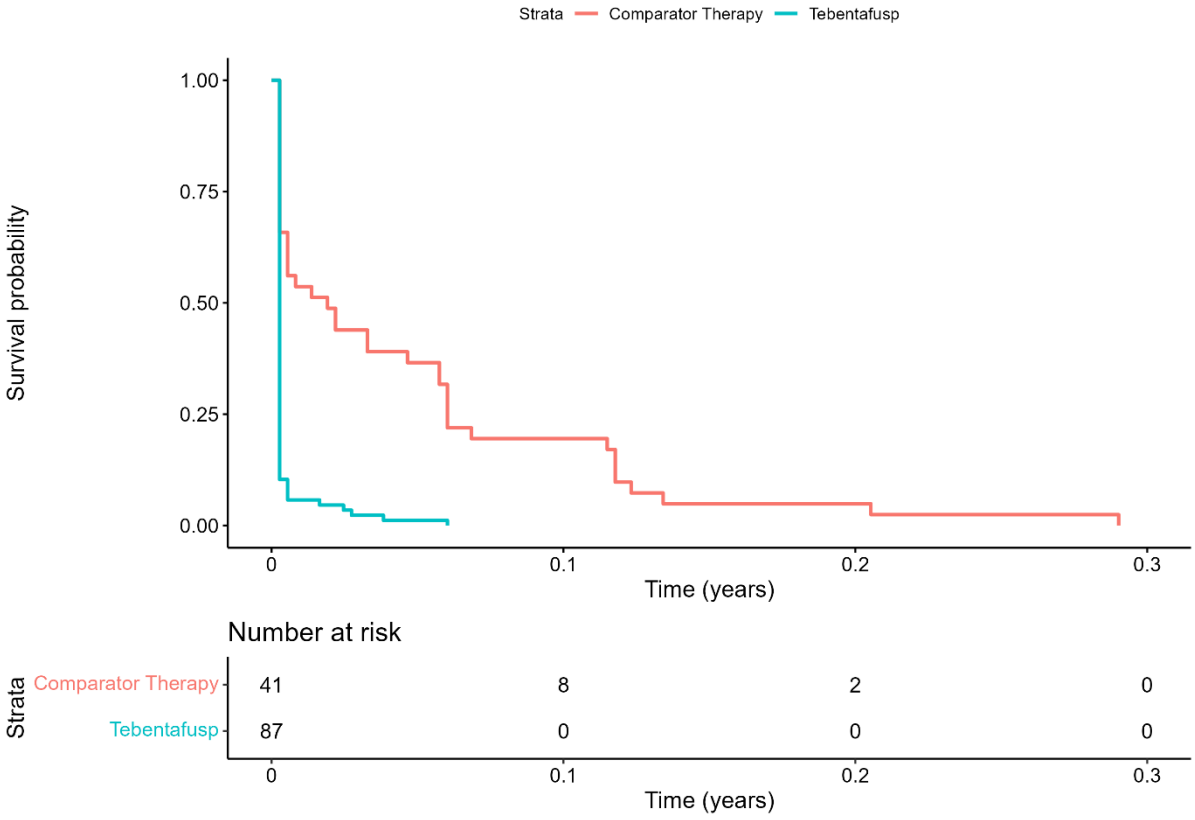
Alkalische Phosphatase (ALP) (Baseline): >ULN



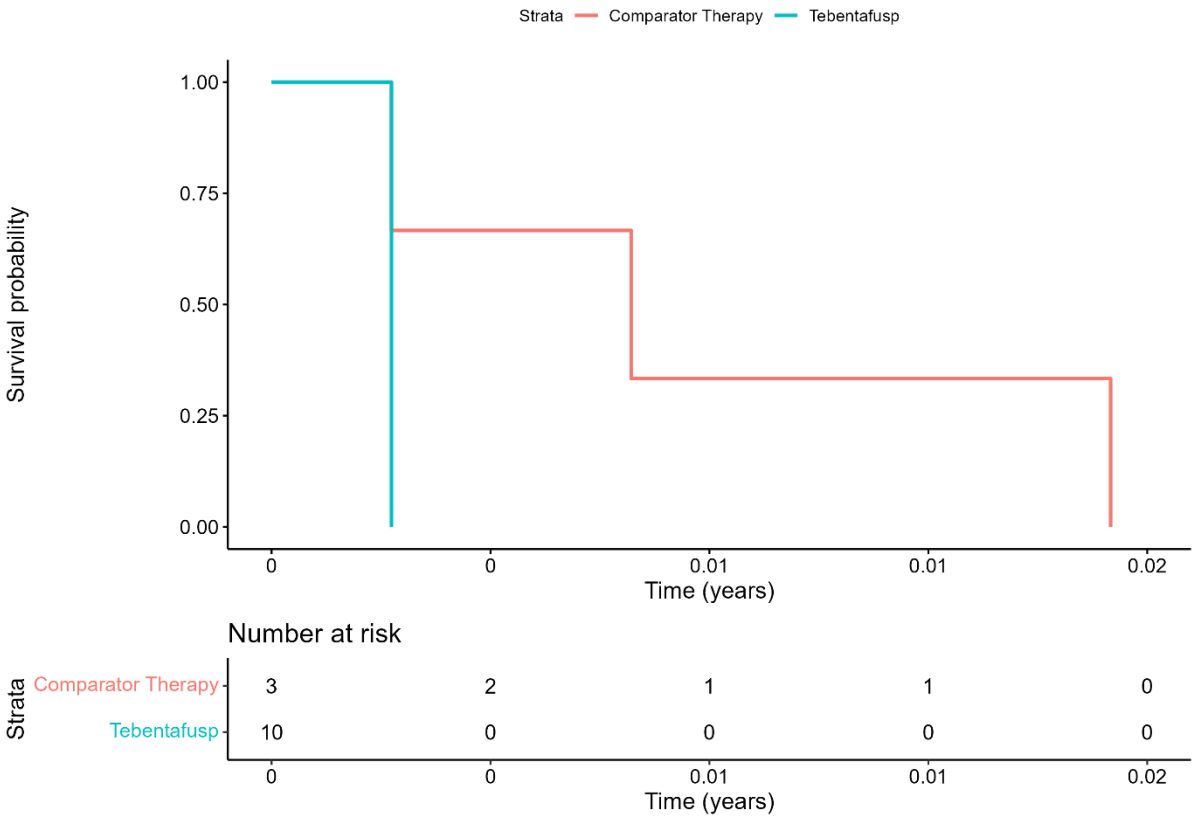
LDH: ≤ULN



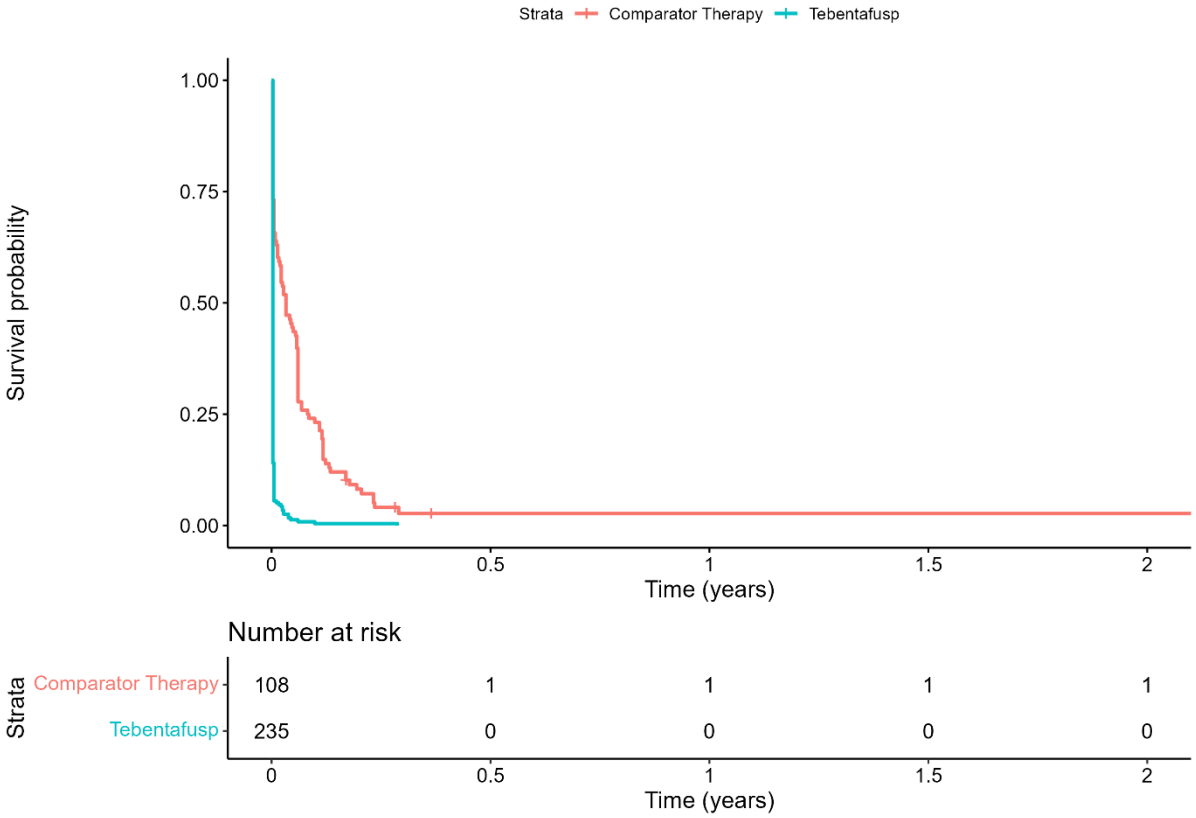
LDH: >ULN



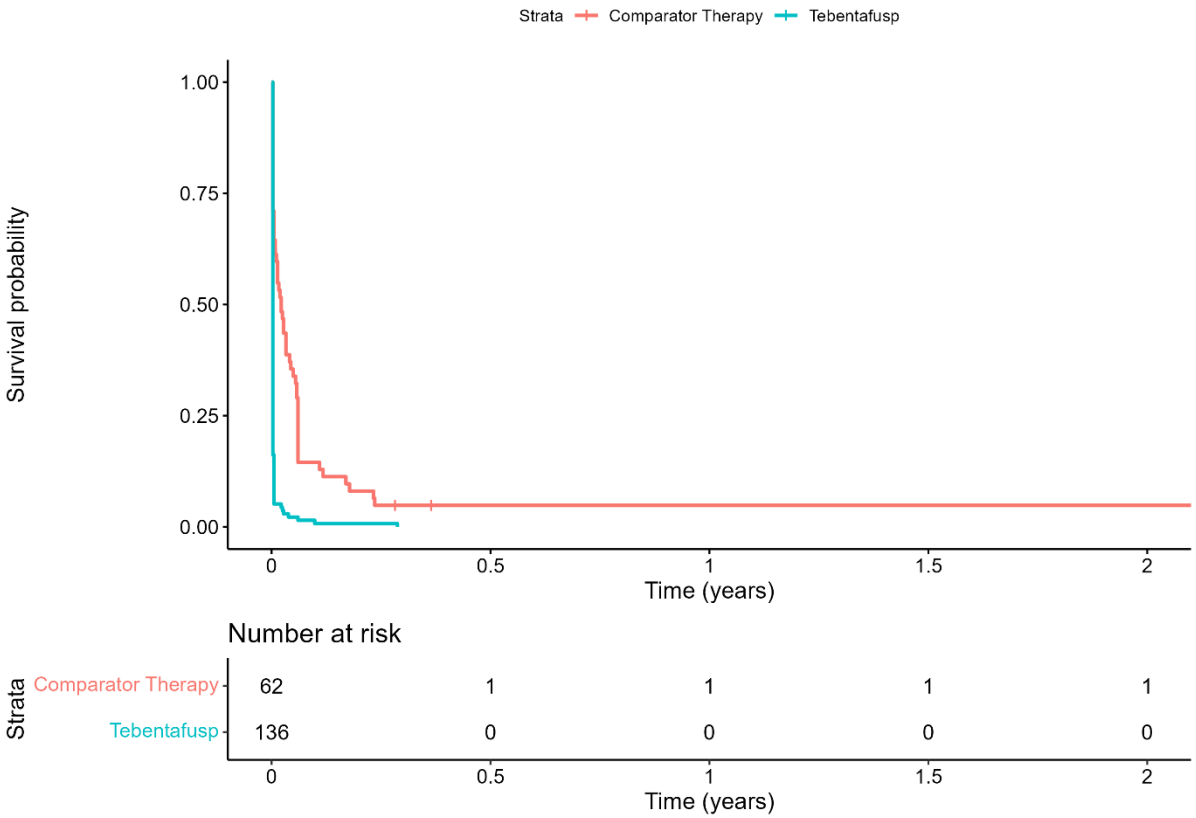
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



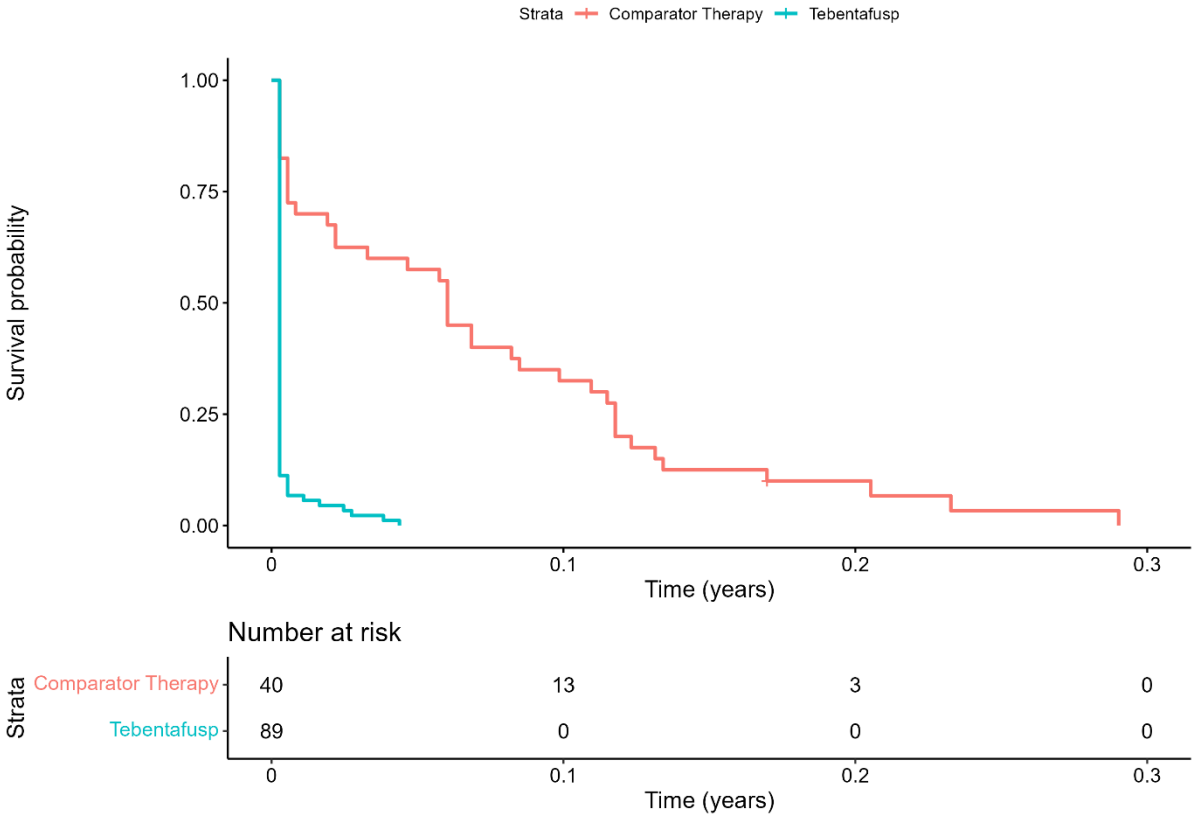
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



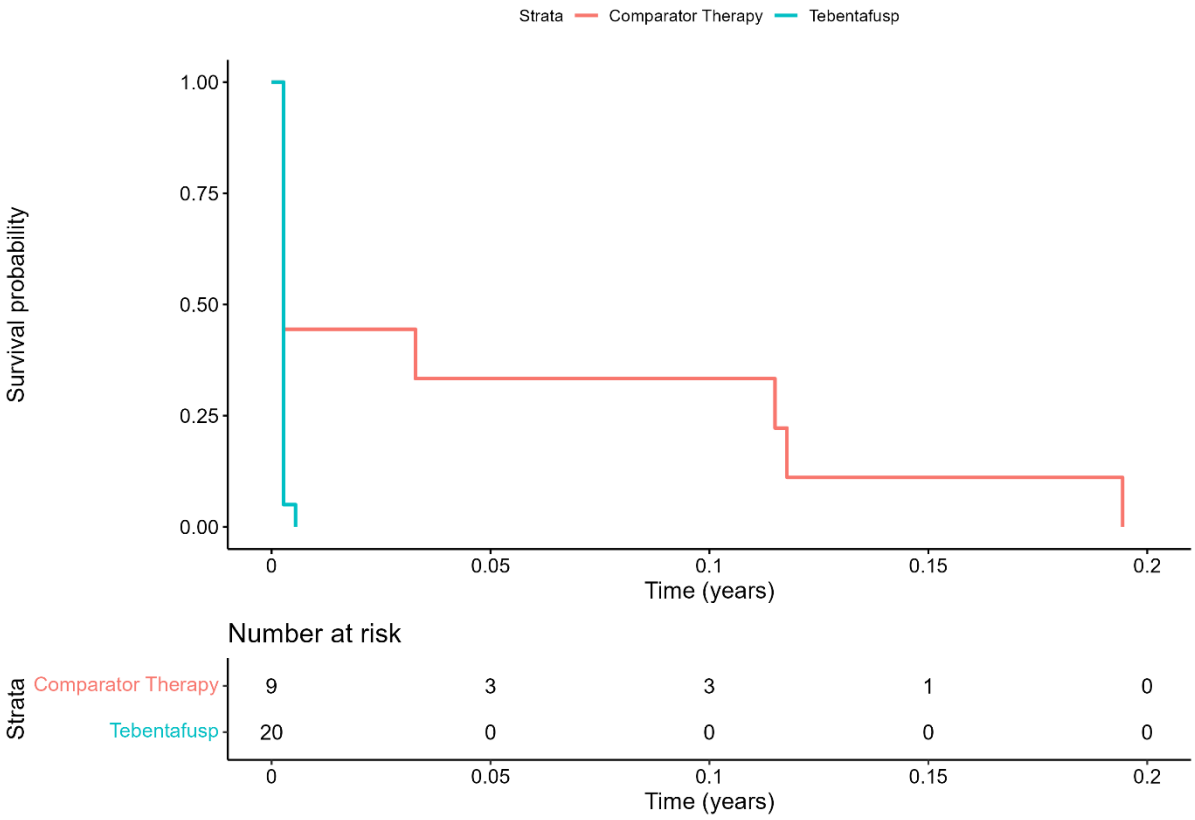
Größte metastatische Läsion (Baseline): ≤3,0 cm



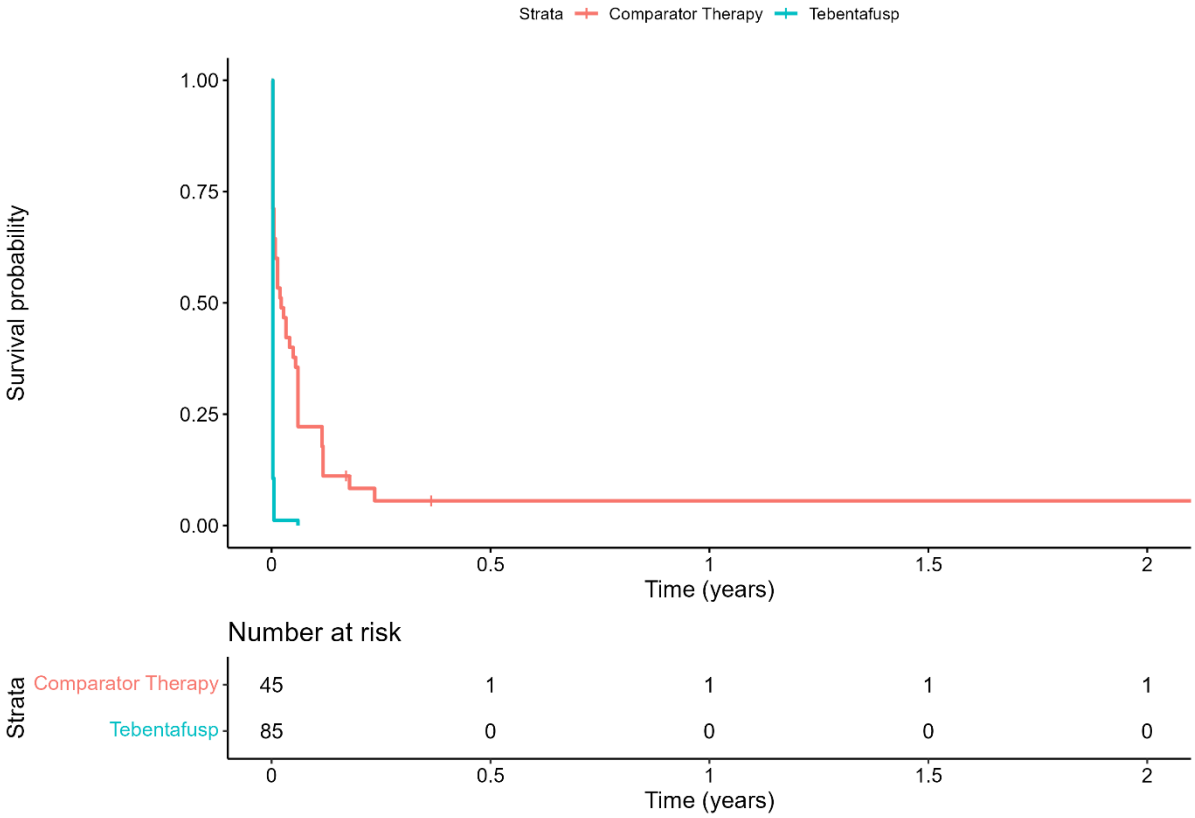
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



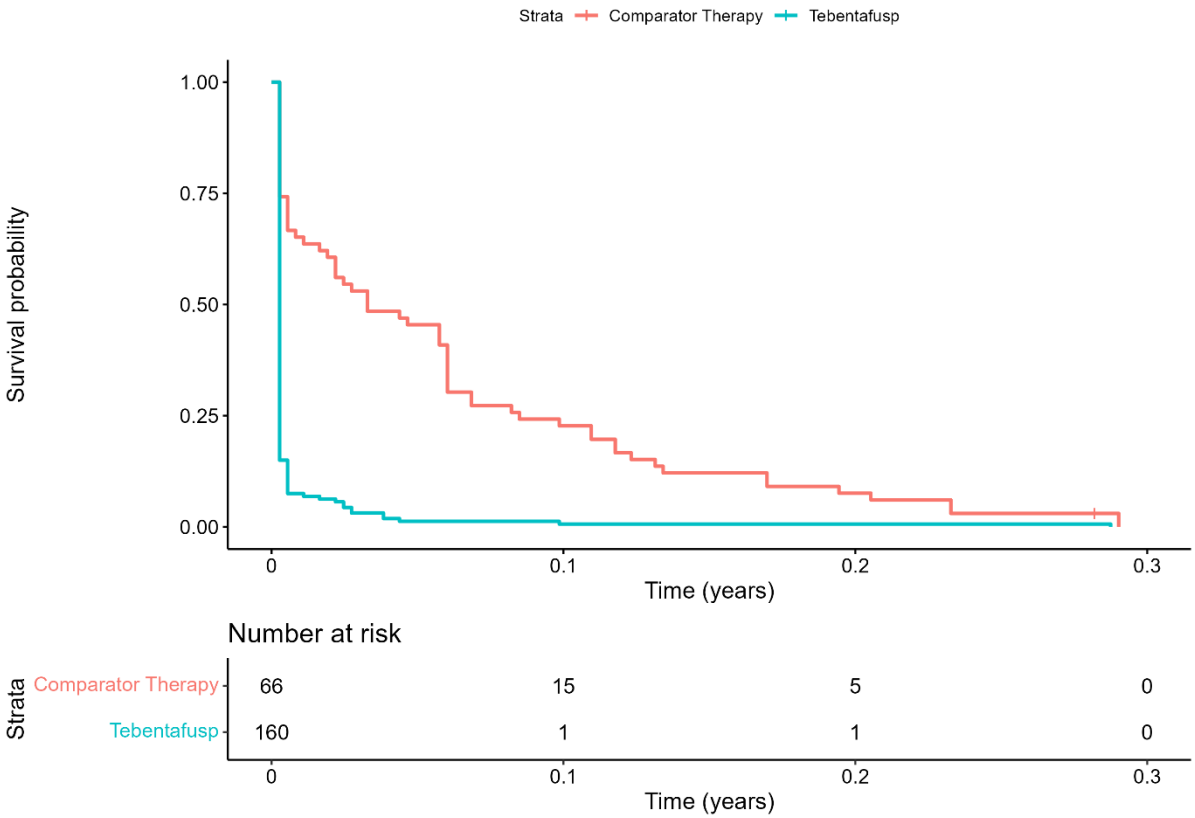
Größte metastatische Läsion (Baseline): ≥8,1 cm



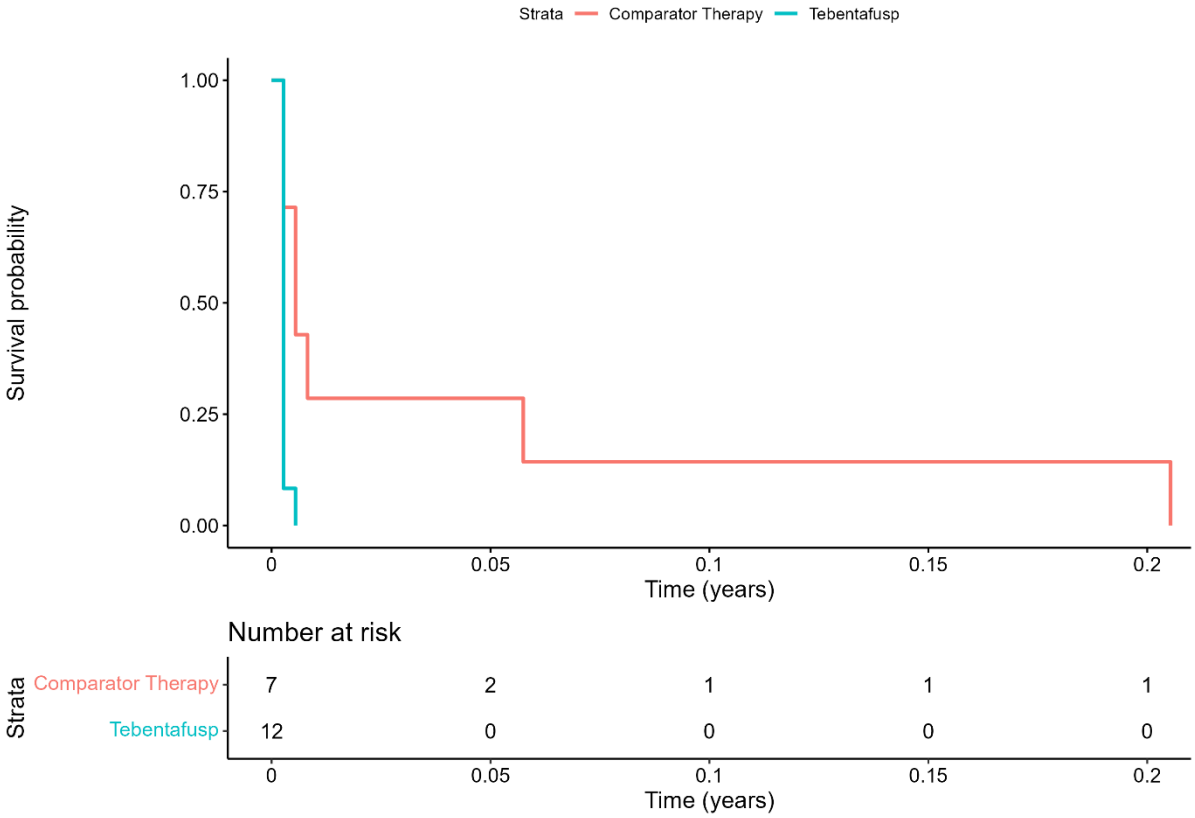
Region: Nordamerika



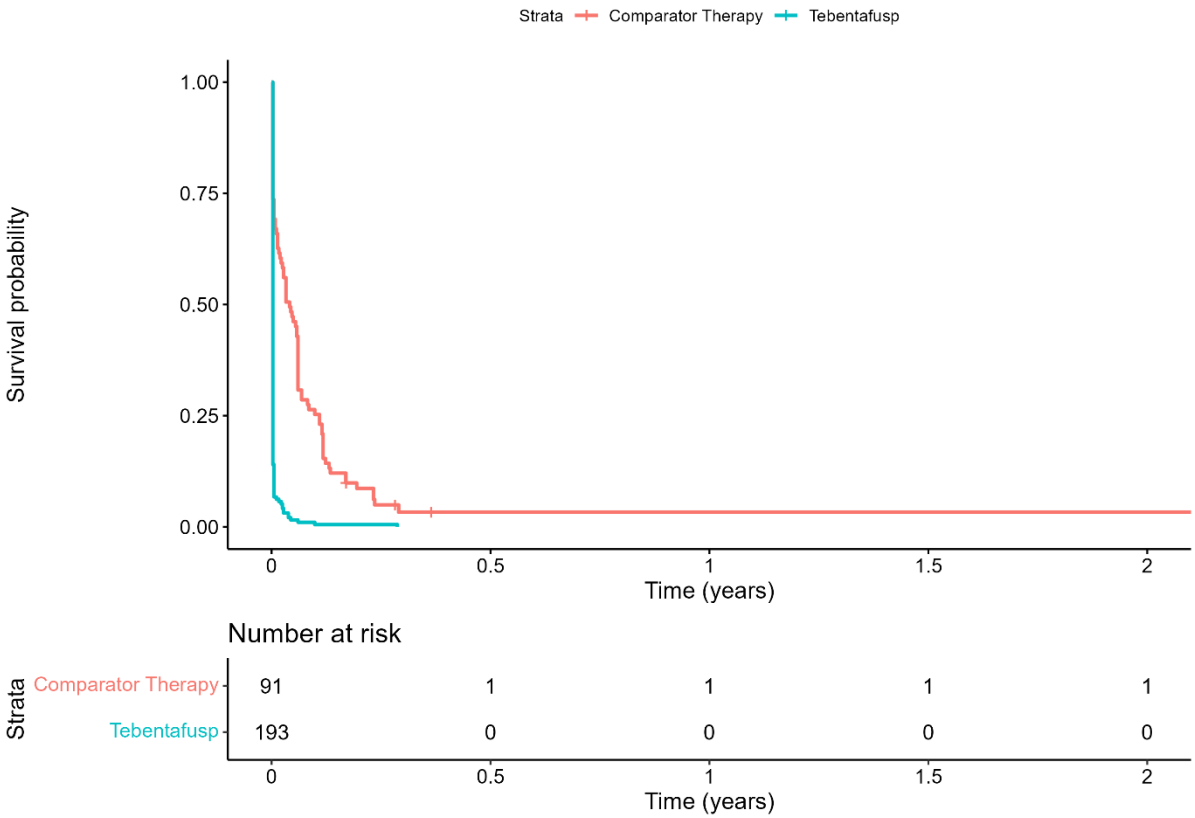
Region: Nicht-Nordamerika



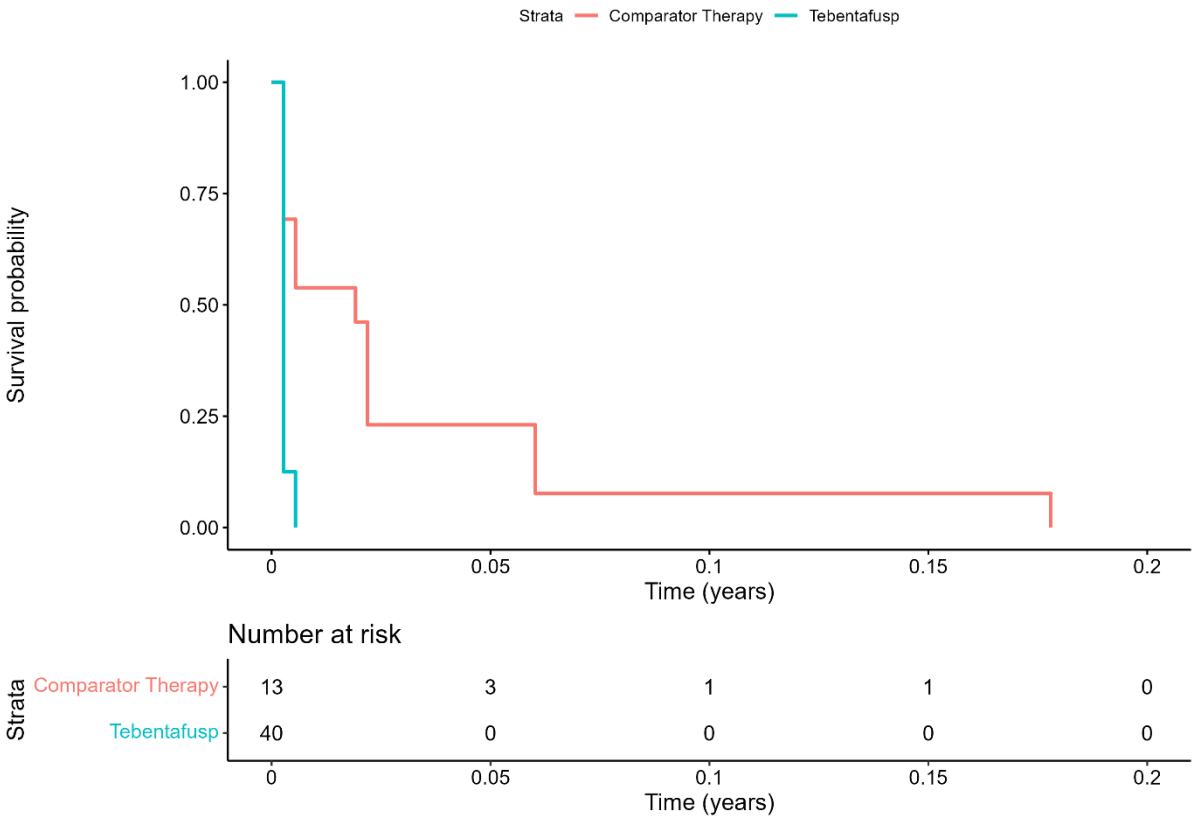
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

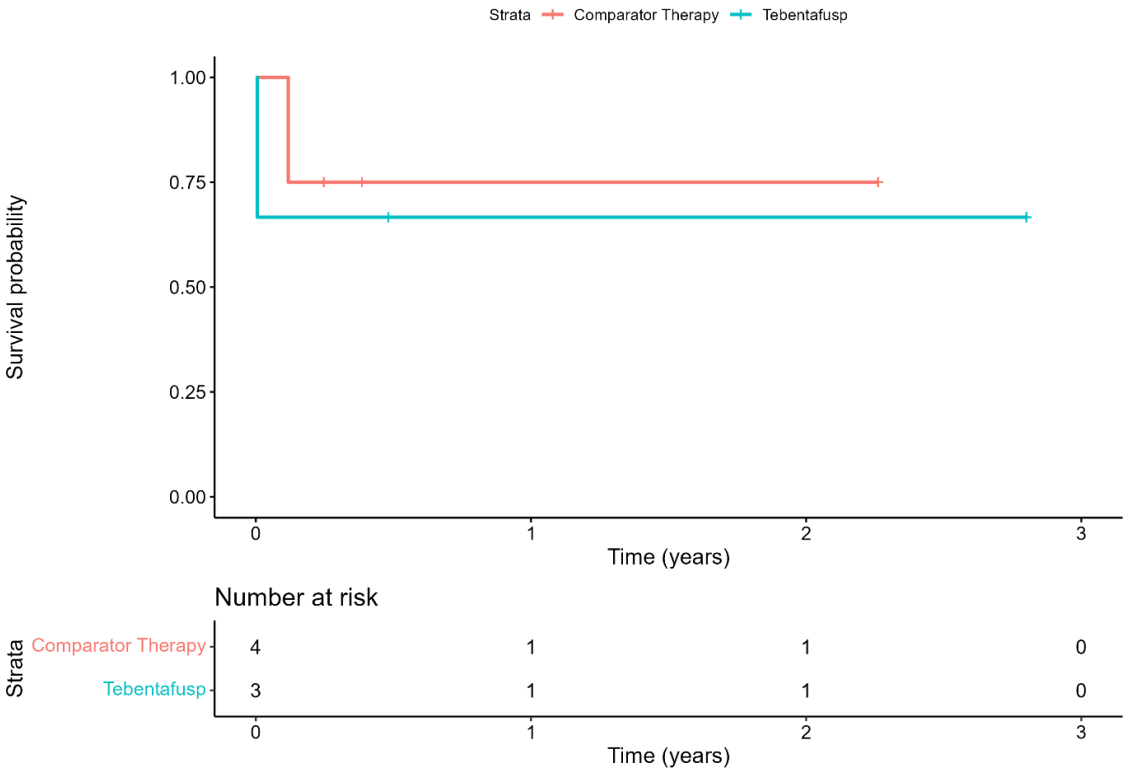


Vorauswahl der Chemotherapie: Ipilimumab

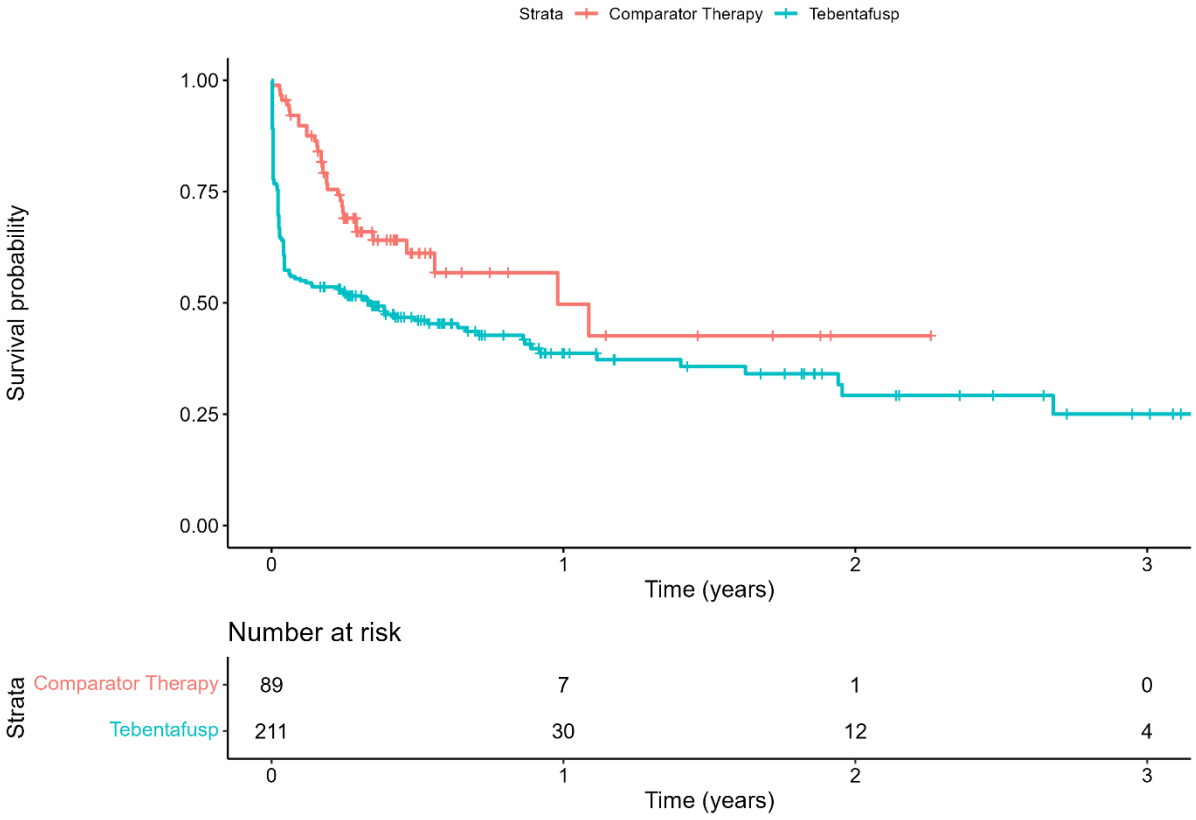


59.2 Jegliches UE mit CTCAE-Grad ≥ 3 (Tabelle 4-216)

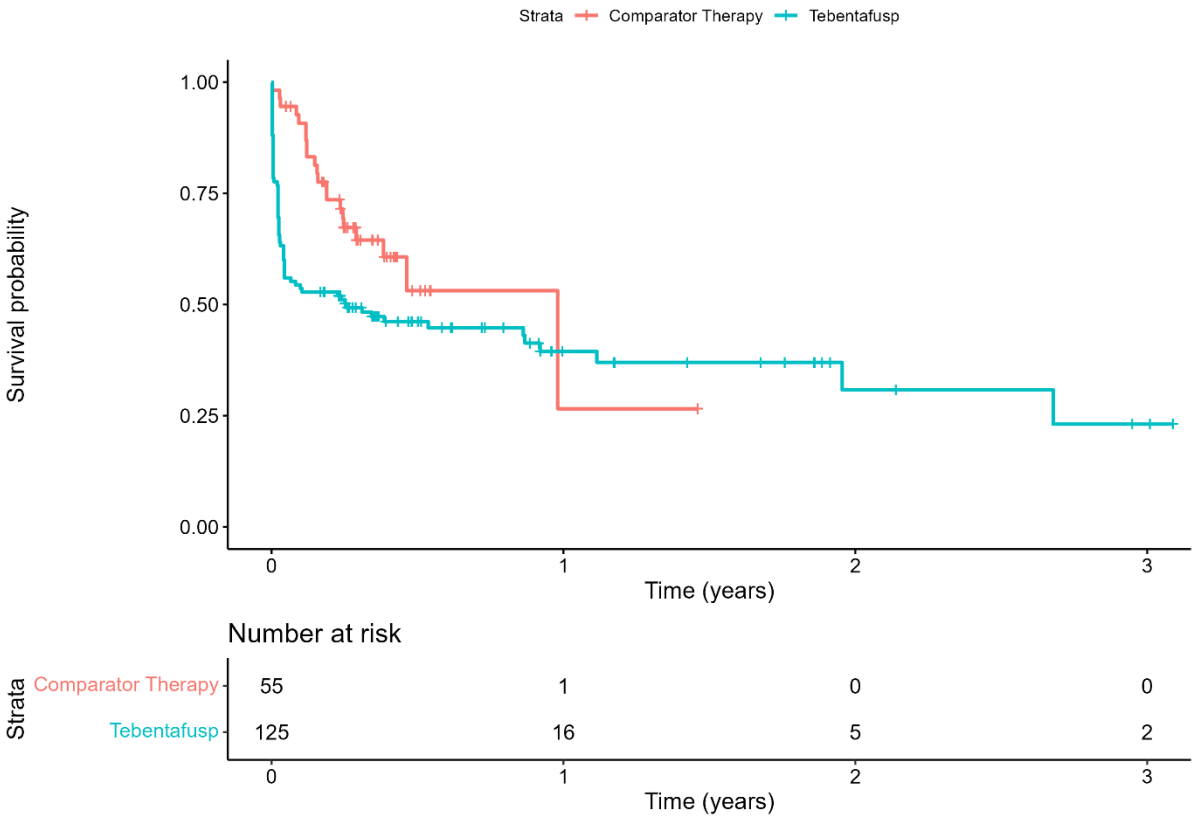
Herkunft: Hispanisch



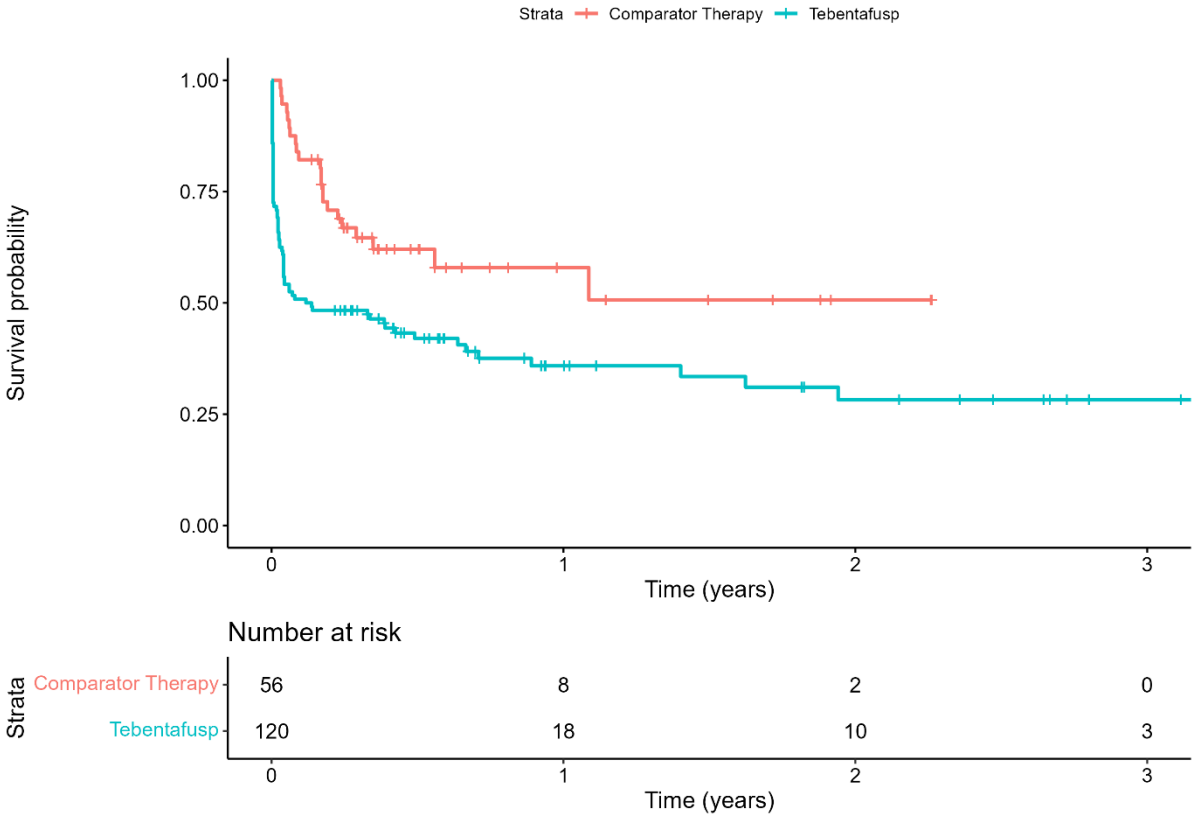
Herkunft: Nicht-hispanisch



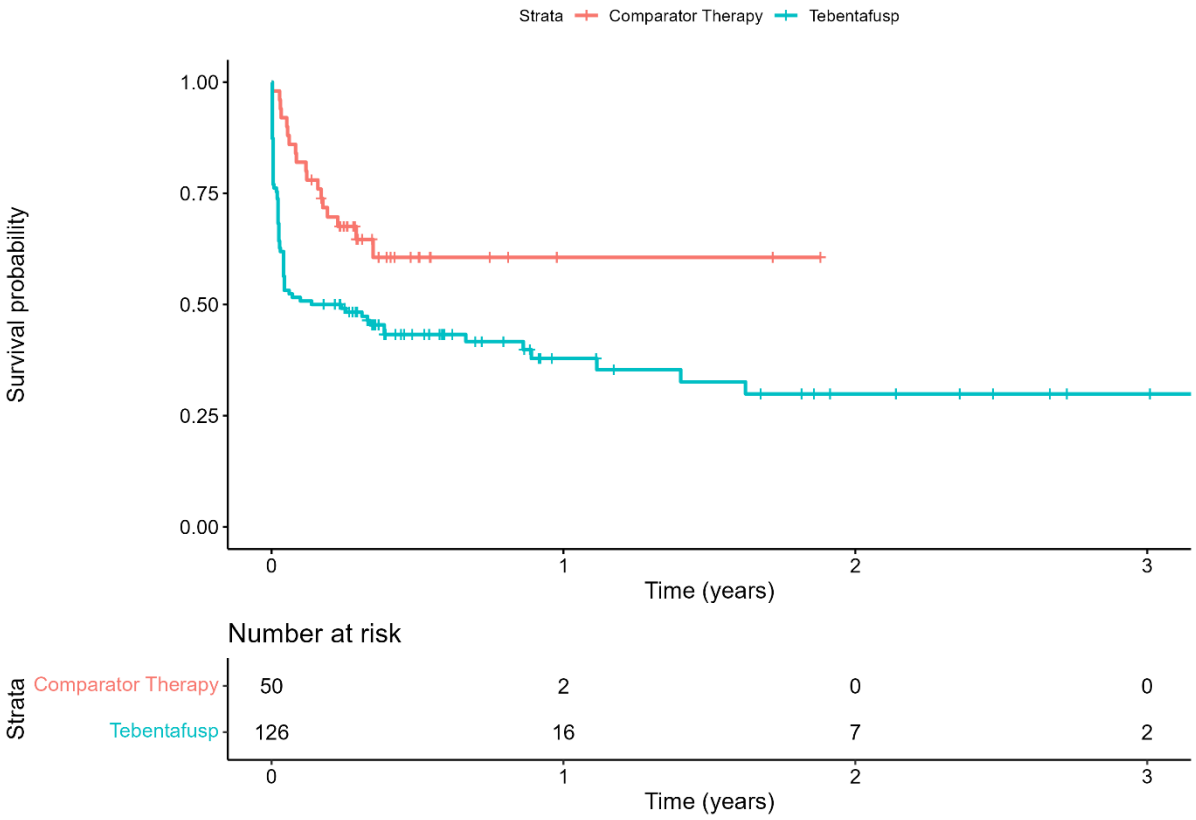
Geschlecht: Männlich



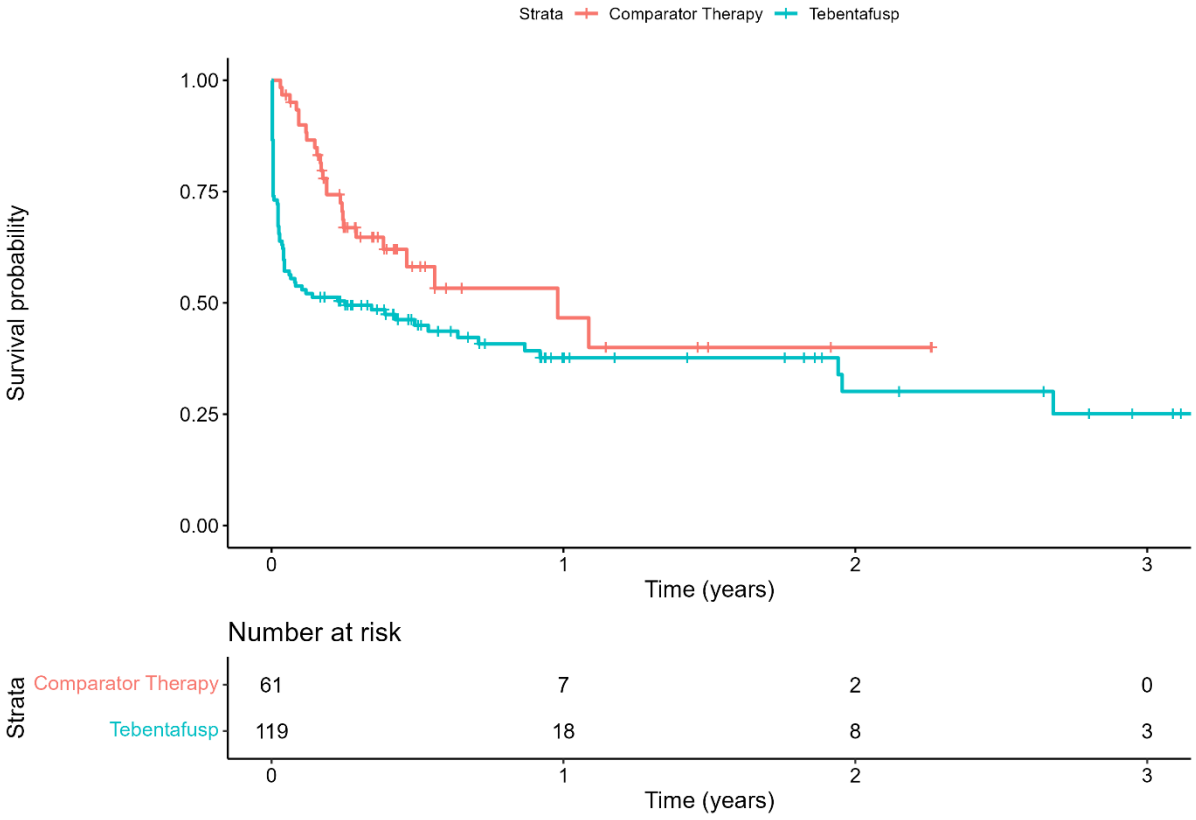
Geschlecht: Weiblich



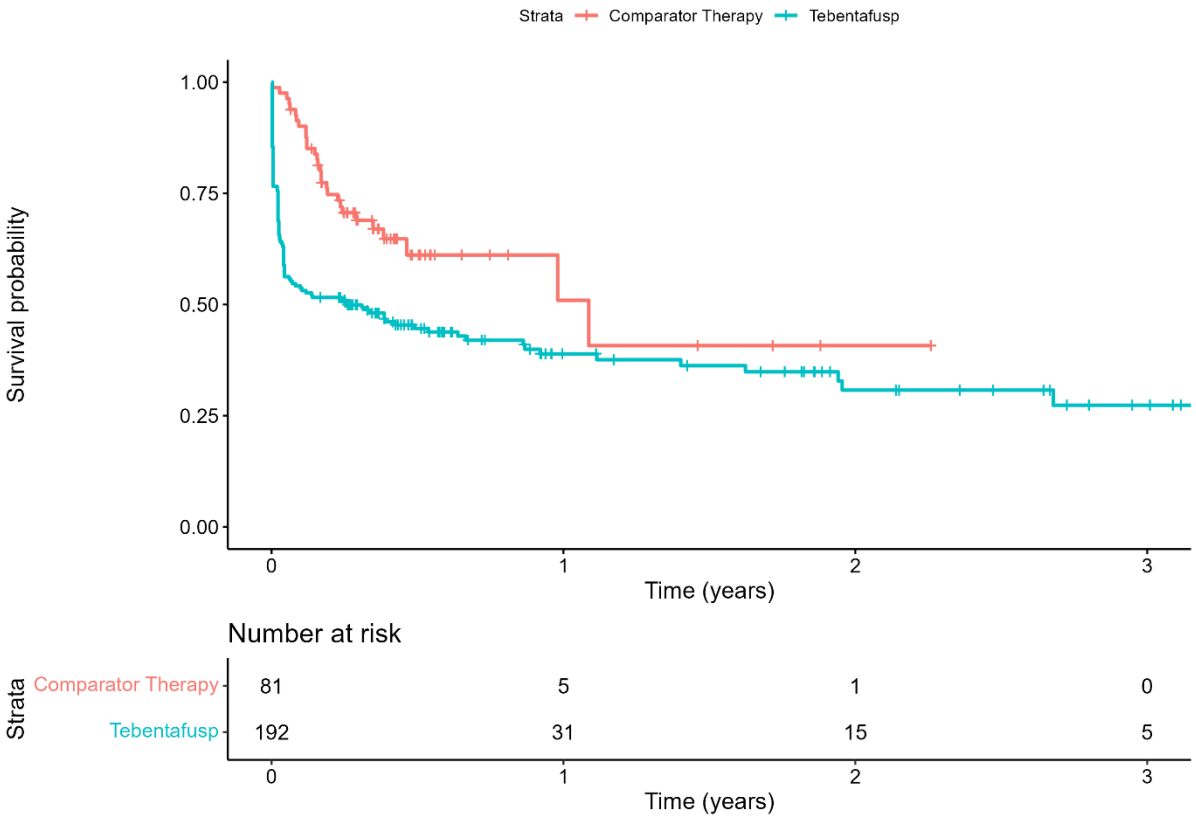
Alter: <65 Jahre



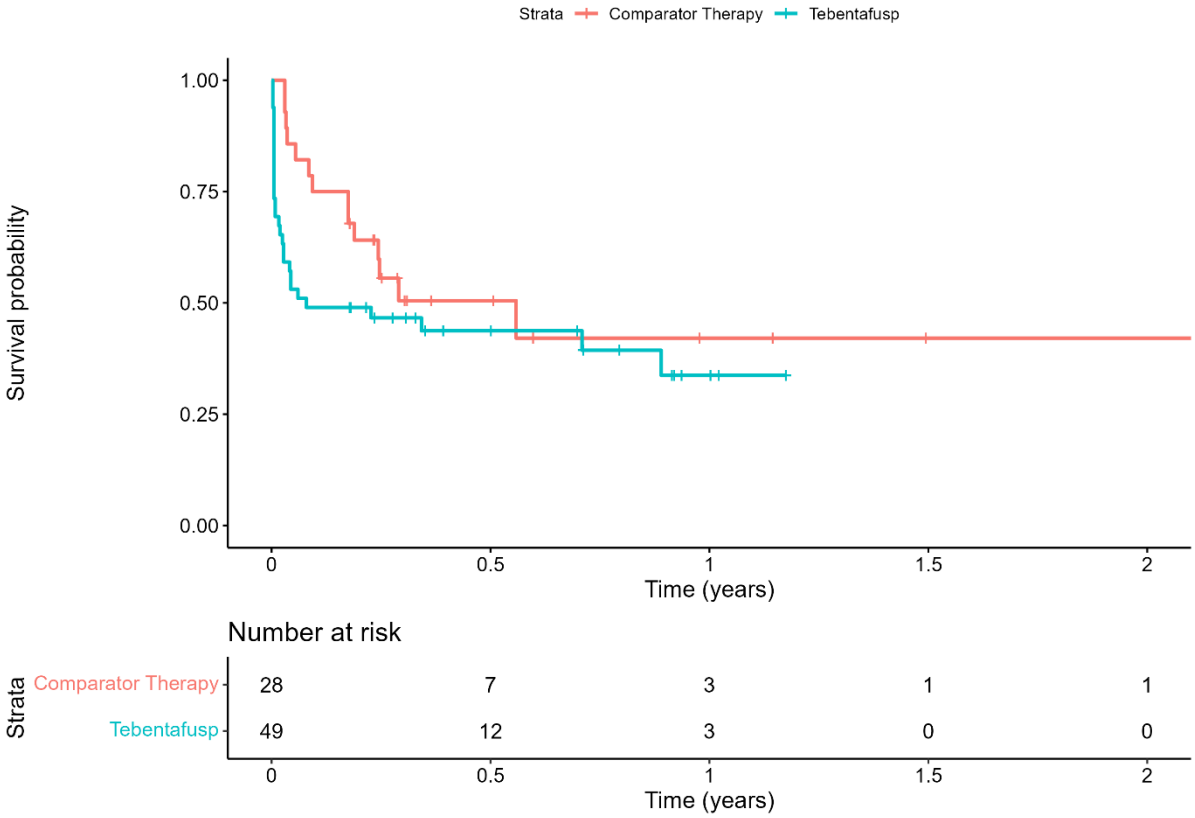
Alter: ≥65 Jahre



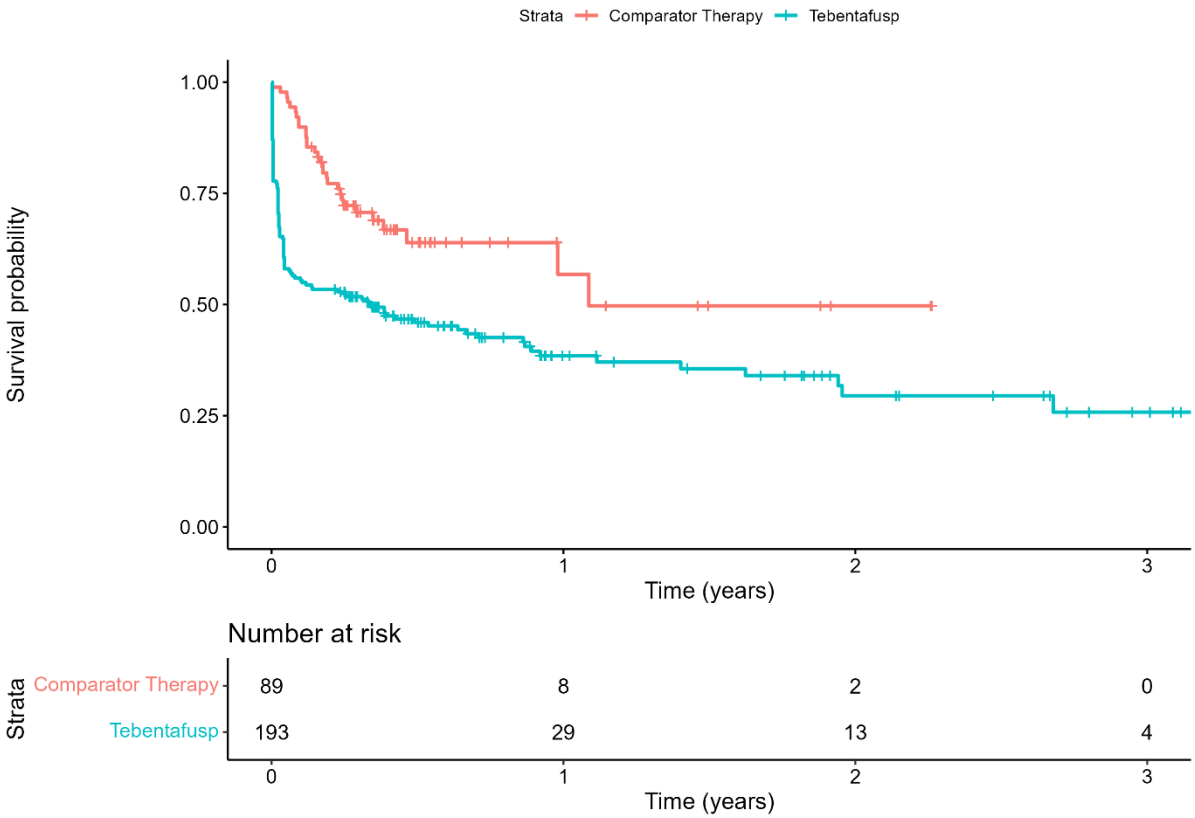
ECOG-Performance-Status: 0



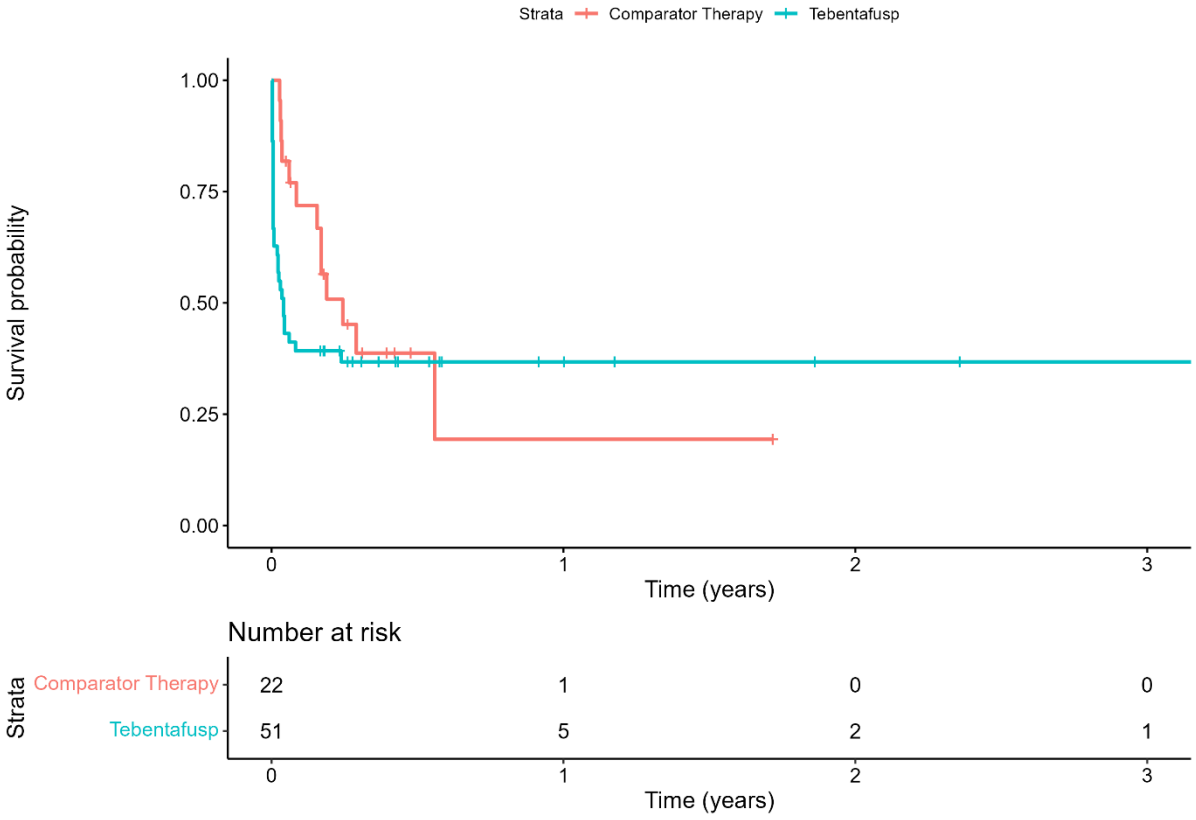
ECOG-Performance-Status: 1



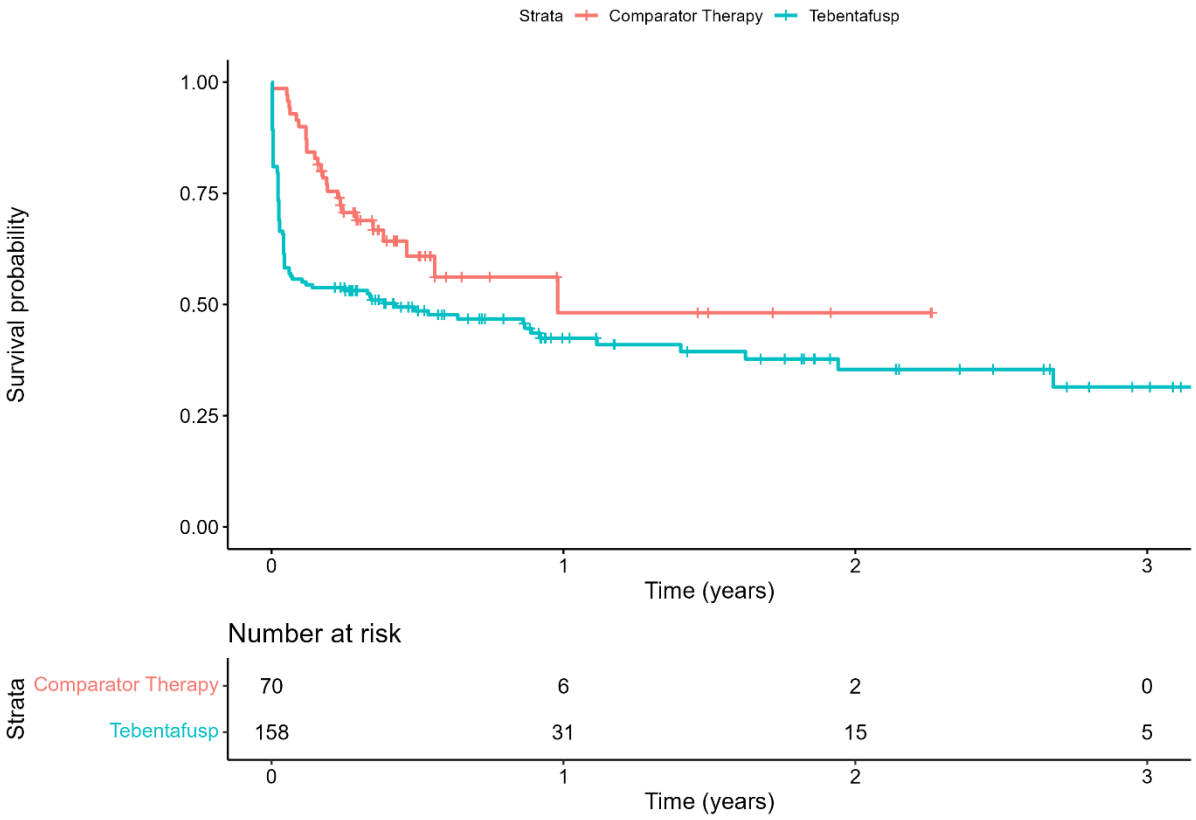
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



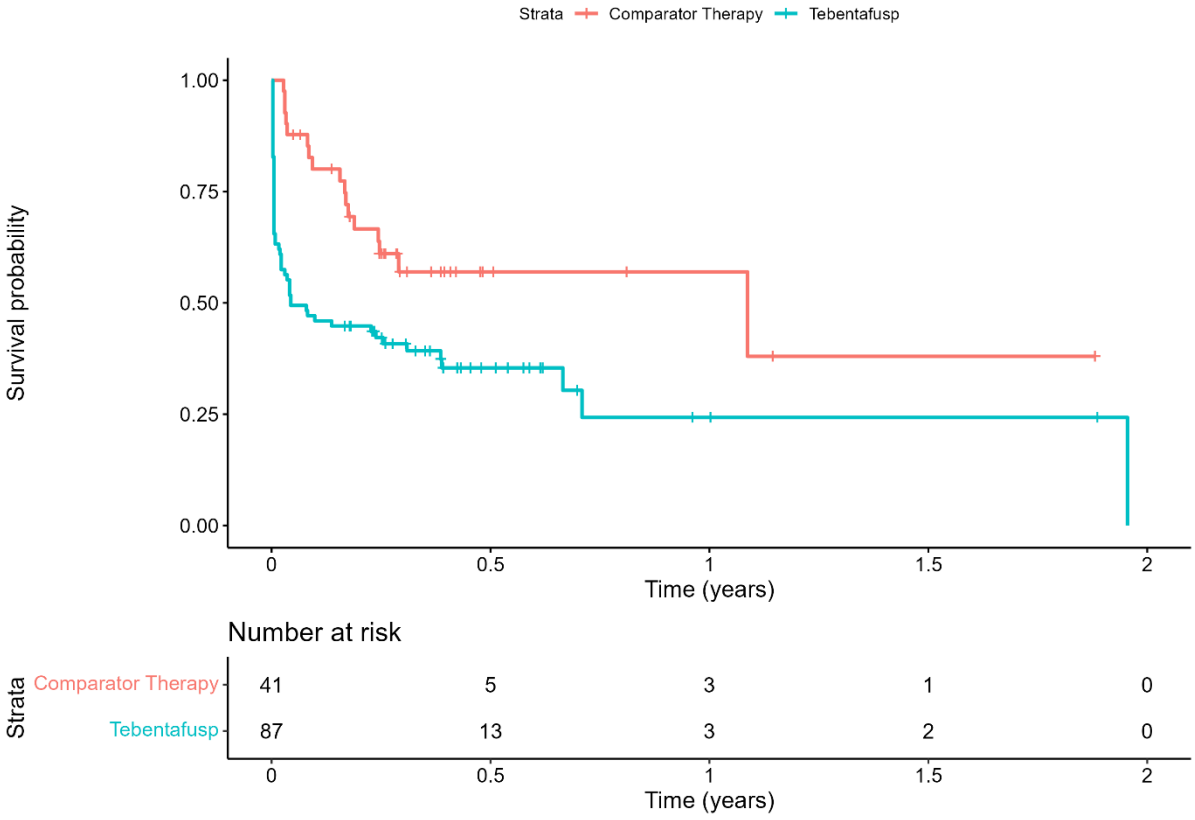
Alkalische Phosphatase (ALP) (Baseline): >ULN



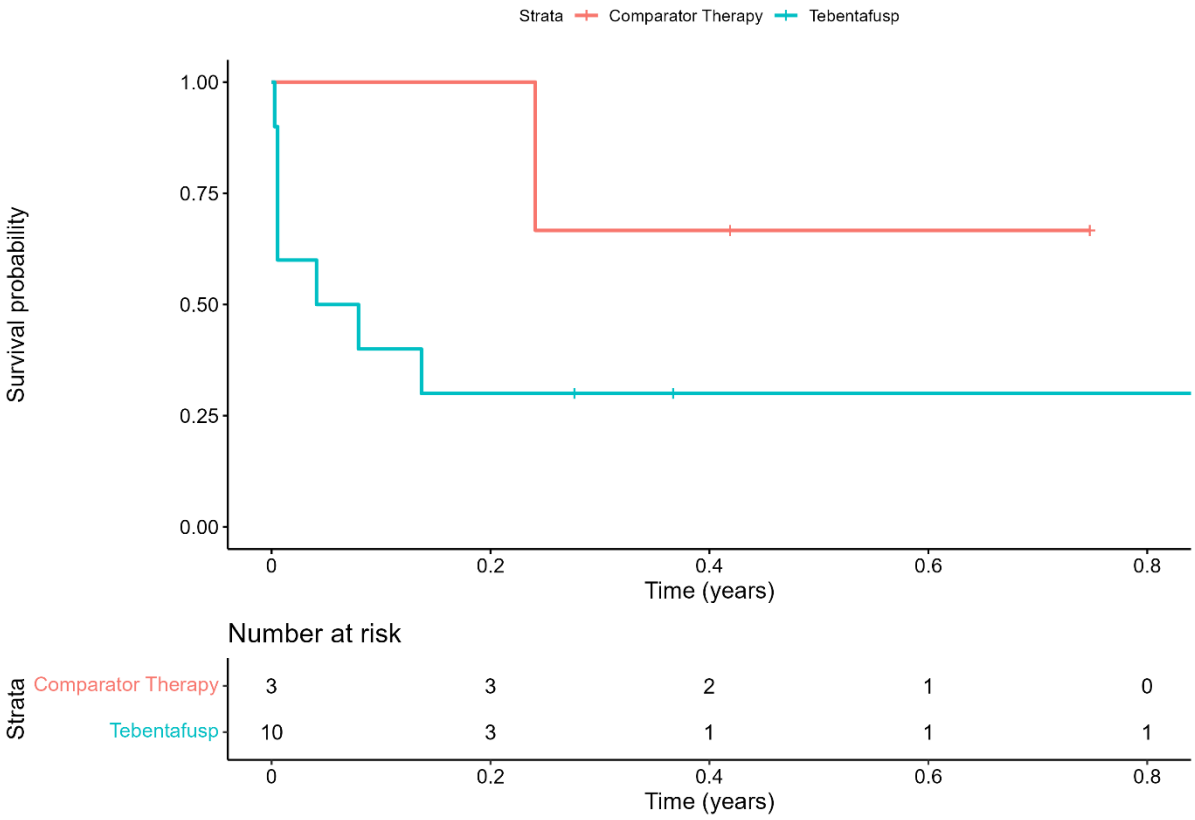
LDH: ≤ULN



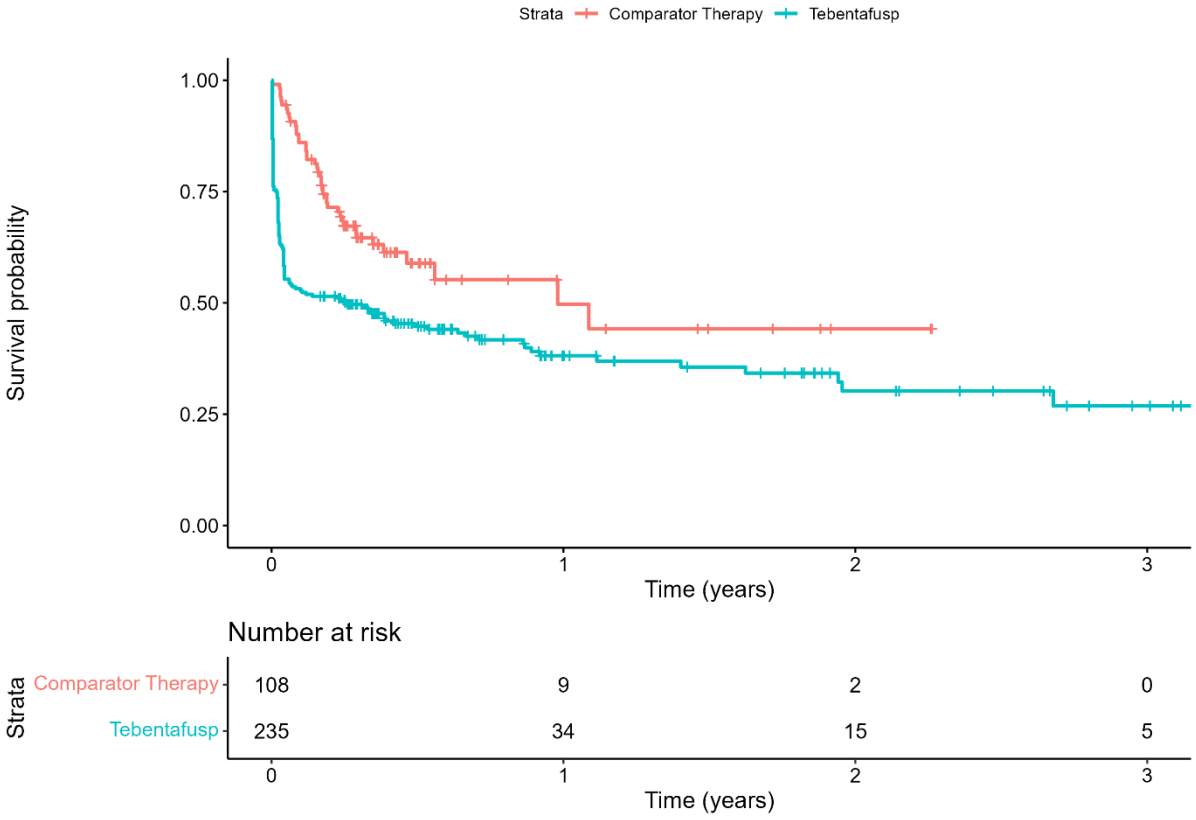
LDH: >ULN



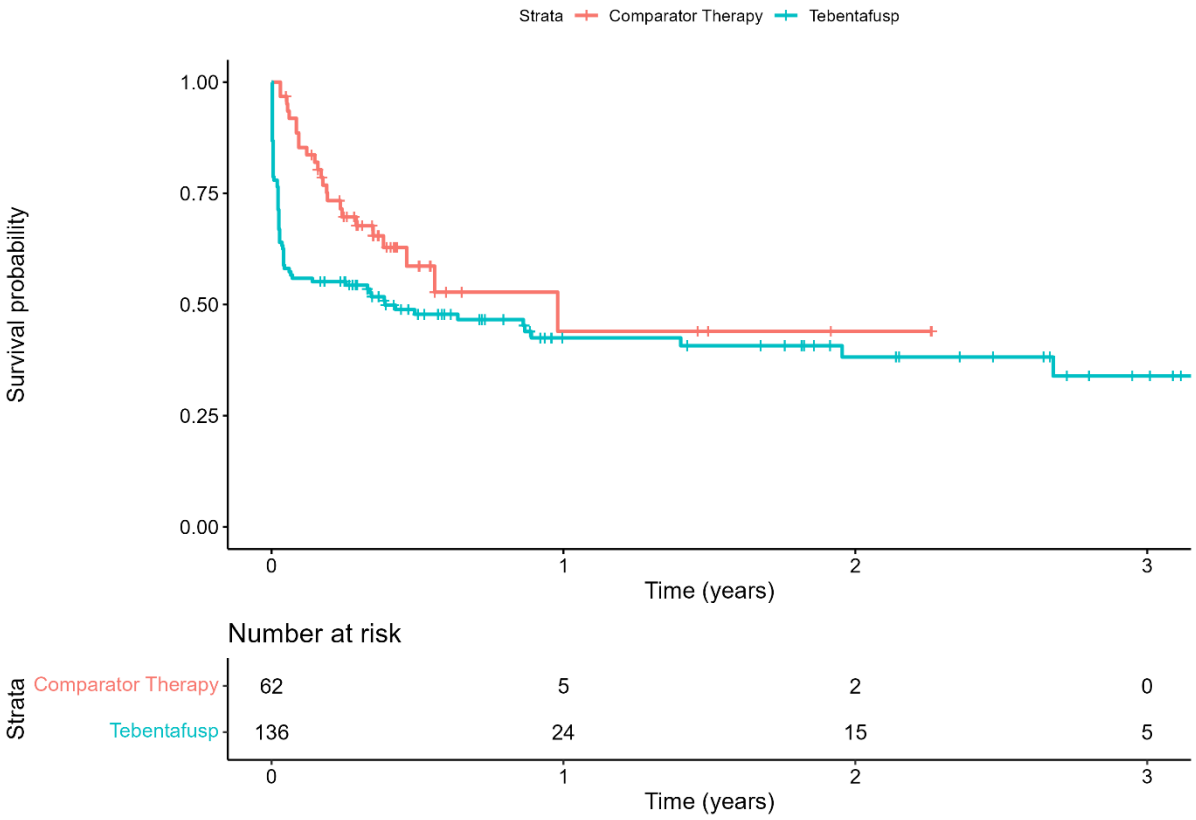
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



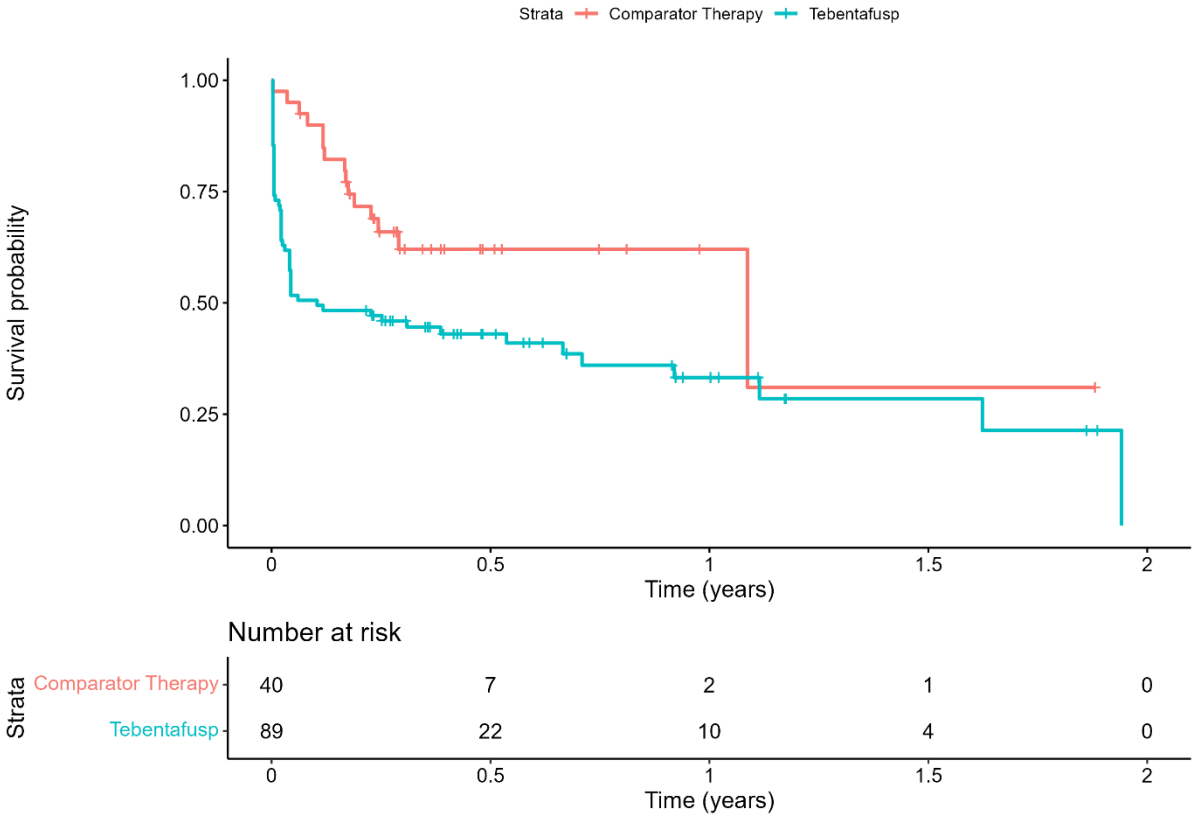
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



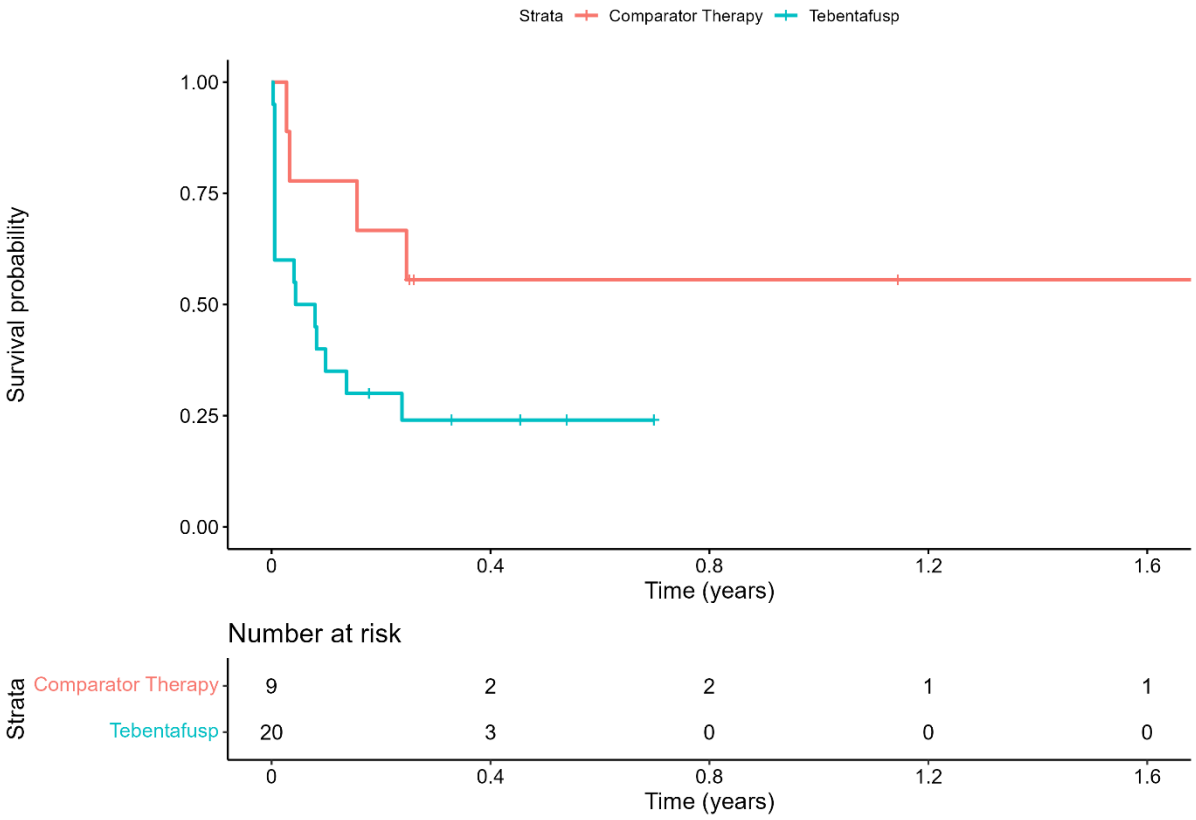
Größte metastatische Läsion (Baseline): ≤3,0 cm



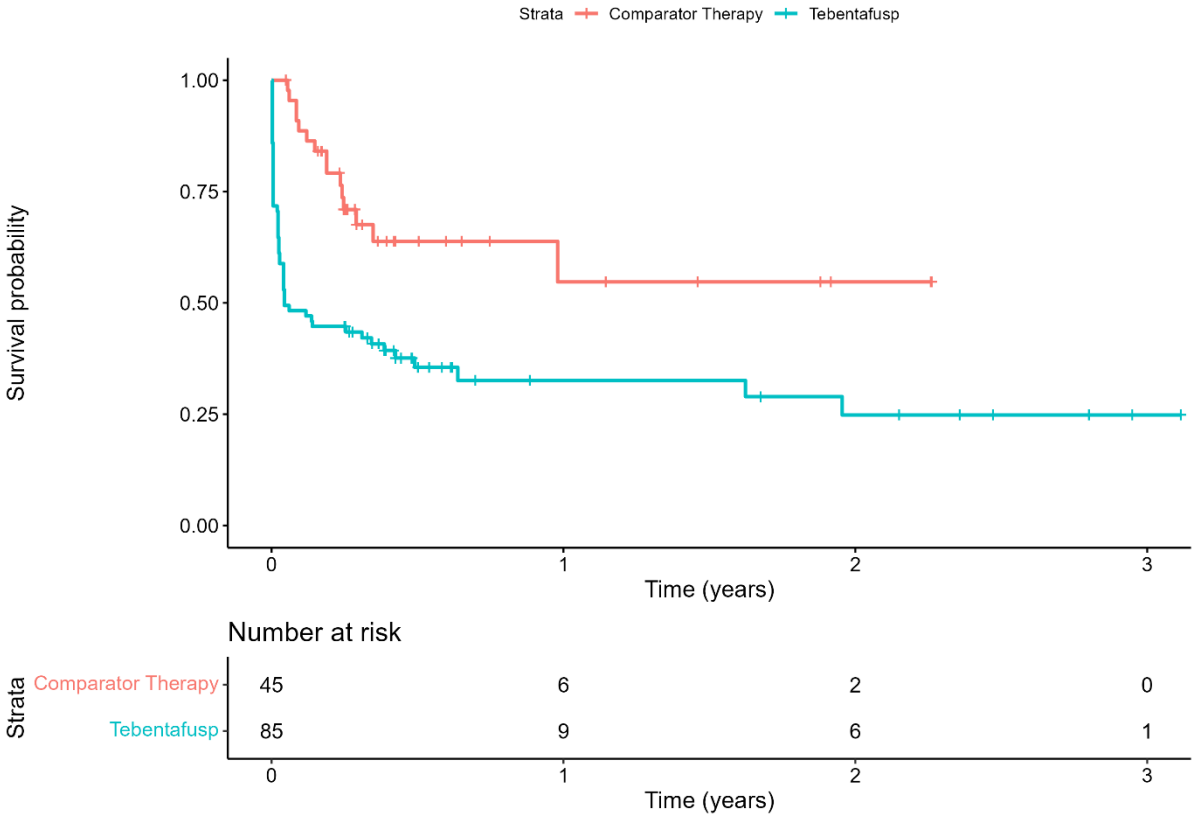
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



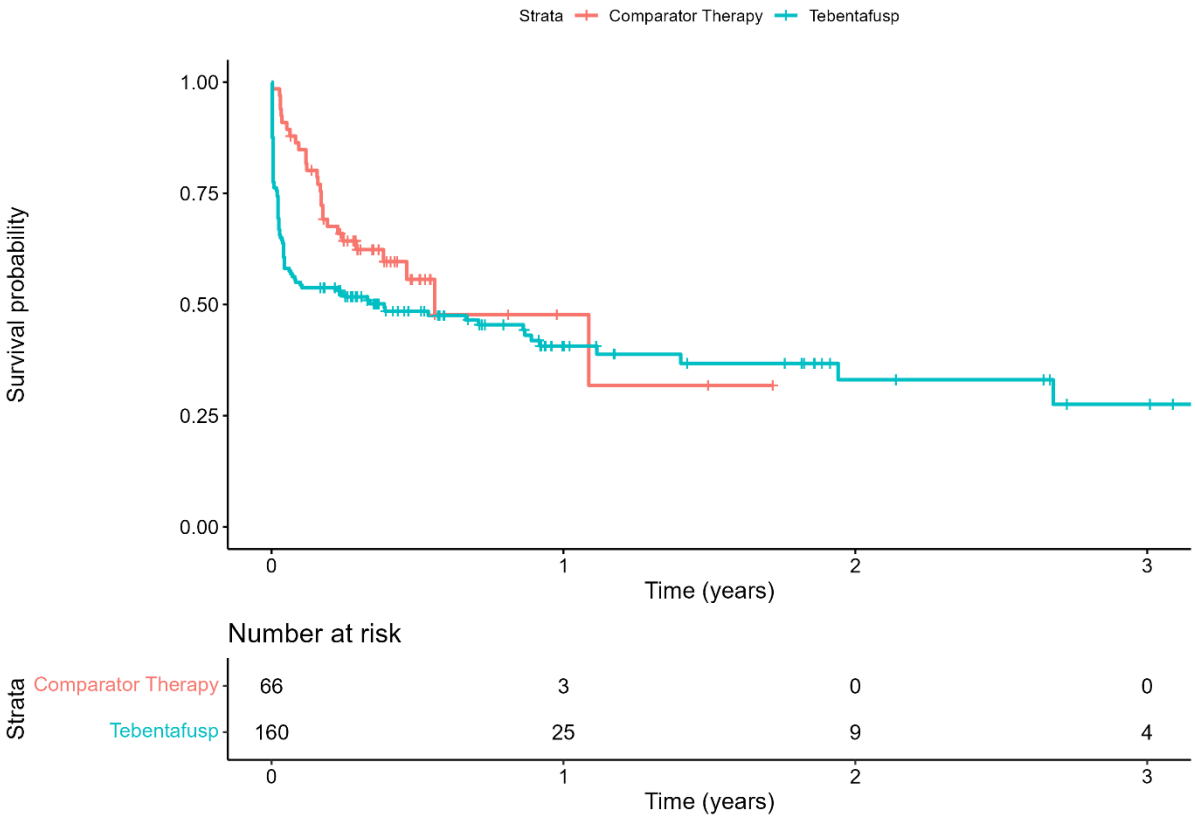
Größte metastatische Läsion (Baseline): ≥8,1 cm



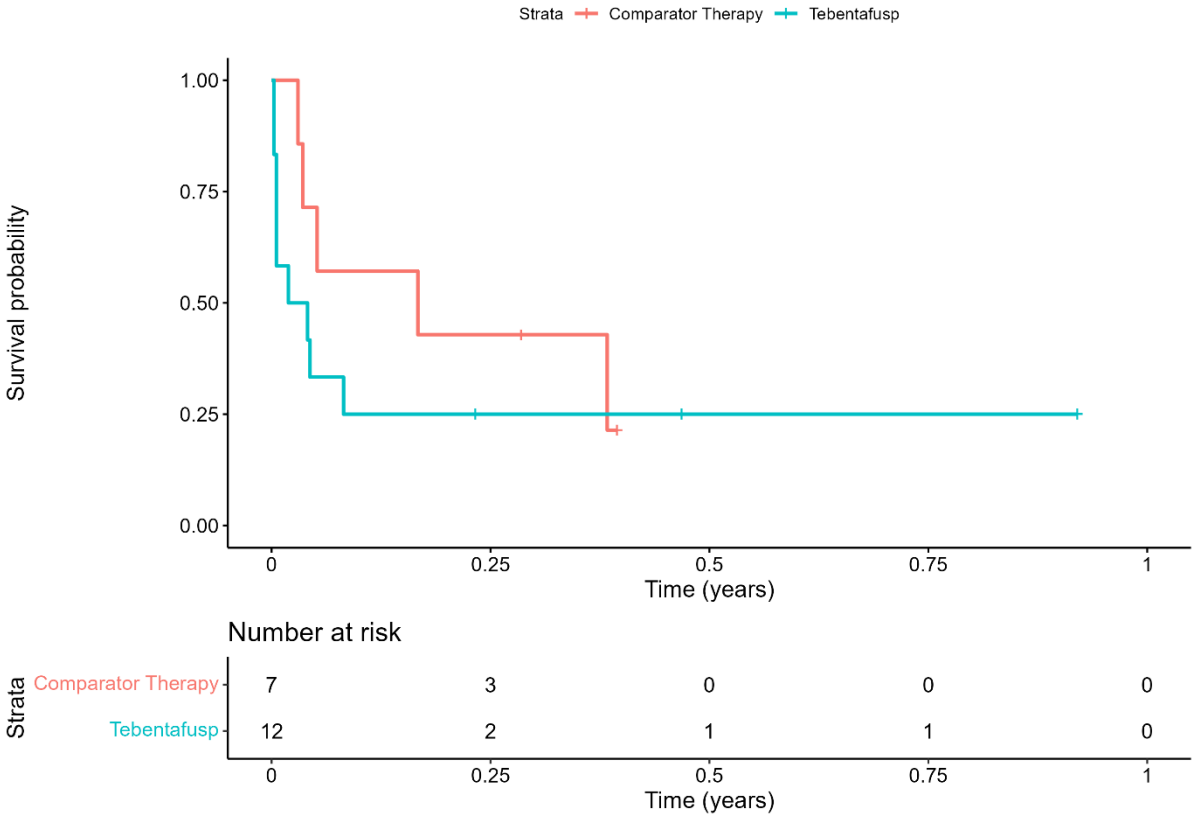
Region: Nordamerika



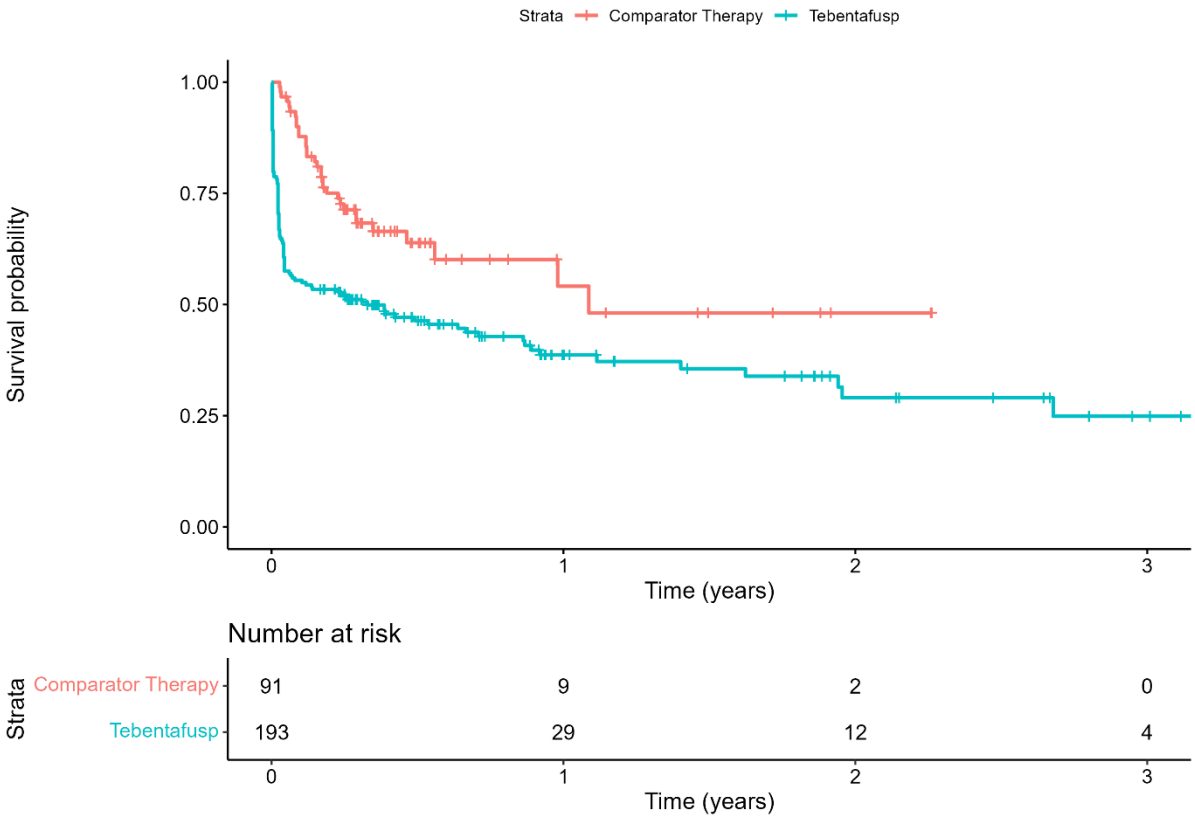
Region: Nicht-Nordamerika



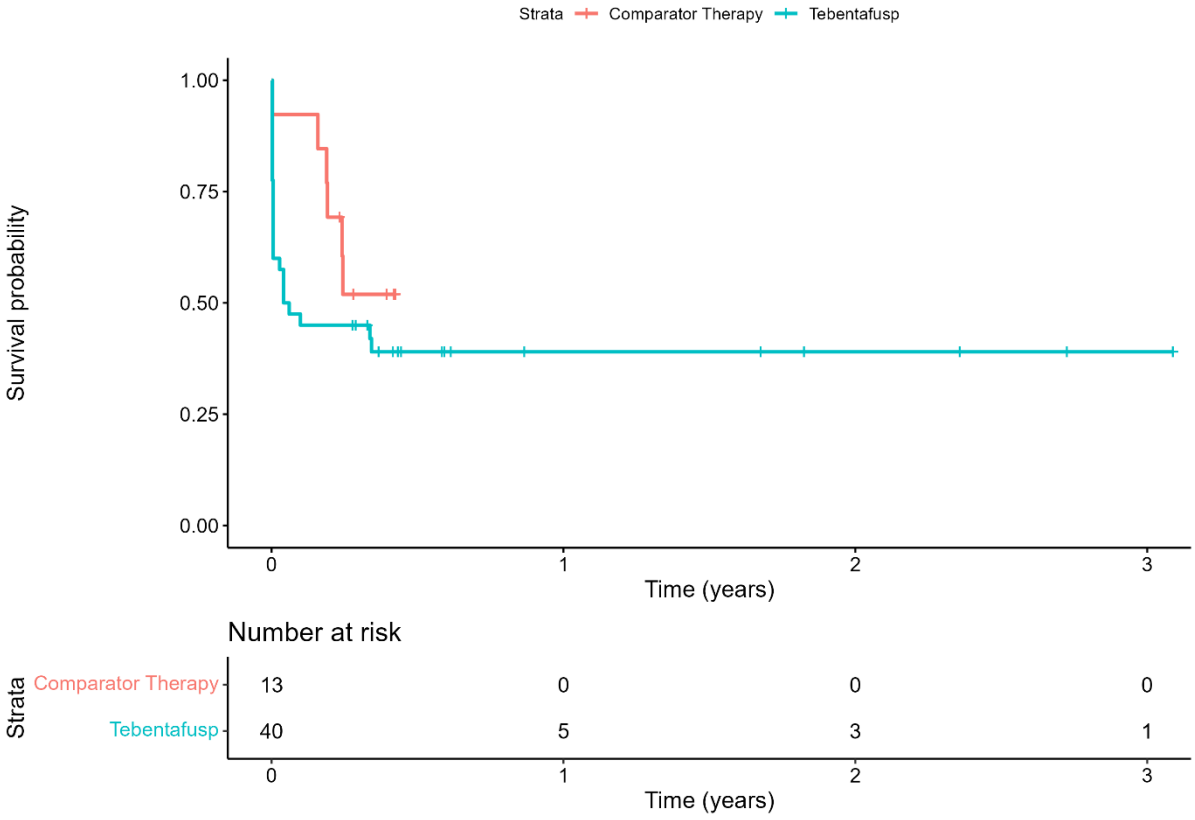
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

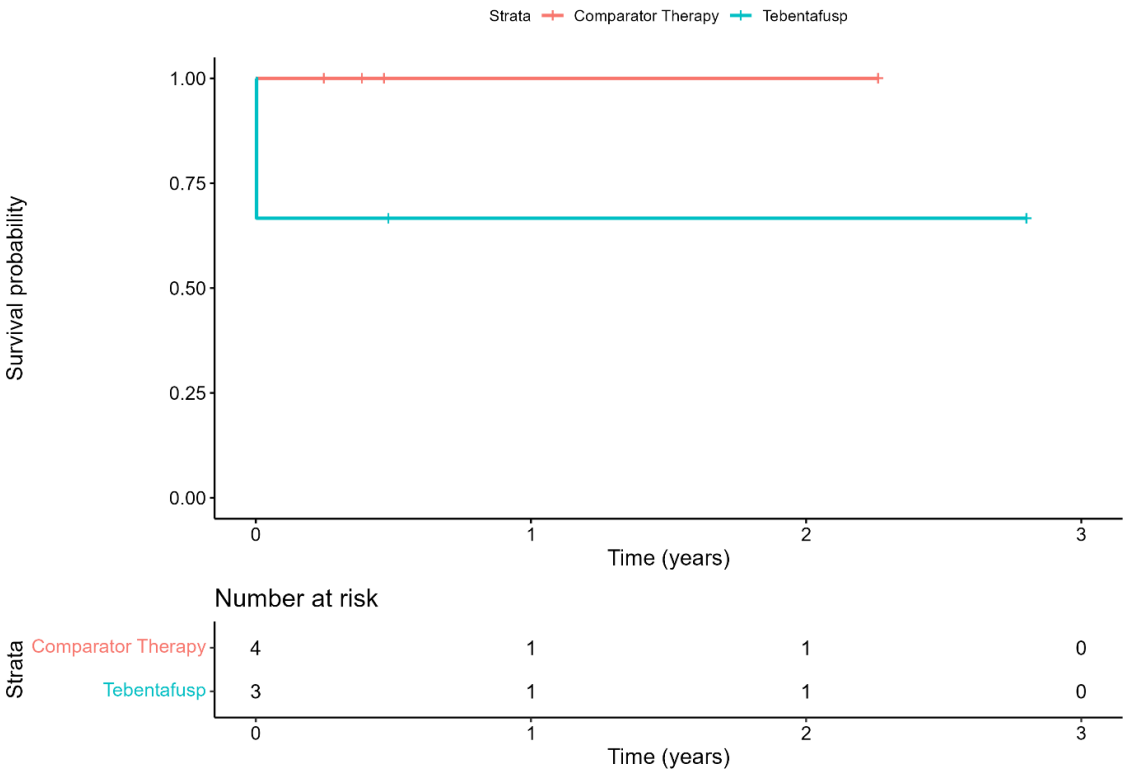


Vorauswahl der Chemotherapie: Ipilimumab

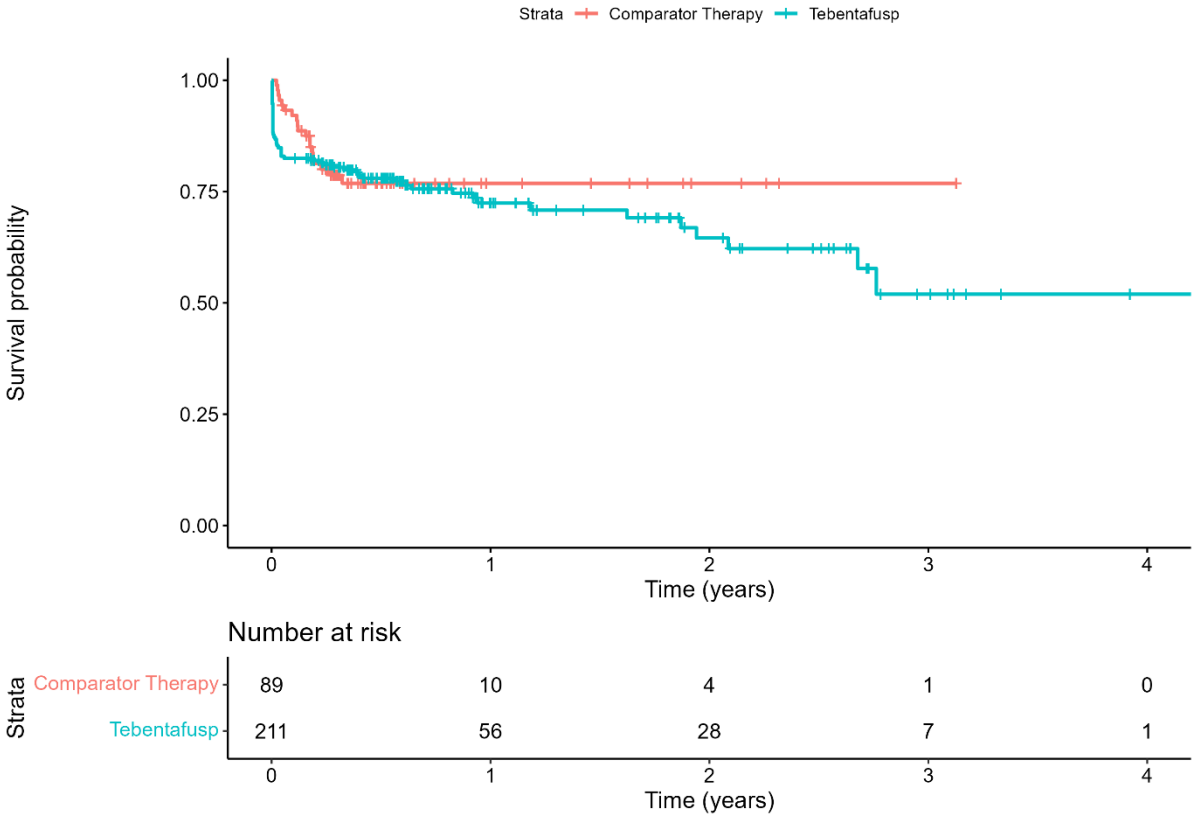


59.3 Jegliches SUE (Tabelle 4-218)

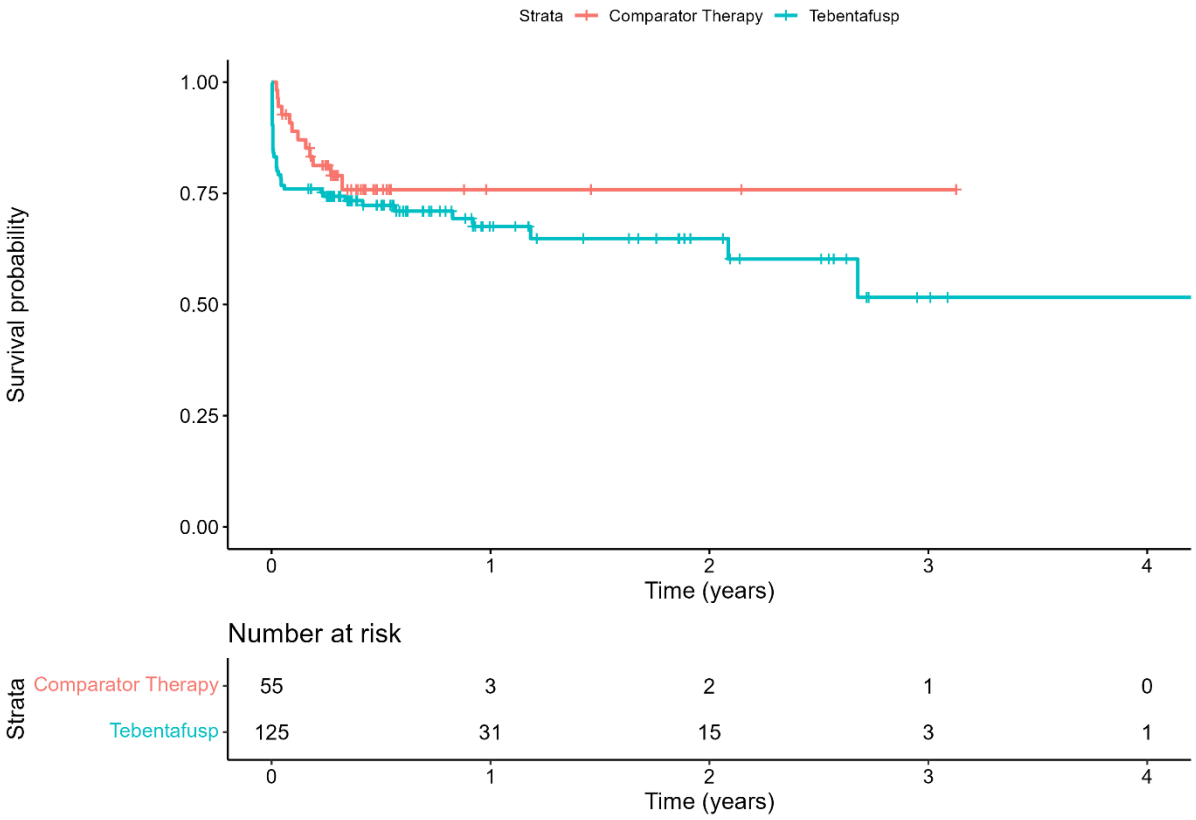
Herkunft: Hispanisch



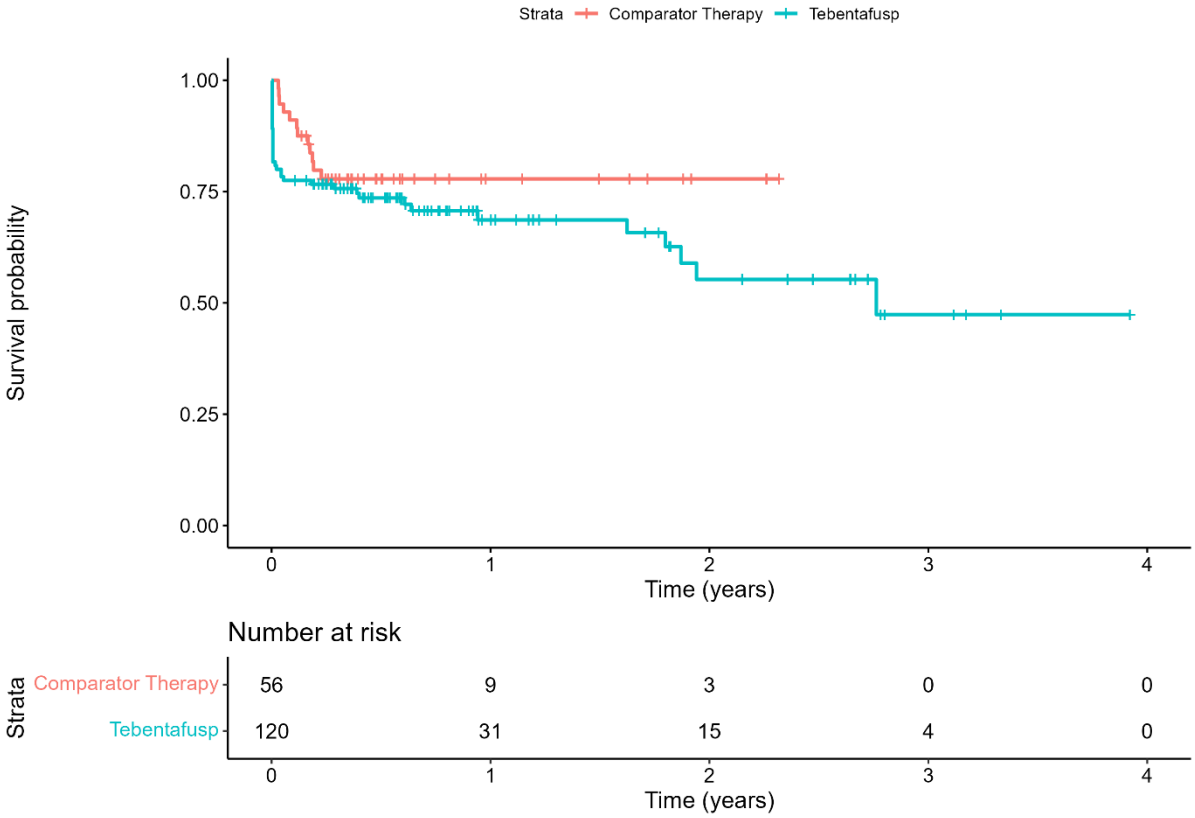
Herkunft: Nicht-hispanisch



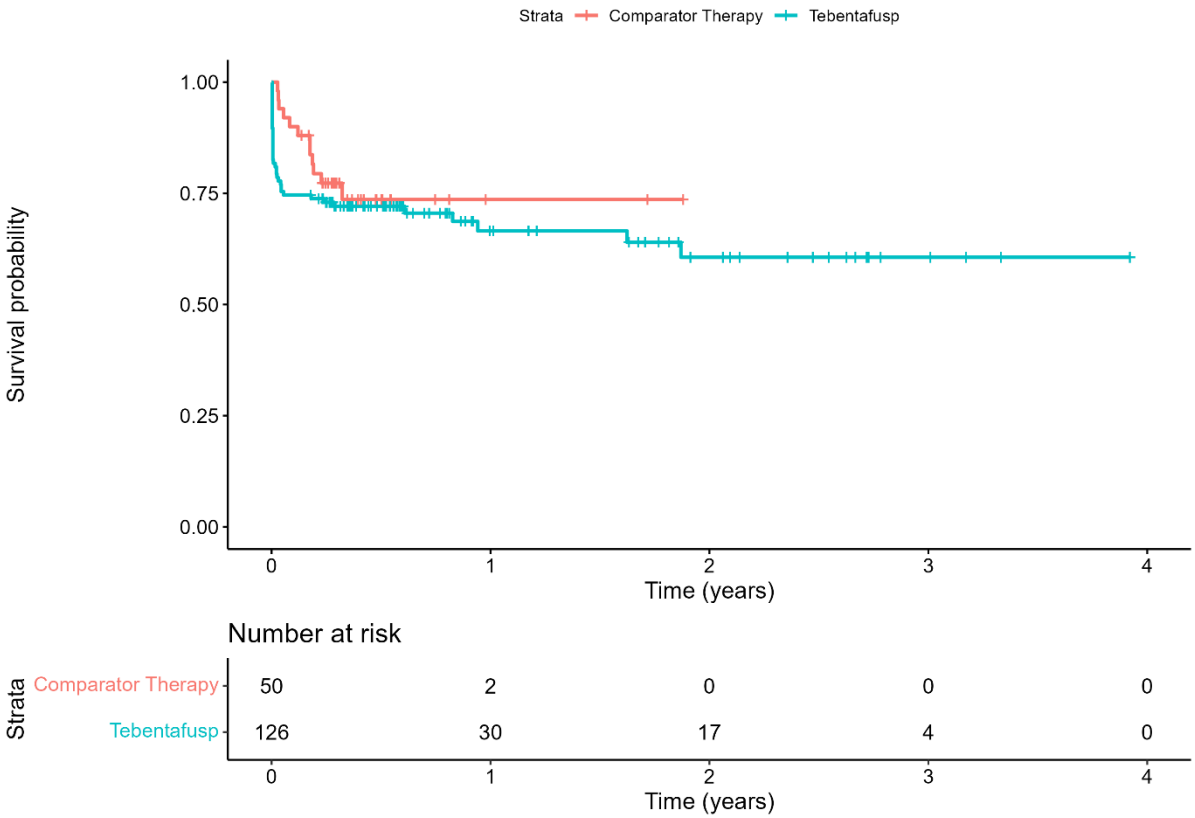
Geschlecht: Männlich



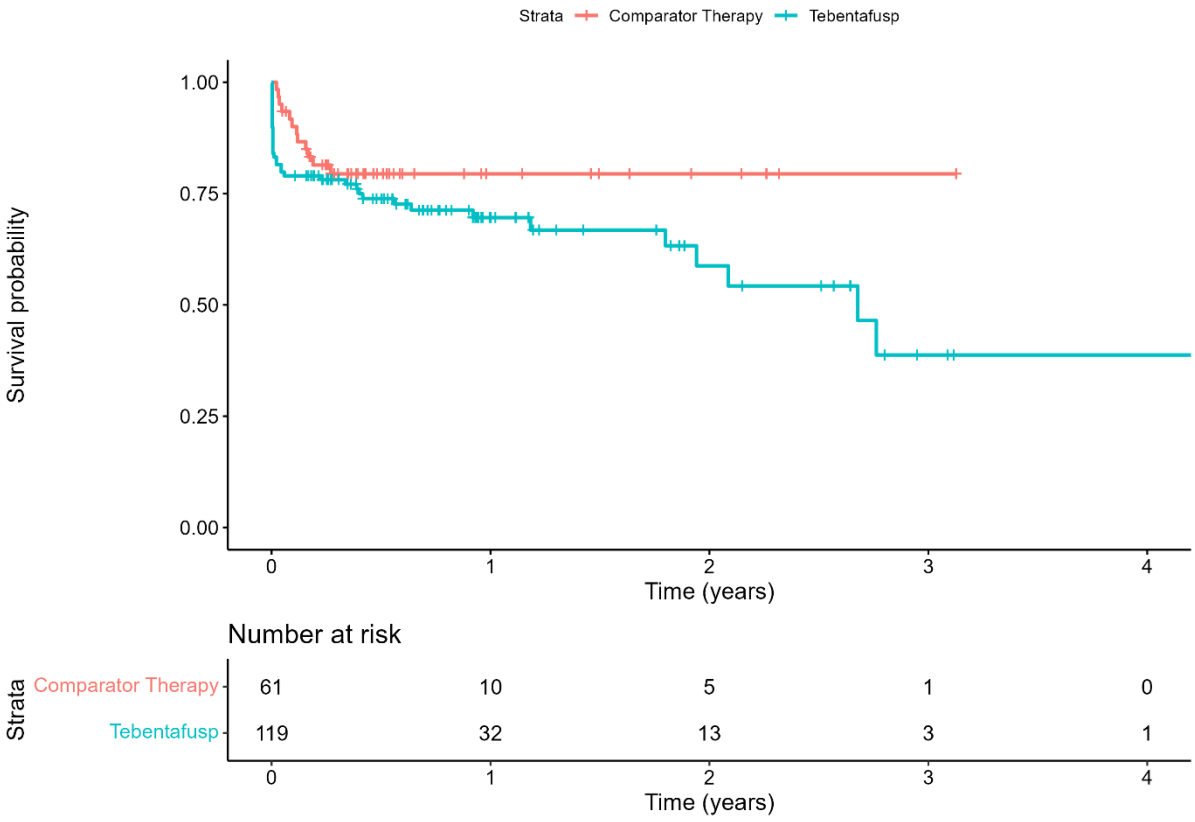
Geschlecht: Weiblich



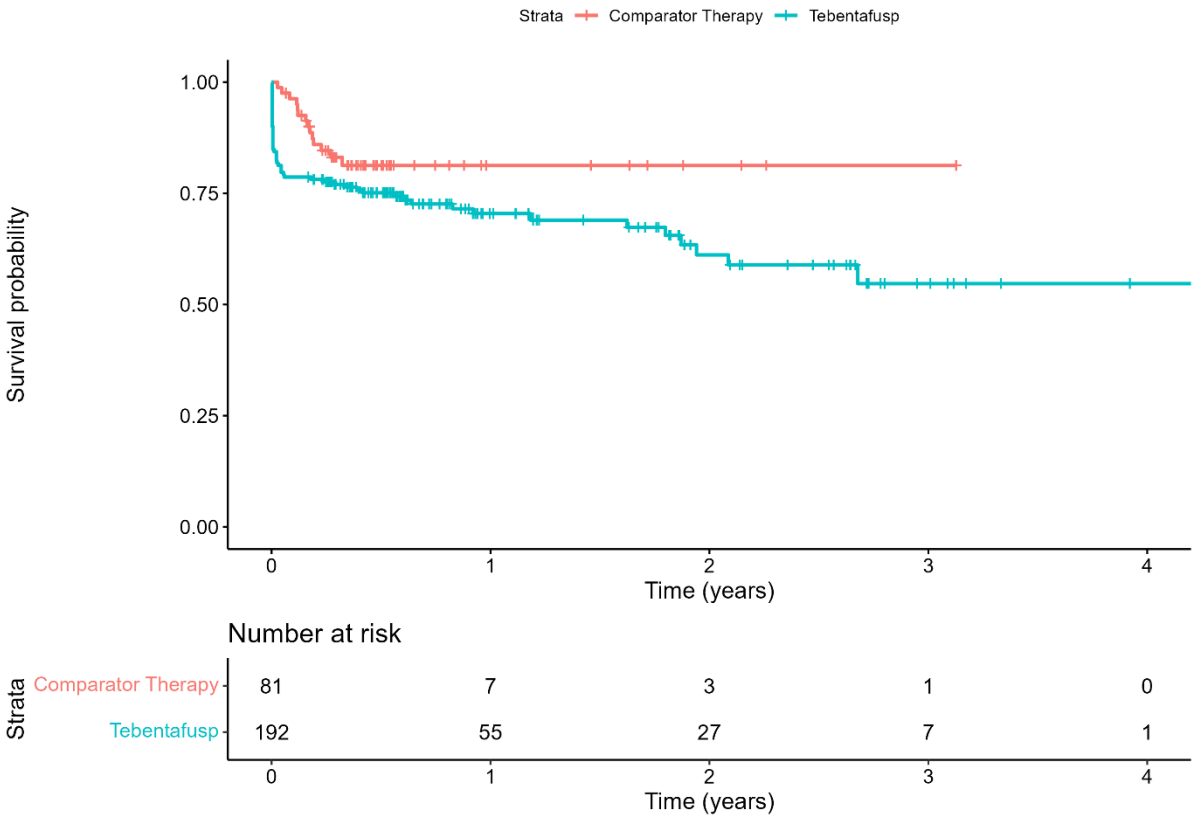
Alter: <65 Jahre



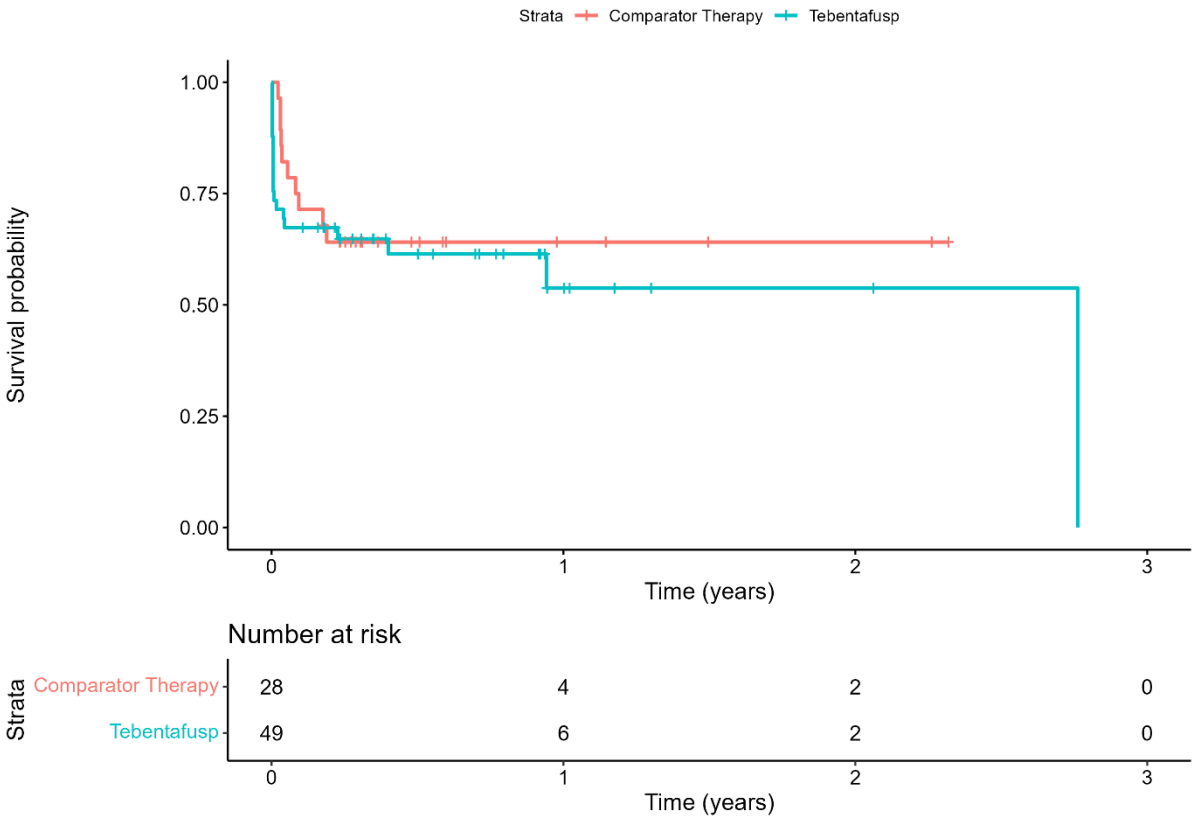
Alter: ≥65 Jahre



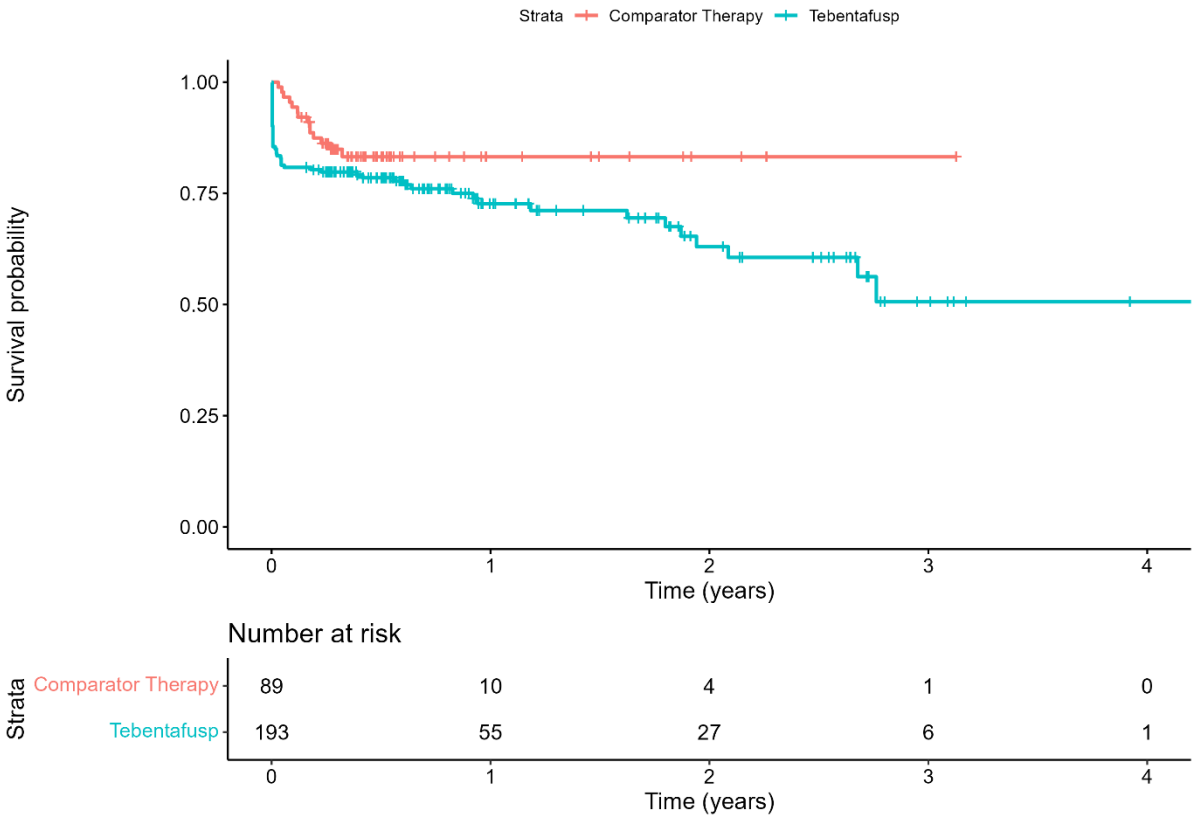
ECOG-Performance-Status: 0



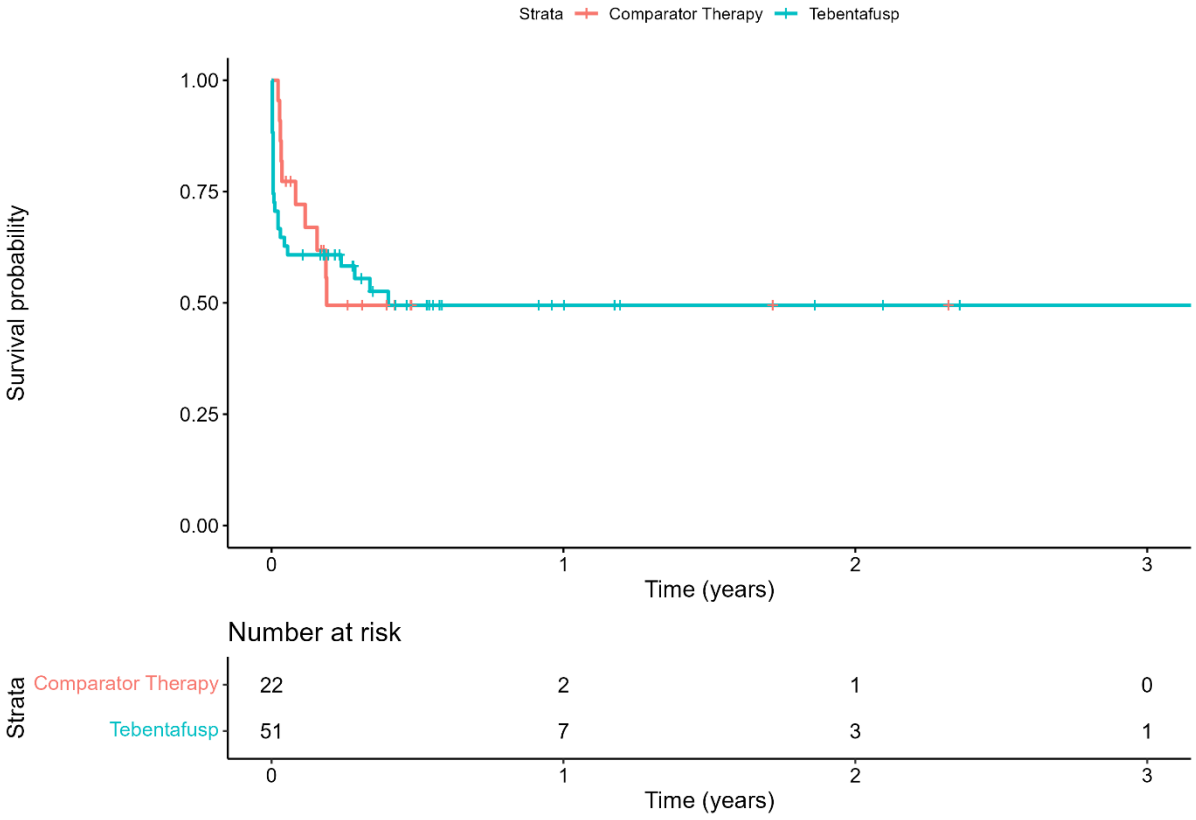
ECOG-Performance-Status: 1



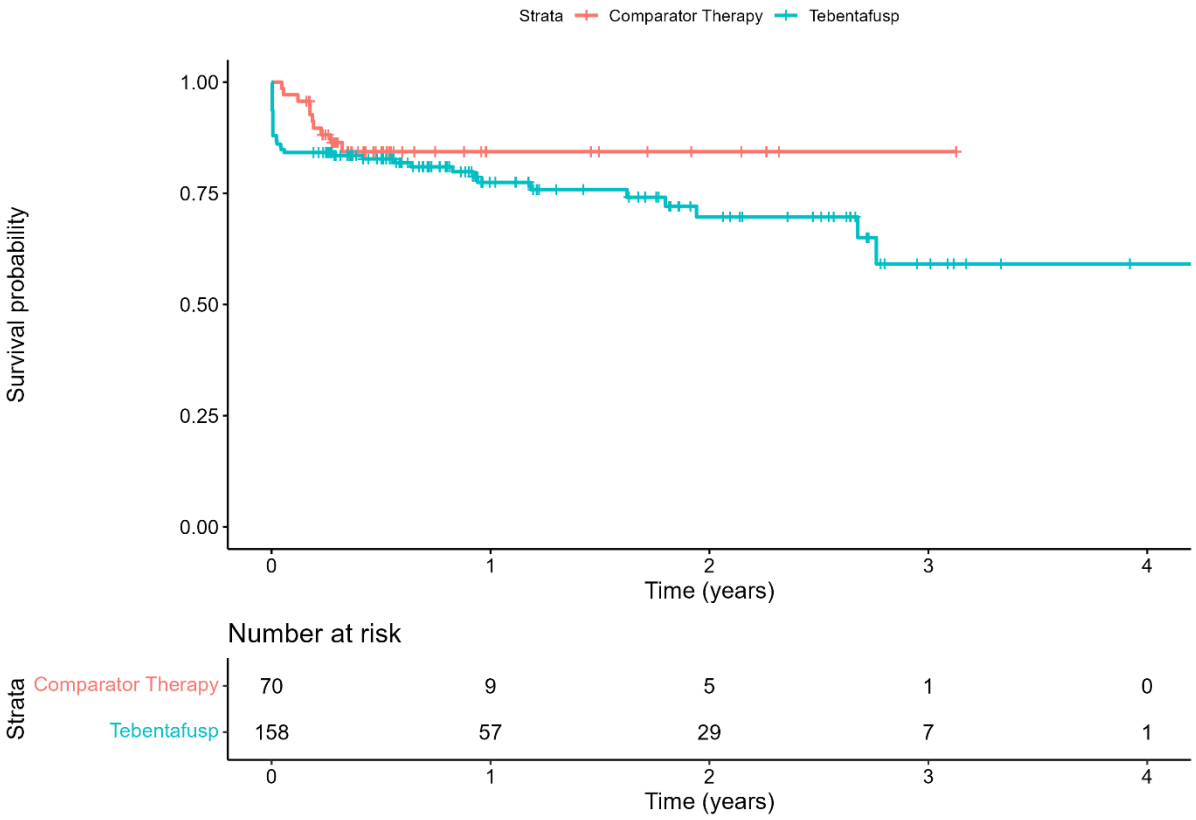
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



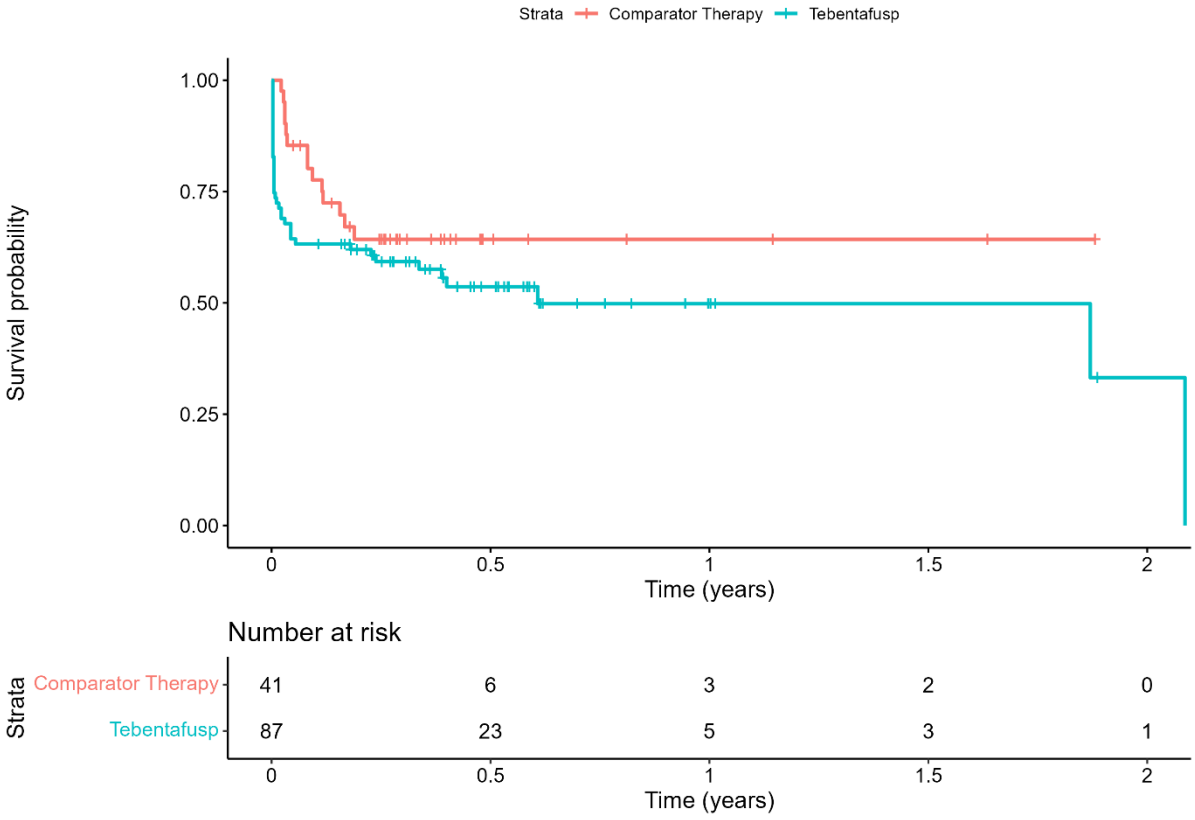
Alkalische Phosphatase (ALP) (Baseline): >ULN



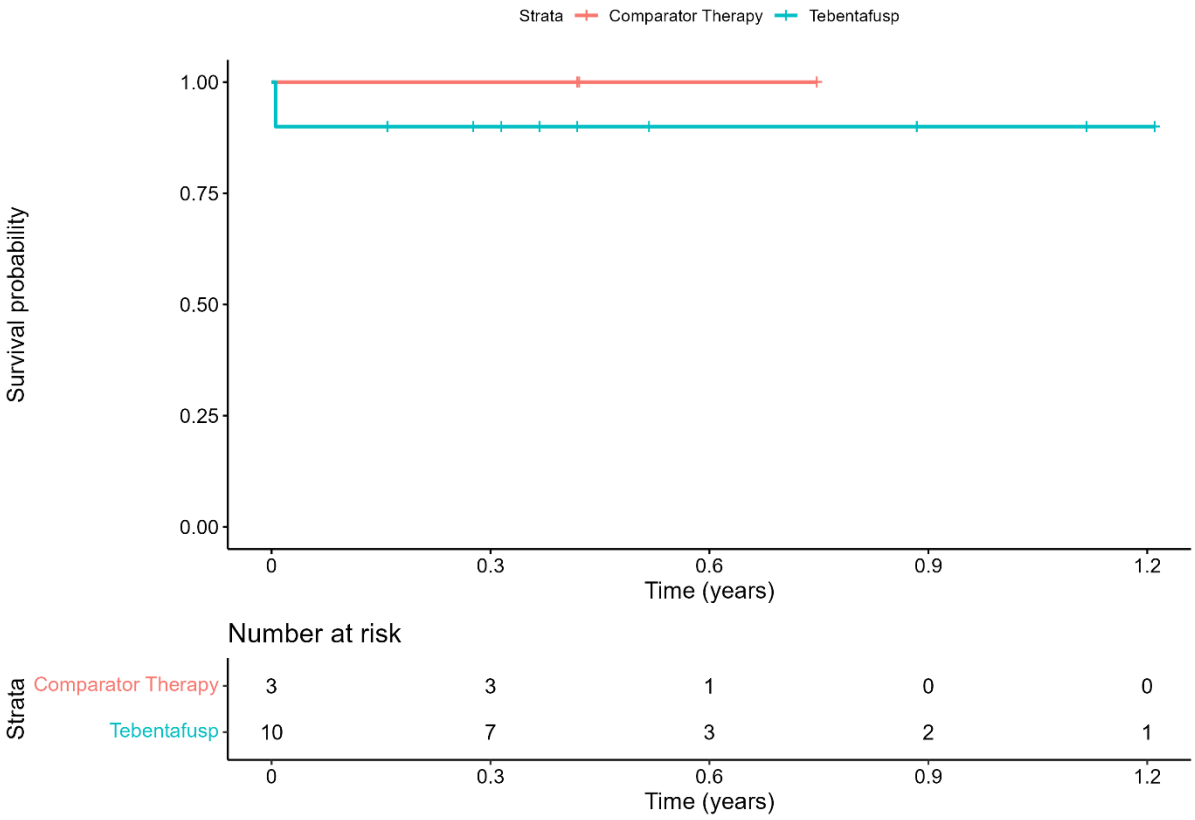
LDH: ≤ULN



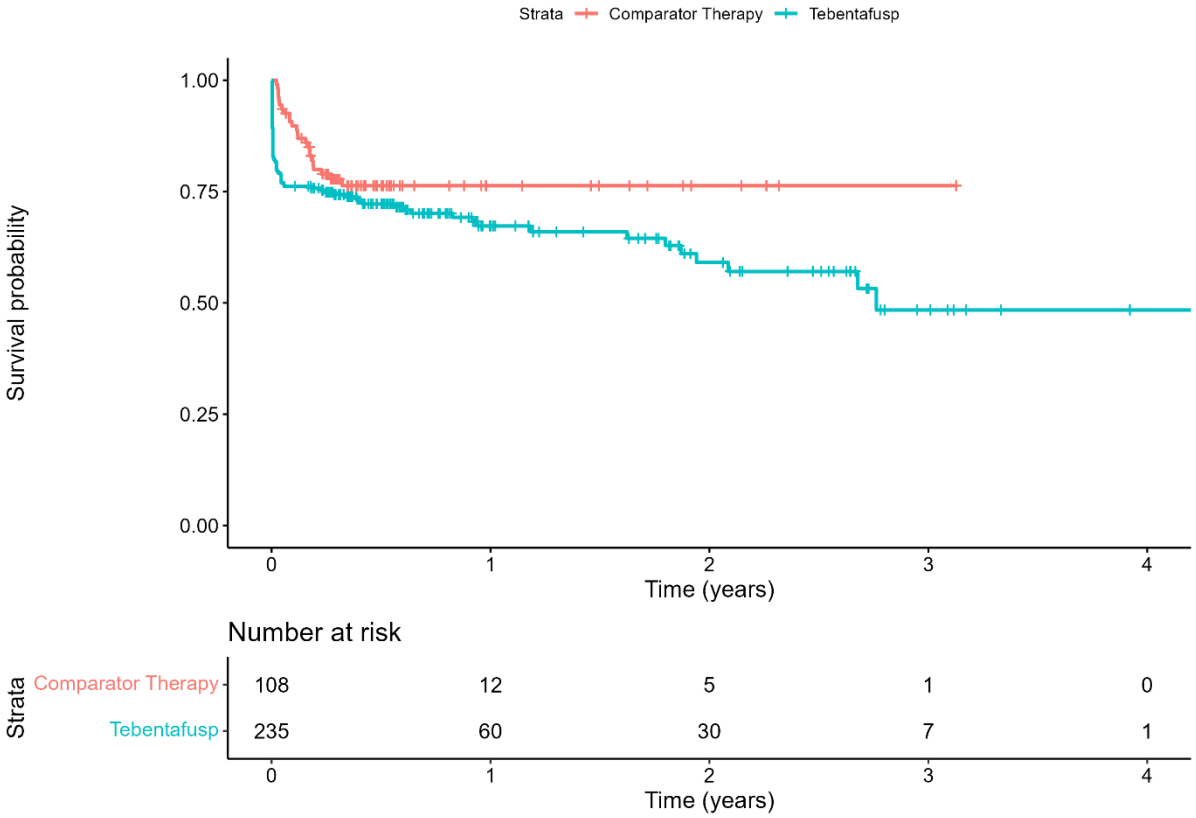
LDH: >ULN



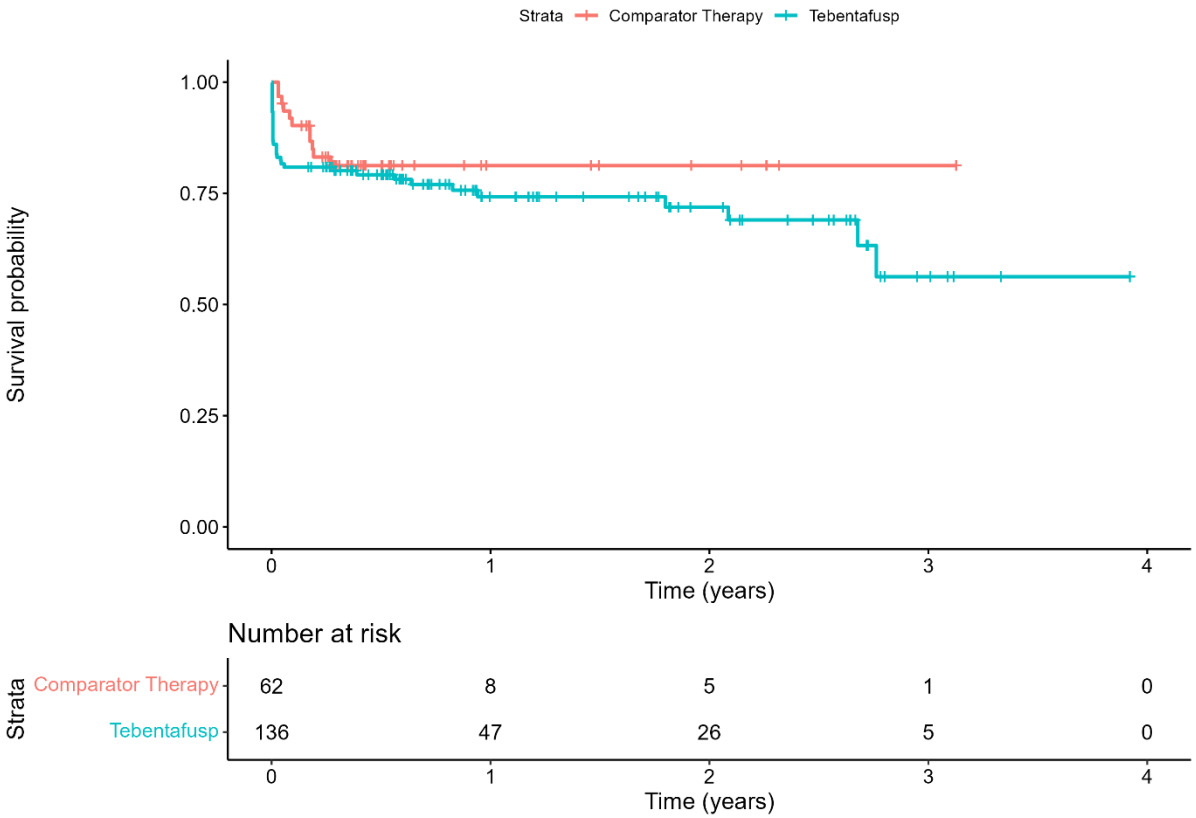
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



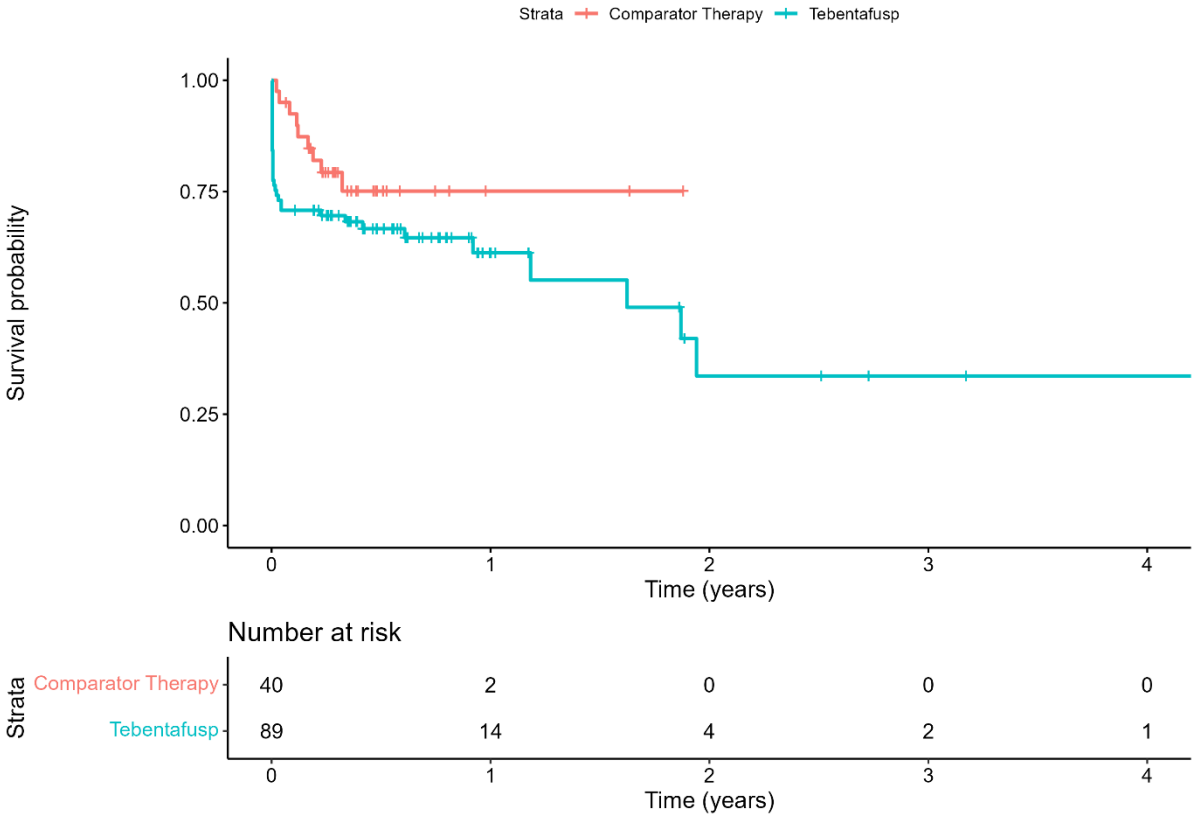
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



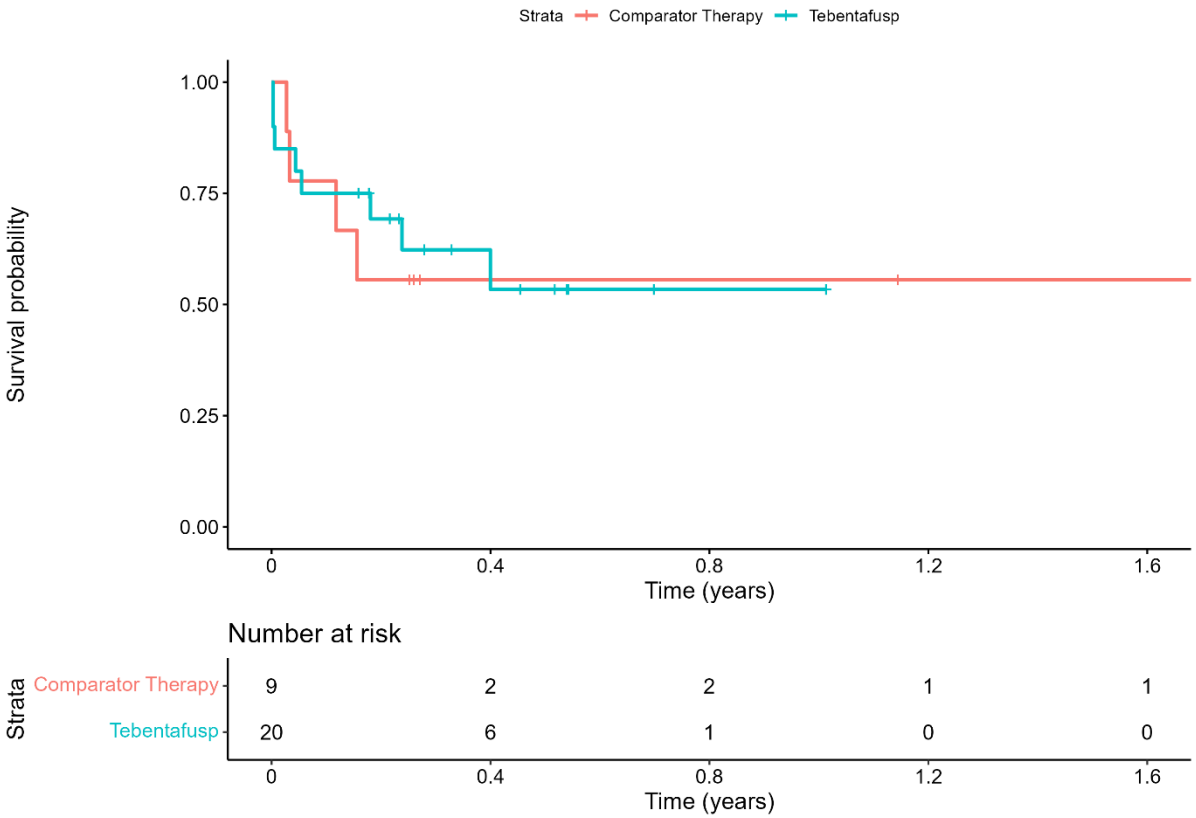
Größte metastatische Läsion (Baseline): ≤3,0 cm



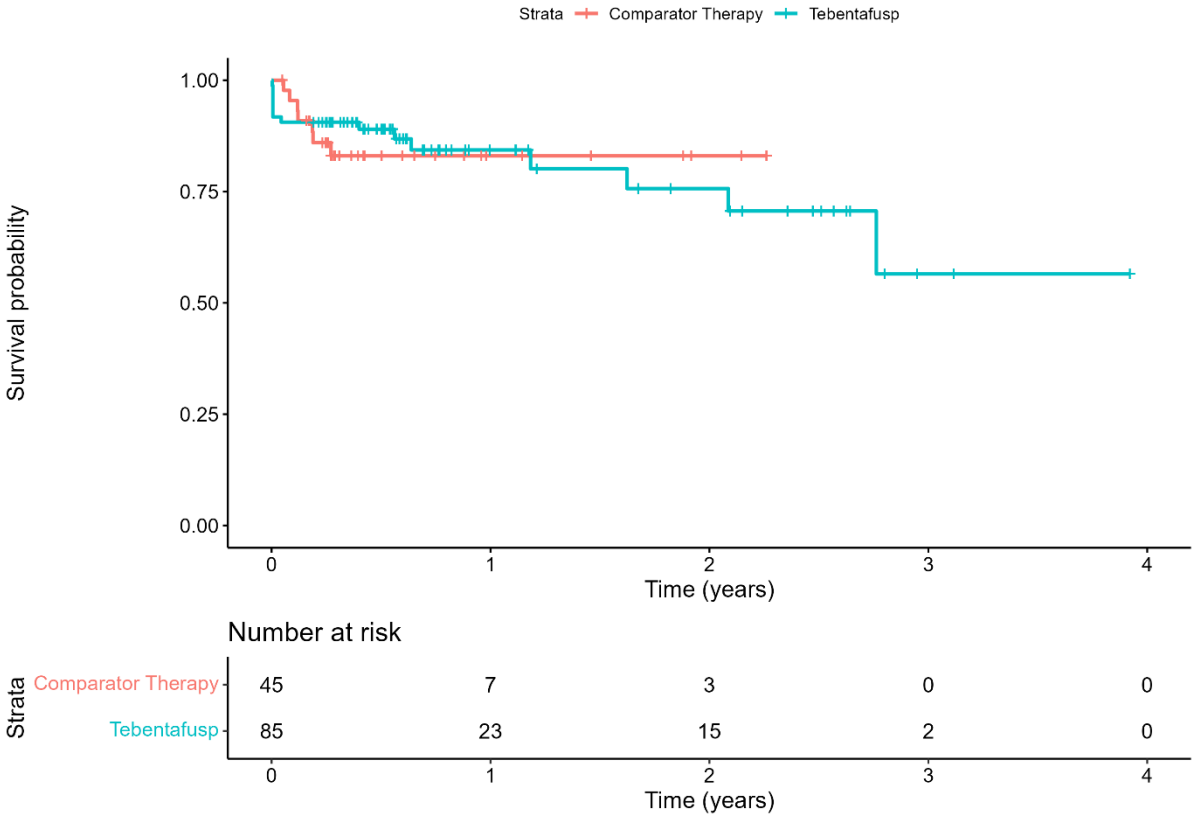
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



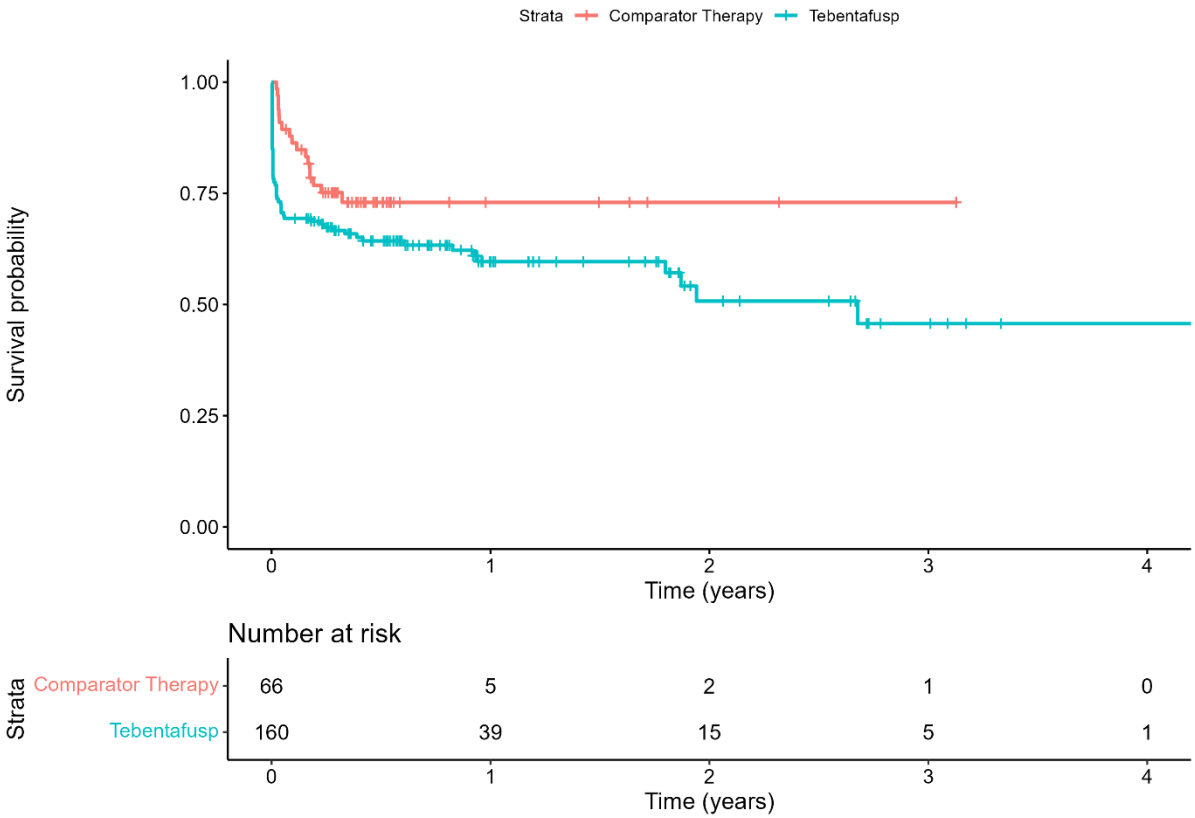
Größte metastatische Läsion (Baseline): ≥8,1 cm



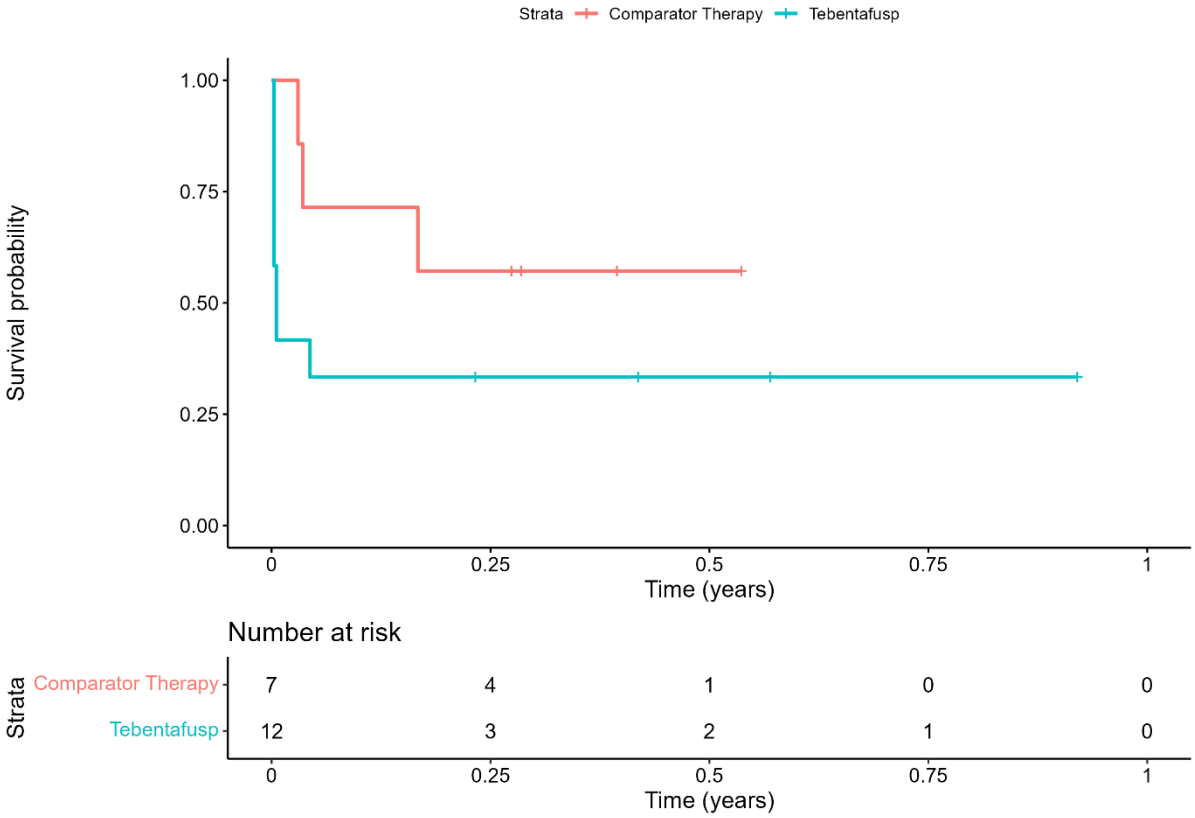
Region: Nordamerika



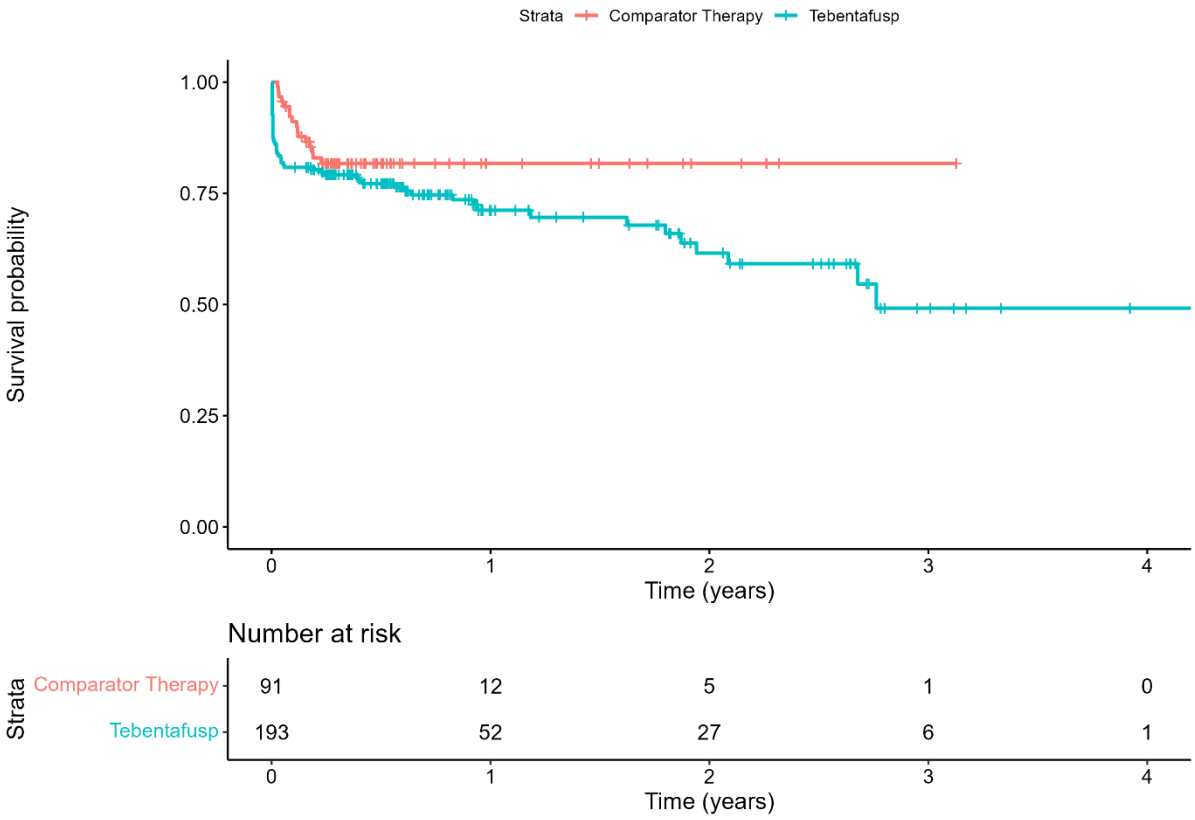
Region: Nicht-Nordamerika



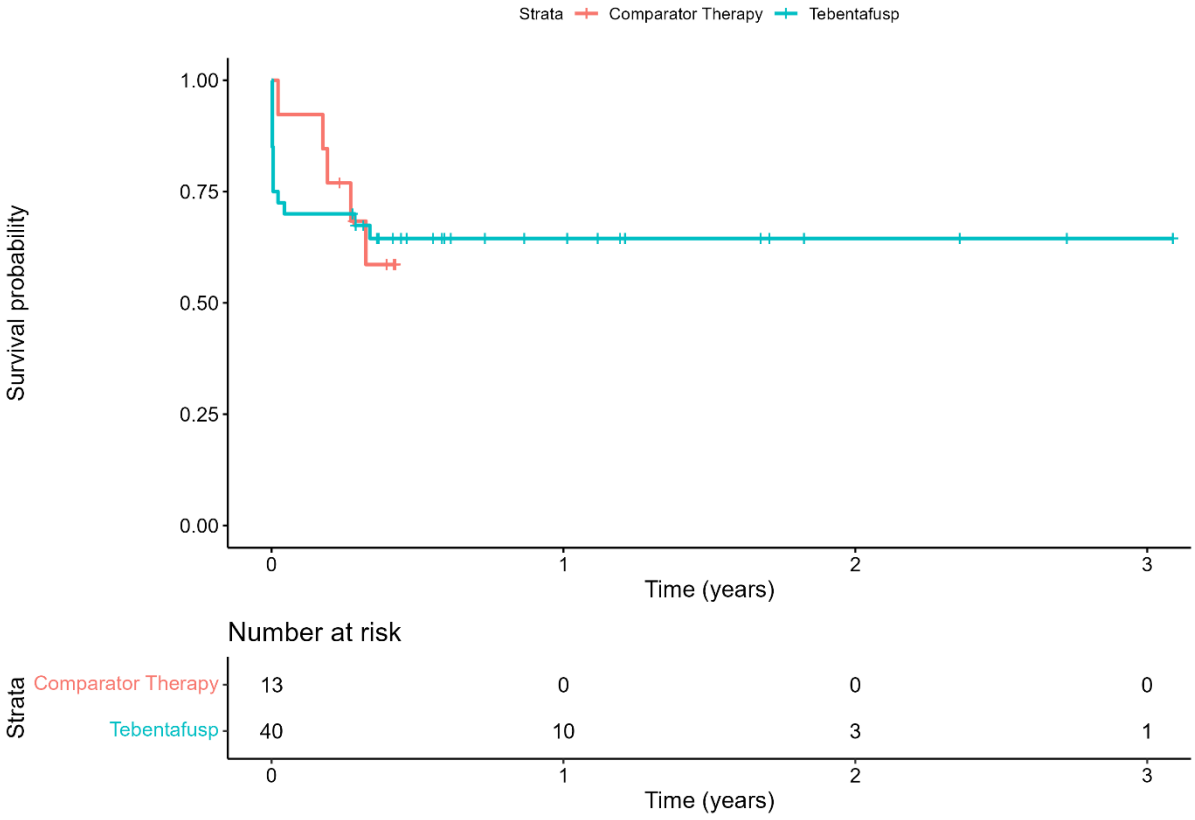
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

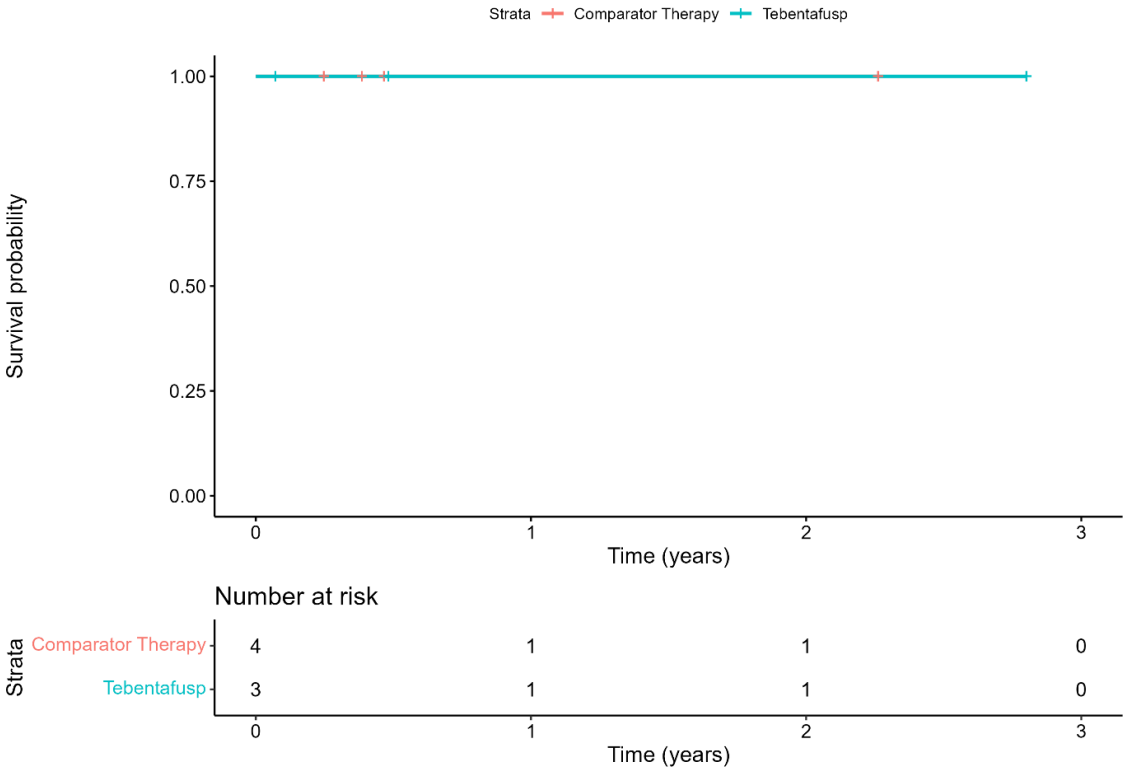


Vorauswahl der Chemotherapie: Ipilimumab

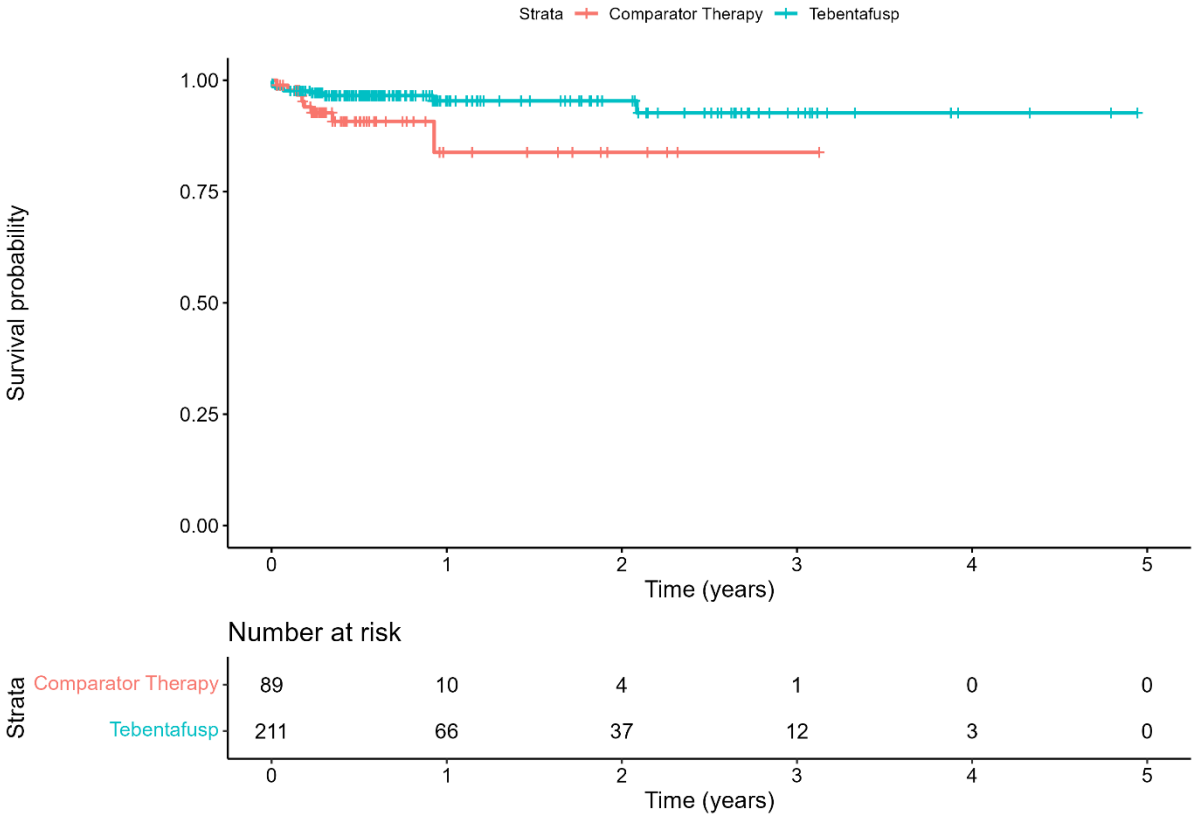


59.4 Jegliches UE, das zum Absetzen des Studienmedikaments führte (Tabelle 4-220)

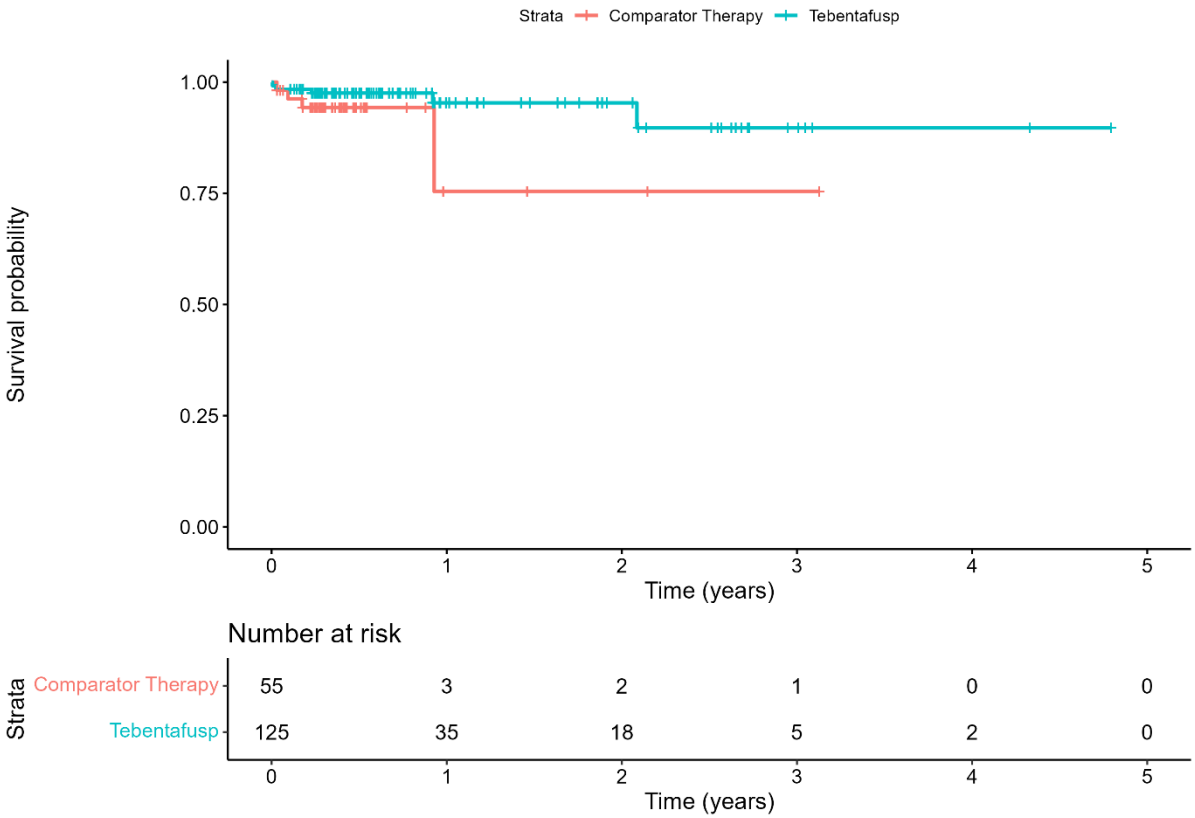
Herkunft: Hispanisch



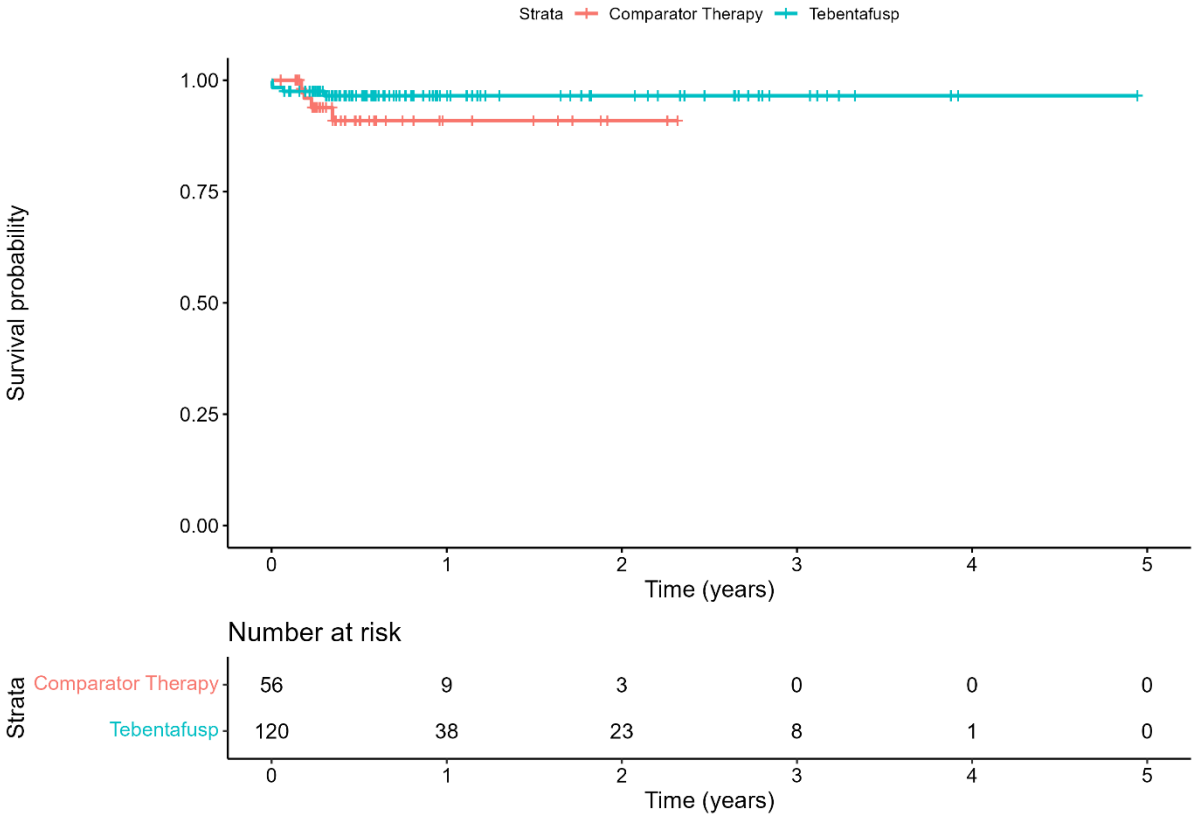
Herkunft: Nicht-hispanisch



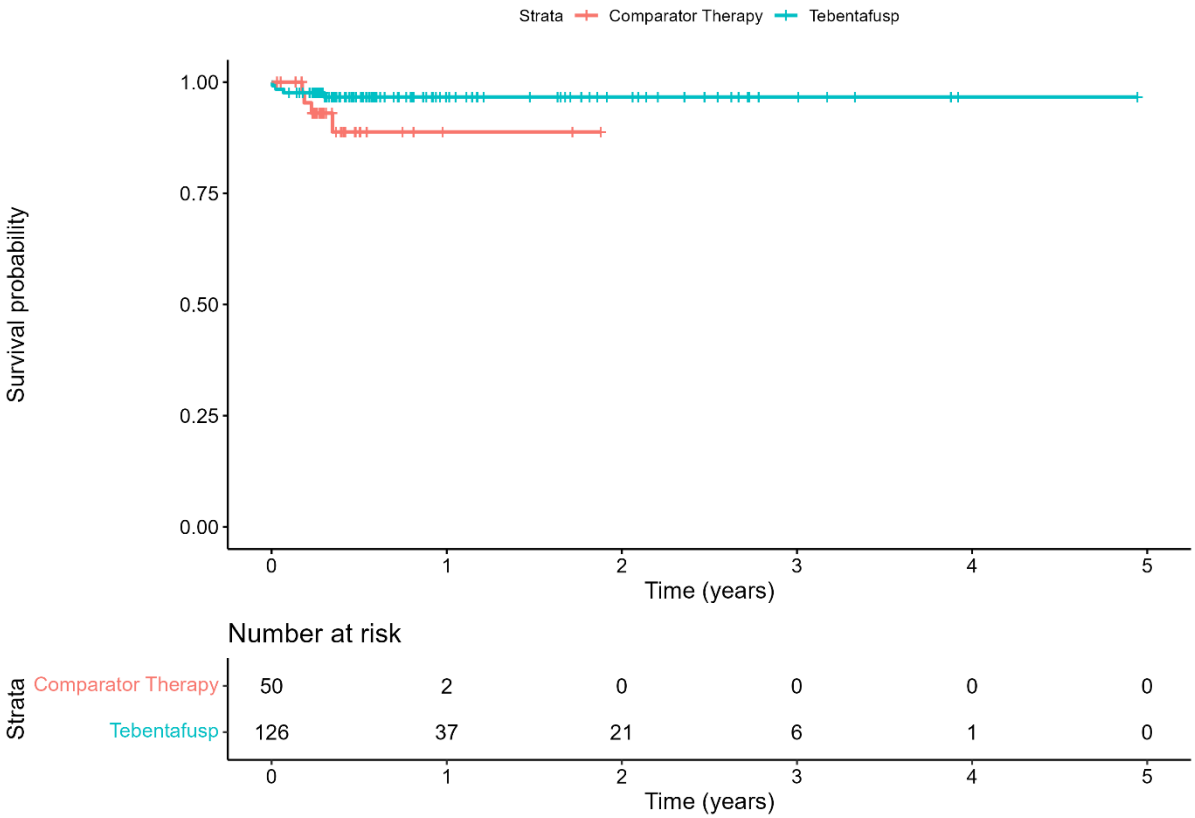
Geschlecht: Männlich



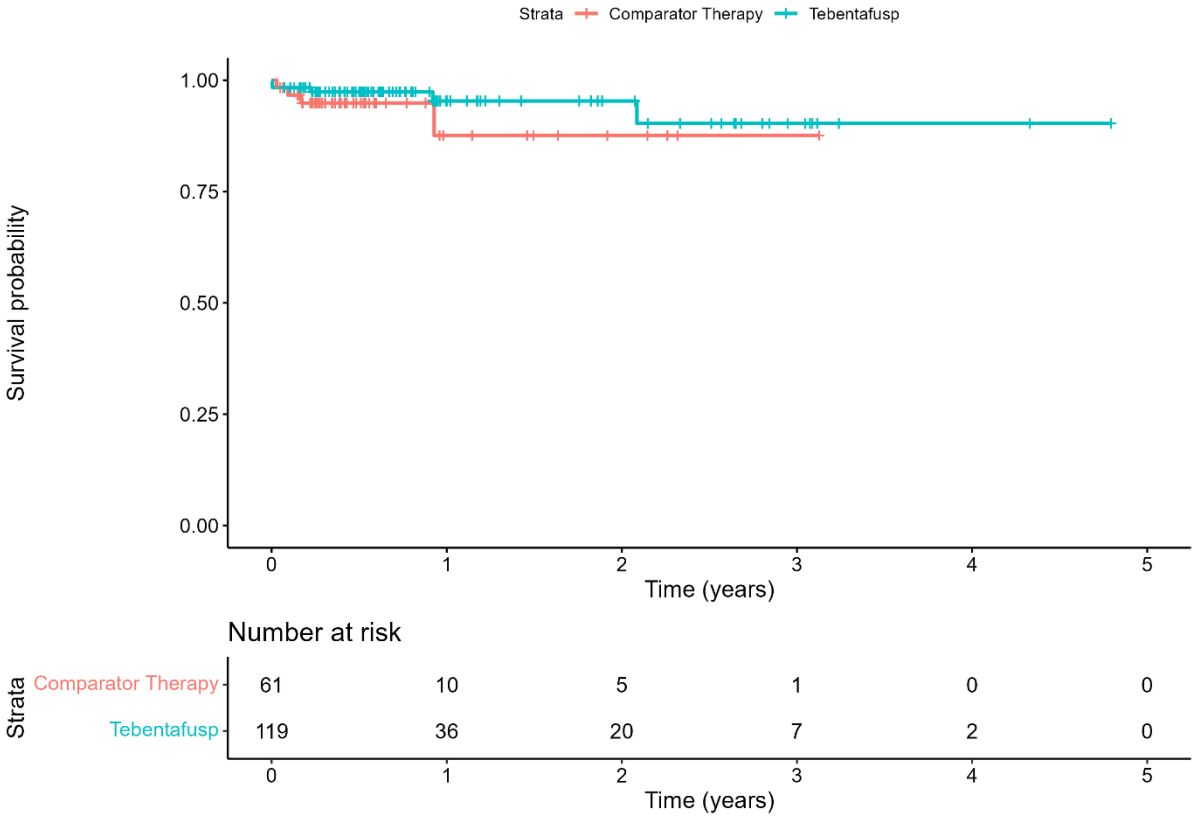
Geschlecht: Weiblich



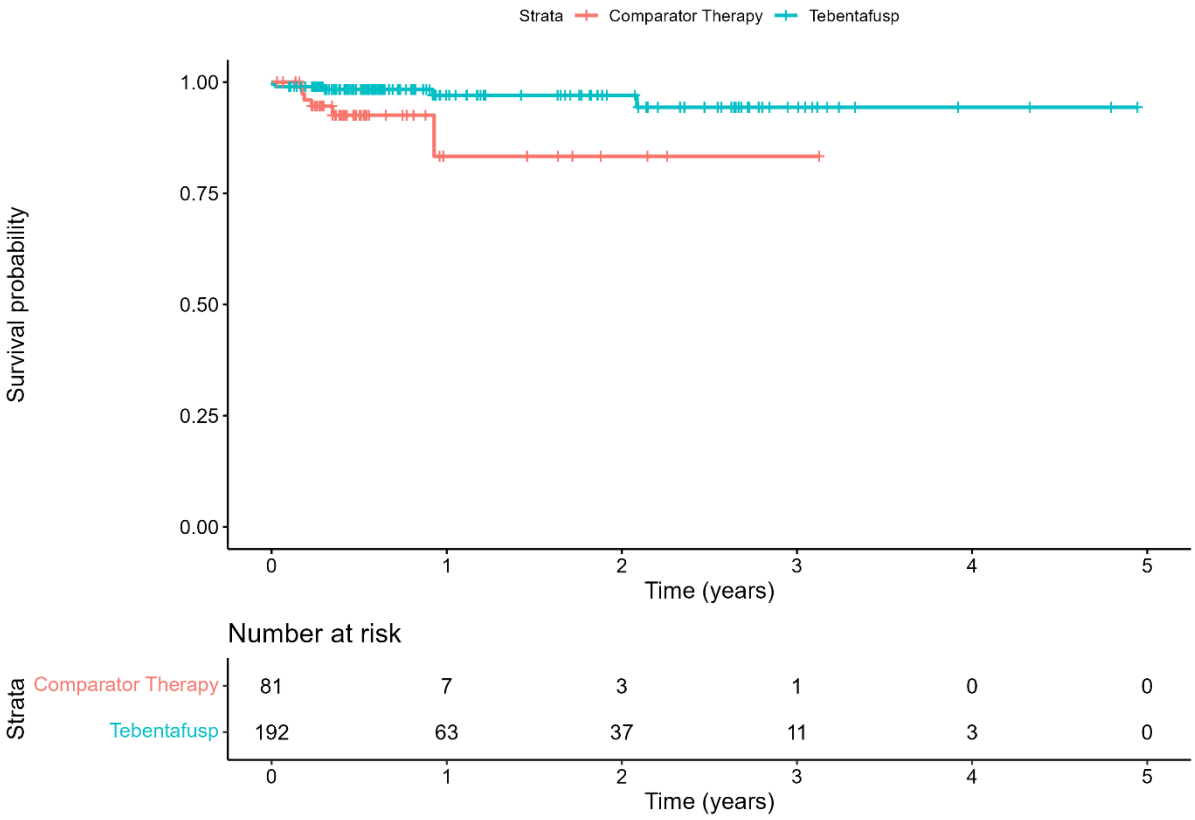
Alter: <65 Jahre



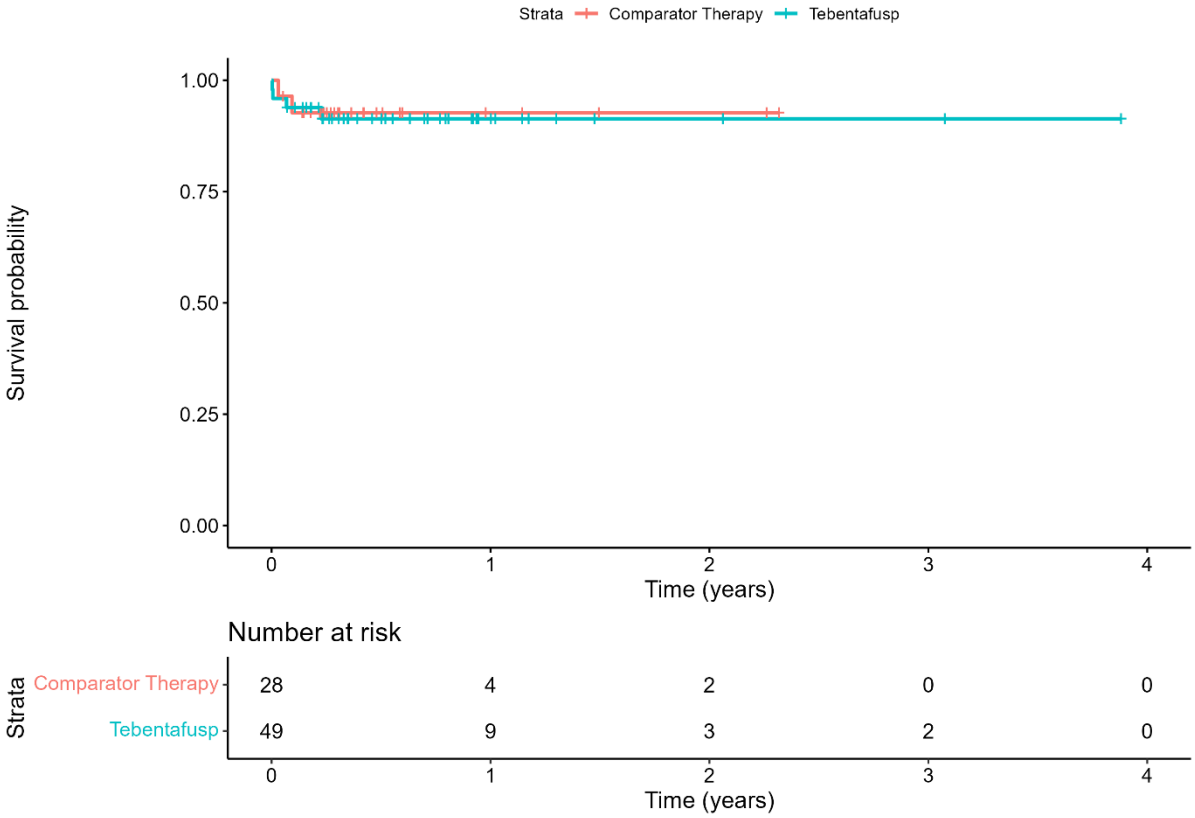
Alter: ≥65 Jahre



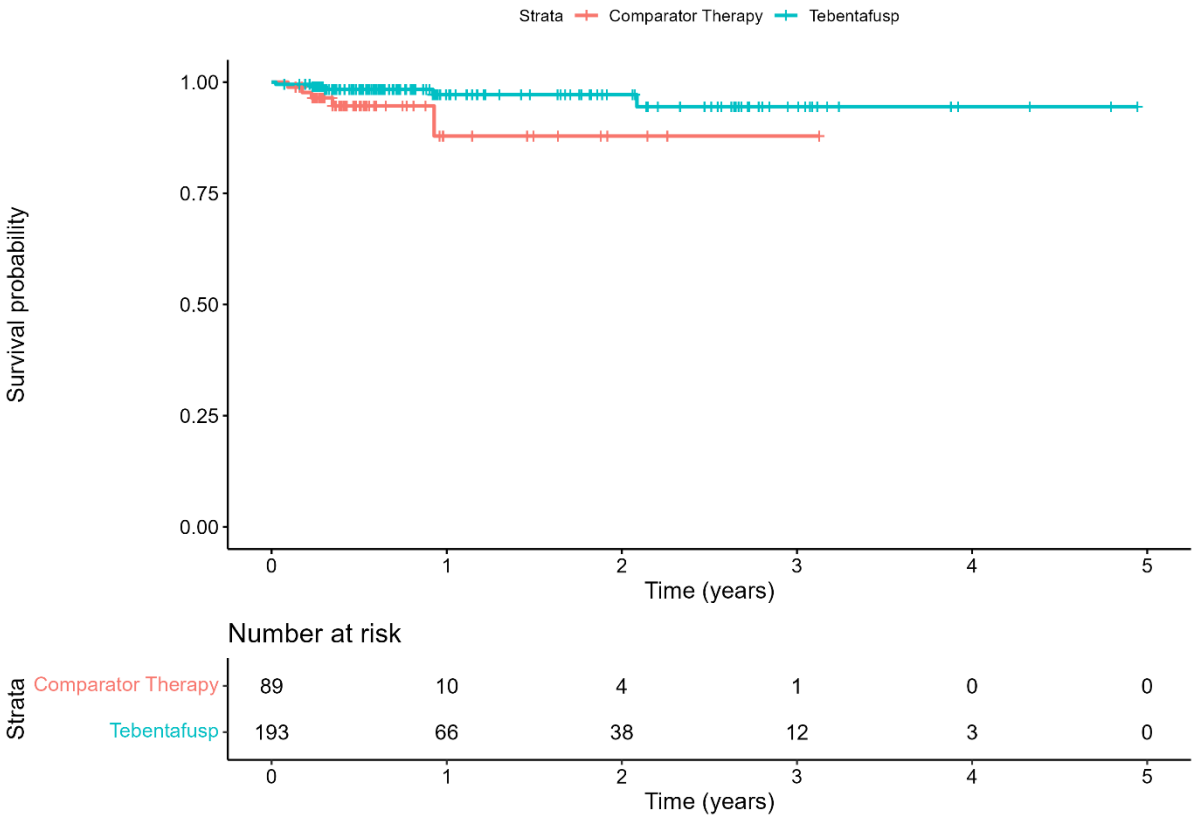
ECOG-Performance-Status: 0



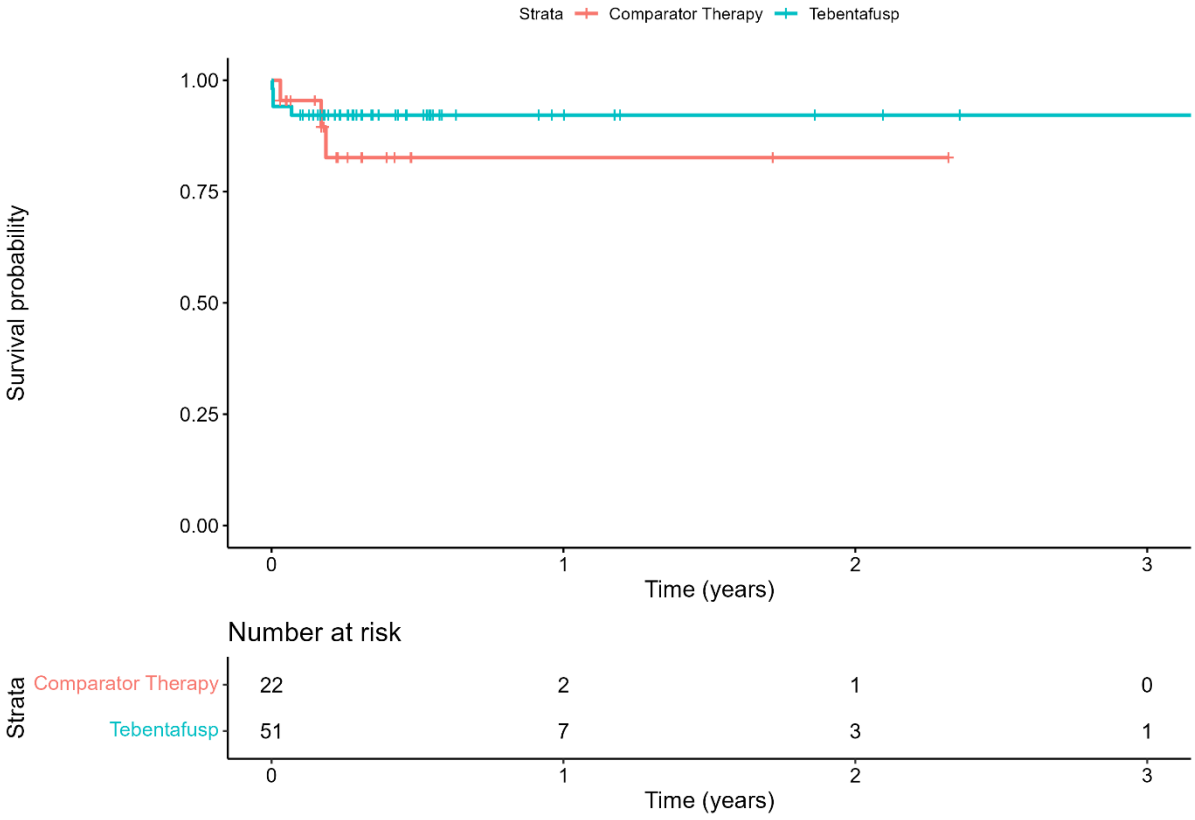
ECOG-Performance-Status: 1



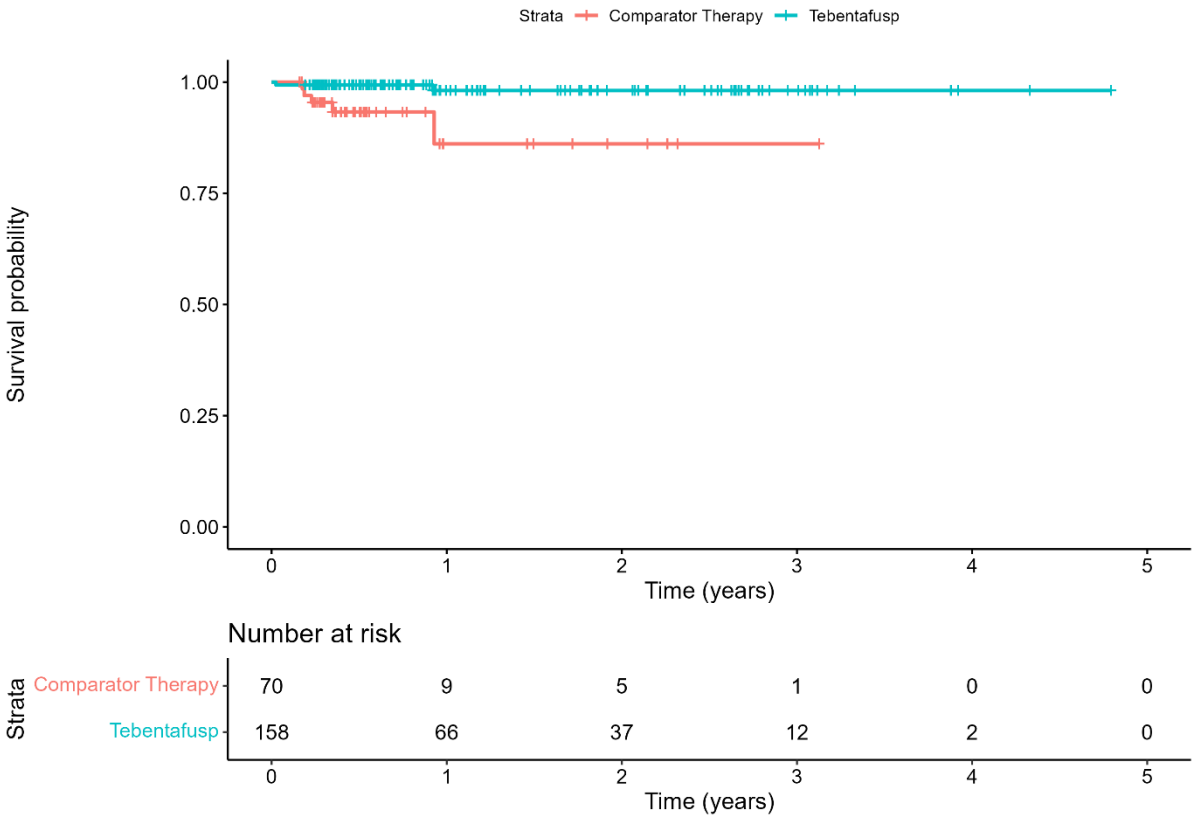
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



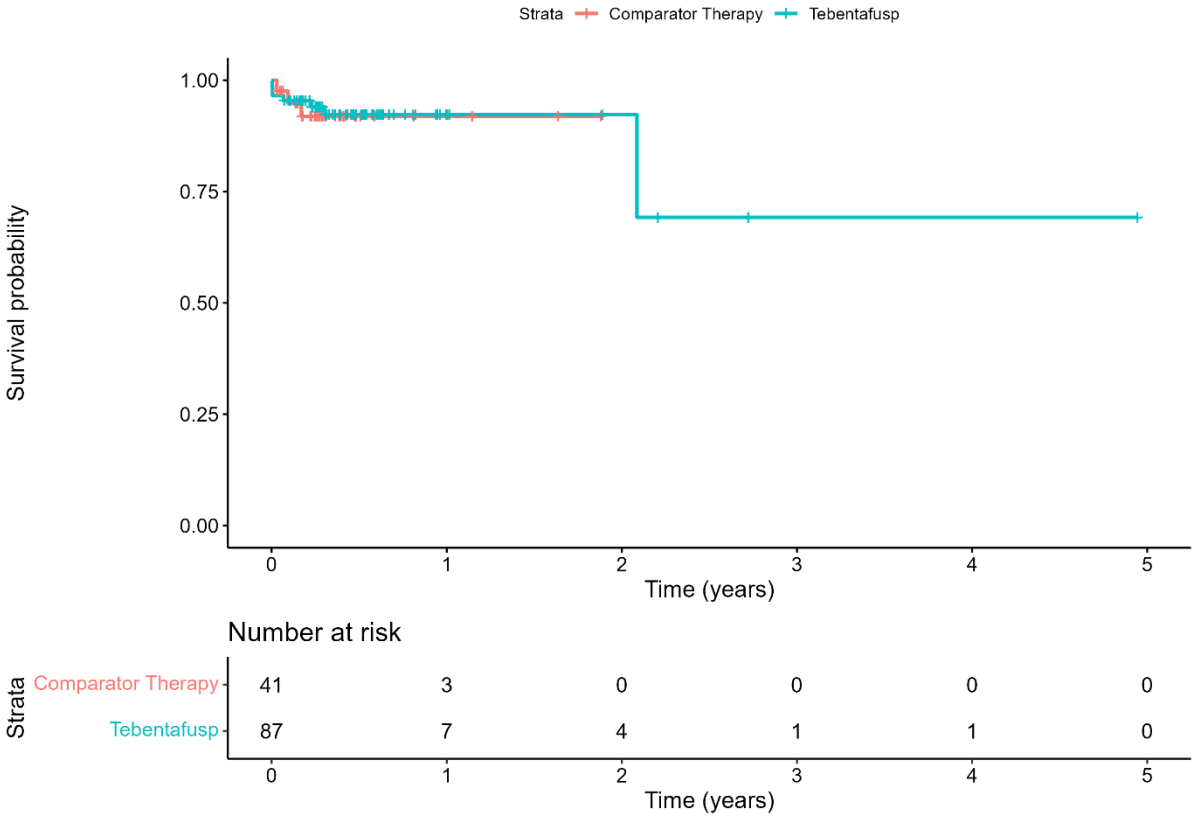
Alkalische Phosphatase (ALP) (Baseline): >ULN



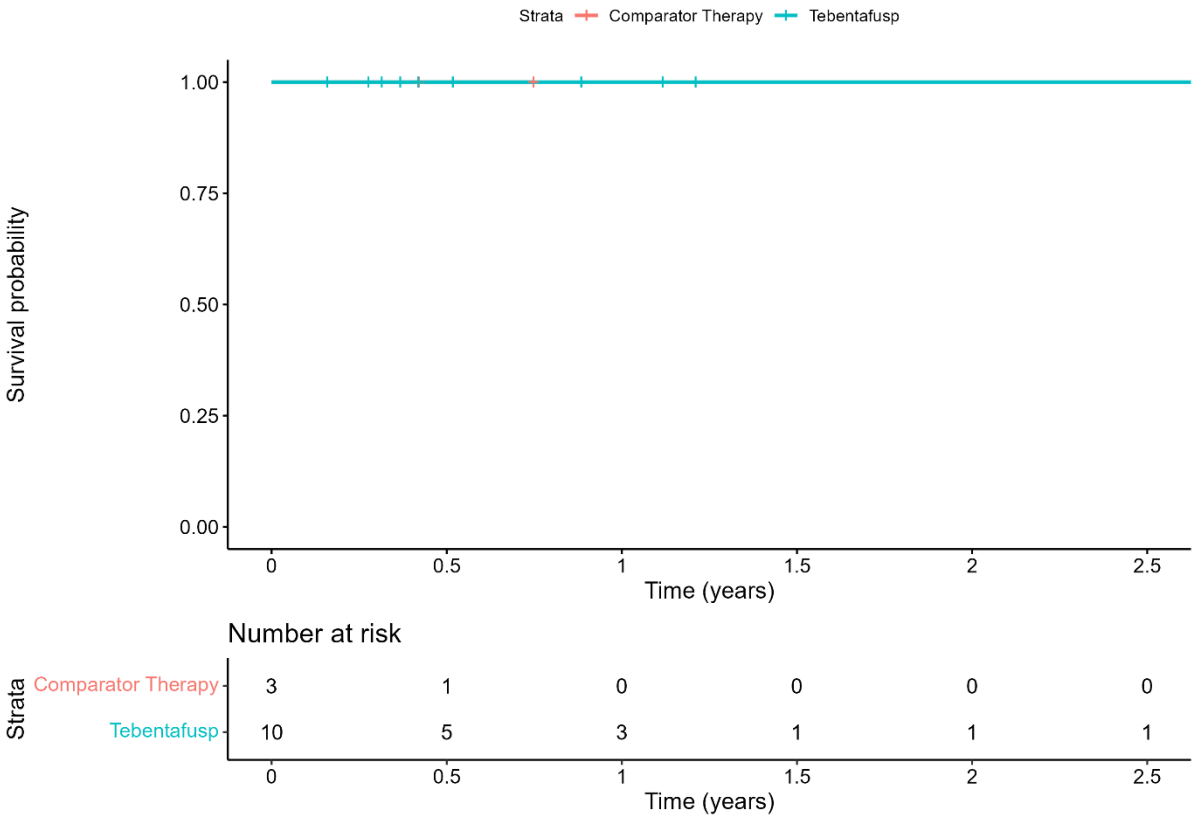
LDH: ≤ULN



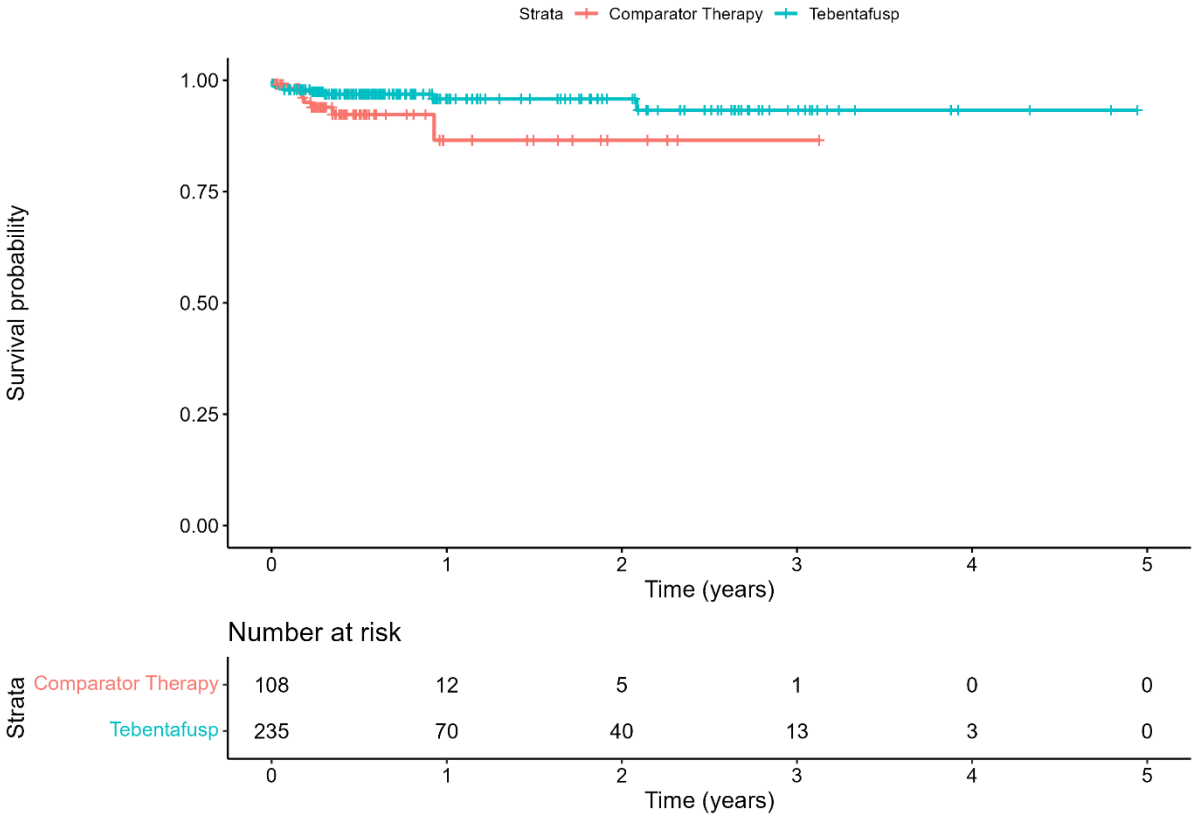
LDH: >ULN



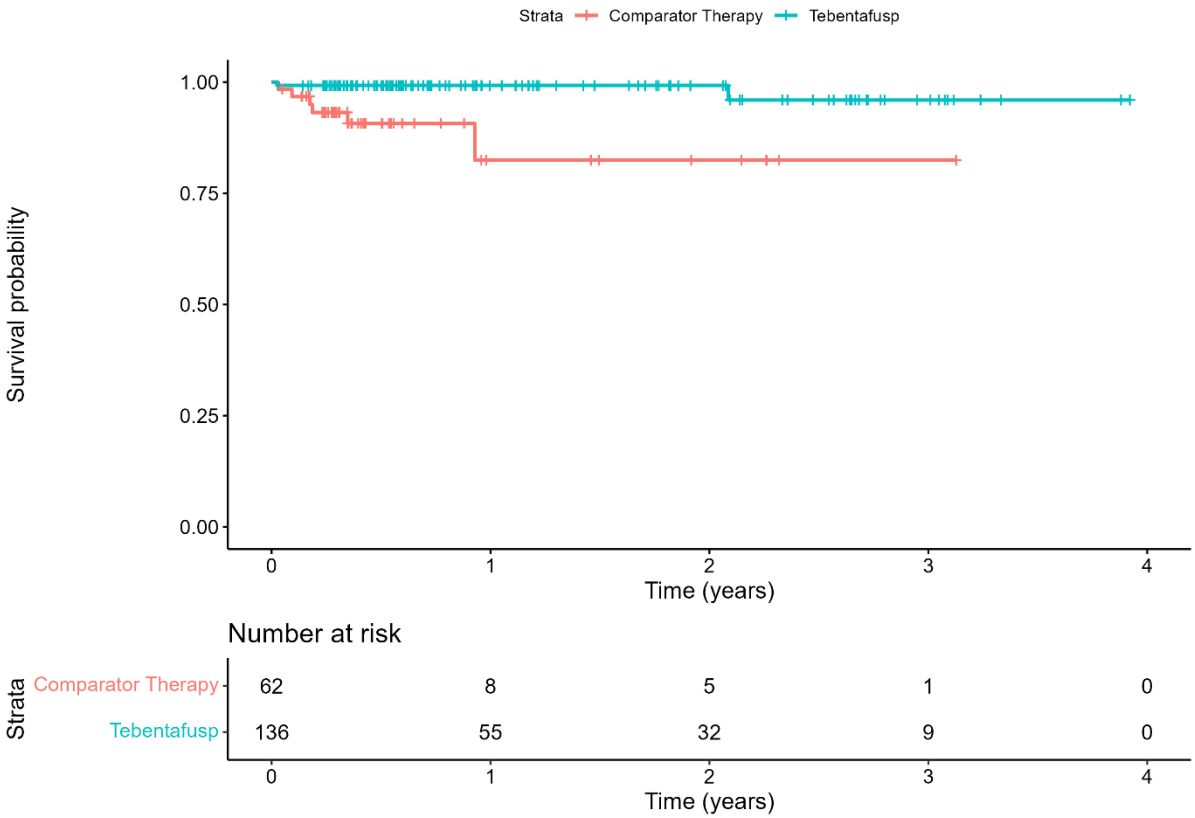
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



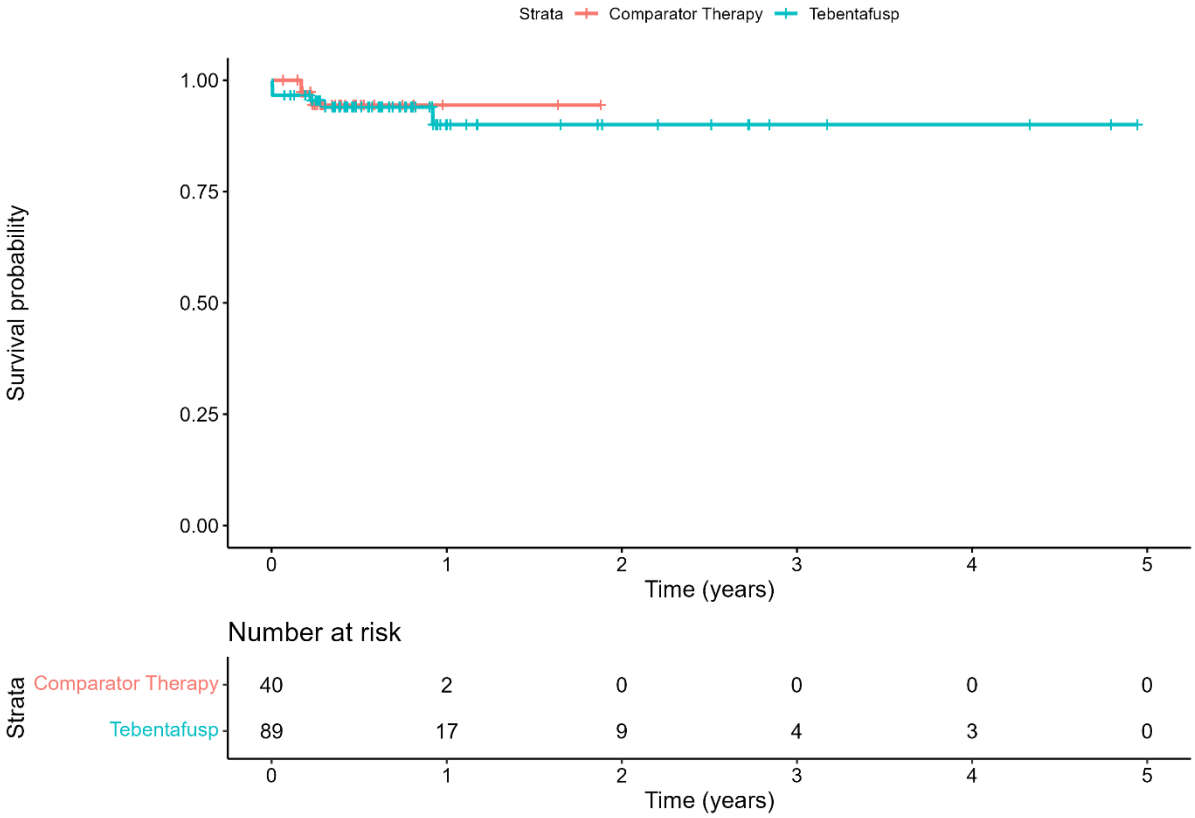
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



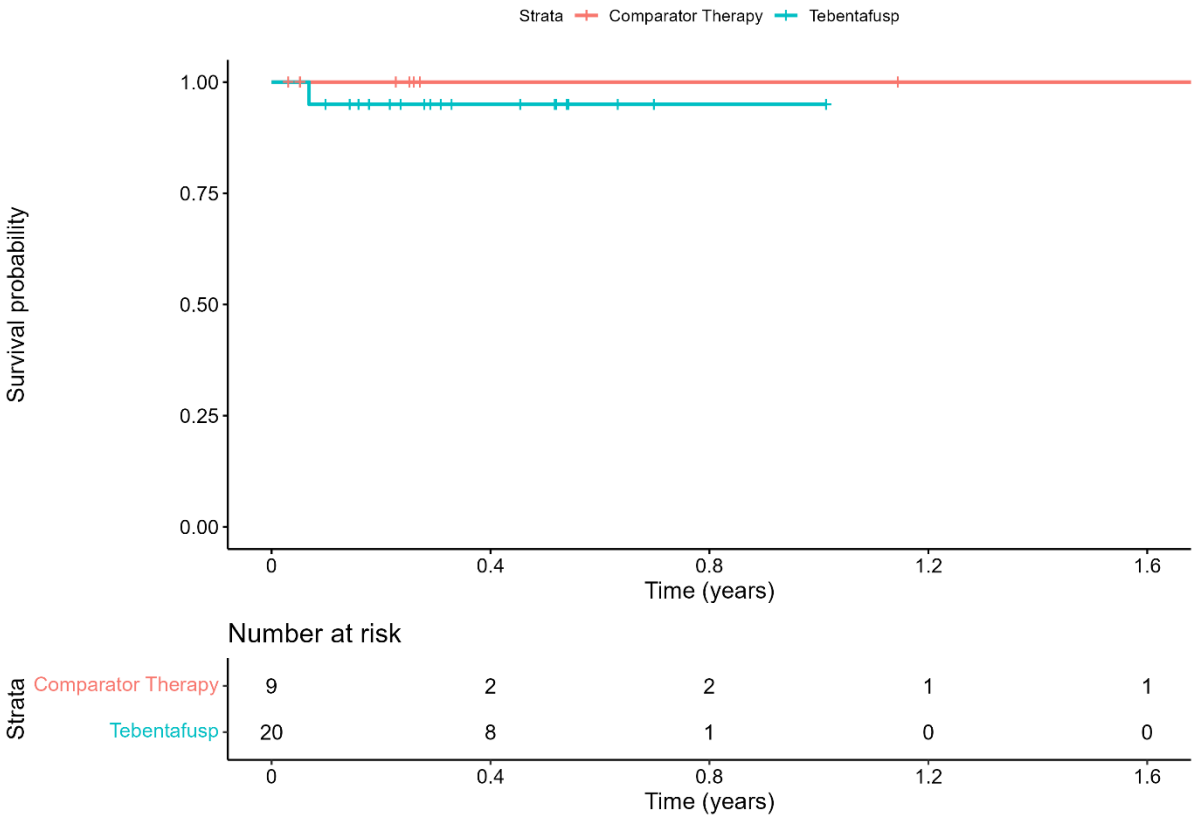
Größte metastatische Läsion (Baseline): ≤3,0 cm



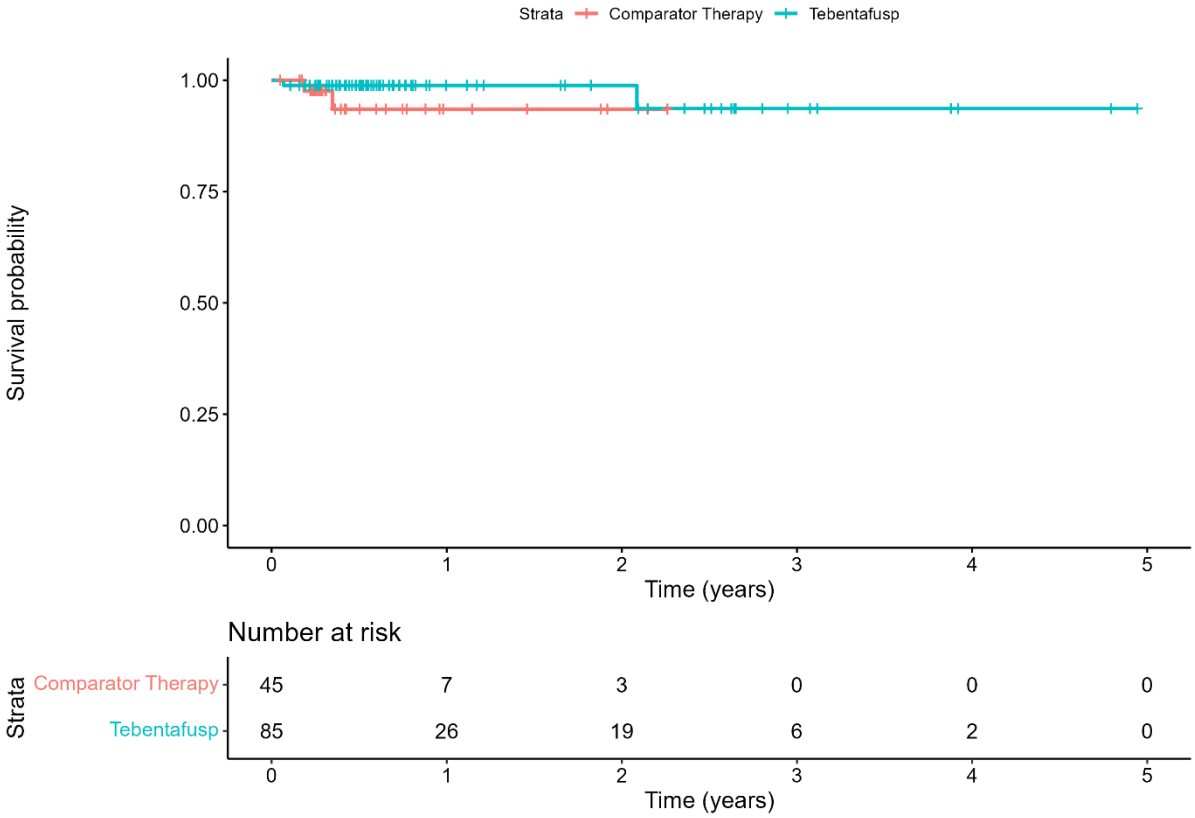
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



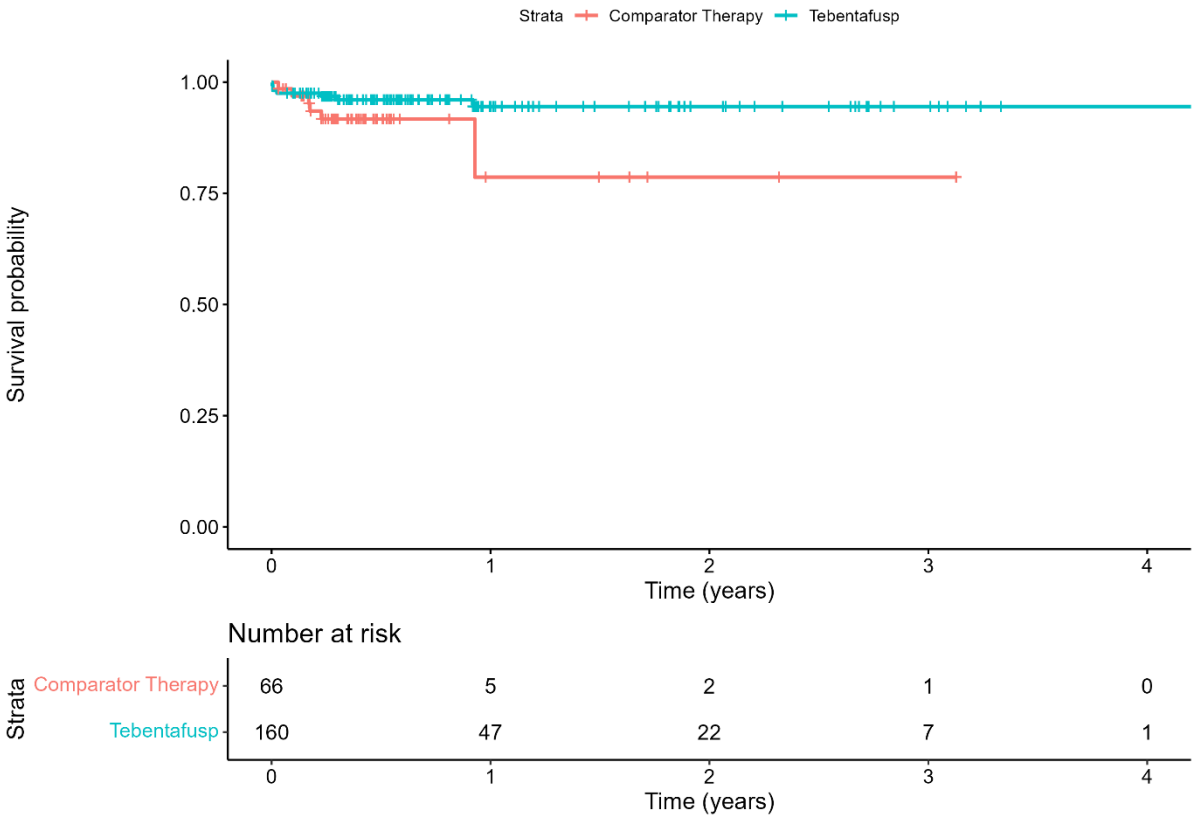
Größte metastatische Läsion (Baseline): ≥8,1 cm



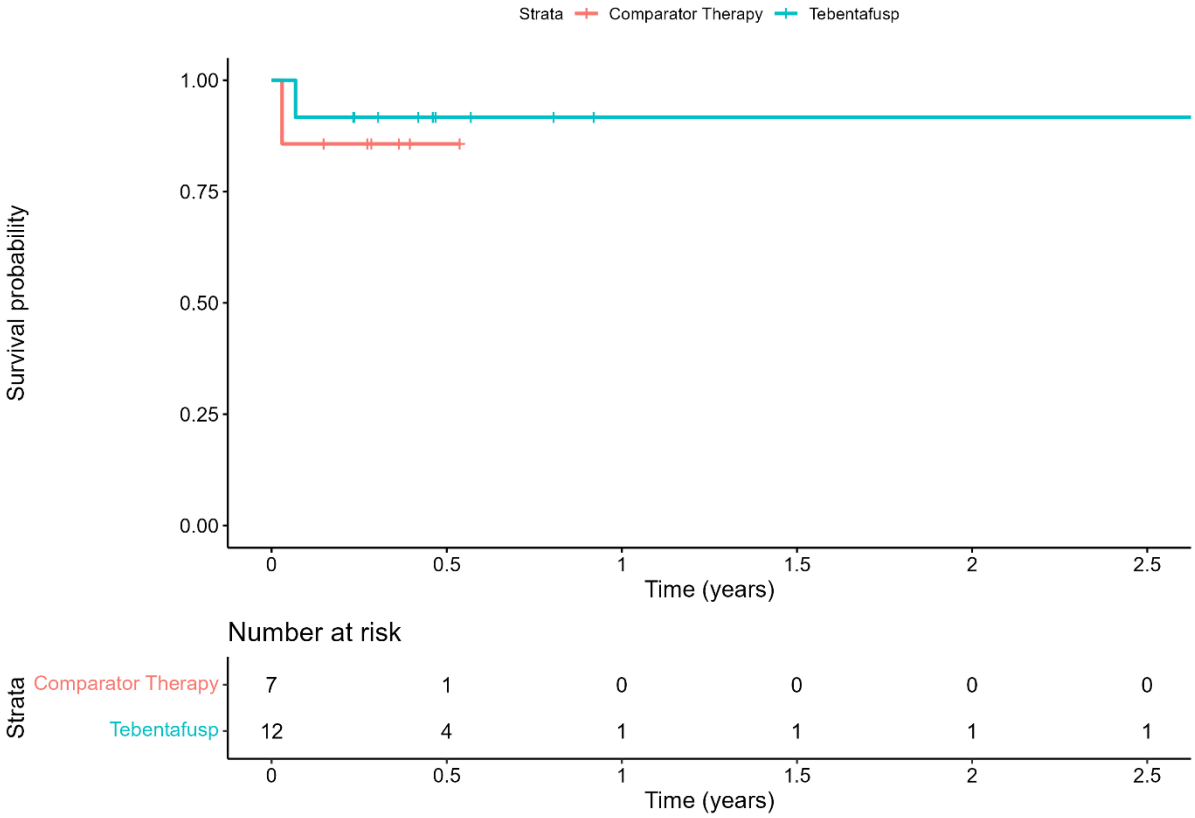
Region: Nordamerika



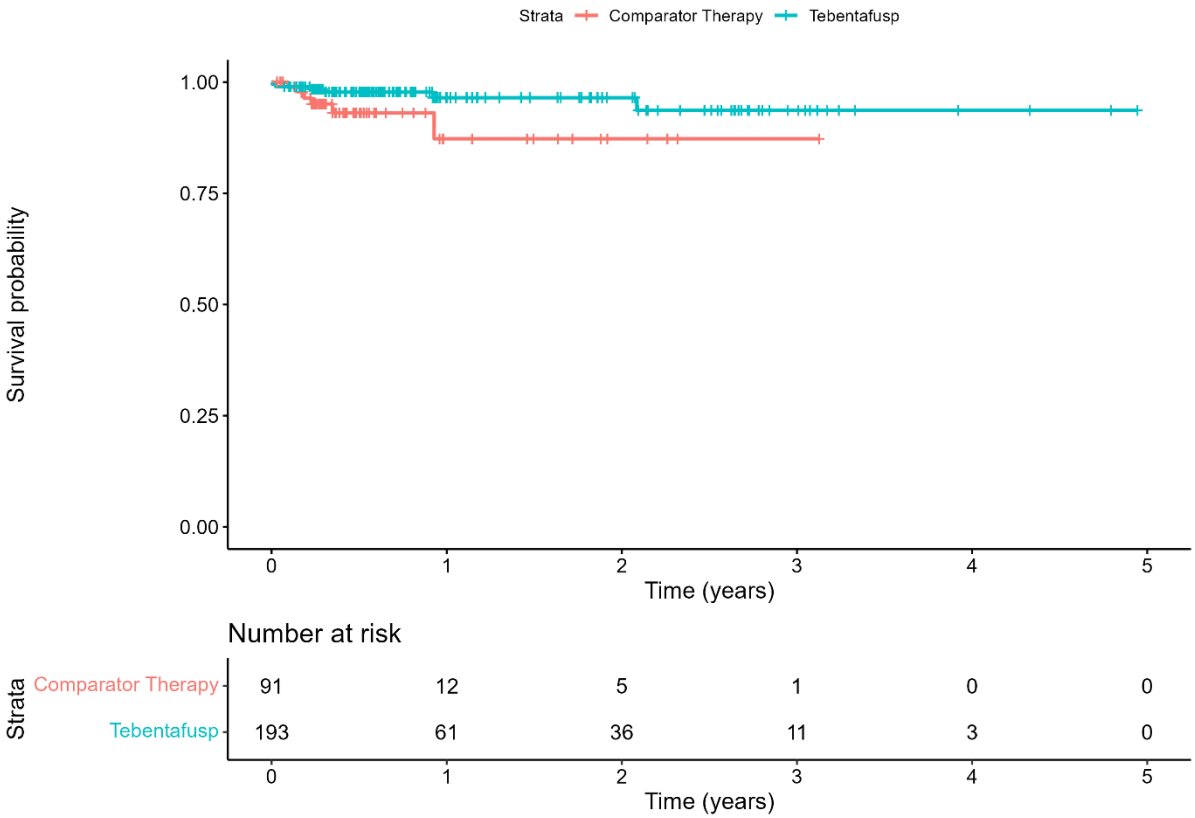
Region: Nicht-Nordamerika



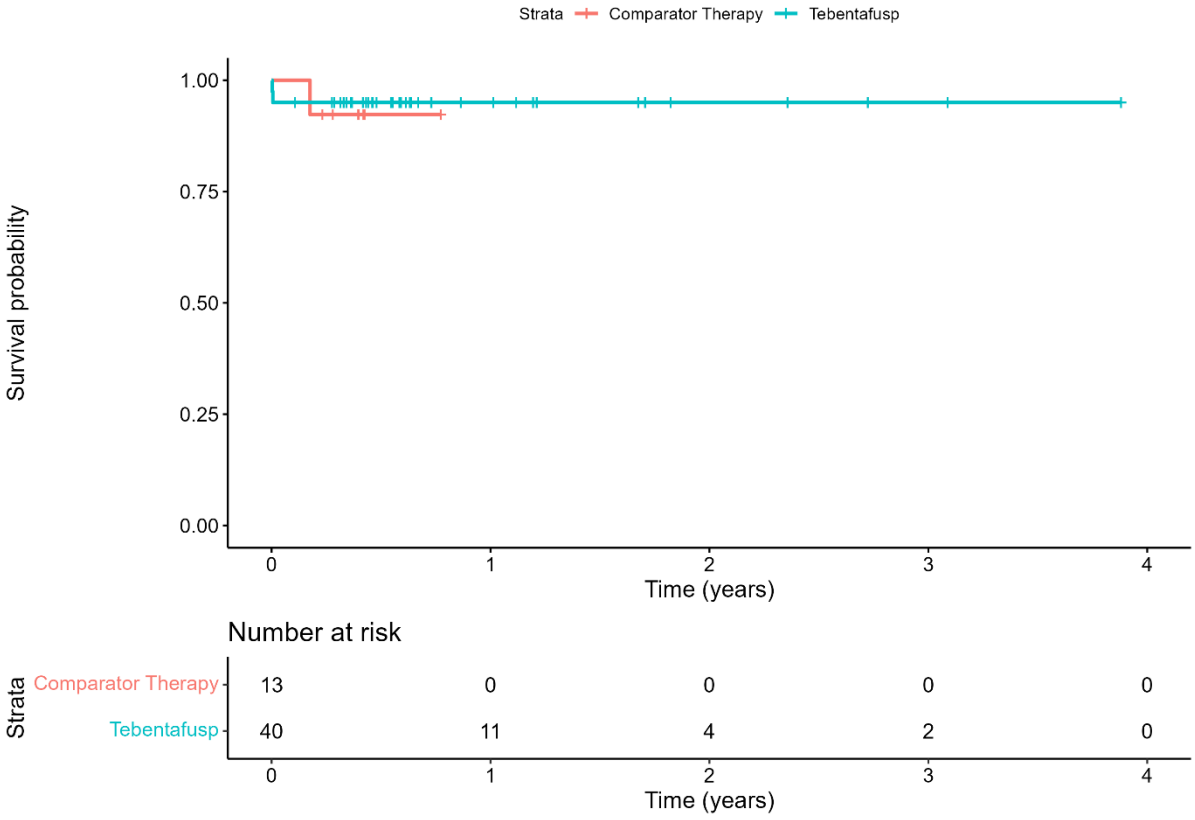
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

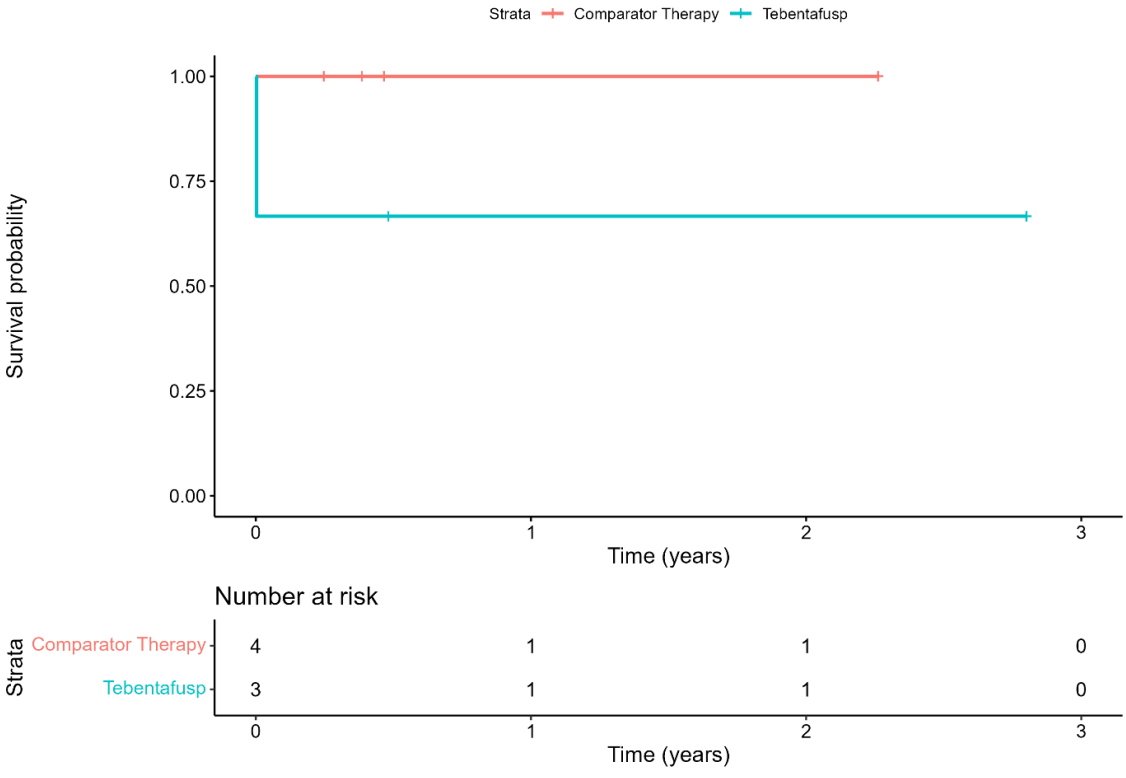


Vorauswahl der Chemotherapie: Ipilimumab

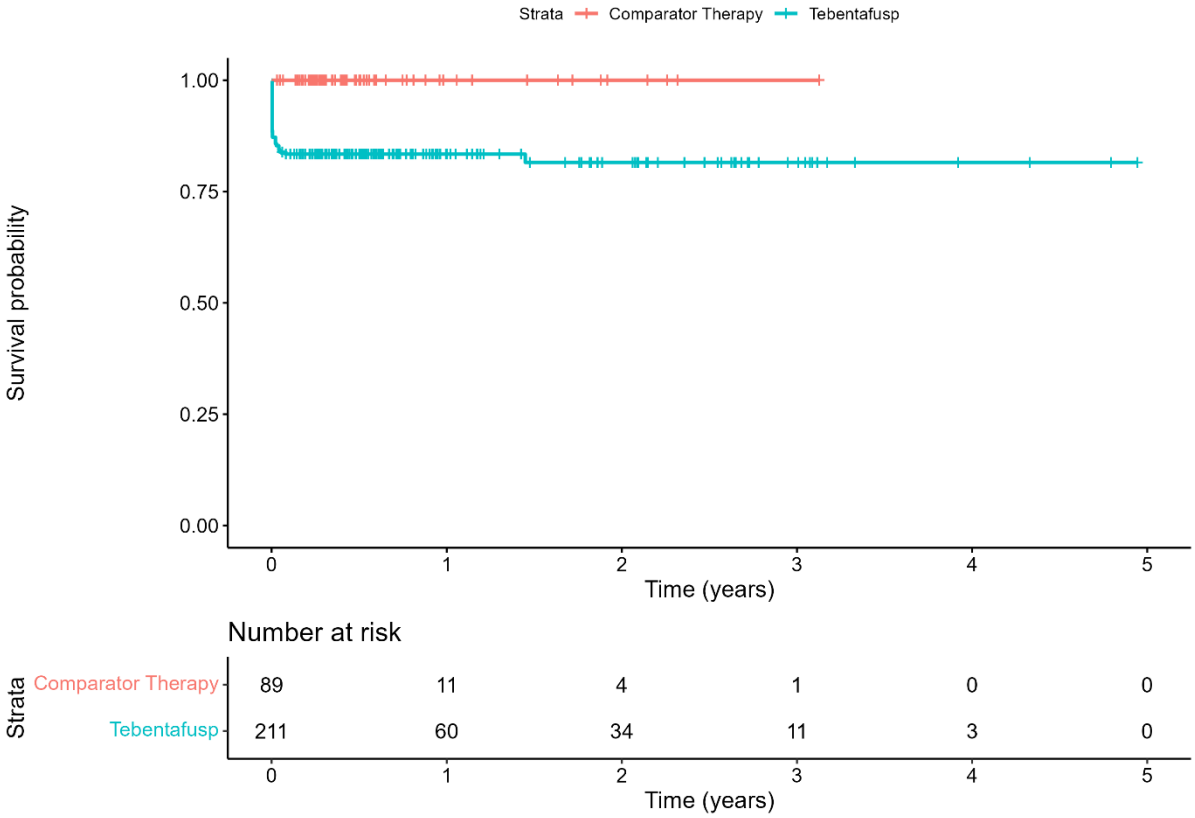


59.5 Zytokin-Freisetzungssyndrom (CRS) (Tabelle 4-222)

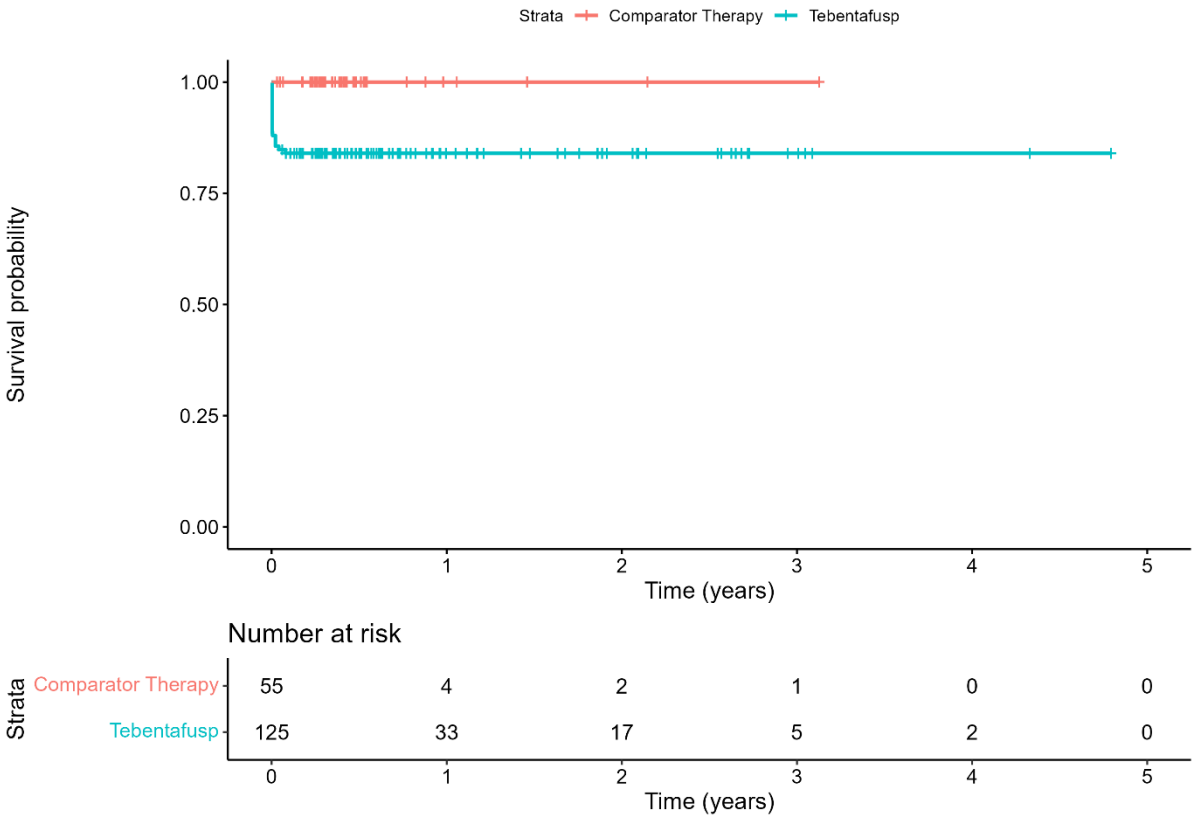
Herkunft: Hispanisch



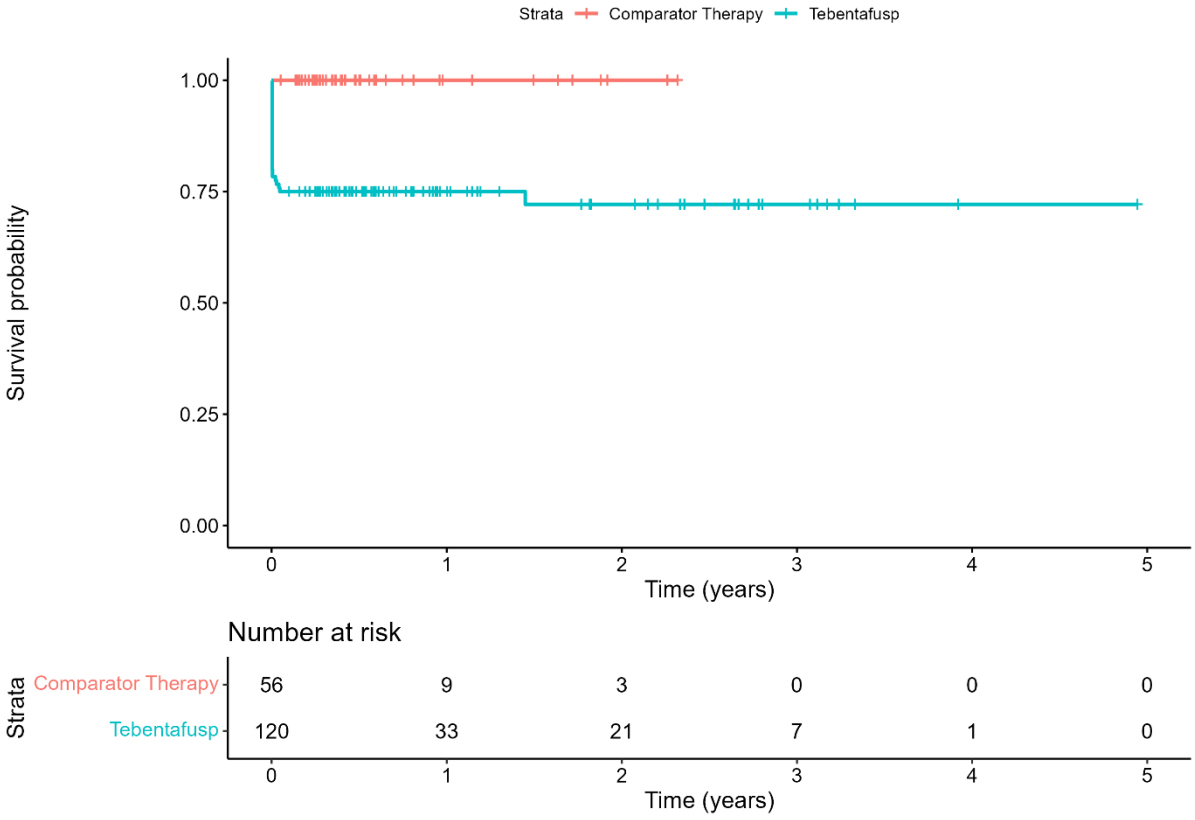
Herkunft: Nicht-hispanisch



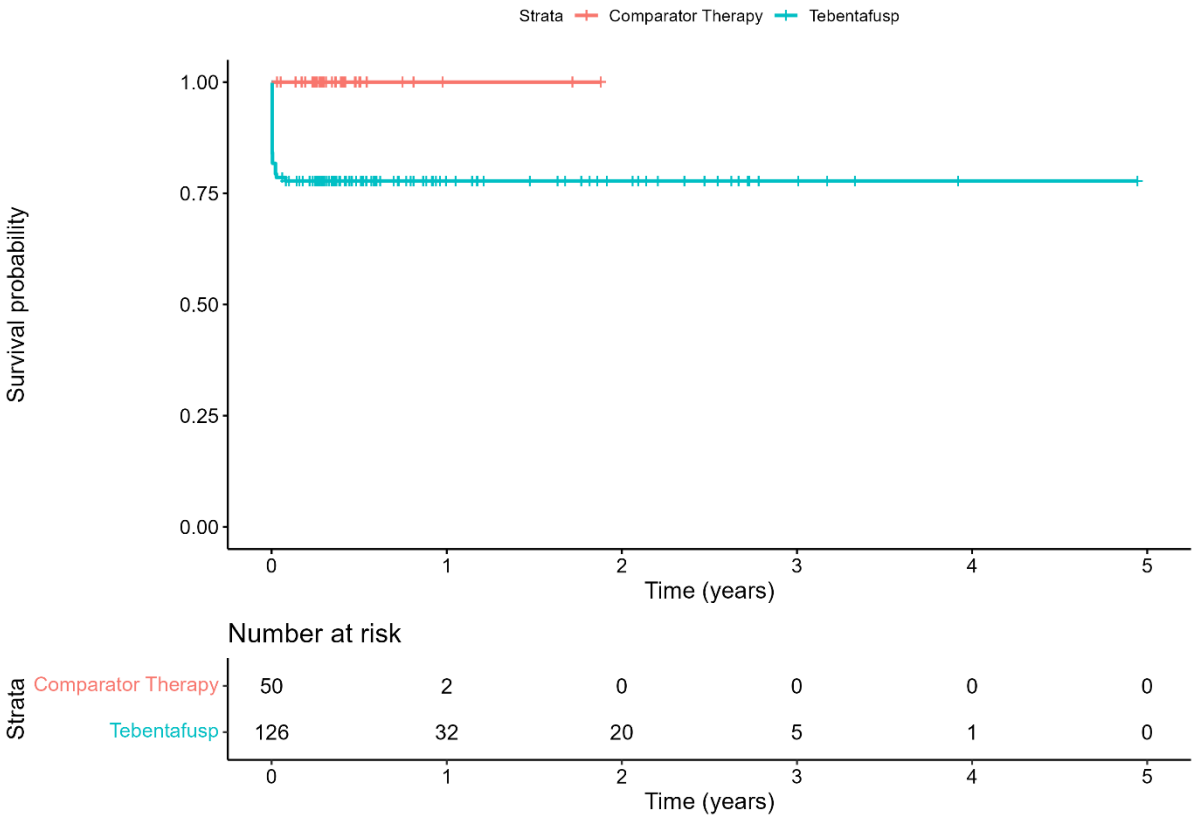
Geschlecht: Männlich



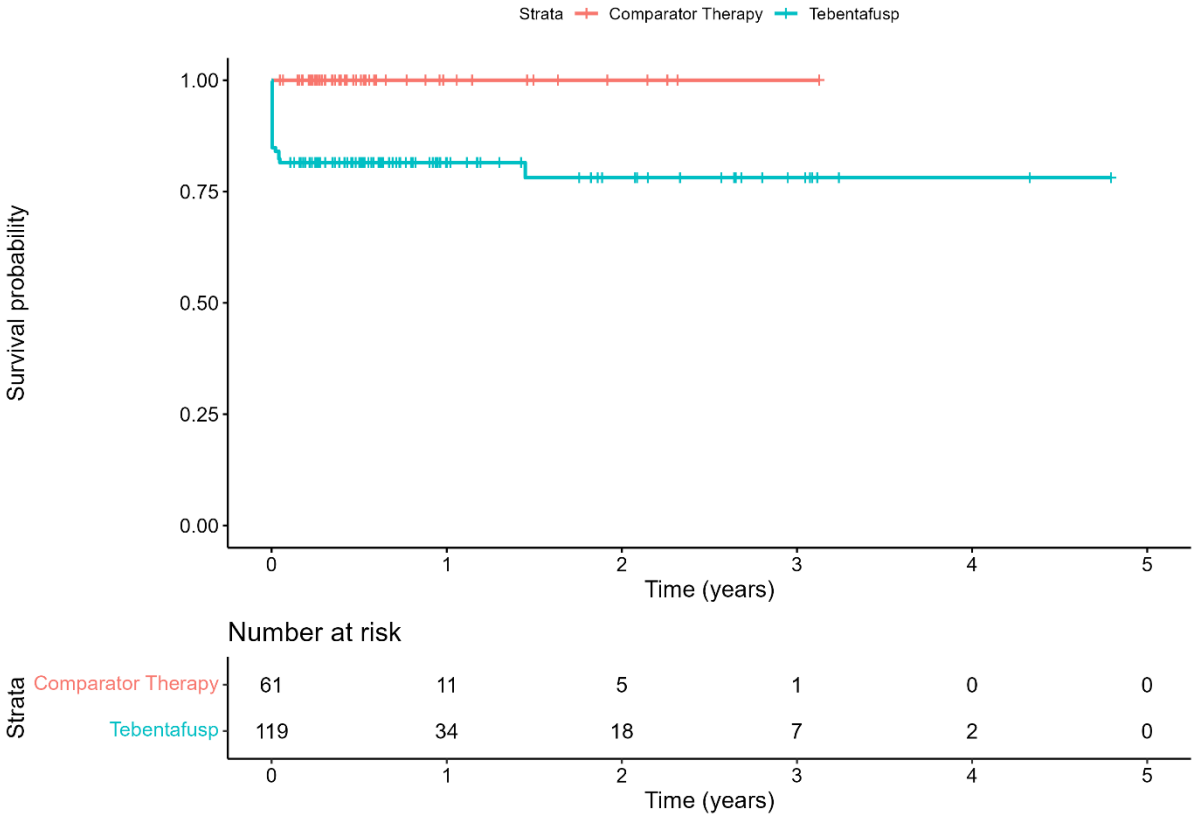
Geschlecht: Weiblich



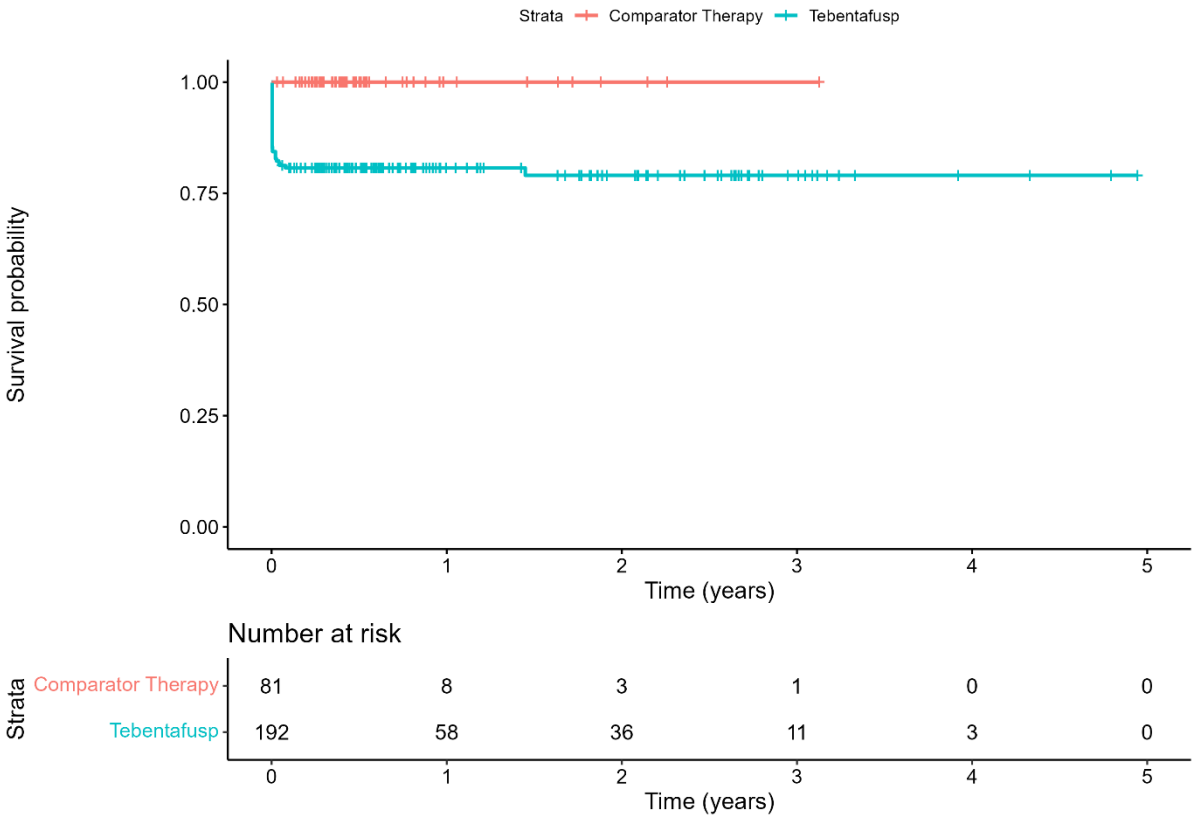
Alter: <65 Jahre



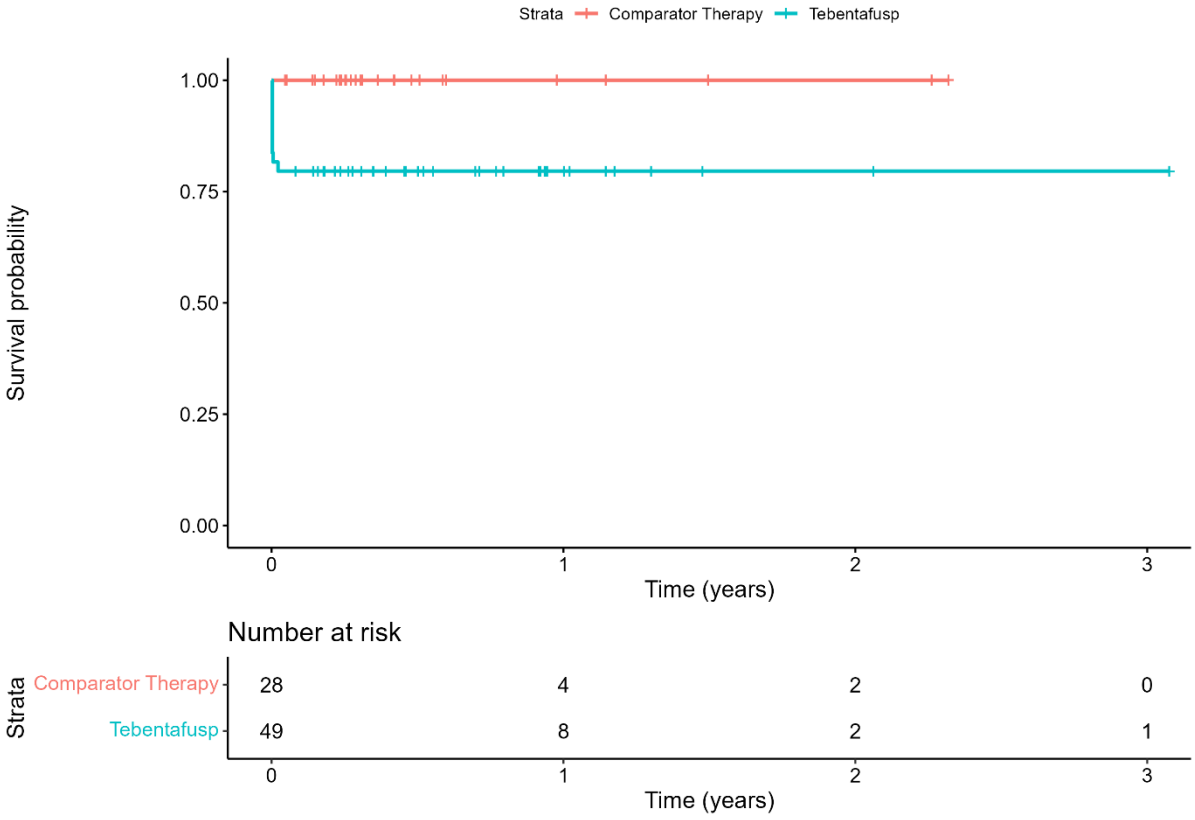
Alter: ≥65 Jahre



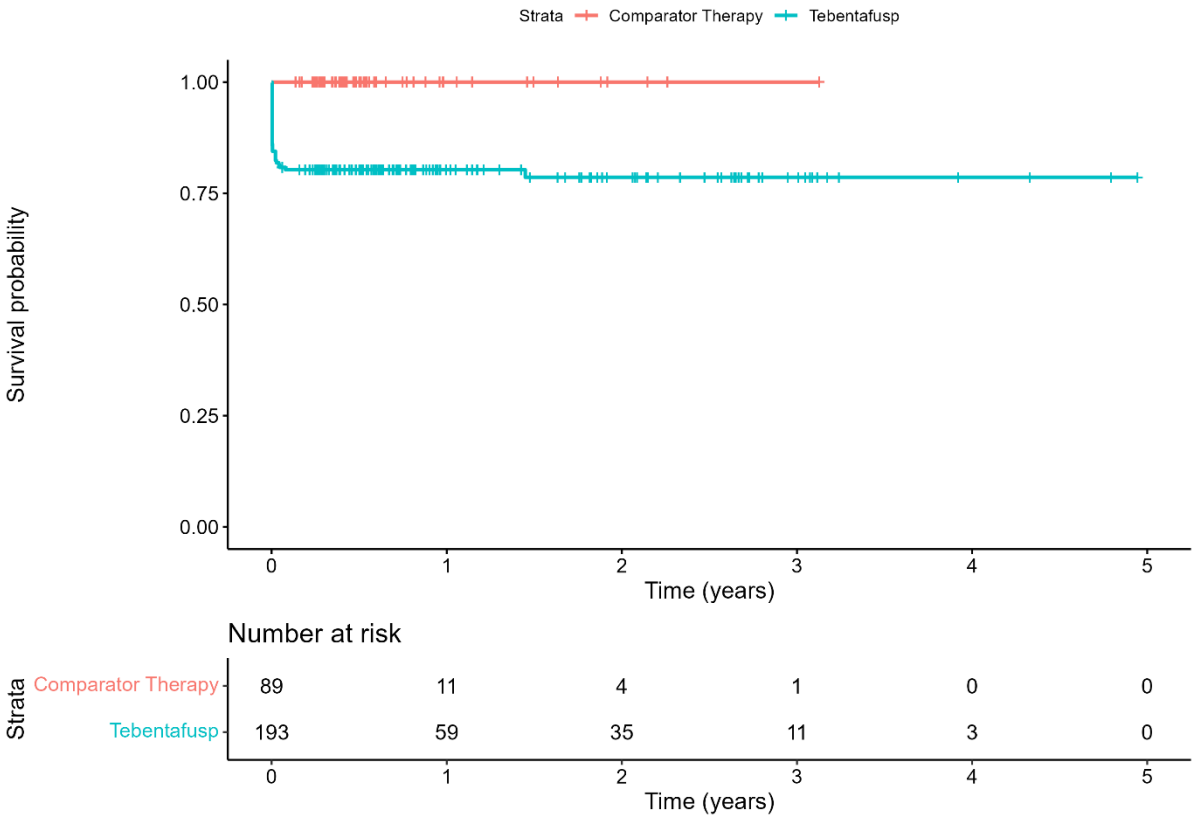
ECOG-Performance-Status: 0



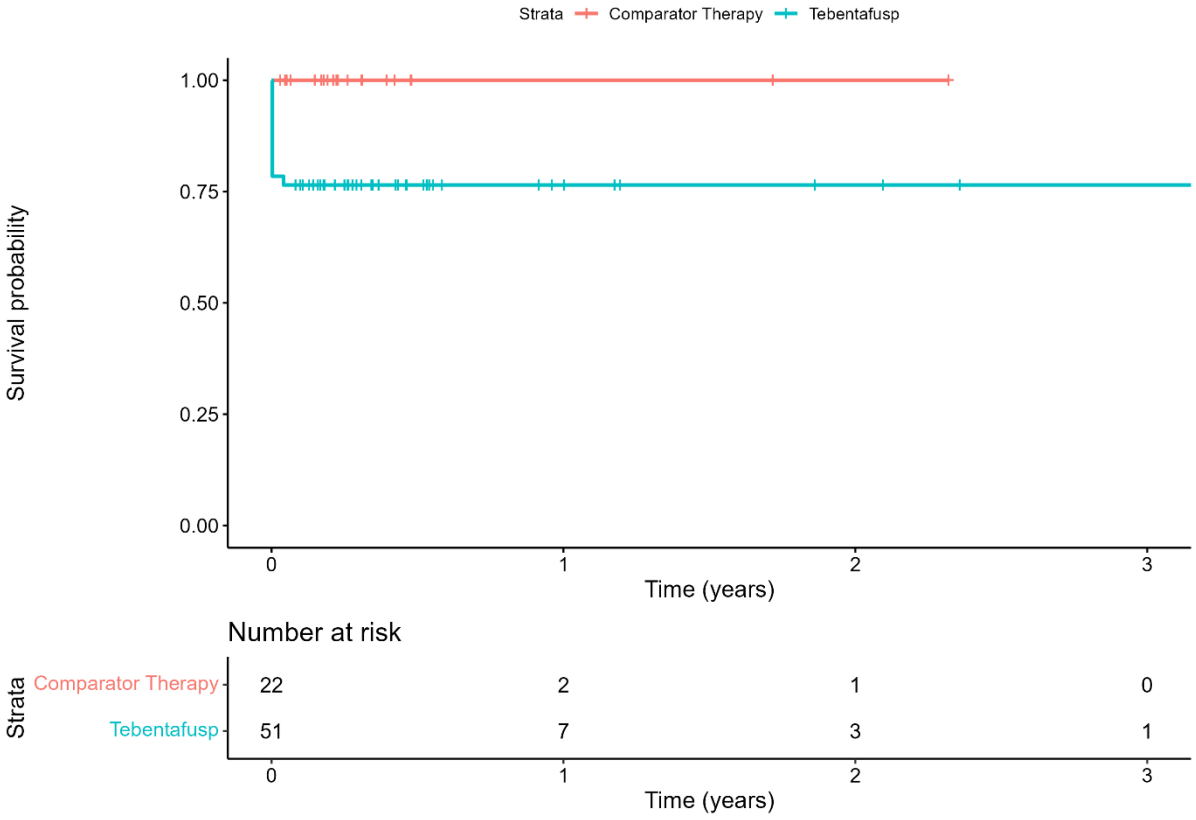
ECOG-Performance-Status: 1



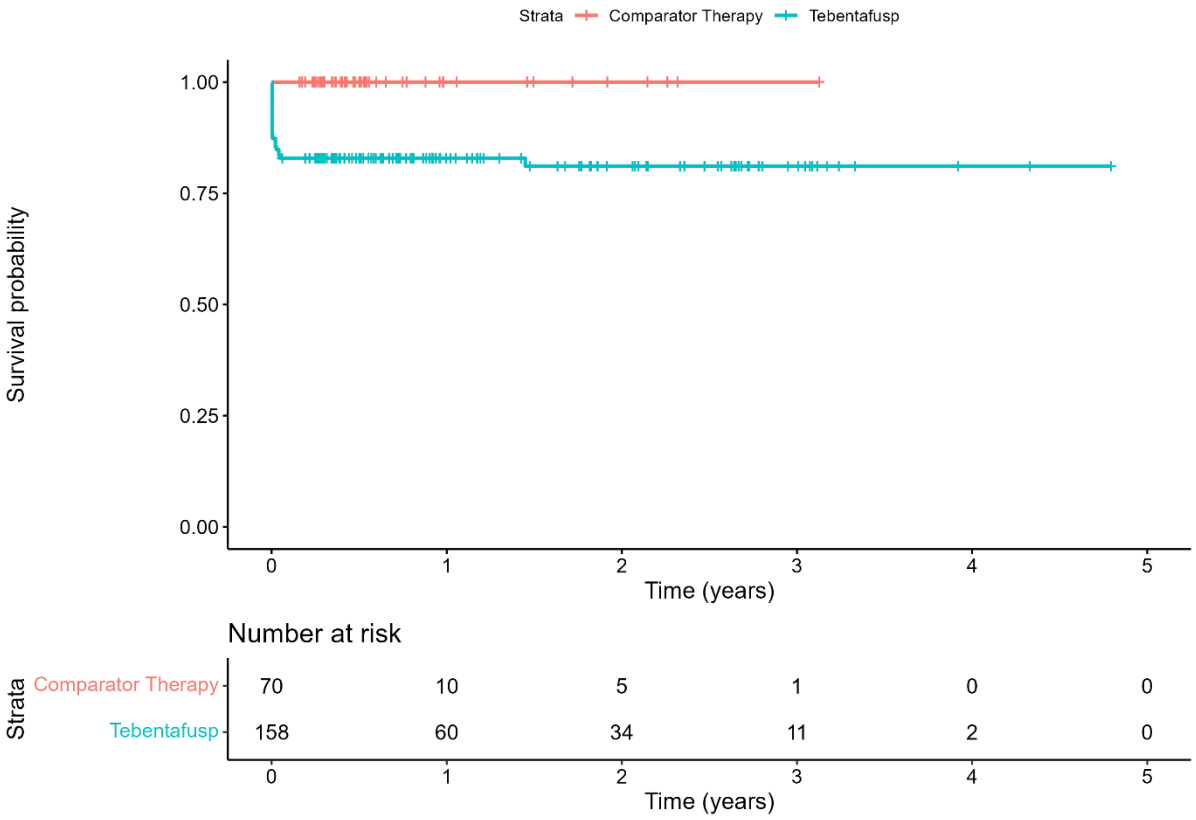
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



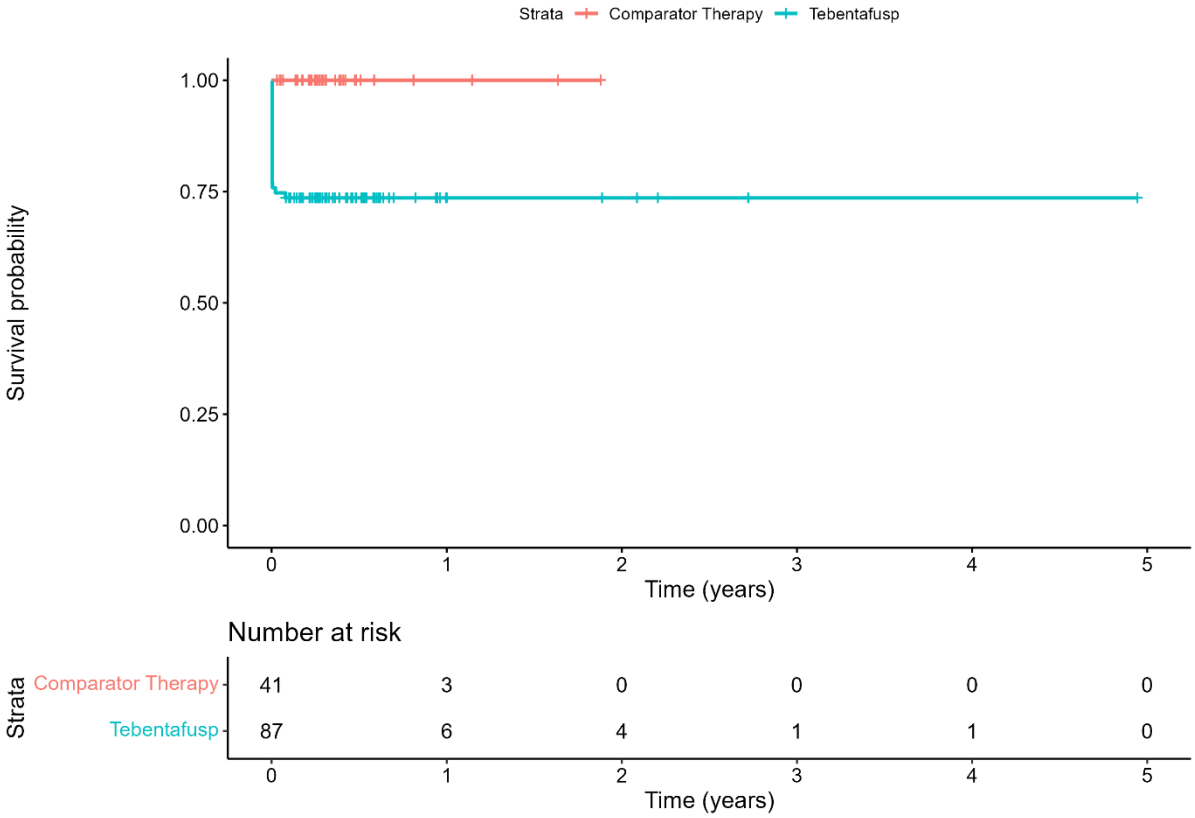
Alkalische Phosphatase (ALP) (Baseline): >ULN



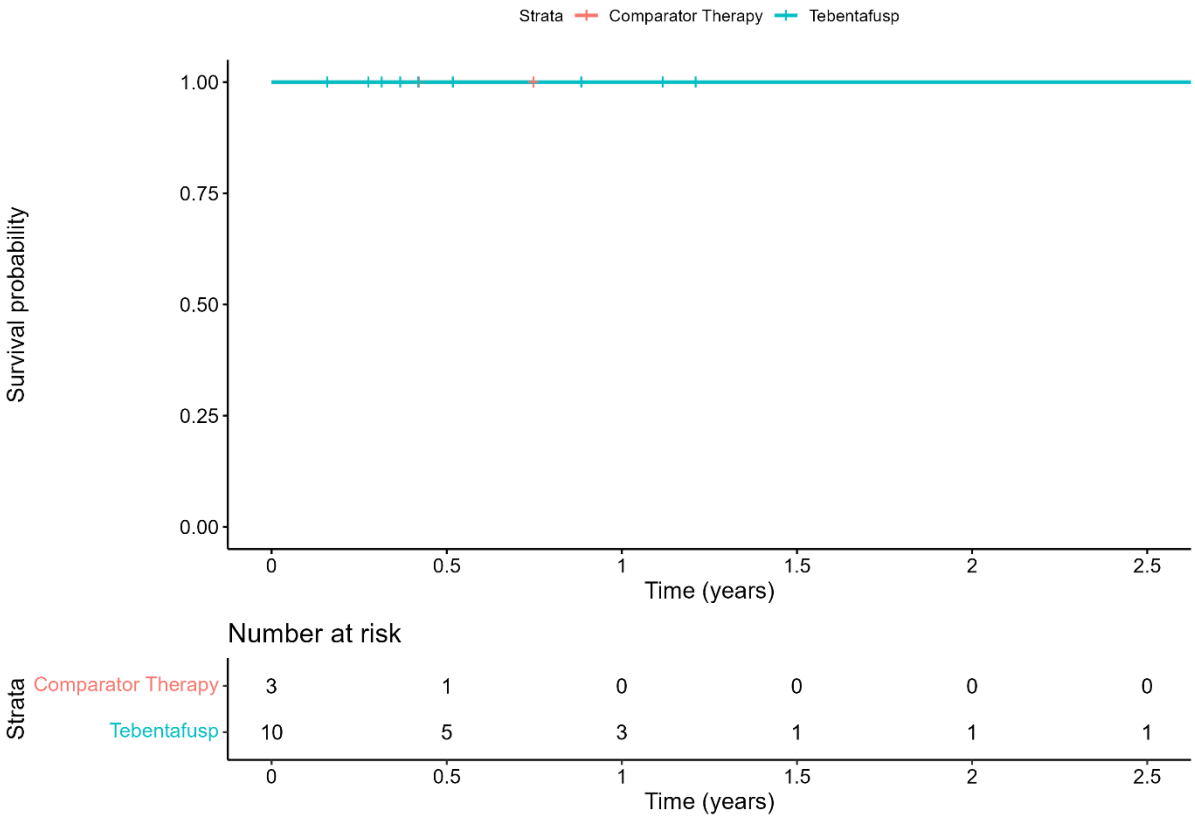
LDH: ≤ULN



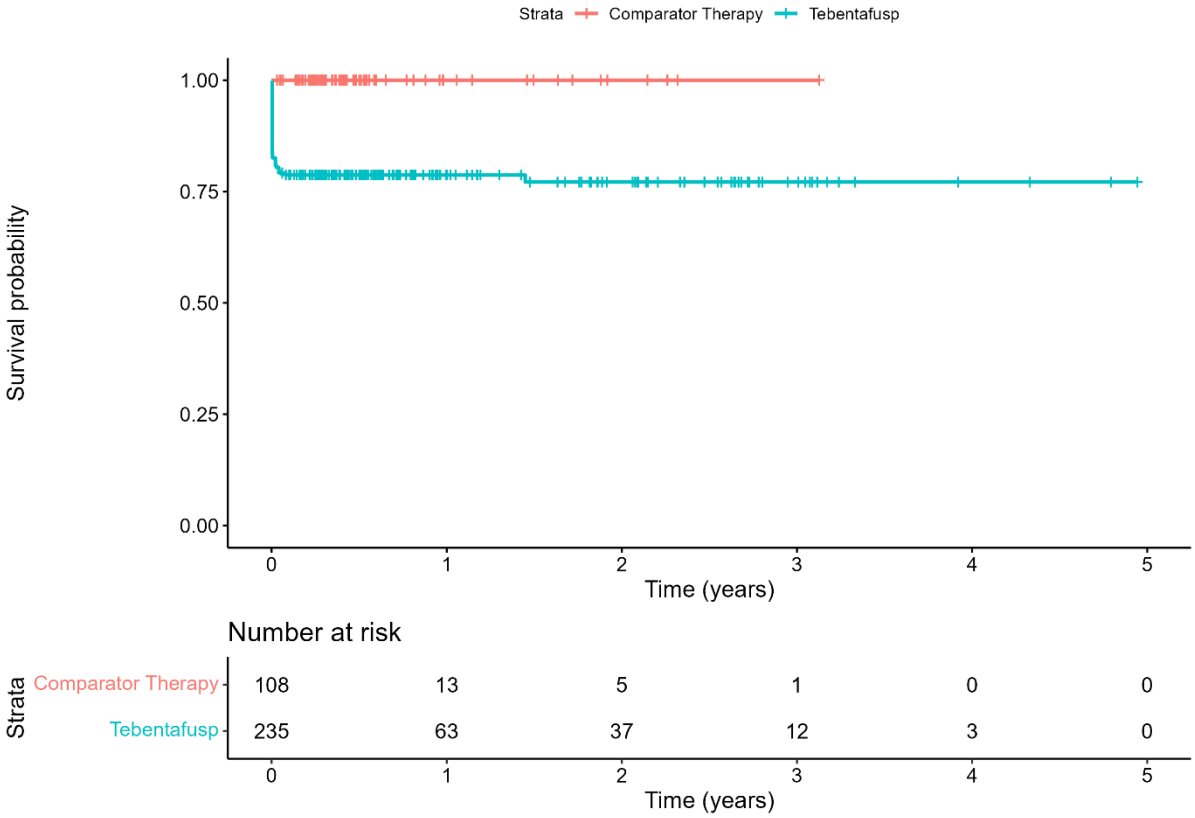
LDH: >ULN



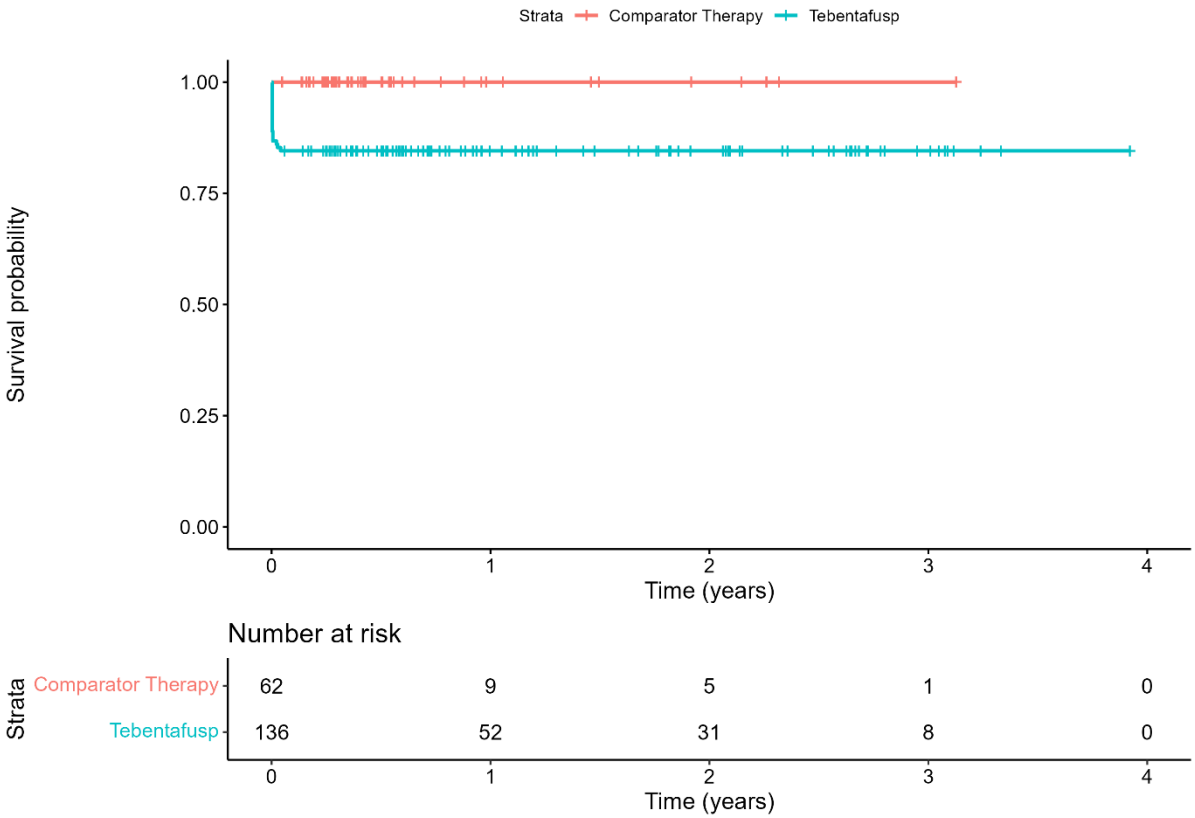
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



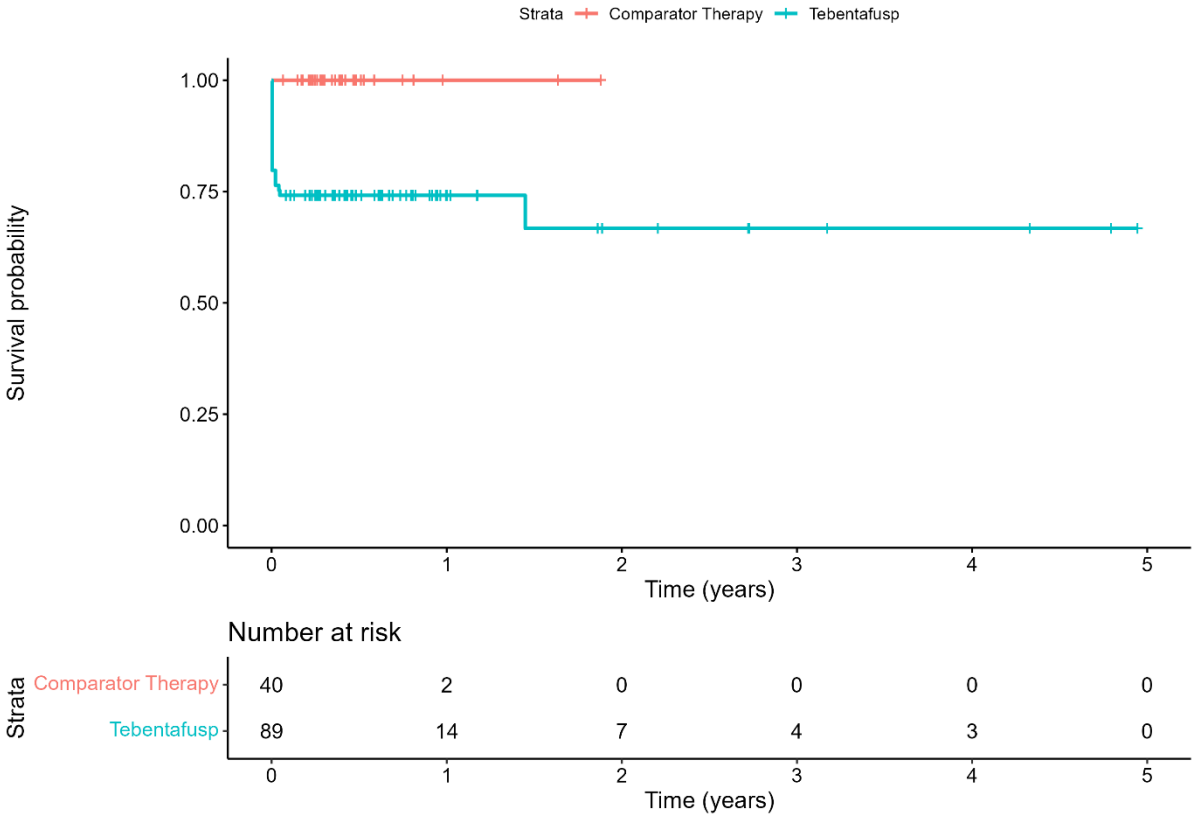
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



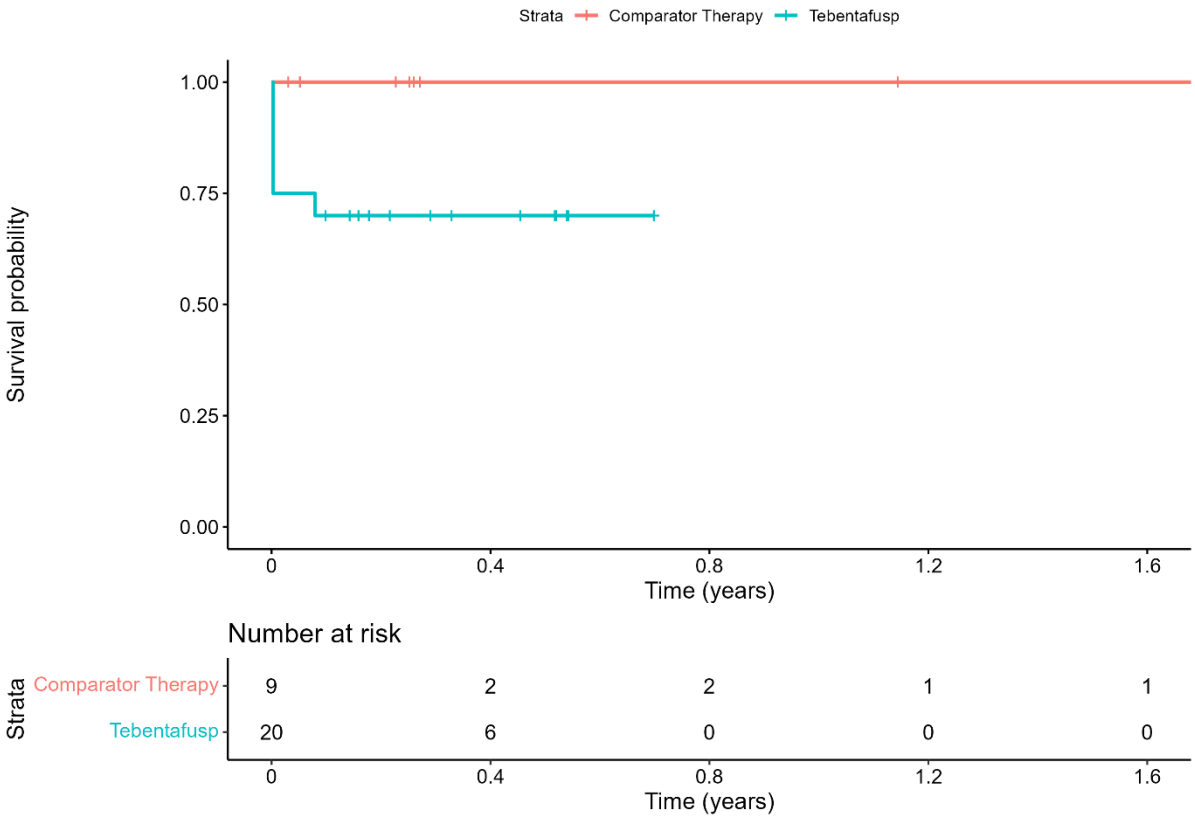
Größte metastatische Läsion (Baseline): ≤3,0 cm



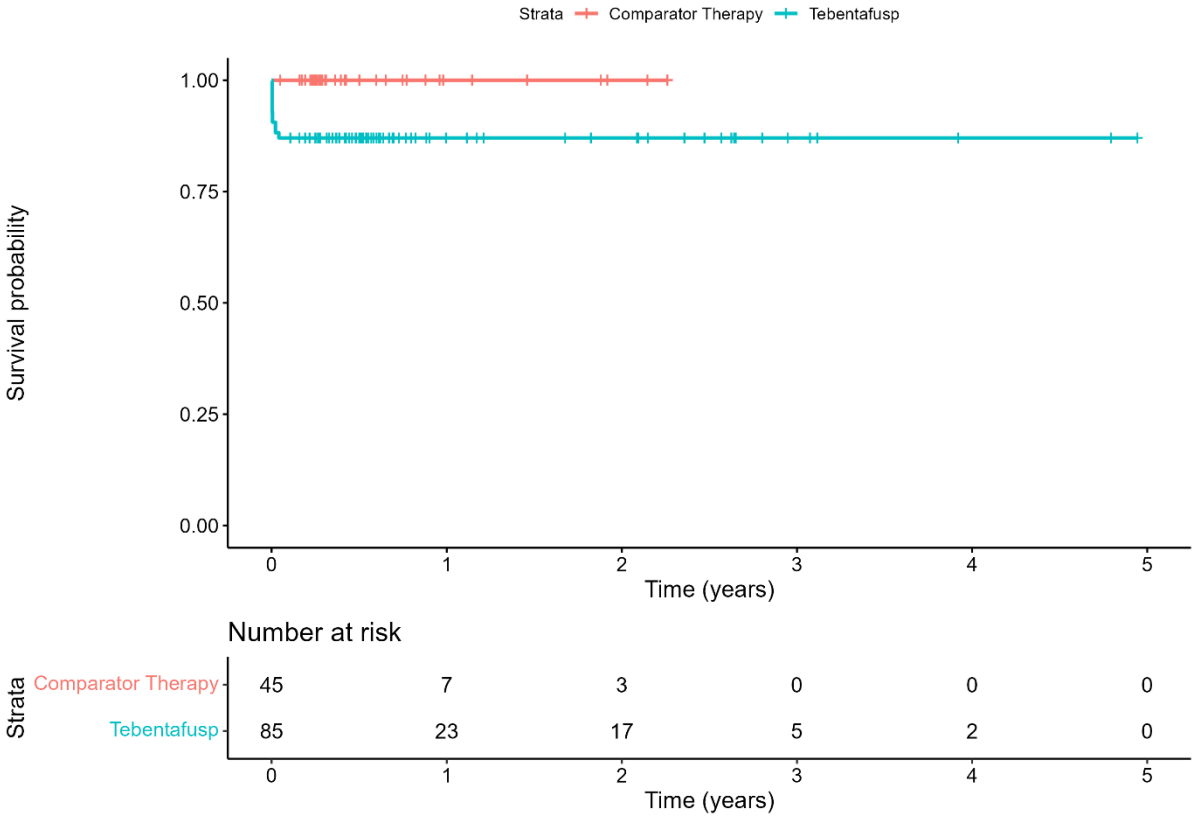
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



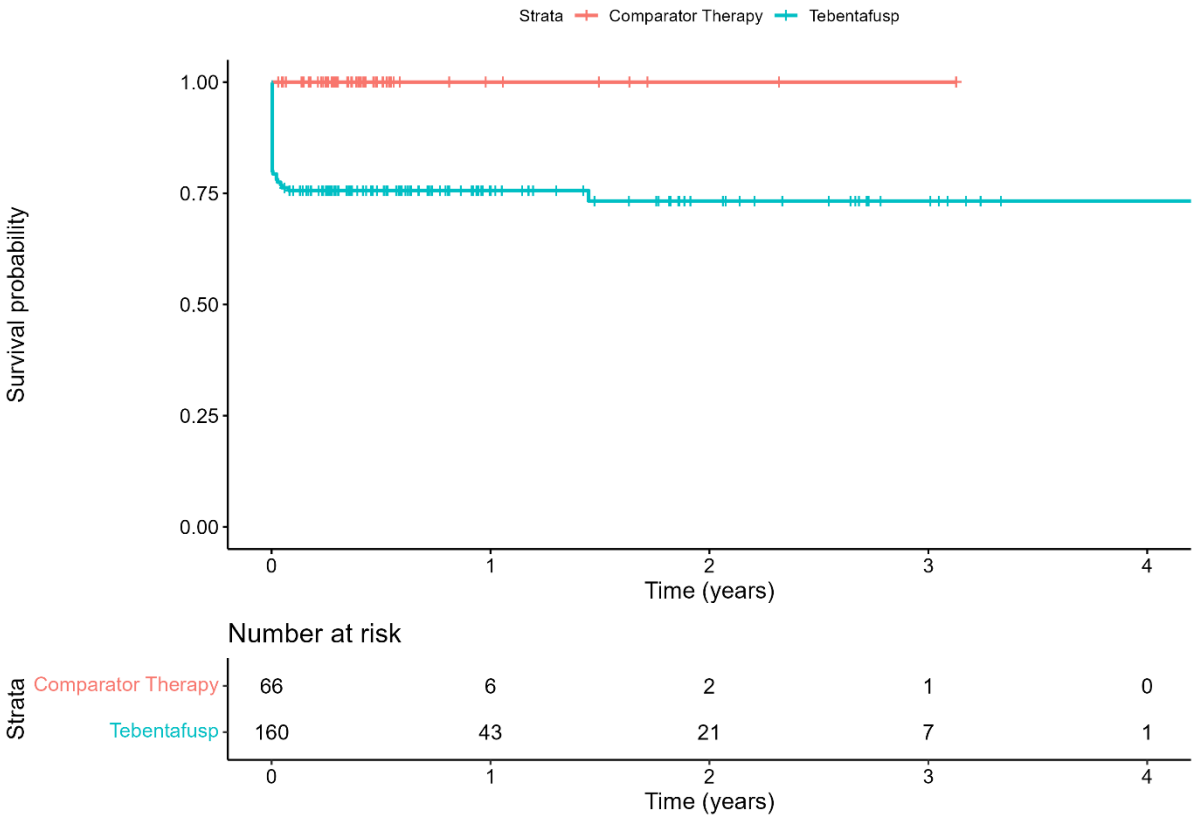
Größte metastatische Läsion (Baseline): ≥8,1 cm



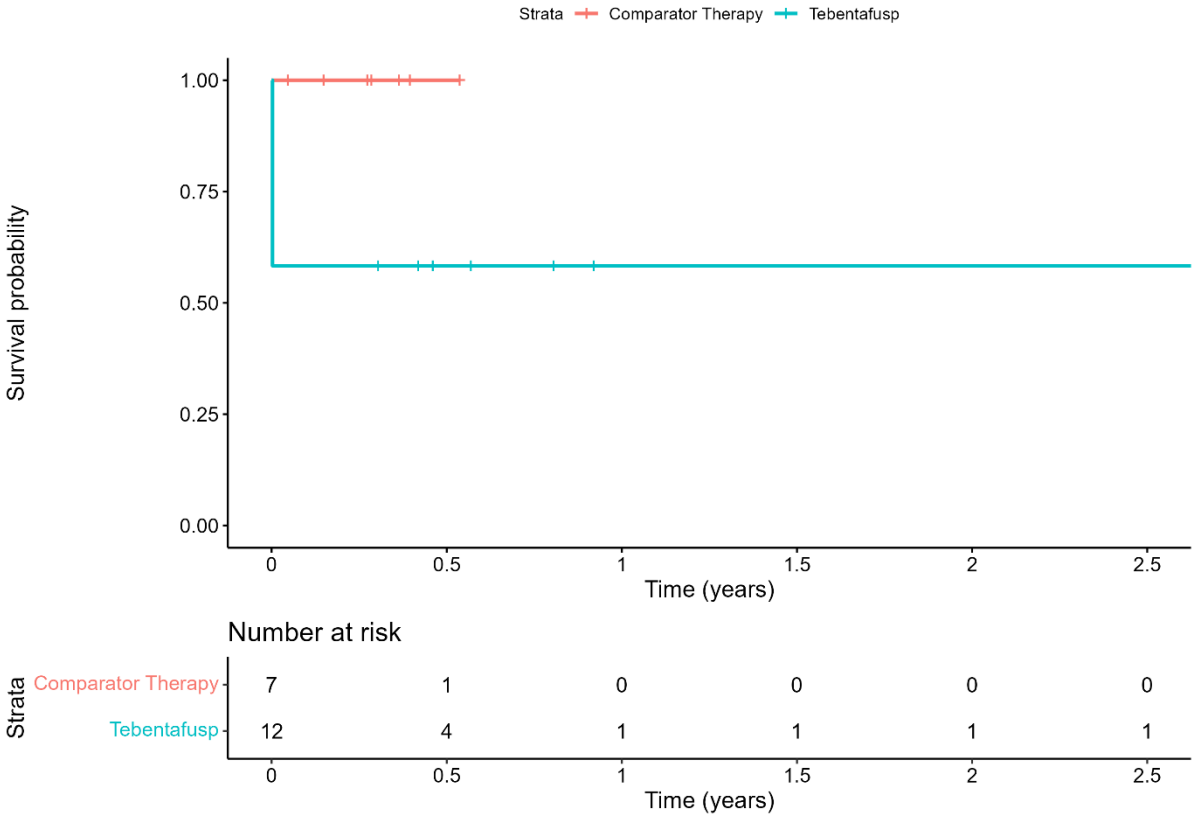
Region: Nordamerika



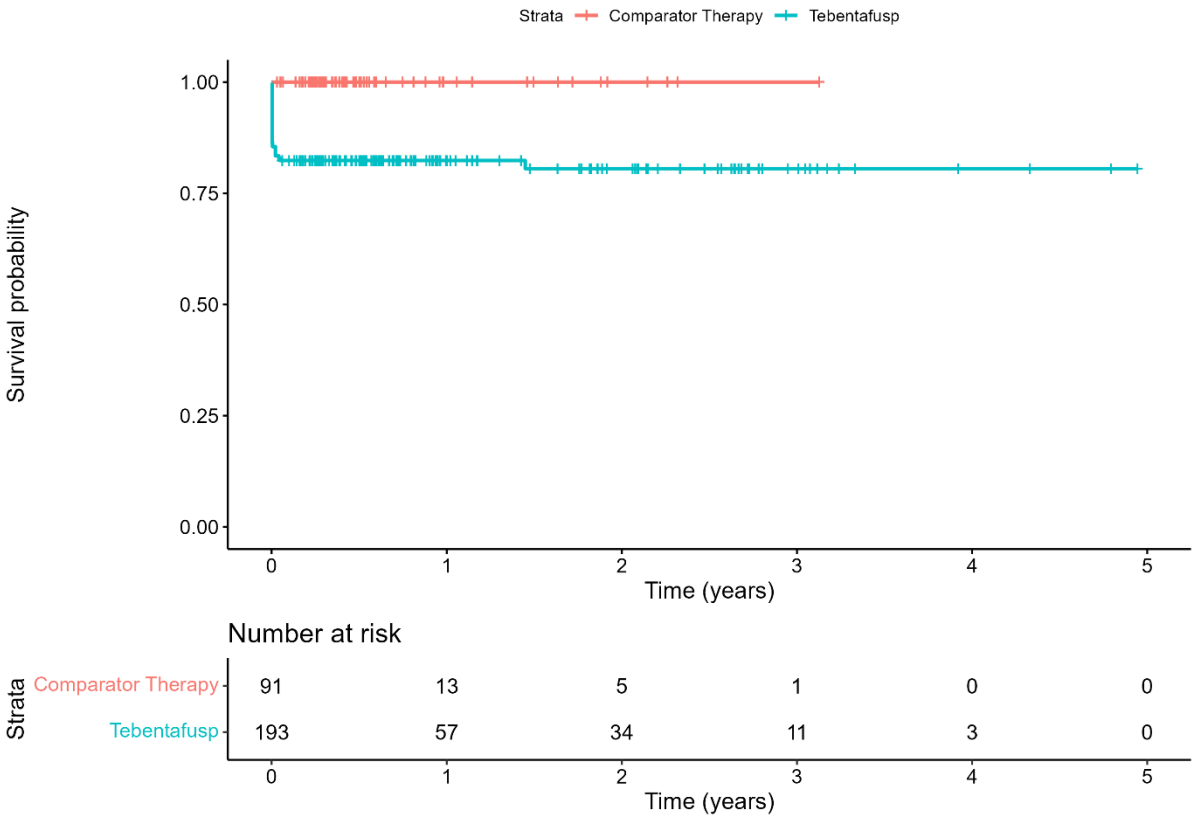
Region: Nicht-Nordamerika



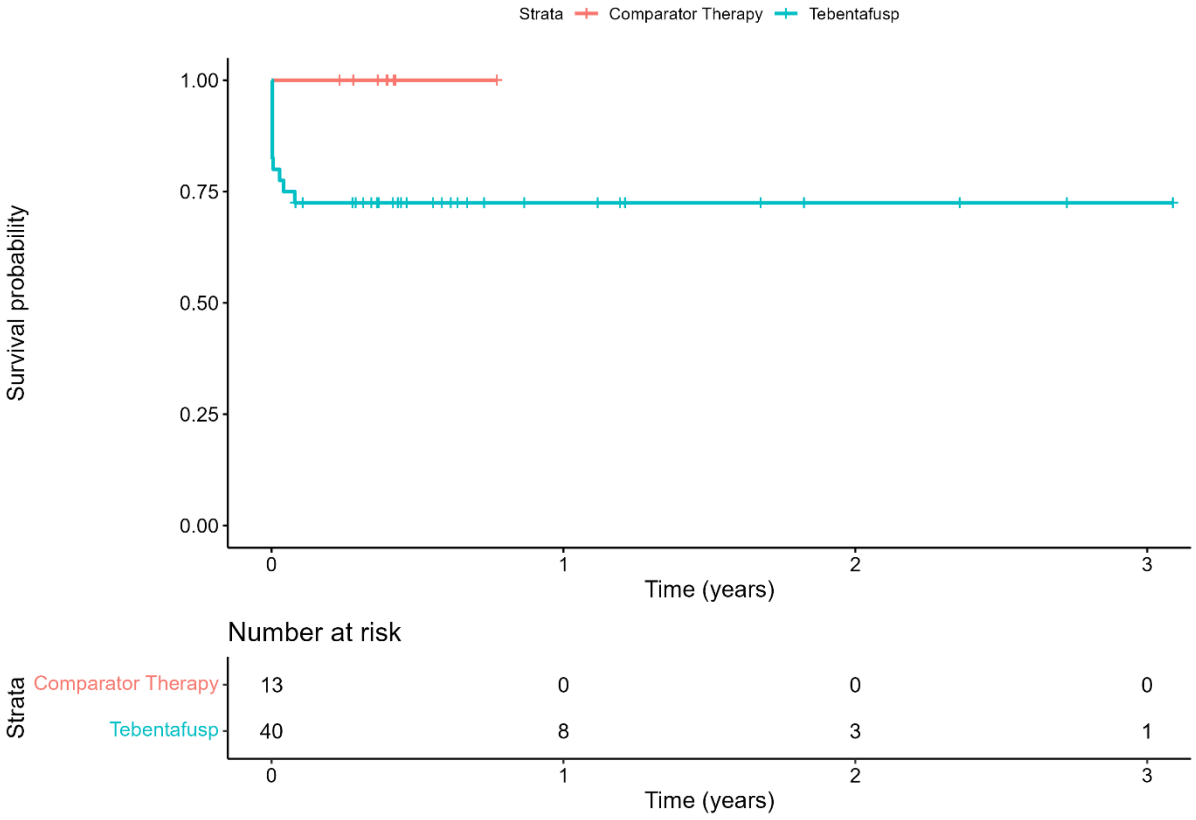
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

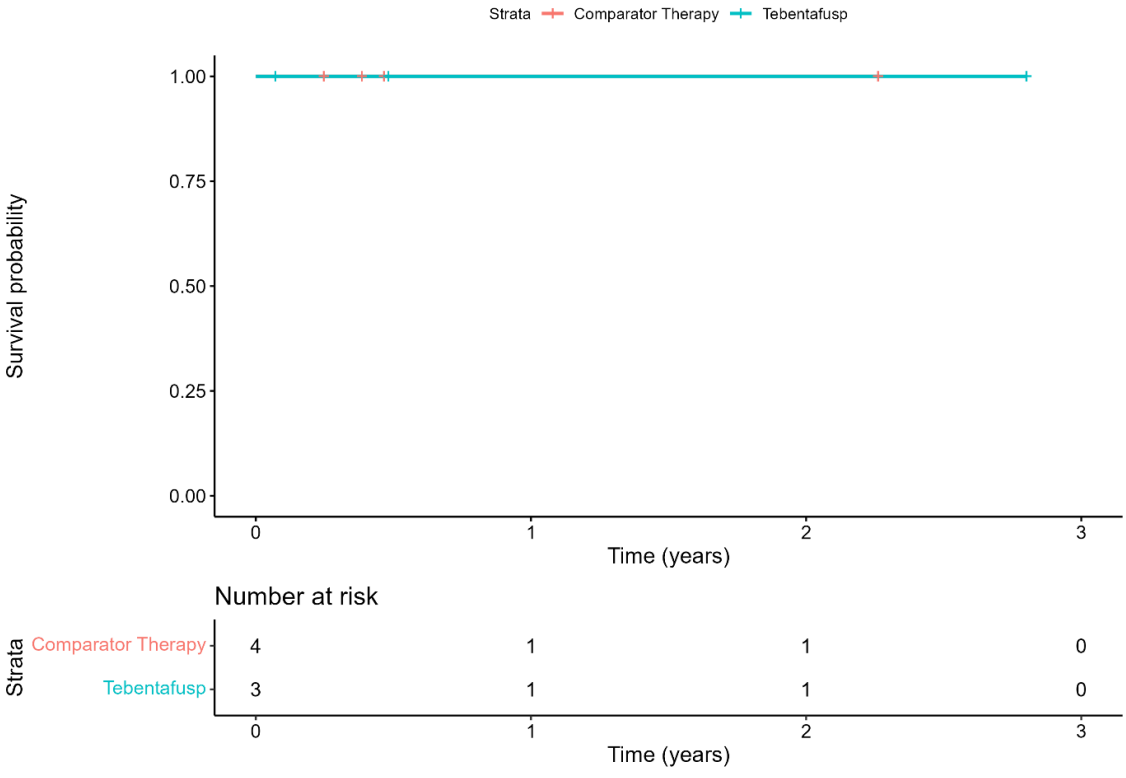


Vorauswahl der Chemotherapie: Ipilimumab

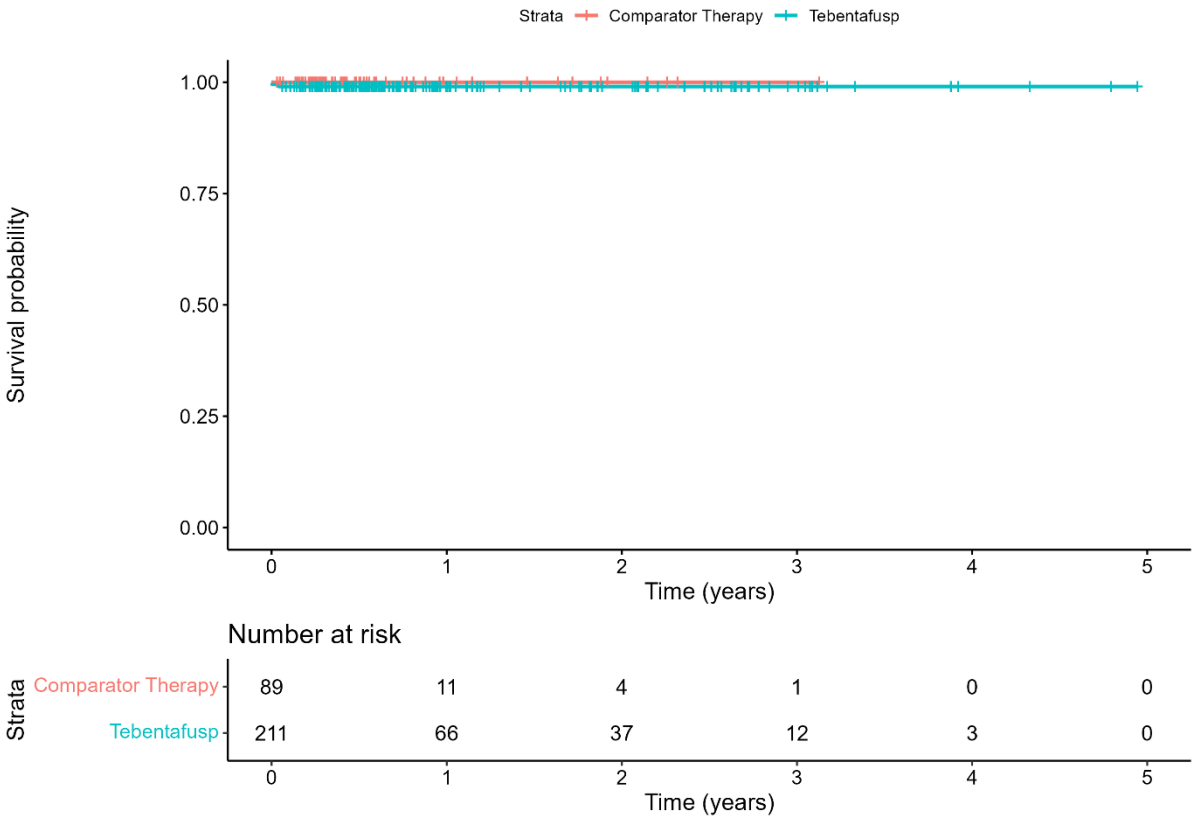


59.6 Zytokin-Freisetzungssyndrom mit CTCAE-Grad ≥ 3 (Tabelle 4-224)

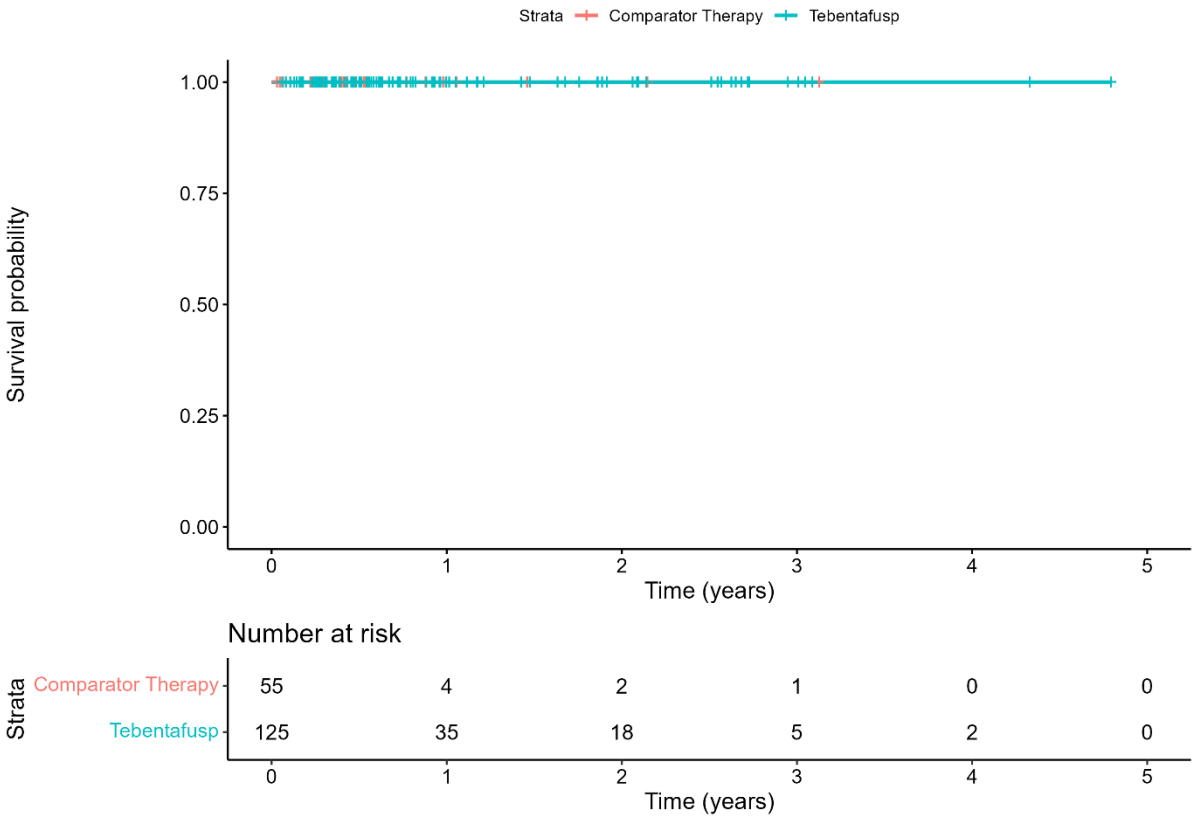
Herkunft: Hispanisch



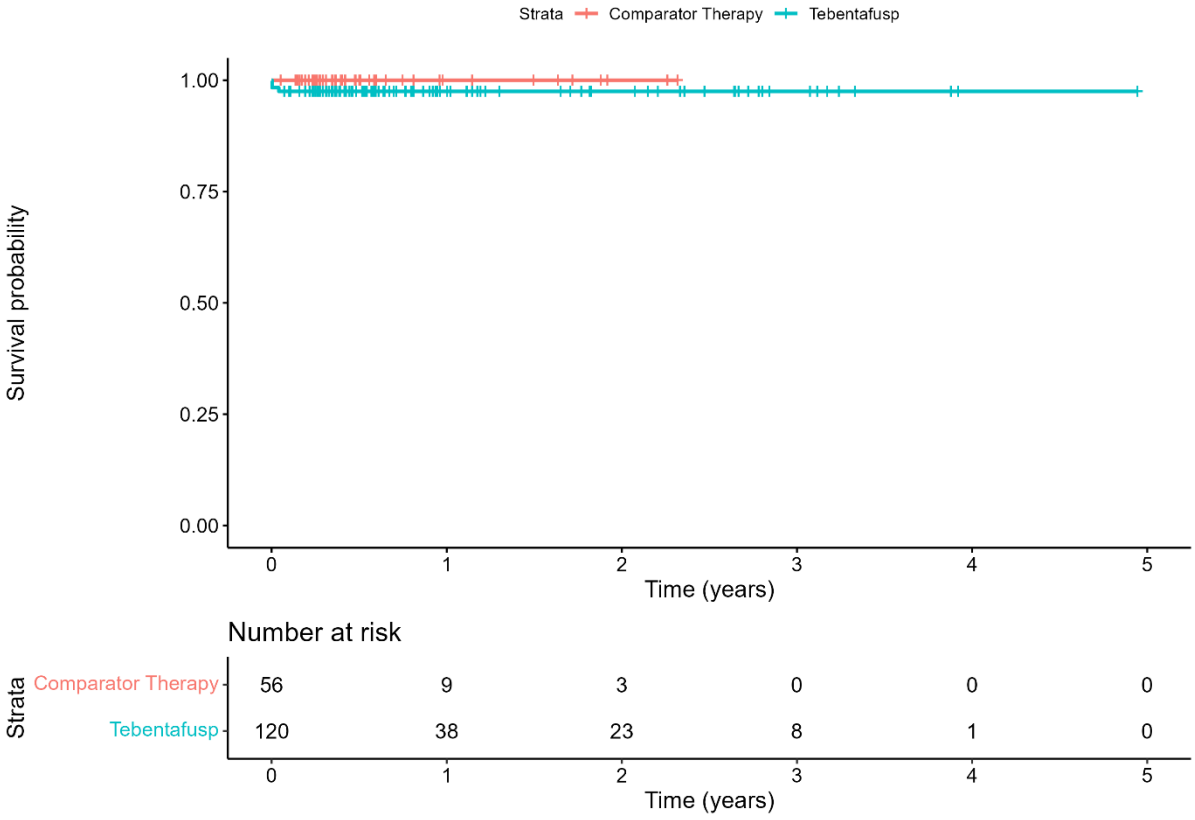
Herkunft: Nicht-hispanisch



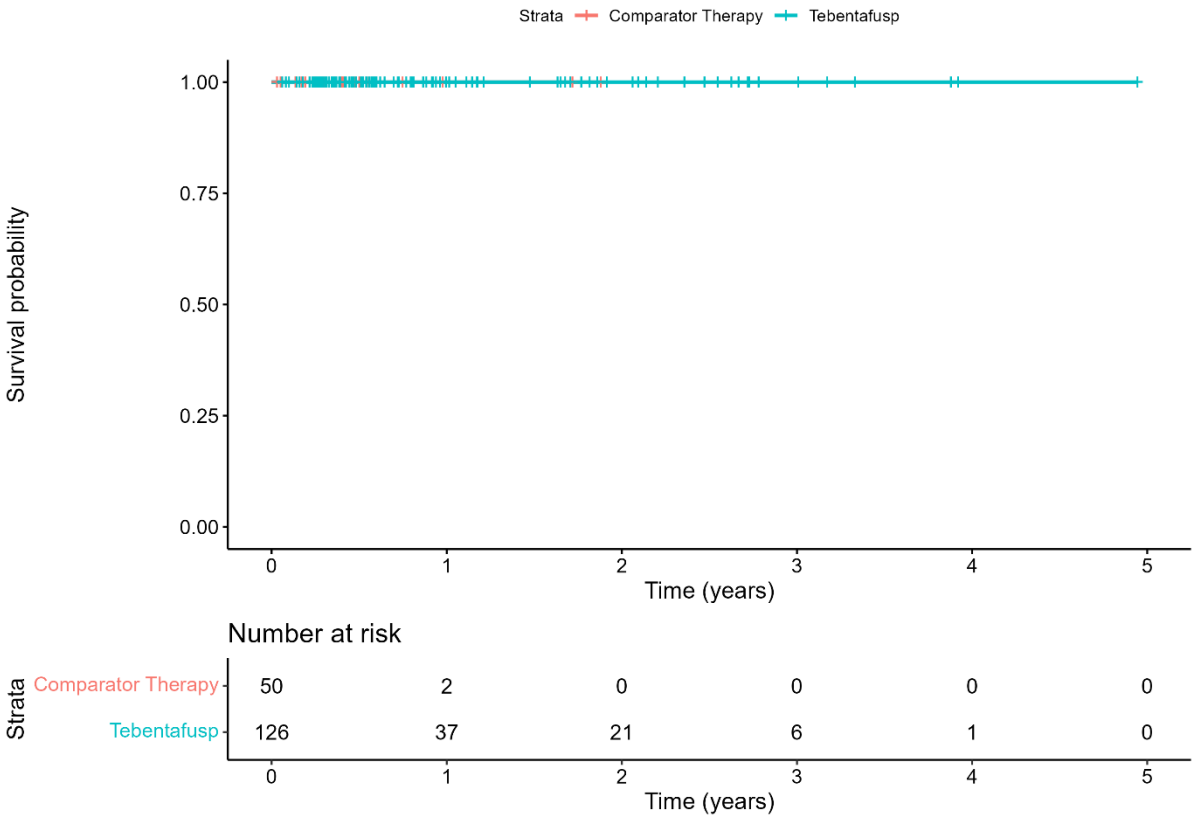
Geschlecht: Männlich



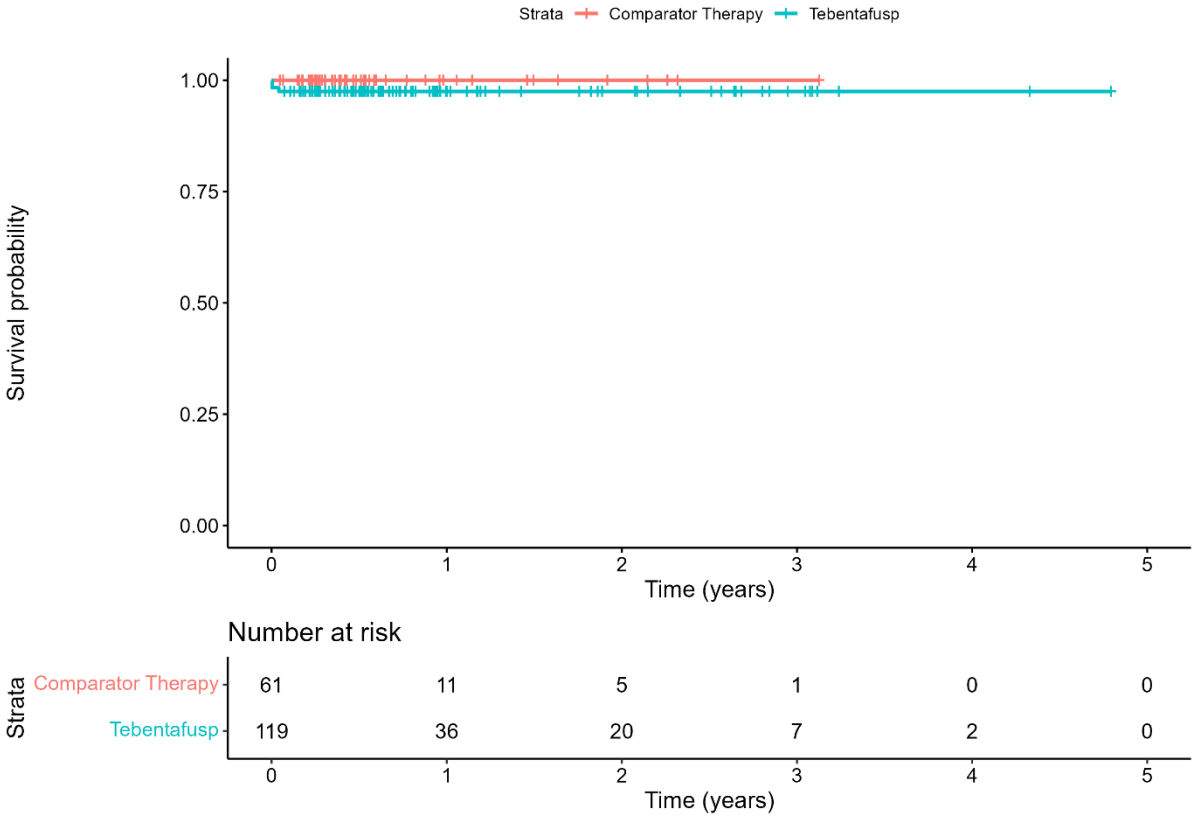
Geschlecht: Weiblich



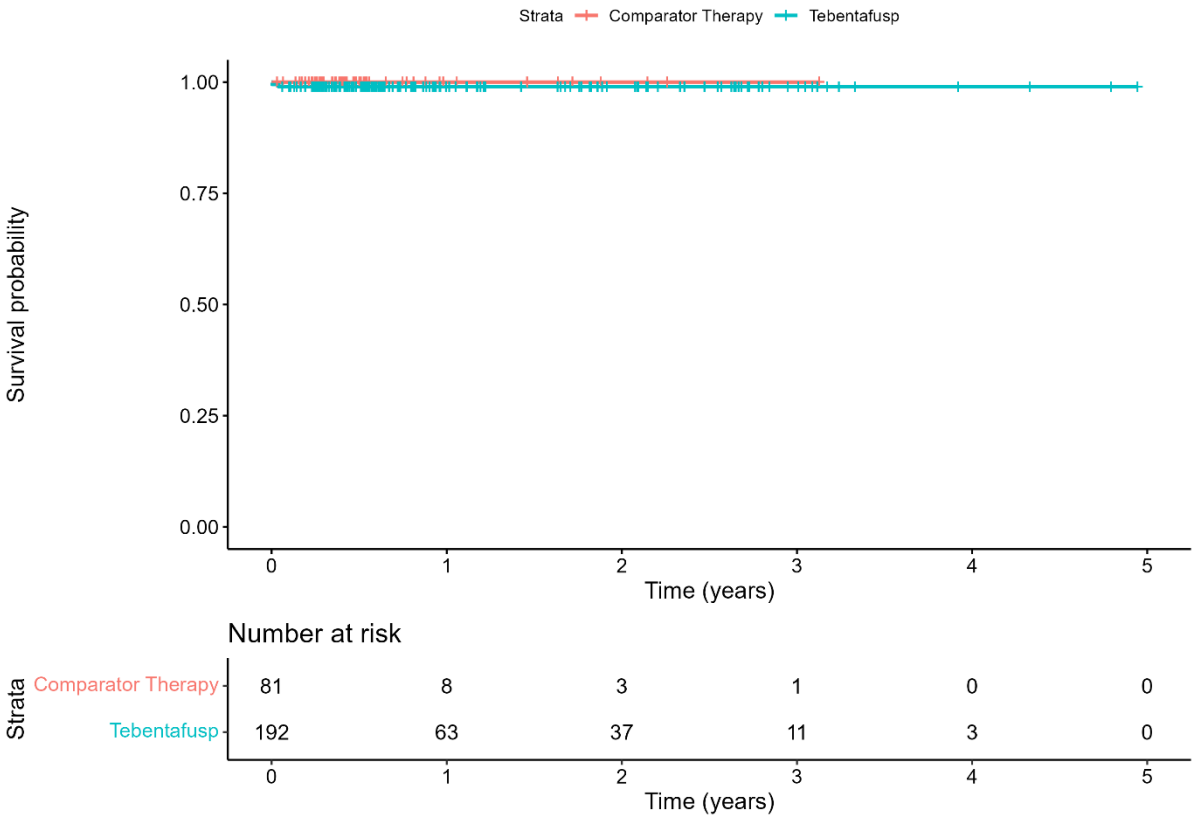
Alter: <65 Jahre



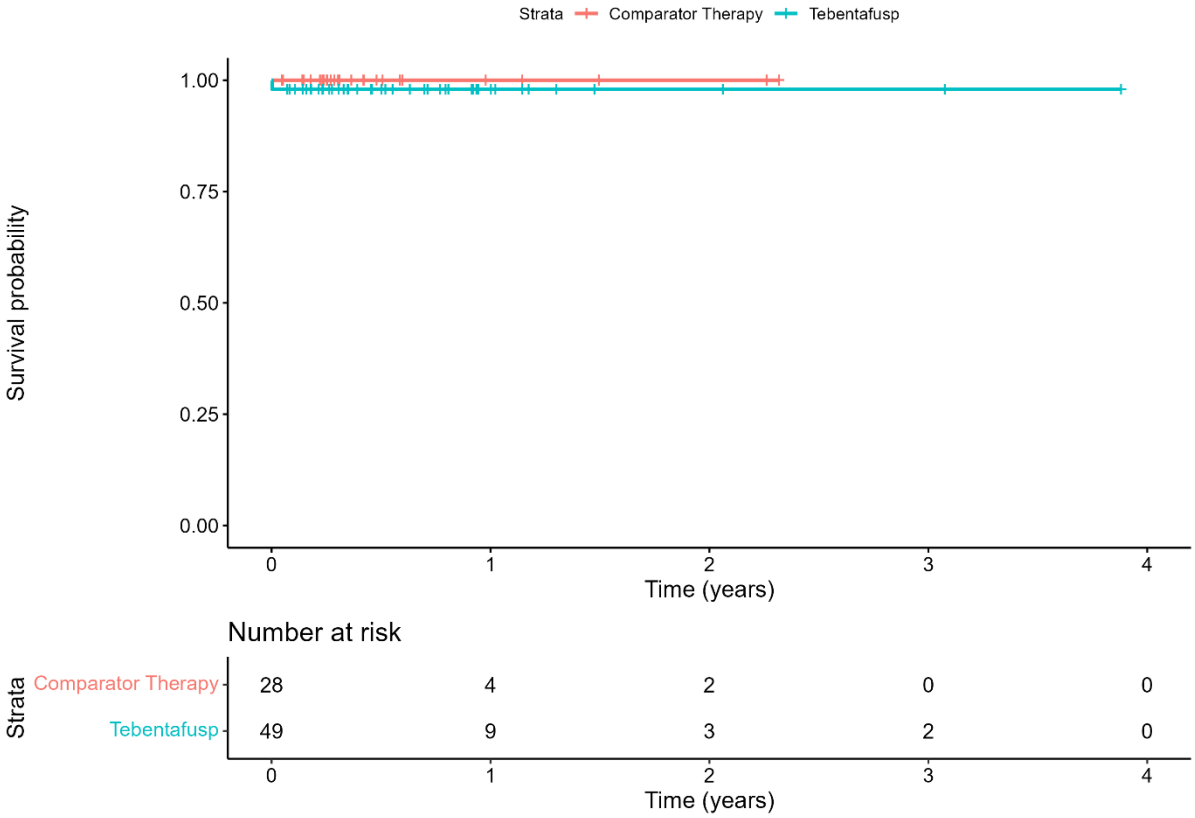
Alter: ≥65 Jahre



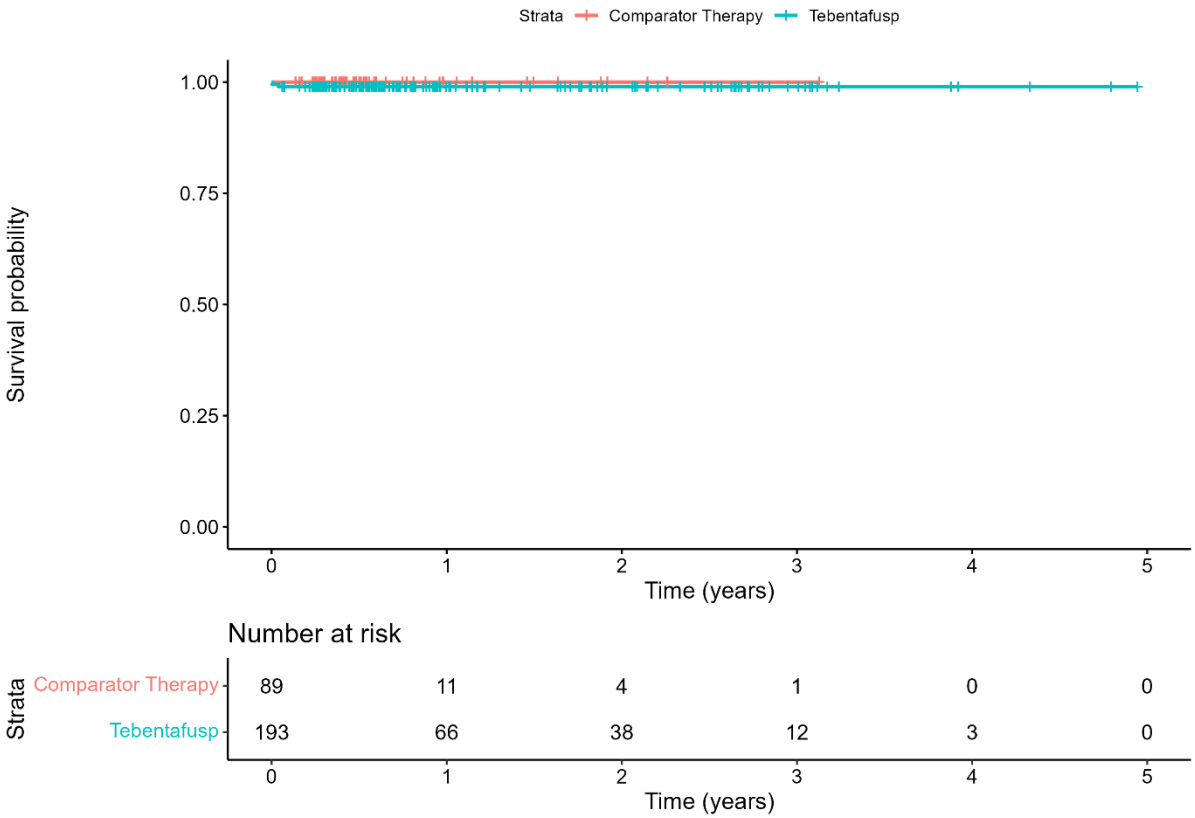
ECOG-Performance-Status: 0



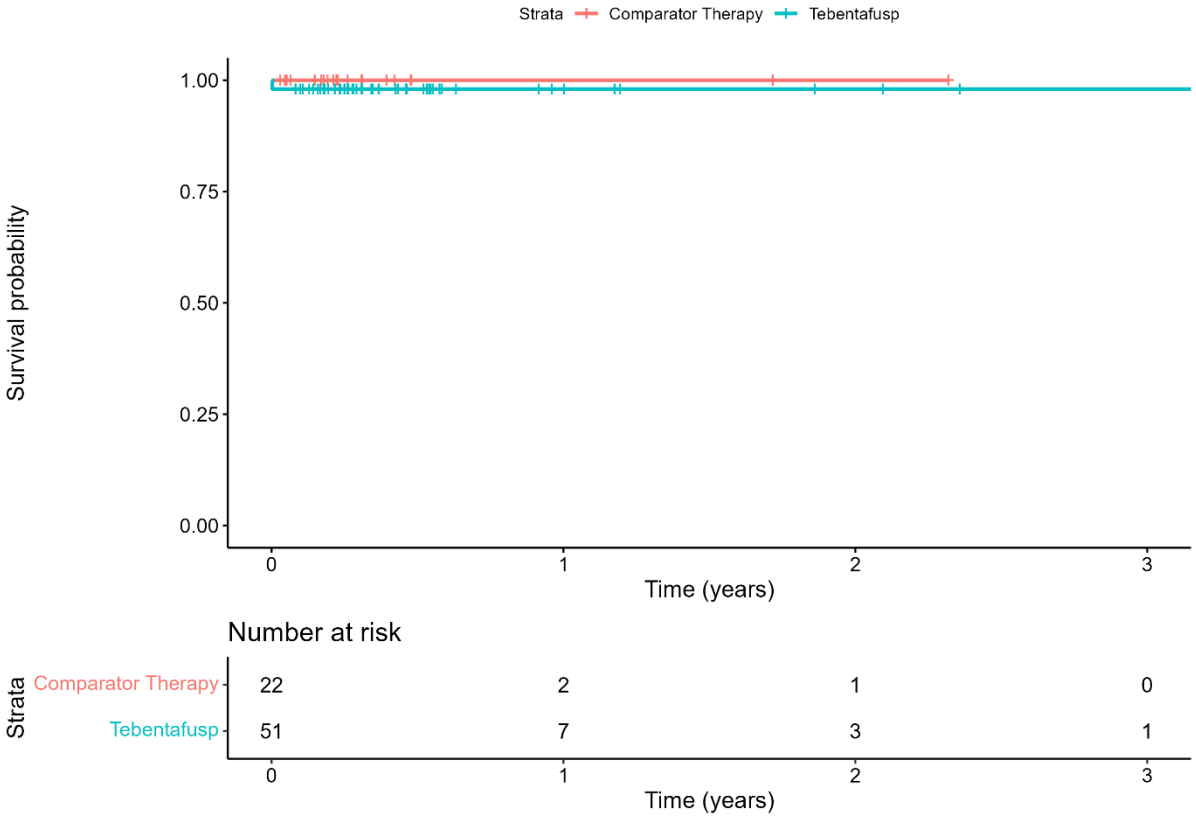
ECOG-Performance-Status: 1



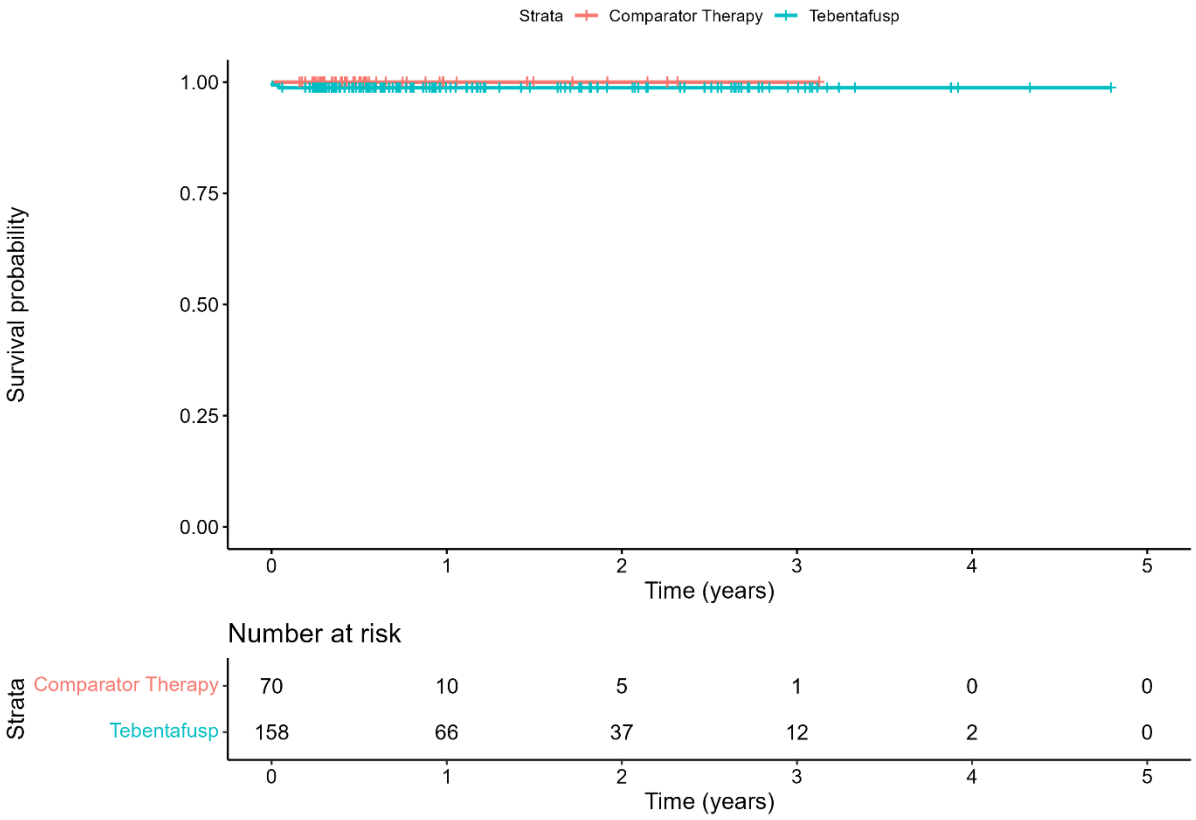
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



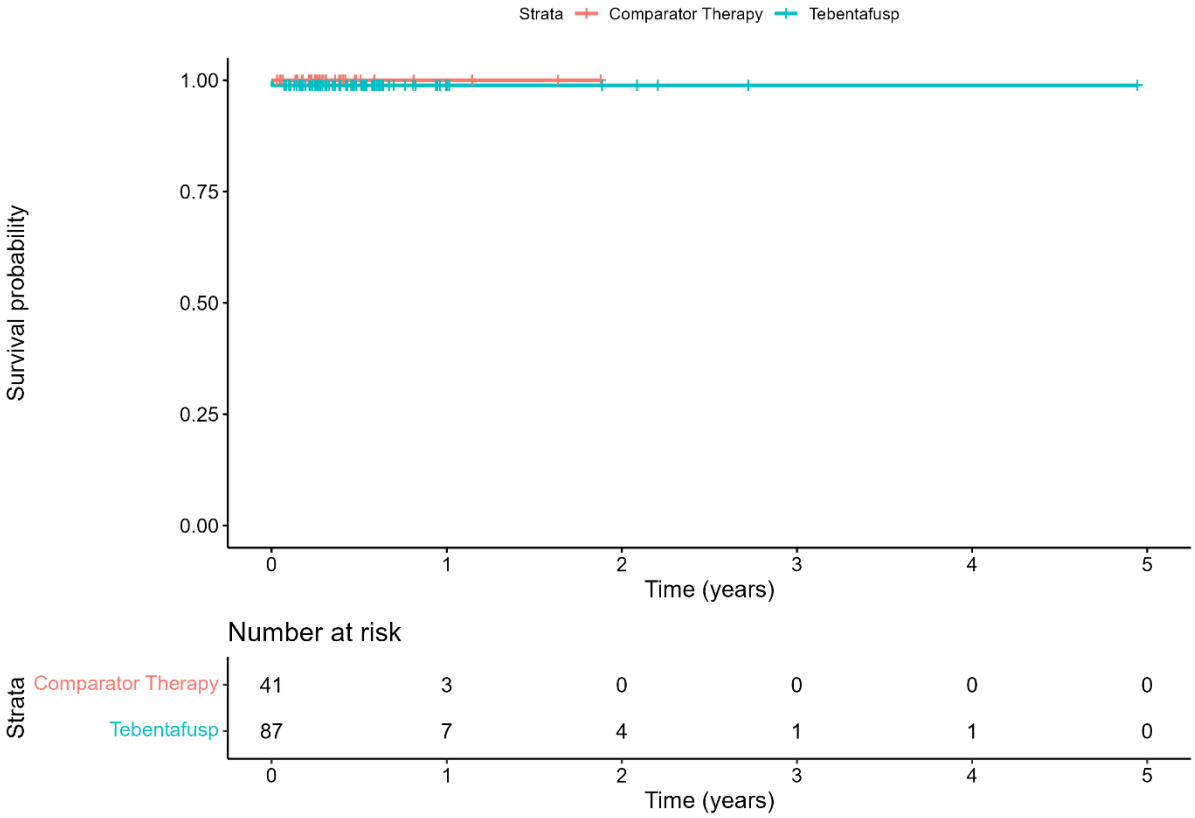
Alkalische Phosphatase (ALP) (Baseline): >ULN



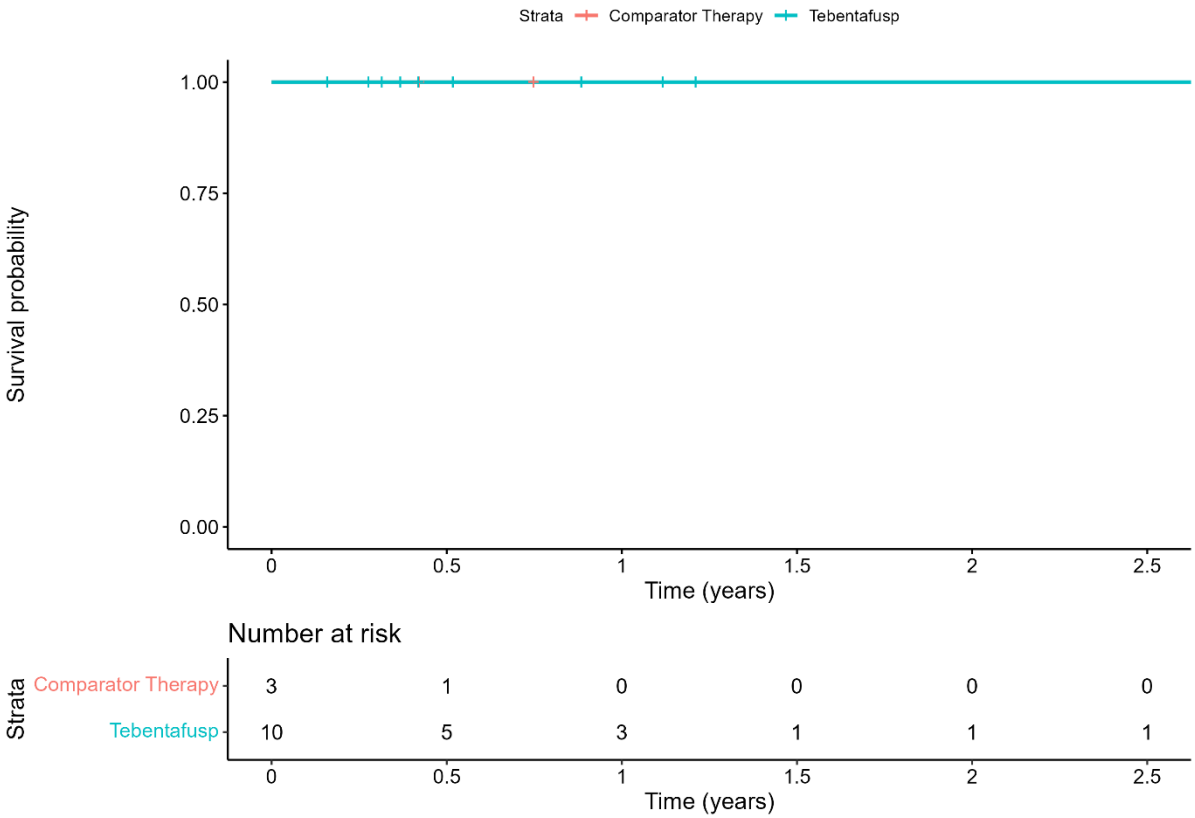
LDH: ≤ULN



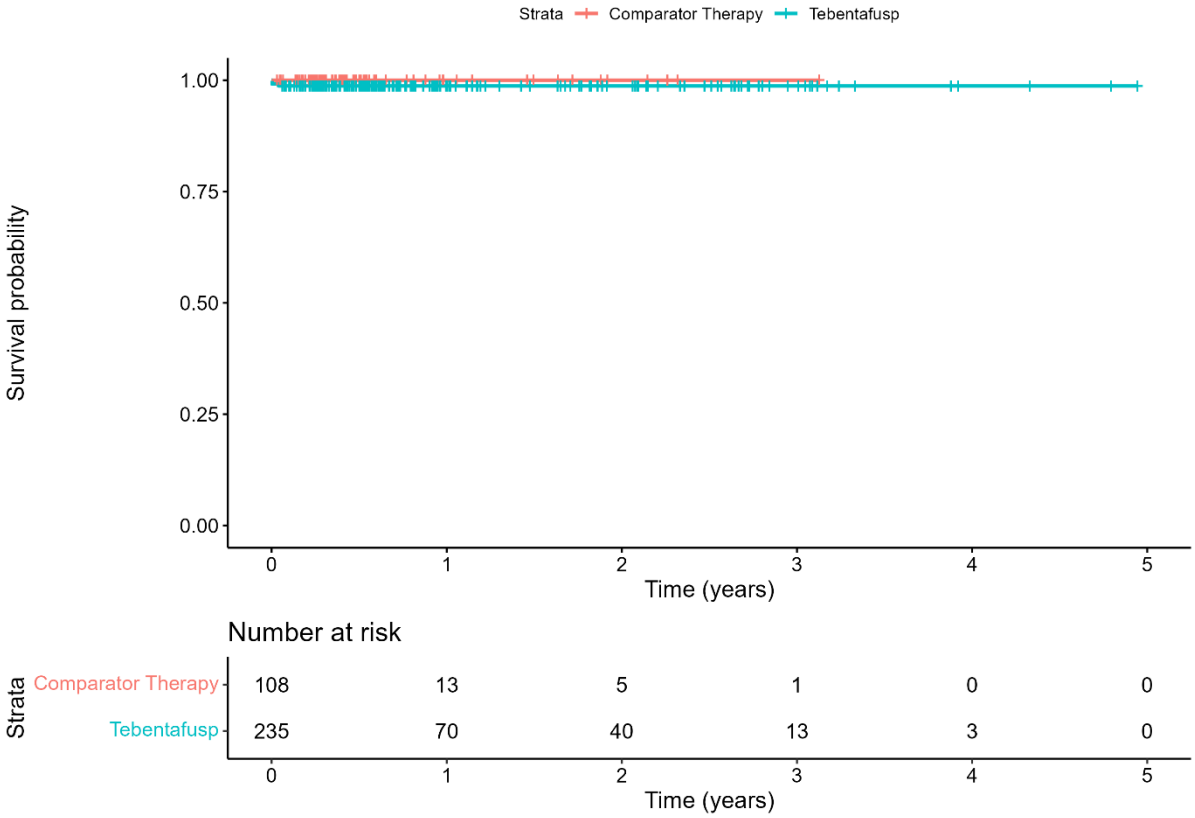
LDH: >ULN



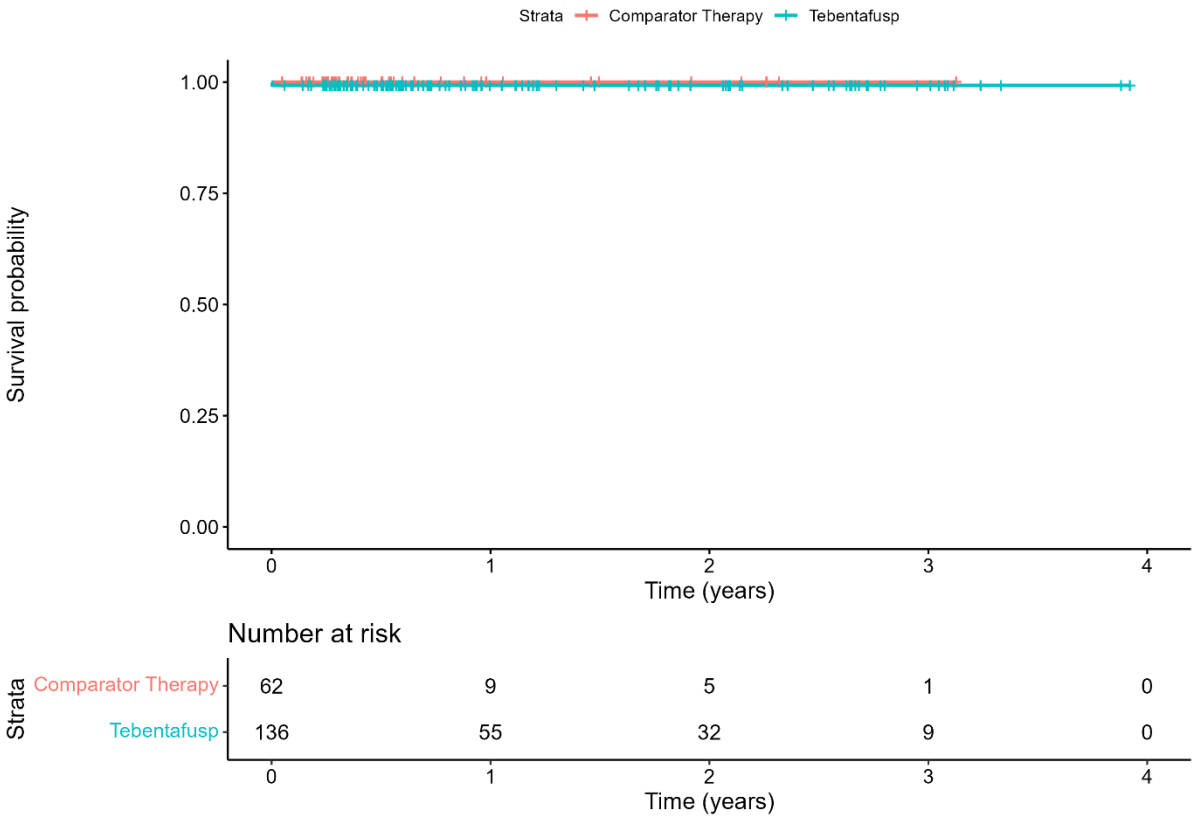
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



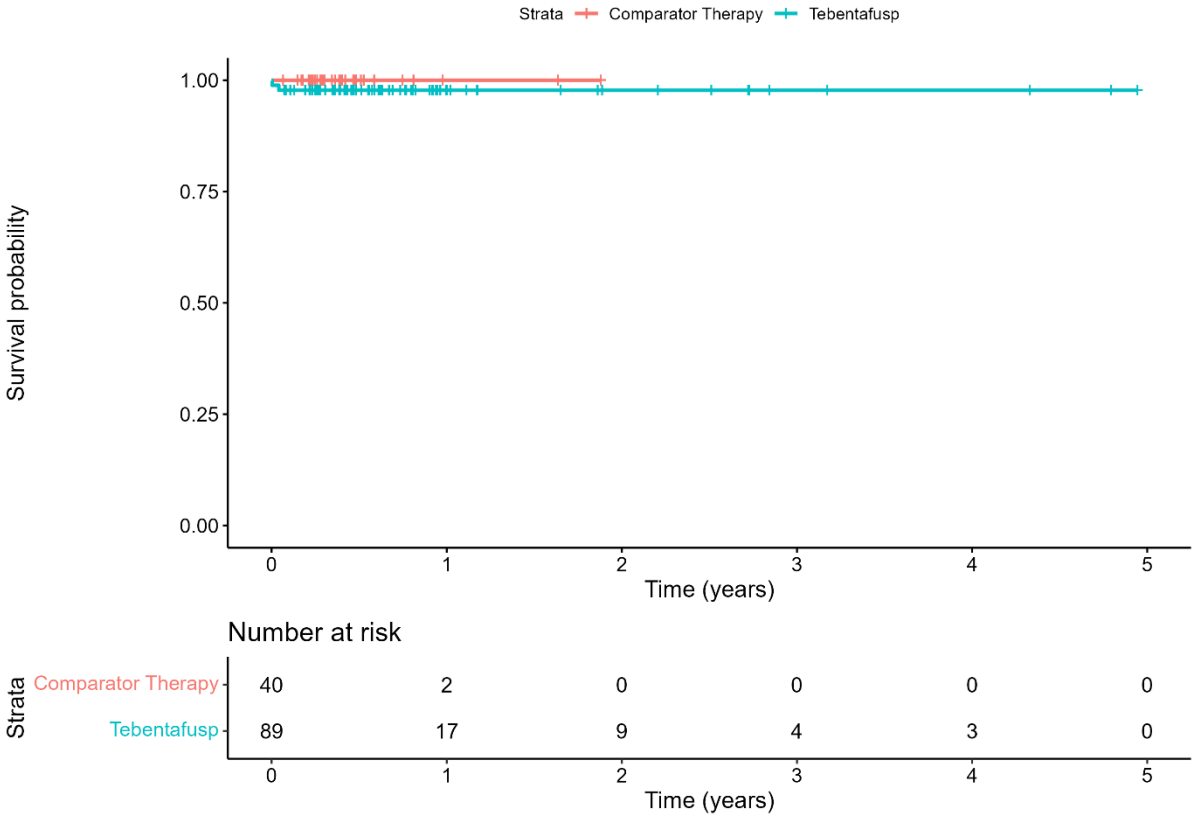
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



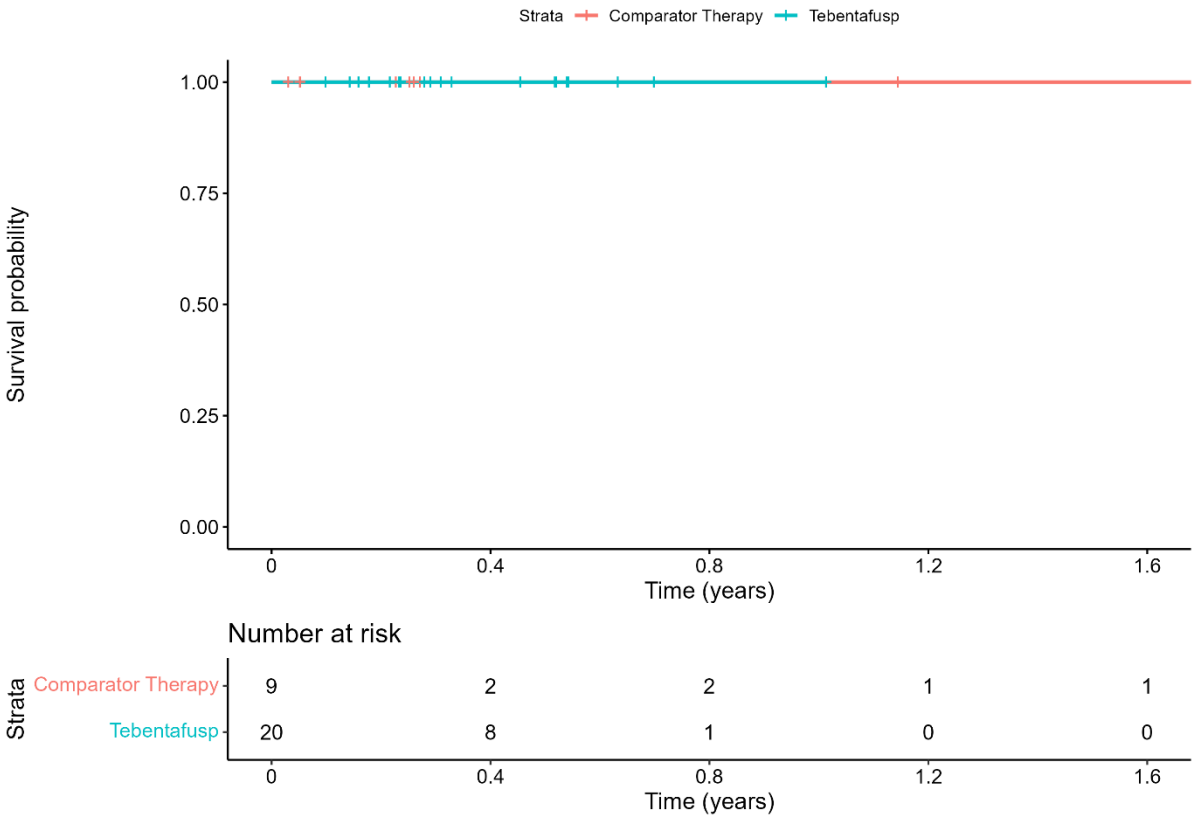
Größte metastatische Läsion (Baseline): ≤3,0 cm



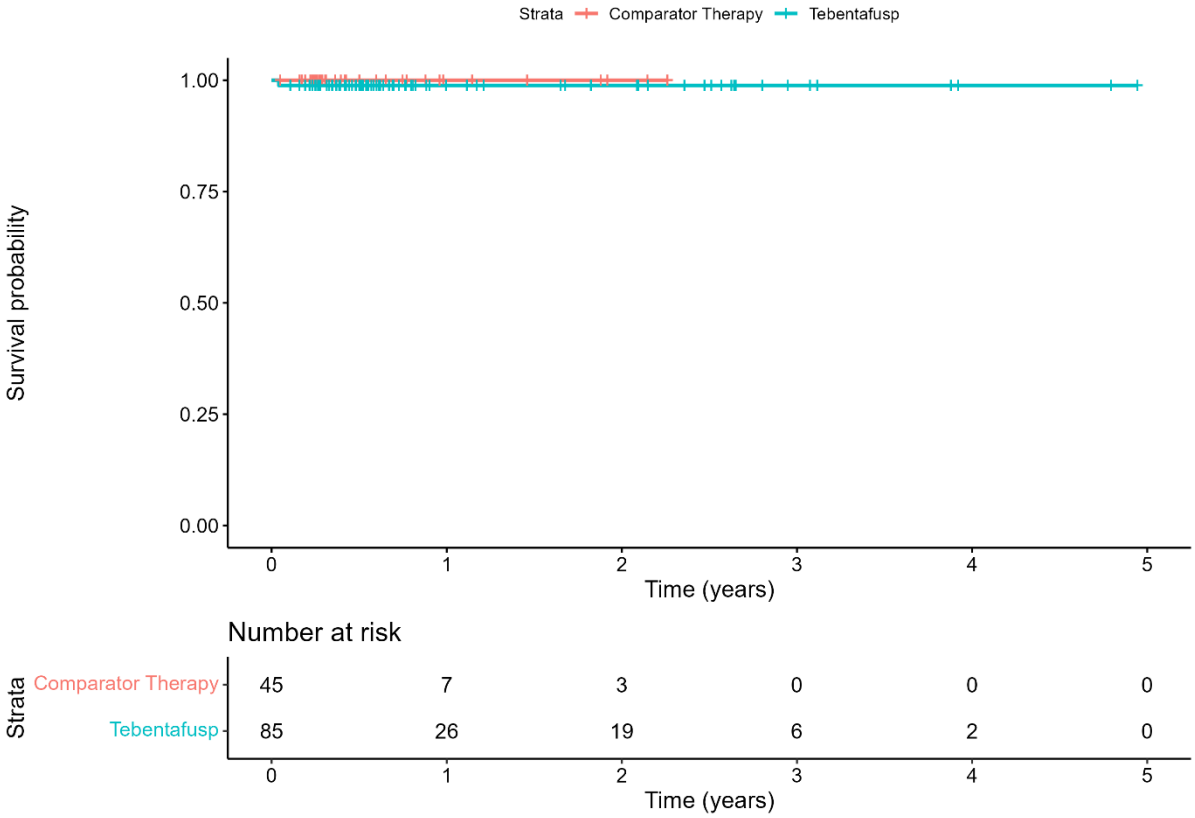
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



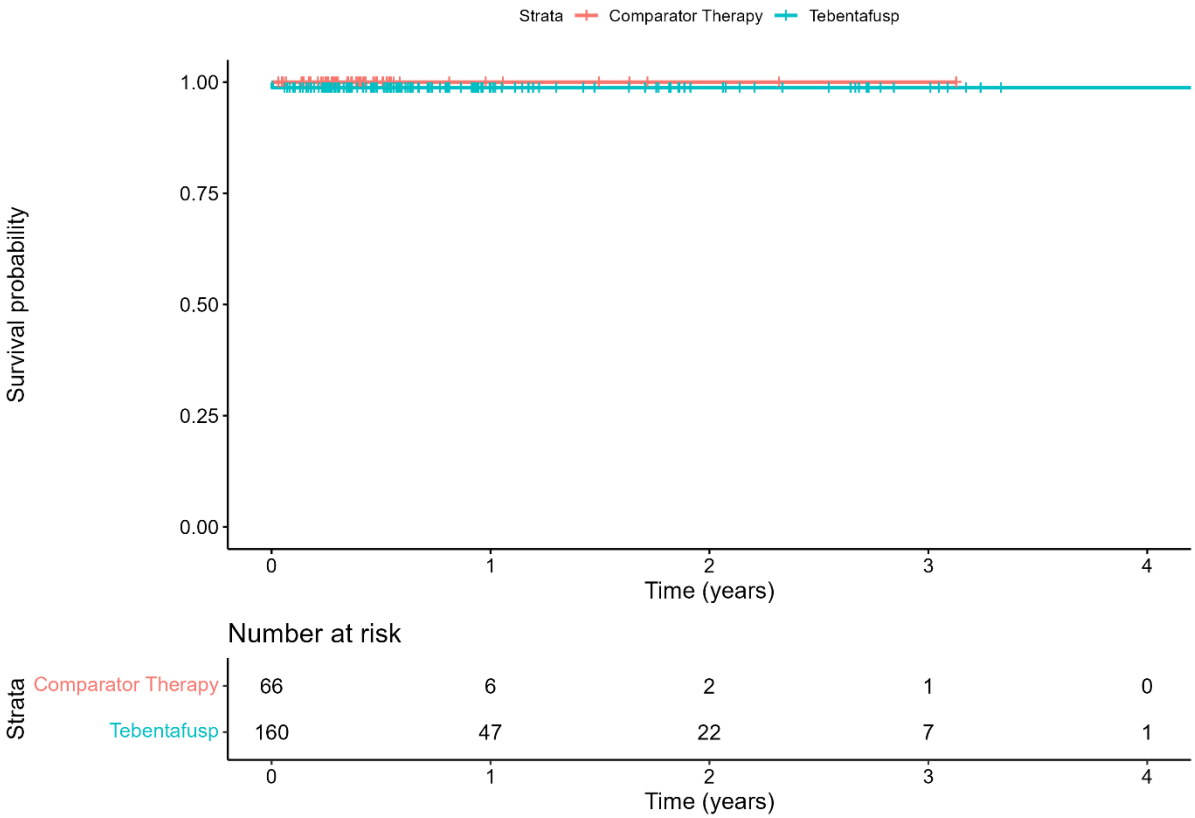
Größte metastatische Läsion (Baseline): ≥8,1 cm



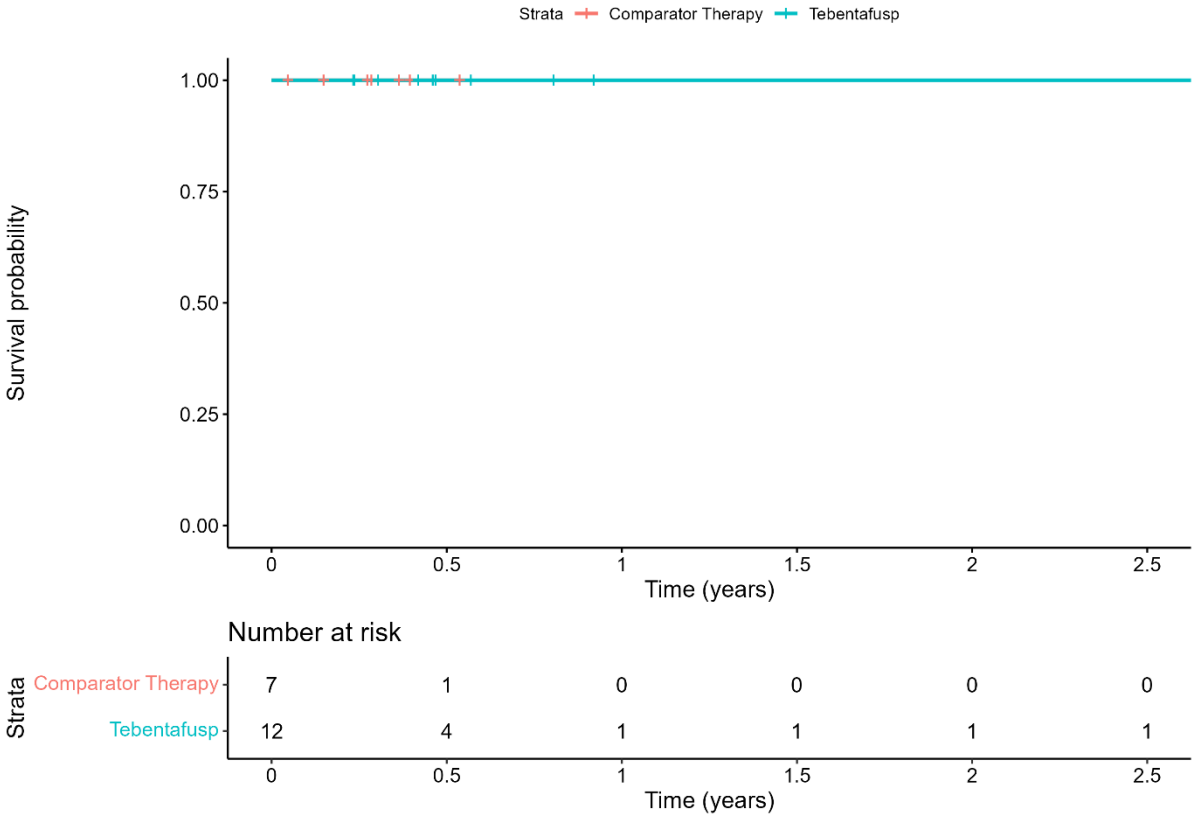
Region: Nordamerika



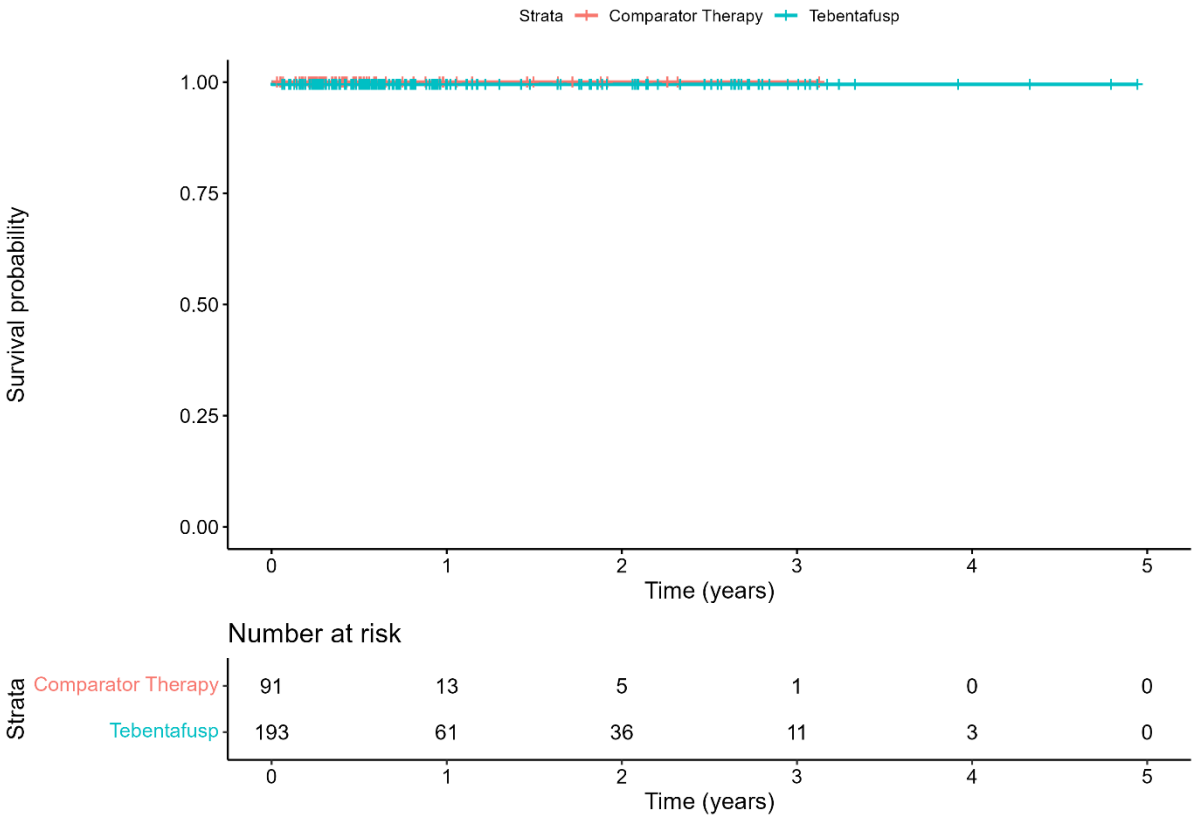
Region: Nicht-Nordamerika



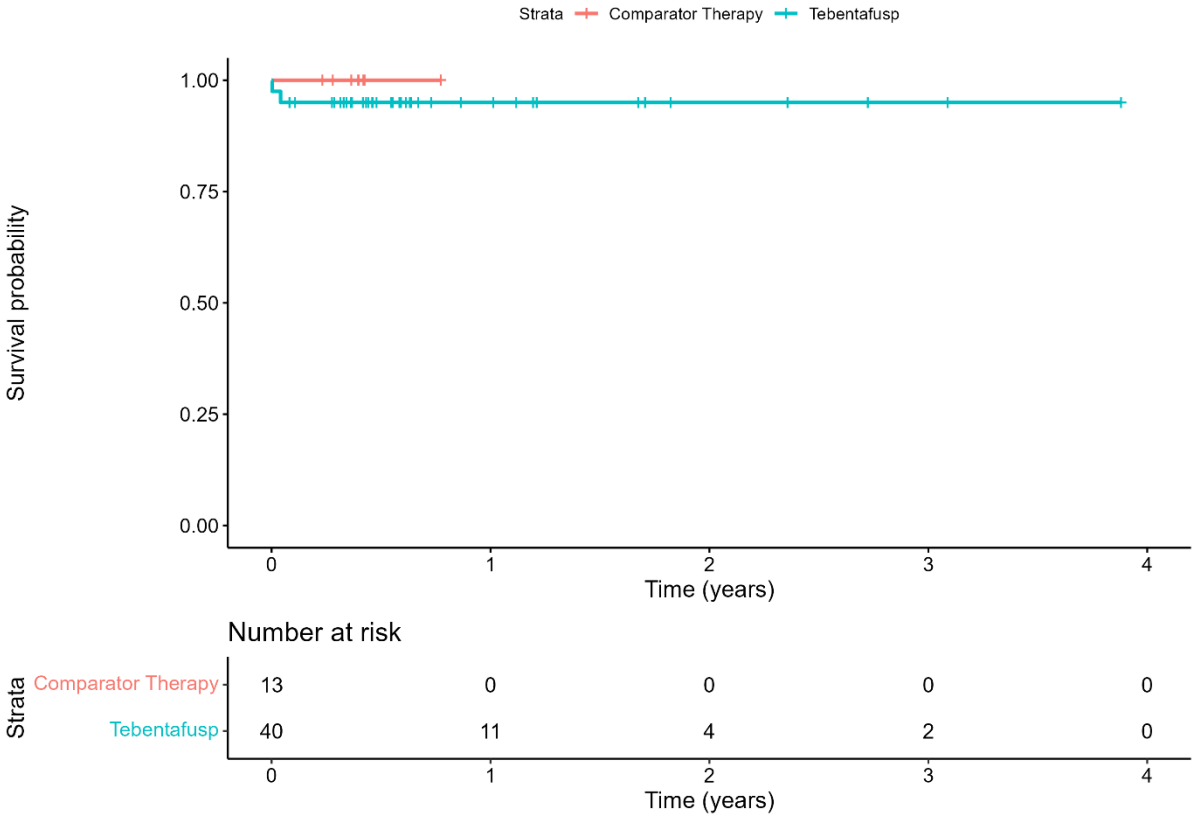
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

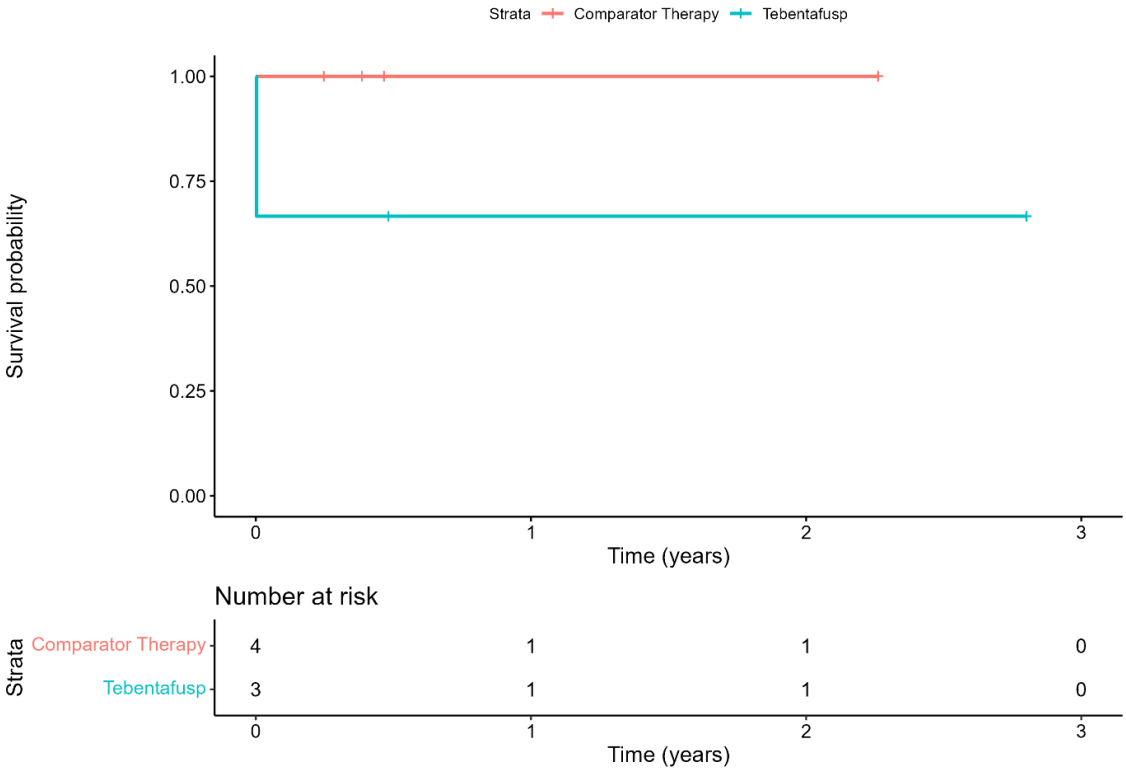


Vorauswahl der Chemotherapie: Ipilimumab

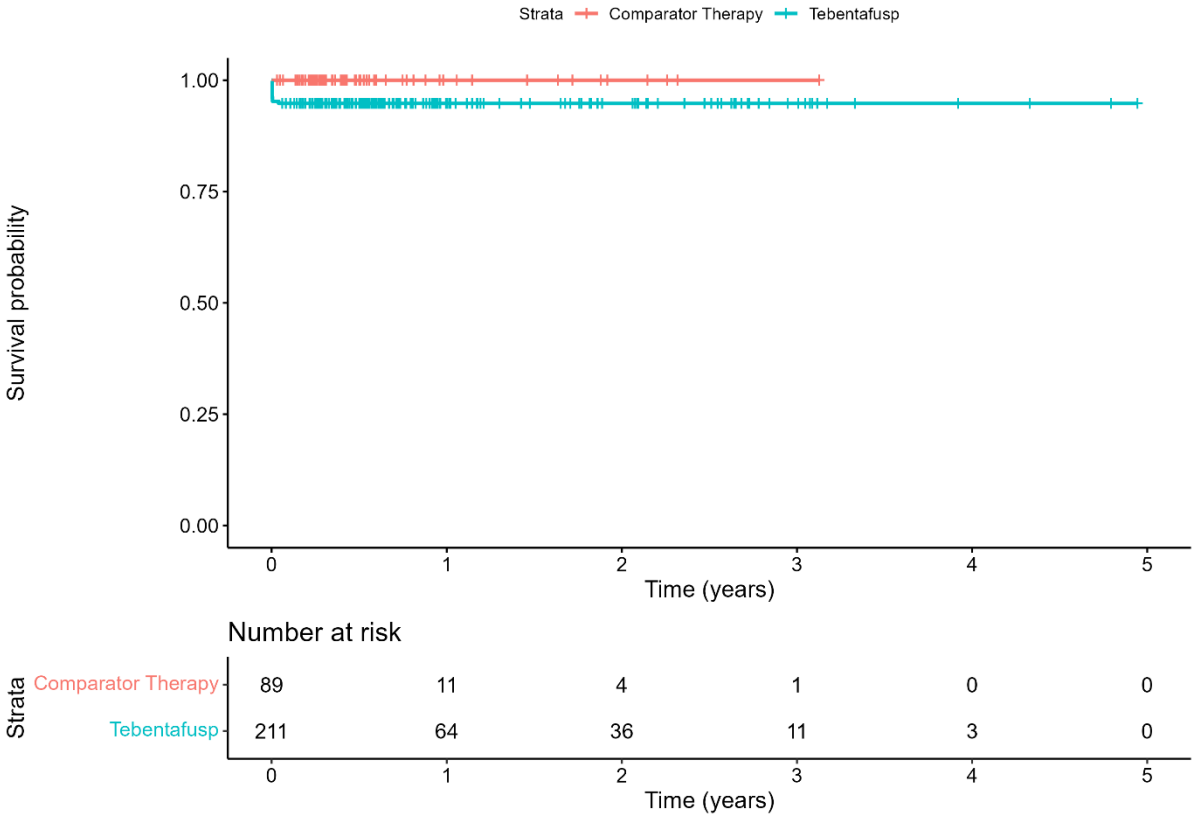


59.7 Schwerwiegendes Zytokin-Freisetzungssyndrom (Tabelle 4-226)

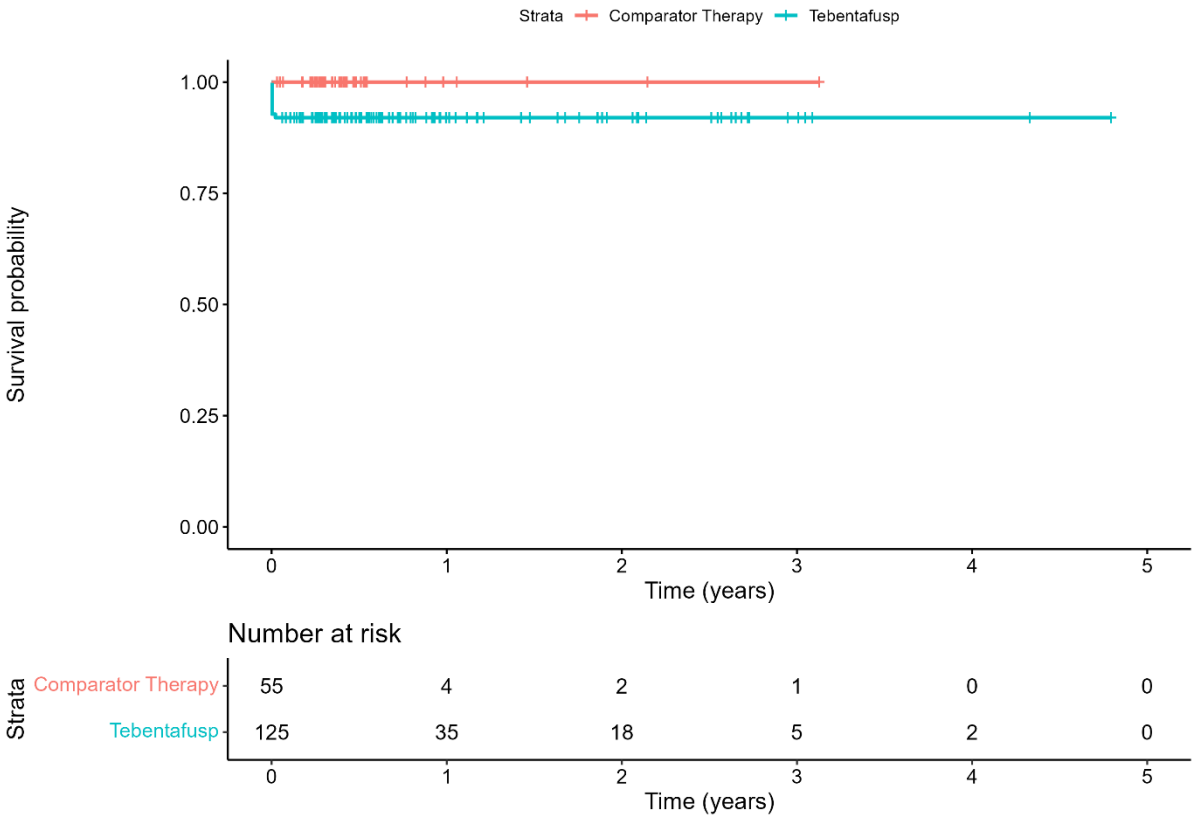
Herkunft: Hispanisch



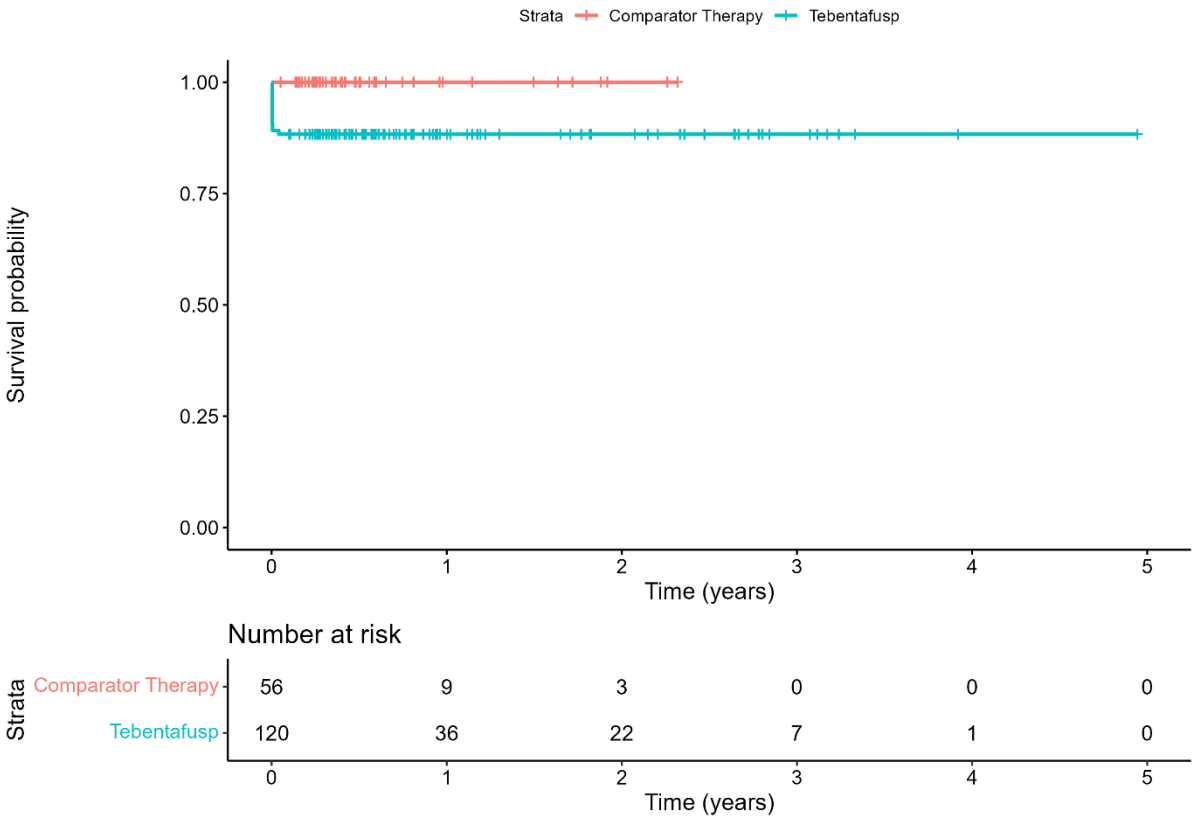
Herkunft: Nicht-hispanisch



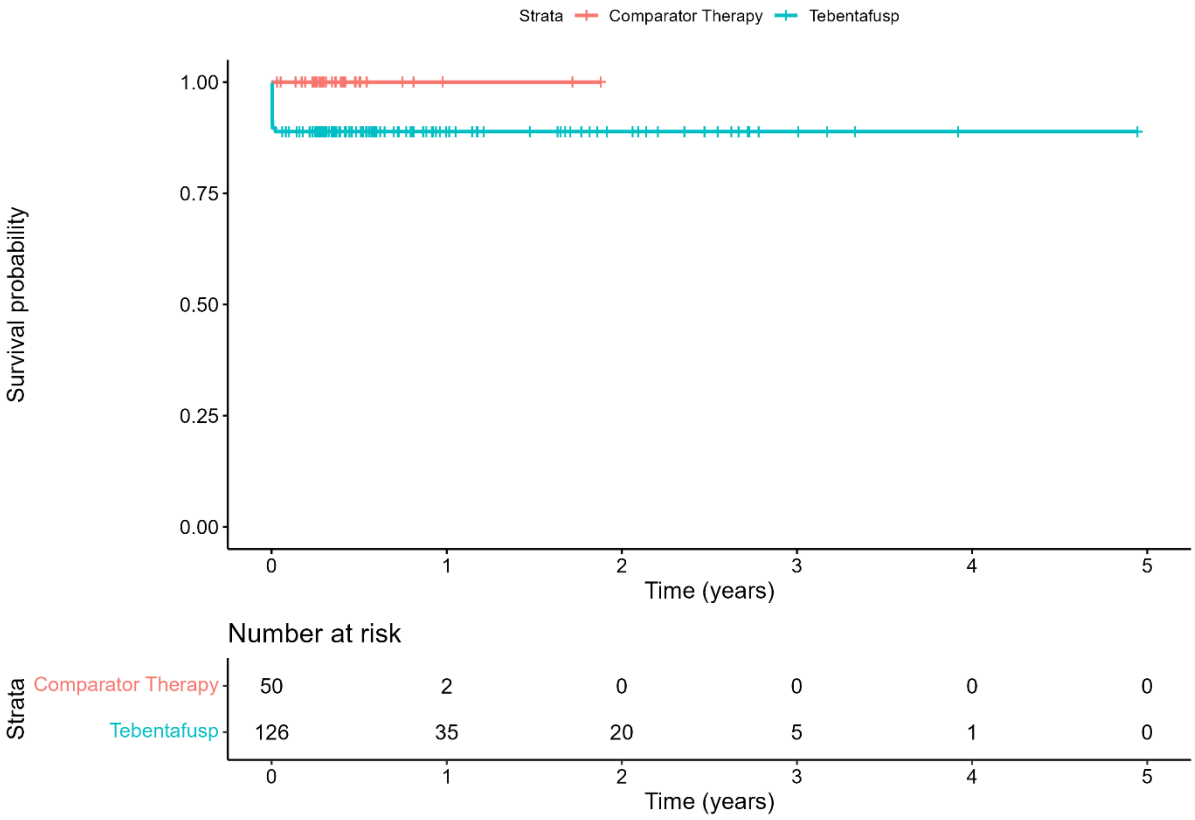
Geschlecht: Männlich



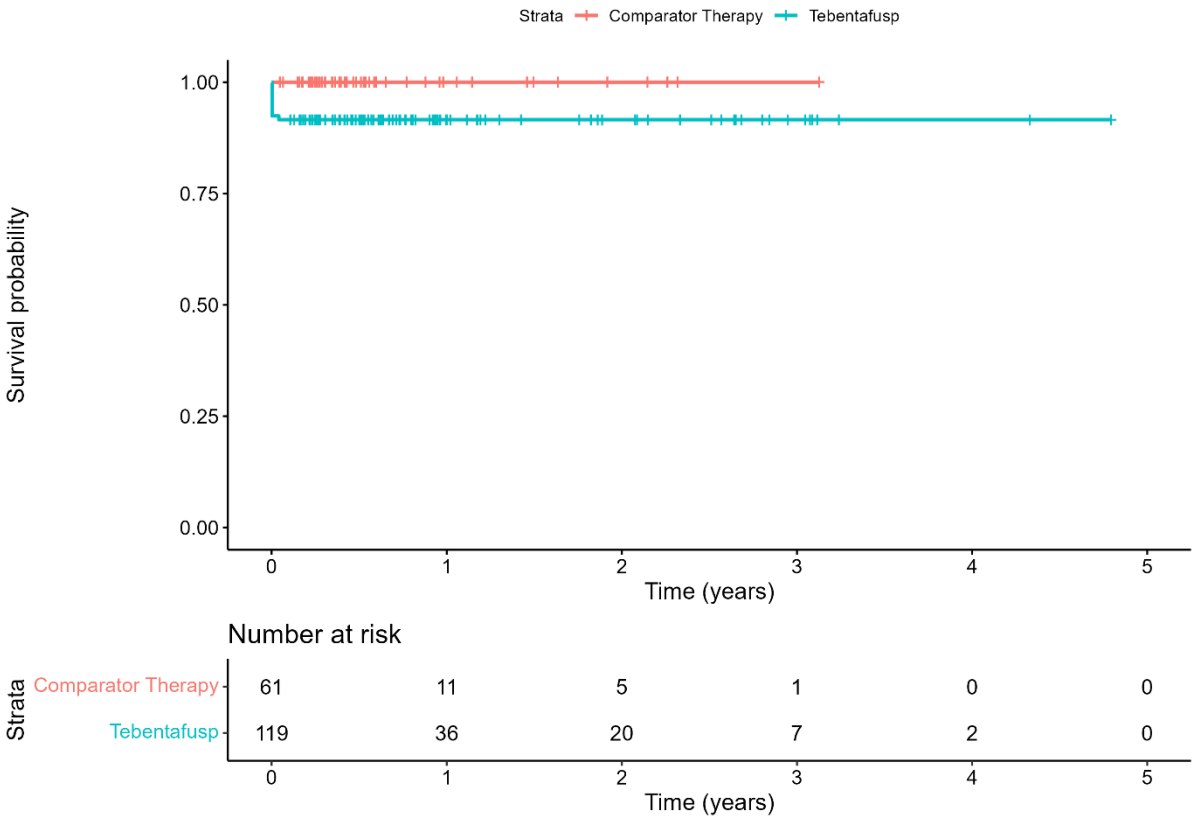
Geschlecht: Weiblich



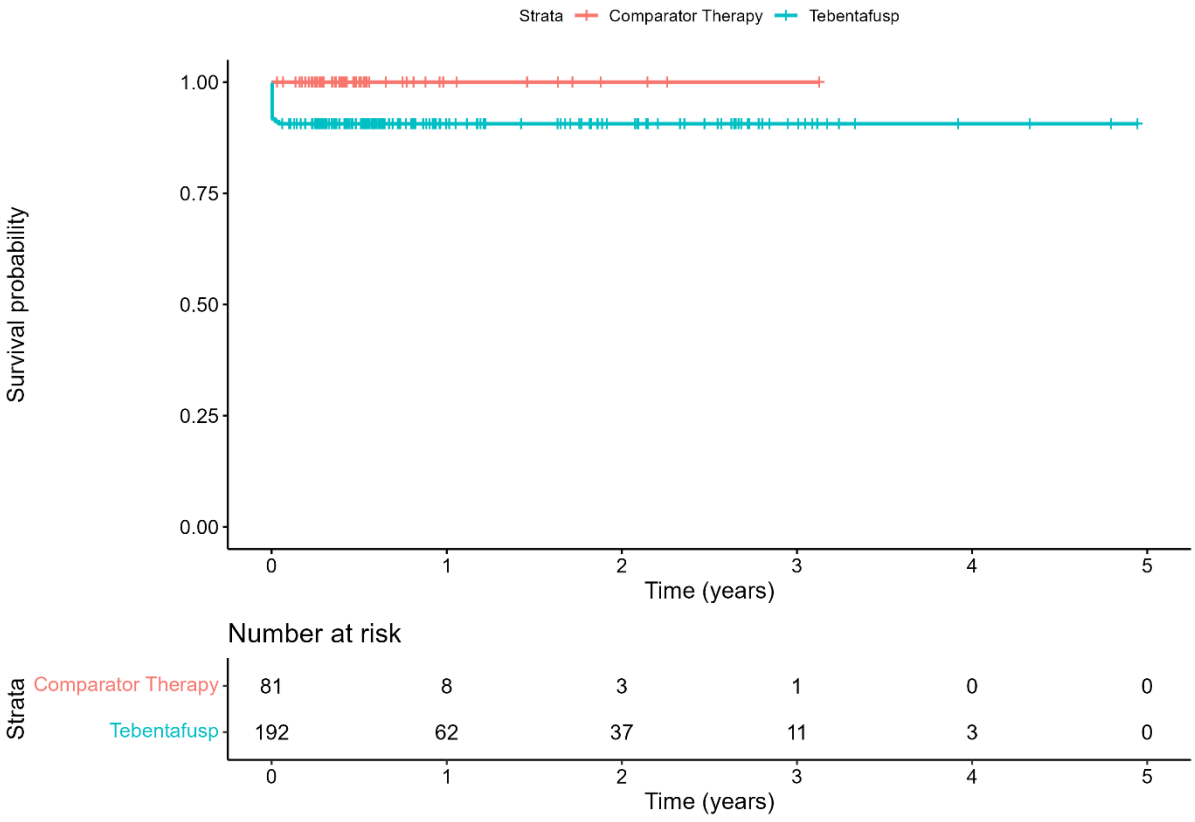
Alter: <65 Jahre



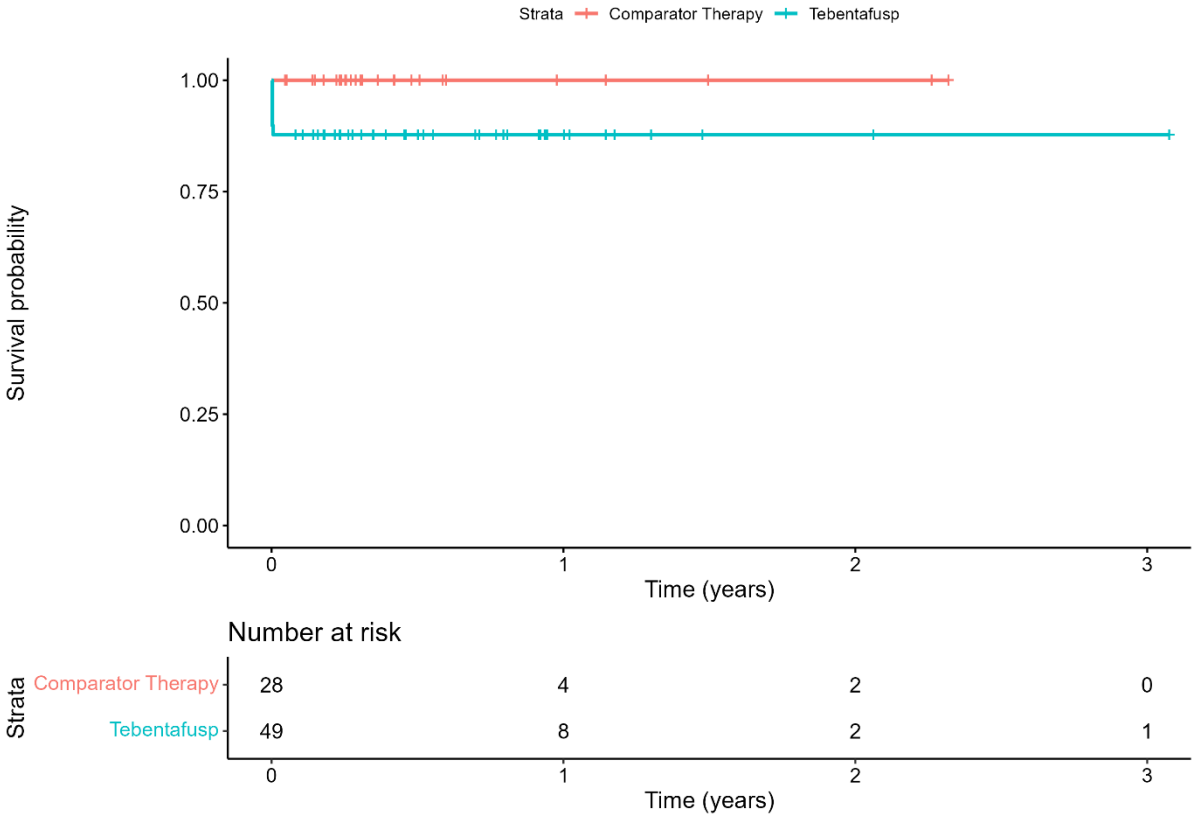
Alter: ≥65 Jahre



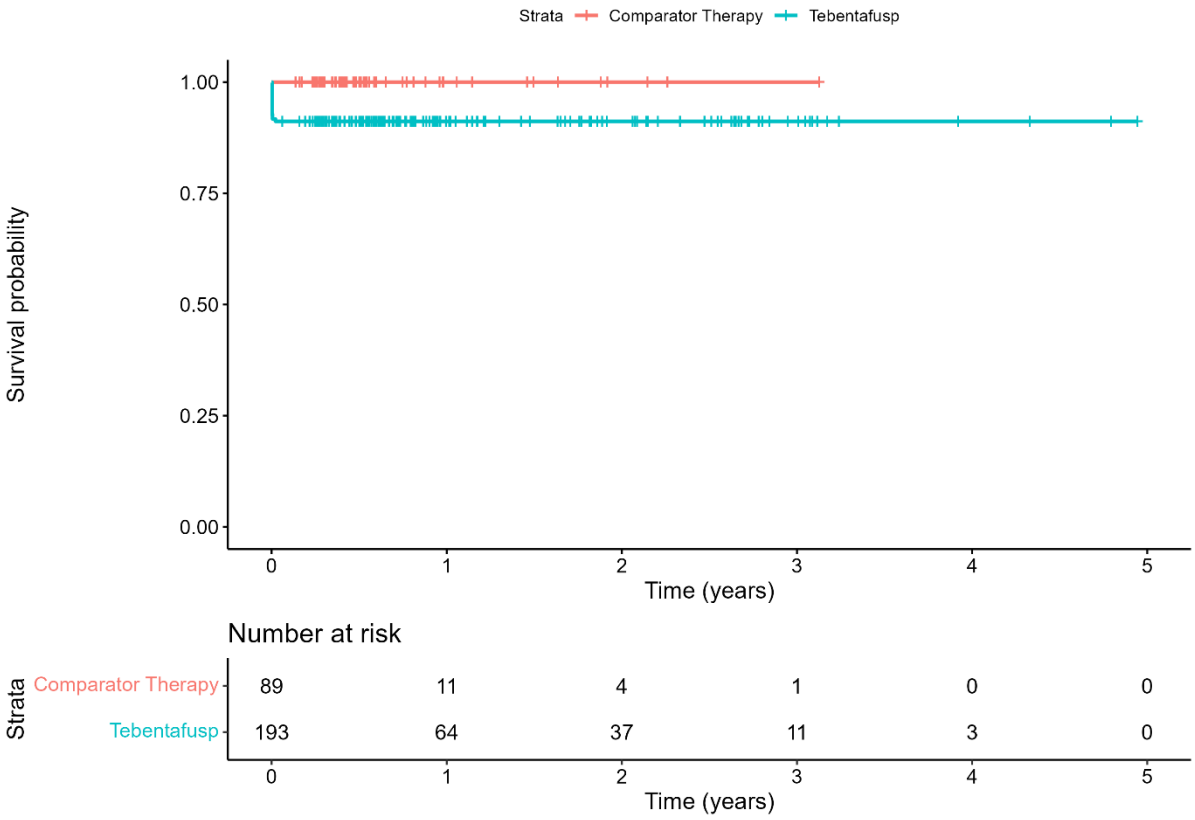
ECOG-Performance-Status: 0



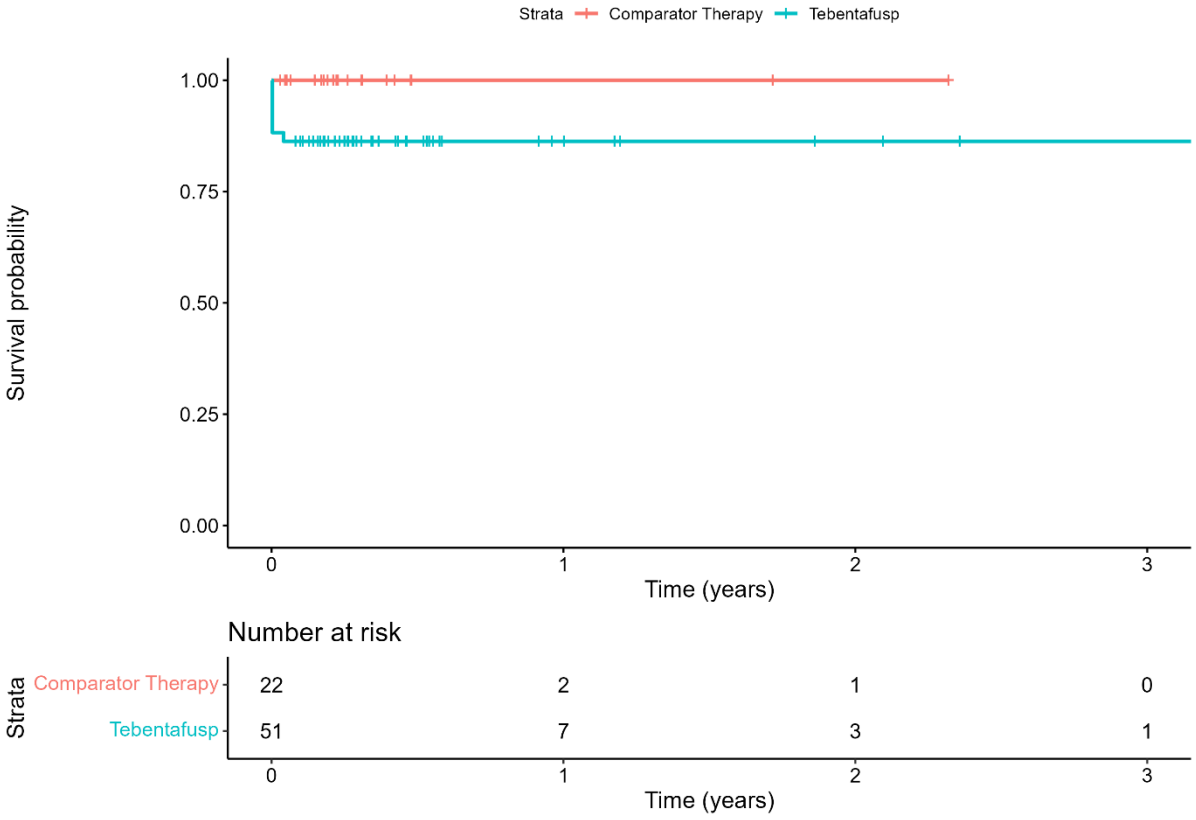
ECOG-Performance-Status: 1



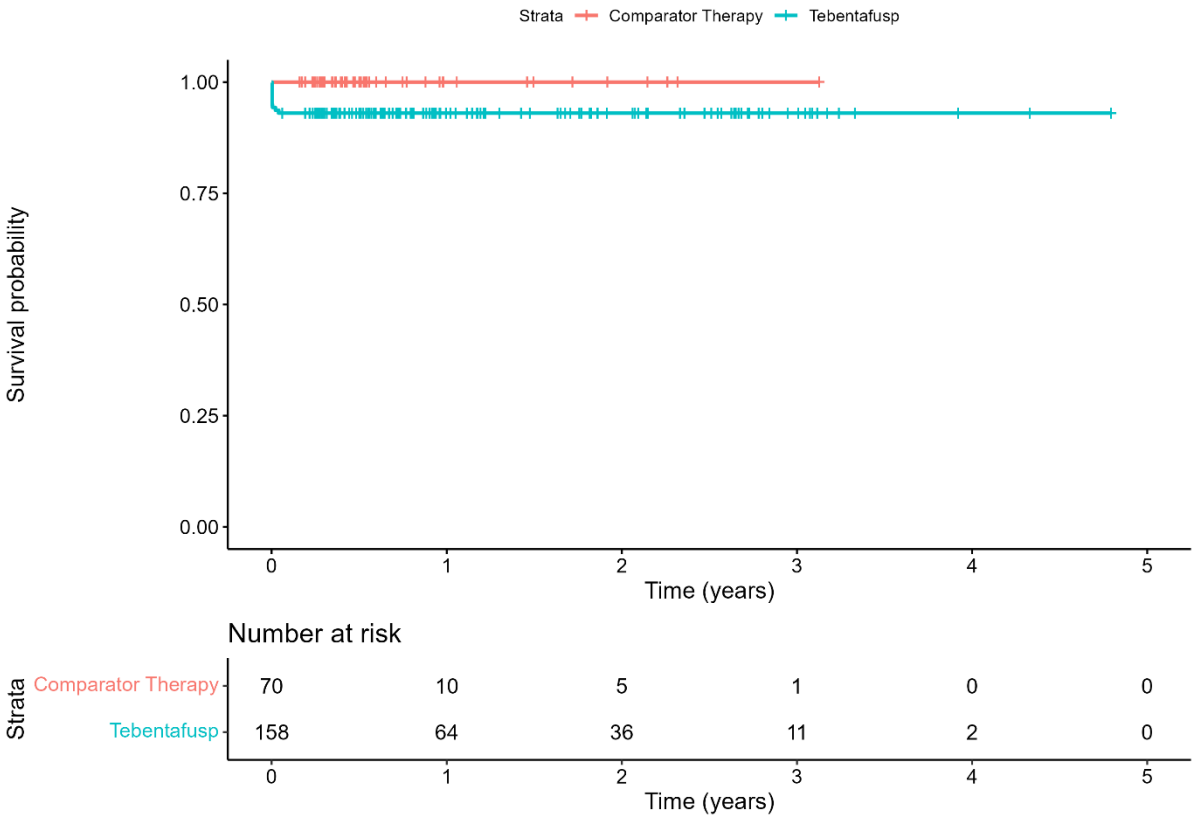
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



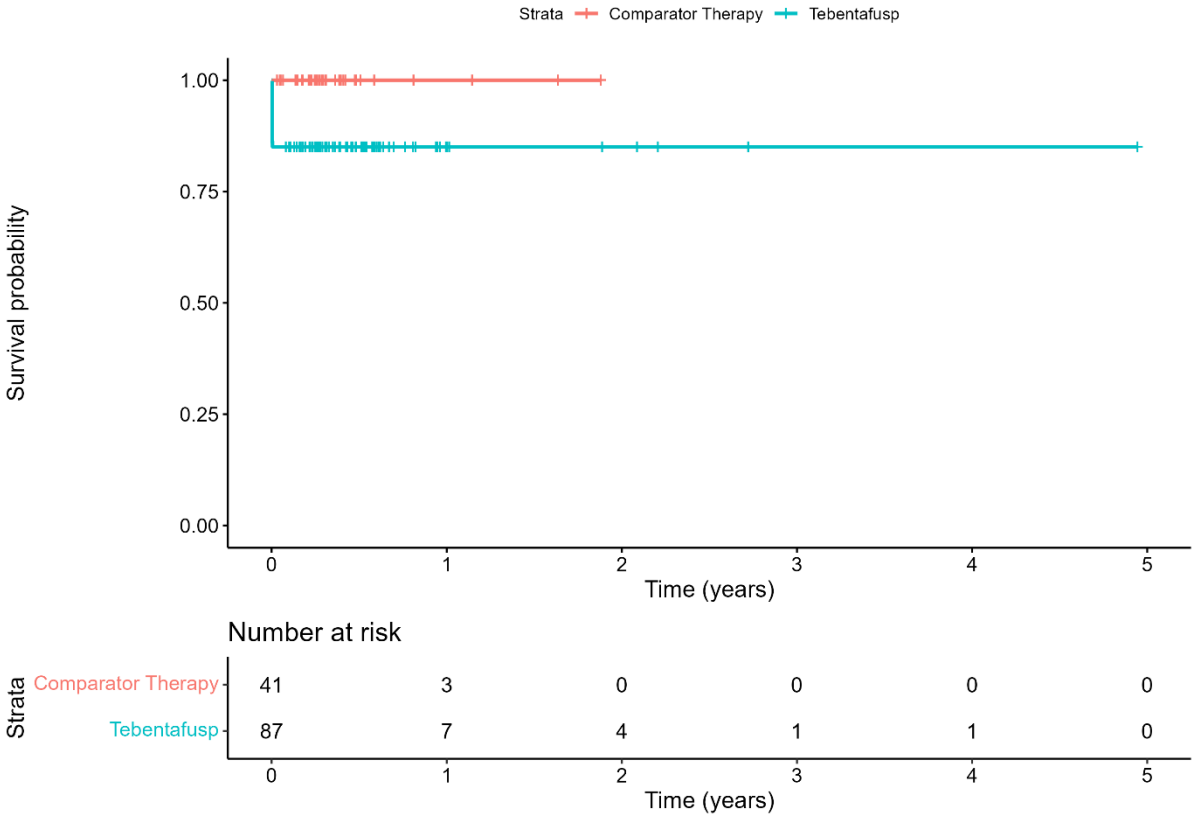
Alkalische Phosphatase (ALP) (Baseline): >ULN



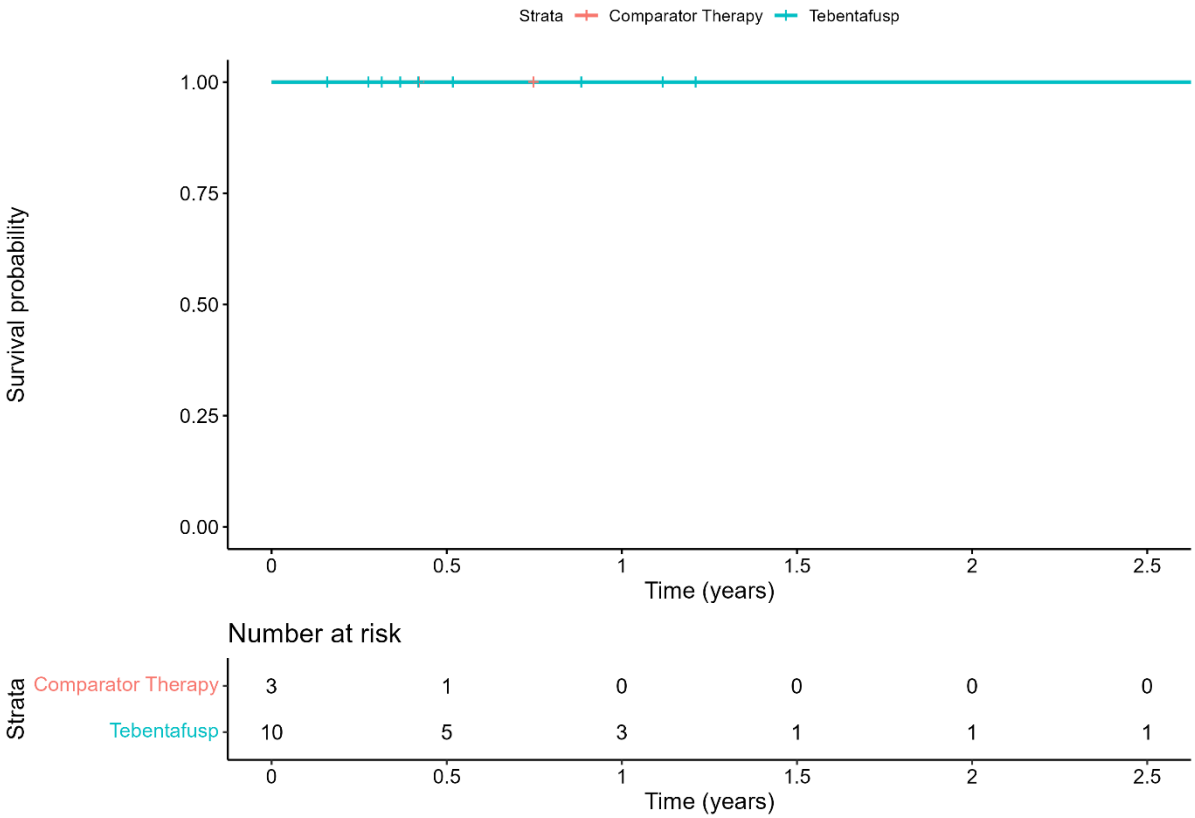
LDH: ≤ULN



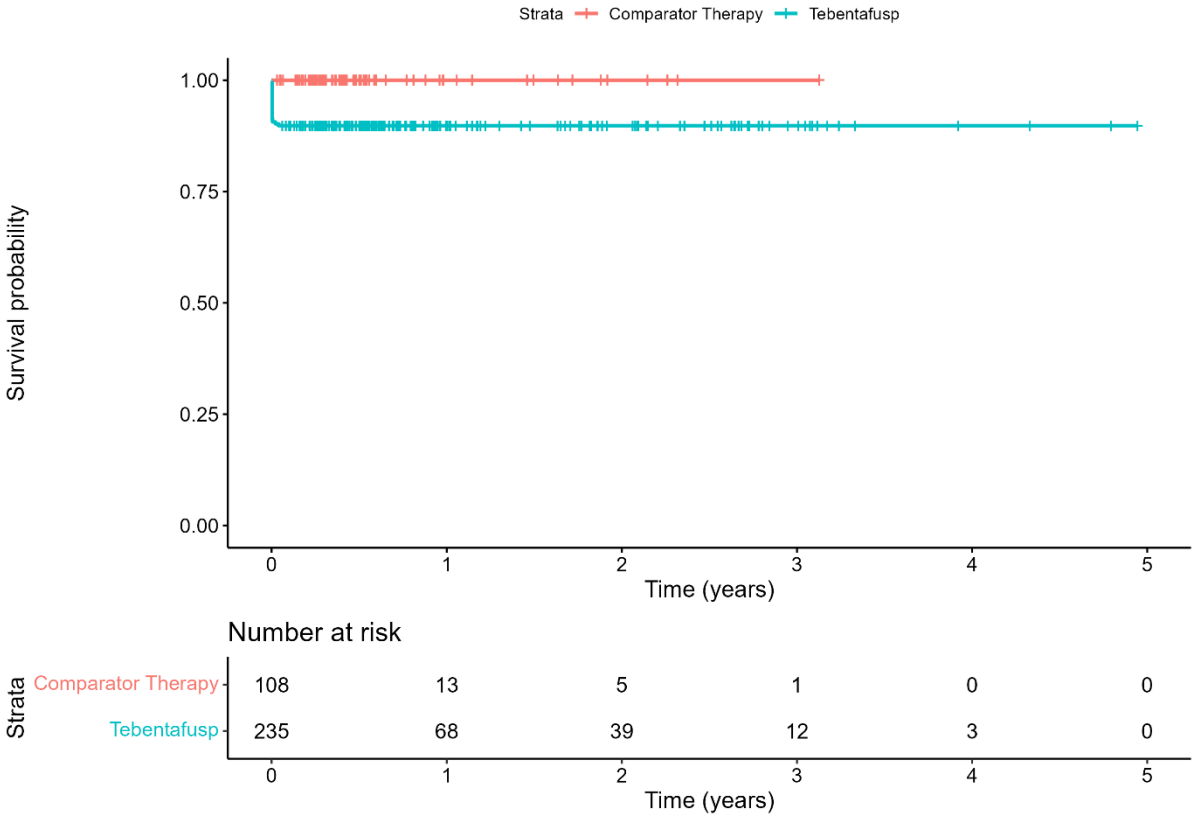
LDH: >ULN



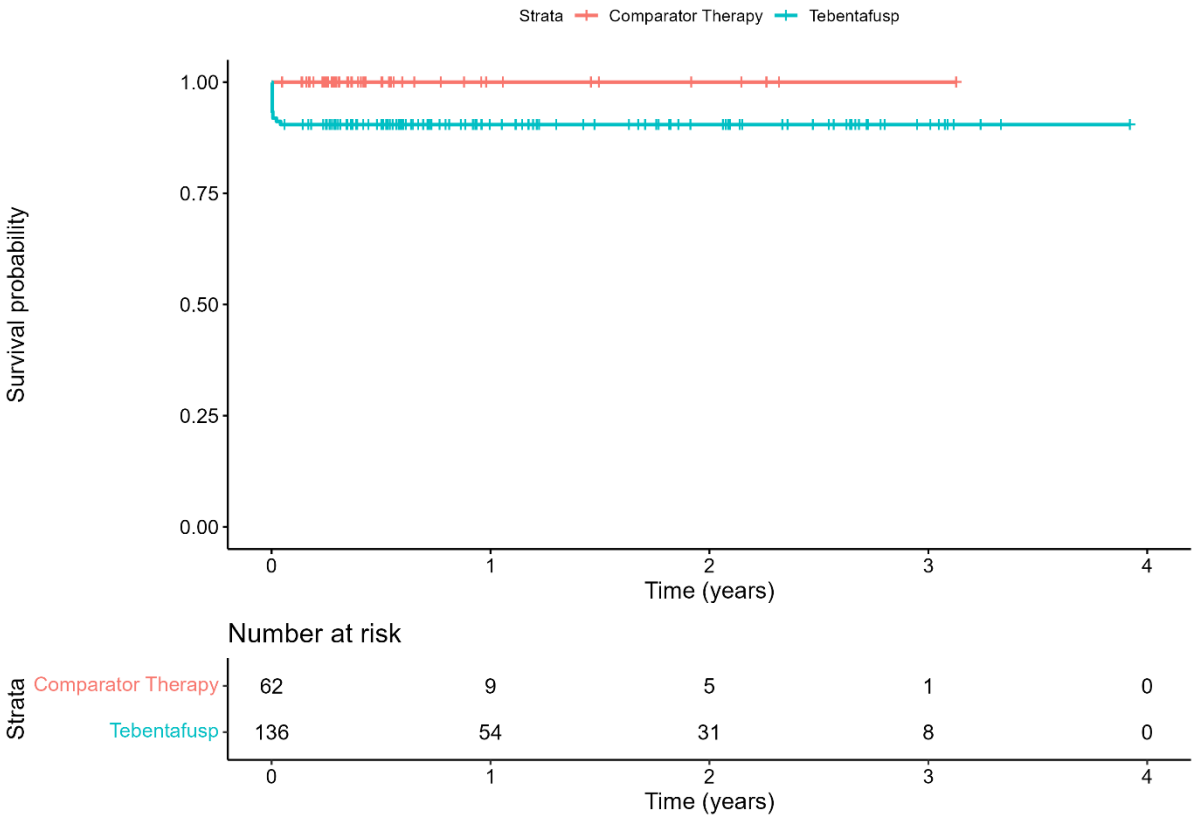
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



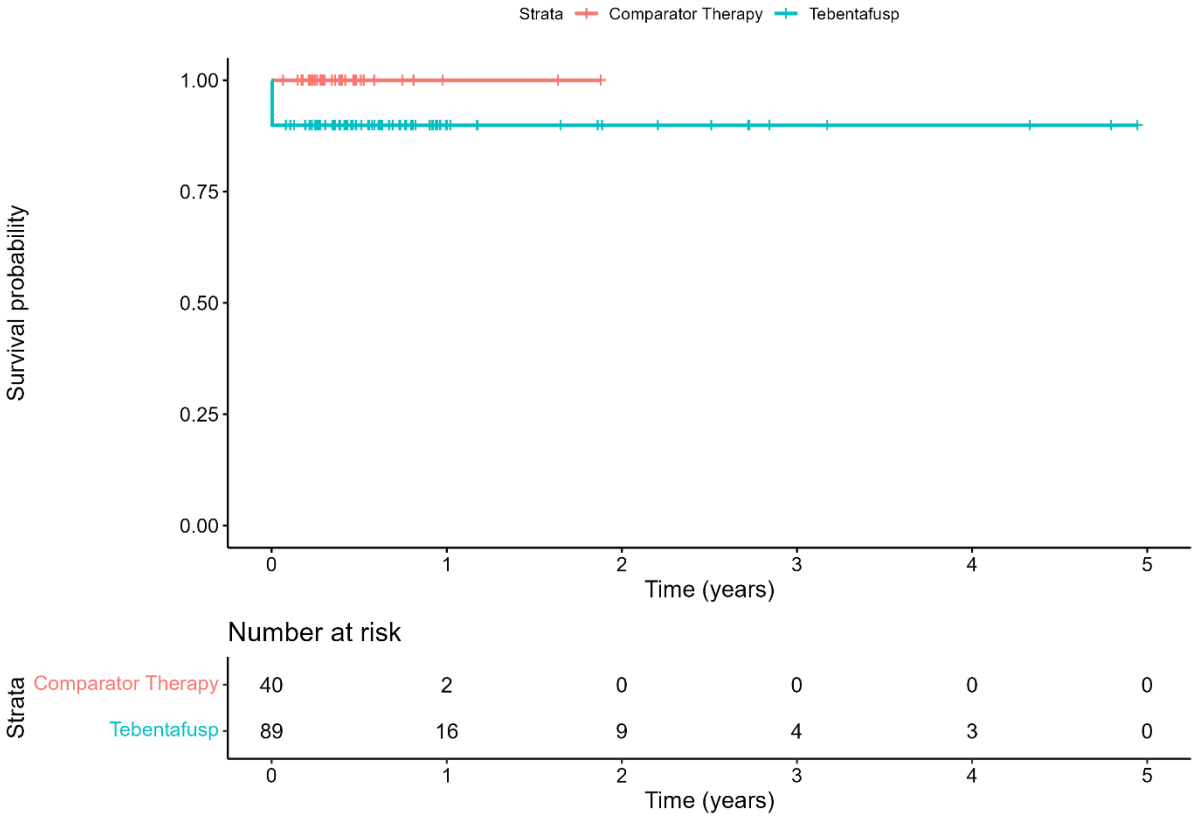
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



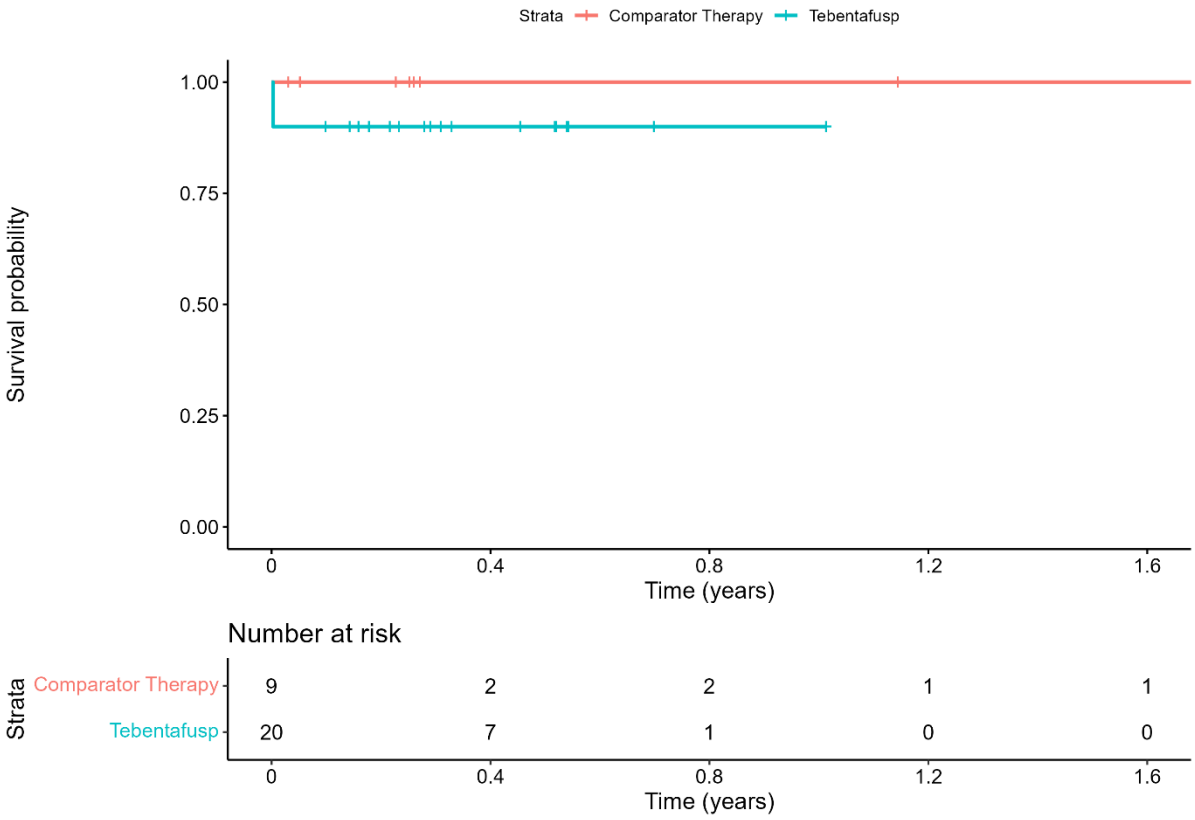
Größte metastatische Läsion (Baseline): ≤3,0 cm



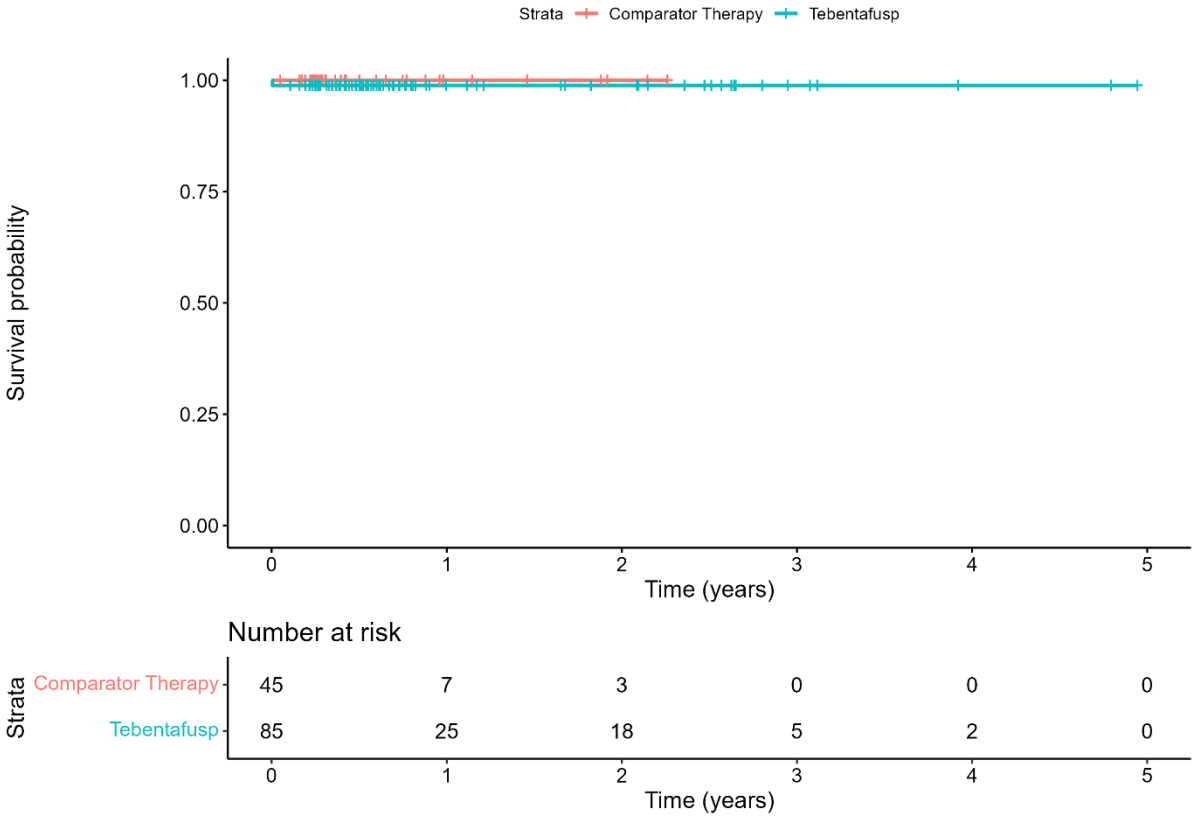
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



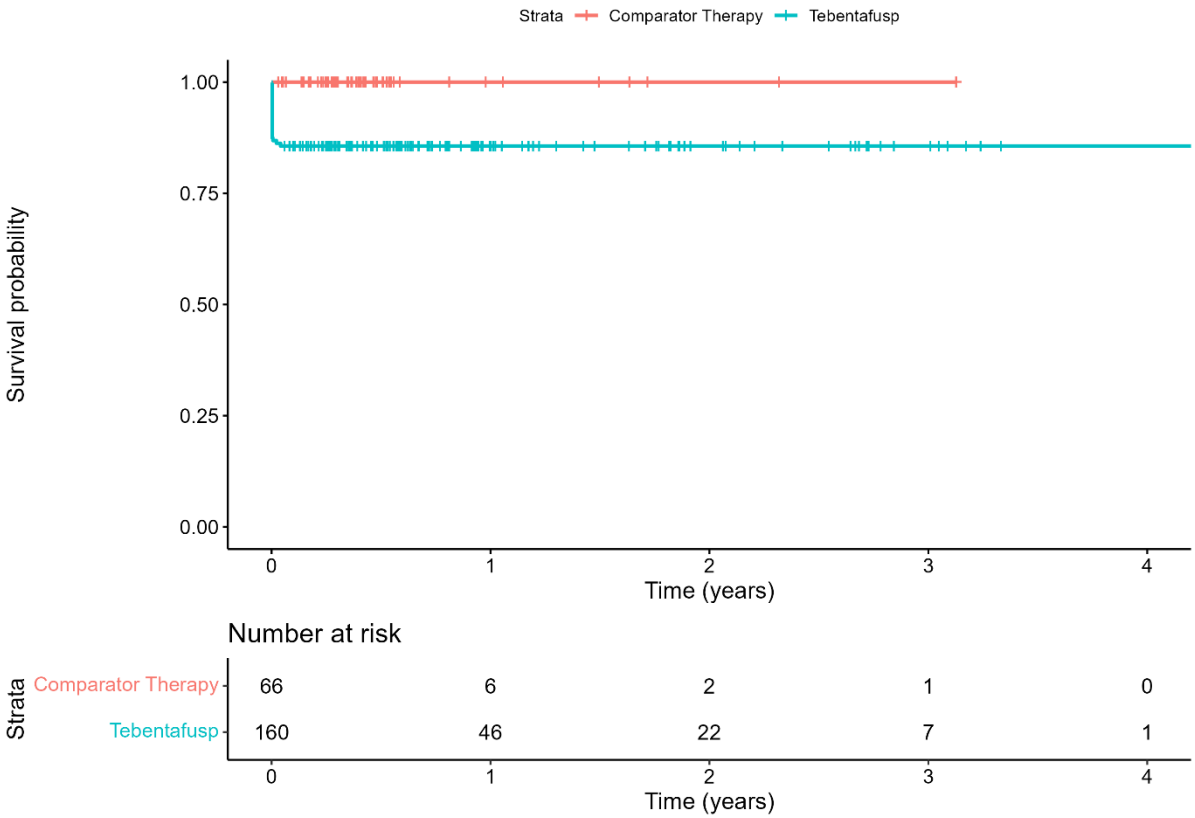
Größte metastatische Läsion (Baseline): ≥8,1 cm



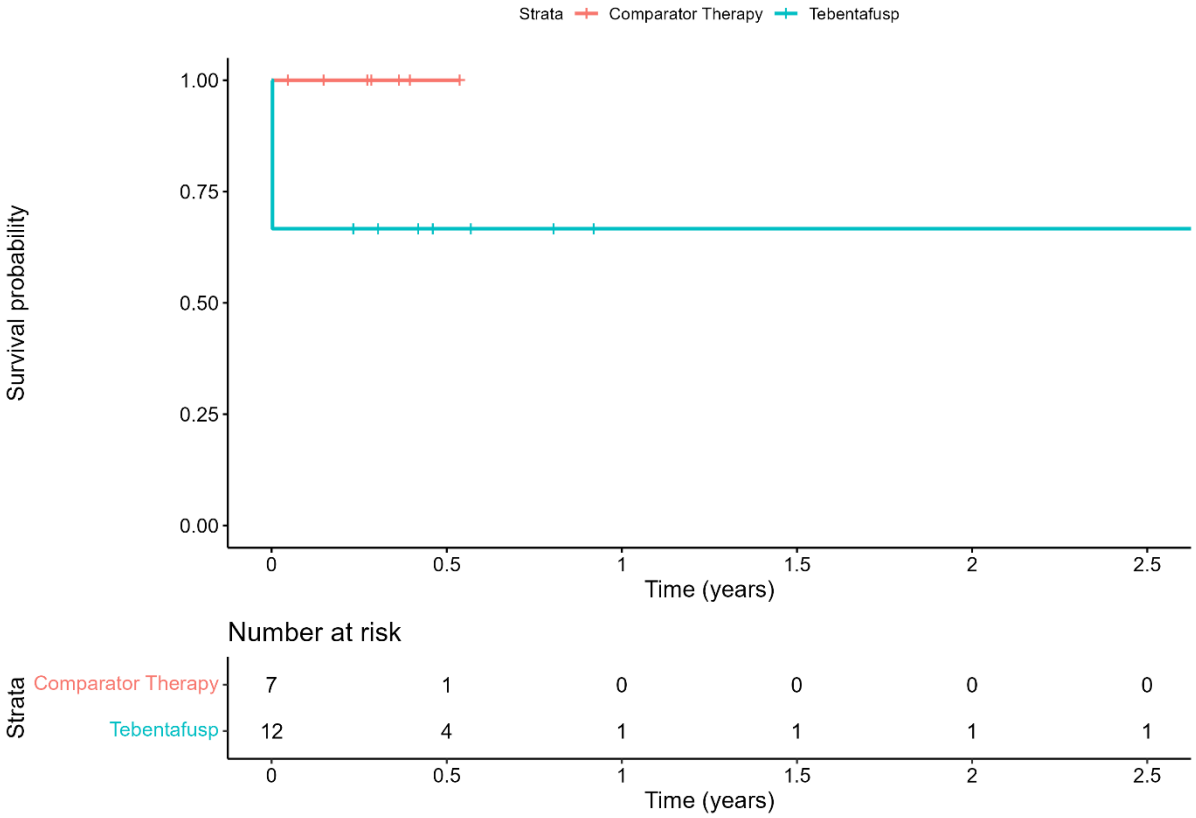
Region: Nordamerika



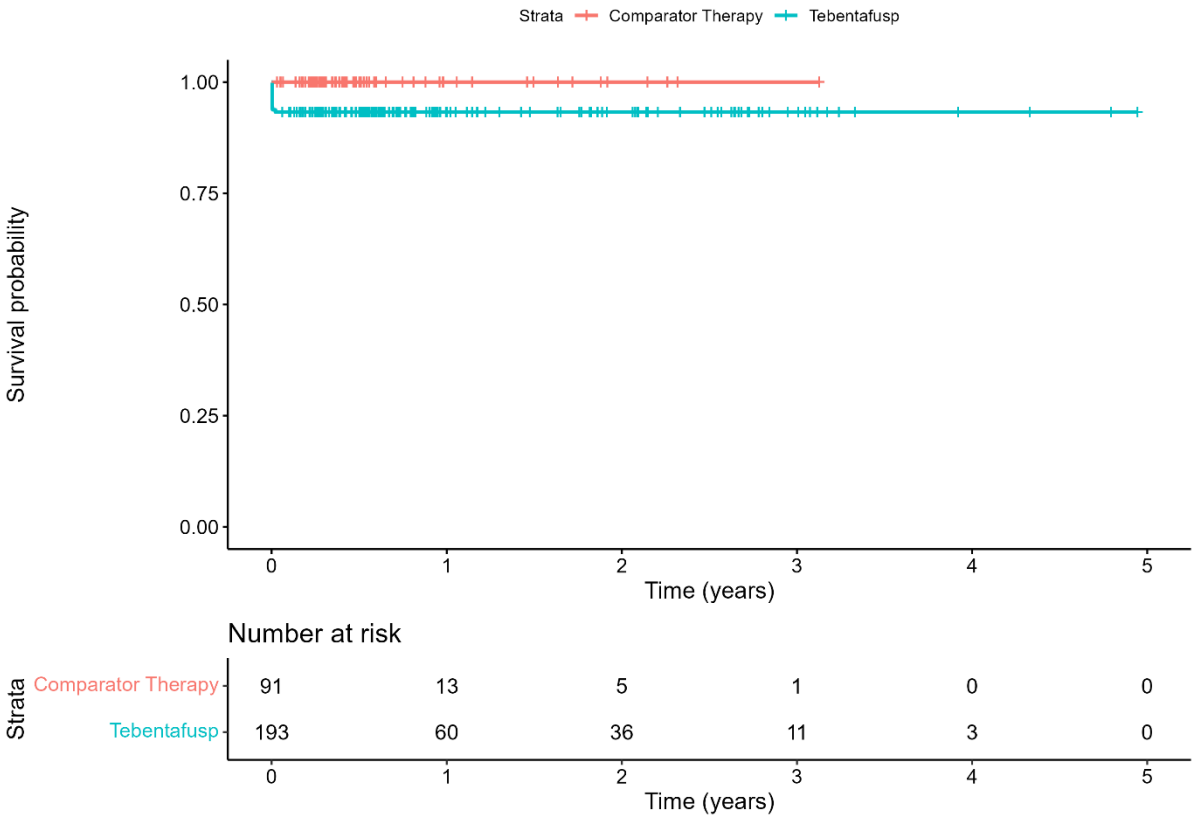
Region: Nicht-Nordamerika



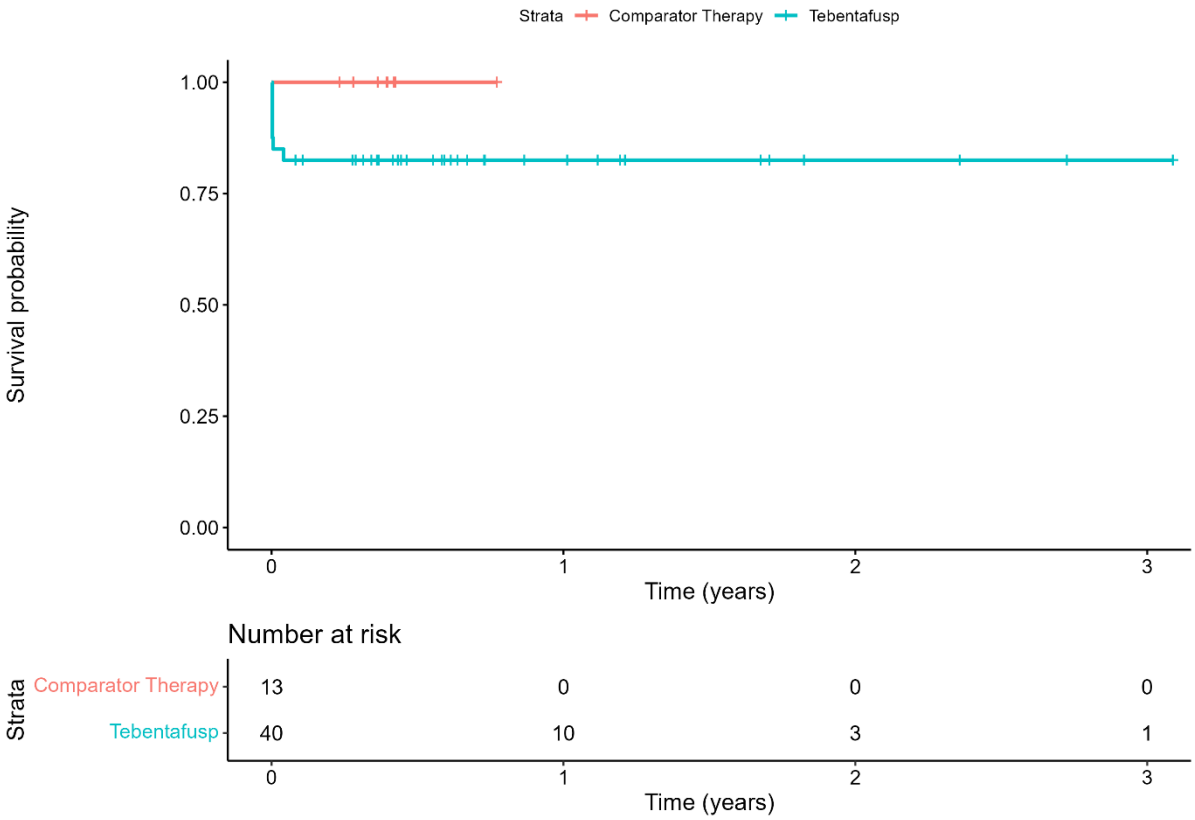
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

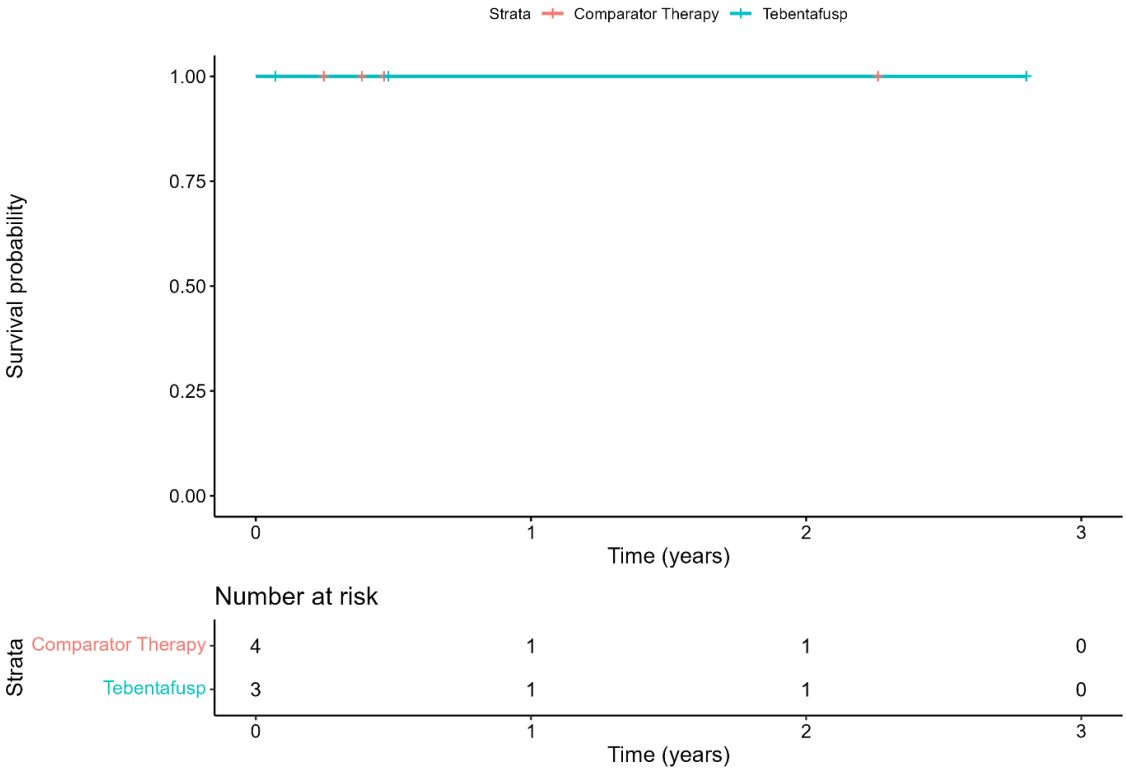


Vorauswahl der Chemotherapie: Ipilimumab

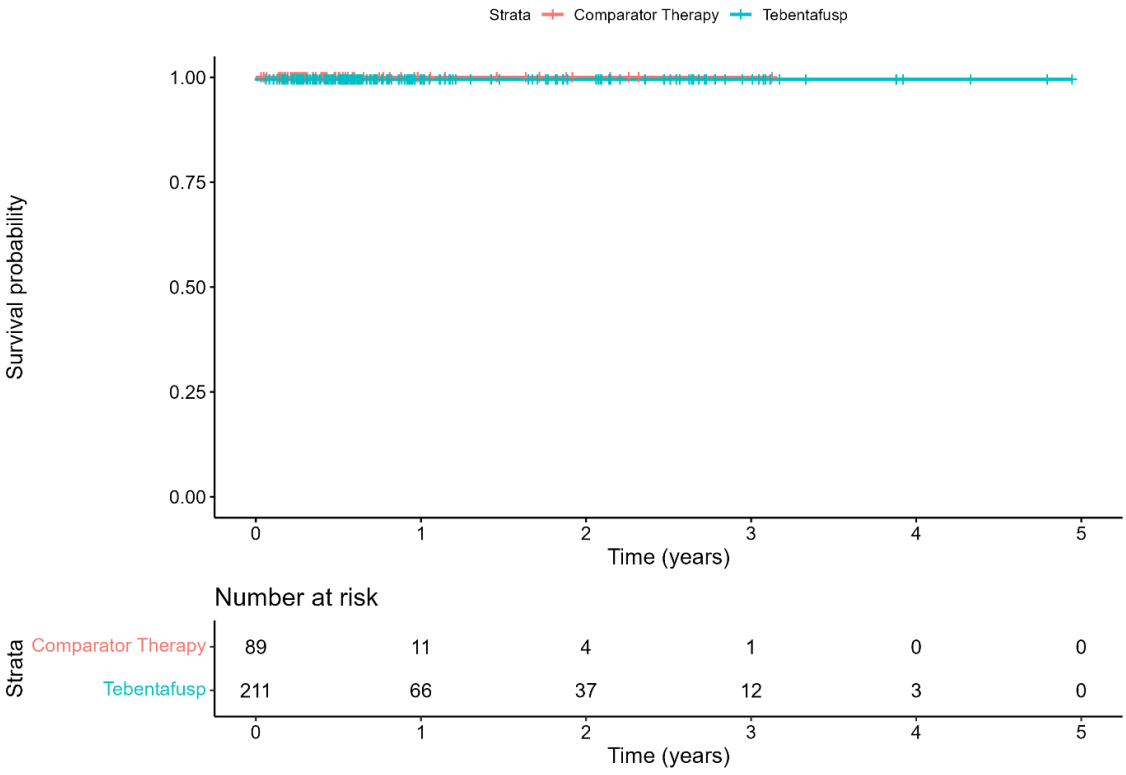


59.8 Zytokin-Freisetzungssyndrom, das zum Absetzen des Studienmedikaments führte (Tabelle 4-228)

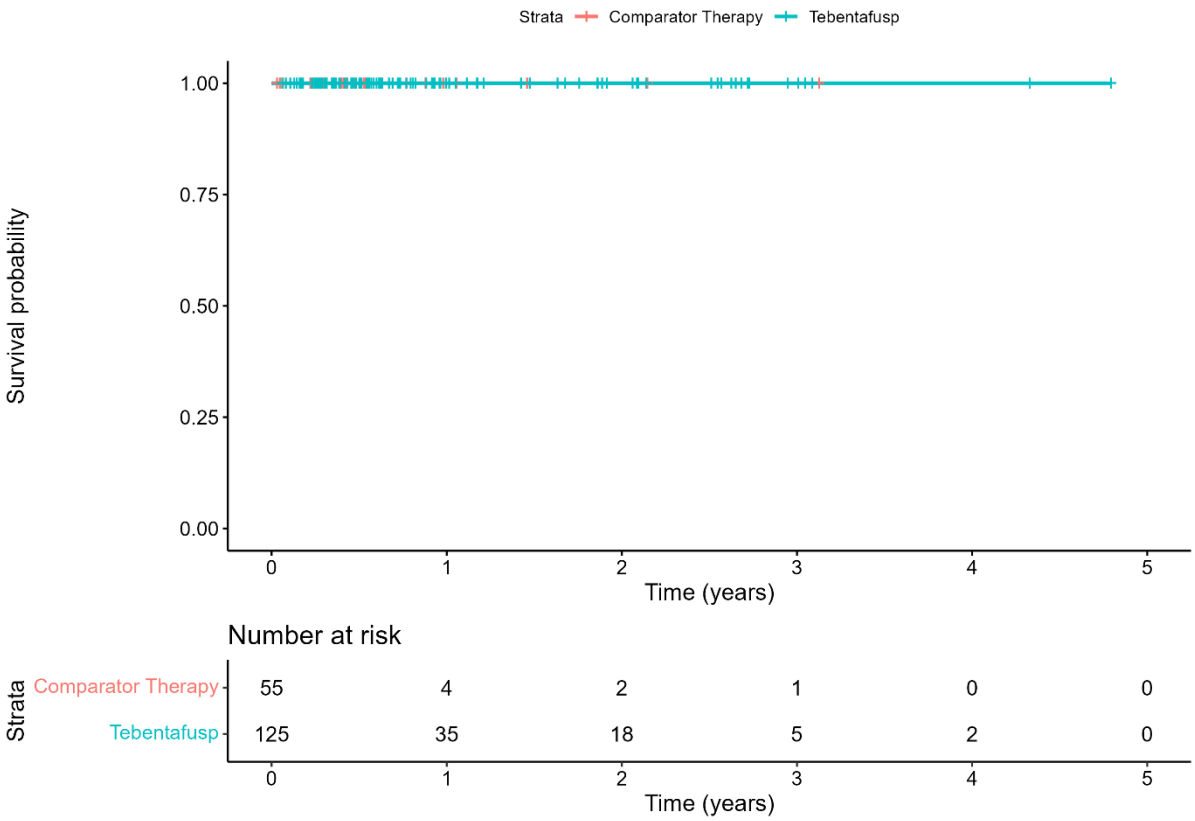
Herkunft: Hispanisch



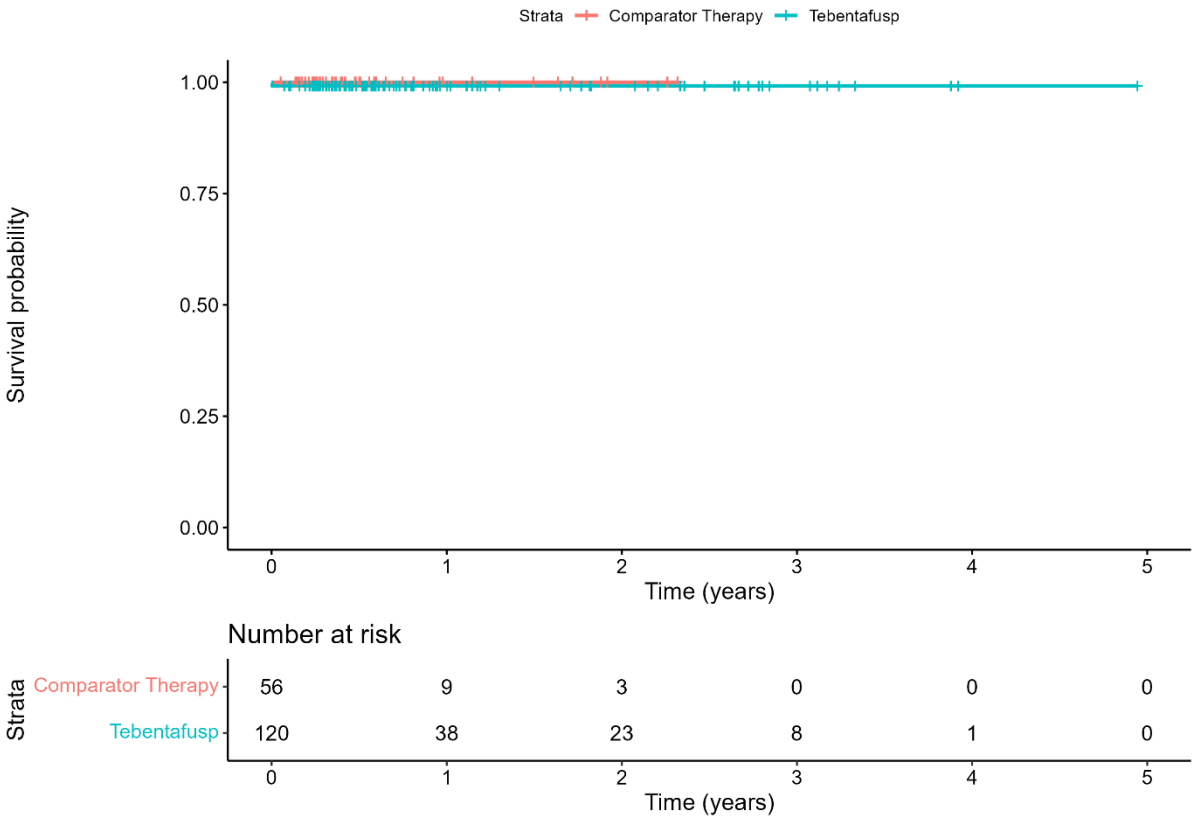
Herkunft: Nicht-hispanisch



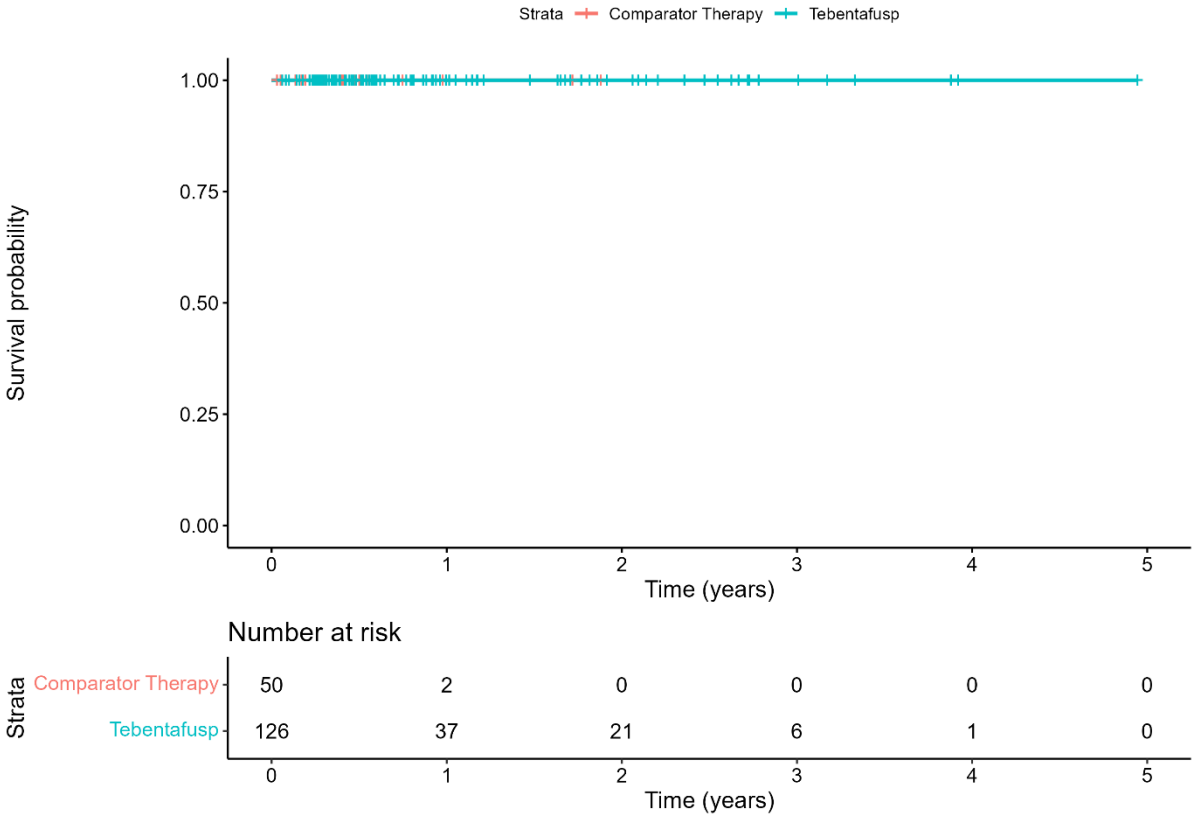
Geschlecht: Männlich



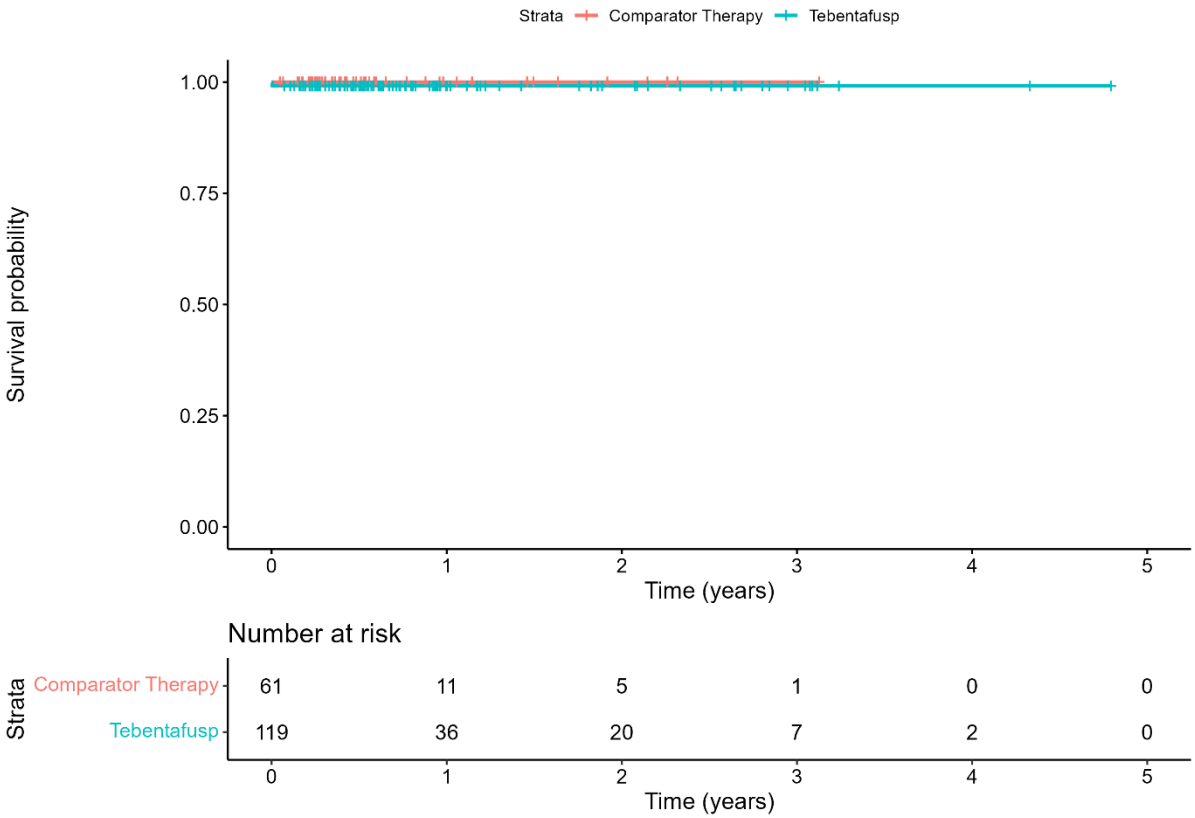
Geschlecht: Weiblich



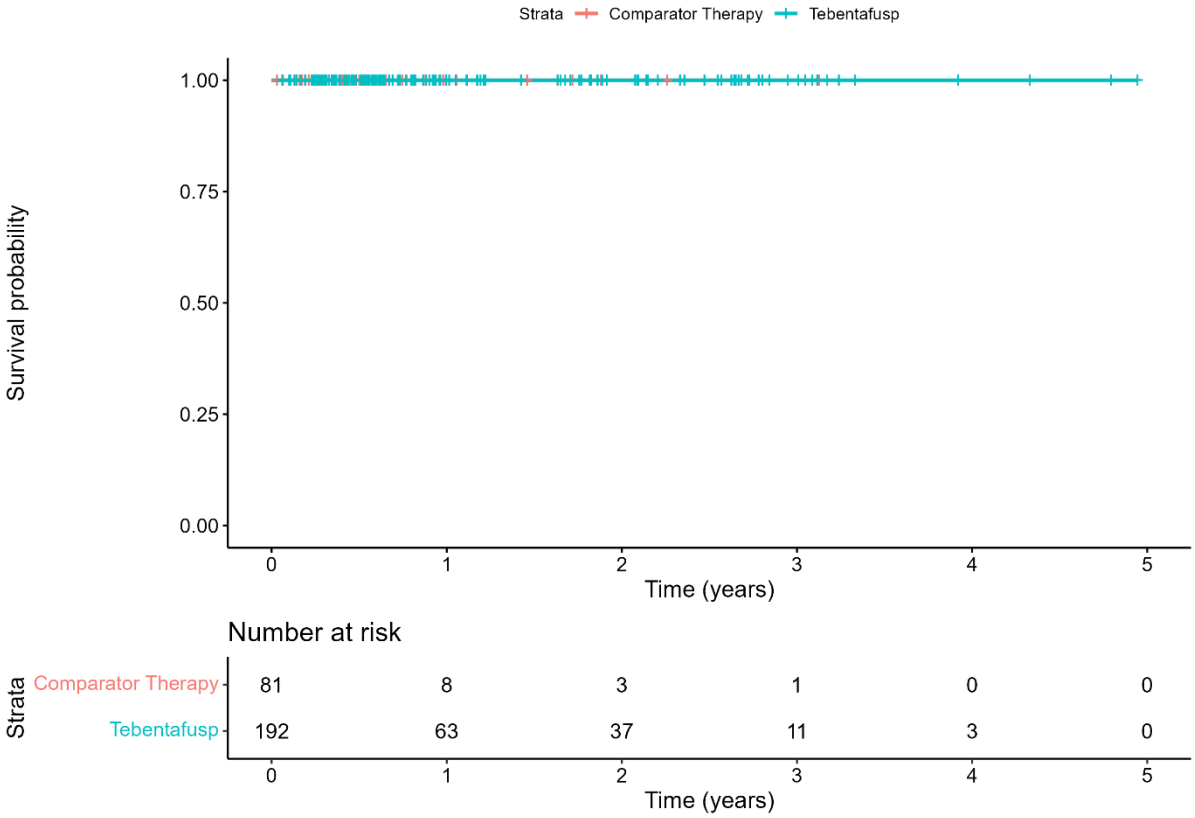
Alter: <65 Jahre



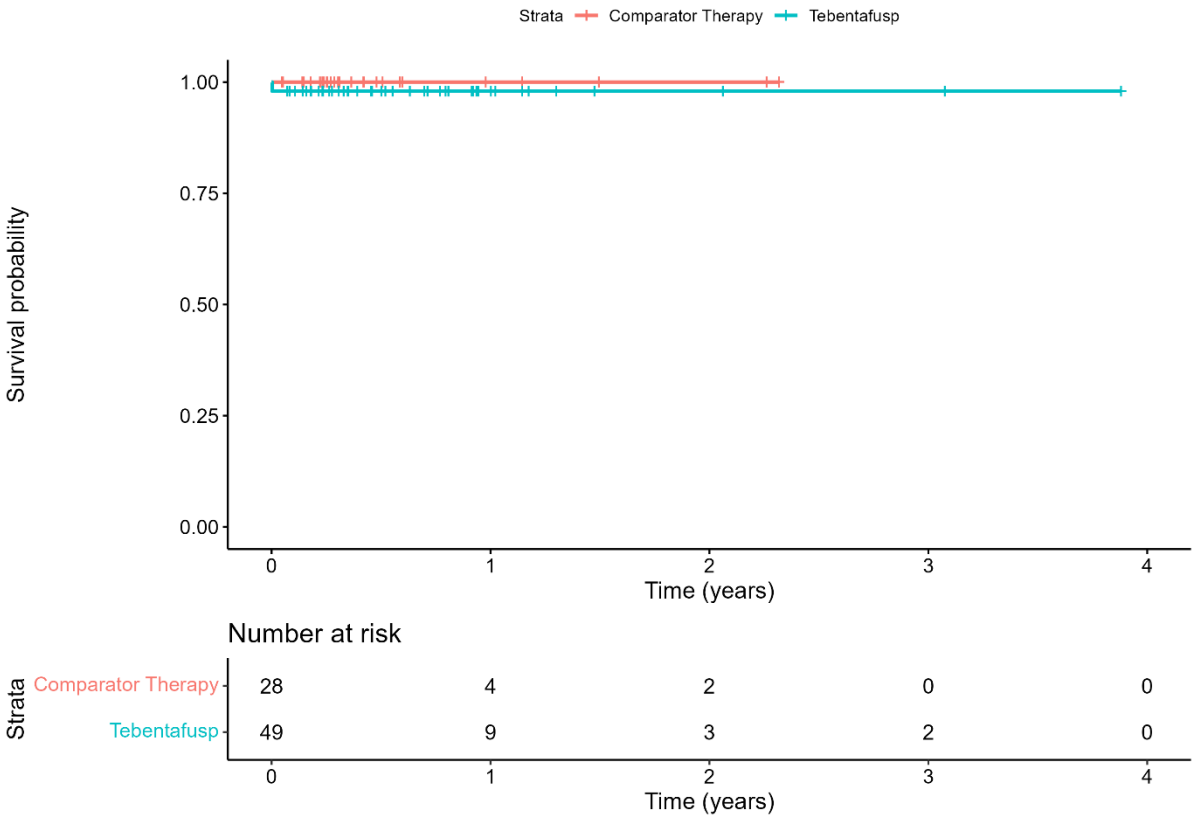
Alter: ≥65 Jahre



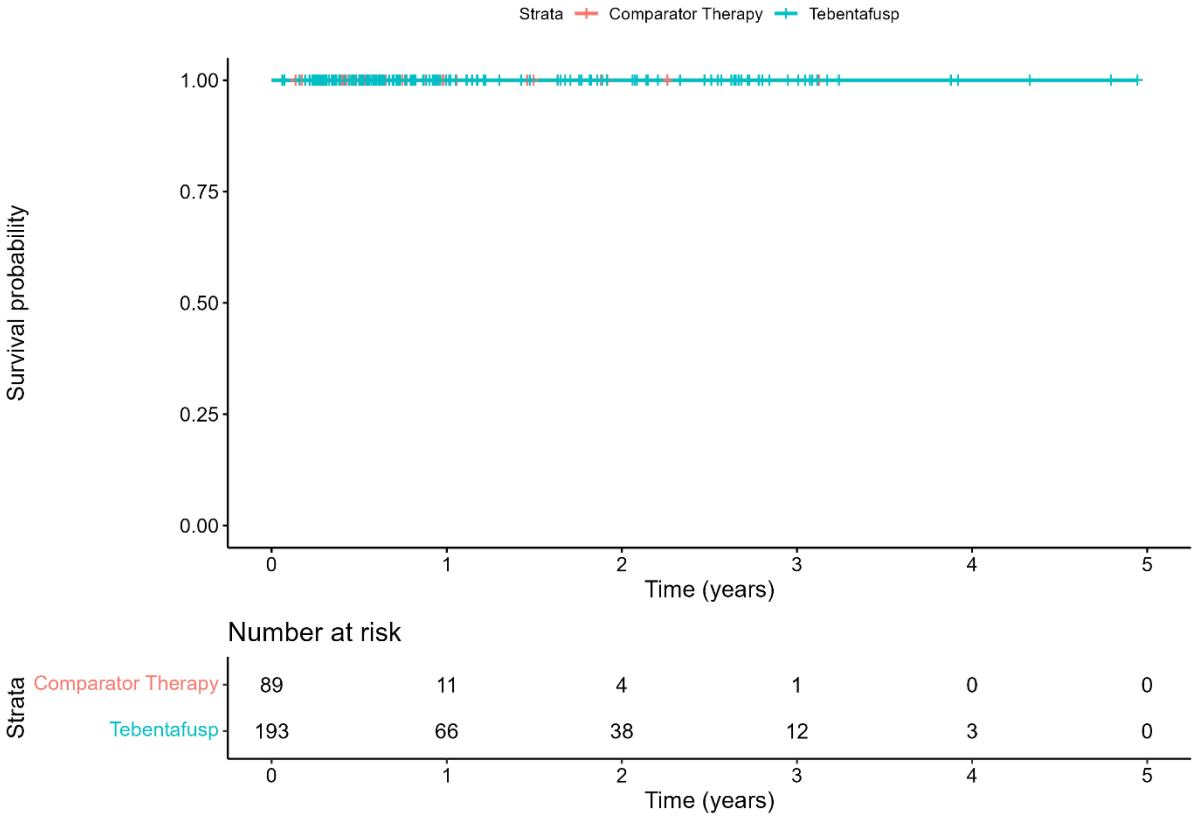
ECOG-Performance-Status: 0



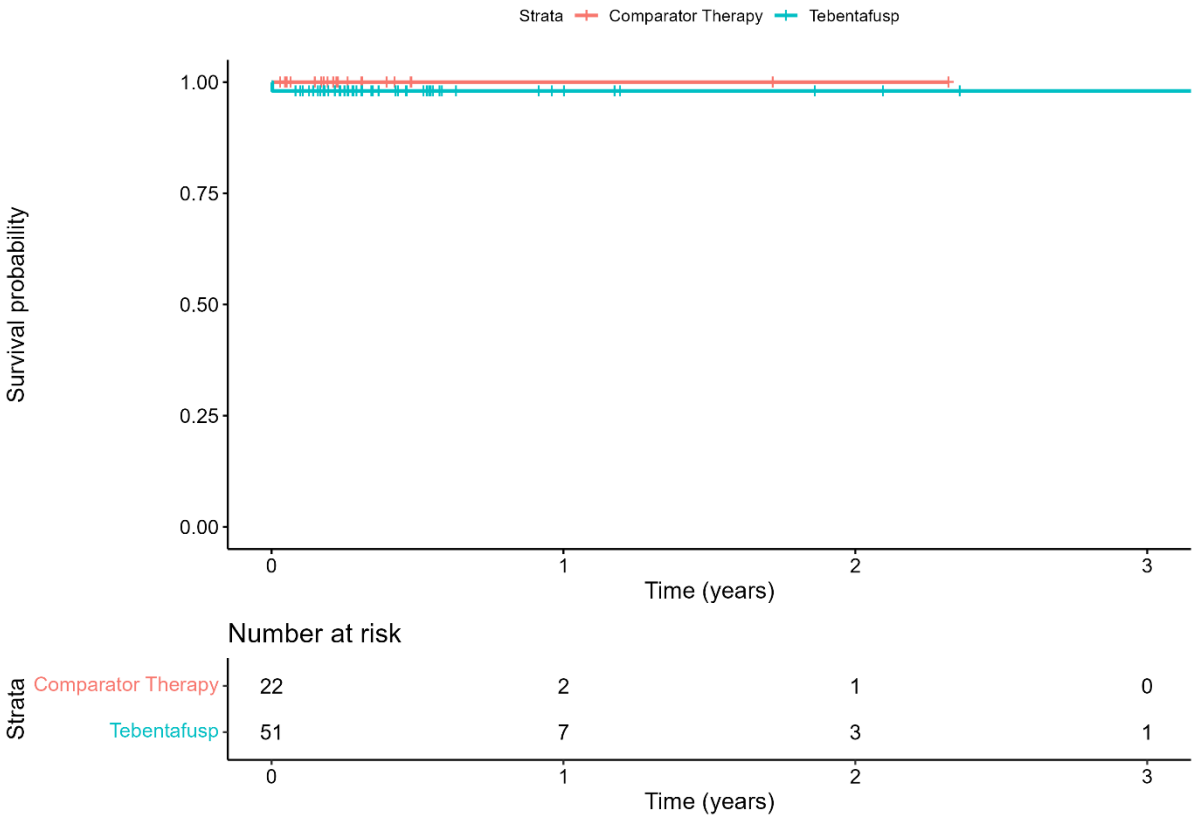
ECOG-Performance-Status: 1



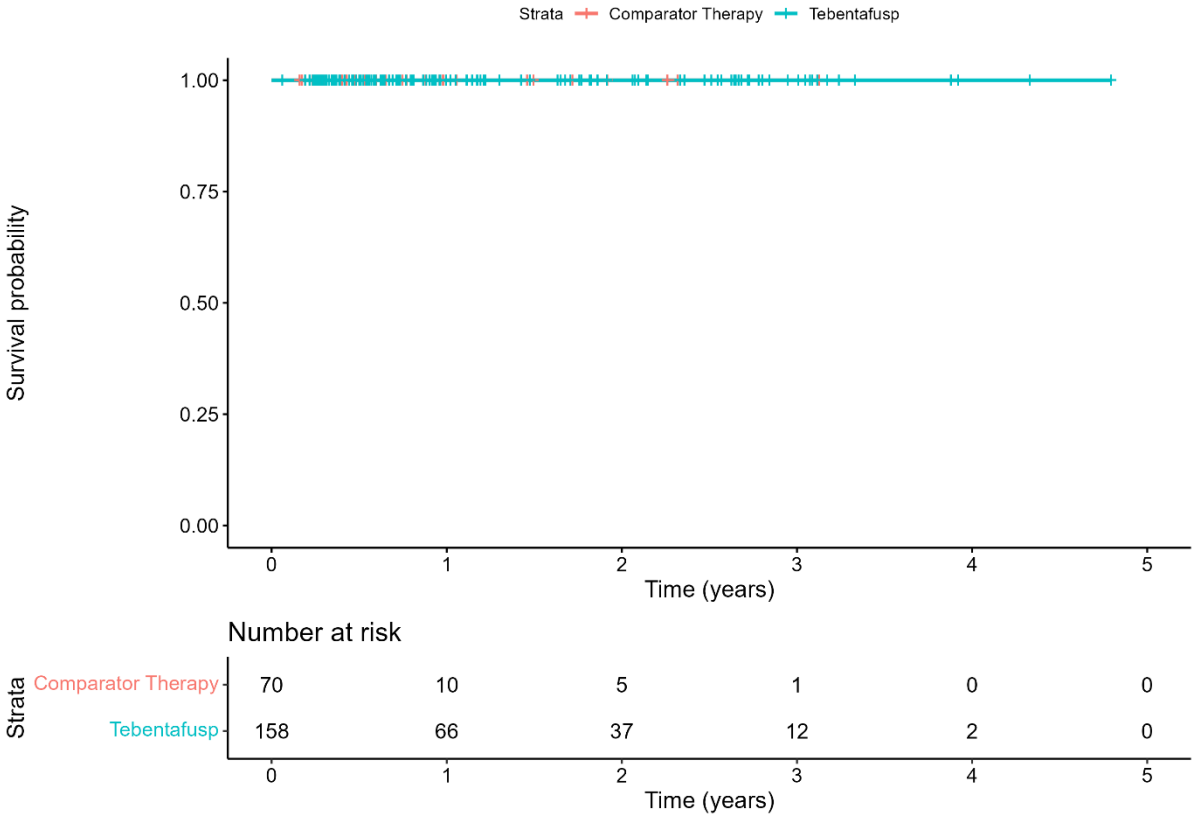
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



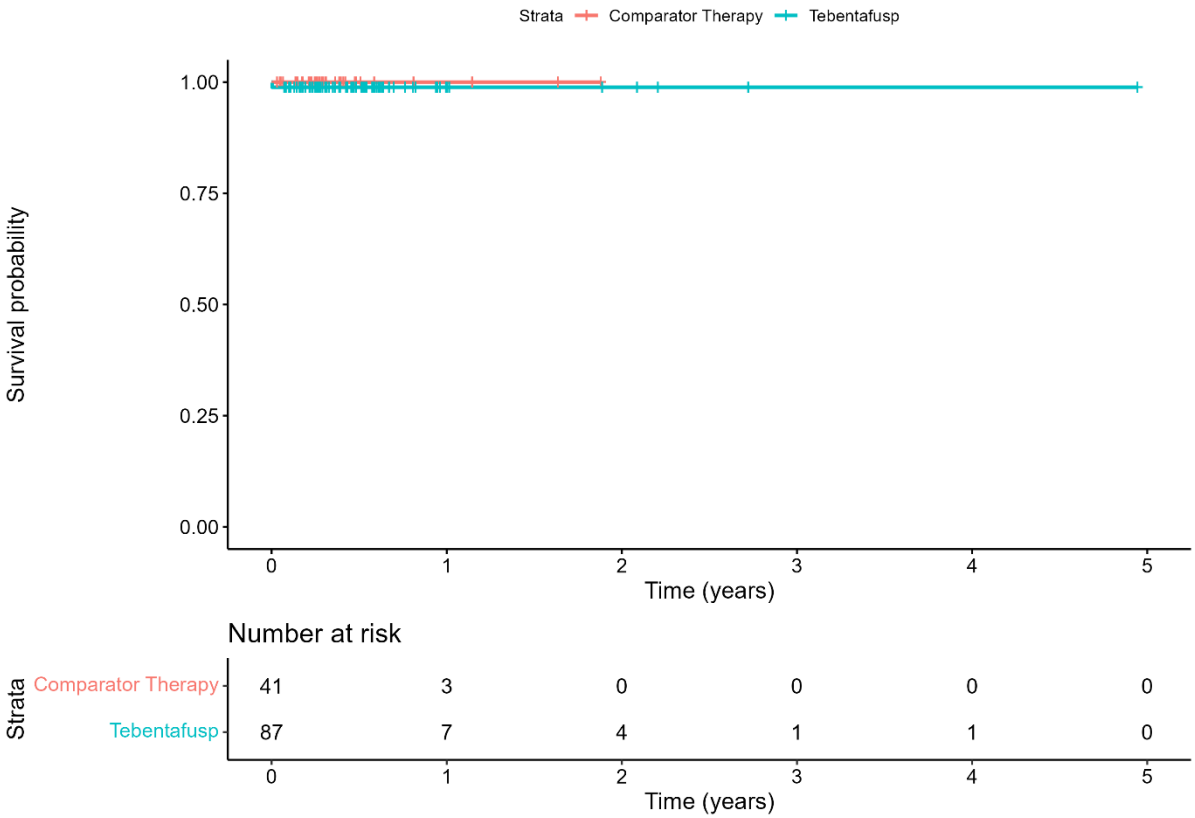
Alkalische Phosphatase (ALP) (Baseline): >ULN



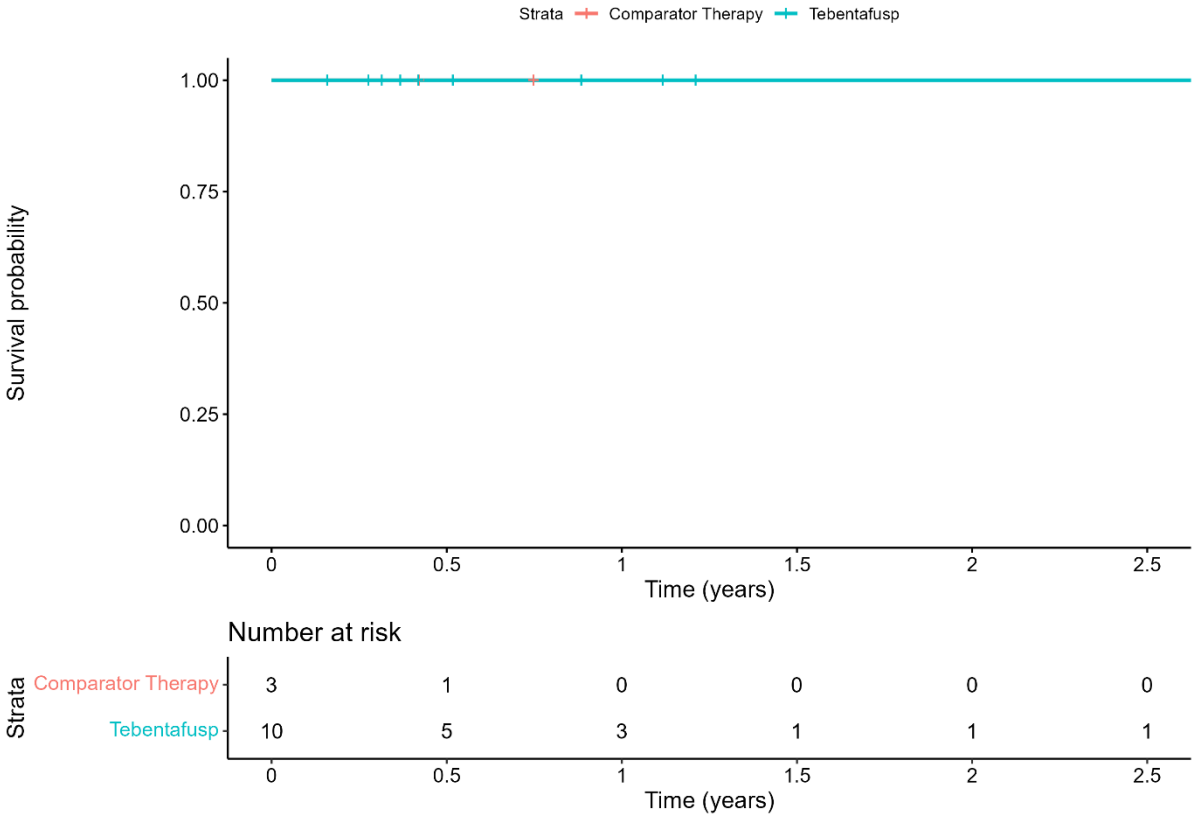
LDH: ≤ULN



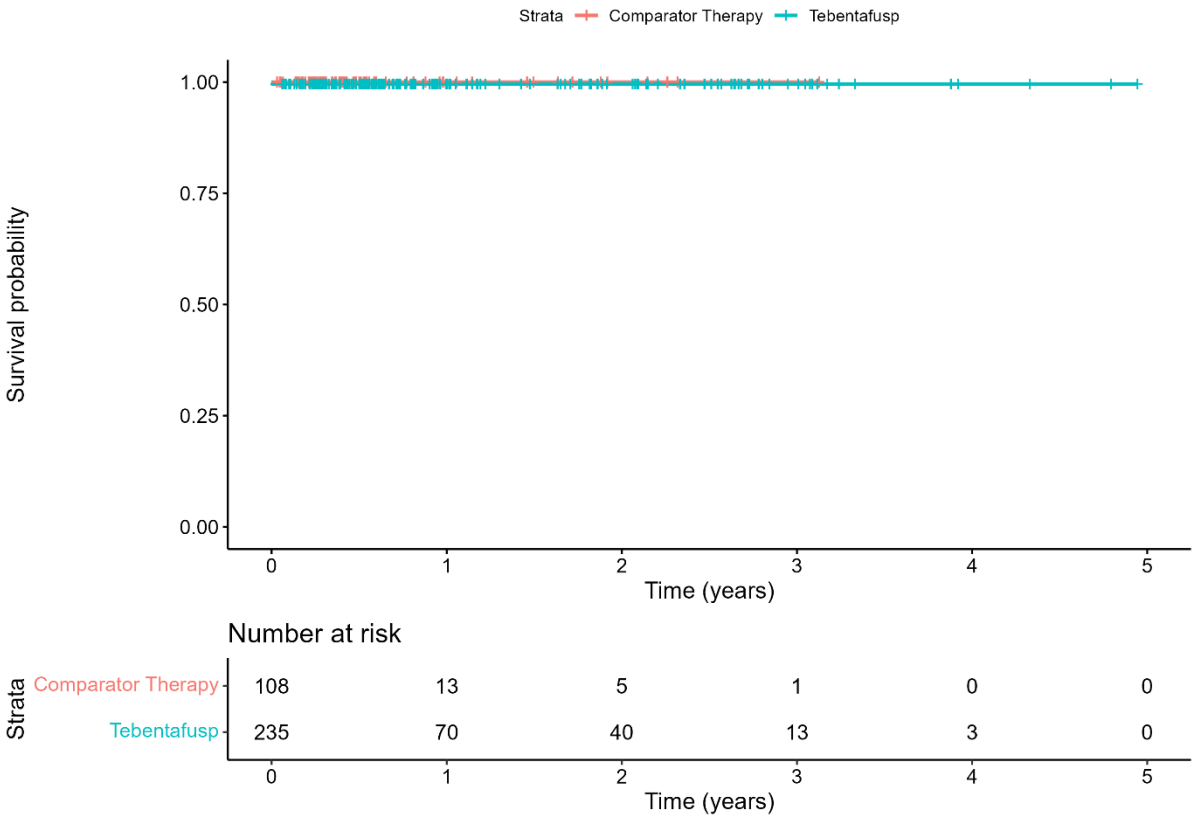
LDH: >ULN



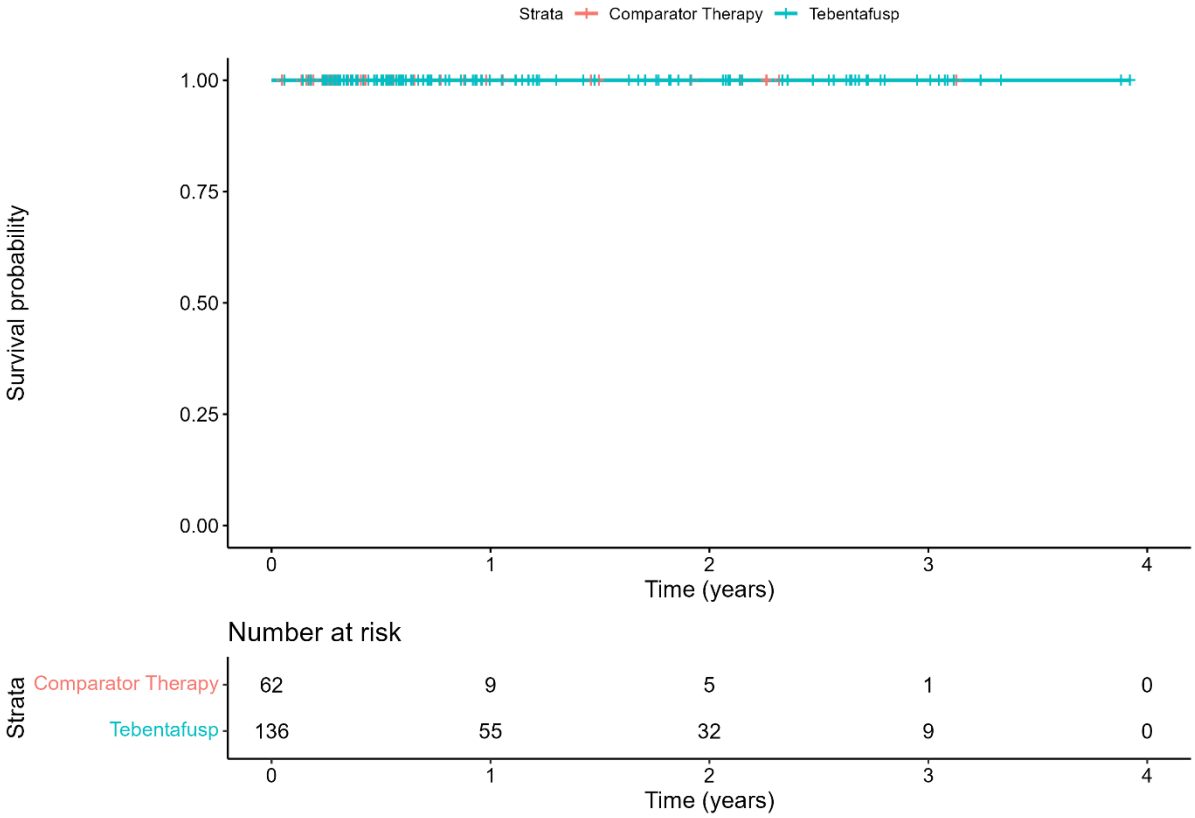
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



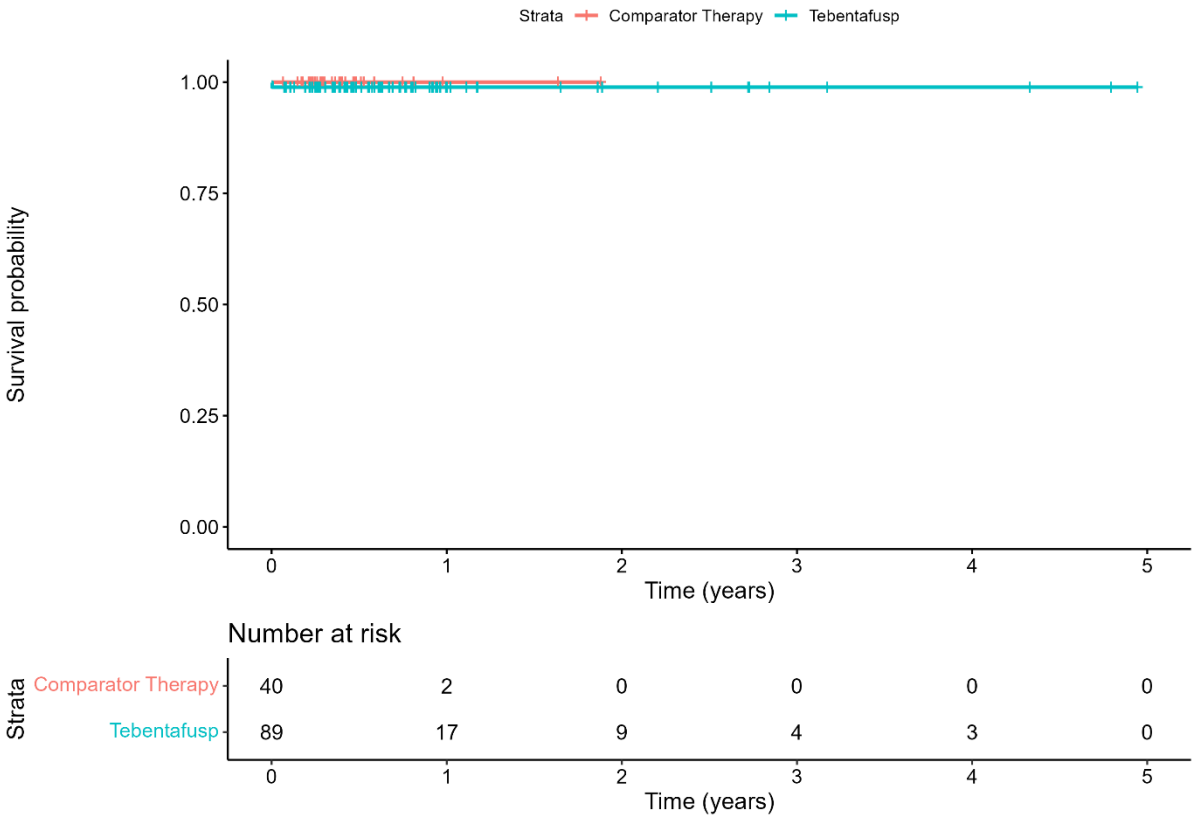
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



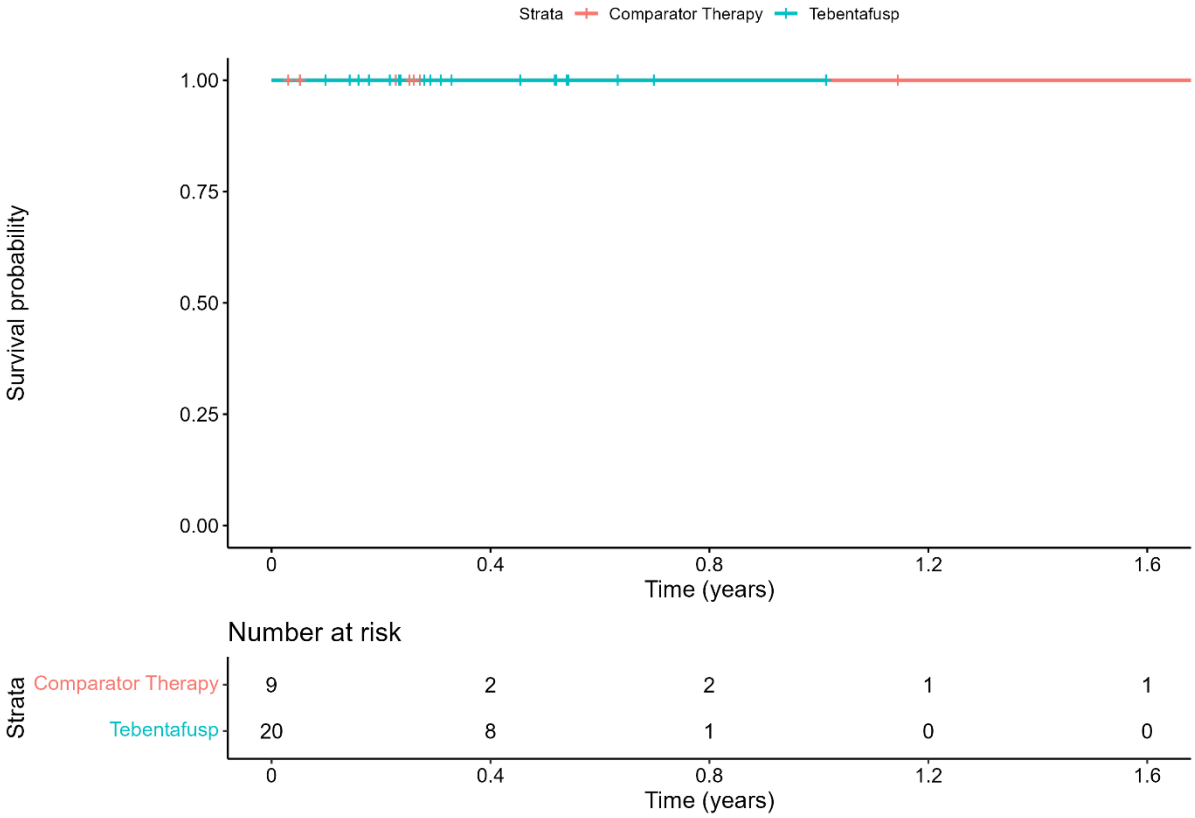
Größte metastatische Läsion (Baseline): ≤3,0 cm



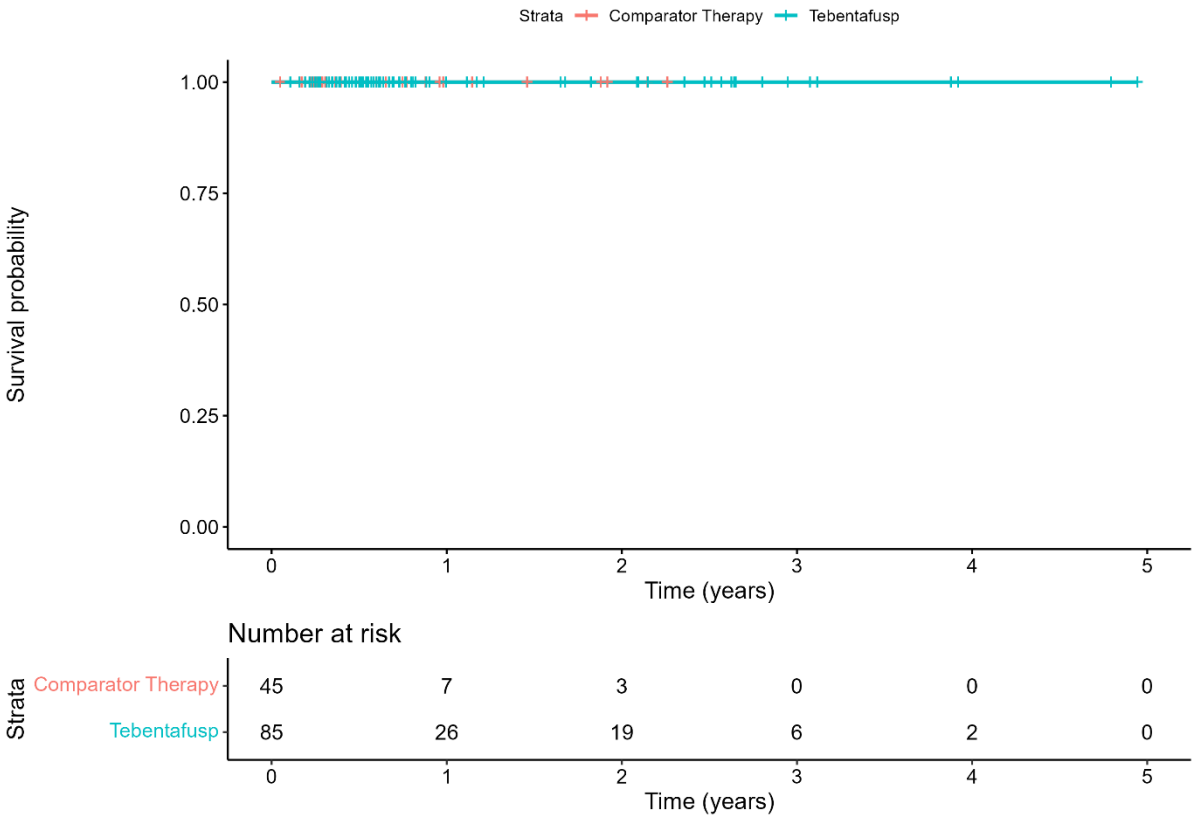
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



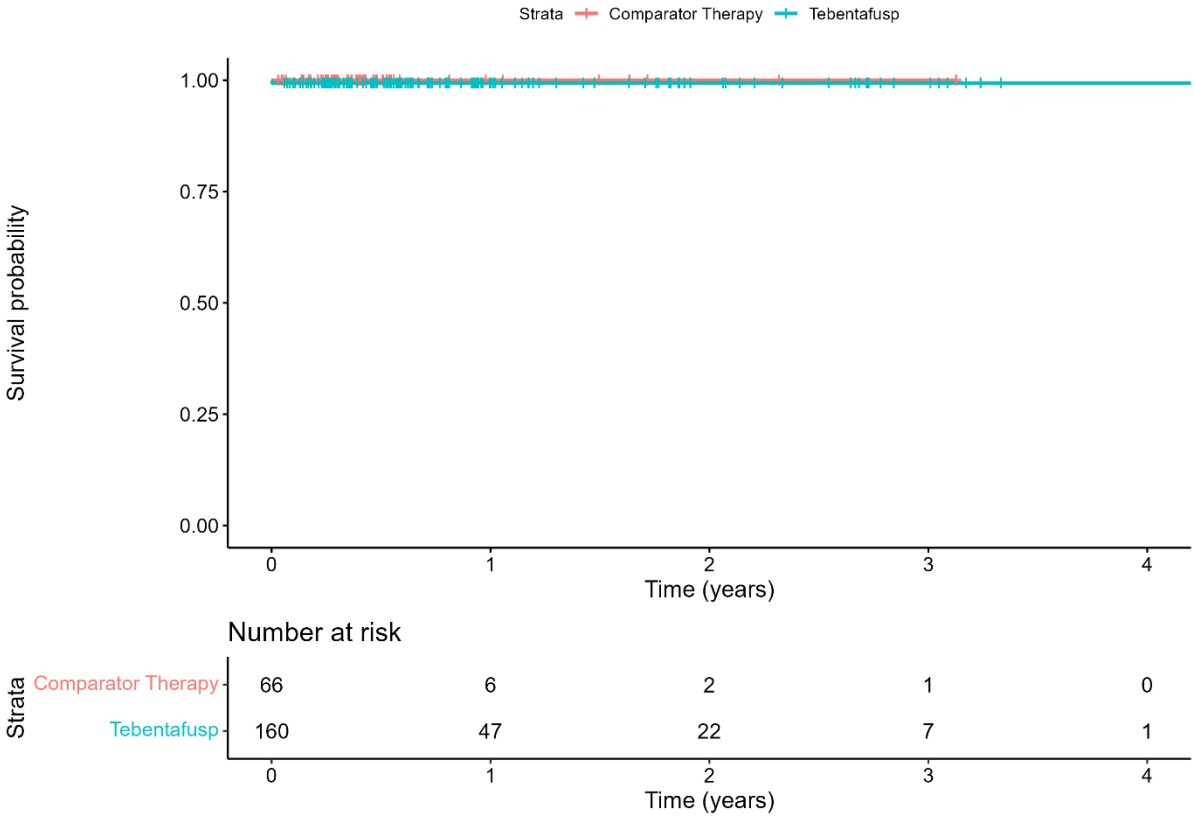
Größte metastatische Läsion (Baseline): ≥8,1 cm



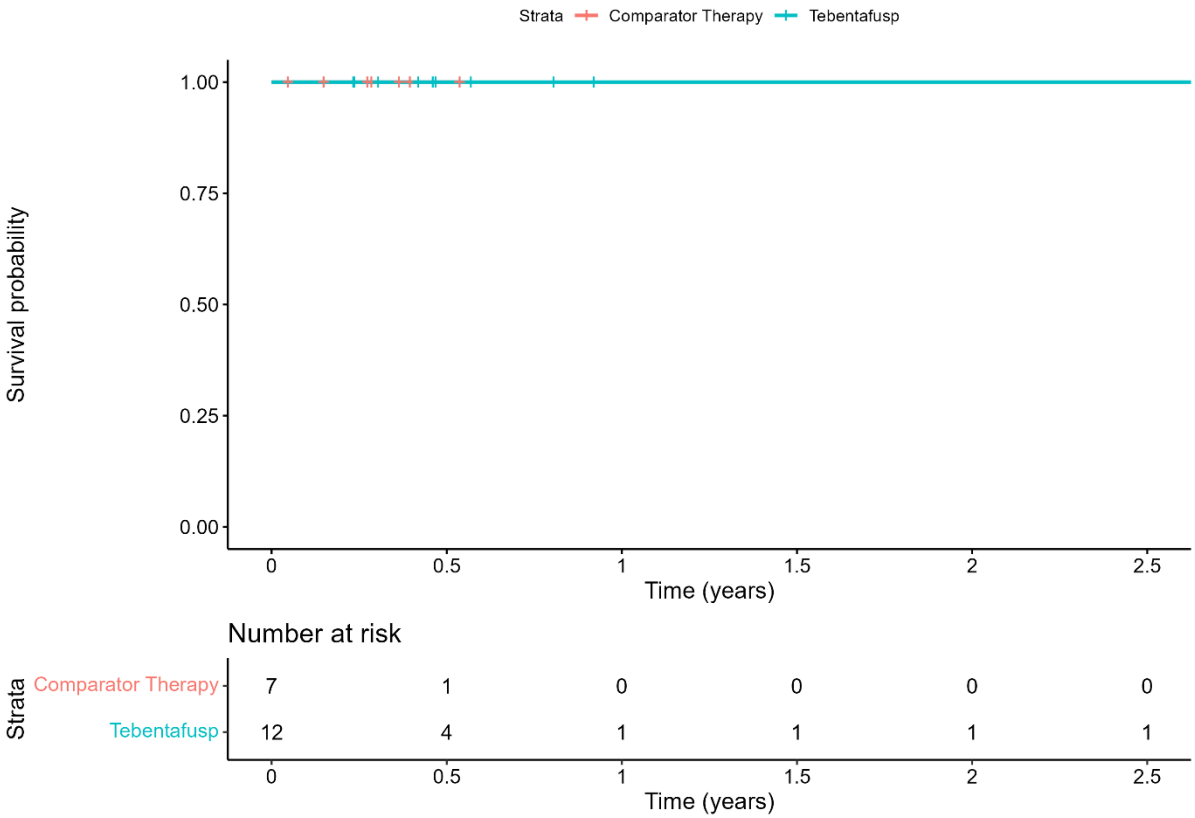
Region: Nordamerika



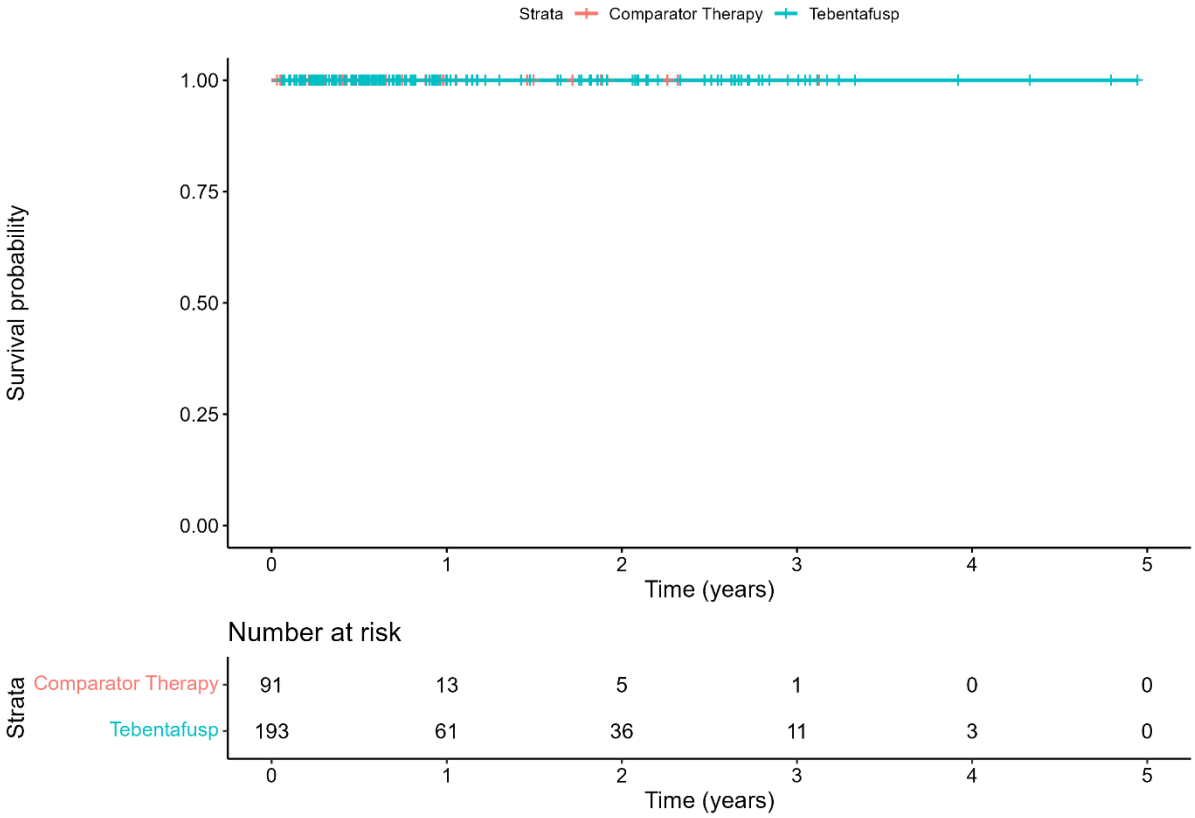
Region: Nicht-Nordamerika



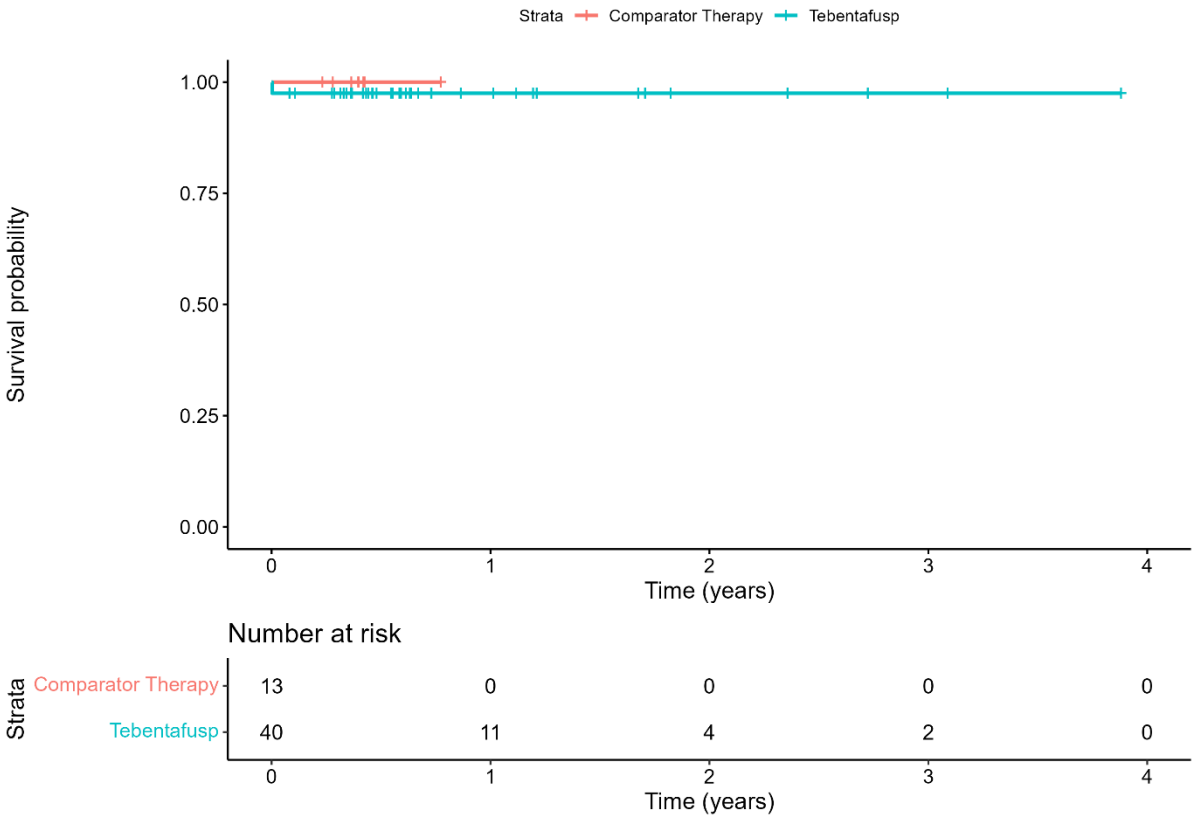
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

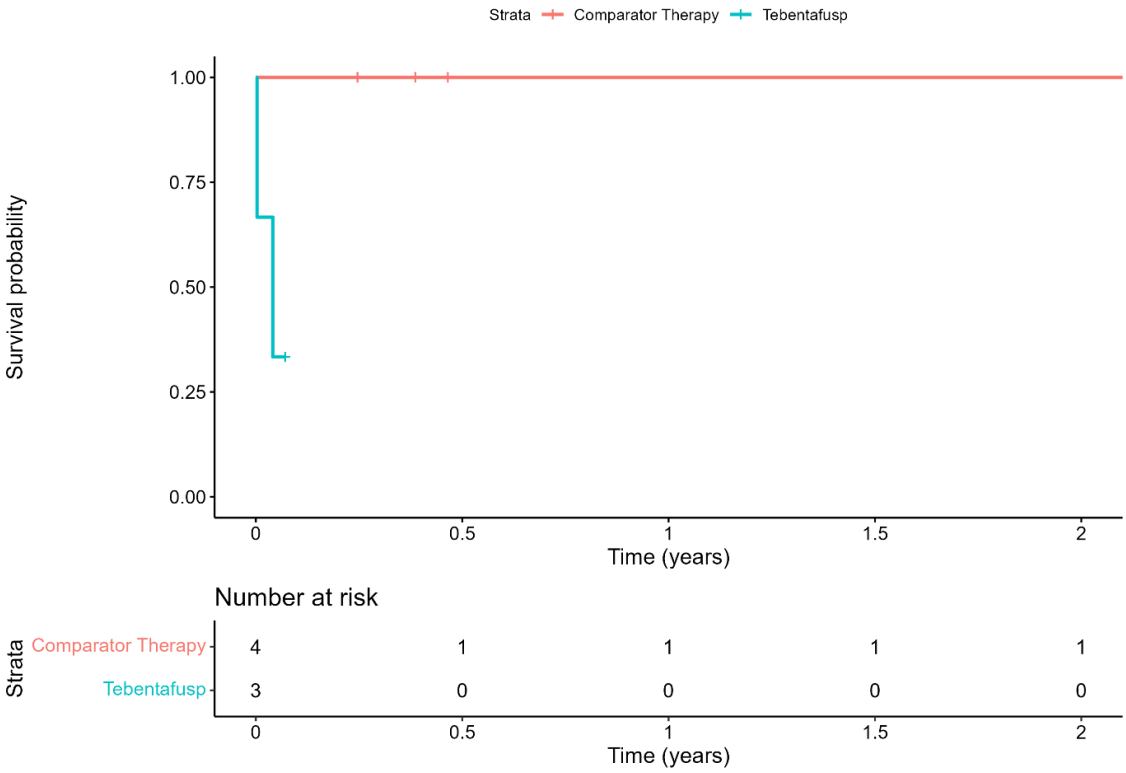


Vorauswahl der Chemotherapie: Ipilimumab

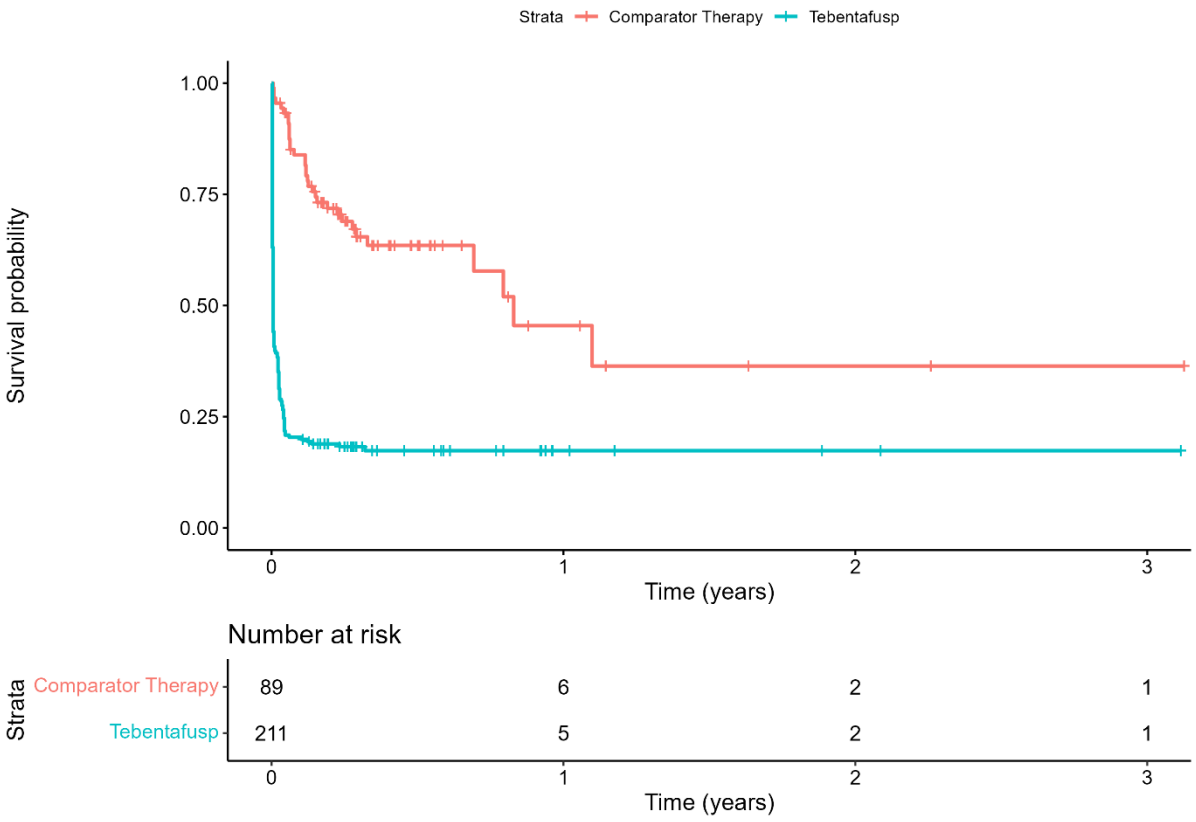


59.9 Hautausschlag (Tabelle 4-230)

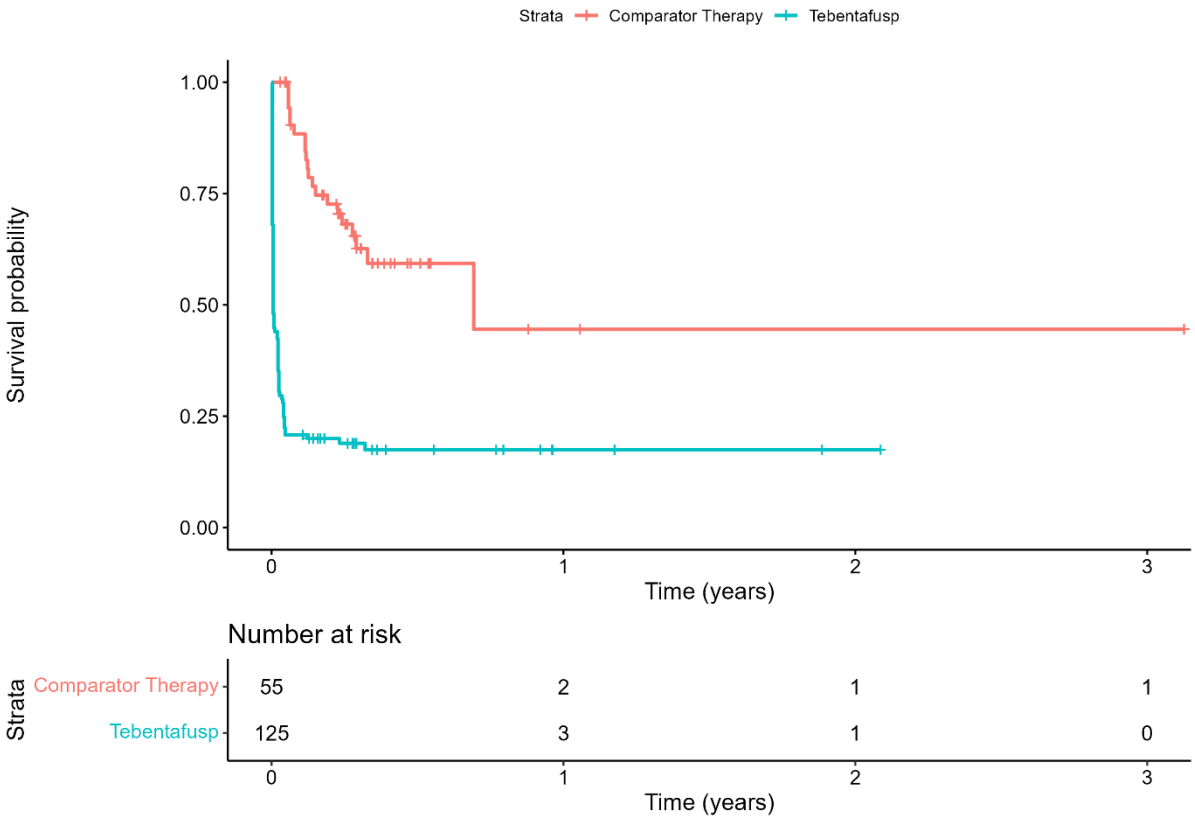
Herkunft: Hispanisch



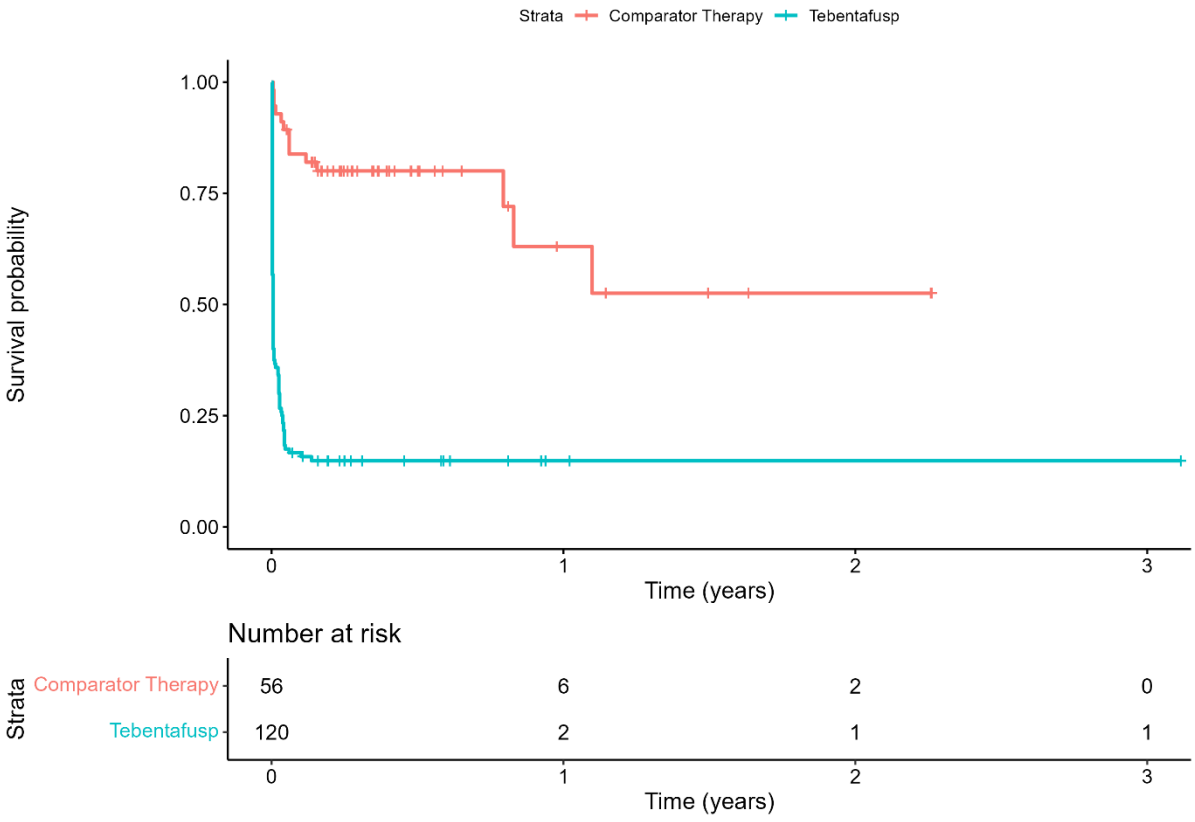
Herkunft: Nicht-hispanisch



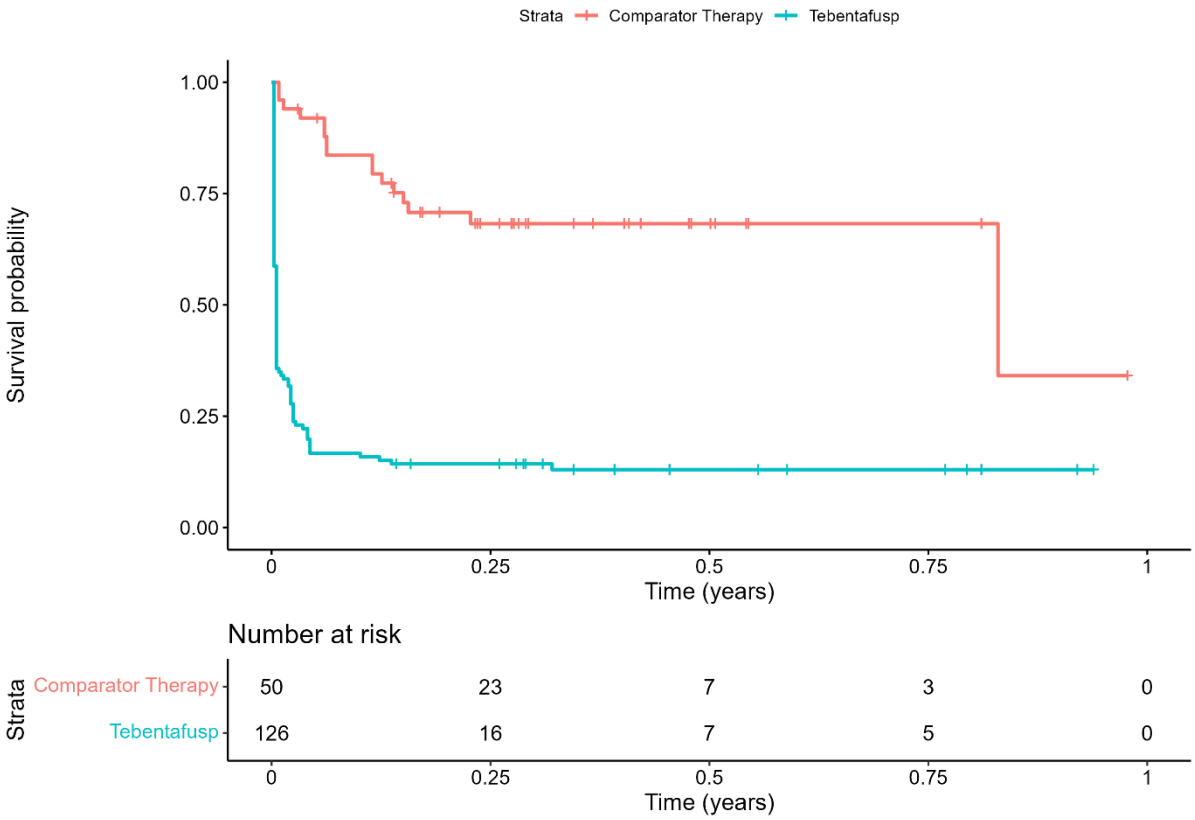
Geschlecht: Männlich



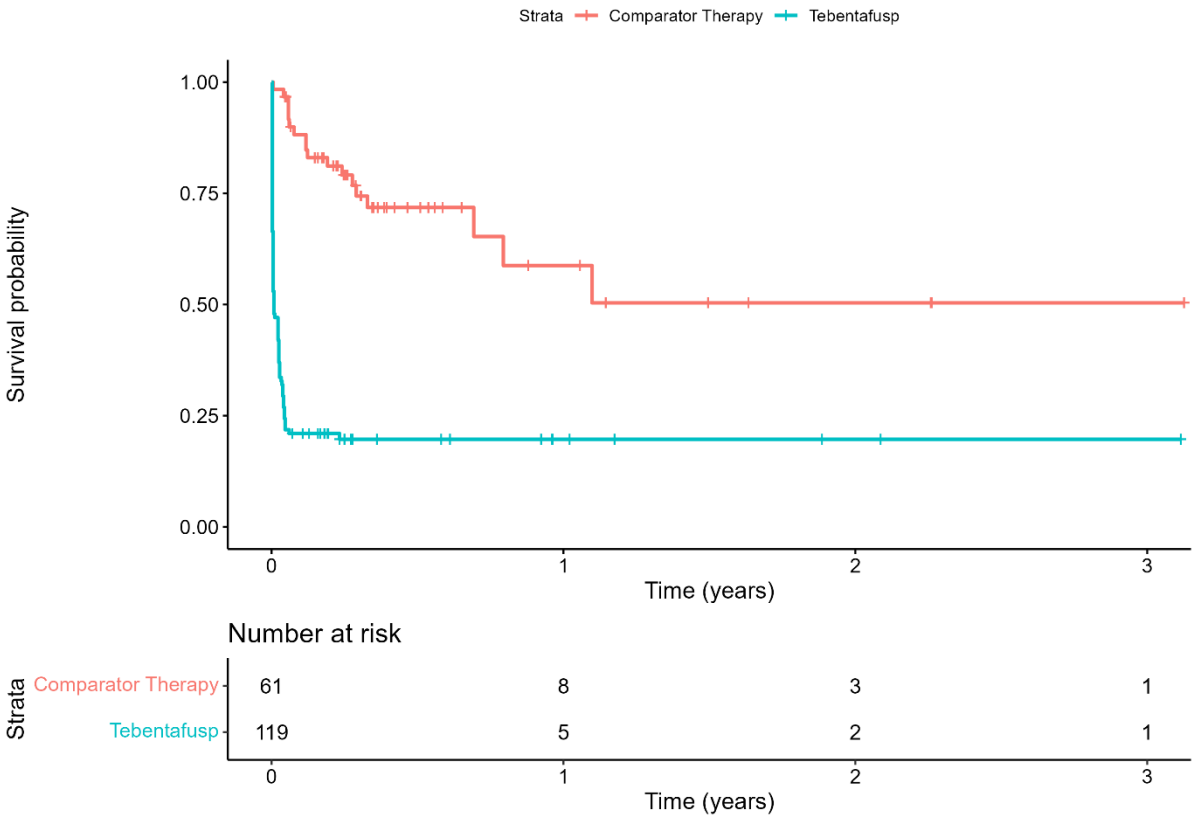
Geschlecht: Weiblich



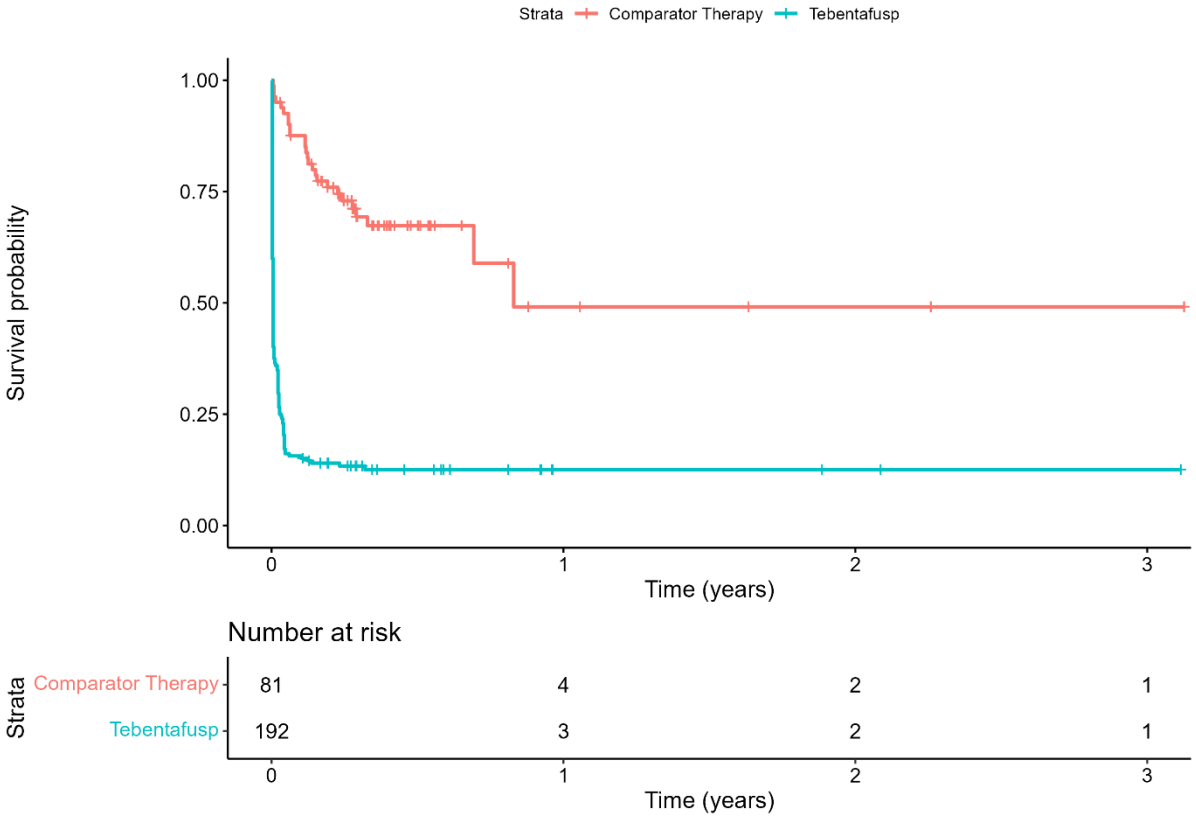
Alter: <65 Jahre



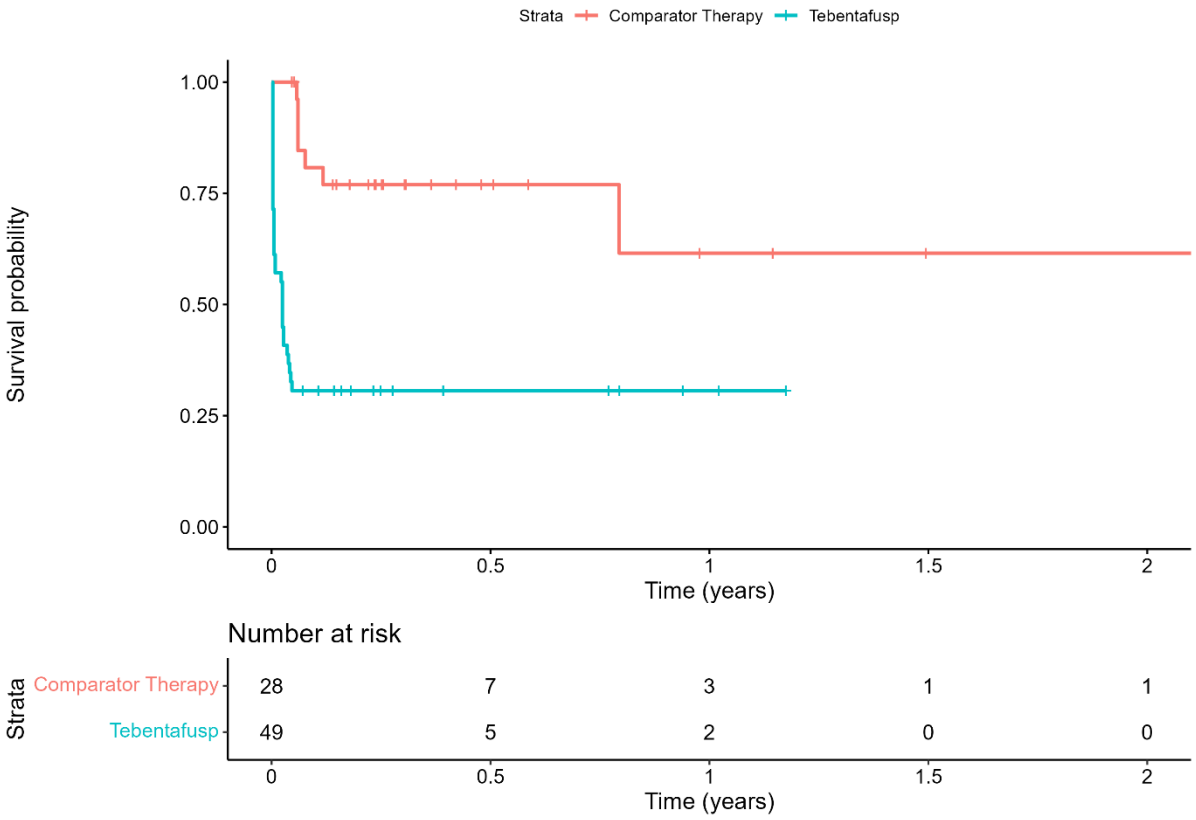
Alter: ≥65 Jahre



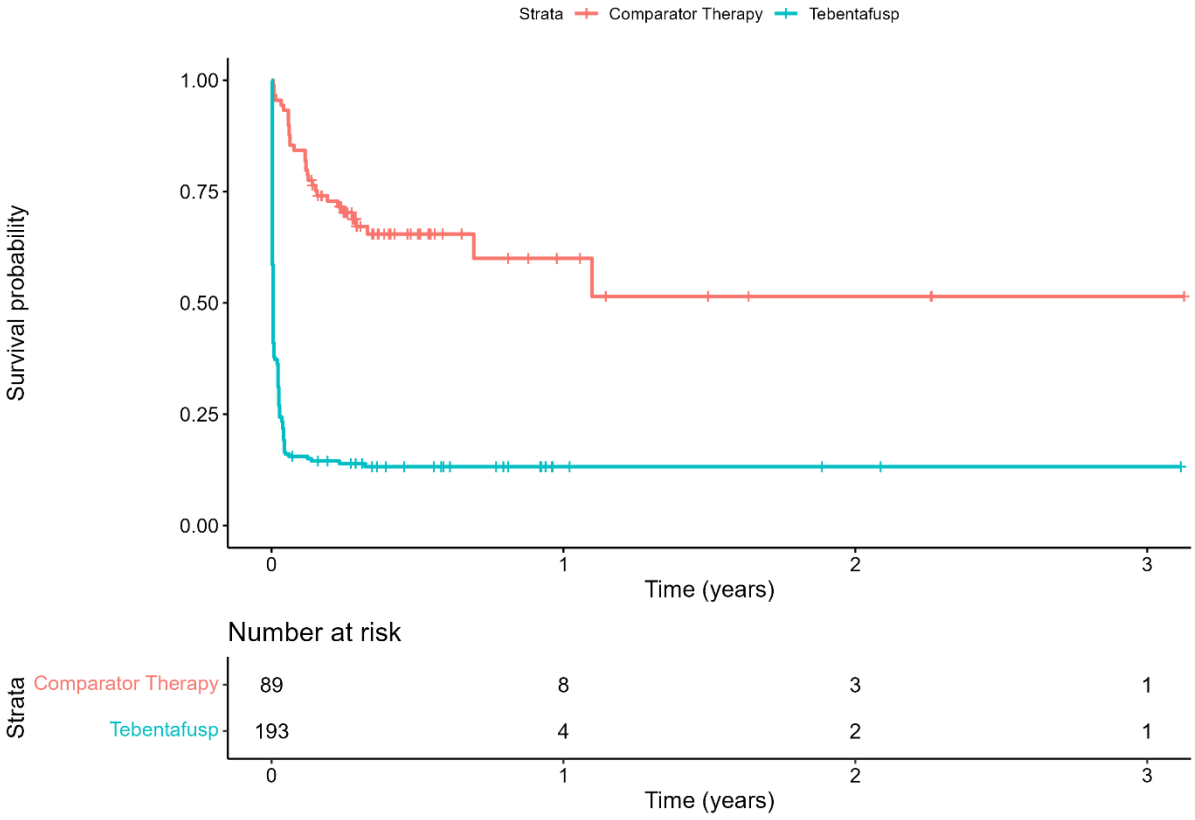
ECOG-Performance-Status: 0



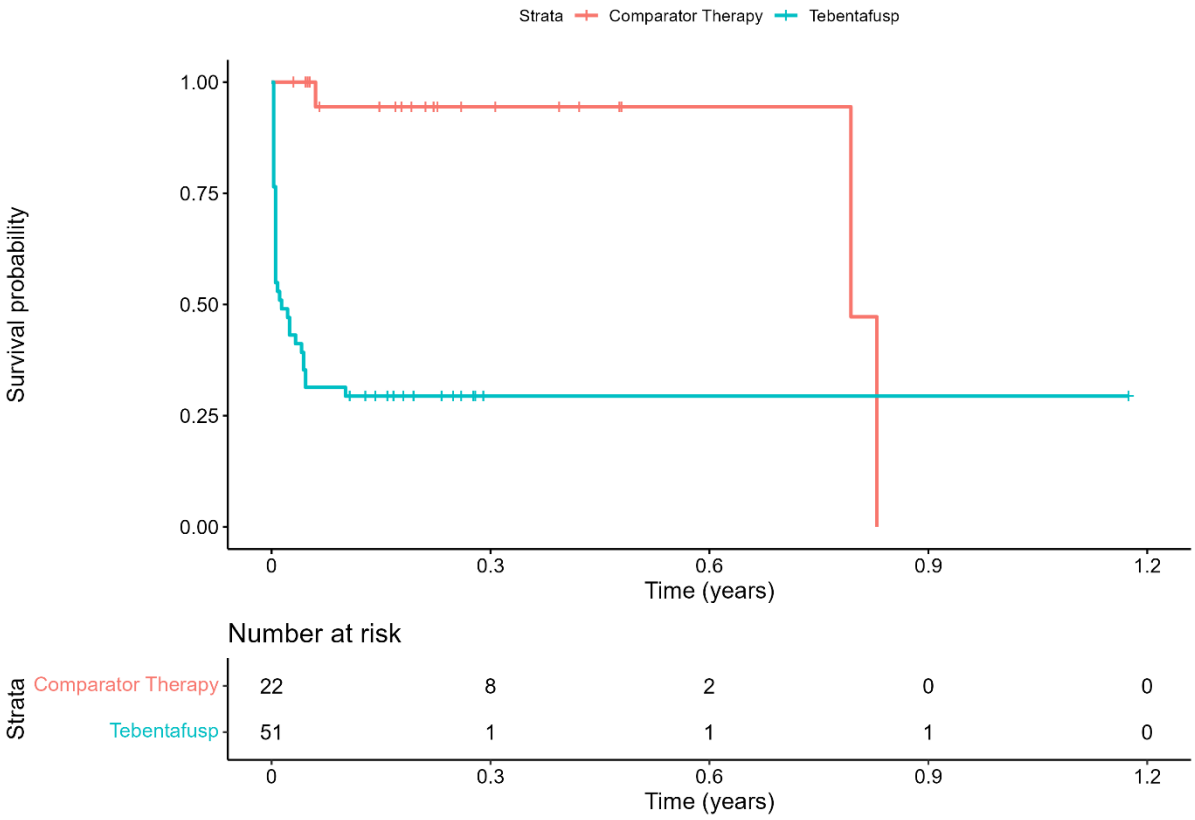
ECOG-Performance-Status: 1



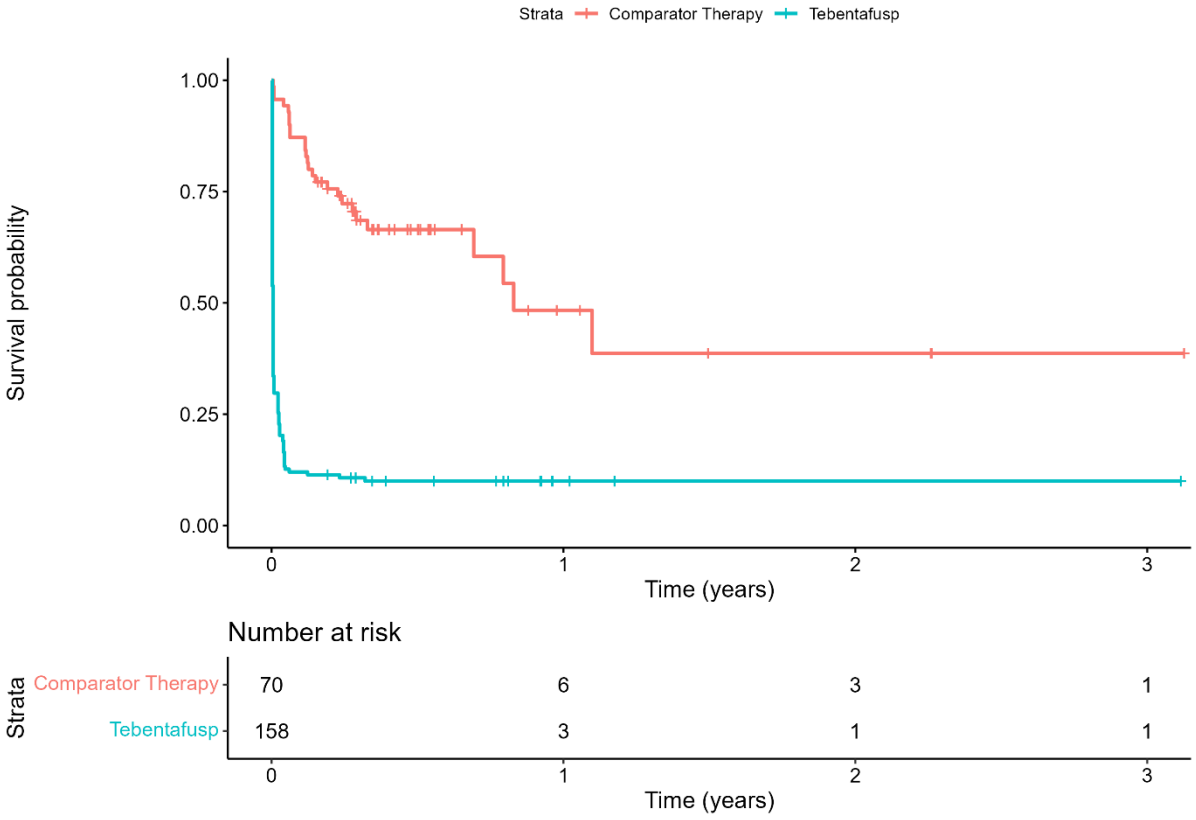
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



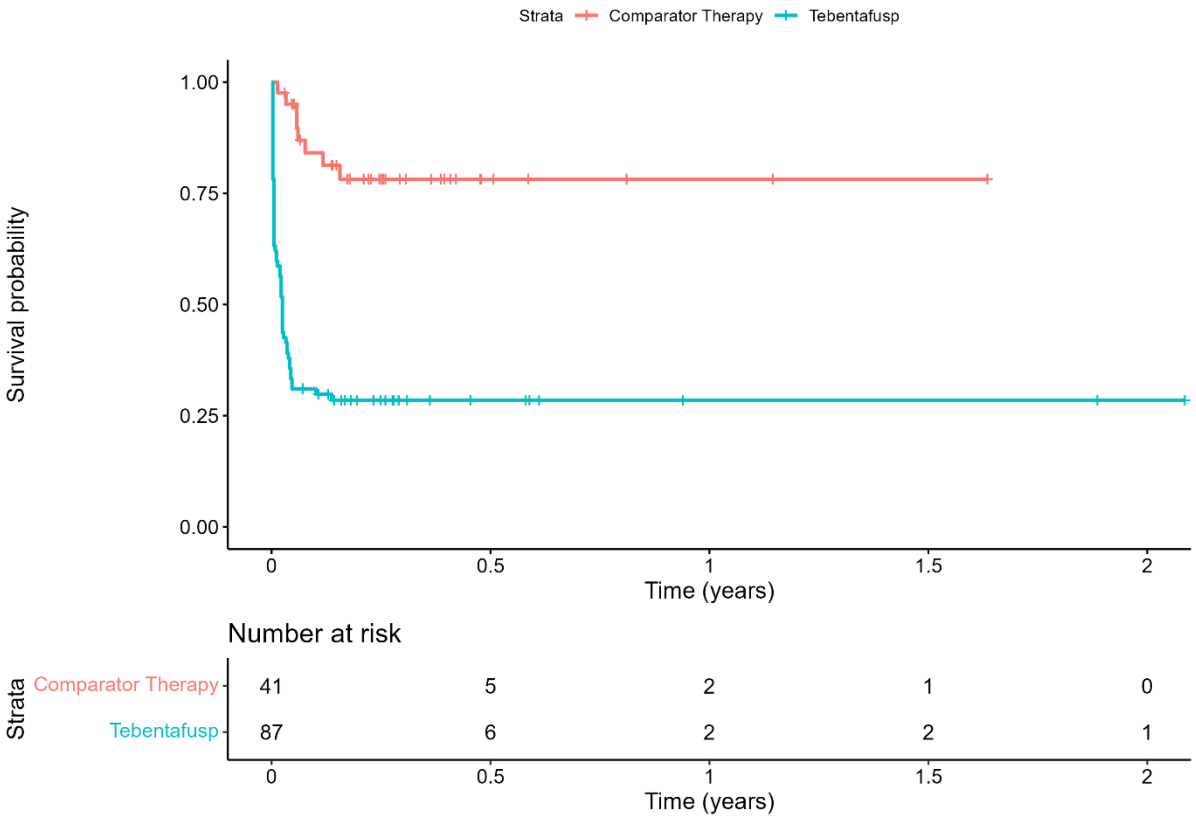
Alkalische Phosphatase (ALP) (Baseline): >ULN



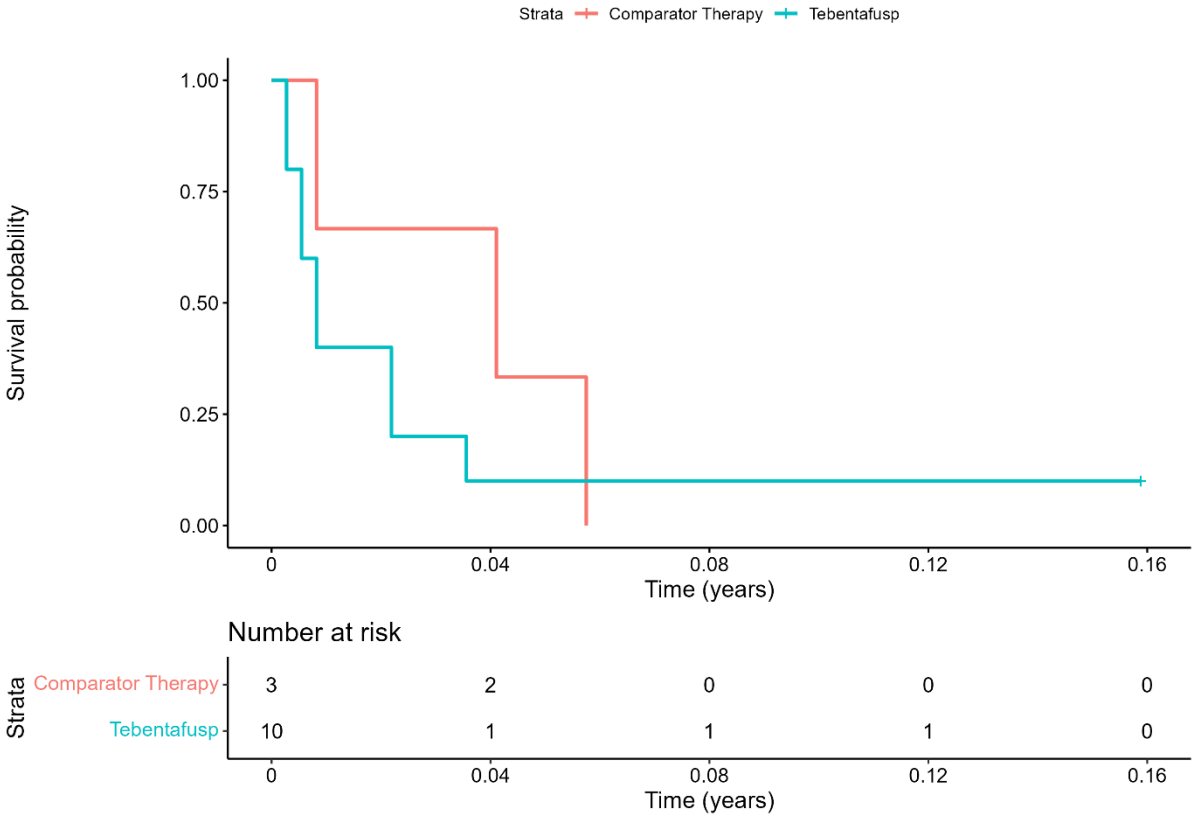
LDH: ≤ULN



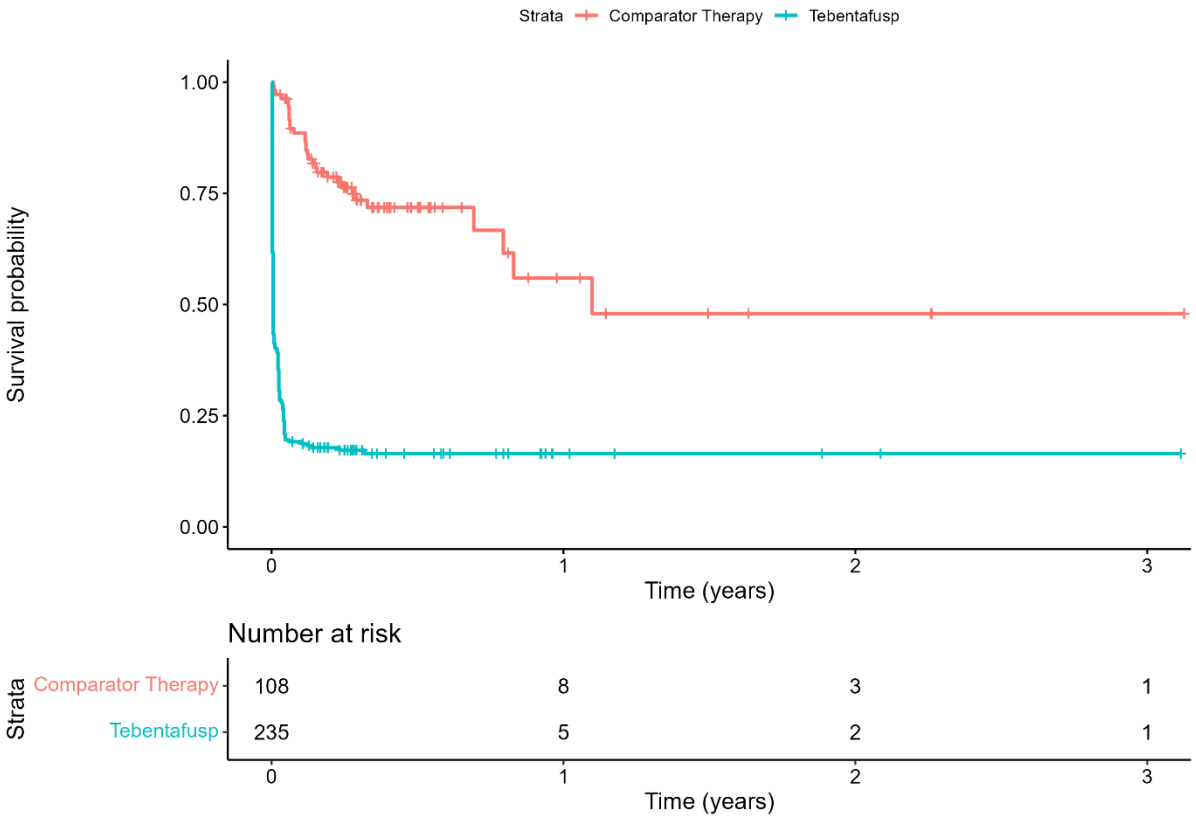
LDH: >ULN



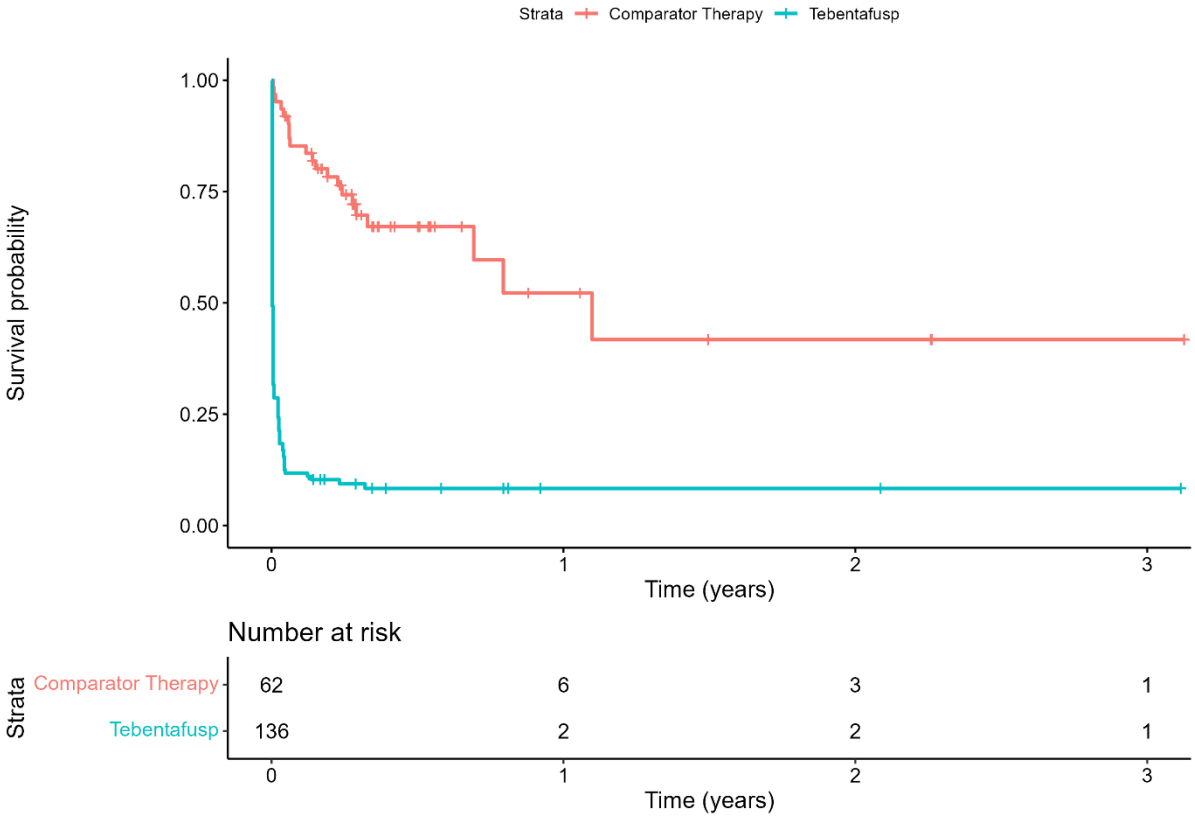
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



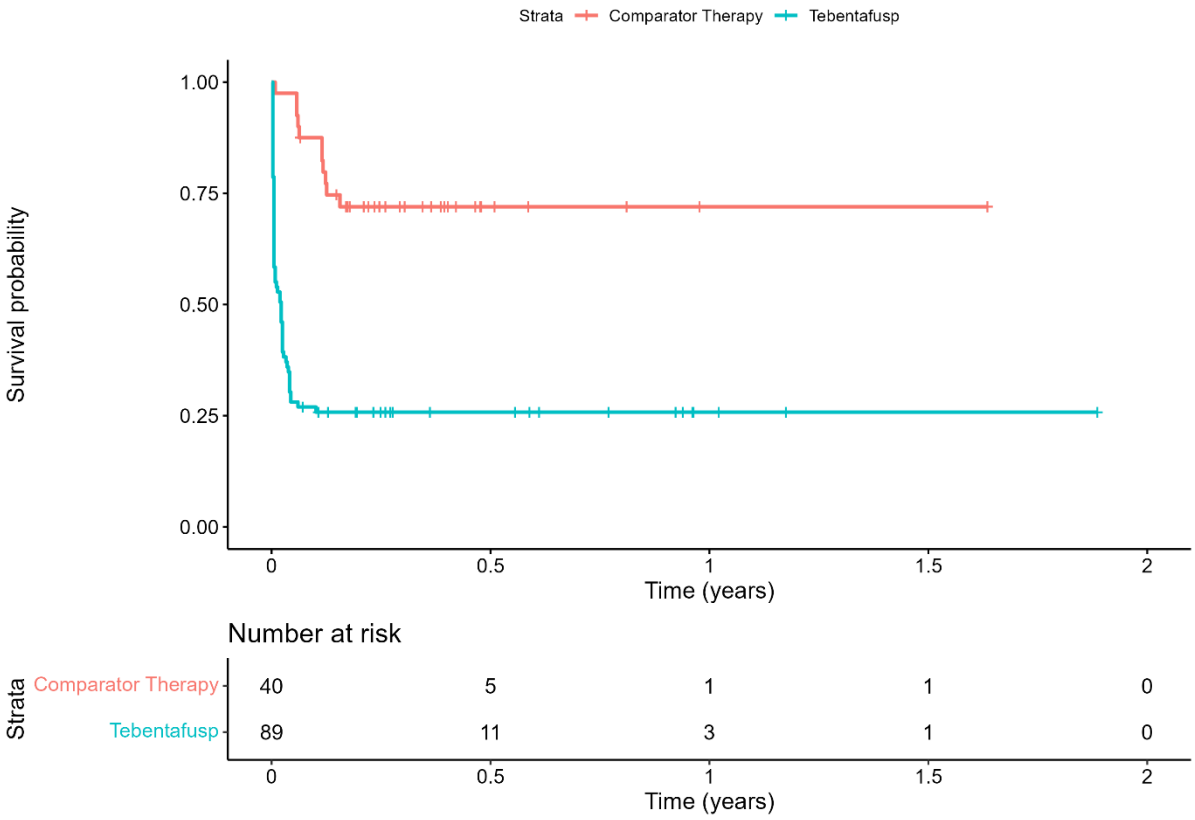
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



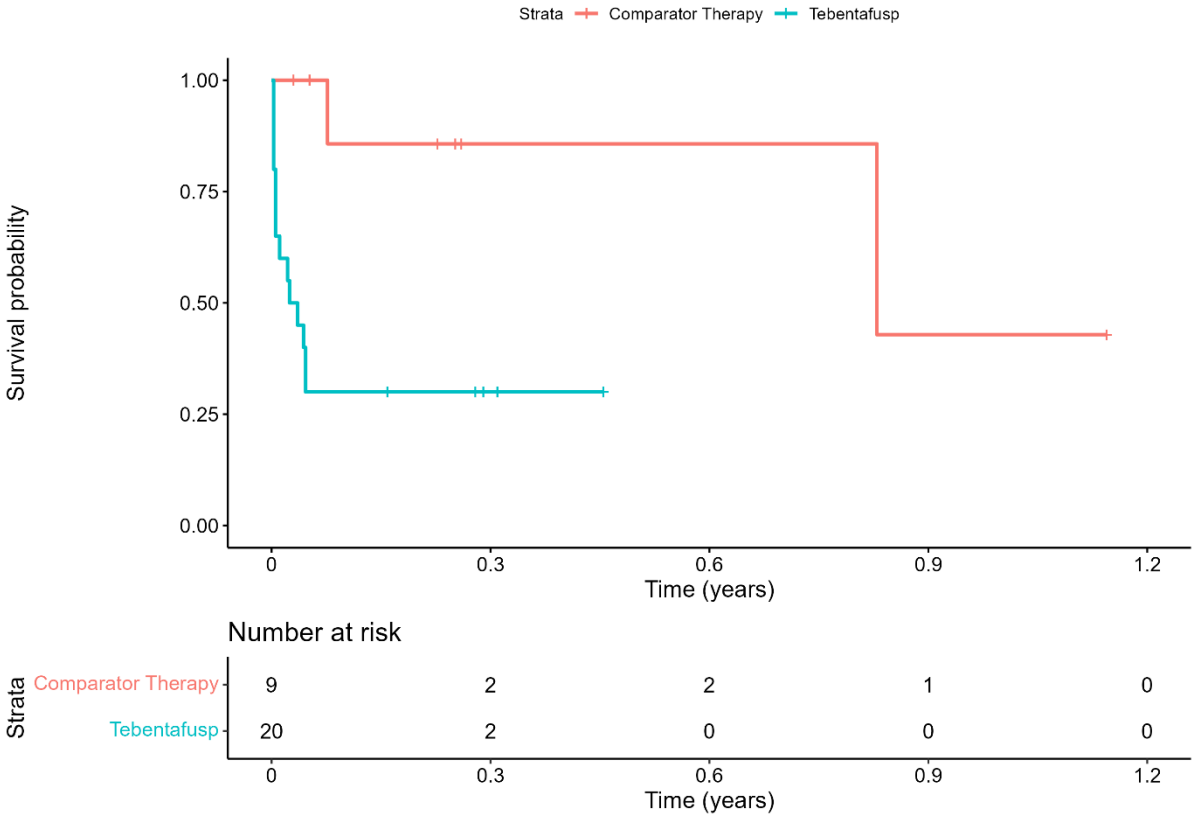
Größte metastatische Läsion (Baseline): ≤3,0 cm



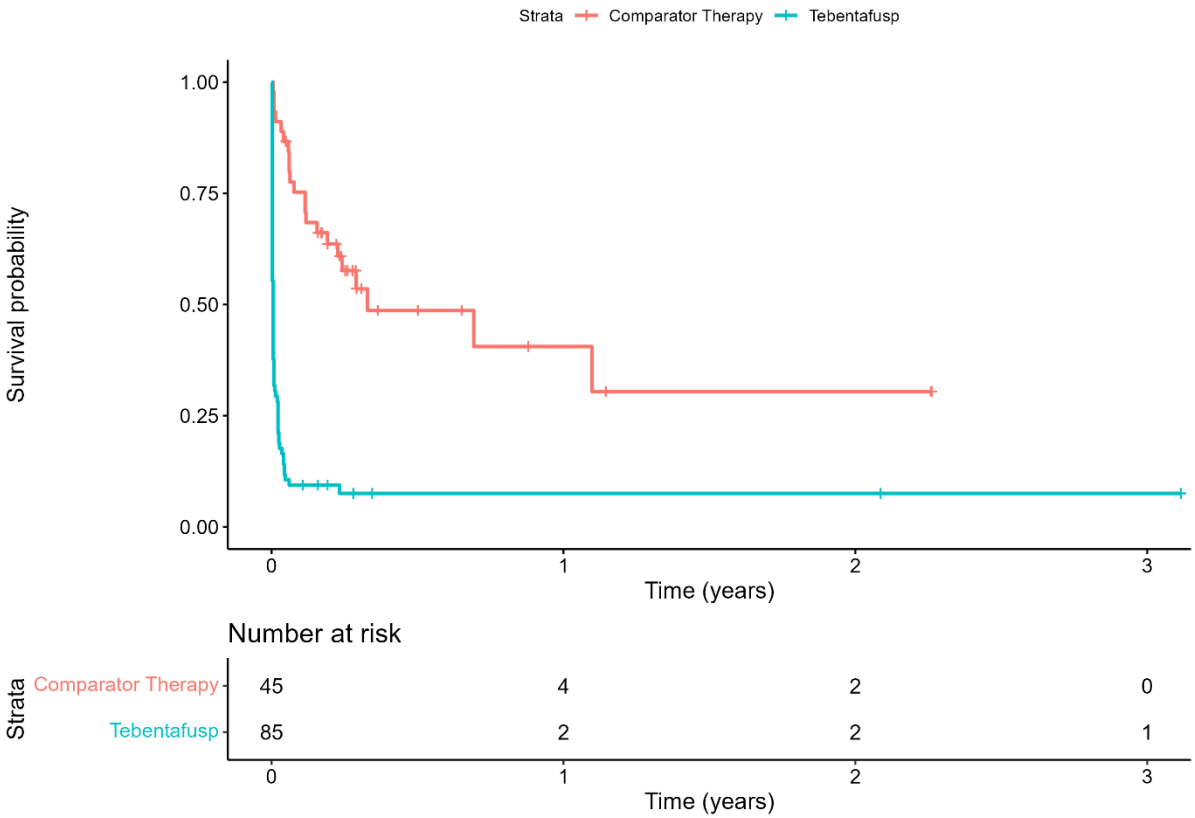
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



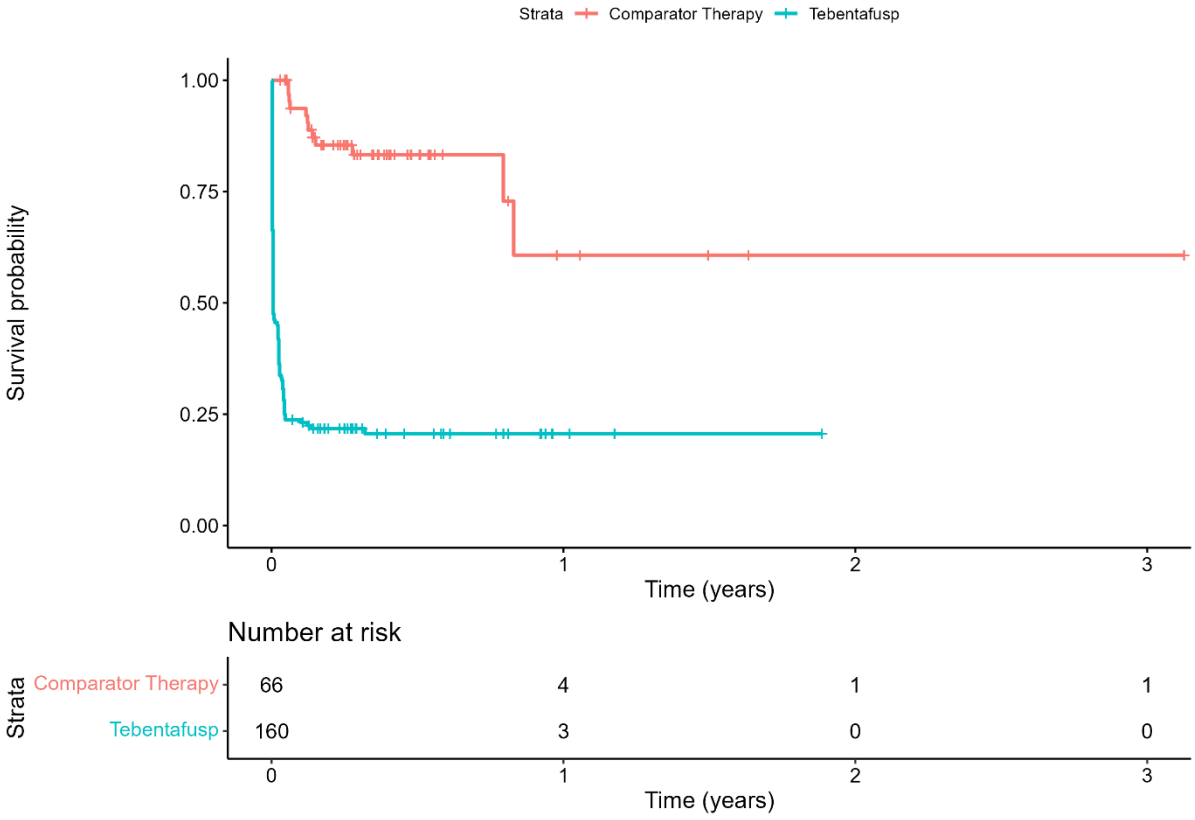
Größte metastatische Läsion (Baseline): ≥8,1 cm



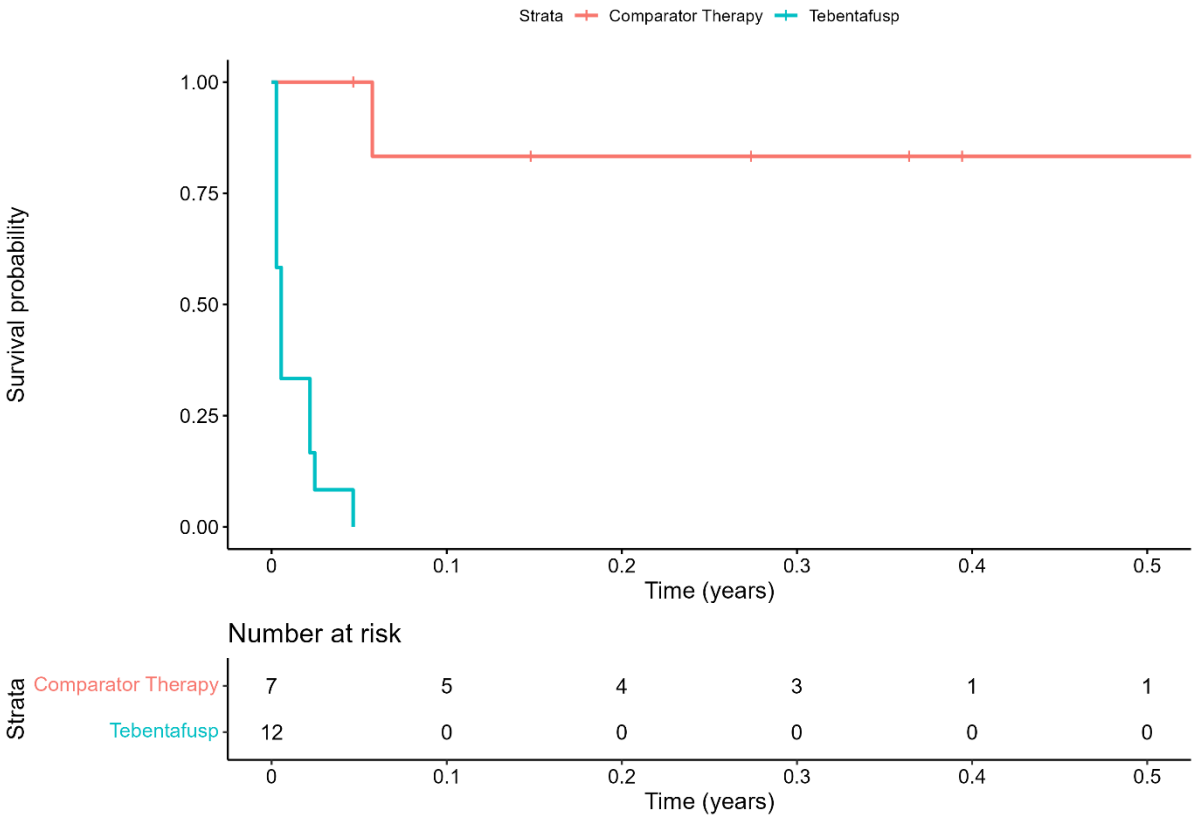
Region: Nordamerika



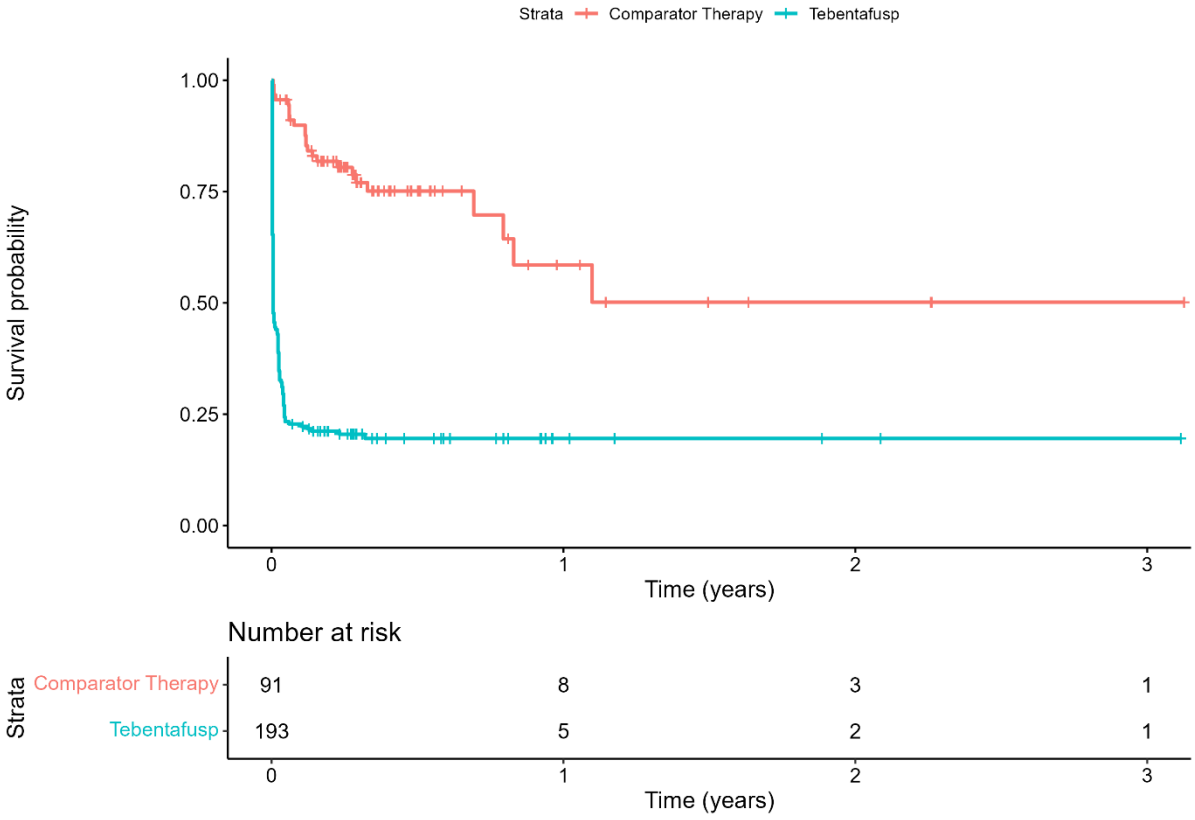
Region: Nicht-Nordamerika



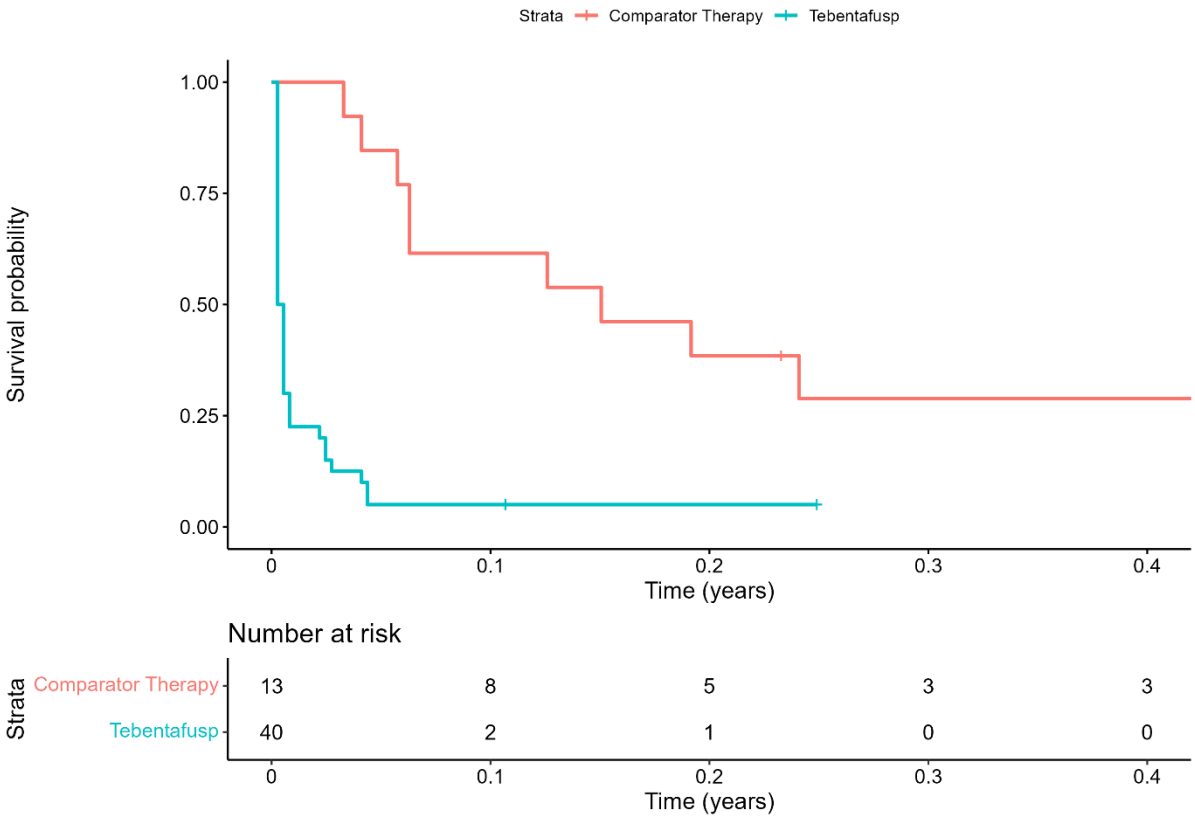
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

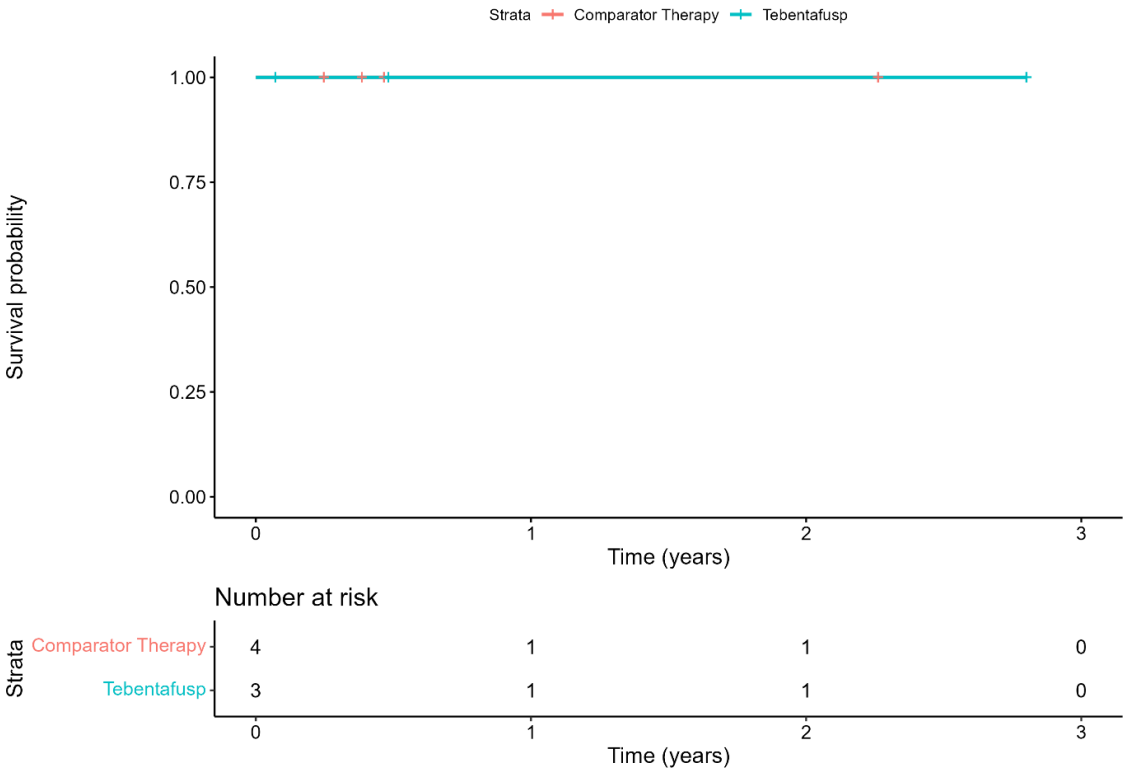


Vorauswahl der Chemotherapie: Ipilimumab

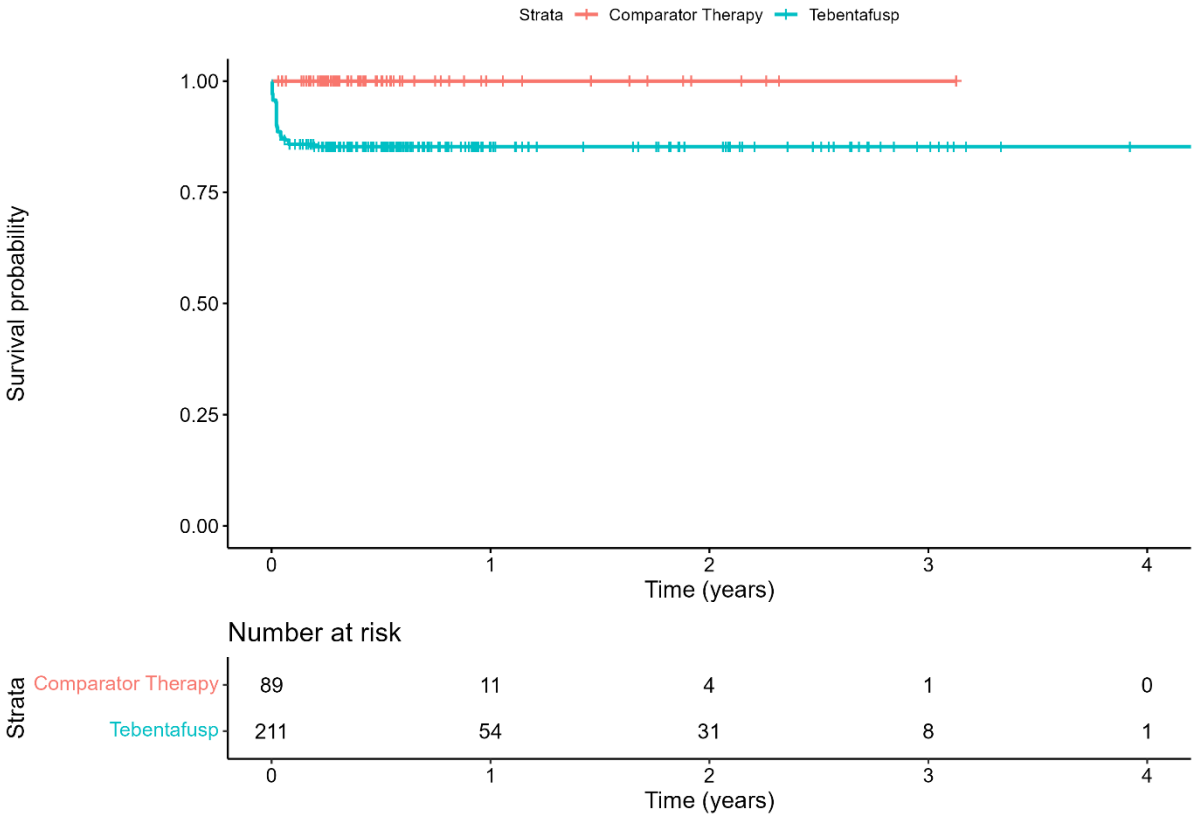


59.10 Hautausschlag mit CTCAE-Grad ≥ 3 (Tabelle 4-232)

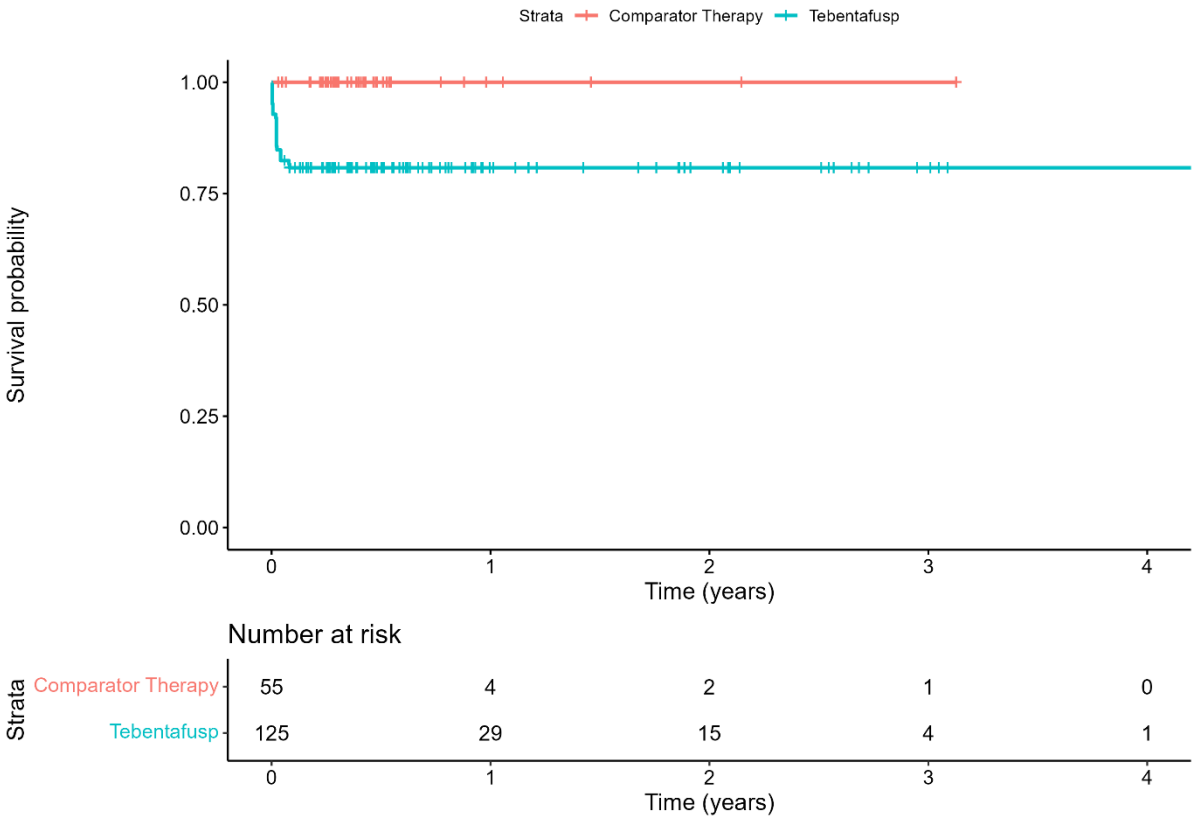
Herkunft: Hispanisch



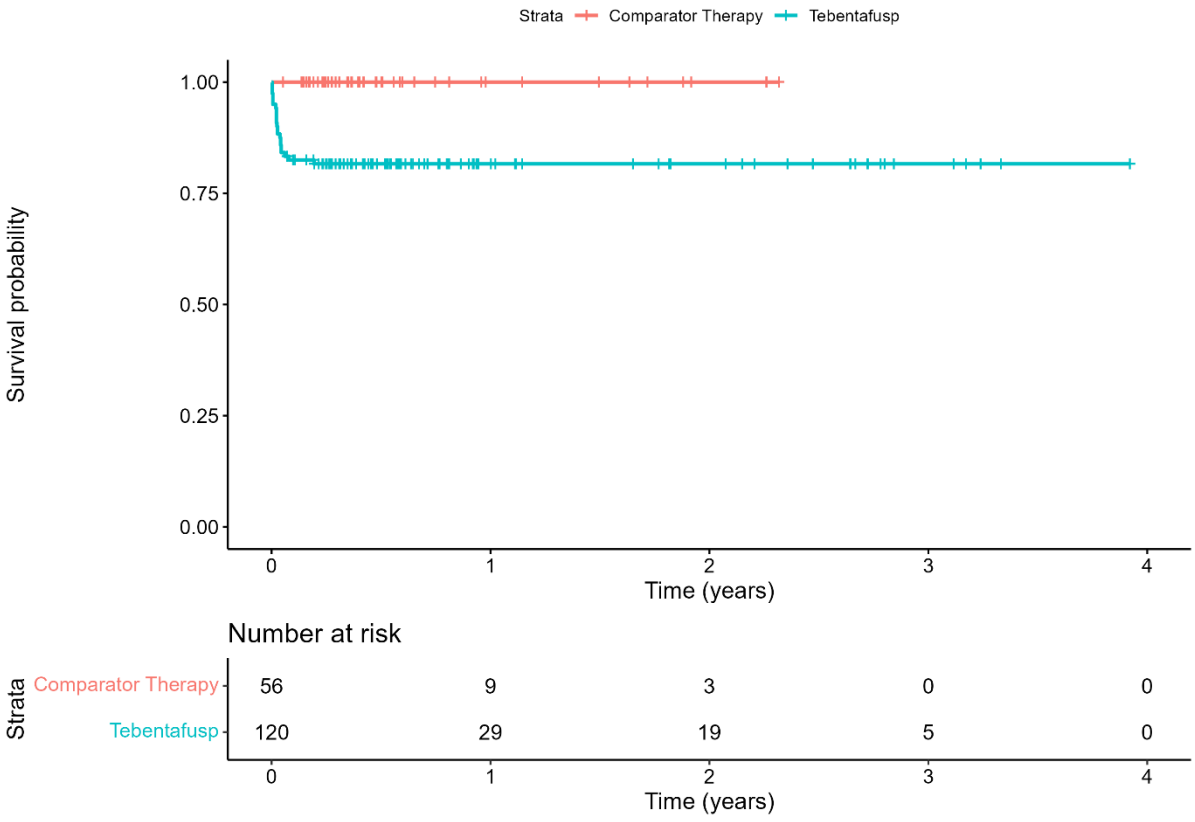
Herkunft: Nicht-hispanisch



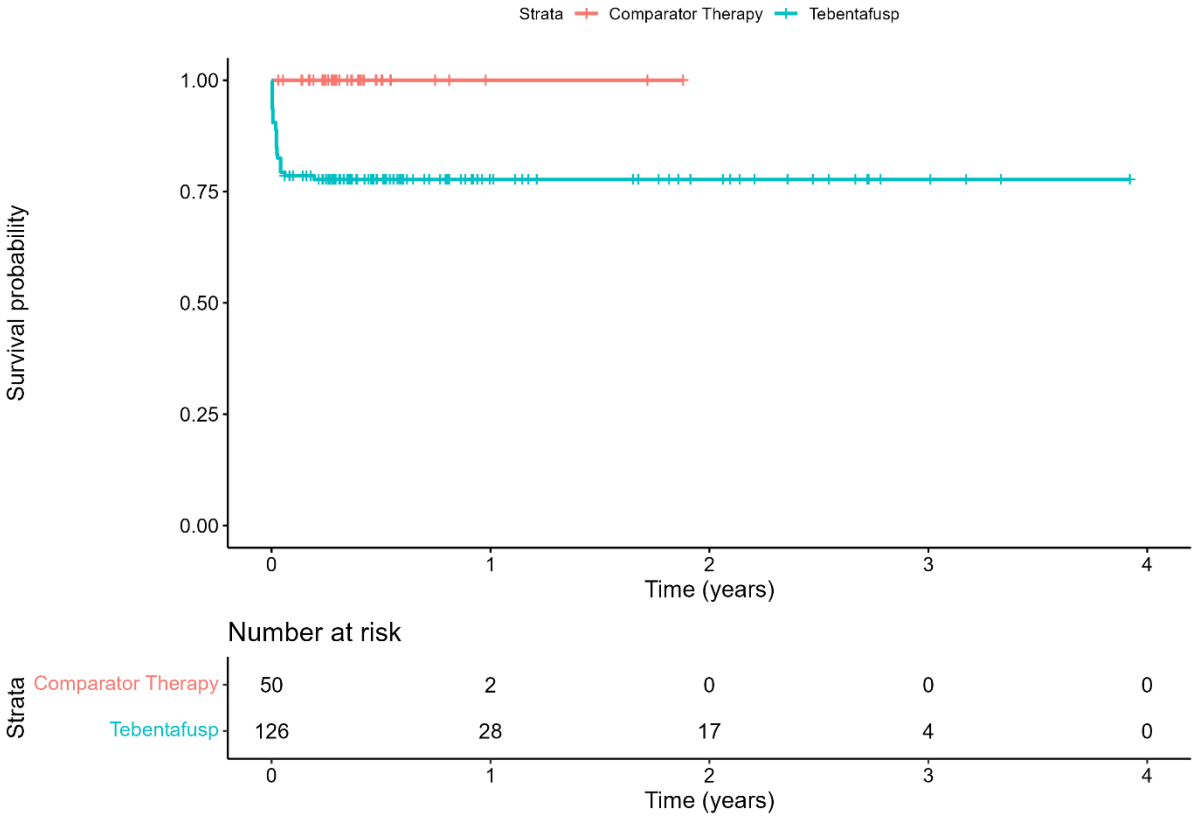
Geschlecht: Männlich



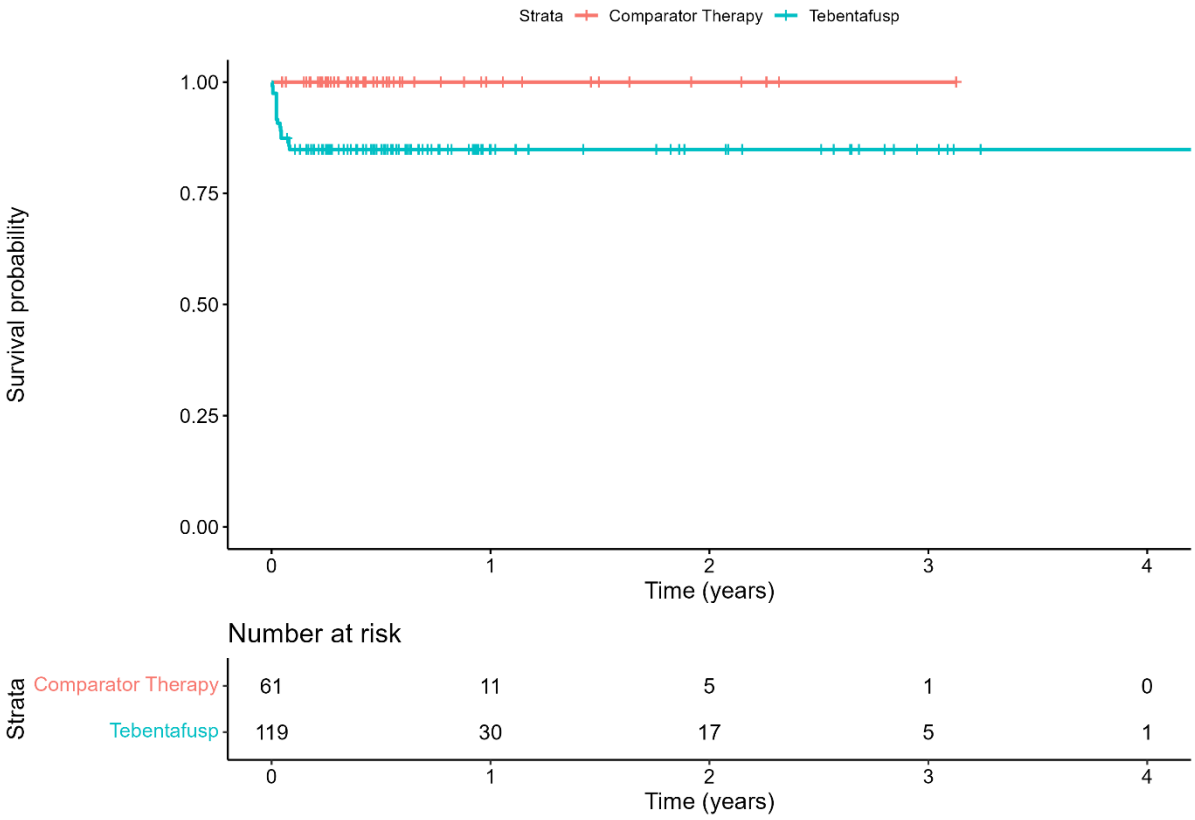
Geschlecht: Weiblich



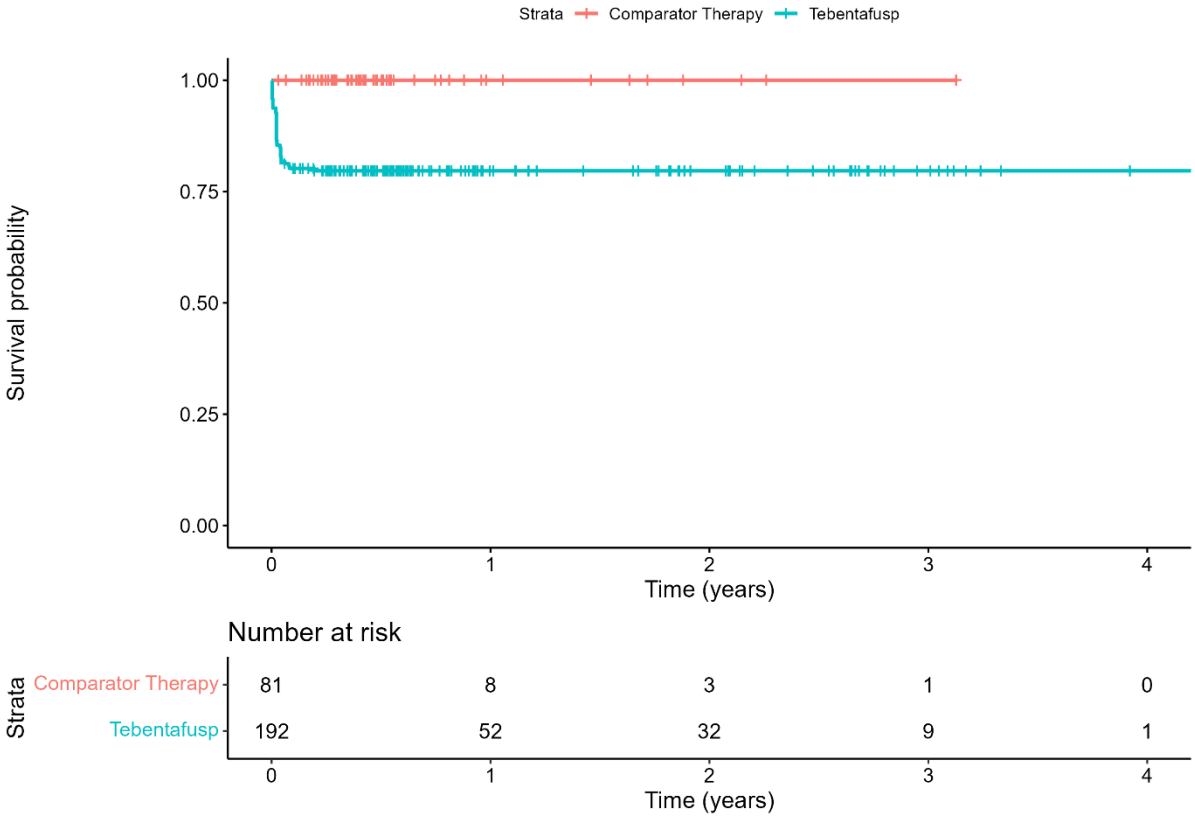
Alter: <65 Jahre



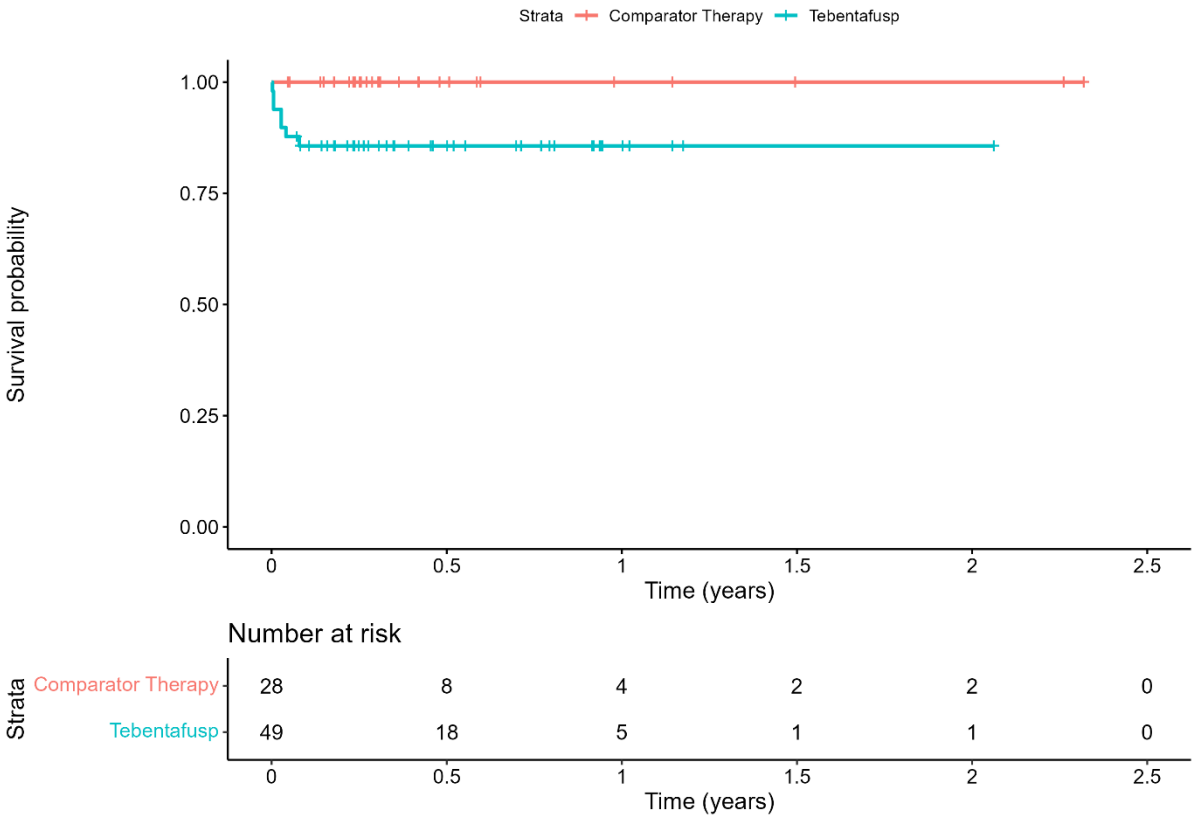
Alter: ≥65 Jahre



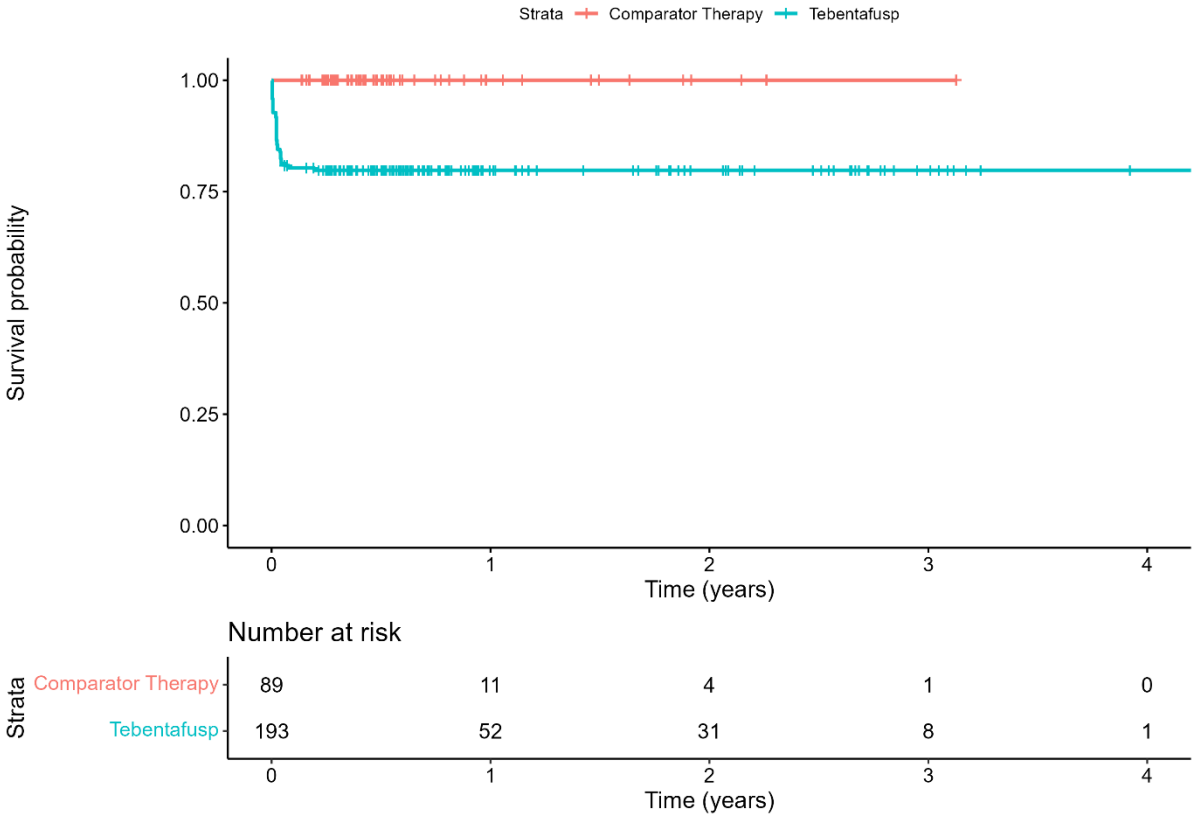
ECOG-Performance-Status: 0



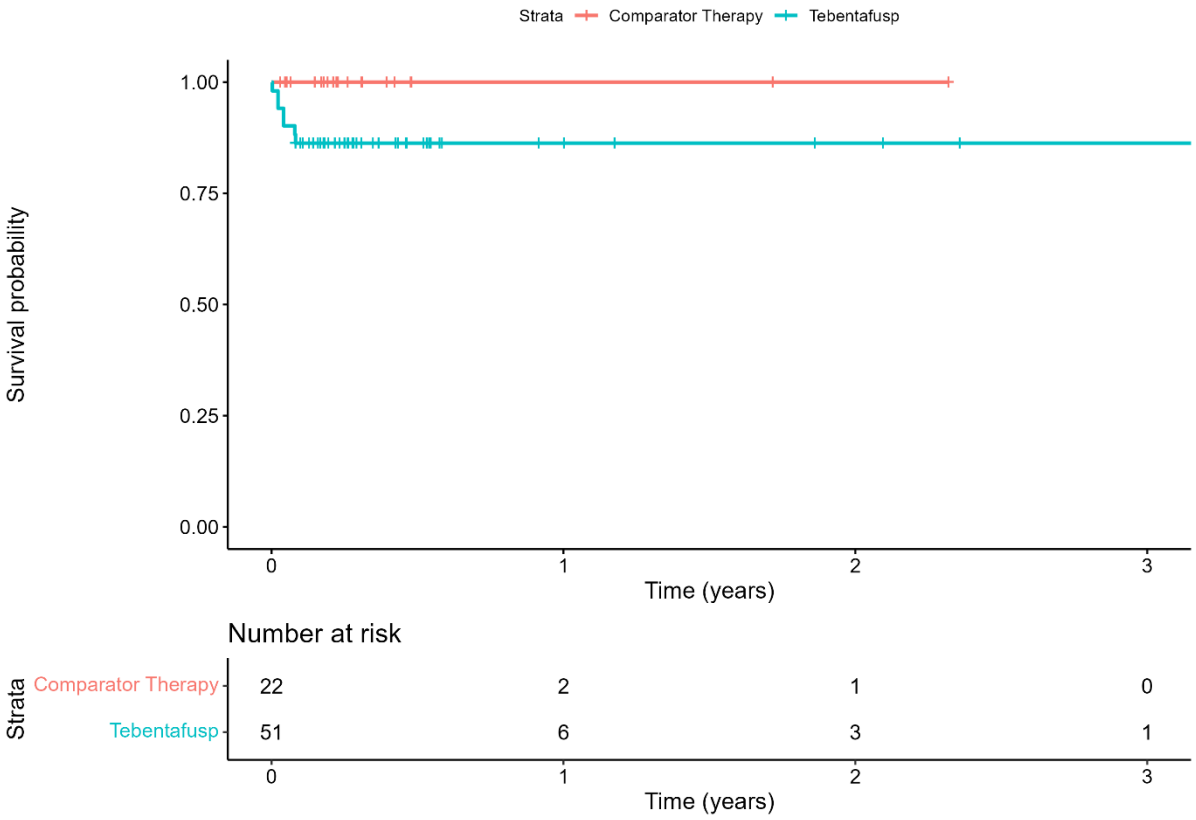
ECOG-Performance-Status: 1



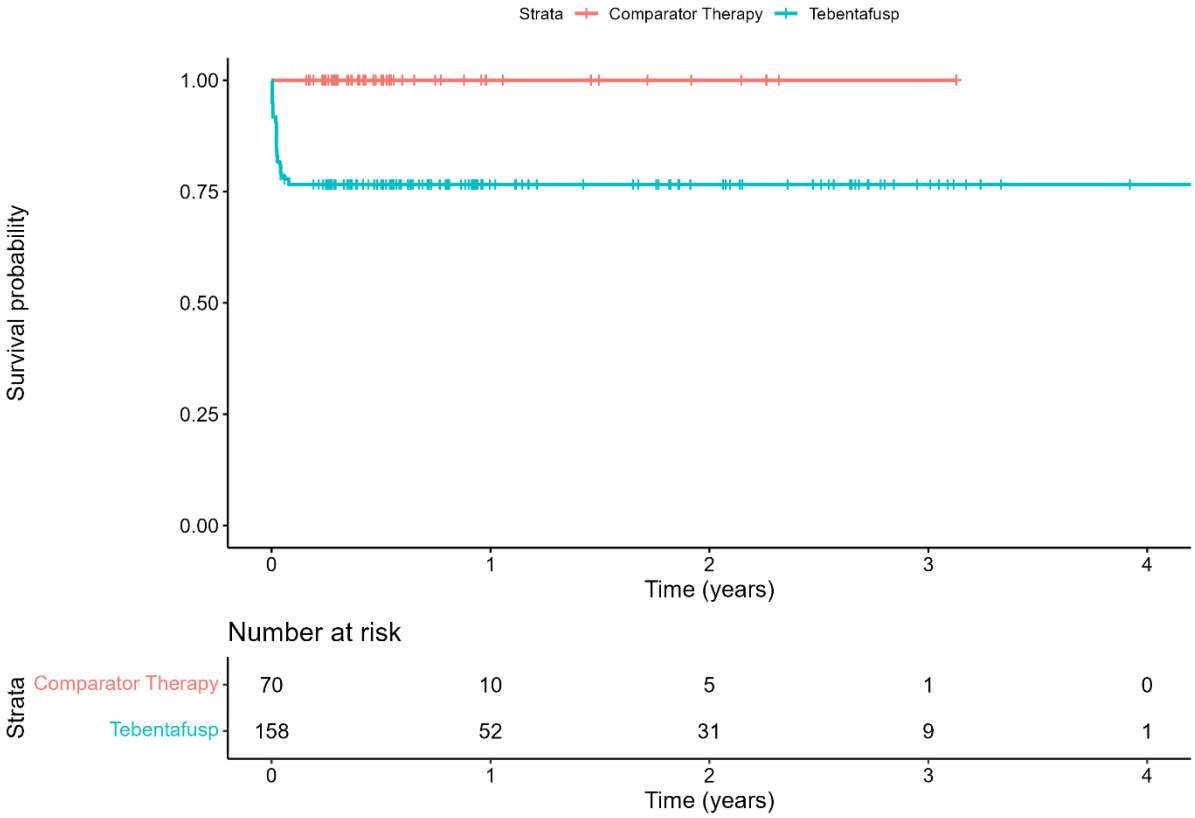
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



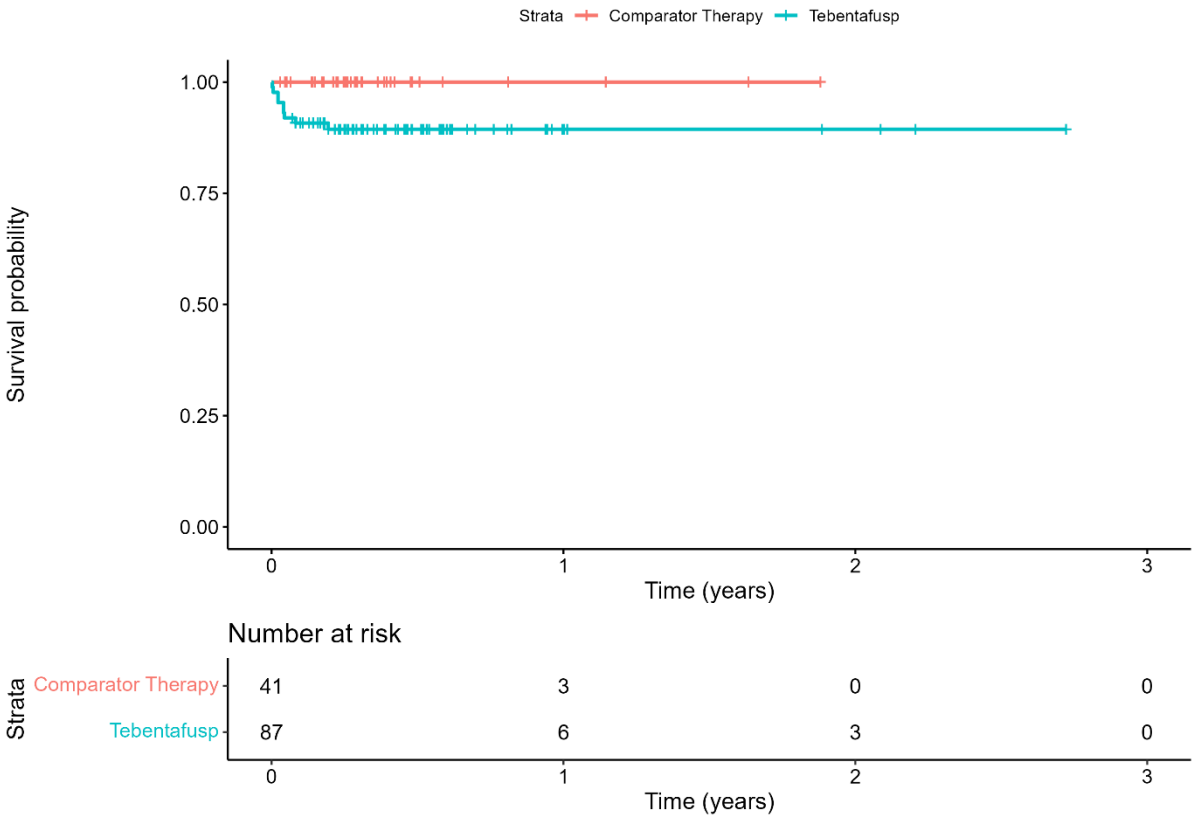
Alkalische Phosphatase (ALP) (Baseline): >ULN



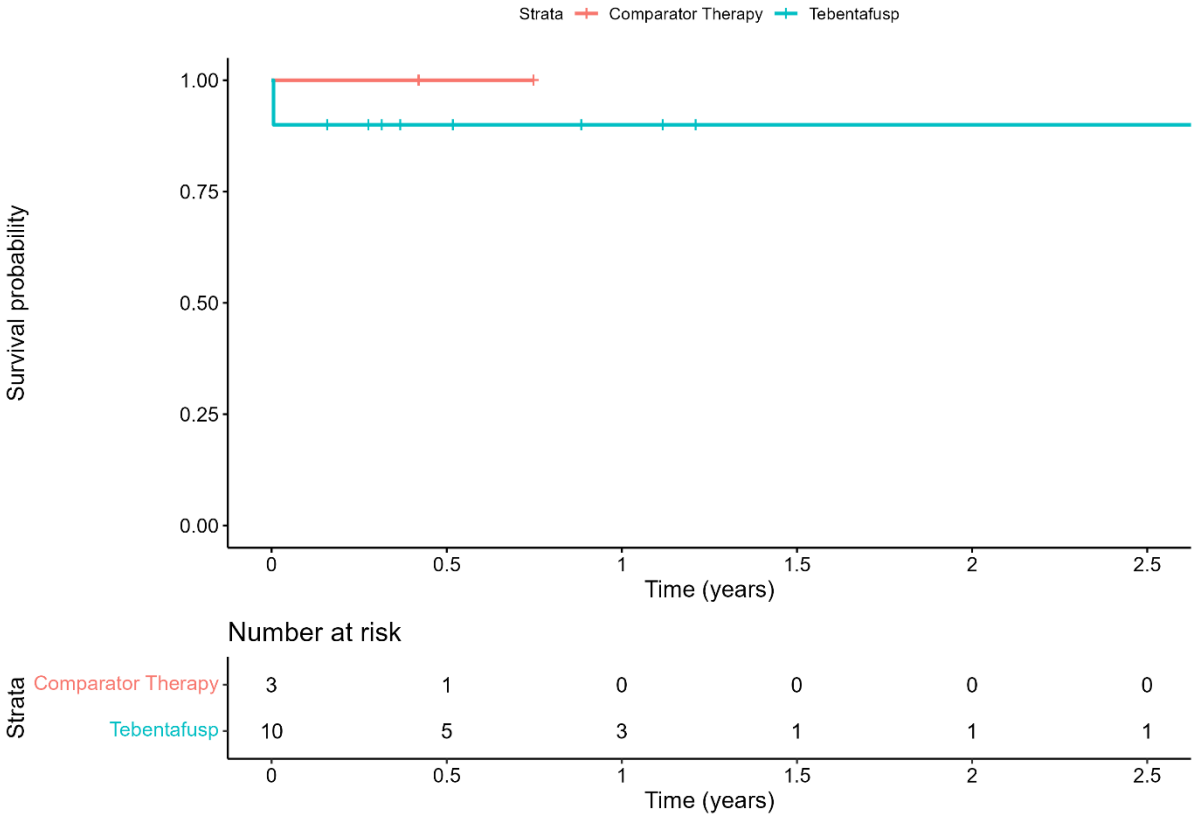
LDH: ≤ULN



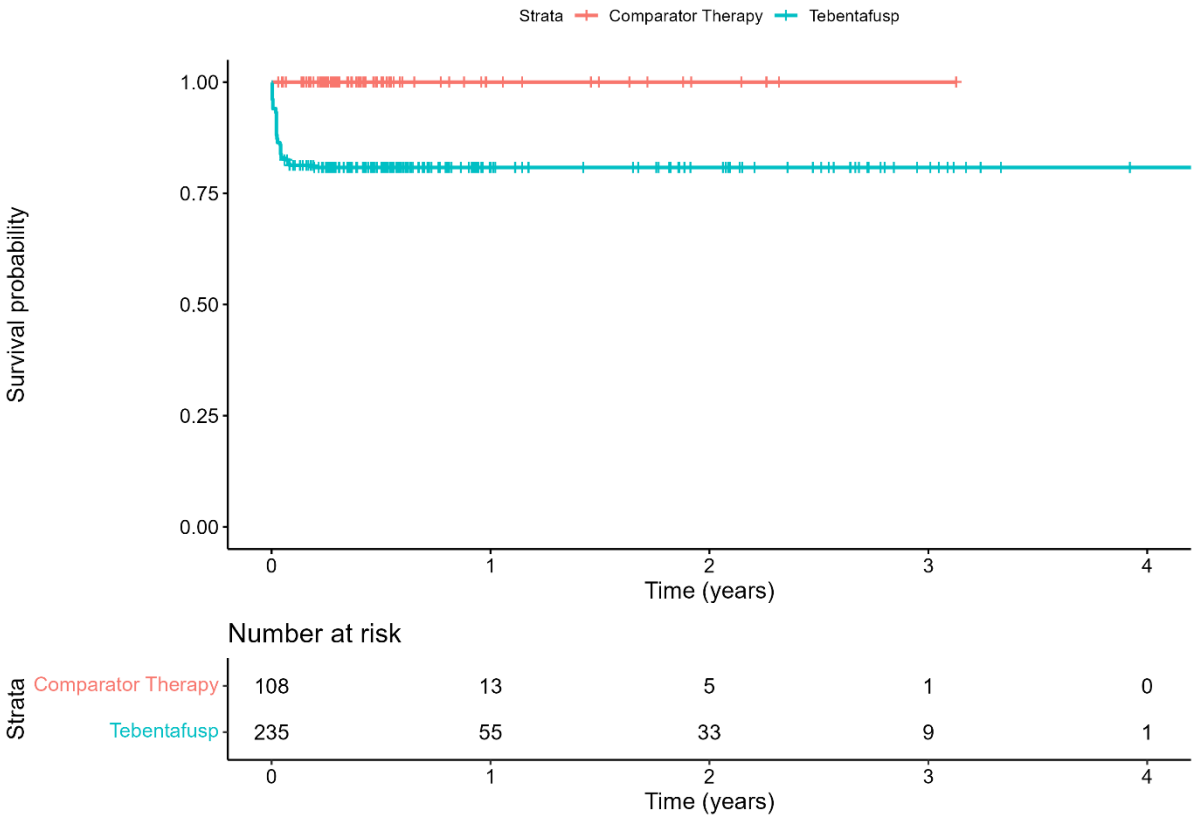
LDH: >ULN



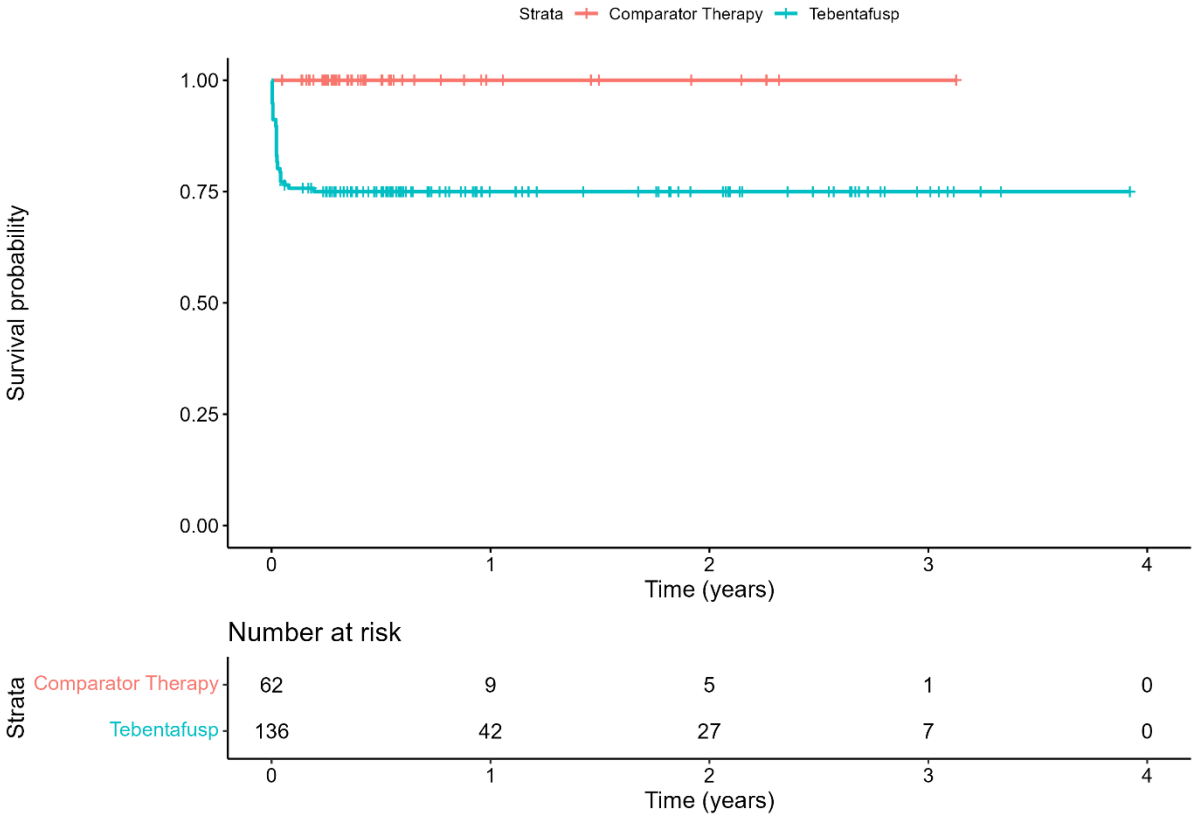
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



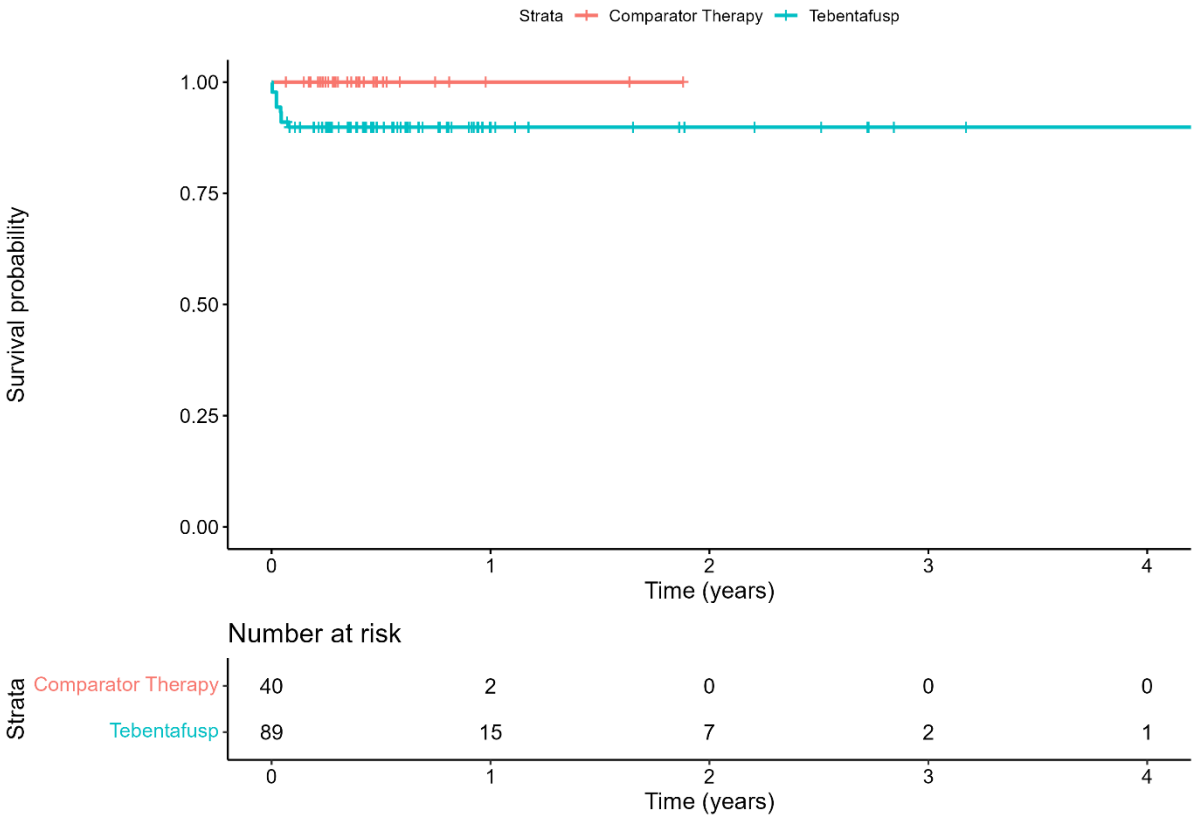
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



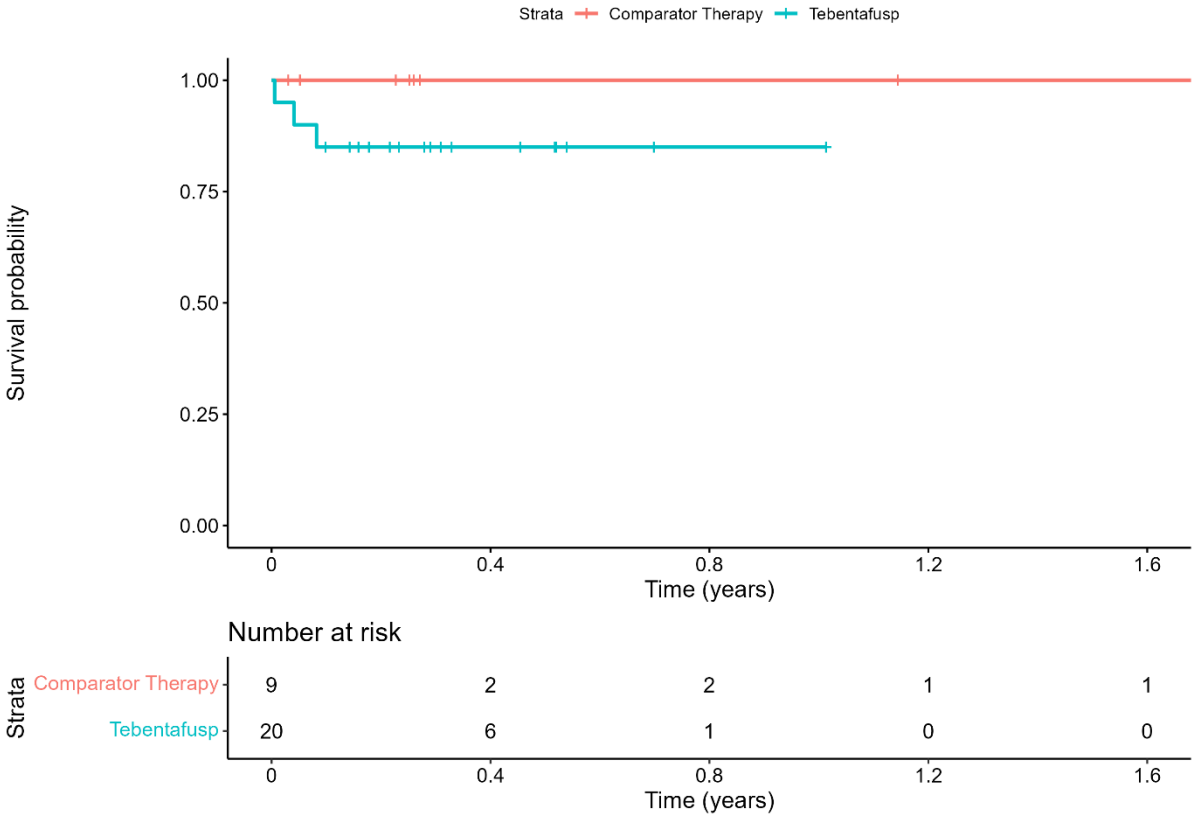
Größte metastatische Läsion (Baseline): ≤3,0 cm



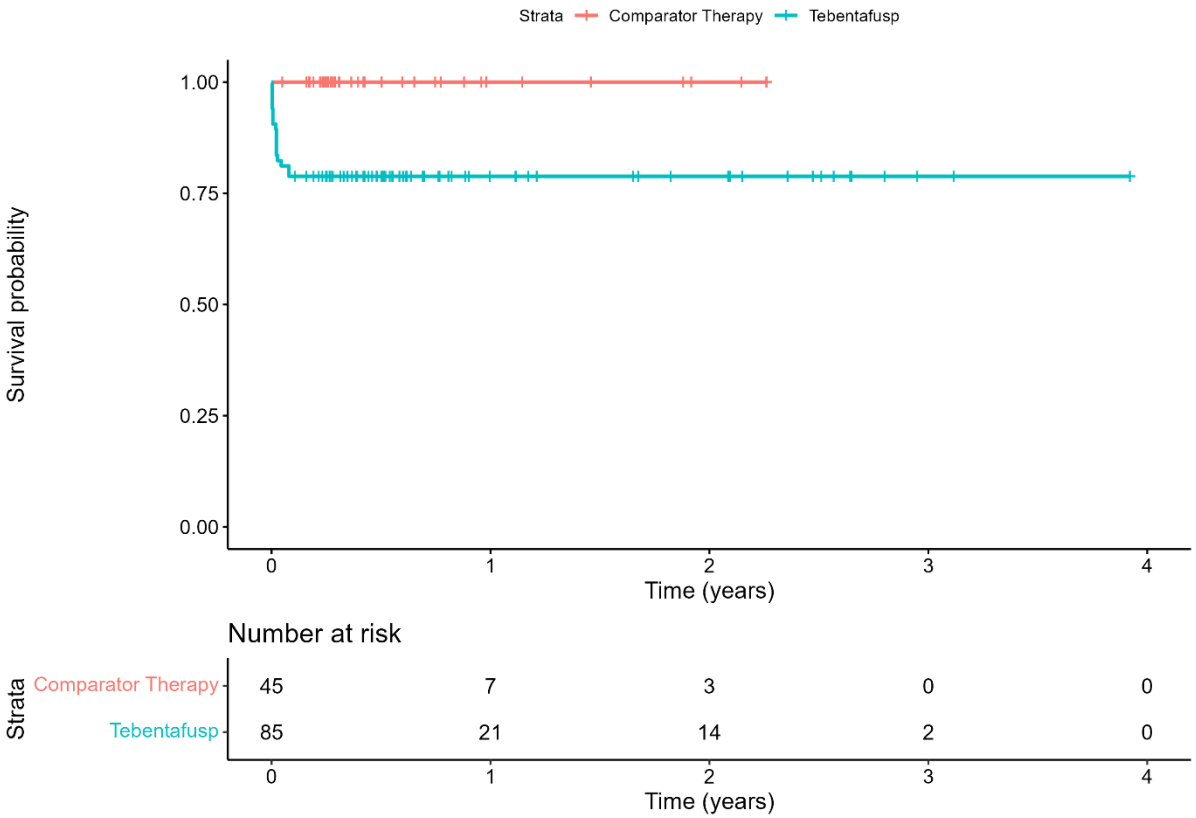
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



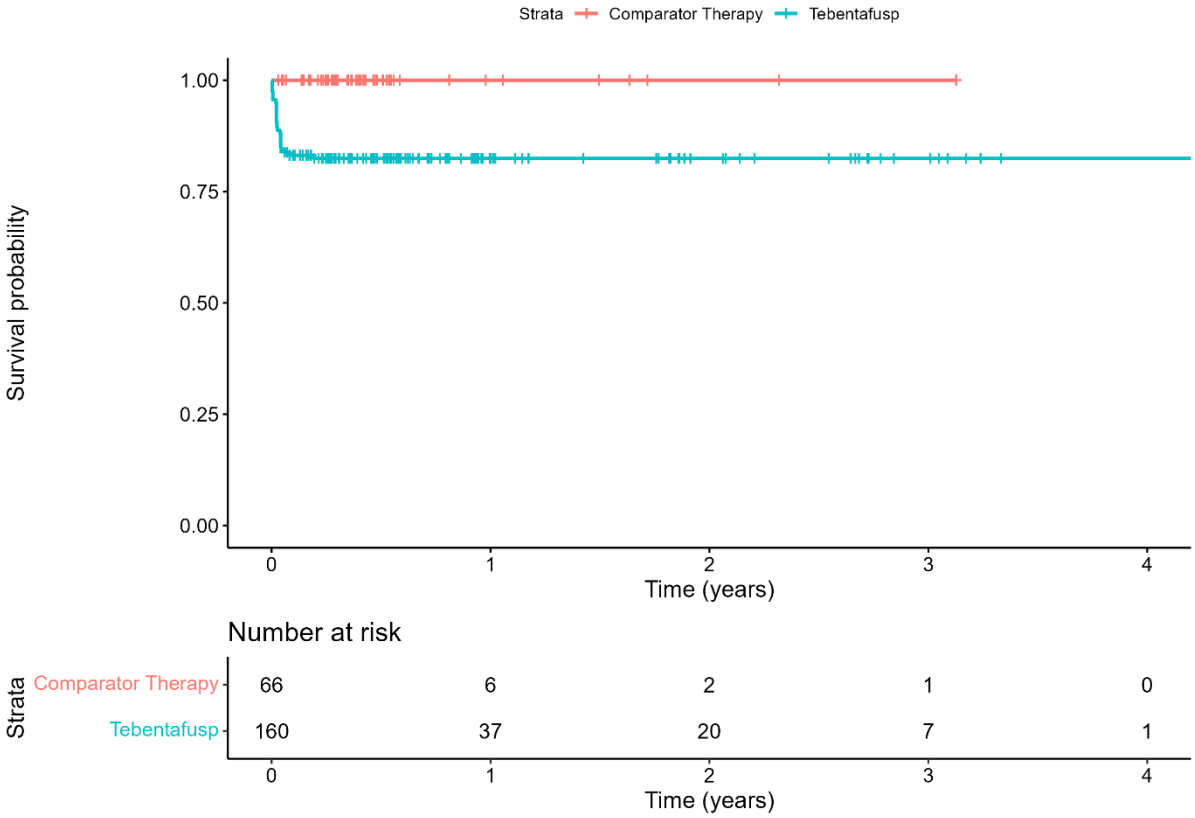
Größte metastatische Läsion (Baseline): ≥8,1 cm



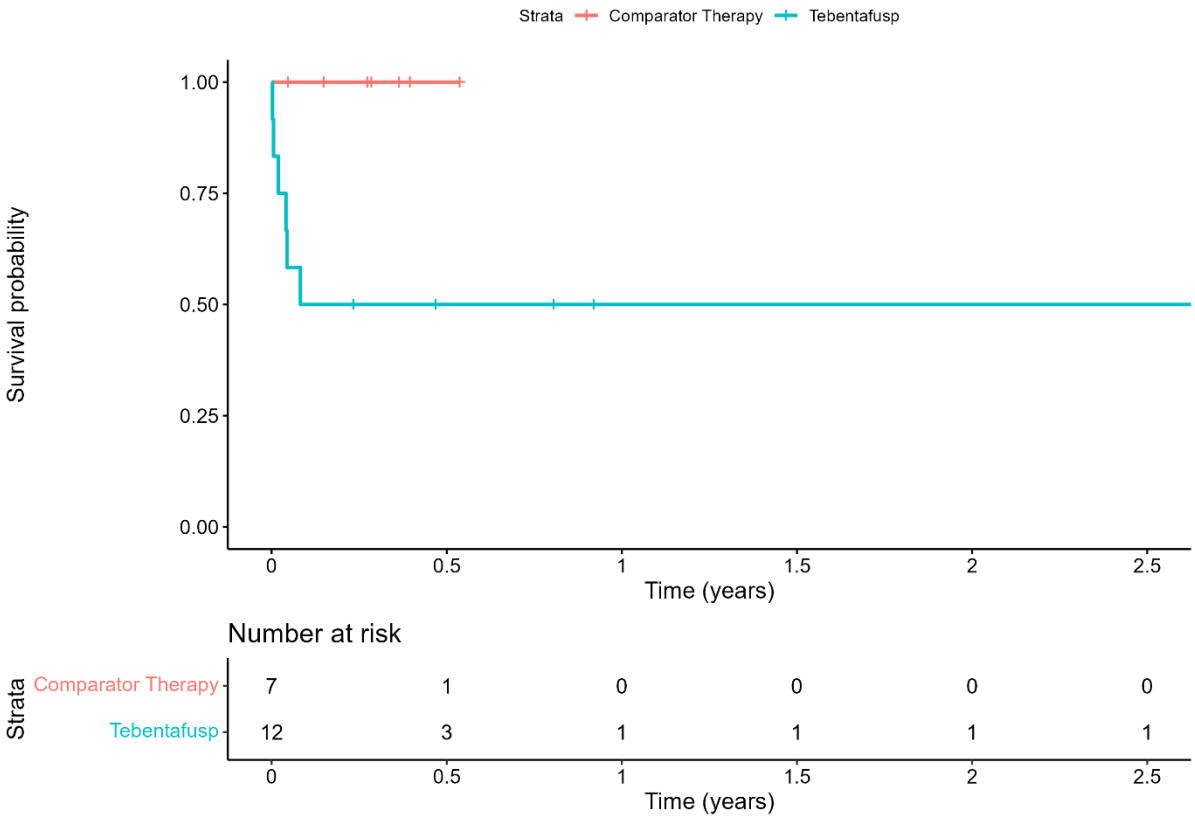
Region: Nordamerika



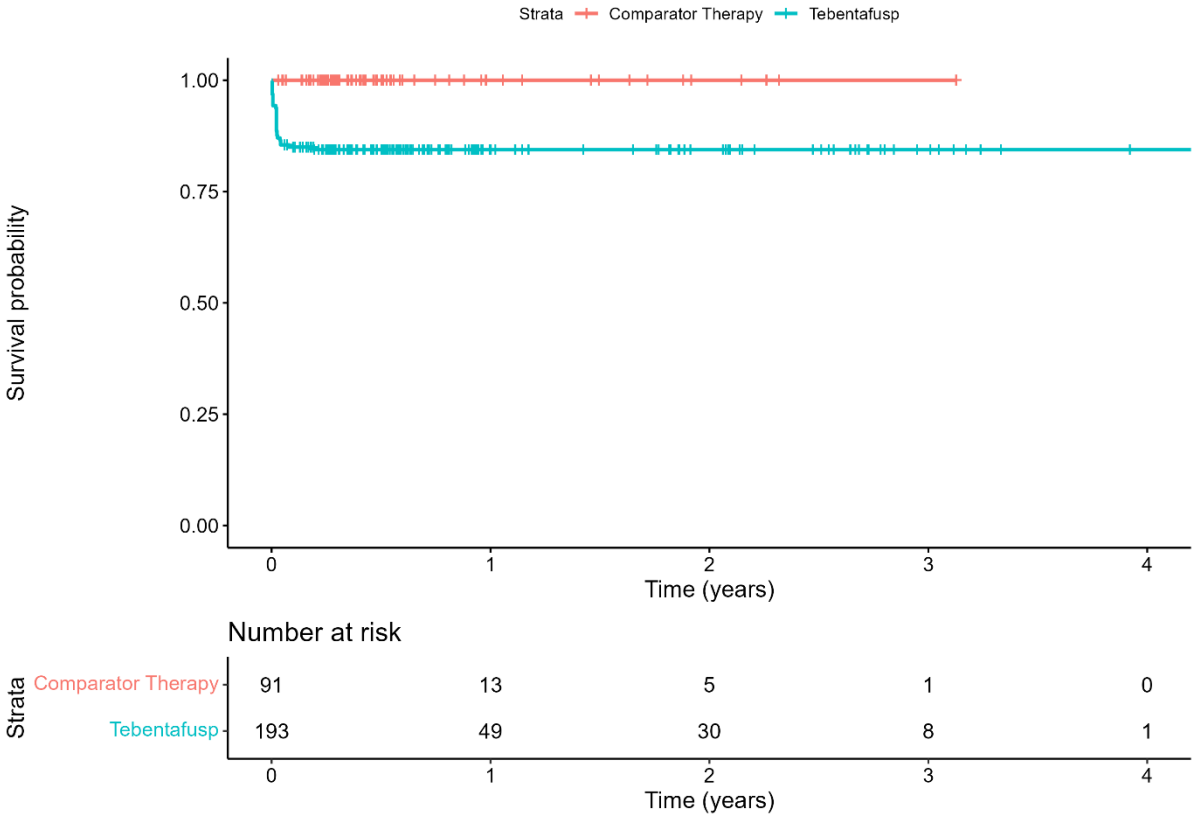
Region: Nicht-Nordamerika



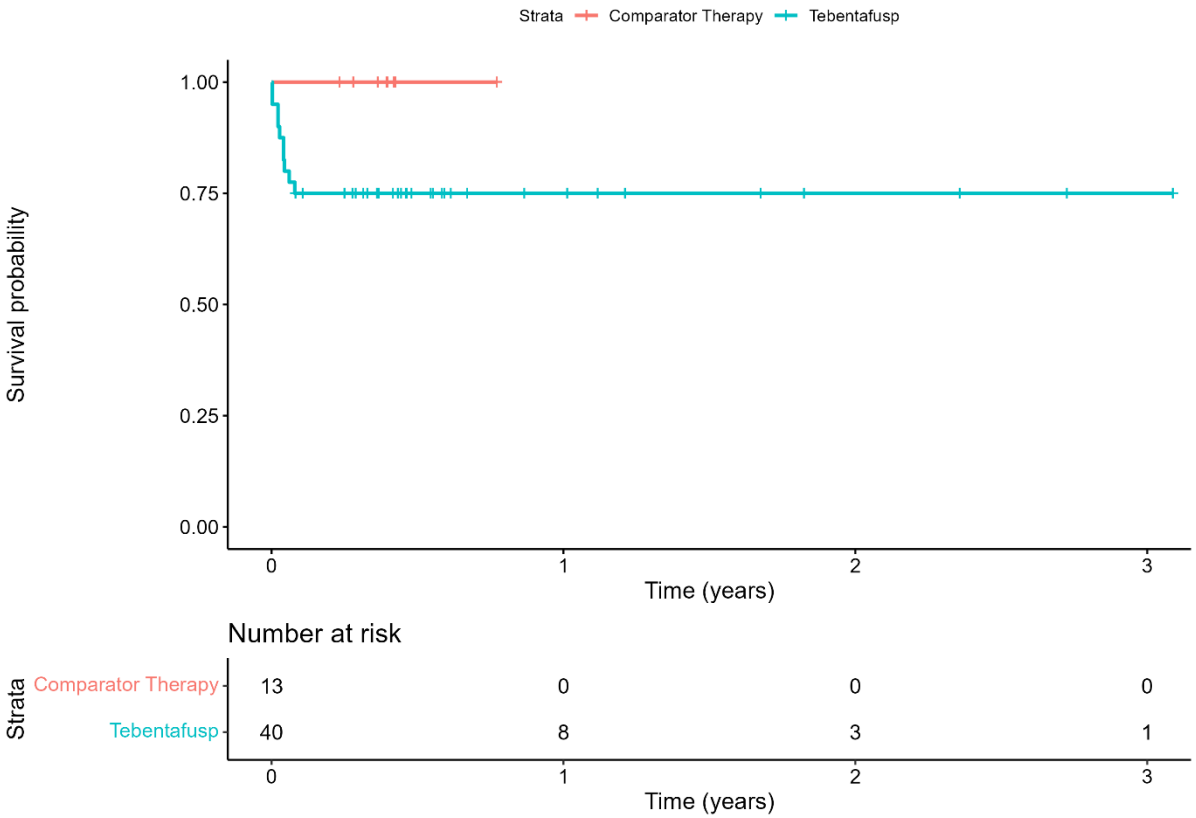
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

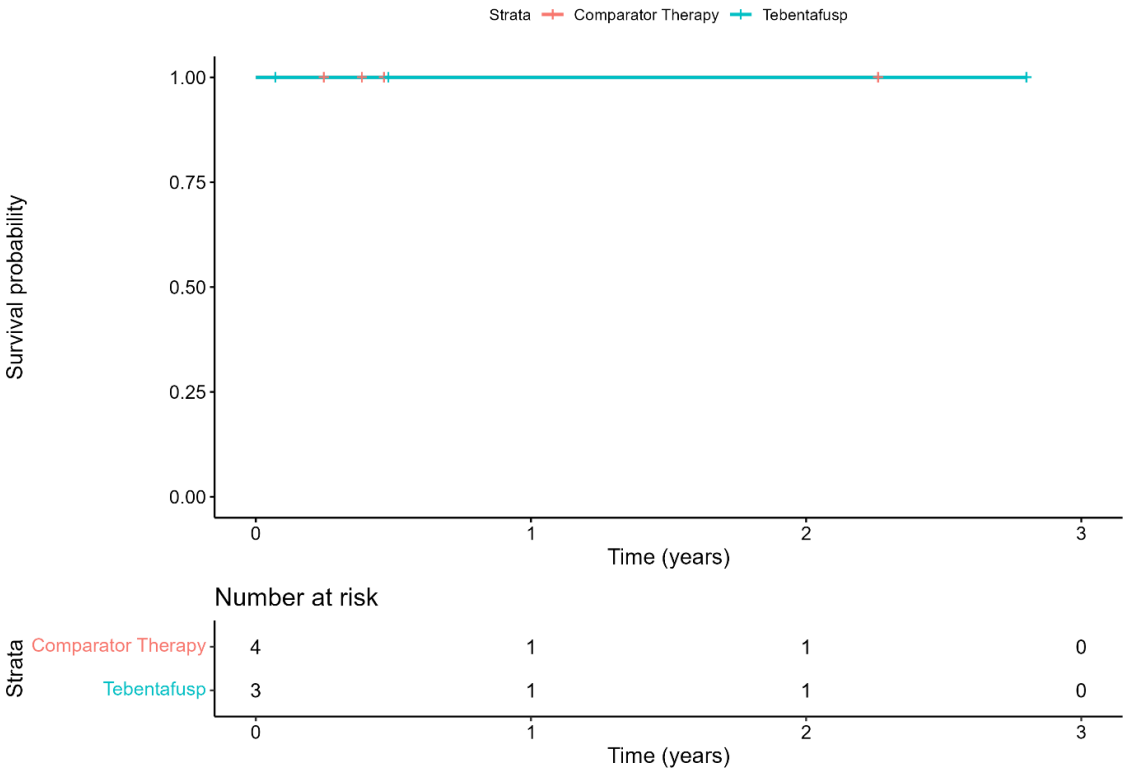


Vorauswahl der Chemotherapie: Ipilimumab

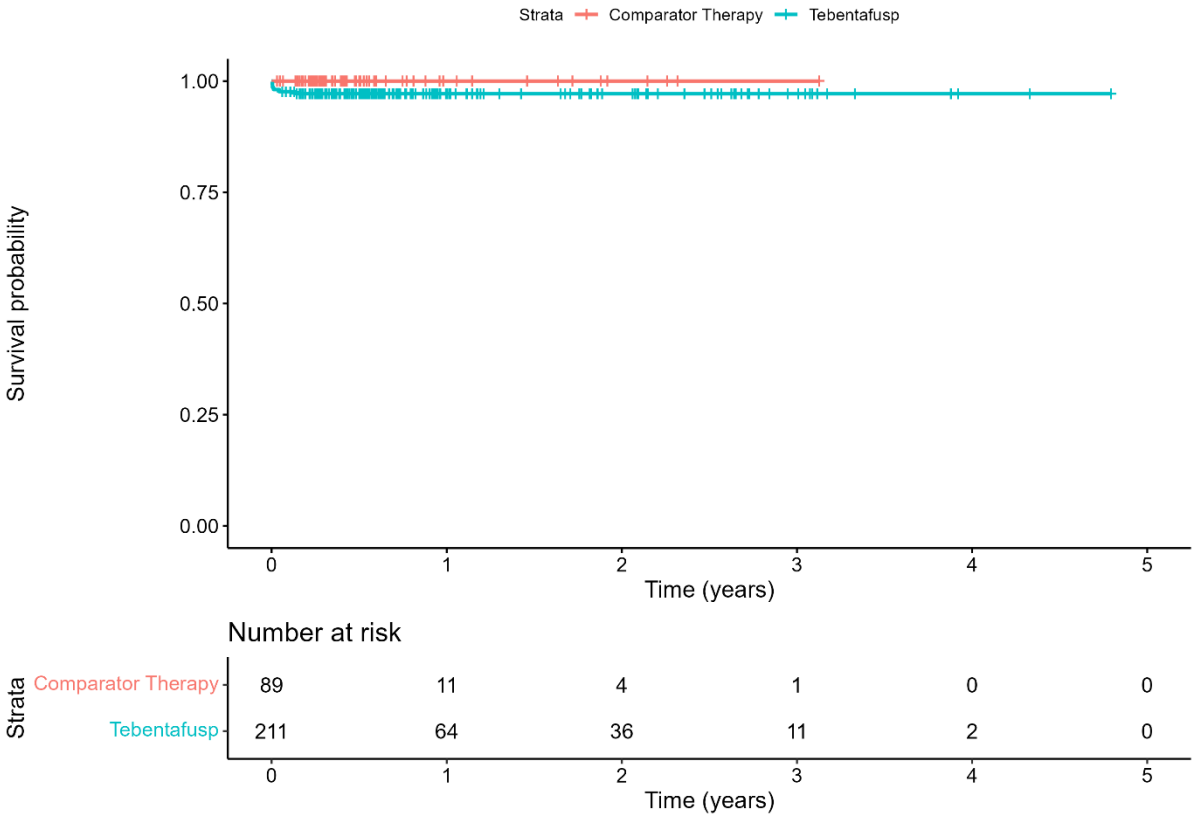


59.11 Schwerwiegender Hautausschlag (Tabelle 4-234)

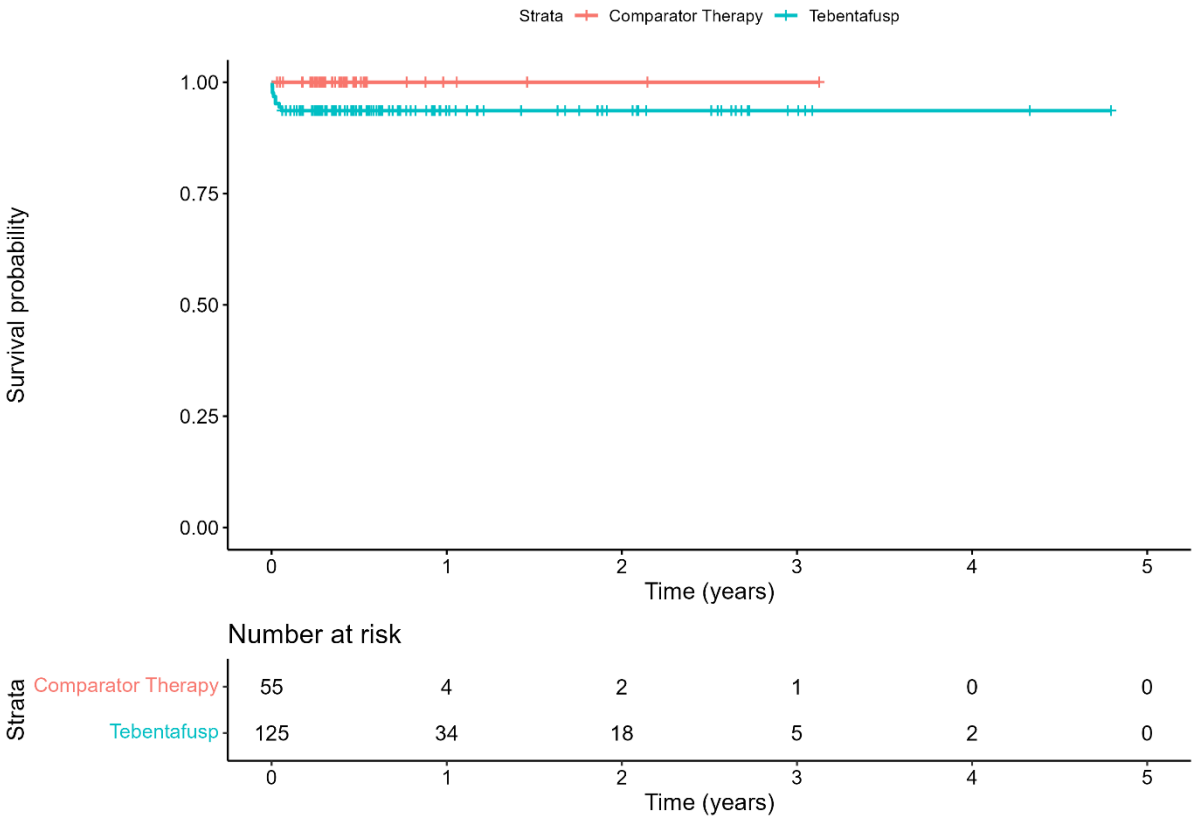
Herkunft: Hispanisch



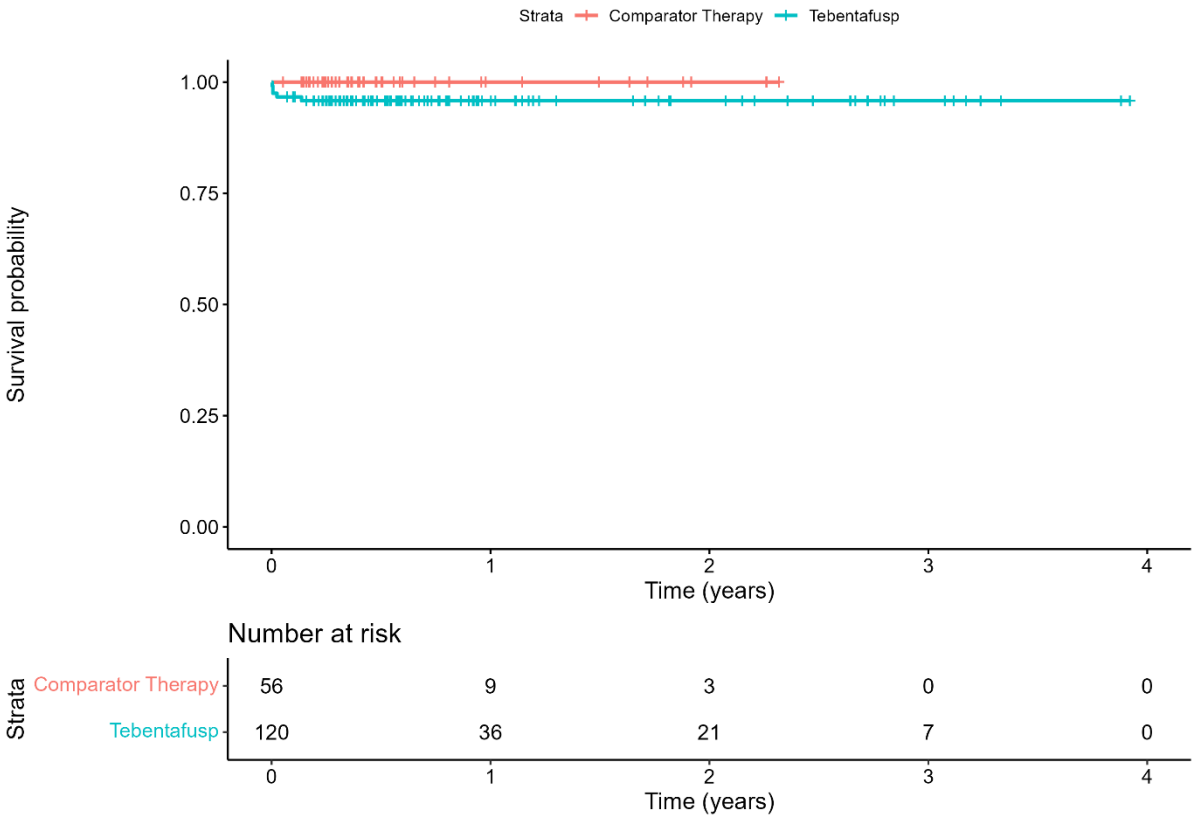
Herkunft: Nicht-hispanisch



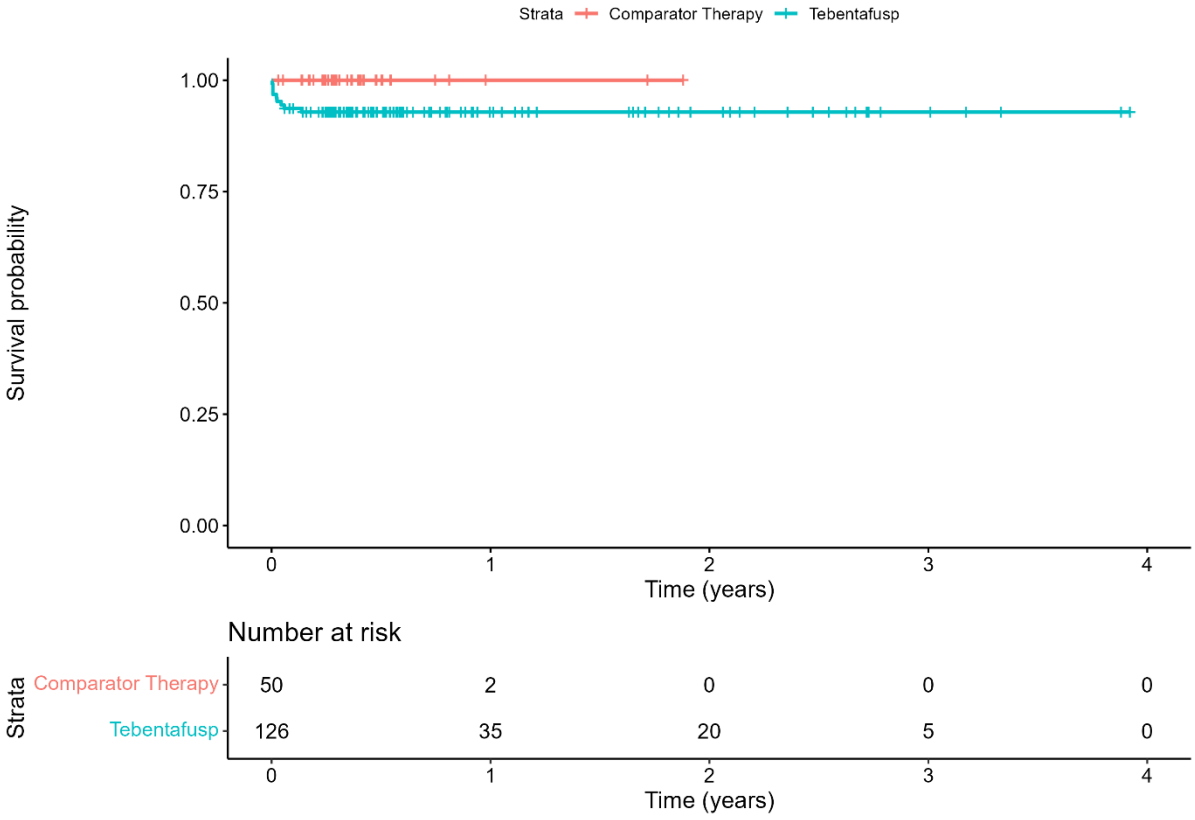
Geschlecht: Männlich



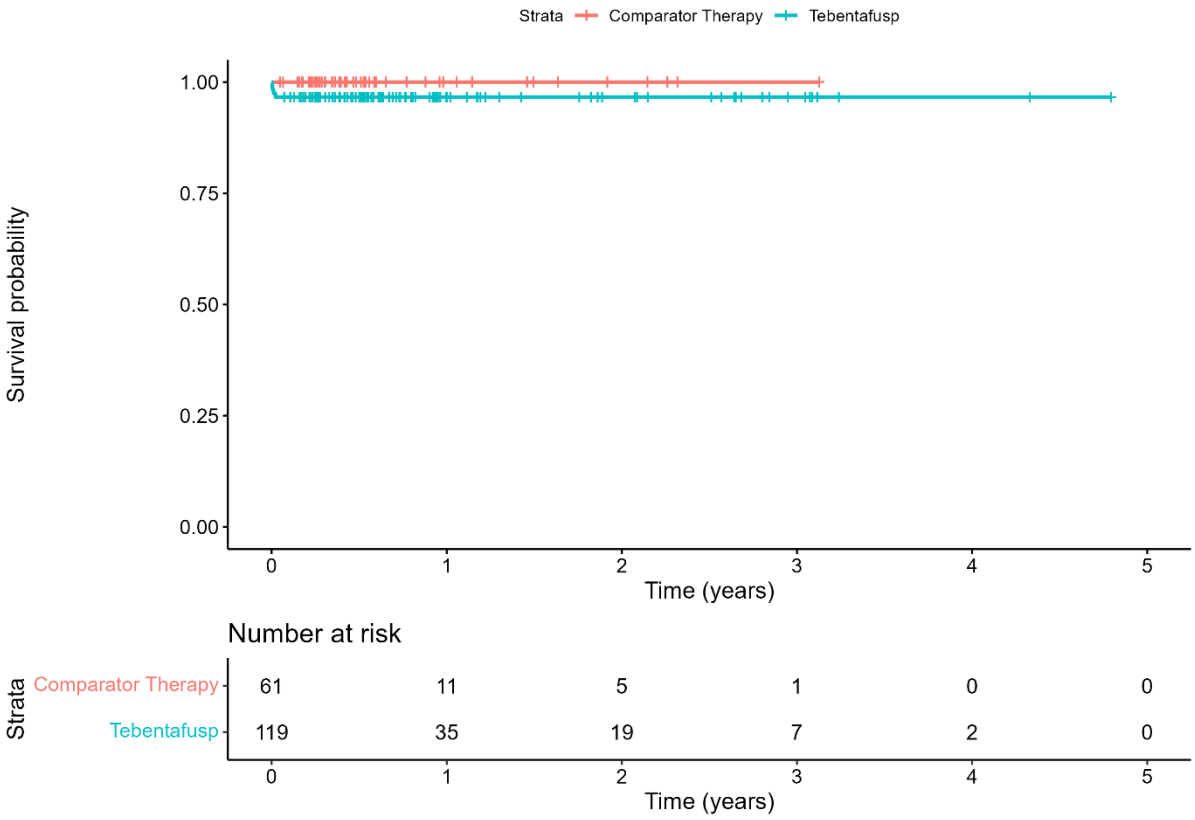
Geschlecht: Weiblich



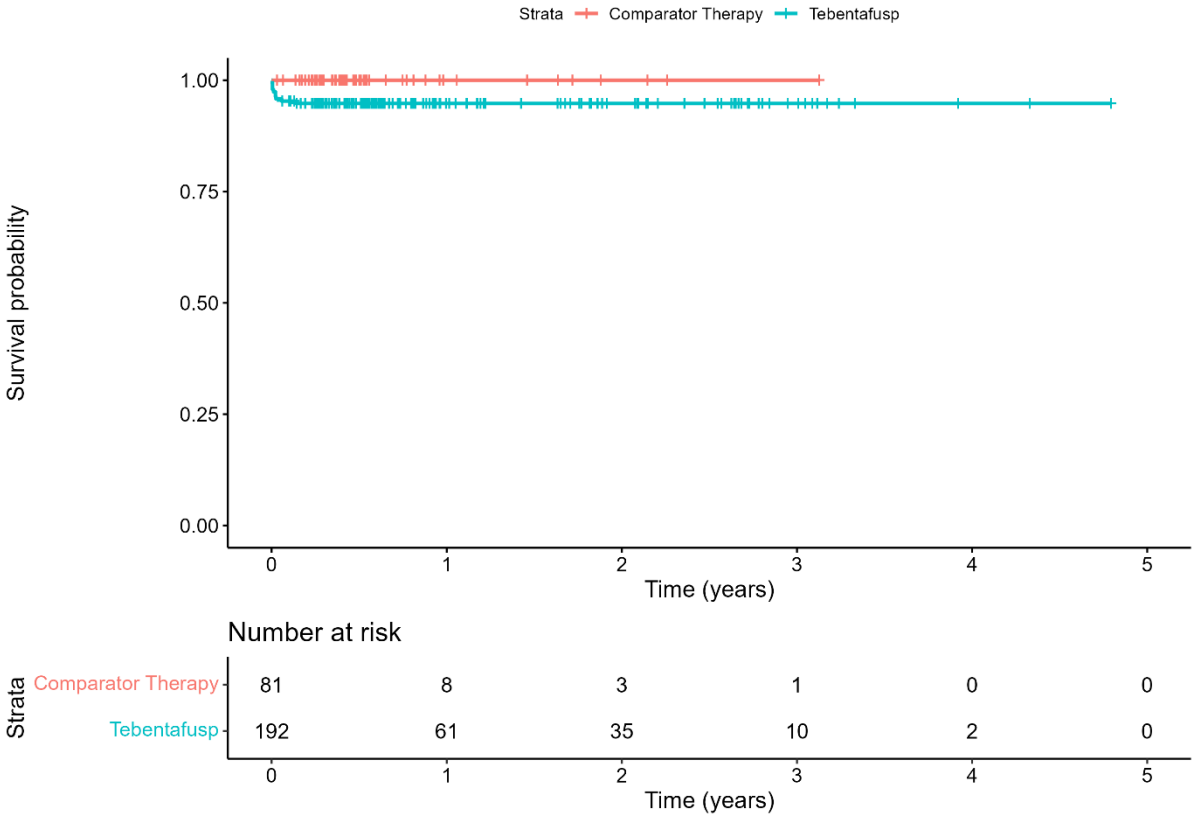
Alter: <65 Jahre



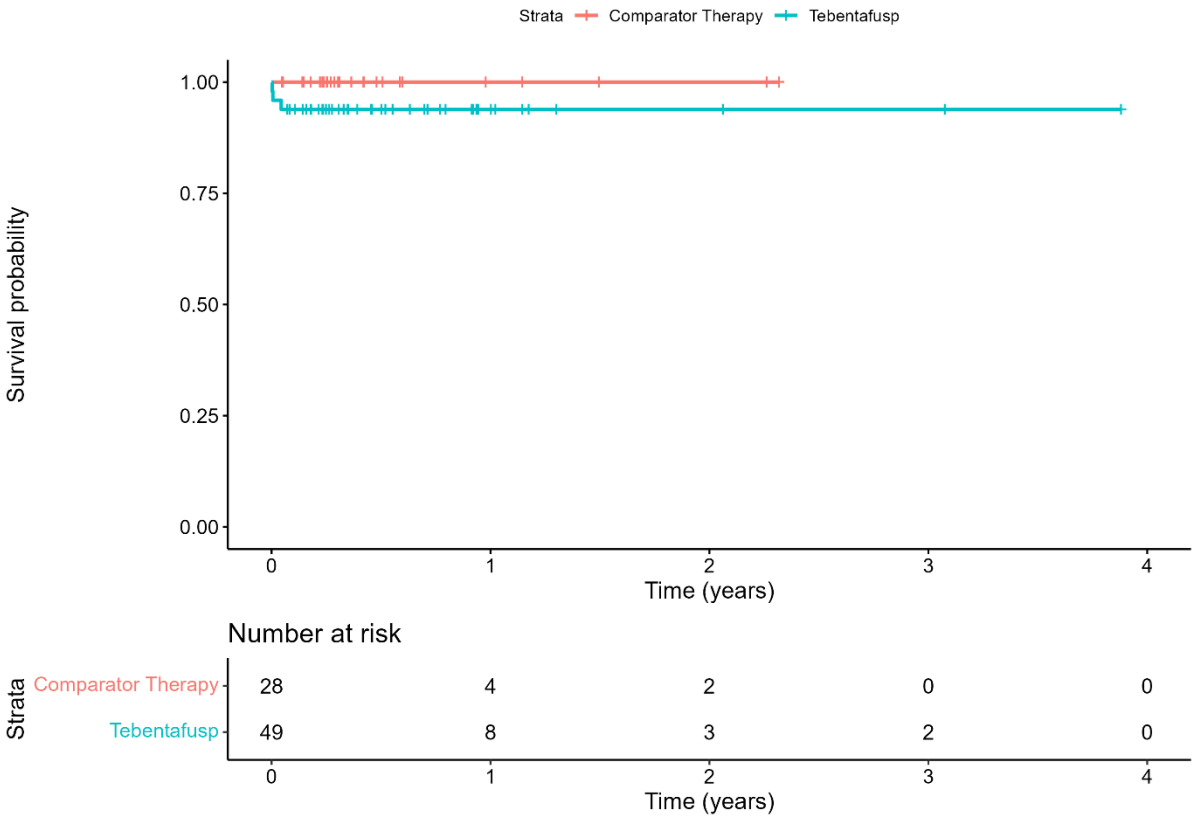
Alter: ≥65 Jahre



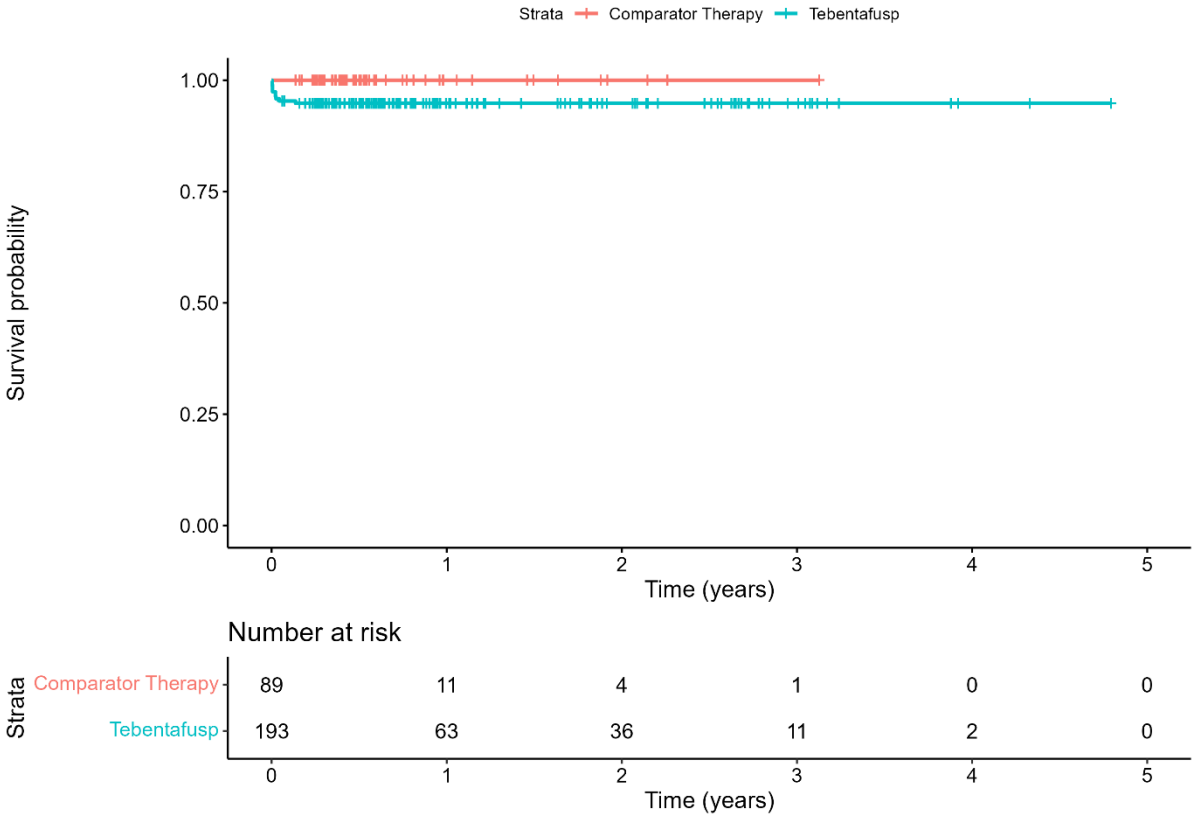
ECOG-Performance-Status: 0



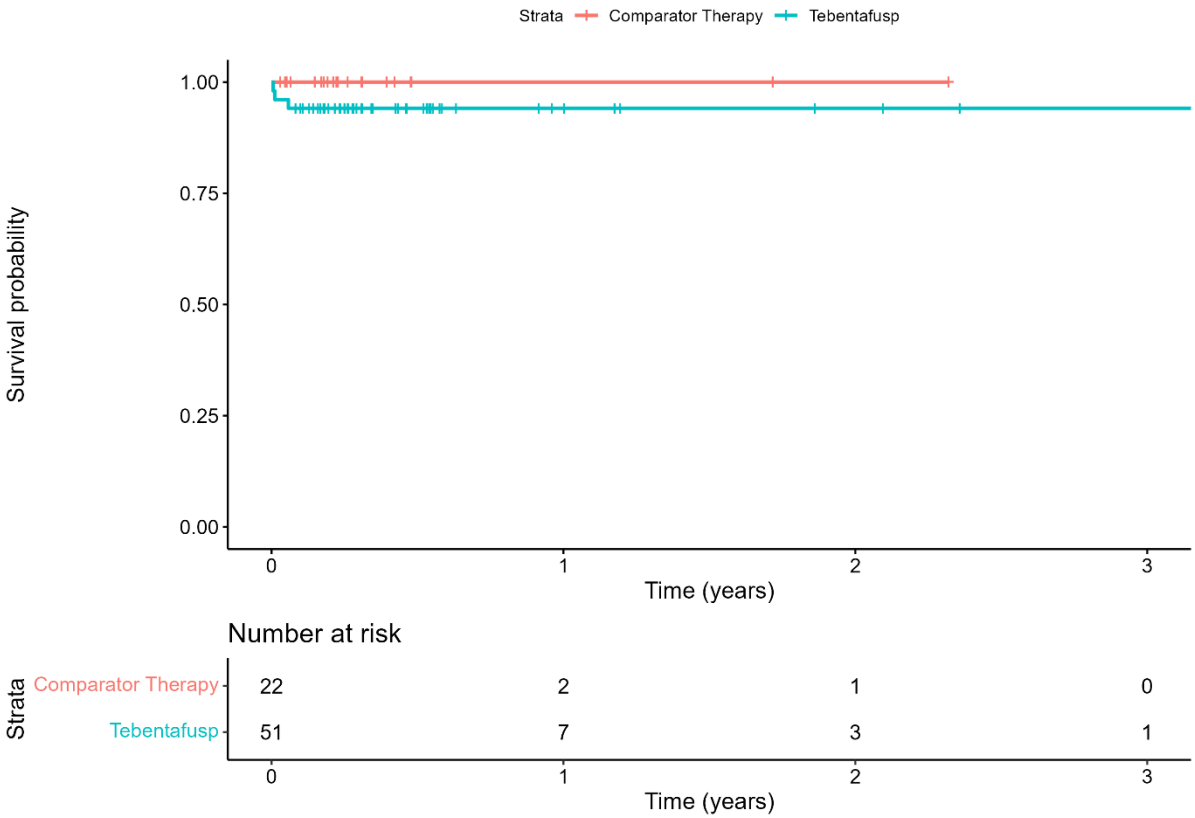
ECOG-Performance-Status: 1



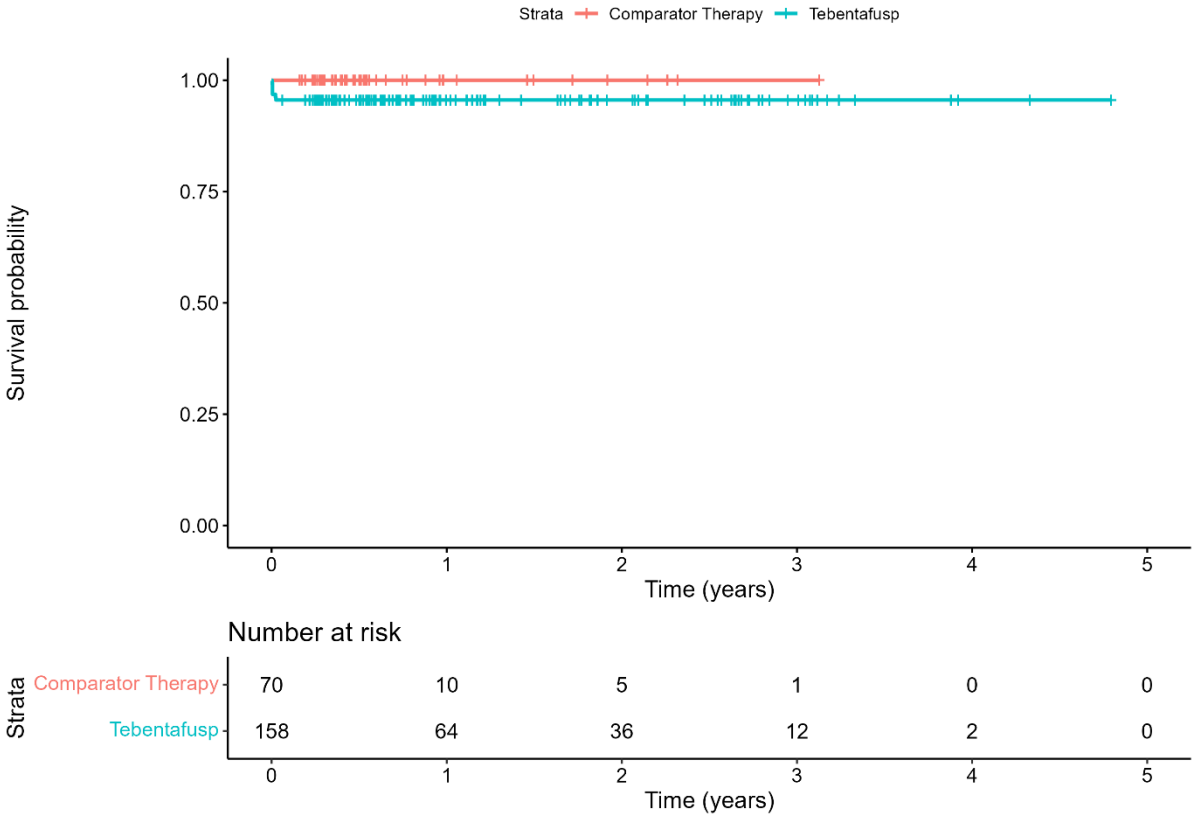
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



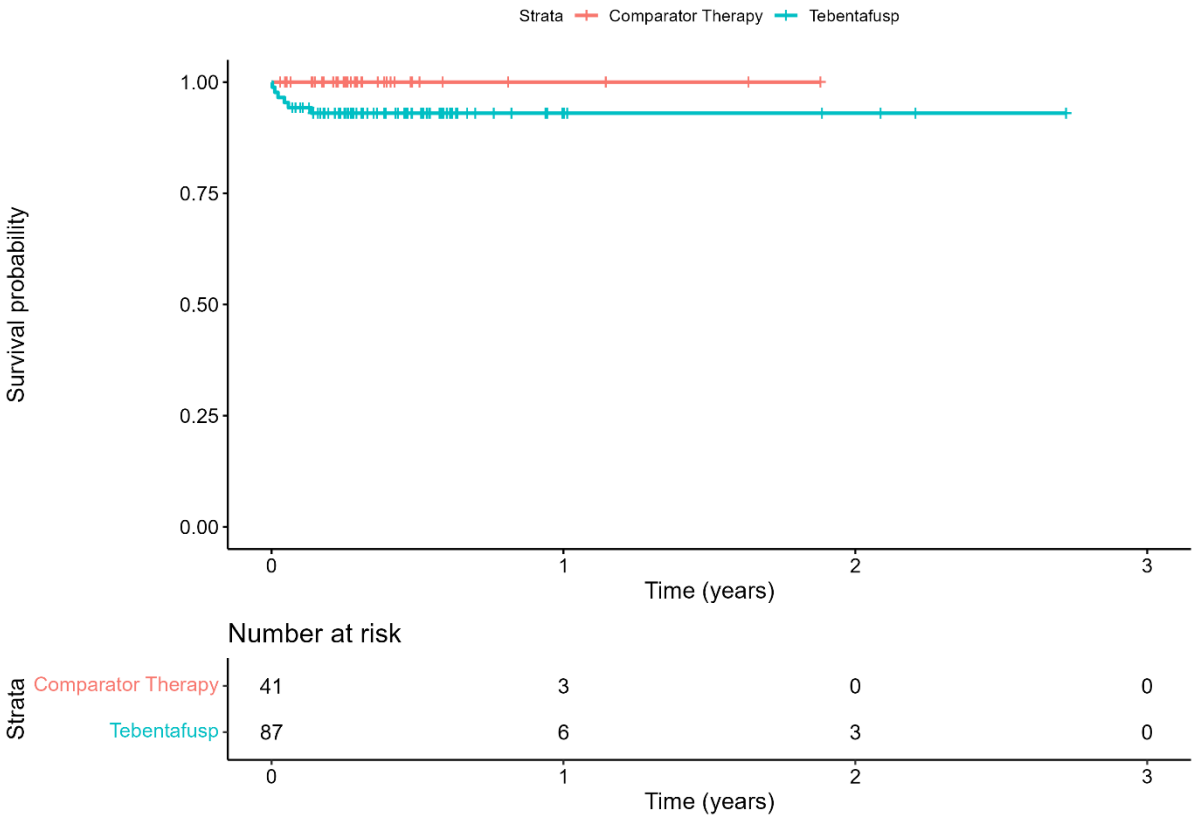
Alkalische Phosphatase (ALP) (Baseline): >ULN



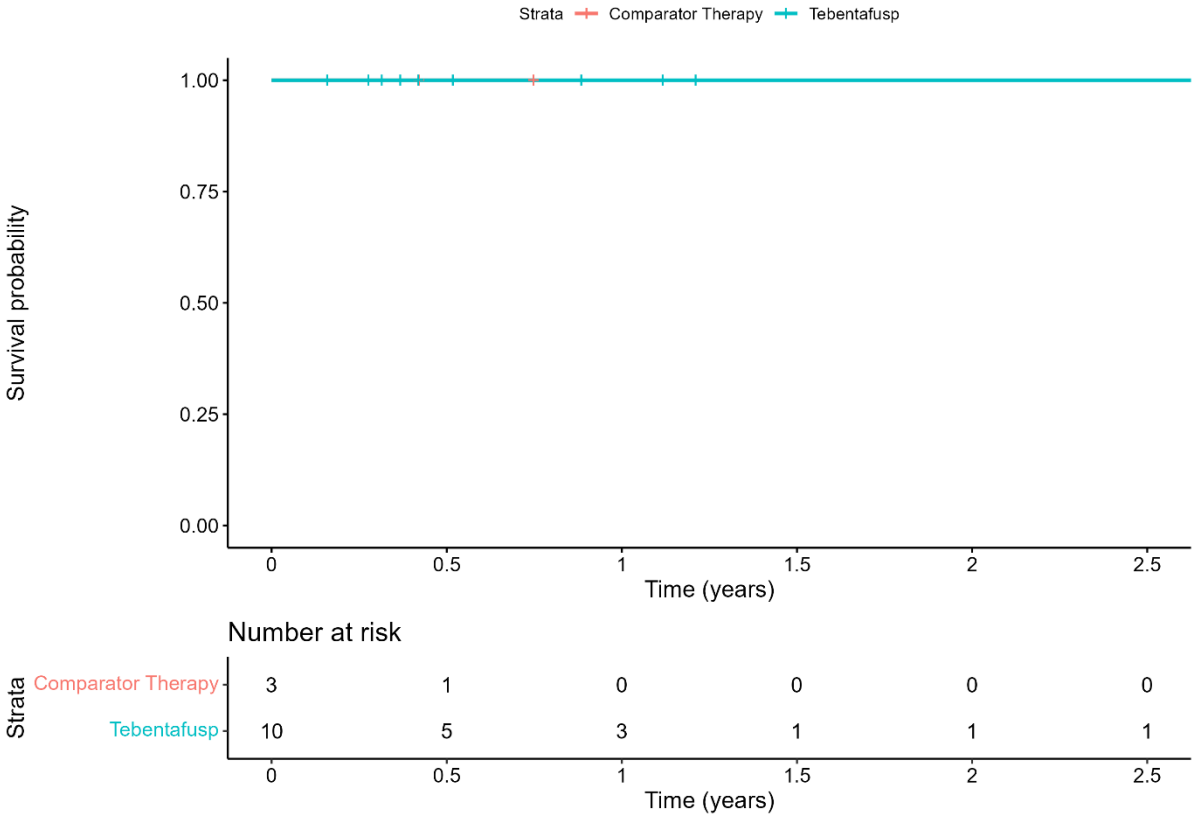
LDH: ≤ULN



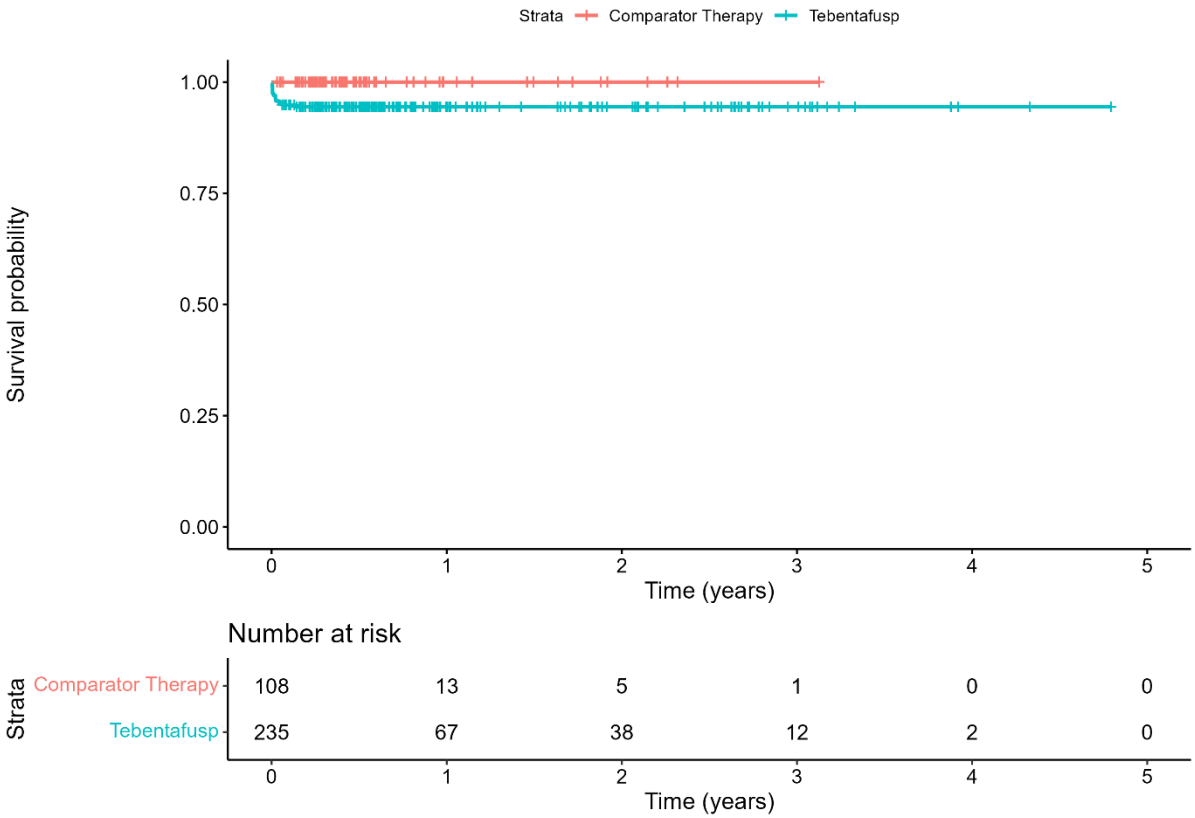
LDH: >ULN



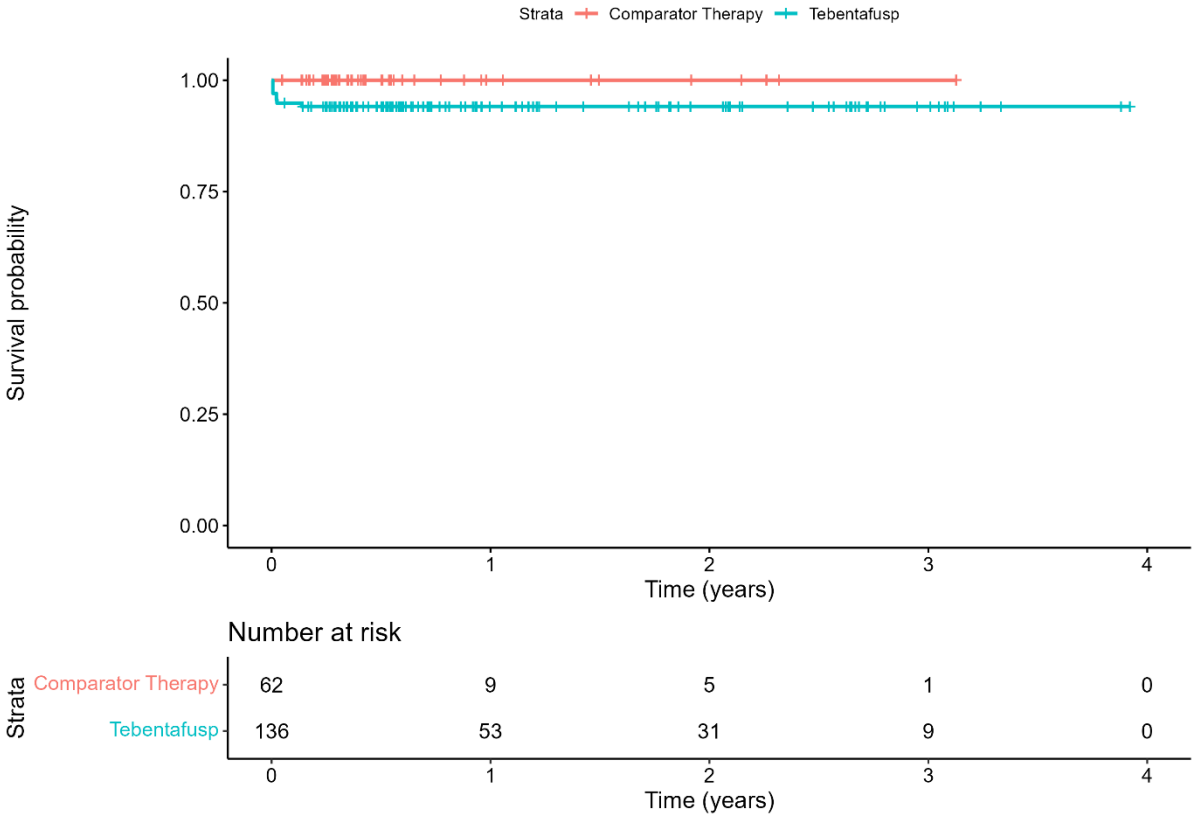
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



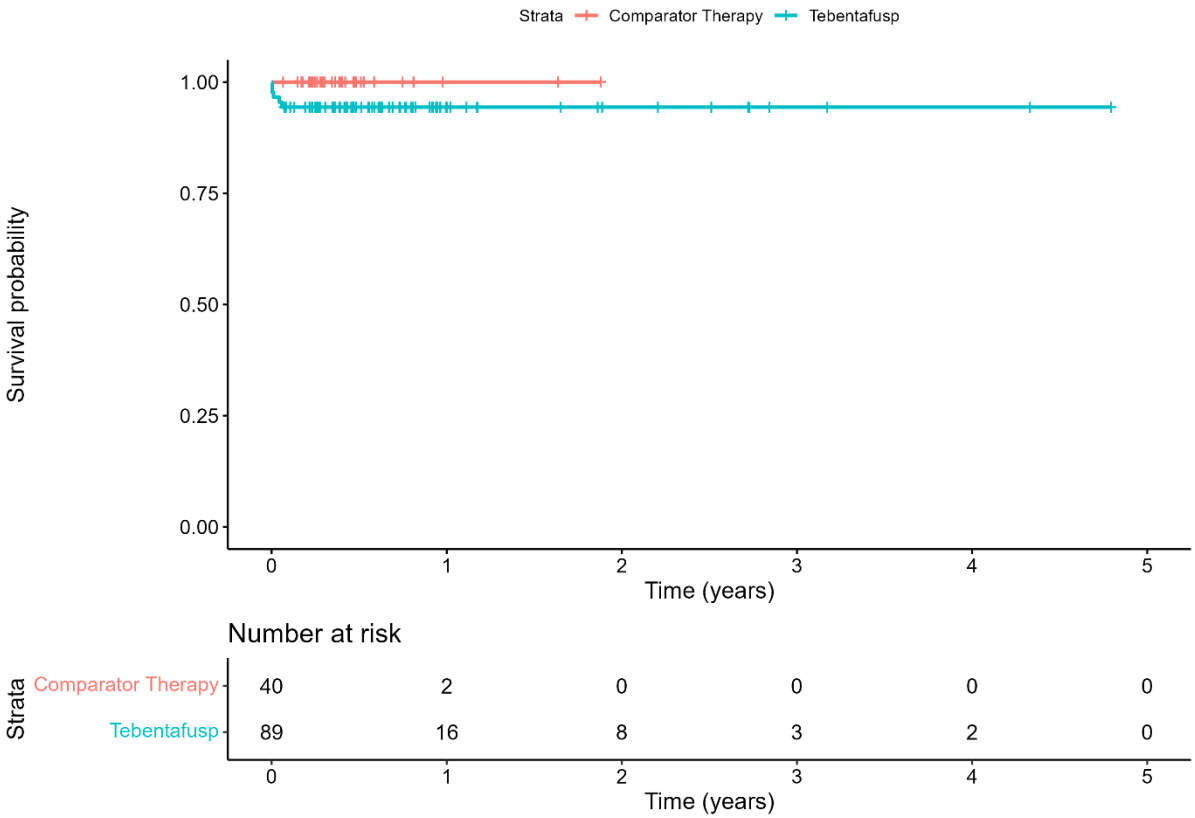
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



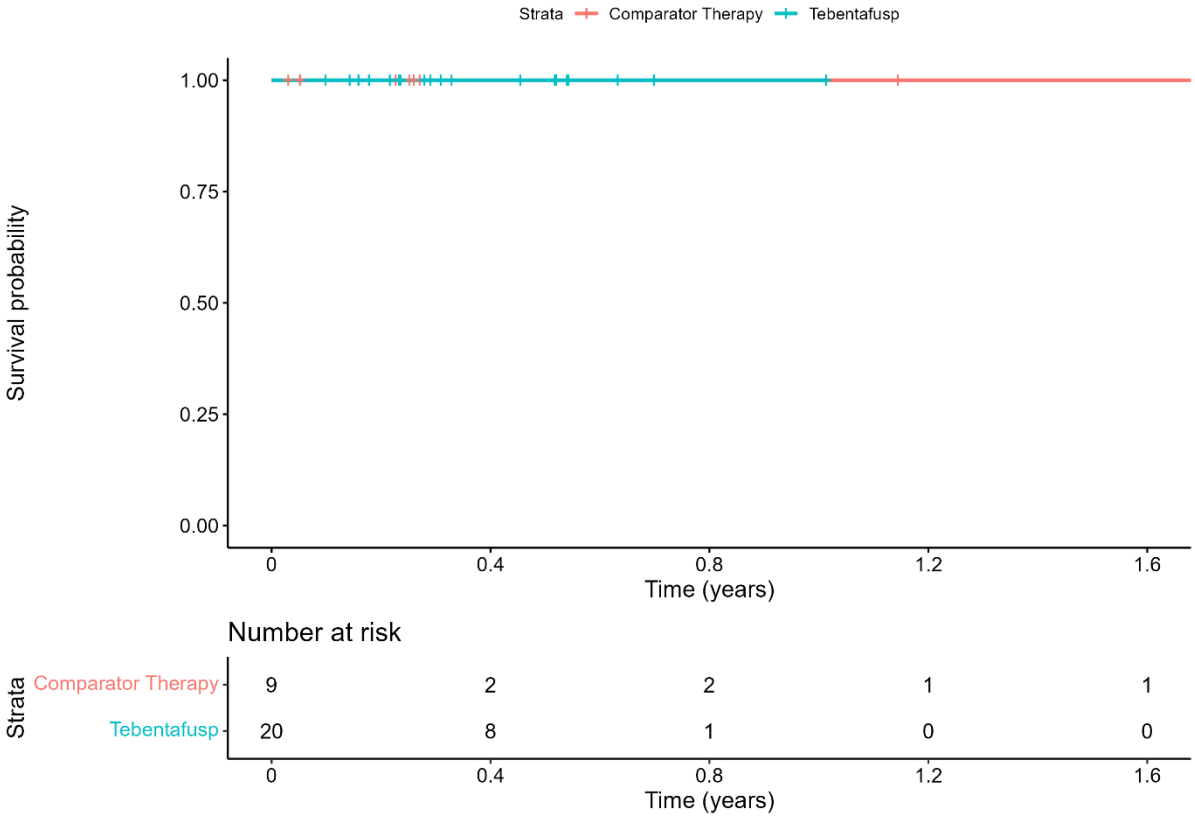
Größte metastatische Läsion (Baseline): ≤3,0 cm



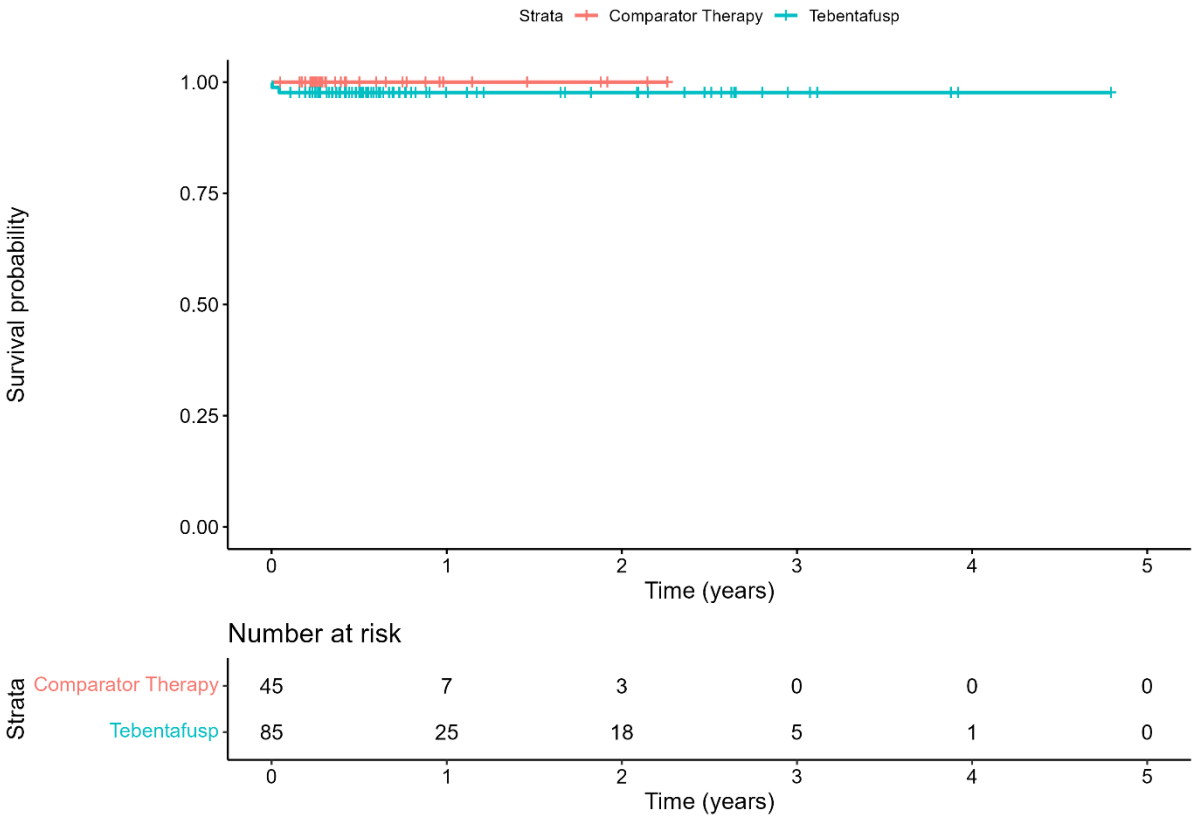
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



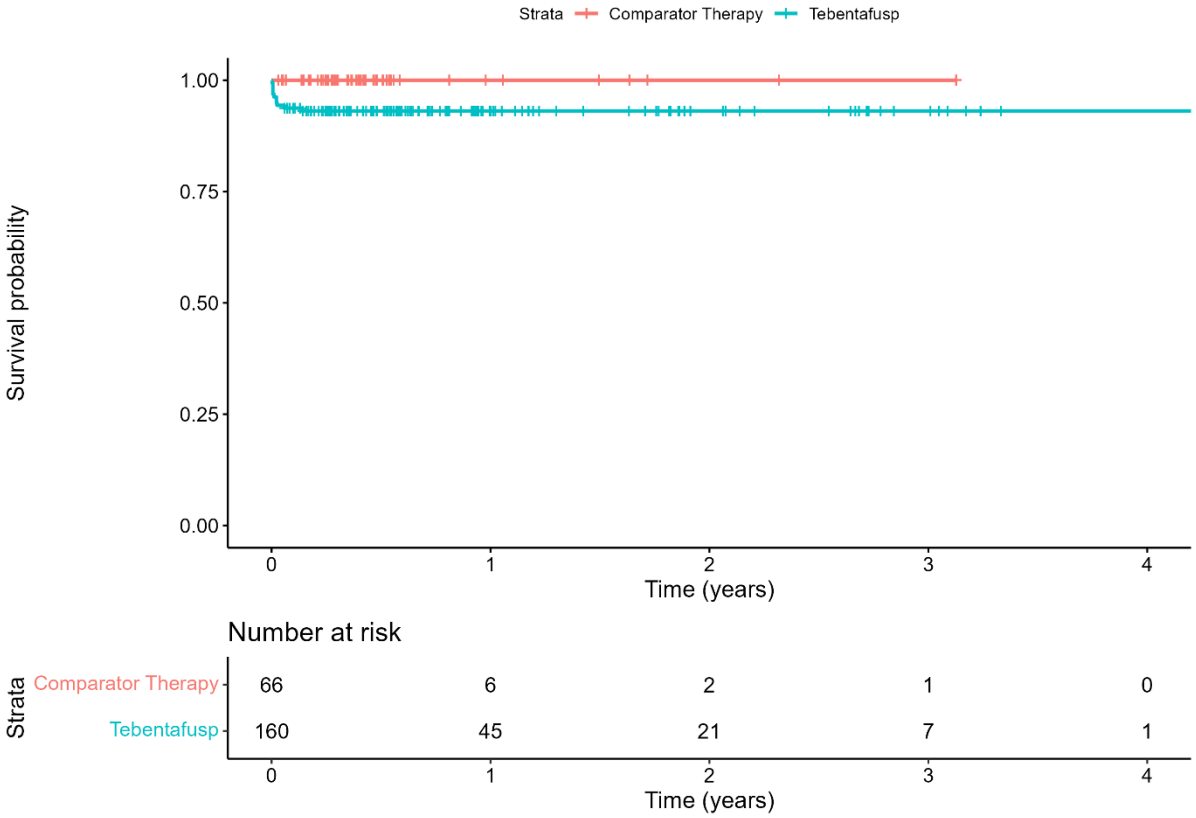
Größte metastatische Läsion (Baseline): ≥8,1 cm



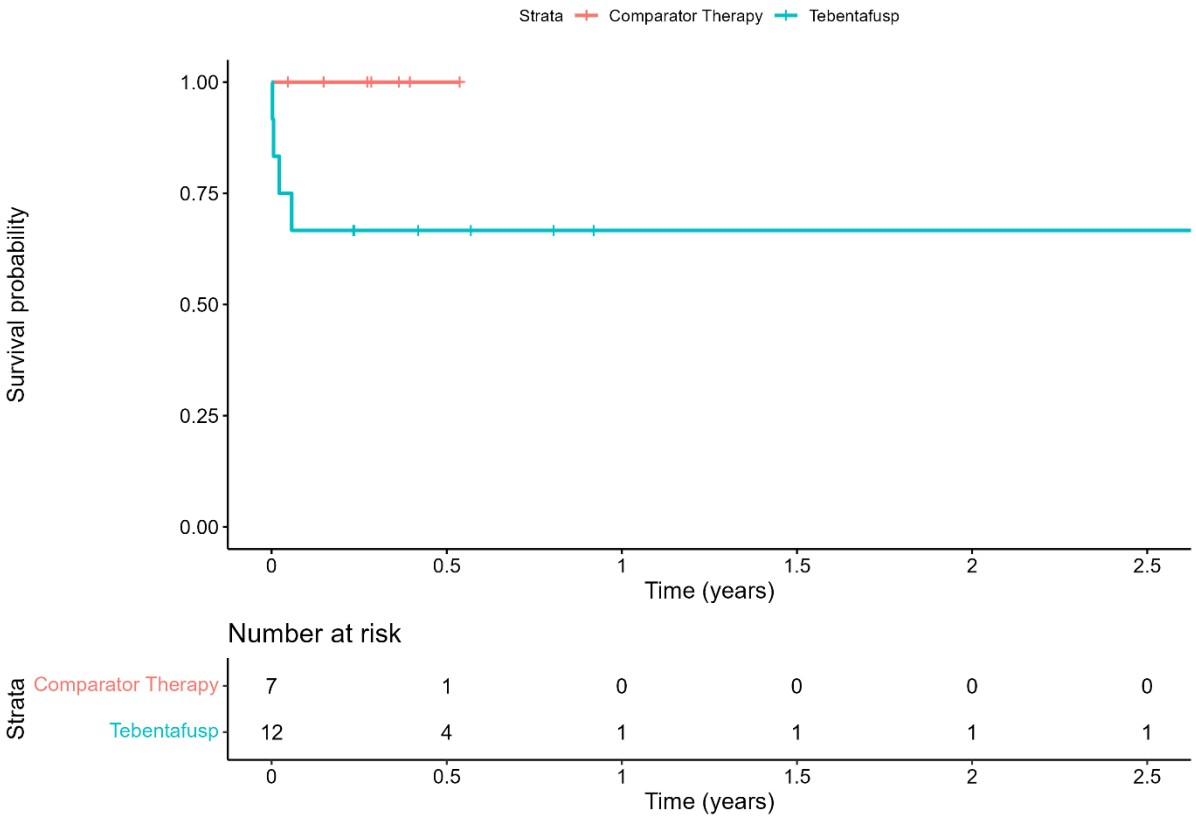
Region: Nordamerika



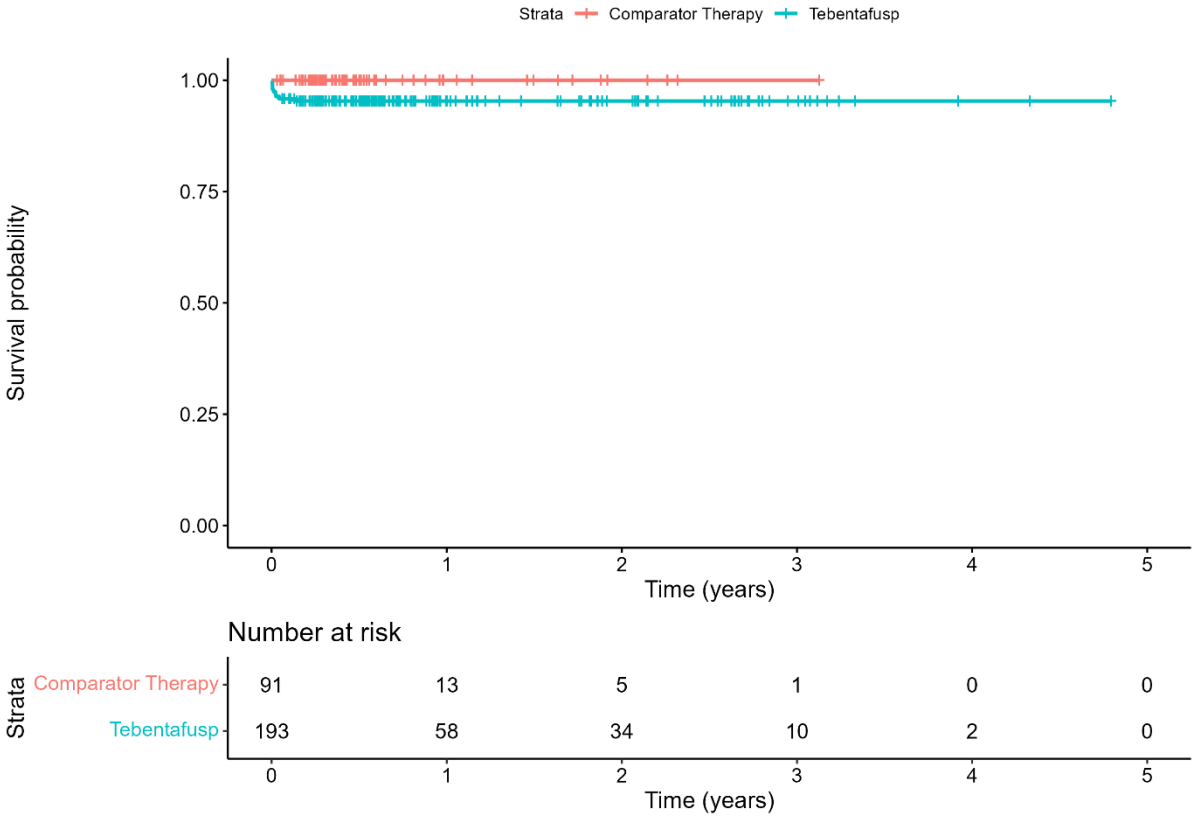
Region: Nicht-Nordamerika



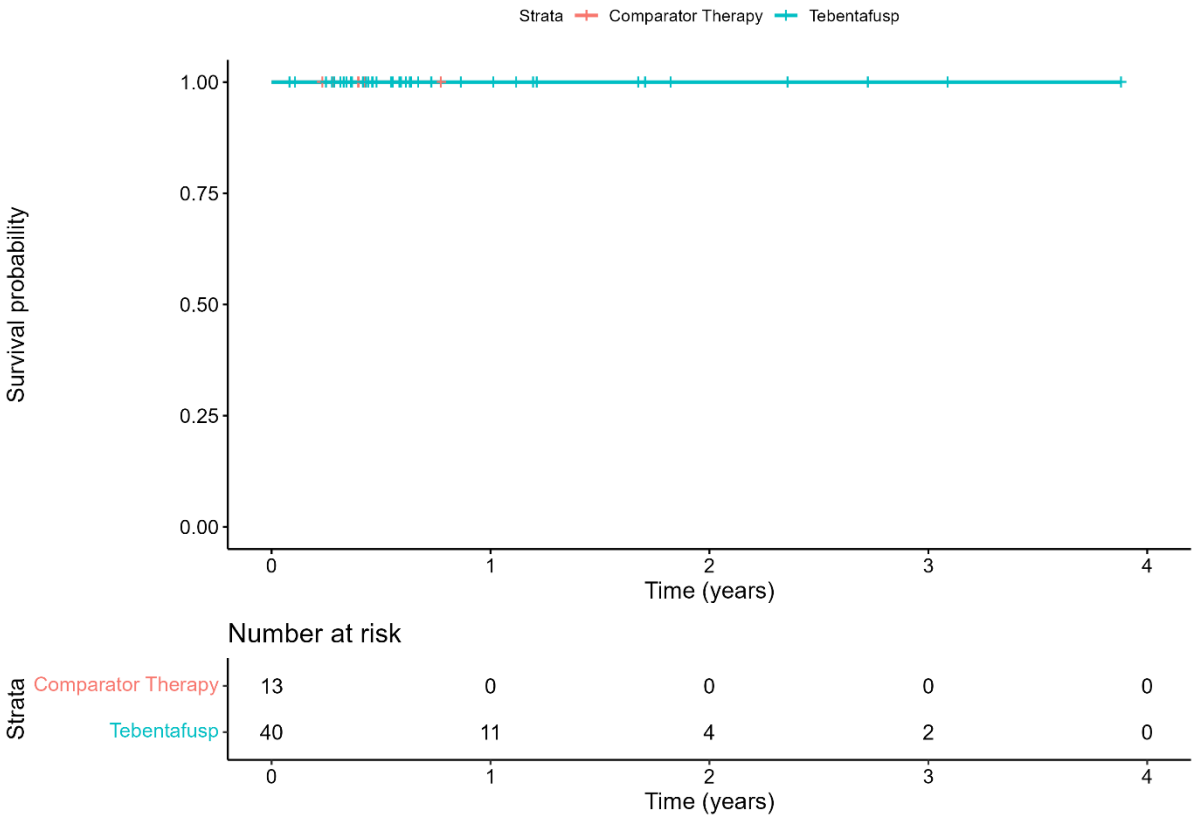
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

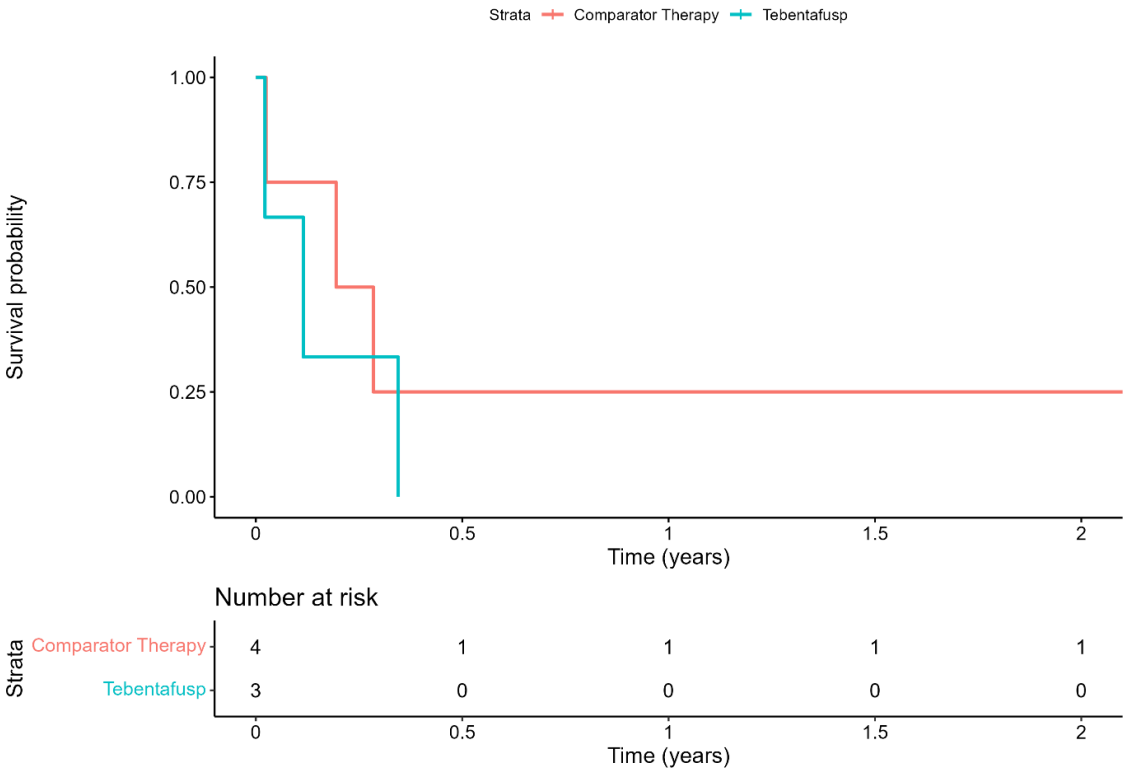


Vorauswahl der Chemotherapie: Ipilimumab

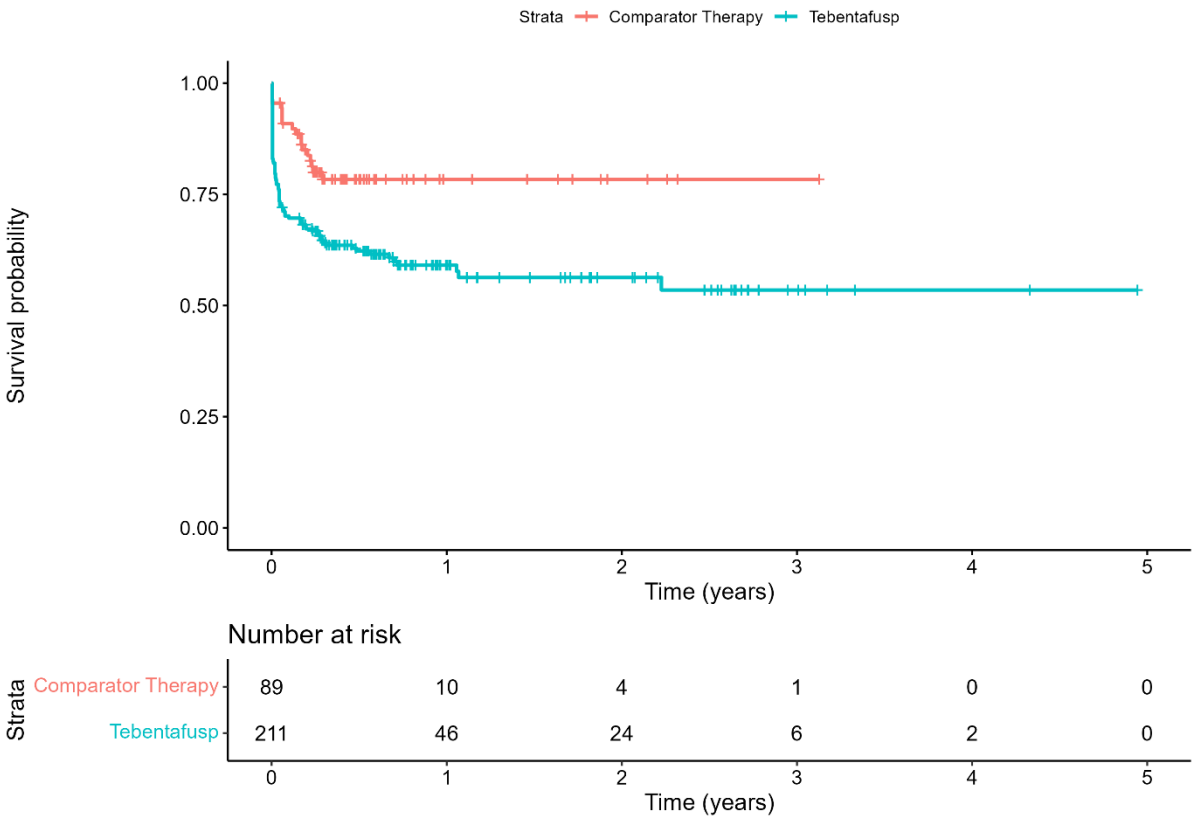


59.12 LFT-Erhöhung (Tabelle 4-237)

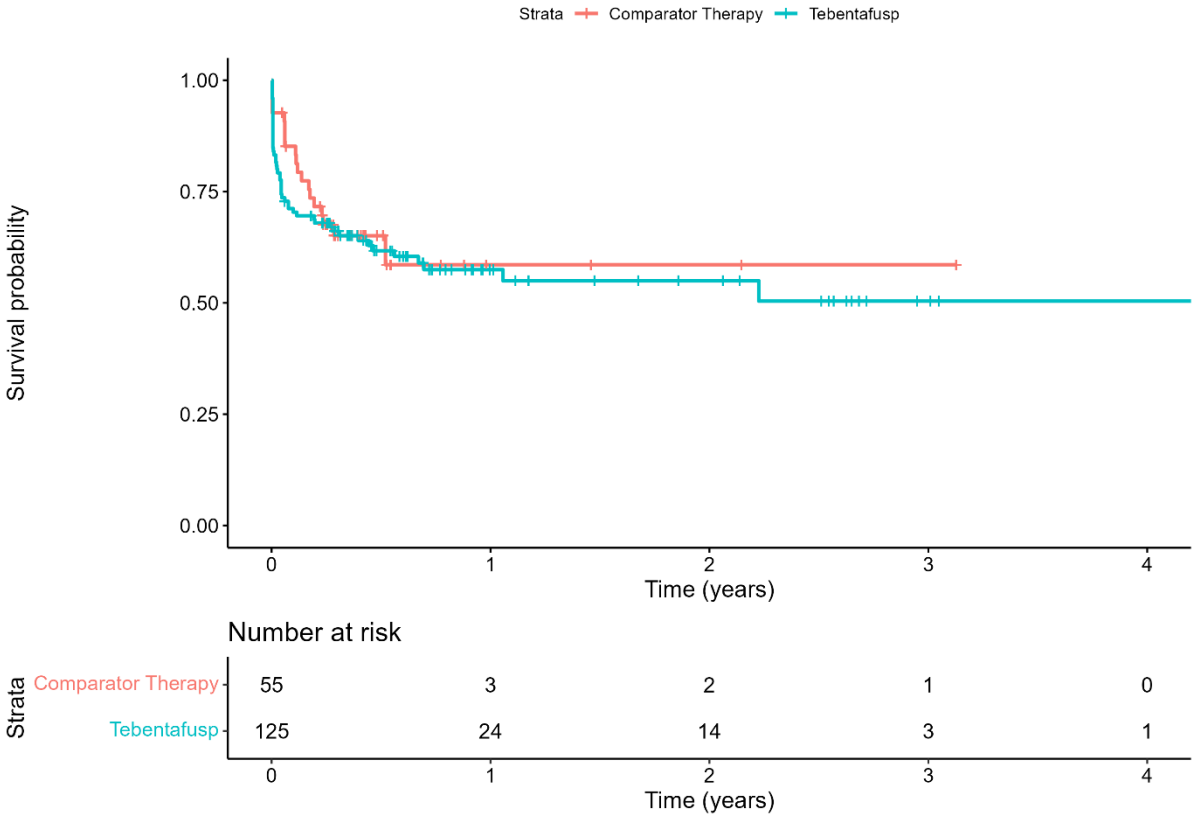
Herkunft: Hispanisch



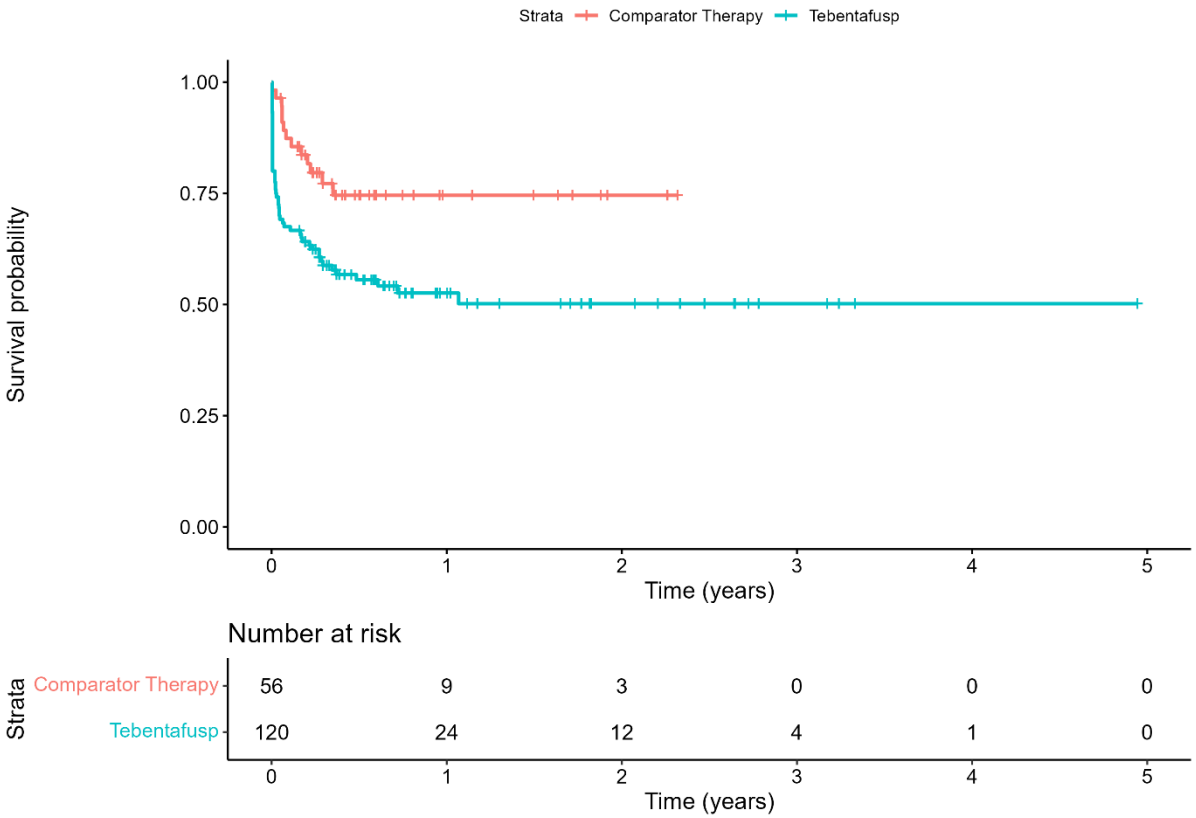
Herkunft: Nicht-hispanisch



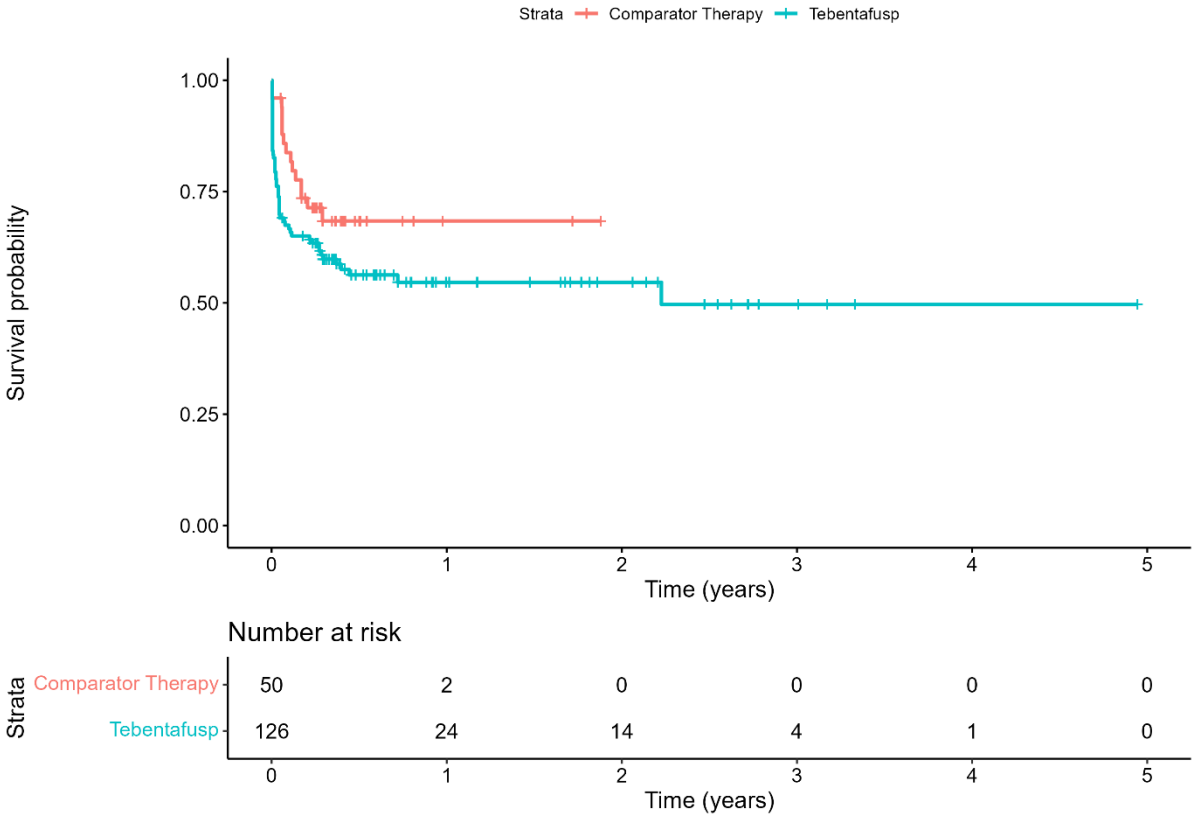
Geschlecht: Männlich



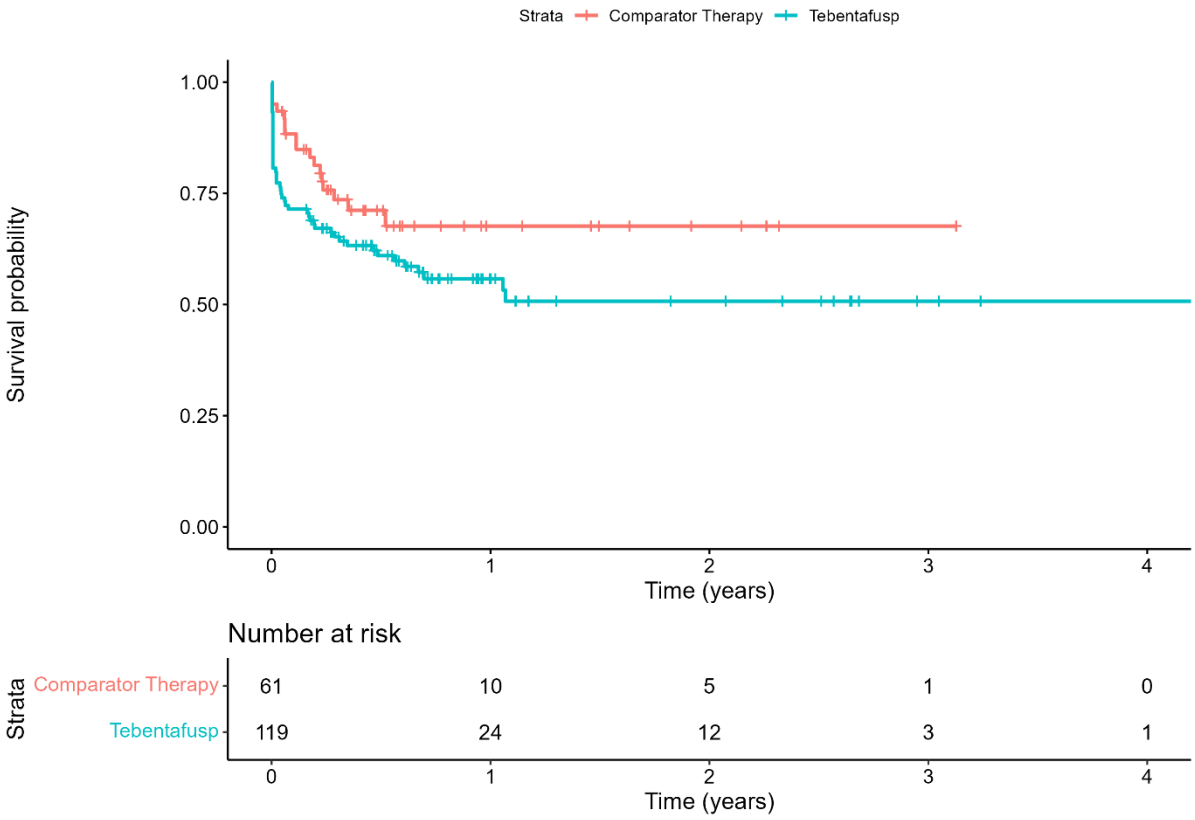
Geschlecht: Weiblich



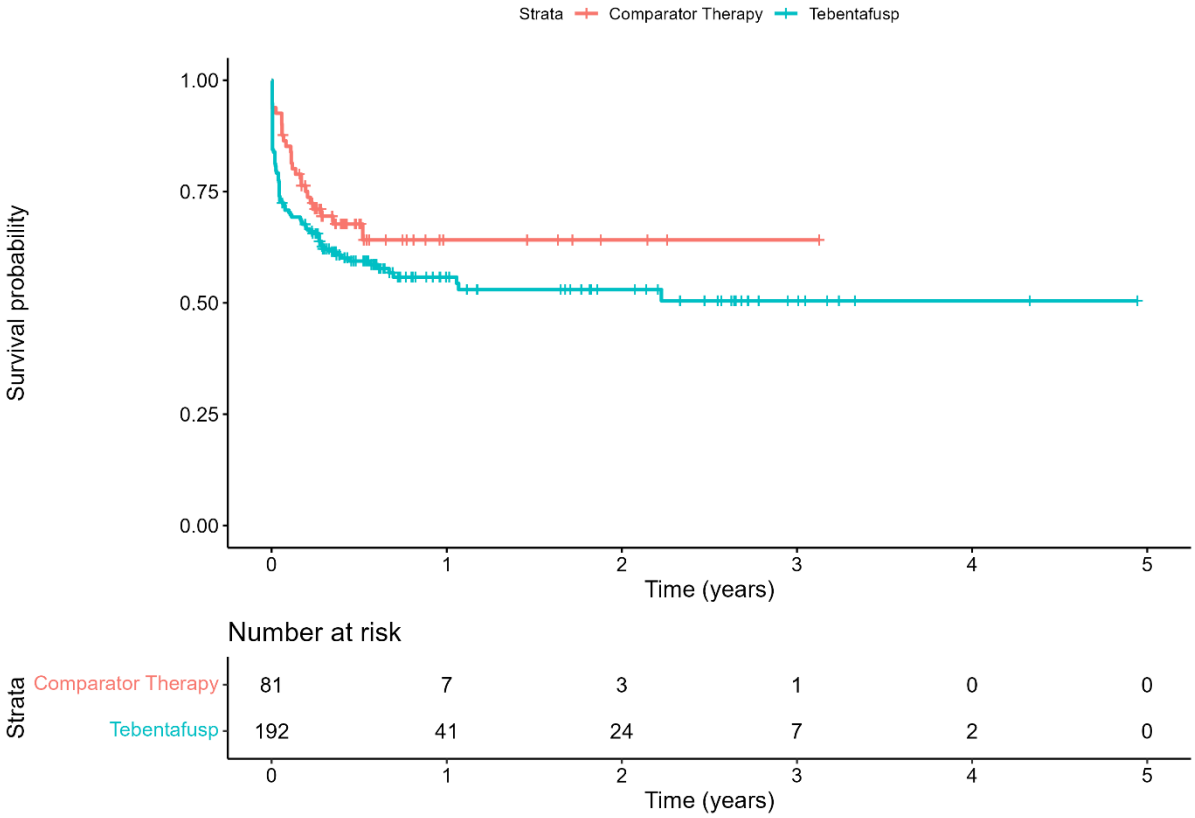
Alter: <65 Jahre



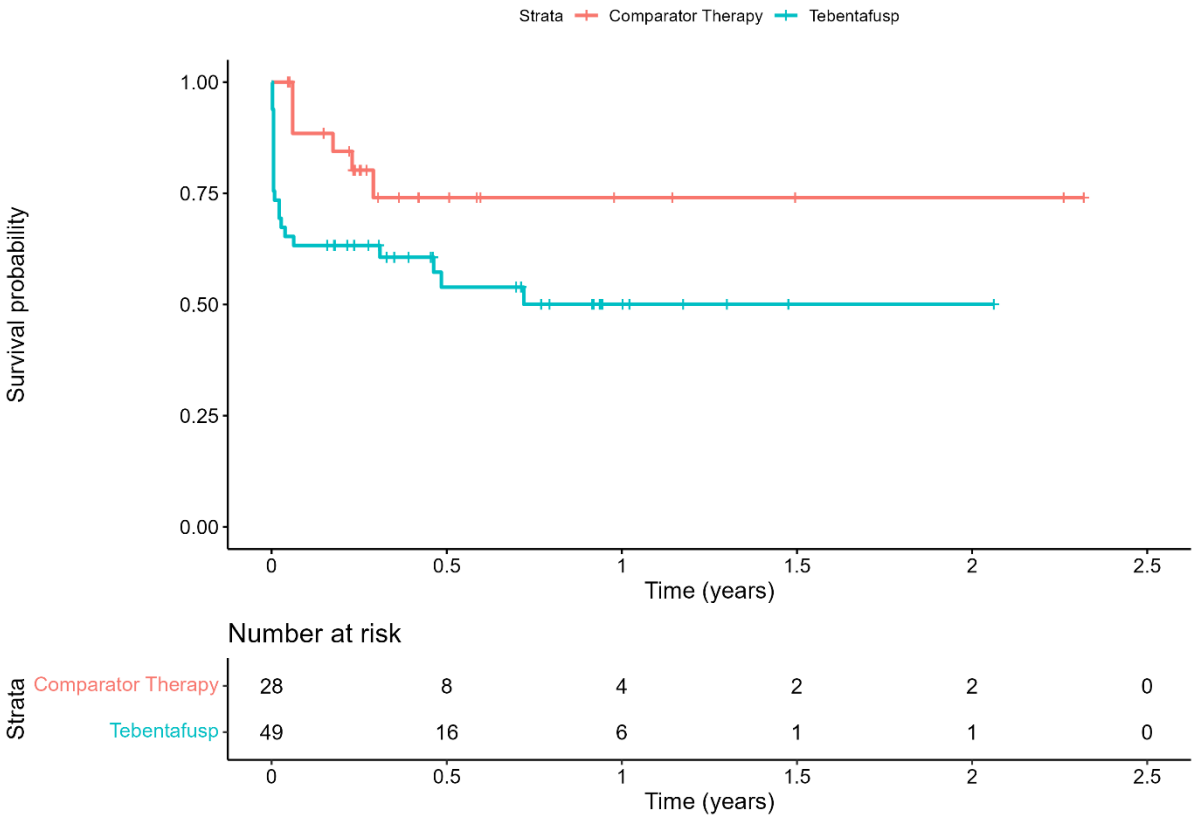
Alter: ≥65 Jahre



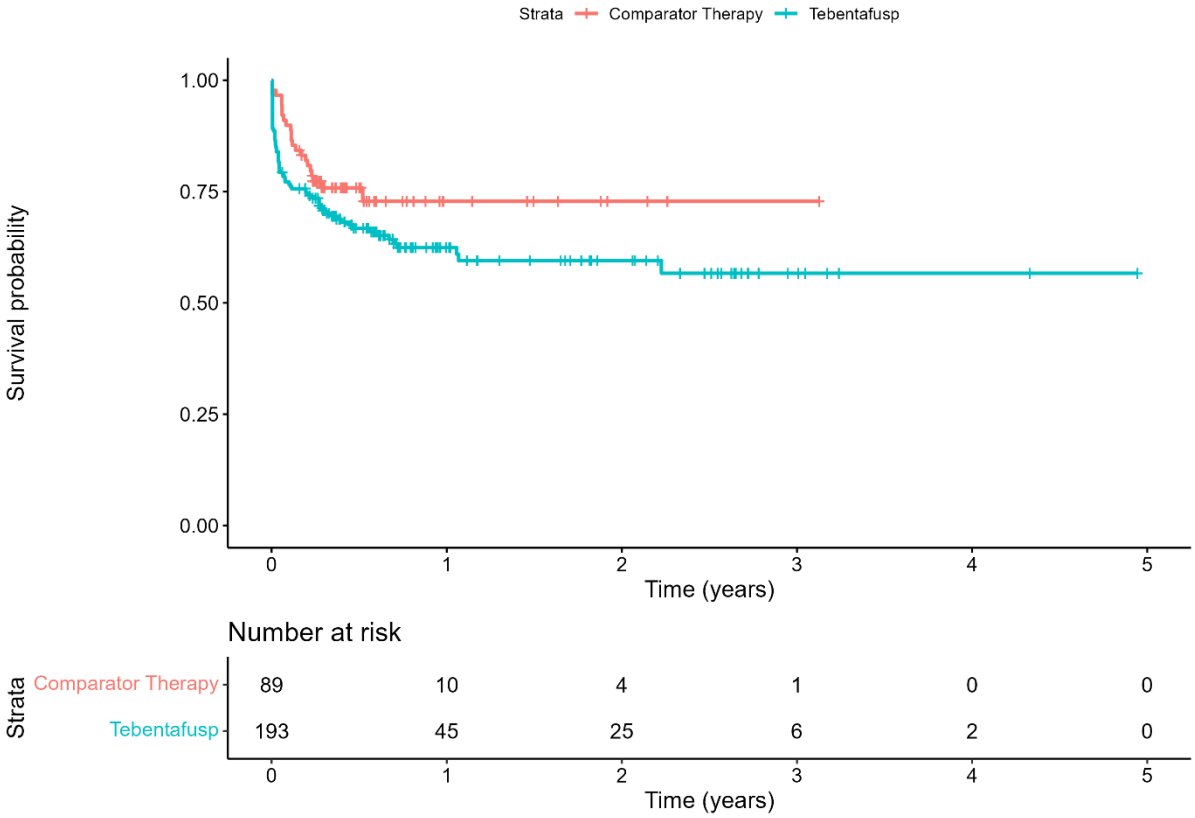
ECOG-Performance-Status: 0



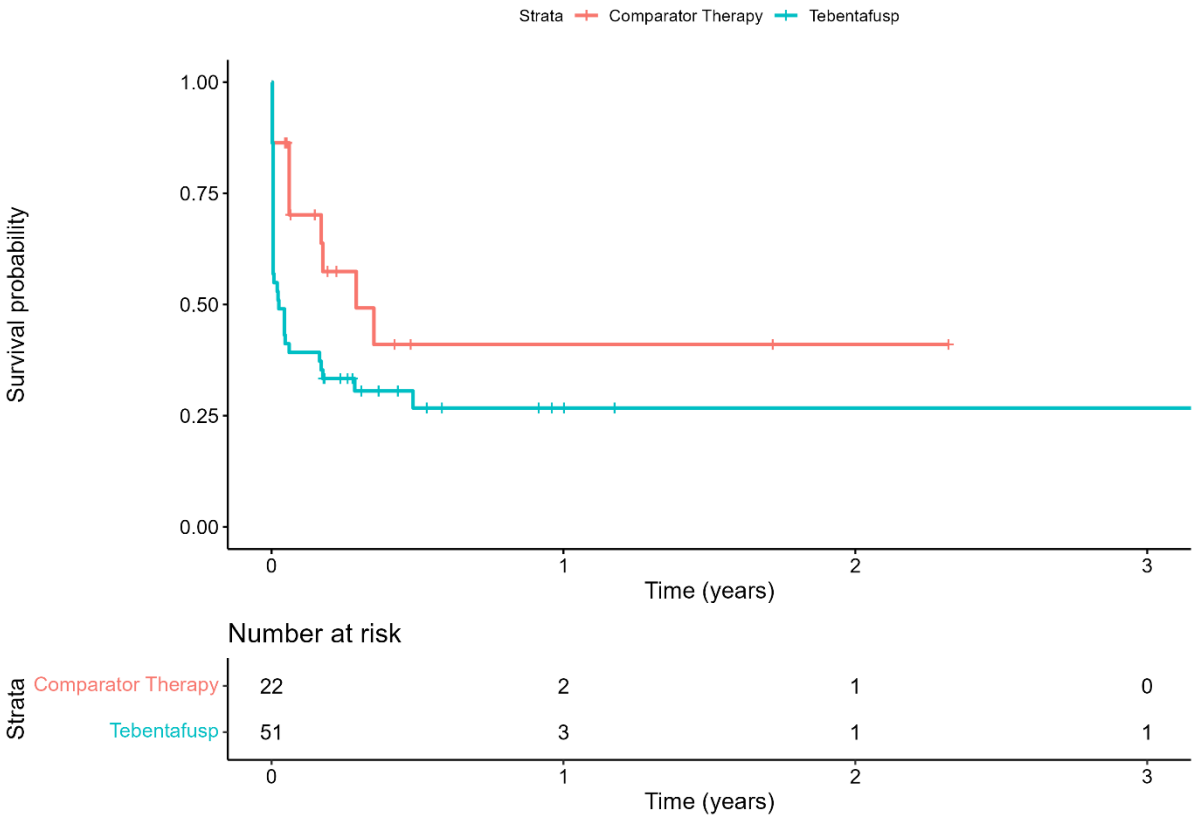
ECOG-Performance-Status: 1



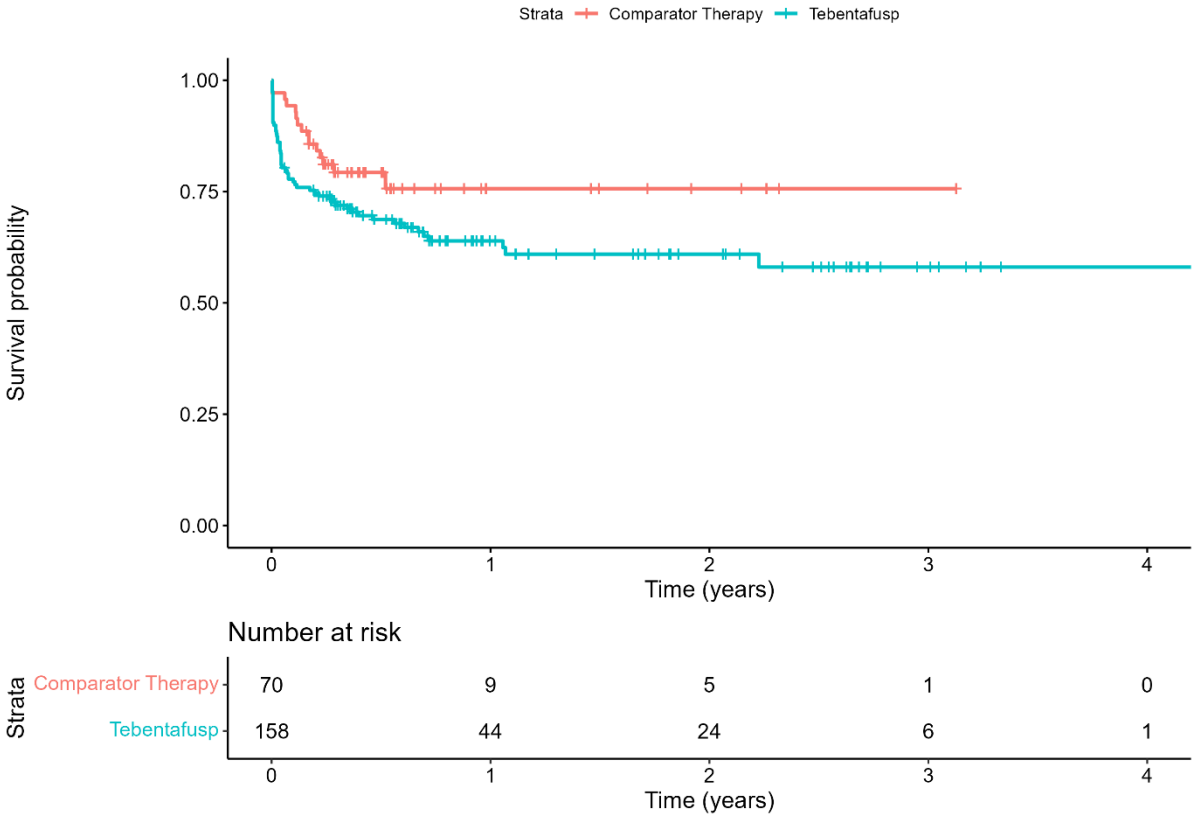
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



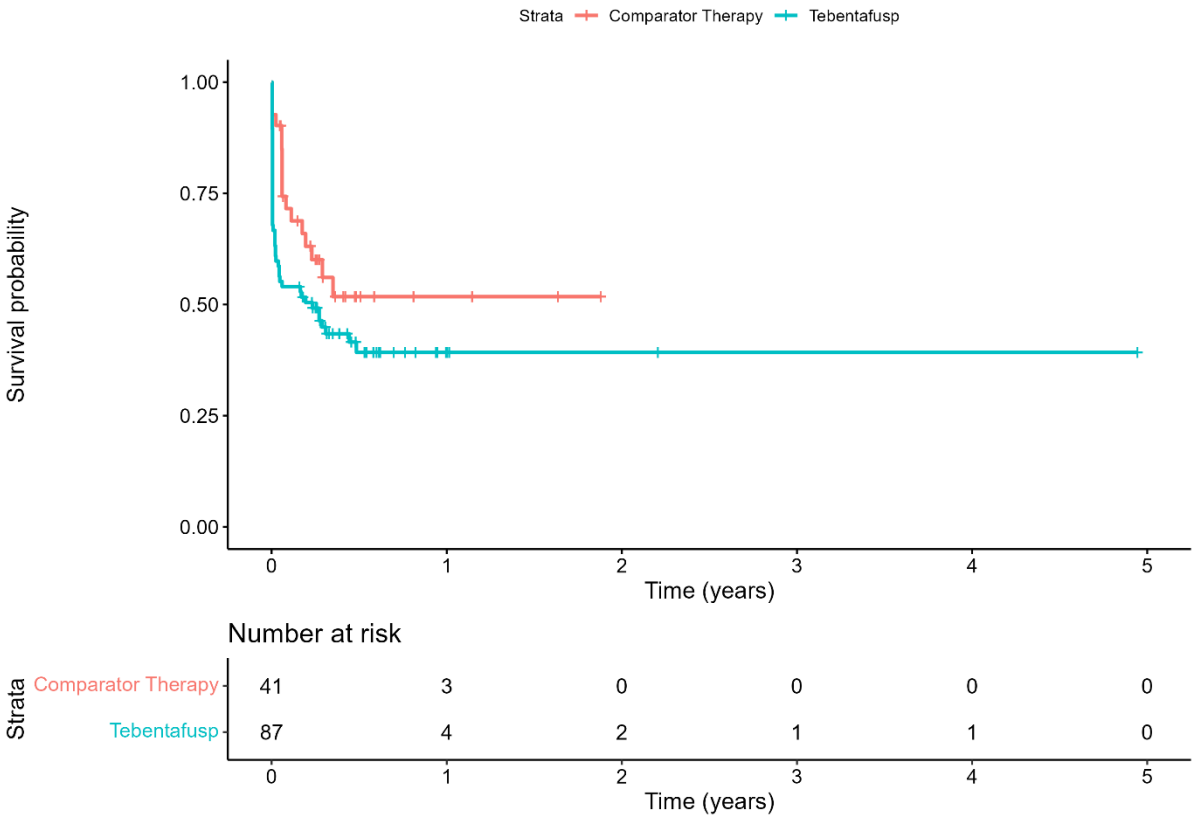
Alkalische Phosphatase (ALP) (Baseline): >ULN



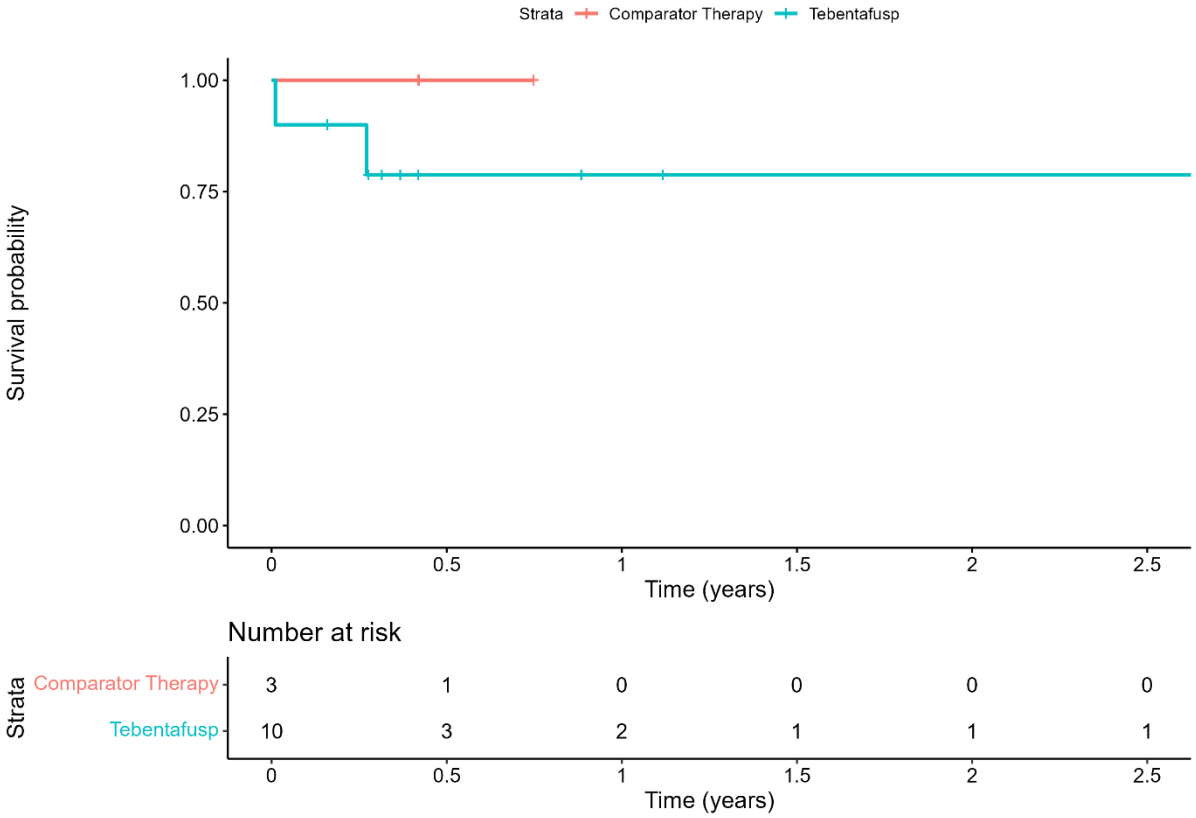
LDH: ≤ULN



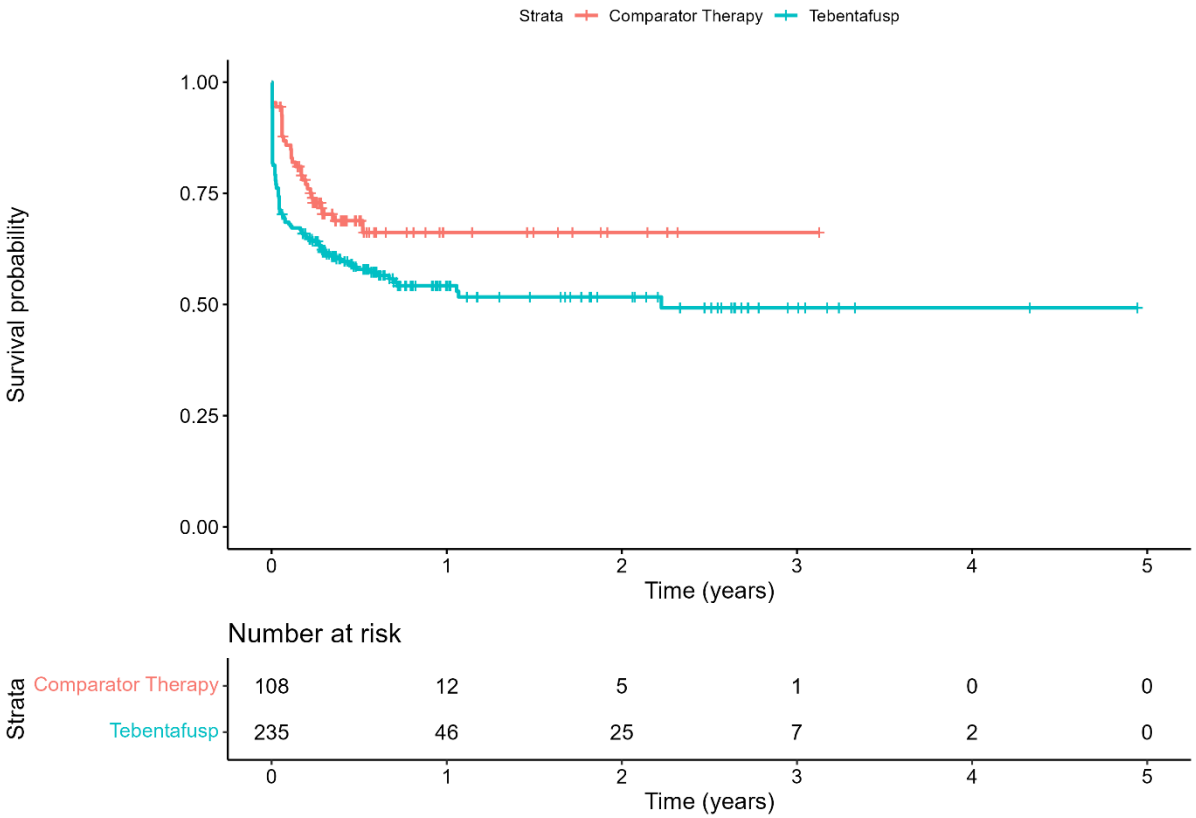
LDH: >ULN



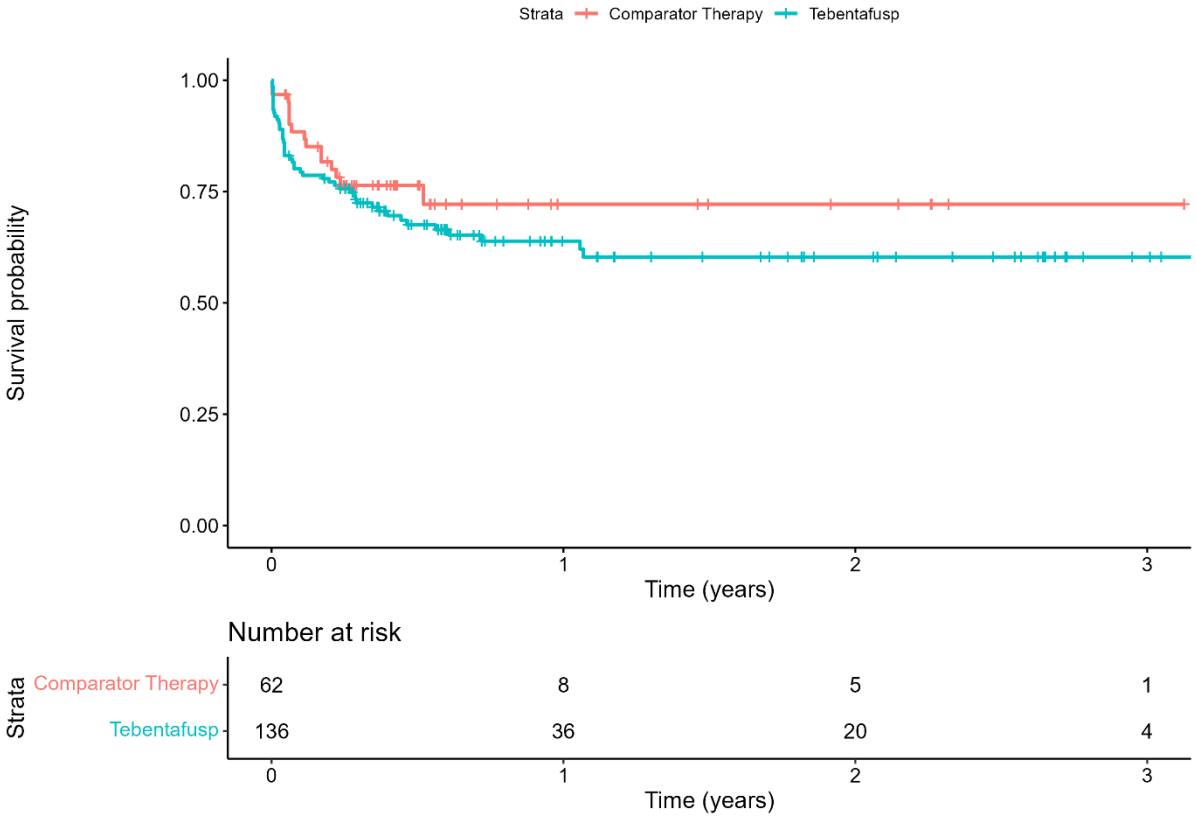
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



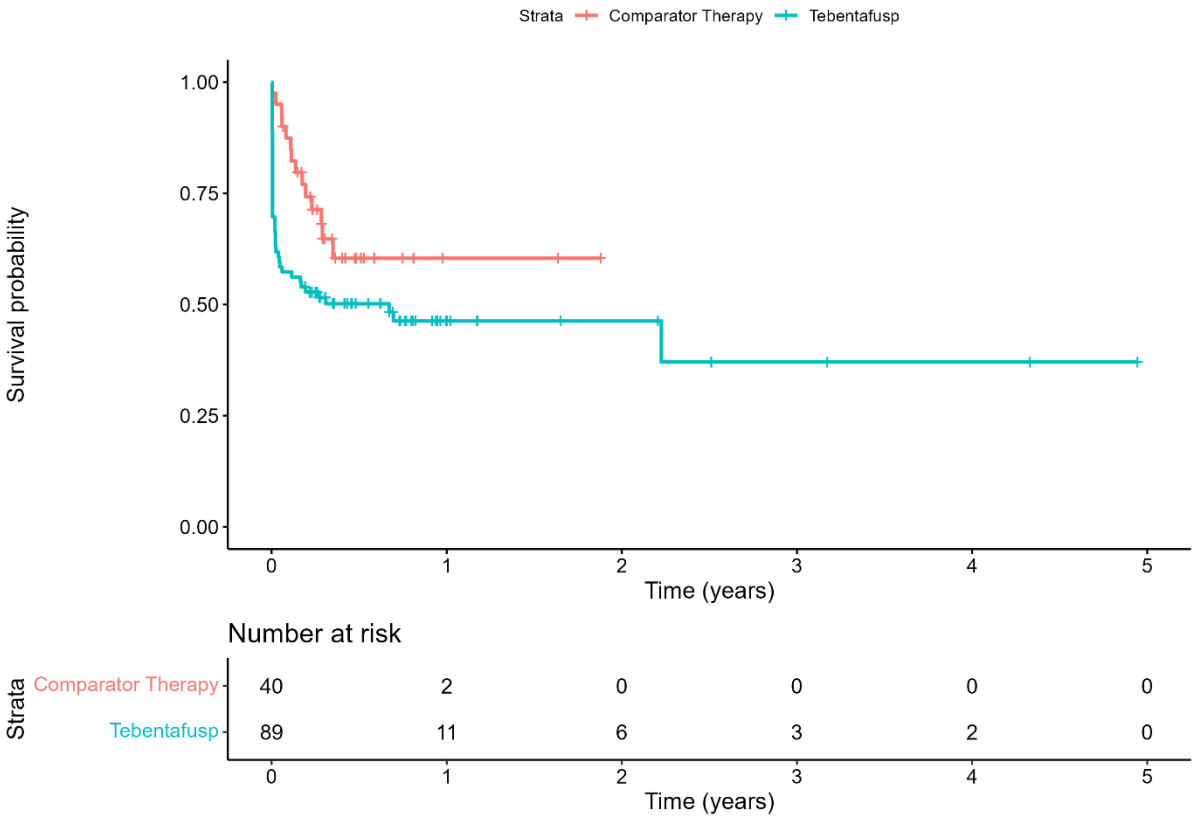
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



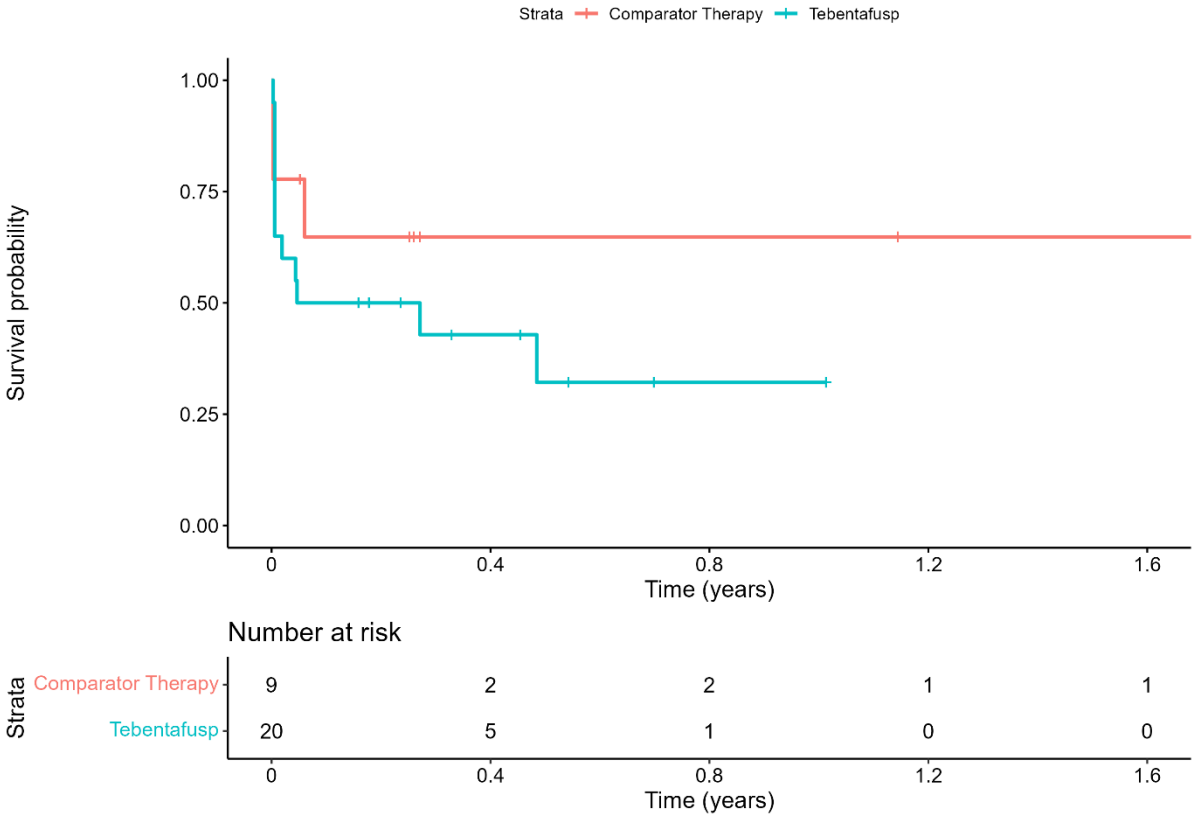
Größte metastatische Läsion (Baseline): ≤3,0 cm



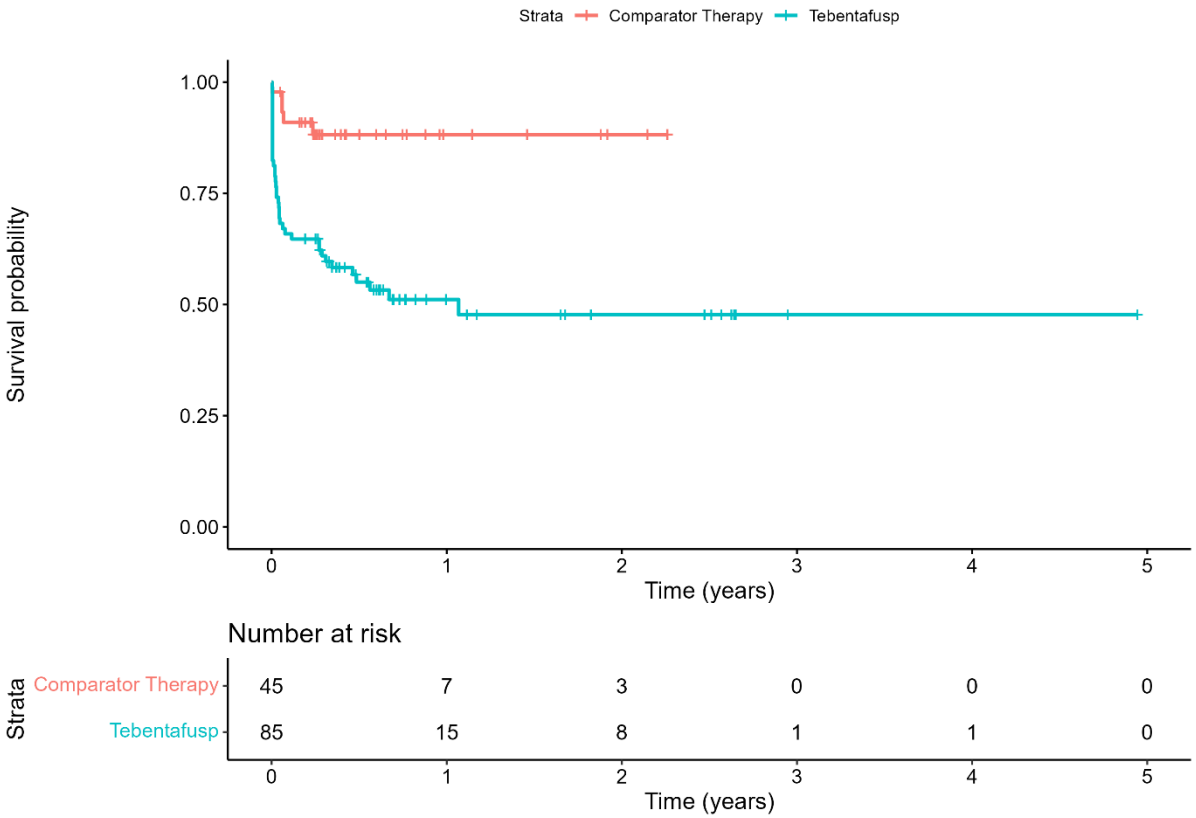
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



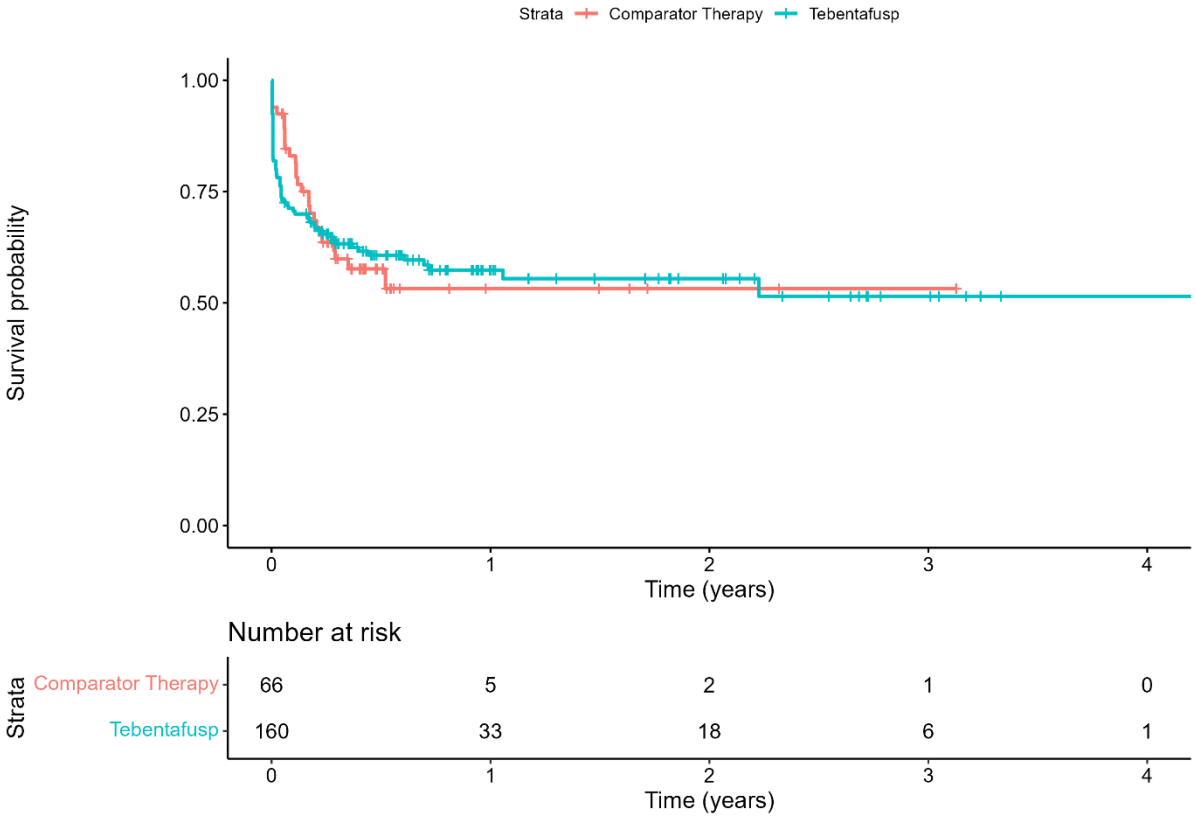
Größte metastatische Läsion (Baseline): ≥8,1 cm



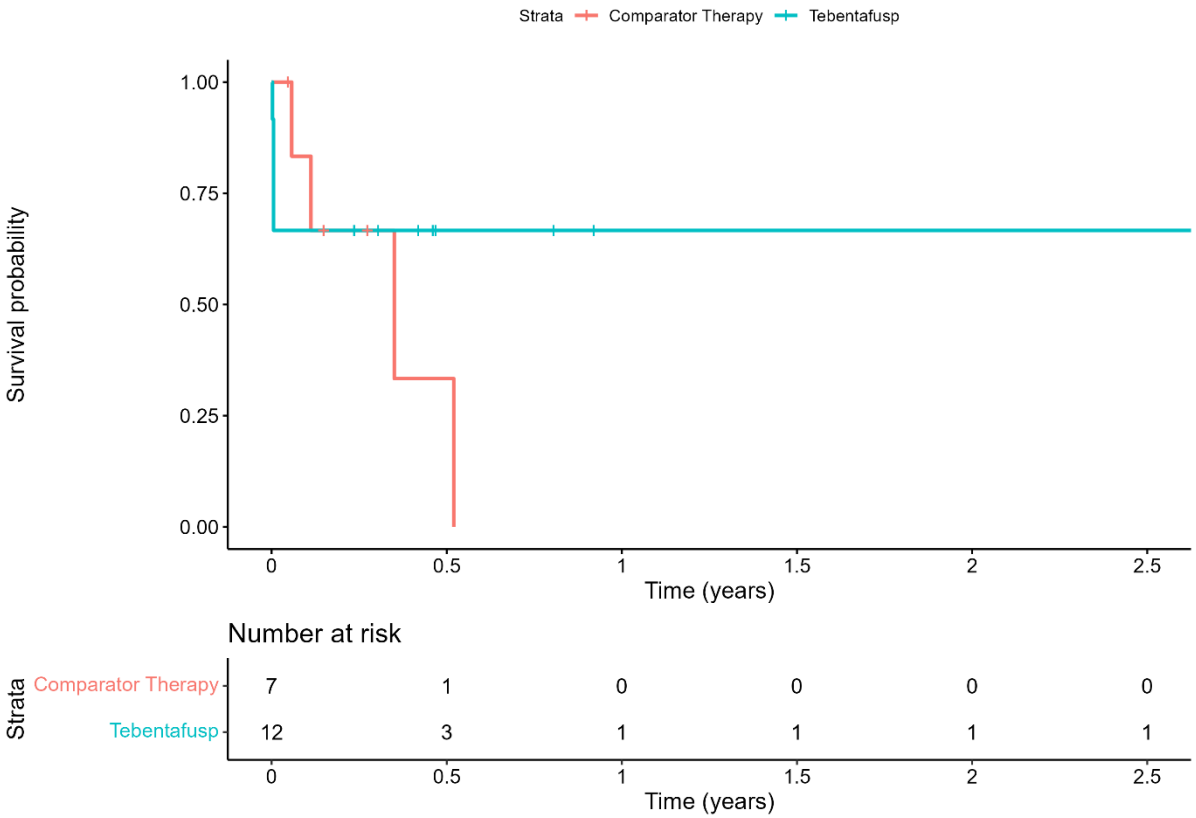
Region: Nordamerika



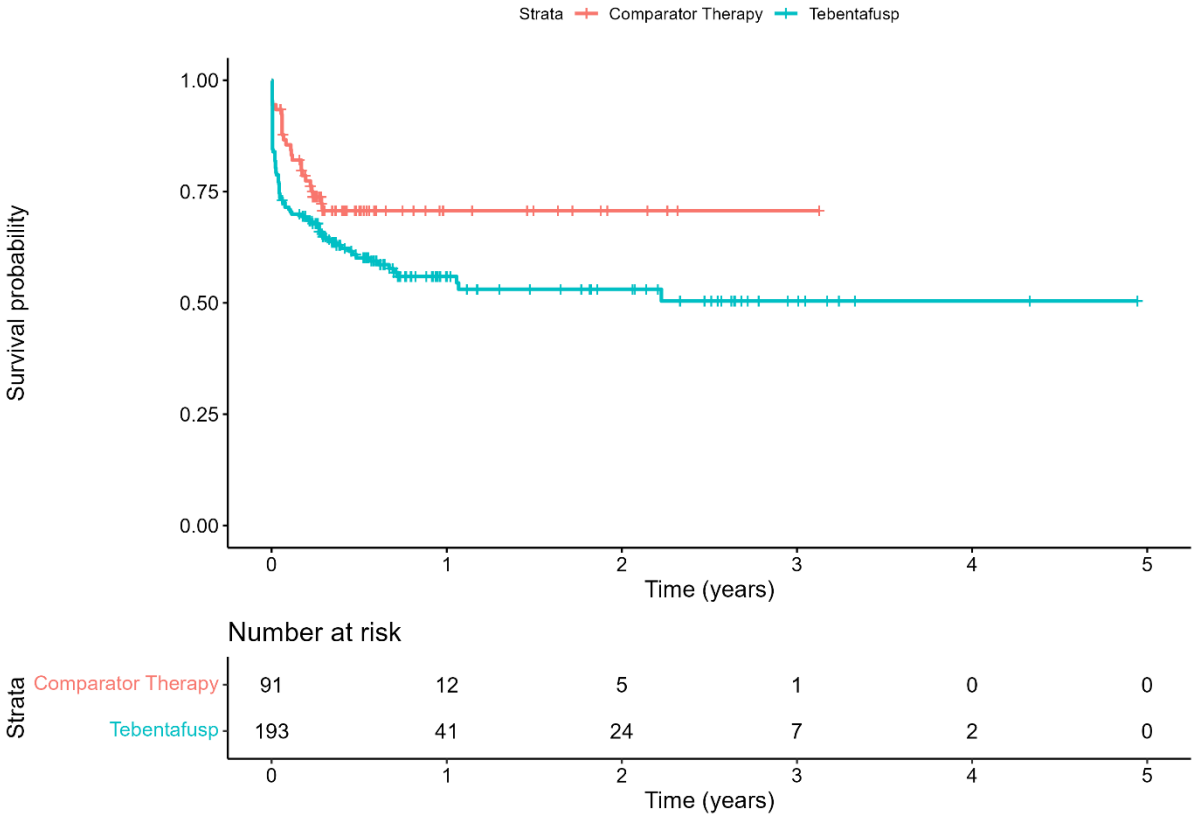
Region: Nicht-Nordamerika



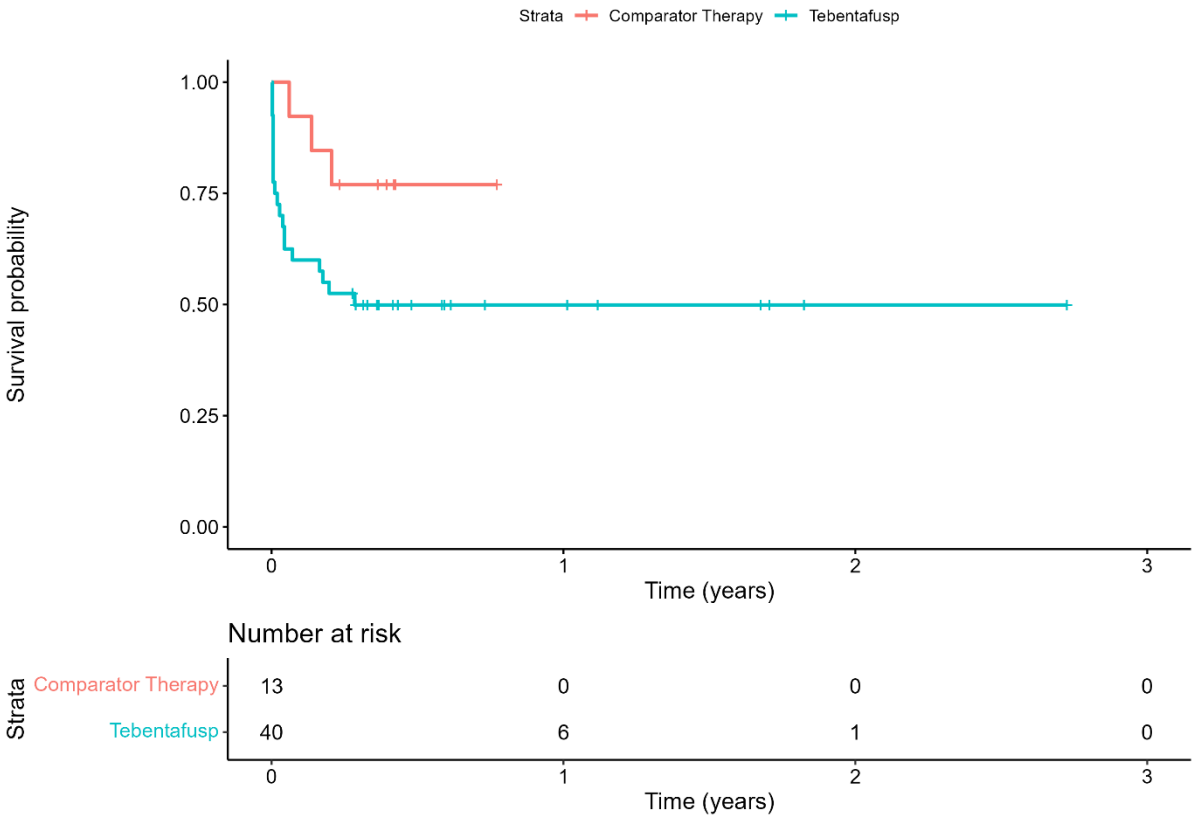
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

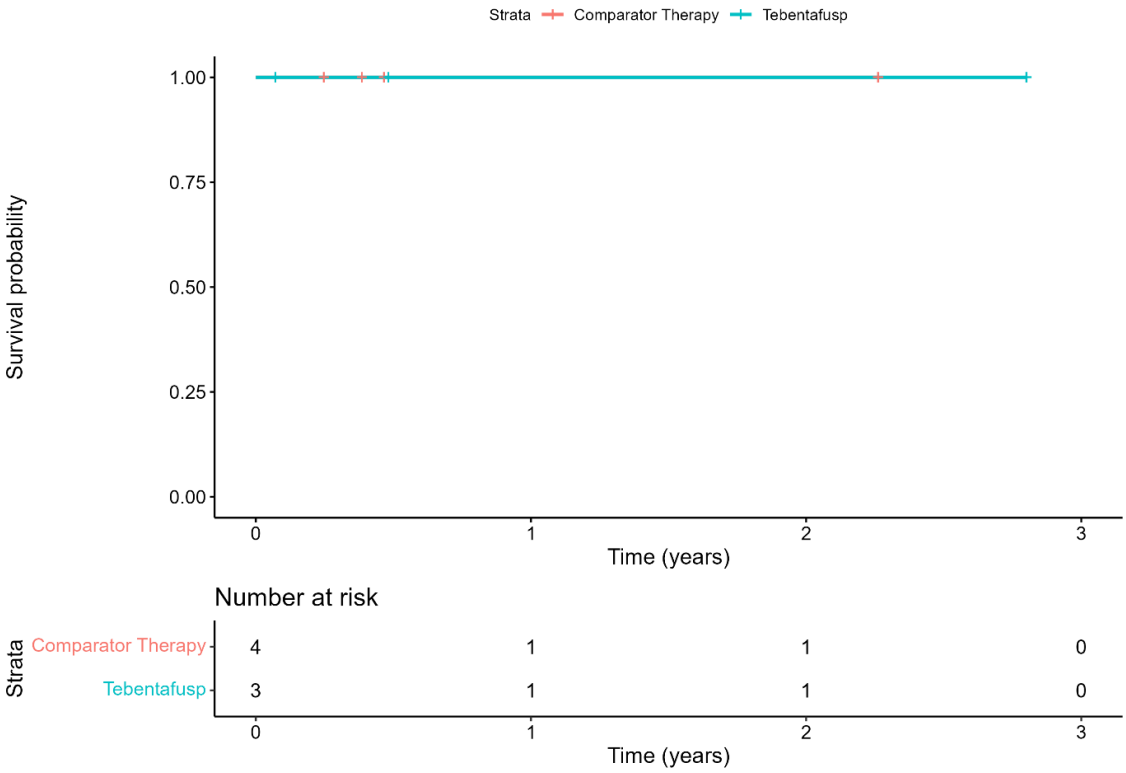


Vorauswahl der Chemotherapie: Ipilimumab

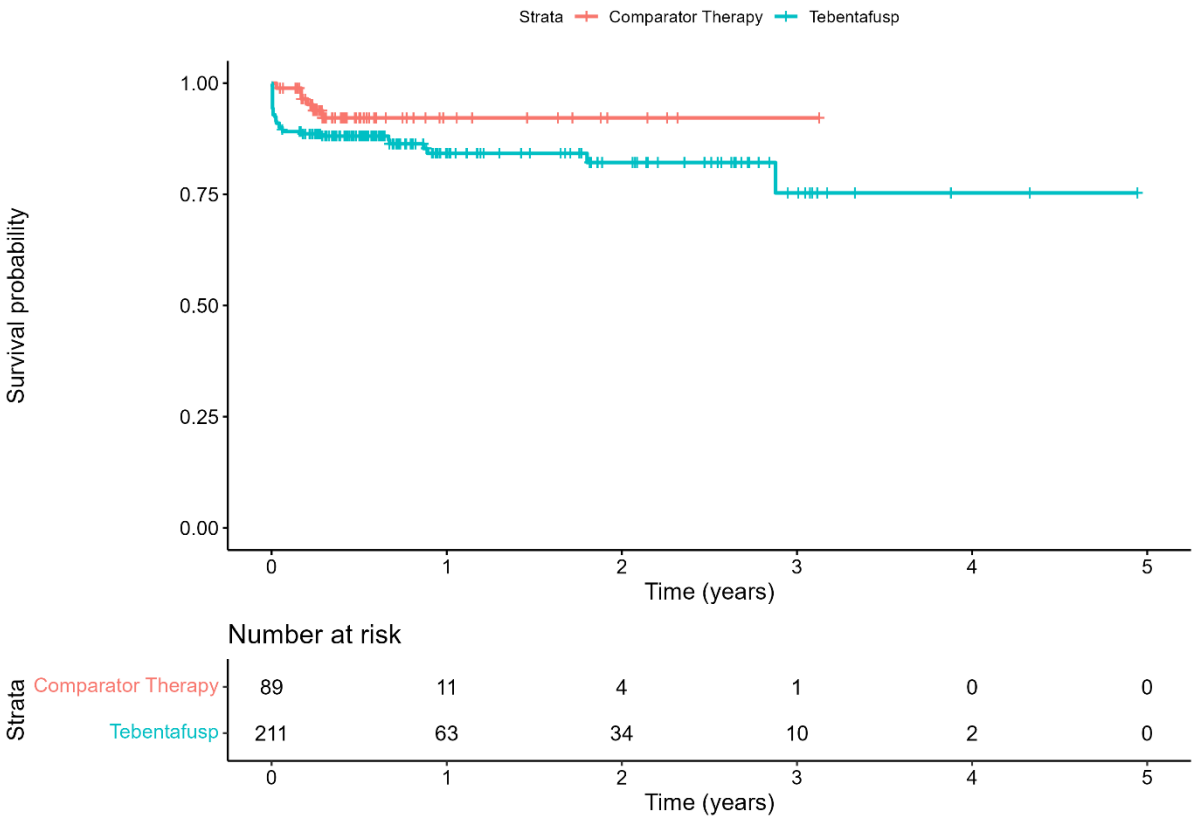


59.13 LFT-Erhöhung mit CTCAE-Grad ≥ 3 (Tabelle 4-239)

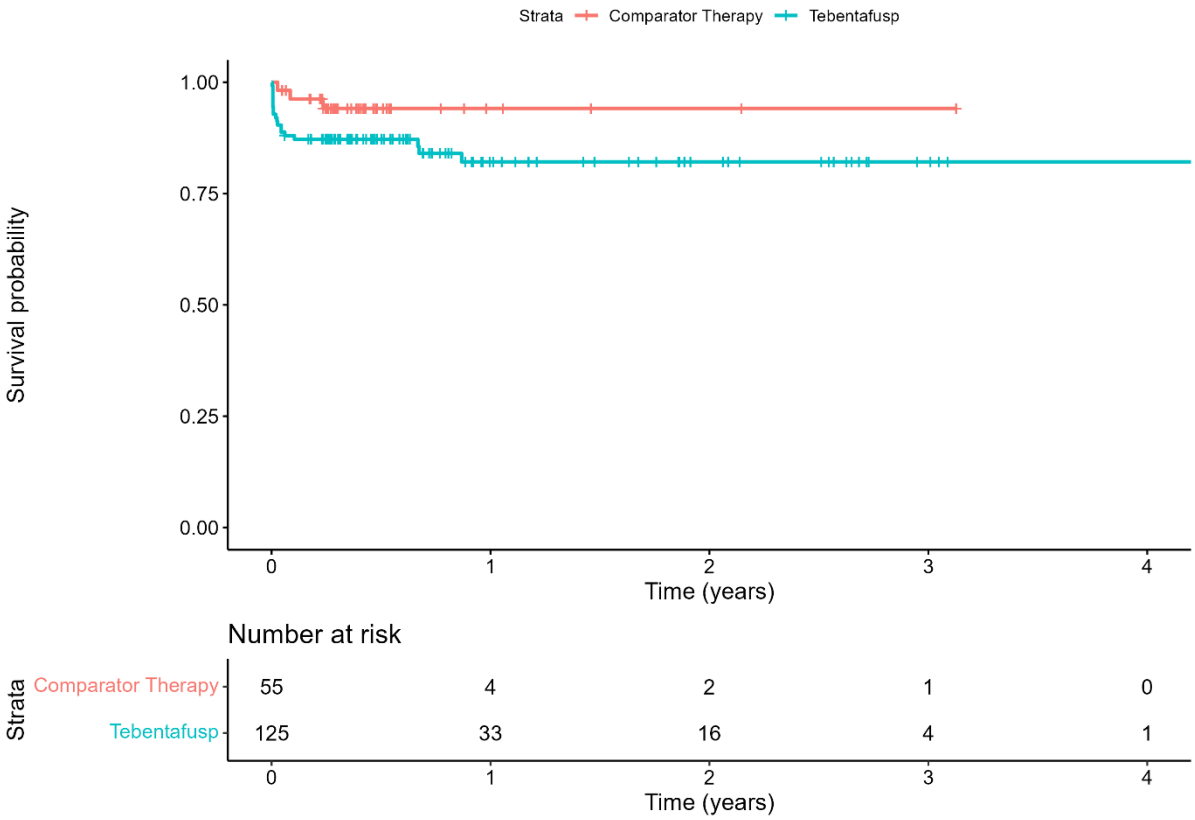
Herkunft: Hispanisch



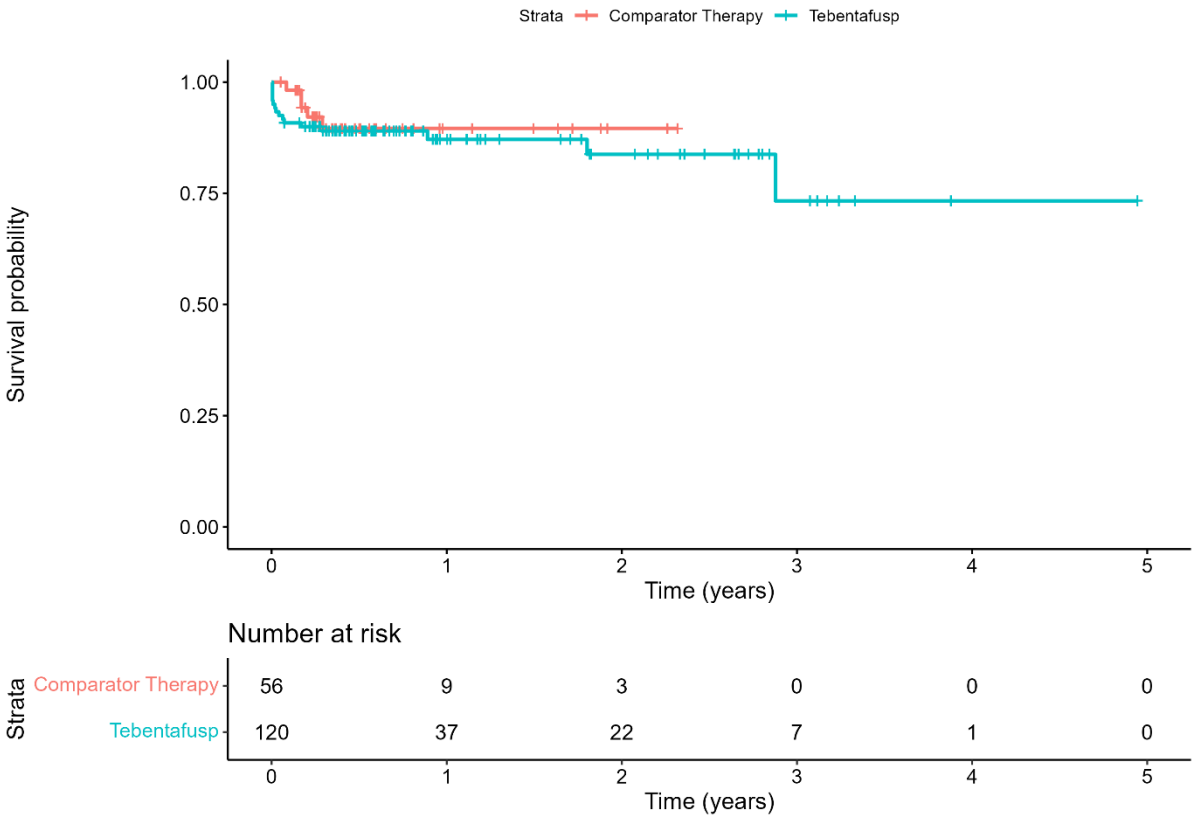
Herkunft: Nicht-hispanisch



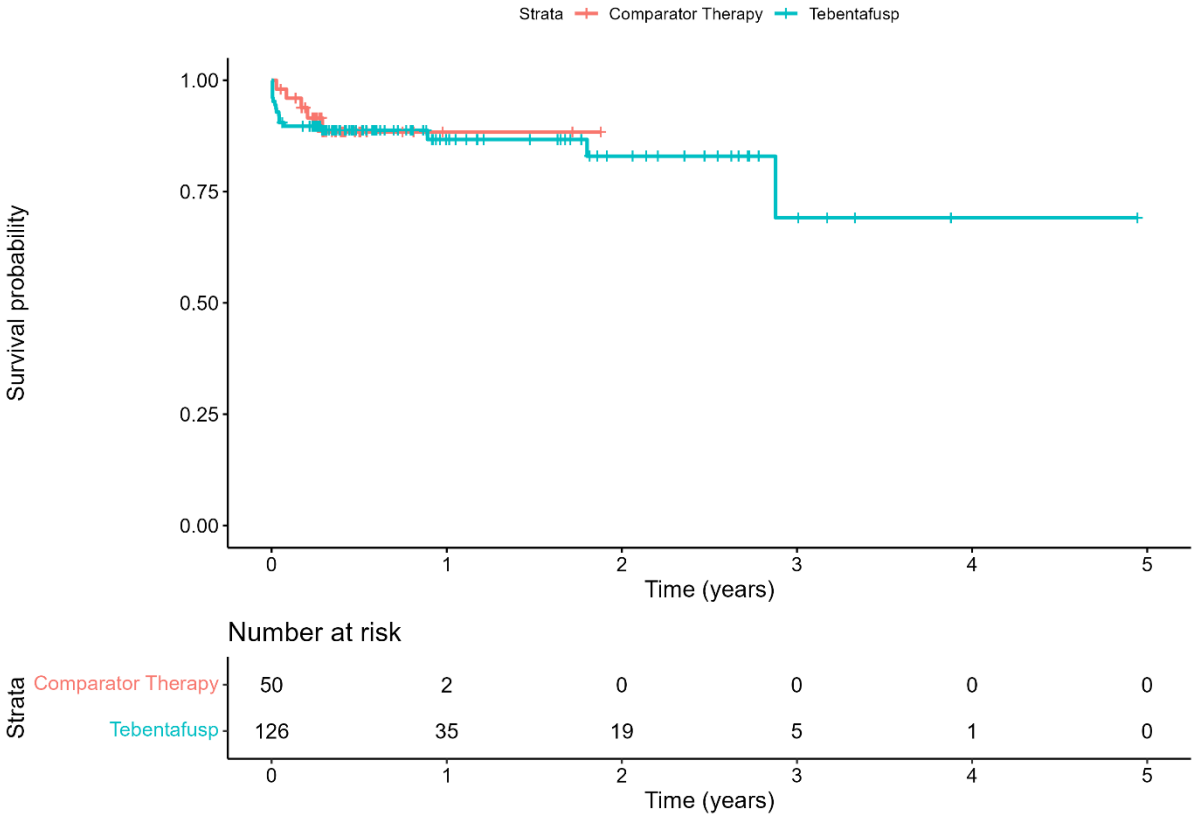
Geschlecht: Männlich



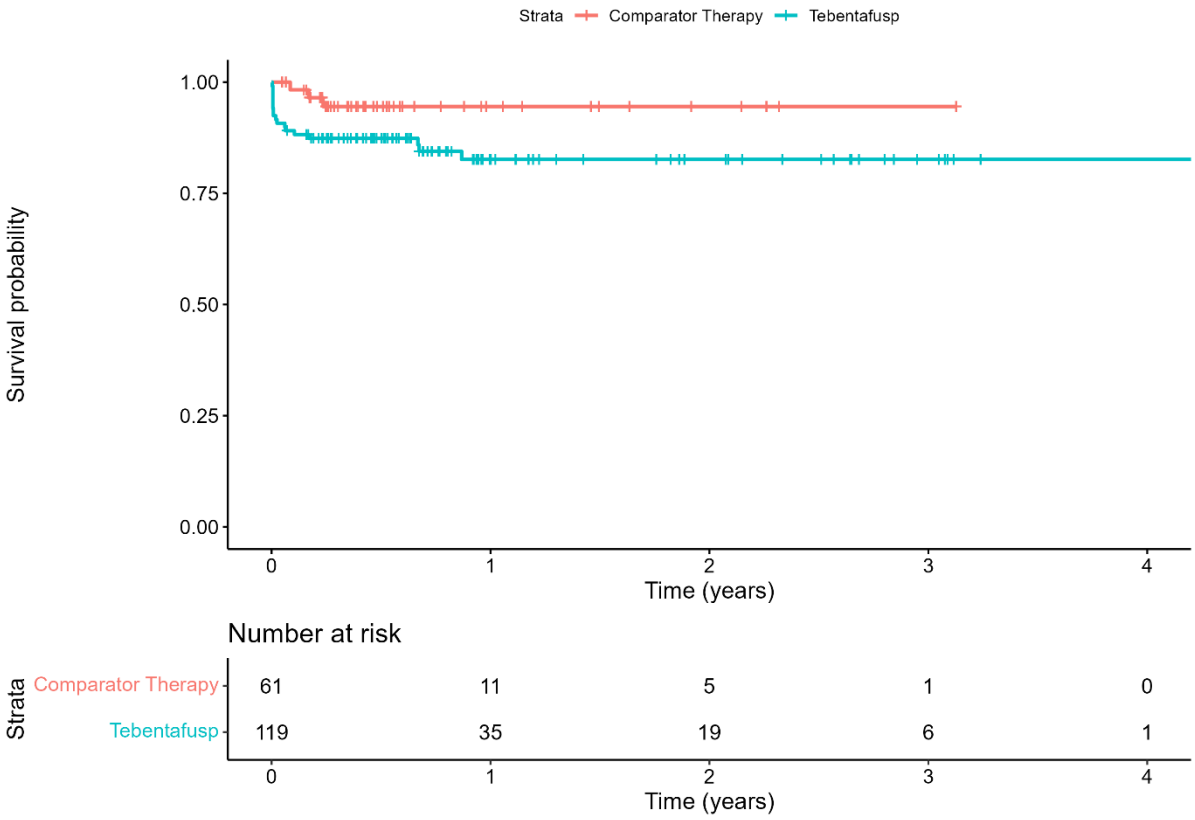
Geschlecht: Weiblich



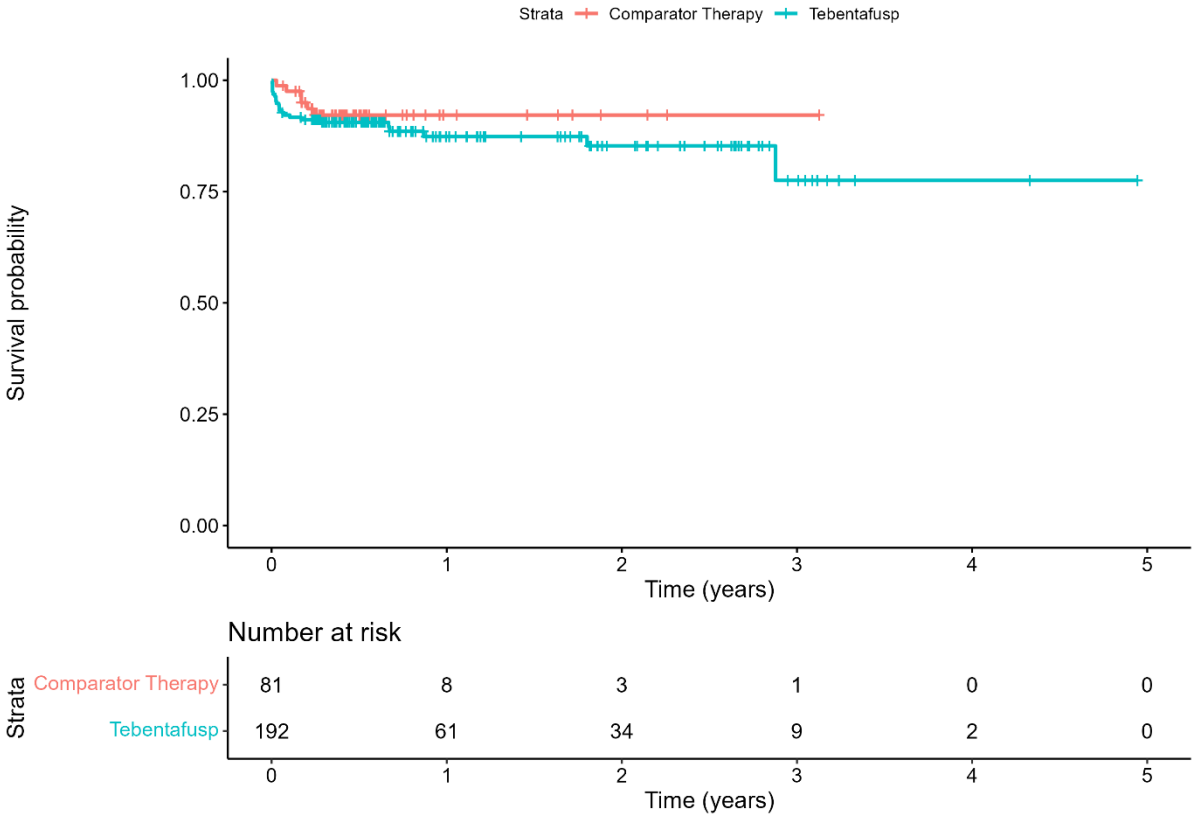
Alter: <65 Jahre



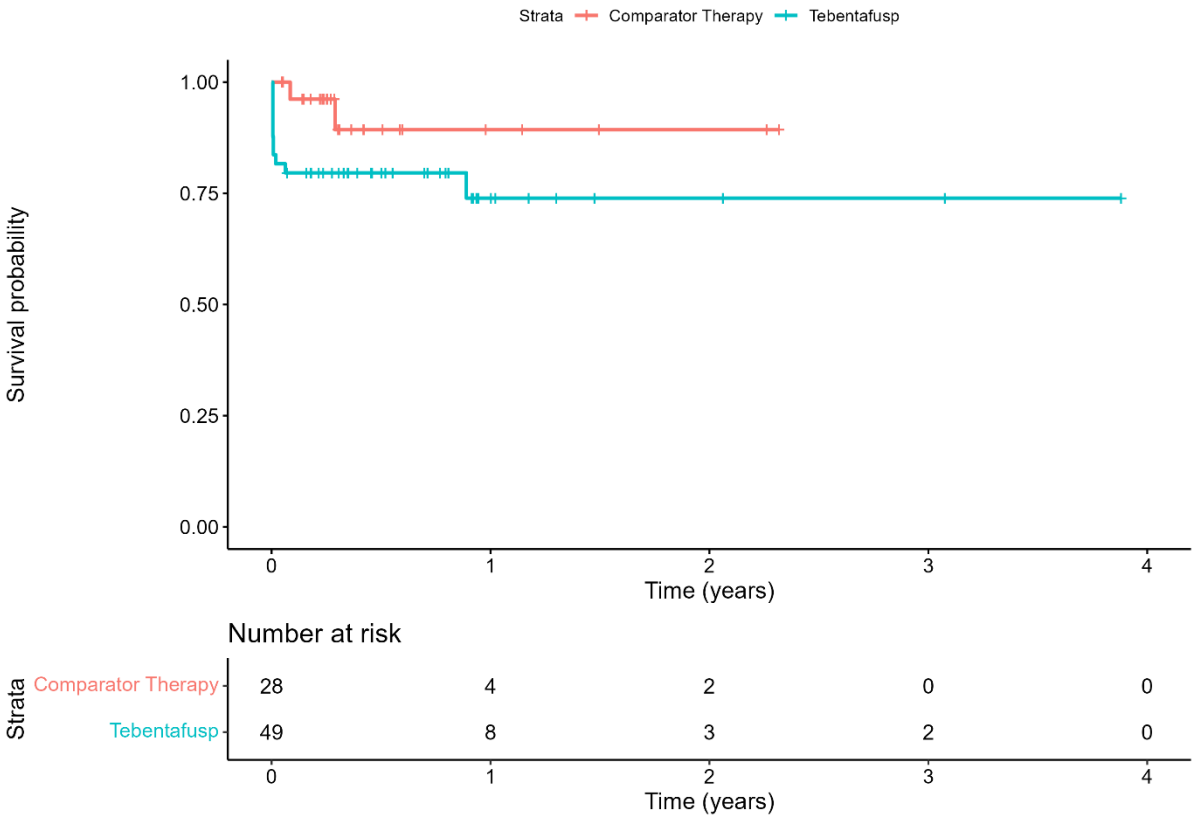
Alter: ≥65 Jahre



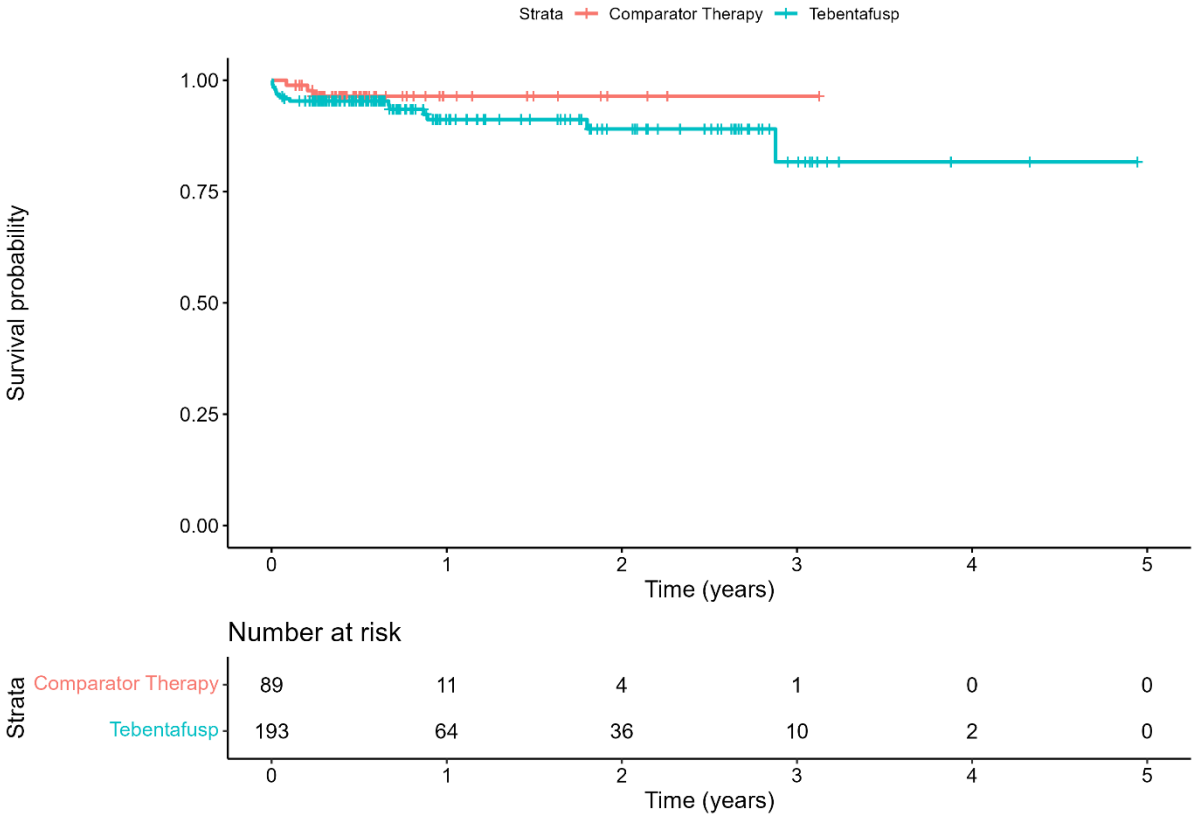
ECOG-Performance-Status: 0



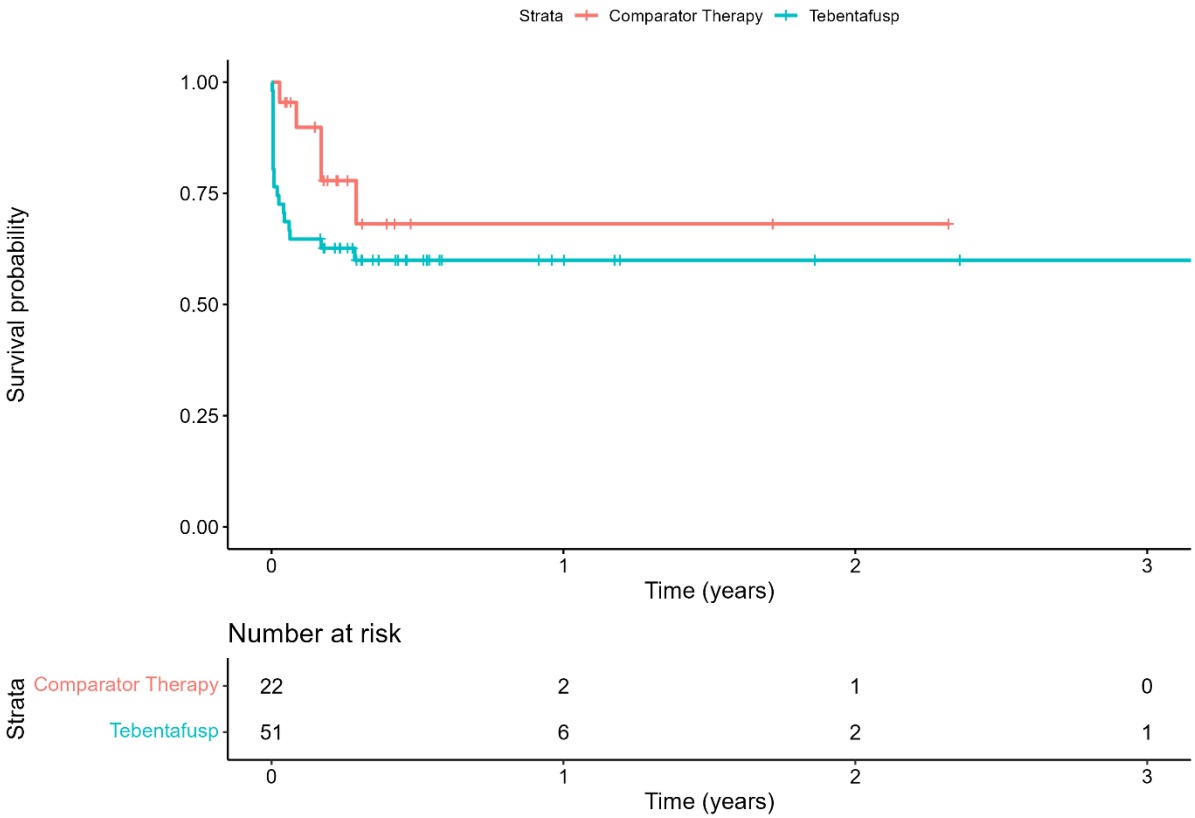
ECOG-Performance-Status: 1



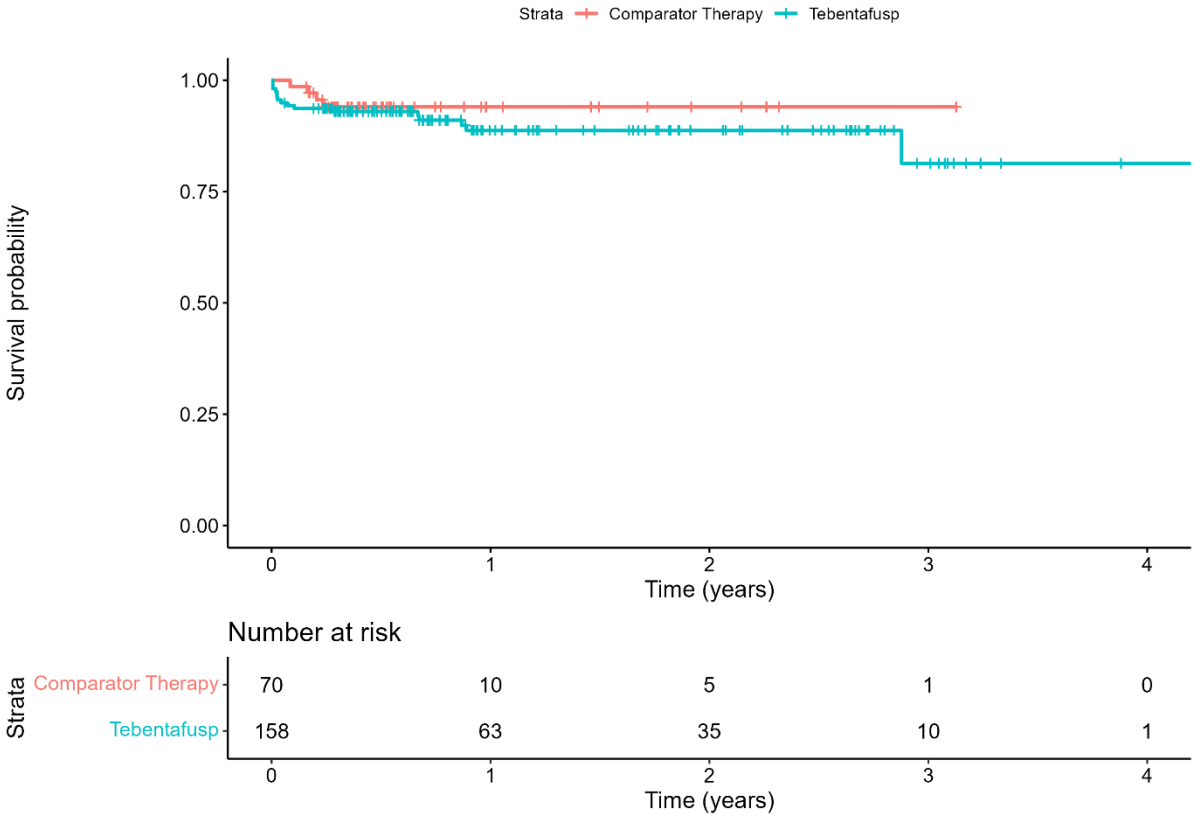
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



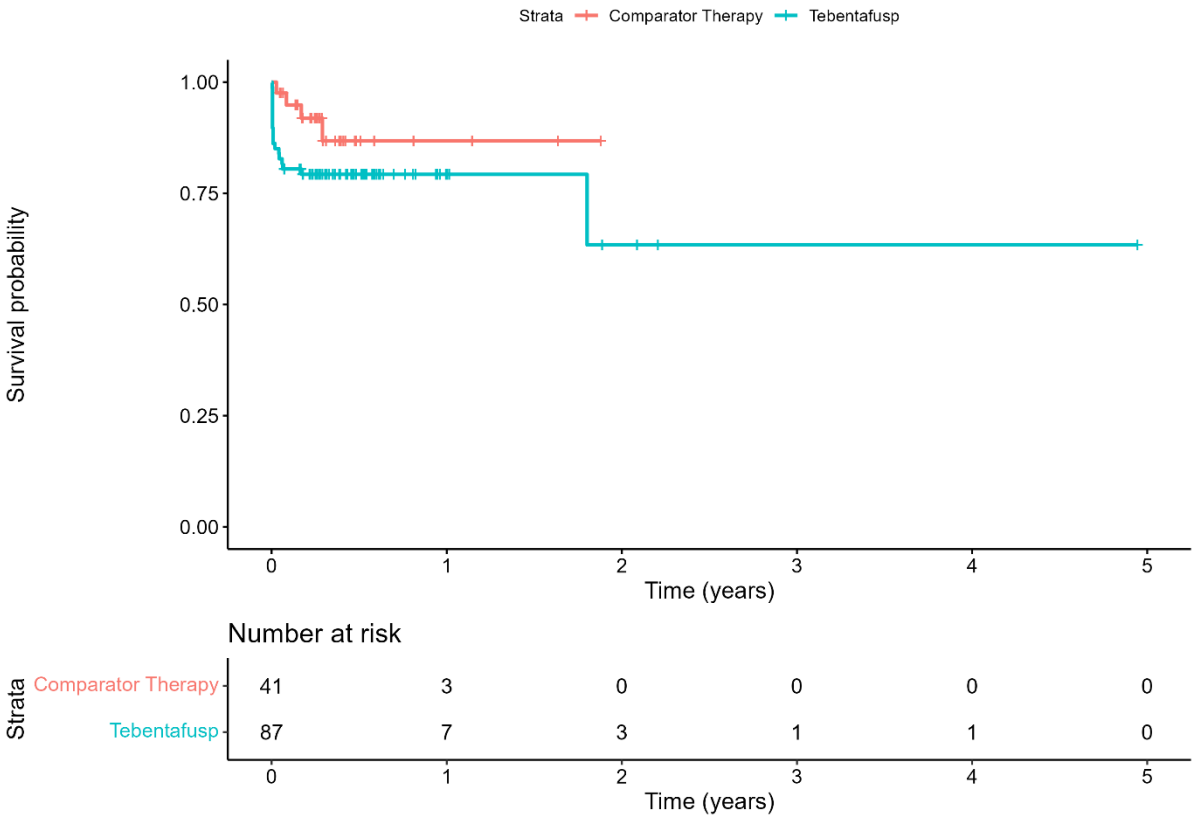
Alkalische Phosphatase (ALP) (Baseline): >ULN



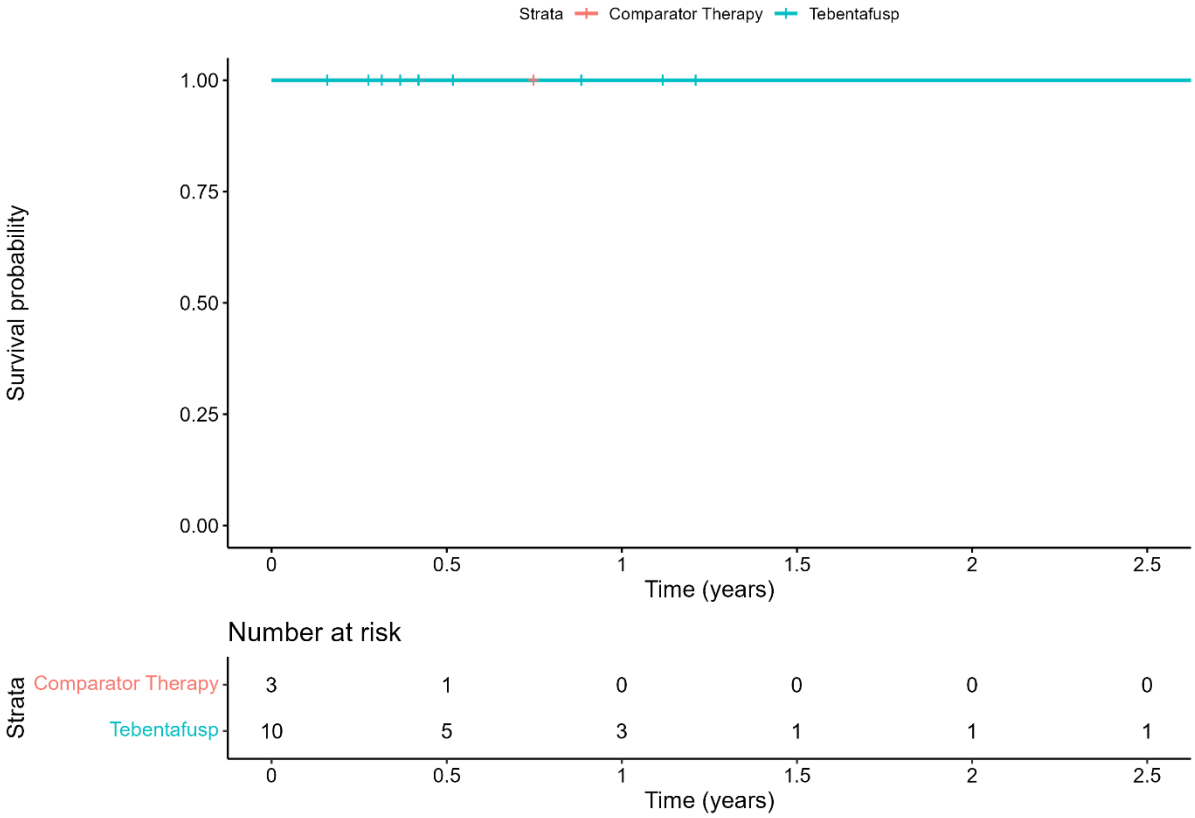
LDH: ≤ULN



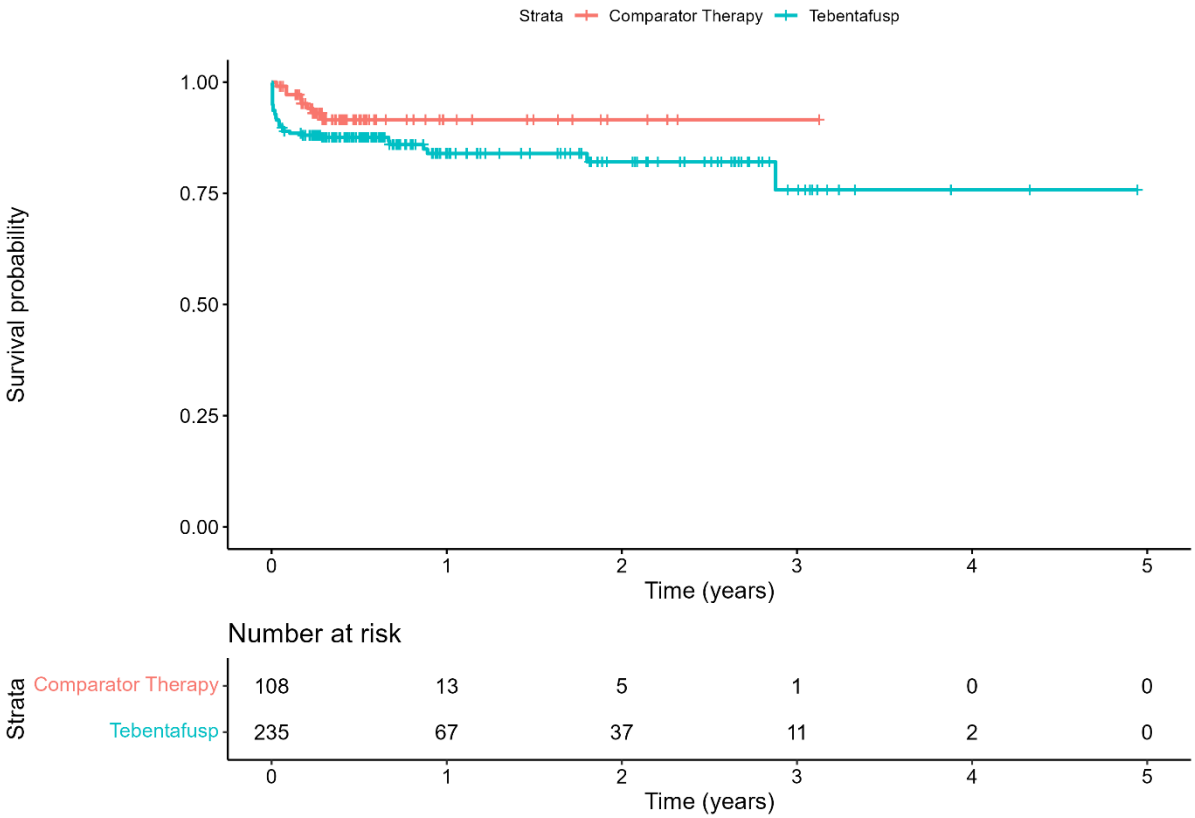
LDH: >ULN



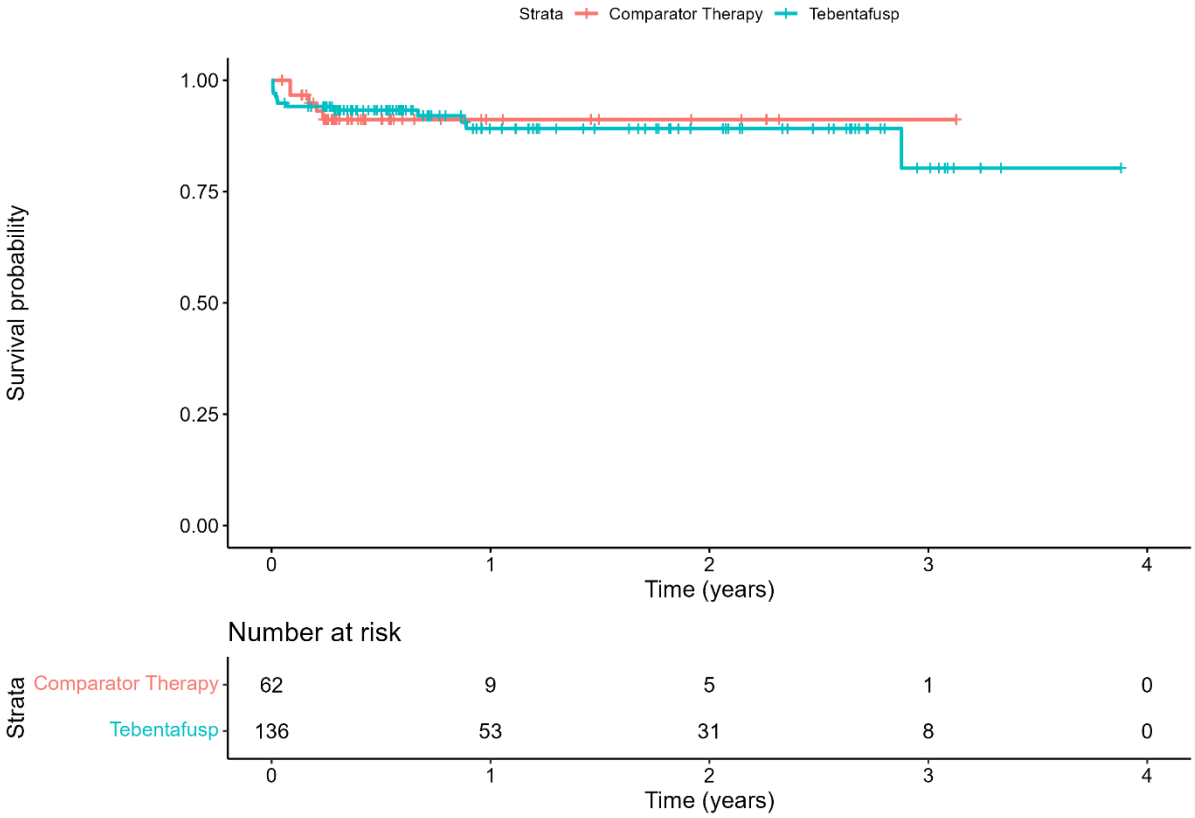
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



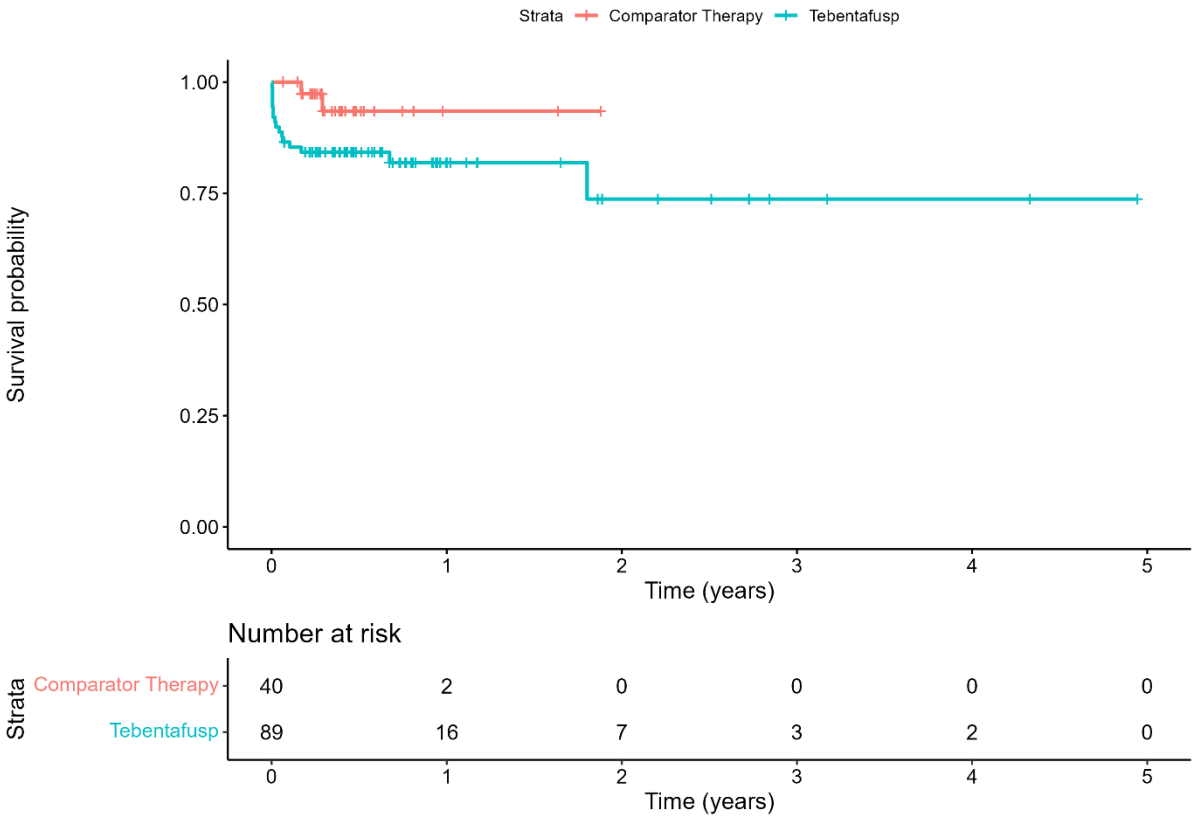
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



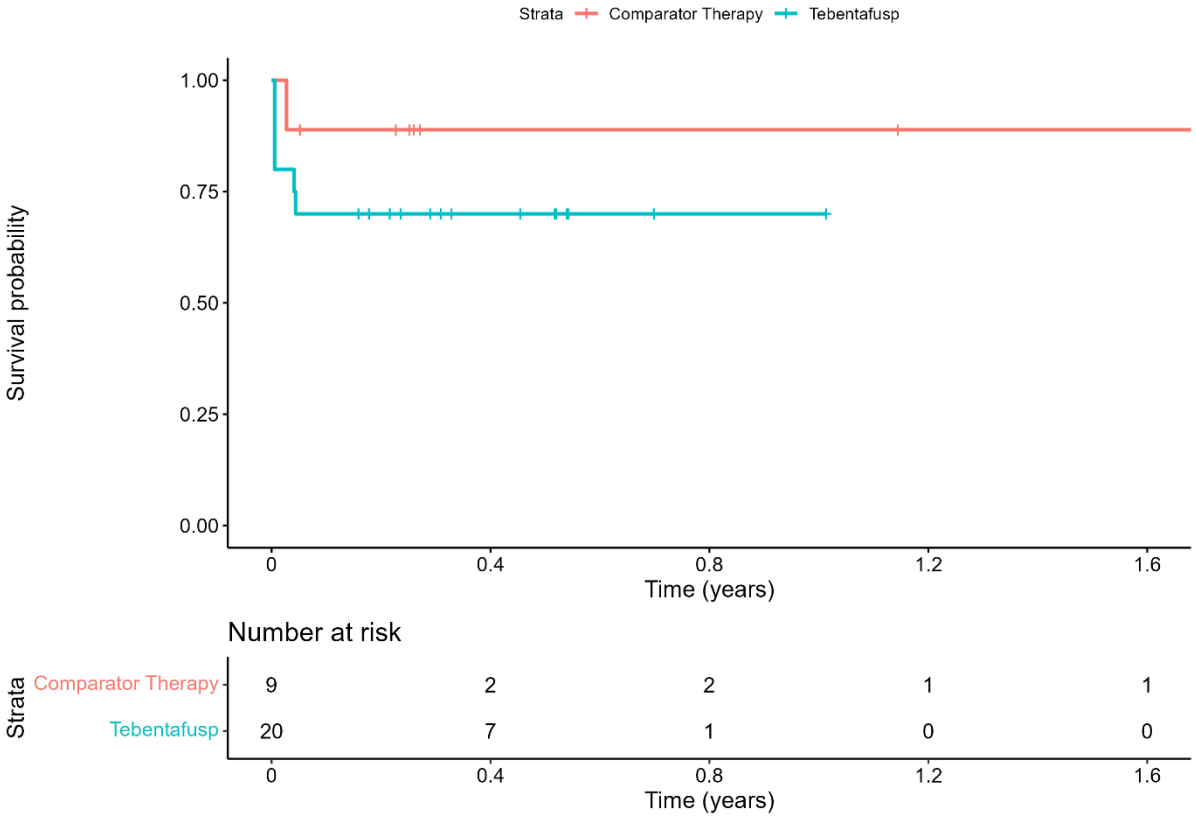
Größte metastatische Läsion (Baseline): ≤3,0 cm



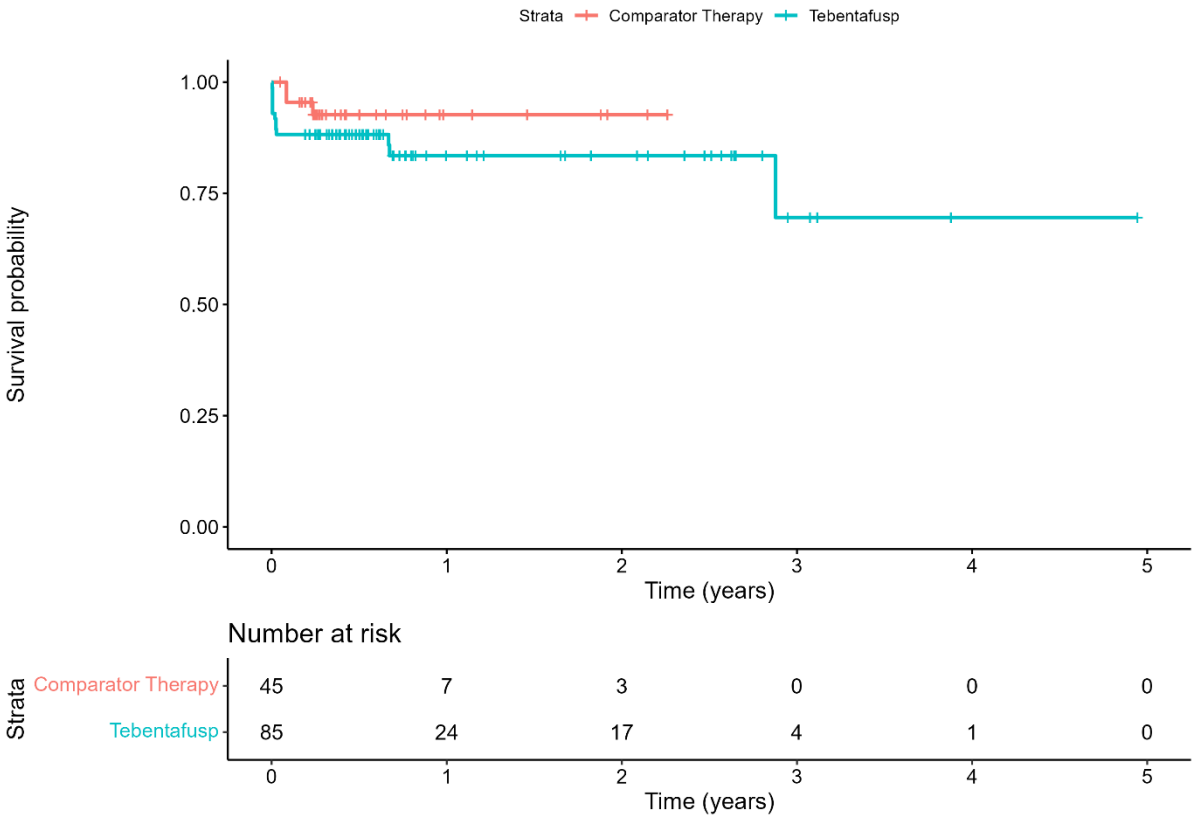
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



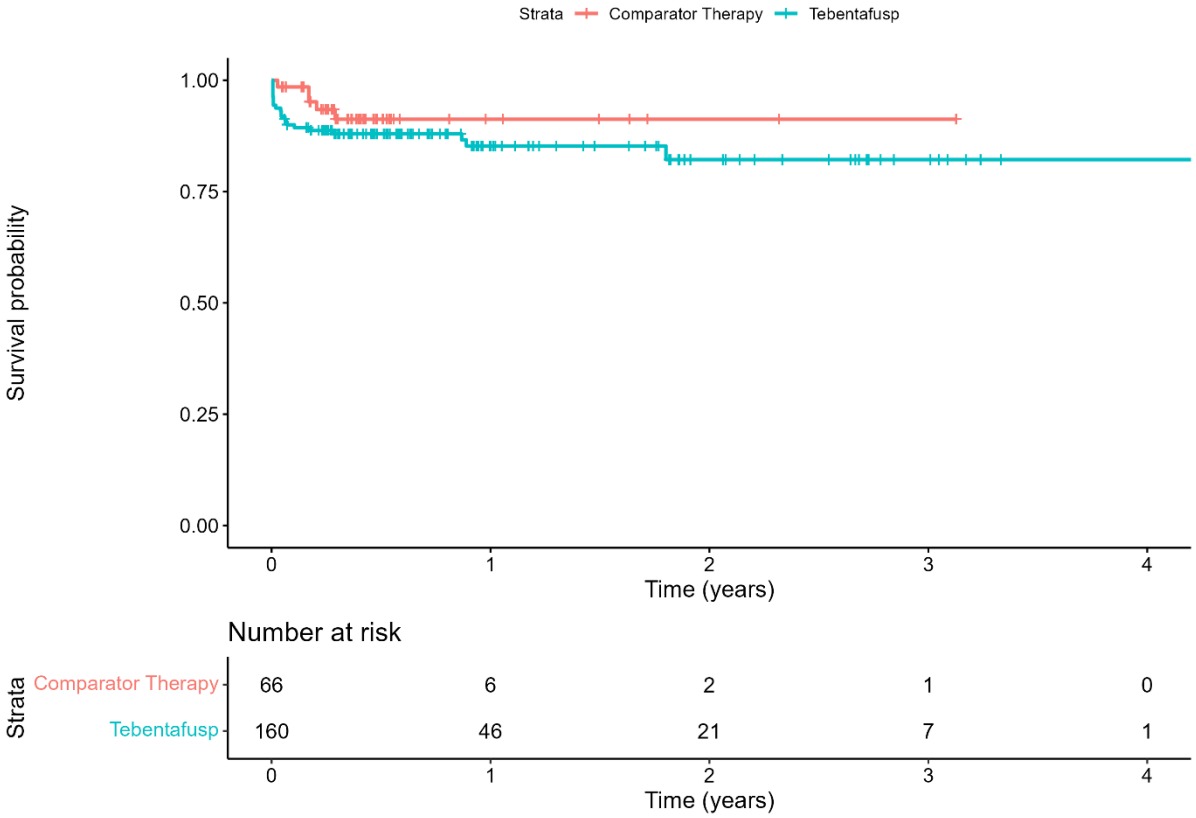
Größte metastatische Läsion (Baseline): ≥8,1 cm



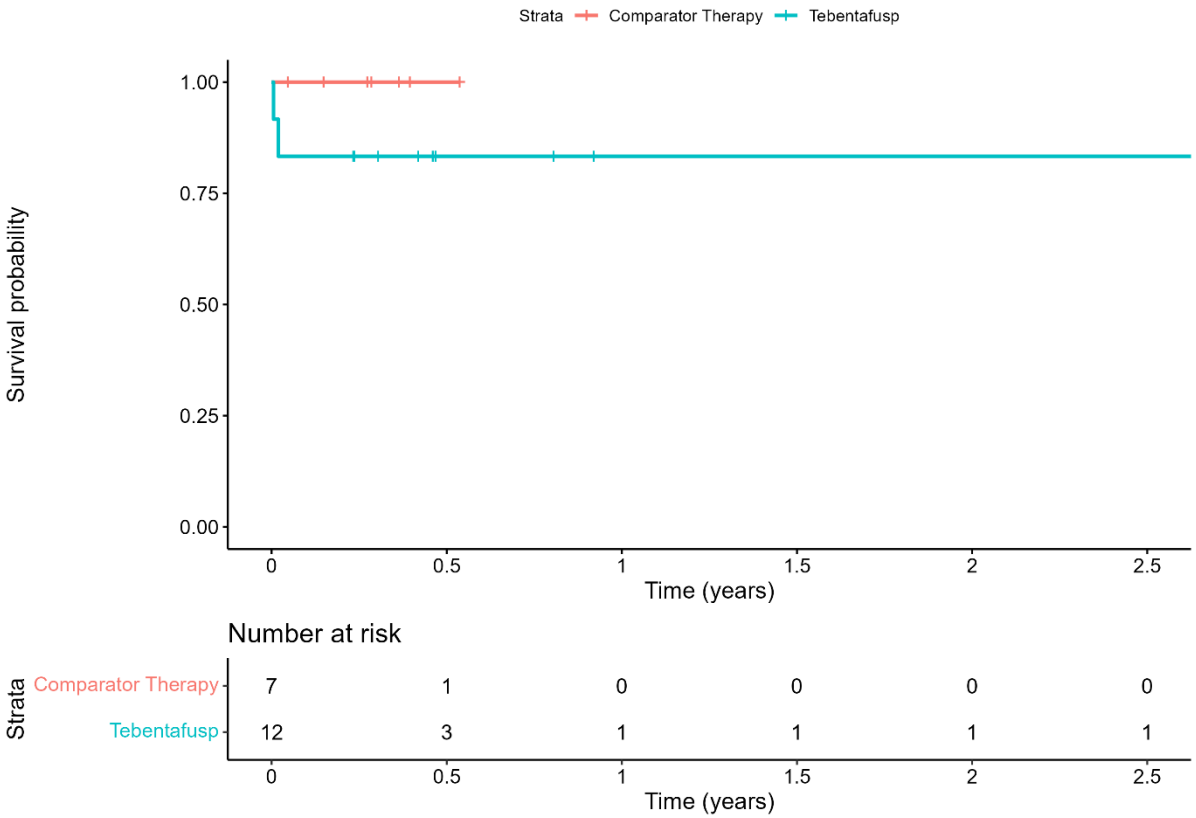
Region: Nordamerika



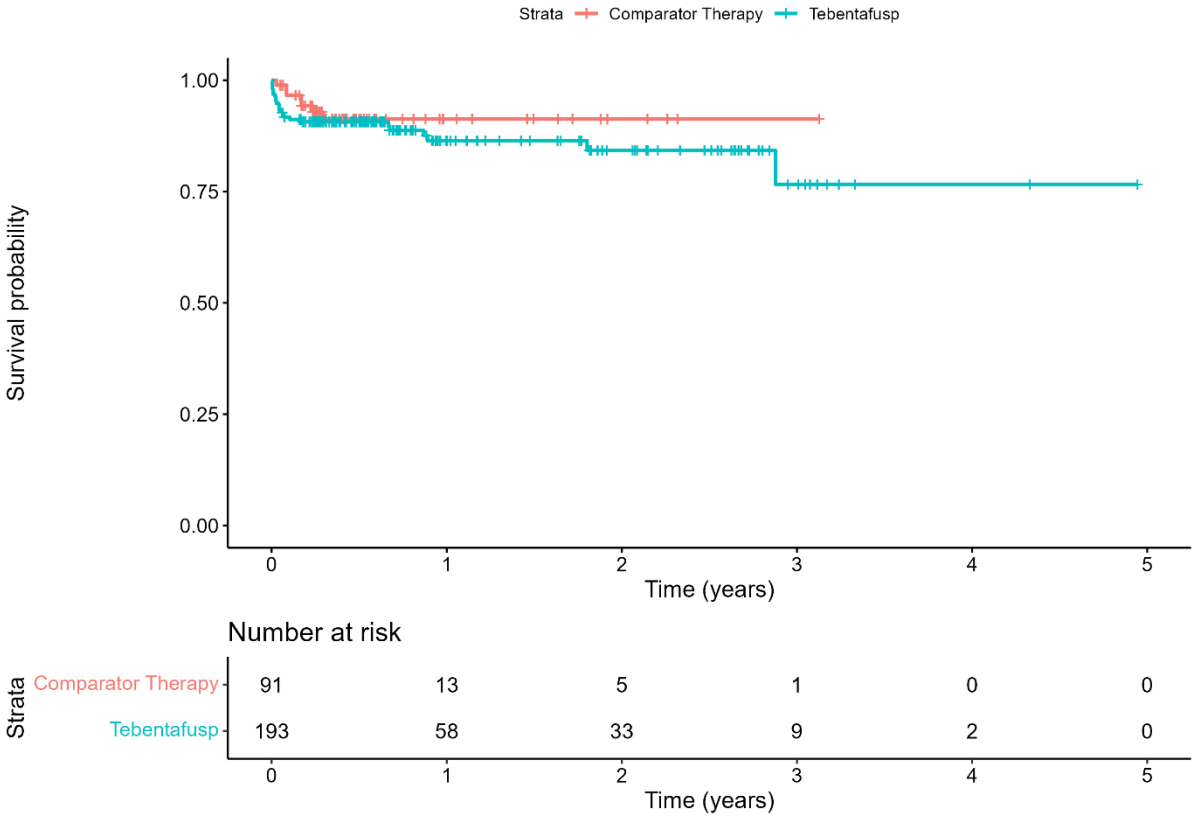
Region: Nicht-Nordamerika



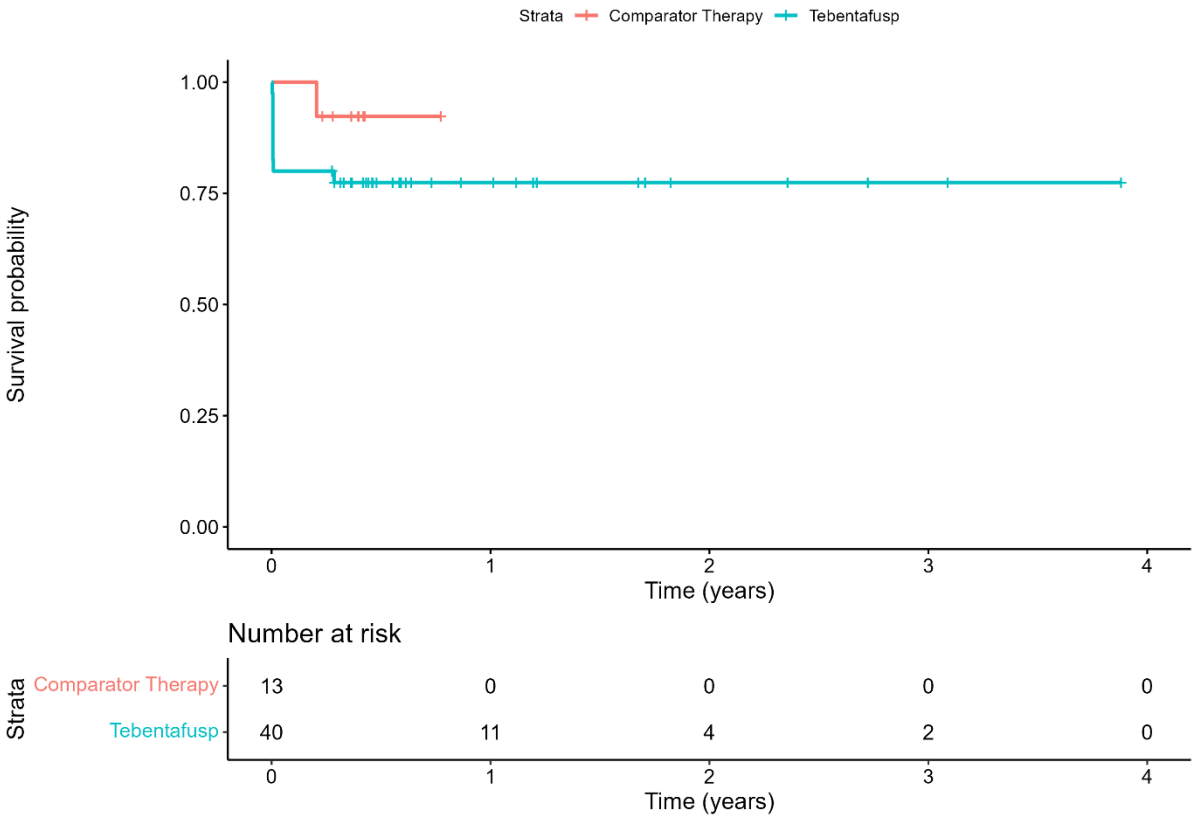
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

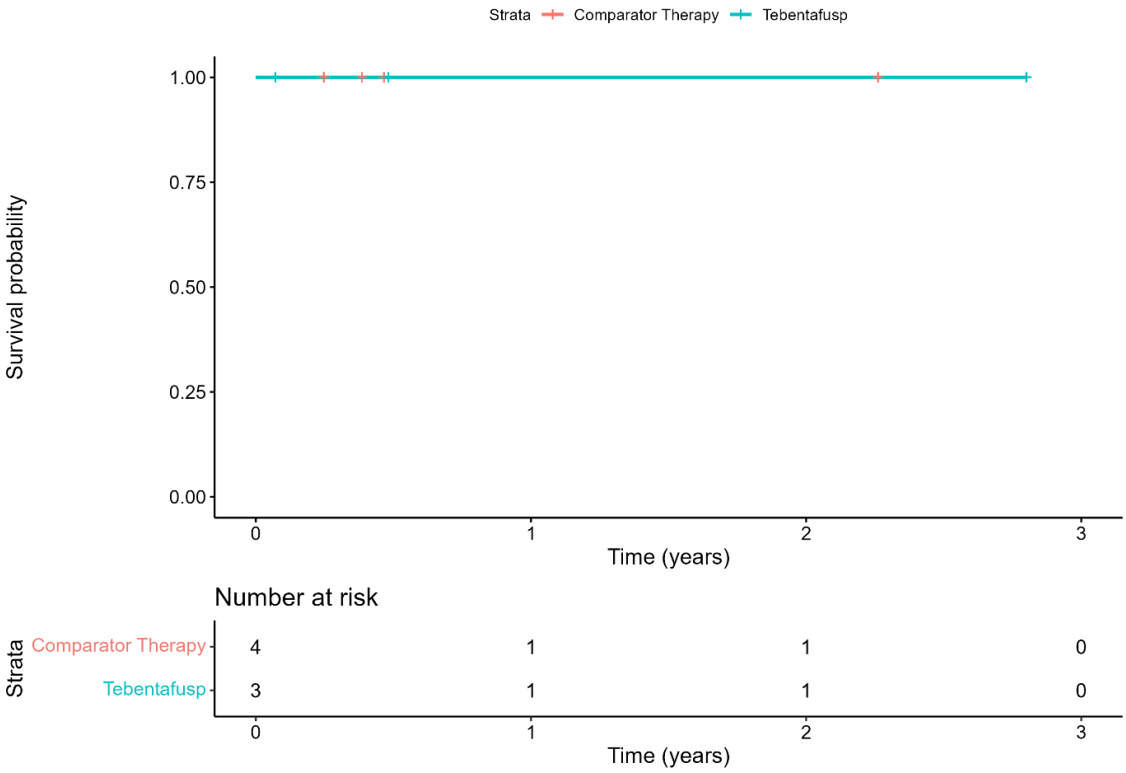


Vorauswahl der Chemotherapie: Ipilimumab

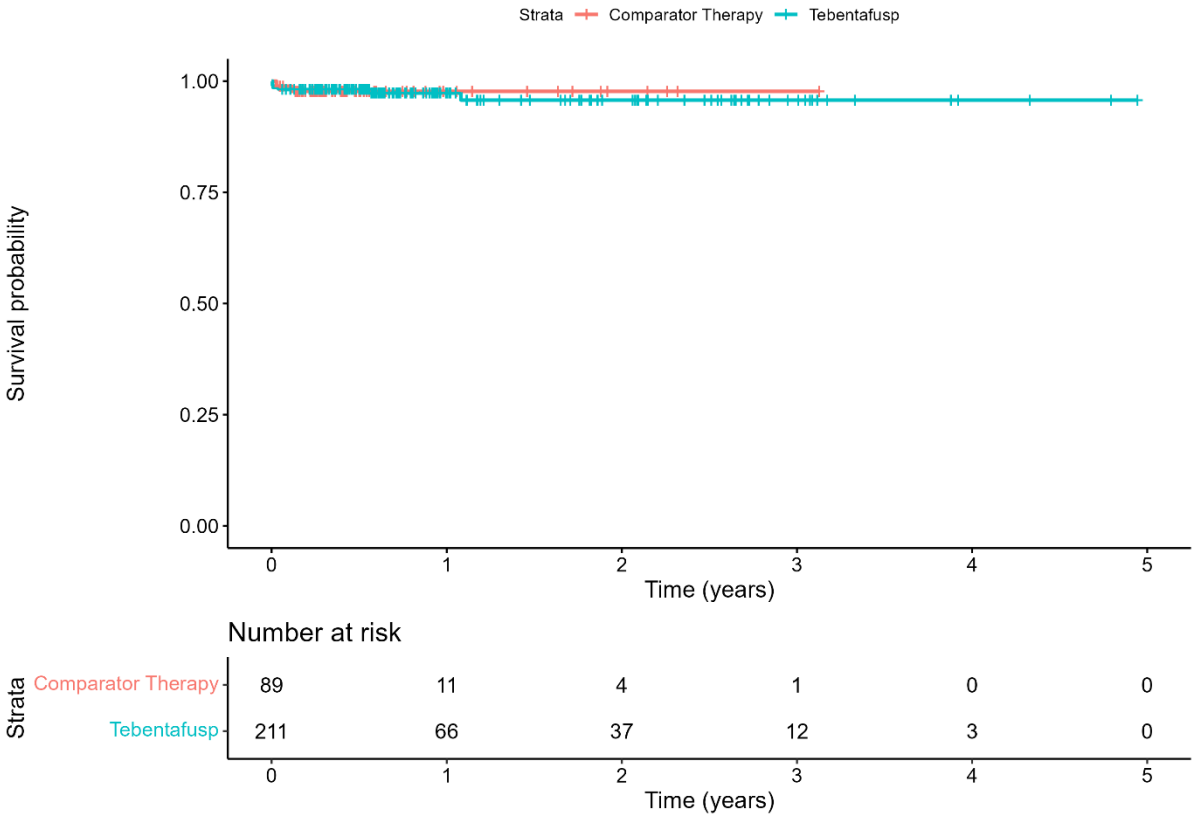


59.14 Schwerwiegende LFT-Erhöhung (Tabelle 4-241)

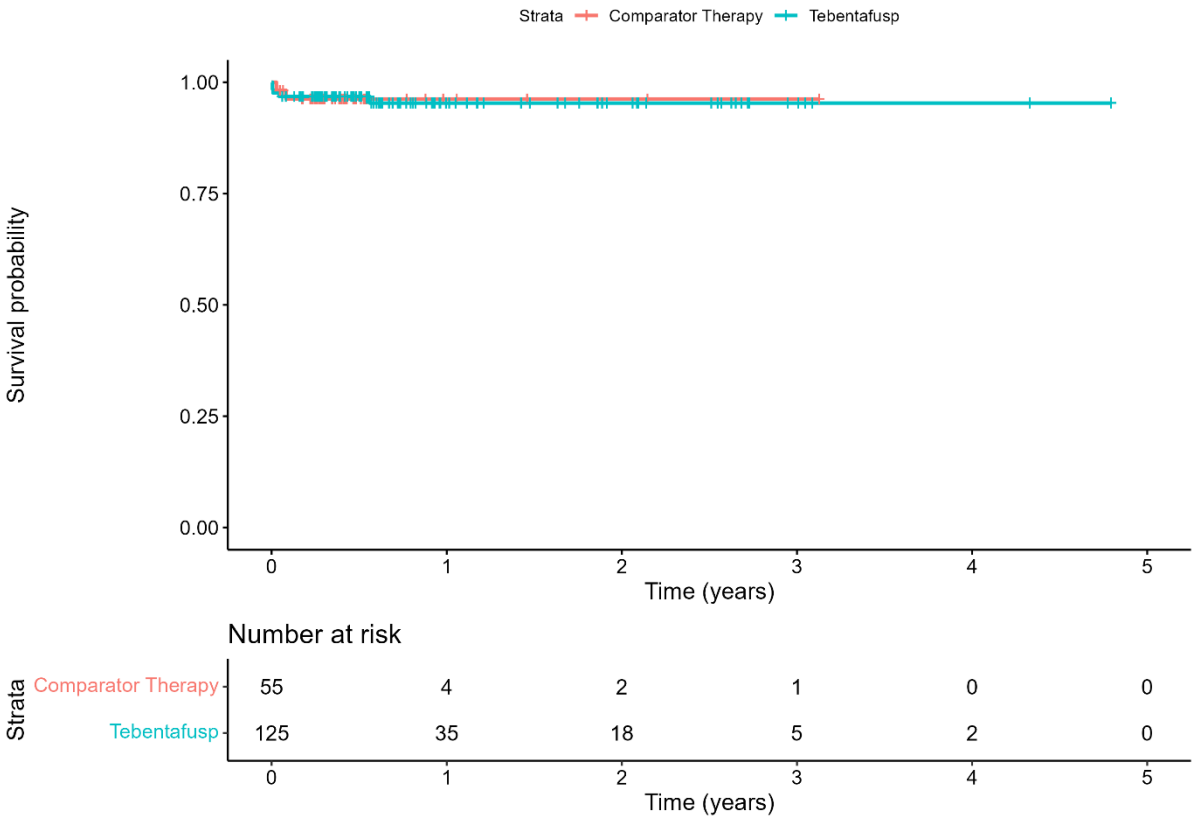
Herkunft: Hispanisch



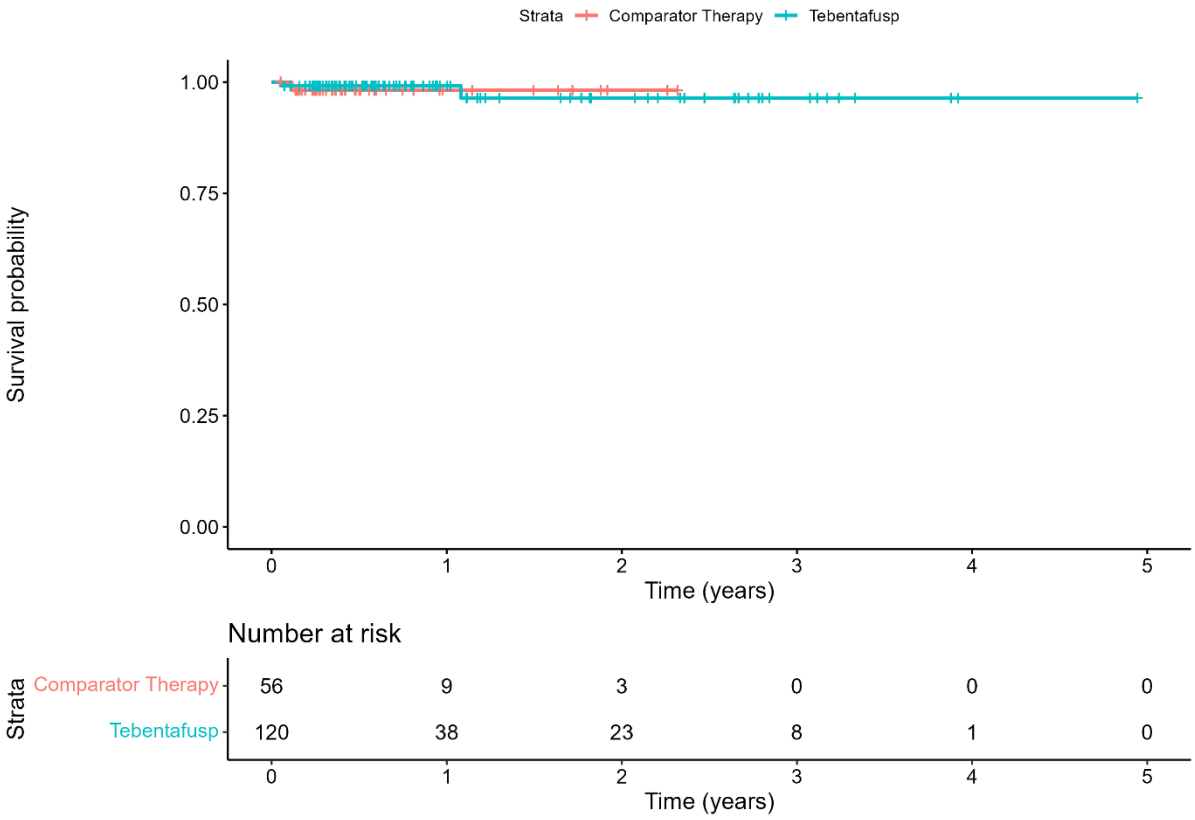
Herkunft: Nicht-hispanisch



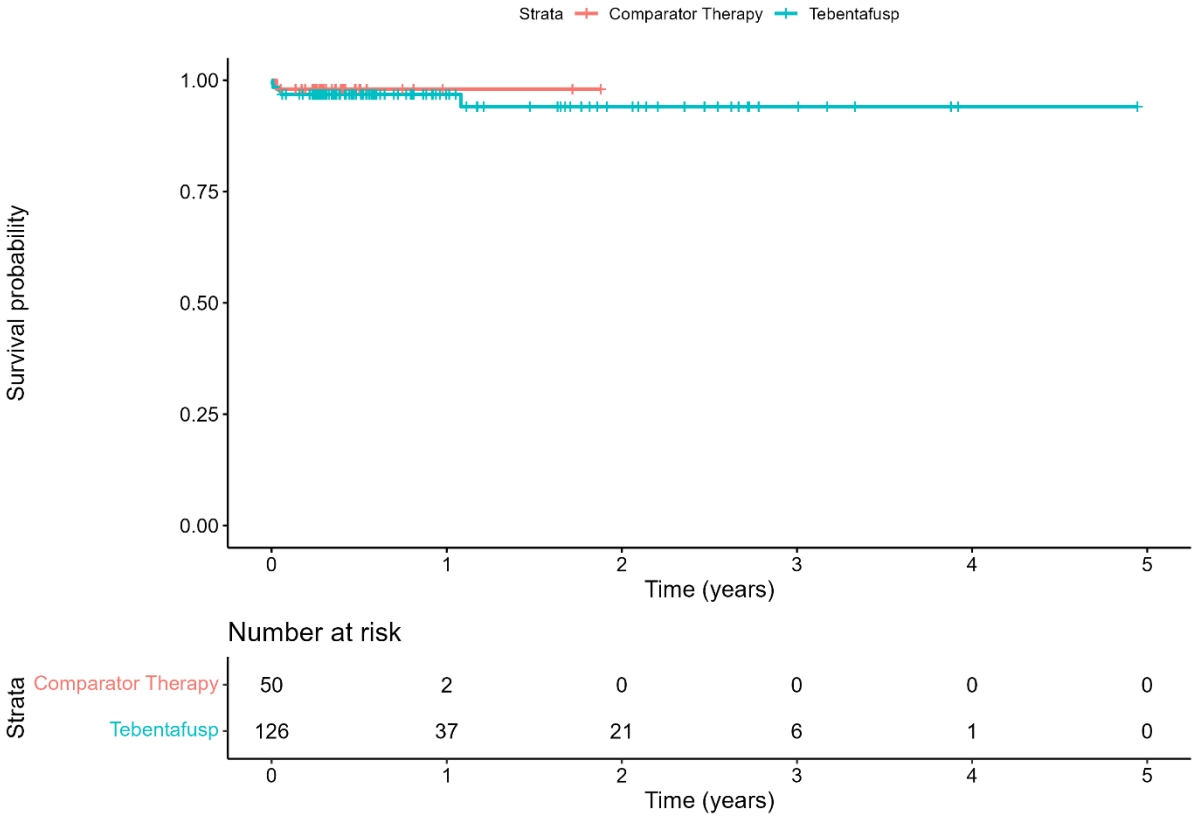
Geschlecht: Männlich



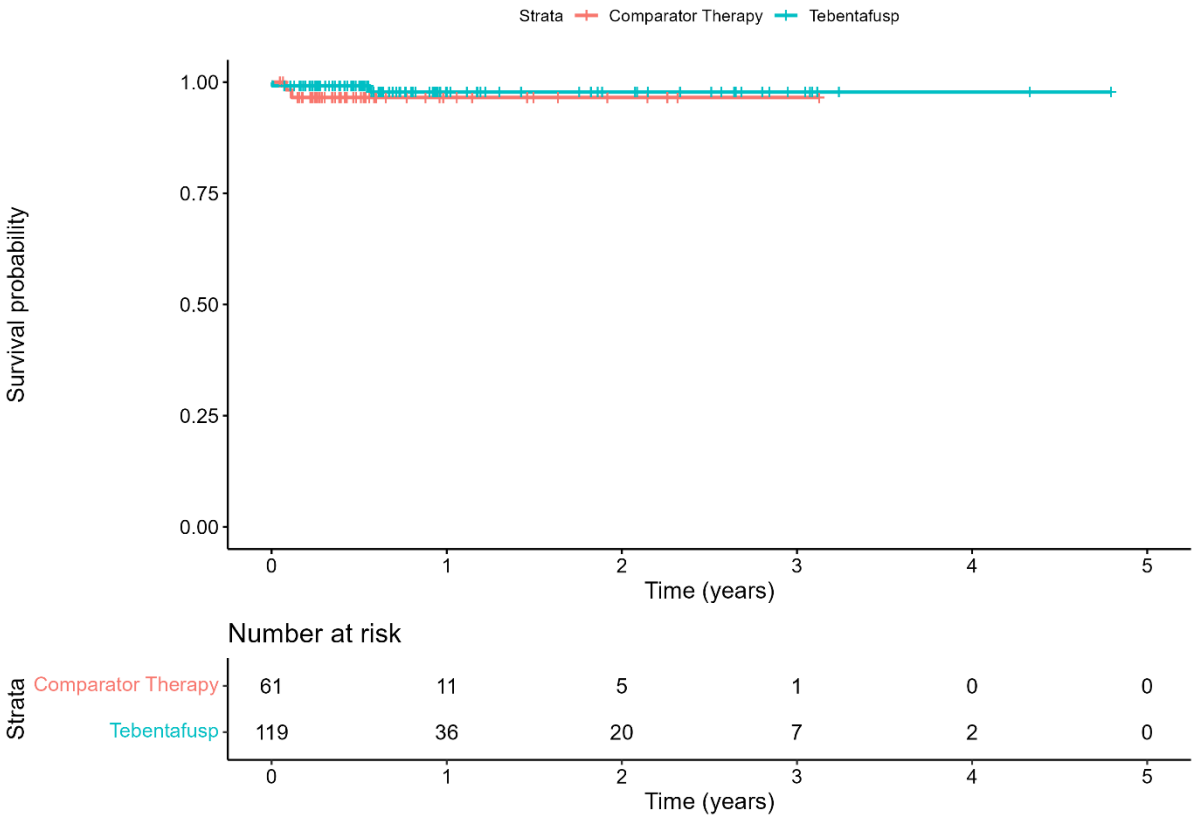
Geschlecht: Weiblich



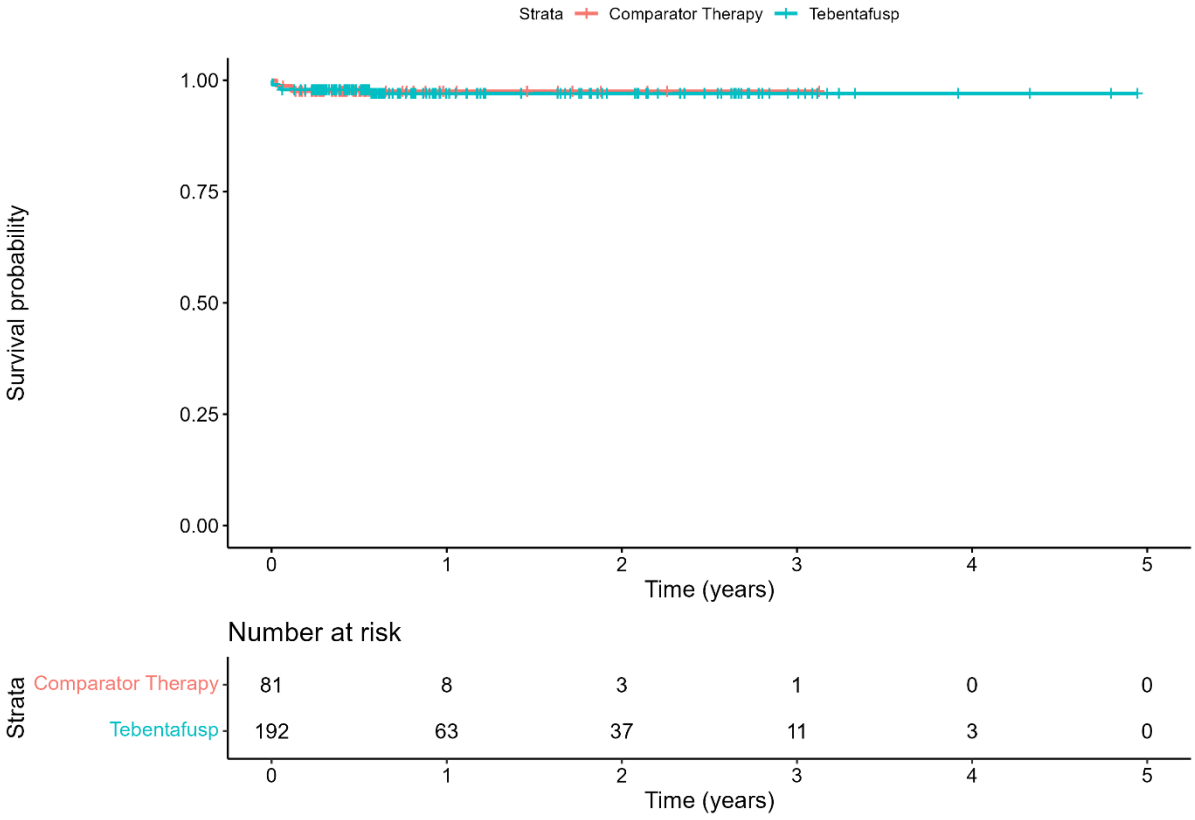
Alter: <65 Jahre



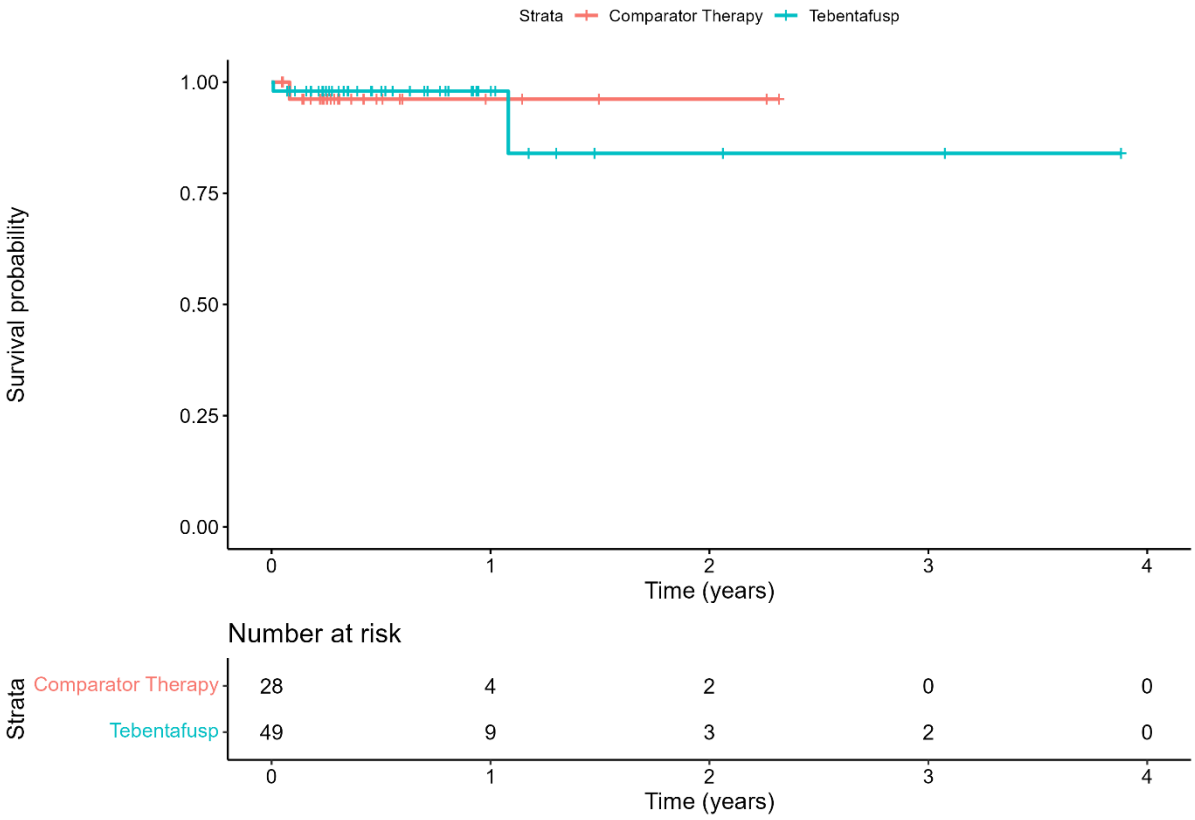
Alter: ≥65 Jahre



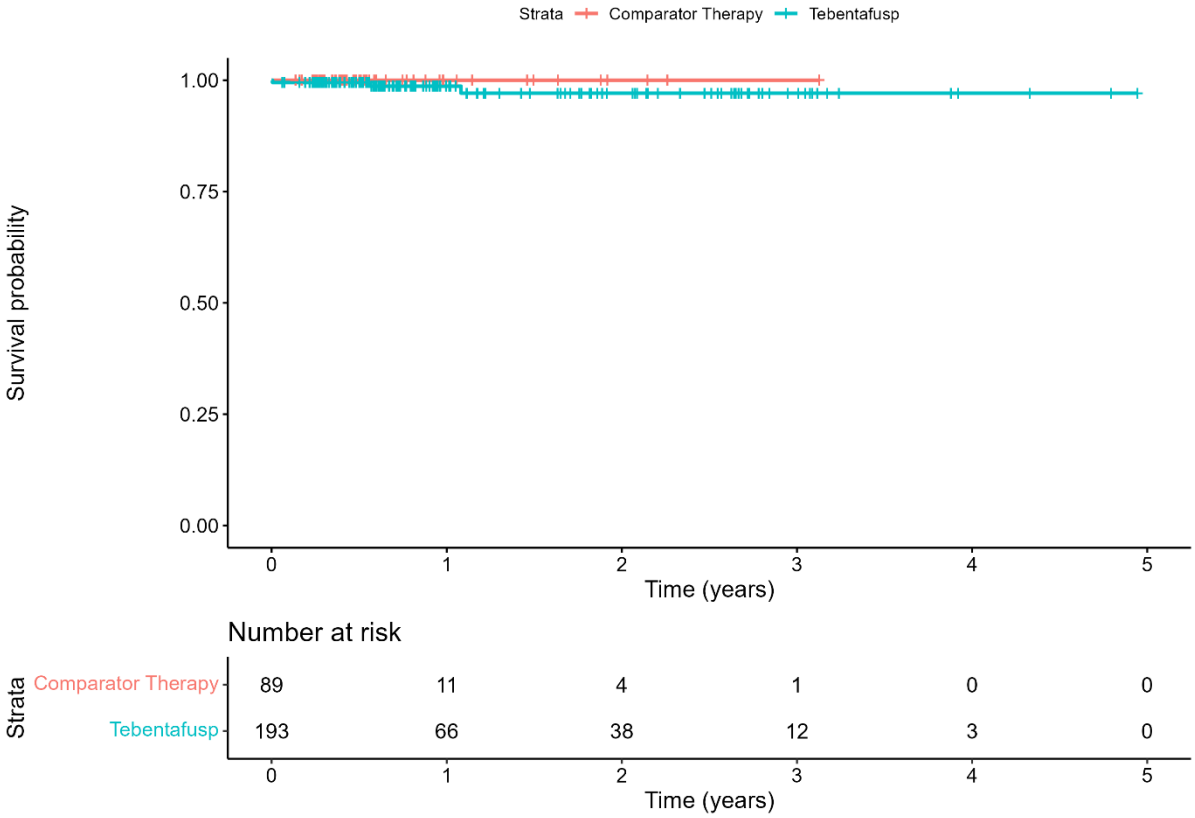
ECOG-Performance-Status: 0



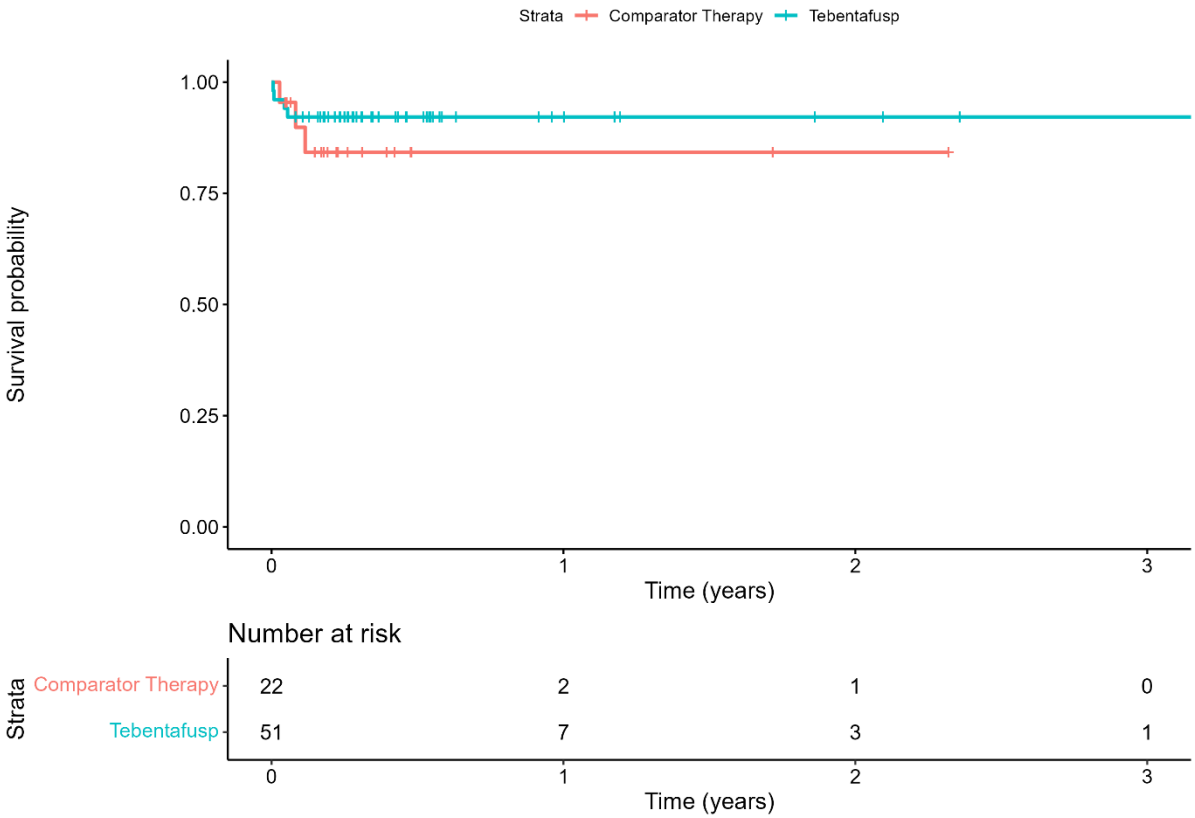
ECOG-Performance-Status: 1



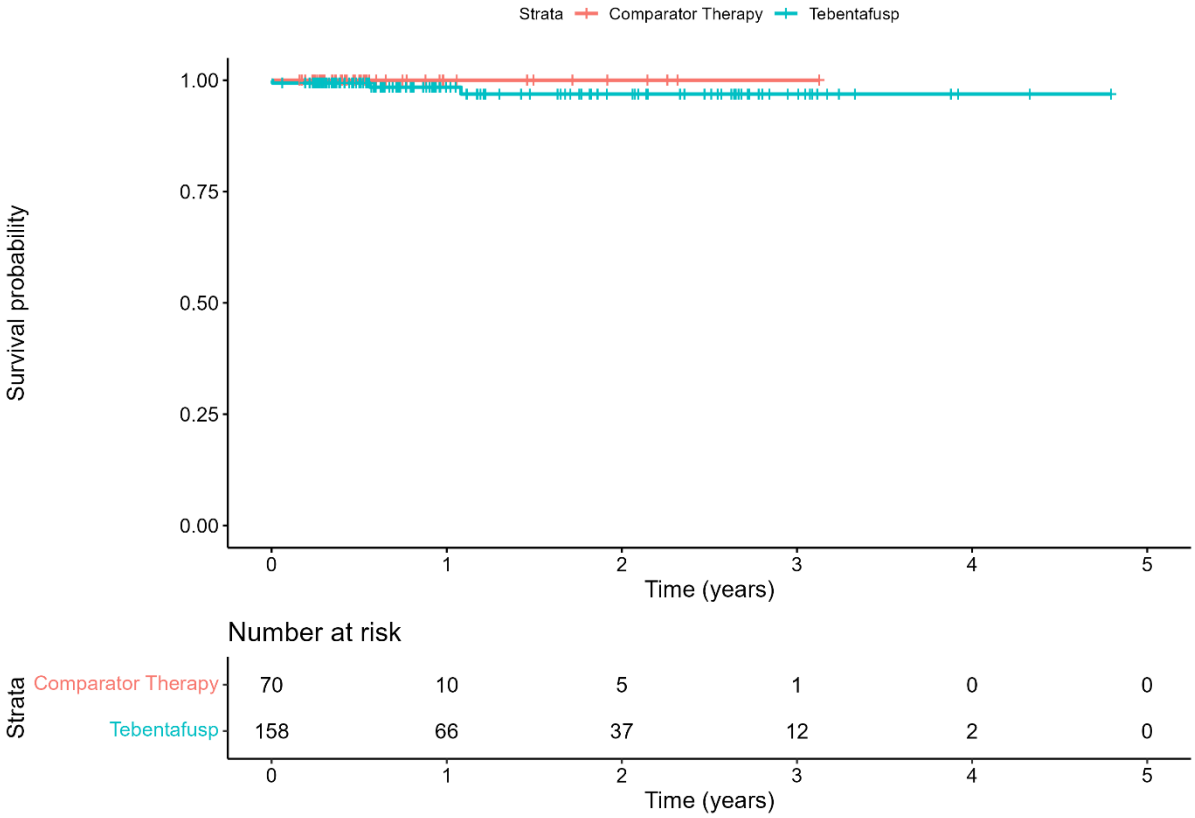
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



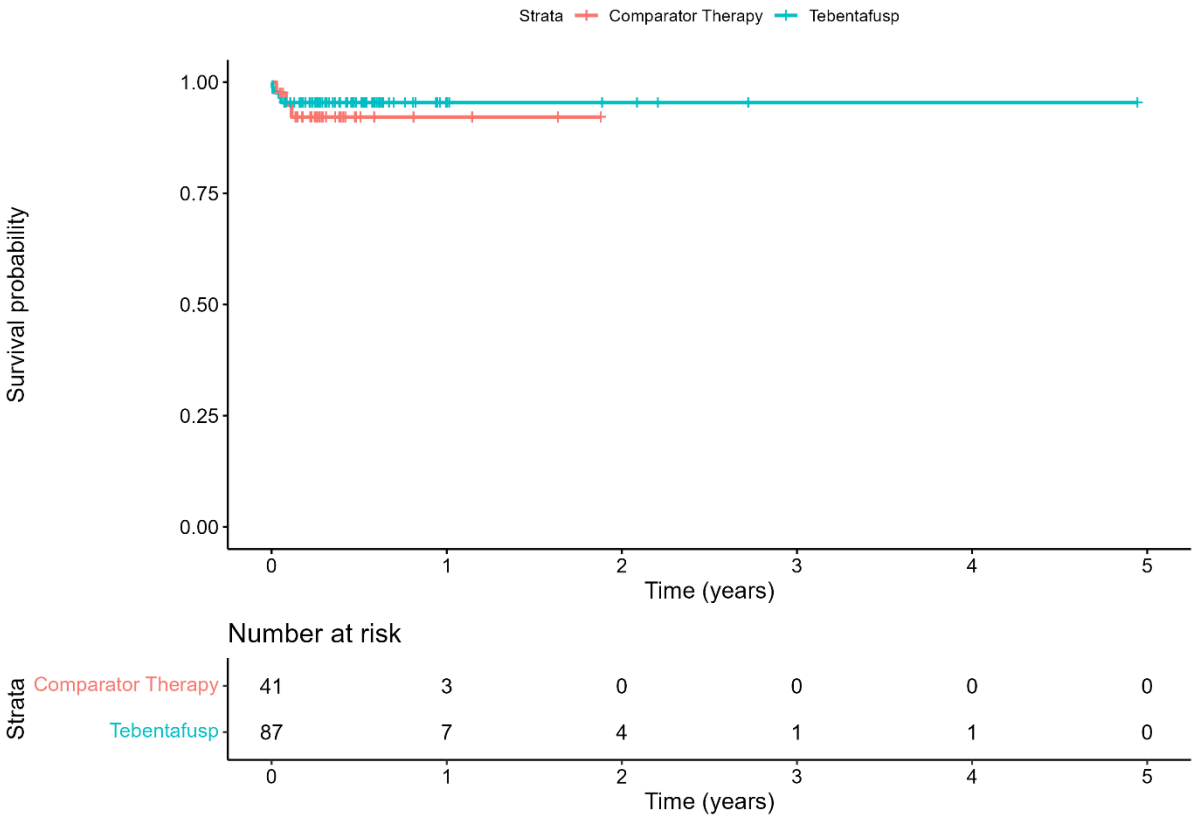
Alkalische Phosphatase (ALP) (Baseline): >ULN



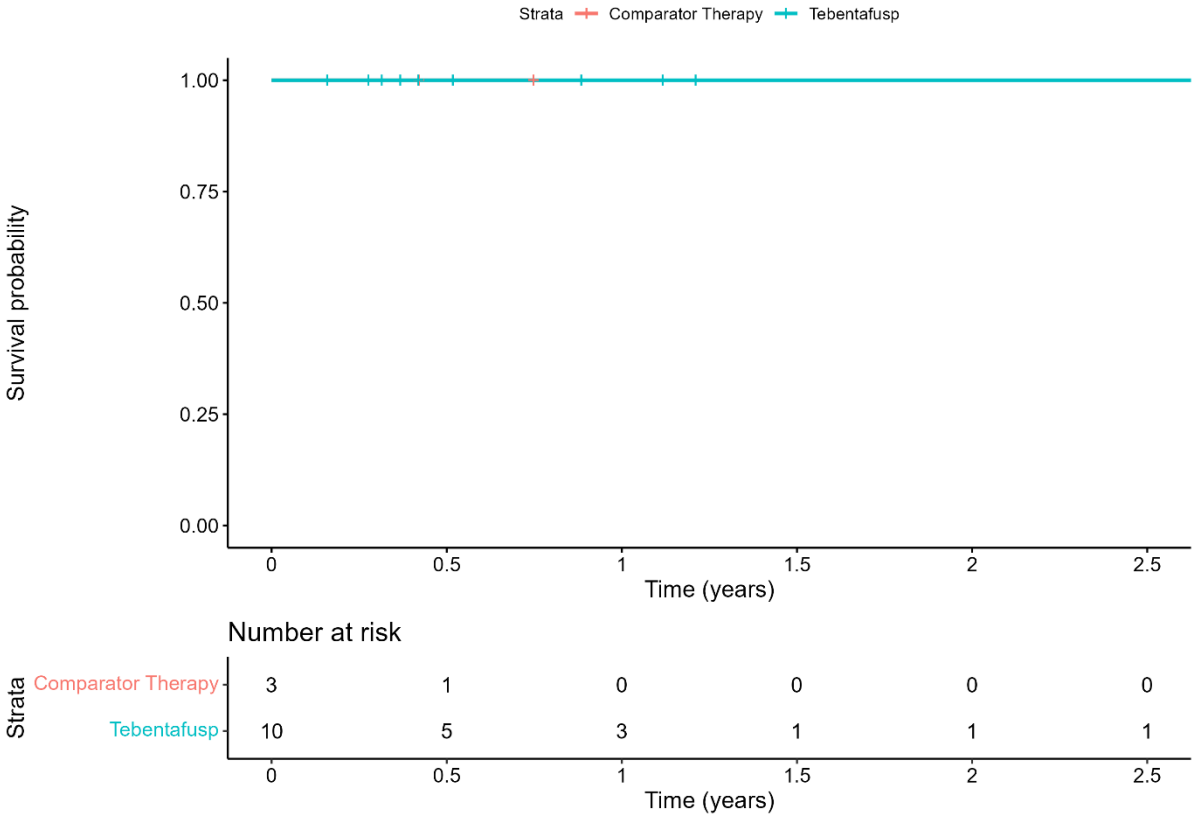
LDH: ≤ULN



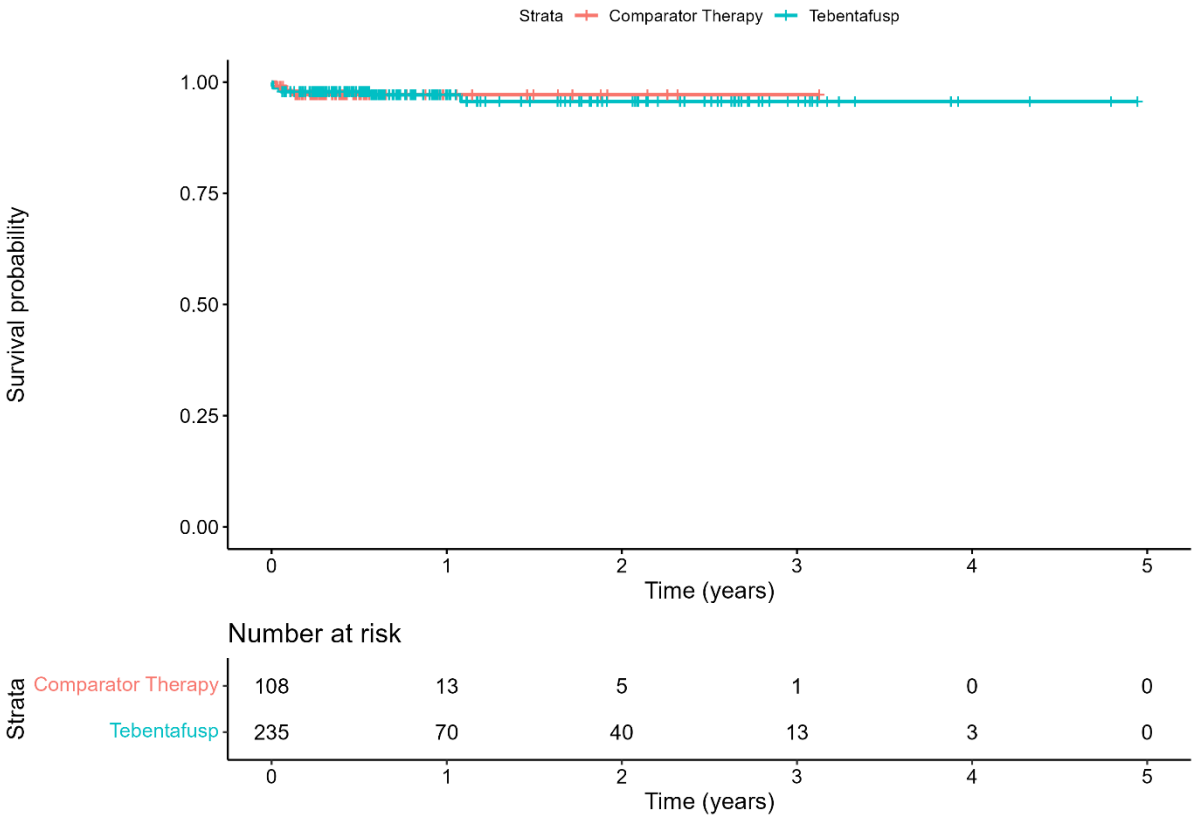
LDH: >ULN



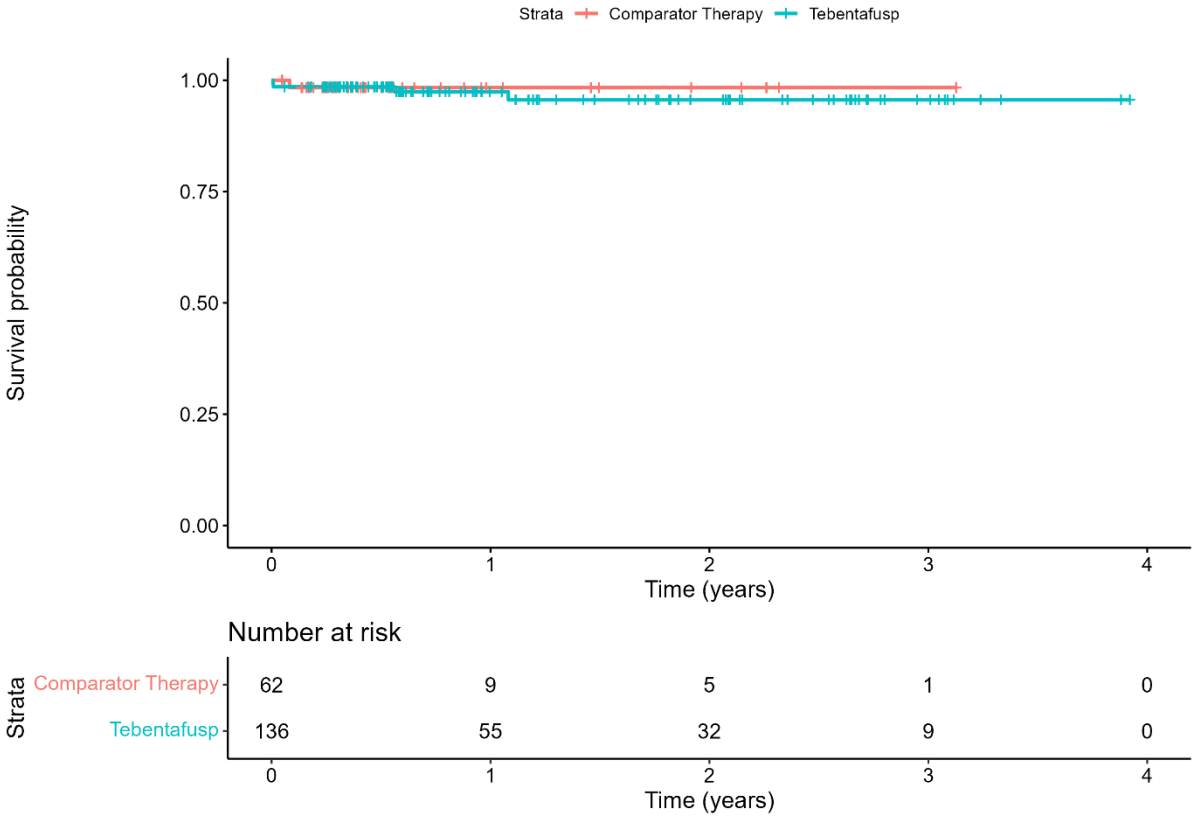
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



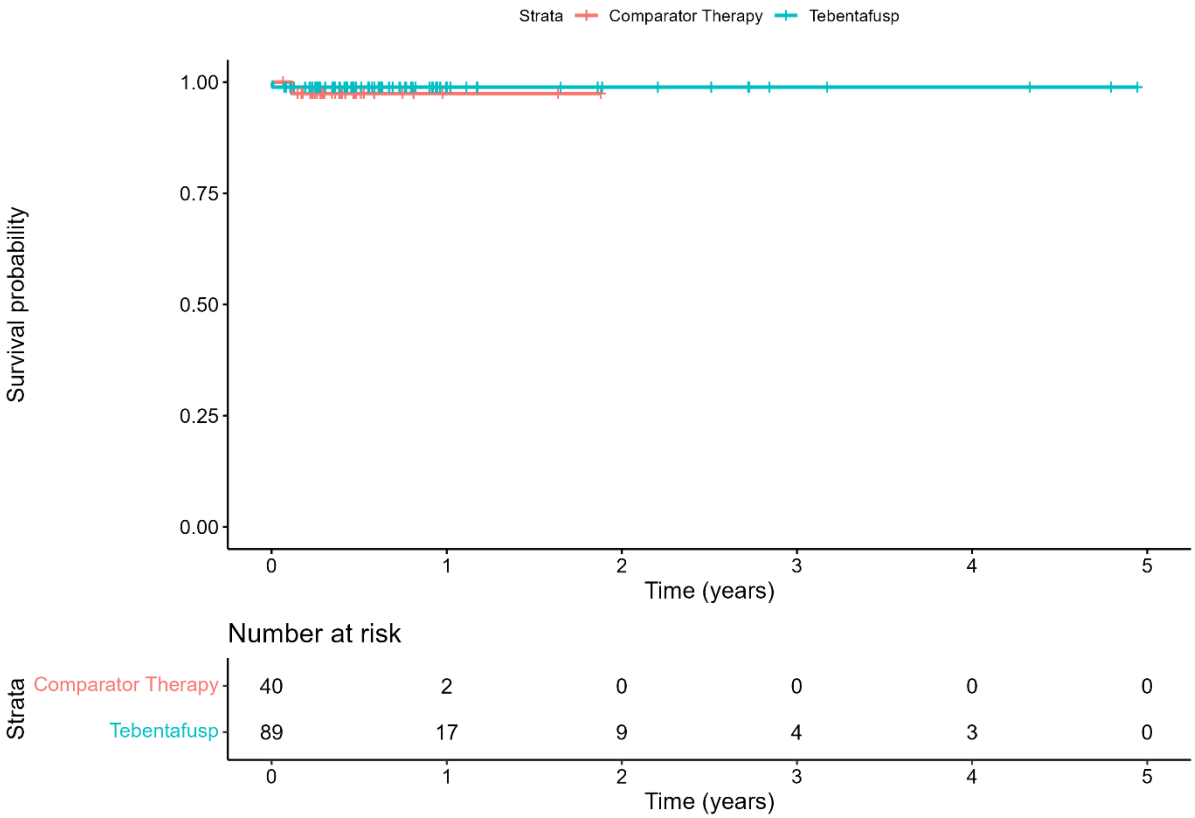
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



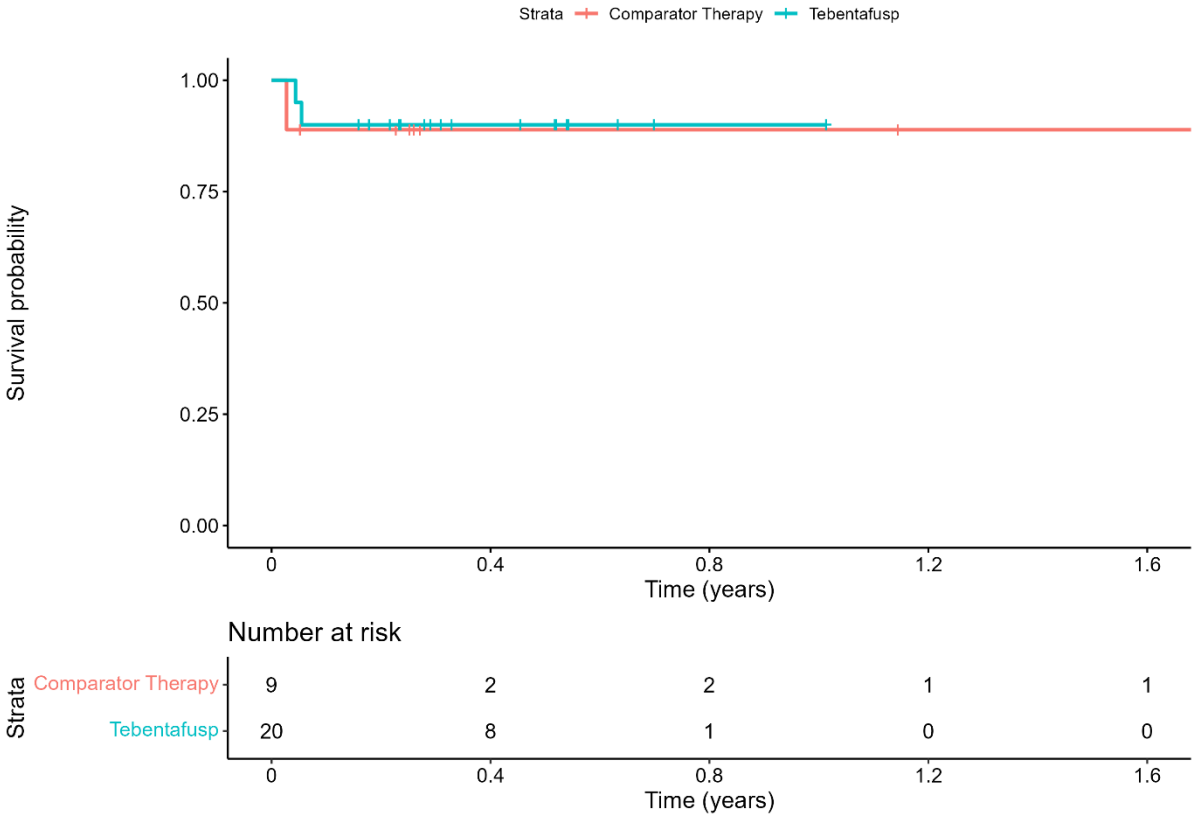
Größte metastatische Läsion (Baseline): ≤3,0 cm



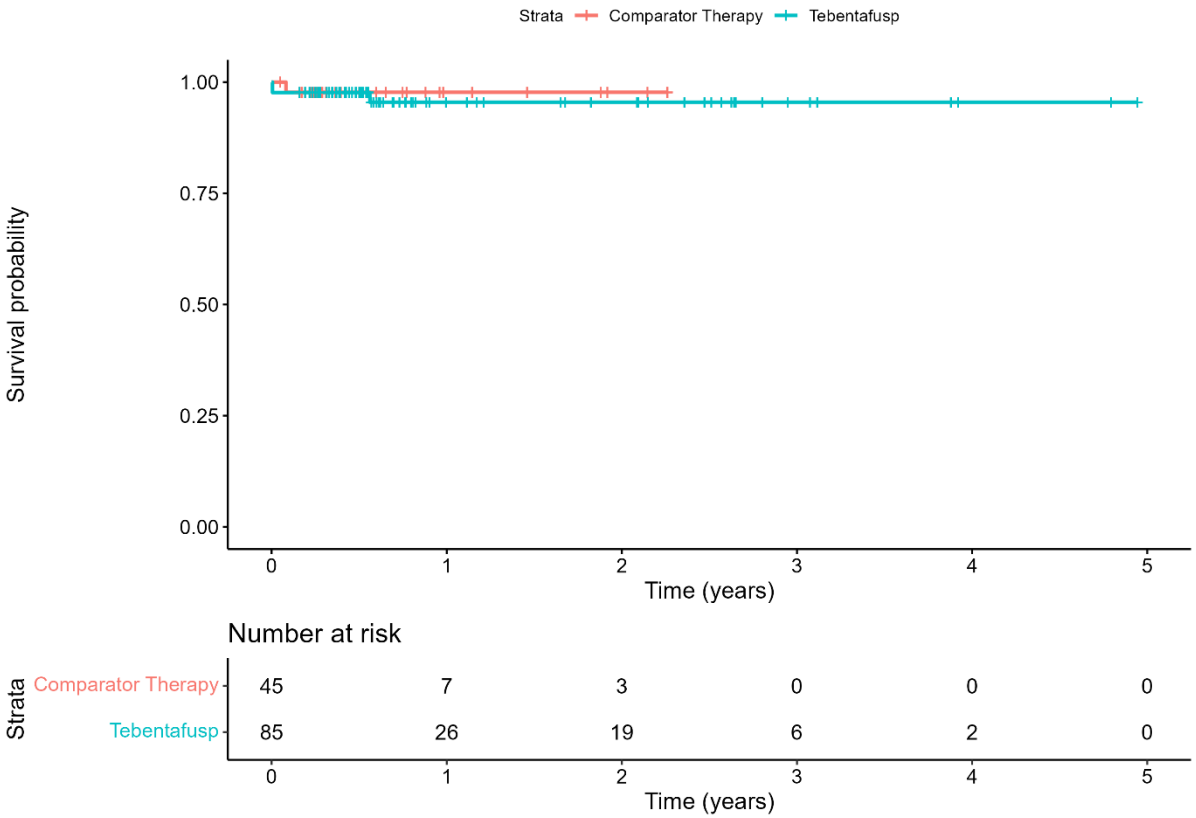
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



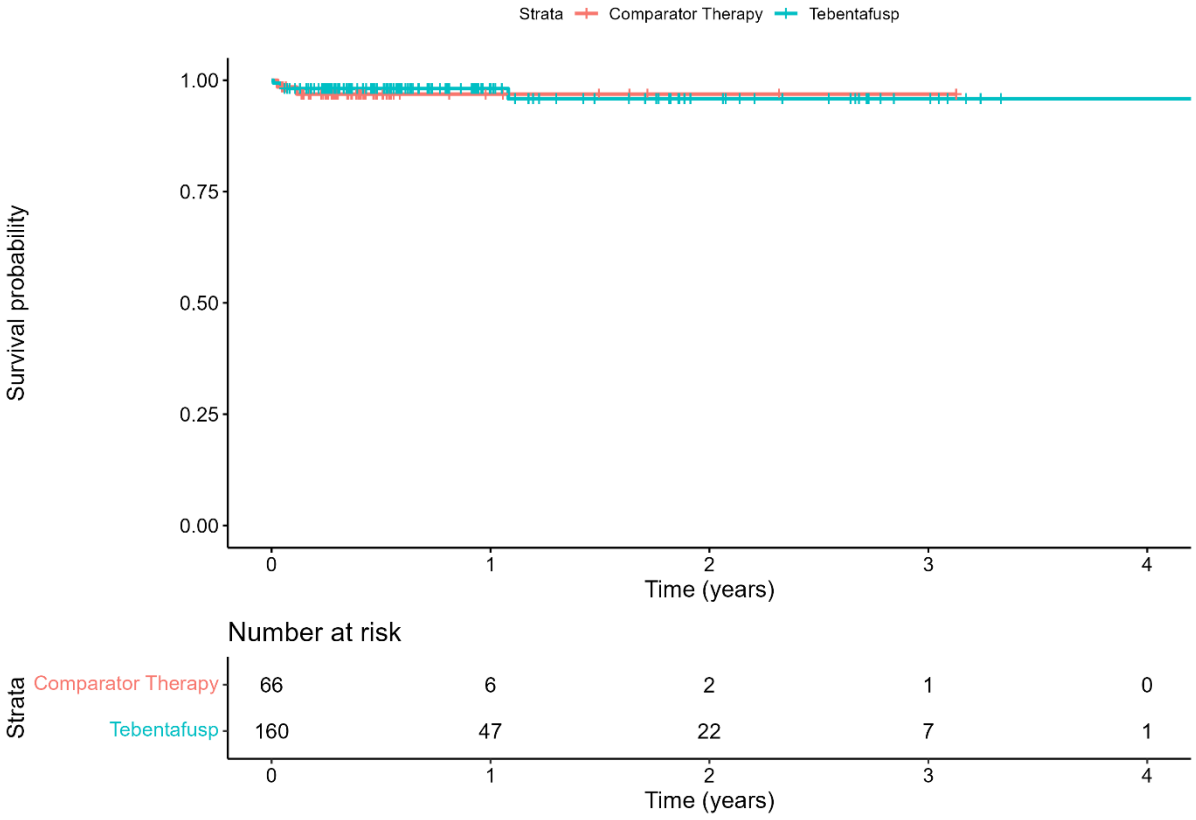
Größte metastatische Läsion (Baseline): ≥8,1 cm



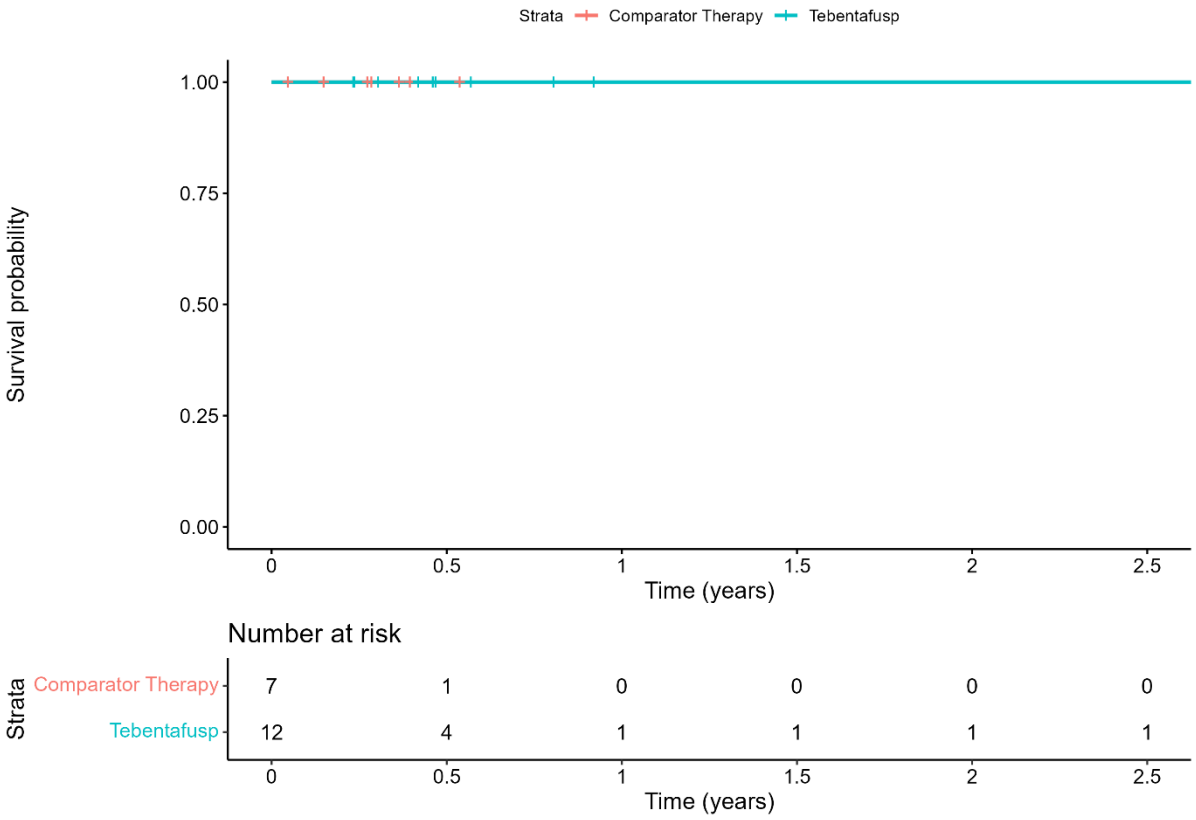
Region: Nordamerika



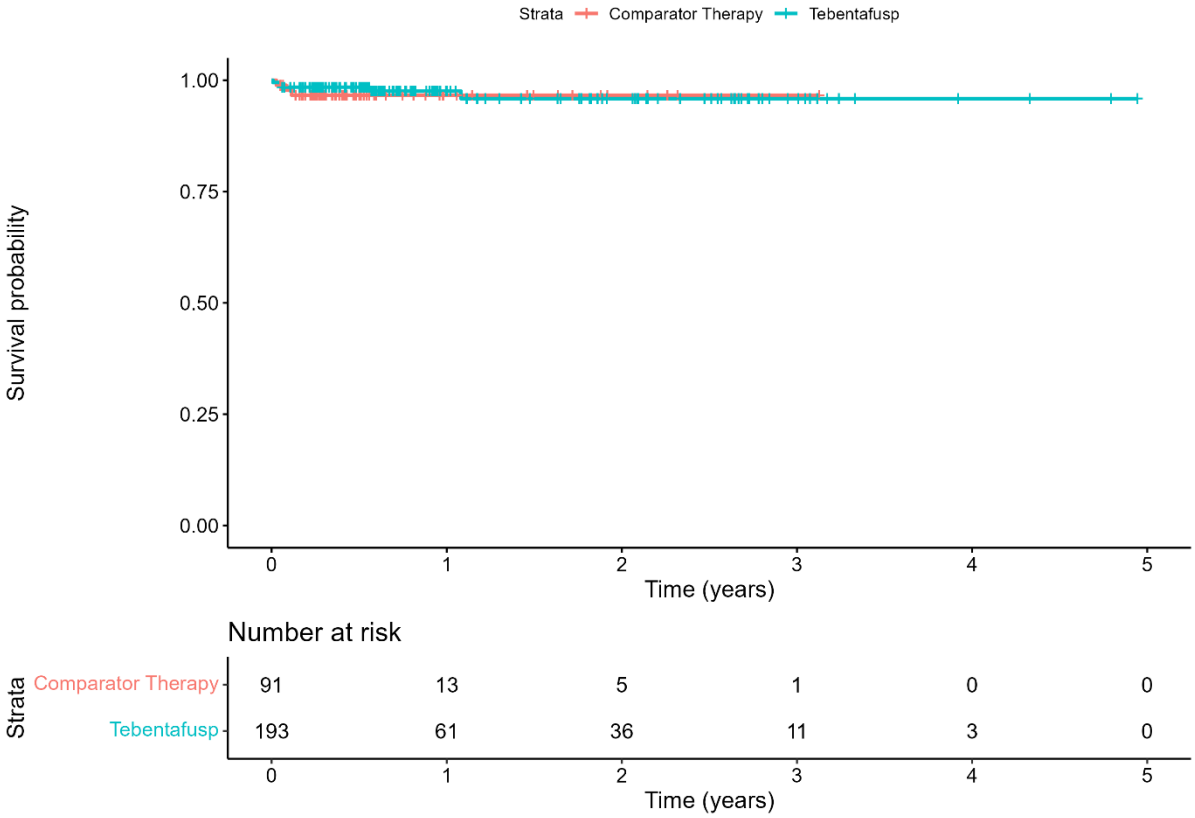
Region: Nicht-Nordamerika



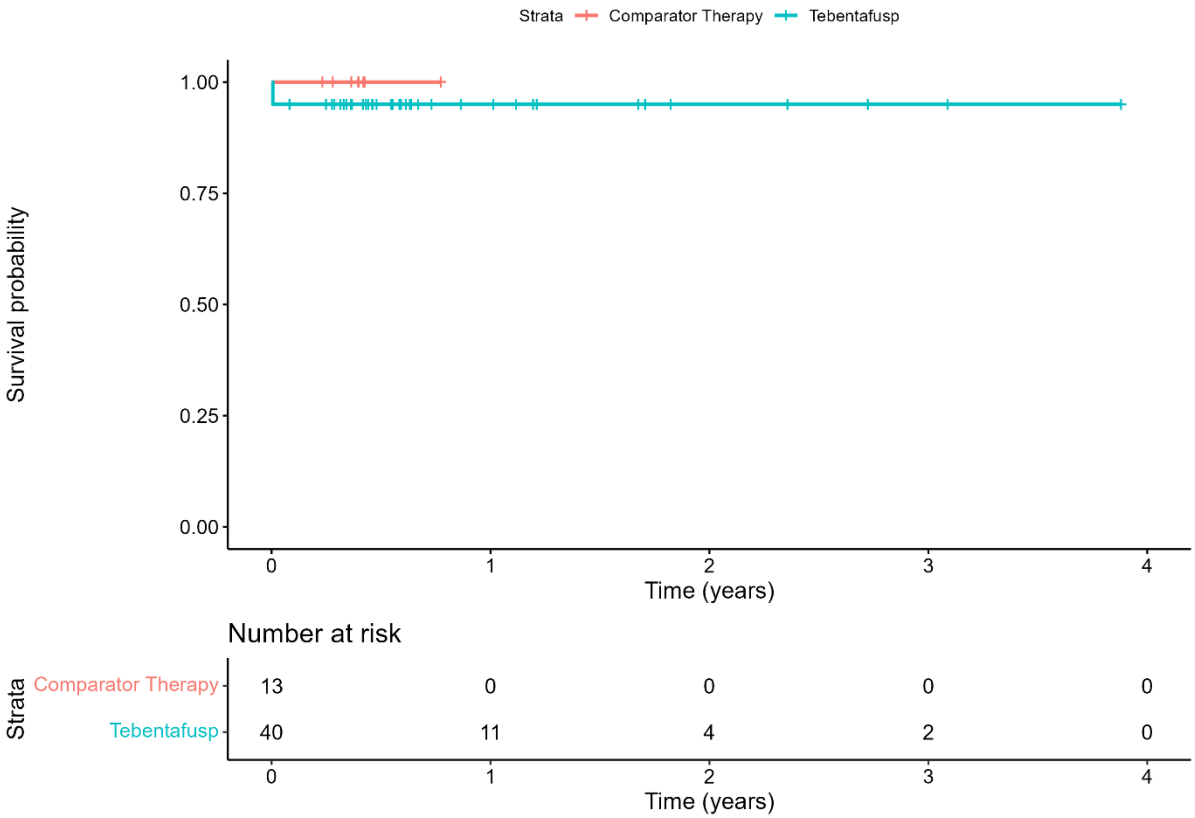
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab

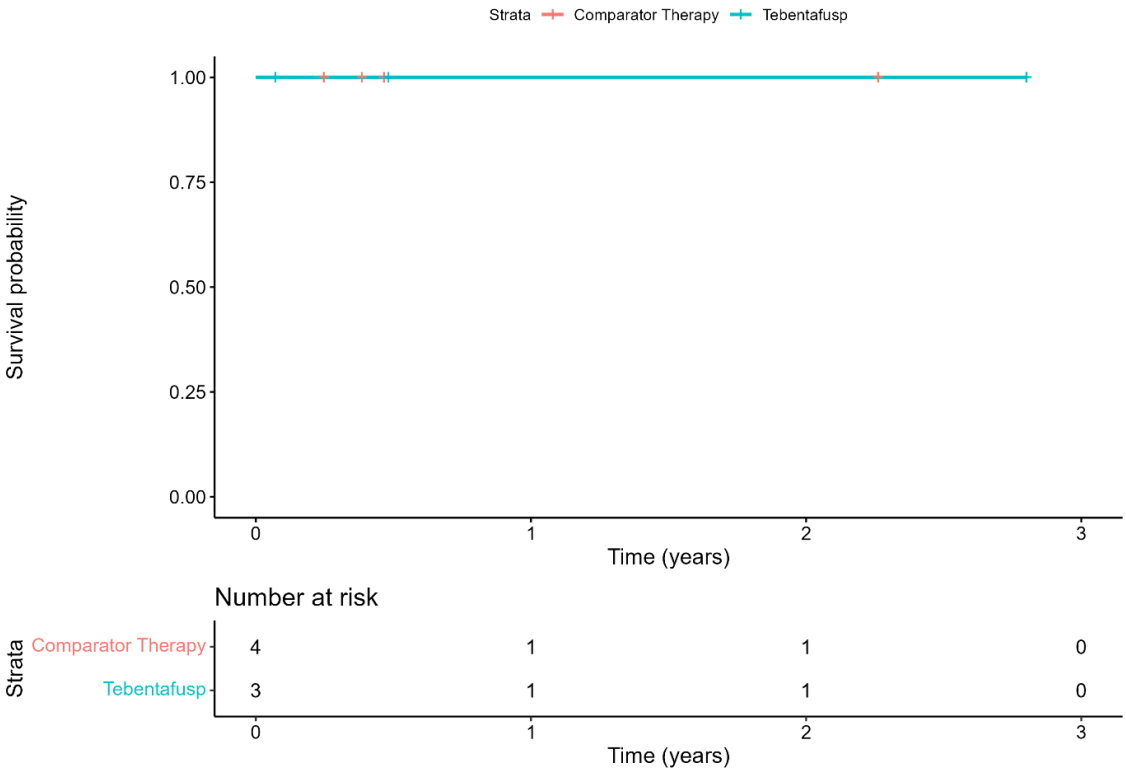


Vorauswahl der Chemotherapie: Ipilimumab

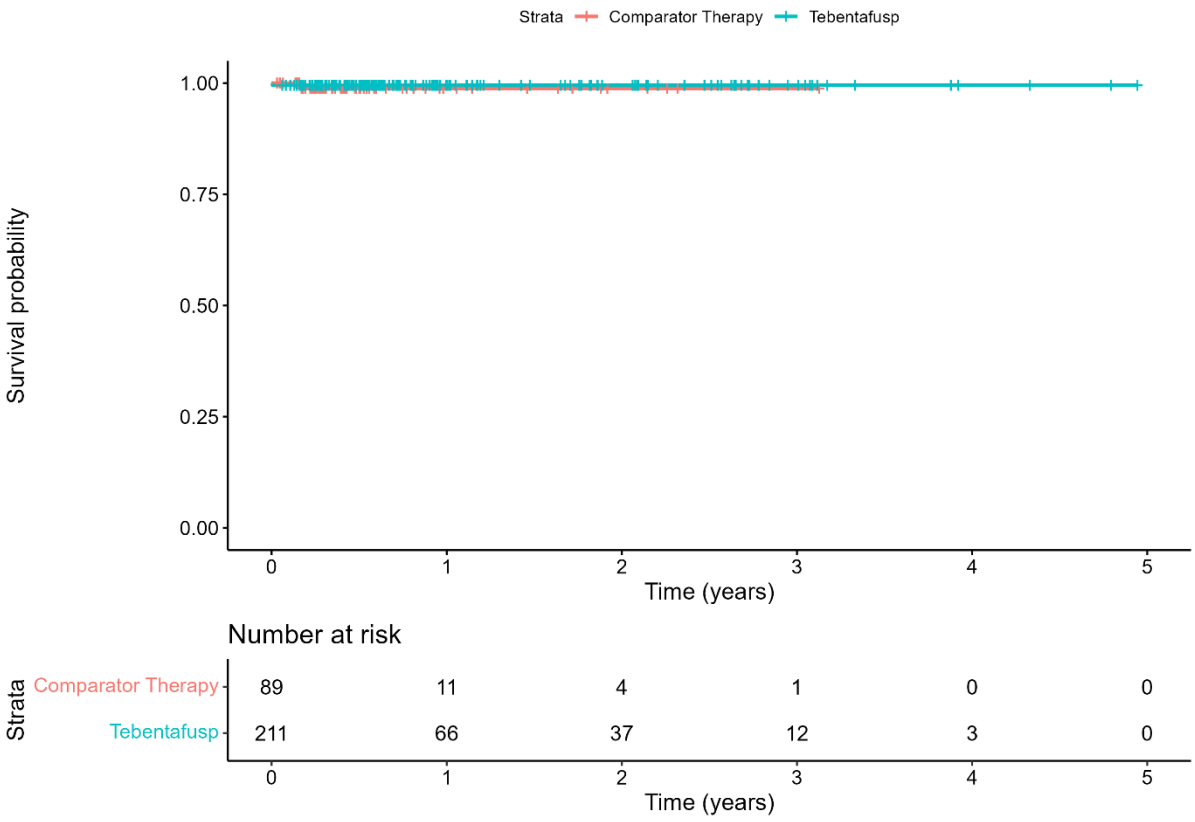


59.15 LFT-Erhöhung, die zum Absetzen des Studienmedikaments führte (Tabelle 4-243)

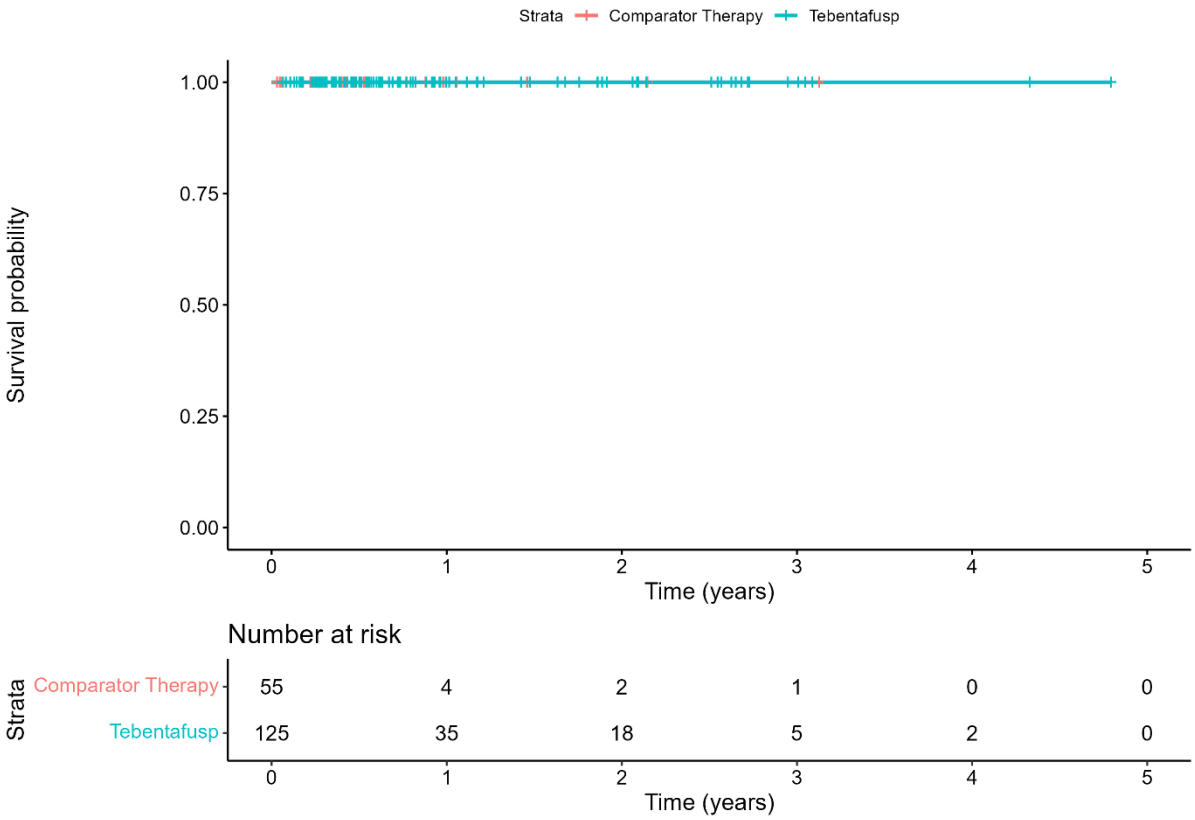
Herkunft: Hispanisch



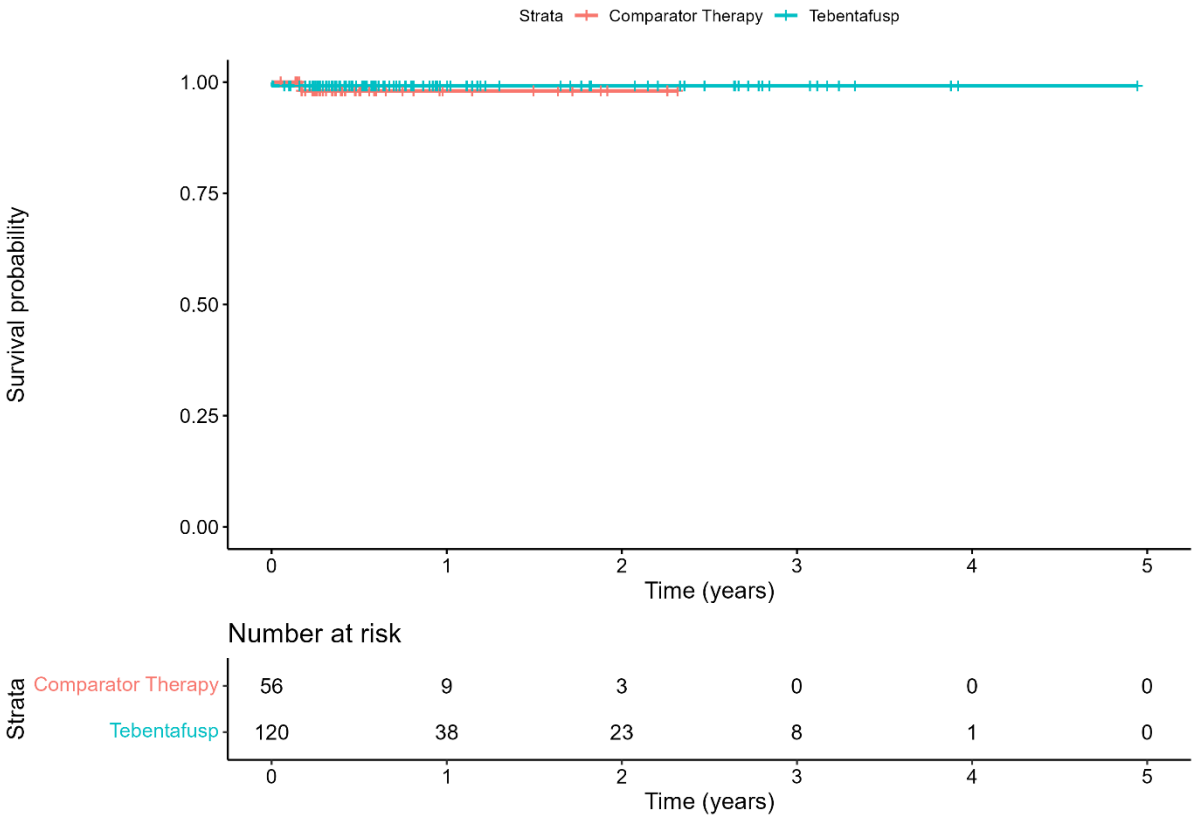
Herkunft: Nicht-hispanisch



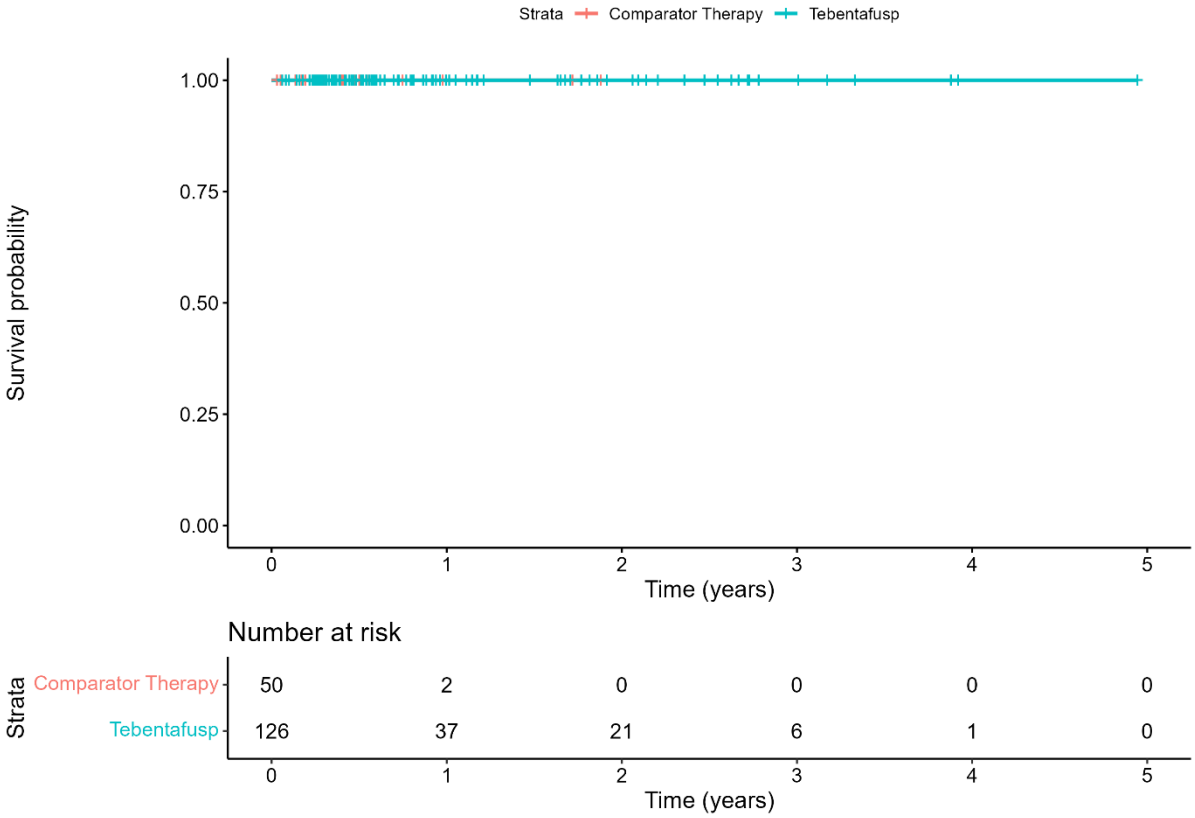
Geschlecht: Männlich



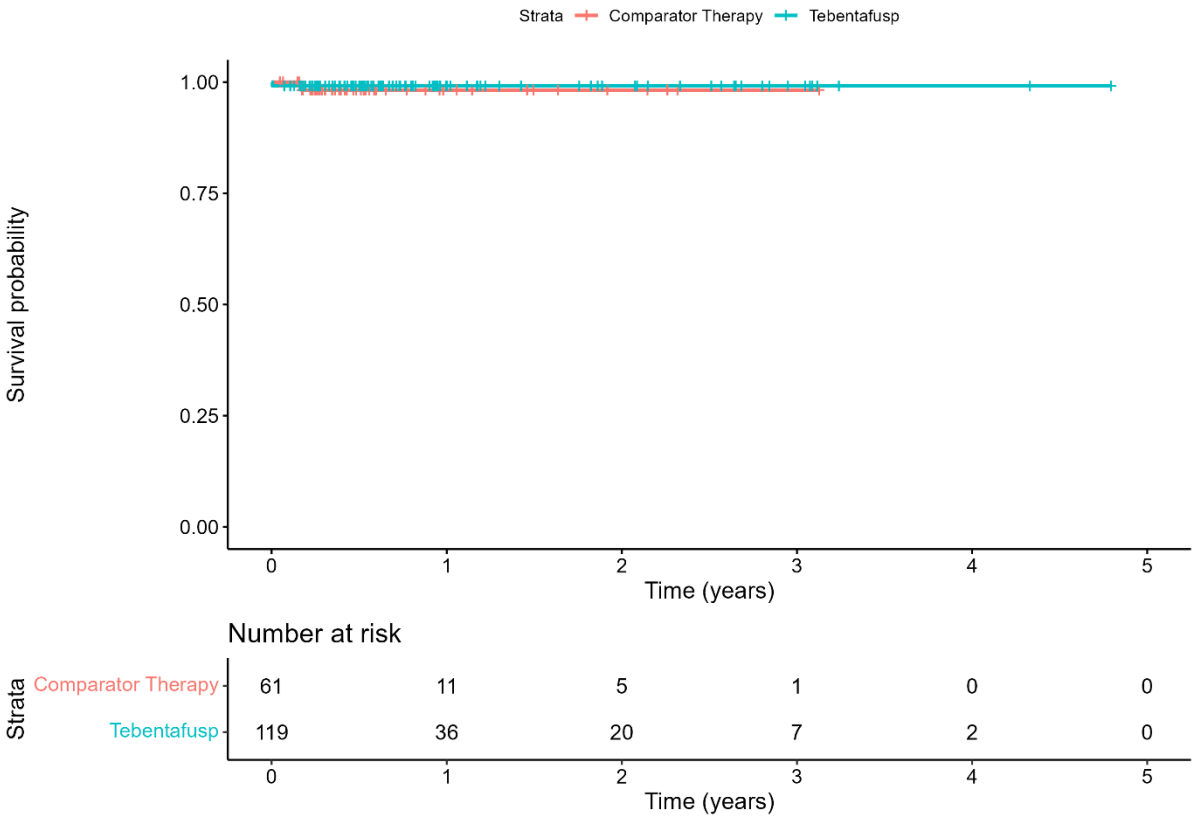
Geschlecht: Weiblich



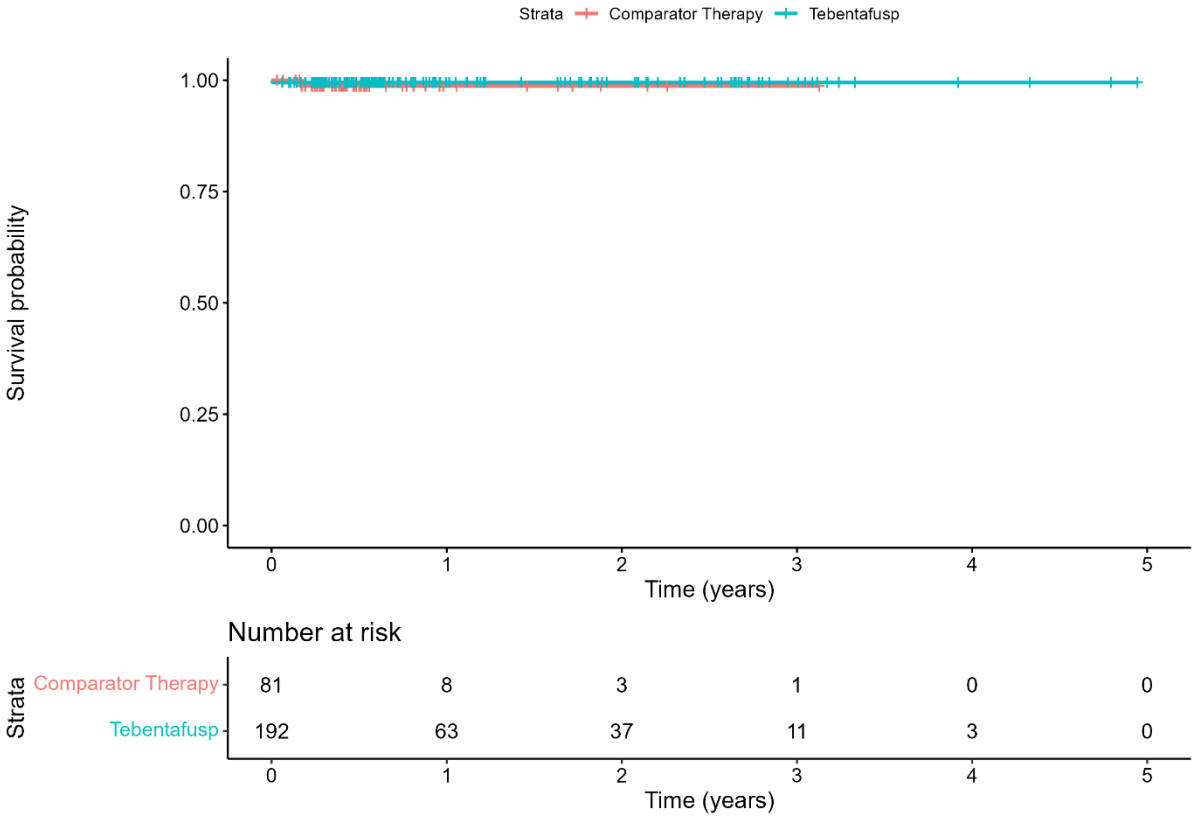
Alter: <65 Jahre



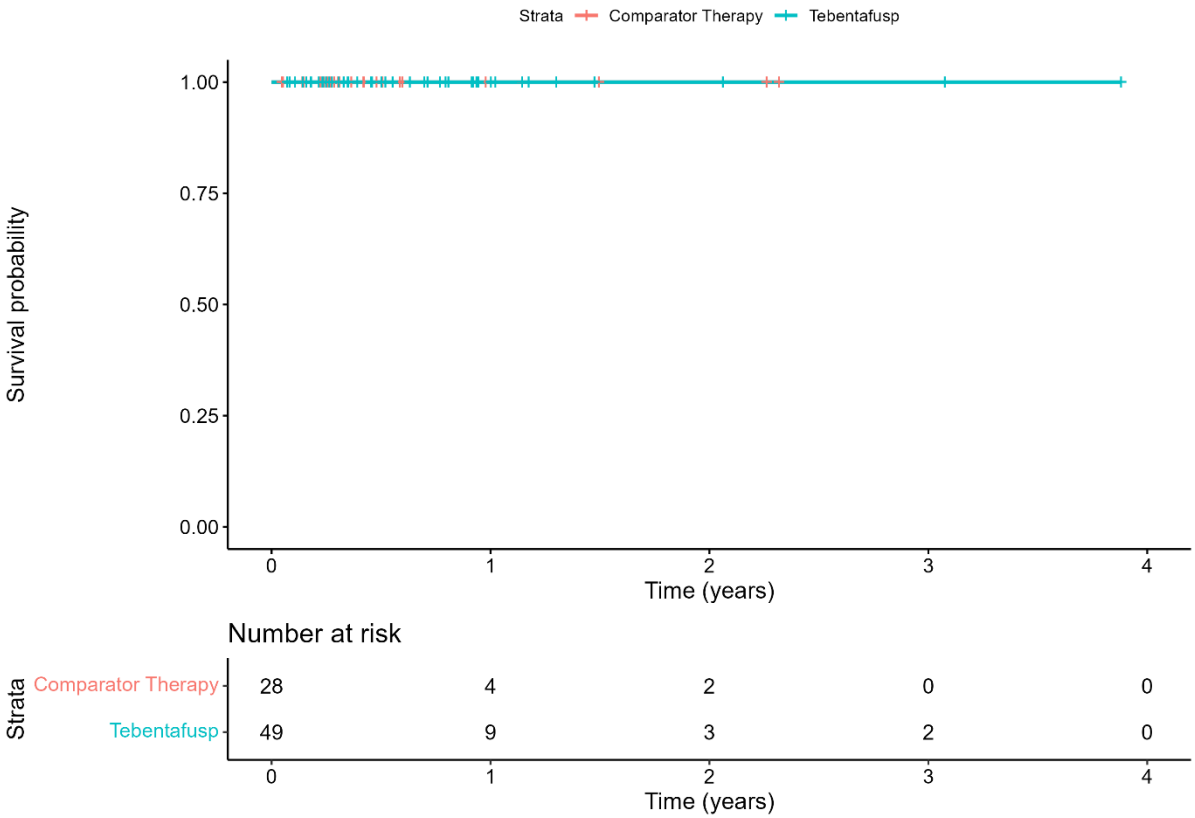
Alter: ≥65 Jahre



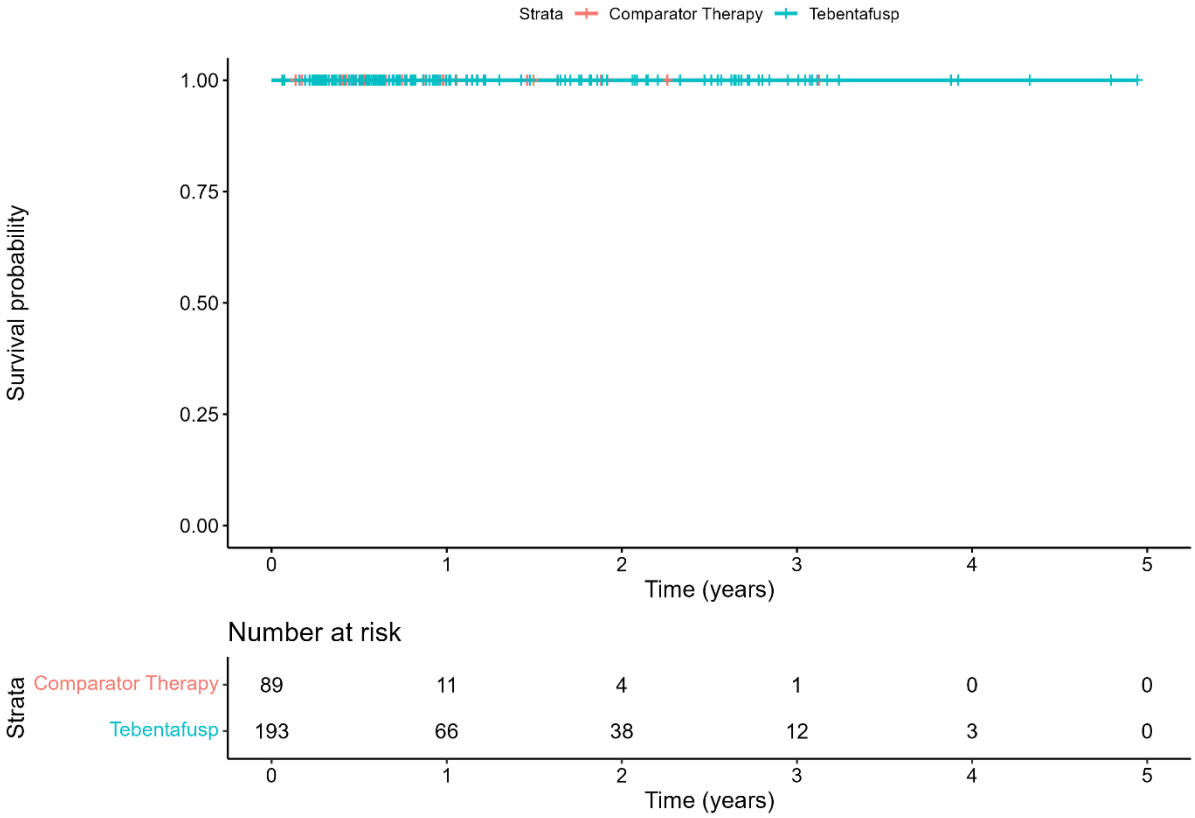
ECOG-Performance-Status: 0



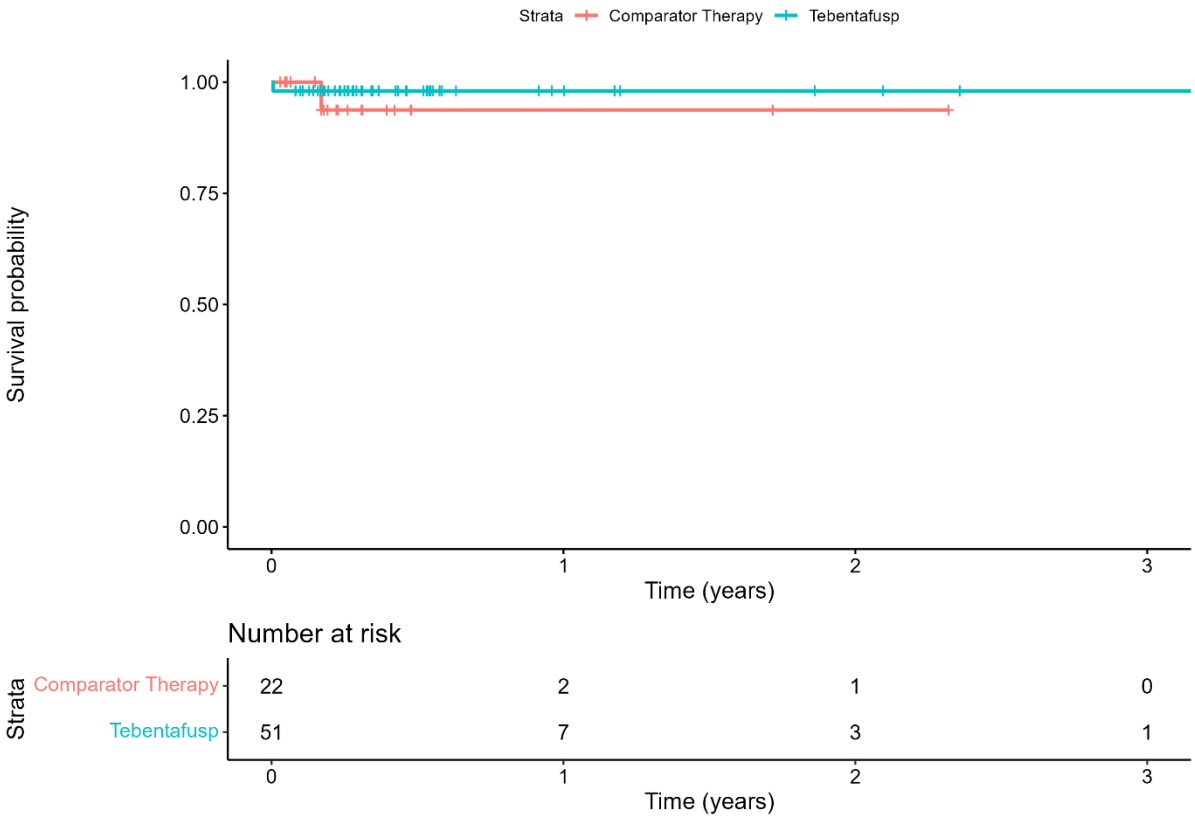
ECOG-Performance-Status: 1



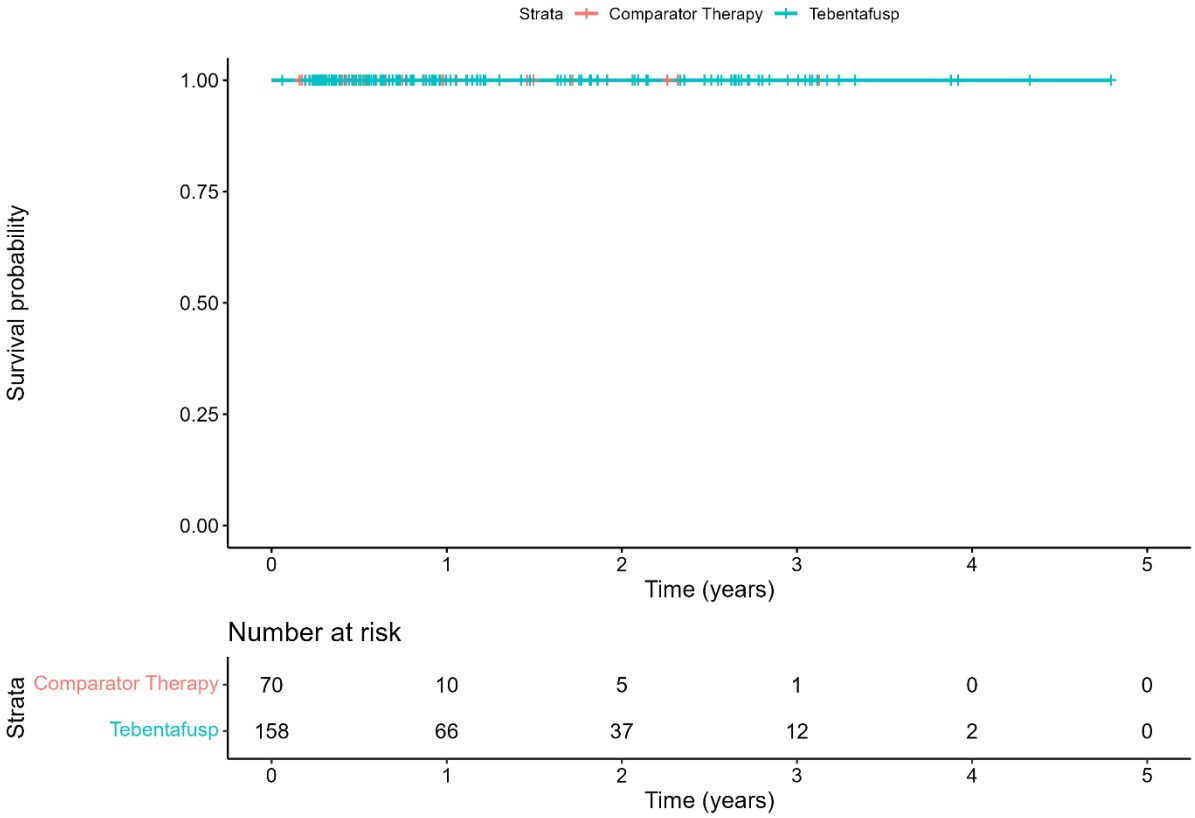
Alkalische Phosphatase (ALP) (Baseline): ≤ULN



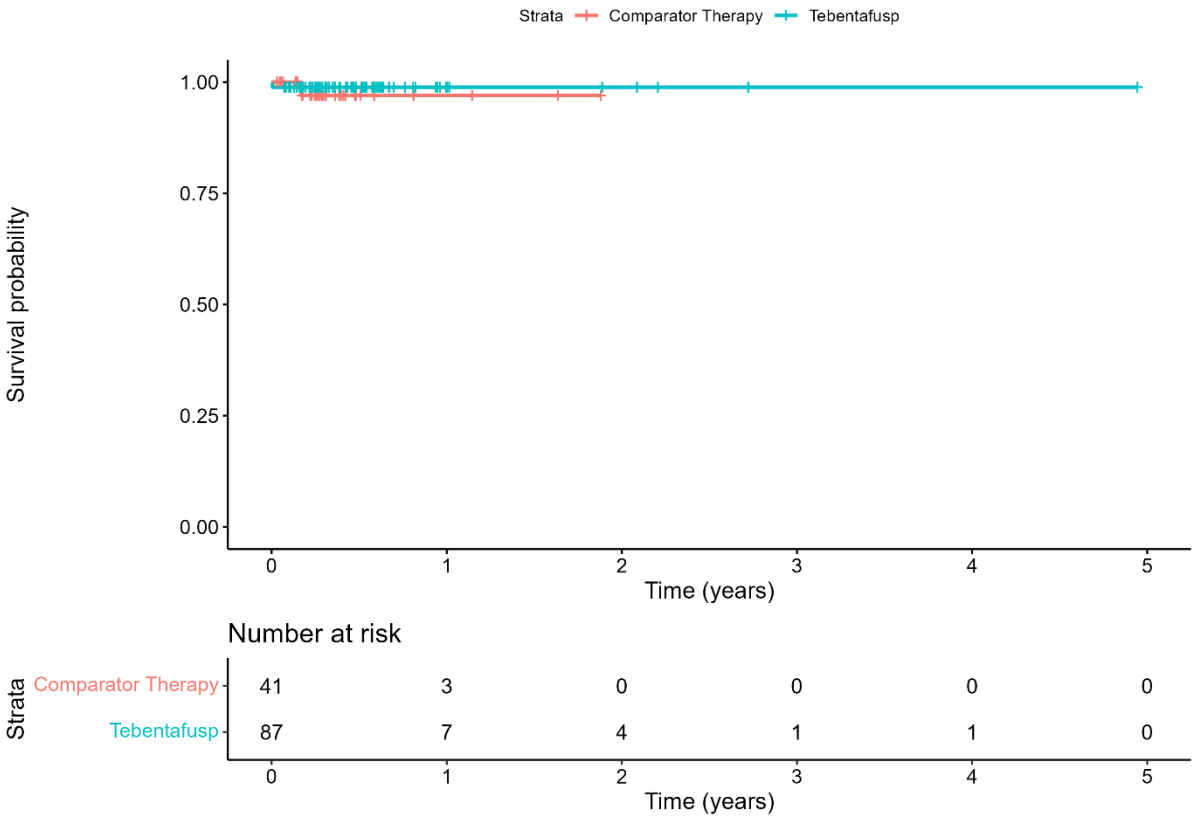
Alkalische Phosphatase (ALP) (Baseline): >ULN



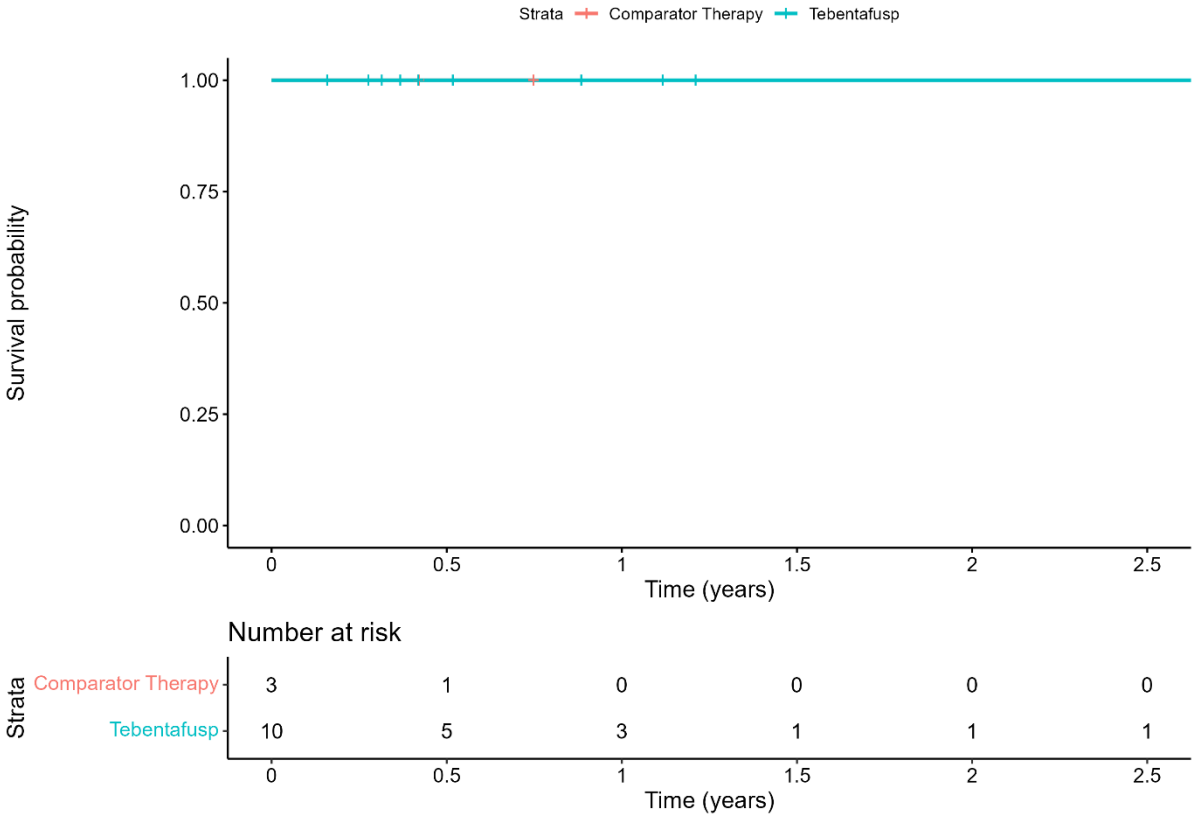
LDH: ≤ULN



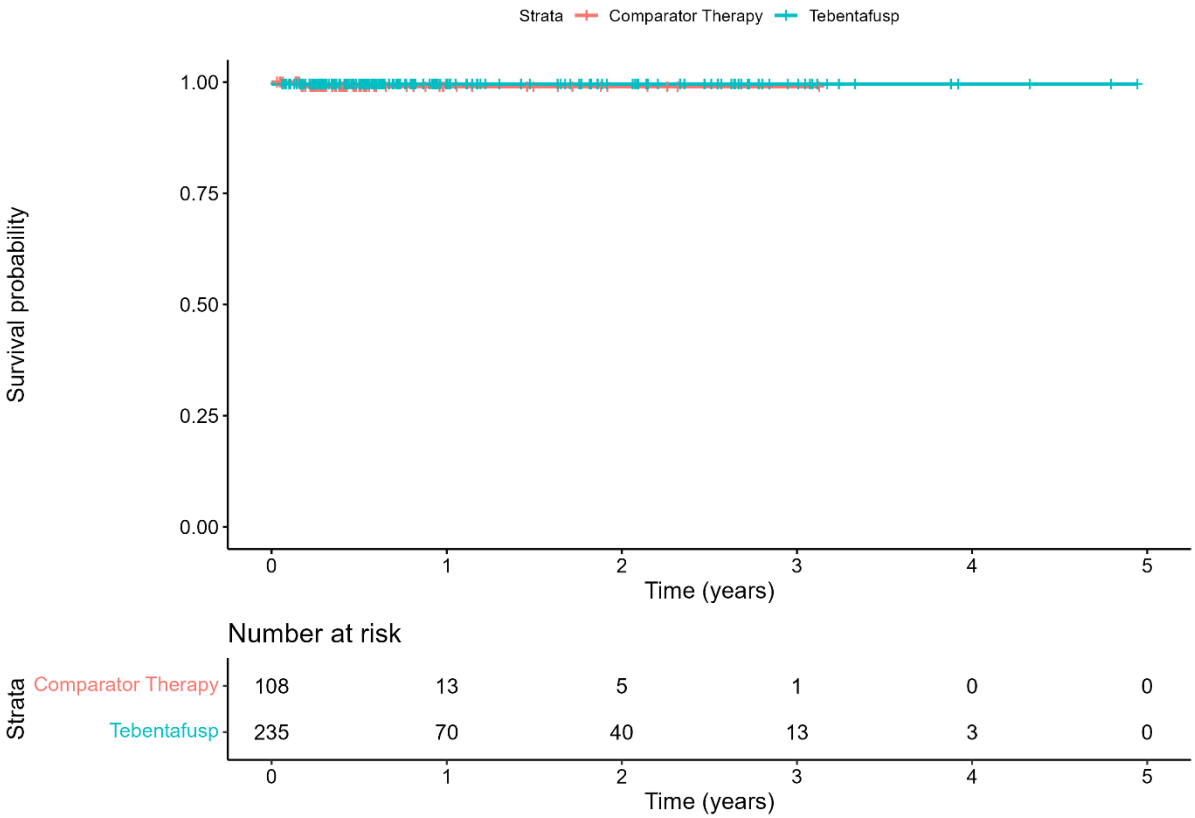
LDH: >ULN



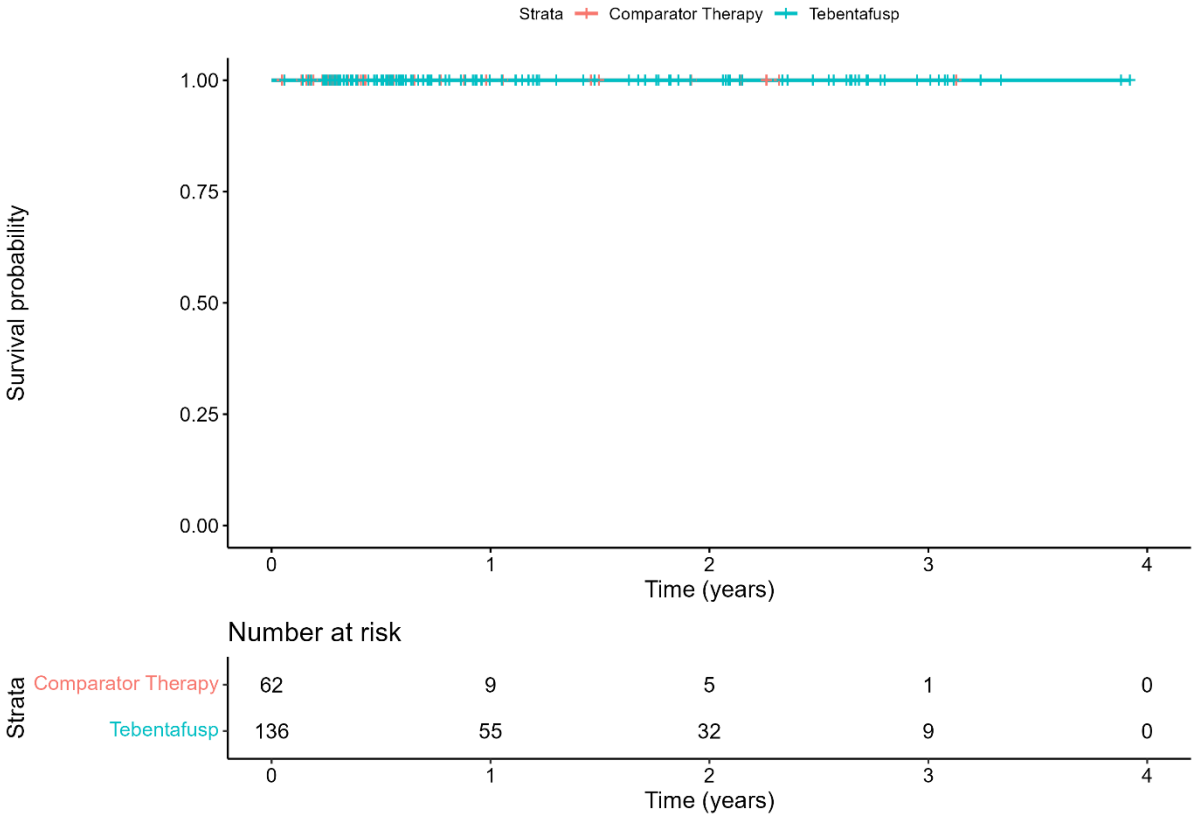
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Ja



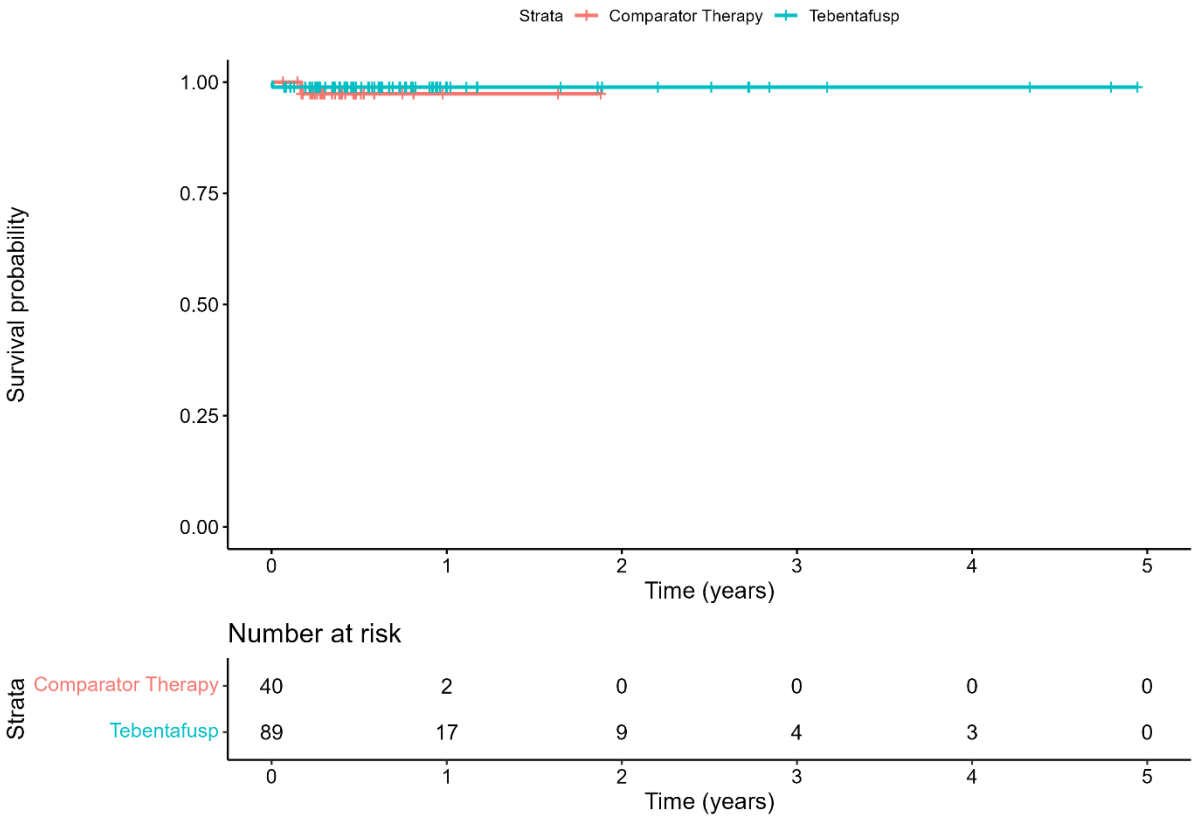
Vorherige systemische Therapie im adjuvanten/neoadjuvanten Setting: Nein



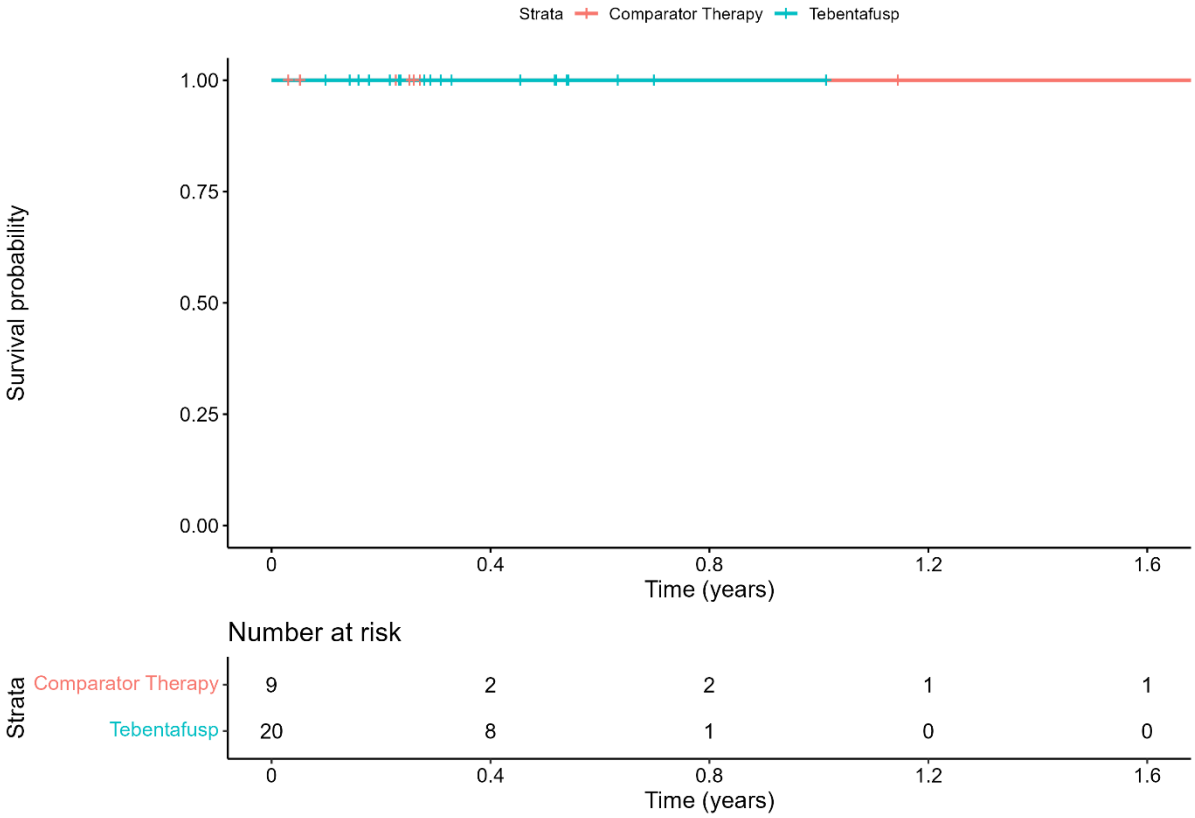
Größte metastatische Läsion (Baseline): ≤3,0 cm



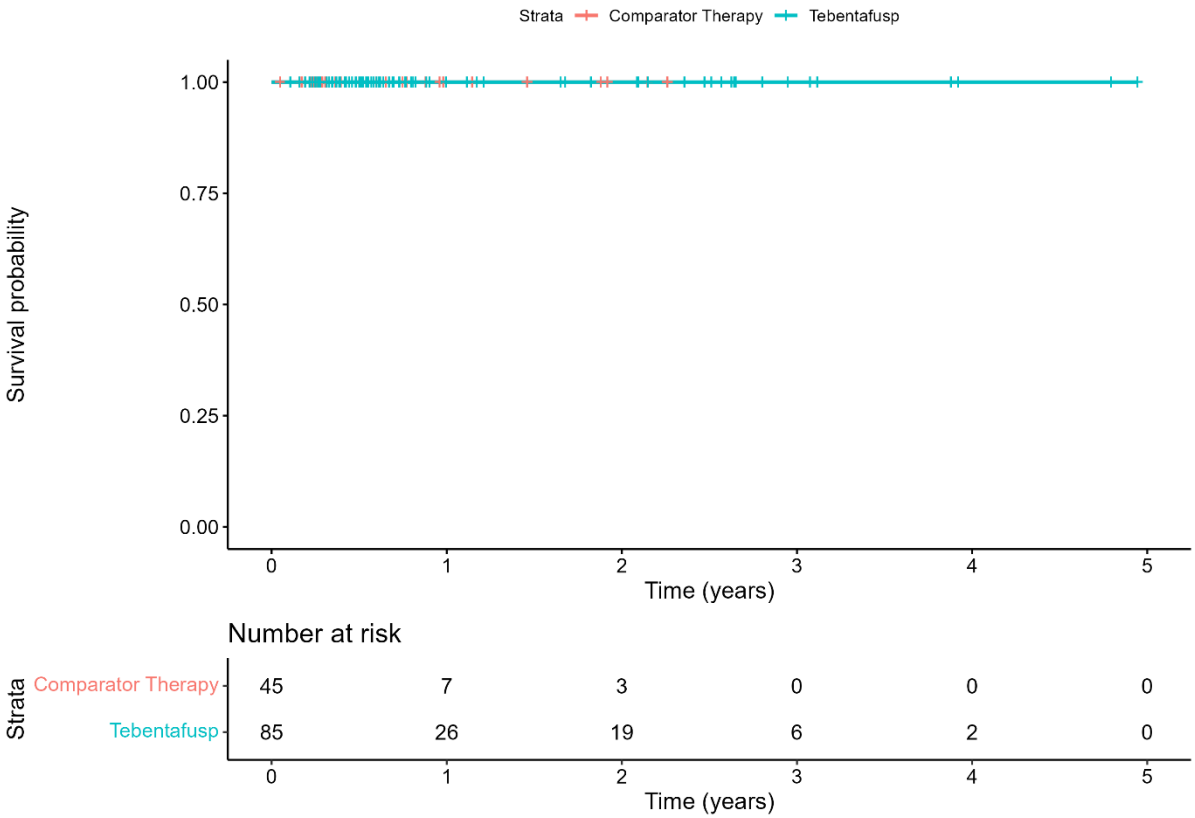
Größte metastatische Läsion (Baseline): 3,1-8,0 cm



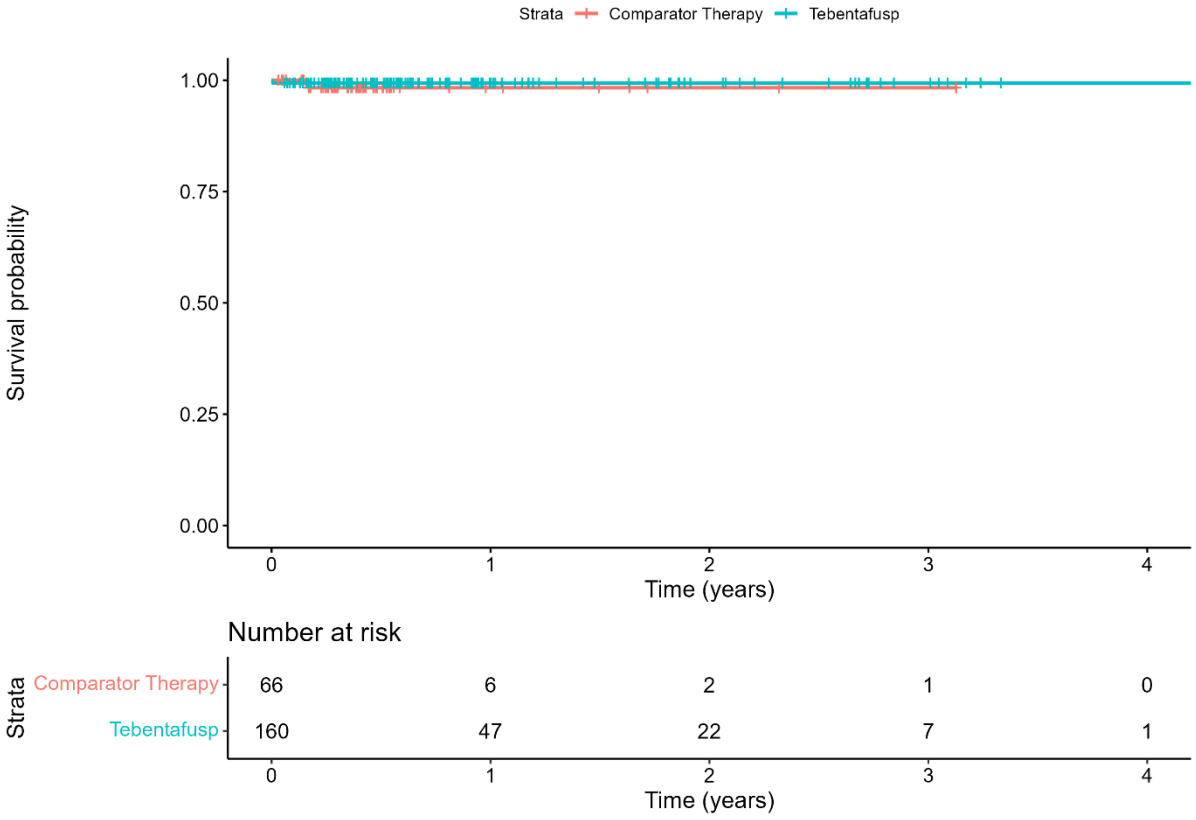
Größte metastatische Läsion (Baseline): ≥8,1 cm



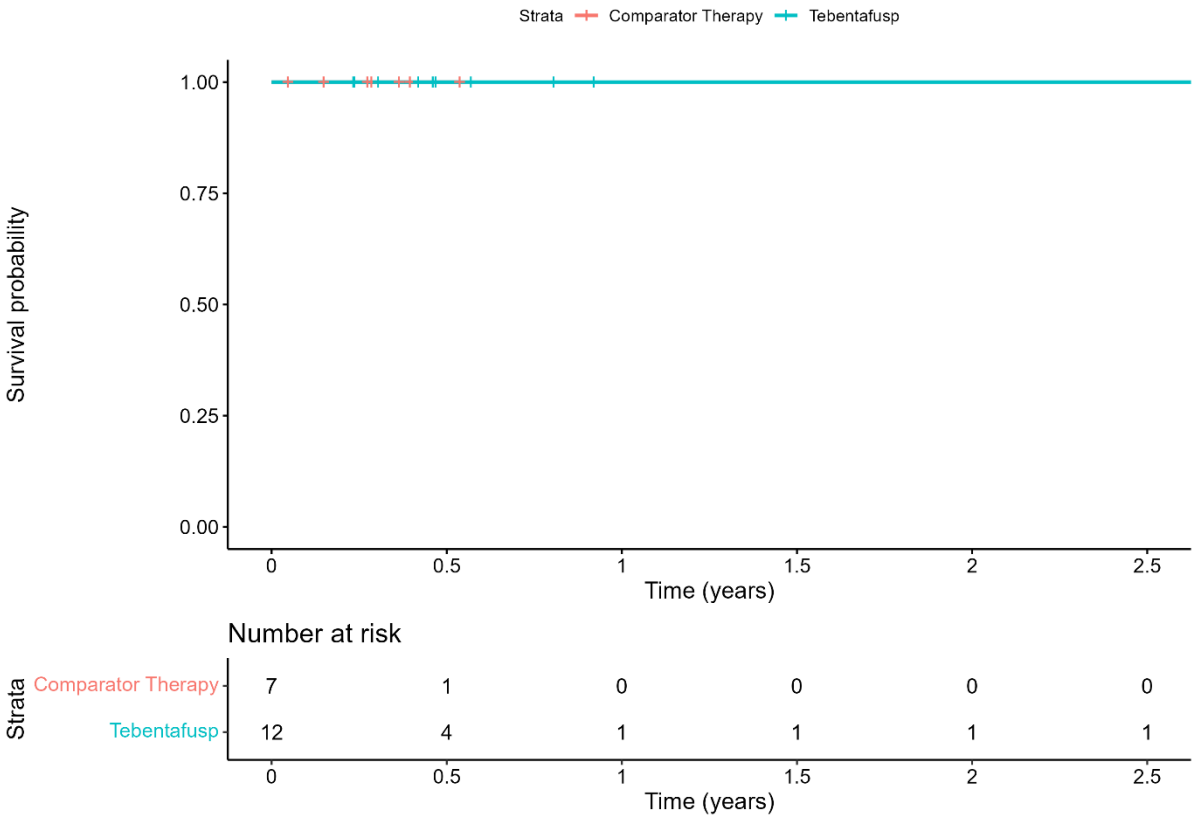
Region: Nordamerika



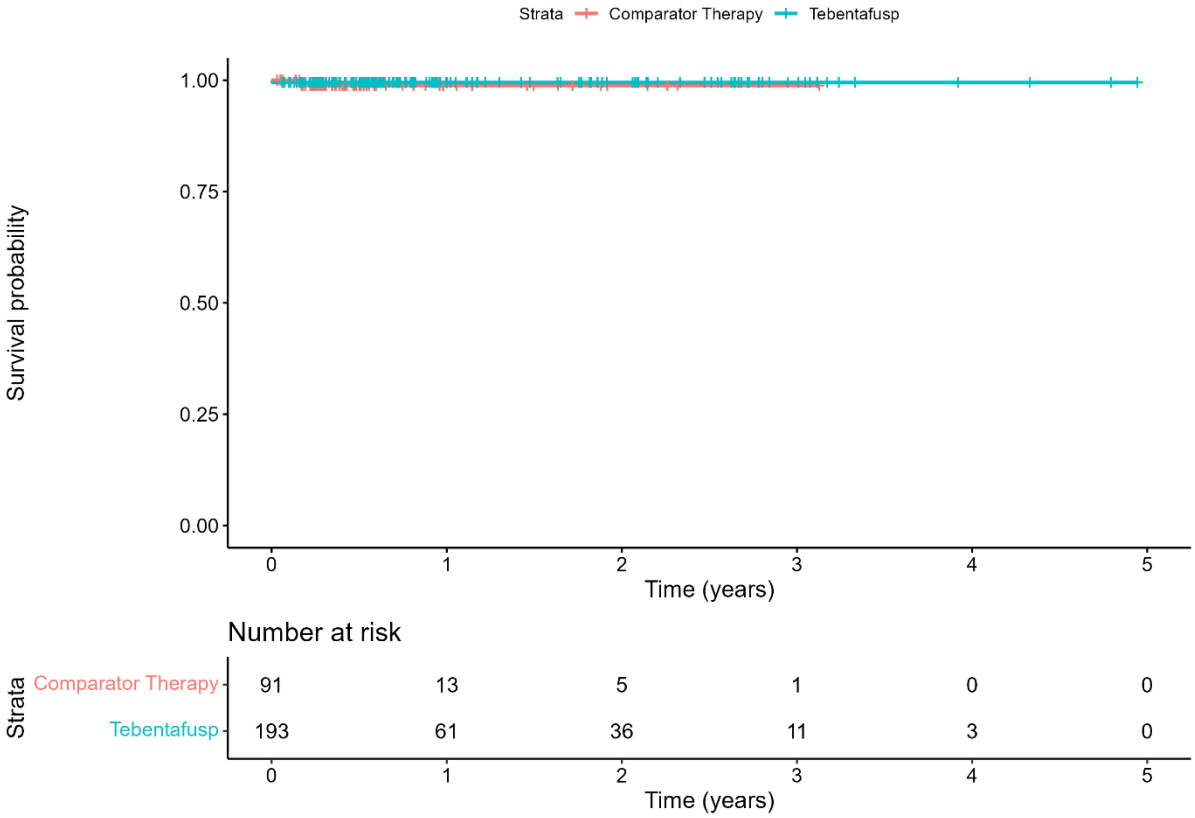
Region: Nicht-Nordamerika



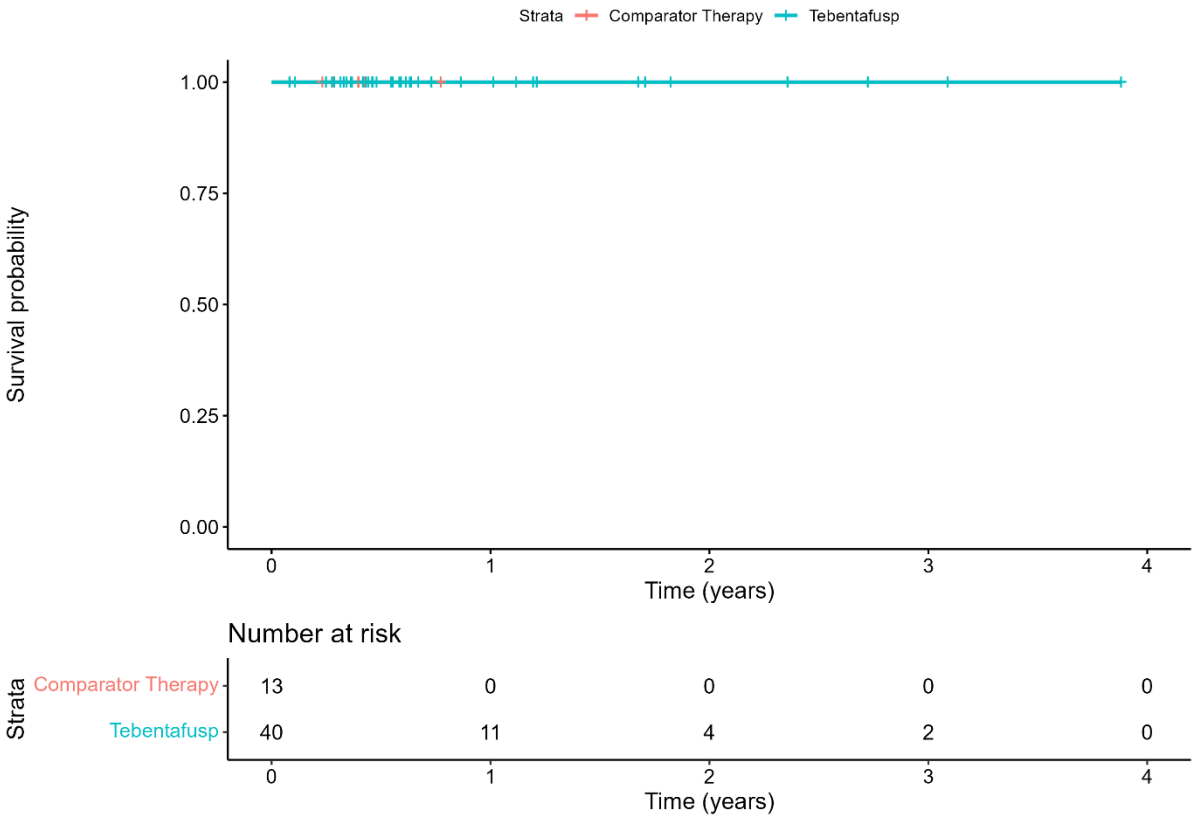
Vorauswahl der Chemotherapie: Dacarbazin



Vorauswahl der Chemotherapie: Pembrolizumab



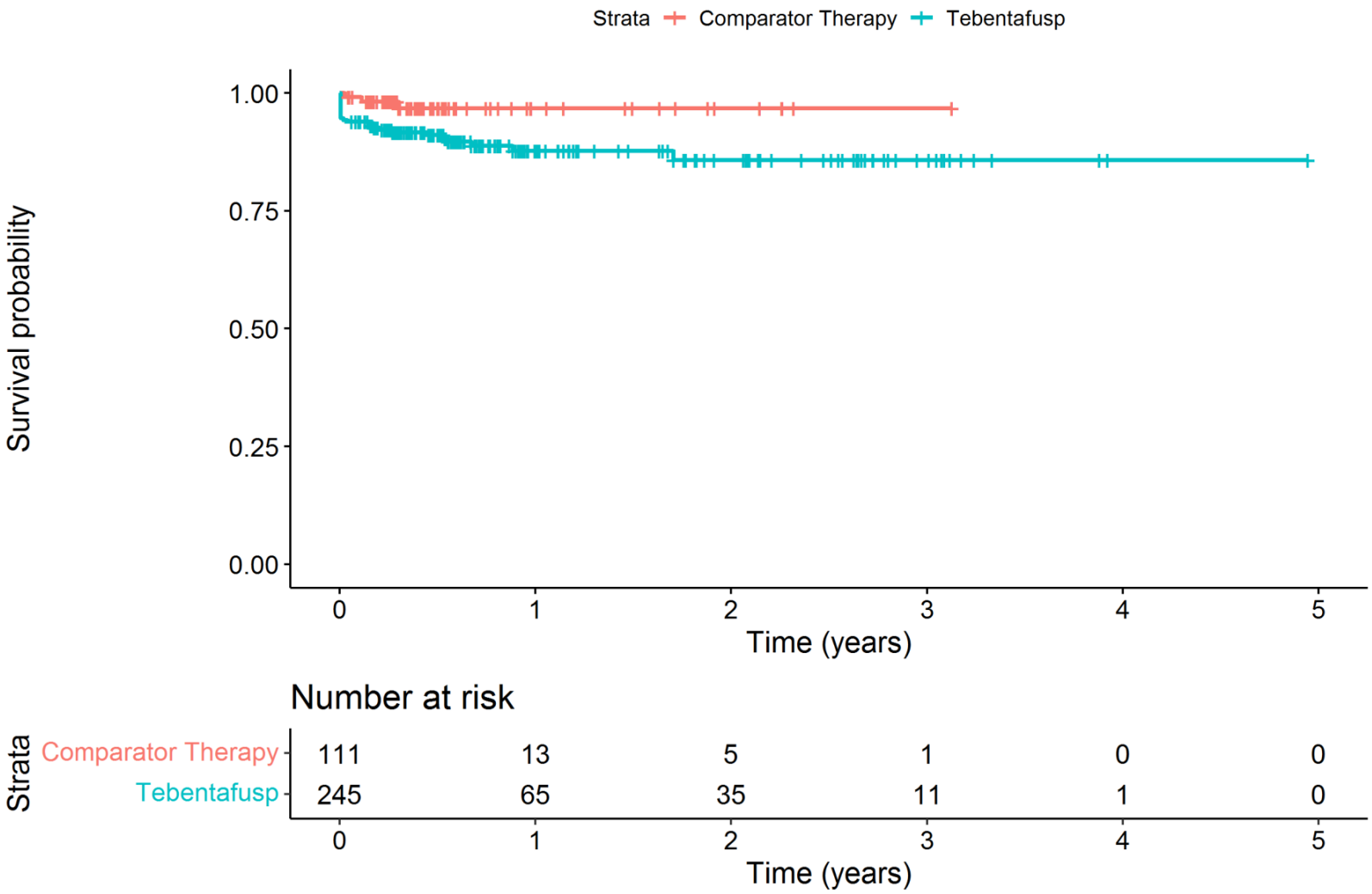
Vorauswahl der Chemotherapie: Ipilimumab



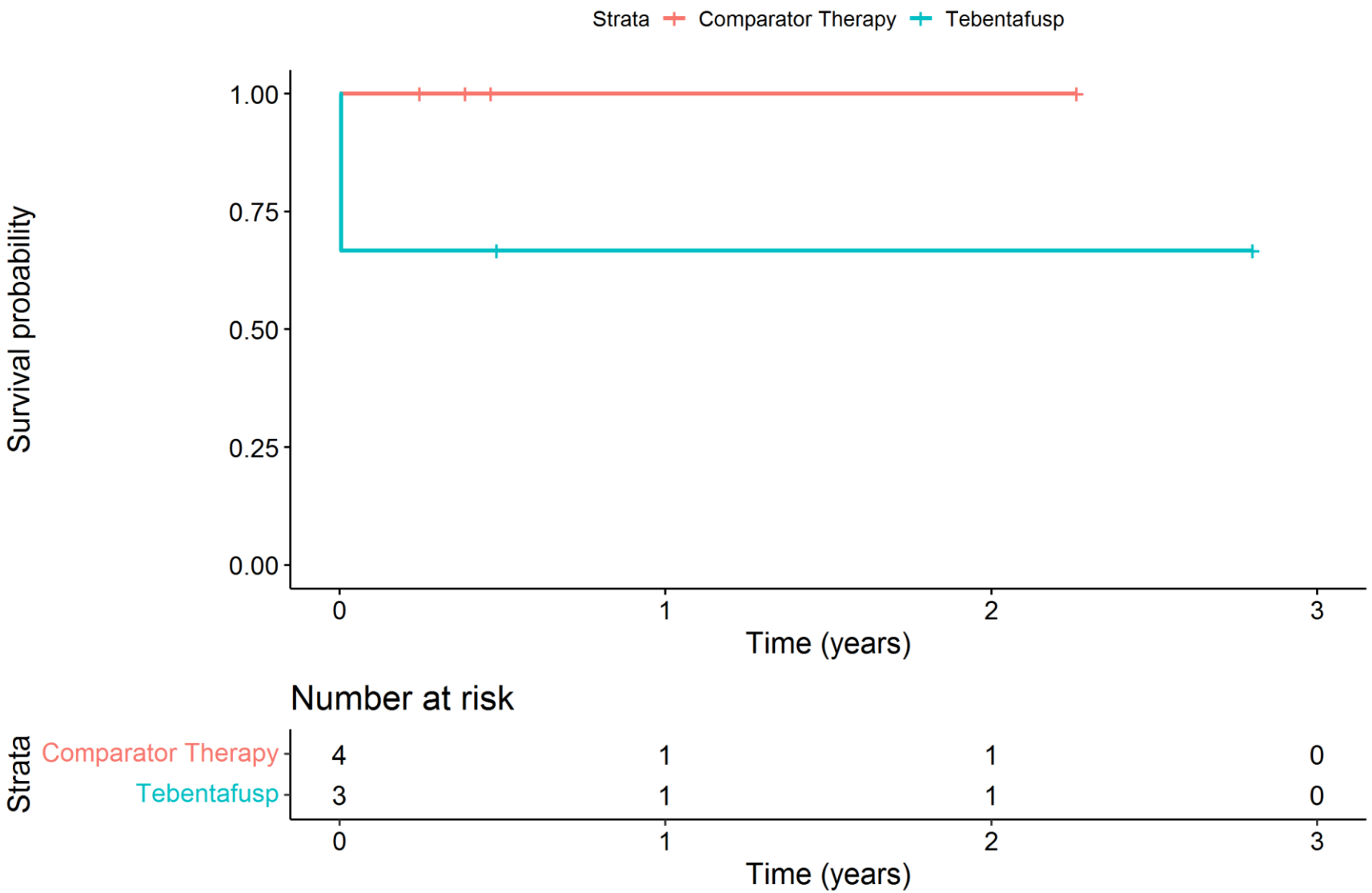
59.16 Unerwünschte Ereignisse nach SOC und PT

60 UEs (PT), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-245)

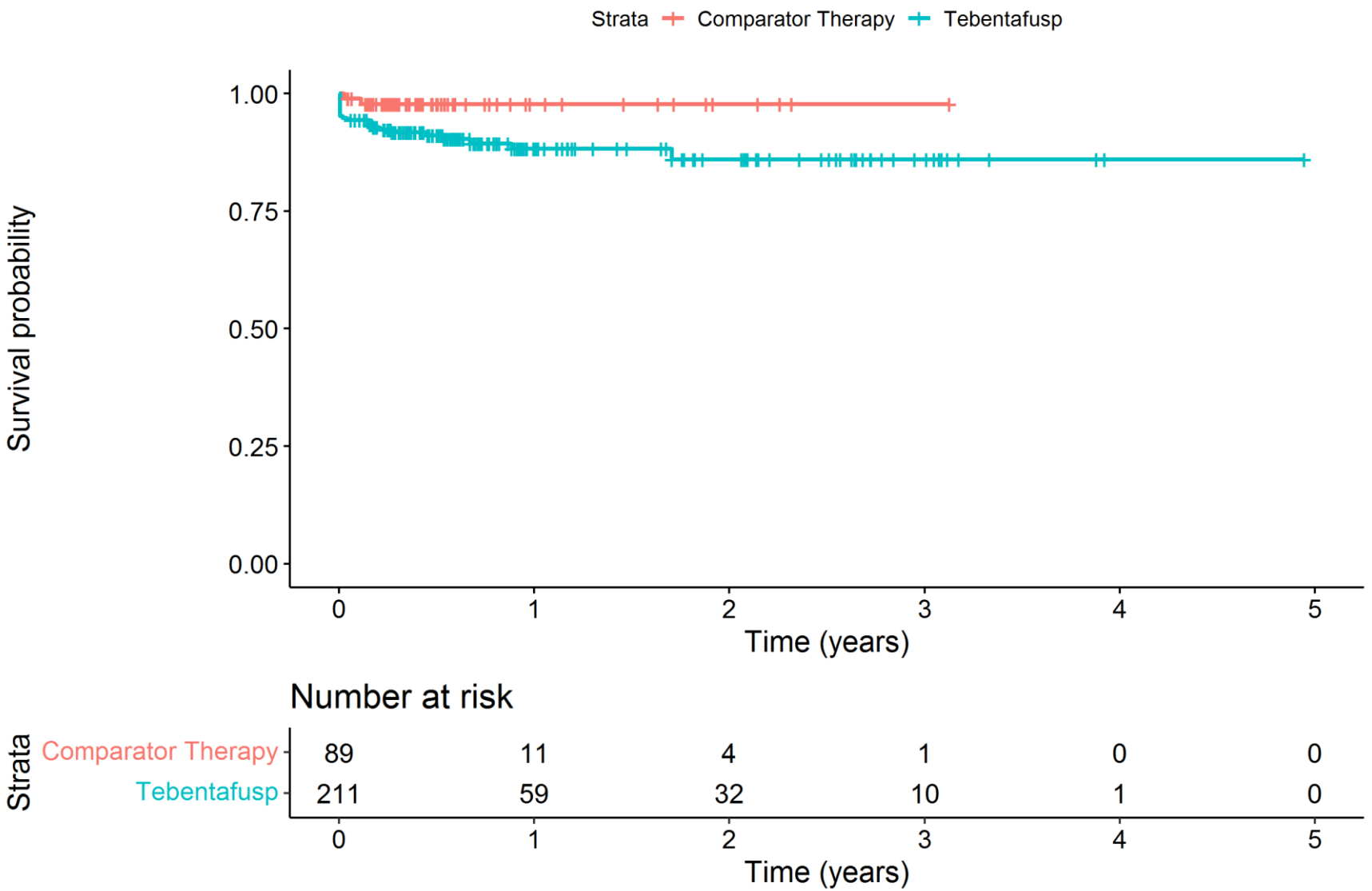
Lymphopenie – Gesamt



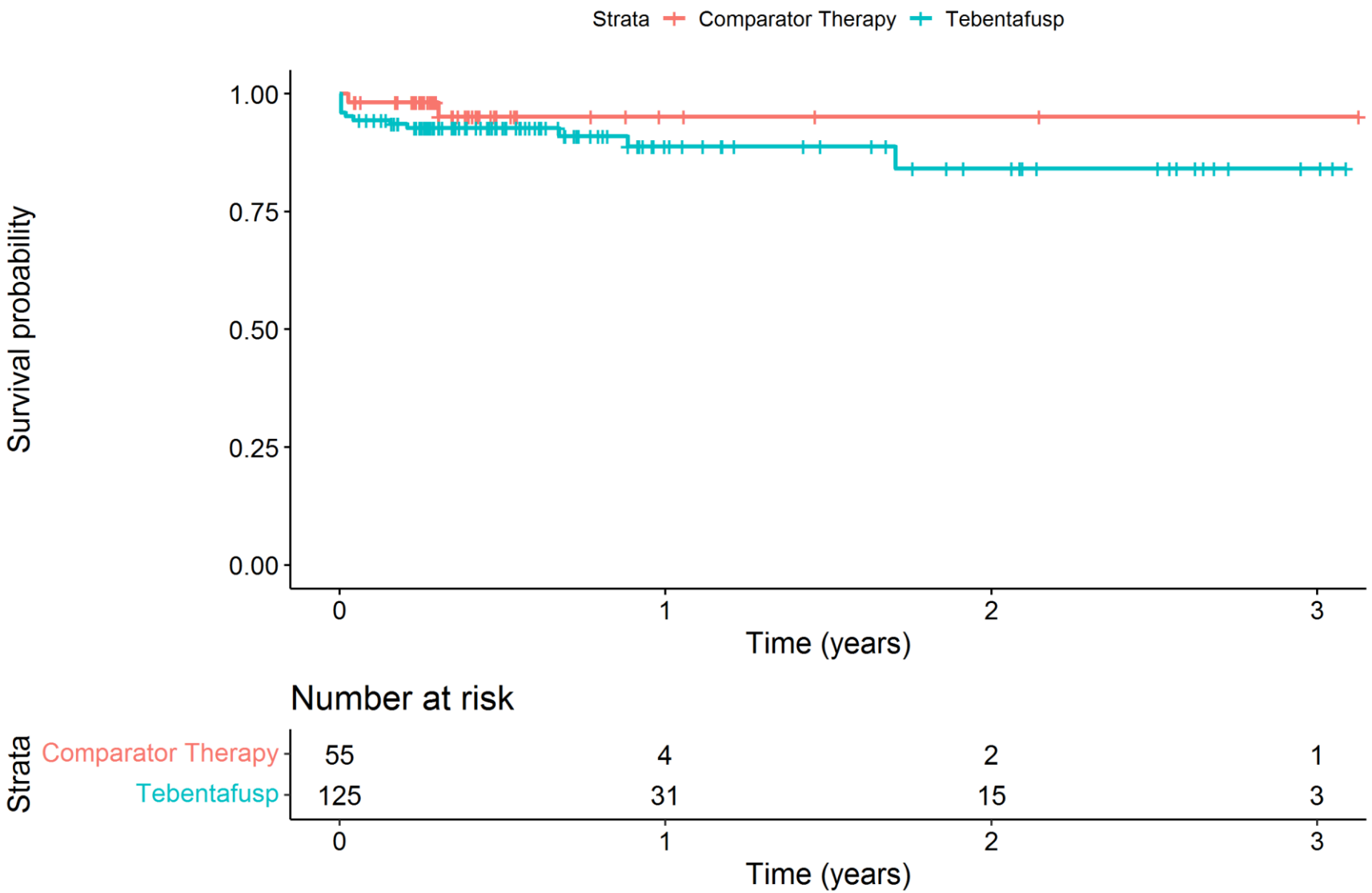
Lymphopenie – Hispanisch



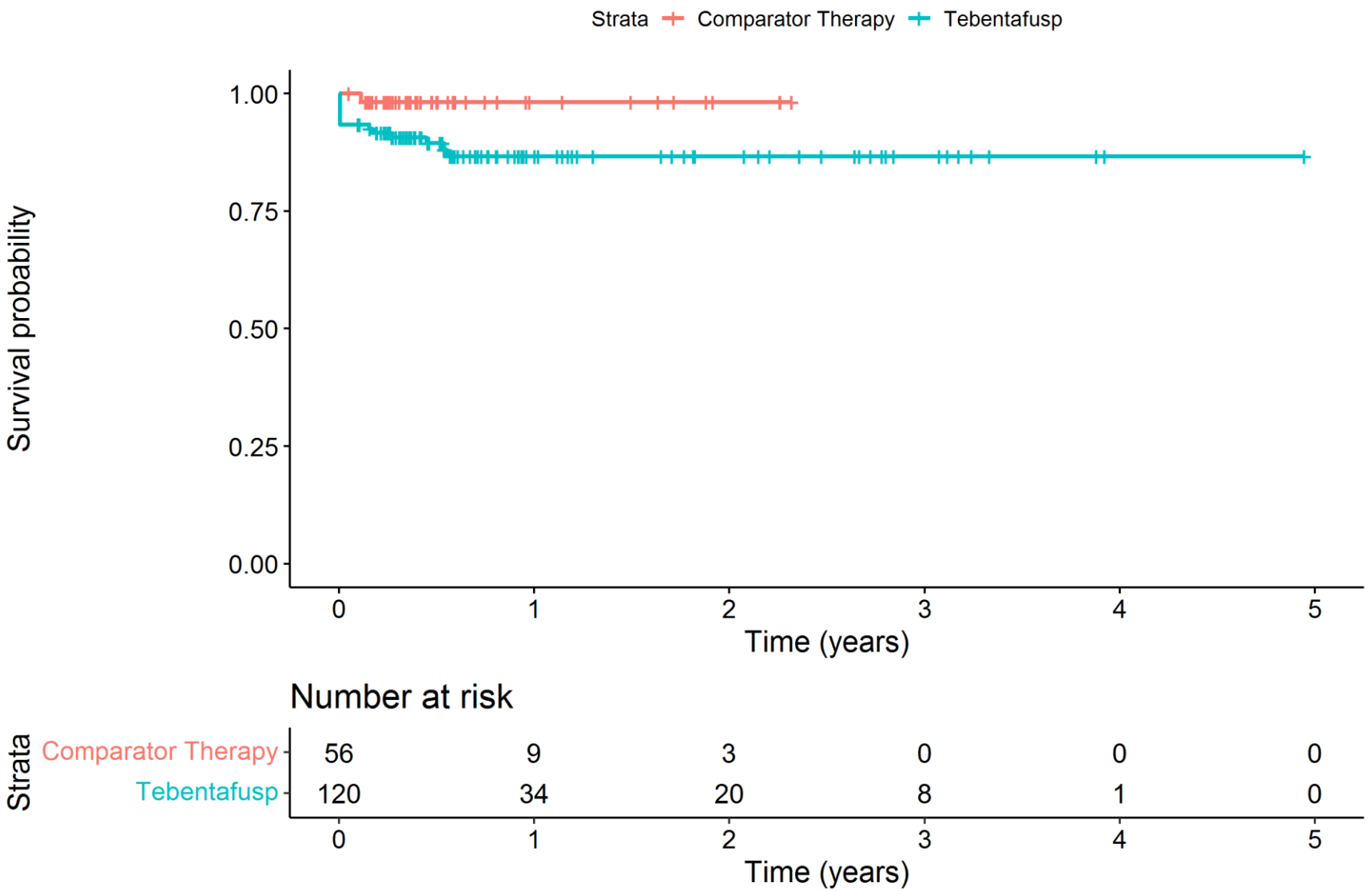
Lymphopenie - Nicht-hispanisch



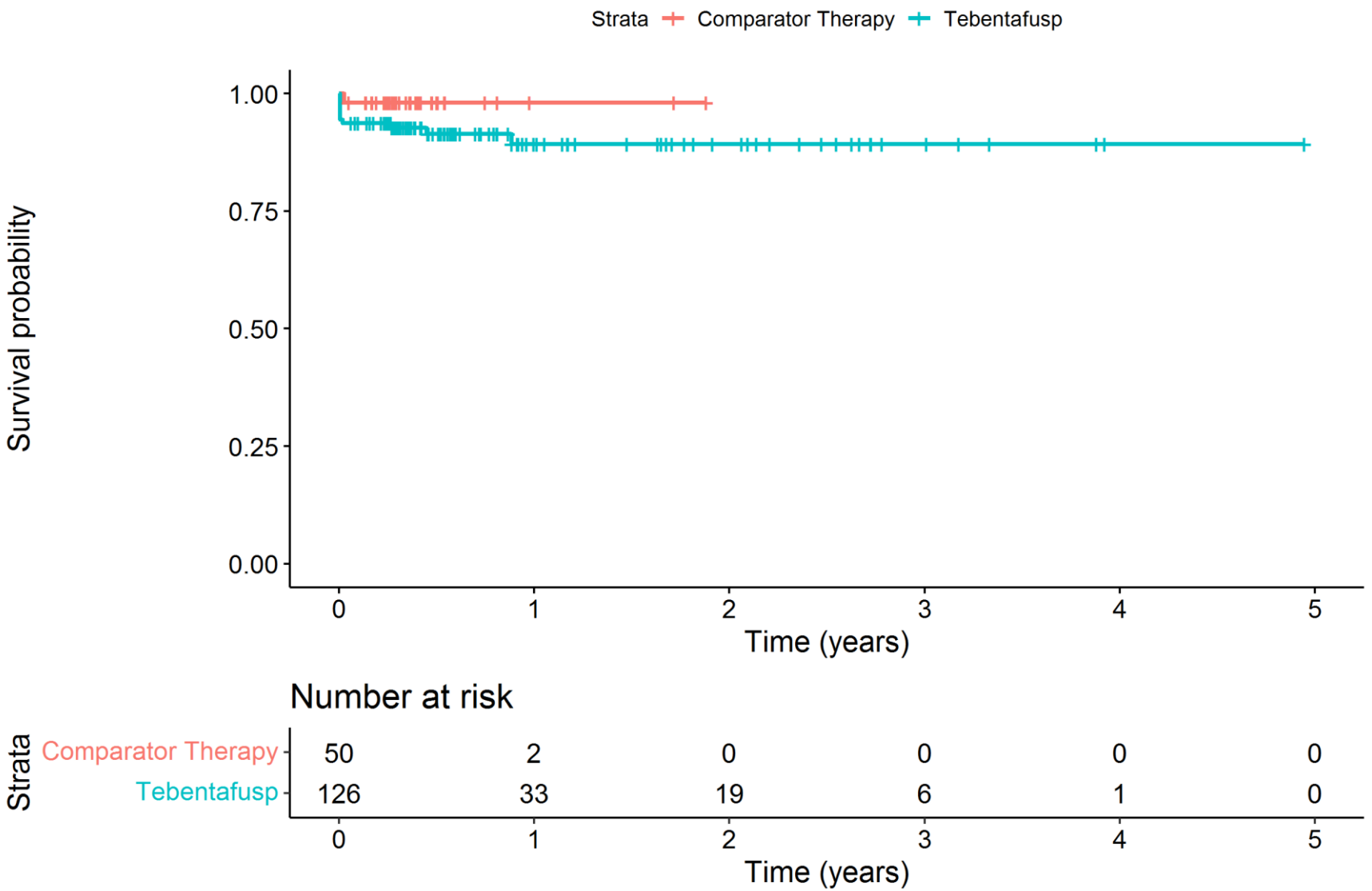
Lymphopenie - Männlich



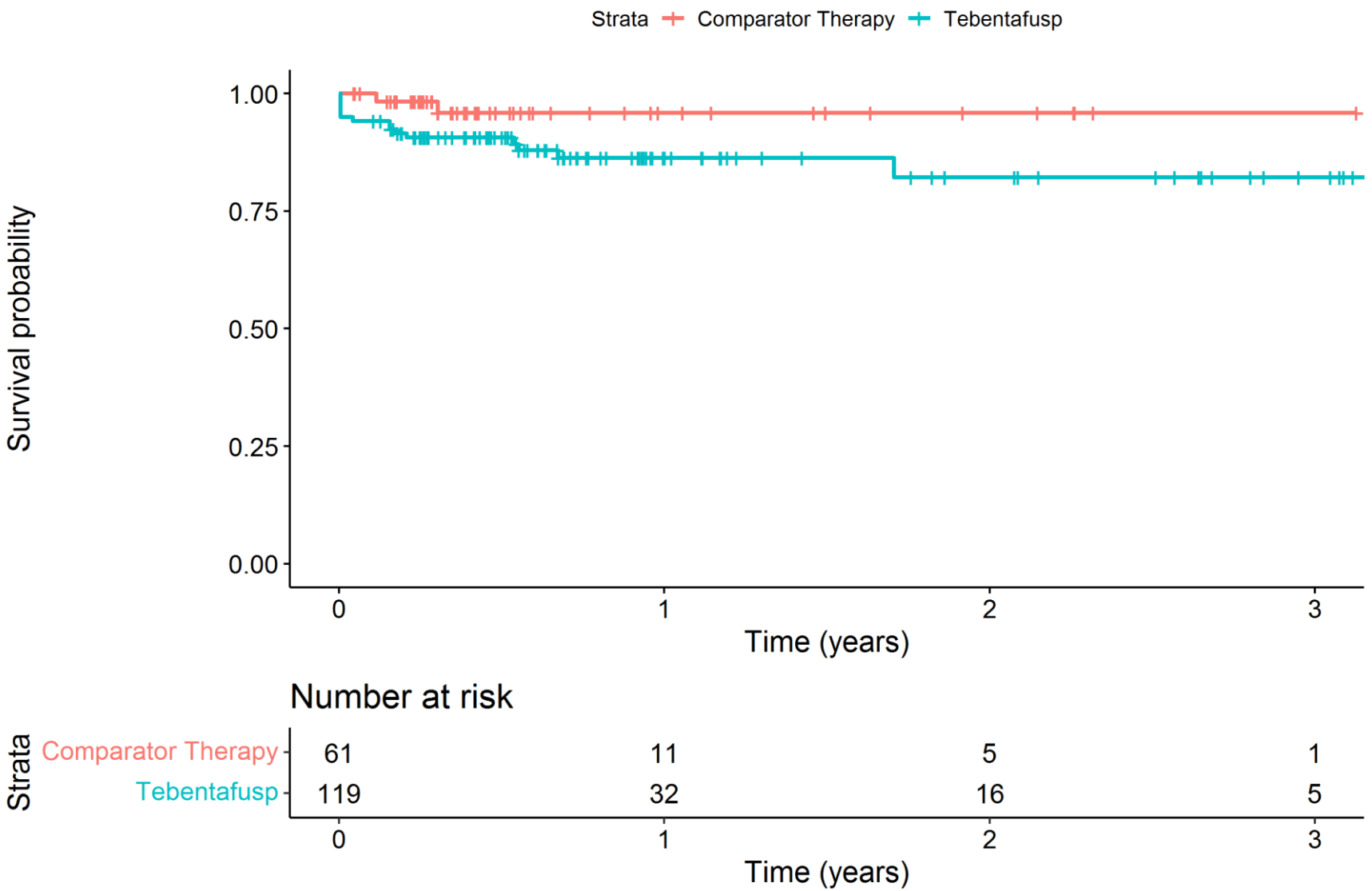
Lymphopenie - Weiblich



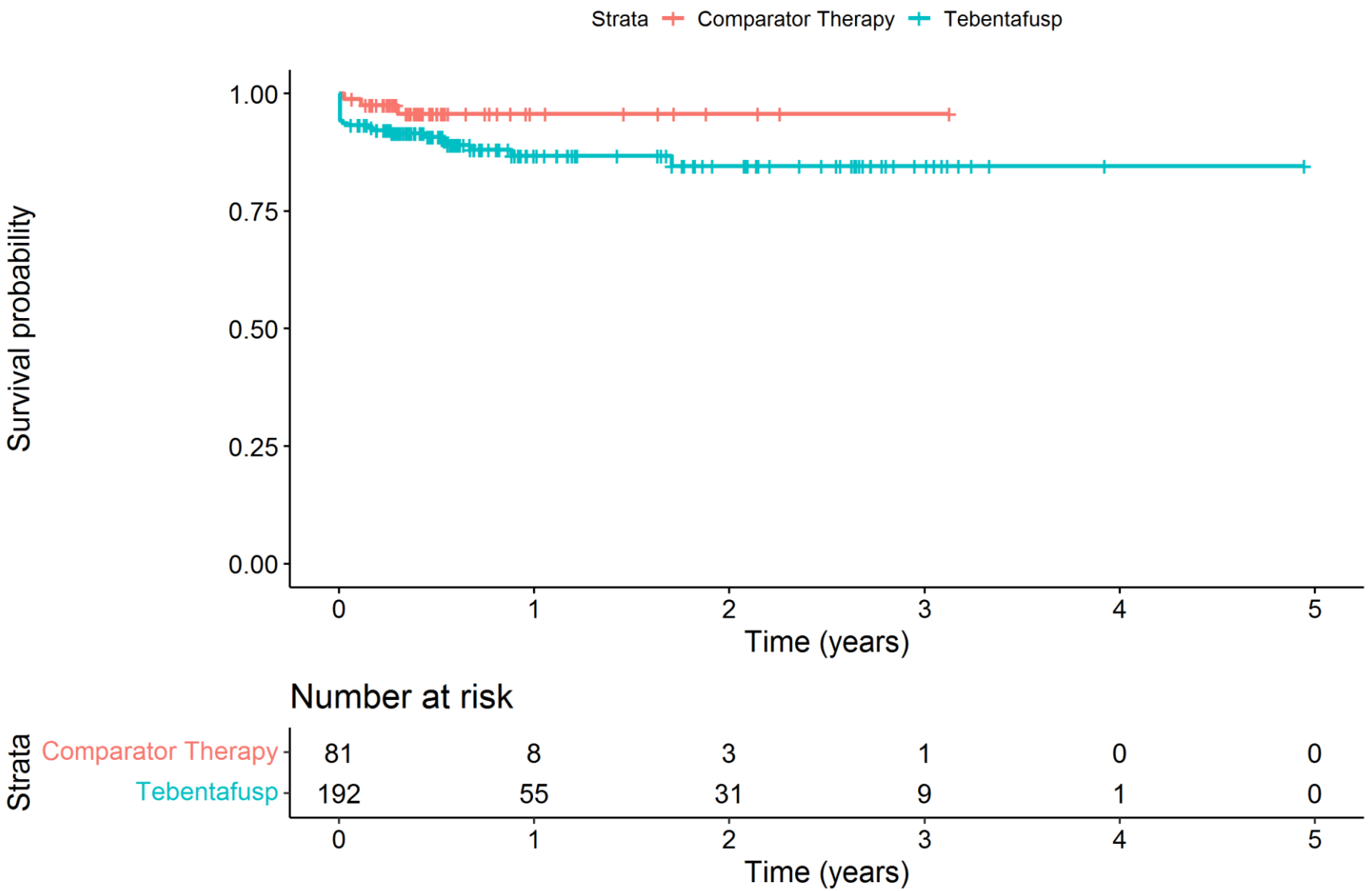
Lymphopenie - <65



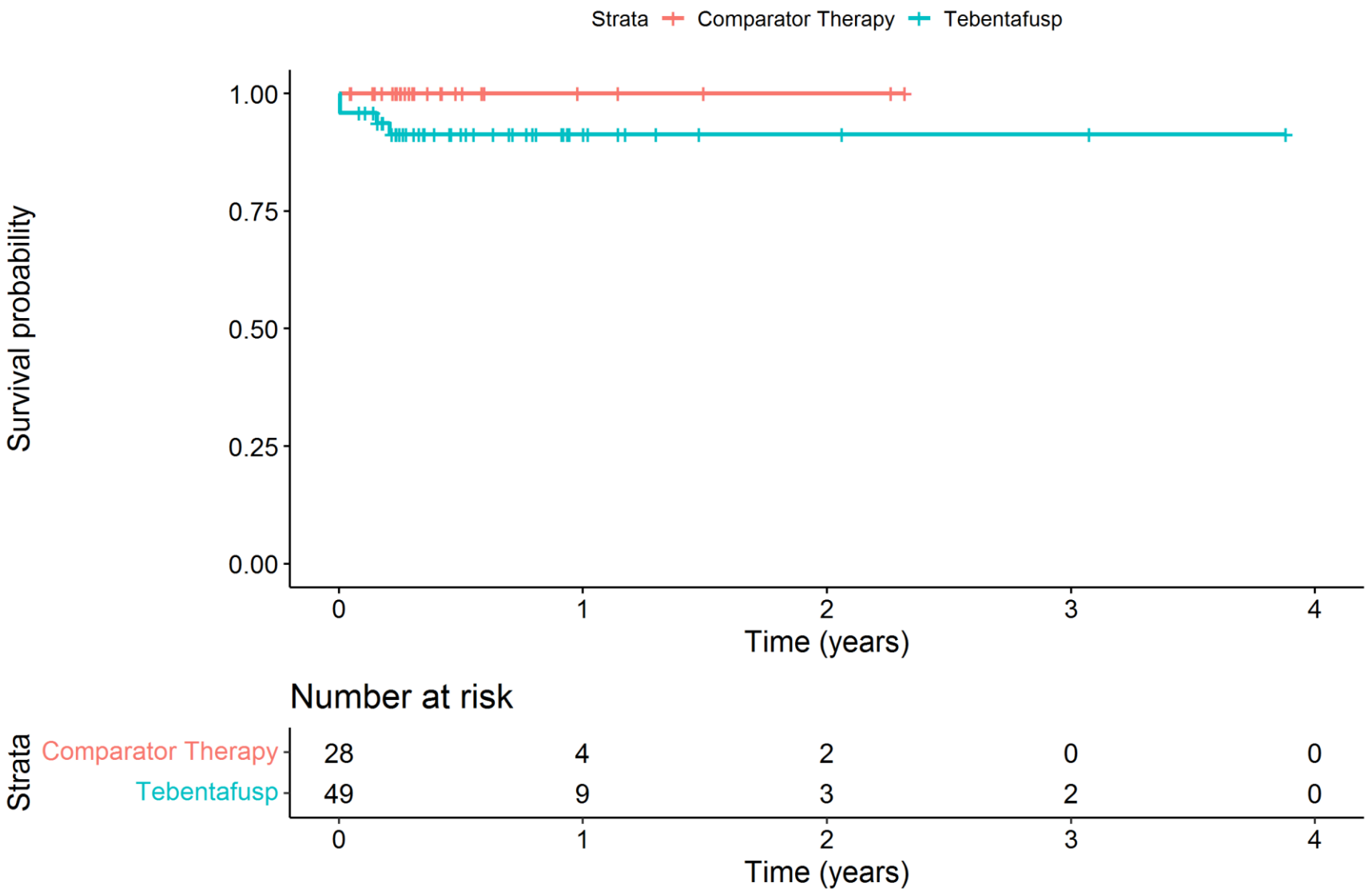
Lymphopenie - ≥65



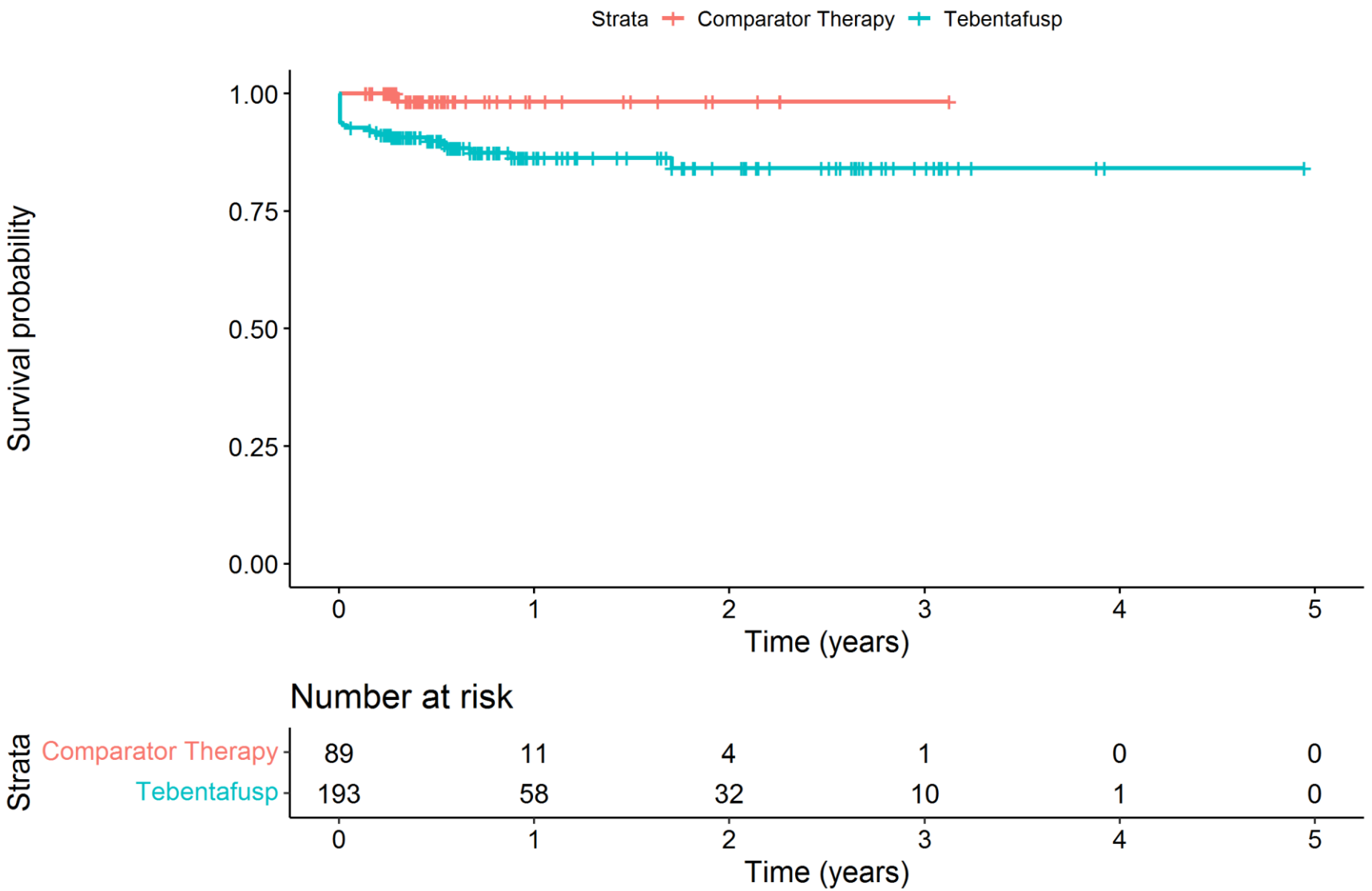
Lymphopenie - ECOG 0



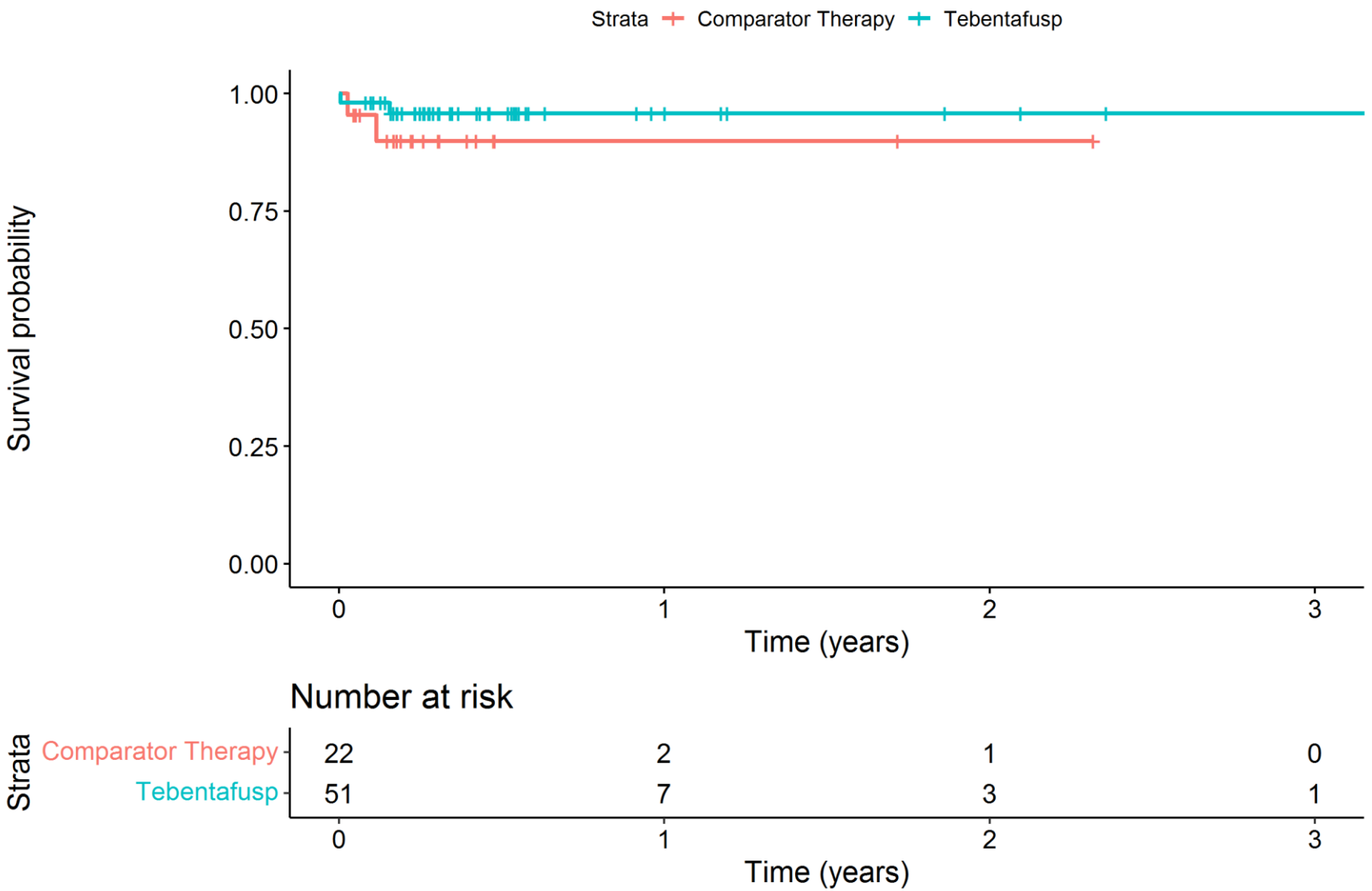
Lymphopenie - ECOG 1



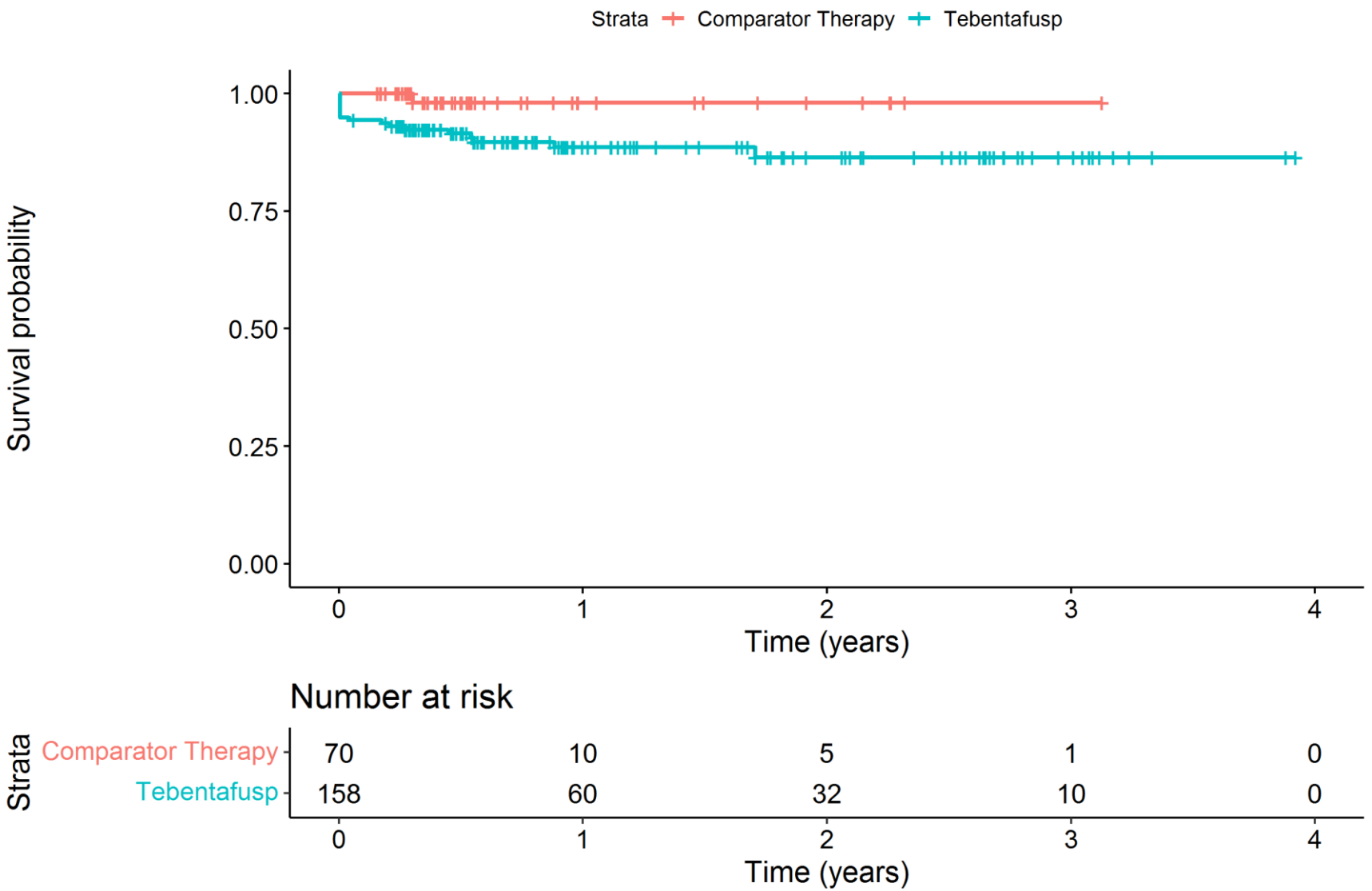
Lymphopenie - ALP ≤ ULN



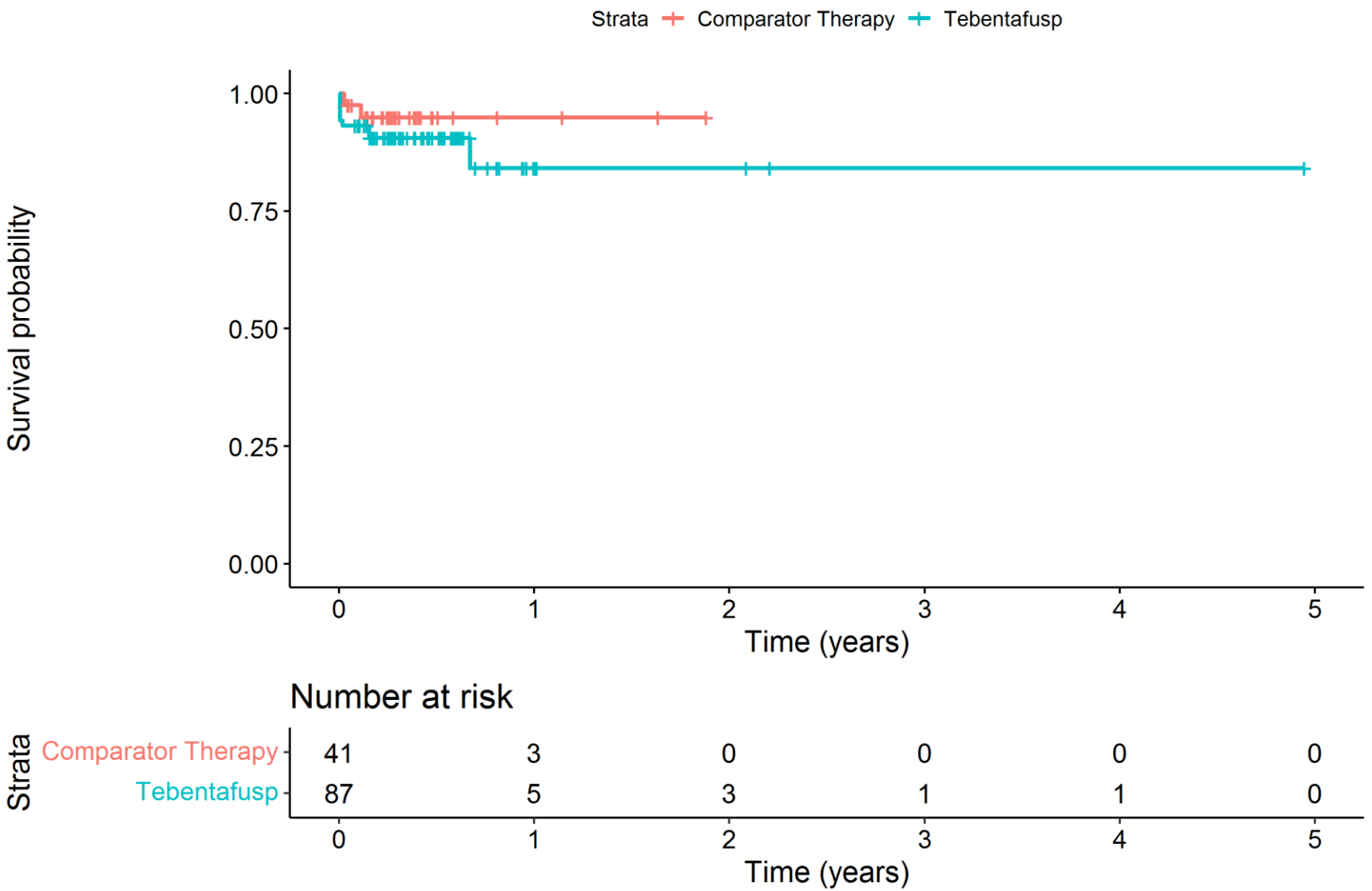
Lymphopenie - ALP > ULN



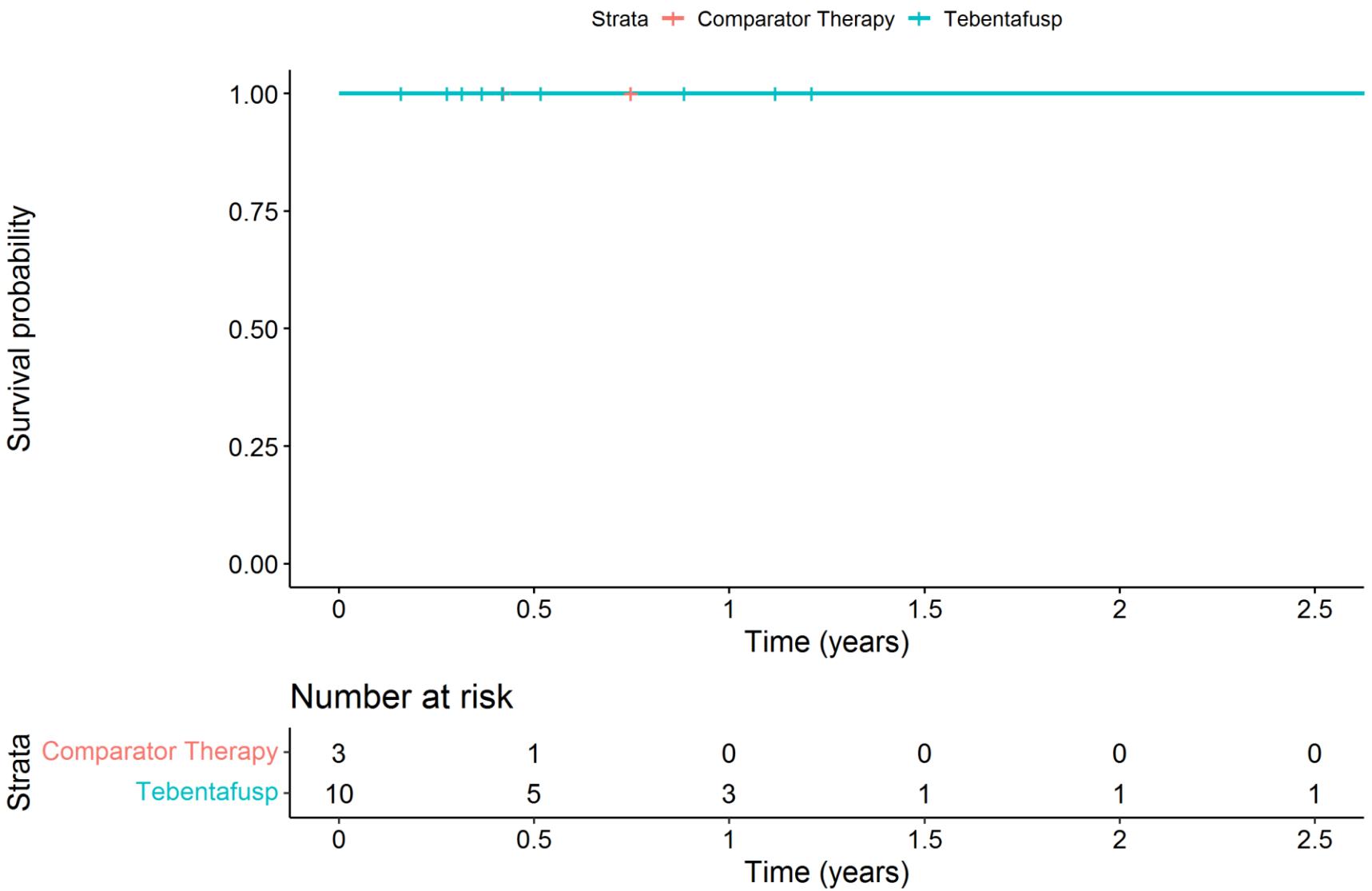
Lymphopenie - LDH =< ULN



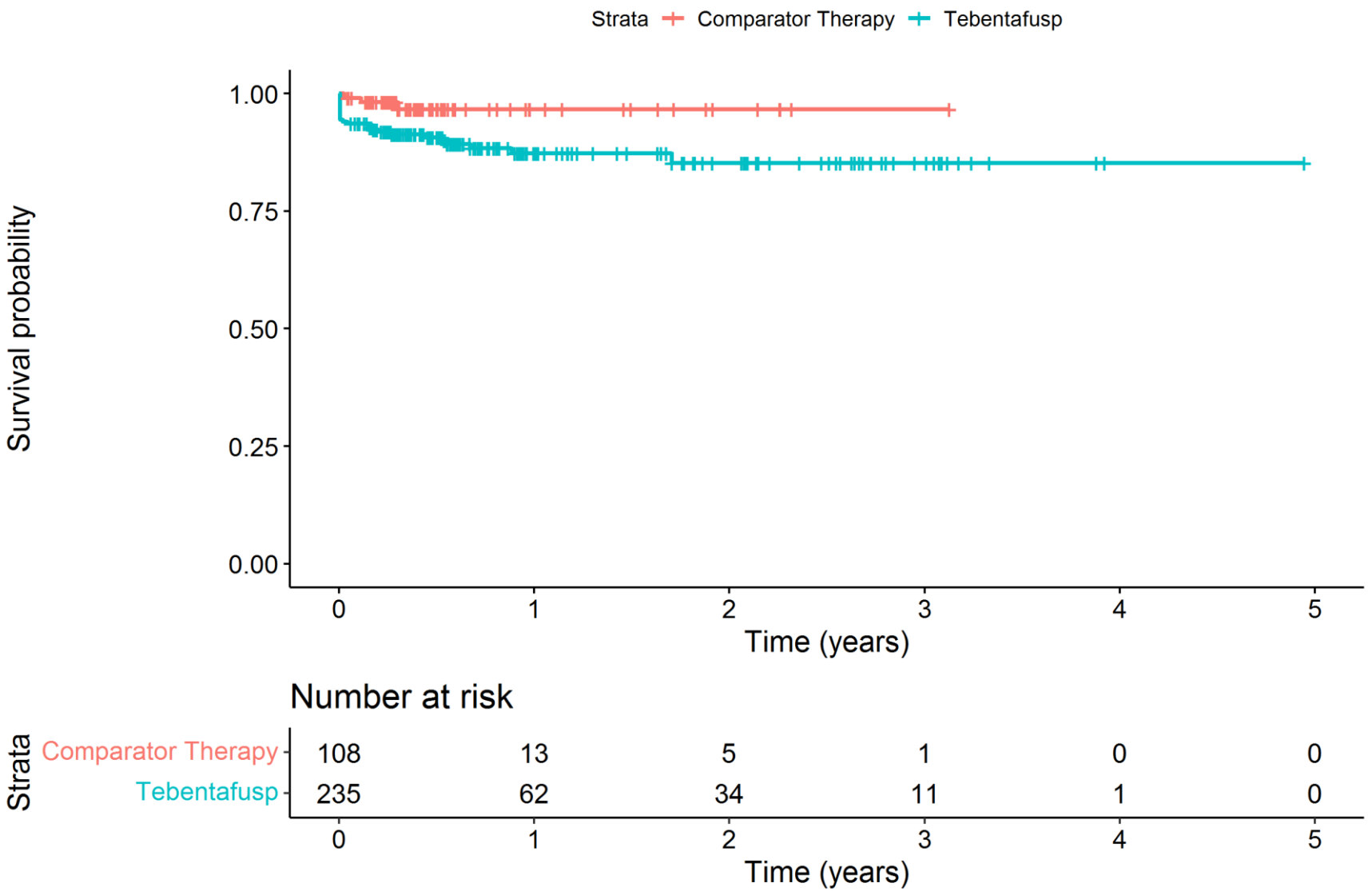
Lymphopenie - LDH > ULN



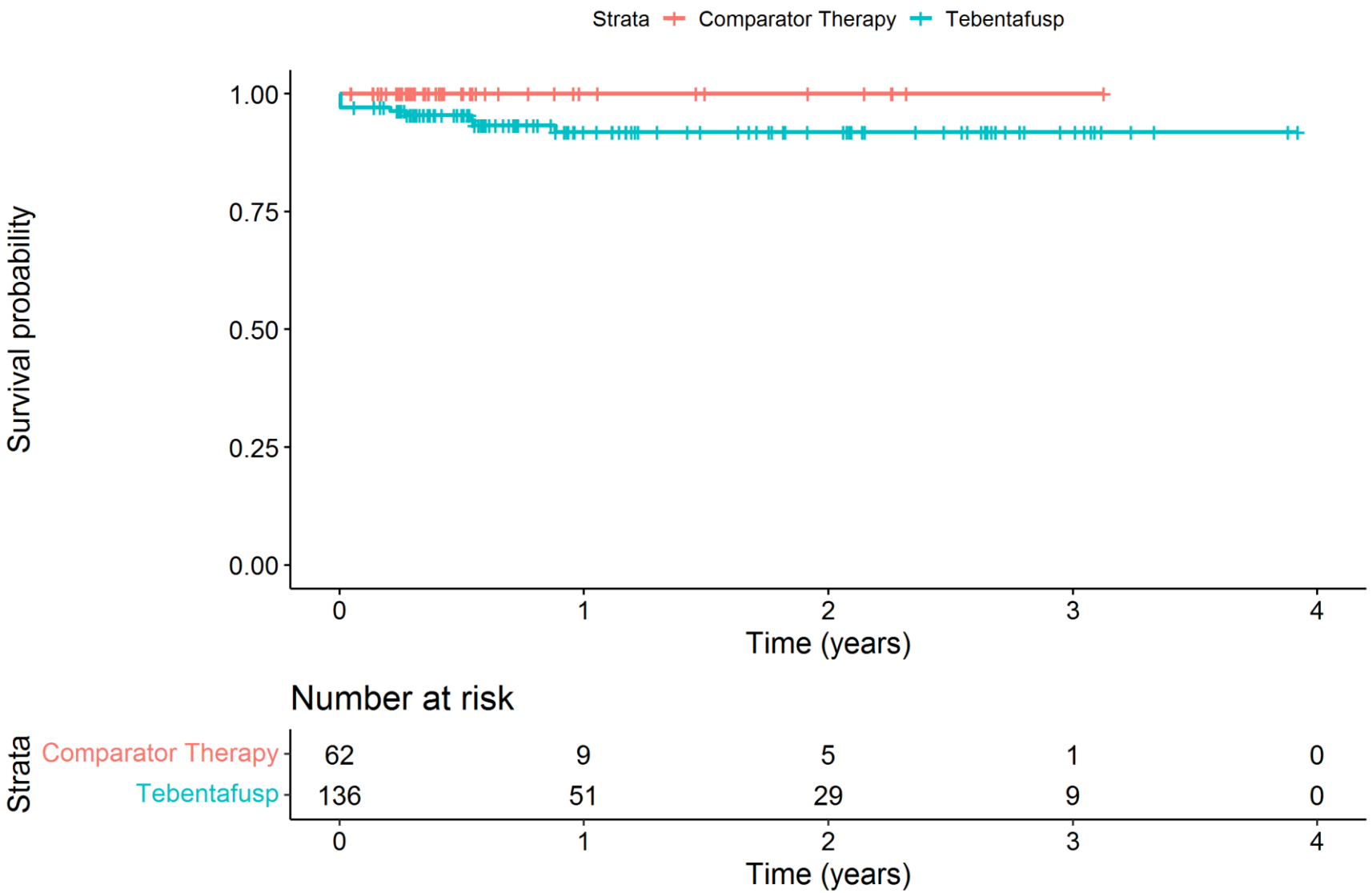
Lymphopenie - Vorherige Therapie adjuvant/neoadjuvant



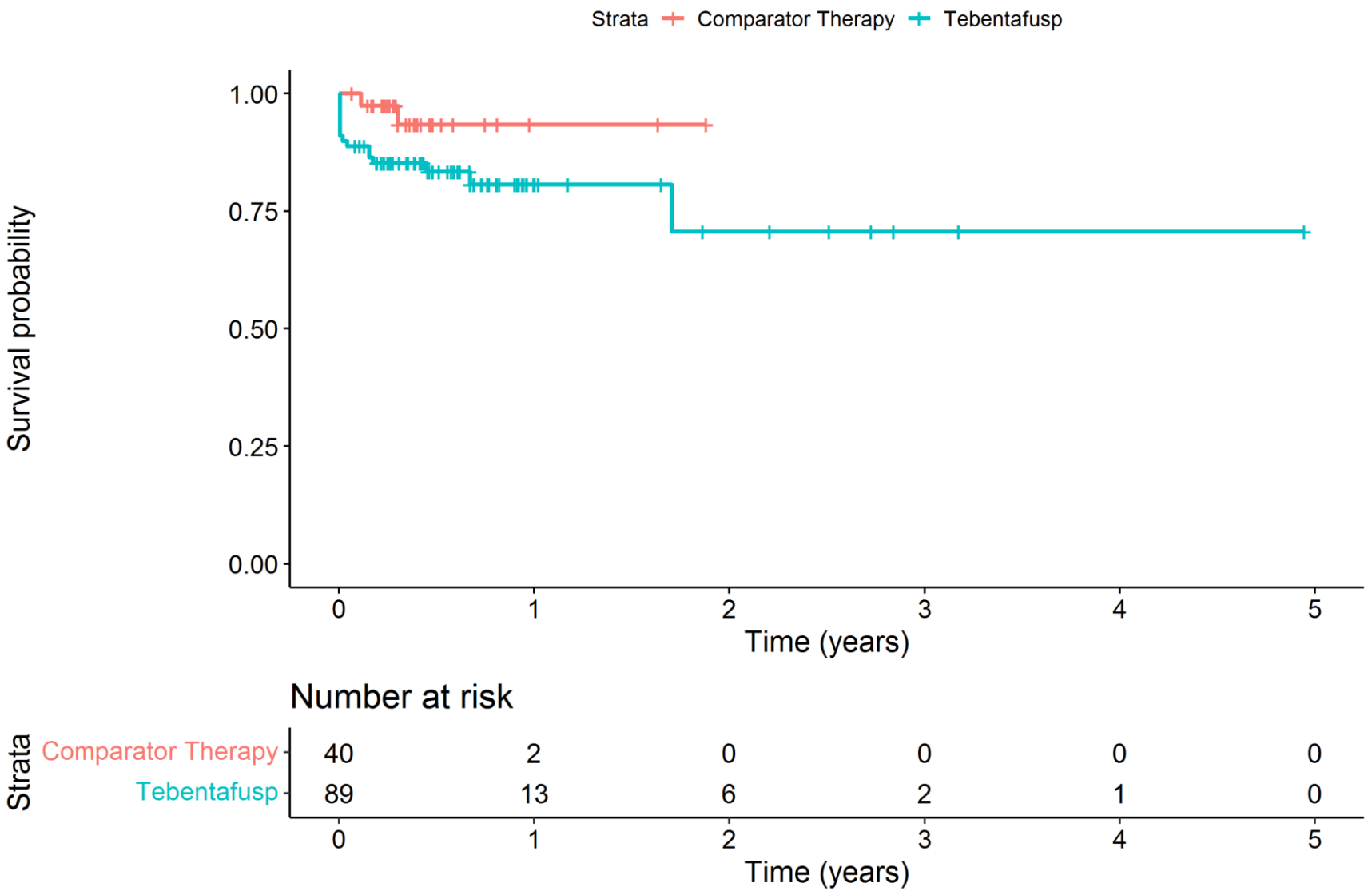
Lymphopenie - Keine Vorherige Therapie adjuvant/neoadjuvant



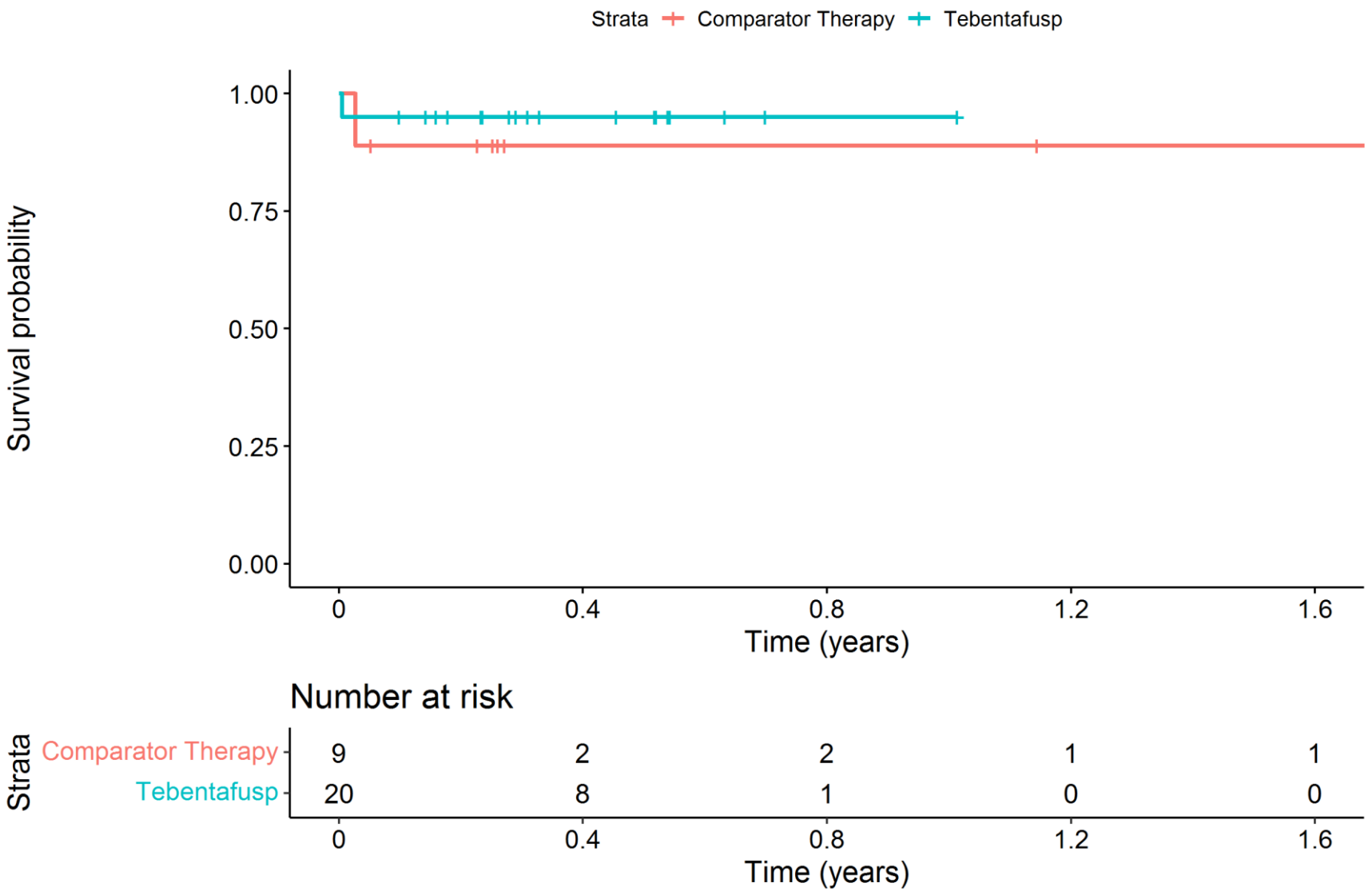
Lymphopenie - Läsion ≤ 3cm



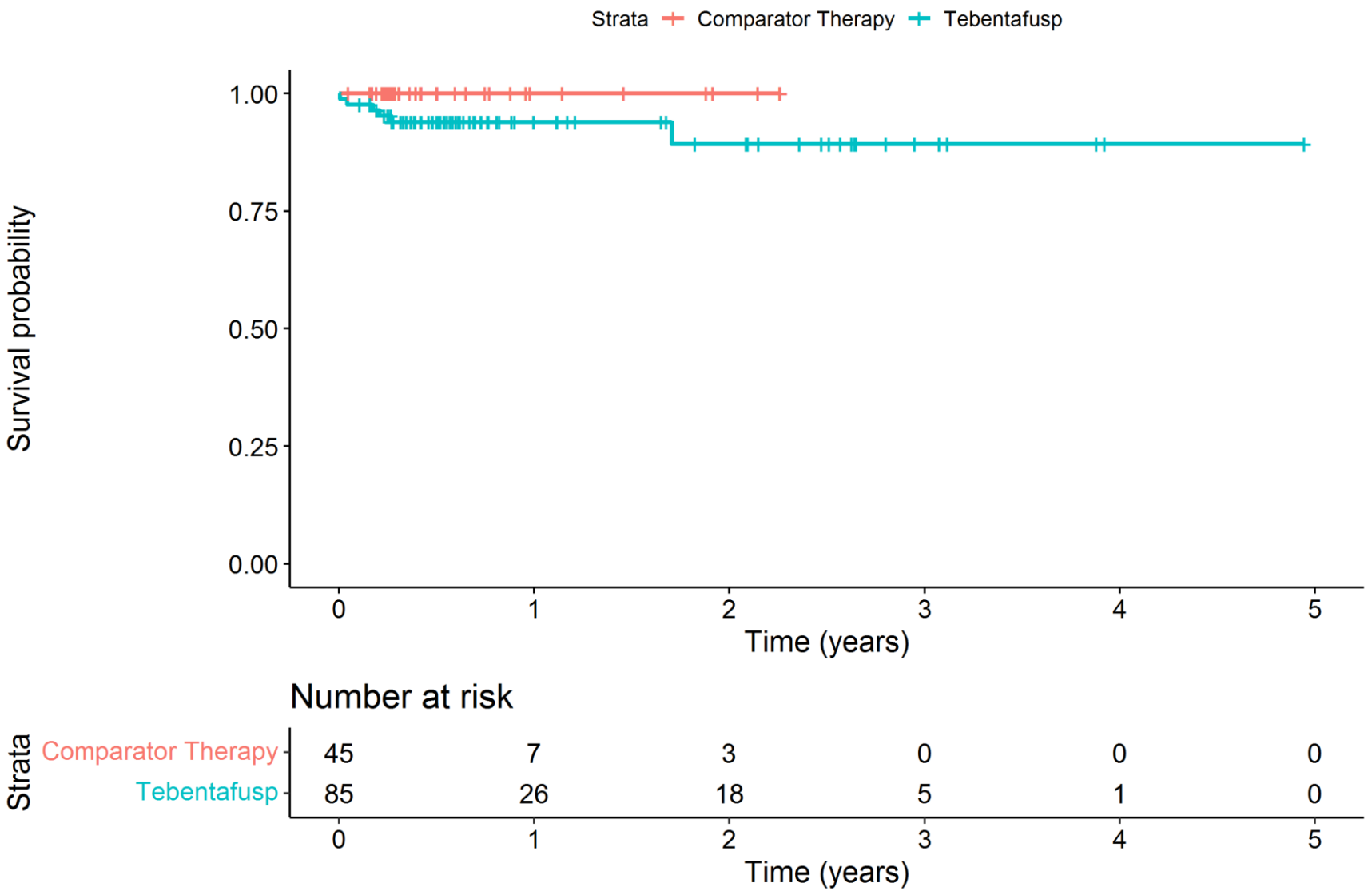
Lymphopenie - Läsion 3,1-8,0 cm



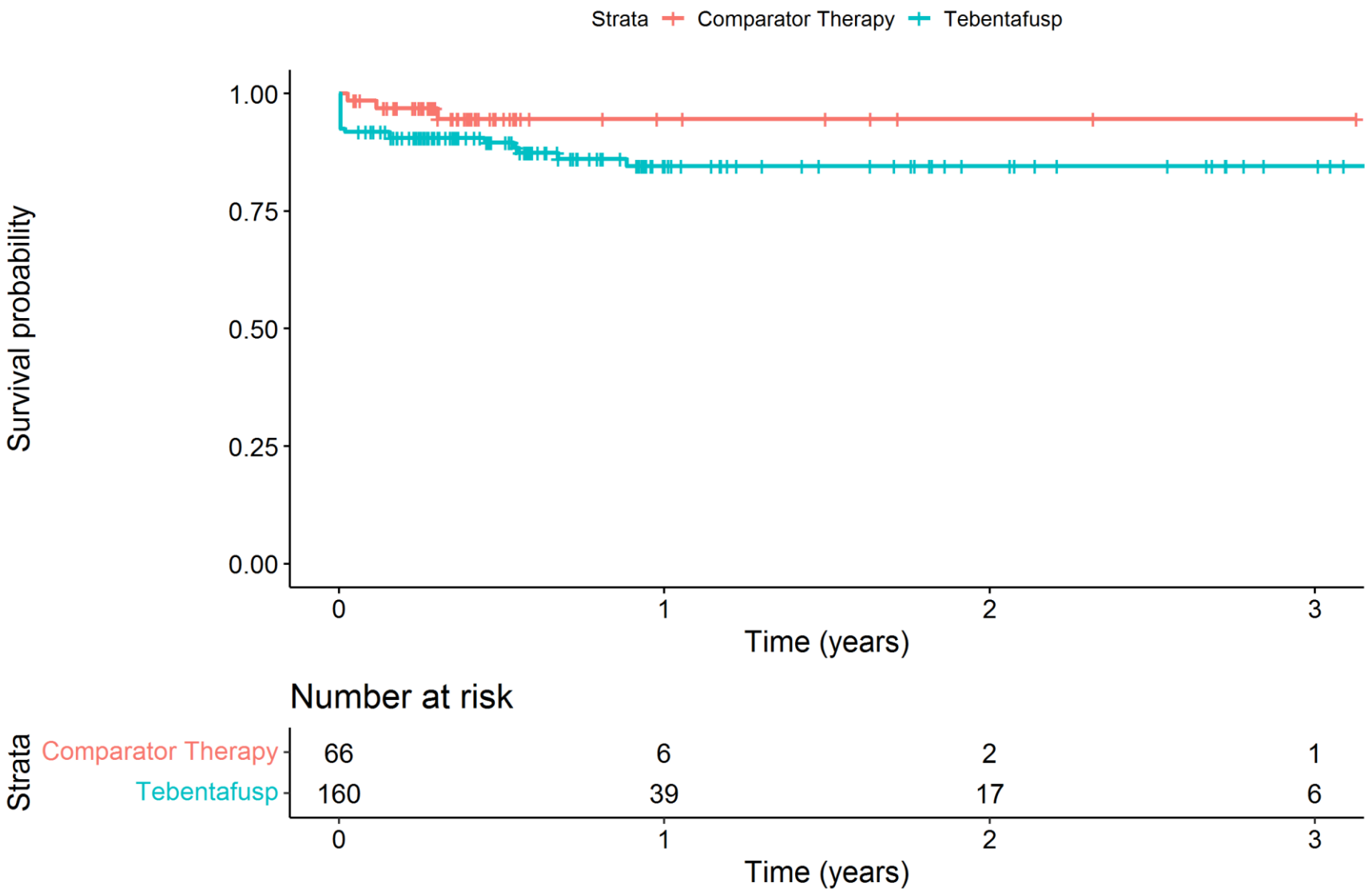
Lymphopenie - Läsion ≥8,1 cm



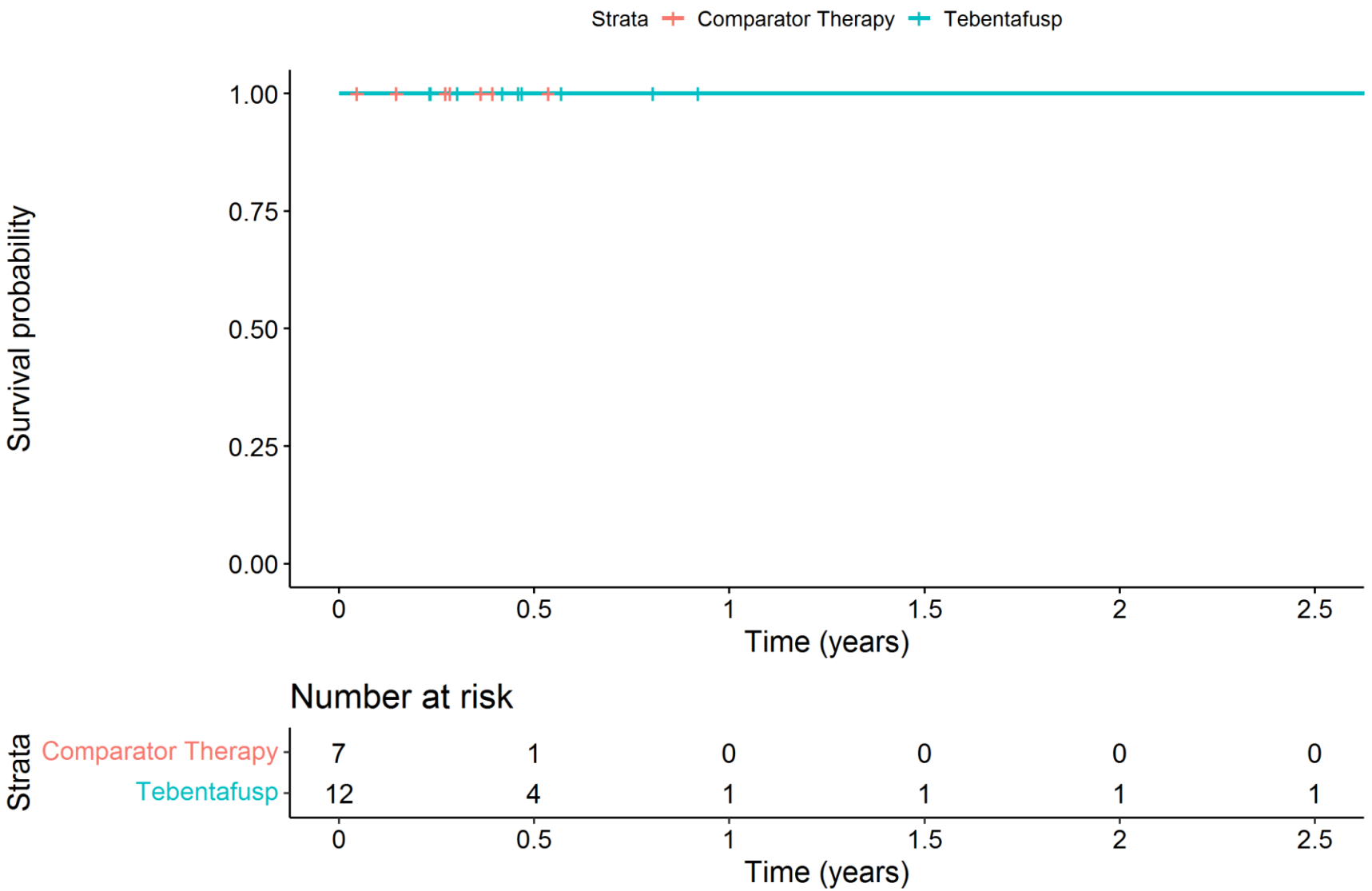
Lymphopenie - Nordamerika



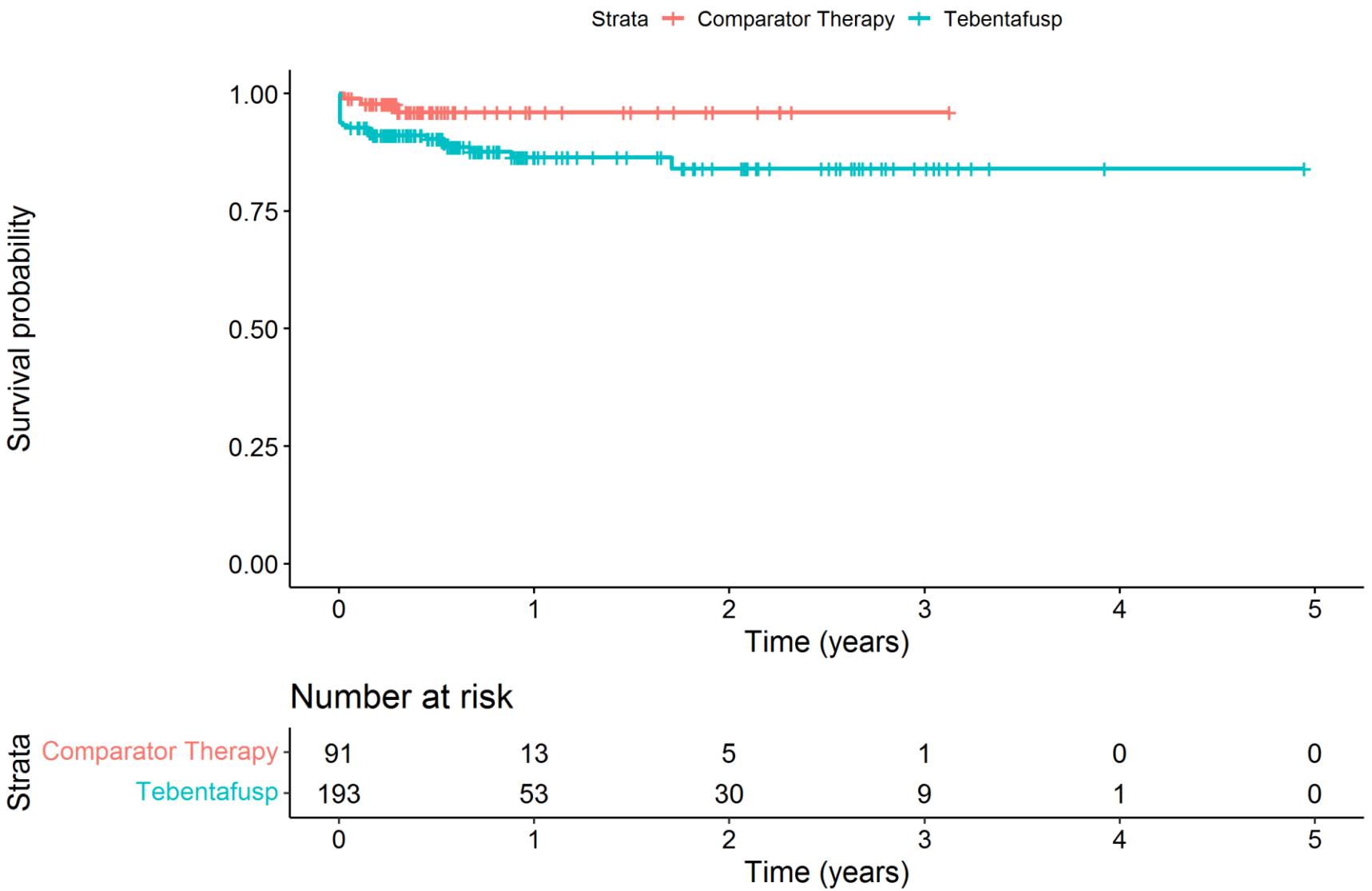
Lymphopenie - Nicht-Nordamerika



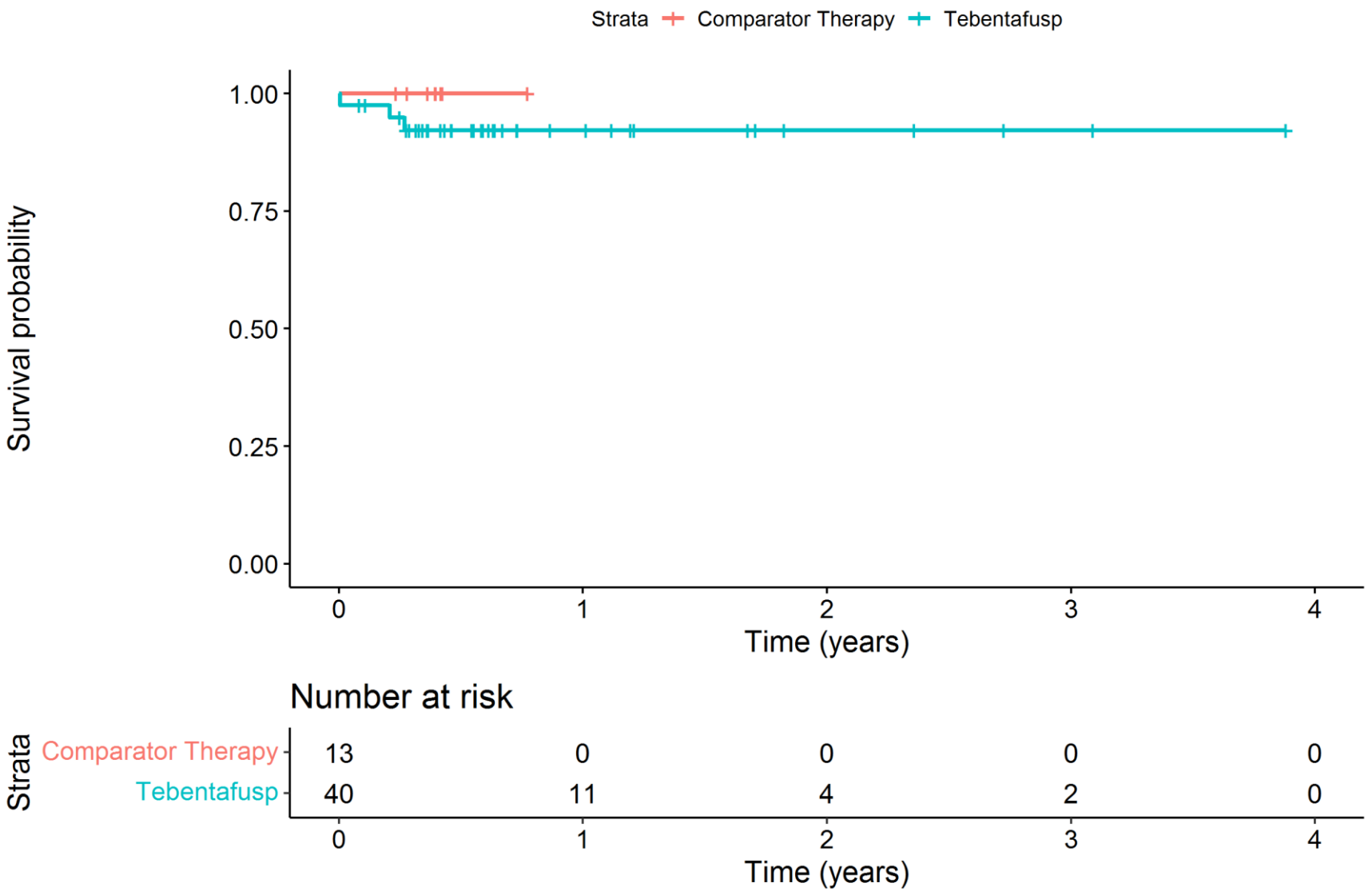
Lymphopenie - Dacarbazin



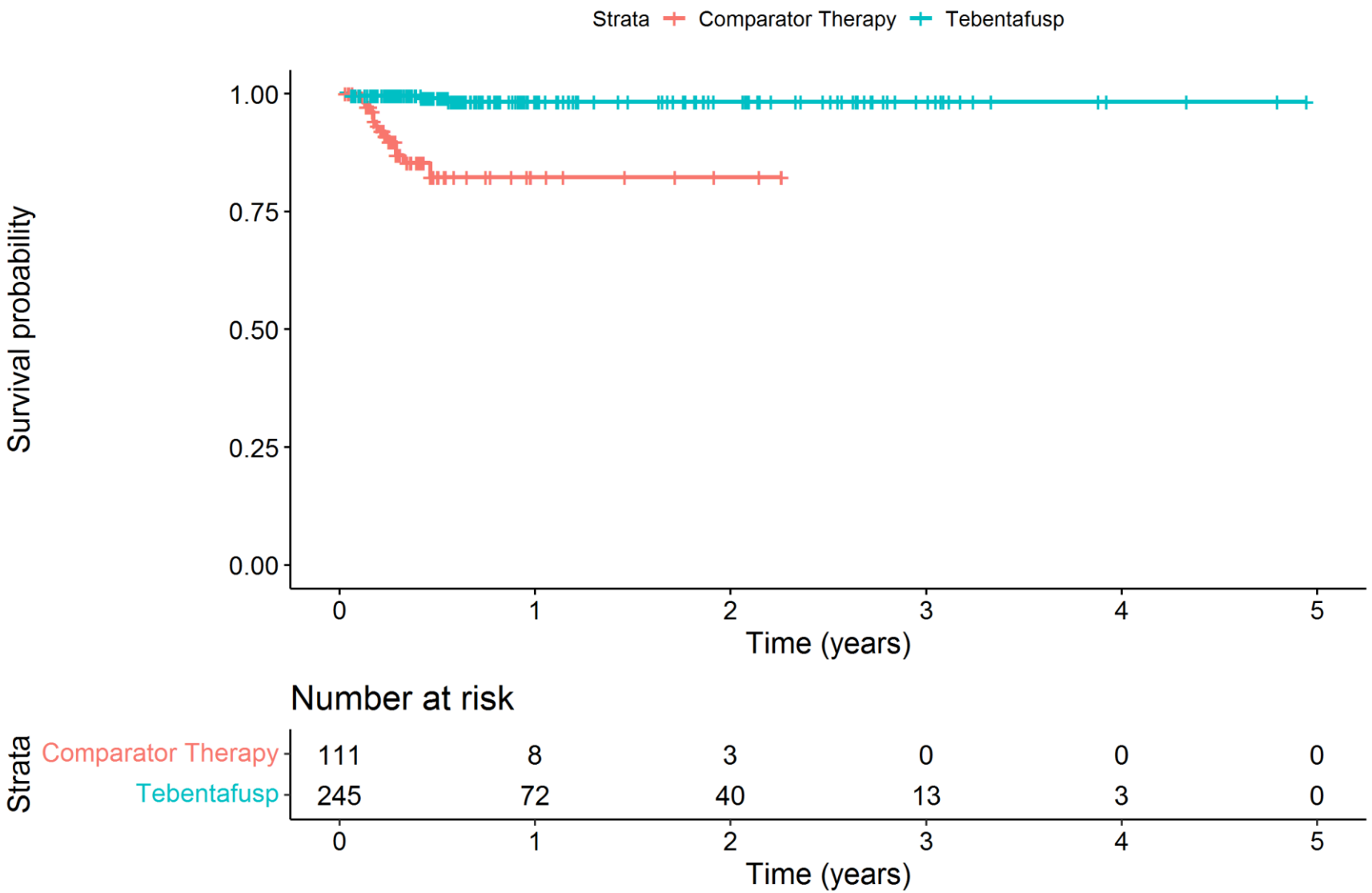
Lymphopenie - Pembrolizumab



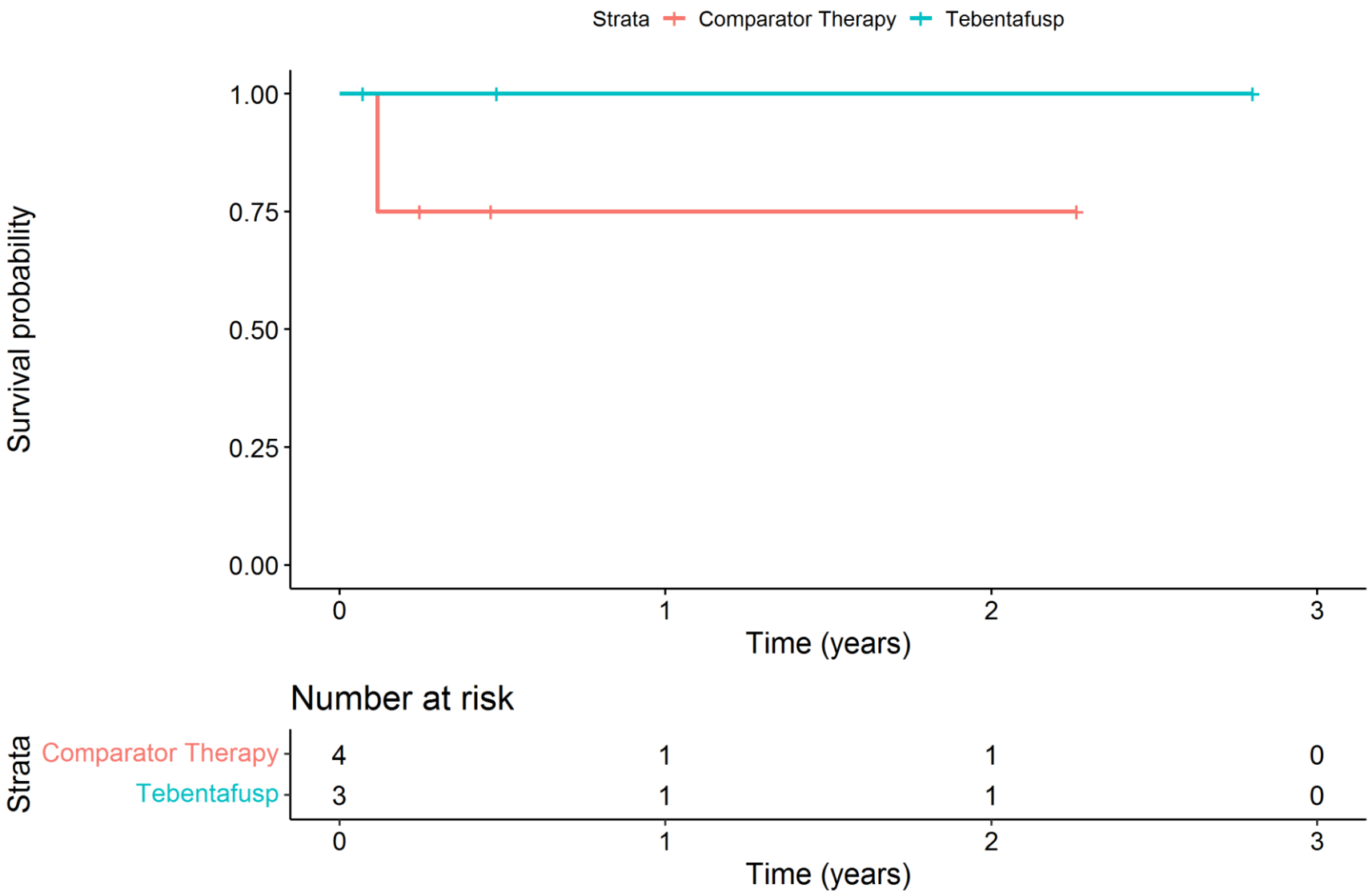
Lymphopenie - Ipilimumab



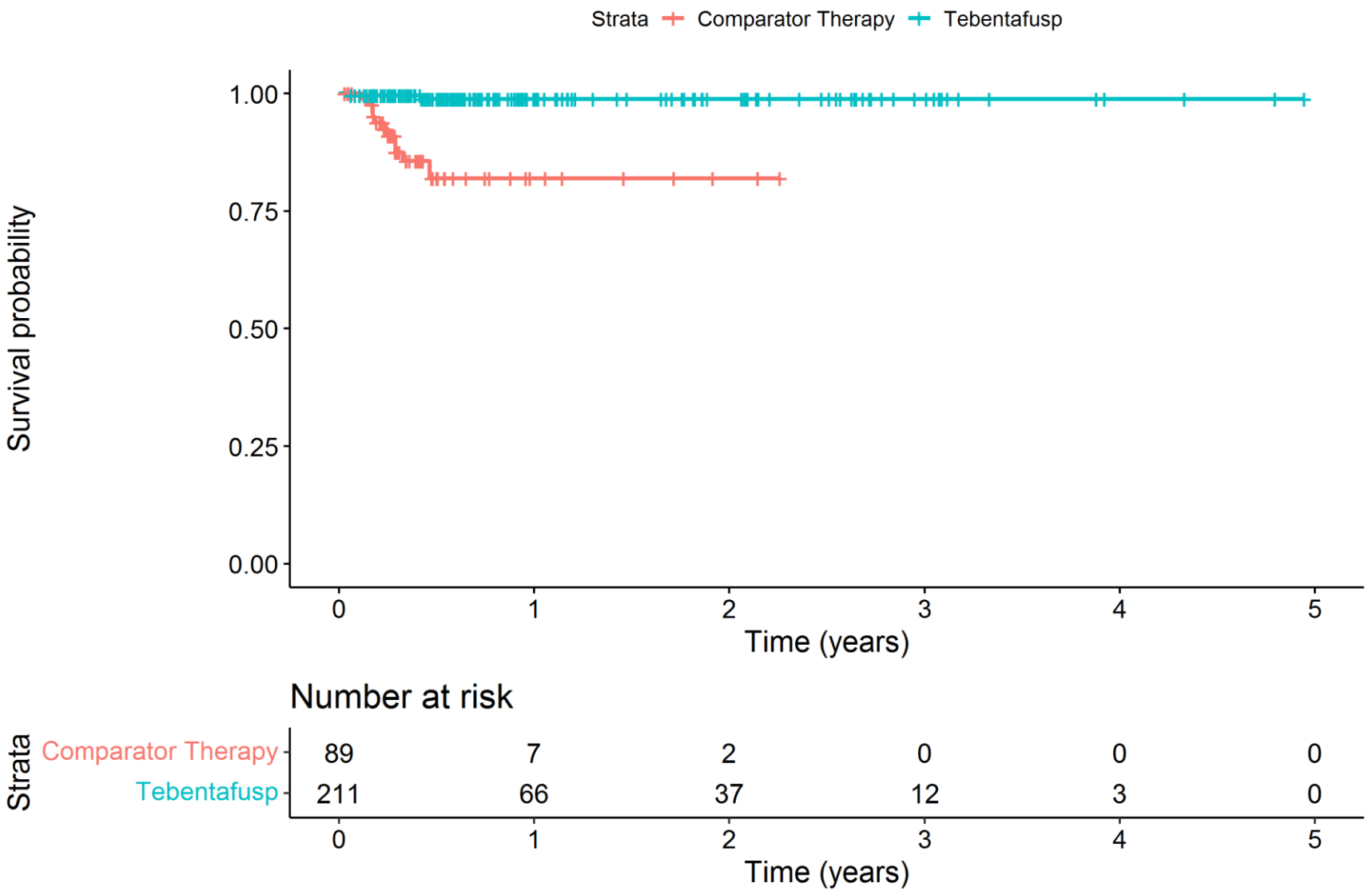
Hypothyreose - Gesamt



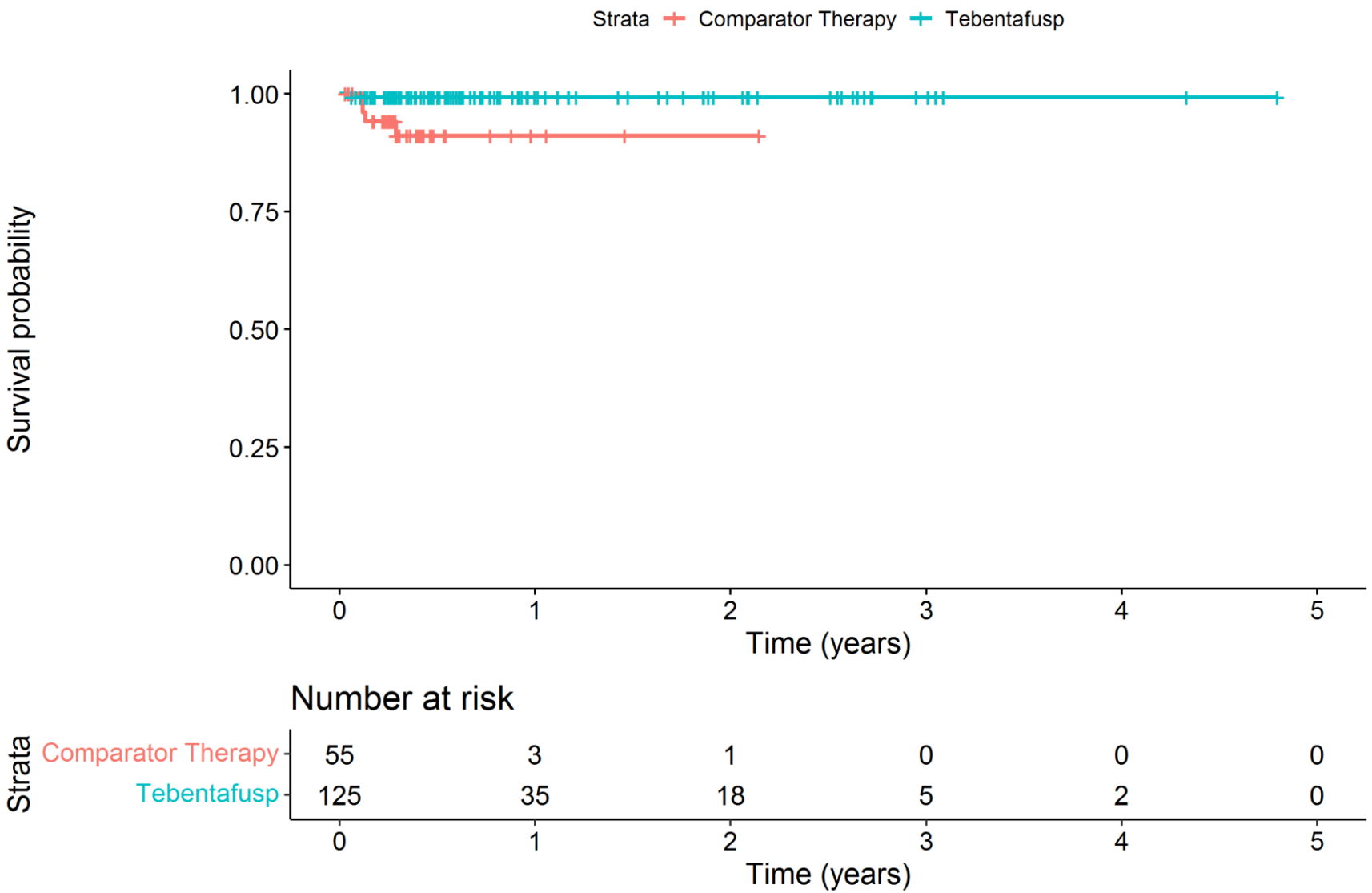
Hypothyreose - Hispanisch



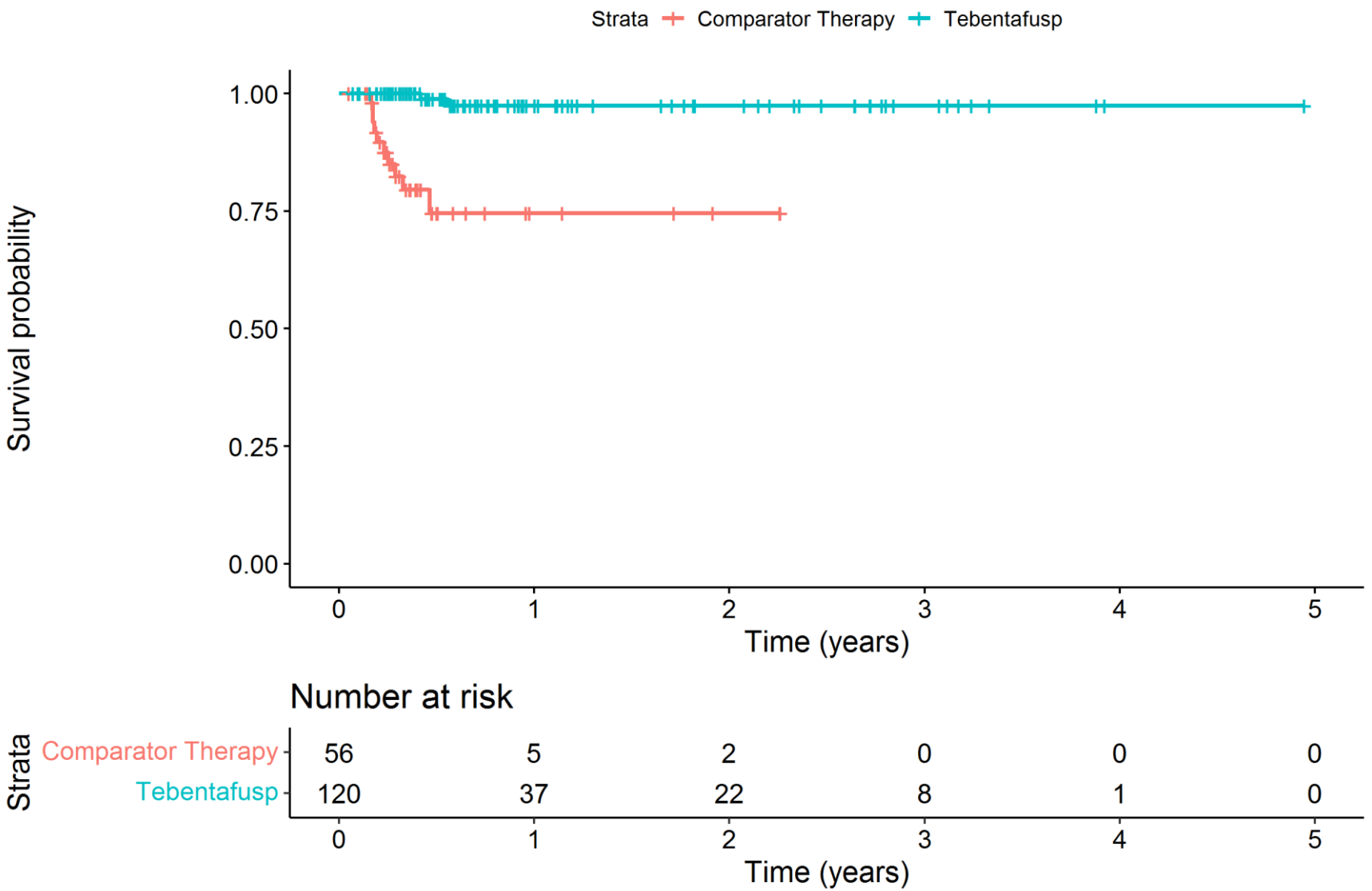
Hypothyreose - Nicht-hispanisch



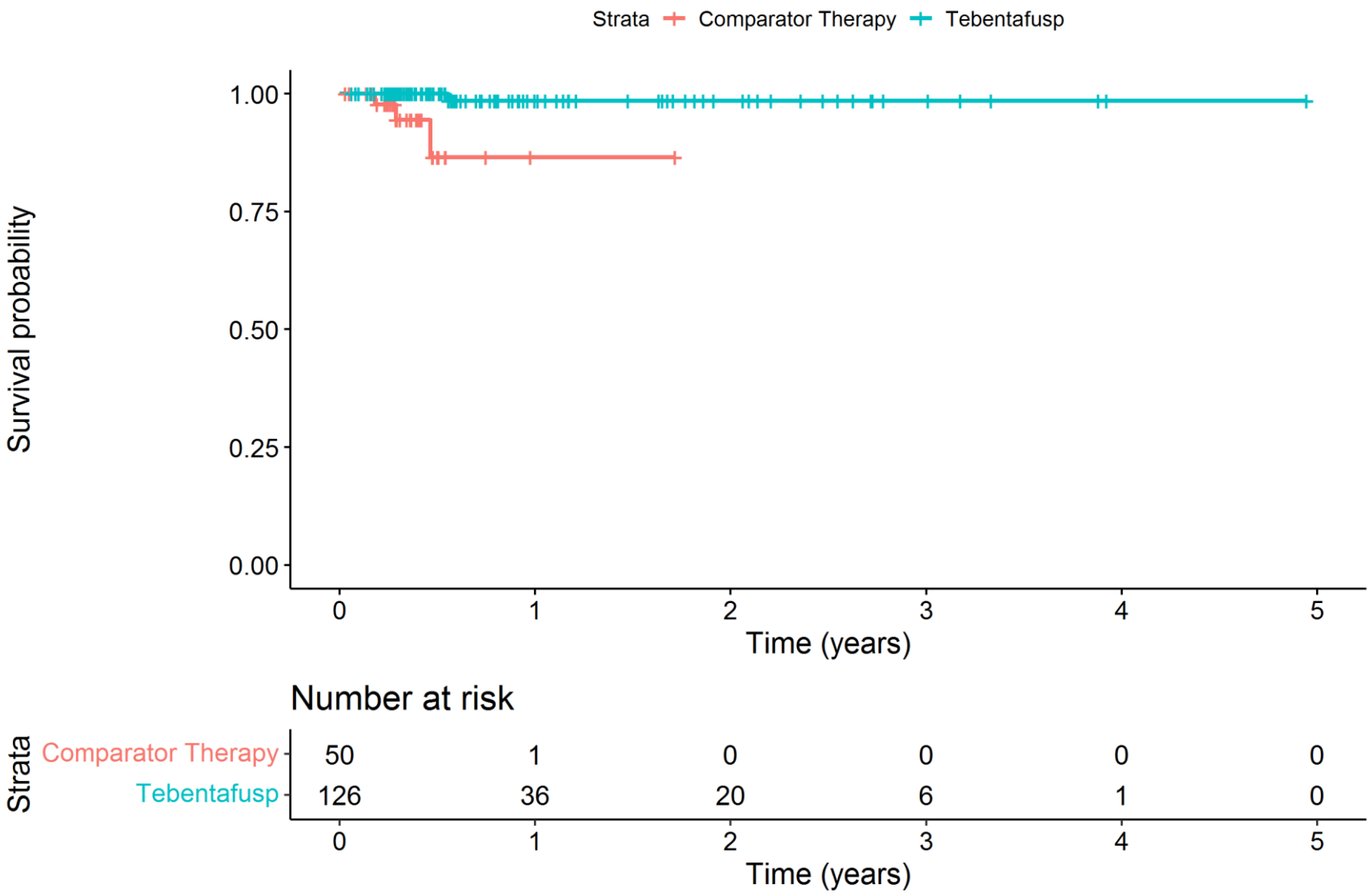
Hypothyreose - Männlich



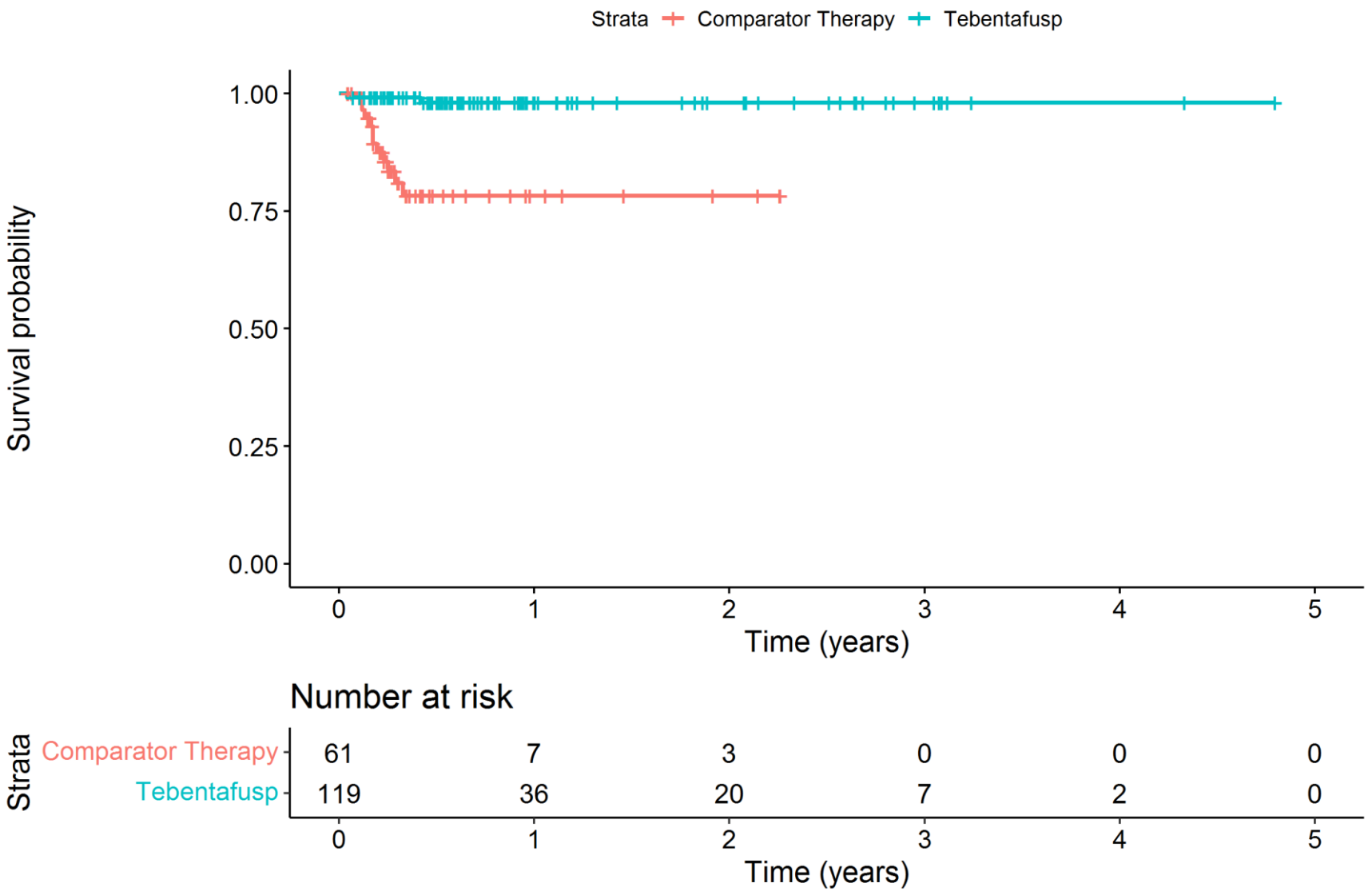
Hypothyreose - Weiblich



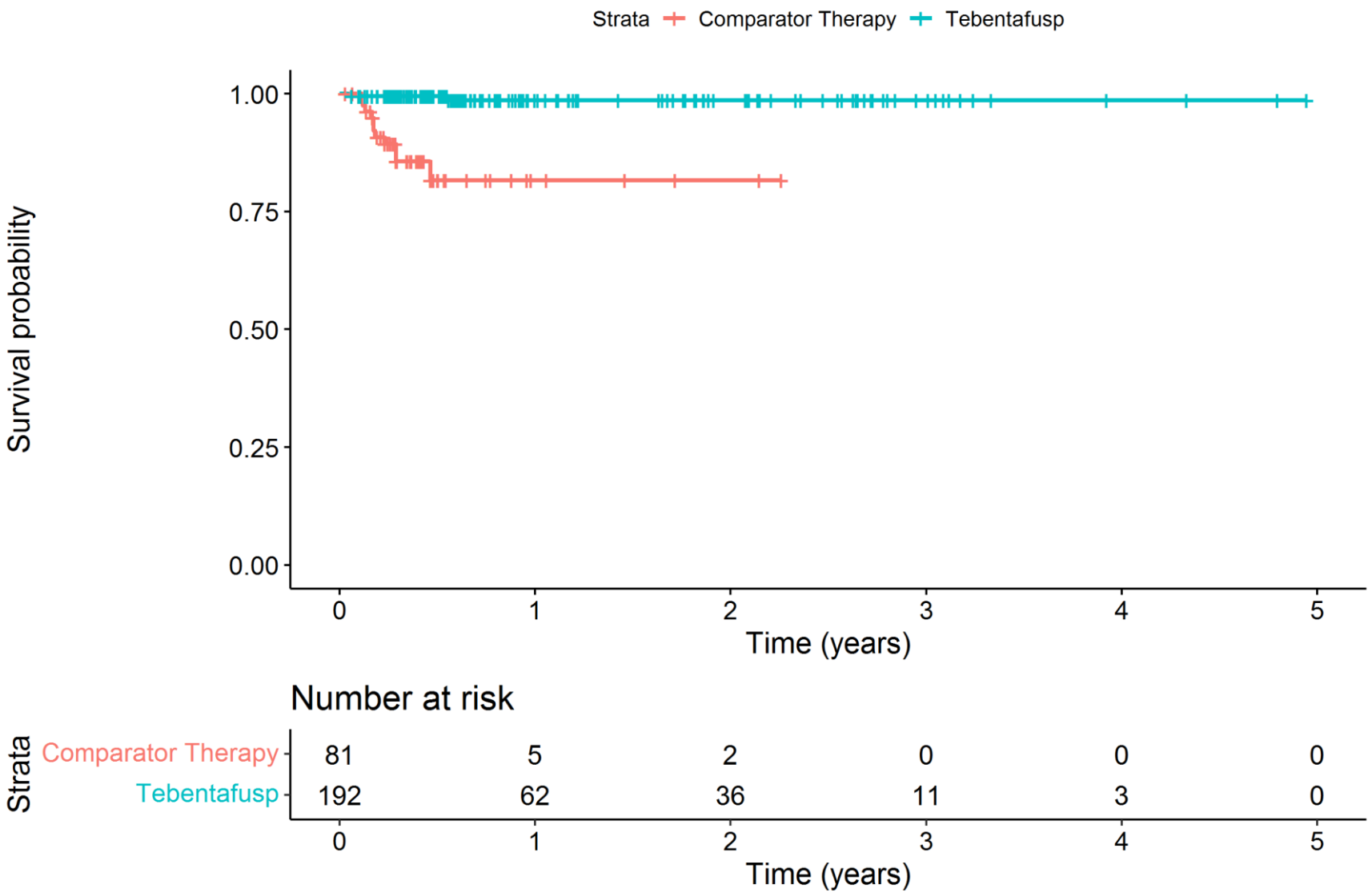
Hypothyreose - <65



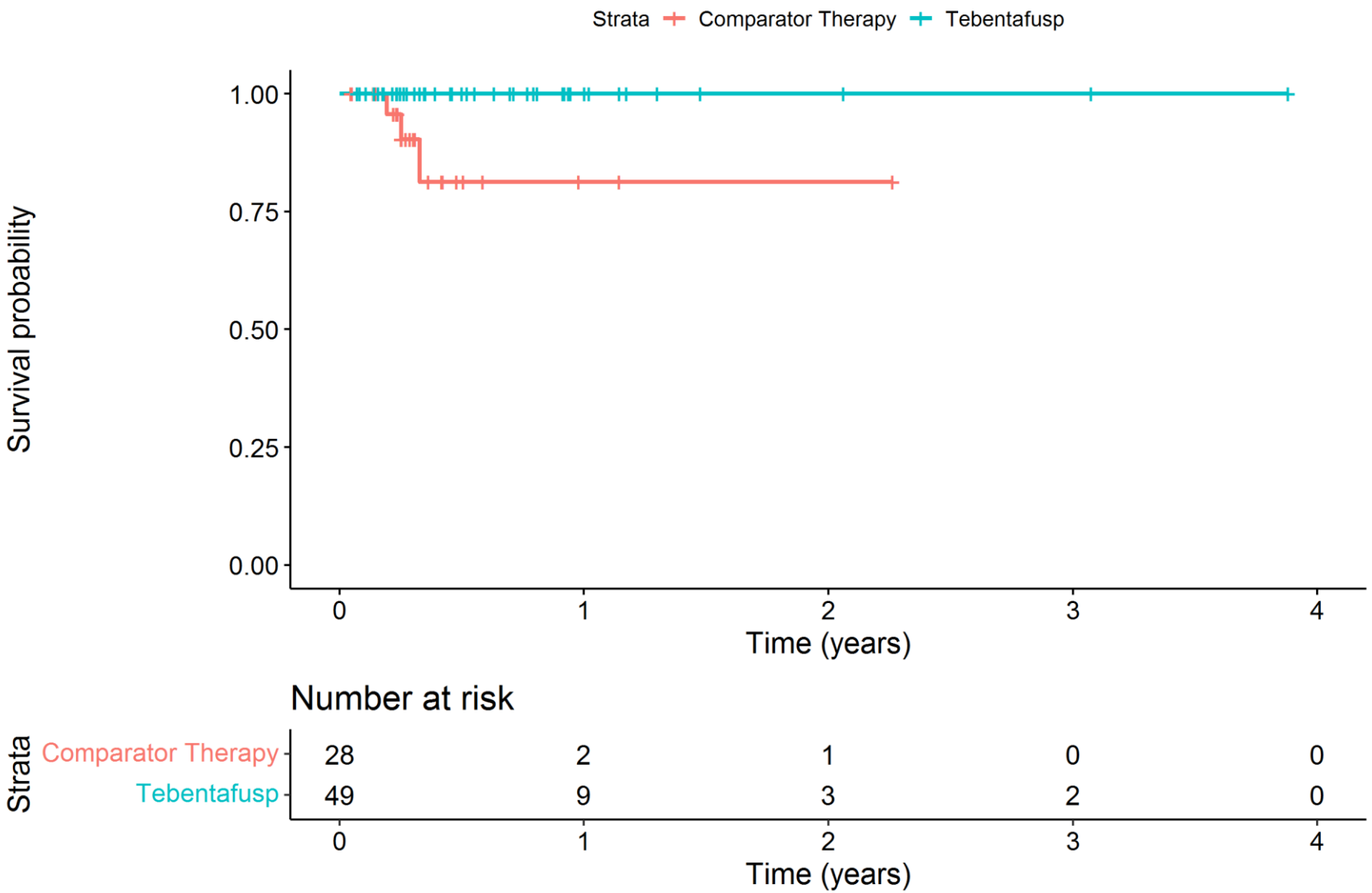
Hypothyreose - ≥65



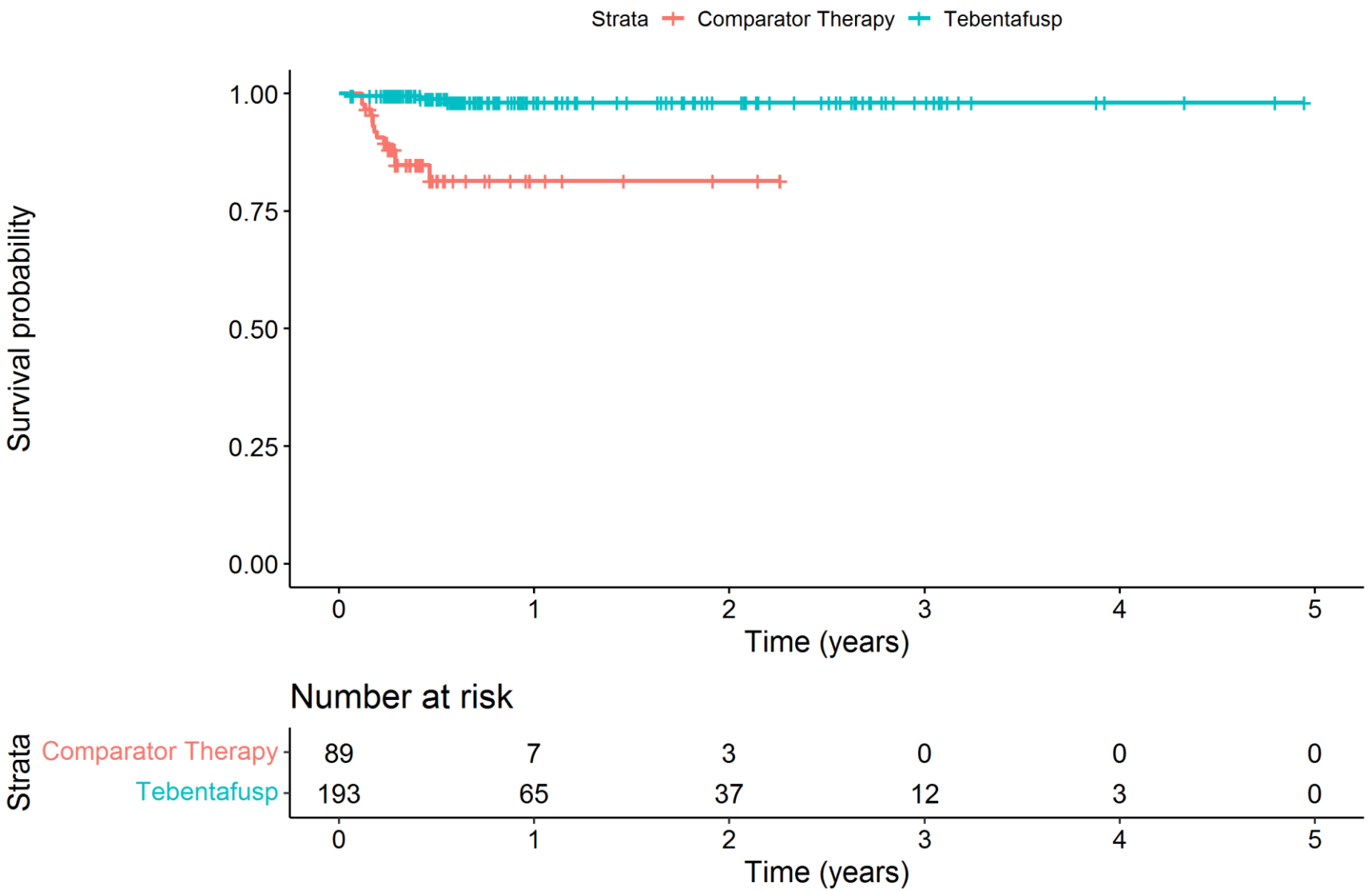
Hypothyreose - ECOG 0



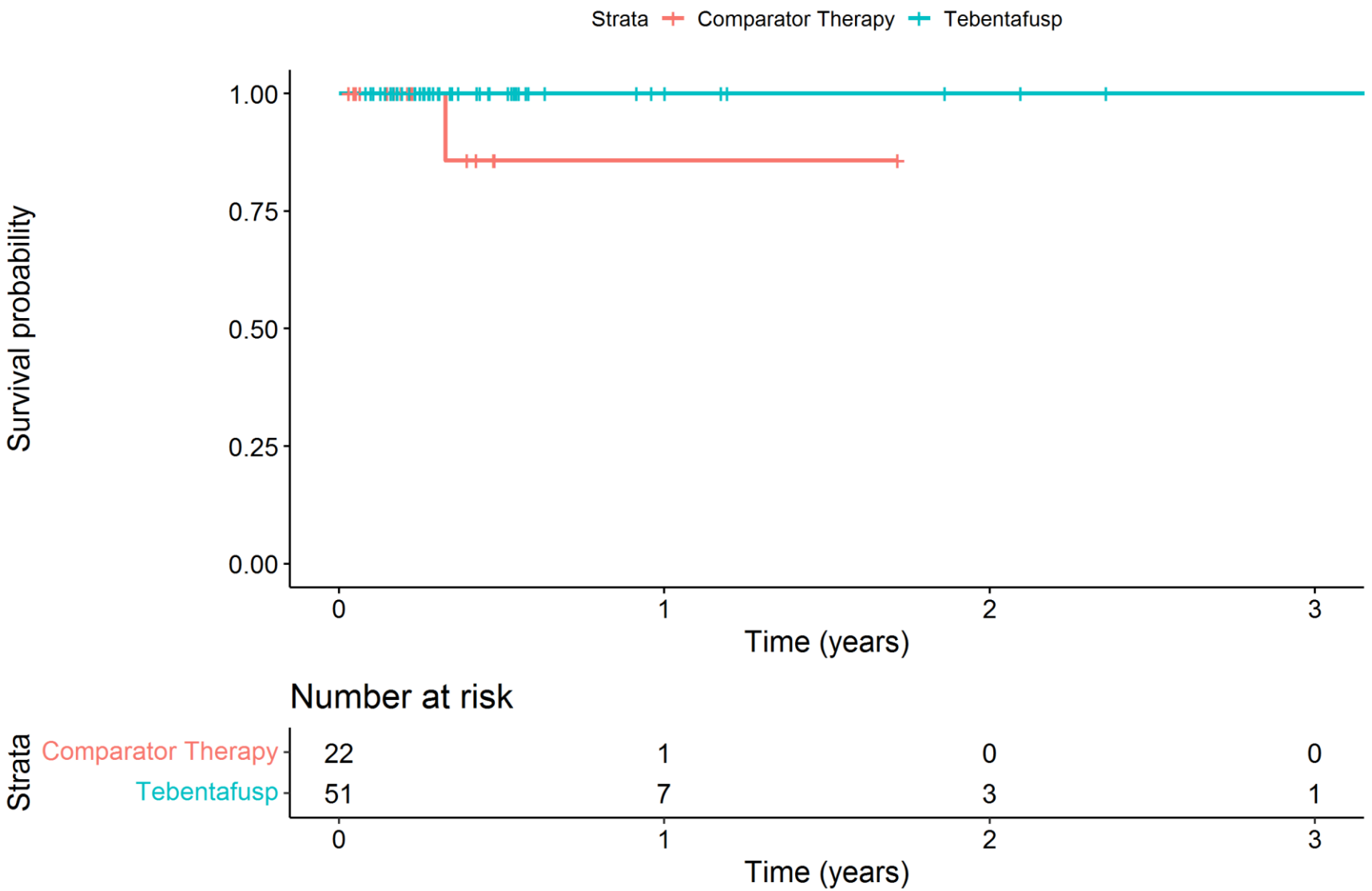
Hypothyreose - ECOG 1



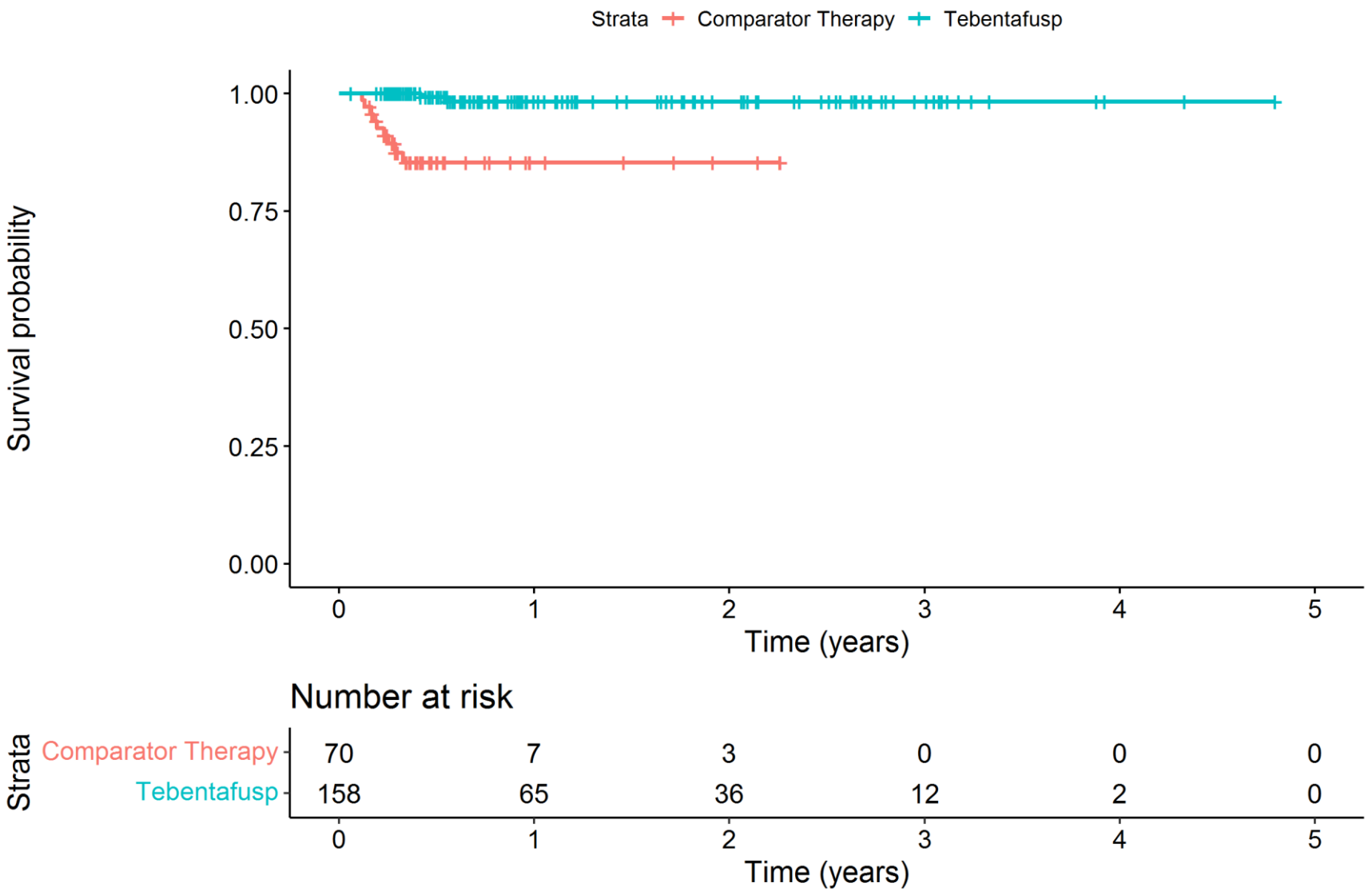
Hypothyreose - ALP ≤ ULN



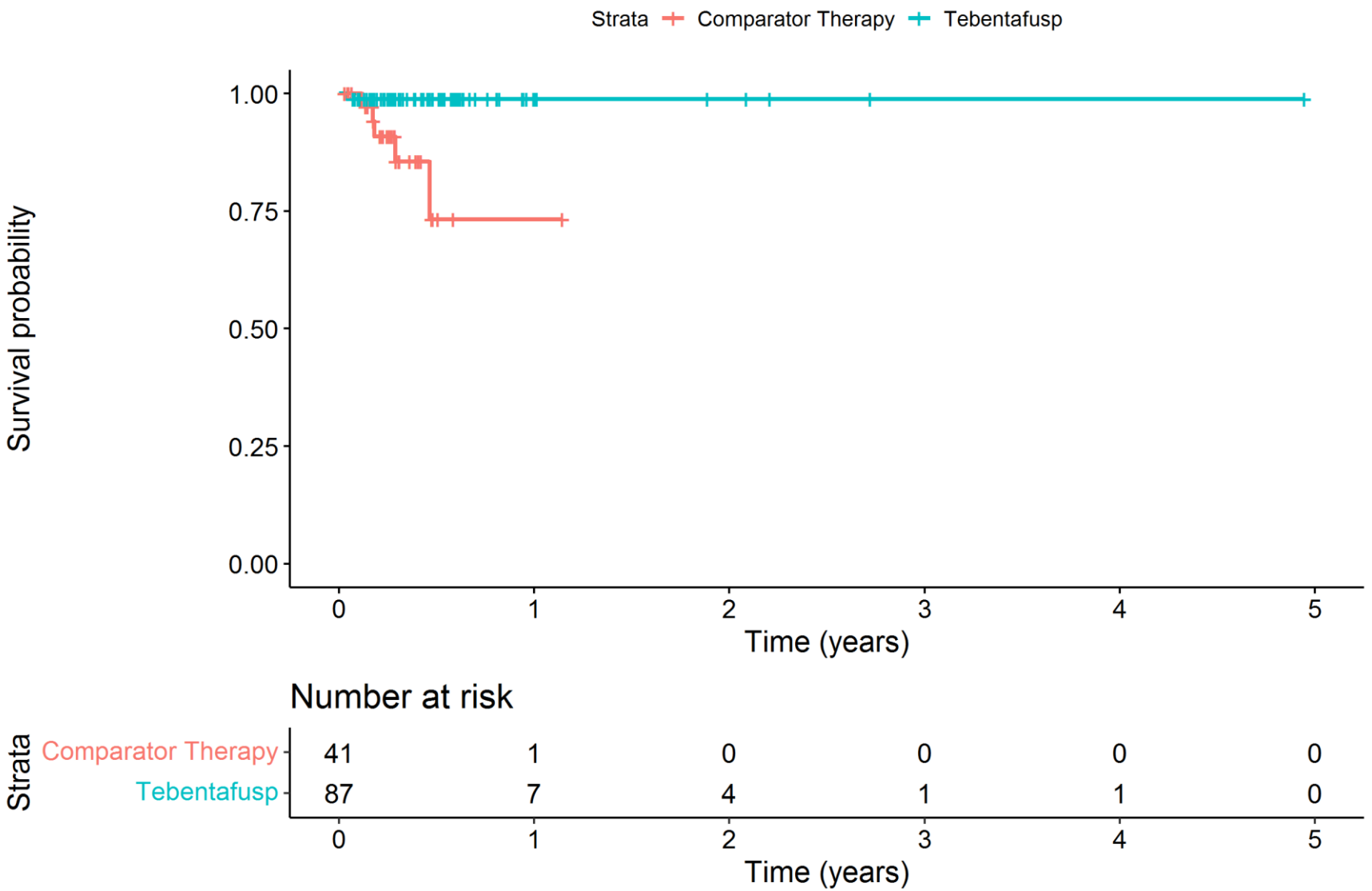
Hypothyreose - ALP > ULN



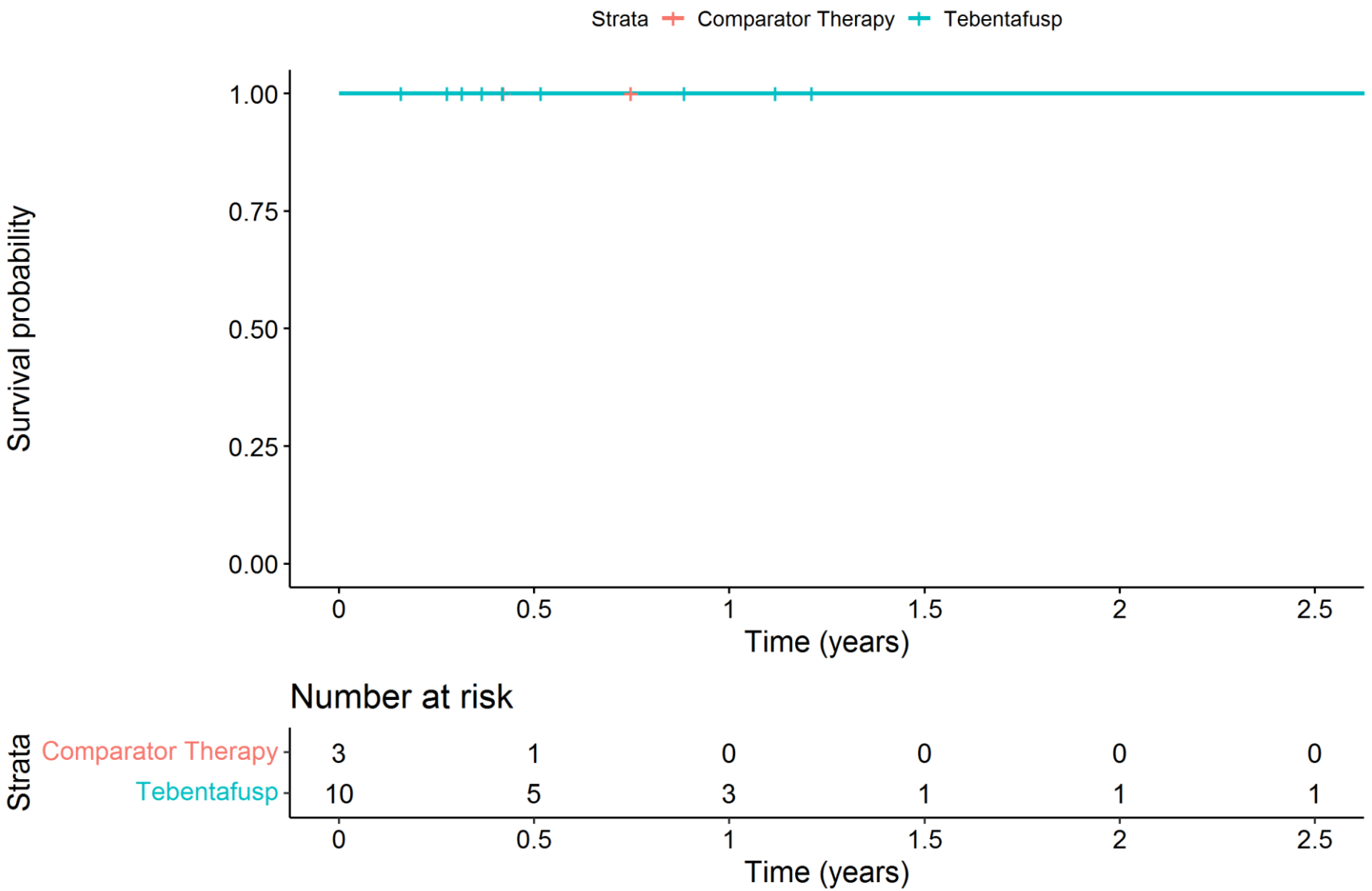
Hypothyreose - LDH =< ULN



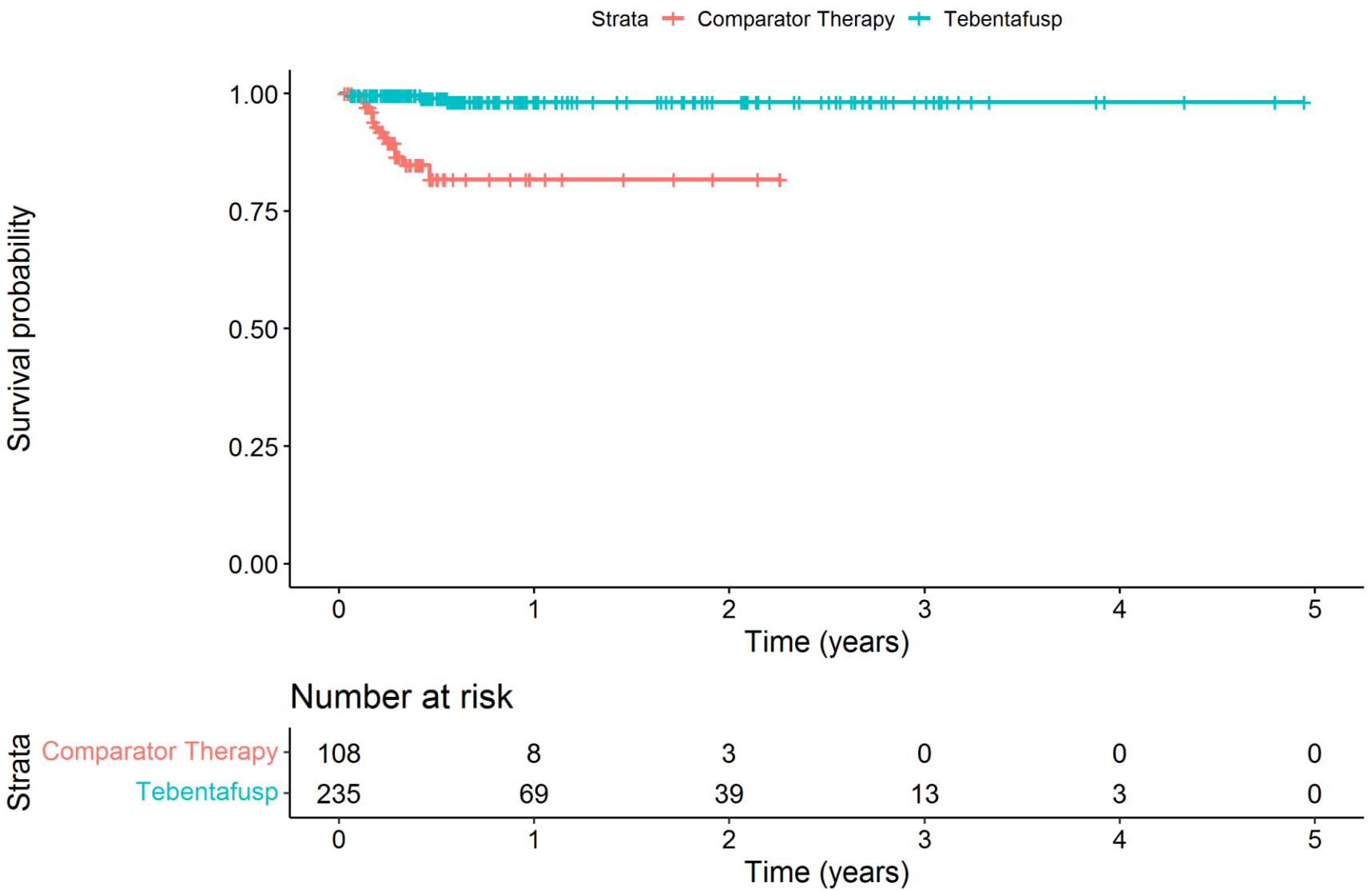
Hypothyreose - LDH > ULN



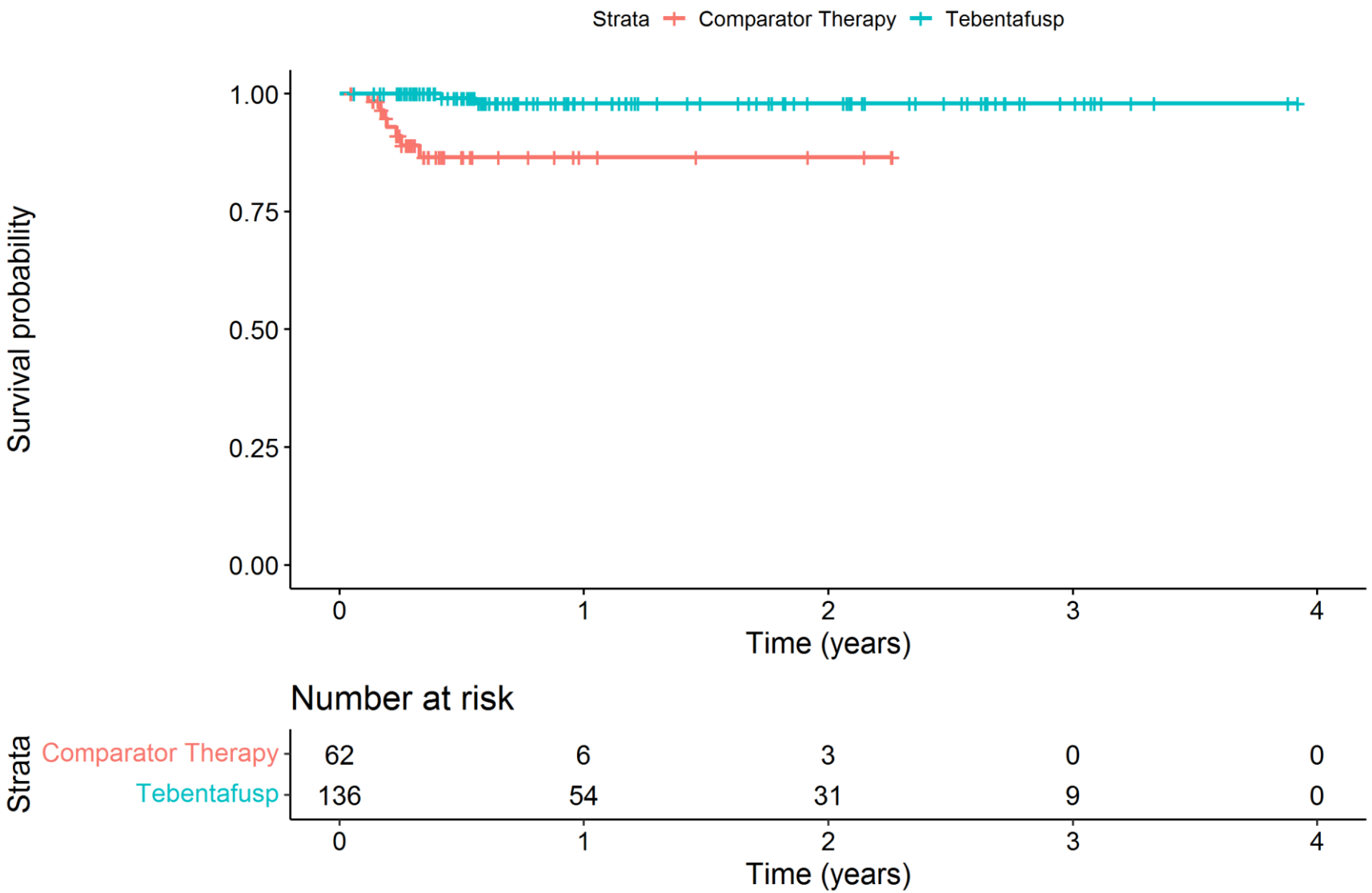
Hypothyreose - Vorherige Therapie adjuvant/neoadjuvant



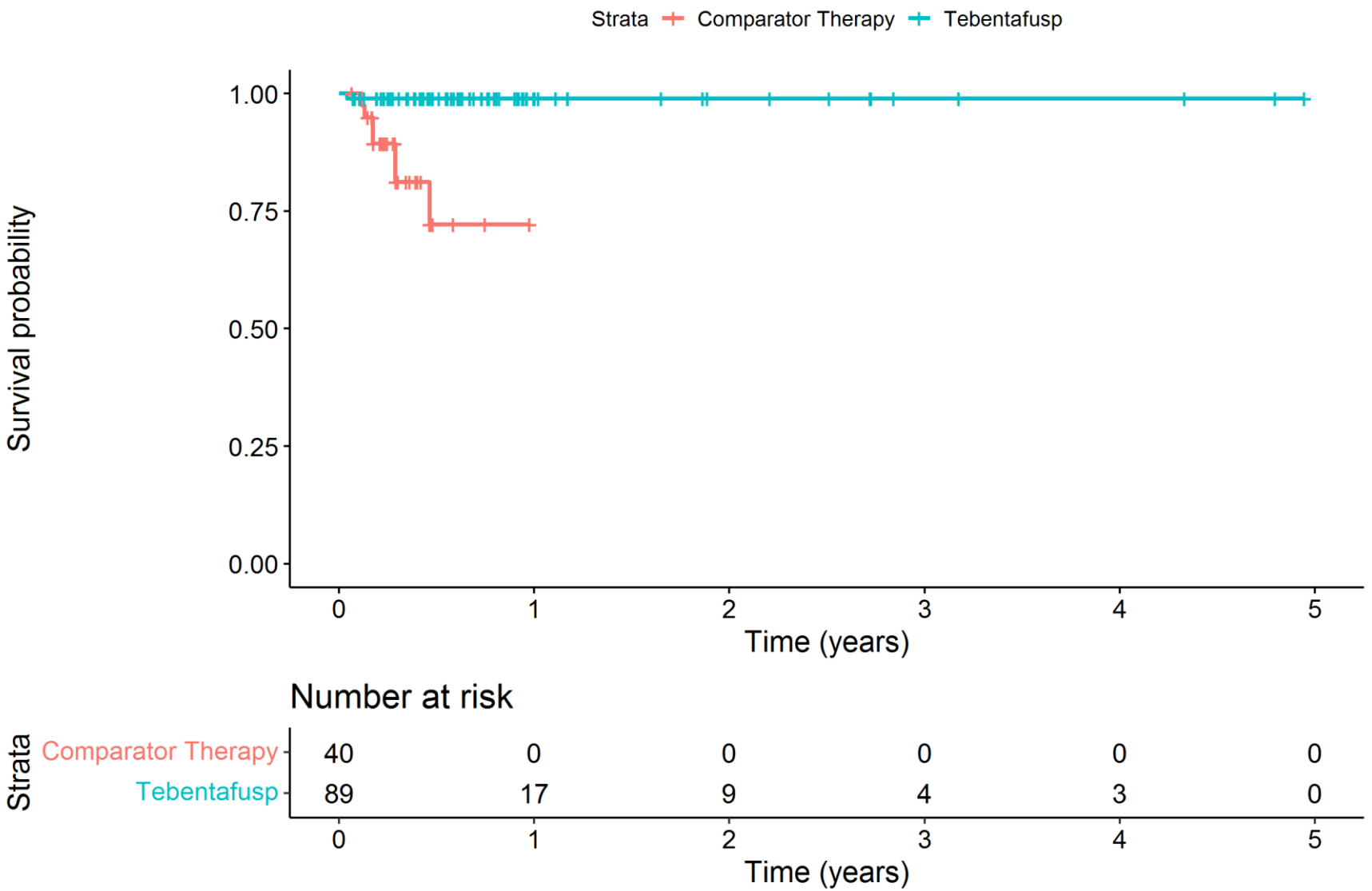
Hypothyreose - Keine Vorherige Therapie adjuvant/neoadjuvant



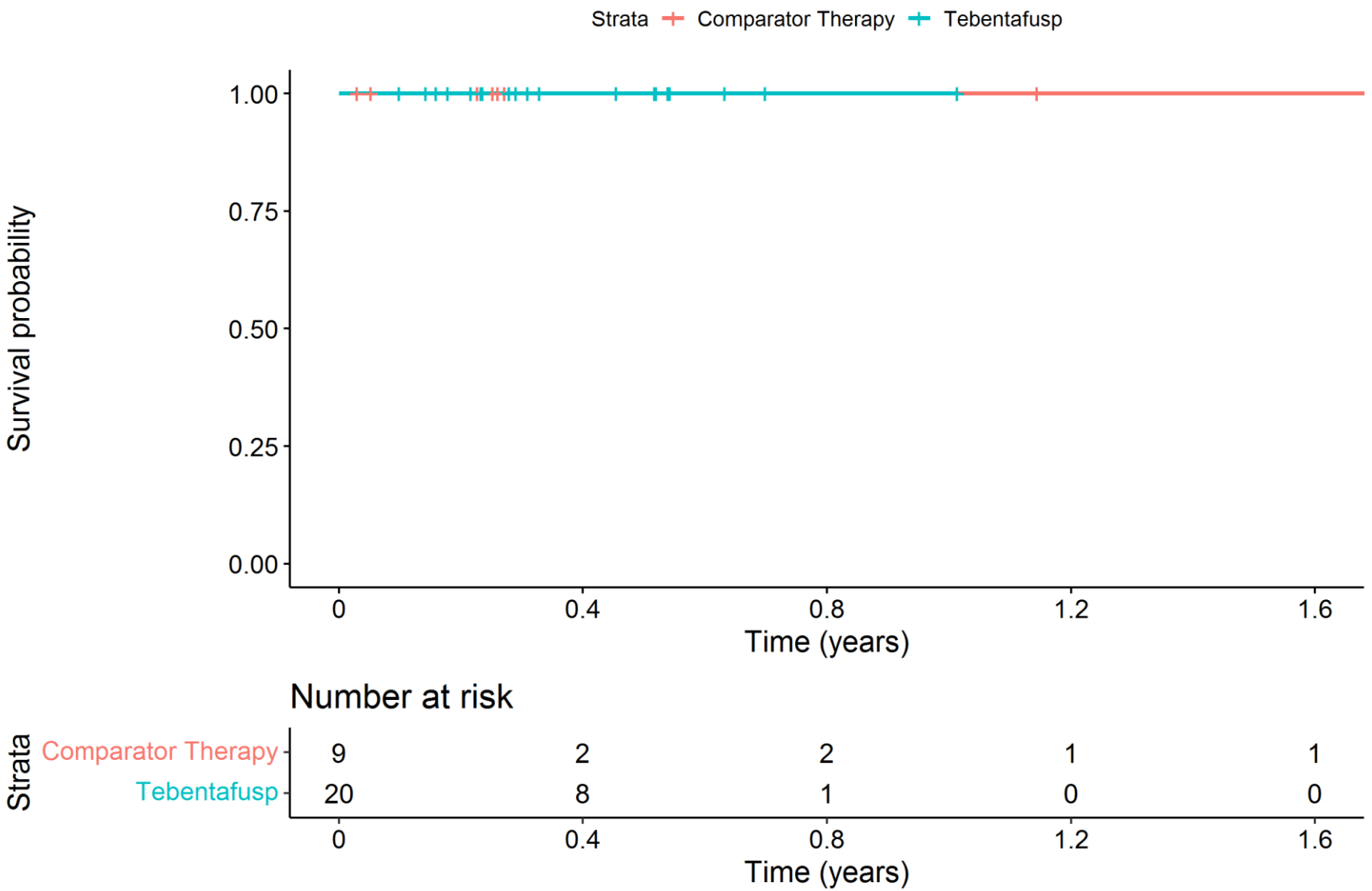
Hypothyreose - Läsion ≤ 3cm



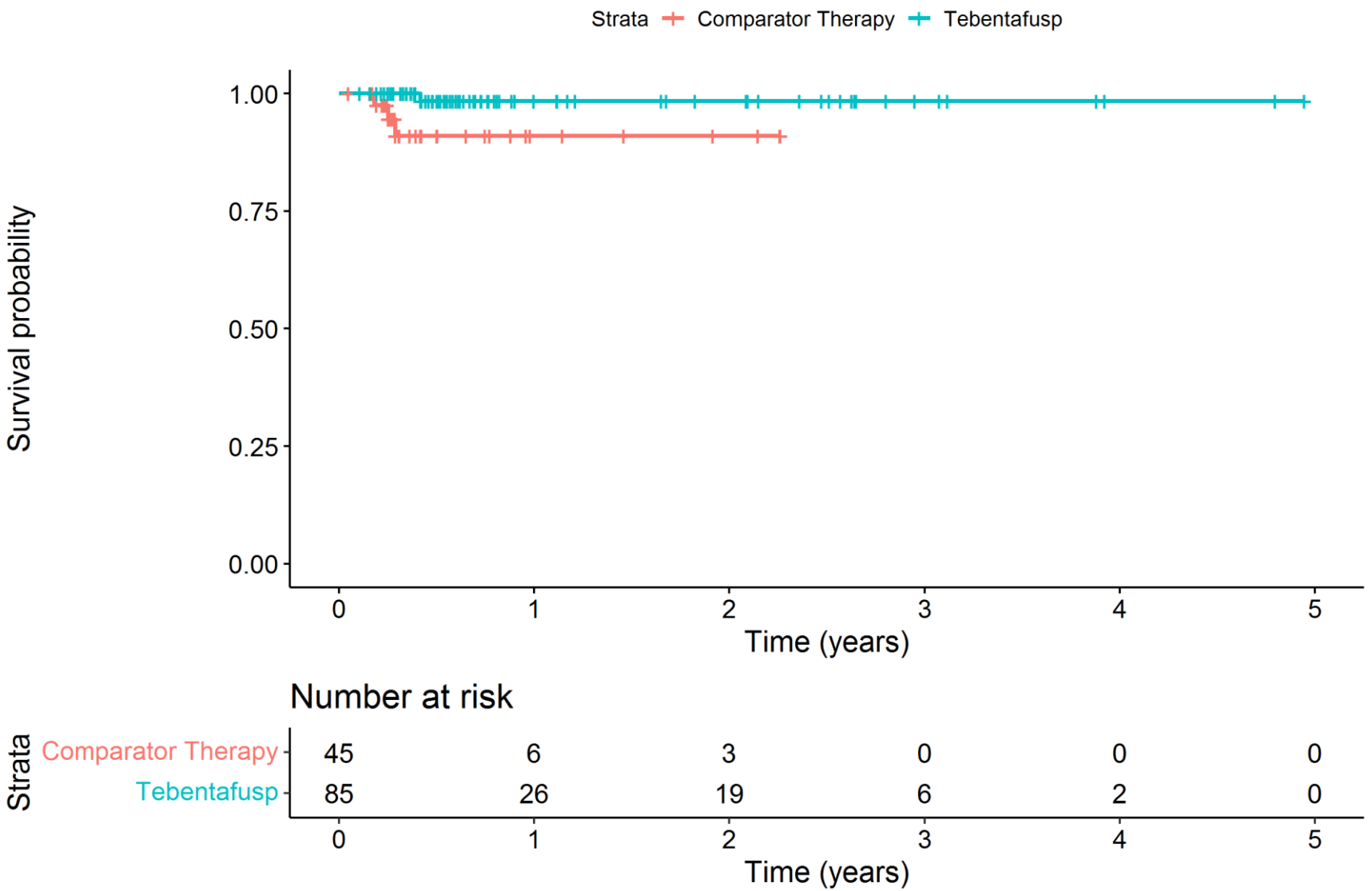
Hypothyreose - Läsion 3,1-8,0 cm



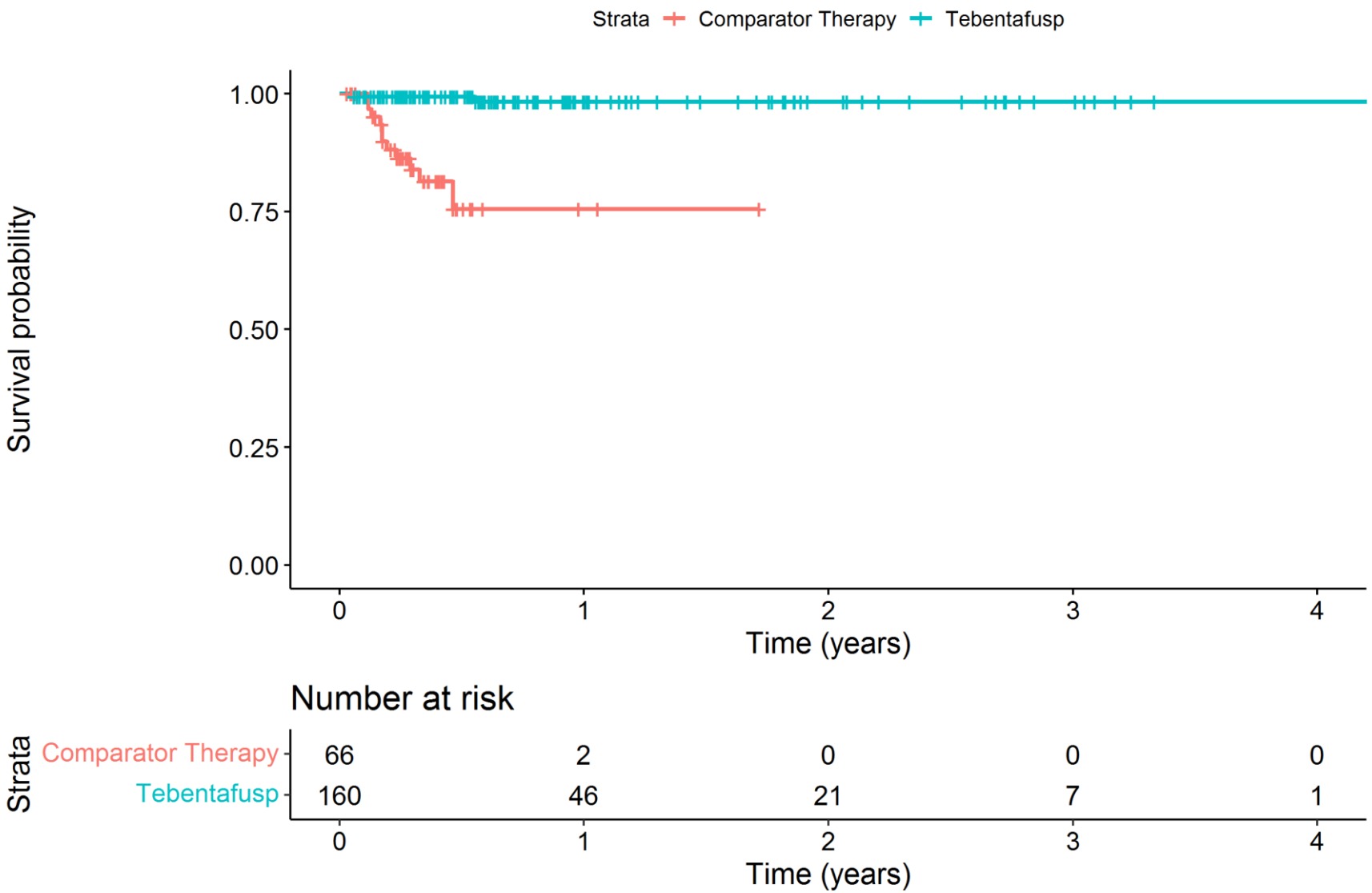
Hypothyreose - Läsion ≥8,1 cm



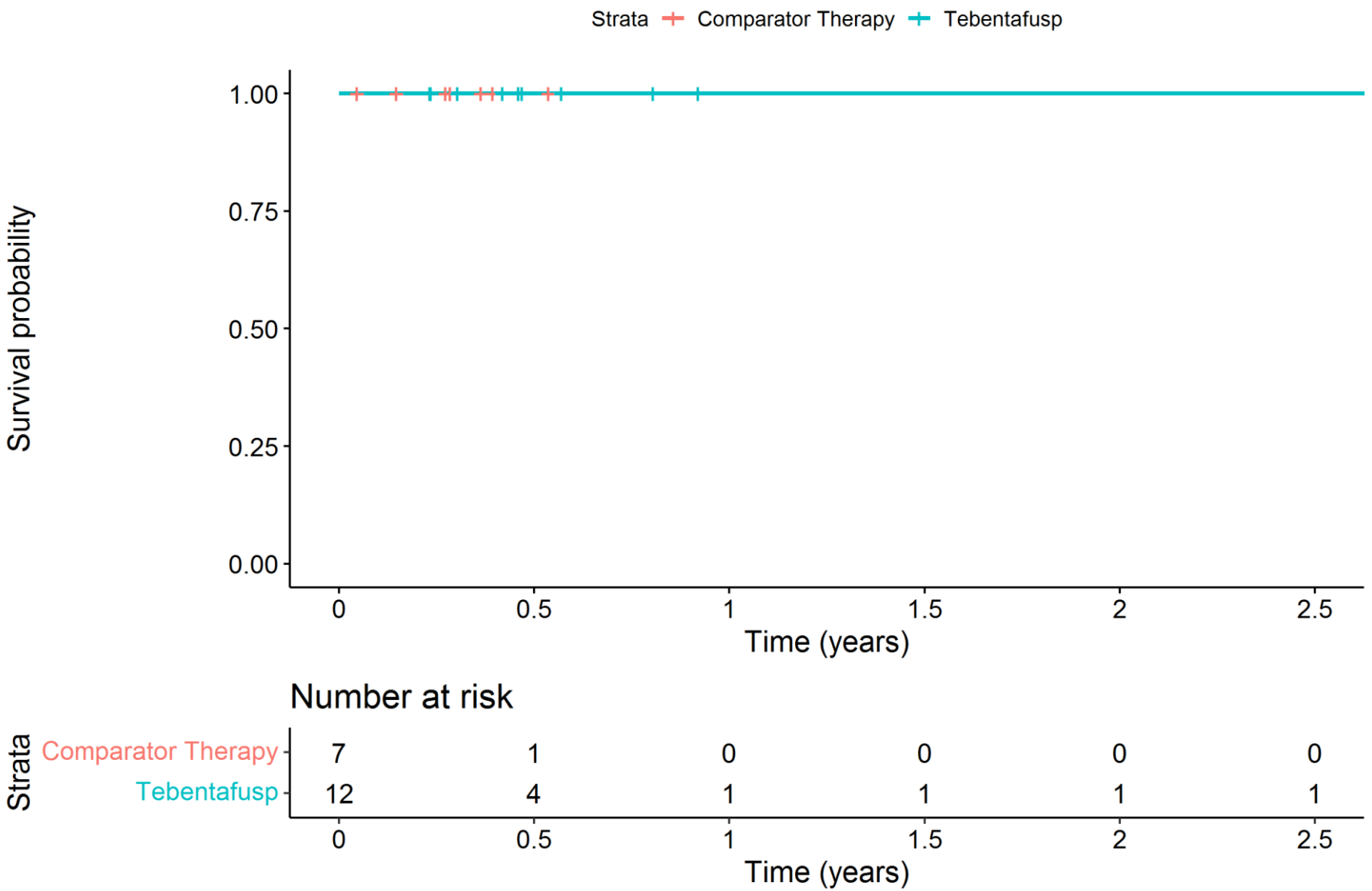
Hypothyreose - Nordamerika



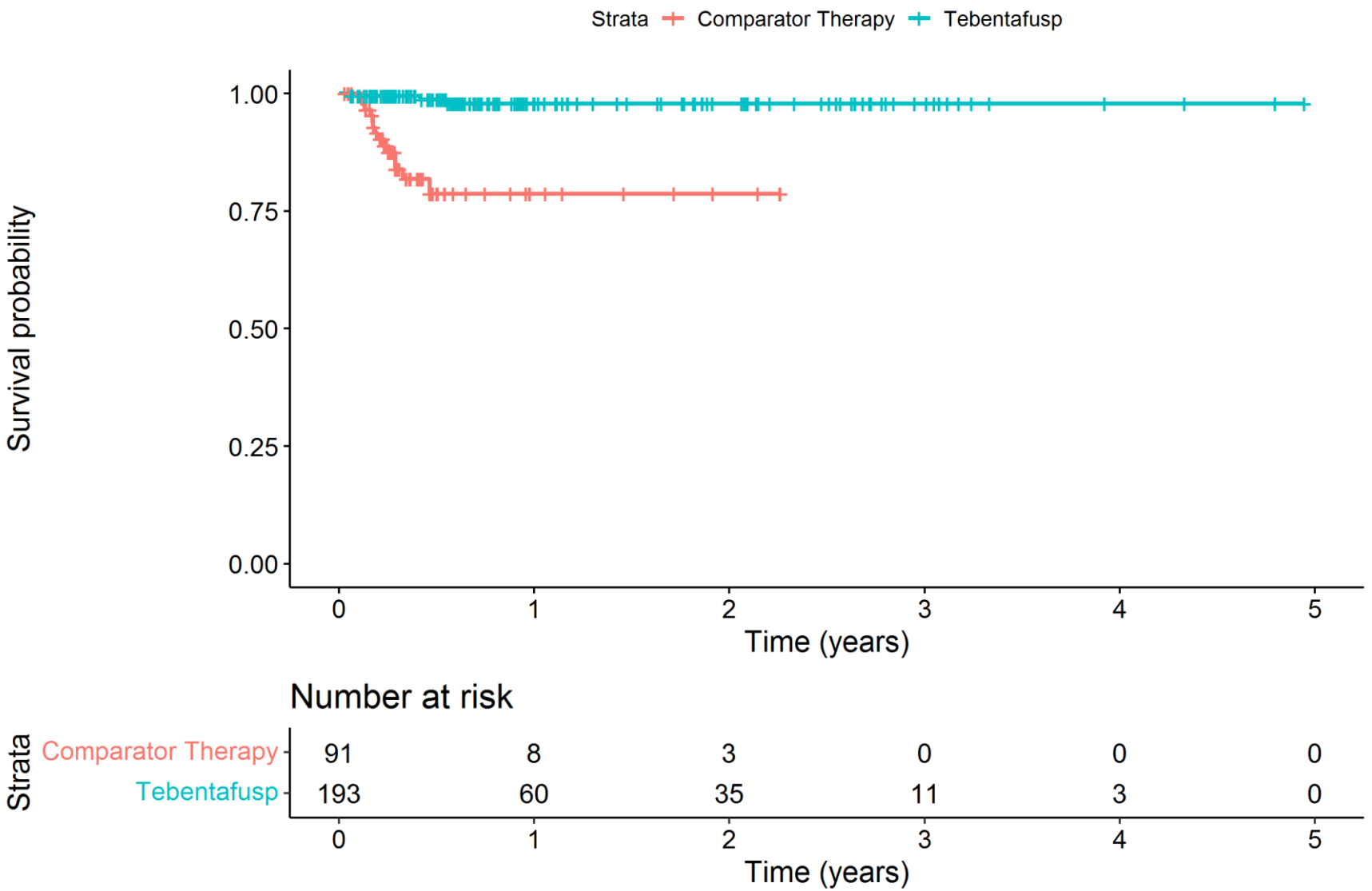
Hypothyreose - Nicht-Nordamerika



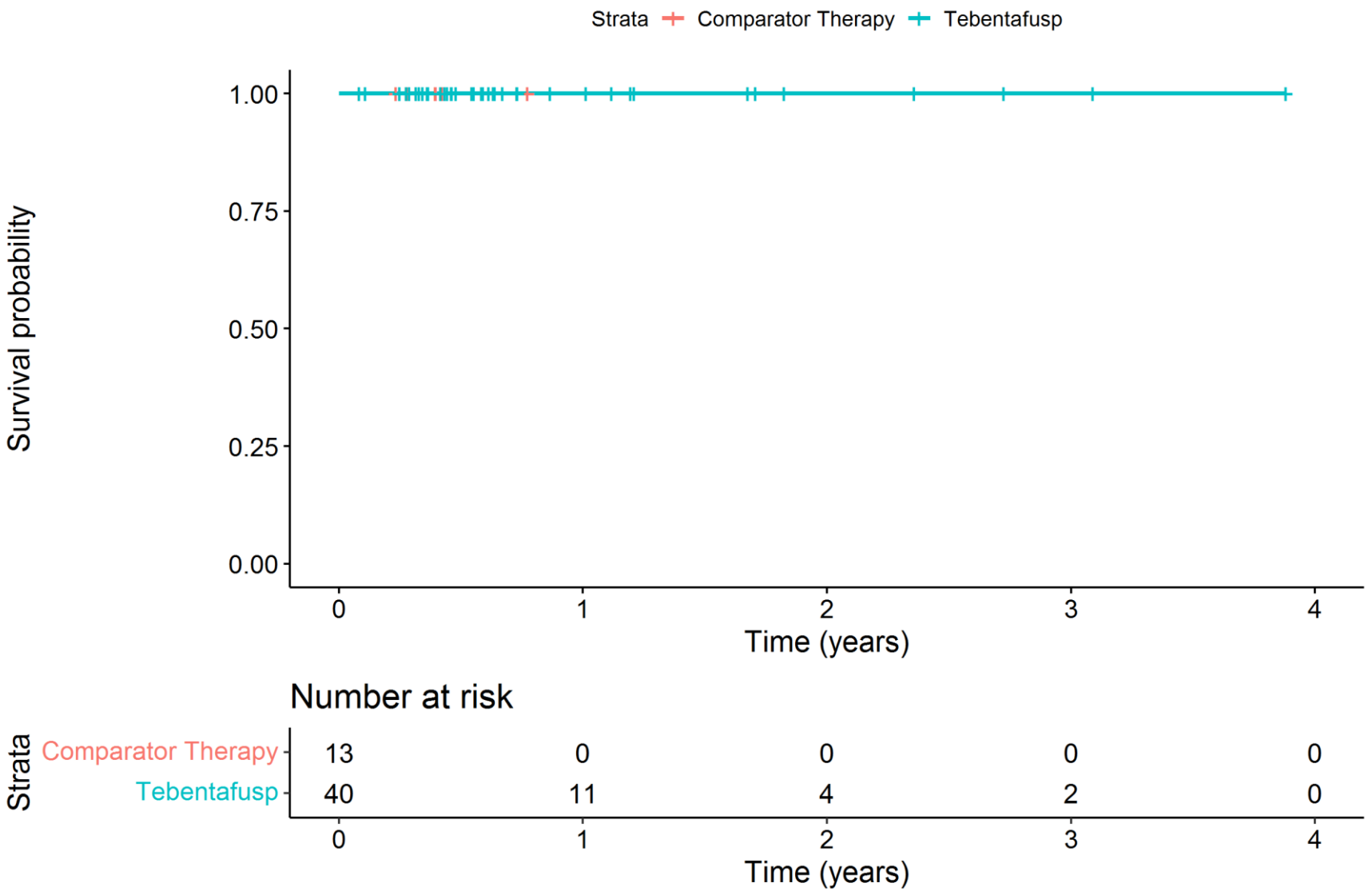
Hypothyreose - Dacarbazin



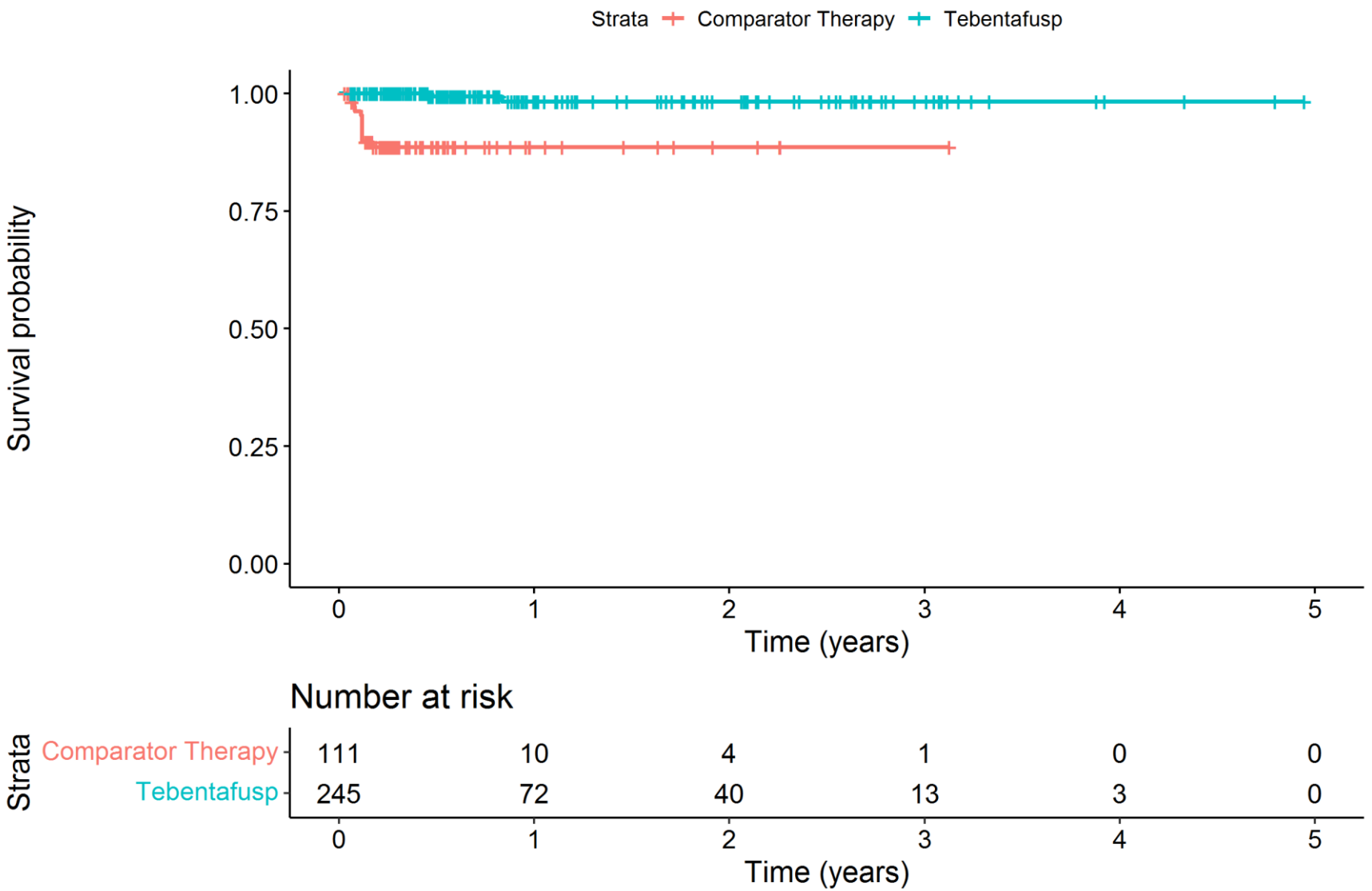
Hypothyreose - Pembrolizumab



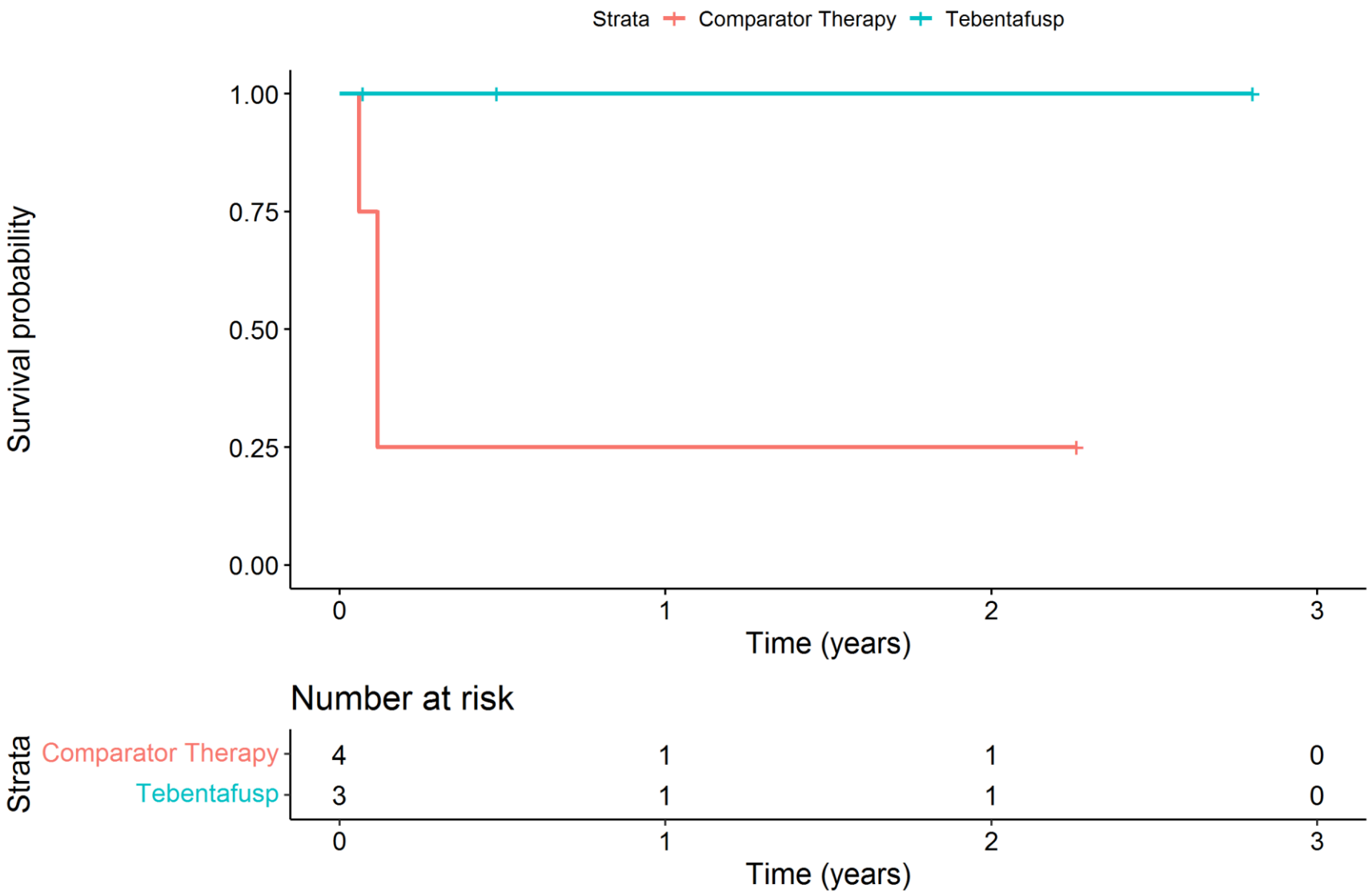
Hypothyreose - Ipilimumab



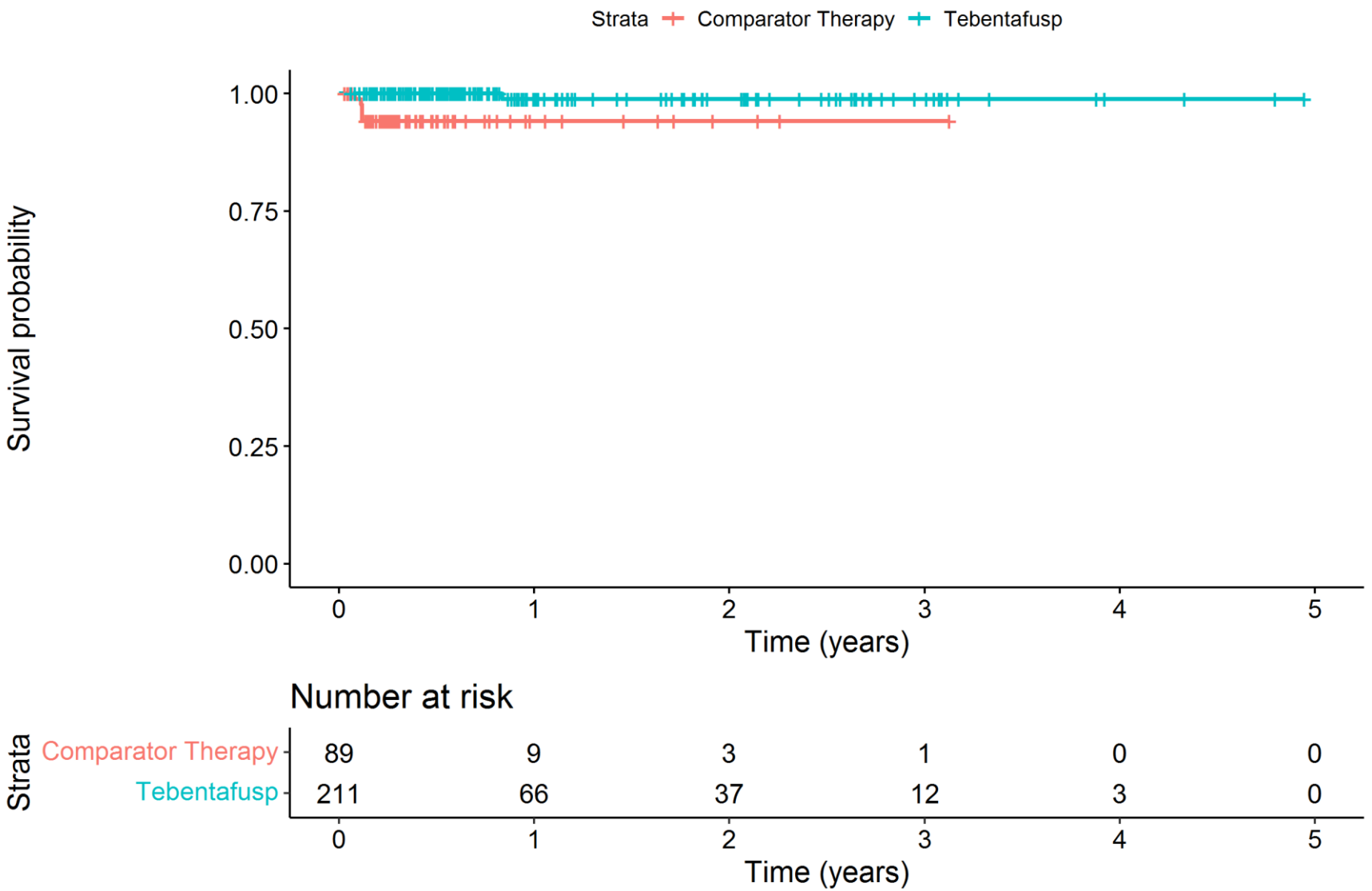
Hyperthyreose - Gesamt



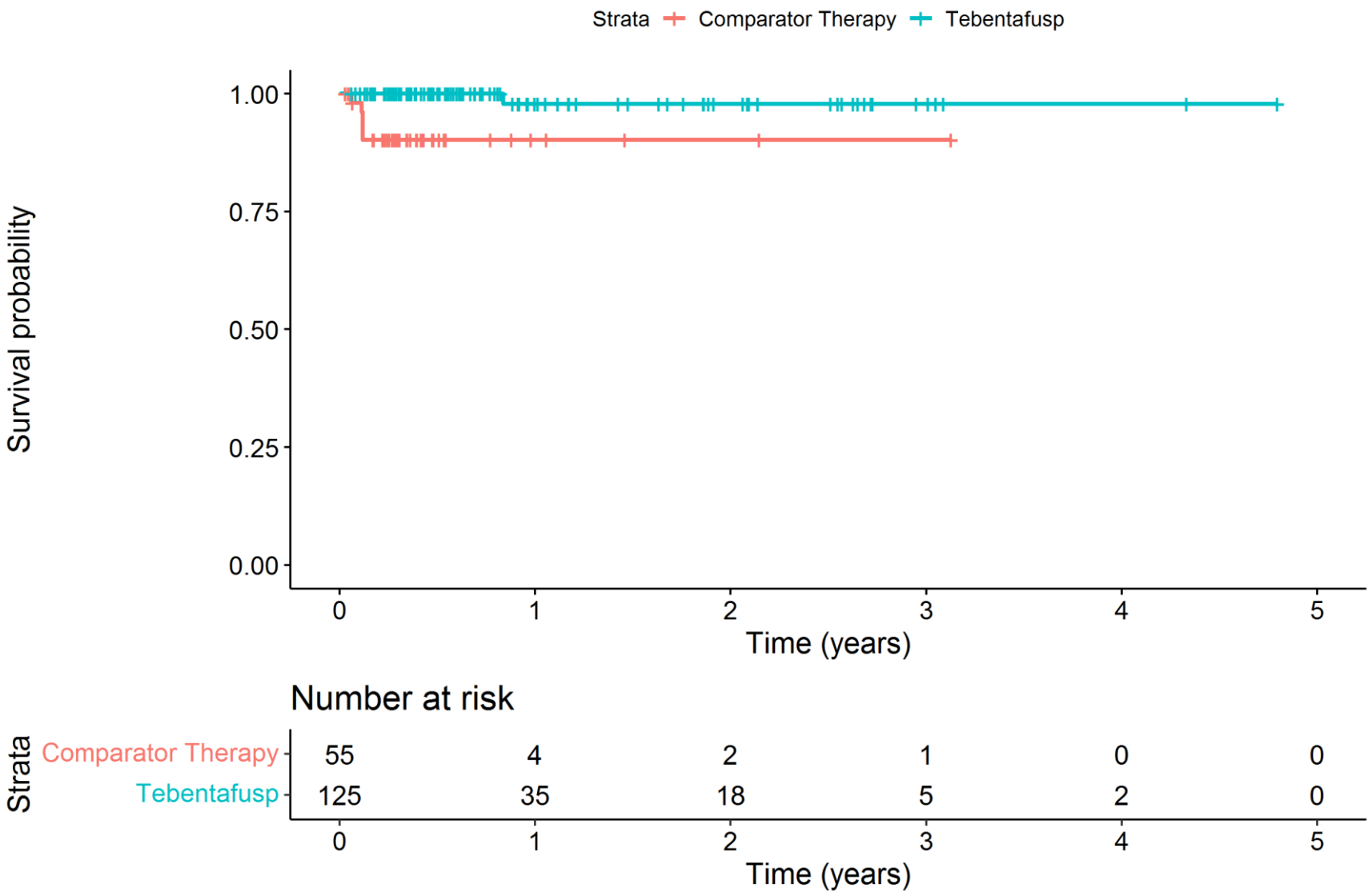
Hyperthyreose - Hispanisch



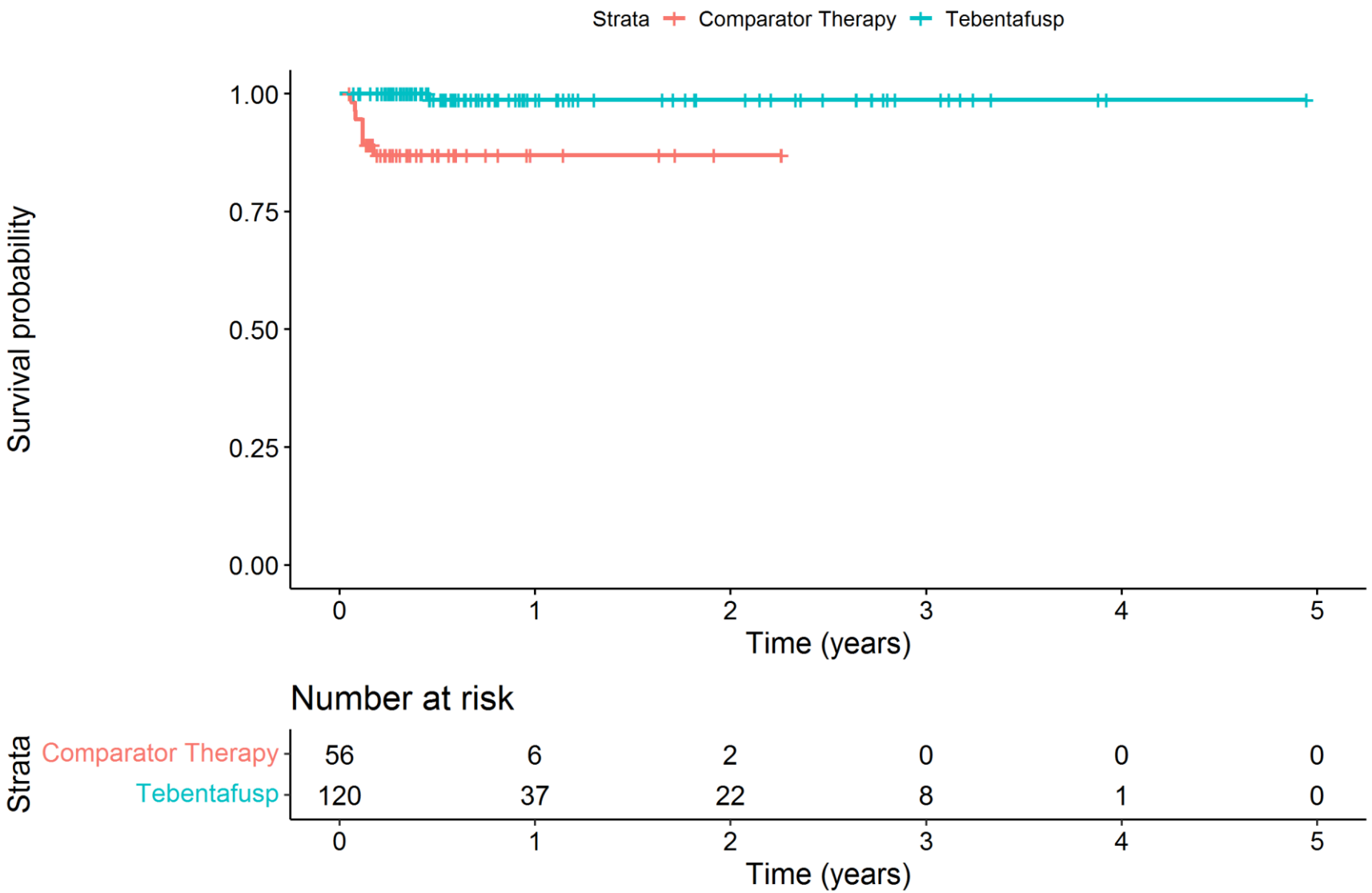
Hyperthyreose - Nicht-hispanisch



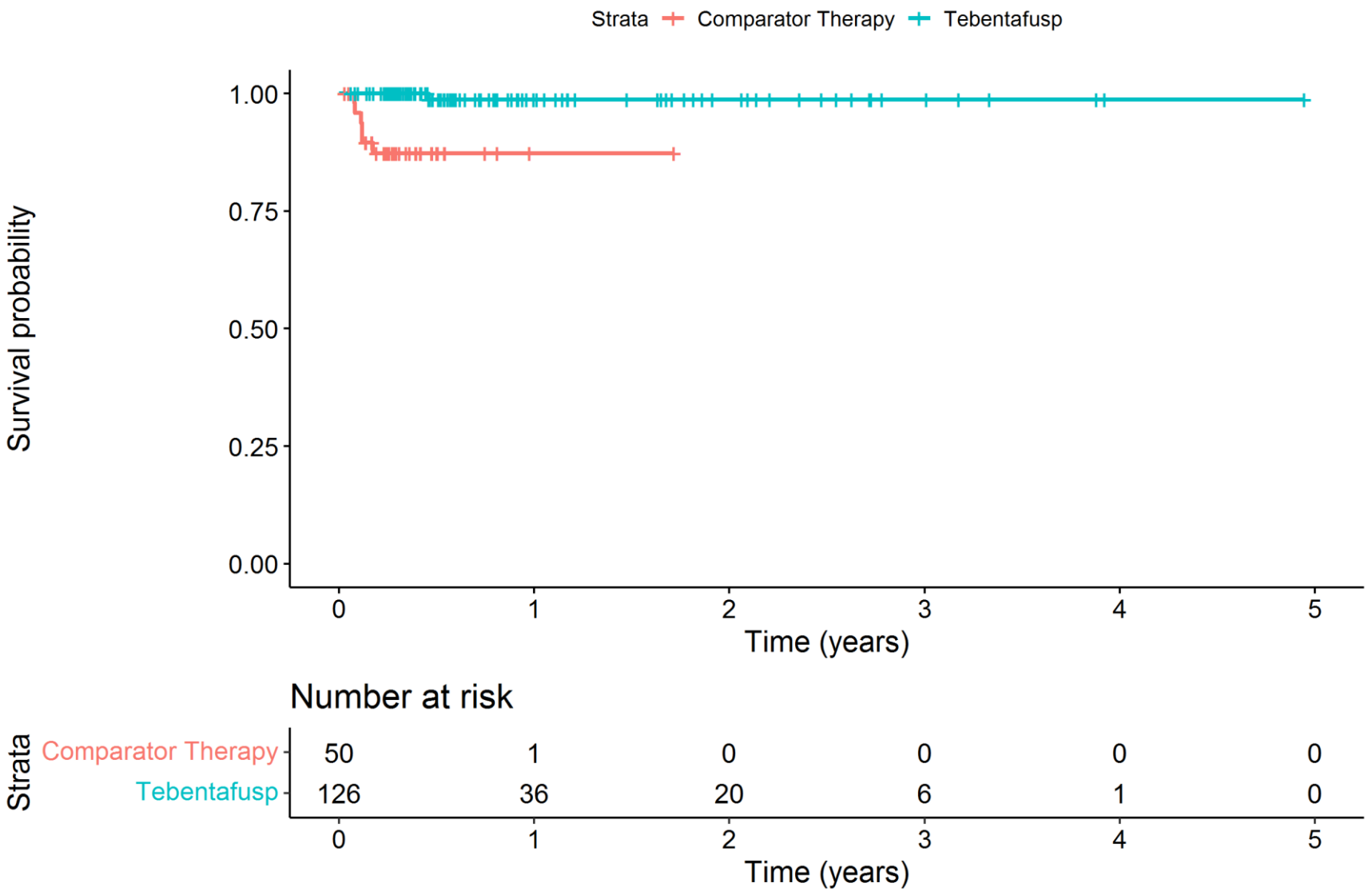
Hyperthyreose - Männlich



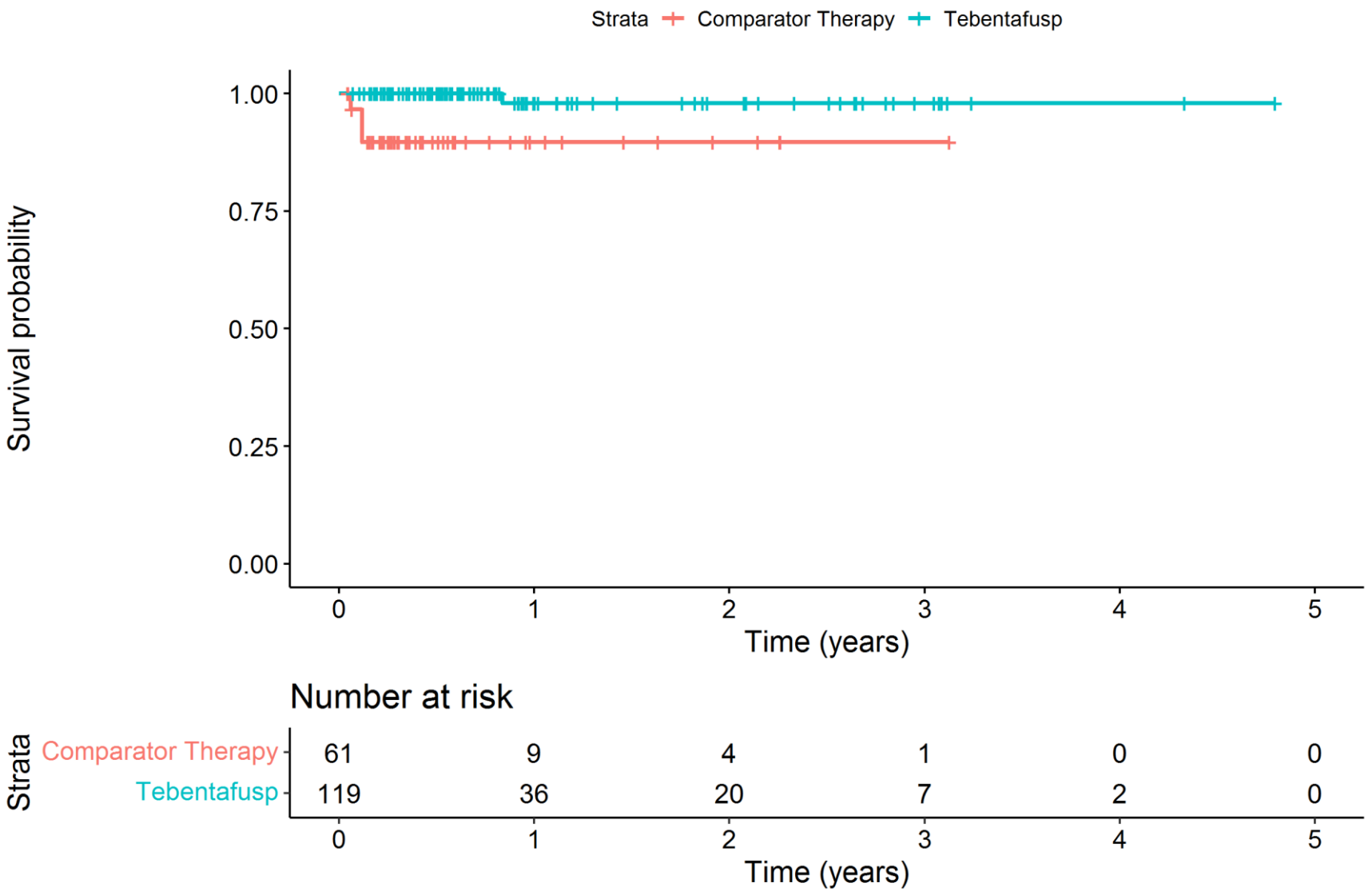
Hyperthyreose - Weiblich



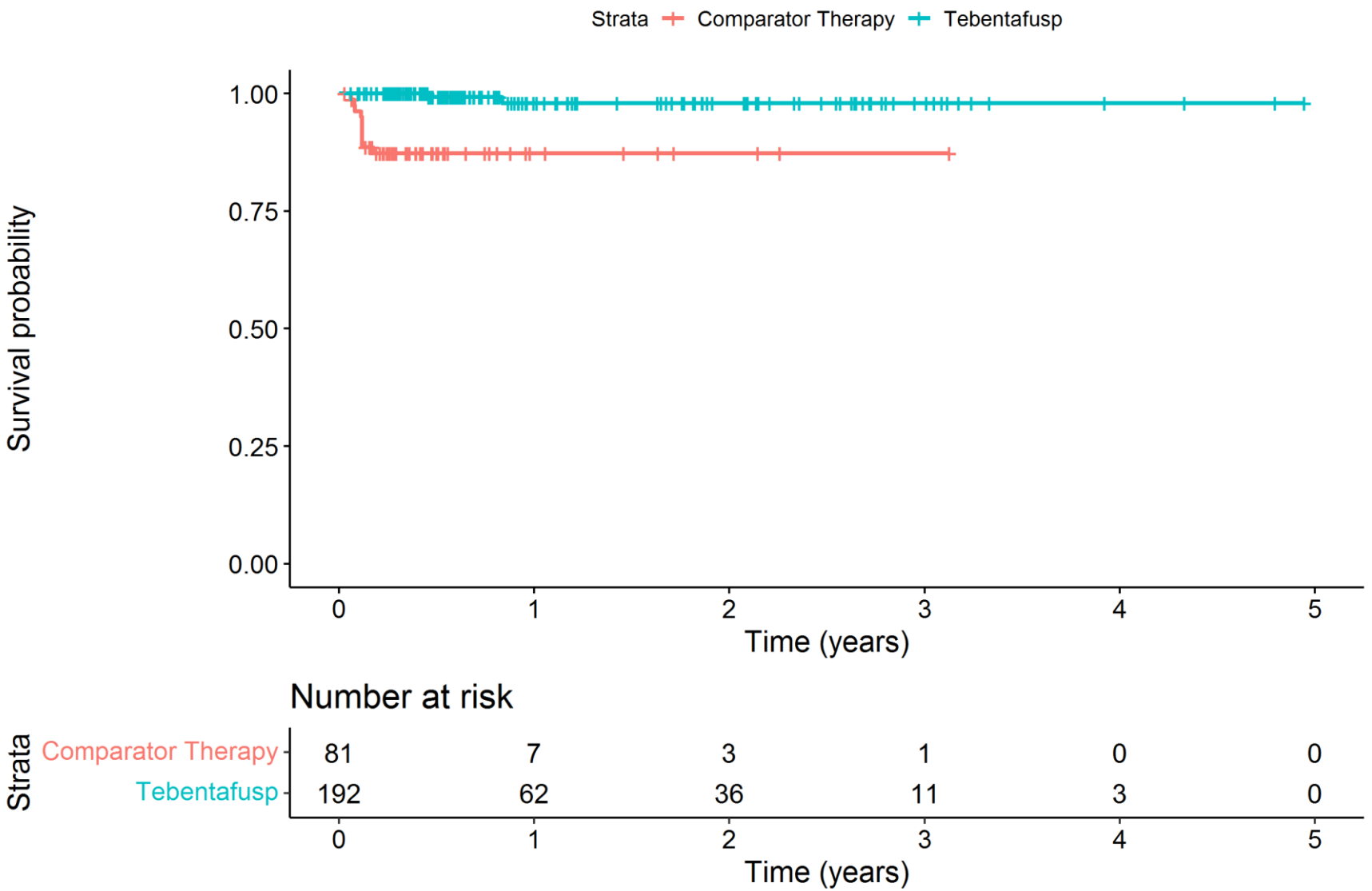
Hyperthyreose - <65



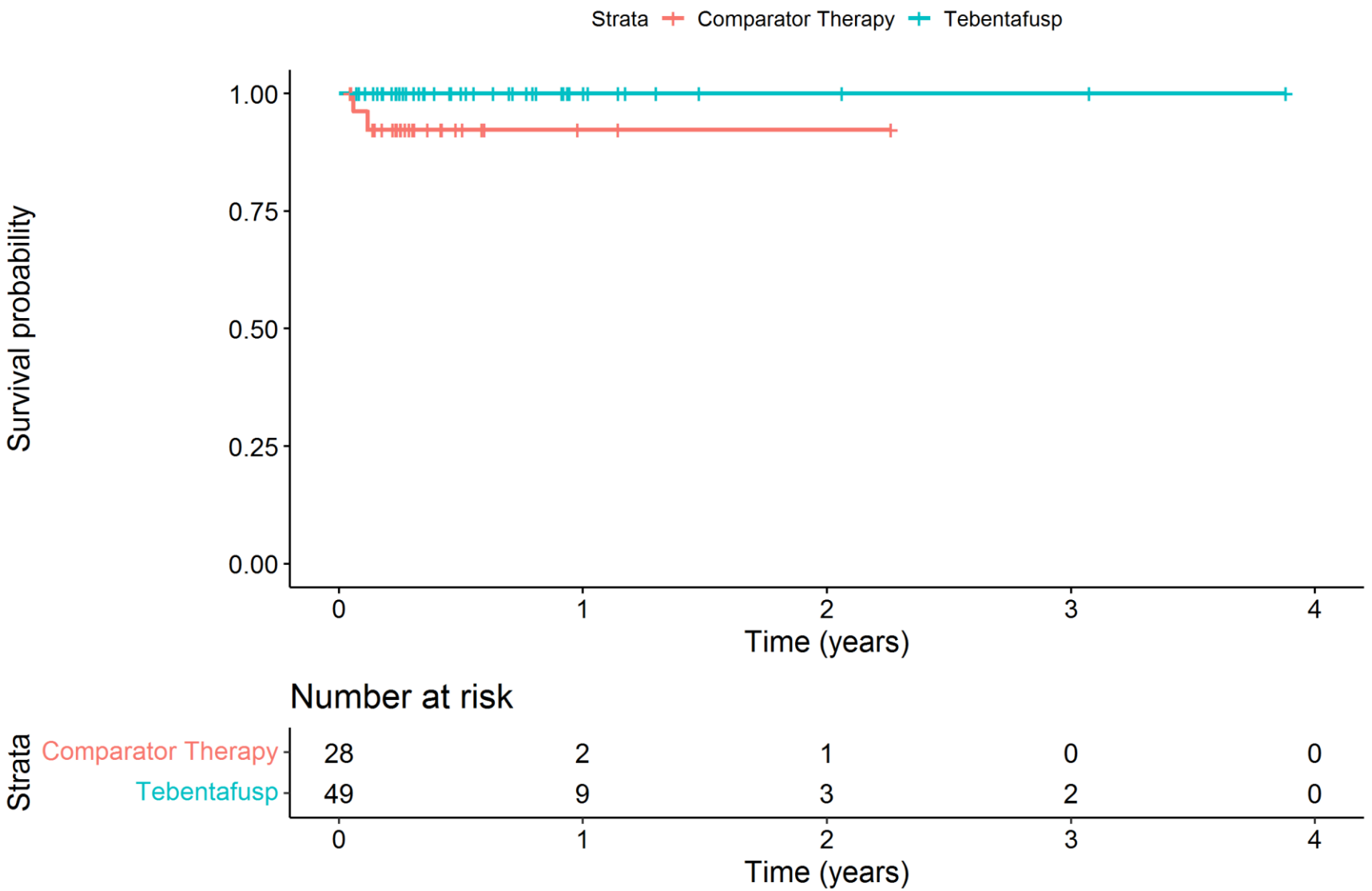
Hyperthyreose - ≥65



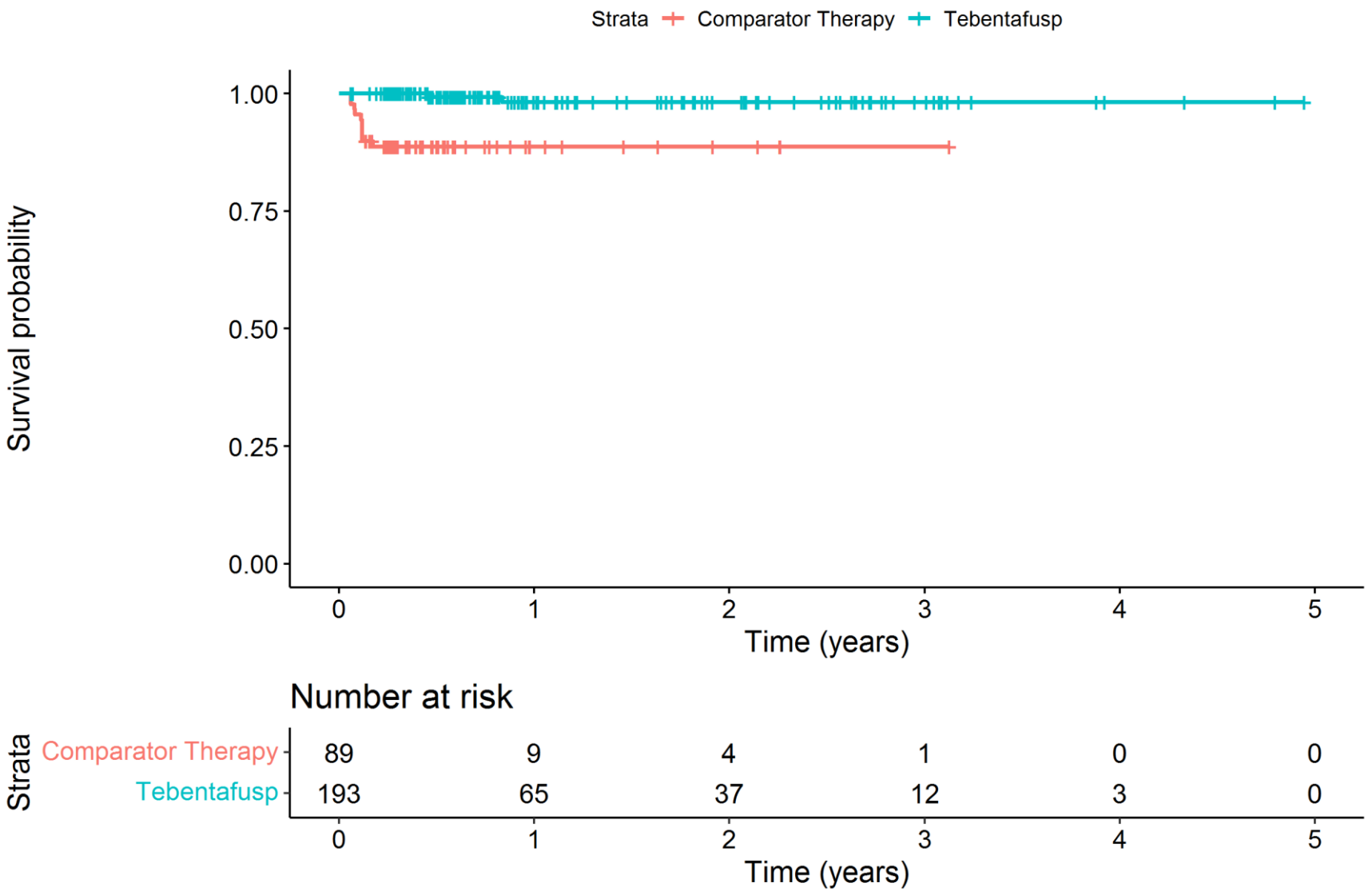
Hyperthyreose - ECOG 0



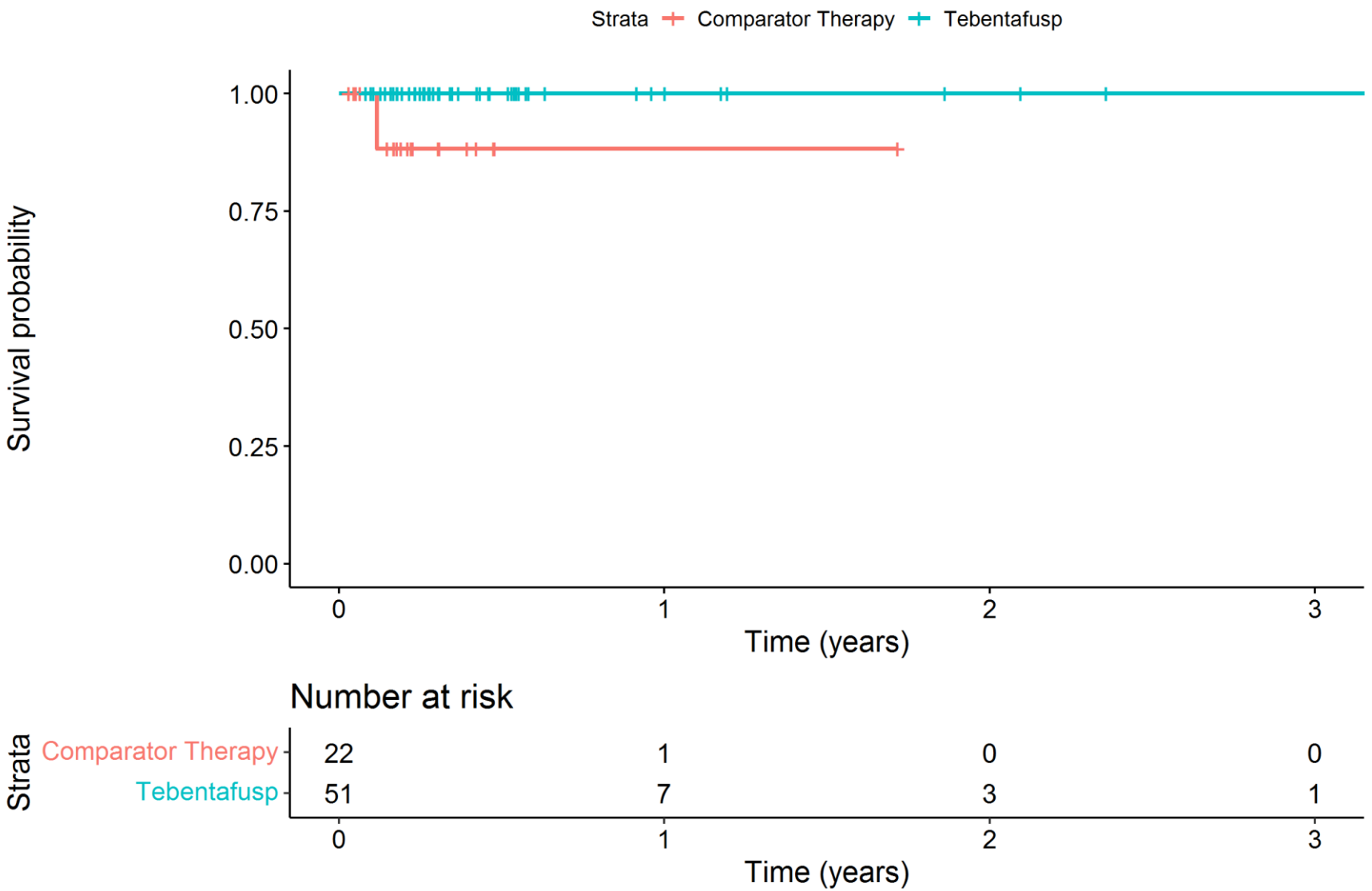
Hyperthyreose - ECOG 1



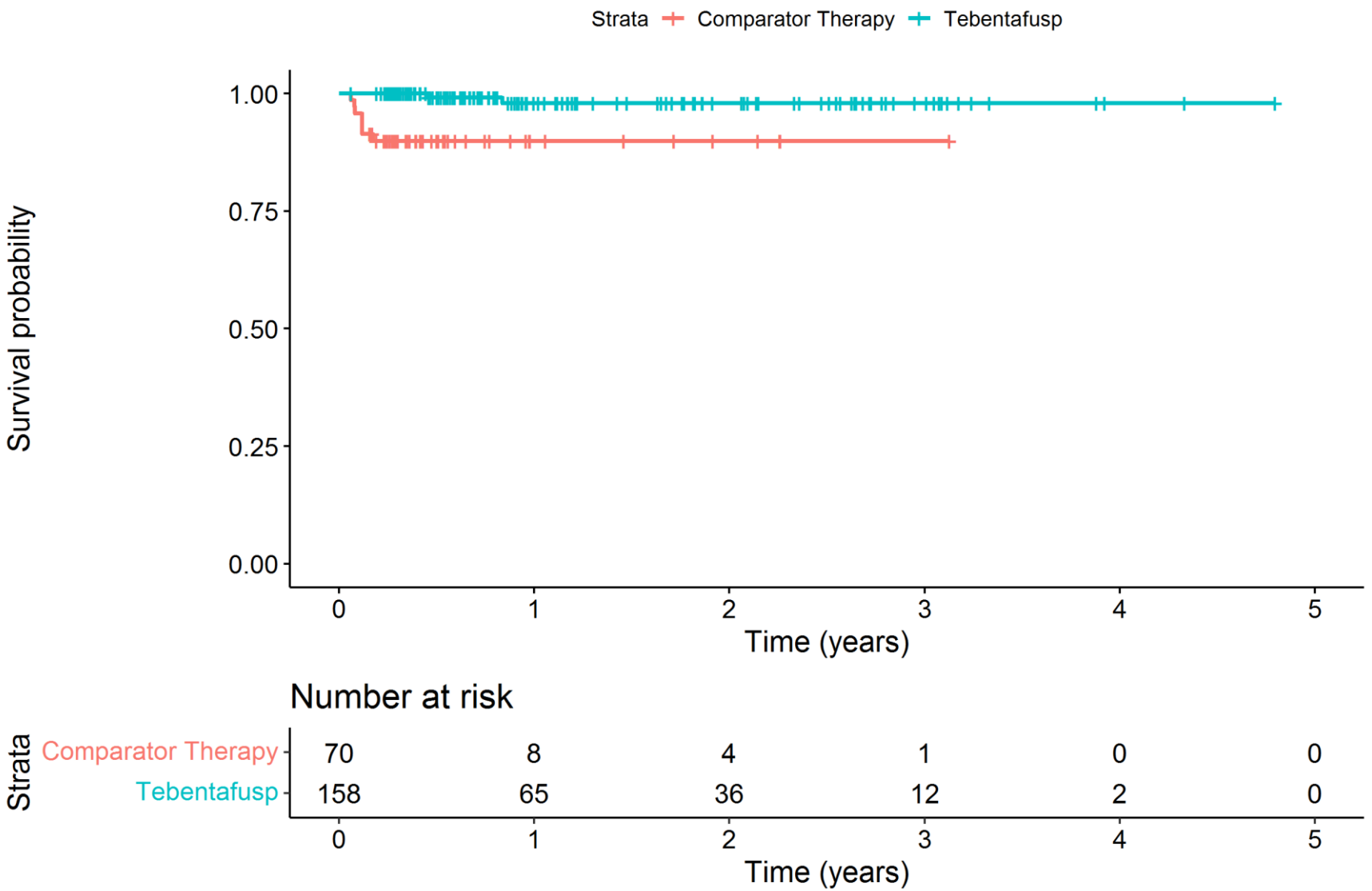
Hyperthyreose - ALP ≤ ULN



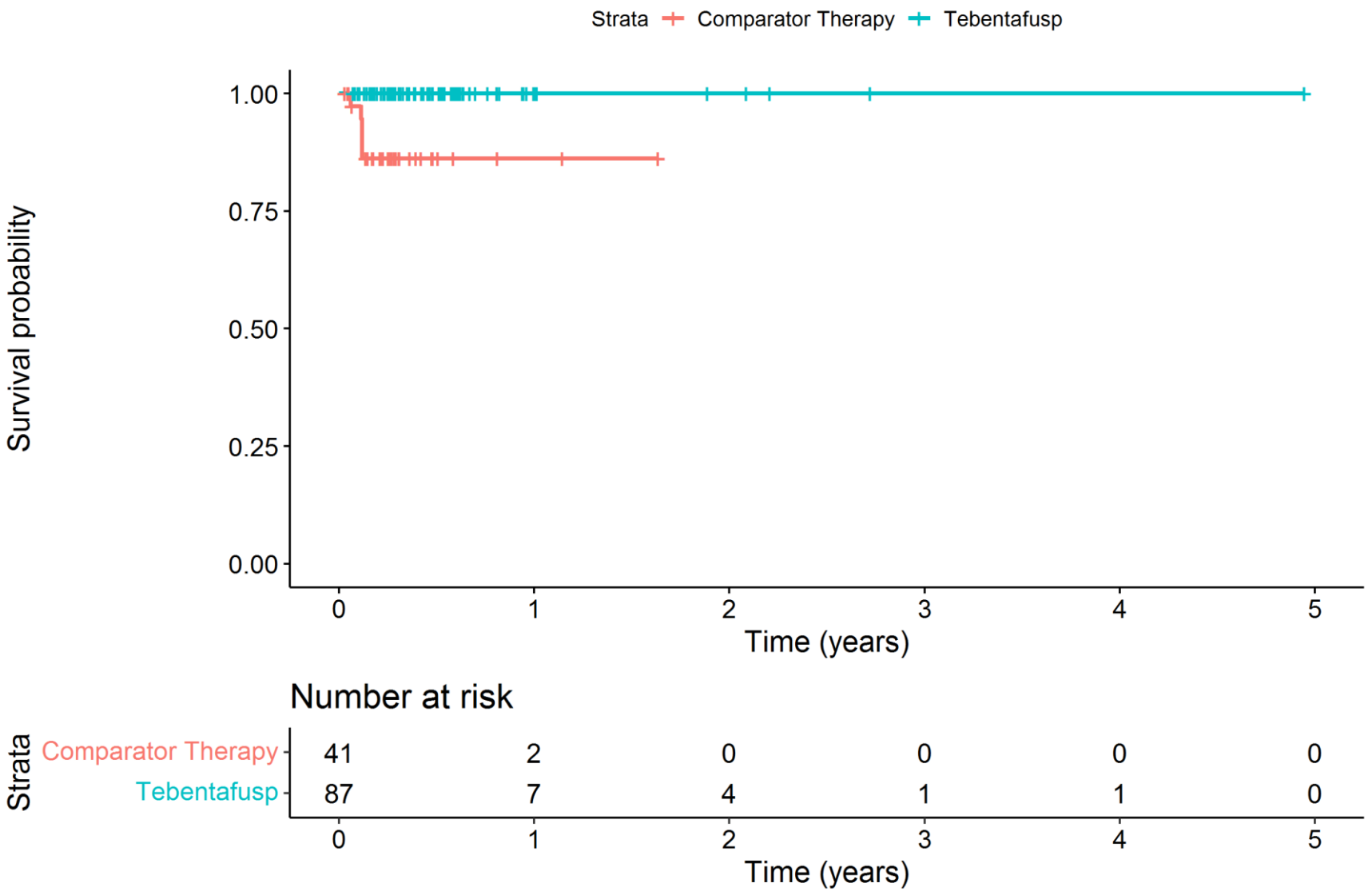
Hyperthyreose - ALP > ULN



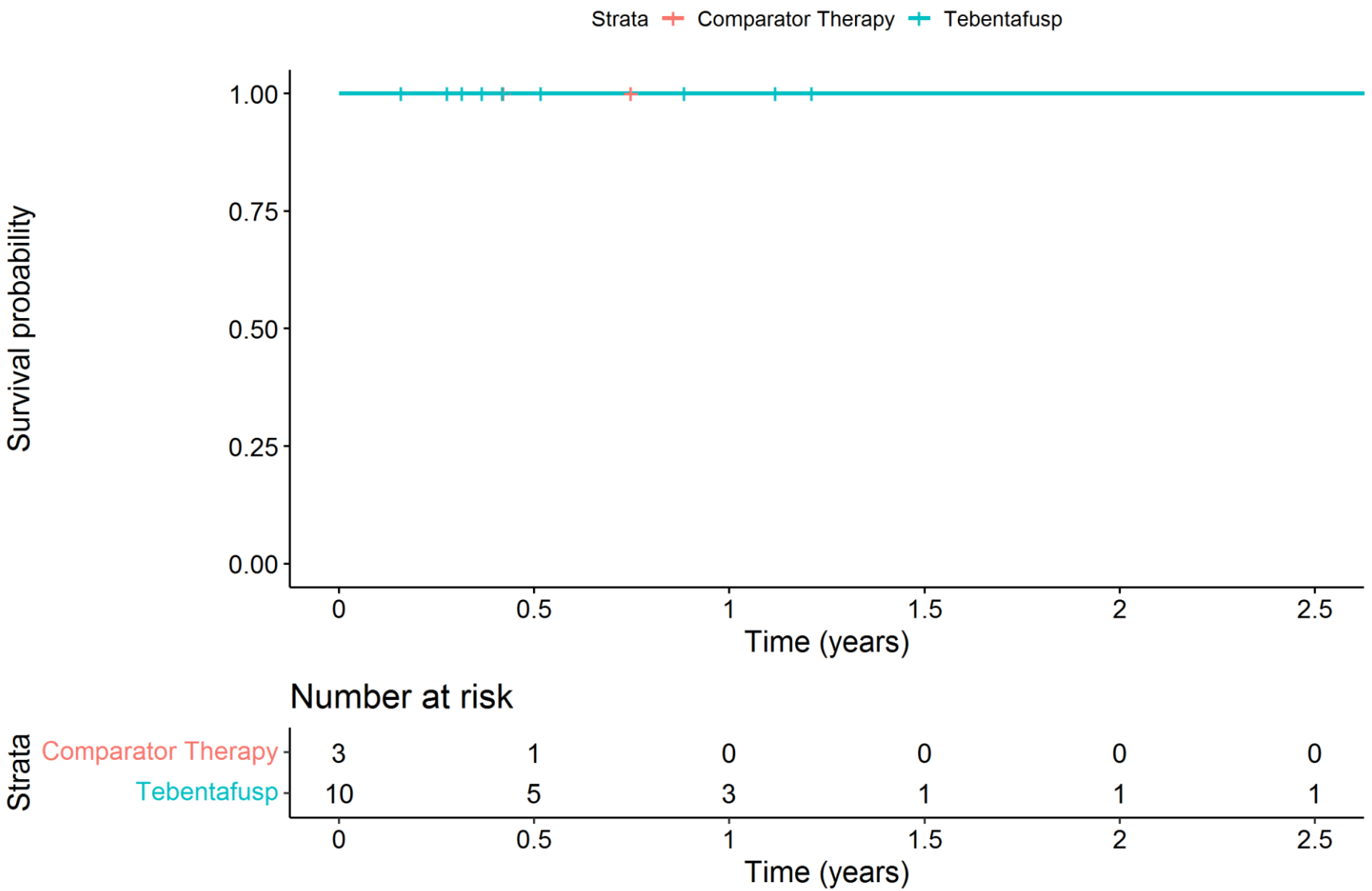
Hyperthyreose - LDH =< ULN



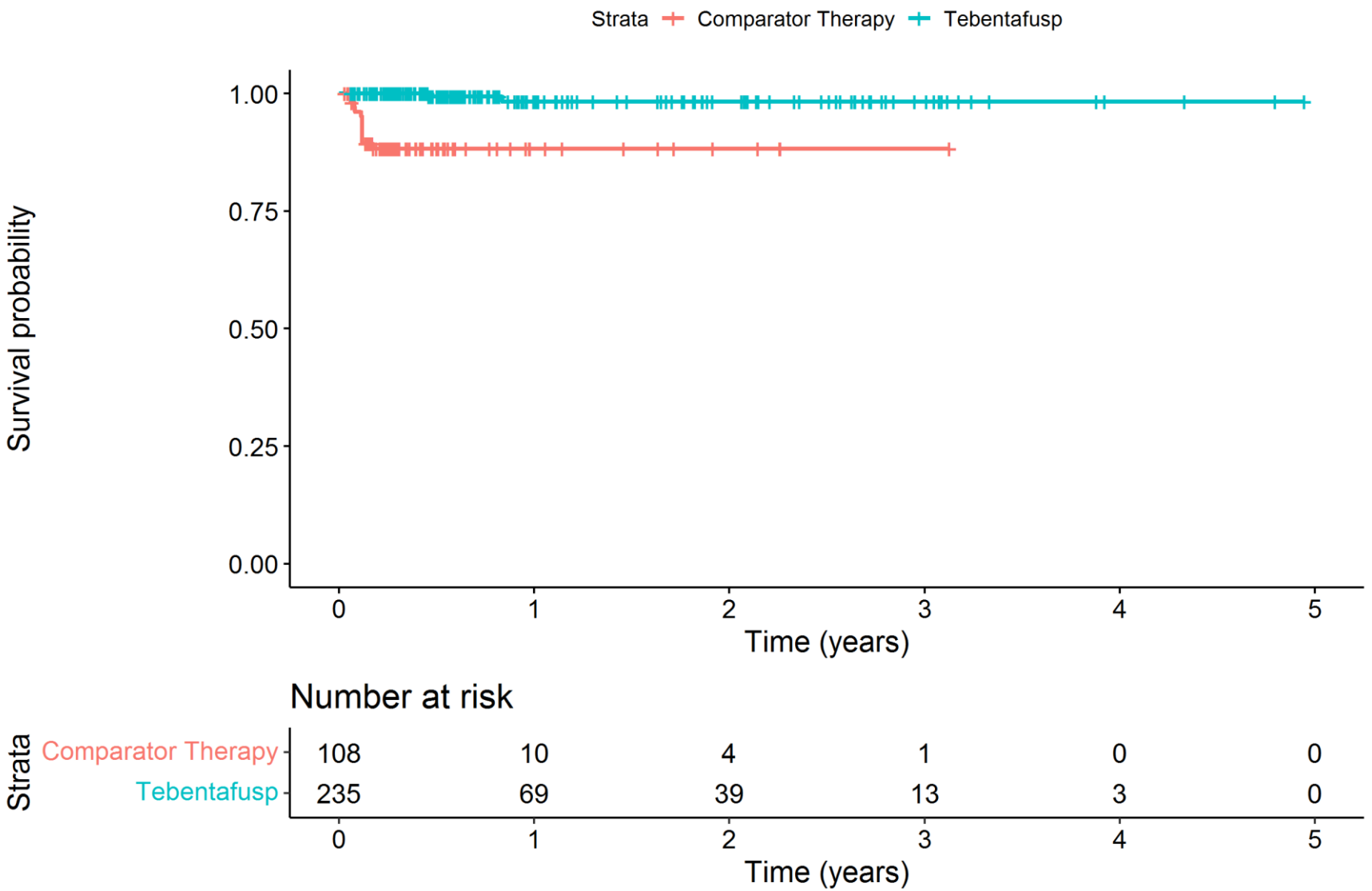
Hyperthyreose - LDH > ULN



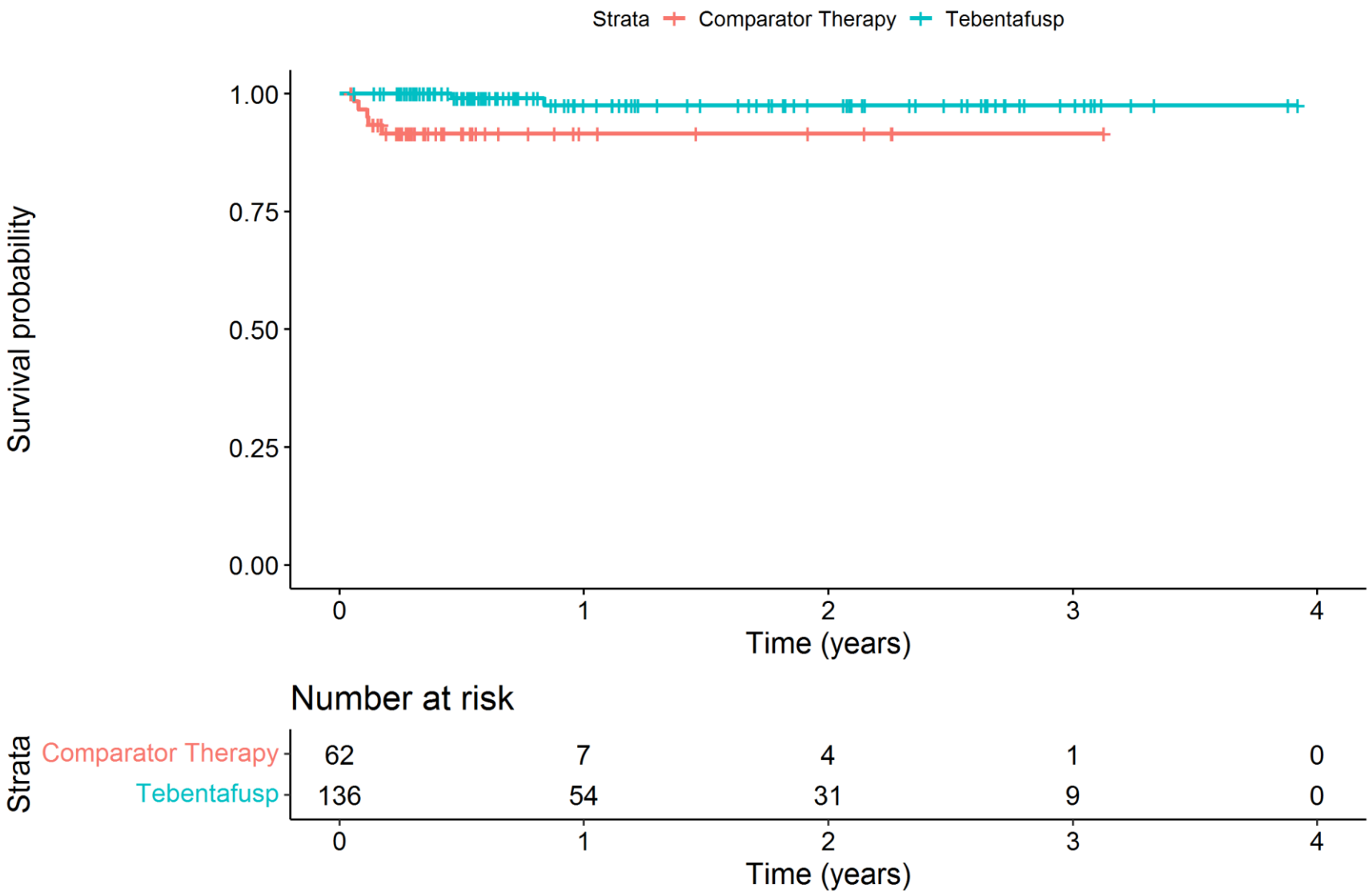
Hyperthyreose - Vorherige Therapie adjuvant/neoadjuvant



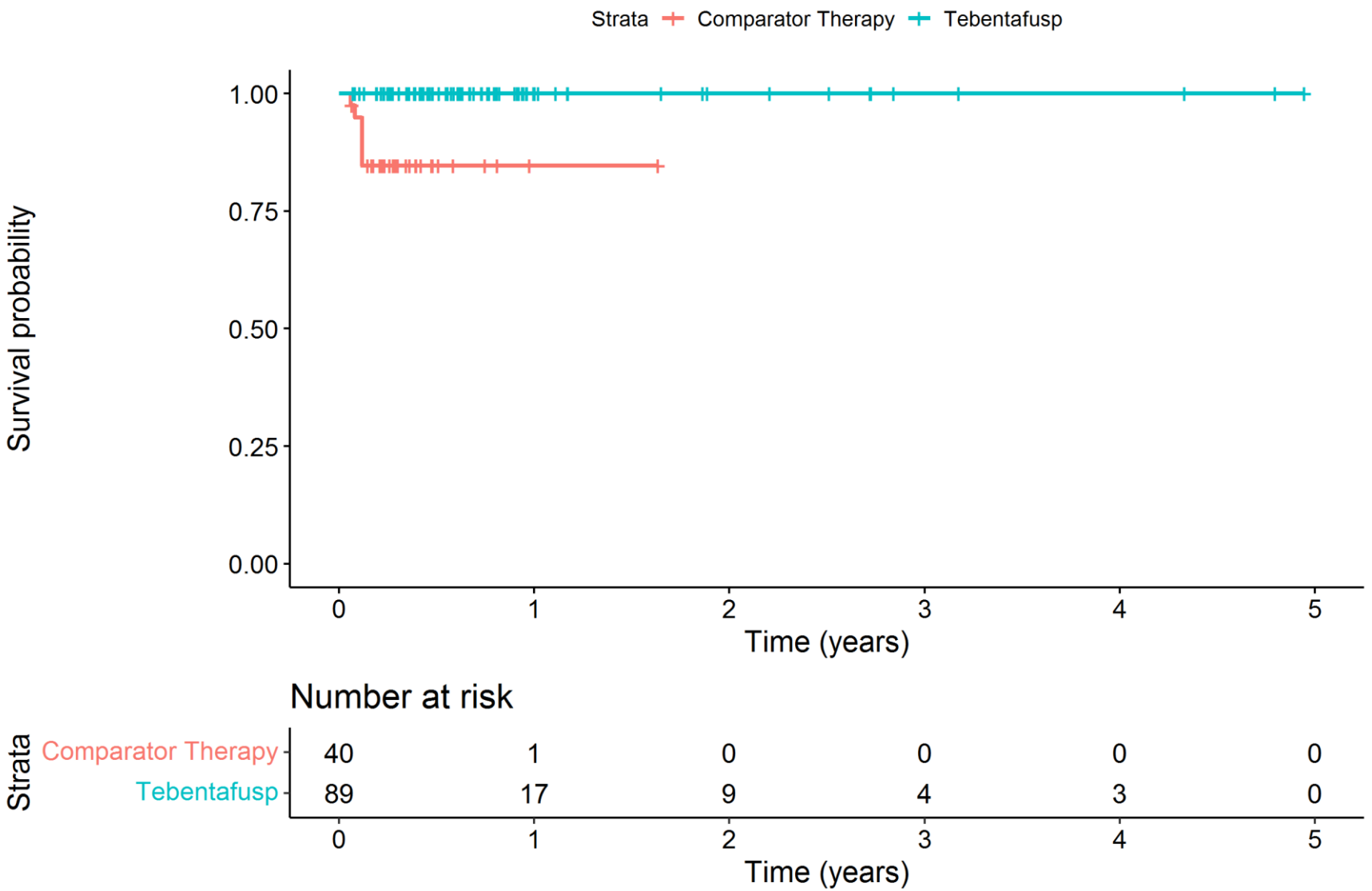
Hyperthyreose - Keine Vorherige Therapie adjuvant/neoadjuvant



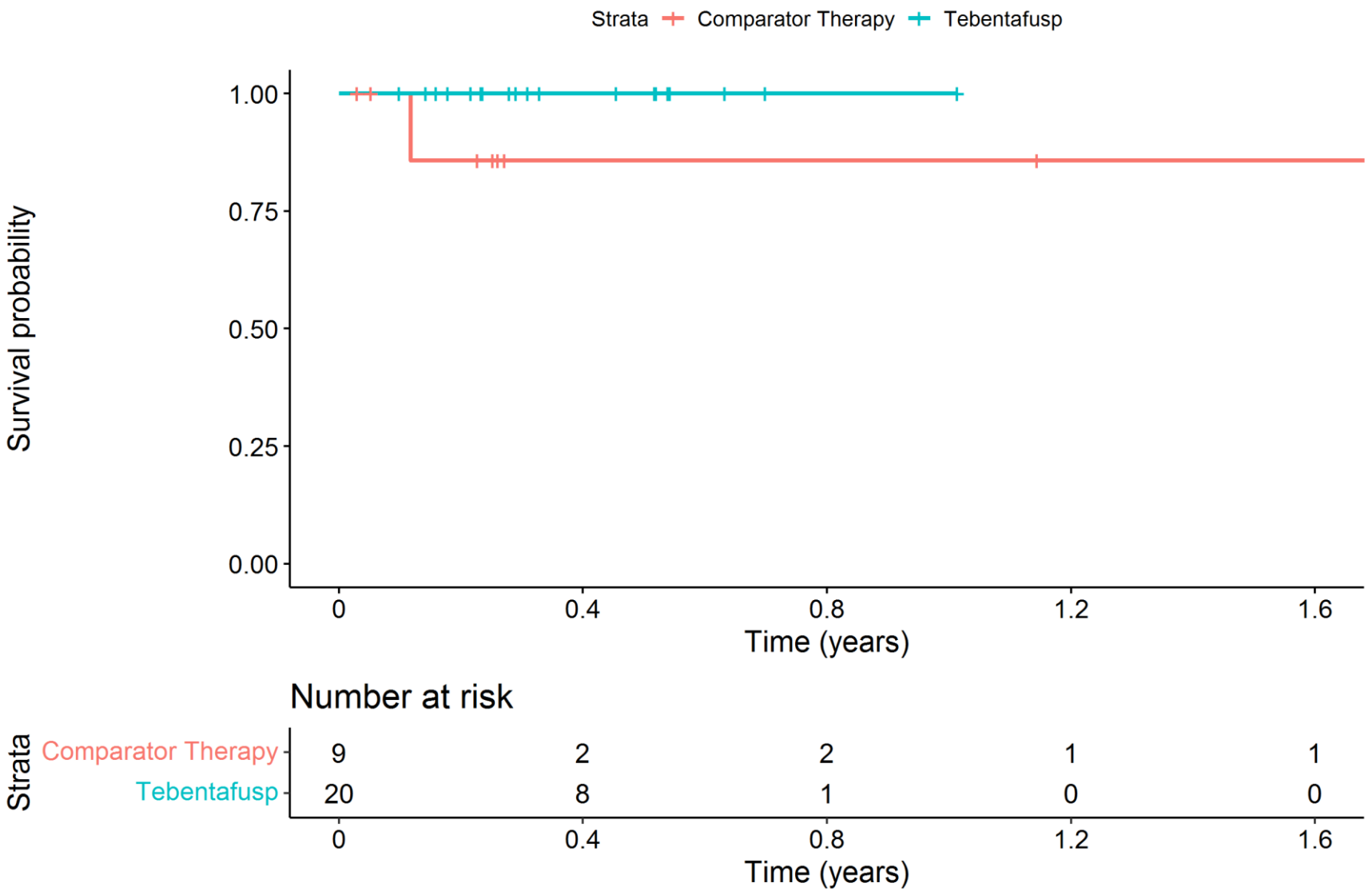
Hyperthyreose - Läsion ≤ 3cm



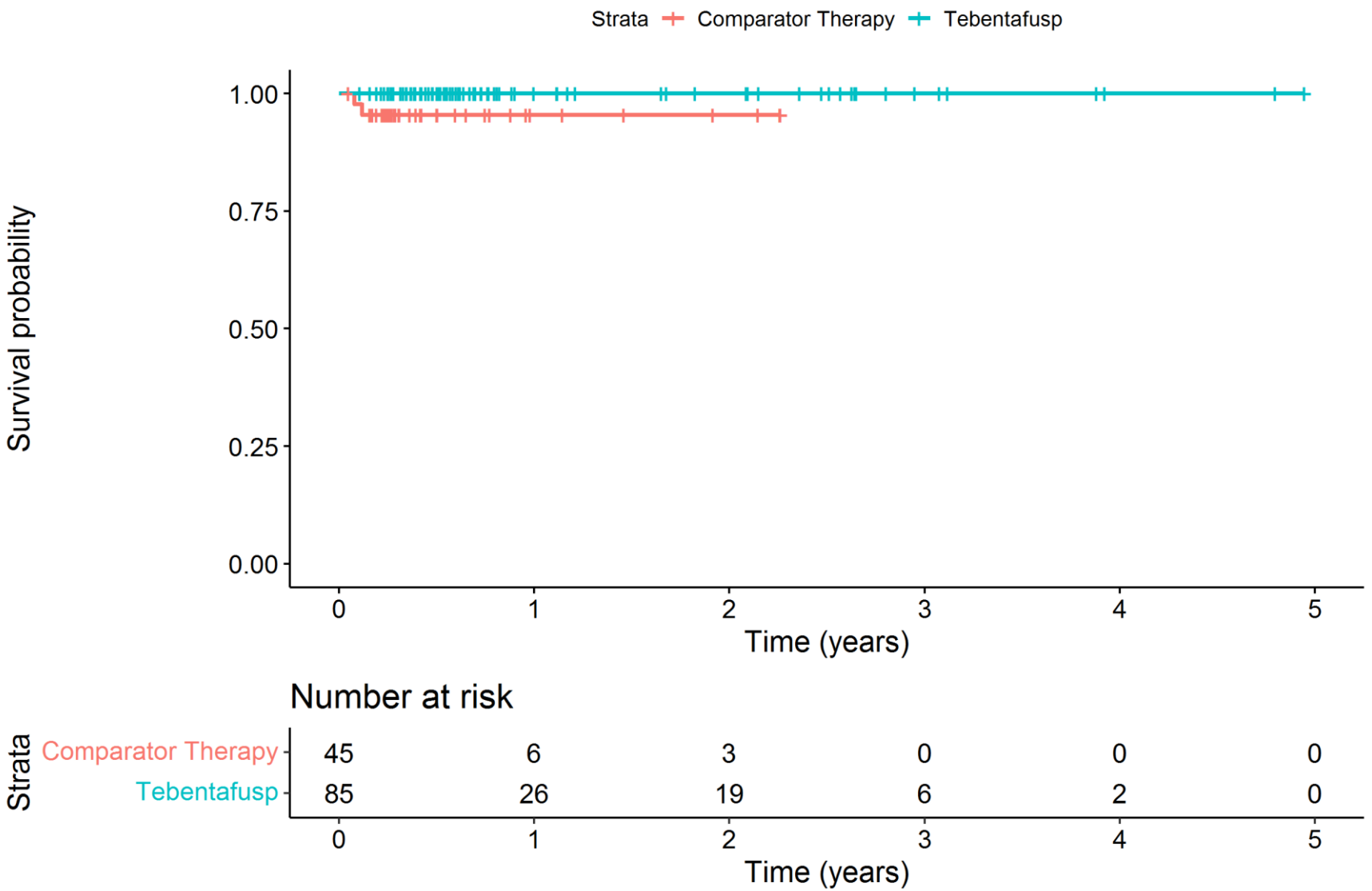
Hyperthyreose - Läsion 3,1-8,0 cm



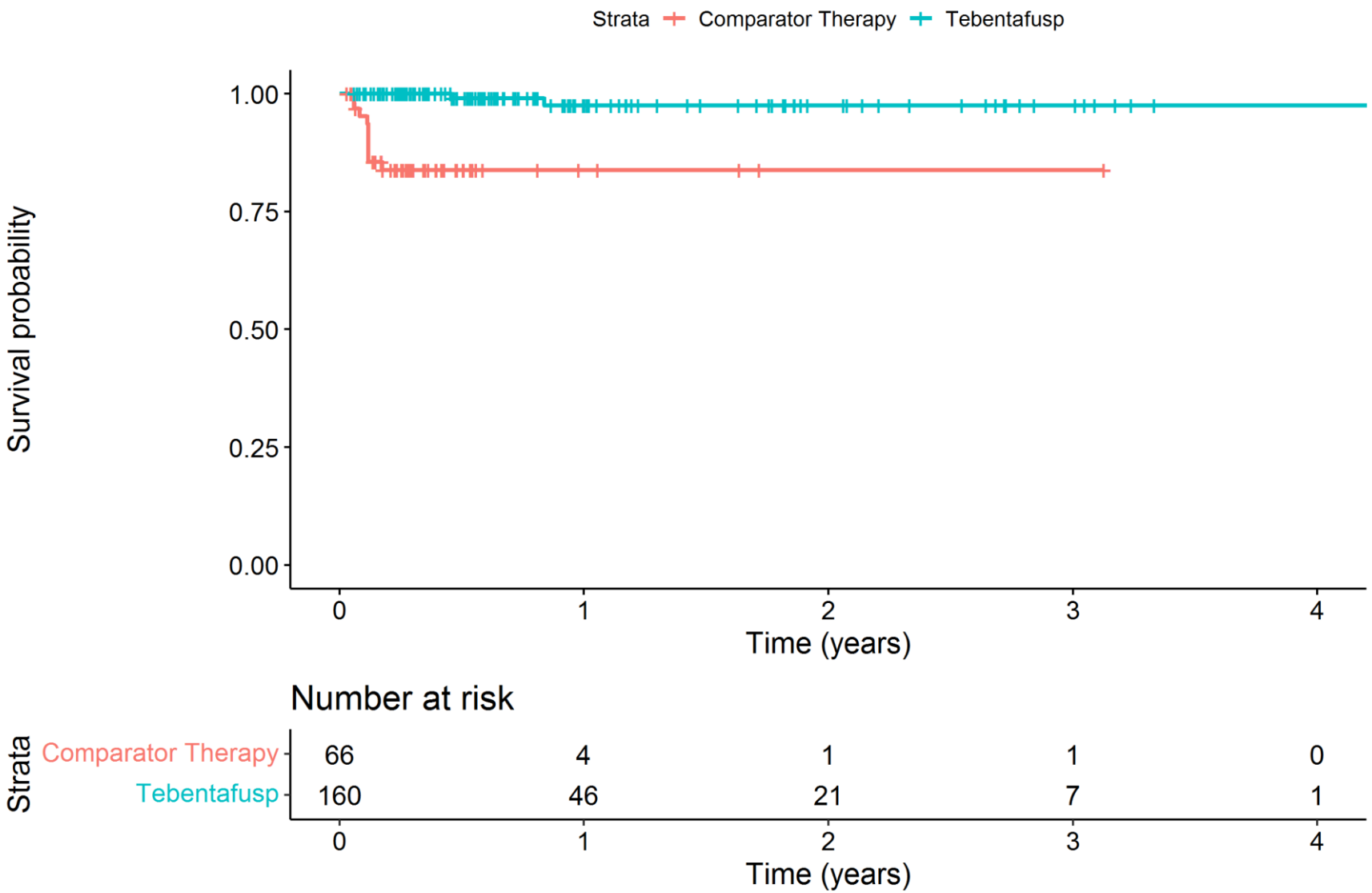
Hyperthyreose - Läsion ≥8,1 cm



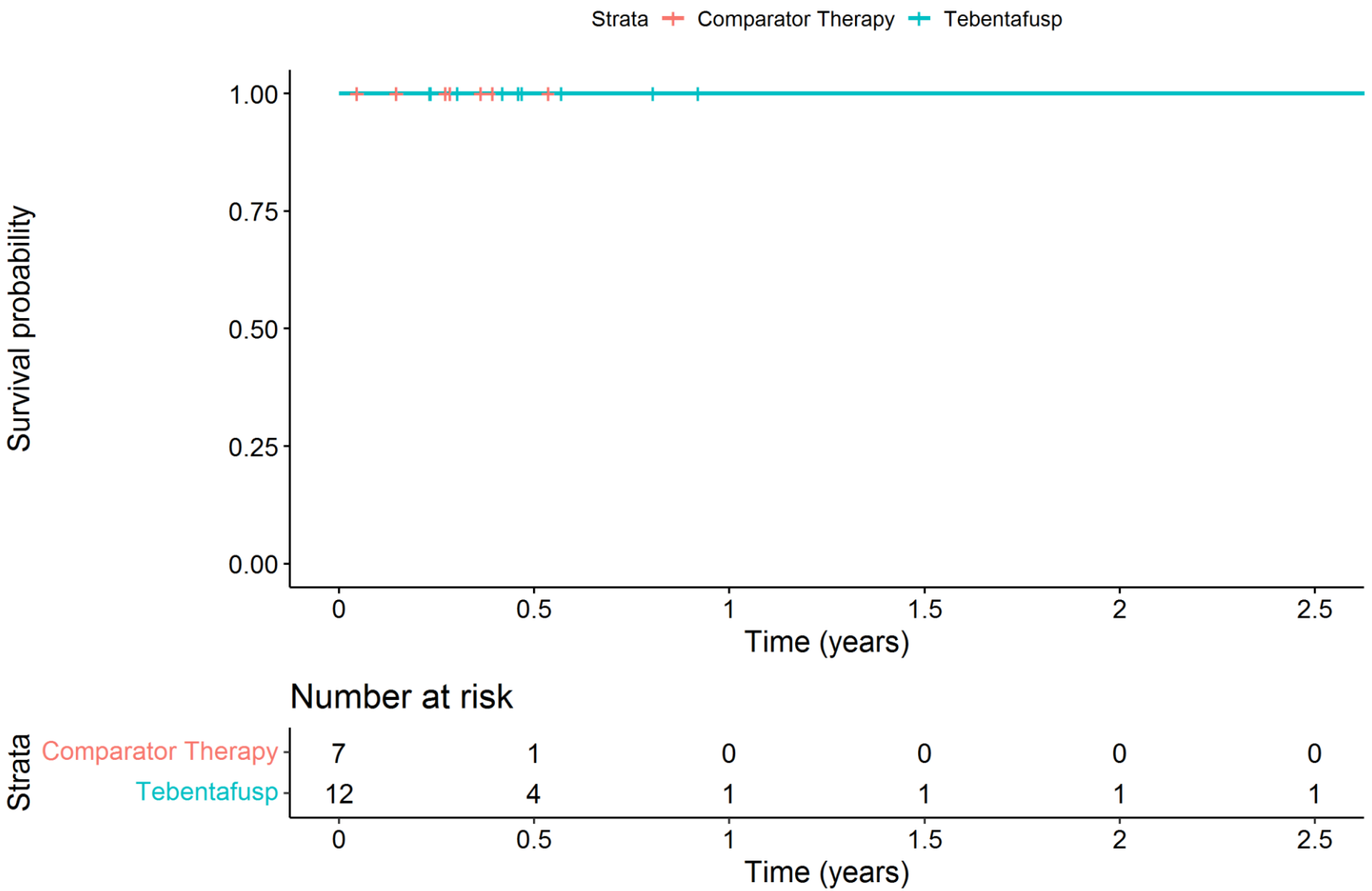
Hyperthyreose - Nordamerika



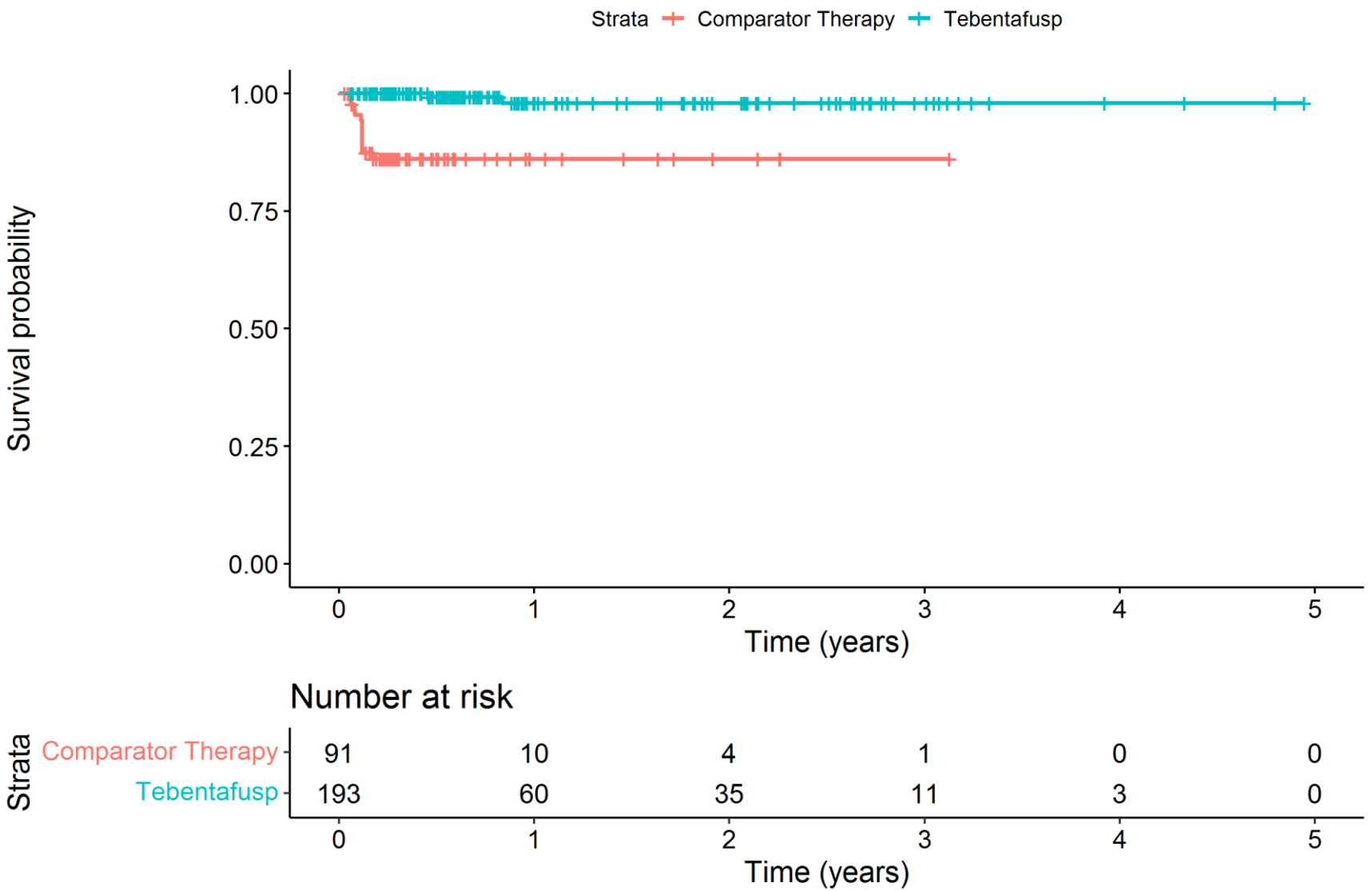
Hyperthyreose - Nicht-Nordamerika



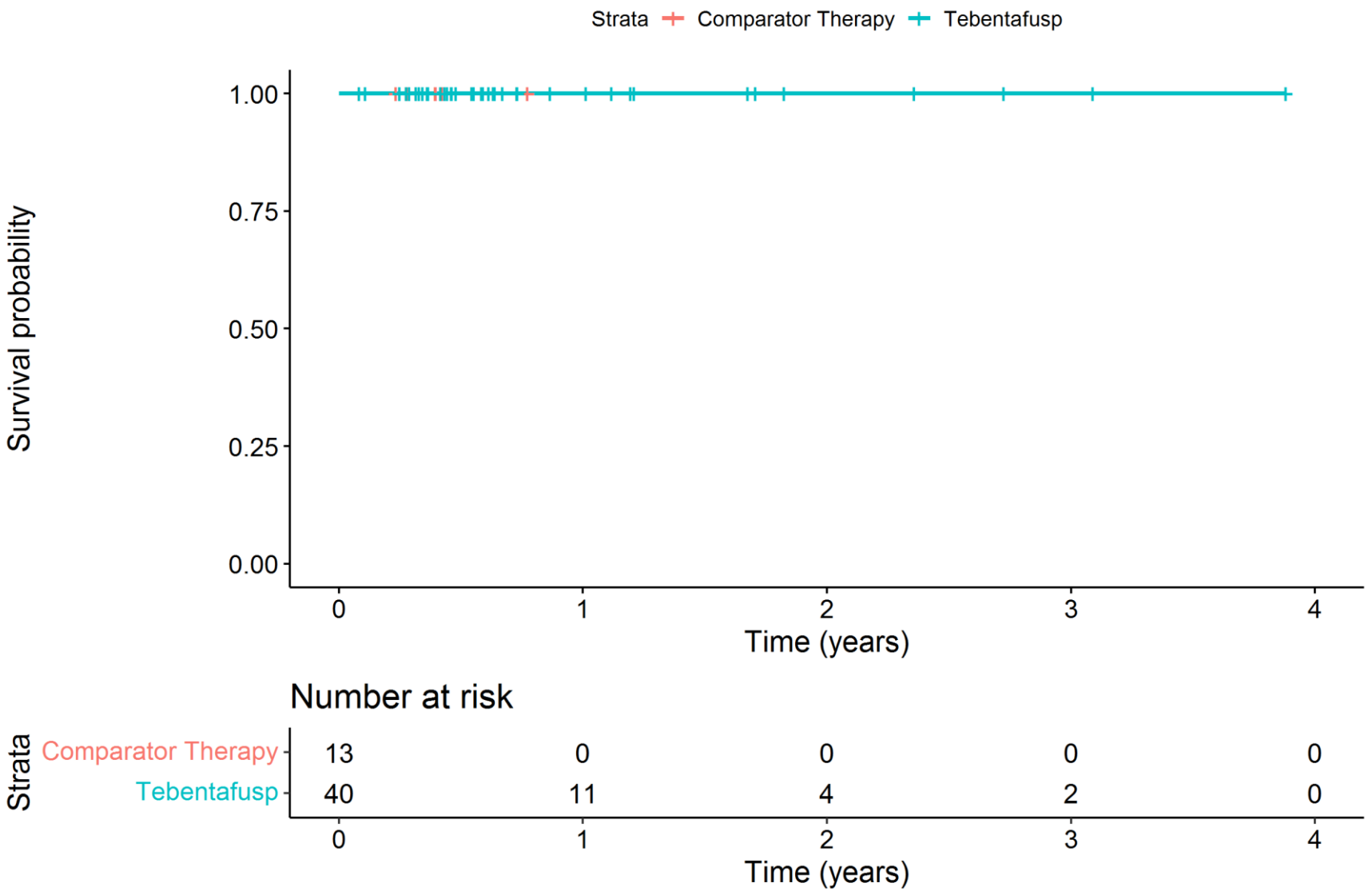
Hyperthyreose - Dacarbazin



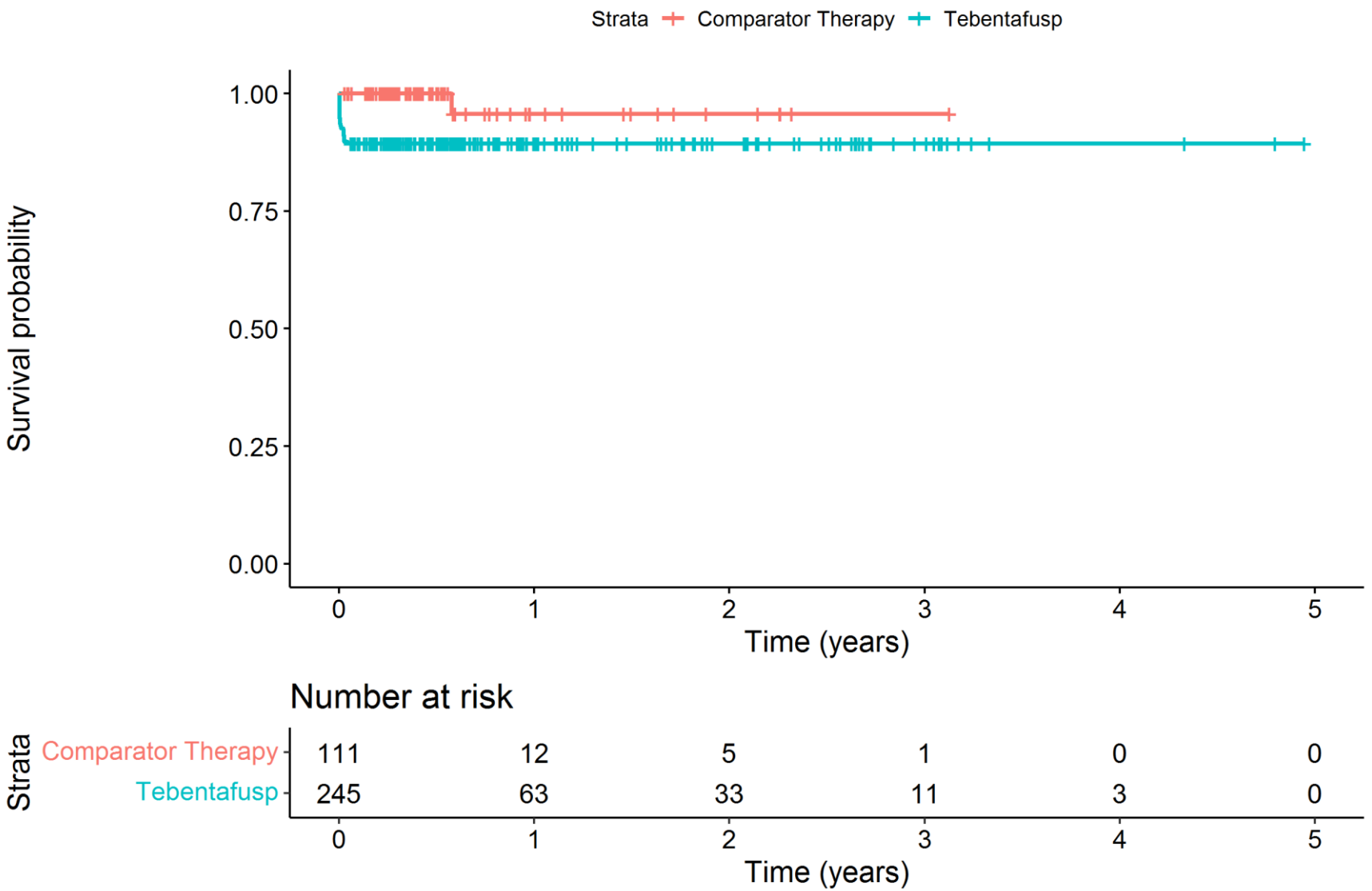
Hyperthyreose - Pembrolizumab



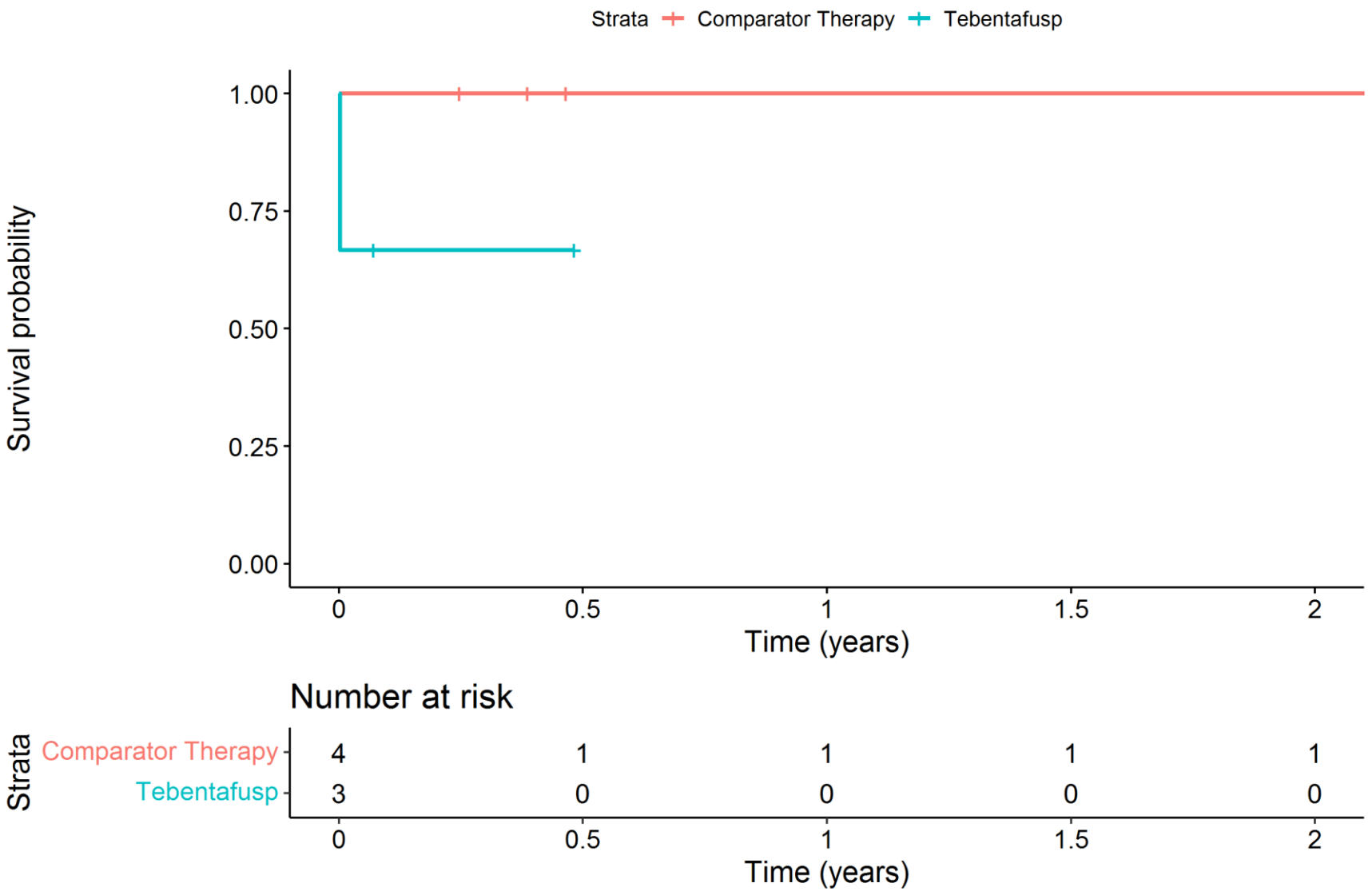
Hyperthyreose - Ipilimumab



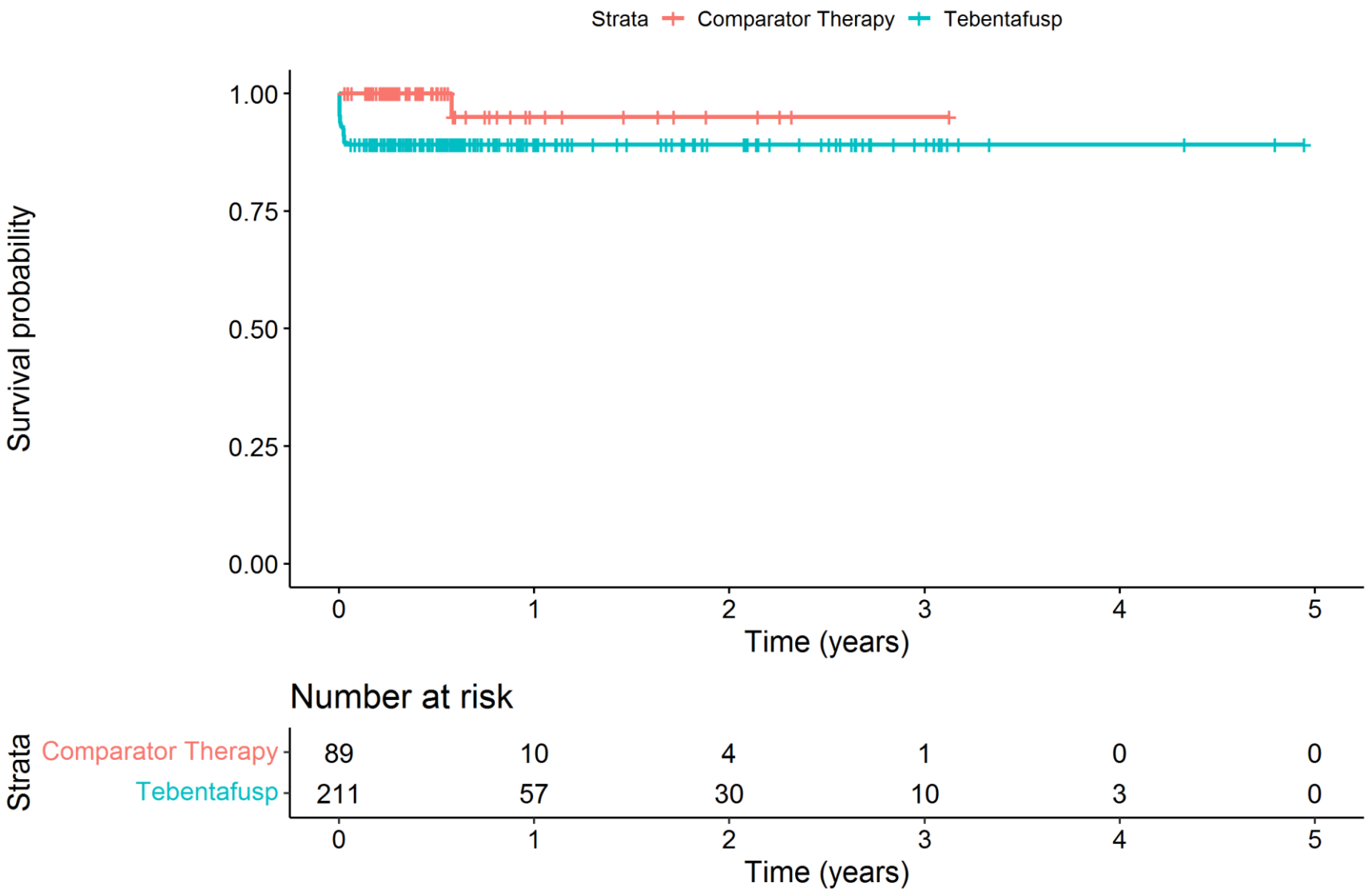
Periorbitales Ödem- Gesamt



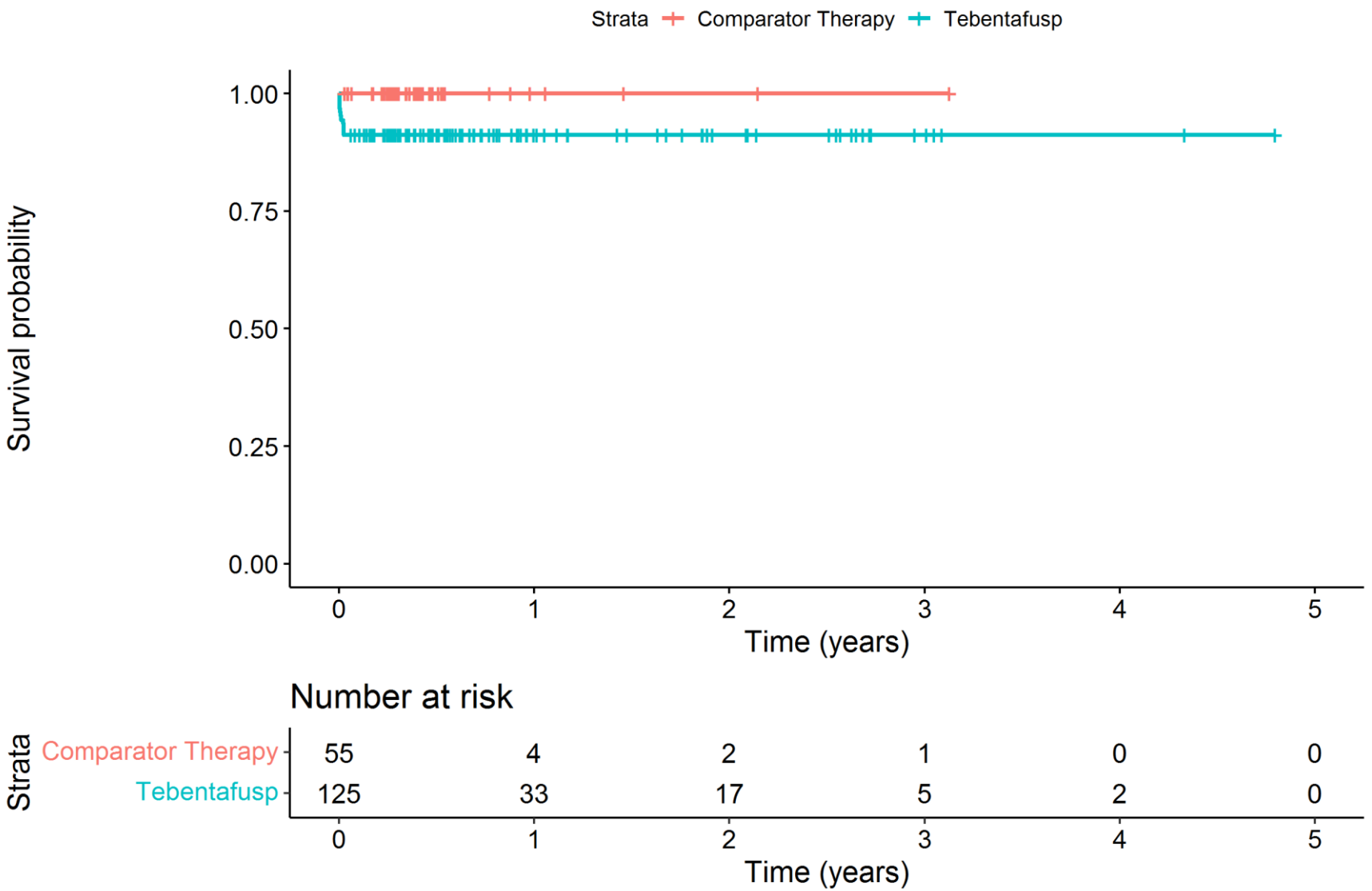
Periorbitales Ödem- Hispanisch



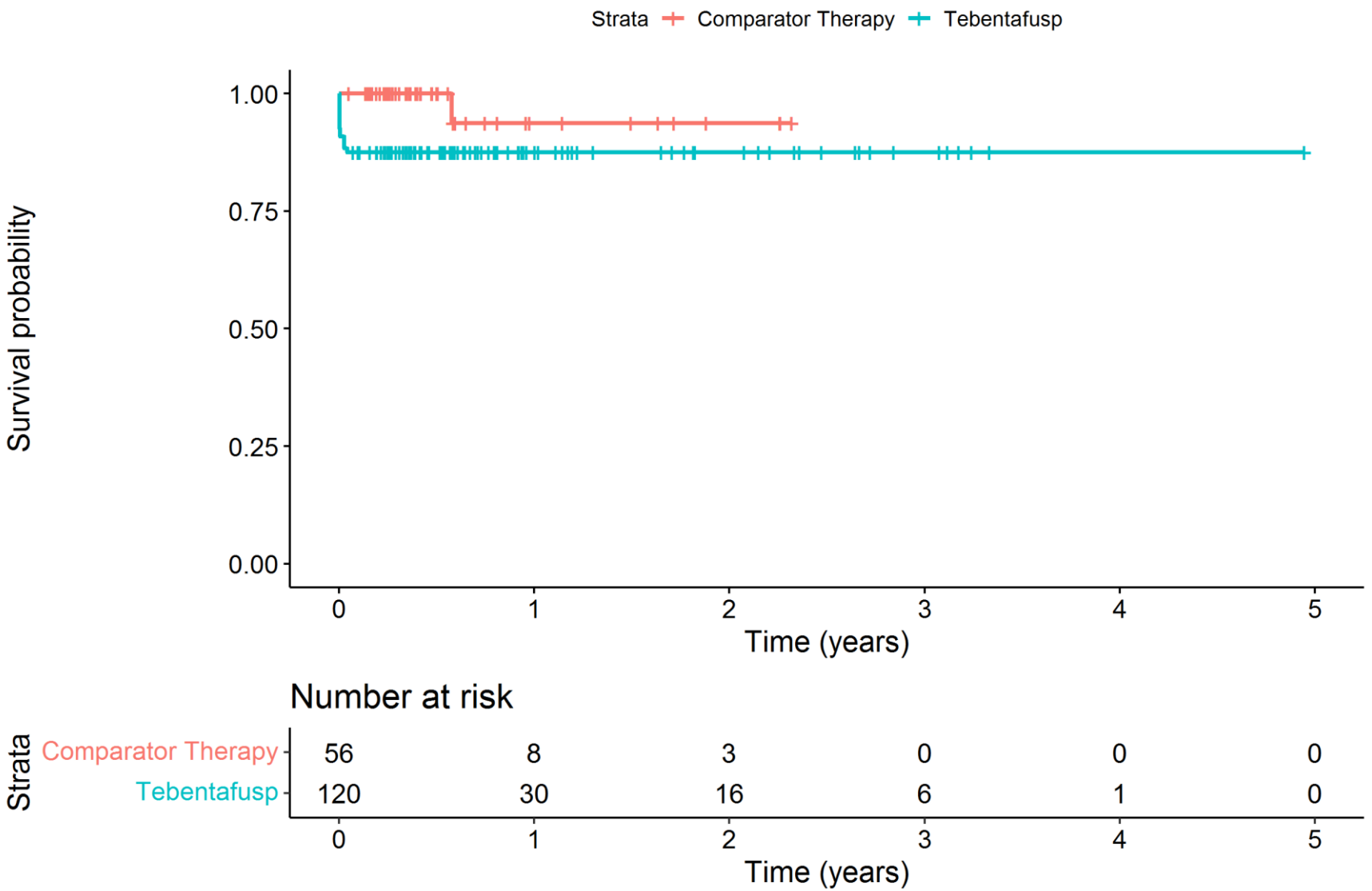
Periorbitales Ödem- Nicht-hispanisch



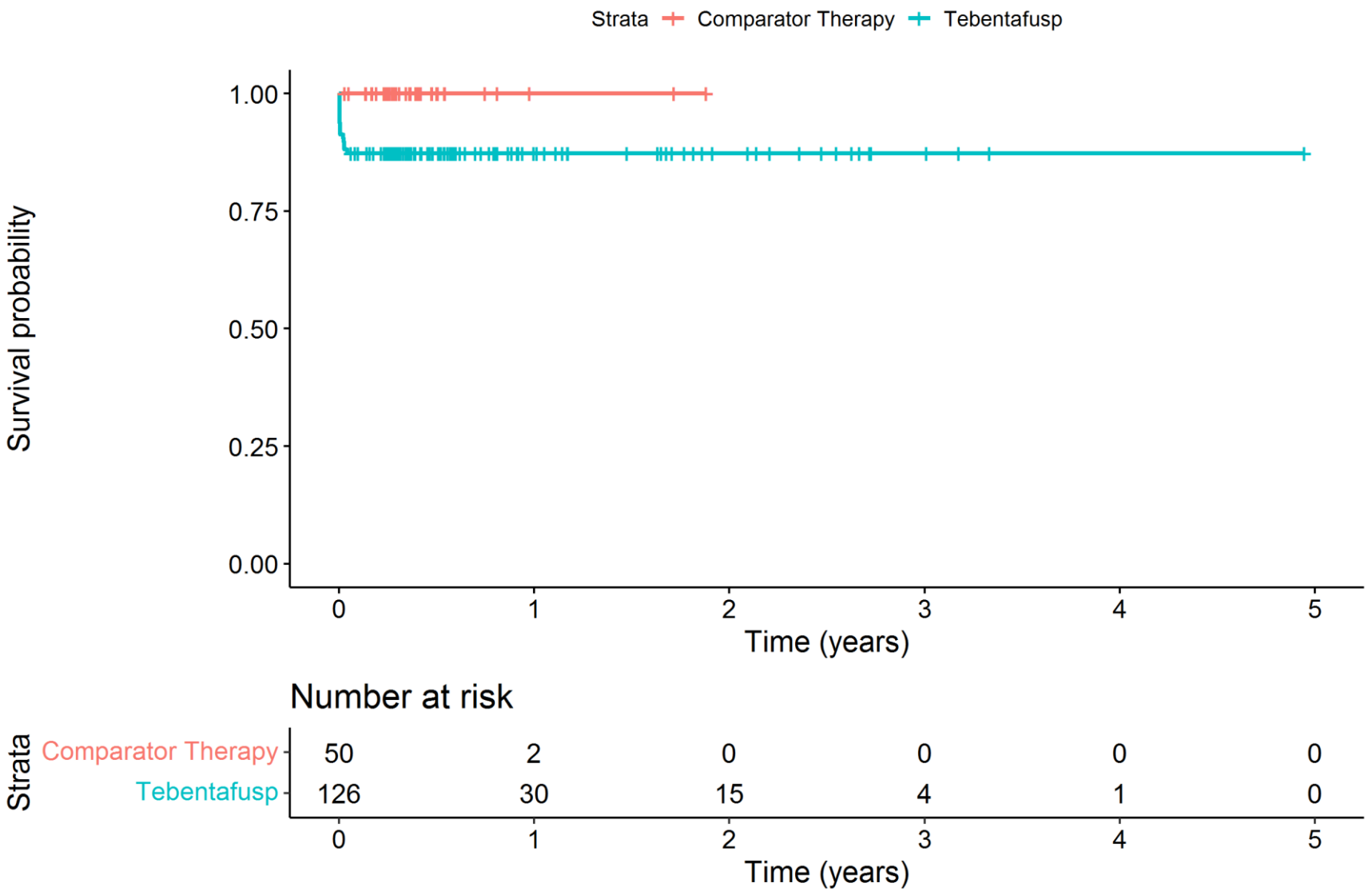
Periorbitales Ödem- Männlich



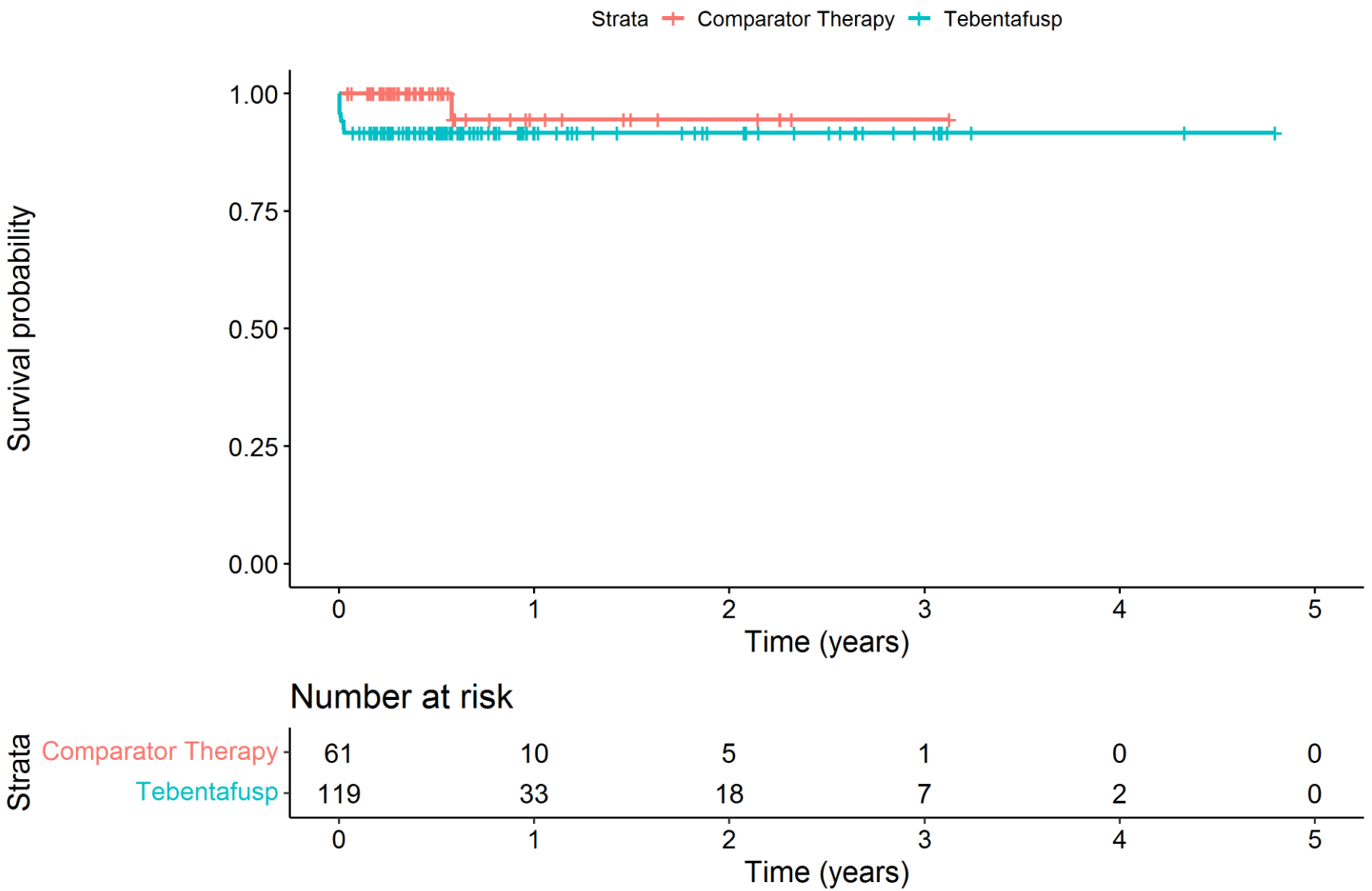
Periorbitales Ödem- Weiblich



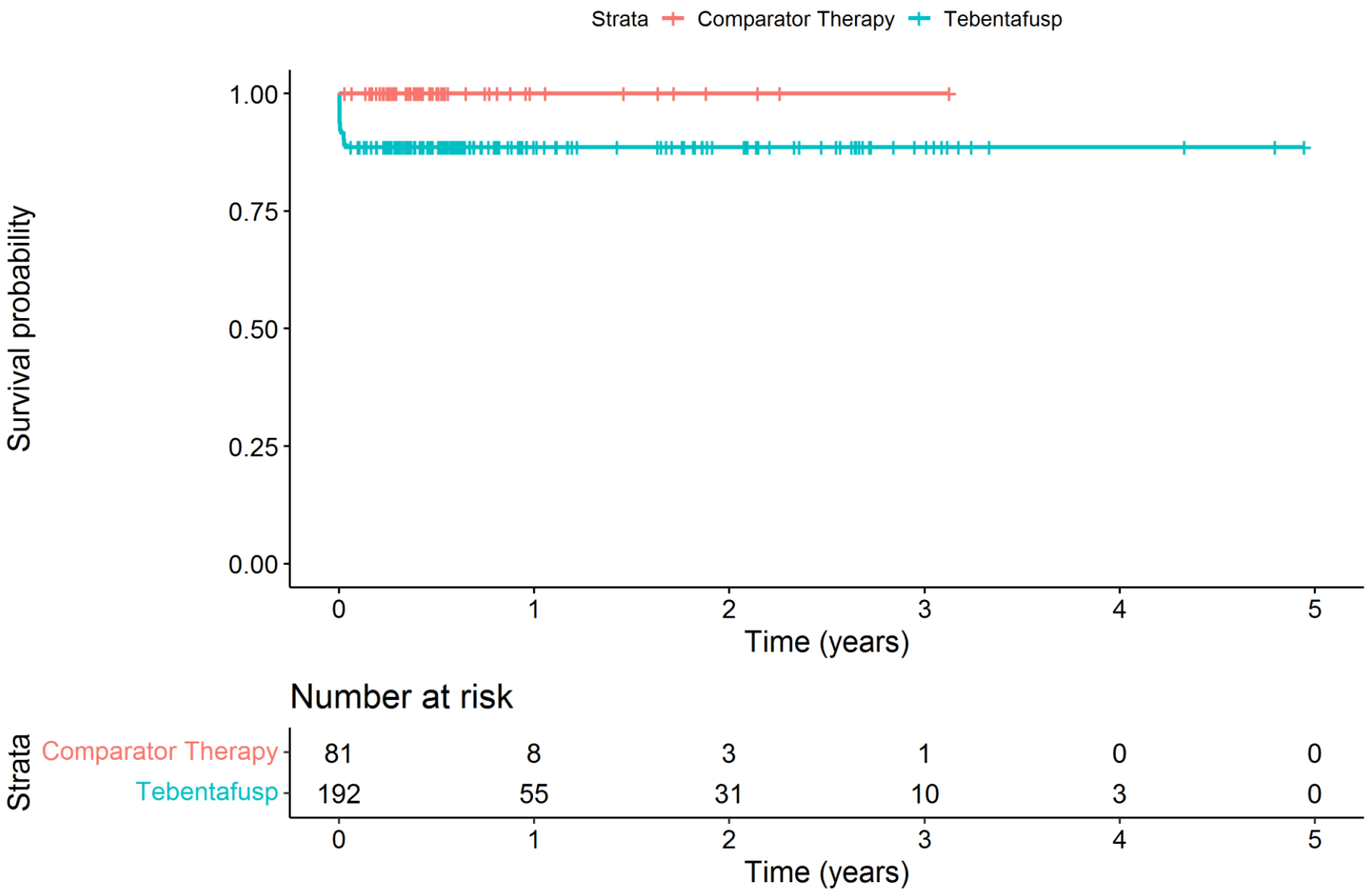
Periorbitales Ödem- <65



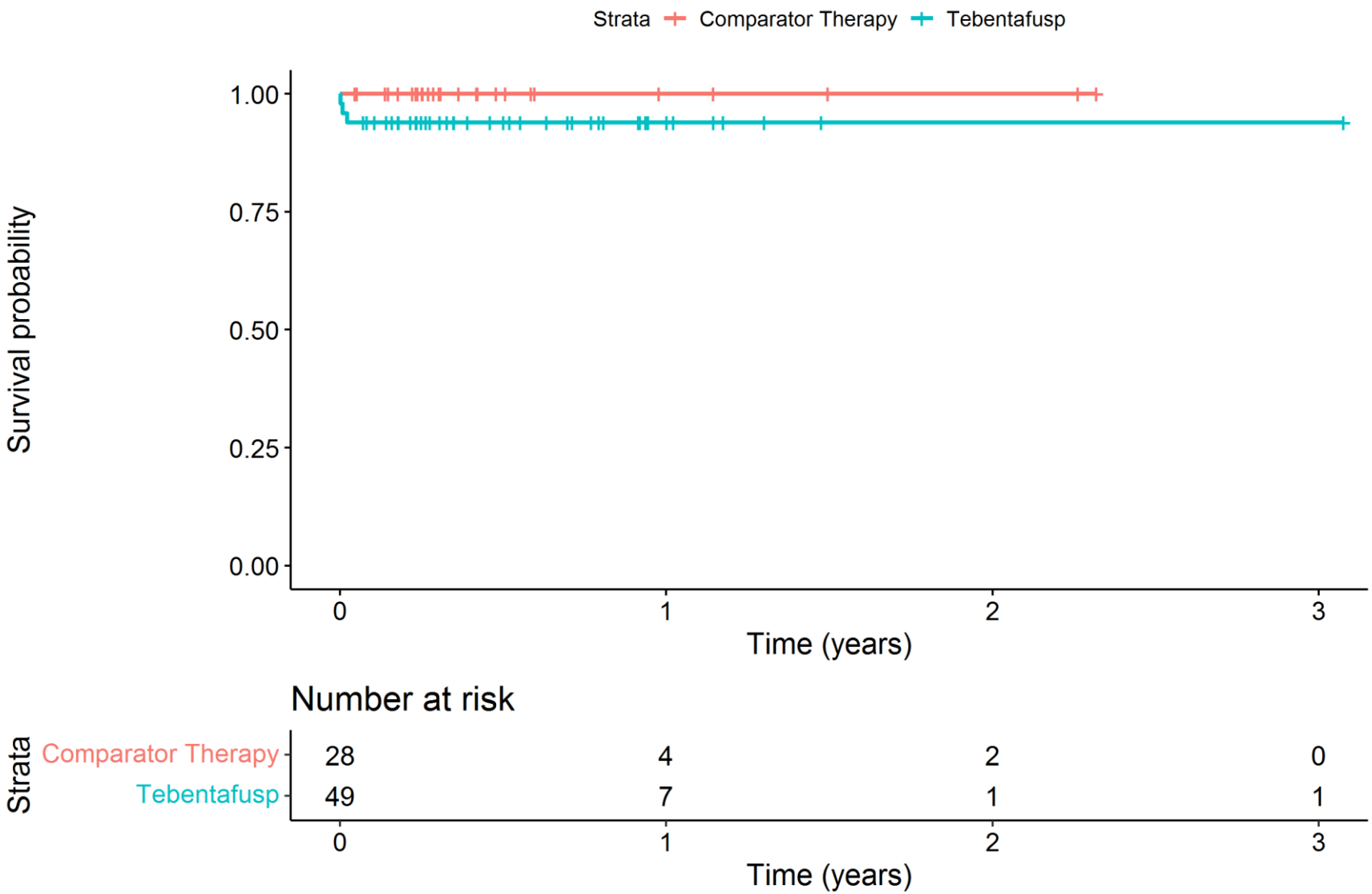
Periorbitales Ödem- ≥65



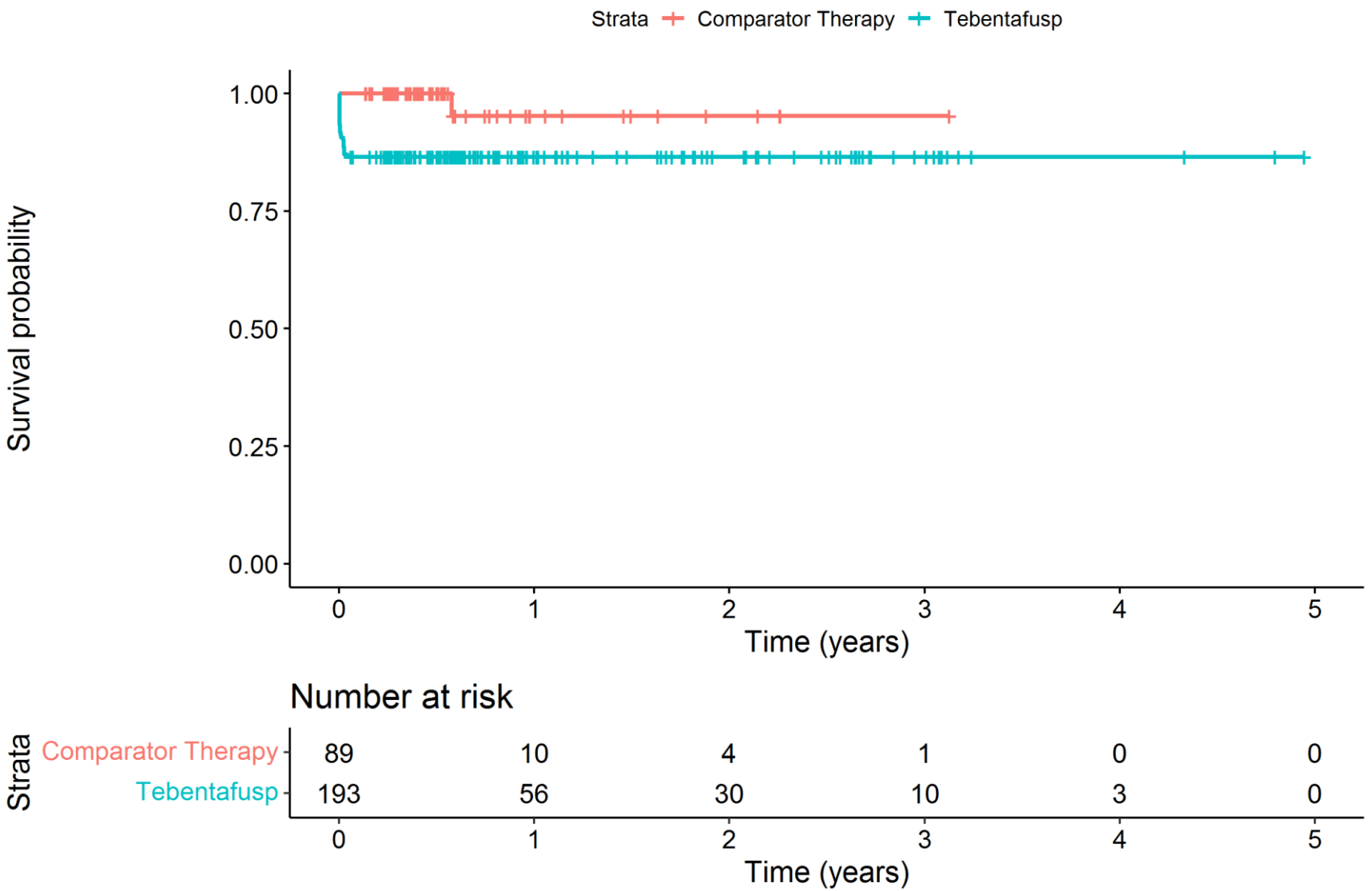
Periorbitales Ödem- ECOG 0



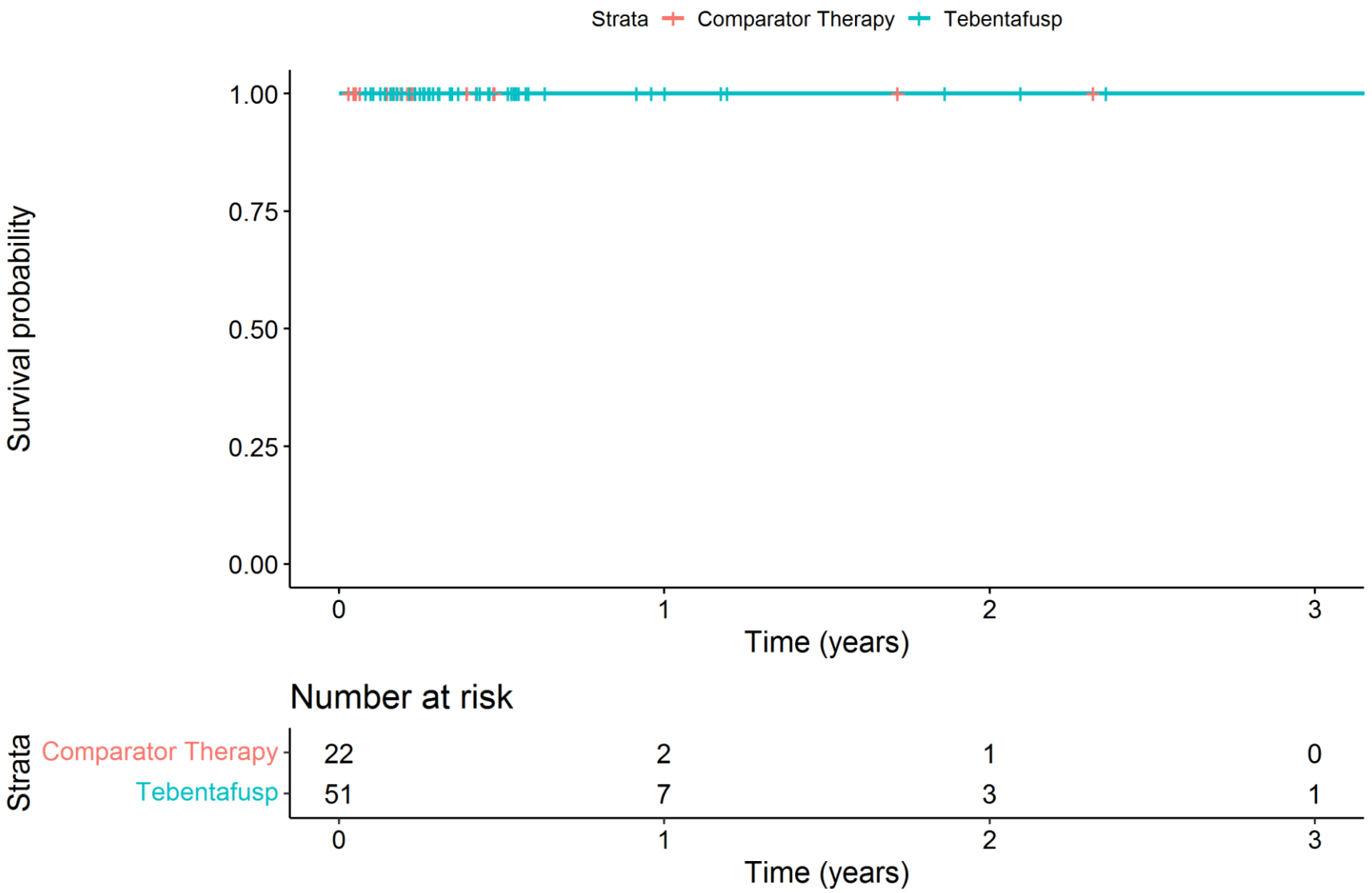
Periorbitales Ödem- ECOG 1



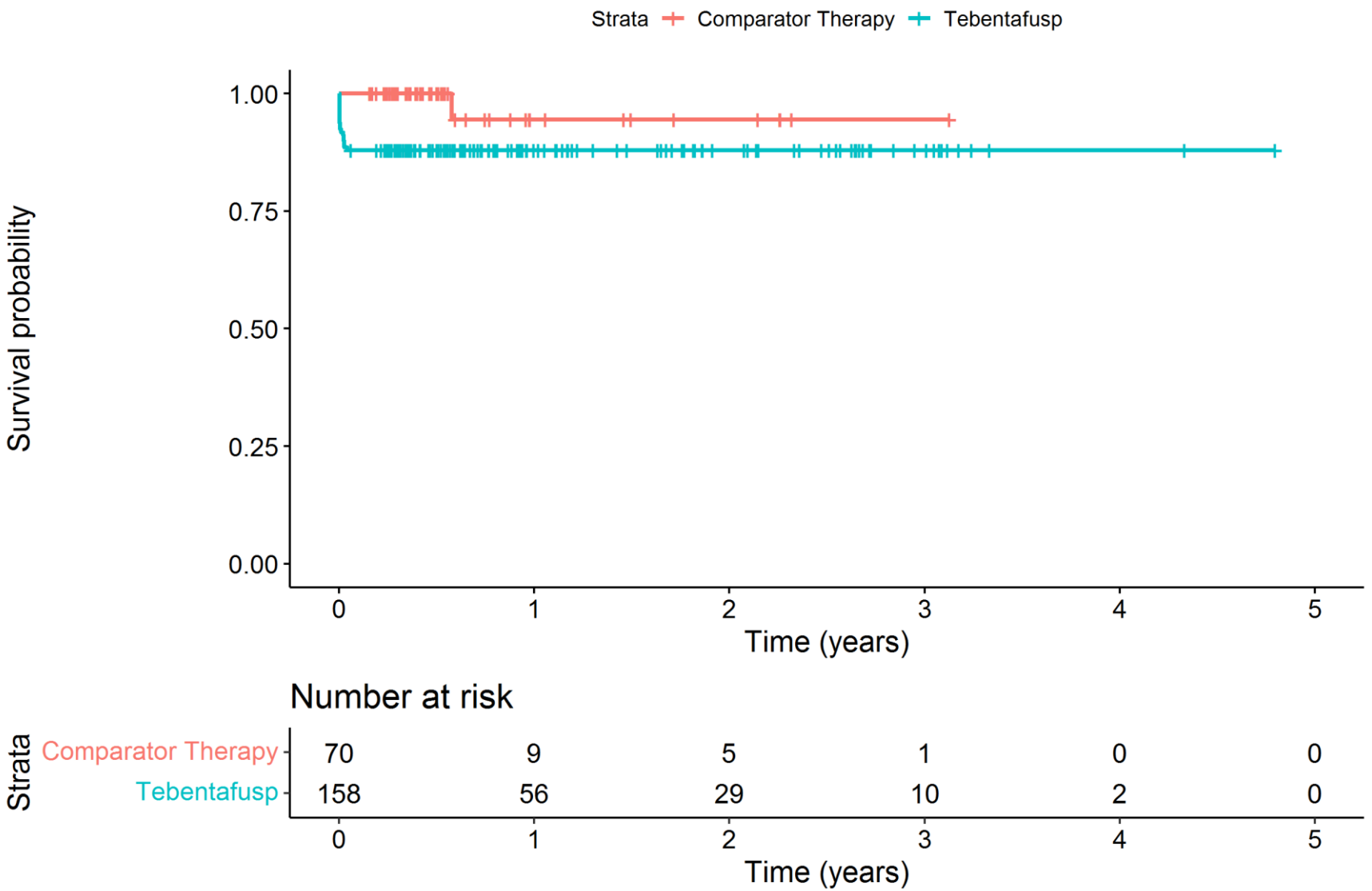
Periorbitales Ödem- ALP ≤ ULN



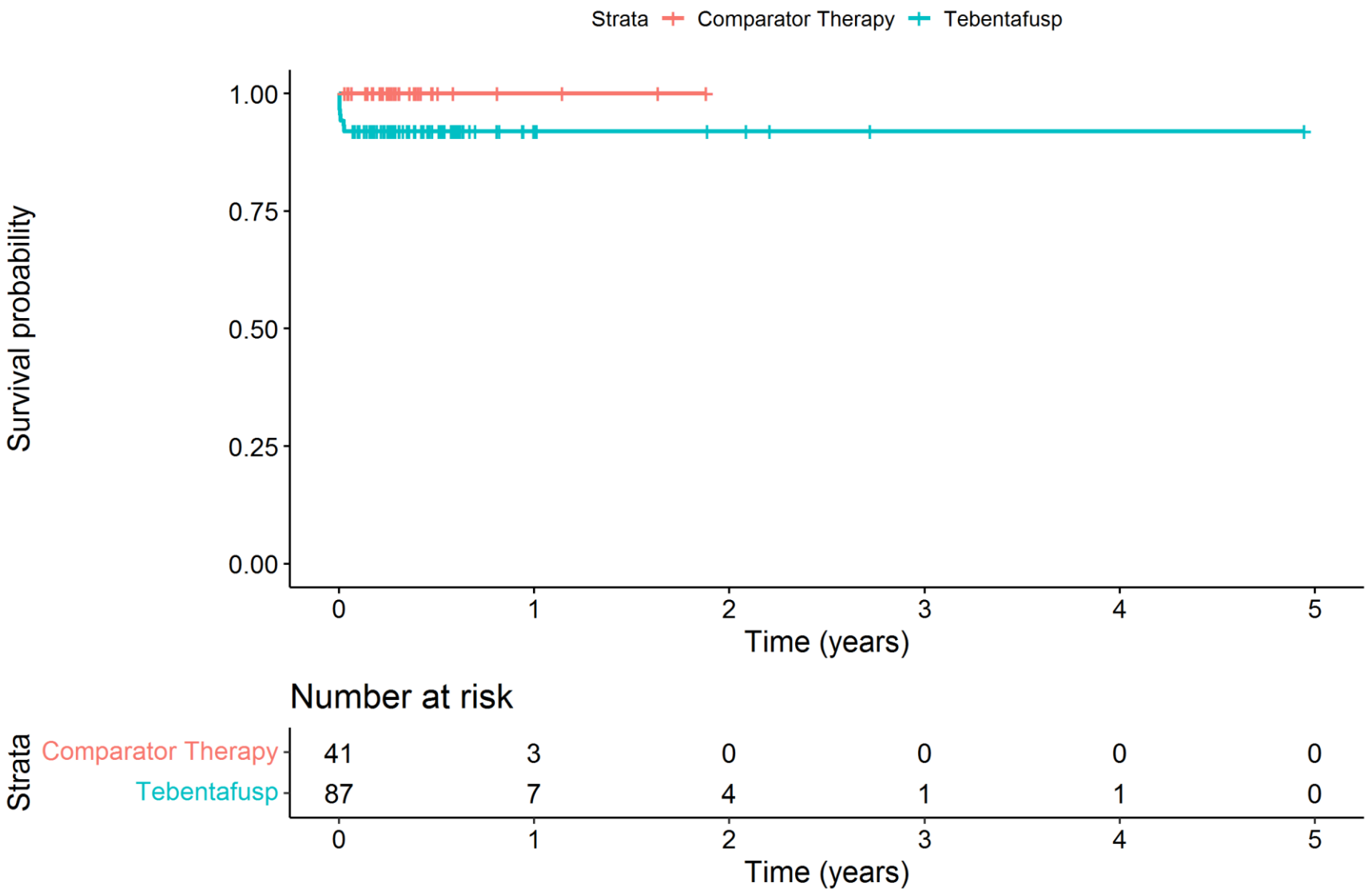
Periorbitales Ödem- ALP > ULN



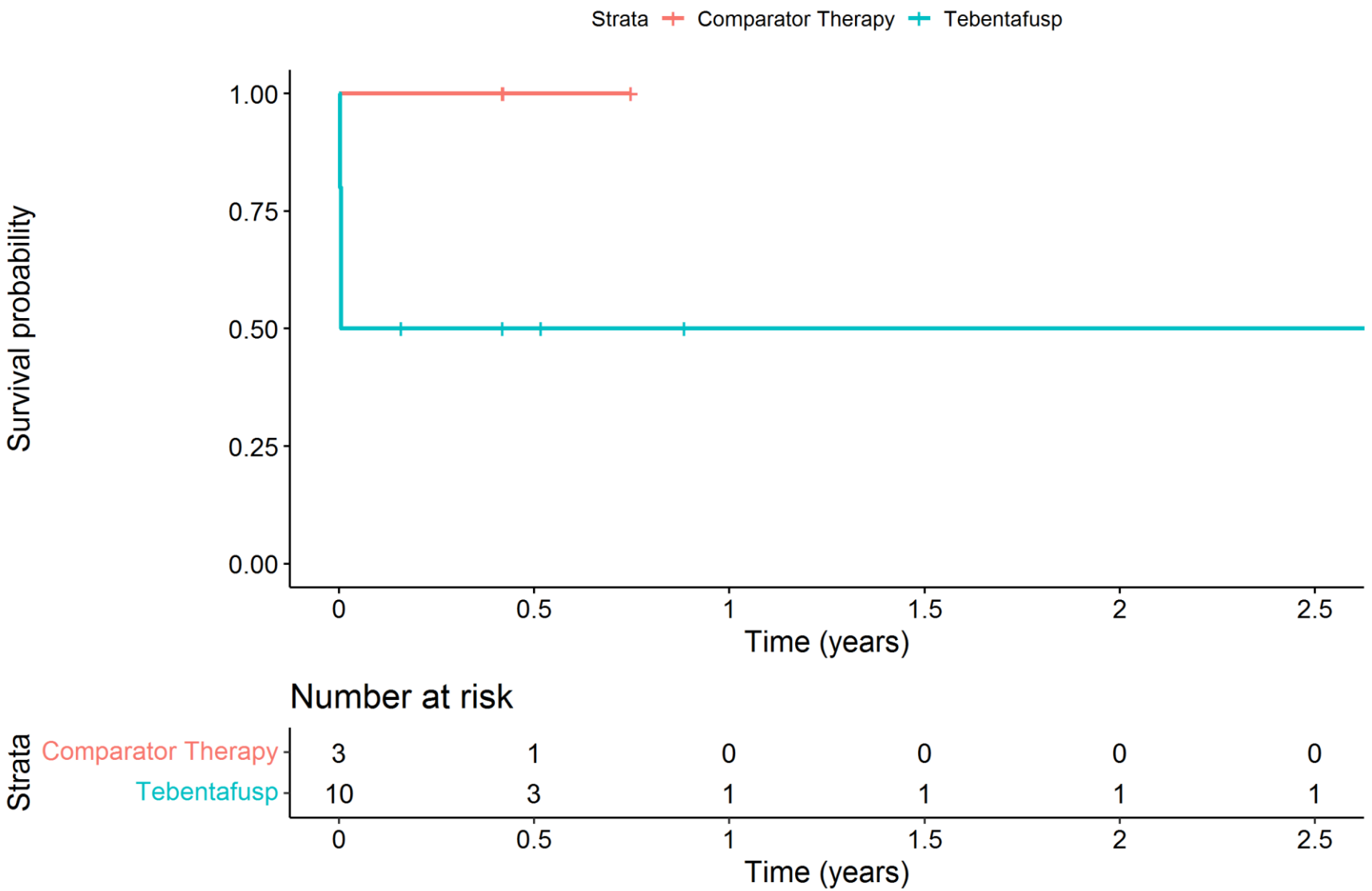
Periorbitales Ödem- LDH =< ULN



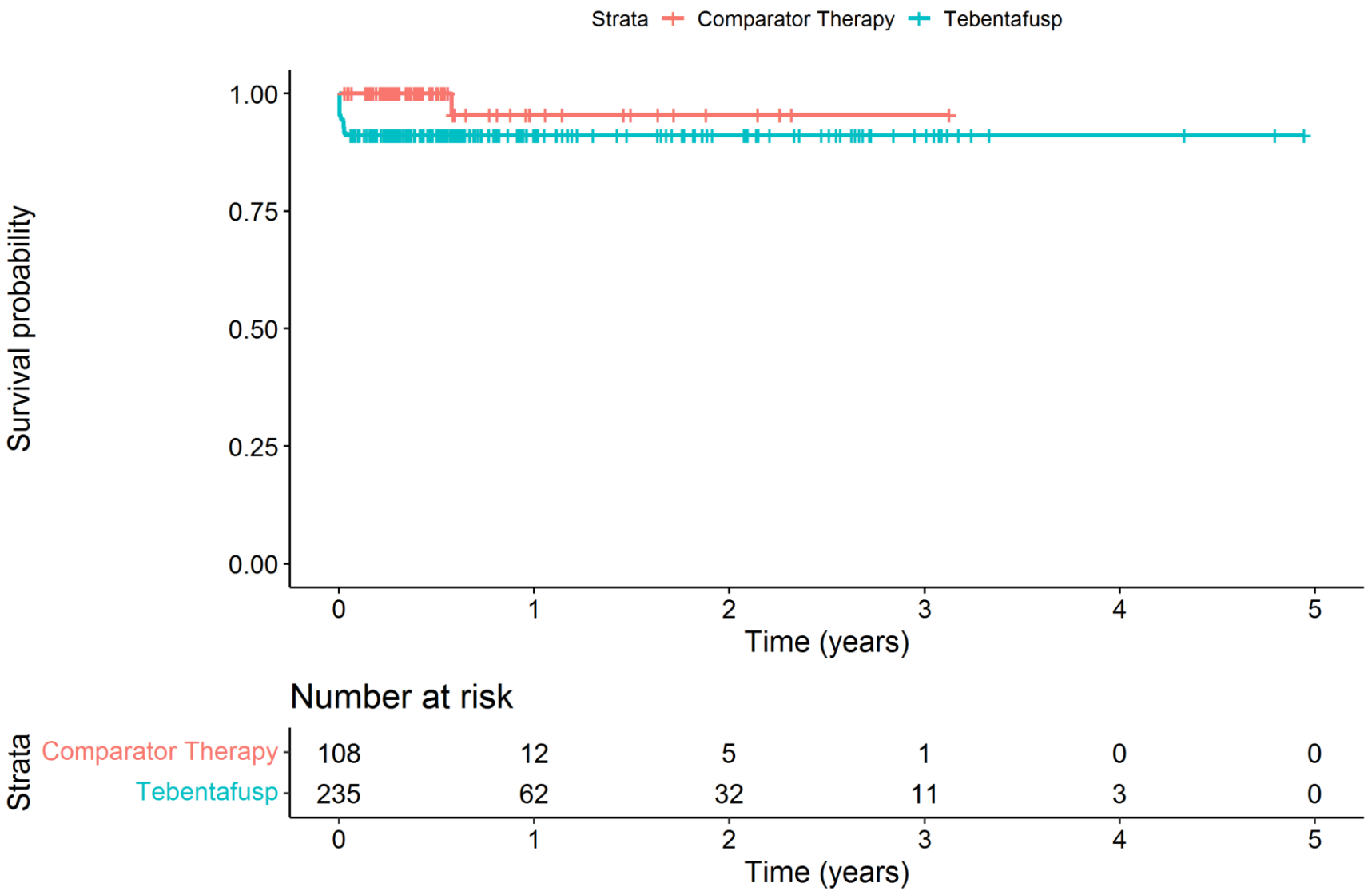
Periorbitales Ödem- LDH > ULN



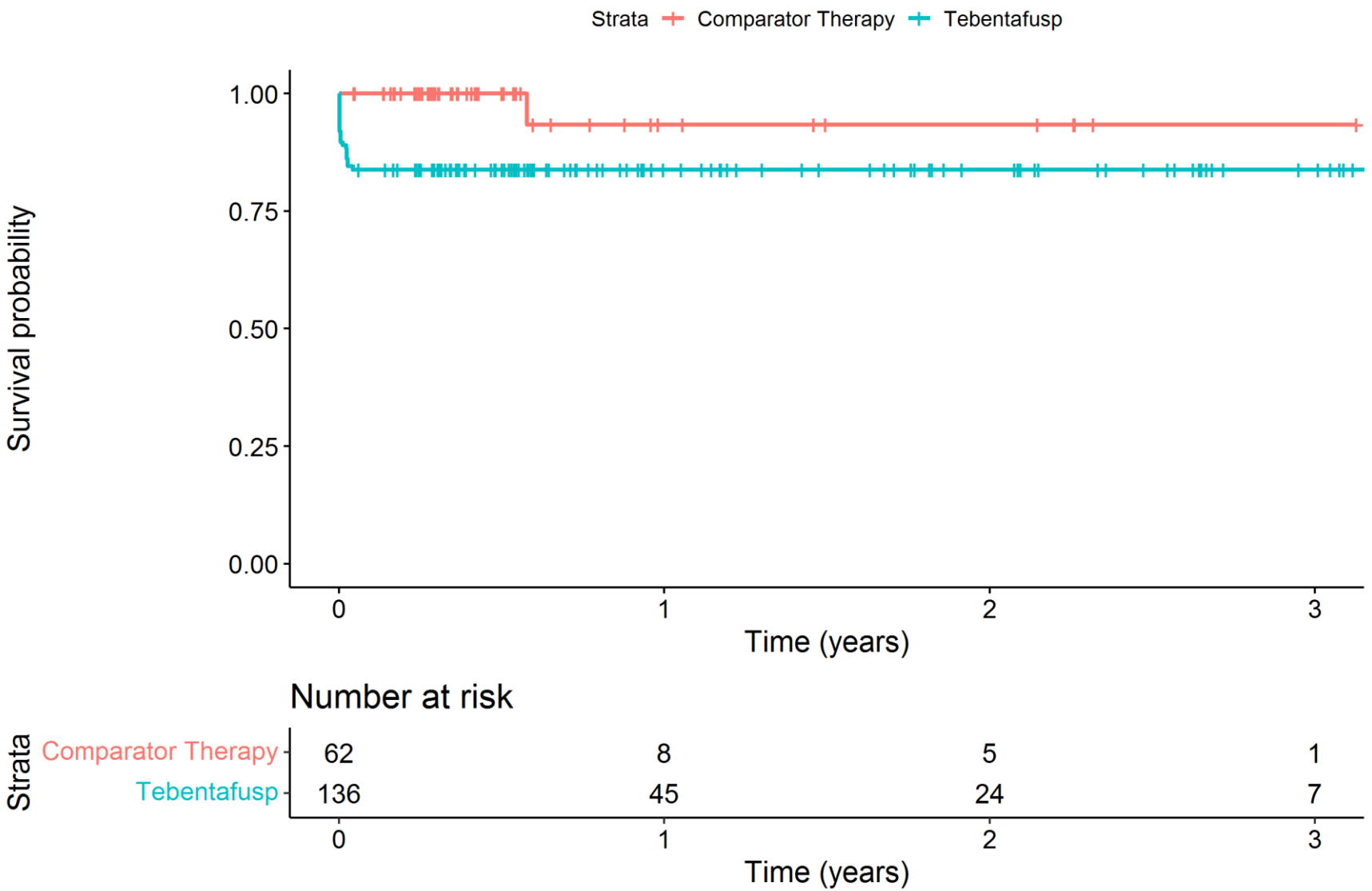
Periorbitales Ödem- Vorherige Therapie adjuvant/neoadjuvant



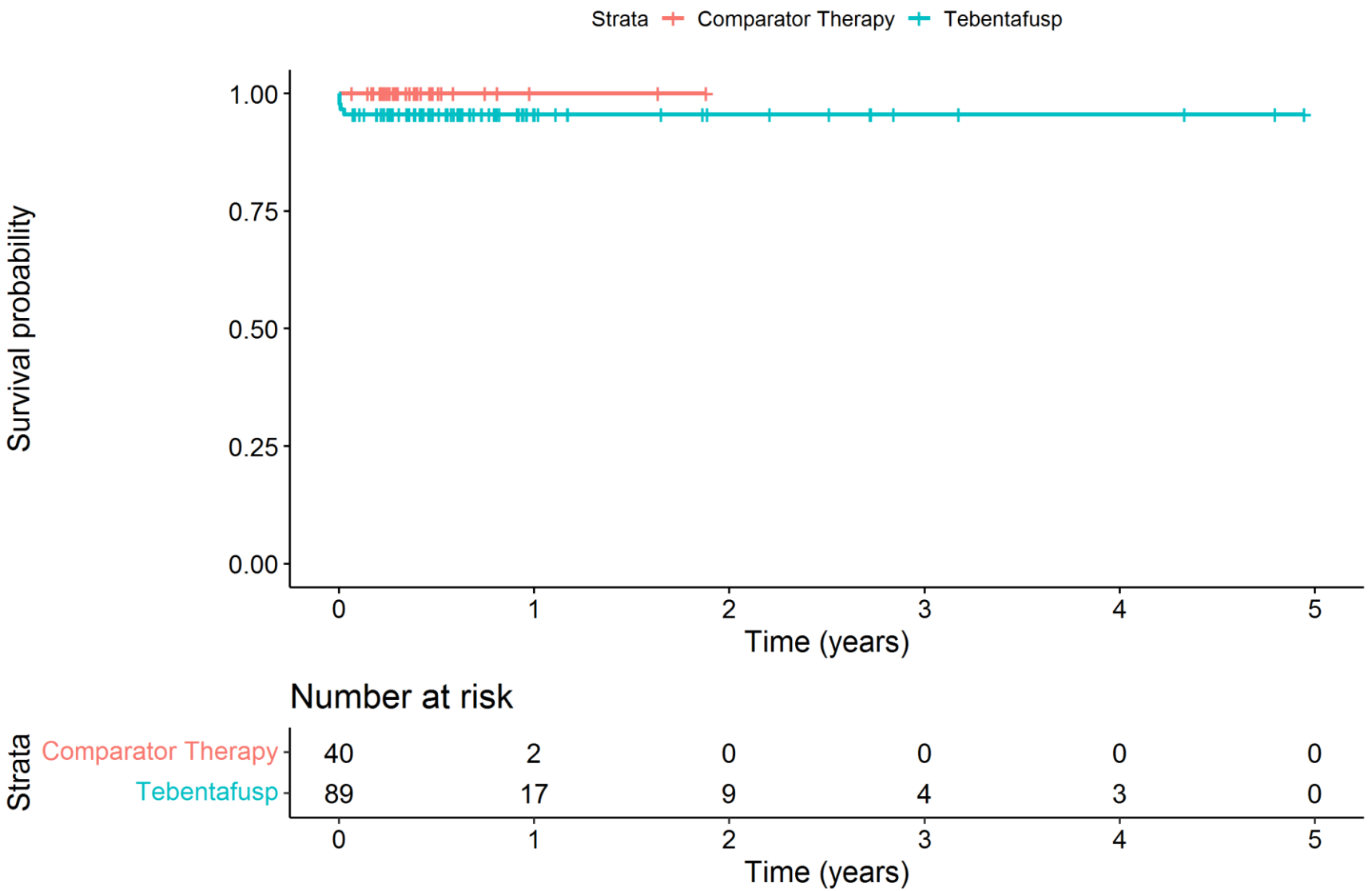
Periorbitales Ödem- Keine Vorherige Therapie adjuvant/neoadjuvant



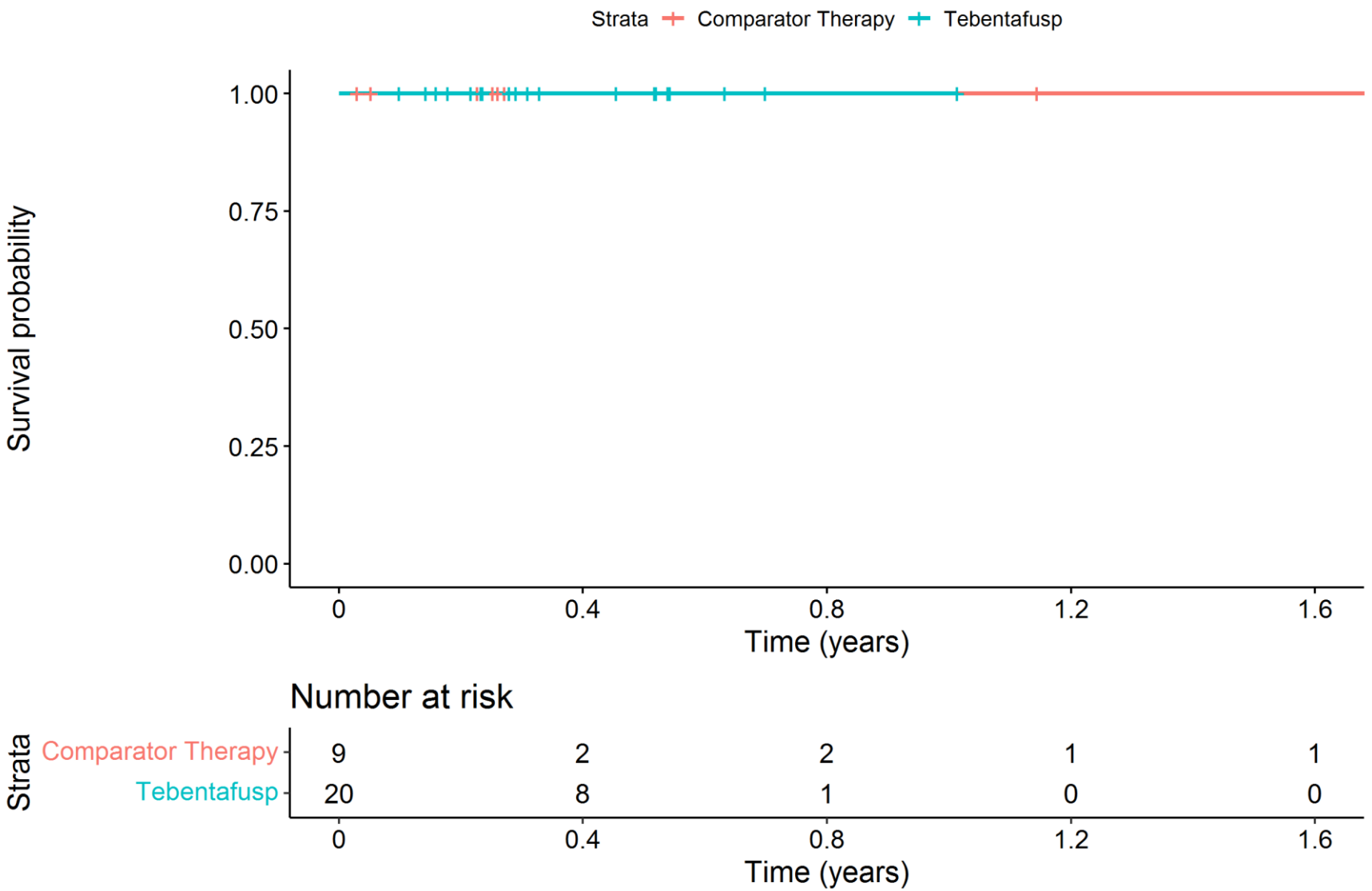
Periorbitales Ödem- Läsion ≤ 3cm



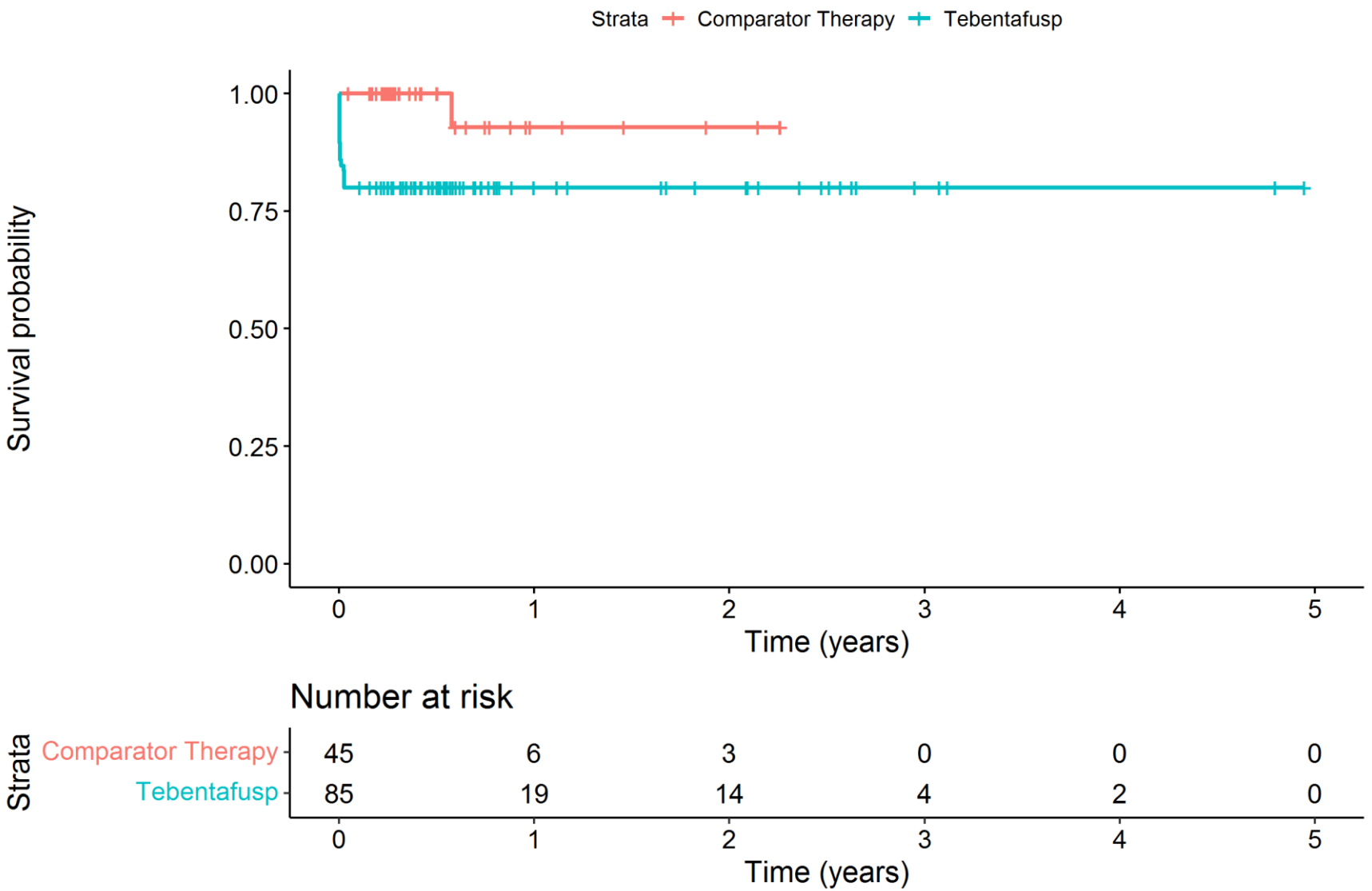
Periorbitales Ödem- Läsion 3,1-8,0 cm



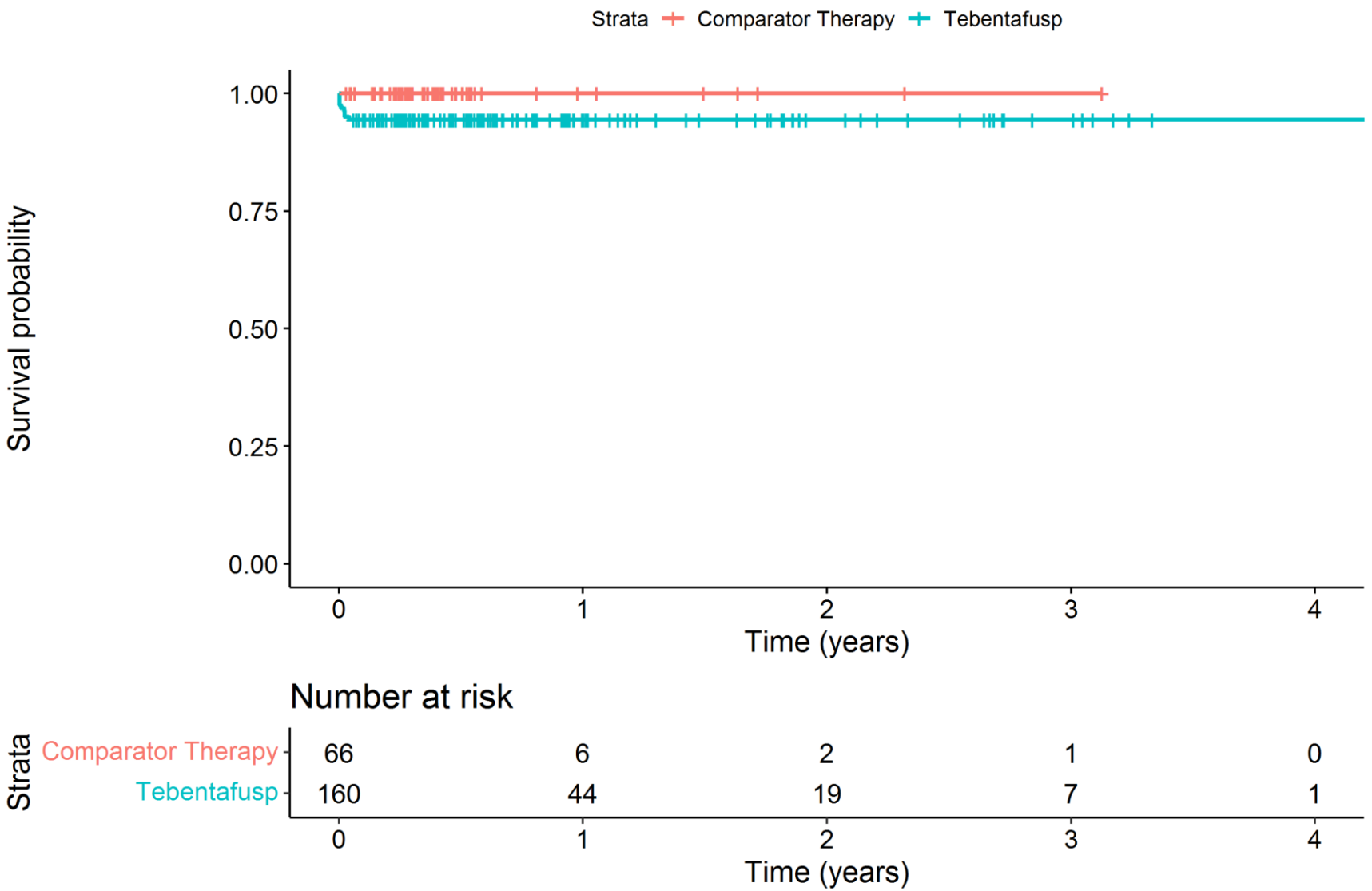
Periorbitales Ödem- Läsion ≥8,1 cm



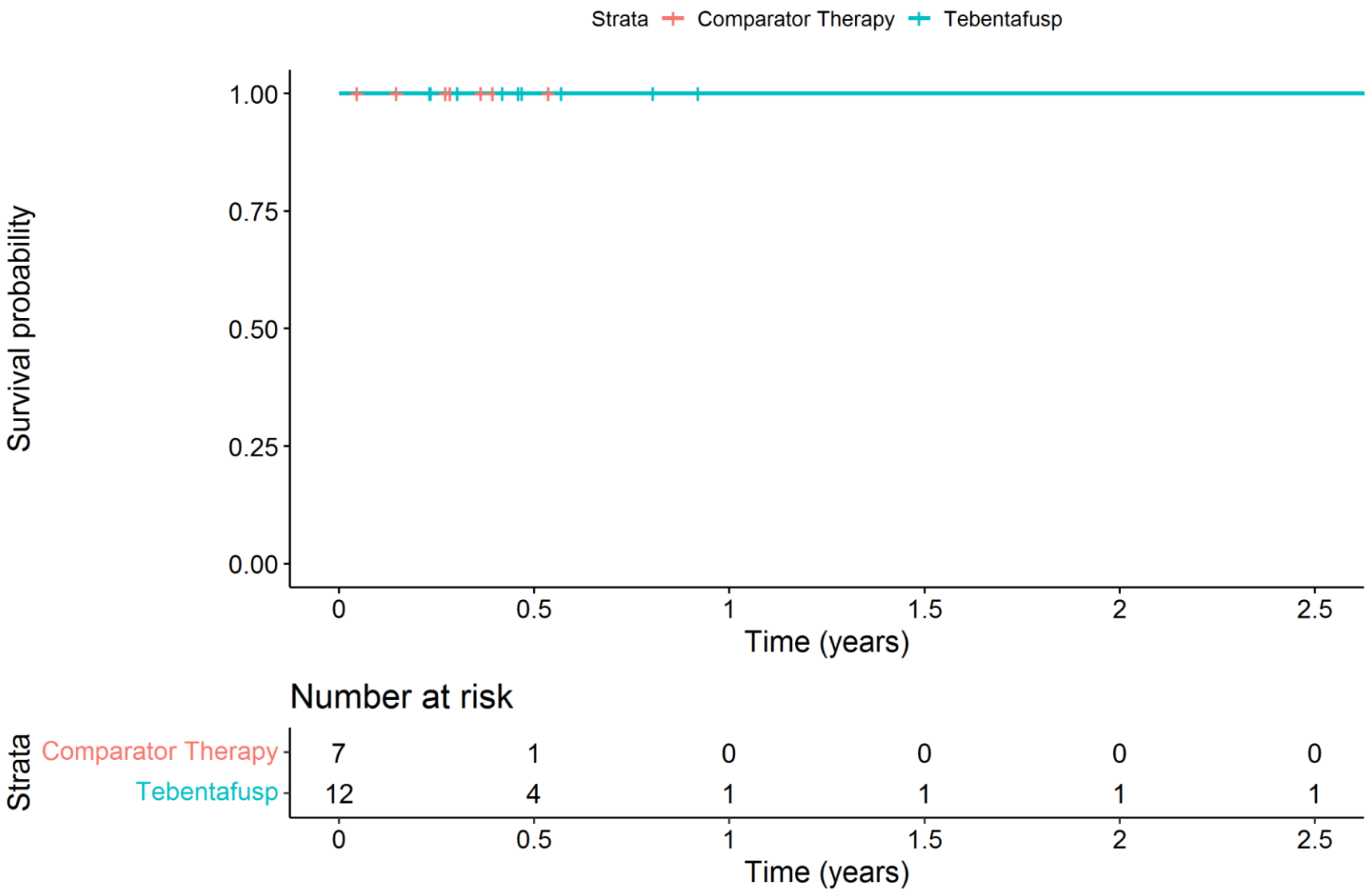
Periorbitales Ödem- Nordamerika



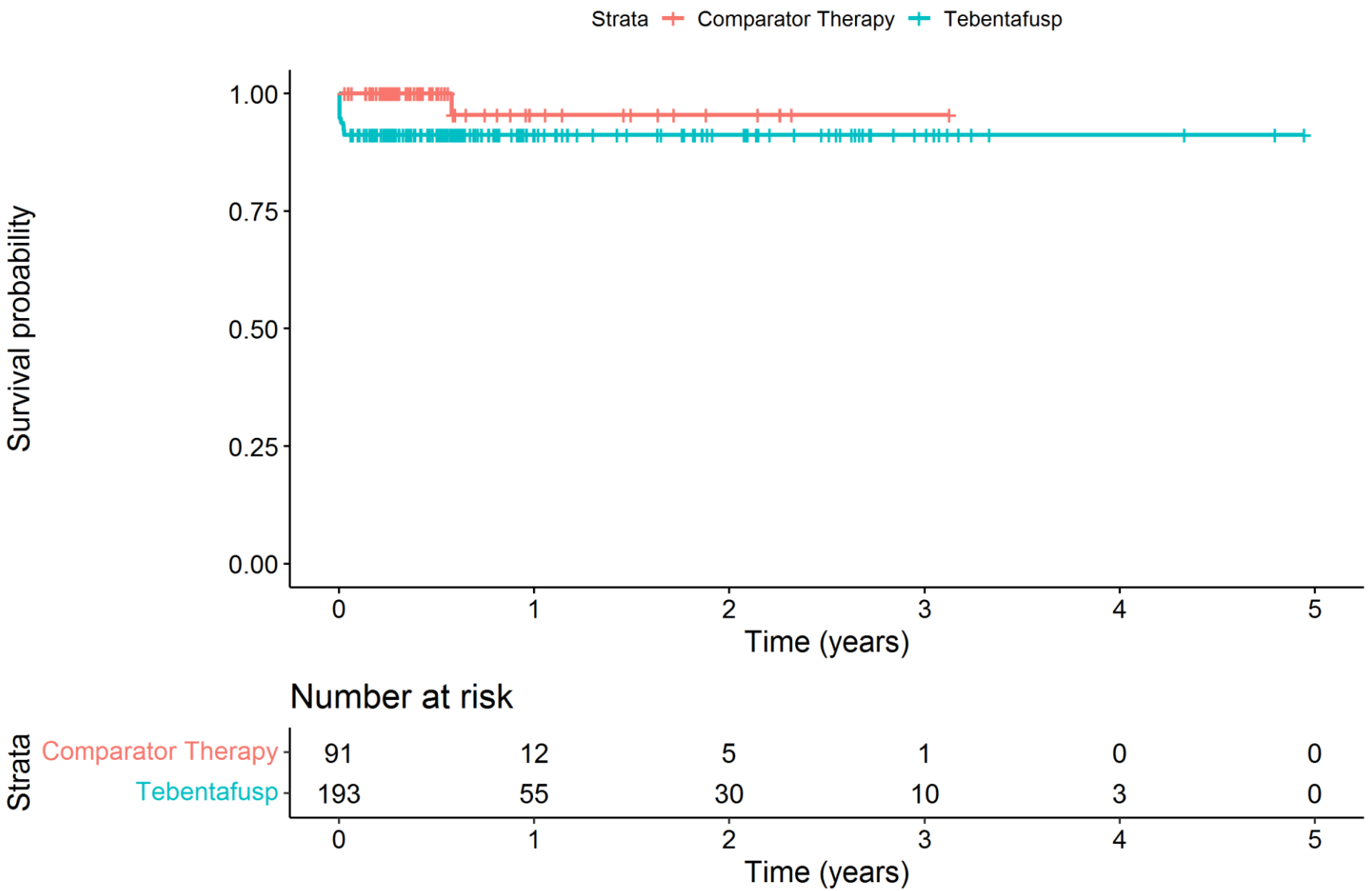
Periorbitales Ödem- Nicht-Nordamerika



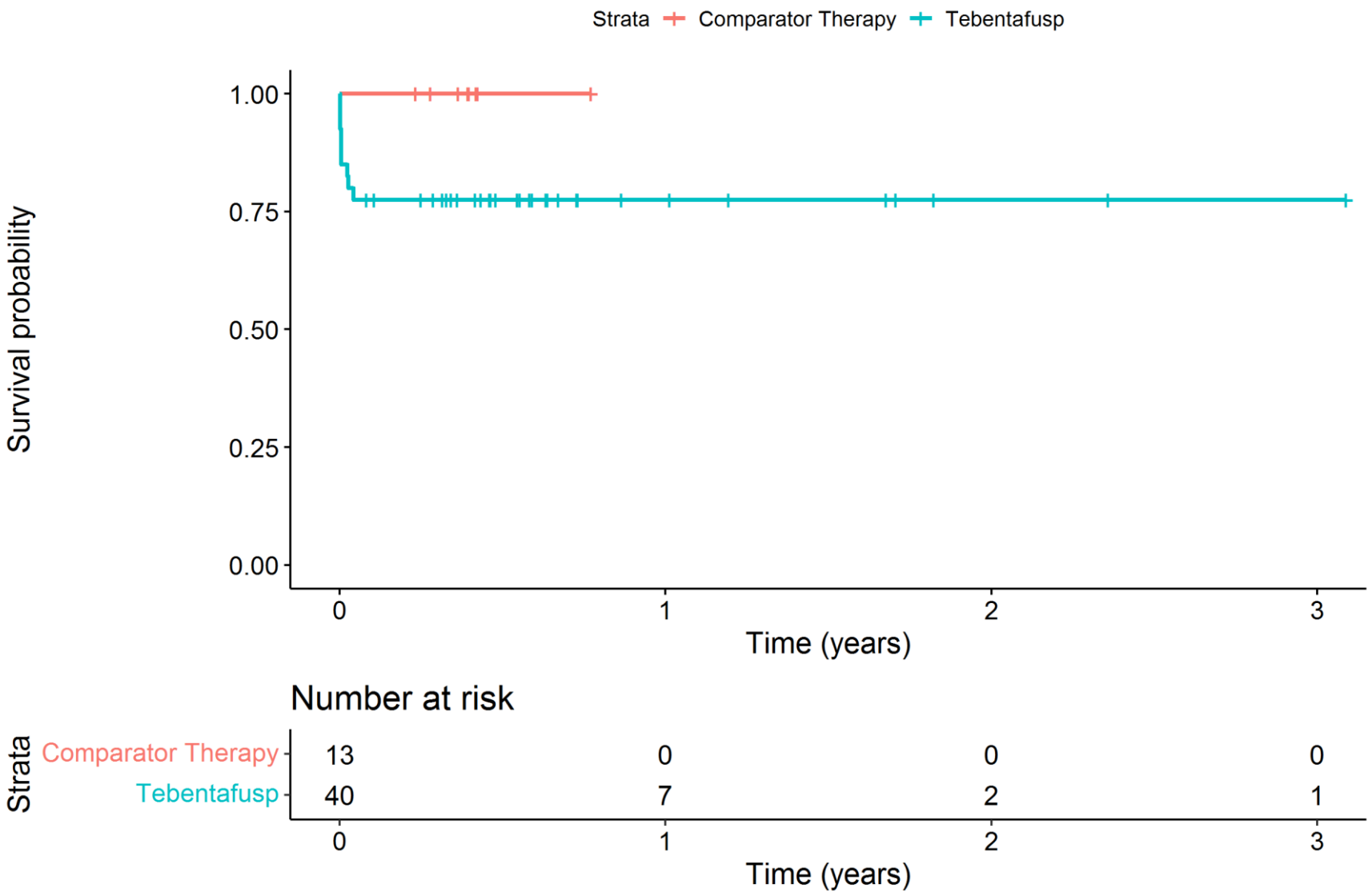
Periorbitales Ödem- Dacarbazin



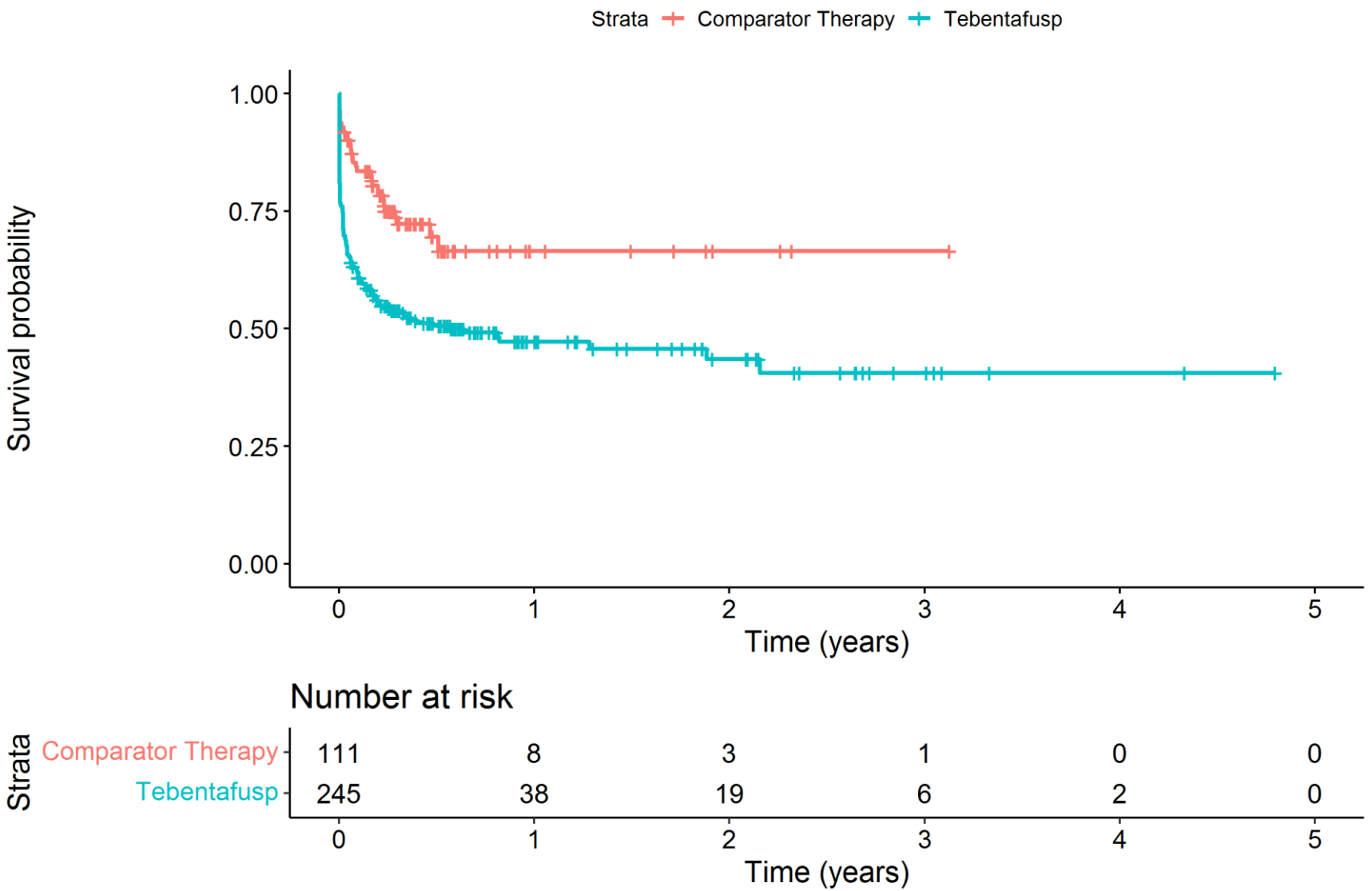
Periorbitales Ödem- Pembrolizumab



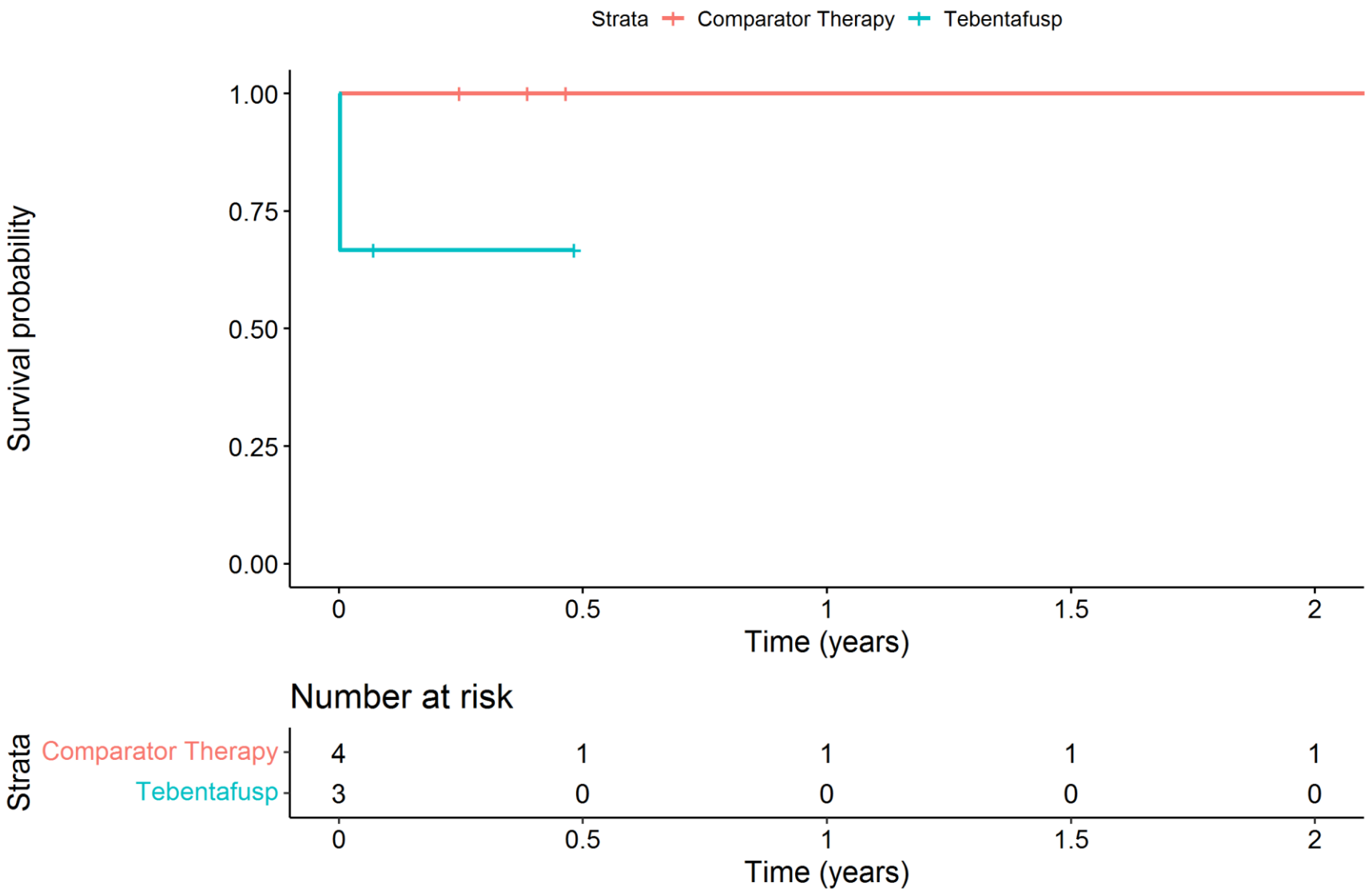
Periorbitales Ödem- Ipilimumab



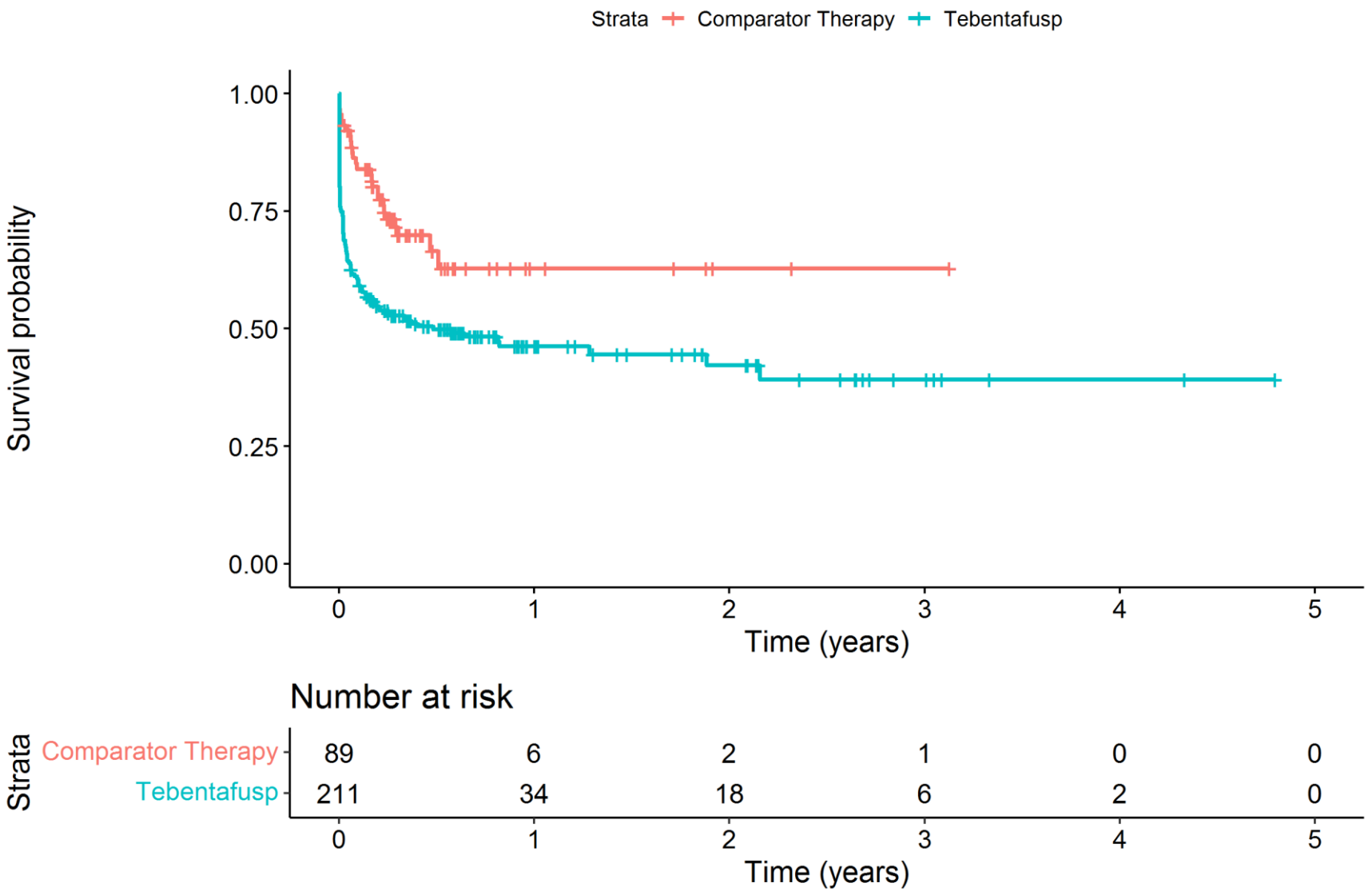
Übelkeit - Gesamt



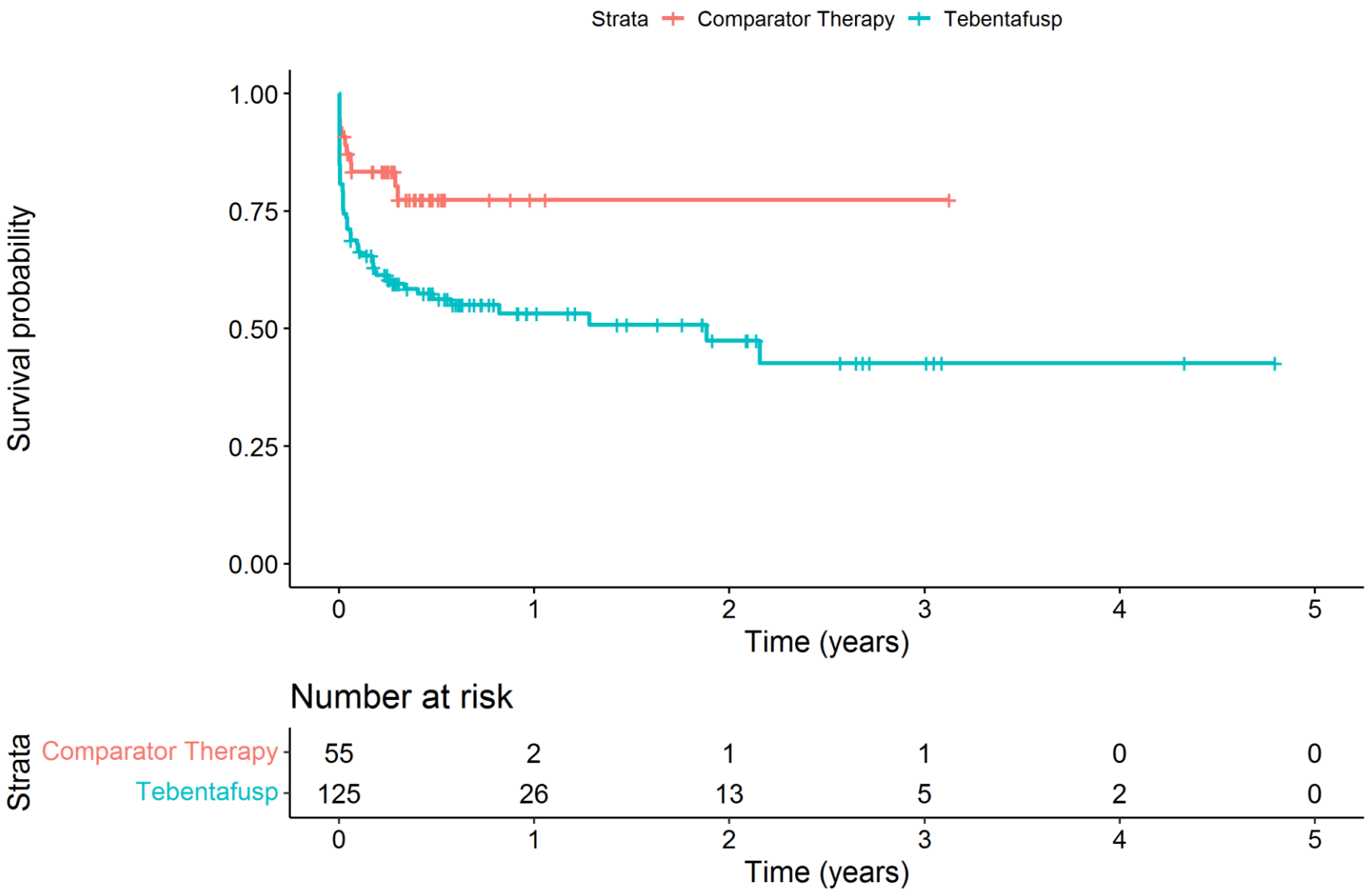
Übelkeit - Hispanisch



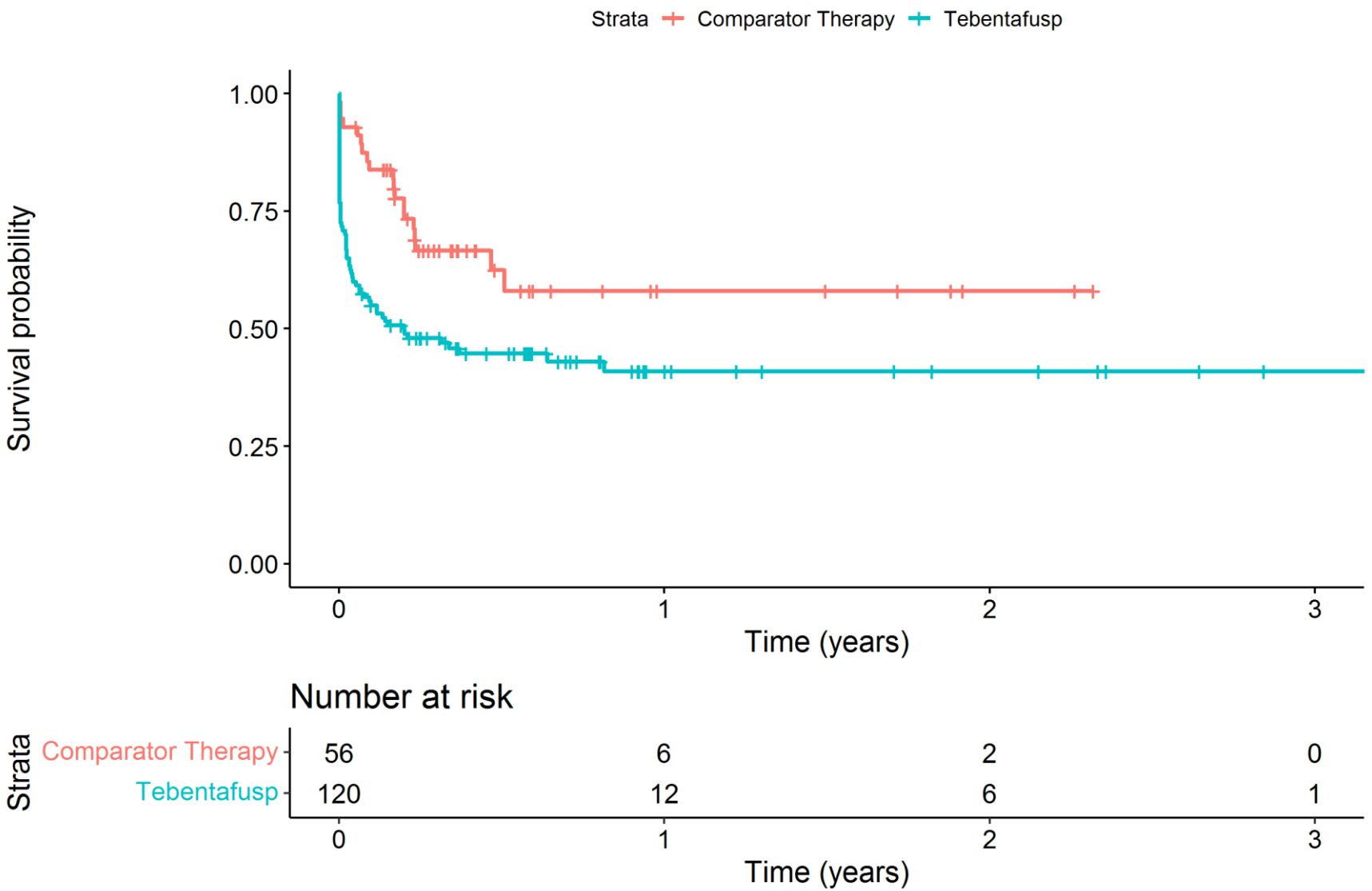
Übelkeit - Nicht-hispanisch



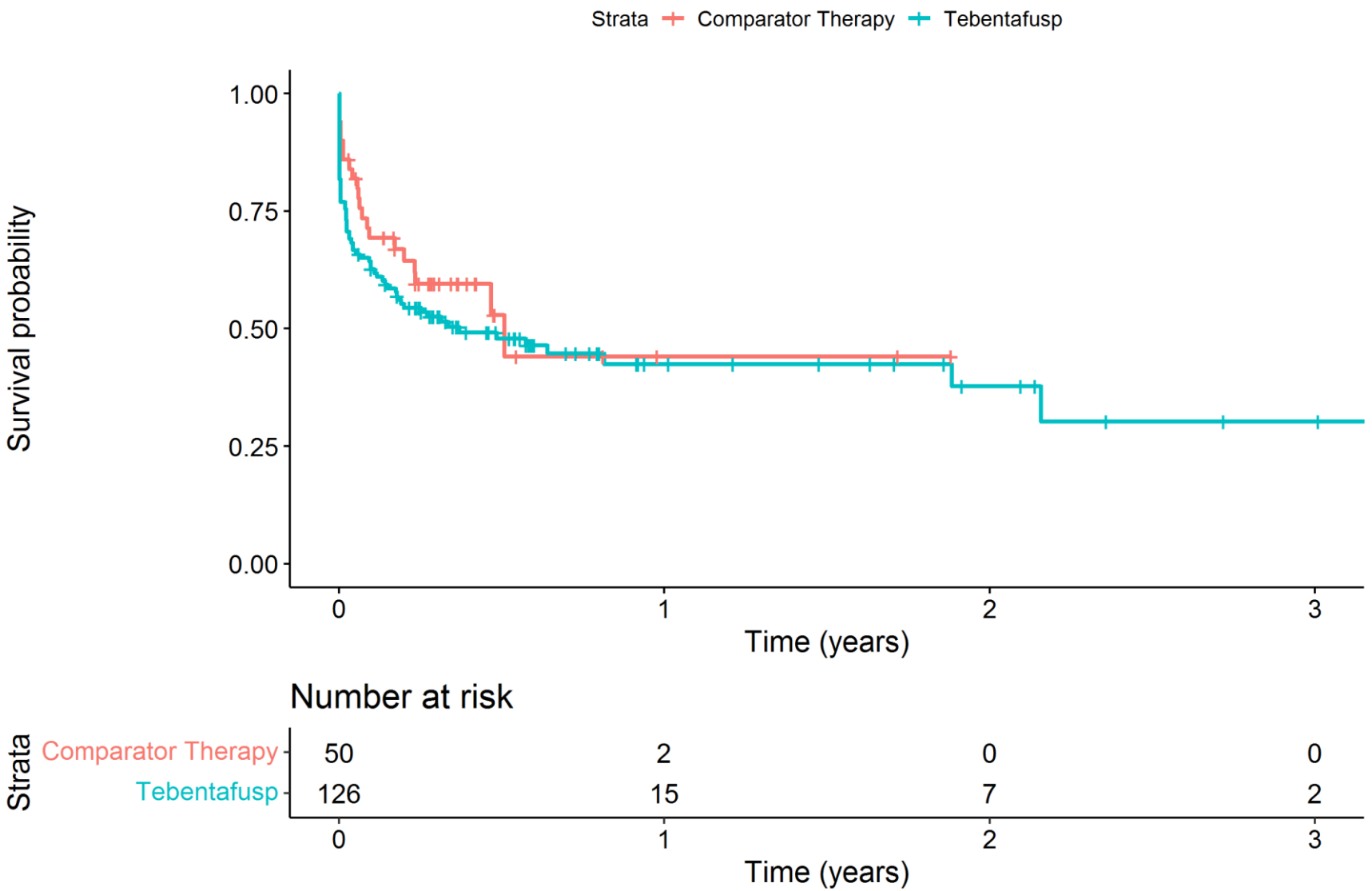
Übelkeit - Männlich



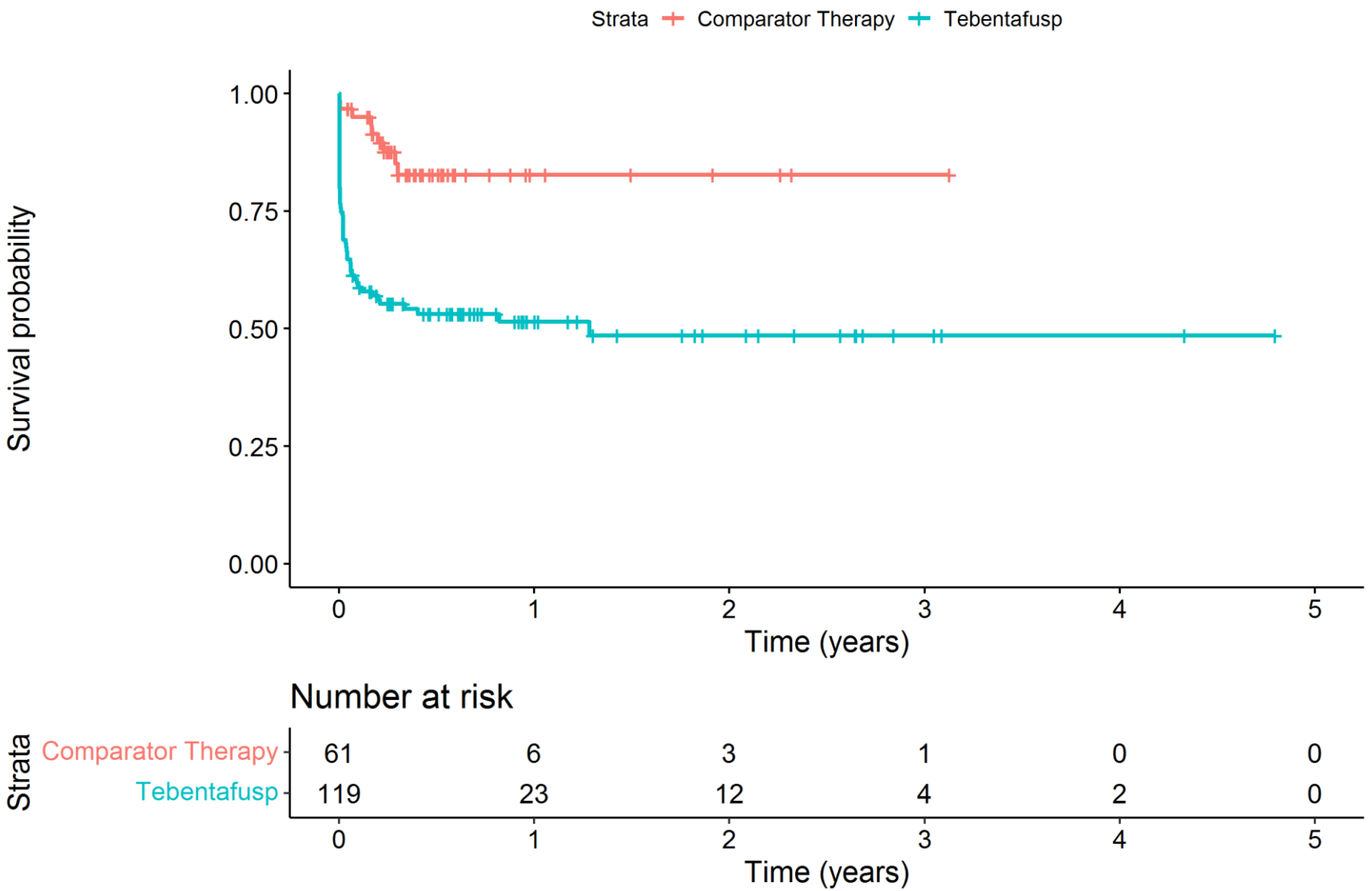
Übelkeit - Weiblich



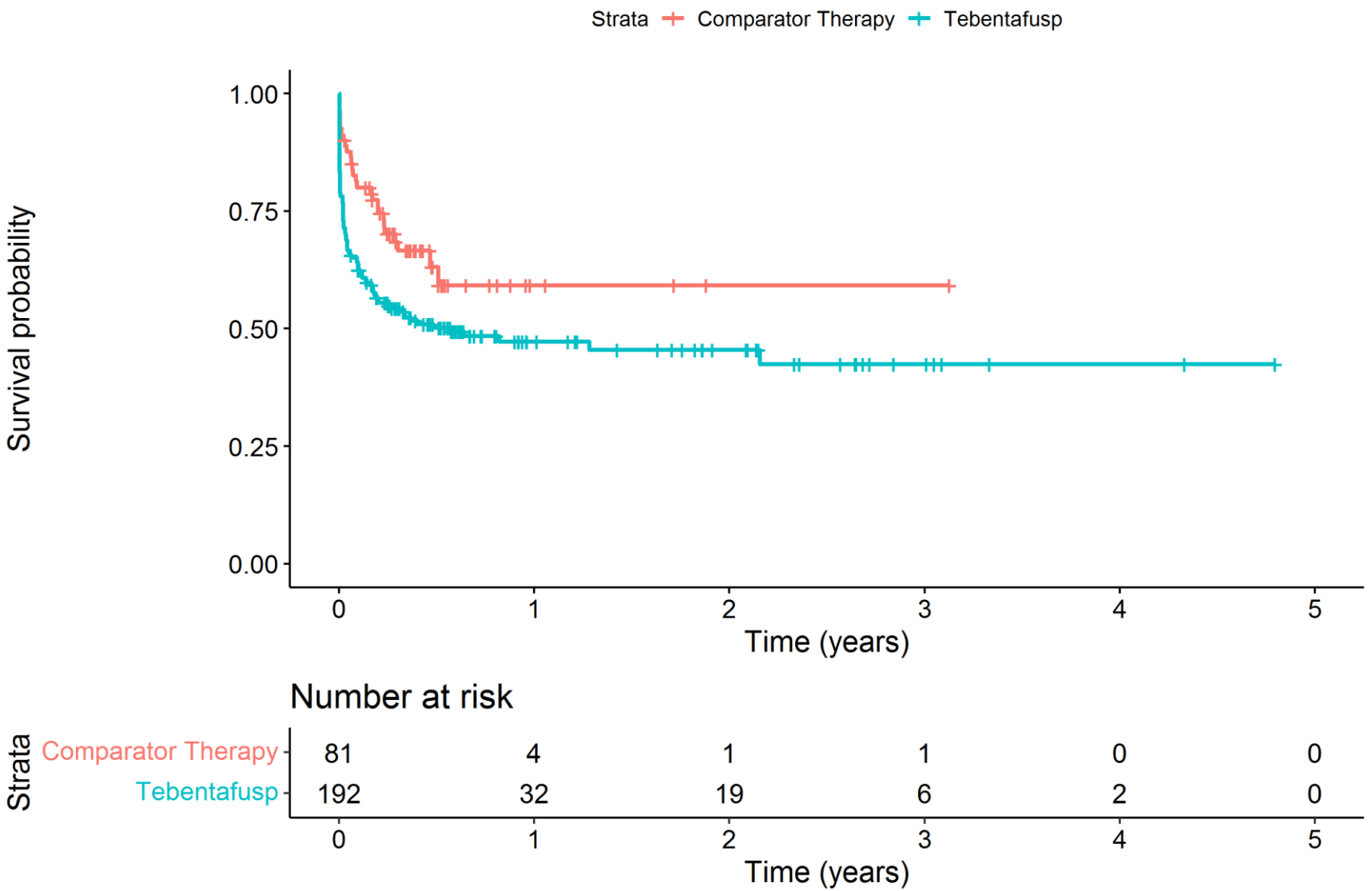
Übelkeit - <65


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
50
2
0
0
126
15
7
2
0
1
2
3
Time (years)

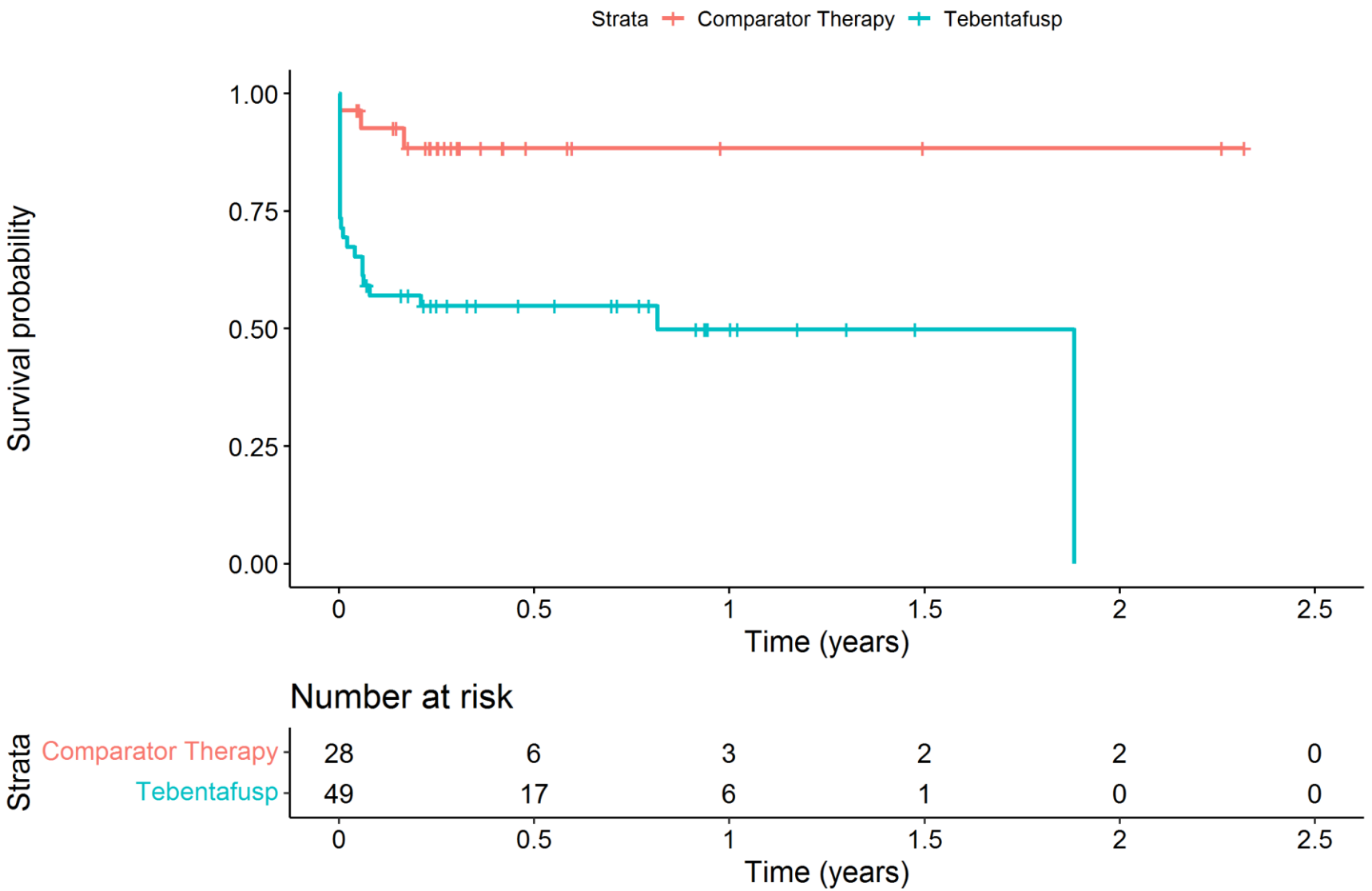
Übelkeit - ≥65


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
4
5
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
61
6
3
1
0
0
119
23
12
4
2
0
0
1
2
3
4
5
Time (years)

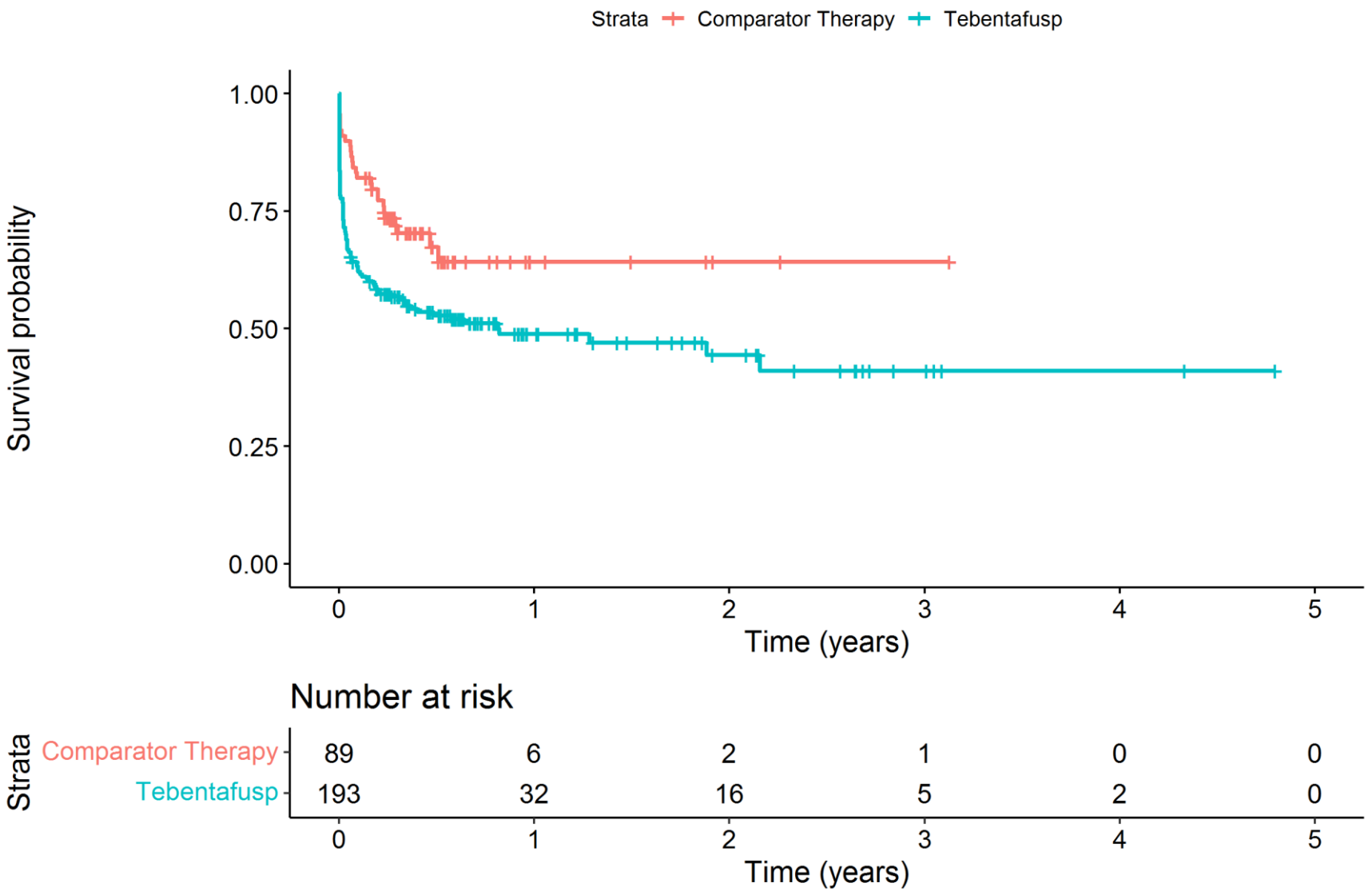
Übelkeit - ECOG 0



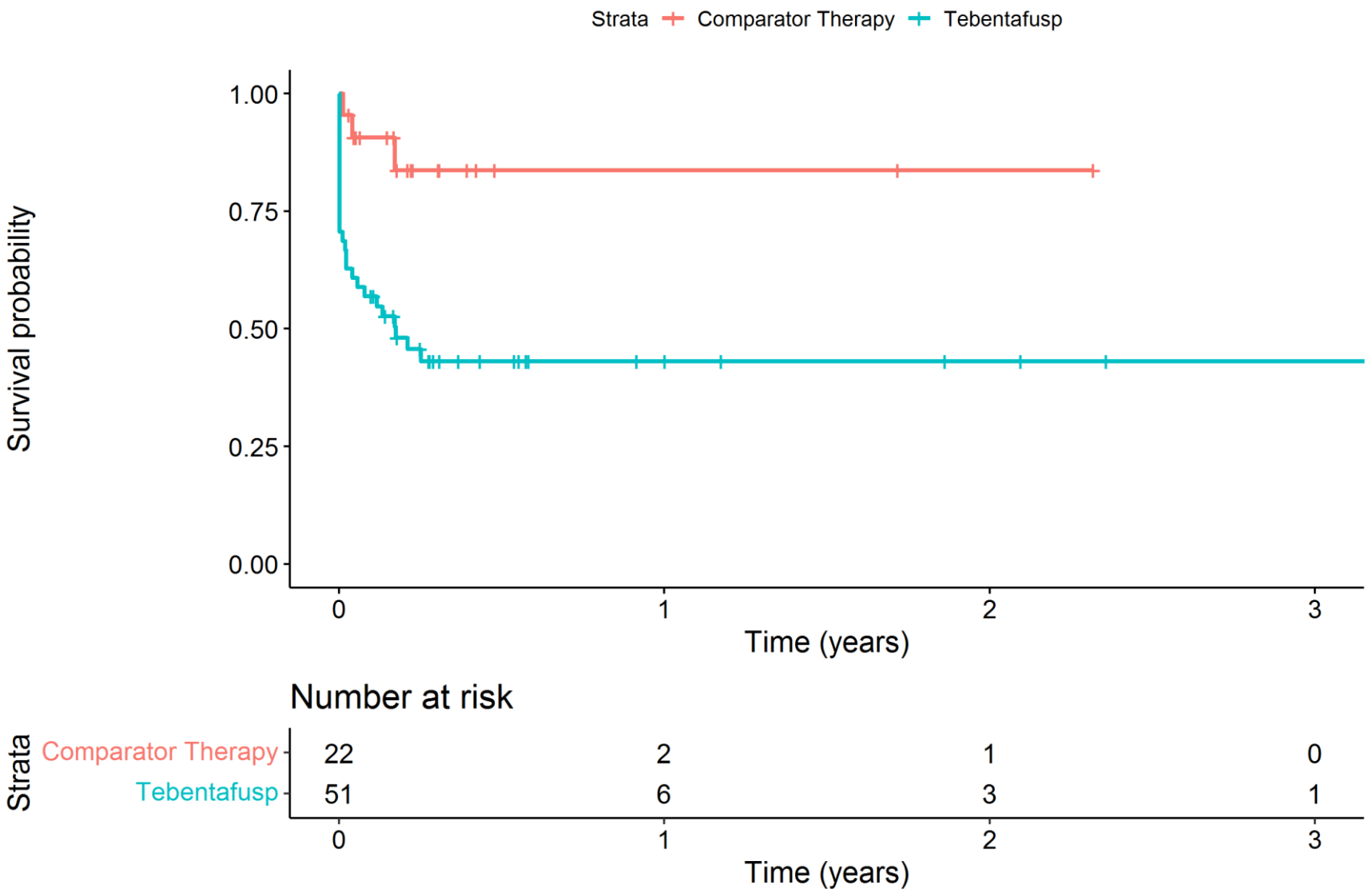
Übelkeit - ECOG 1



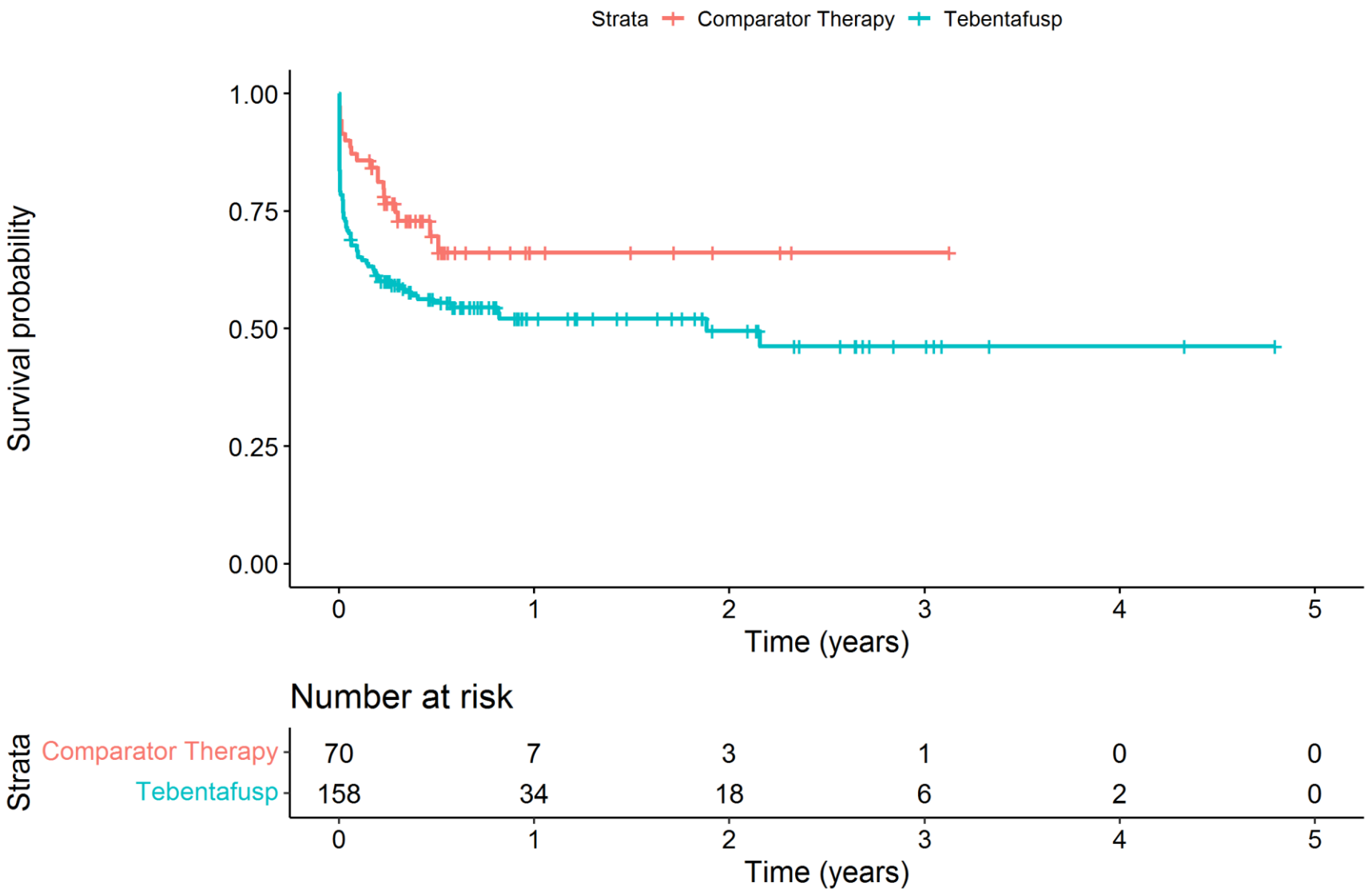
Übelkeit - ALP ≤ ULN



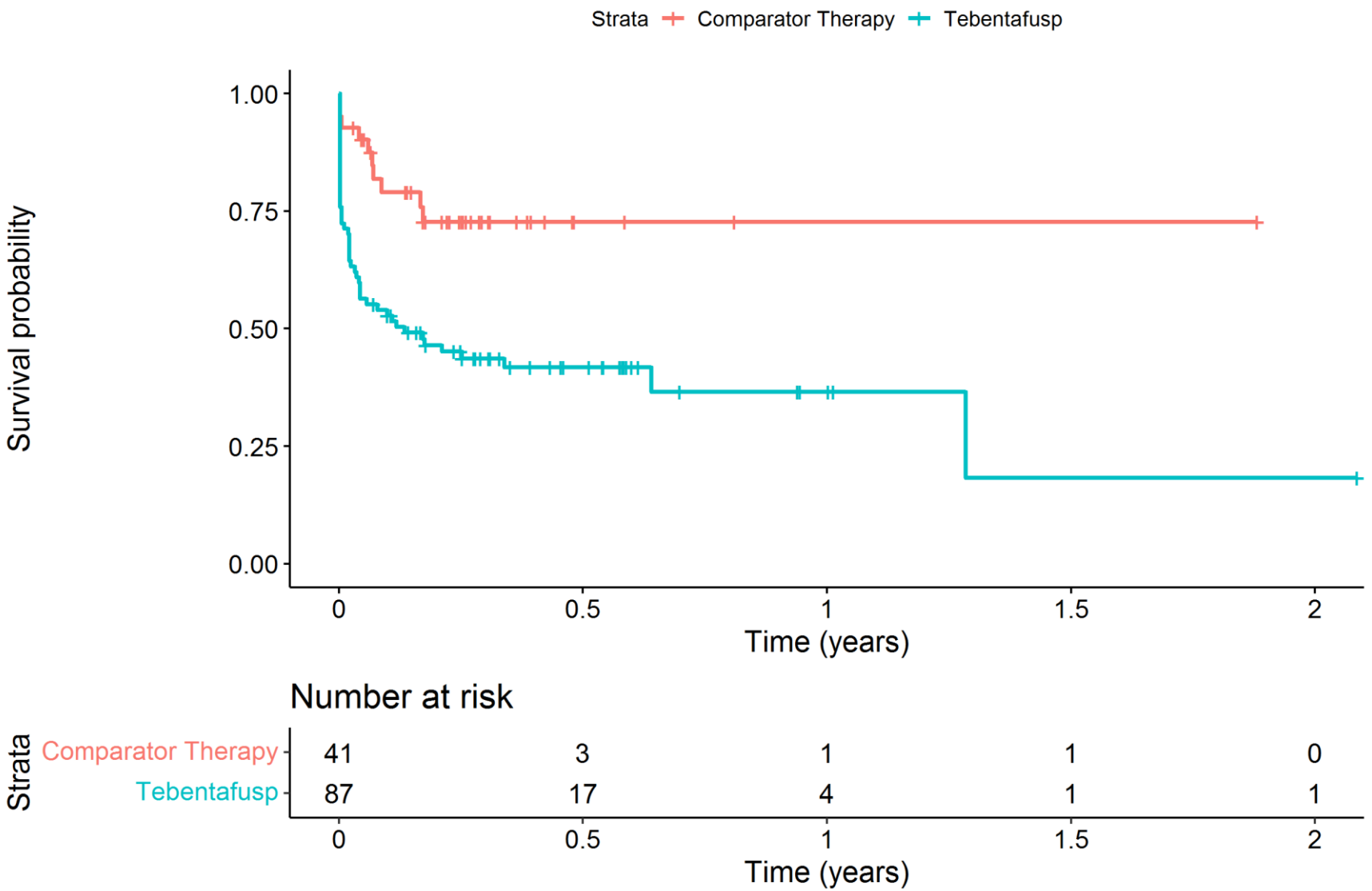
Übelkeit - ALP > ULN



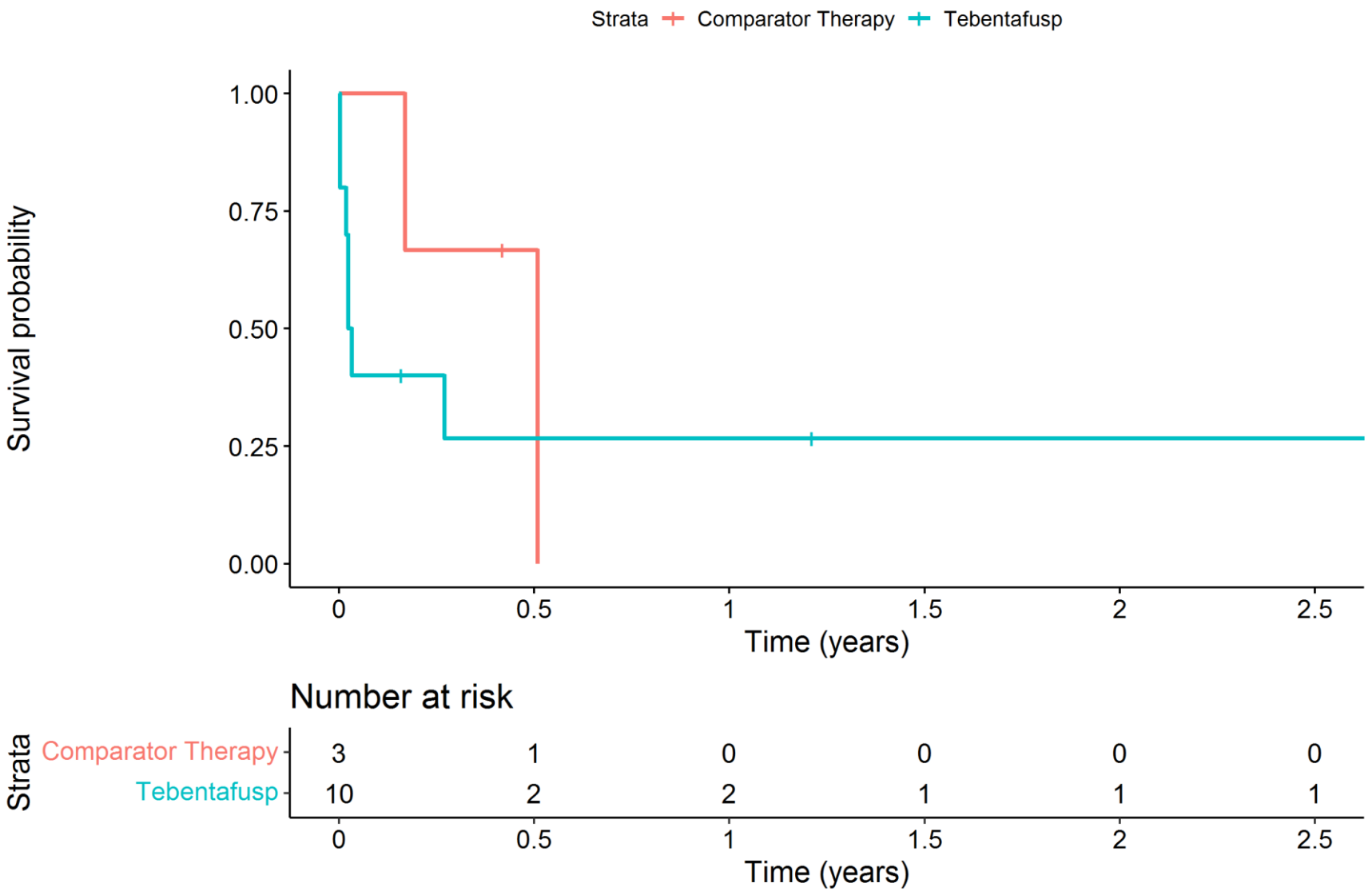
Übelkeit - LDH =< ULN



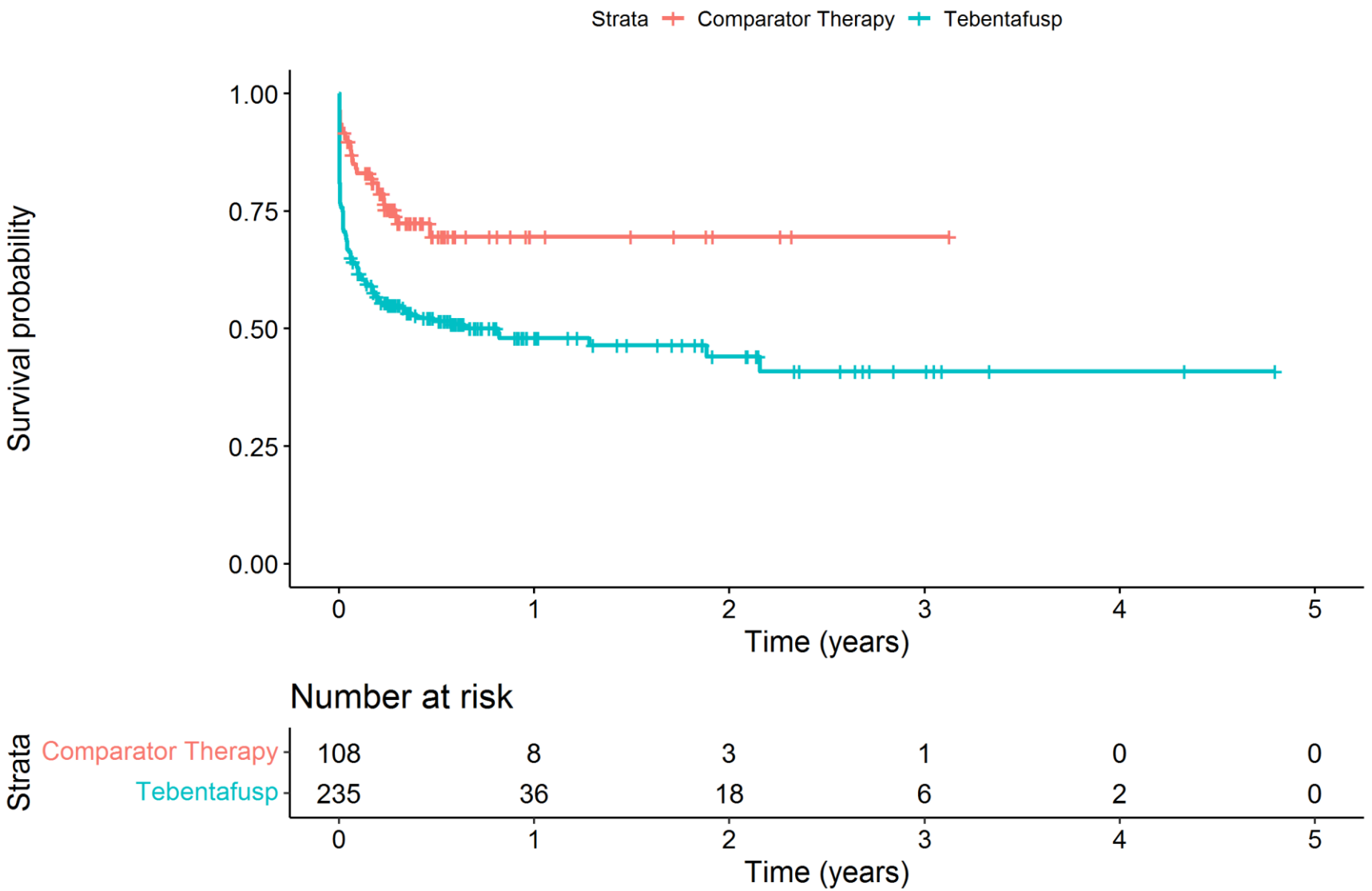
Übelkeit - LDH > ULN



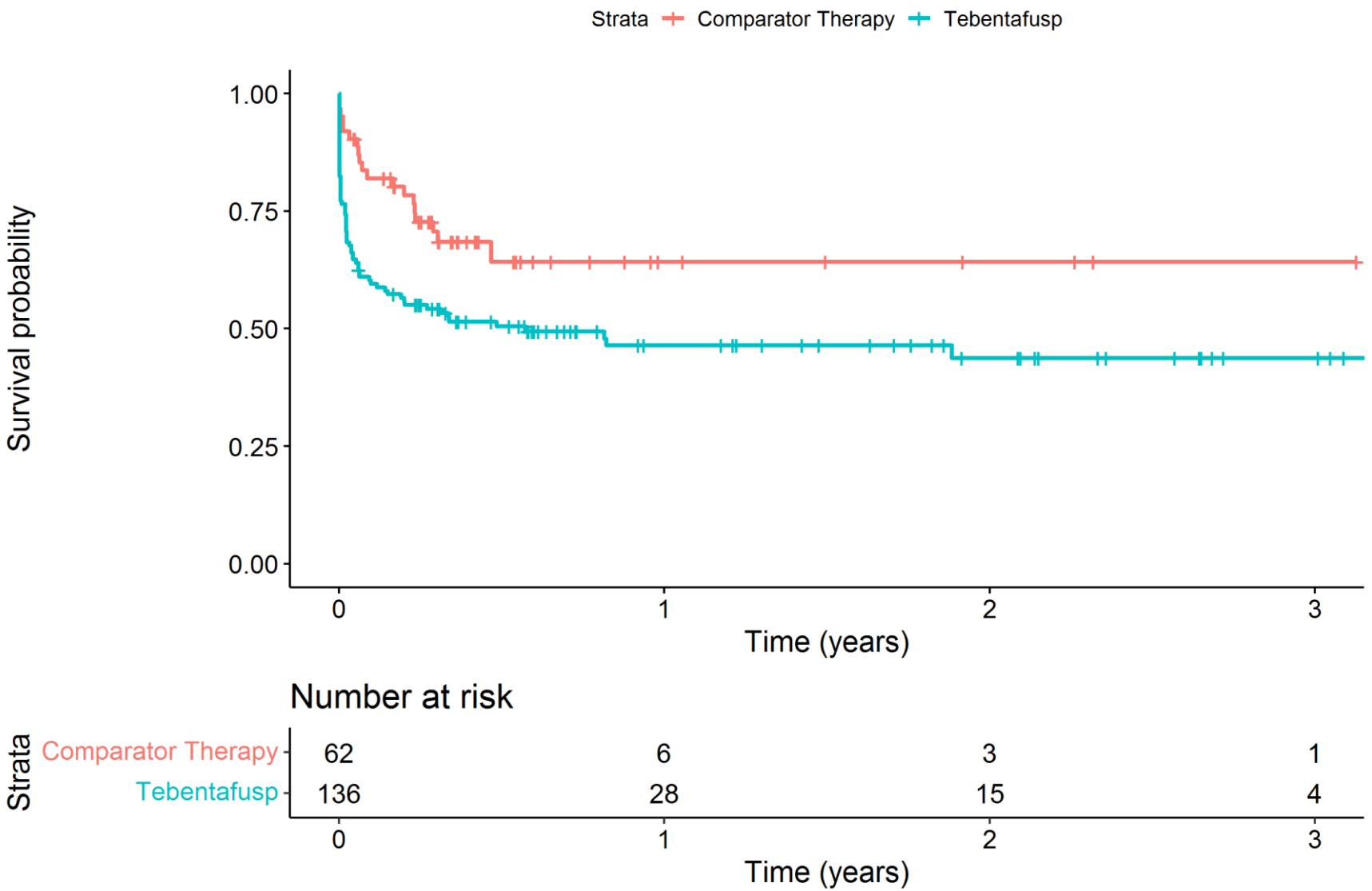
Übelkeit - Vorherige Therapie adjuvant/neoadjuvant



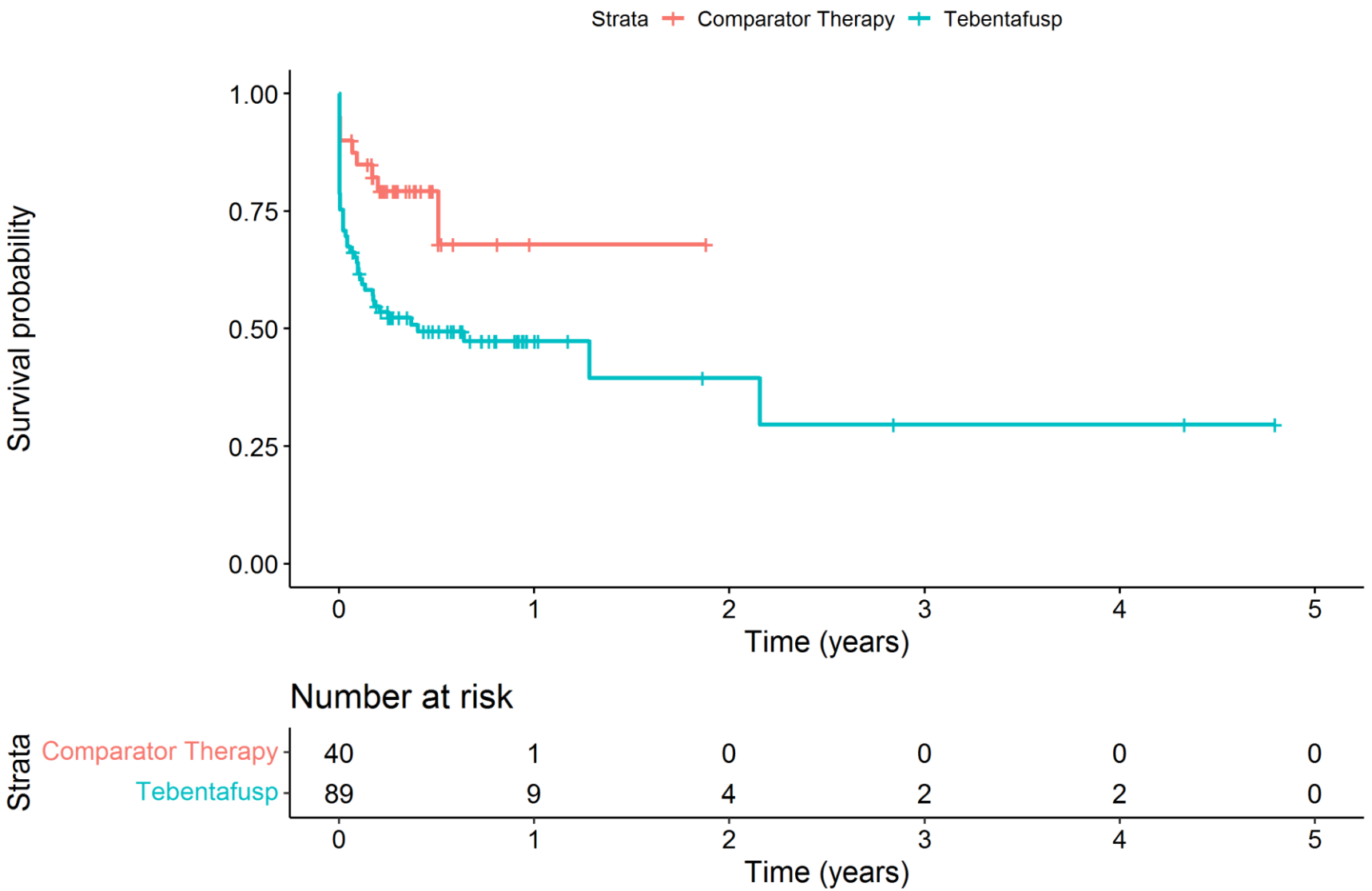
Übelkeit - Keine Vorherige Therapie adjuvant/neoadjuvant



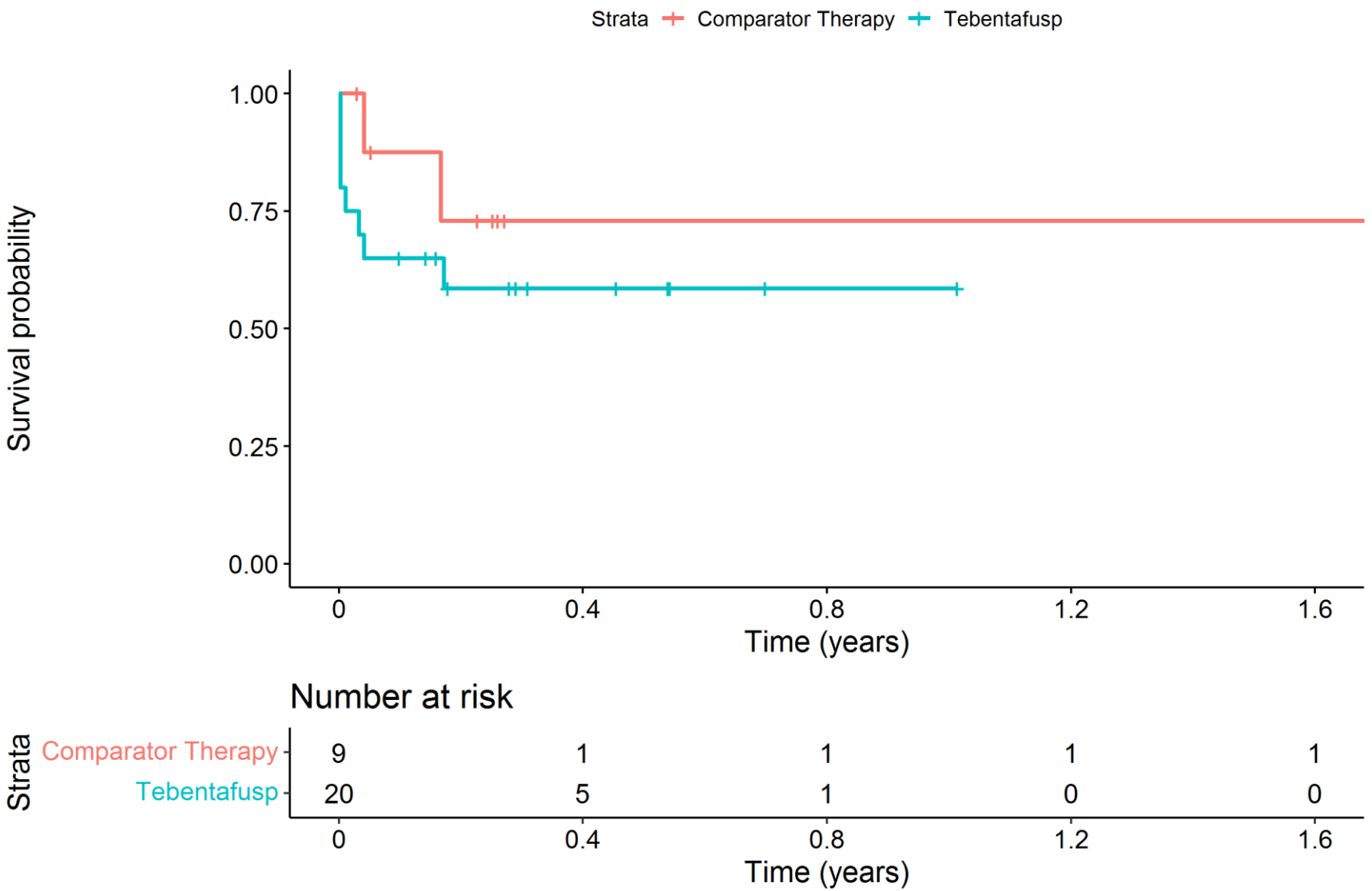
Übelkeit - Läsion ≤ 3cm



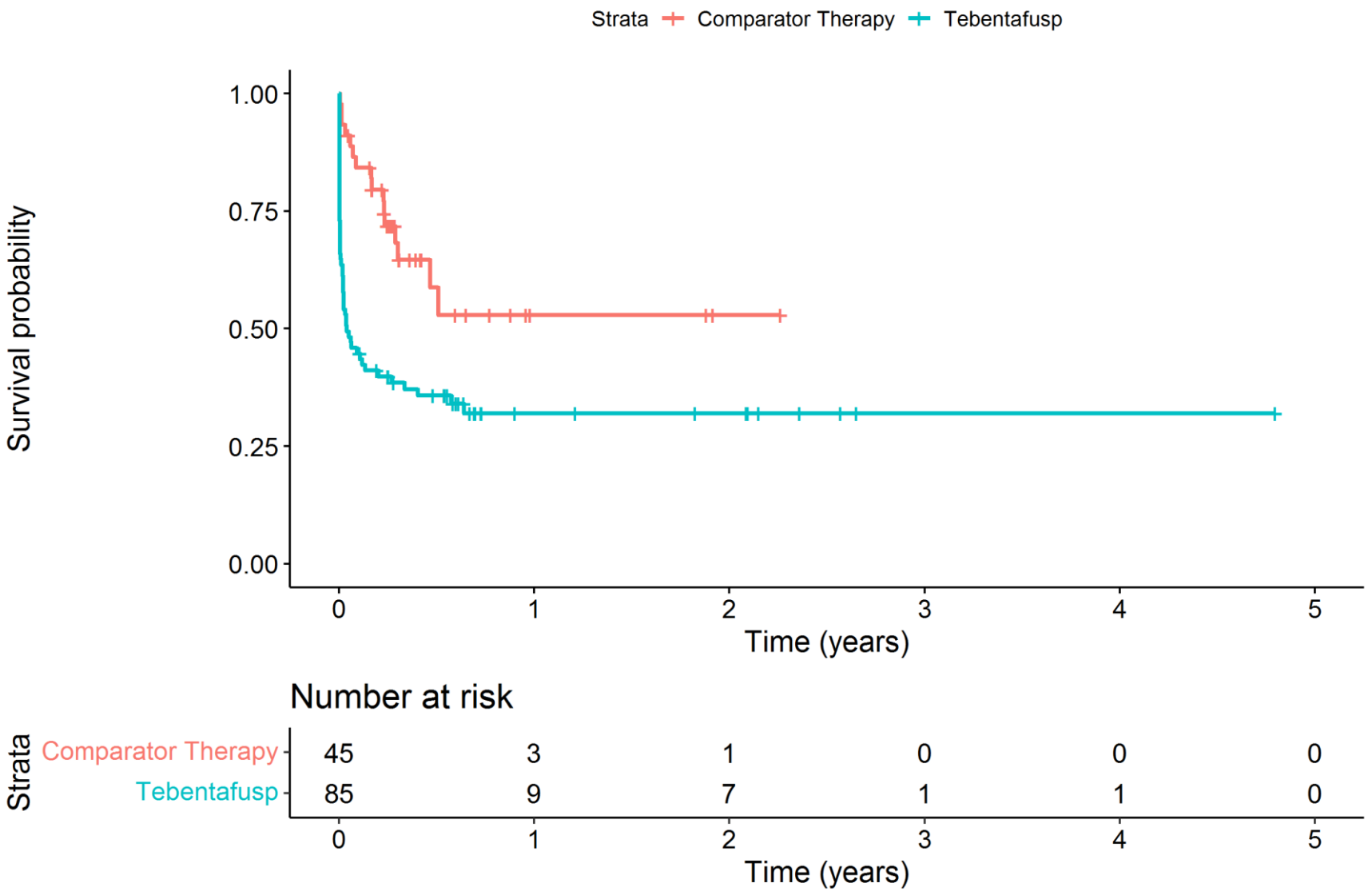
Übelkeit - Läsion 3,1-8,0 cm



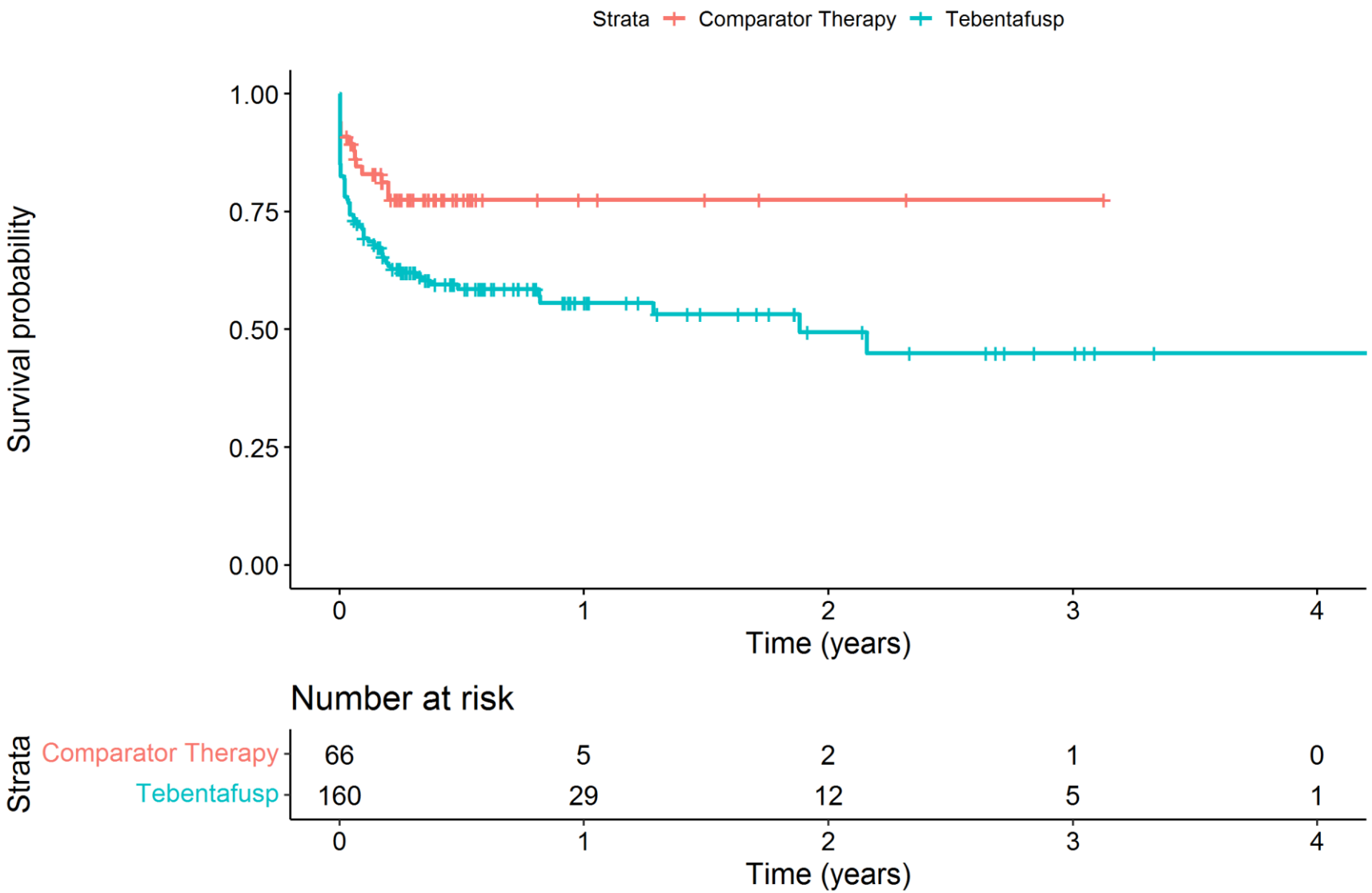
Übelkeit - Läsion ≥8,1 cm



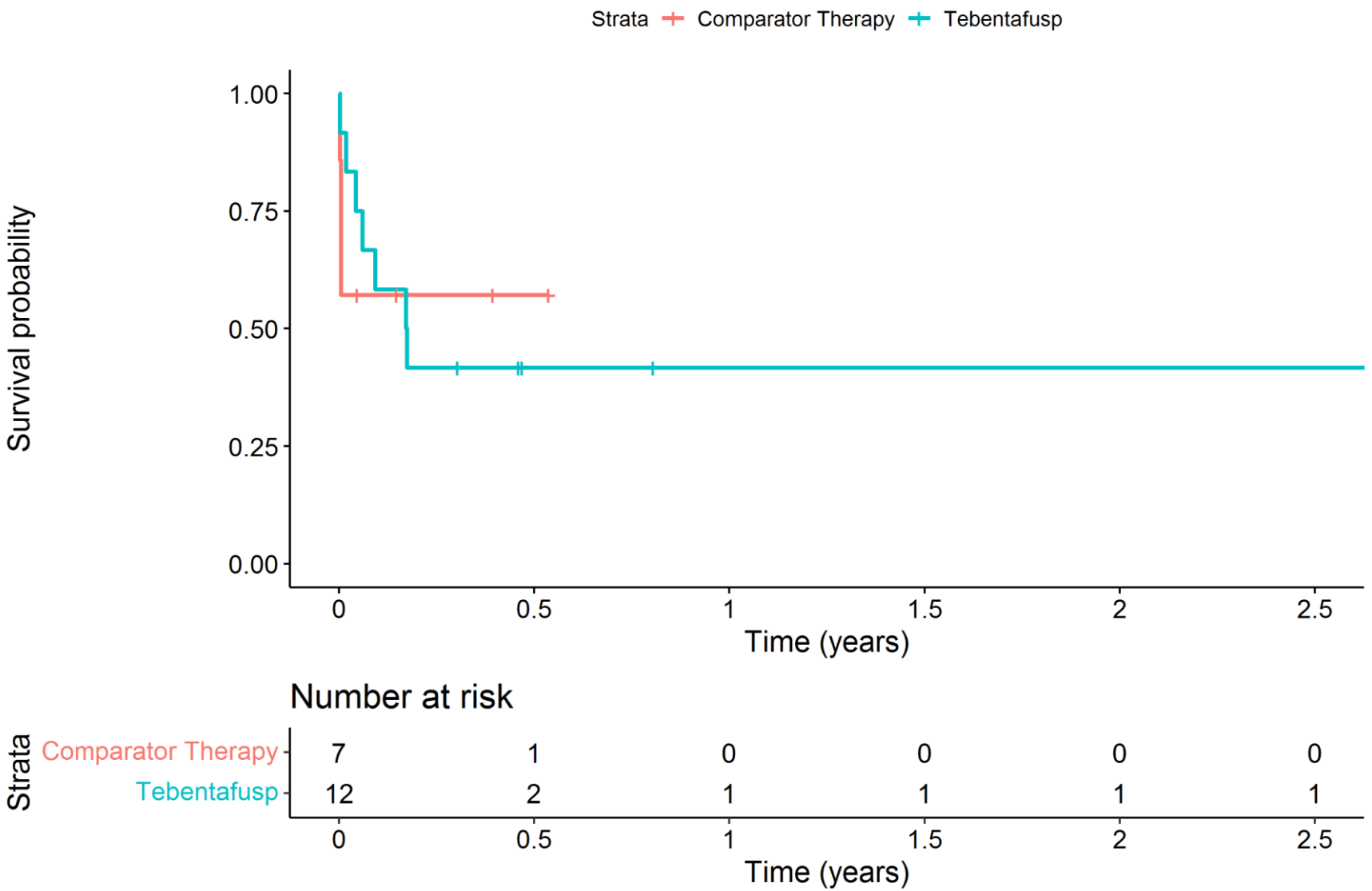
Übelkeit - Nordamerika



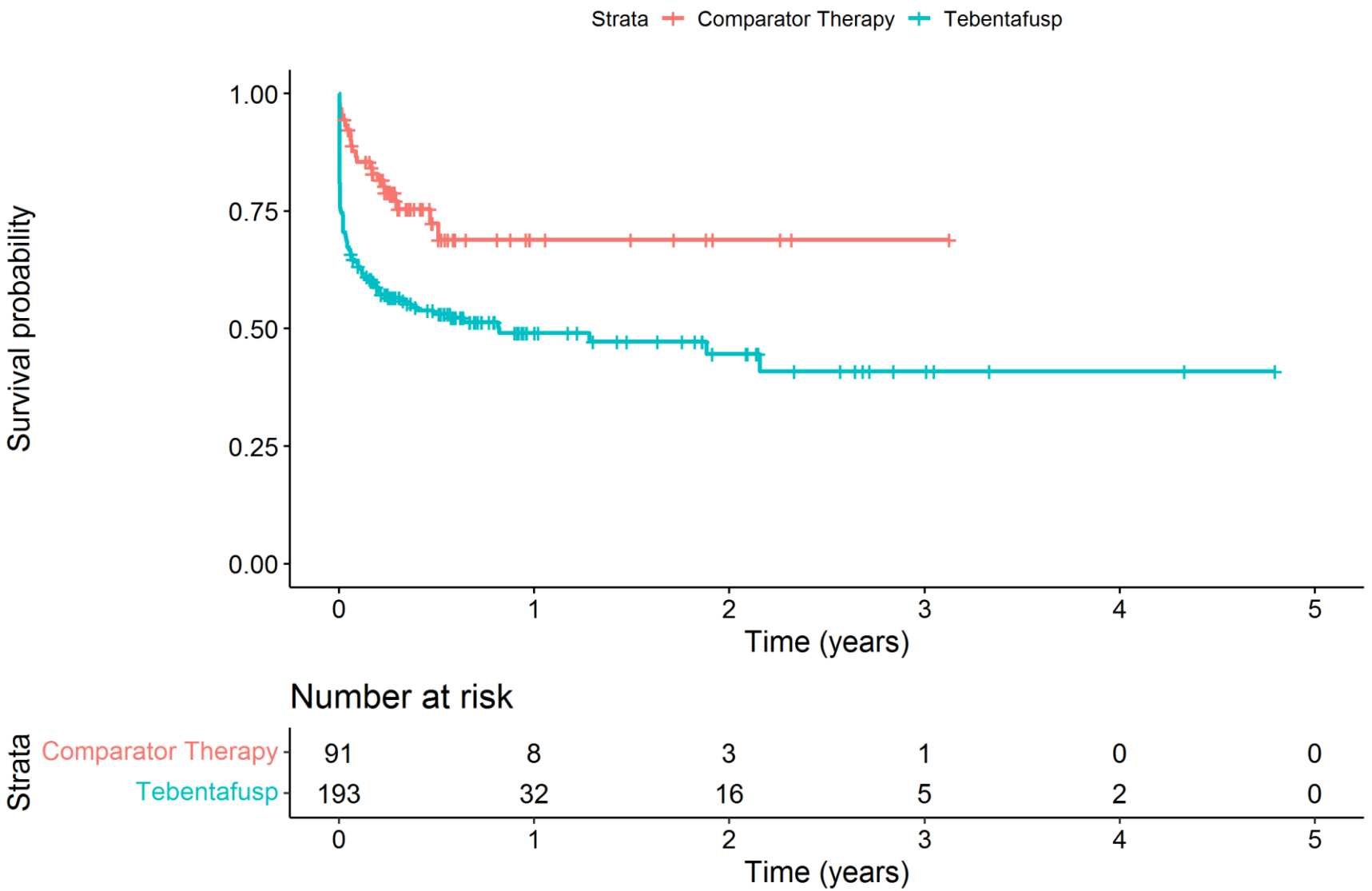
Übelkeit - Nicht-Nordamerika



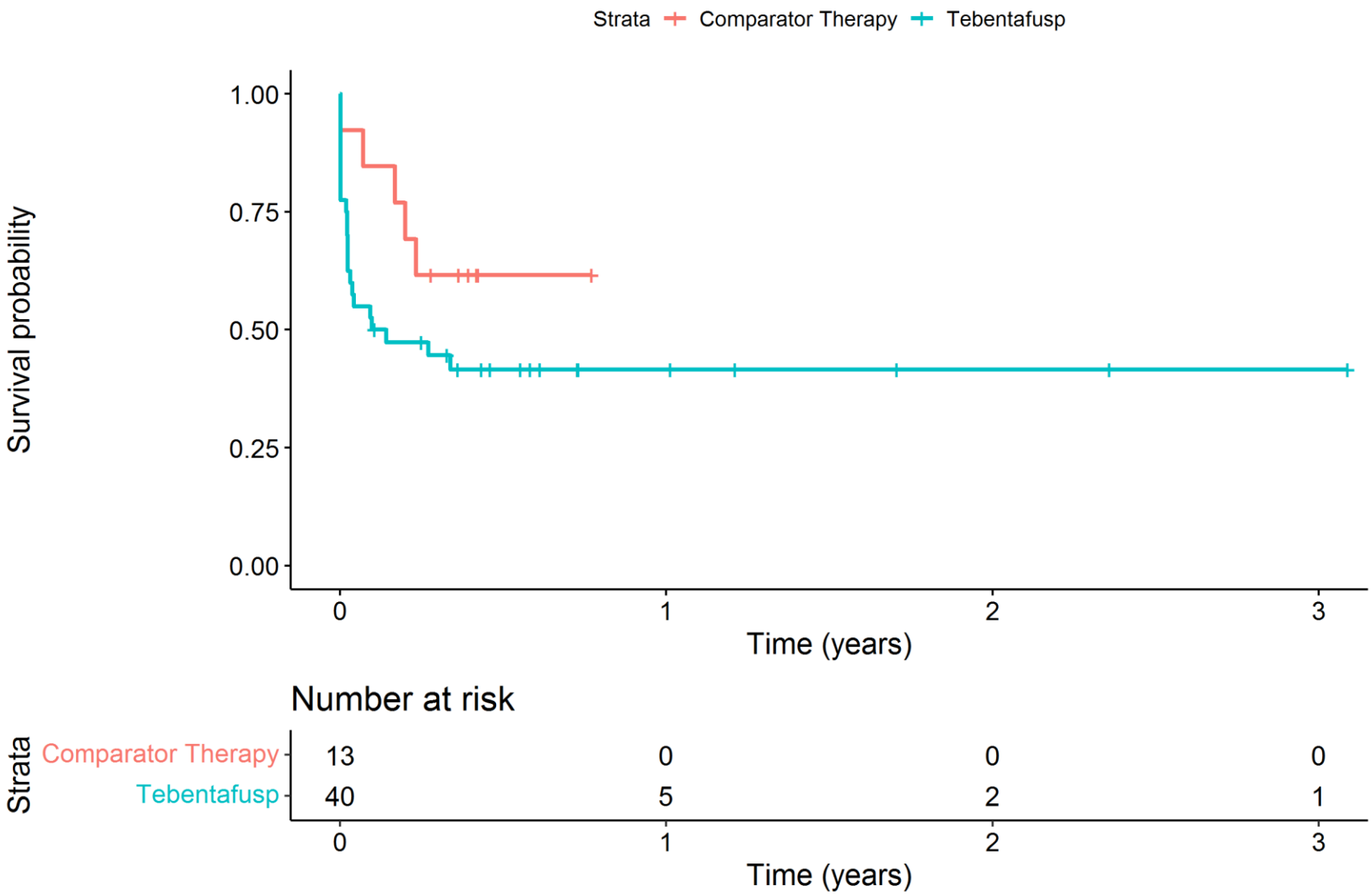
Übelkeit - Dacarbazin



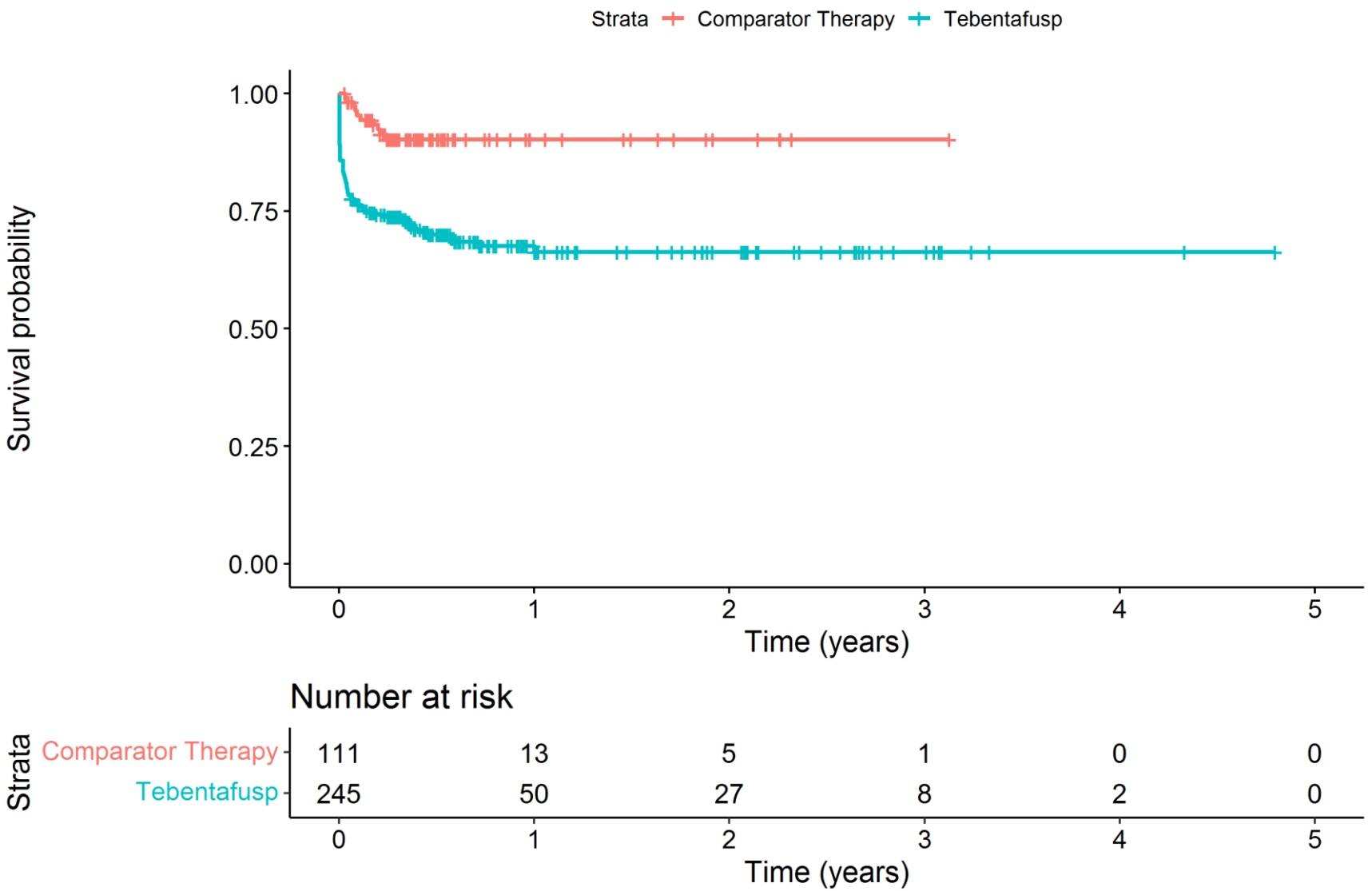
Übelkeit - Pembrolizumab



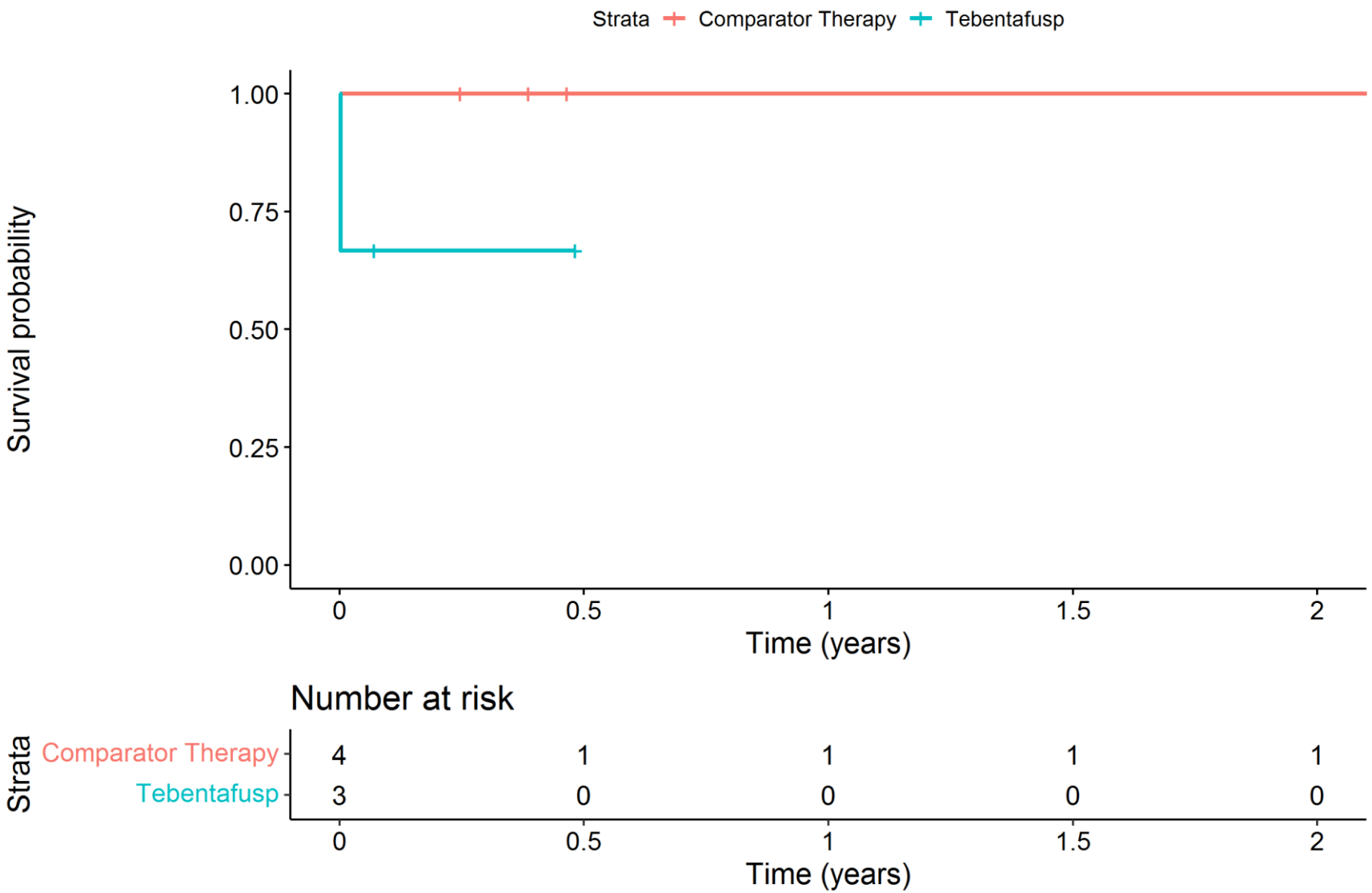
Übelkeit - Ipilimumab



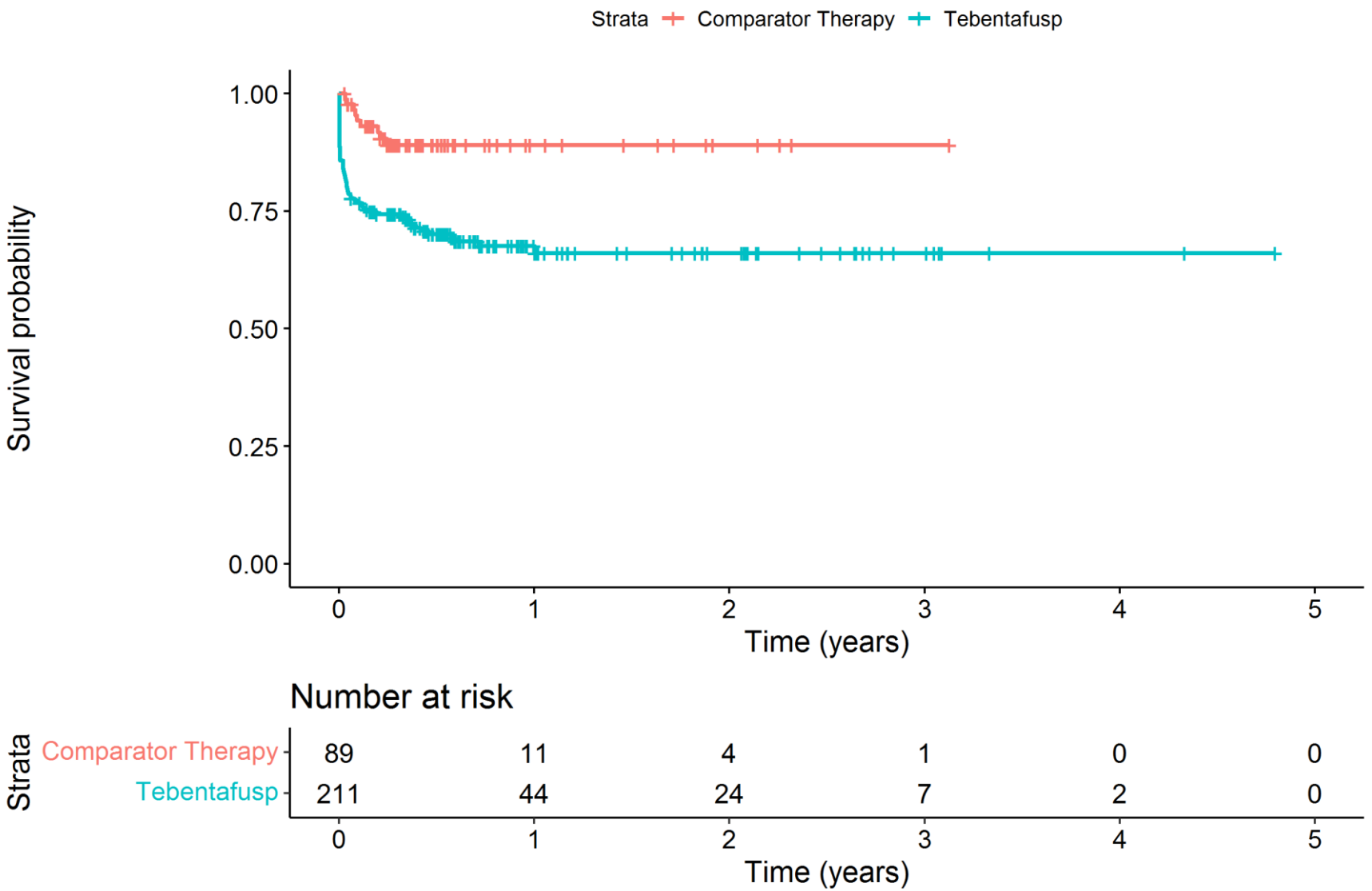
Erbrechen - Gesamt



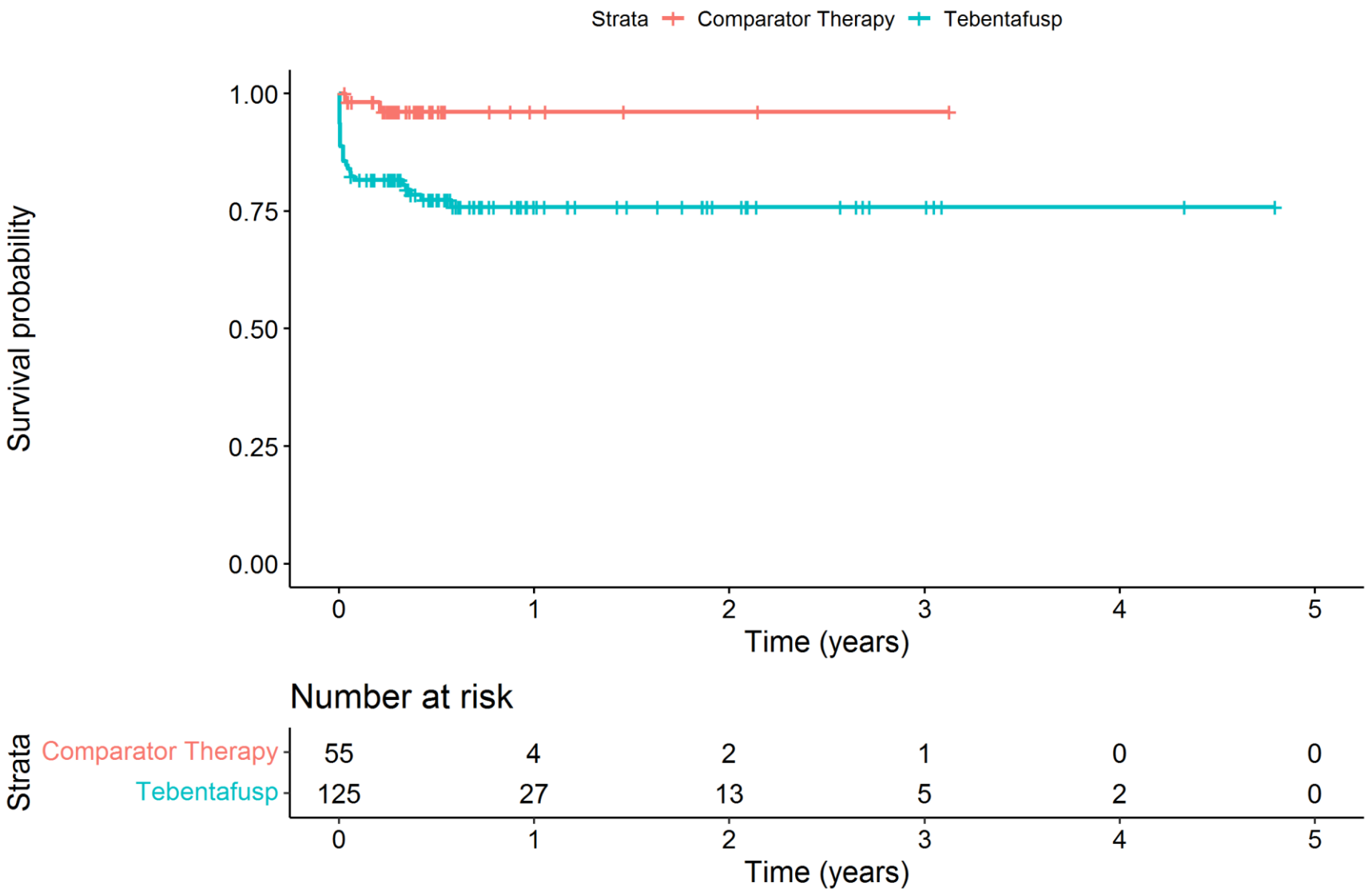
Erbrechen - Hispanisch



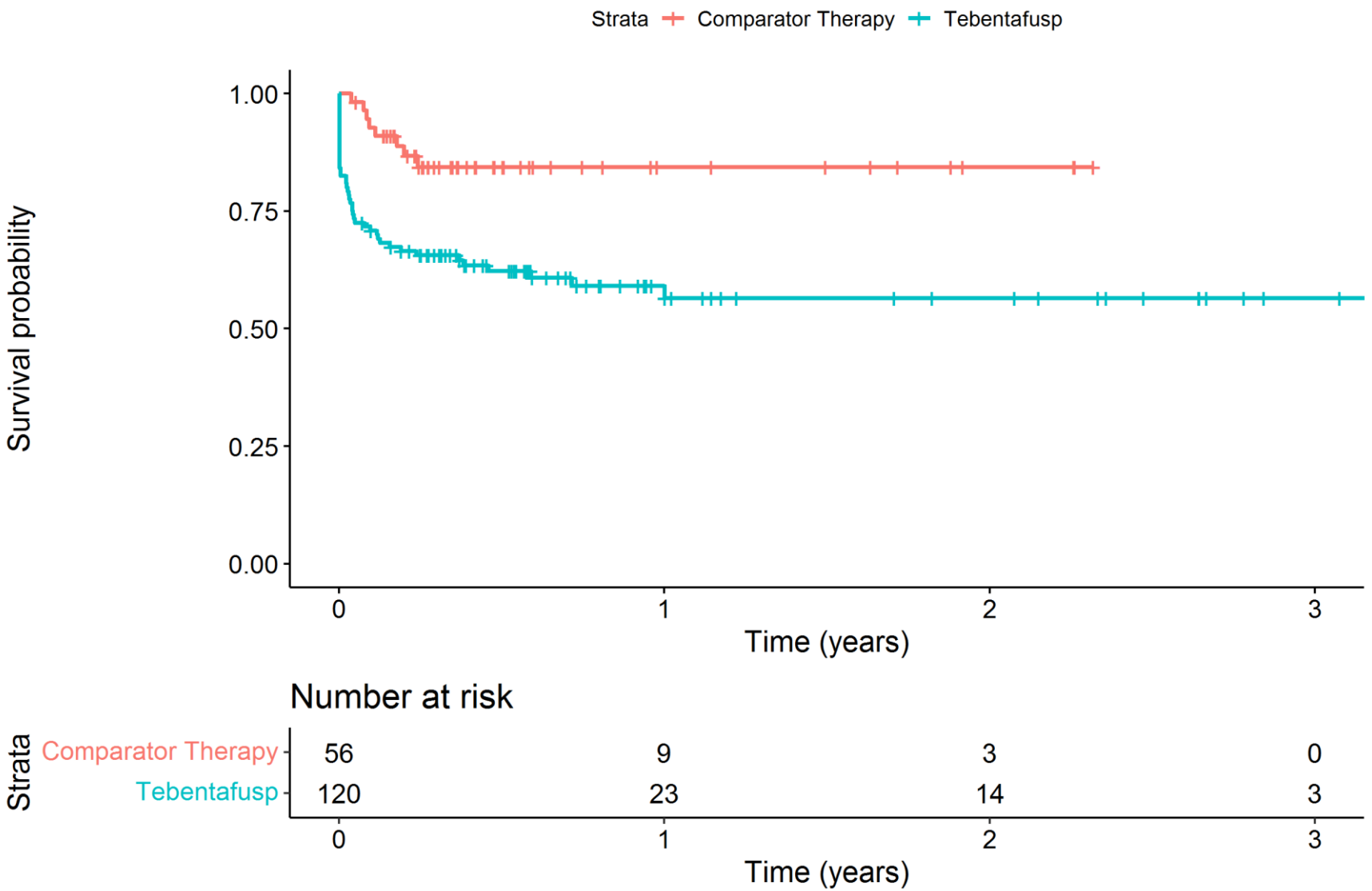
Erbrechen - Nicht-hispanisch



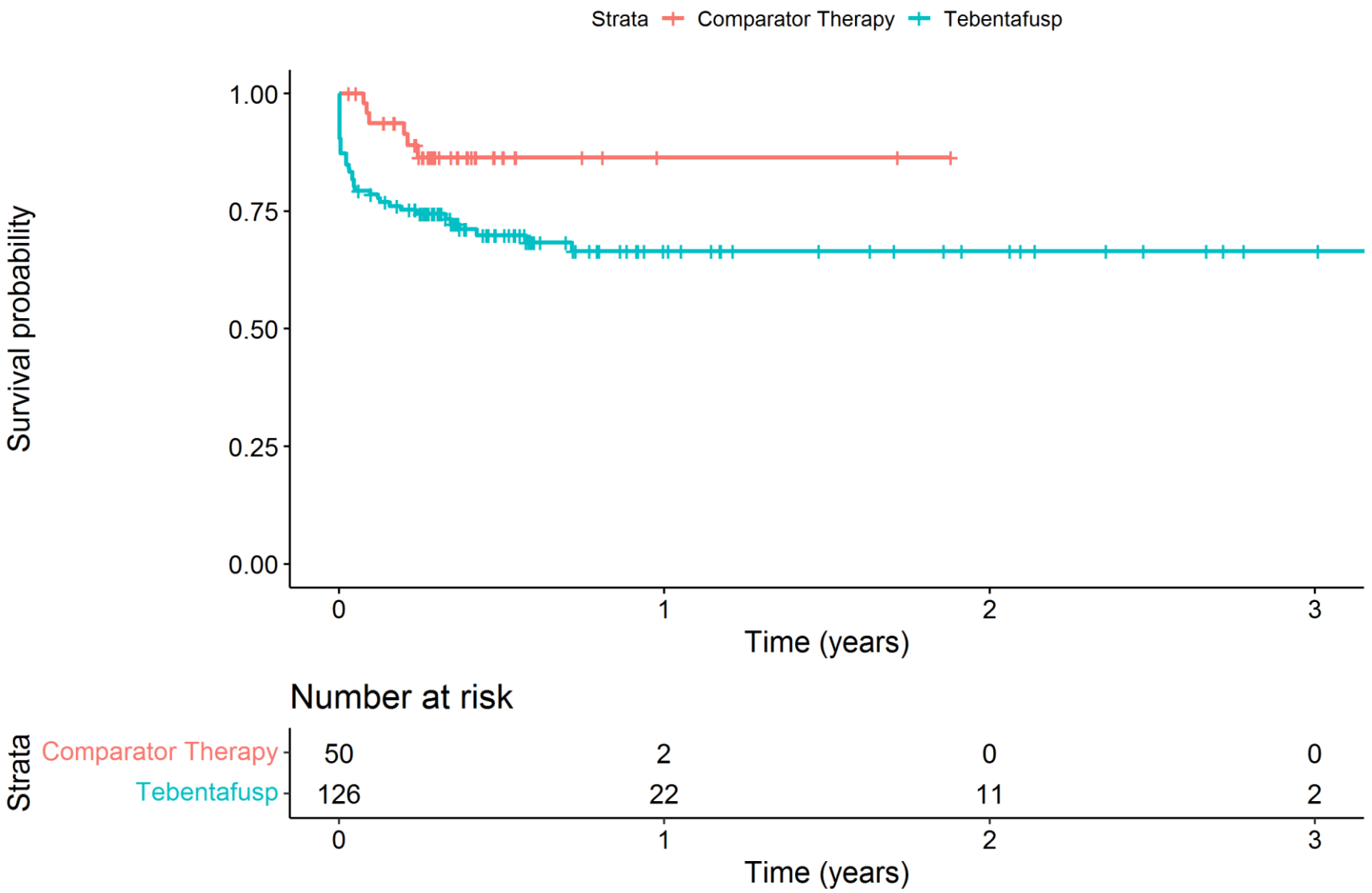
Erbrechen - Männlich



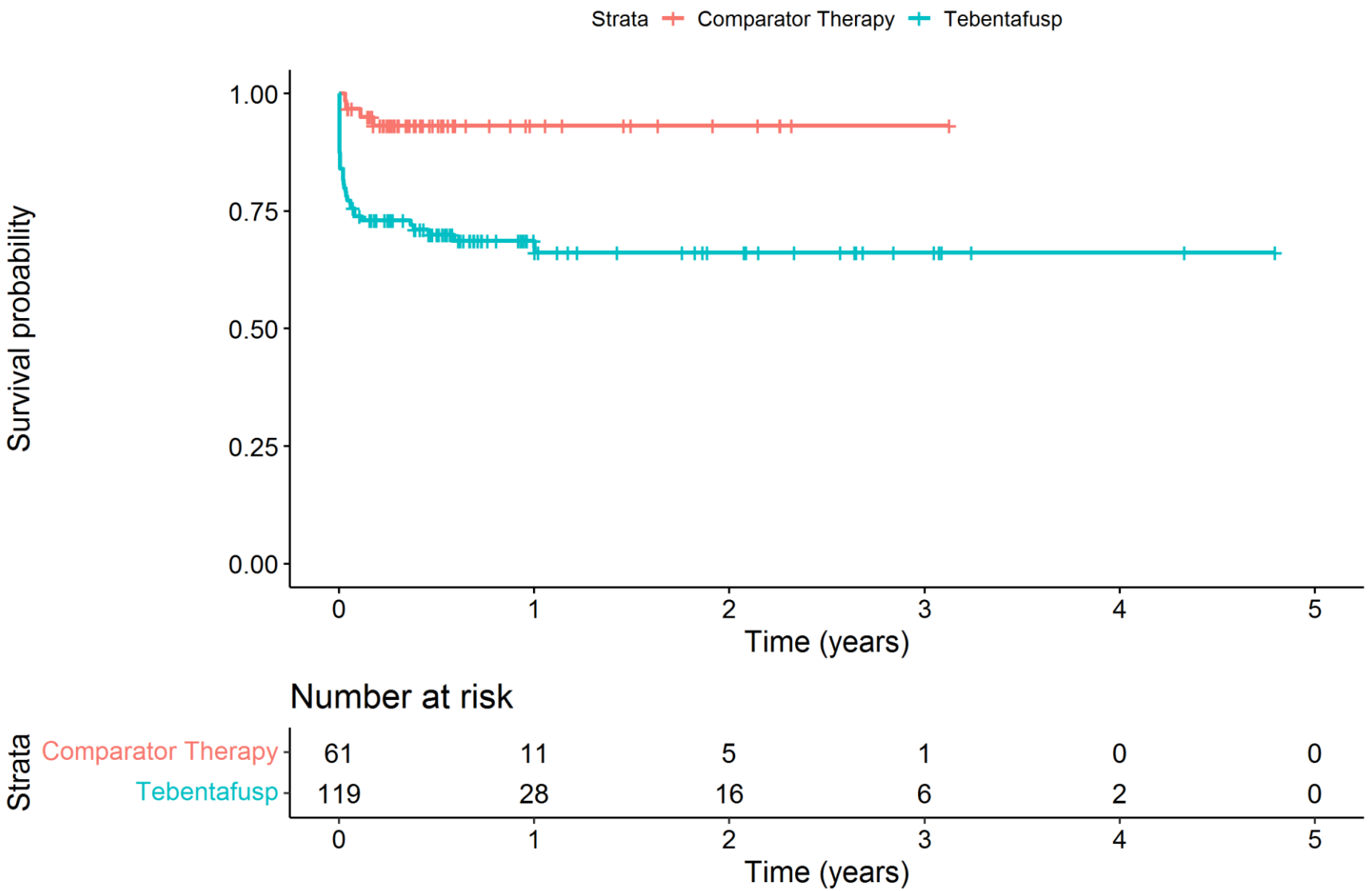
Erbrechen - Weiblich



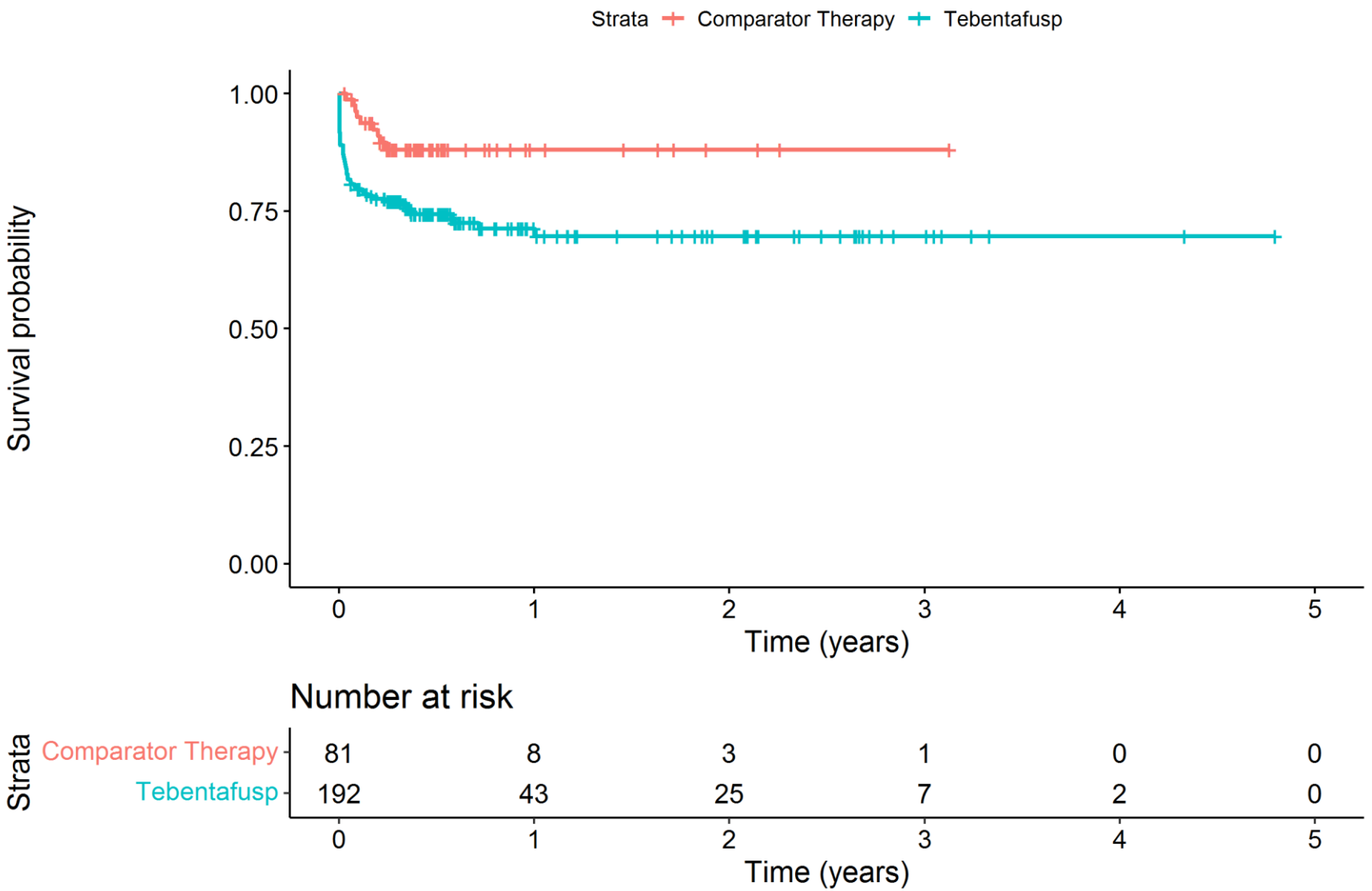
Erbrechen - <65



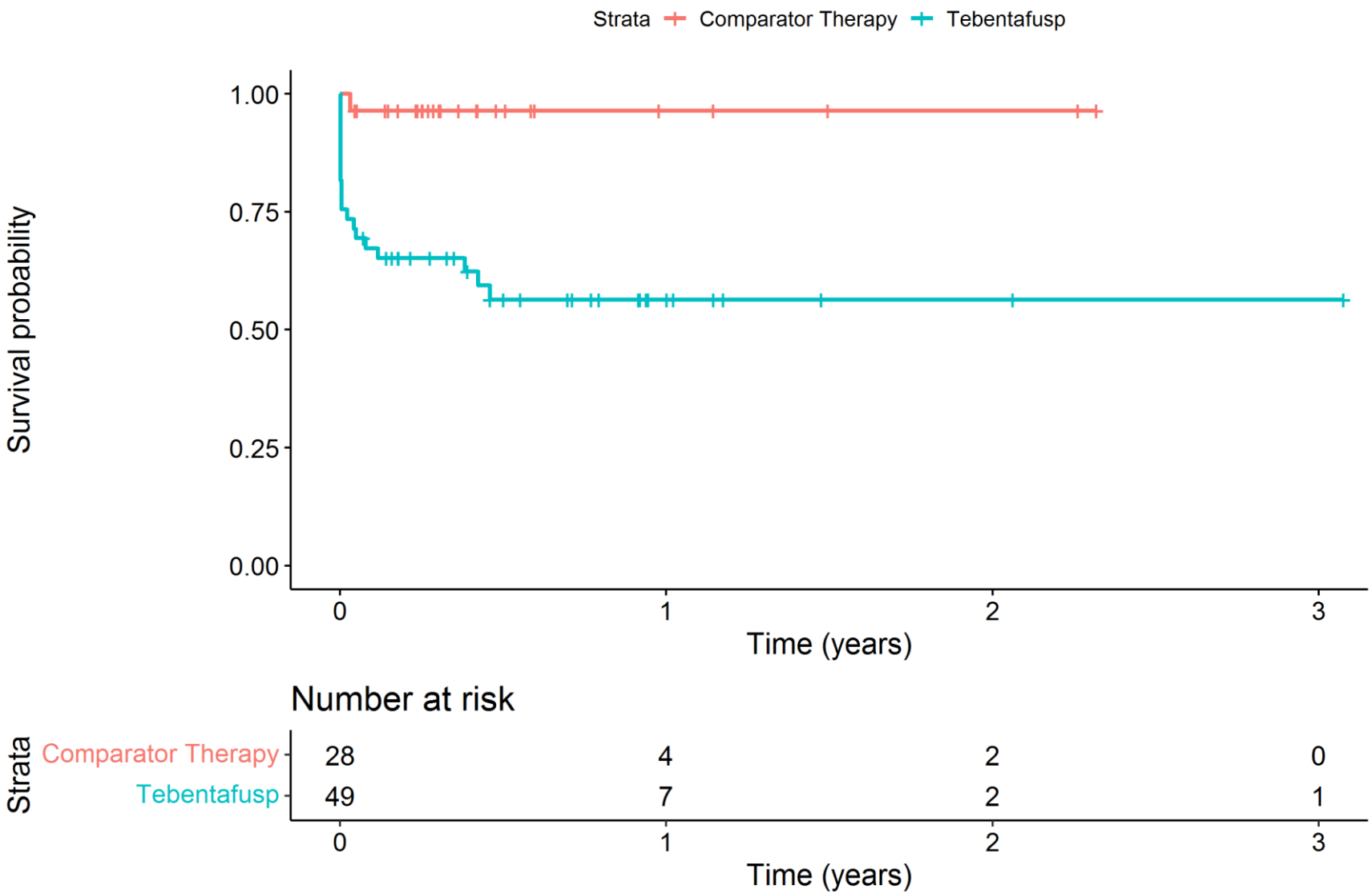
Erbrechen - ≥65



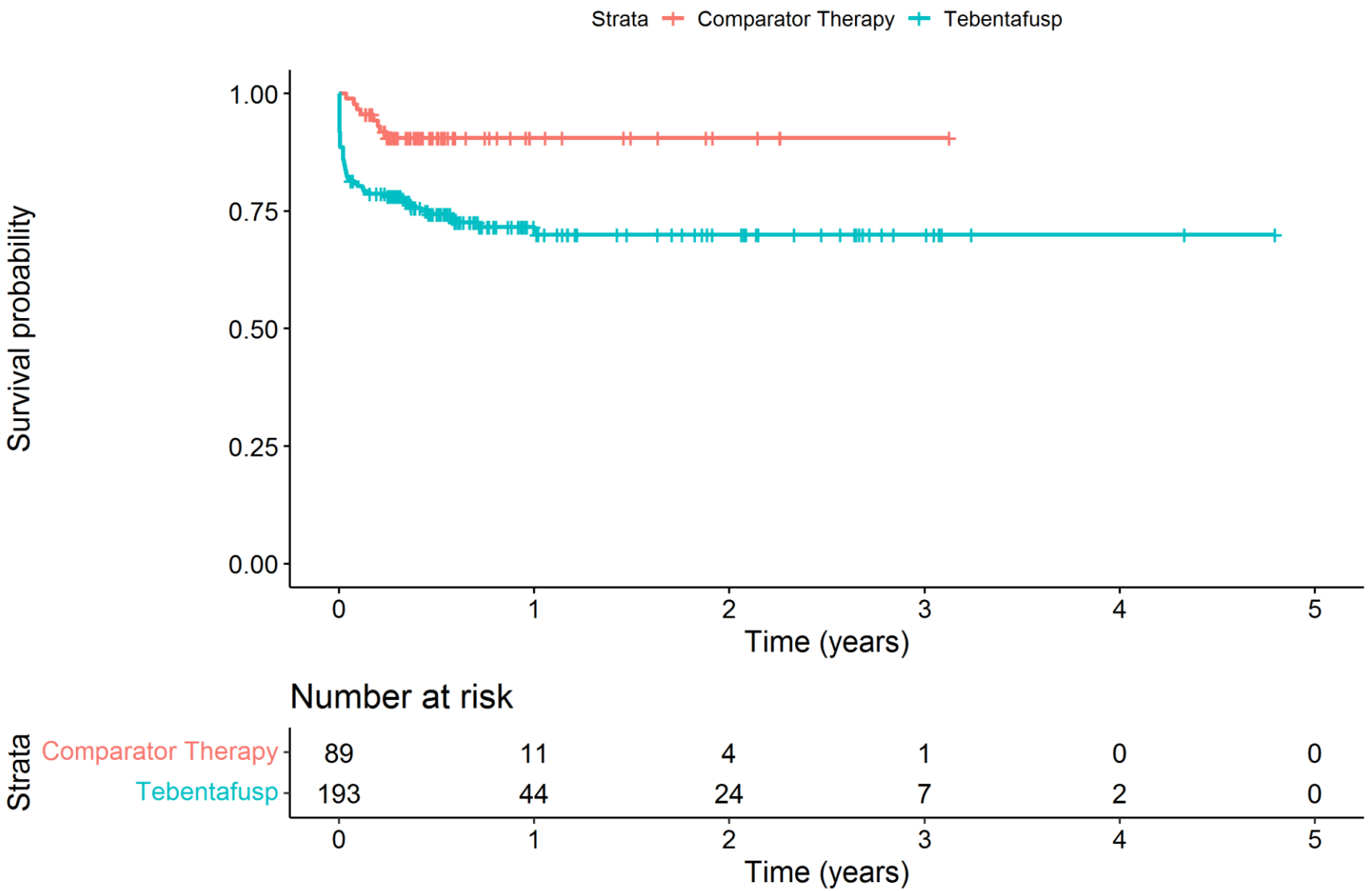
Erbrechen - ECOG 0



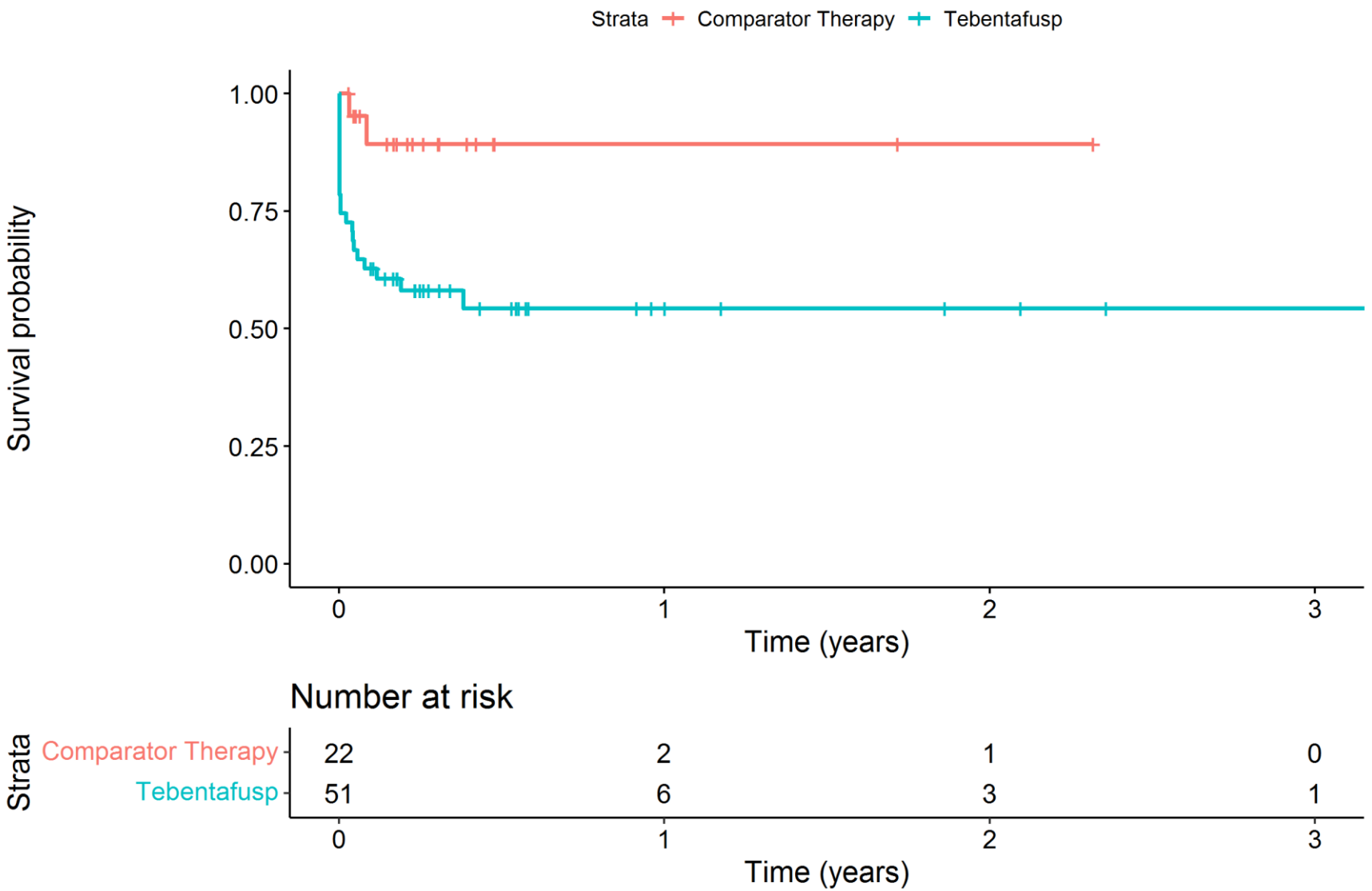
Erbrechen - ECOG 1



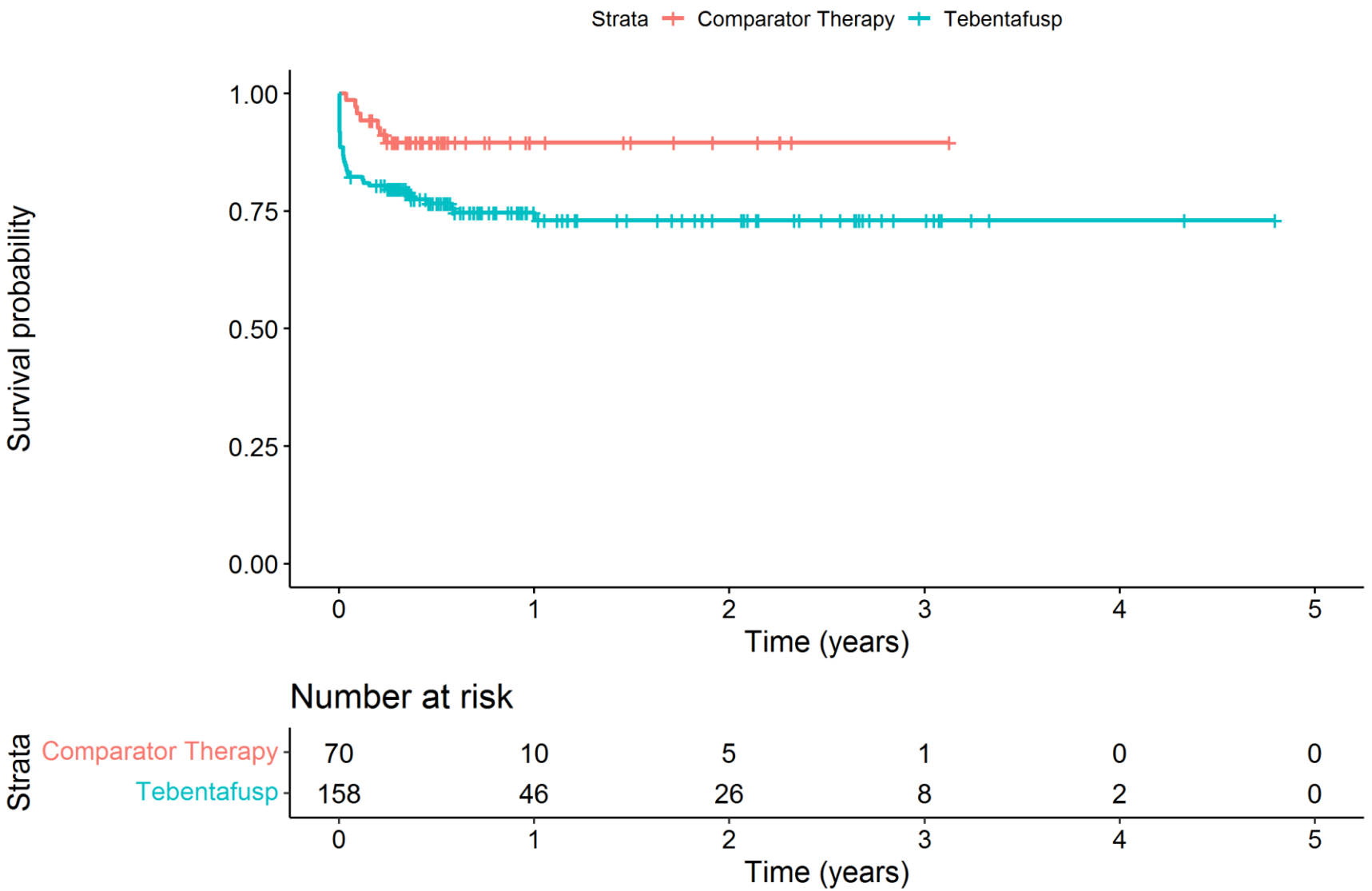
Erbrechen - ALP ≤ ULN



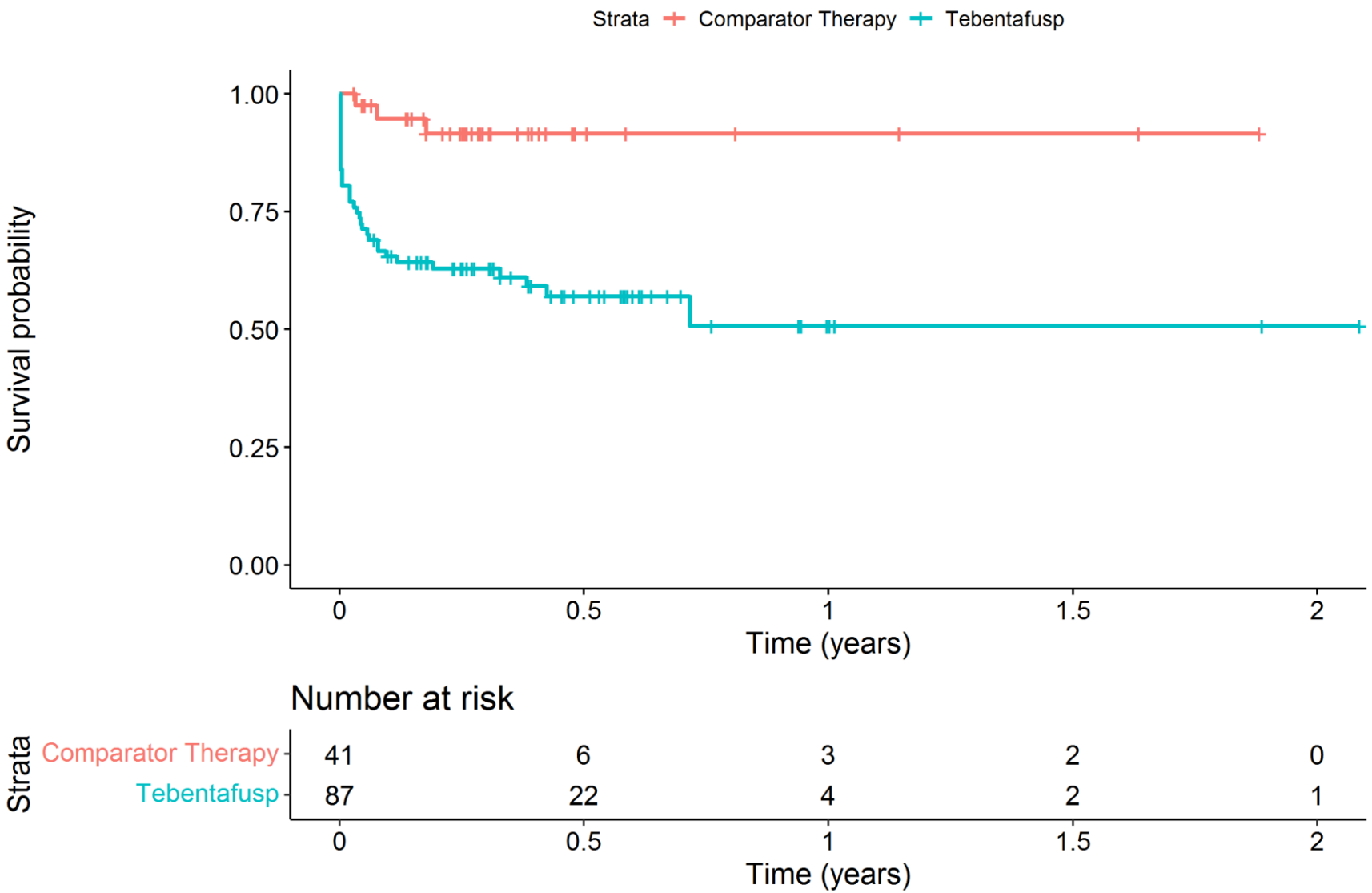
Erbrechen - ALP > ULN



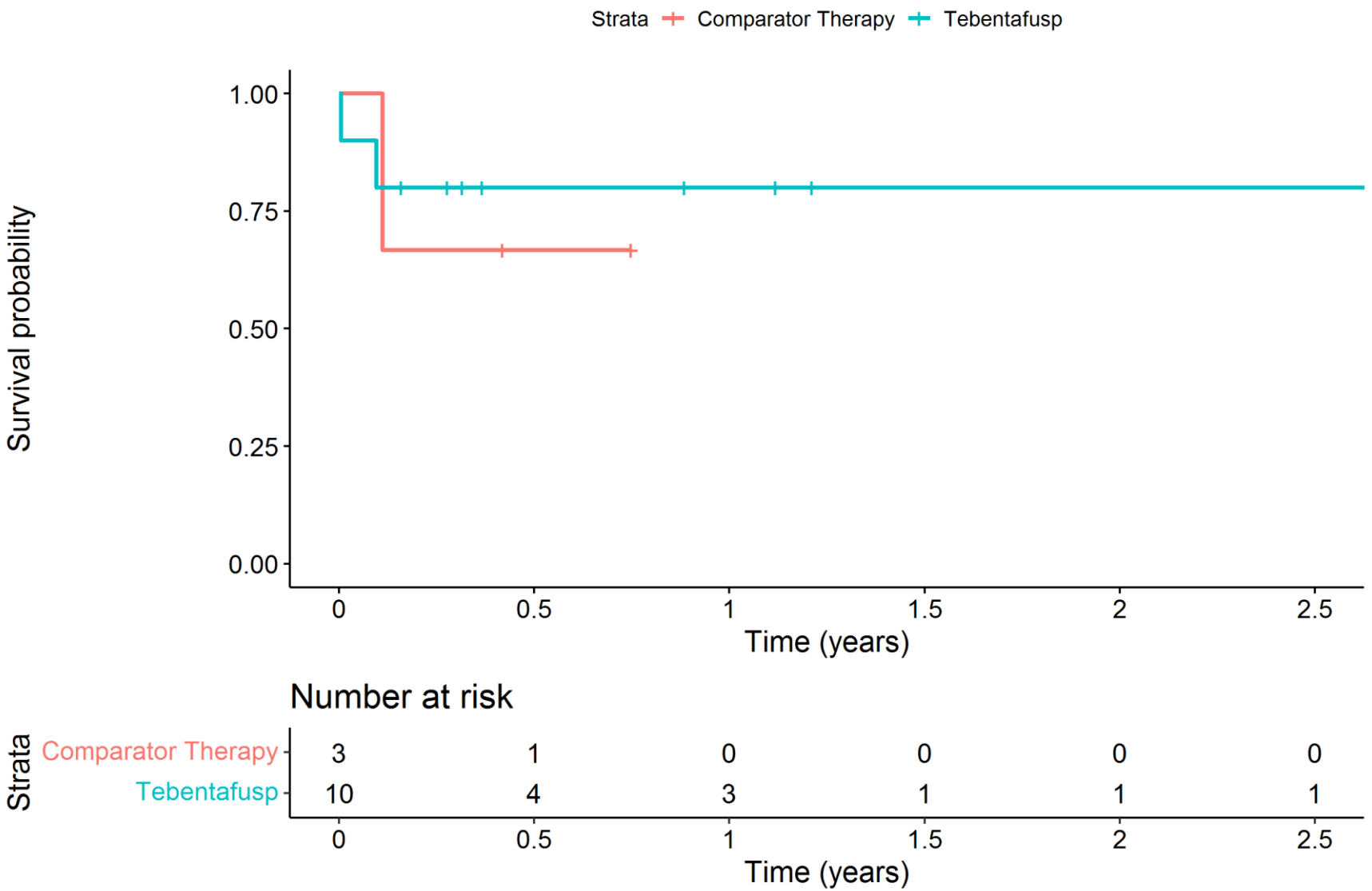
Erbrechen - LDH =< ULN



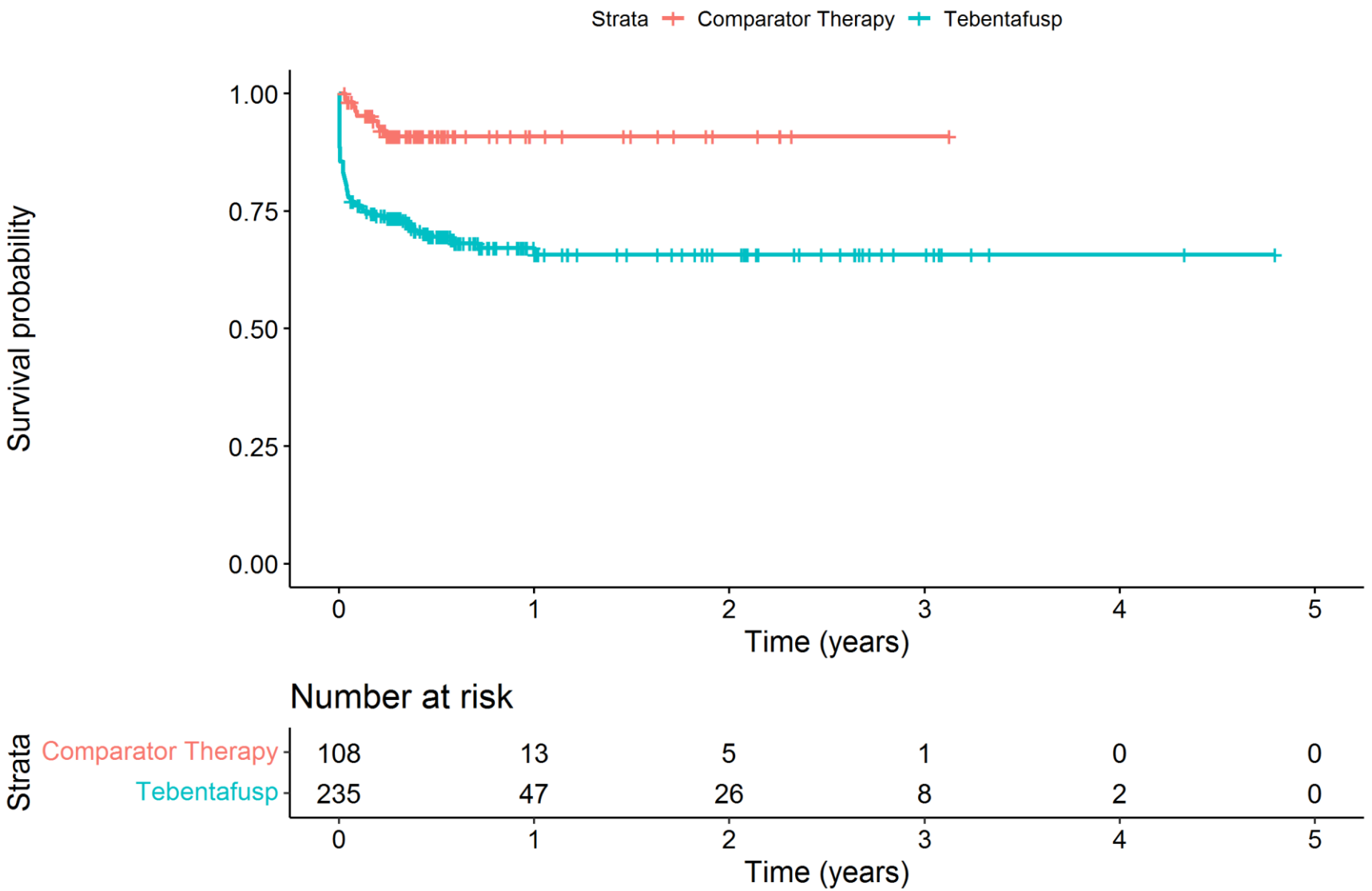
Erbrechen - LDH > ULN



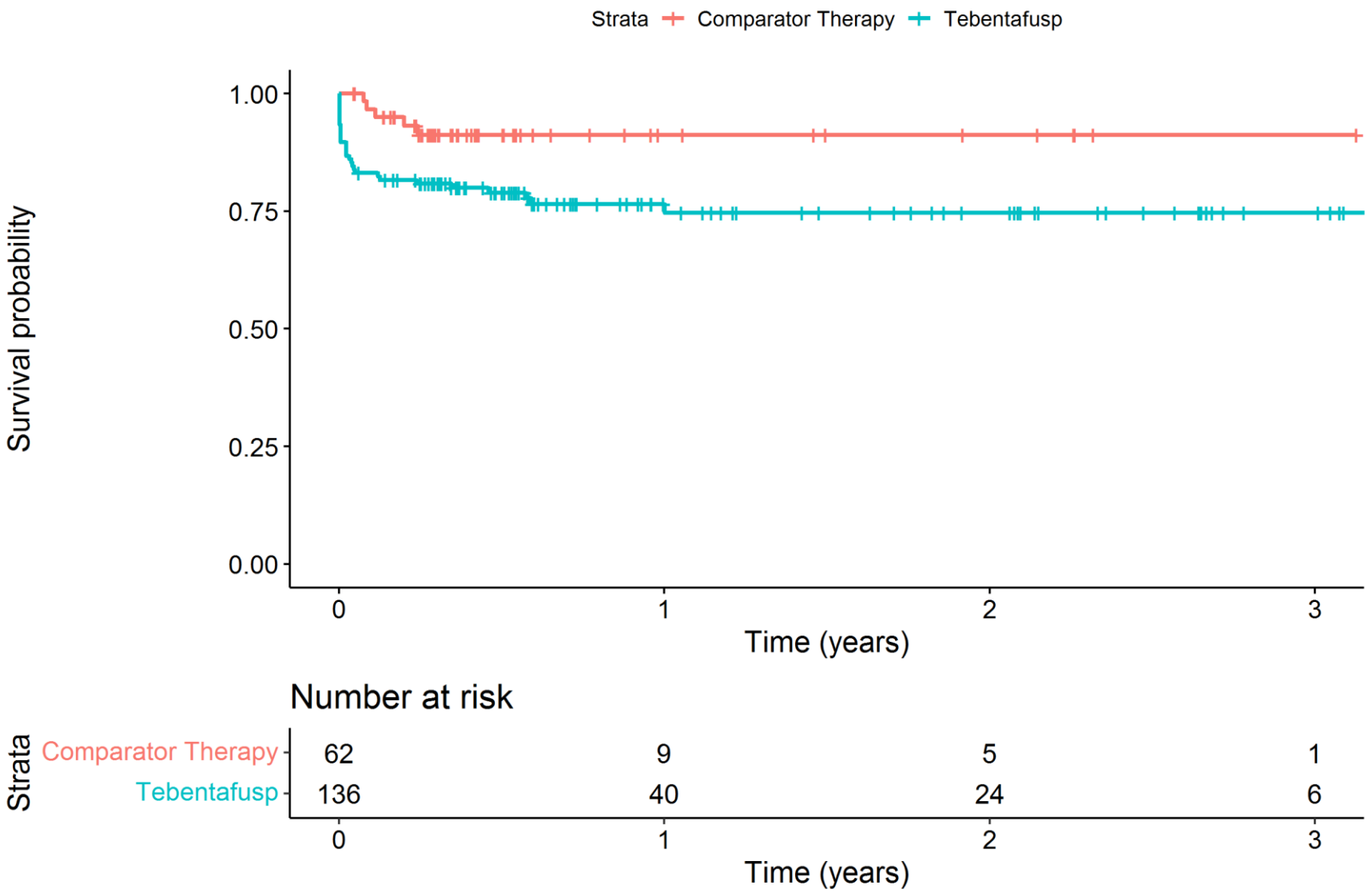
Erbrechen - Vorherige Therapie adjuvant/neoadjuvant



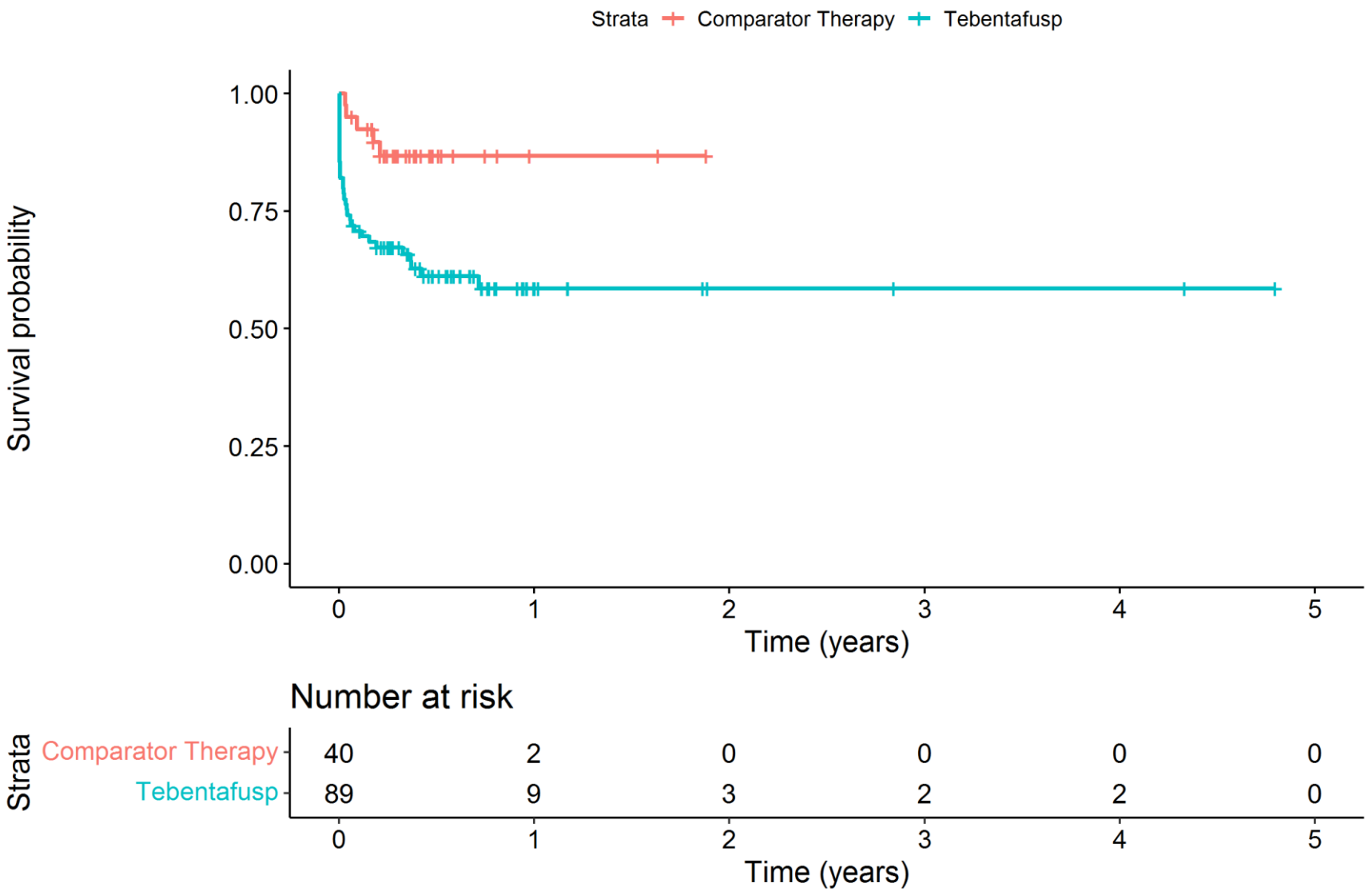
Erbrechen - Keine Vorherige Therapie adjuvant/neoadjuvant



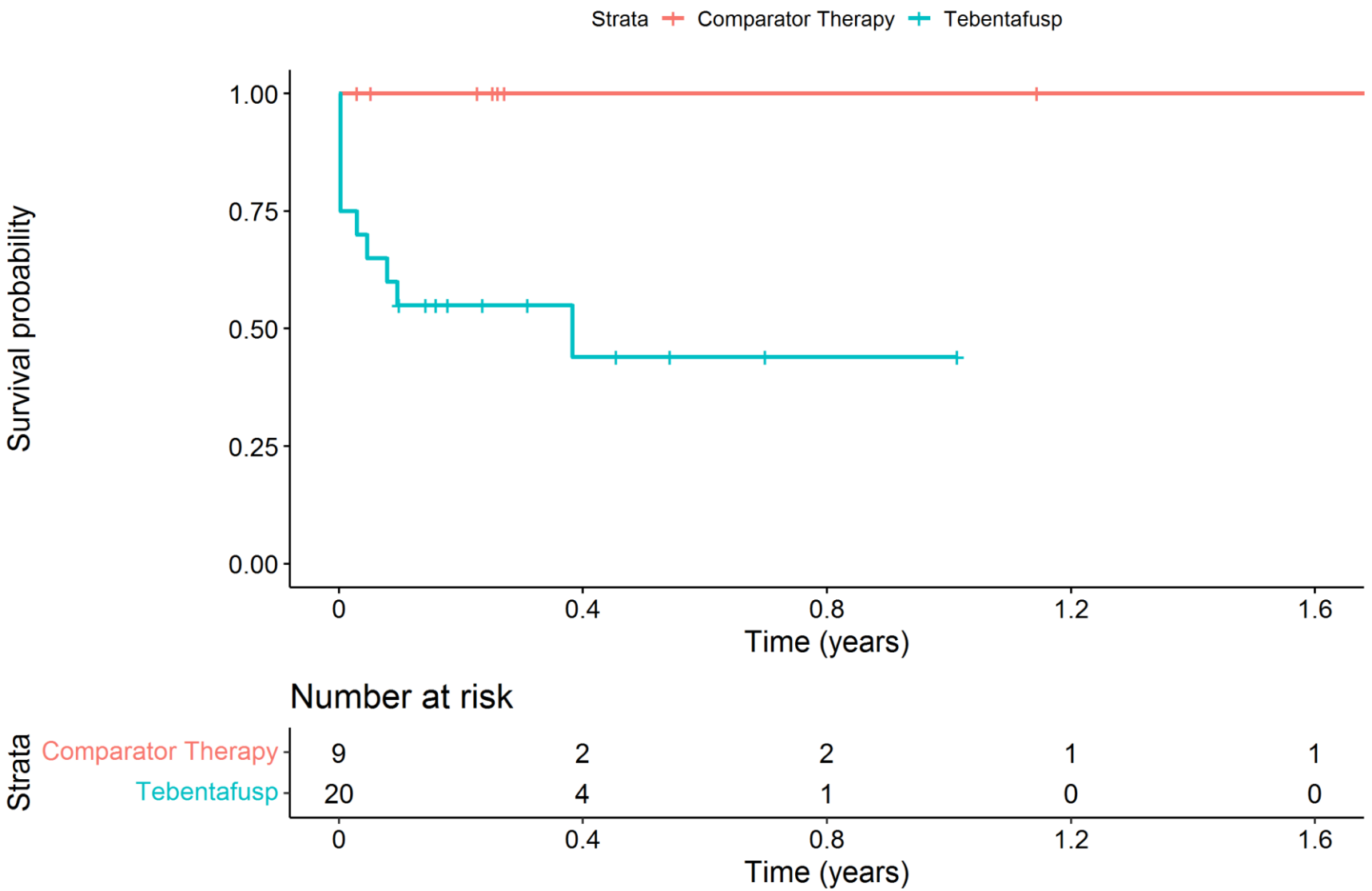
Erbrechen - Läsion ≤ 3cm



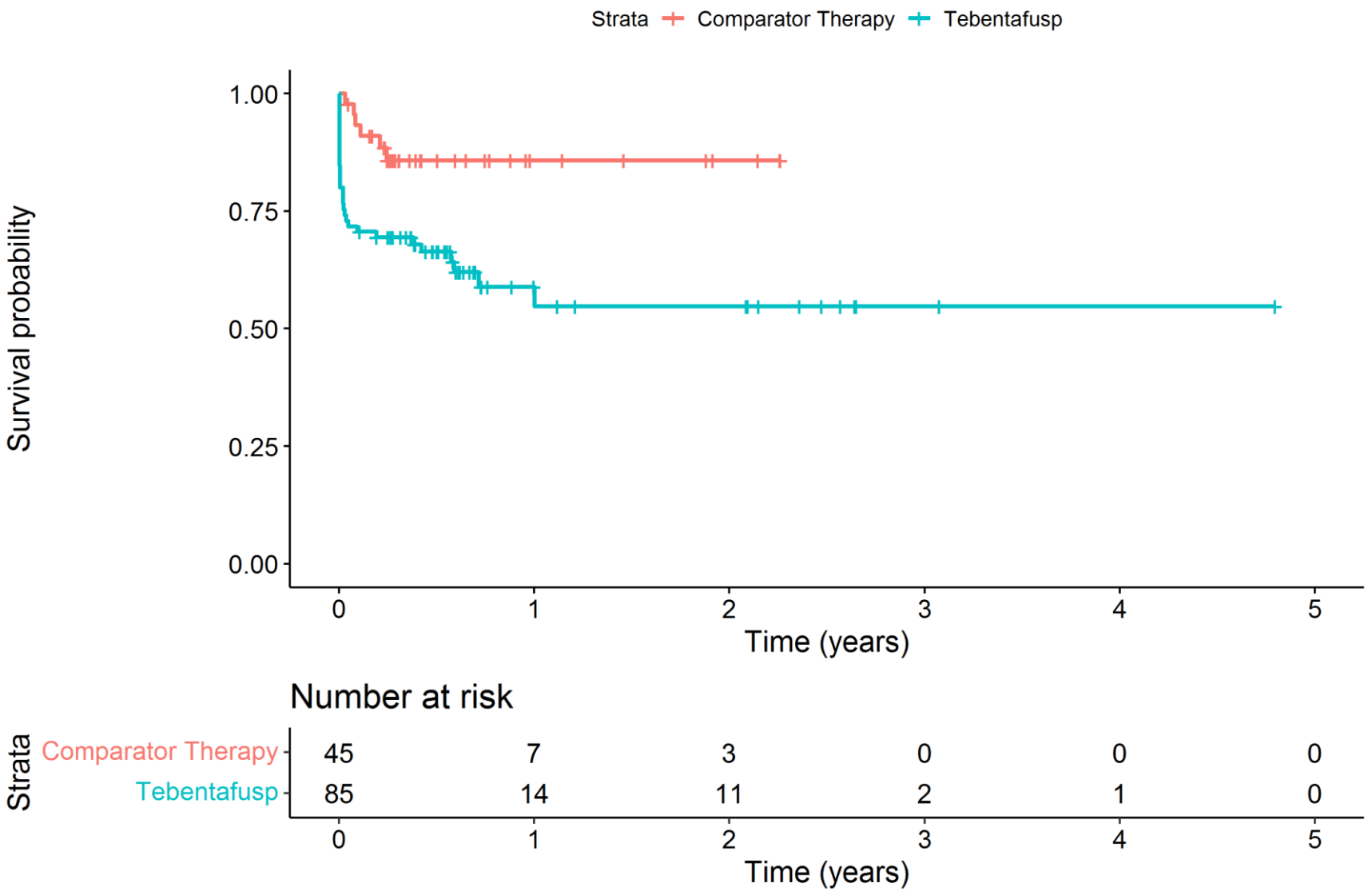
Erbrechen - Läsion 3,1-8,0 cm



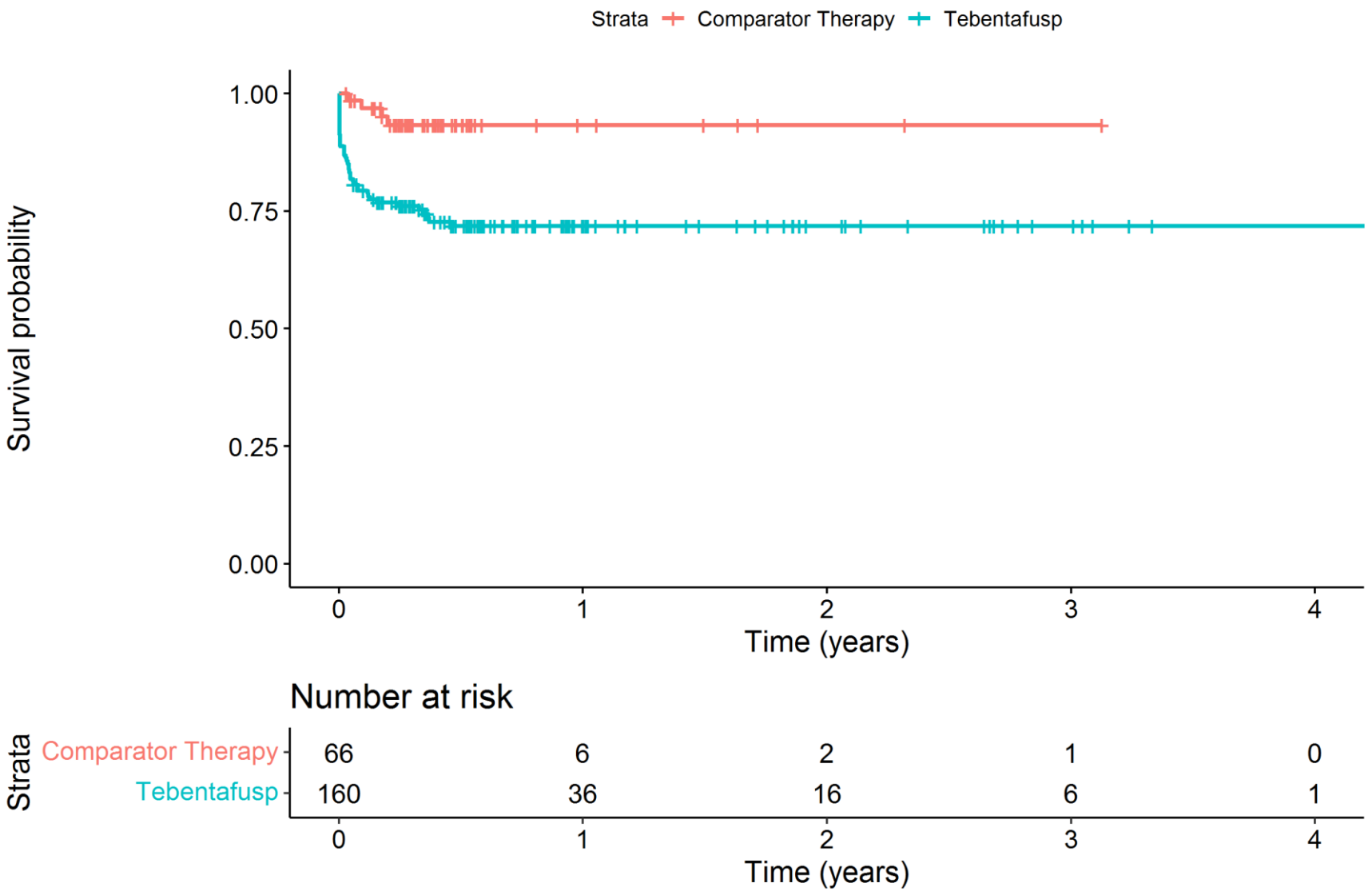
Erbrechen - Läsion ≥8,1 cm



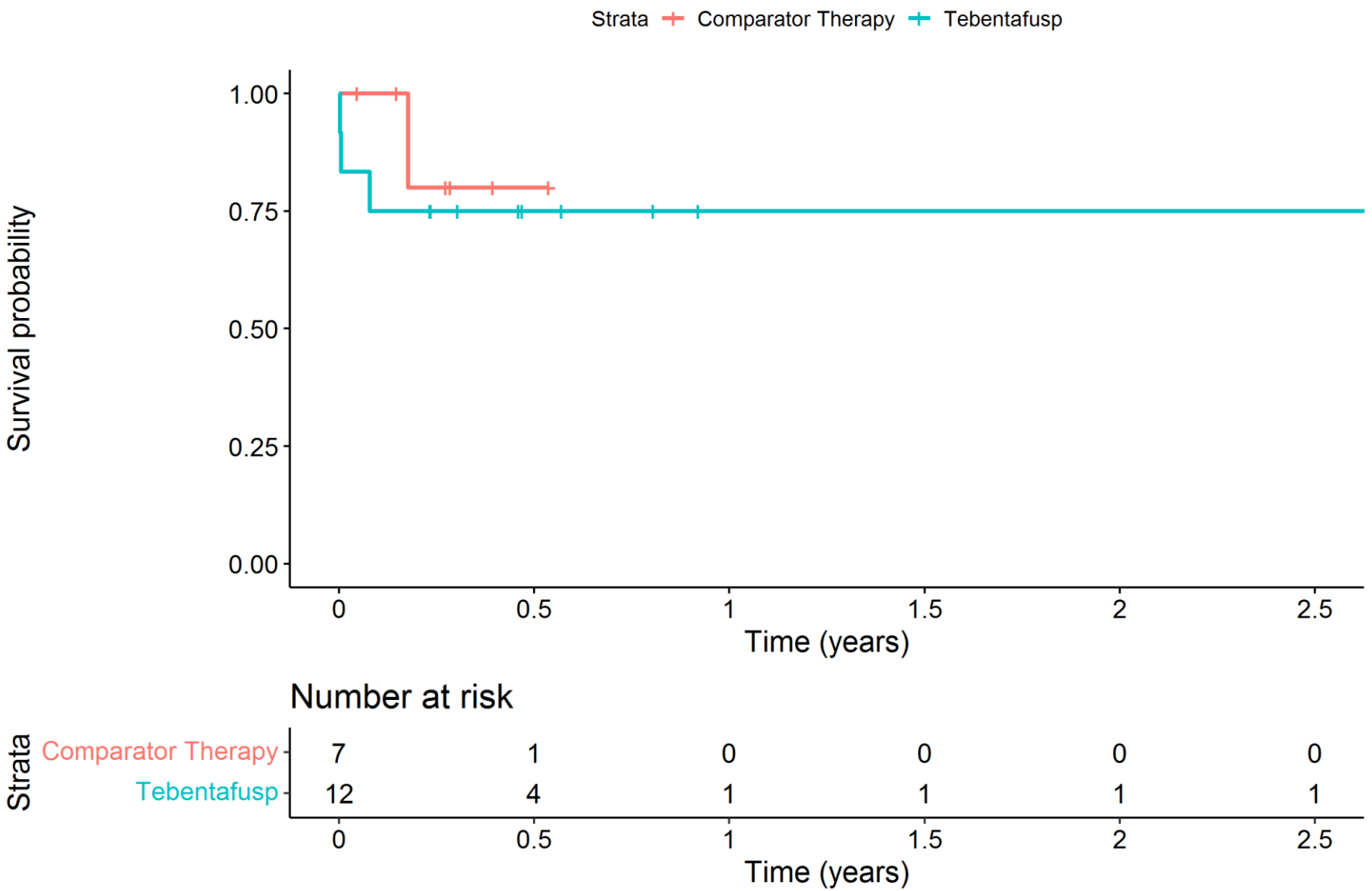
Erbrechen - Nordamerika



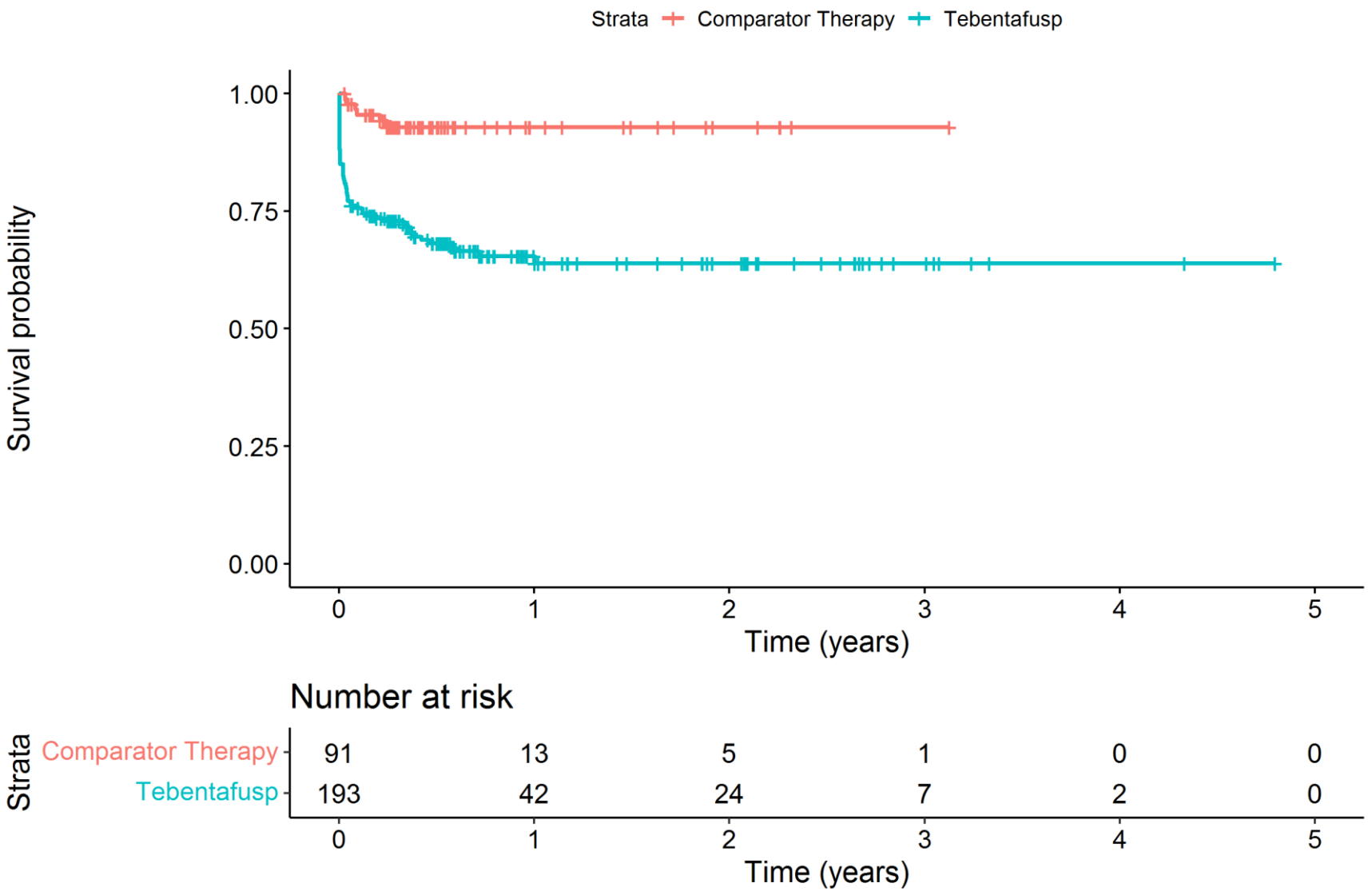
Erbrechen - Nicht-Nordamerika



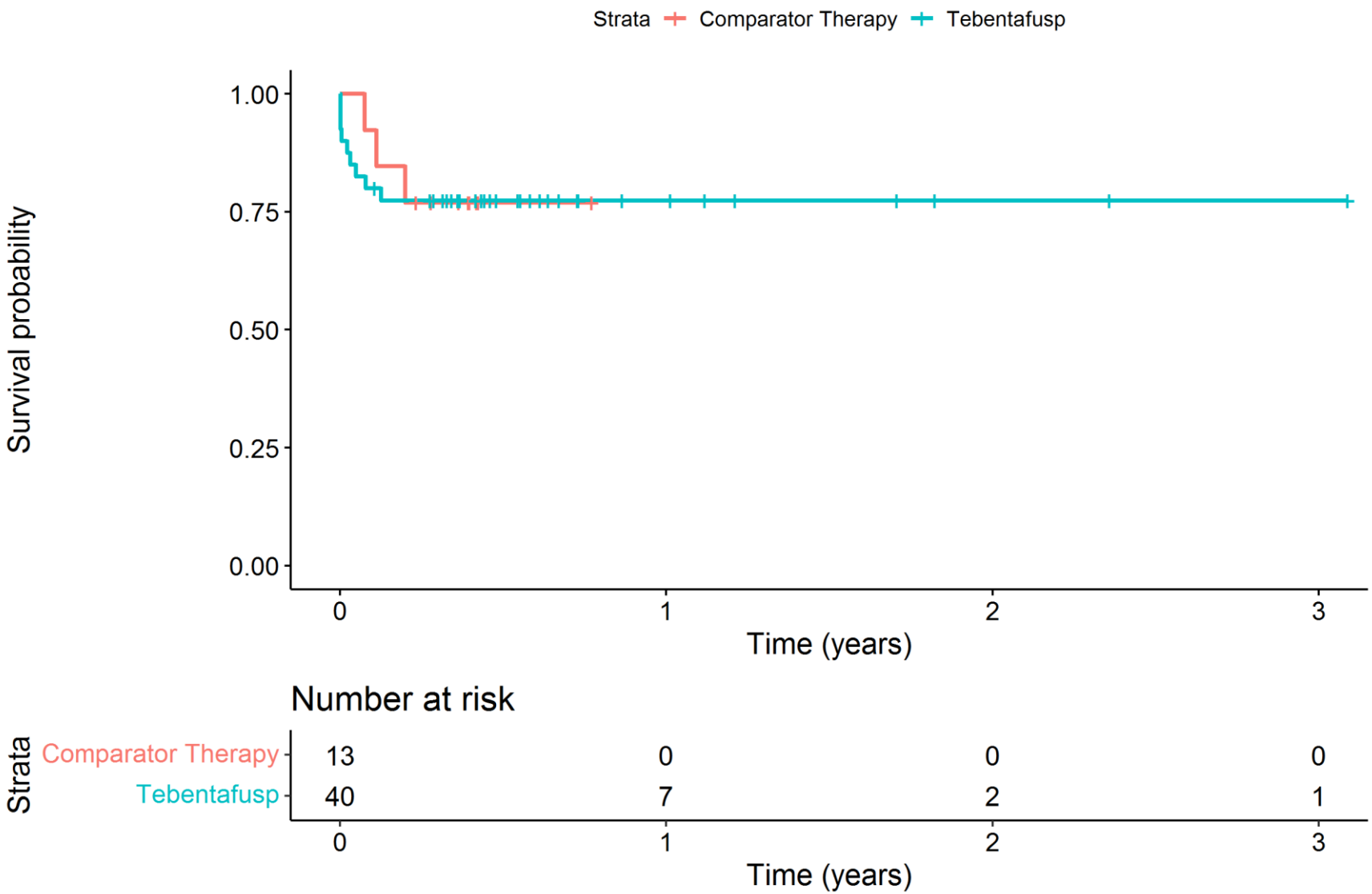
Erbrechen - Dacarbazin



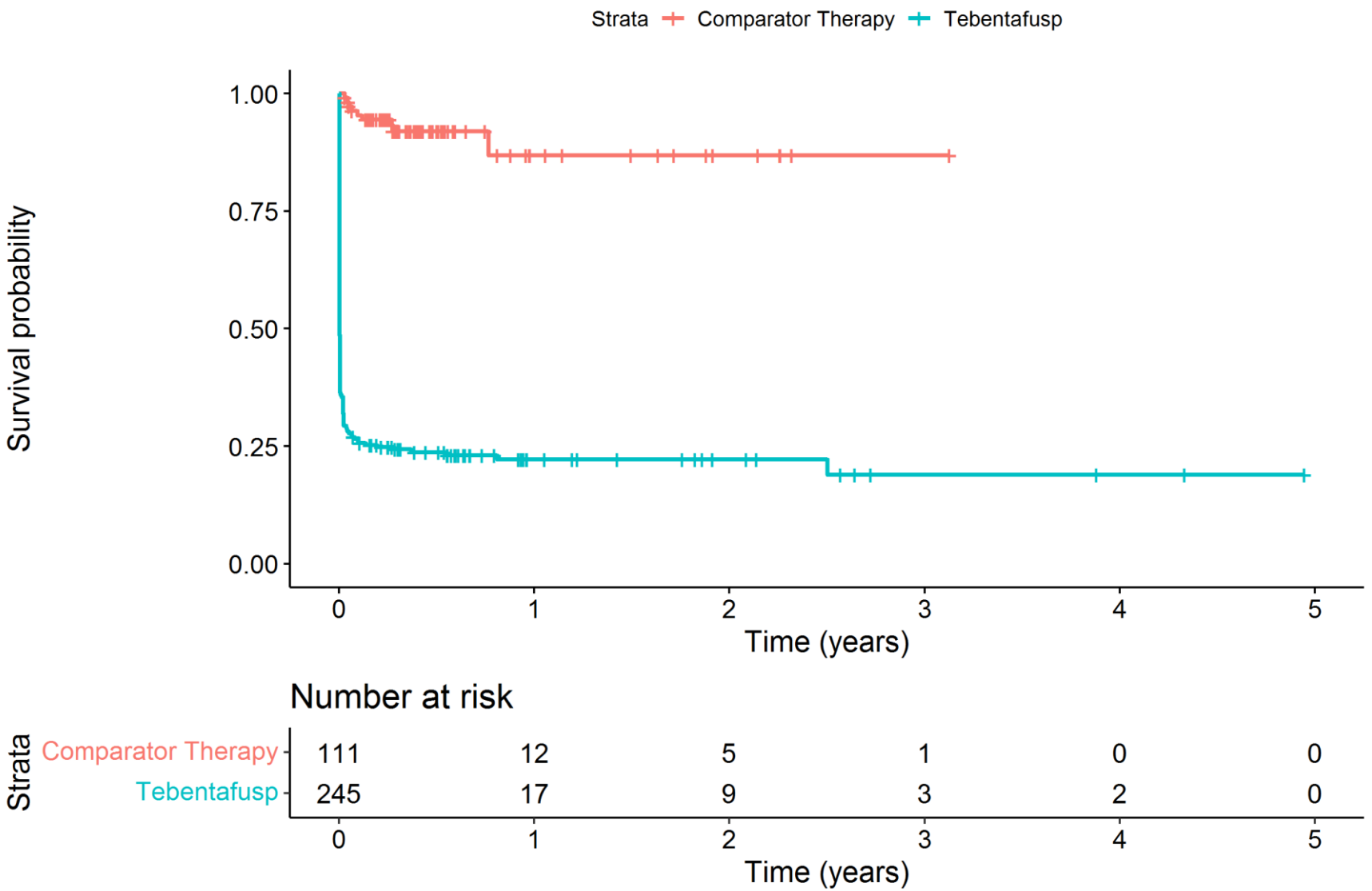
Erbrechen - Pembrolizumab



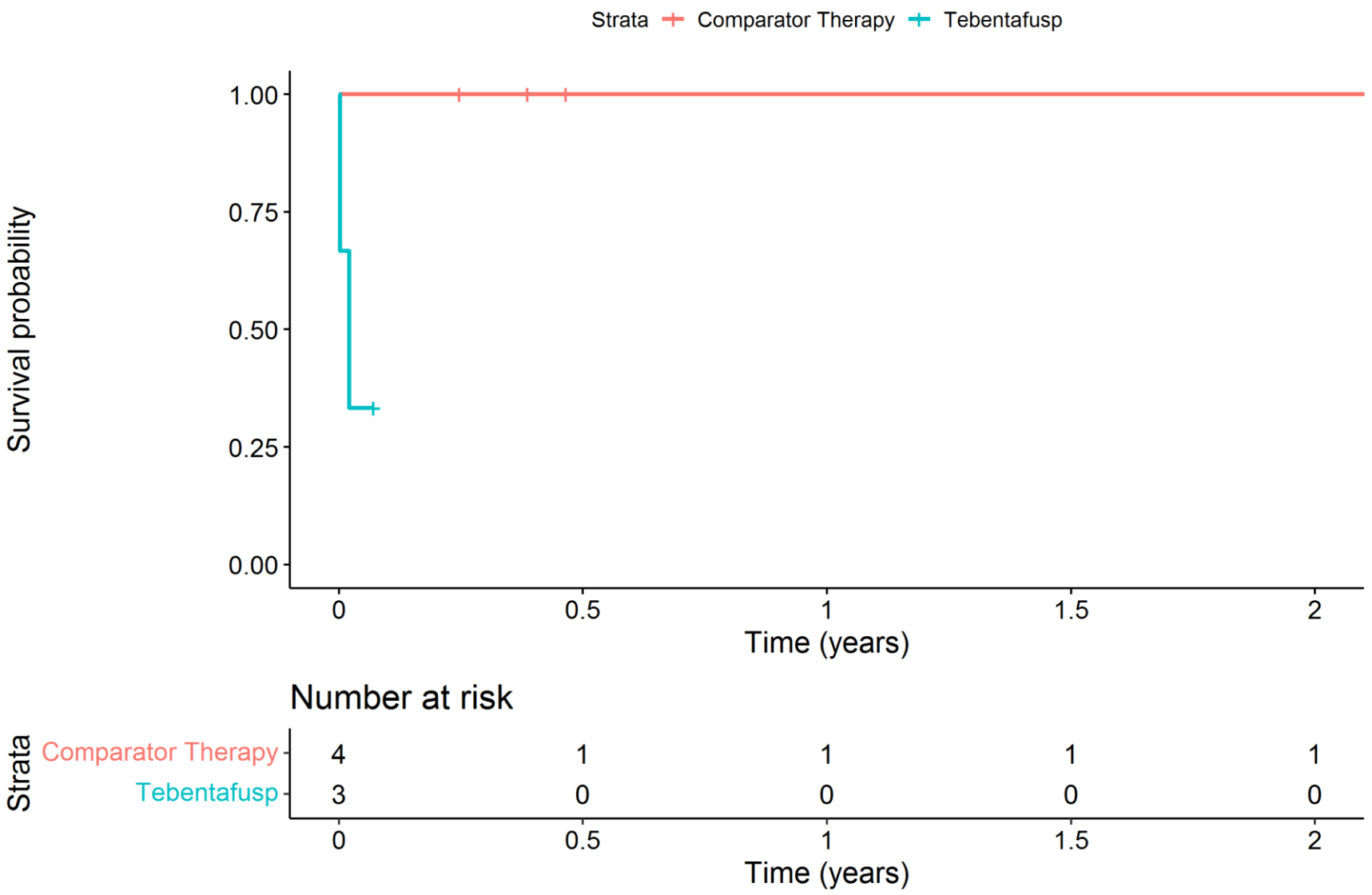
Erbrechen - Ipilimumab



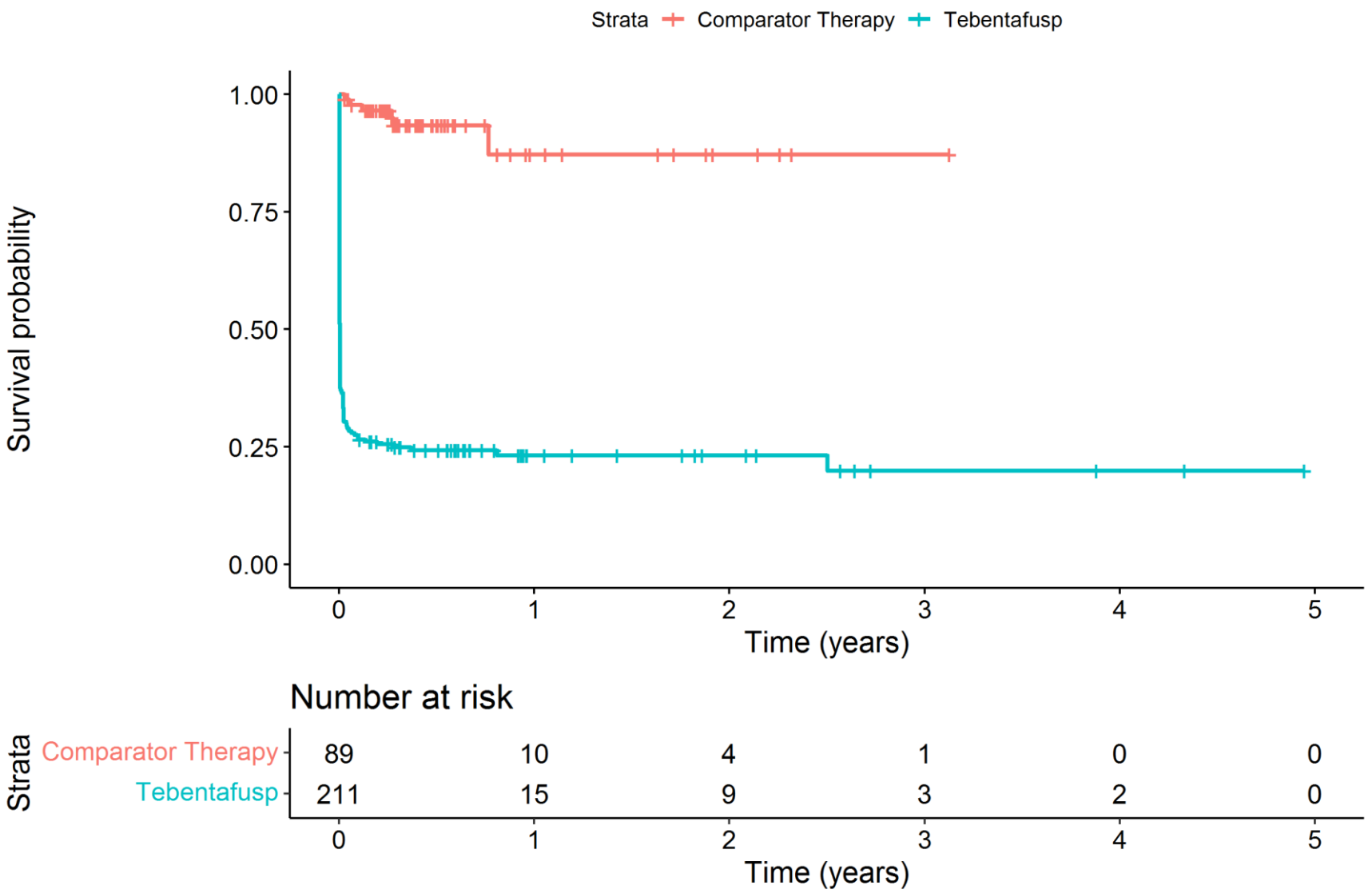
Fieber - Gesamt



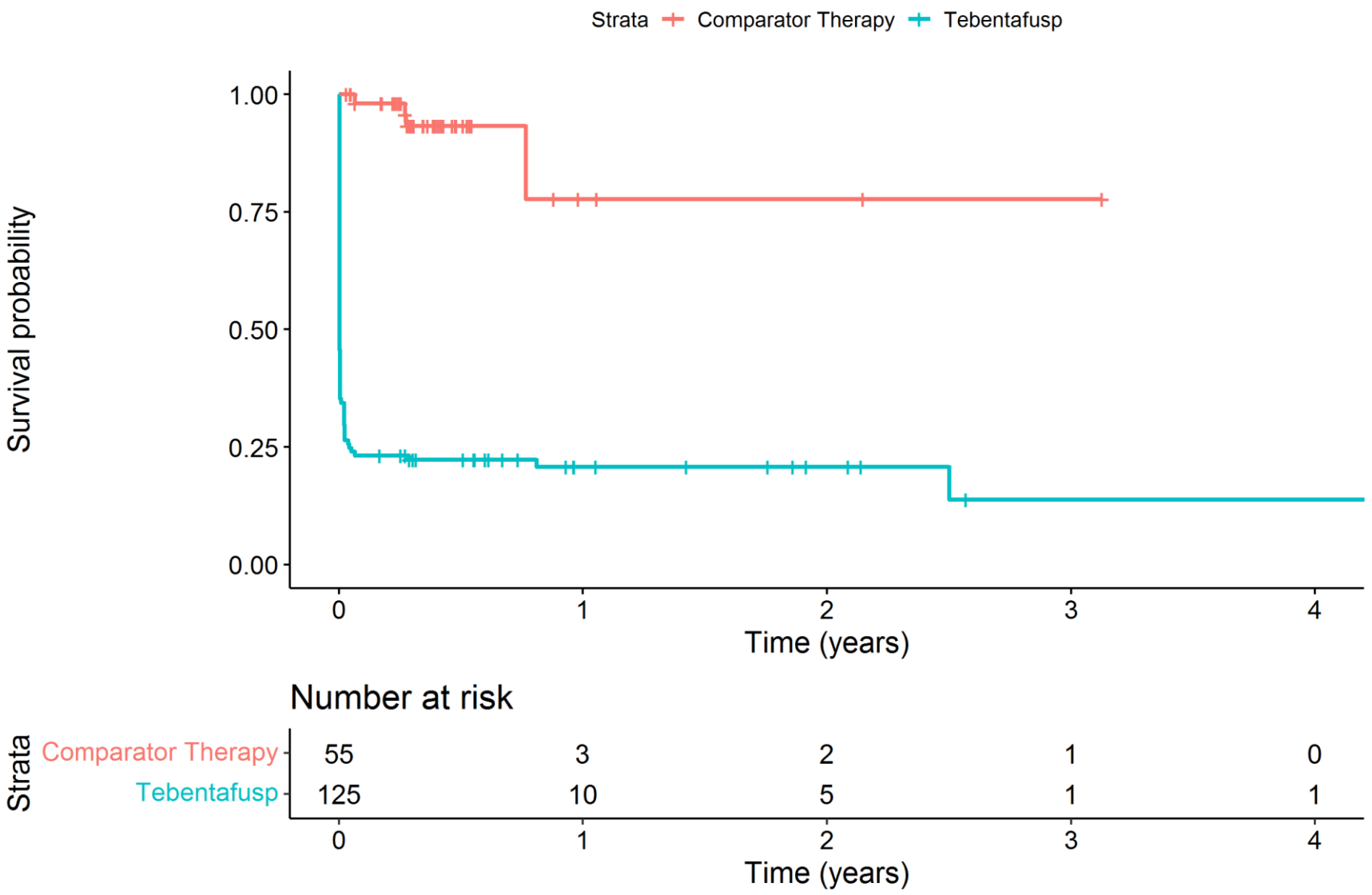
60.1 Fieber - Hispanisch



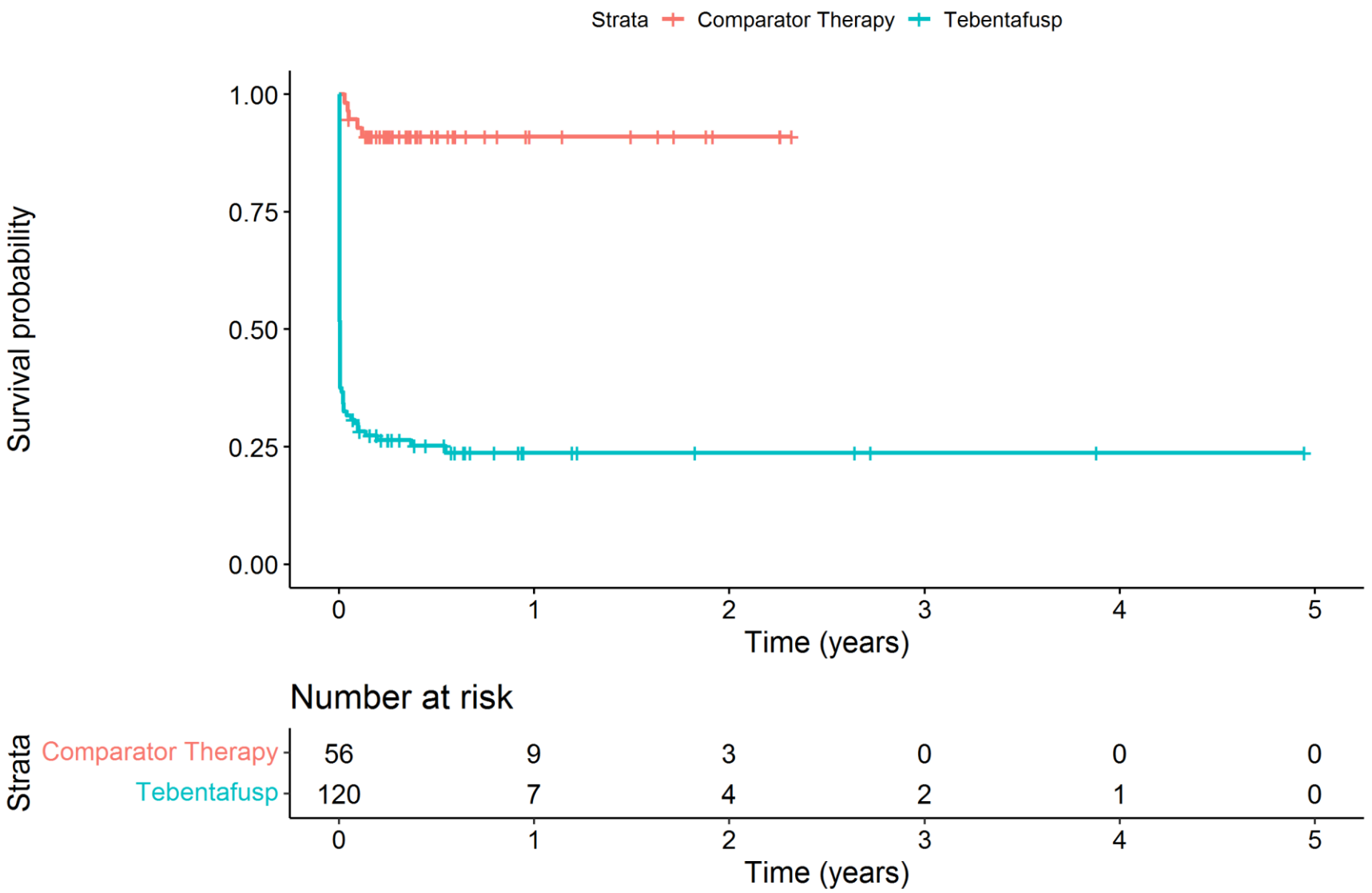
60.2 Fieber - Nicht-hispanisch



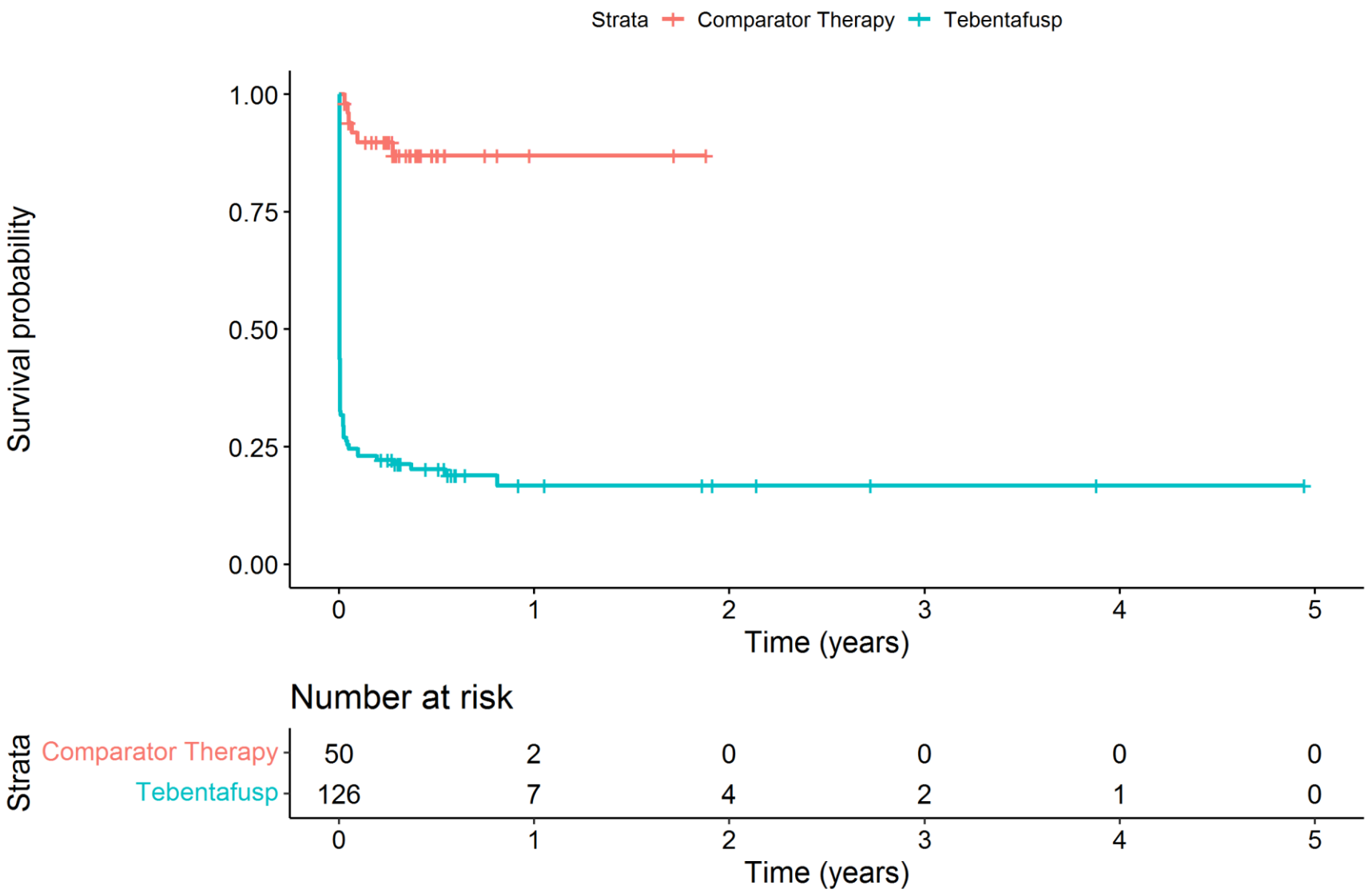
60.3 Fieber - Männlich



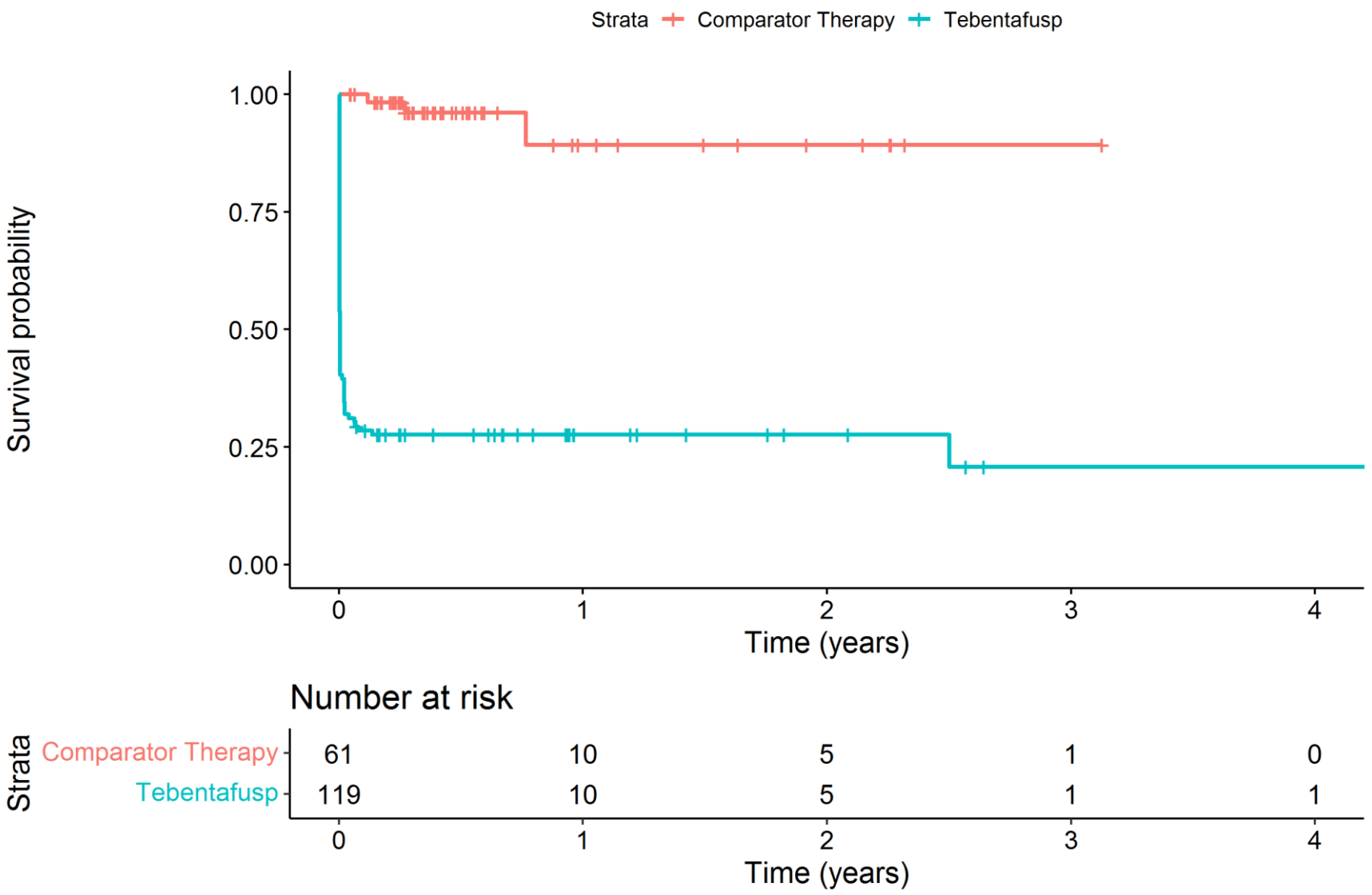
60.4 Fieber - Weiblich



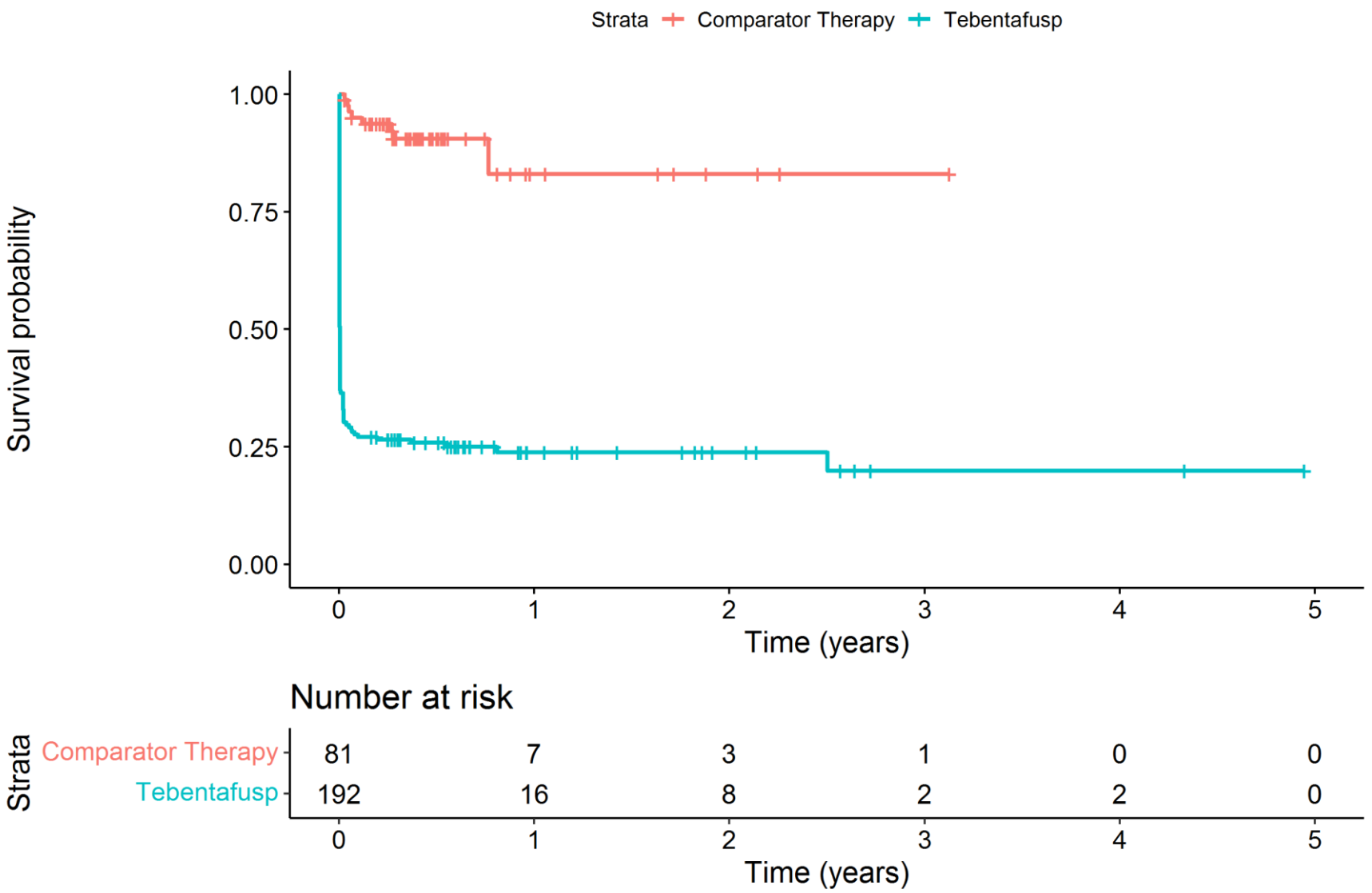
60.5 Fieber - <65



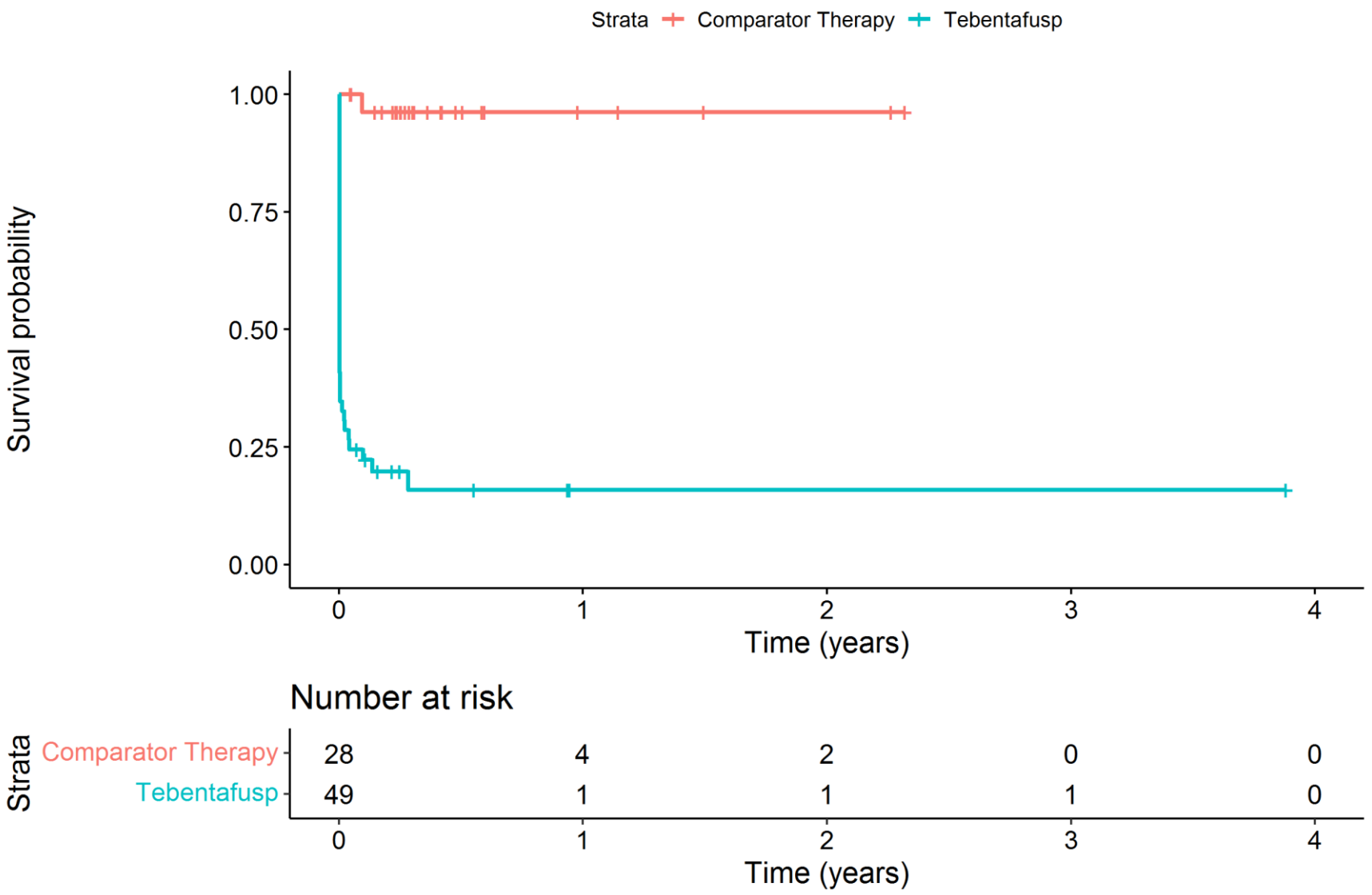
60.6 Fieber - ≥65



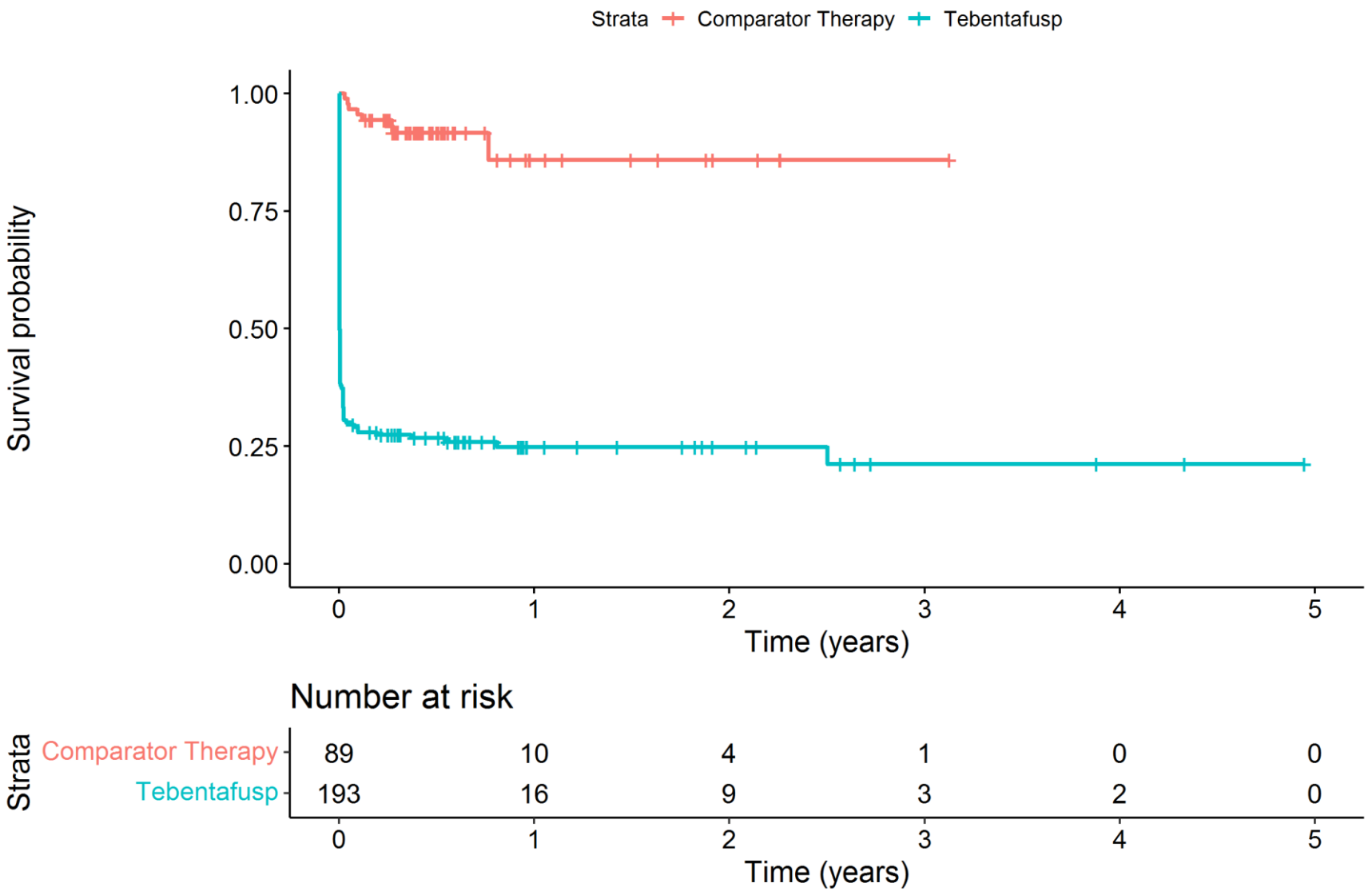
60.7 Fieber - ECOG 0



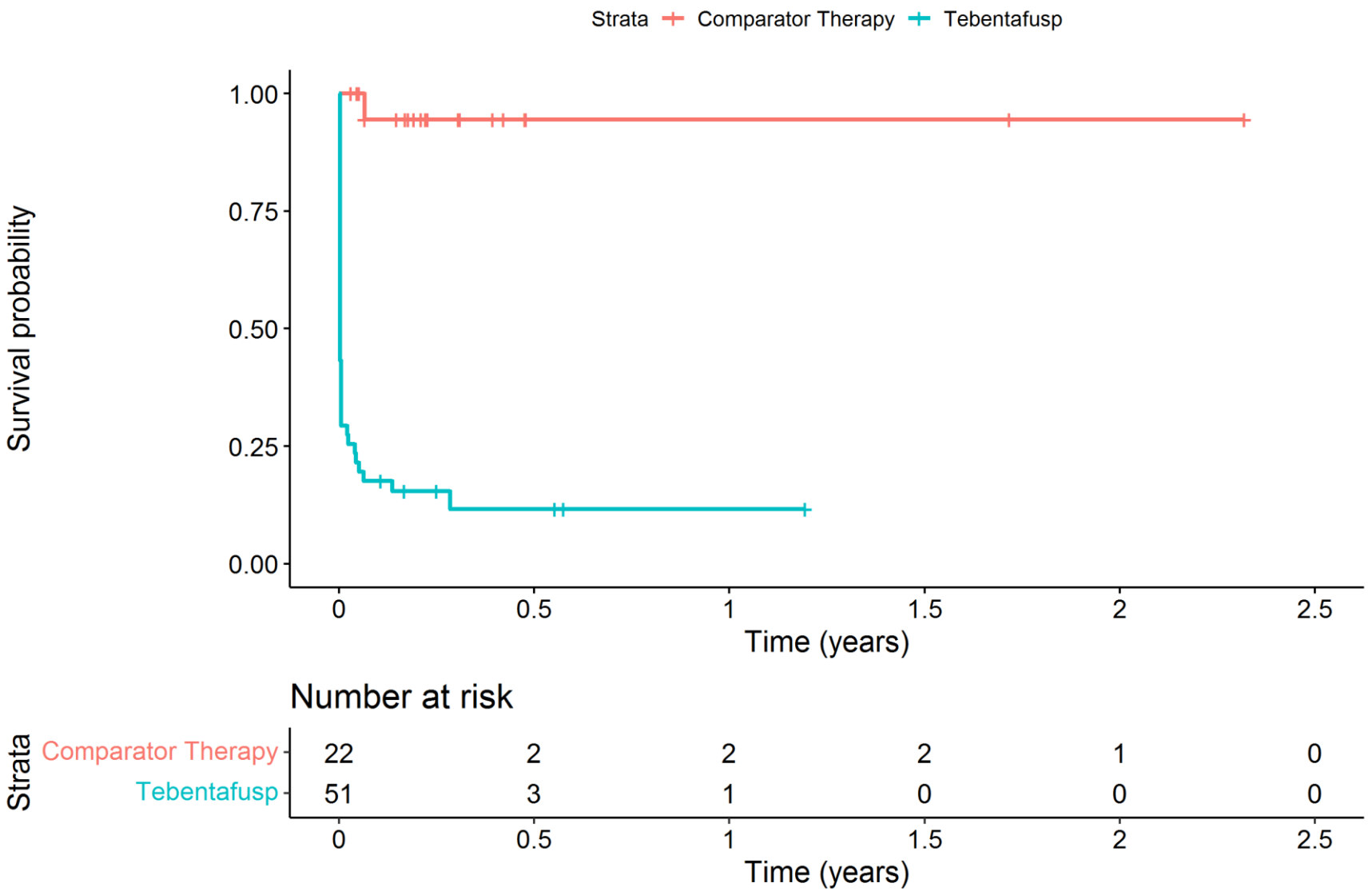
60.8 Fieber - ECOG 1



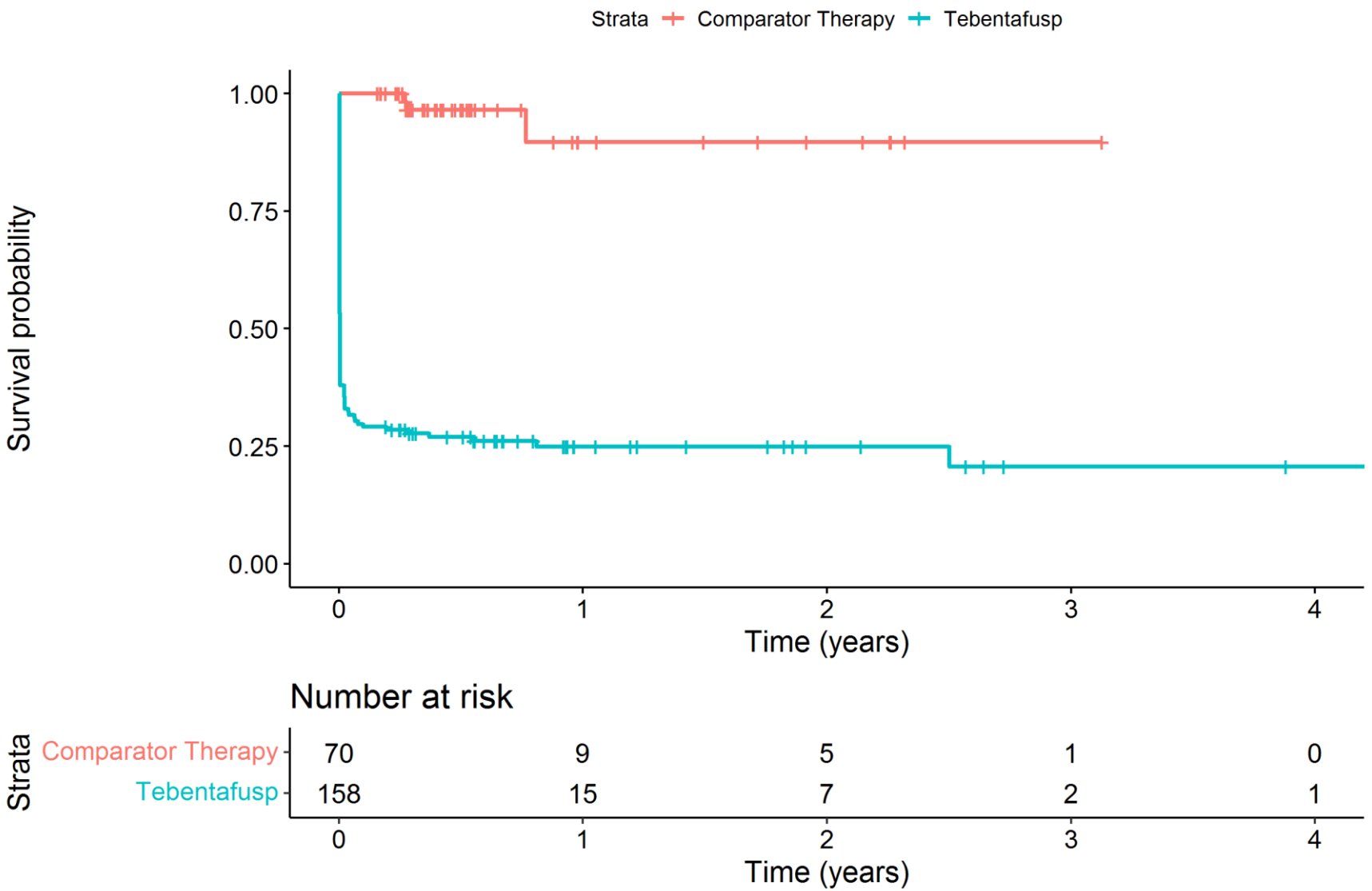
Fieber - ALP ≤ ULN



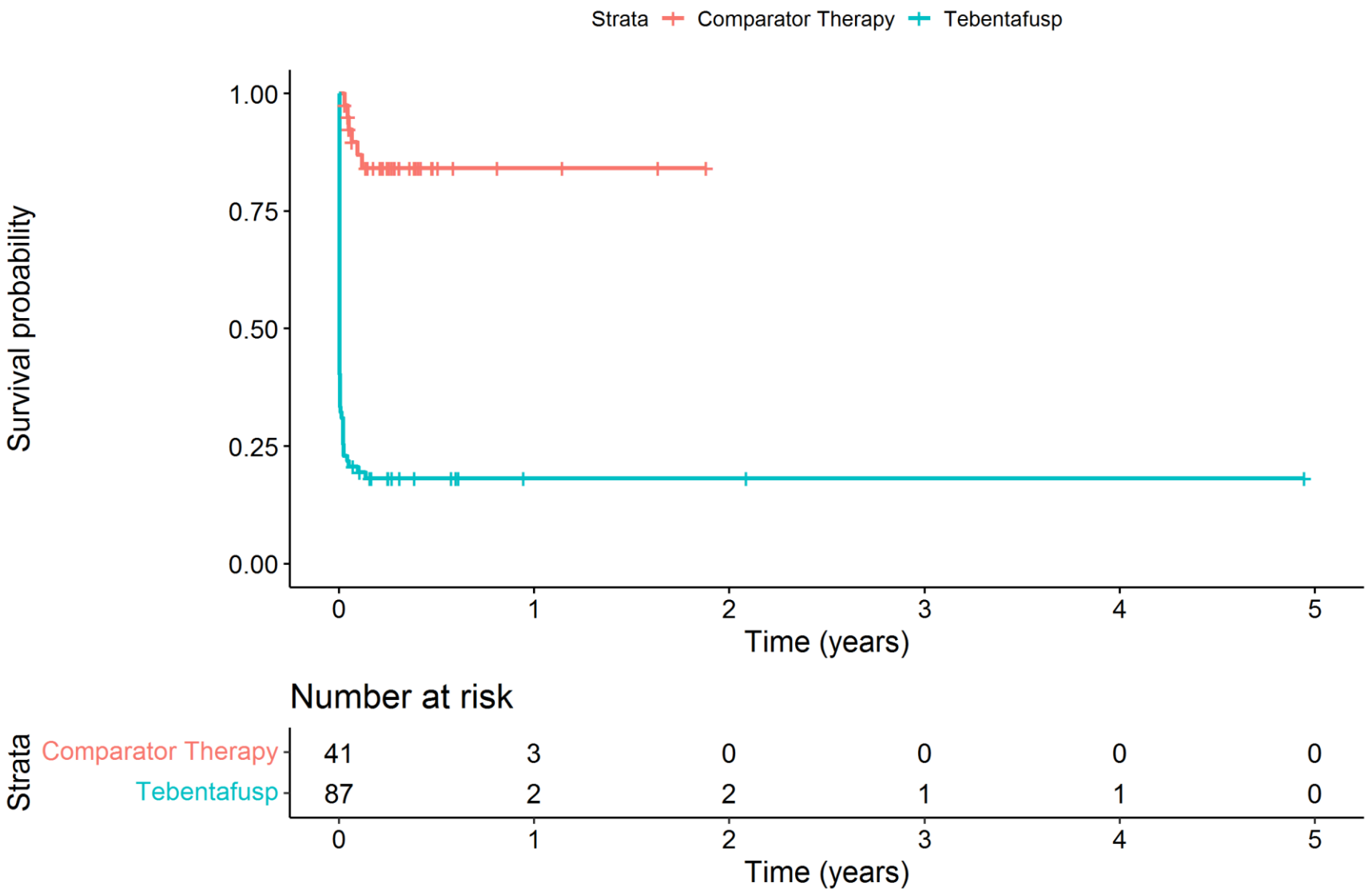
Fieber - ALP > ULN



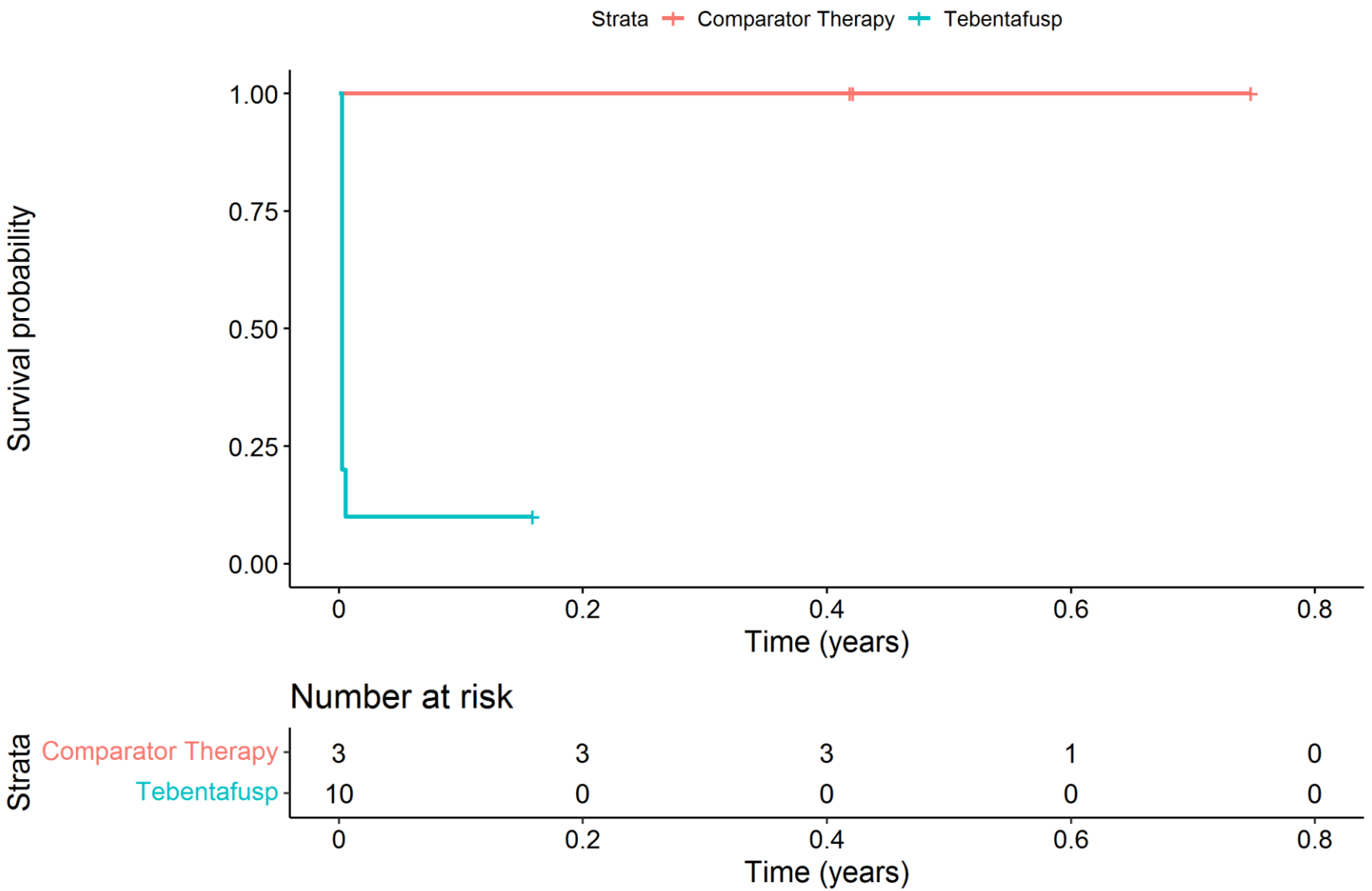
Fieber - LDH =< ULN



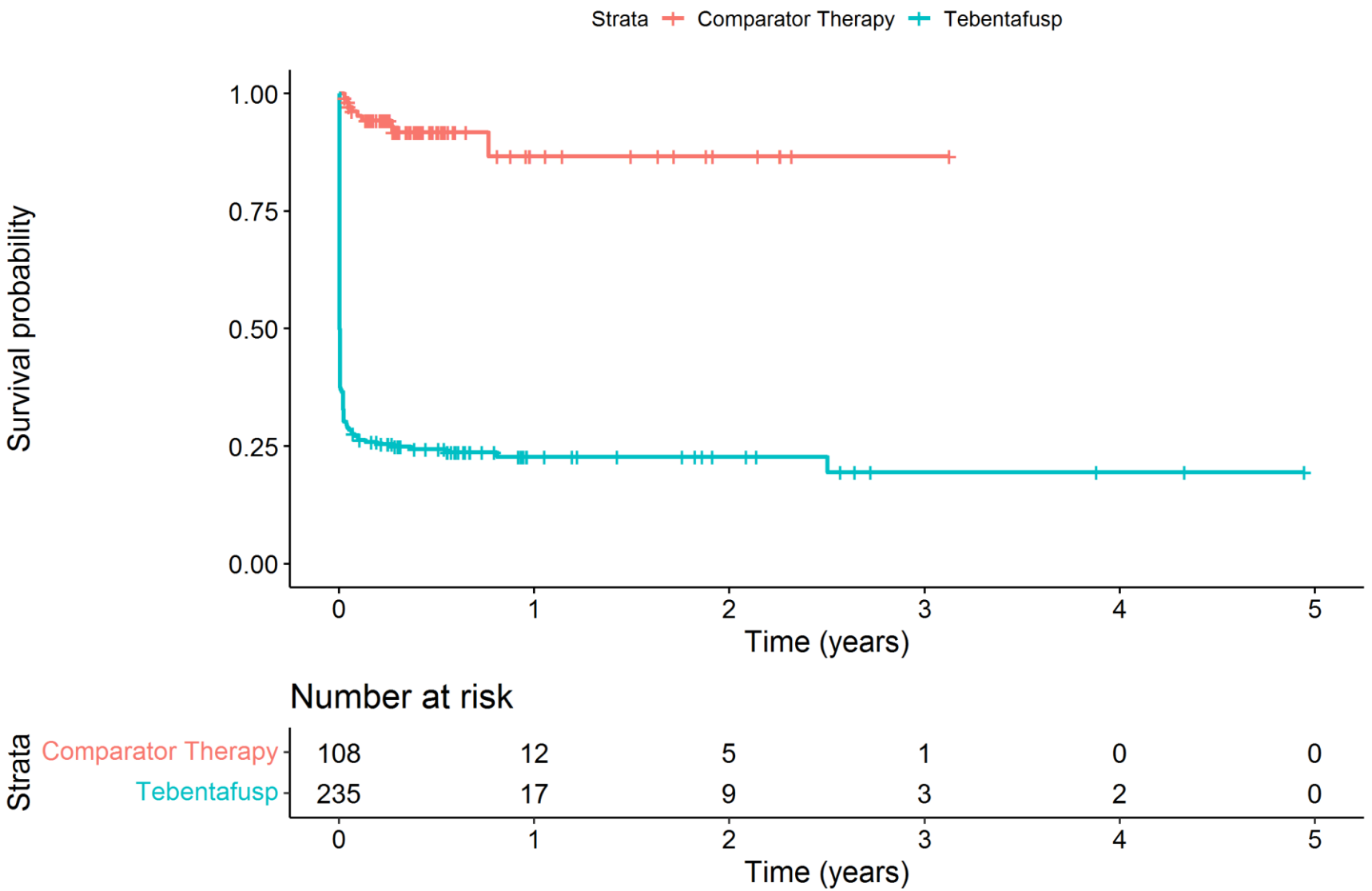
Fieber - LDH > ULN



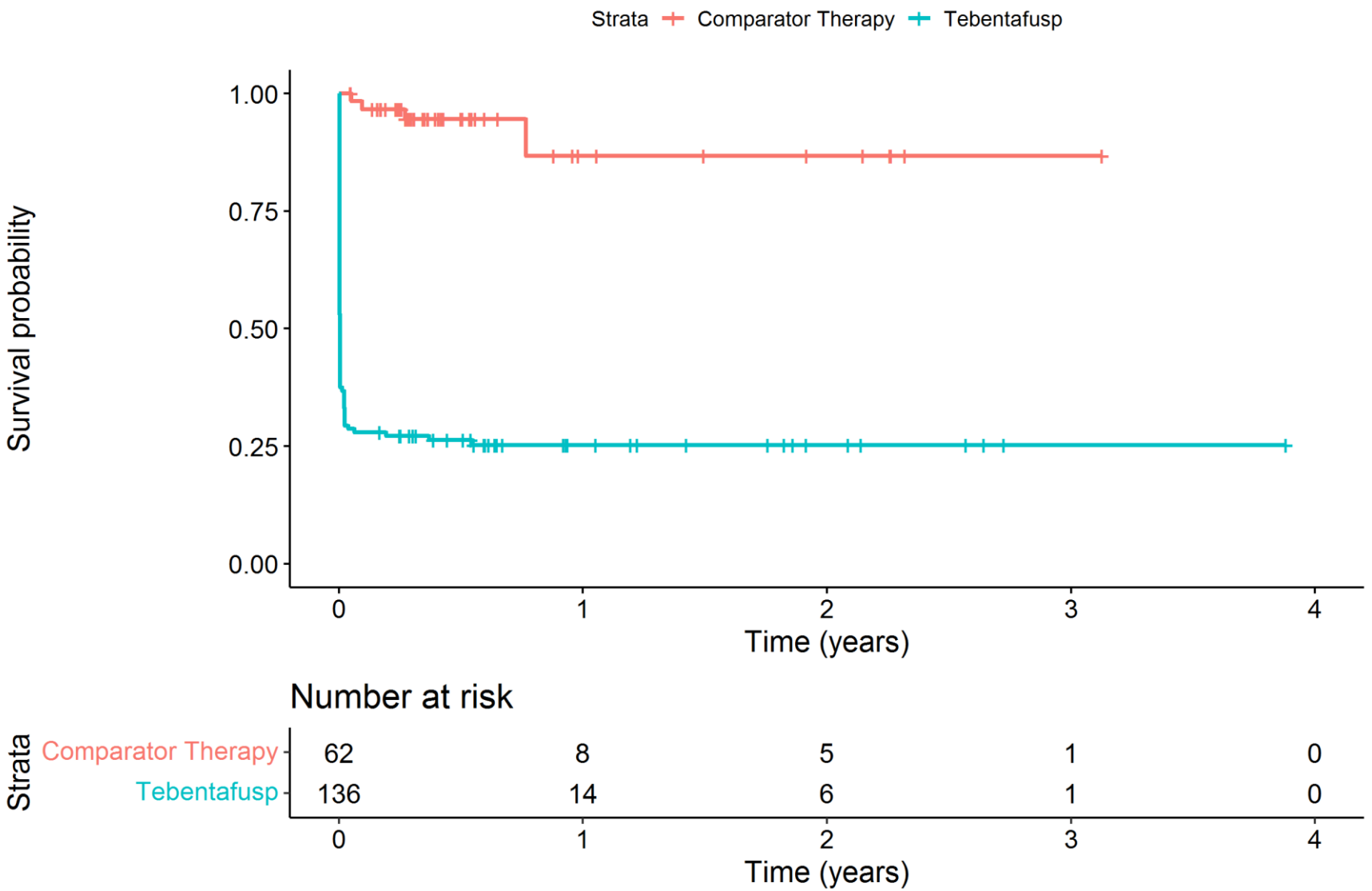
Fieber - Vorherige Therapie adjuvant/neoadjuvant



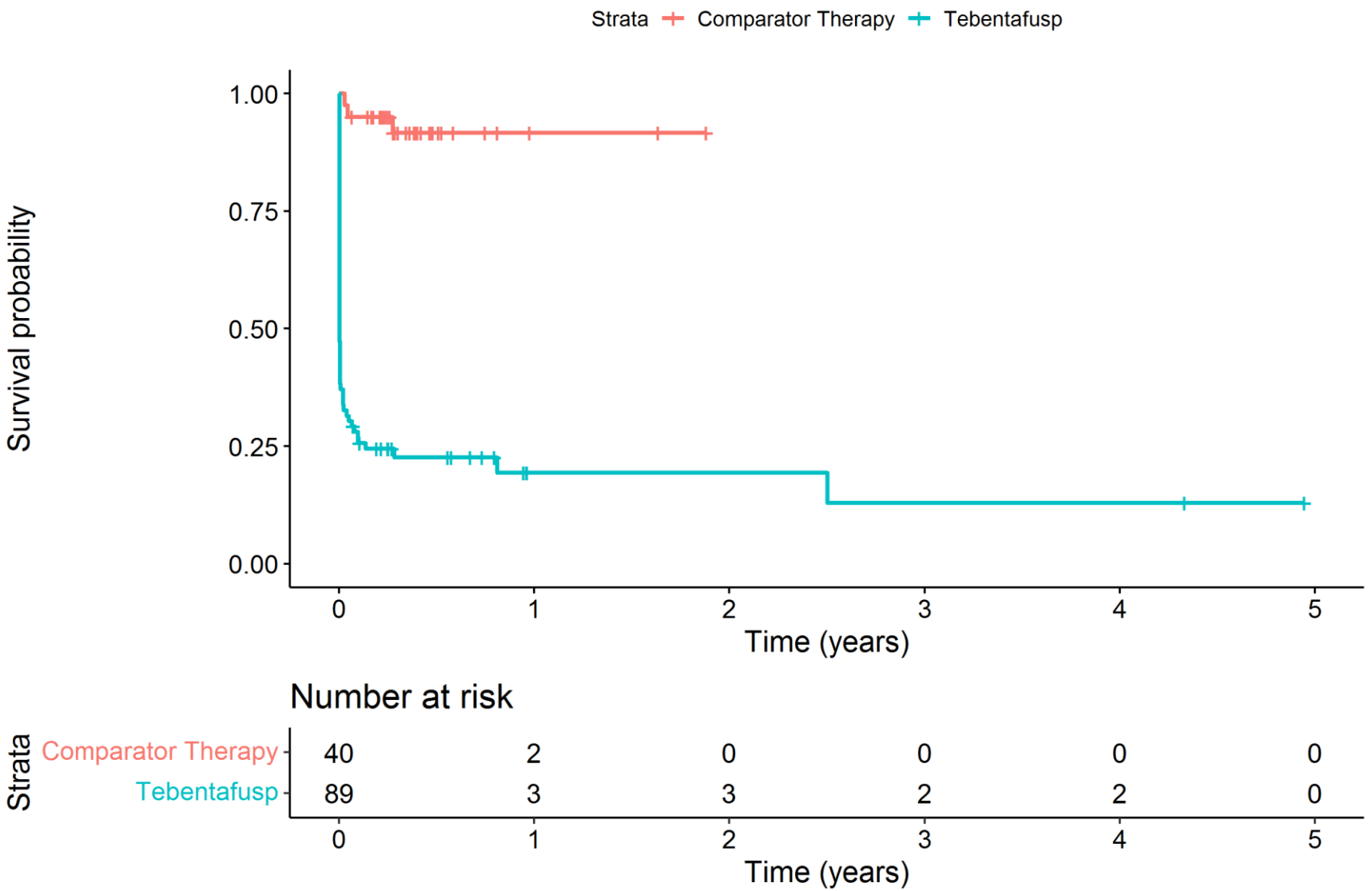
Fieber - Keine Vorherige Therapie adjuvant/neoadjuvant



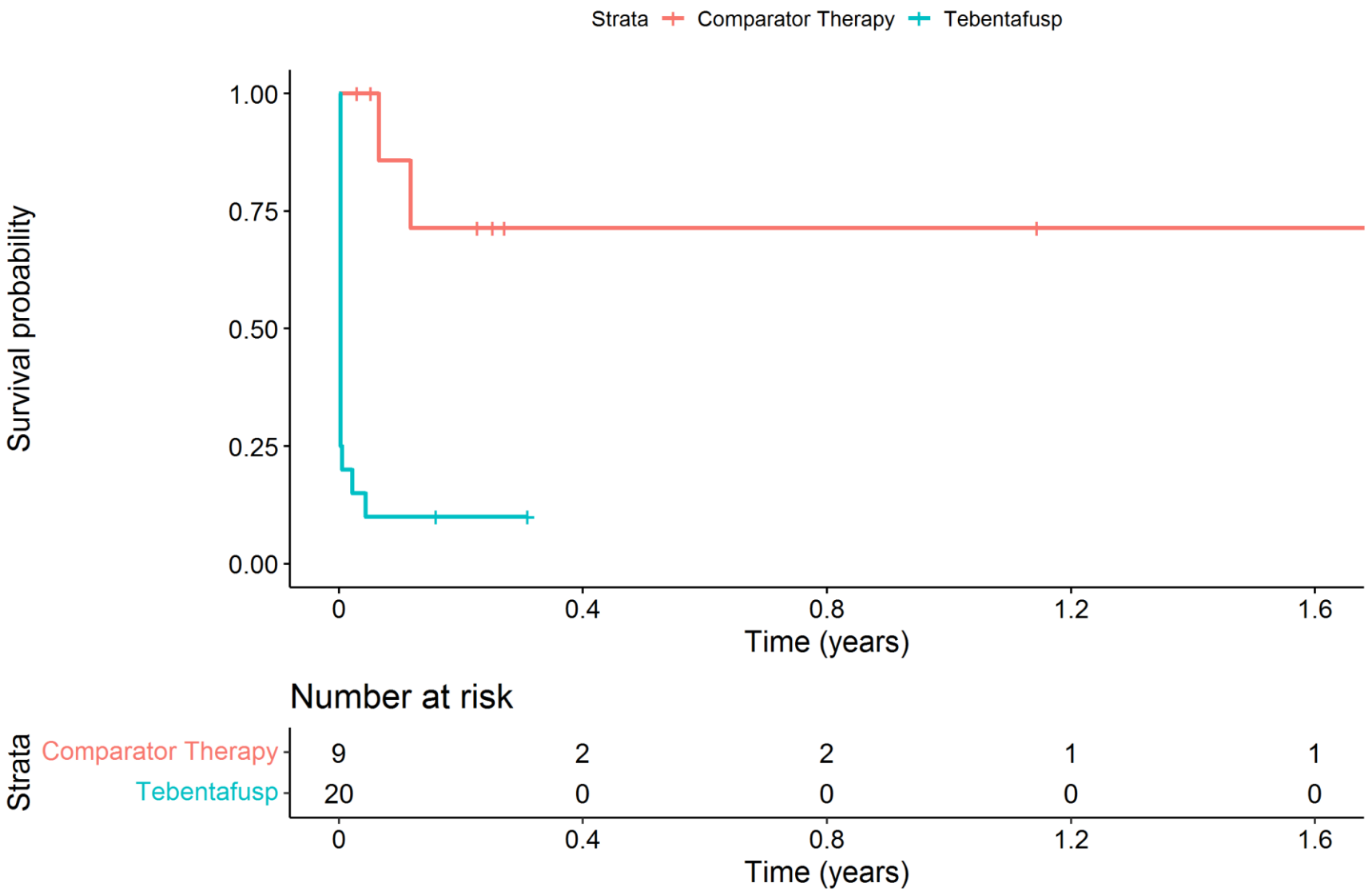
Fieber - Läsion ≤ 3cm



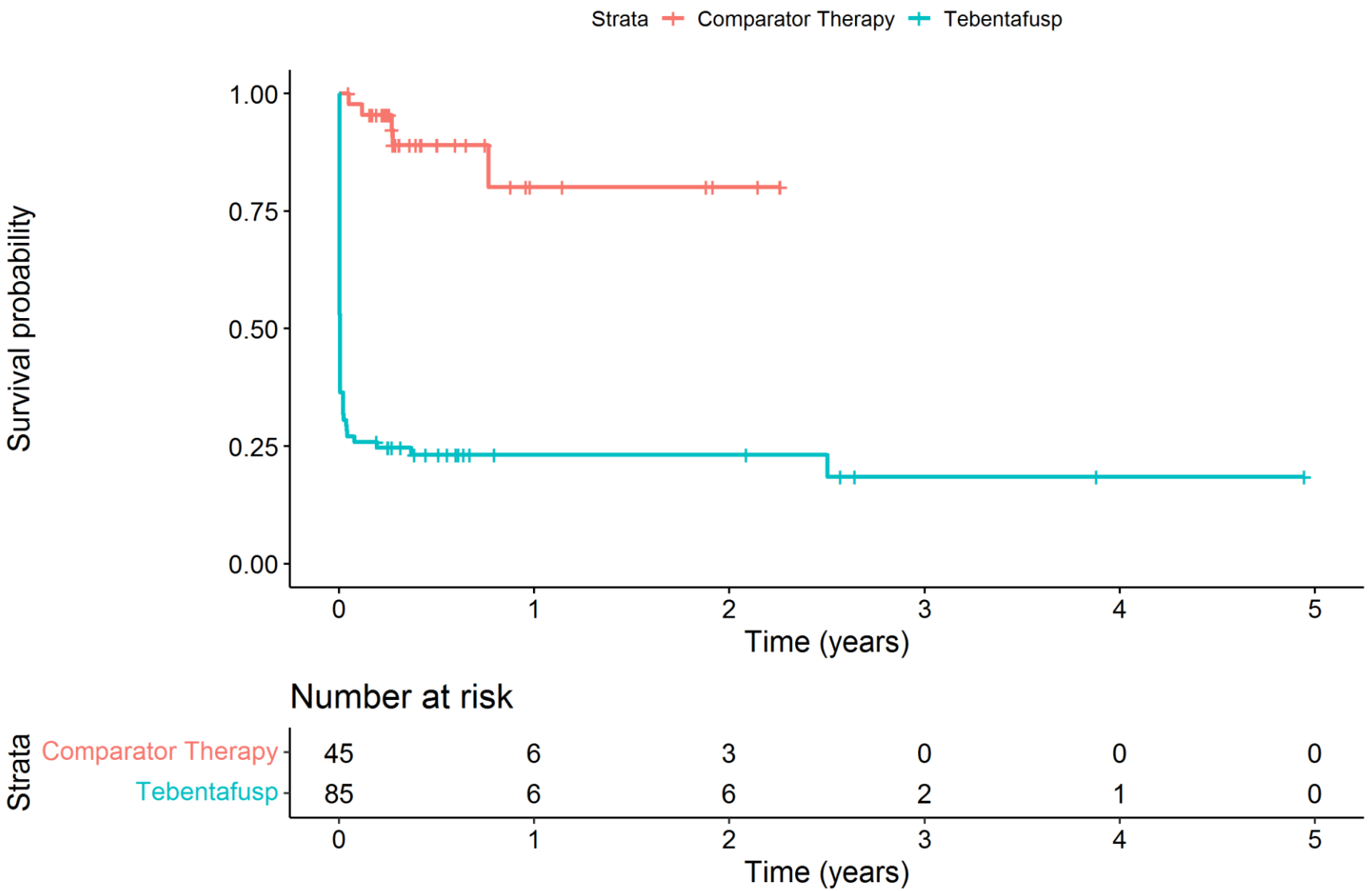
Fieber - Läsion 3,1-8,0 cm



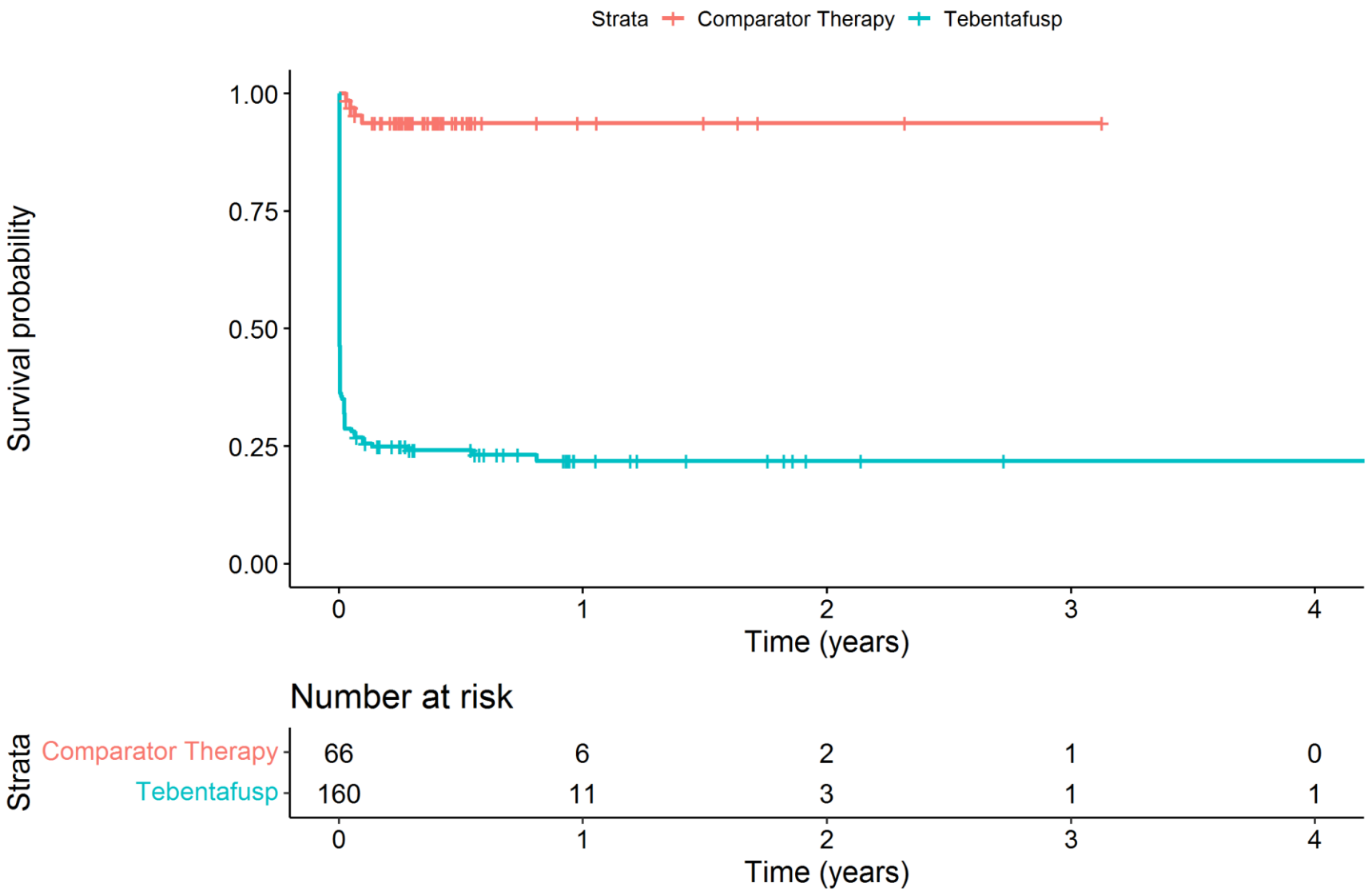
Fieber - Läsion ≥8,1 cm



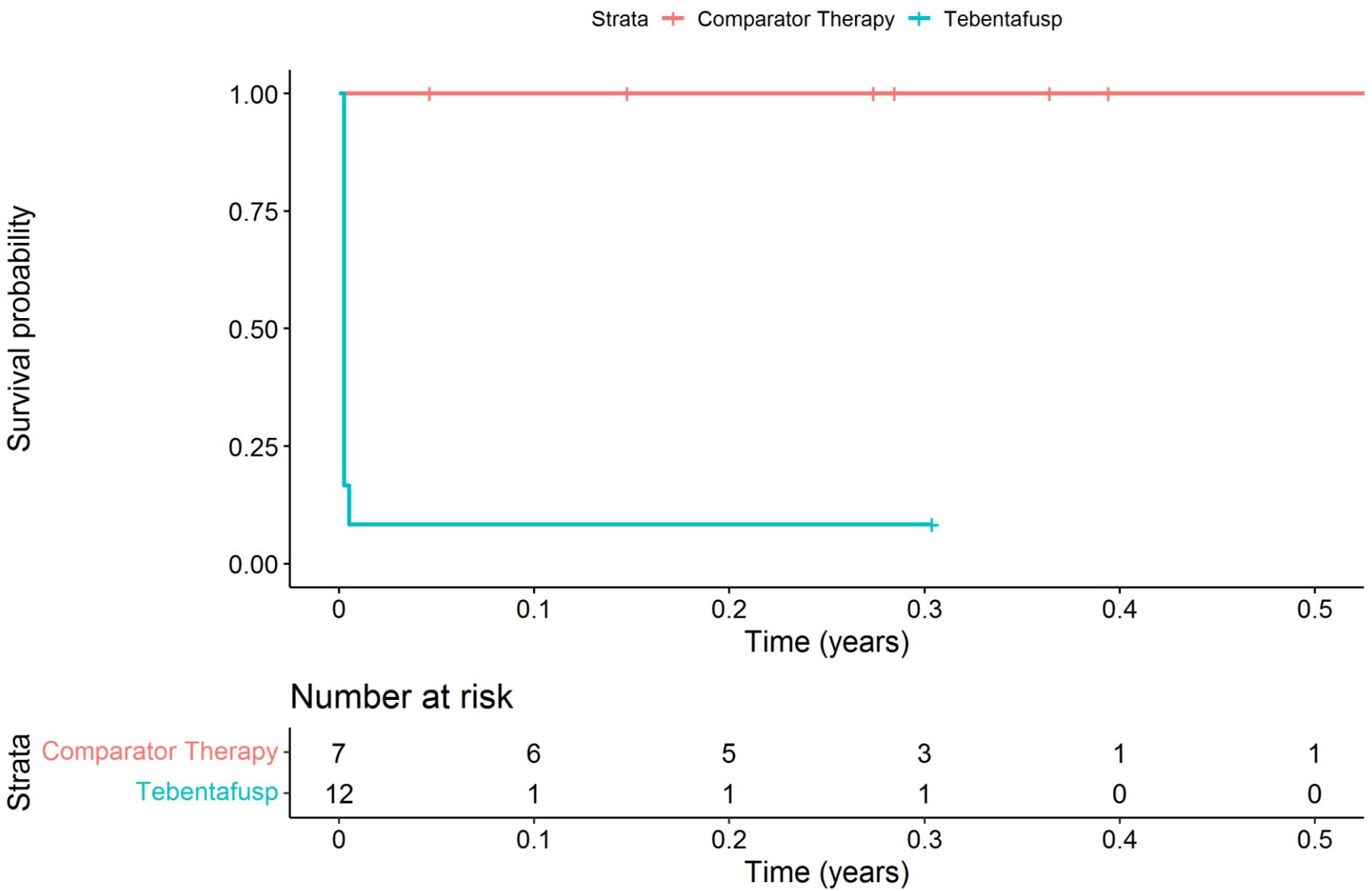
Fieber - Nordamerika



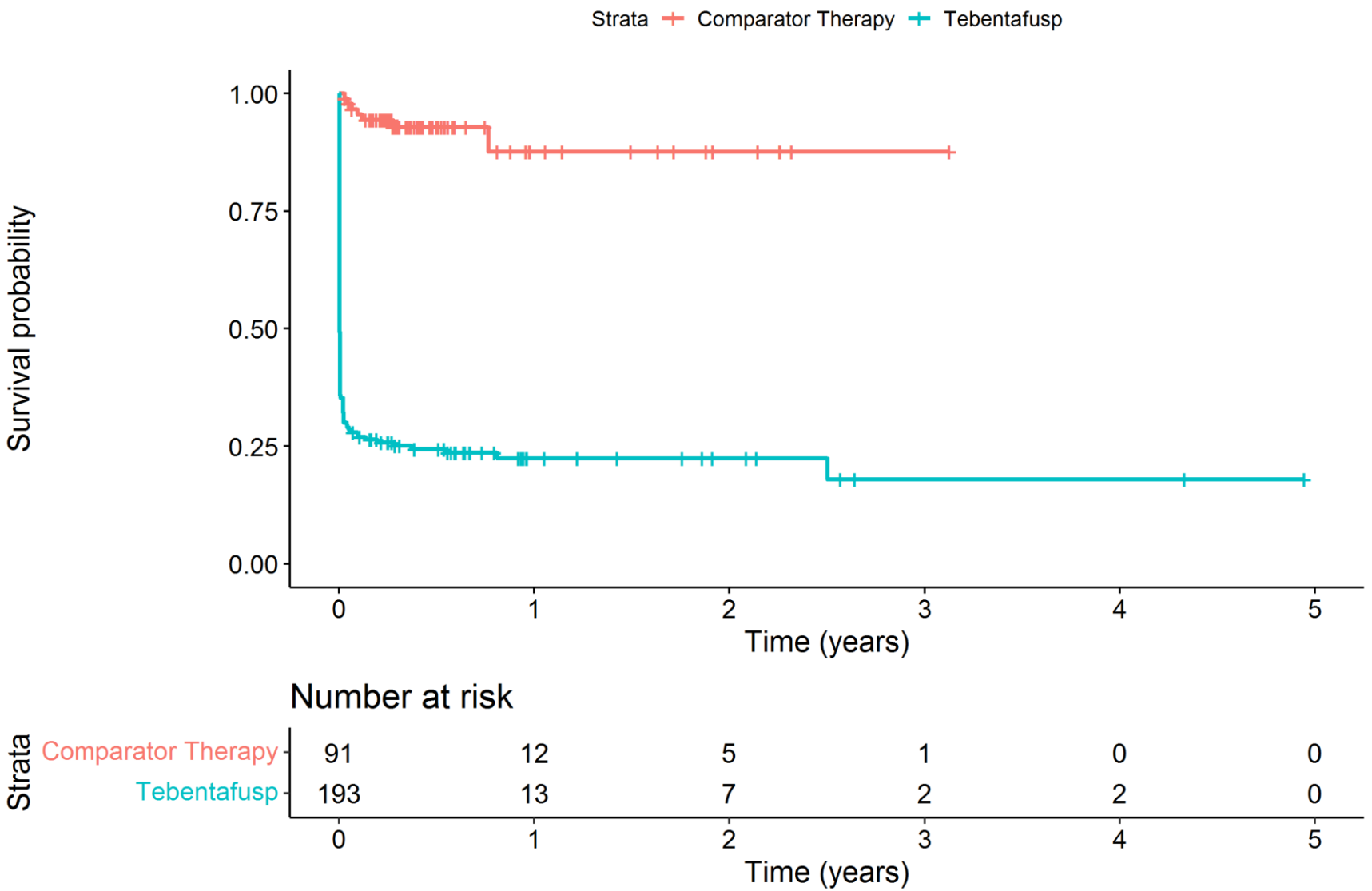
Fieber - Nicht-Nordamerika



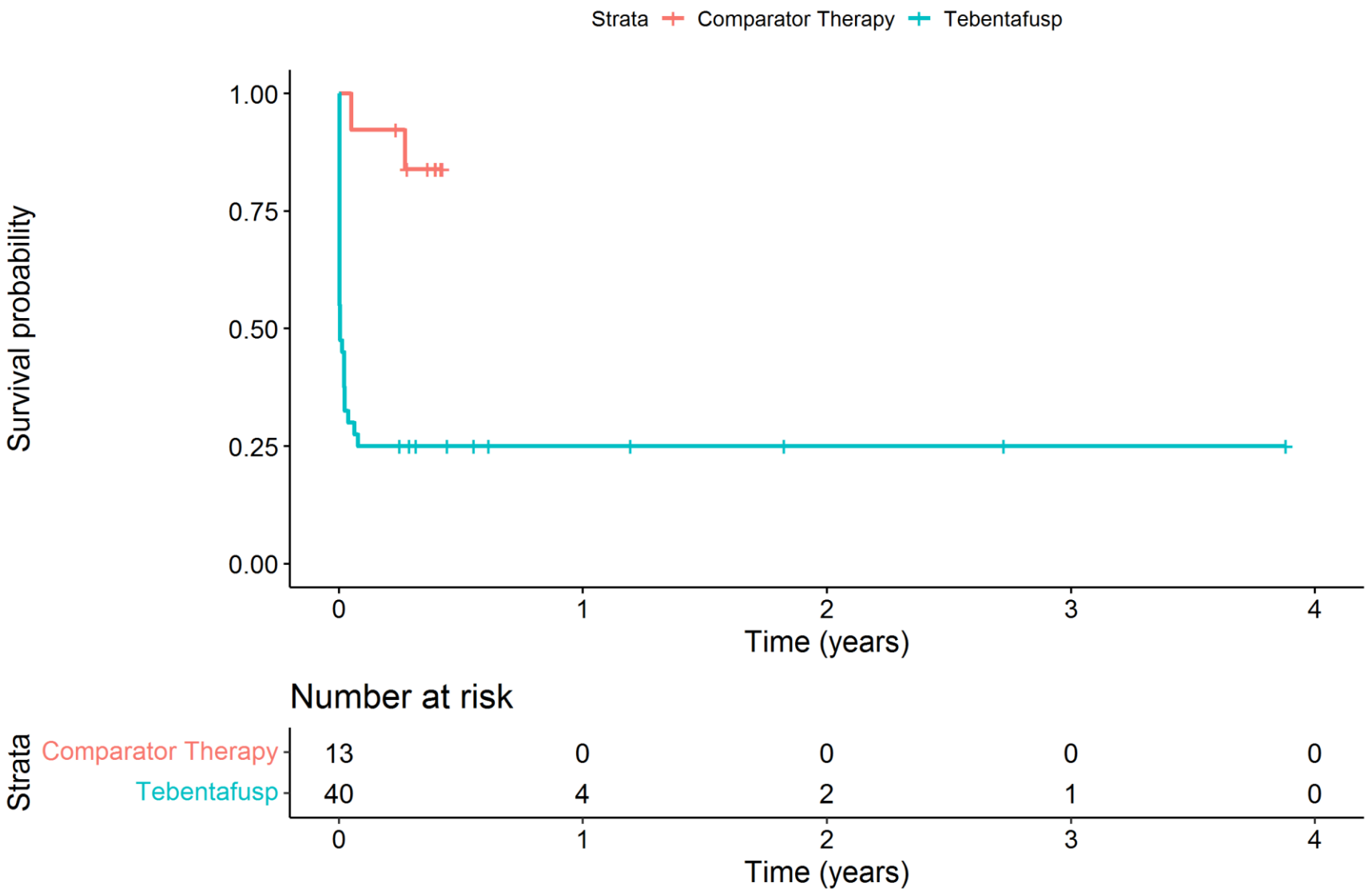
Fieber - Dacarbazin



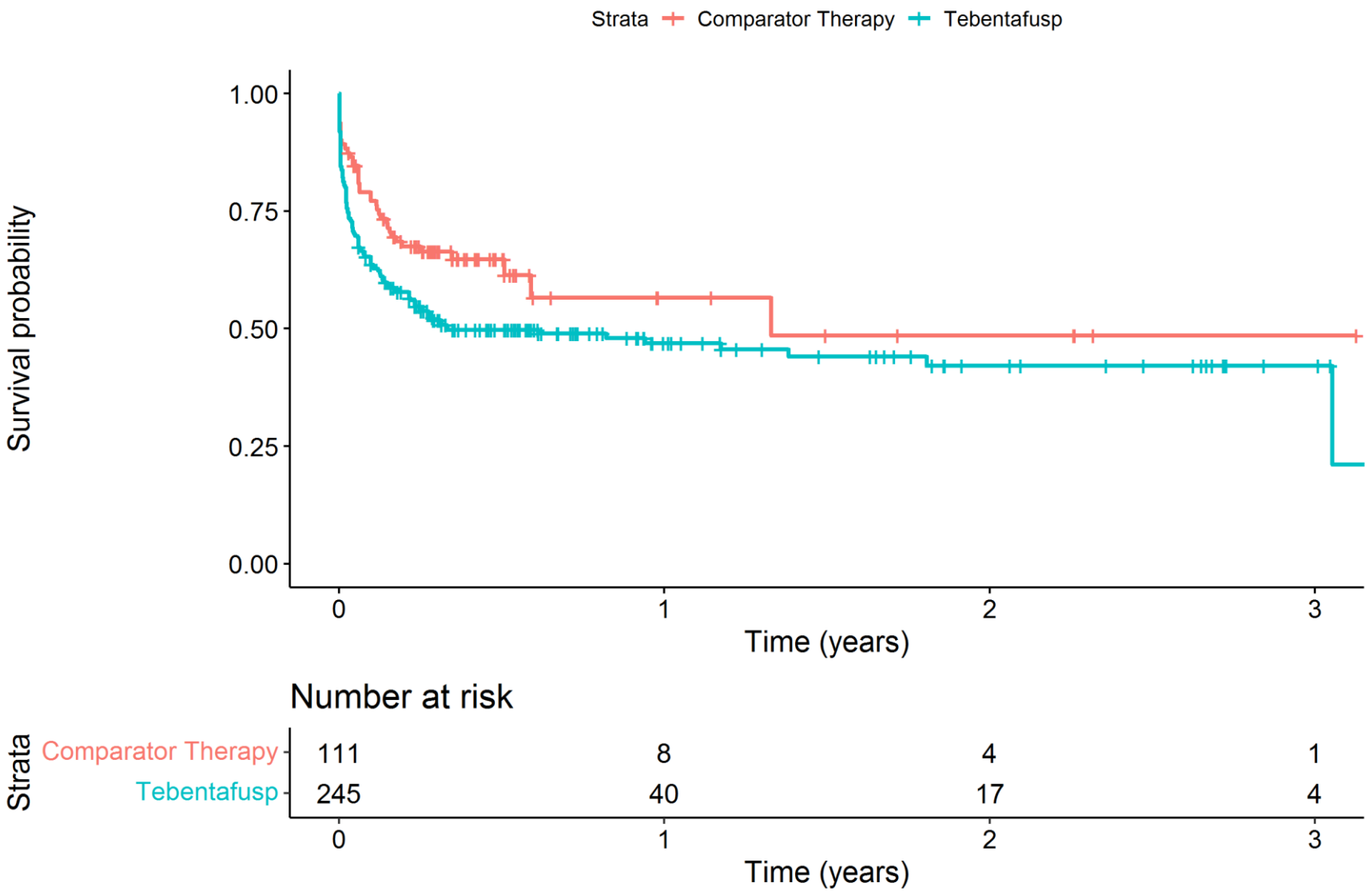
Fieber - Pembrolizumab



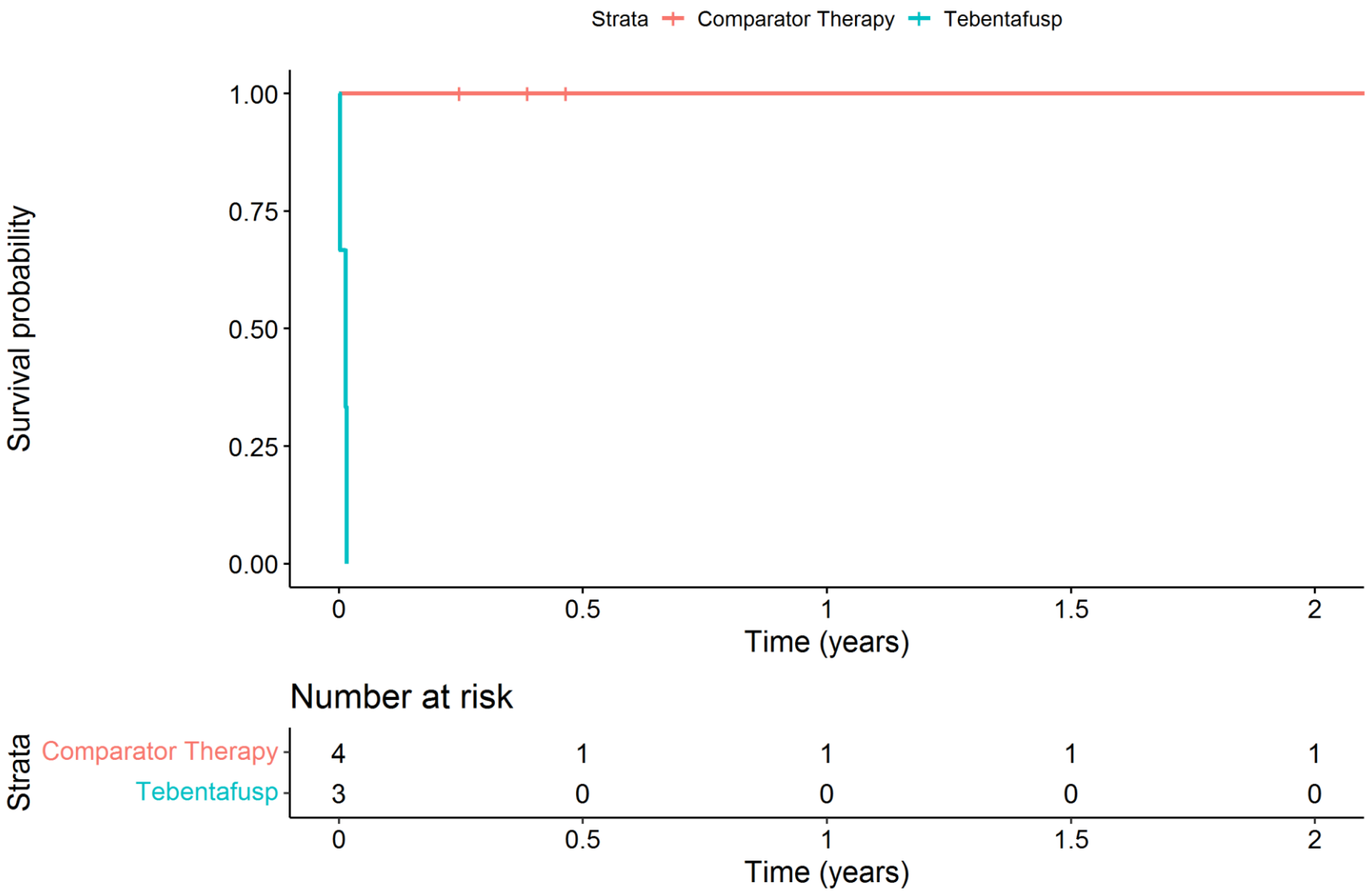
Fieber - Ipilimumab



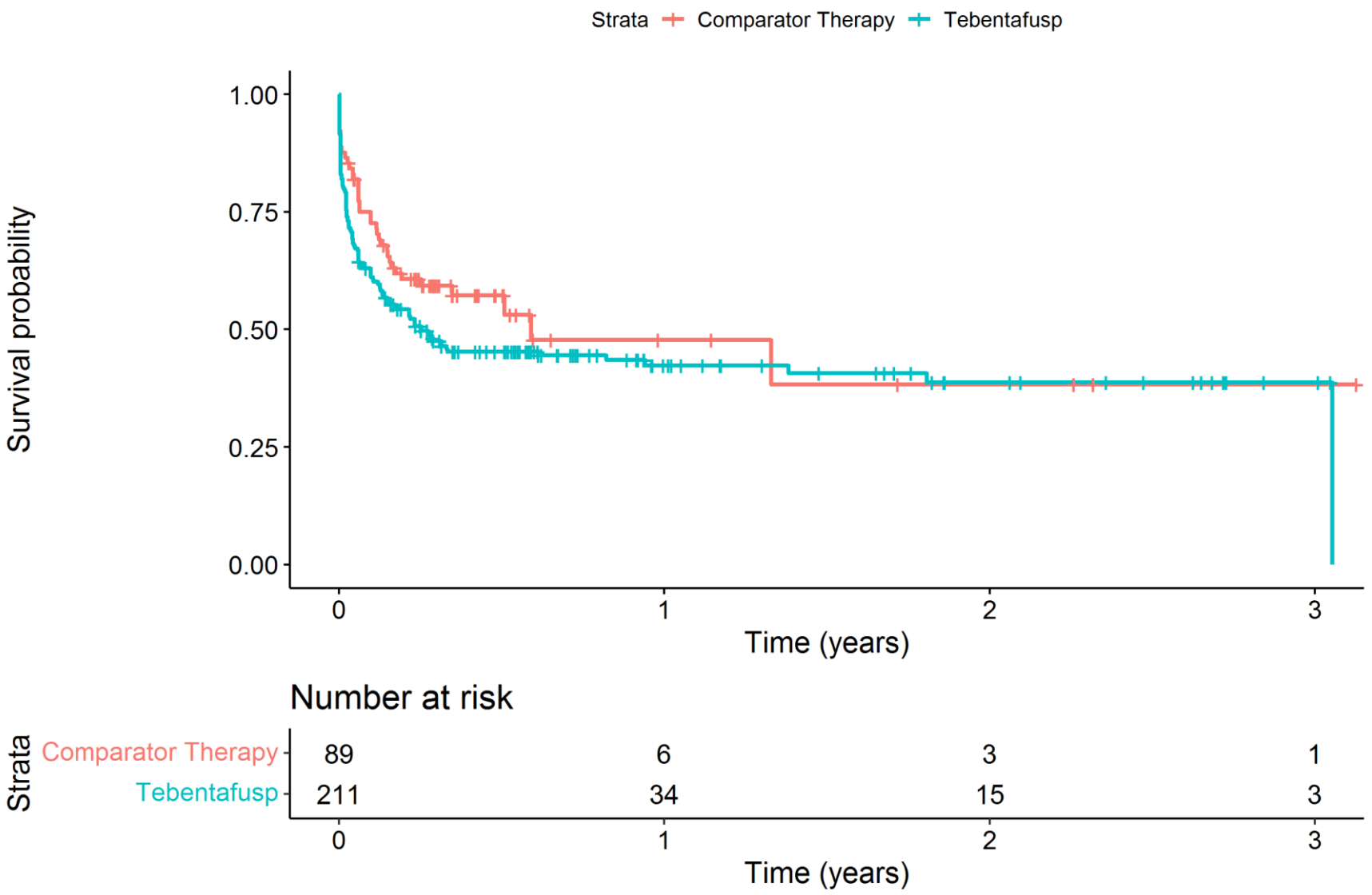
Müdigkeit - Gesamt



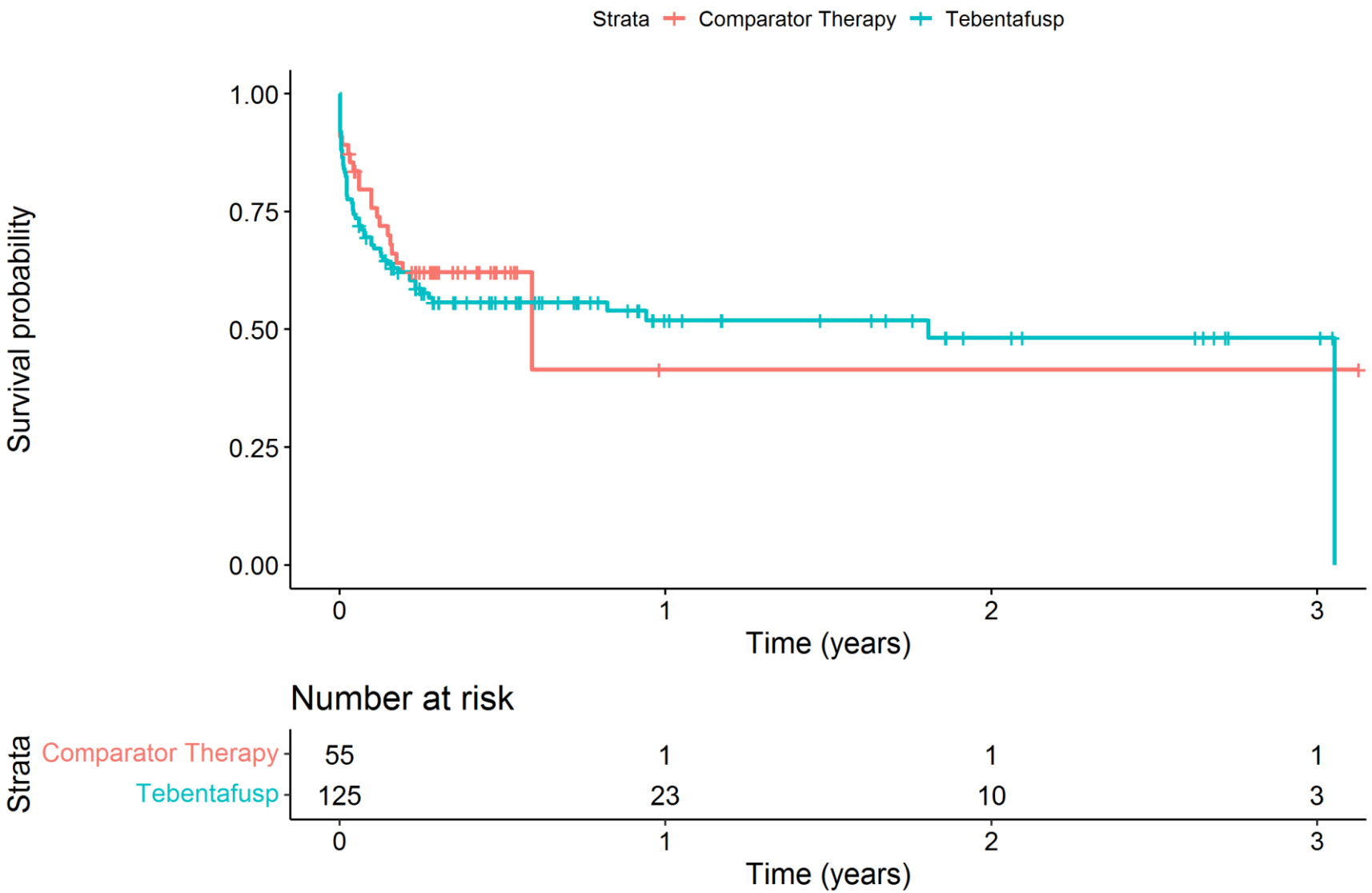
Müdigkeit - Hispanisch



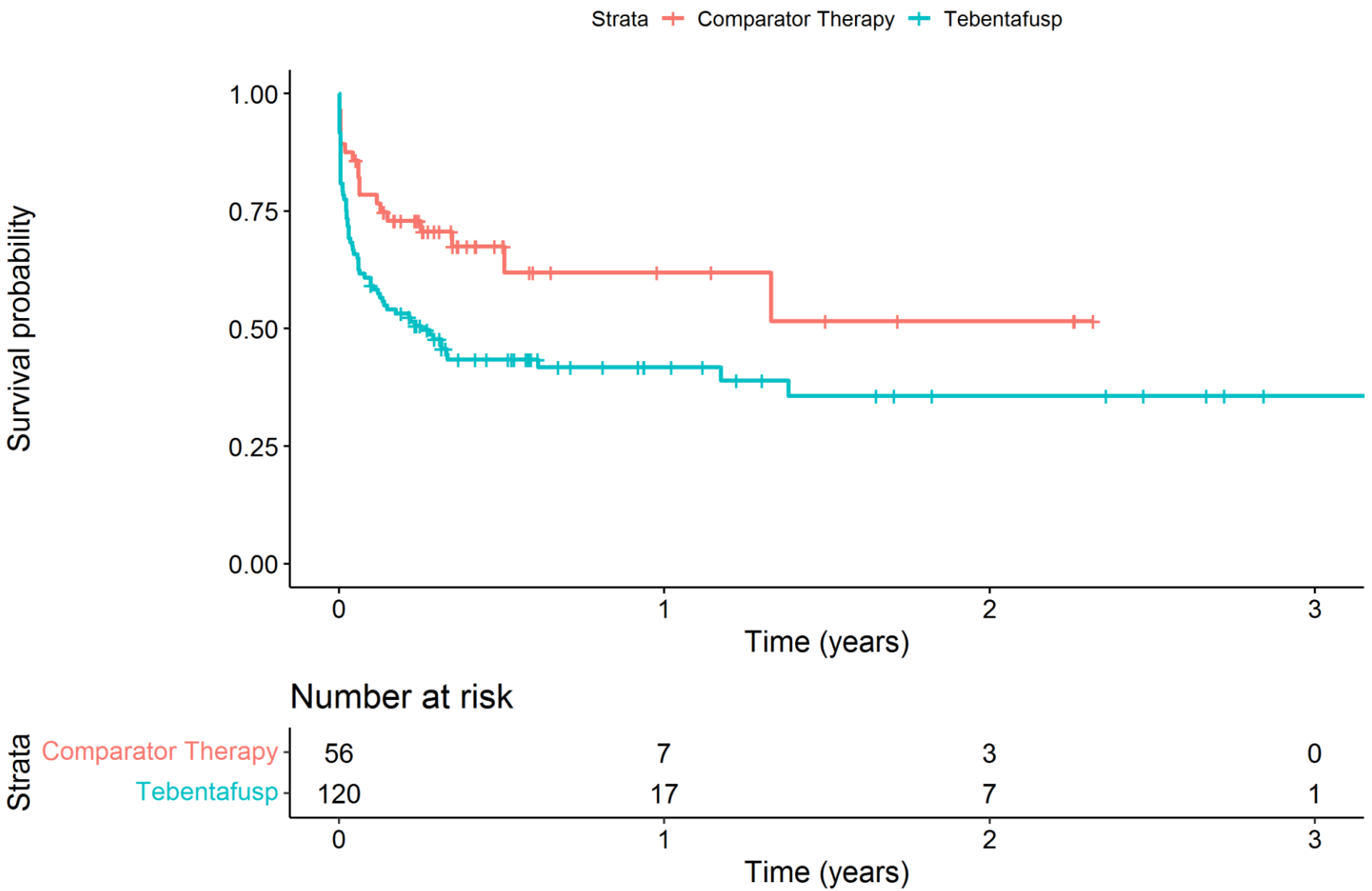
60.9 Müdigkeit - Nicht-hispanisch



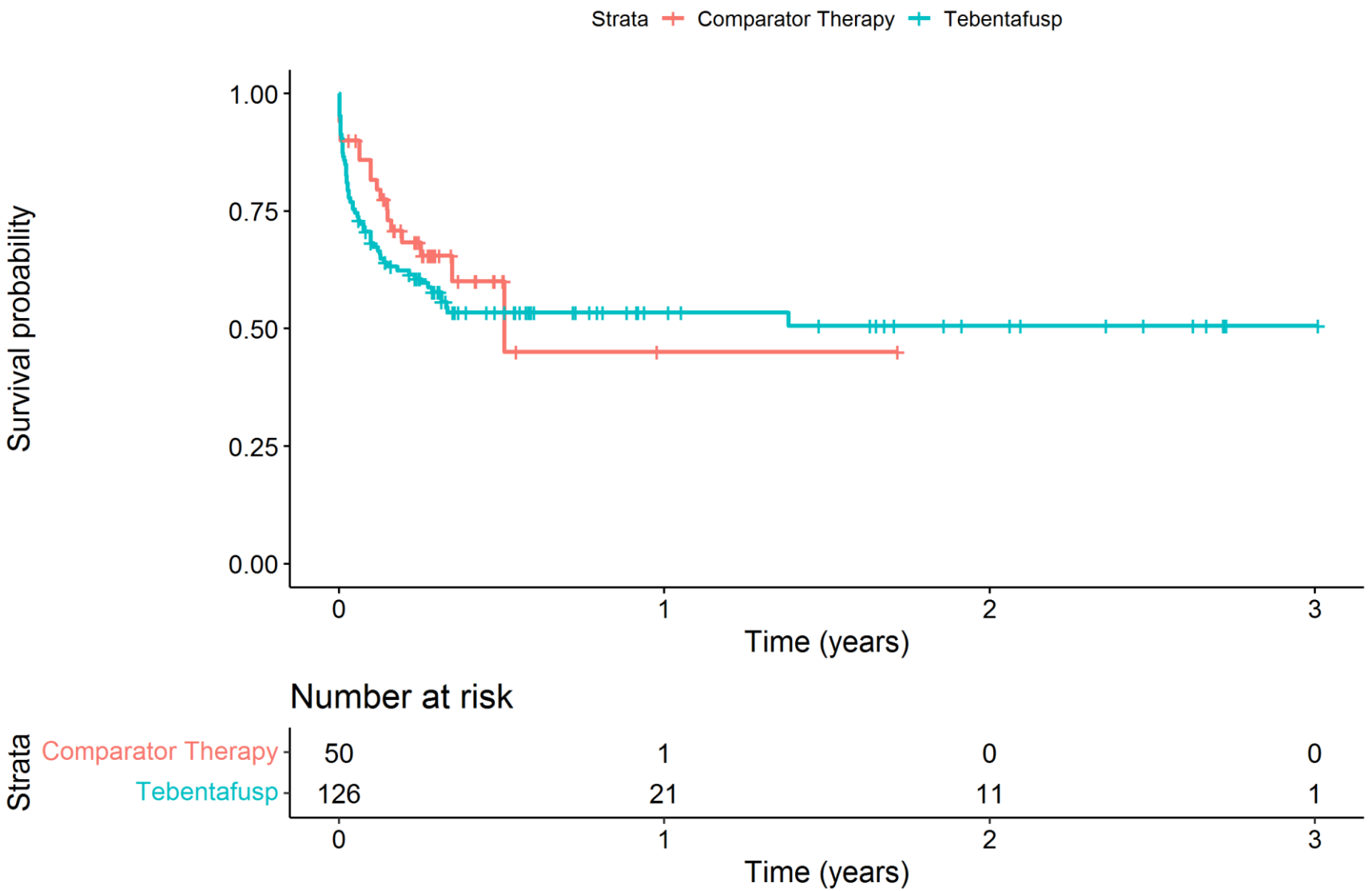
Müdigkeit - Männlich



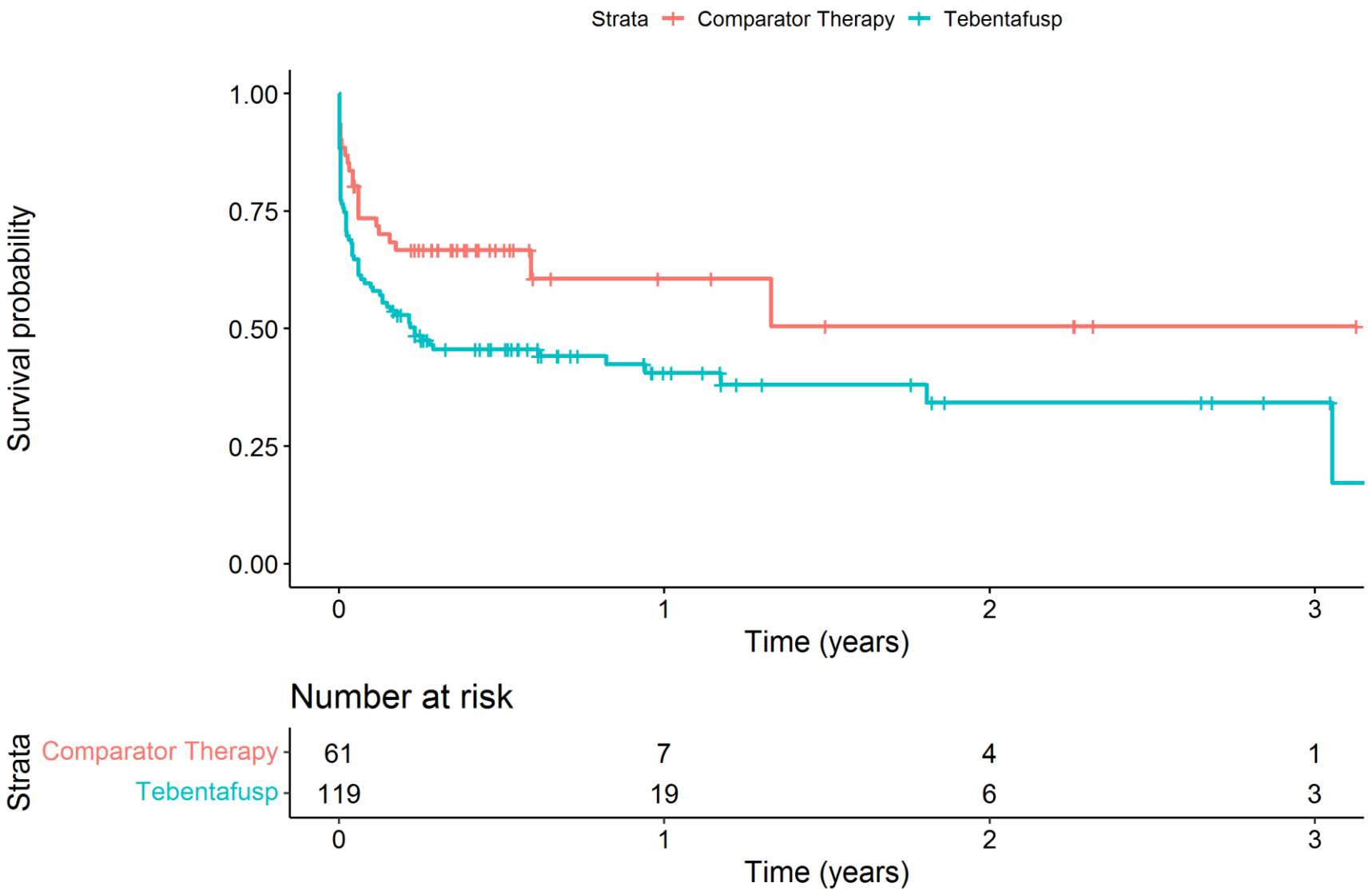
Müdigkeit - Weiblich



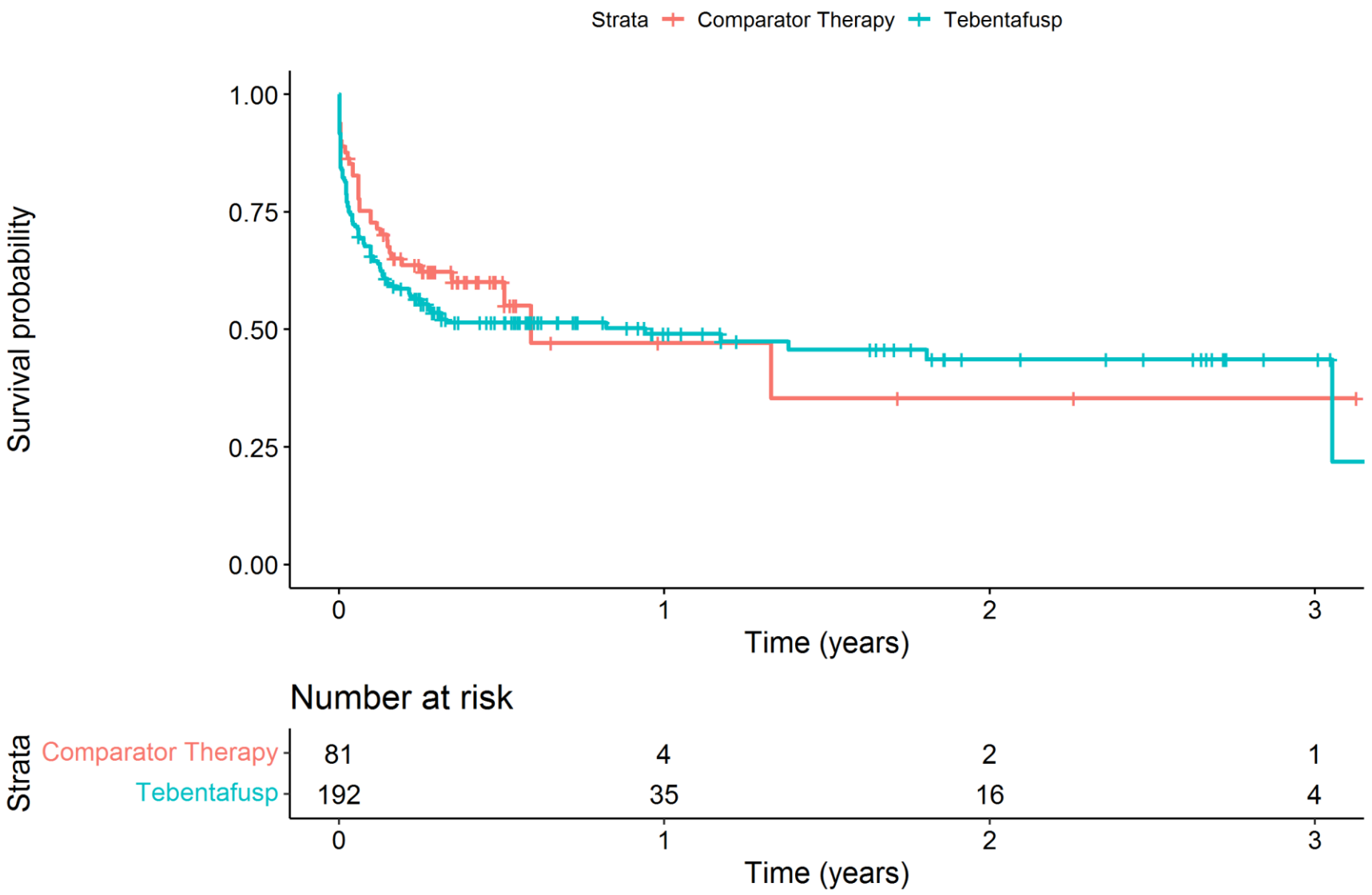
Müdigkeit - <65



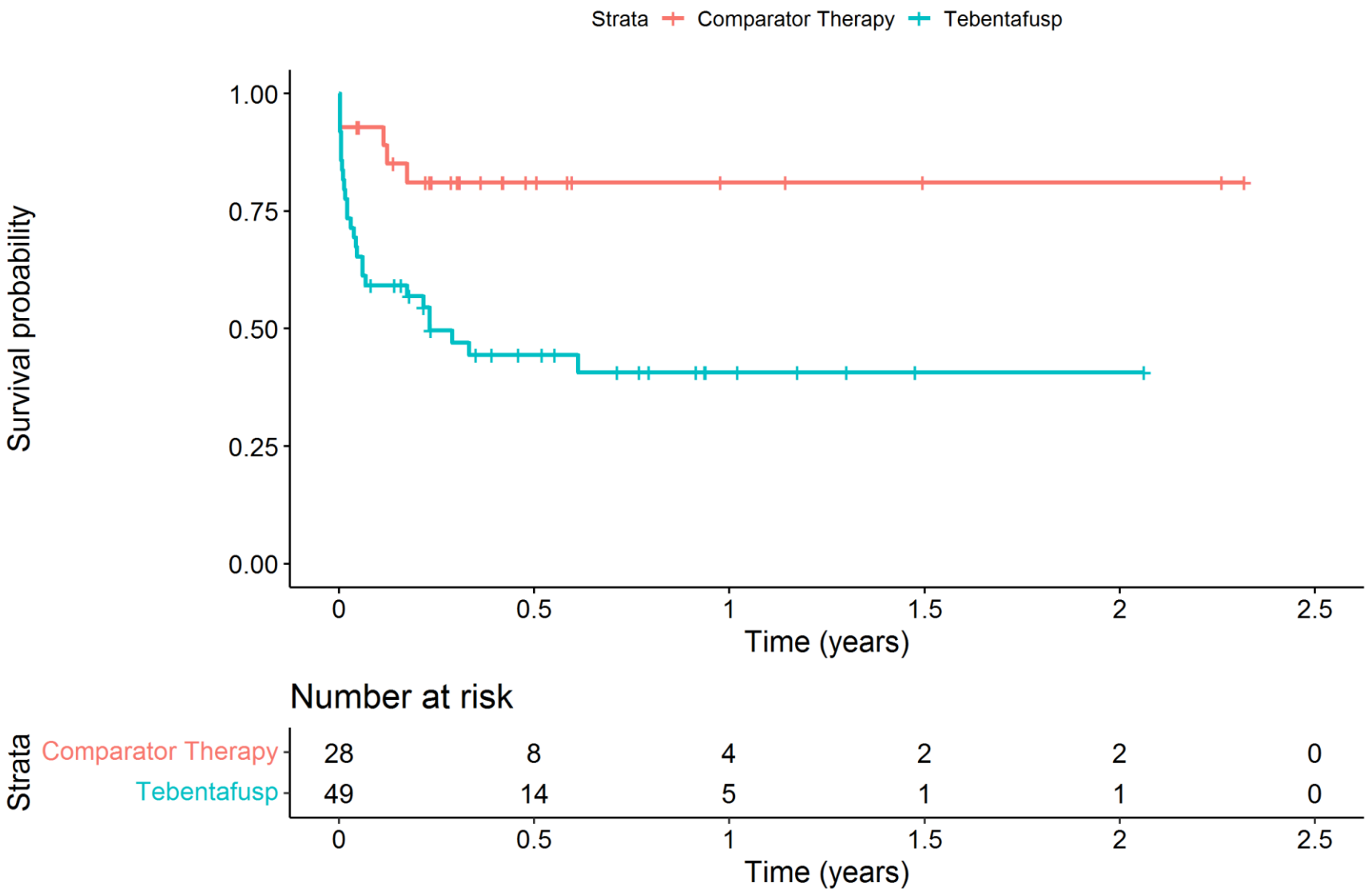
Müdigkeit - ≥65



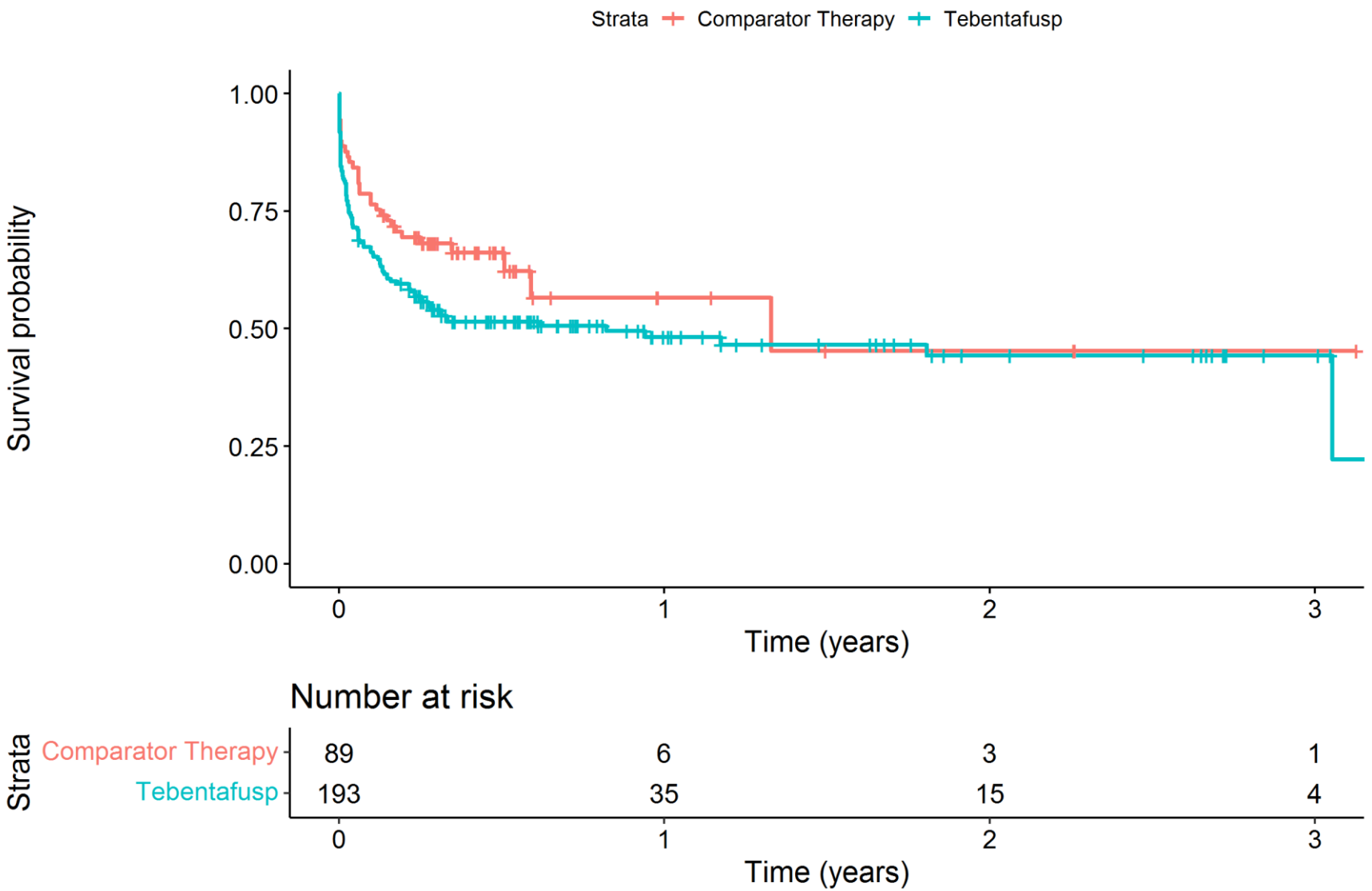
60.10 Müdigkeit - ECOG 0



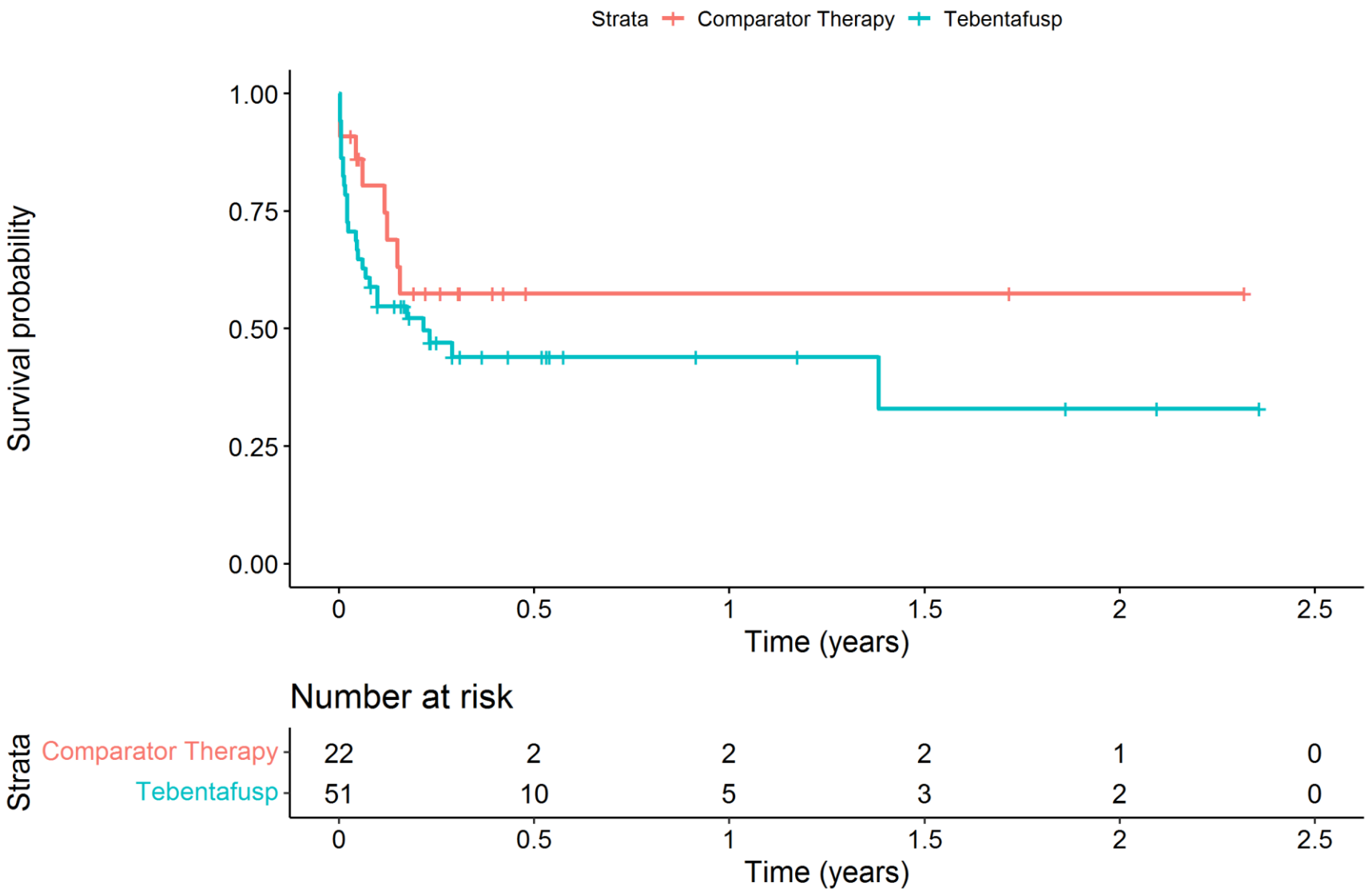
Müdigkeit - ECOG 1



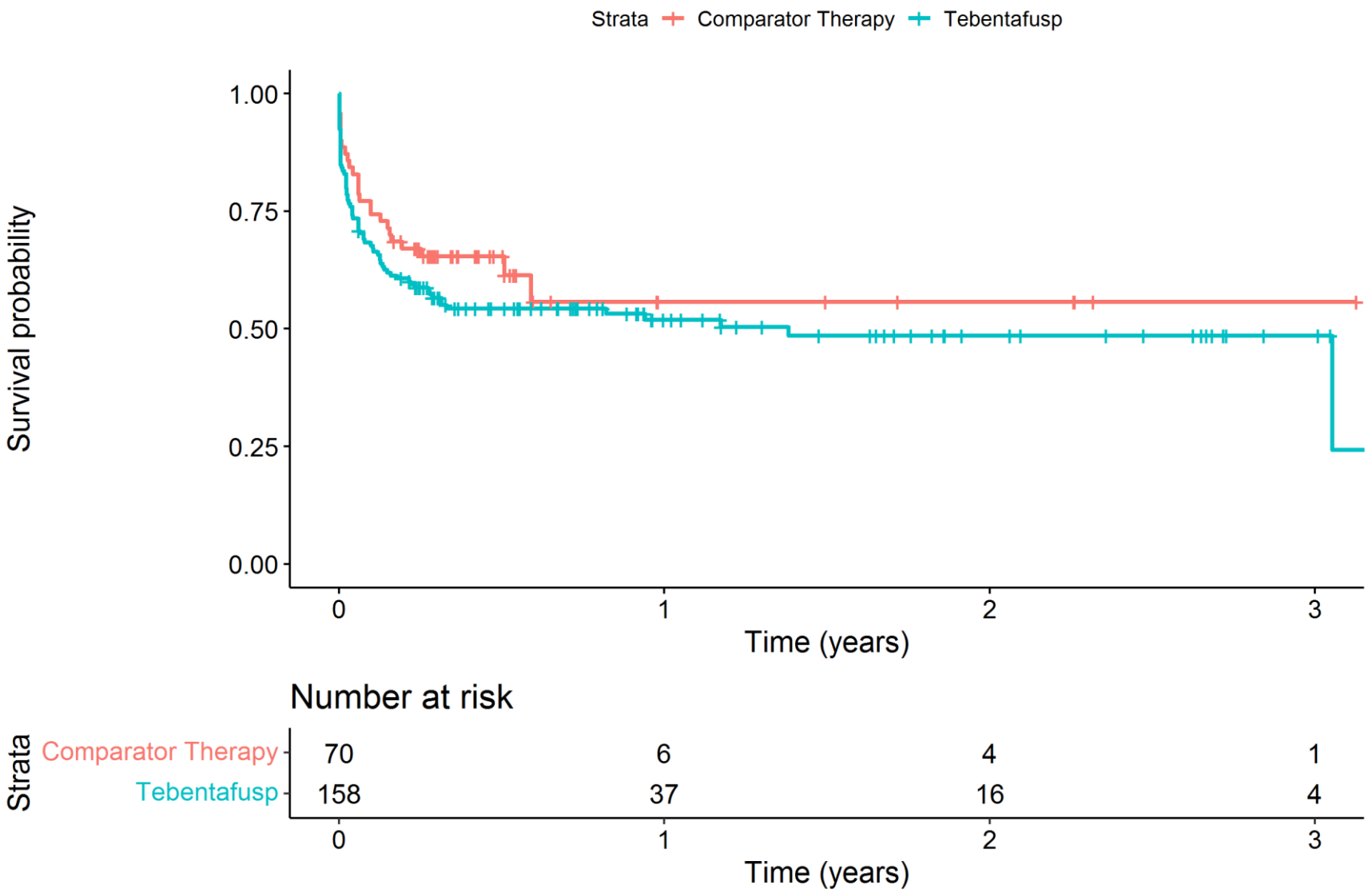
Müdigkeit - ALP ≤ ULN



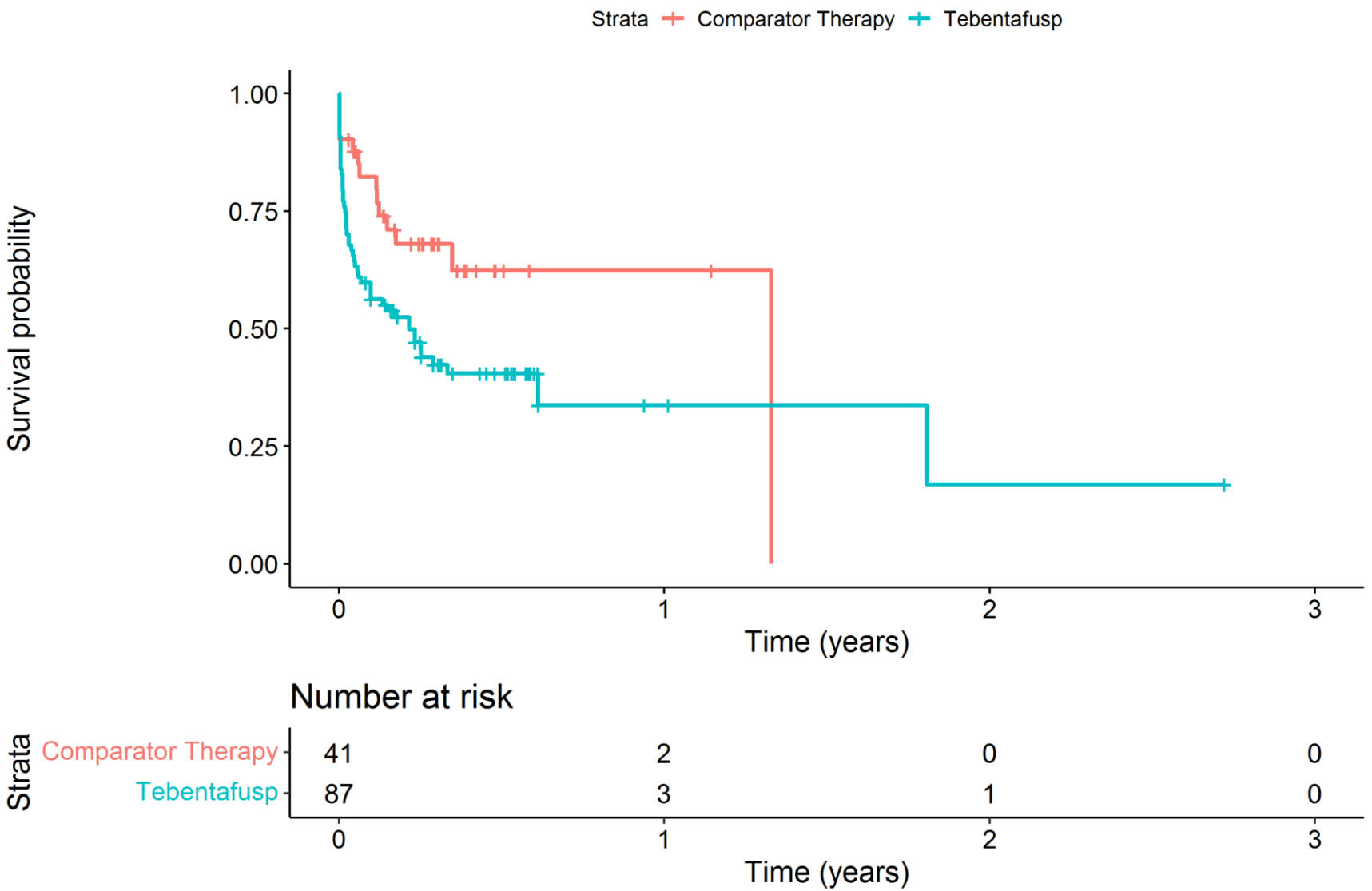
Müdigkeit - ALP > ULN



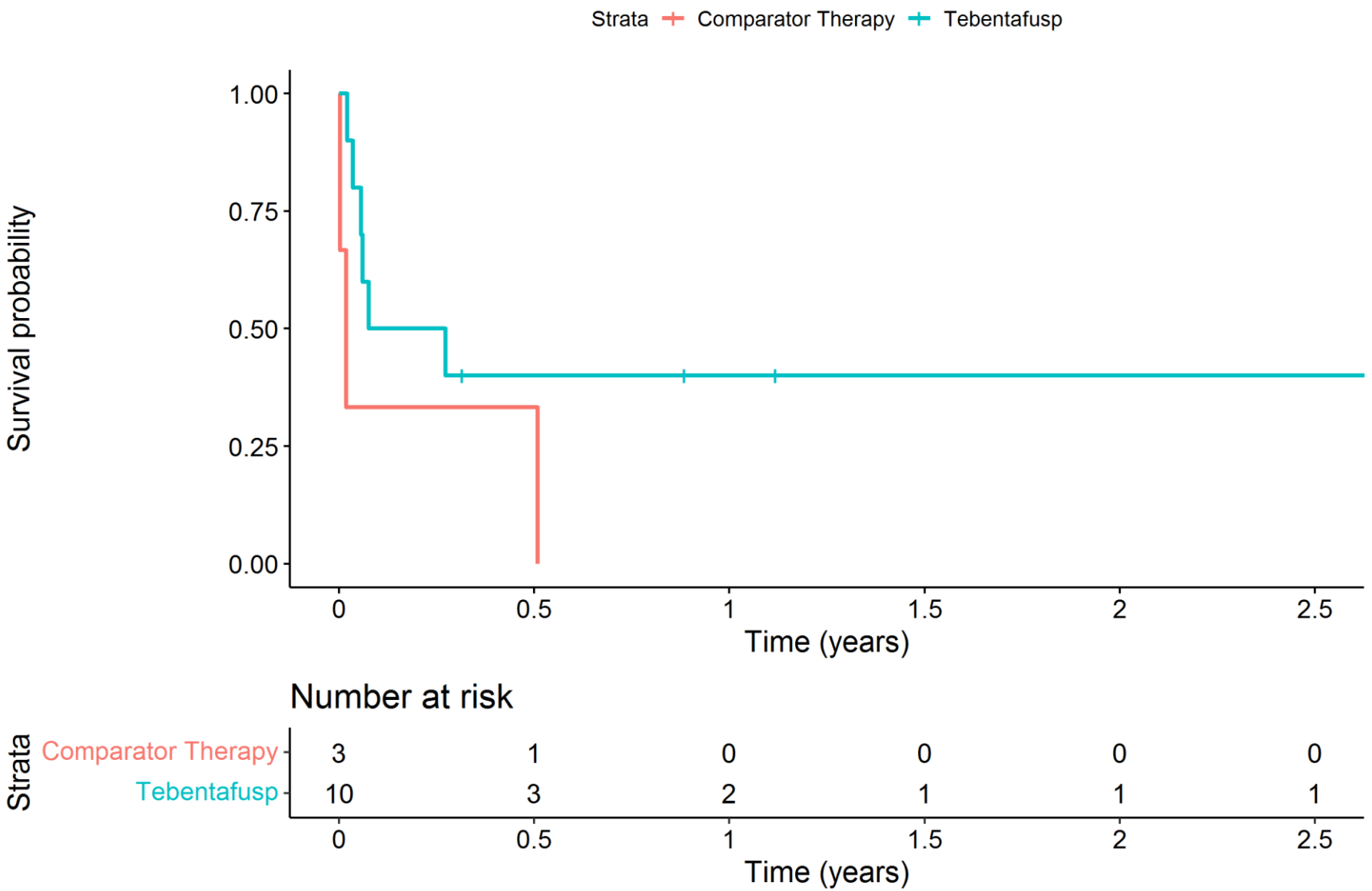
Müdigkeit - LDH =< ULN



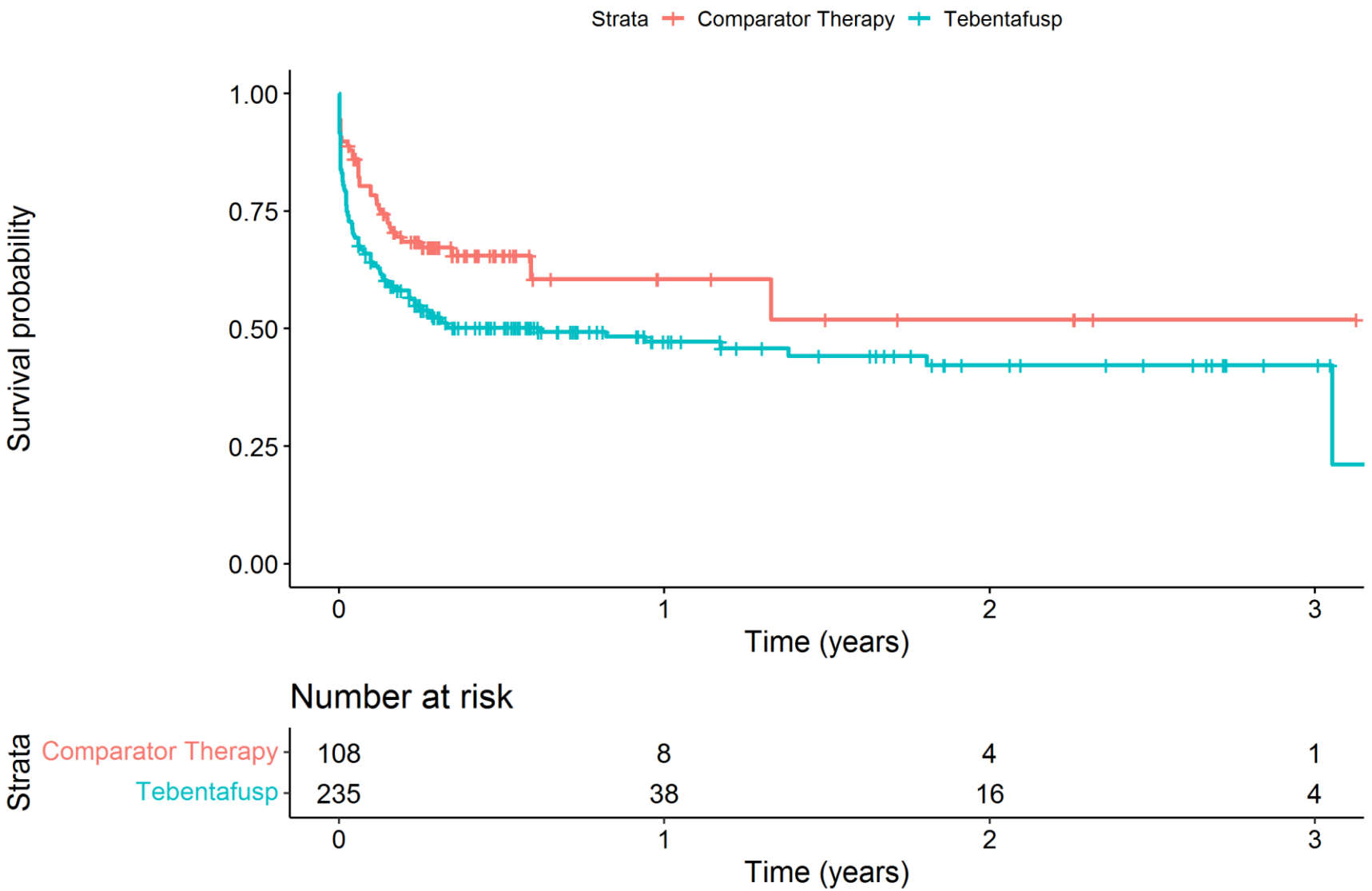
Müdigkeit - LDH > ULN



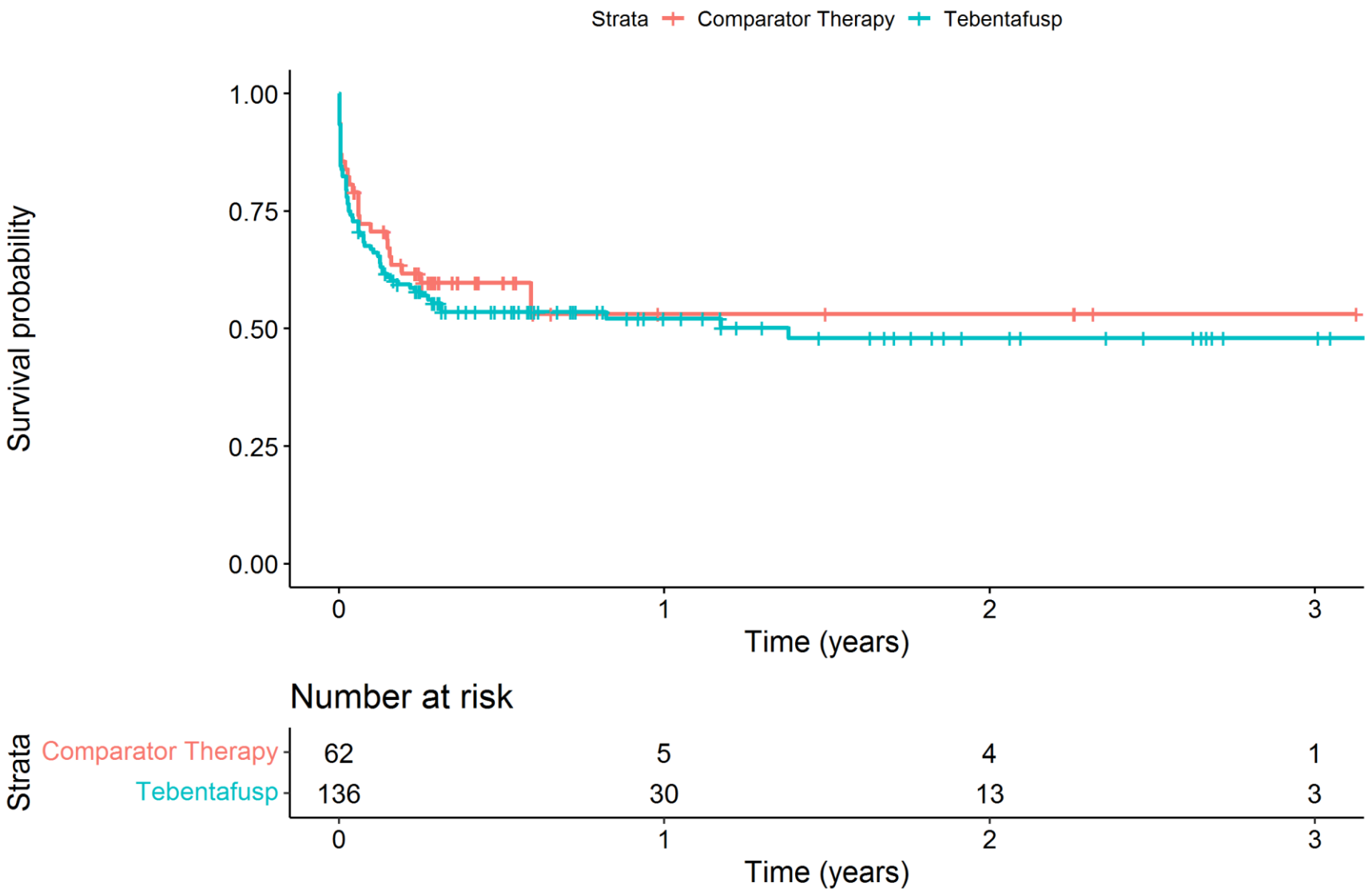
Müdigkeit - Vorherige Therapie adjuvant/neoadjuvant



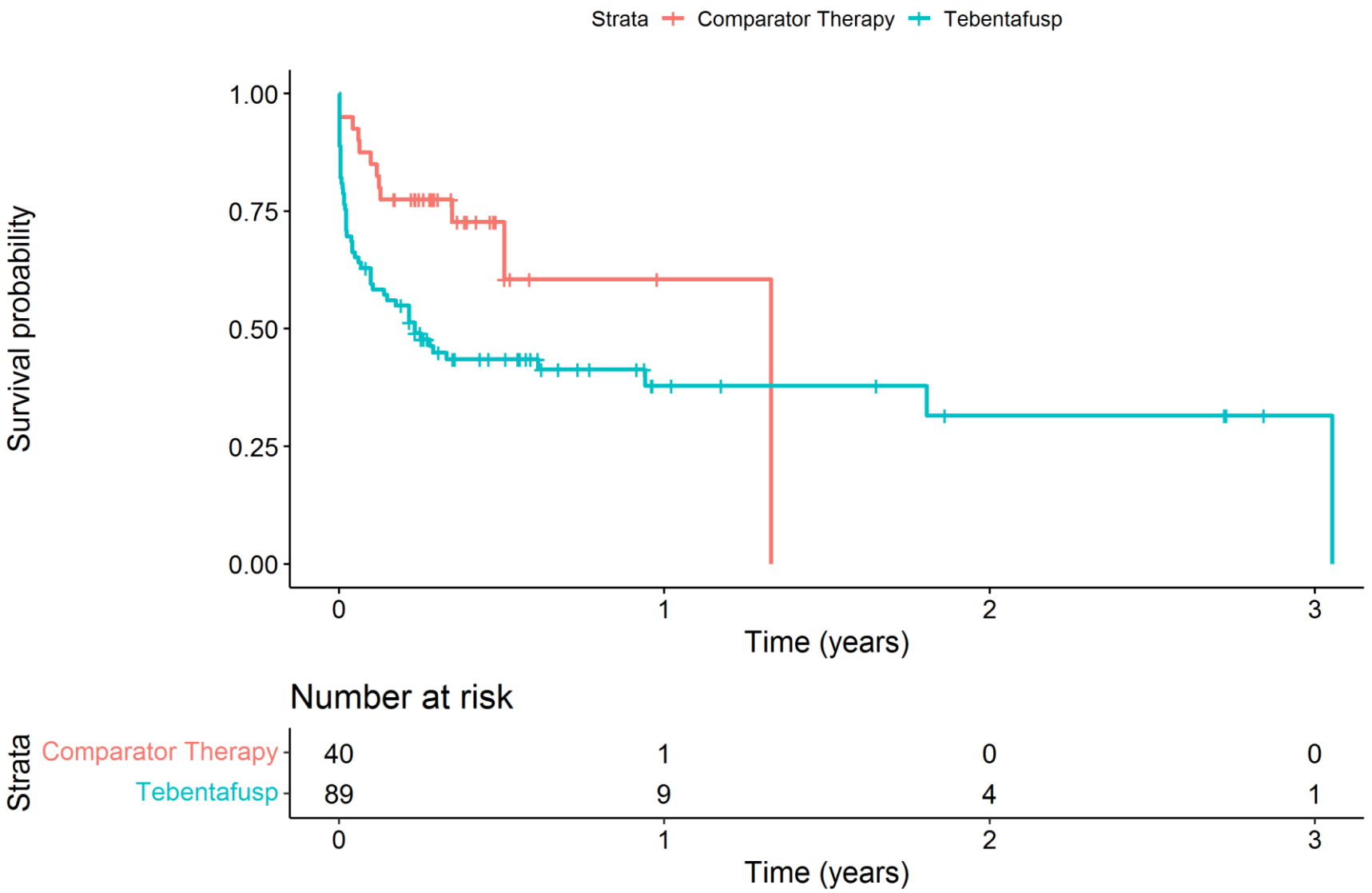
Müdigkeit - Keine Vorherige Therapie adjuvant/neoadjuvant



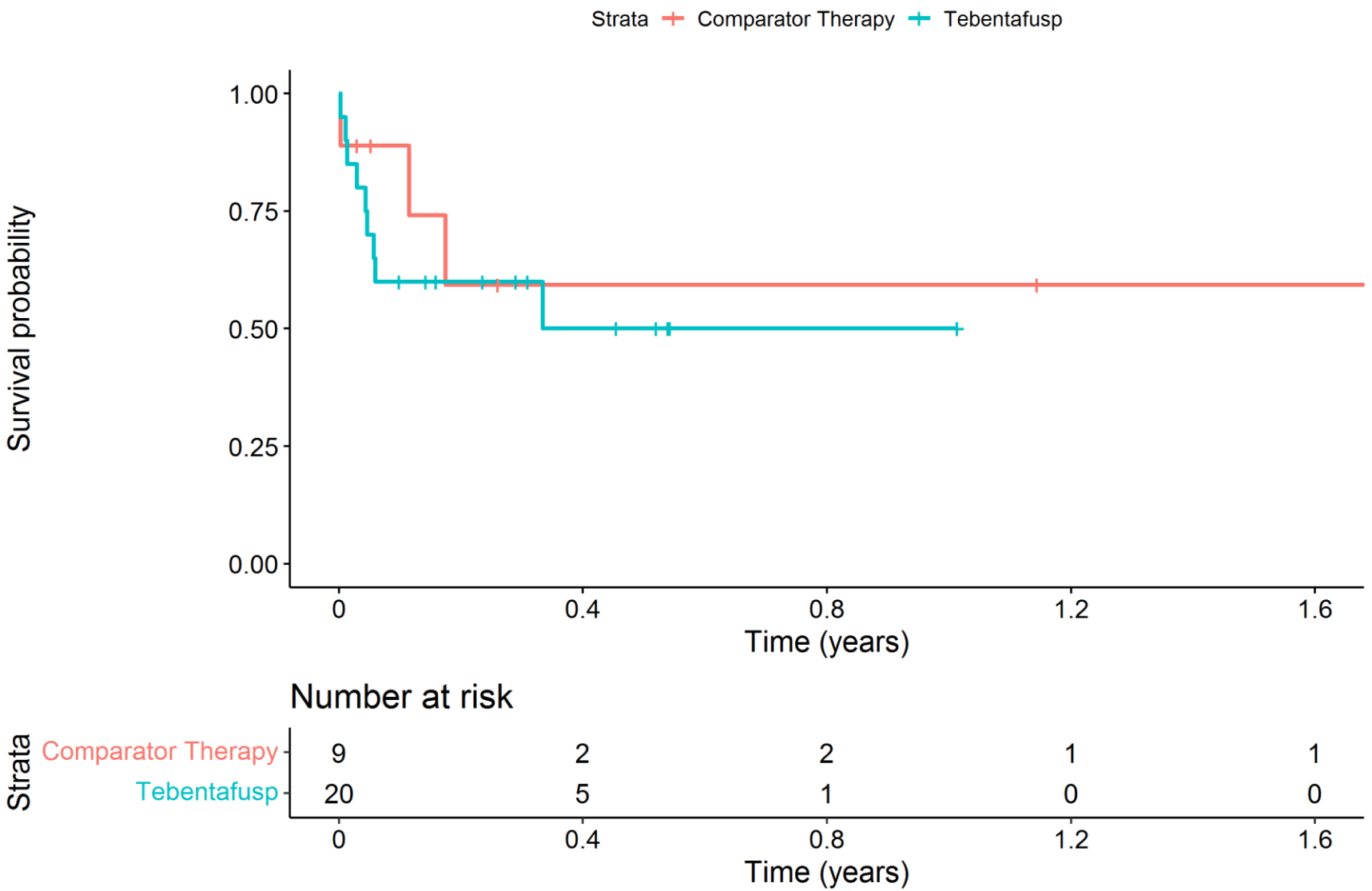
Müdigkeit - Läsion ≤ 3cm



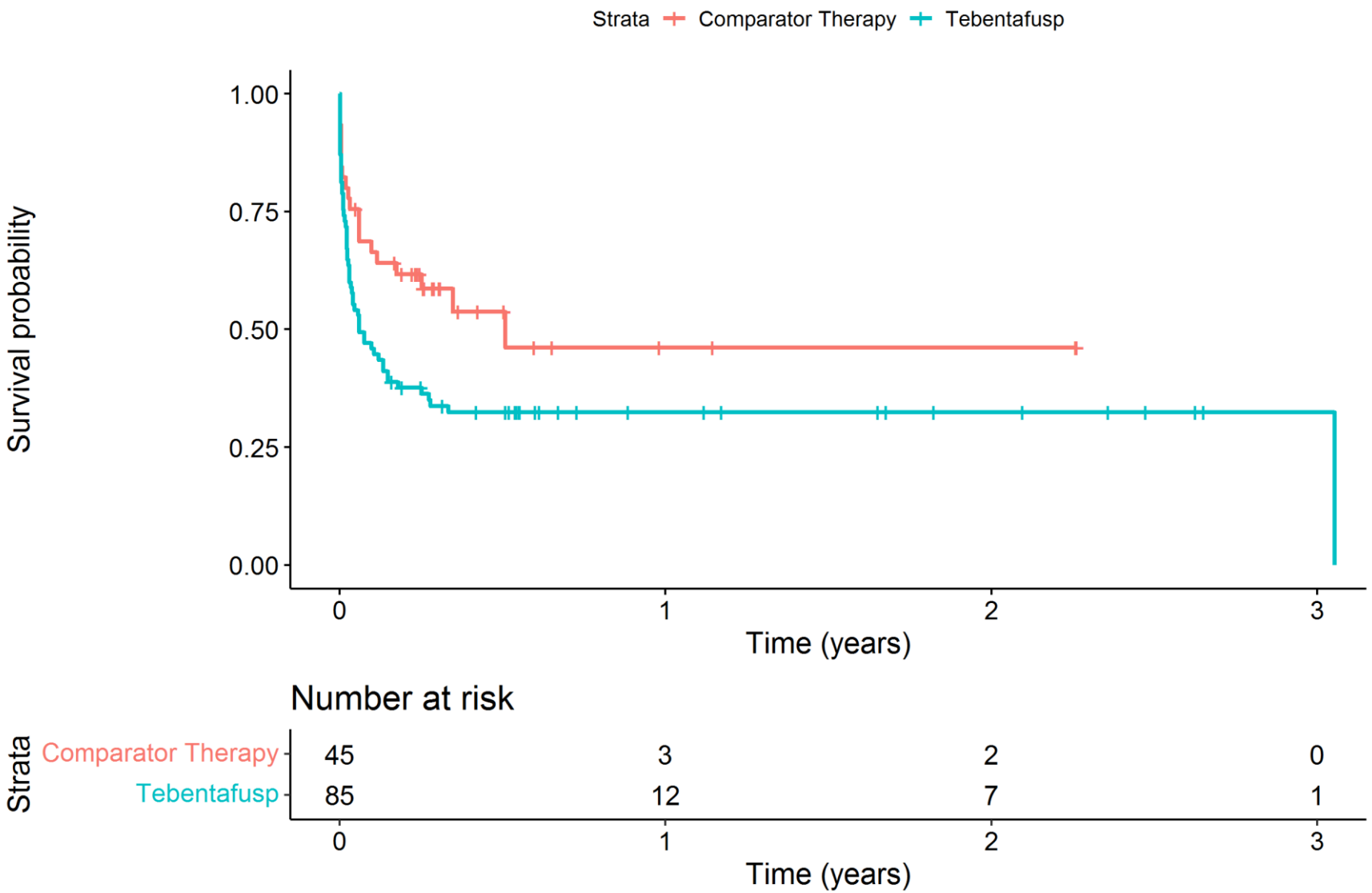
Müdigkeit - Läsion 3,1-8,0 cm



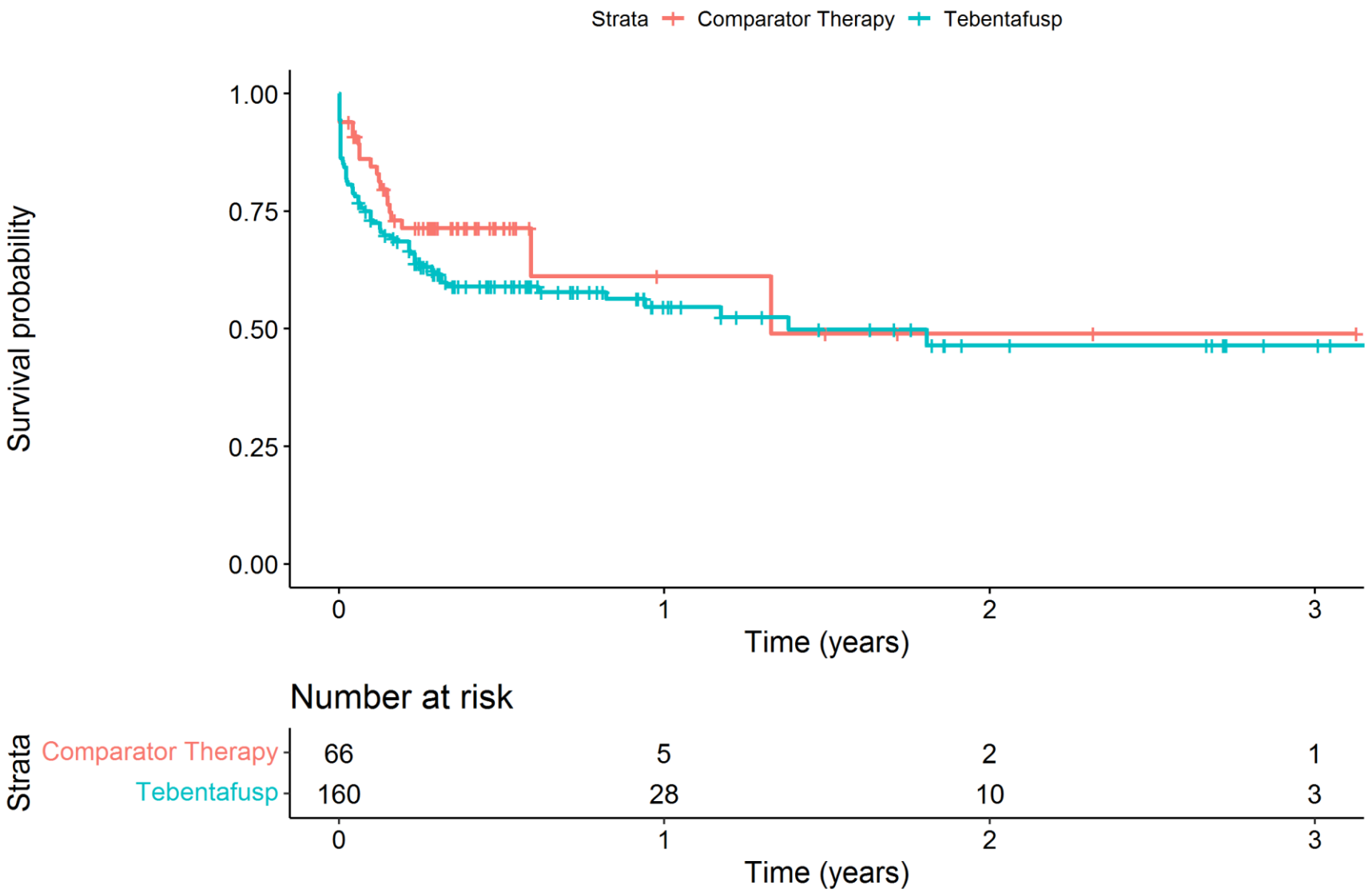
Müdigkeit - Läsion ≥8,1 cm



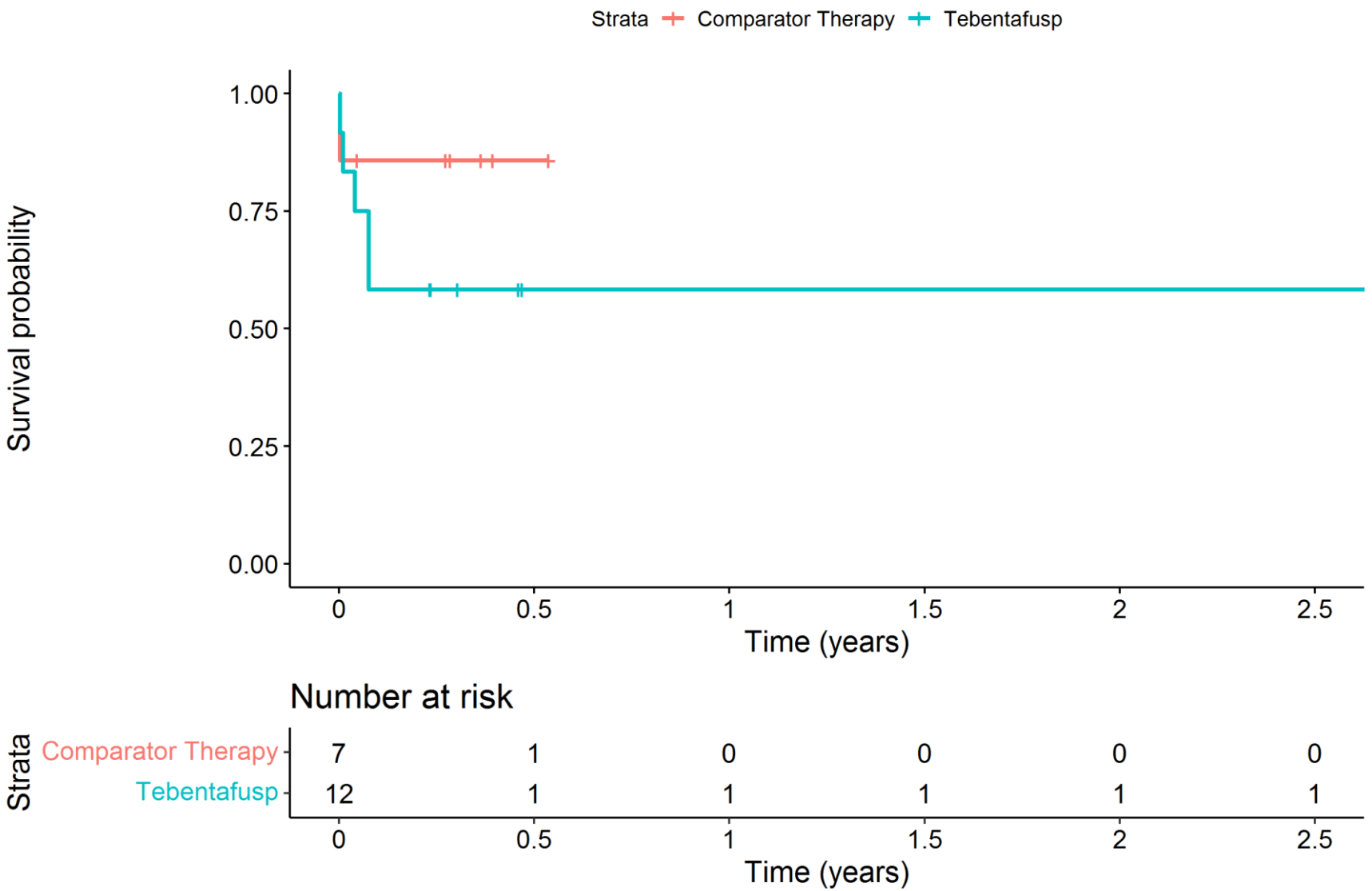
Müdigkeit - Nordamerika



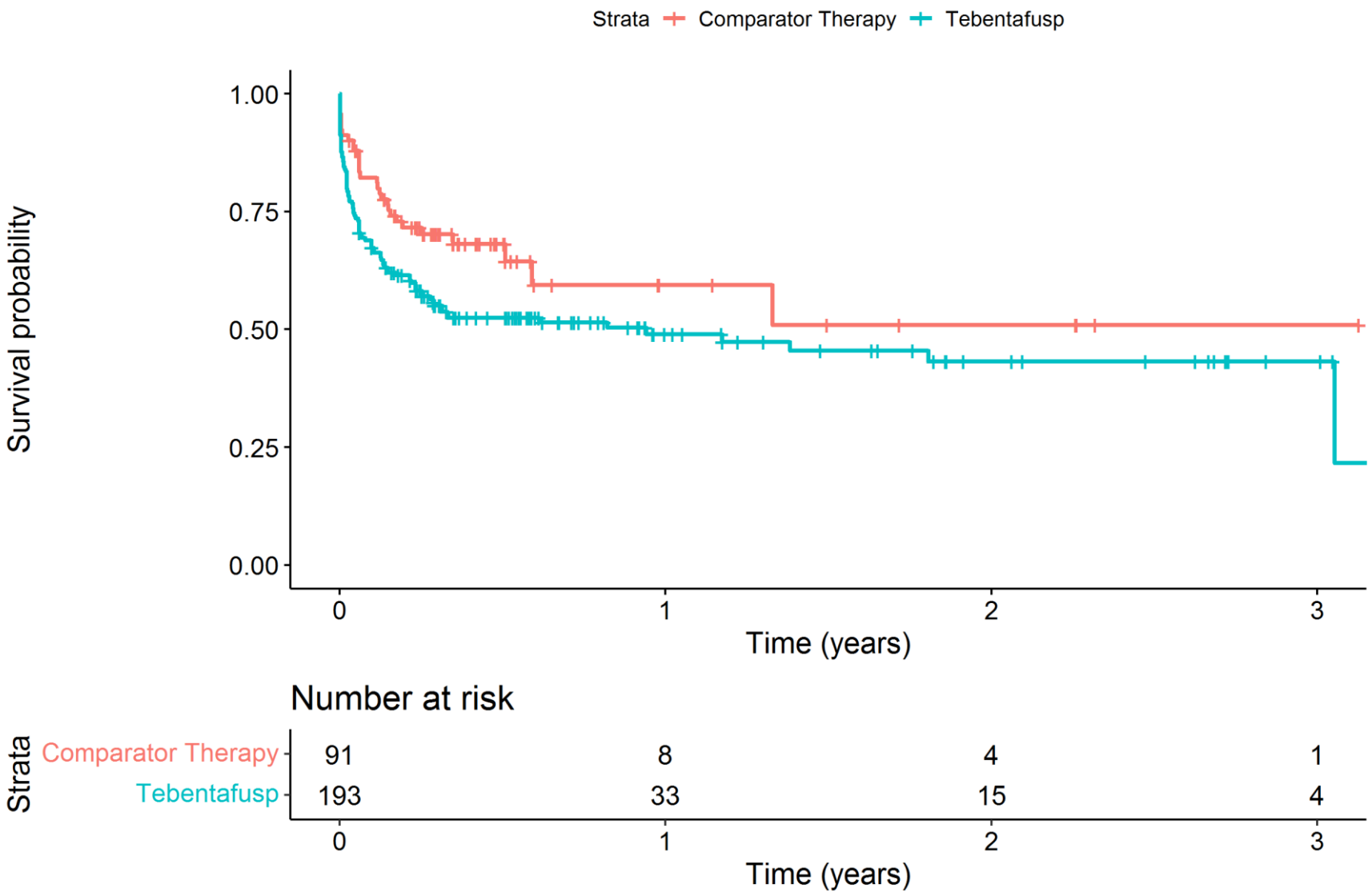
Müdigkeit - Nicht-Nordamerika



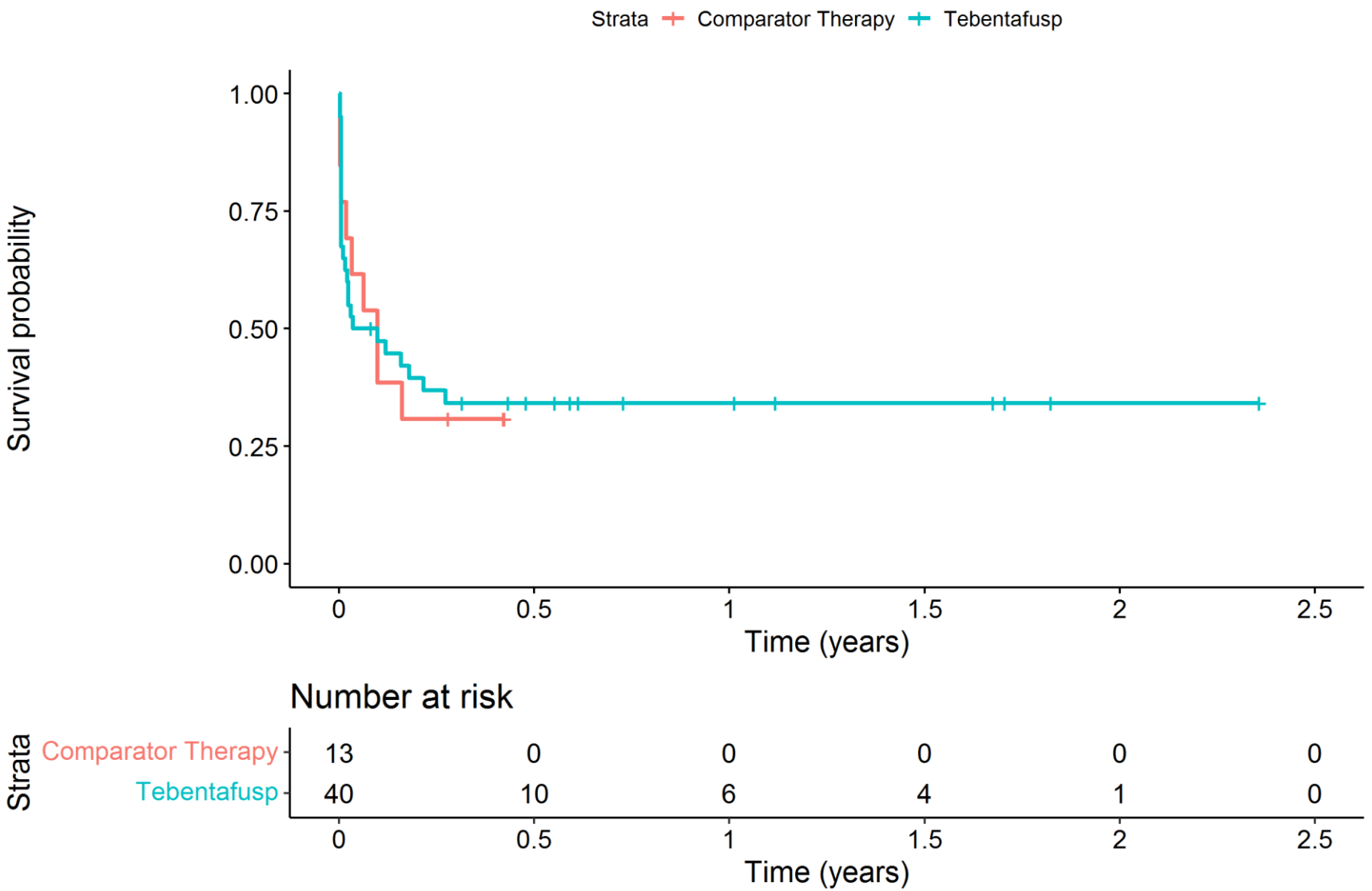
Müdigkeit - Dacarbazin



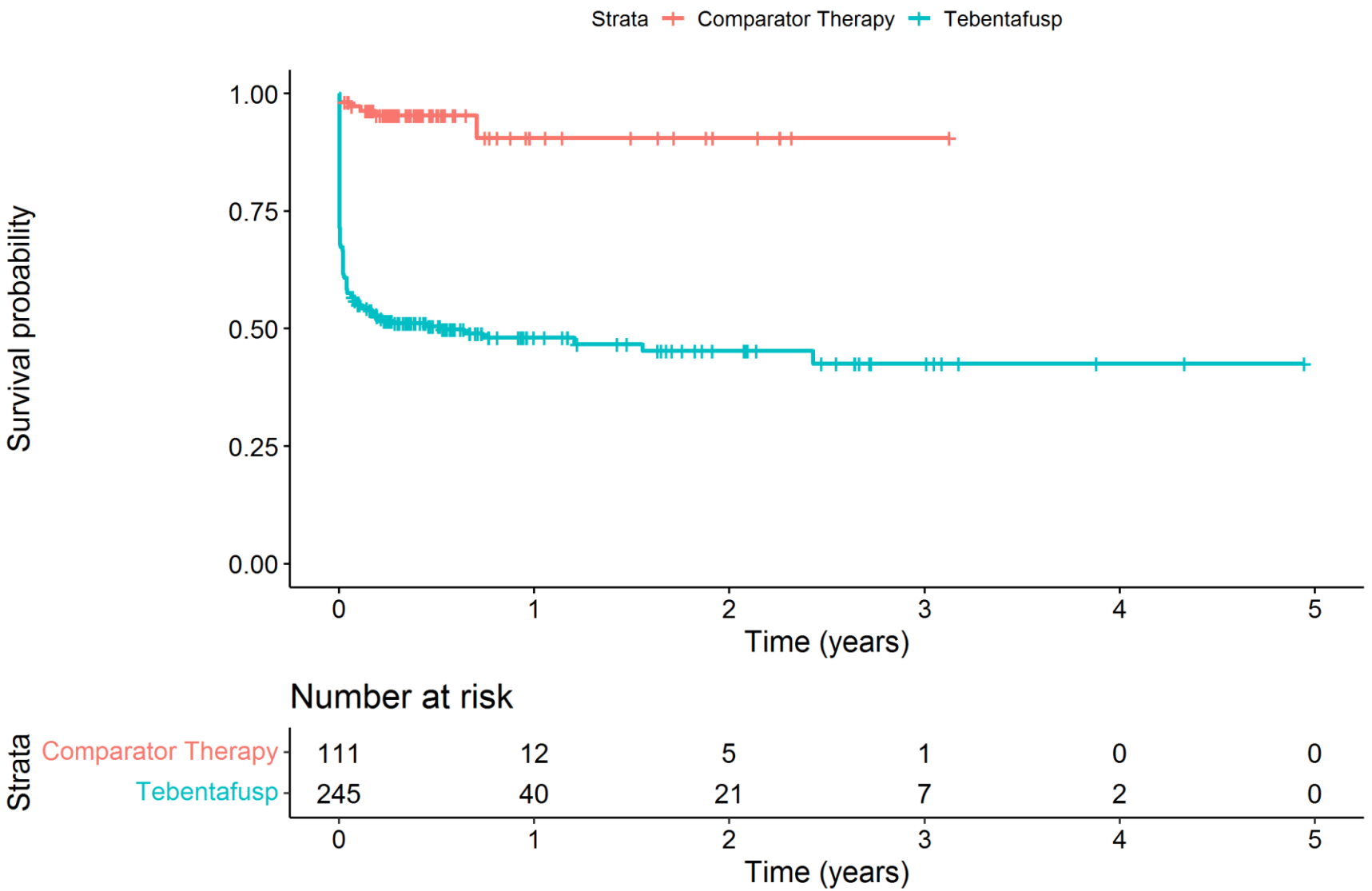
Müdigkeit - Pembrolizumab



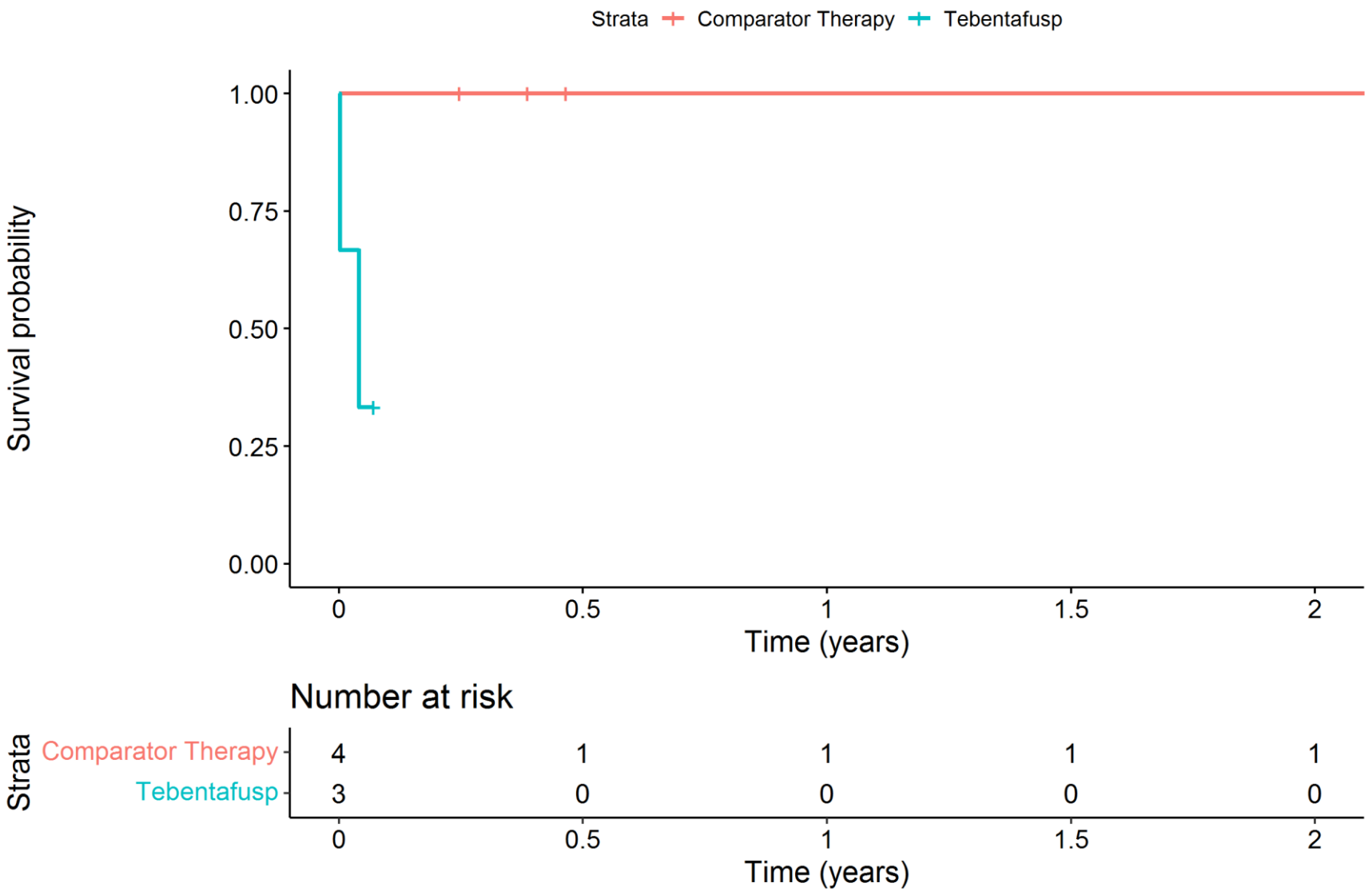
Müdigkeit - Ipilimumab



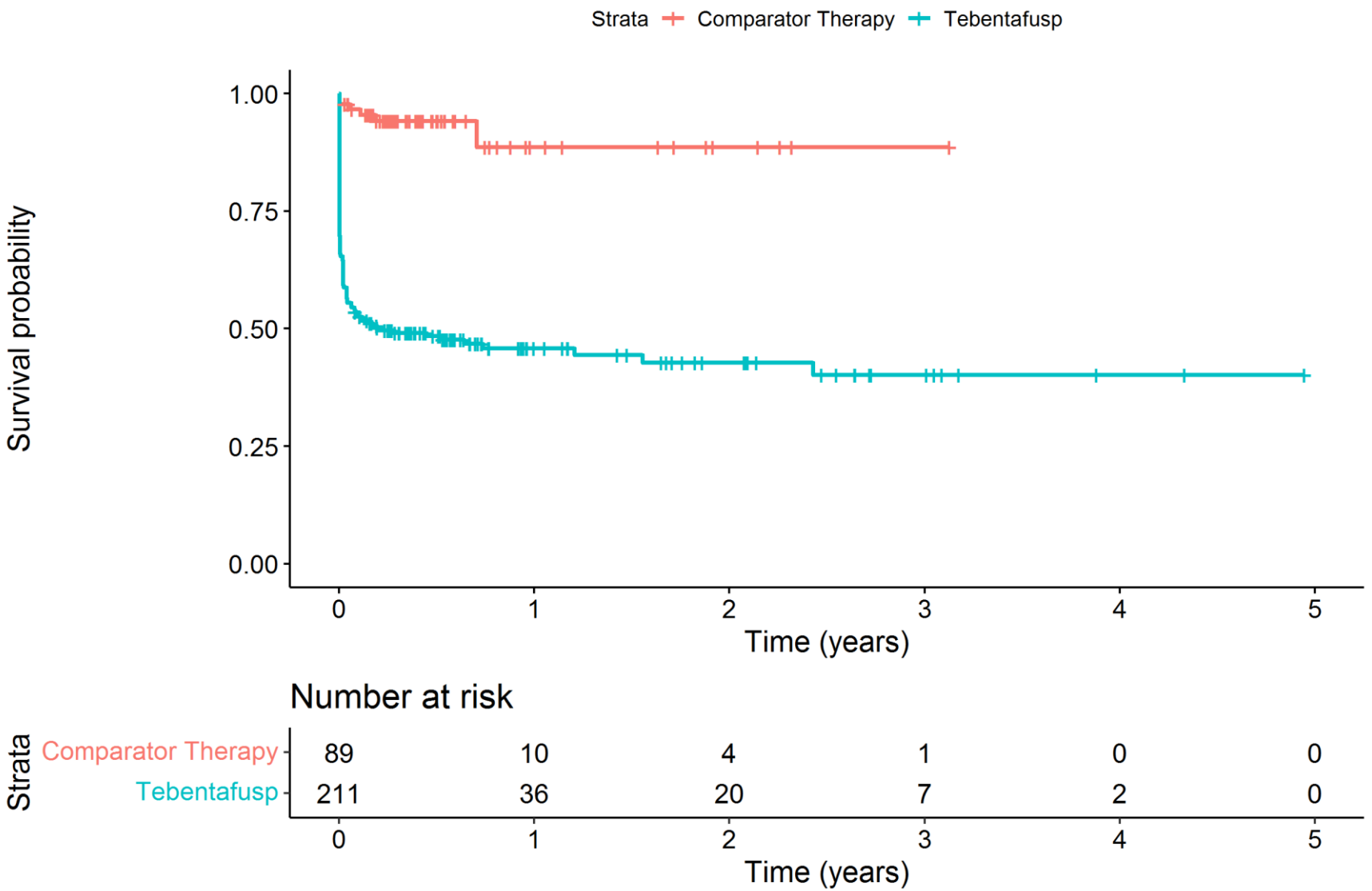
Schüttelfrost - Gesamt



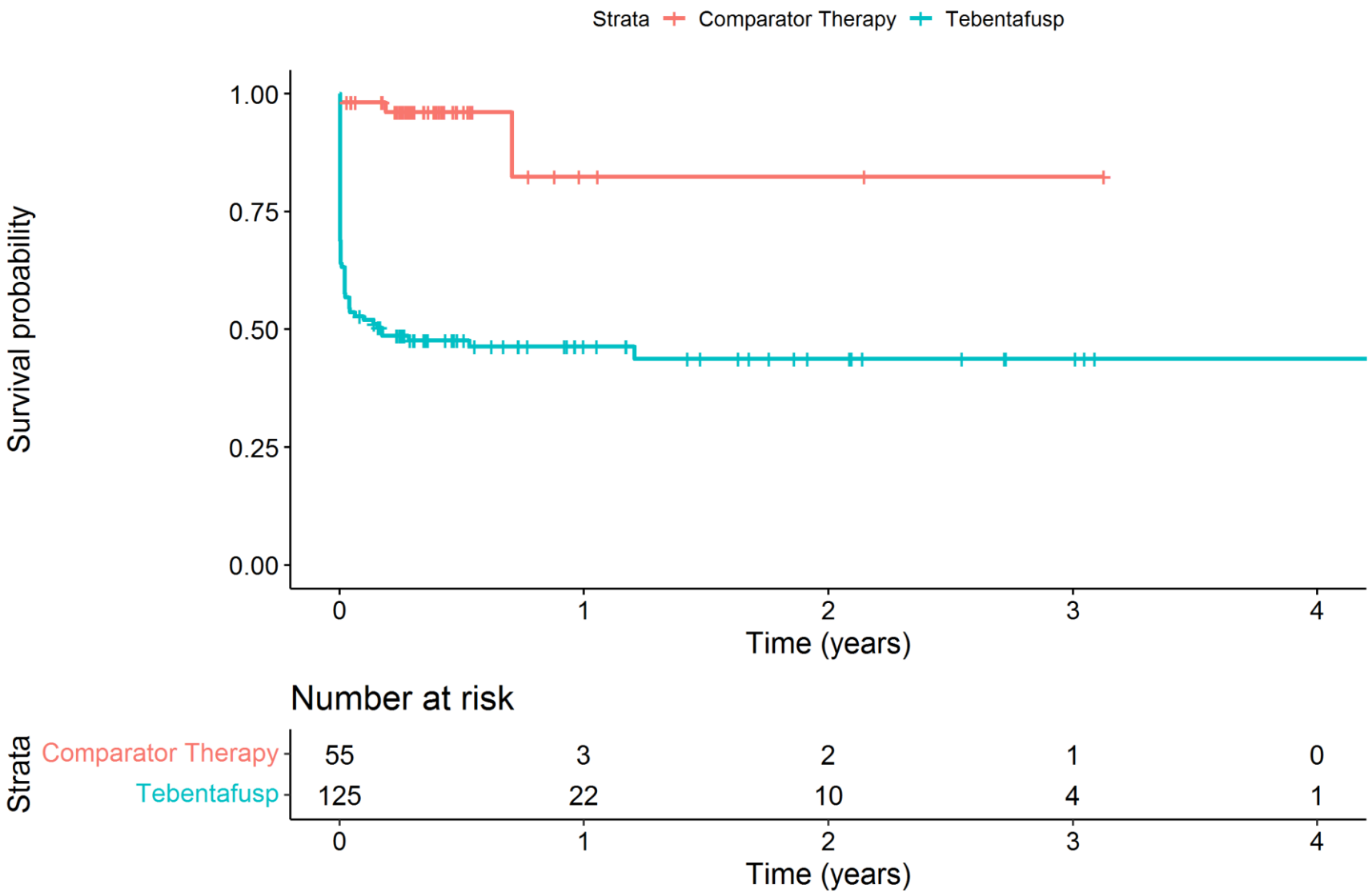
Schüttelfrost - Hispanisch



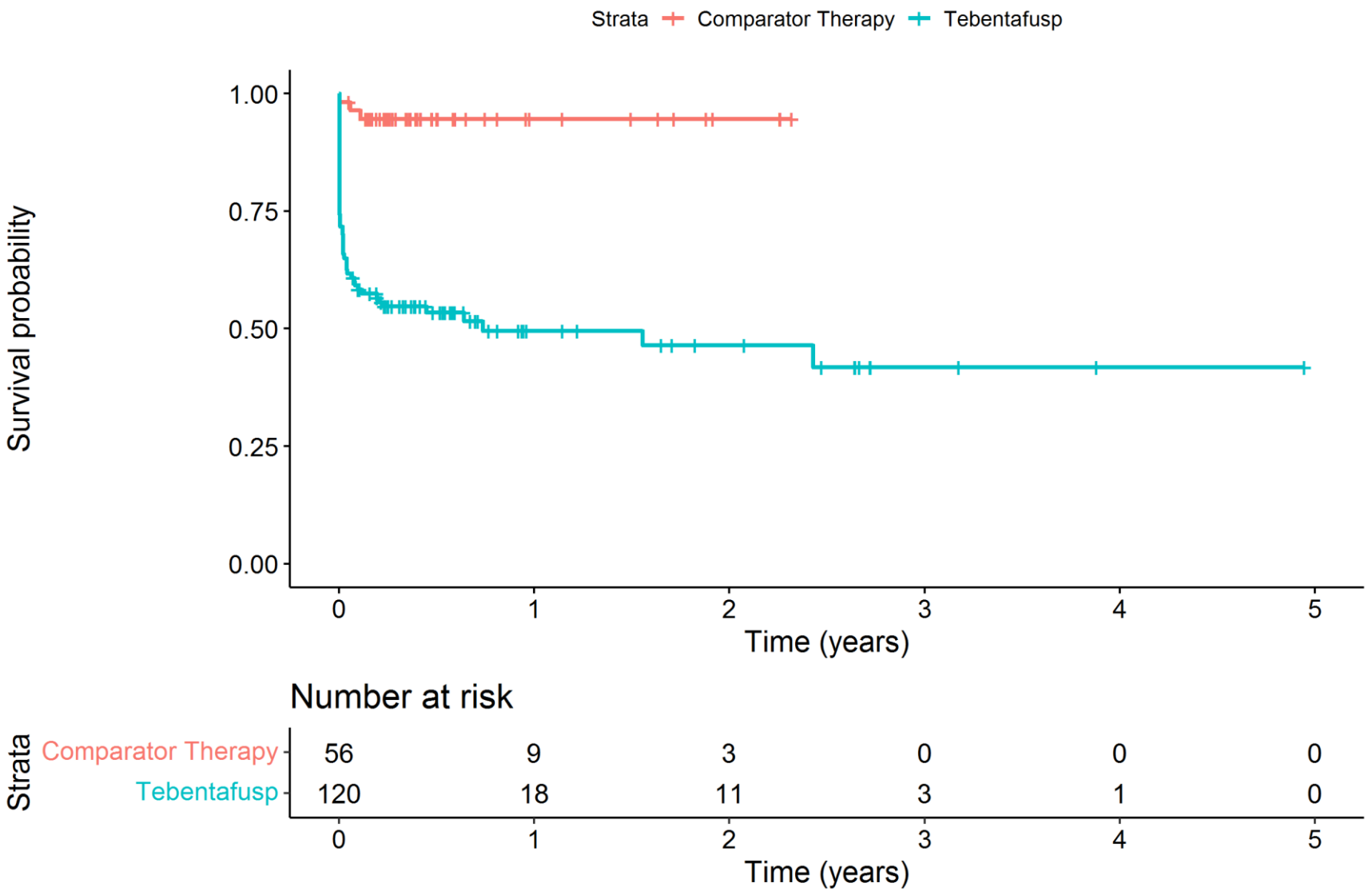
Schüttelfrost - Nicht-hispanisch



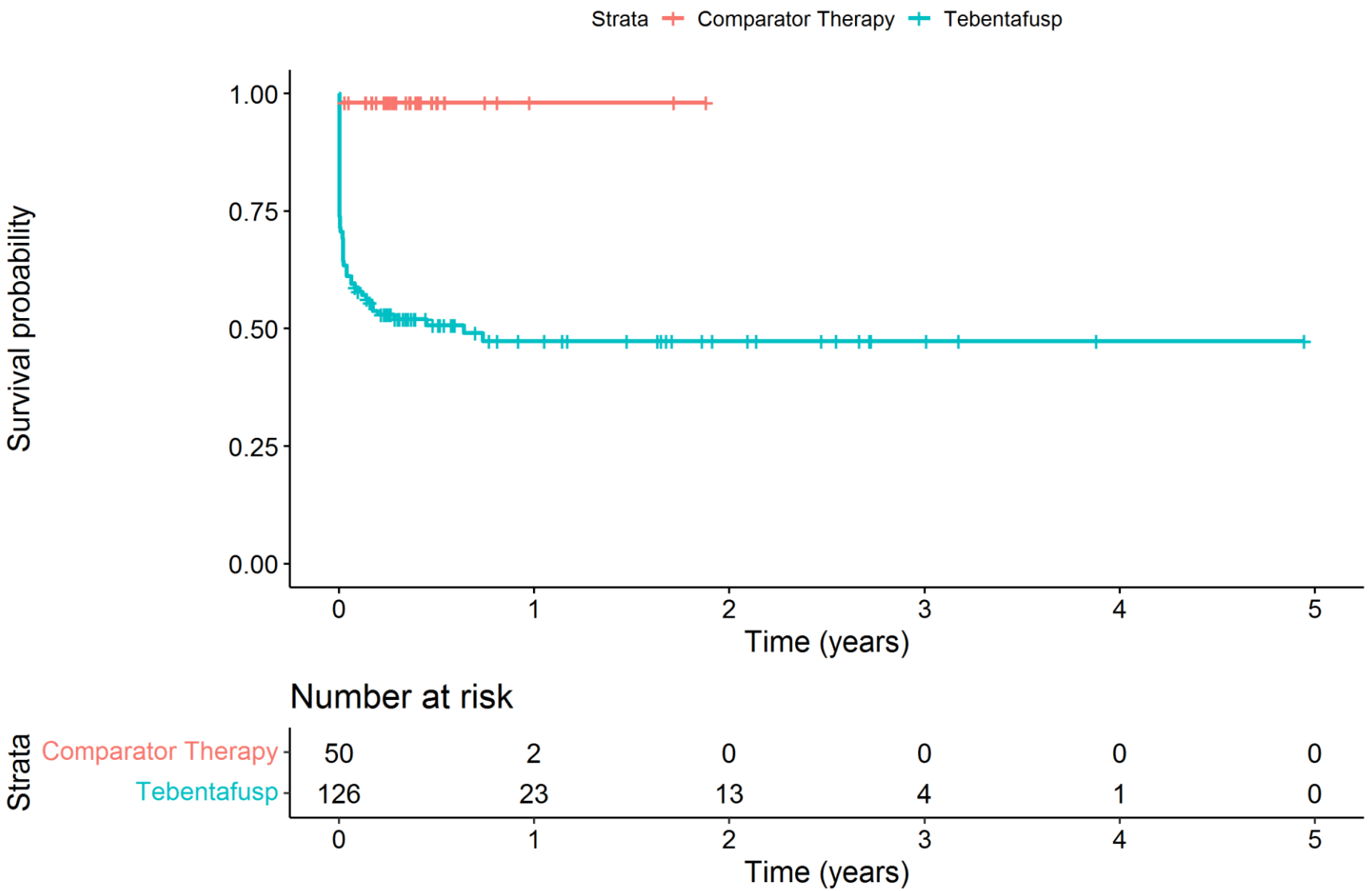
Schüttelfrost - Männlich



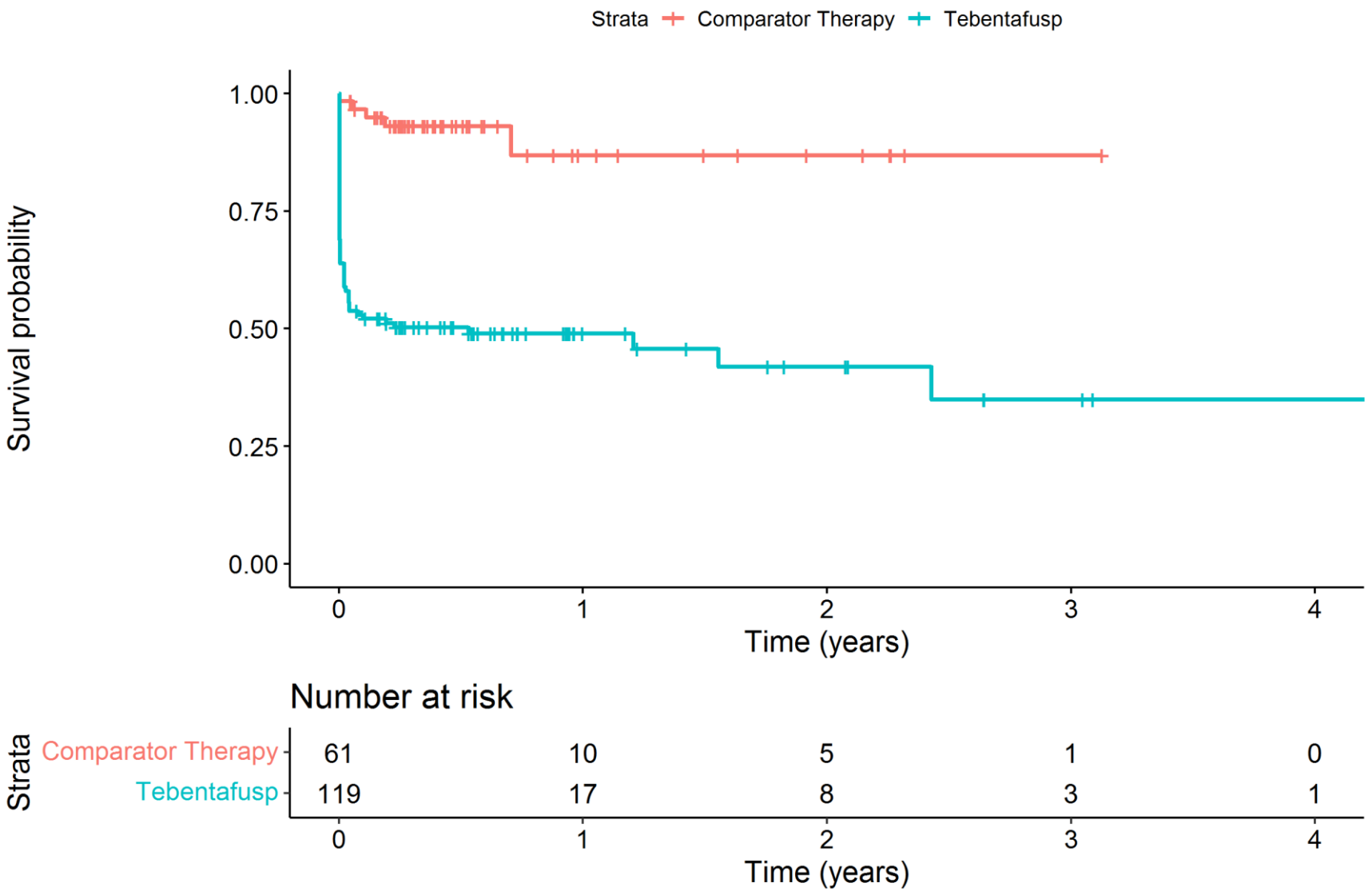
Schüttelfrost - Weiblich



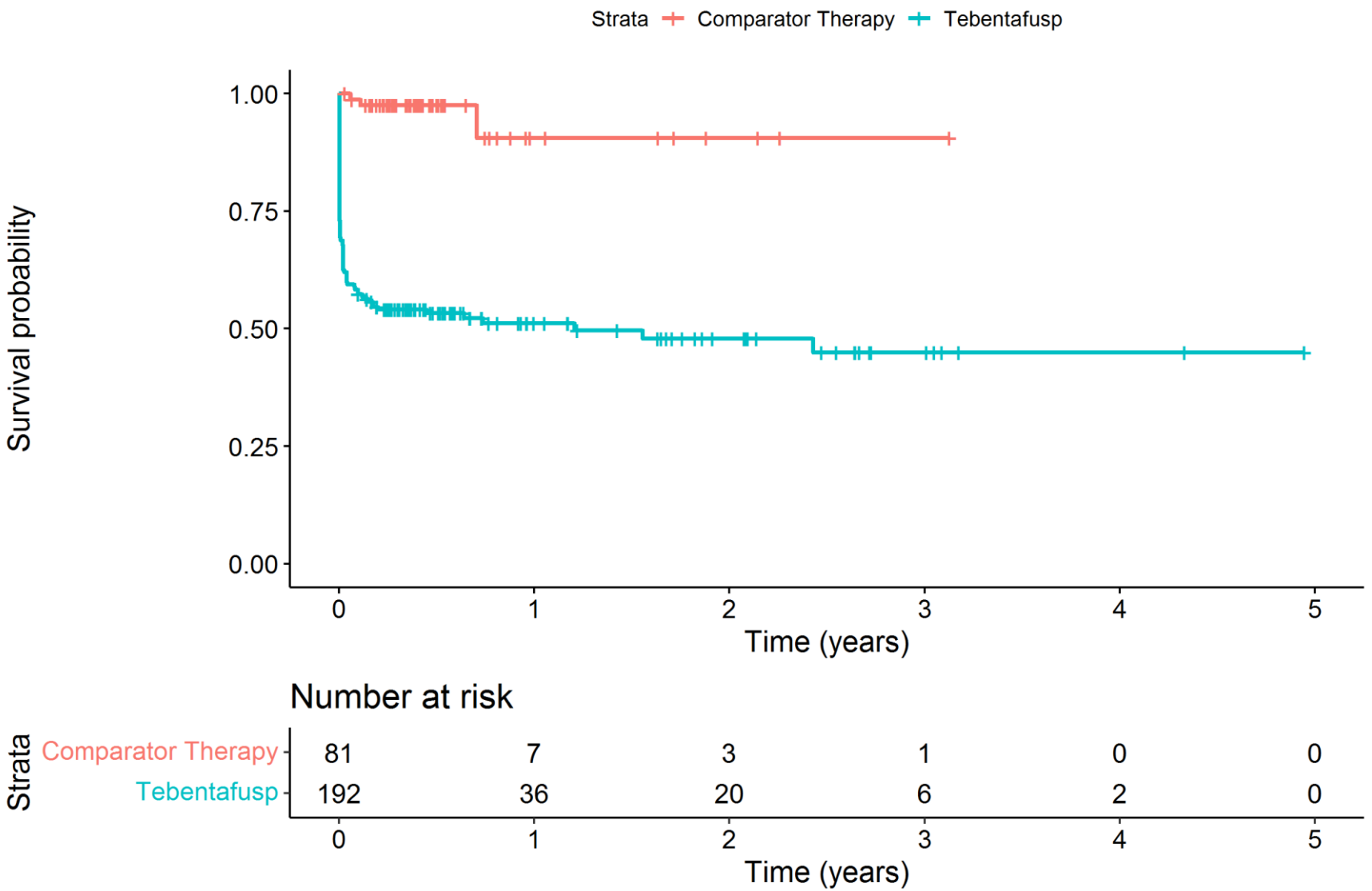
Schüttelfrost - <65



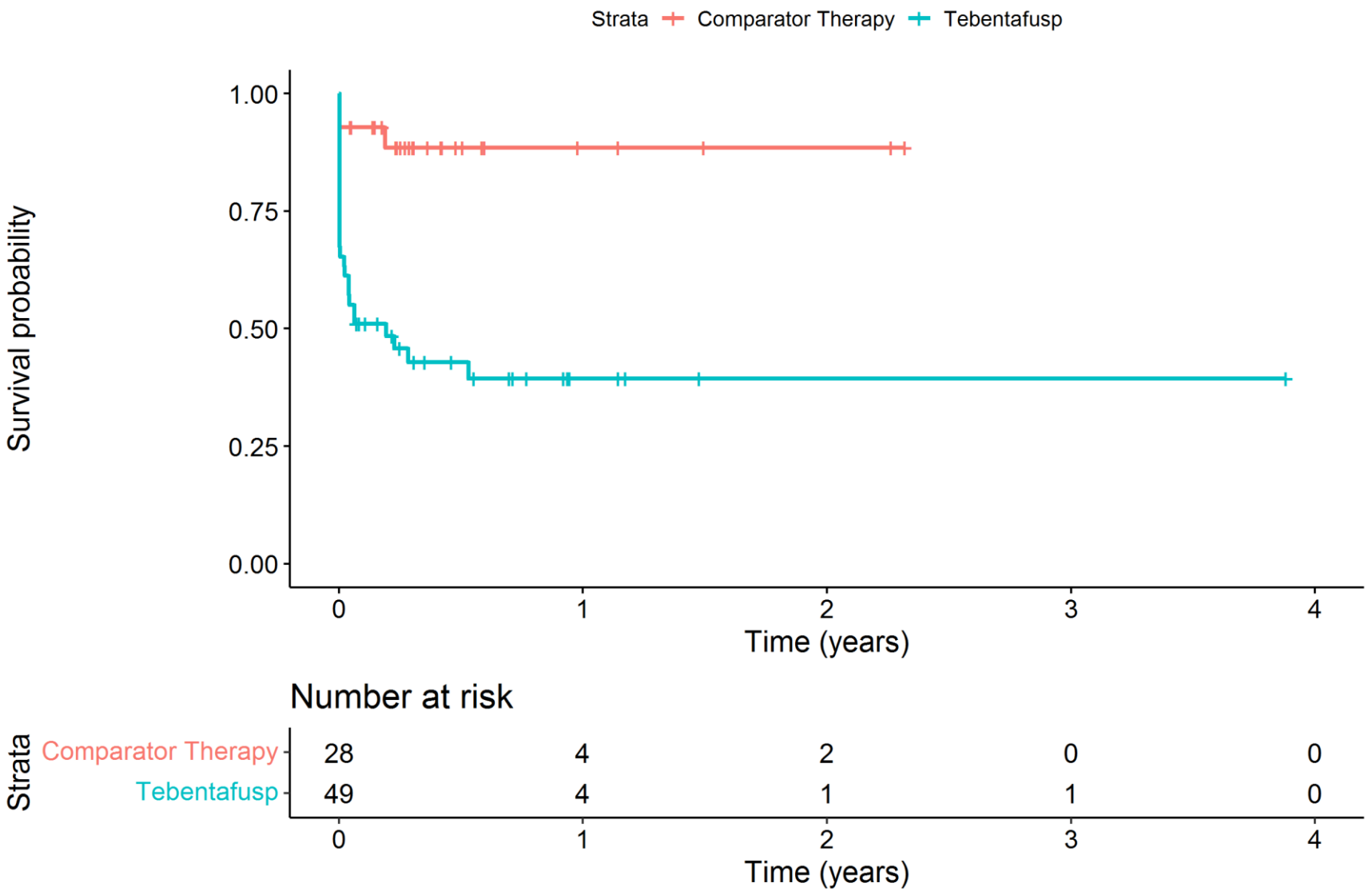
Schüttelfrost - ≥65



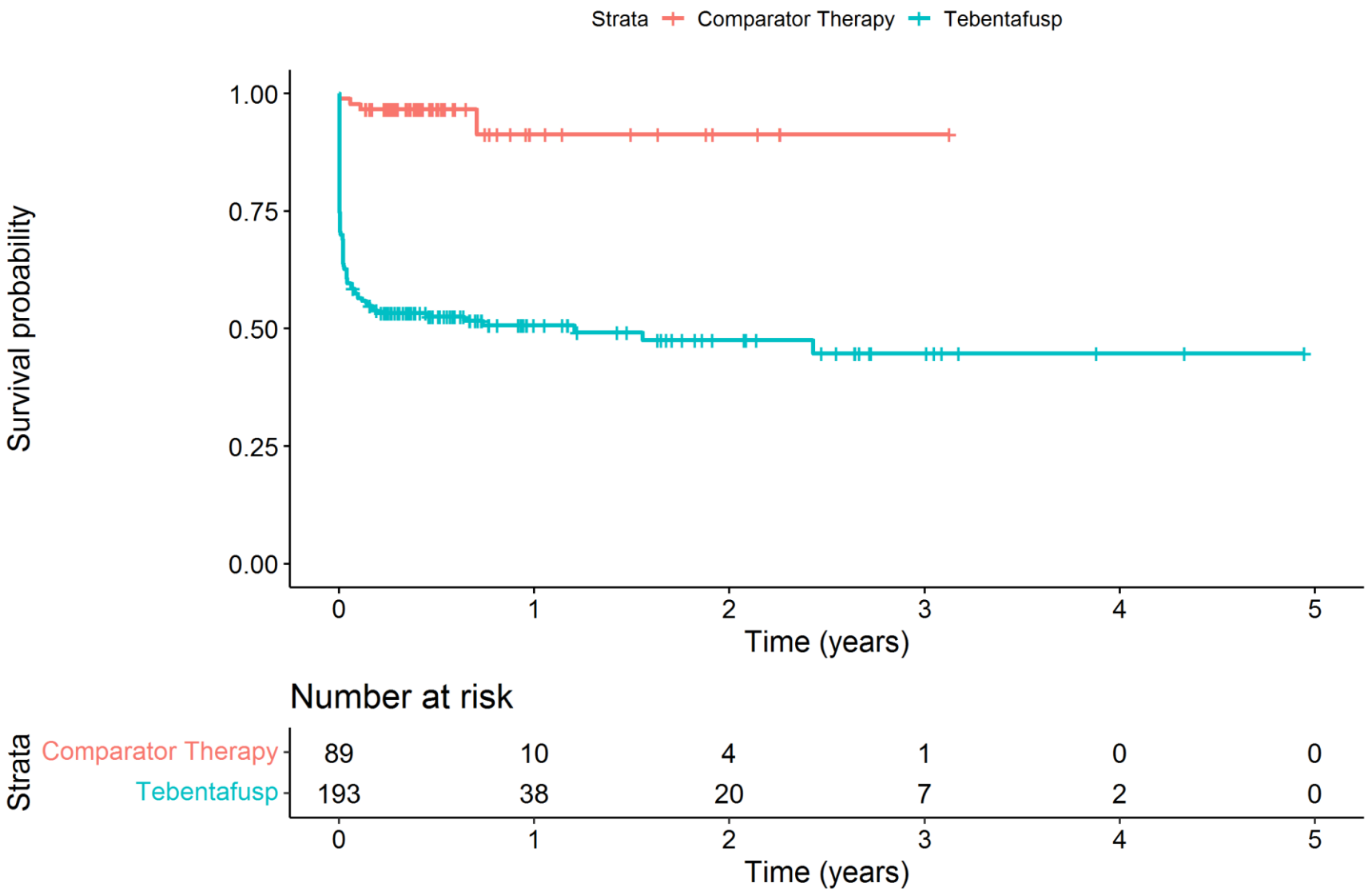
Schüttelfrost - ECOG 0



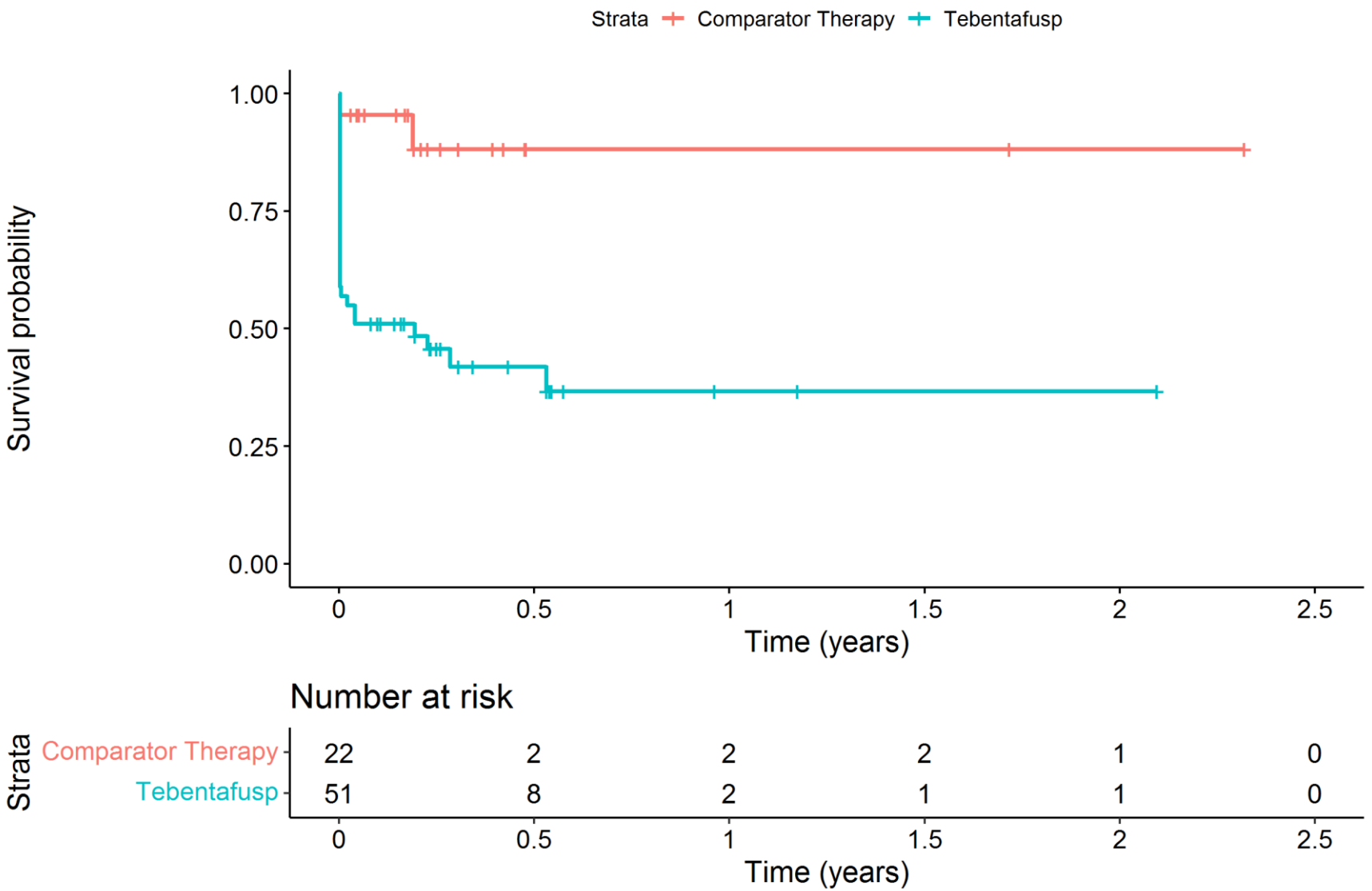
Schüttelfrost - ECOG 1



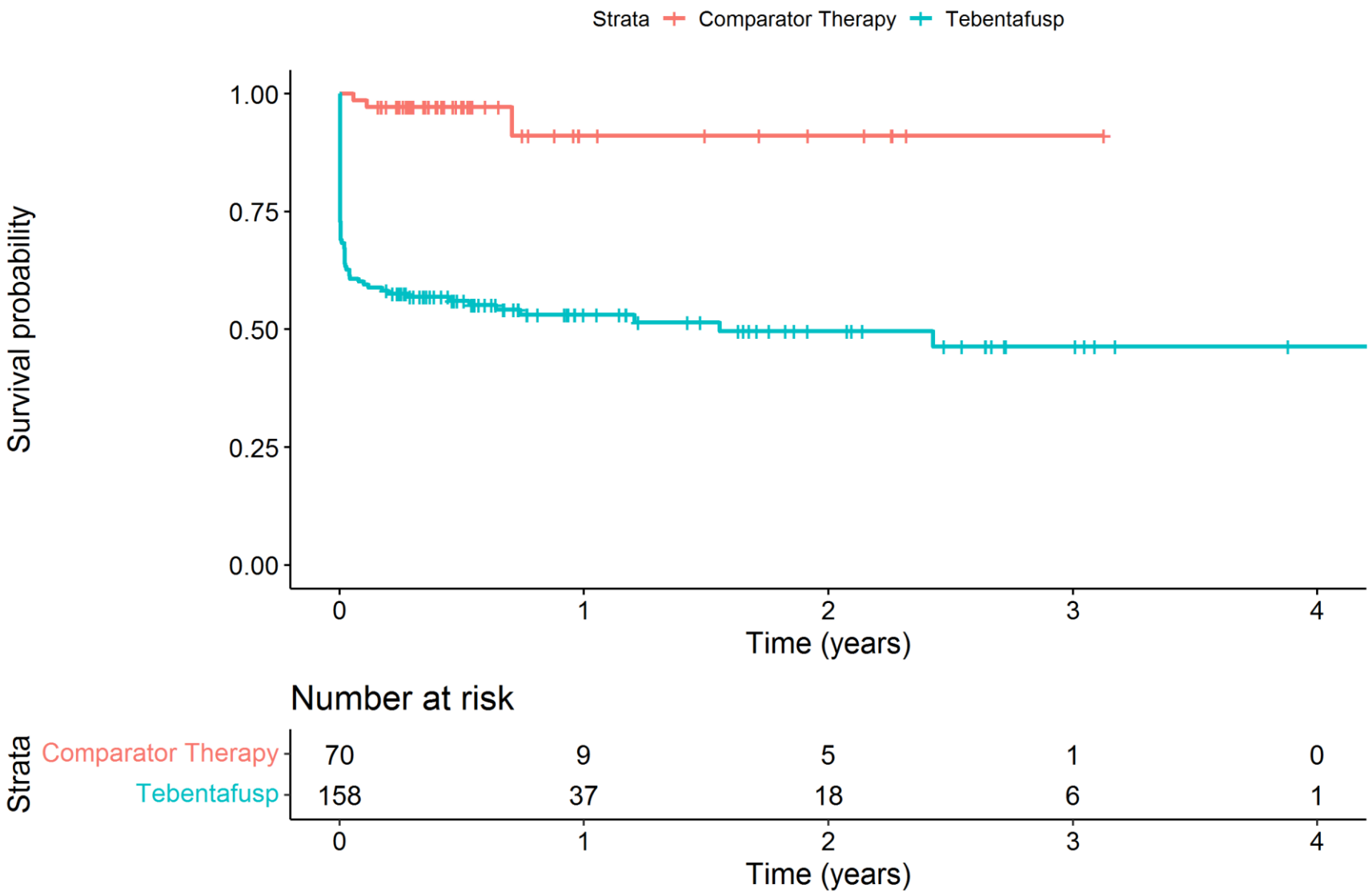
Schüttelfrost - ALP ≤ ULN



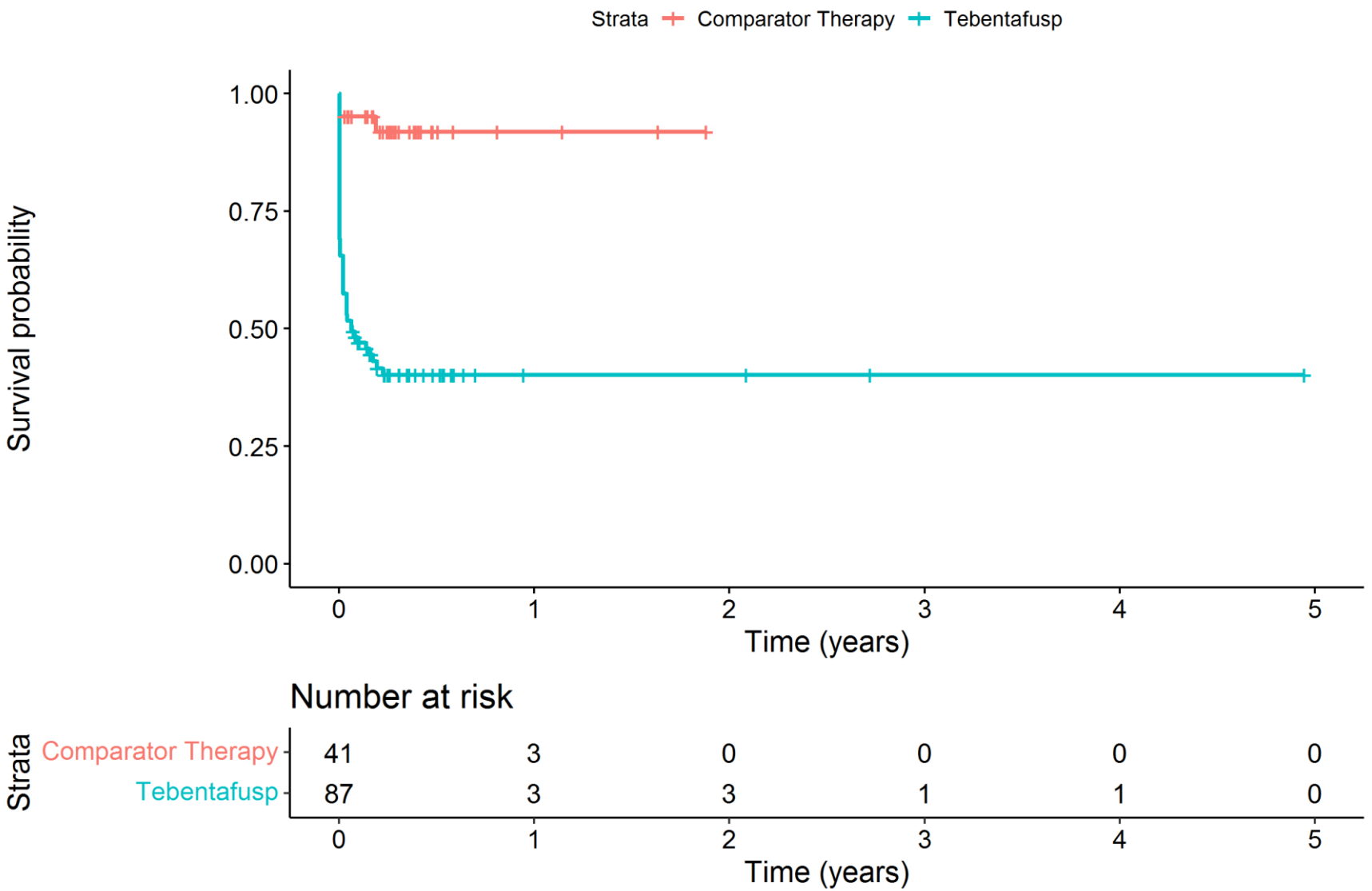
Schüttelfrost - ALP > ULN



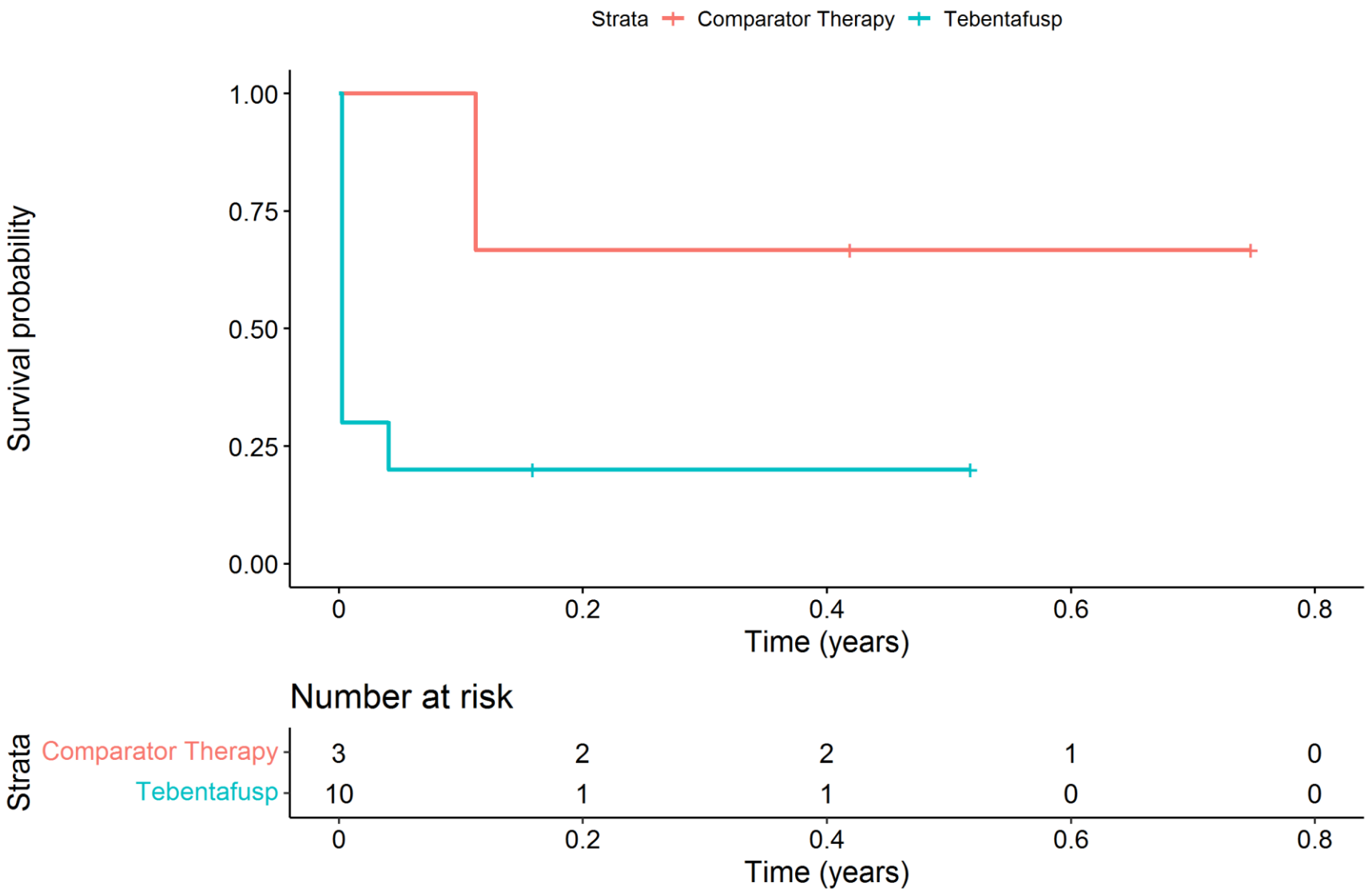
Schüttelfrost - LDH =< ULN



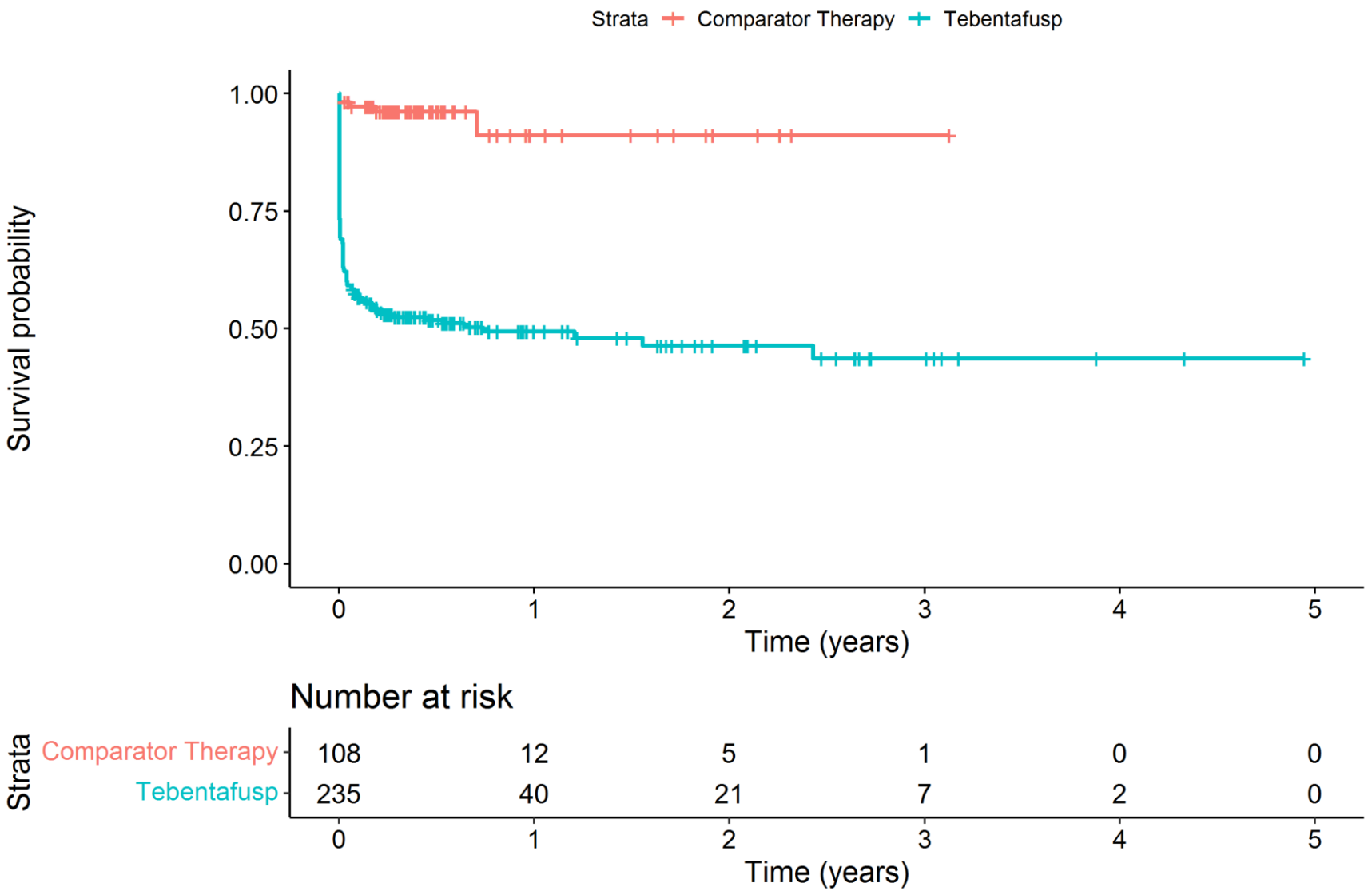
Schüttelfrost - LDH > ULN



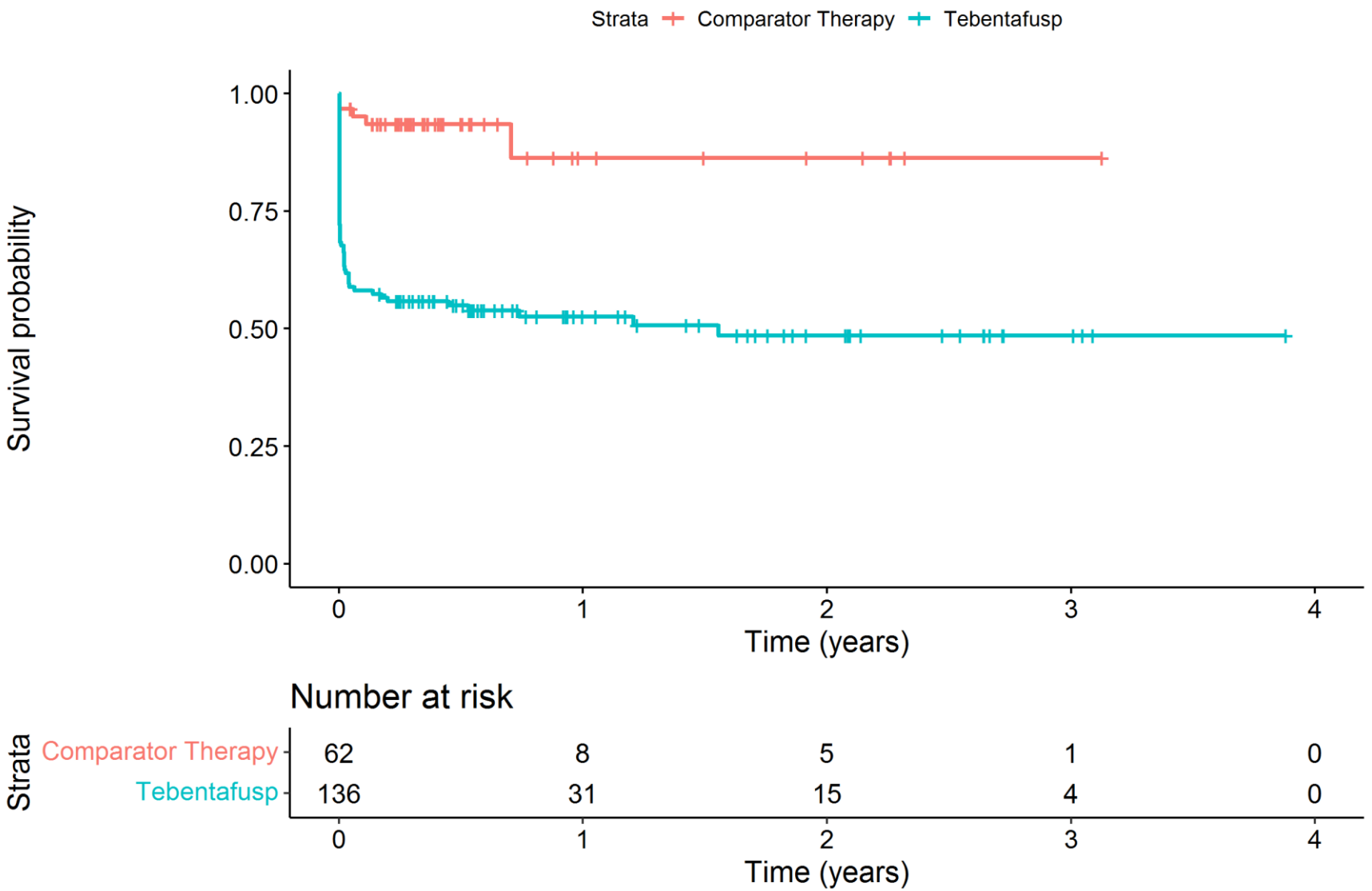
Schüttelfrost - Vorherige Therapie adjuvant/neoadjuvant



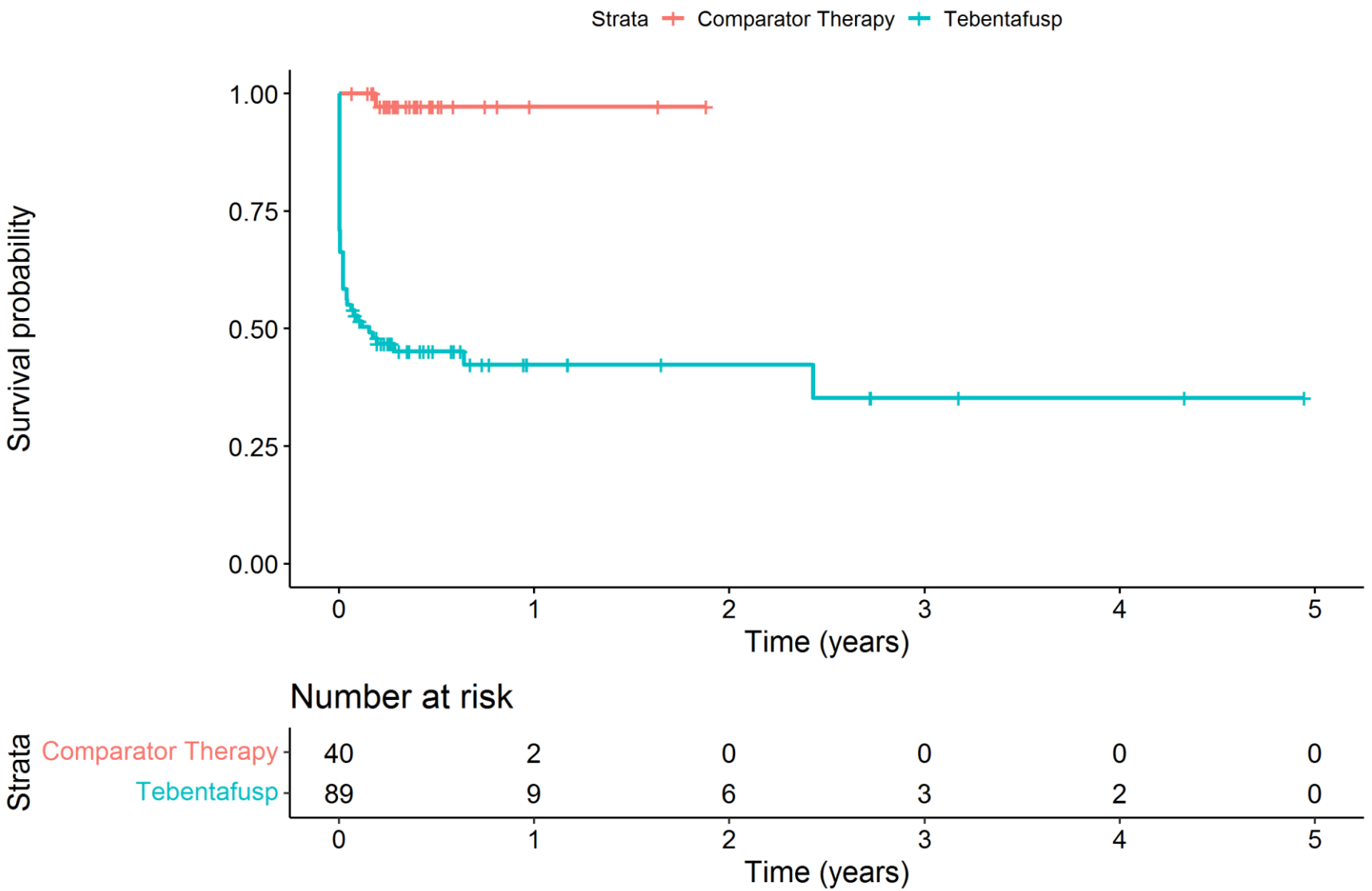
Schüttelfrost - Keine Vorherige Therapie adjuvant/neoadjuvant



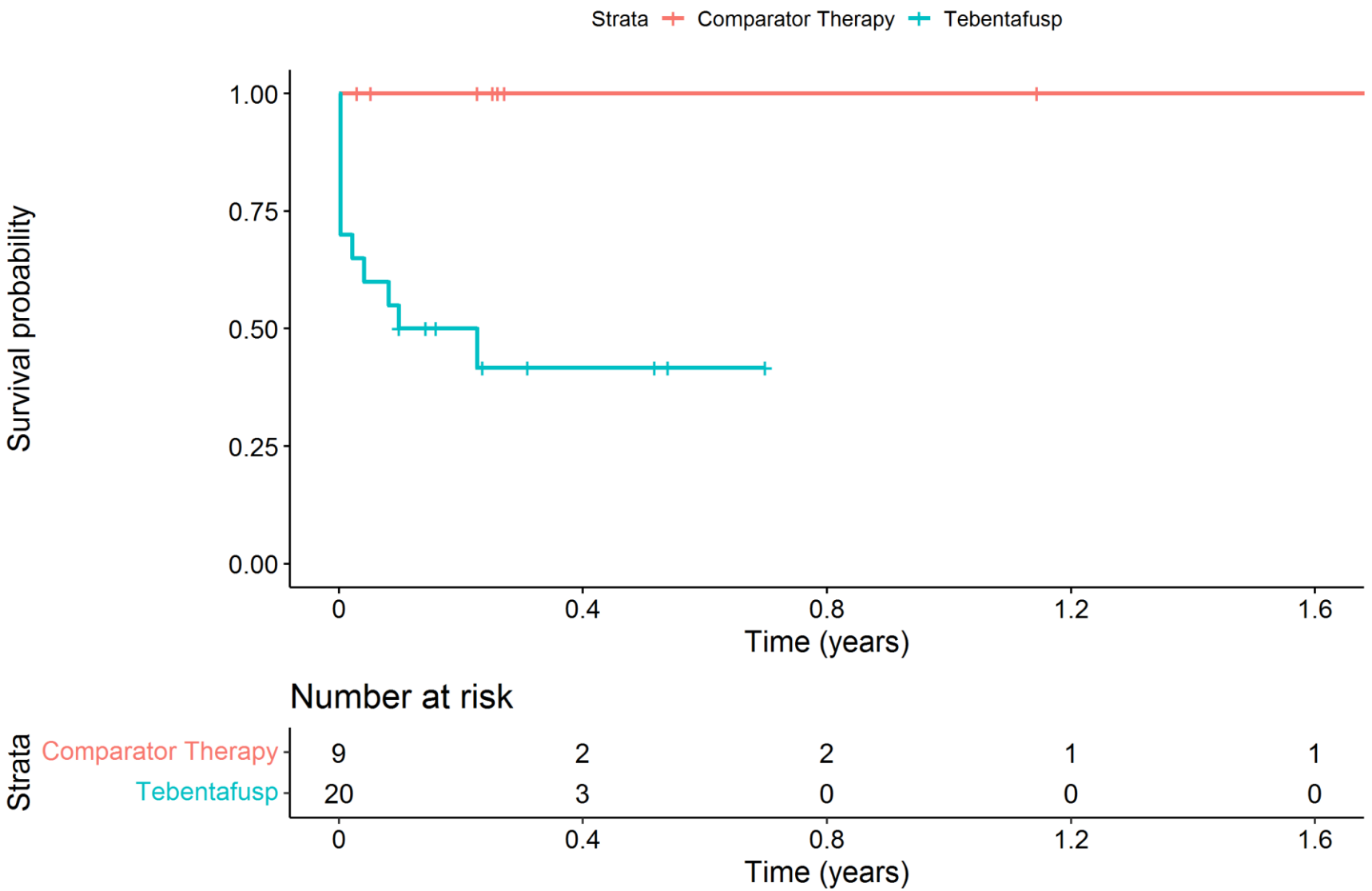
Schüttelfrost - Läsion ≤ 3cm



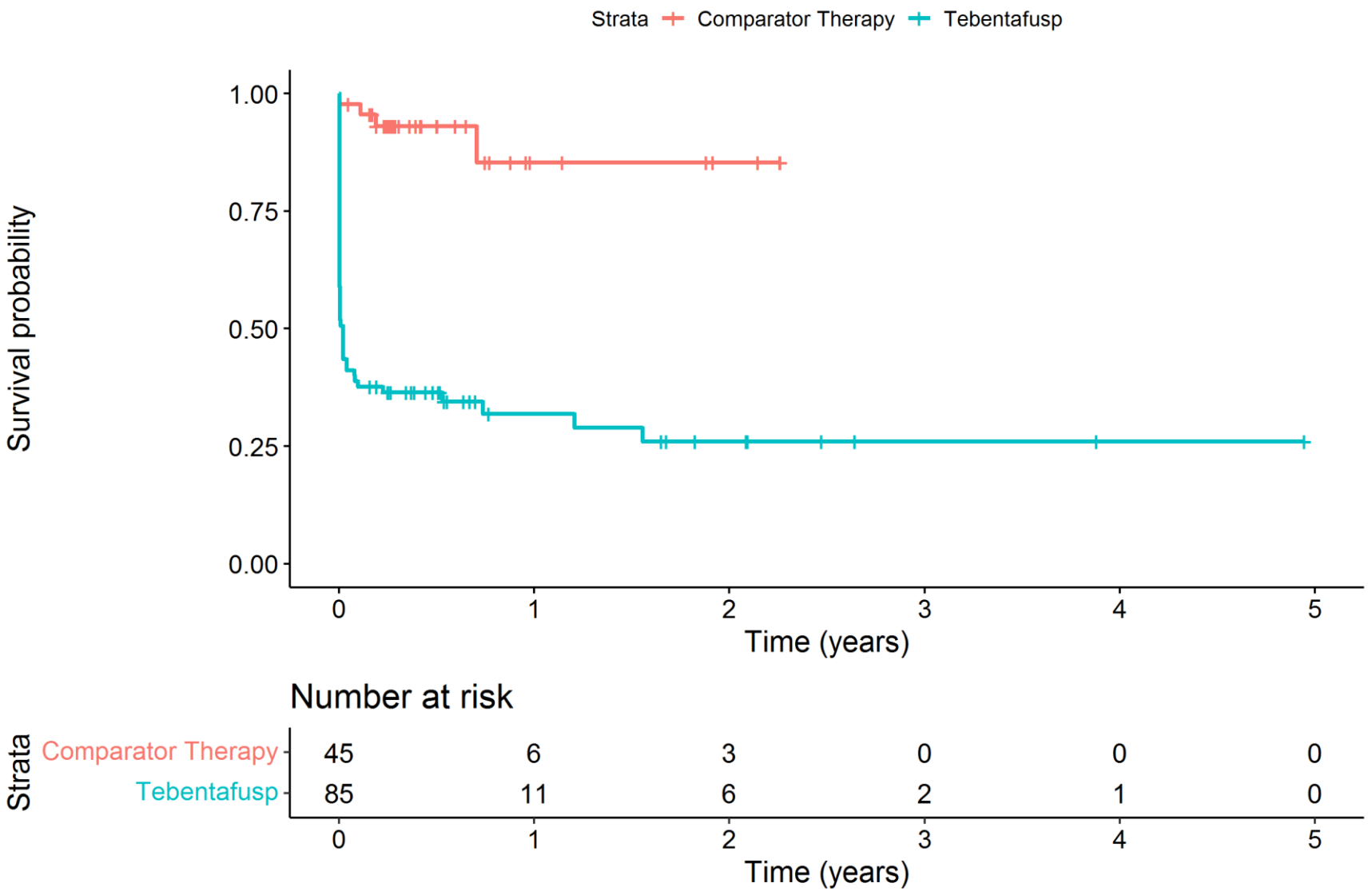
Schüttelfrost - Läsion 3,1-8,0 cm



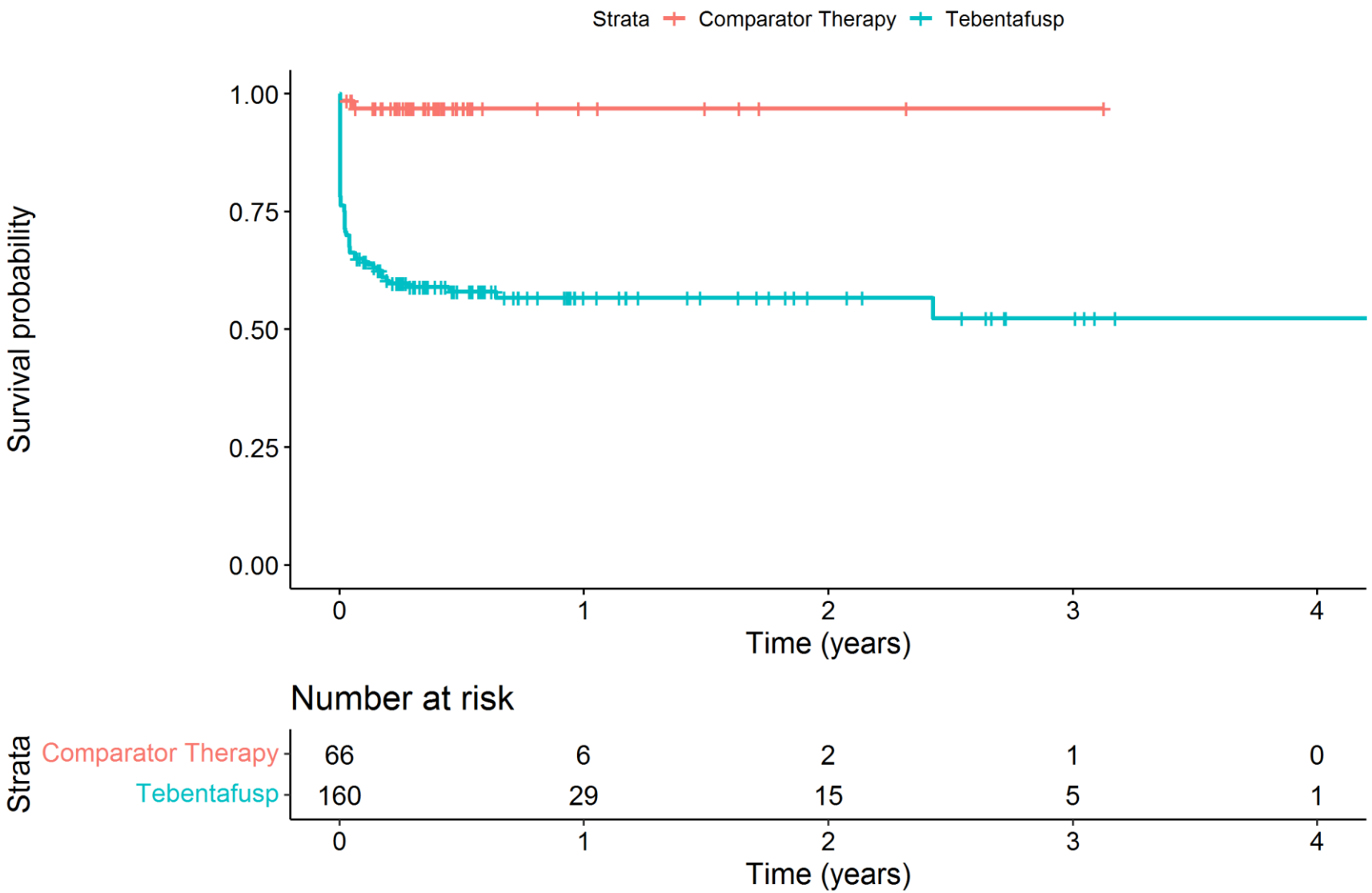
Schüttelfrost - Läsion ≥8,1 cm



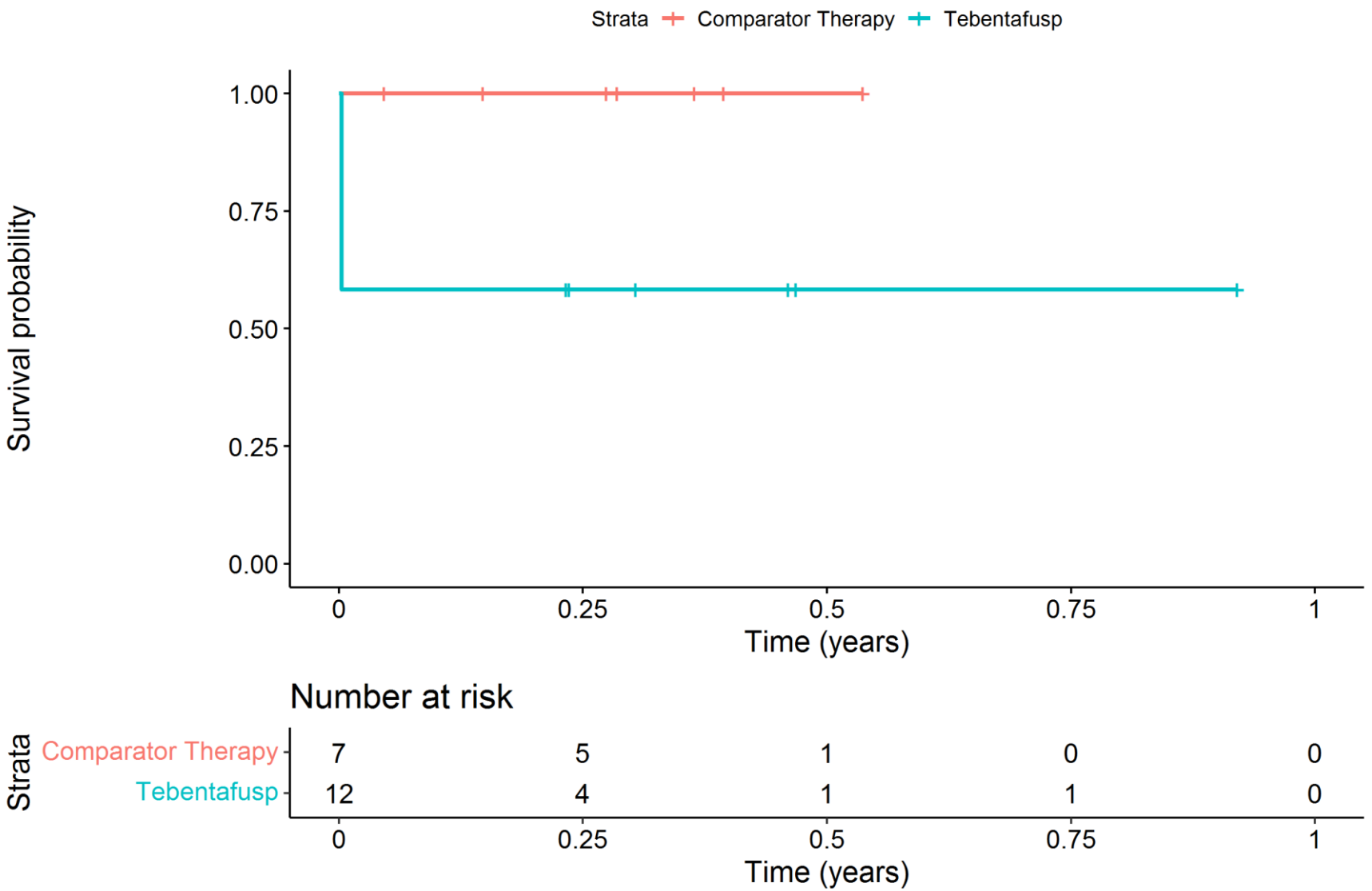
Schüttelfrost - Nordamerika



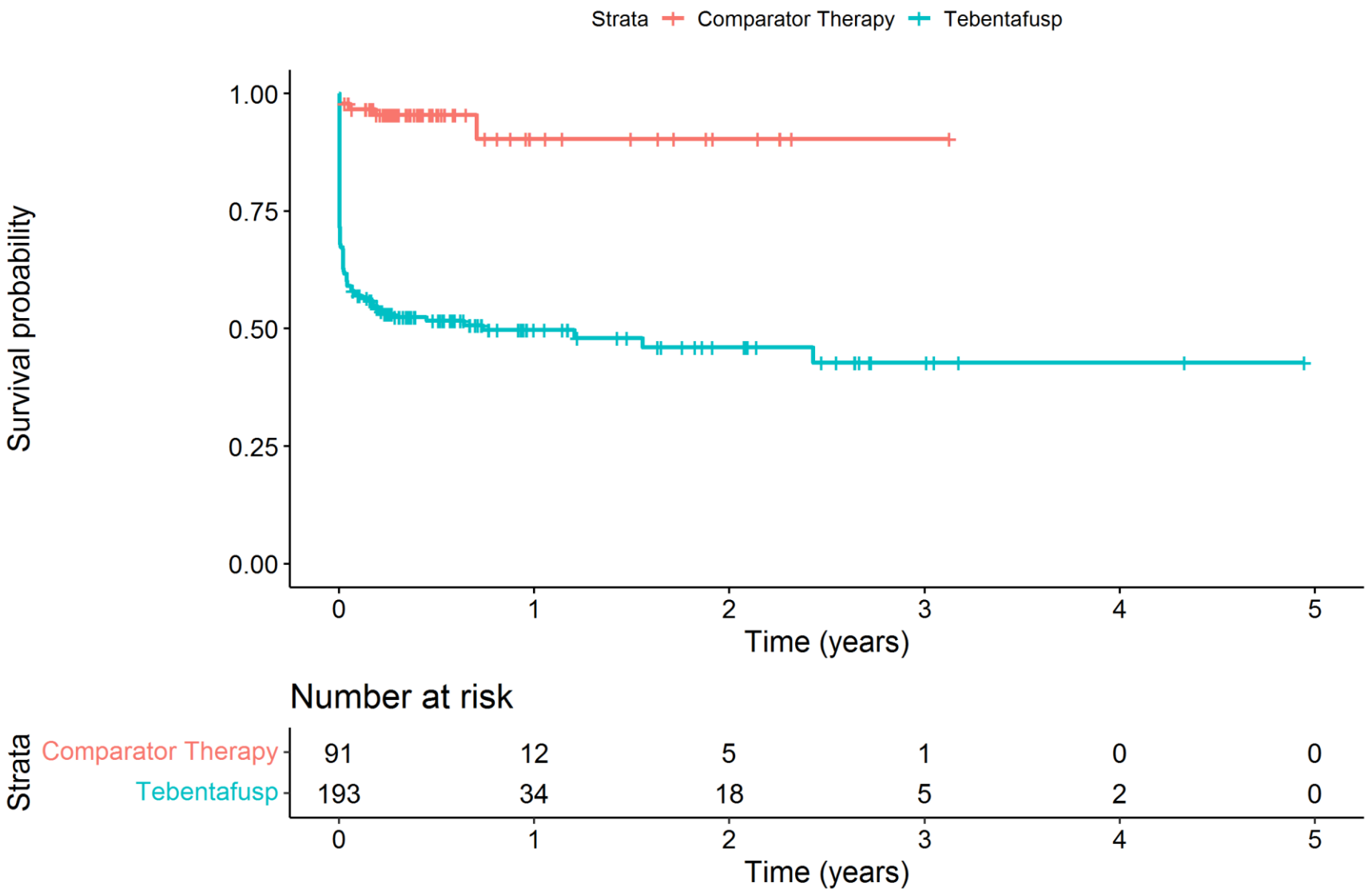
Schüttelfrost - Nicht-Nordamerika



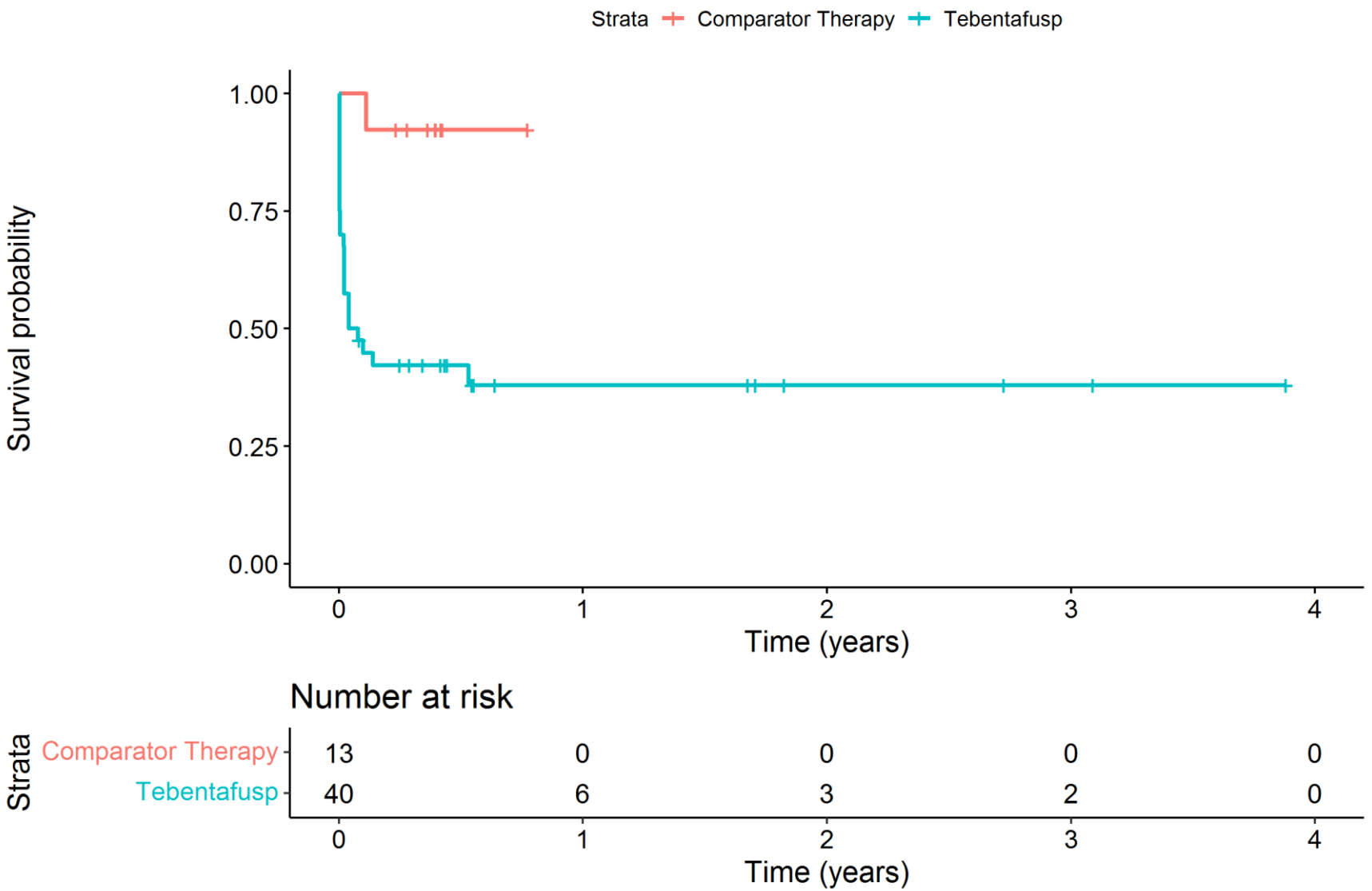
Schüttelfrost - Dacarbazin



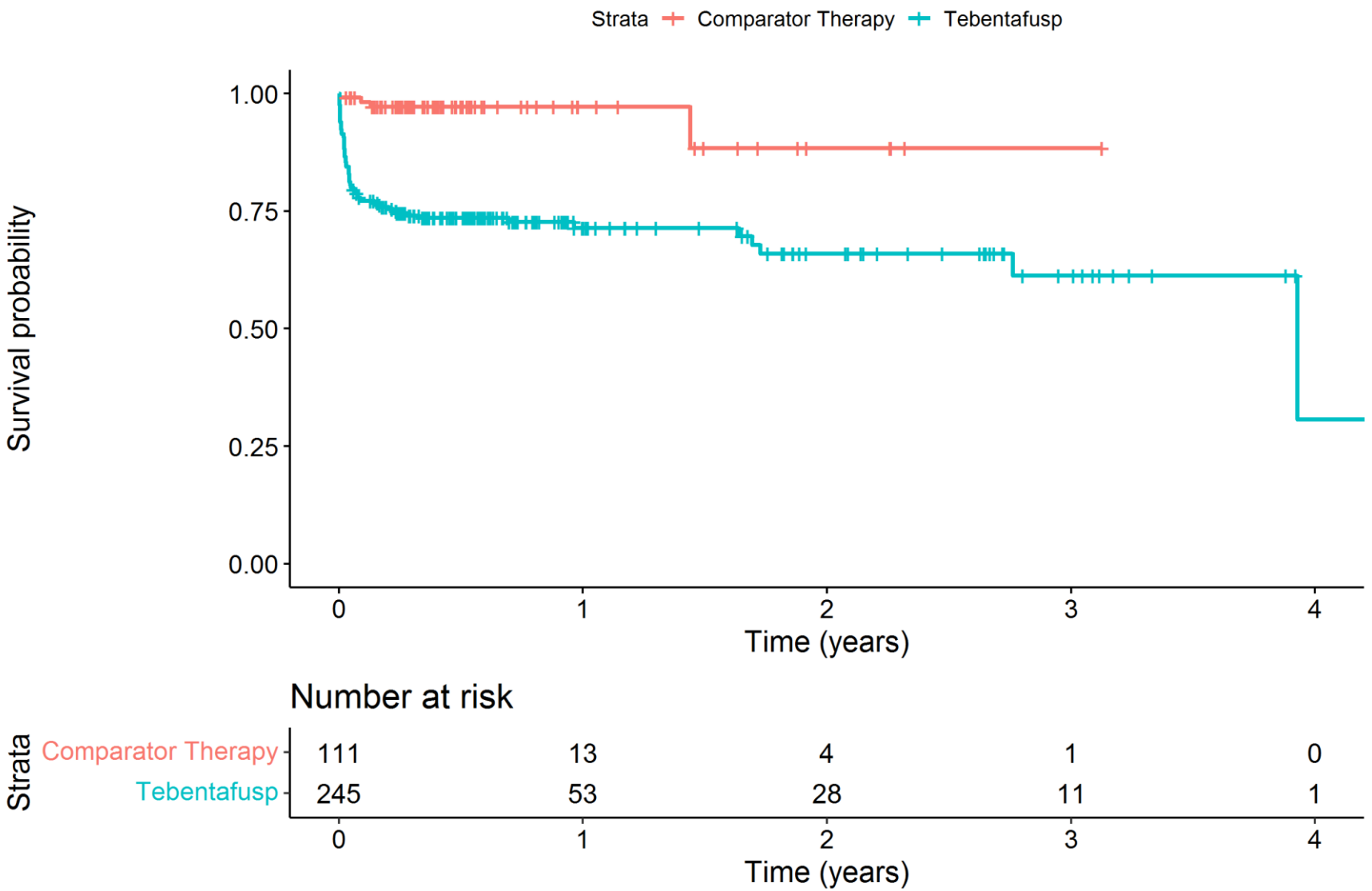
Schüttelfrost - Pembrolizumab



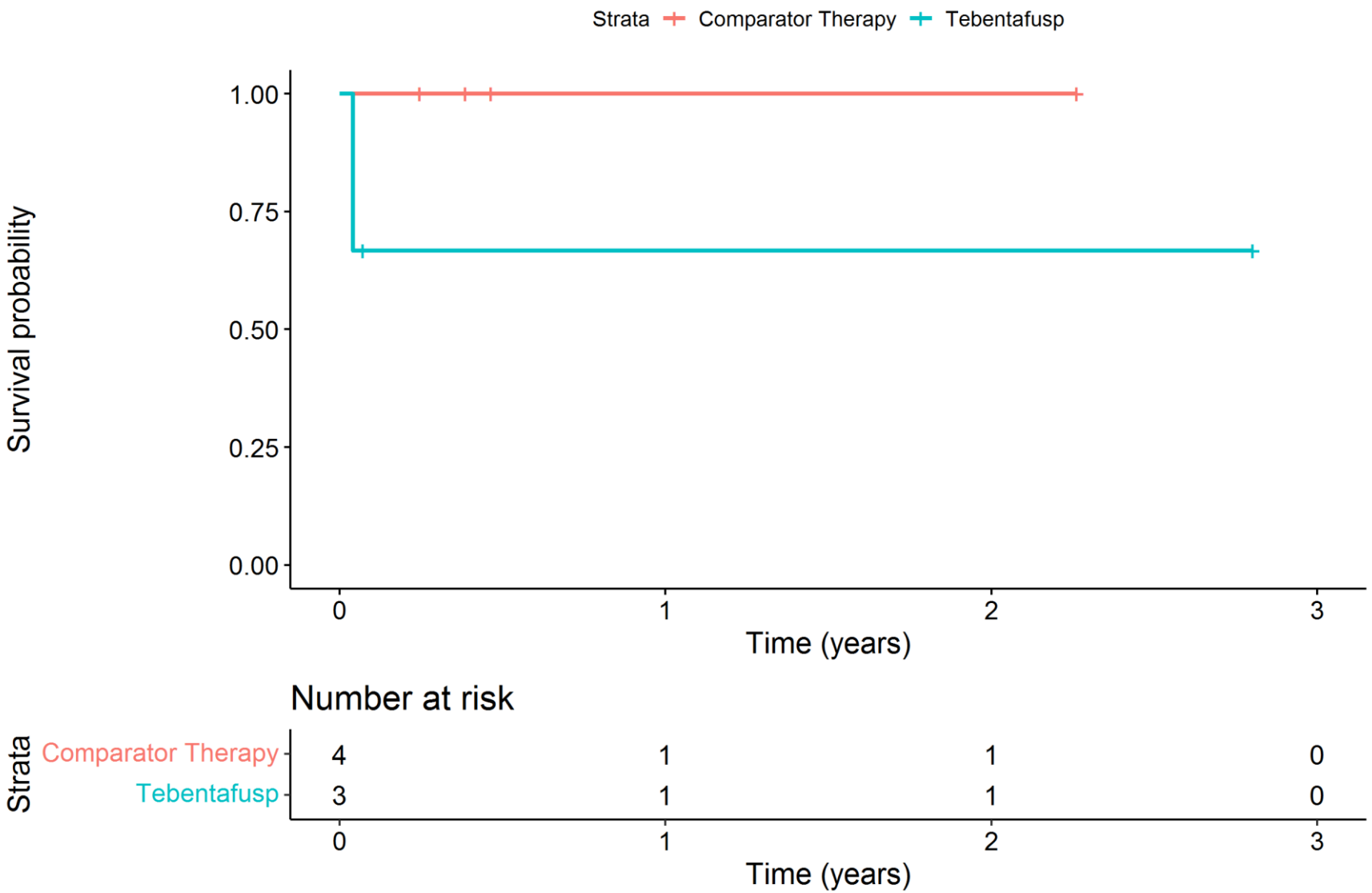
Schüttelfrost - Ipilimumab



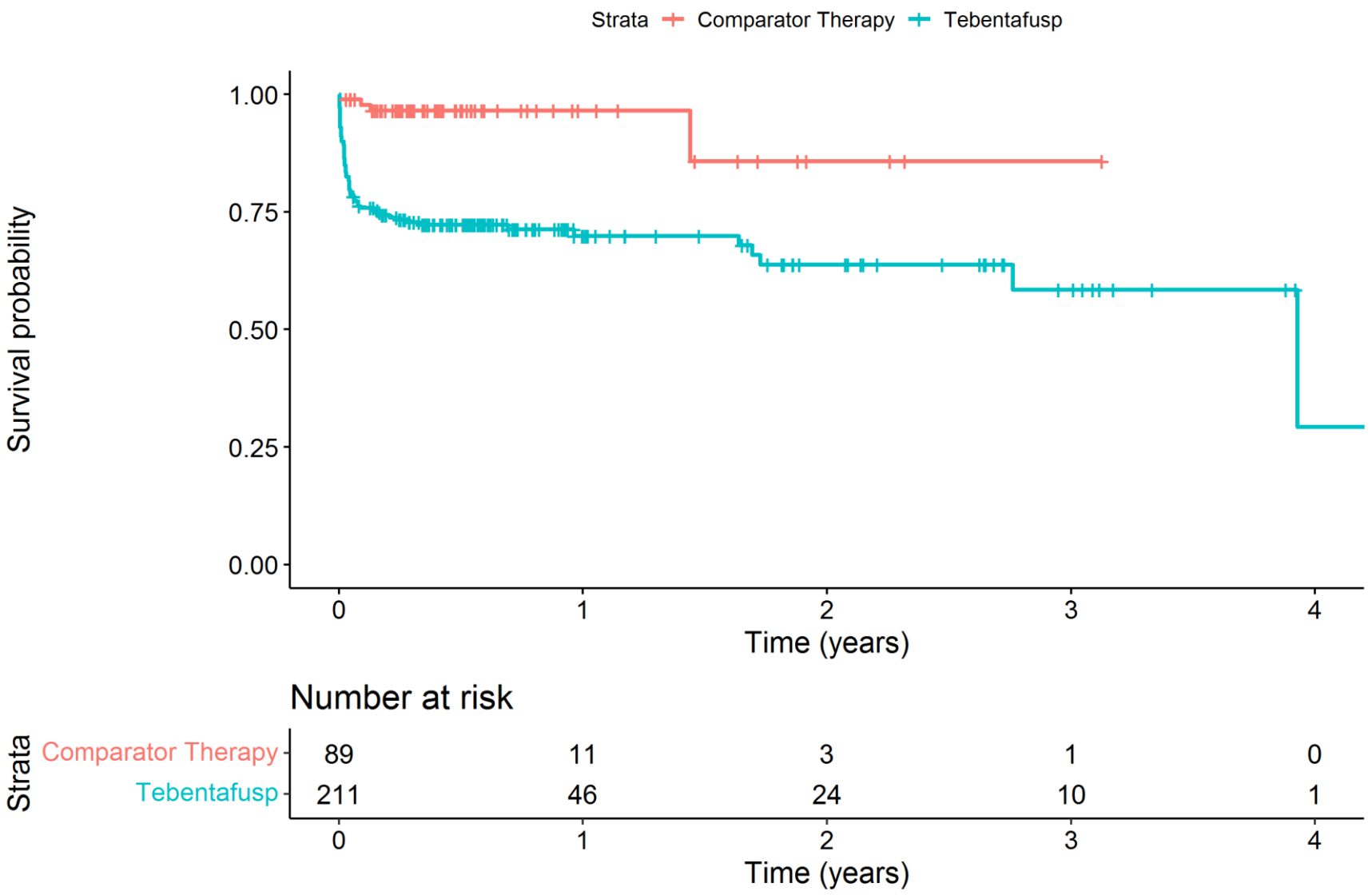
Periphere Ödeme - Gesamt



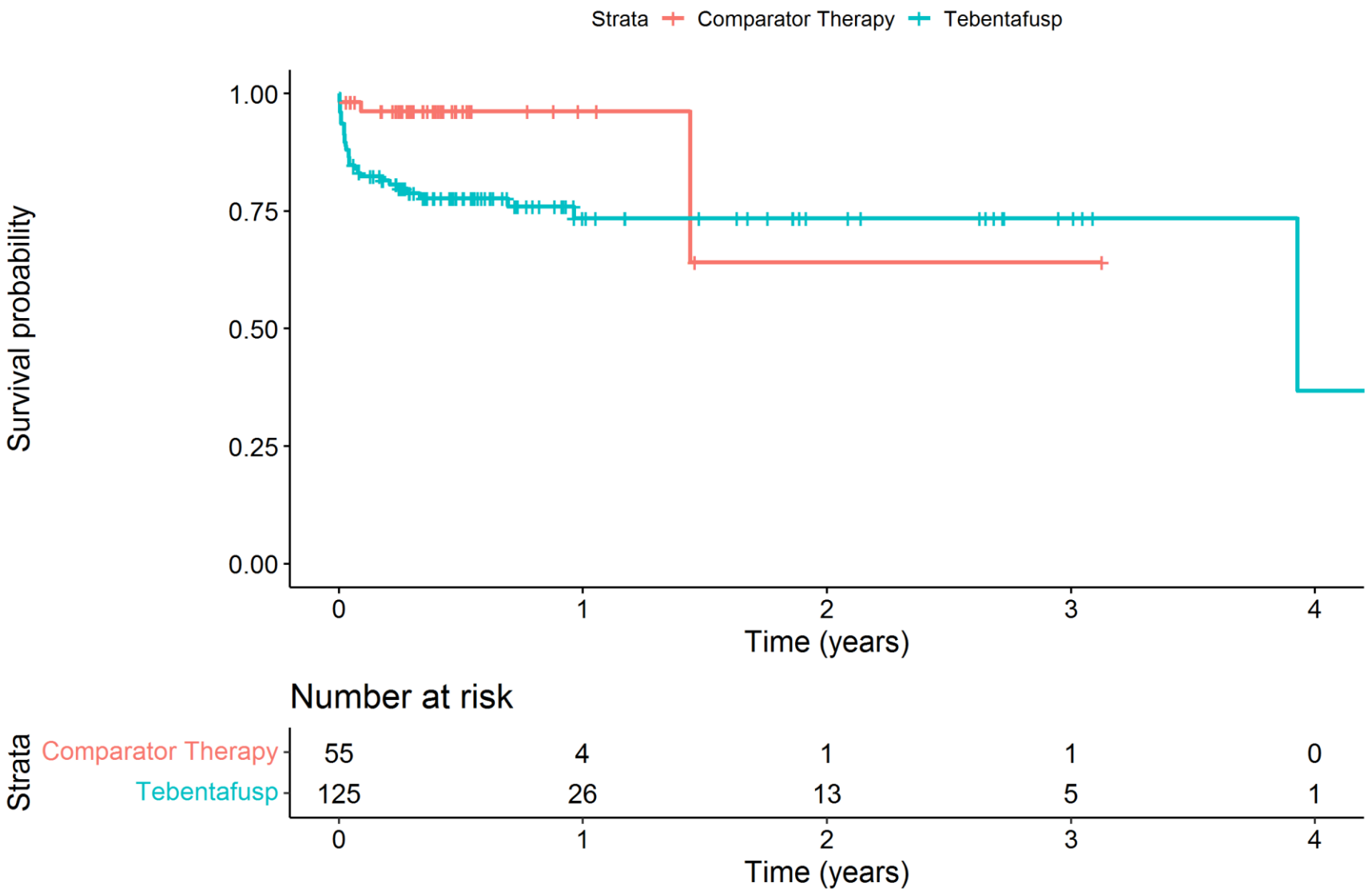
Periphere Ödeme - Hispanisch



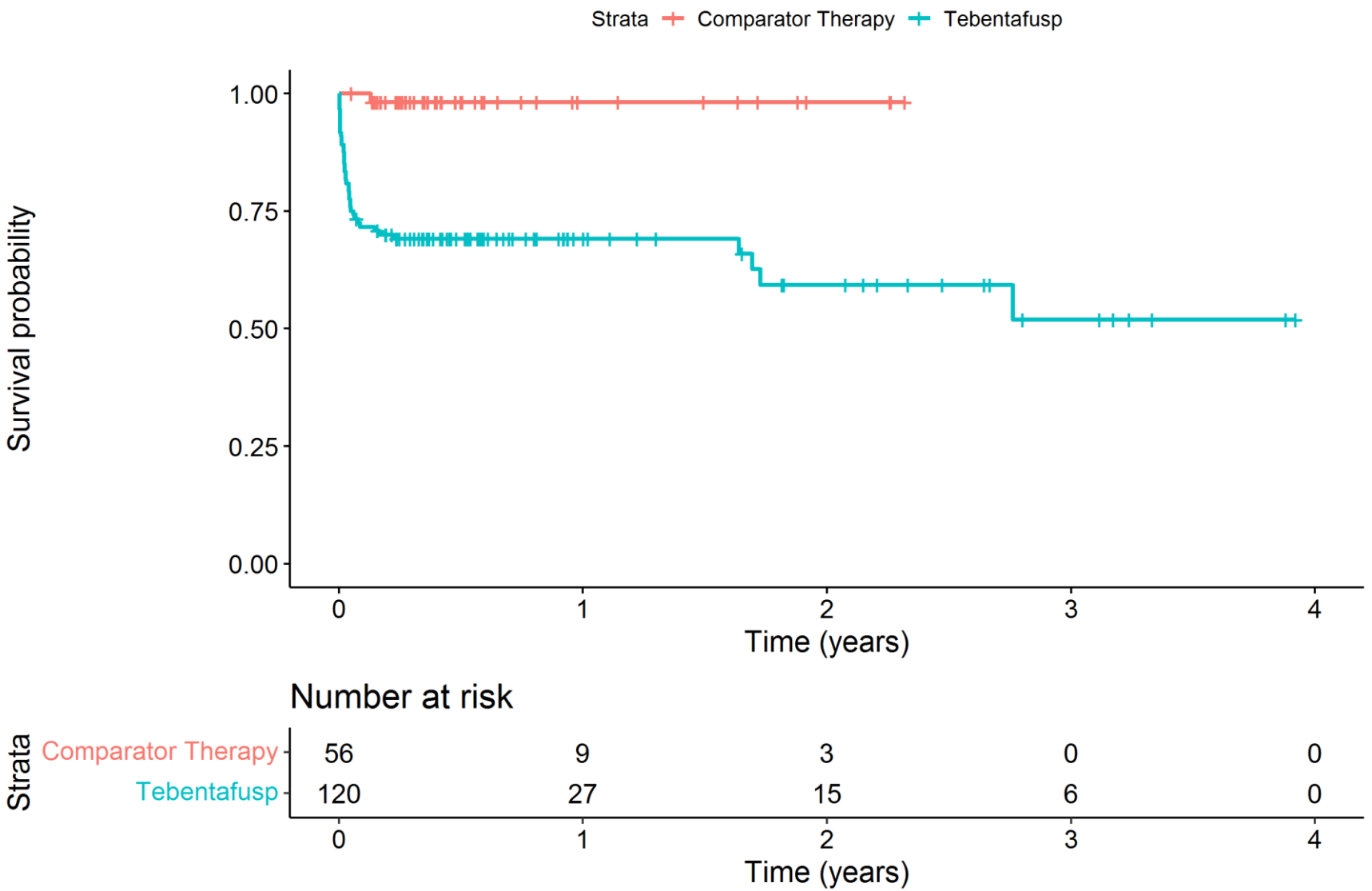
60.11 Periphere Ödeme - Nicht-hispanisch



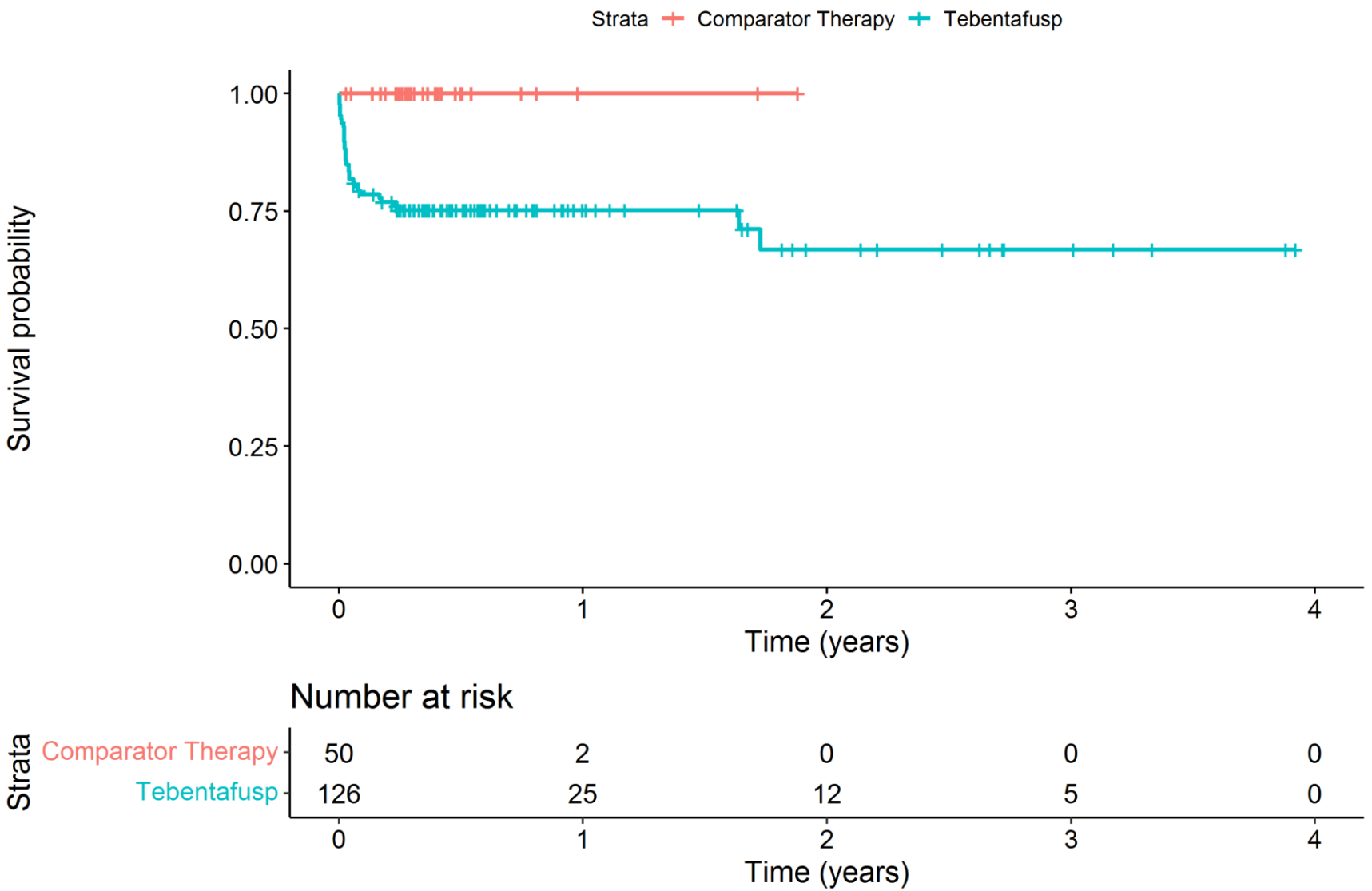
Periphere Ödeme - Männlich



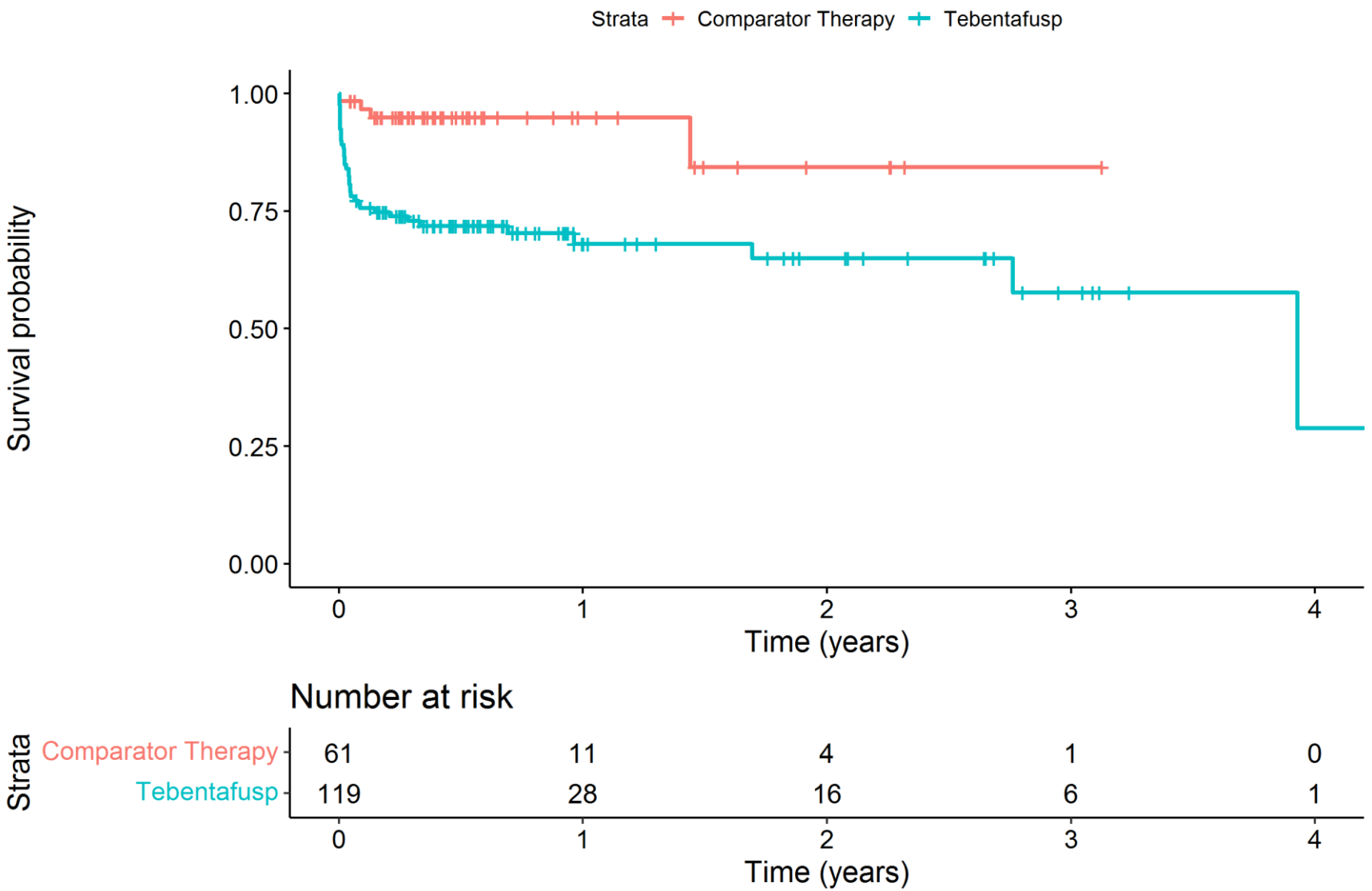
Periphere Ödeme - Weiblich



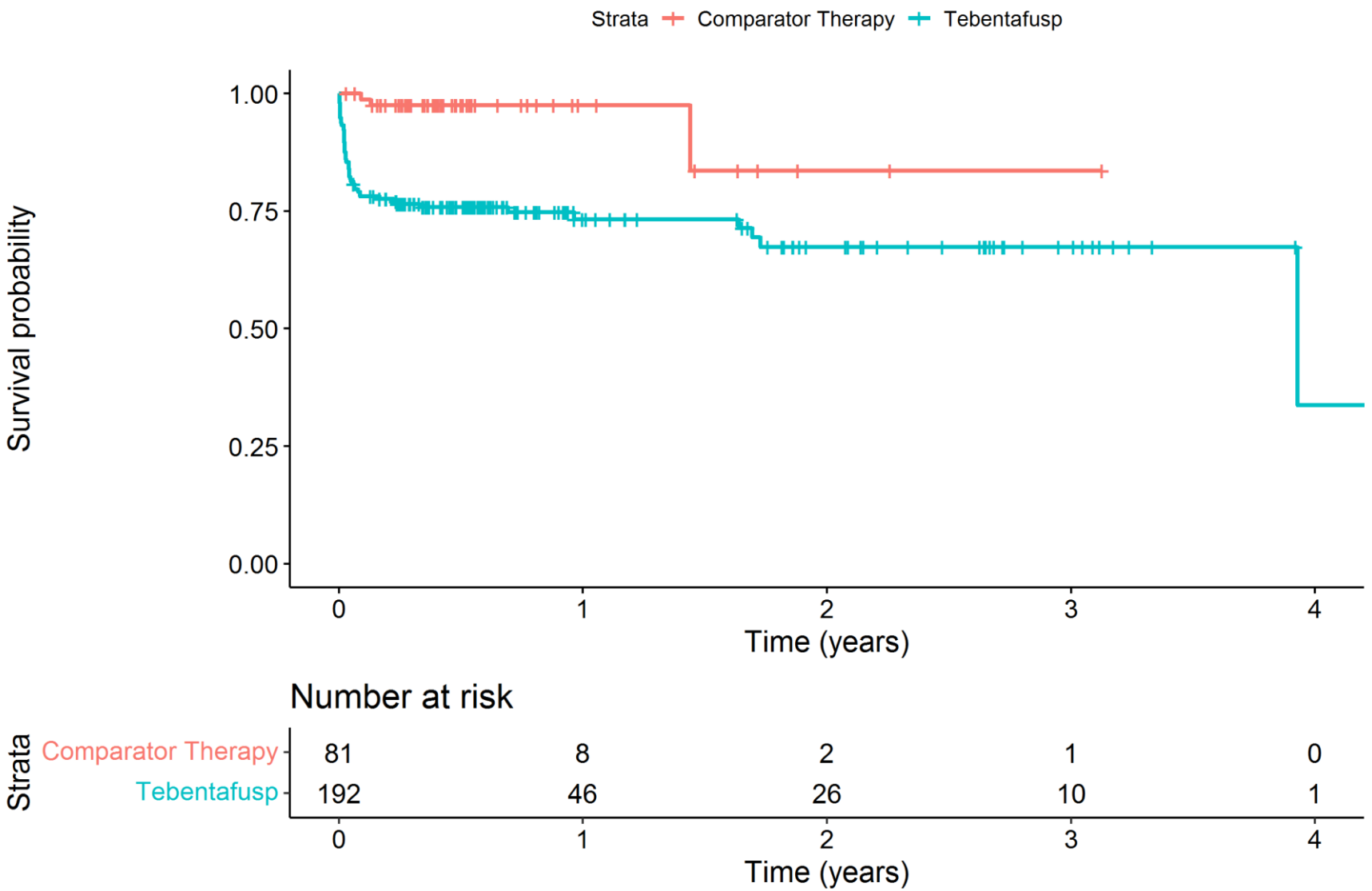
Peripheres Ödeme - <65



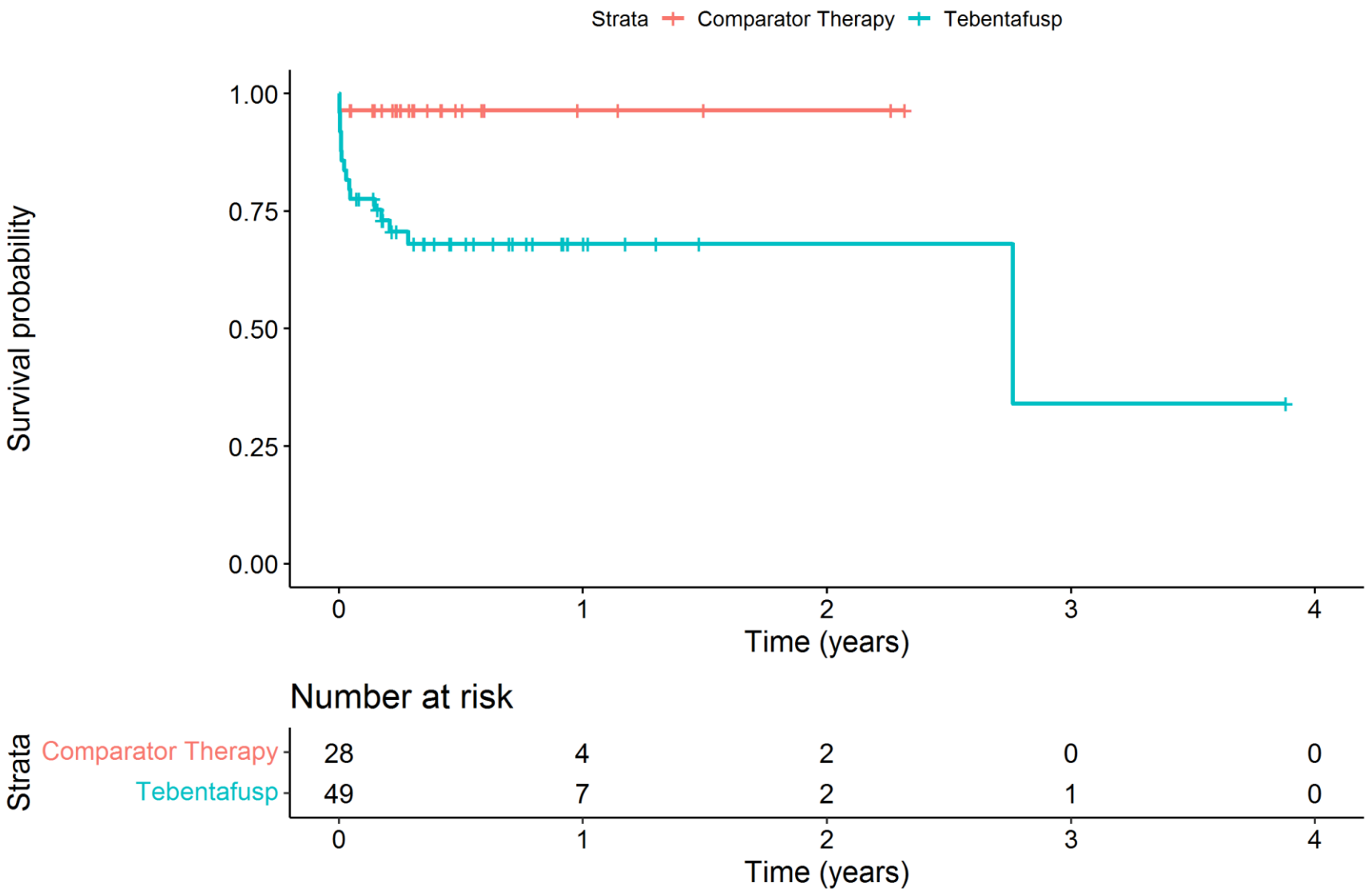
Peripheres Ödeme - ≥65



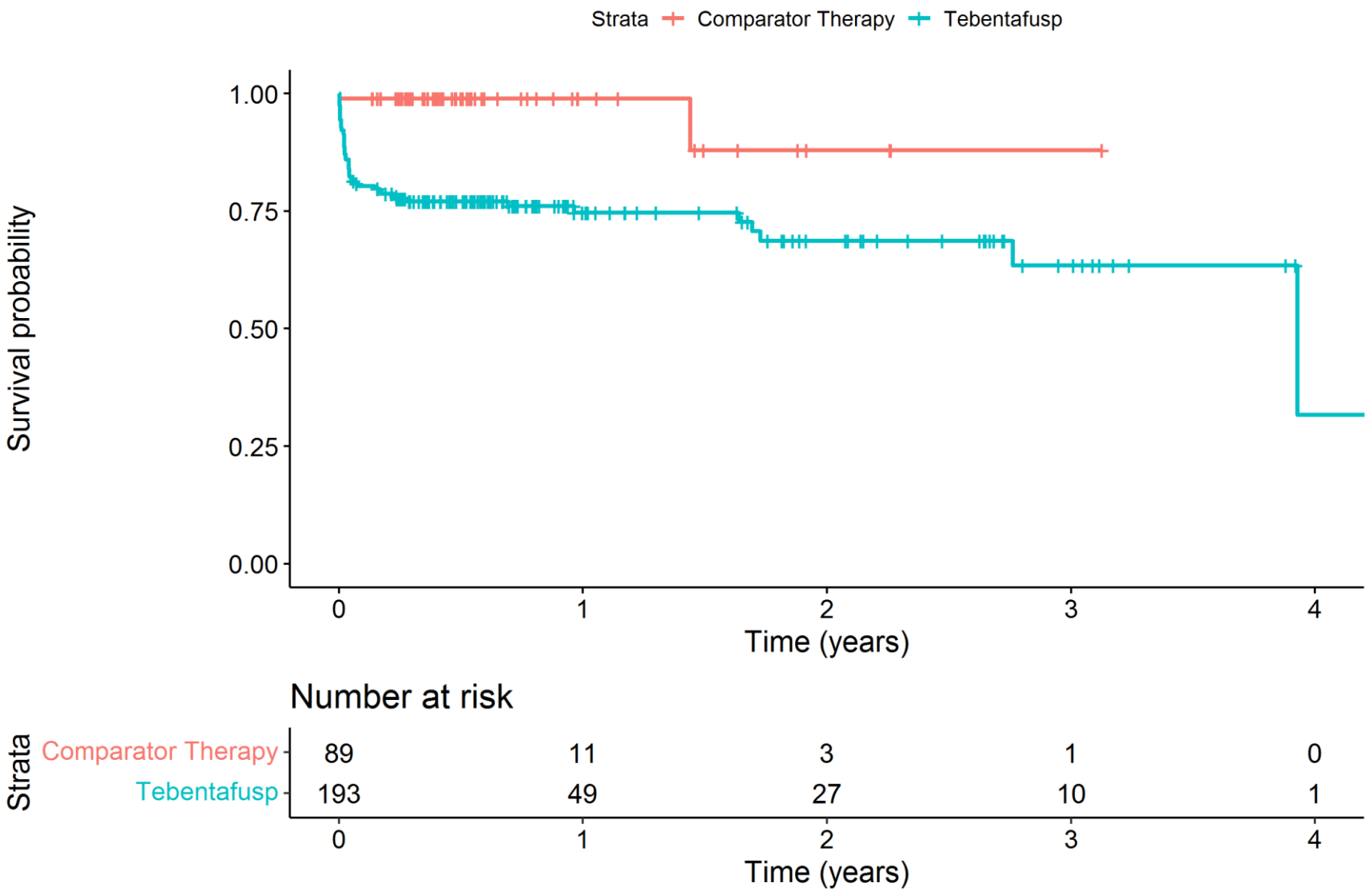
Periphere Ödeme - ECOG 0



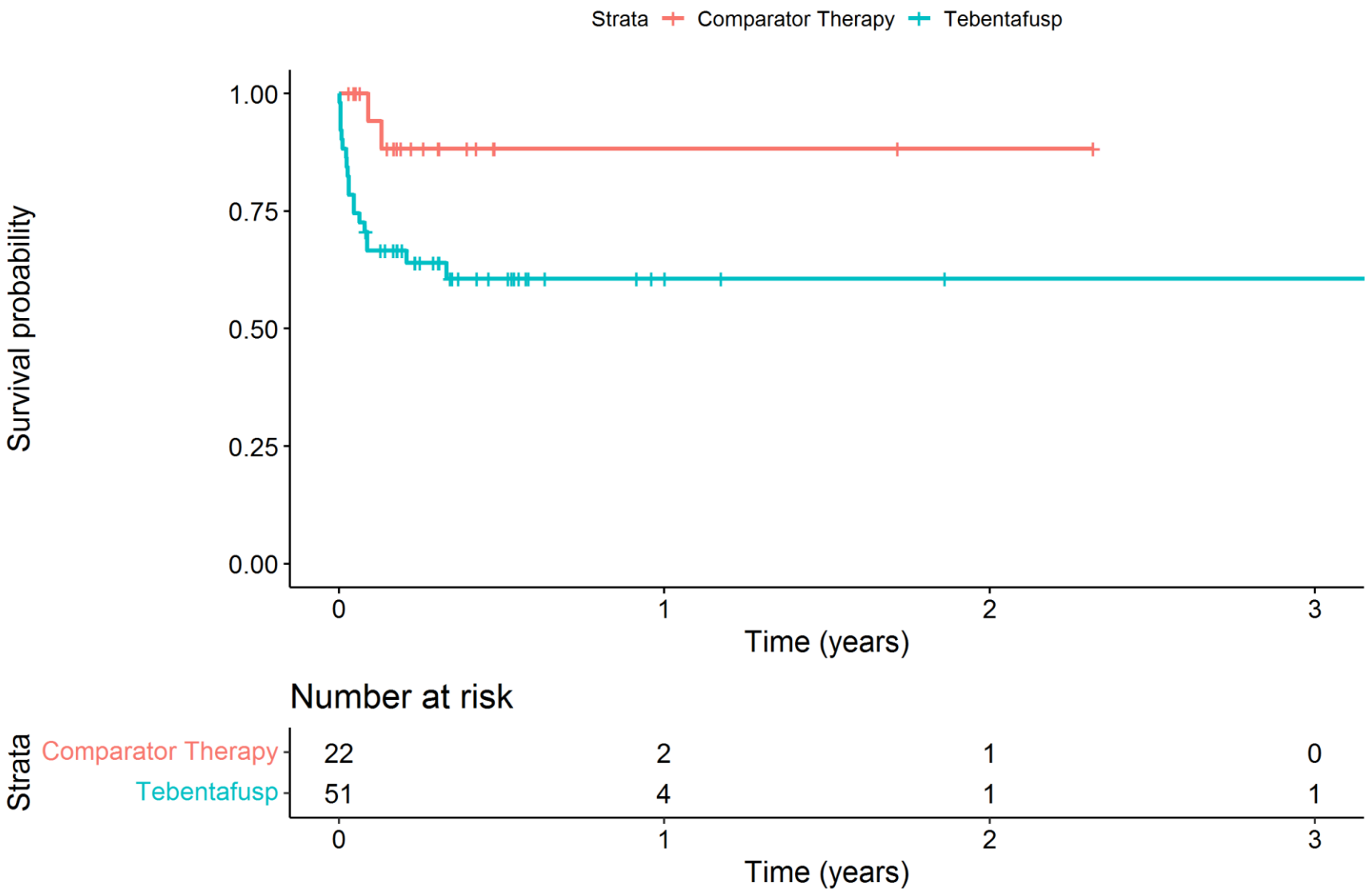
Periphere Ödeme - ECOG 1



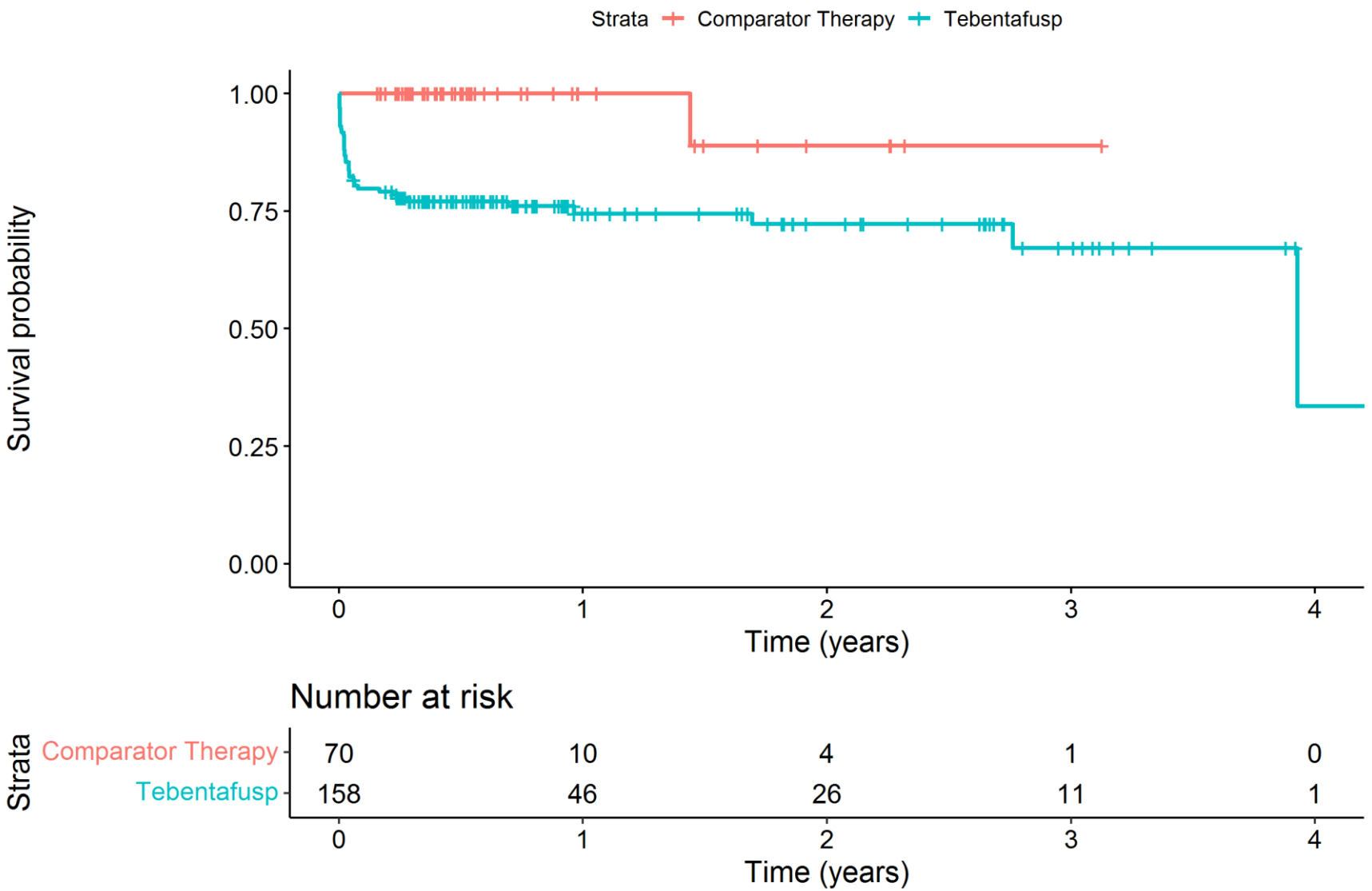
Peripheres Ödeme - ALP ≤ ULN



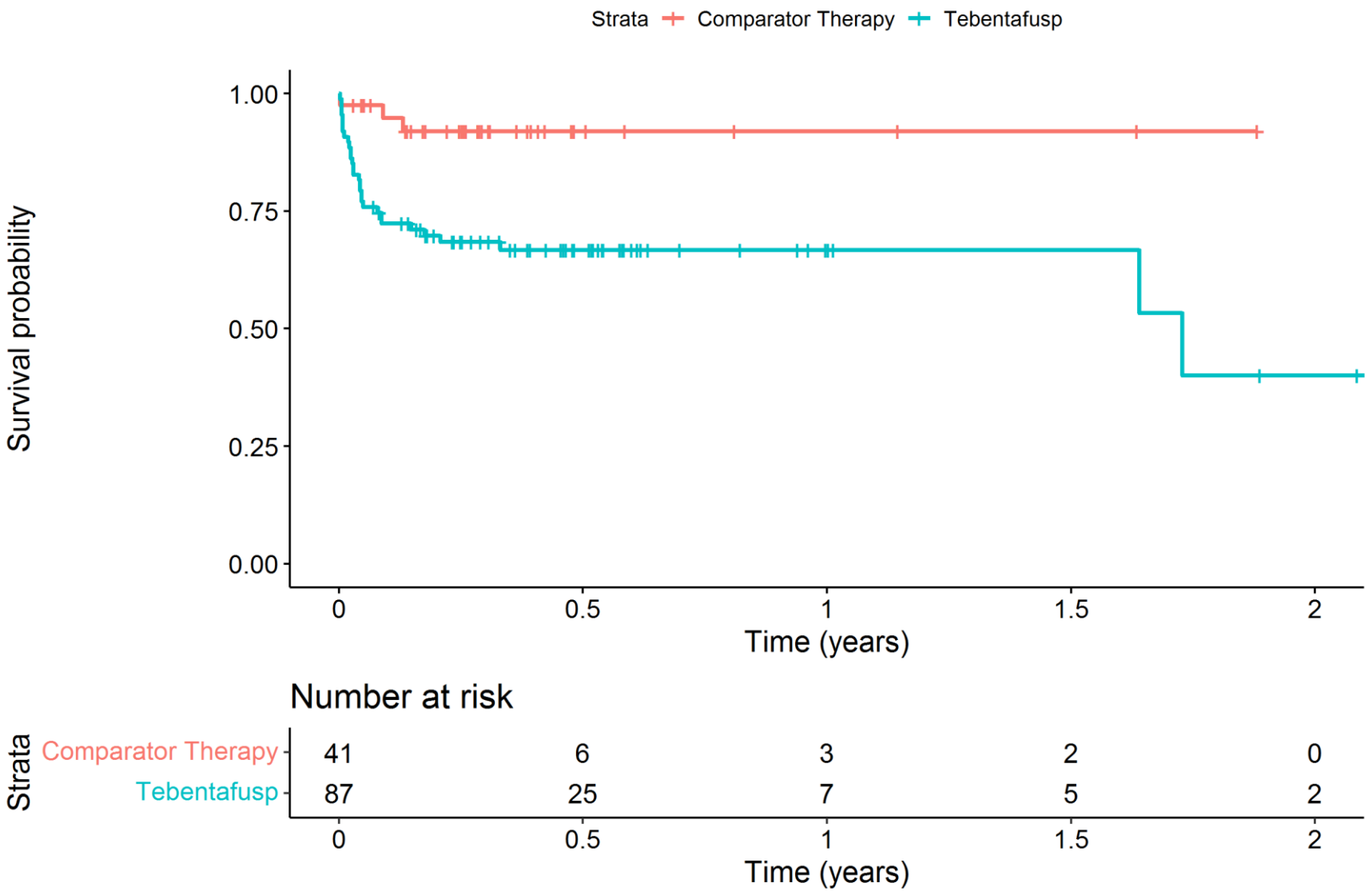
Periphere Ödeme - ALP > ULN



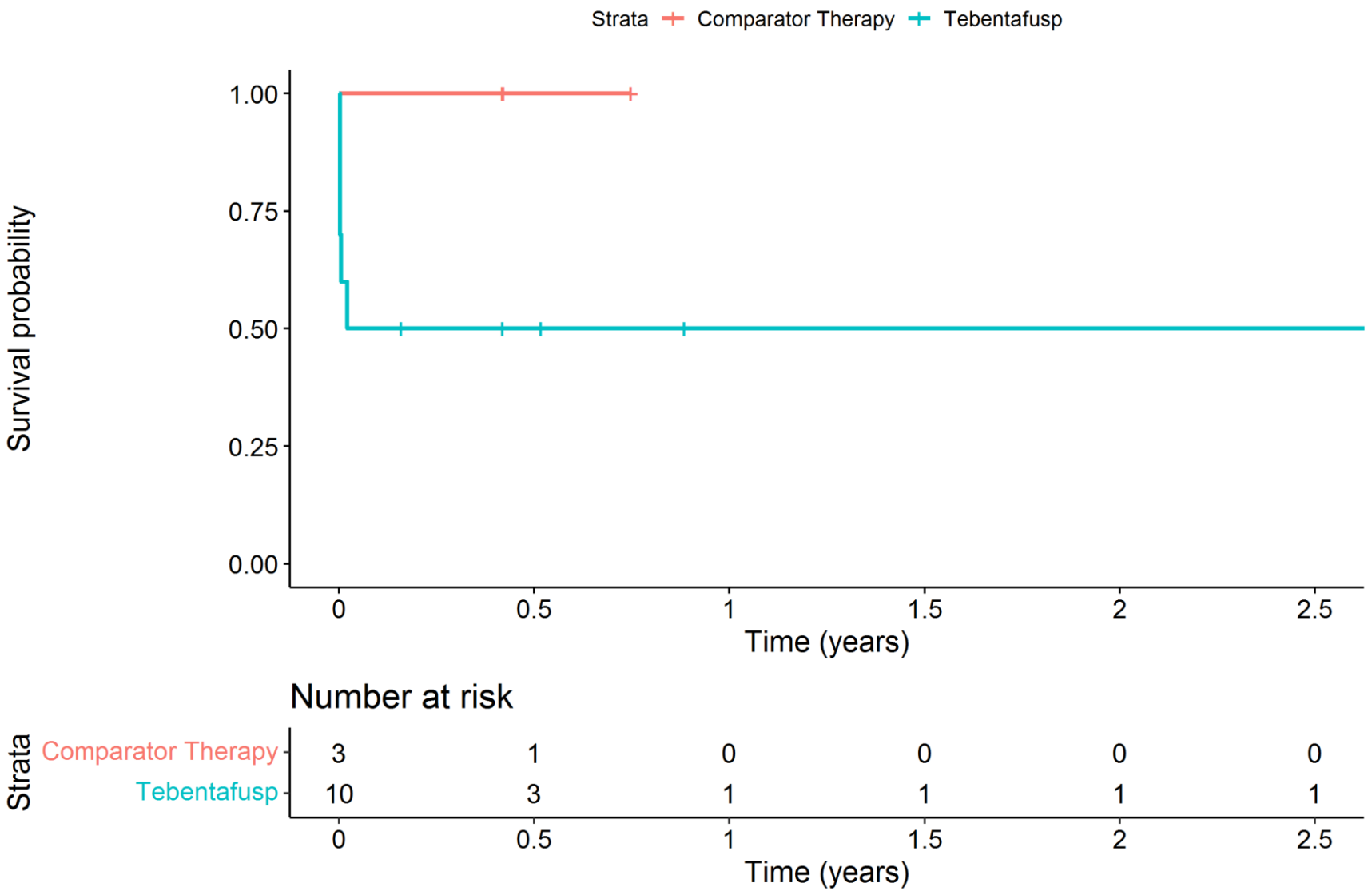
Periphere Ödeme - LDH =< ULN



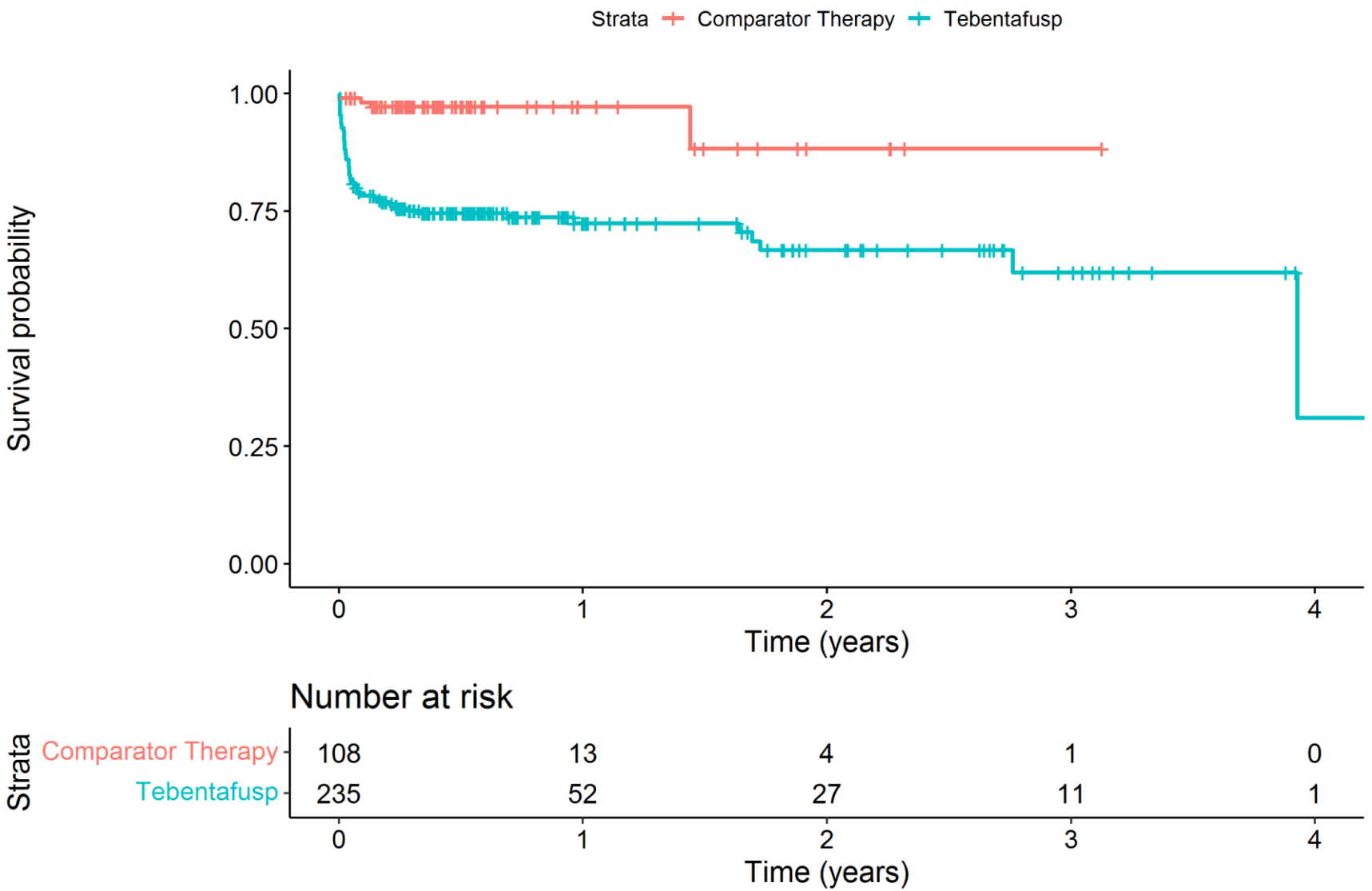
Periphere Ödeme - LDH > ULN



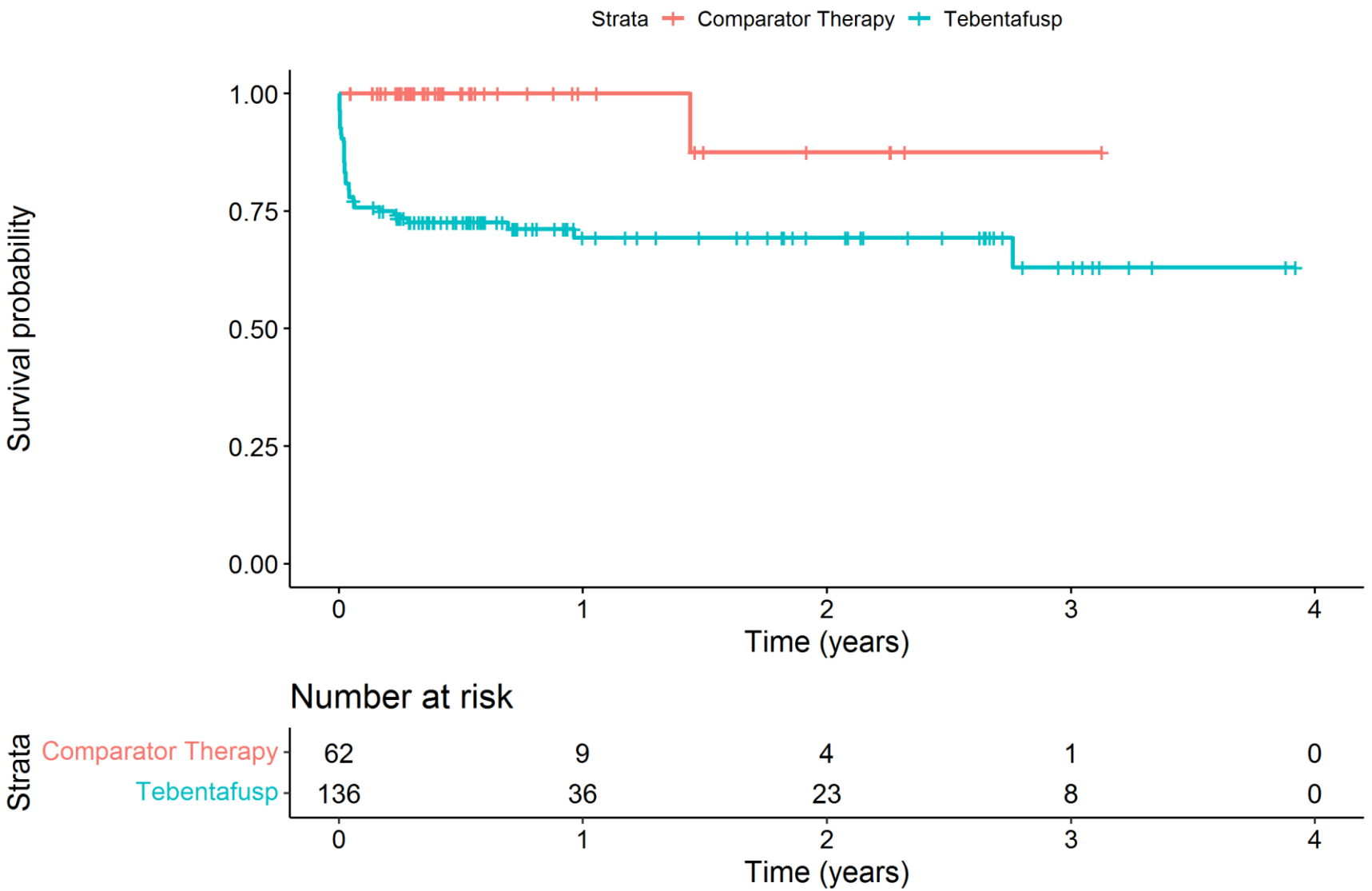
Periphere Ödeme - Vorherige Therapie adjuvant/neoadjuvant



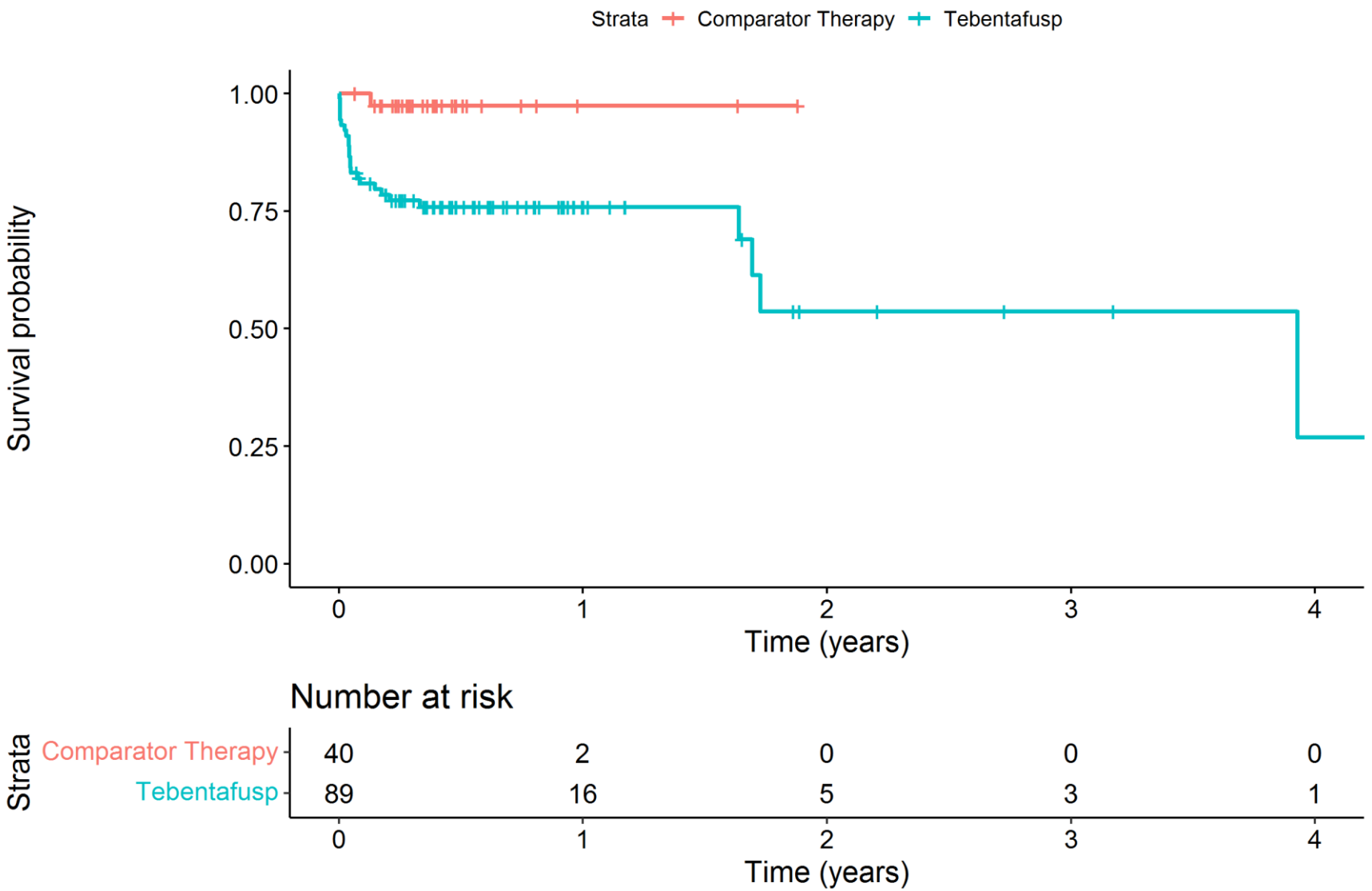
Periphere Ödeme - Keine Vorherige Therapie adjuvant/neoadjuvant



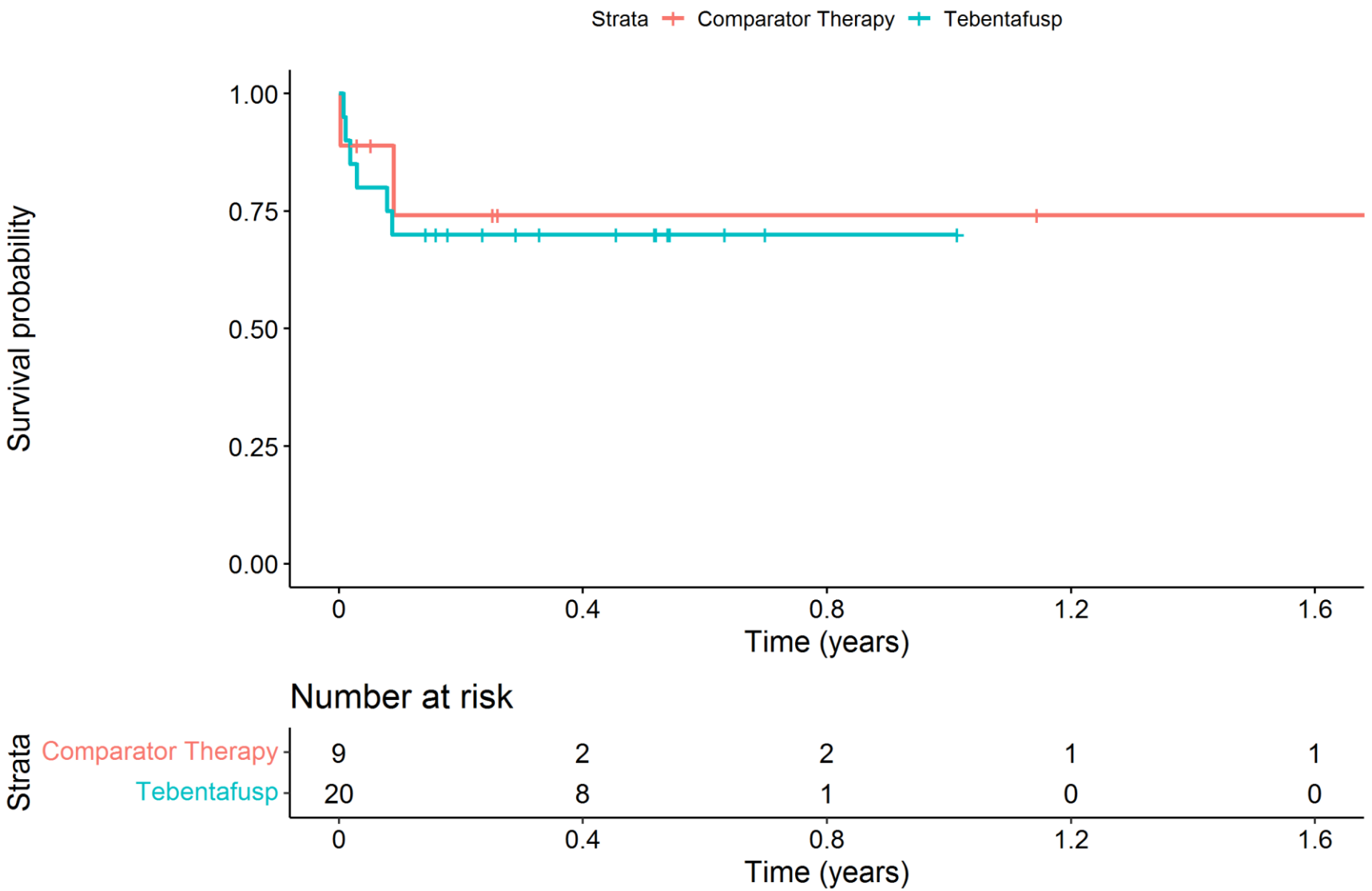
Peripheres Ödeme - Läsion ≤ 3cm



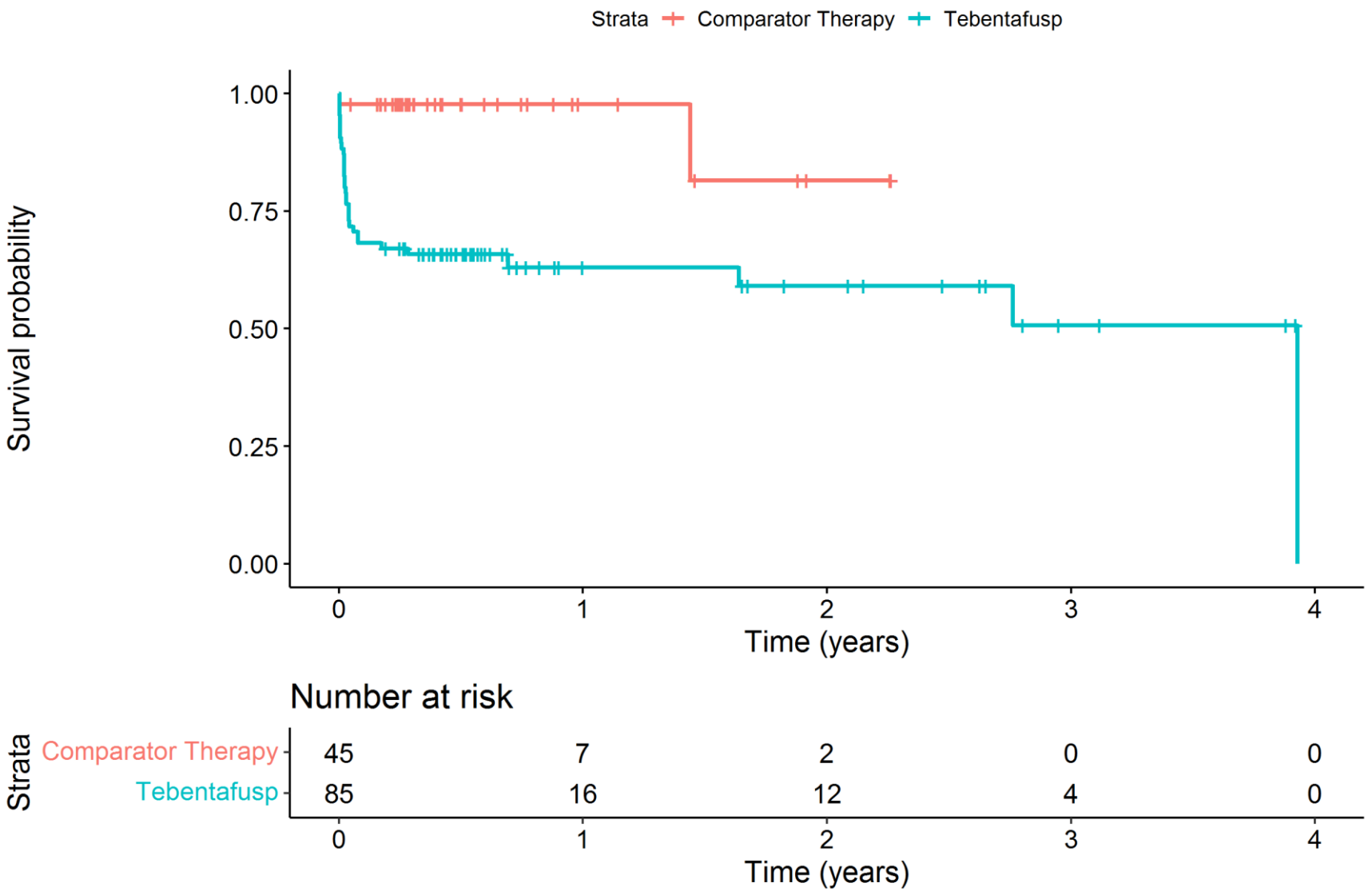
Periphere Ödeme - Läsion 3,1-8,0 cm



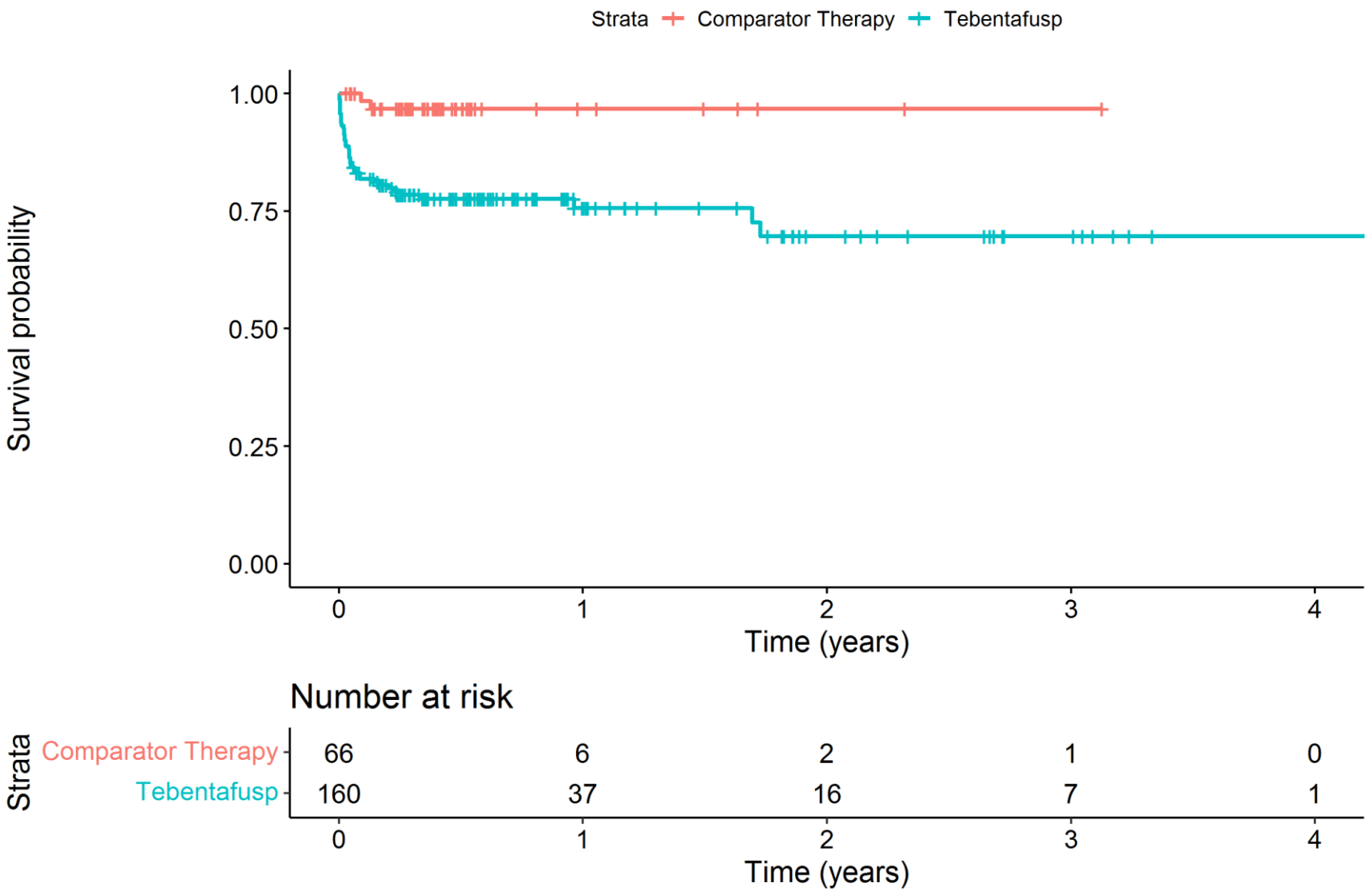
Peripheres Ödeme - Läsion ≥8,1 cm



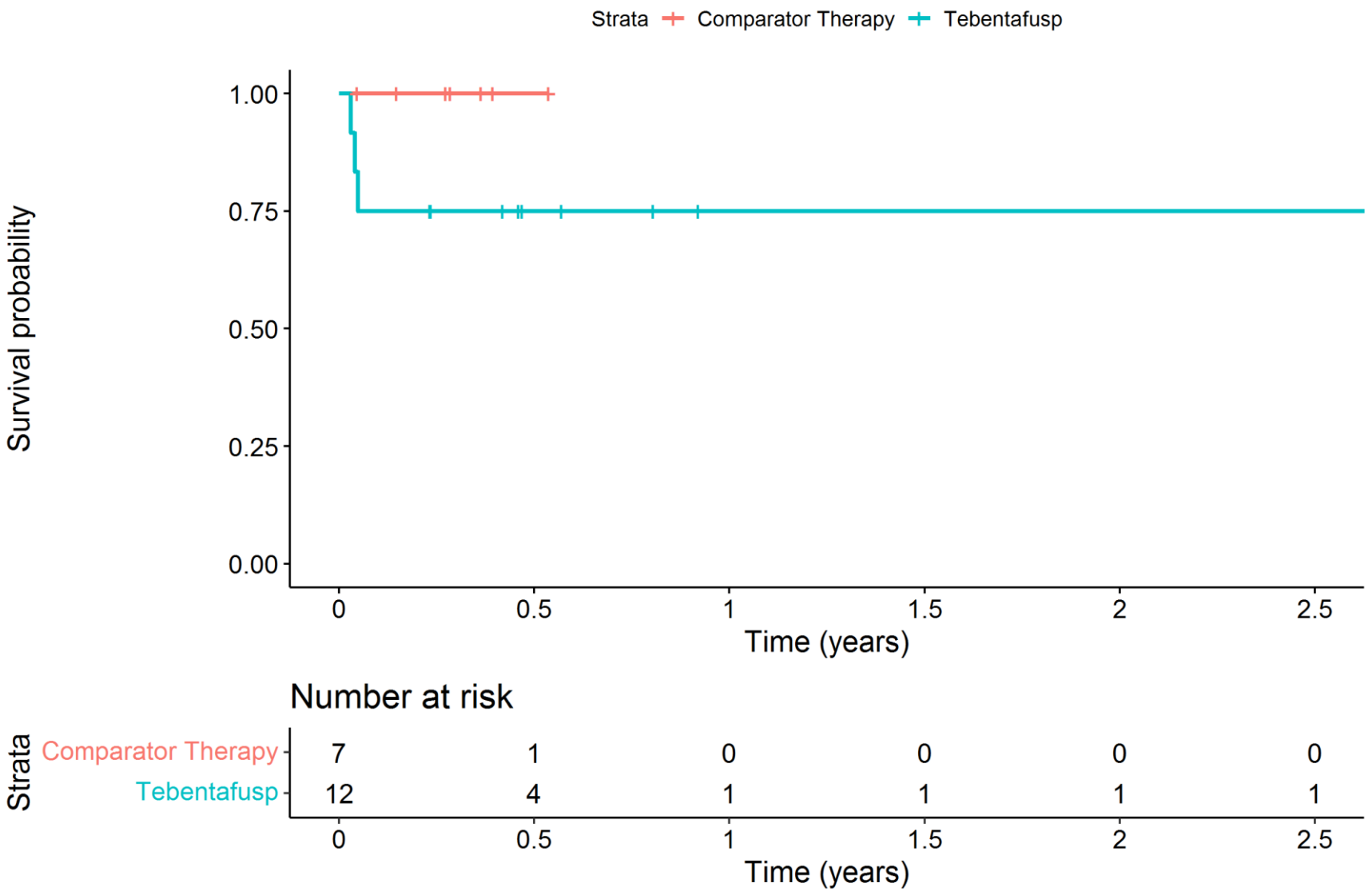
Periphere Ödeme - Nordamerika



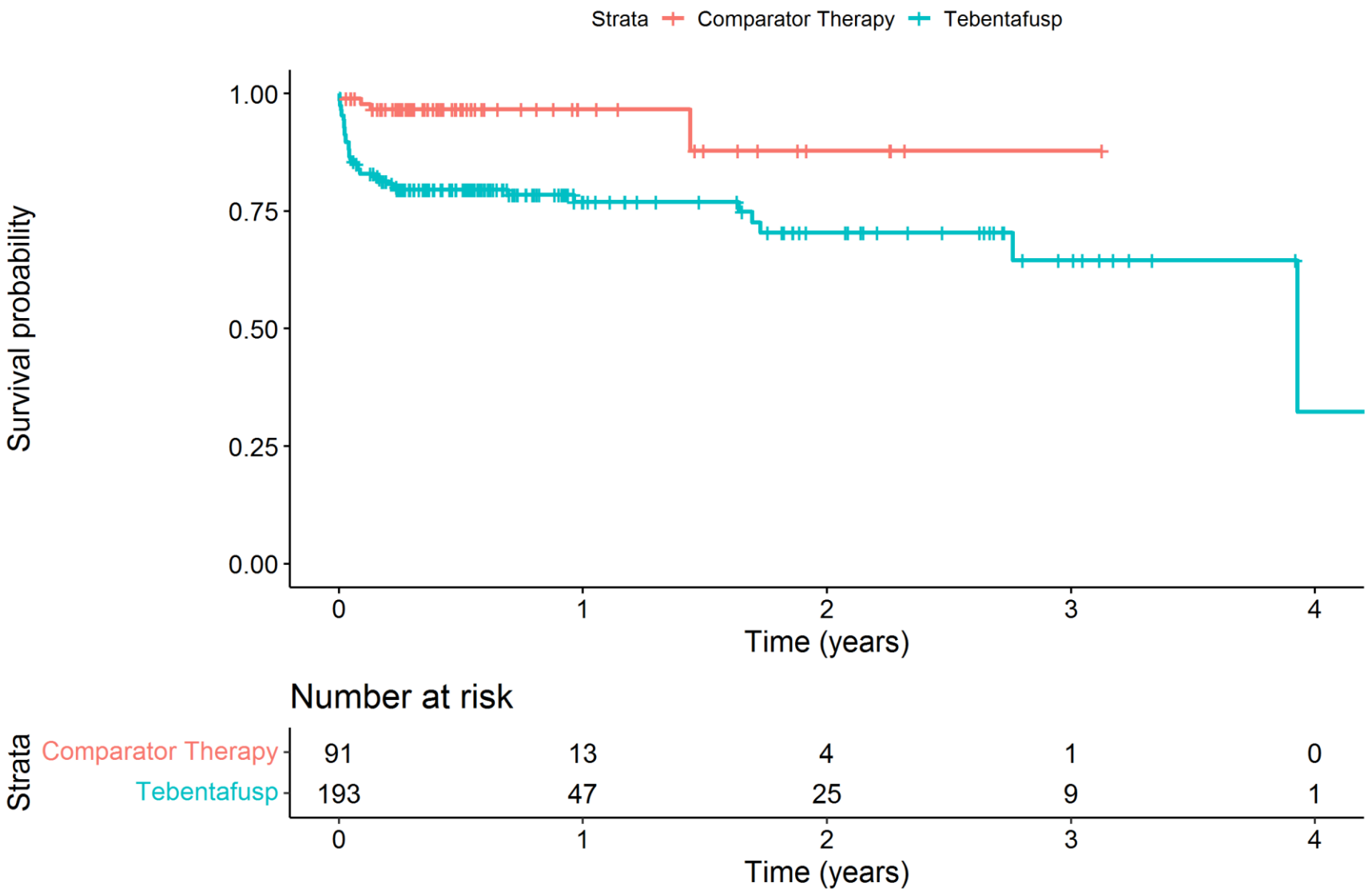
Periphere Ödeme - Nicht-Nordamerika



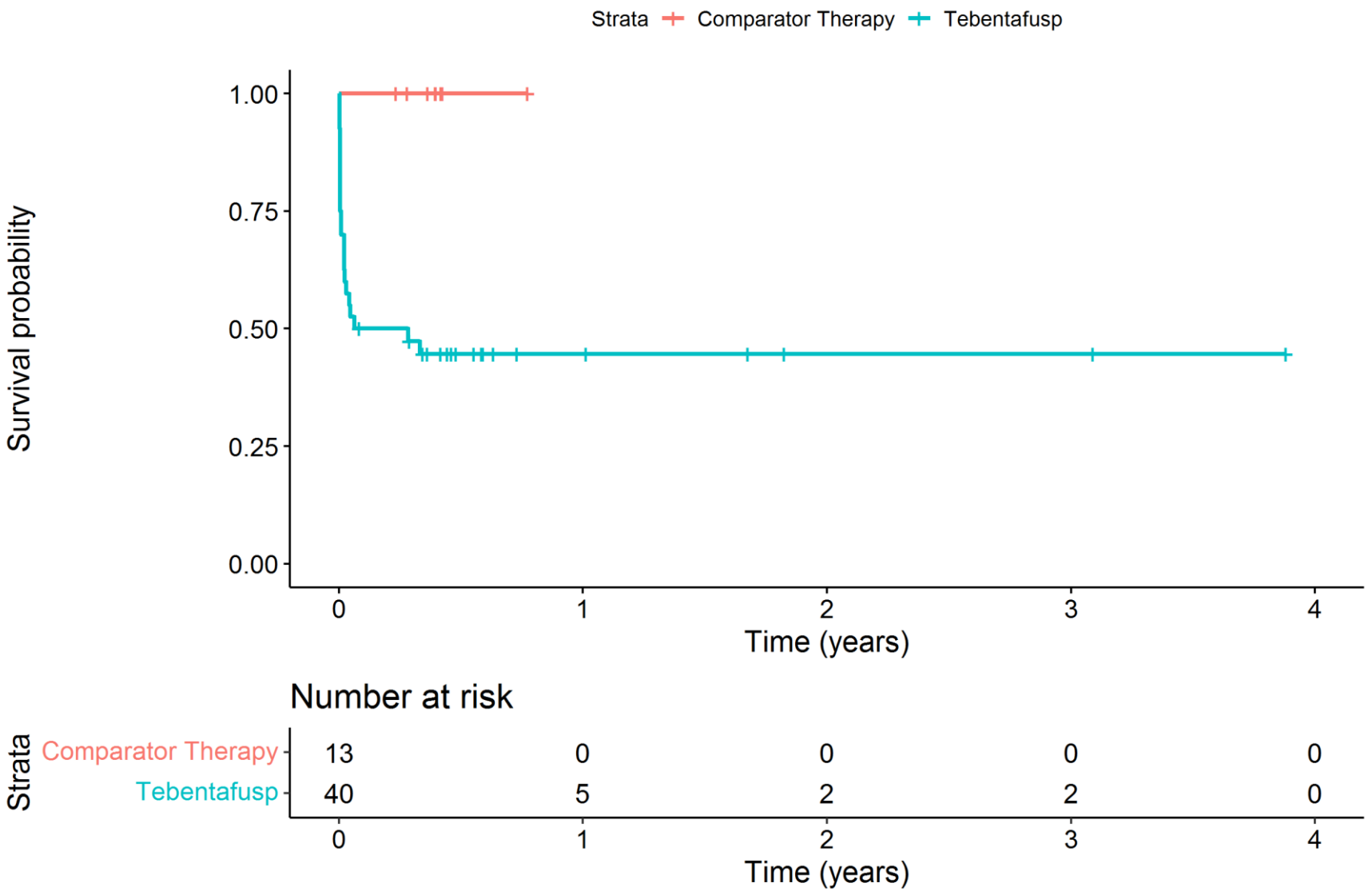
Periphere Ödeme - Dacarbazin



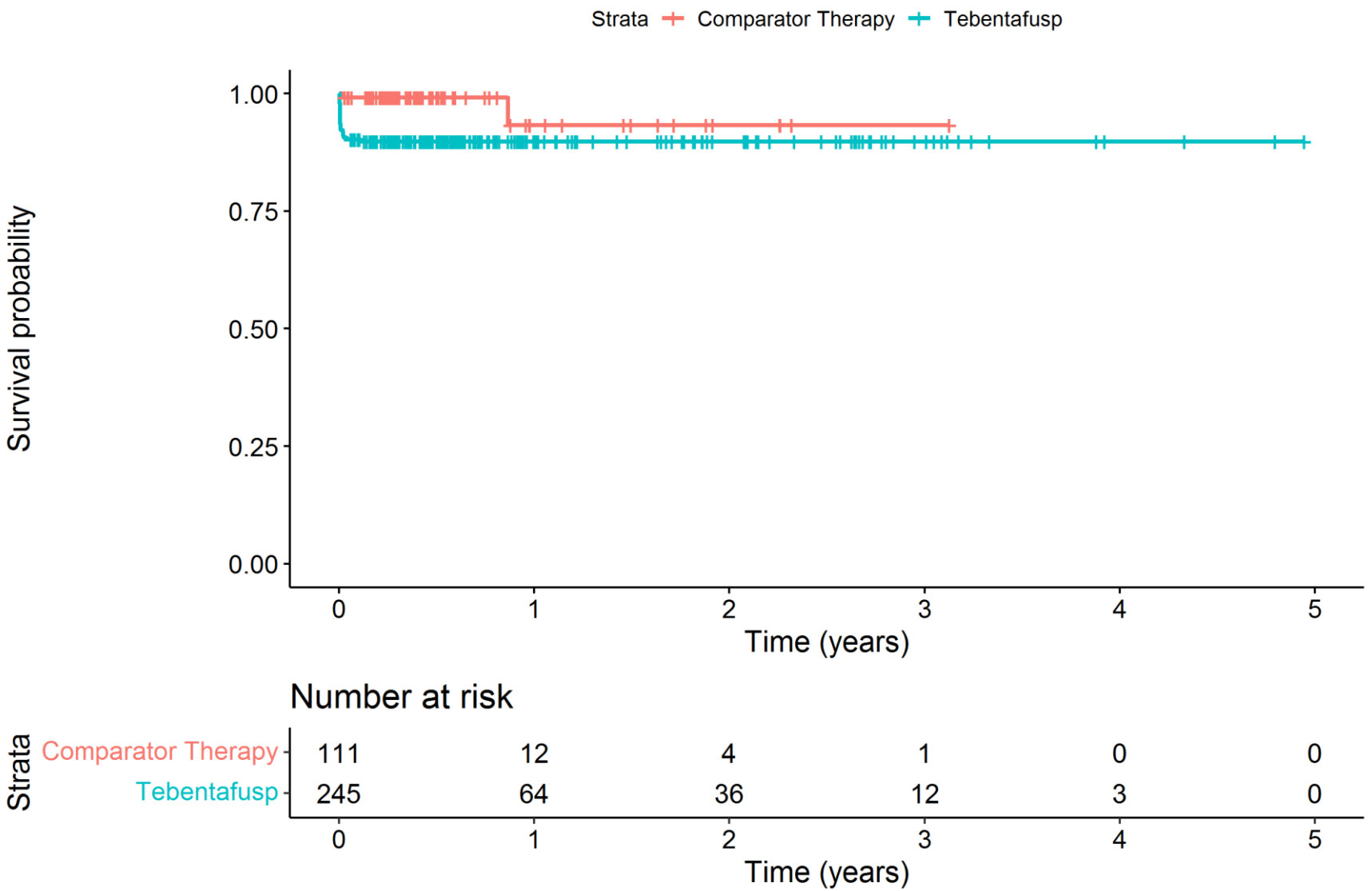
Periphere Ödeme - Pembrolizumab



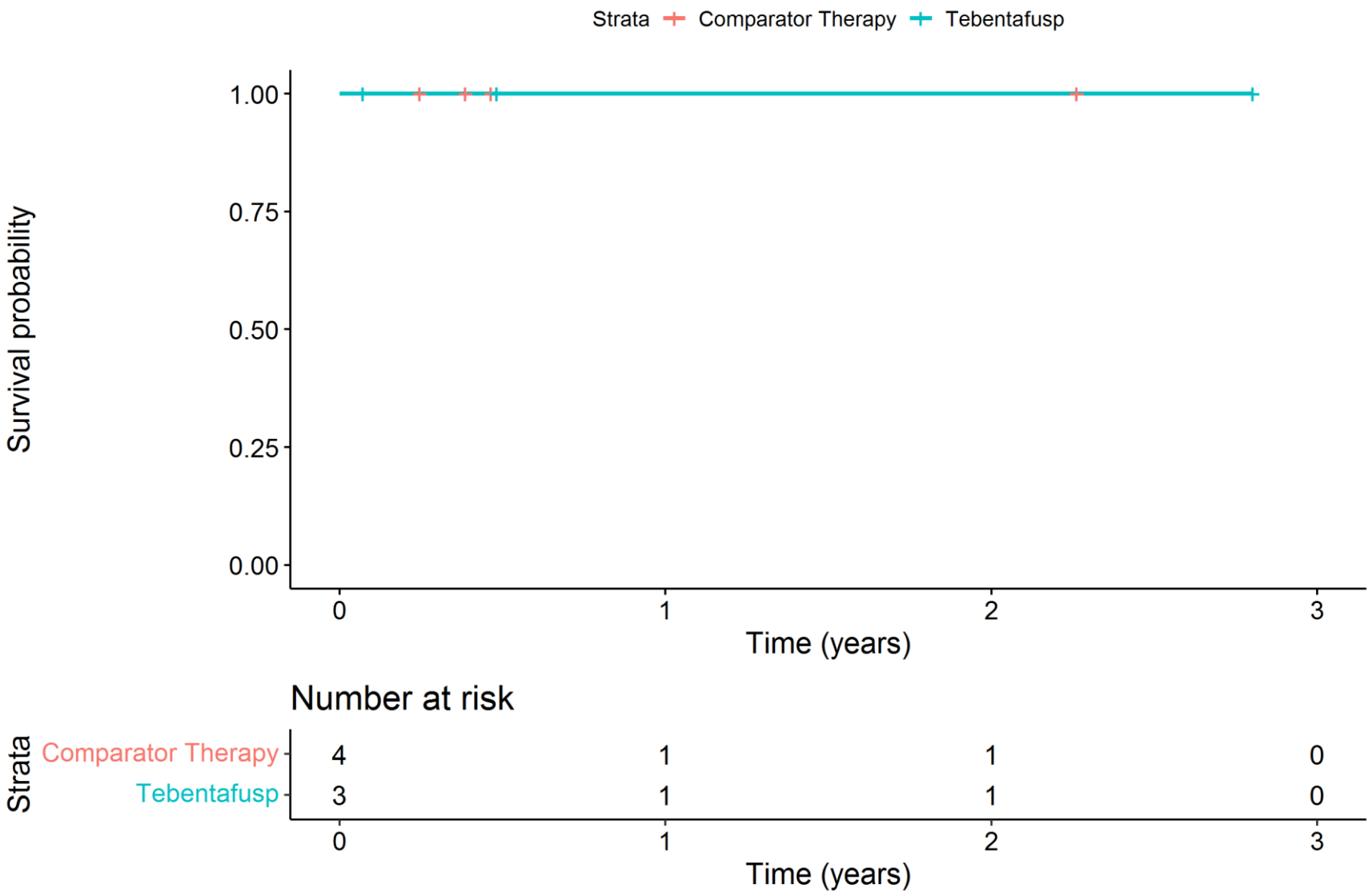
Periphere Ödeme - Ipilimumab



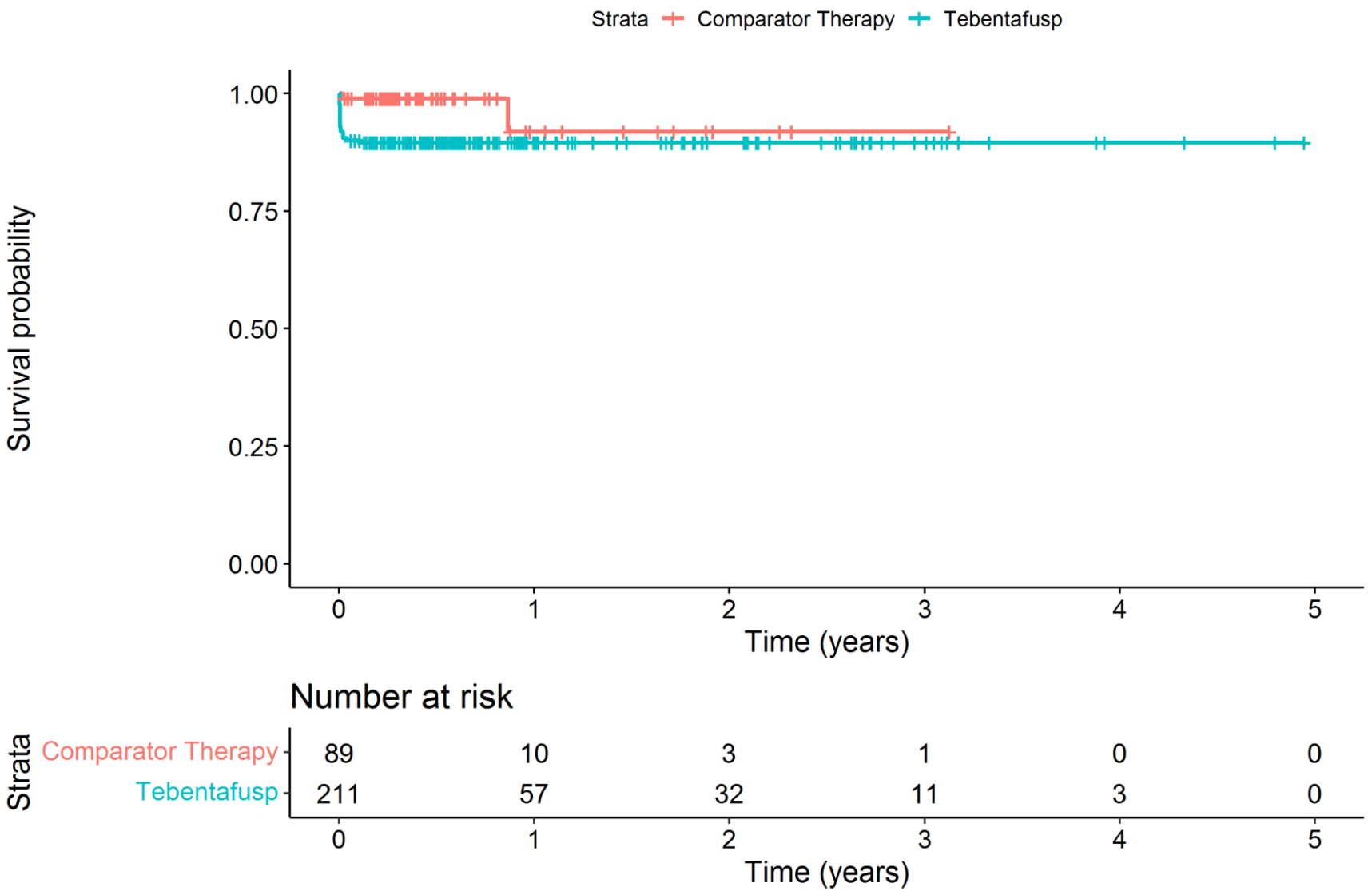
Gesichtsödeme - Gesamt



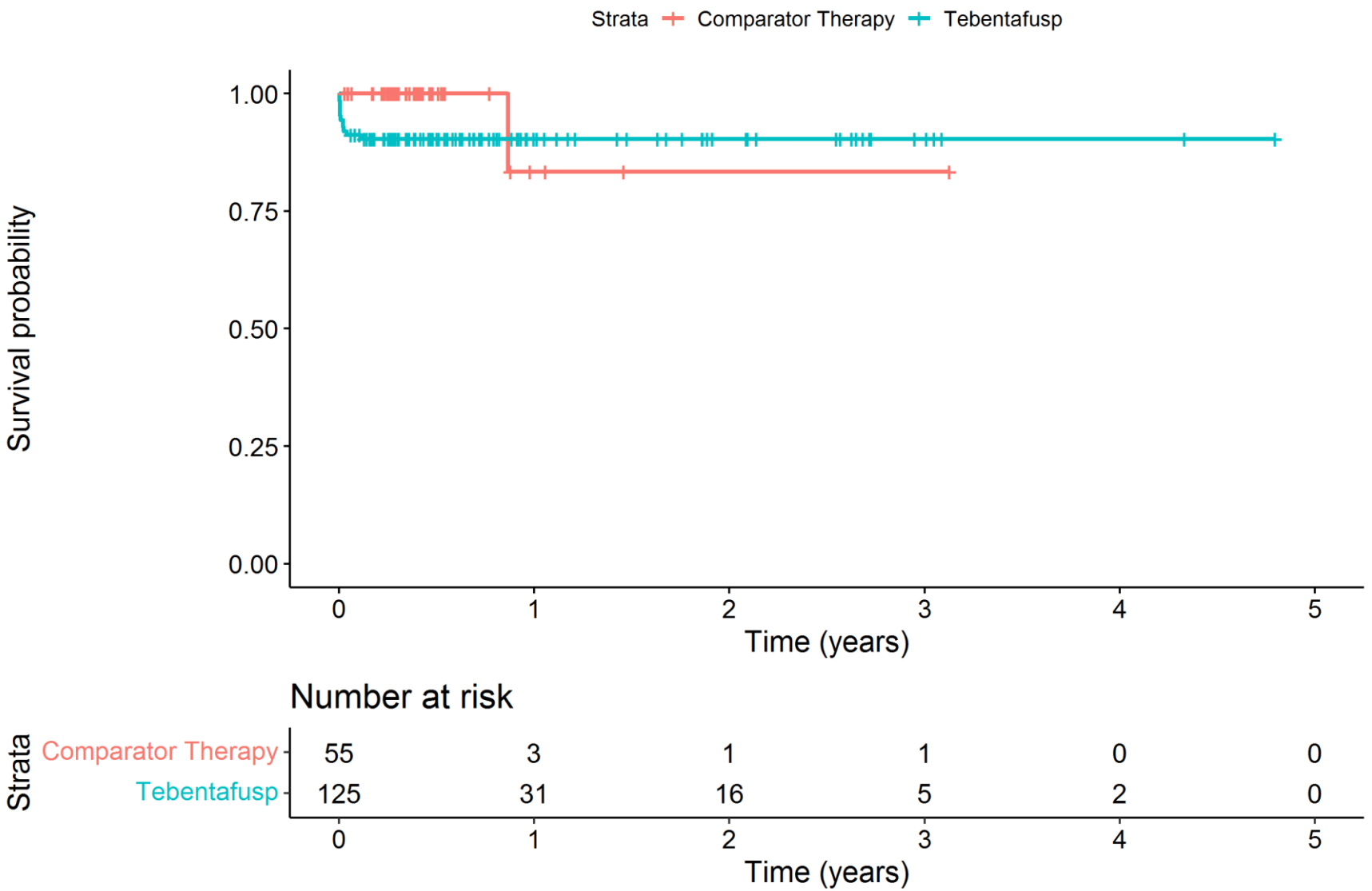
Gesichtsödeme - Hispanisch



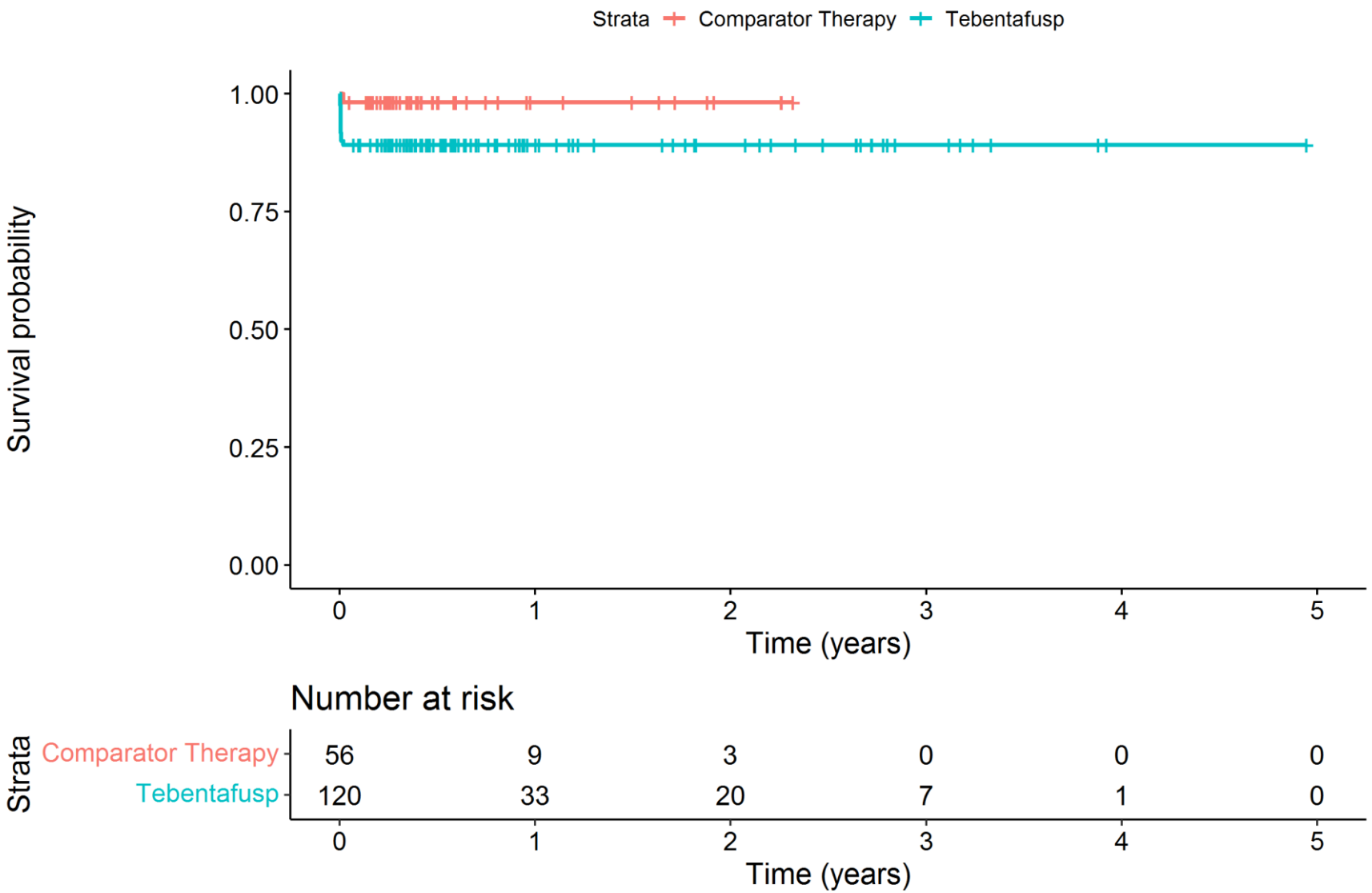
Gesichtsödeme - Nicht-hispanisch



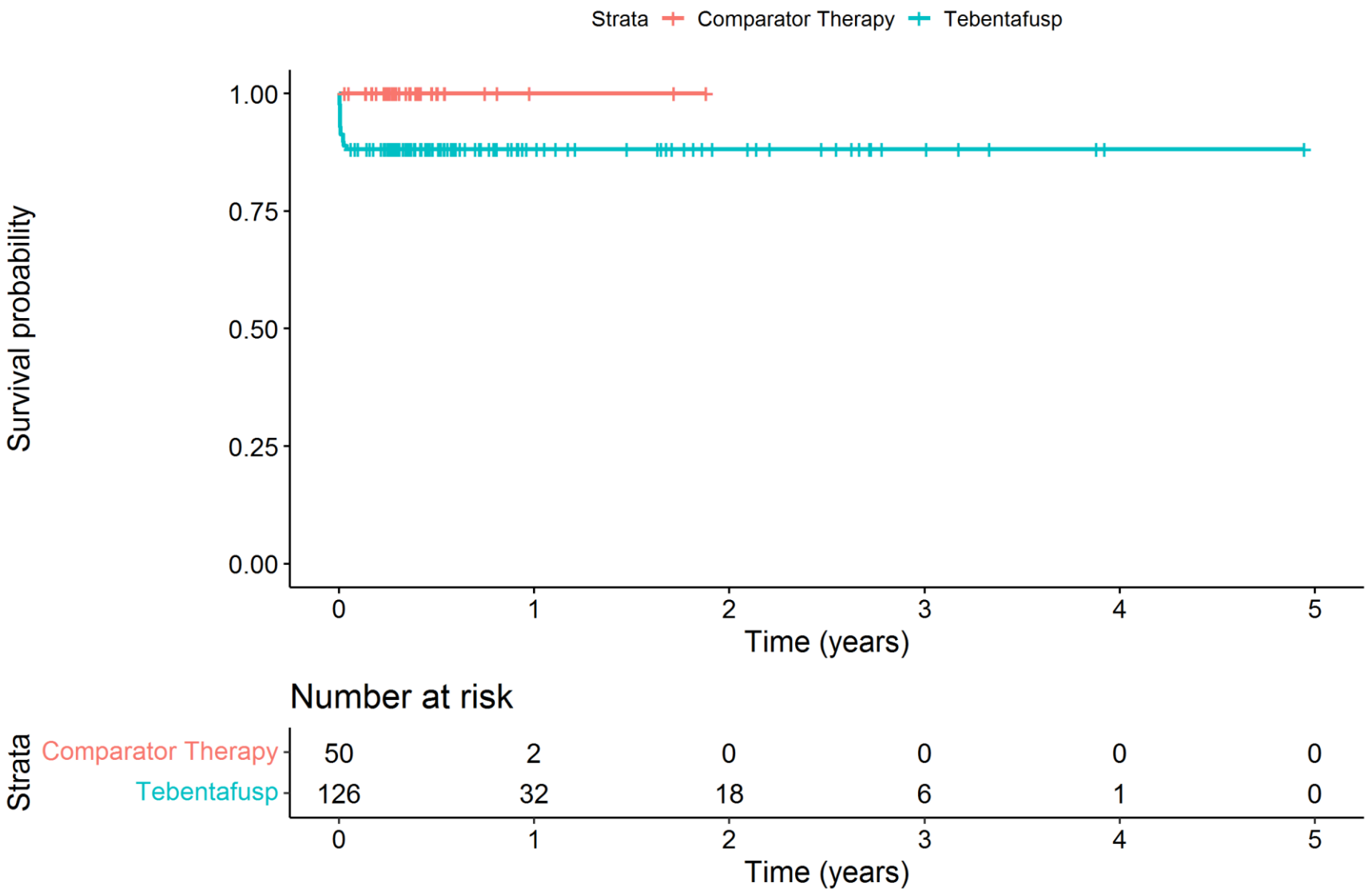
Gesichtsödeme - Männlich



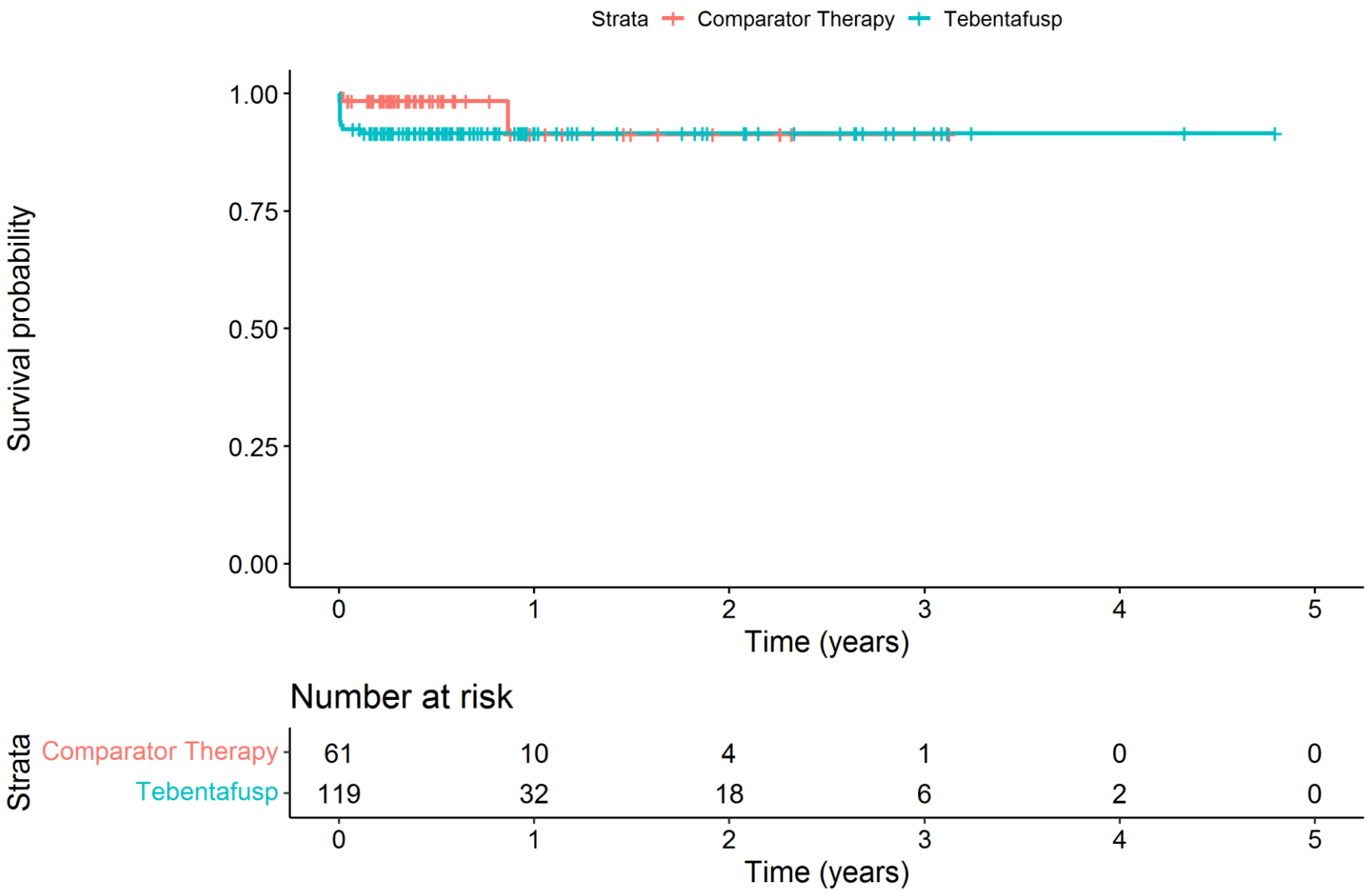
Gesichtsödeme - Weiblich



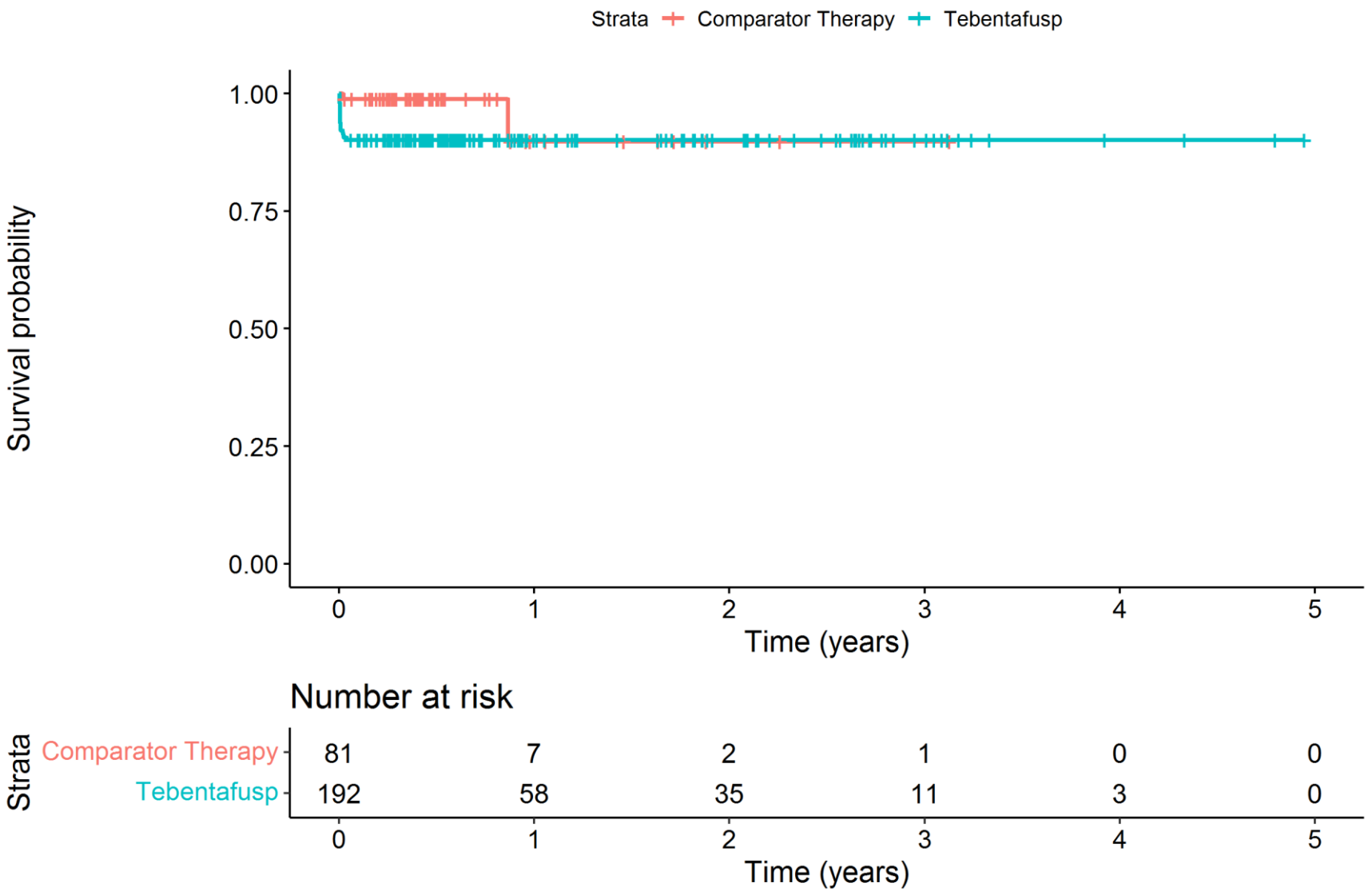
Gesichtsödeme - <65



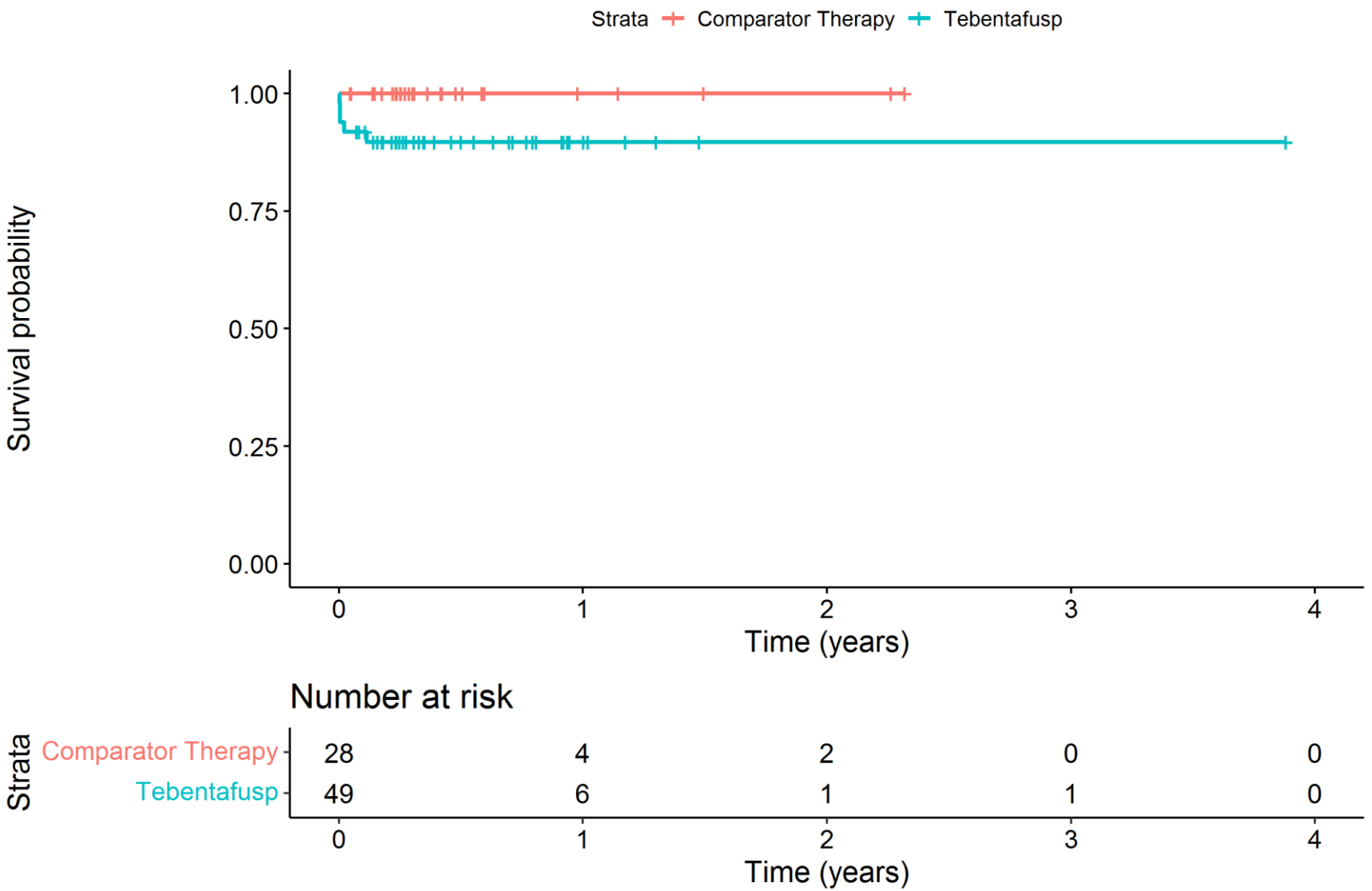
Gesichtsödeme - ≥65



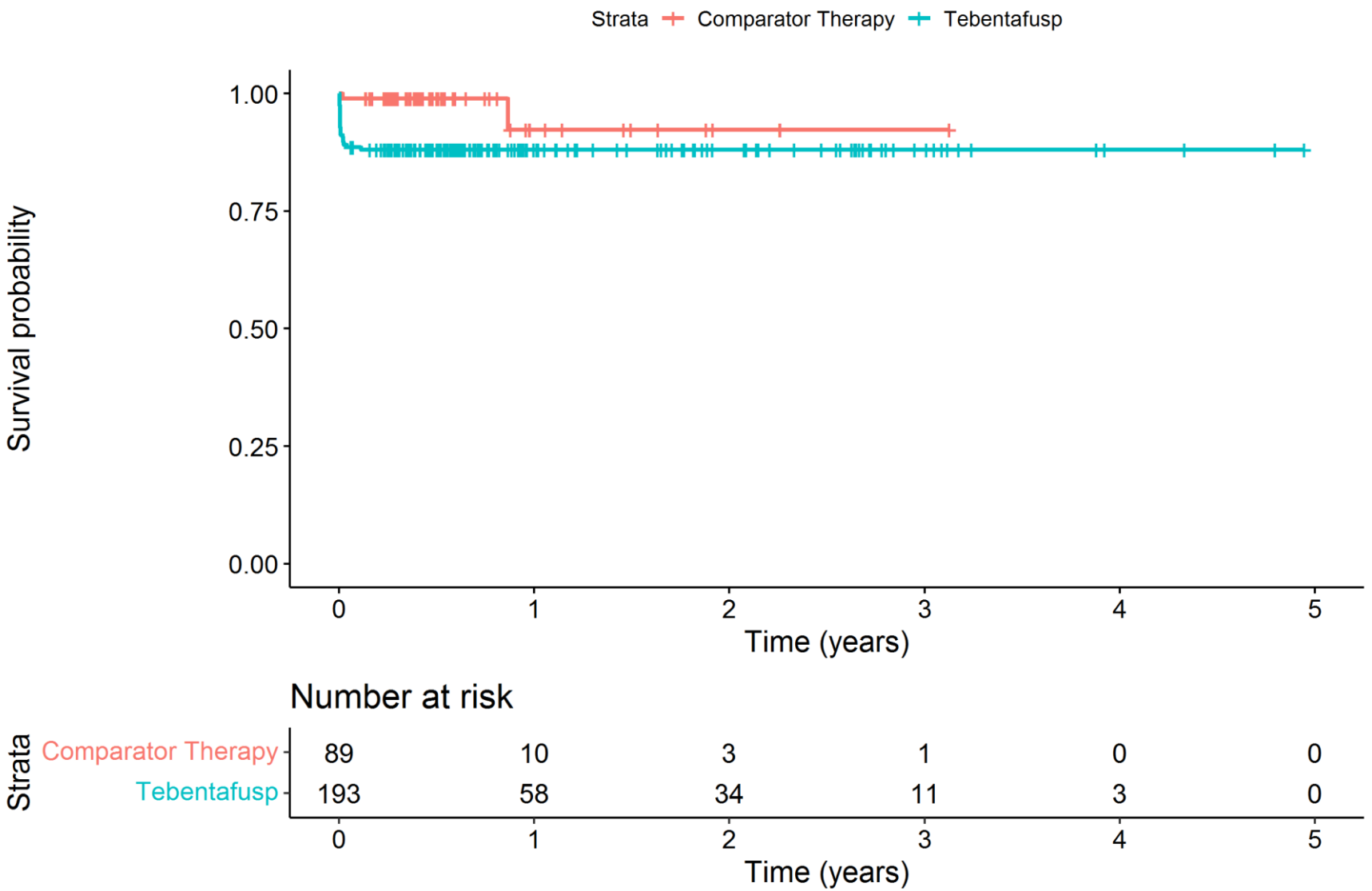
Gesichtsödeme - ECOG 0



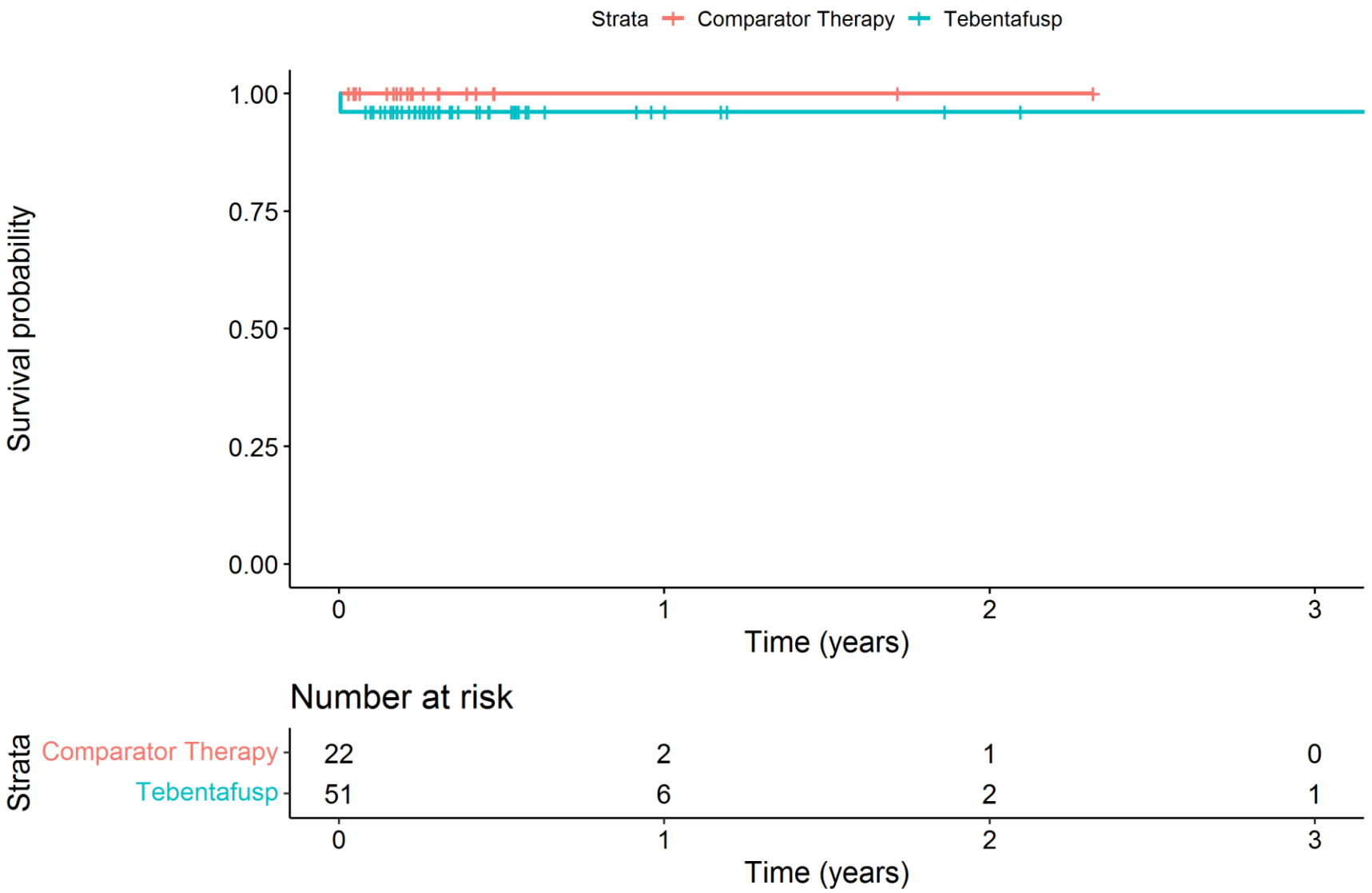
Gesichtsödeme - ECOG 1



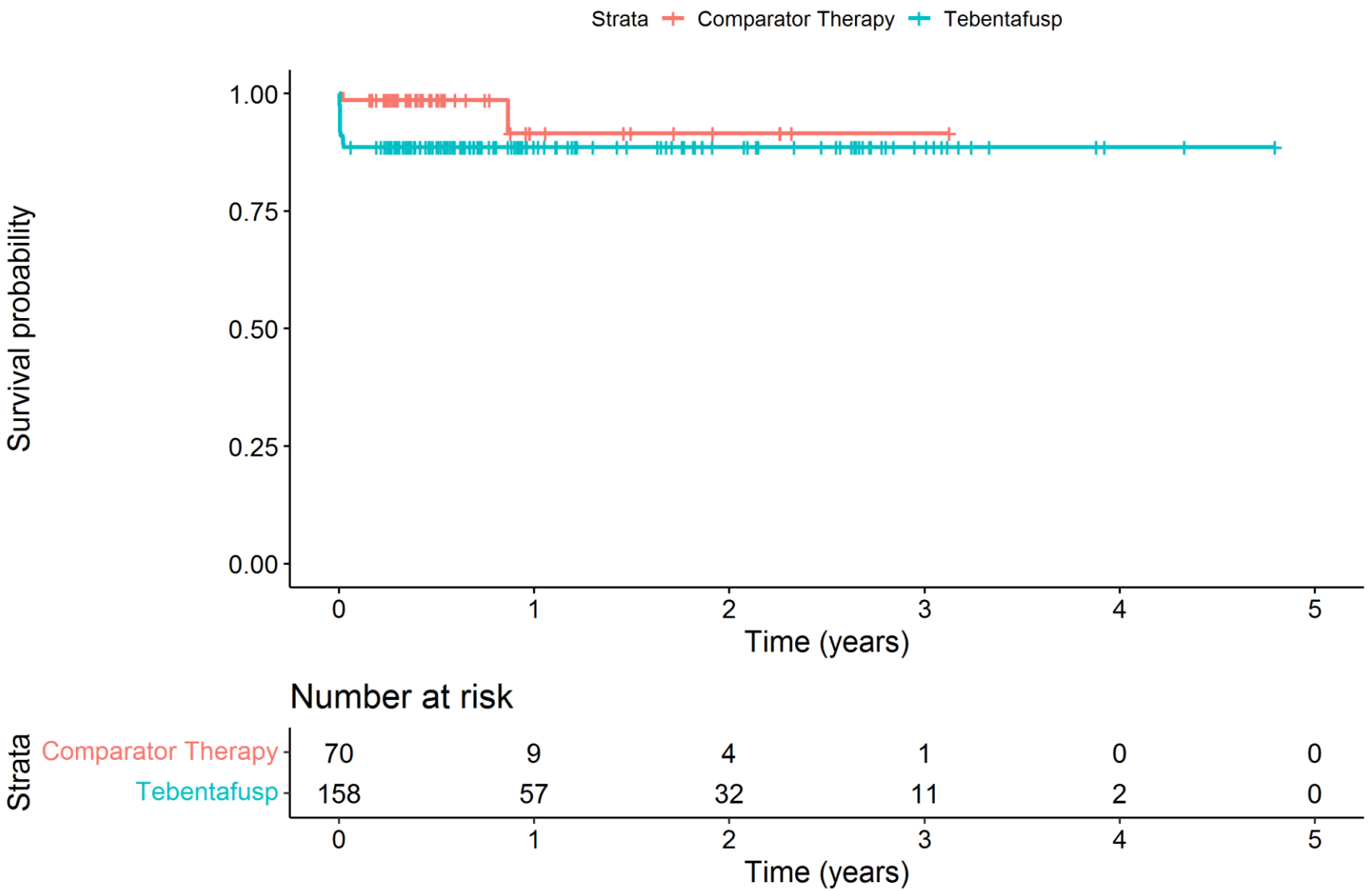
Gesichtsödeme - ALP ≤ ULN



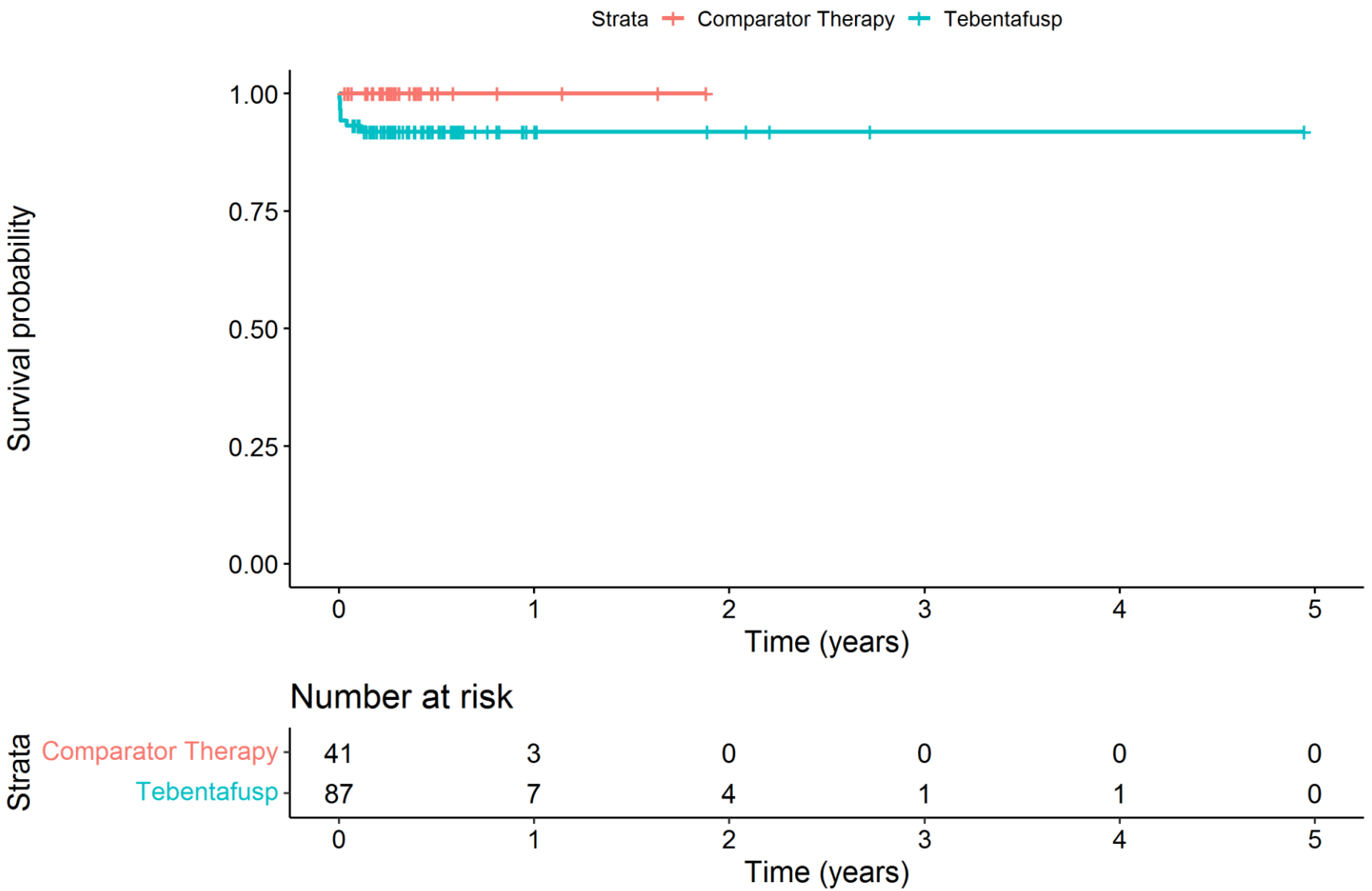
Gesichtsödeme - ALP > ULN



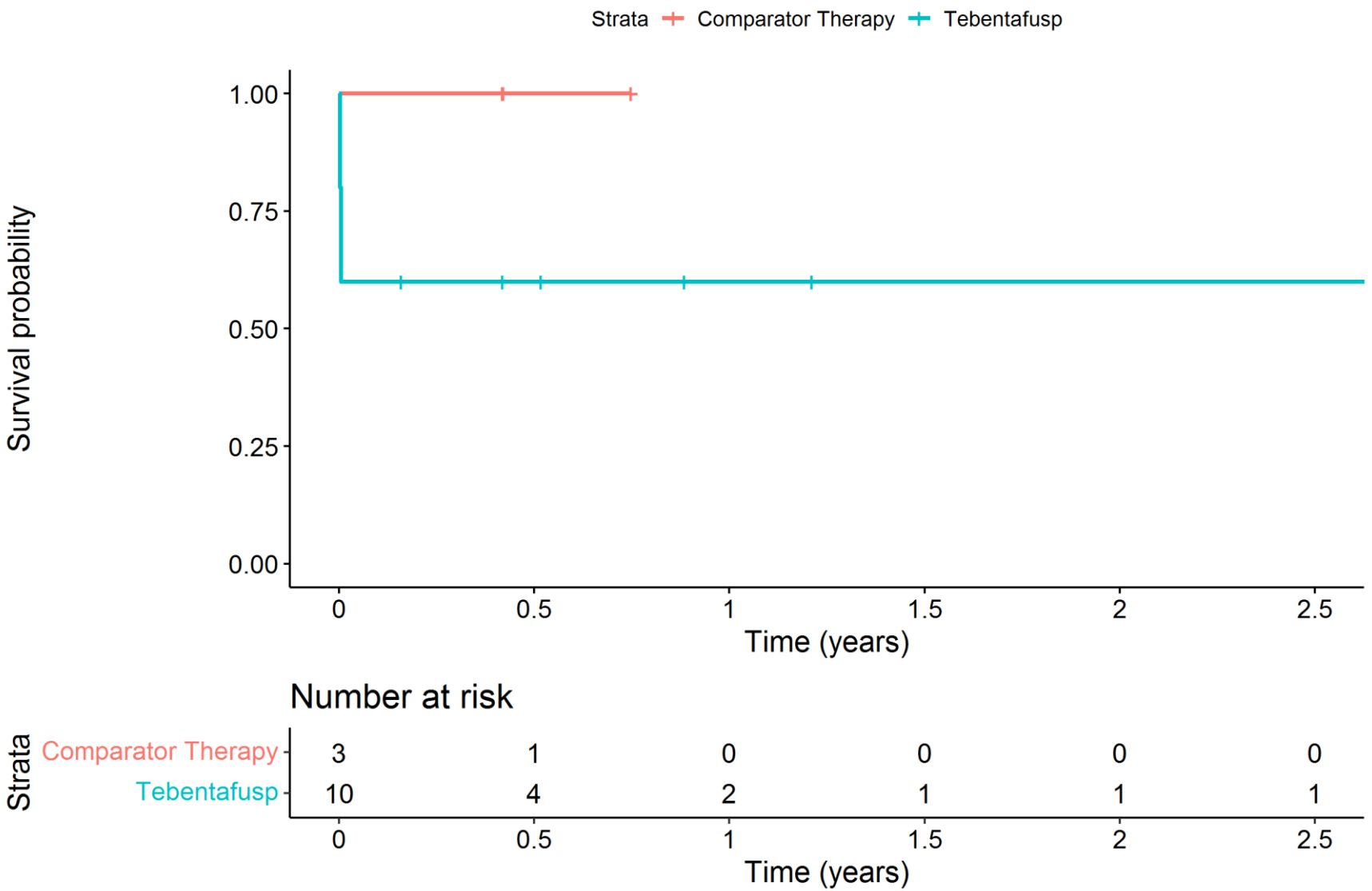
Gesichtsödeme - LDH =< ULN



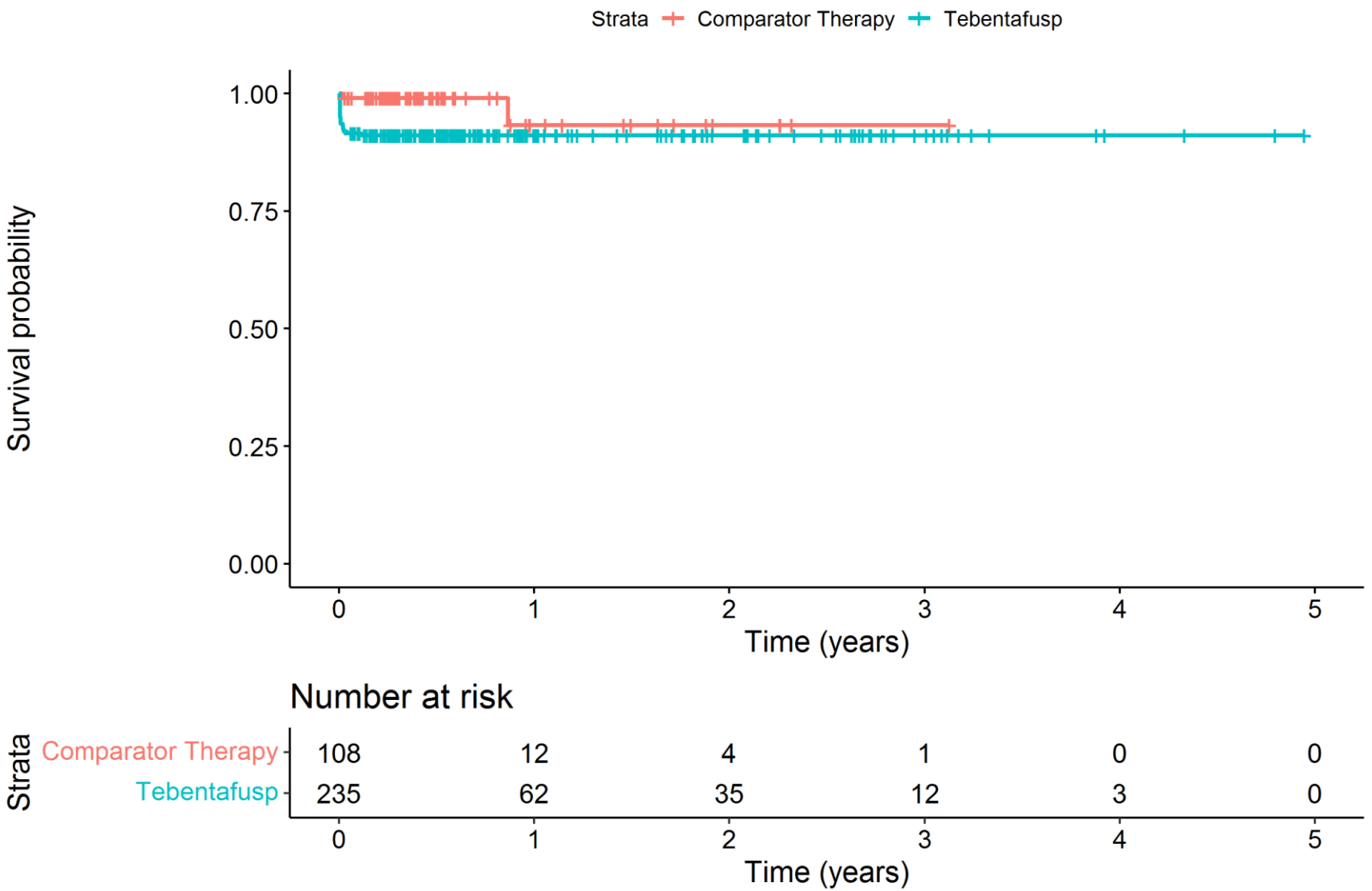
Gesichtsödeme - LDH > ULN



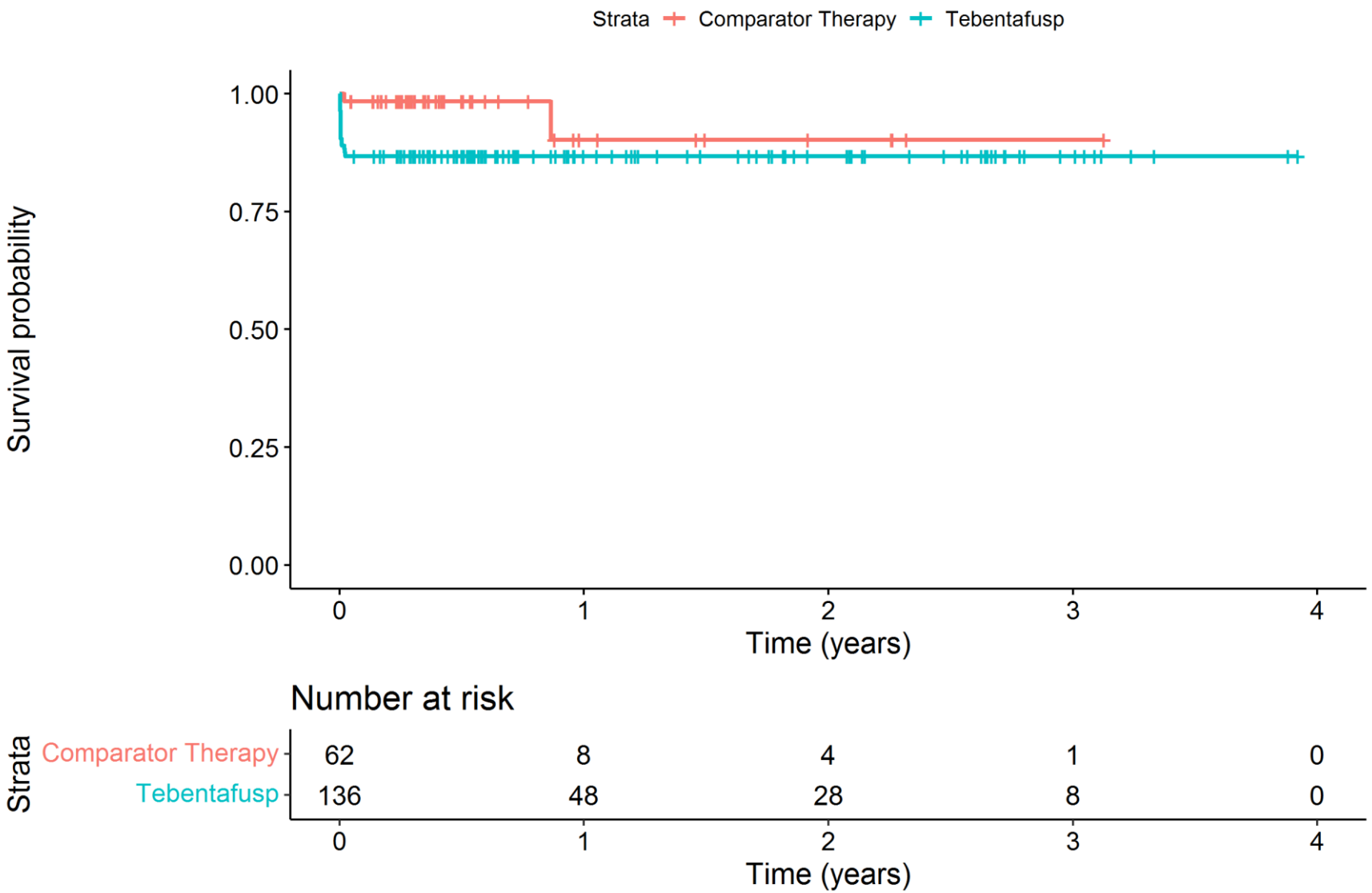
Gesichtsödeme - Vorherige Therapie adjuvant/neoadjuvant



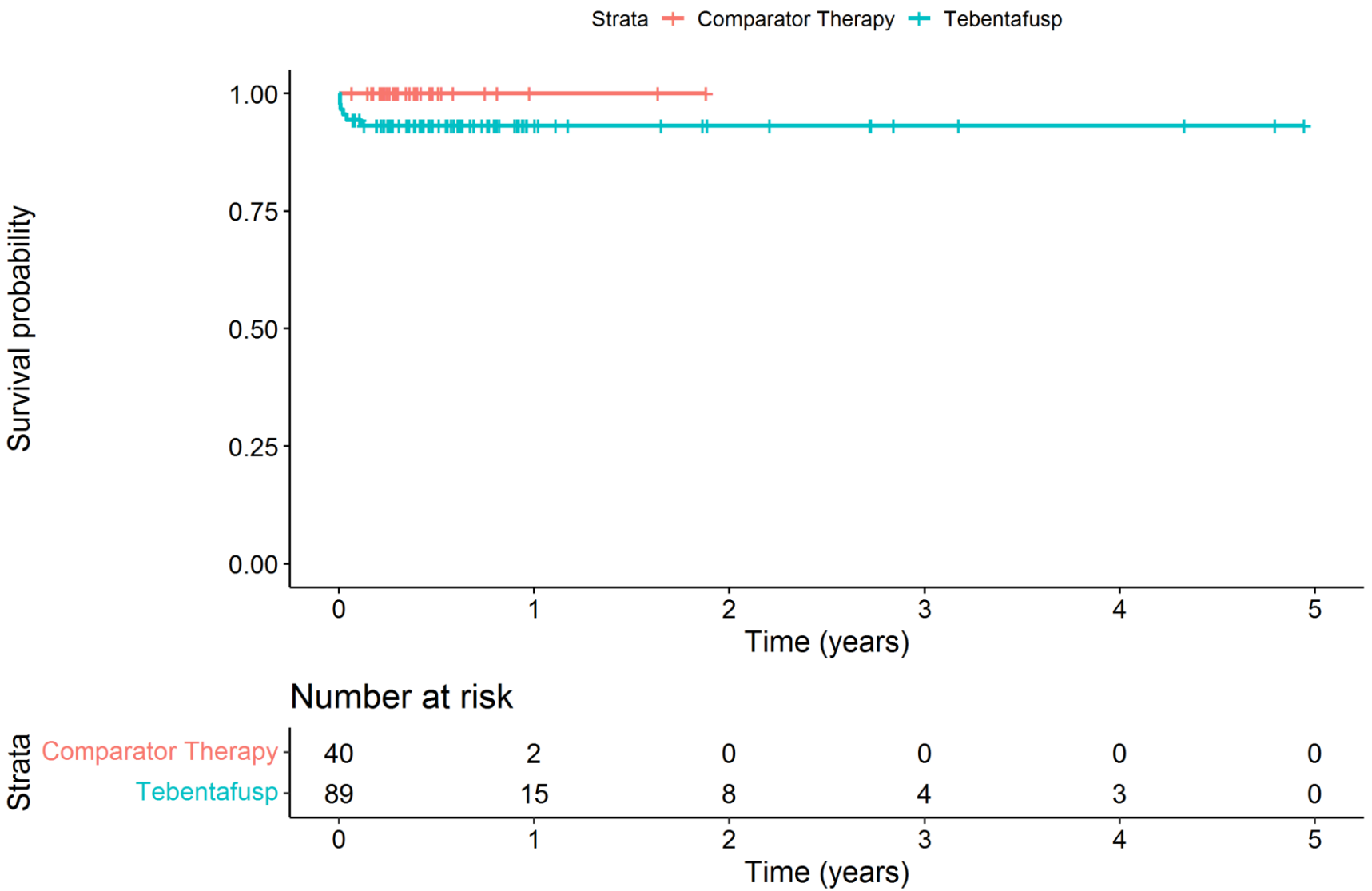
Gesichtsödeme - Keine Vorherige Therapie adjuvant/neoadjuvant



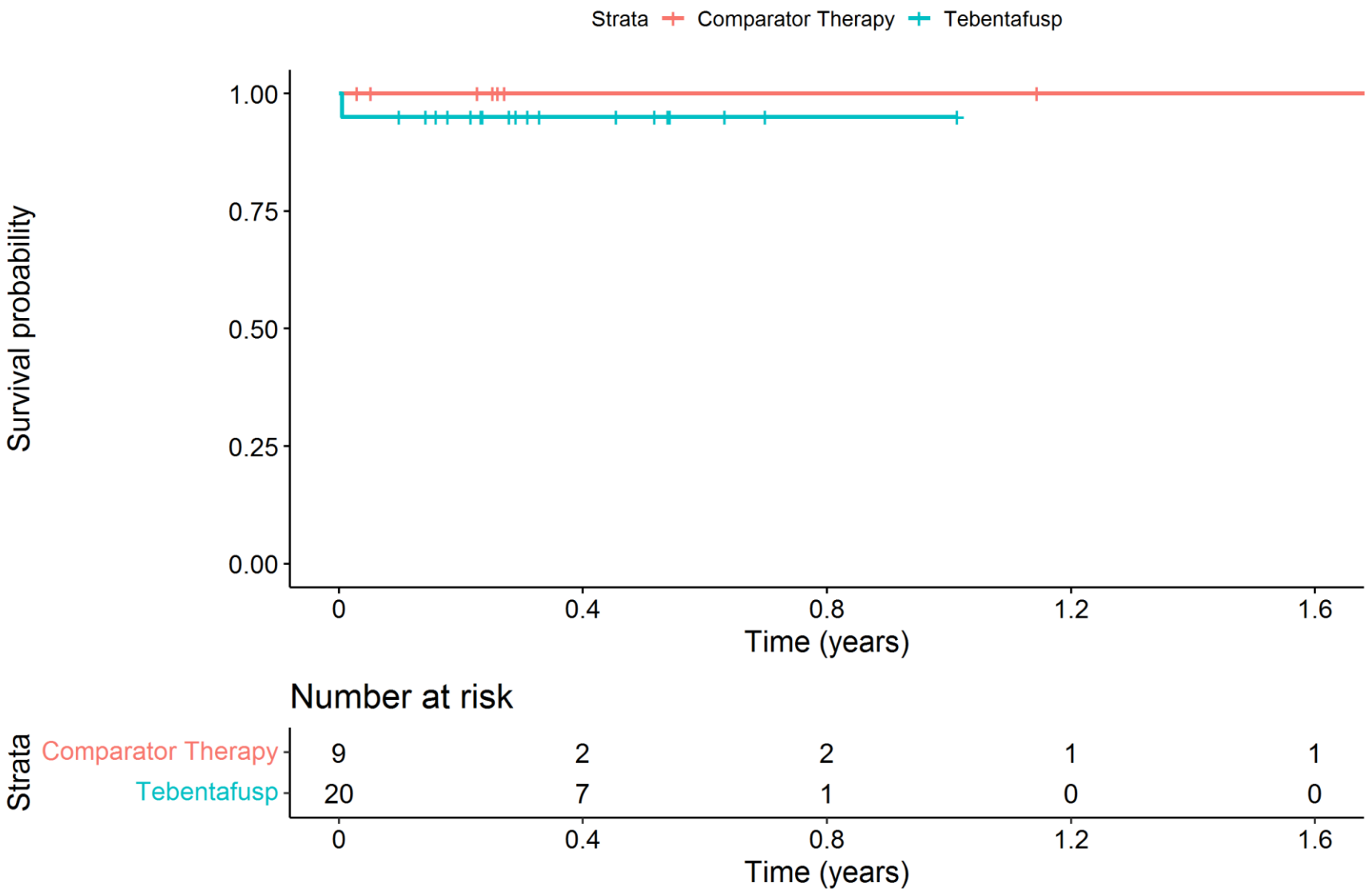
Gesichtsödeme - Läsion ≤ 3cm



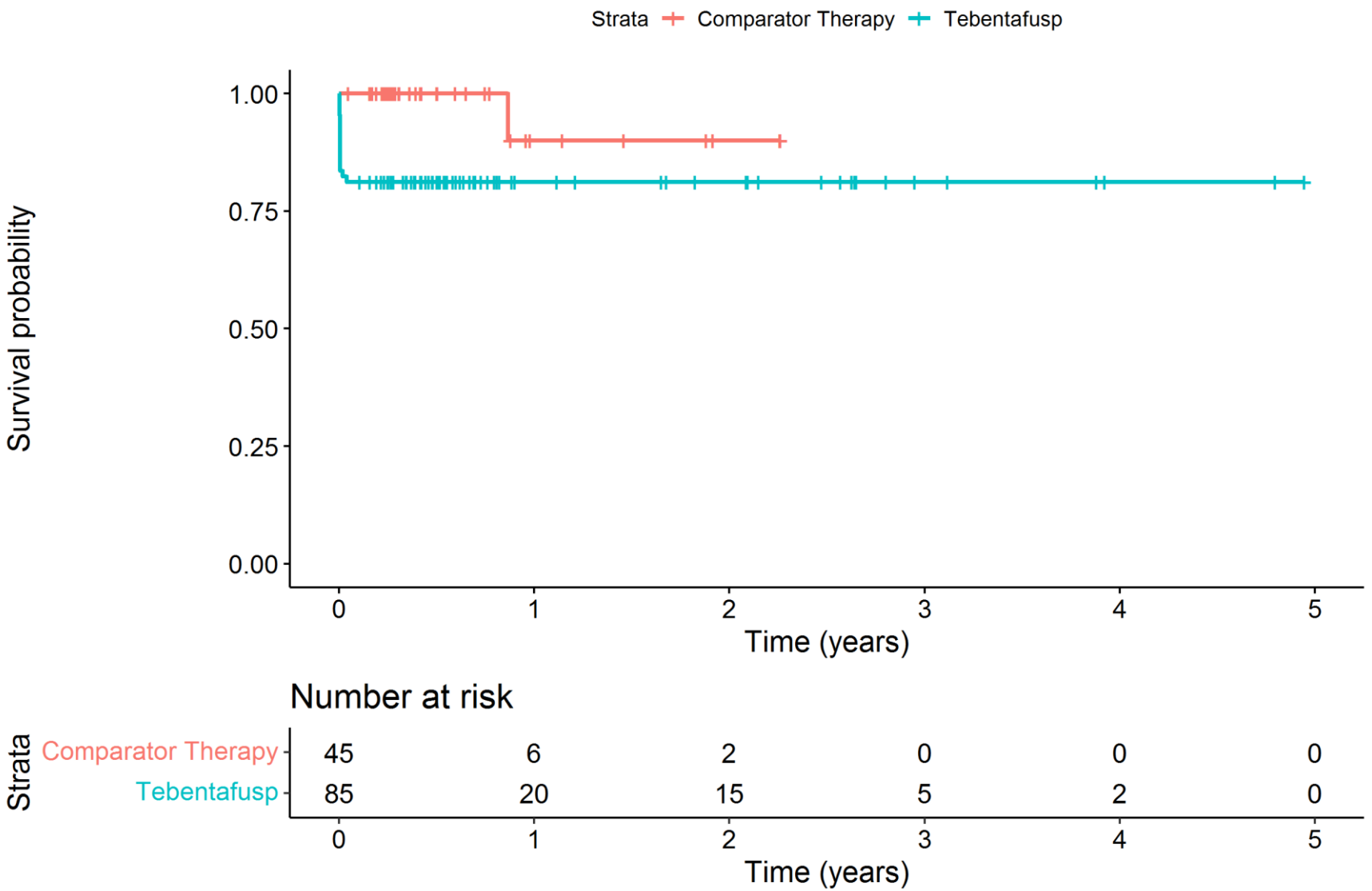
Gesichtsödeme - Läsion 3,1-8,0 cm



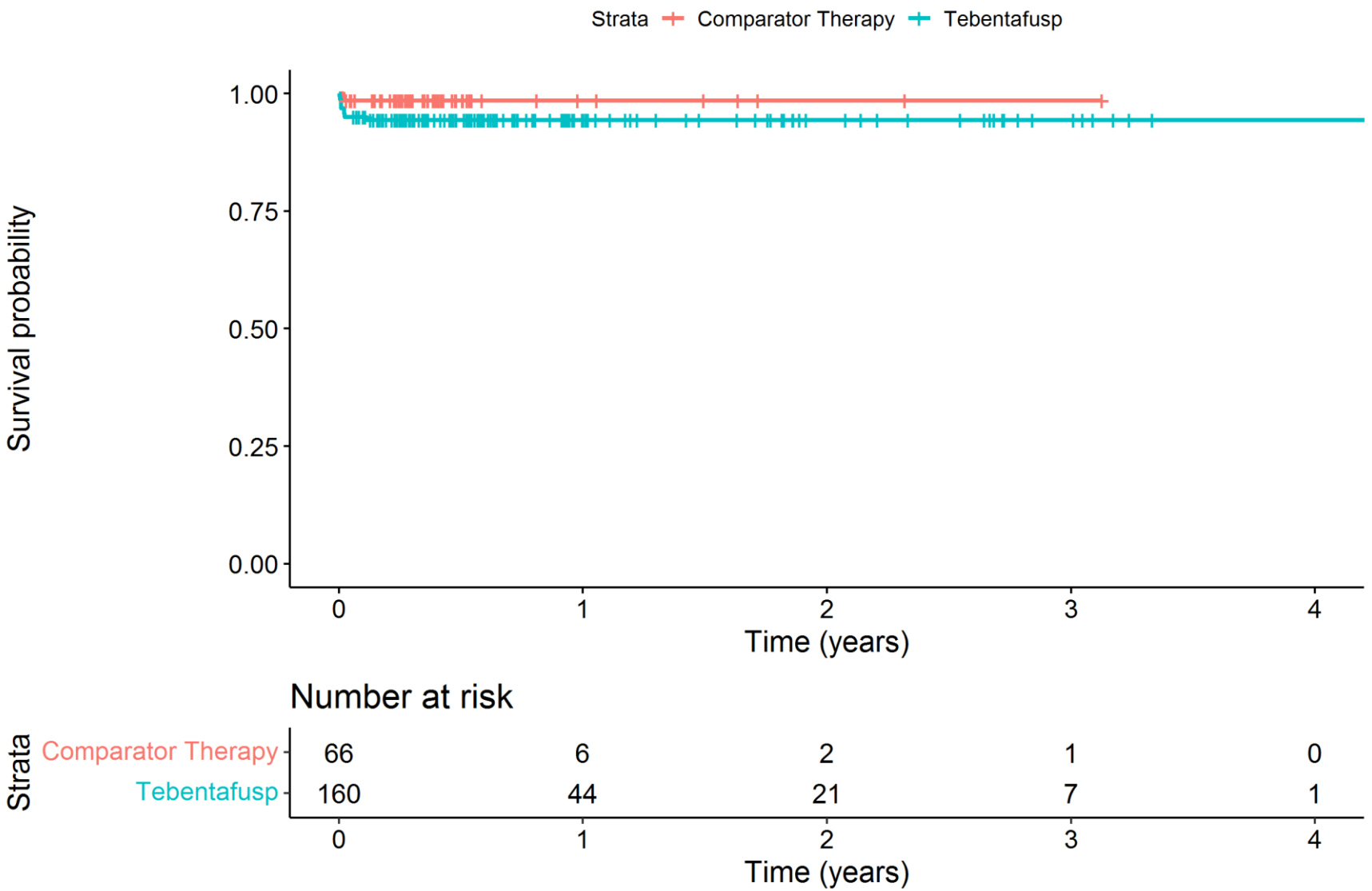
Gesichtsödeme - Läsion ≥8,1 cm



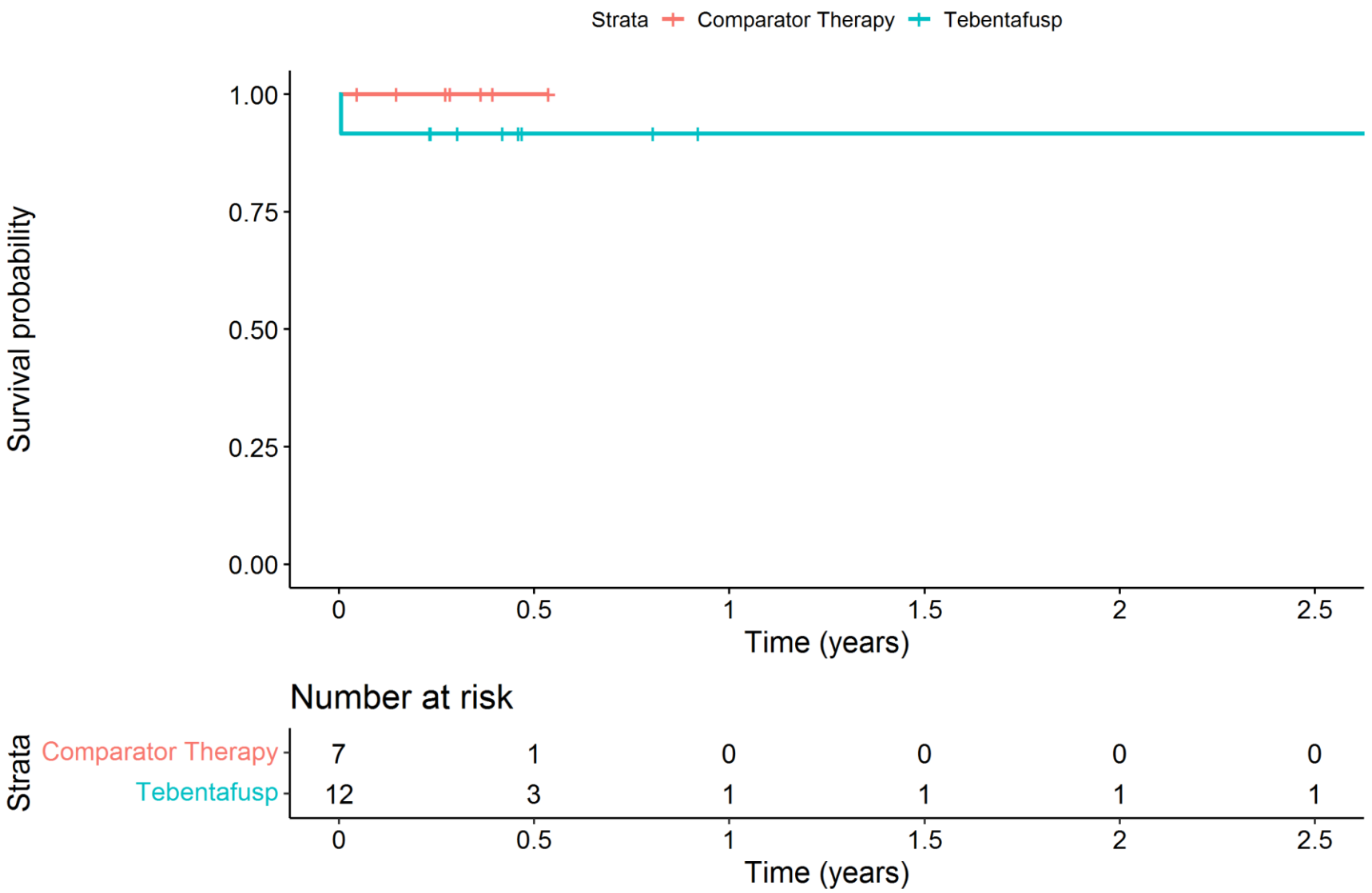
Gesichtsödeme - Nordamerika



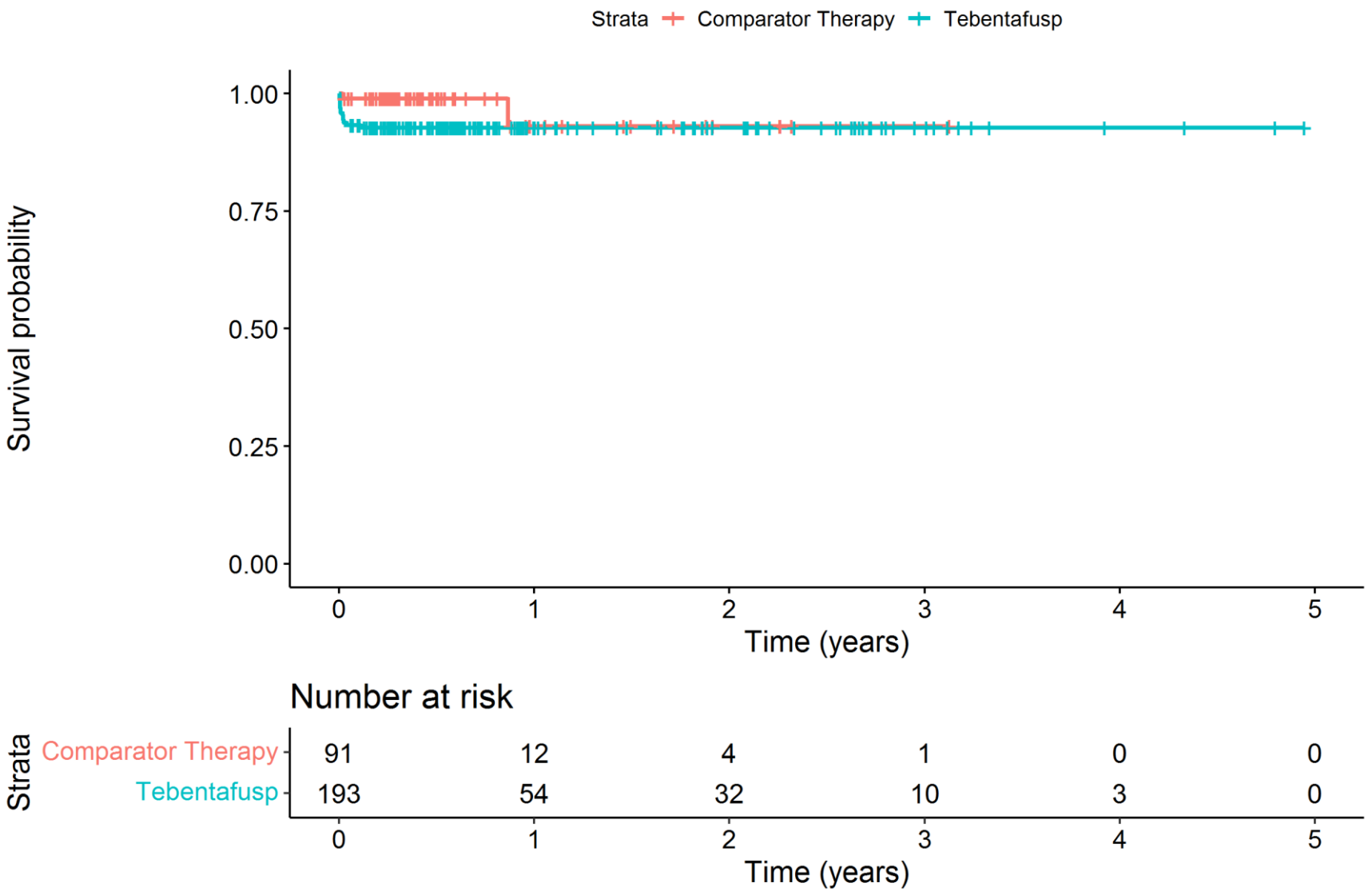
Gesichtsödeme - Nicht-Nordamerika



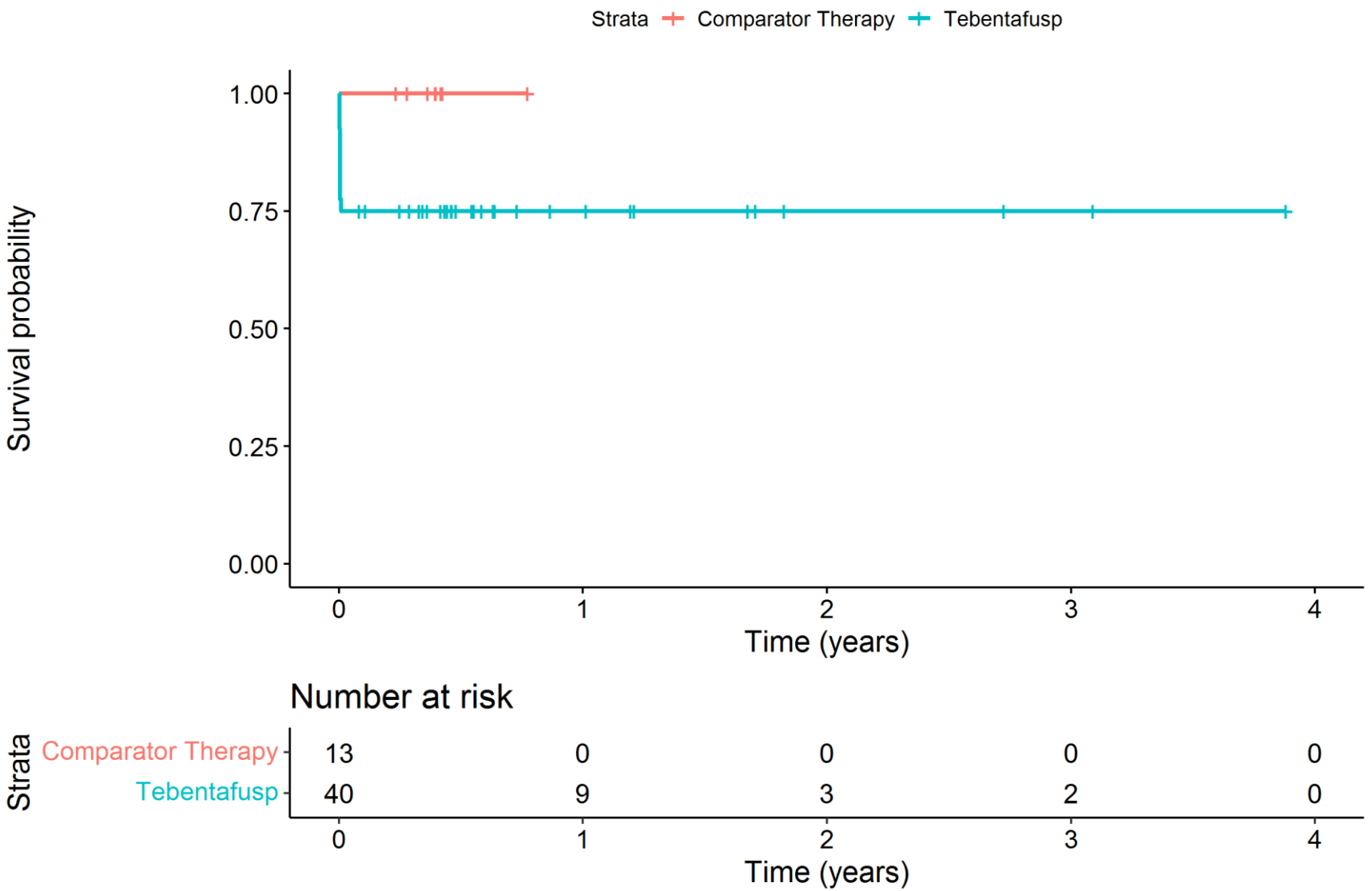
60.12 Gesichtsödeme - Dacarbazin



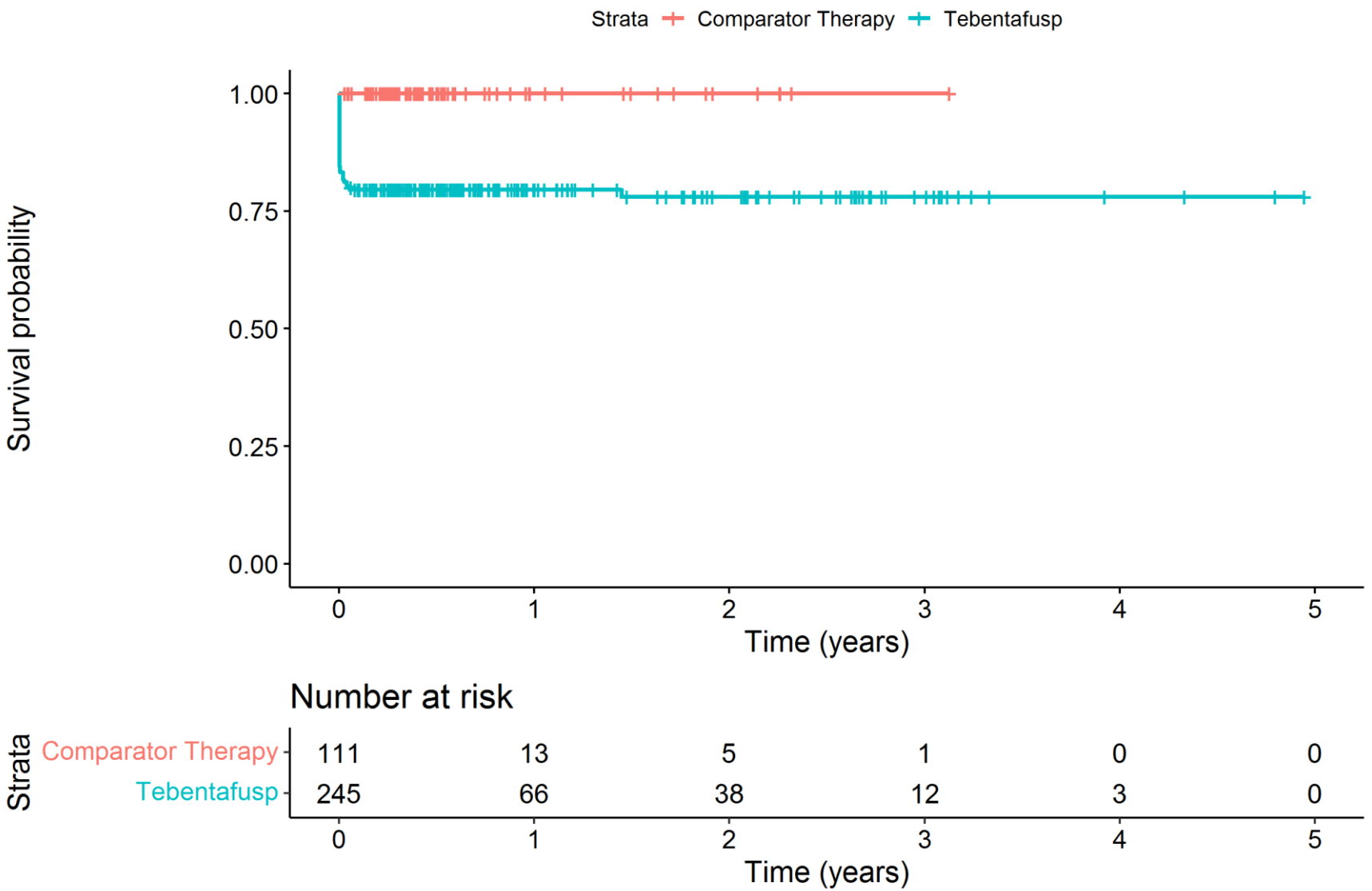
Gesichtsödeme - Pembrolizumab



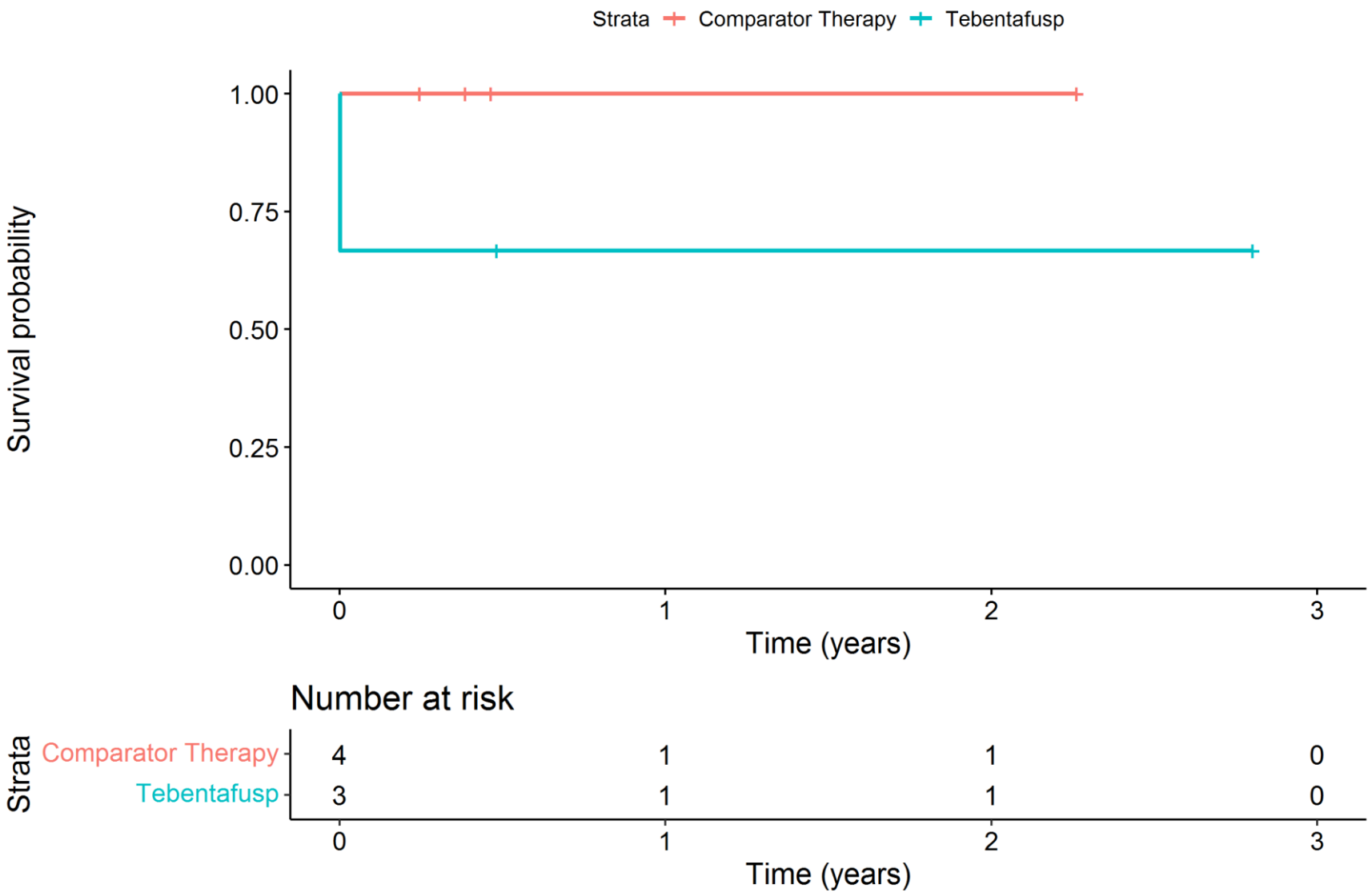
Gesichtsödeme - Ipilimumab



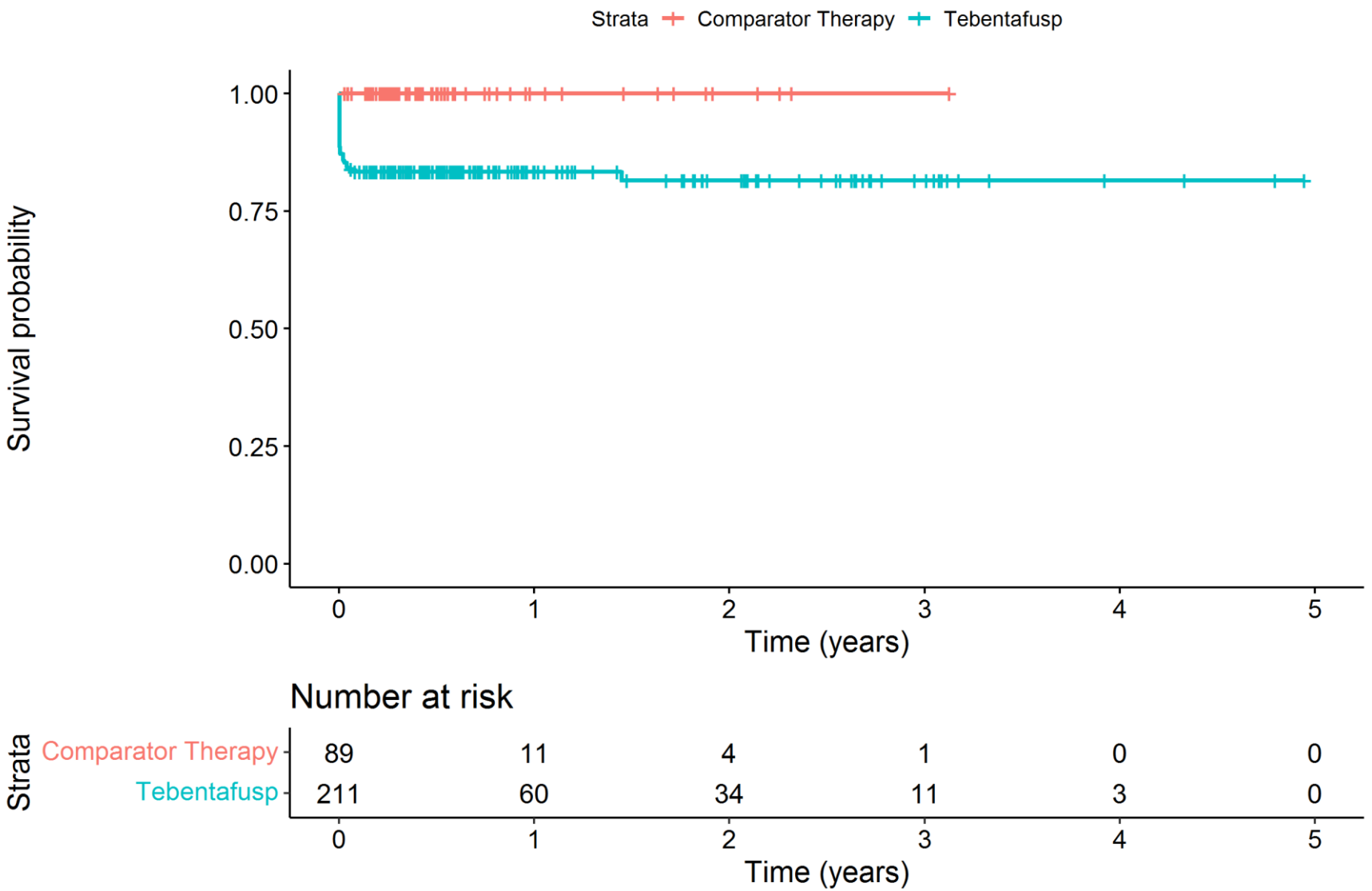
Zytokin-Freisetzungssyndrom- Gesamt



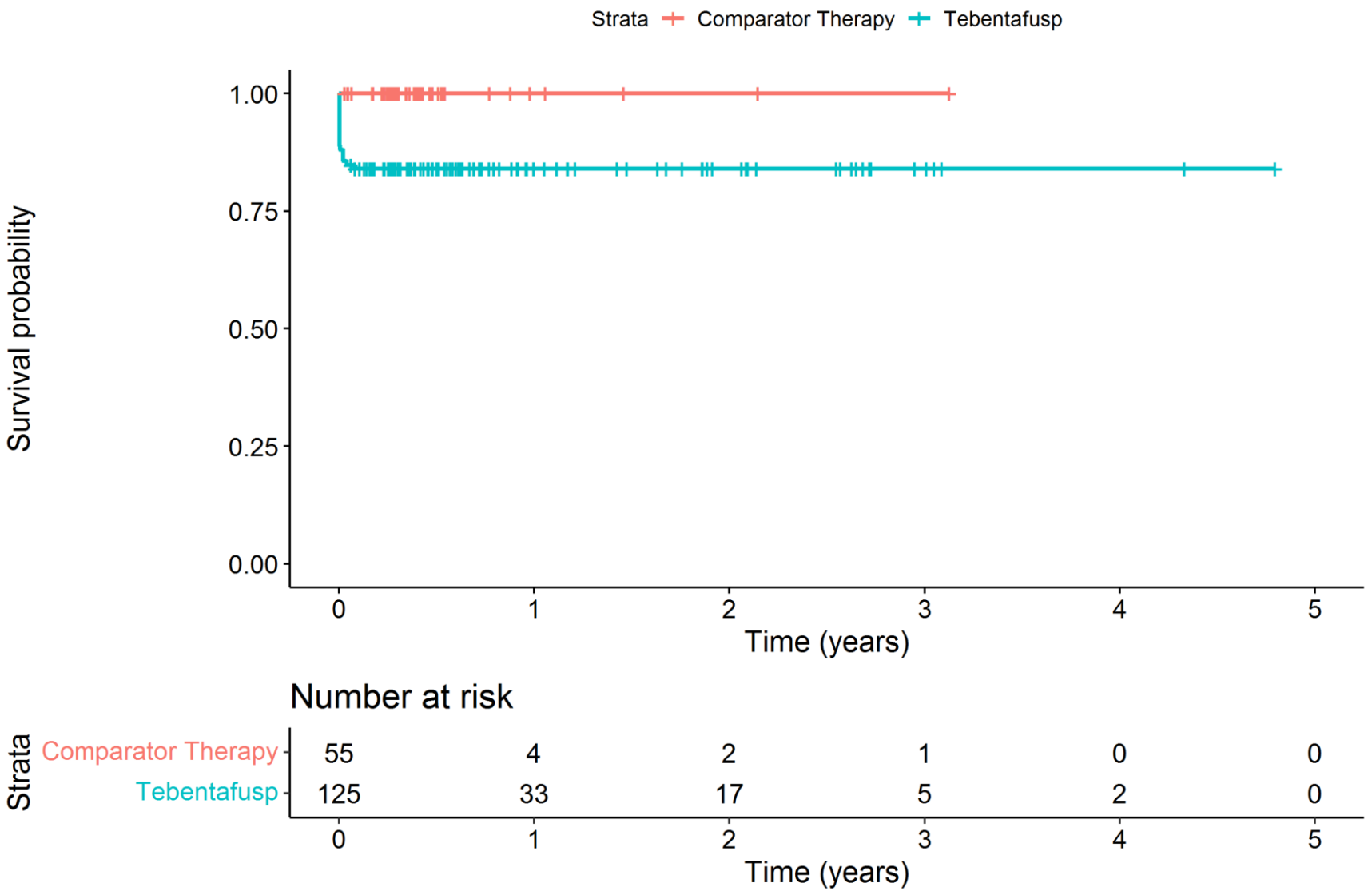
Zytokin-Freisetzungssyndrom- Hispanisch



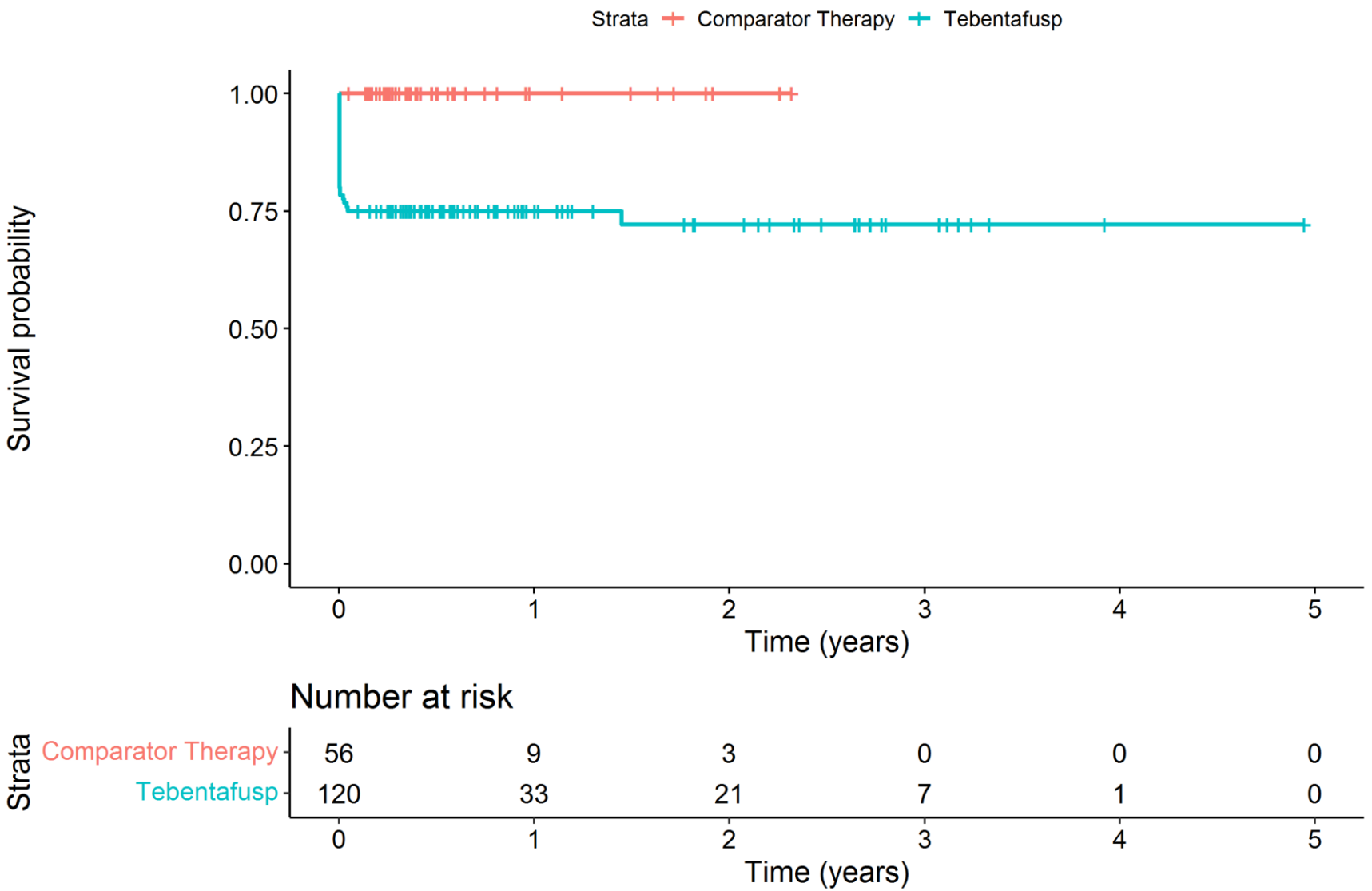
Zytokin-Freisetzungssyndrom- Nicht-hispanisch



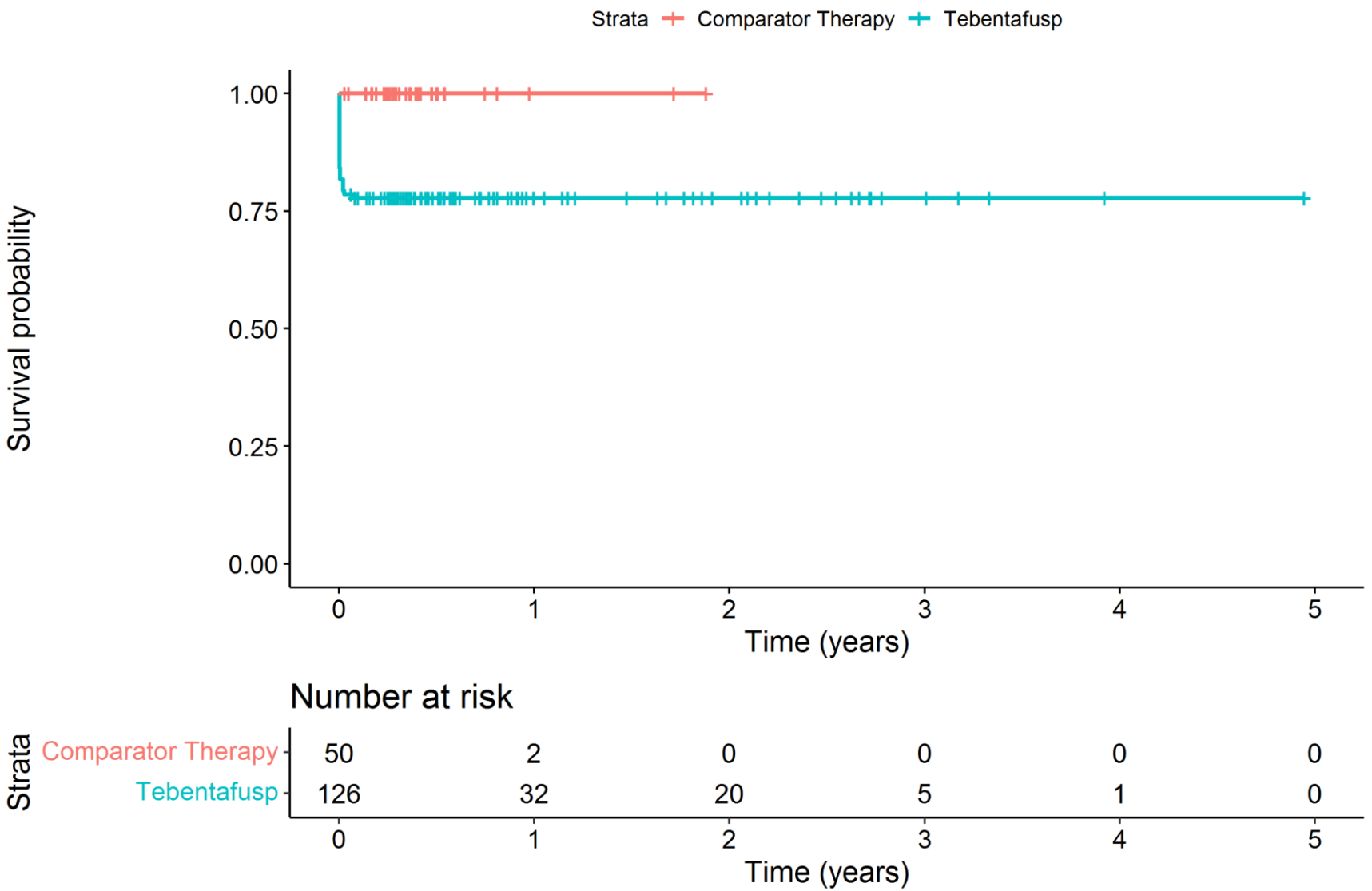
Zytokin-Freisetzungssyndrom- Männlich



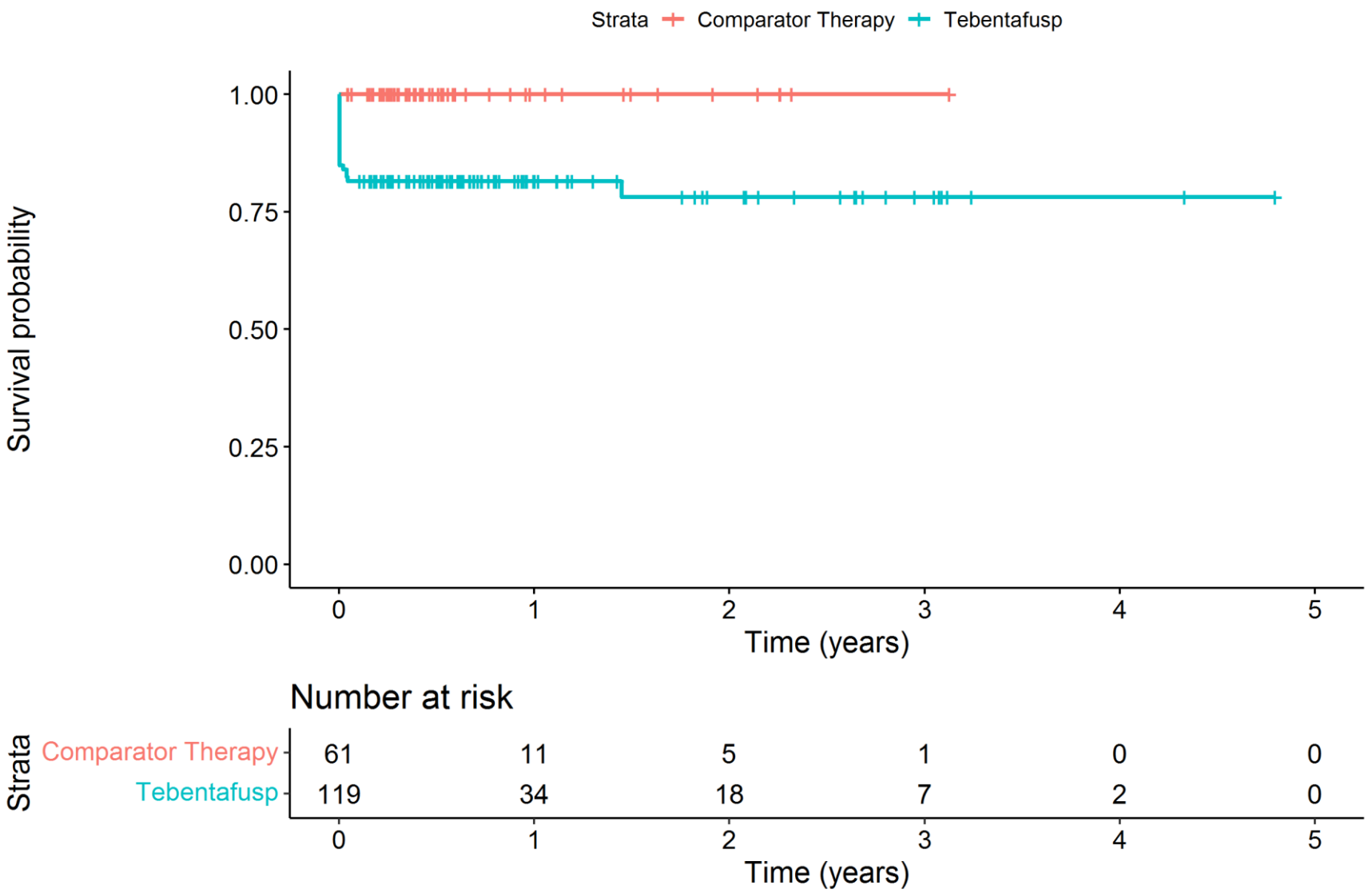
Zytokin-Freisetzungssyndrom- Weiblich



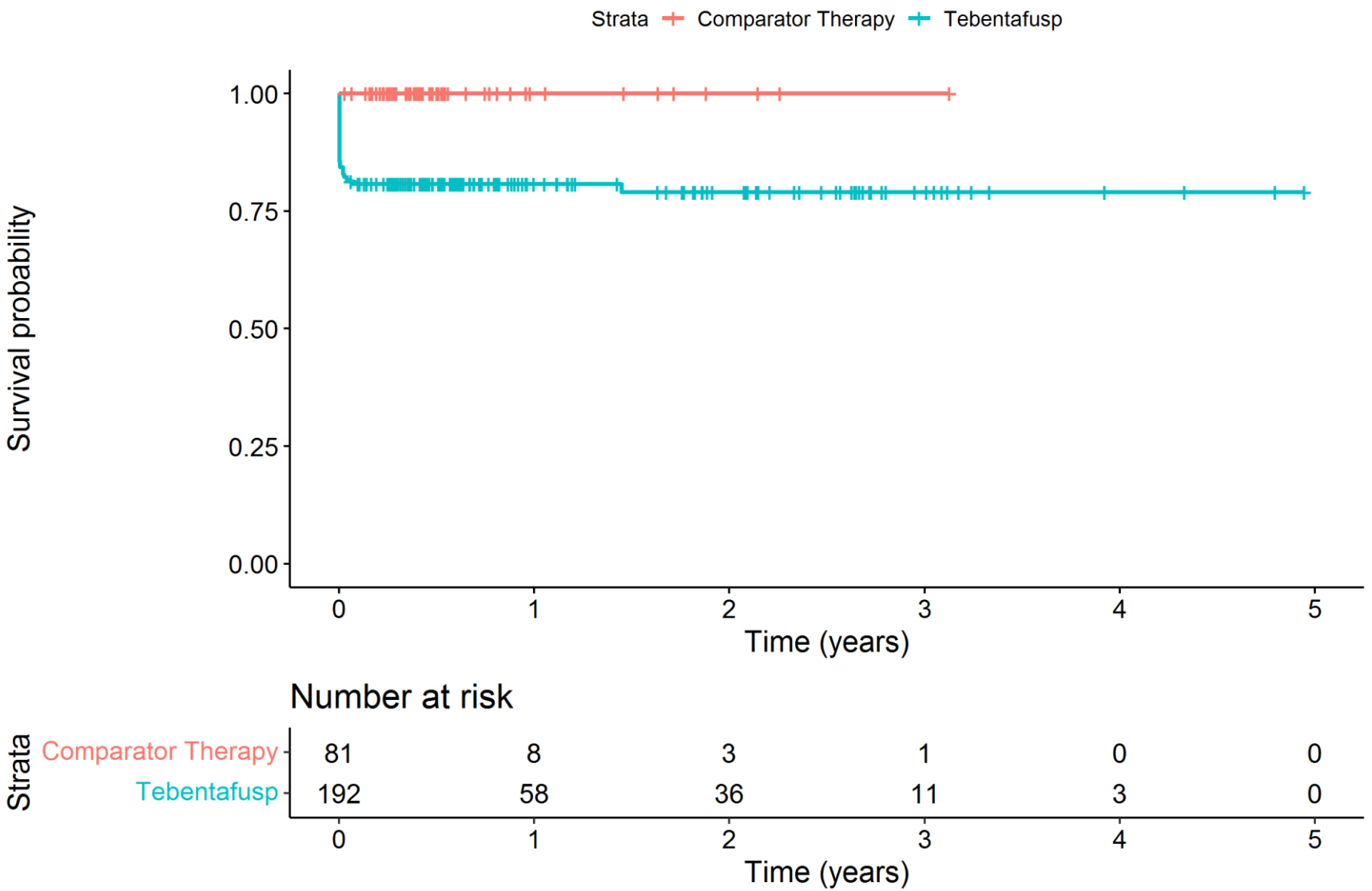
Zytokin-Freisetzungssyndrom- <65



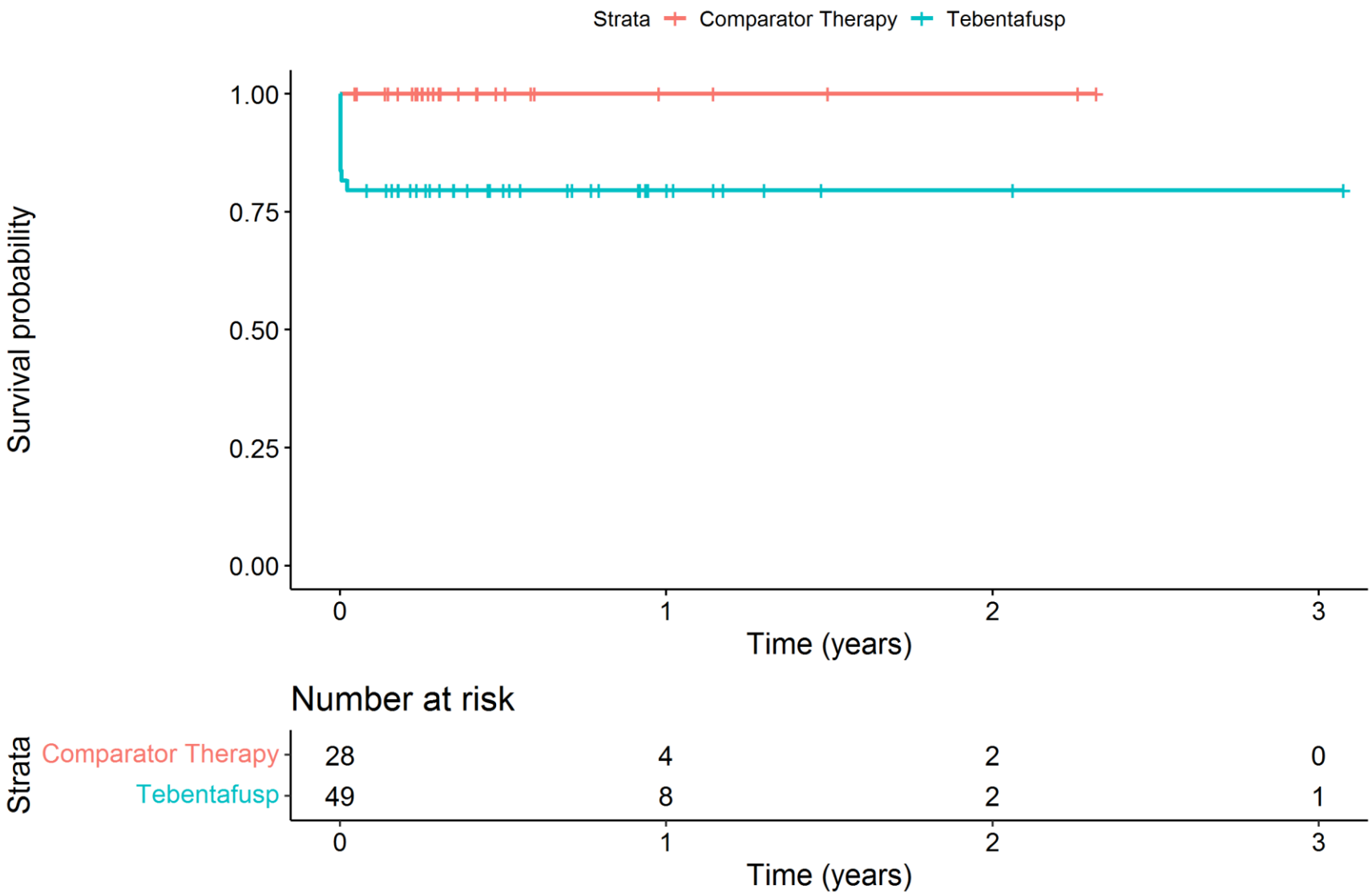
60.13 Zytokin-Freisetzungssyndrom- ≥65



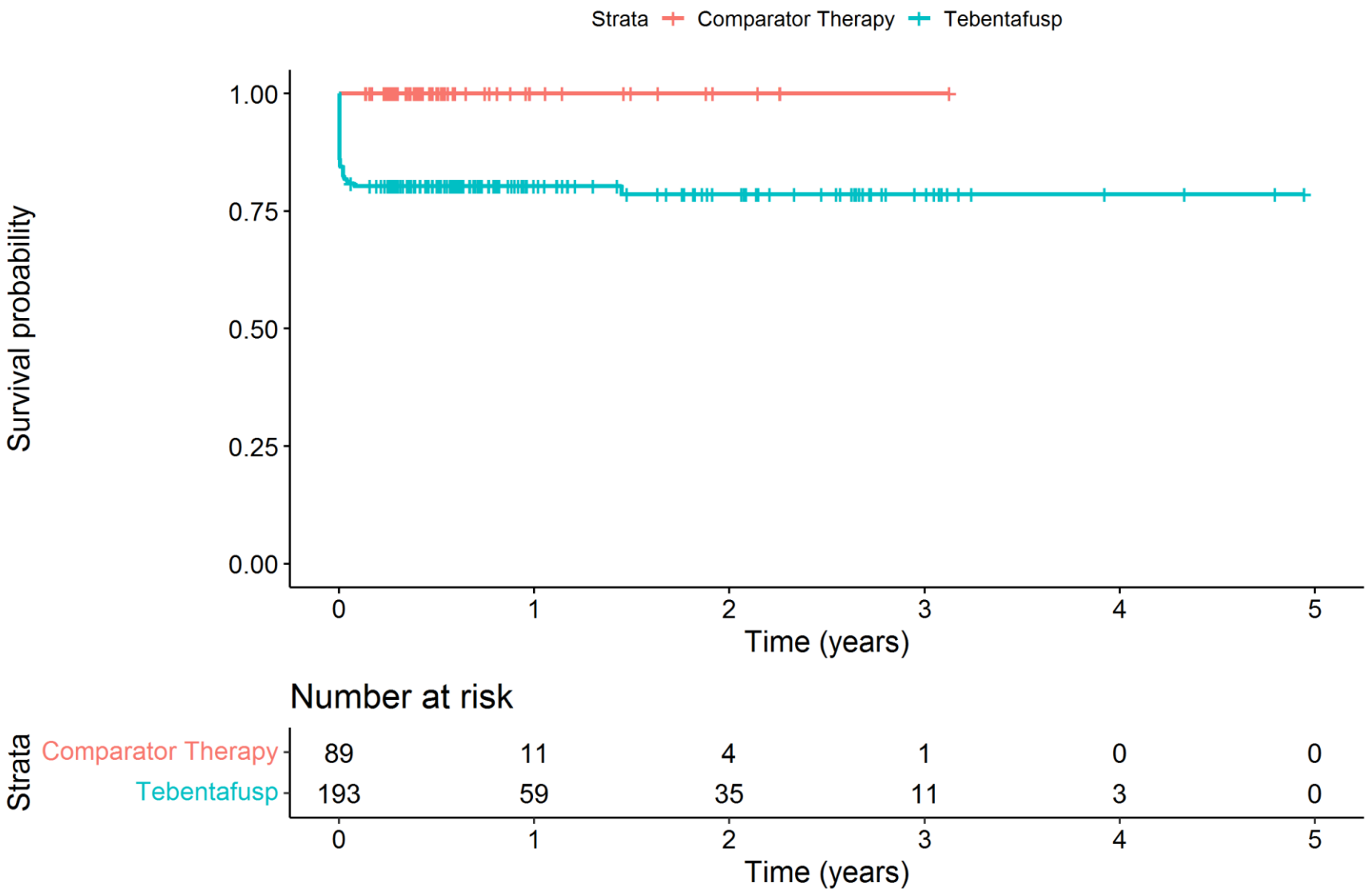
Zytokin-Freisetzungssyndrom- ECOG 0



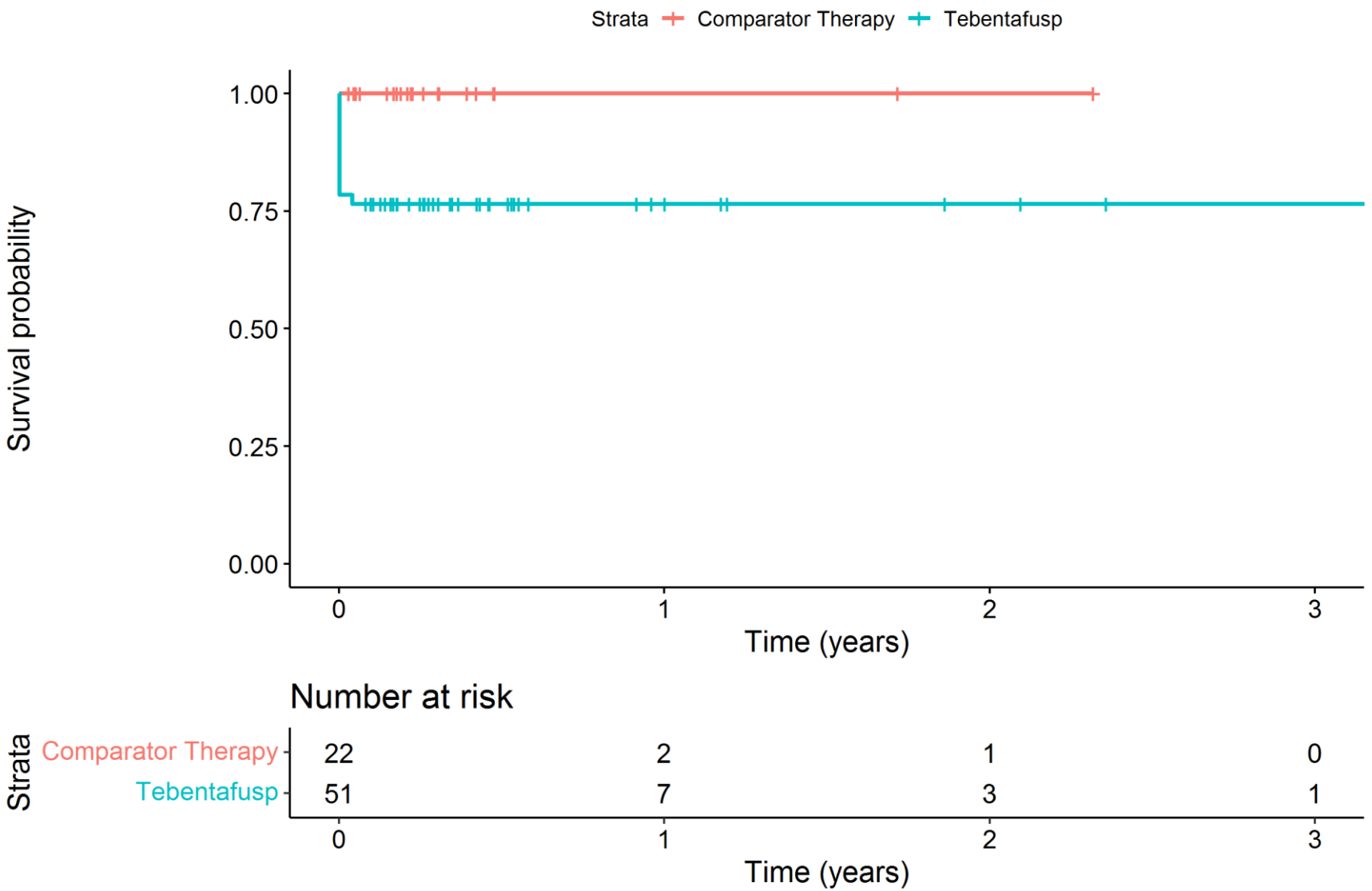
Zytokin-Freisetzungssyndrom- ECOG 1



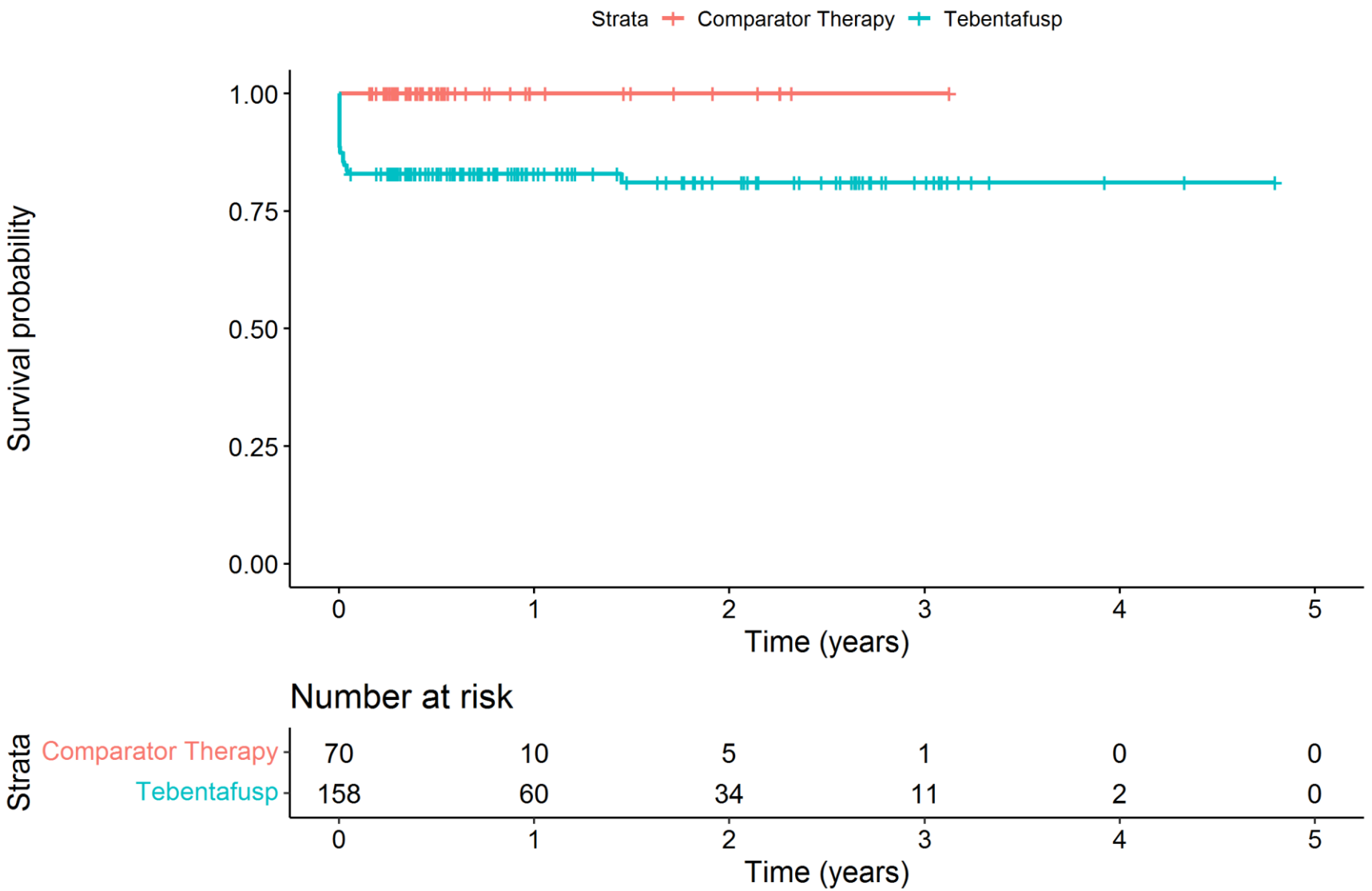
Zytokin-Freisetzungssyndrom- ALP ≤ ULN



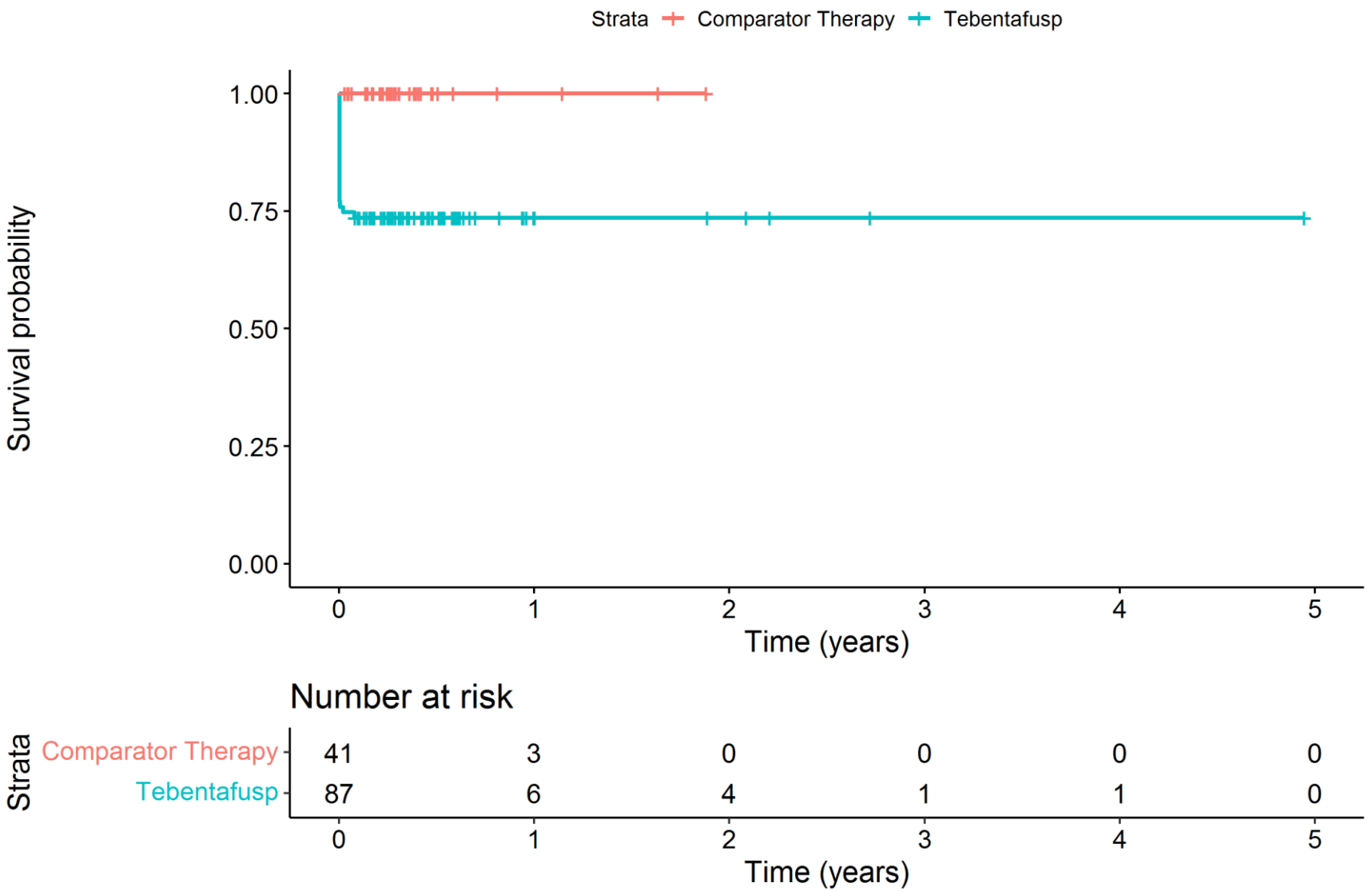
Zytokin-Freisetzungssyndrom- ALP > ULN



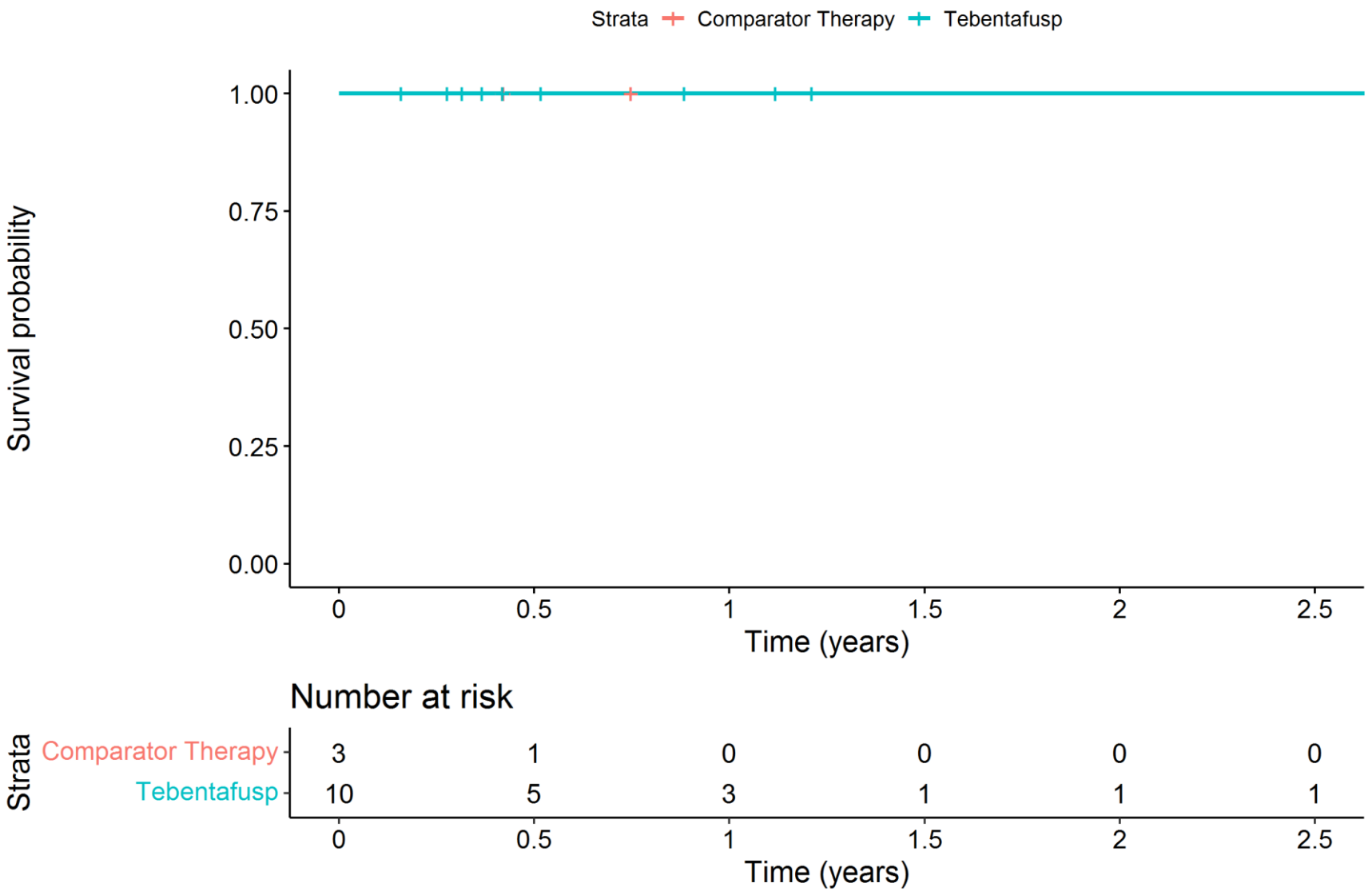
Zytokin-Freisetzungssyndrom- LDH =< ULN



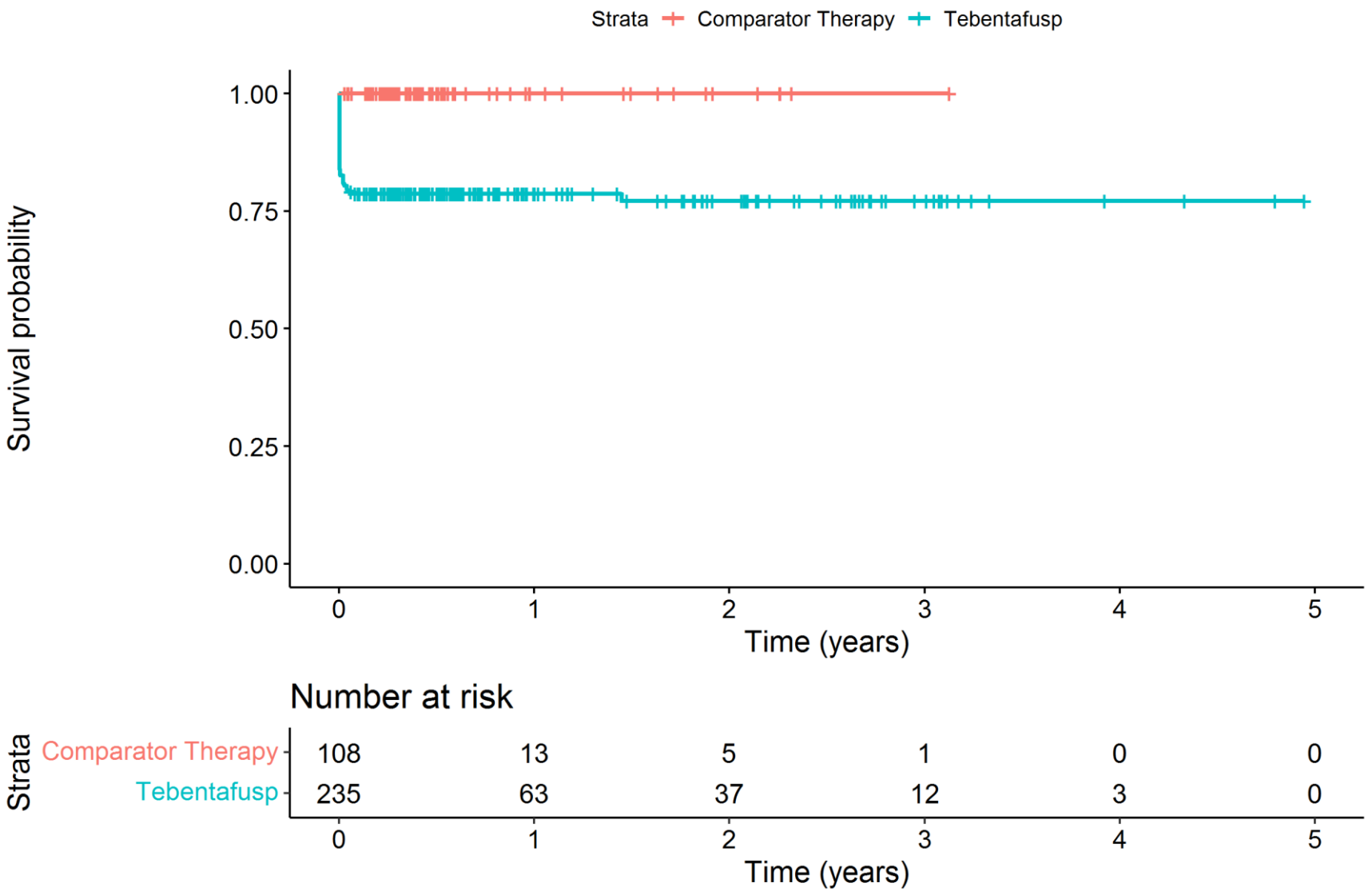
Zytokin-Freisetzungssyndrom- LDH > ULN



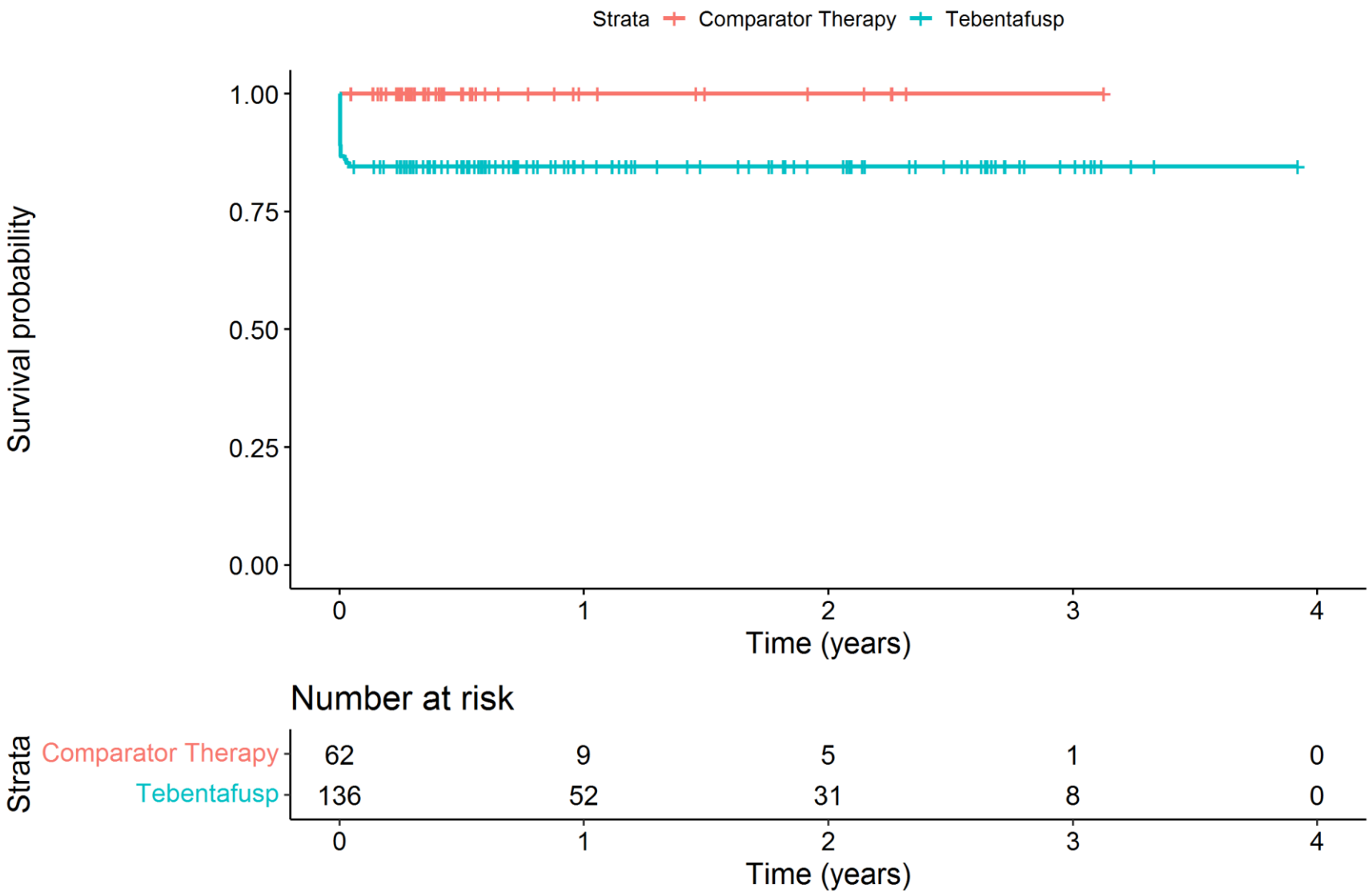
Zytokin-Freisetzungssyndrom- Vorherige Therapie adjuvant/neoadjuvant



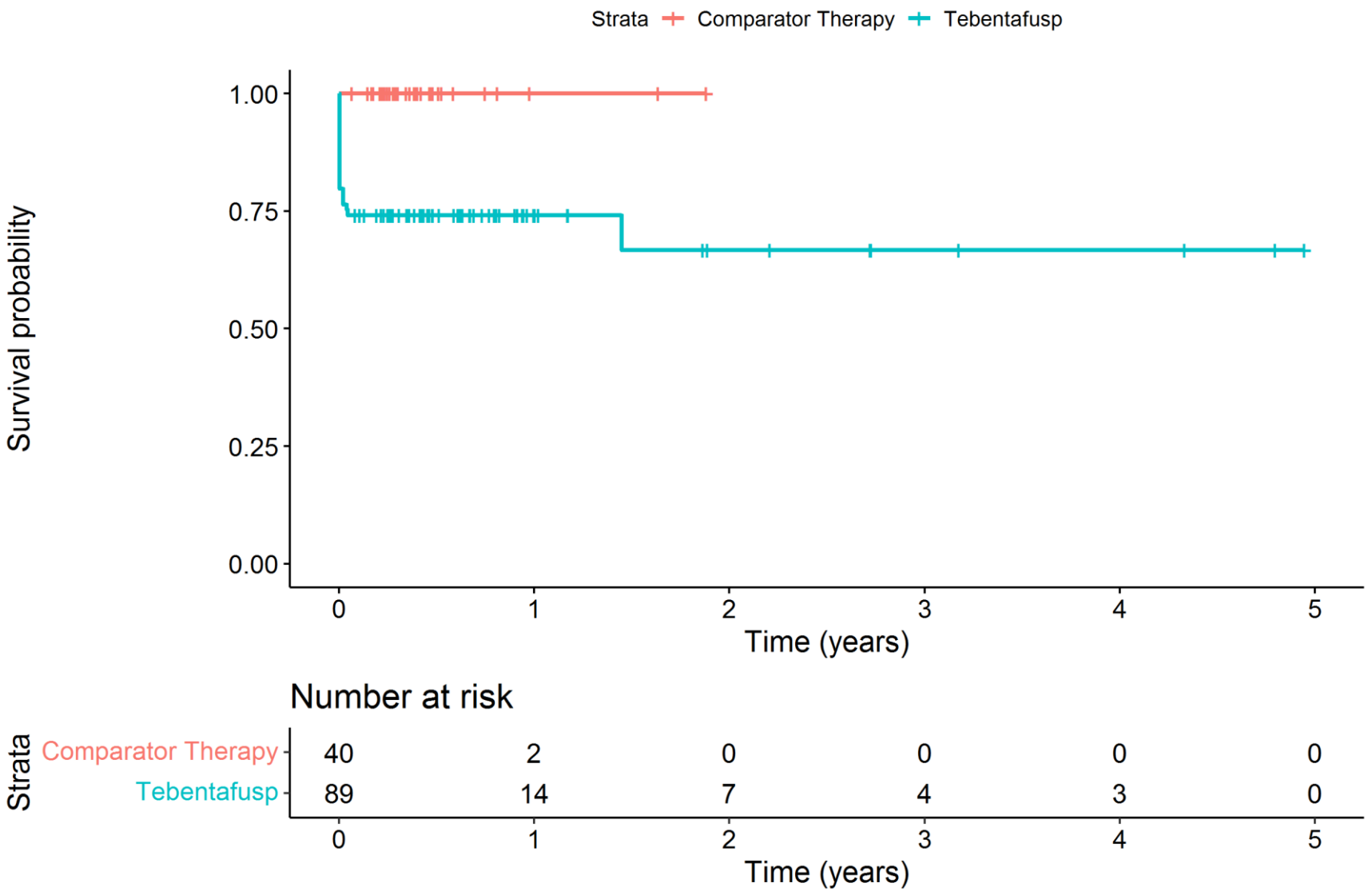
Zytokin-Freisetzungssyndrom- Keine Vorherige Therapie adjuvant/neoadjuvant



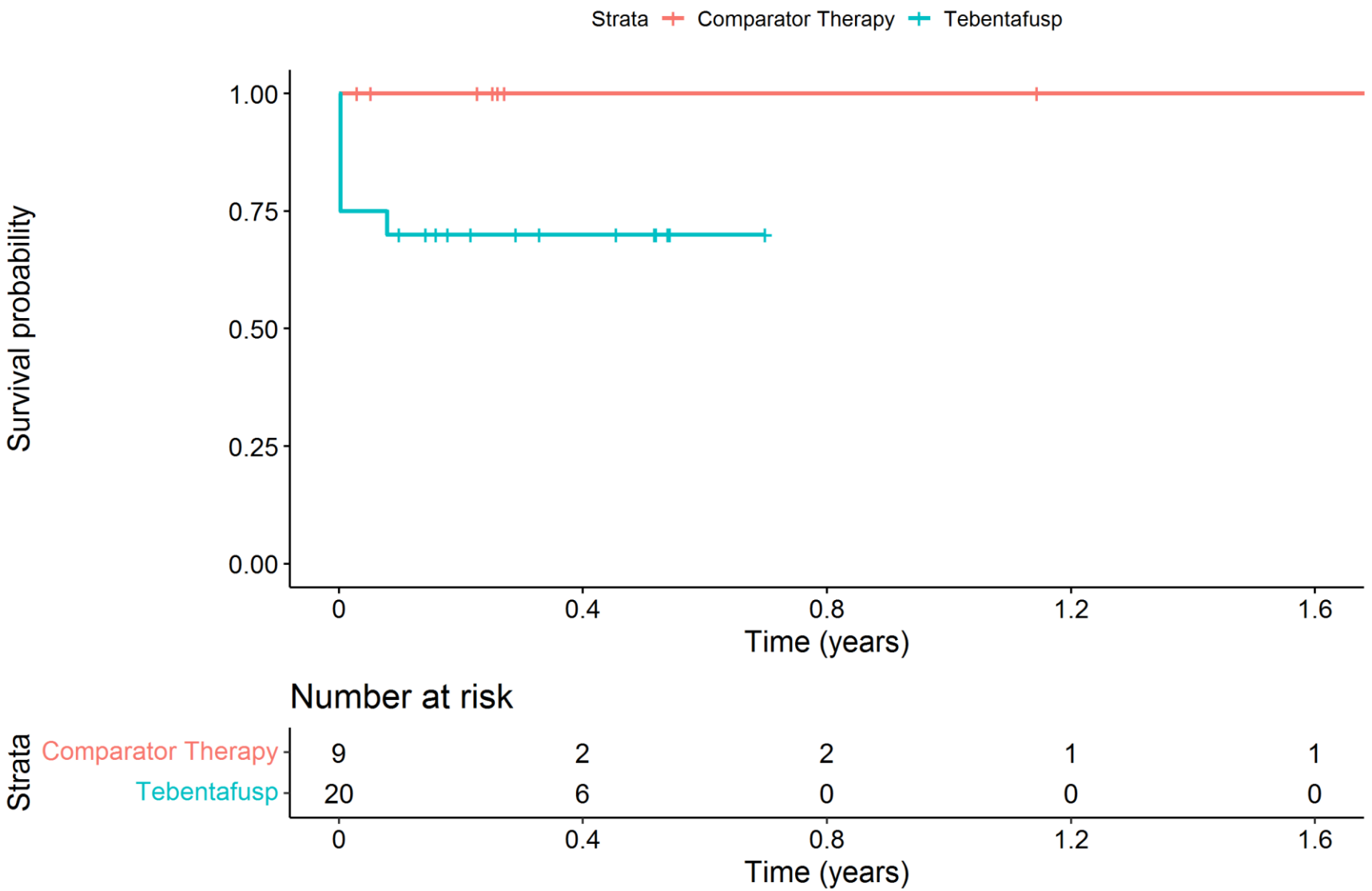
Zytokin-Freisetzungssyndrom- Läsion ≤ 3cm



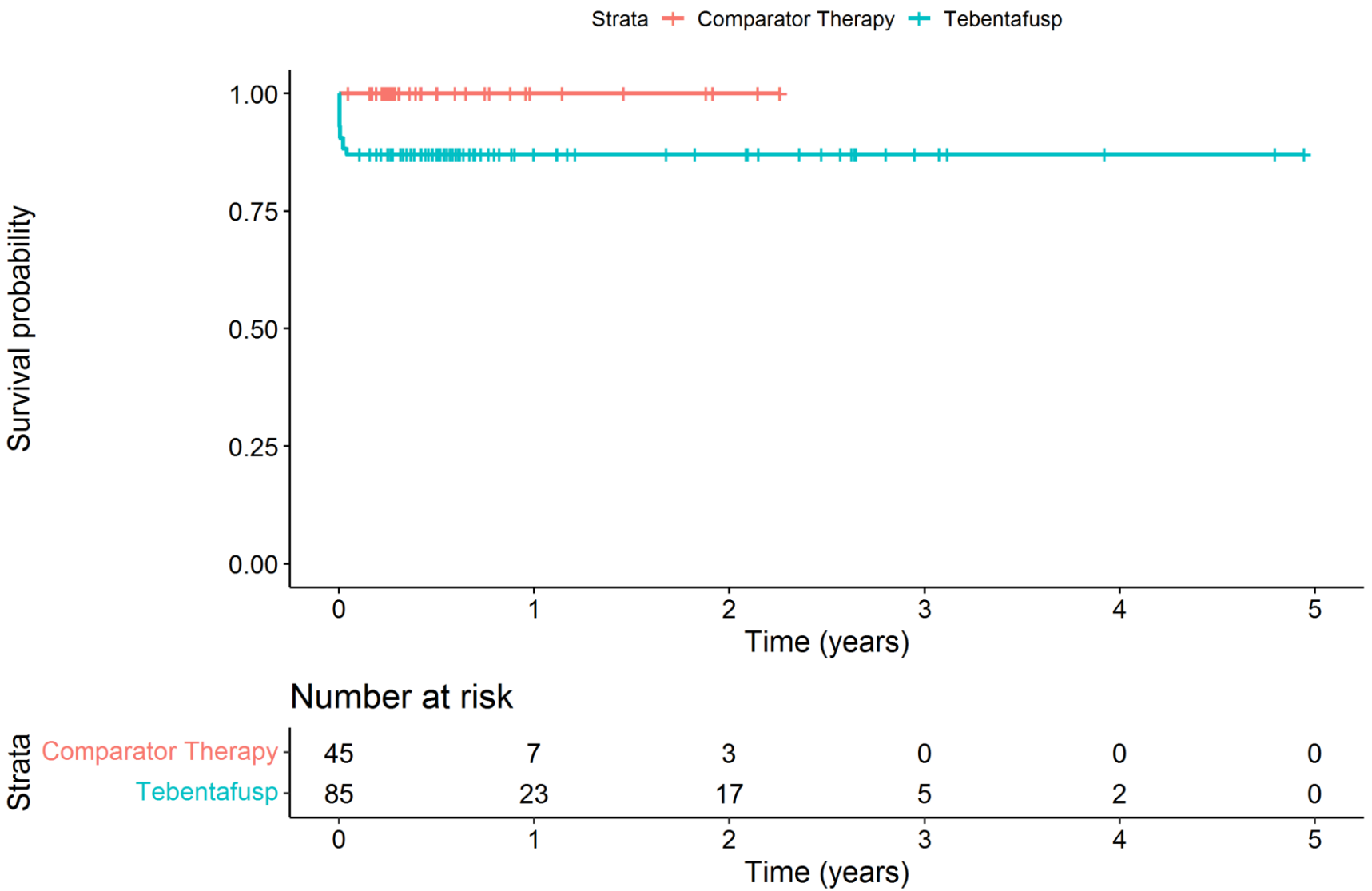
Zytokin-Freisetzungssyndrom- Läsion 3,1-8,0 cm



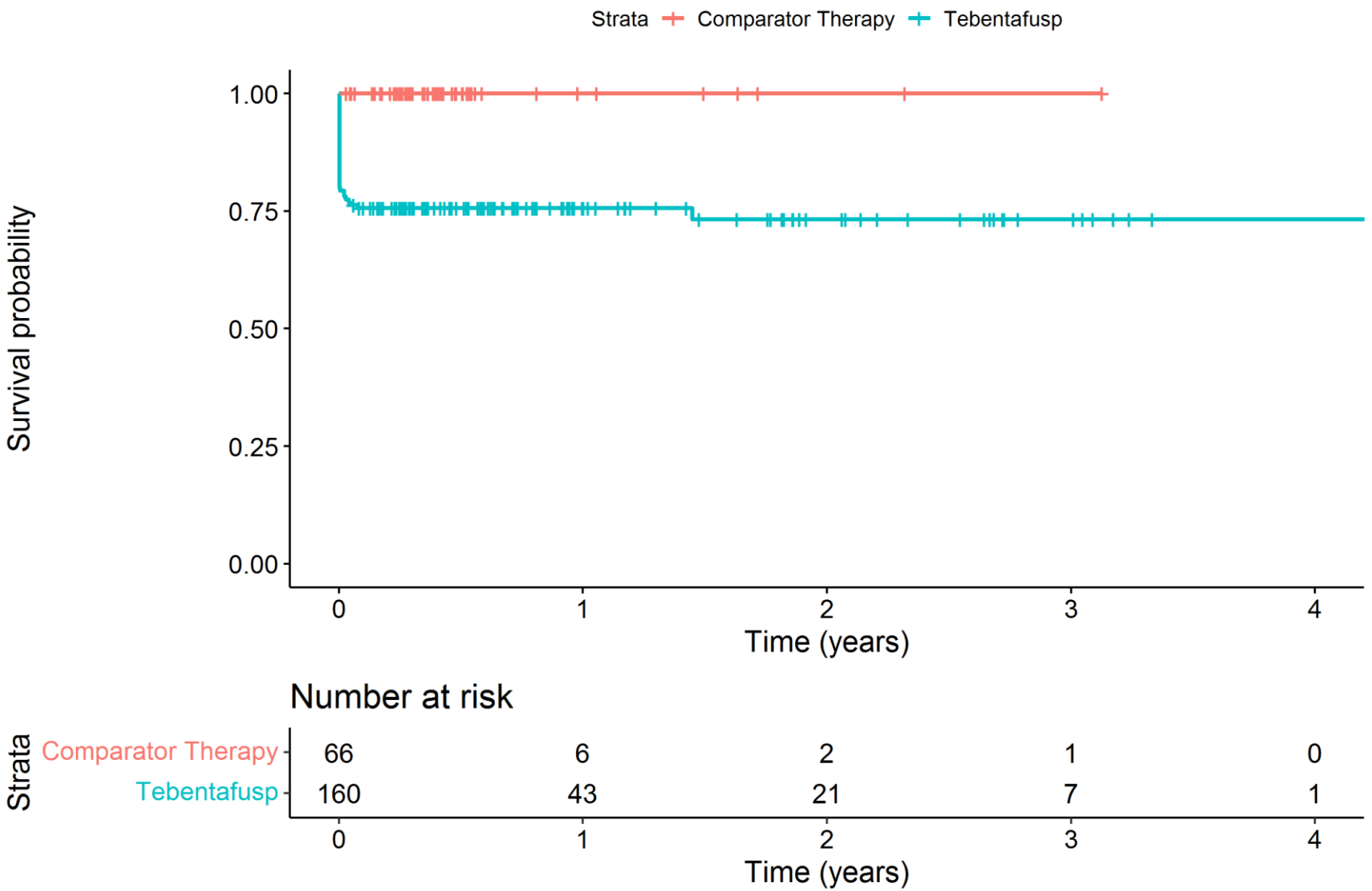
Zytokin-Freisetzungssyndrom- Läsion ≥8,1 cm



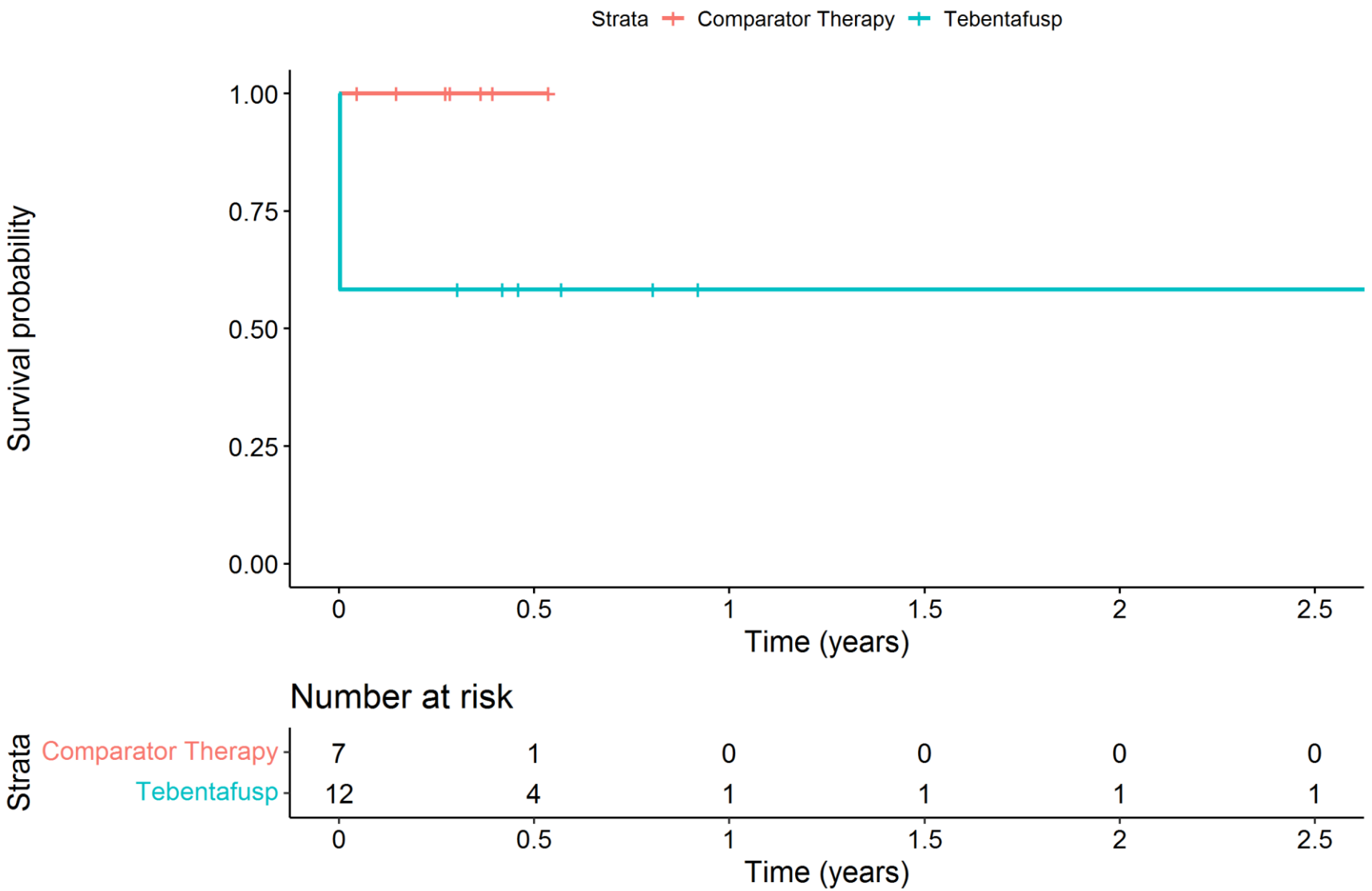
Zytokin-Freisetzungssyndrom- Nordamerika



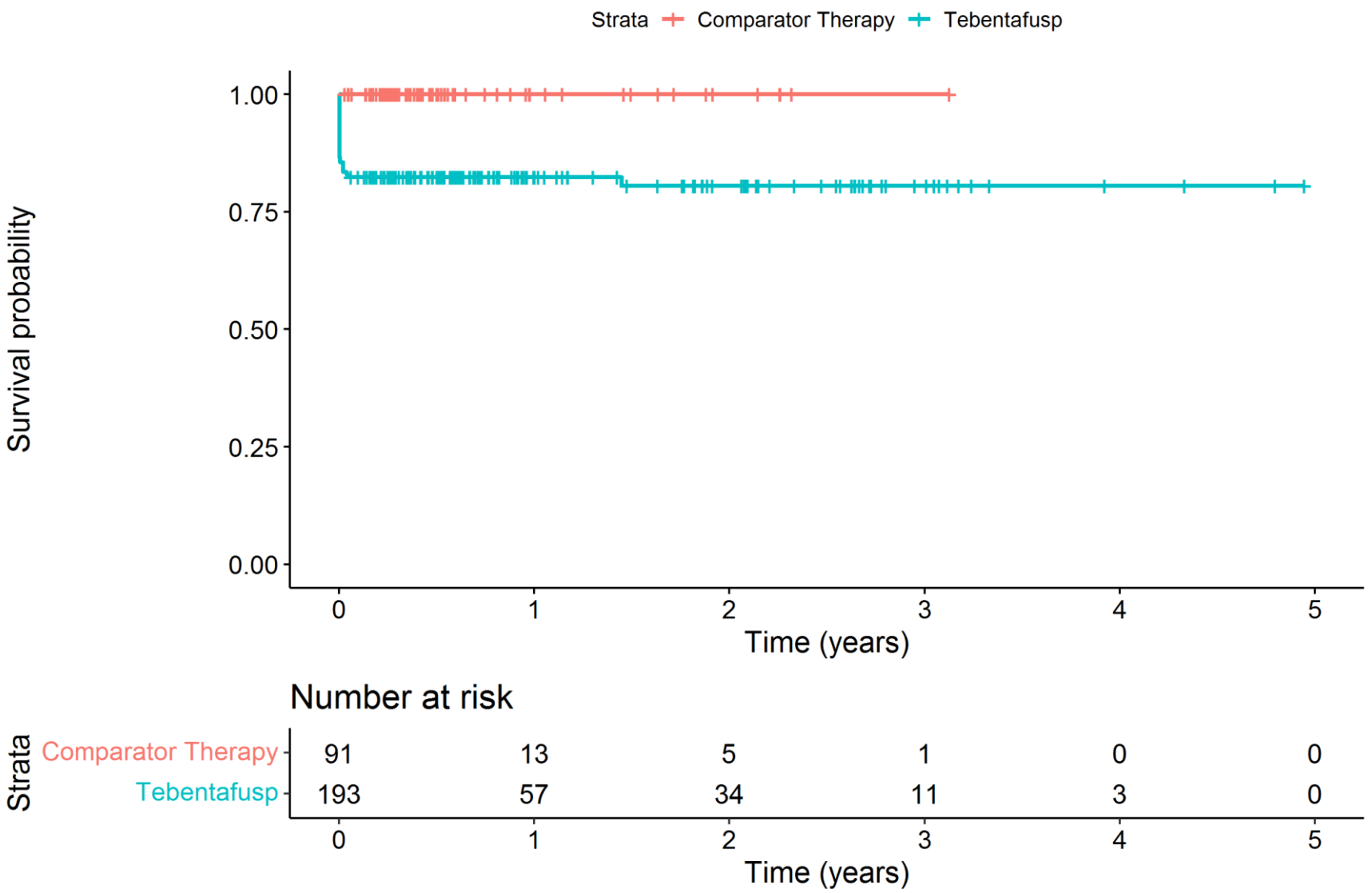
Zytokin-Freisetzungssyndrom- Nicht-Nordamerika



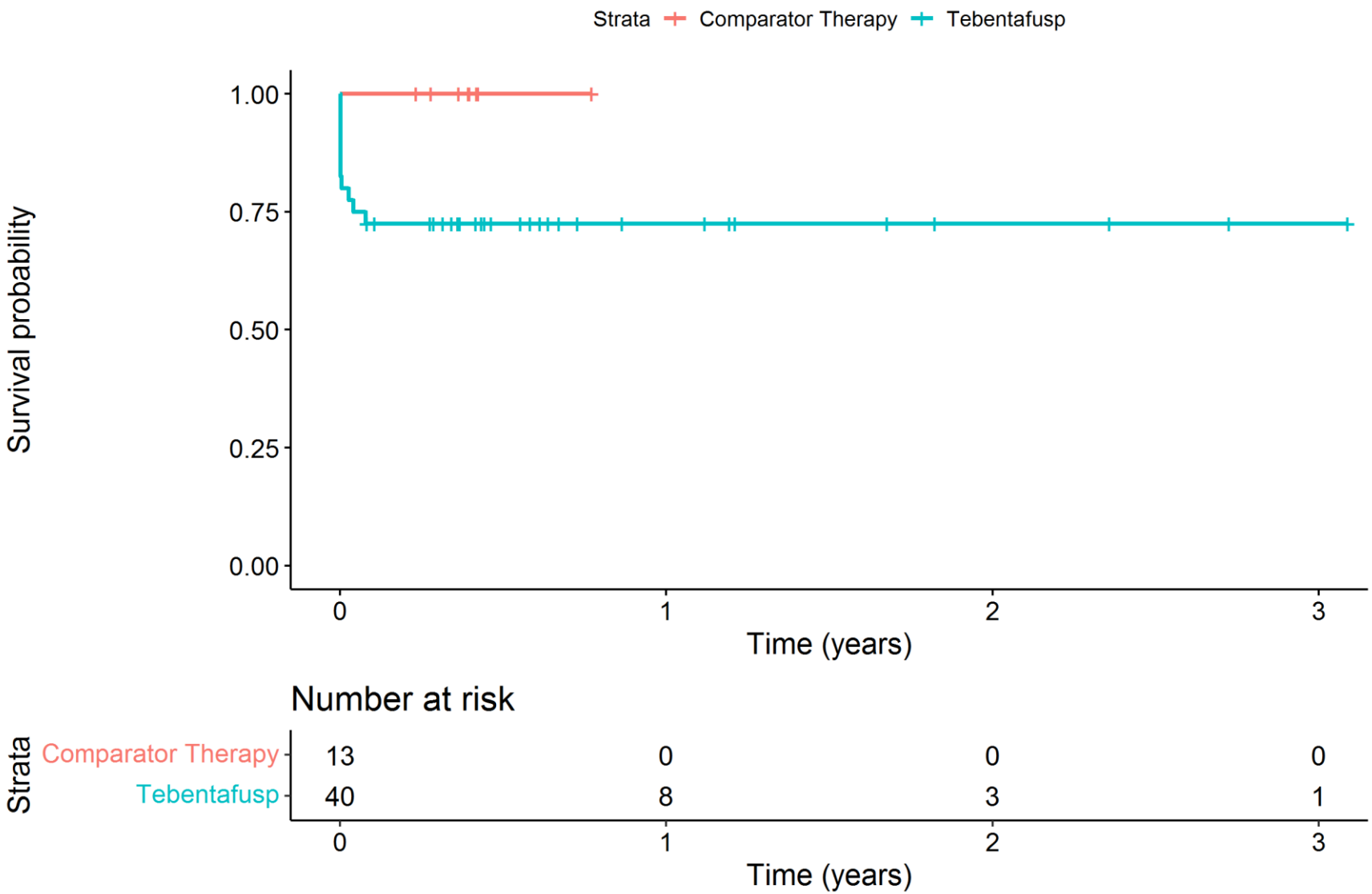
Zytokin-Freisetzungssyndrom- Dacarbazin



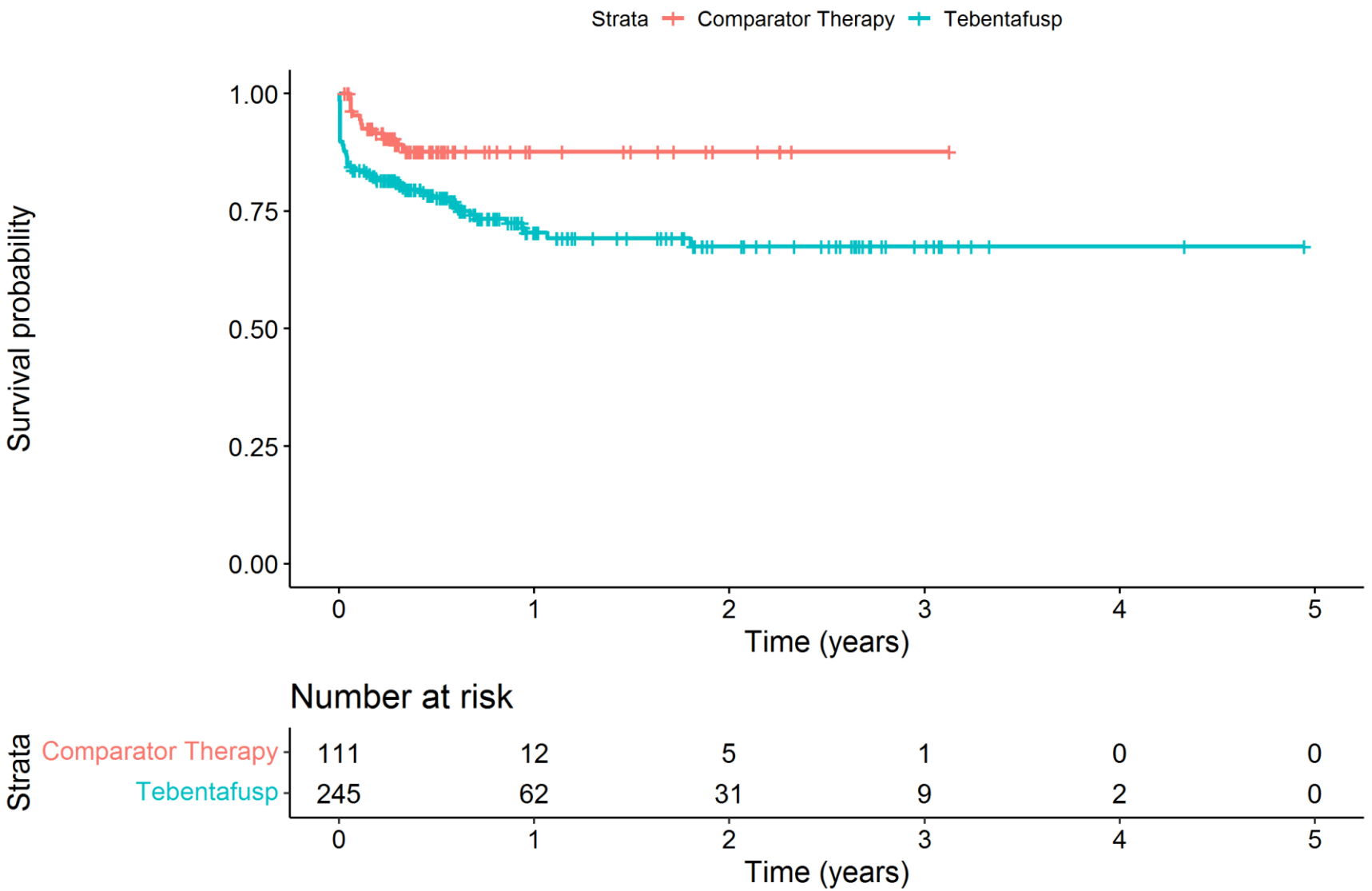
60.14 Zytokin-Freisetzungssyndrom- Pembrolizumab



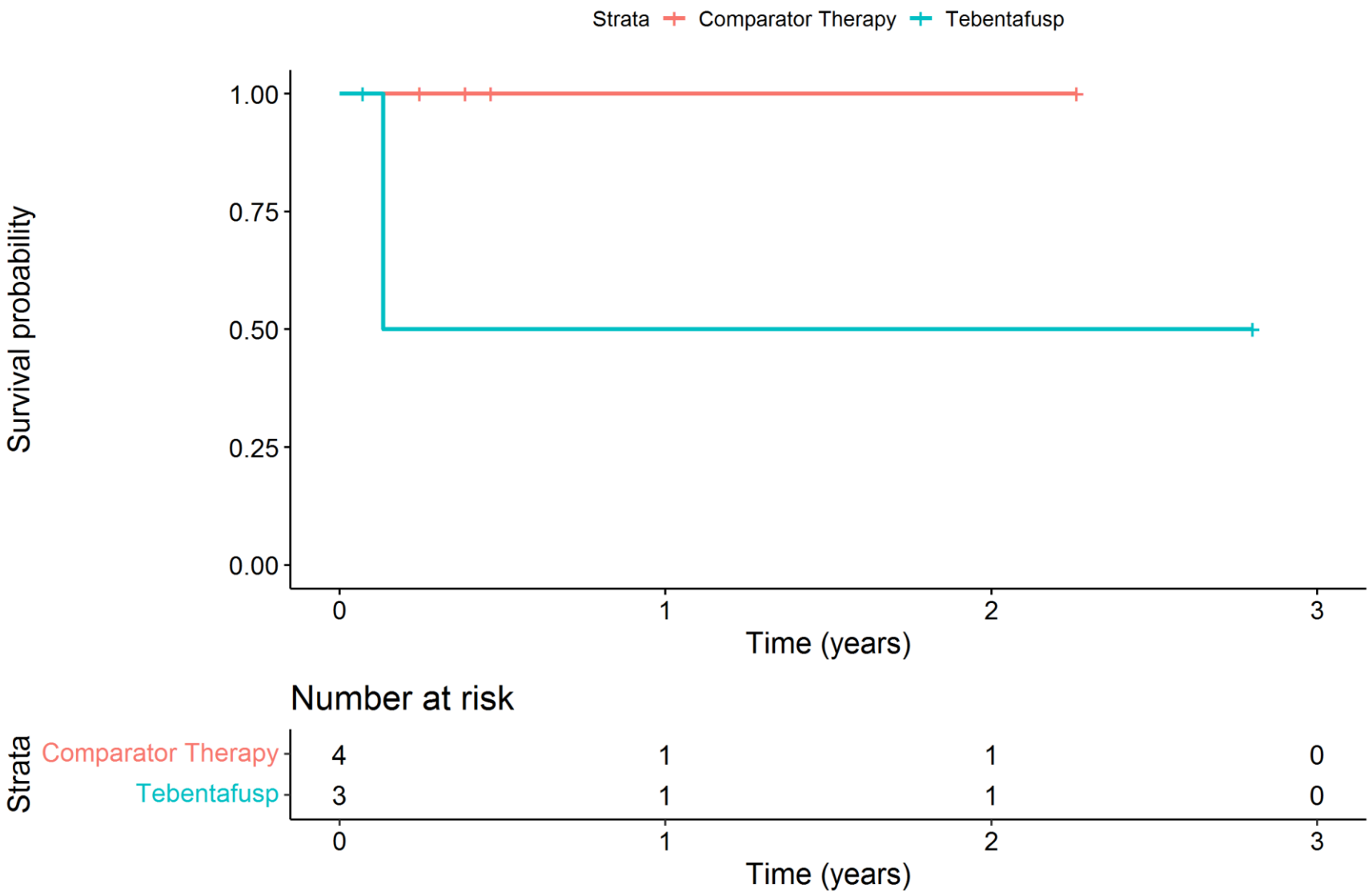
Zytokin-Freisetzungssyndrom- Ipilimumab



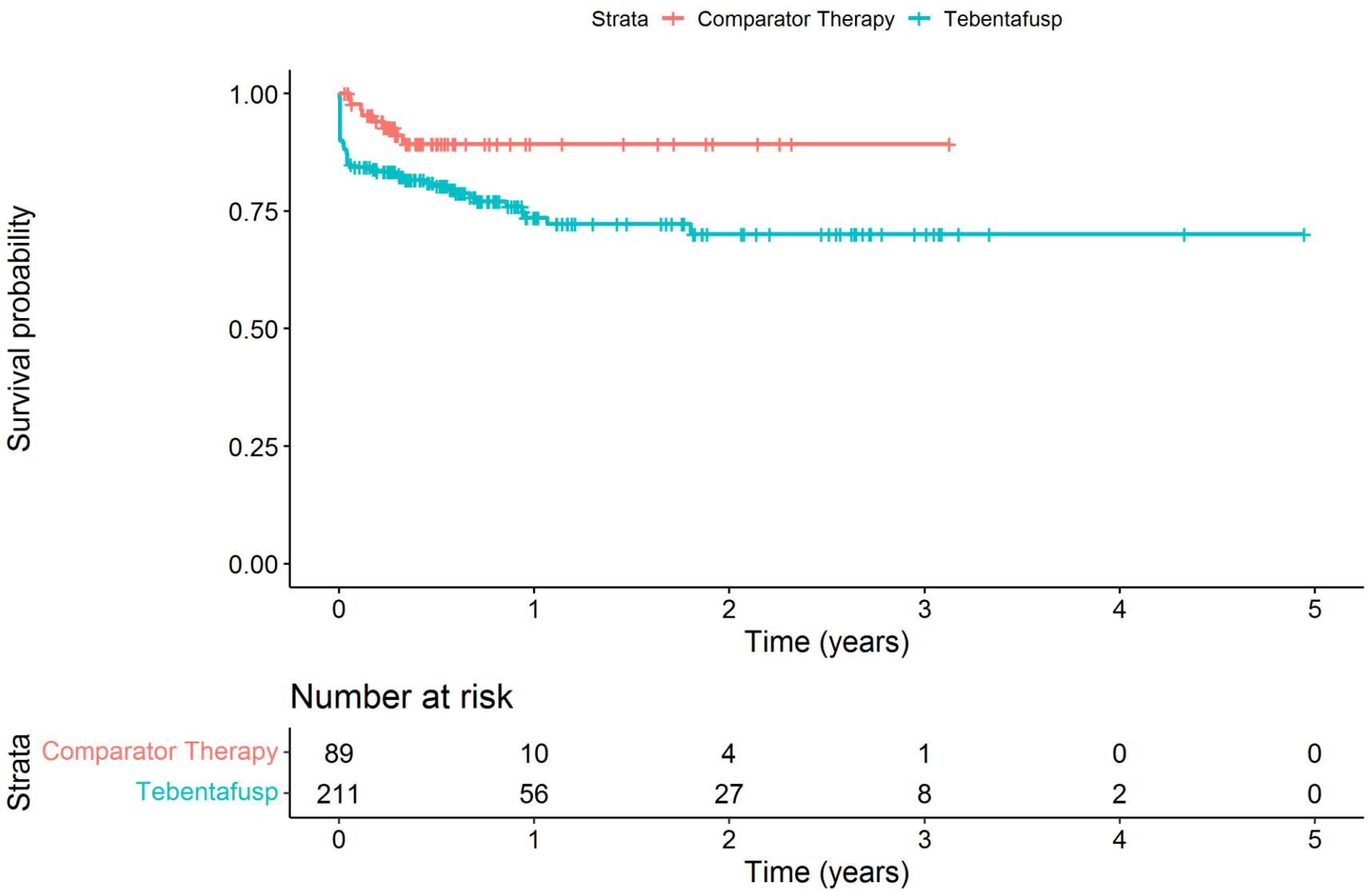
Erhöhte Aspartat-Aminotransferase - Gesamt



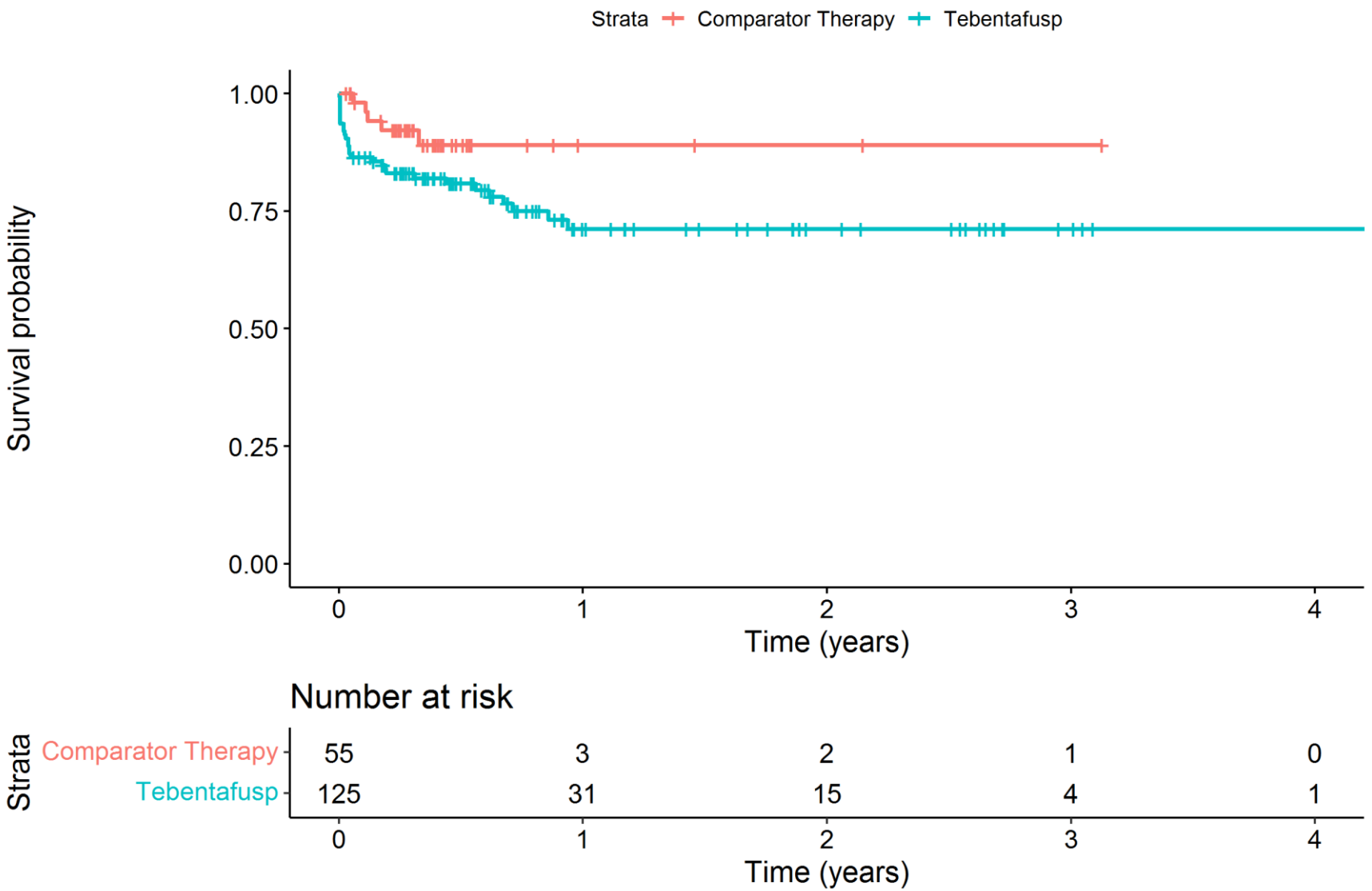
Erhöhte Aspartat-Aminotransferase - Hispanisch



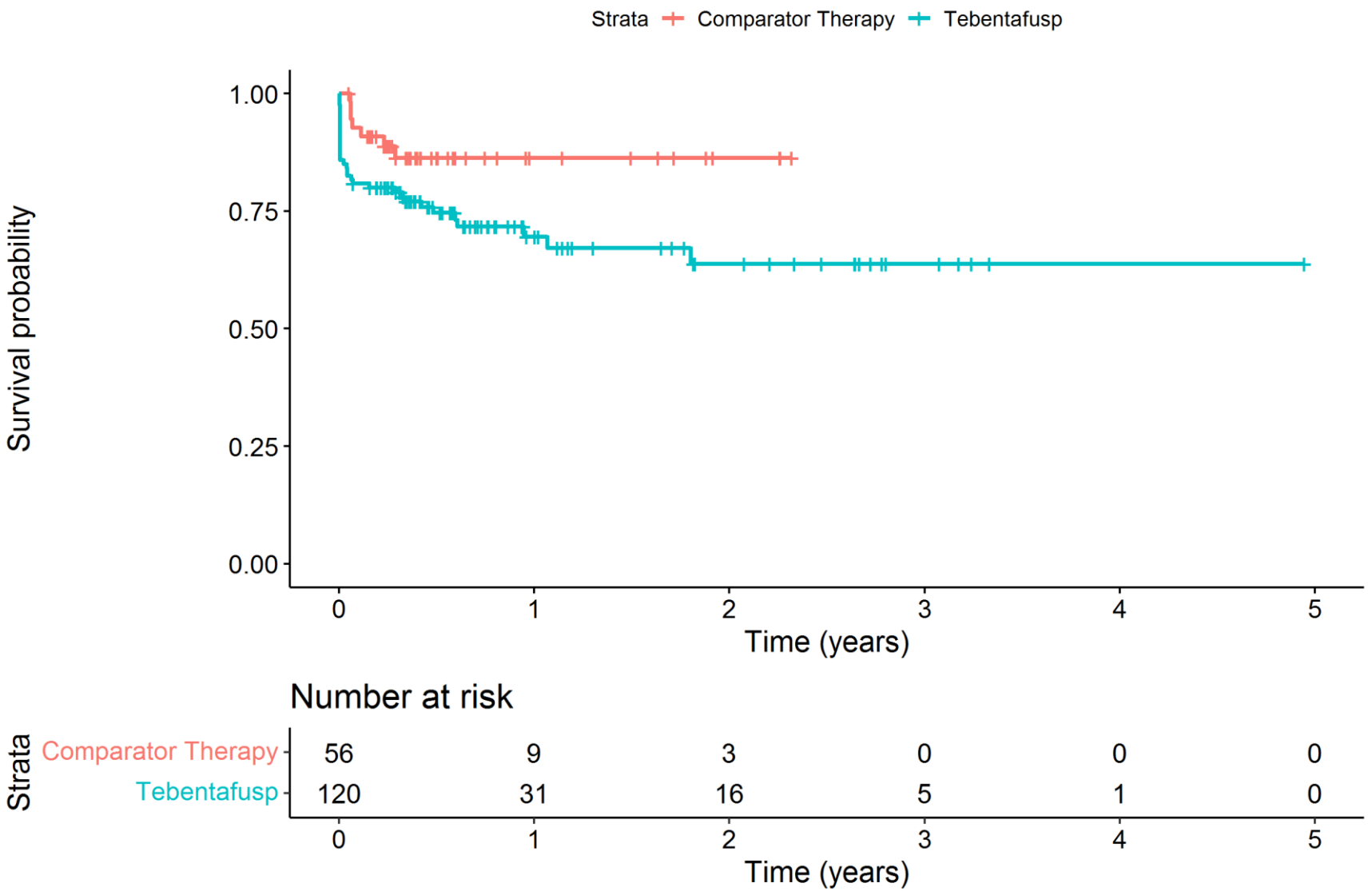
Erhöhte Aspartat-Aminotransferase - Nicht-hispanisch



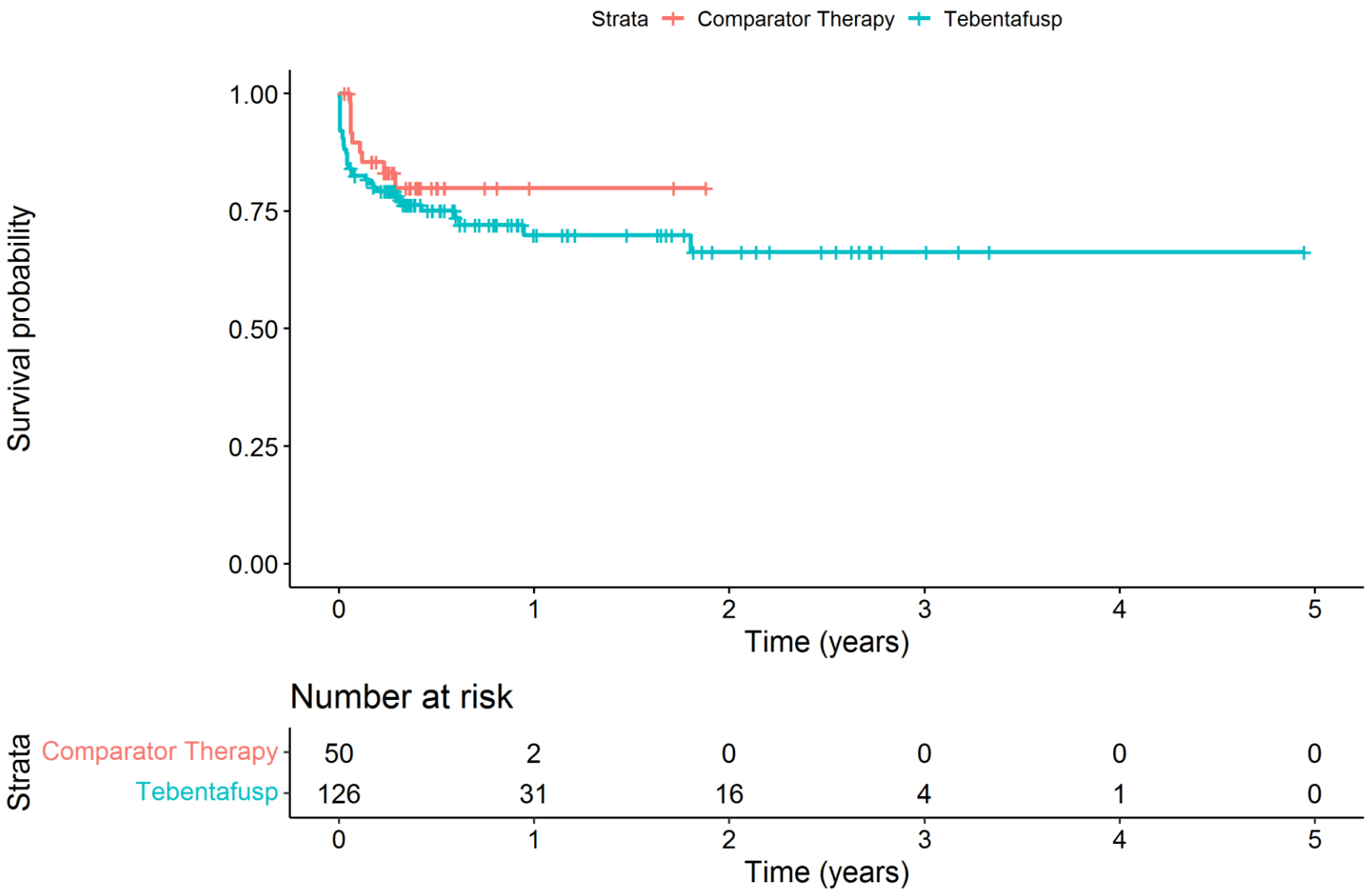
Erhöhte Aspartat-Aminotransferase - Männlich



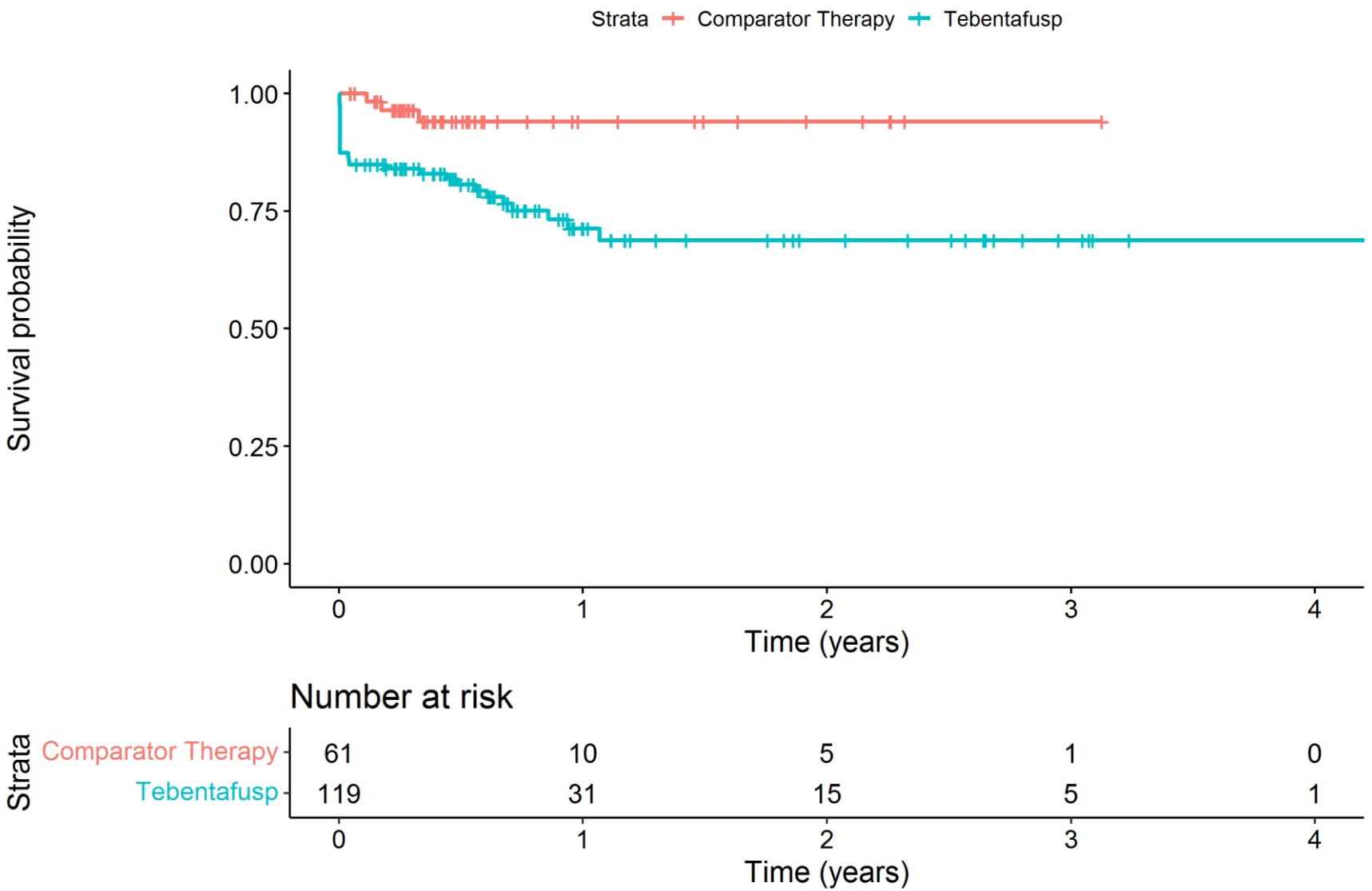
Erhöhte Aspartat-Aminotransferase - Weiblich



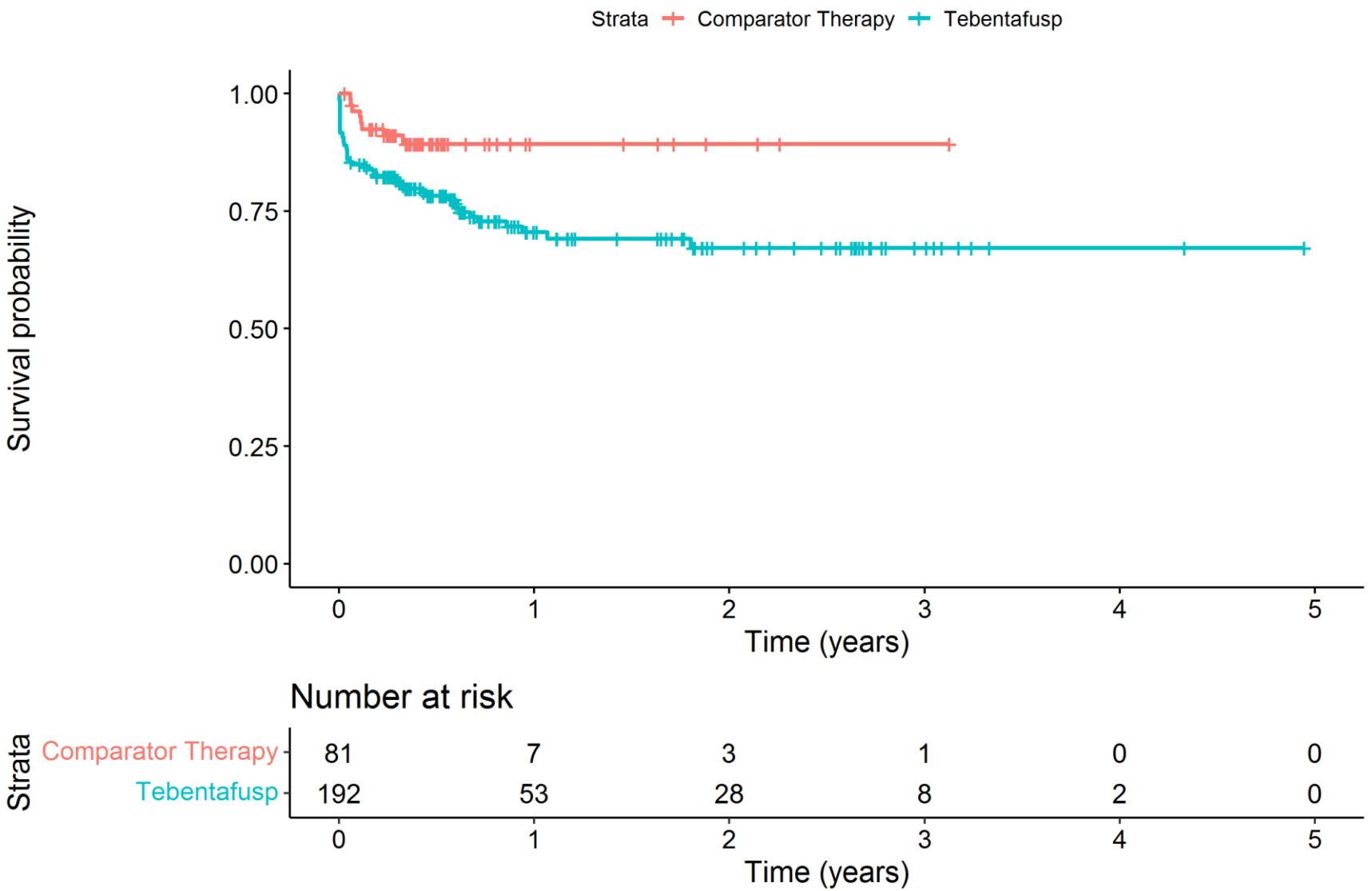
Erhöhte Aspartat-Aminotransferase - <65



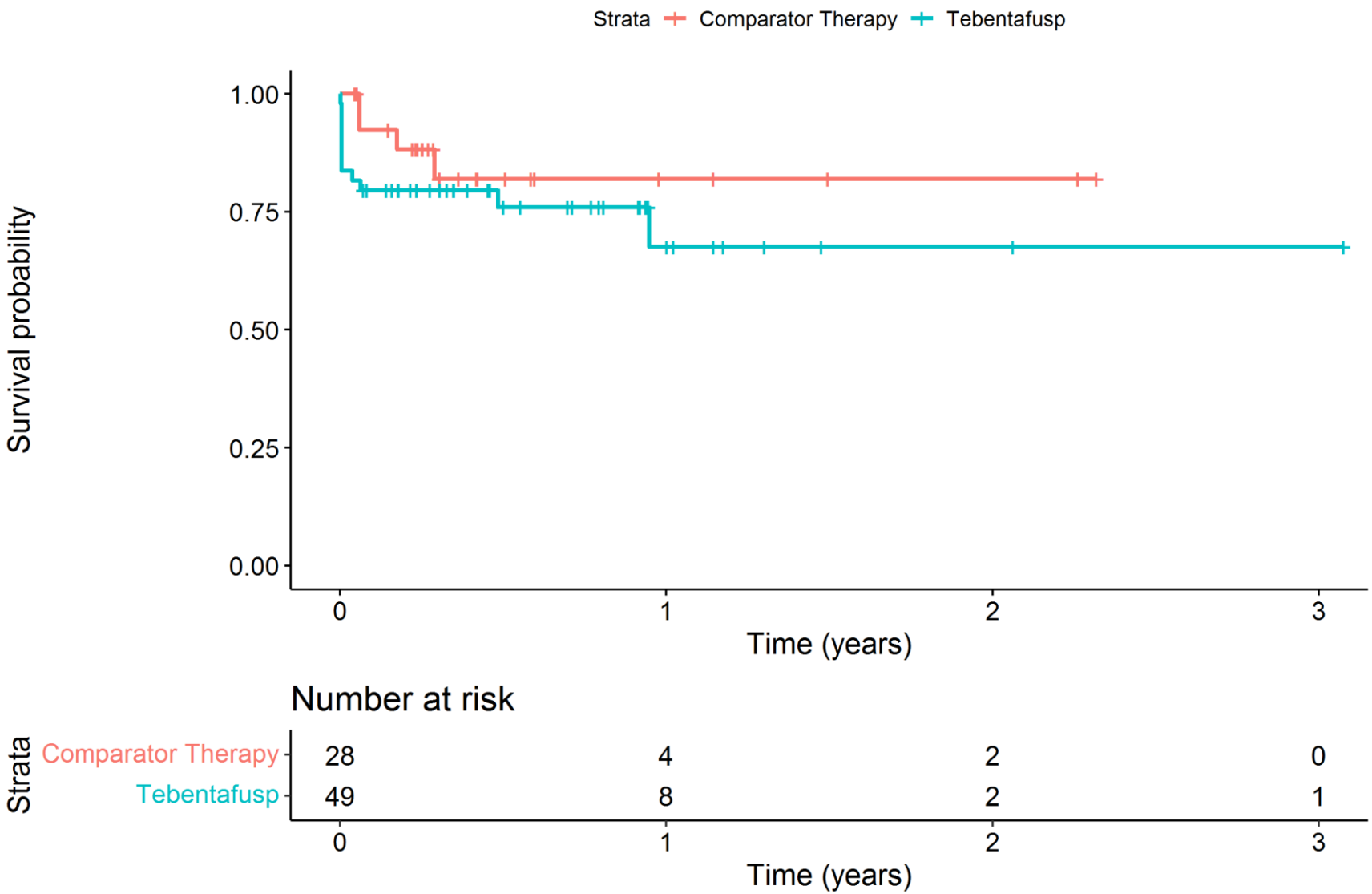
Erhöhte Aspartat-Aminotransferase - ≥65



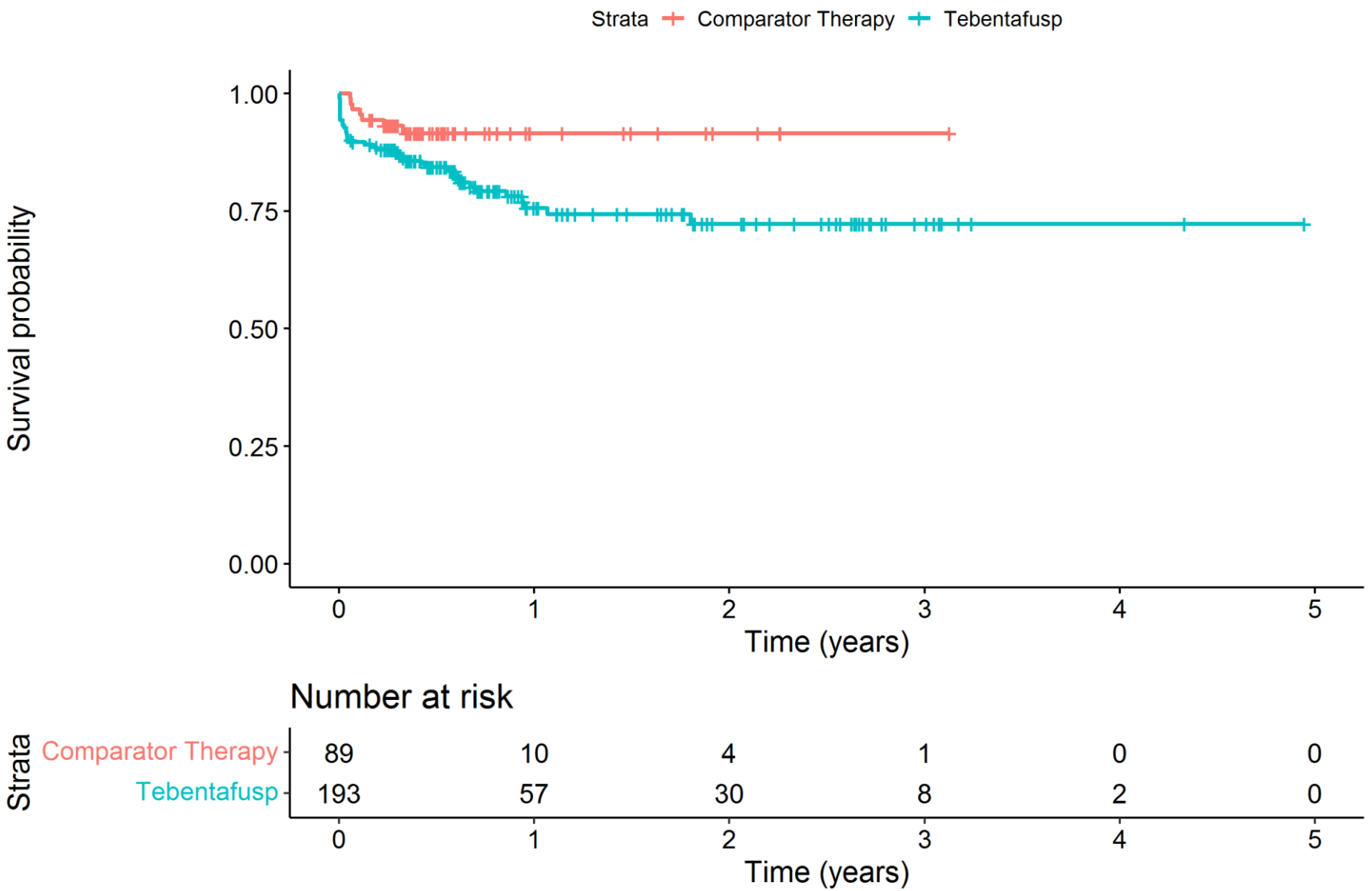
Erhöhte Aspartat-Aminotransferase - ECOG 0



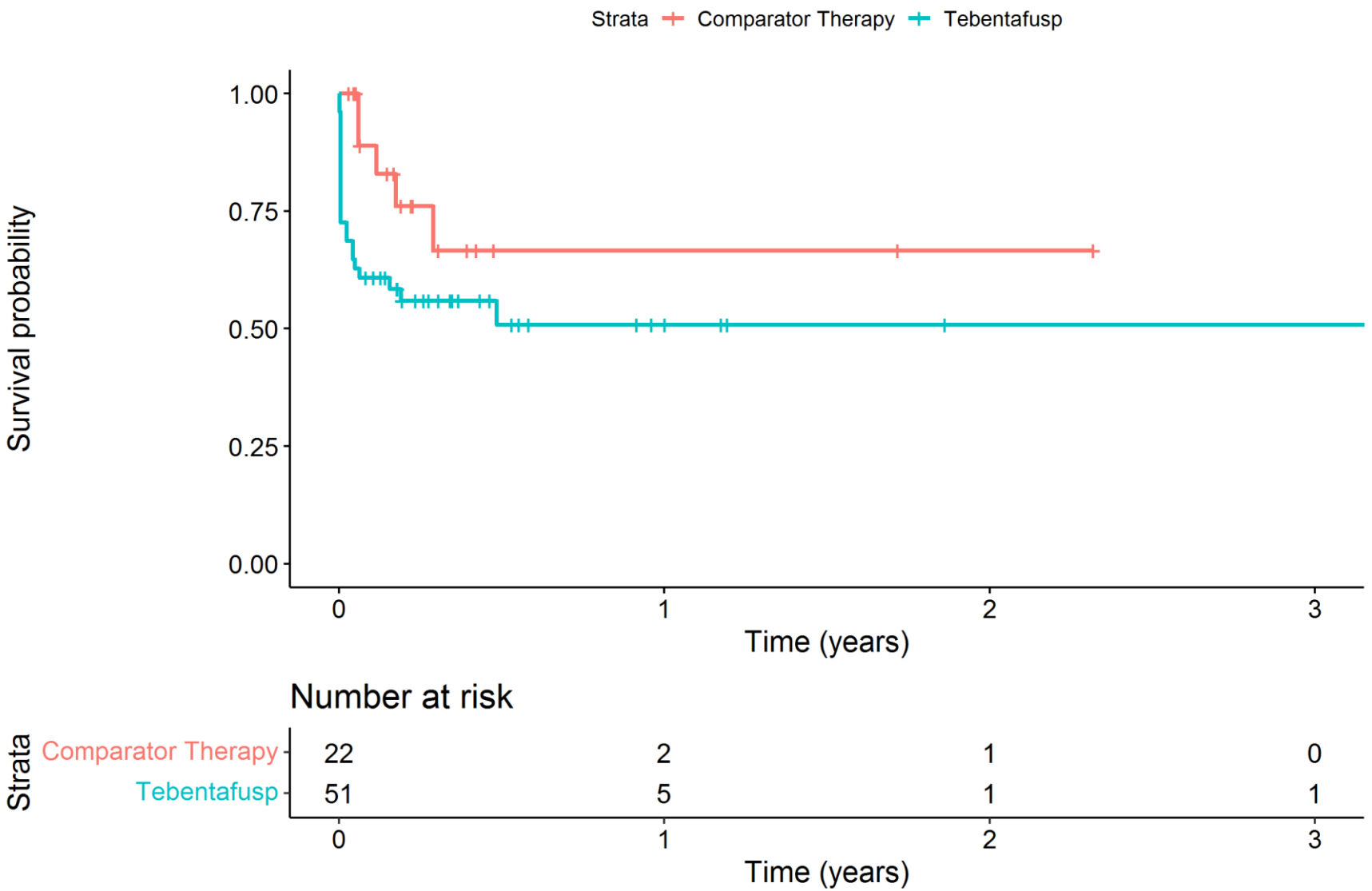
Erhöhte Aspartat-Aminotransferase - ECOG 1



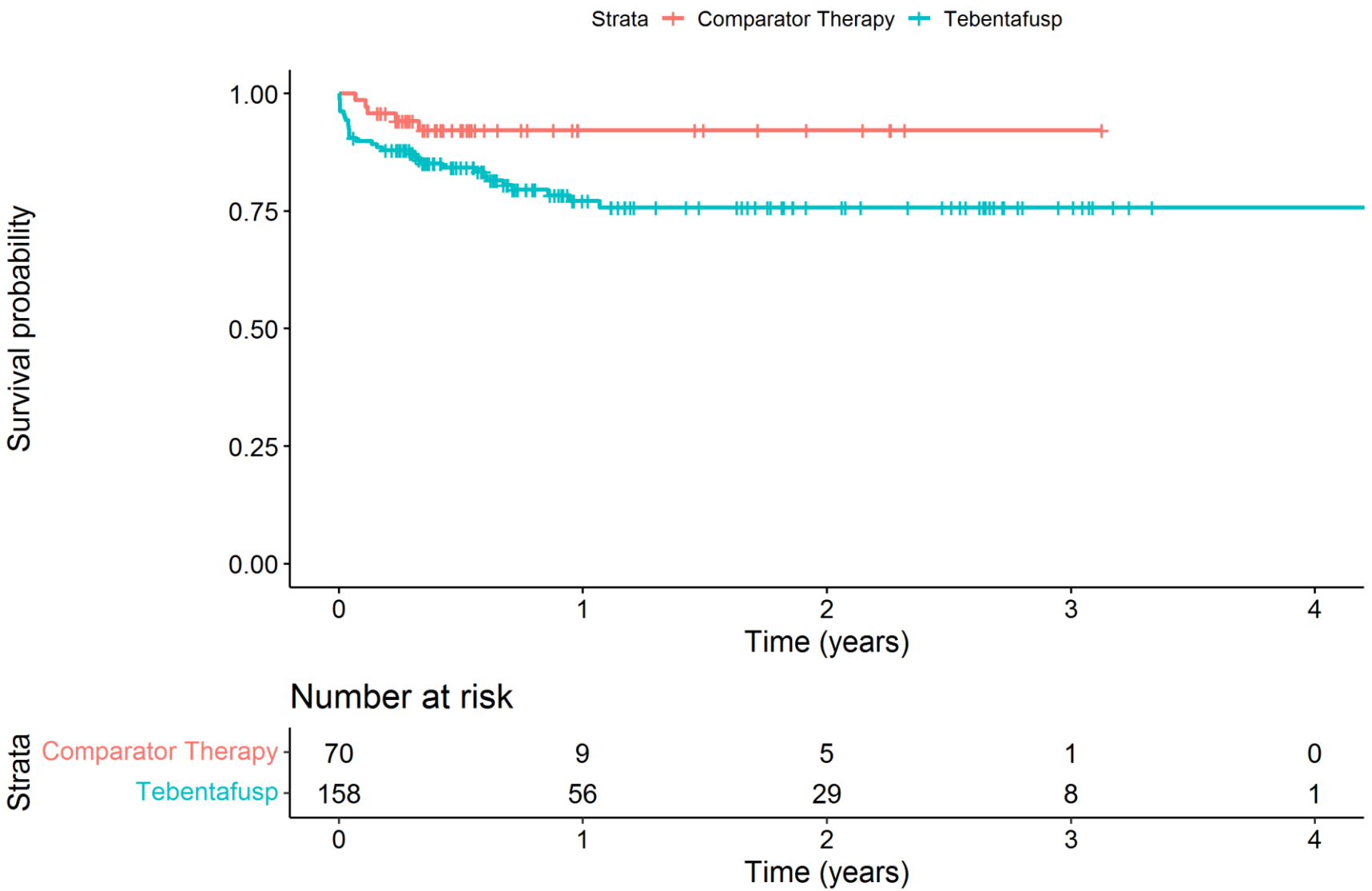
Erhöhte Aspartat-Aminotransferase - ALP ≤ ULN



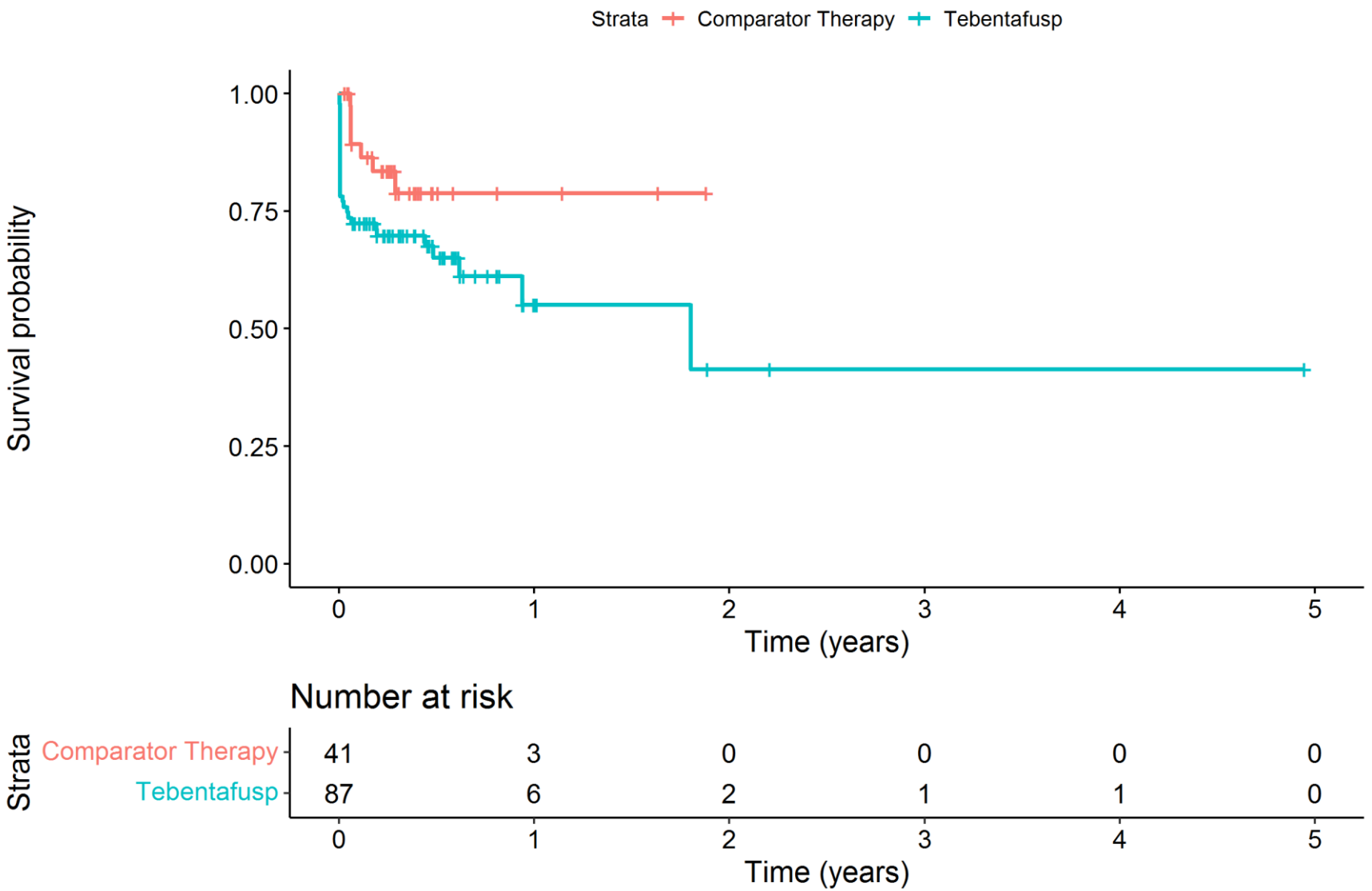
Erhöhte Aspartat-Aminotransferase - ALP > ULN



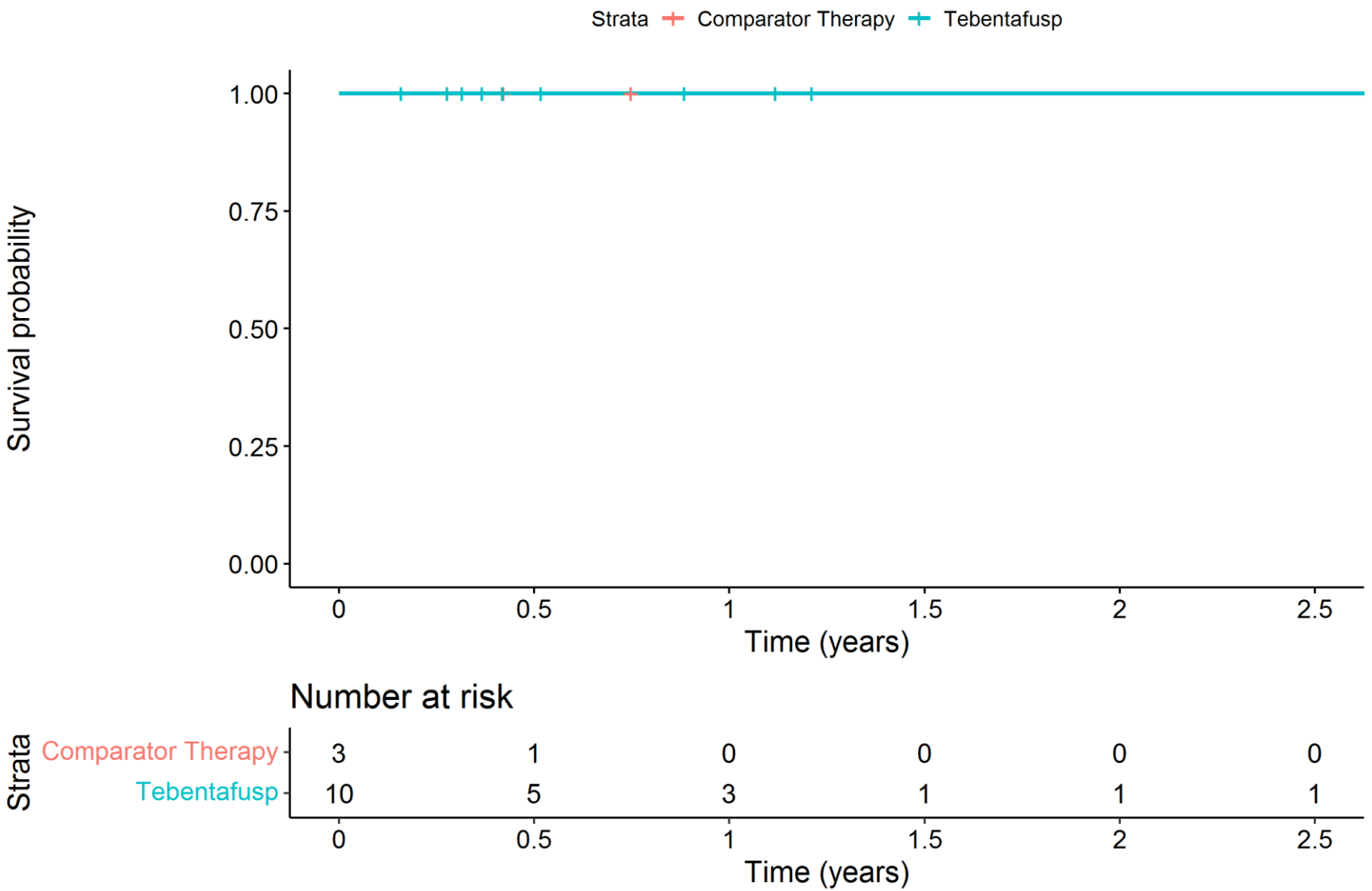
Erhöhte Aspartat-Aminotransferase - LDH =< ULN



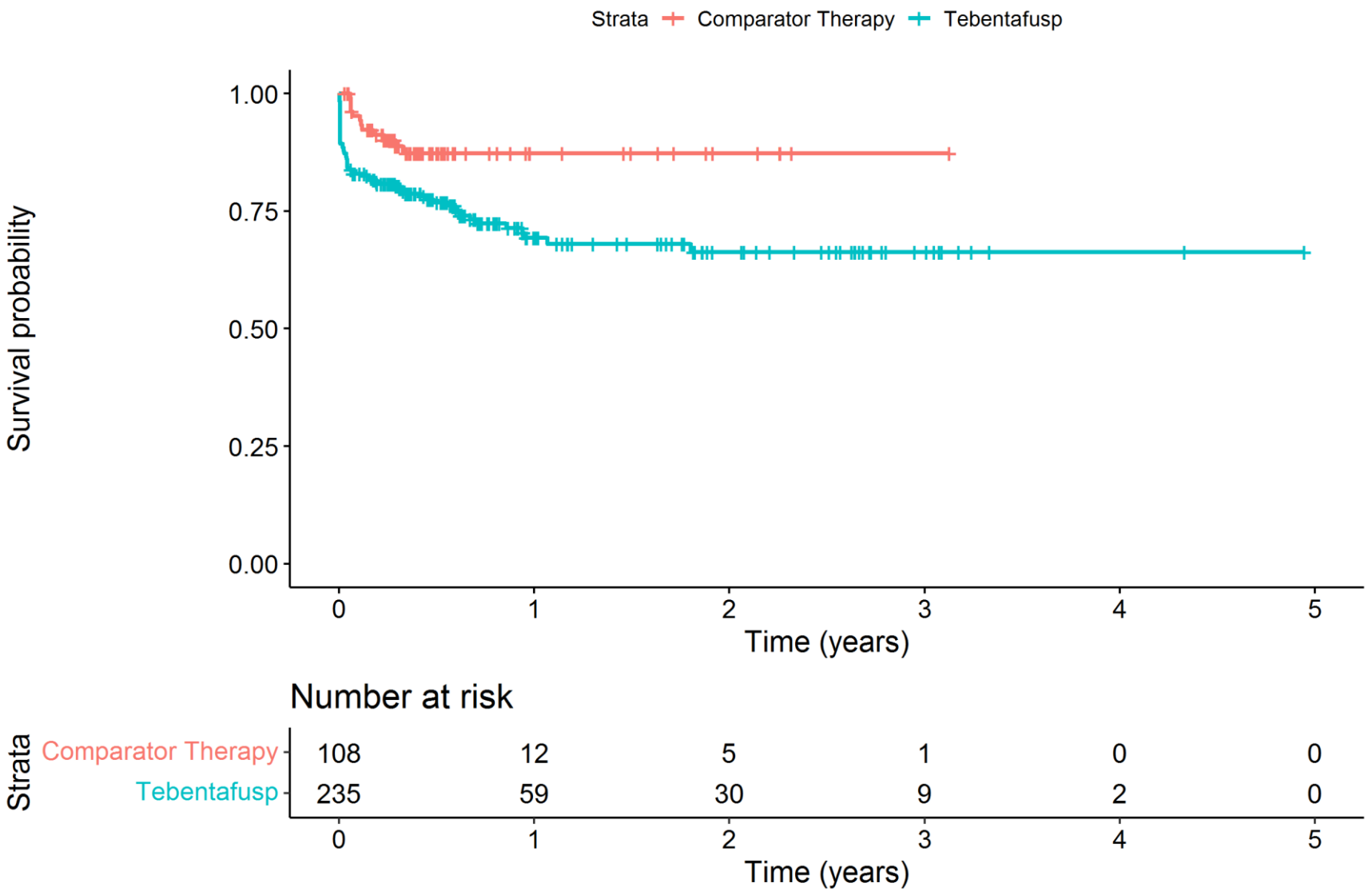
Erhöhte Aspartat-Aminotransferase - LDH > ULN



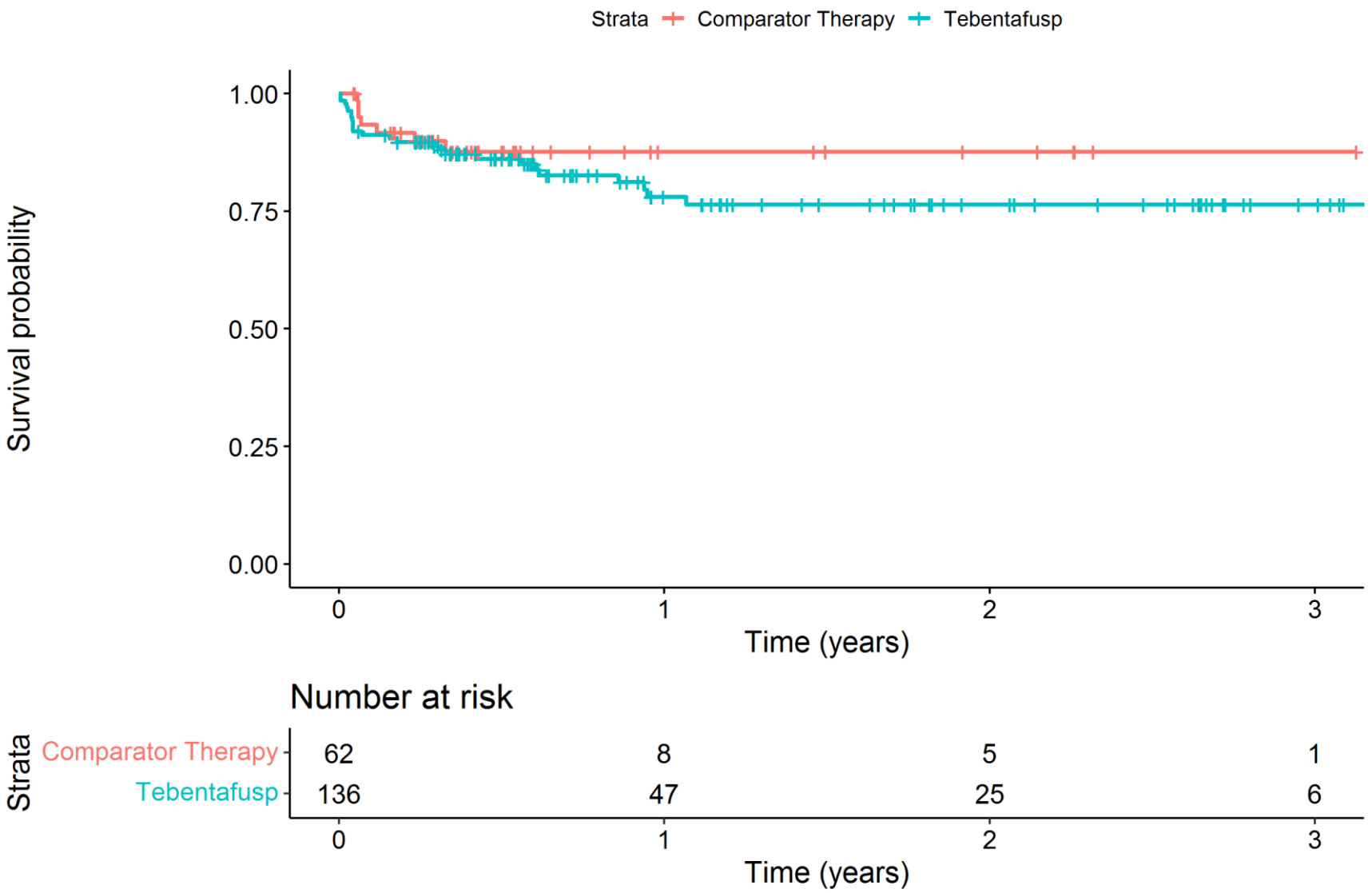
Erhöhte Aspartat-Aminotransferase - Vorherige Therapie adjuvant/neoadjuvant



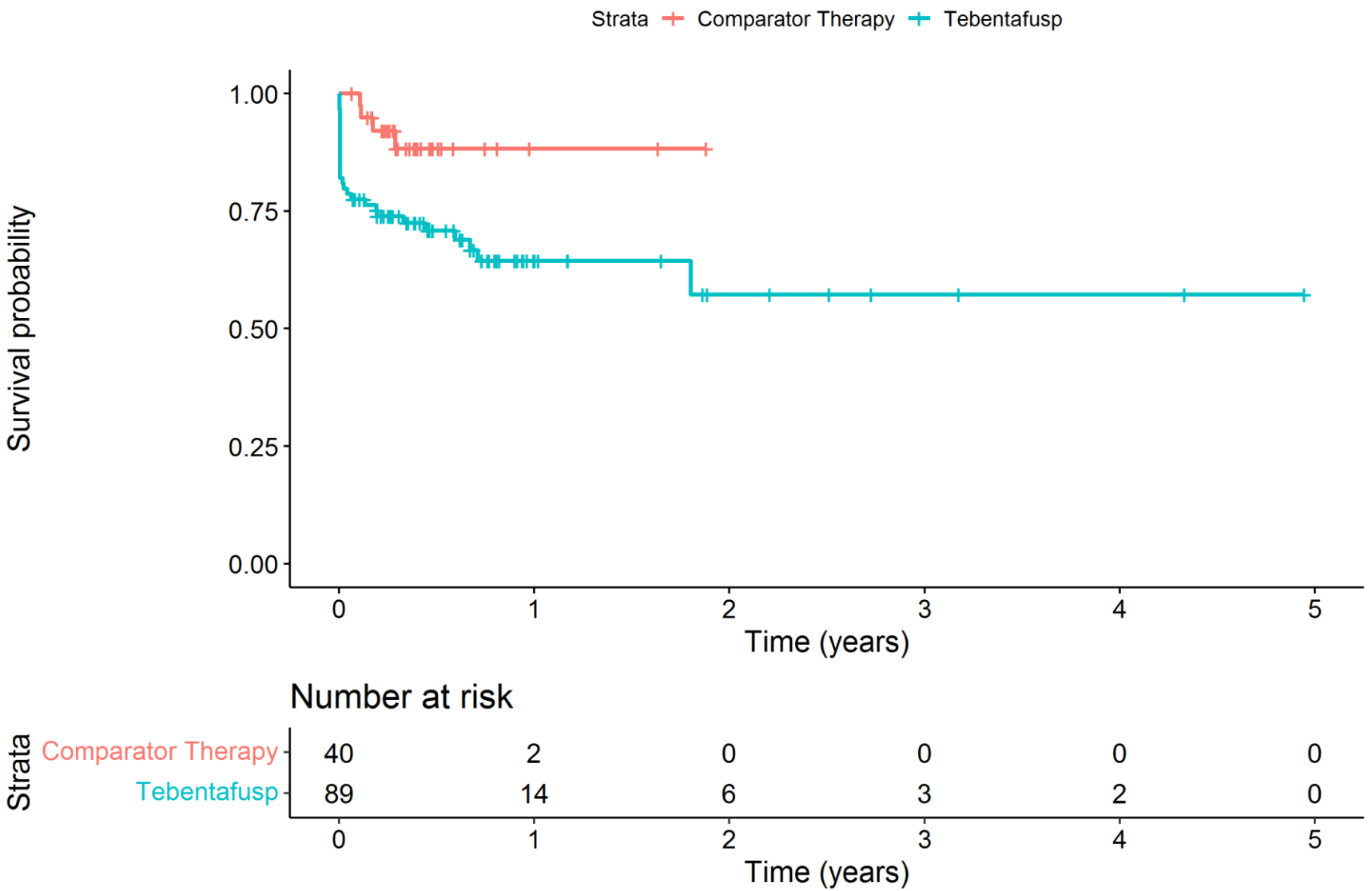
Erhöhte Aspartat-Aminotransferase - Keine Vorherige Therapie adjuvant/neoadjuvant



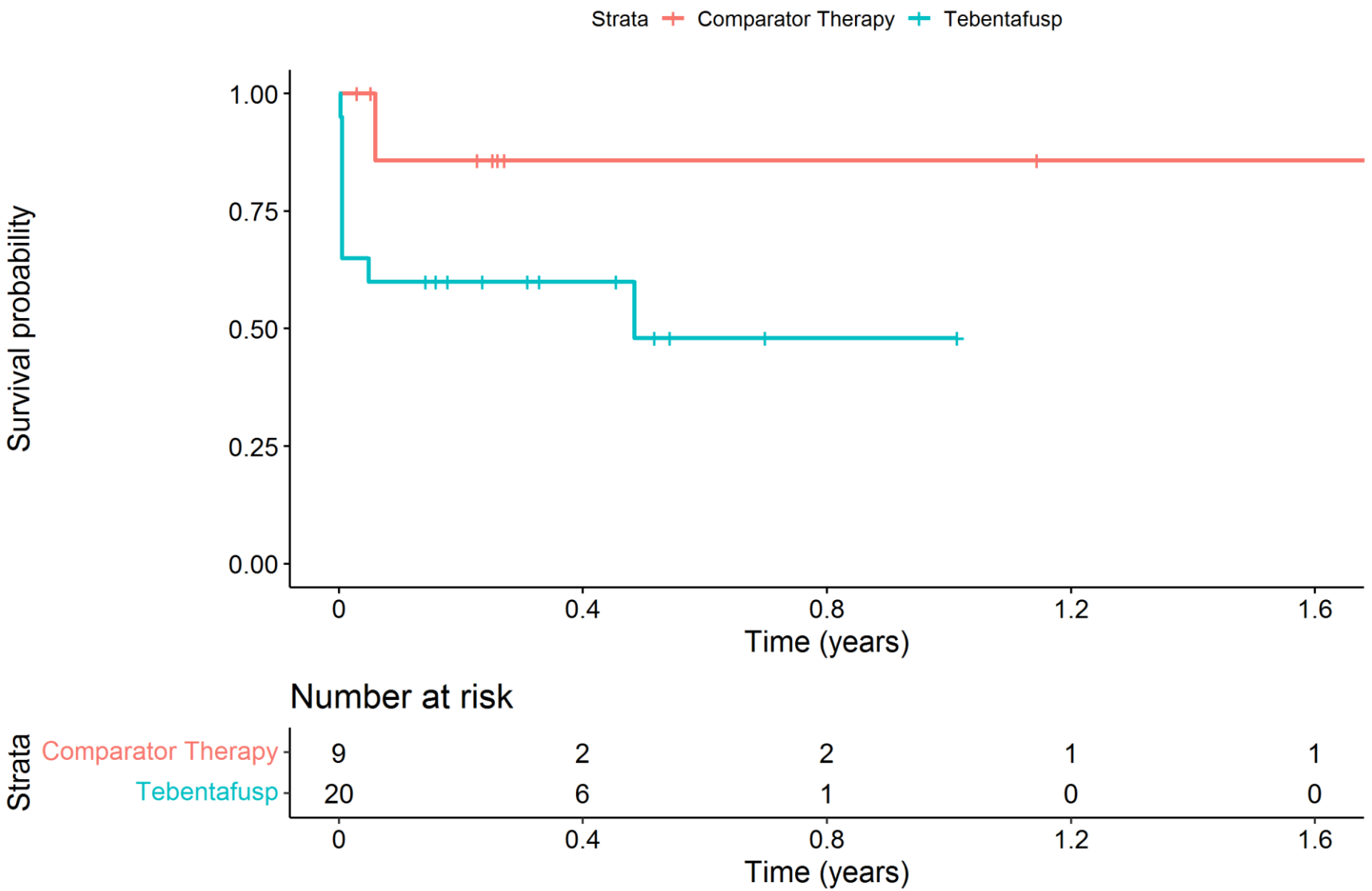
Erhöhte Aspartat-Aminotransferase - Läsion ≤ 3cm



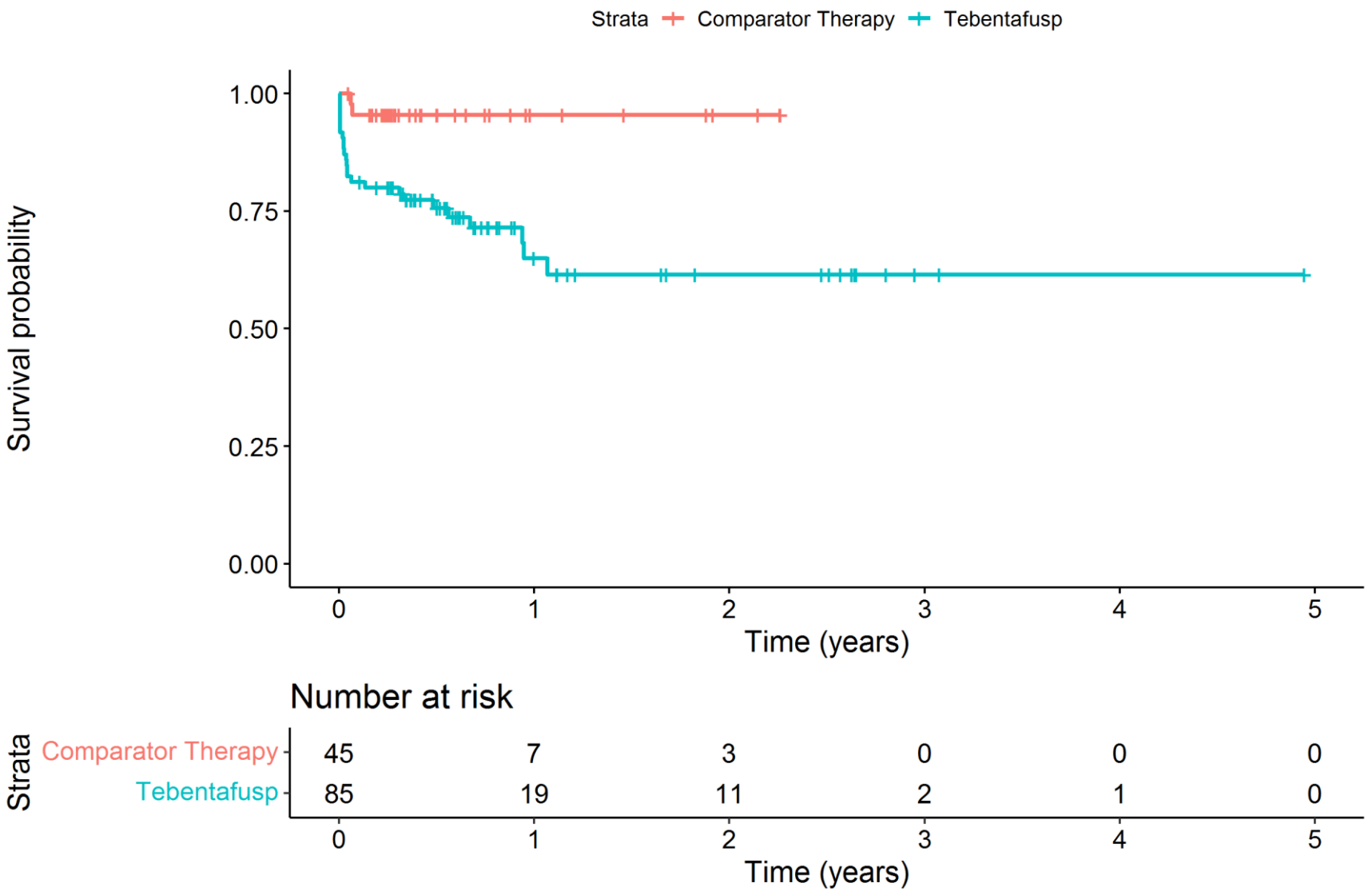
Erhöhte Aspartat-Aminotransferase - Läsion 3,1-8,0 cm



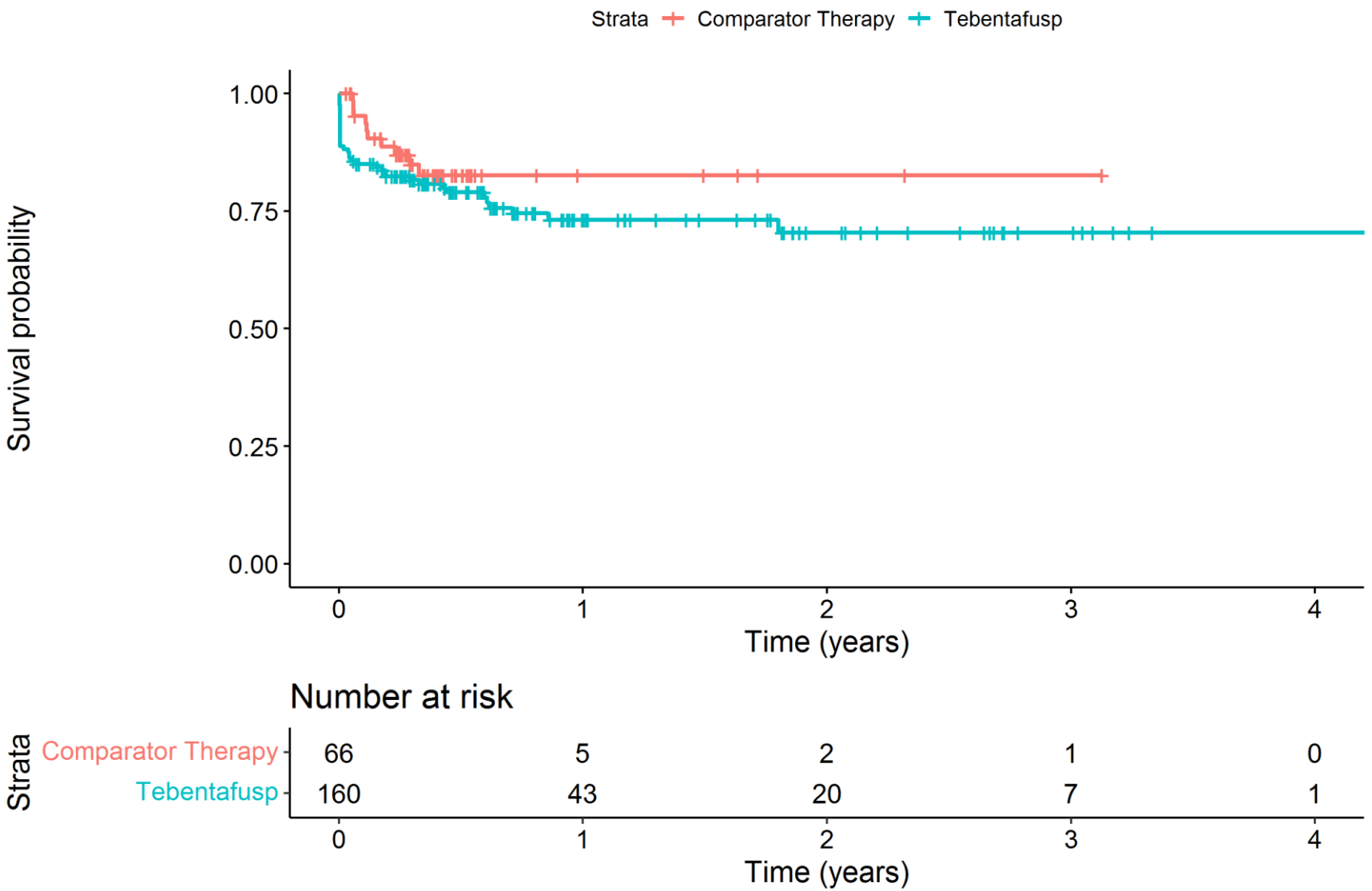
Erhöhte Aspartat-Aminotransferase - Läsion ≥8,1 cm



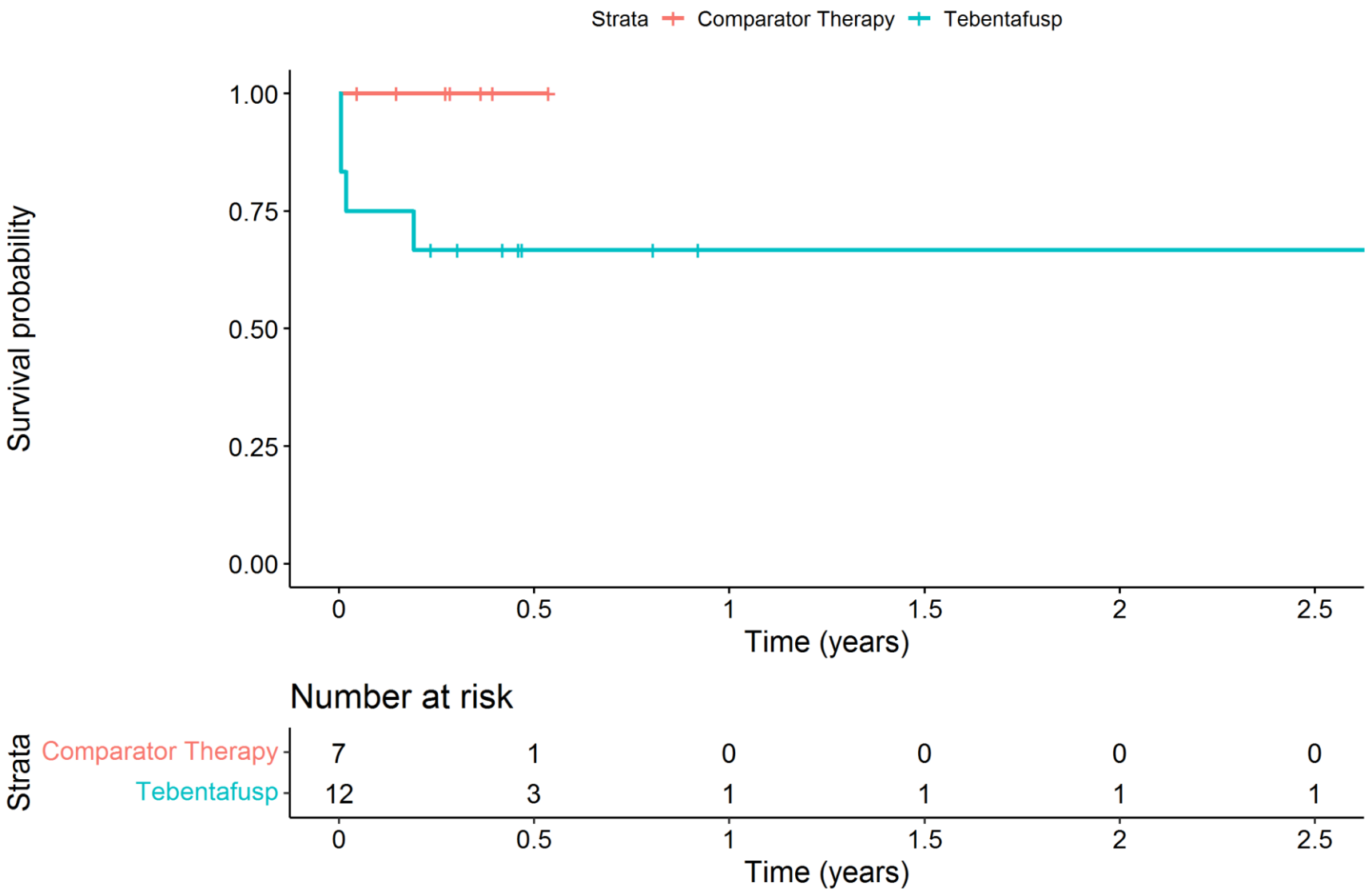
Erhöhte Aspartat-Aminotransferase - Nordamerika



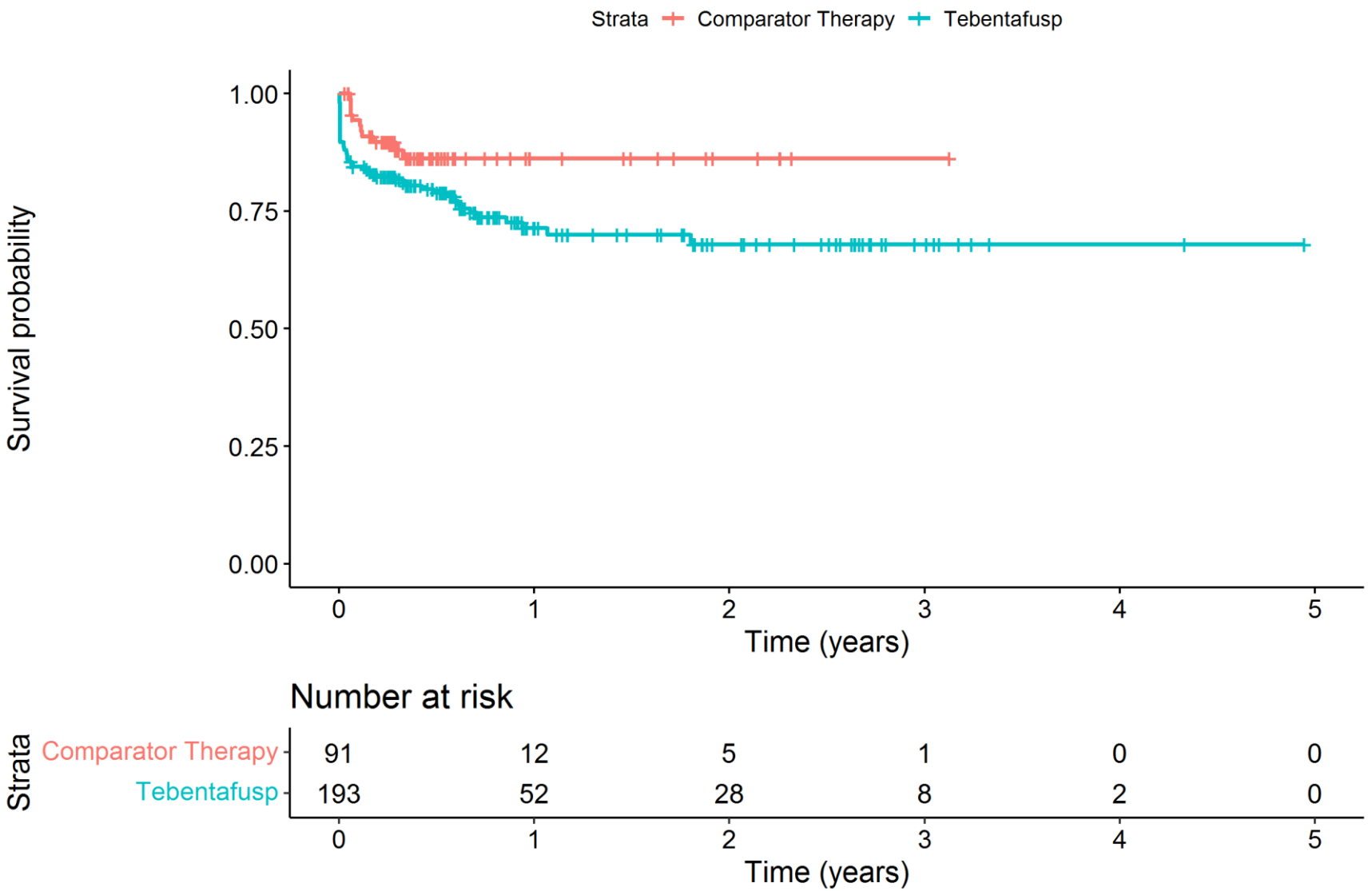
Erhöhte Aspartat-Aminotransferase - Nicht-Nordamerika



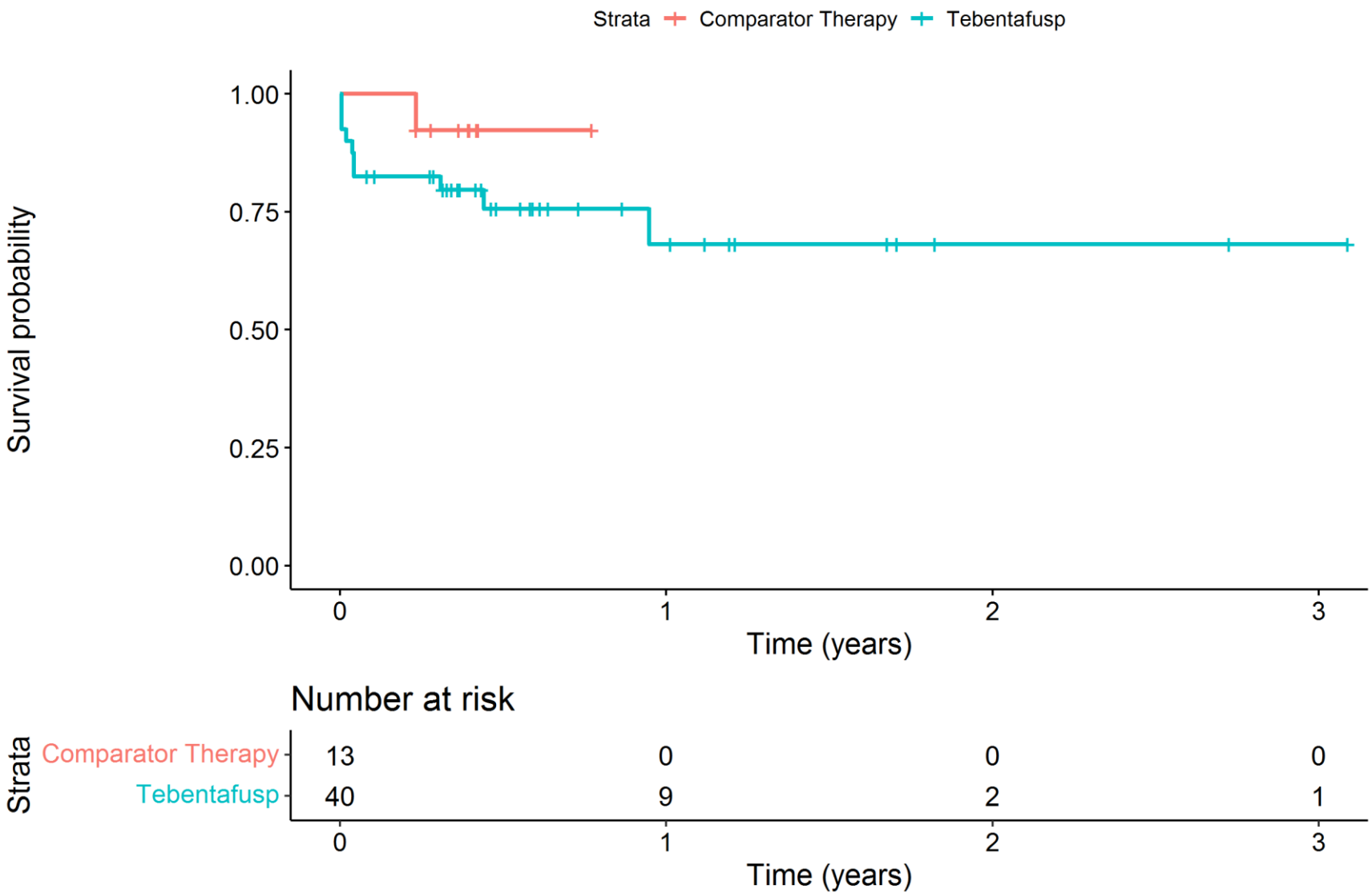
Erhöhte Aspartat-Aminotransferase - Dacarbazin



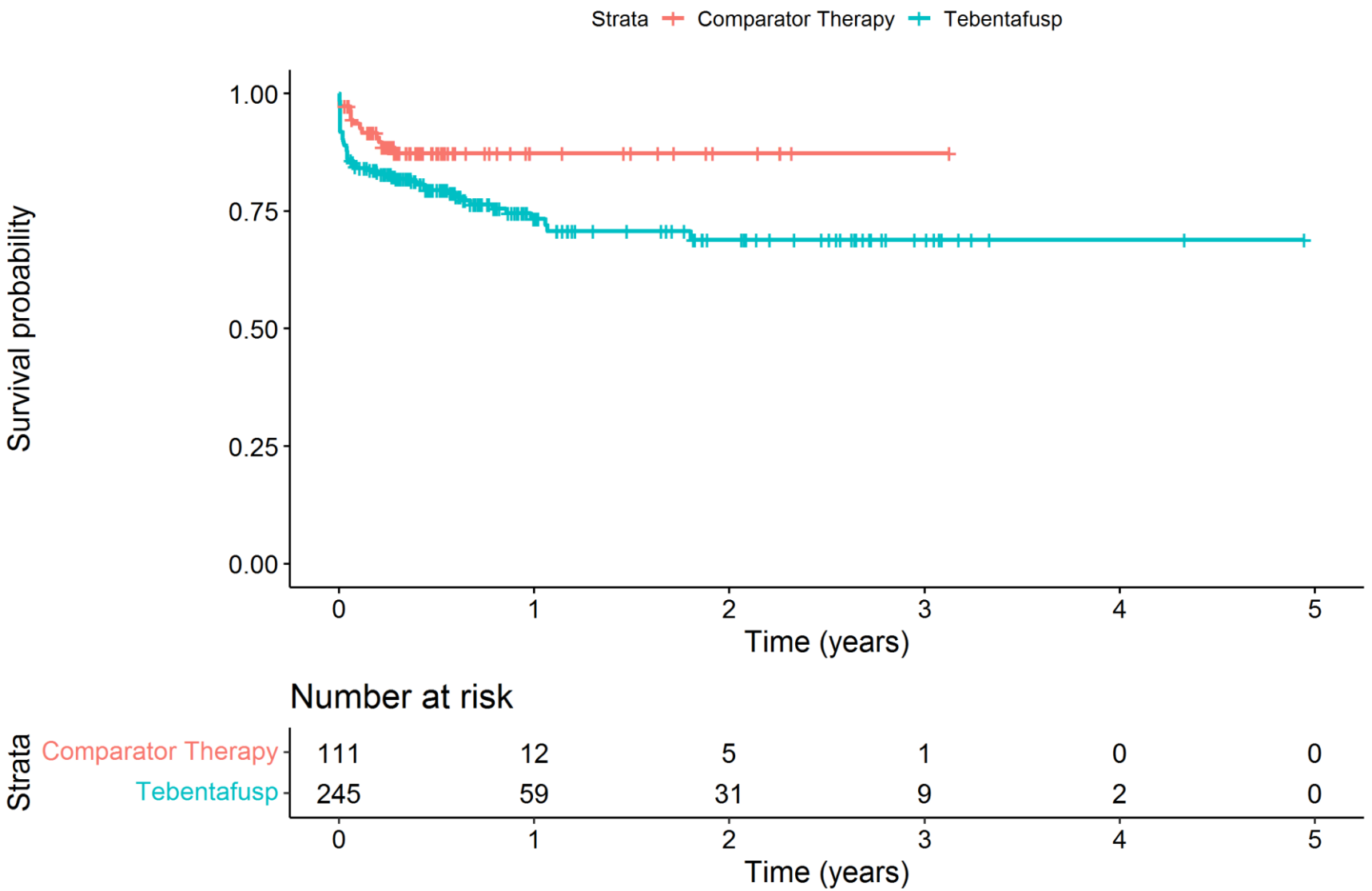
Erhöhte Aspartat-Aminotransferase - Pembrolizumab



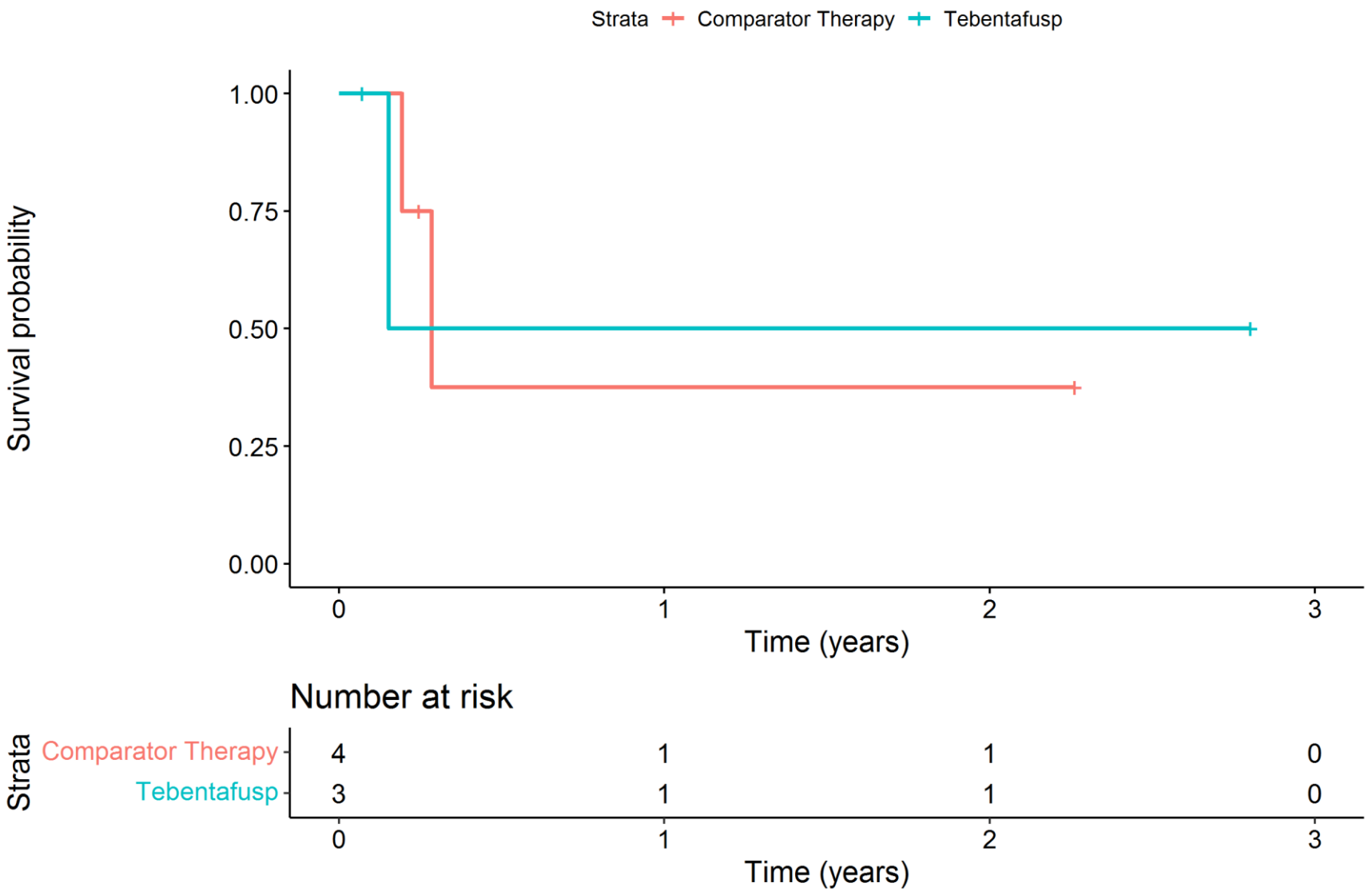
Erhöhte Aspartat-Aminotransferase - Ipilimumab



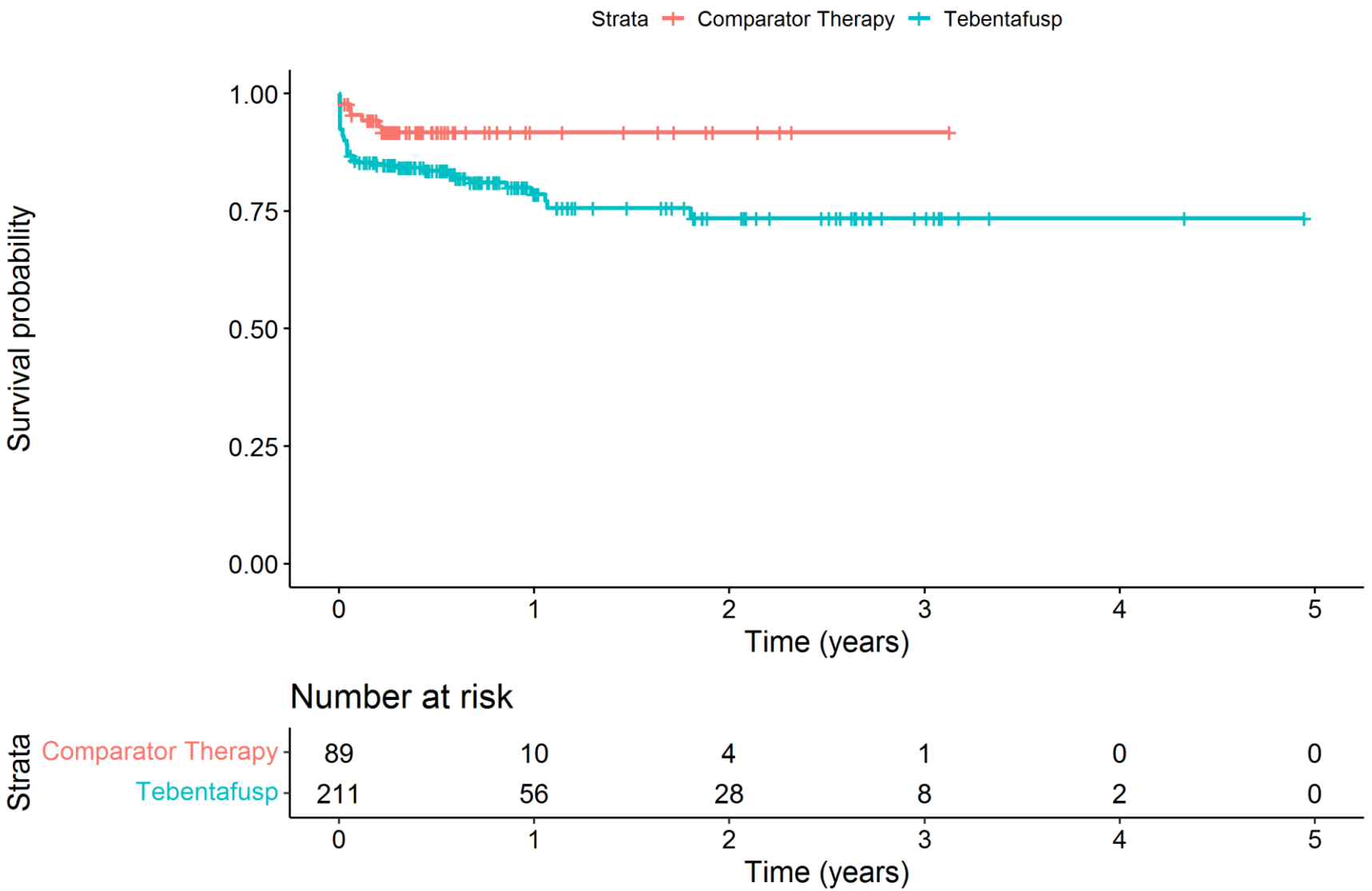
Erhöhte Alanin-Aminotransferase - Gesamt



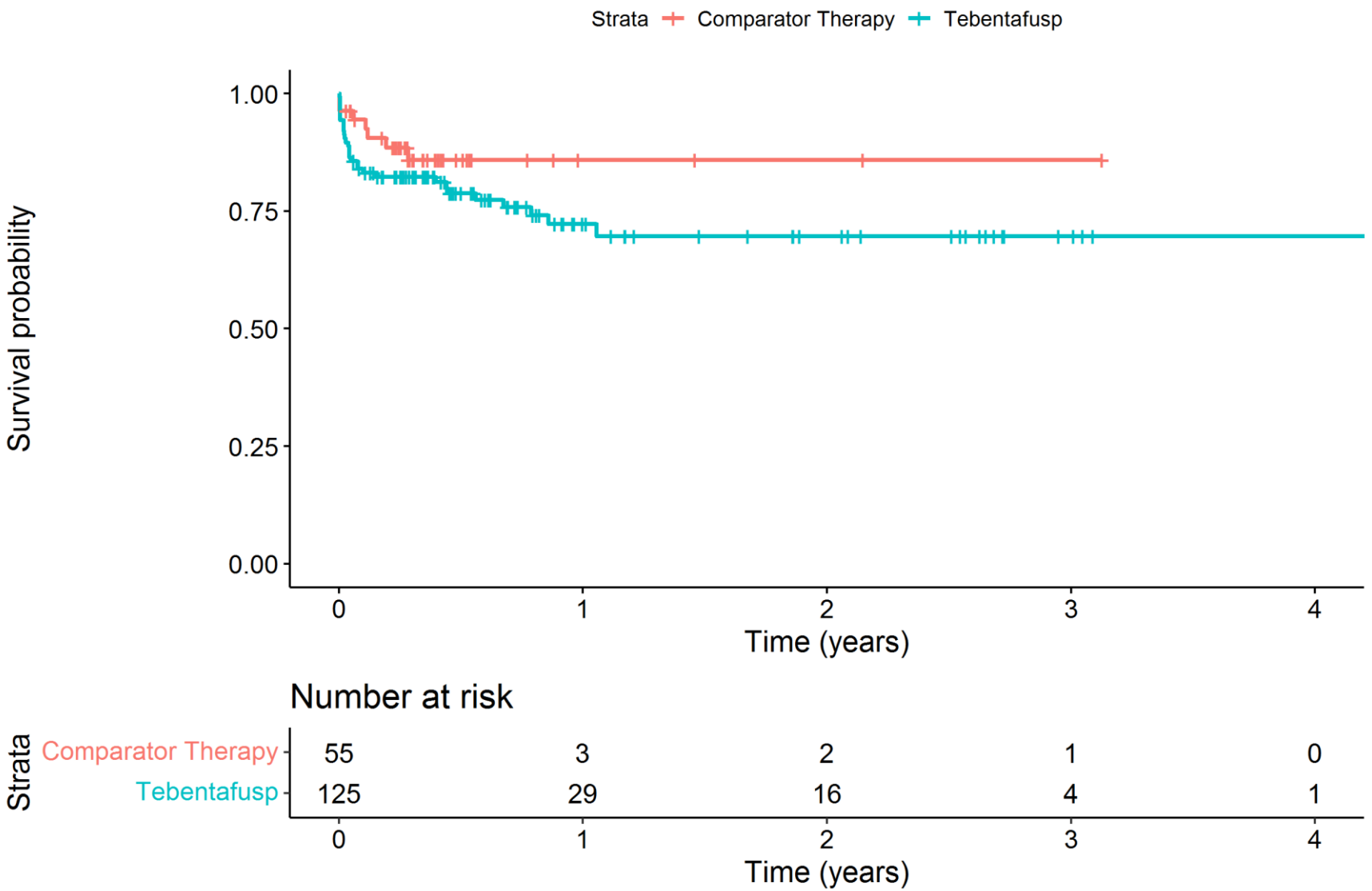
Erhöhte Alanin-Aminotransferase - Hispanisch



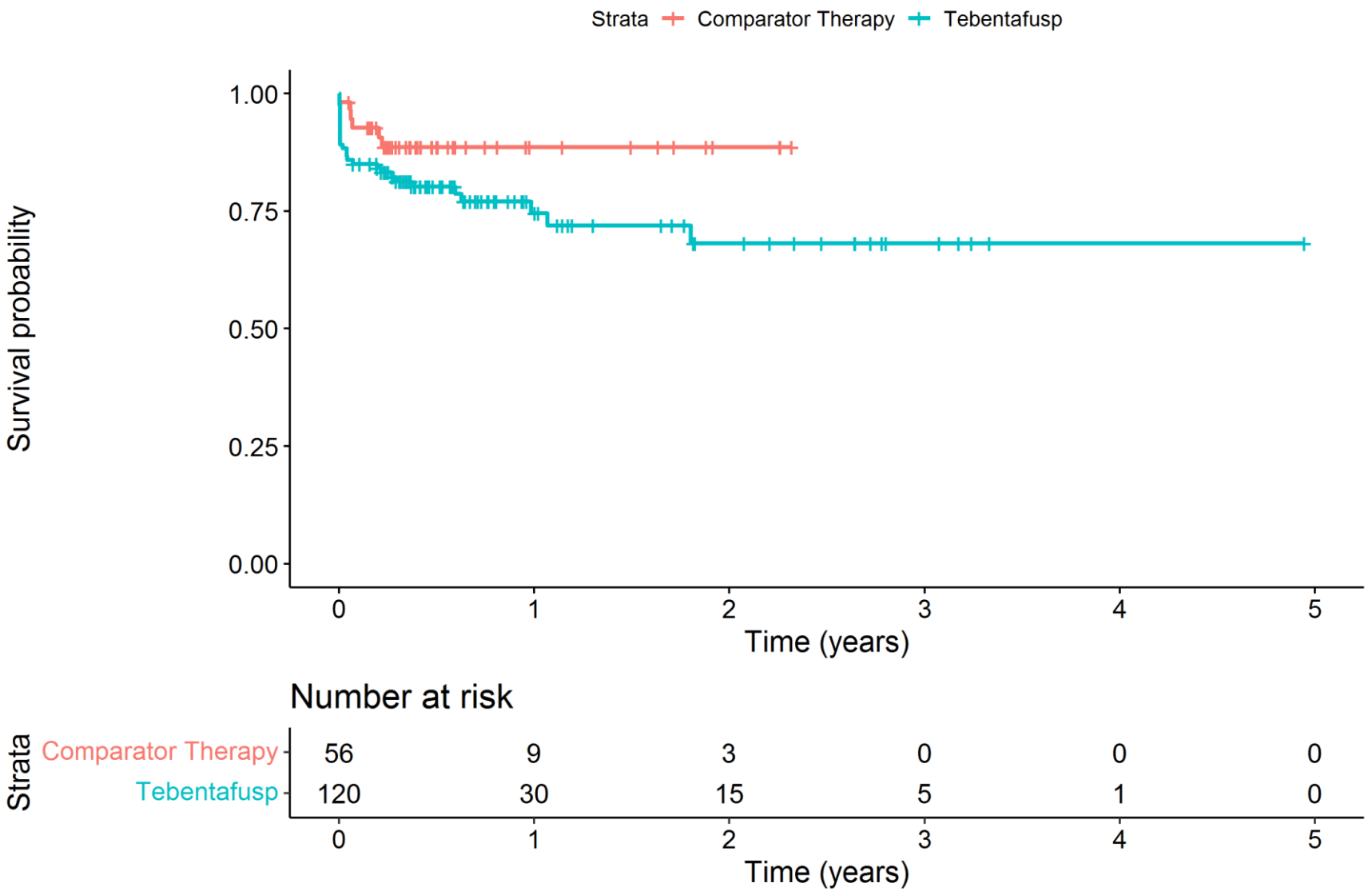
Erhöhte Alanin-Aminotransferase - Nicht-hispanisch



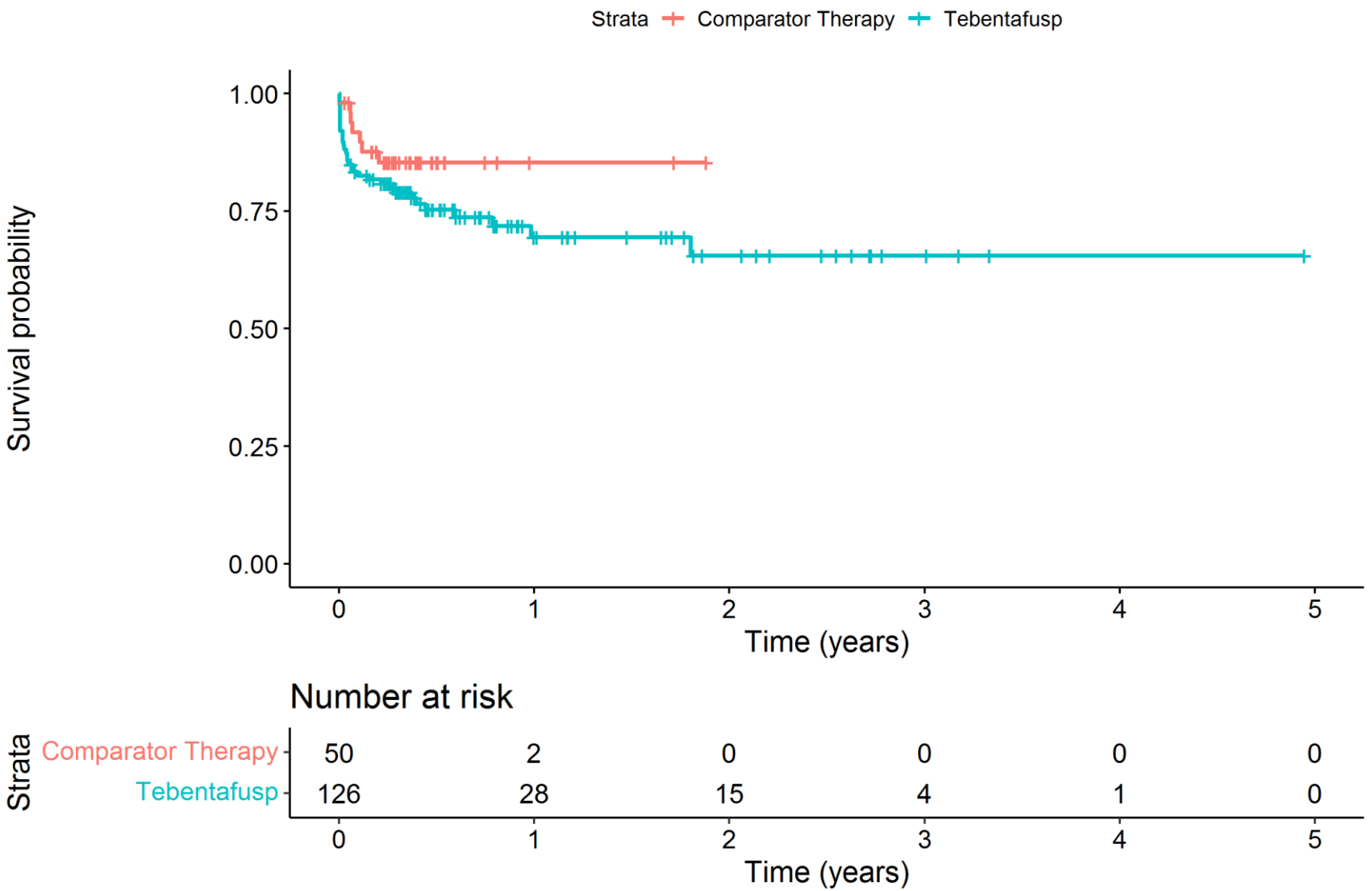
Erhöhte Alanin-Aminotransferase - Männlich



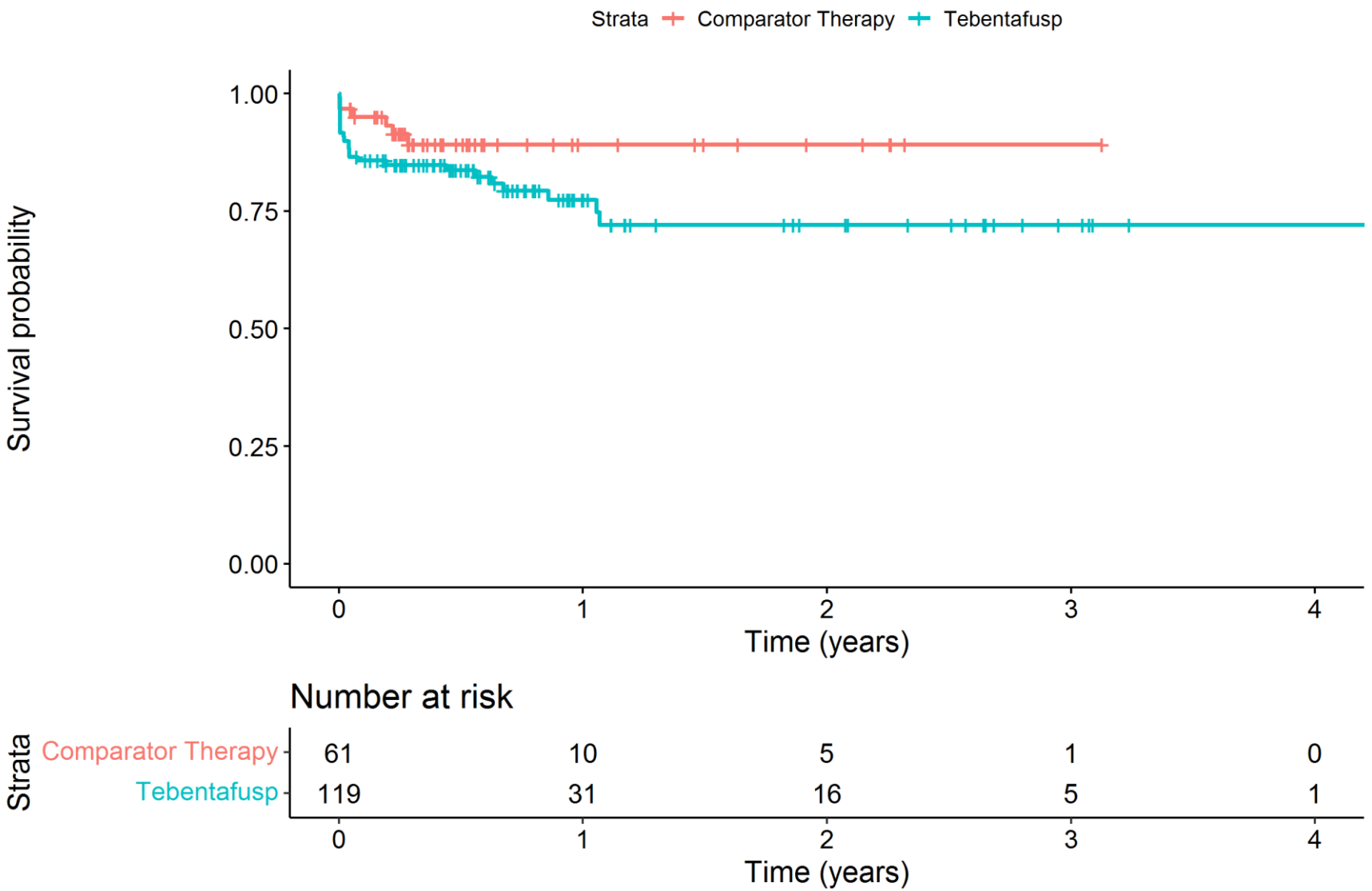
Erhöhte Alanin-Aminotransferase - Weiblich



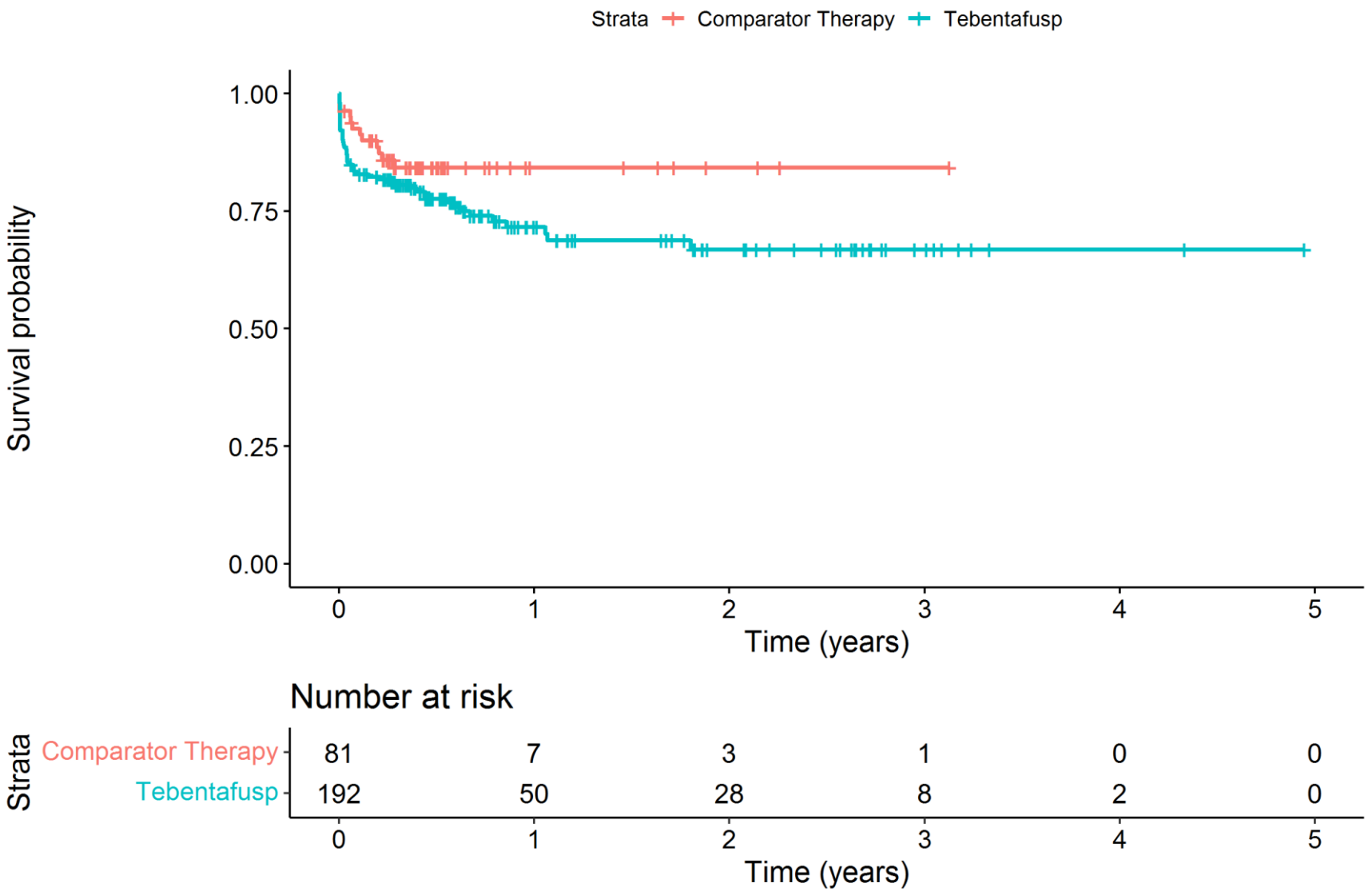
Erhöhte Alanin-Aminotransferase - <65



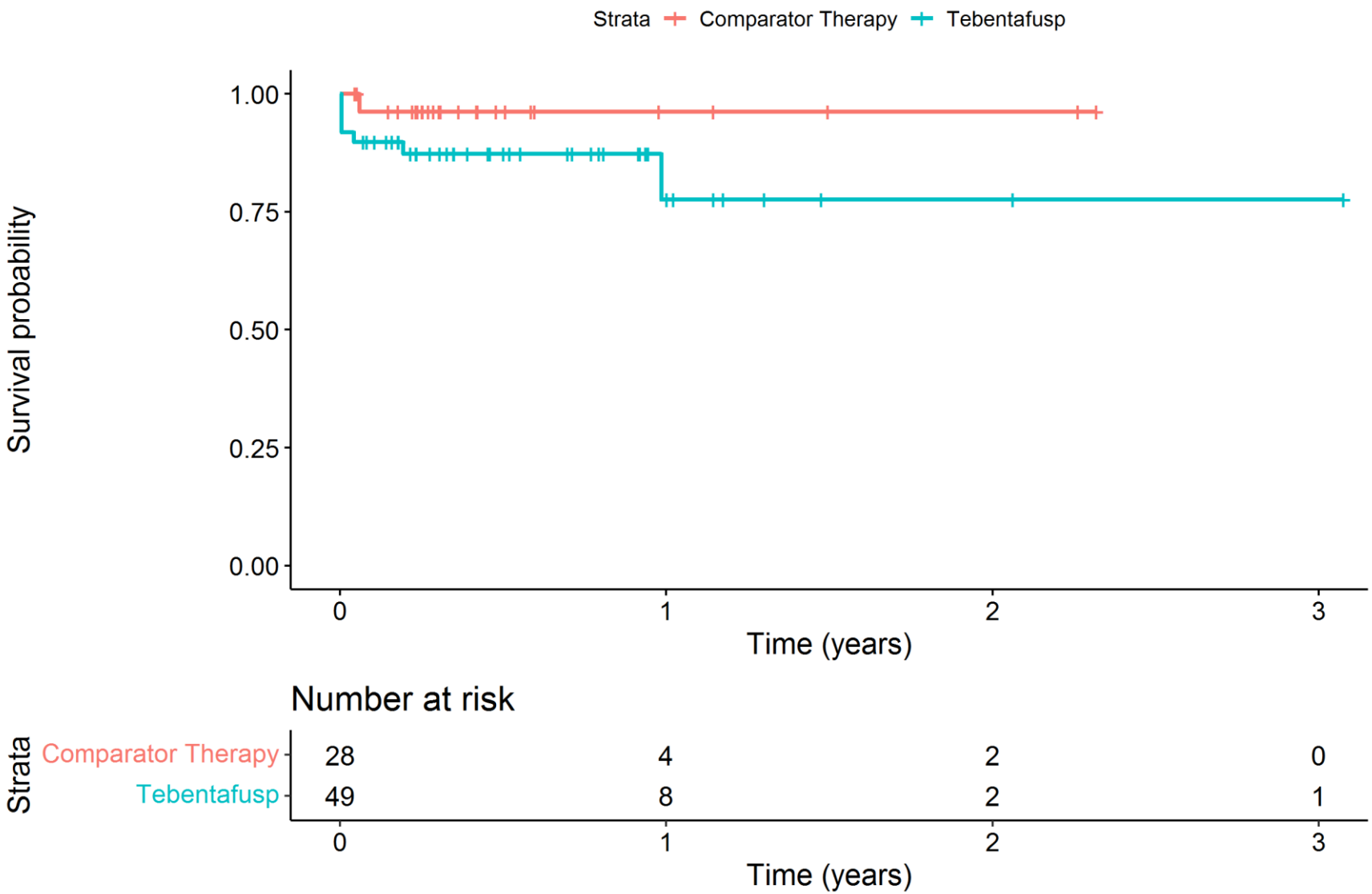
Erhöhte Alanin-Aminotransferase - ≥65



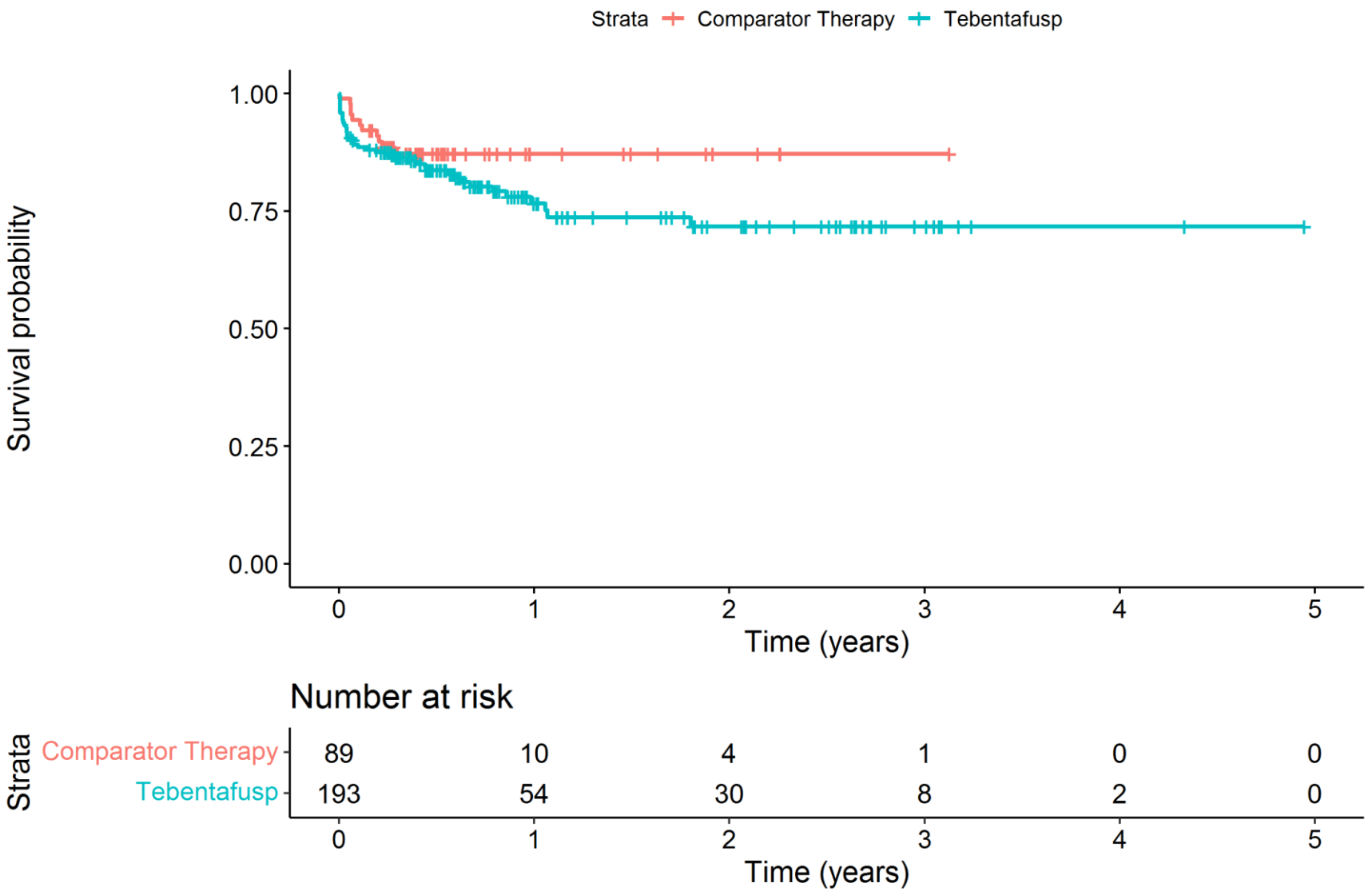
Erhöhte Alanin-Aminotransferase - ECOG 0



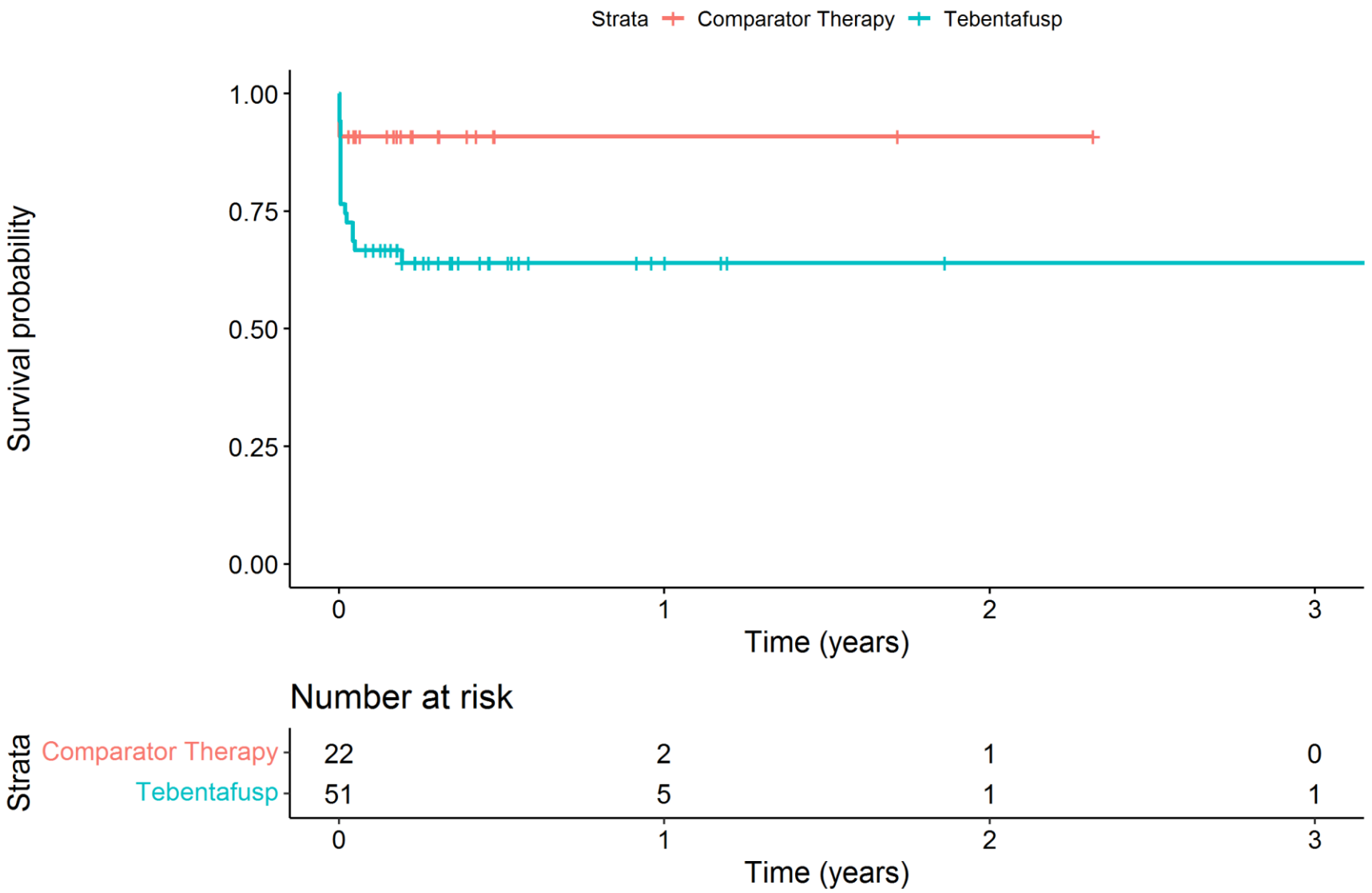
Erhöhte Alanin-Aminotransferase - ECOG 1



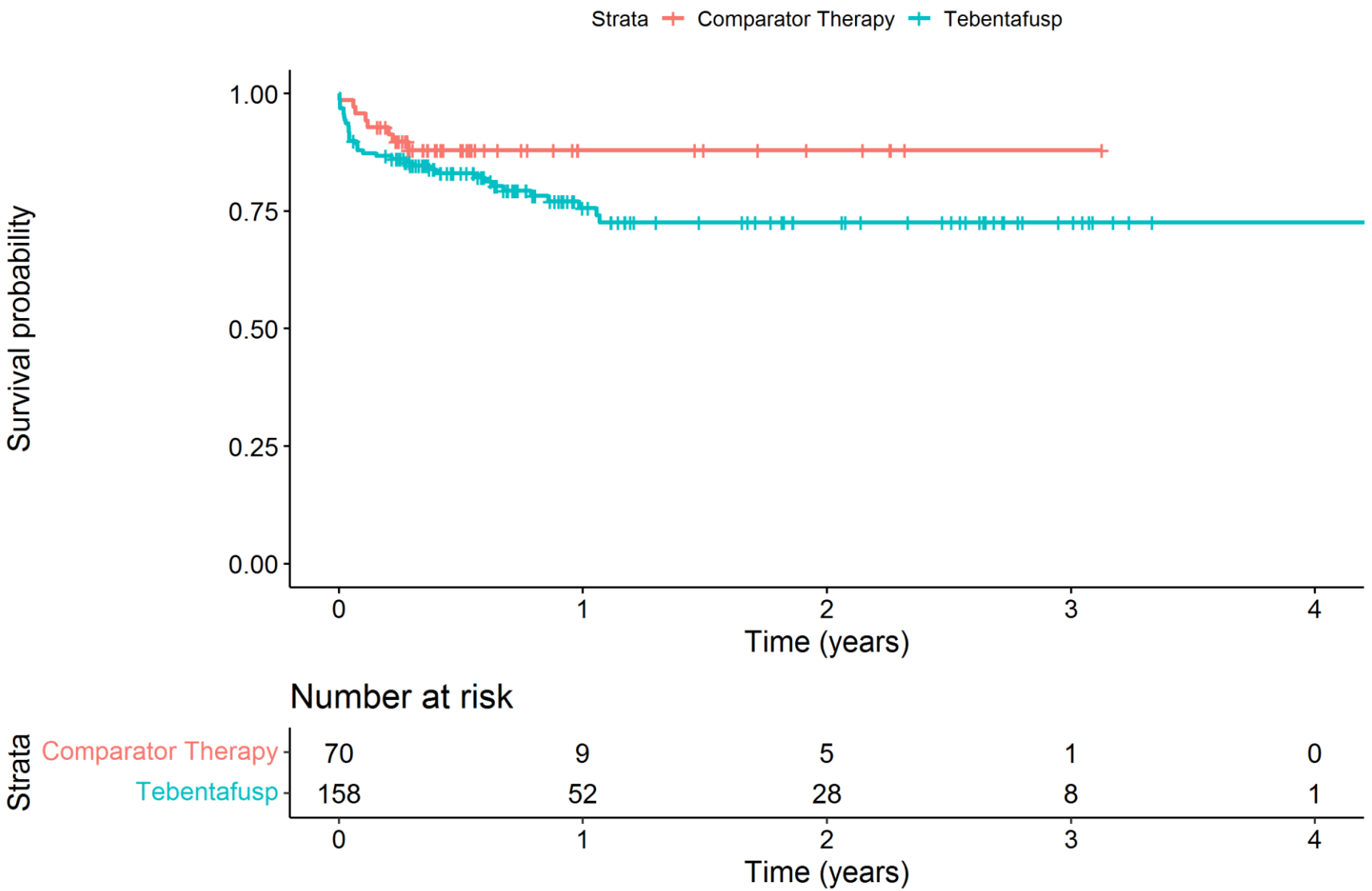
Erhöhte Alanin-Aminotransferase - ALP ≤ ULN



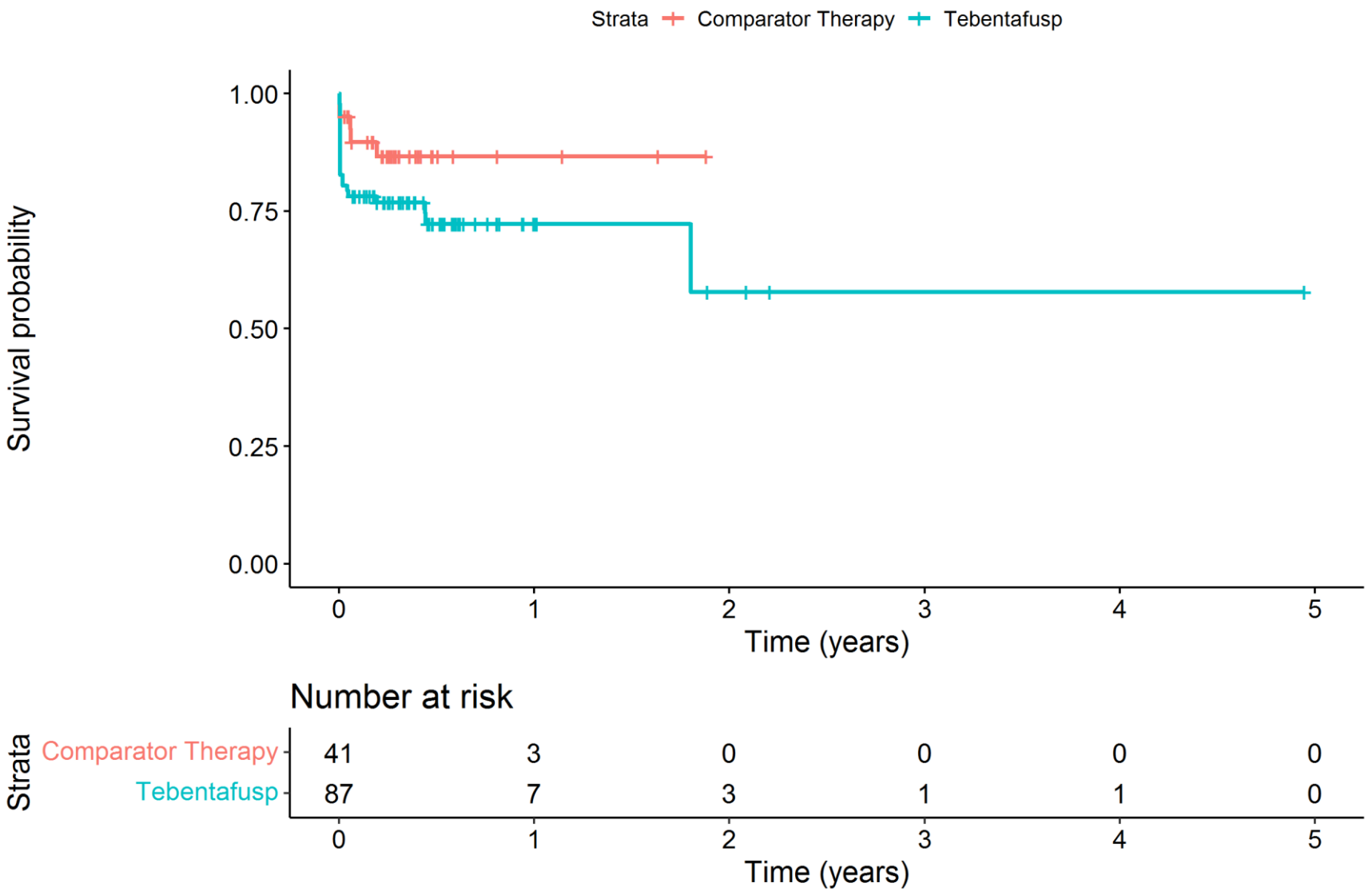
Erhöhte Alanin-Aminotransferase - ALP > ULN



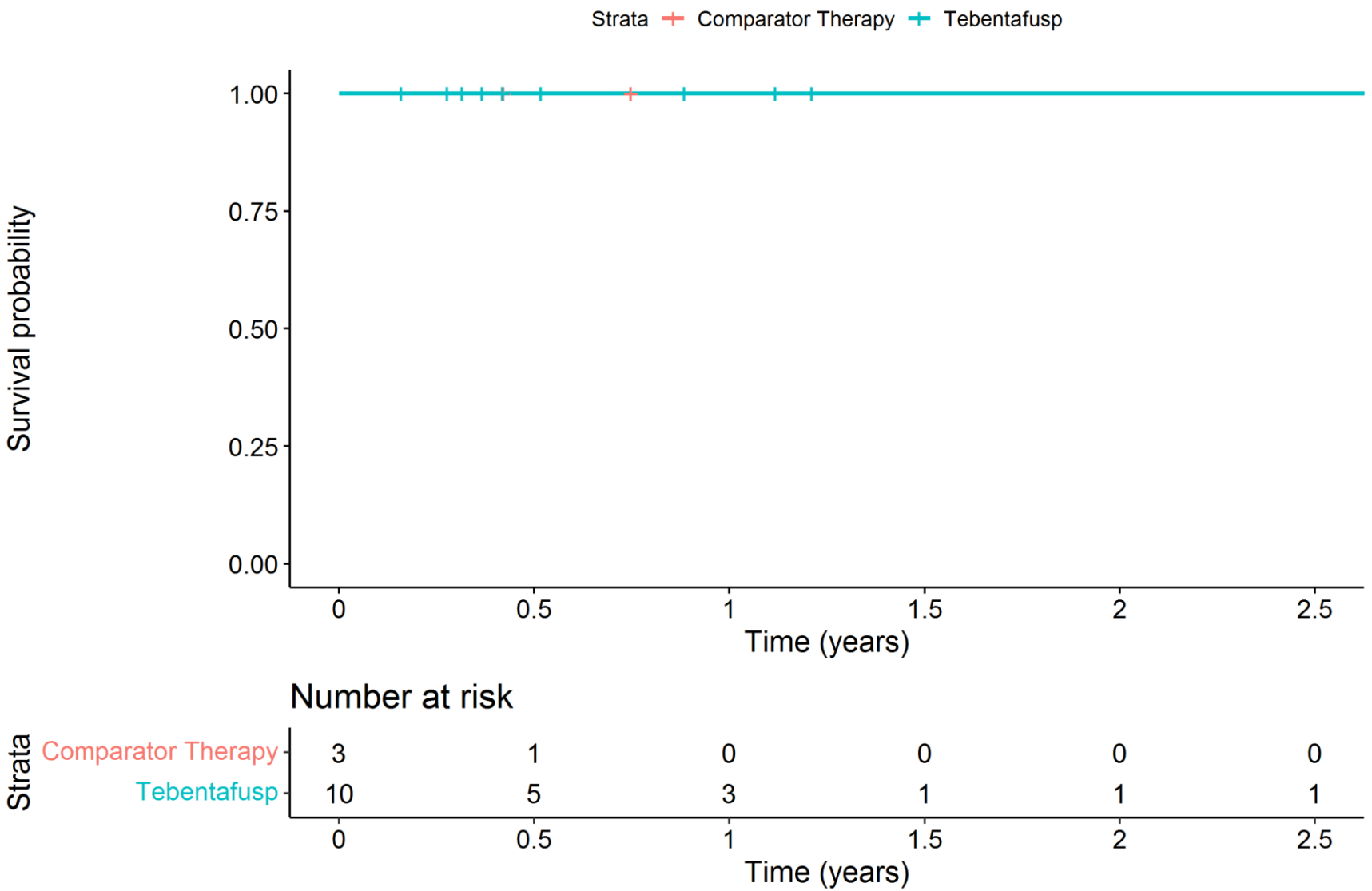
Erhöhte Alanin-Aminotransferase - LDH =< ULN



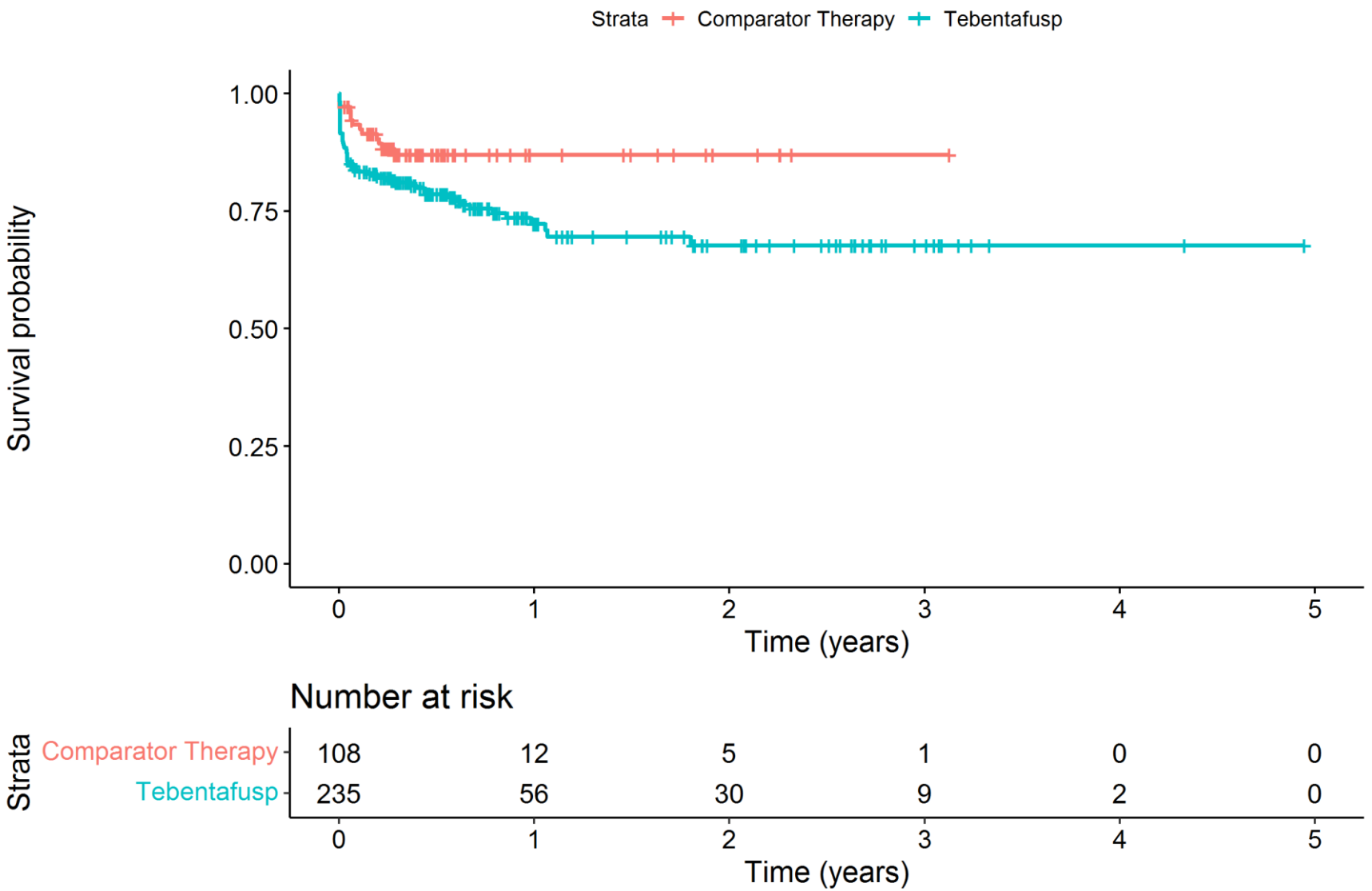
Erhöhte Alanin-Aminotransferase - LDH > ULN



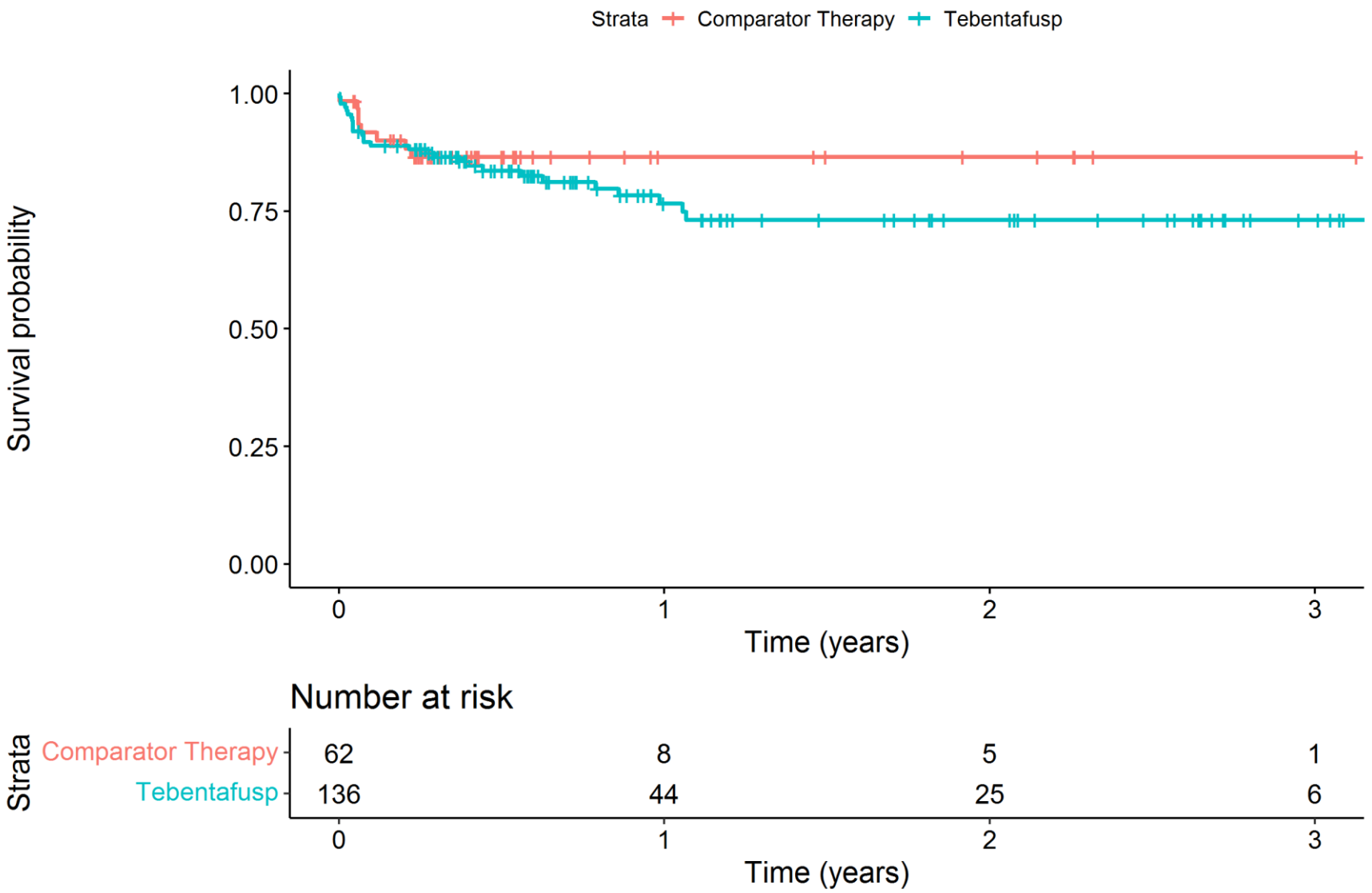
Erhöhte Alanin-Aminotransferase - Vorherige Therapie adjuvant/neoadjuvant



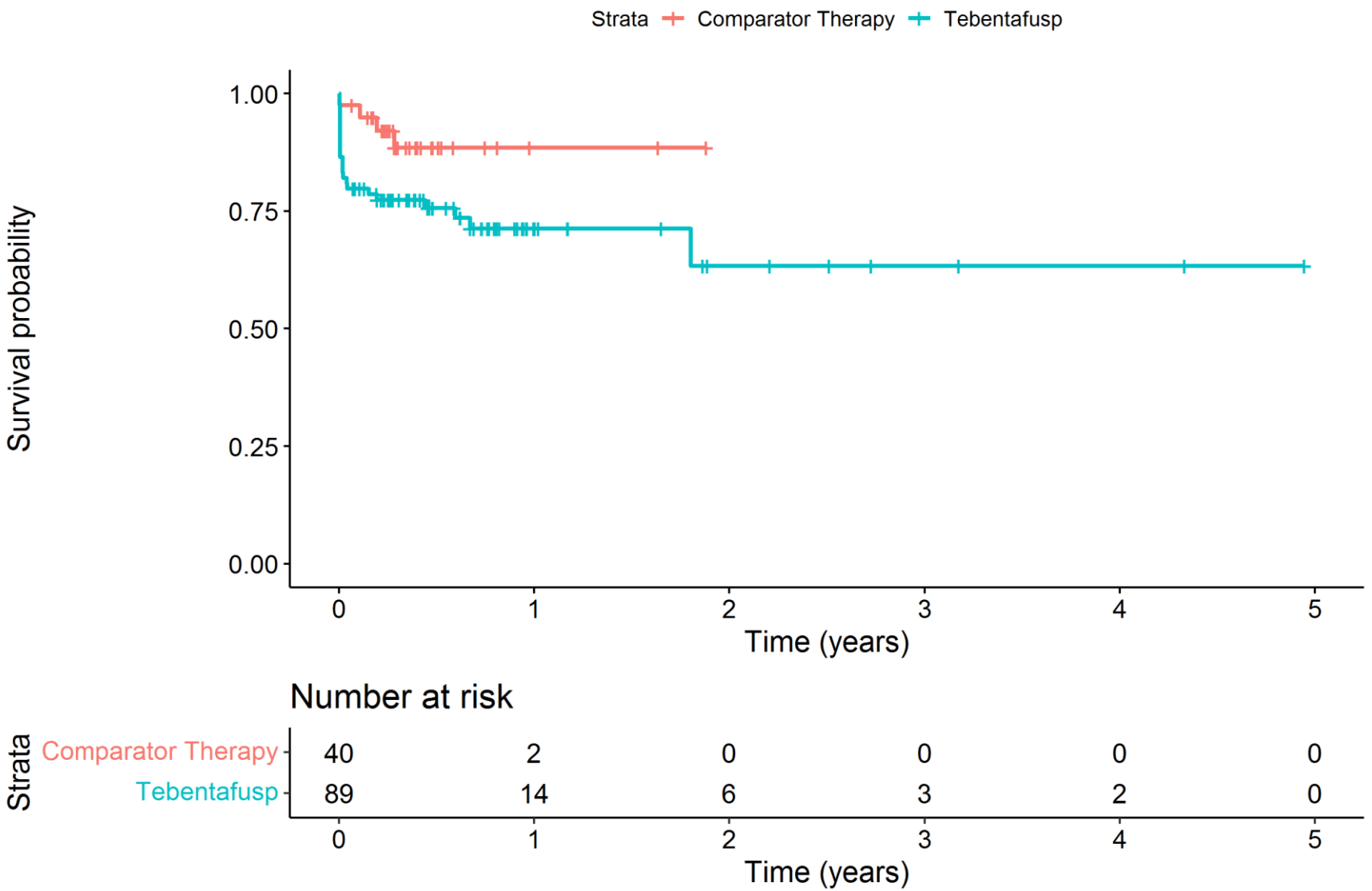
Erhöhte Alanin-Aminotransferase - Keine Vorherige Therapie adjuvant/neoadjuvant



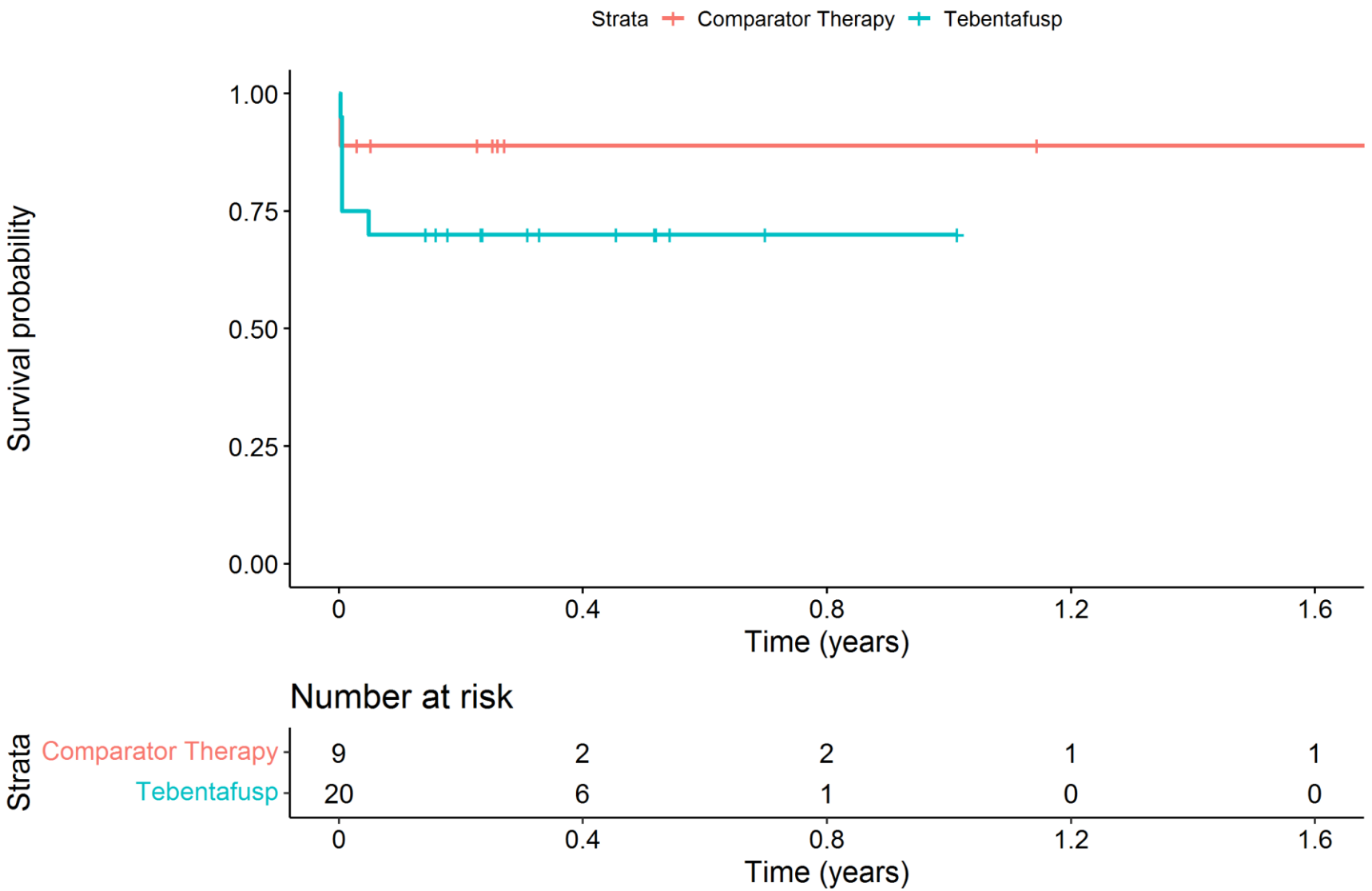
Erhöhte Alanin-Aminotransferase - Läsion ≤ 3cm



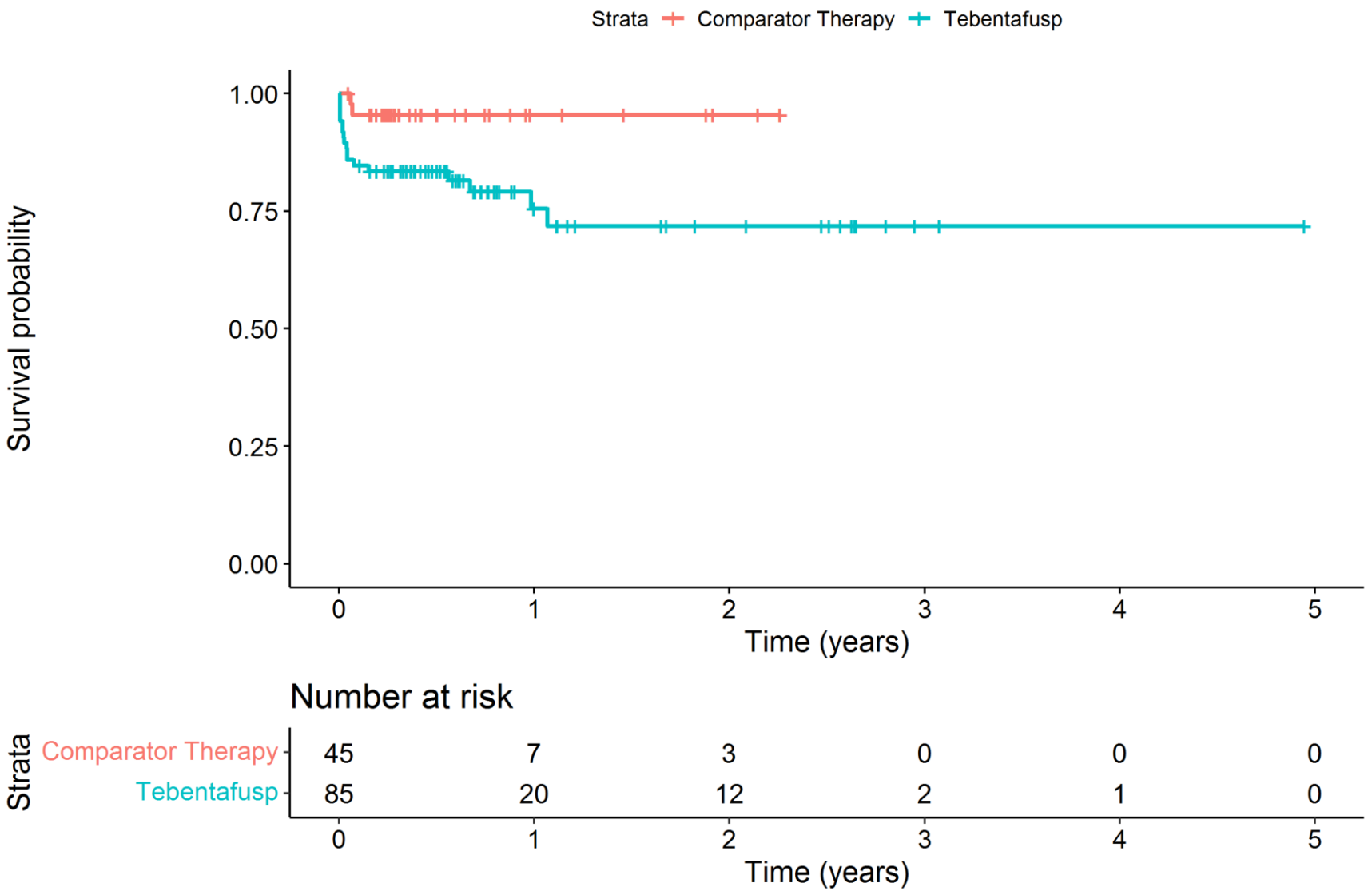
Erhöhte Alanin-Aminotransferase - Läsion 3,1-8,0 cm



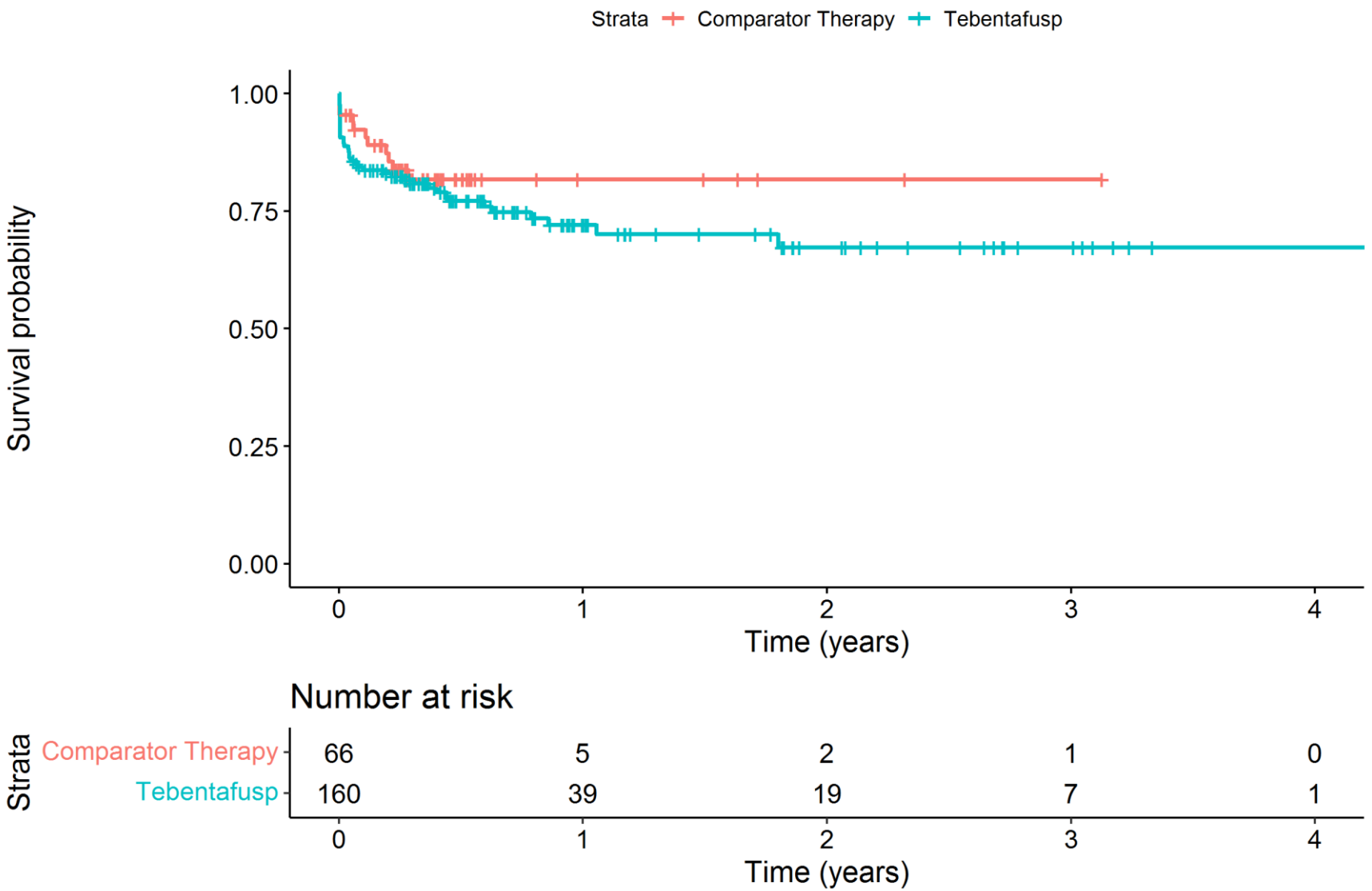
Erhöhte Alanin-Aminotransferase - Läsion ≥8,1 cm



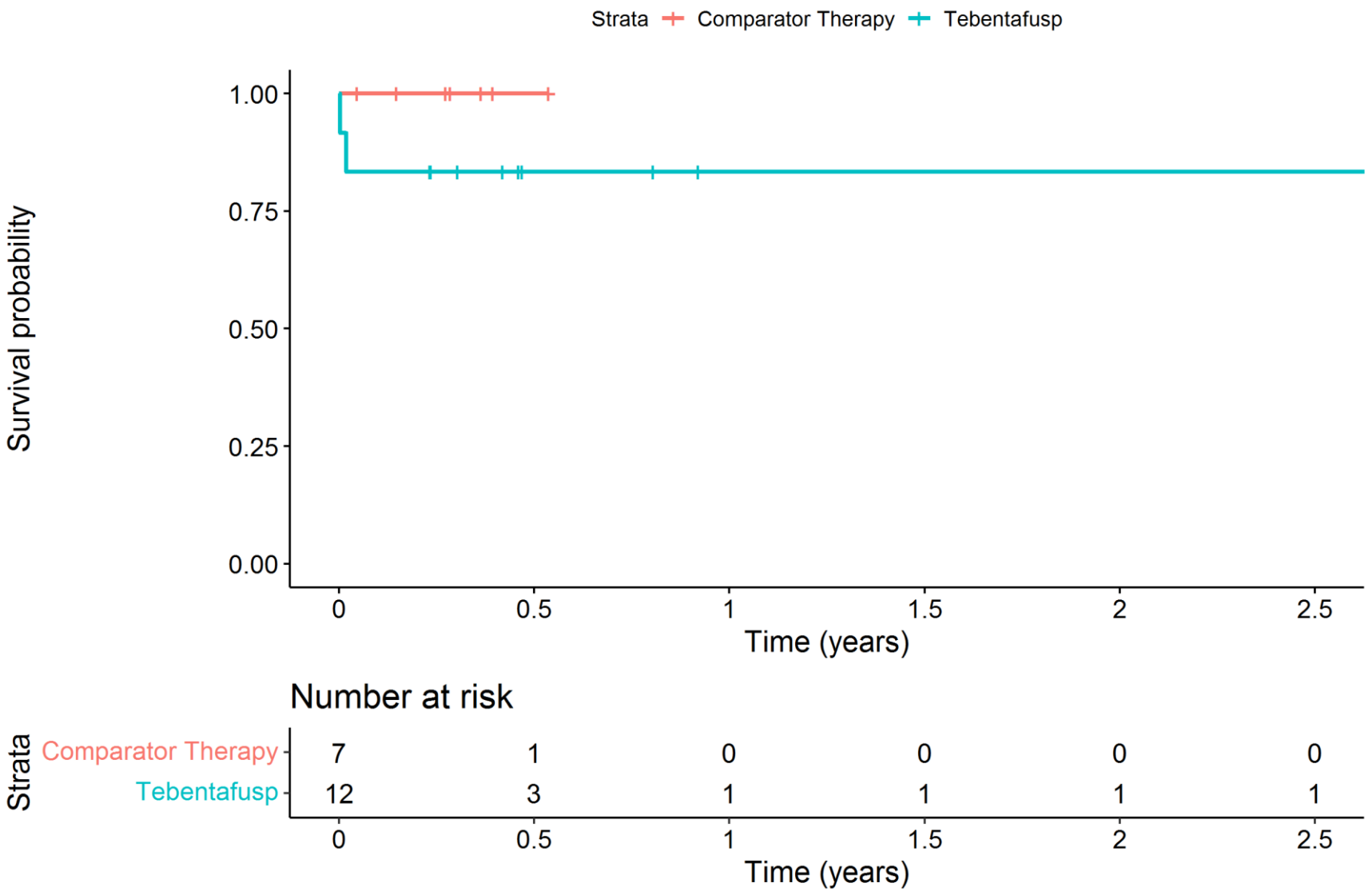
Erhöhte Alanin-Aminotransferase - Nordamerika



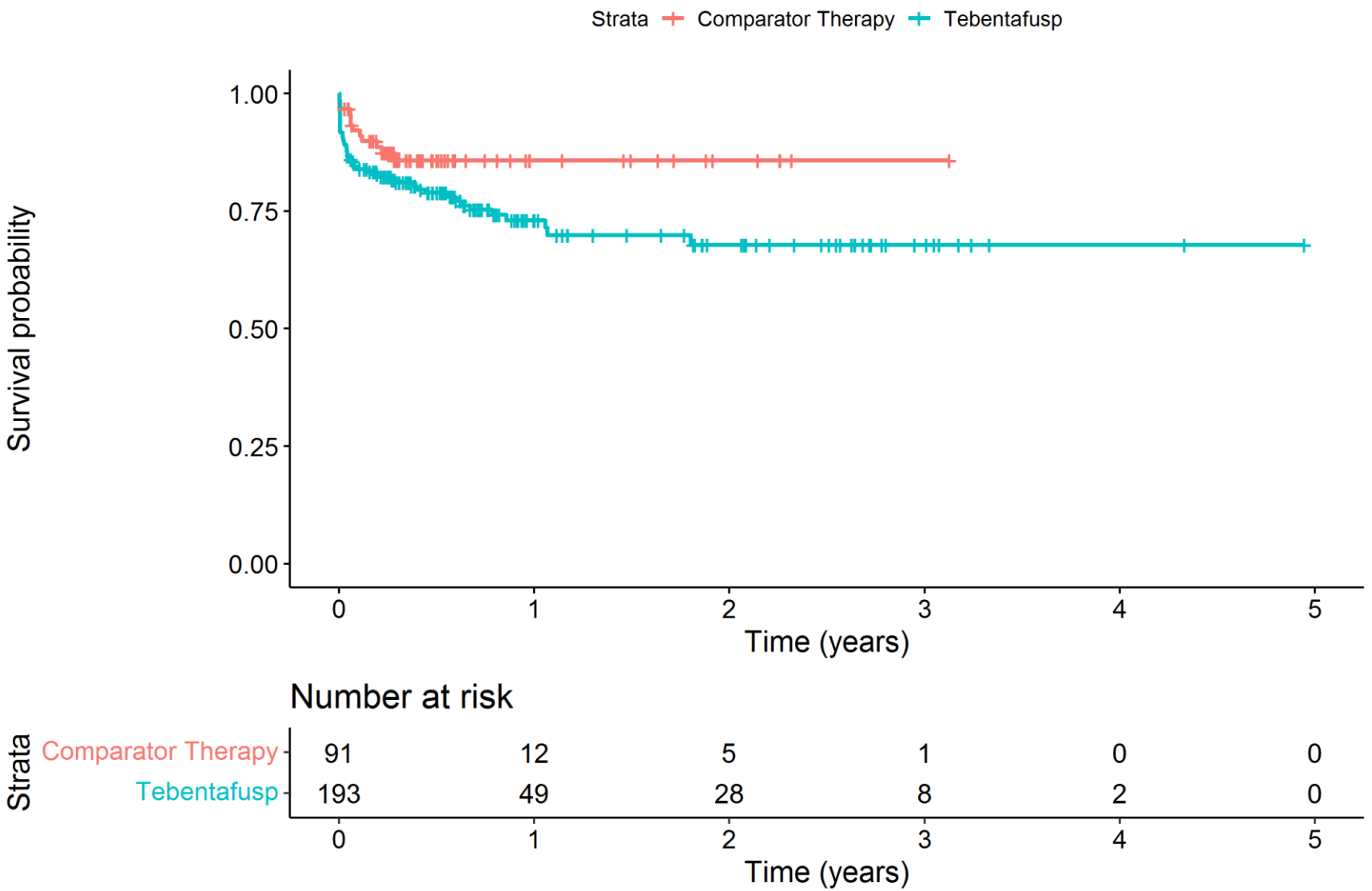
Erhöhte Alanin-Aminotransferase - Nicht-Nordamerika



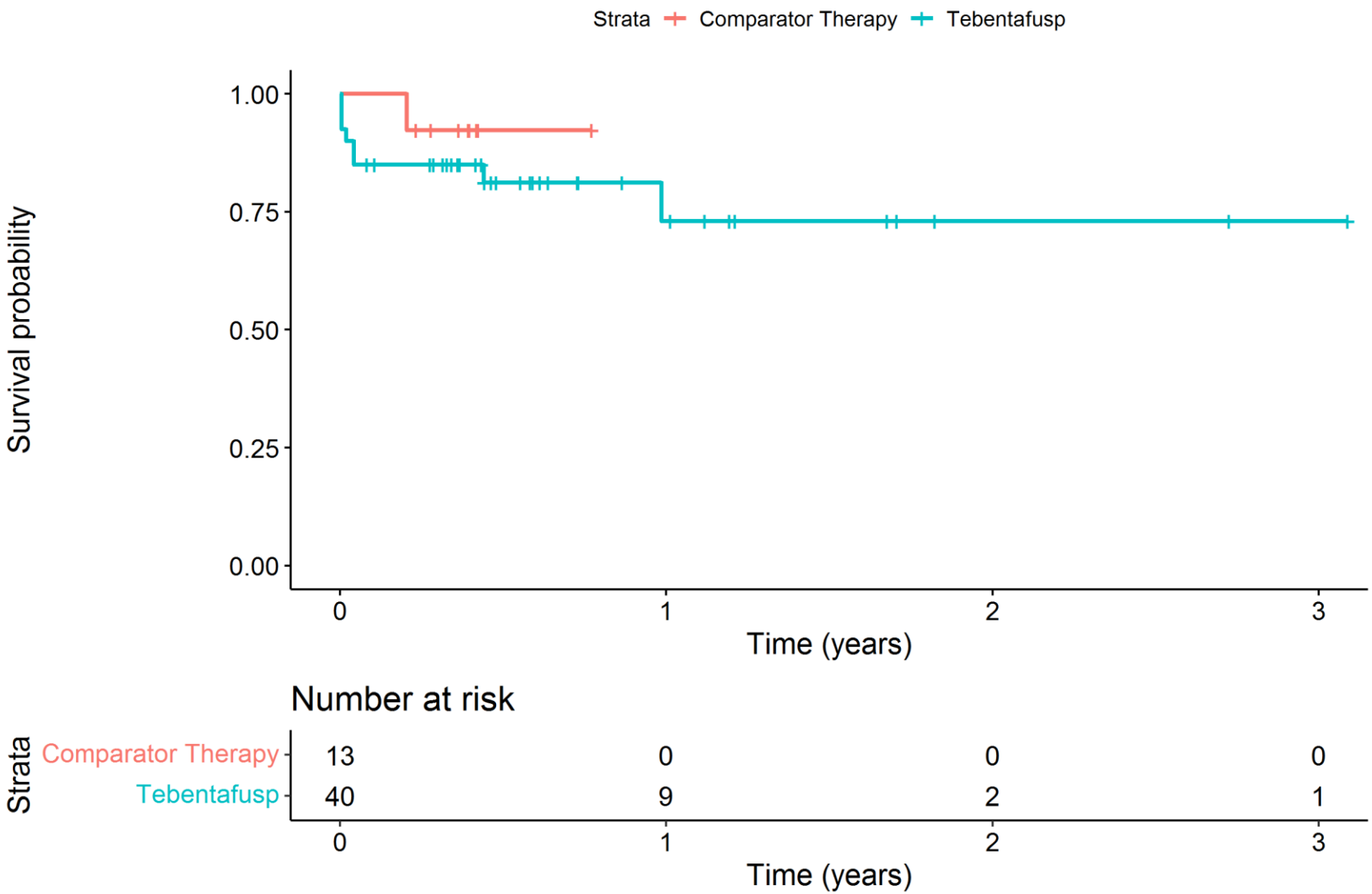
Erhöhte Alanin-Aminotransferase - Dacarbazin



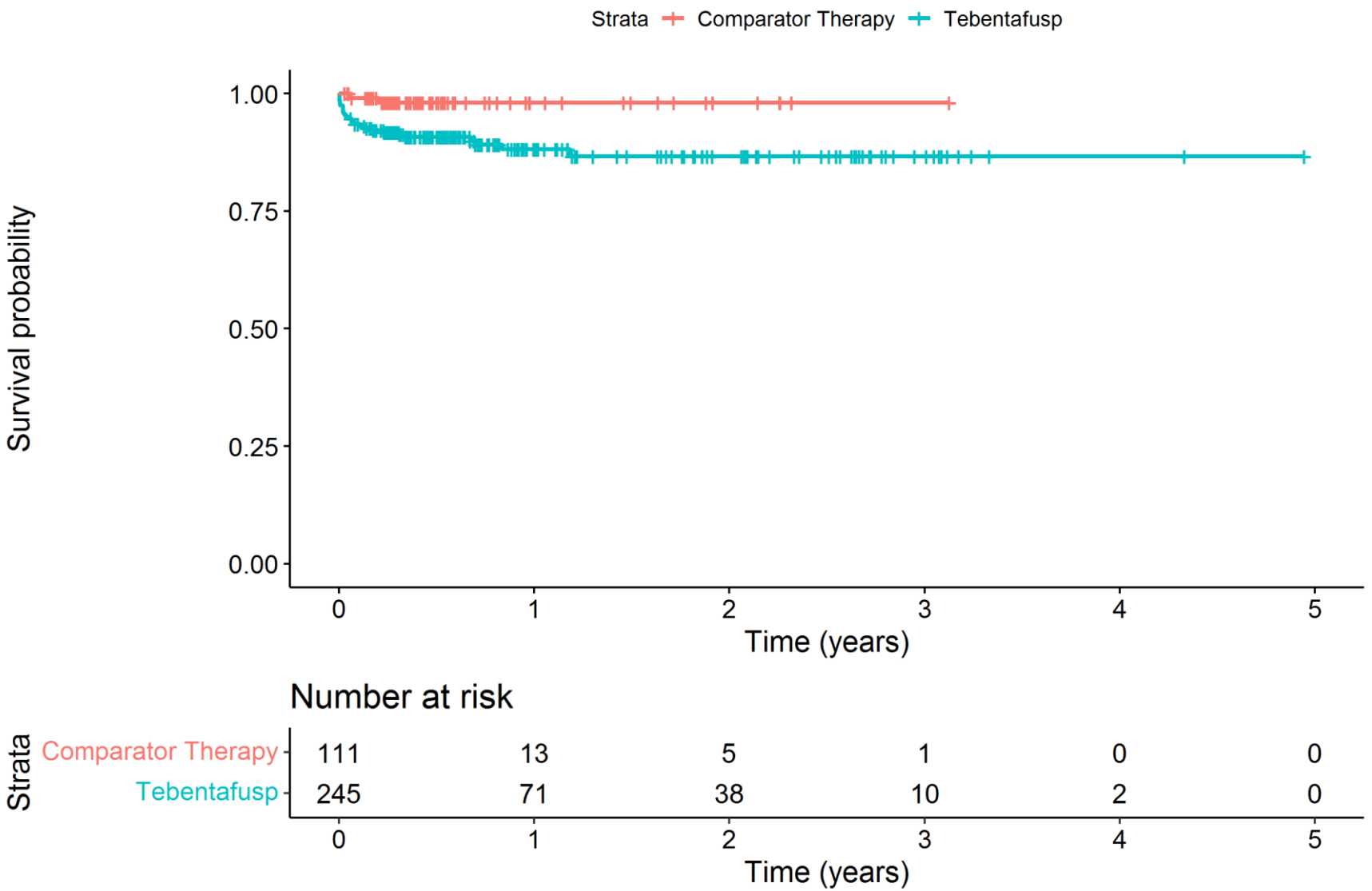
Erhöhte Alanin-Aminotransferase - Pembrolizumab



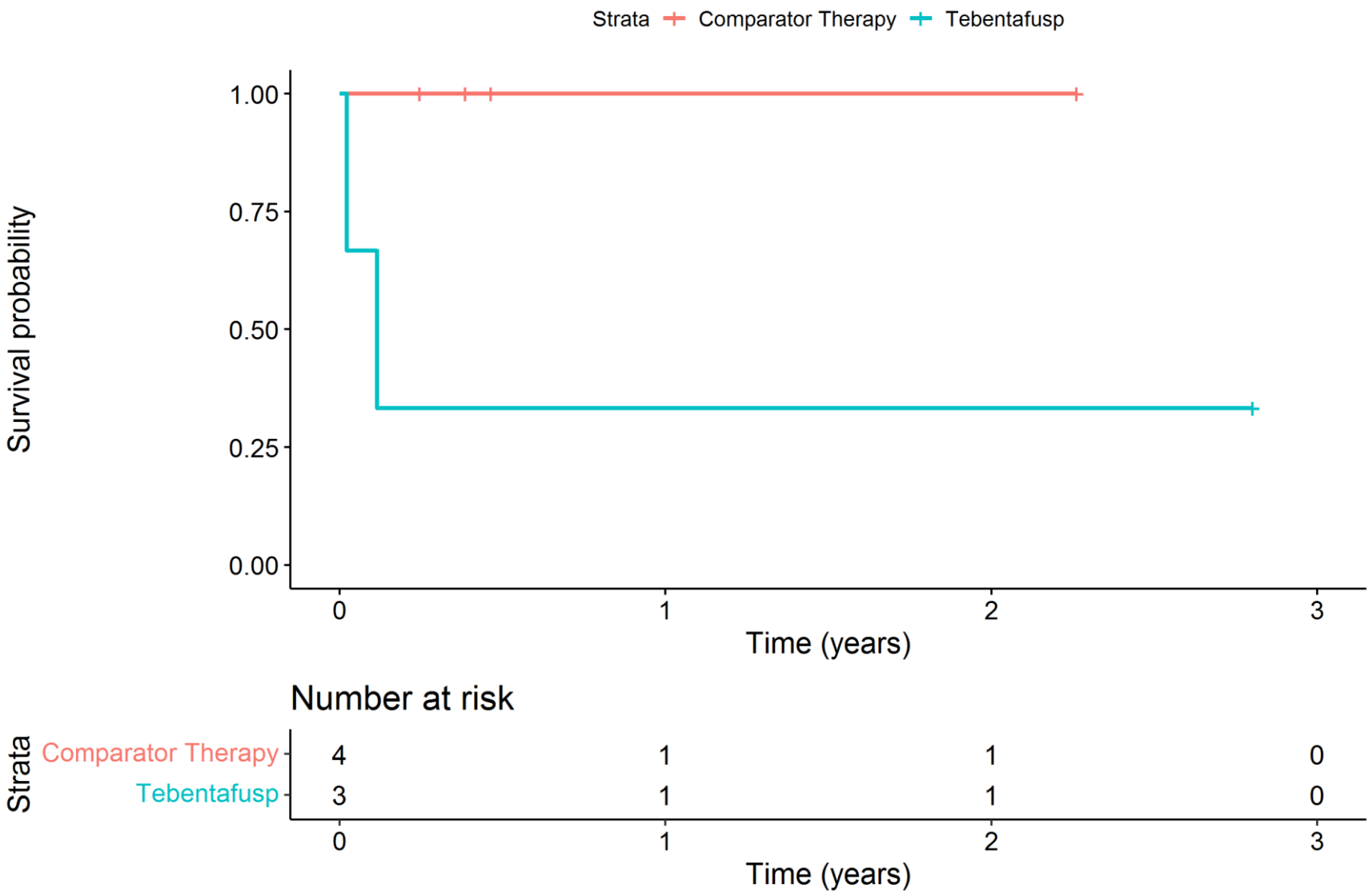
Erhöhte Alanin-Aminotransferase - Ipilimumab



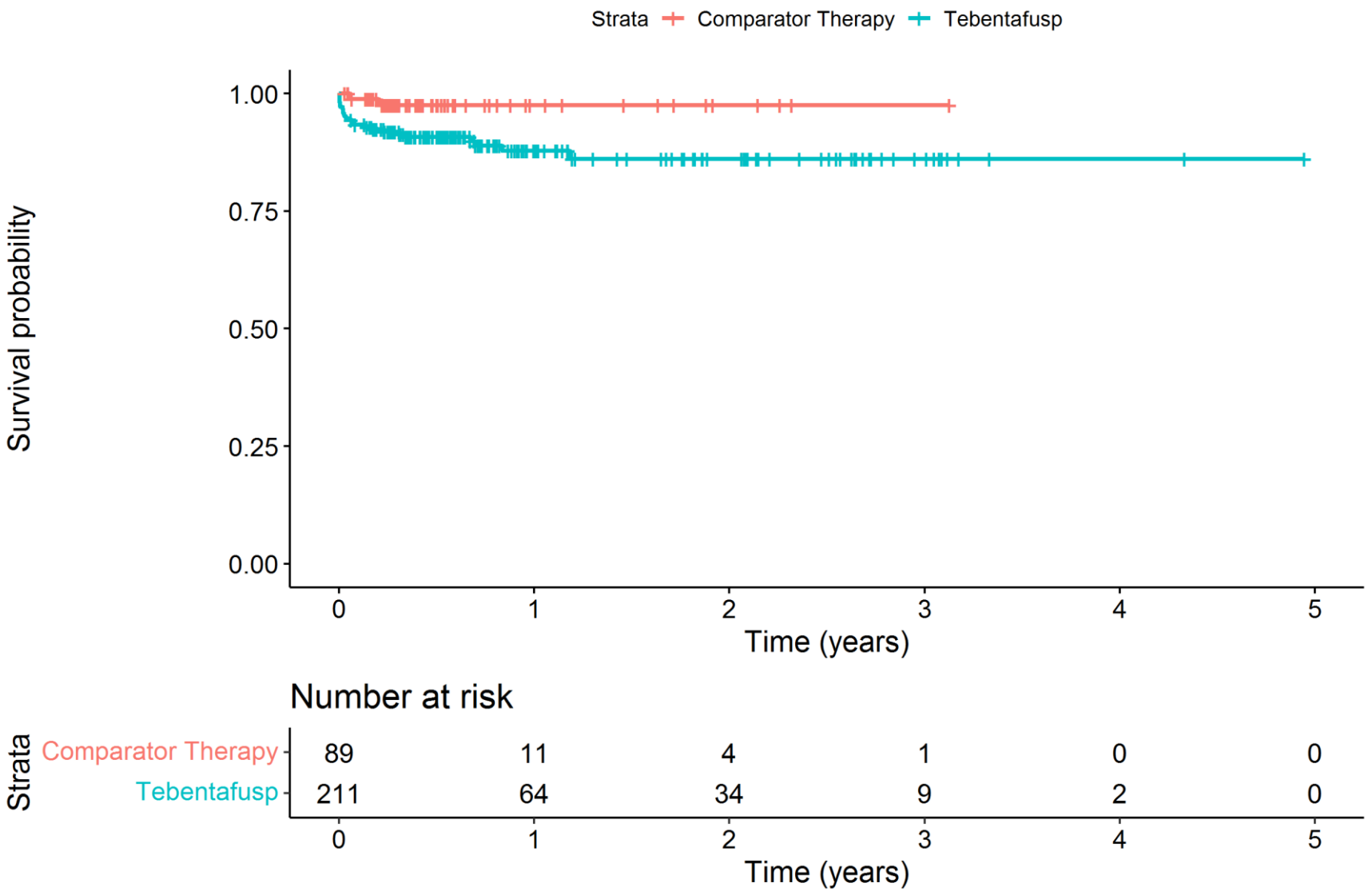
Erhöhte Alkalische Phosphatase - Gesamt



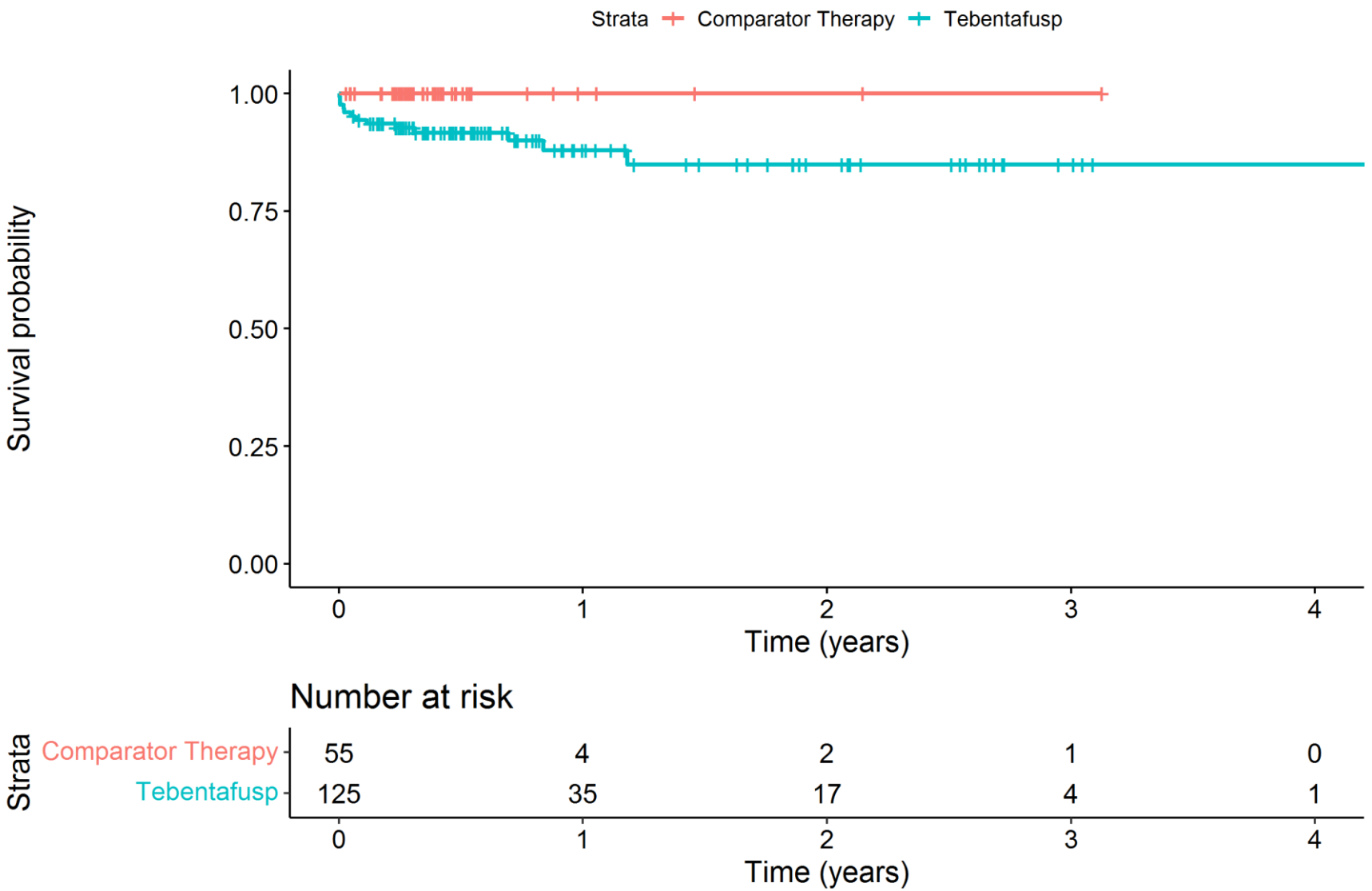
Erhöhte Alkalische Phosphatase - Hispanisch



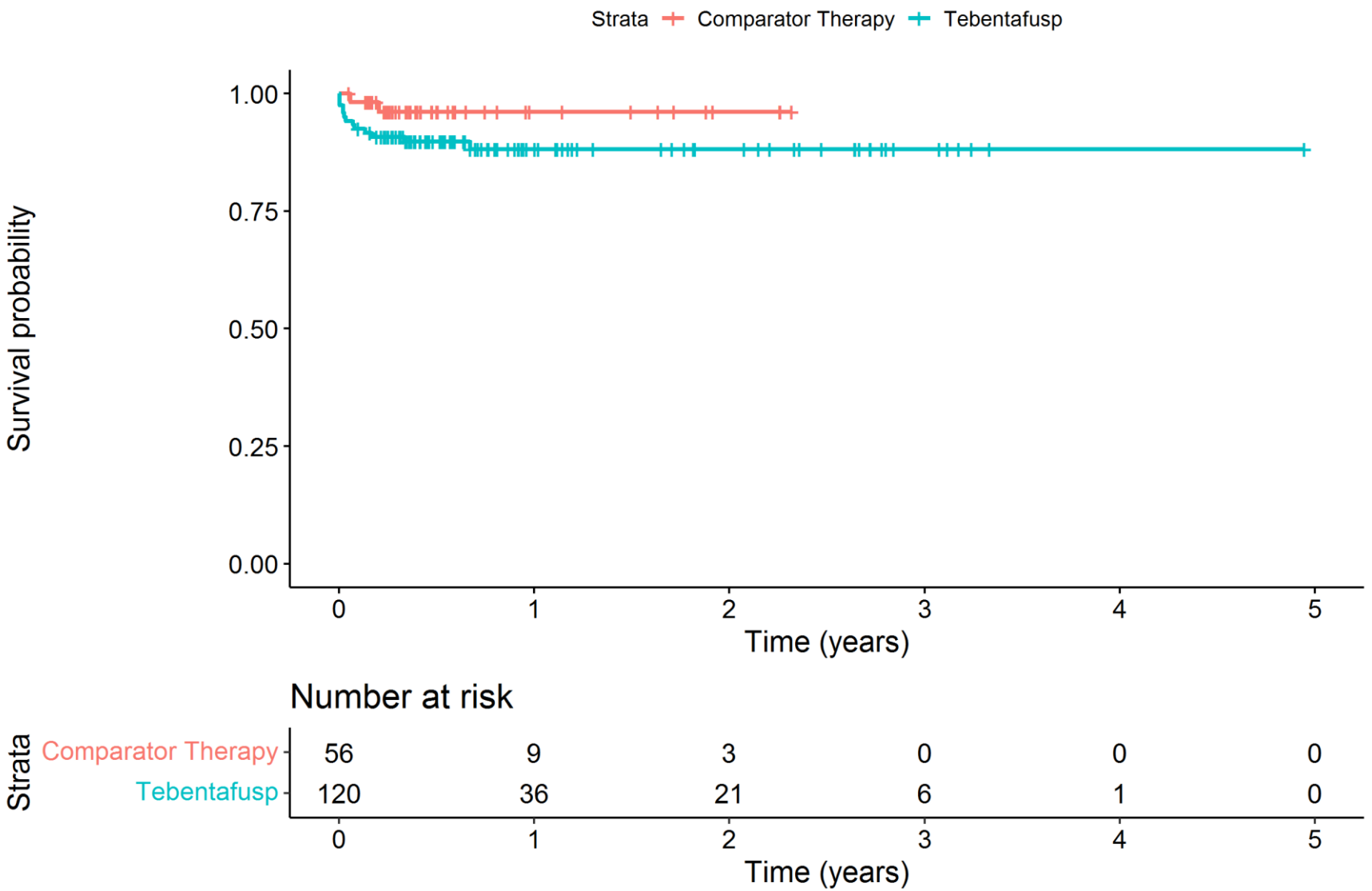
Erhöhte Alkalische Phosphatase - Nicht-hispanisch



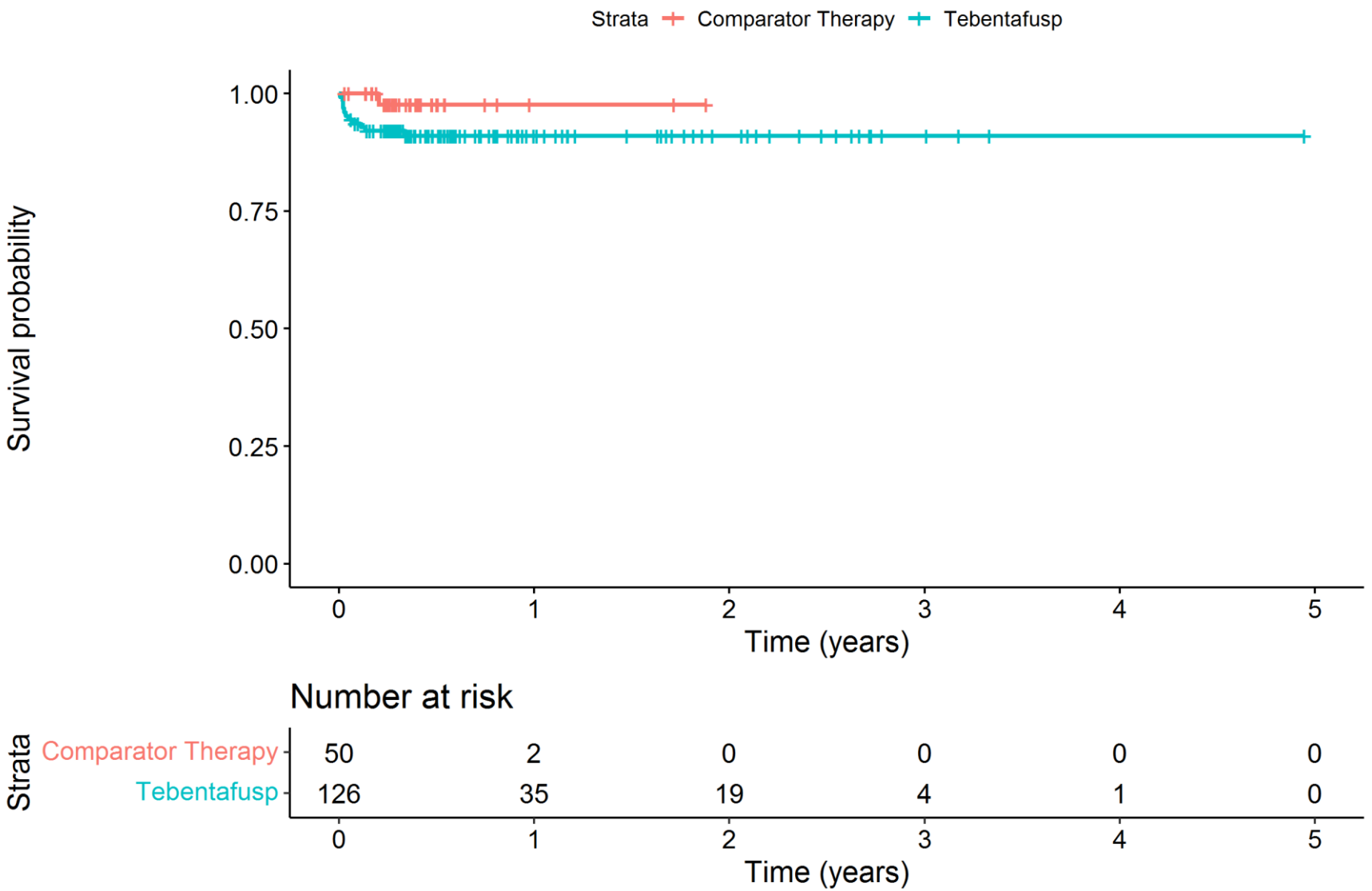
Erhöhte Alkalische Phosphatase - Männlich



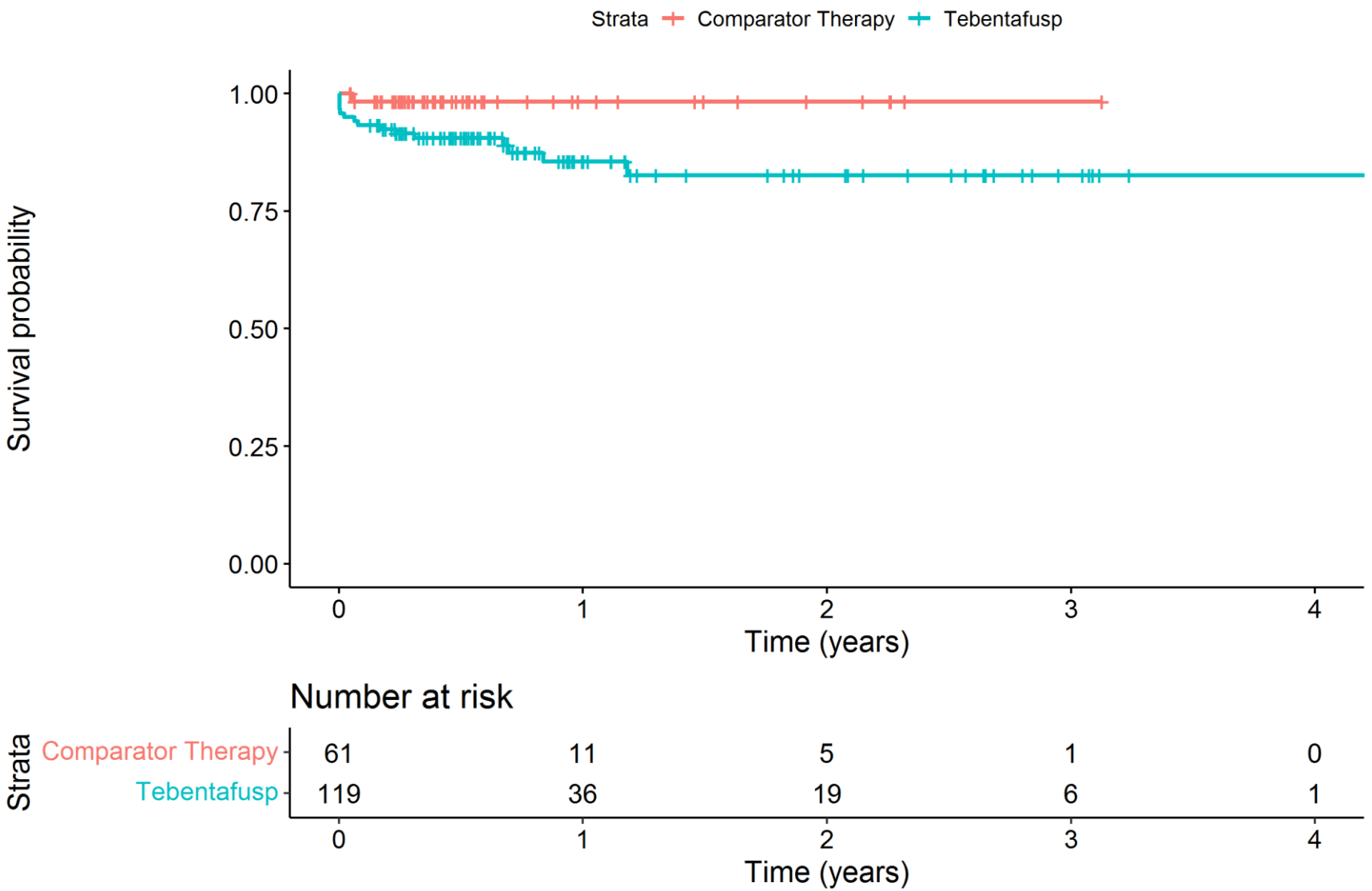
Erhöhte Alkalische Phosphatase - Weiblich



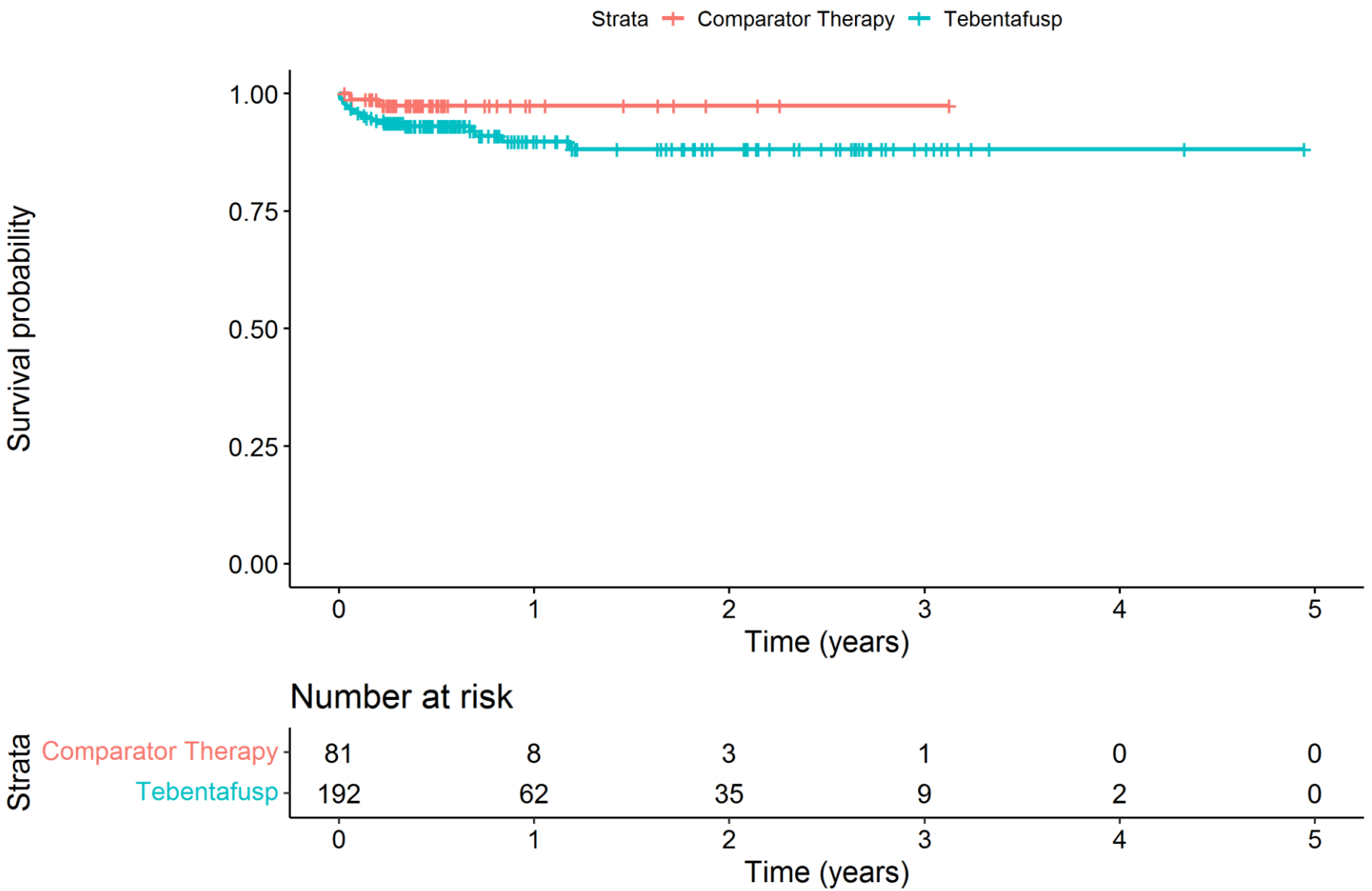
Erhöhte Alkalische Phosphatase - <65



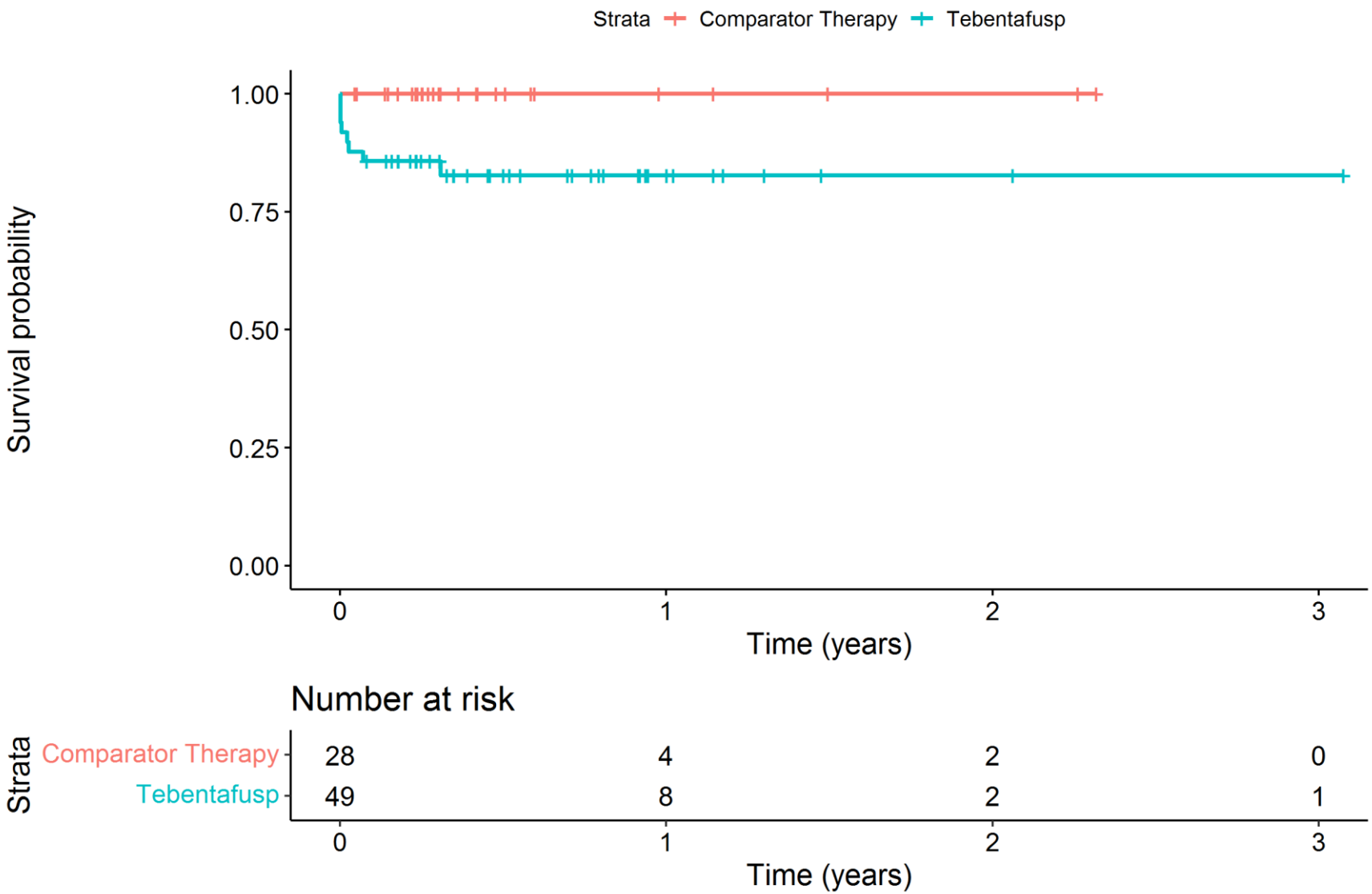
Erhöhte Alkalische Phosphatase - ≥65



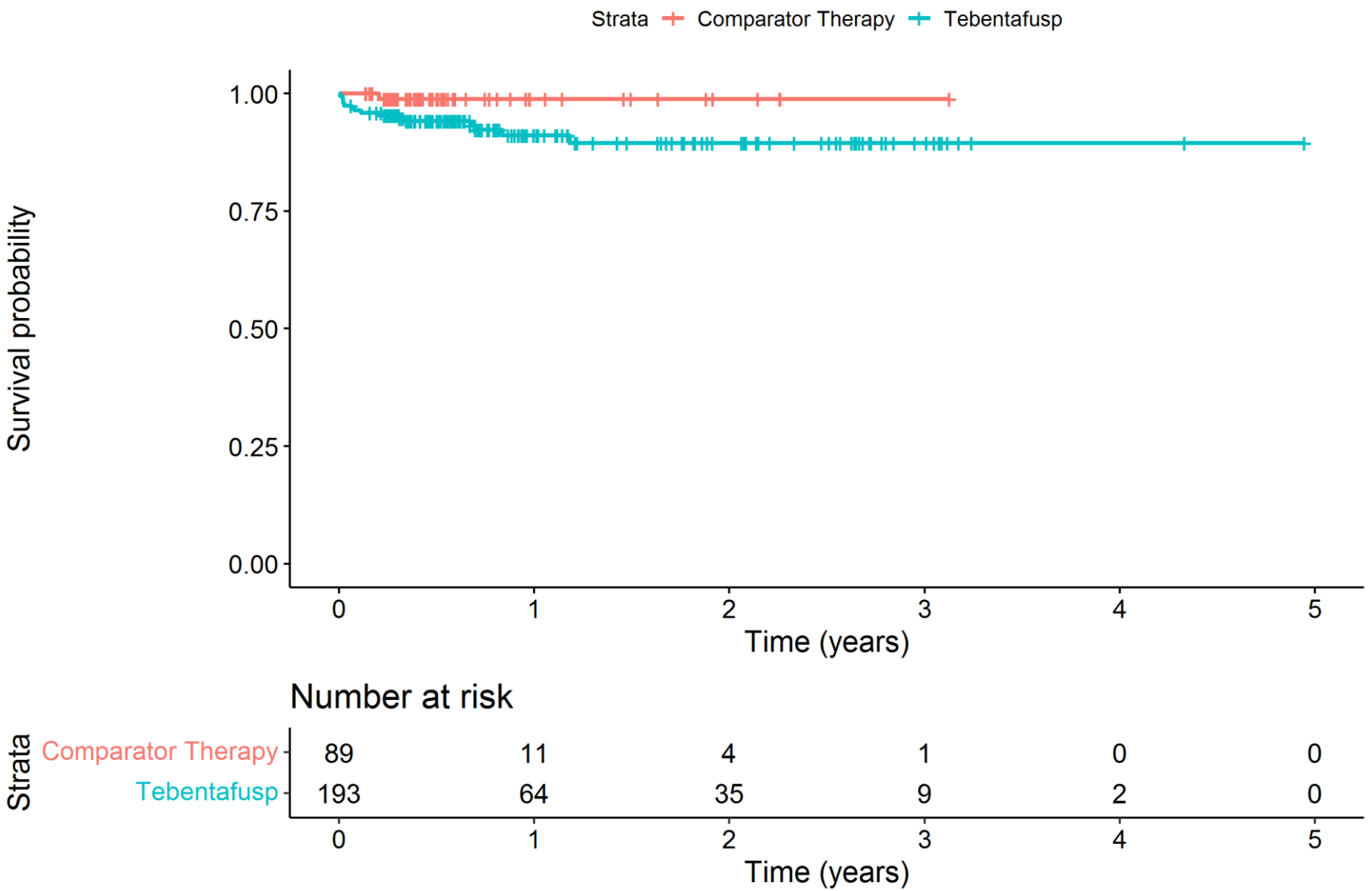
Erhöhte Alkalische Phosphatase - ECOG 0



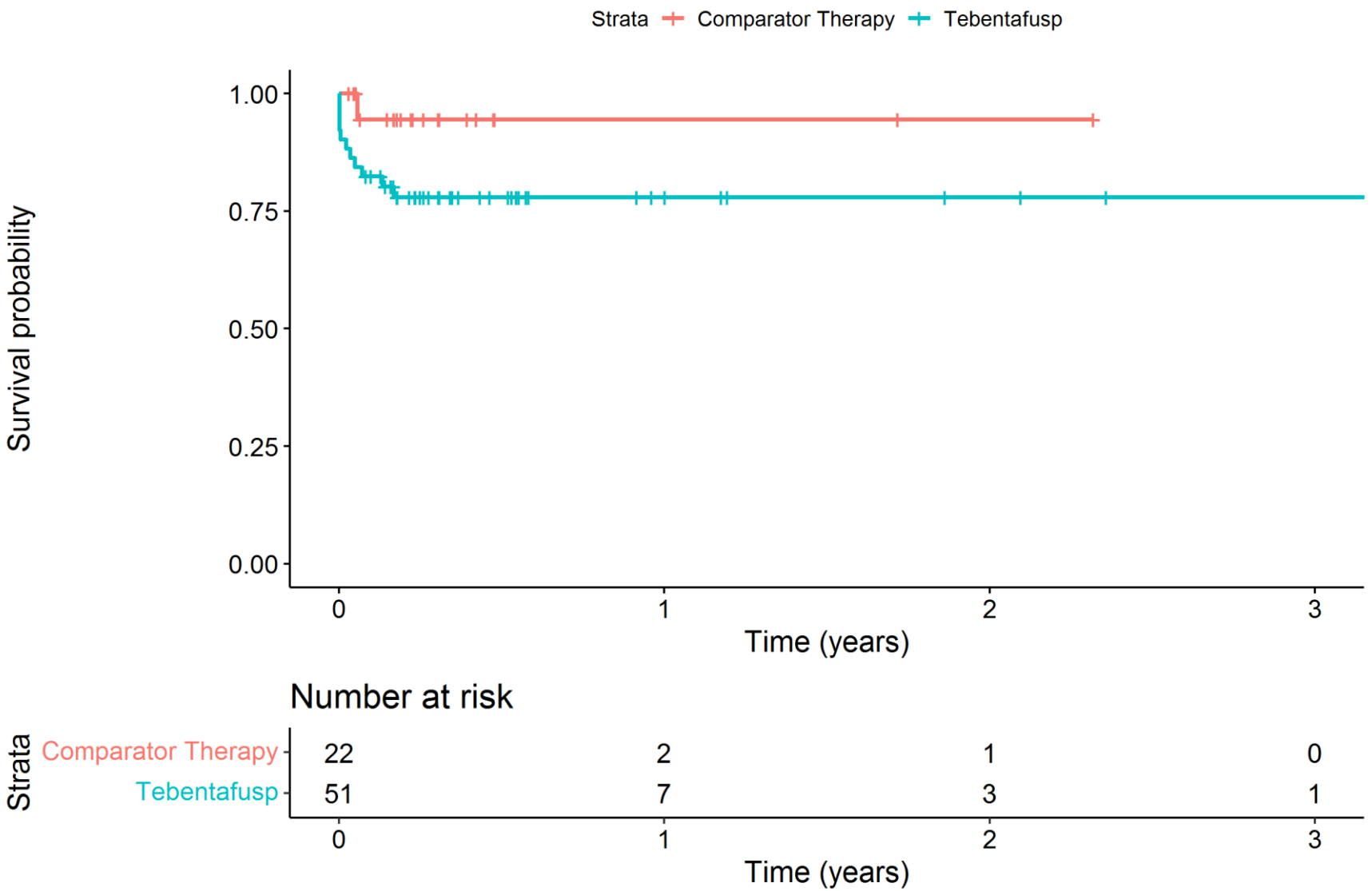
Erhöhte Alkalische Phosphatase - ECOG 1



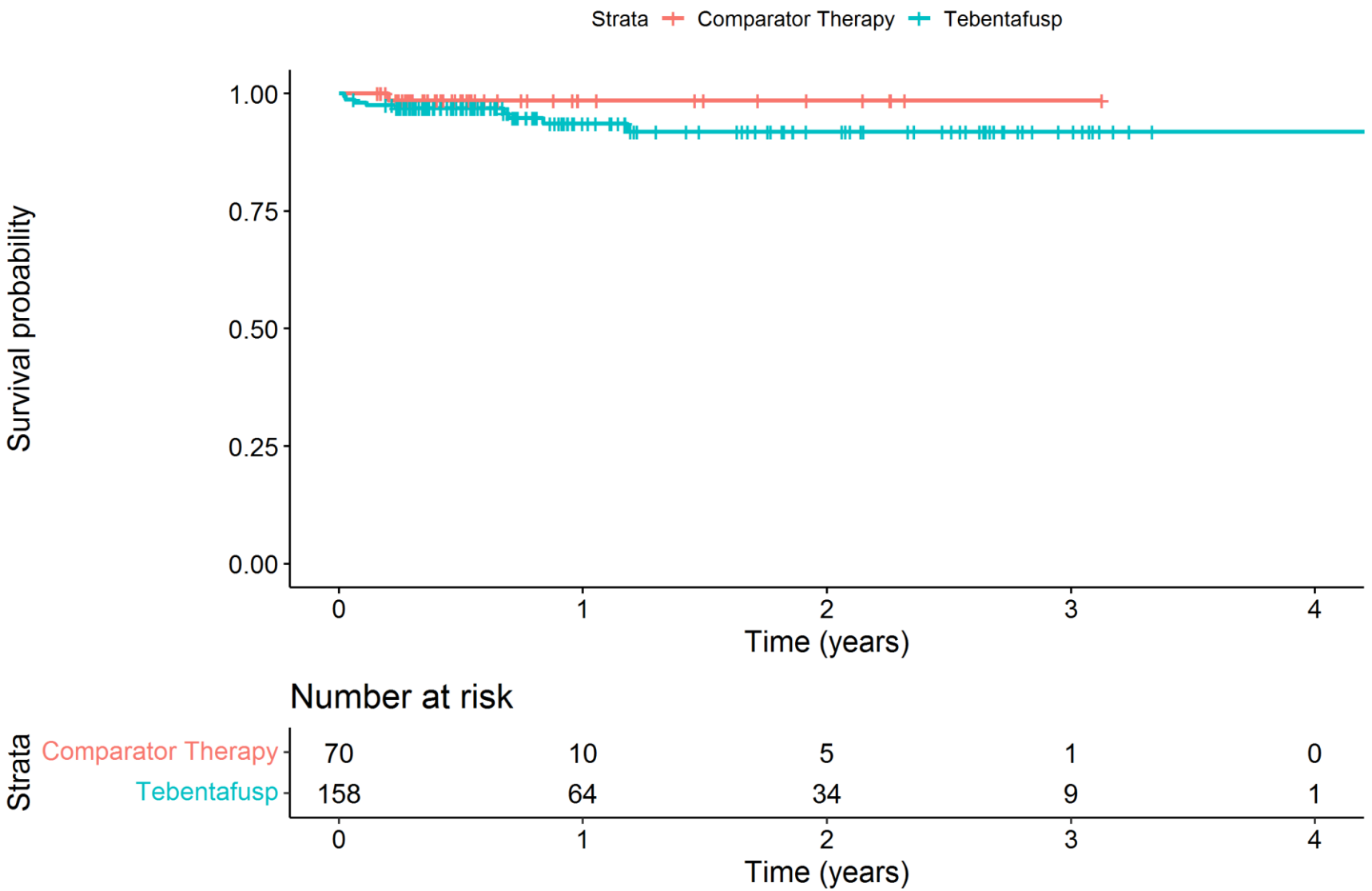
Erhöhte Alkalische Phosphatase - ALP ≤ ULN



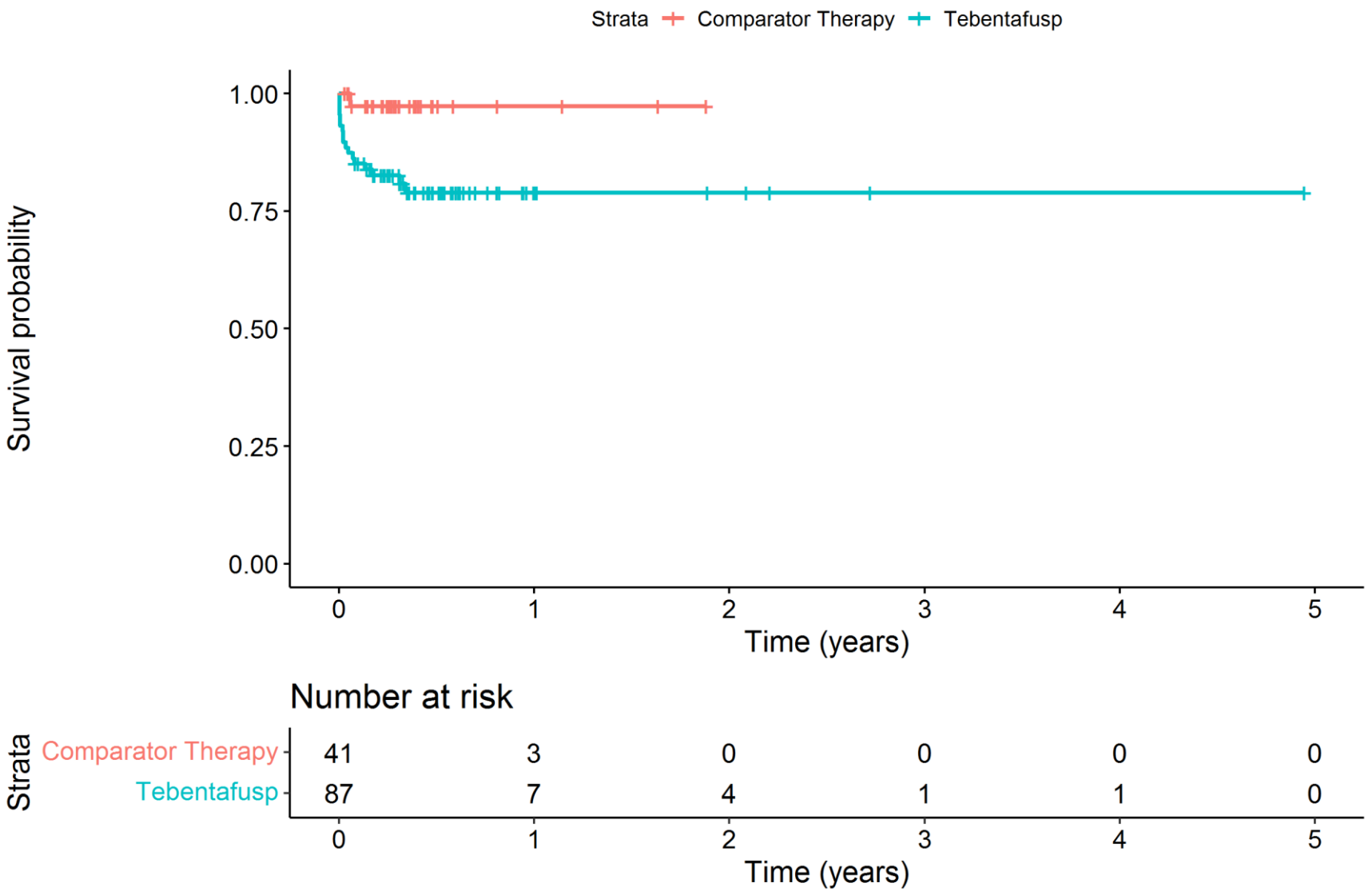
Erhöhte Alkalische Phosphatase - ALP > ULN



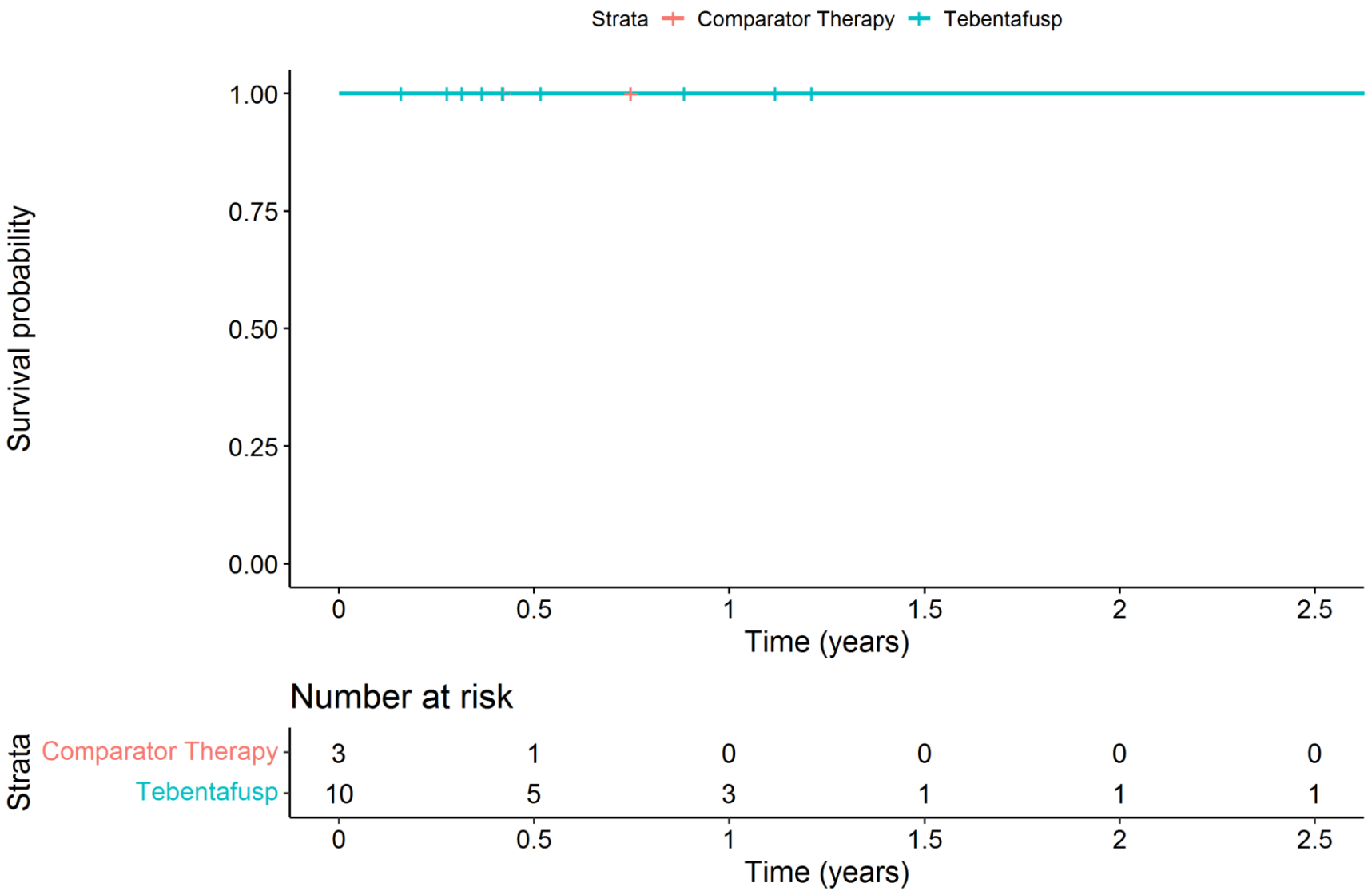
Erhöhte Alkalische Phosphatase - LDH =< ULN



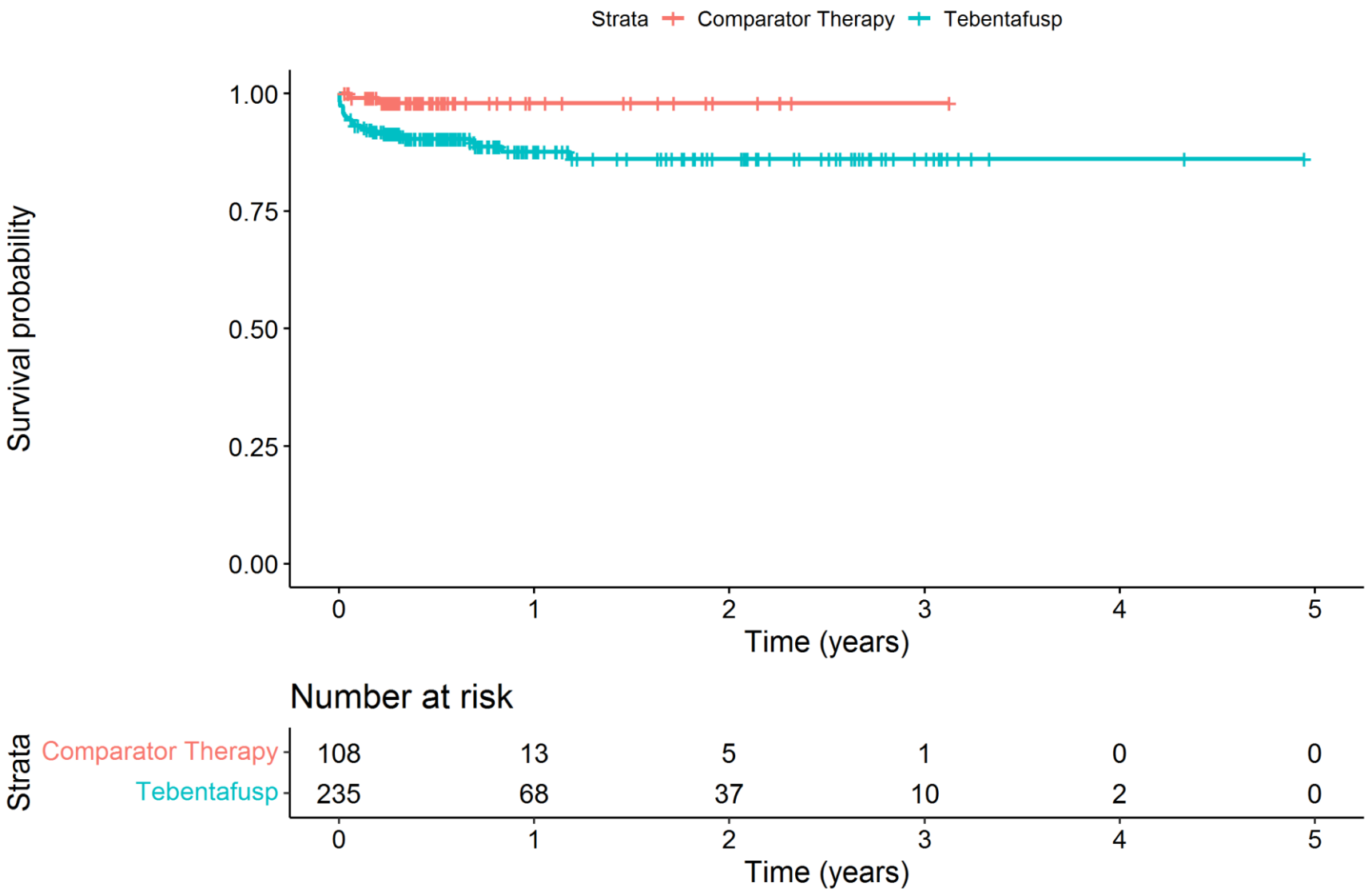
Erhöhte Alkalische Phosphatase - LDH > ULN



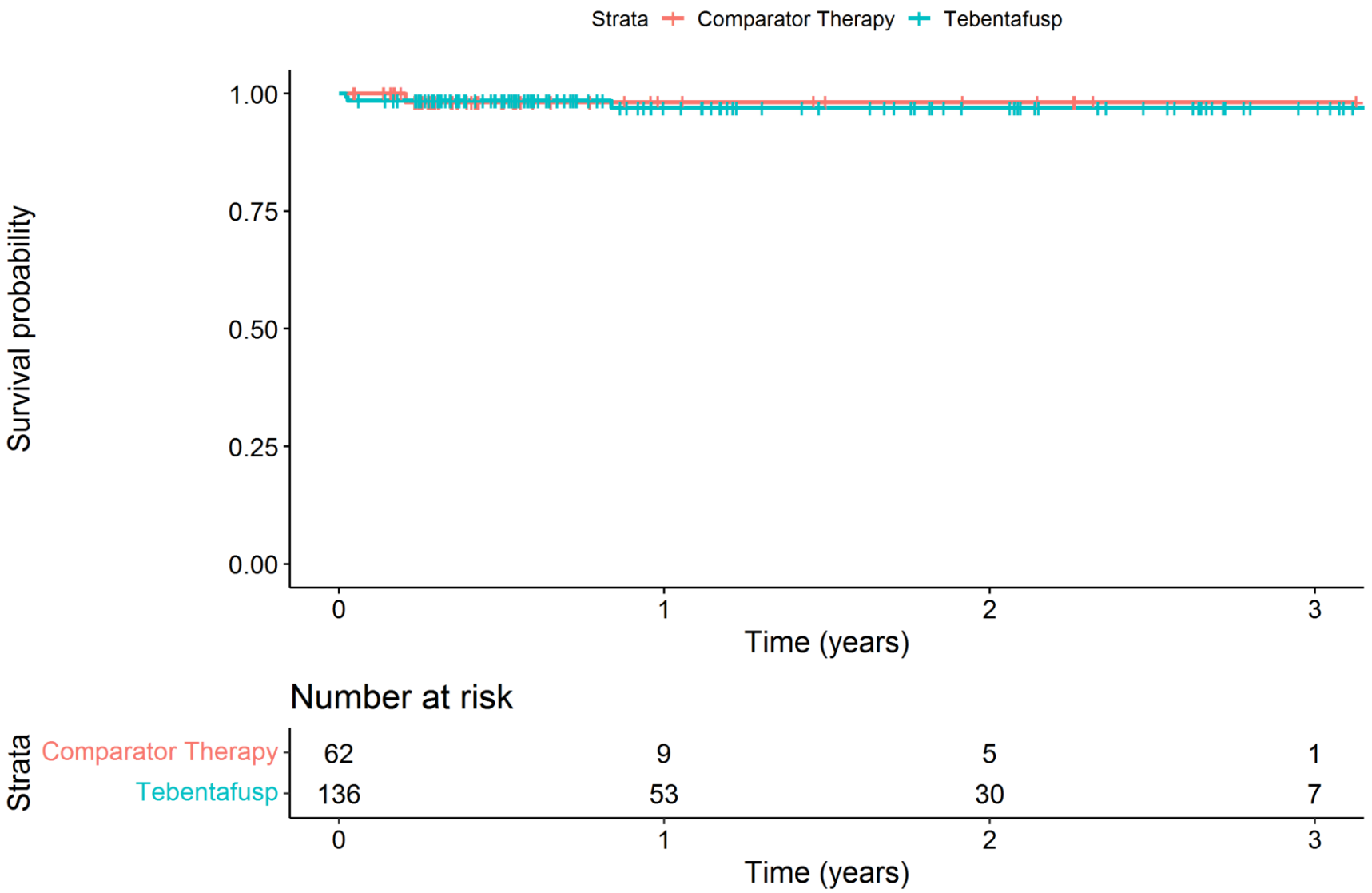
Erhöhte Alkalische Phosphatase - Vorherige Therapie adjuvant/neoadjuvant



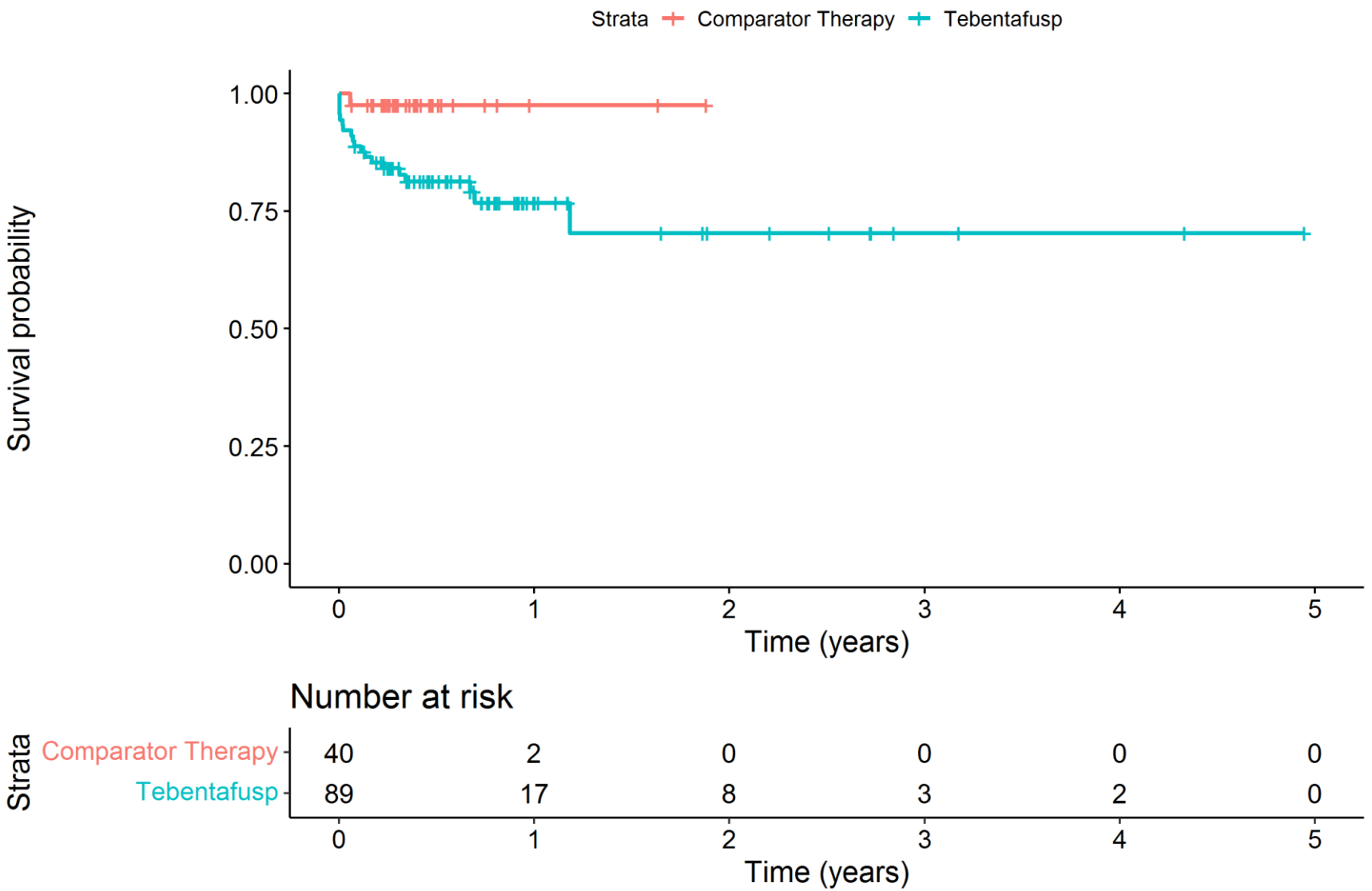
Erhöhte Alkalische Phosphatase - Keine Vorherige Therapie adjuvant/neoadjuvant



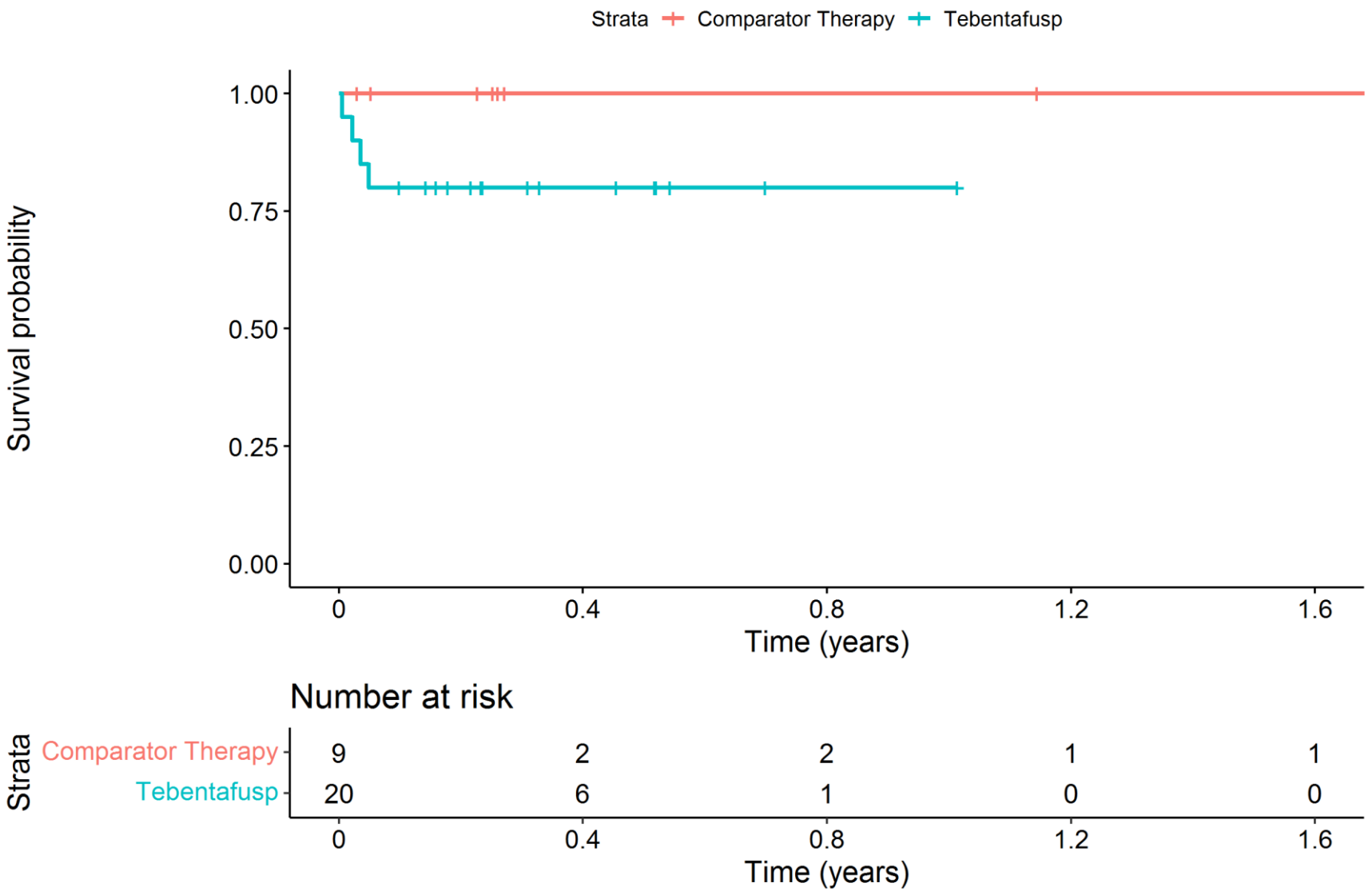
Erhöhte Alkalische Phosphatase - Läsion ≤ 3cm



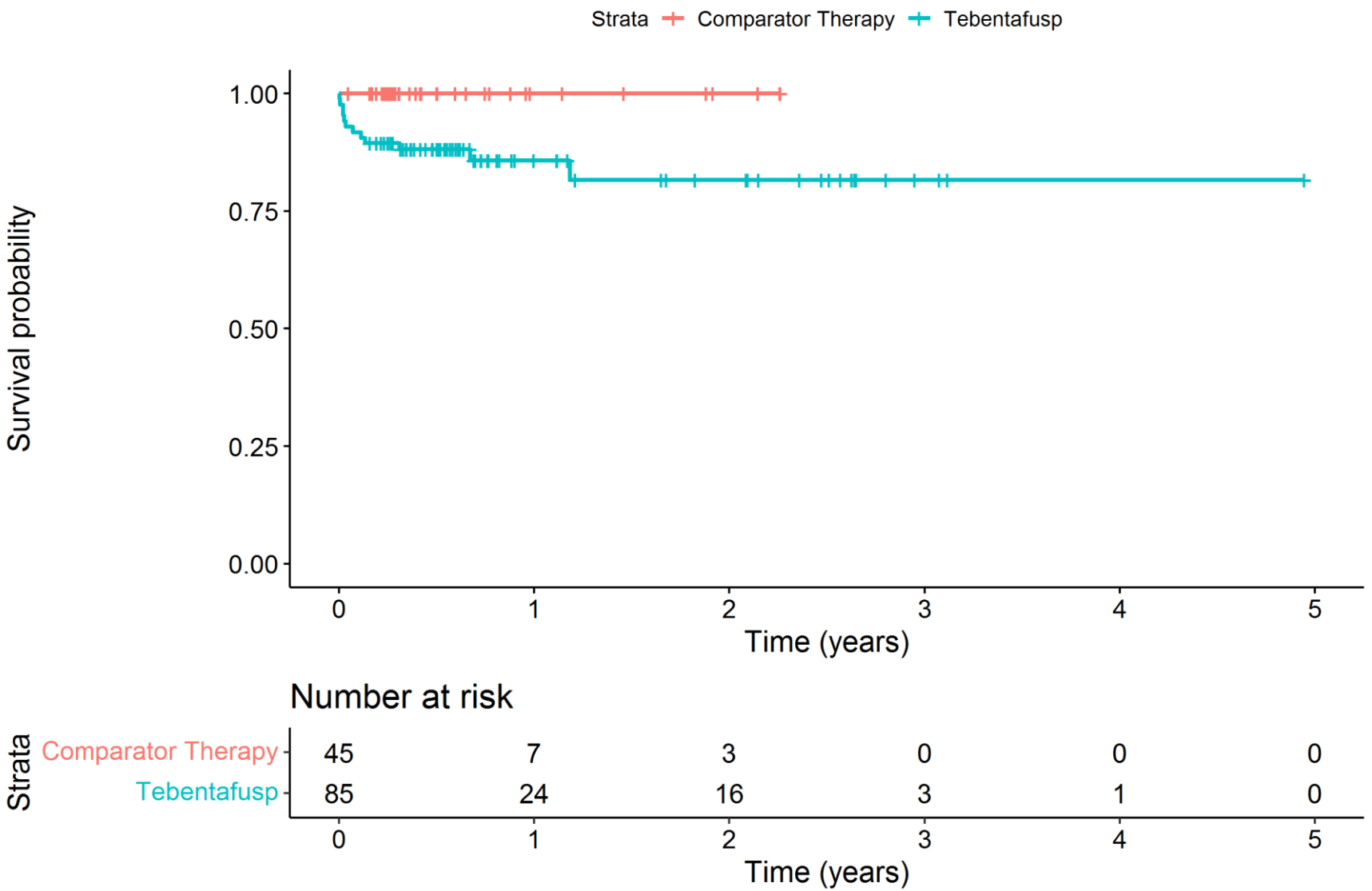
Erhöhte Alkalische Phosphatase - Läsion 3,1-8,0 cm



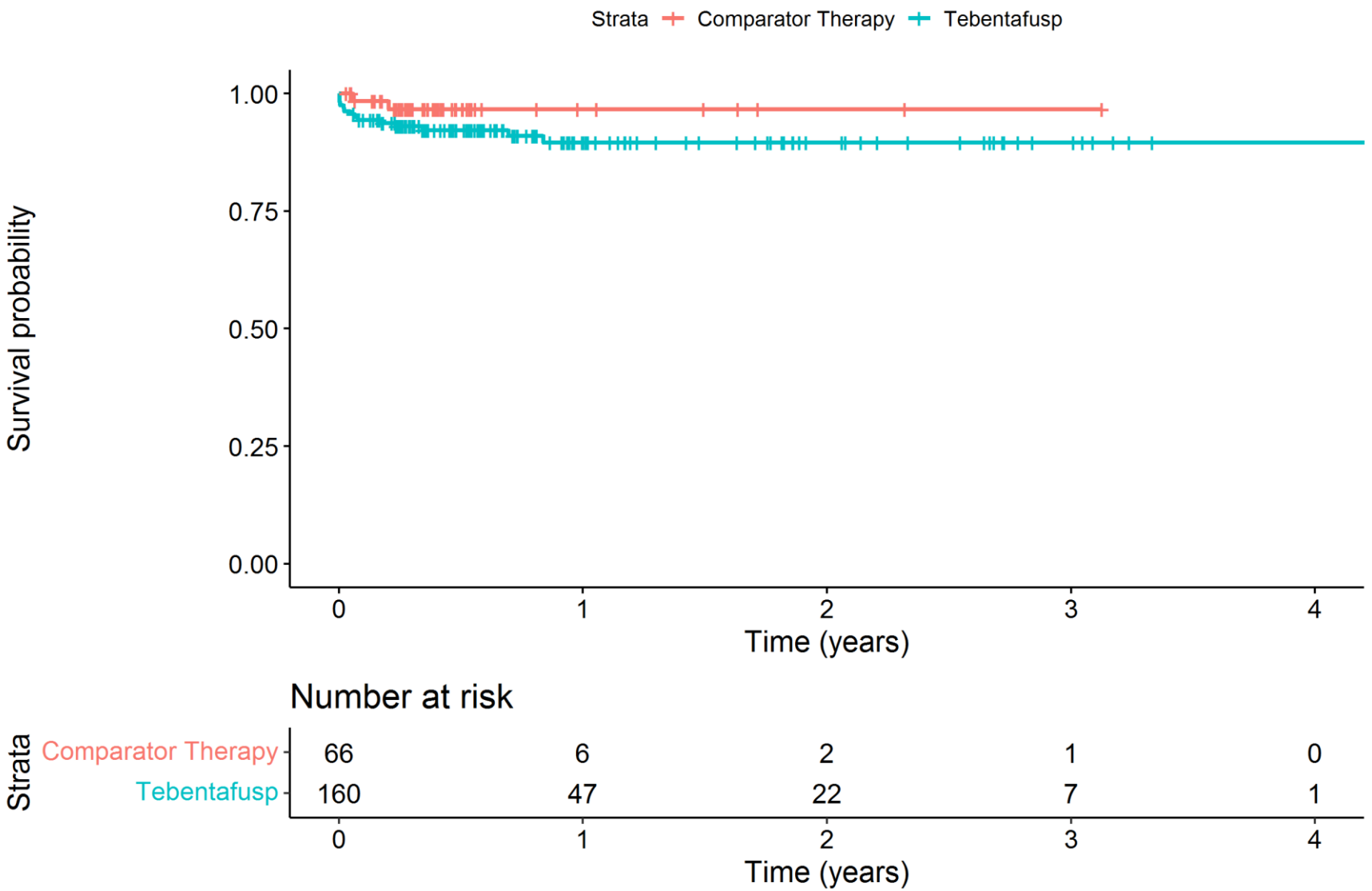
Erhöhte Alkalische Phosphatase - Läsion ≥8,1 cm



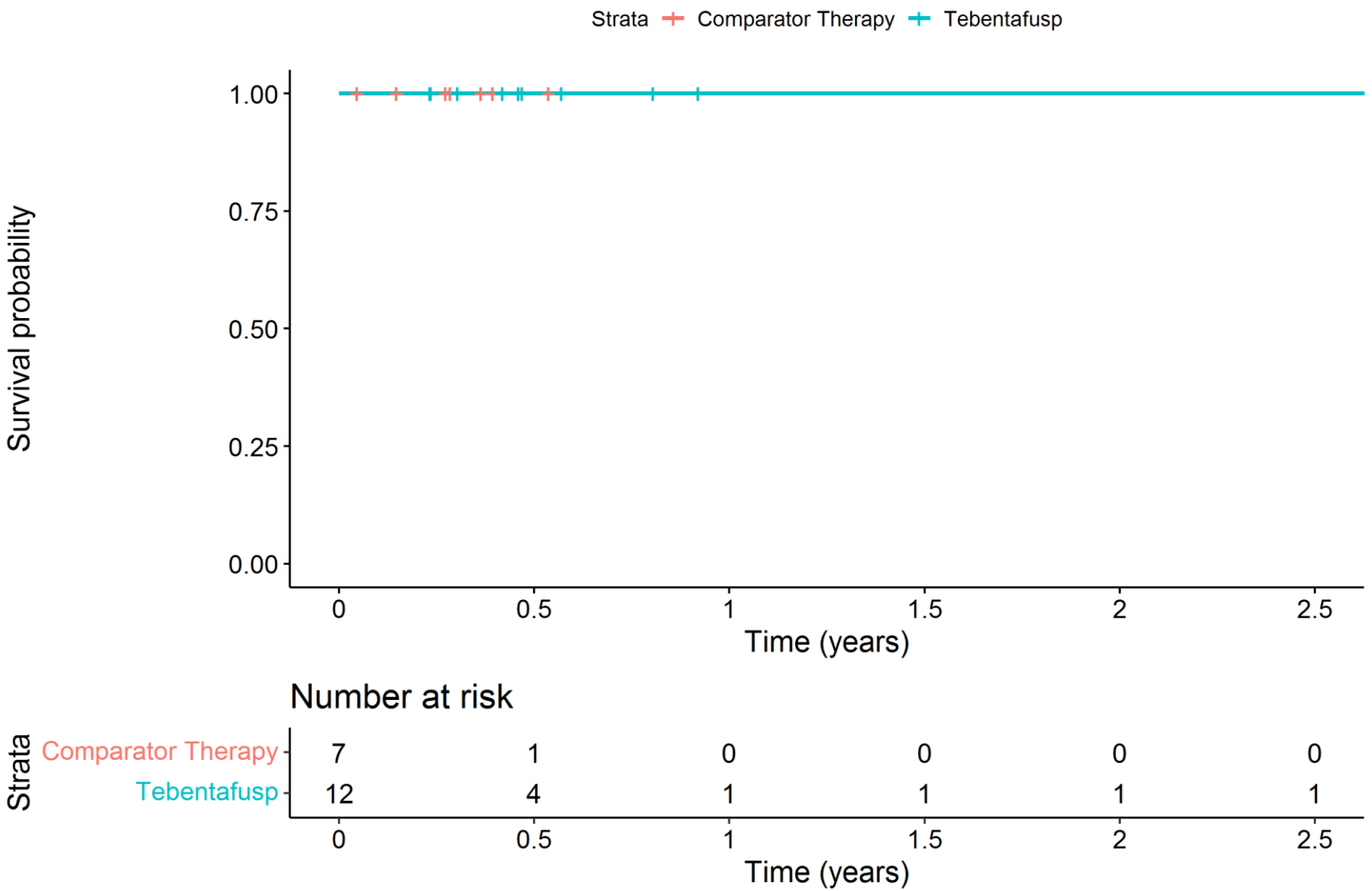
Erhöhte Alkalische Phosphatase - Nordamerika



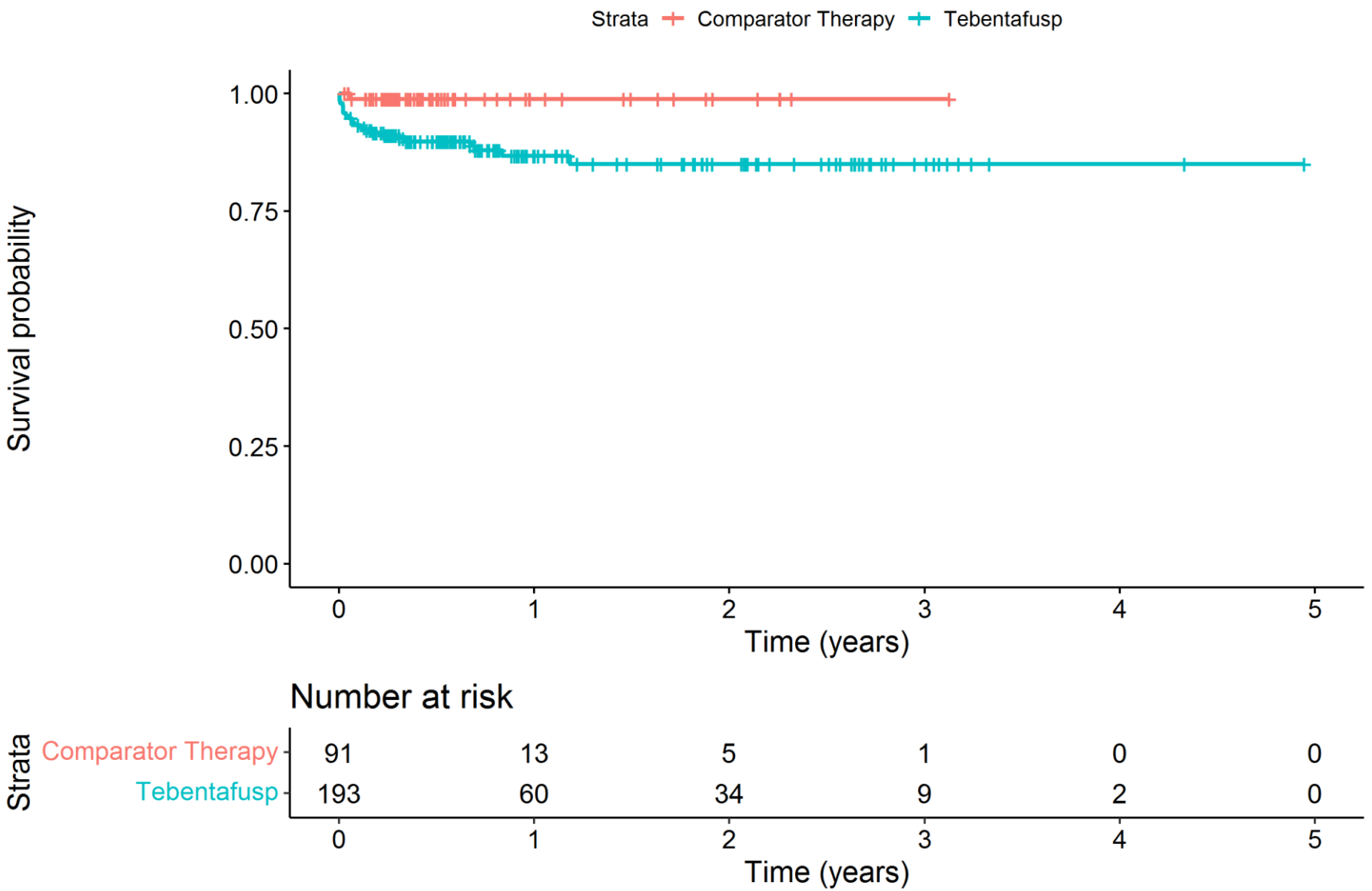
Erhöhte Alkalische Phosphatase - Nicht-Nordamerika



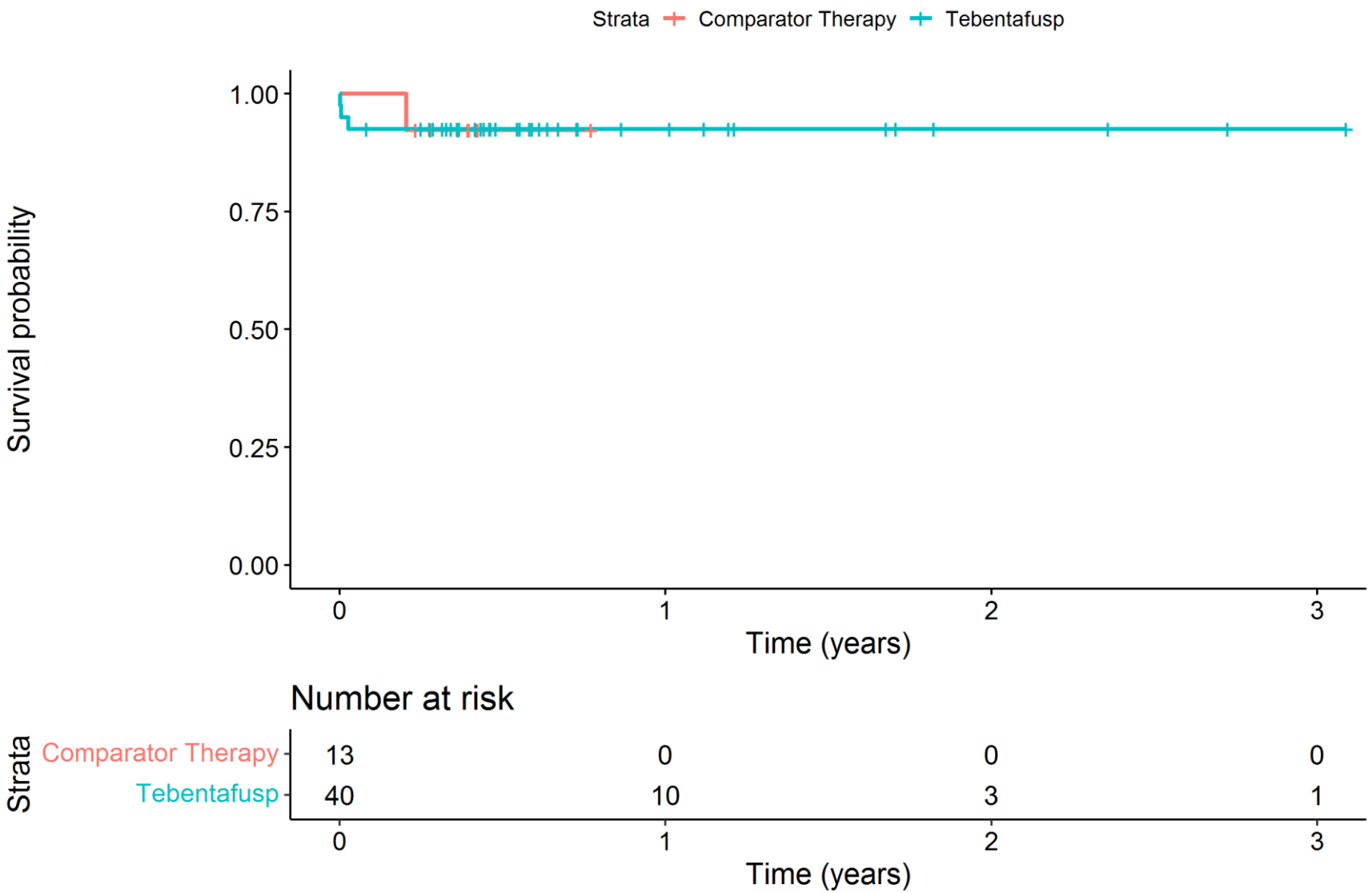
Erhöhte Alkalische Phosphatase - Dacarbazin



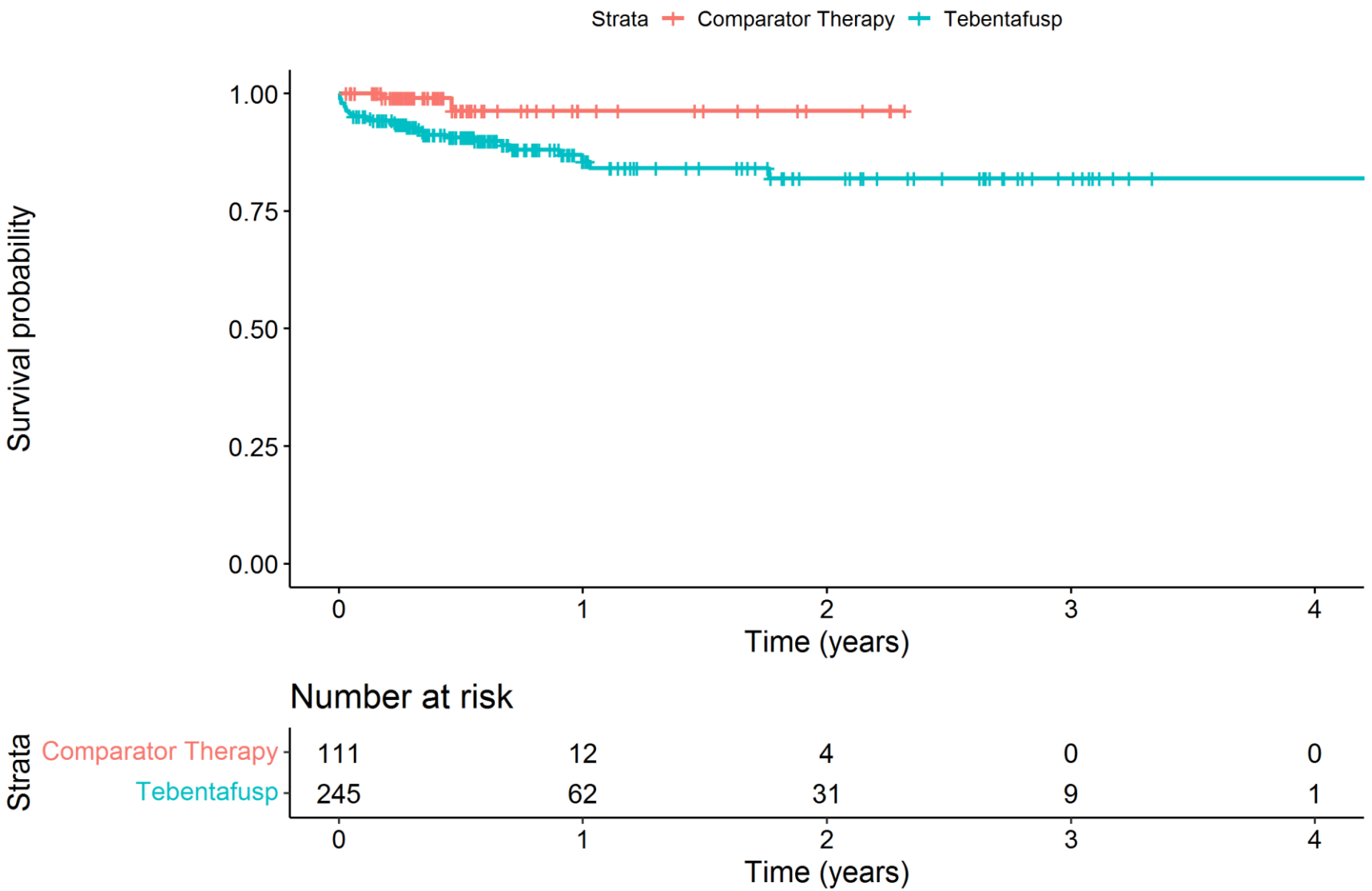
Erhöhte Alkalische Phosphatase - Pembrolizumab



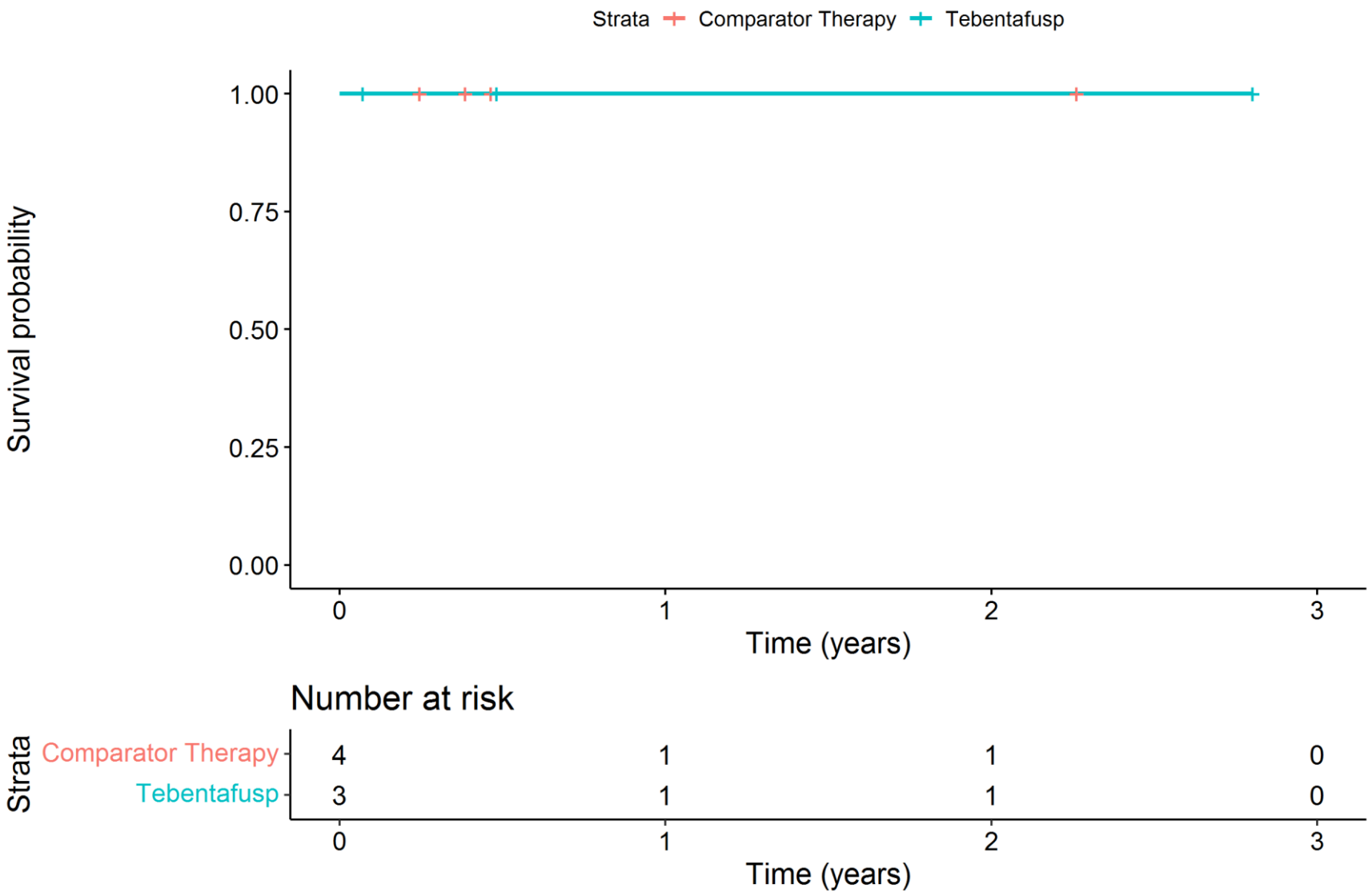
Erhöhte Alkalische Phosphatase - Ipilimumab



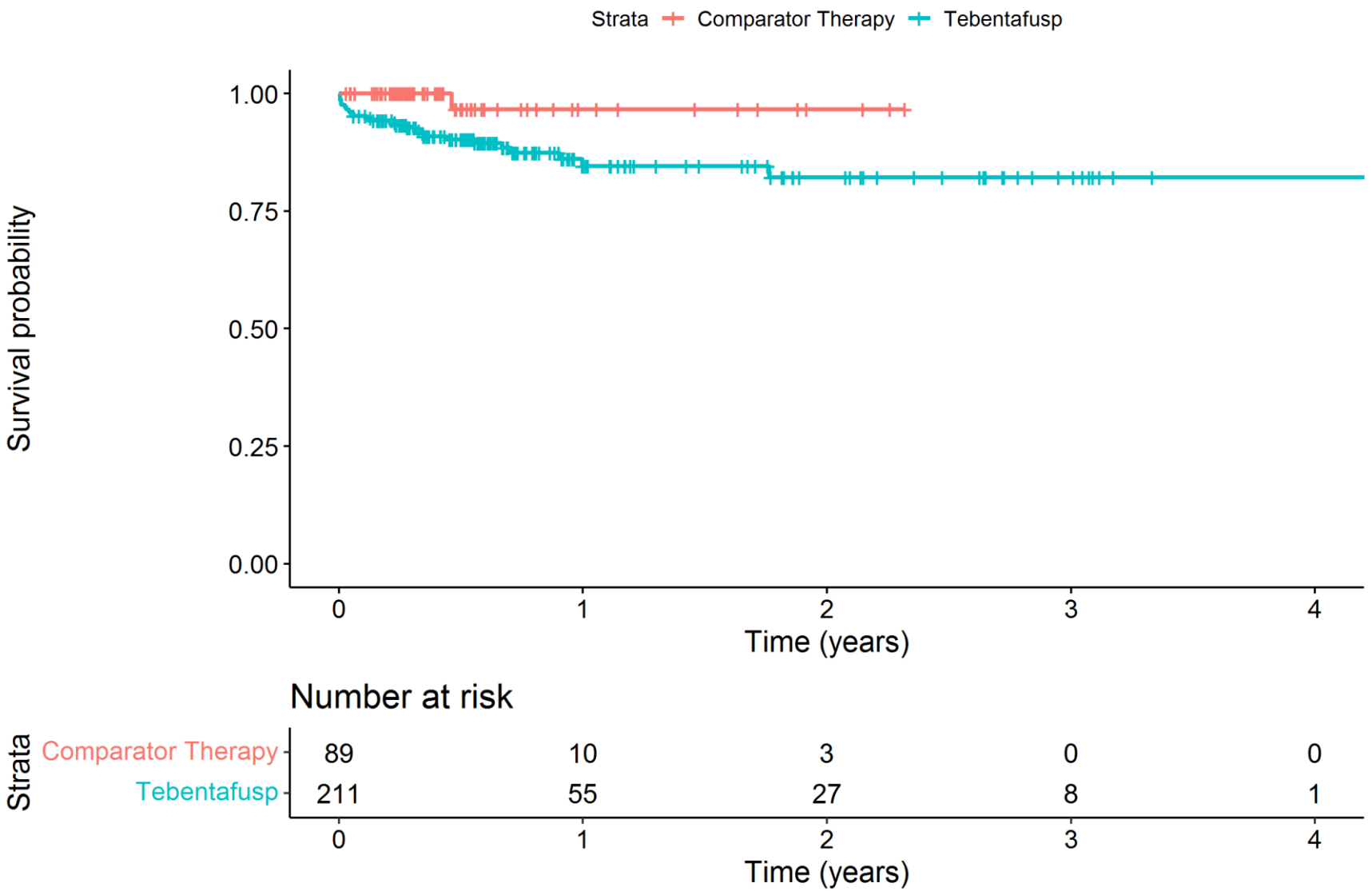
Hypophosphatämie- Gesamt



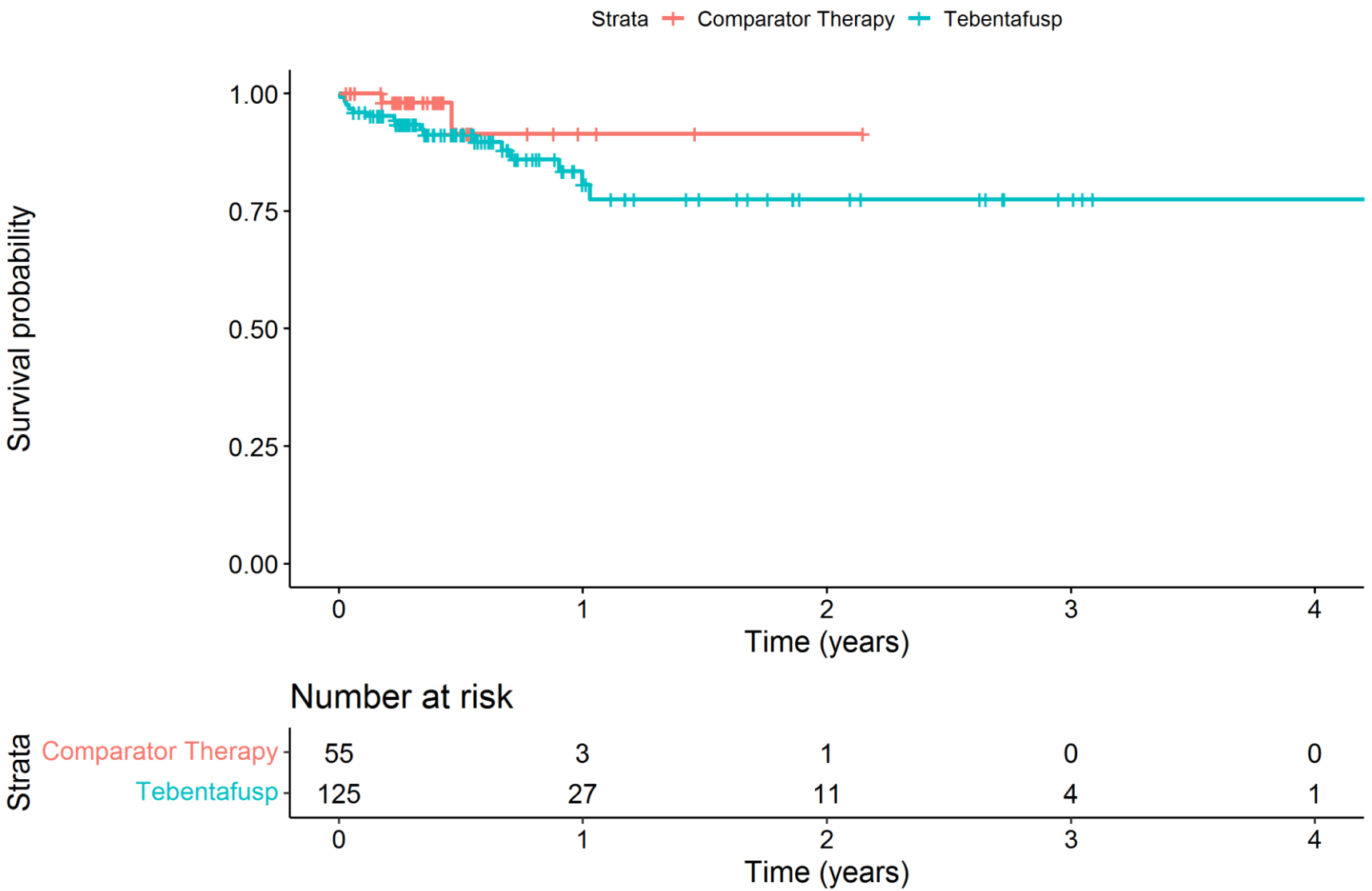
Hypophosphatämie- Hispanisch



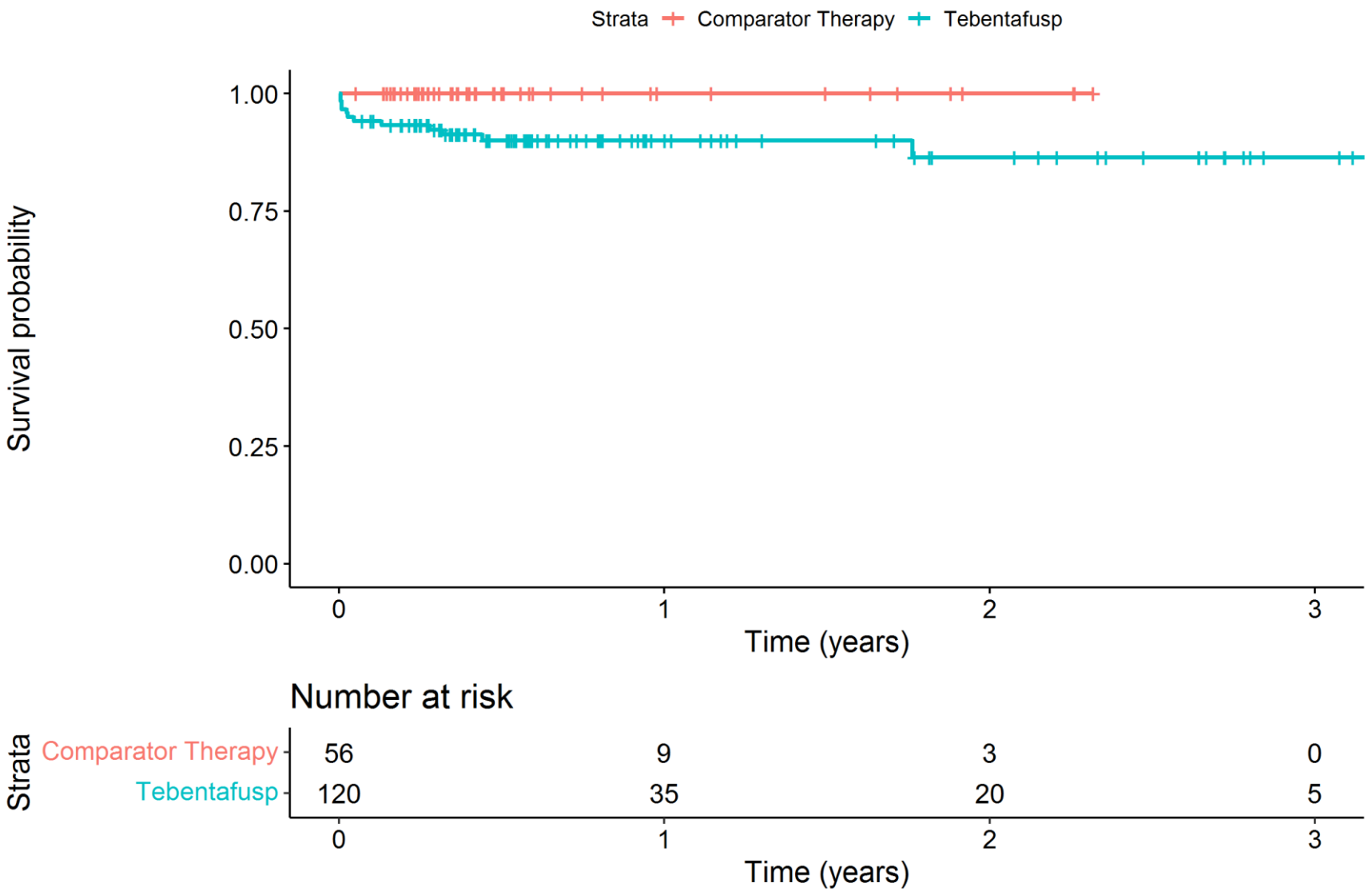
Hypophosphatämie- Nicht-hispanisch



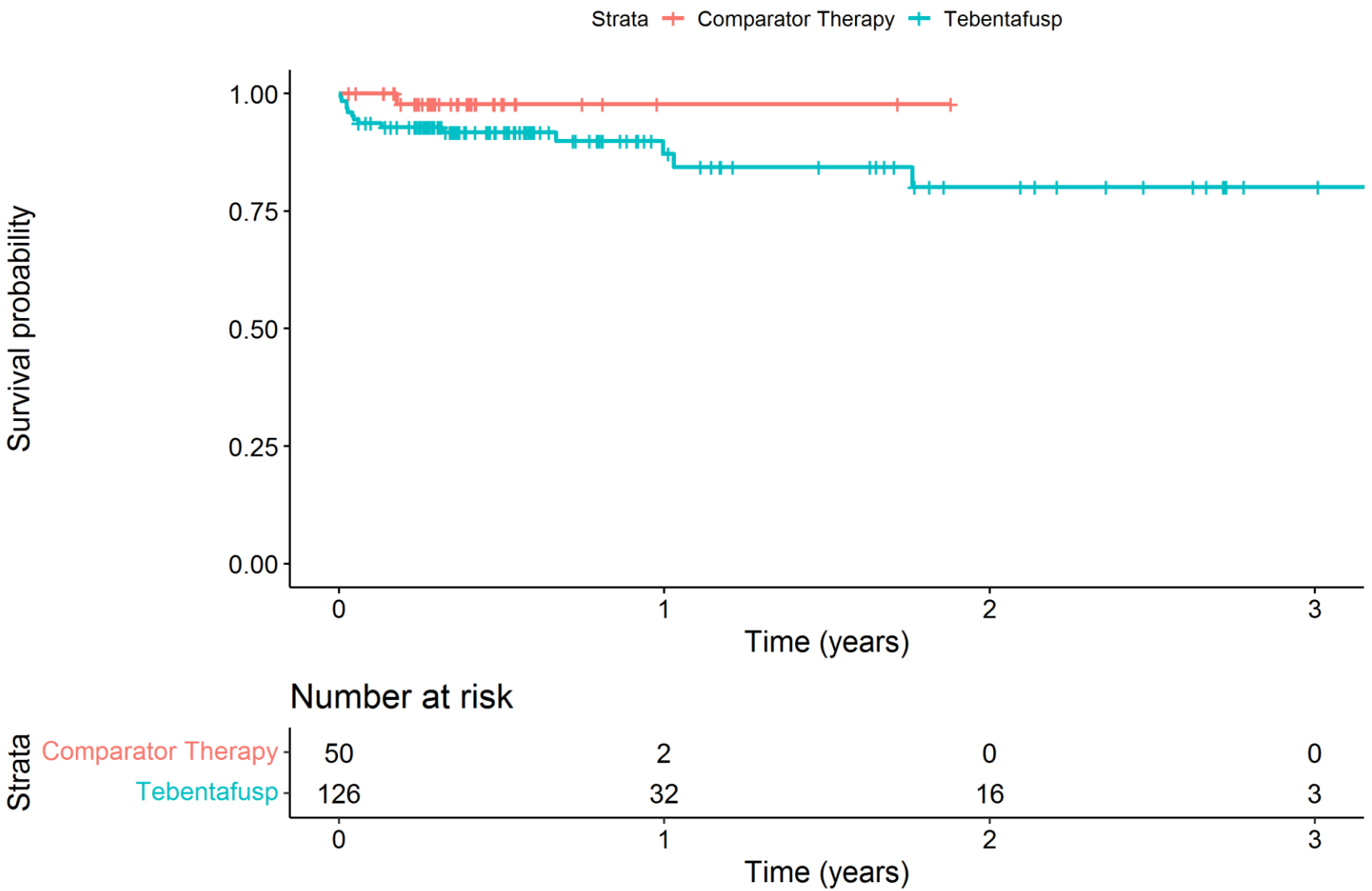
Hypophosphatämie- Männlich



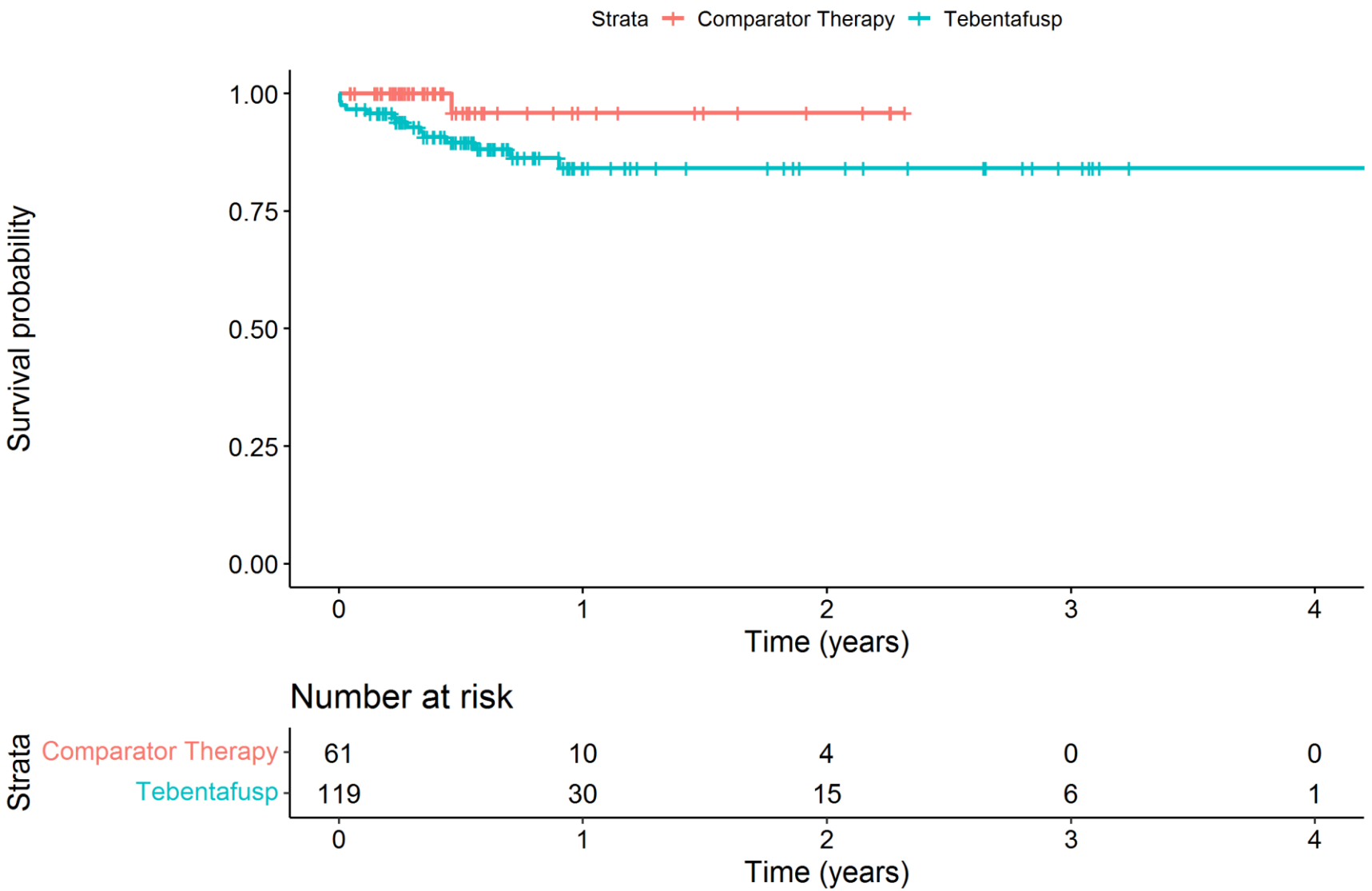
Hypophosphatämie- Weiblich



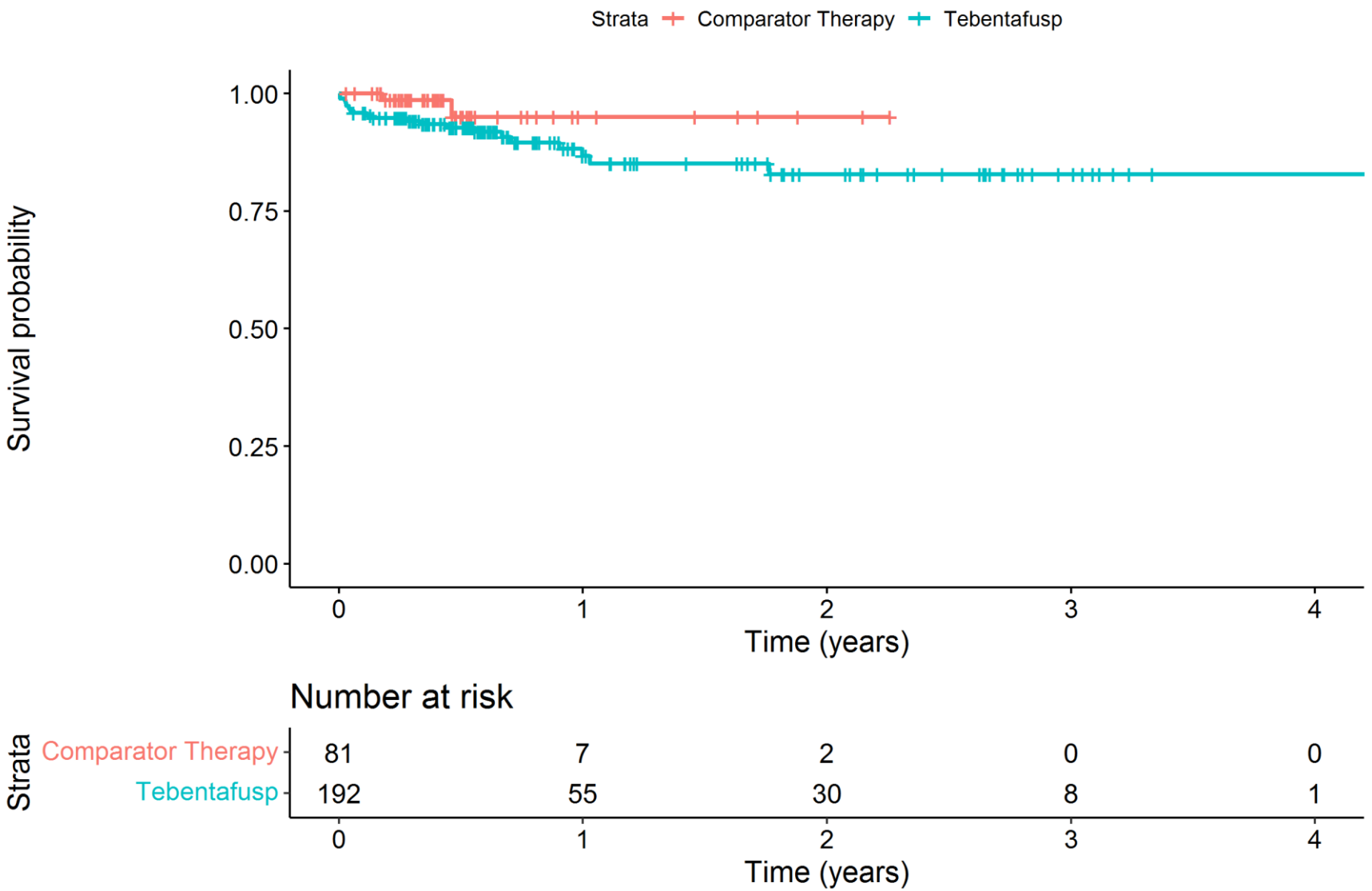
Hypophosphatämie- <65



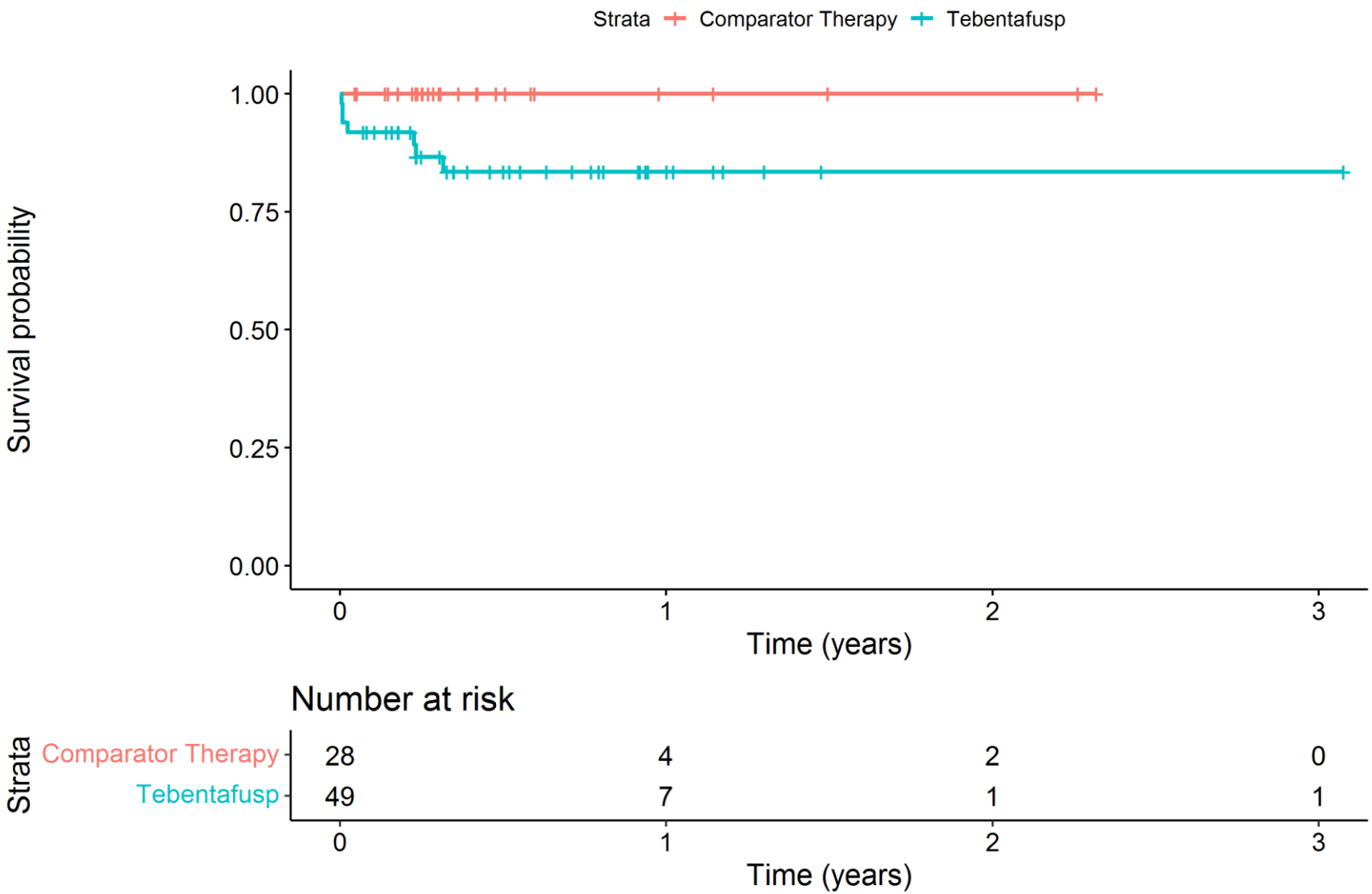
Hypophosphatämie- ≥65



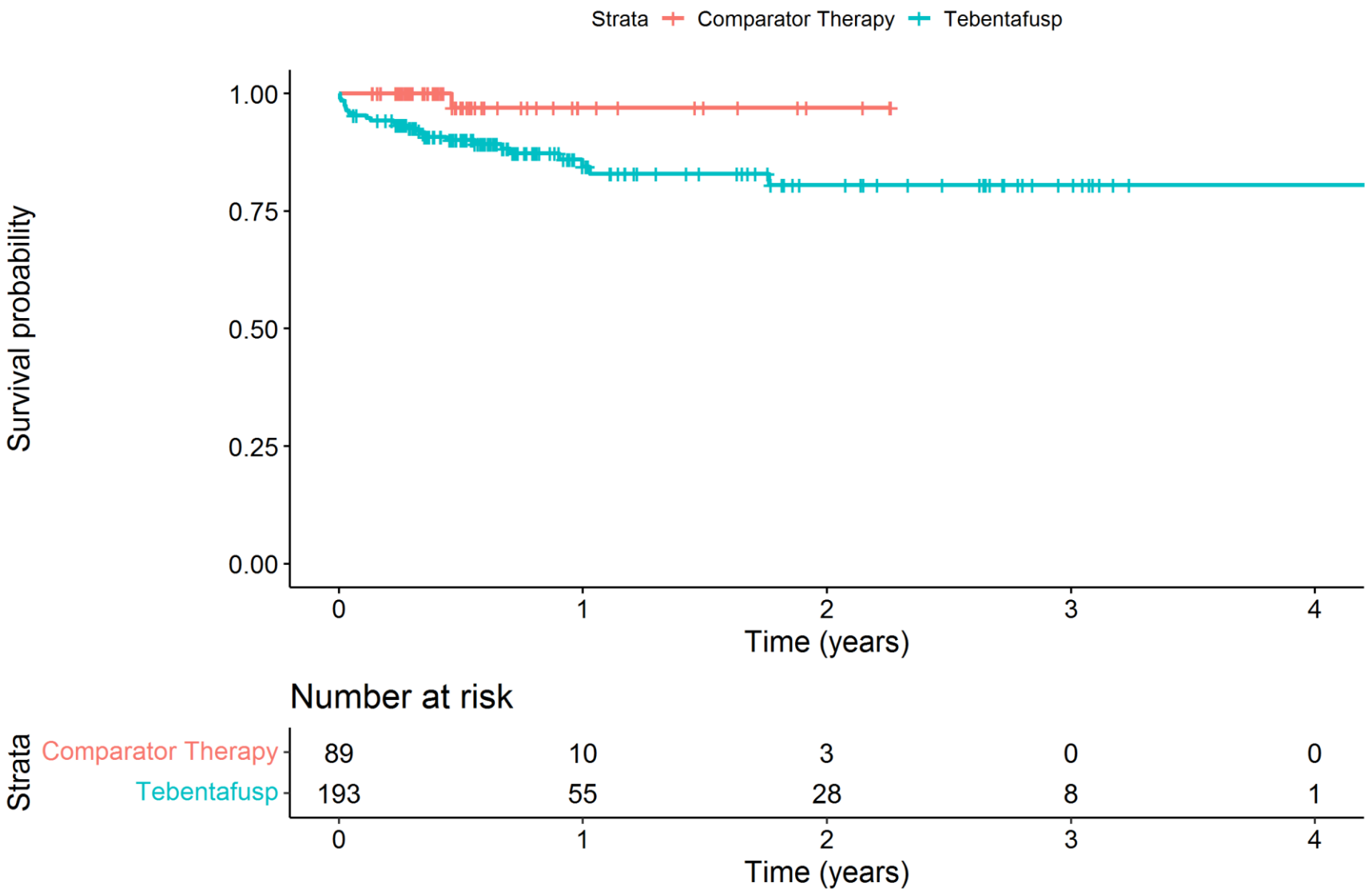
Hypophosphatämie- ECOG 0



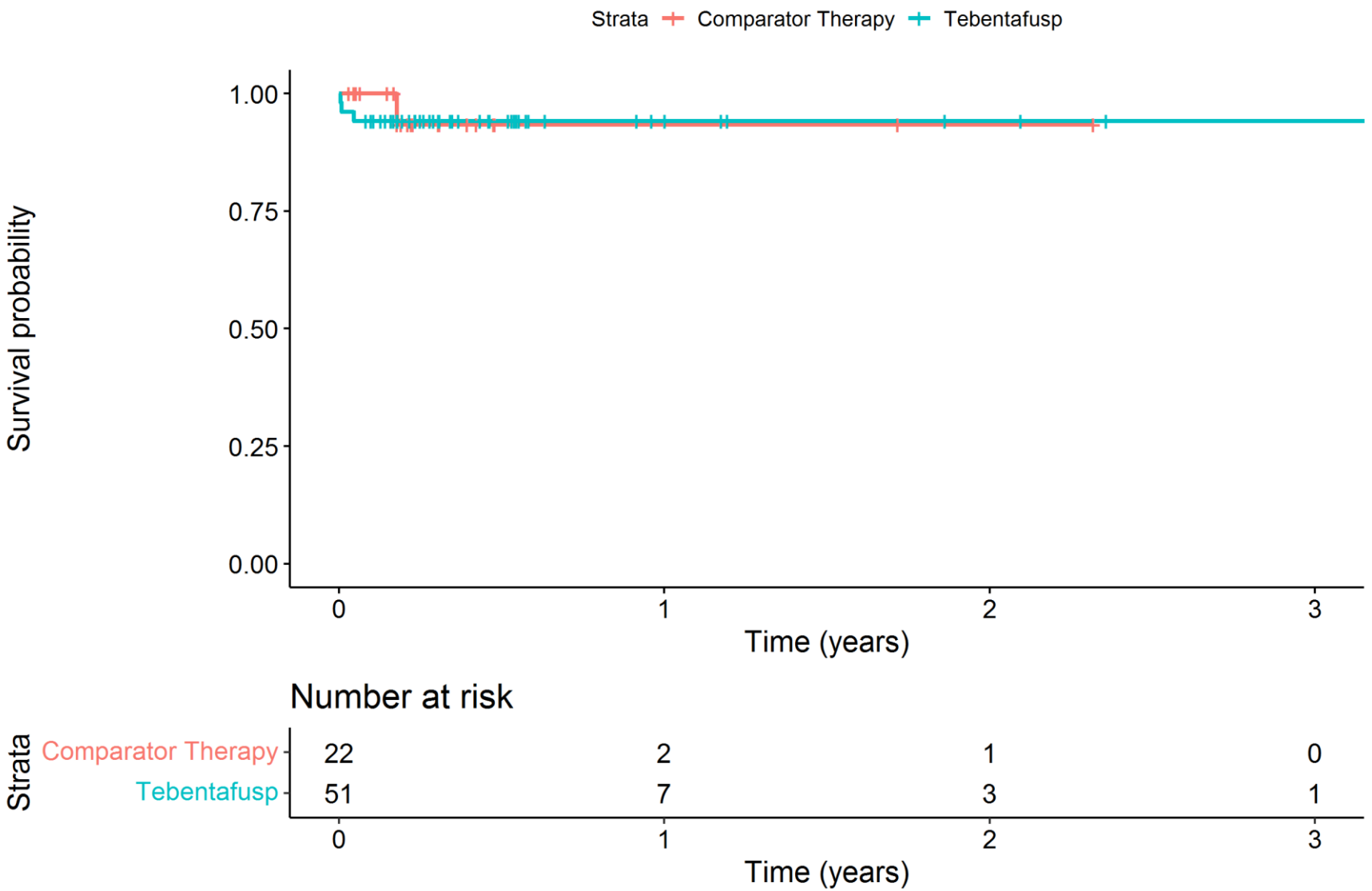
Hypophosphatämie- ECOG 1



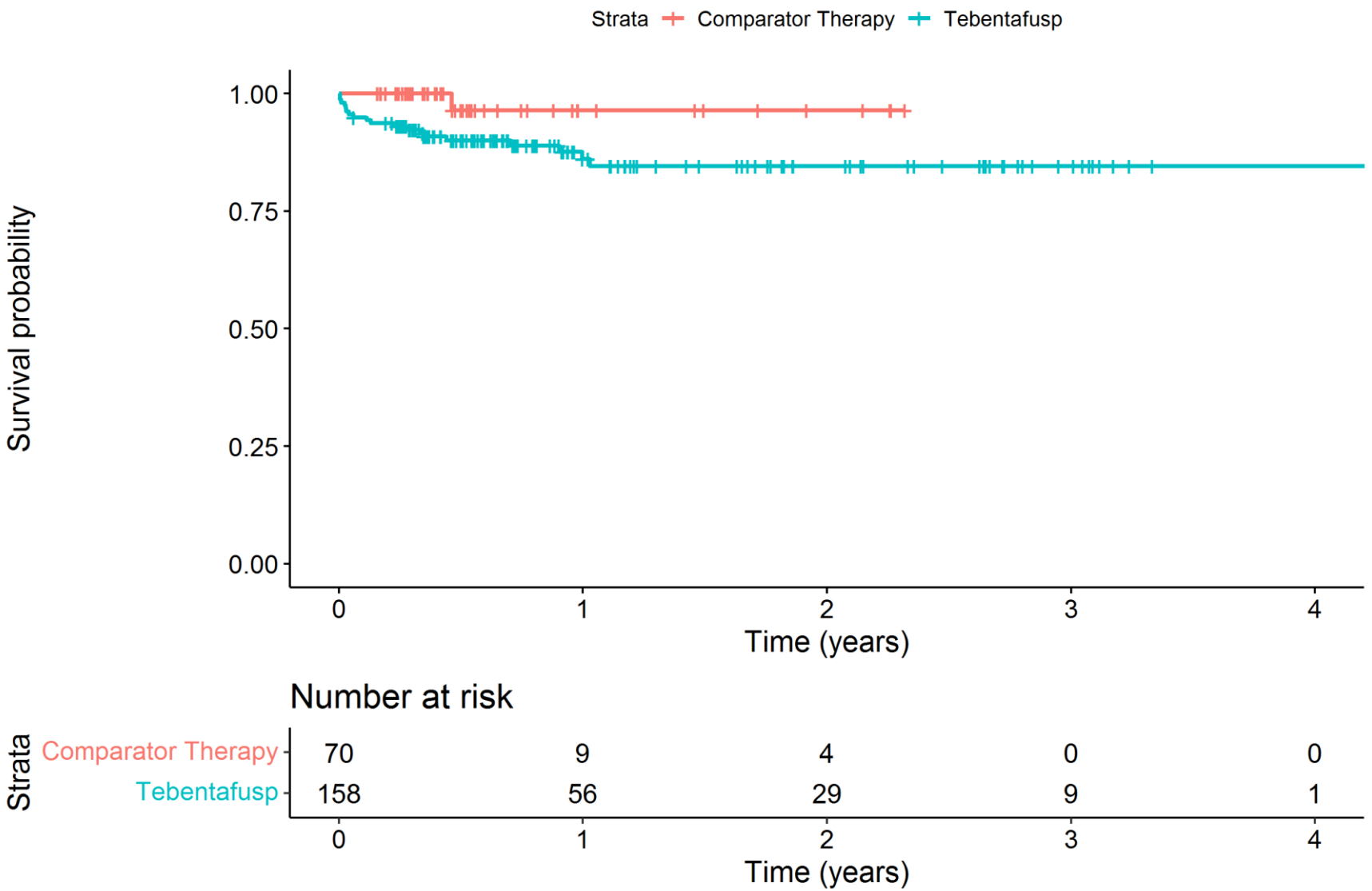
Hypophosphatämie- ALP ≤ ULN



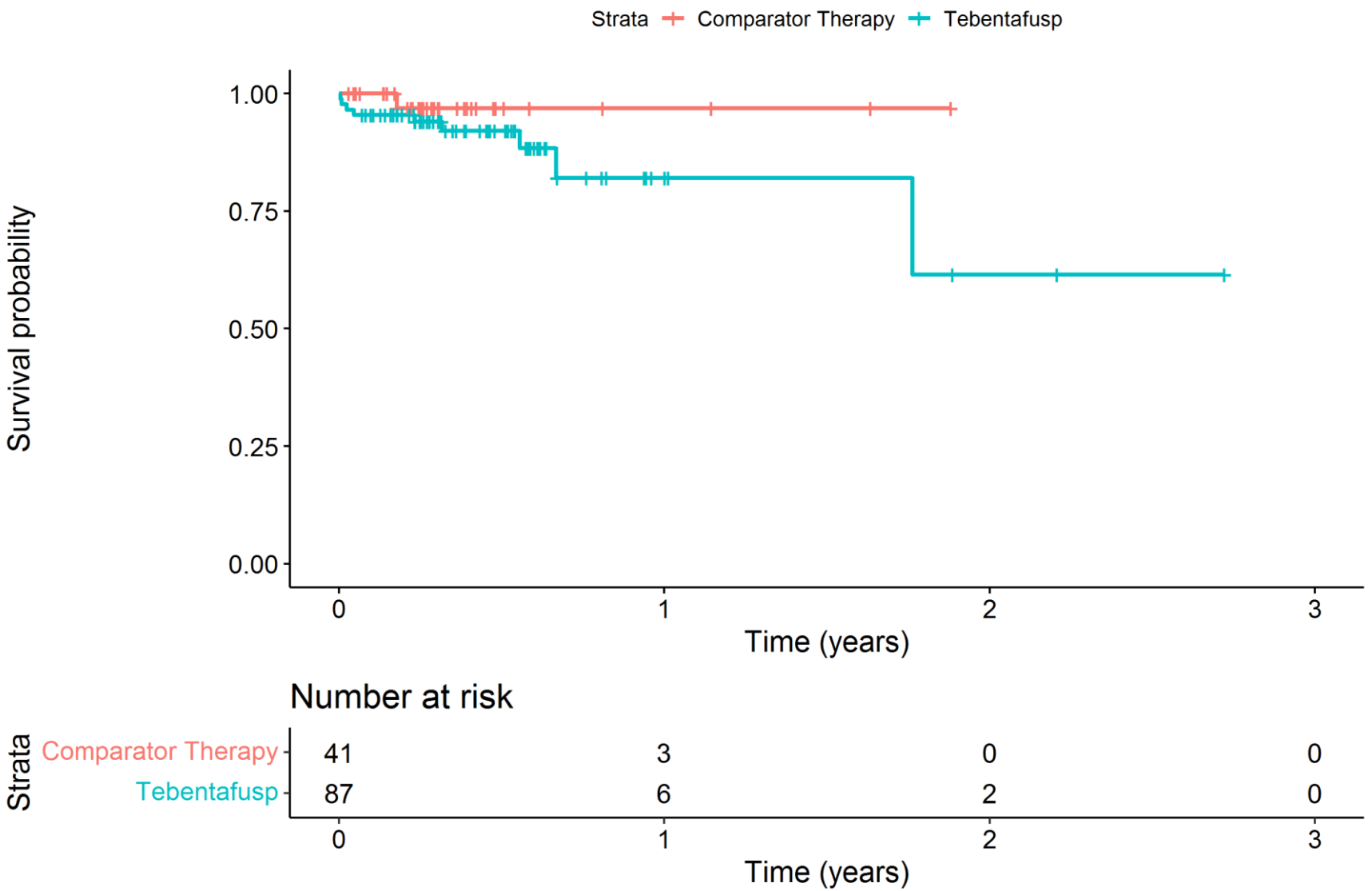
Hypophosphatämie- ALP > ULN



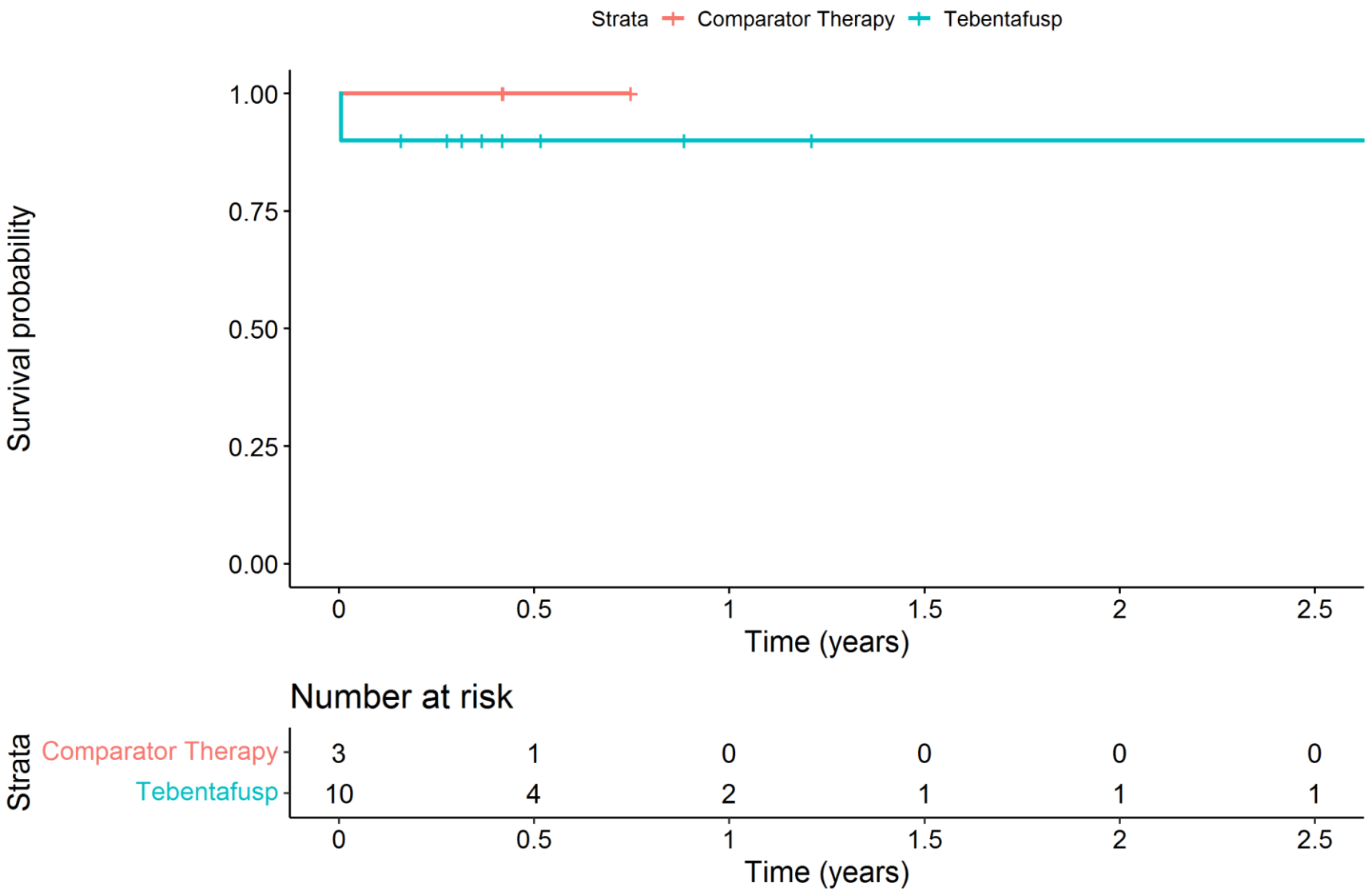
Hypophosphatämie- LDH =< ULN



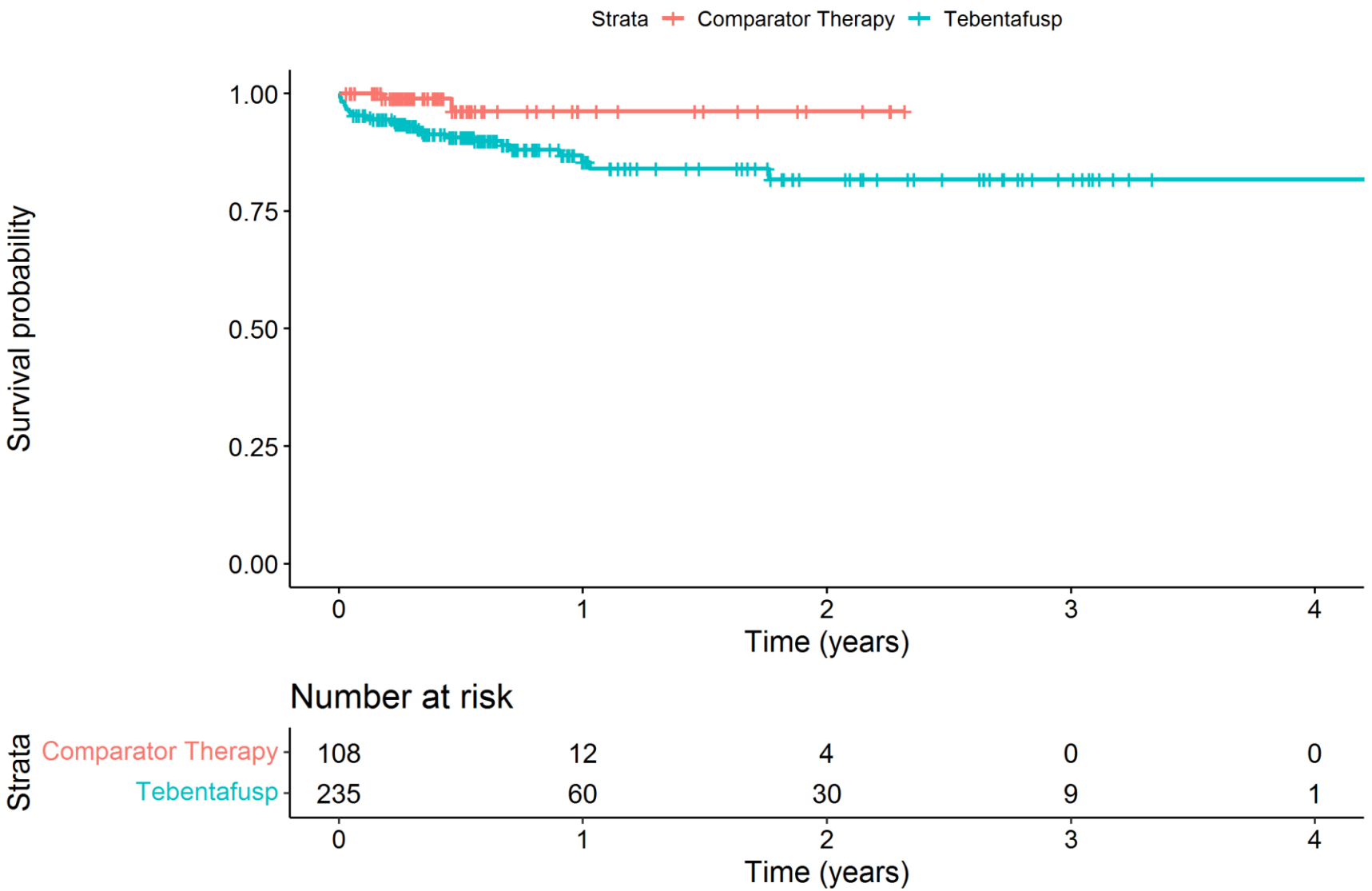
Hypophosphatämie- LDH > ULN



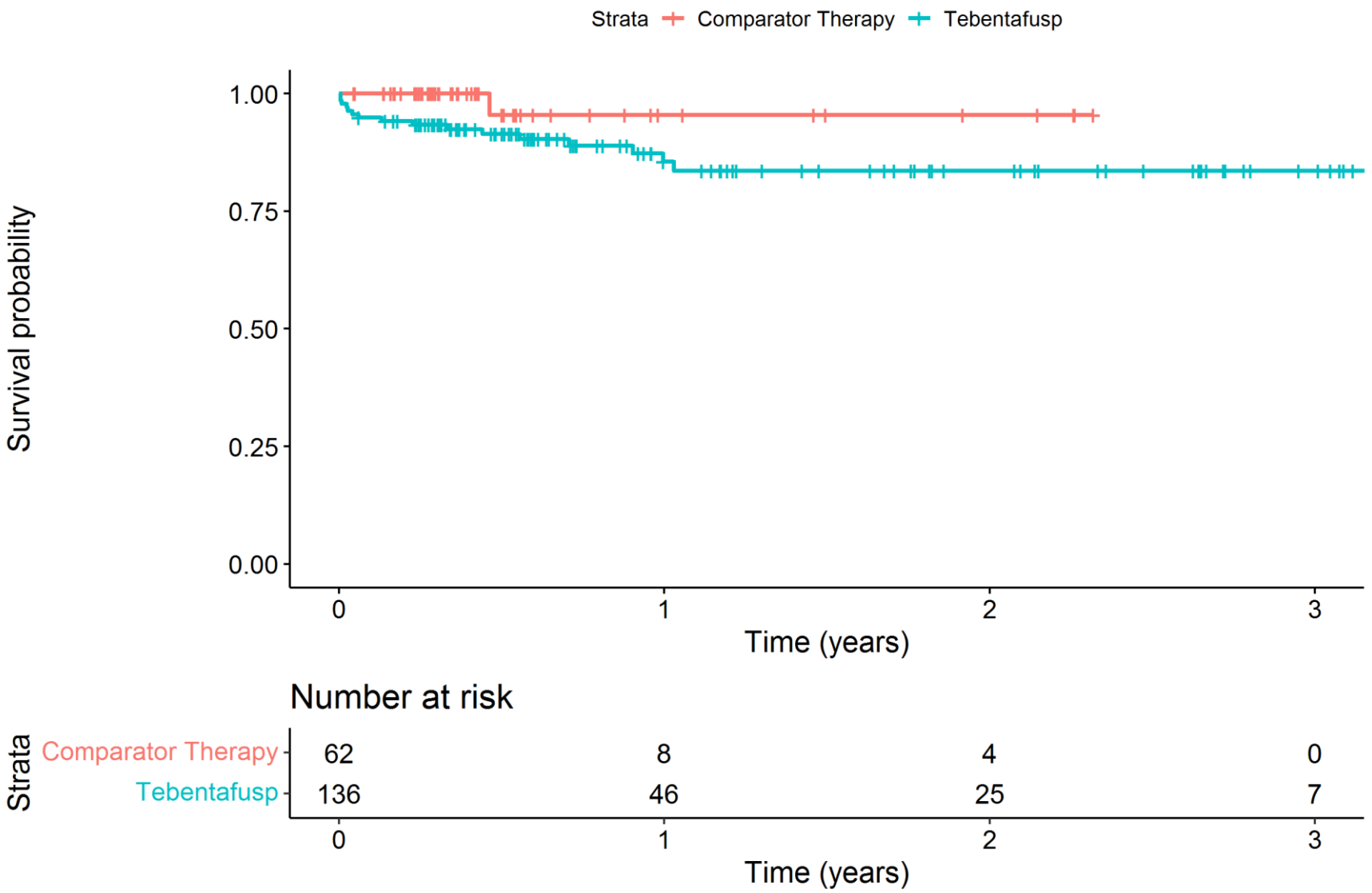
Hypophosphatämie- Vorherige Therapie adjuvant/neoadjuvant



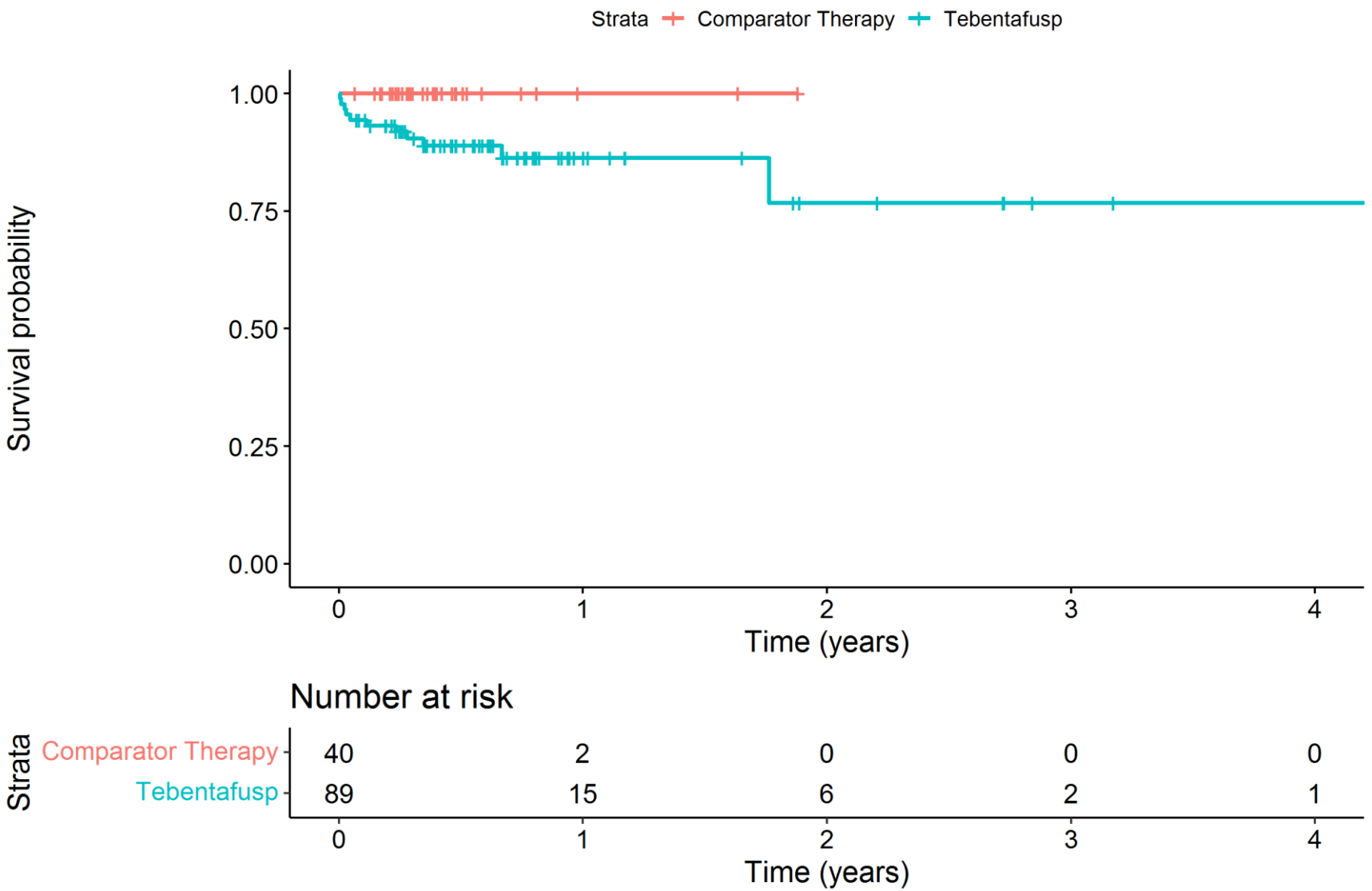
Hypophosphatämie- Keine Vorherige Therapie adjuvant/neoadjuvant



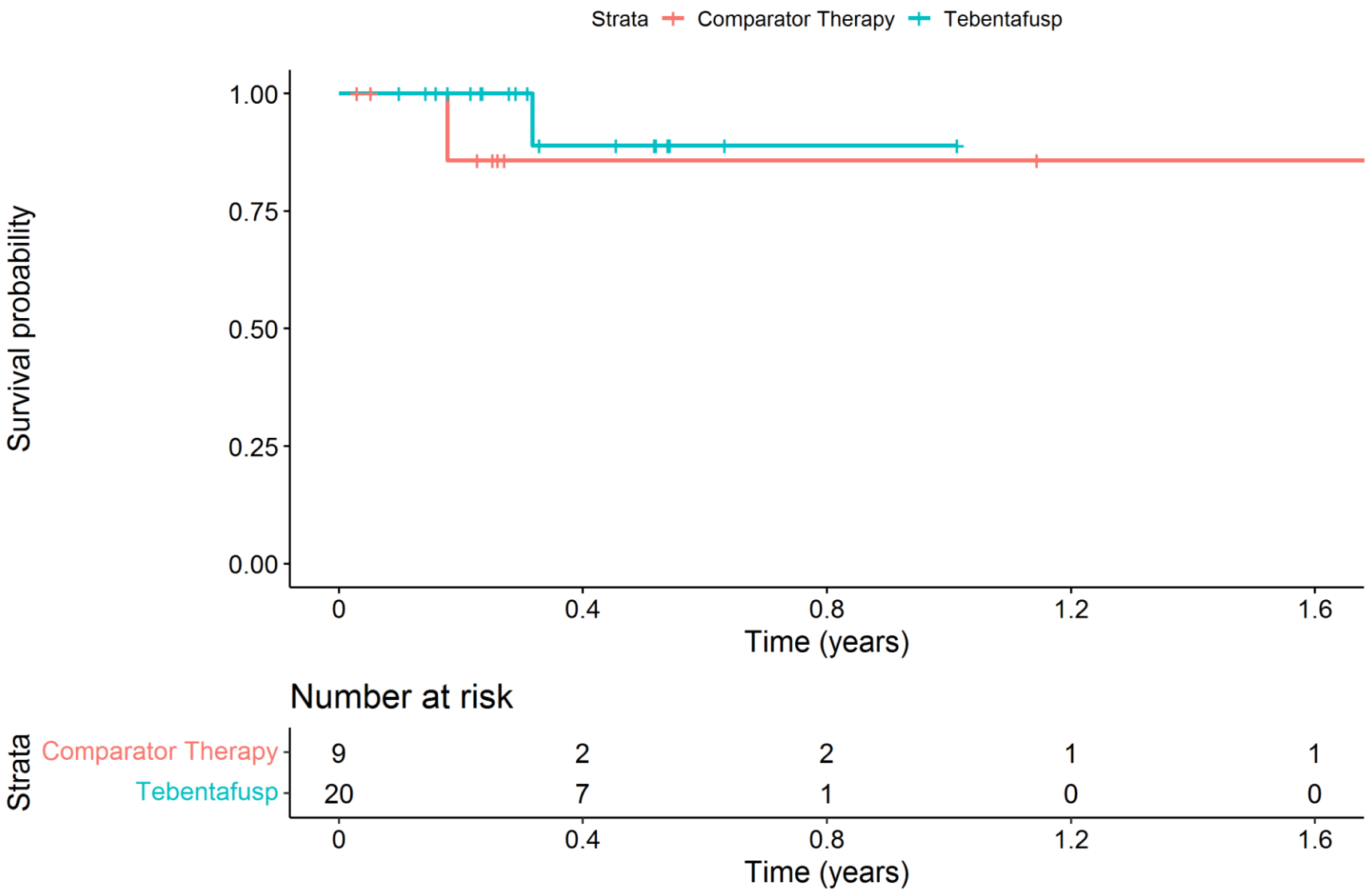
Hypophosphatämie- Läsion ≤ 3cm



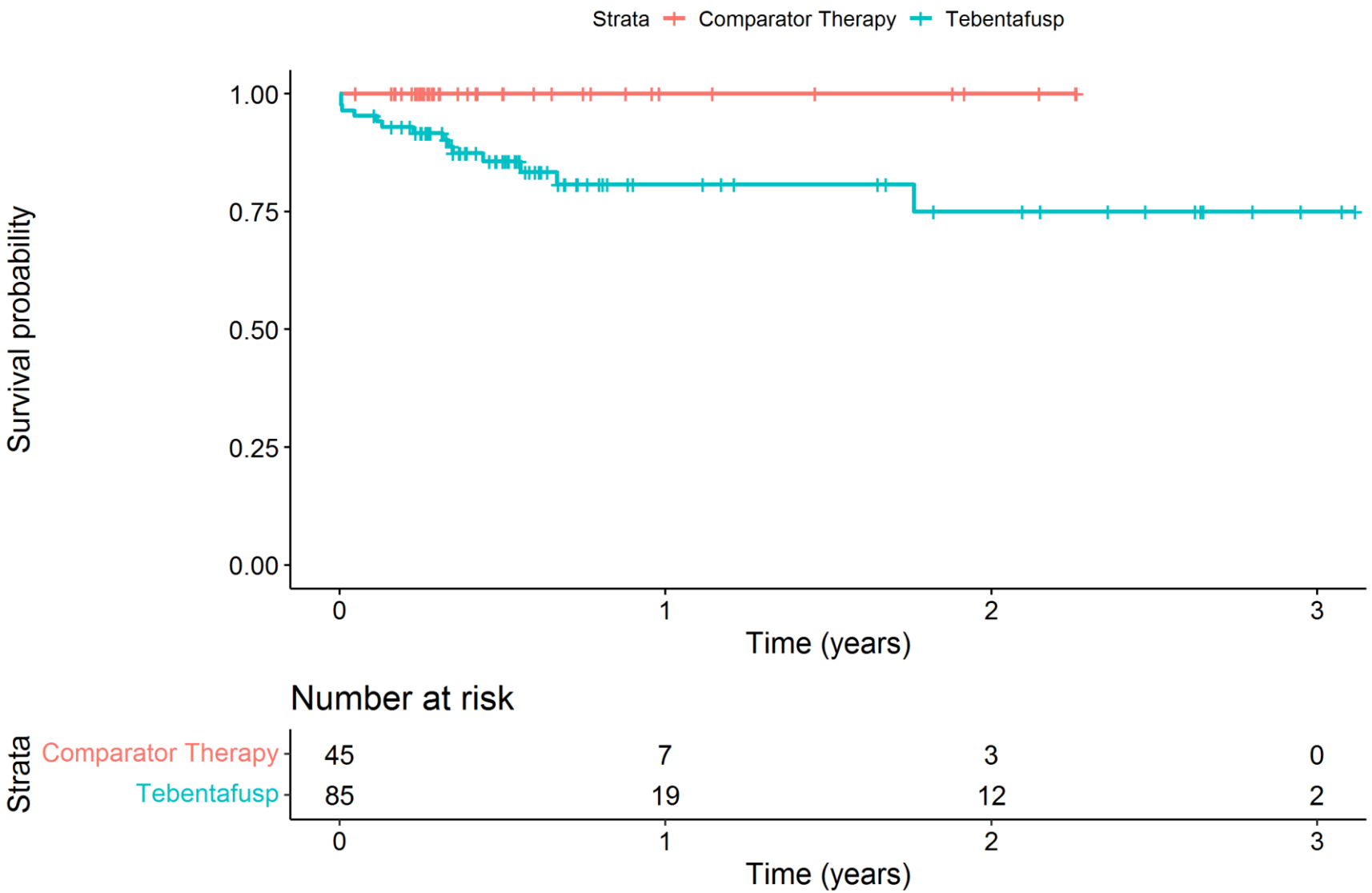
Hypophosphatämie- Läsion 3,1-8,0 cm



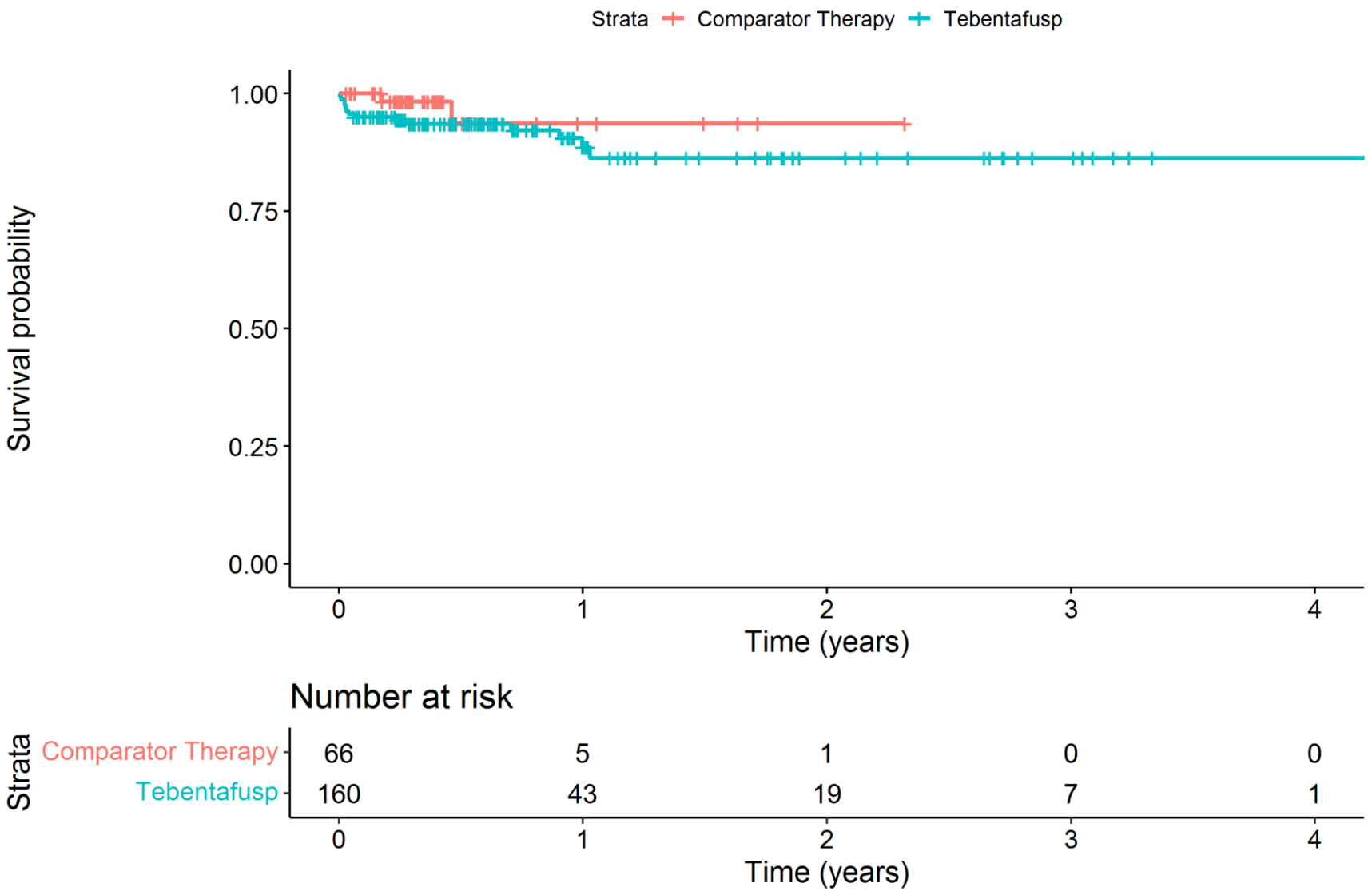
Hypophosphatämie- Läsion ≥8,1 cm



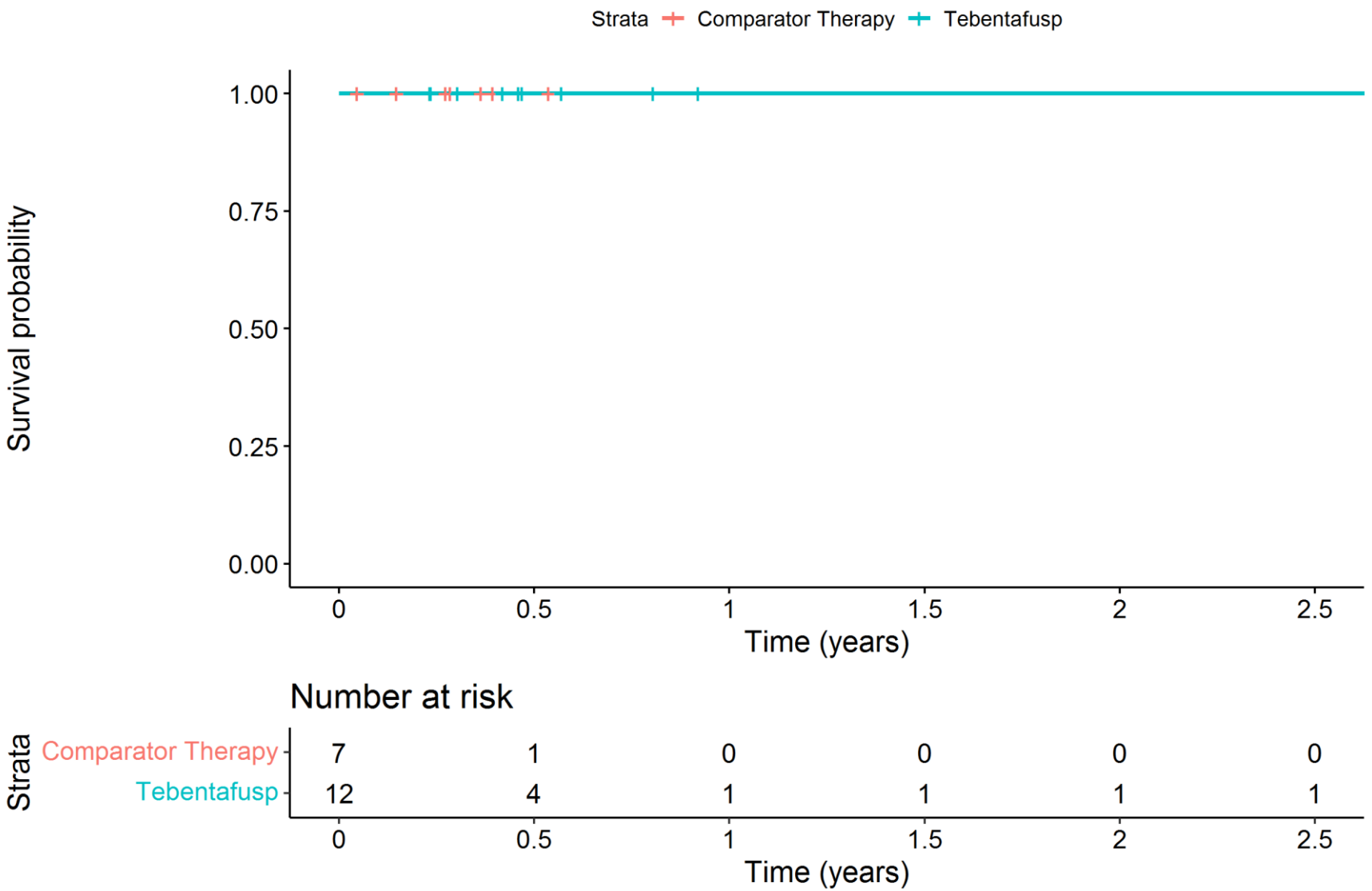
Hypophosphatämie- Nordamerika



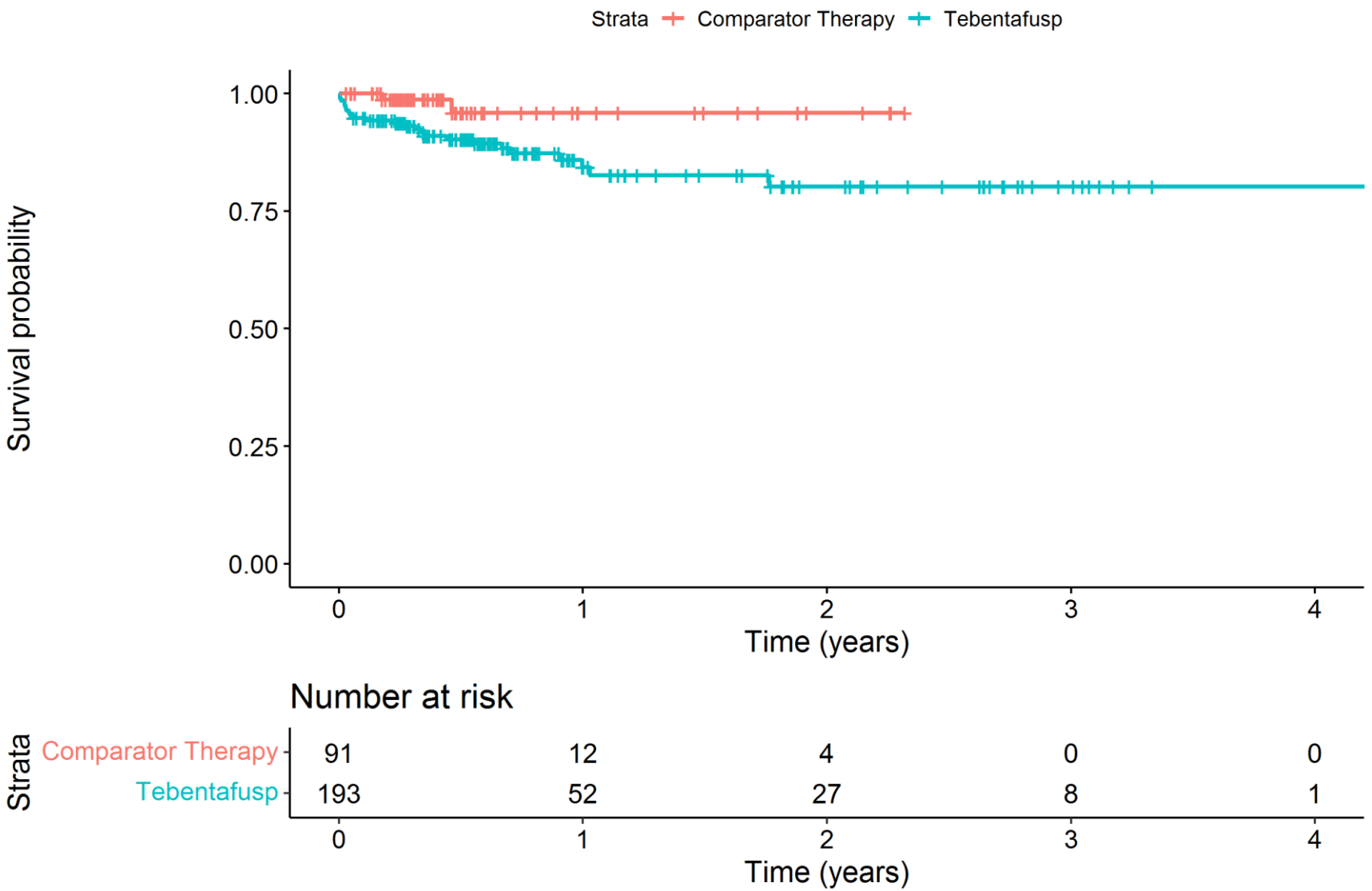
Hypophosphatämie- Nicht-Nordamerika



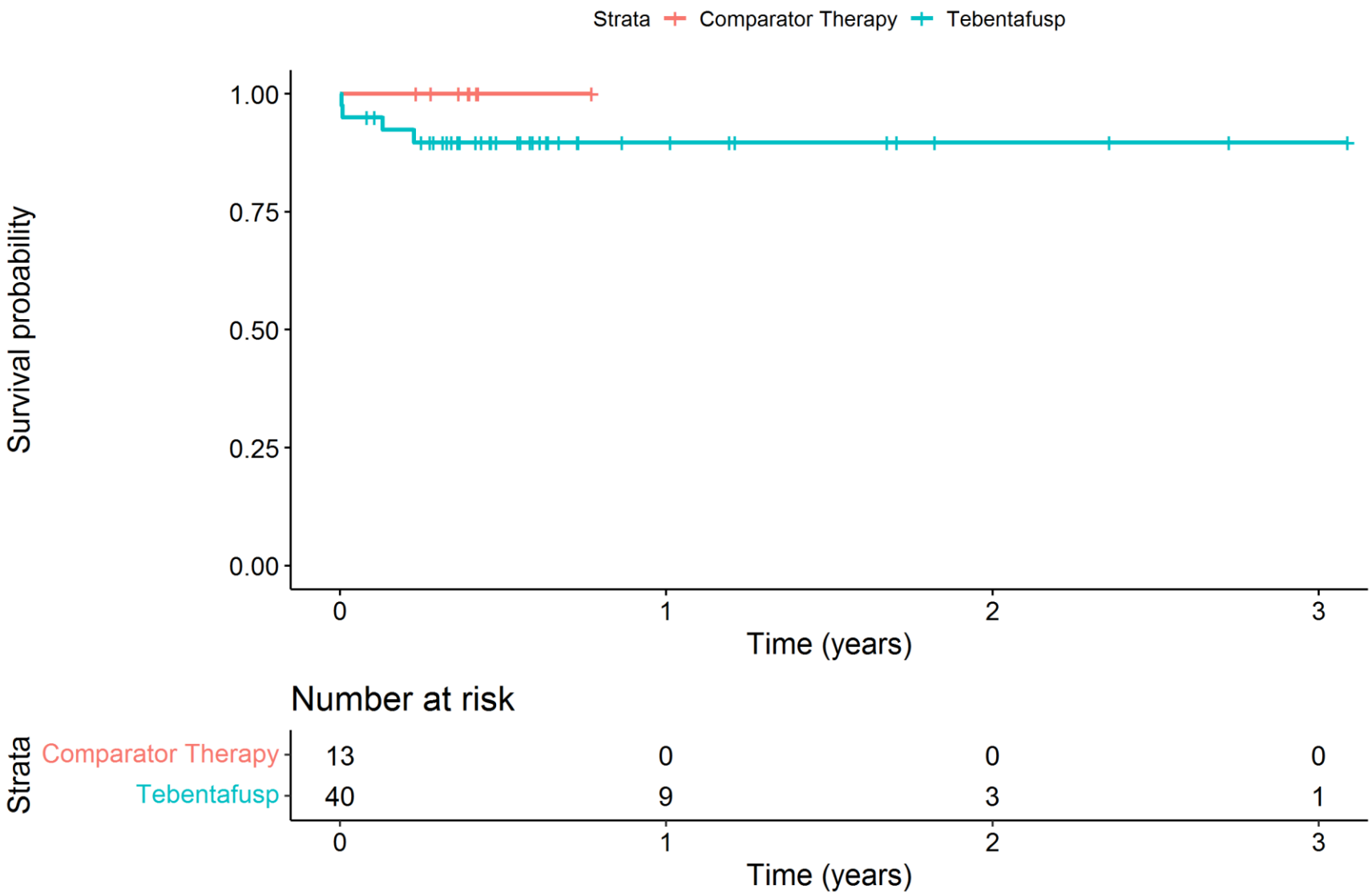
Hypophosphatämie- Dacarbazin



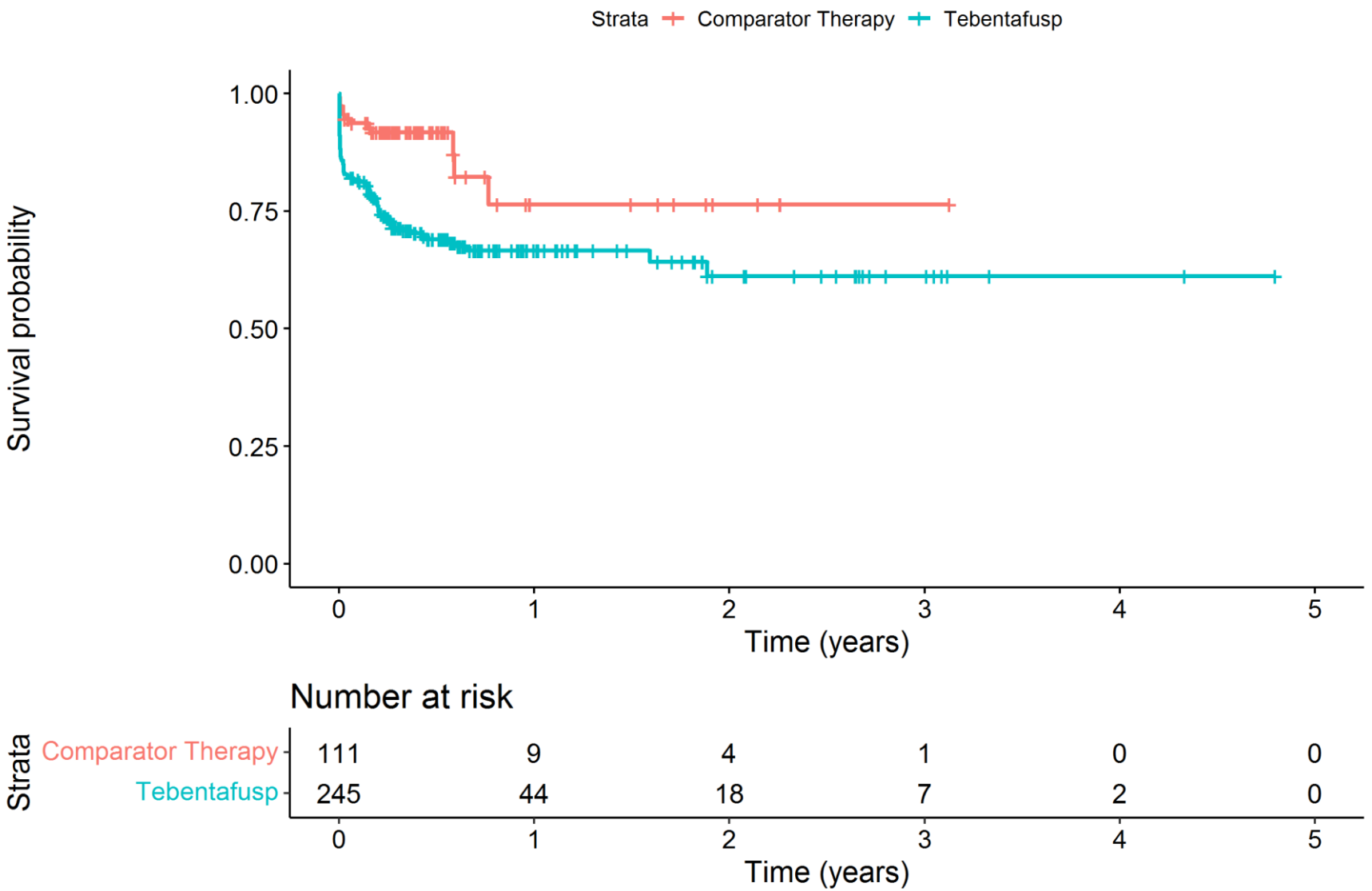
Hypophosphatämie- Pembrolizumab



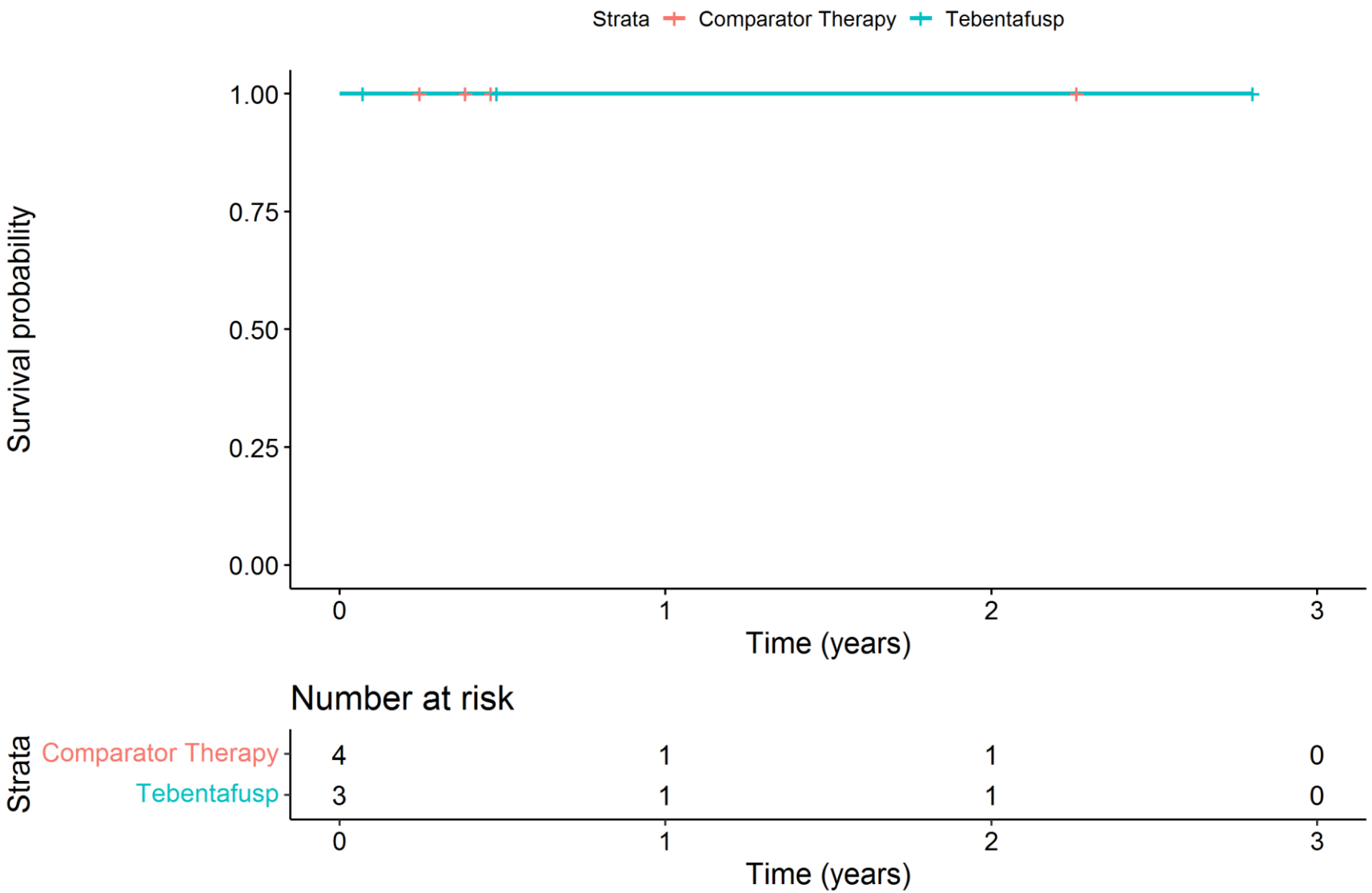
Hypophosphatämie- Ipilimumab



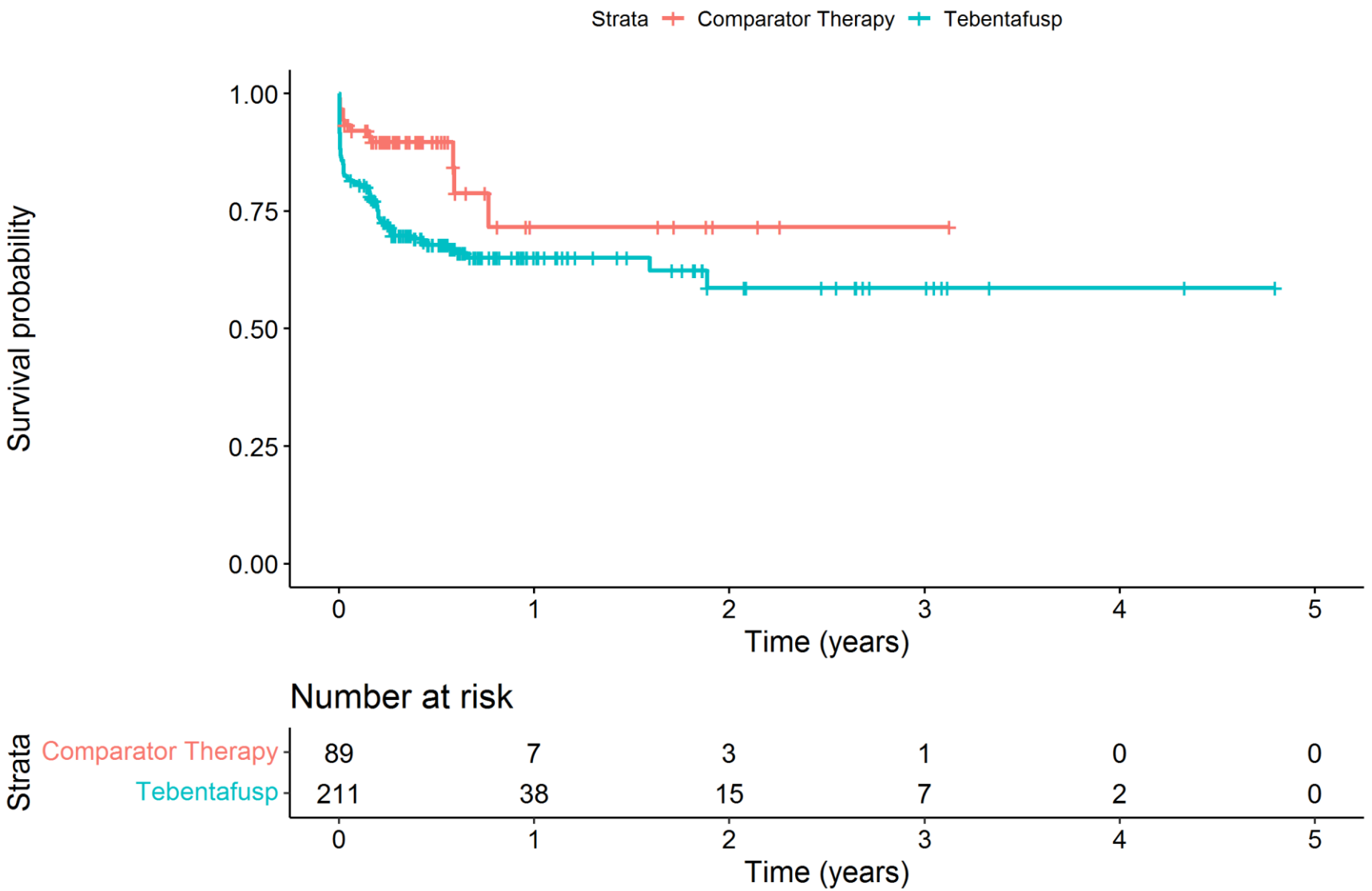
Kopfschmerzen - Gesamt



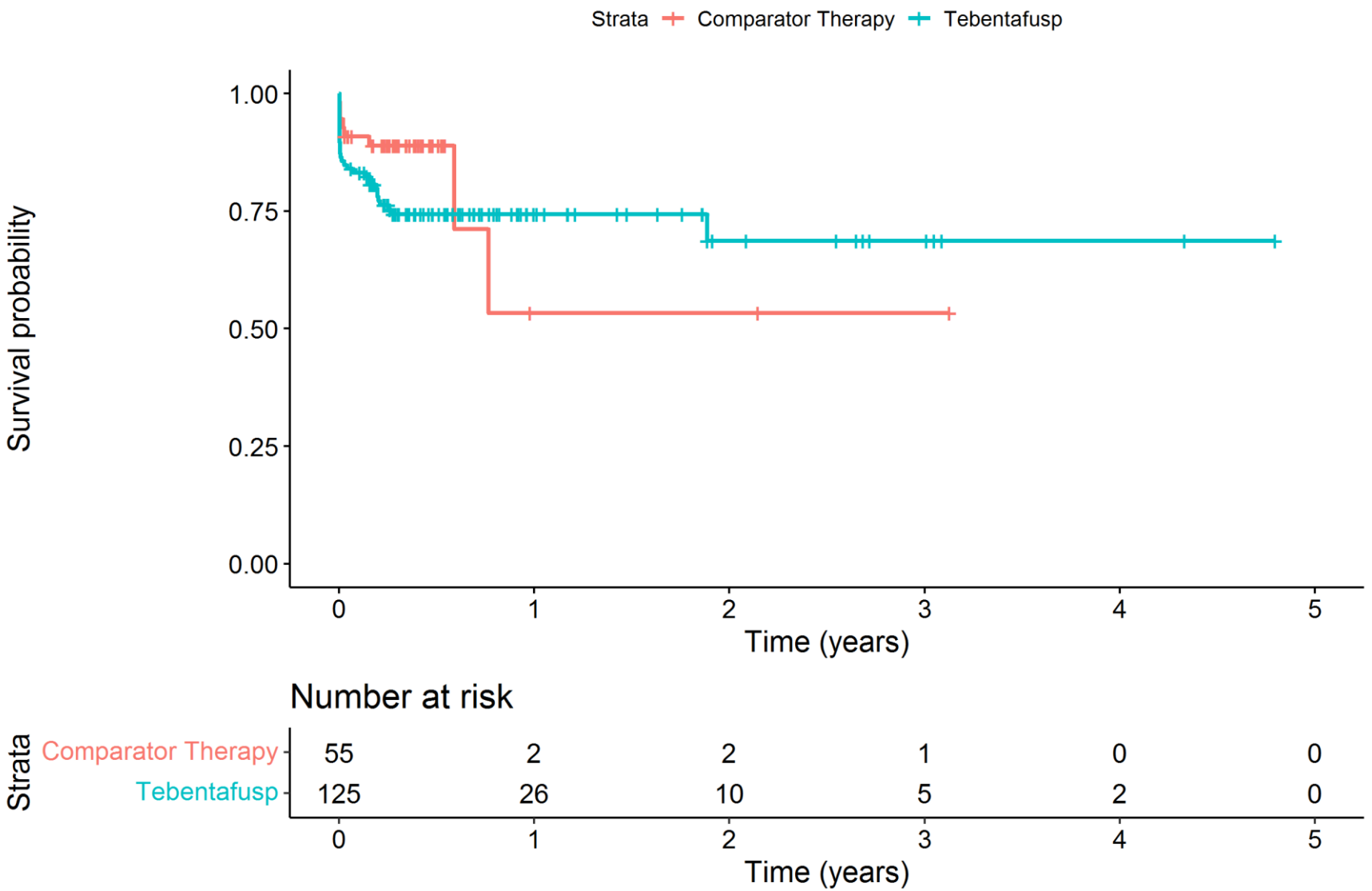
Kopfschmerzen - Hispanisch



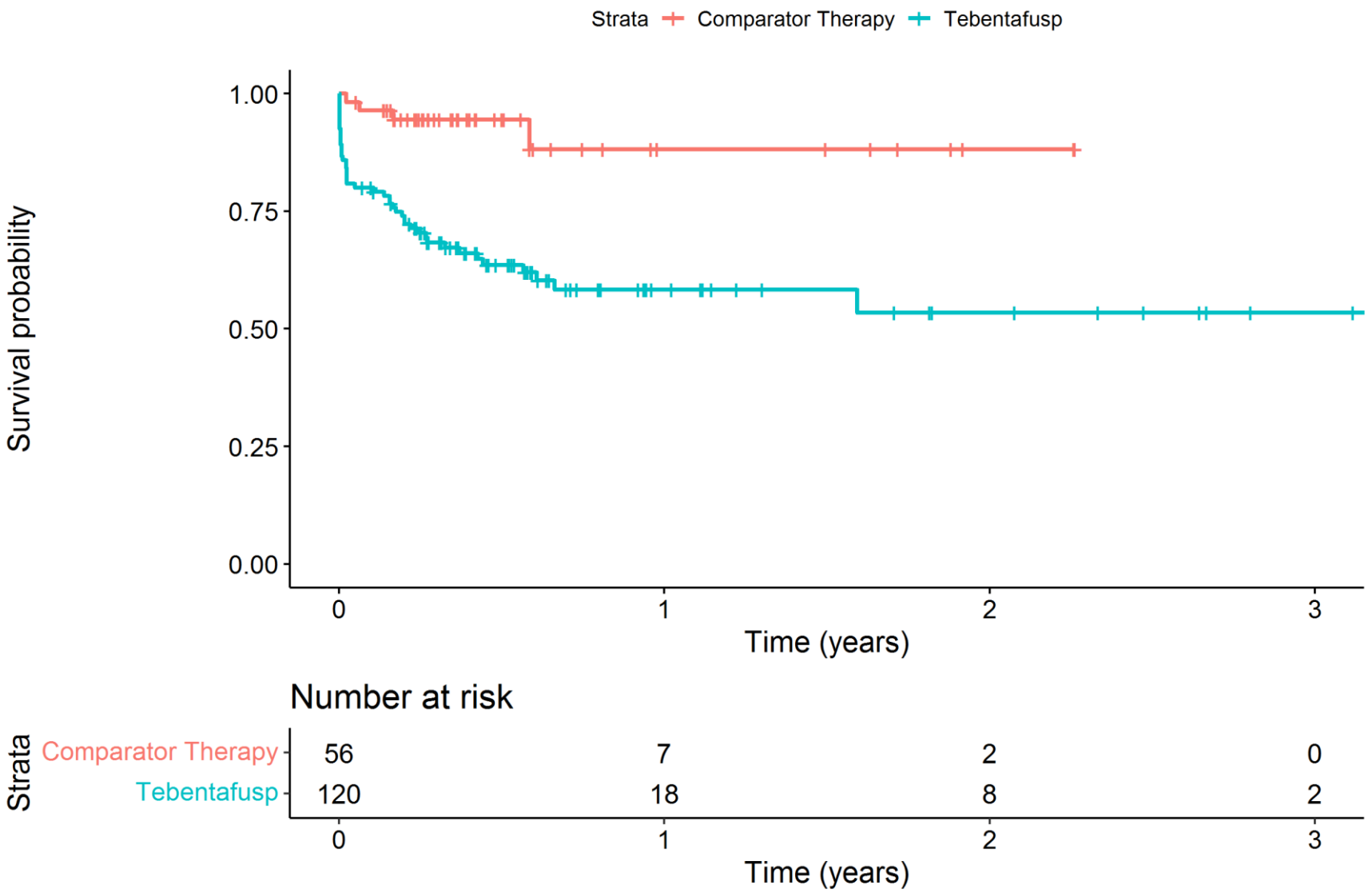
Kopfschmerzen - Nicht-hispanisch



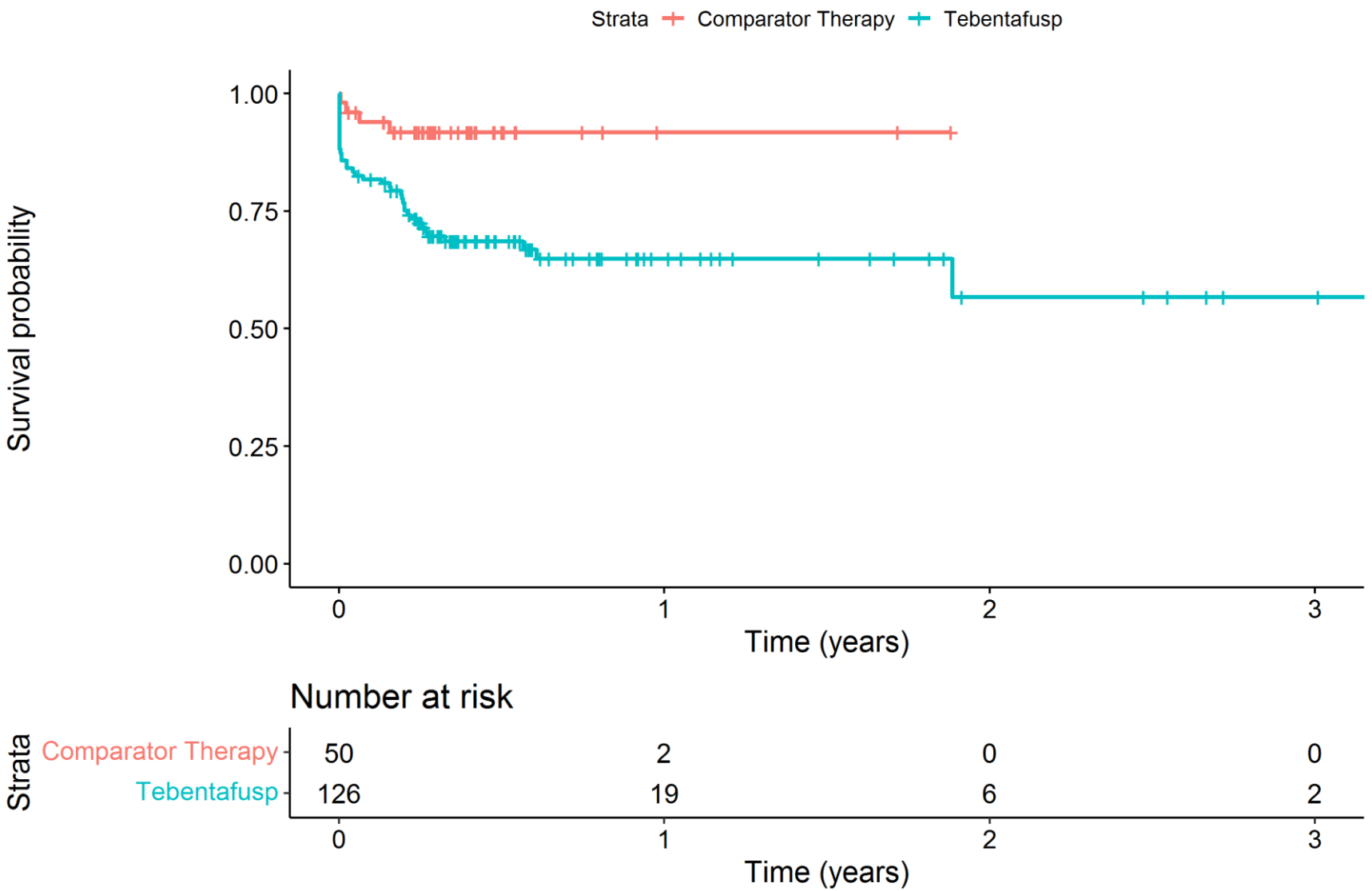
Kopfschmerzen - Männlich



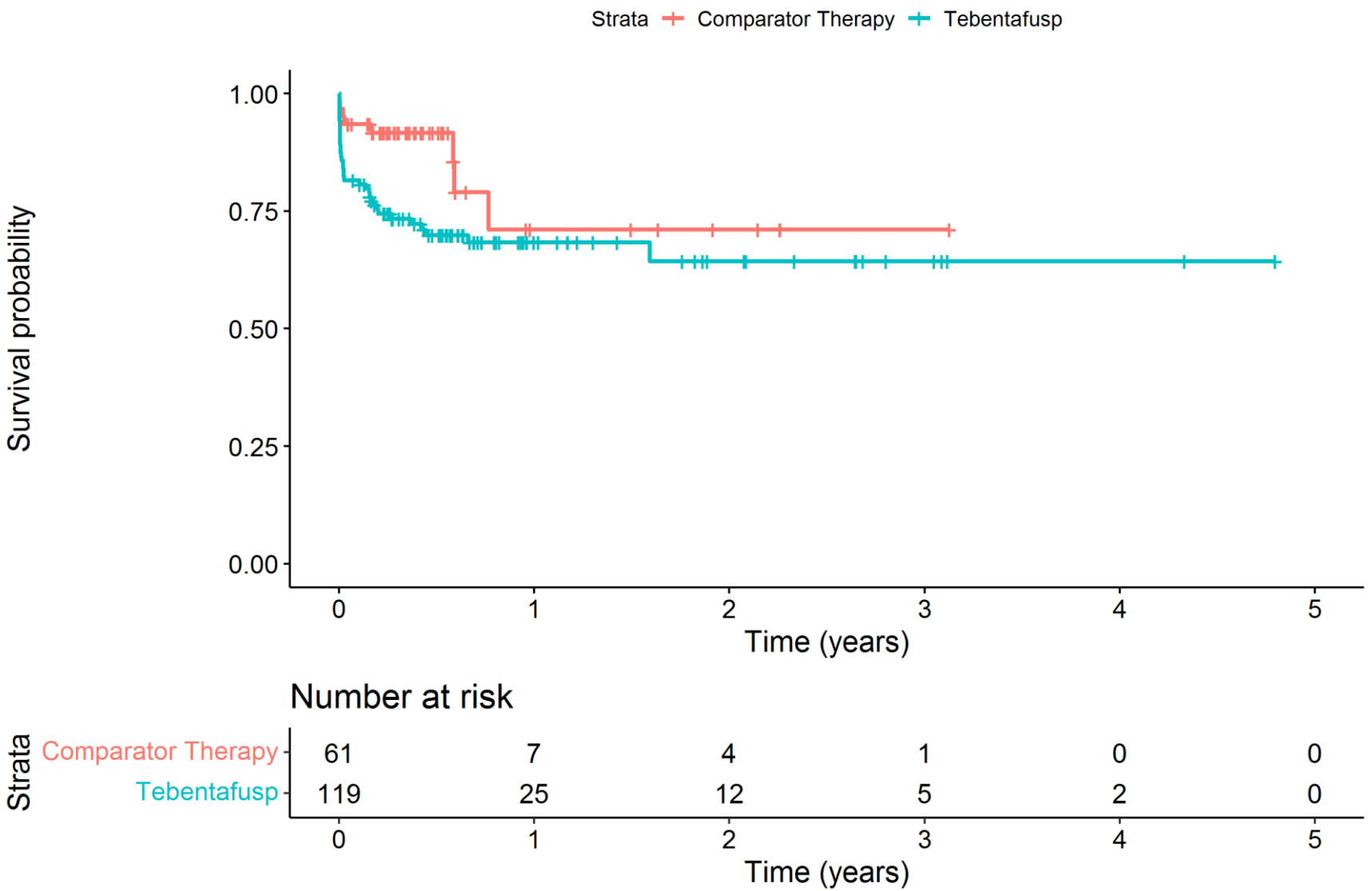
Kopfschmerzen - Weiblich



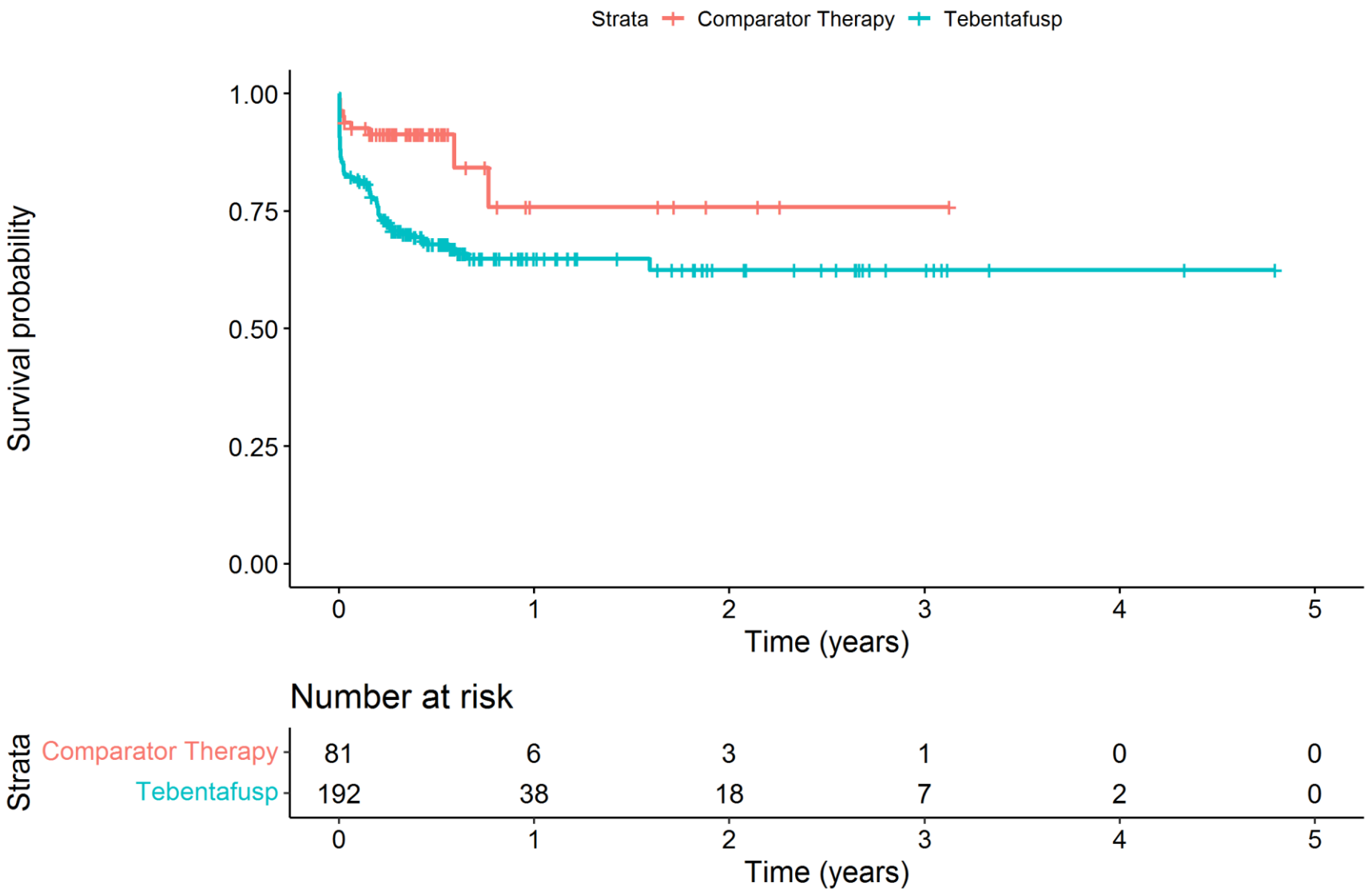
Kopfschmerzen - <65



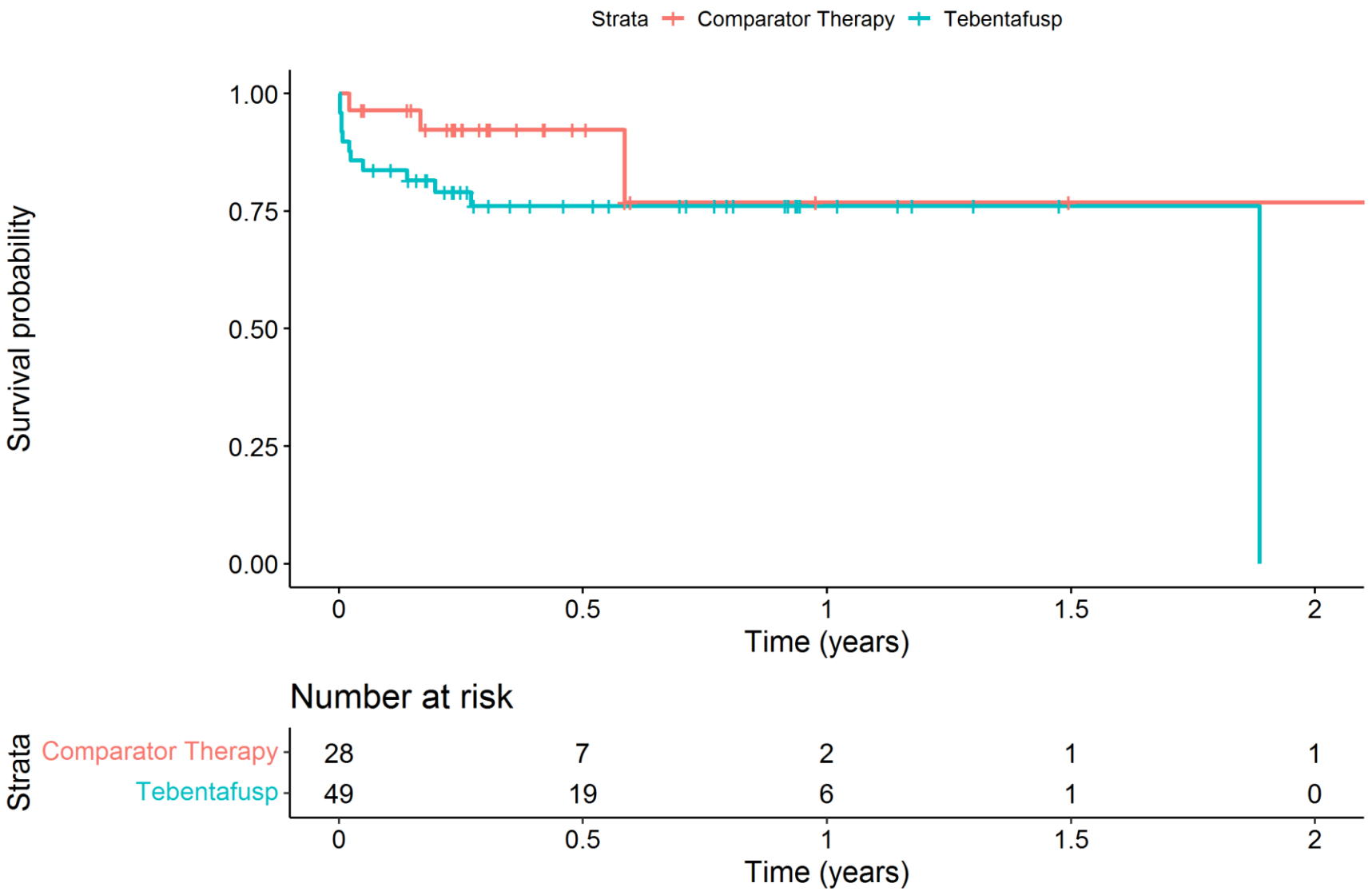
Kopfschmerzen - ≥65



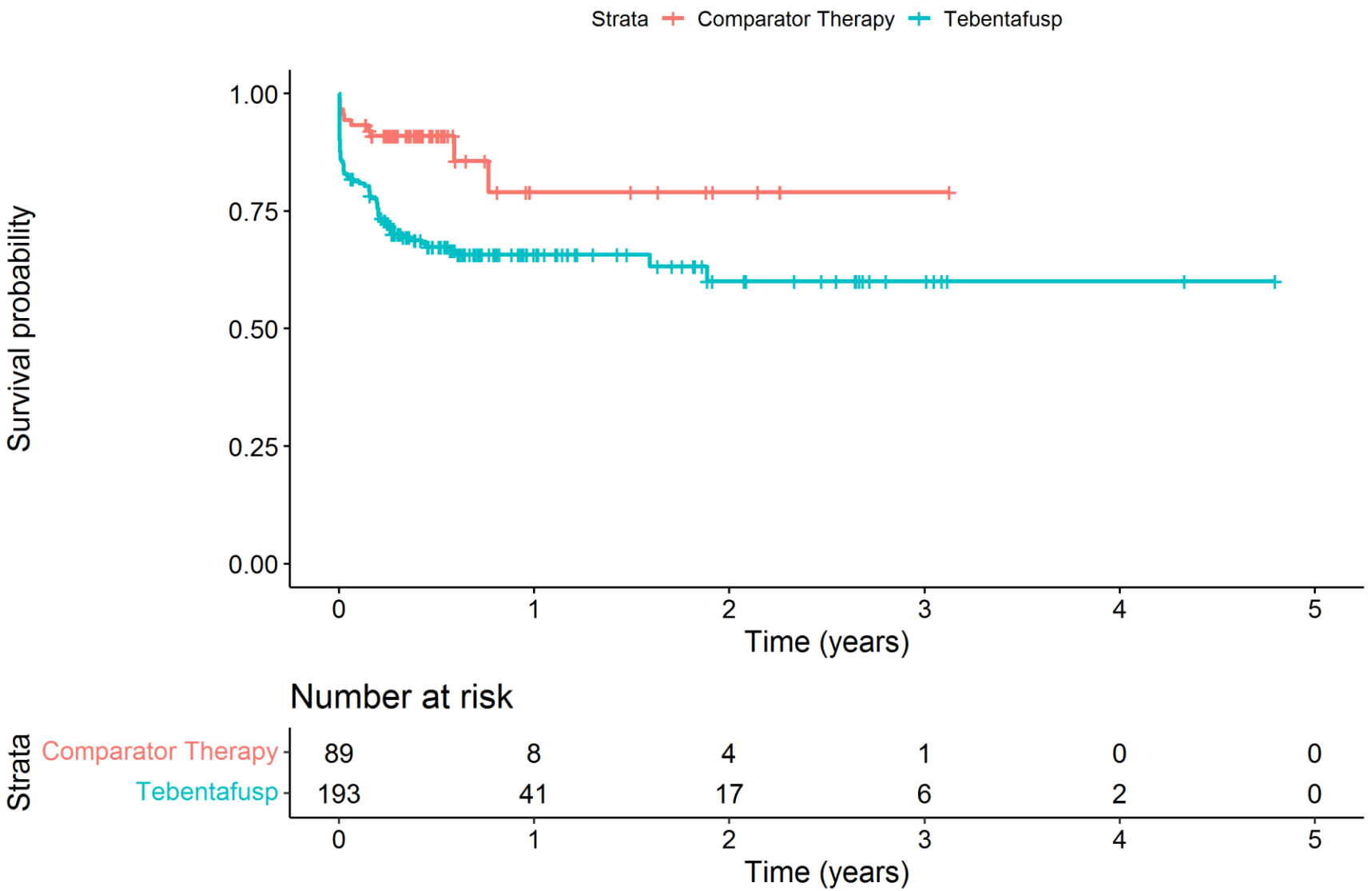
Kopfschmerzen - ECOG 0



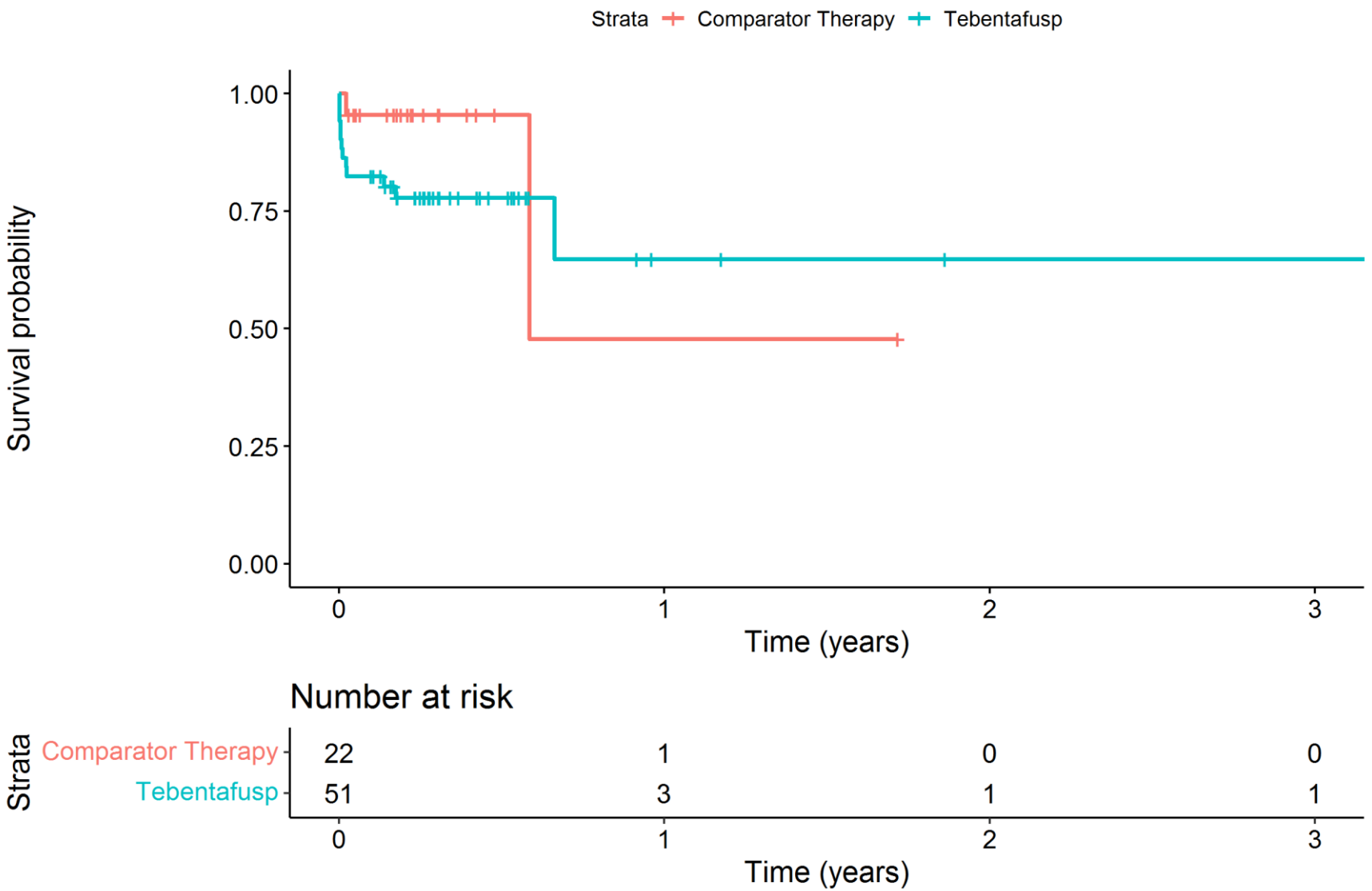
Kopfschmerzen - ECOG 1



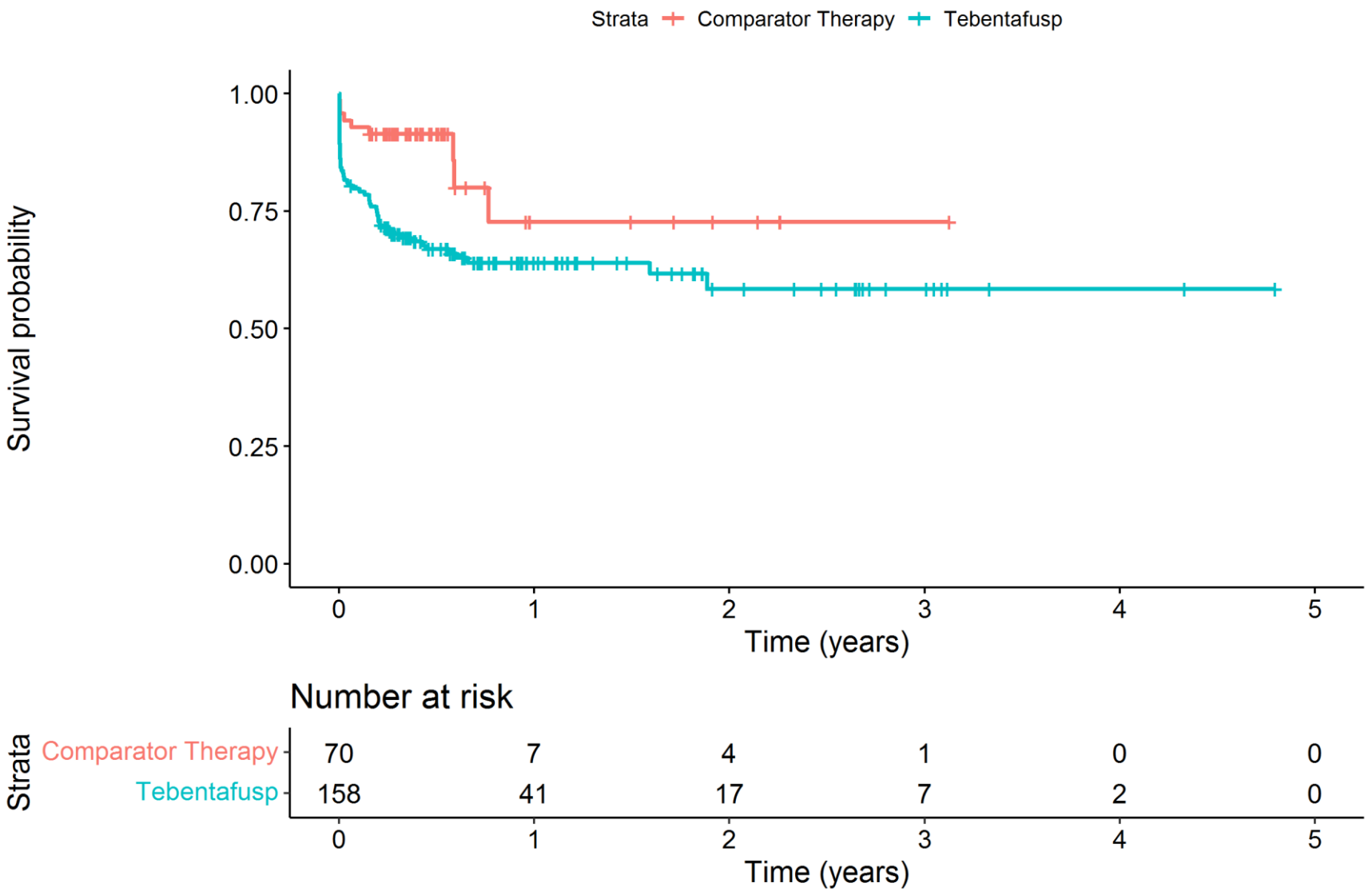
Kopfschmerzen - ALP ≤ ULN



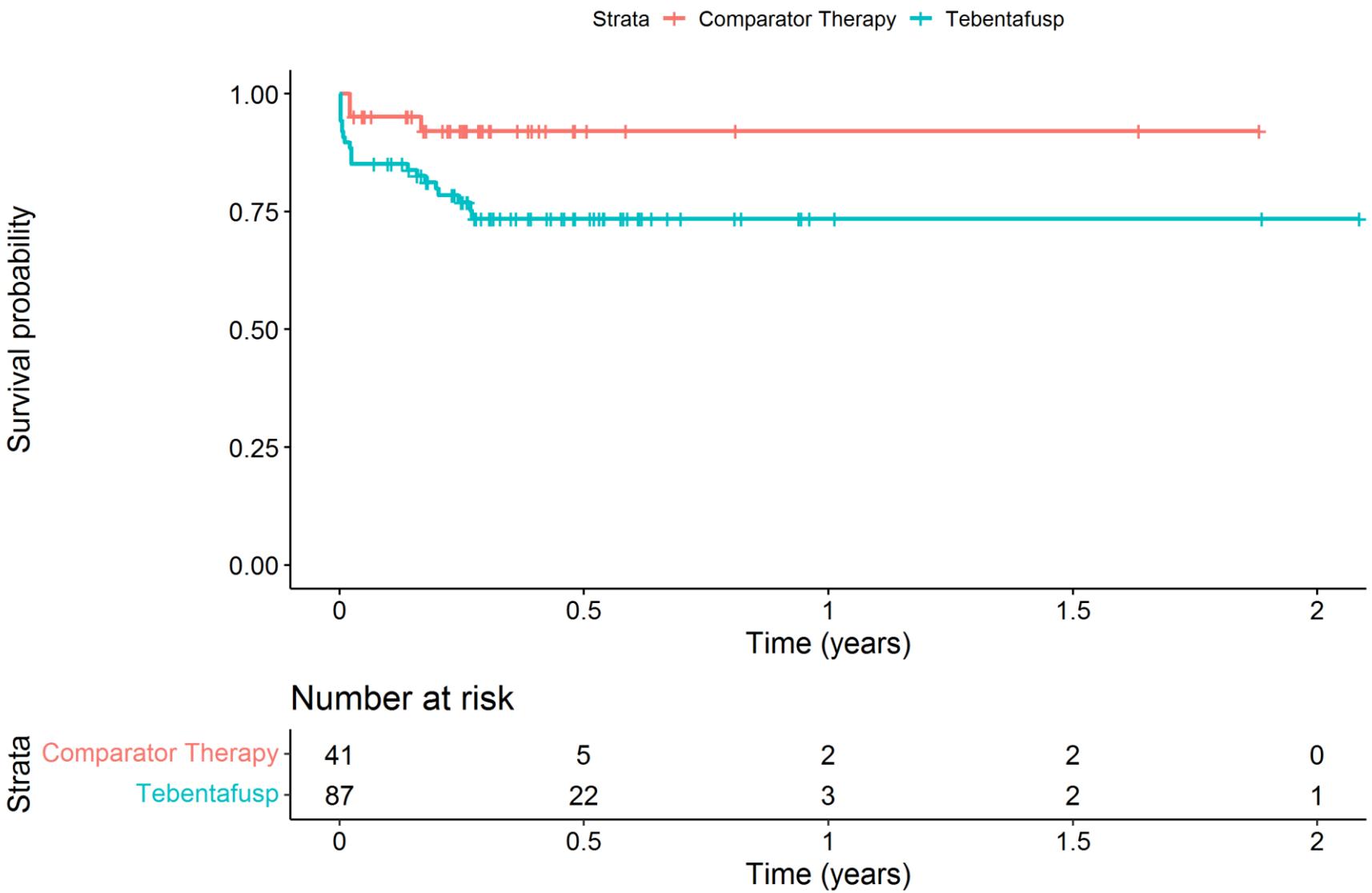
Kopfschmerzen - ALP > ULN



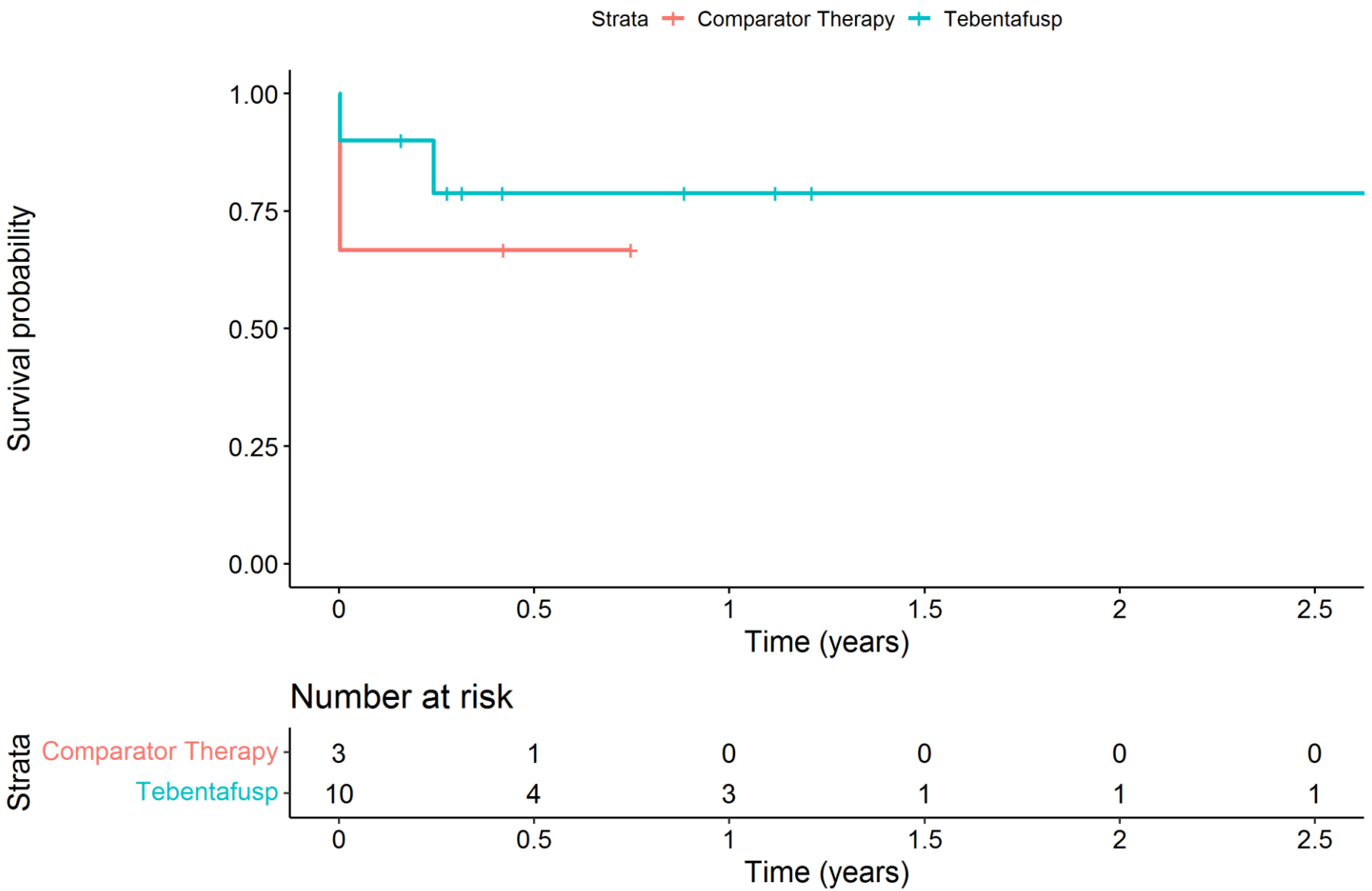
Kopfschmerzen - LDH =< ULN



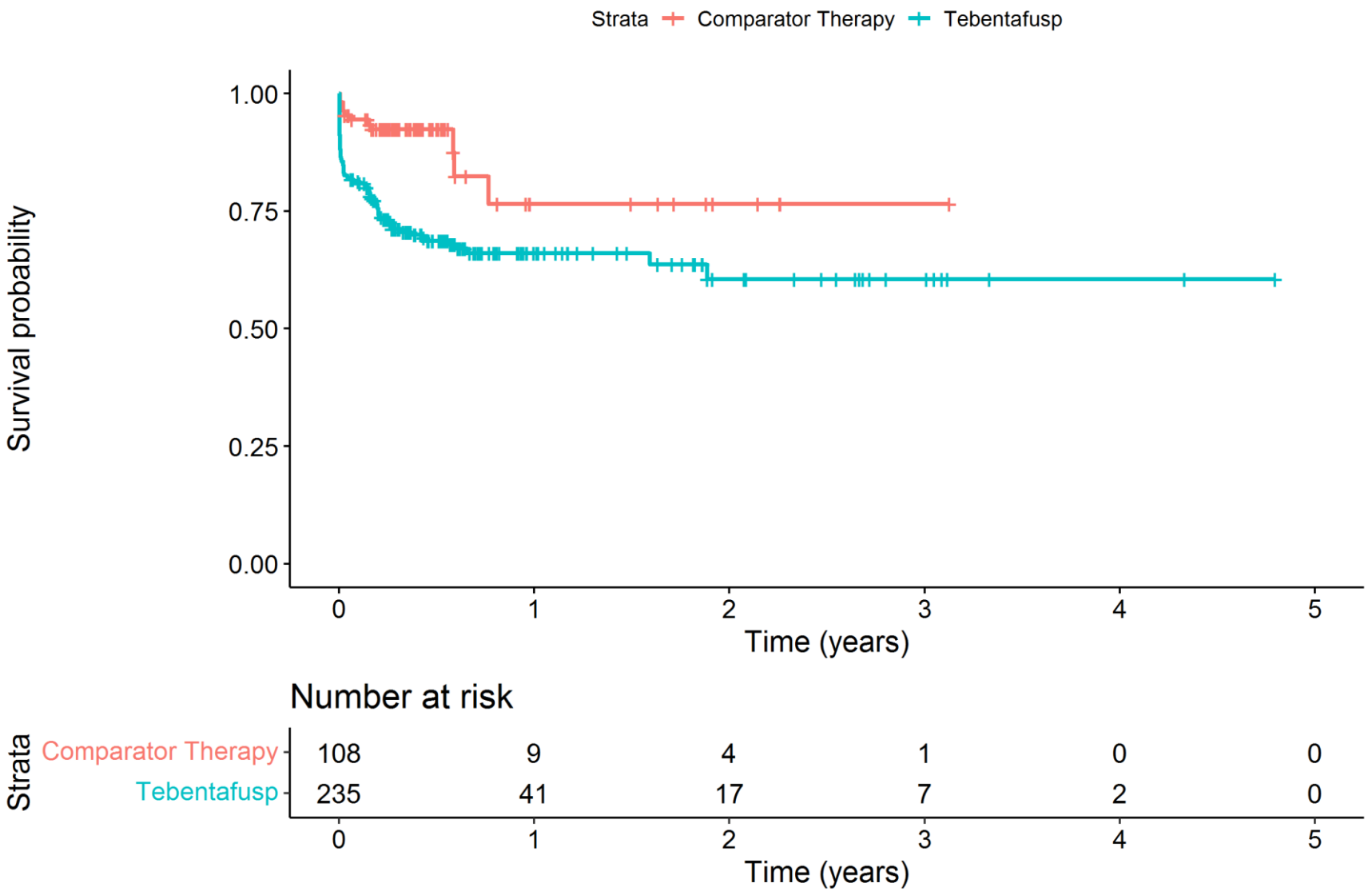
Kopfschmerzen - LDH > ULN



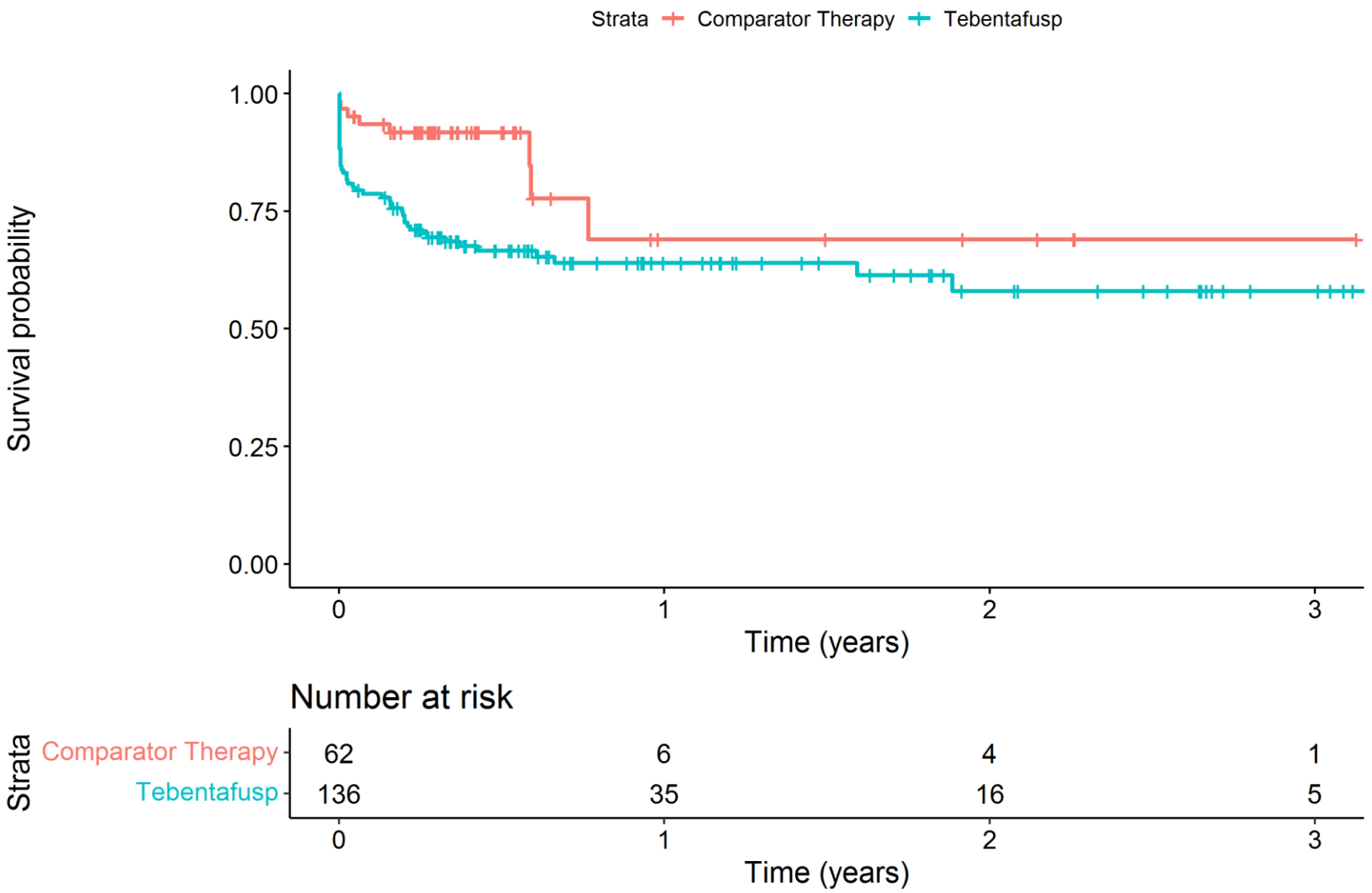
Kopfschmerzen - Vorherige Therapie adjuvant/neoadjuvant



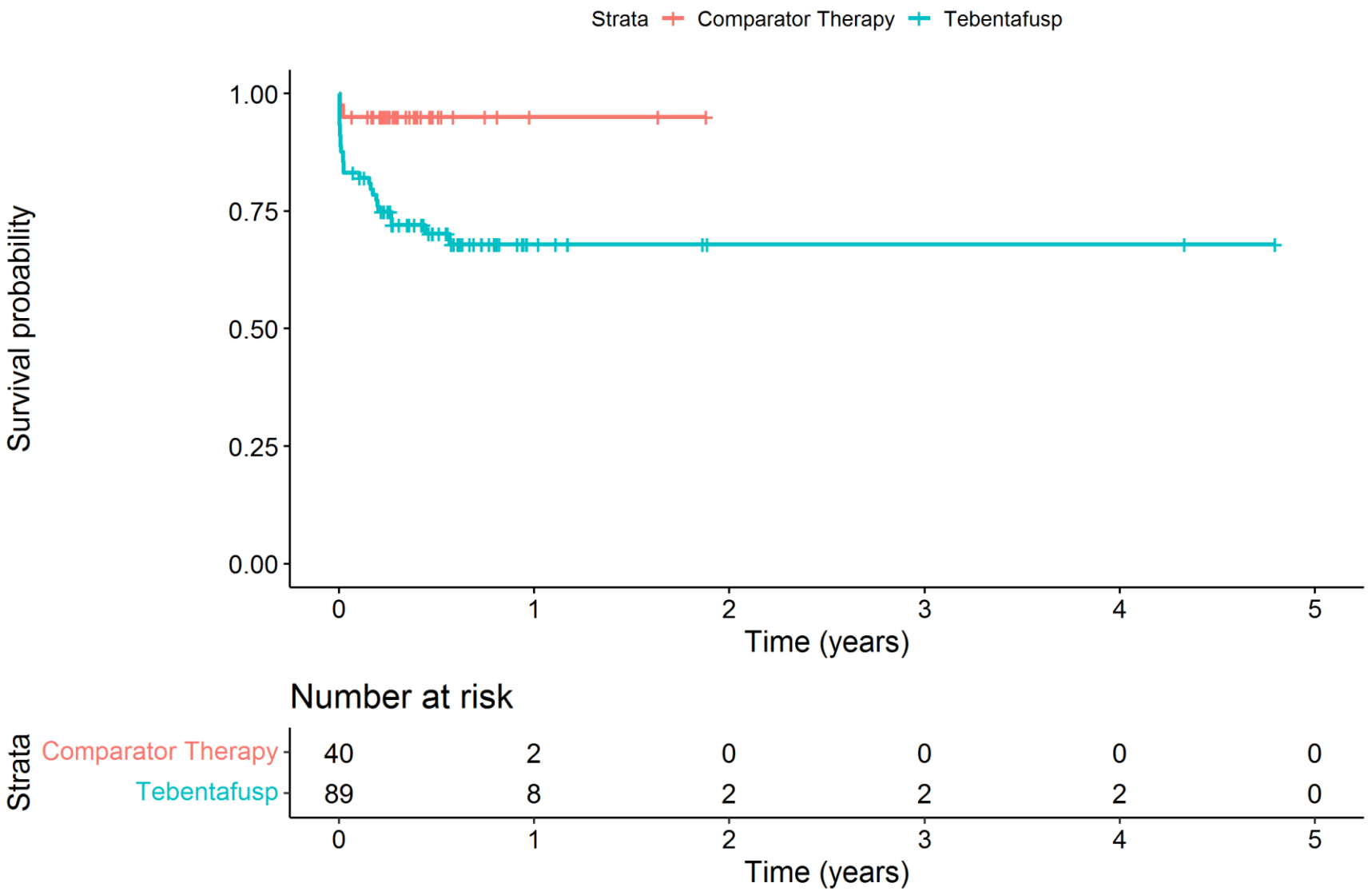
Kopfschmerzen - Keine Vorherige Therapie adjuvant/neoadjuvant



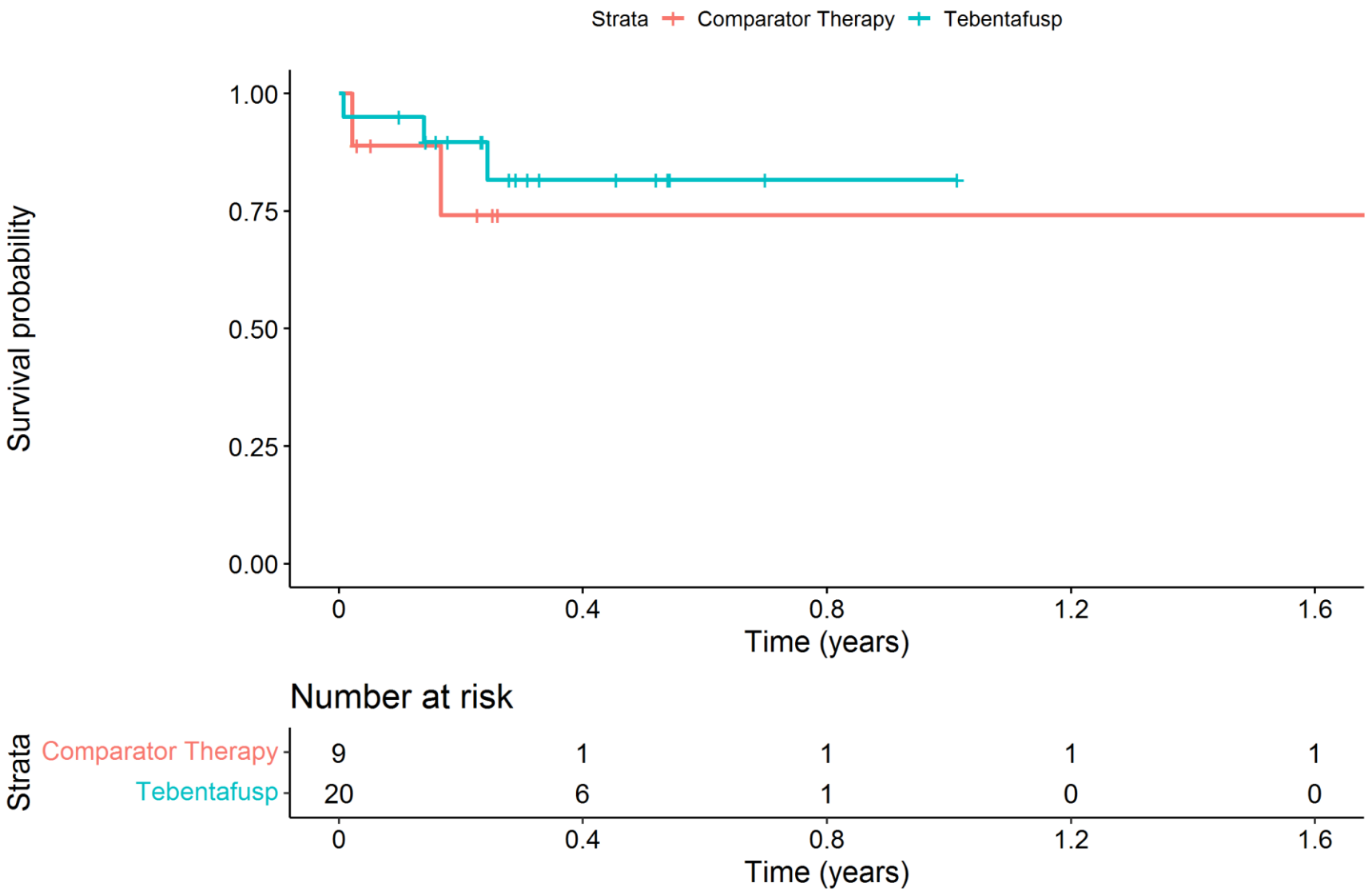
Kopfschmerzen - Läsion ≤ 3cm



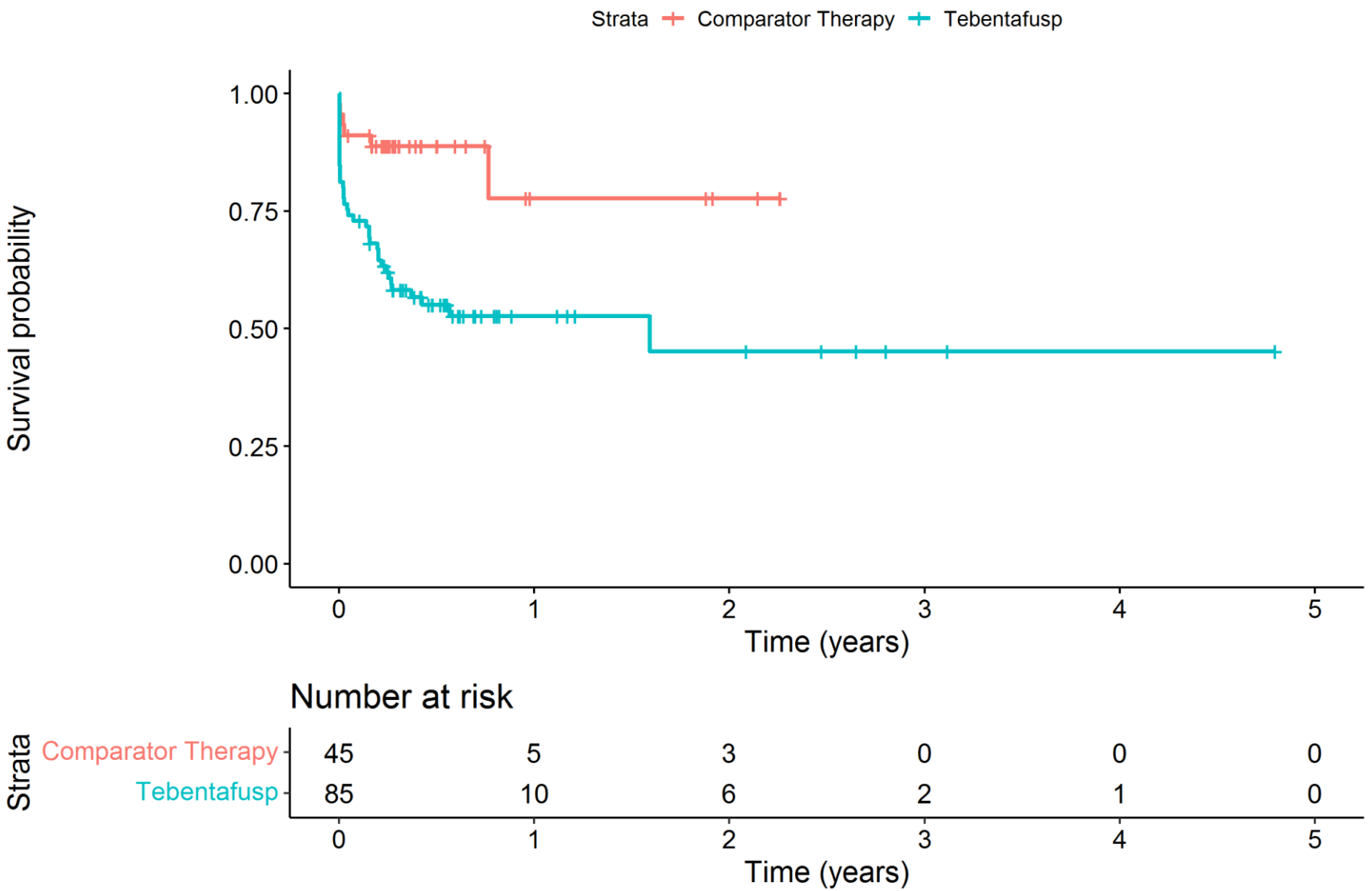
Kopfschmerzen - Läsion 3,1-8,0 cm



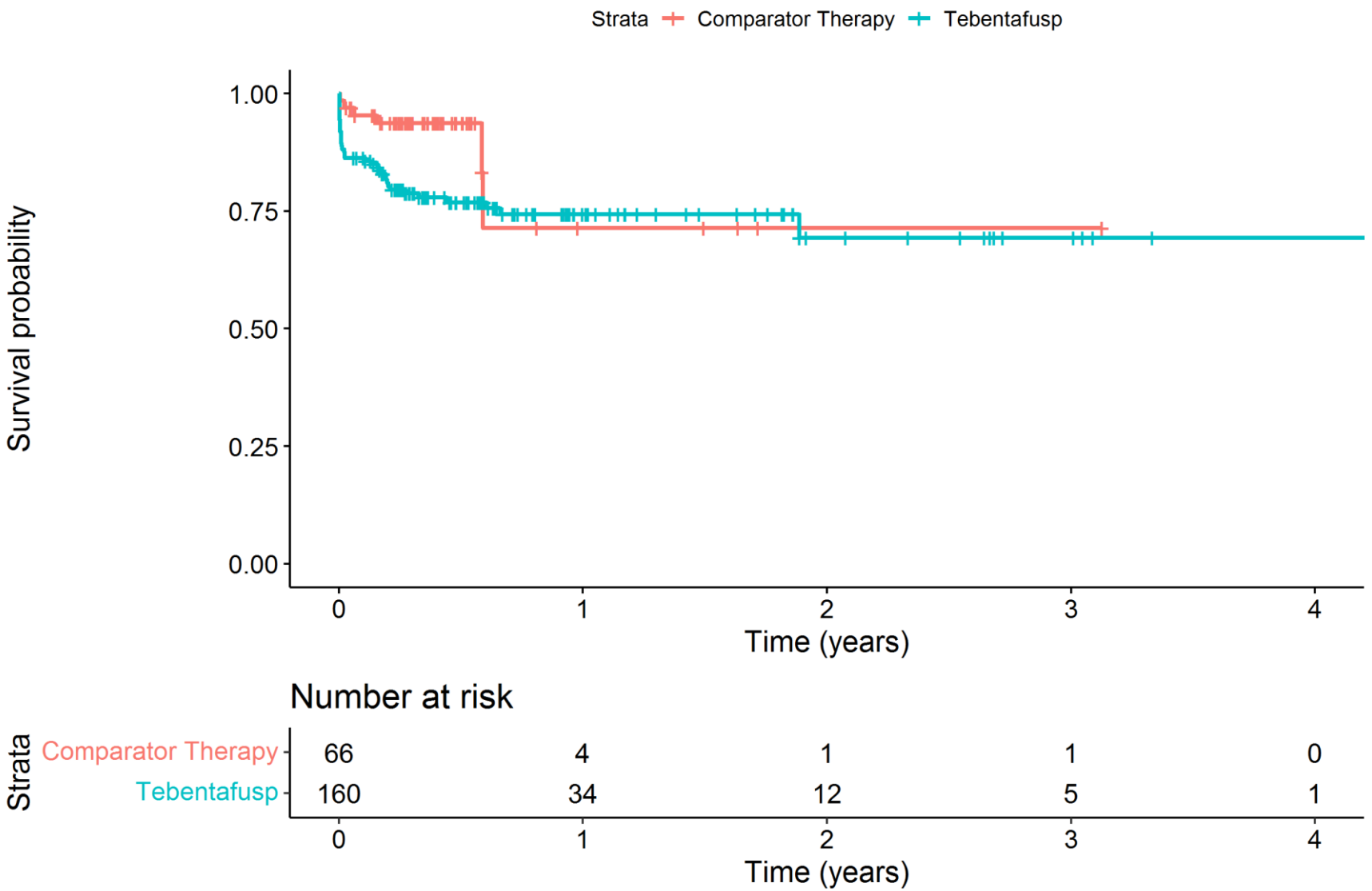
Kopfschmerzen - Läsion ≥8,1 cm



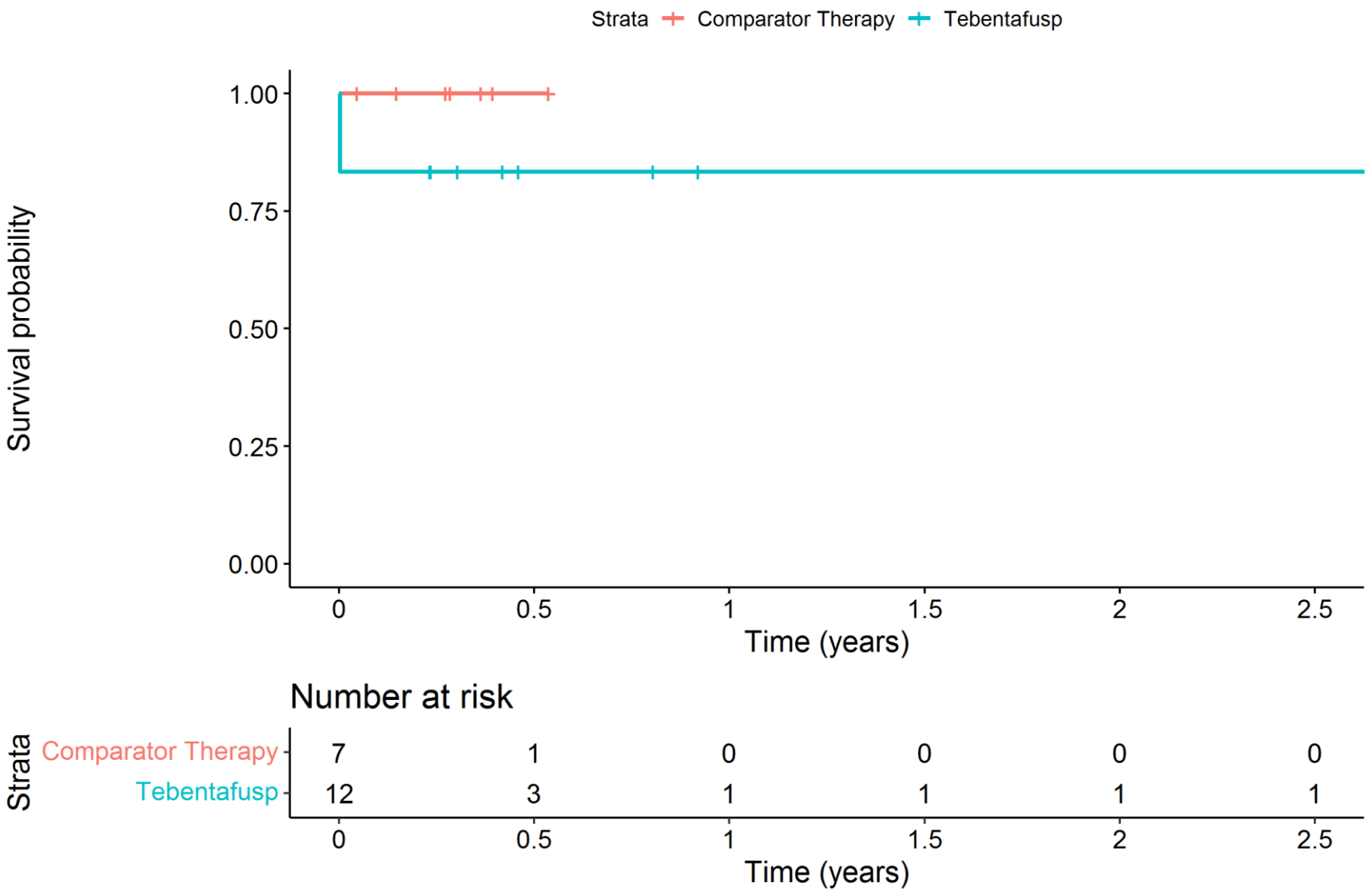
Kopfschmerzen - Nordamerika



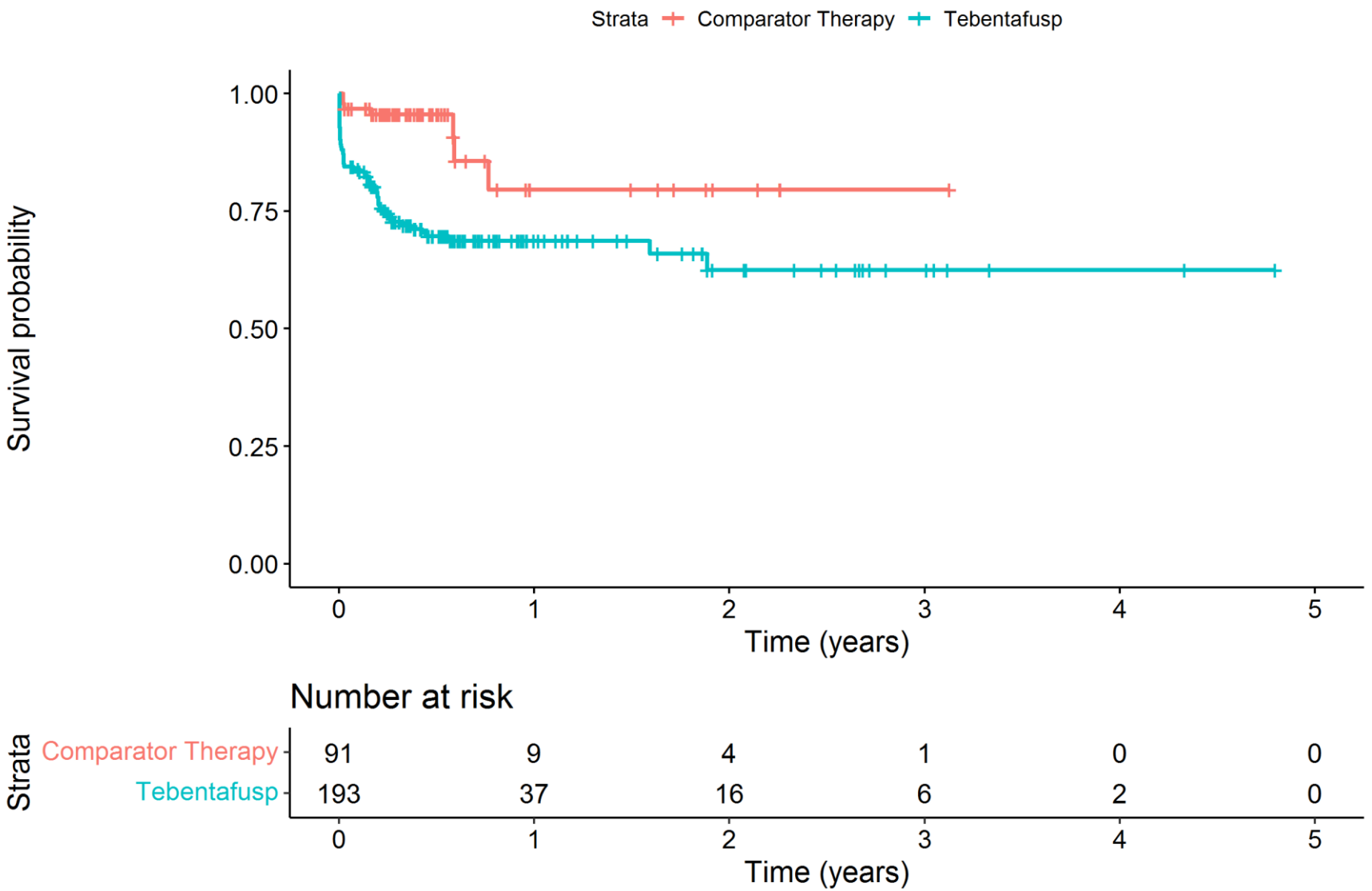
Kopfschmerzen - Nicht-Nordamerika



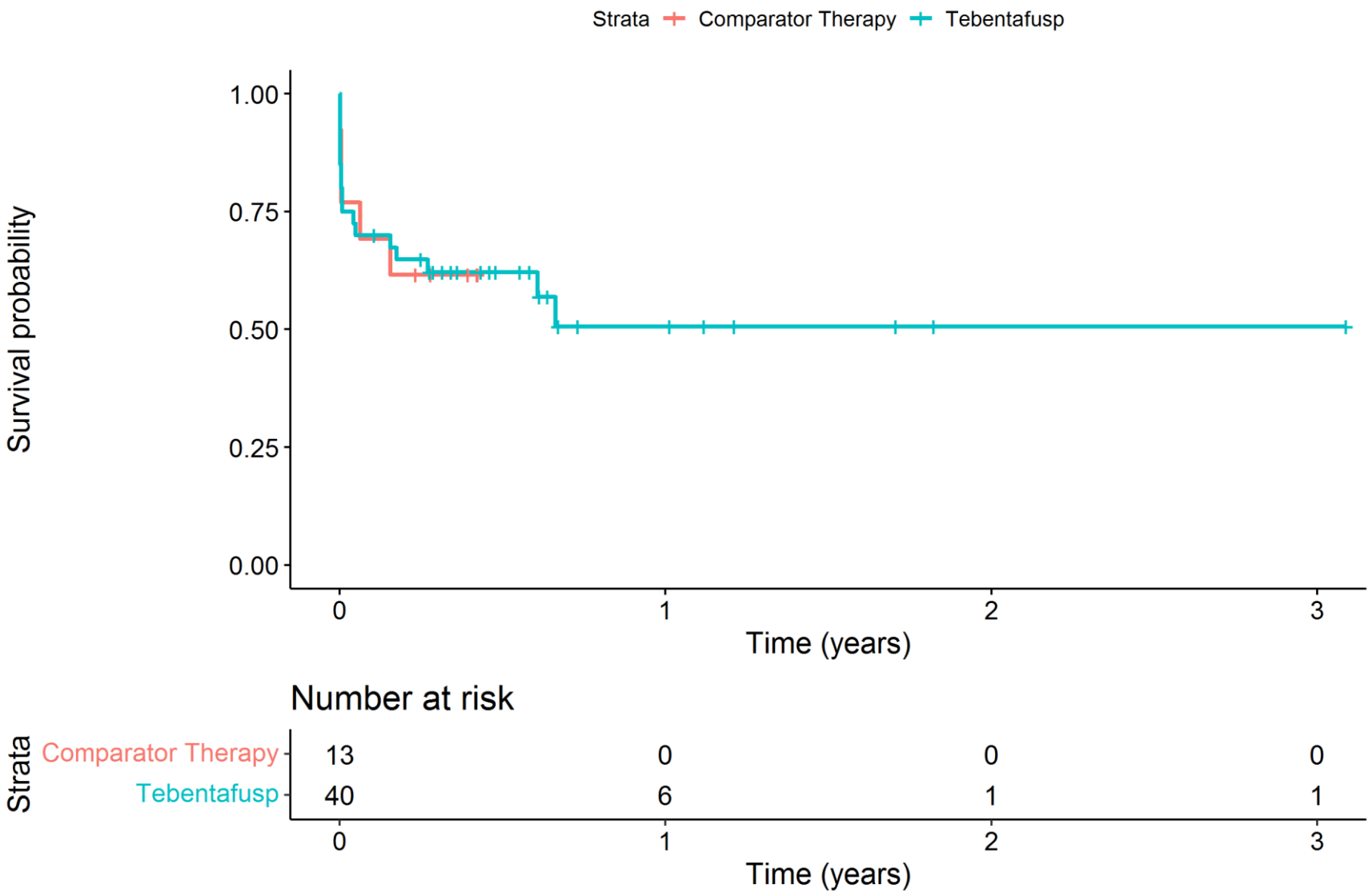
Kopfschmerzen - Dacarbazin



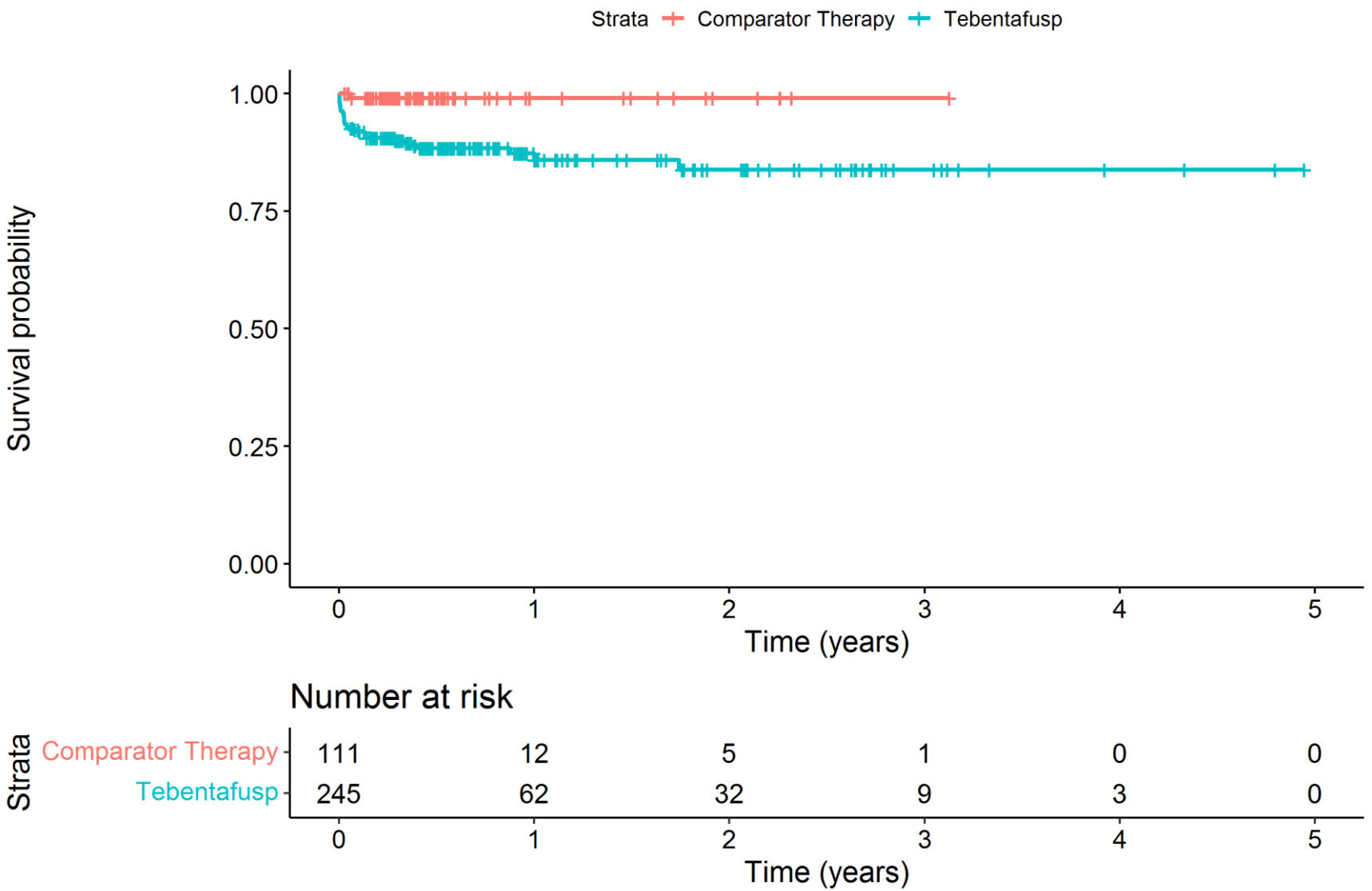
Kopfschmerzen - Pembrolizumab



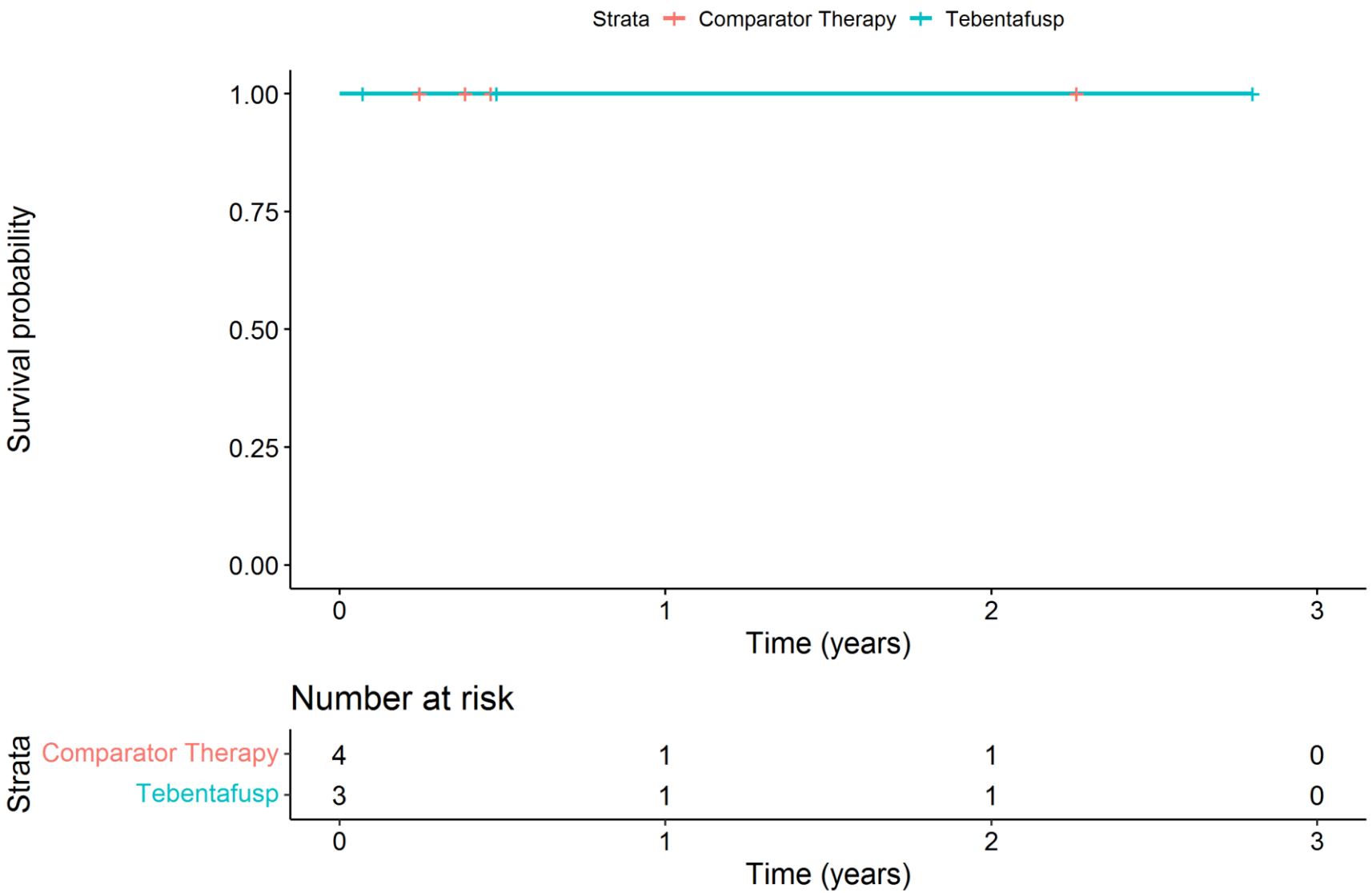
Kopfschmerzen - Ipilimumab



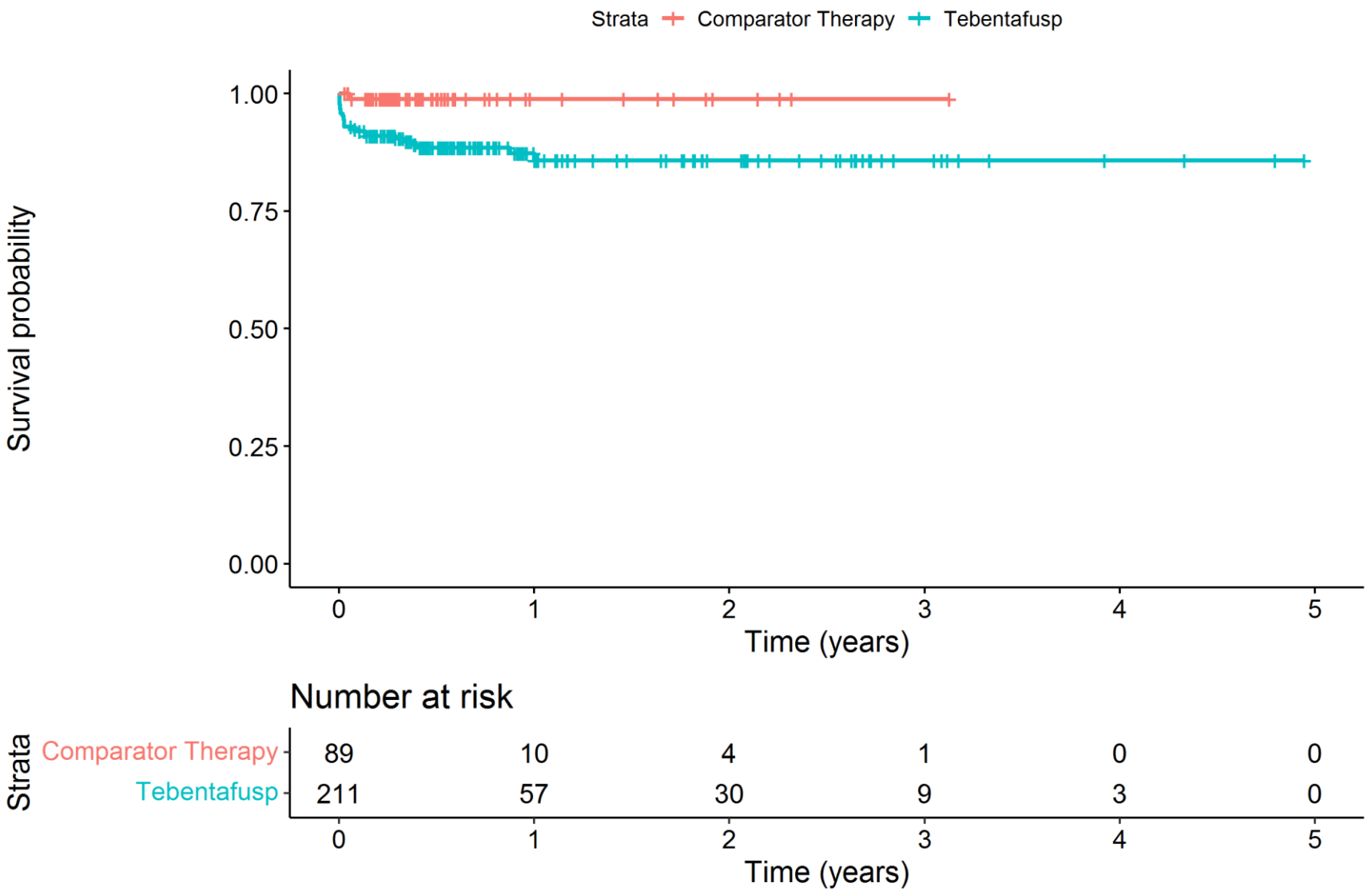
Parästhesie - Gesamt



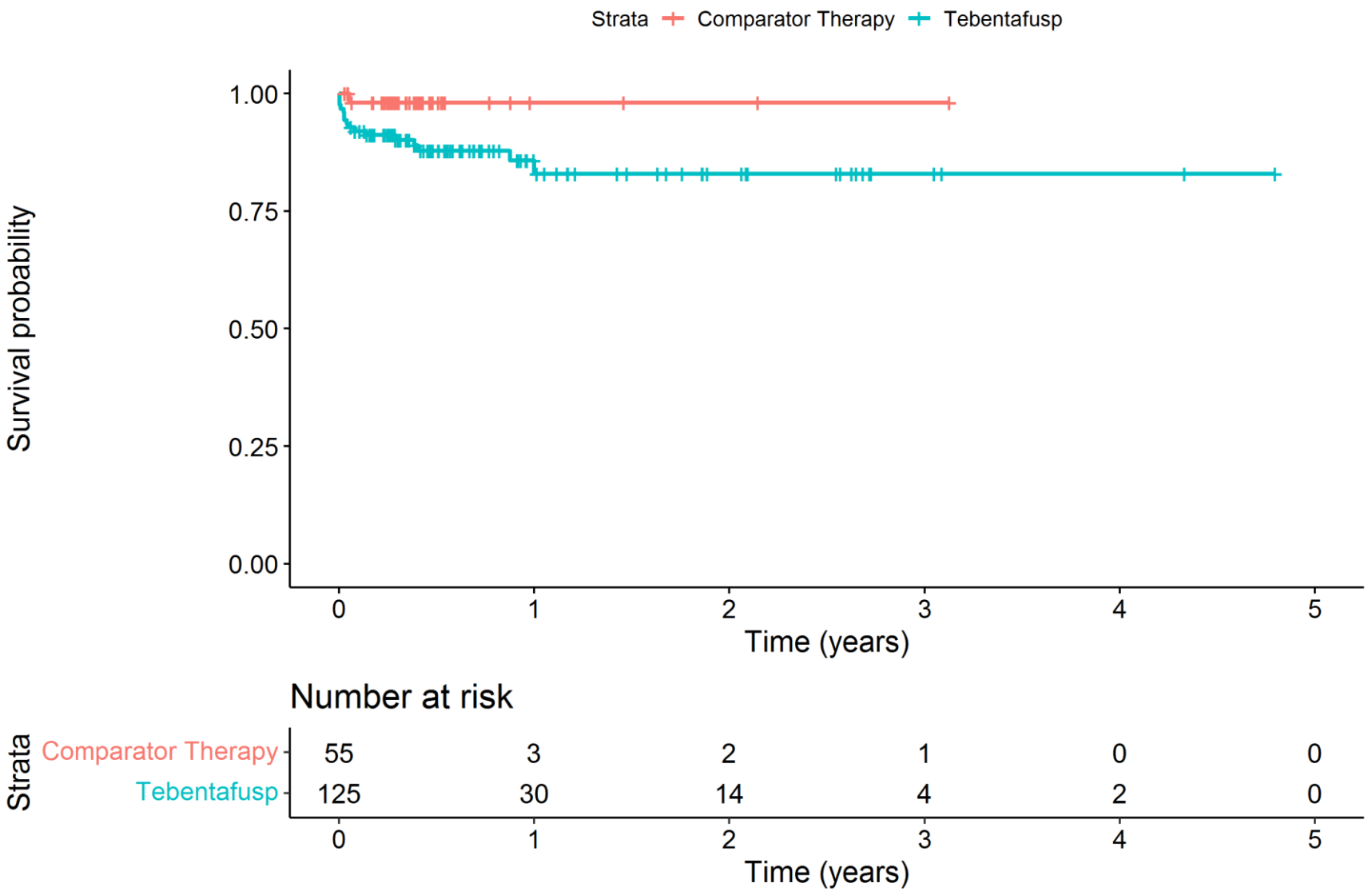
Parästhesie - Hispanisch



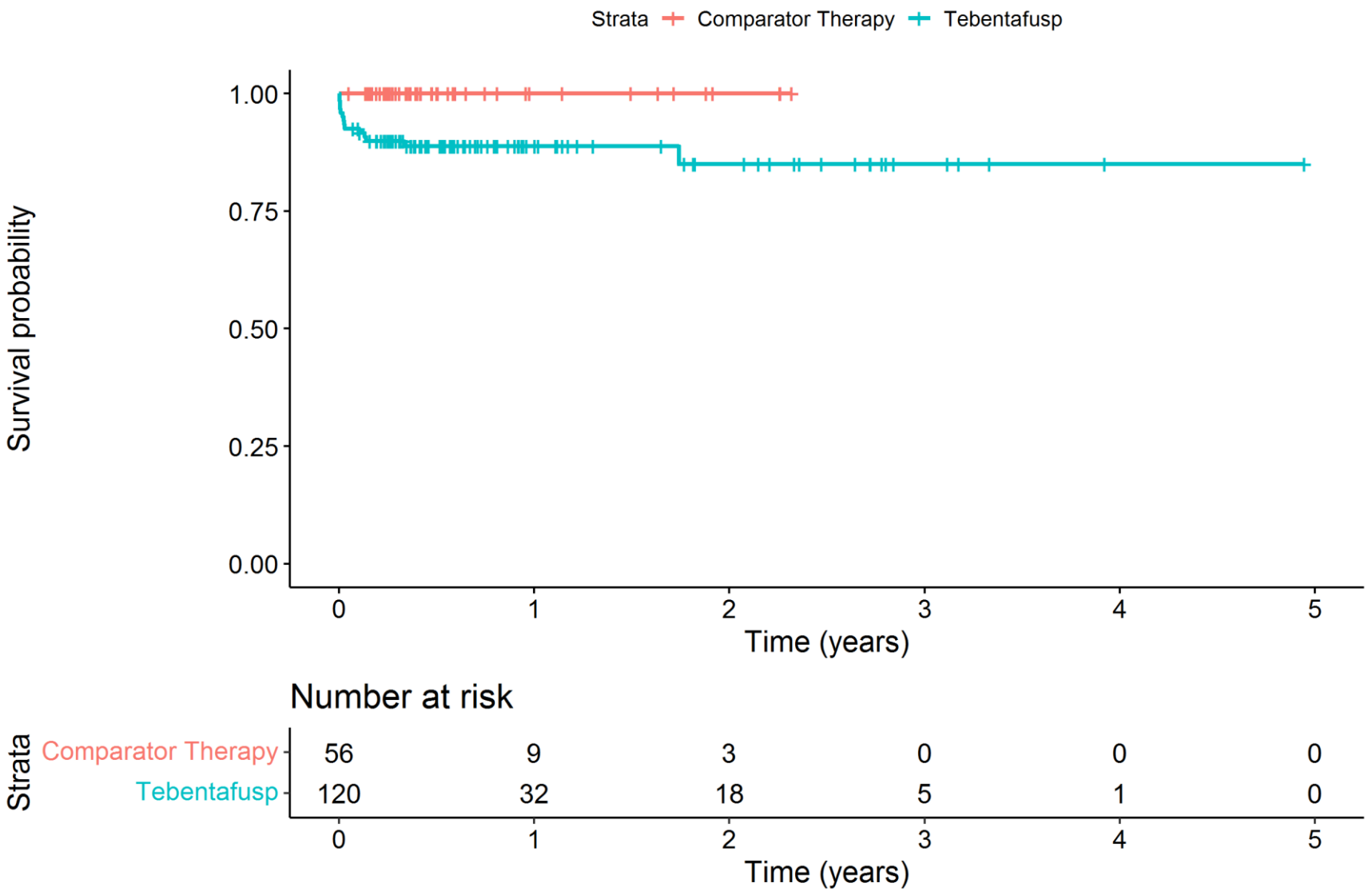
Parästhesie - Nicht-hispanisch



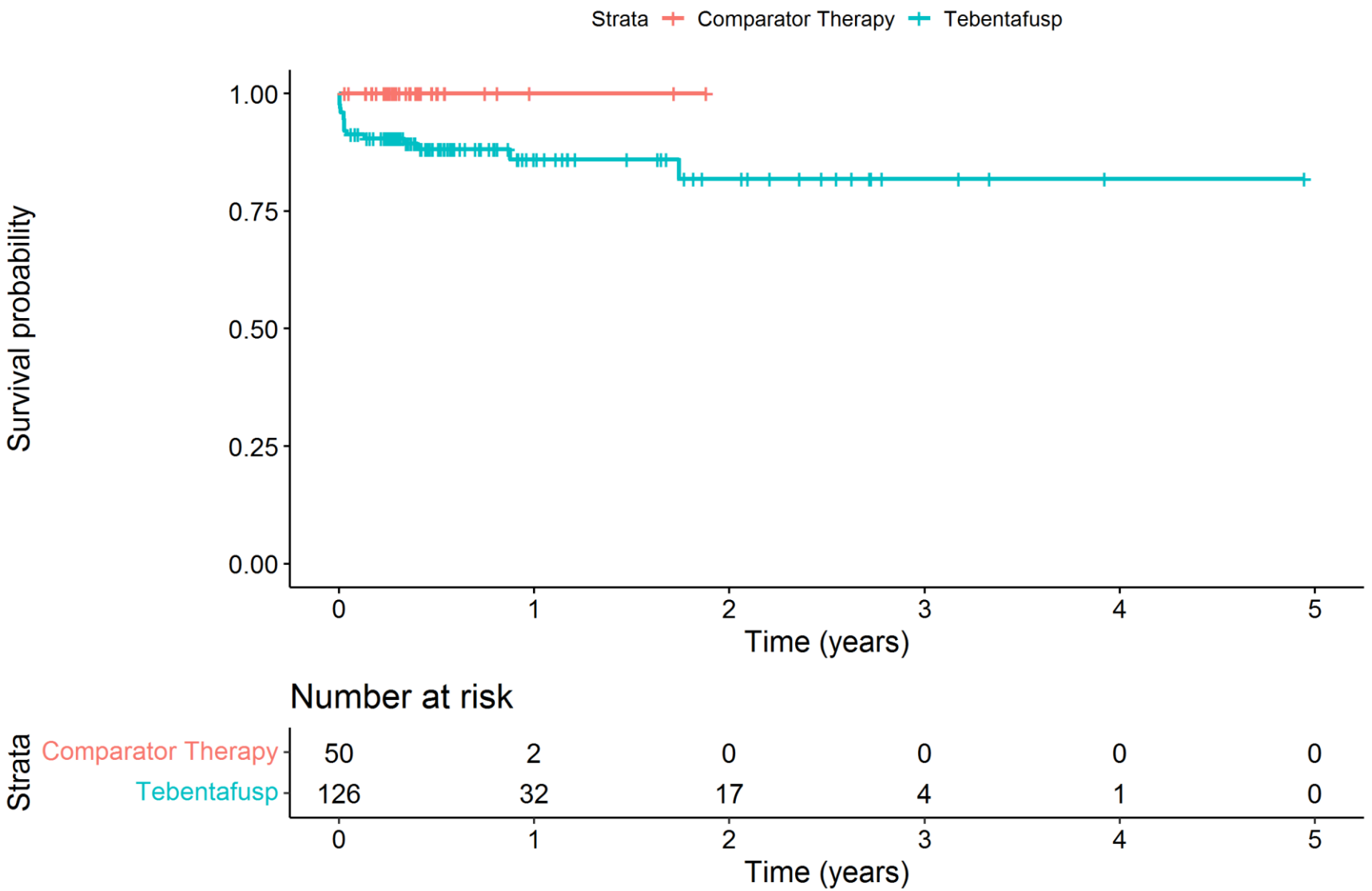
Parästhesie - Männlich



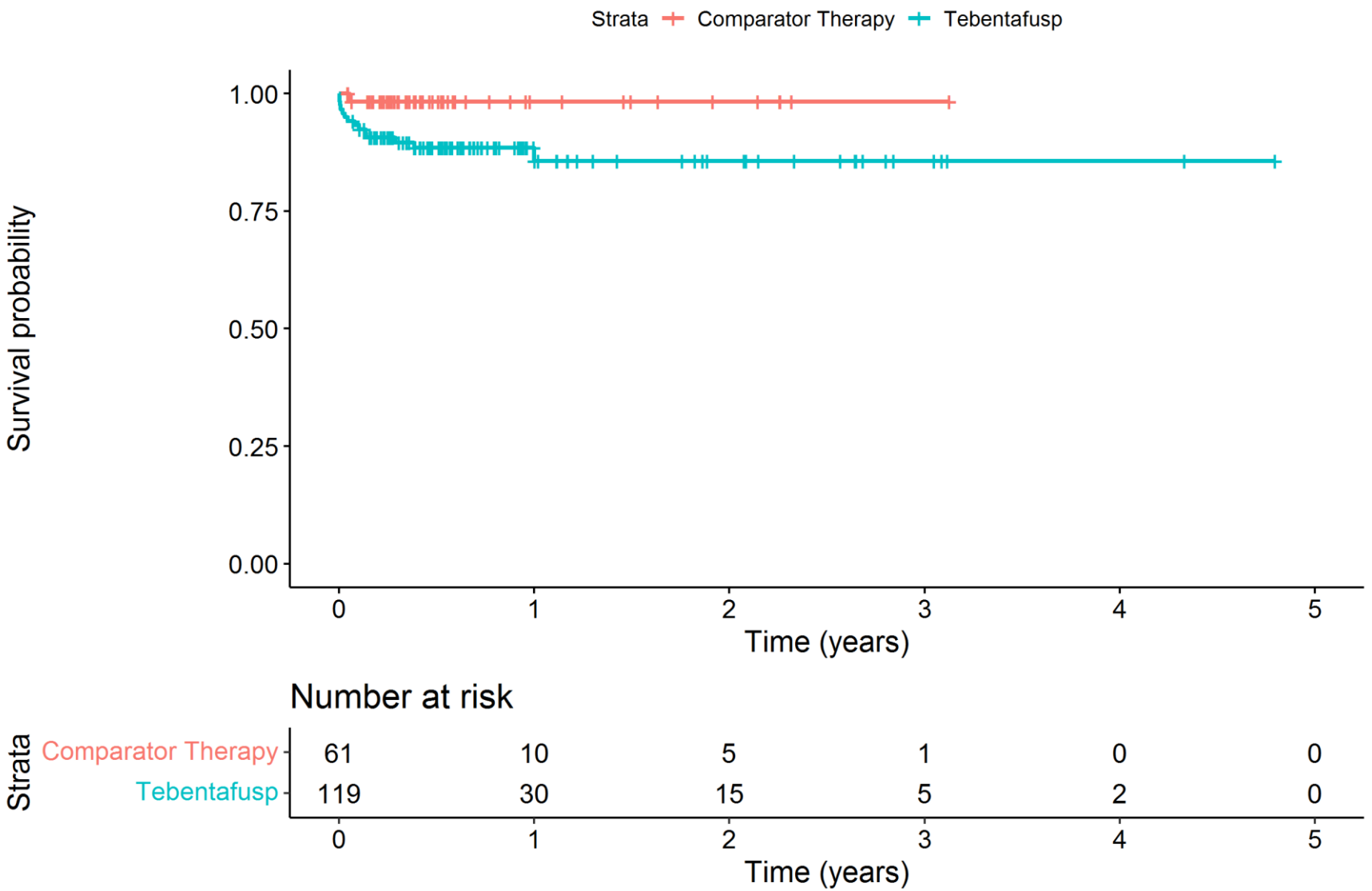
Parästhesie - Weiblich



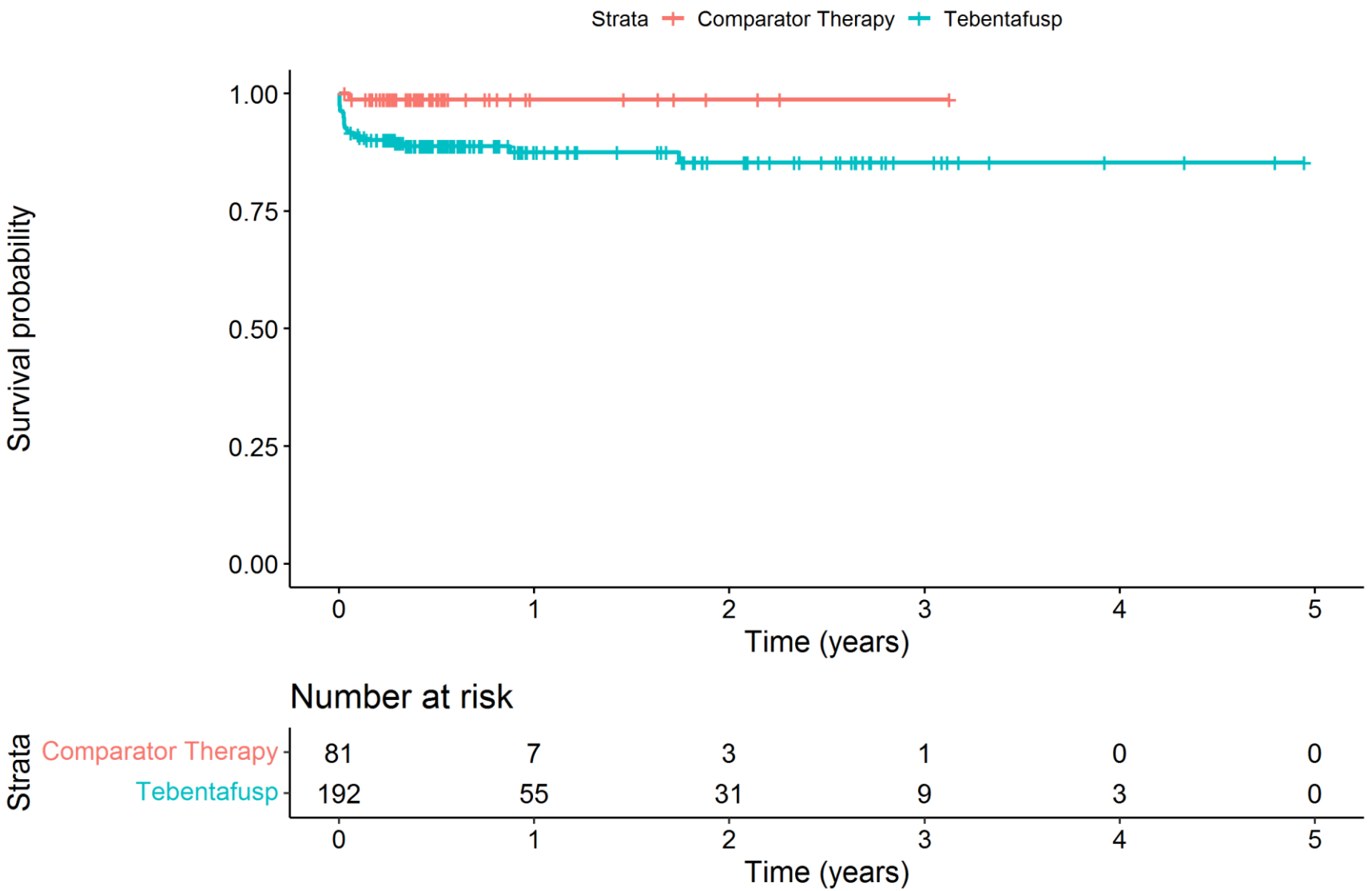
Parästhesie - <65



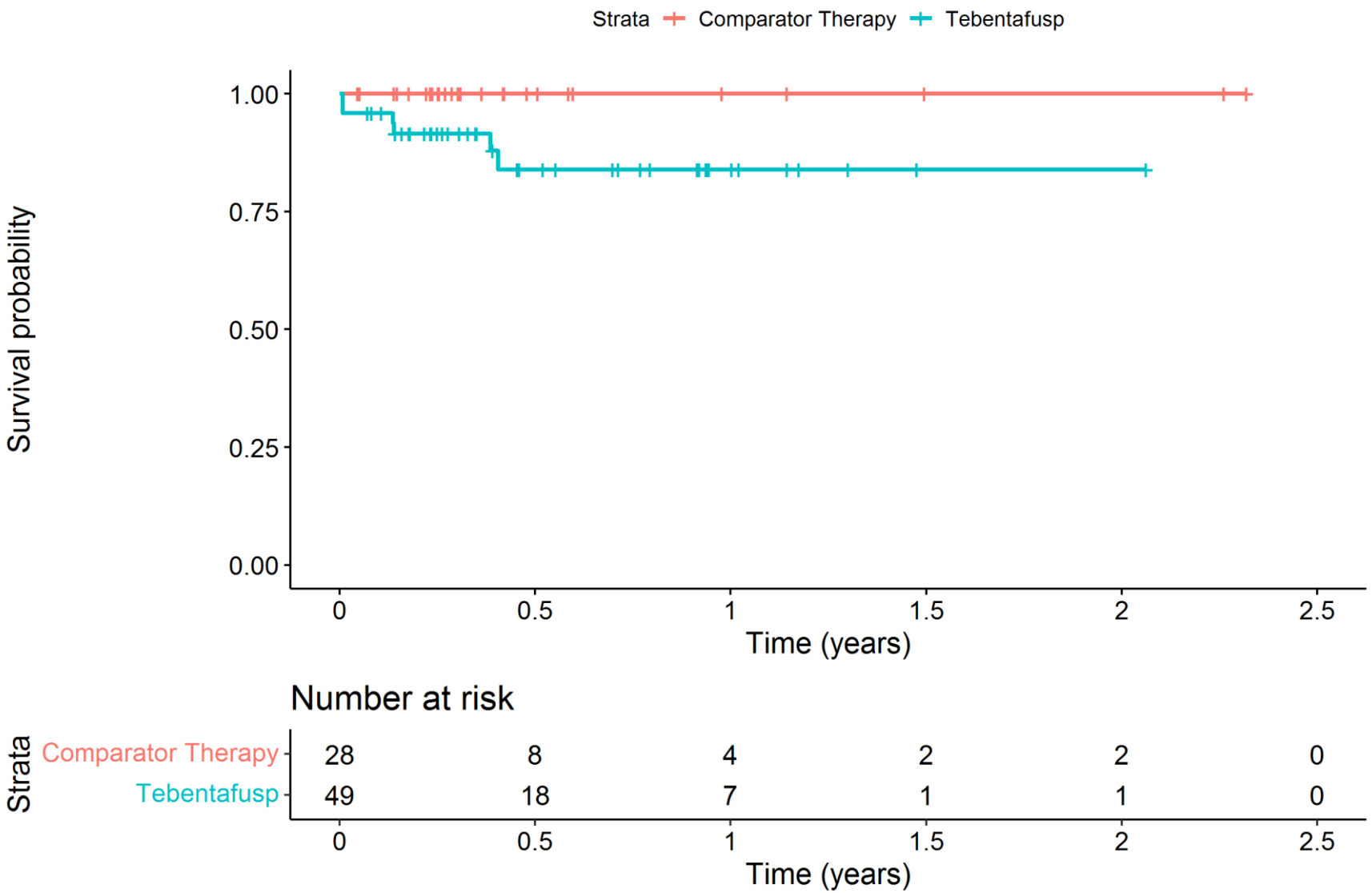
Parästhesie - ≥65



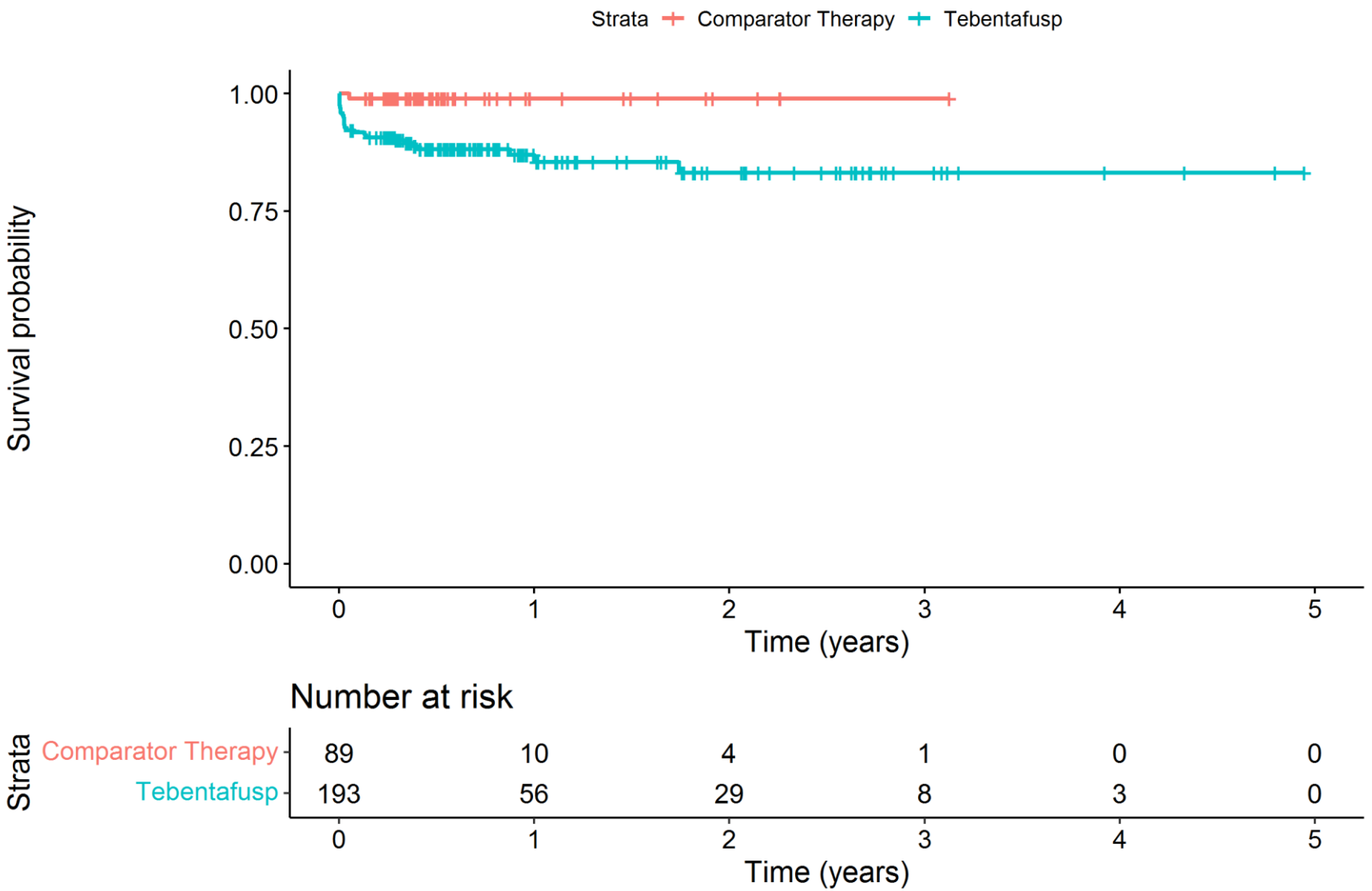
Parästhesie - ECOG 0



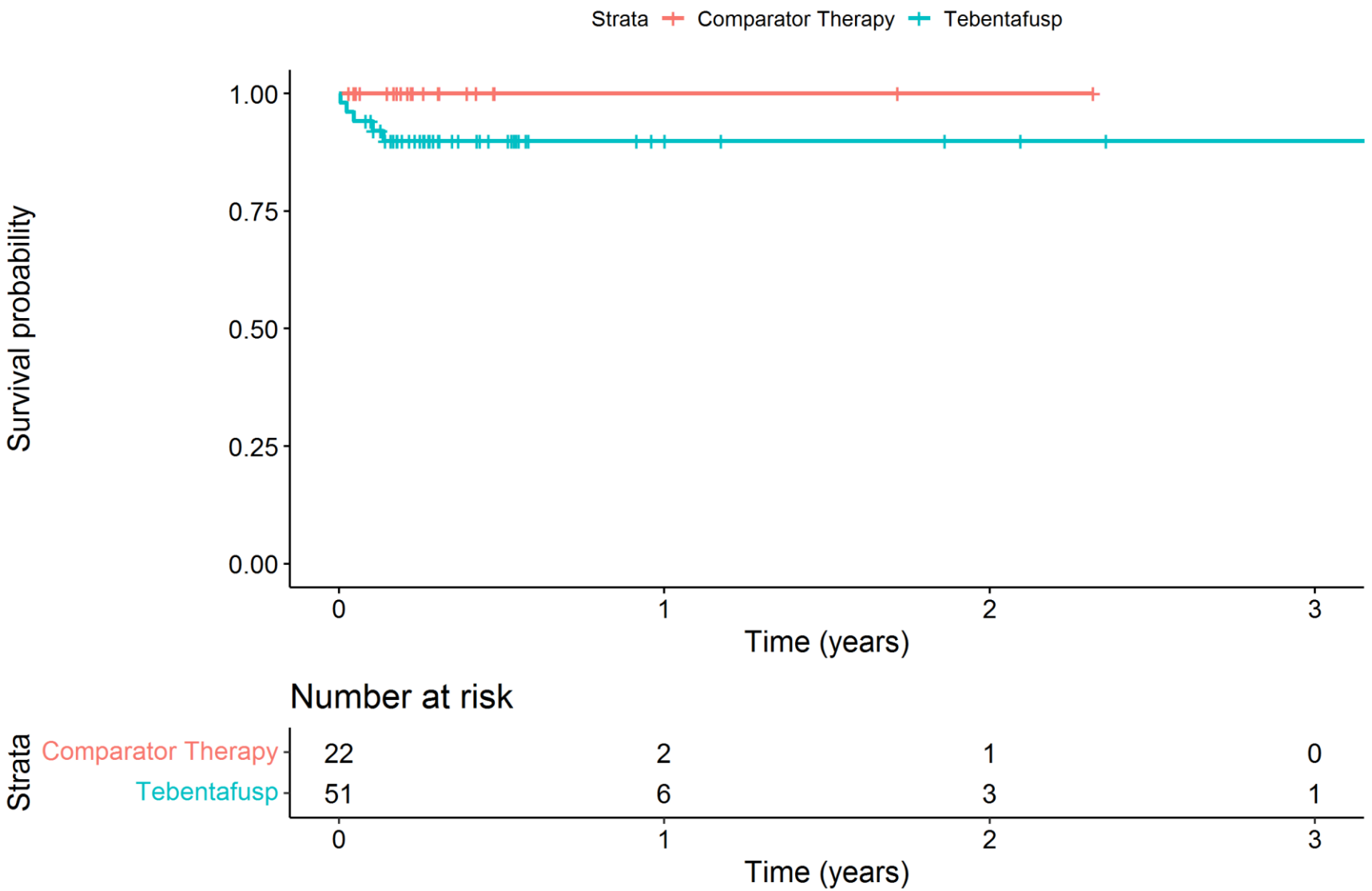
Parästhesie - ECOG 1



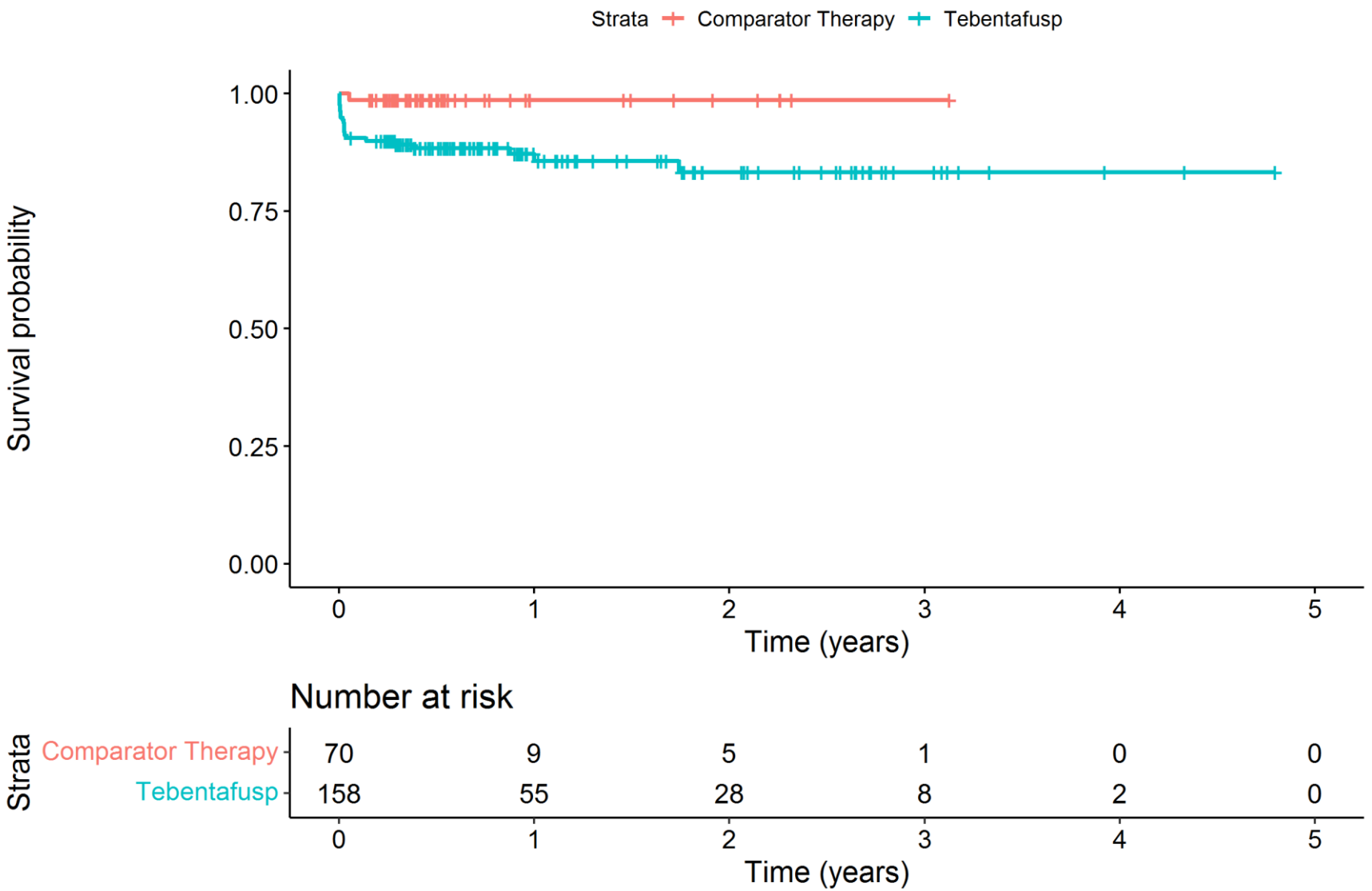
Parästhesie - ALP ≤ ULN



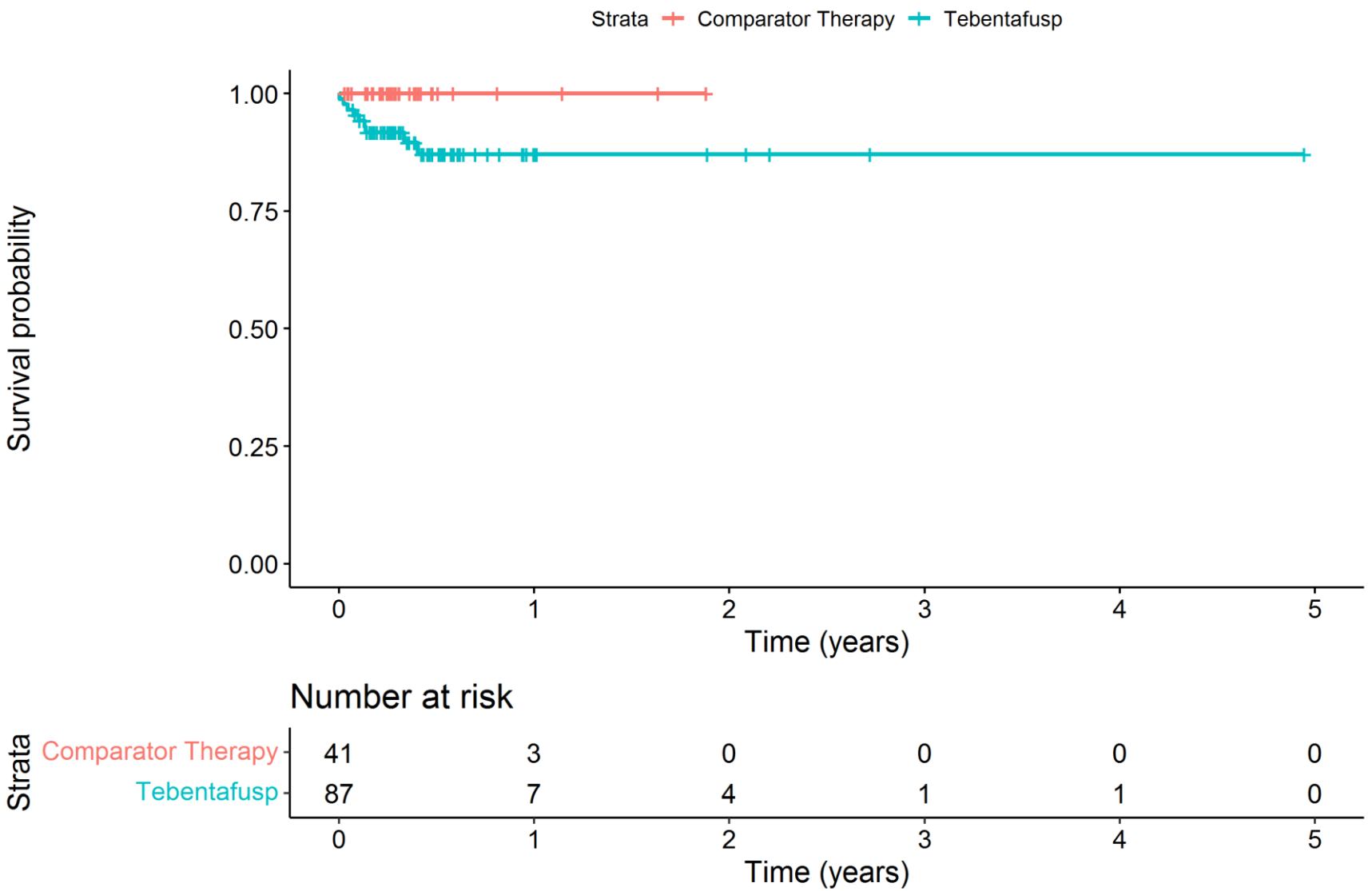
Parästhesie - ALP > ULN



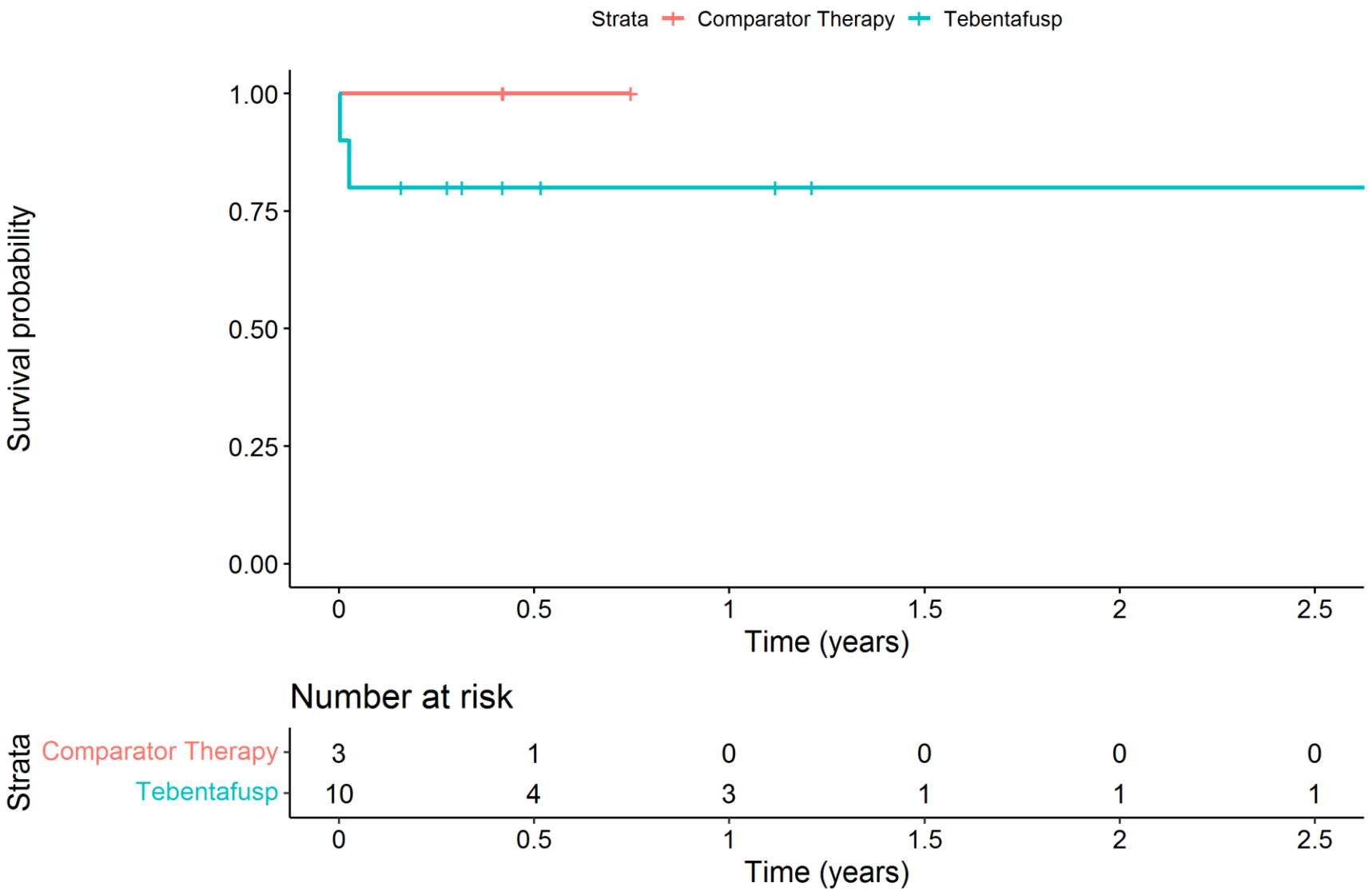
Parästhesie - LDH =< ULN



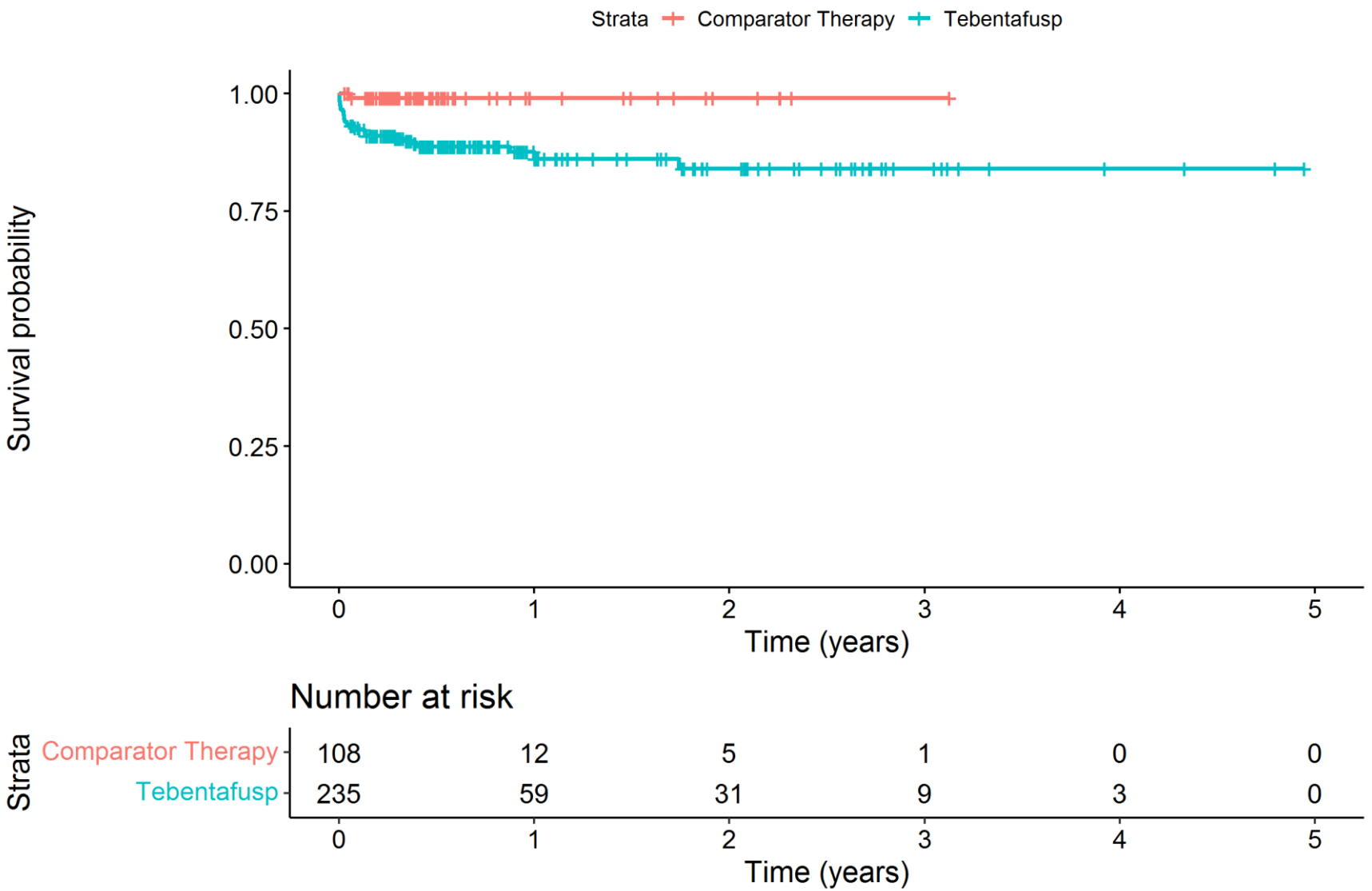
Parästhesie - LDH > ULN



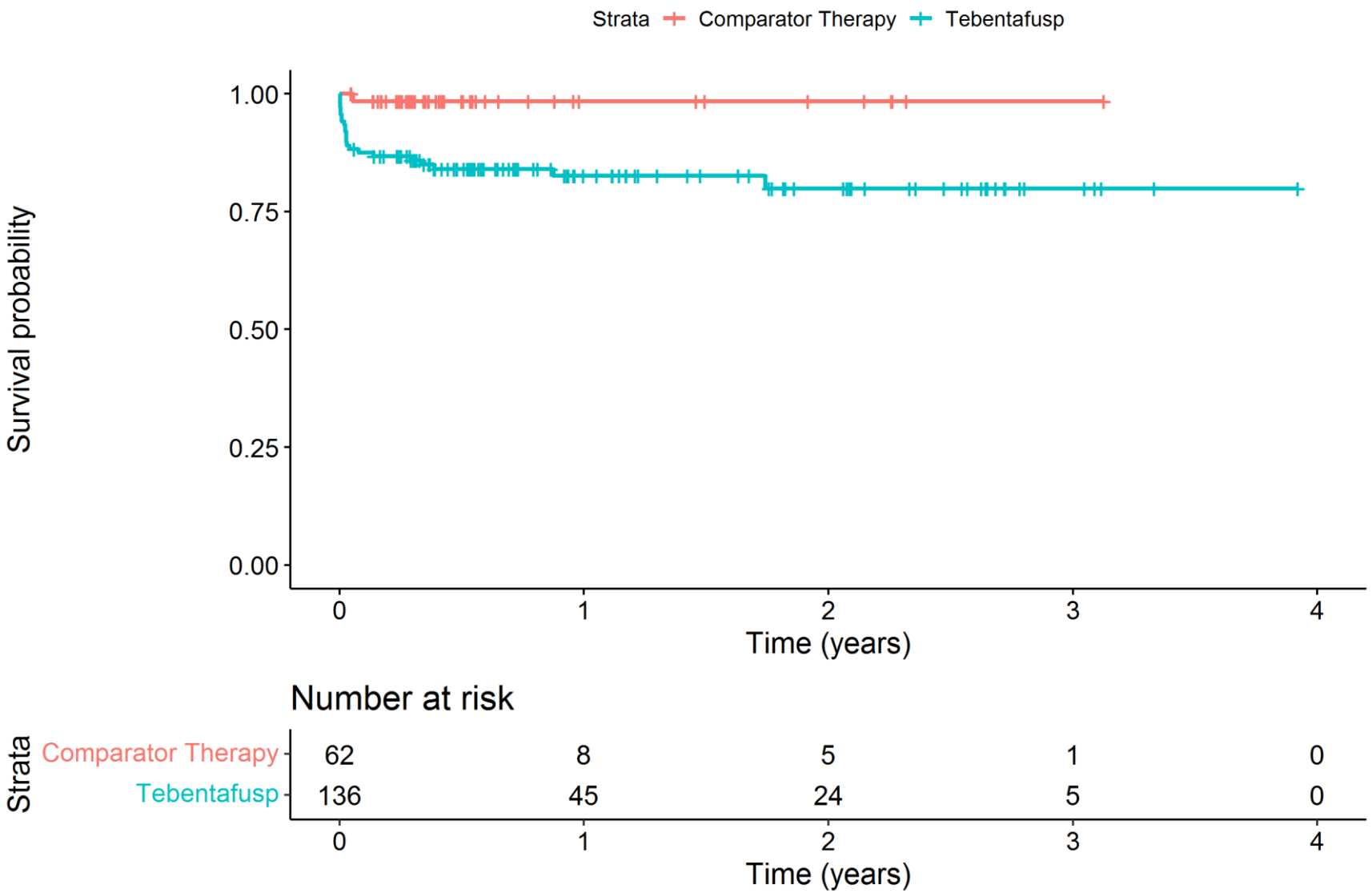
Parästhesie - Vorherige Therapie adjuvant/neoadjuvant



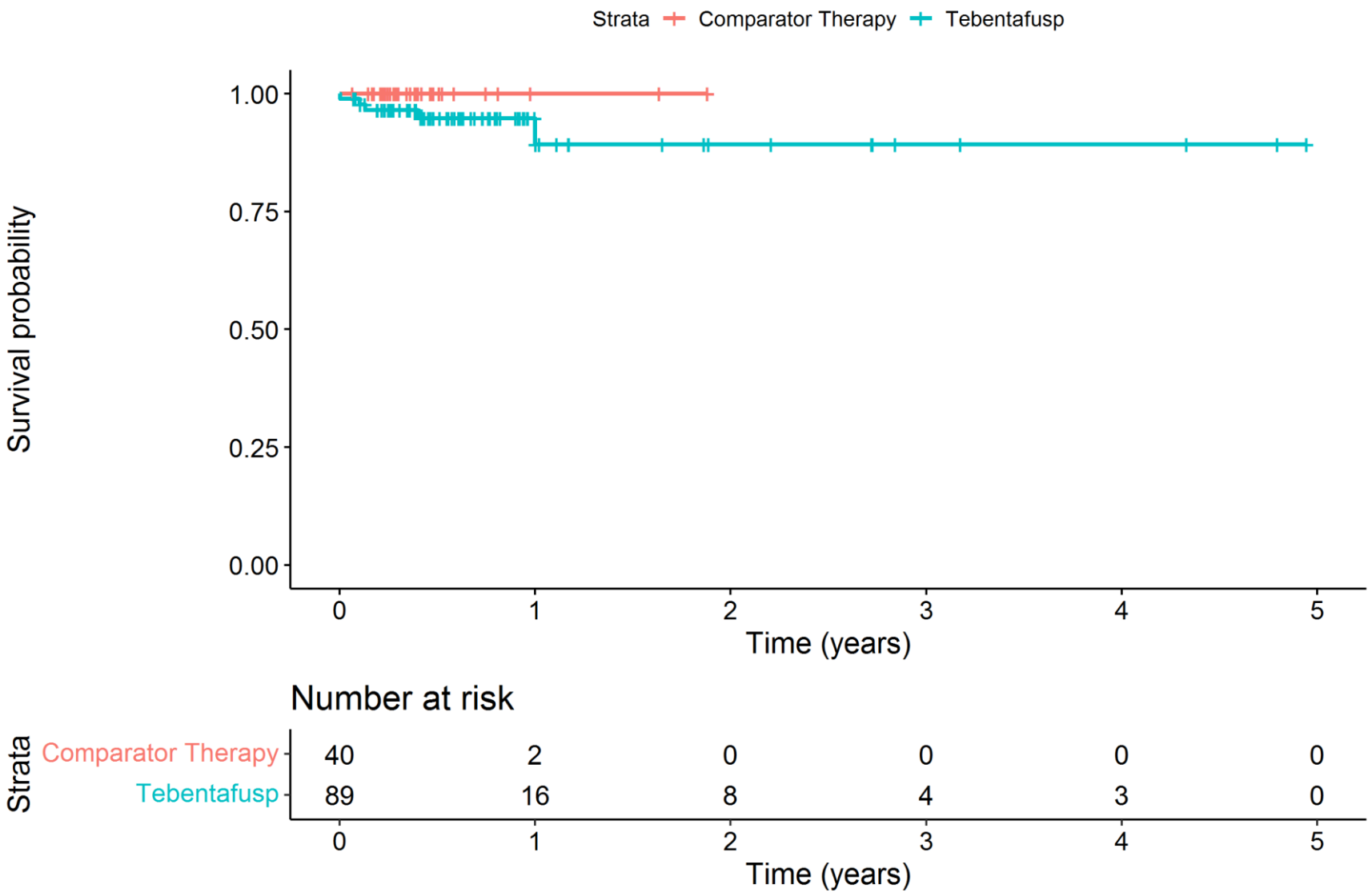
Parästhesie - Keine Vorherige Therapie adjuvant/neoadjuvant



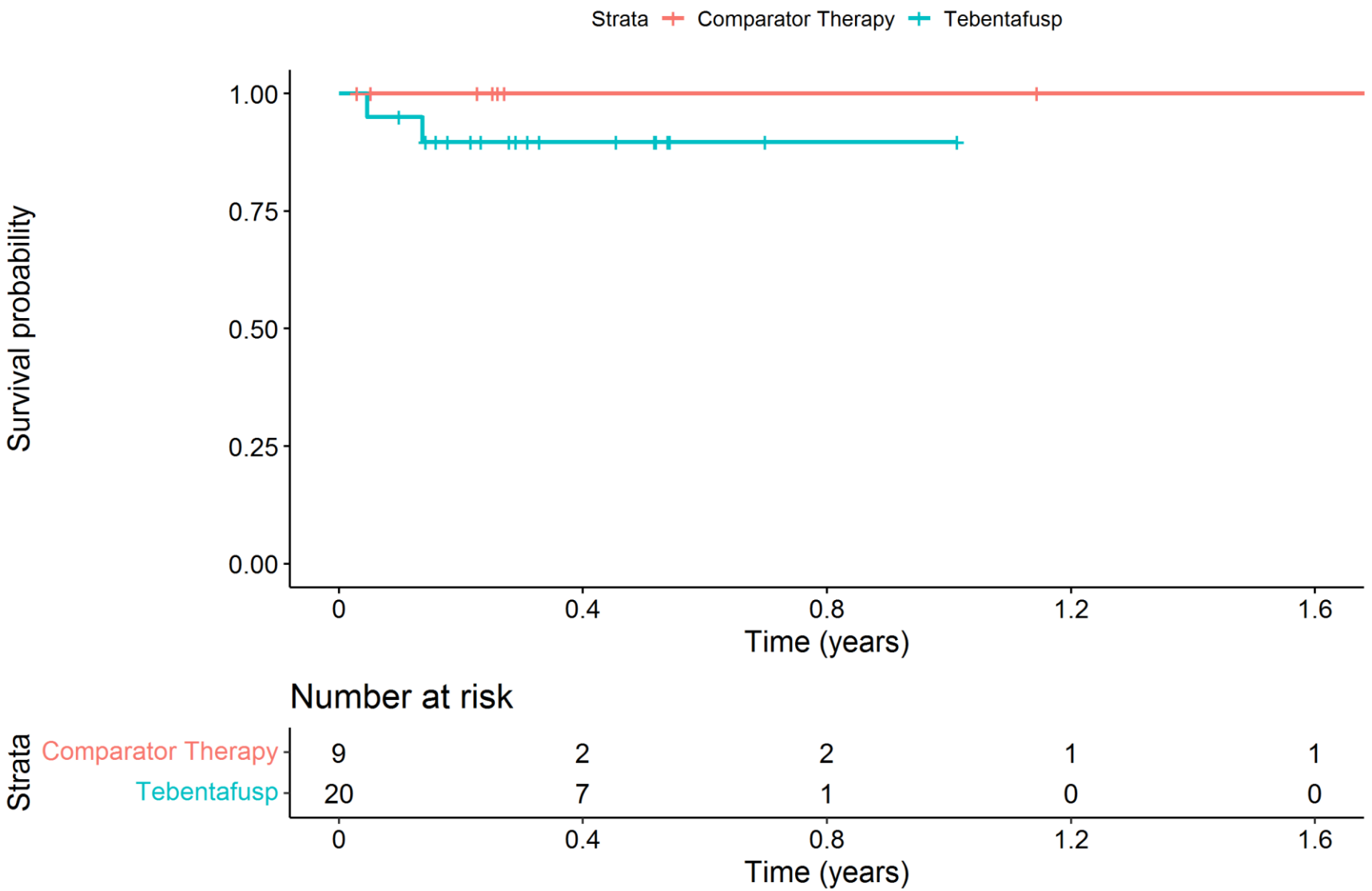
Parästhesie - Läsion ≤ 3cm



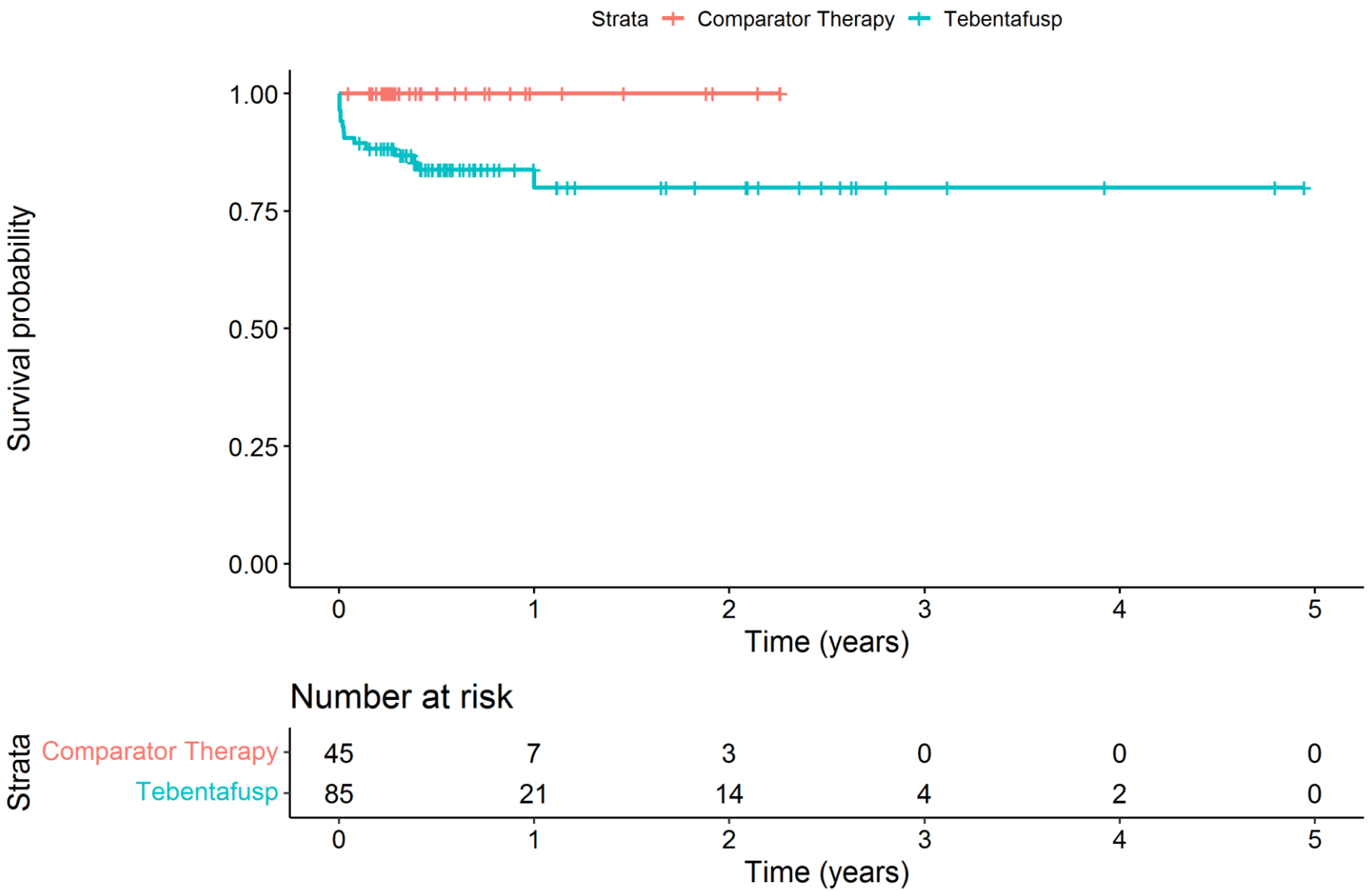
Parästhesie - Läsion 3,1-8,0 cm



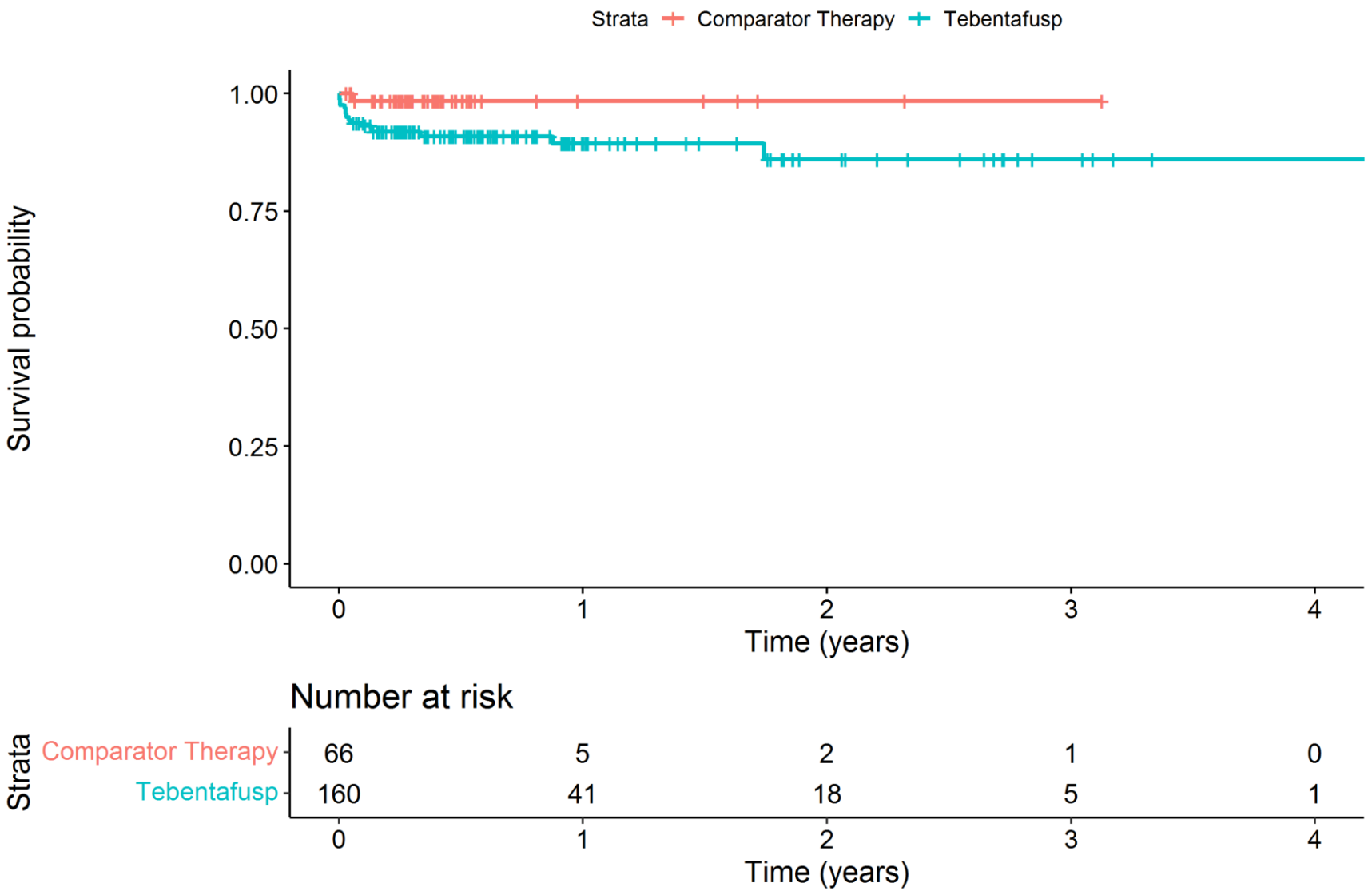
Parästhesie - Läsion ≥8,1 cm



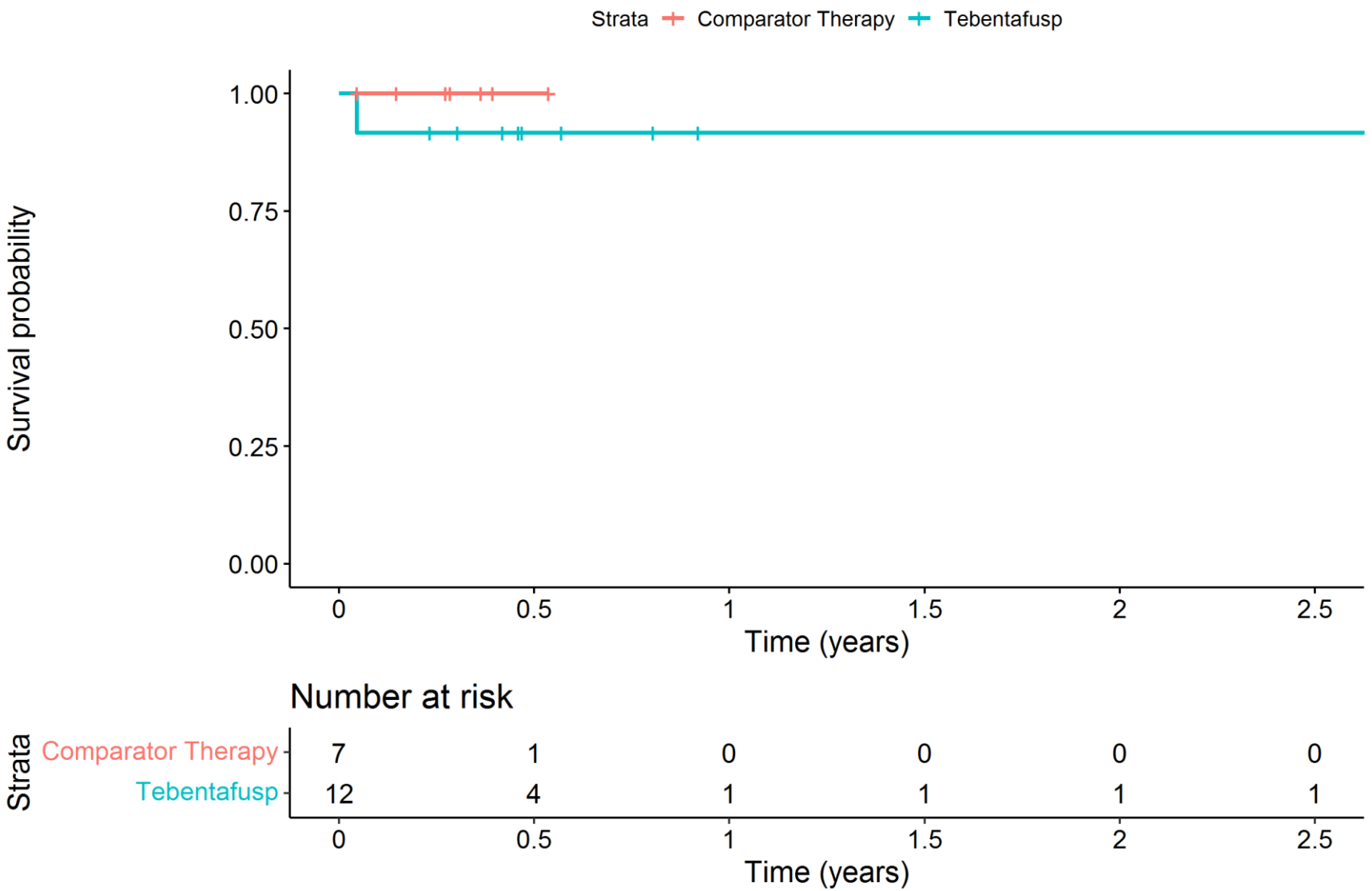
Parästhesie - Nordamerika



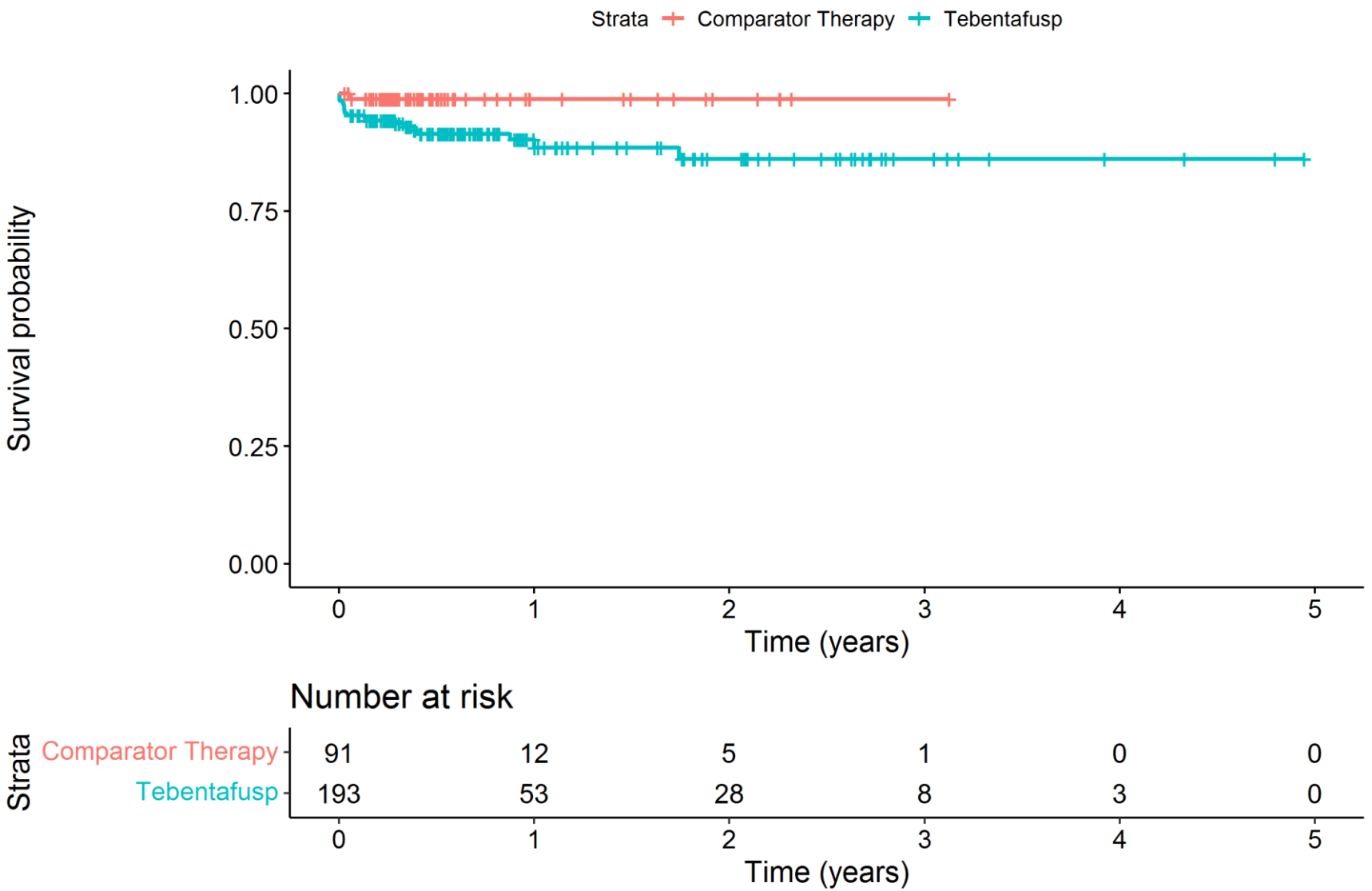
Parästhesie - Nicht-Nordamerika



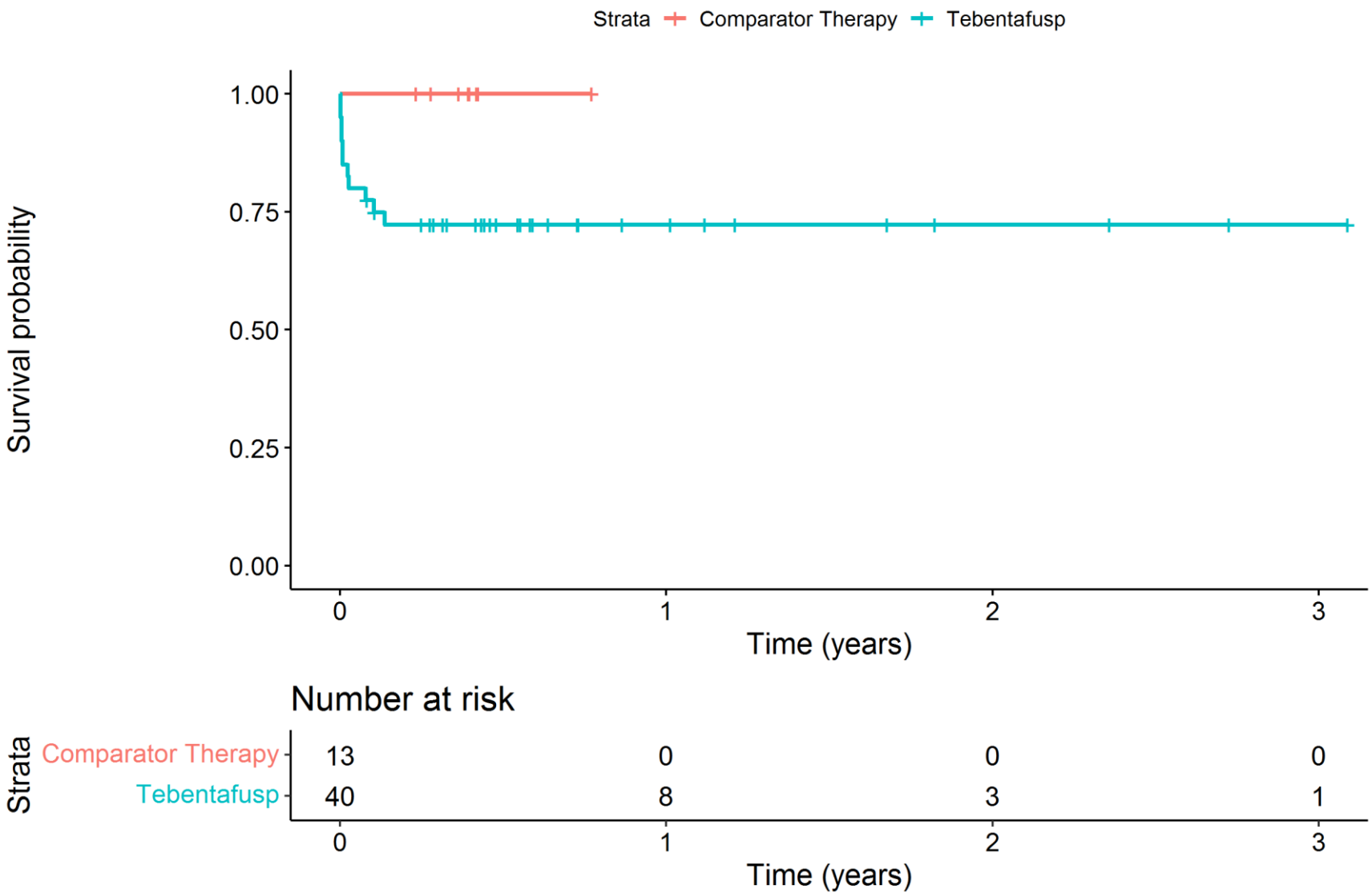
Parästhesie - Dacarbazin



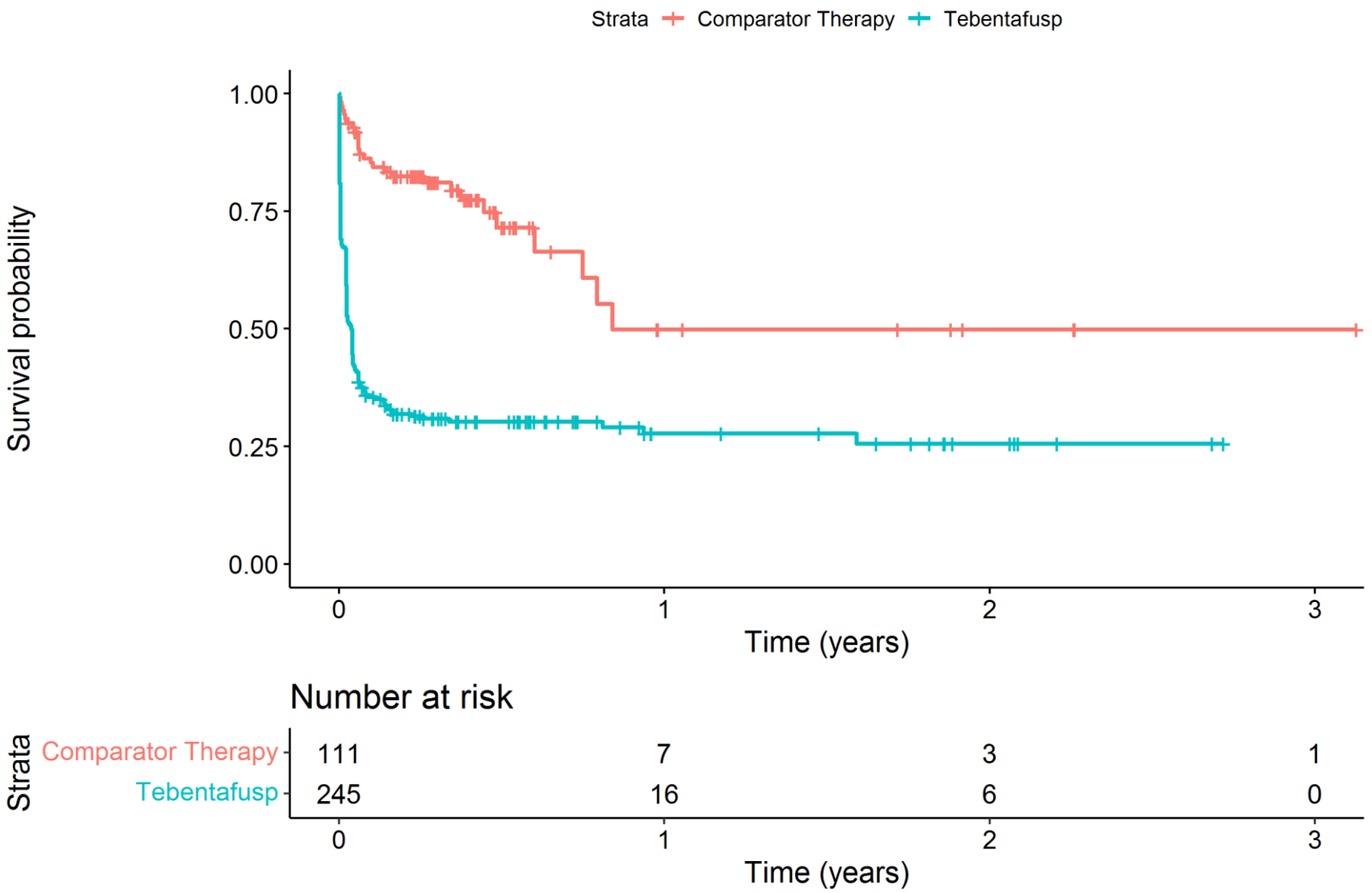
Parästhesie - Pembrolizumab



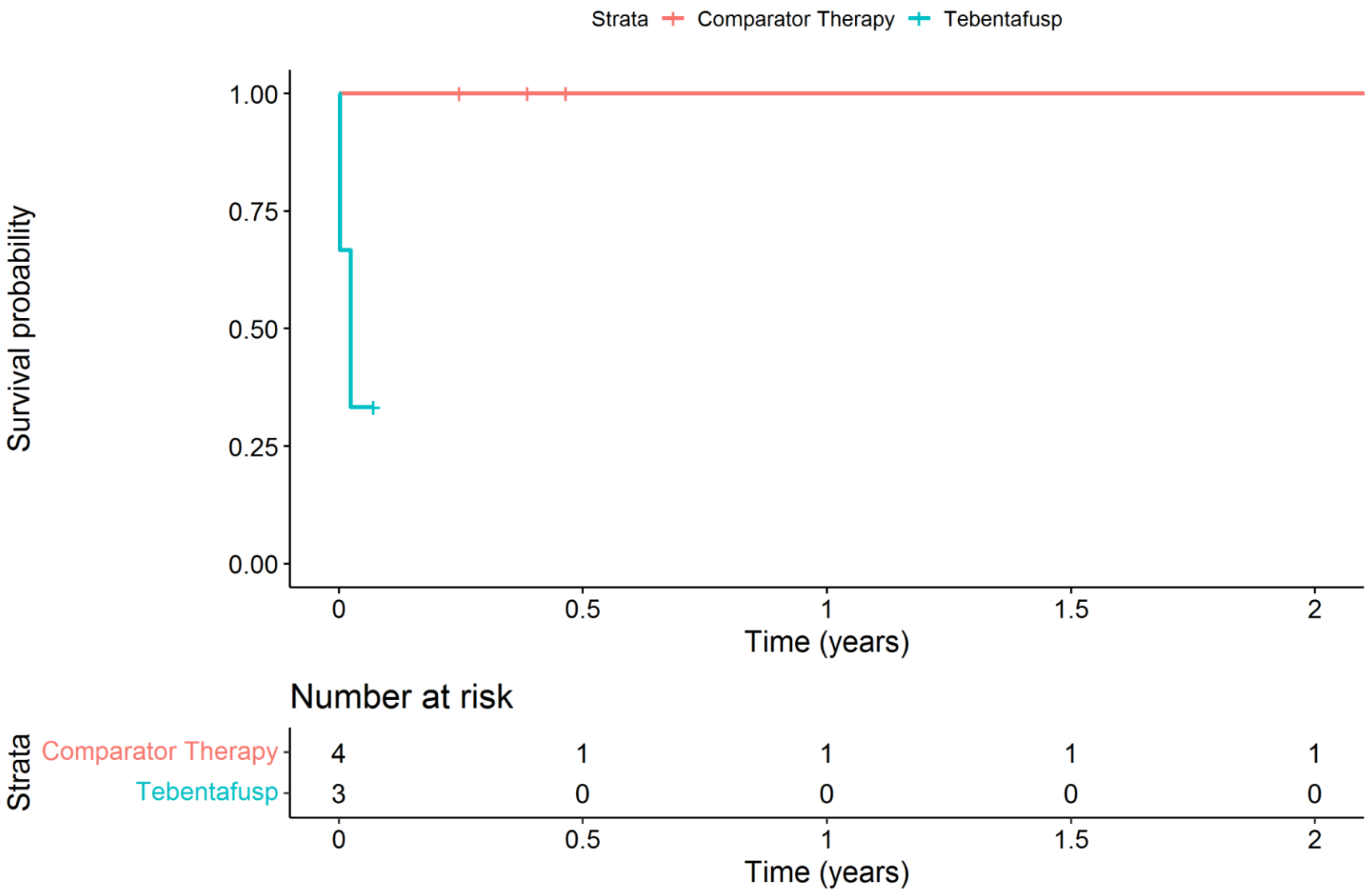
Parästhesie - Ipilimumab



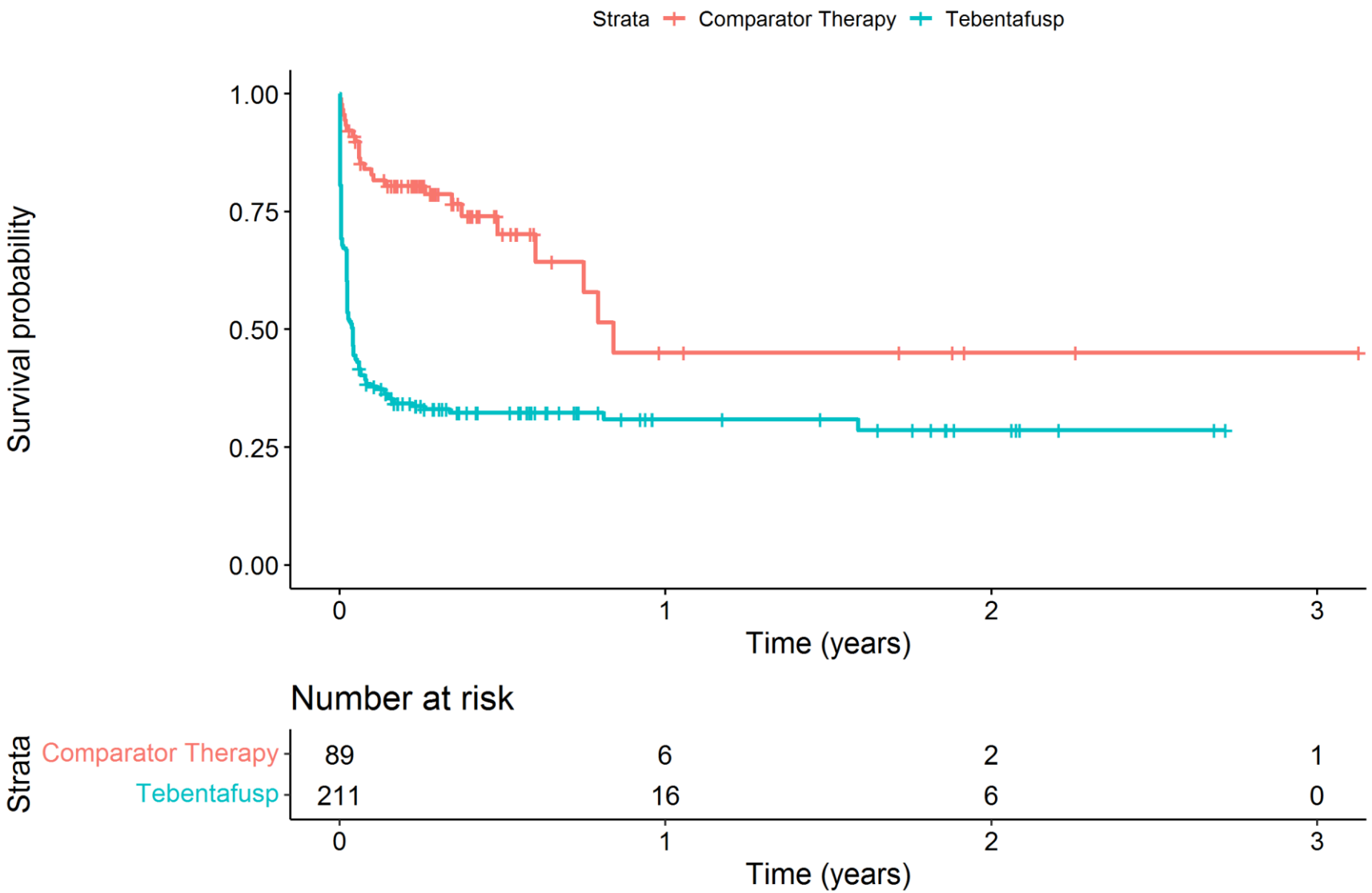
Pruritus - Gesamt



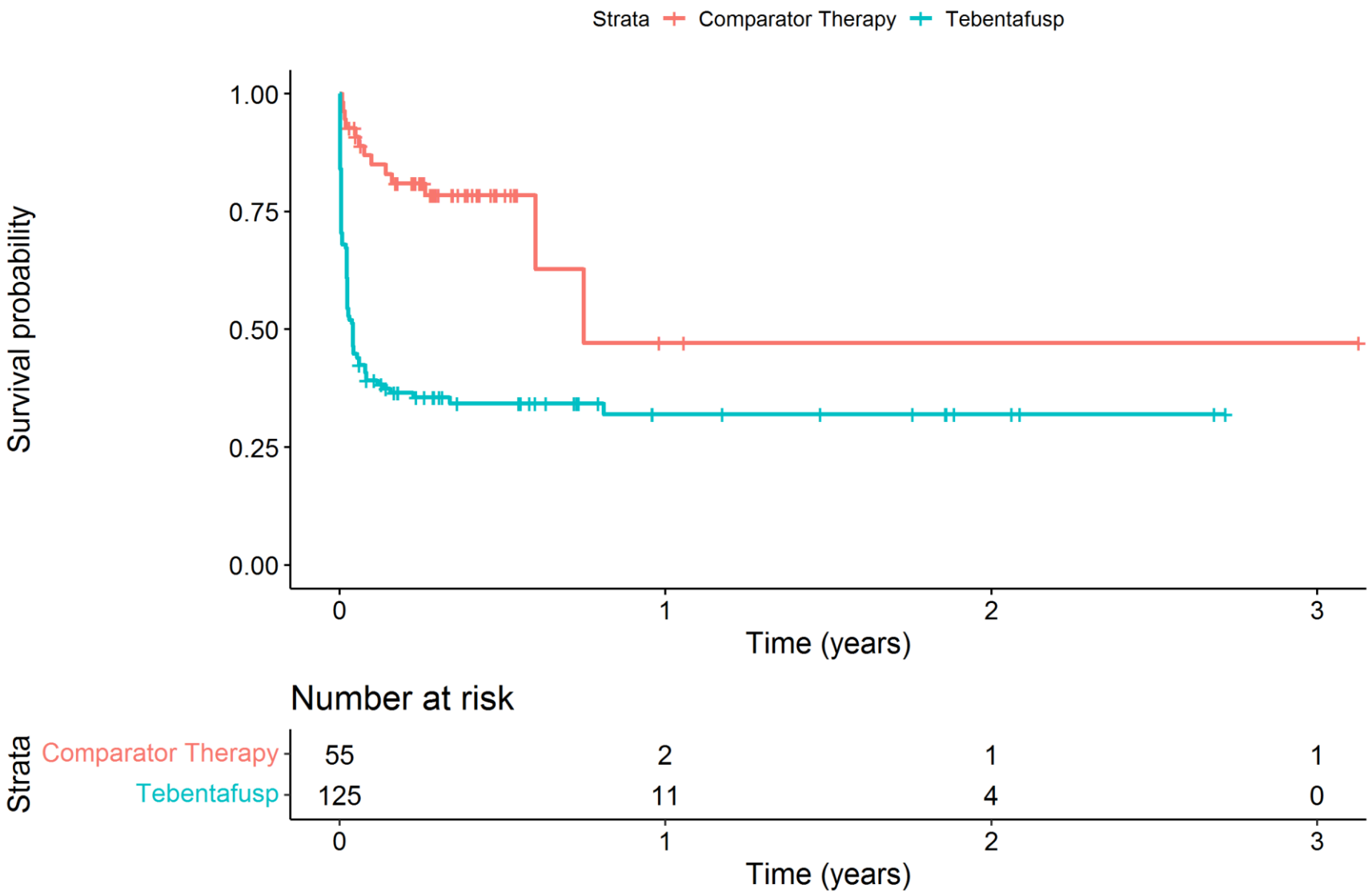
Pruritus - Hispanisch



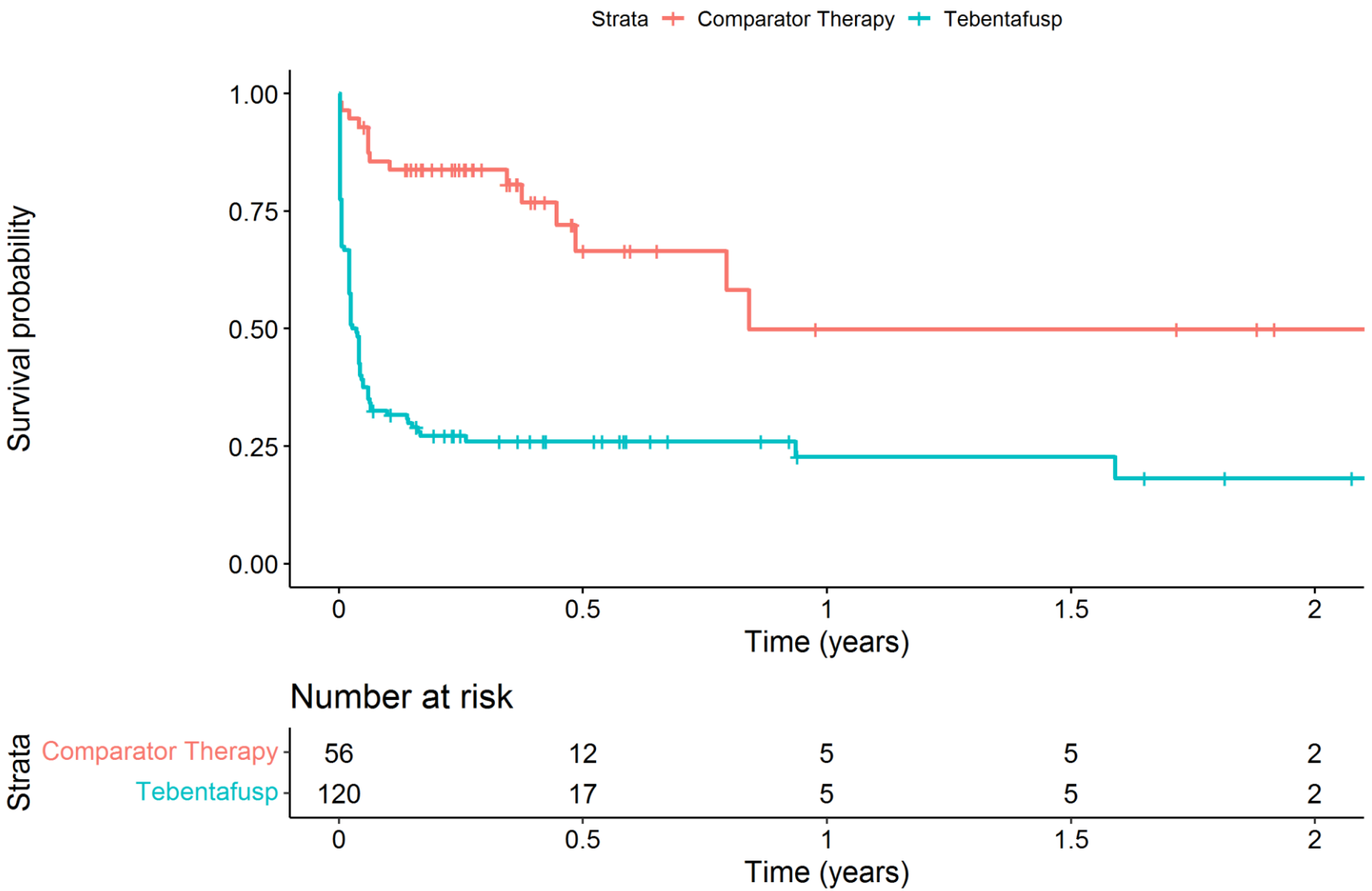
Pruritus - Nicht-hispanisch



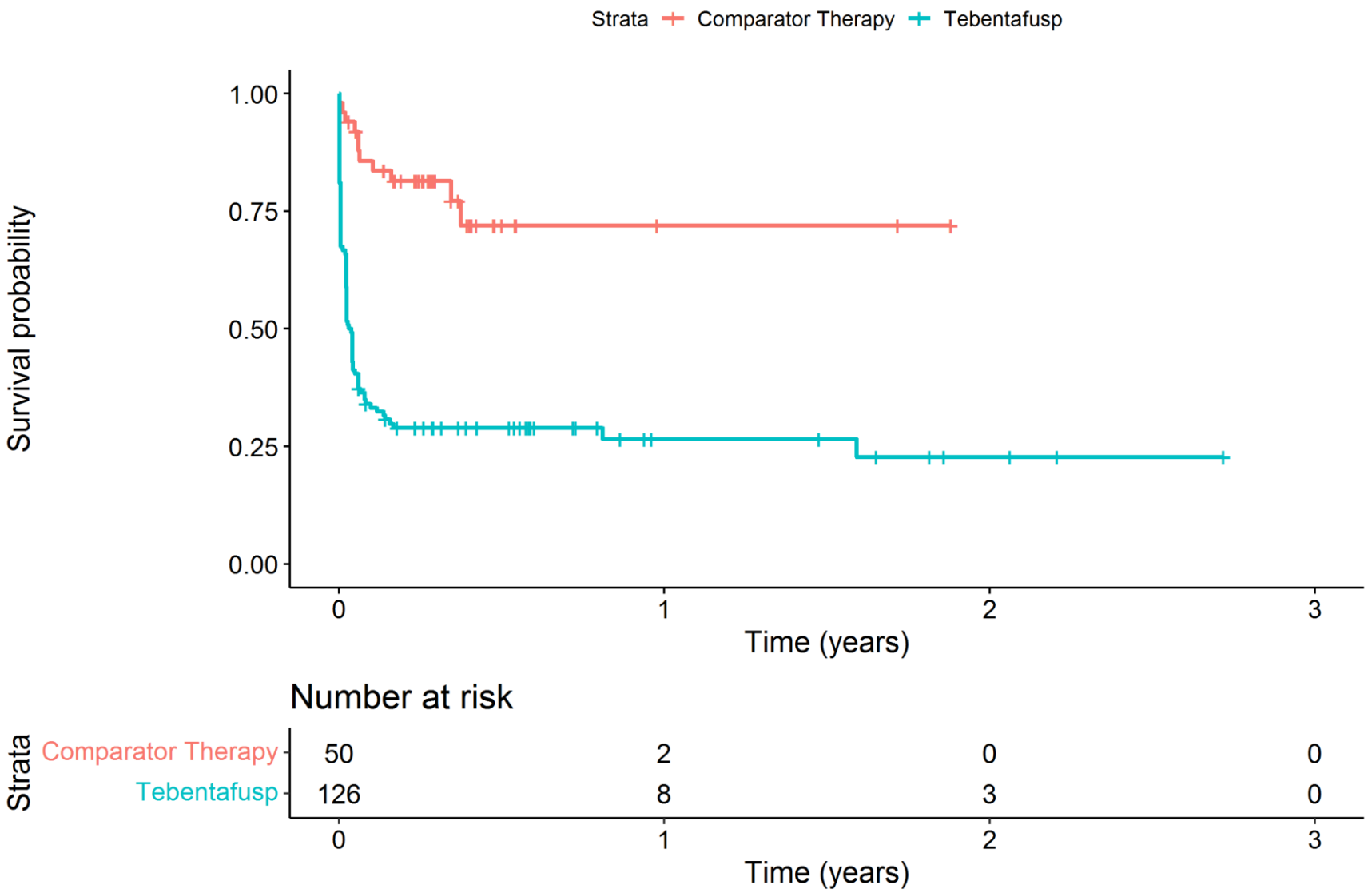
Pruritus - Männlich



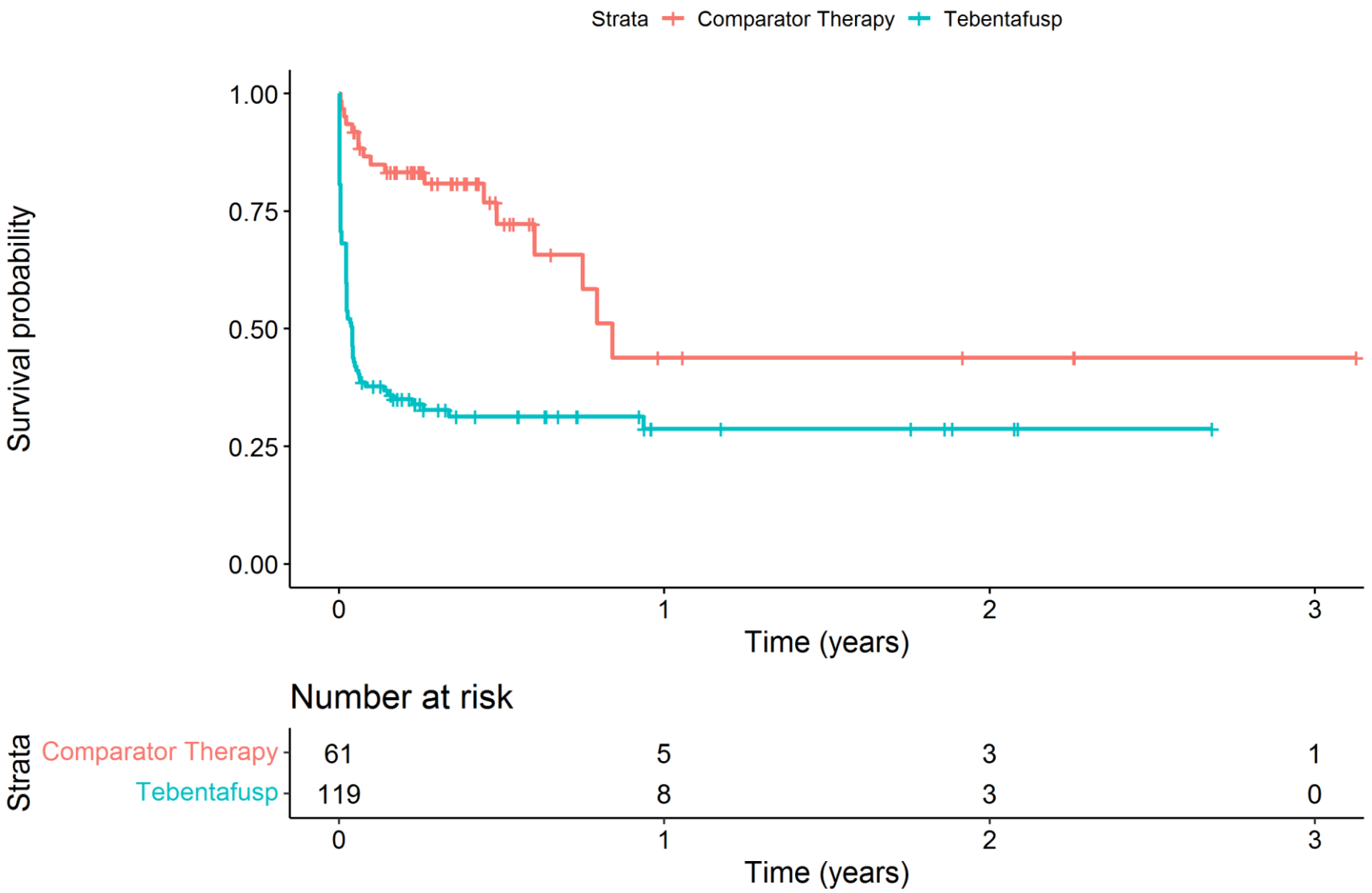
Pruritus - Weiblich



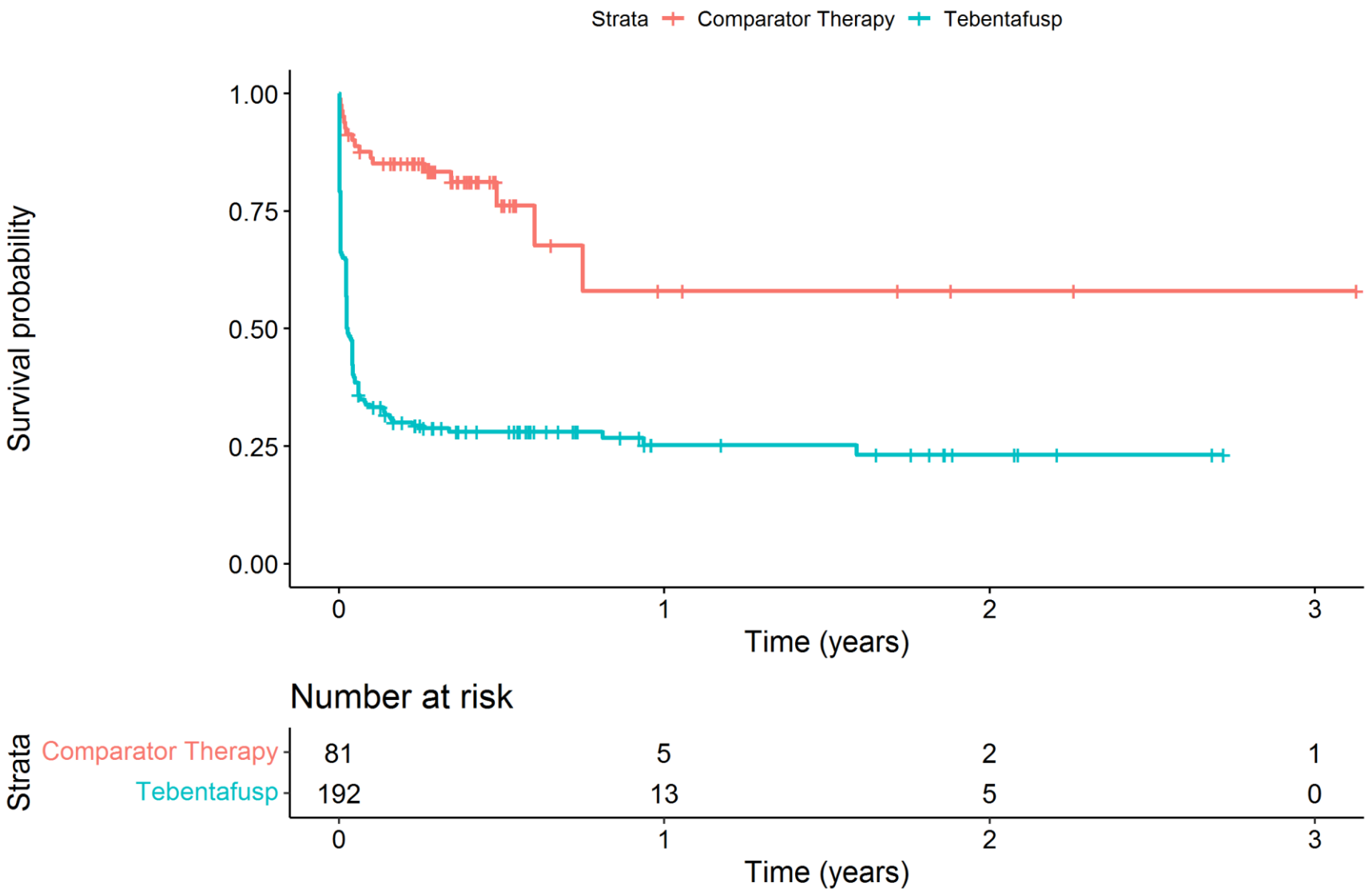
Pruritus - <65


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
50
2
0
0
126
8
3
0
0
1
2
3
Time (years)

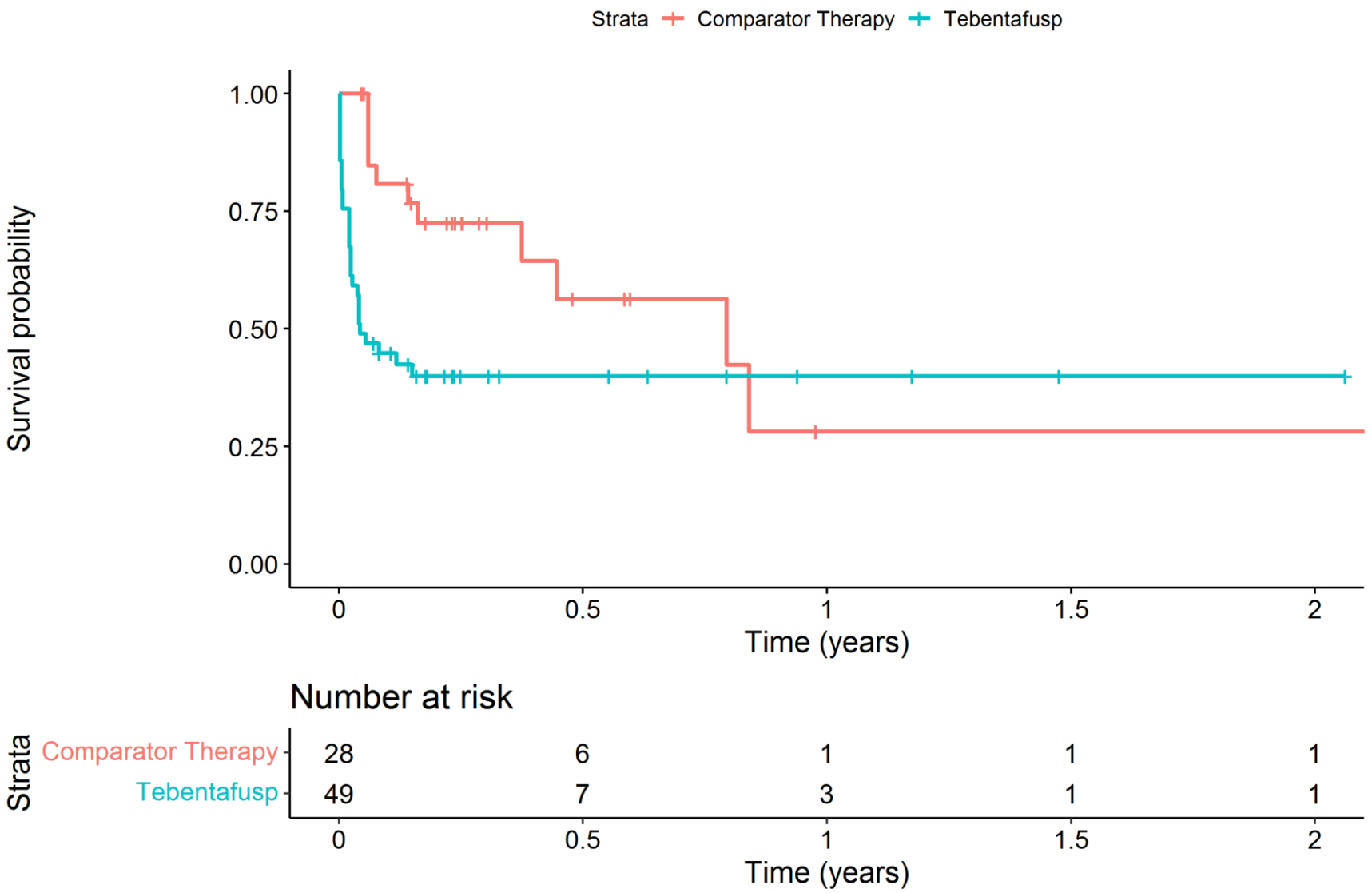
Pruritus - ≥65


Strata
Comparator Therapy
Tebentafusp
Survival probability
1.00
0.75
0.50
0.25
0.00
0
1
2
3
Time (years)
Number at risk
Strata
Comparator Therapy
Tebentafusp
61
5
3
1
119
8
3
0
0
1
2
3
Time (years)

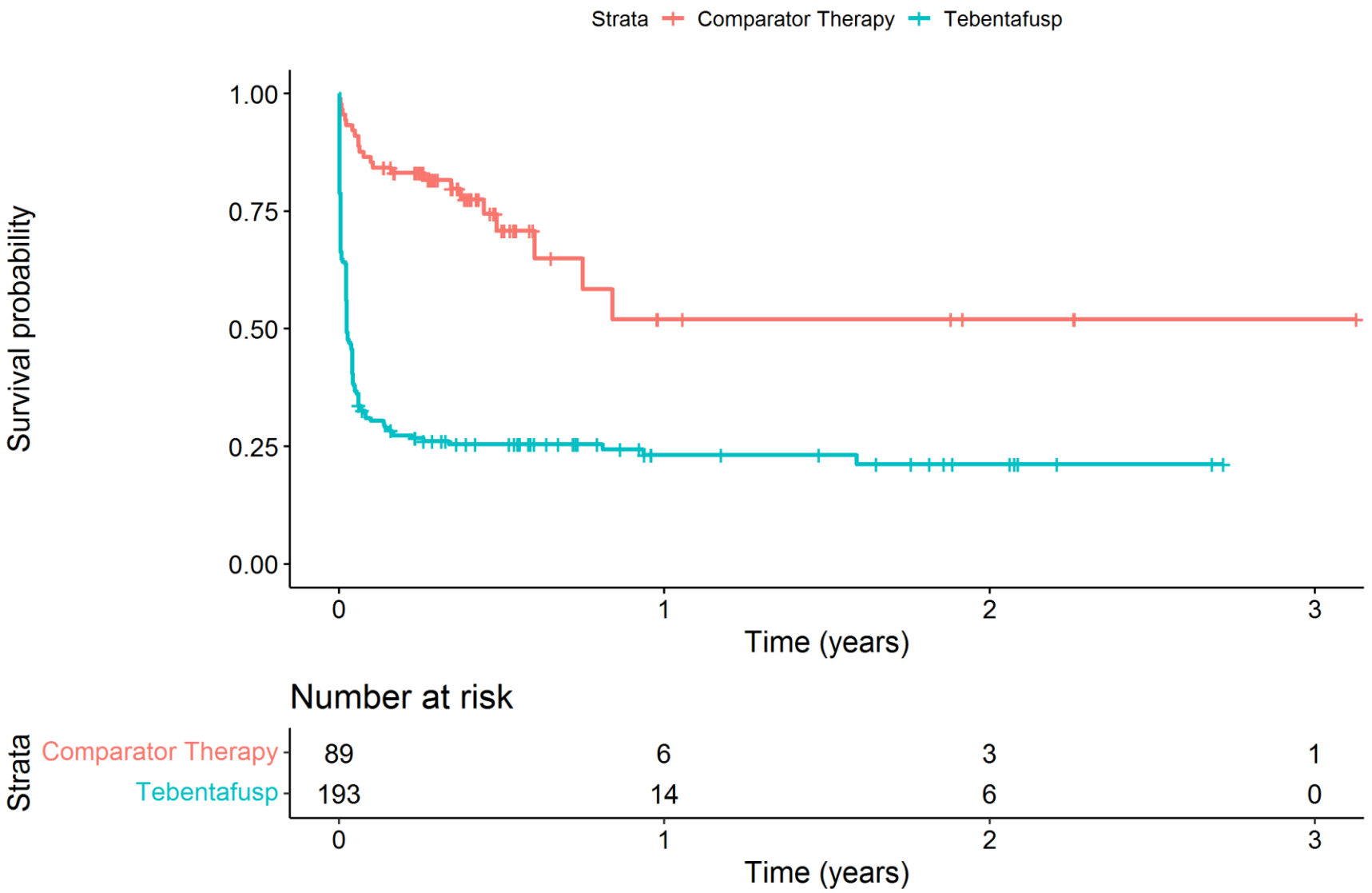
Pruritus - ECOG 0



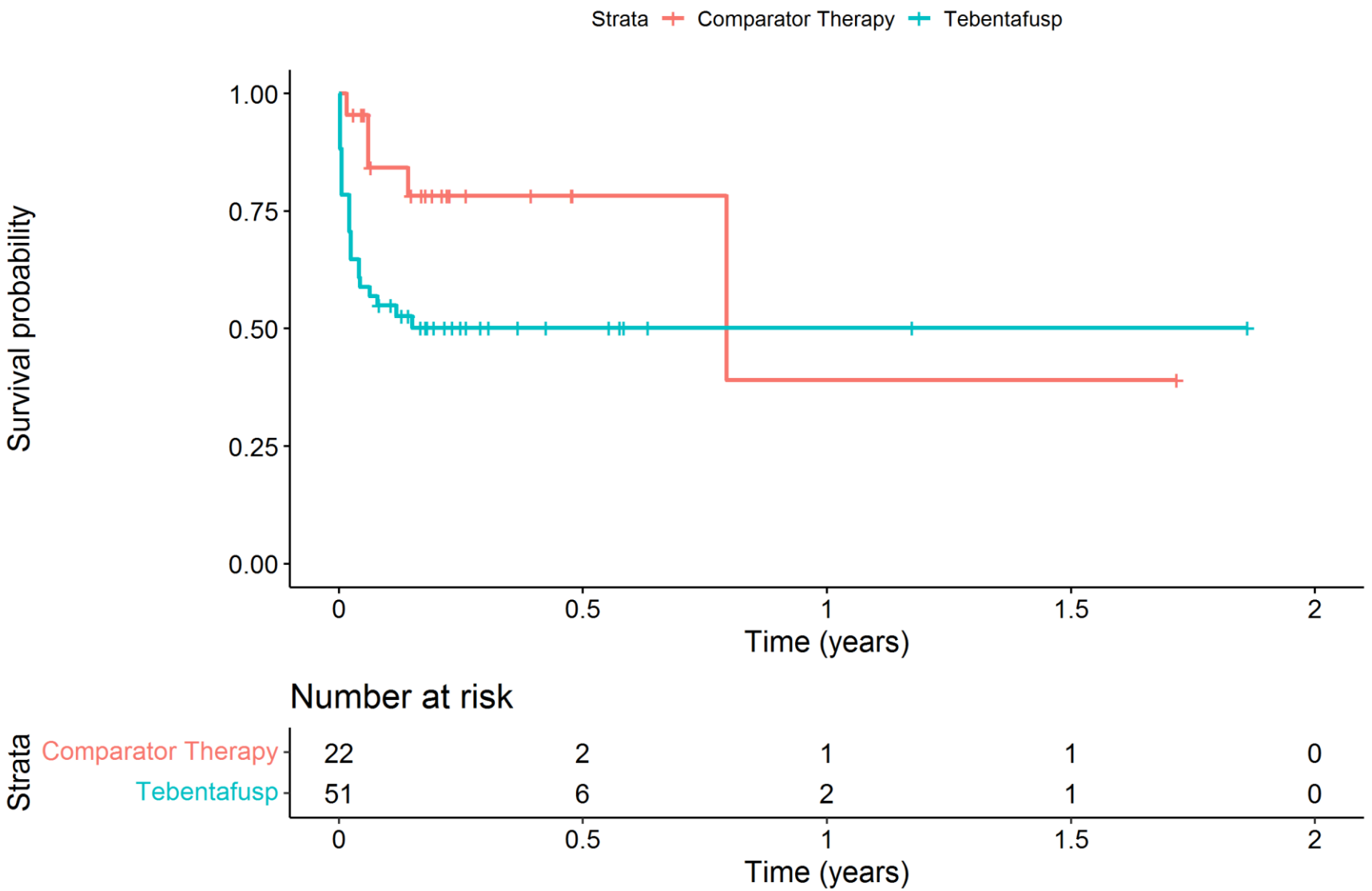
Pruritus - ECOG 1



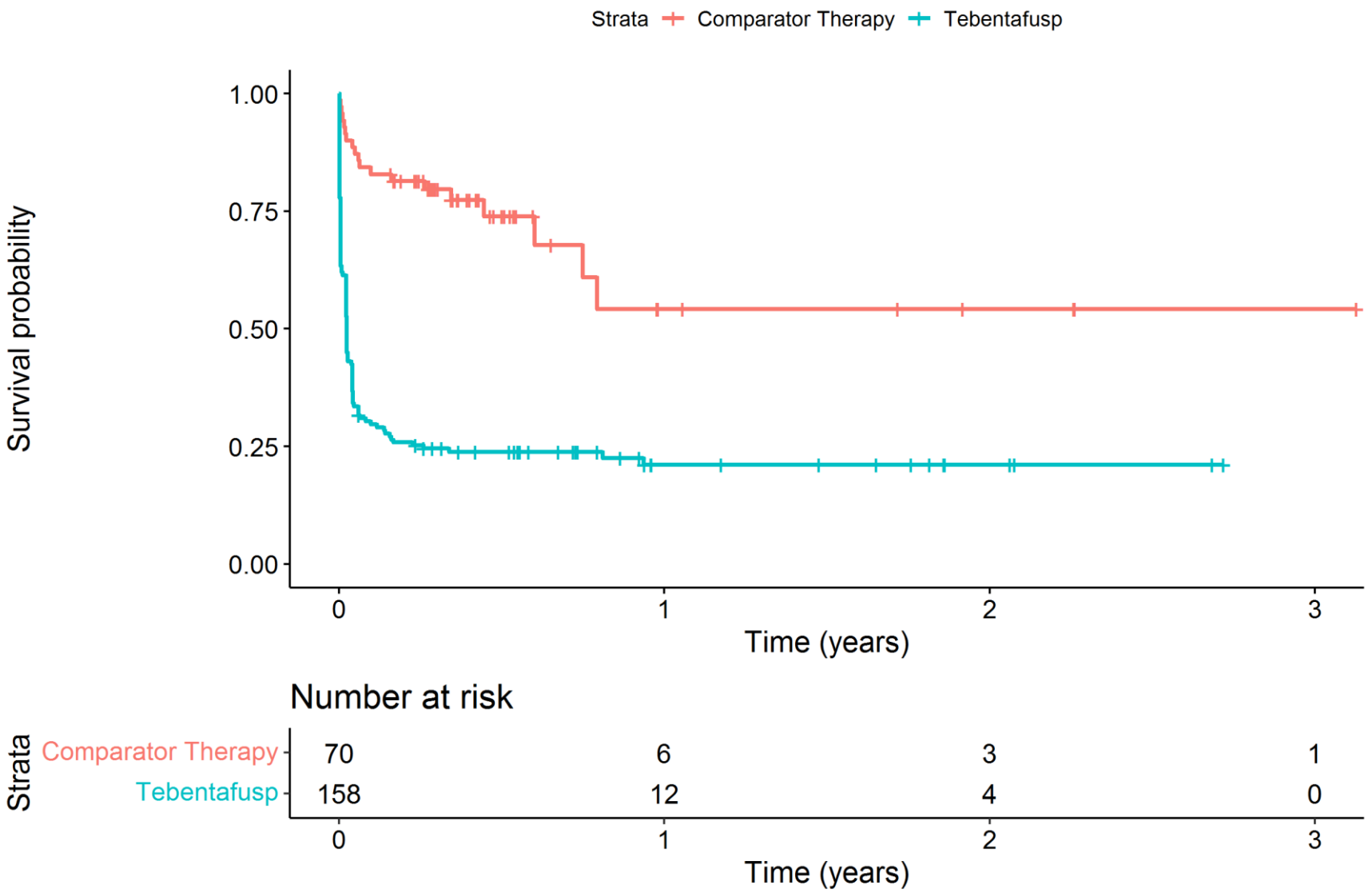
Pruritus - ALP ≤ ULN



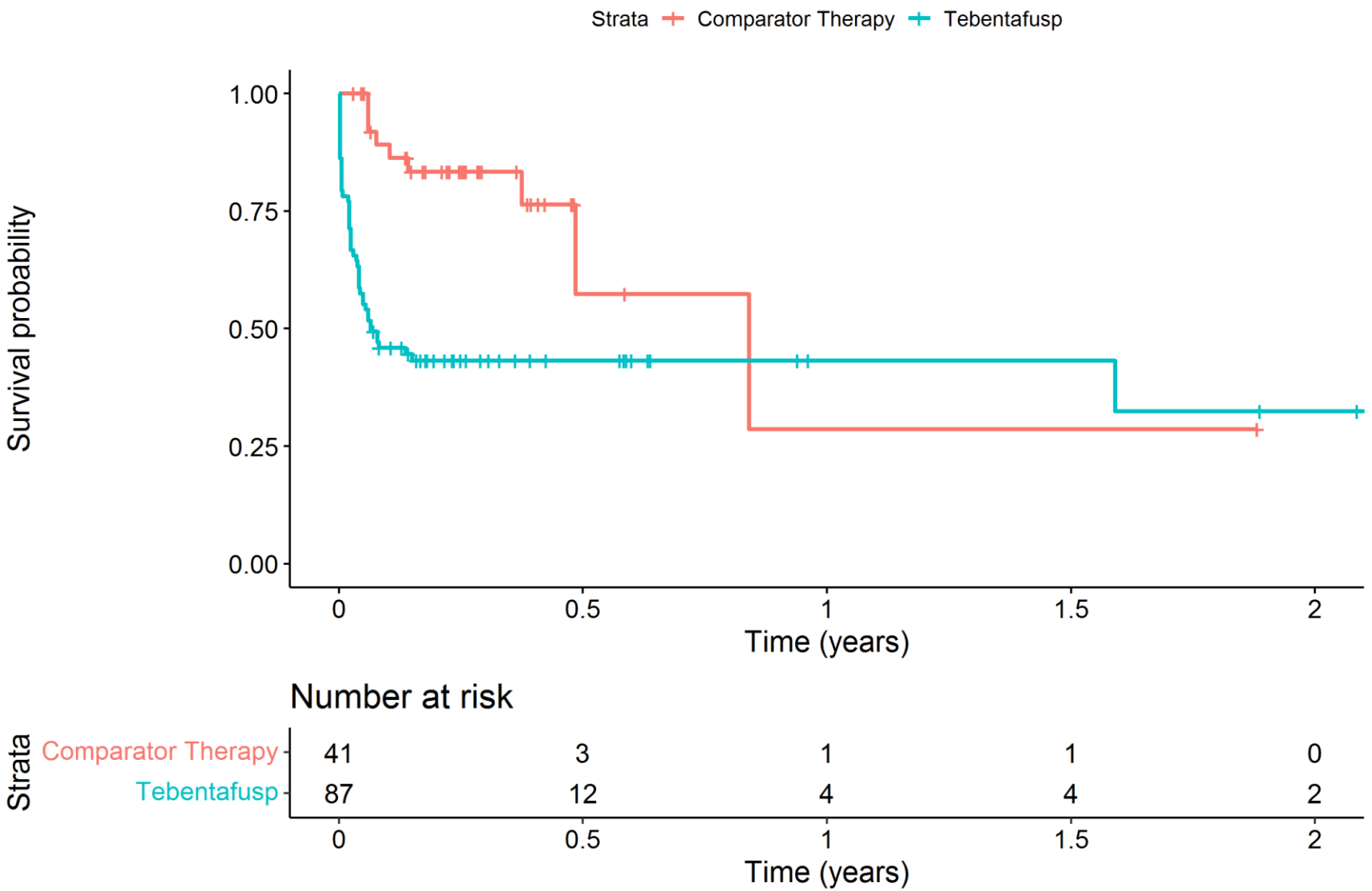
Pruritus - ALP > ULN



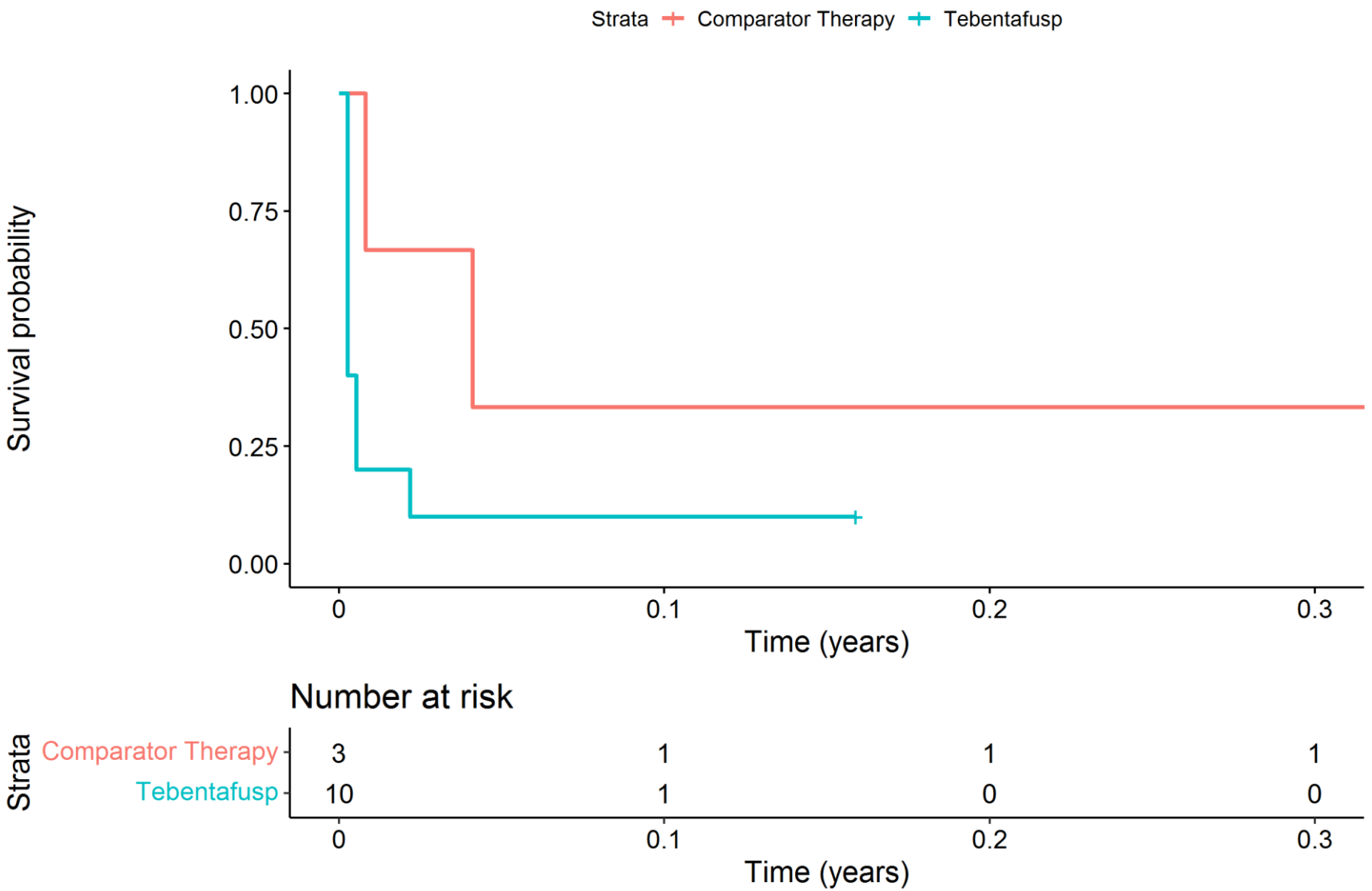
Pruritus - LDH =< ULN



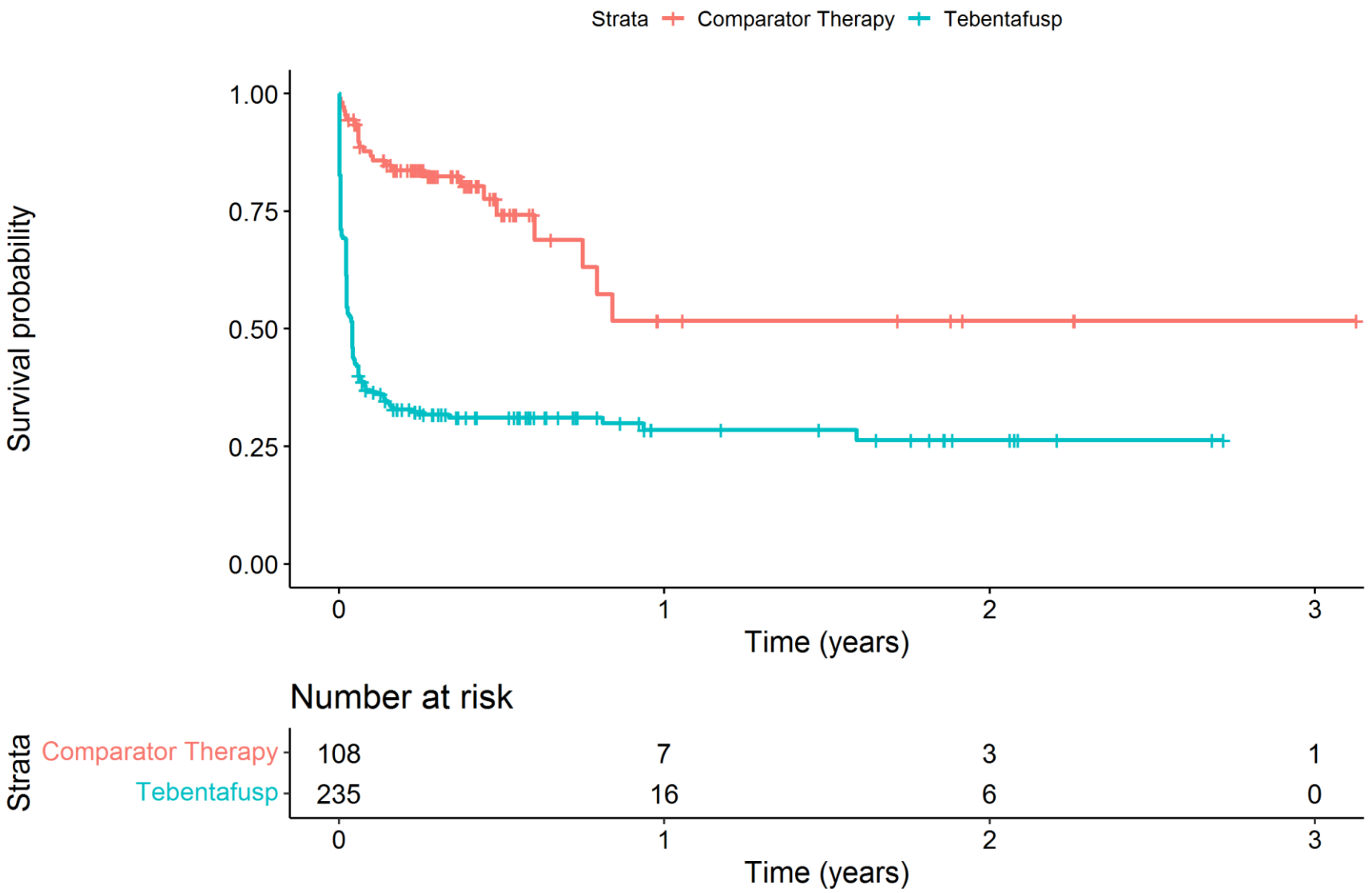
Pruritus - LDH > ULN



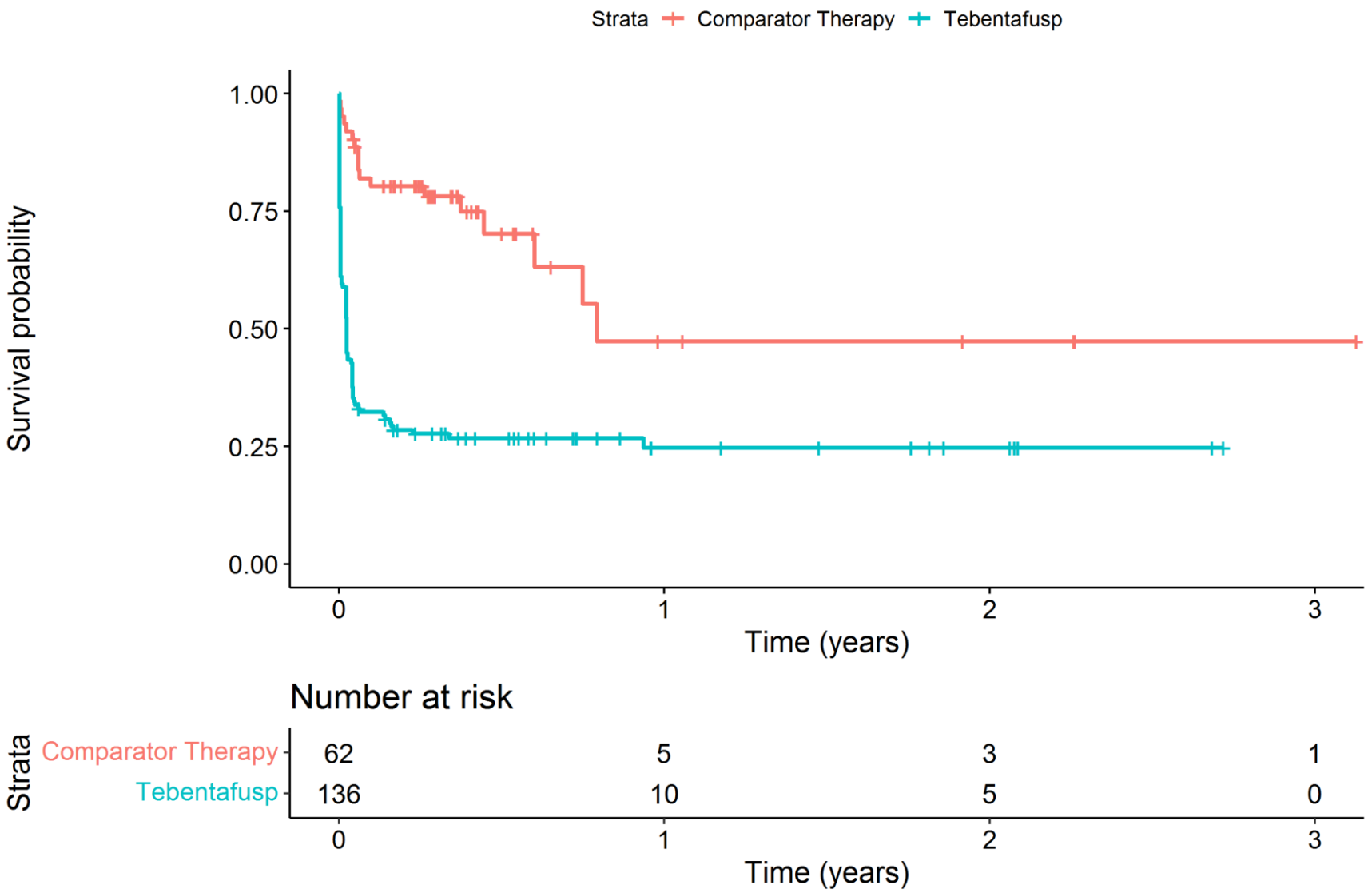
Pruritus - Vorherige Therapie adjuvant/neoadjuvant



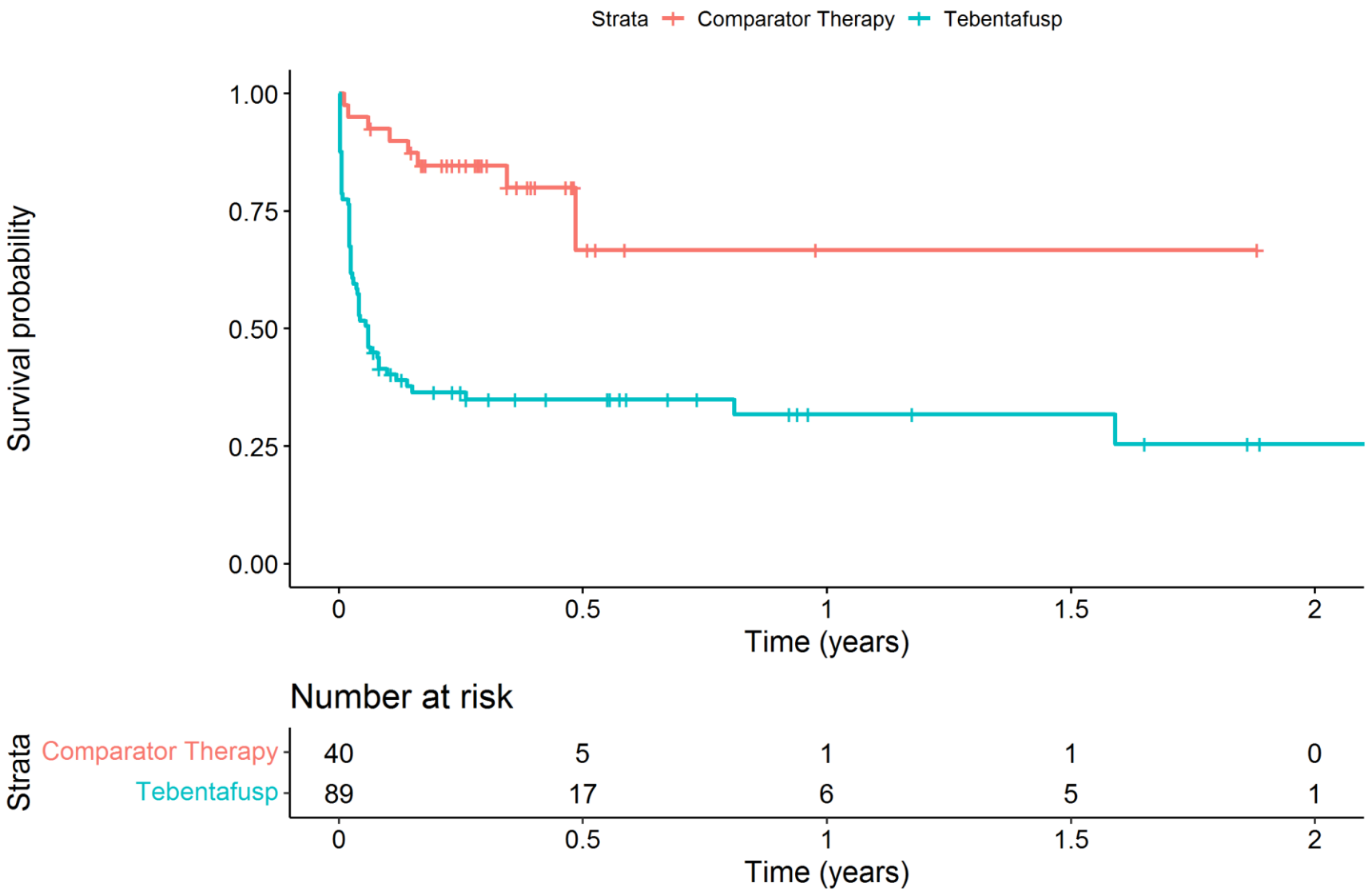
Pruritus - Keine Vorherige Therapie adjuvant/neoadjuvant



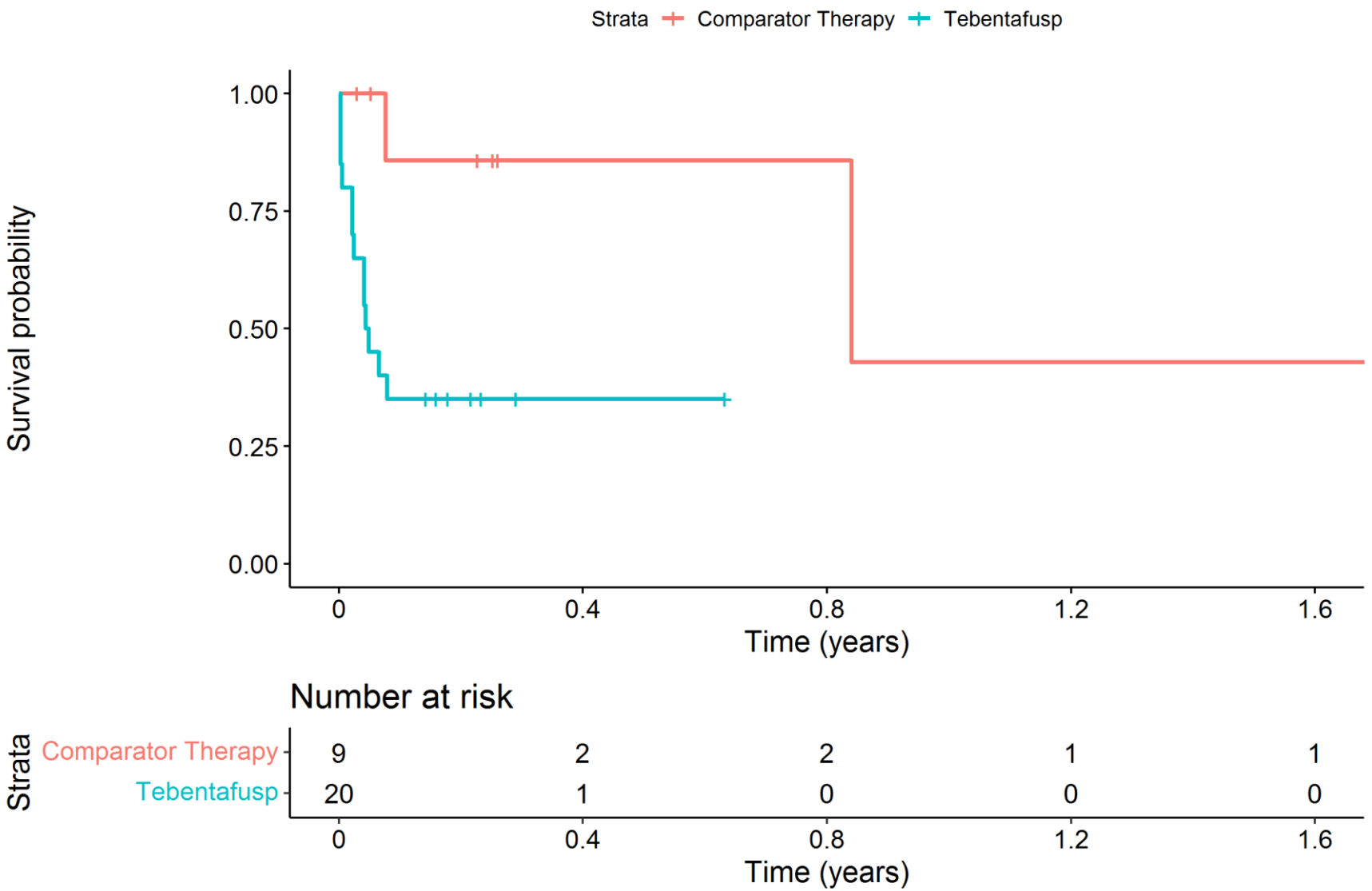
Pruritus - Läsion ≤ 3cm



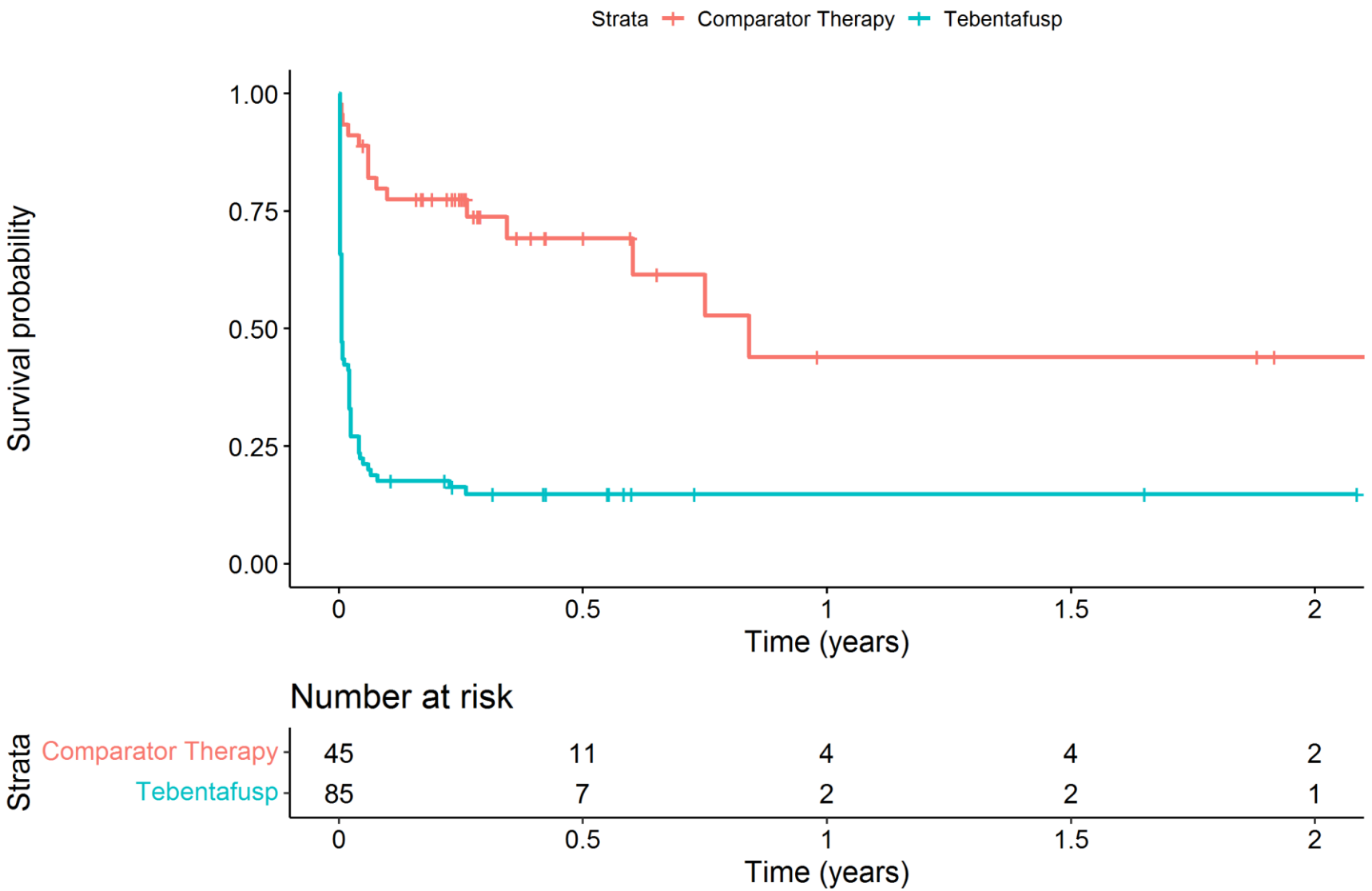
Pruritus - Läsion 3,1-8,0 cm



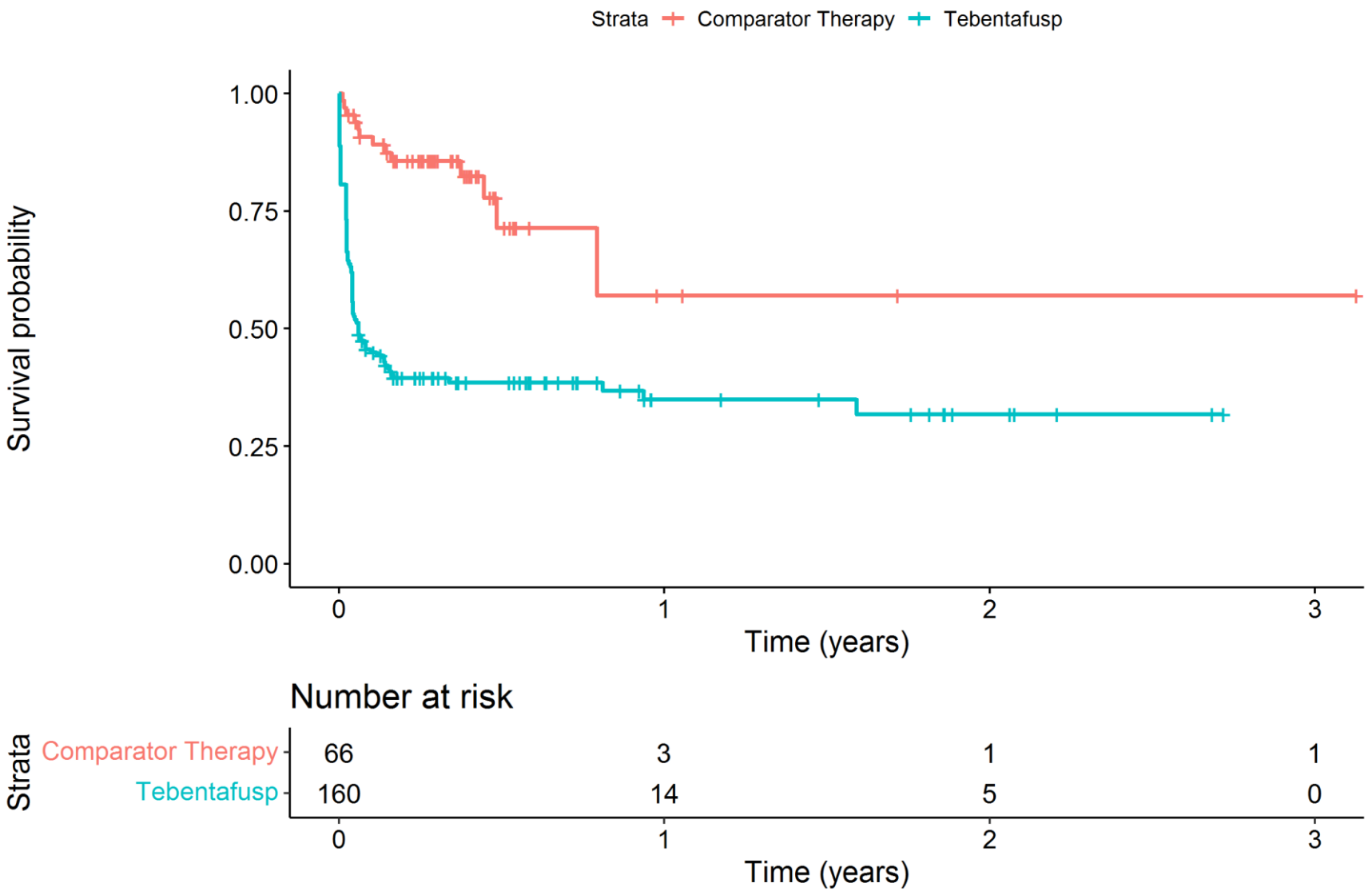
Pruritus - Läsion ≥8,1 cm



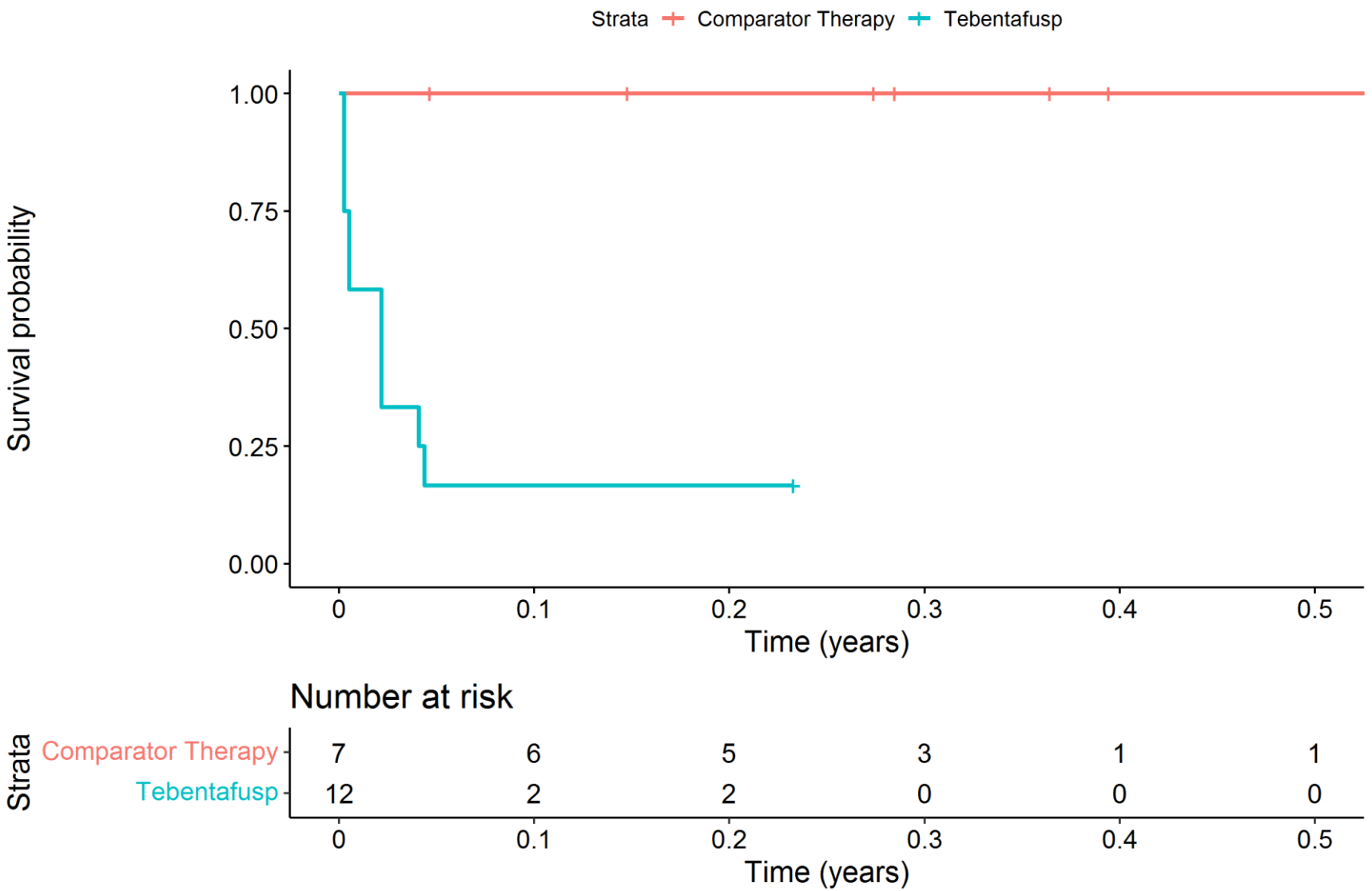
Pruritus - Nordamerika



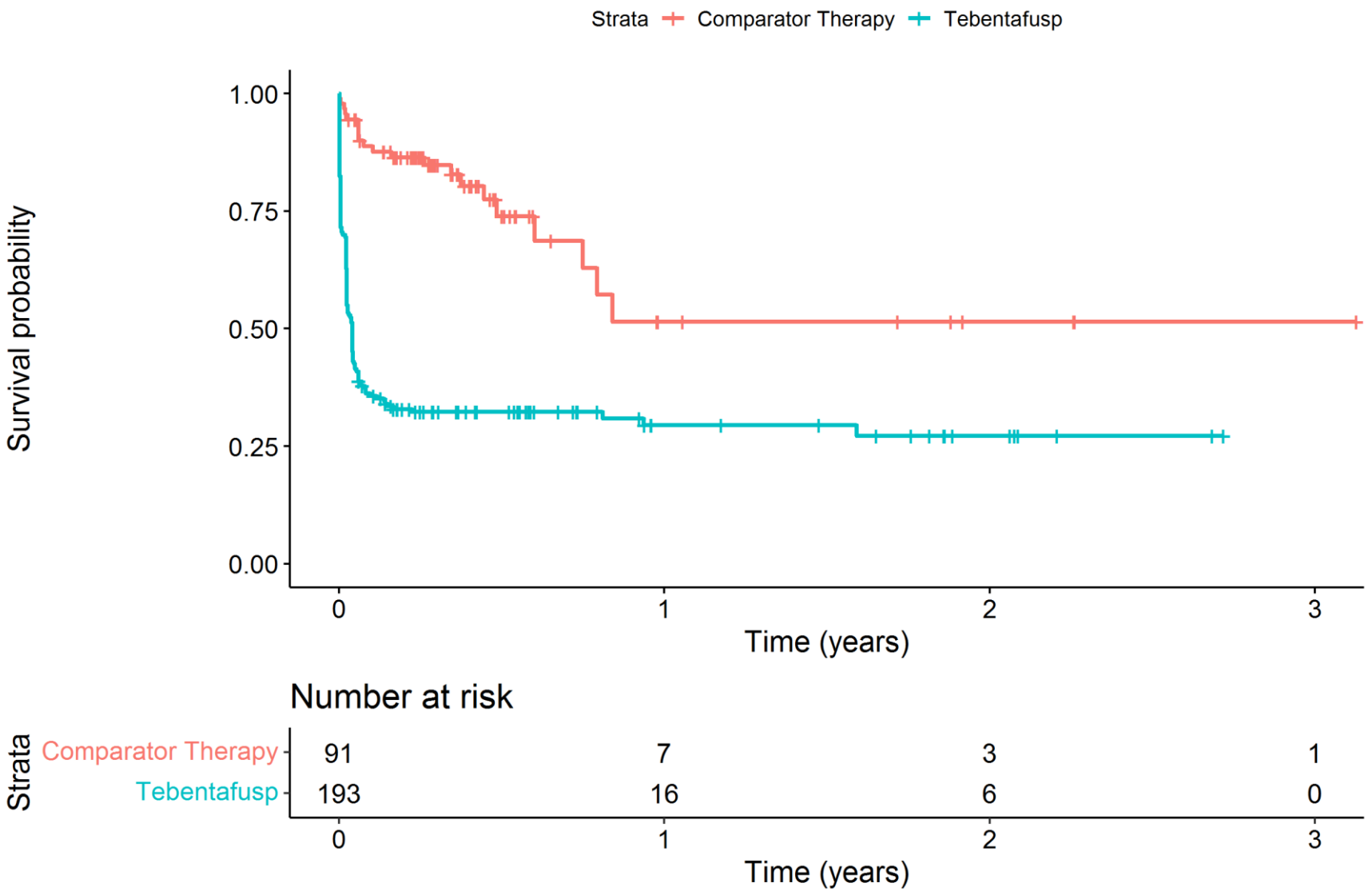
Pruritus - Nicht-Nordamerika



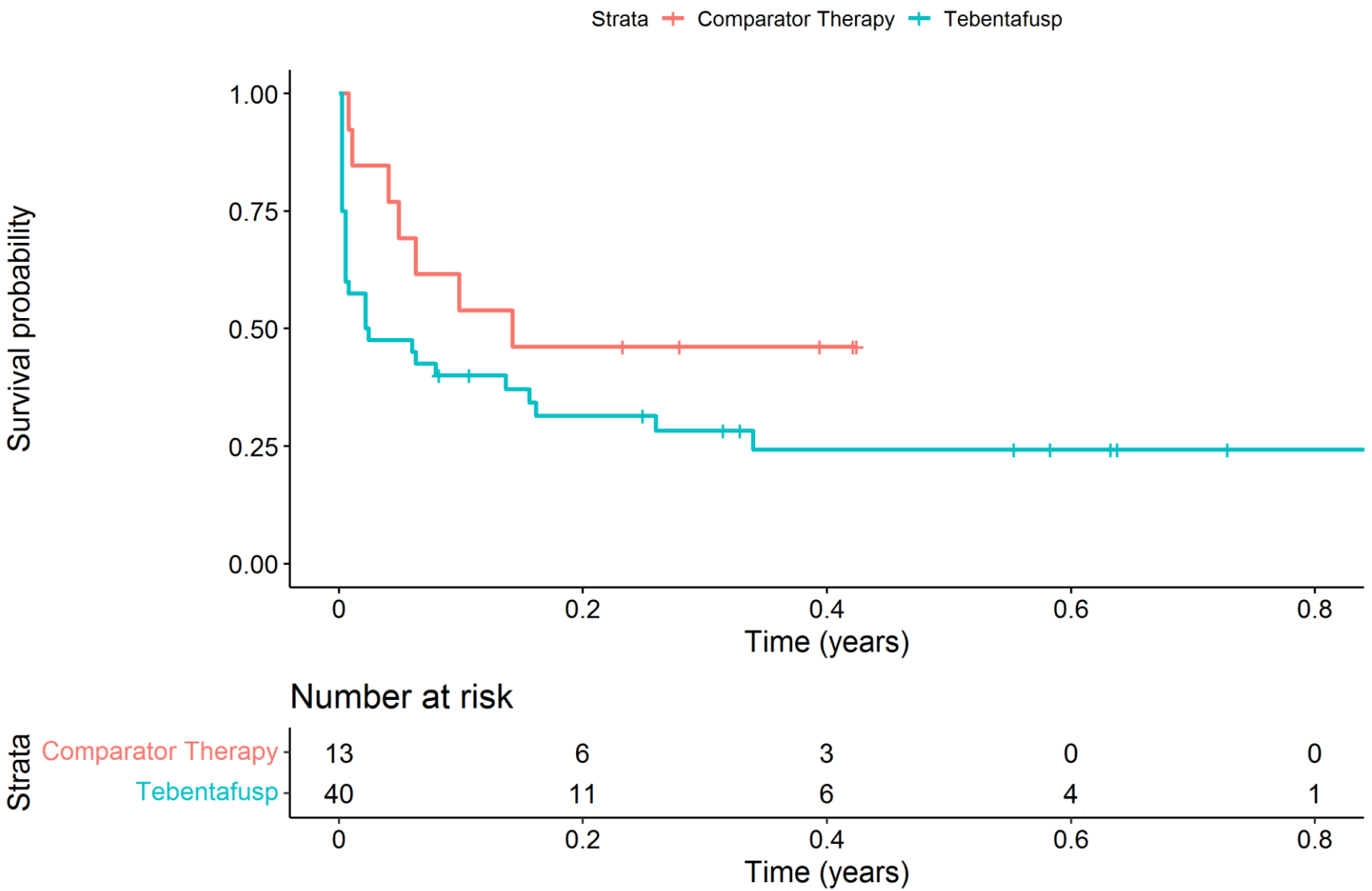
Pruritus - Dacarbazin



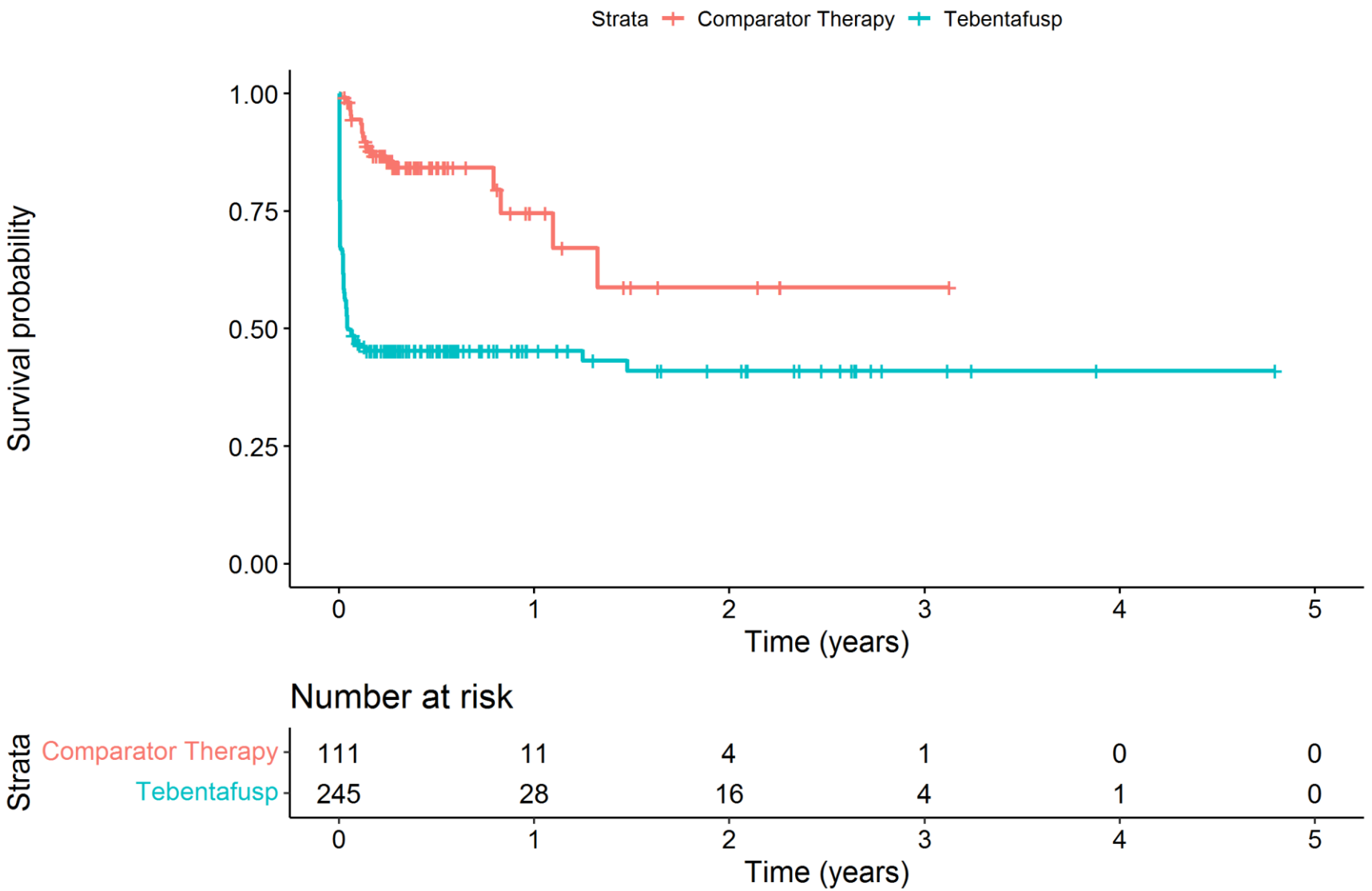
Pruritus - Pembrolizumab



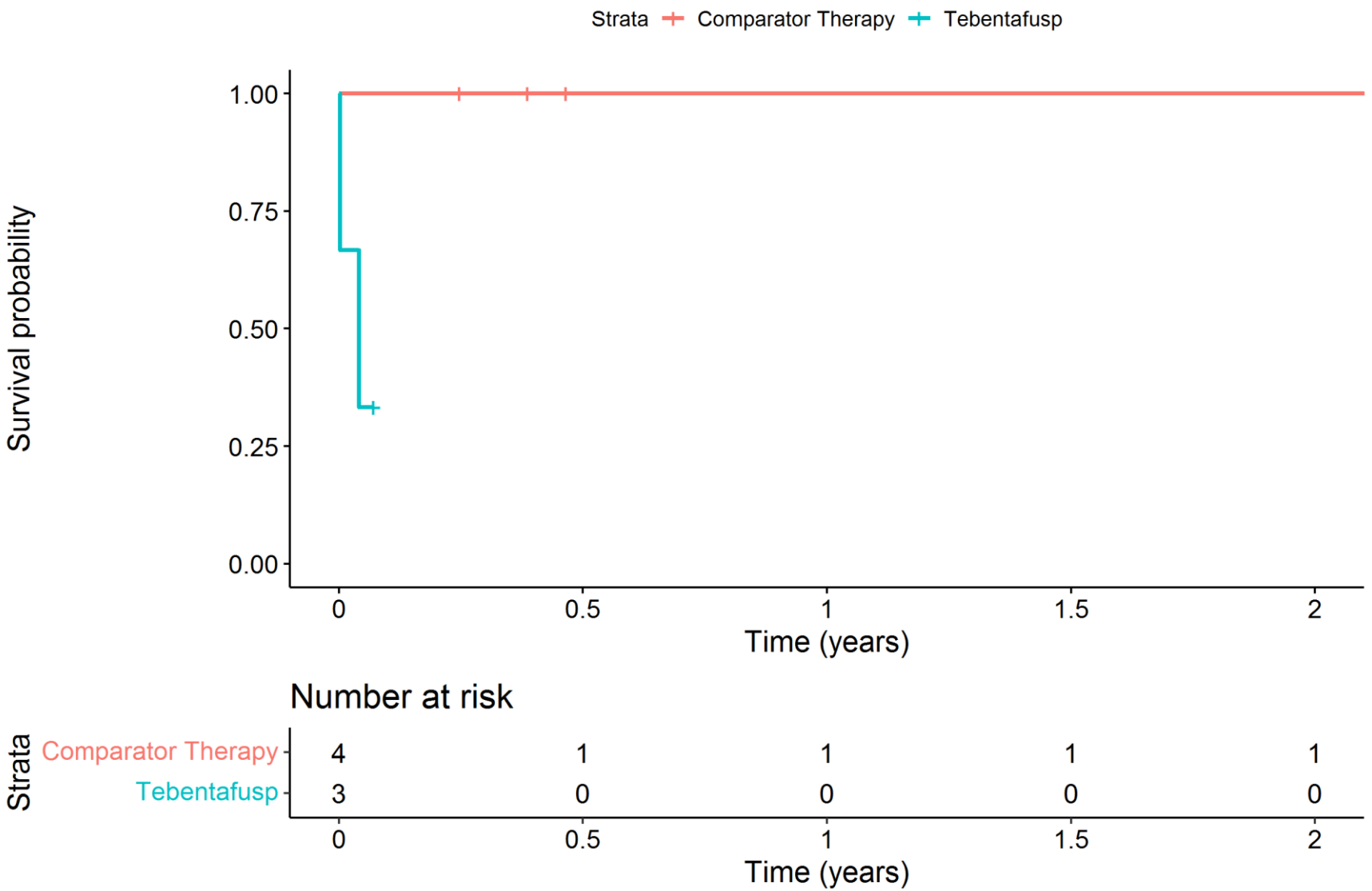
Pruritus - Ipilimumab



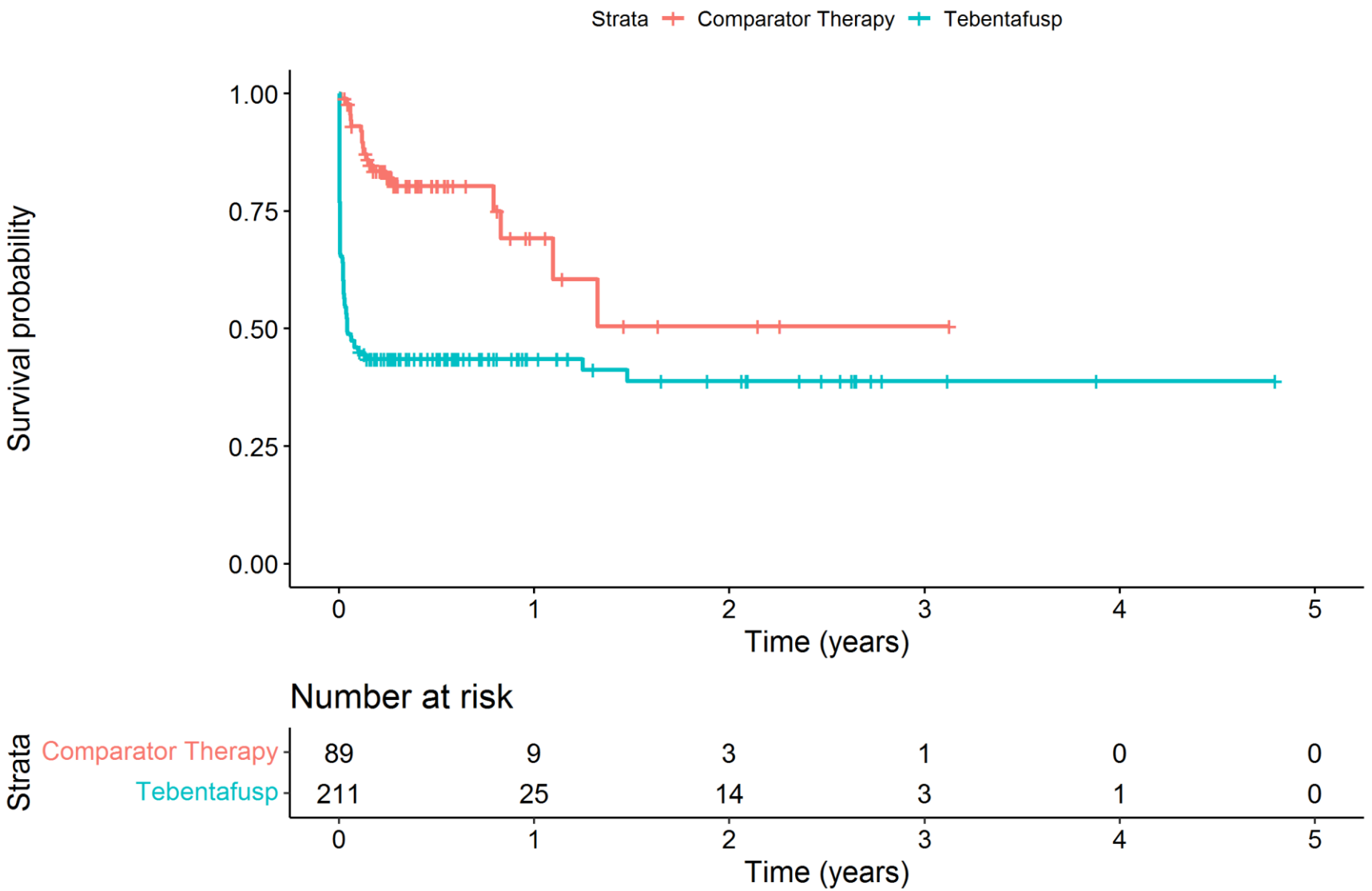
Hautausschlag - Gesamt



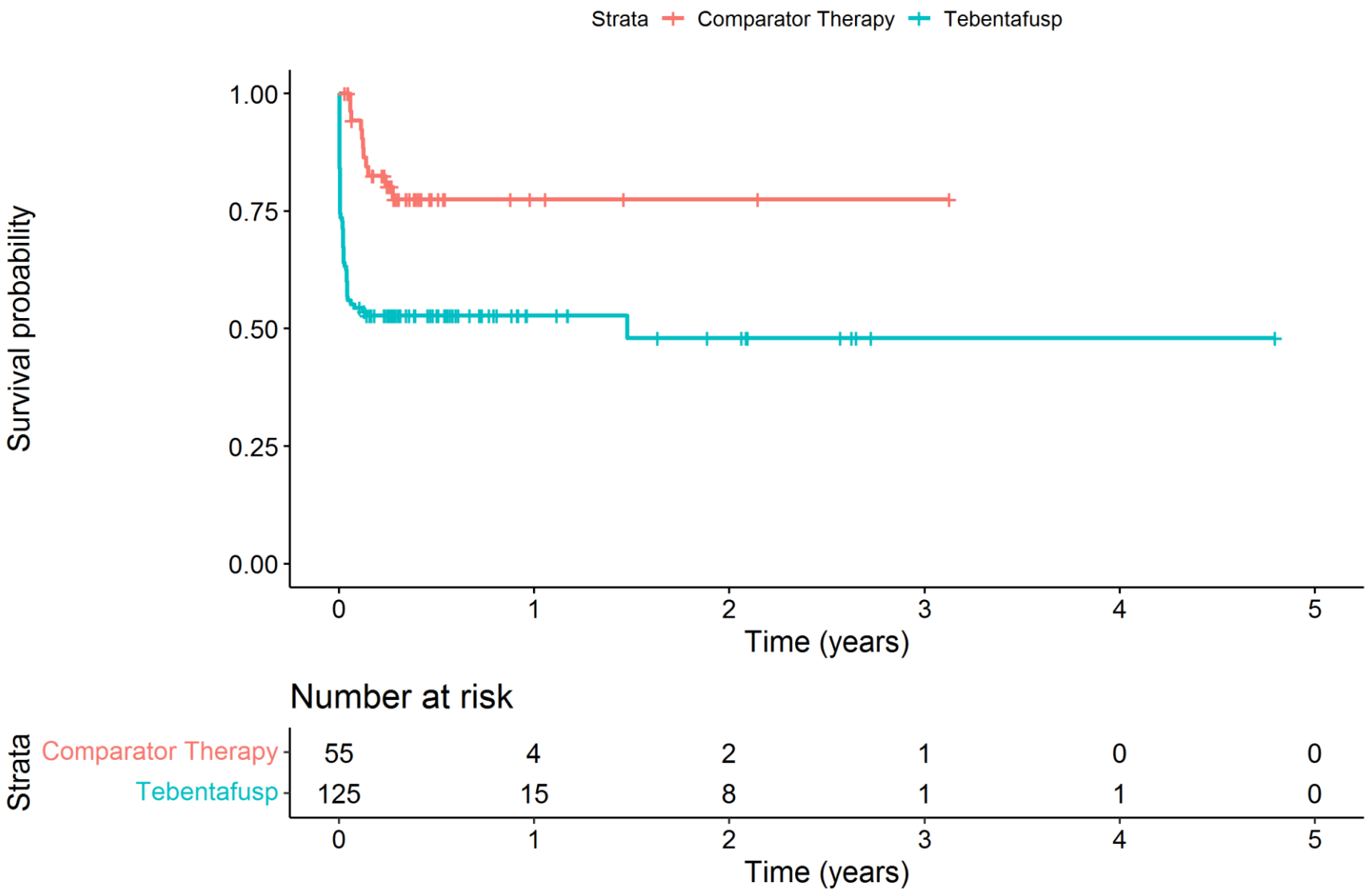
Hautausschlag - Hispanisch



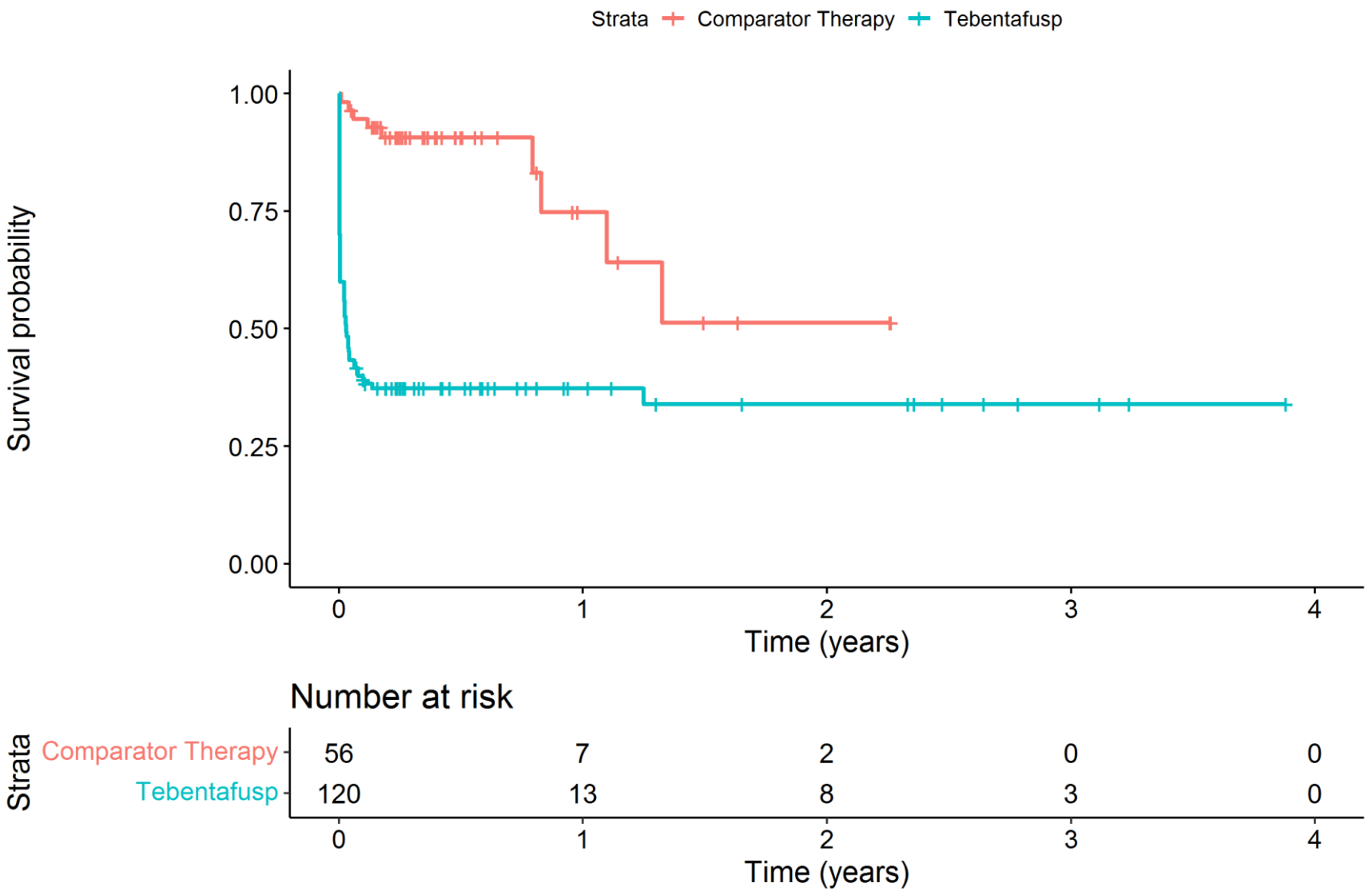
Hautausschlag - Nicht-hispanisch



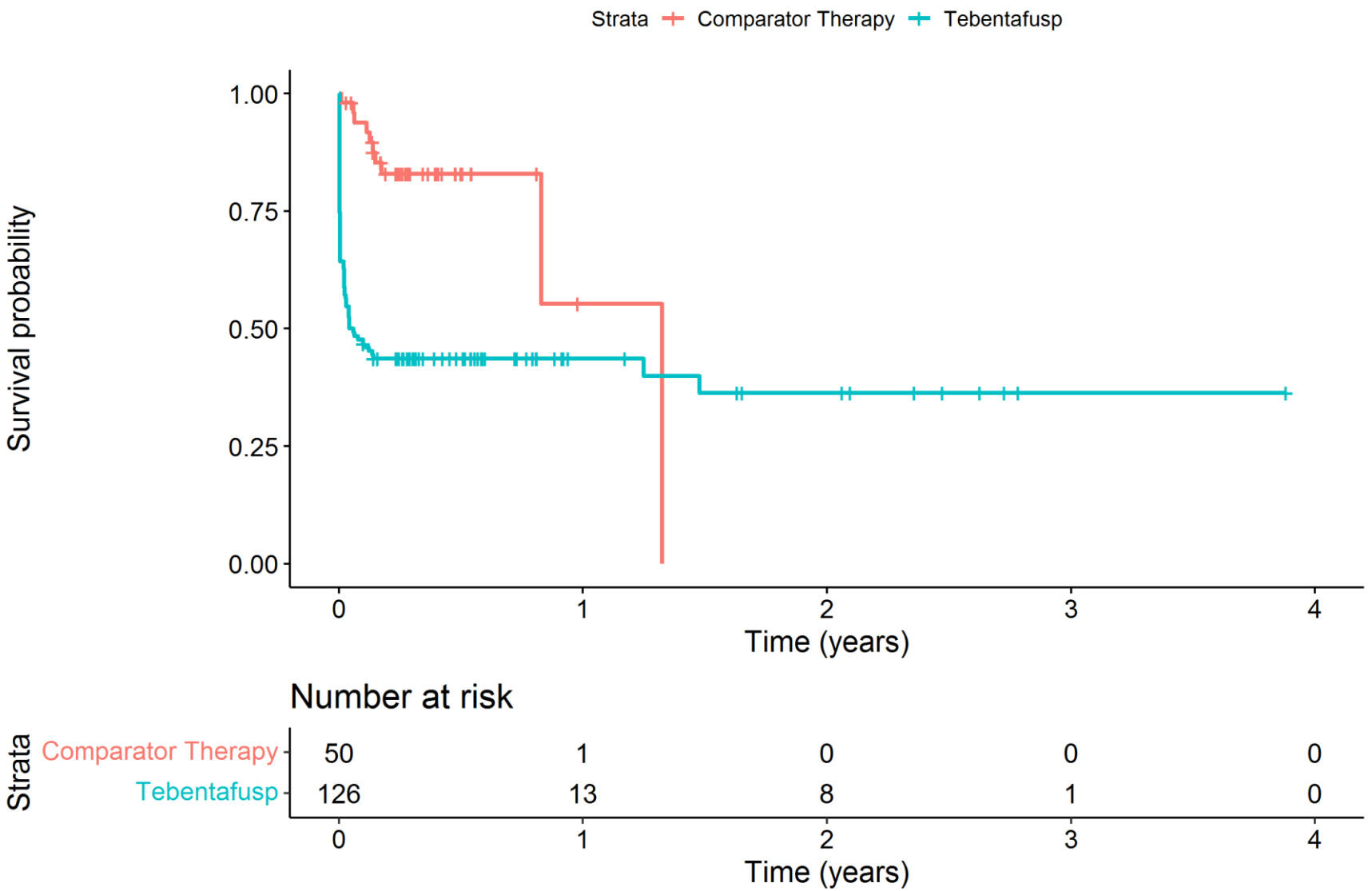
Hautausschlag - Männlich



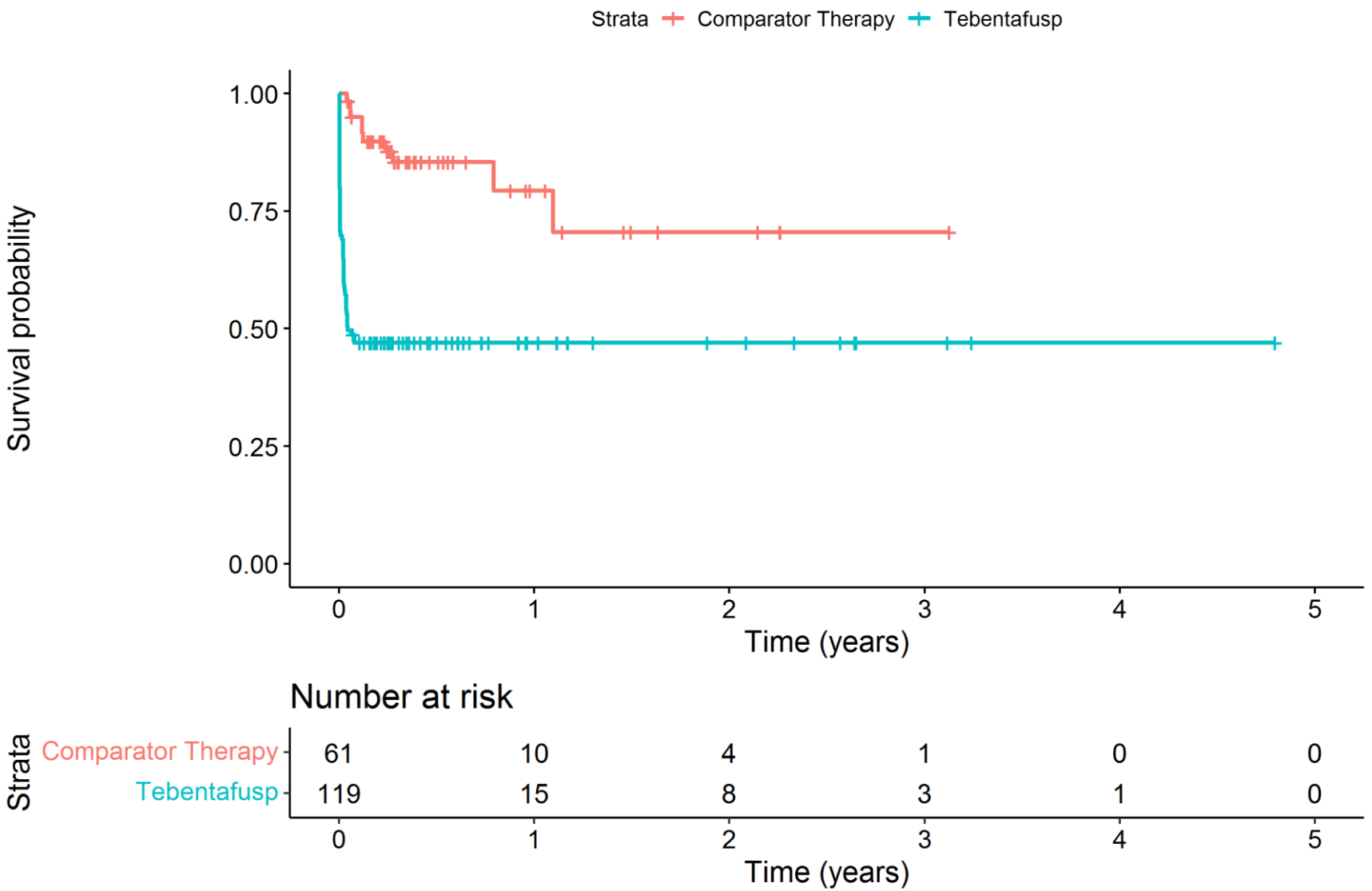
Hautausschlag - Weiblich



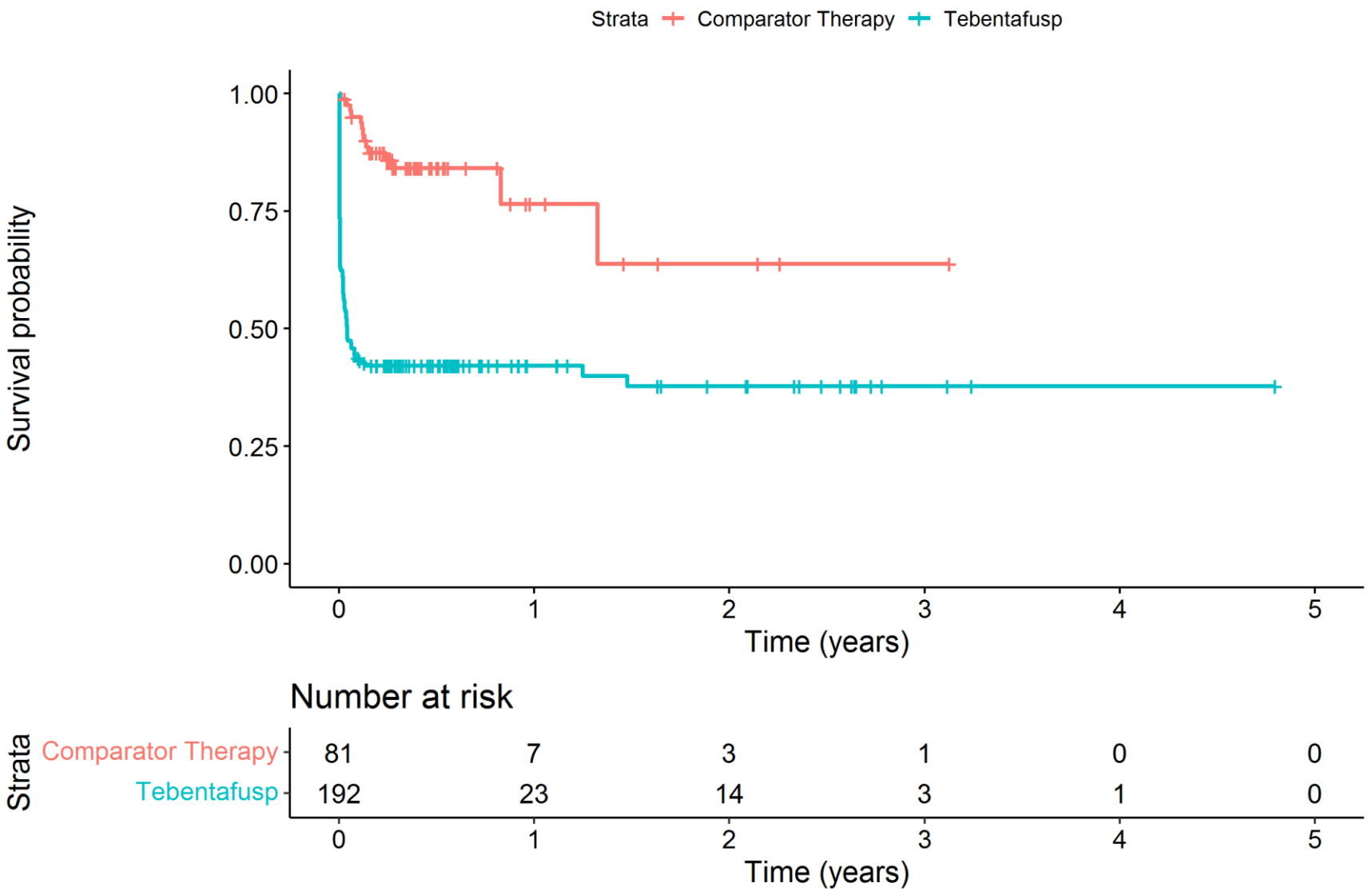
Hautausschlag - <65



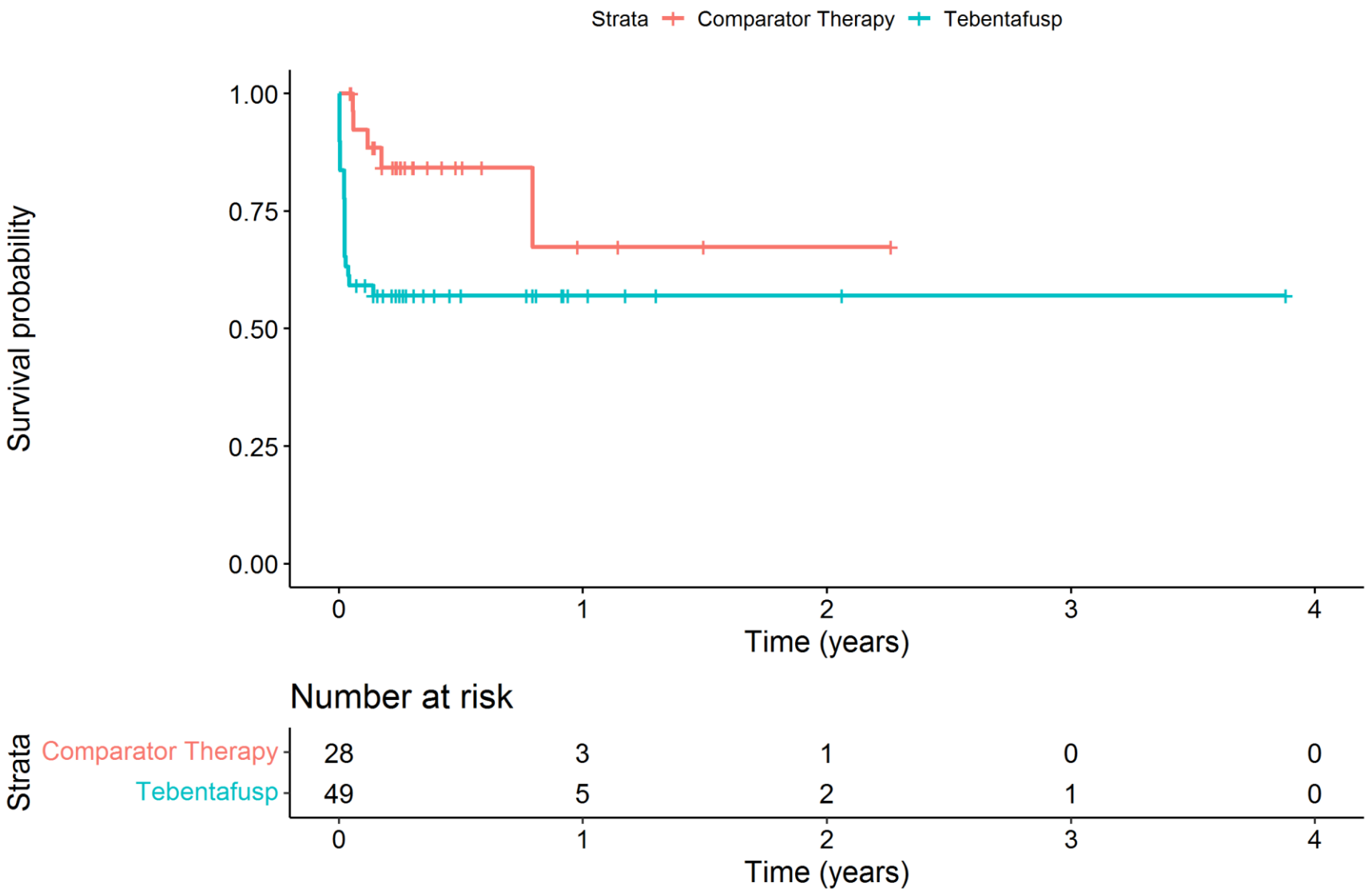
Hautausschlag - ≥65



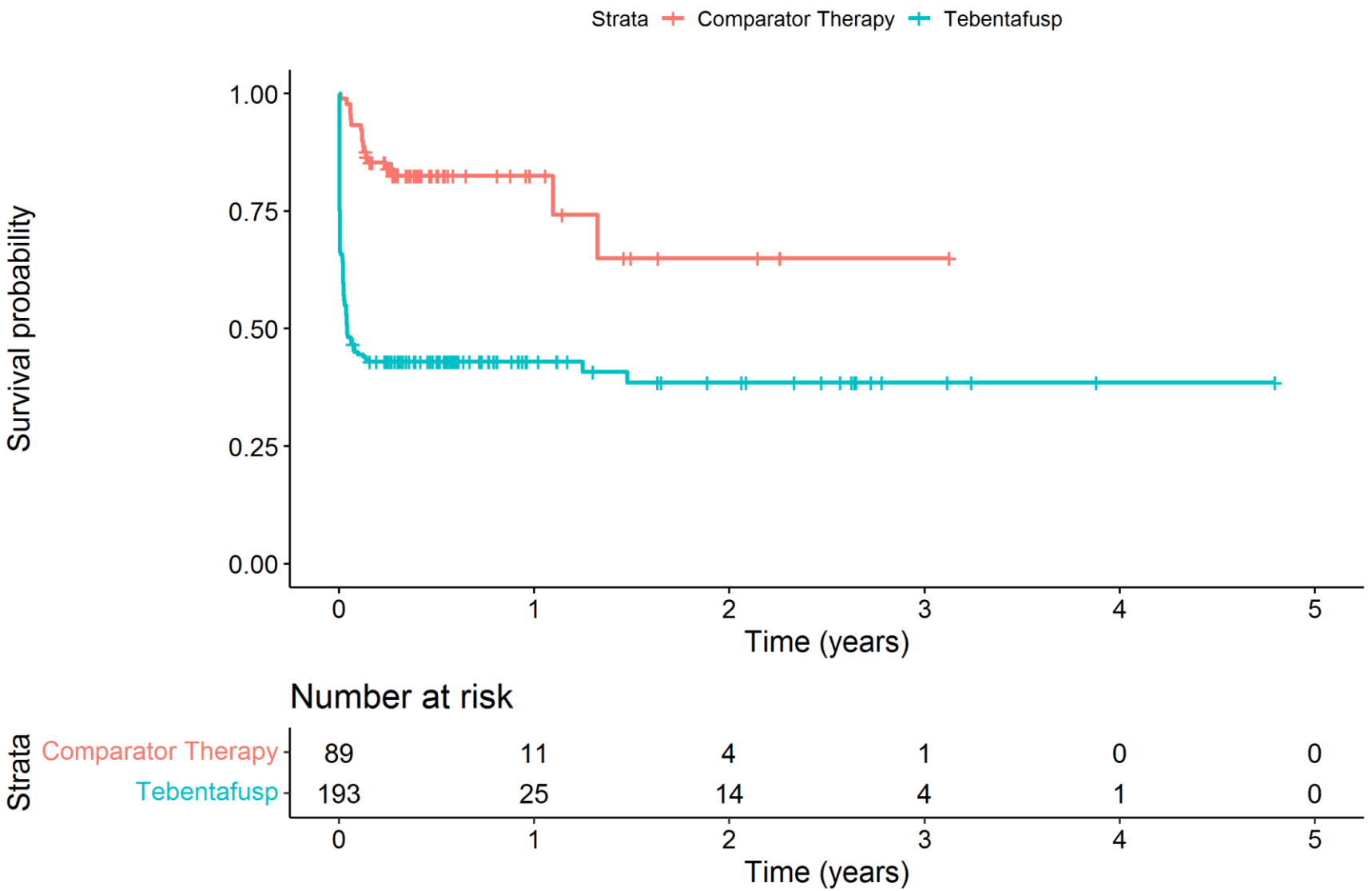
Hautausschlag - ECOG 0



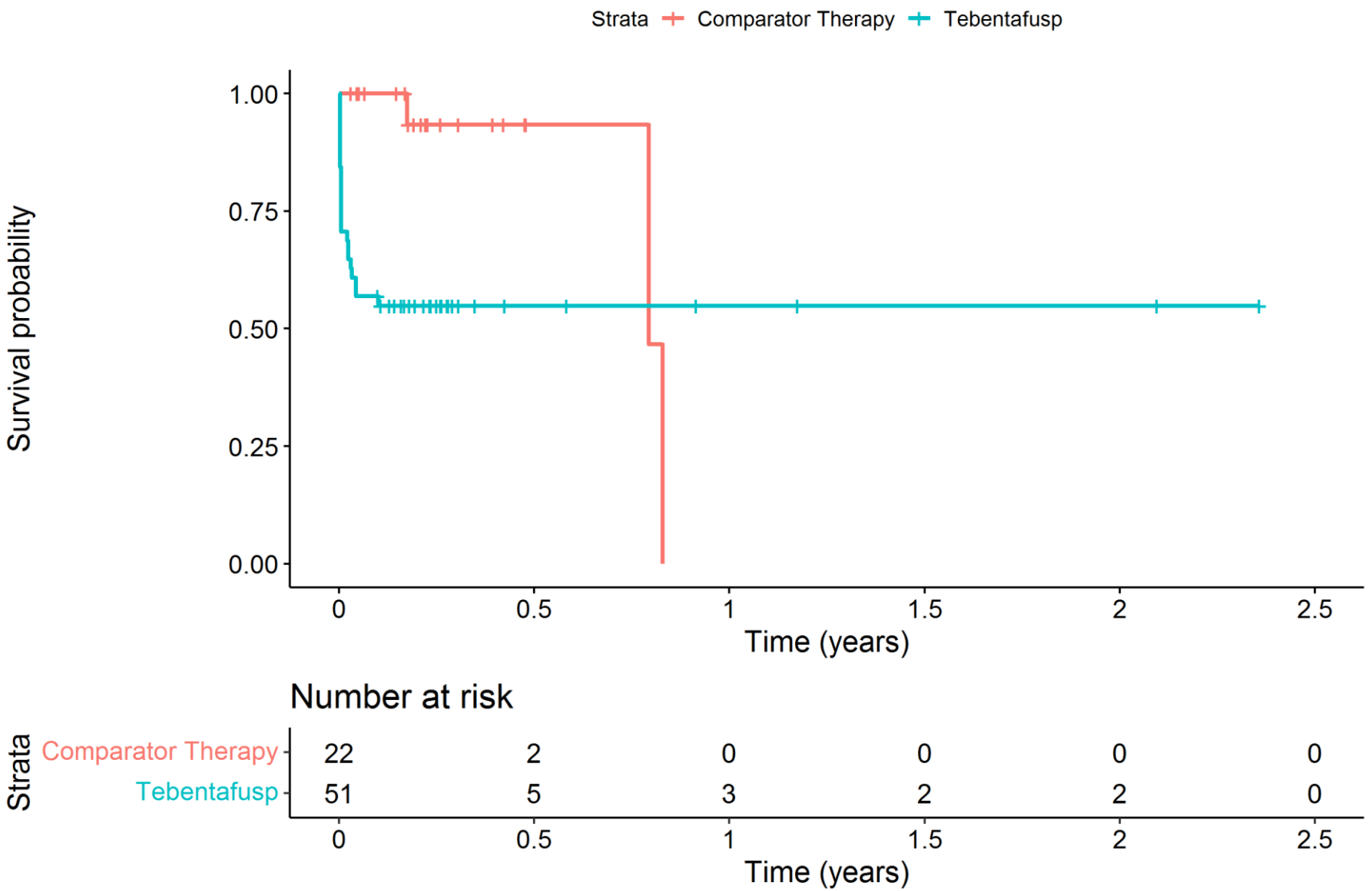
Hautausschlag - ECOG 1



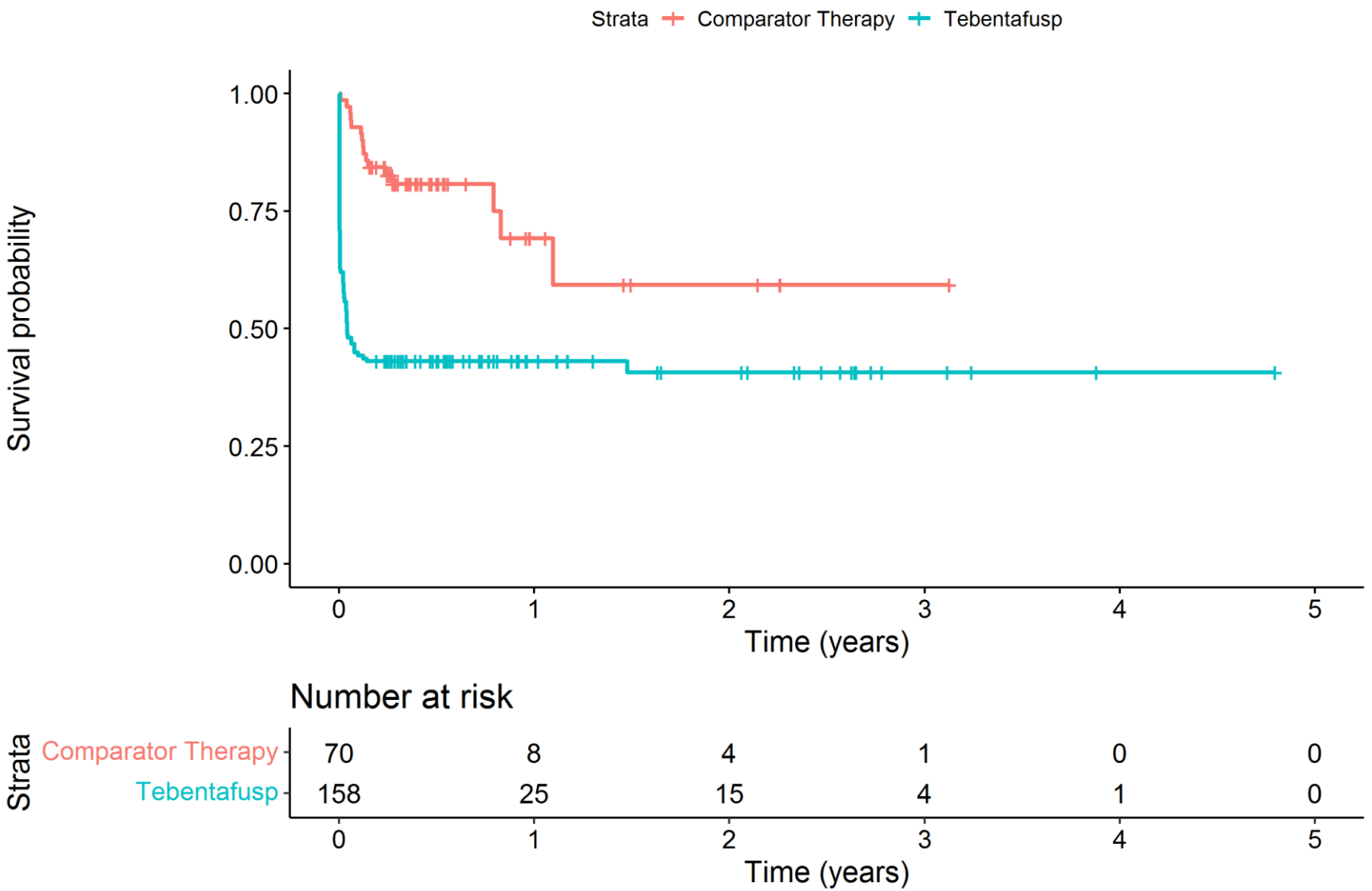
Hautausschlag - ALP ≤ ULN



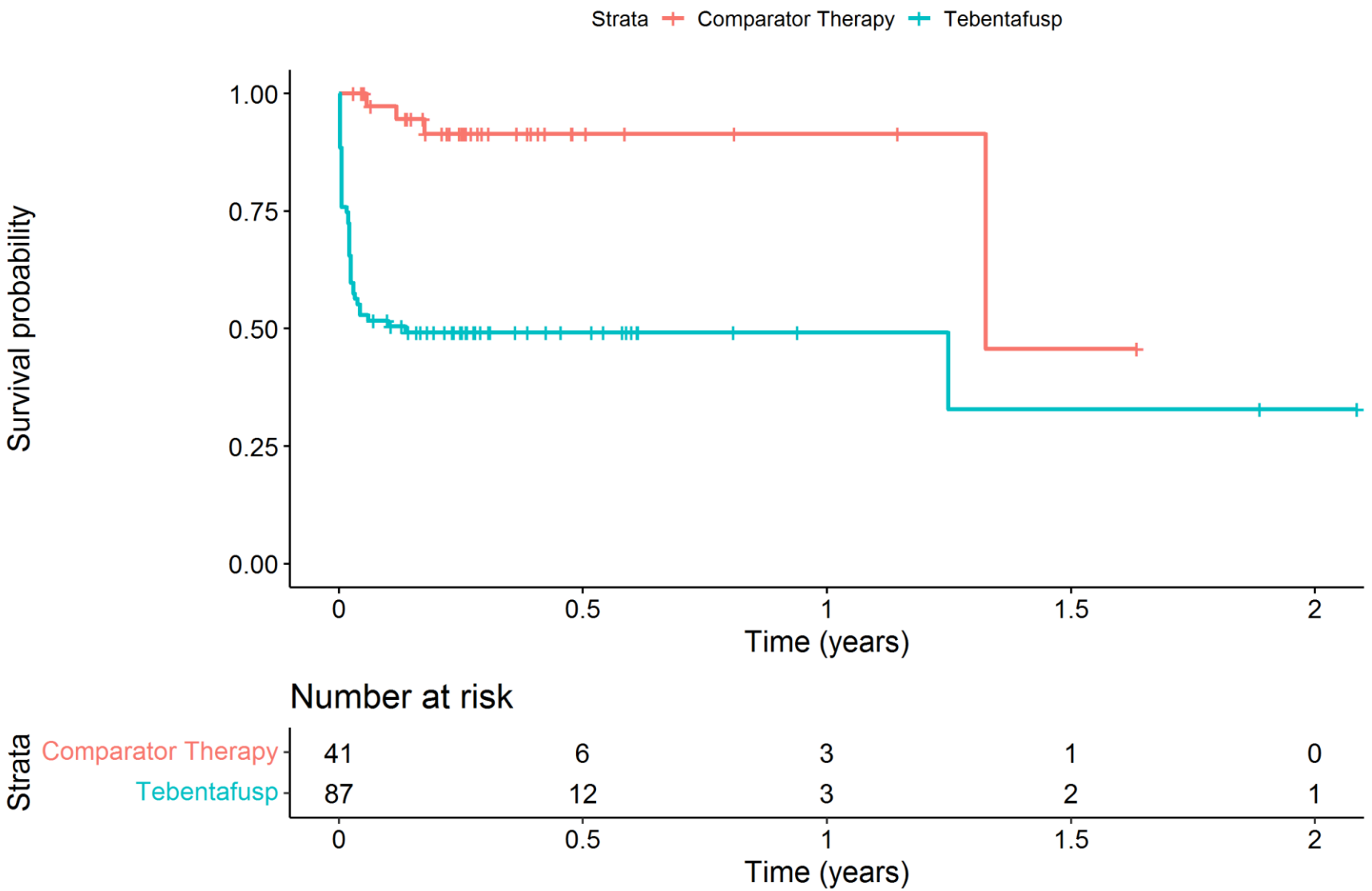
Hautausschlag - ALP > ULN



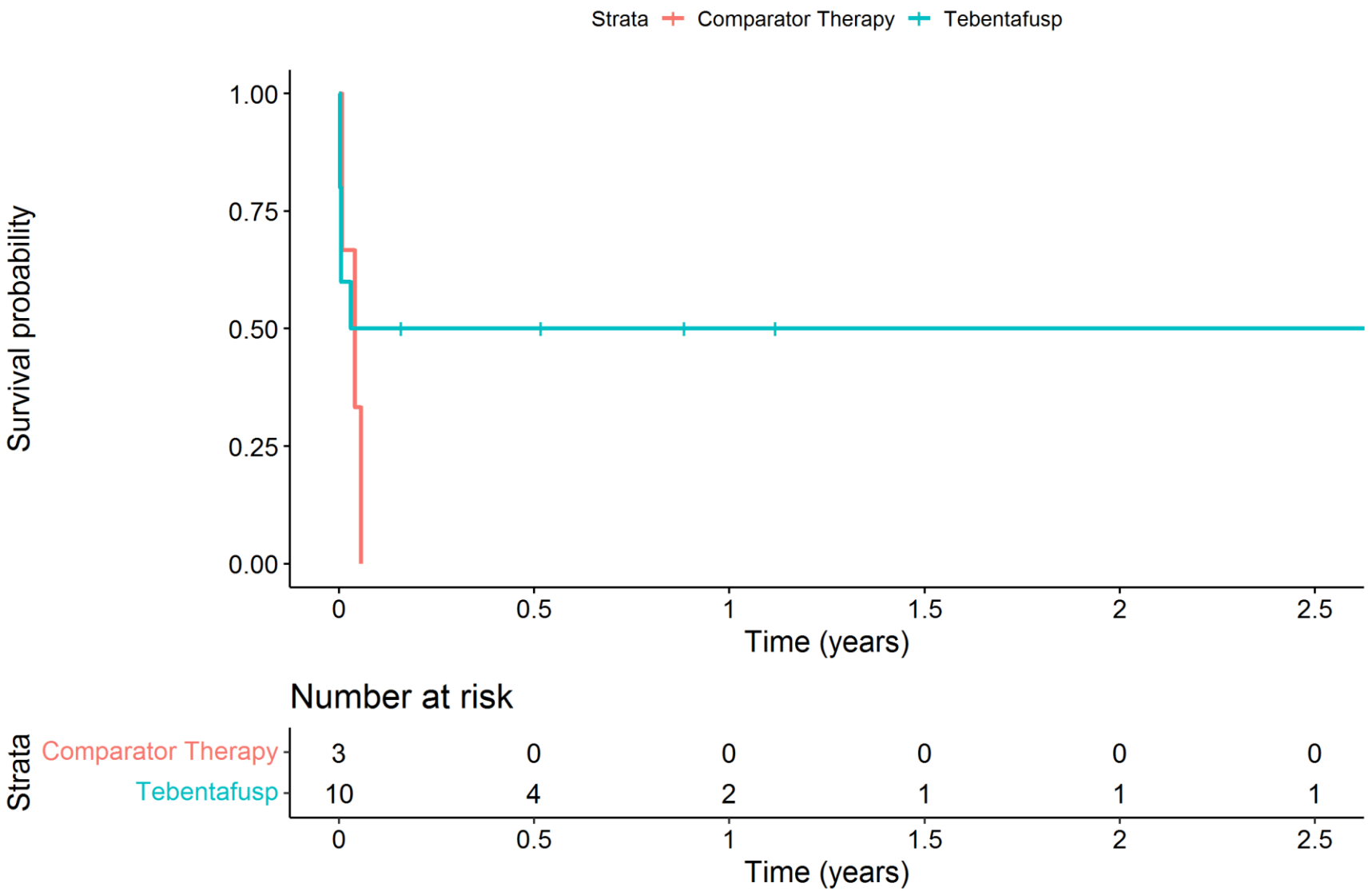
Hautausschlag - LDH =< ULN



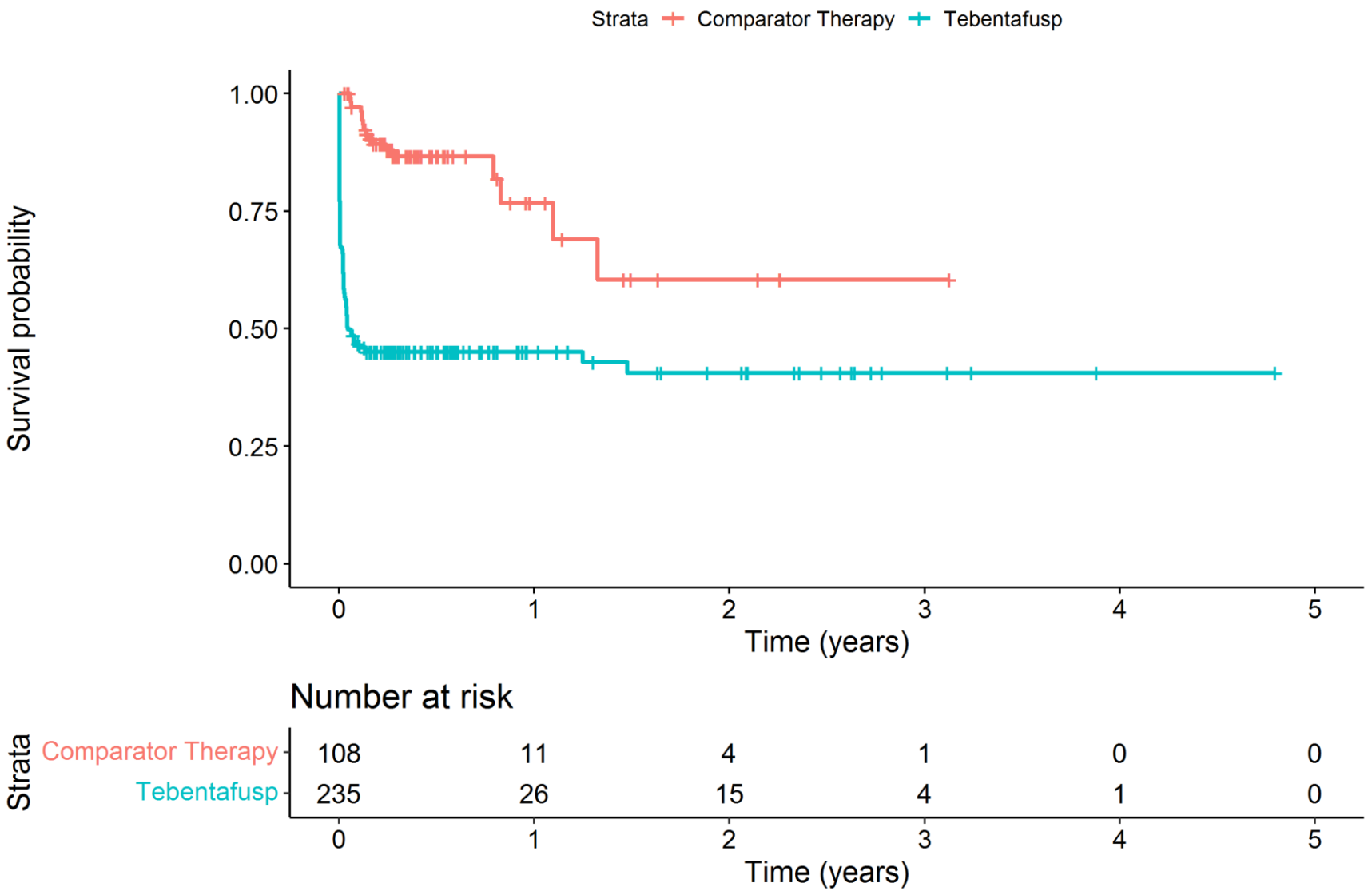
Hautausschlag - LDH > ULN



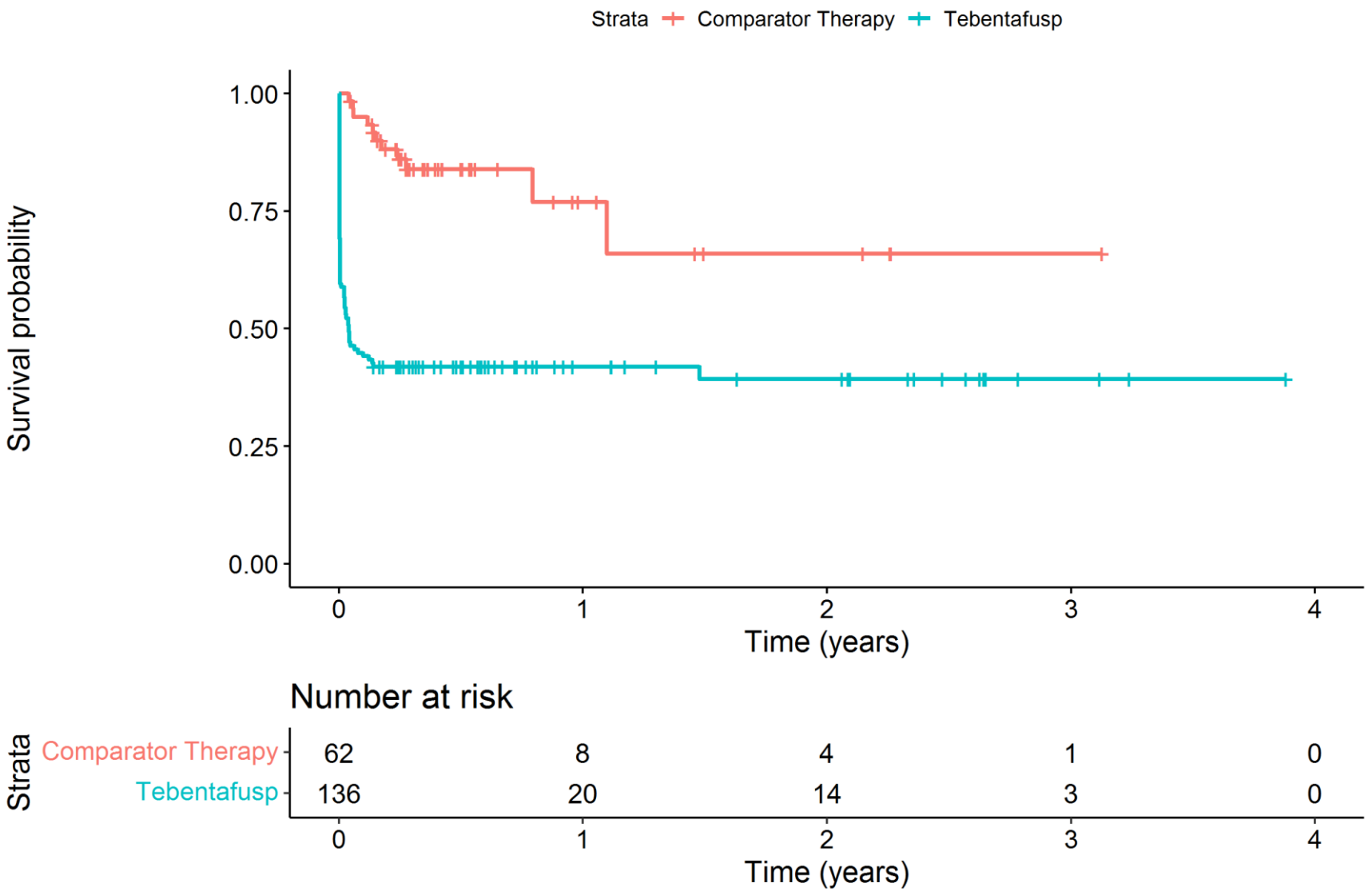
Hautausschlag - Vorherige Therapie adjuvant/neoadjuvant



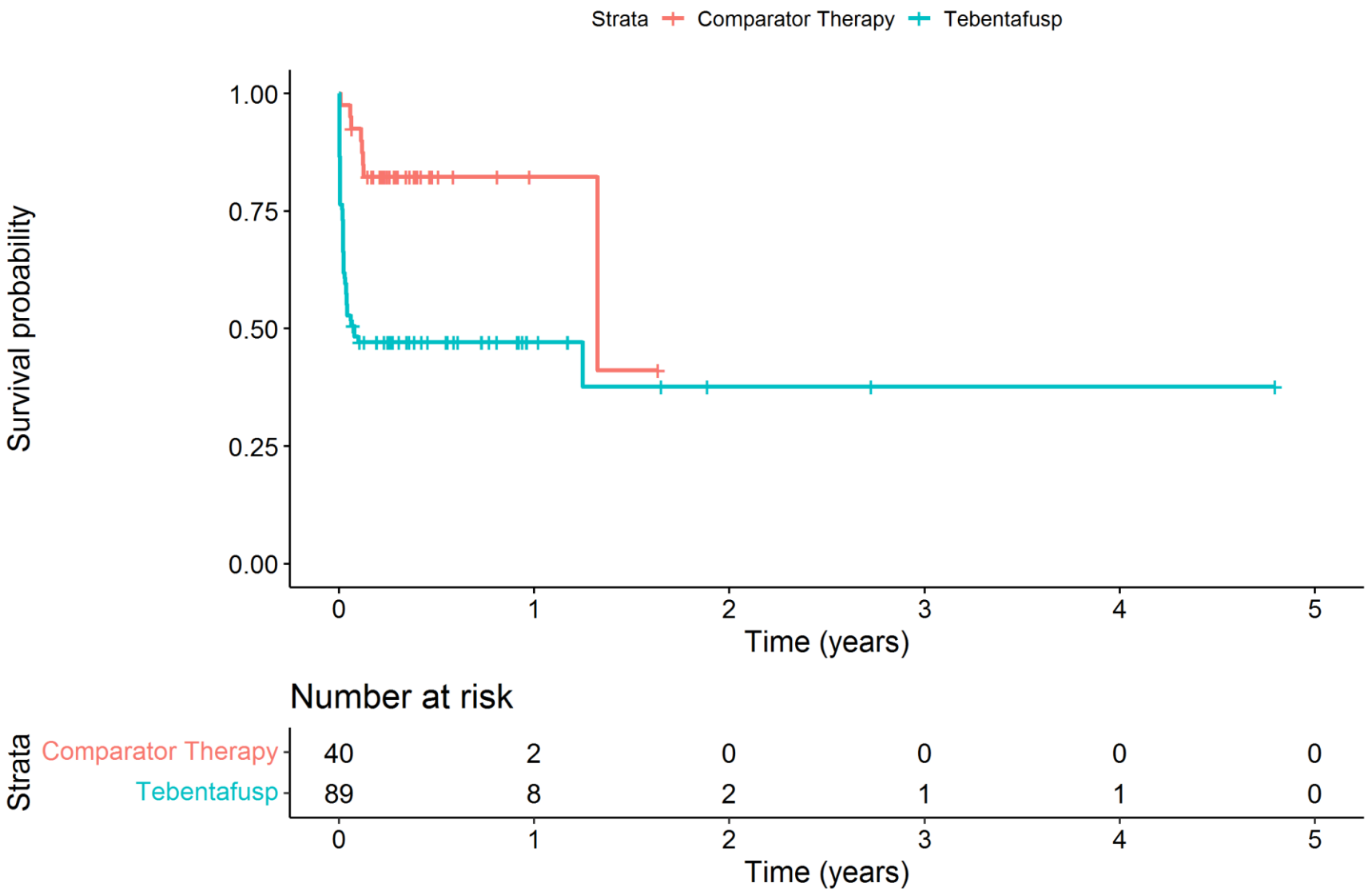
Hautausschlag - Keine Vorherige Therapie adjuvant/neoadjuvant



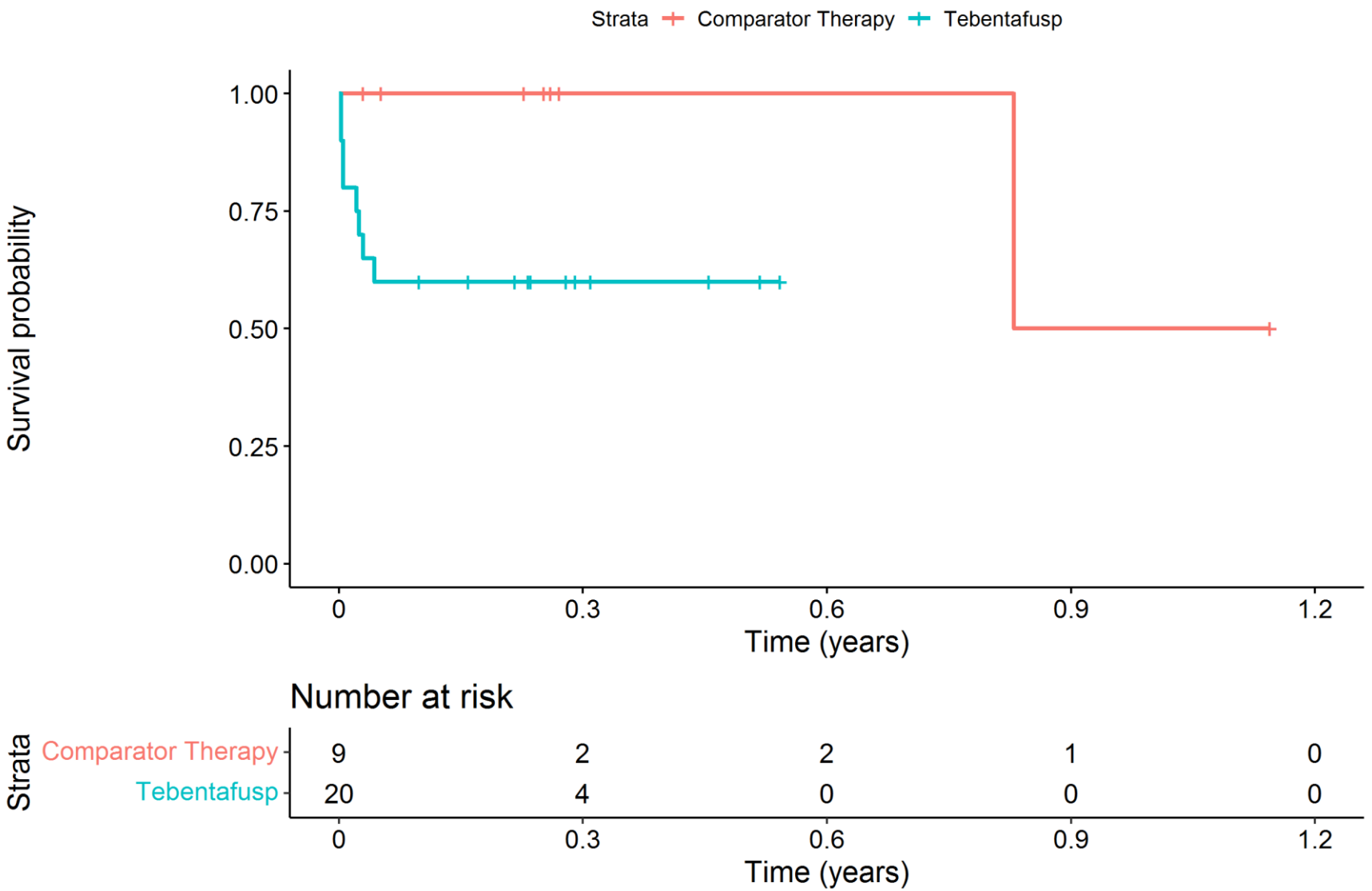
Hautausschlag - Läsion ≤ 3cm



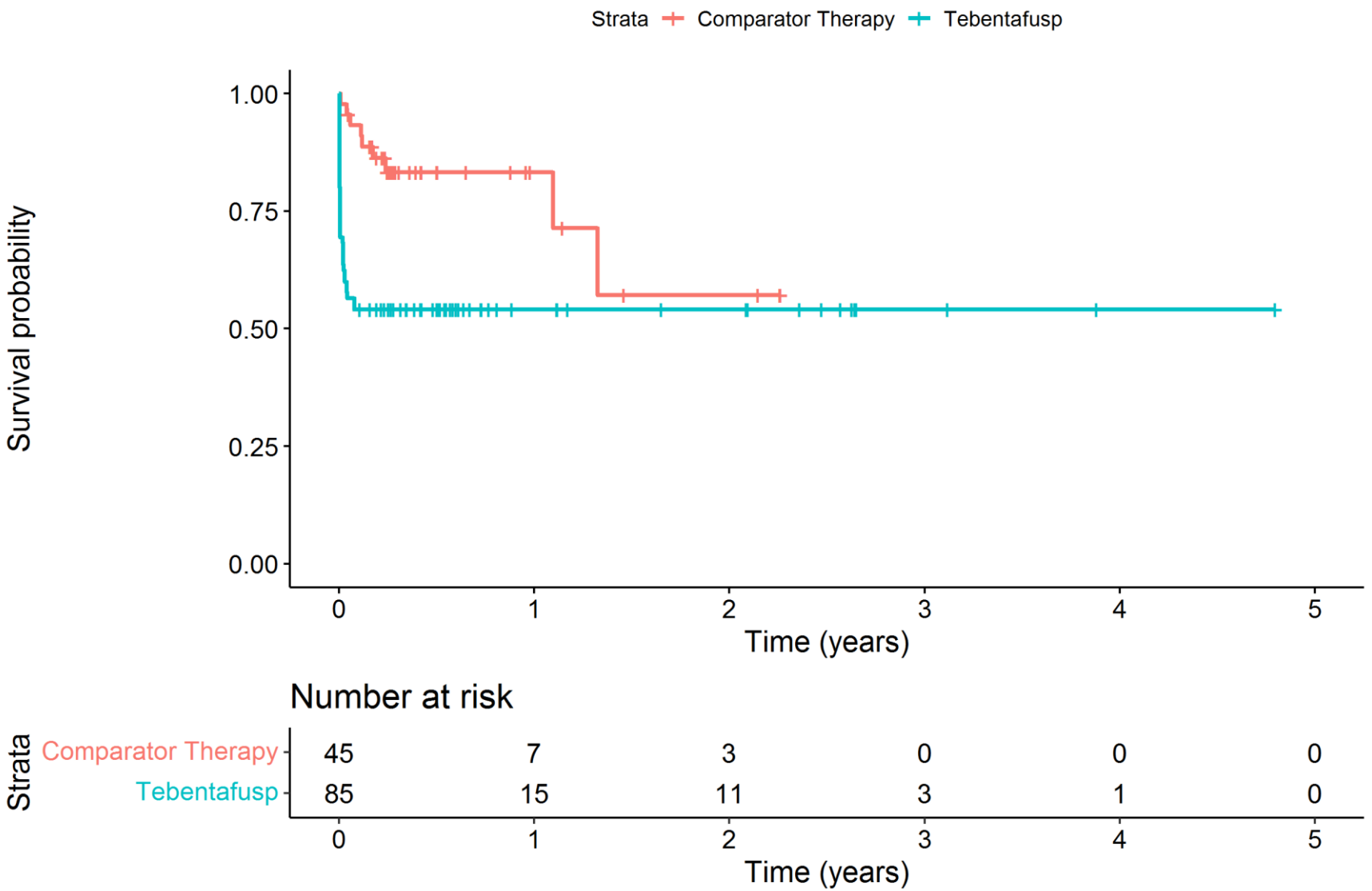
Hautausschlag - Läsion 3,1-8,0 cm



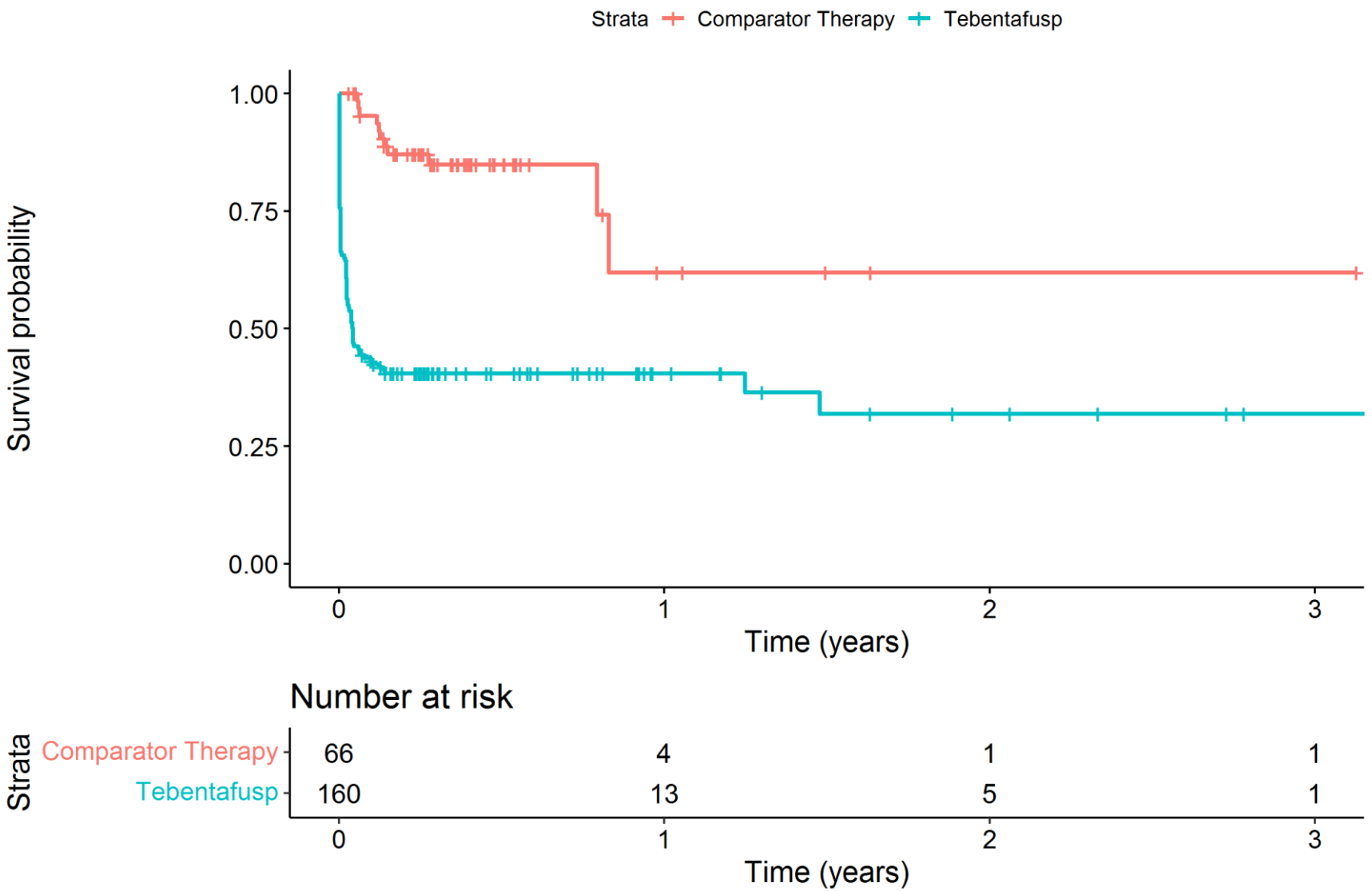
Hautausschlag - Läsion ≥8,1 cm



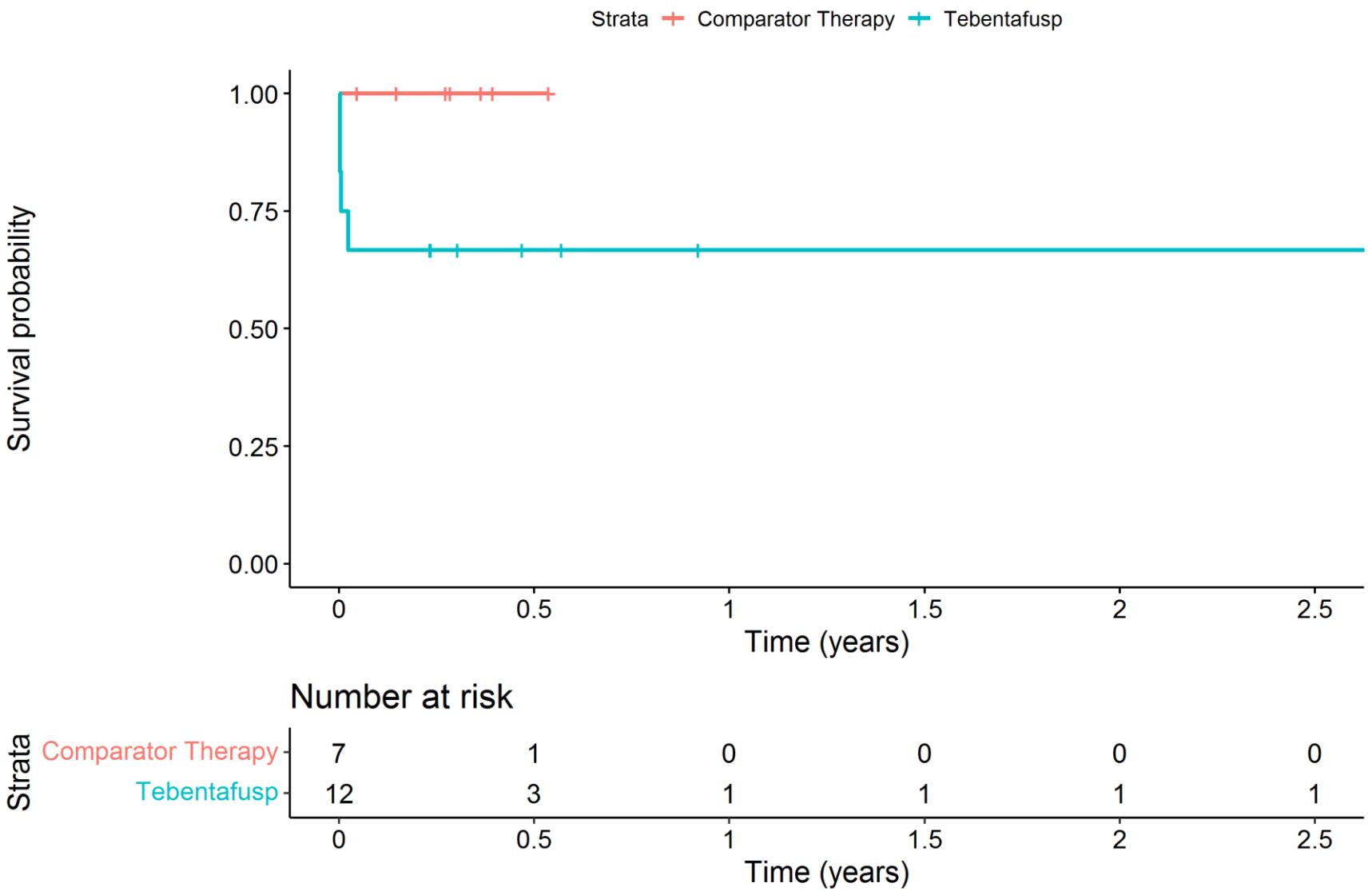
Hautausschlag - Nordamerika



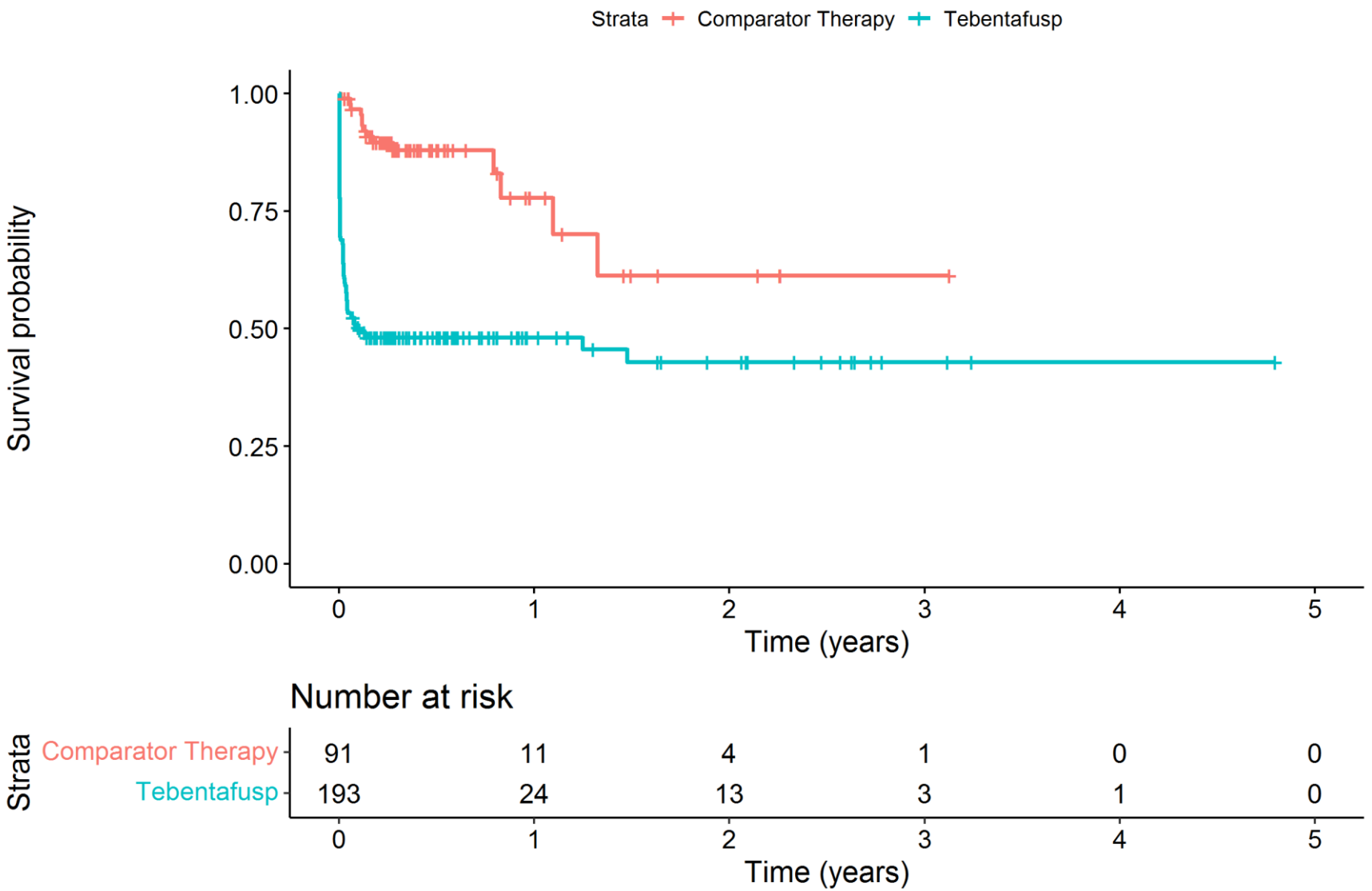
Hautausschlag - Nicht-Nordamerika



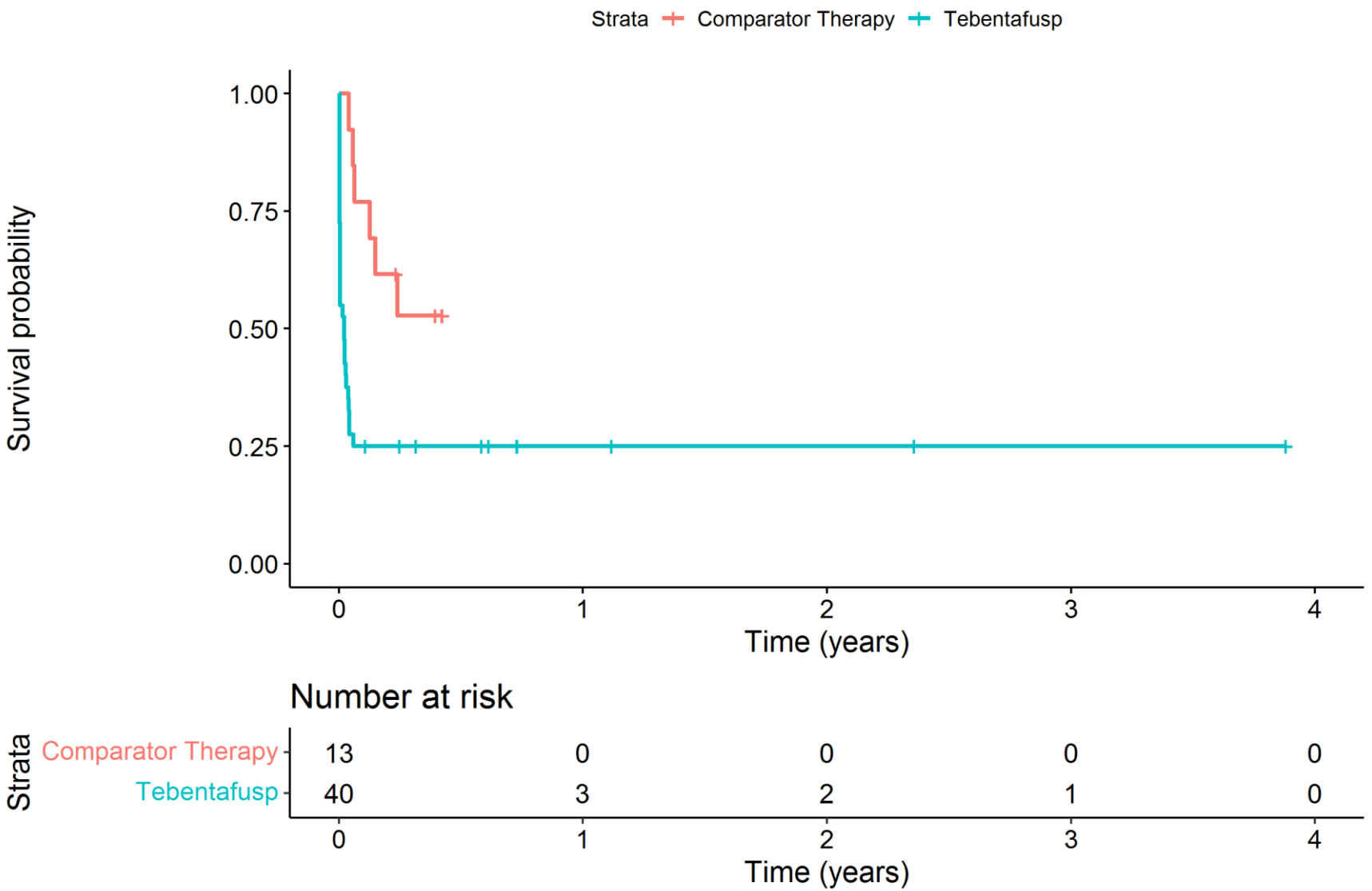
Hautausschlag - Dacarbazin



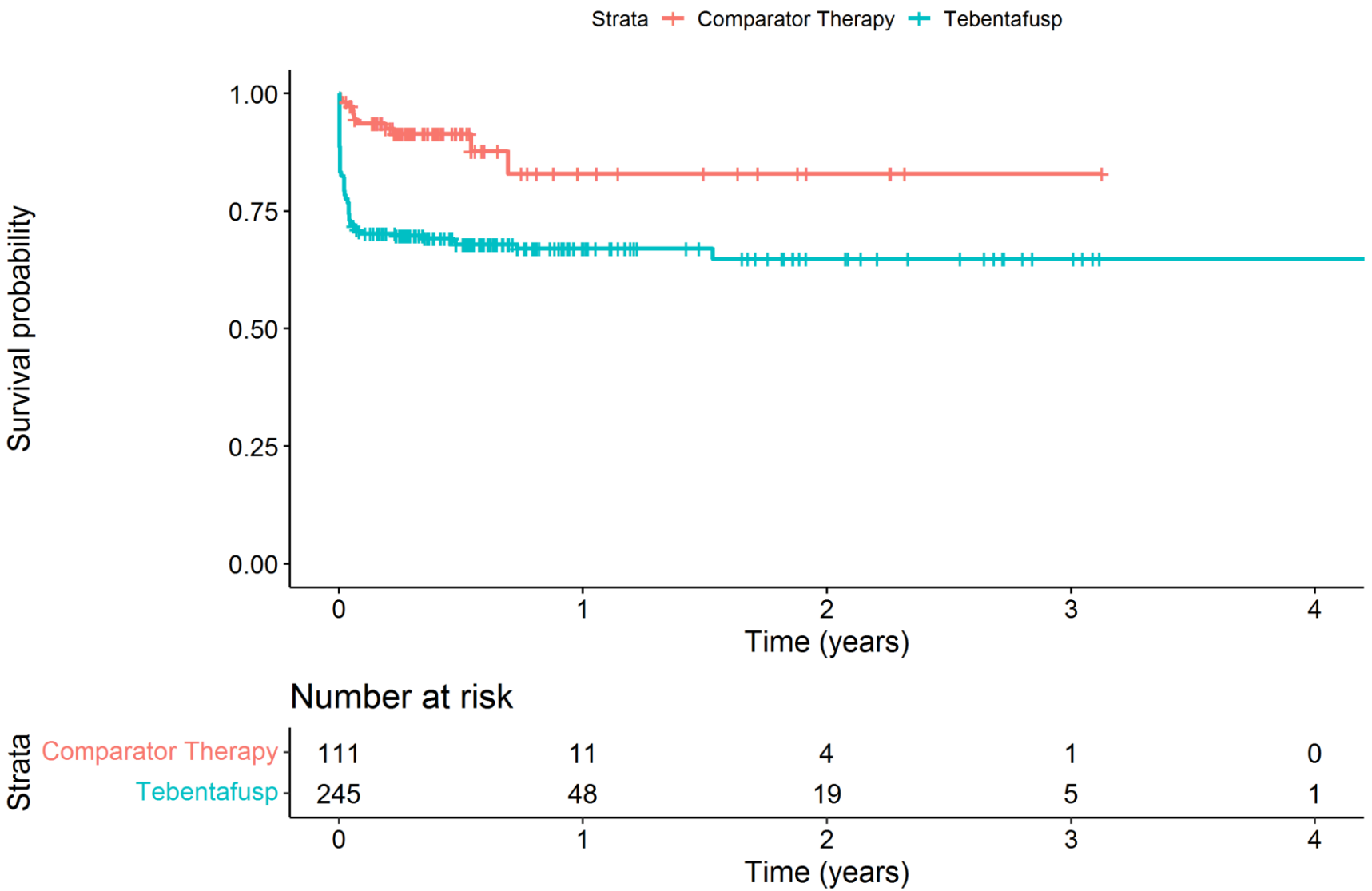
Hautausschlag - Pembrolizumab



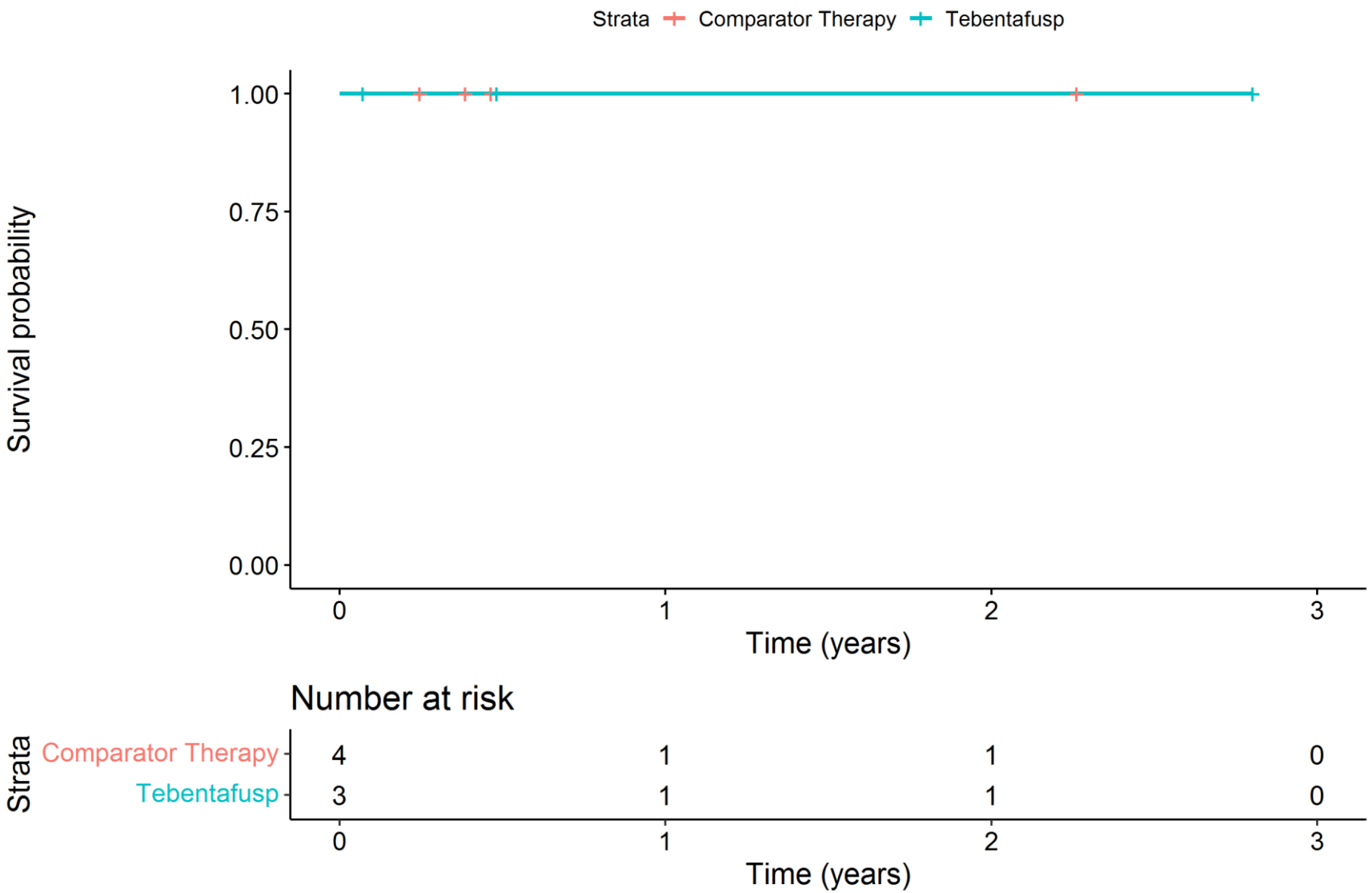
Hautausschlag - Ipilimumab



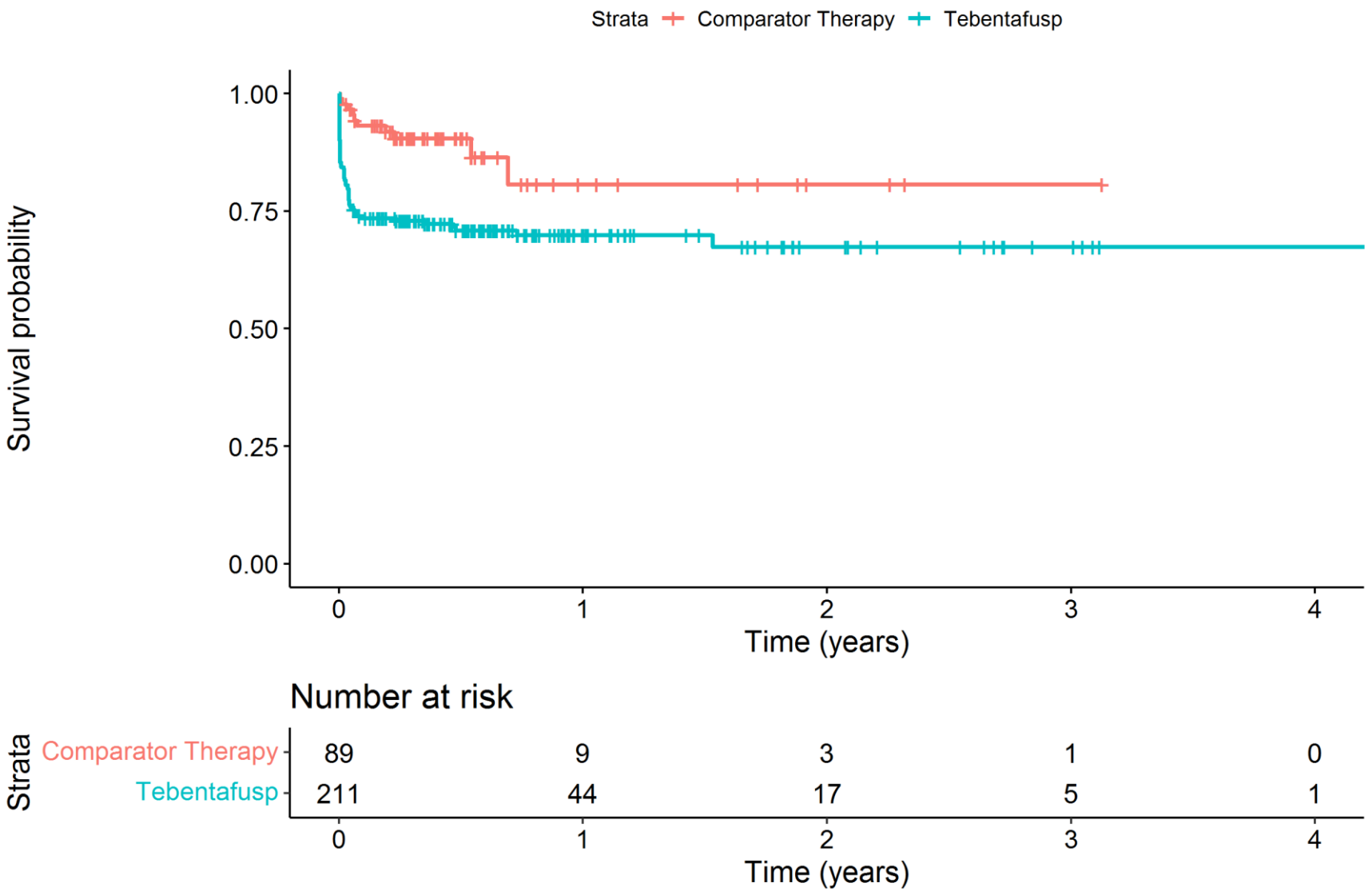
Makulo-papulöser Hautausschlag- Gesamt



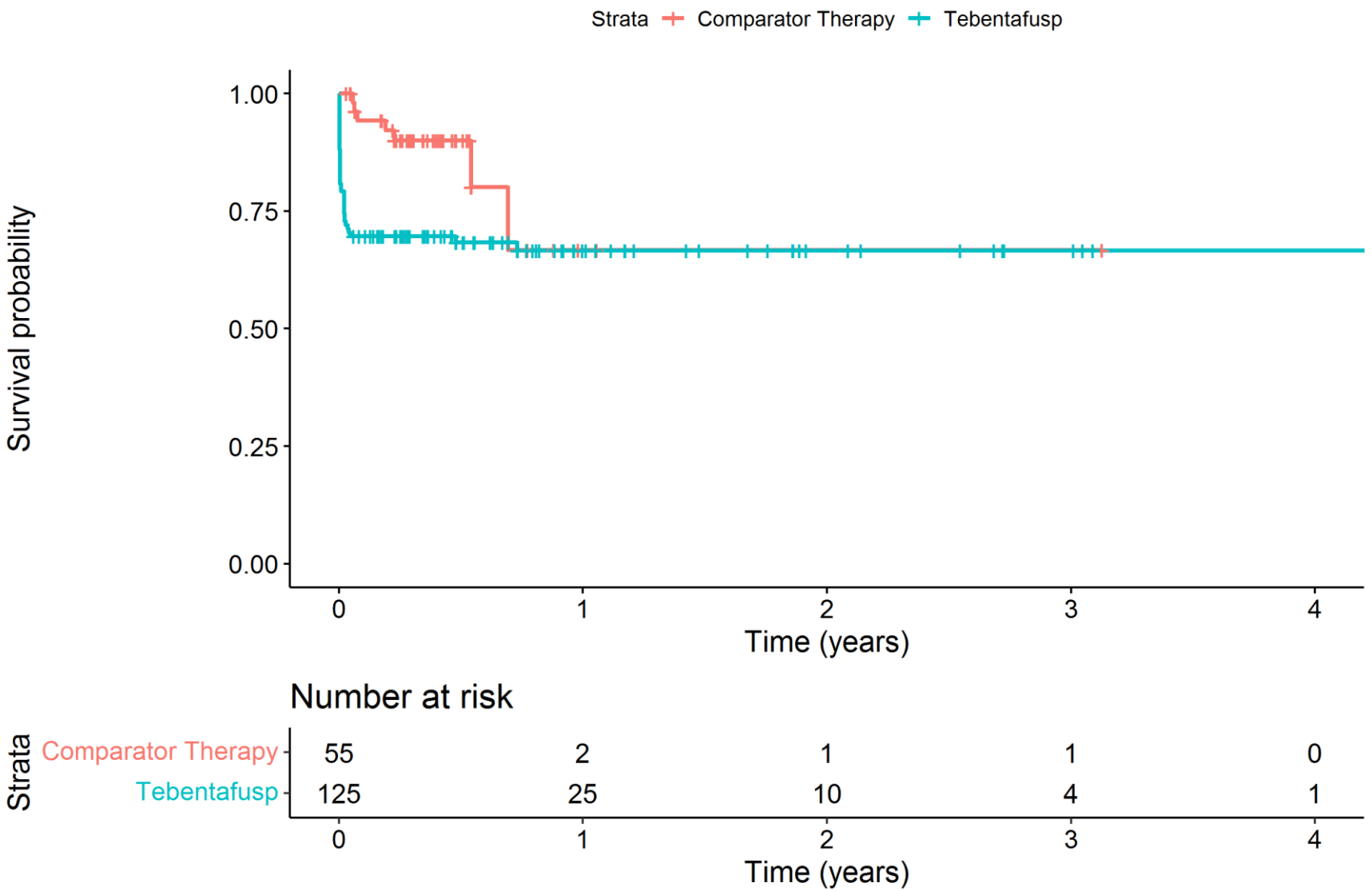
Makulo-papulöser Hautausschlag- Hispanisch



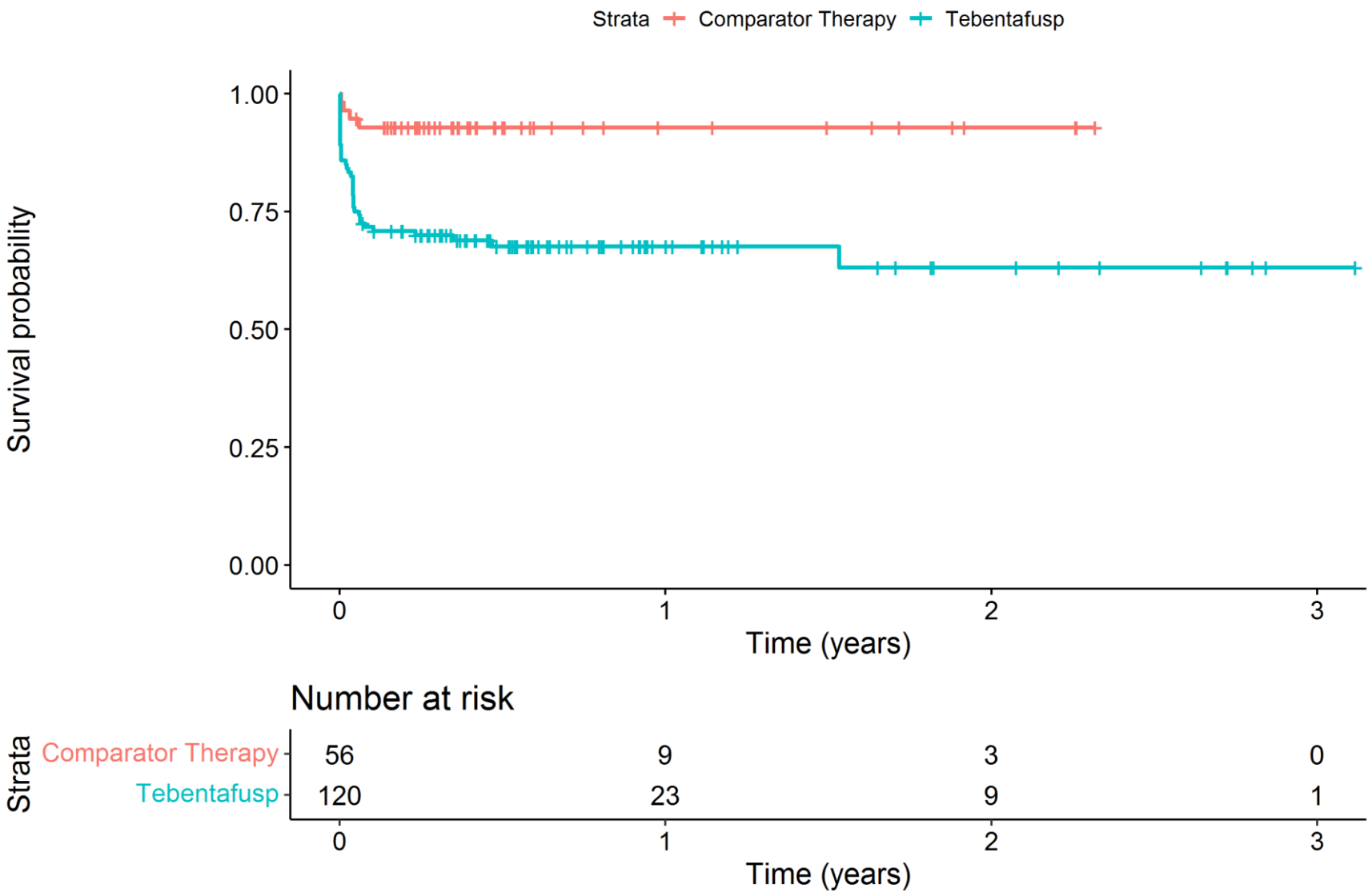
Makulo-papulöser Hautausschlag- Nicht-hispanisch



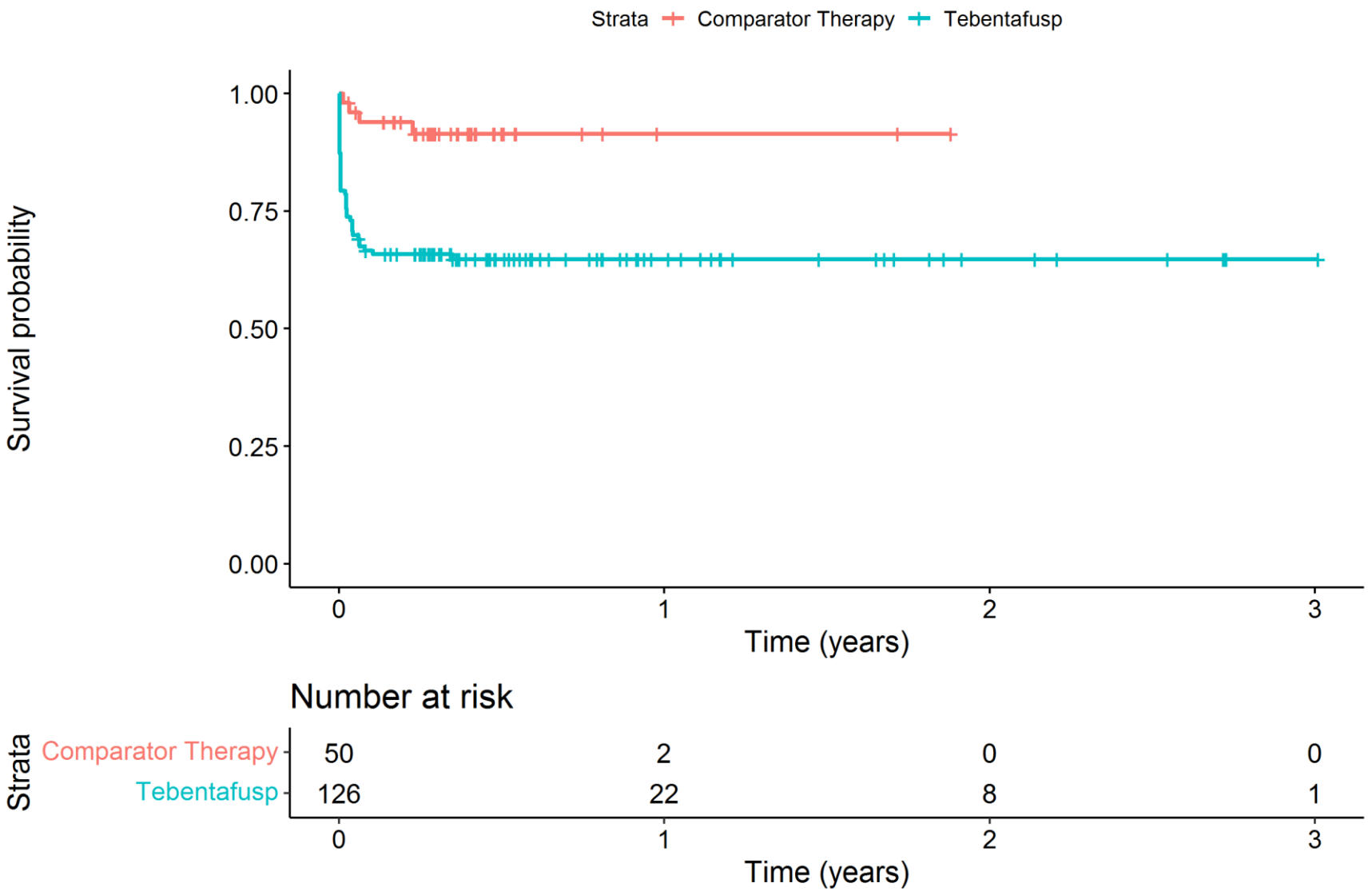
Makulo-papulöser Hautausschlag- Männlich



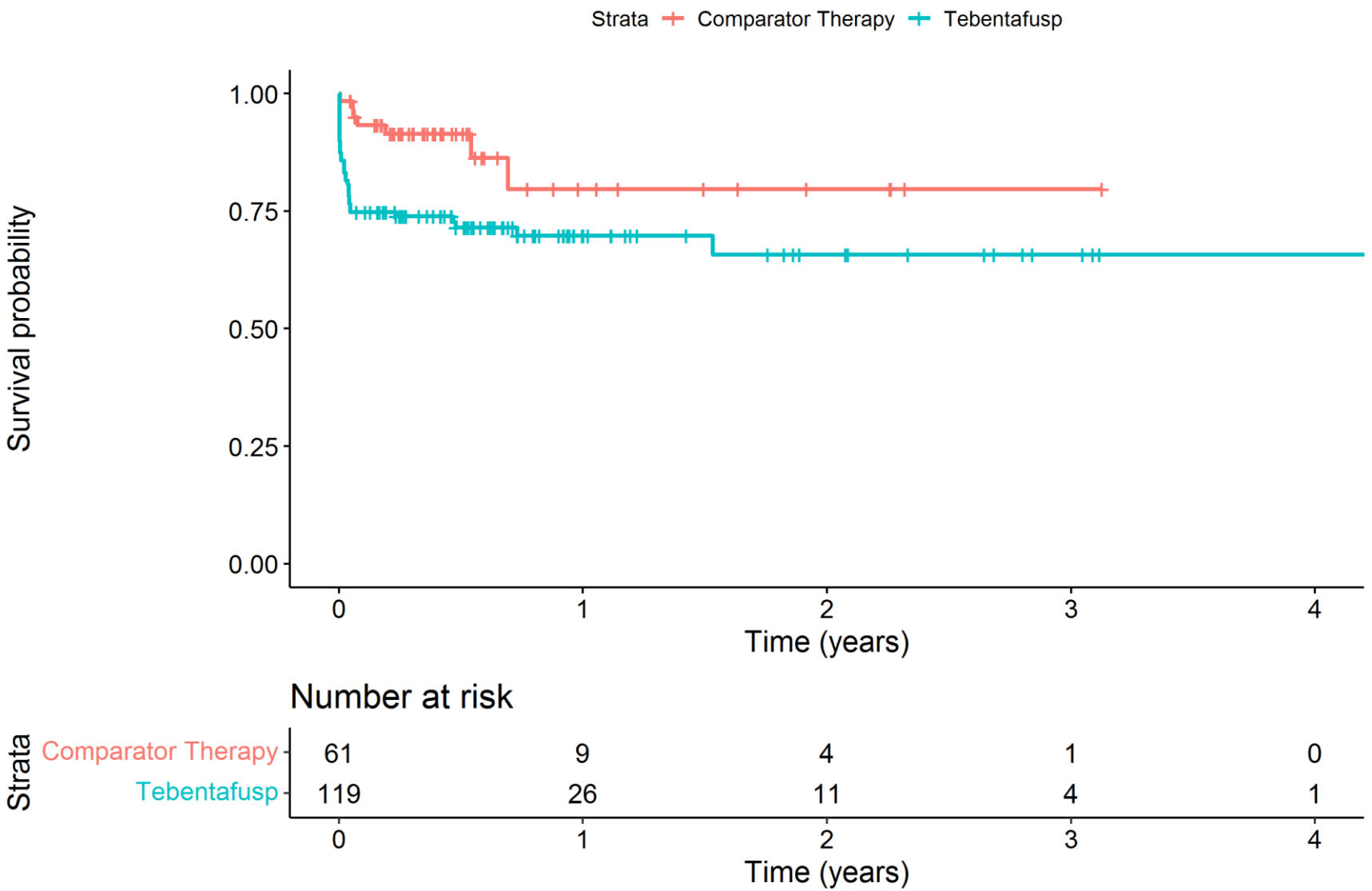
Makulo-papulöser Hautausschlag- Weiblich



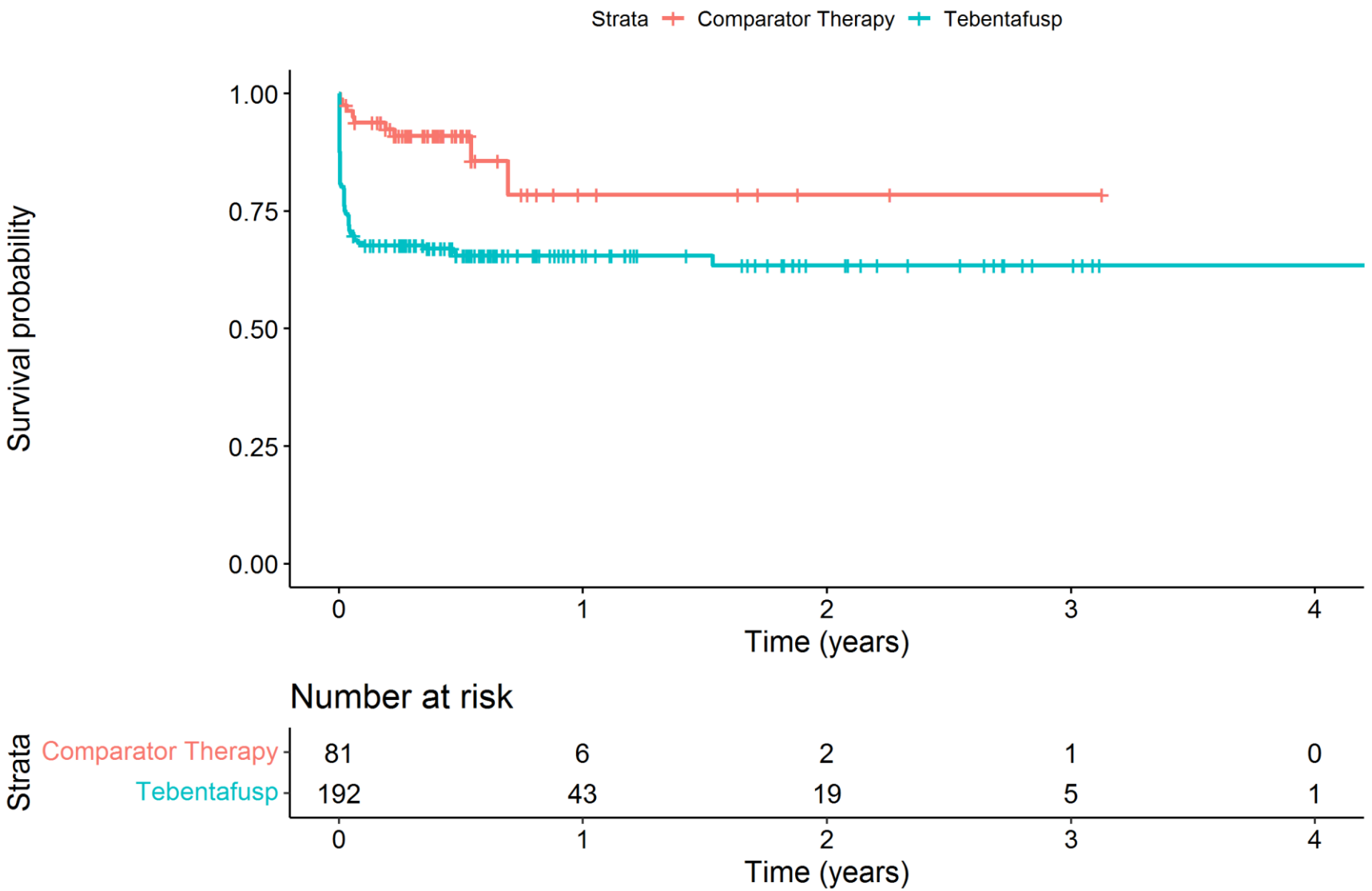
Makulo-papulöser Hautausschlag- <65



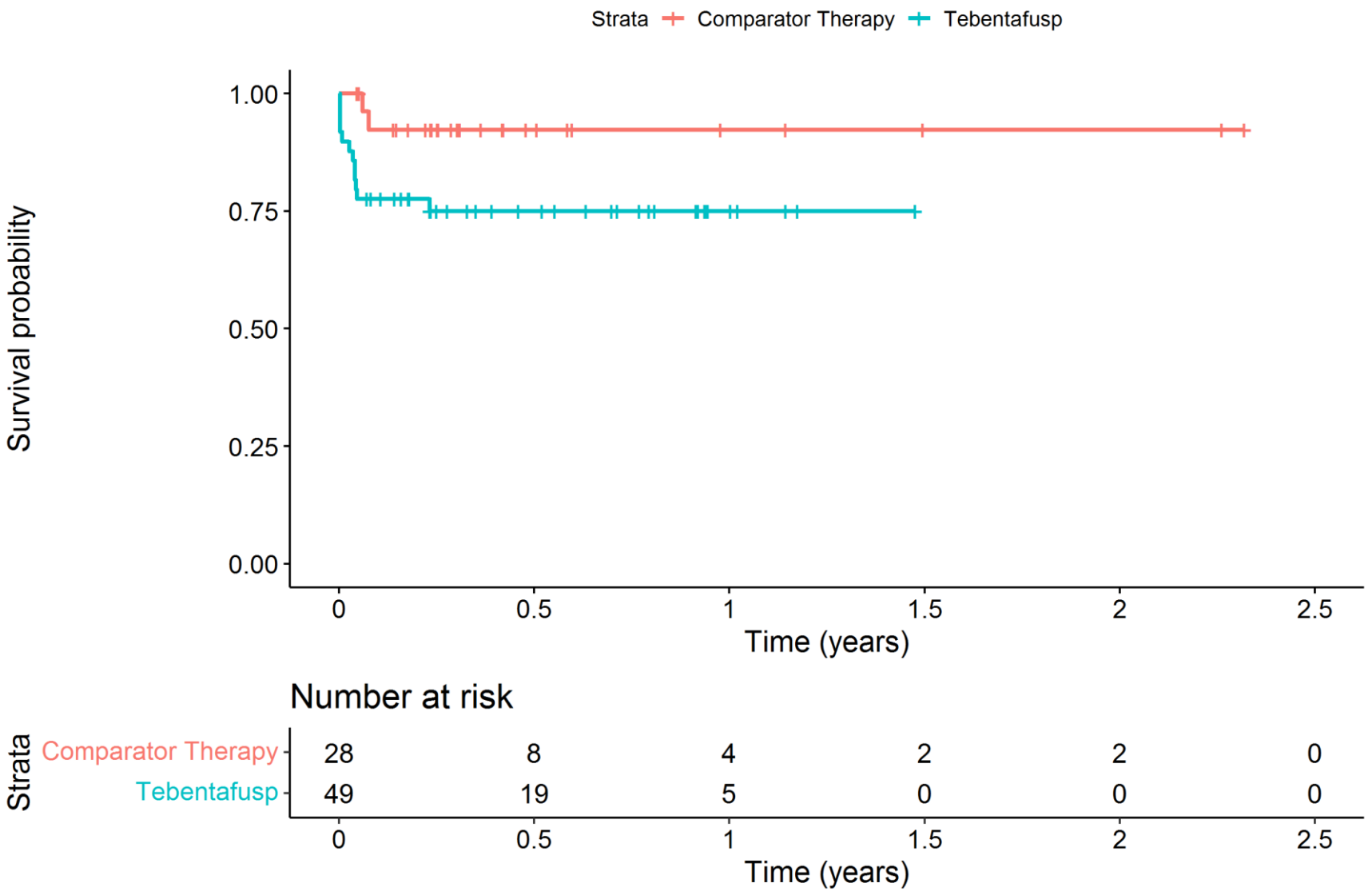
Makulo-papulöser Hautausschlag- ≥65



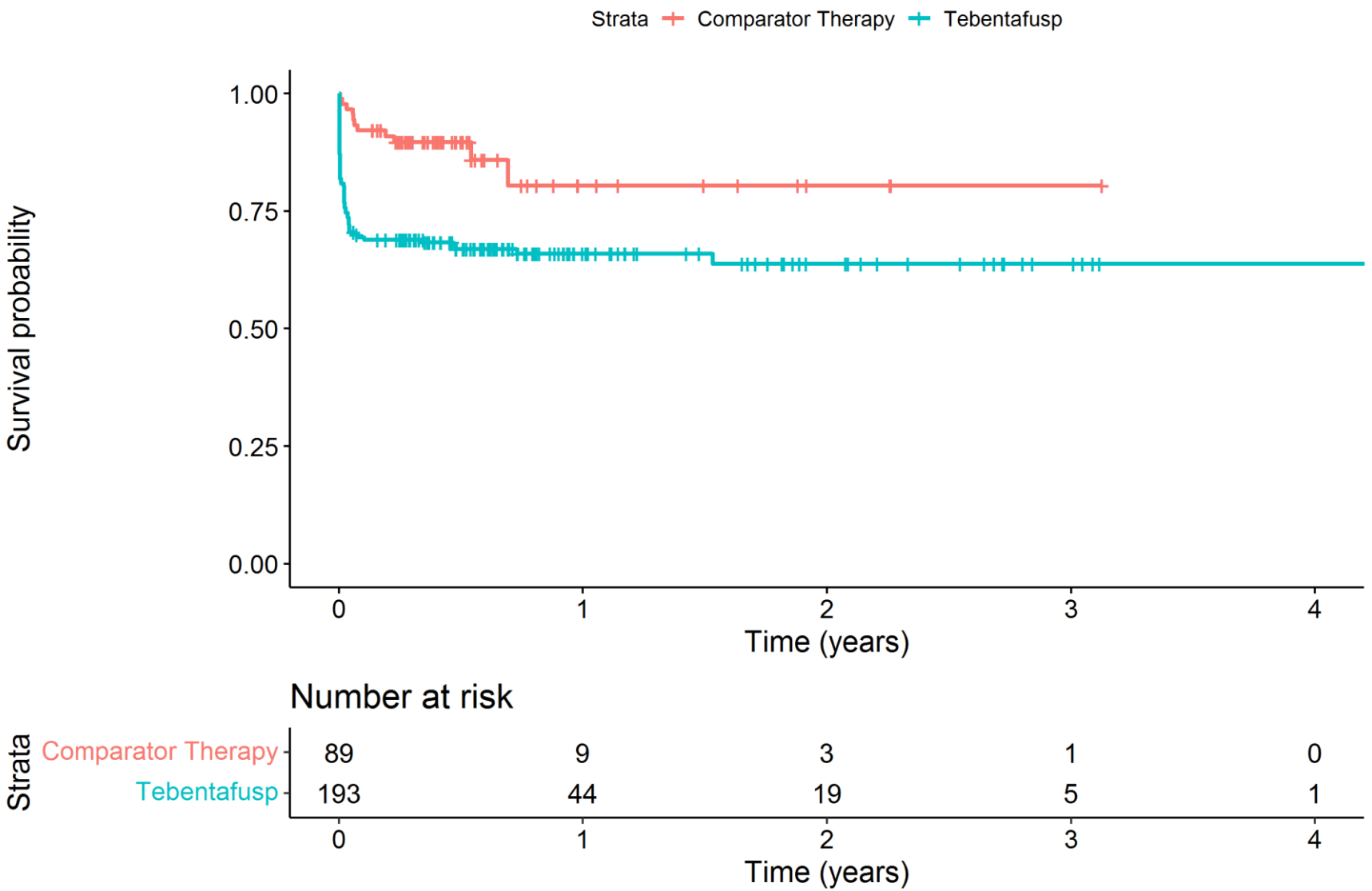
Makulo-papulöser Hautausschlag- ECOG 0



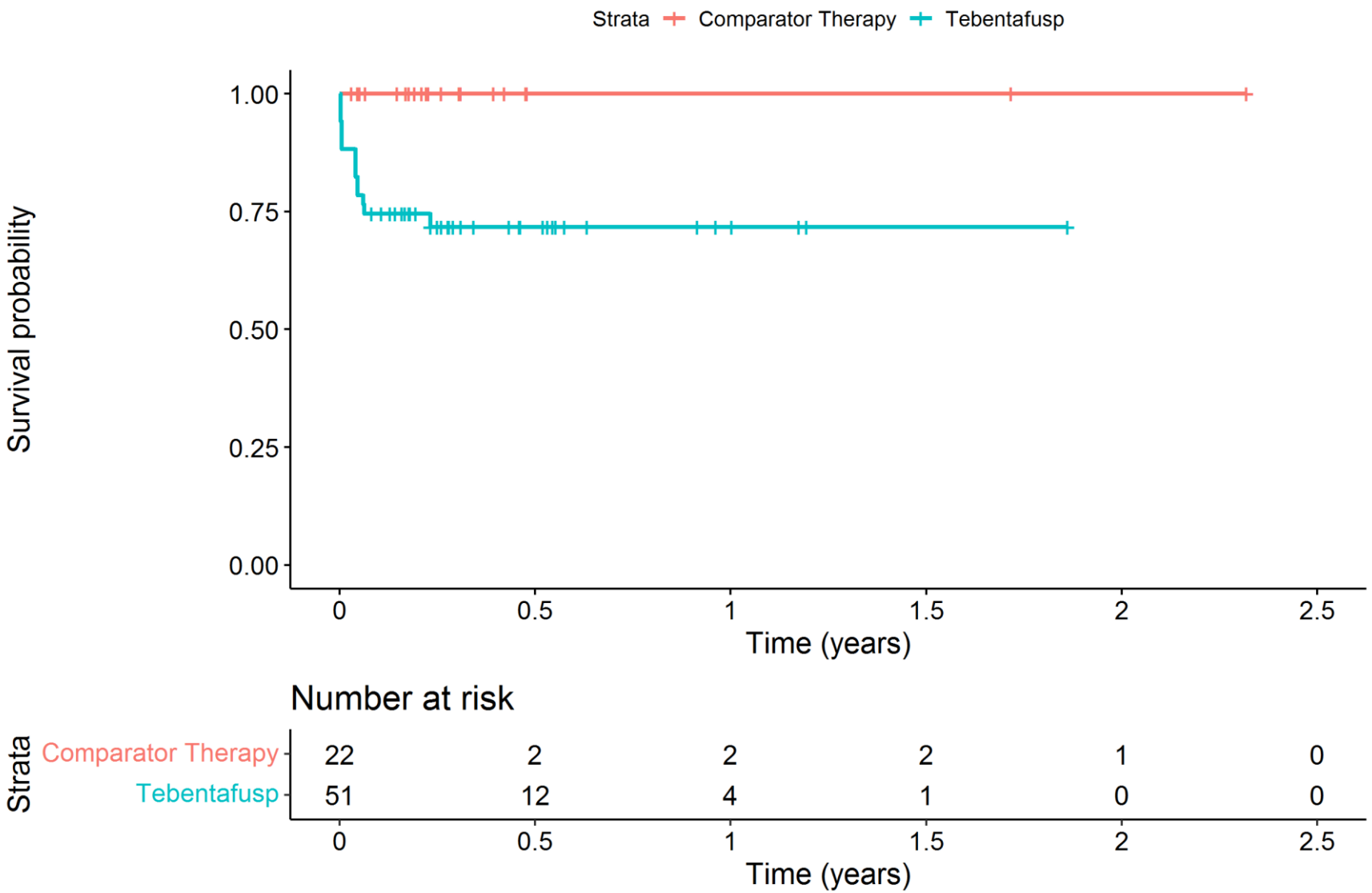
Makulo-papulöser Hautausschlag- ECOG 1



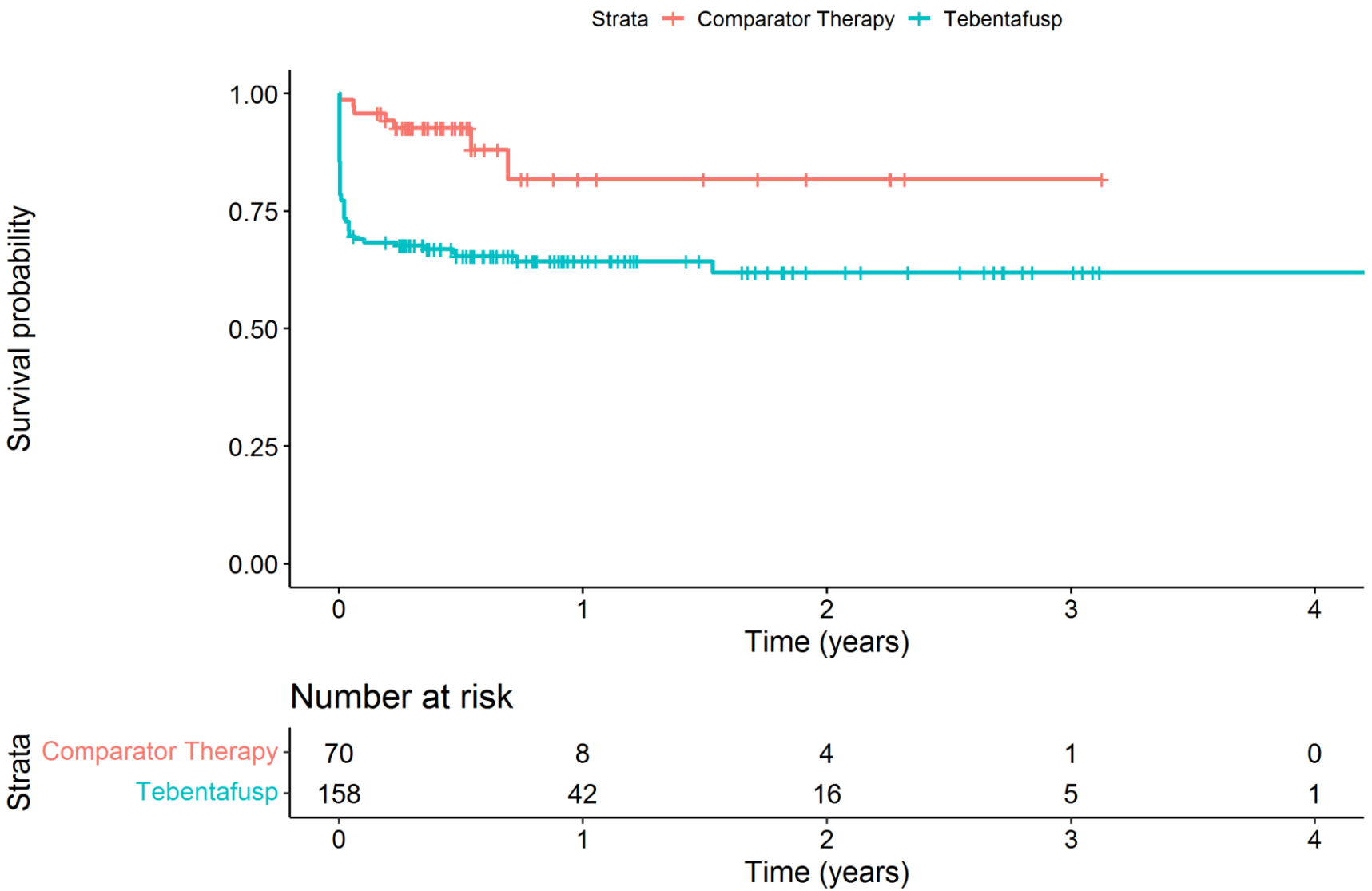
Makulo-papulöser Hautausschlag- ALP ≤ ULN



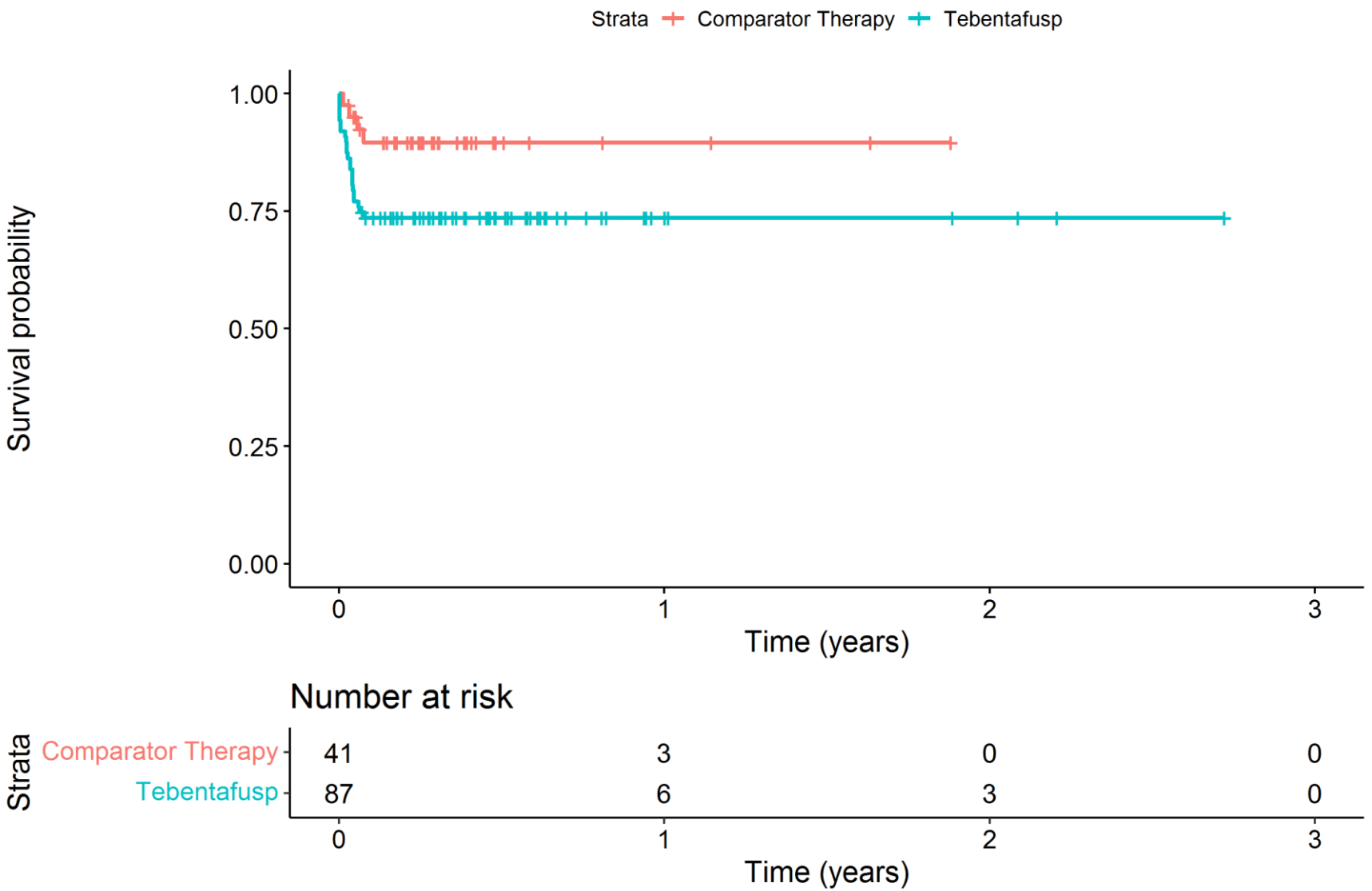
Makulo-papulöser Hautausschlag- ALP > ULN



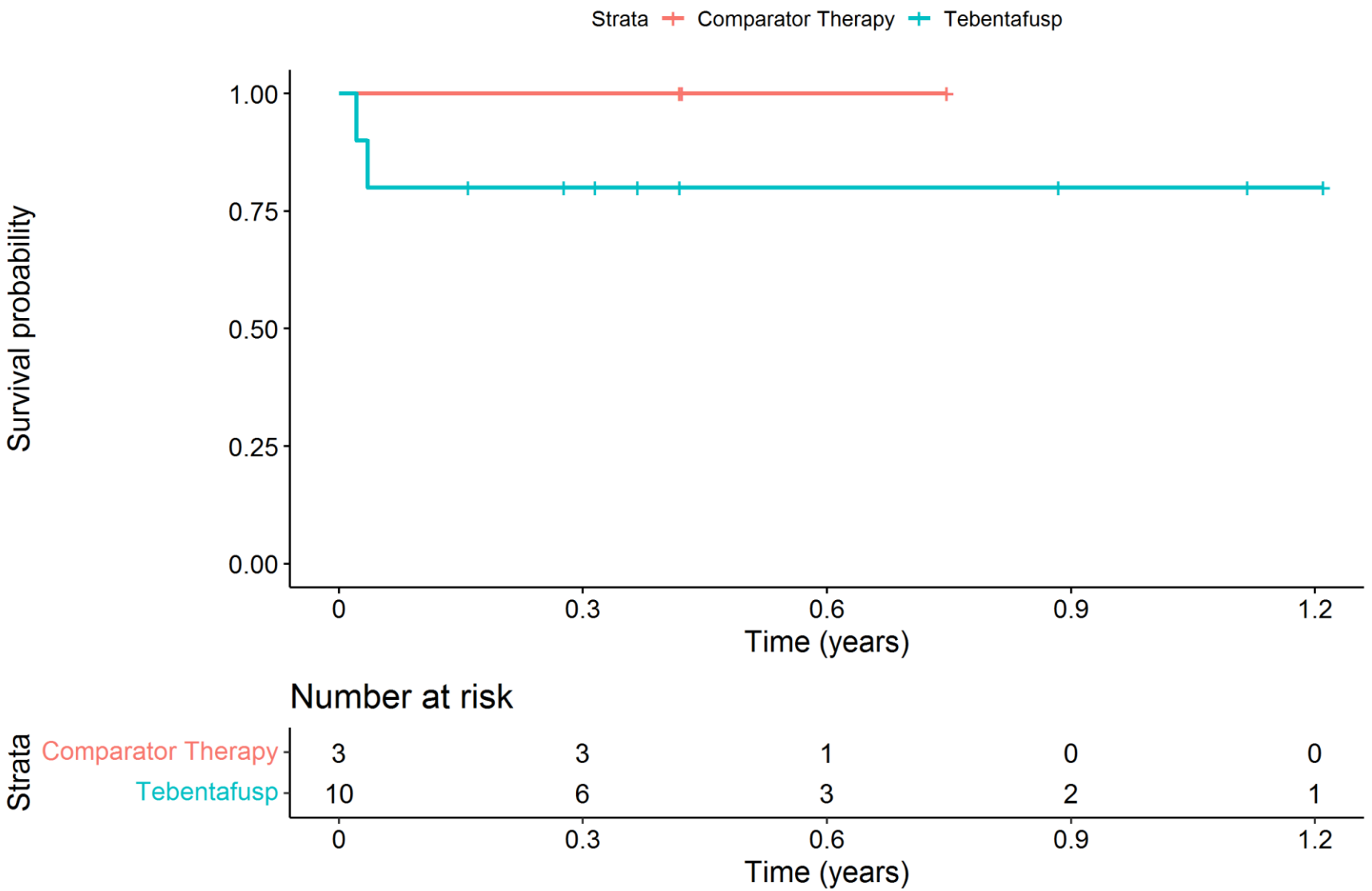
Makulo-papulöser Hautausschlag- LDH =< ULN



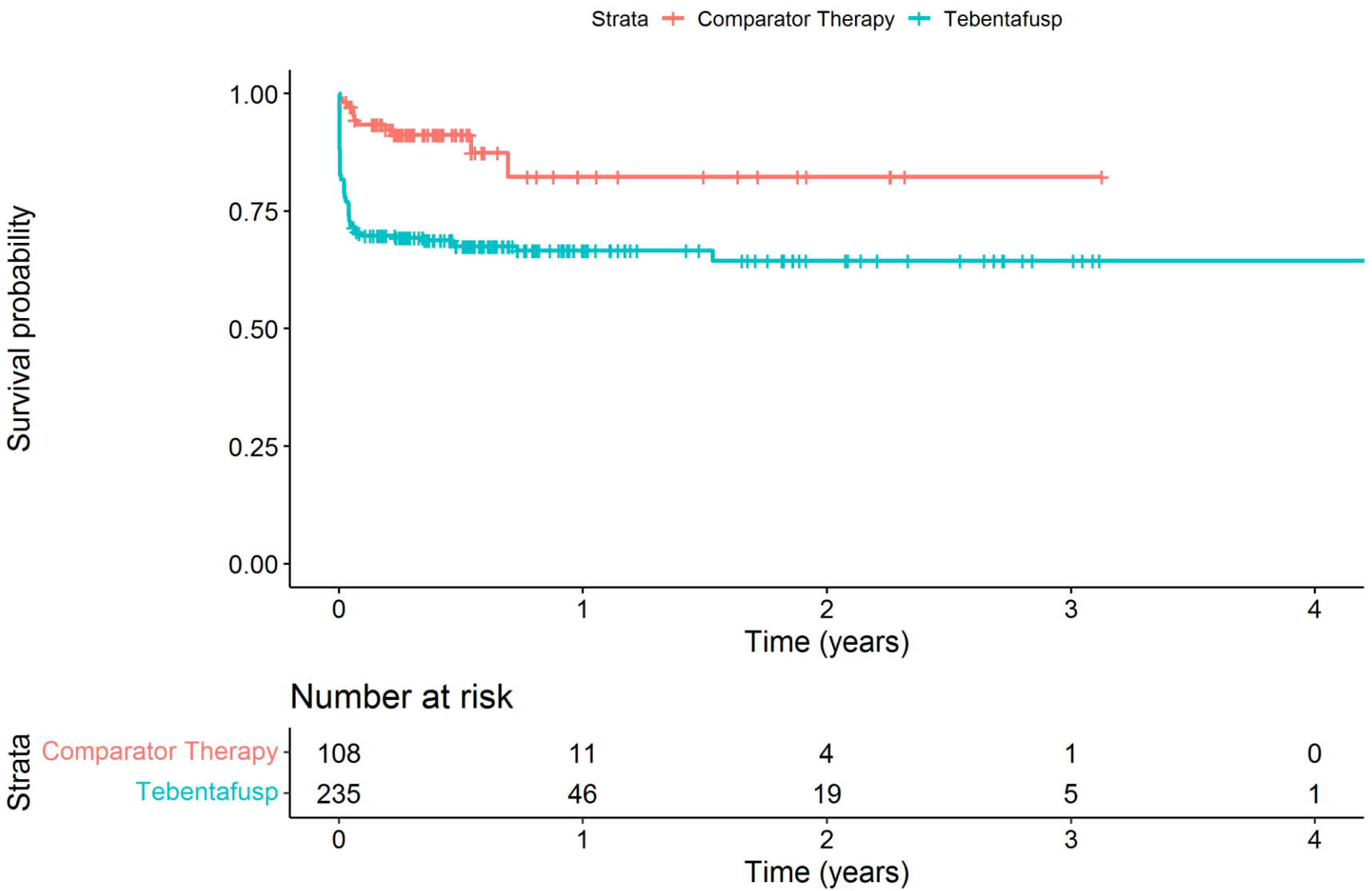
Makulo-papulöser Hautausschlag- LDH > ULN



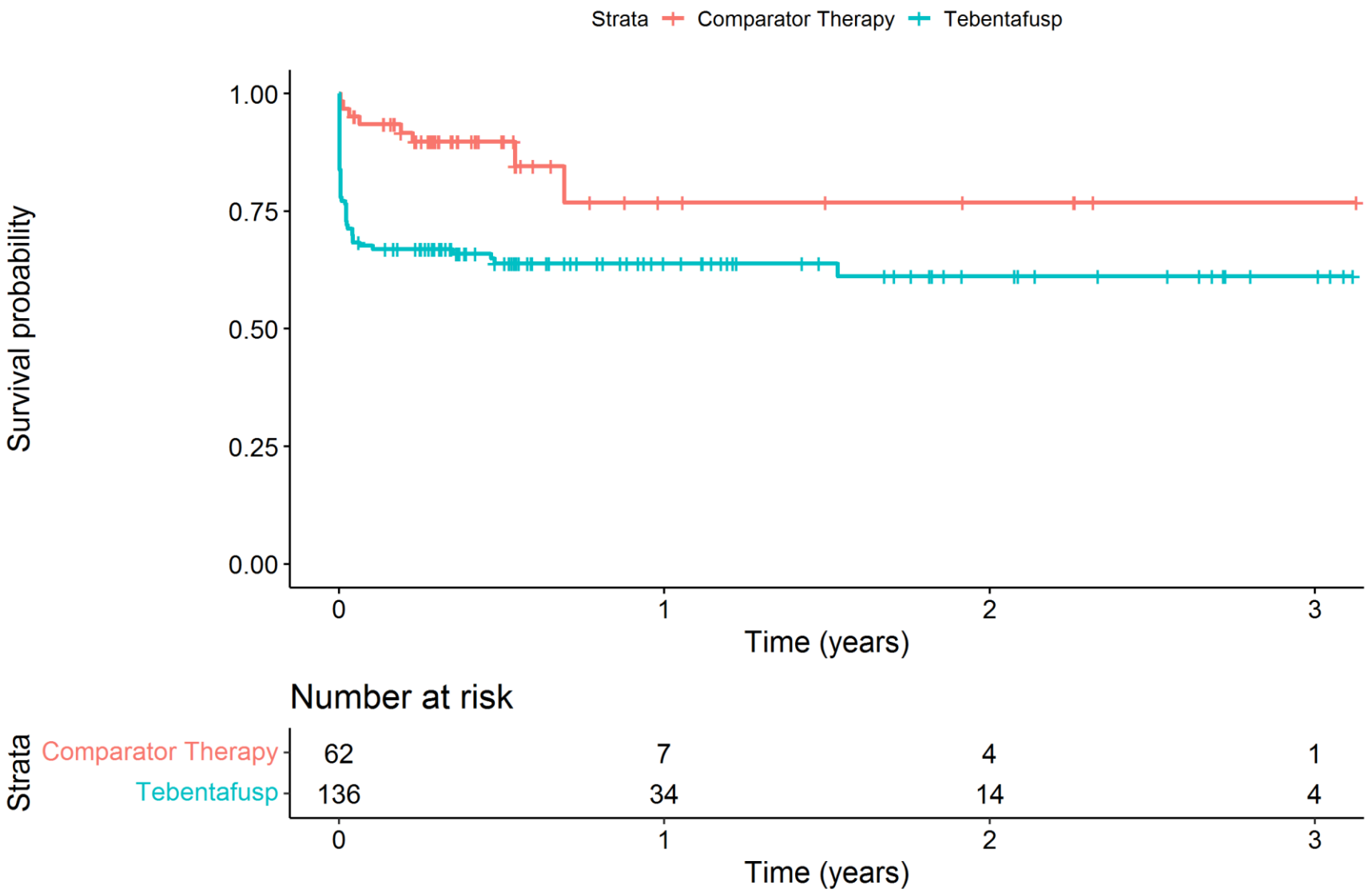
Makulo-papulöser Hautausschlag- Vorherige Therapie adjuvant/neoadjuvant



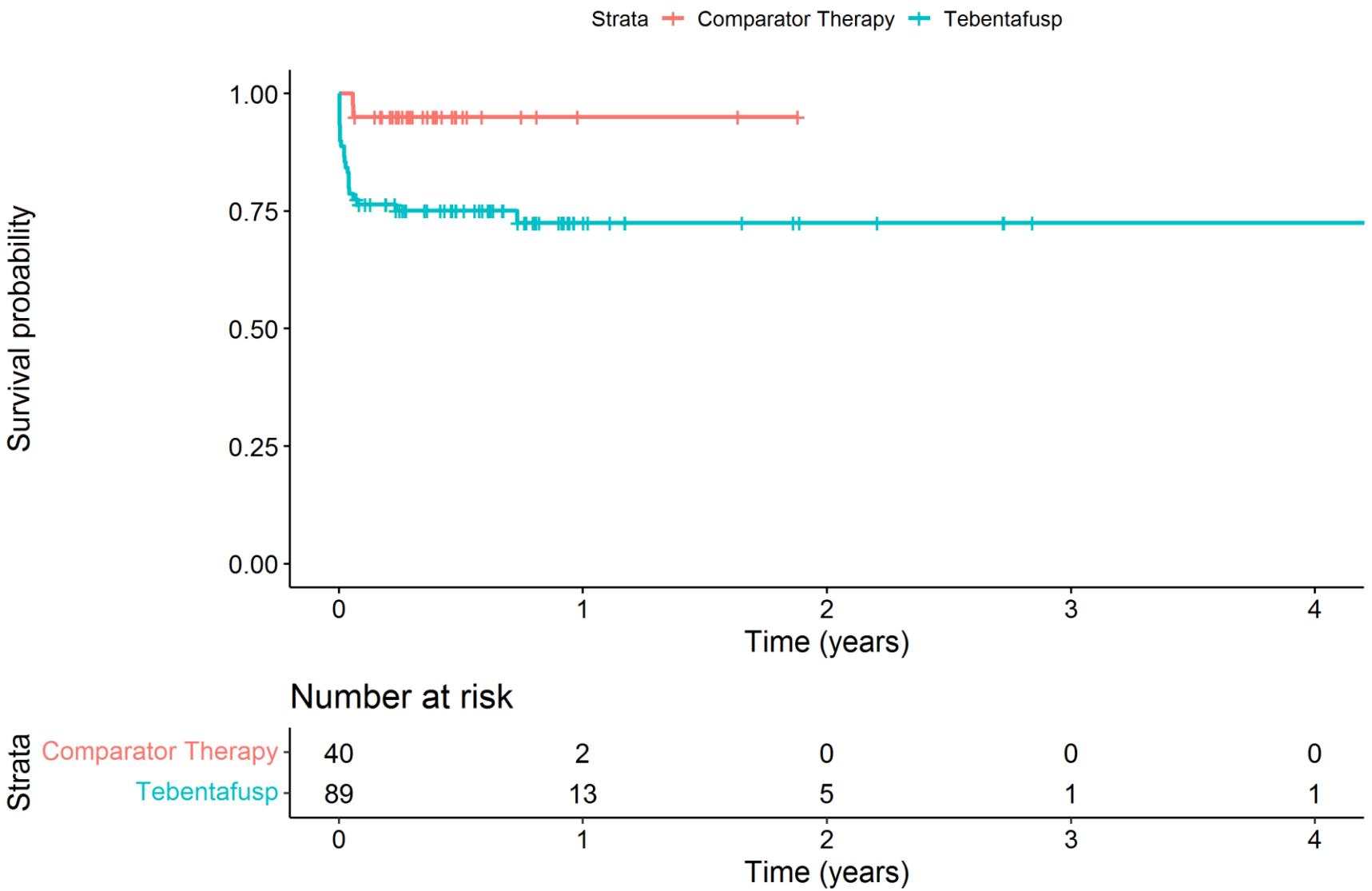
Makulo-papulöser Hautausschlag- Keine Vorherige Therapie adjuvant/neoadjuvant



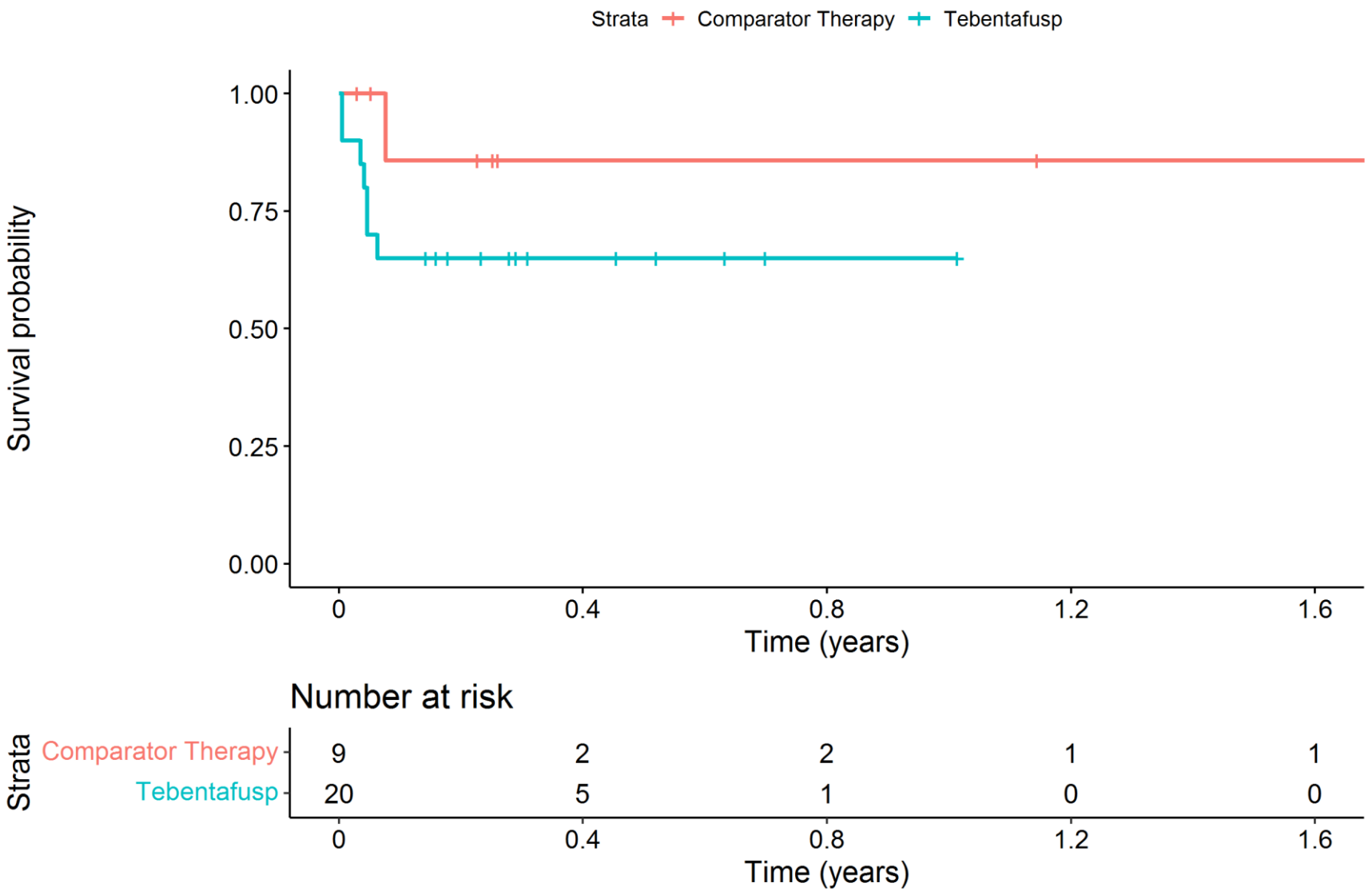
Makulo-papulöser Hautausschlag- Läsion ≤ 3cm



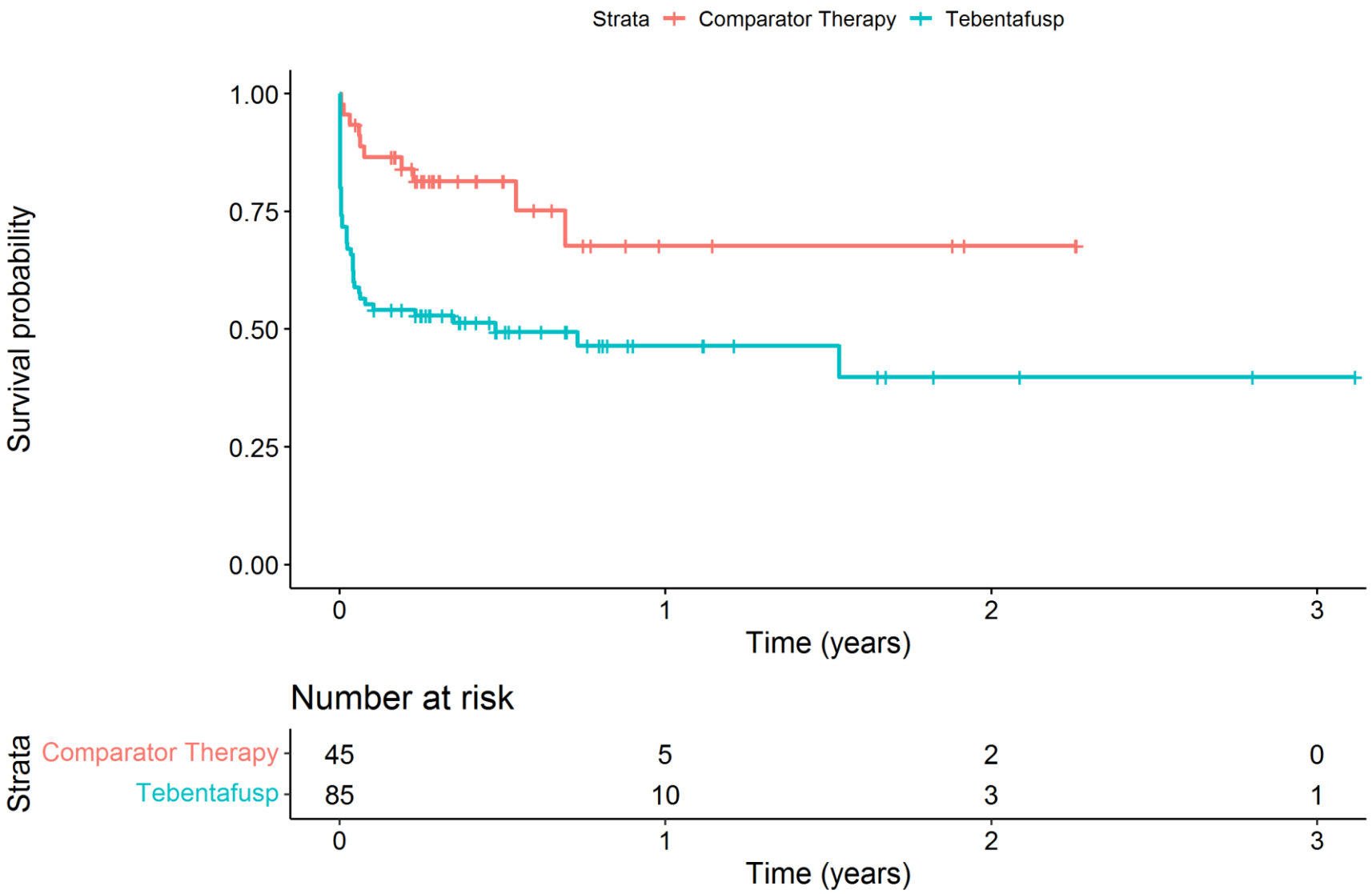
Makulo-papulöser Hautausschlag- Läsion 3,1-8,0 cm



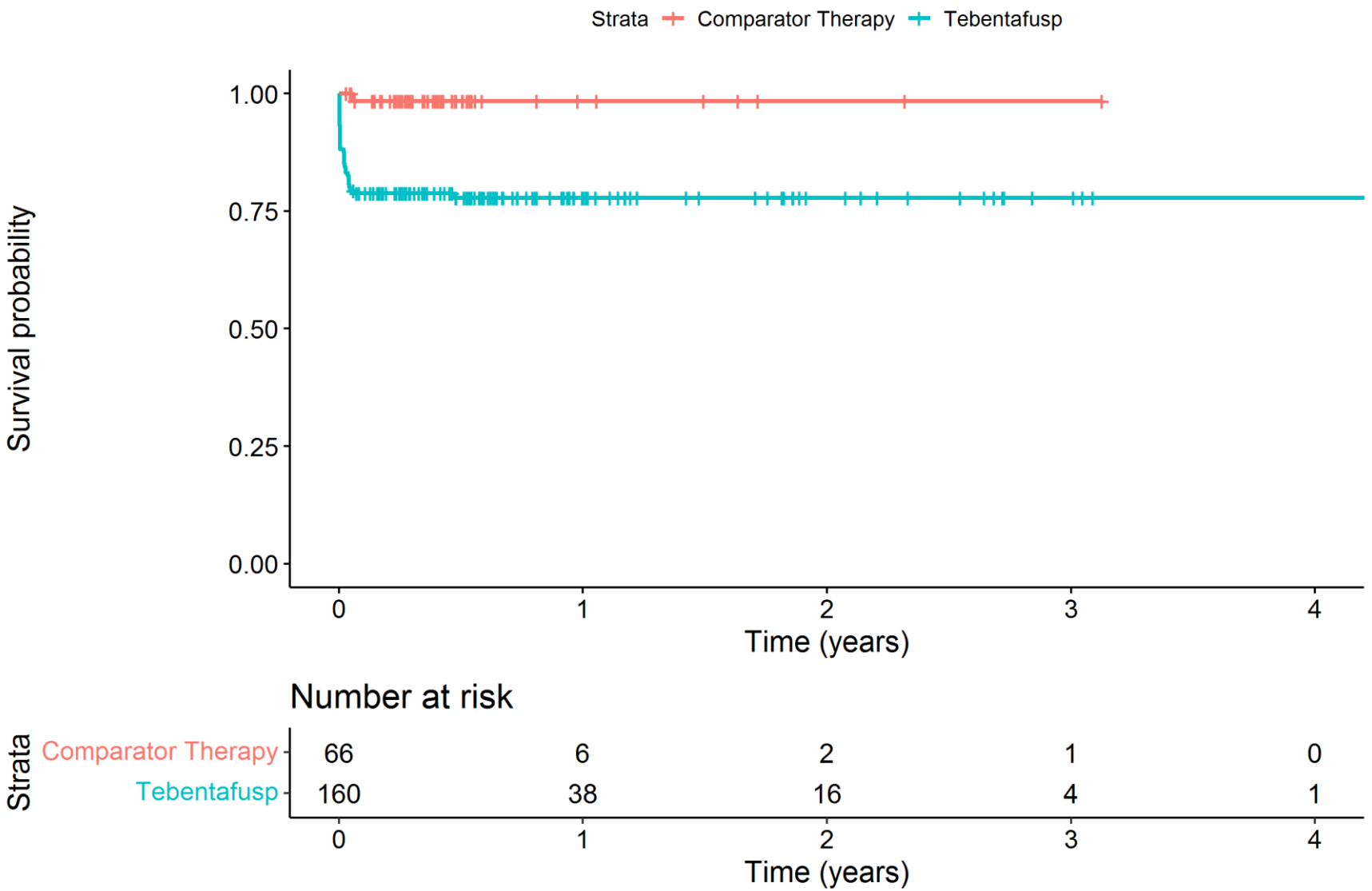
Makulo-papulöser Hautausschlag- Läsion ≥8,1 cm



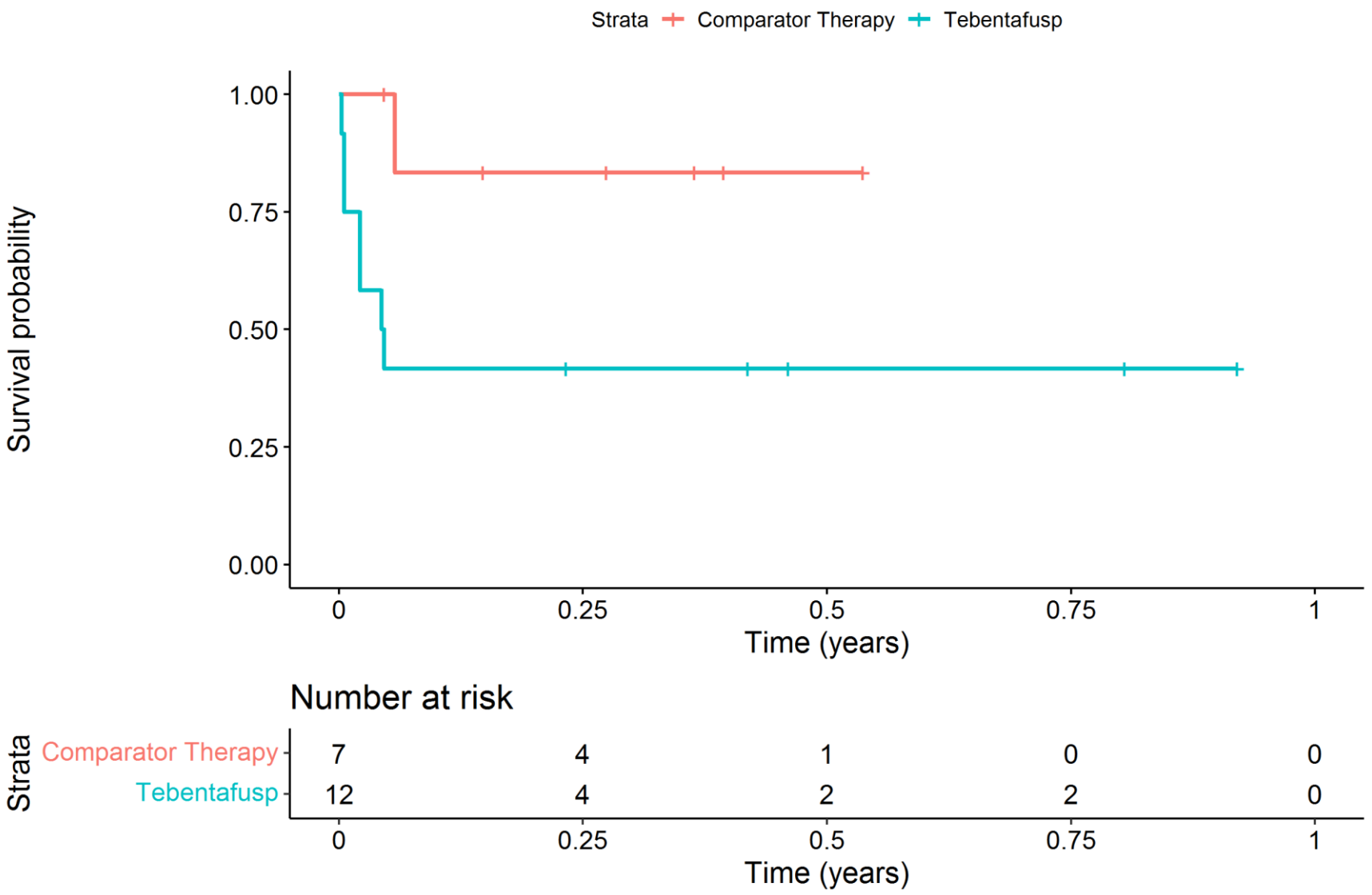
Makulo-papulöser Hautausschlag- Nordamerika



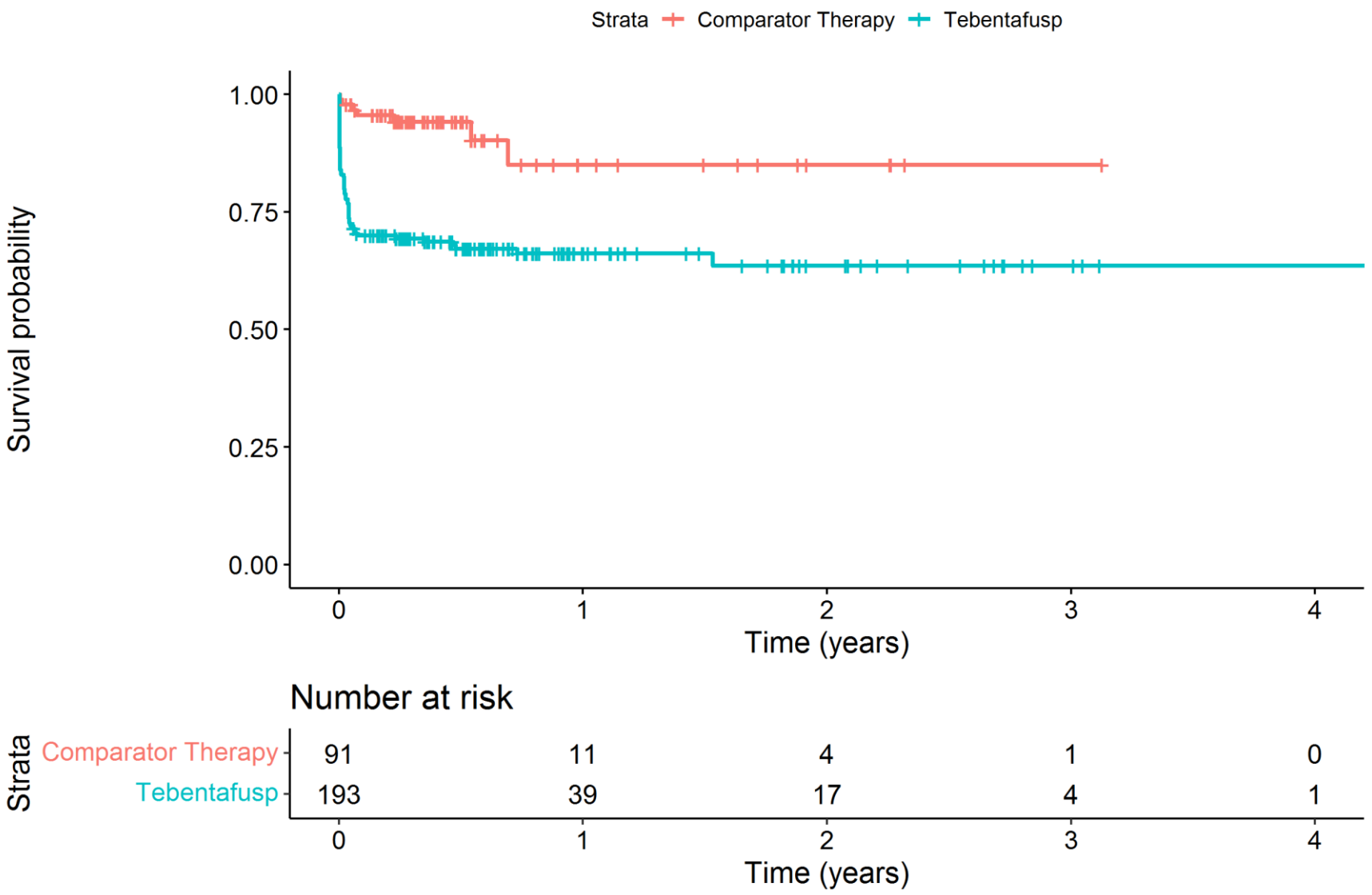
Makulo-papulöser Hautausschlag- Nicht-Nordamerika



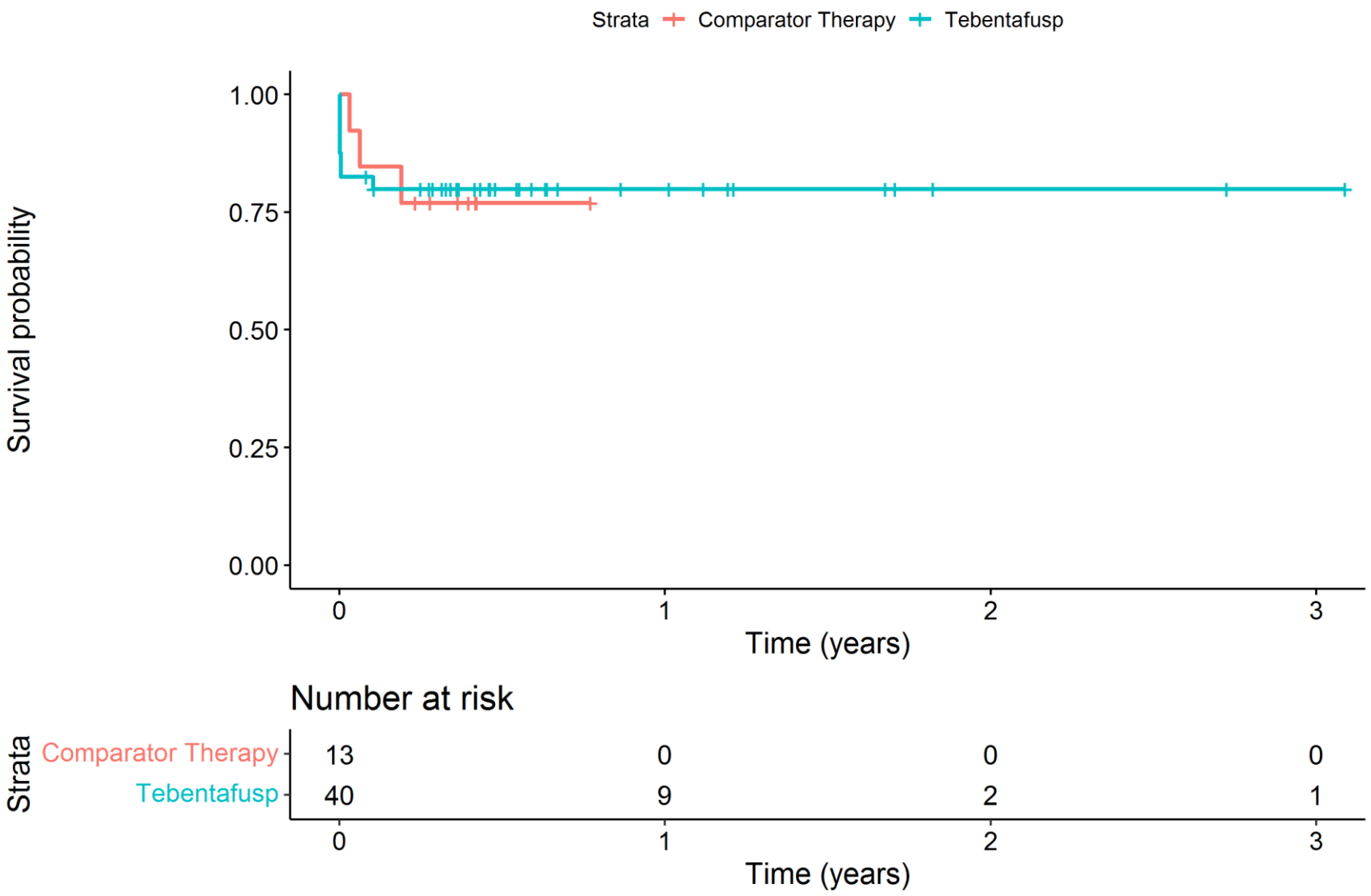
60.15 Makulo-papulöser Hautausschlag- Dacarbazin



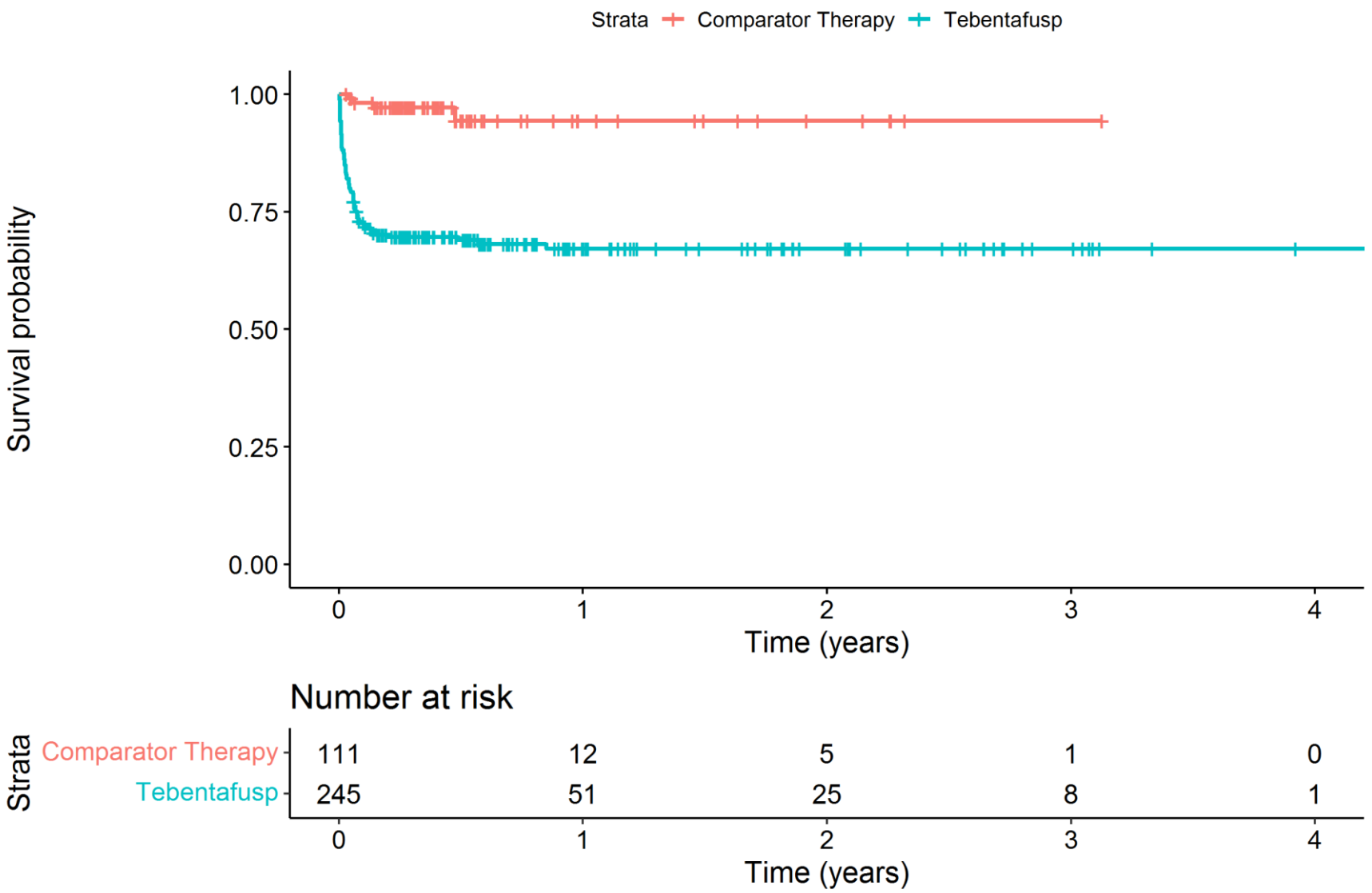
60.16 Makulo-papulöser Hautausschlag- Pembrolizumab



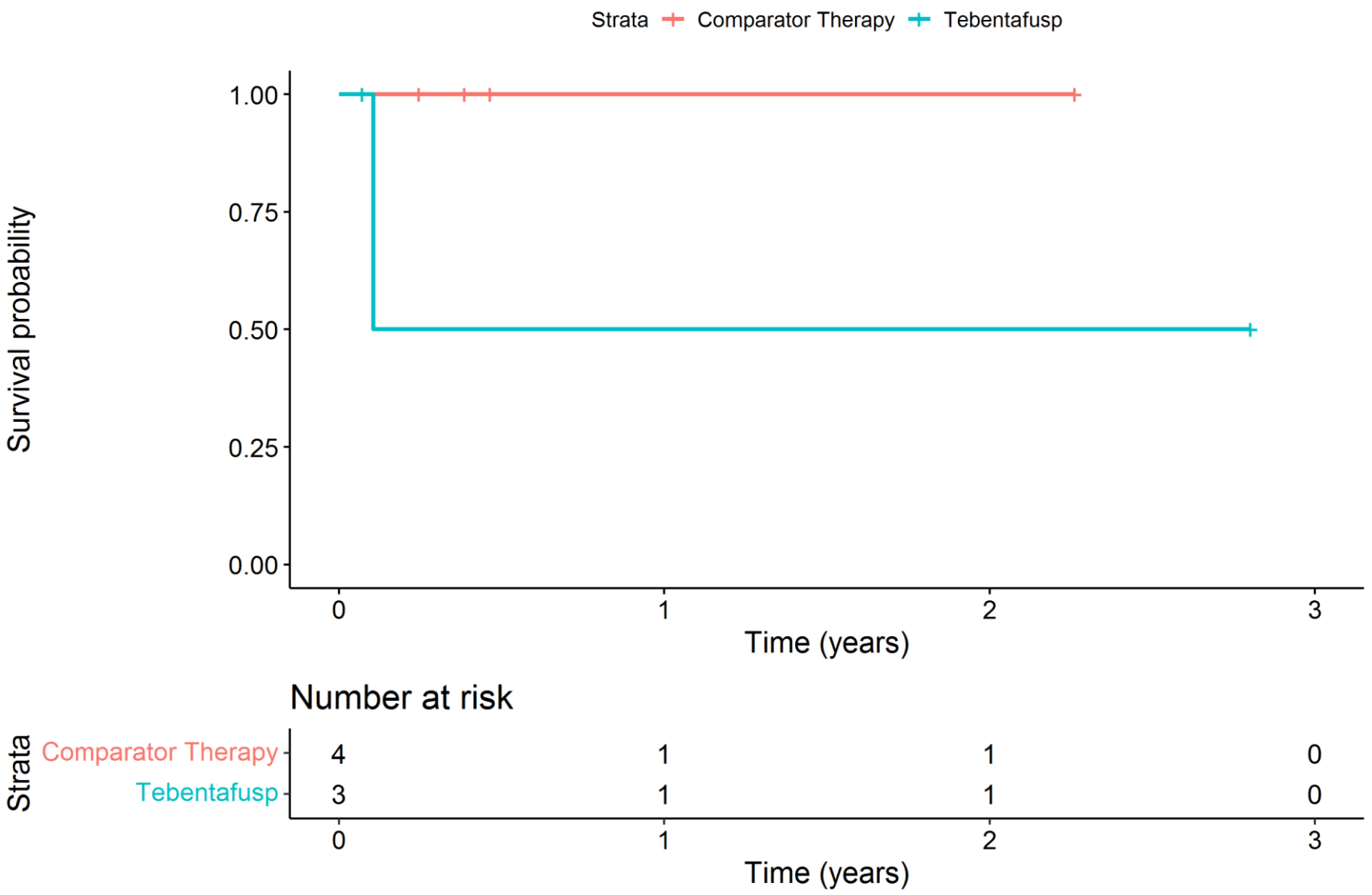
60.17 Makulo-papulöser Hautausschlag- Ipilimumab



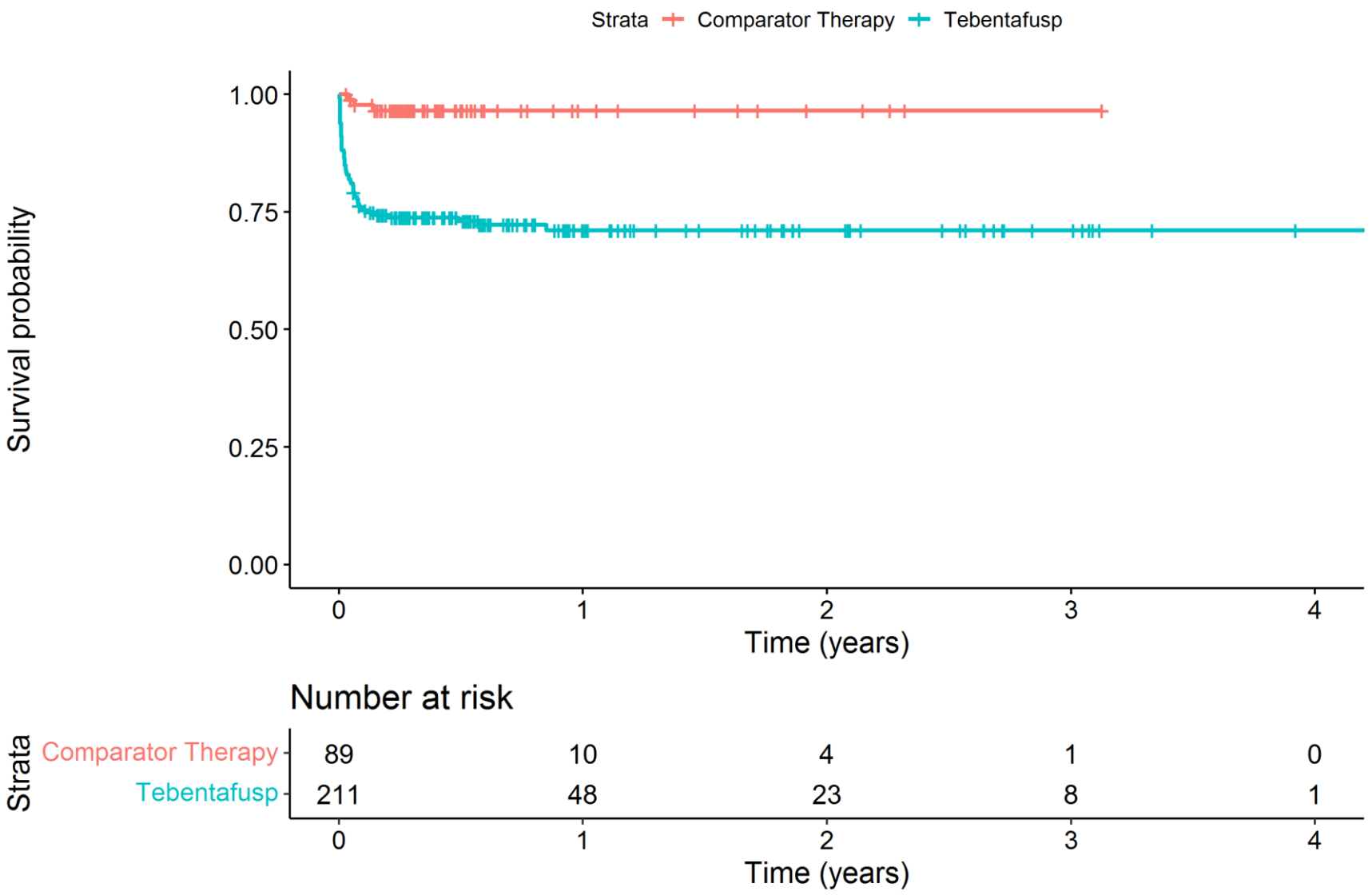
60.18 Trockene Haut - Gesamt



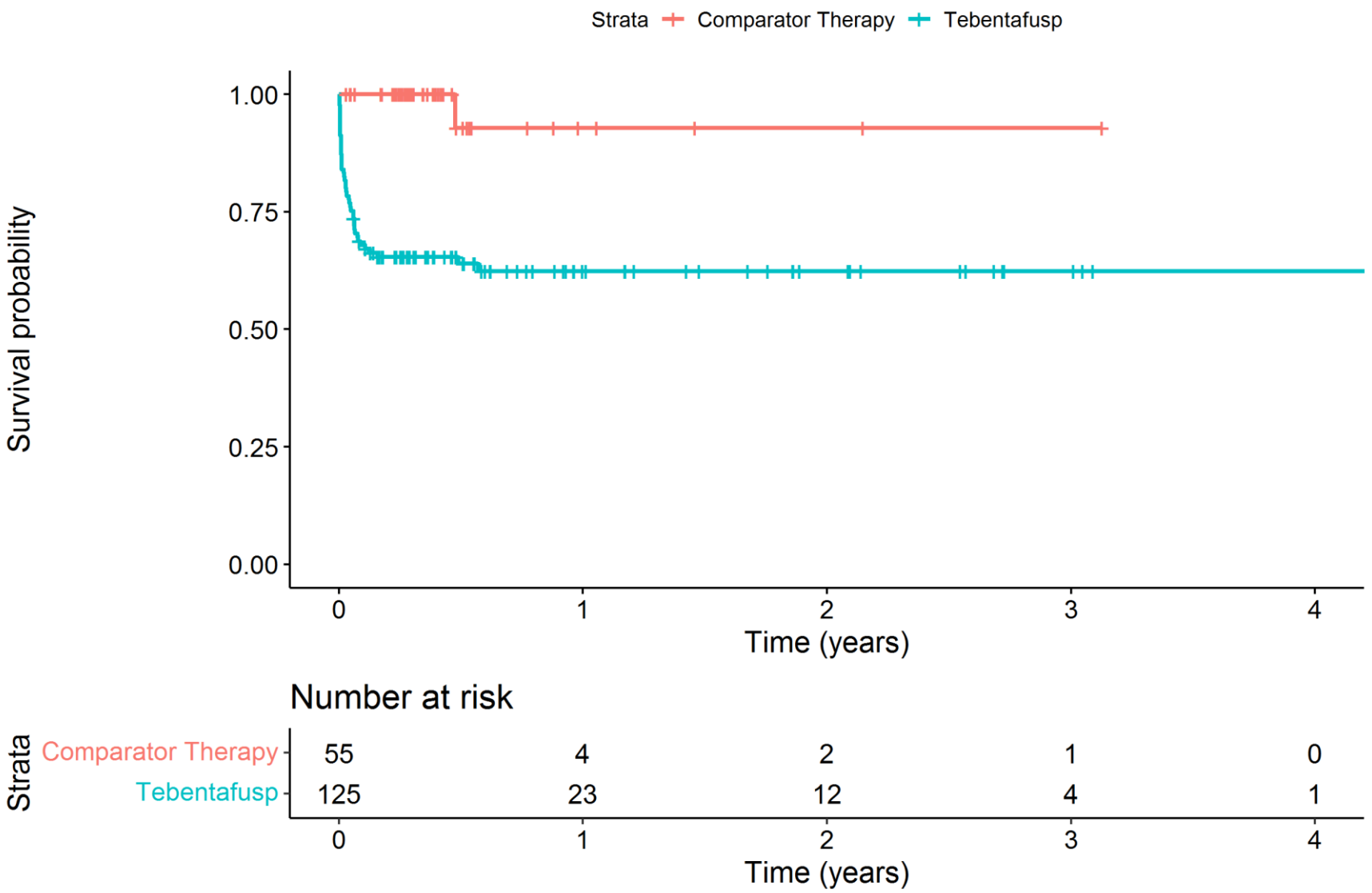
60.19 Trockene Haut - Hispanisch



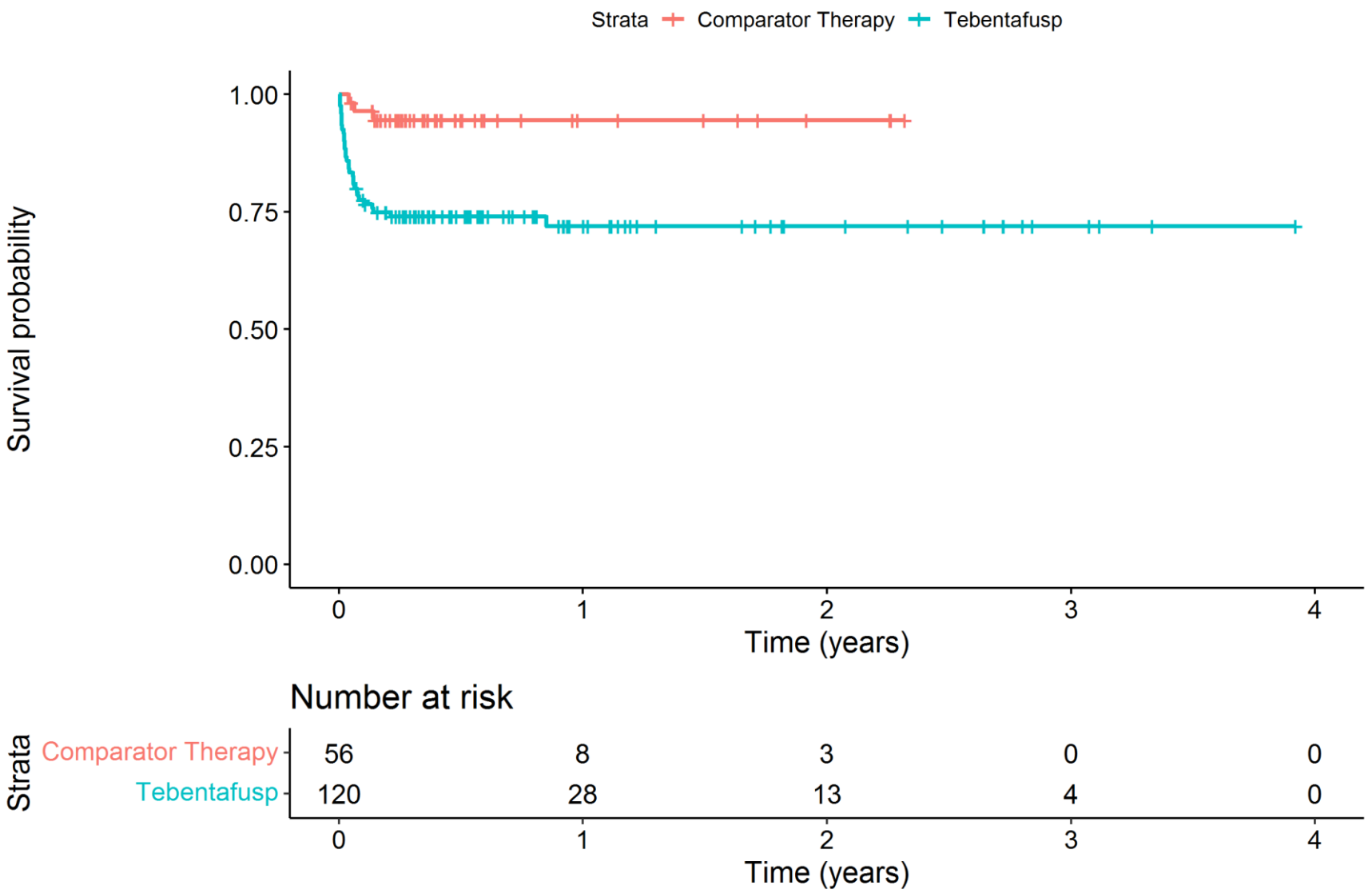
60.20 Trockene Haut - Nicht-hispanisch



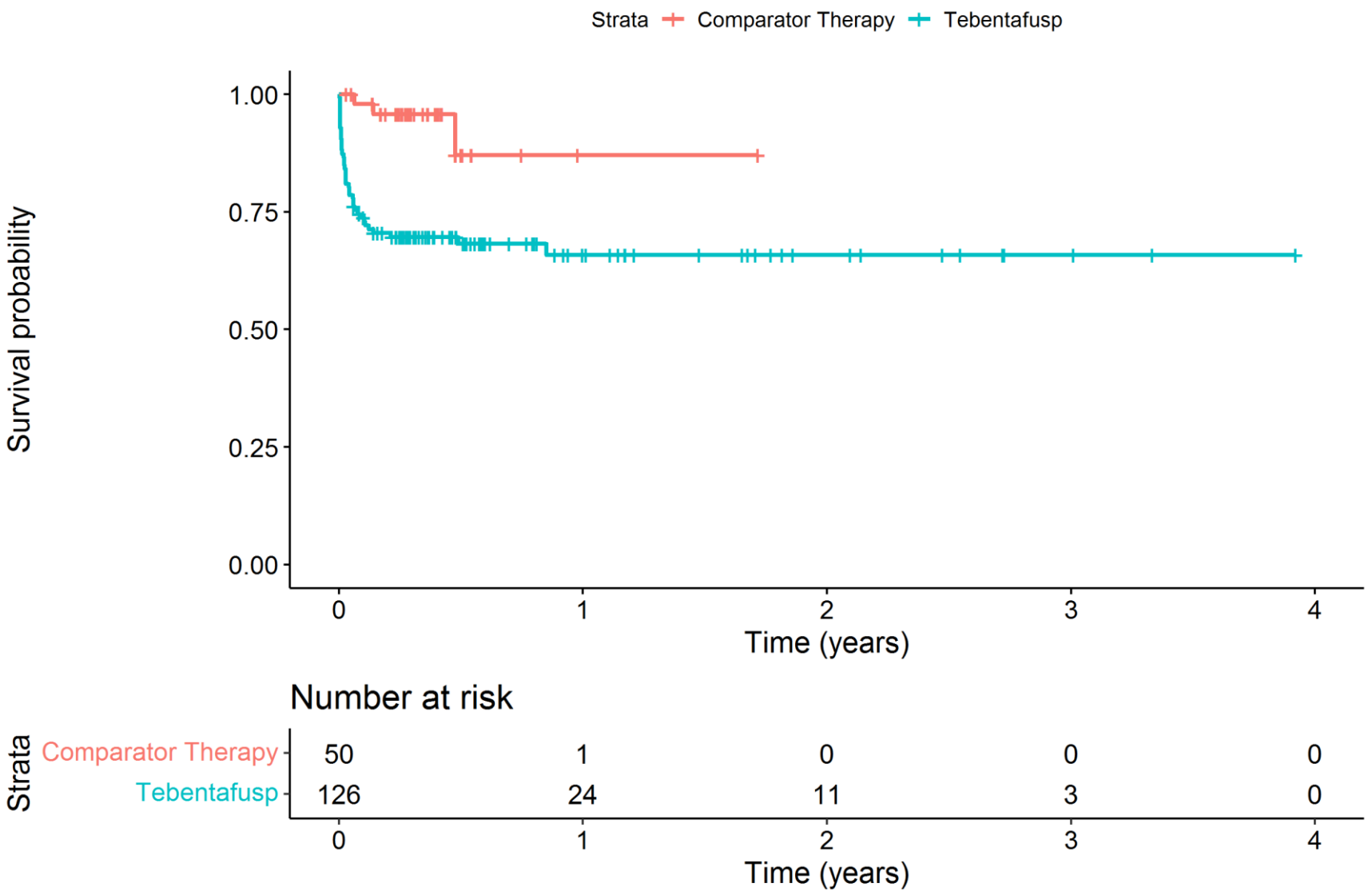
60.21 Trockene Haut - Männlich



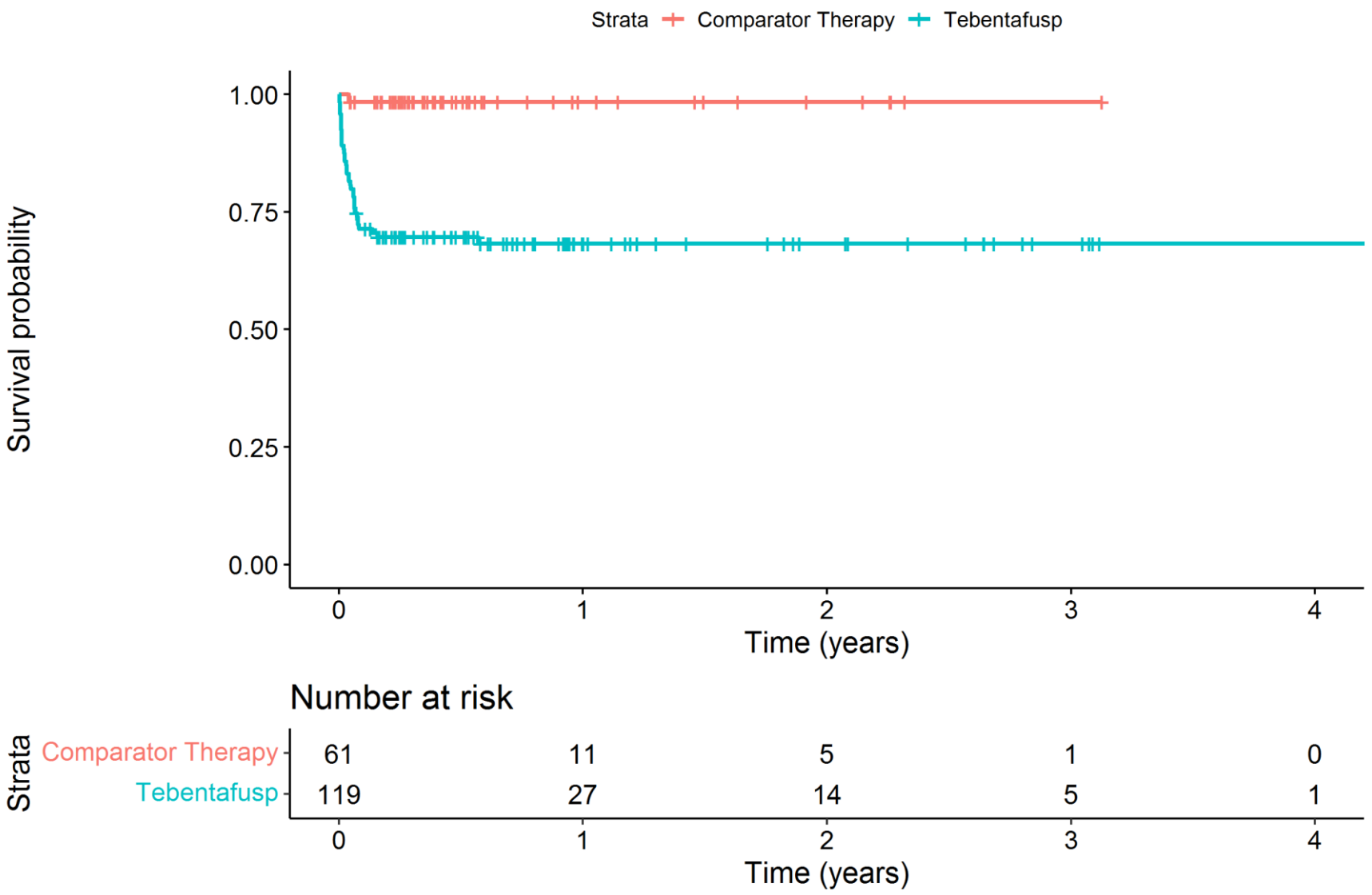
60.22 Trockene Haut - Weiblich



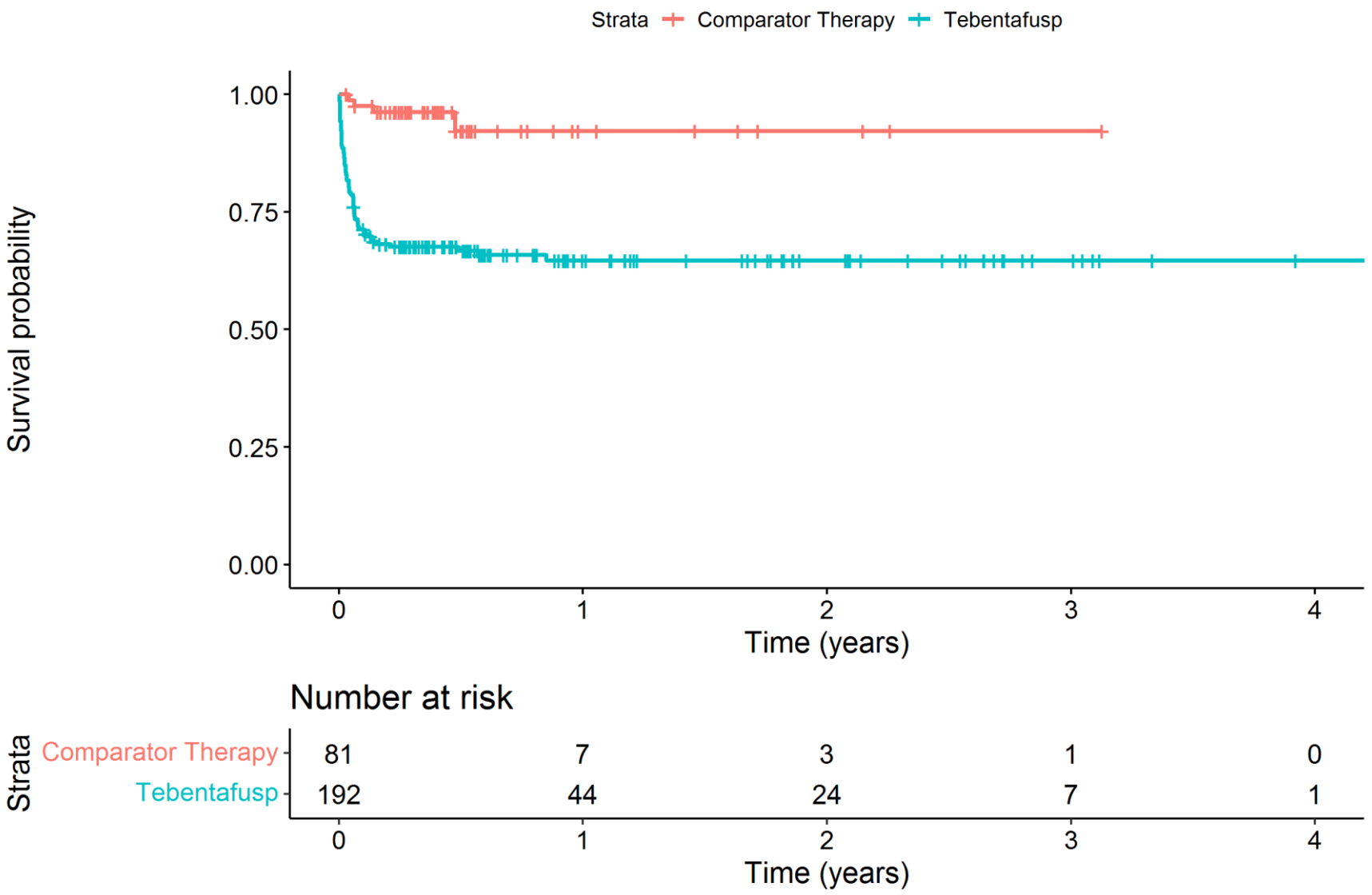
60.23 Trockene Haut - <65



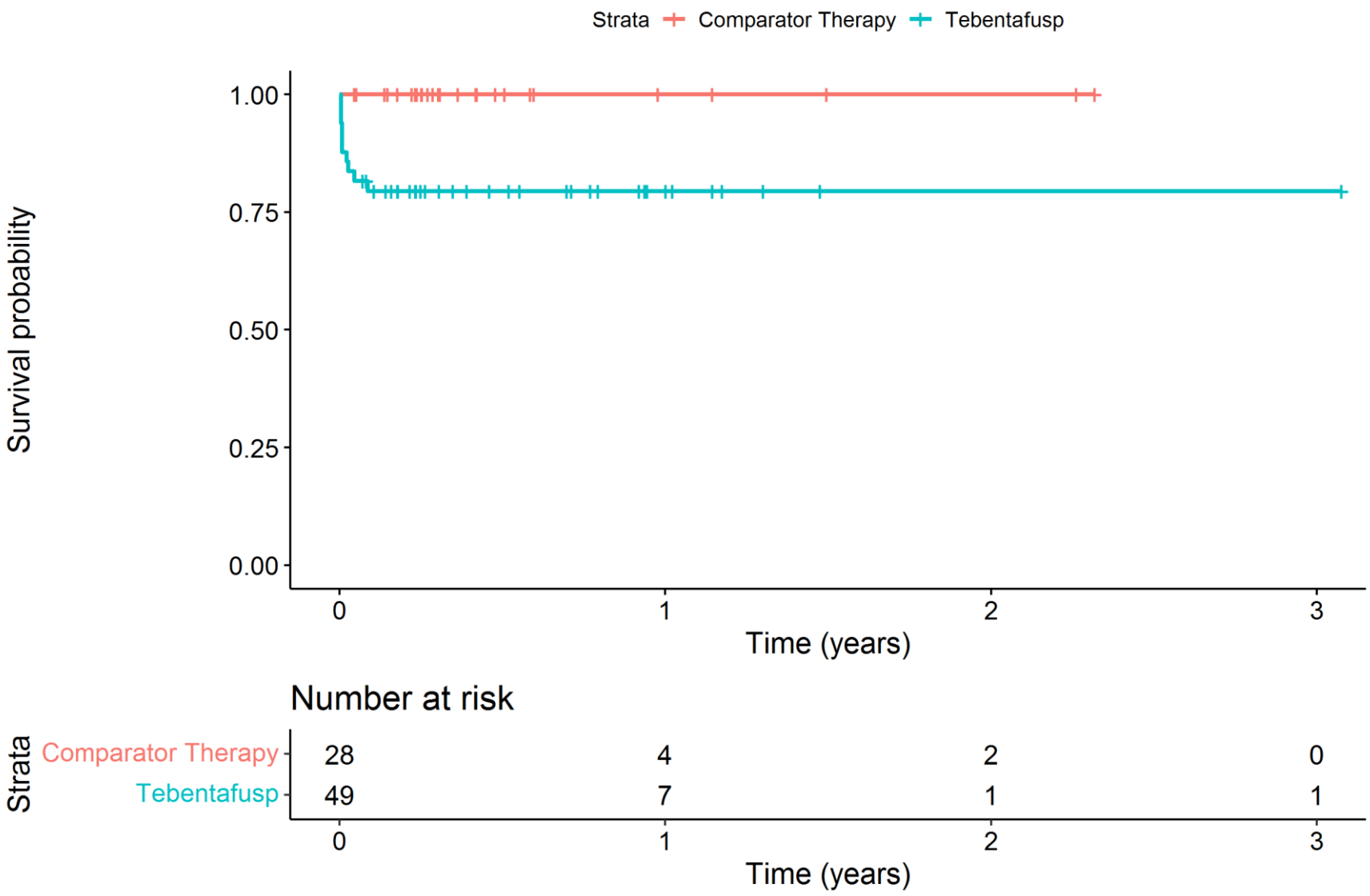
60.24 Trockene Haut - ≥65



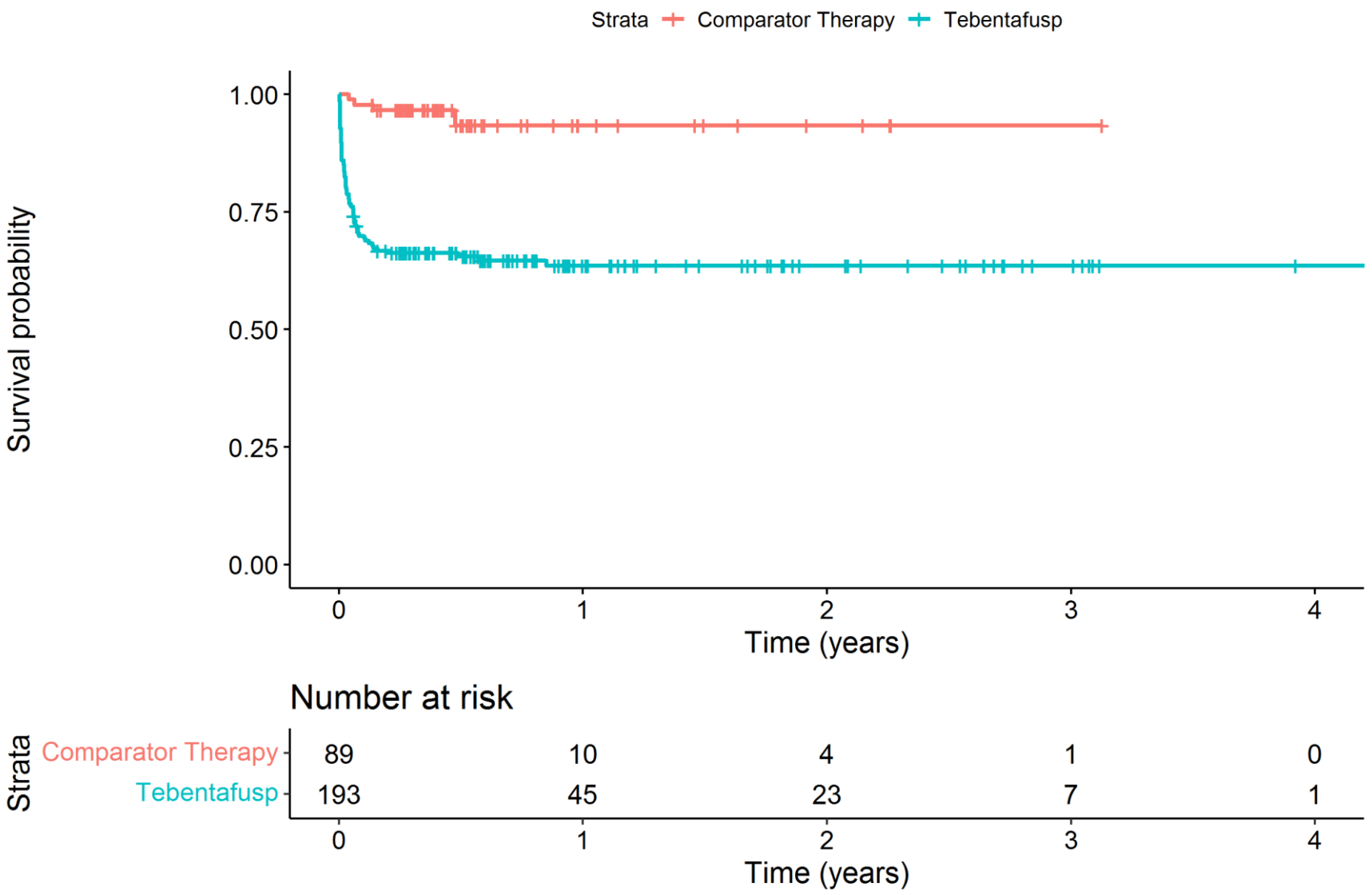
60.25 Trockene Haut - ECOG 0



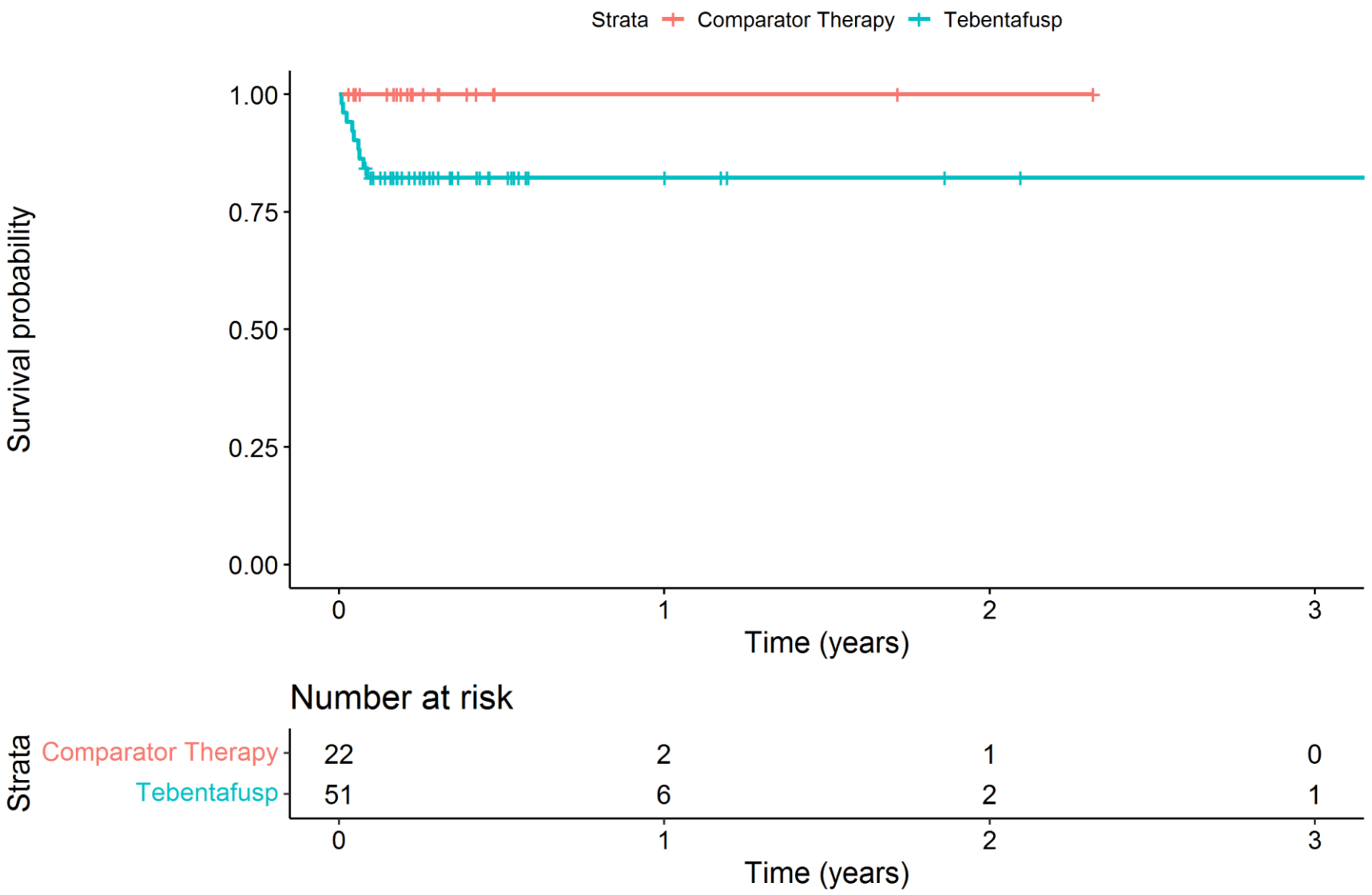
60.26 Trockene Haut - ECOG 1



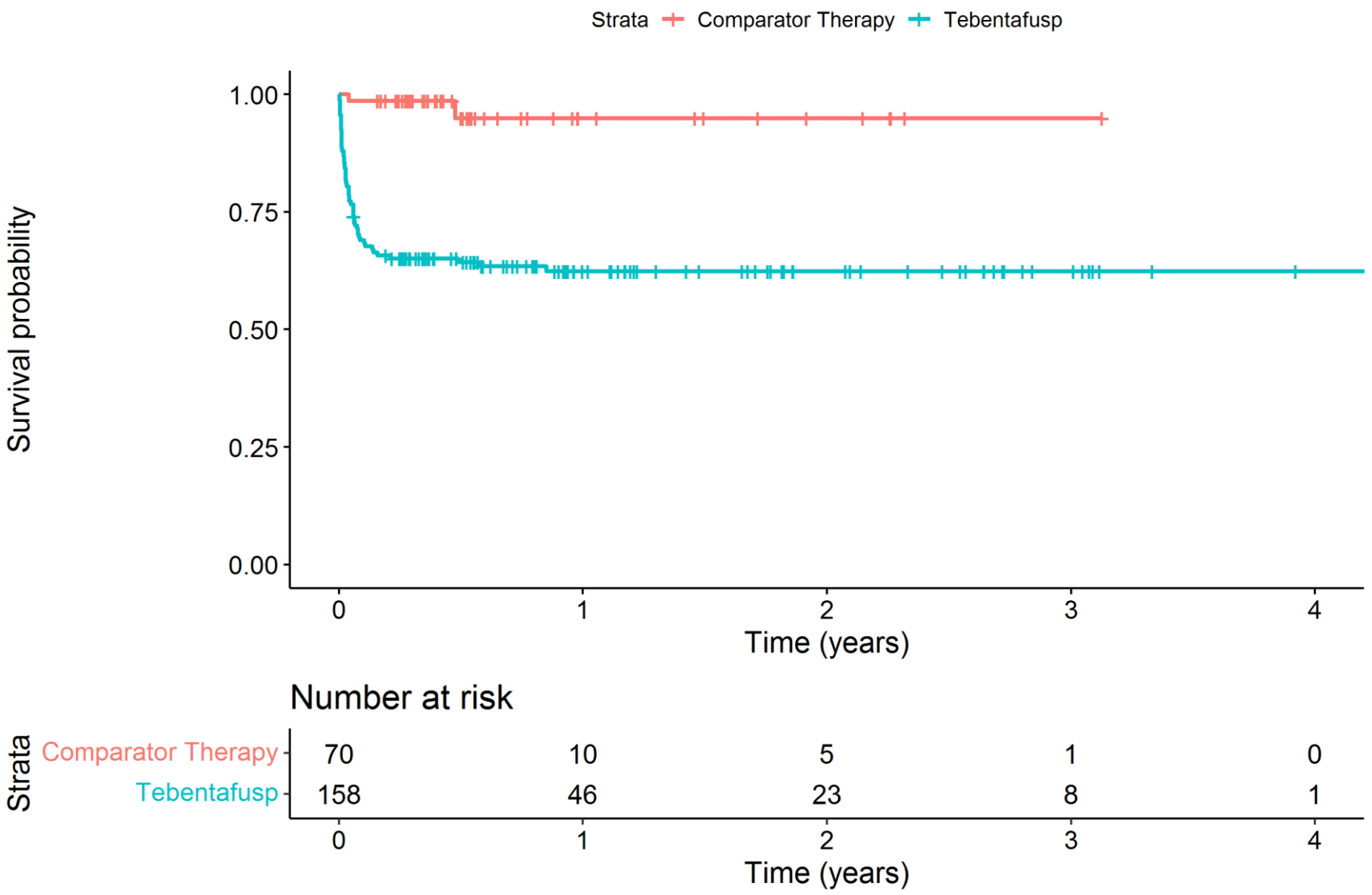
60.27 Trockene Haut - ALP ≤ ULN



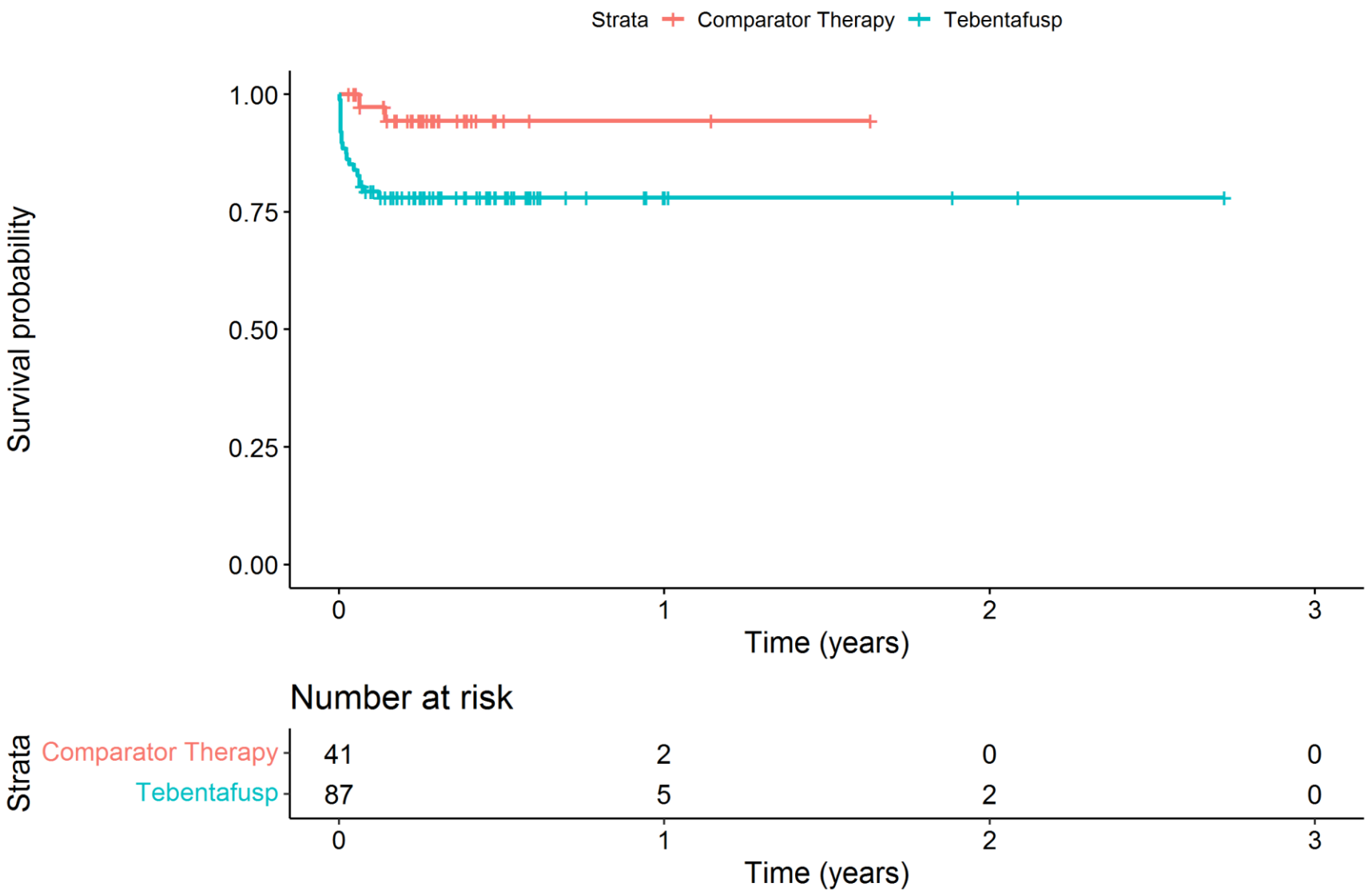
60.28 Trockene Haut - ALP > ULN



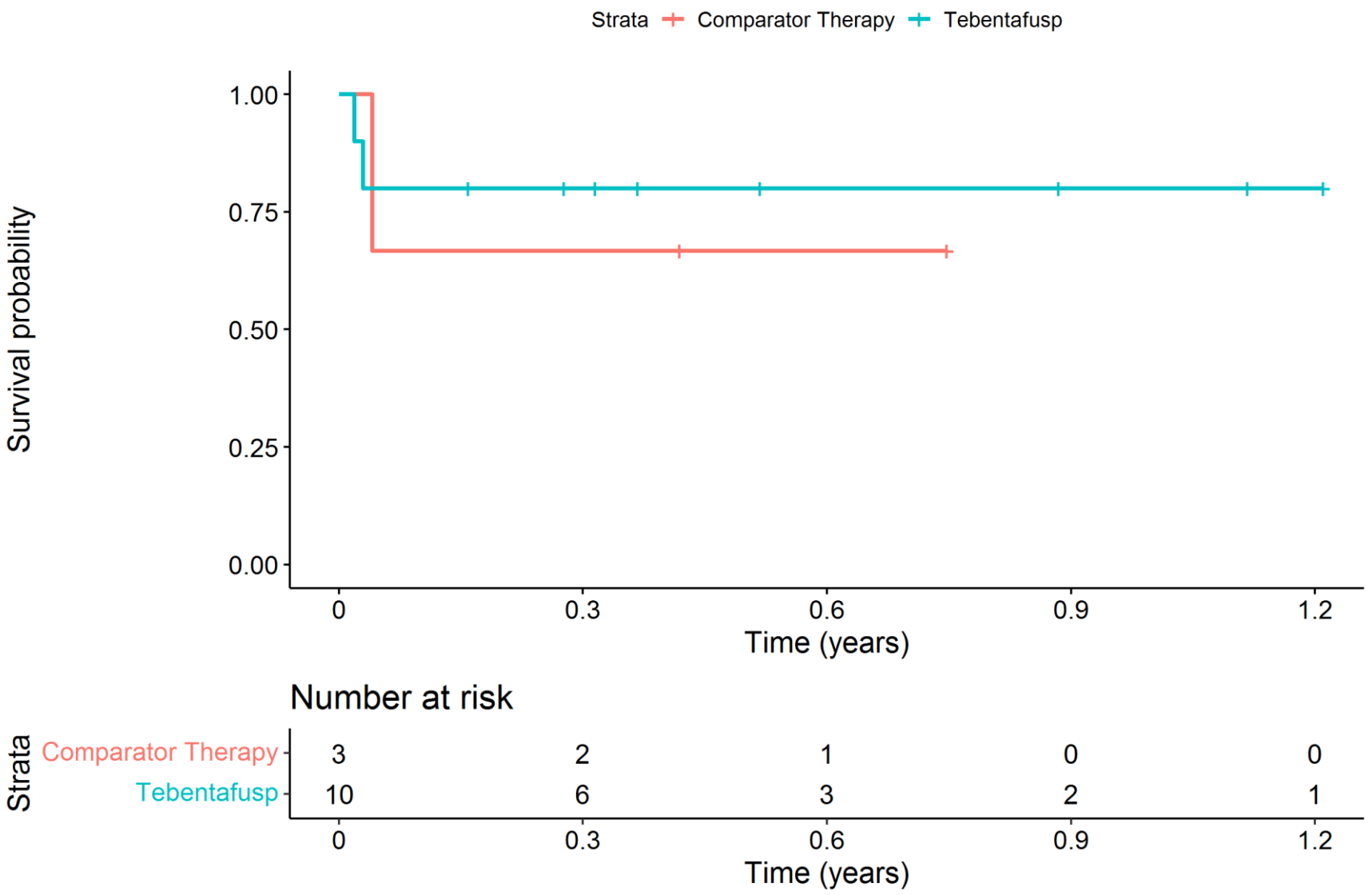
60.29 Trockene Haut - LDH =< ULN



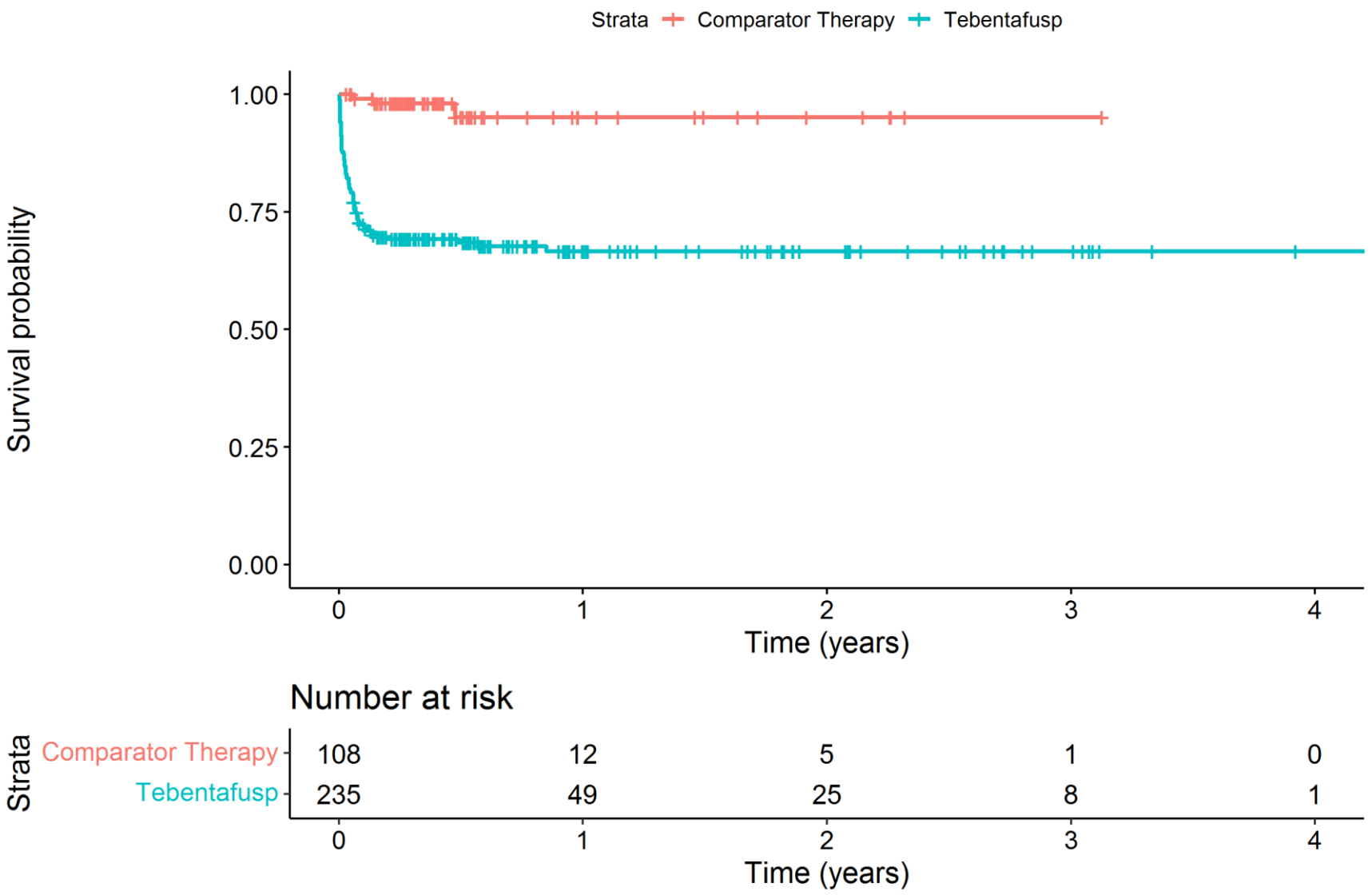
60.30 Trockene Haut - LDH > ULN



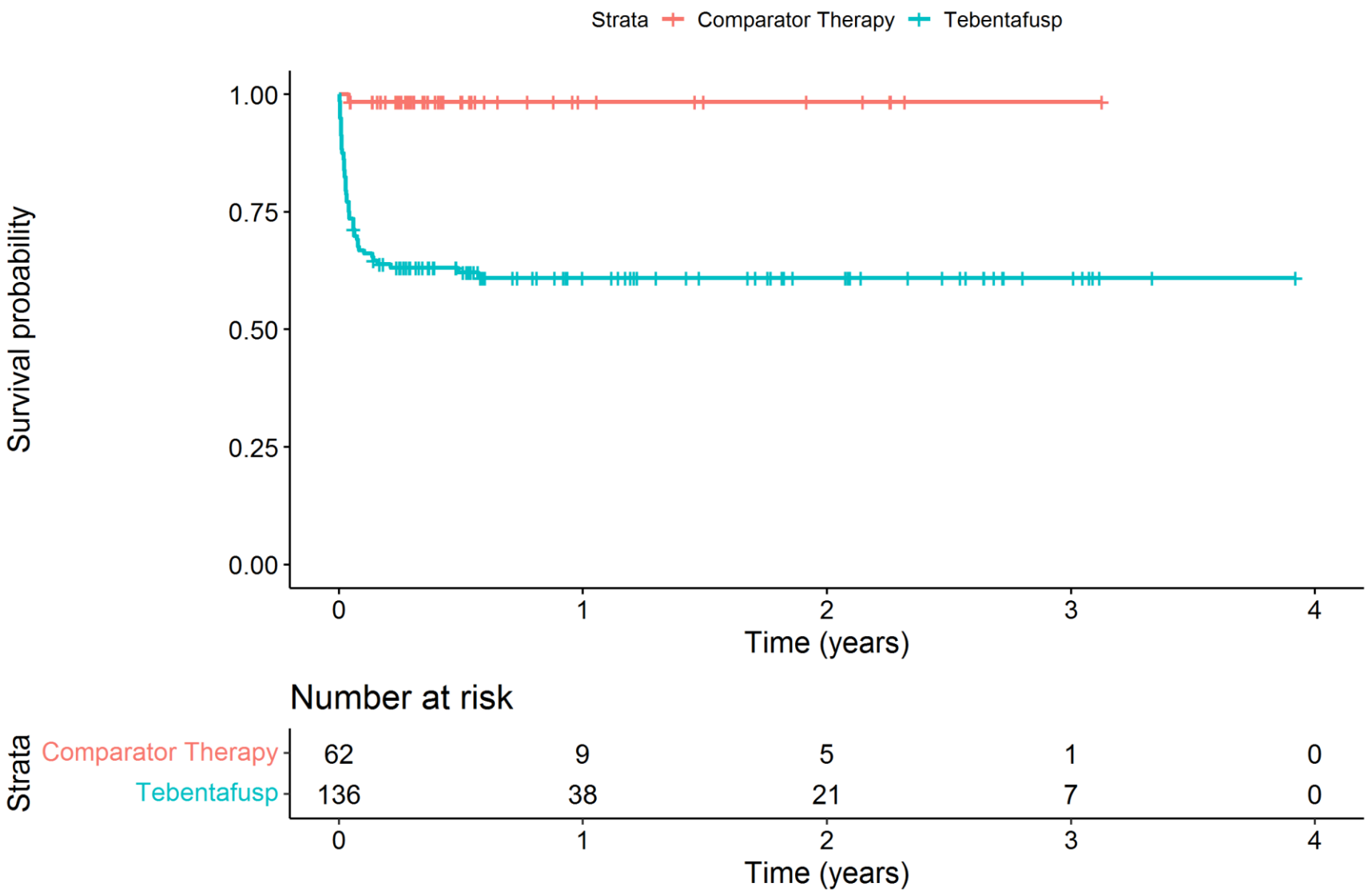
60.31 Trockene Haut - Vorherige Therapie adjuvant/neoadjuvant



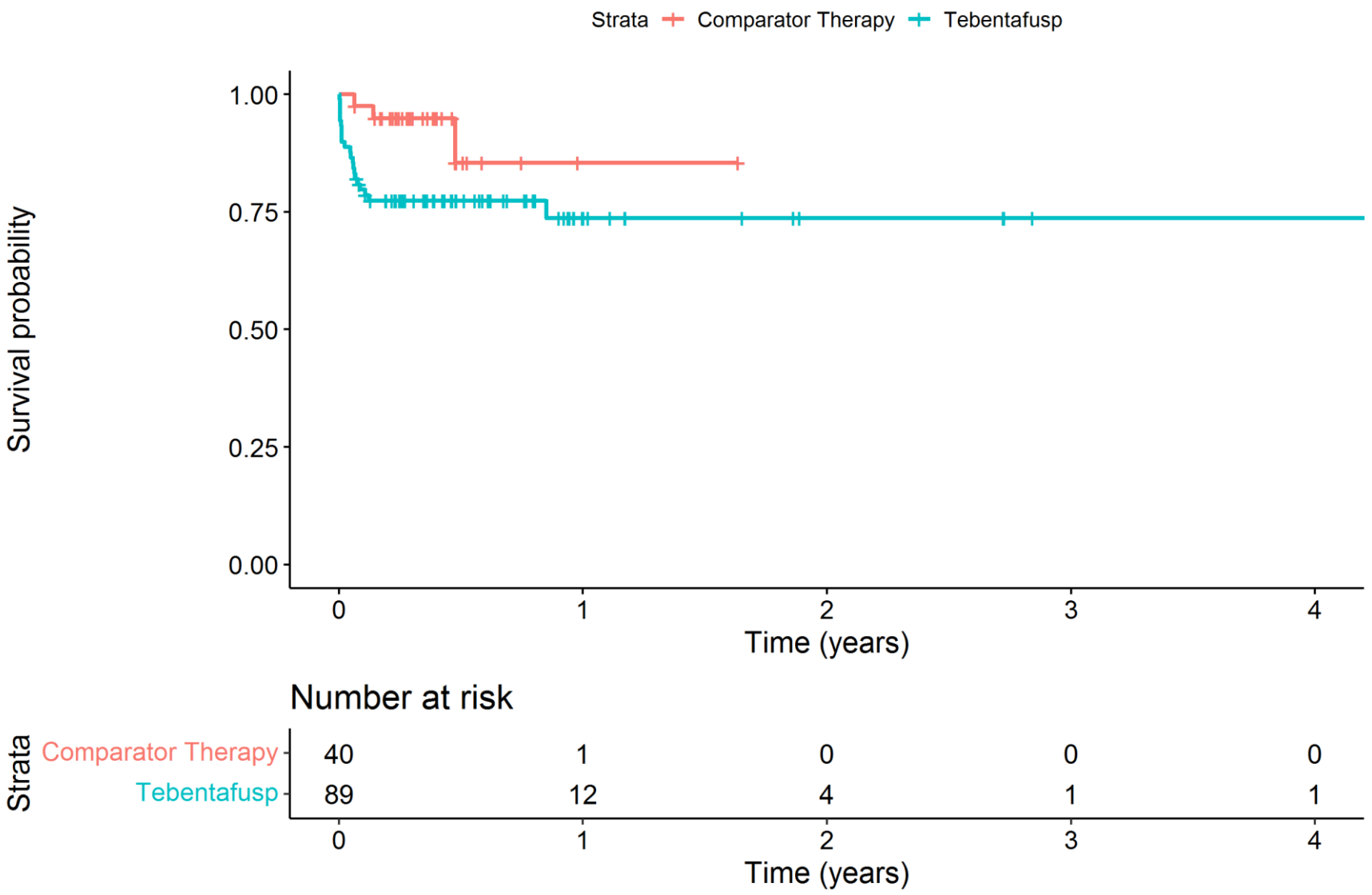
60.32 Trockene Haut - Keine Vorherige Therapie adjuvant/neoadjuvant



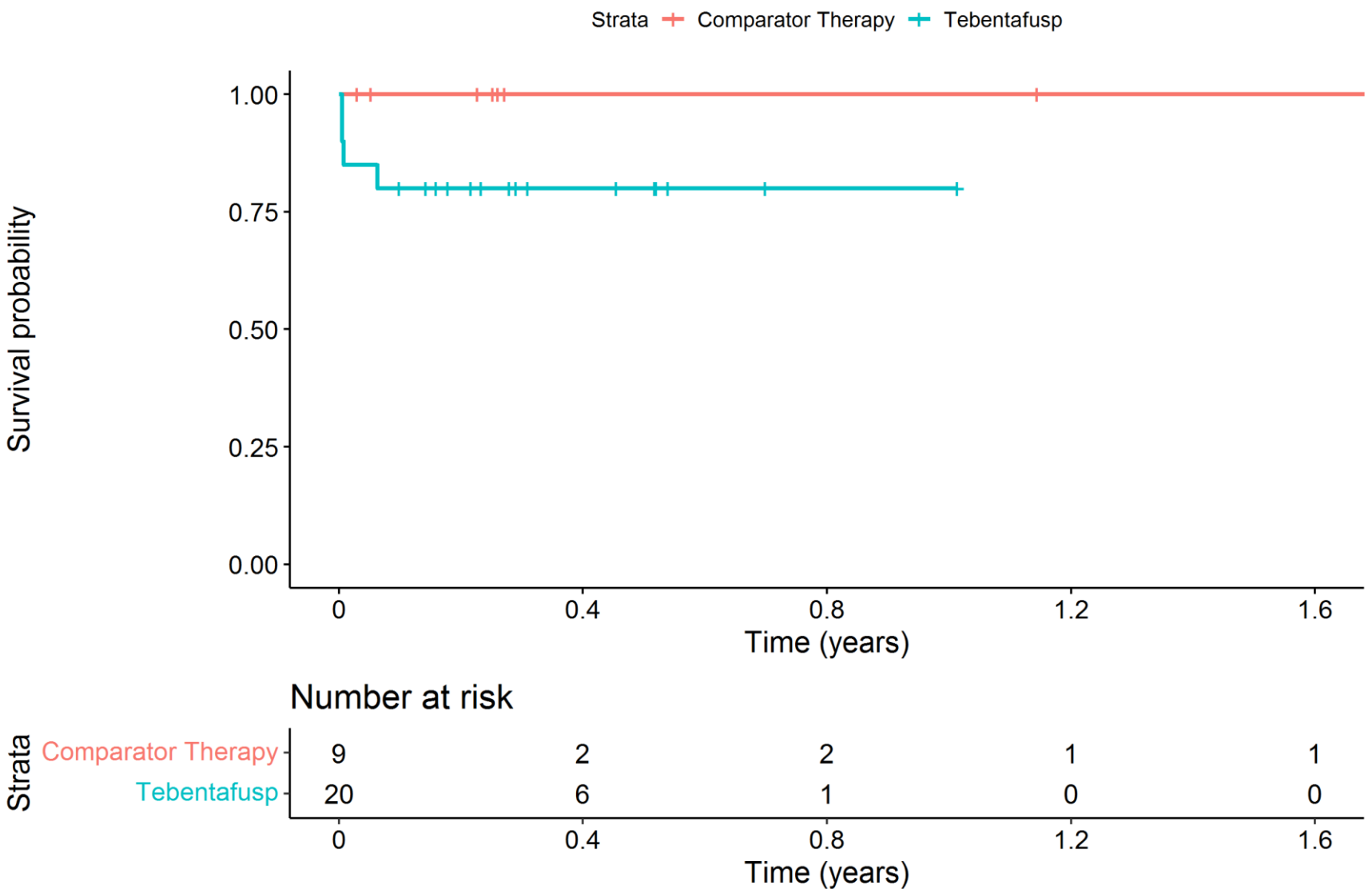
60.33 Trockene Haut - Läsion ≤ 3cm



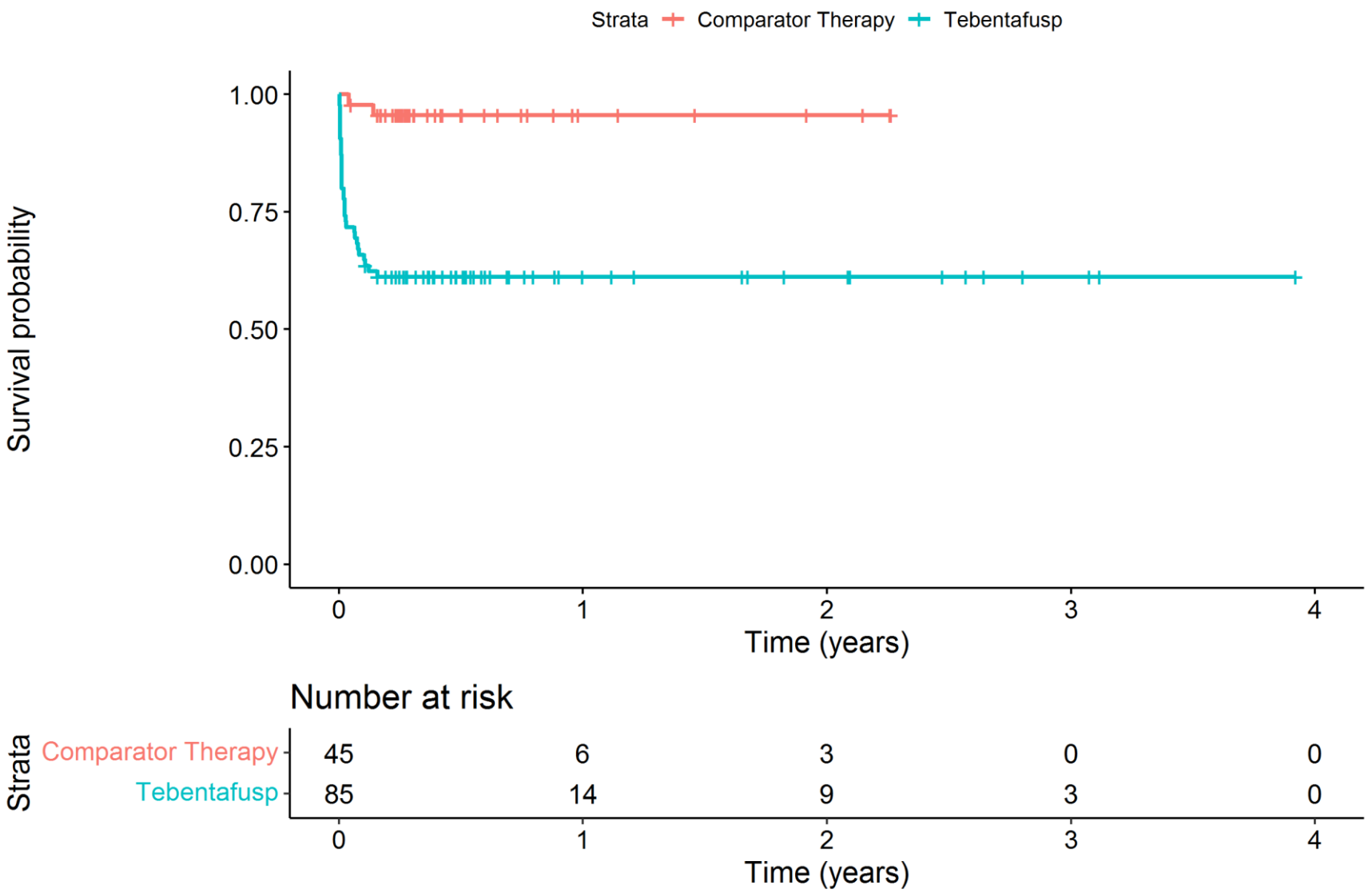
60.34 Trockene Haut - Läsion 3,1-8,0 cm



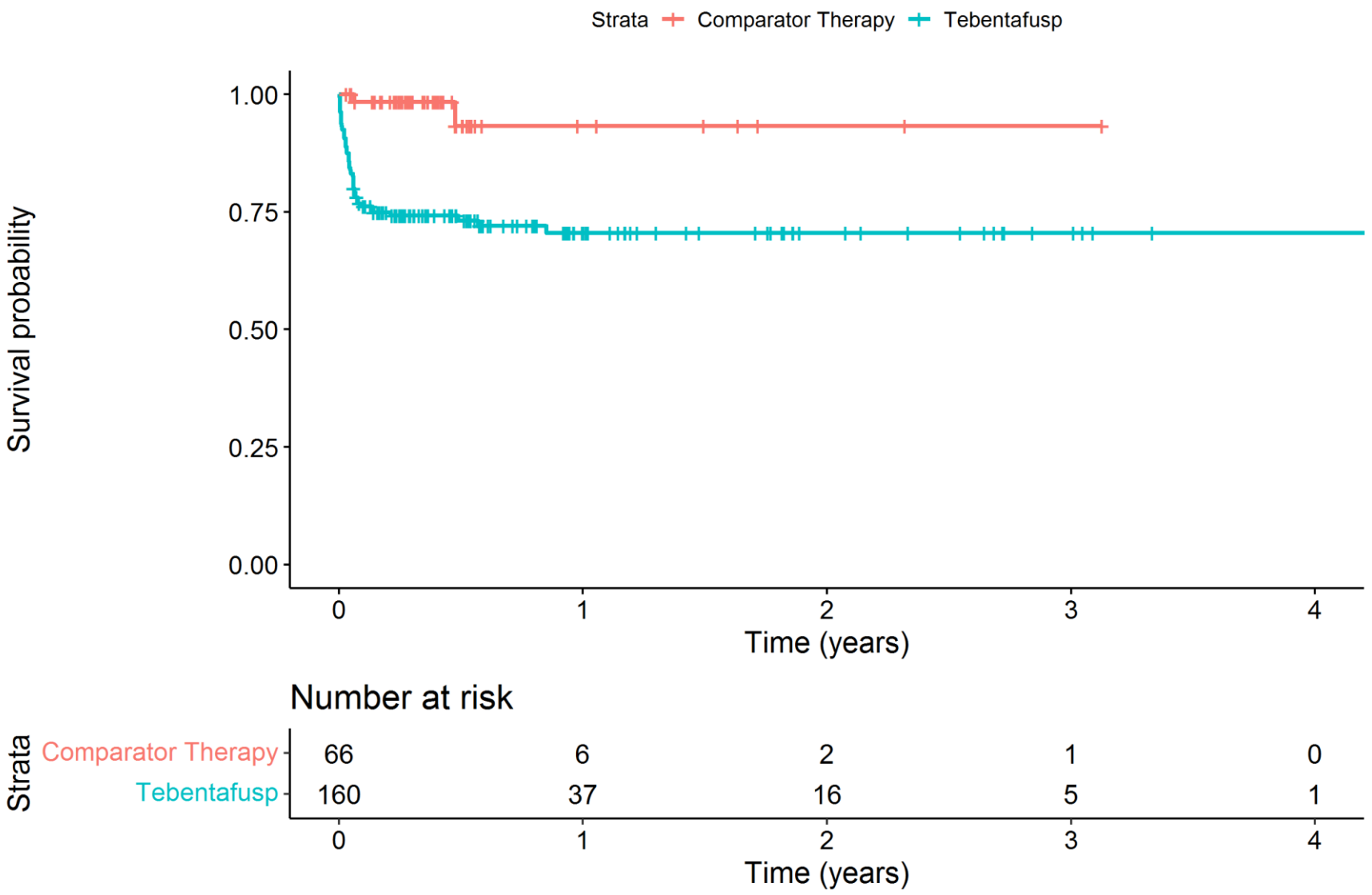
60.35 Trockene Haut - Läsion ≥8,1 cm



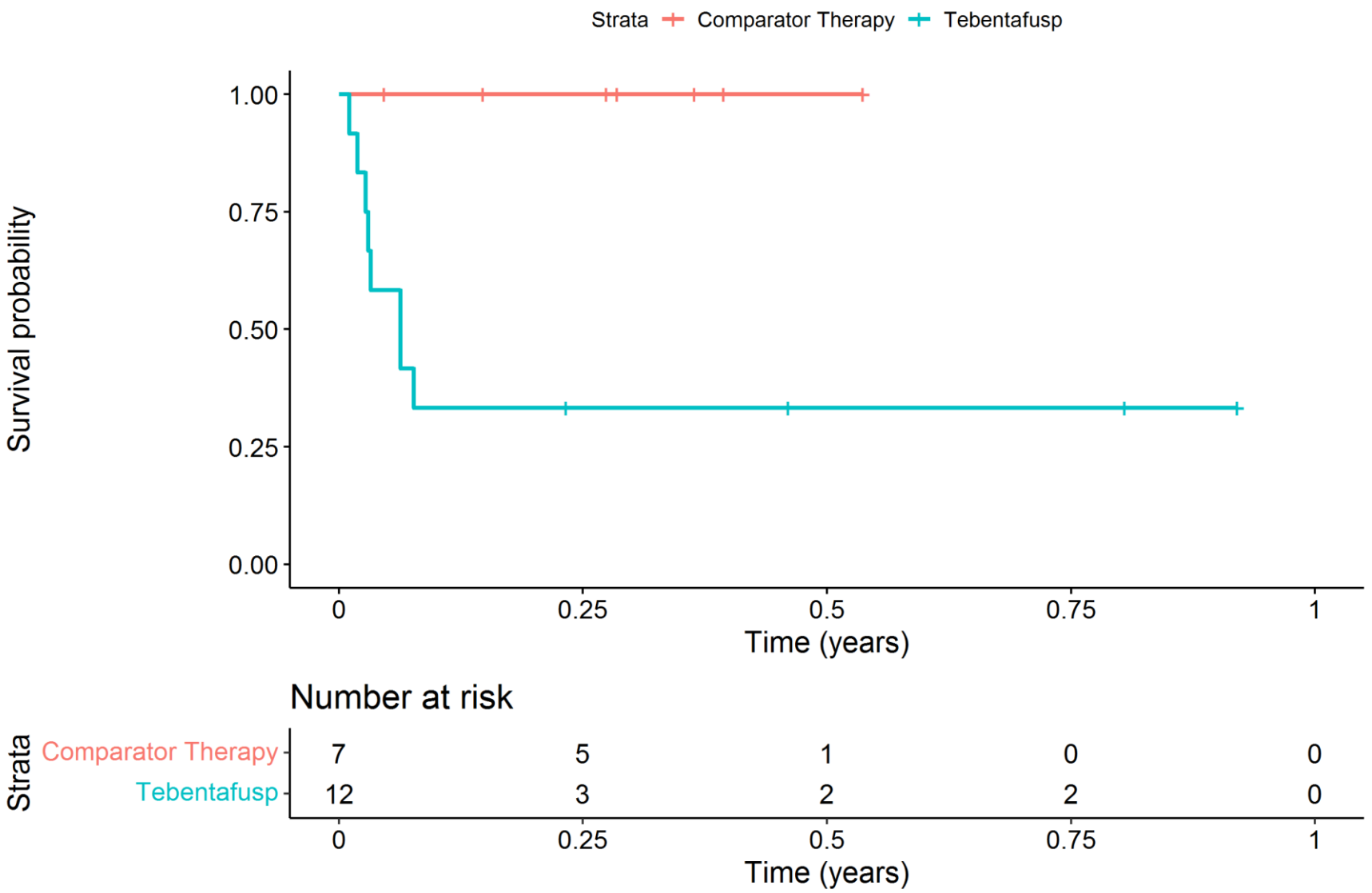
60.36 Trockene Haut - Nordamerika



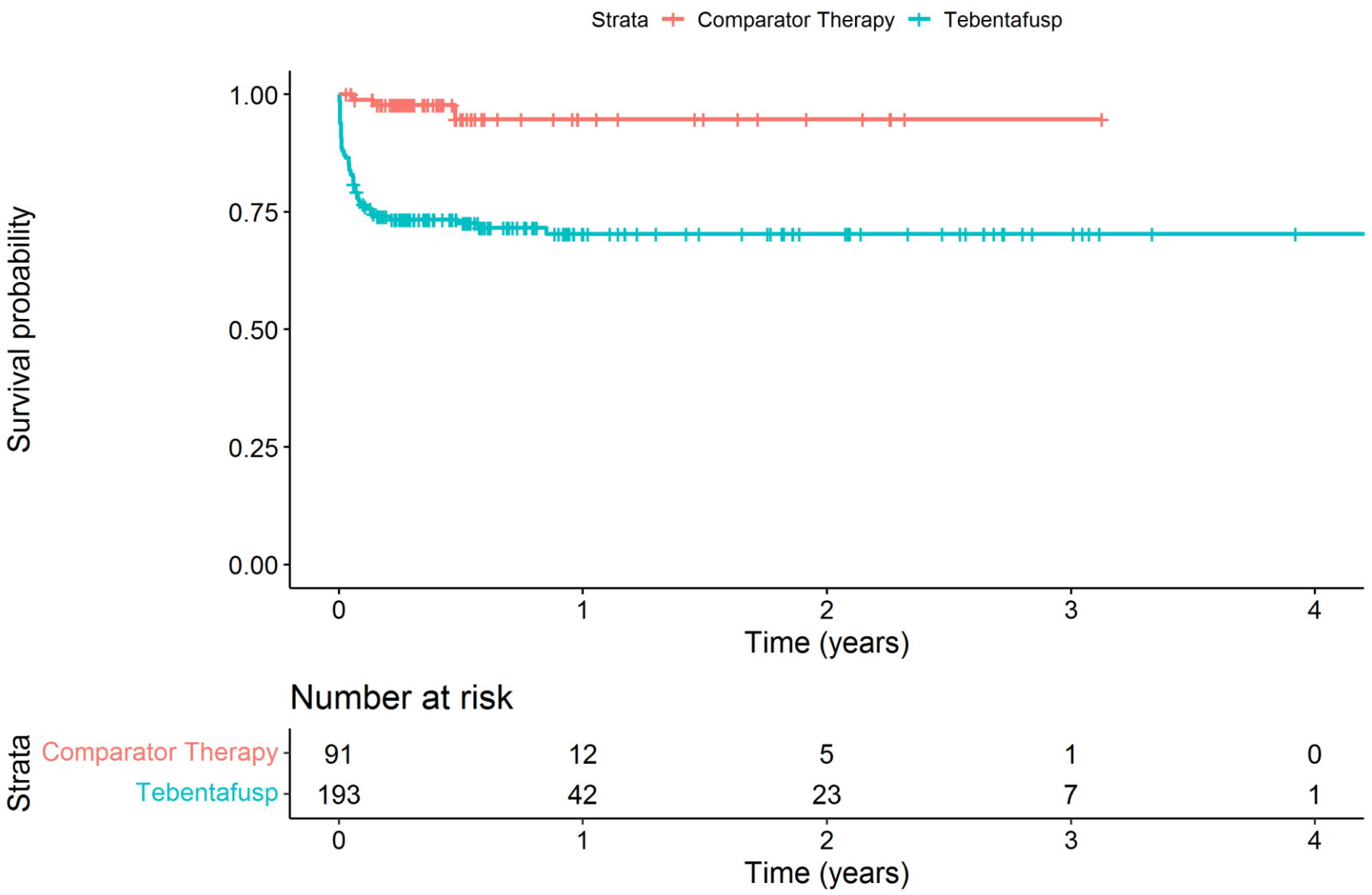
60.37 Trockene Haut - Nicht-Nordamerika



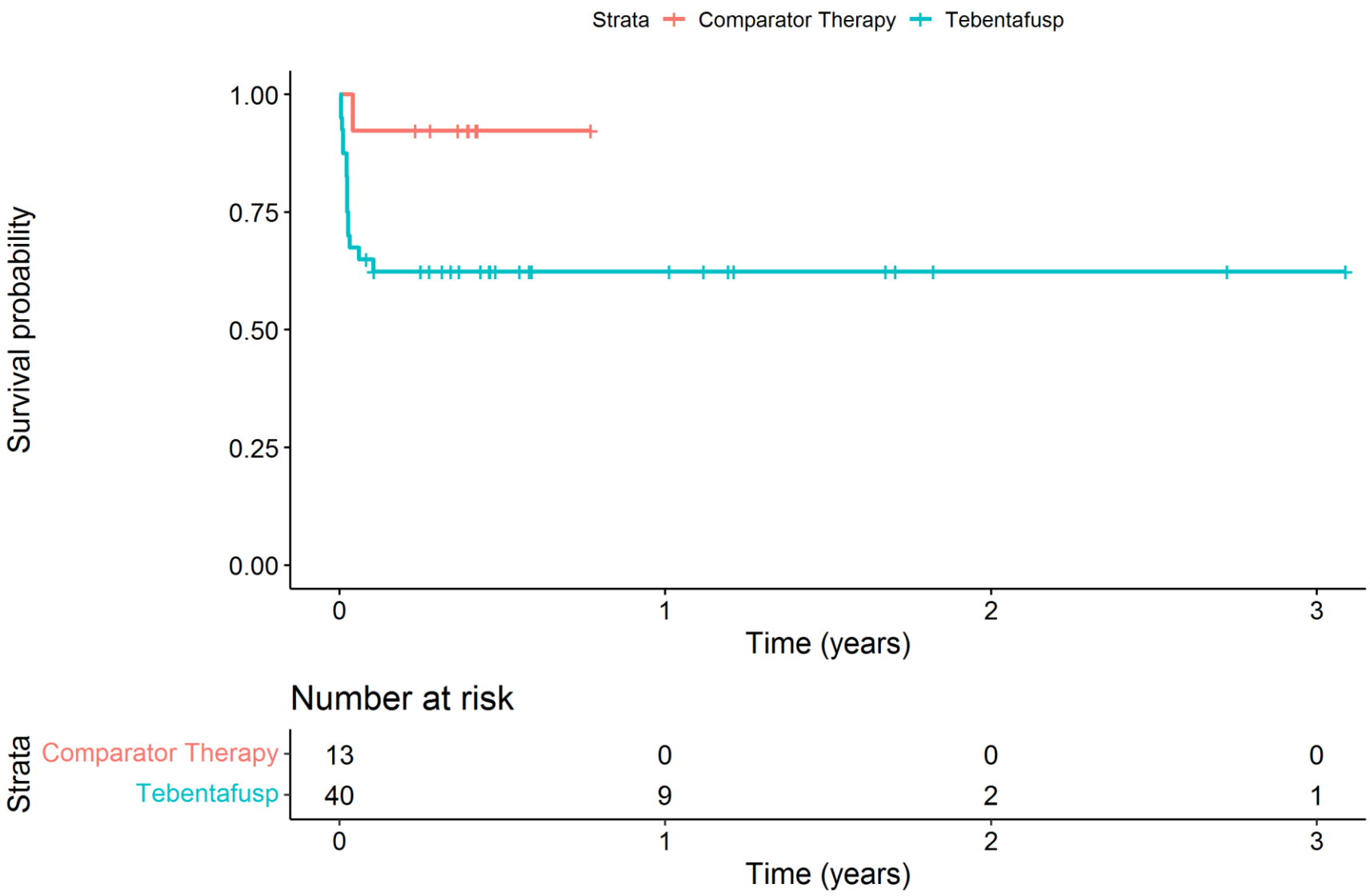
60.38 Trockene Haut - Dacarbazin



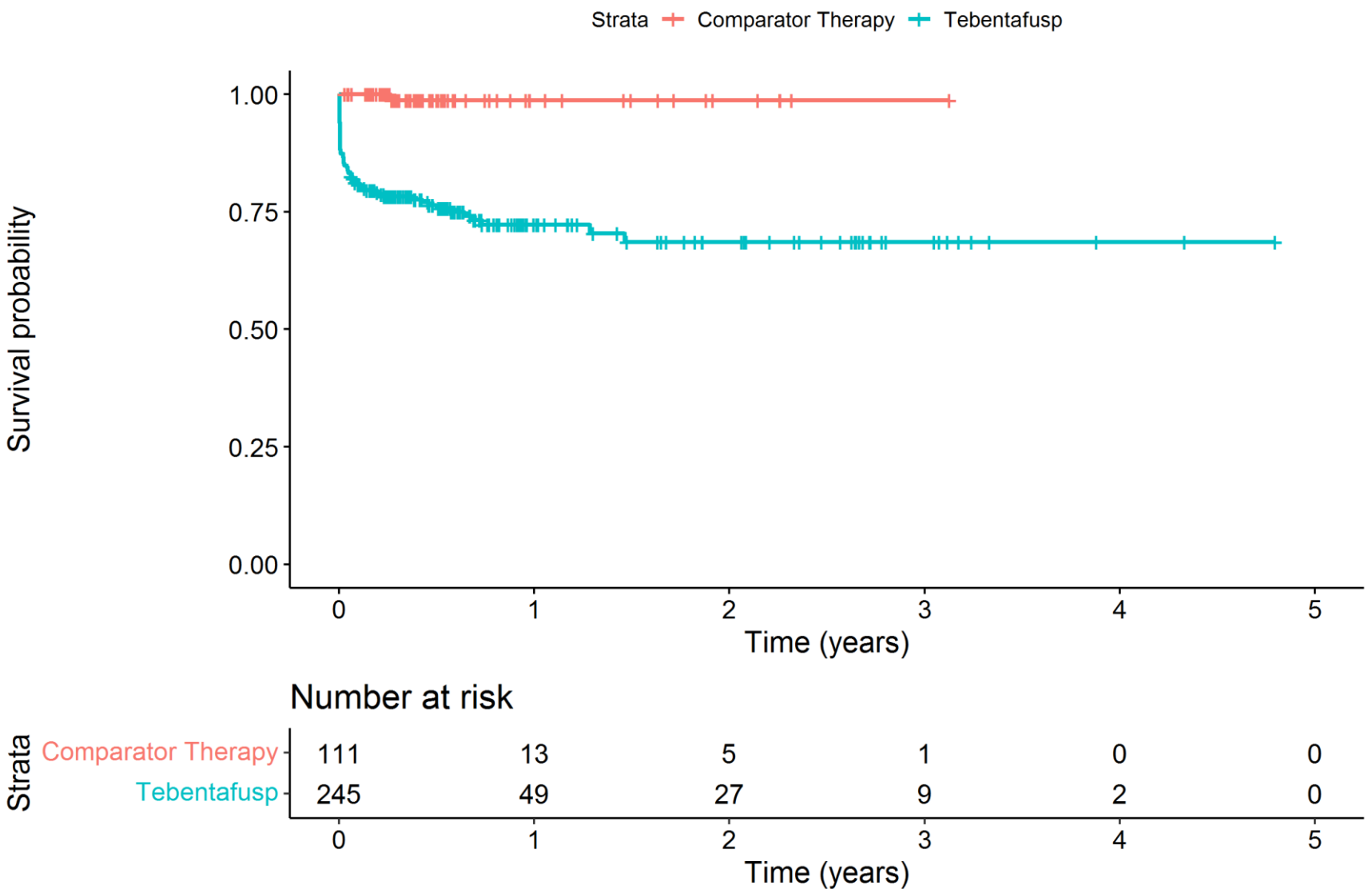
60.39 Trockene Haut - Pembrolizumab



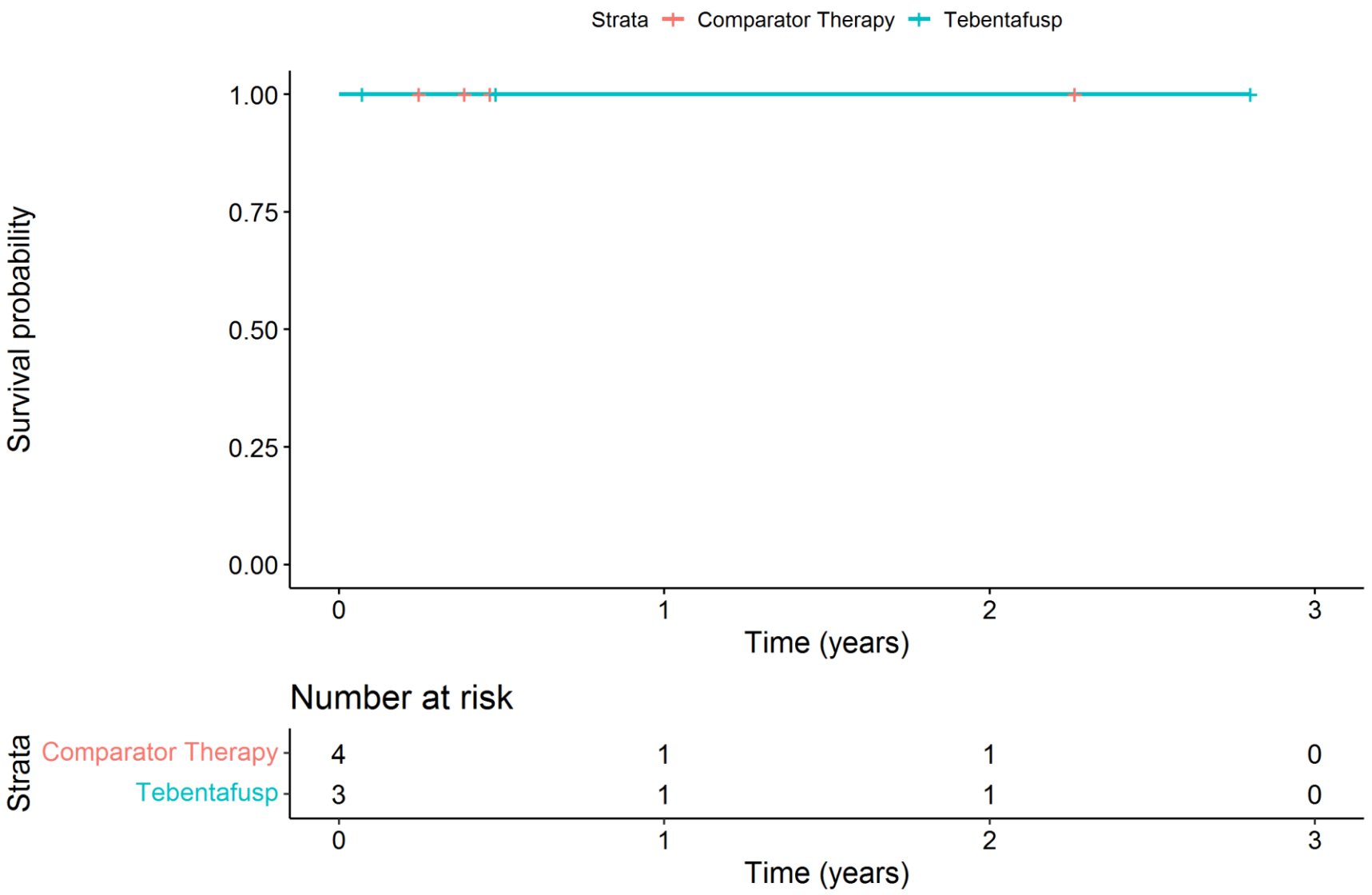
60.40 Trockene Haut - Ipilimumab



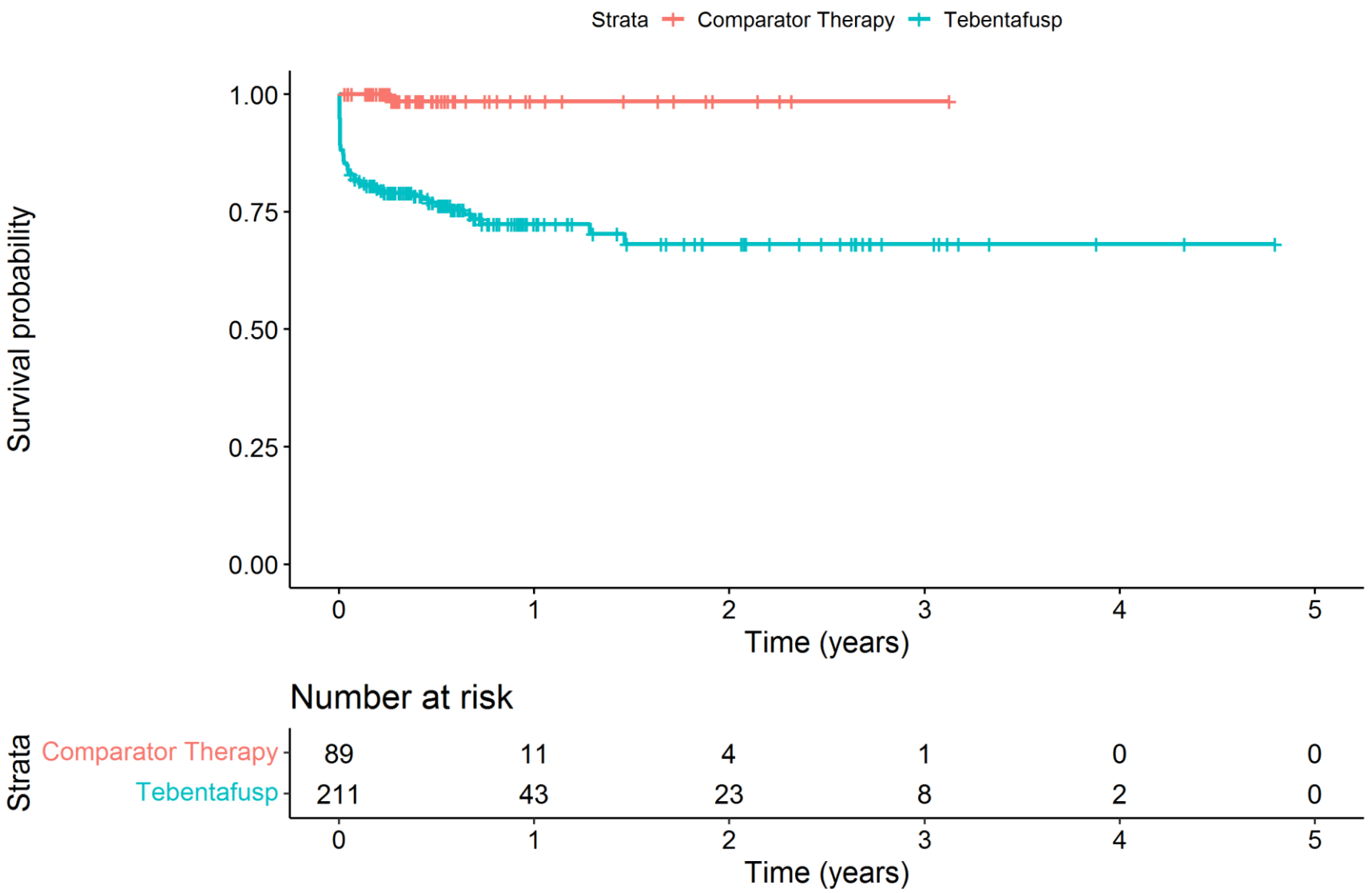
60.41 Erythem - Gesamt



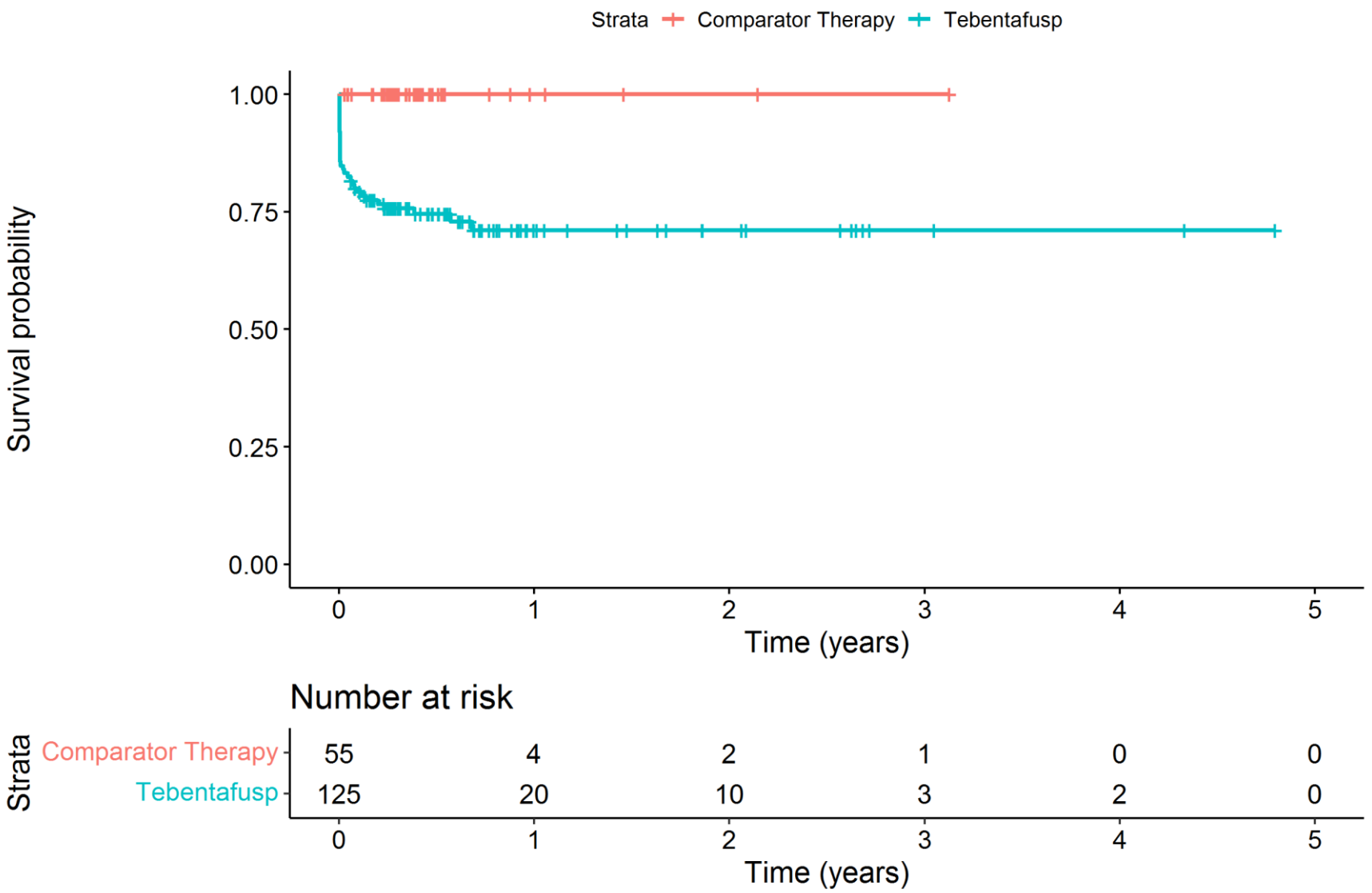
60.42 Erythem - Hispanisch



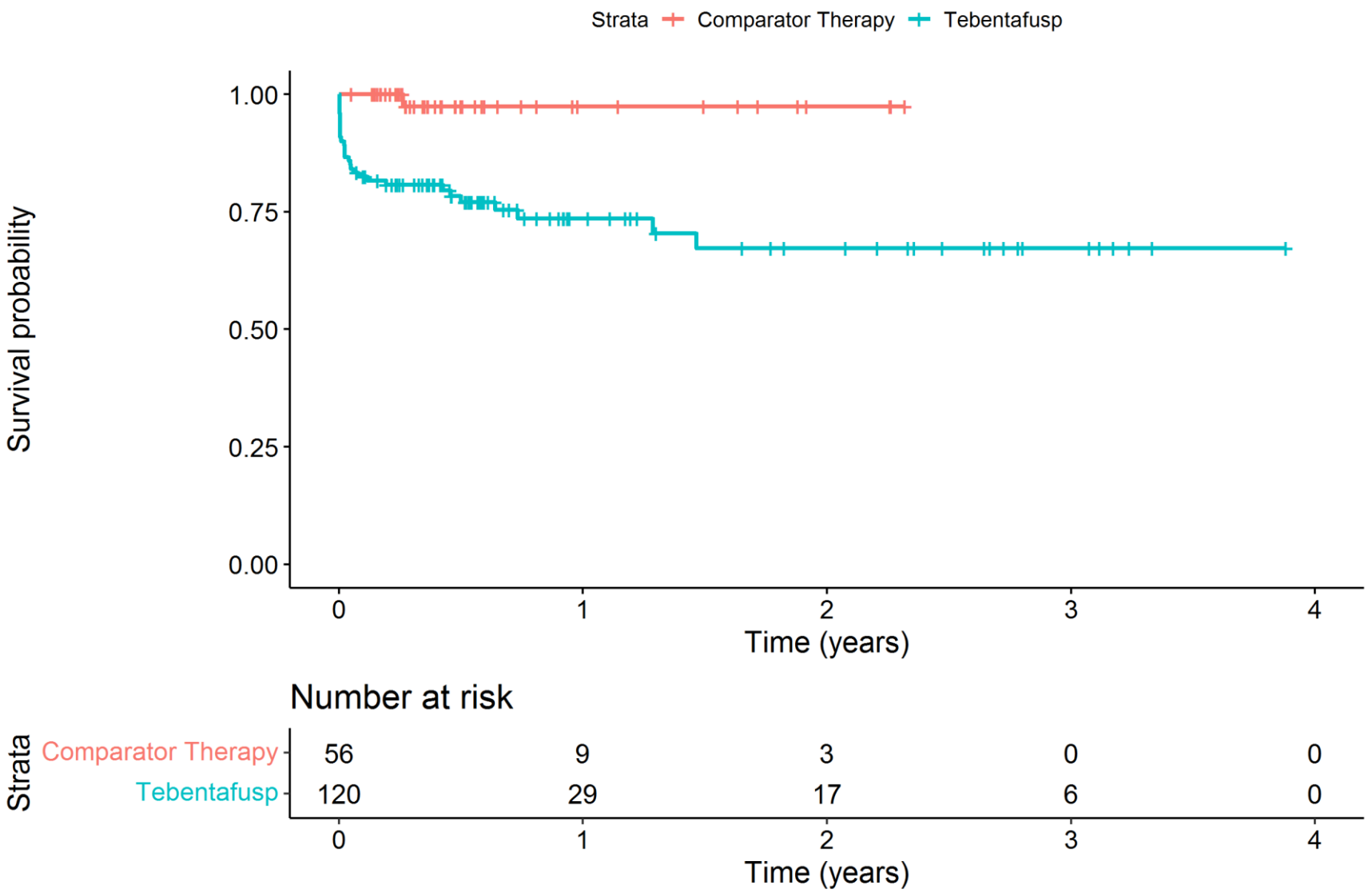
60.43 Erythem - Nicht-hispanisch



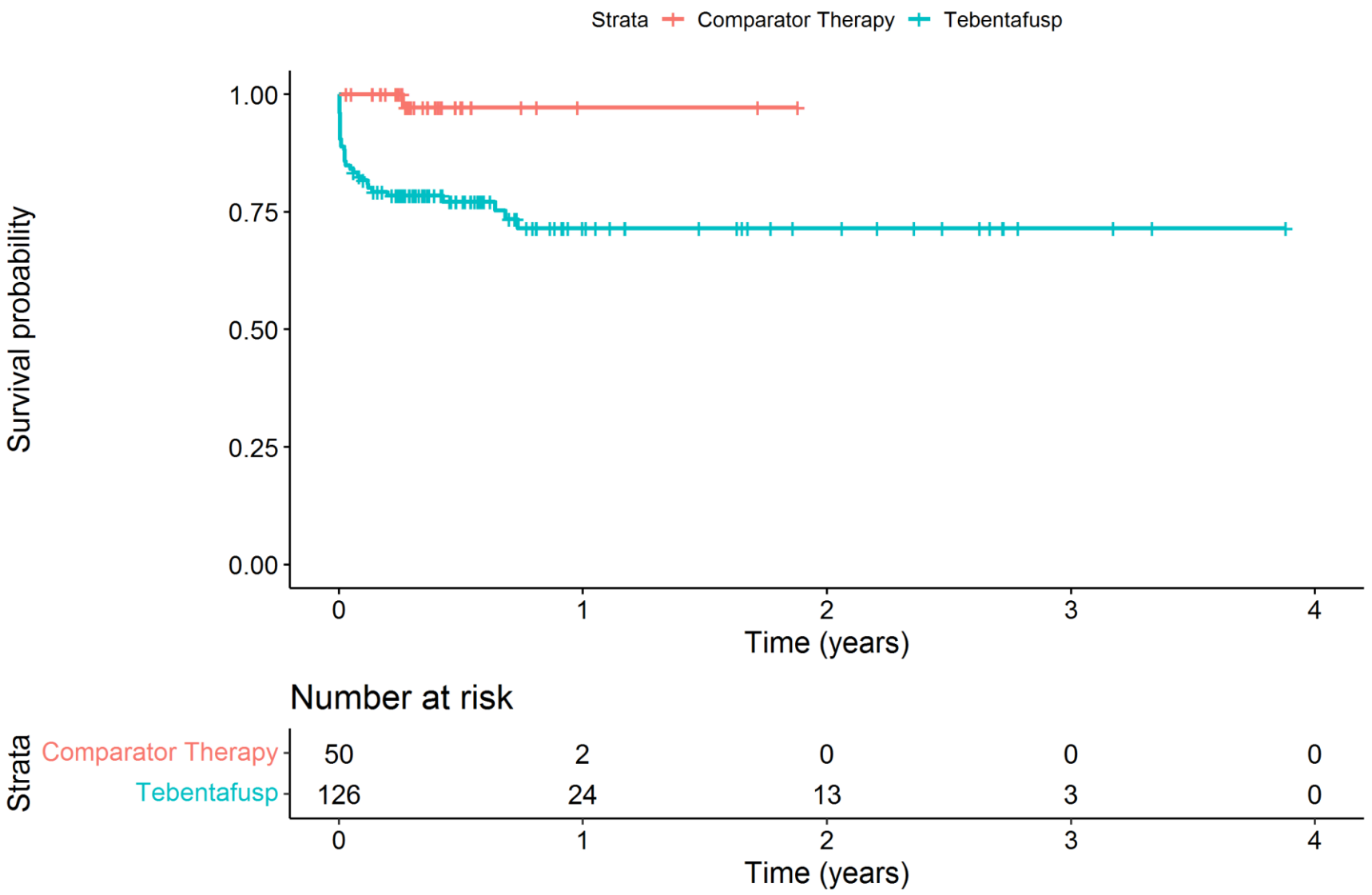
60.44 Erythem - Männlich



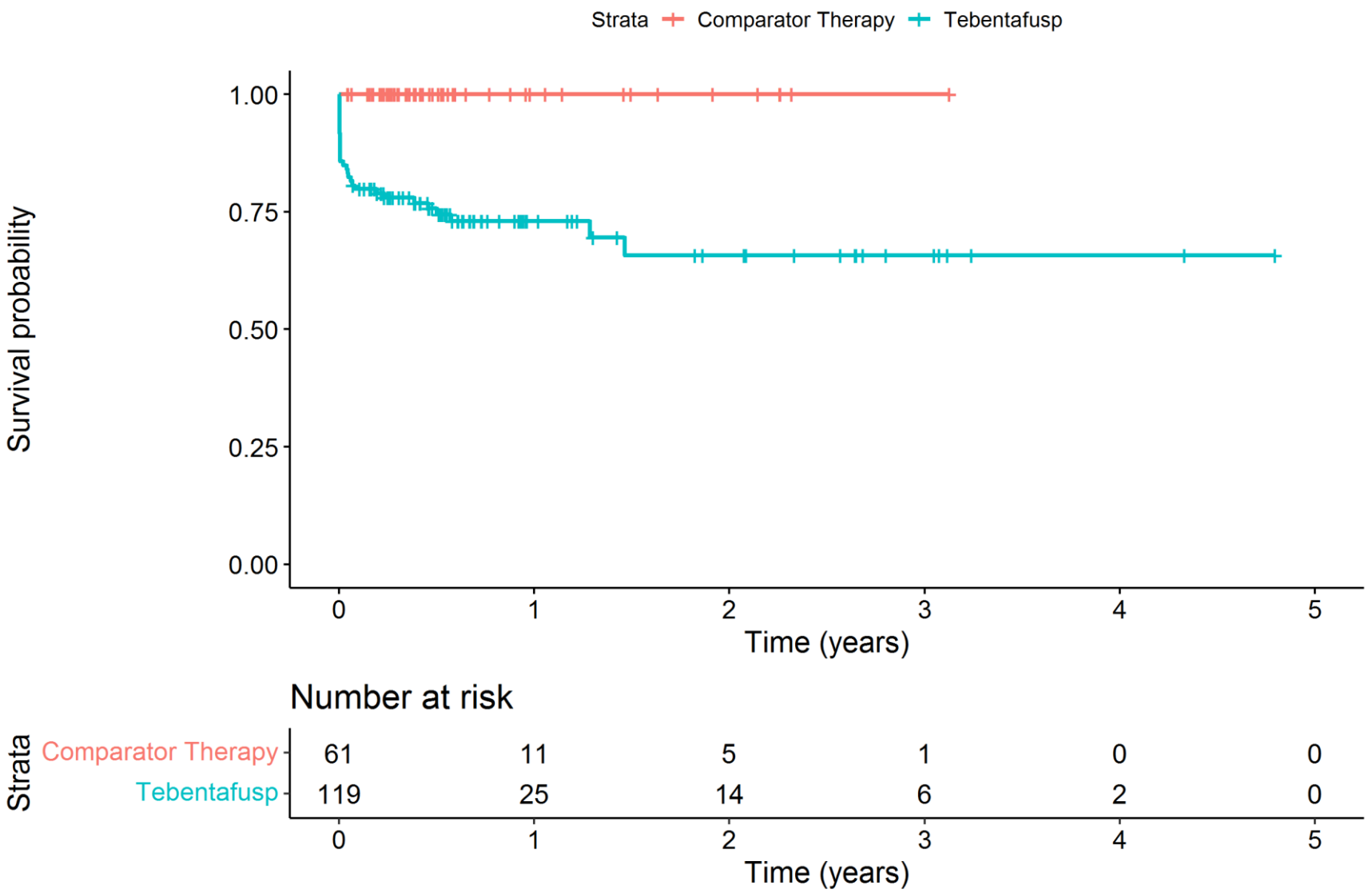
60.45 Erythem - Weiblich



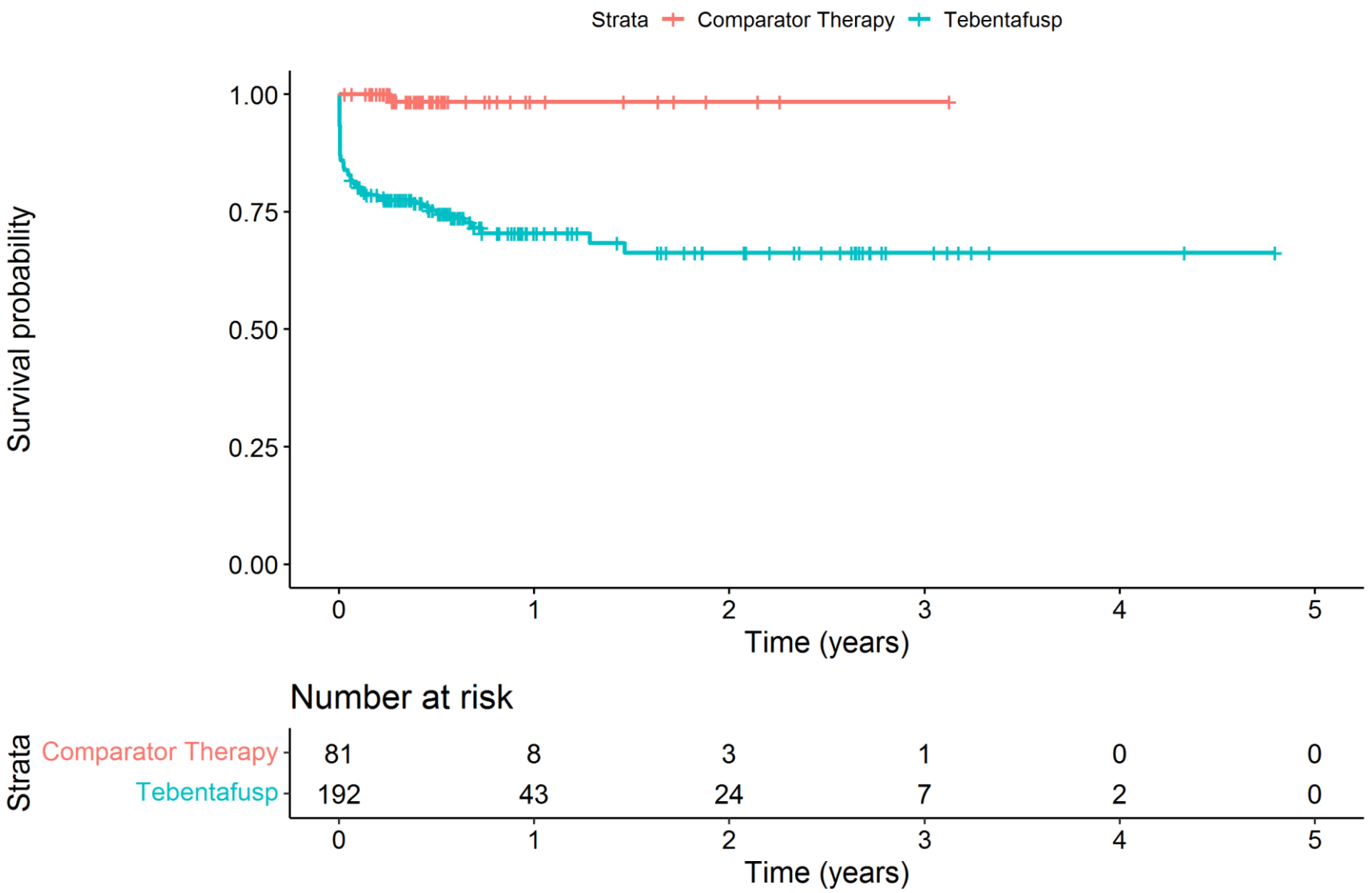
60.46 Erythem - <65



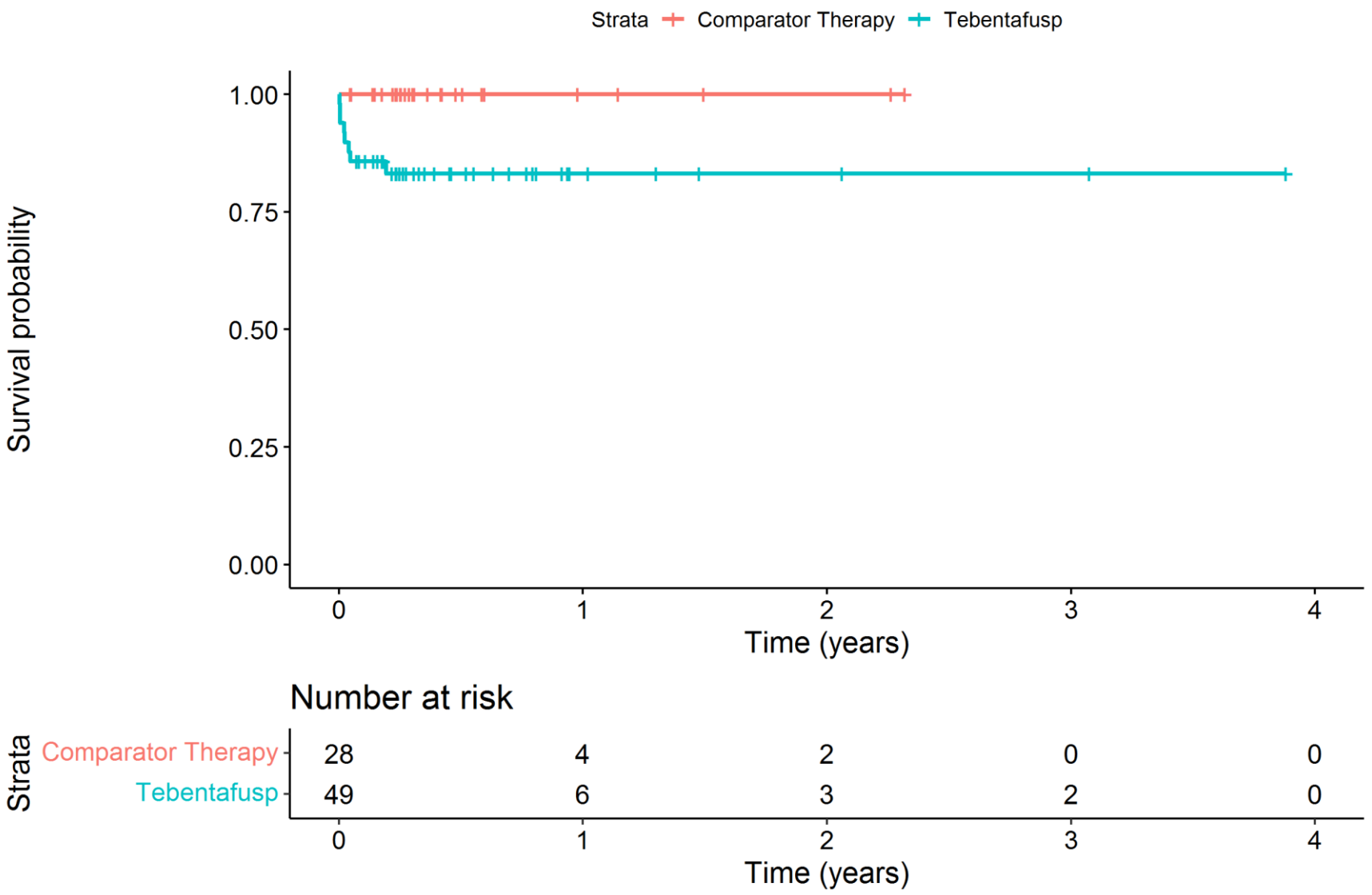
60.47 Erythem - ≥65



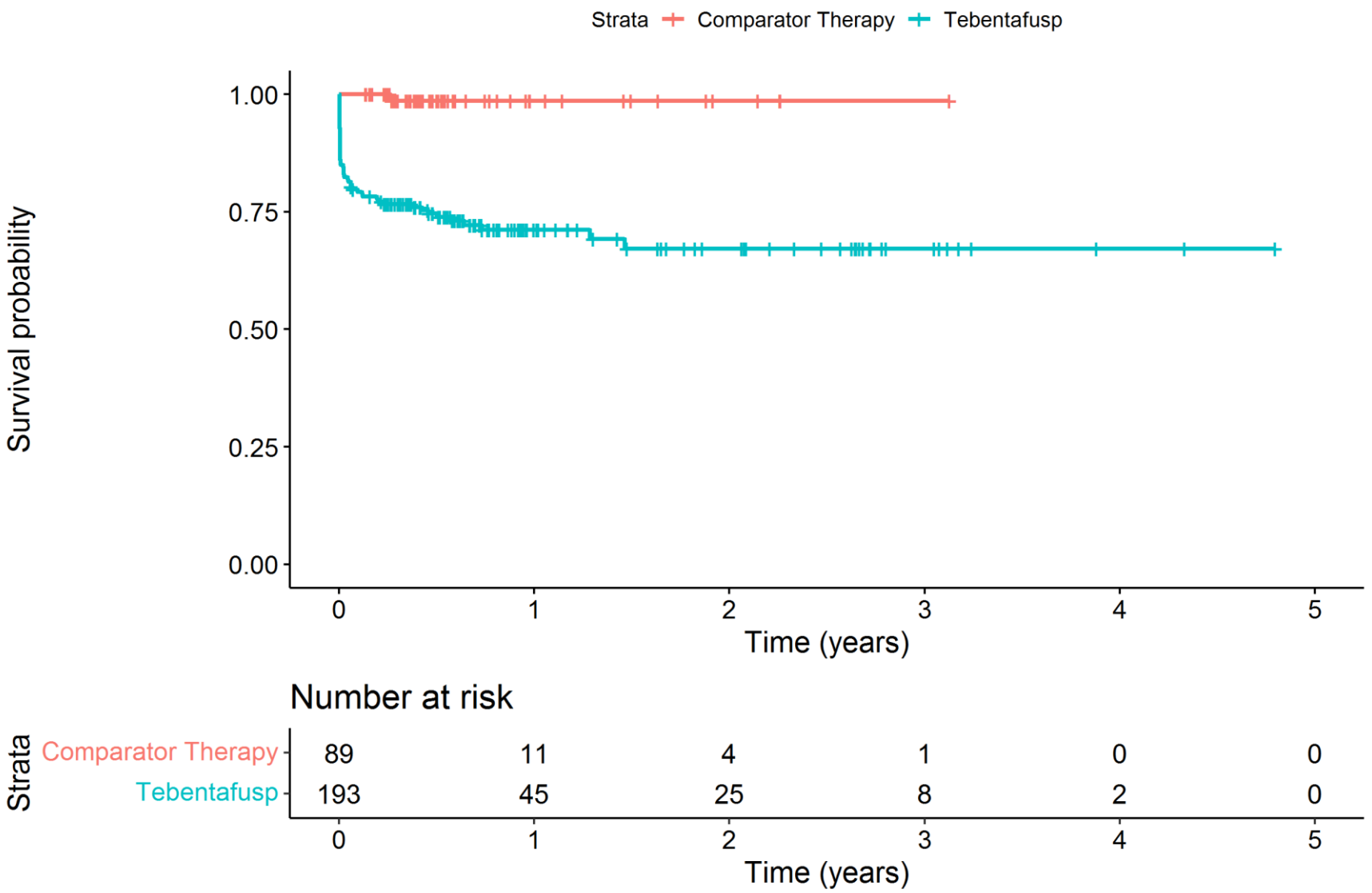
60.48 Erythem - ECOG 0



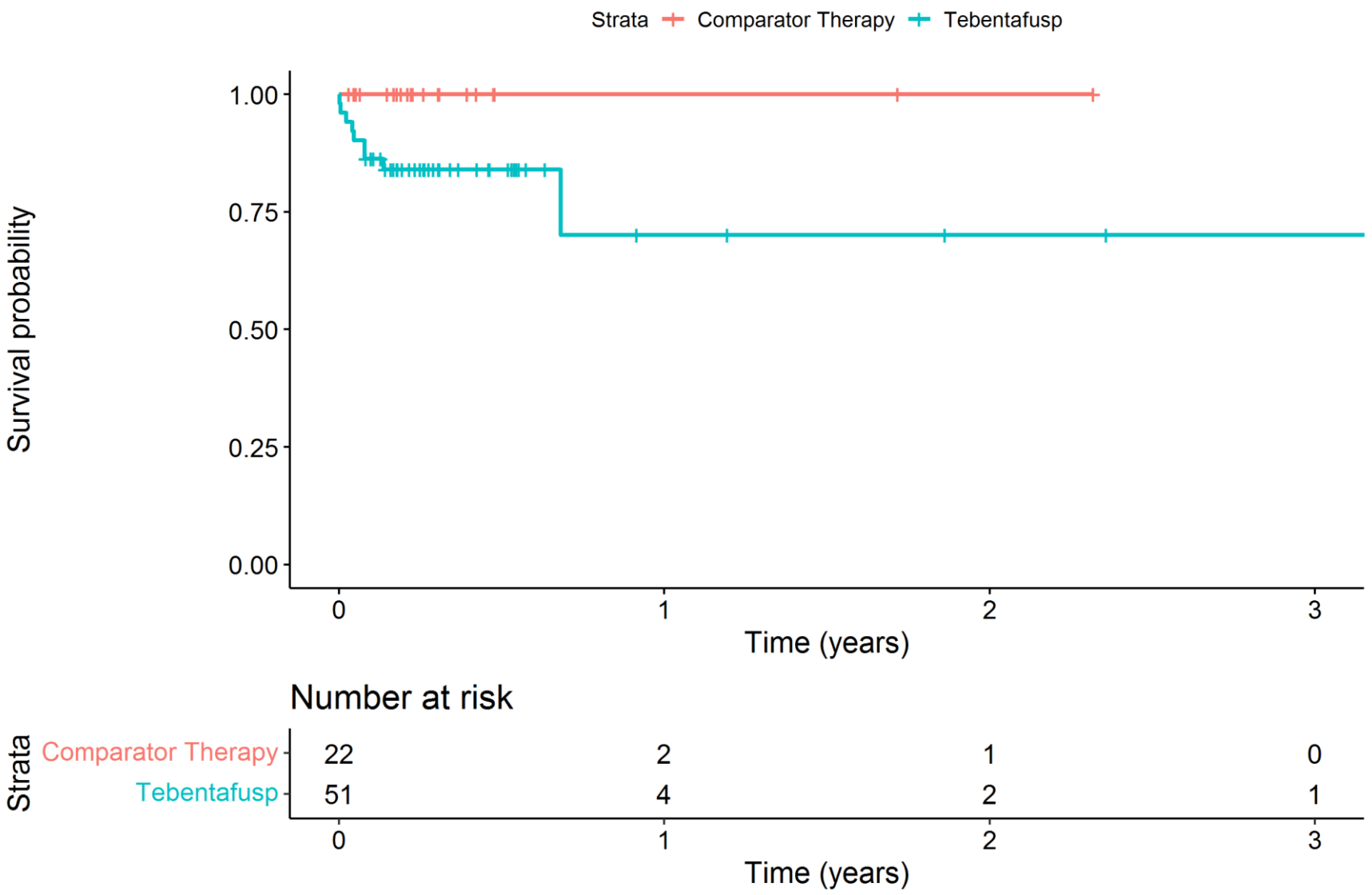
60.49 Erythem - ECOG 1



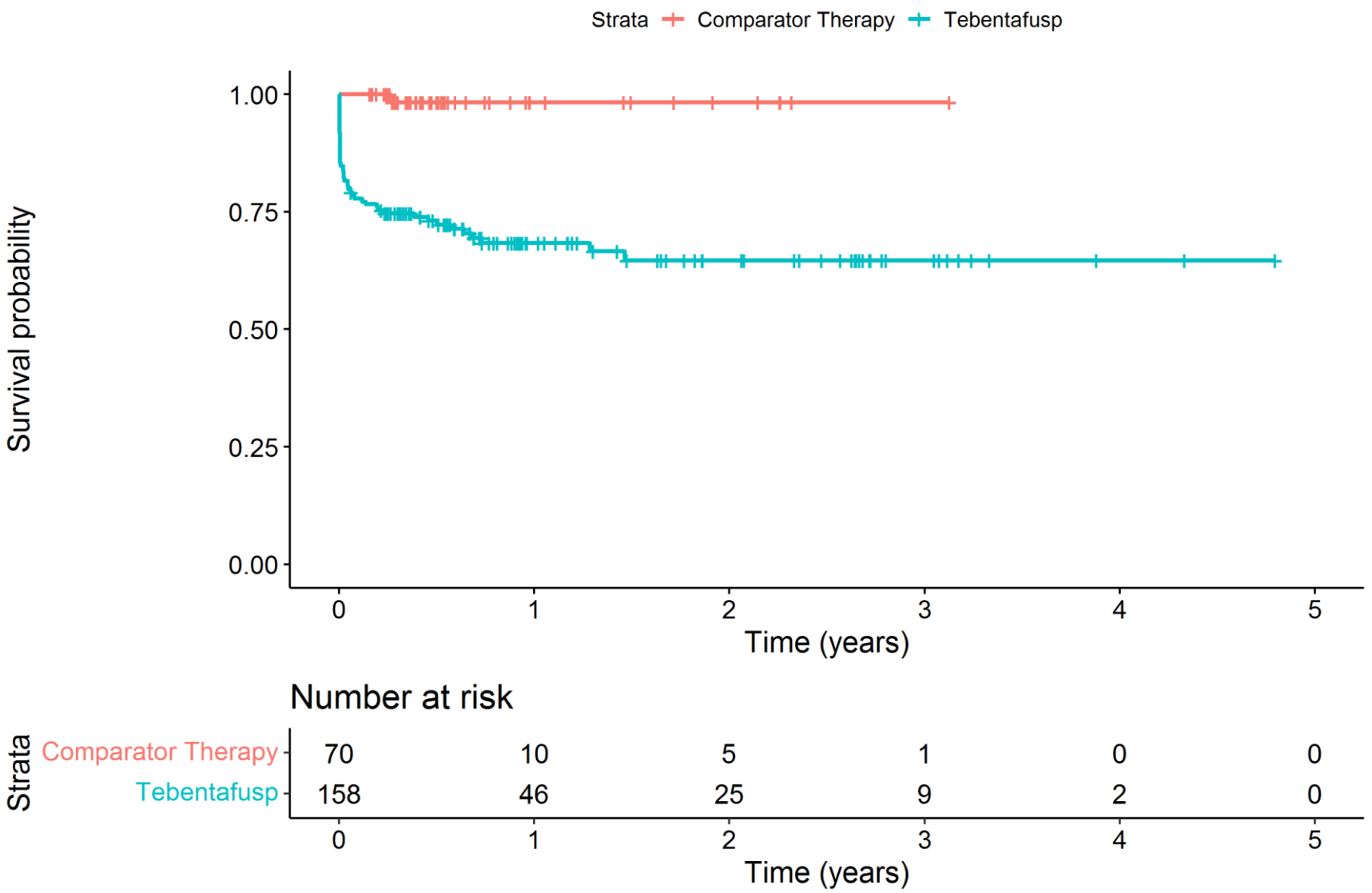
60.50 Erythem - ALP ≤ ULN



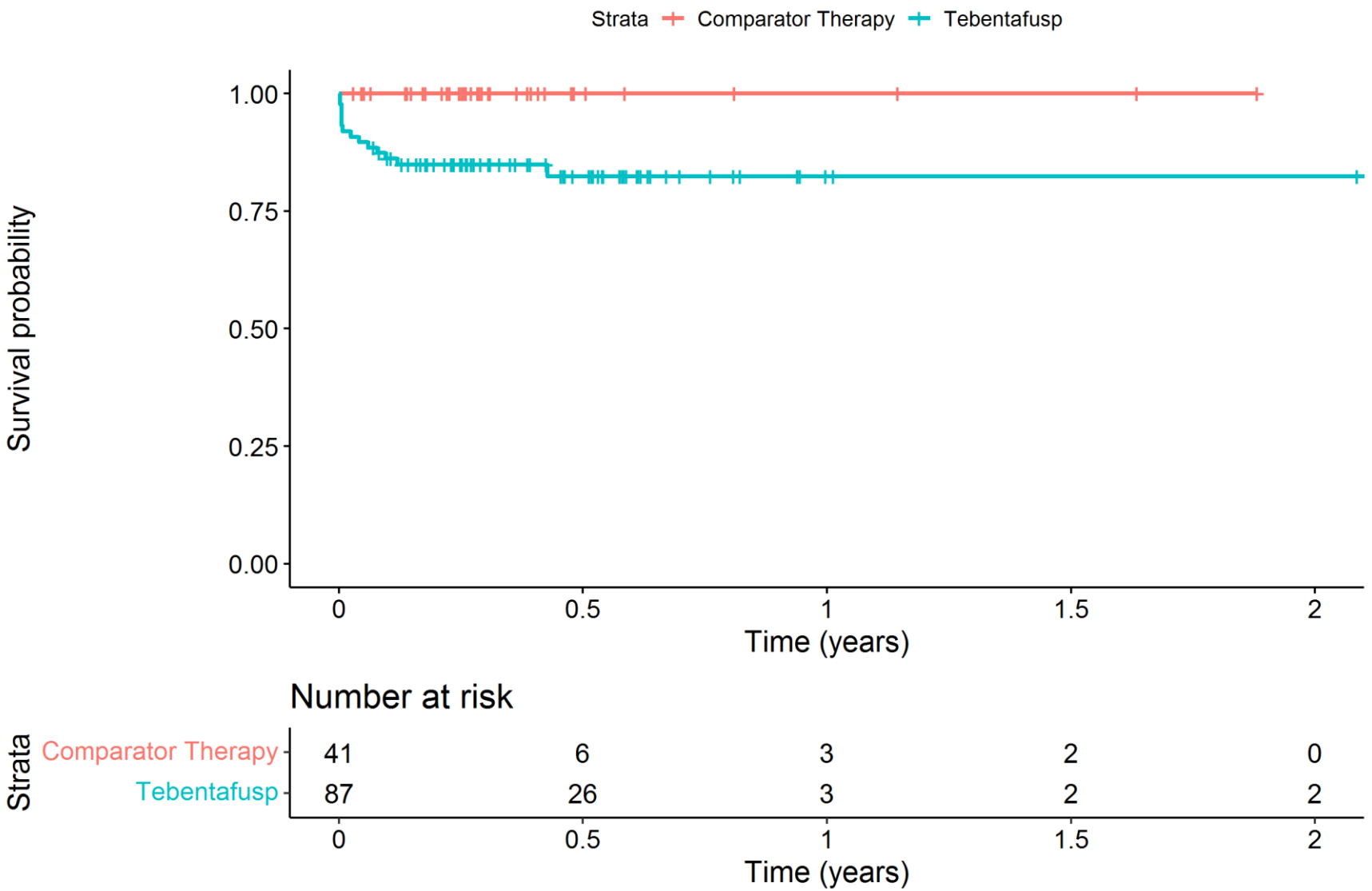
60.51 Erythem - ALP > ULN



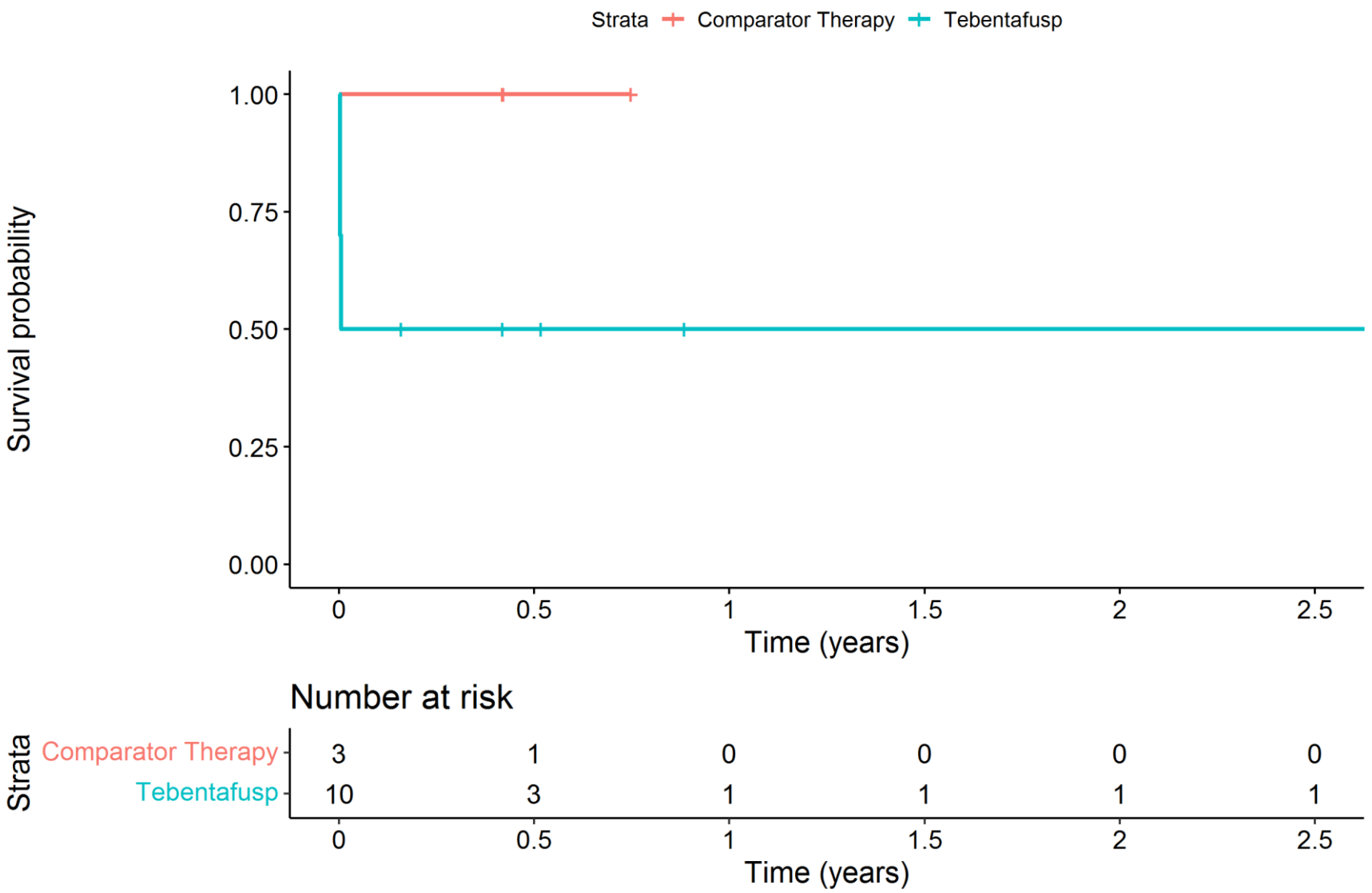
60.52 Erythem - LDH =< ULN



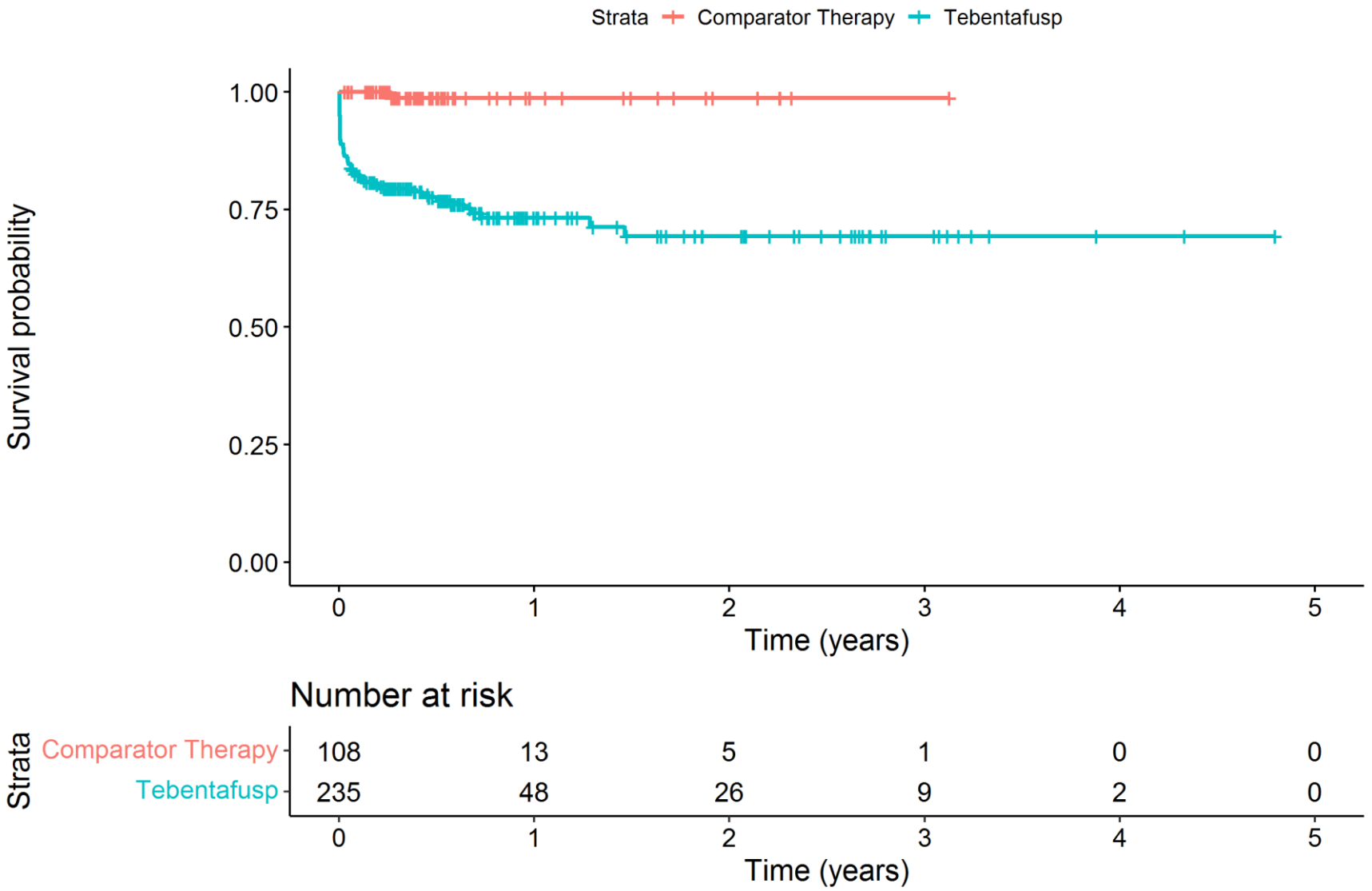
Erythem - LDH > ULN



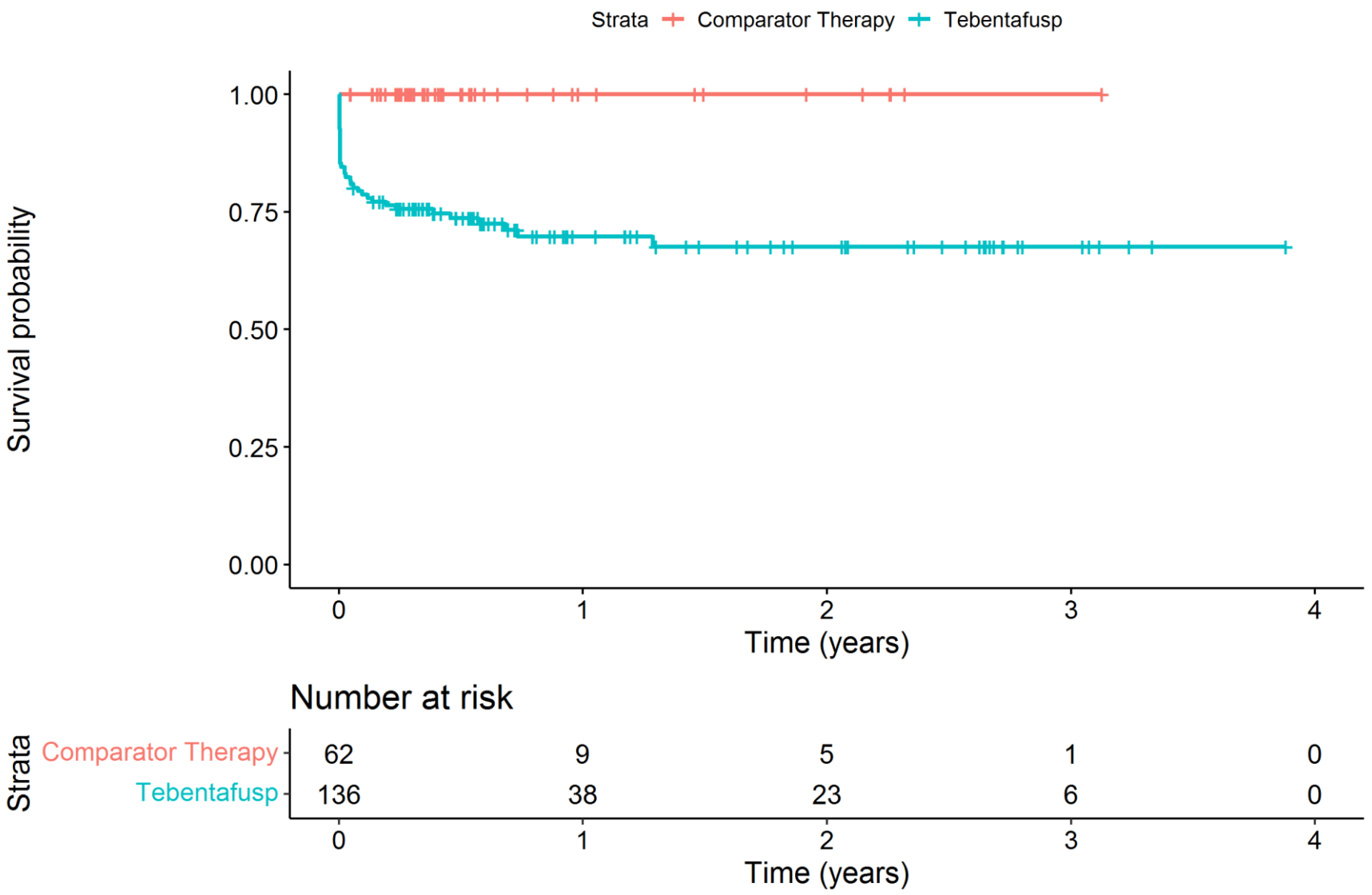
60.53 Erythem - Vorherige Therapie adjuvant/neoadjuvant



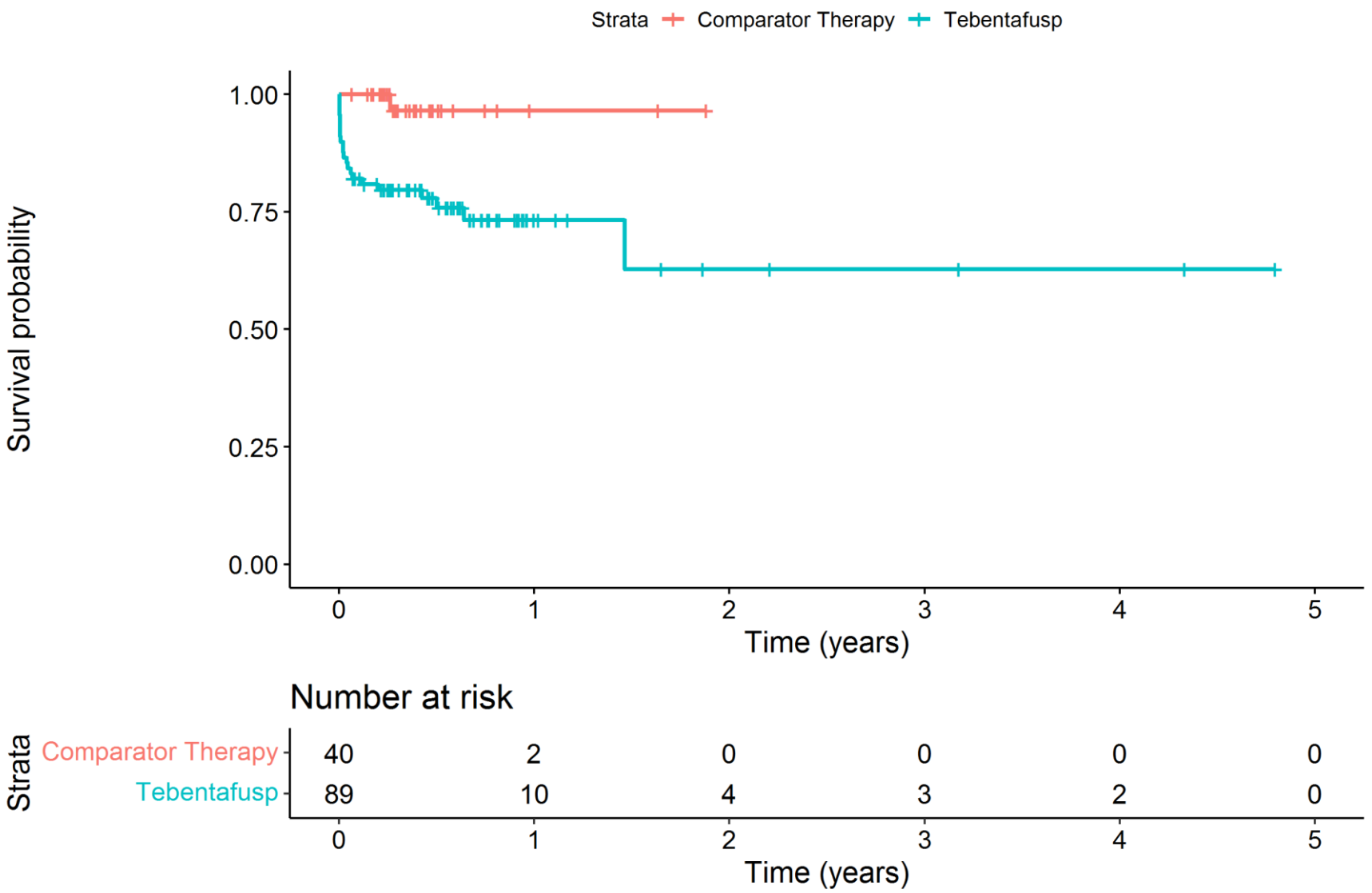
60.54 Erythem - Keine Vorherige Therapie adjuvant/neoadjuvant



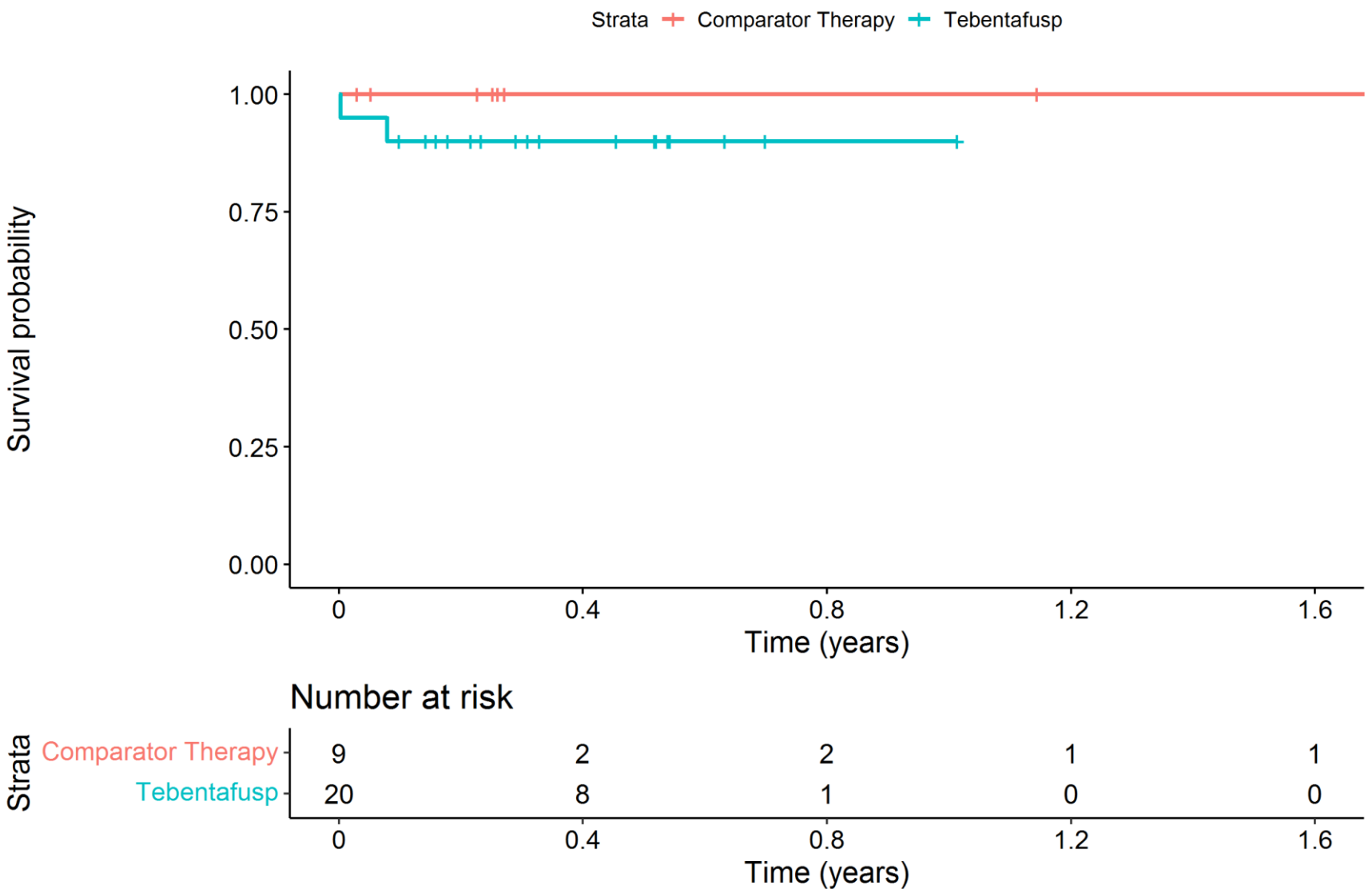
60.55 Erythem - Läsion ≤ 3cm



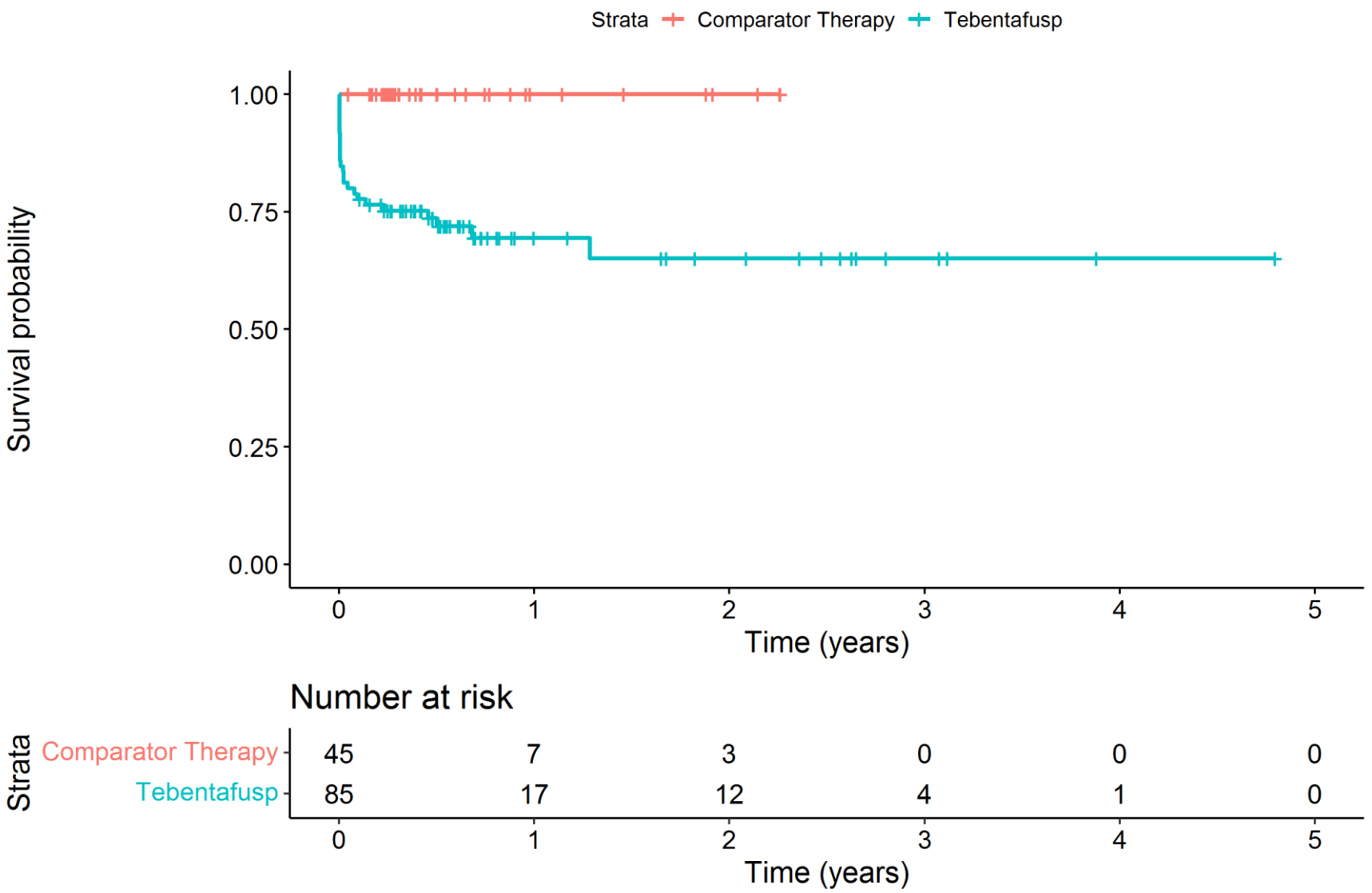
60.56 Erythem - Läsion 3,1-8,0 cm



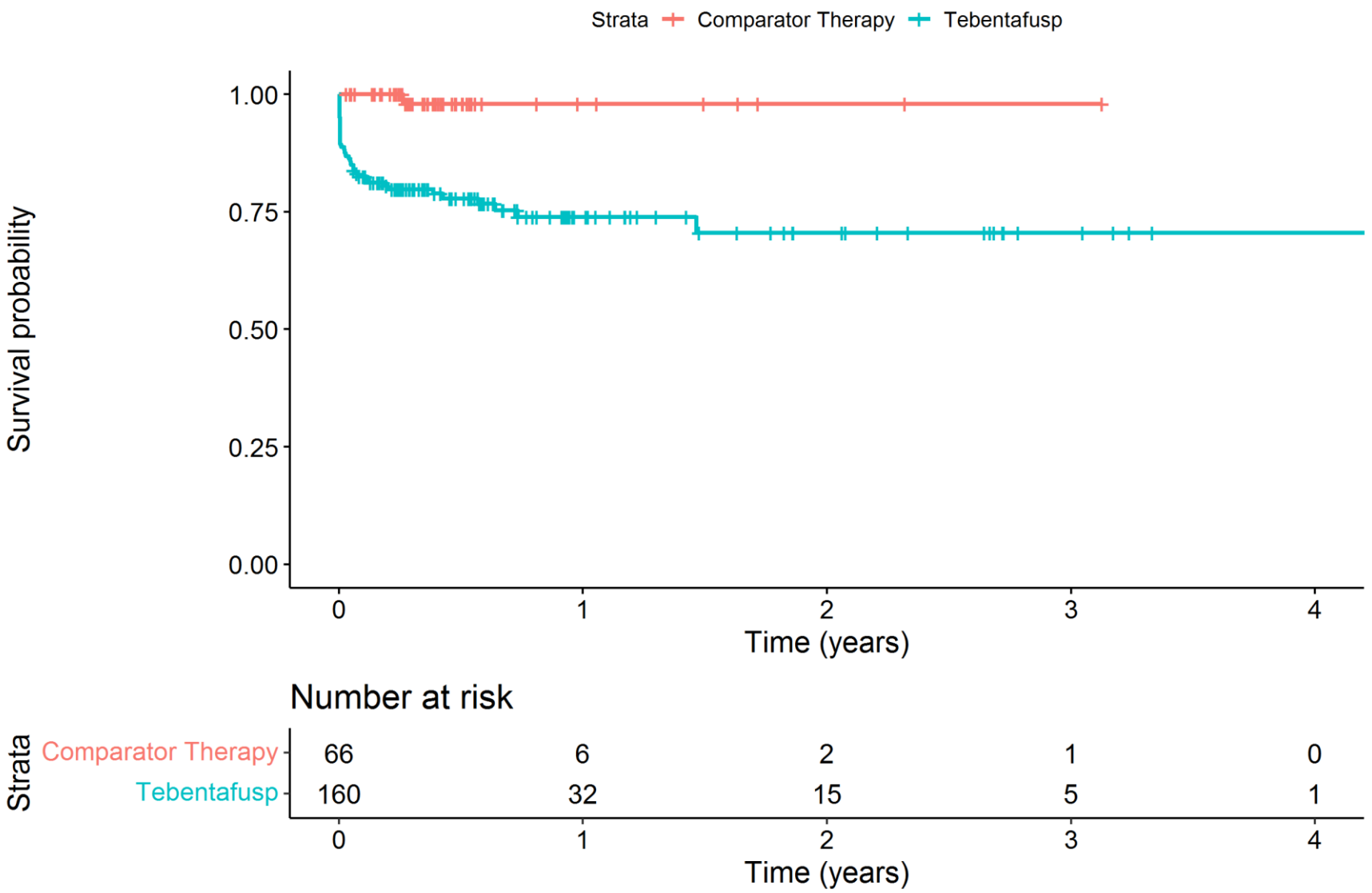
60.57 Erythem - Läsion ≥8,1 cm



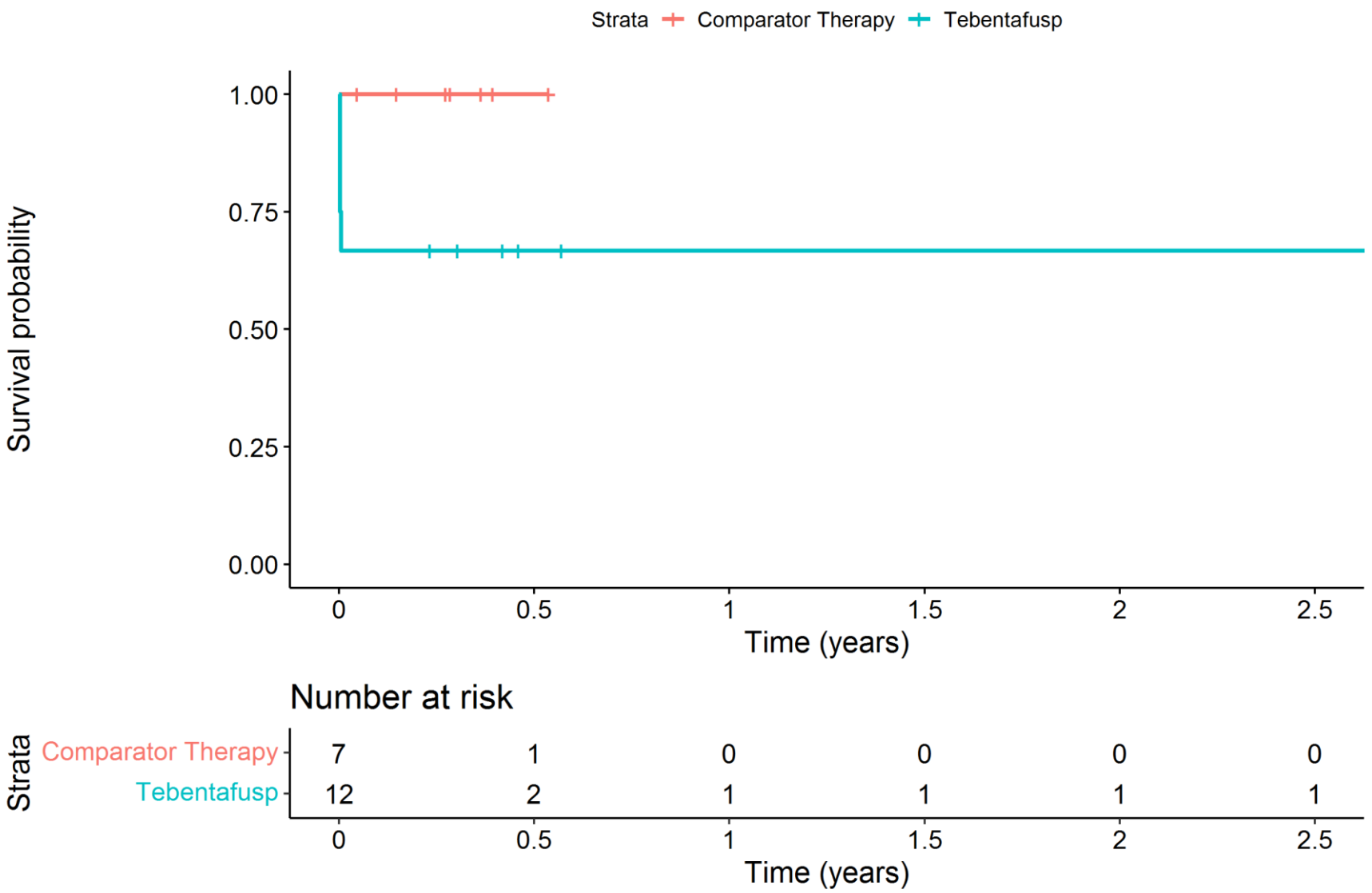
60.58 Erythem - Nordamerika



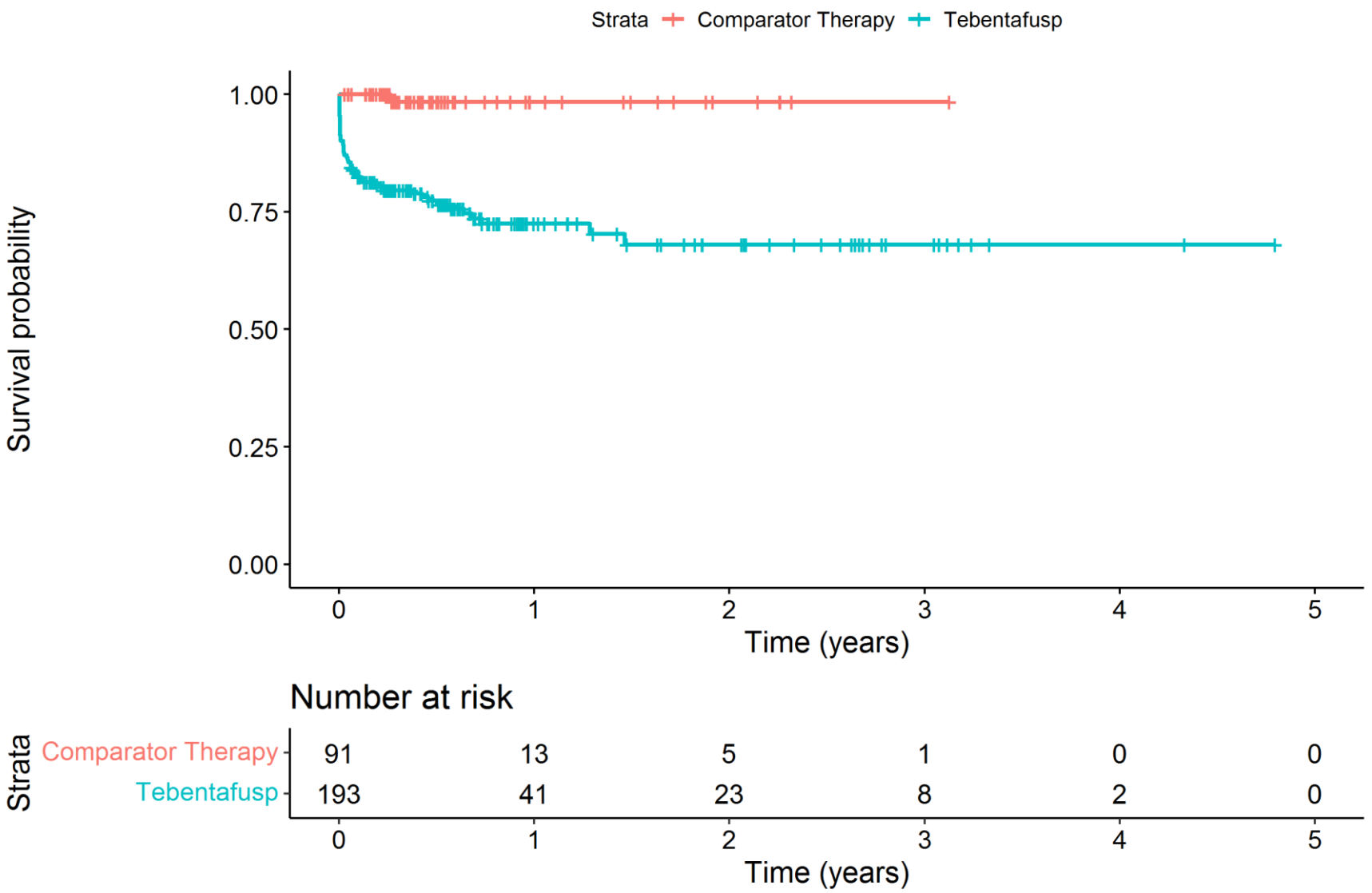
60.59 Erythem - Nicht-Nordamerika



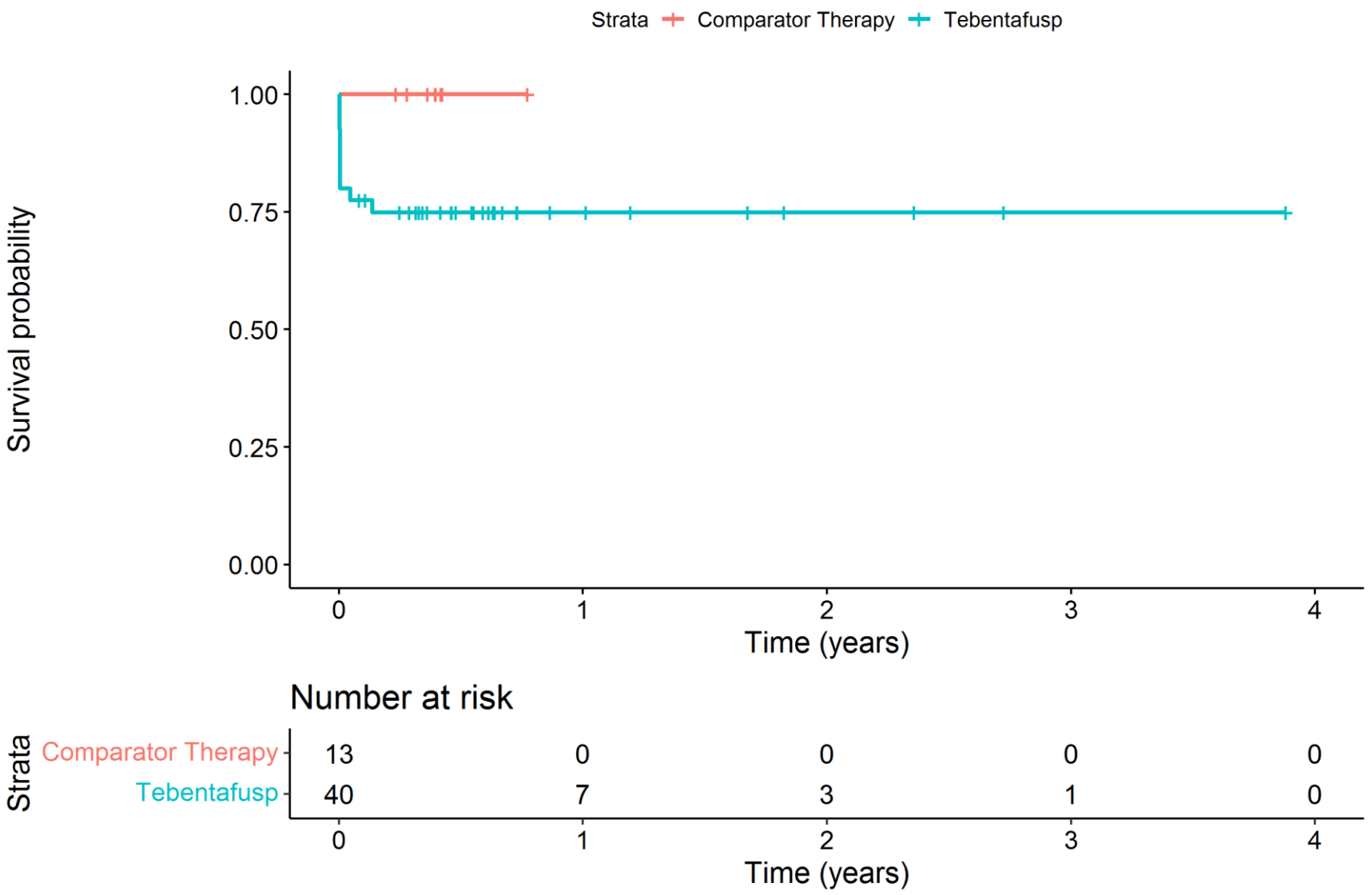
60.60 Erythem - Dacarbazin



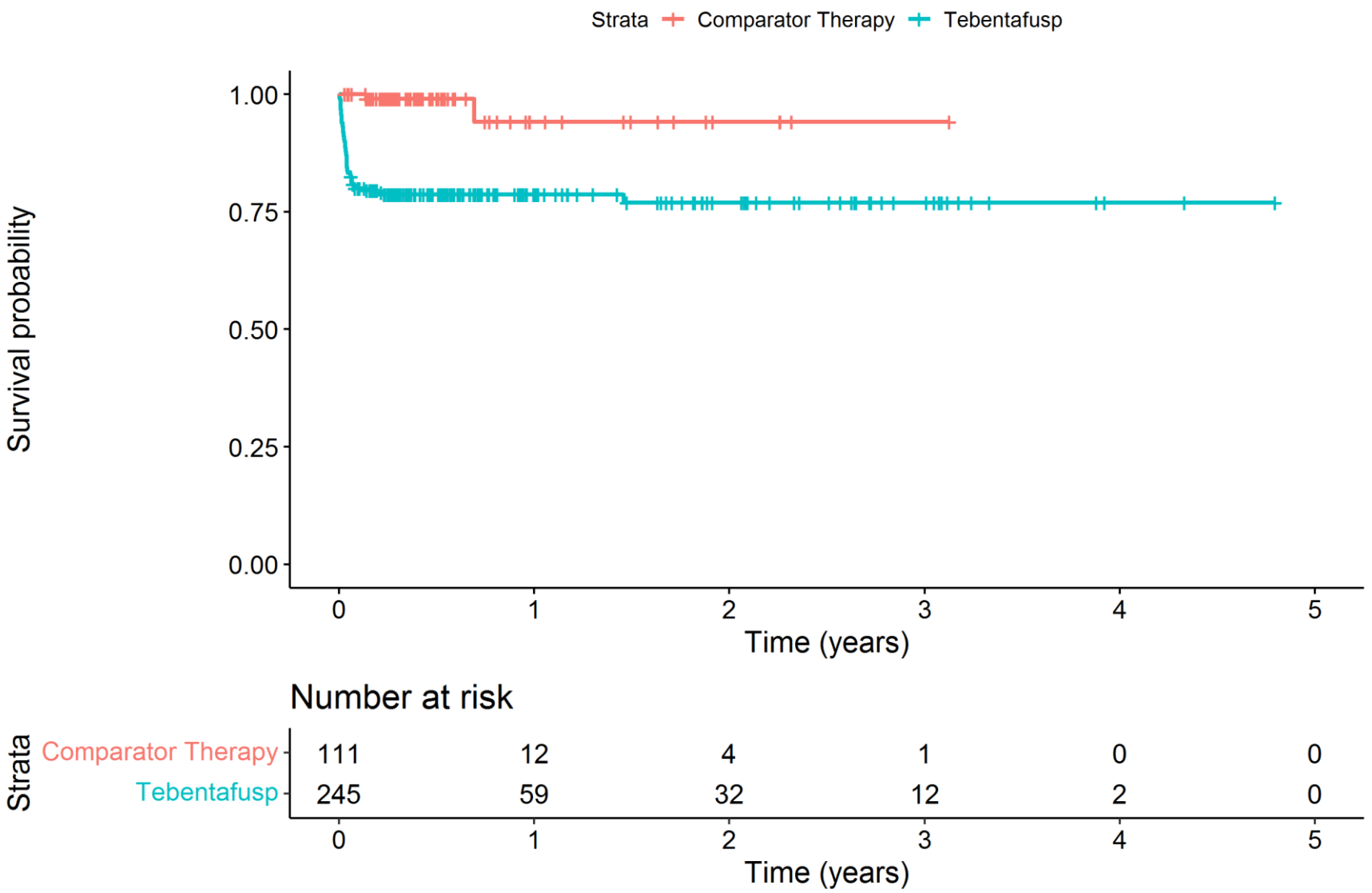
60.61 Erythem - Pembrolizumab



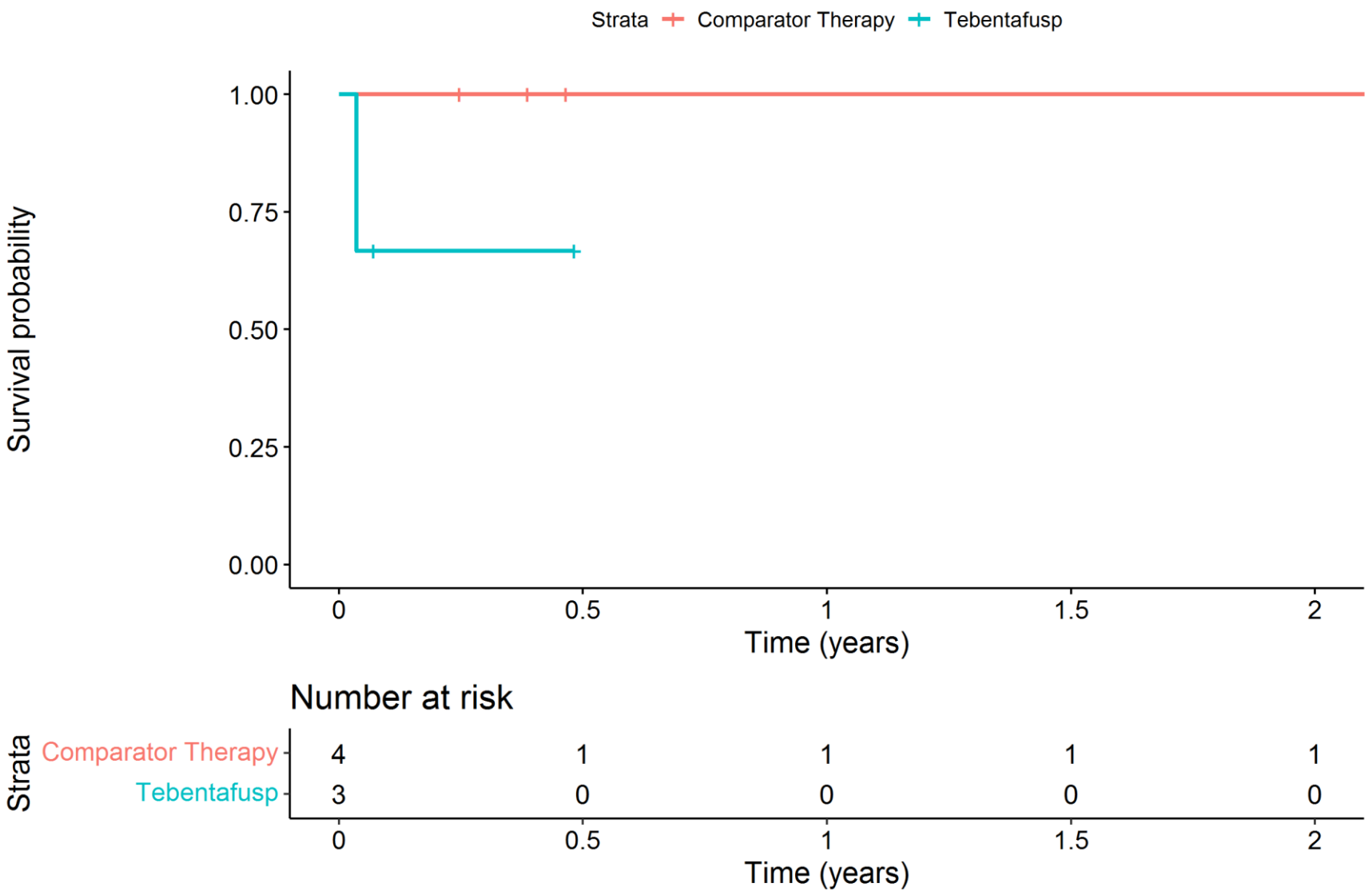
60.62 Erythem - Ipilimumab



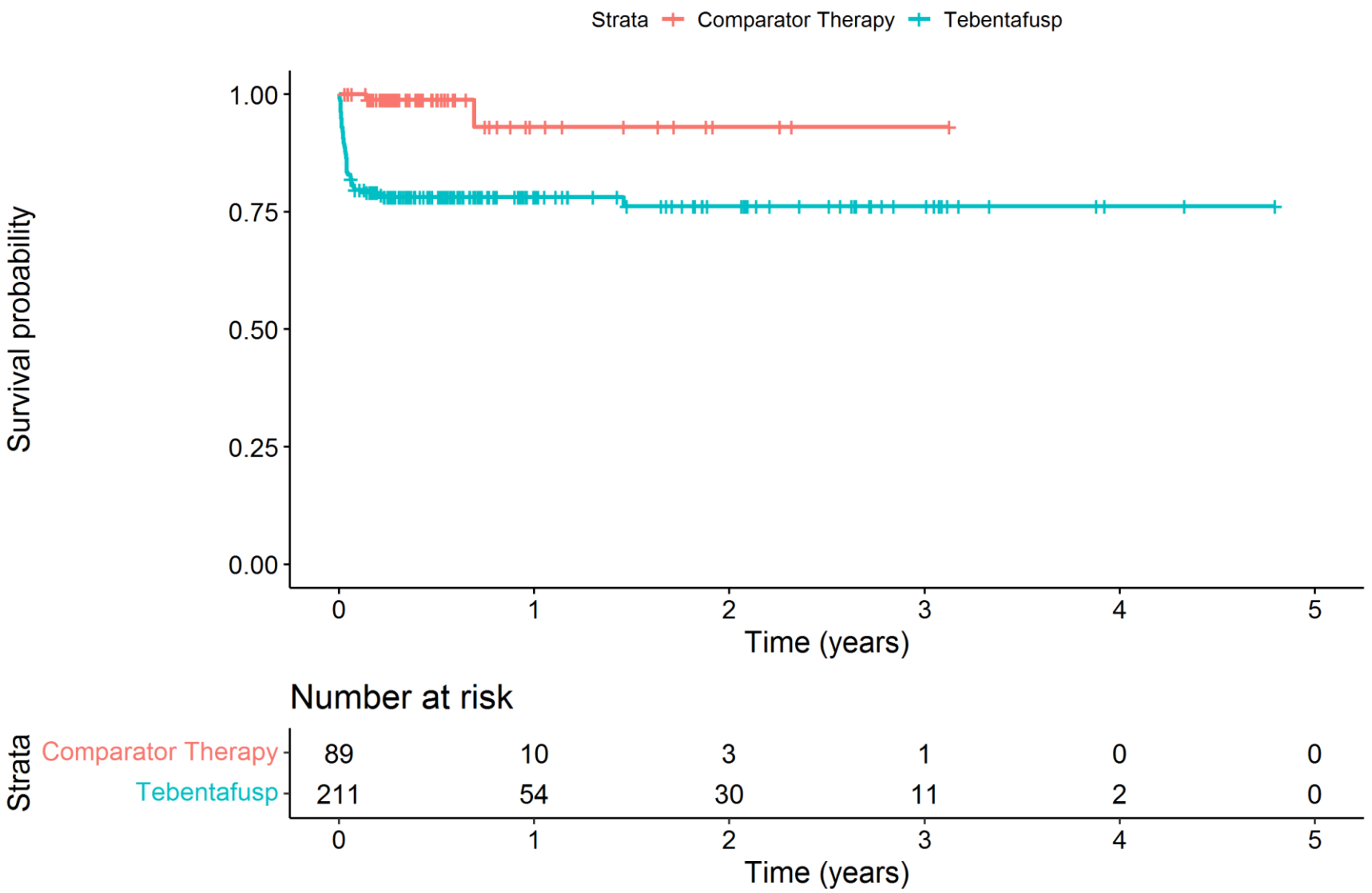
60.63 Exfoliation der Haut - Gesamt



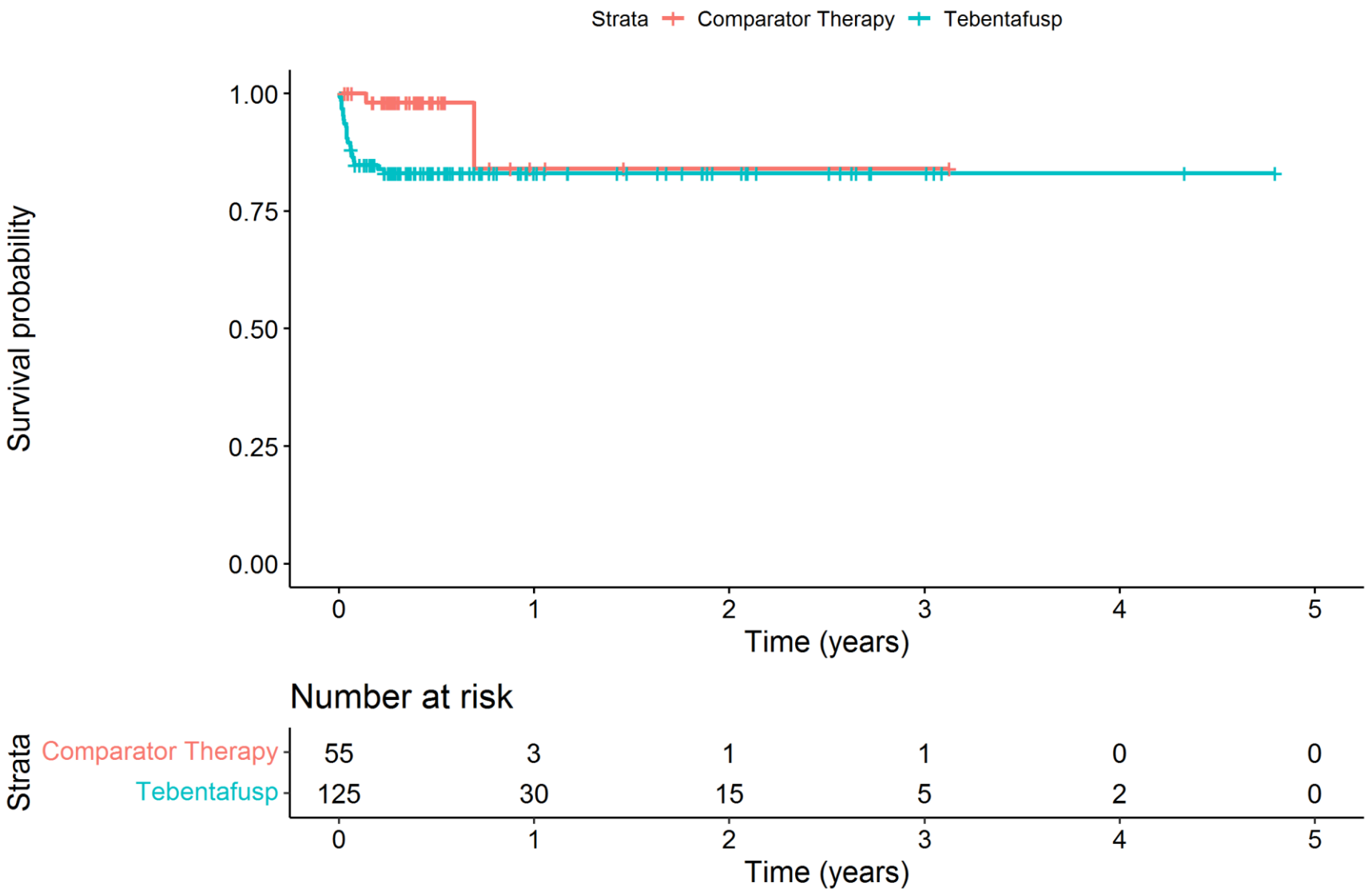
60.64 Exfoliation der Haut - Hispanisch



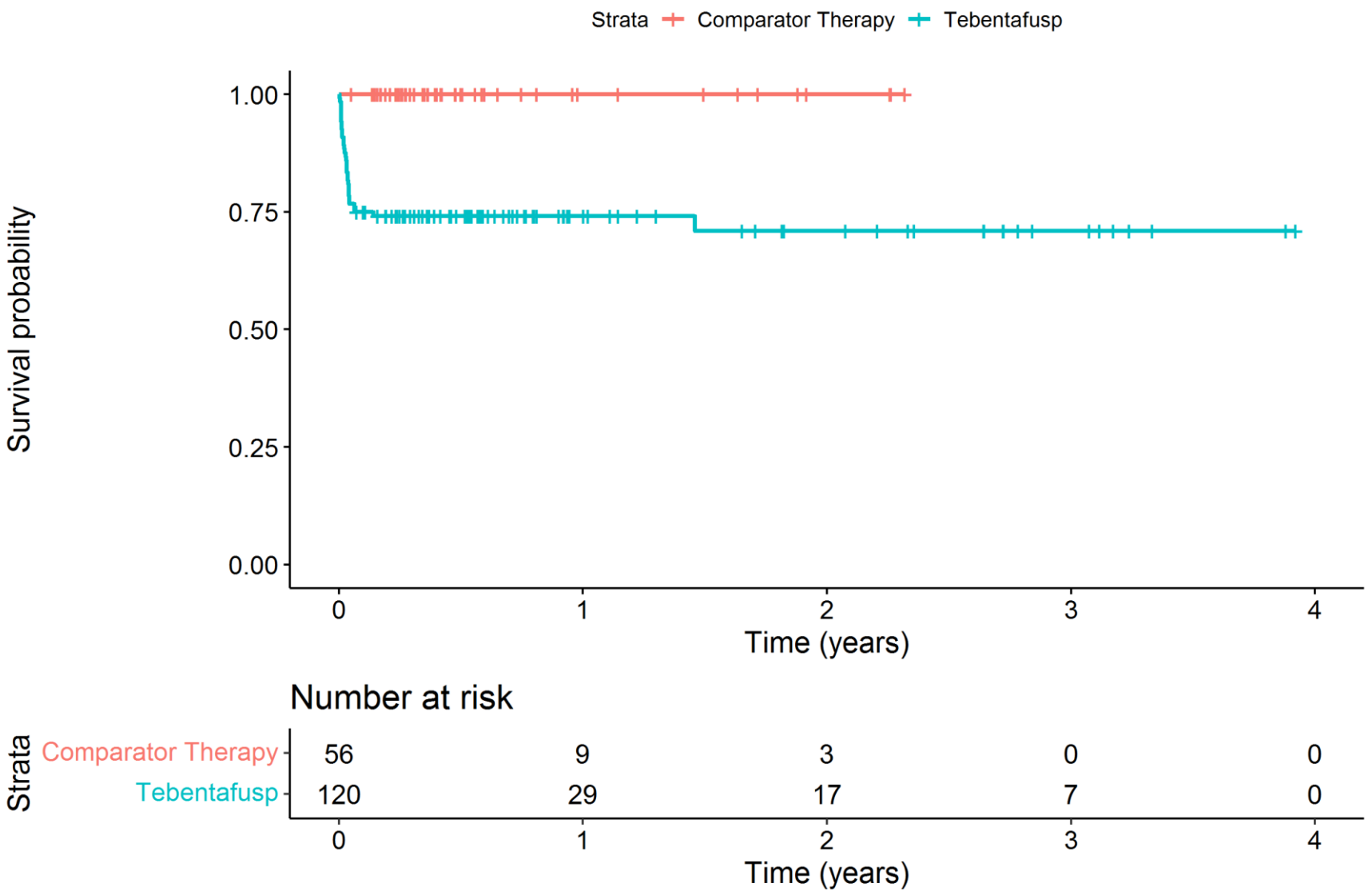
60.65 Exfoliation der Haut - Nicht-hispanisch



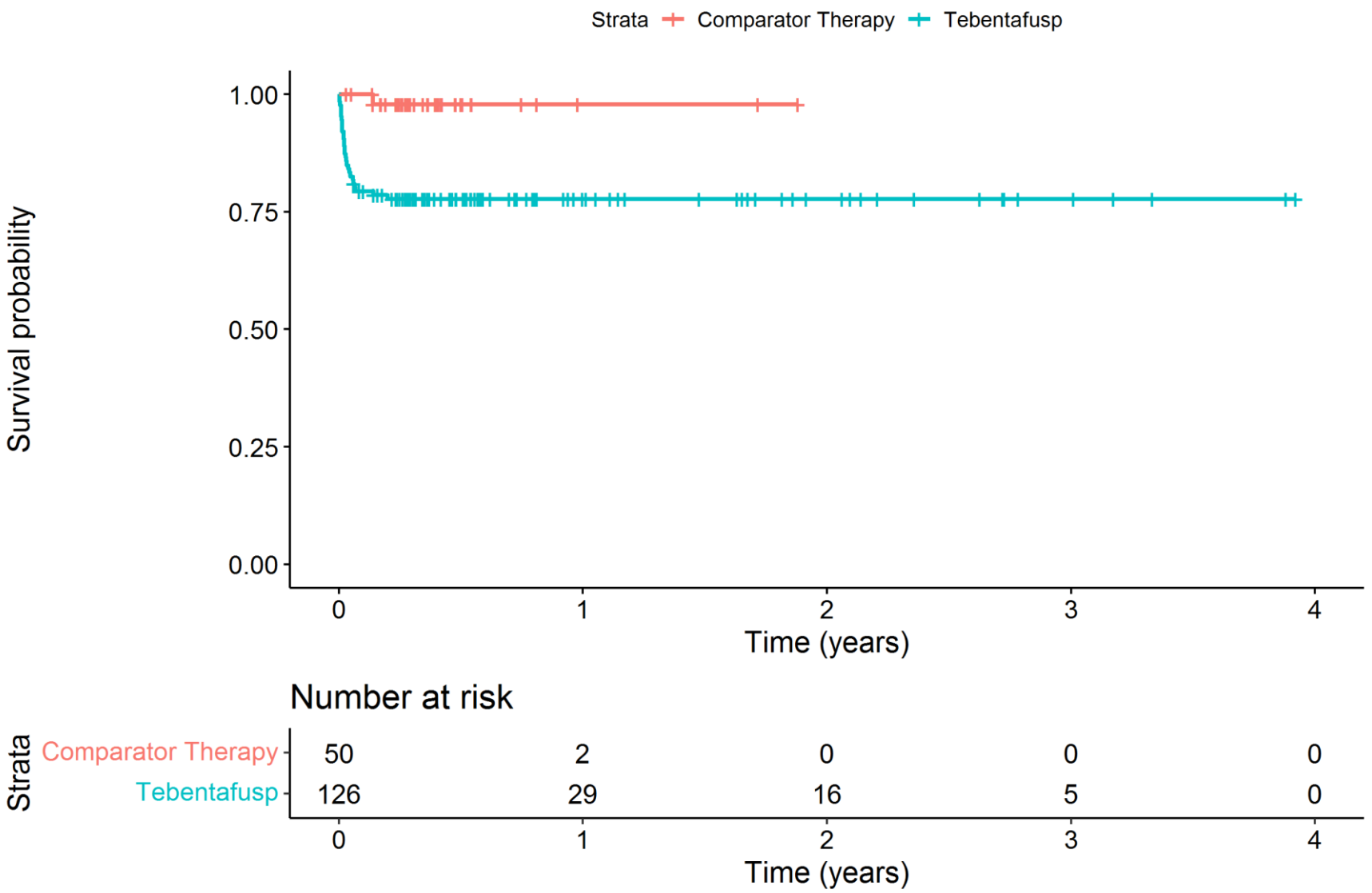
Exfoliation der Haut - Männlich



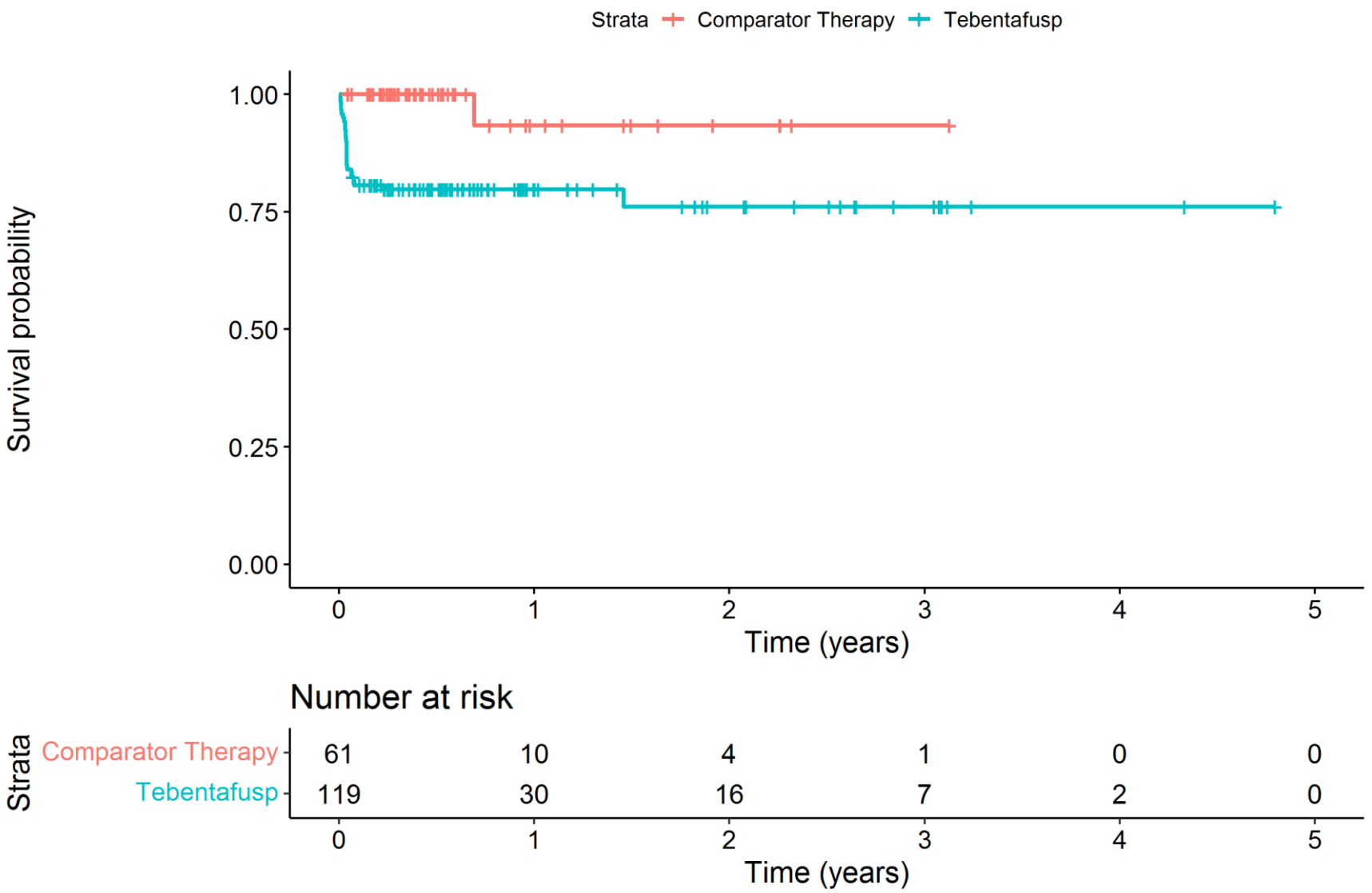
60.66 Exfoliation der Haut - Weiblich



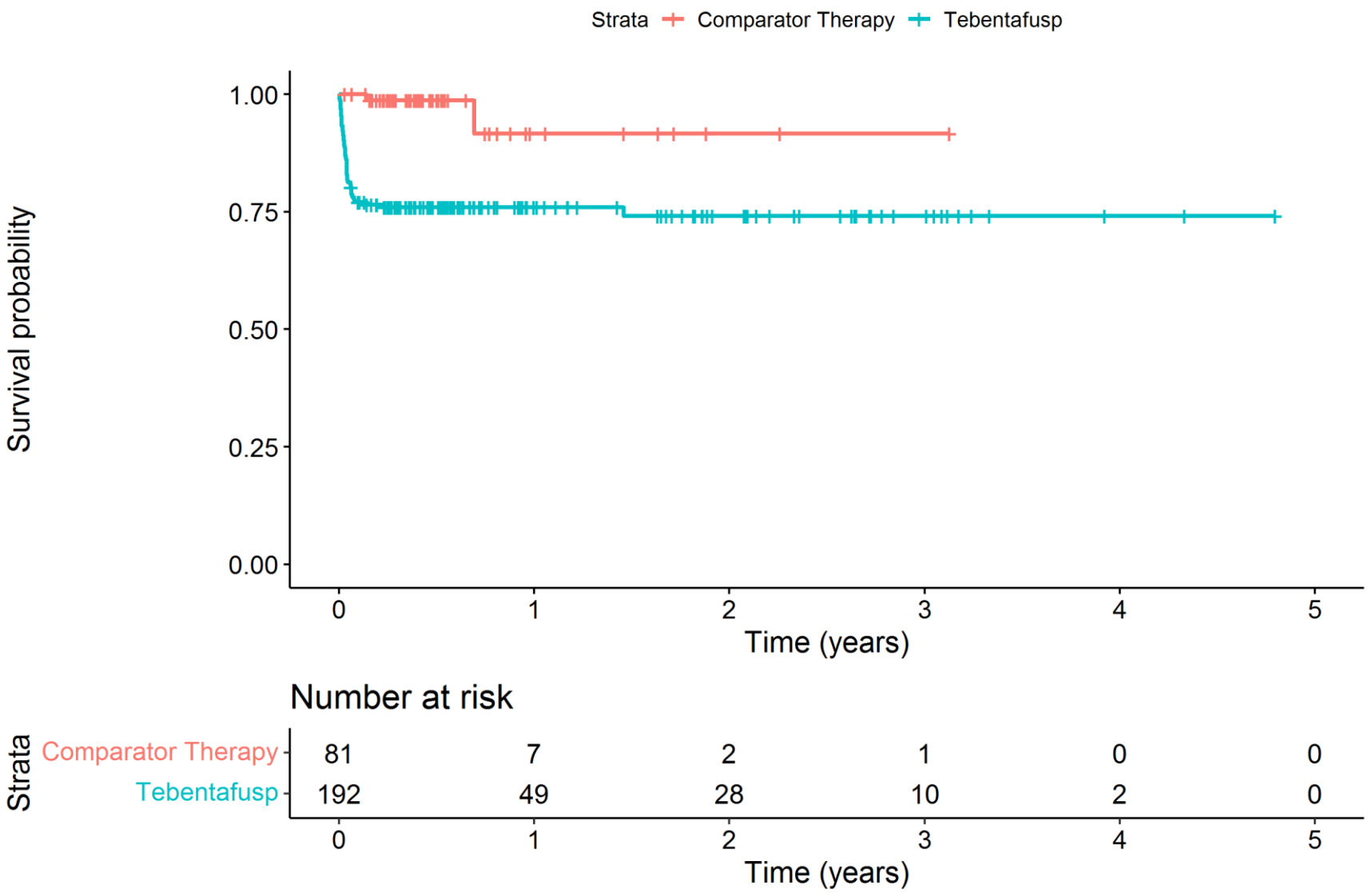
60.67 Exfoliation der Haut - <65



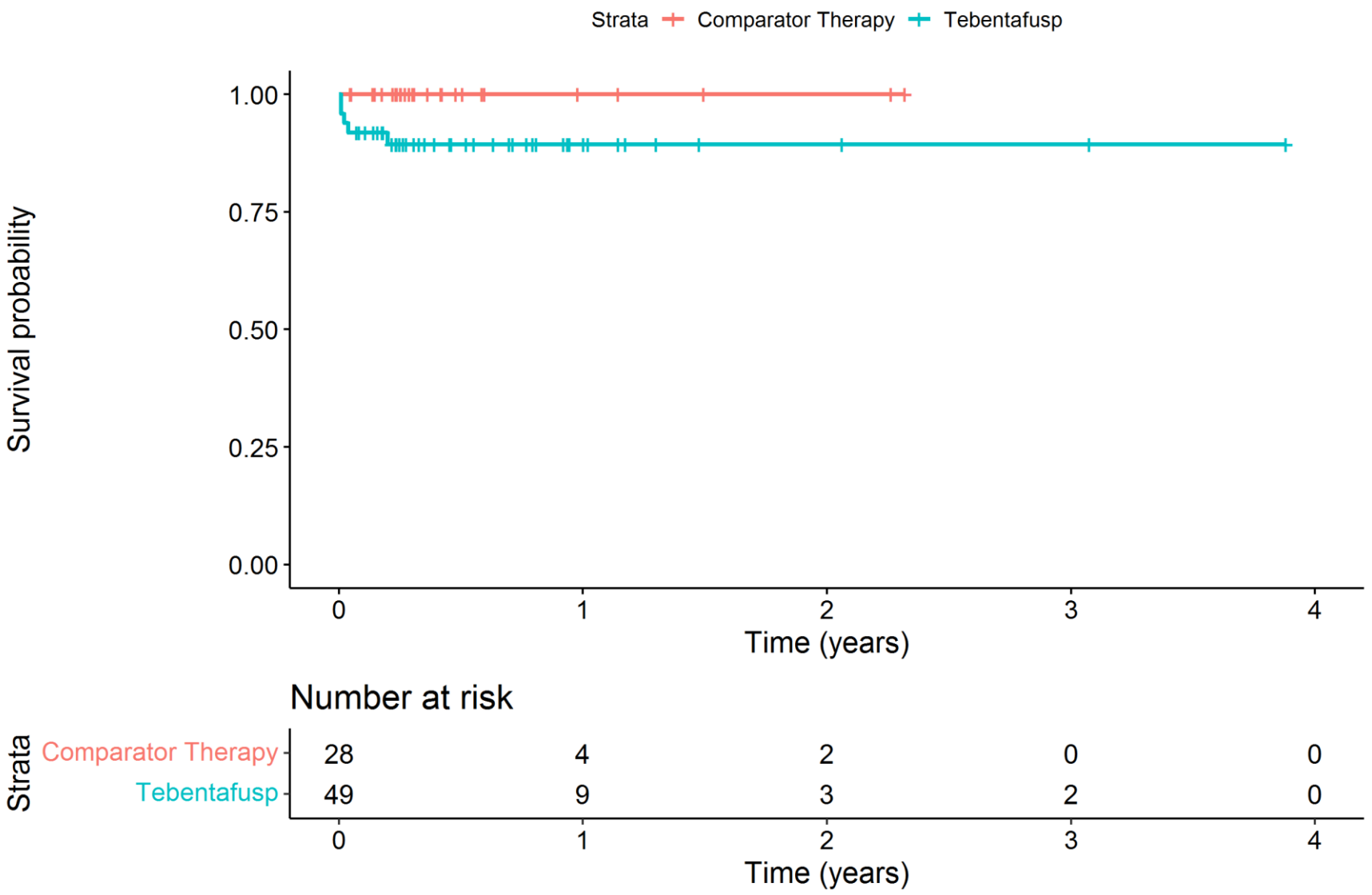
60.68 Exfoliation der Haut - ≥65



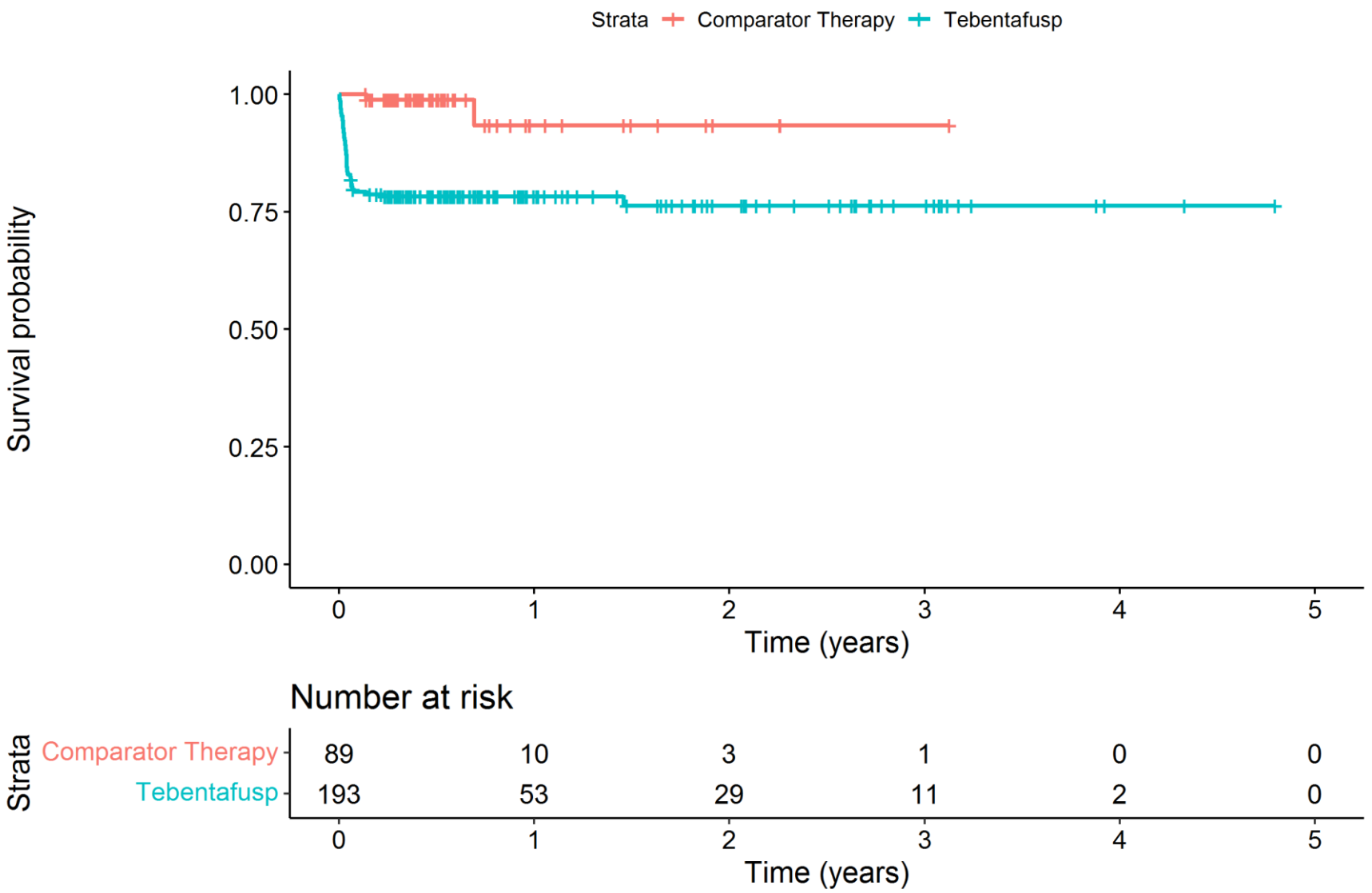
60.69 Exfoliation der Haut - ECOG 0



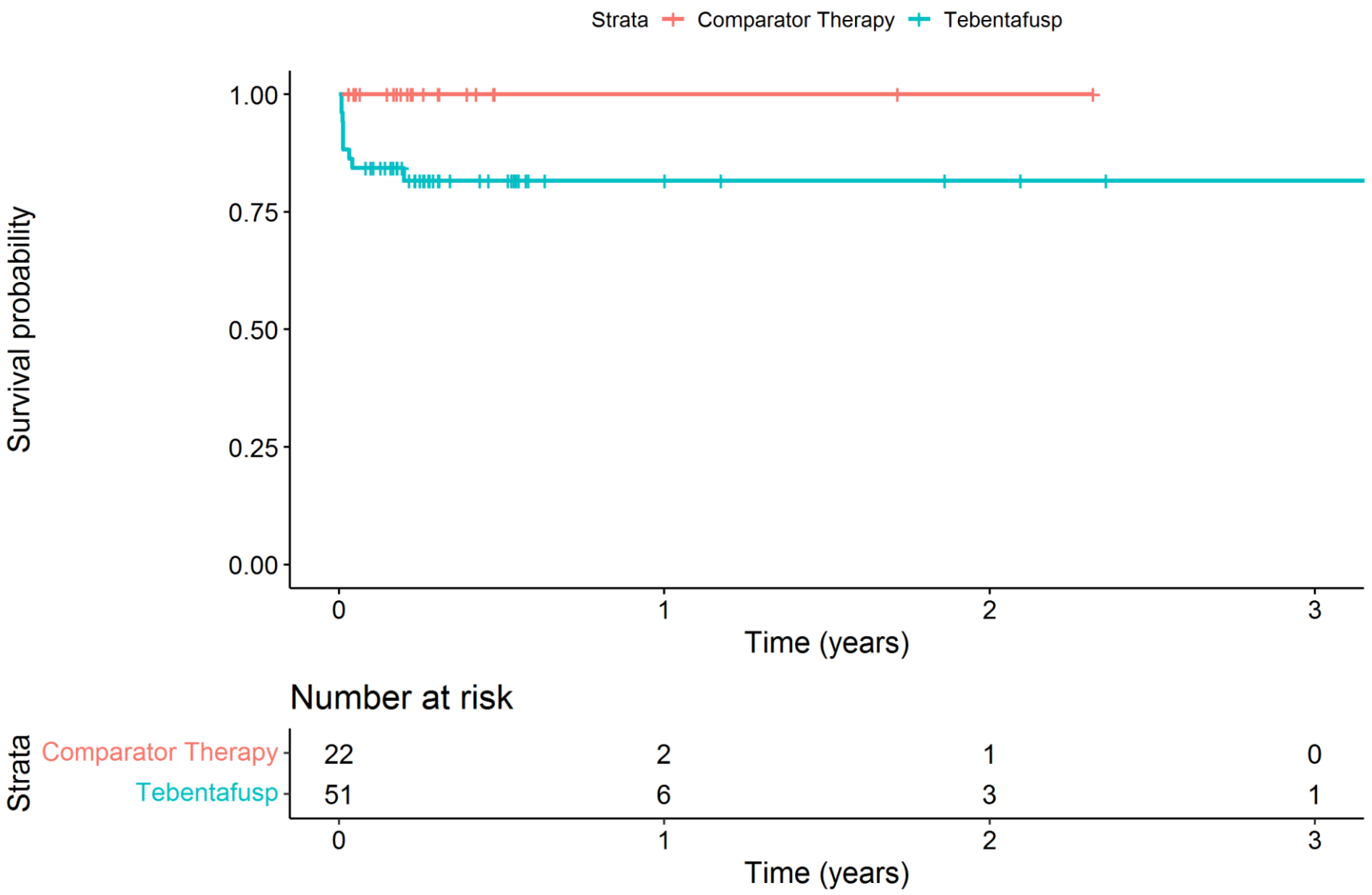
60.70 Exfoliation der Haut - ECOG 1



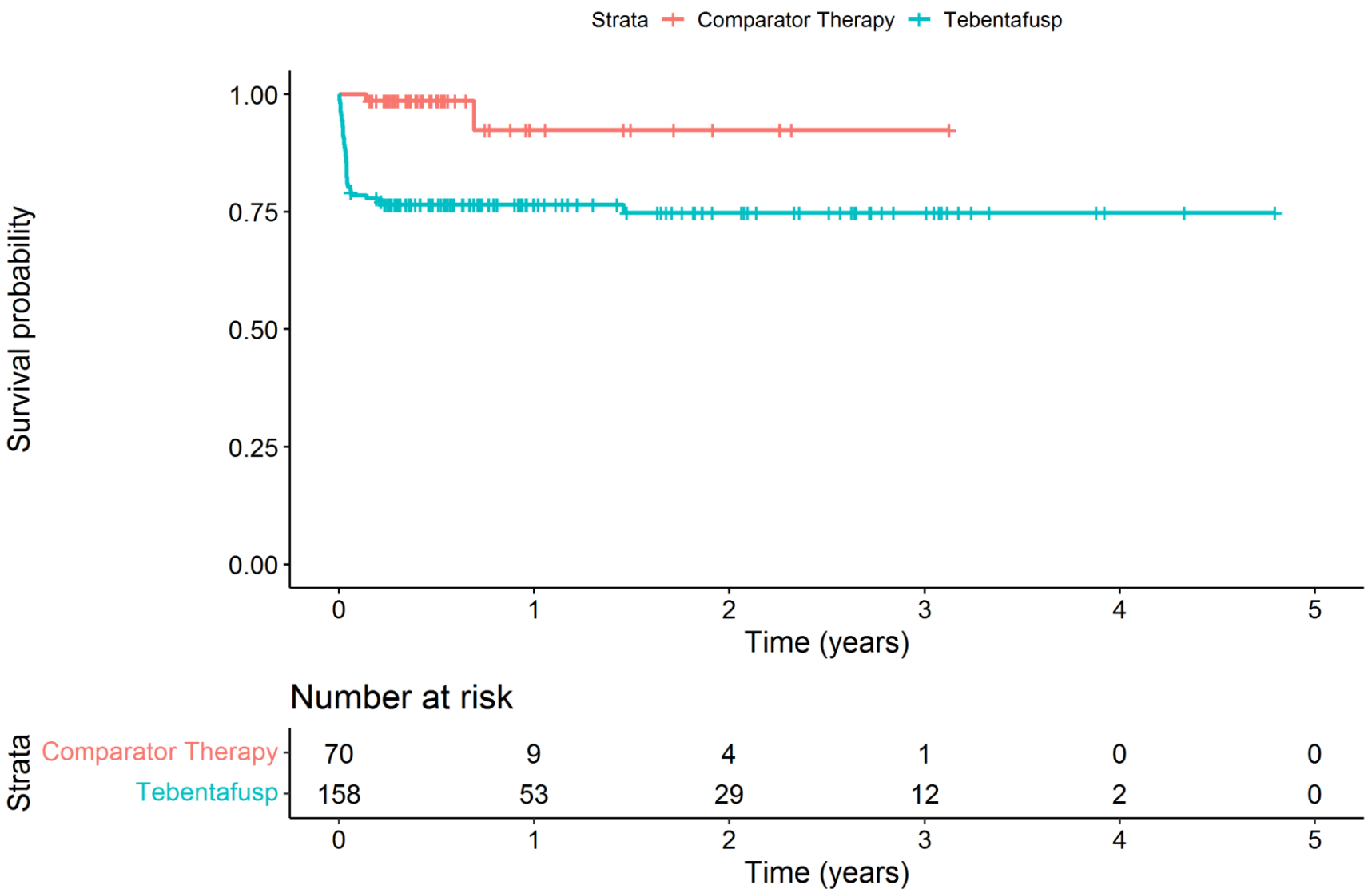
60.71 Exfoliation der Haut - ALP ≤ ULN



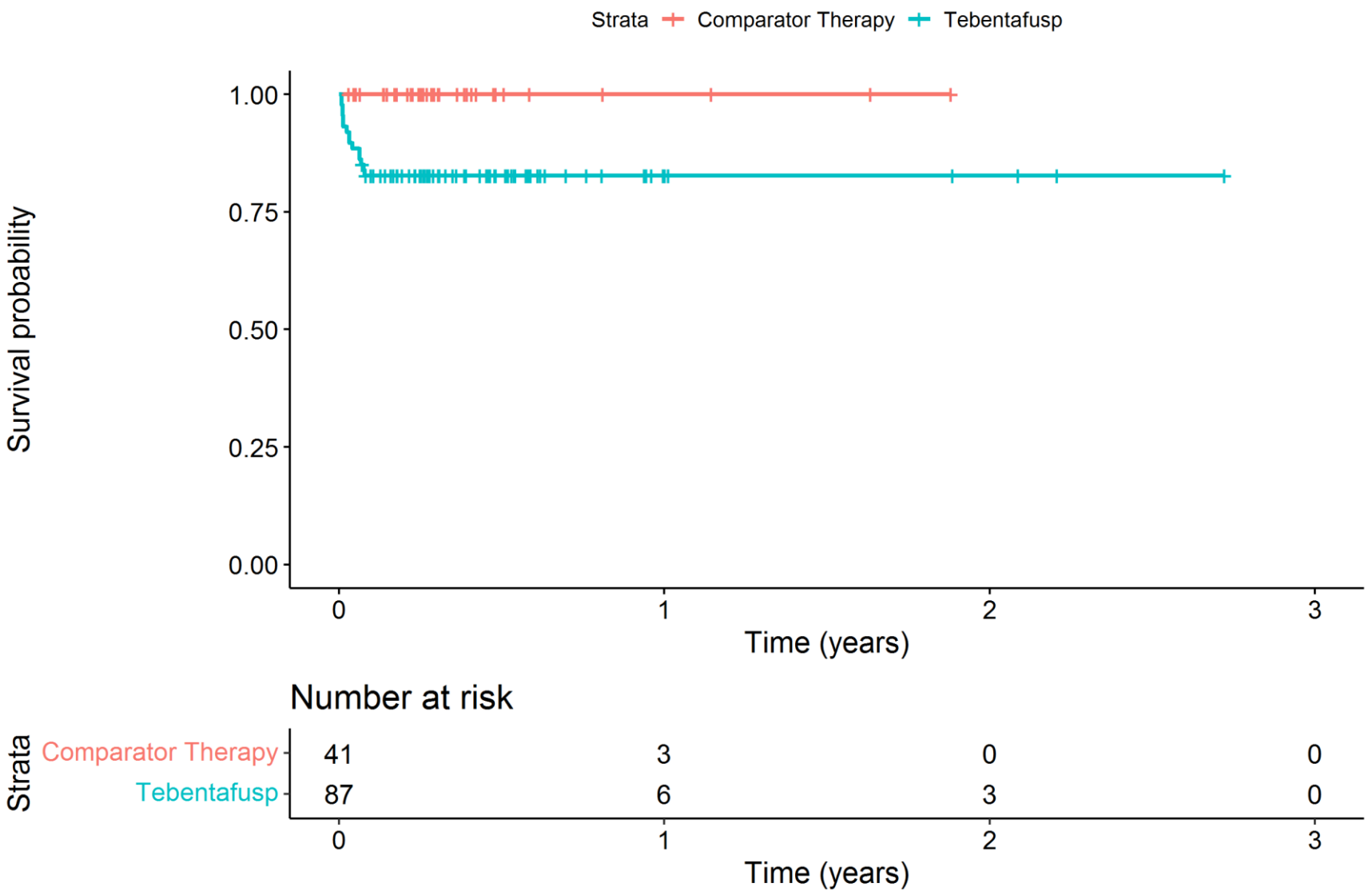
60.72 Exfoliation der Haut - ALP > ULN



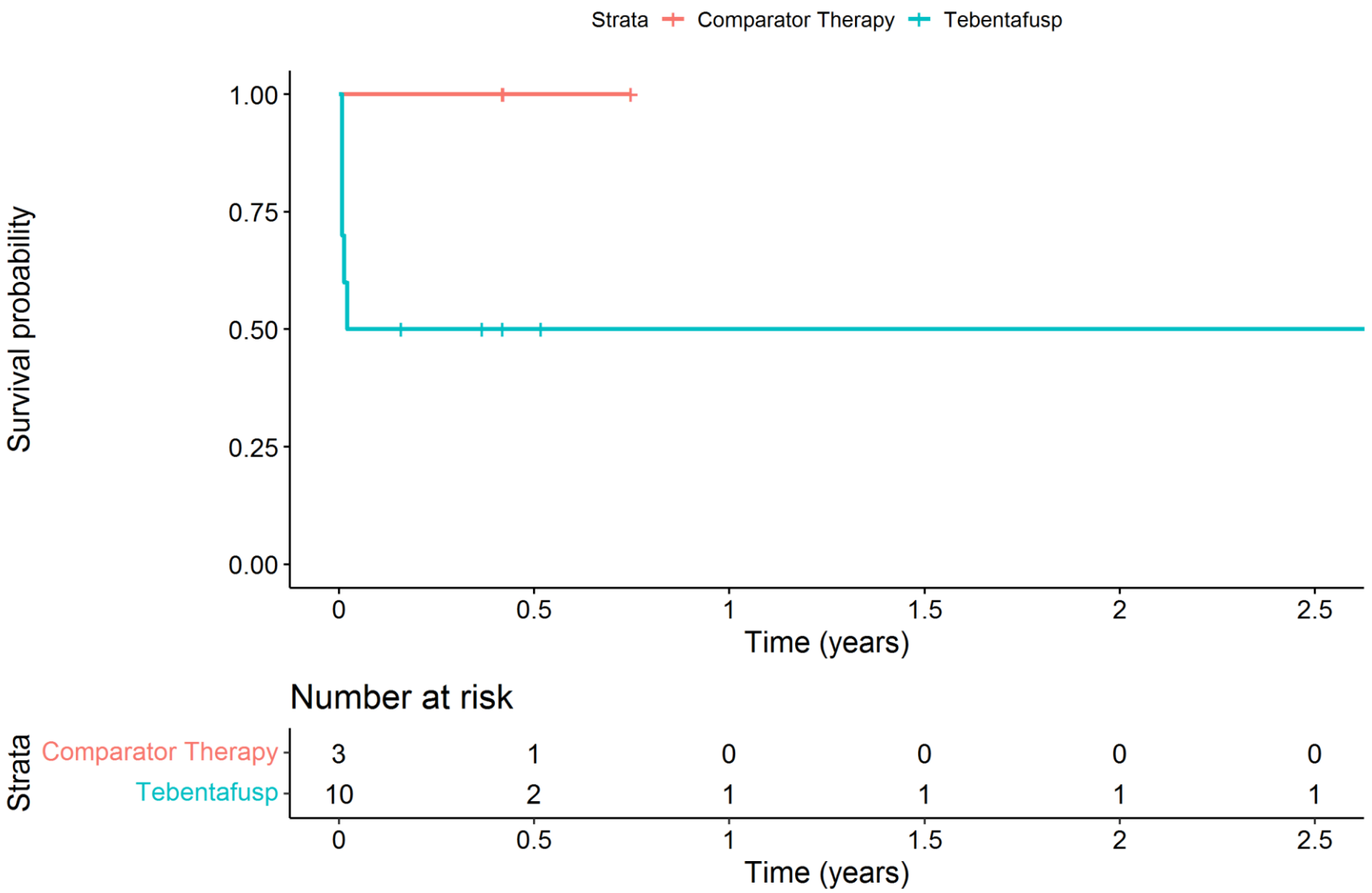
60.73 Exfoliation der Haut - LDH =< ULN



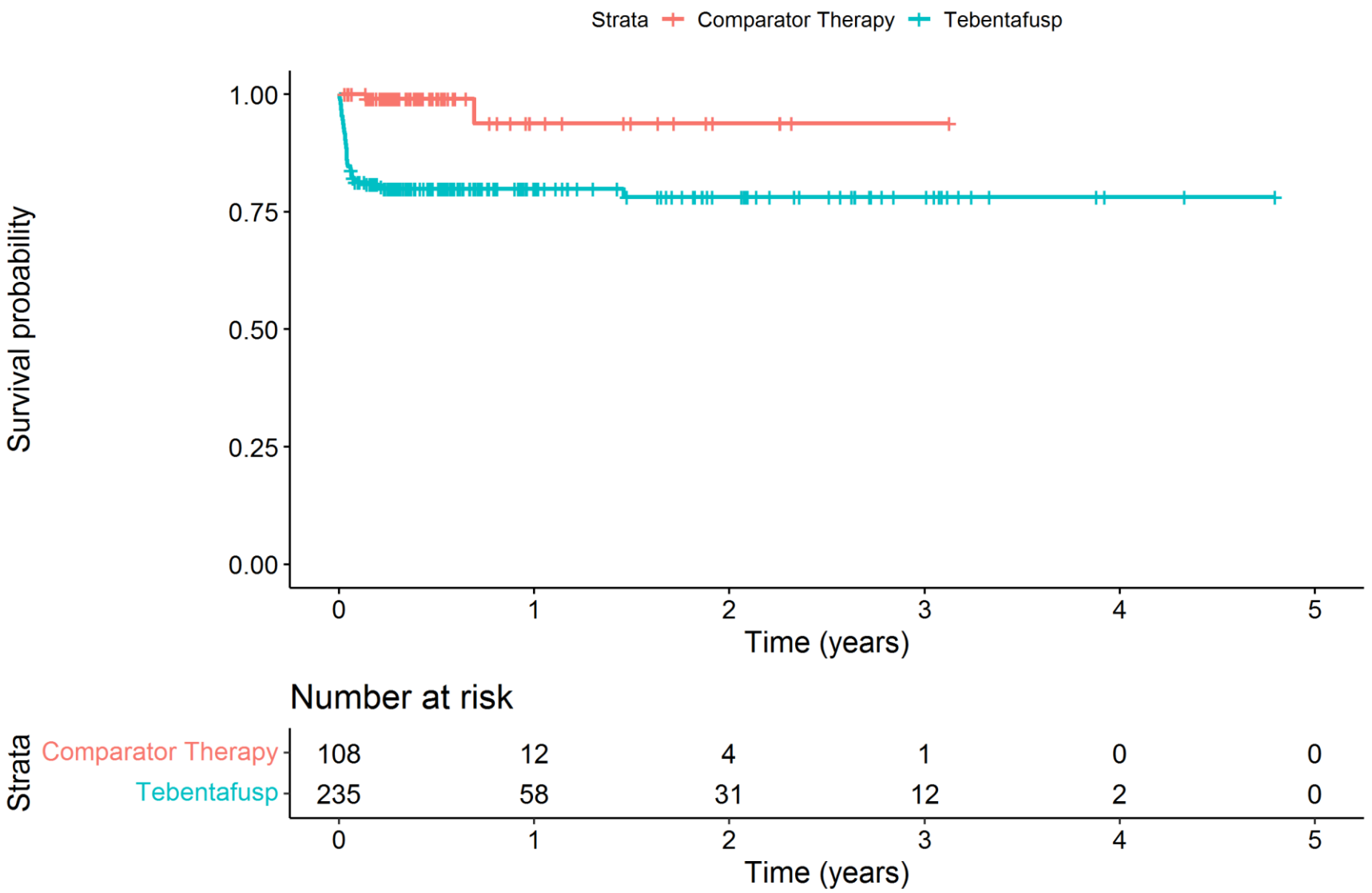
60.74 Exfoliation der Haut - LDH > ULN



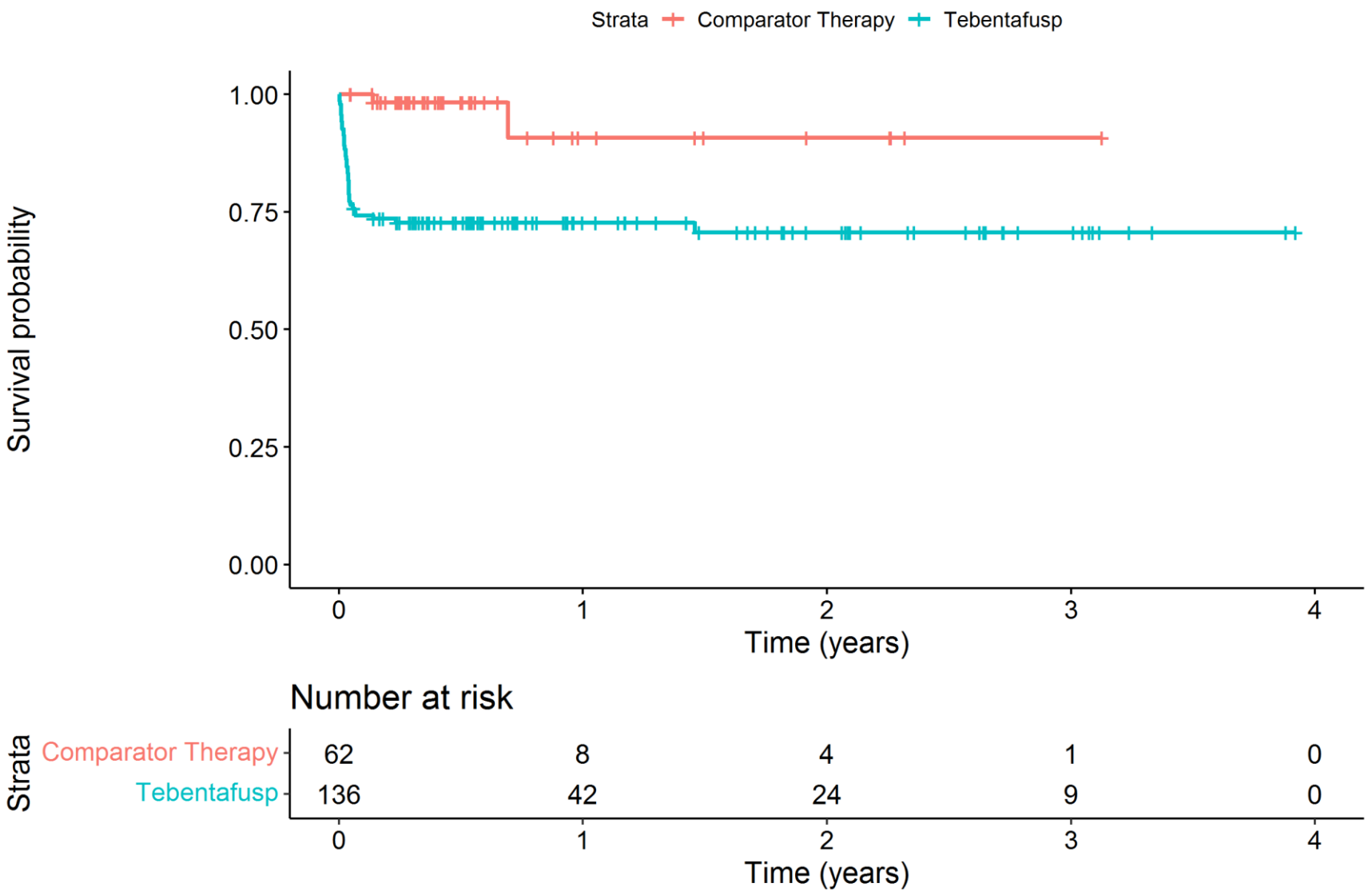
60.75 Exfoliation der Haut - Vorherige Therapie adjuvant/neoadjuvant



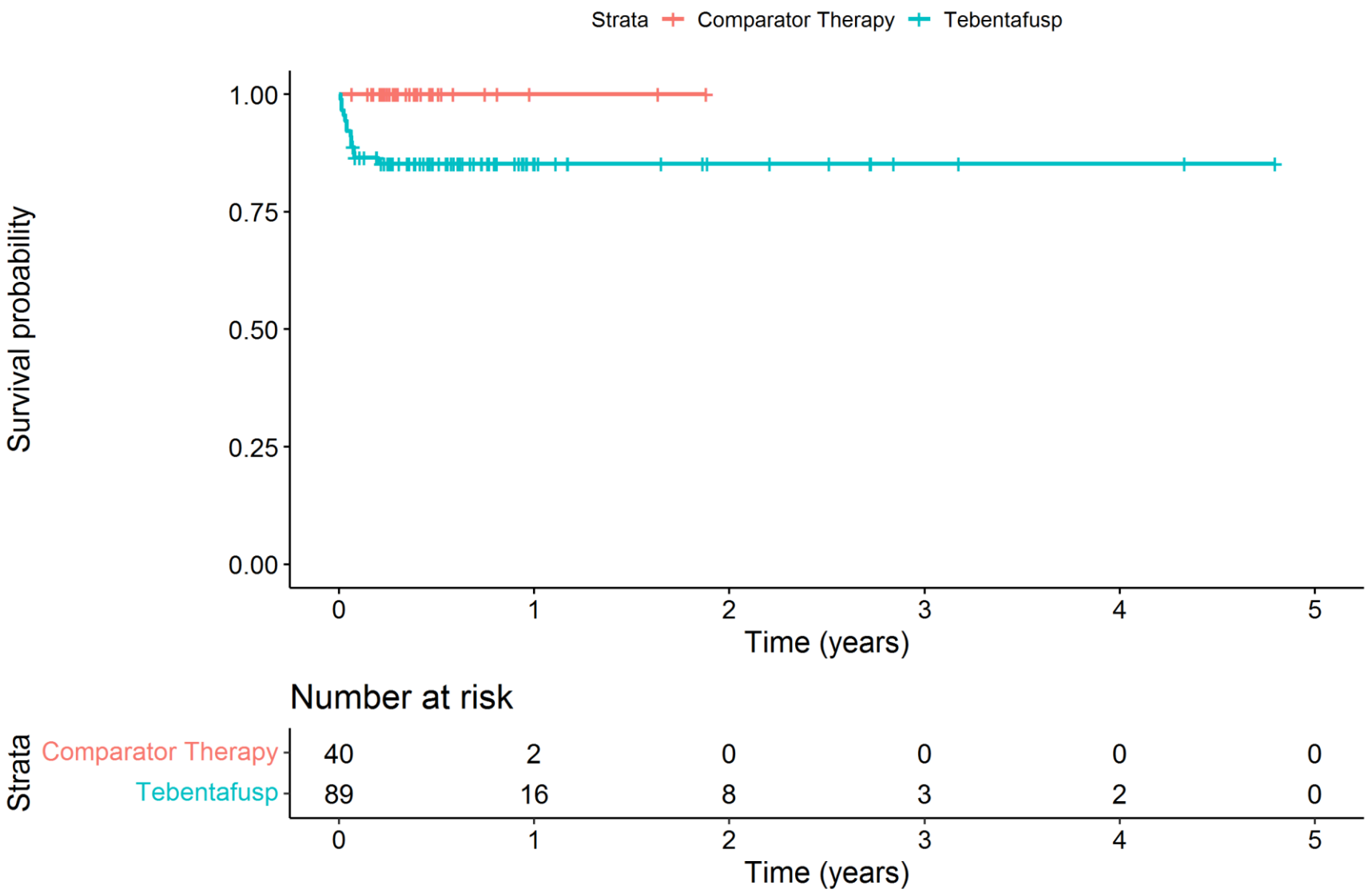
60.76 Exfoliation der Haut - Keine Vorherige Therapie adjuvant/neoadjuvant



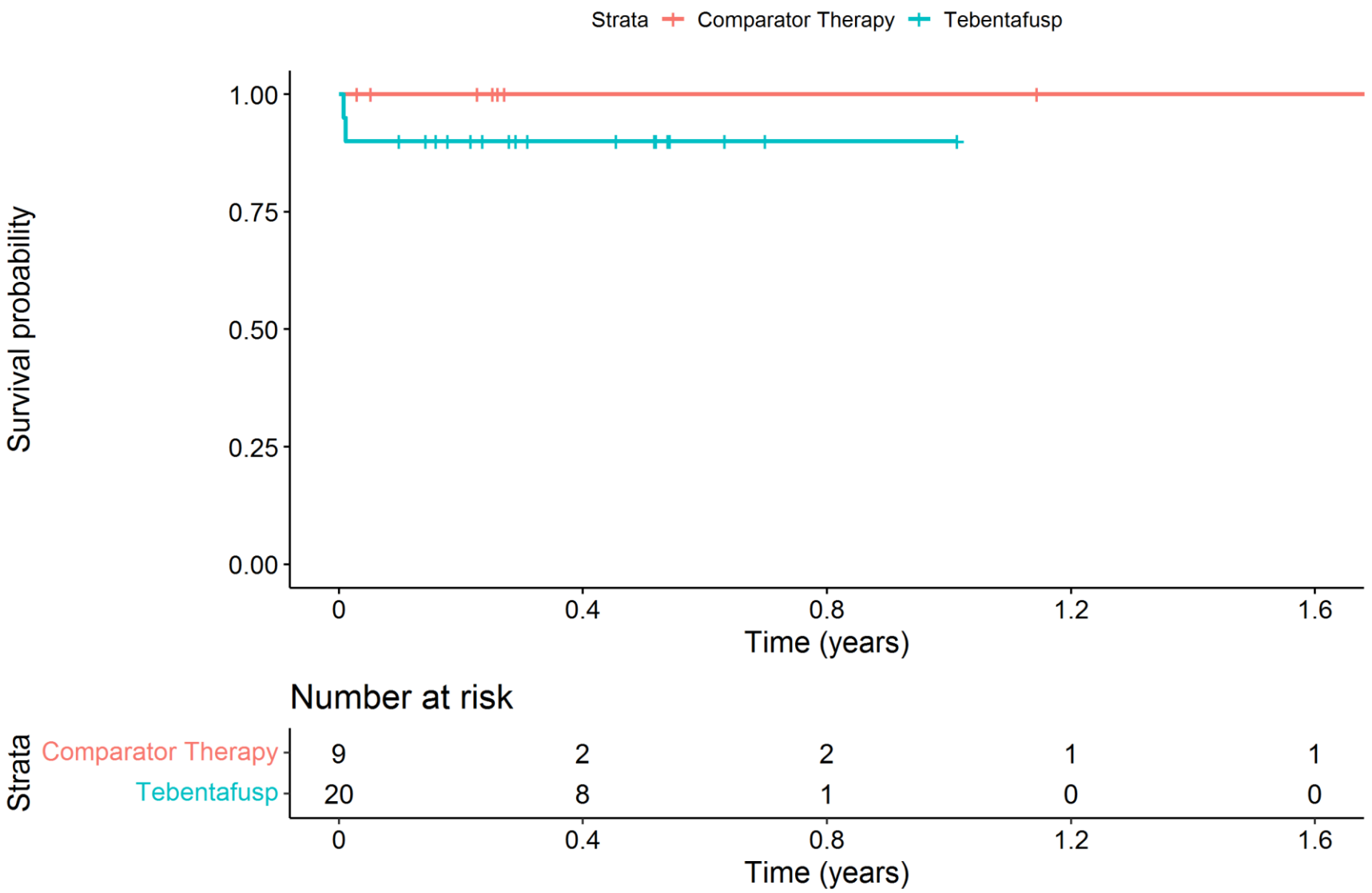
60.77 Exfoliation der Haut - Läsion ≤ 3cm



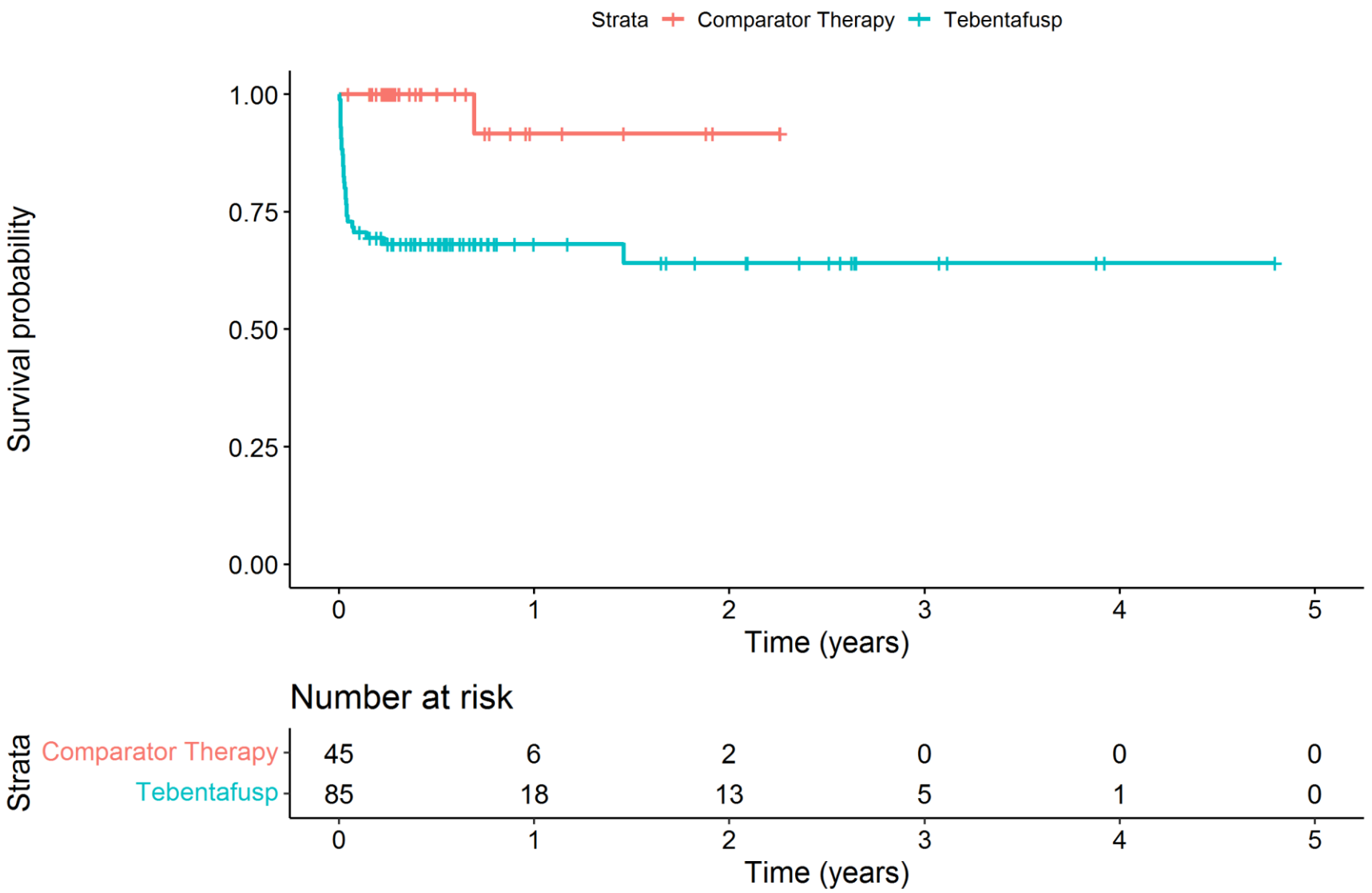
60.78 Exfoliation der Haut - Läsion 3,1-8,0 cm



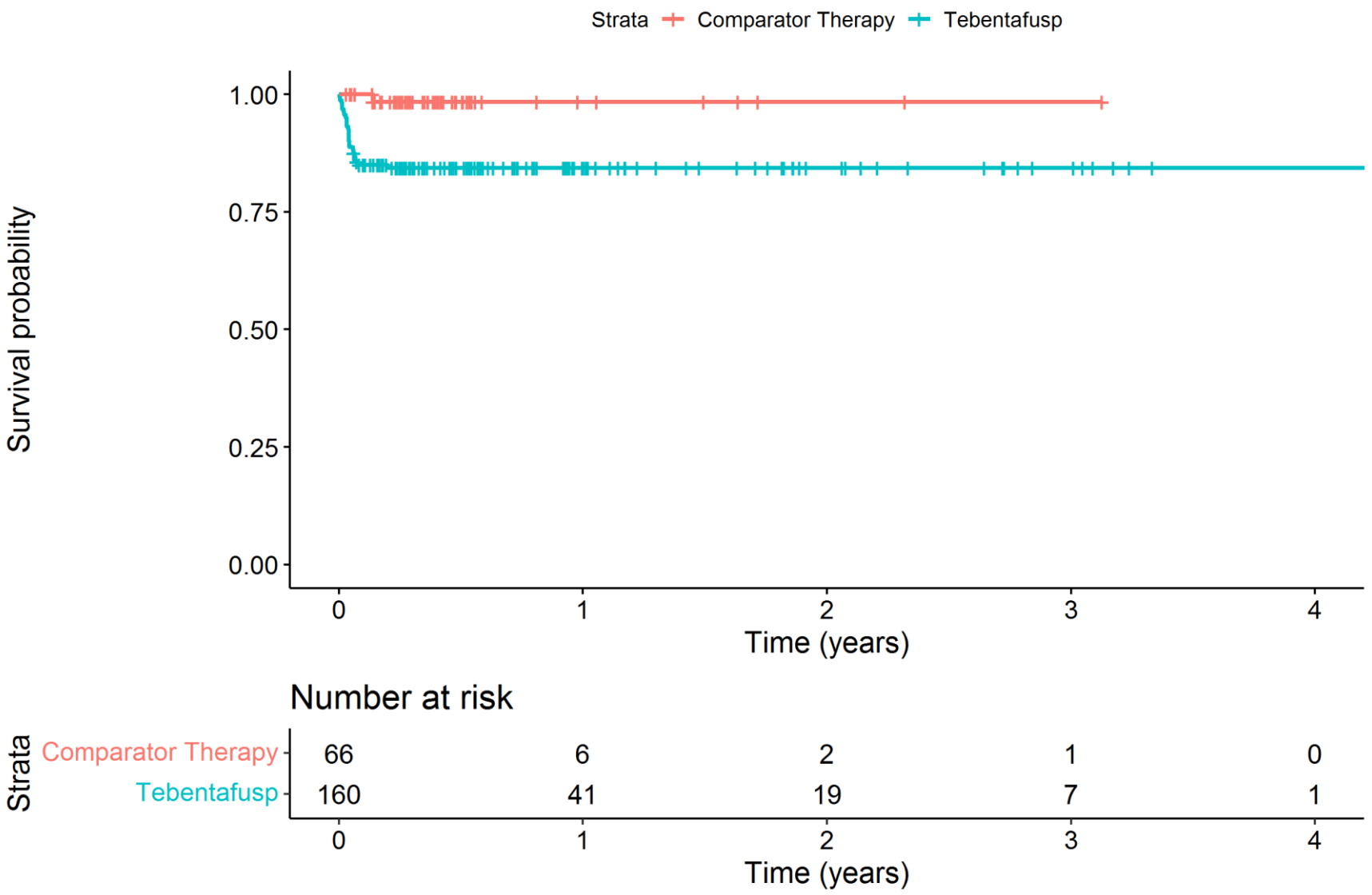
60.79 Exfoliation der Haut - Läsion ≥8,1 cm



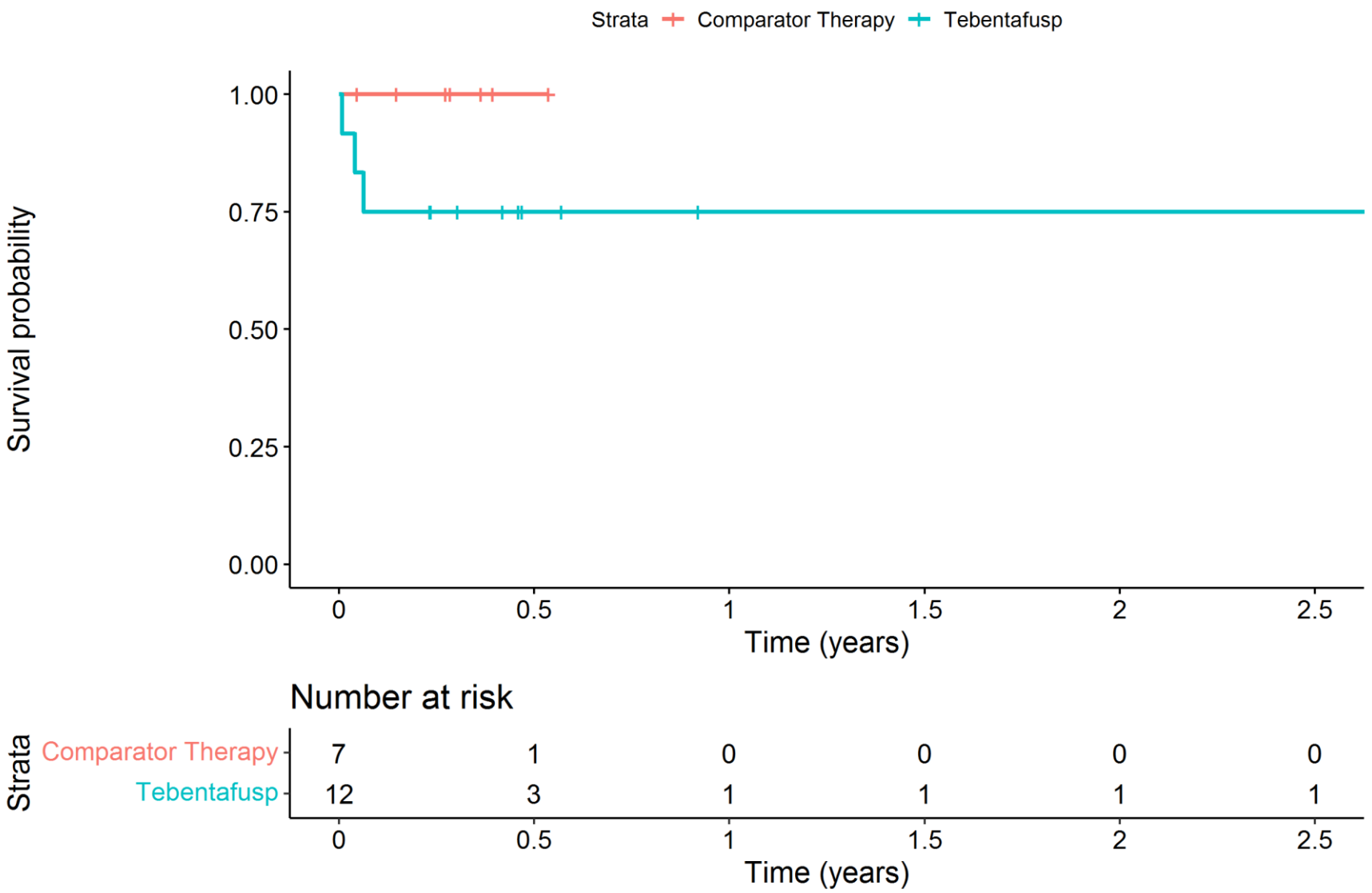
60.80 Exfoliation der Haut - Nordamerika



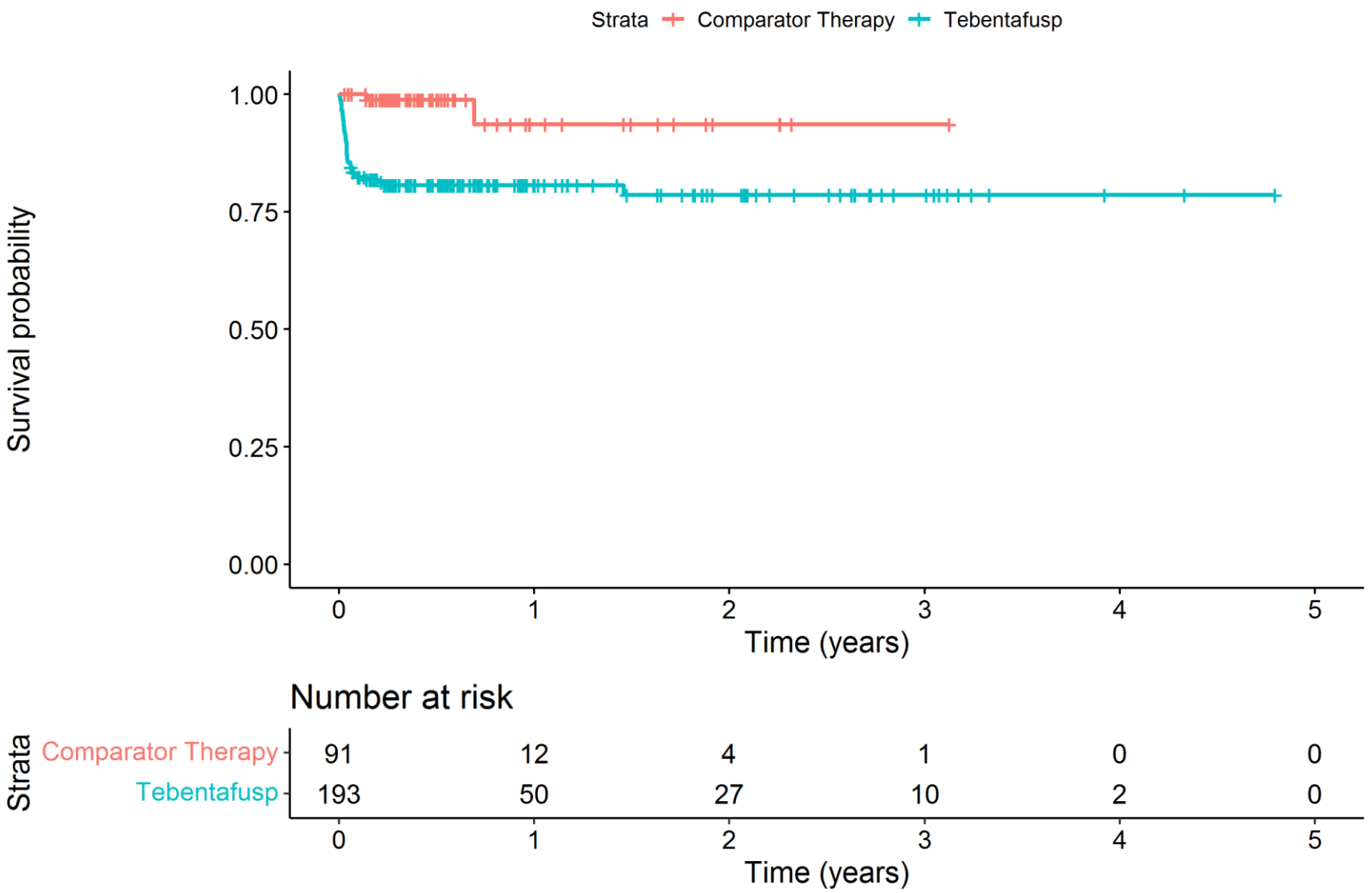
60.81 Exfoliation der Haut - Nicht-Nordamerika



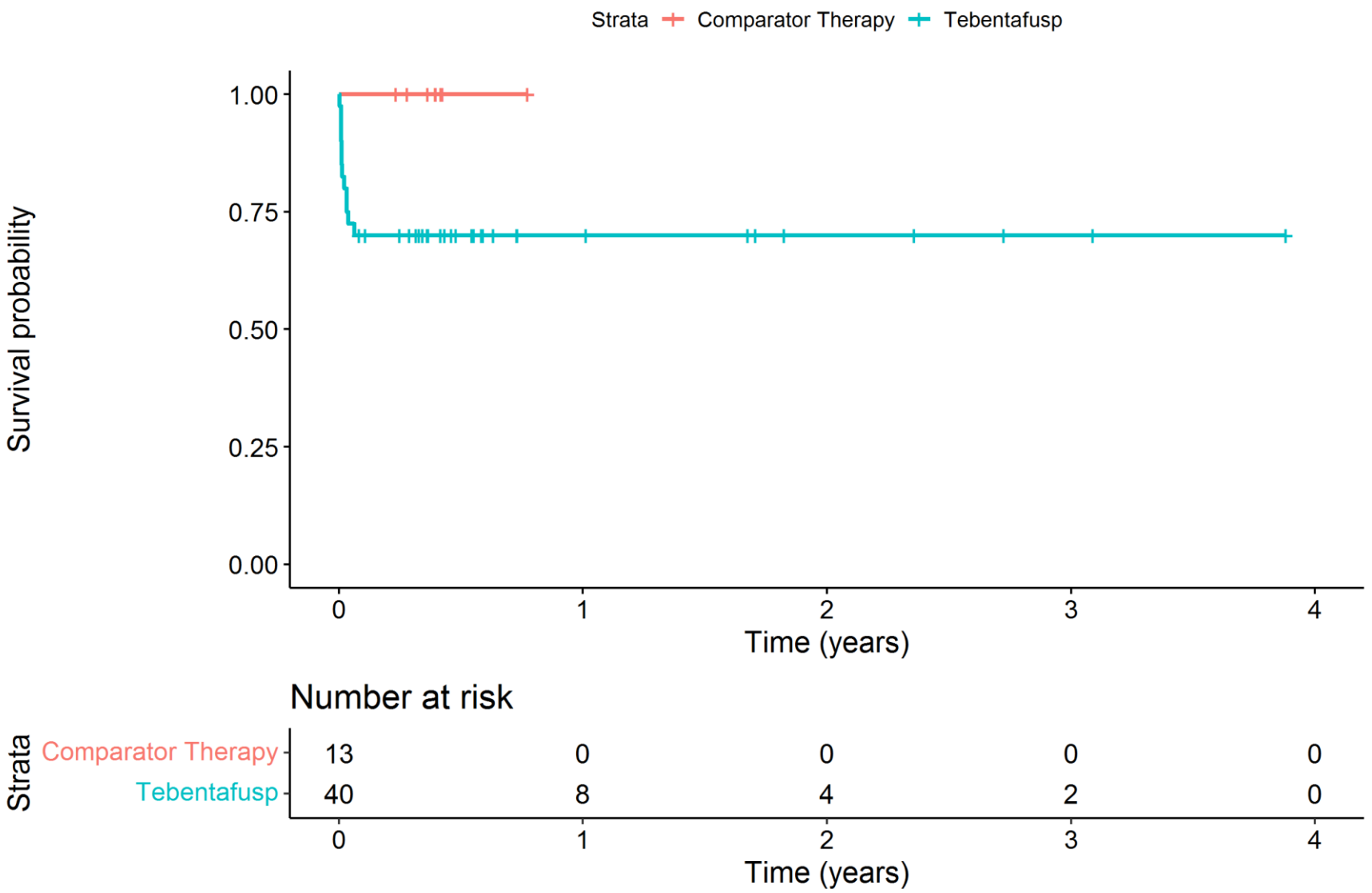
60.82 Exfoliation der Haut - Dacarbazin



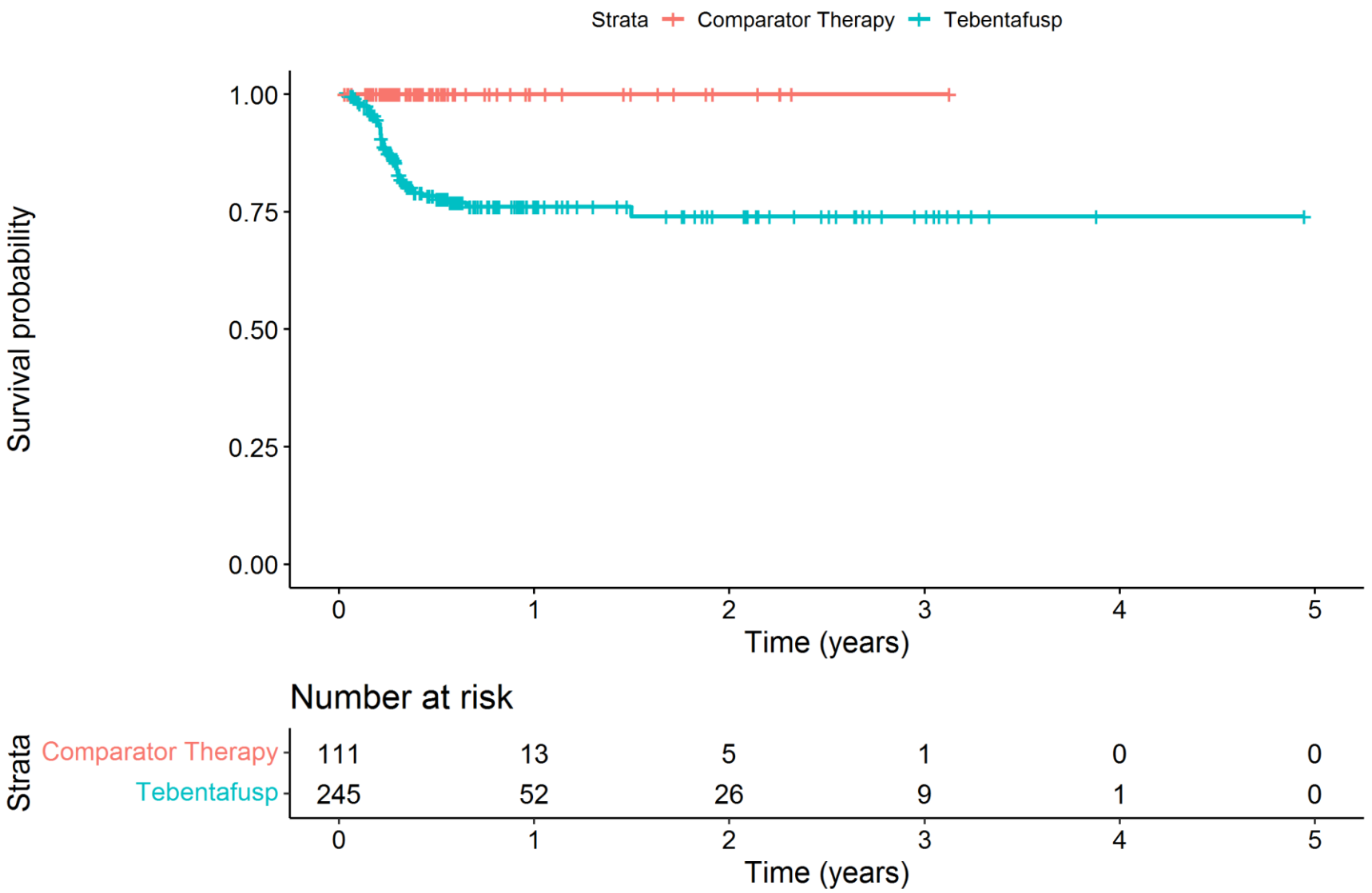
60.83 Exfoliation der Haut - Pembrolizumab



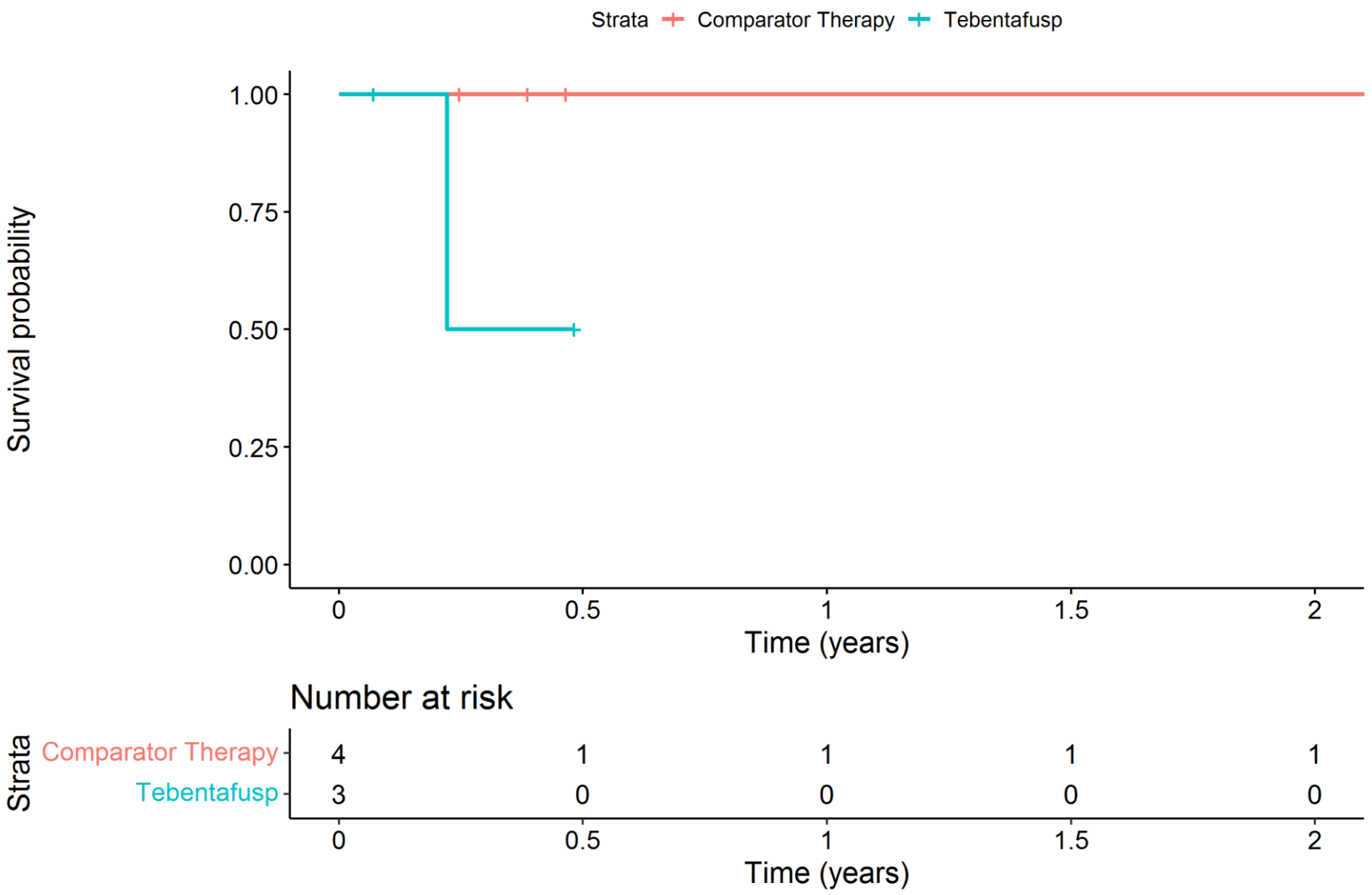
60.84 Exfoliation der Haut - Ipilimumab



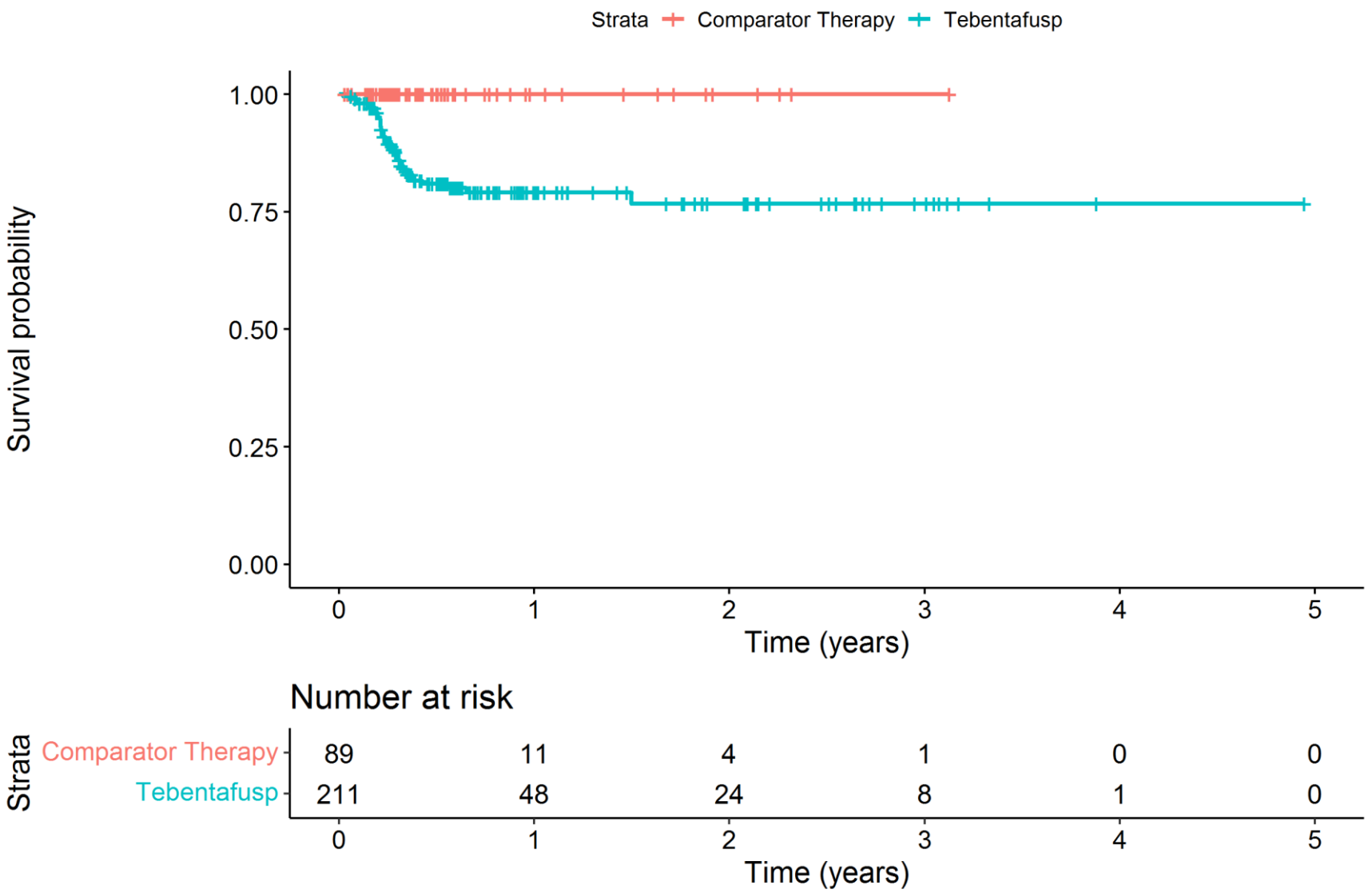
60.85 Veränderung der Haarfarbe- Gesamt



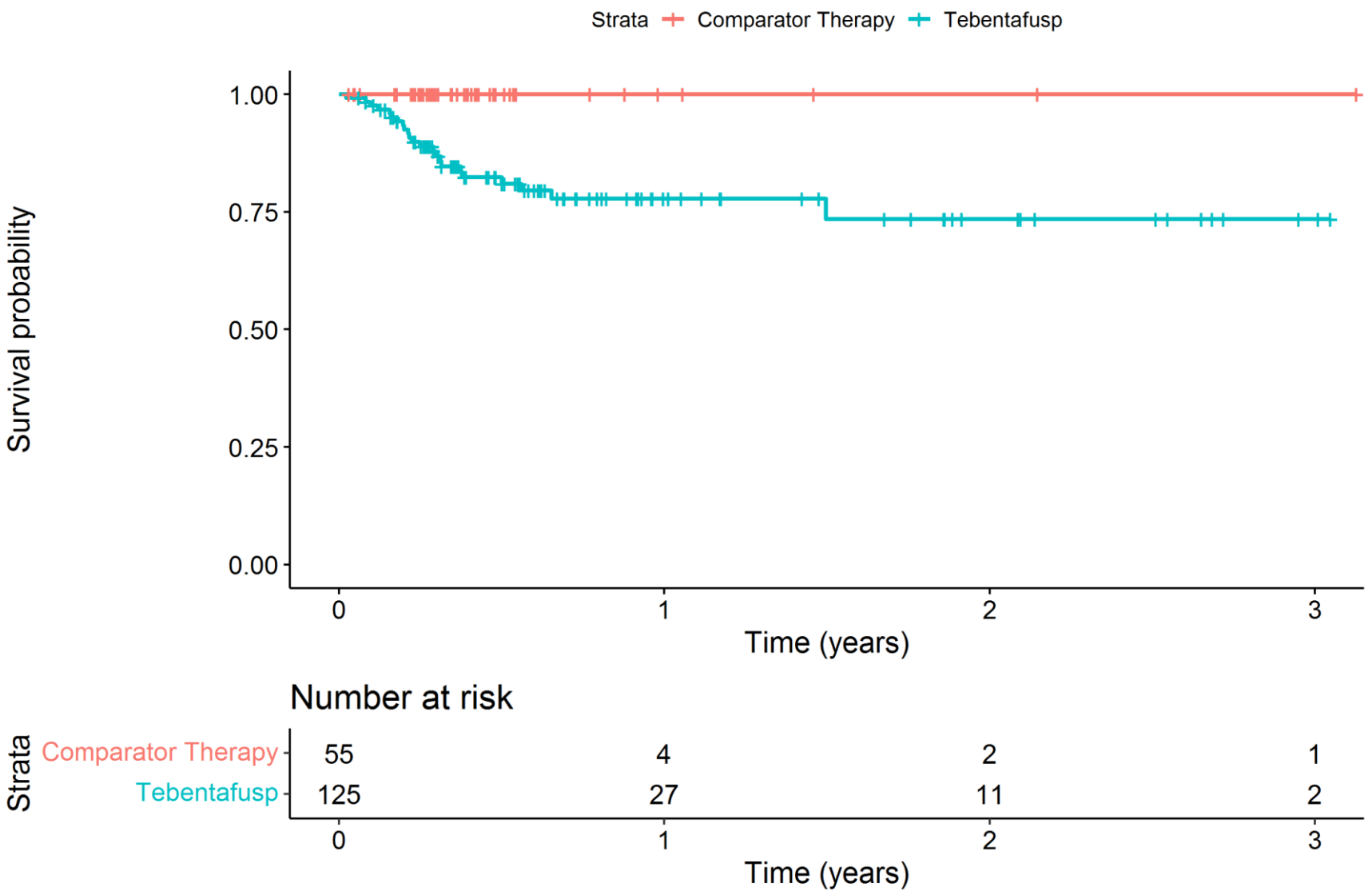
60.86 Veränderung der Haarfarbe- Hispanich



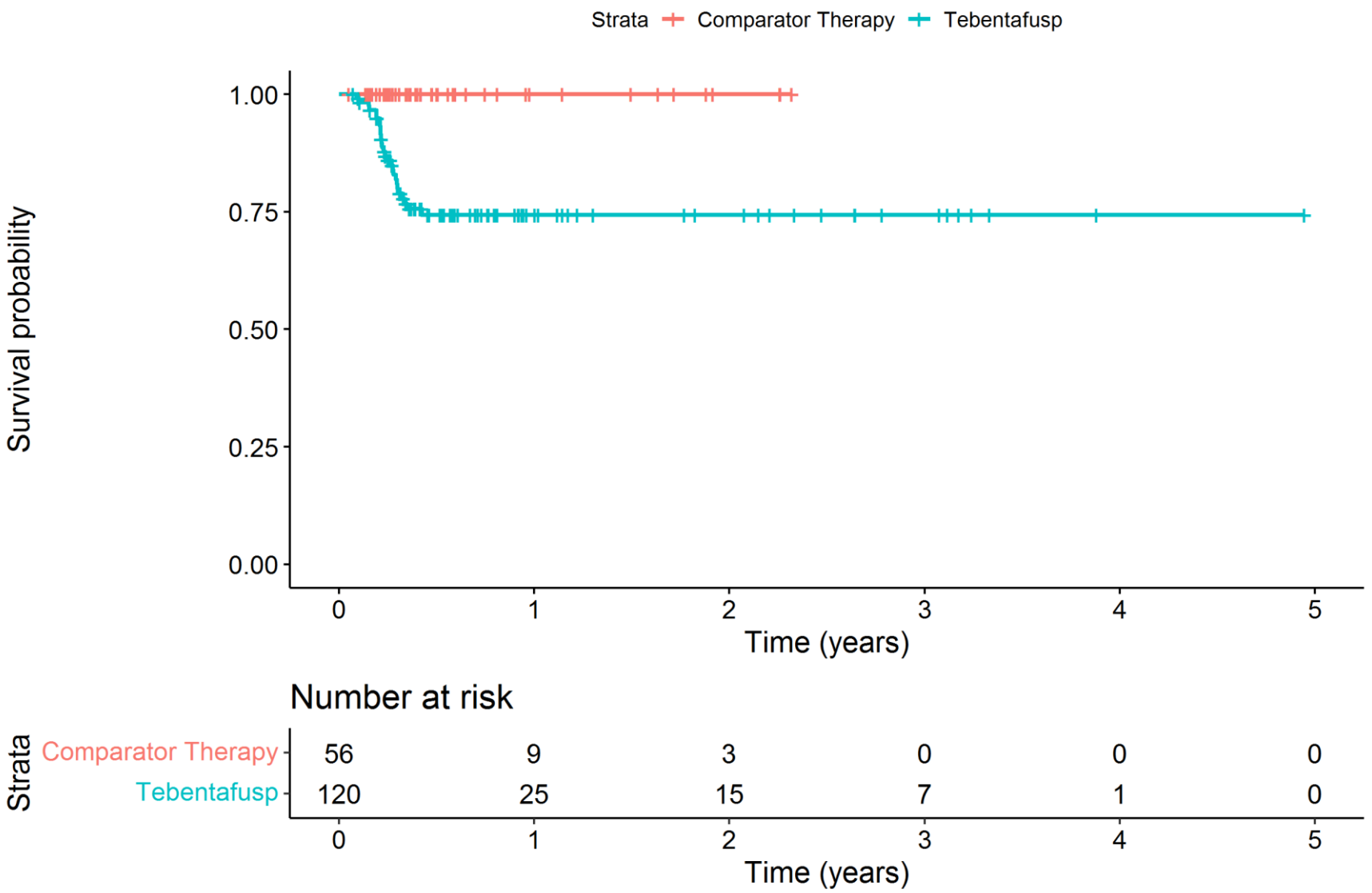
60.87 Veränderung der Haarfarbe- Nicht-hispanisch



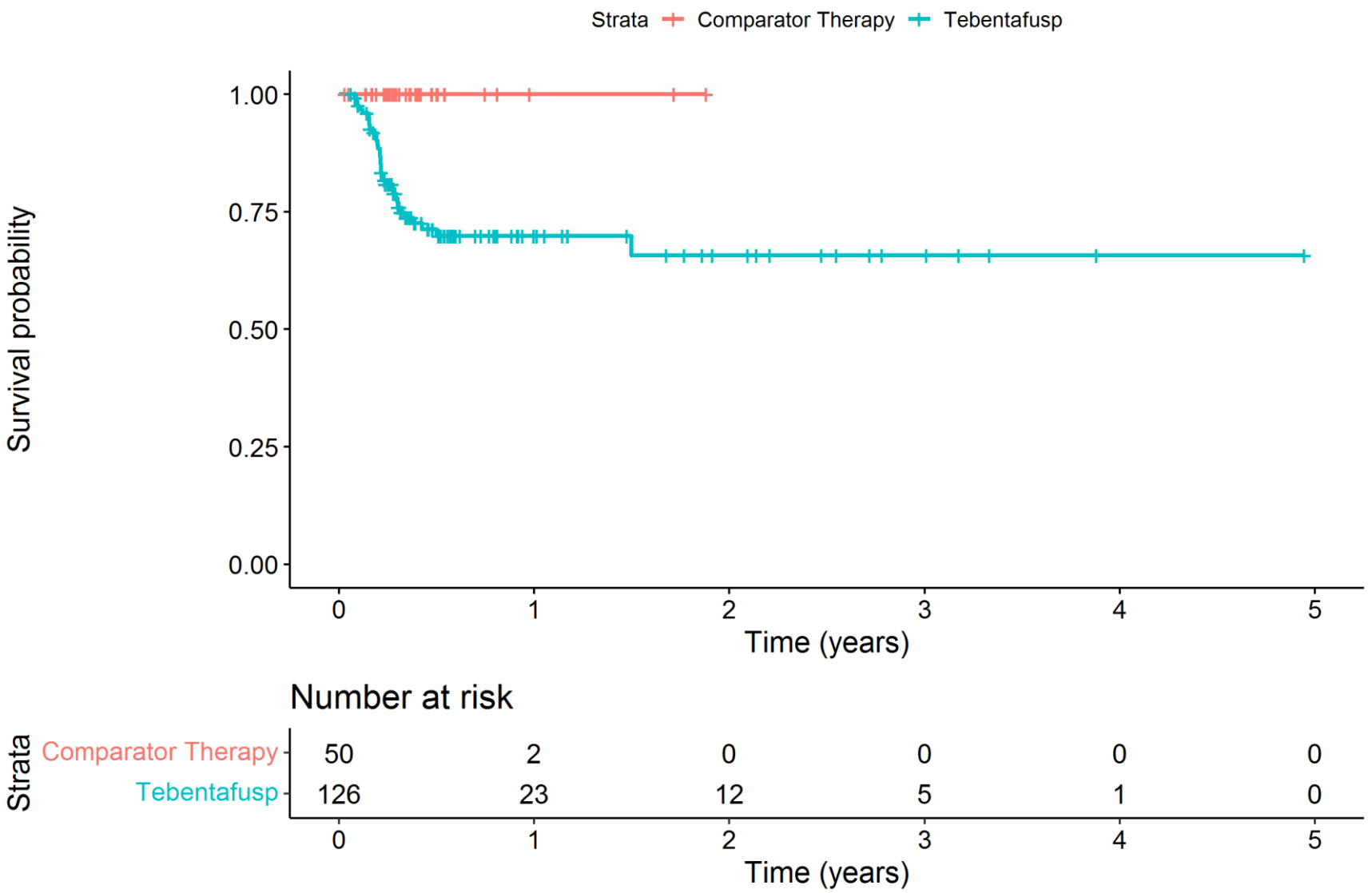
60.88 Veränderung der Haarfarbe- Männlich



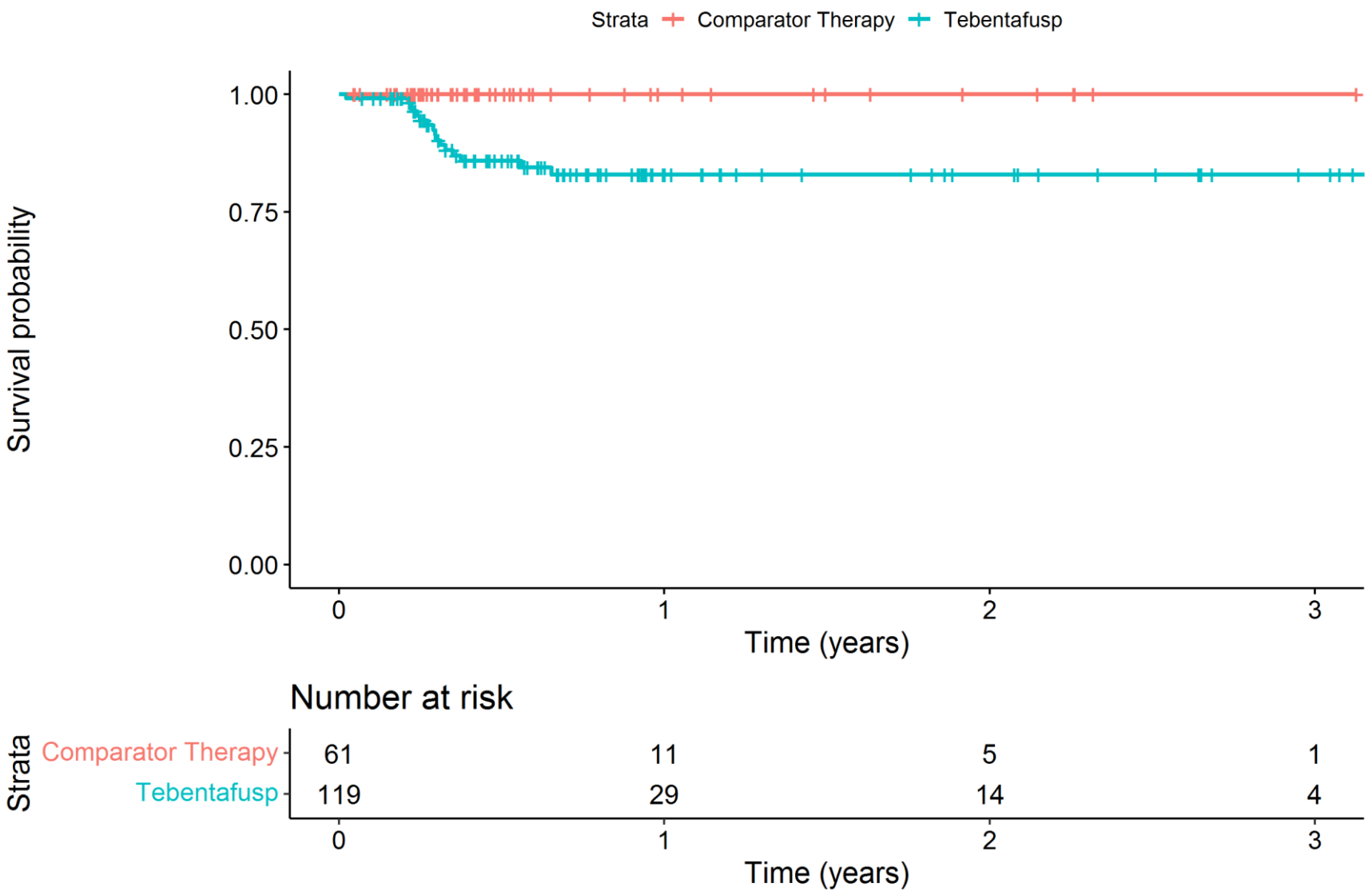
60.89 Veränderung der Haarfarbe- Weiblich



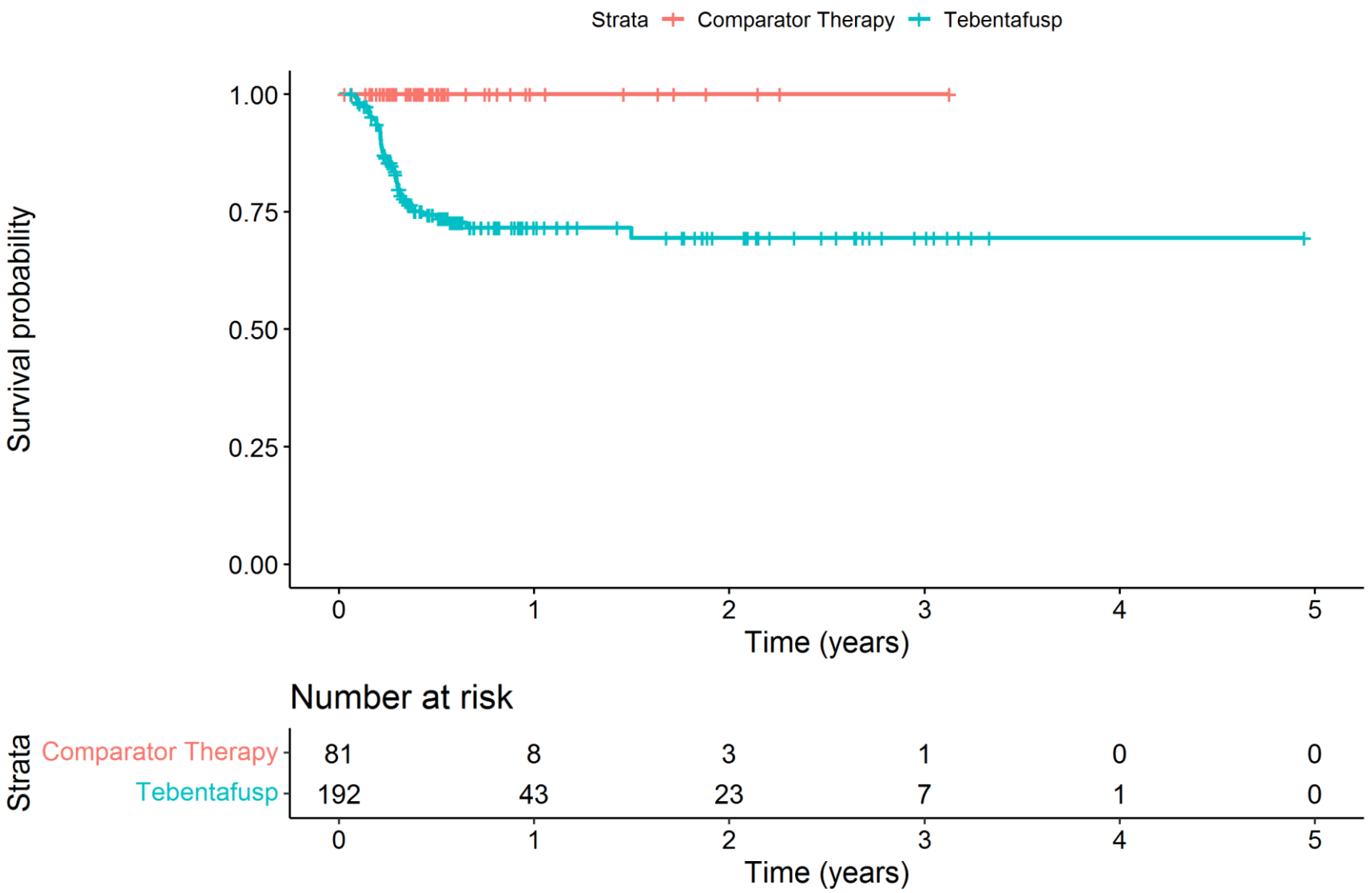
60.90 Veränderung der Haarfarbe- <65



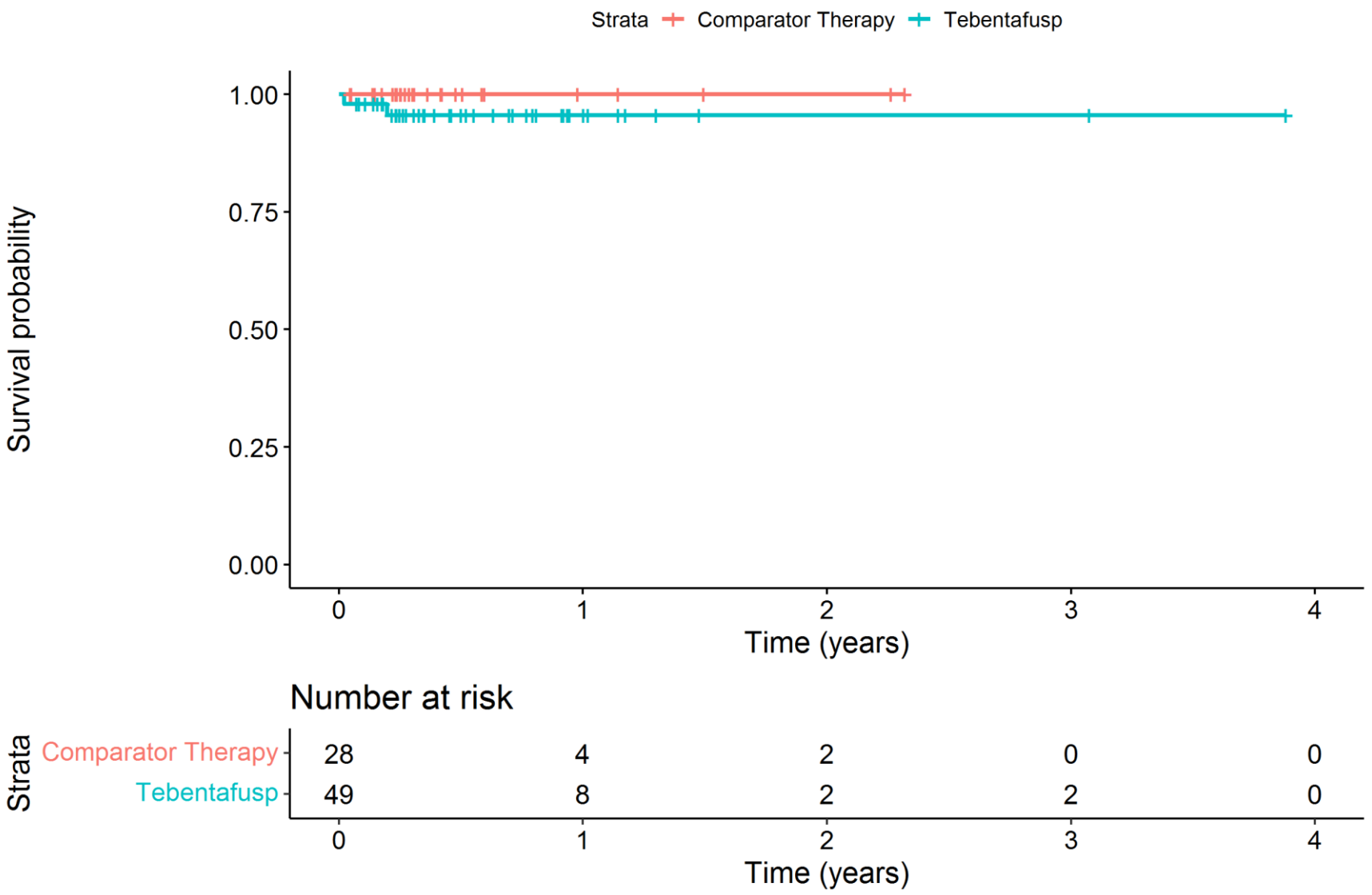
60.91 Veränderung der Haarfarbe- ≥65



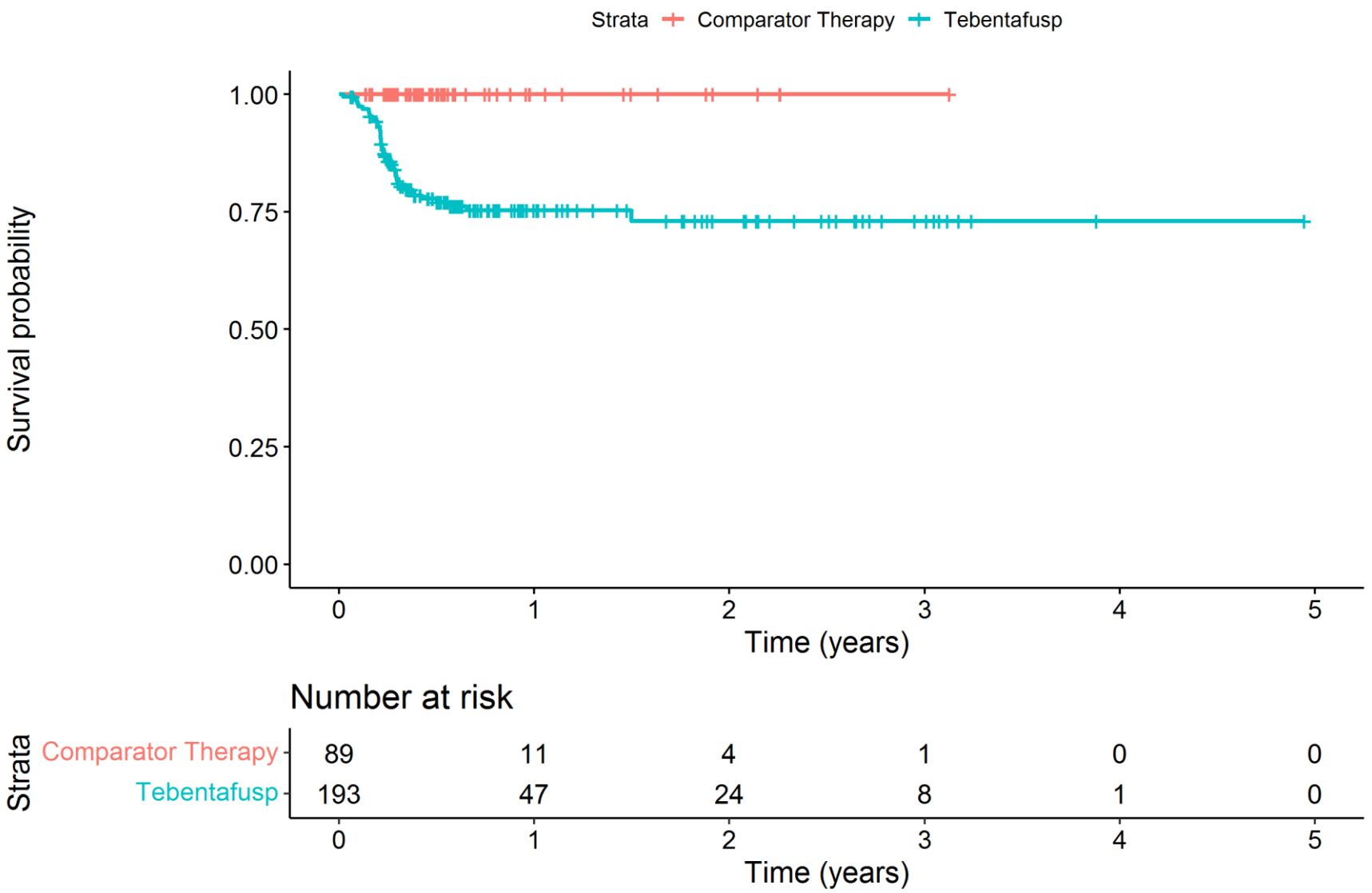
60.92 Veränderung der Haarfarbe- ECOG 0



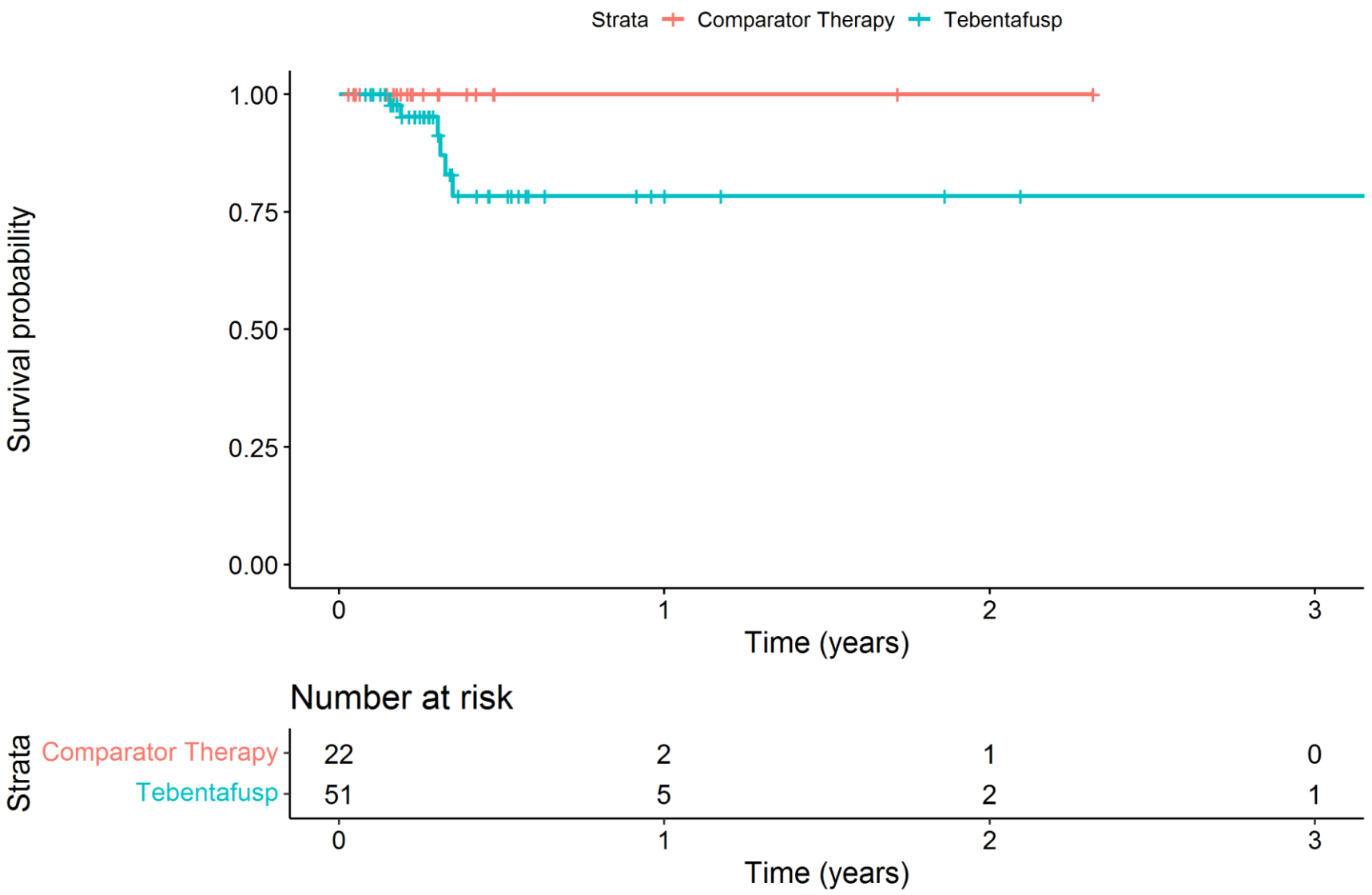
60.93 Veränderung der Haarfarbe- ECOG 1



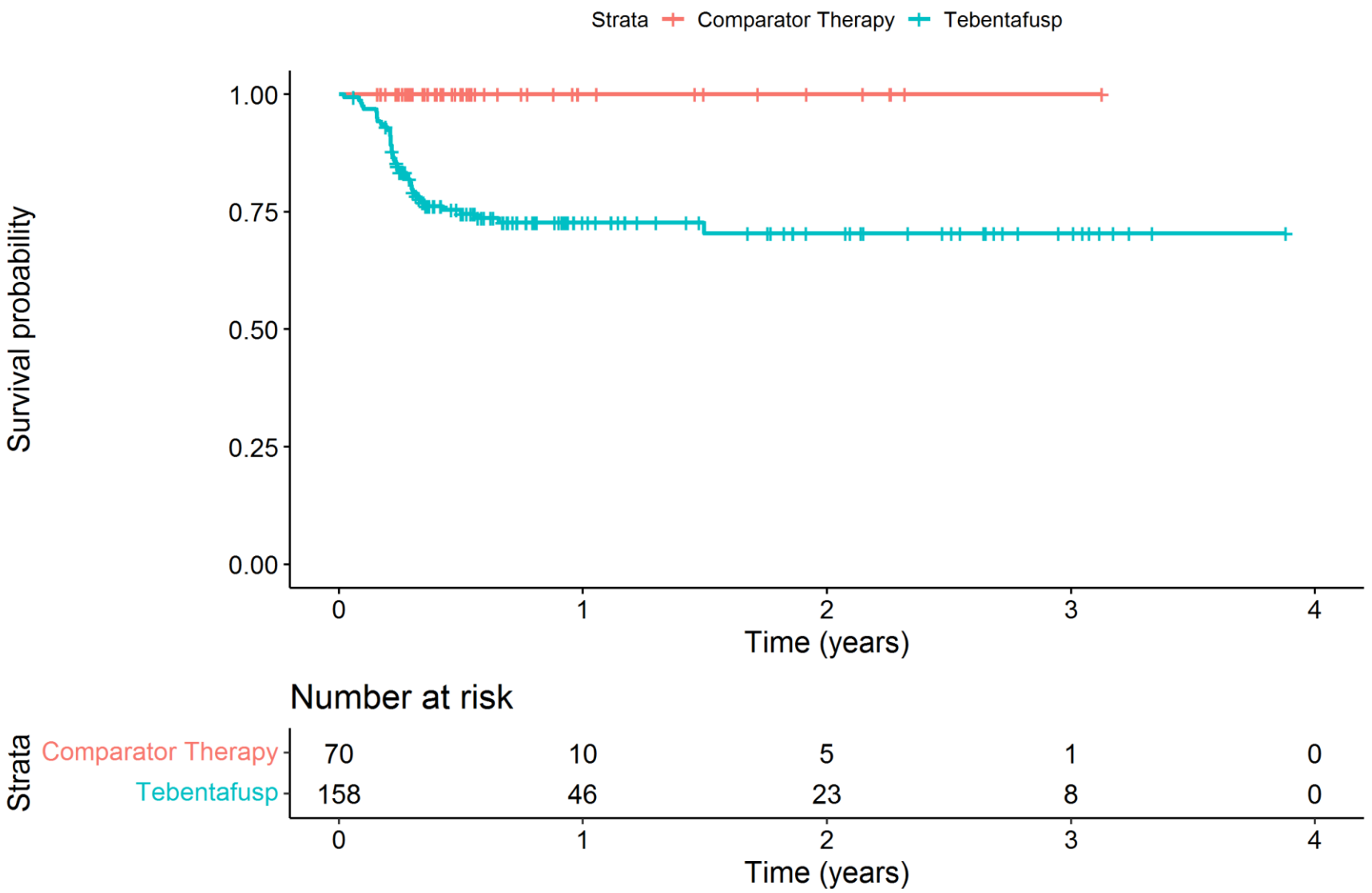
60.94 Veränderung der Haarfarbe- ALP ≤ ULN



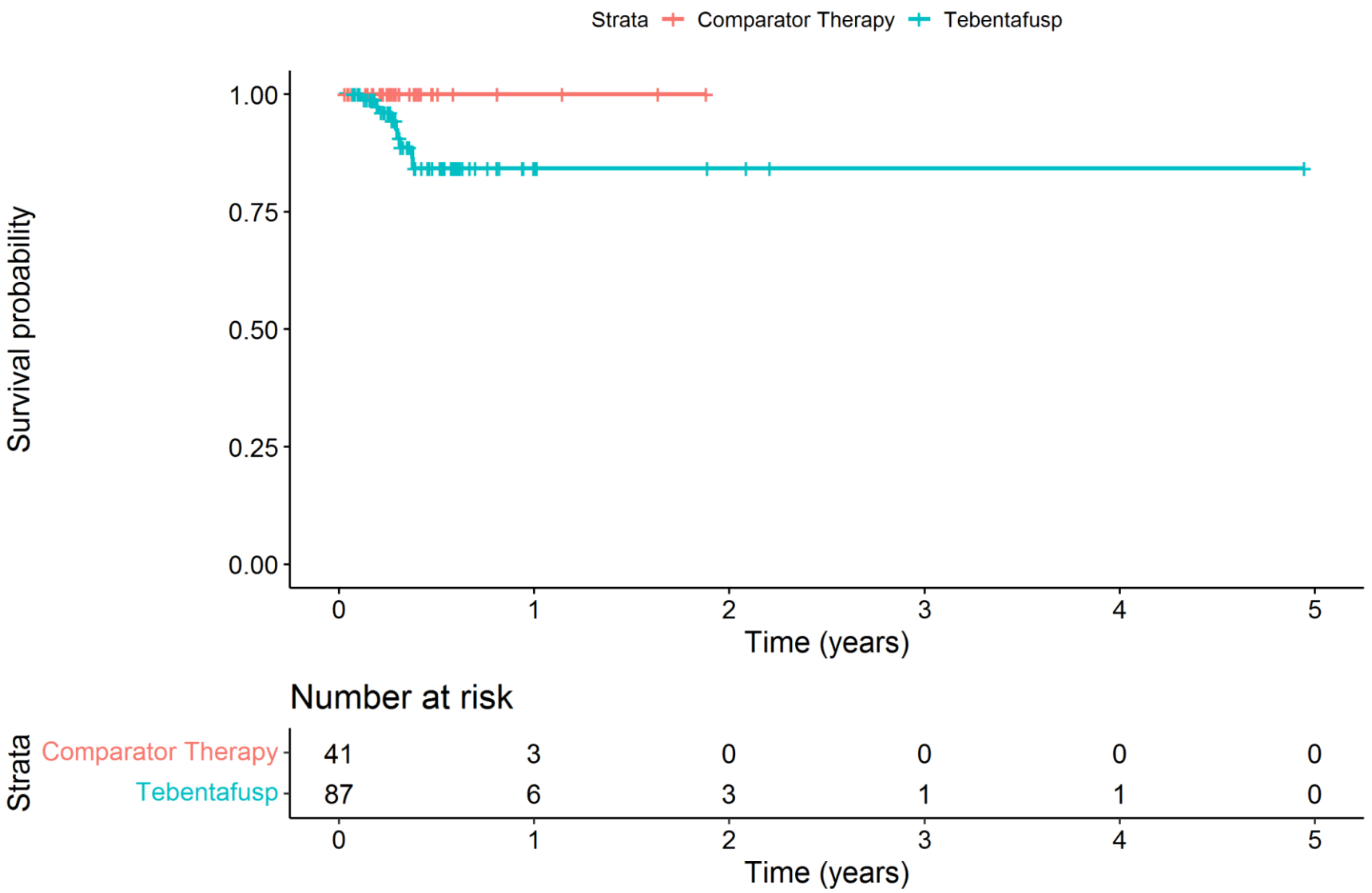
60.95 Veränderung der Haarfarbe- ALP > ULN



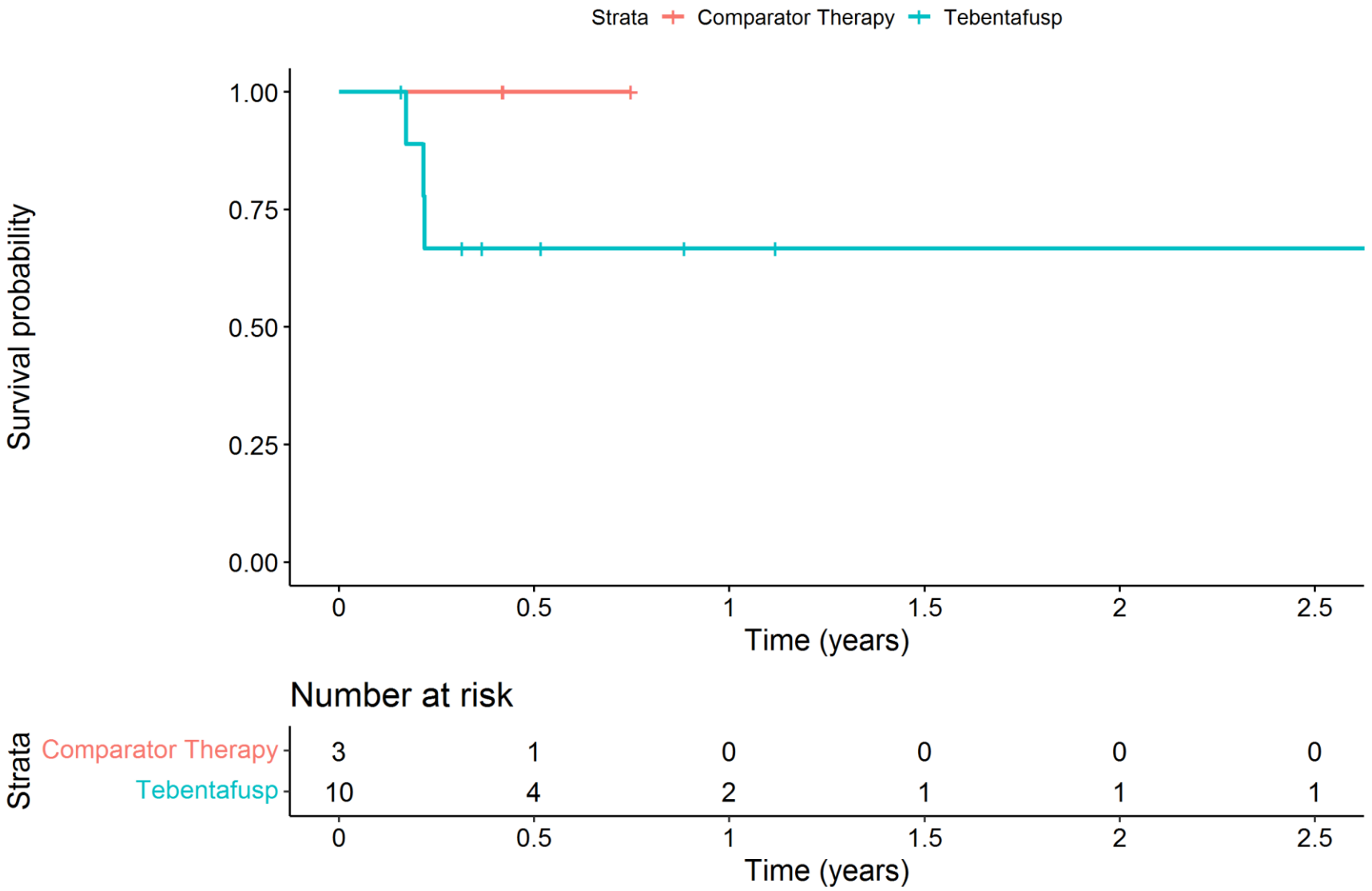
60.96 Veränderung der Haarfarbe- LDH =< ULN



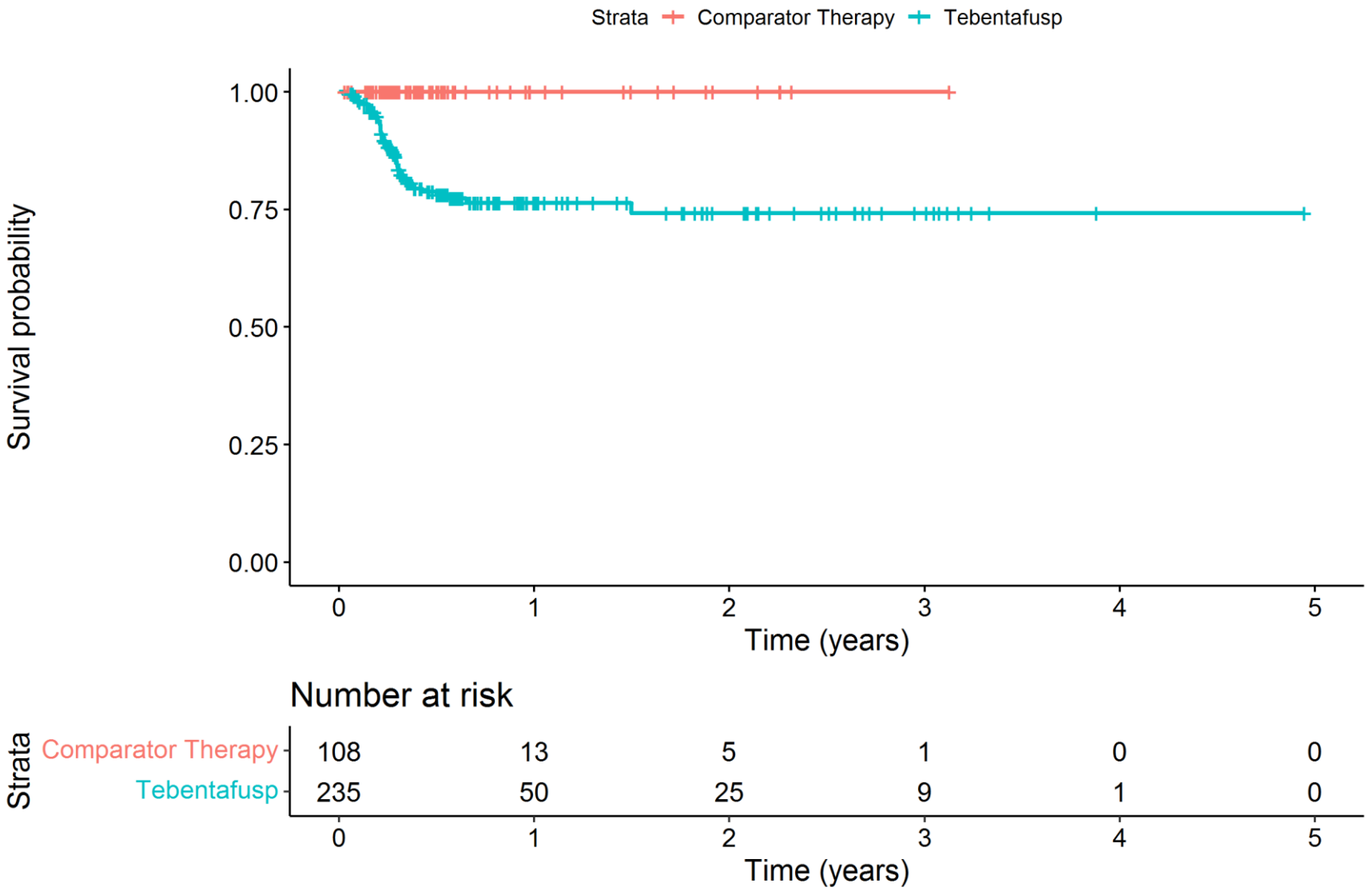
60.97 Veränderung der Haarfarbe- LDH > ULN



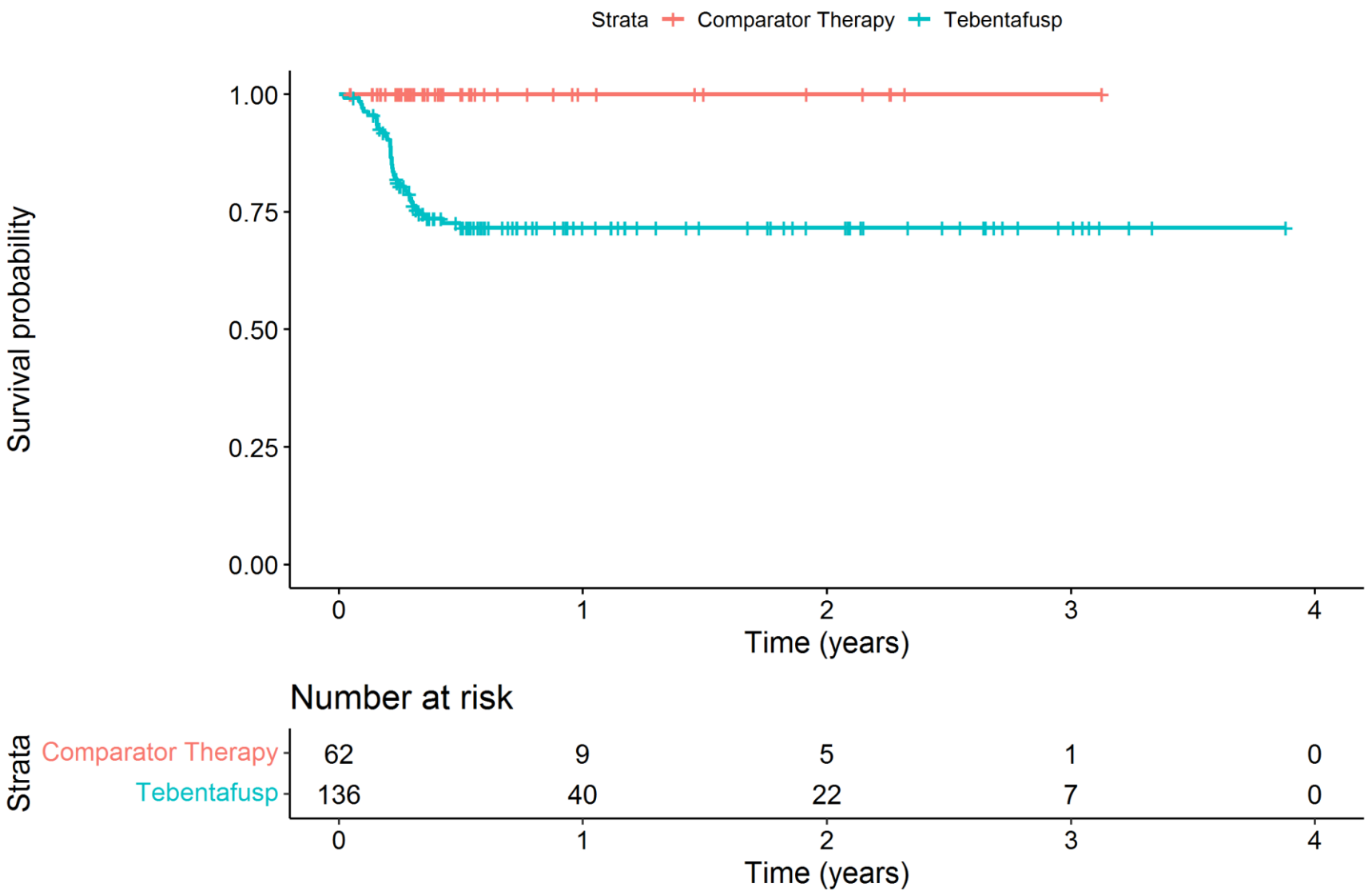
60.98 Veränderung der Haarfarbe- Vorherige Therapie adjuvant/neoadjuvant



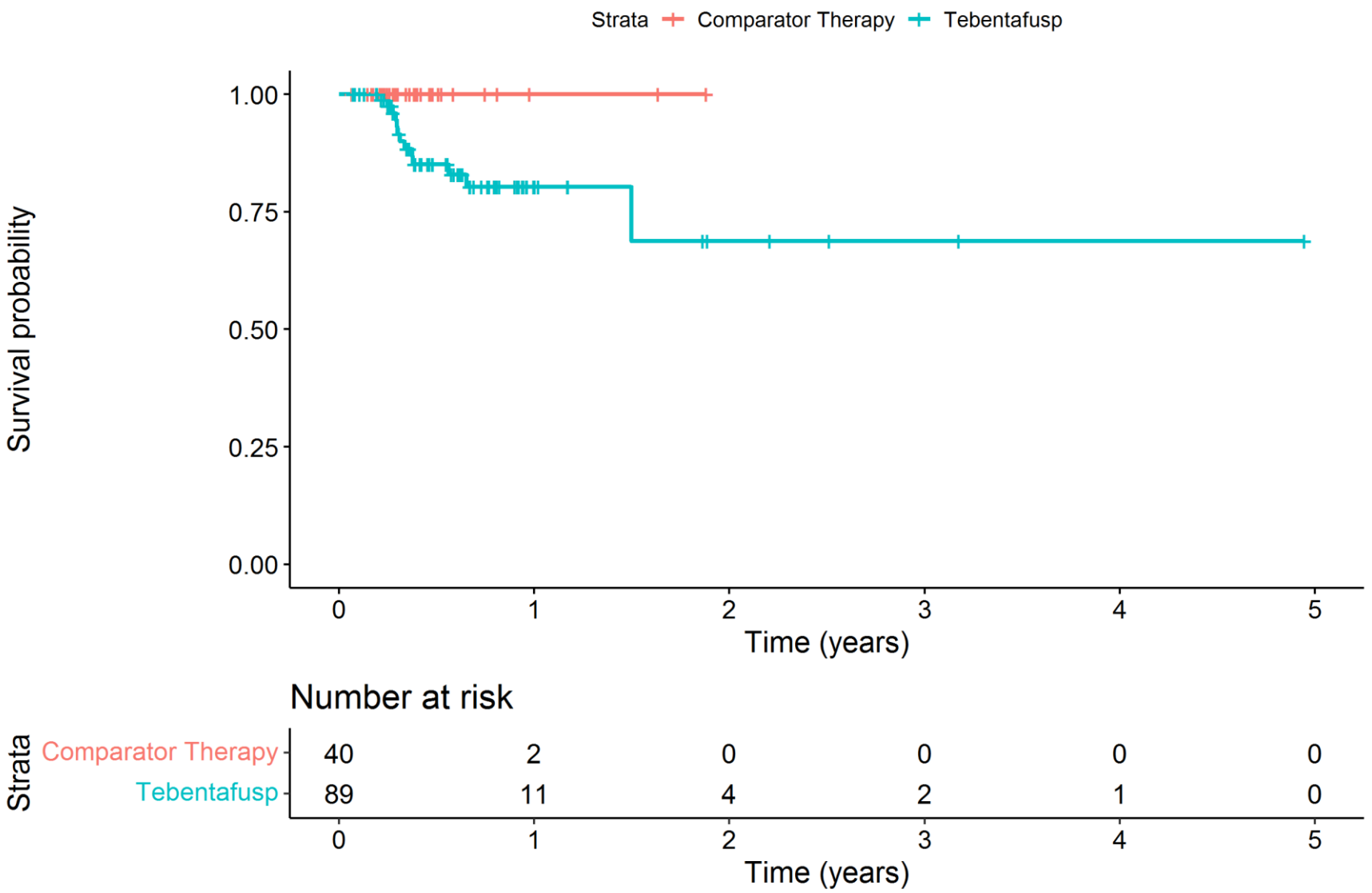
60.99 Veränderung der Haarfarbe- Keine Vorherige Therapie adjuvant/neoadjuvant



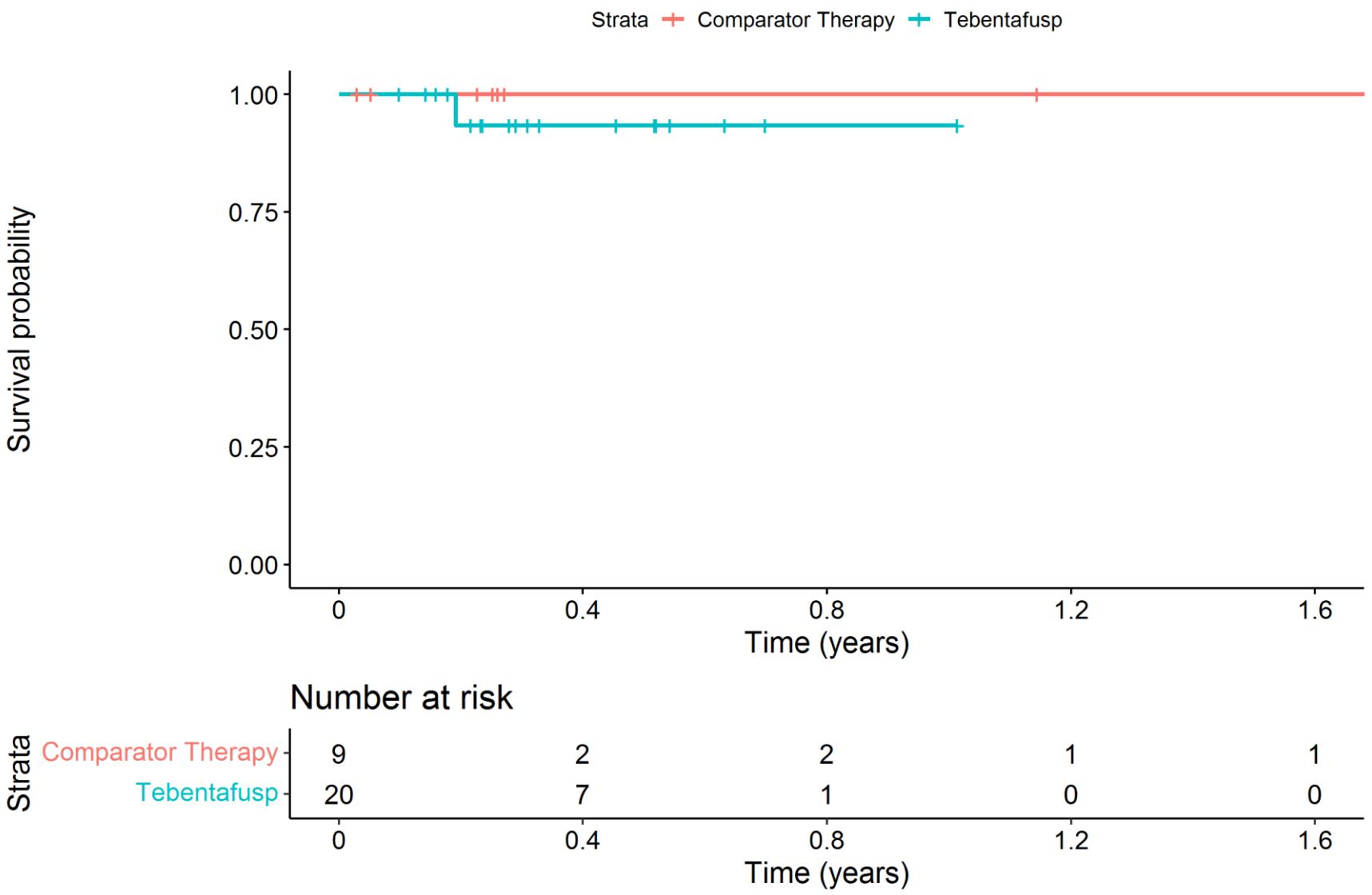
60.100 Veränderung der Haarfarbe- Läsion ≤ 3cm



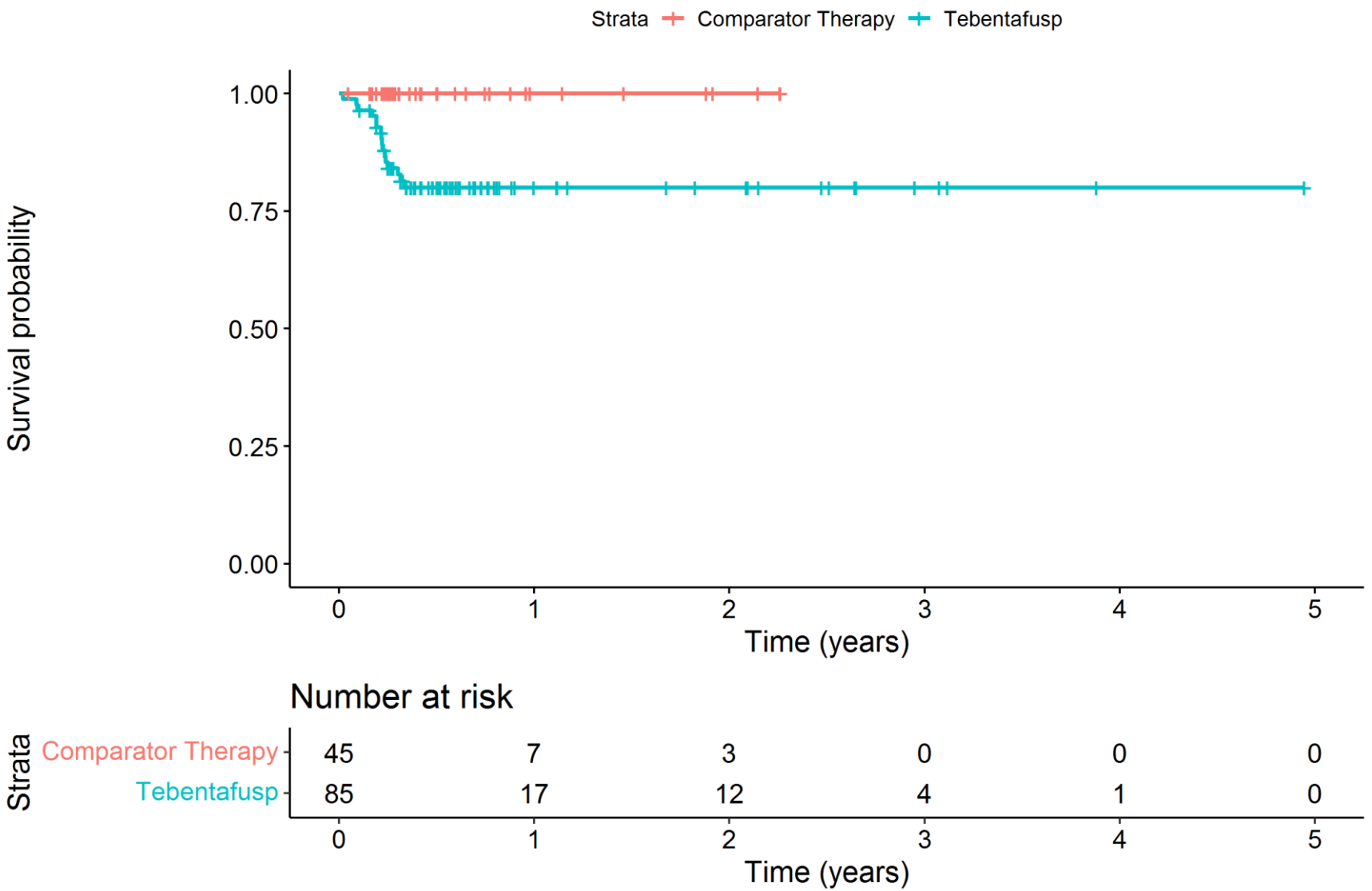
60.101 Veränderung der Haarfarbe- Läsion 3,1-8,0 cm



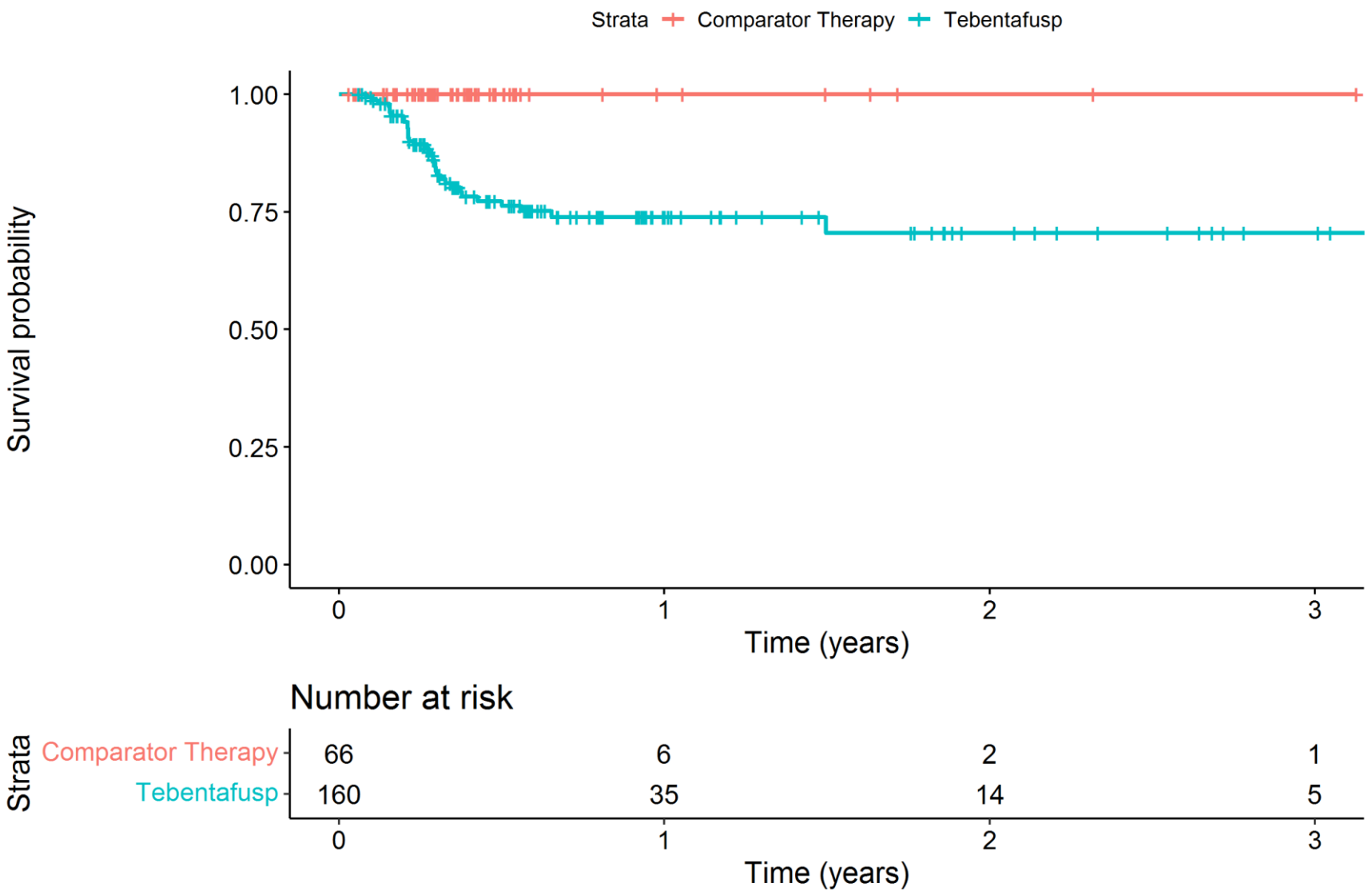
60.102 Veränderung der Haarfarbe- Läsion ≥8,1 cm



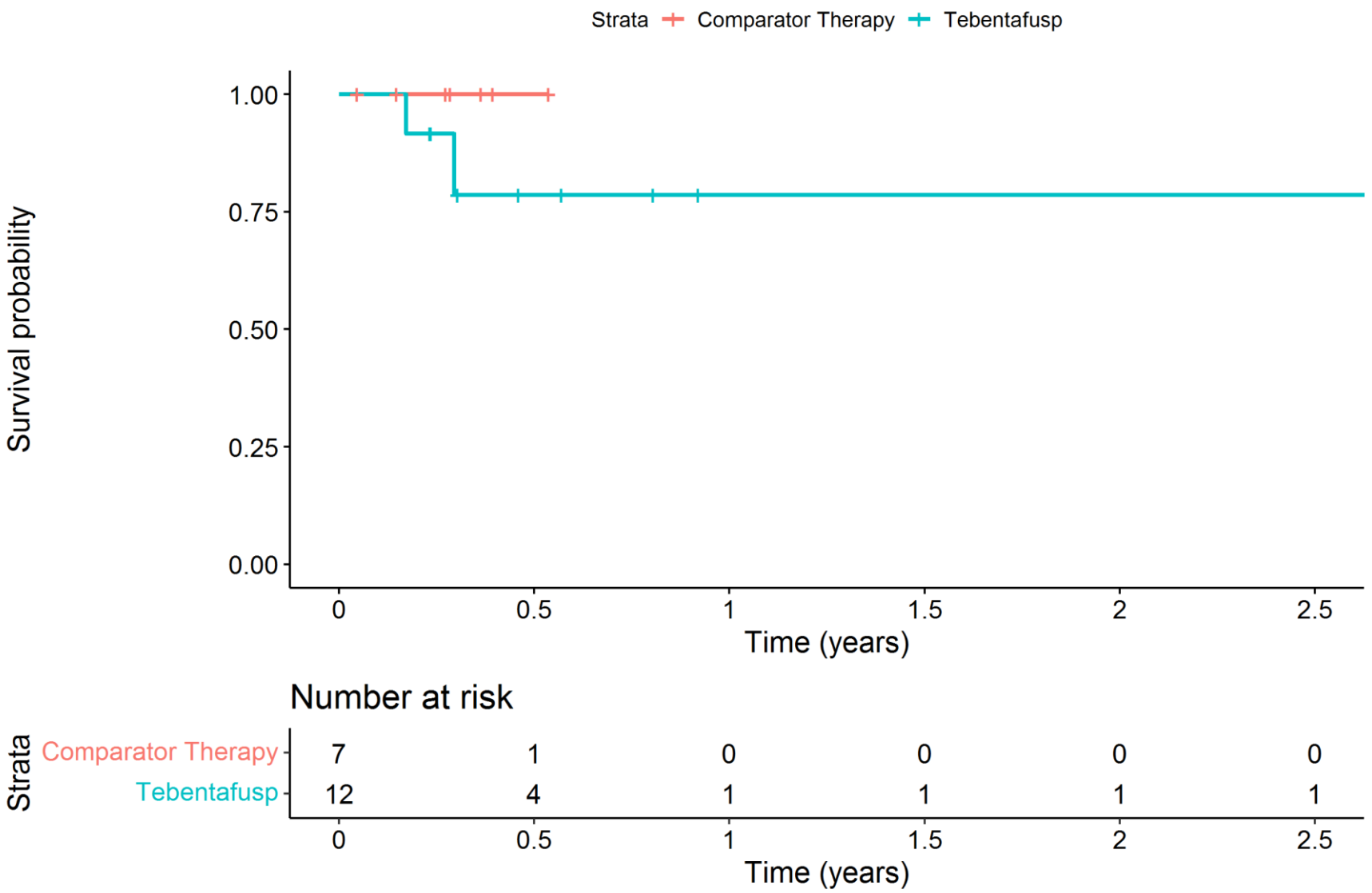
Veränderung der Haarfarbe- Nordamerika



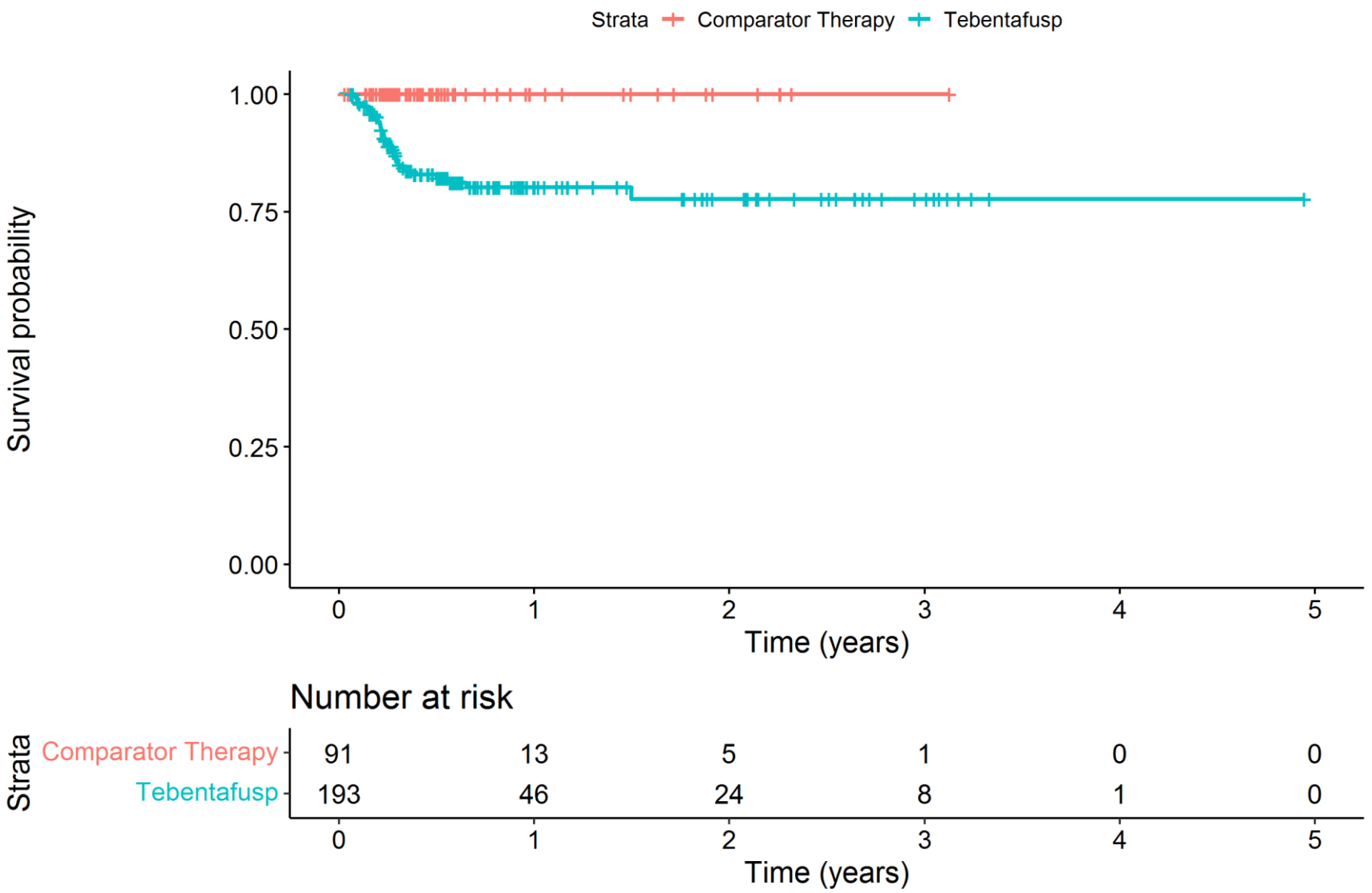
60.103 Veränderung der Haarfarbe- Nicht-Nordamerika



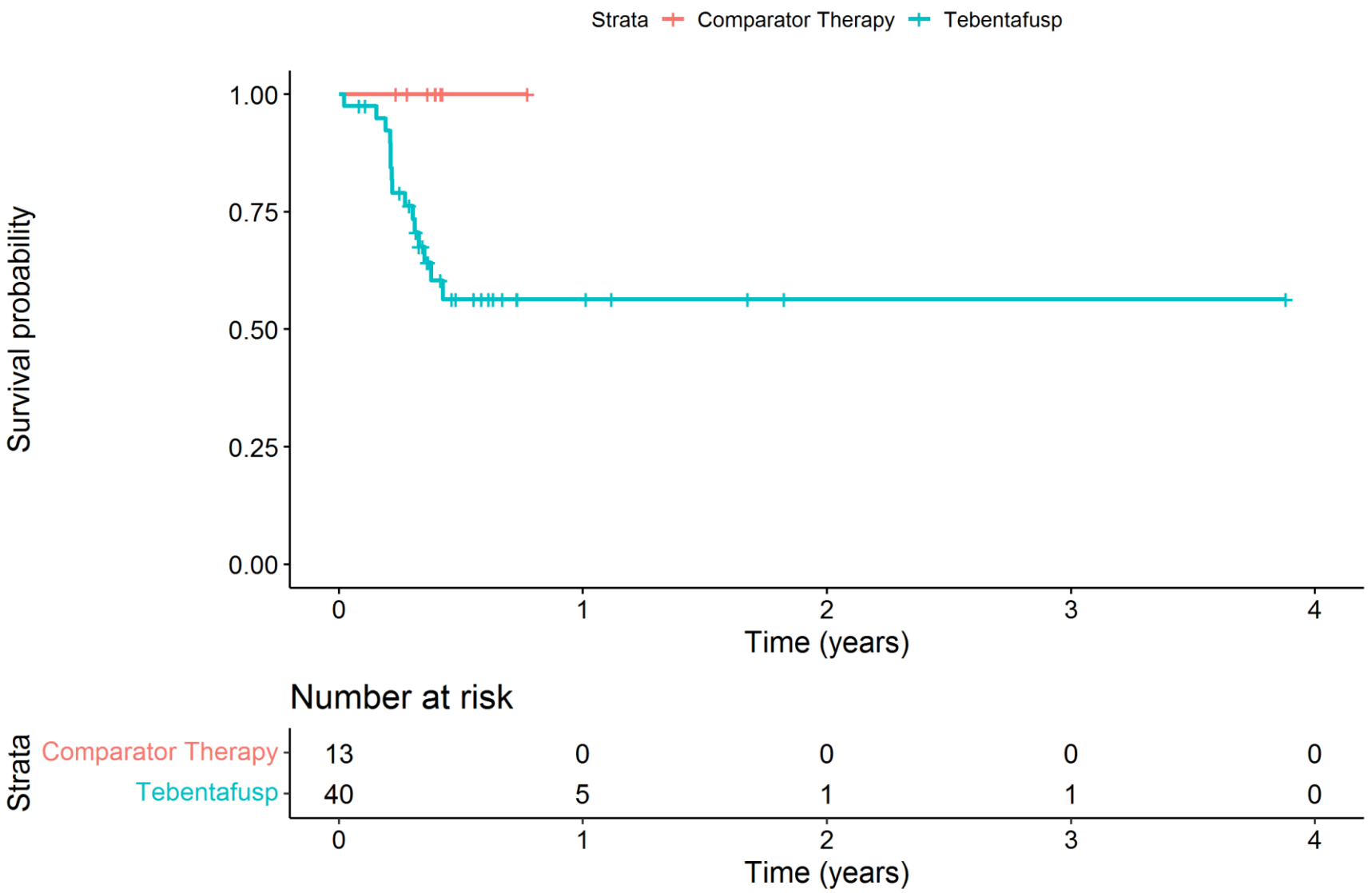
60.104 Veränderung der Haarfarbe- Dacarbazin



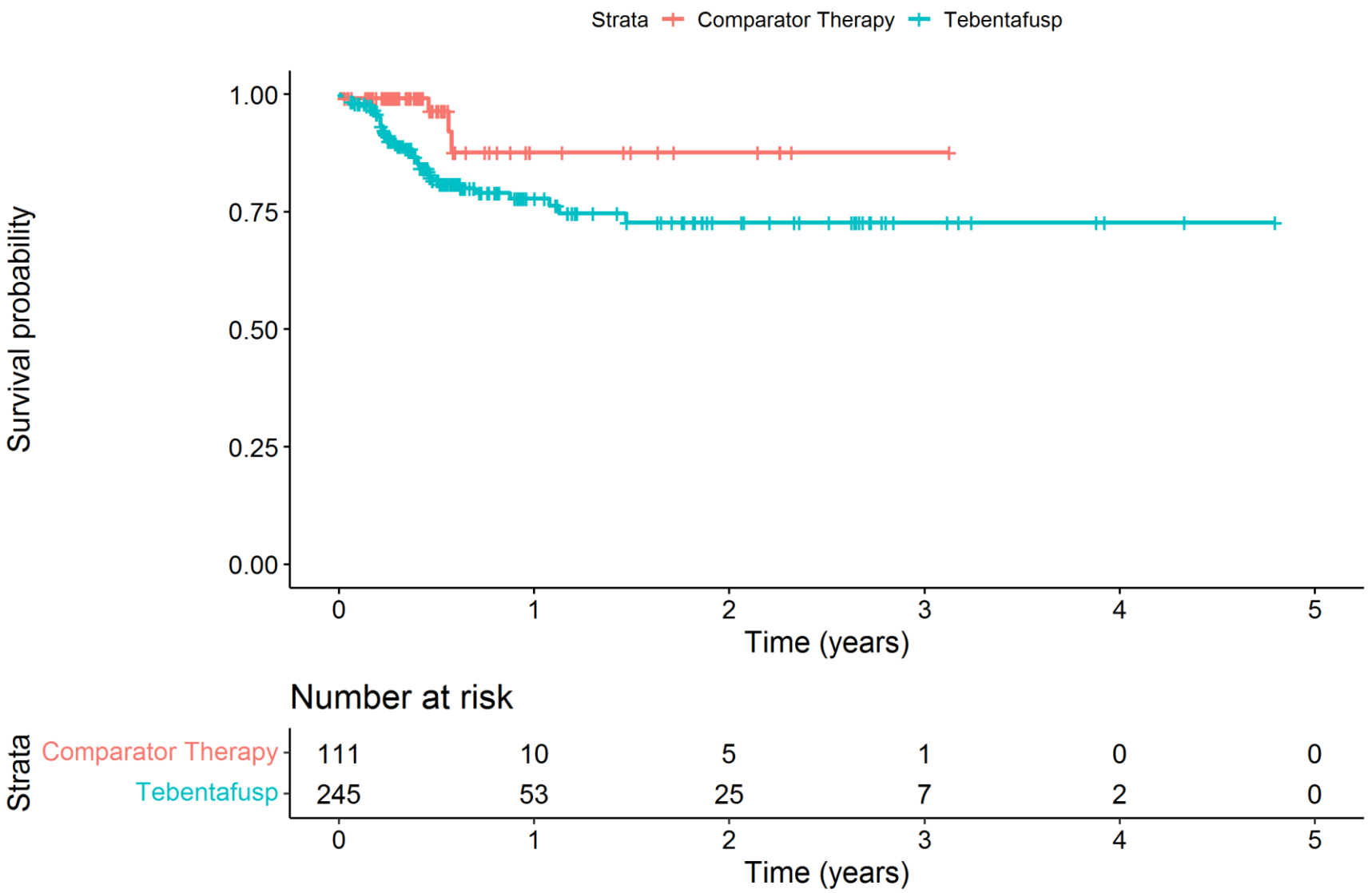
60.105 Veränderung der Haarfarbe- Pembrolizumab



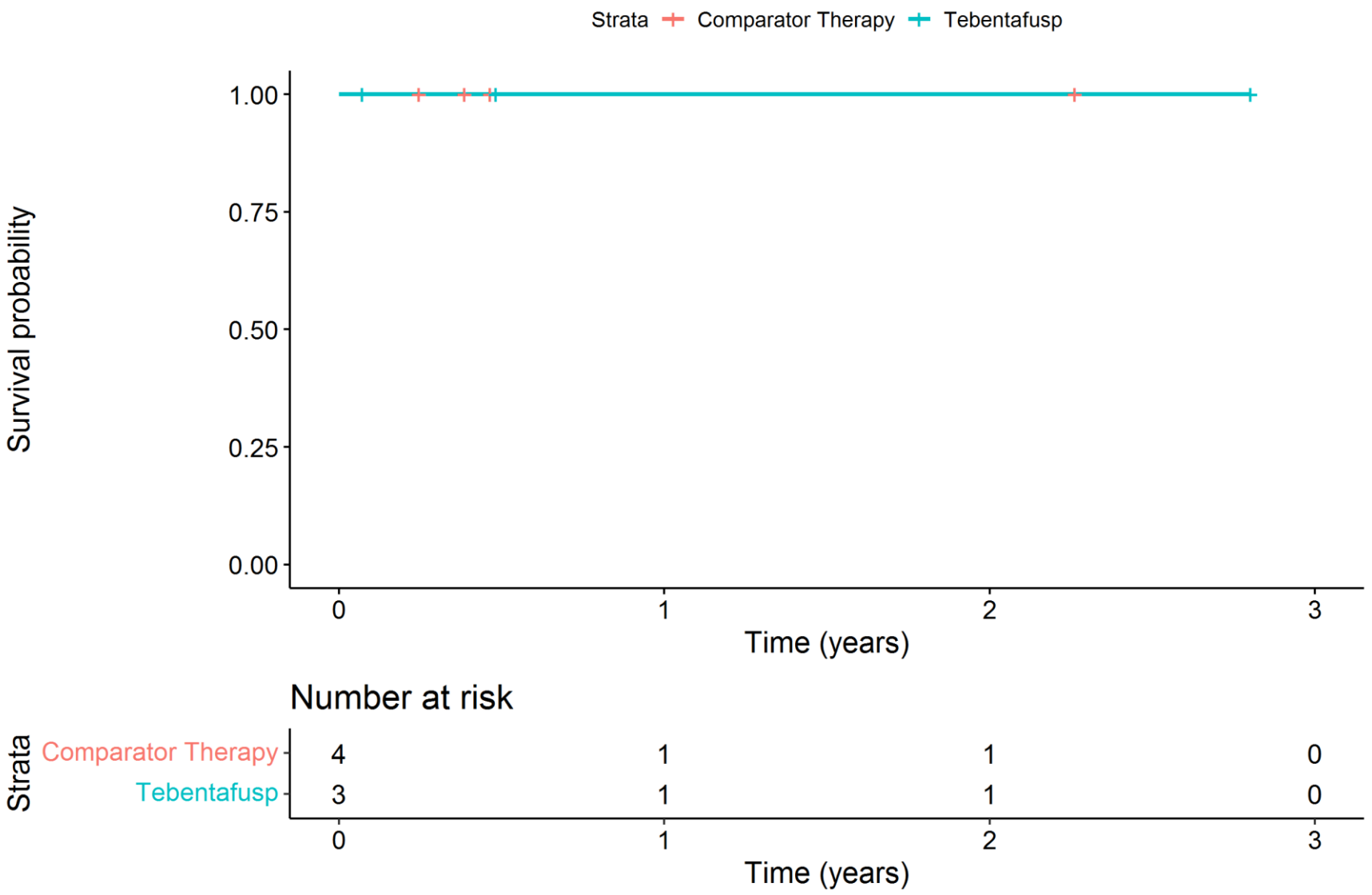
60.106 Veränderung der Haarfarbe- Ipilimumab



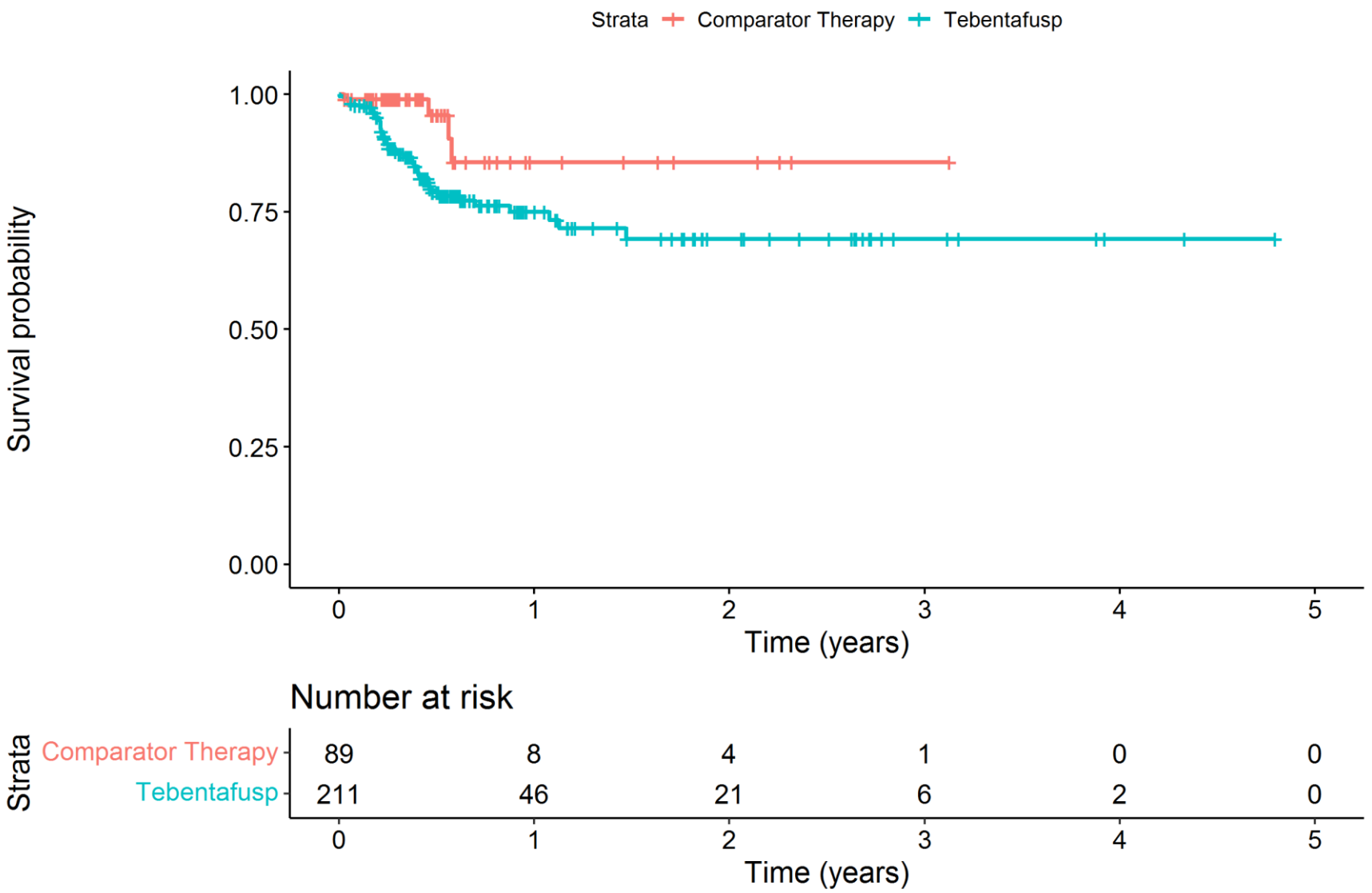
60.107 Vitiligo - Gesamt



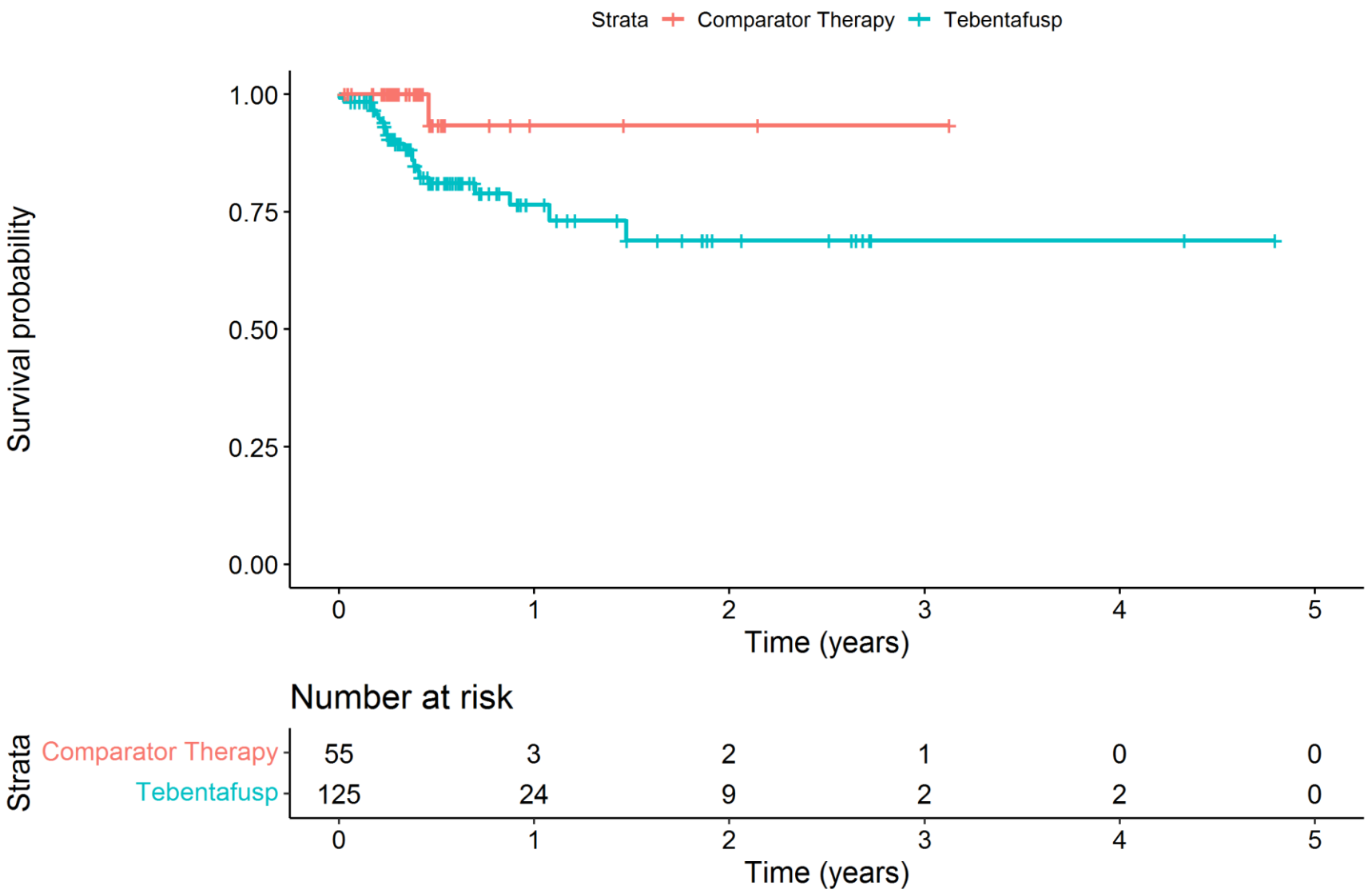
60.108 Vitiligo - Hispanisch



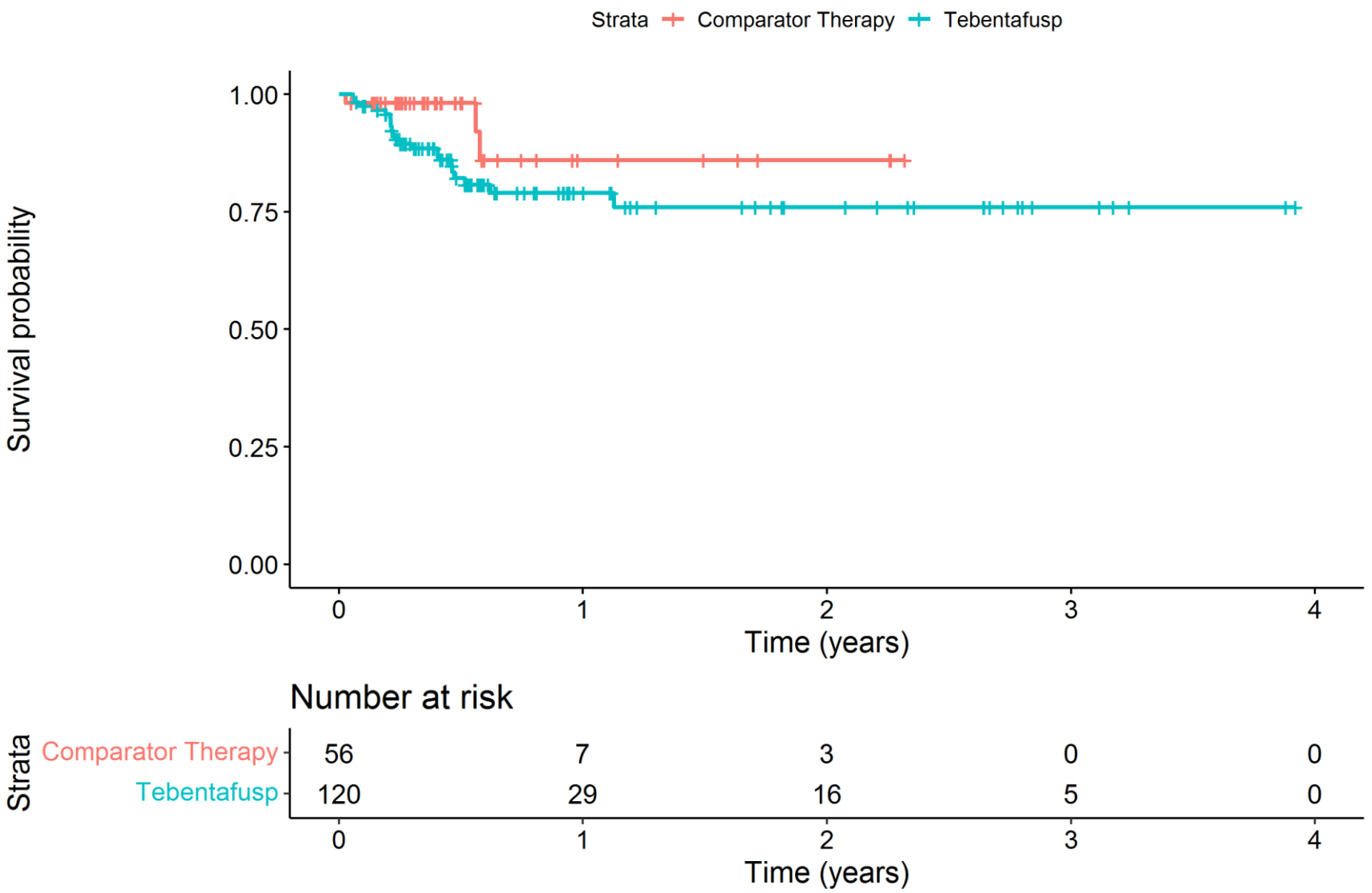
60.109 Vitiligo - Nicht-hispanisch



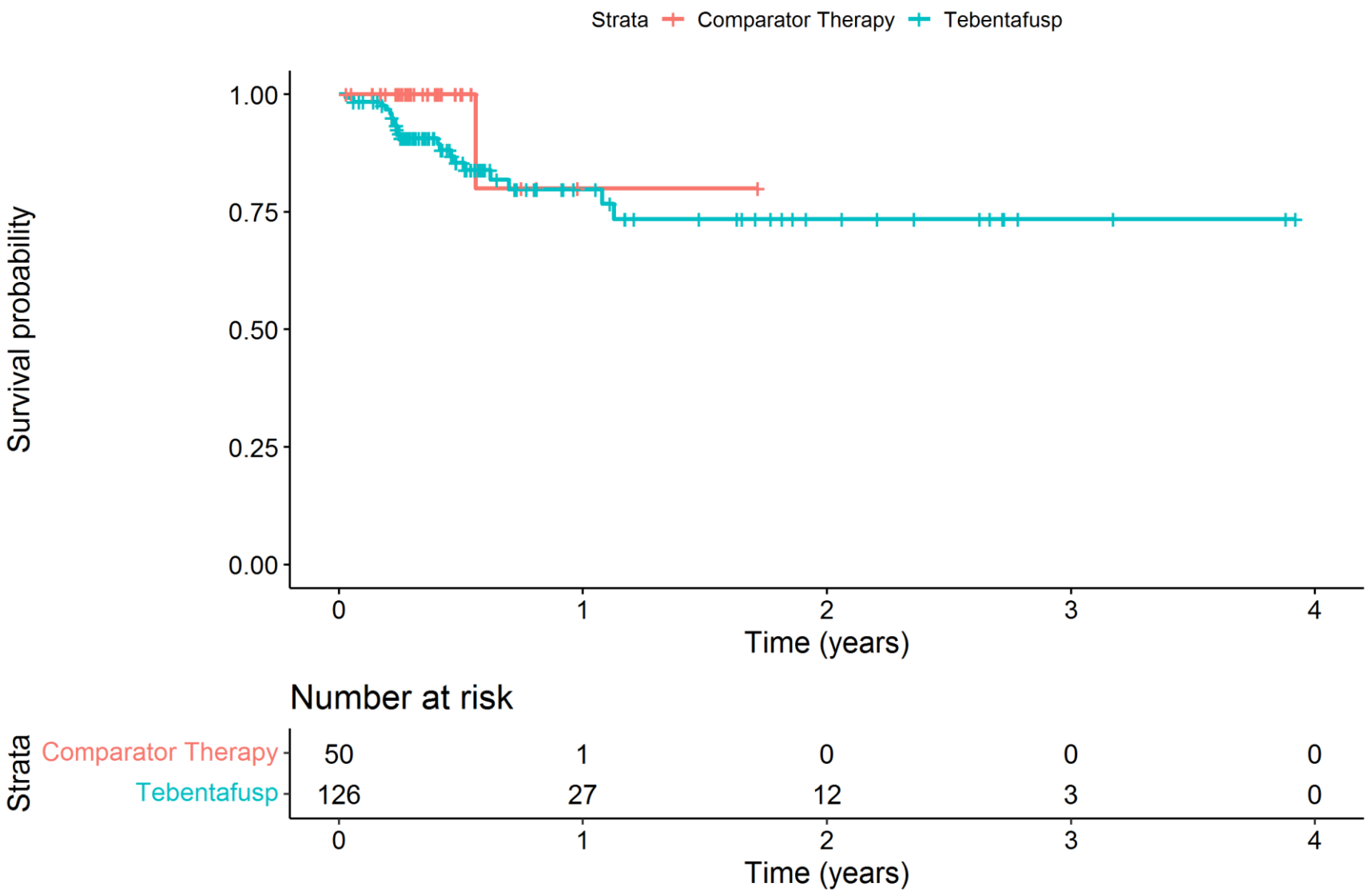
60.110 Vitiligo - Männlich



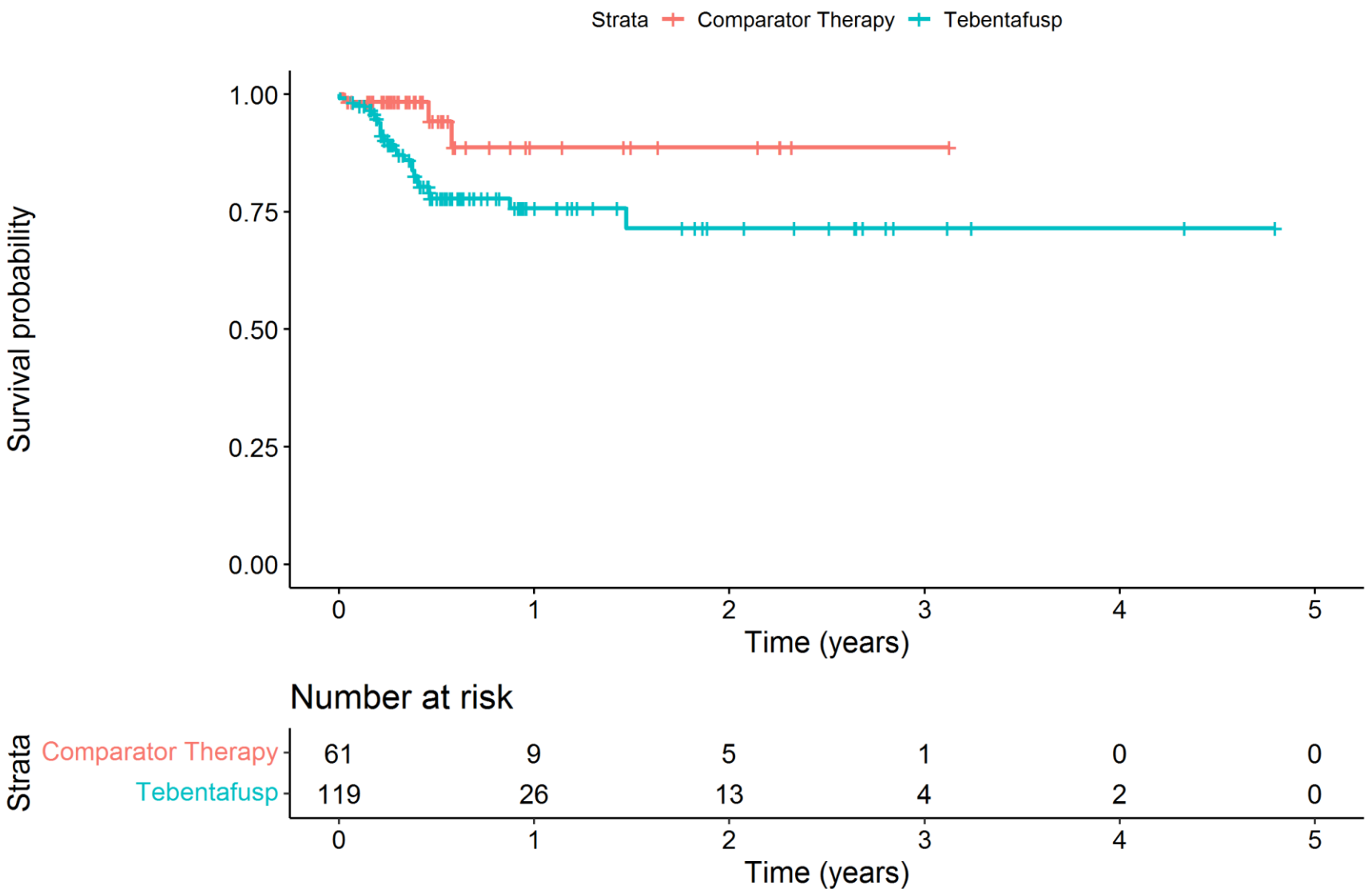
60.111 Vitiligo - Weiblich



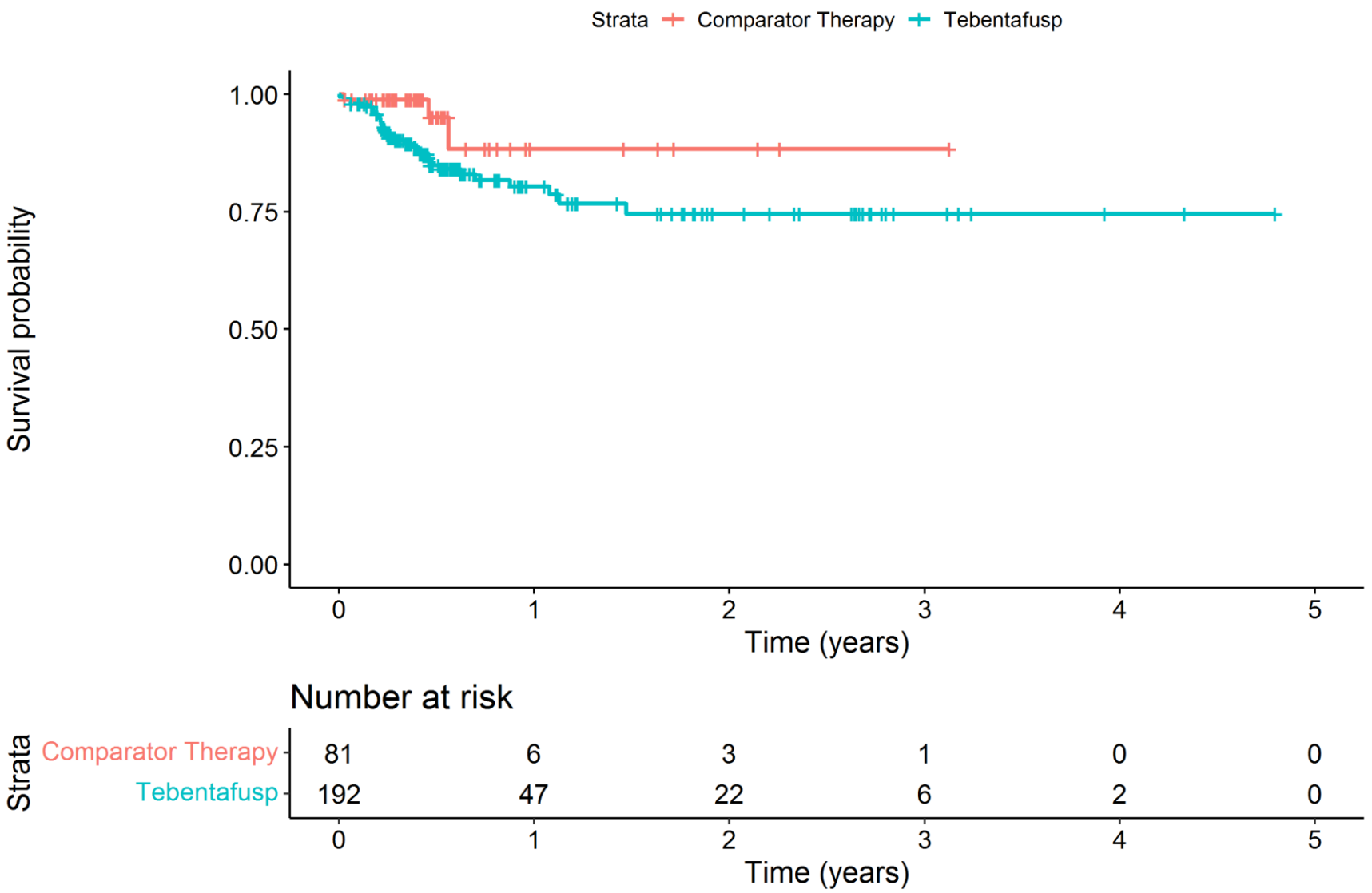
60.112 Vitiligo - <65



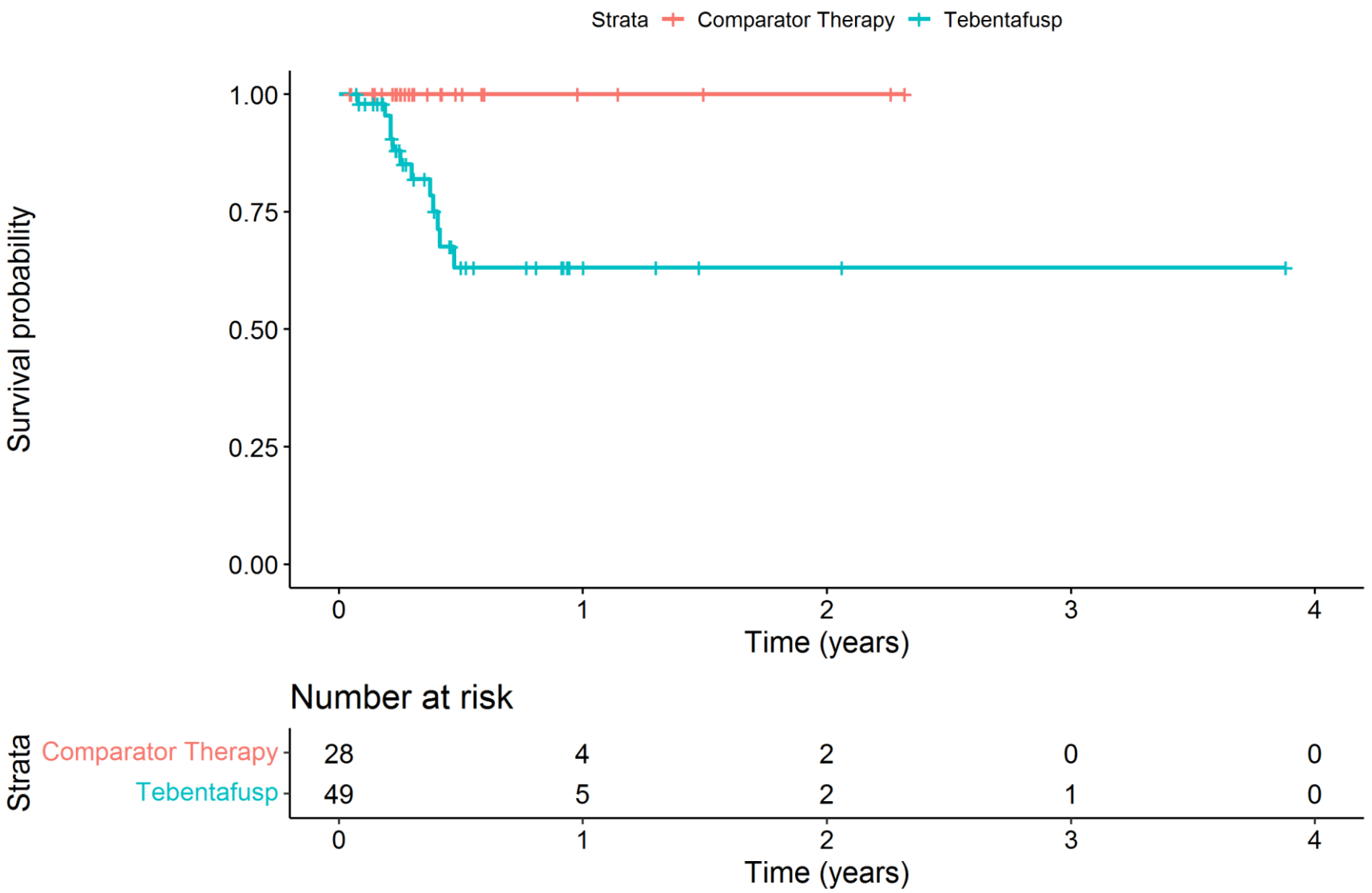
60.113 Vitiligo - ≥65



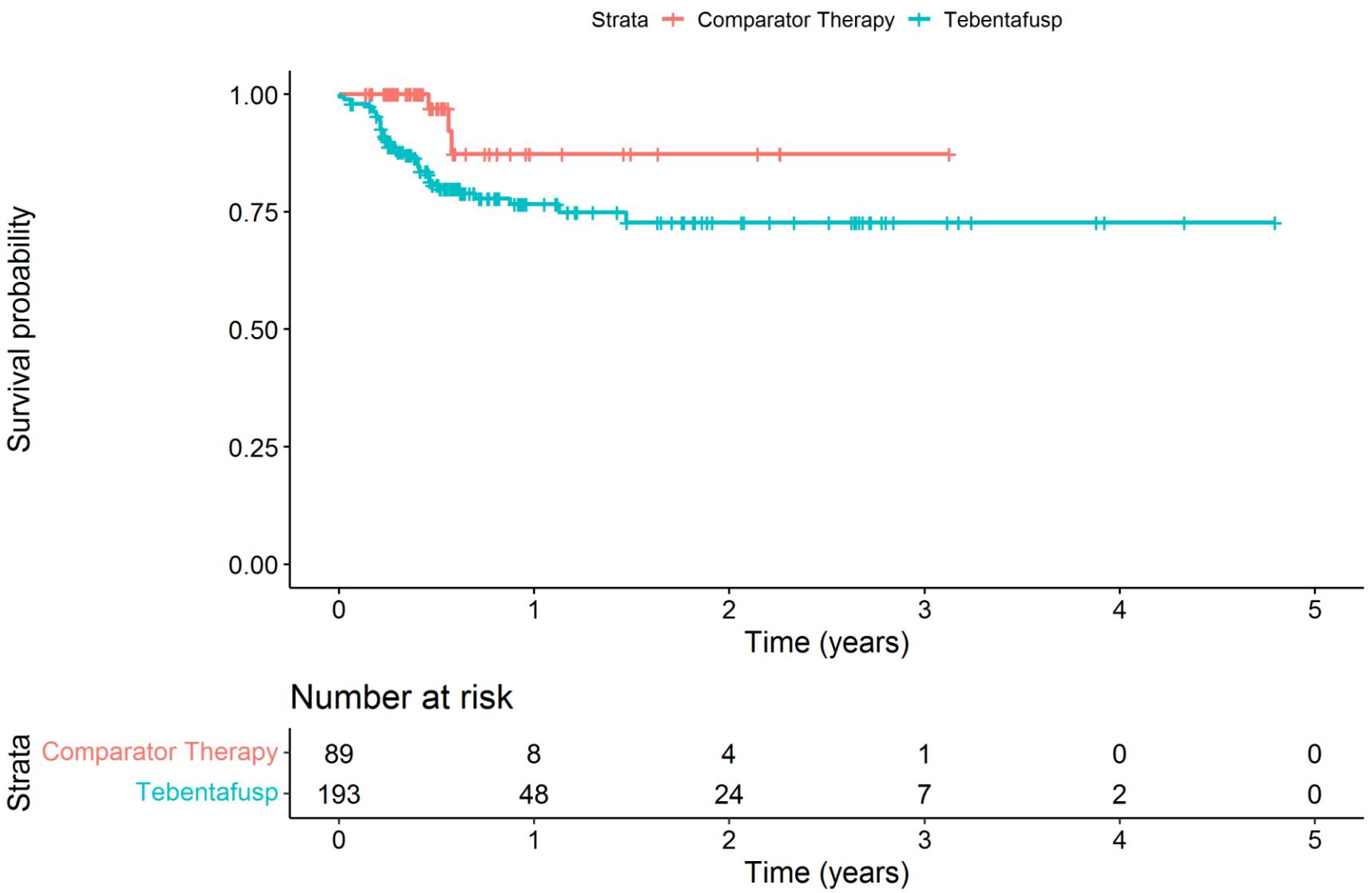
60.114 Vitiligo - ECOG 0



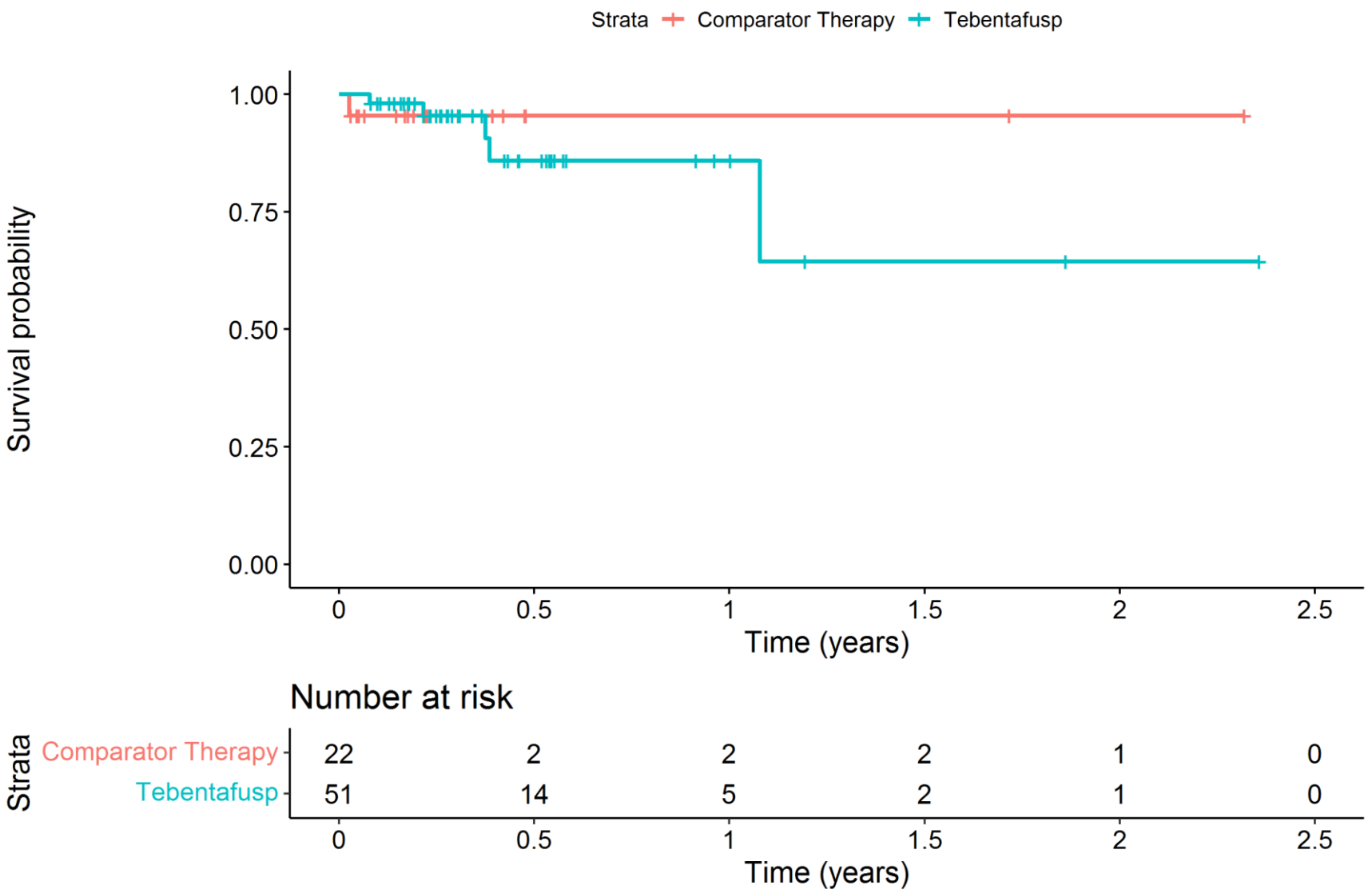
60.115 Vitiligo - ECOG 1



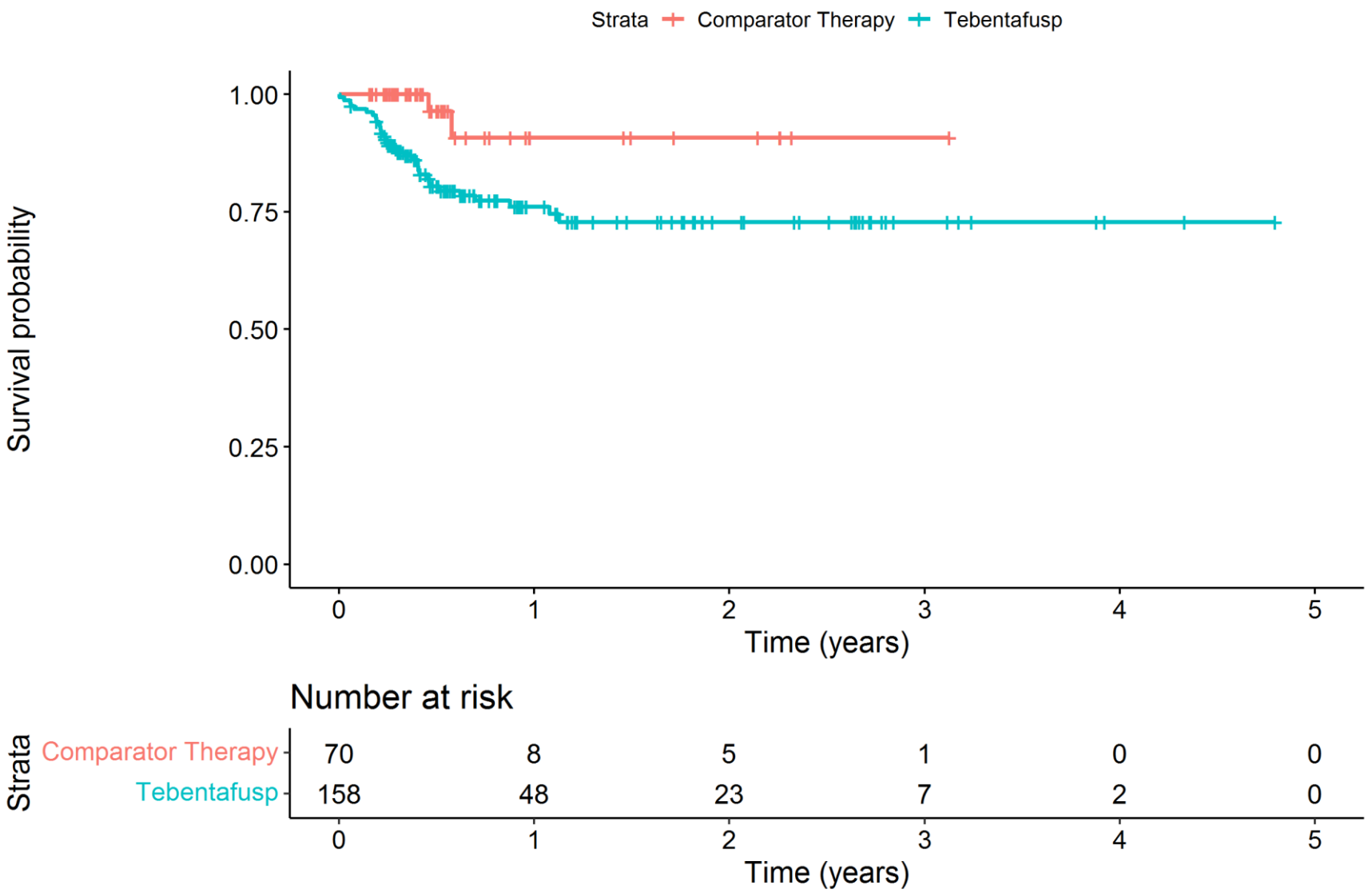
60.116 Vitiligo - ALP ≤ ULN



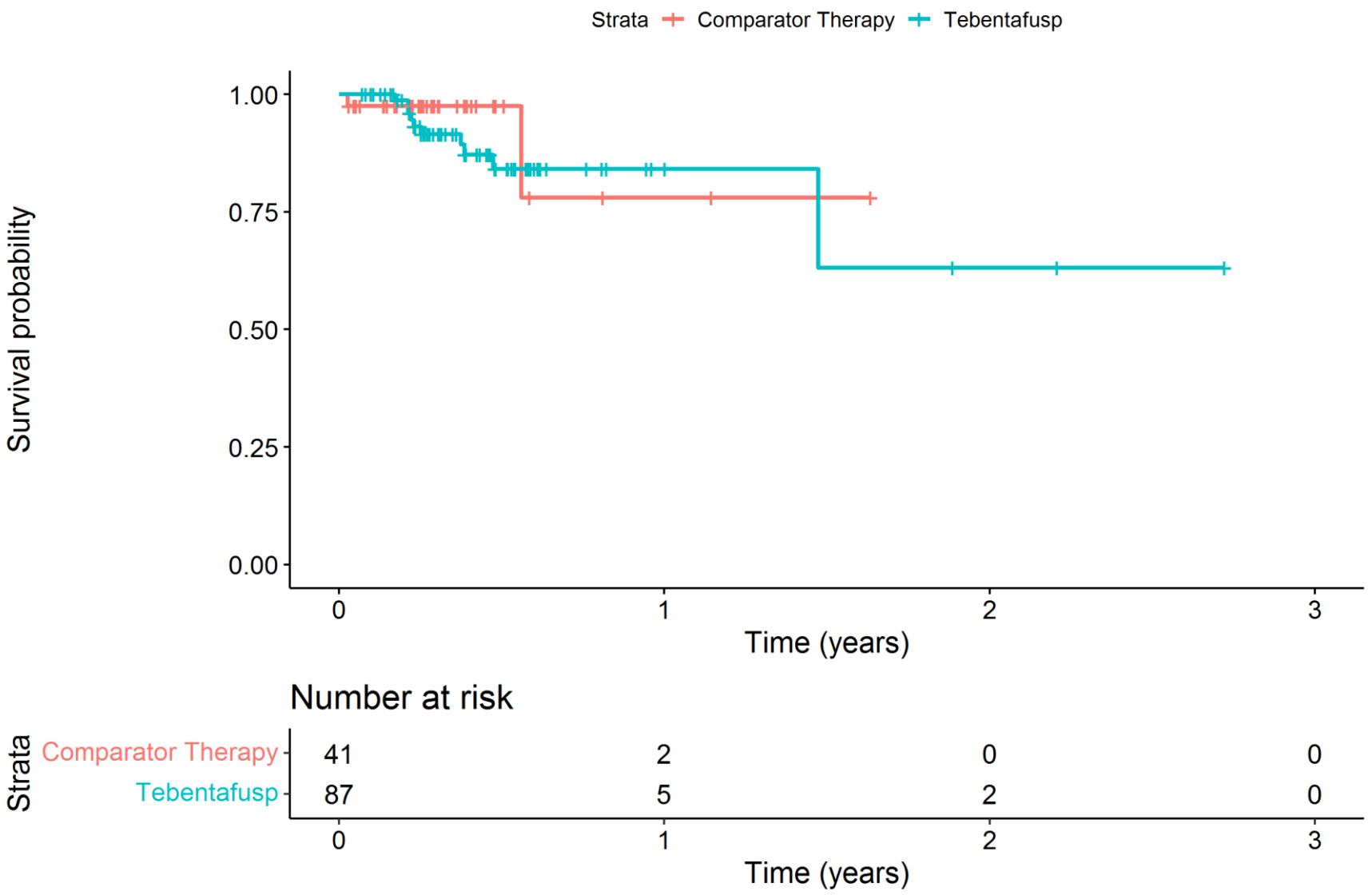
60.117 Vitiligo - ALP > ULN



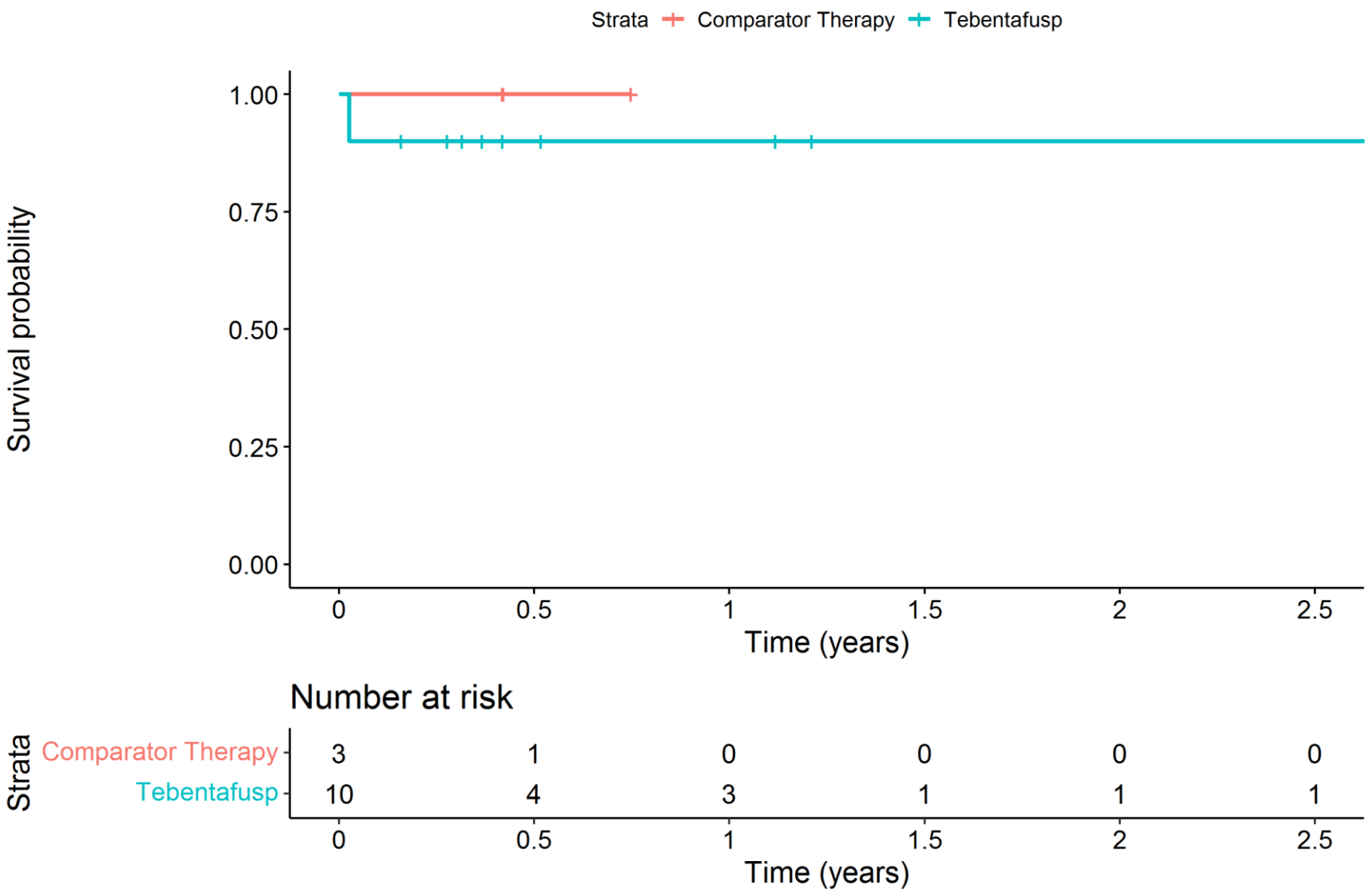
60.118 Vitiligo - LDH =< ULN



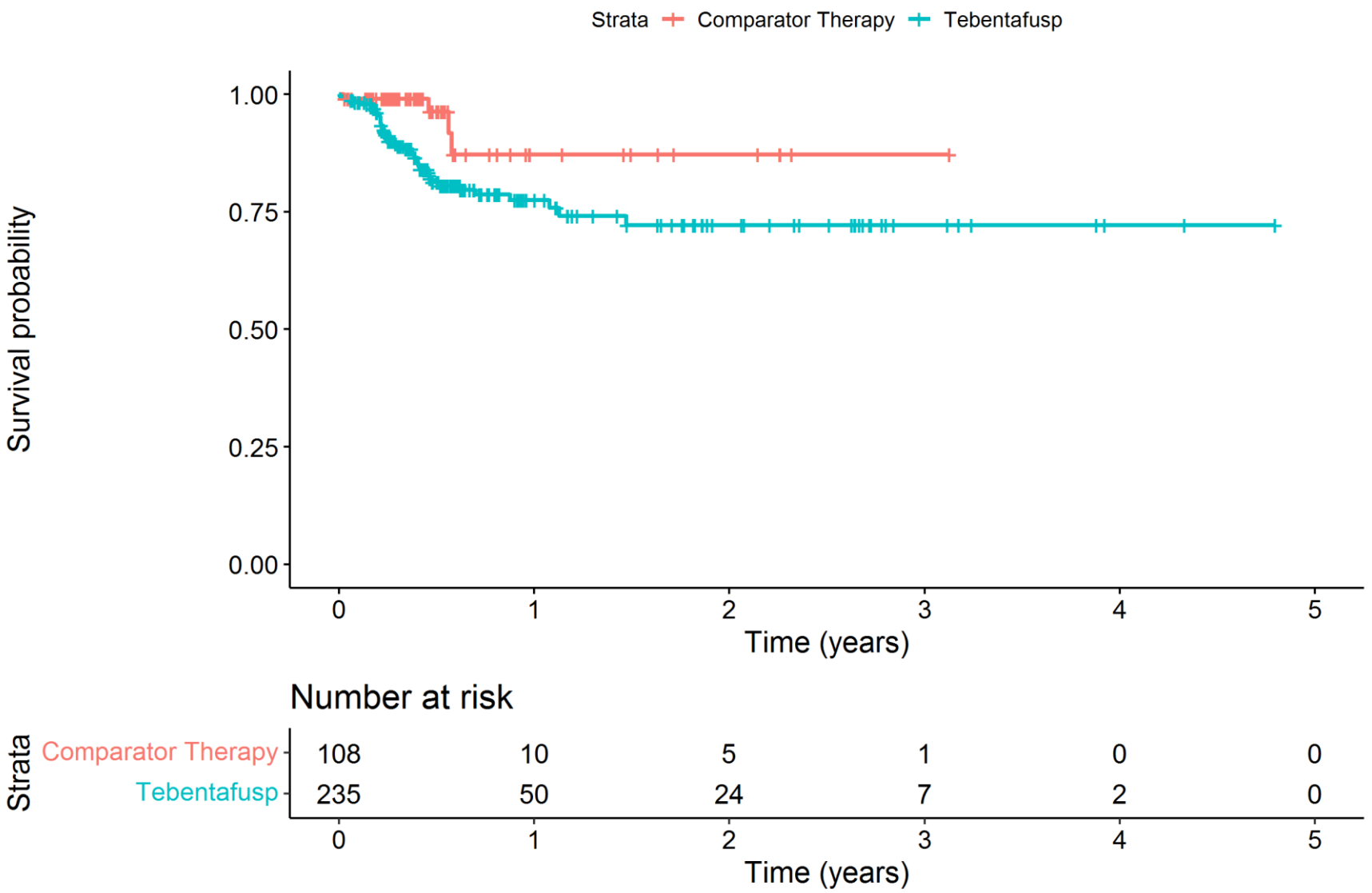
60.119 Vitiligo - LDH > ULN



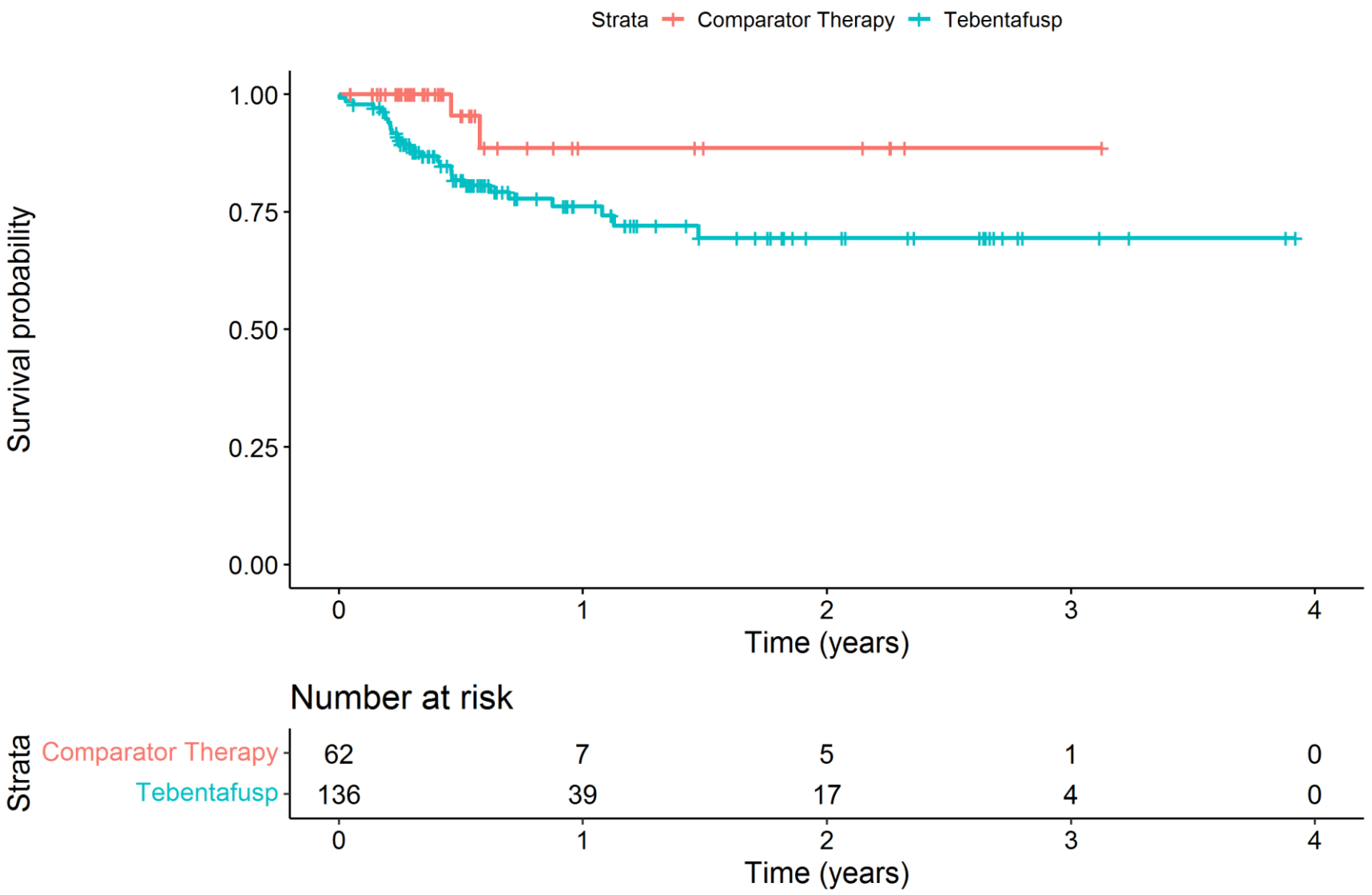
60.120 Vitiligo - Vorherige Therapie adjuvant/neoadjuvant



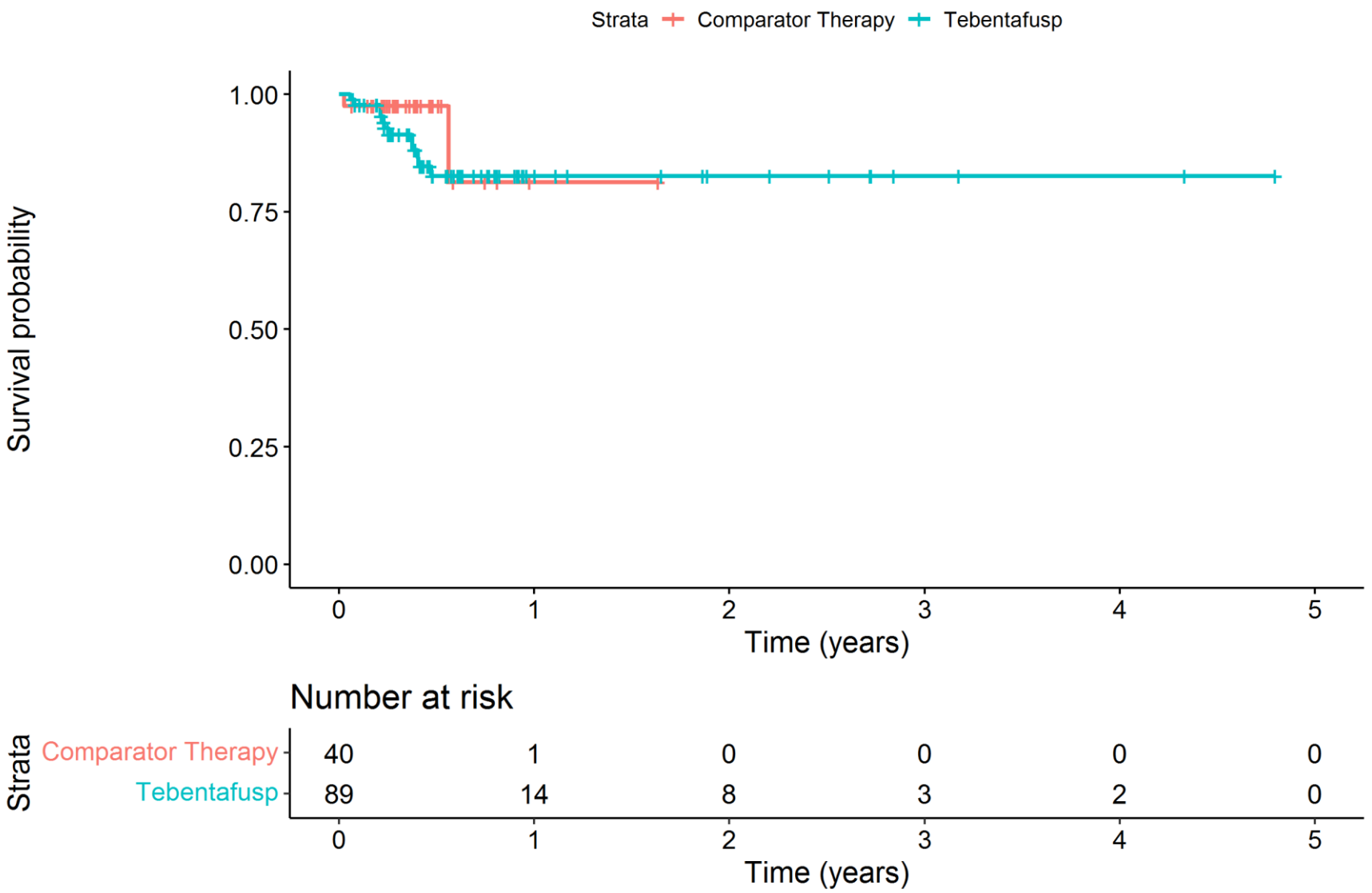
60.121 Vitiligo - Keine Vorherige Therapie adjuvant/neoadjuvant



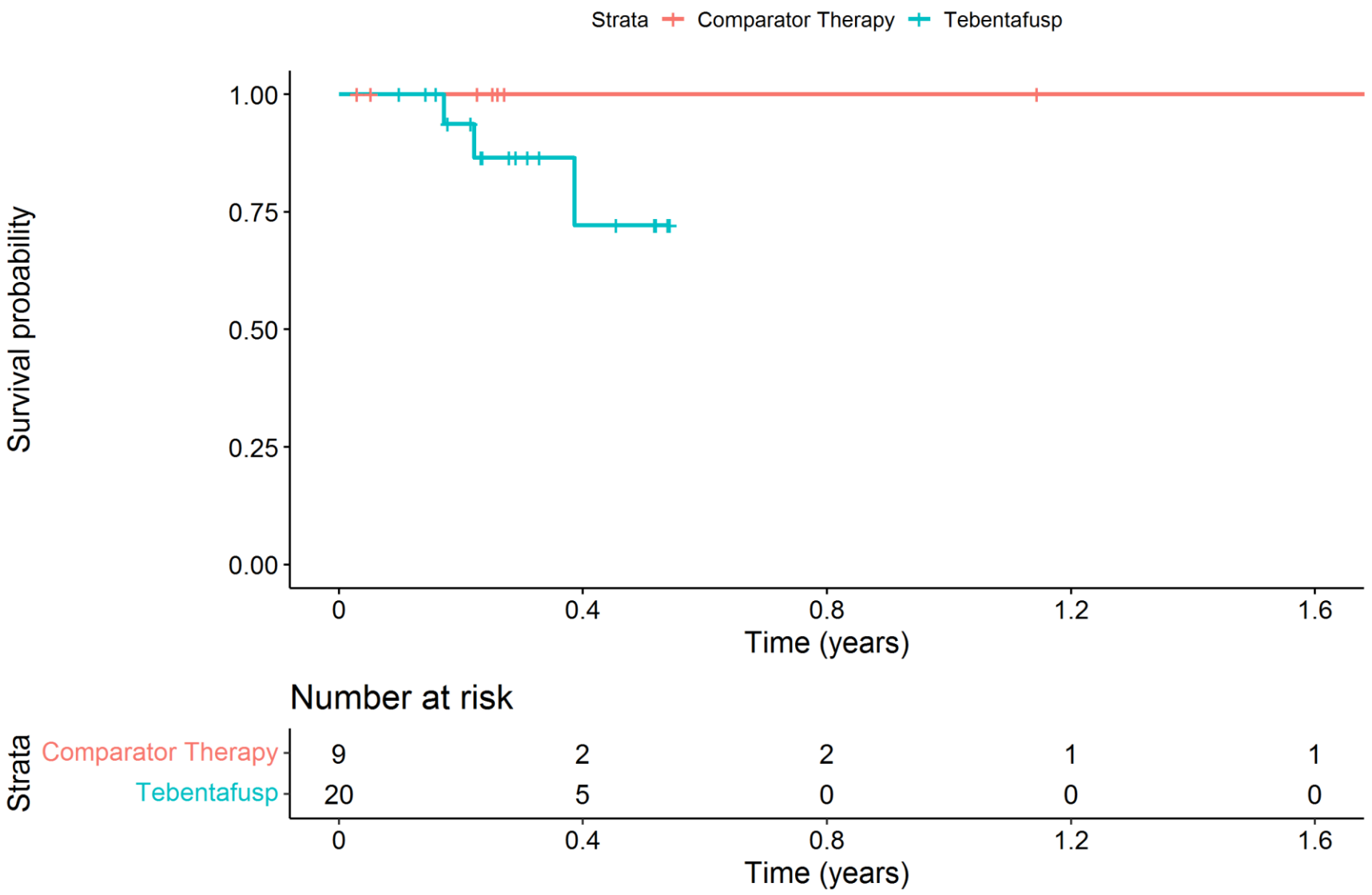
60.122 Vitiligo - Läsion ≤ 3cm



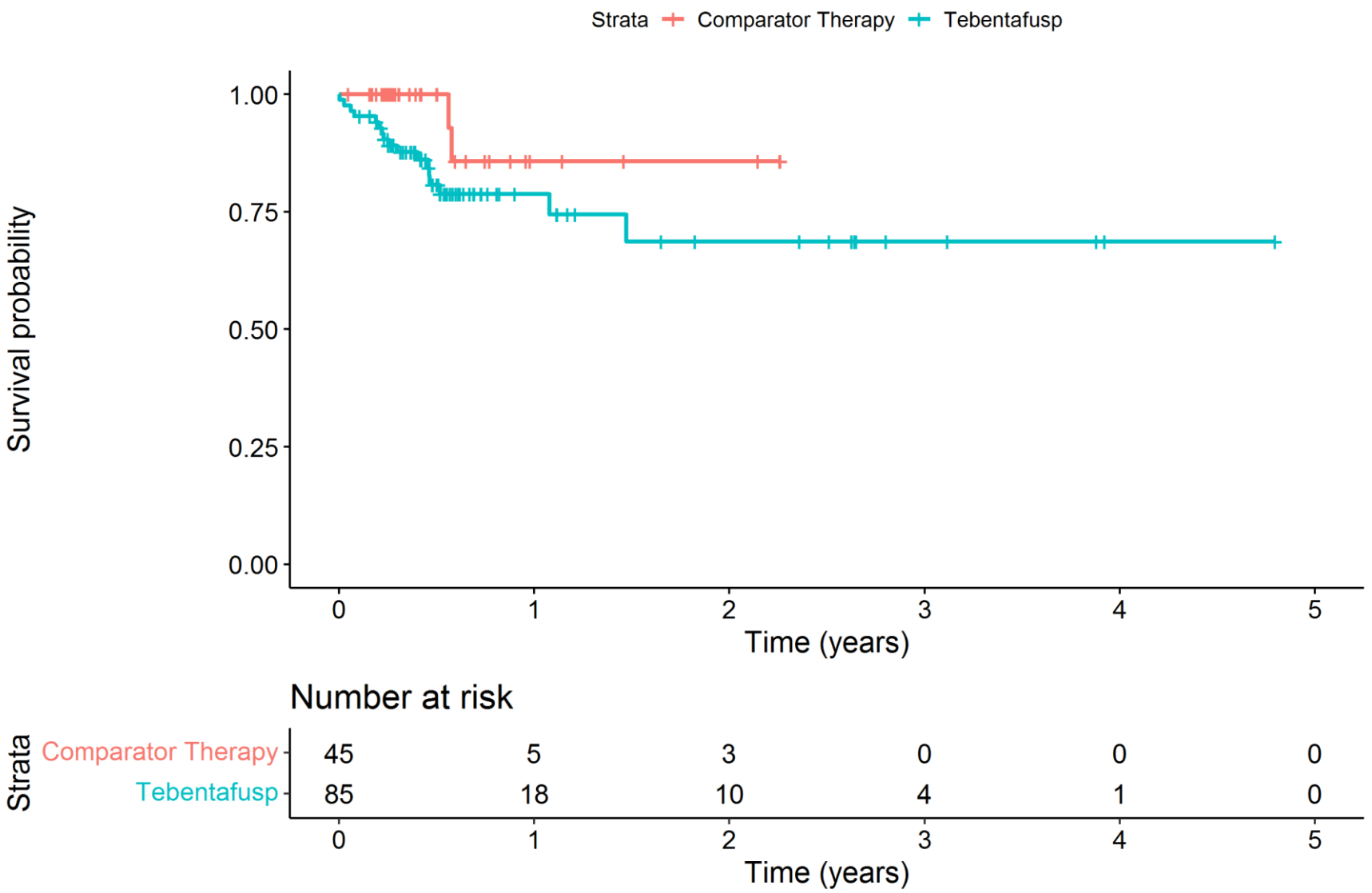
60.123 Vitiligo - Läsion 3,1-8,0 cm



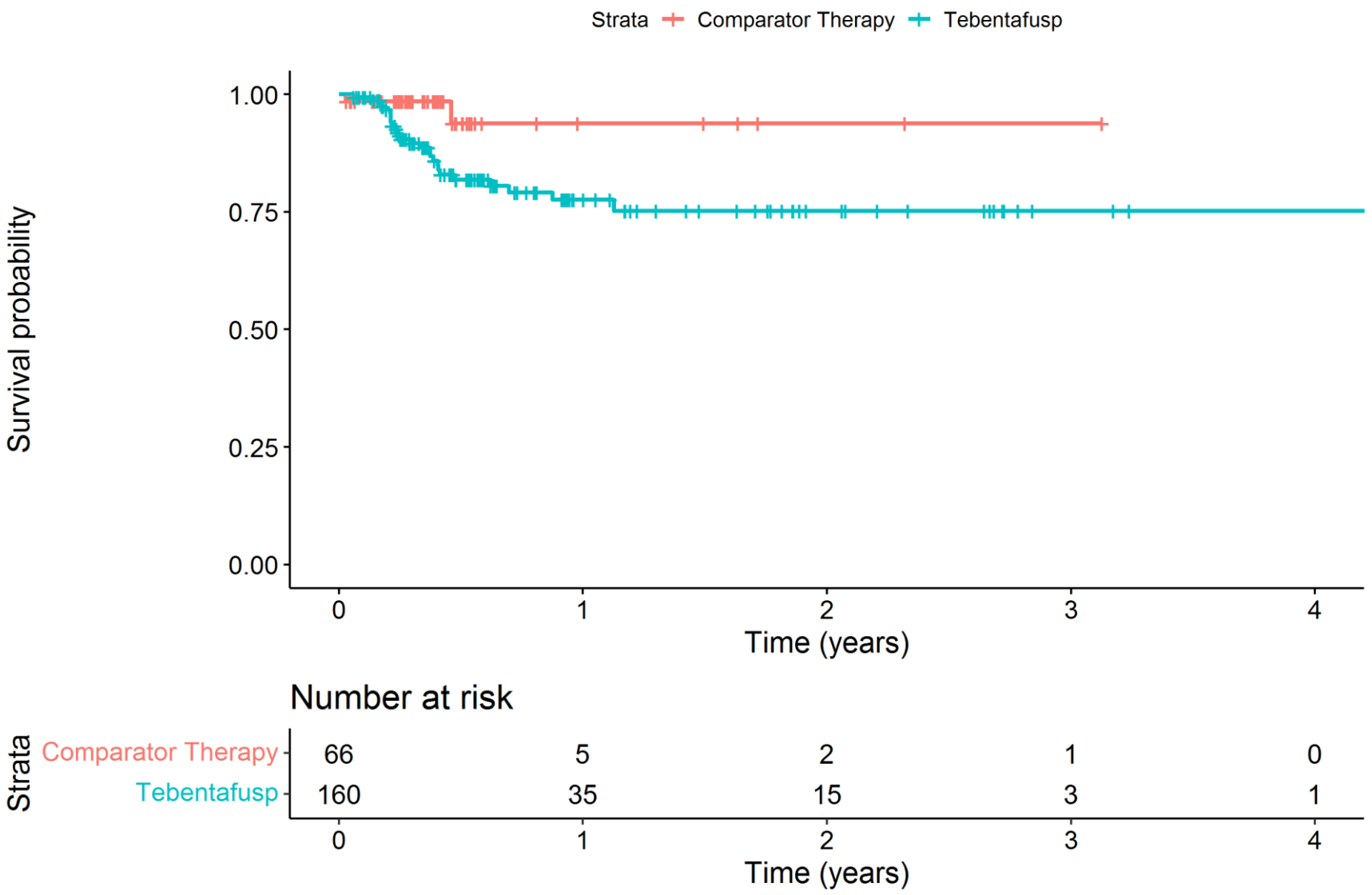
60.124 Vitiligo - Läsion ≥8,1 cm



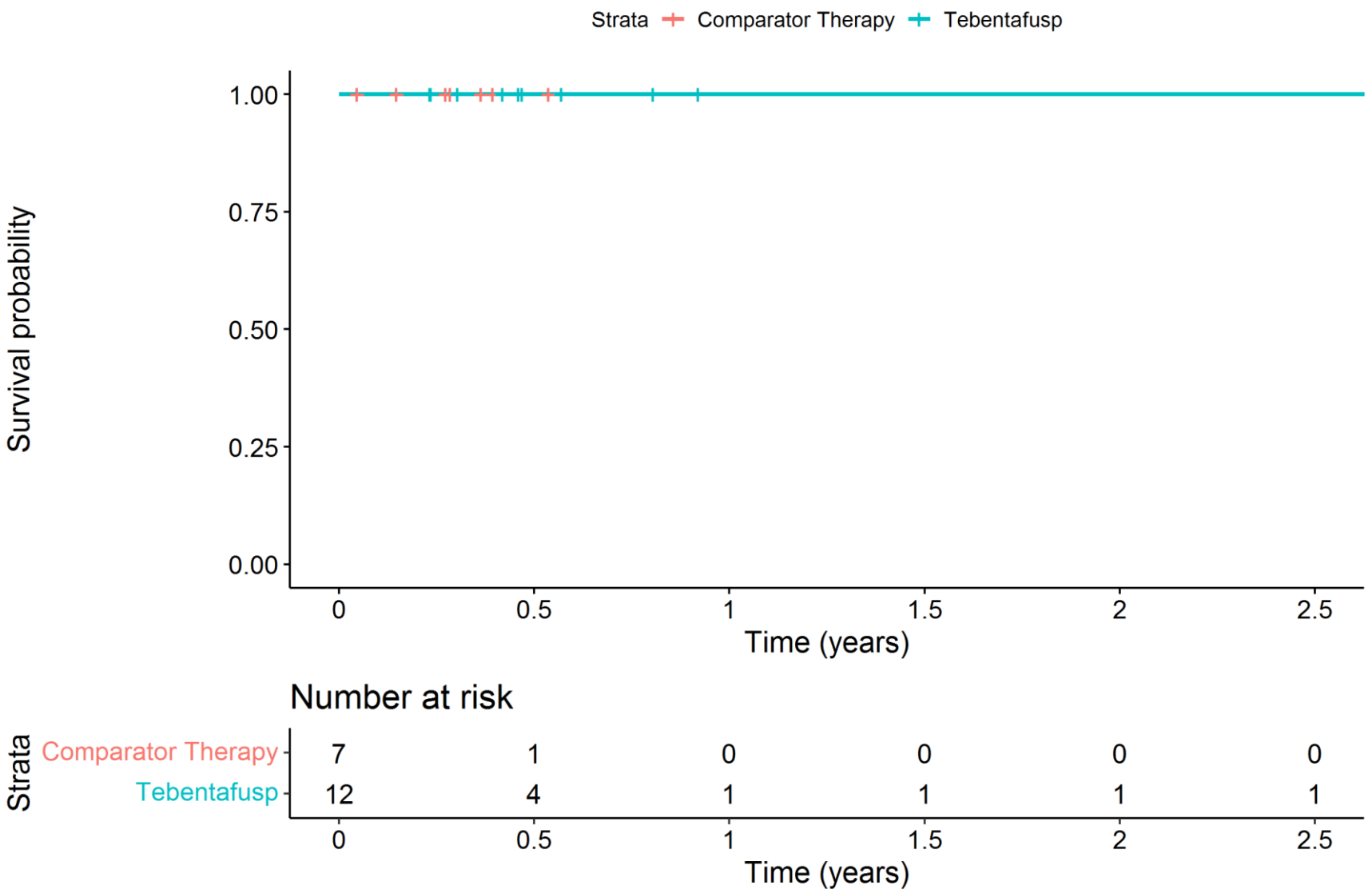
60.125 Vitiligo - Nordamerika



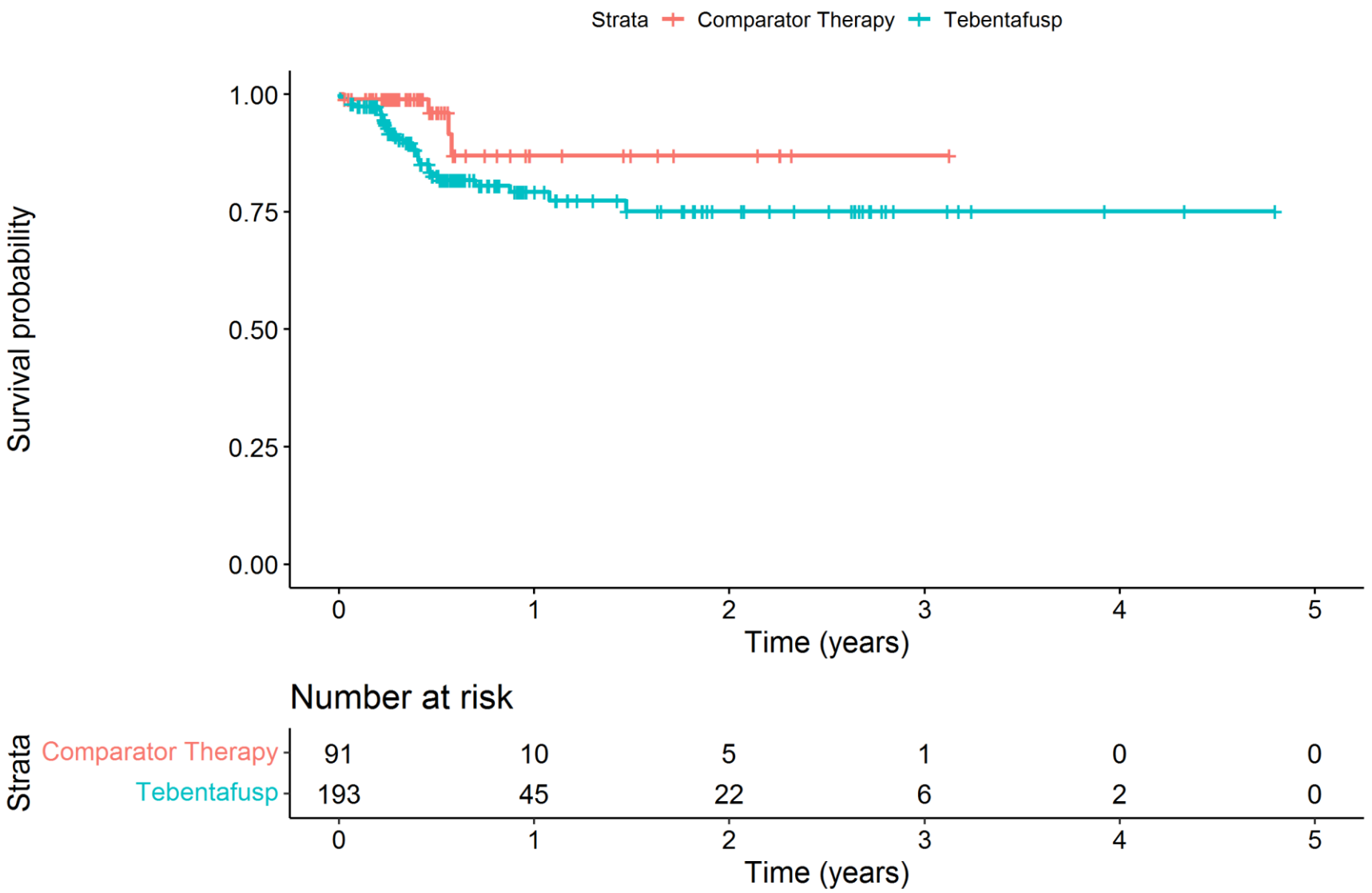
60.126 Vitiligo - Nicht-Nordamerika



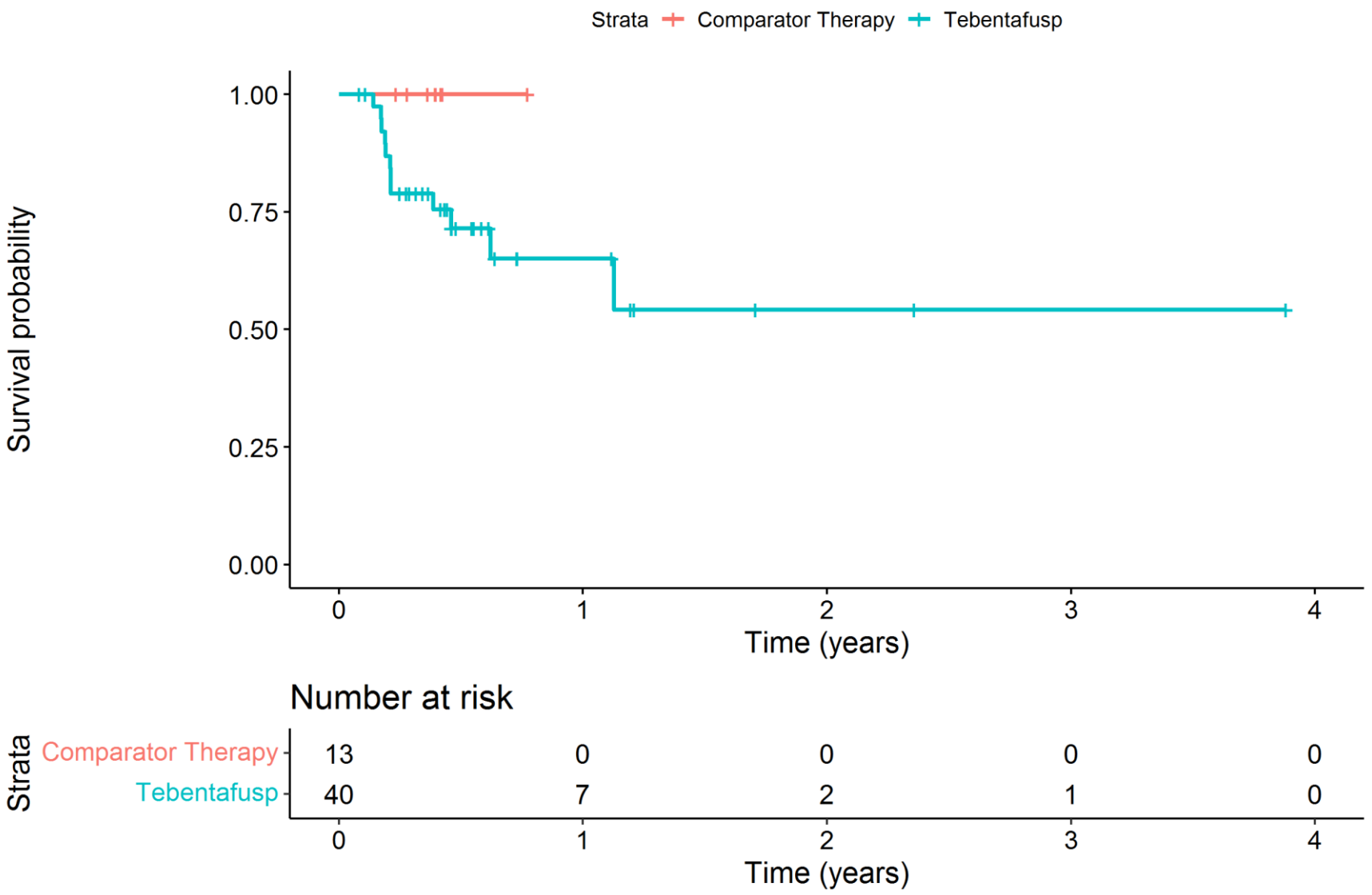
60.127 Vitiligo - Dacarbazin



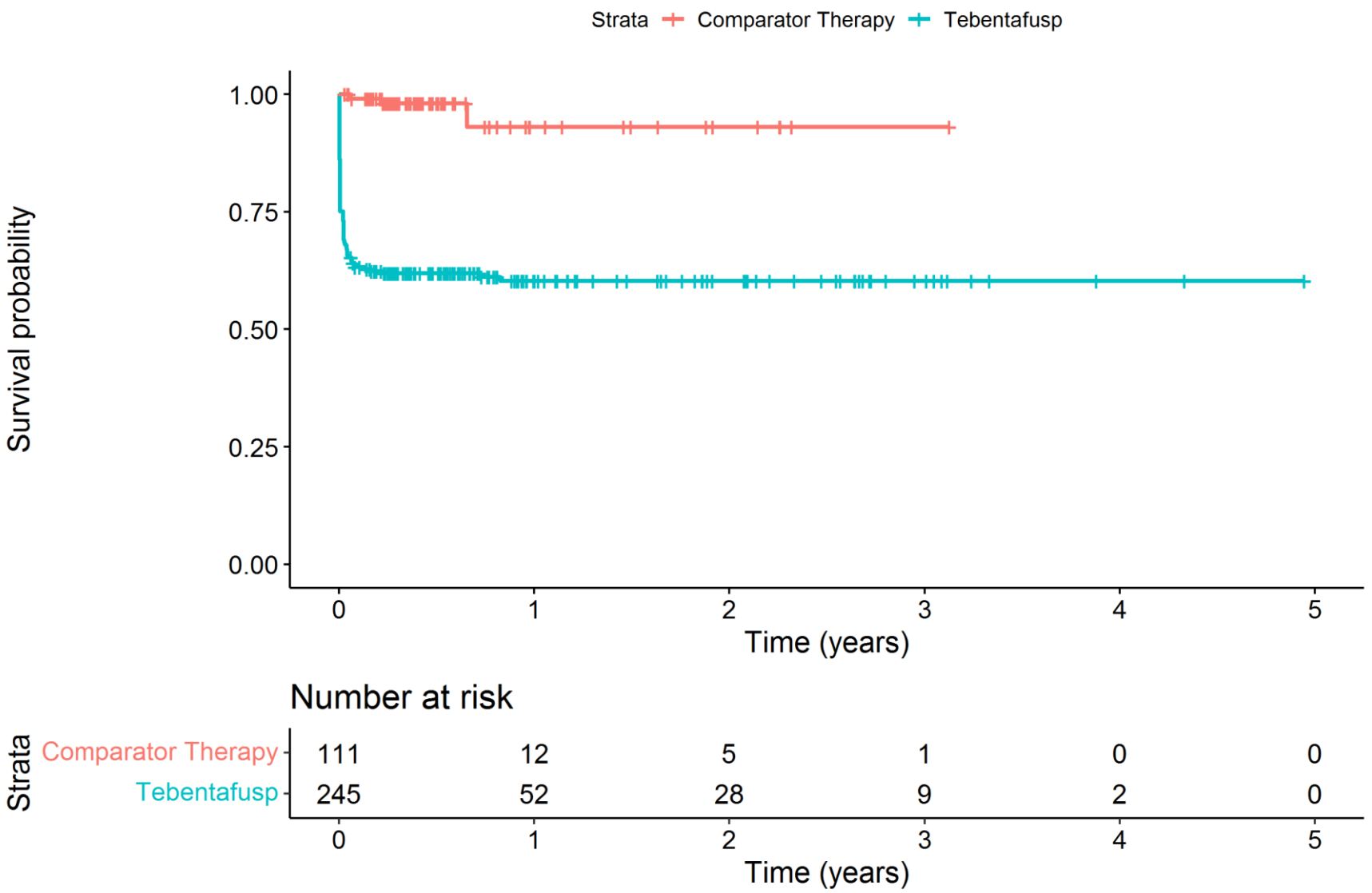
60.128 Vitiligo - Pembrolizumab



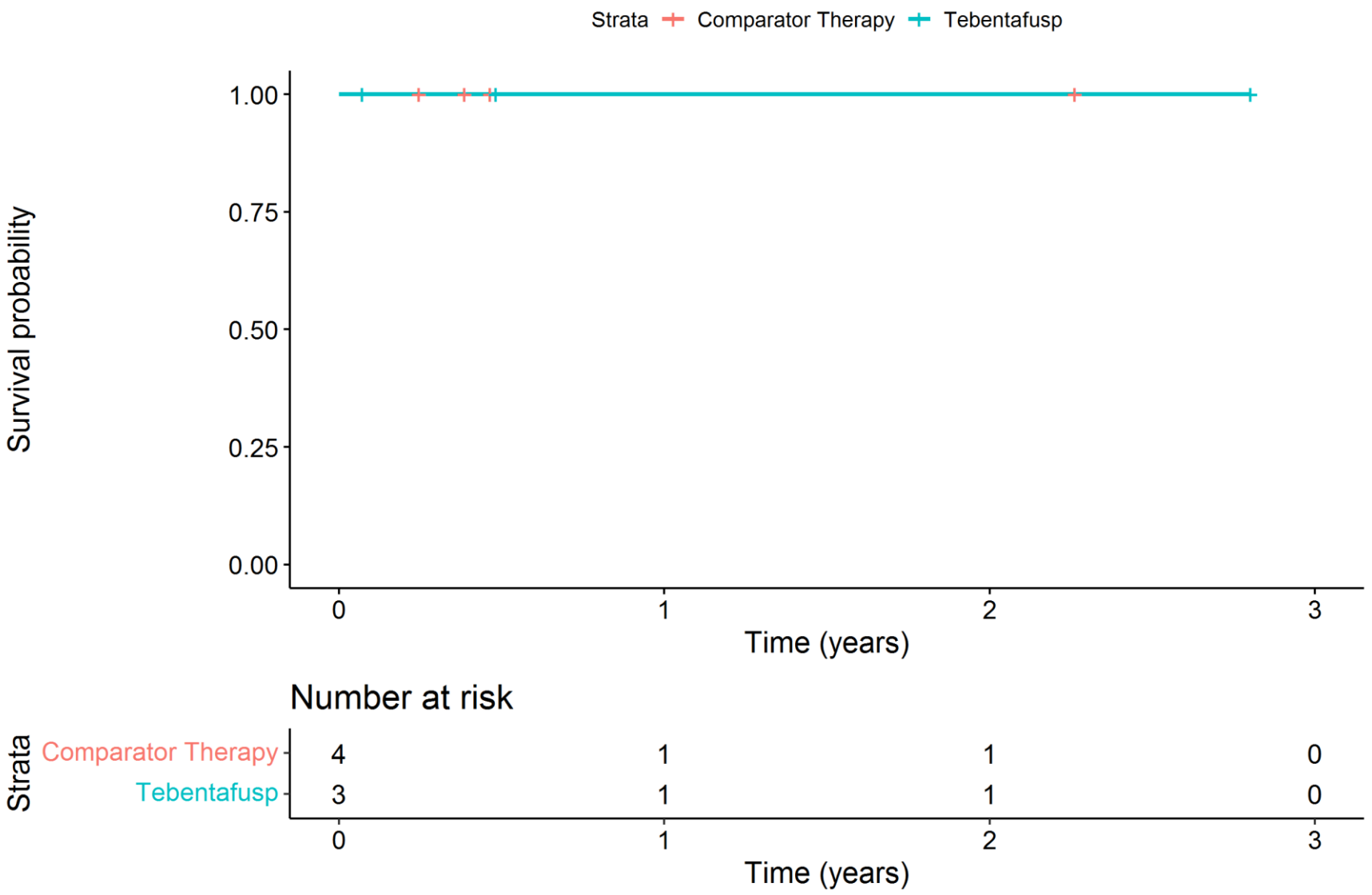
60.129 Vitiligo - Ipilimumab



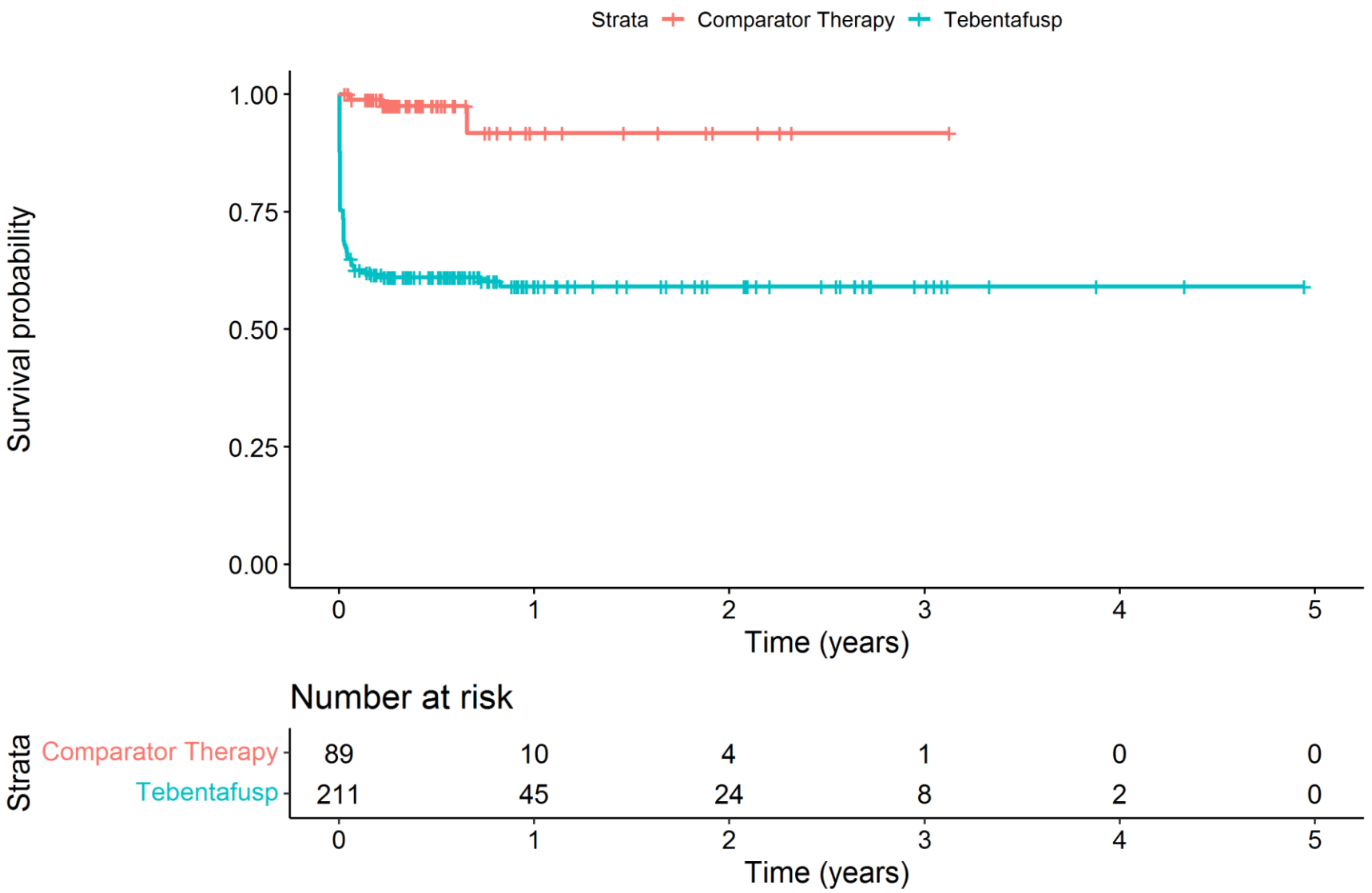
60.130 Hypotonie - Gesamt



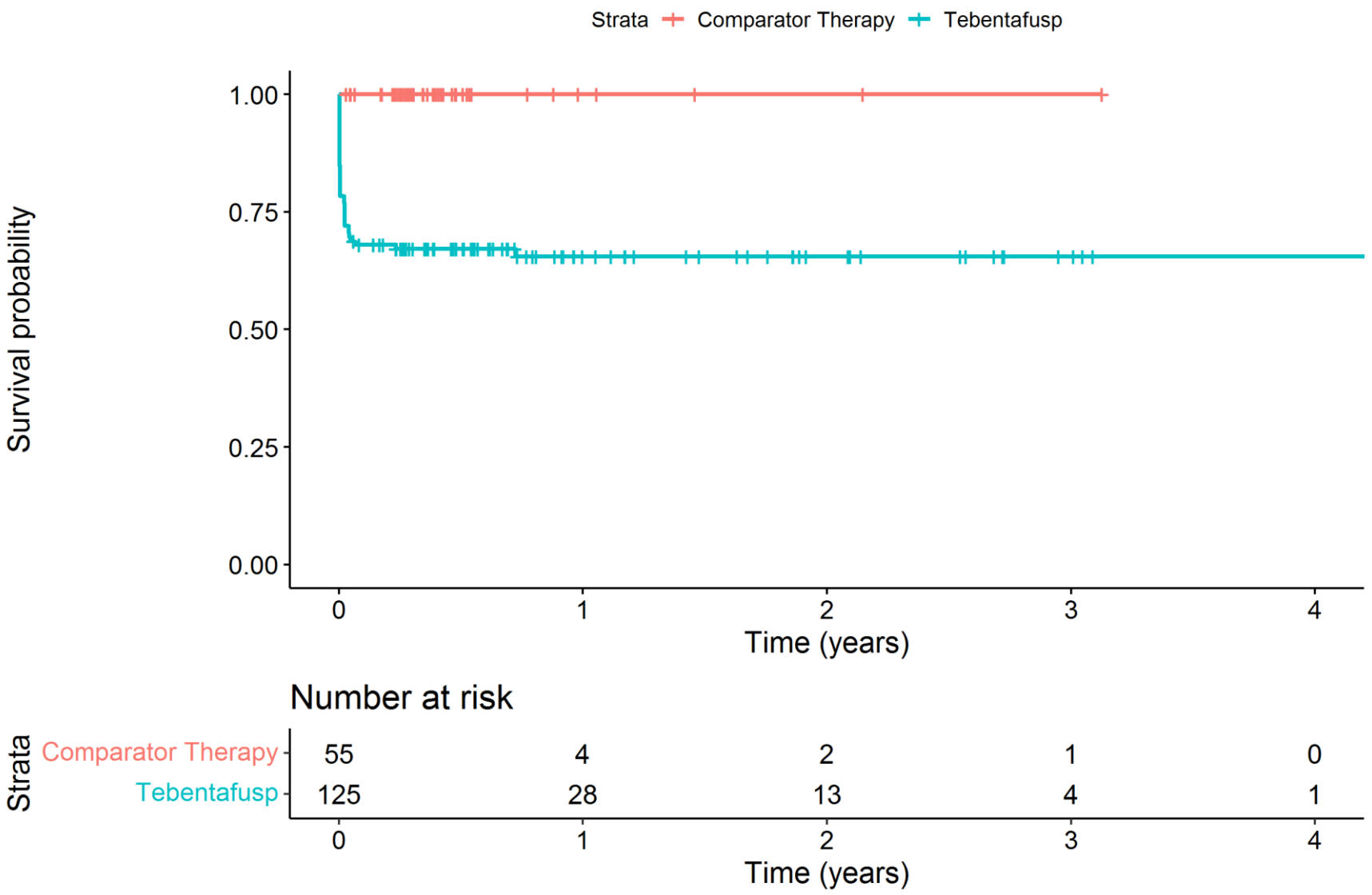
60.131 Hypotonie - Hispanisch



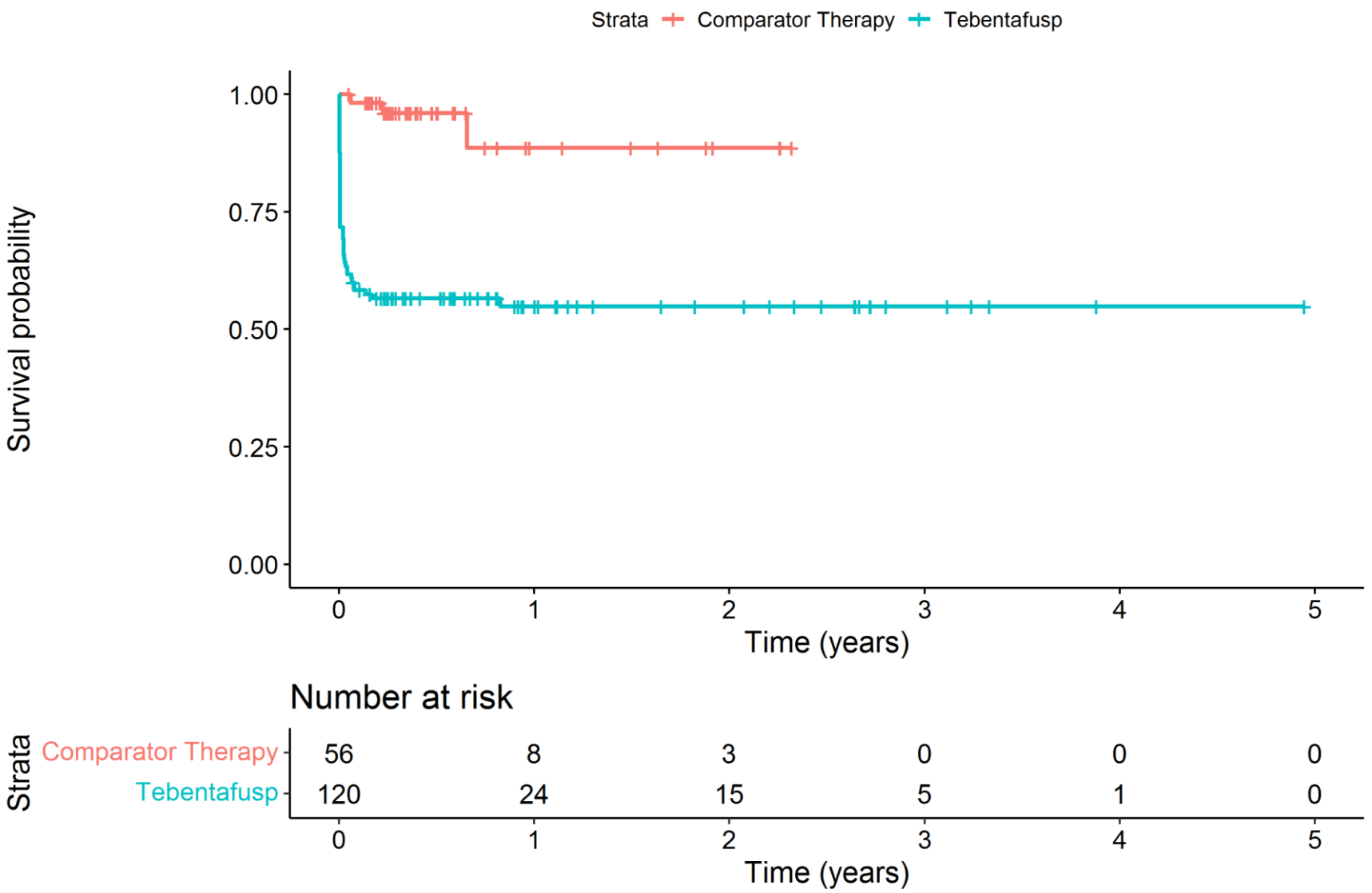
60.132 Hypotonie - Nicht-hispanisch



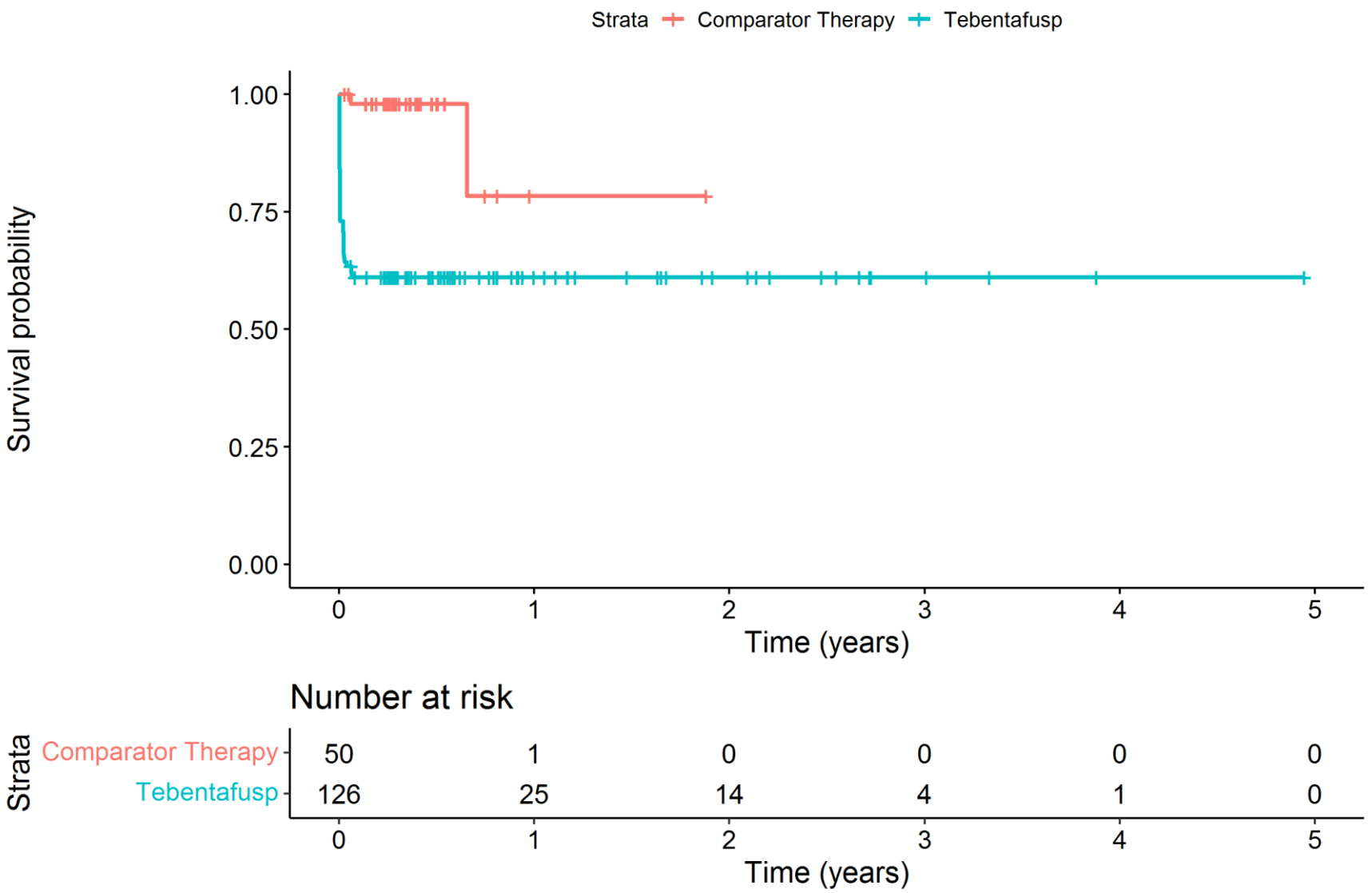
60.133 Hypotonie - Männlich



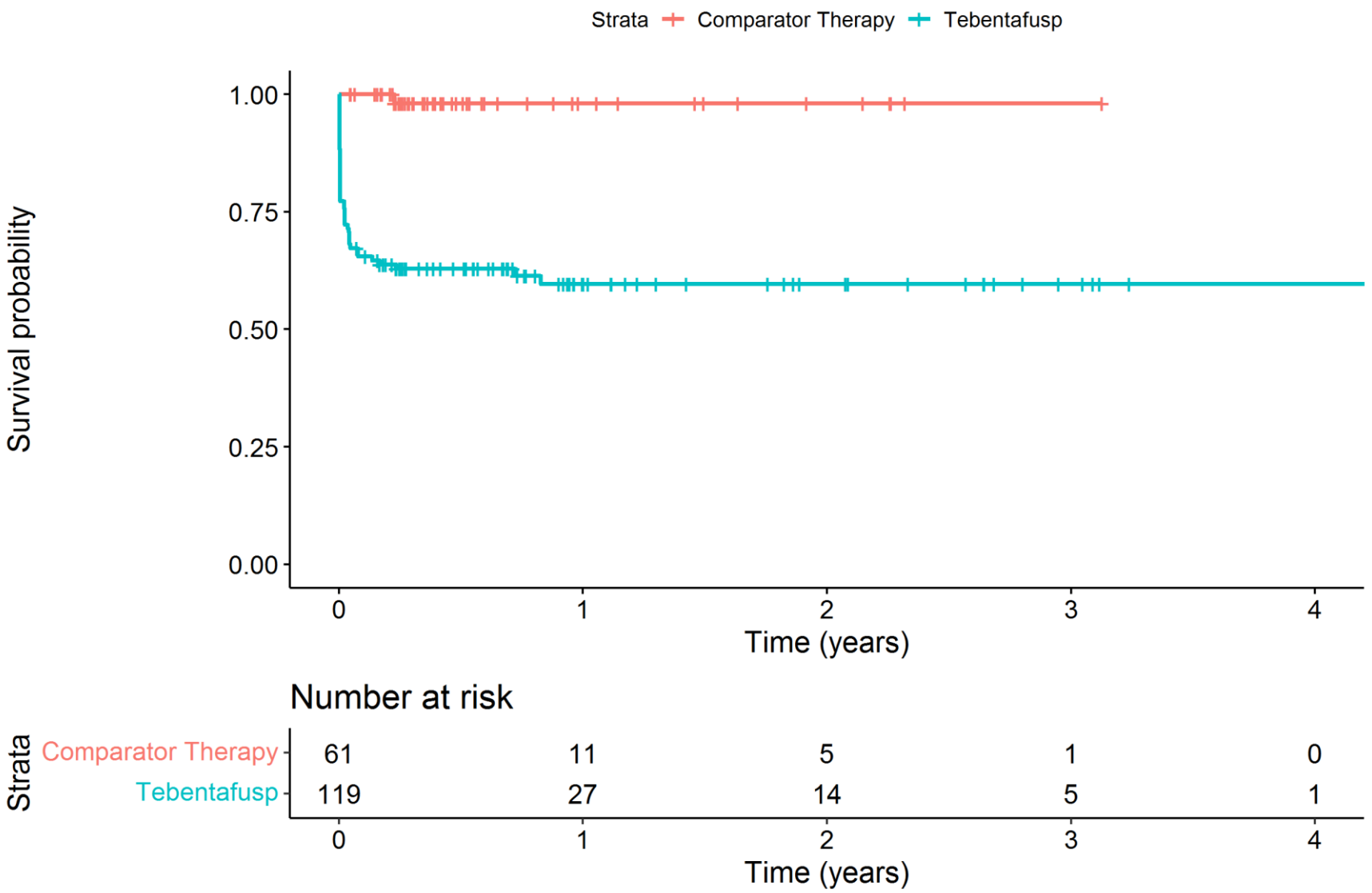
60.134 Hypotonie - Weiblich



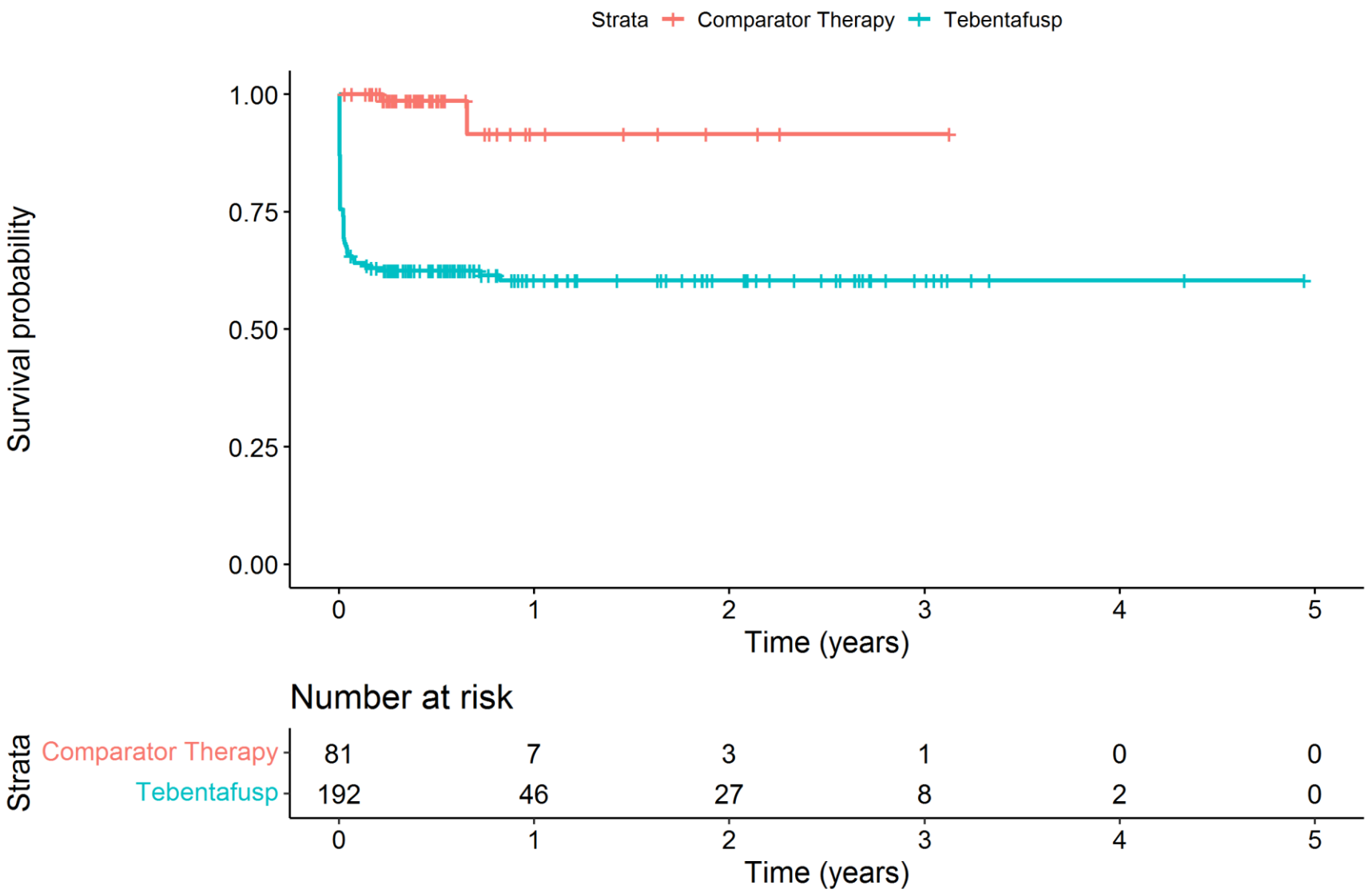
60.135 Hypotonie - <65



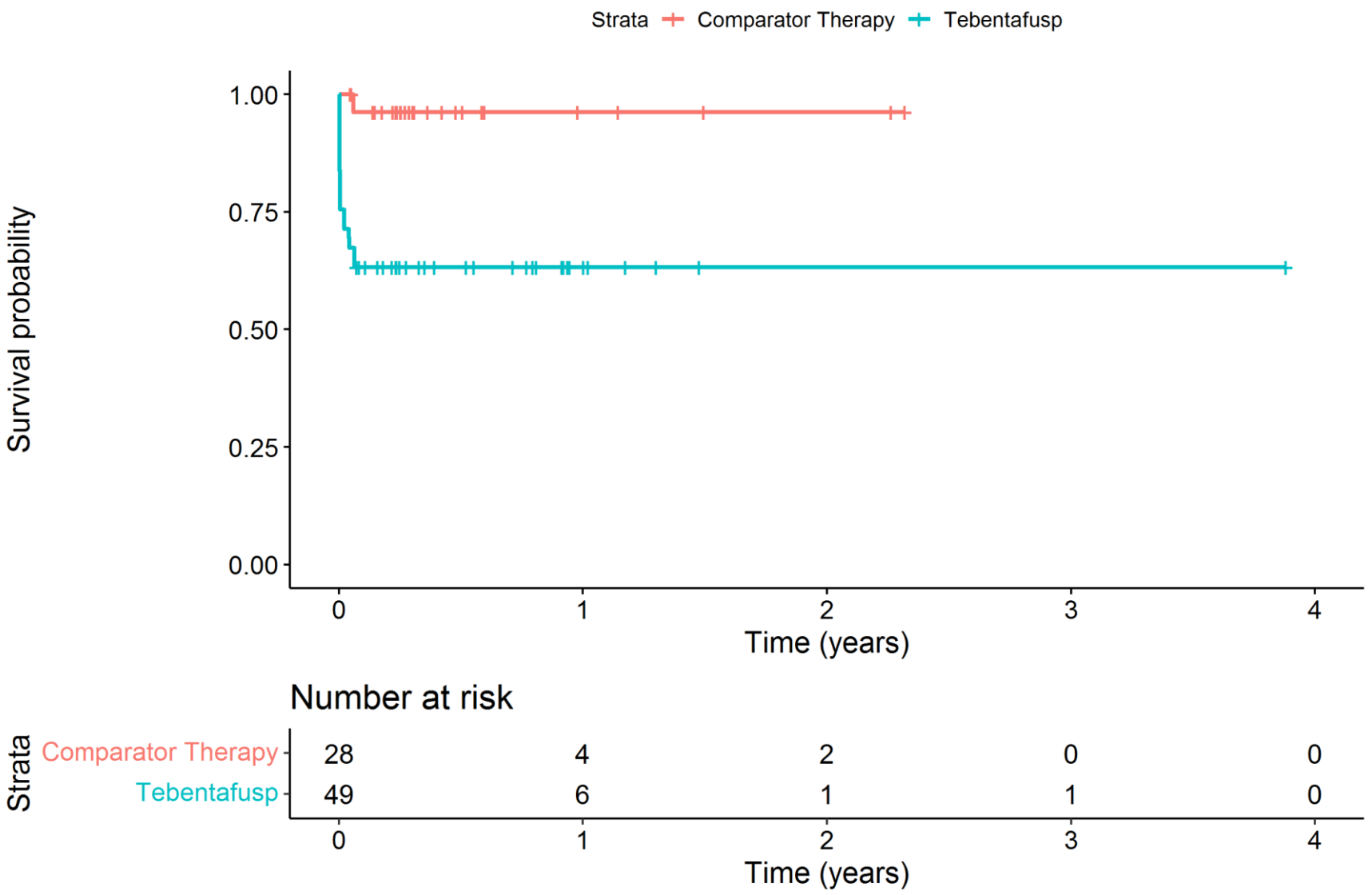
60.136 Hypotonie - ≥65



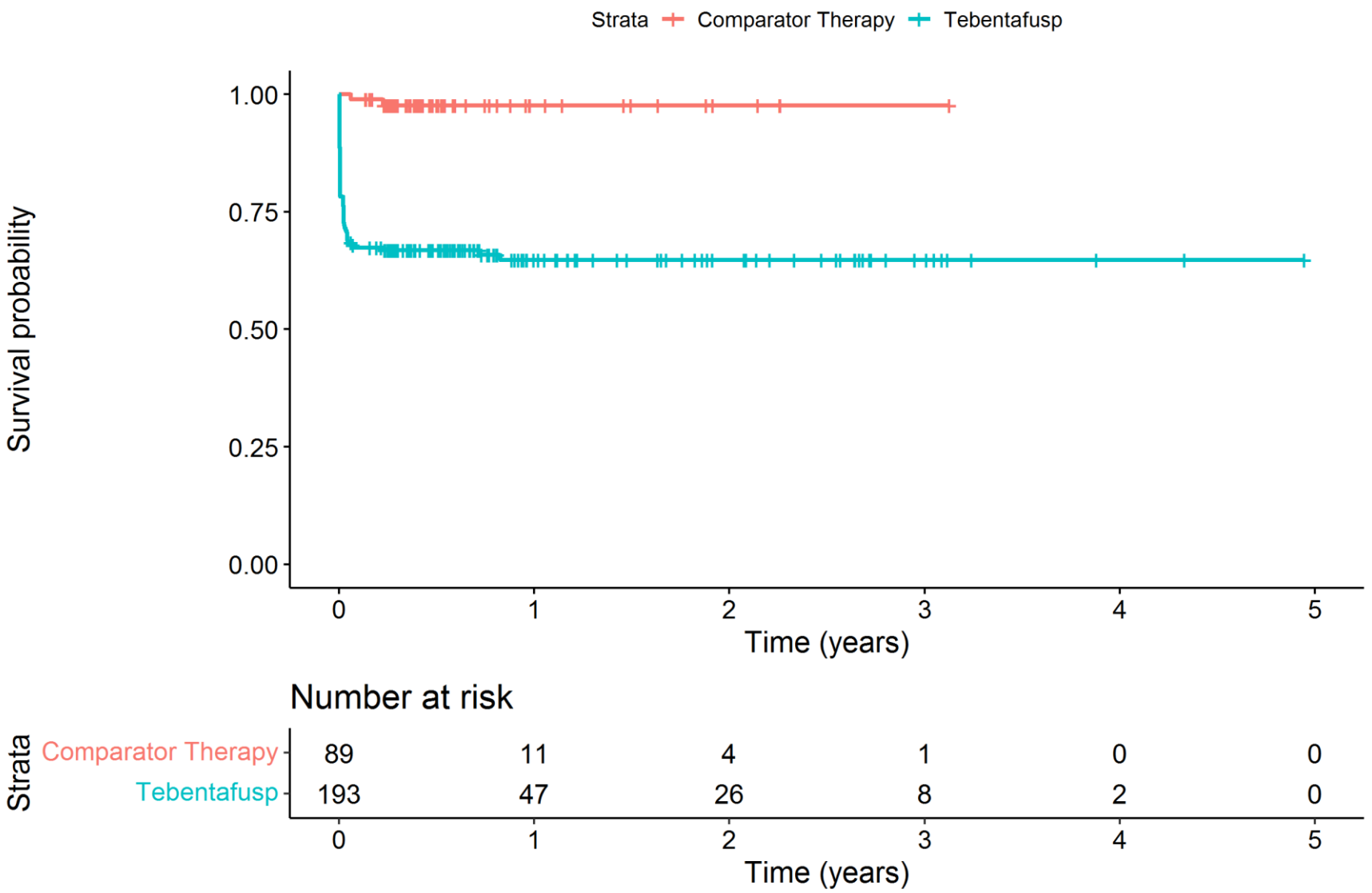
60.137 Hypotonie - ECOG 0



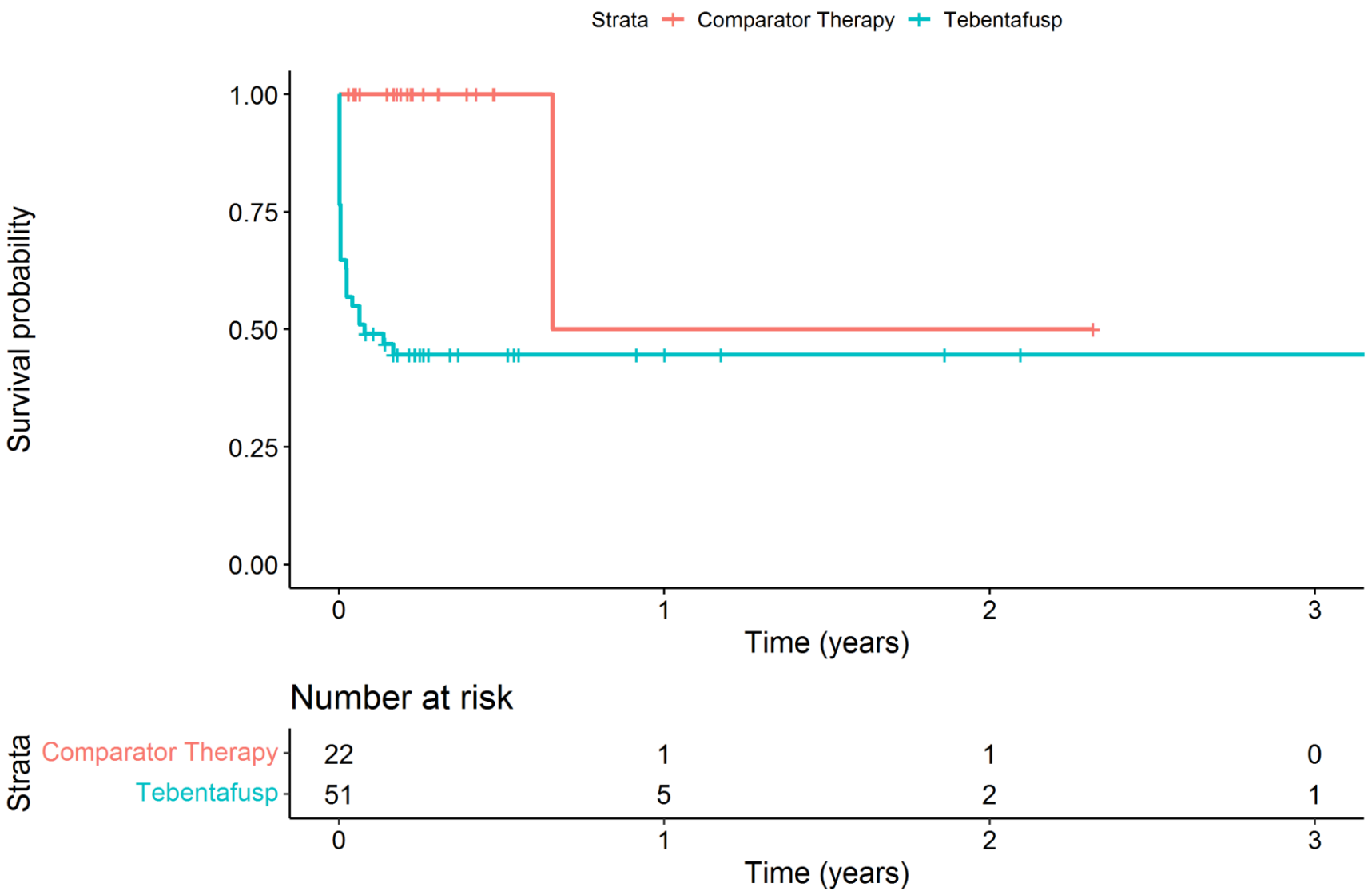
60.138 Hypotonie - ECOG 1



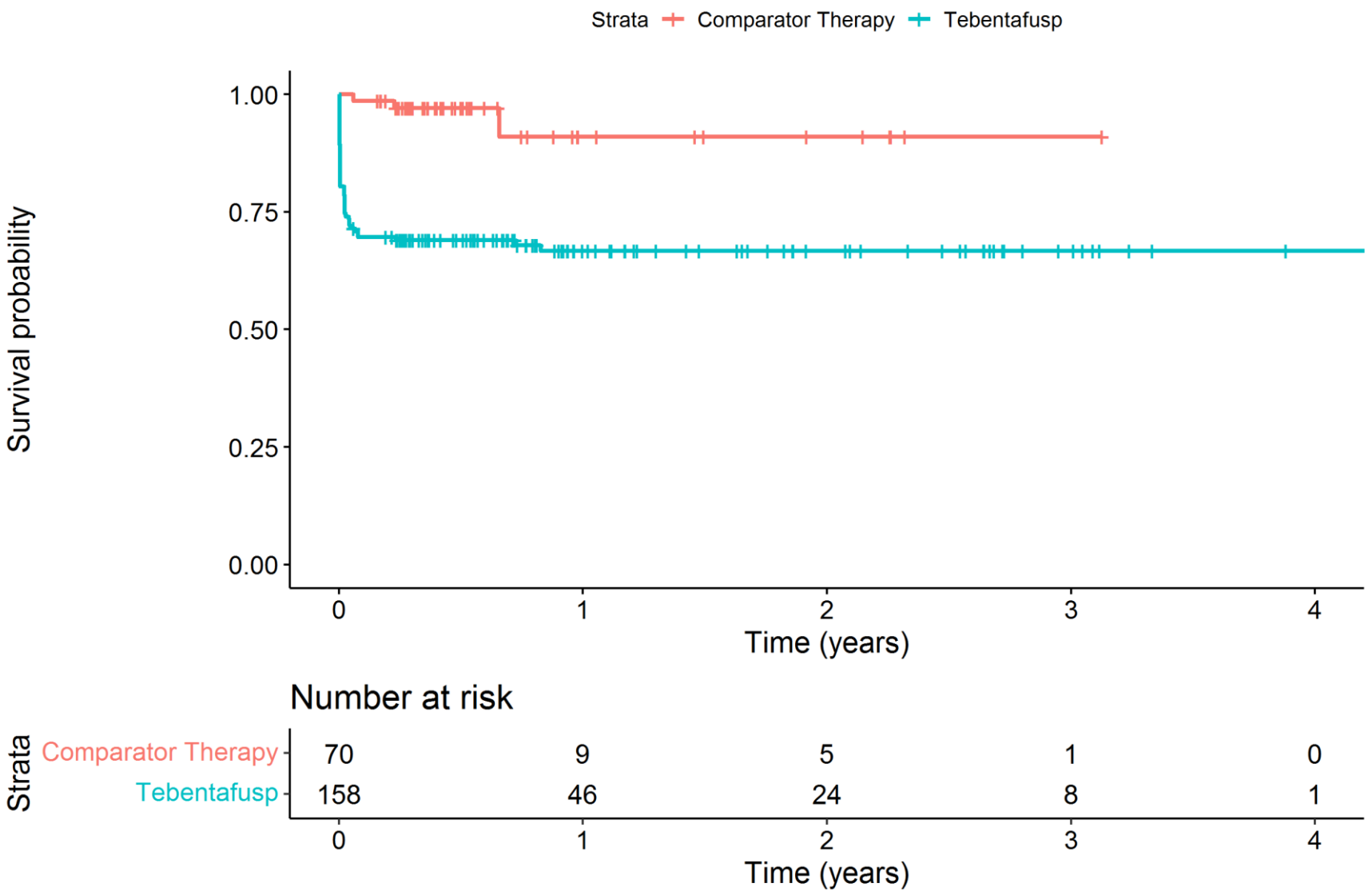
60.139 Hypotonie - ALP ≤ ULN



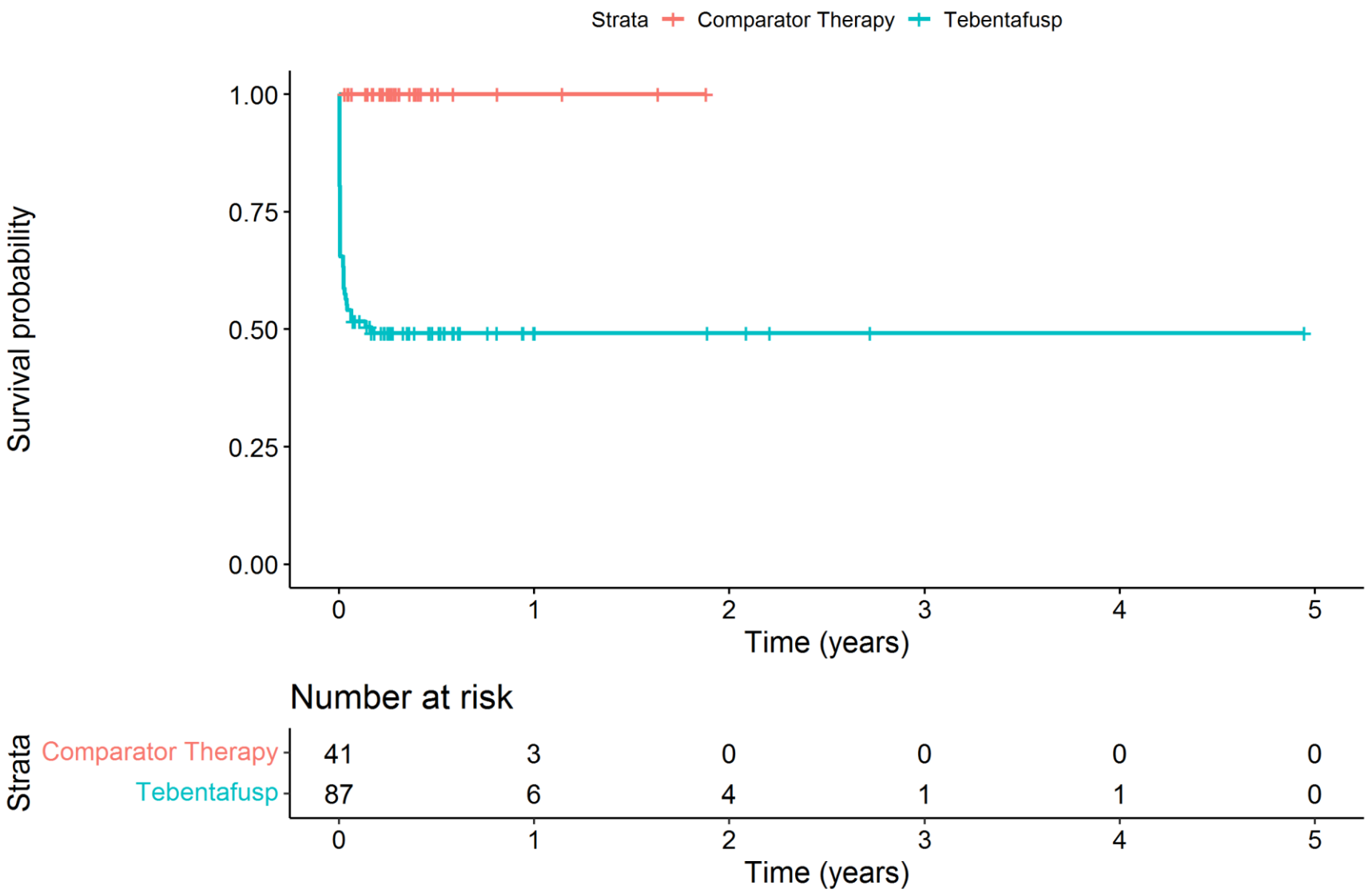
60.140 Hypotonie - ALP > ULN



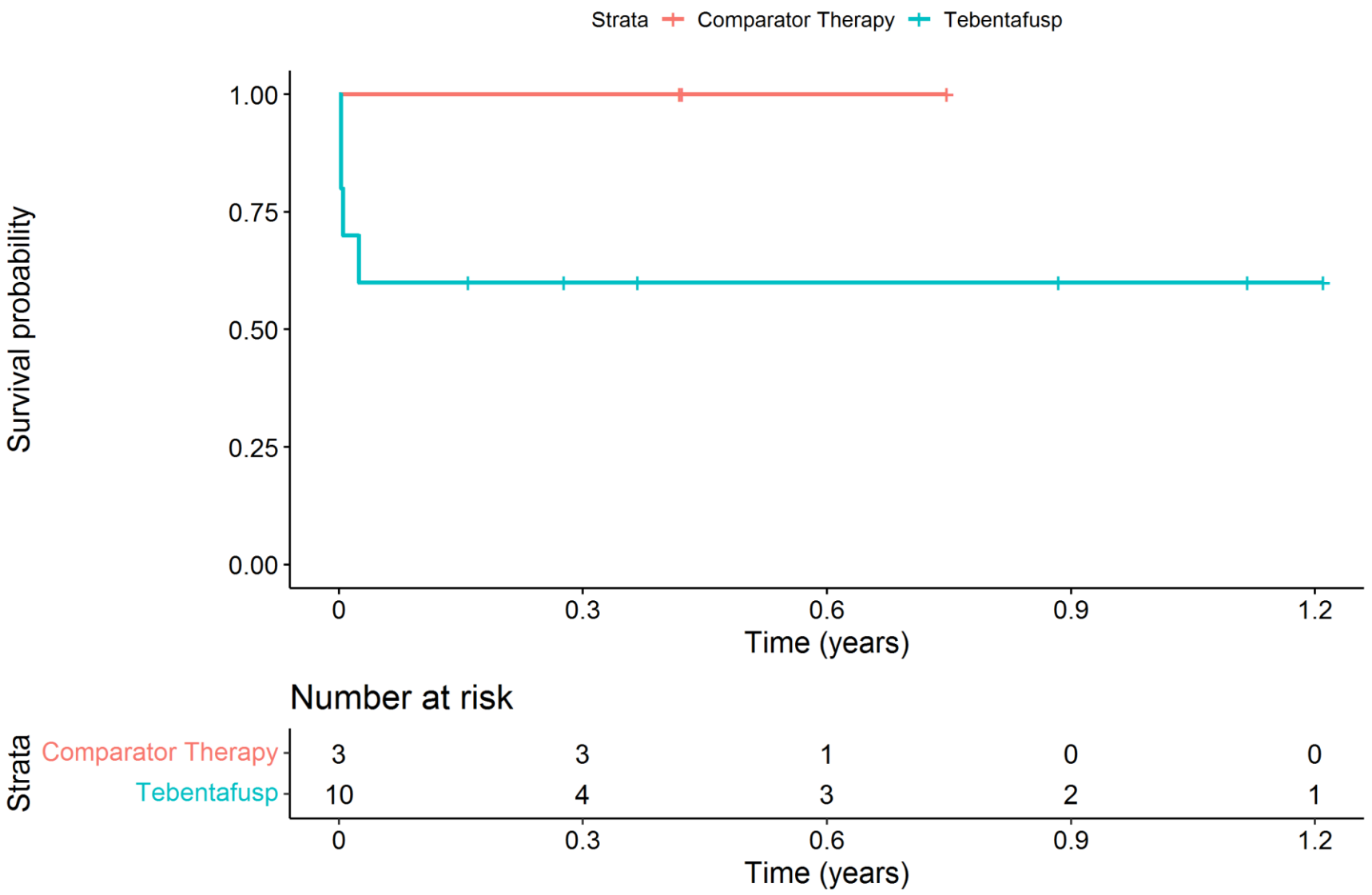
60.141 Hypotonie - LDH =< ULN



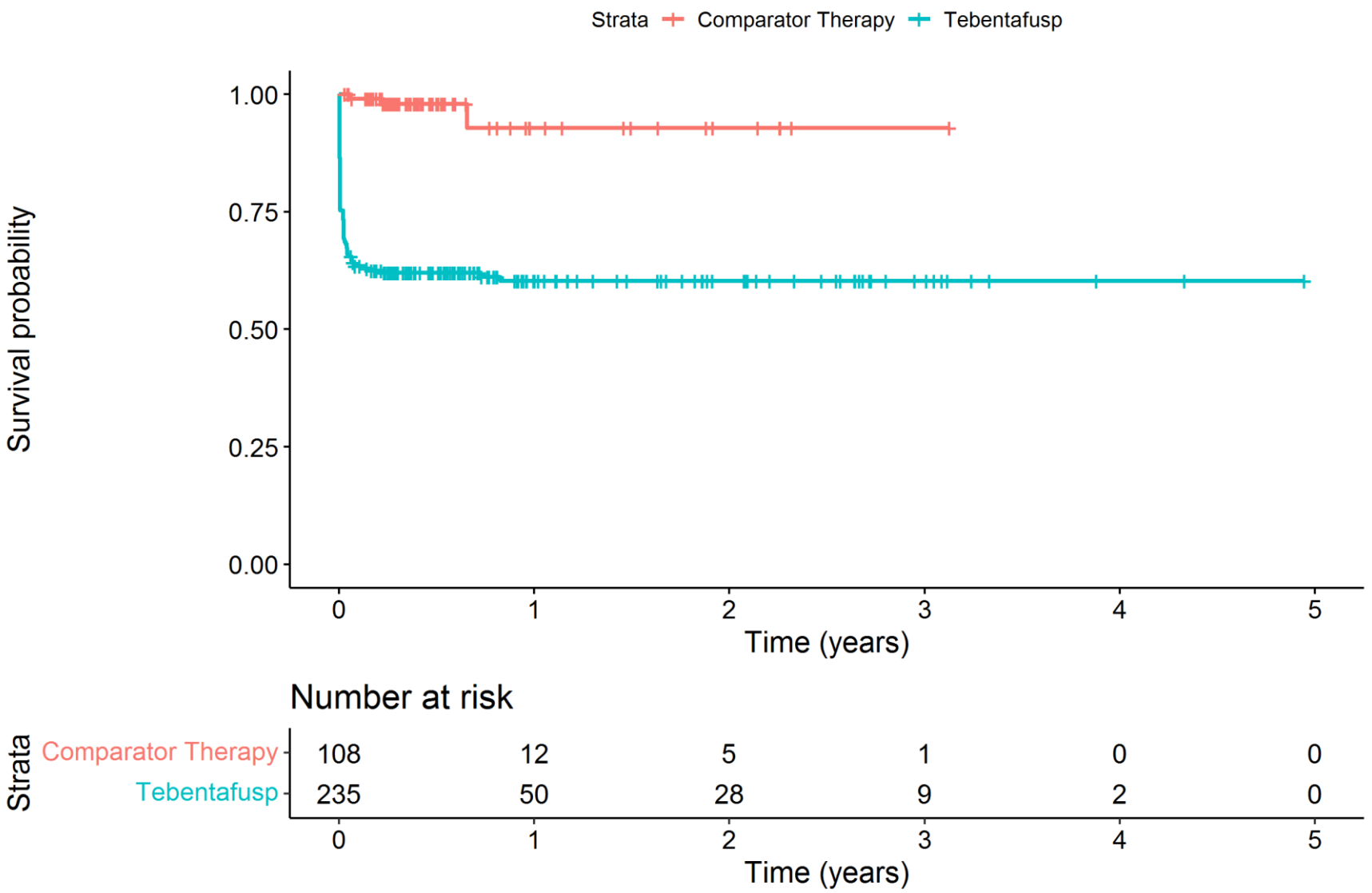
60.142 Hypotonie - LDH > ULN



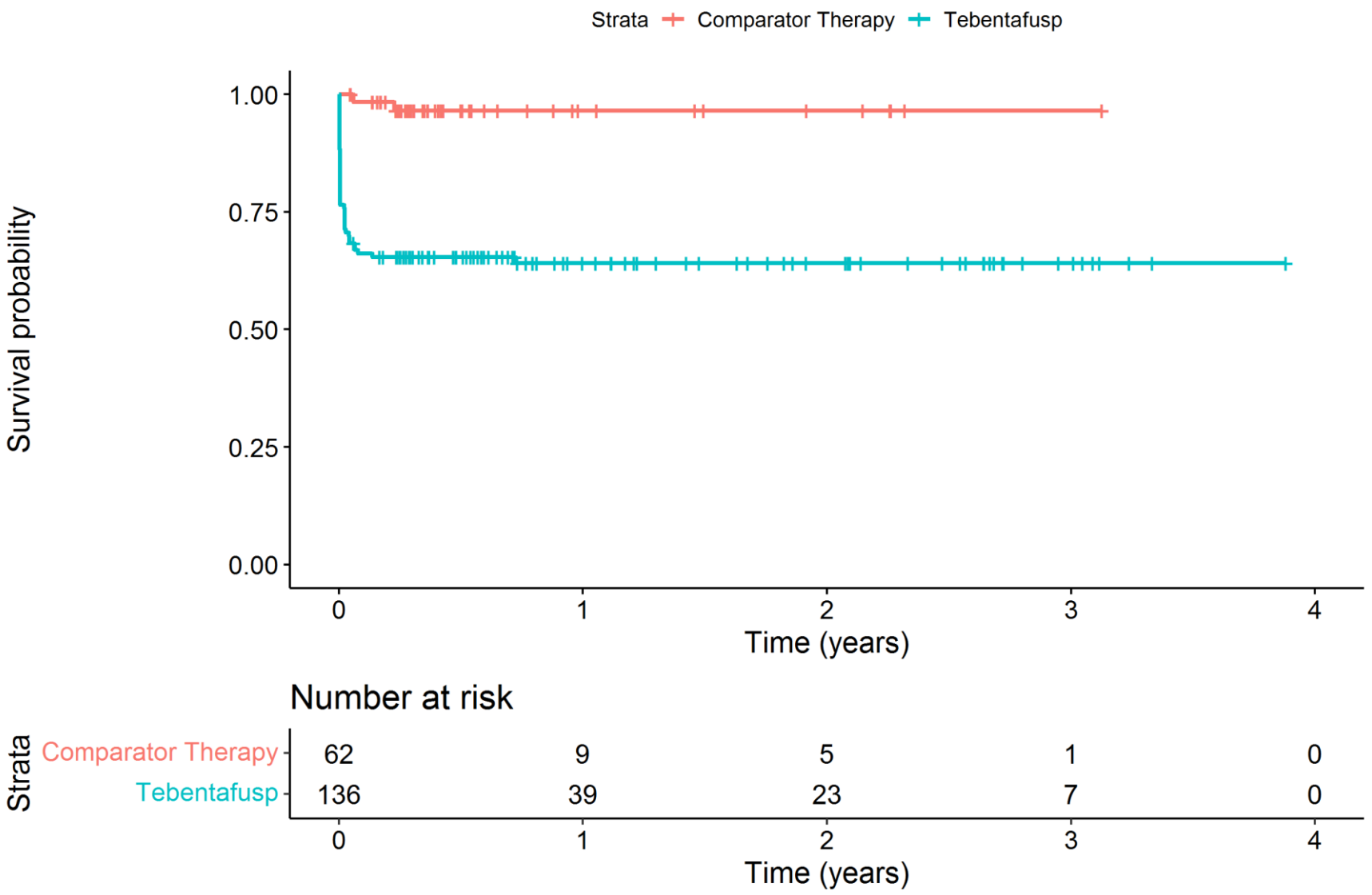
60.143 Hypotonie - Vorherige Therapie adjuvant/neoadjuvant



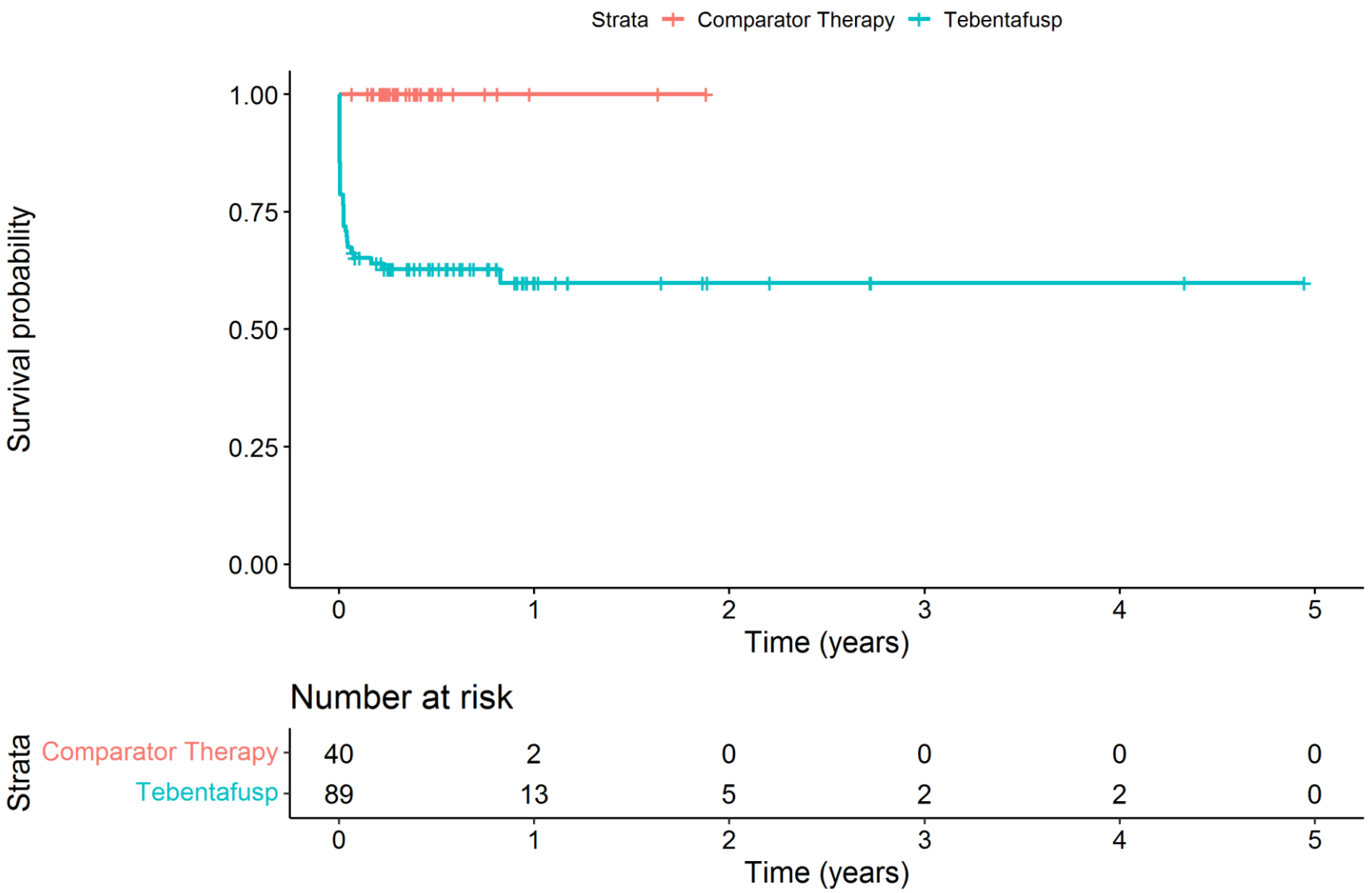
60.144 Hypotonie - Keine Vorherige Therapie adjuvant/neoadjuvant



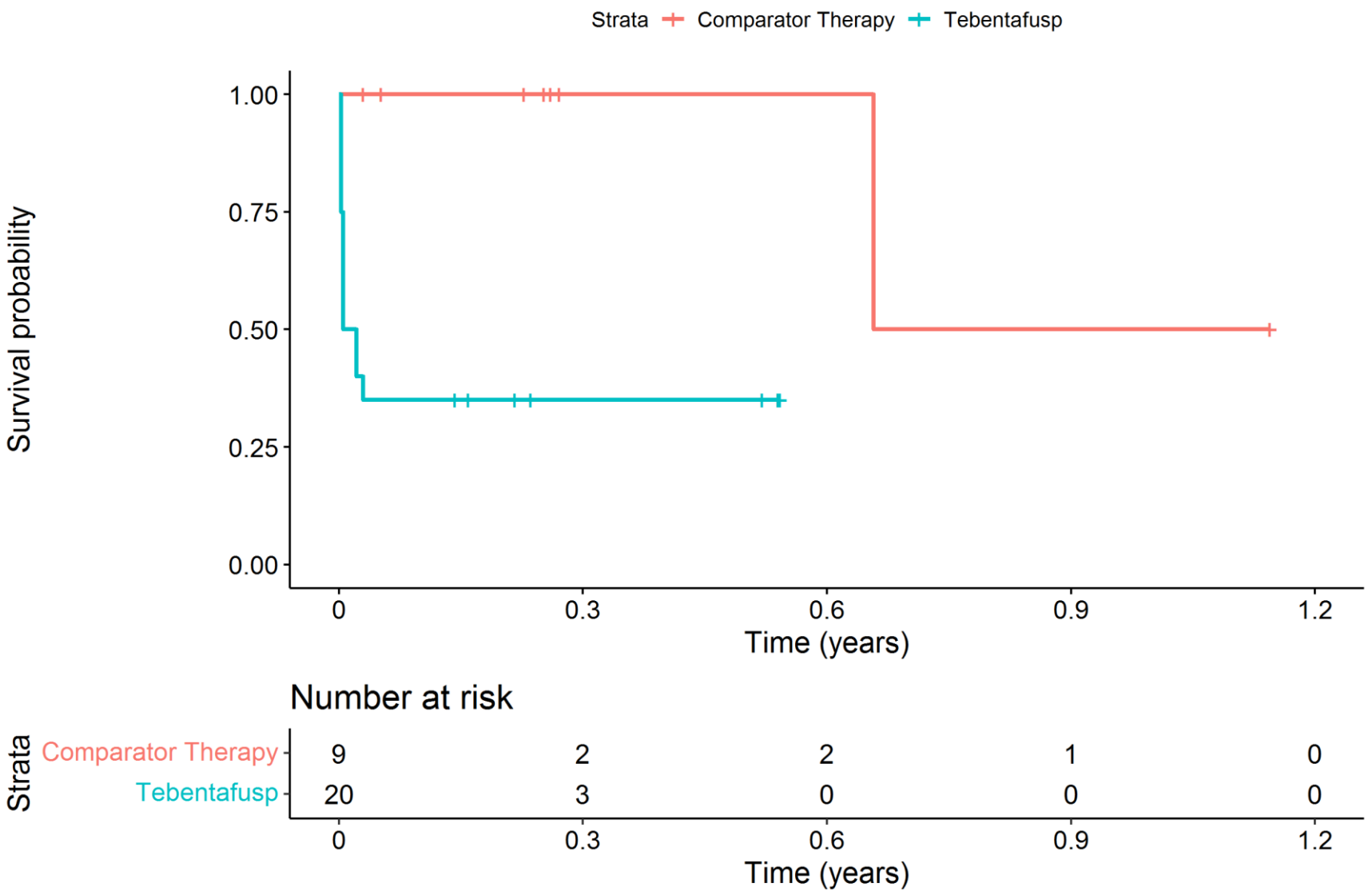
60.145 Hypotonie - Läsion ≤ 3cm



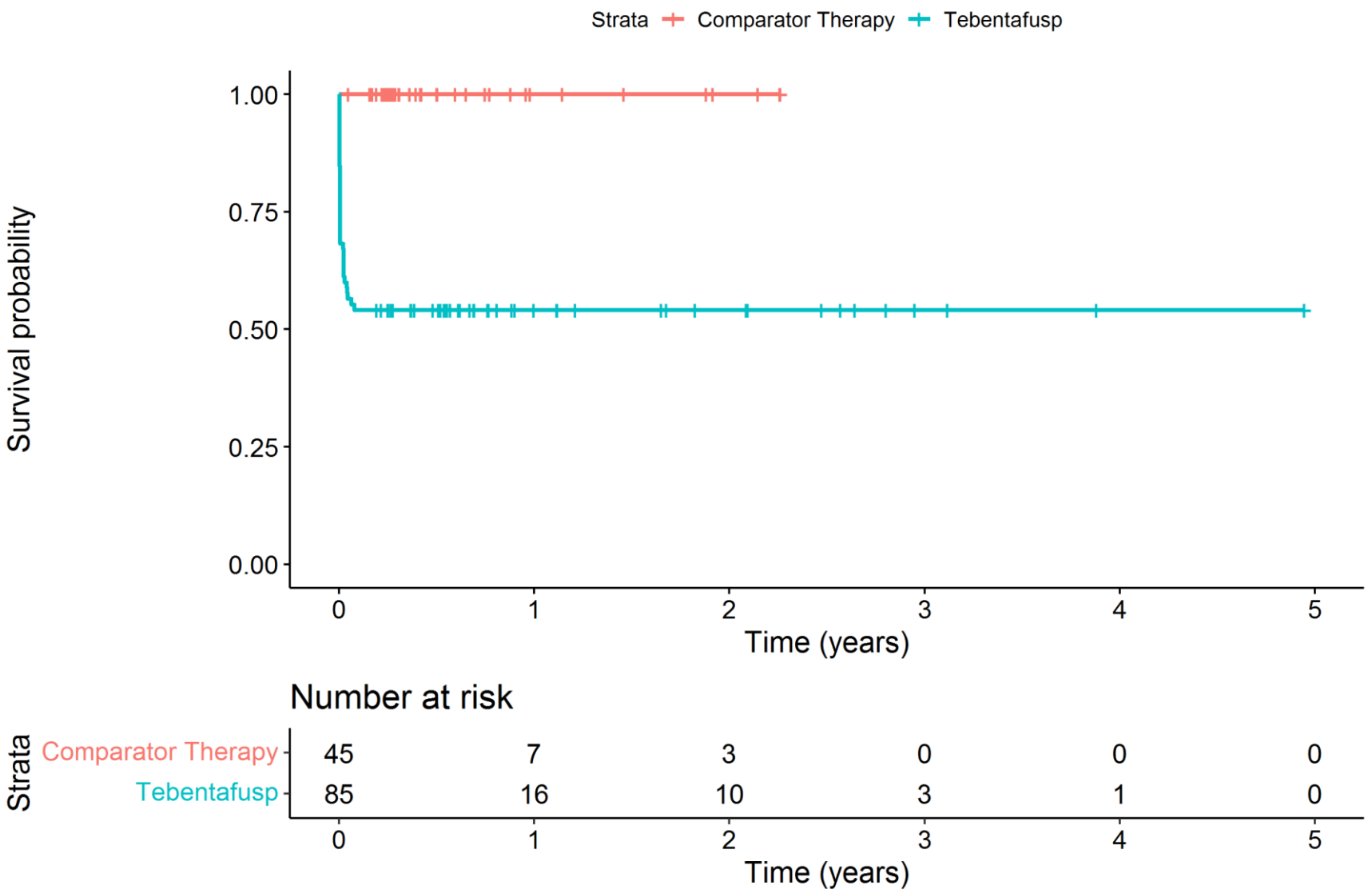
60.146 Hypotonie - Läsion 3,1-8,0 cm



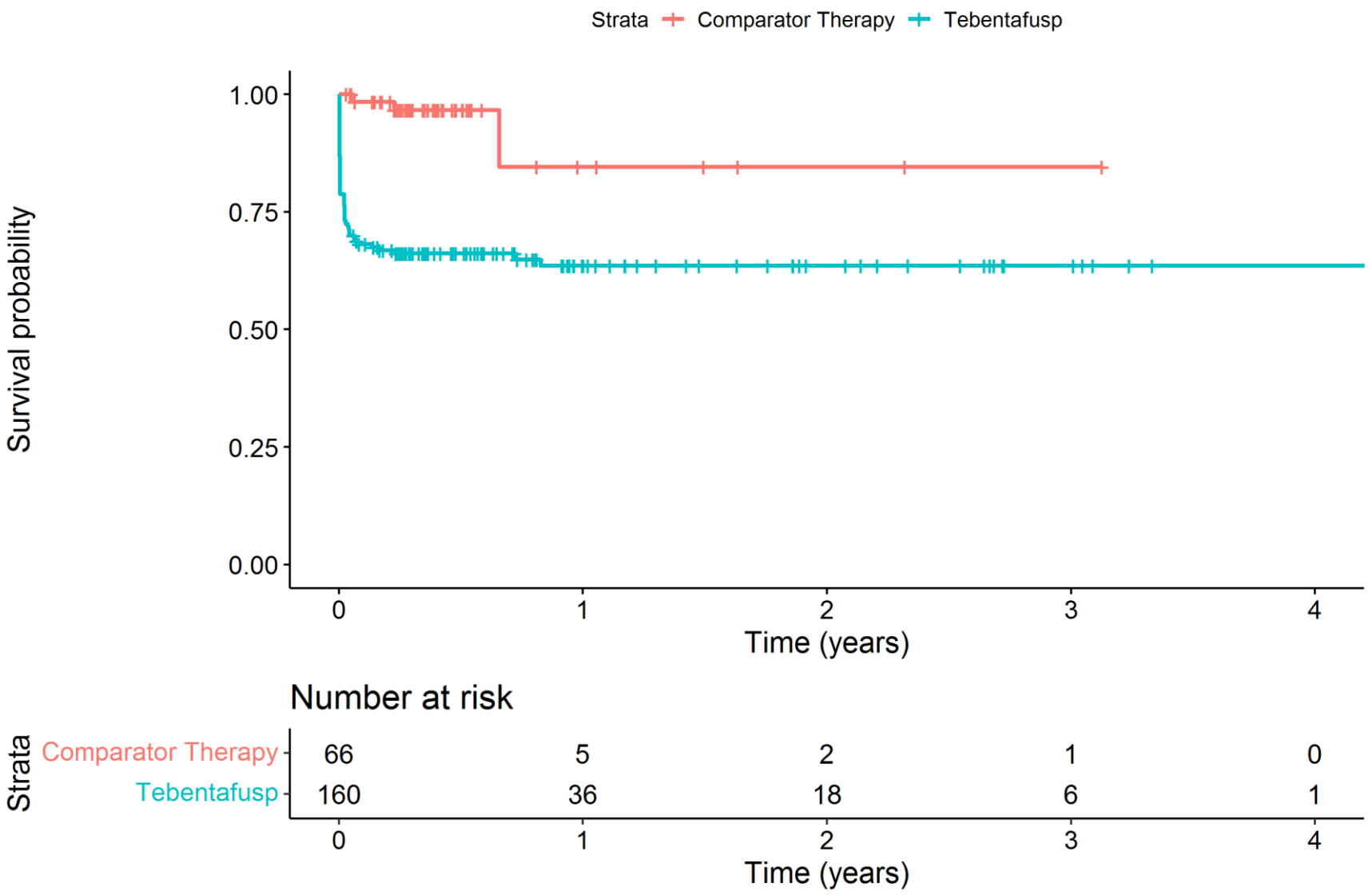
60.147 Hypotonie - Läsion ≥8,1 cm



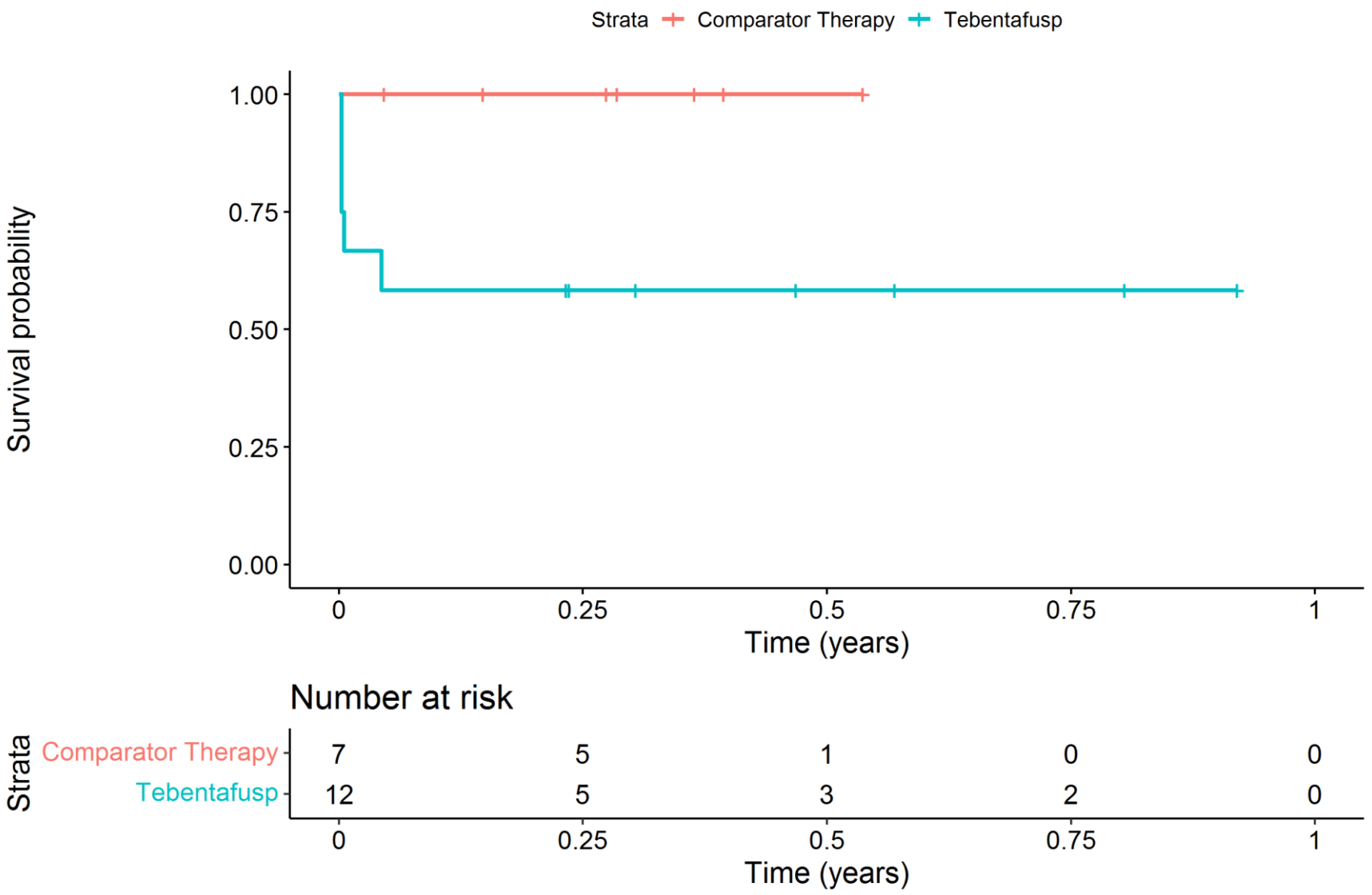
60.148 Hypotonie - Nordamerika



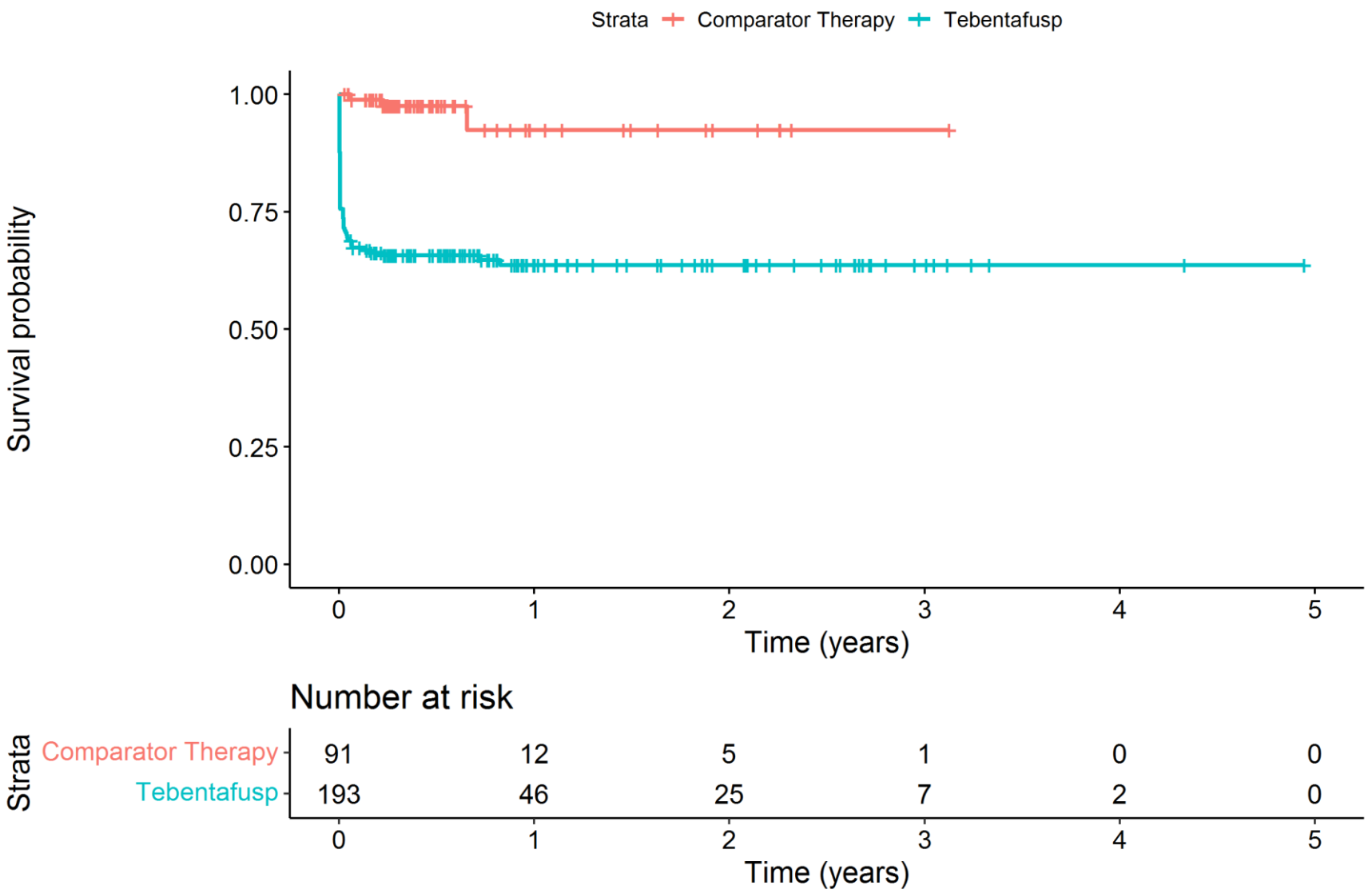
60.149 Hypotonie - Nicht-Nordamerika



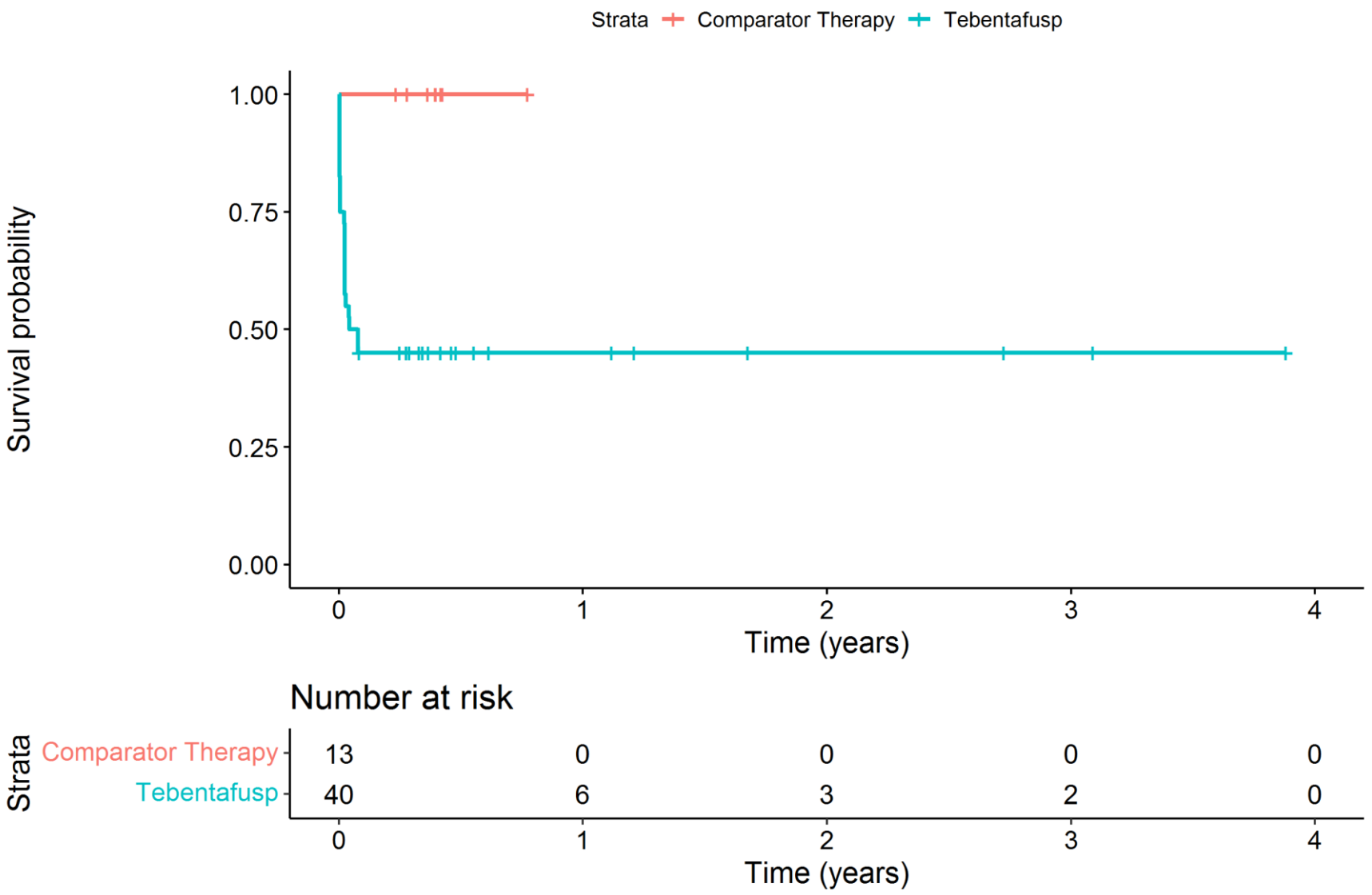
60.150 Hypotonie - Dacarbazin



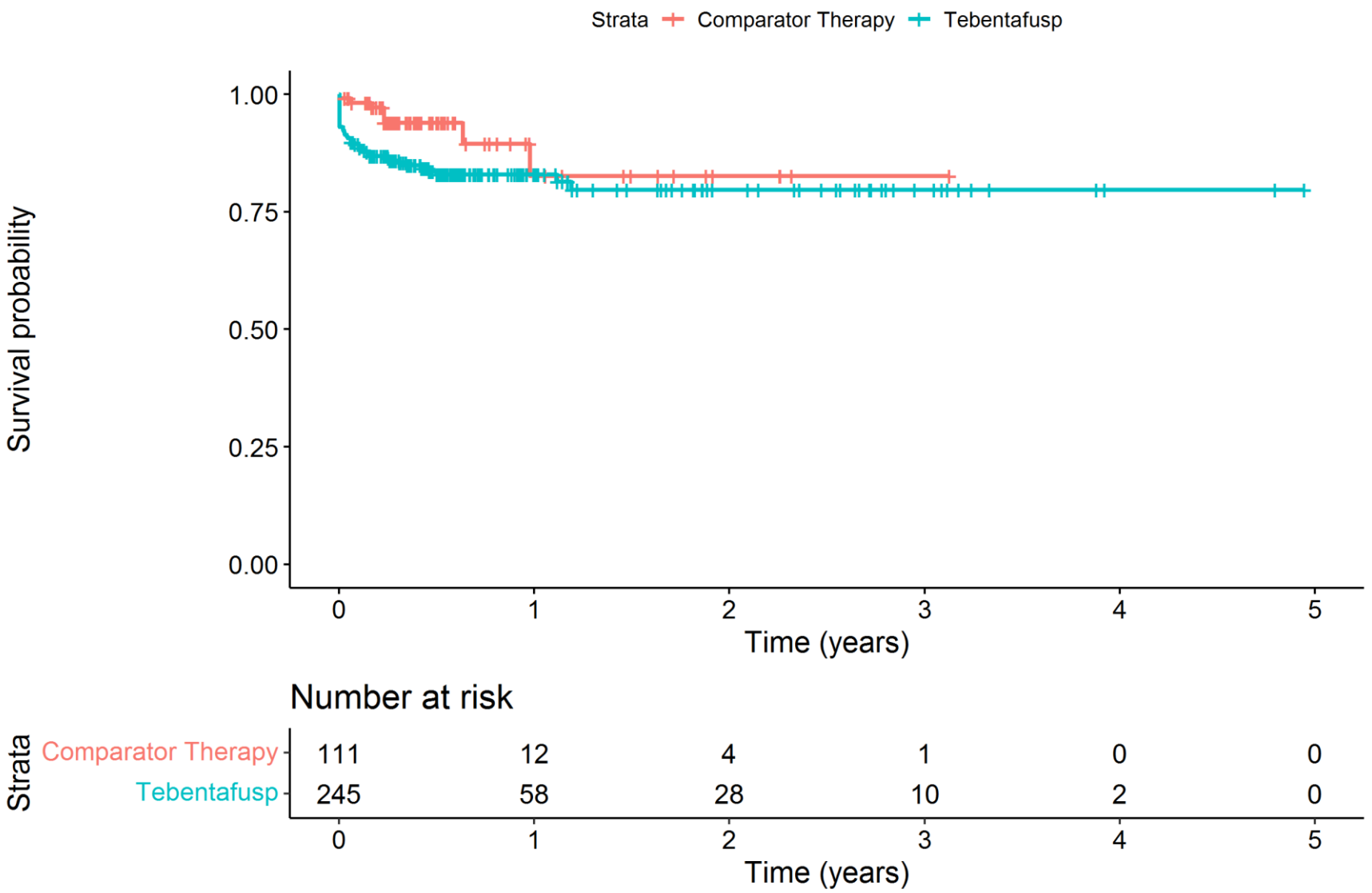
60.151 Hypotonie - Pembrolizumab



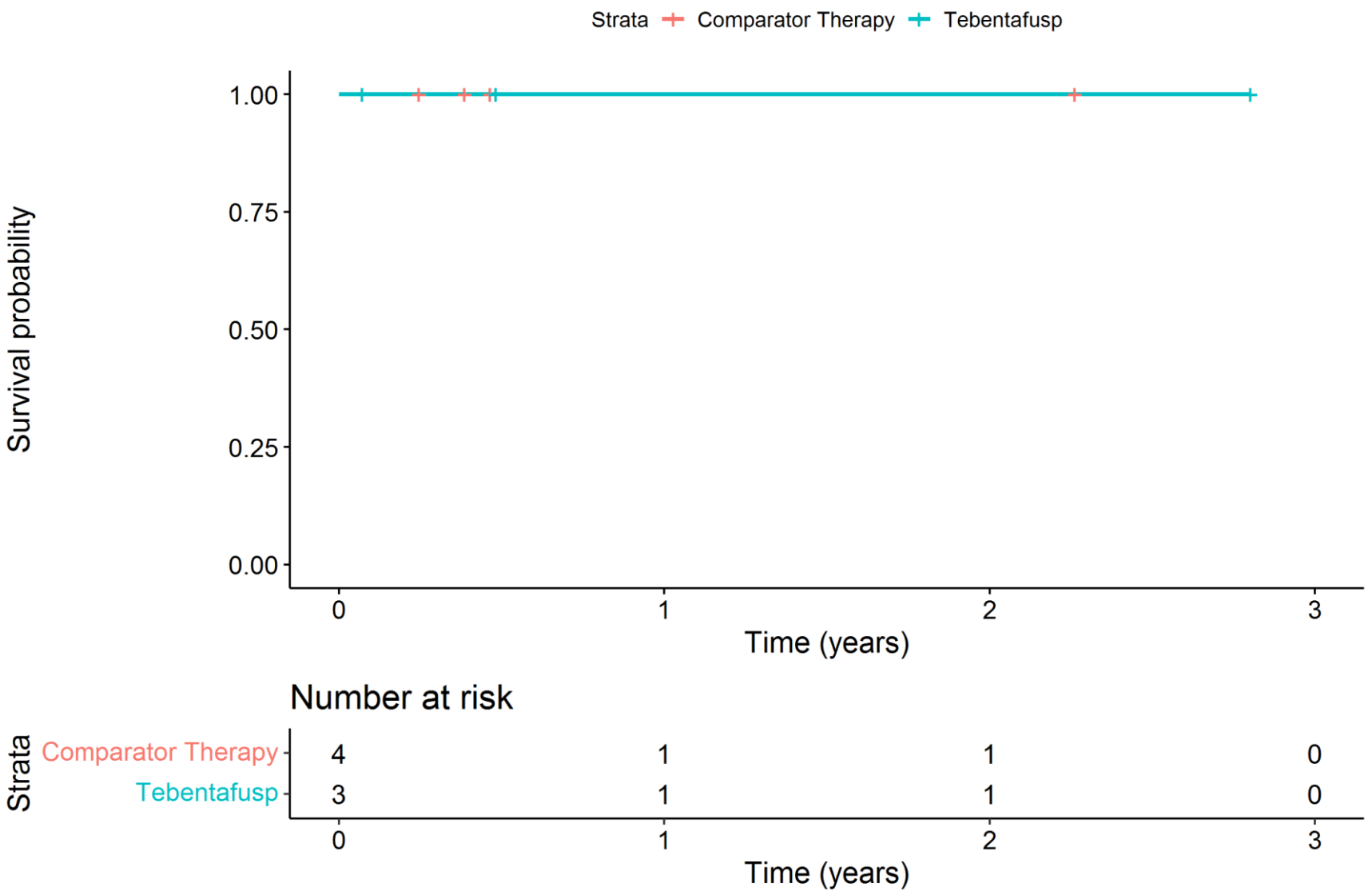
60.152 Hypotonie - Ipilimumab



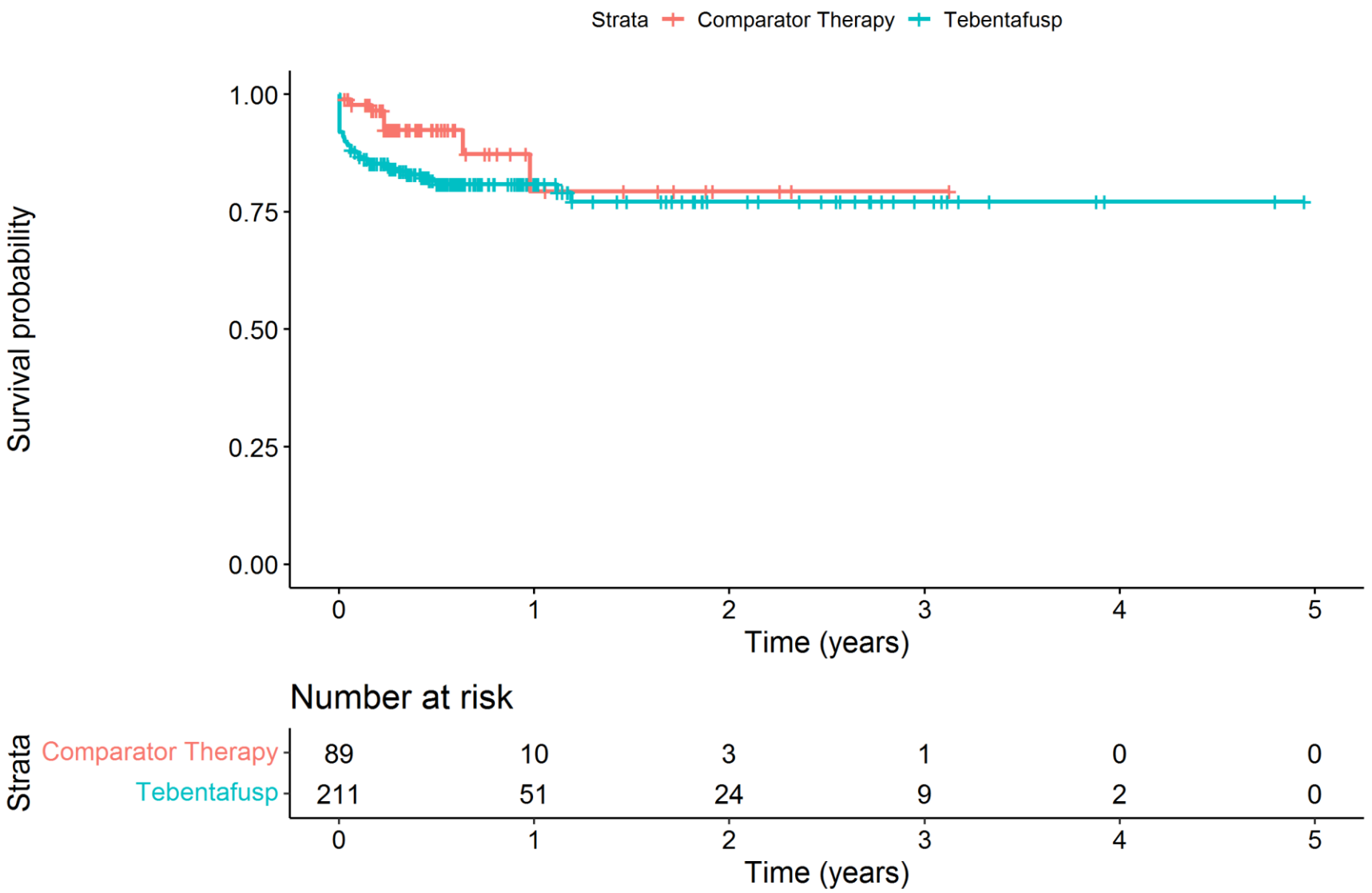
60.153 Hypertonie - Gesamt



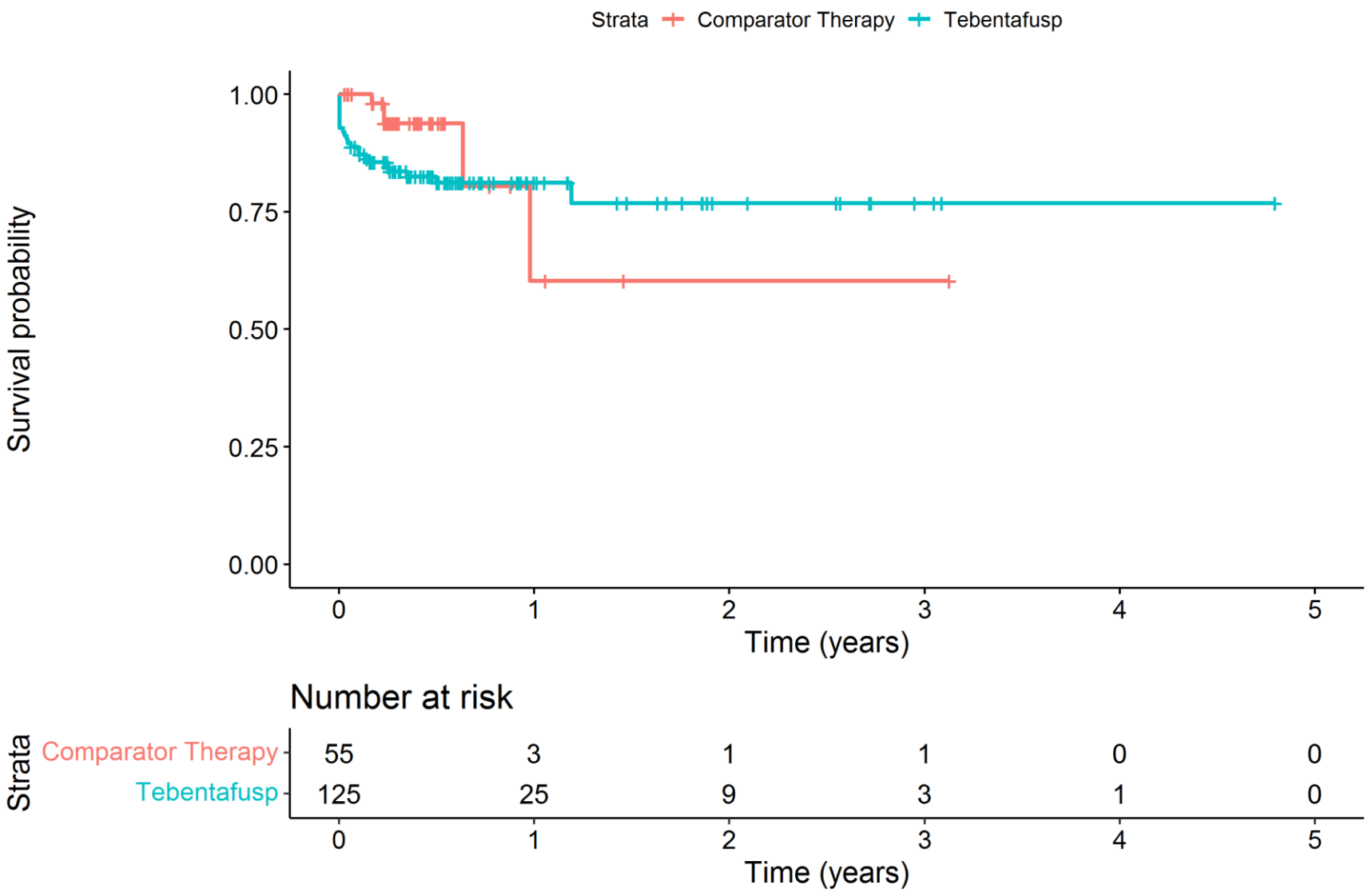
60.154 Hypertonie - Hispanisch



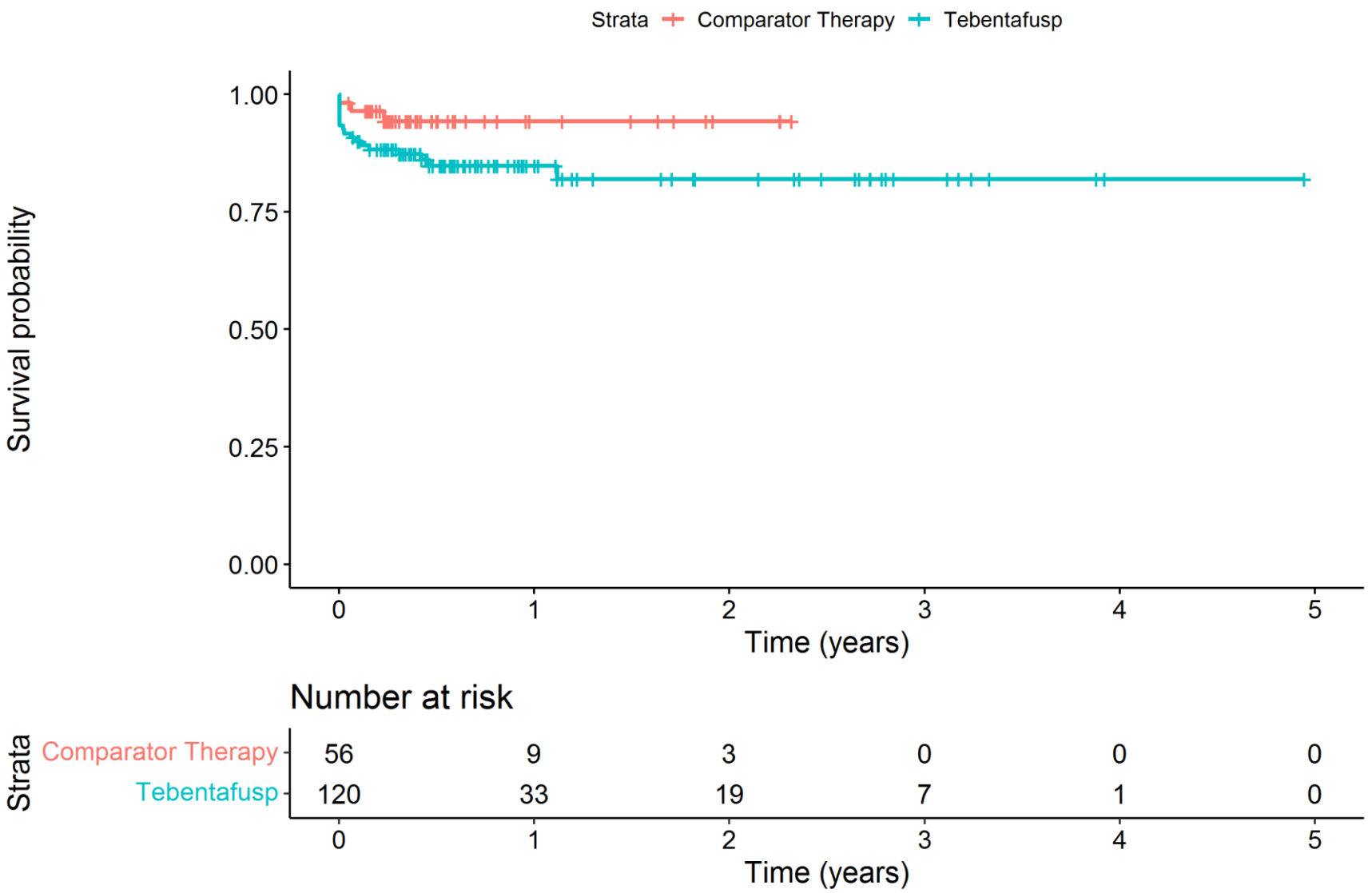
60.155 Hypertonie - Nicht-hispanisch



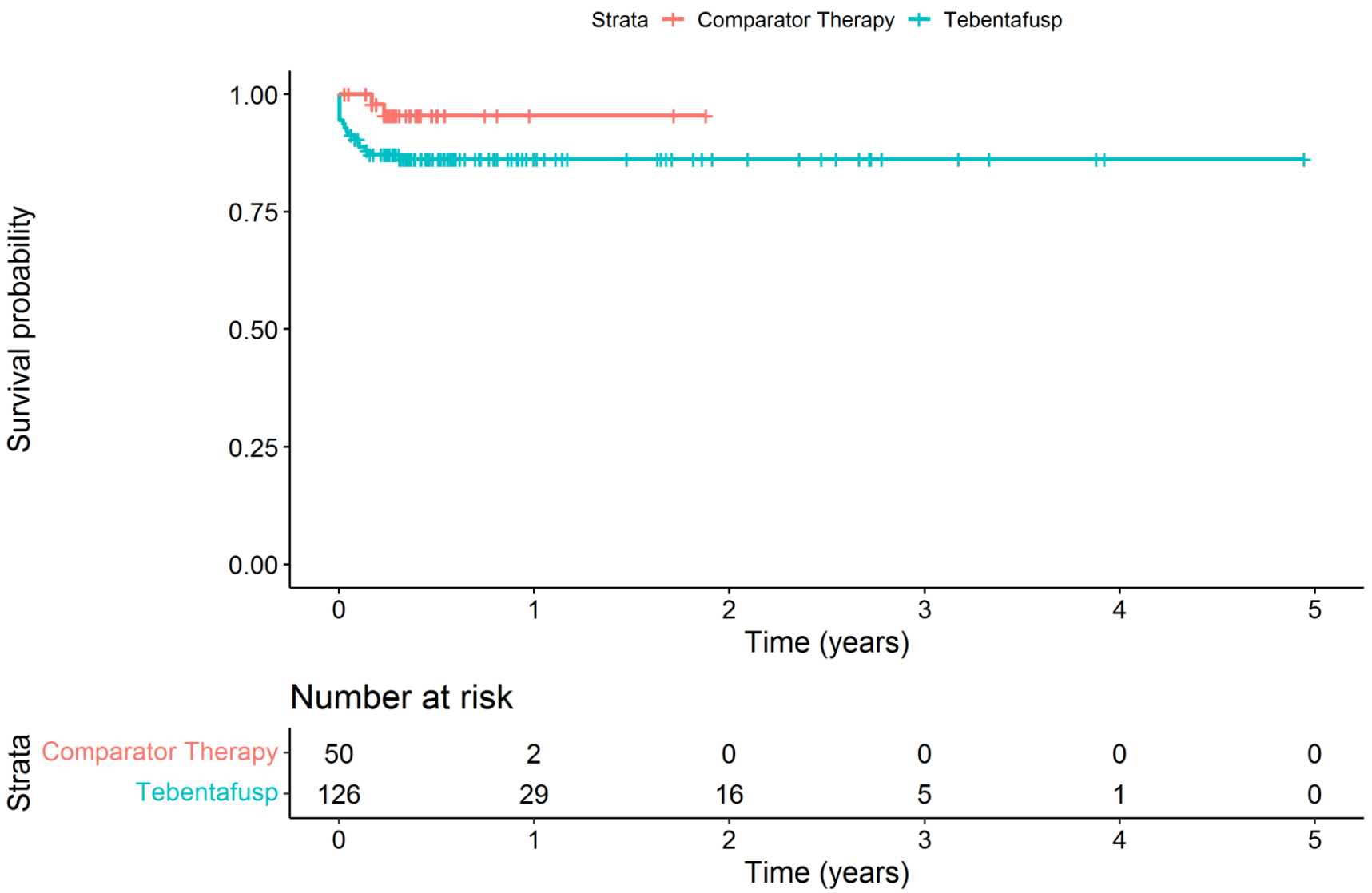
60.156 Hypertonie - Männlich



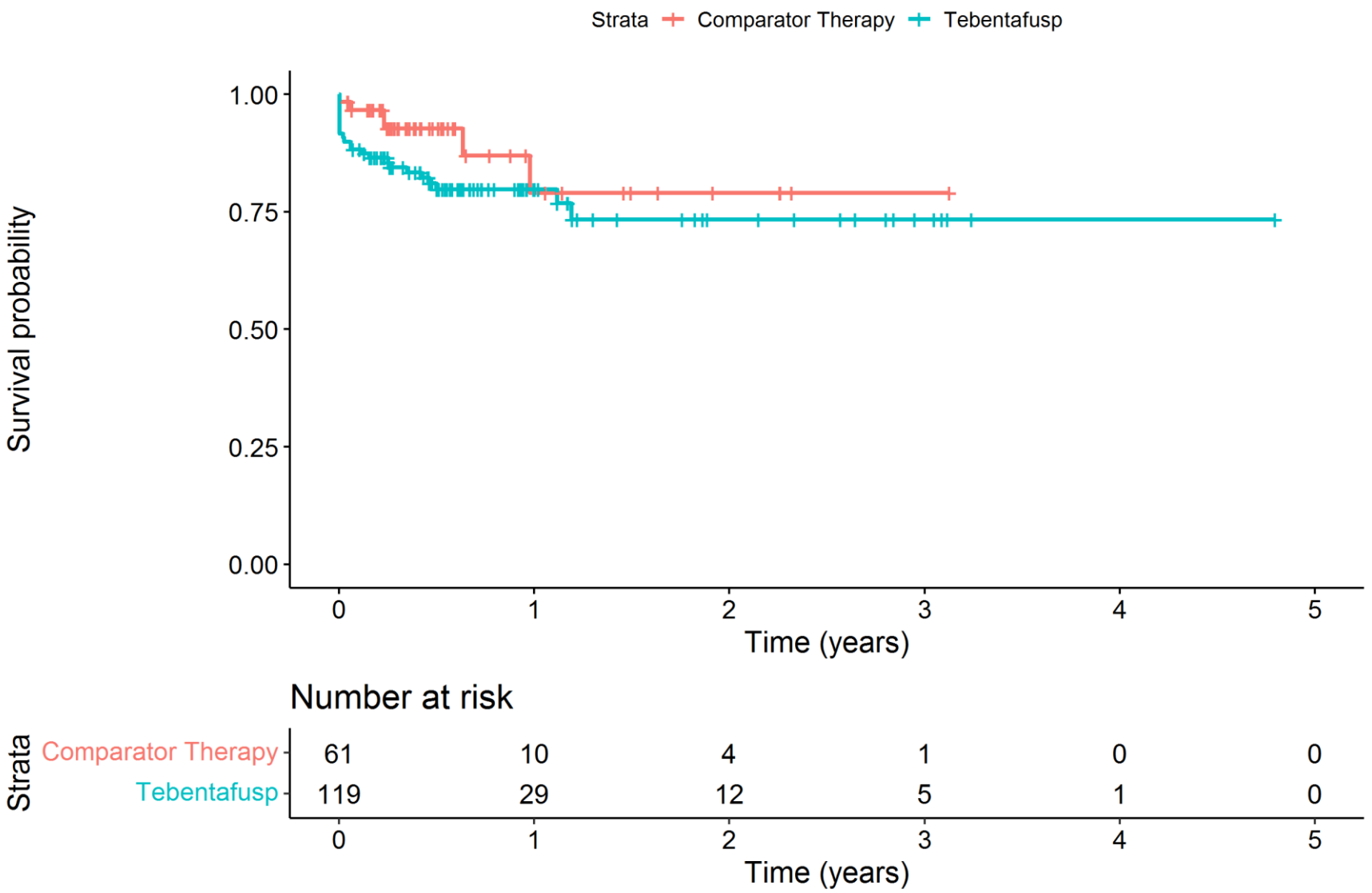
60.157 Hypertonie - Weiblich



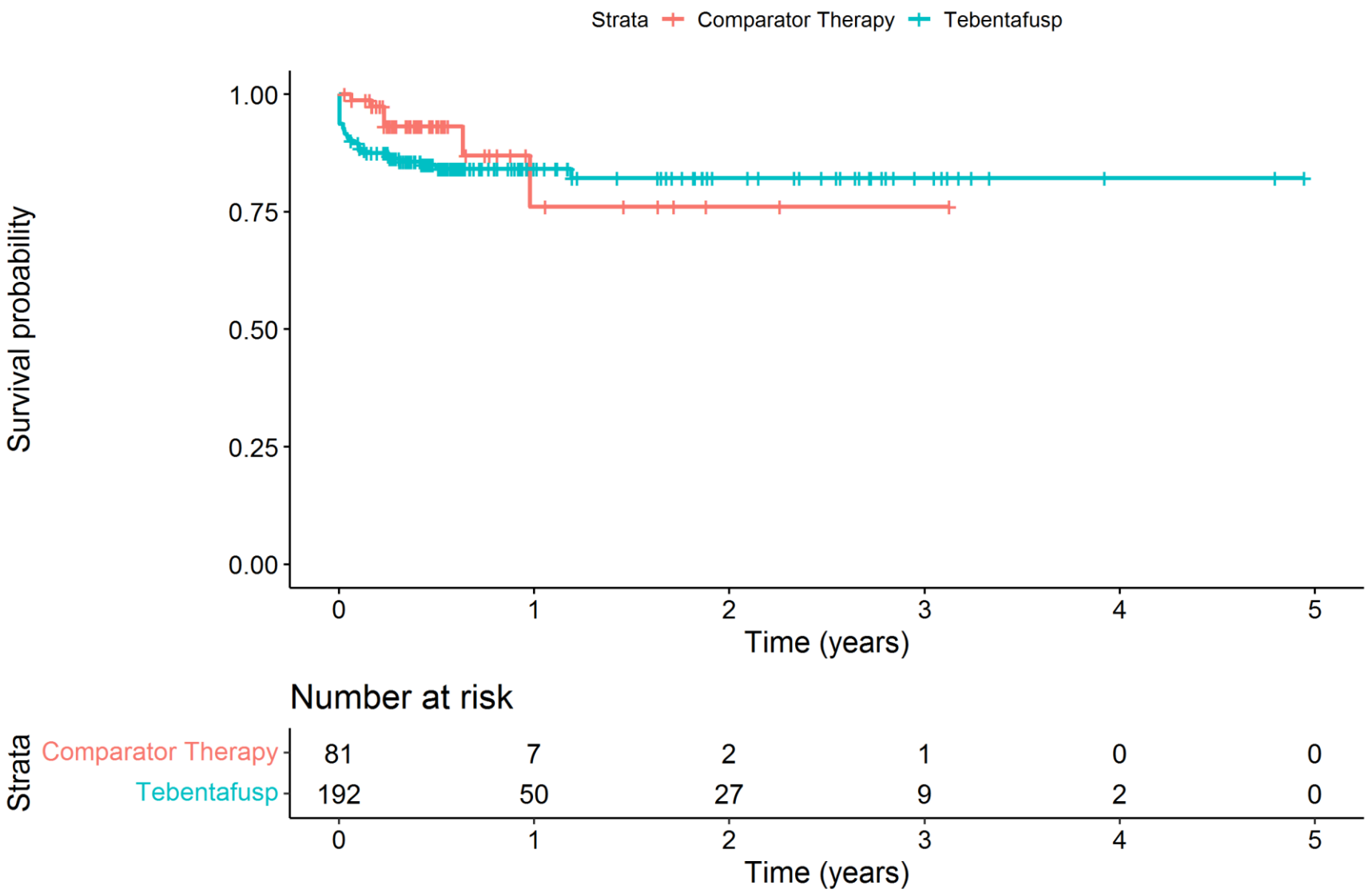
60.158 Hypertonie - <65



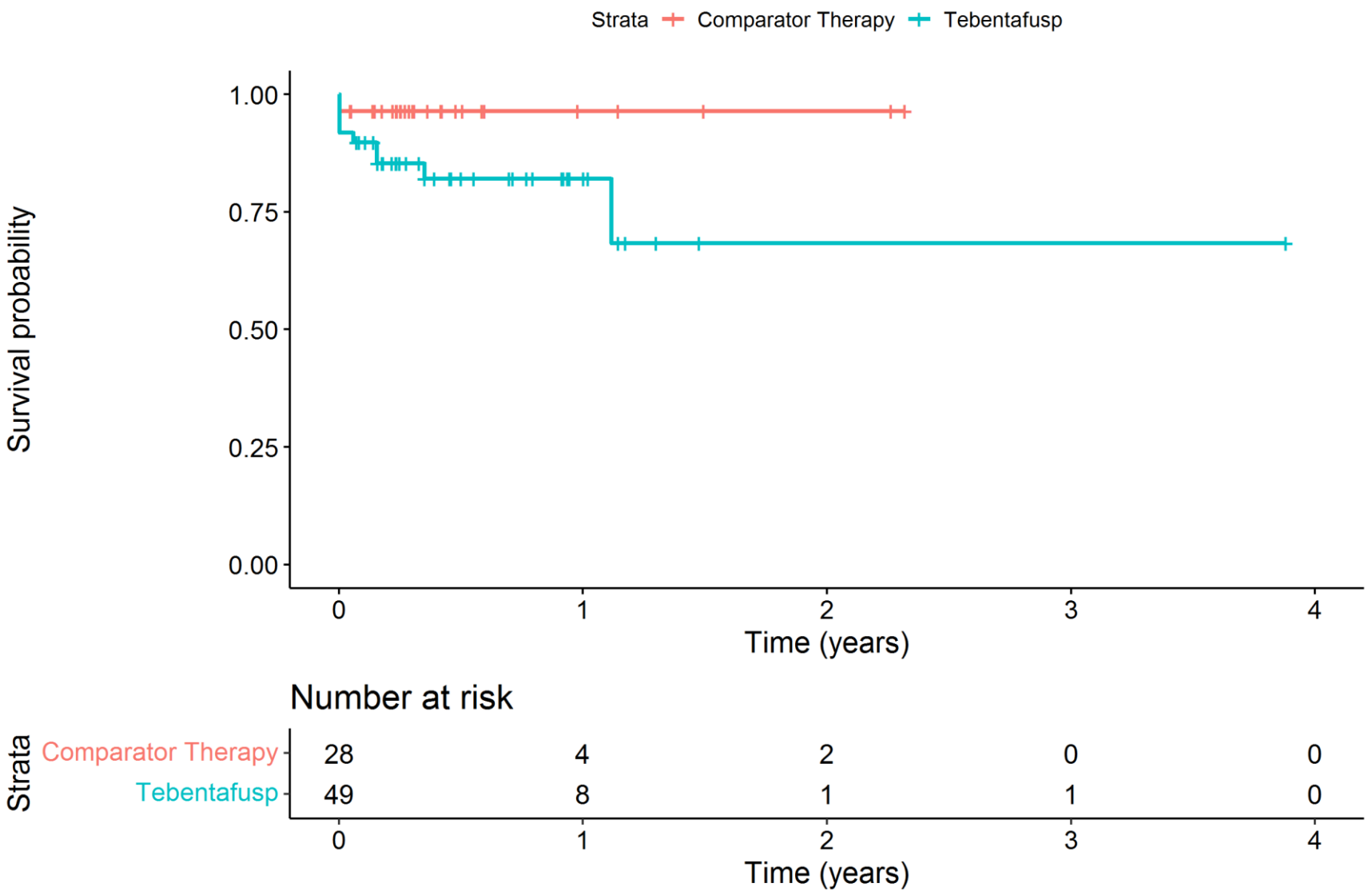
60.159 Hypertonie - ≥65



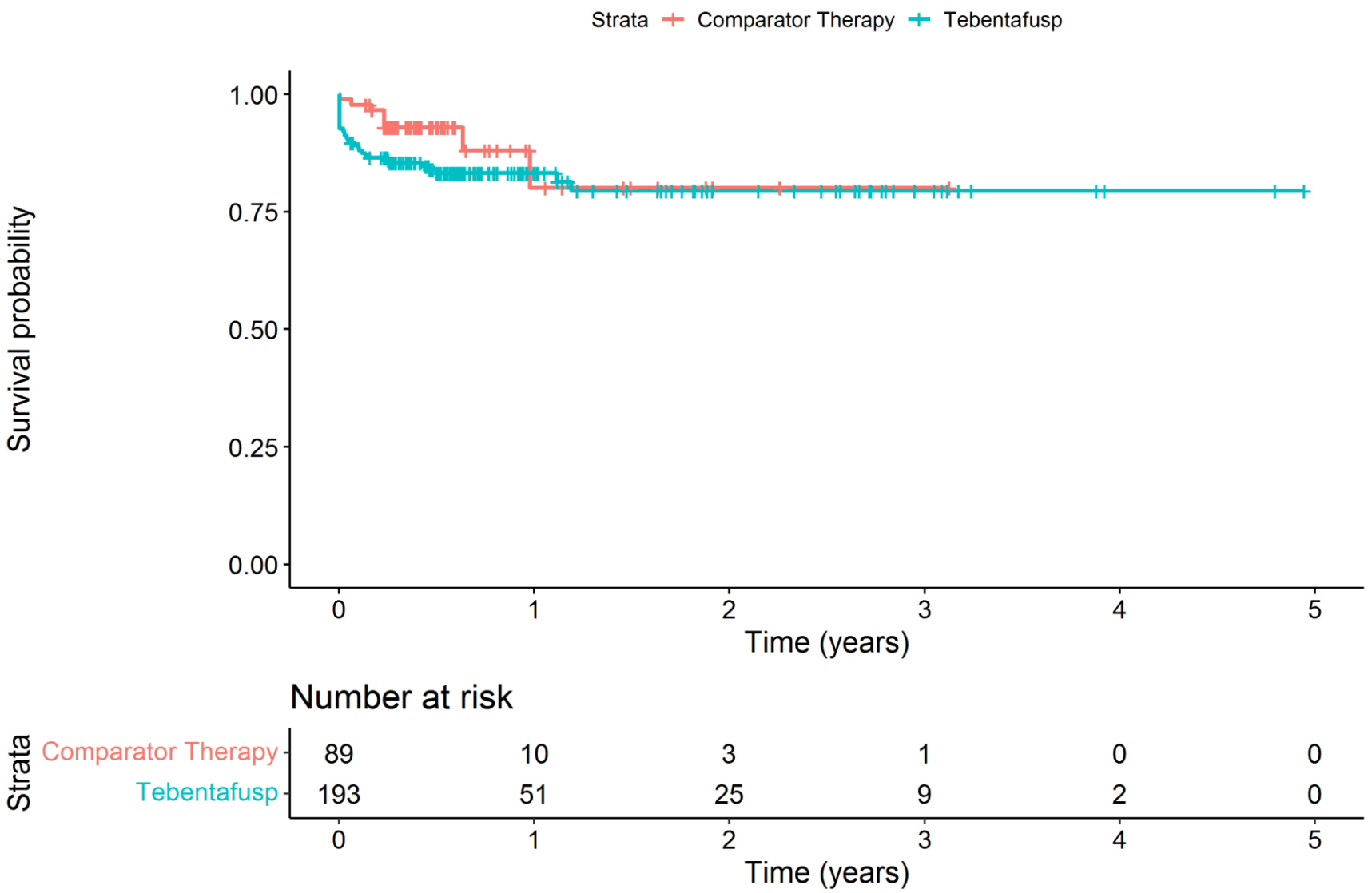
60.160 Hypertonie - ECOG 0



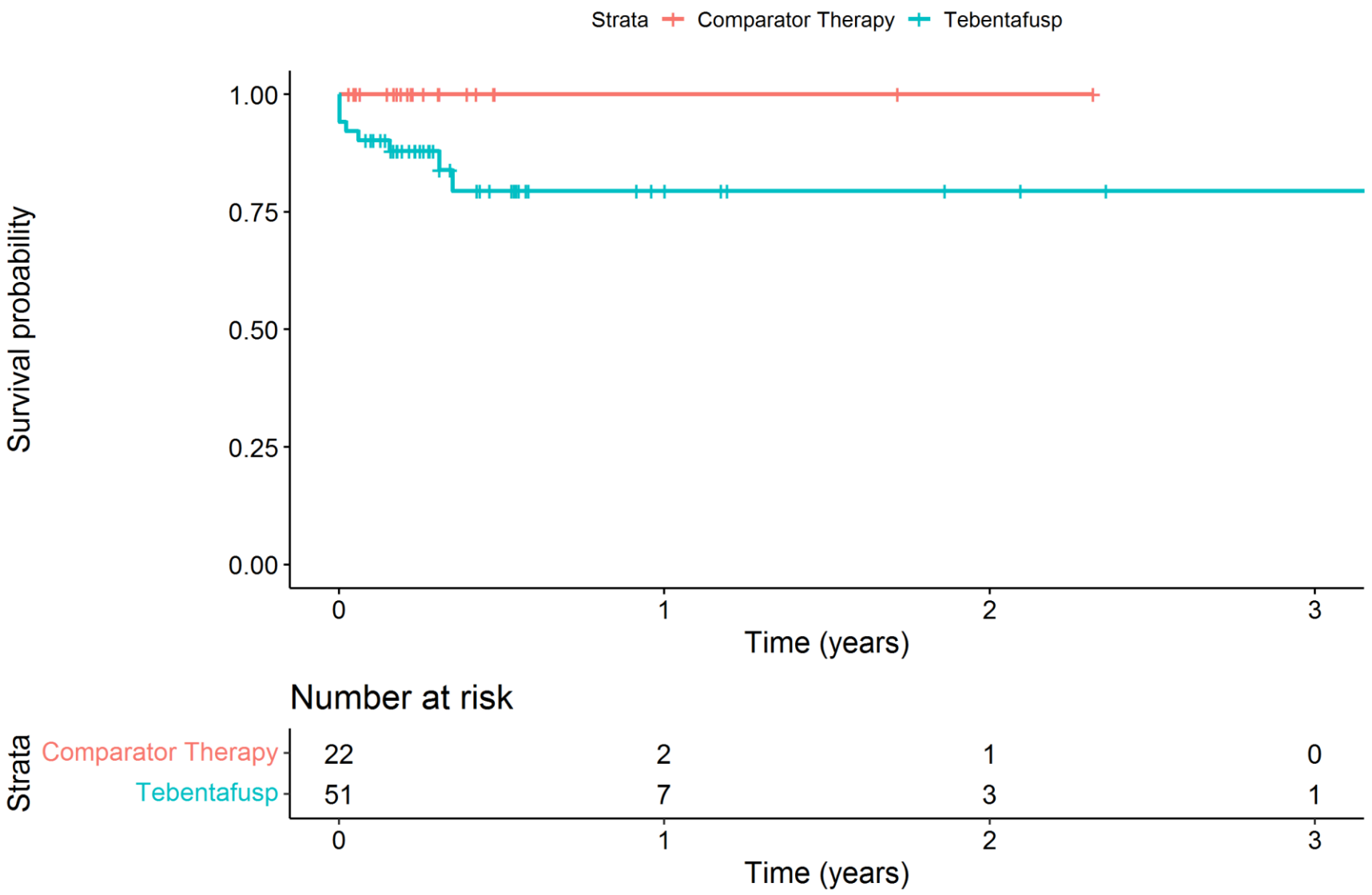
60.161 Hypertonie - ECOG 1



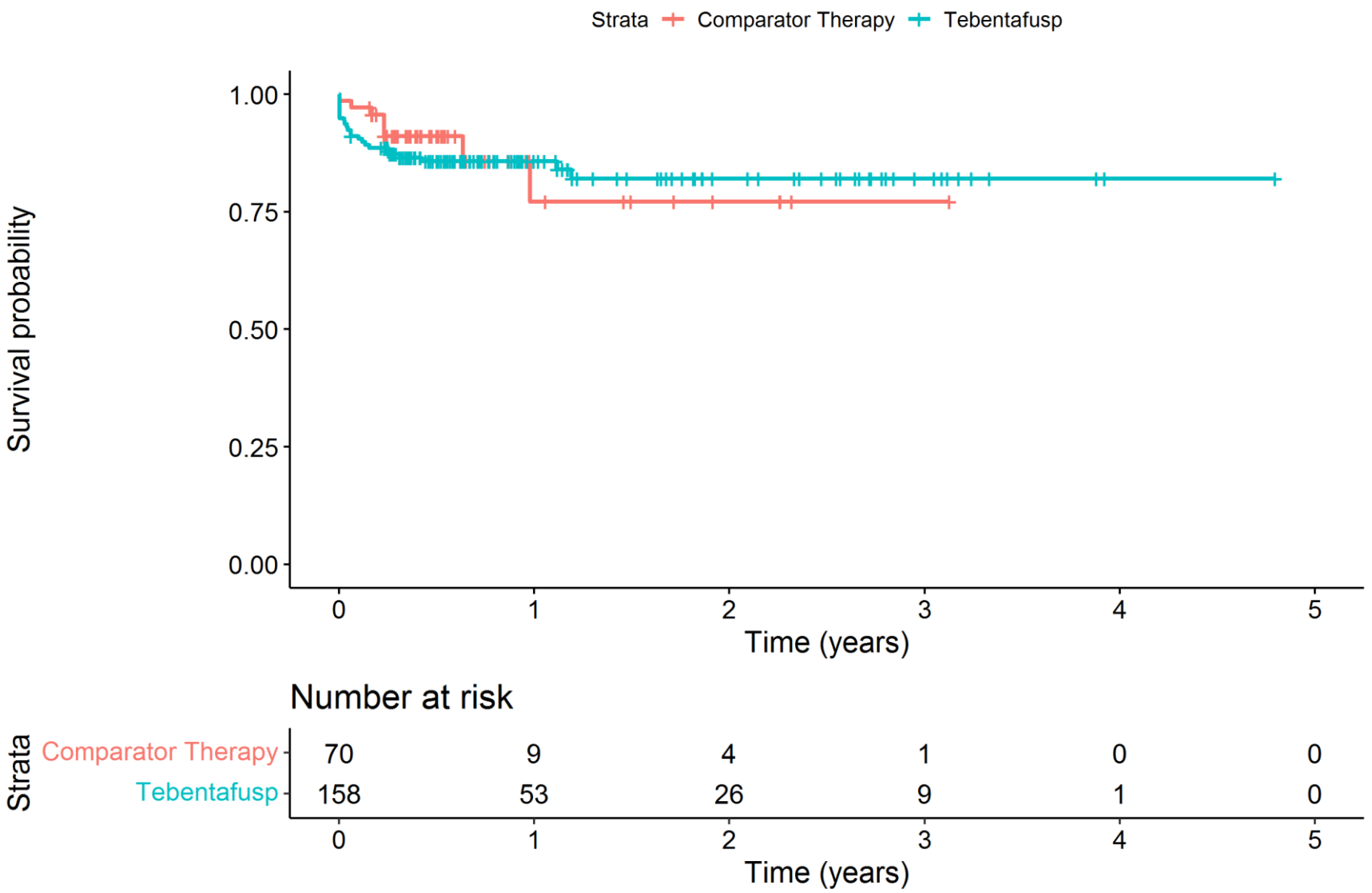
60.162 Hypertonie - ALP ≤ ULN



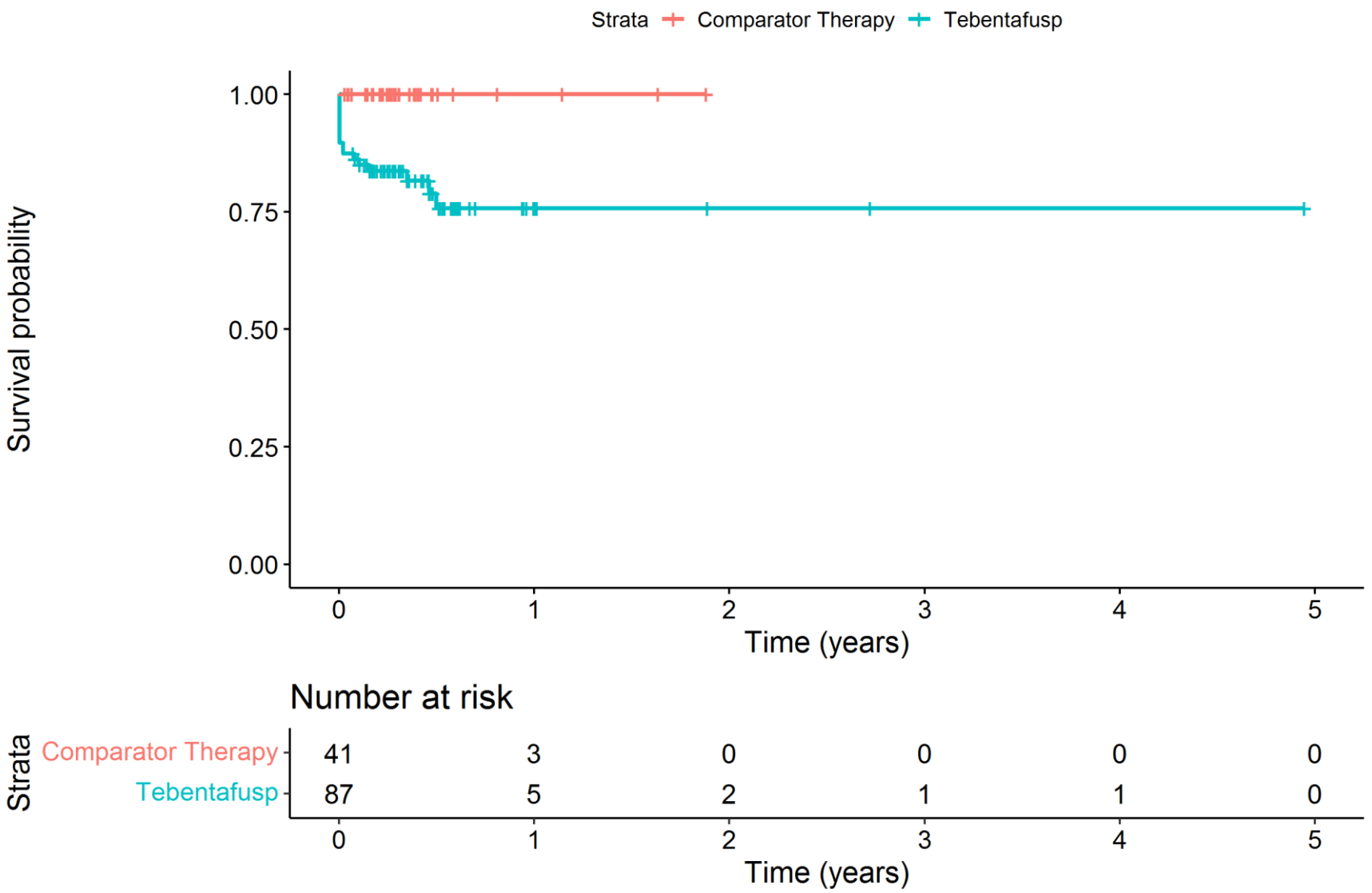
60.163 Hypertonie - ALP > ULN



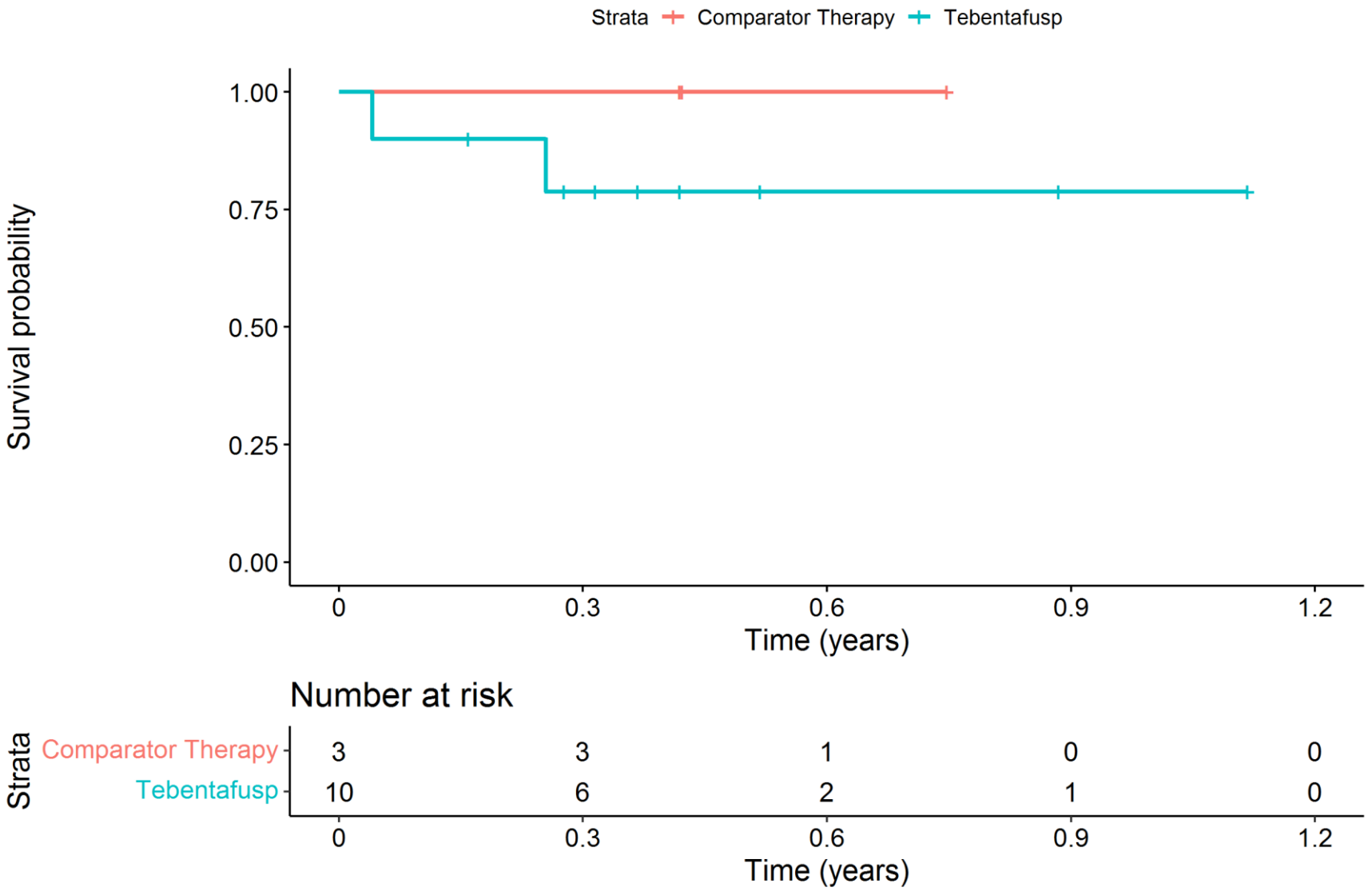
60.164 Hypertonie - LDH =< ULN



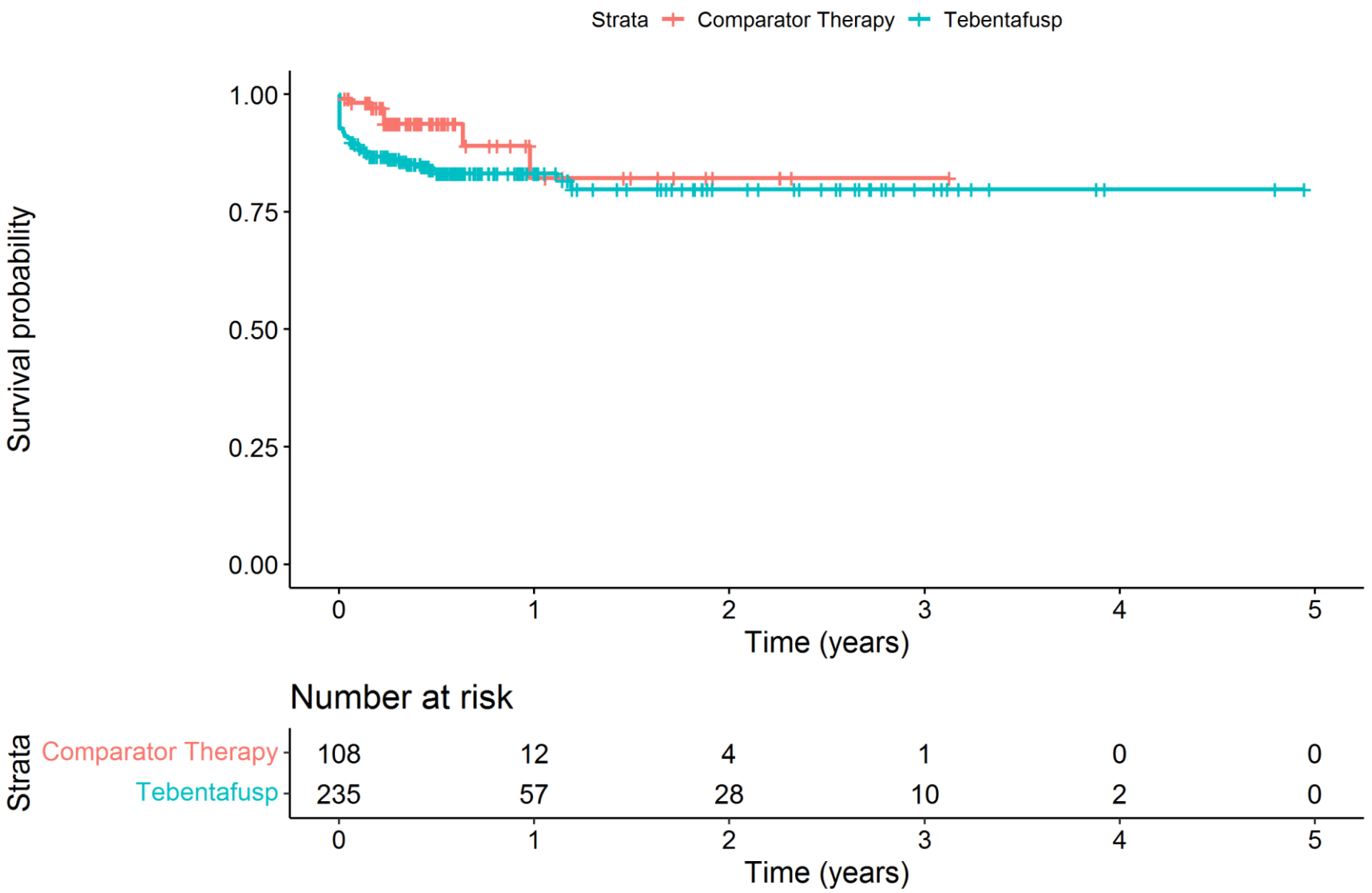
60.165 Hypertonie - LDH > ULN



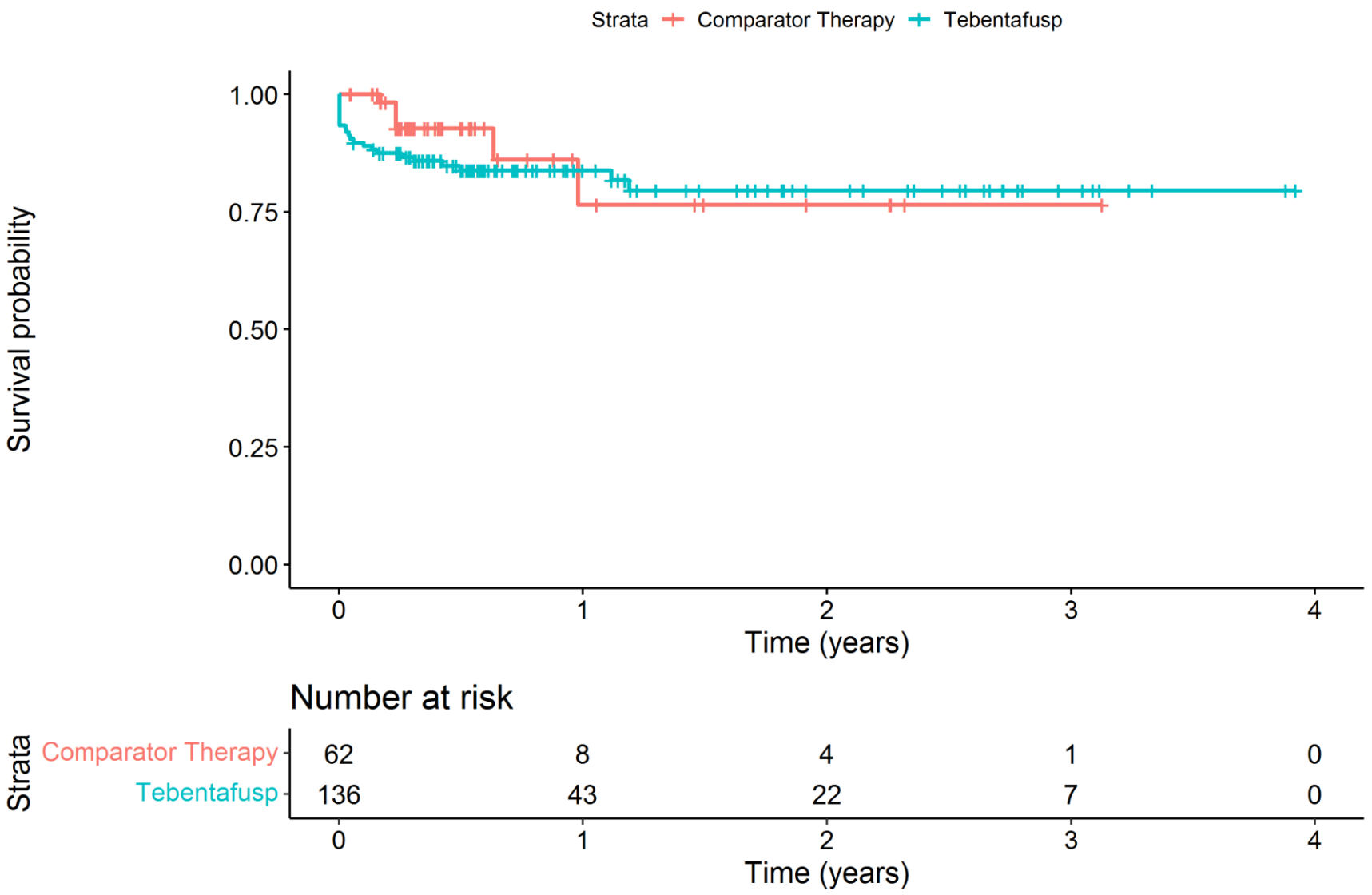
60.166 Hypertonie - Vorherige Therapie adjuvant/neoadjuvant



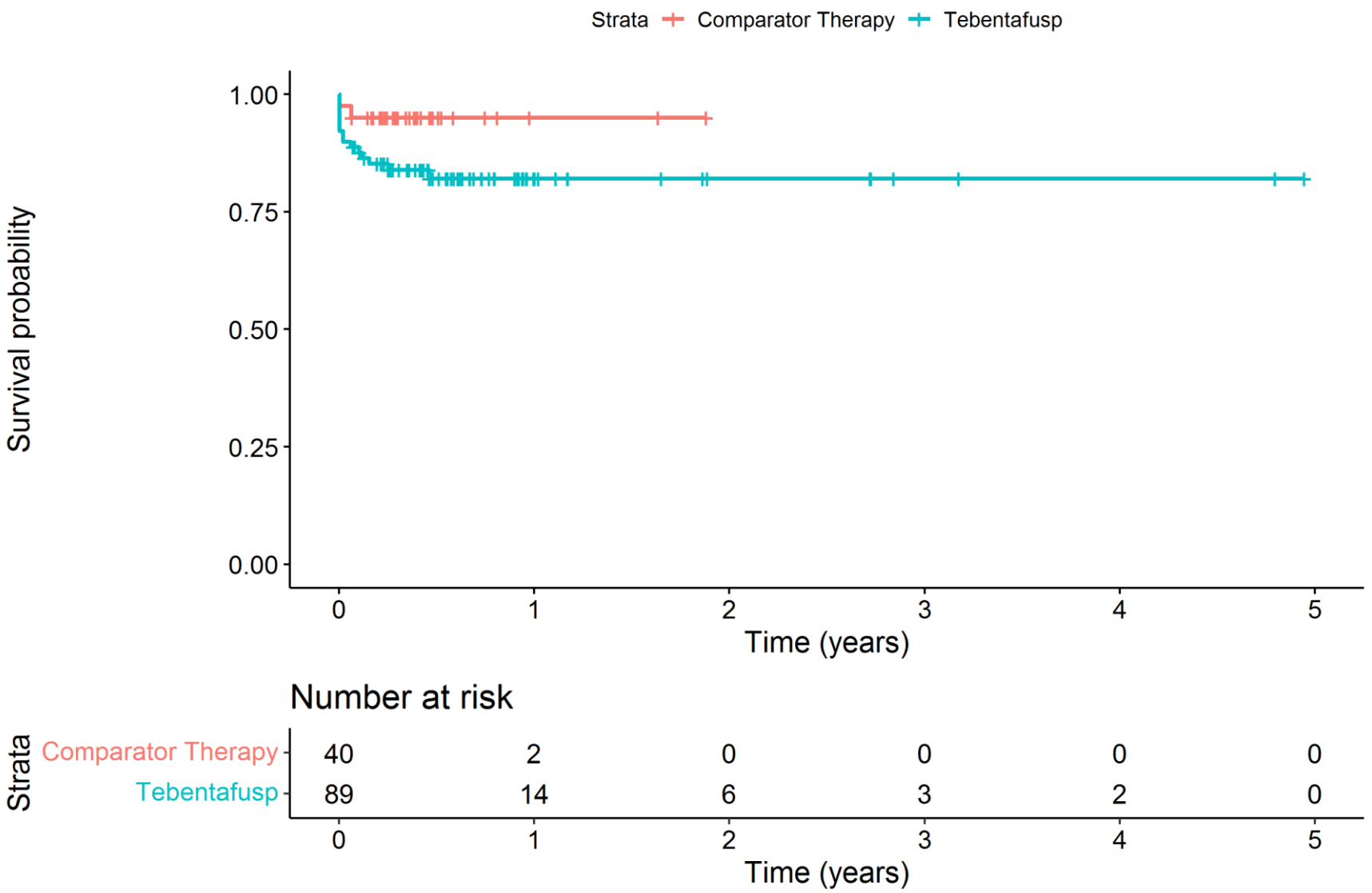
60.167 Hypertonie - Keine Vorherige Therapie adjuvant/neoadjuvant



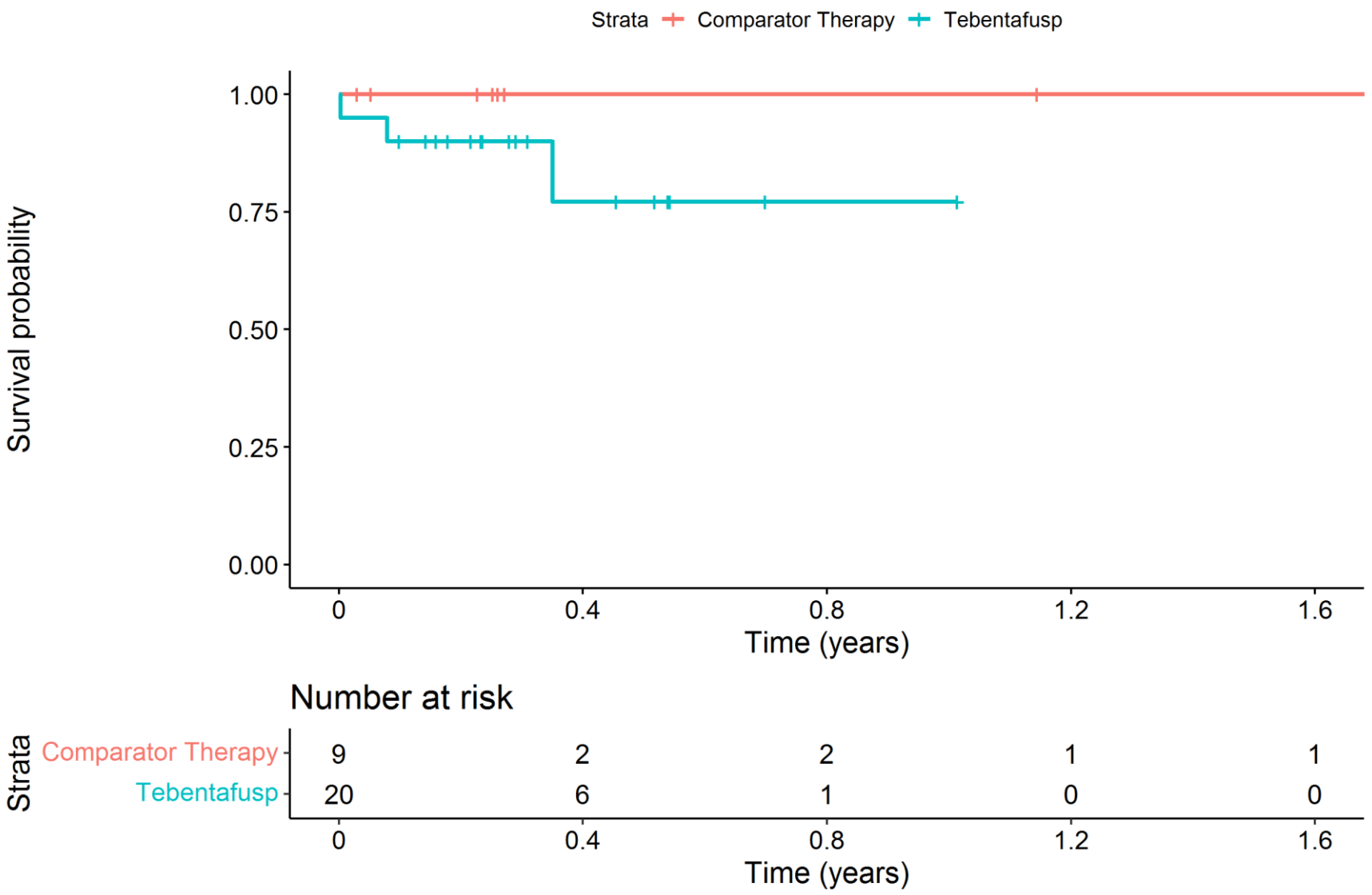
60.168 Hypertonie - Läsion ≤ 3cm



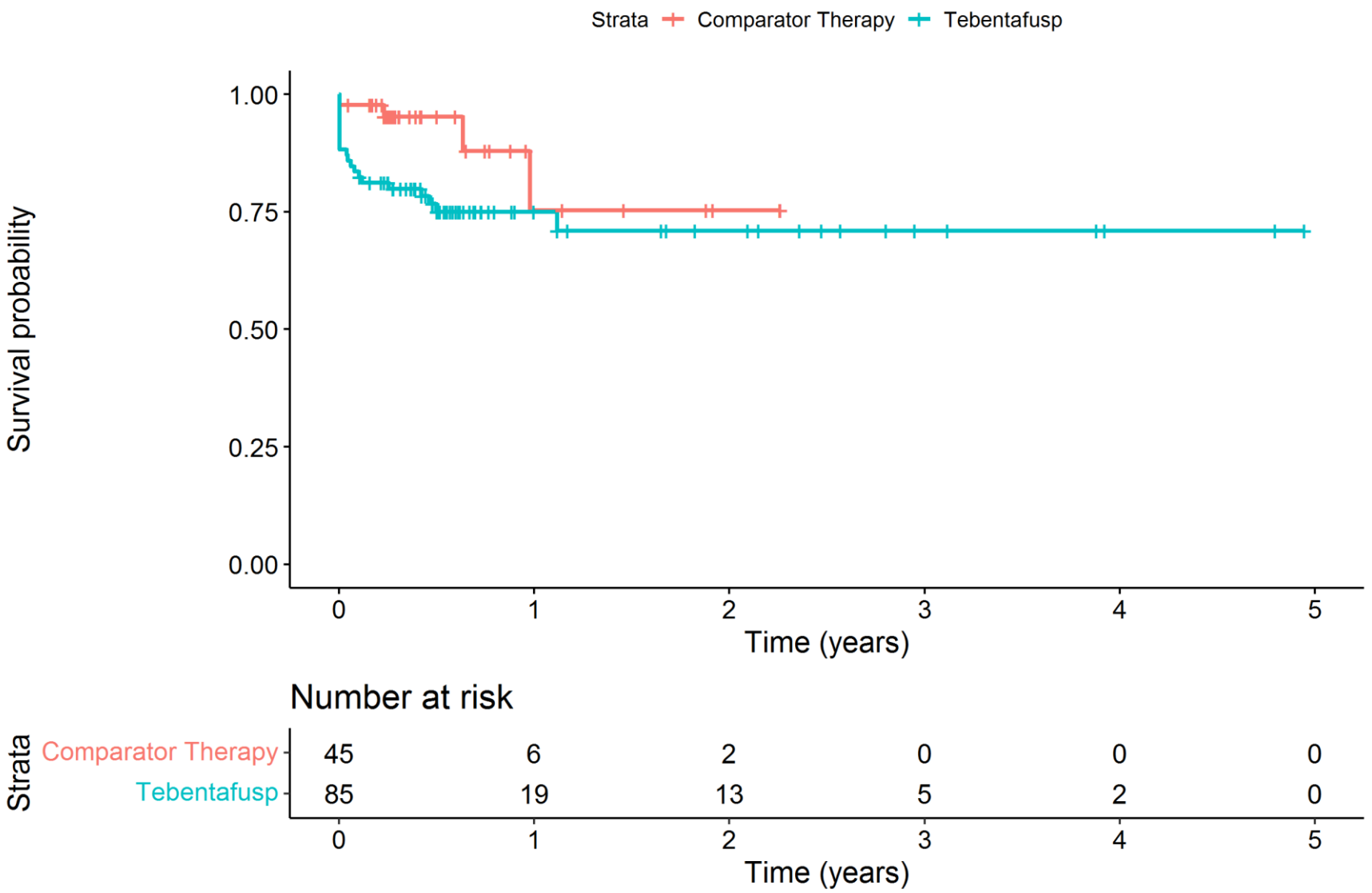
60.169 Hypertonie - Läsion 3,1-8,0 cm



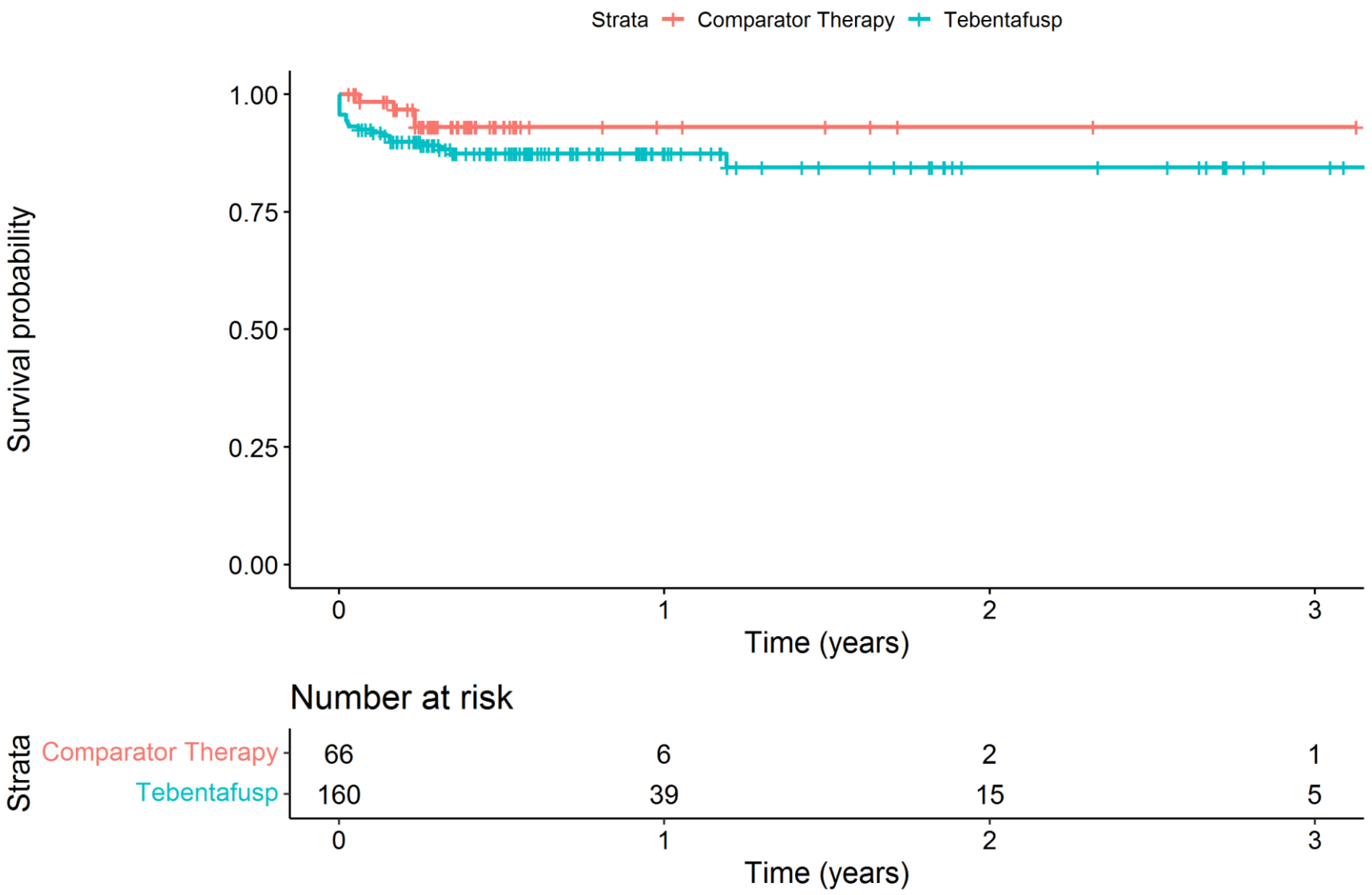
60.170 Hypertonie - Läsion ≥8,1 cm



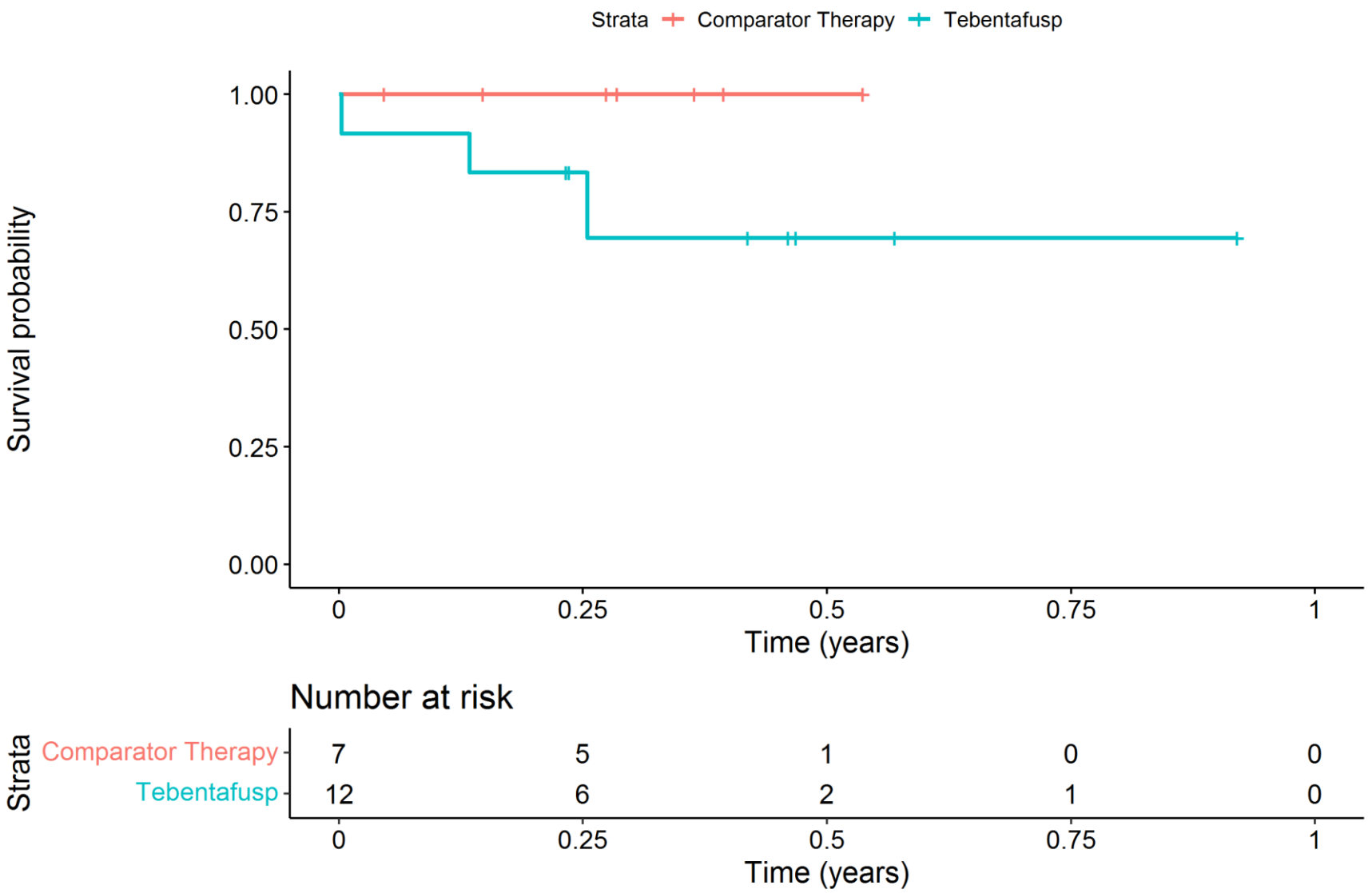
60.171 Hypertonie - Nordamerika



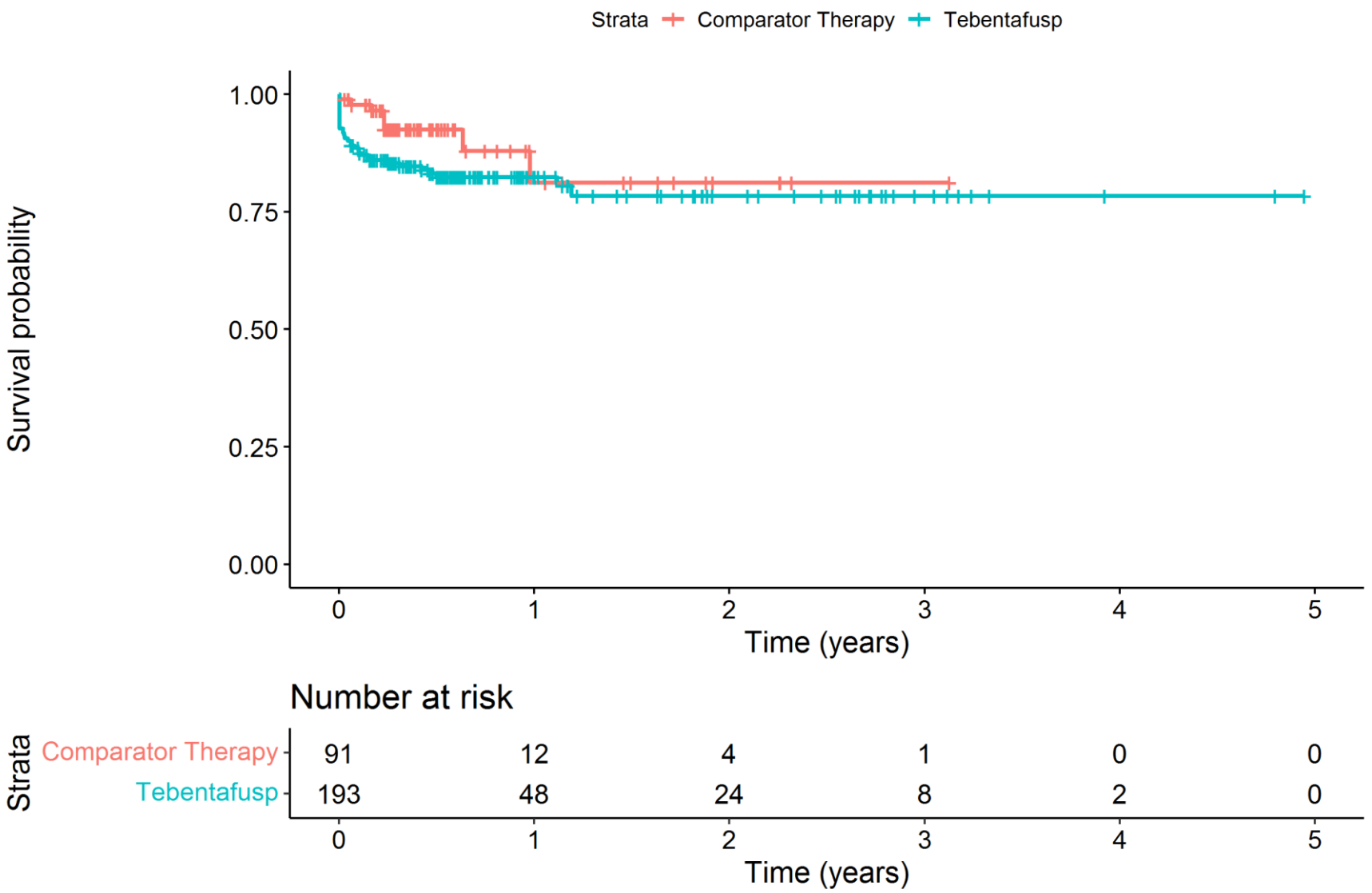
60.172 Hypertonie - Nicht-Nordamerika



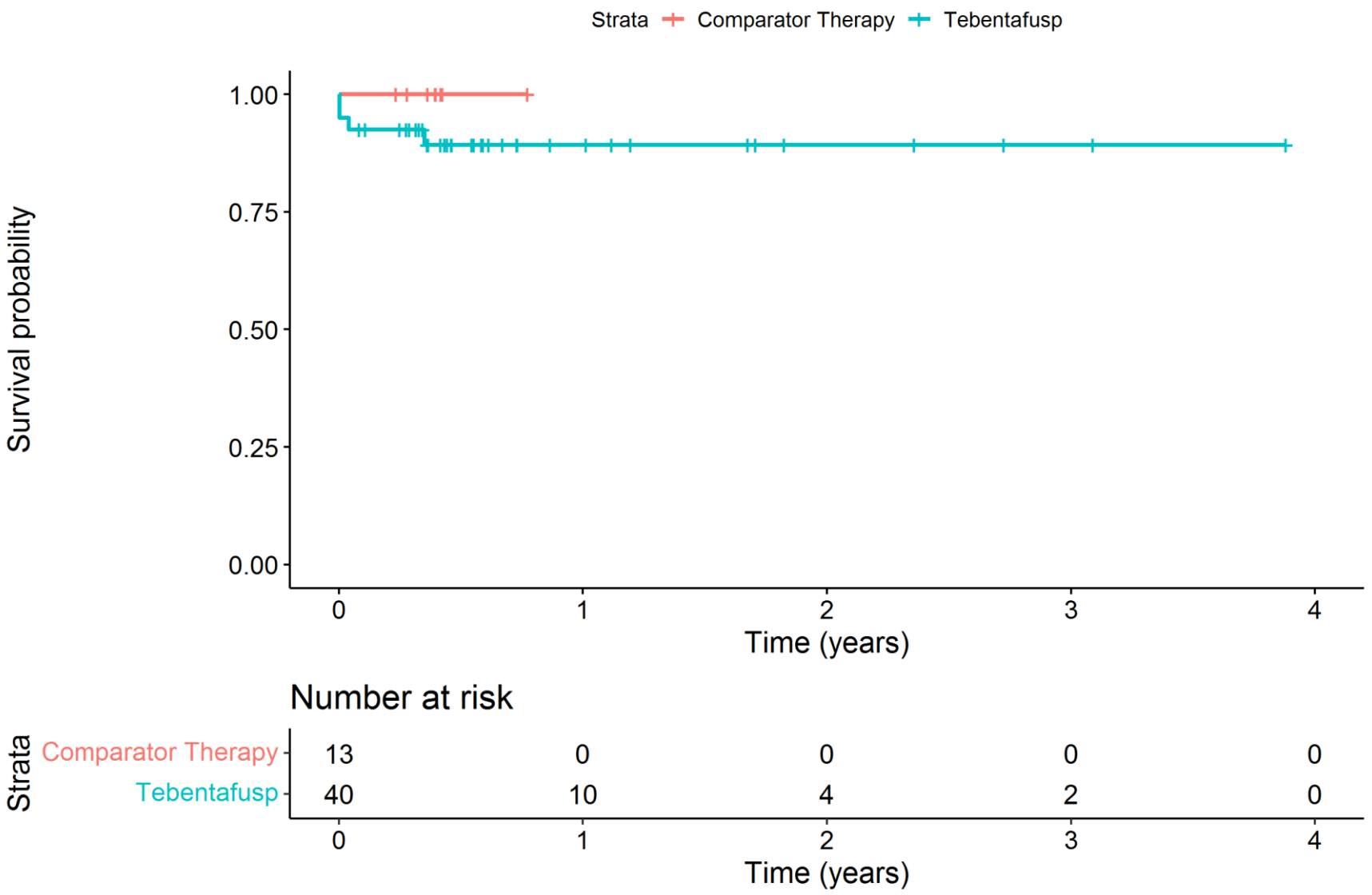
60.173 Hypertonie - Dacarbazin



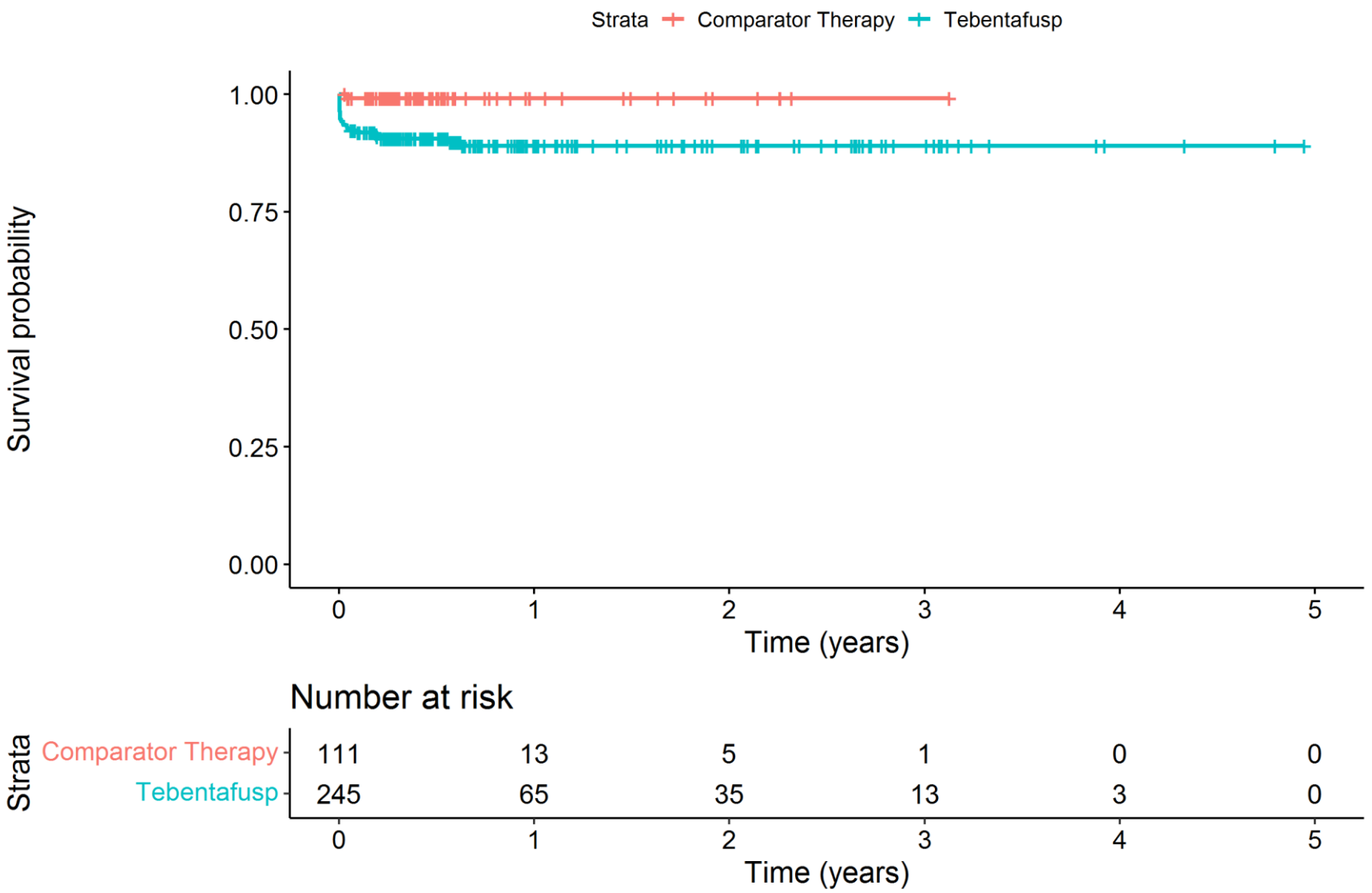
60.174 Hypertonie - Pembrolizumab



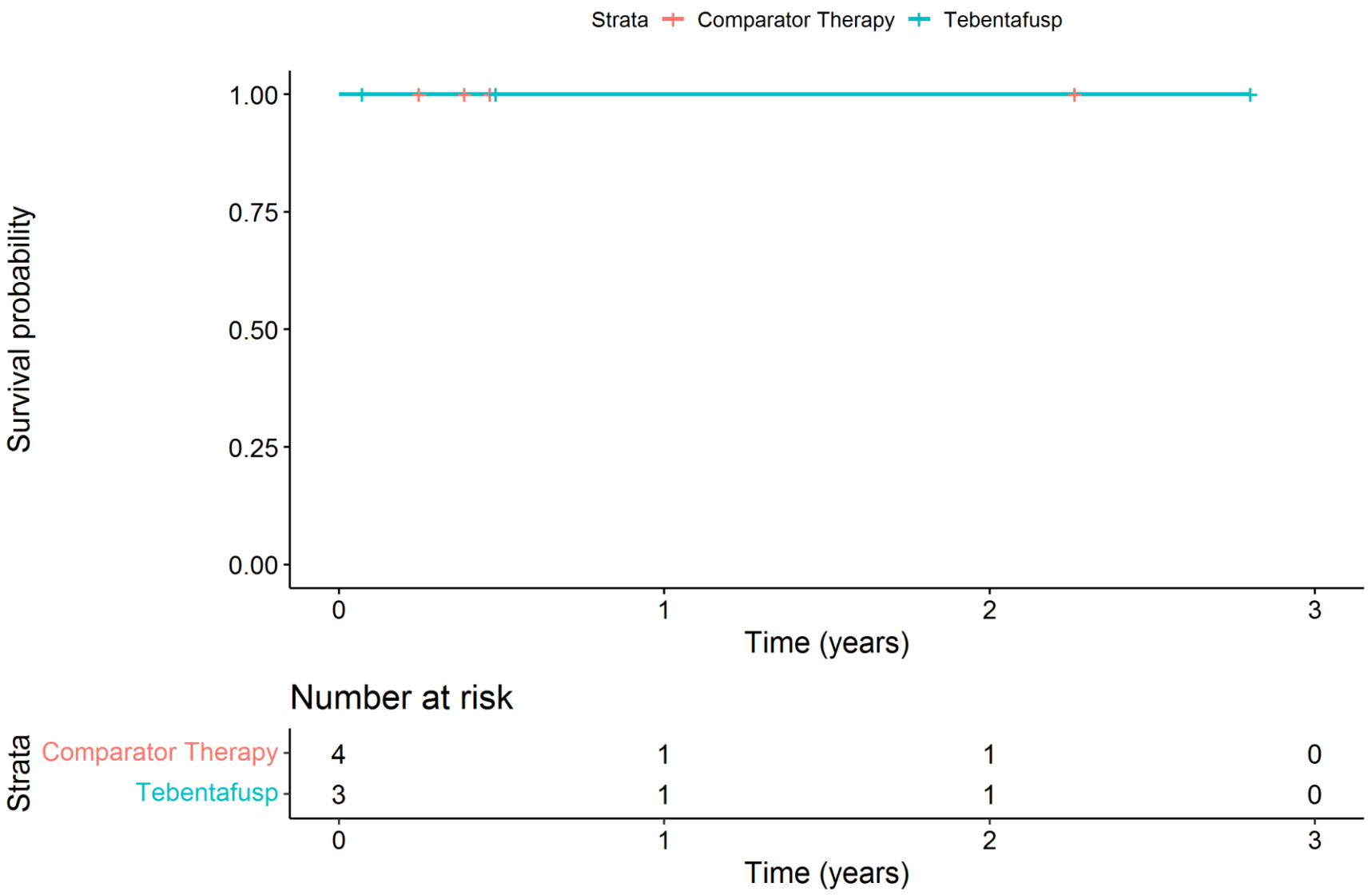
60.175 Hypertonie - Ipilimumab



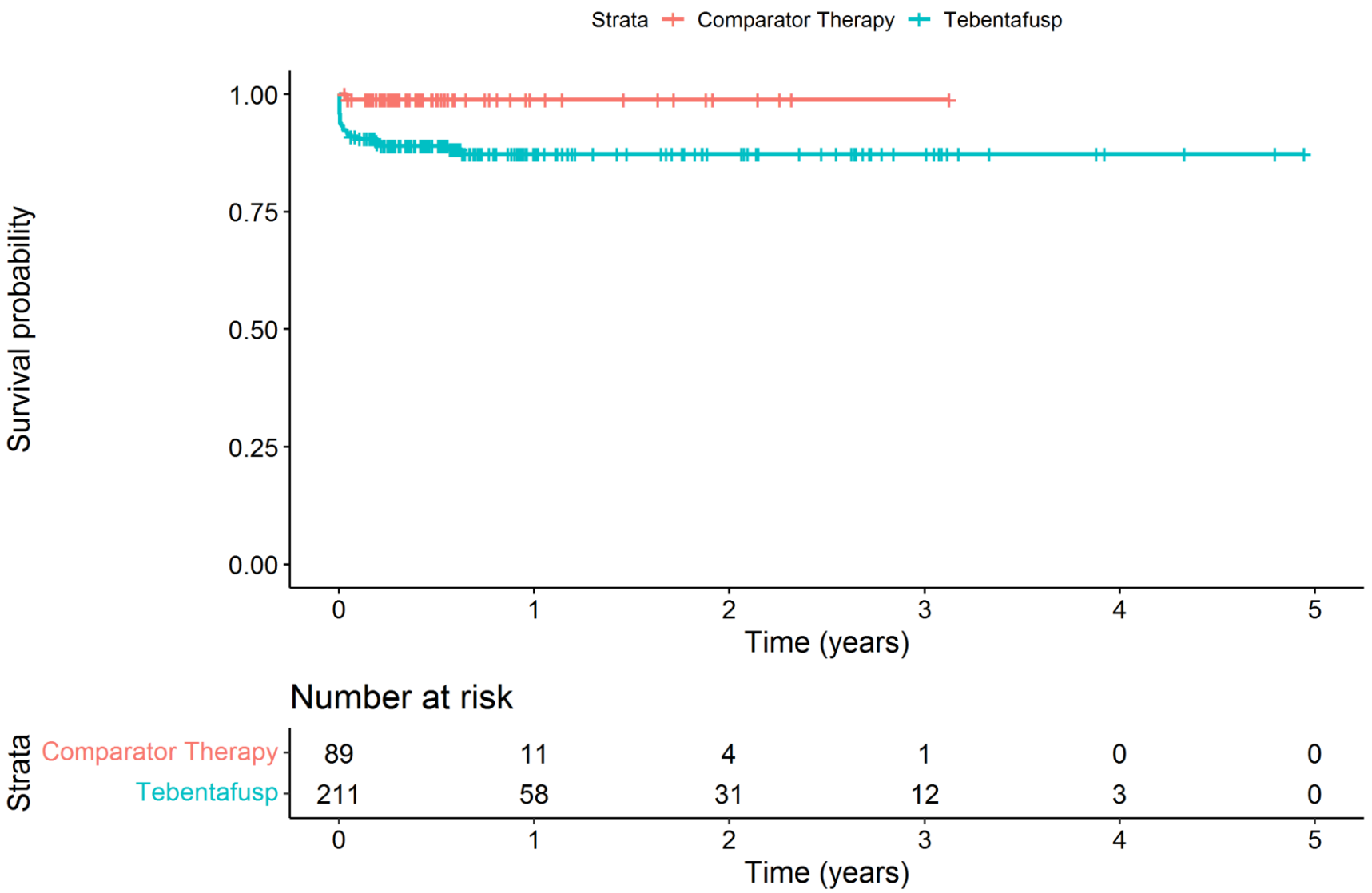
60.176 Hautrötung - Gesamt



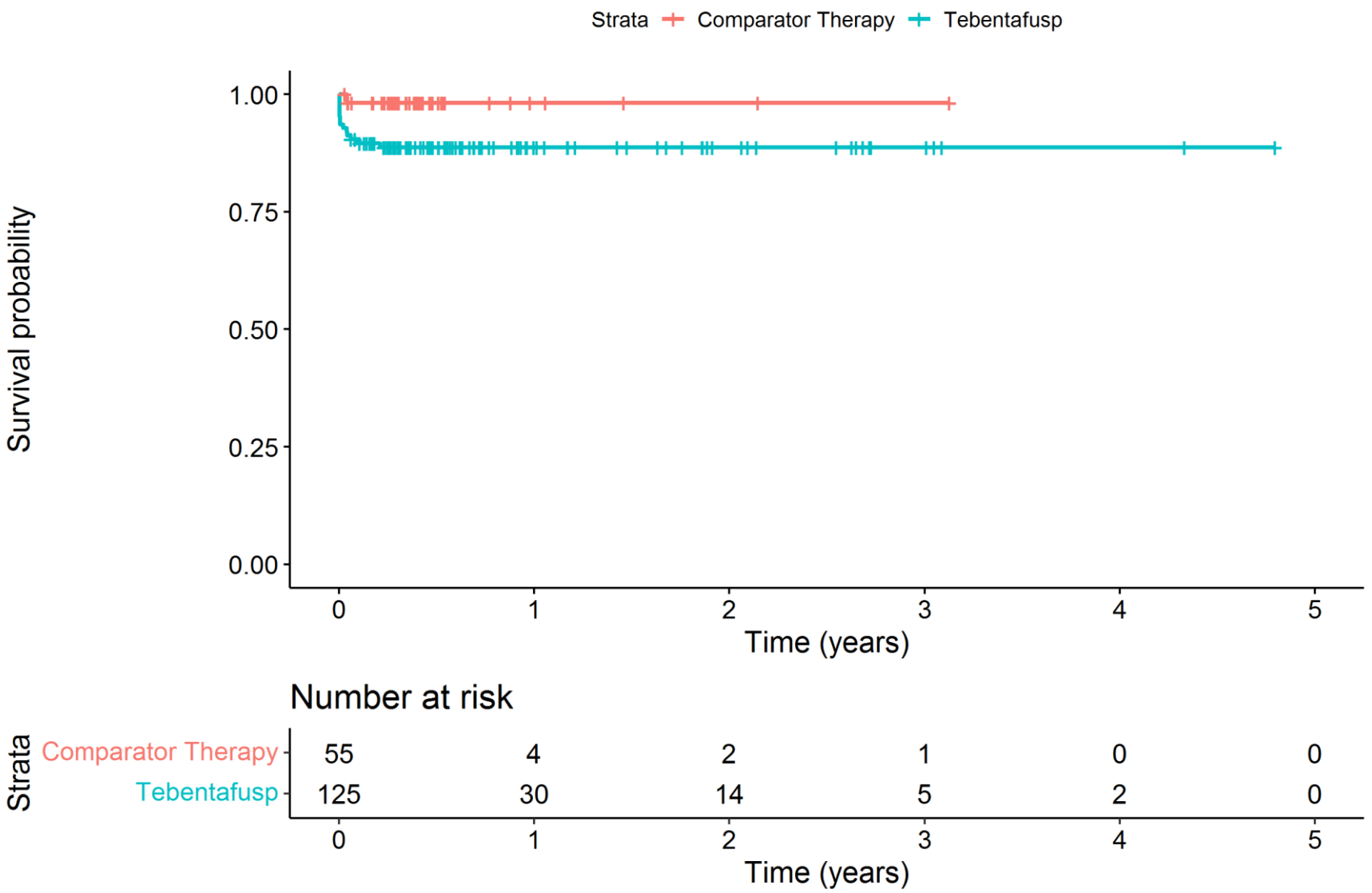
60.177 Hautrötung - Hispanisch



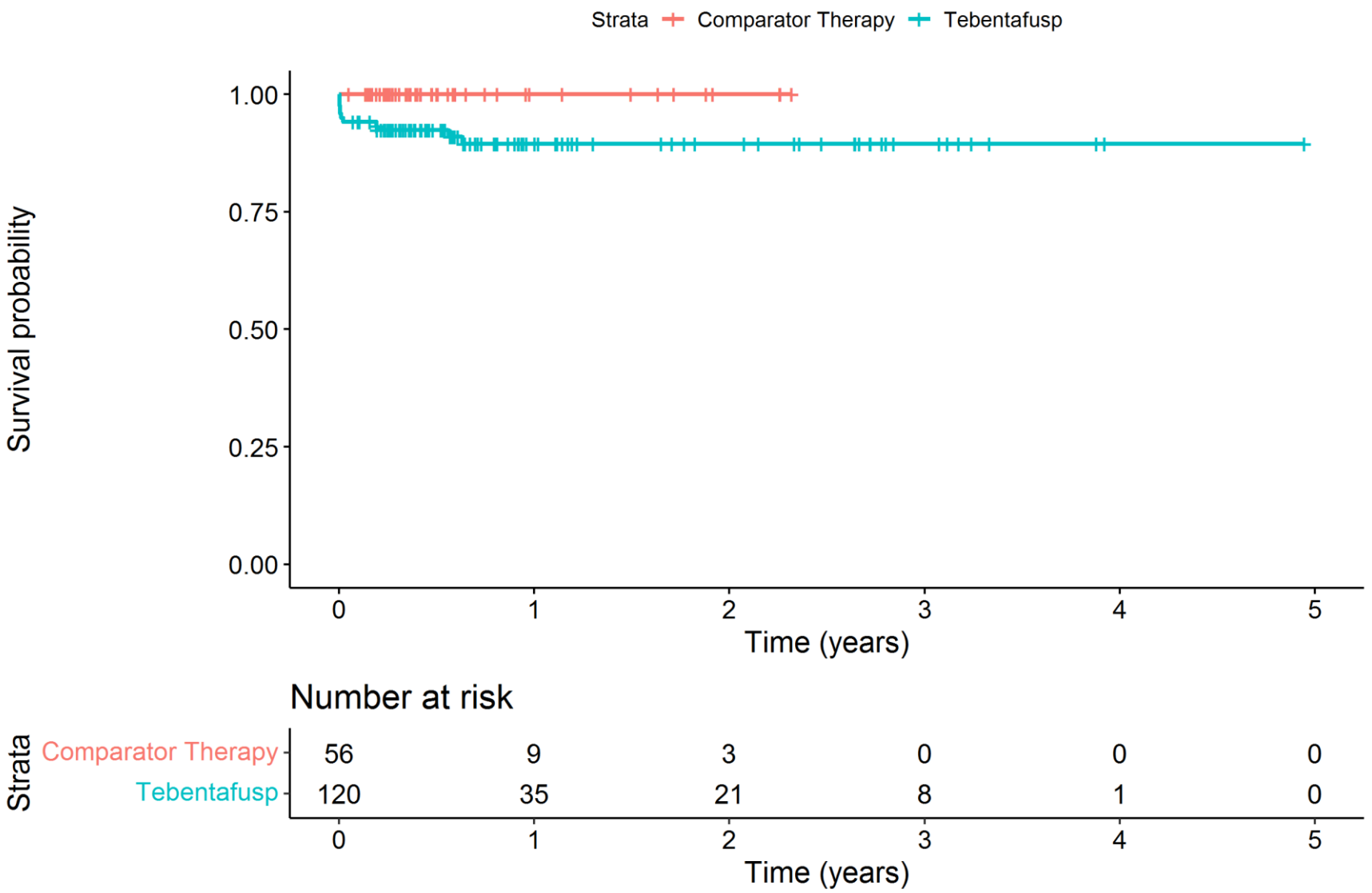
60.178 Hautrötung - Nicht-hispanisch



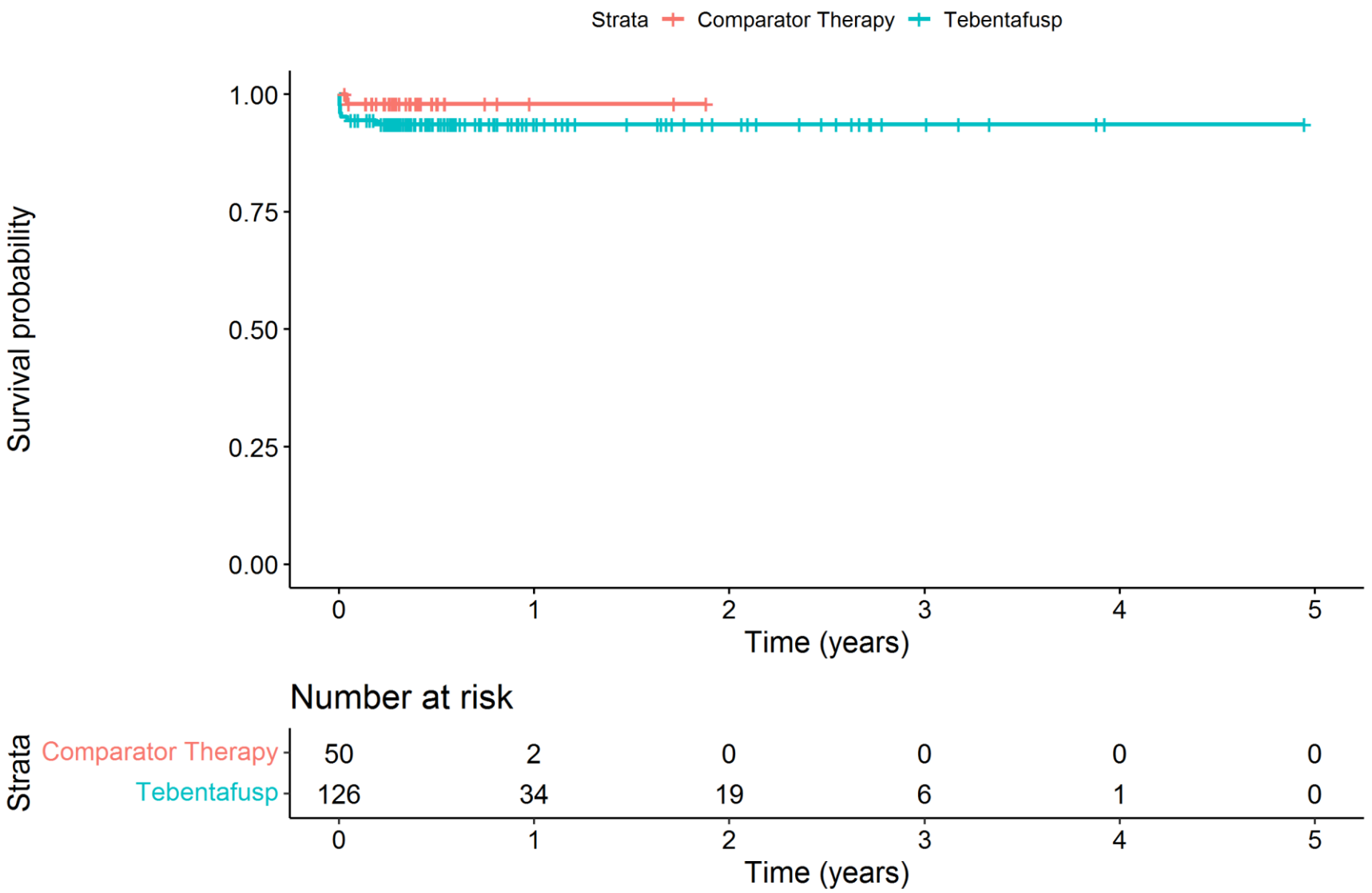
60.179 Hautrötung - Männlich



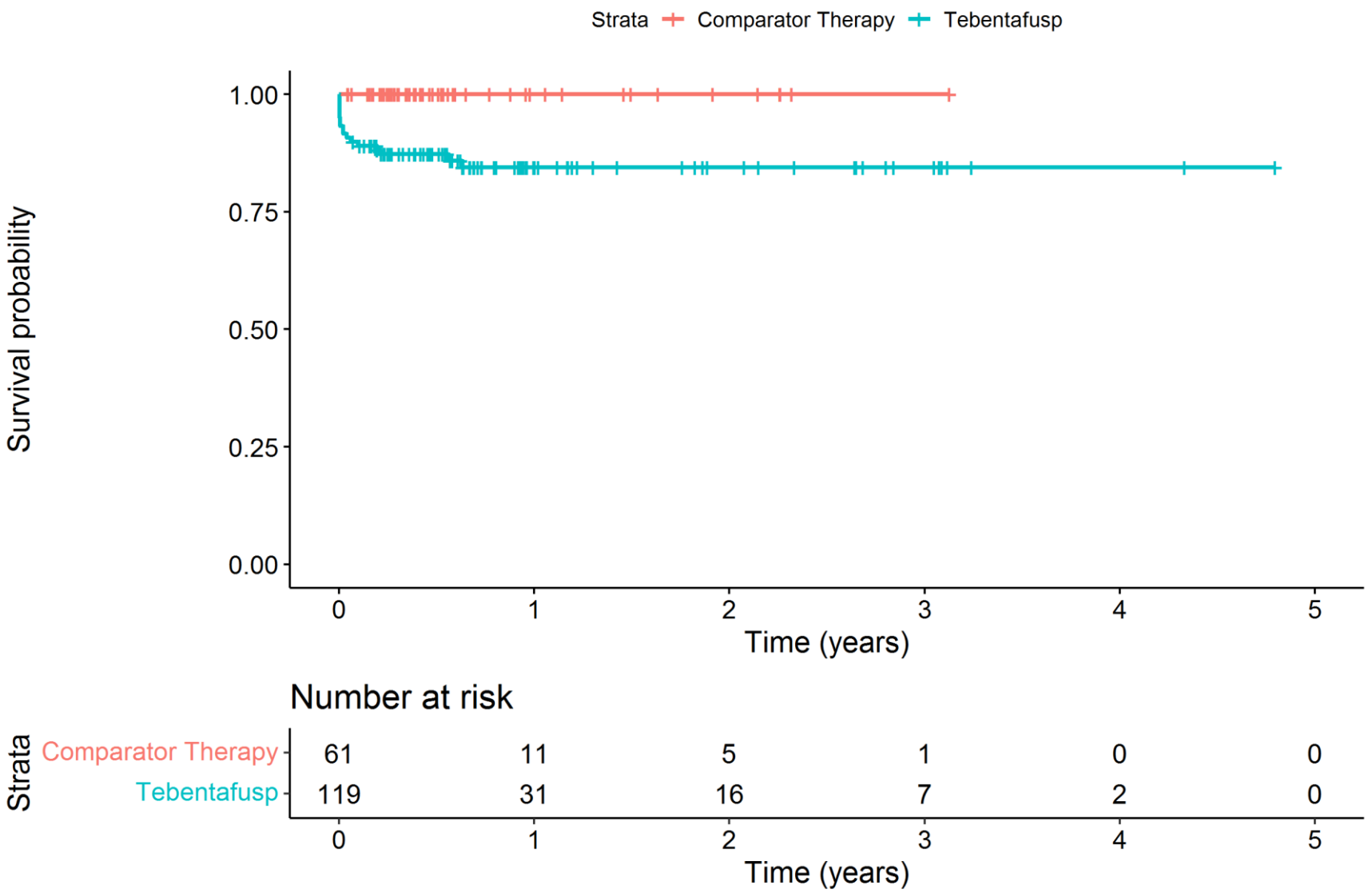
60.180 Hautrötung - Weiblich



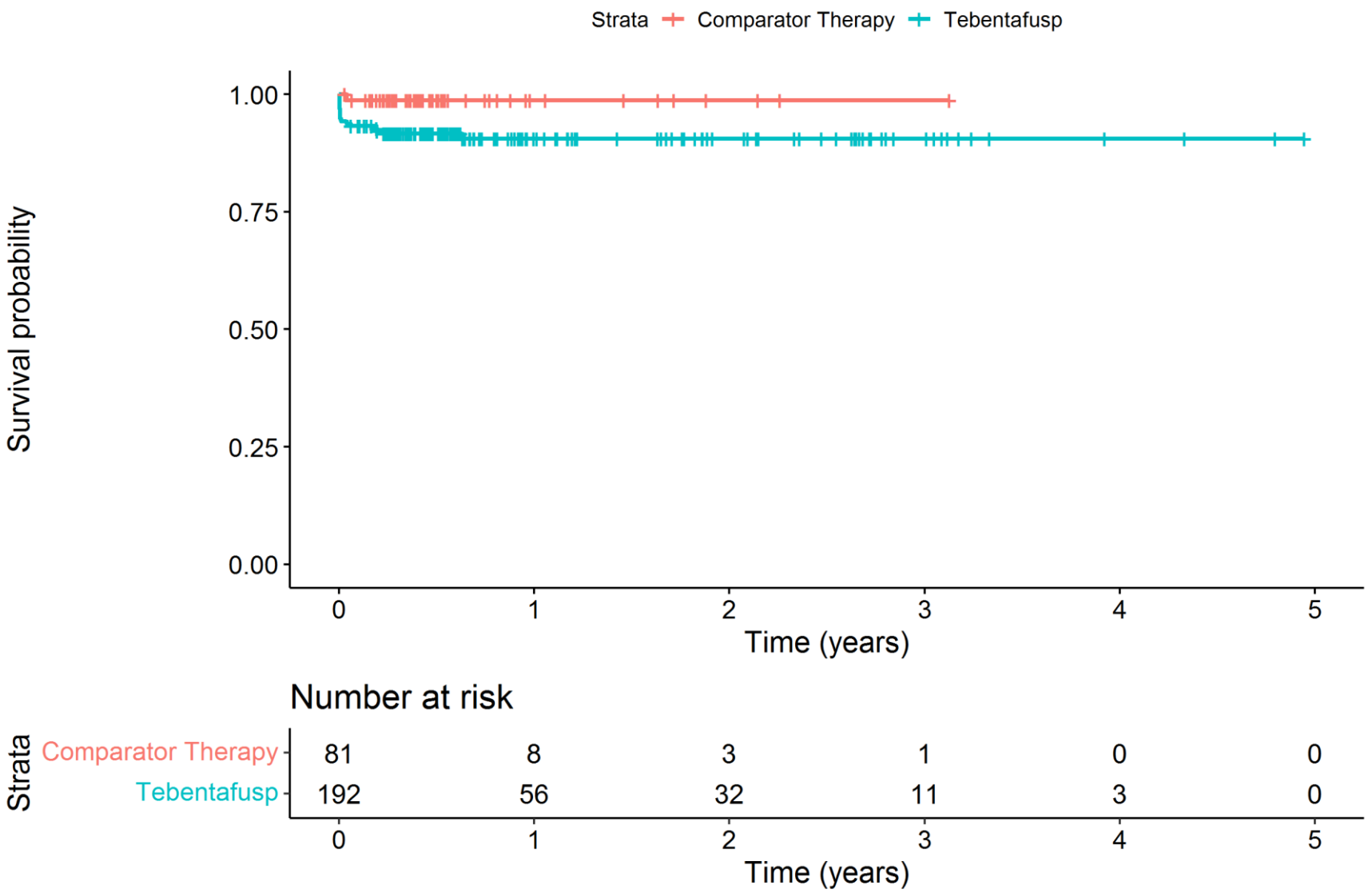
60.181 Hautrötung - <65



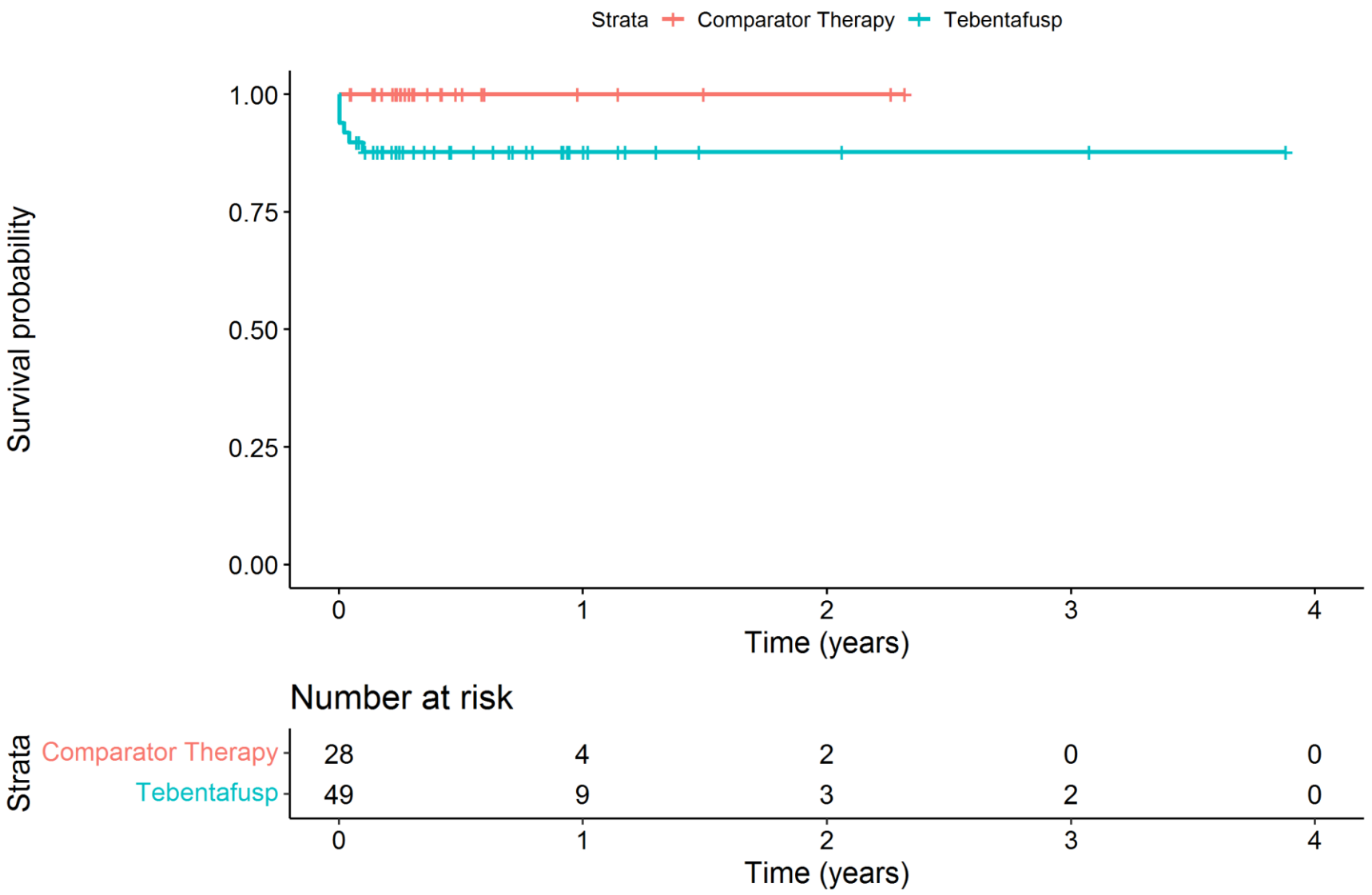
60.182 Hautrötung - ≥65



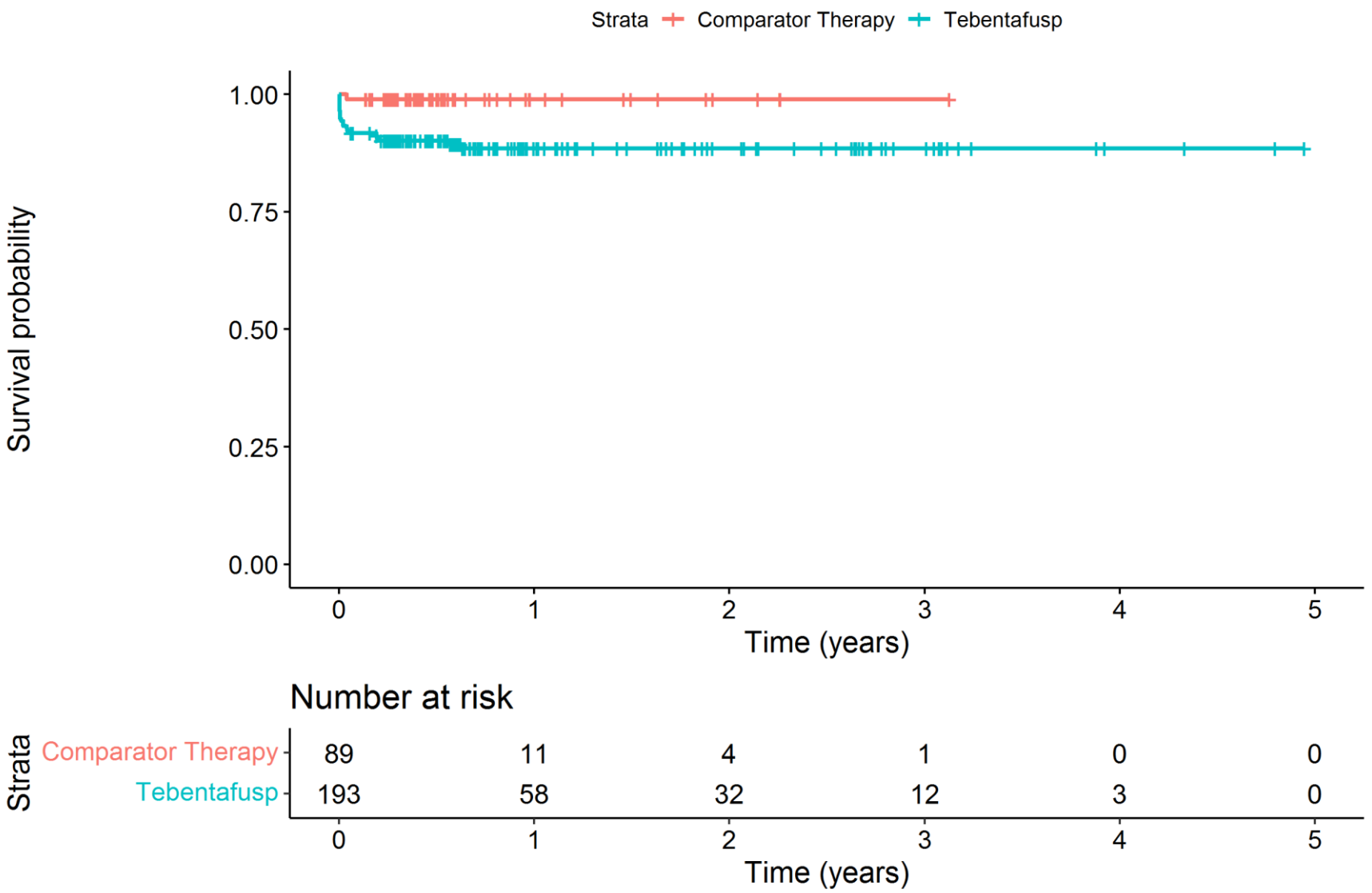
60.183 Hautrötung - ECOG 0



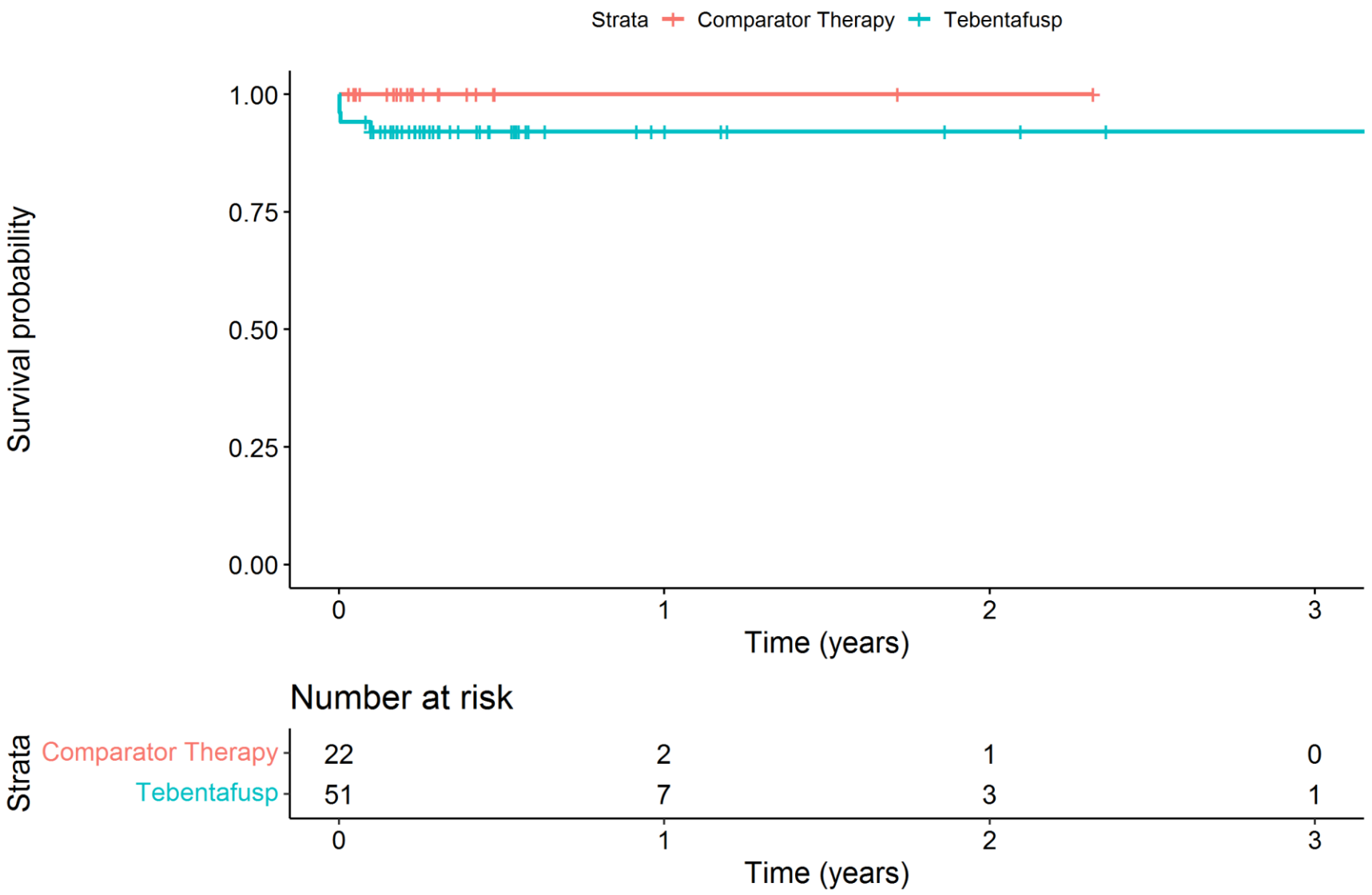
60.184 Hautrötung - ECOG 1



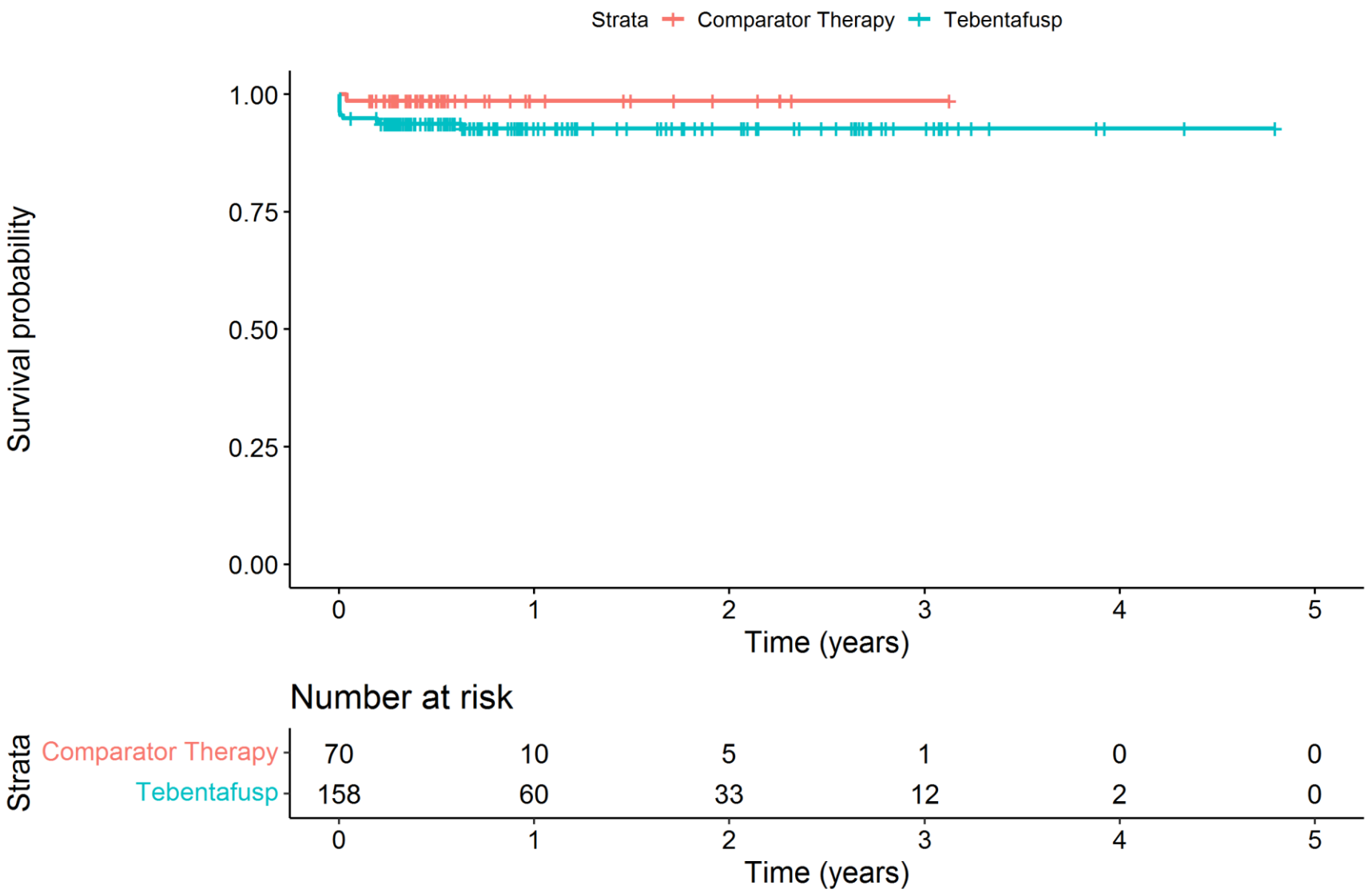
60.185 Hautrötung - ALP ≤ ULN



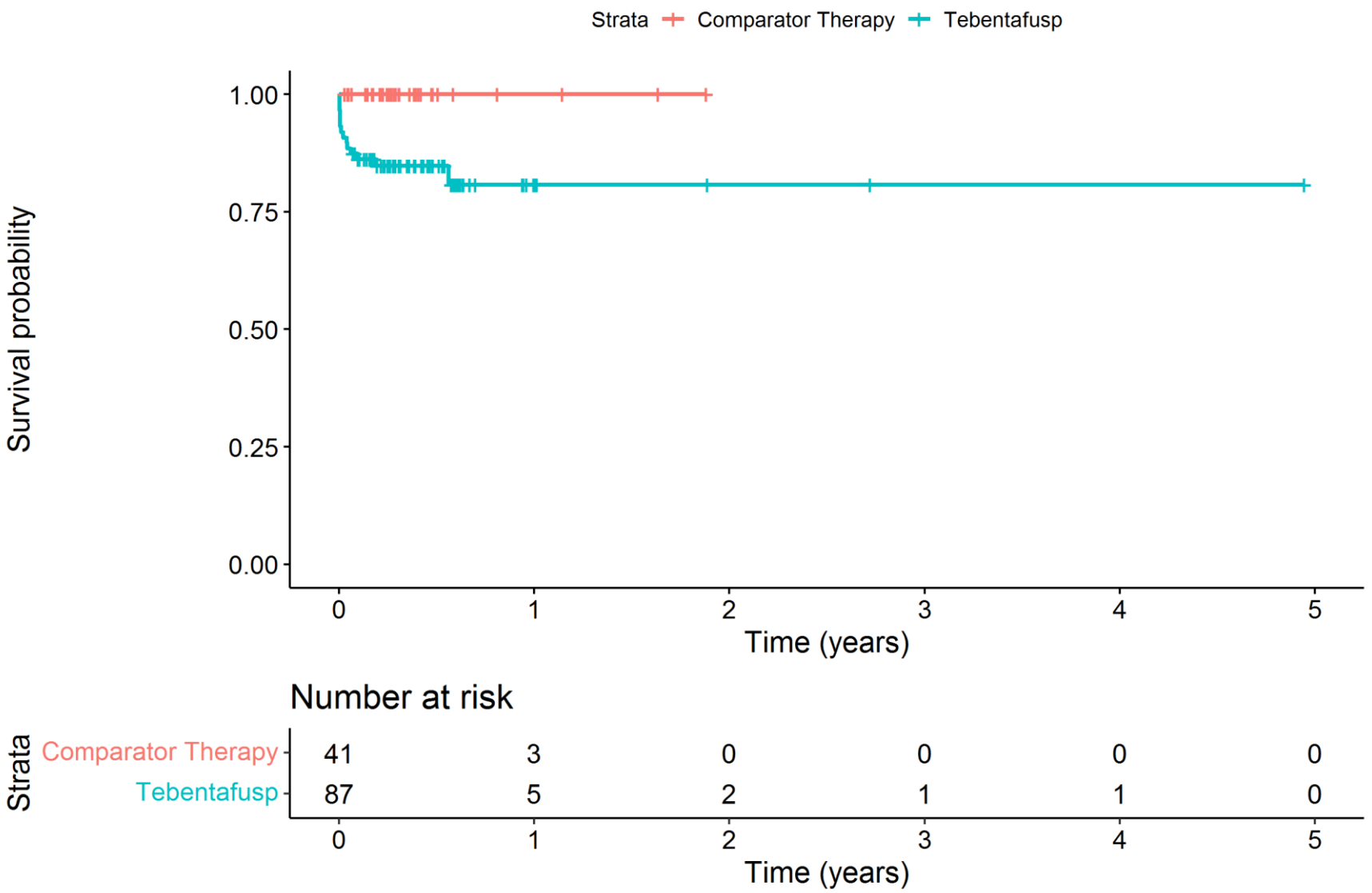
60.186 Hautrötung - ALP > ULN



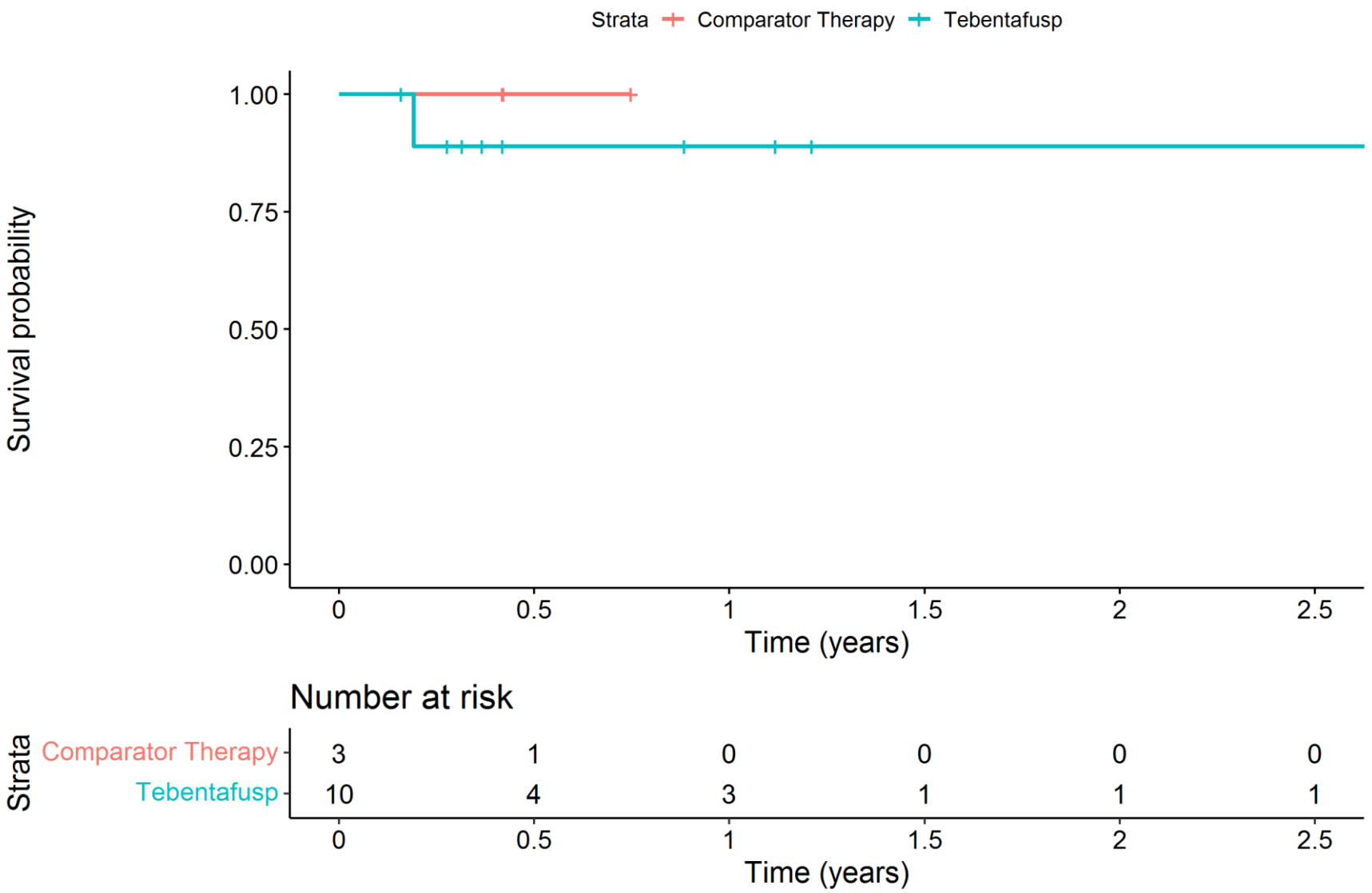
60.187 Hautrötung - LDH =< ULN



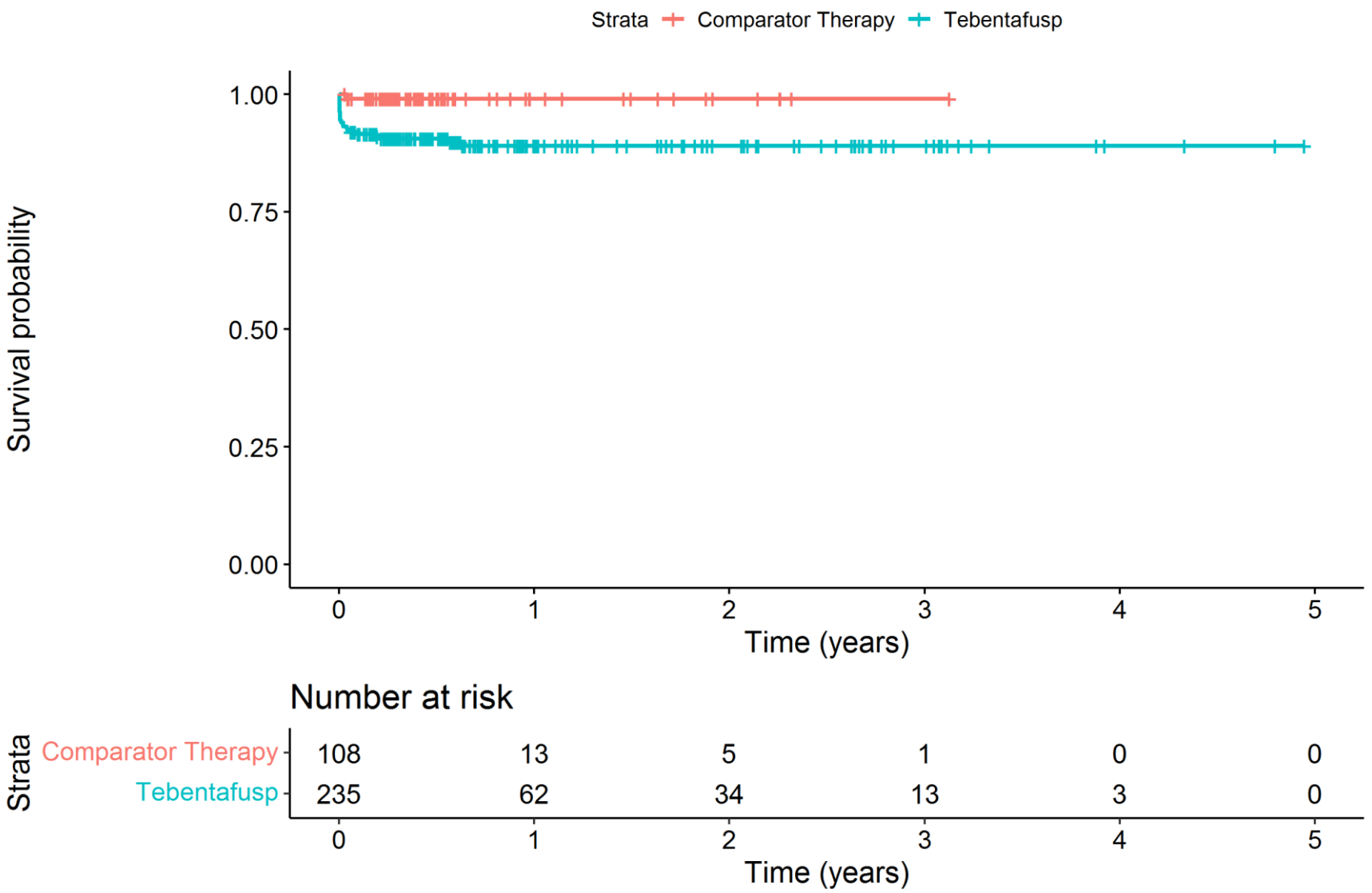
60.188 Hautrötung - LDH > ULN



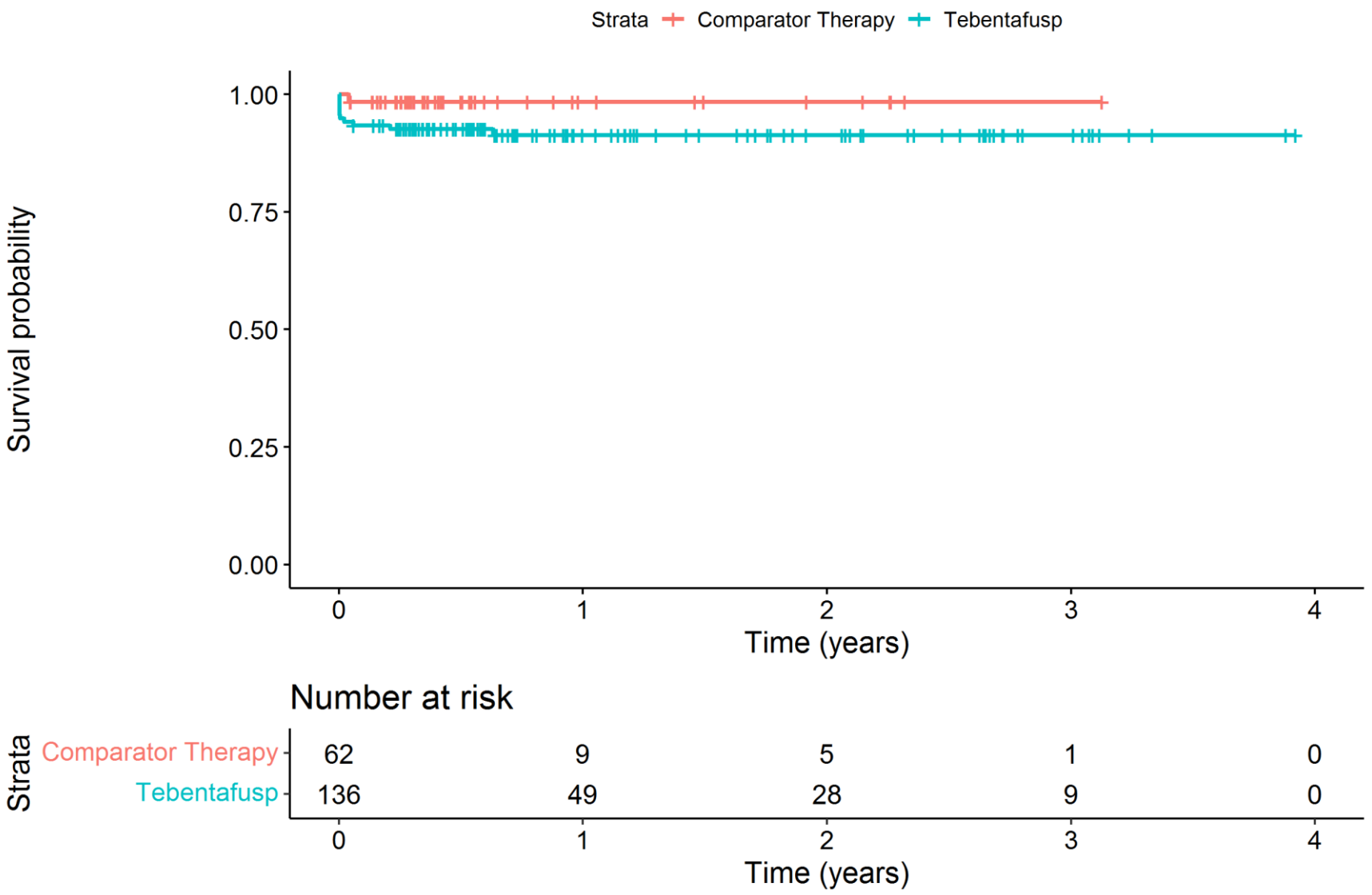
60.189 Hautrötung - Vorherige Therapie adjuvant/neoadjuvant



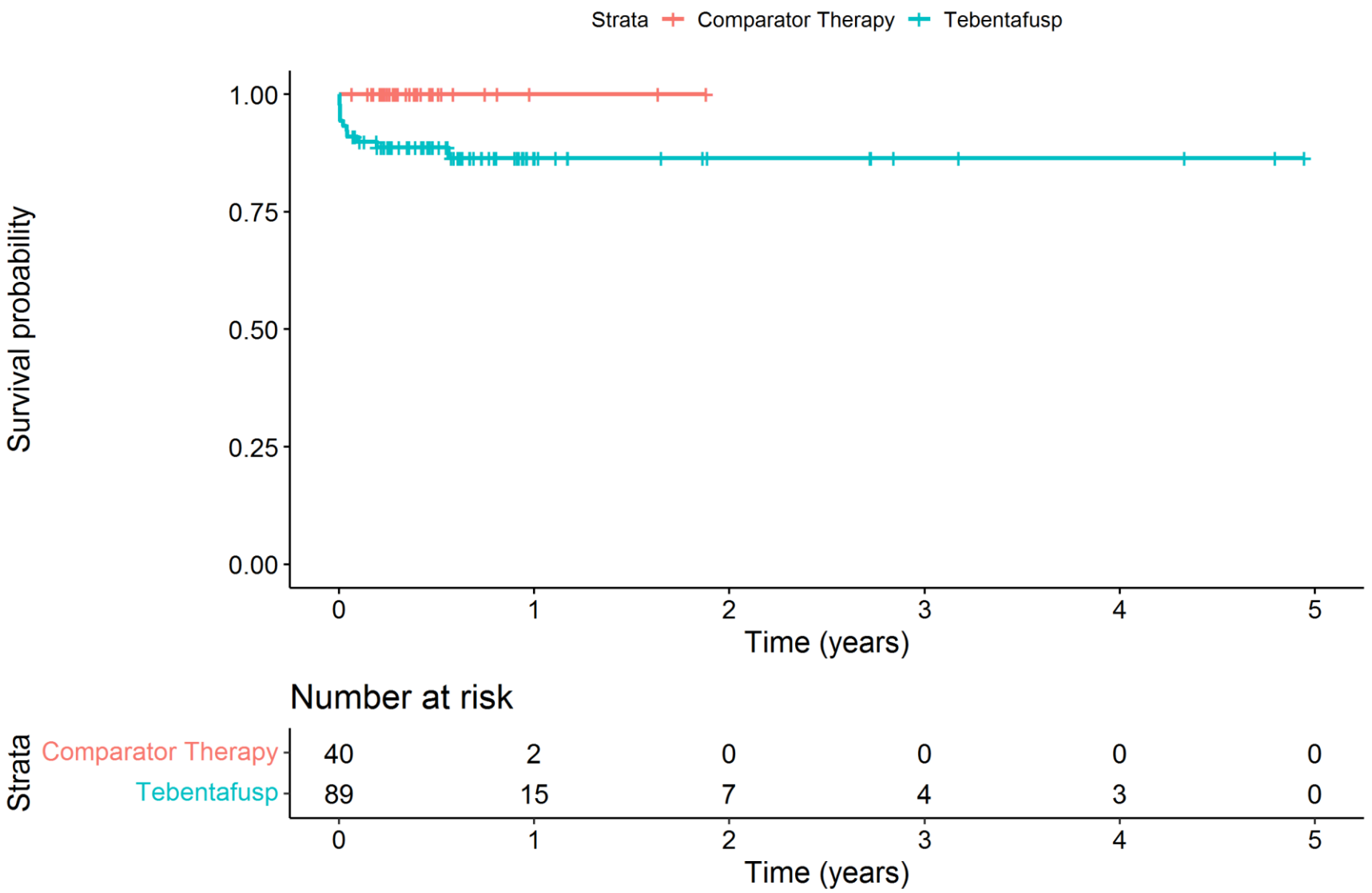
60.190 Hautrötung - Keine Vorherige Therapie adjuvant/neoadjuvant



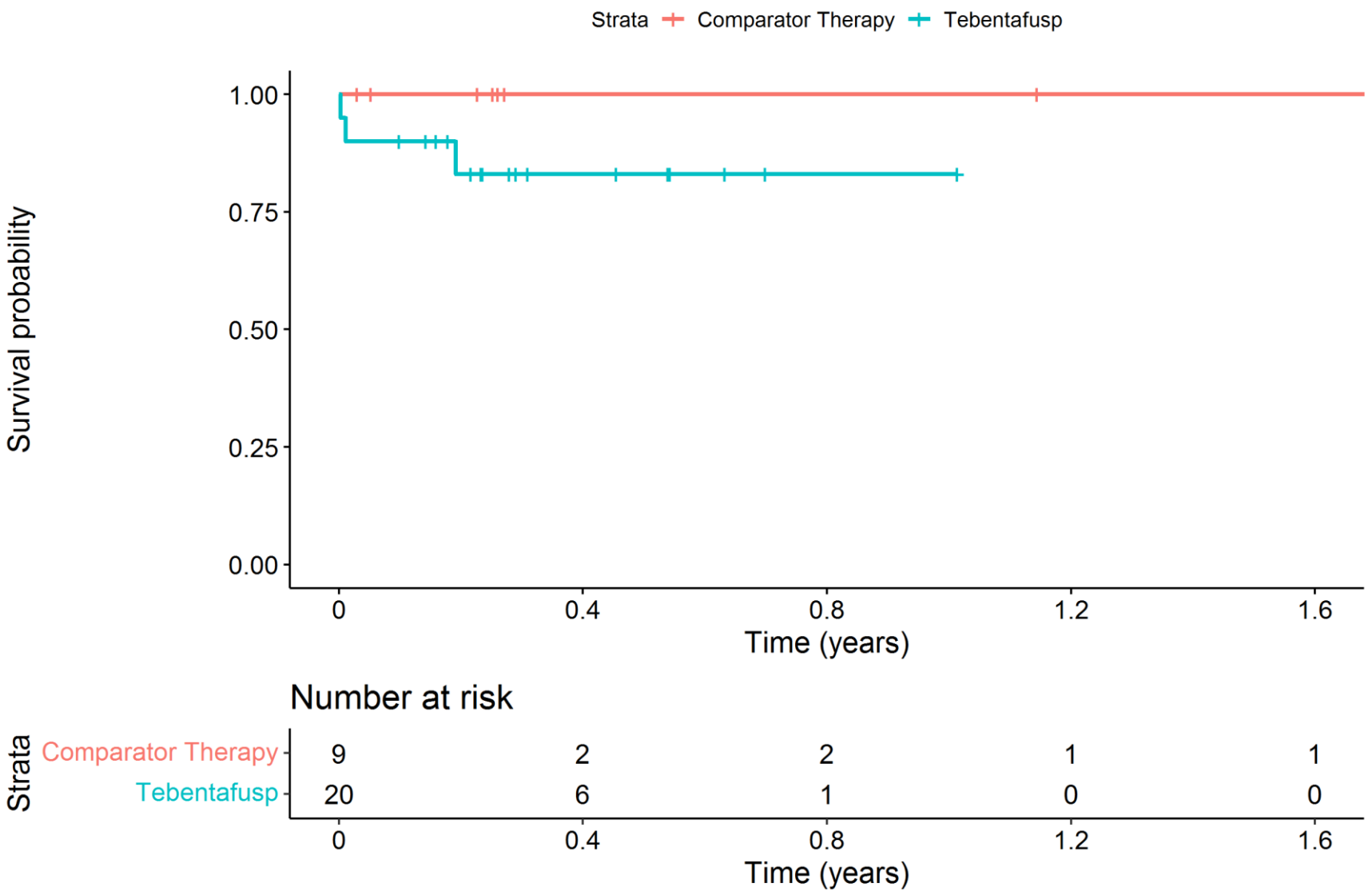
60.191 Hautrötung - Läsion ≤ 3cm



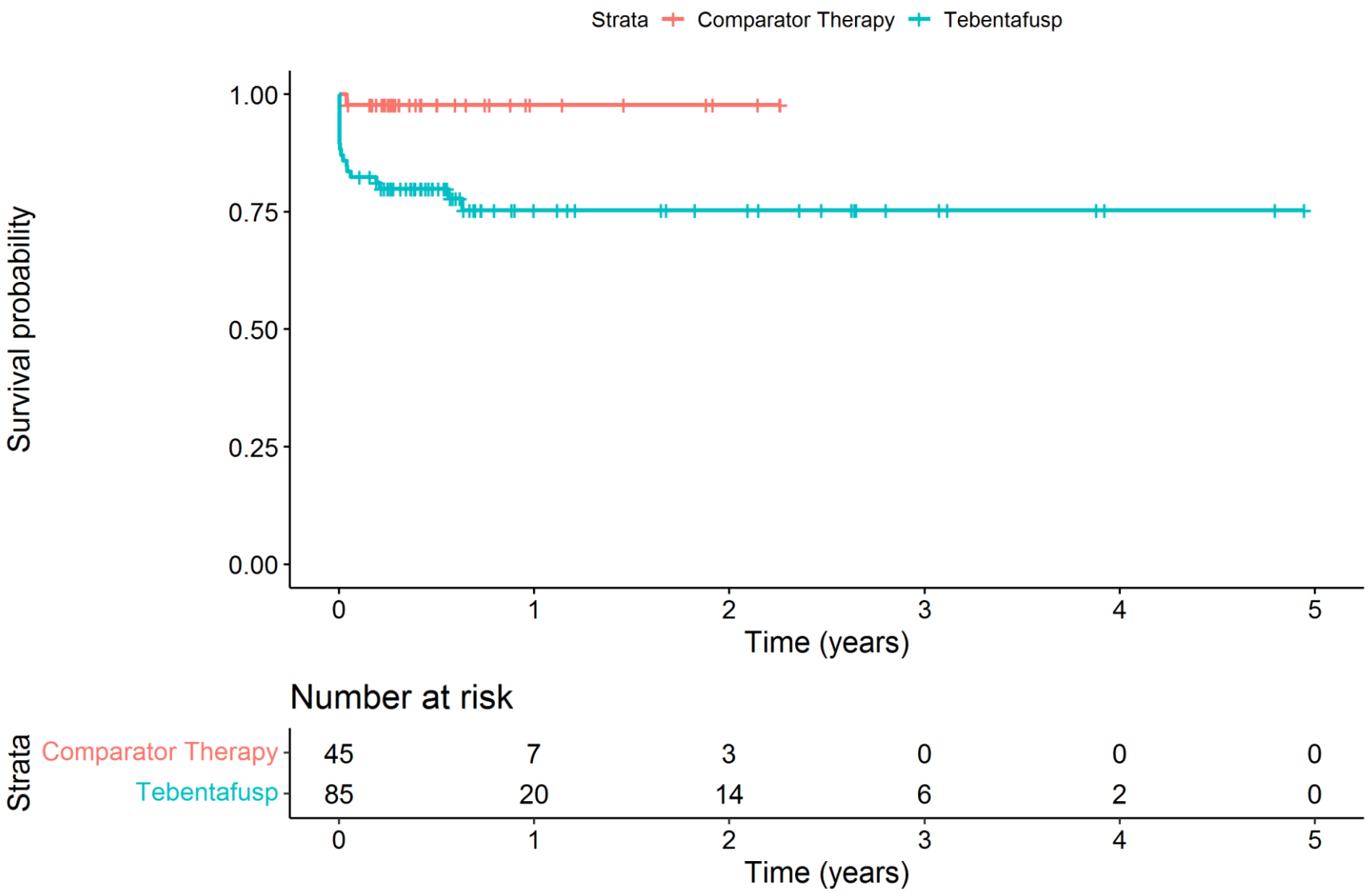
60.192 Hautrötung - Läsion 3,1-8,0 cm



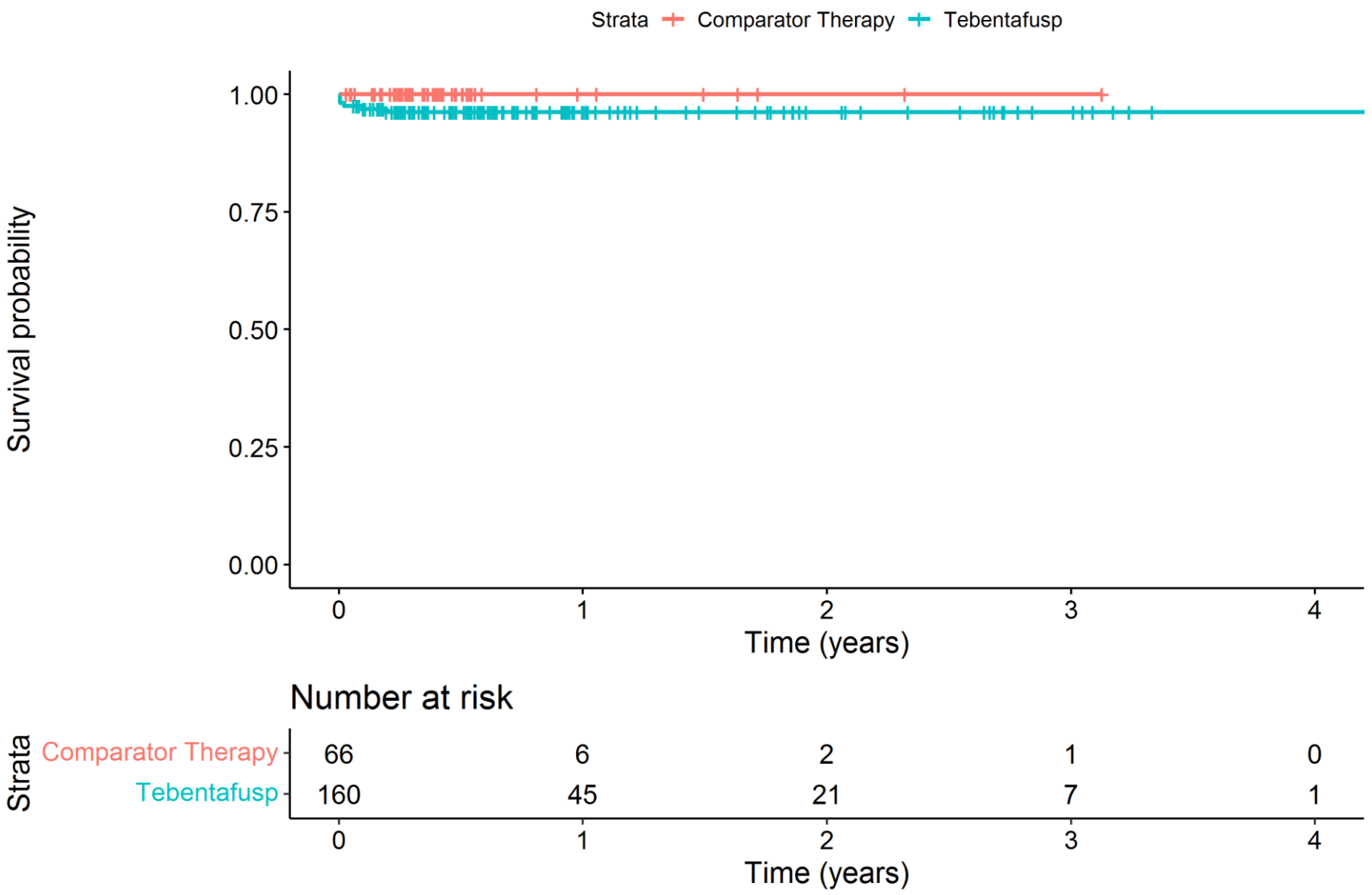
60.193 Hautrötung - Läsion ≥8,1 cm



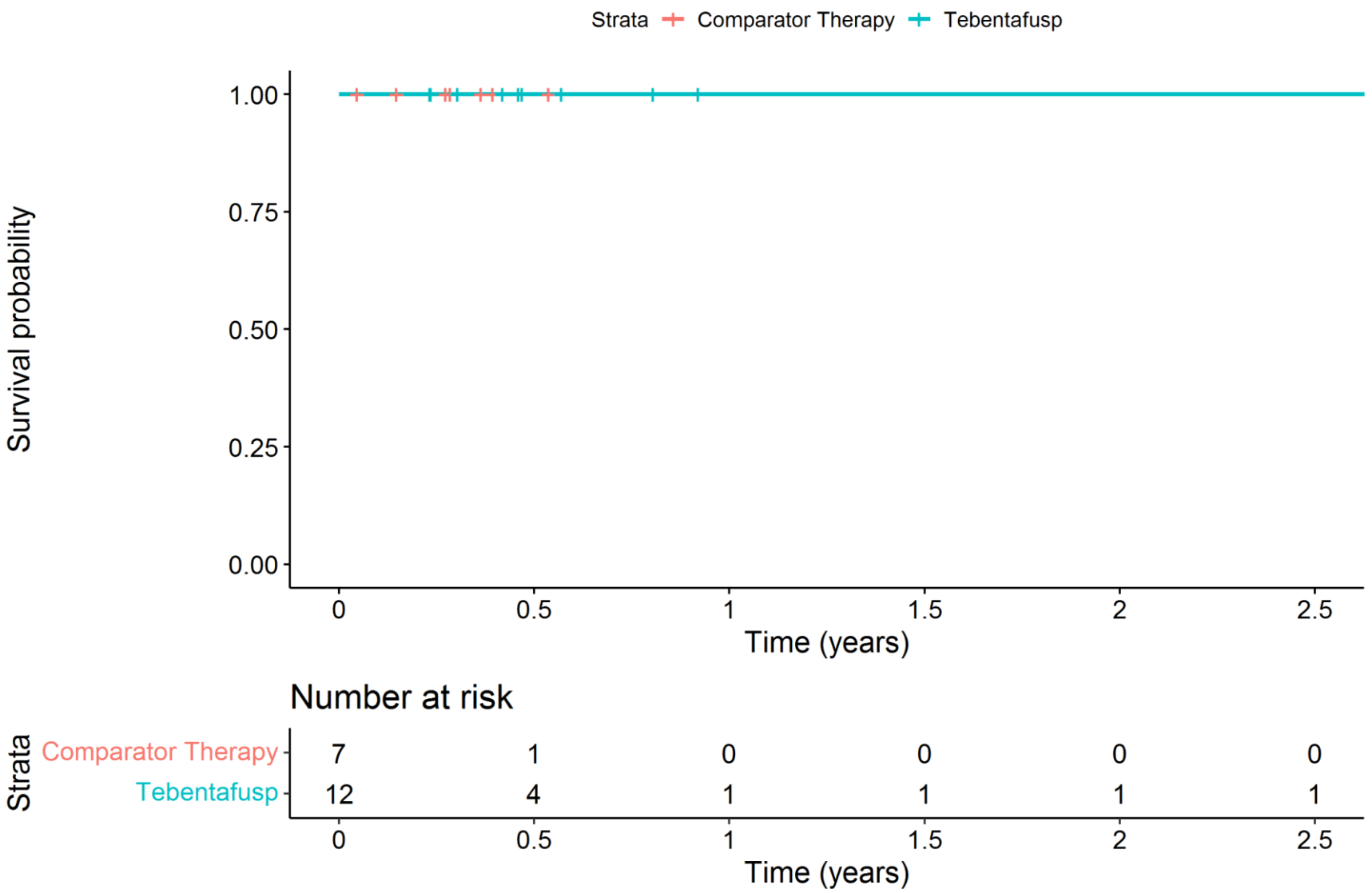
60.194 Hautrötung - Nordamerika



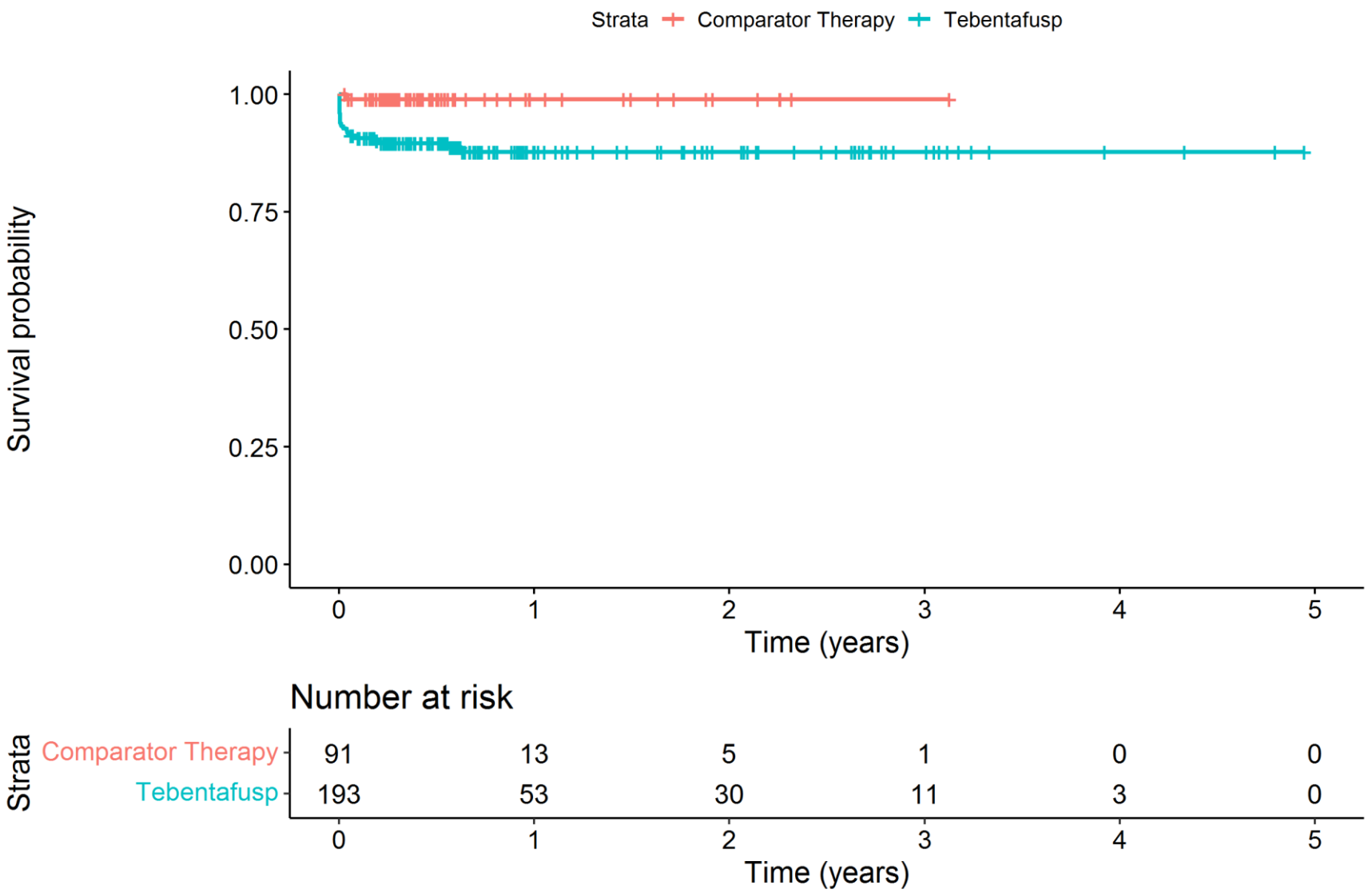
60.195 Hautrötung - Nicht-Nordamerika



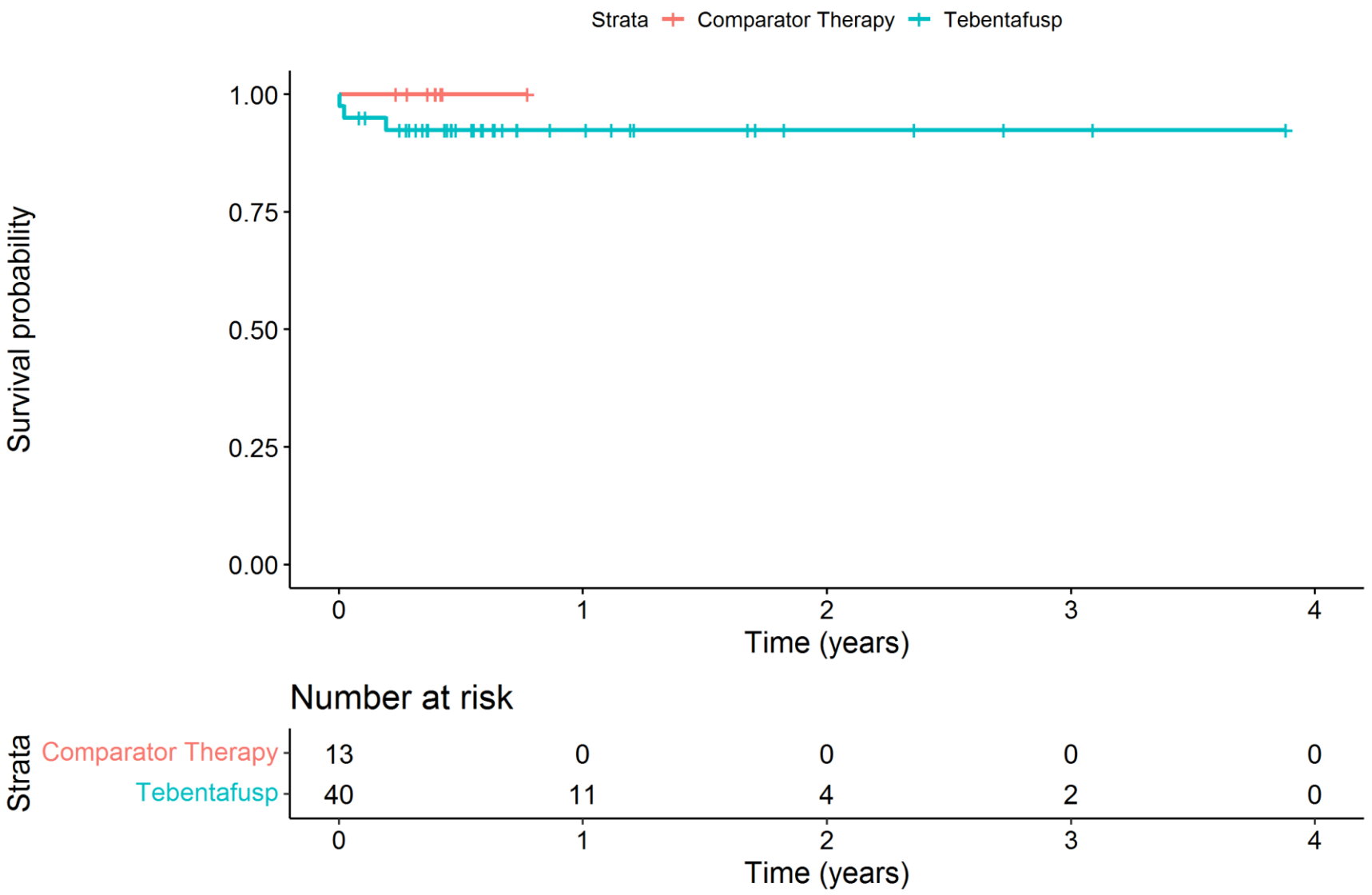
60.196 Hautrötung - Dacarbazin



60.197 Hautrötung - Pembrolizumab

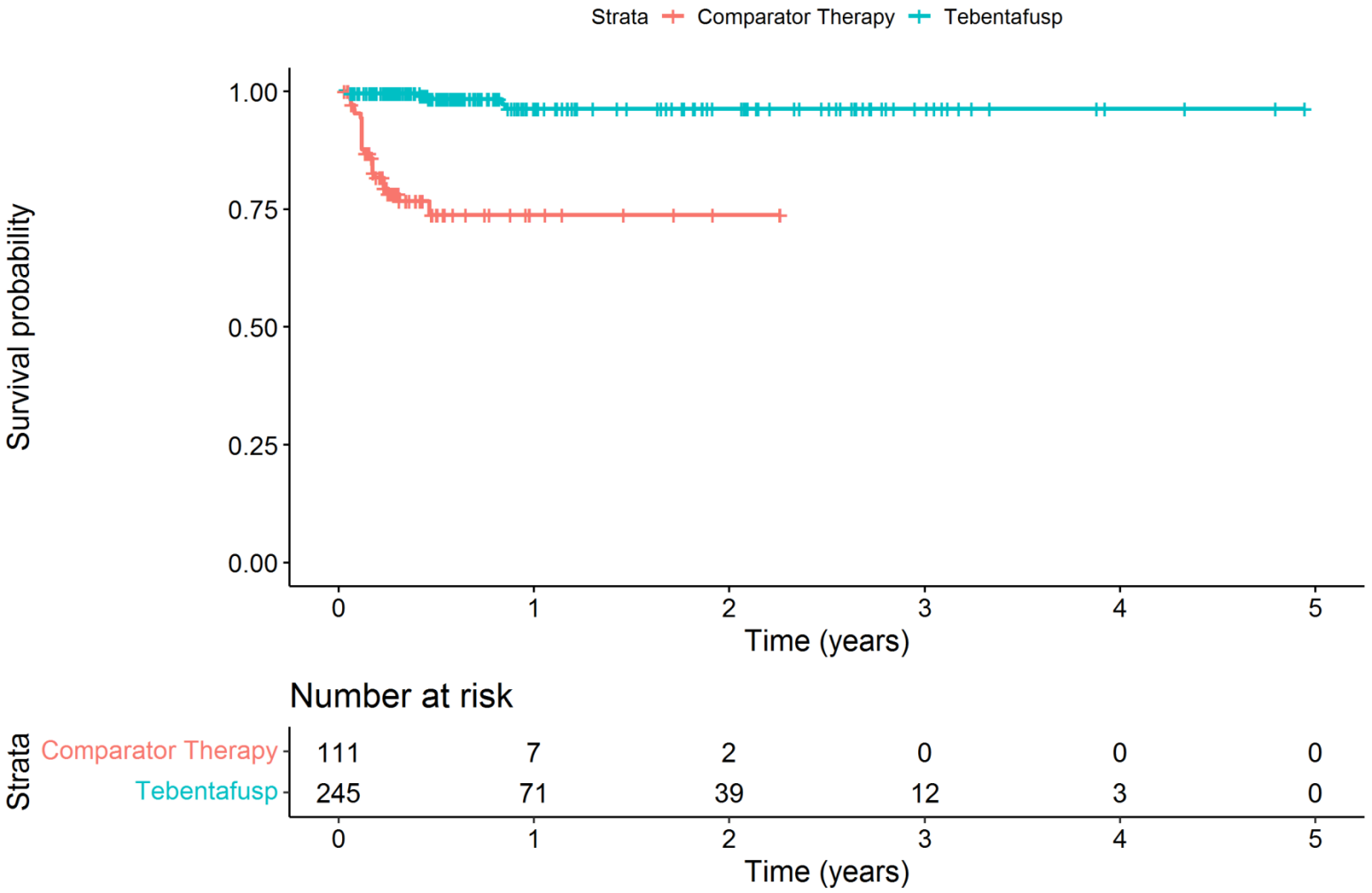


60.198 Hautrötung - Ipilimumab

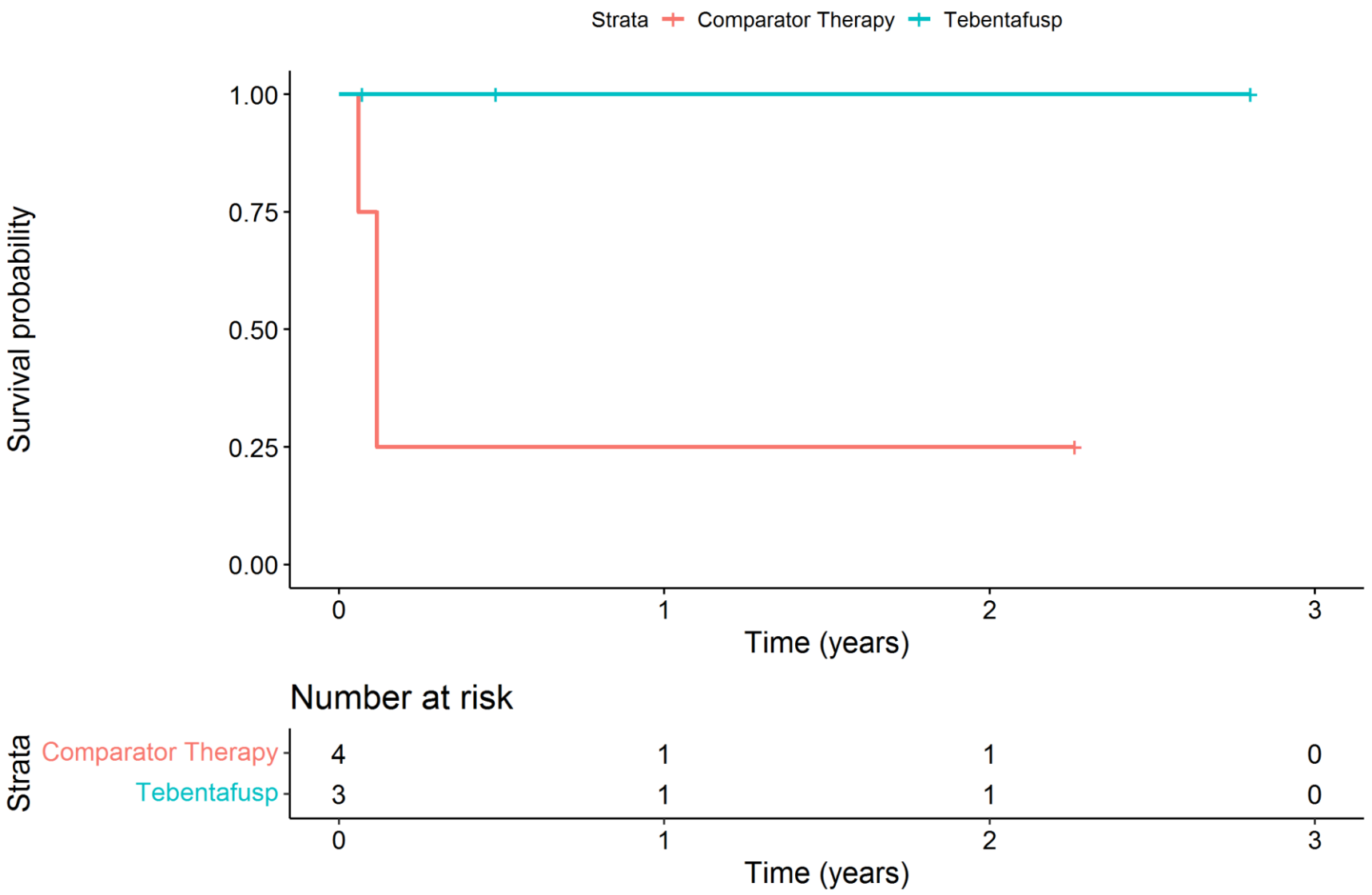


61 UEs (SOC), die bei ≥ 10 % der Patienten in einem Behandlungsarm auftraten(ab Tabelle 4-245)

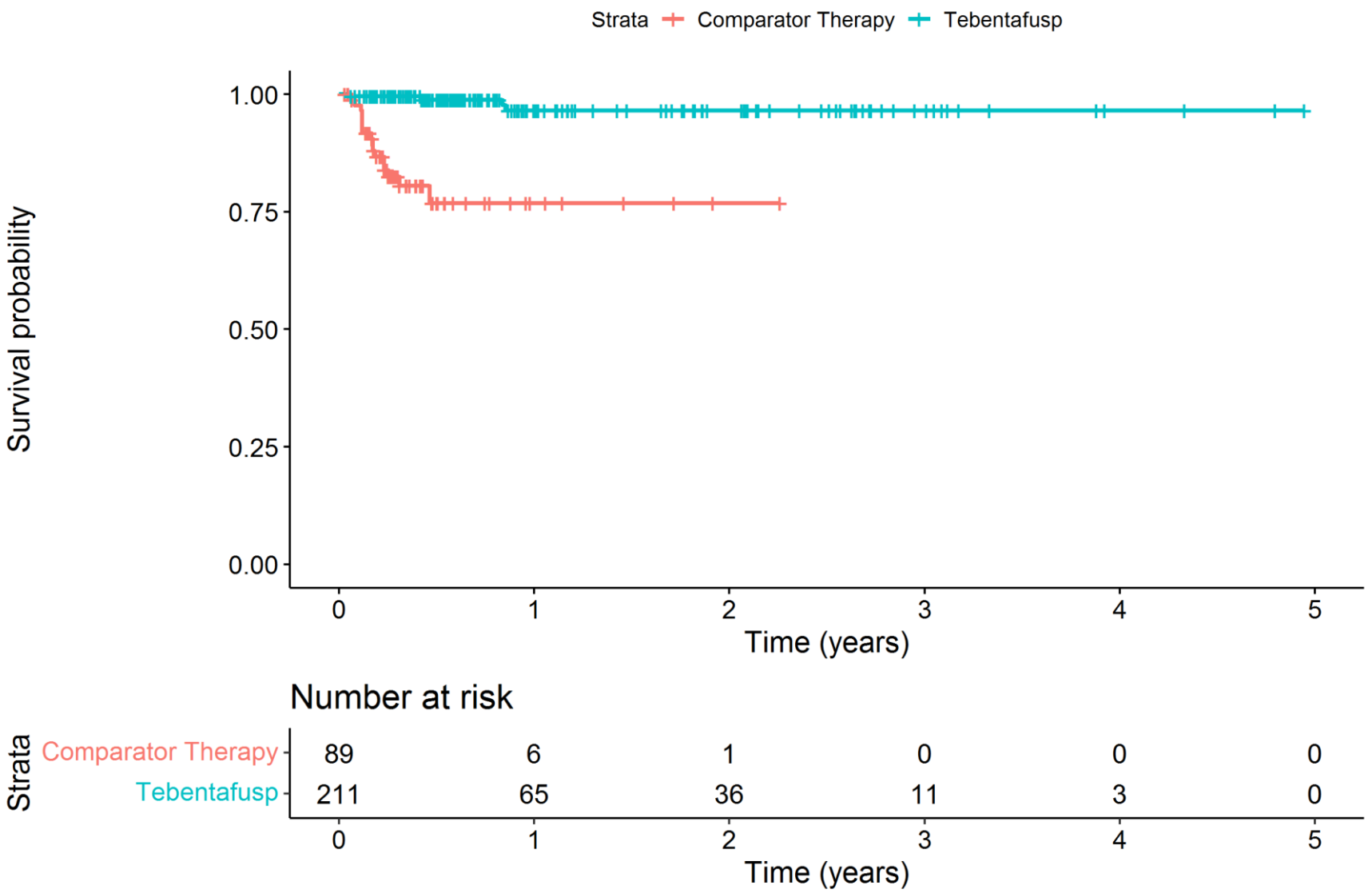
61.1 Endokrine Erkrankungen- Gesamt



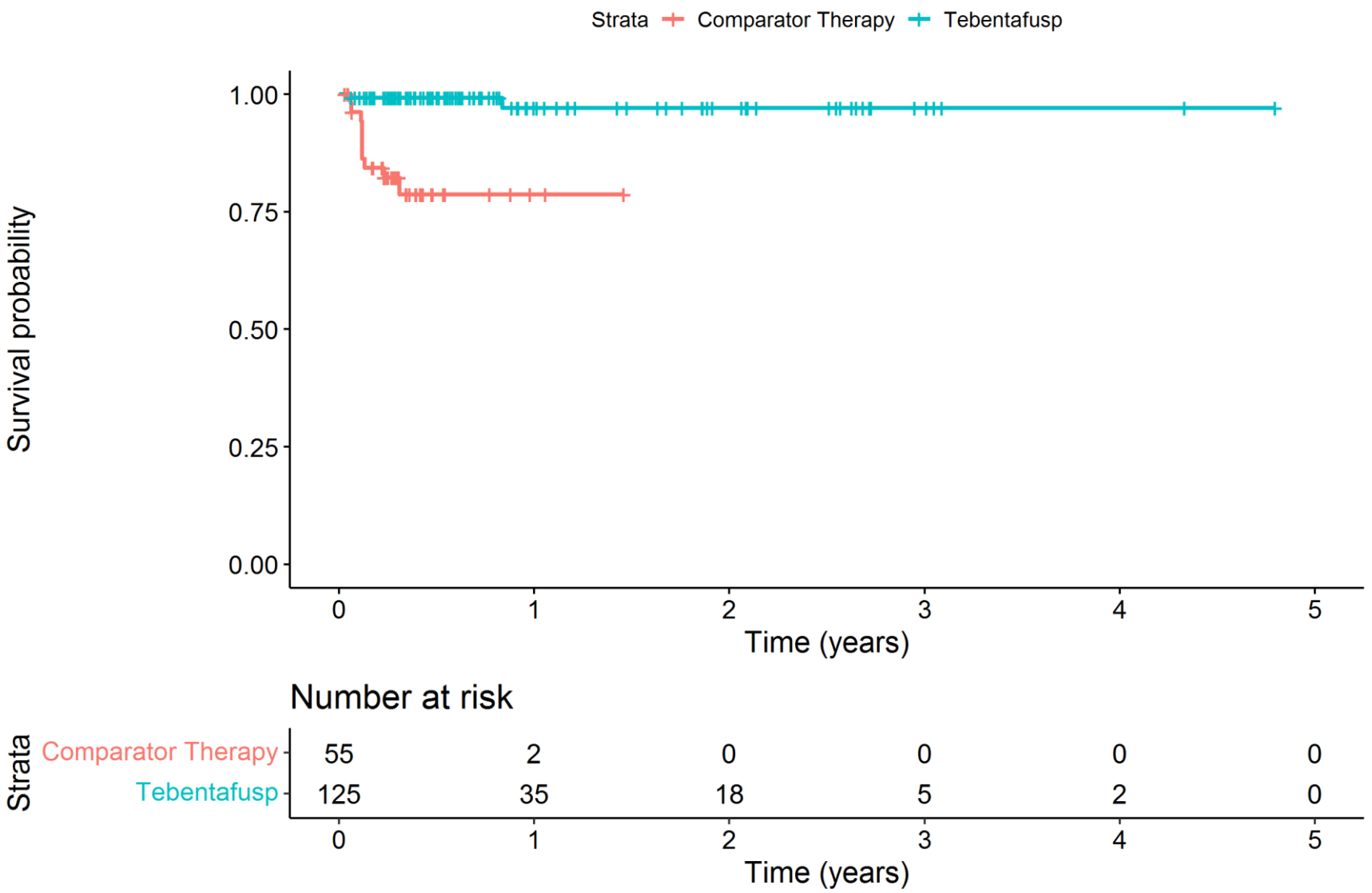
61.2 Endokrine Erkrankungen- Hispanisch



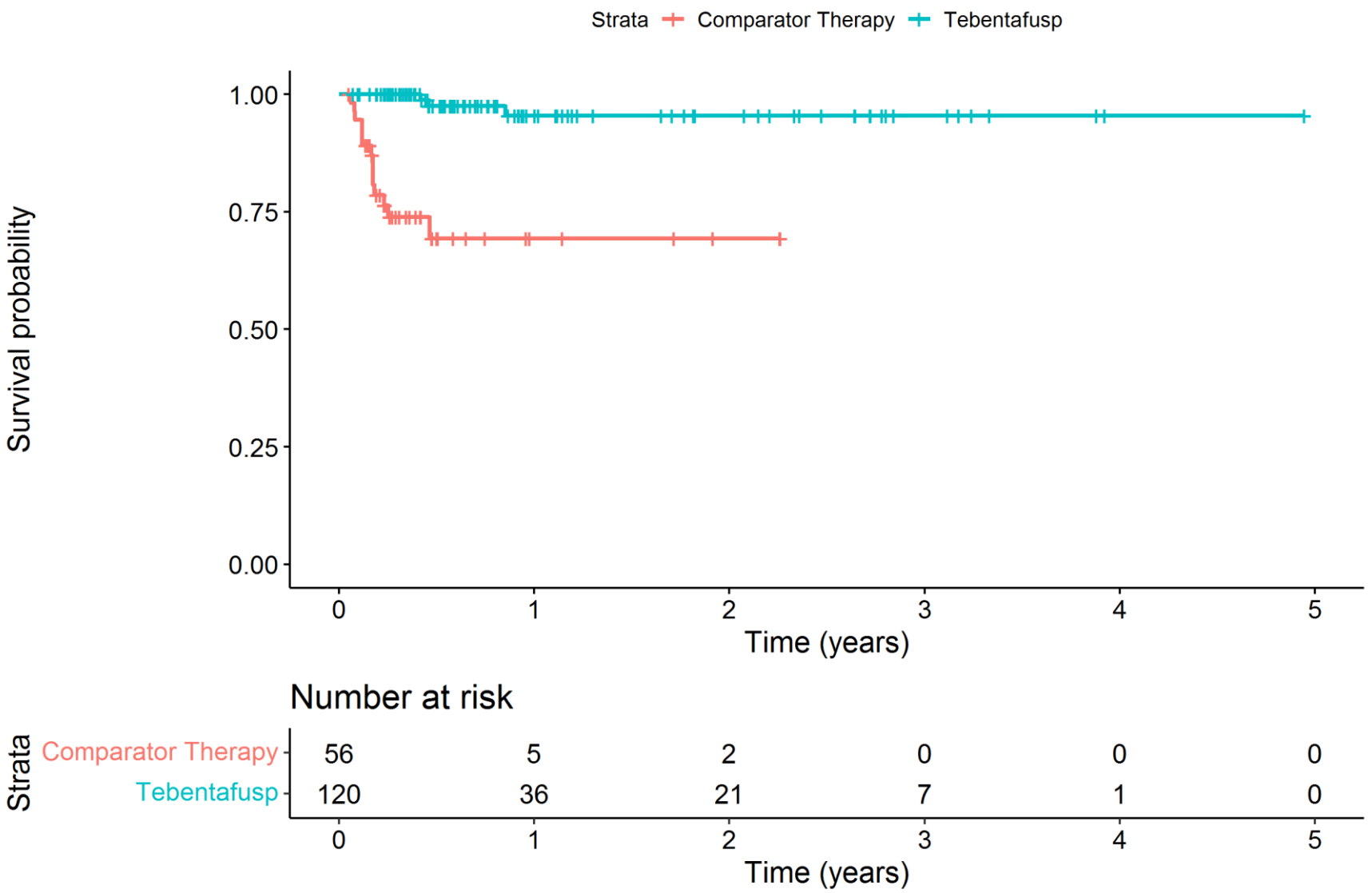
61.3 Endokrine Erkrankungen- Nicht-hispanisch



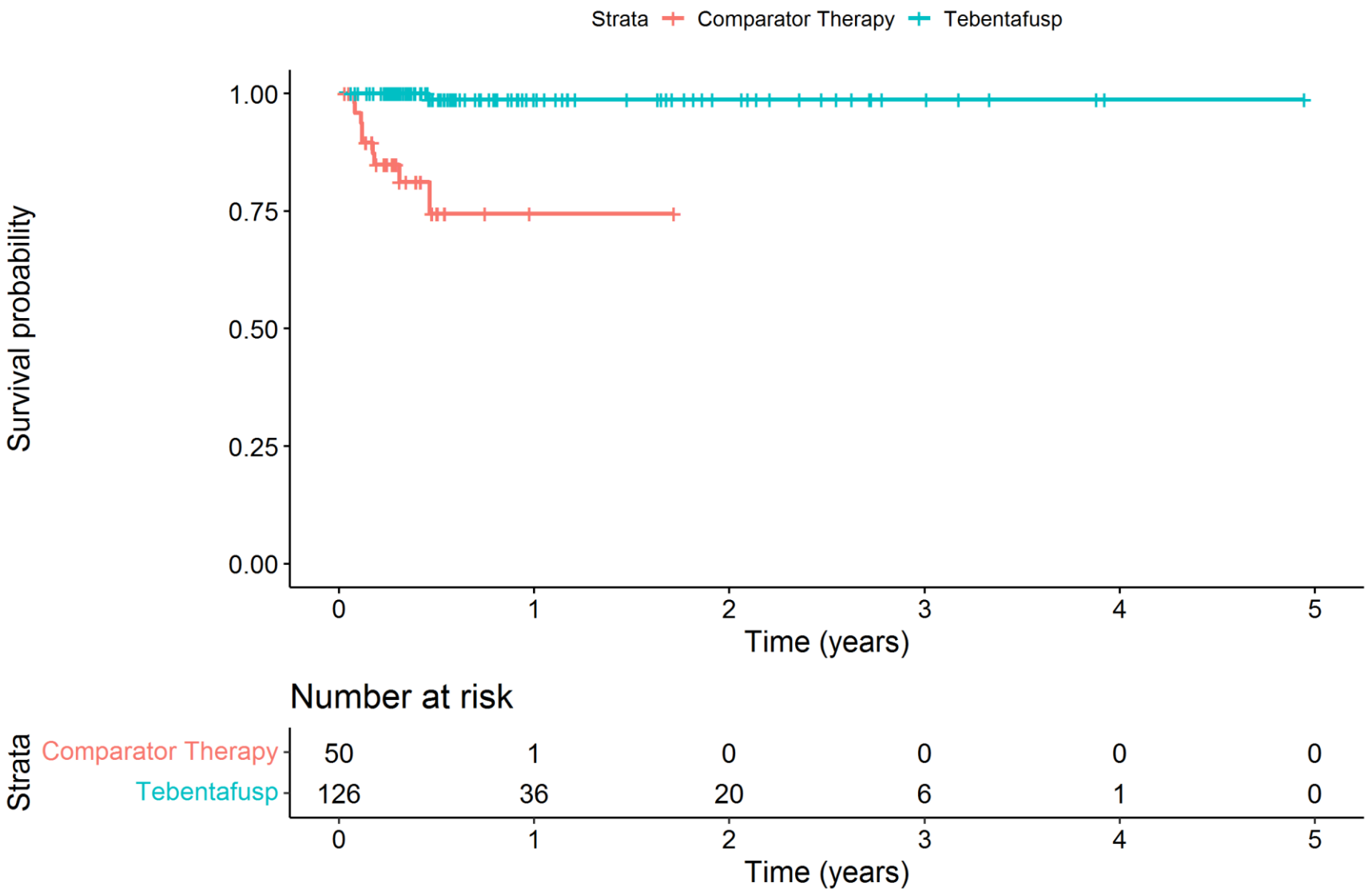
61.4 Endokrine Erkrankungen- Männlich



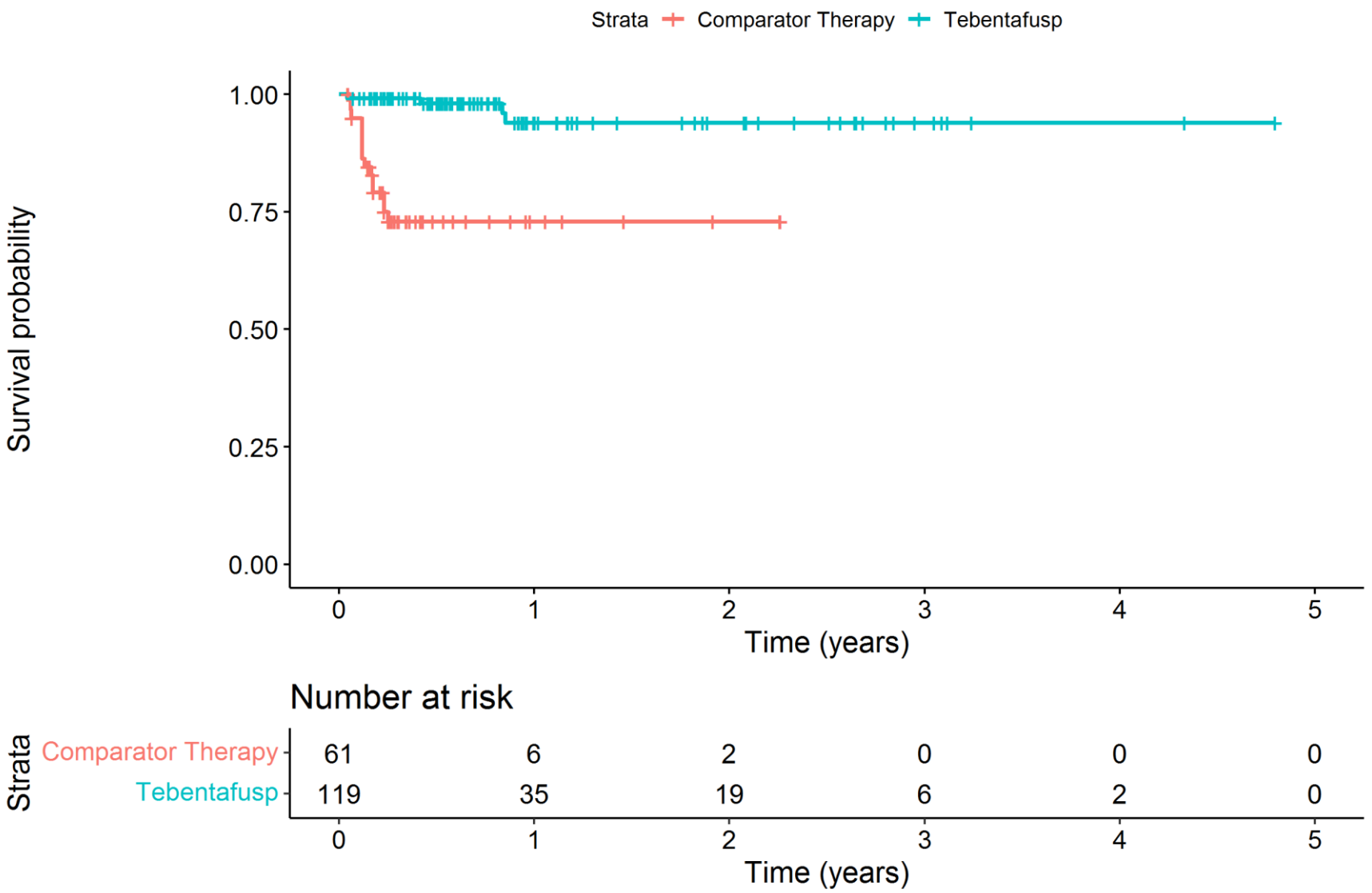
61.5 Endokrine Erkrankungen- Weiblich



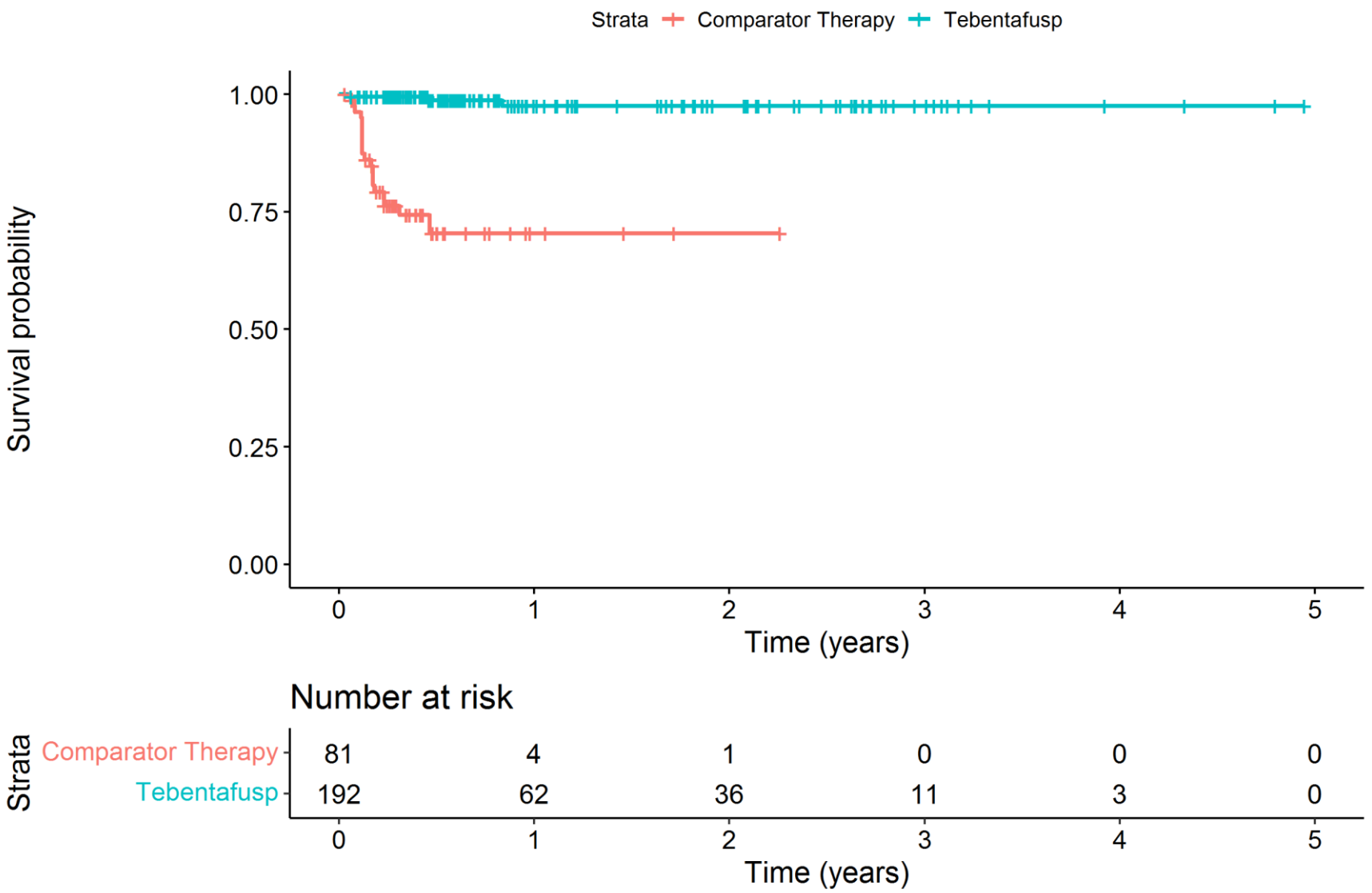
Endokrine Erkrankungen- <65



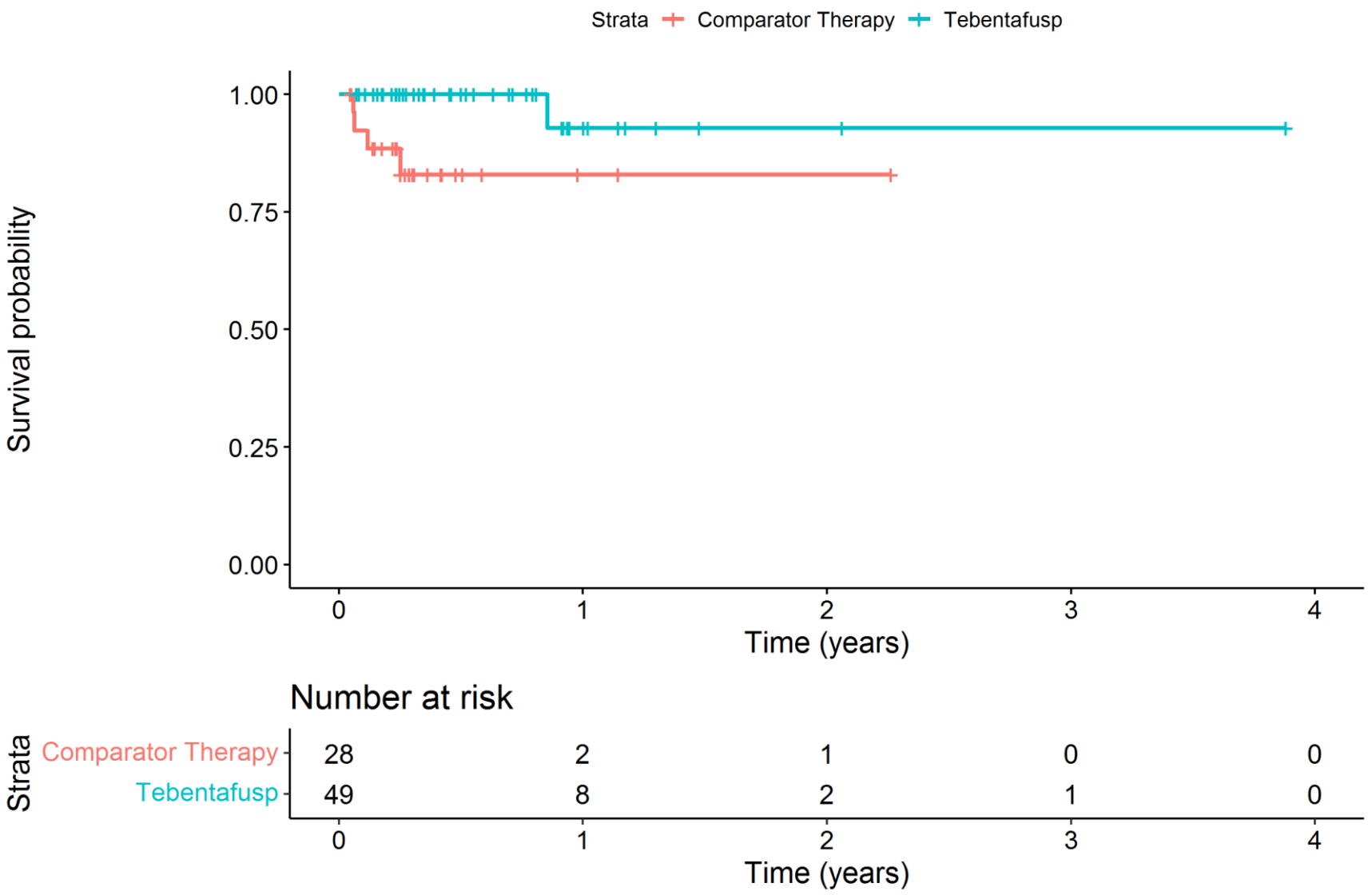
61.6 Endokrine Erkrankungen- ≥65



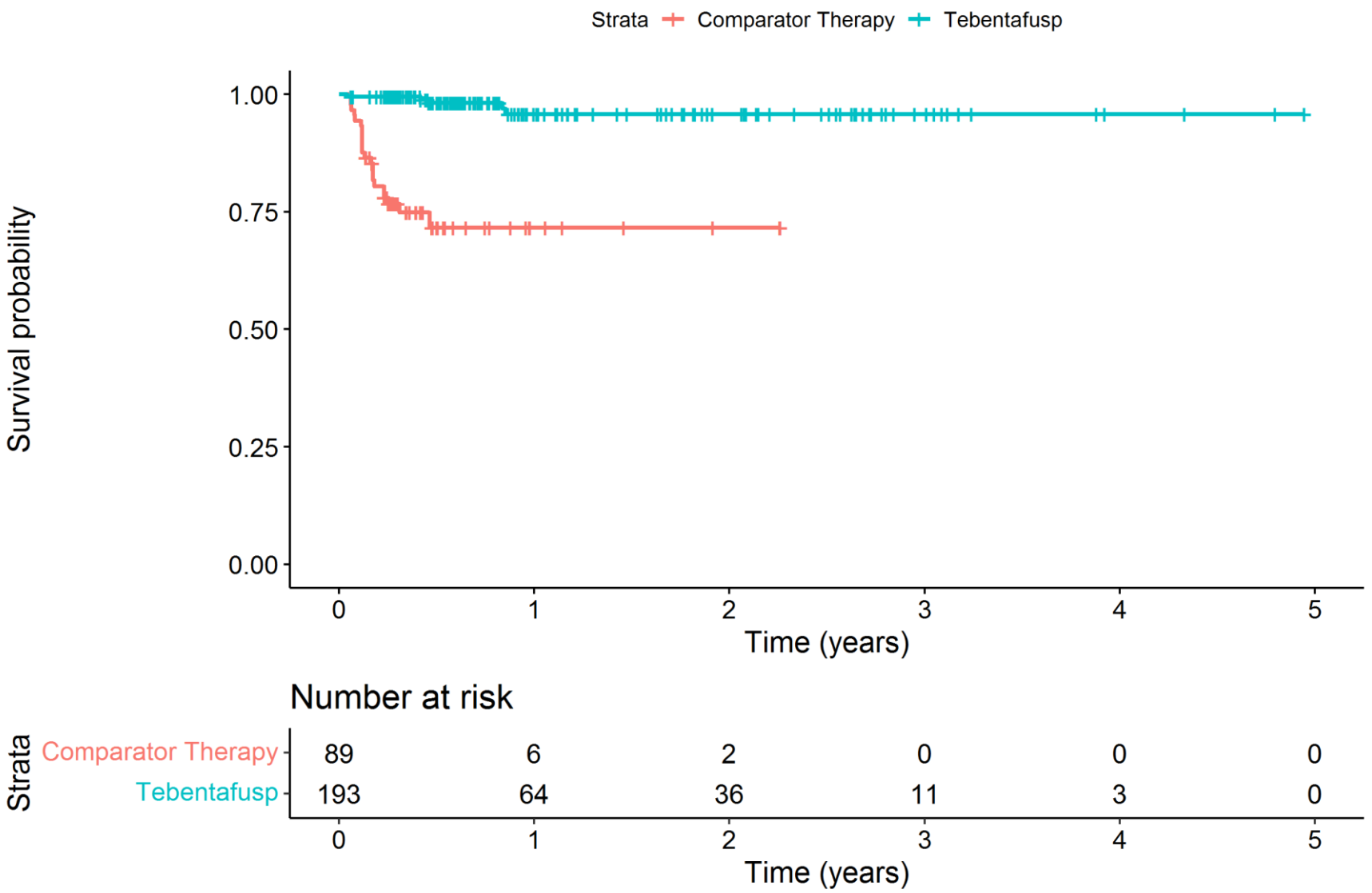
61.7 Endokrine Erkrankungen- ECOG 0



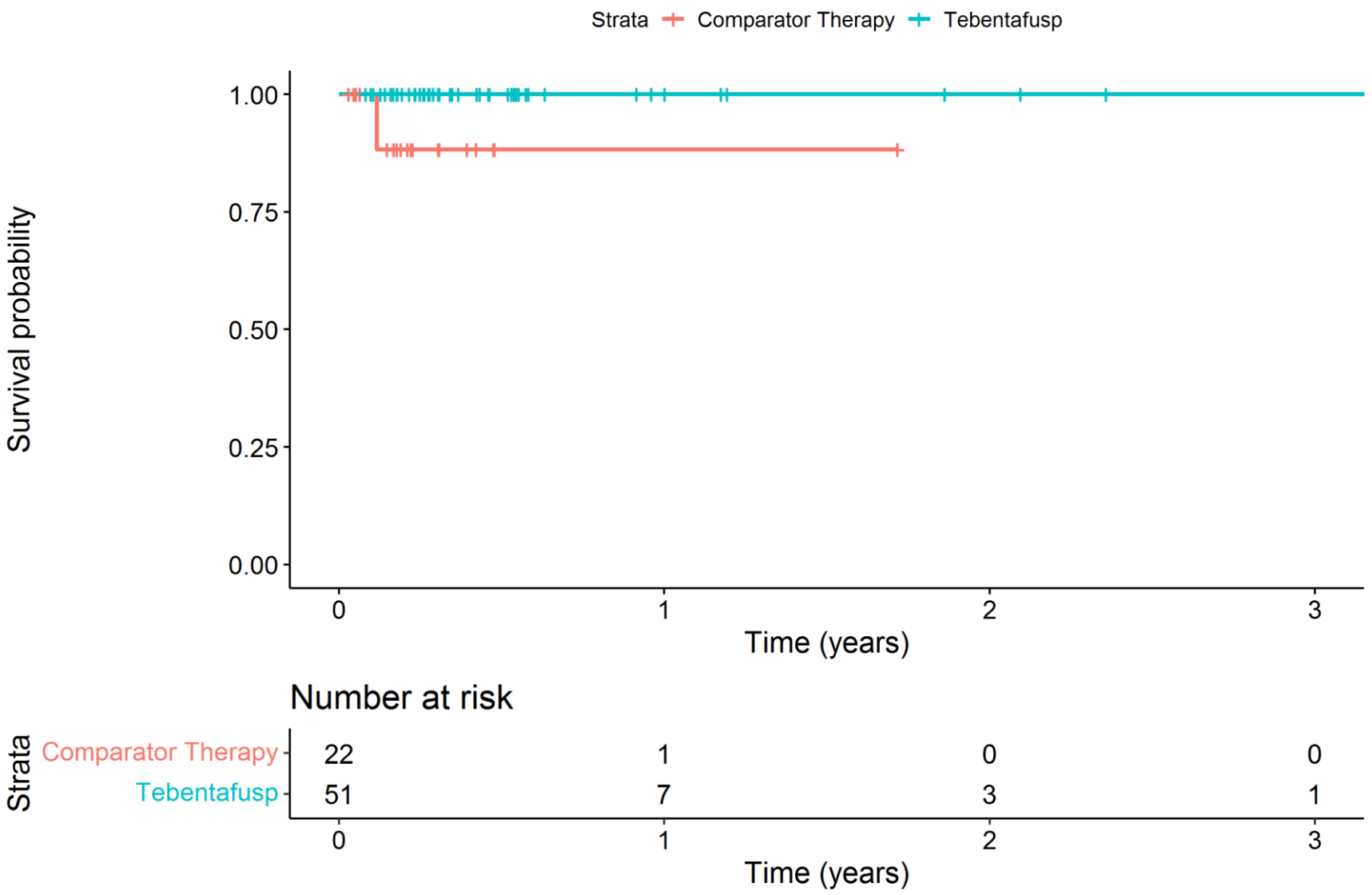
61.8 Endokrine Erkrankungen- ECOG 1



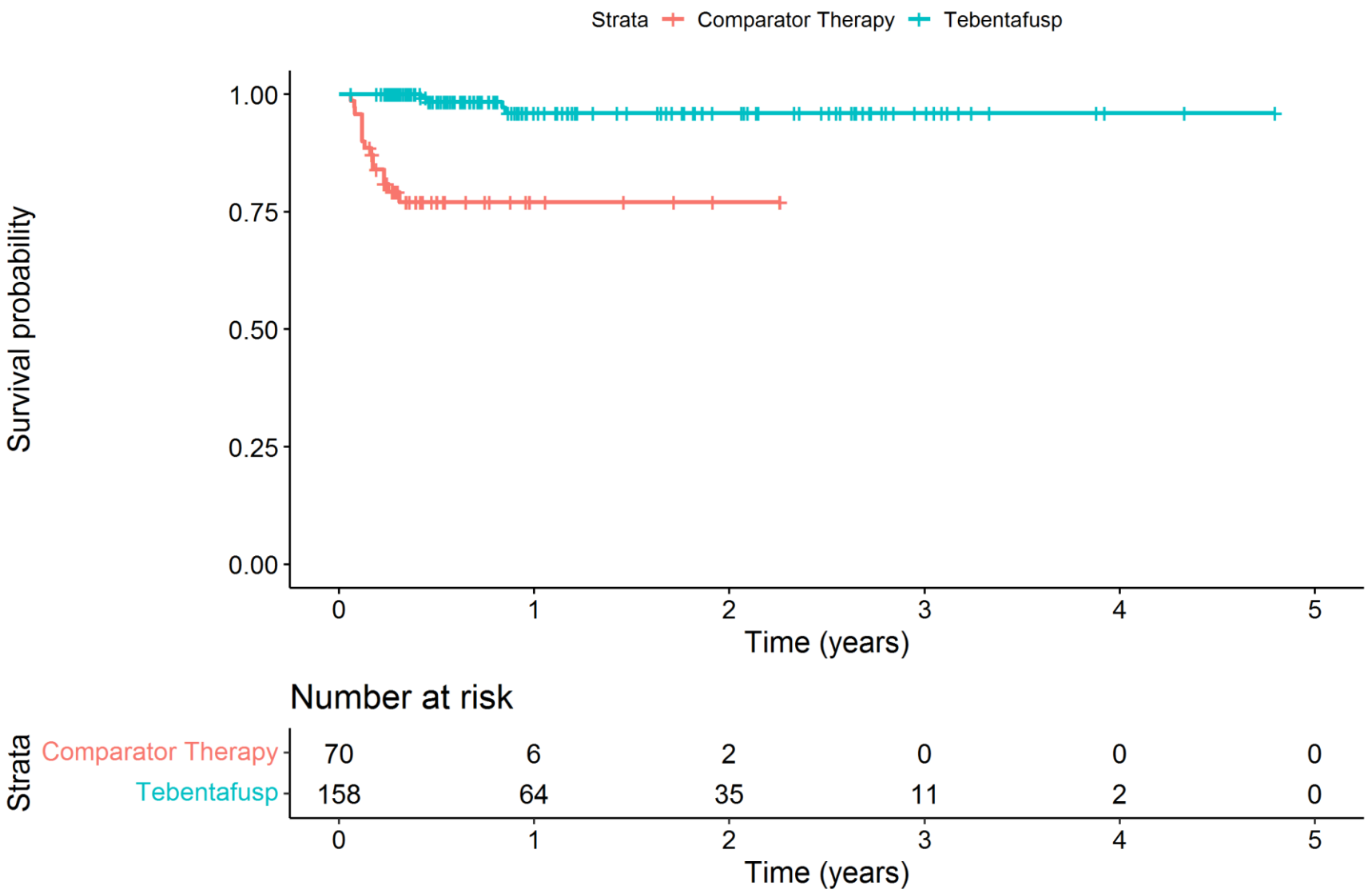
61.9 Endokrine Erkrankungen- ALP ≤ ULN



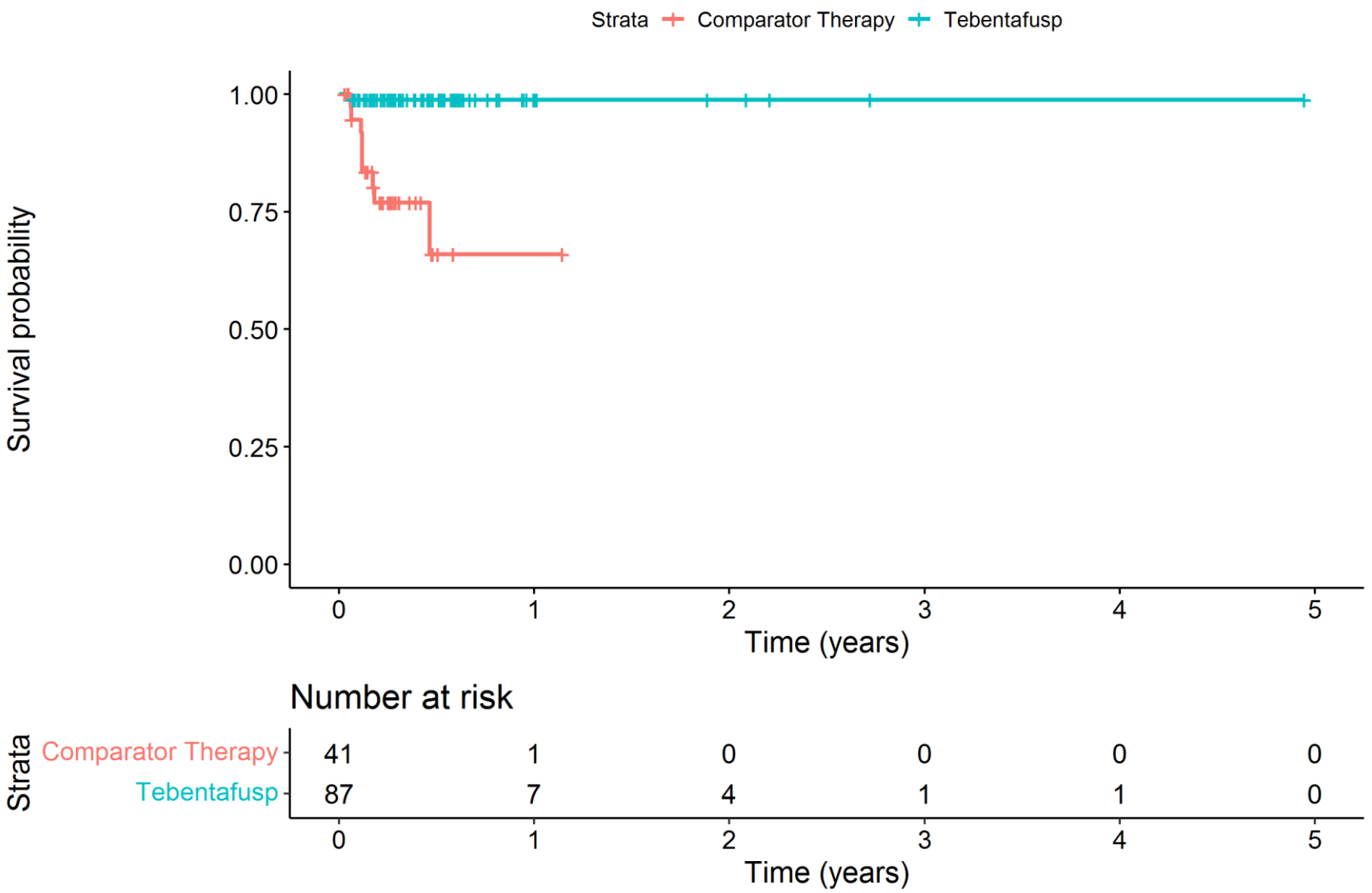
61.10 Endokrine Erkrankungen- ALP > ULN



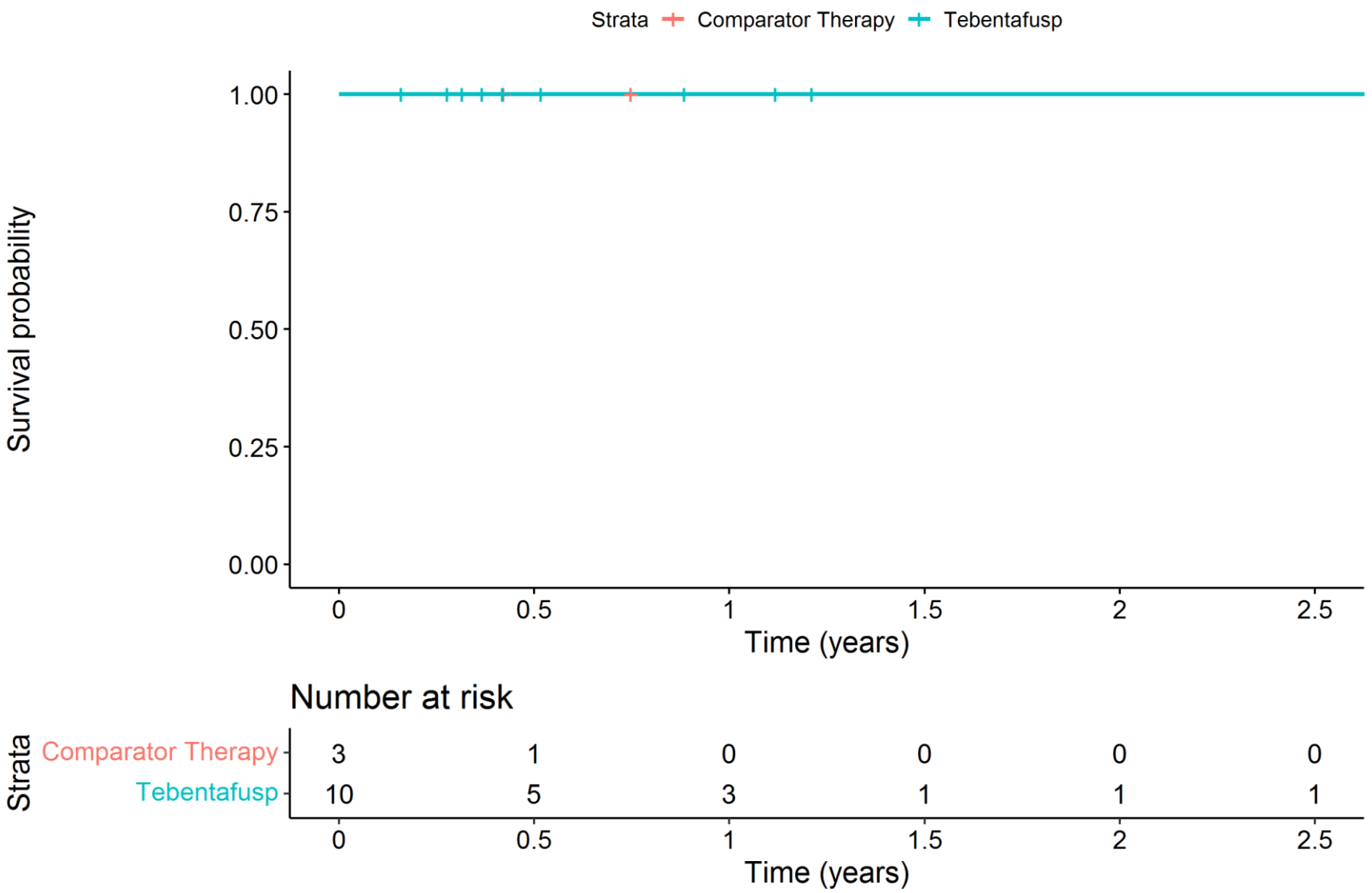
61.11 Endokrine Erkrankungen- LDH =< ULN



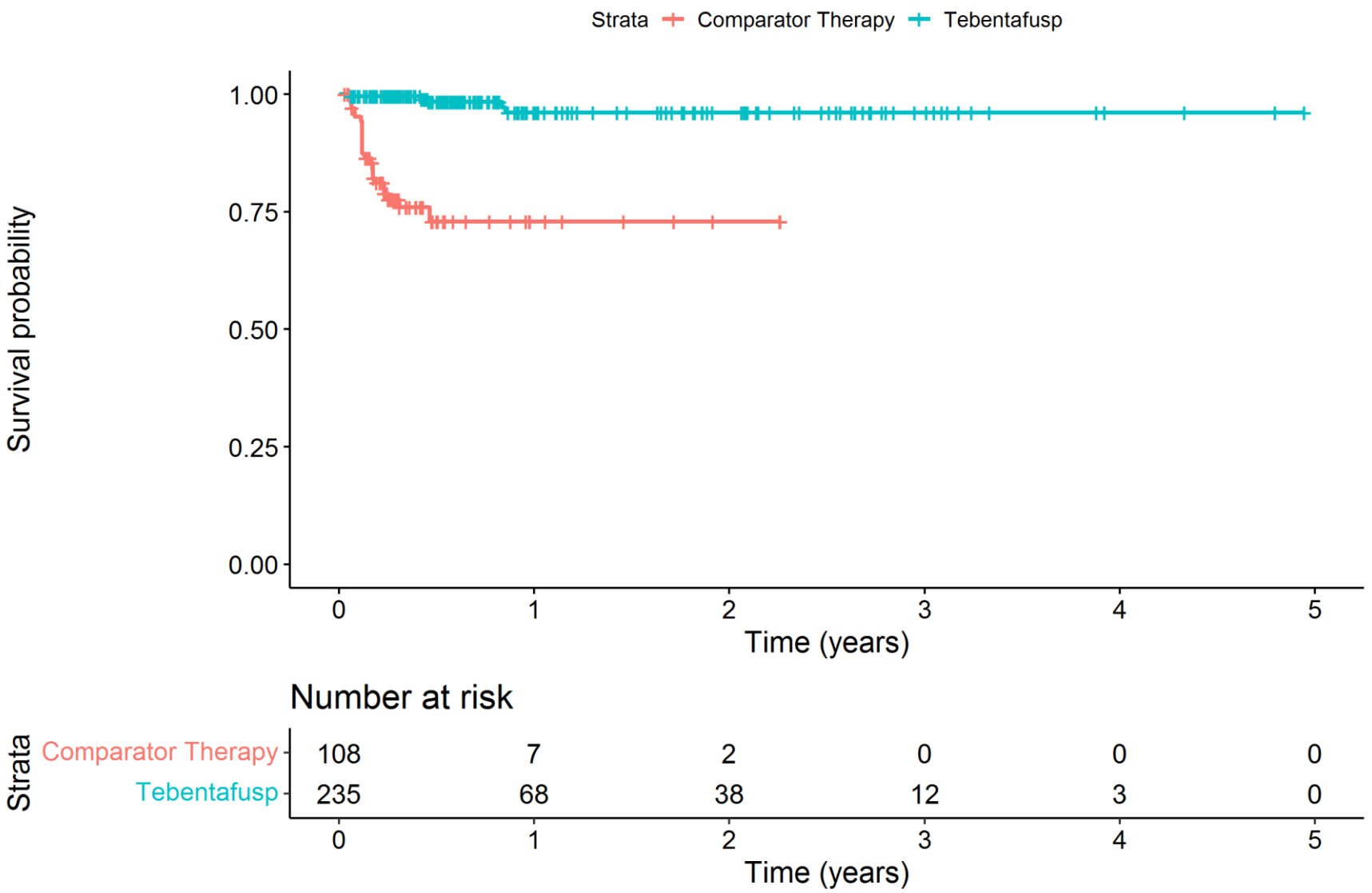
61.12 Endokrine Erkrankungen- LDH > ULN



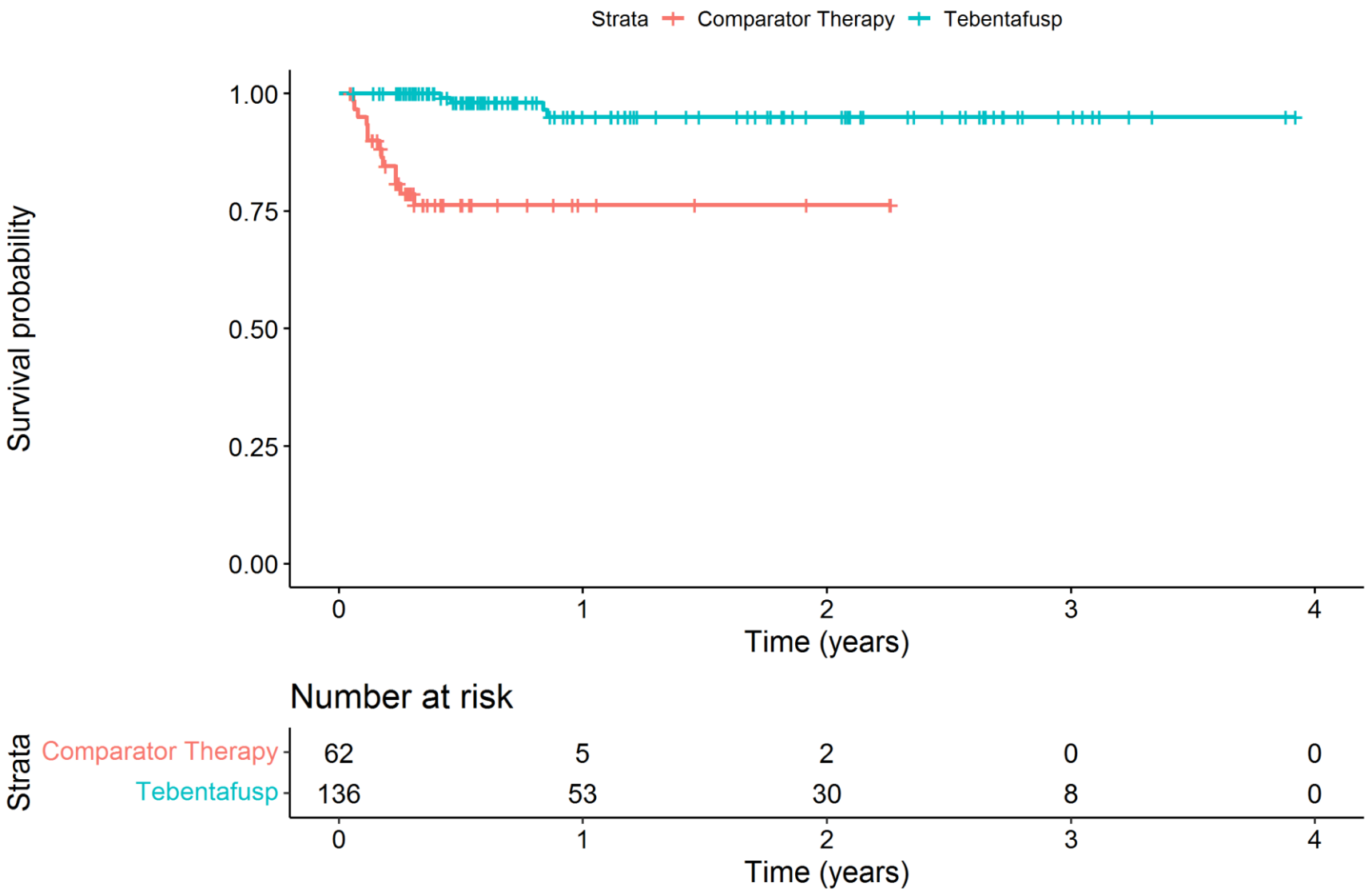
61.13 Endokrine Erkrankungen- Vorherige Therapie adjuvant/neoadjuvant



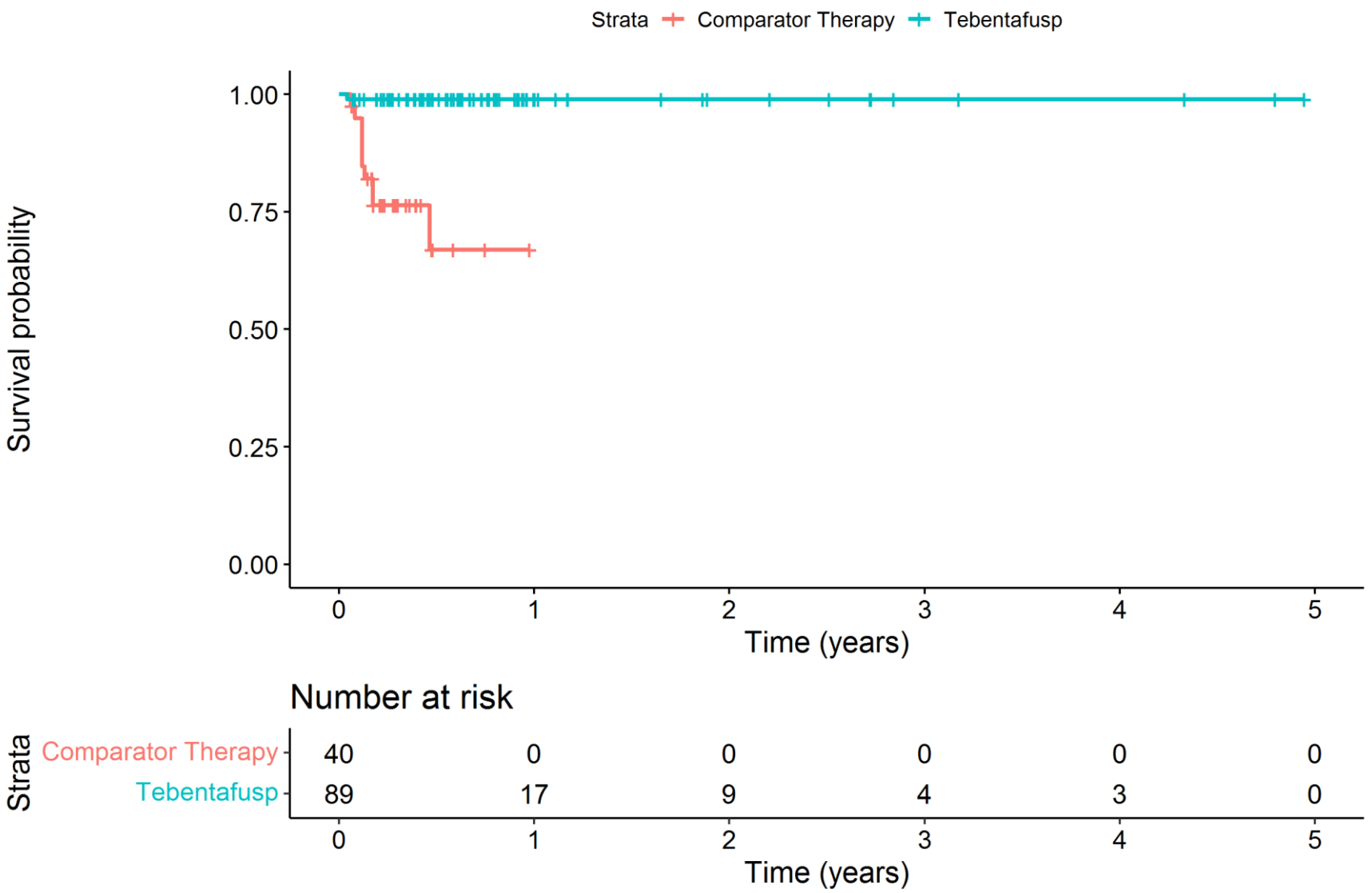
61.14 Endokrine Erkrankungen- Keine Vorherige Therapie adjuvant/neoadjuvant



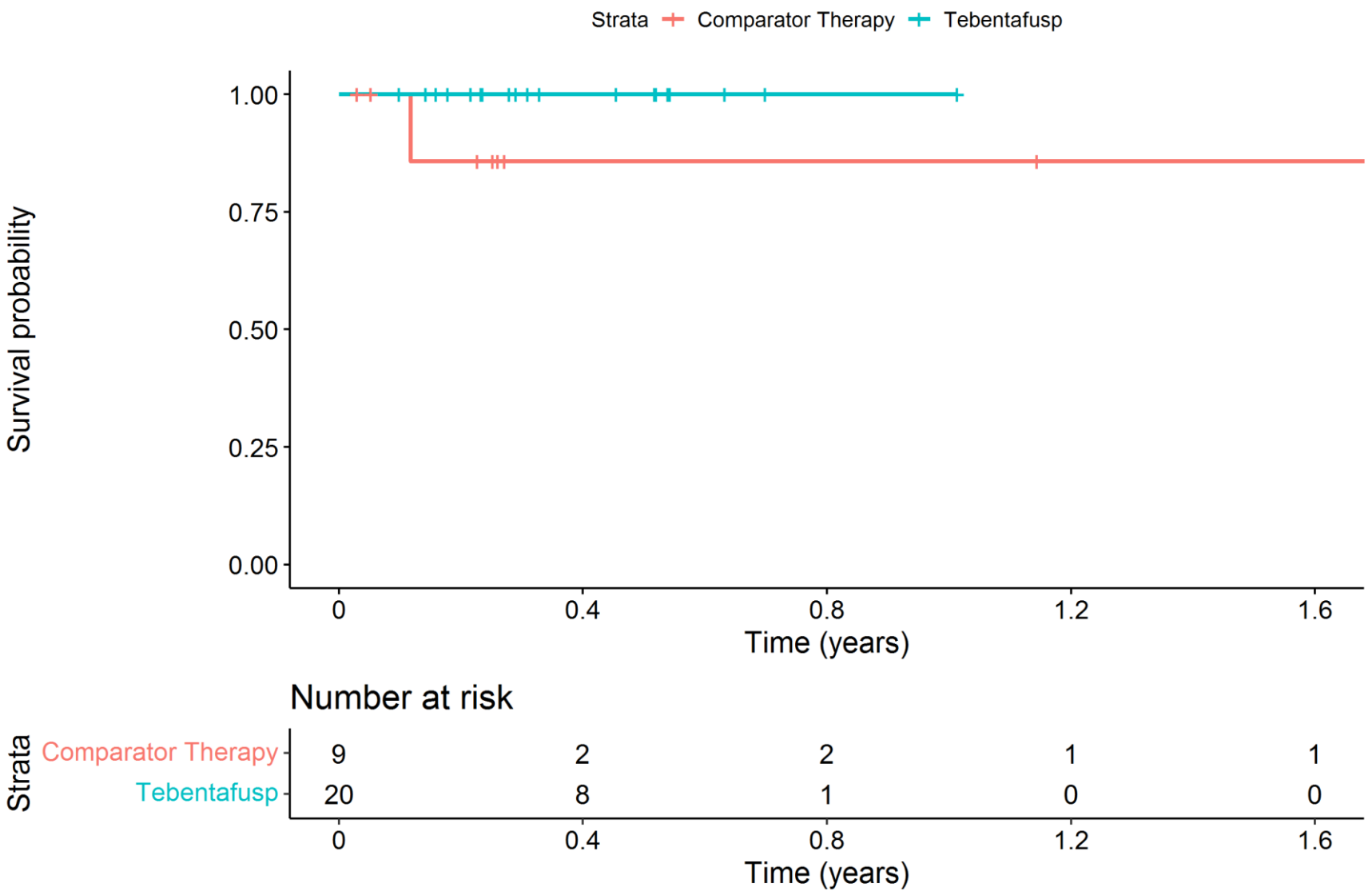
Endokrine Erkrankungen- Läsion ≤ 3cm



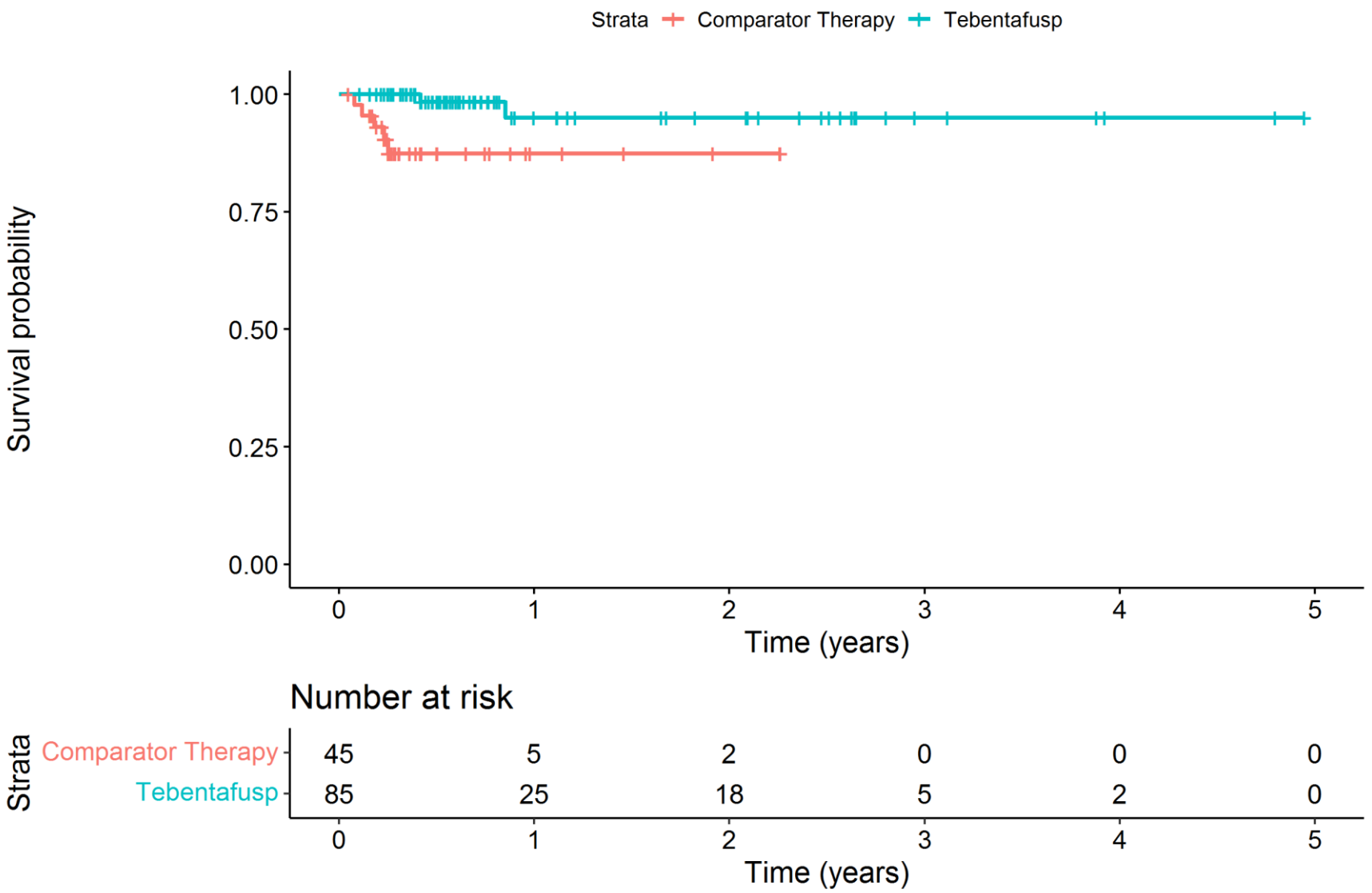
61.15 Endokrine Erkrankungen- Läsion 3,1-8,0 cm



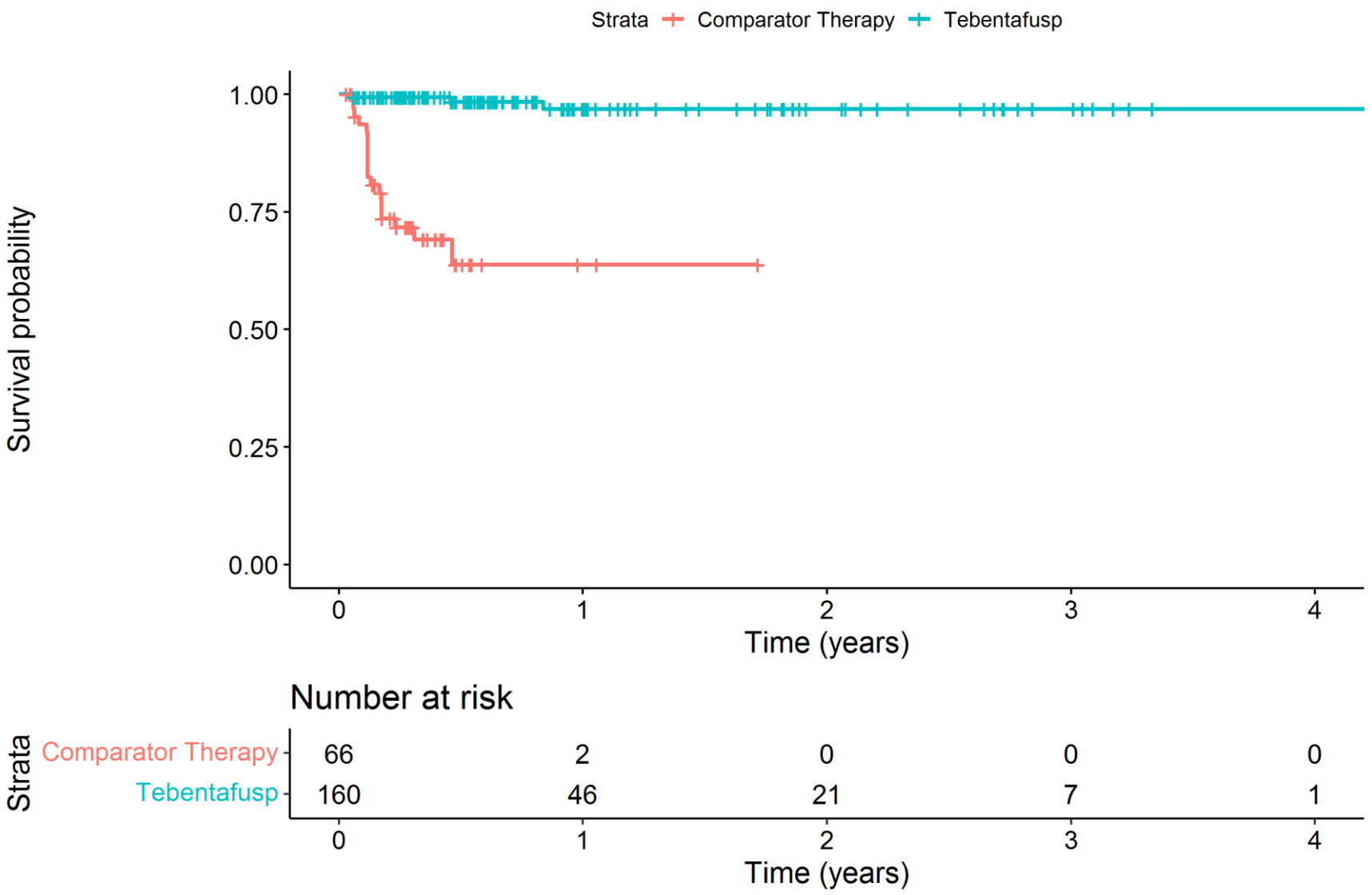
61.16 Endokrine Erkrankungen- Läsion ≥8,1 cm



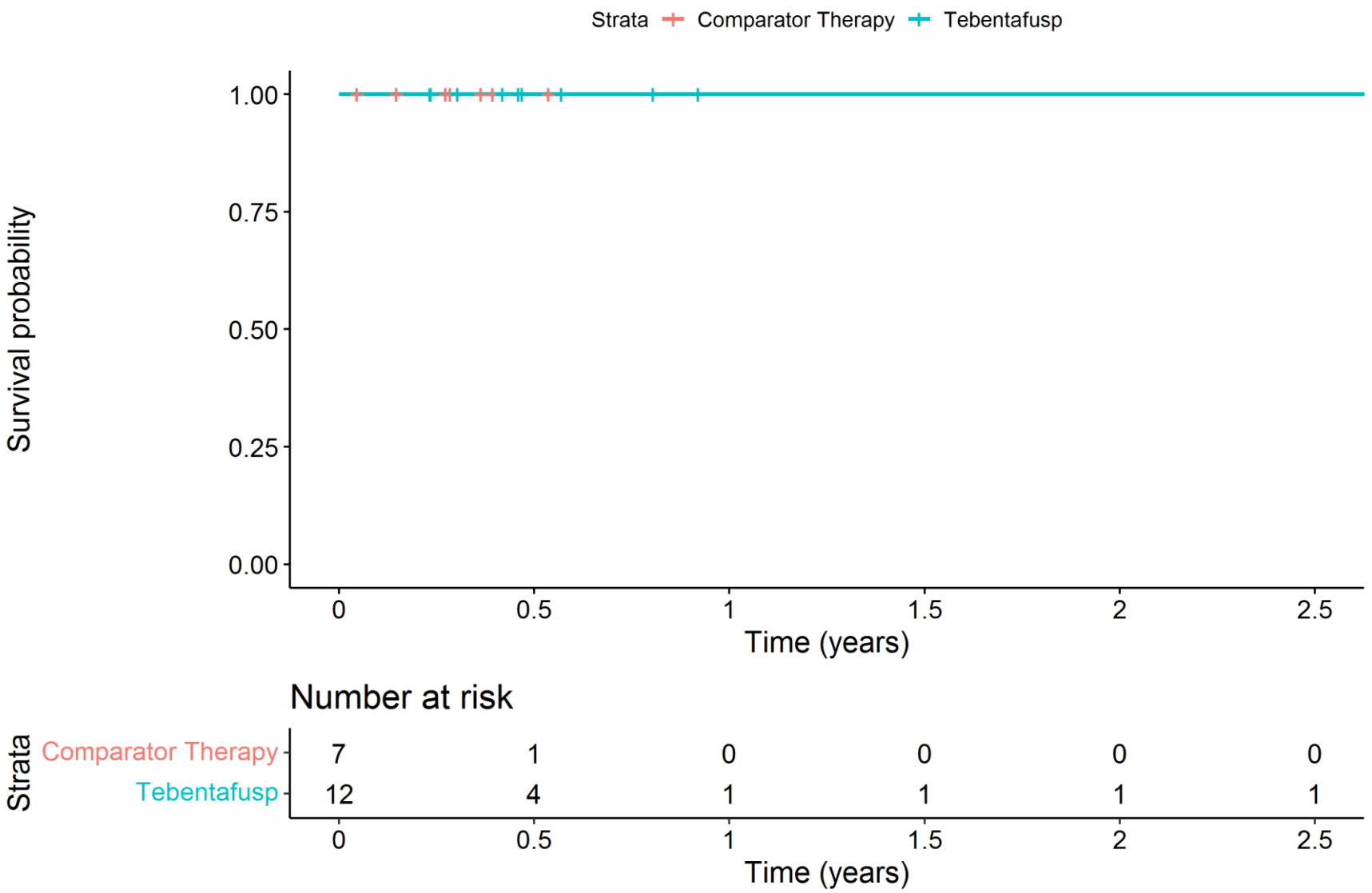
61.17 Endokrine Erkrankungen- Nordamerika



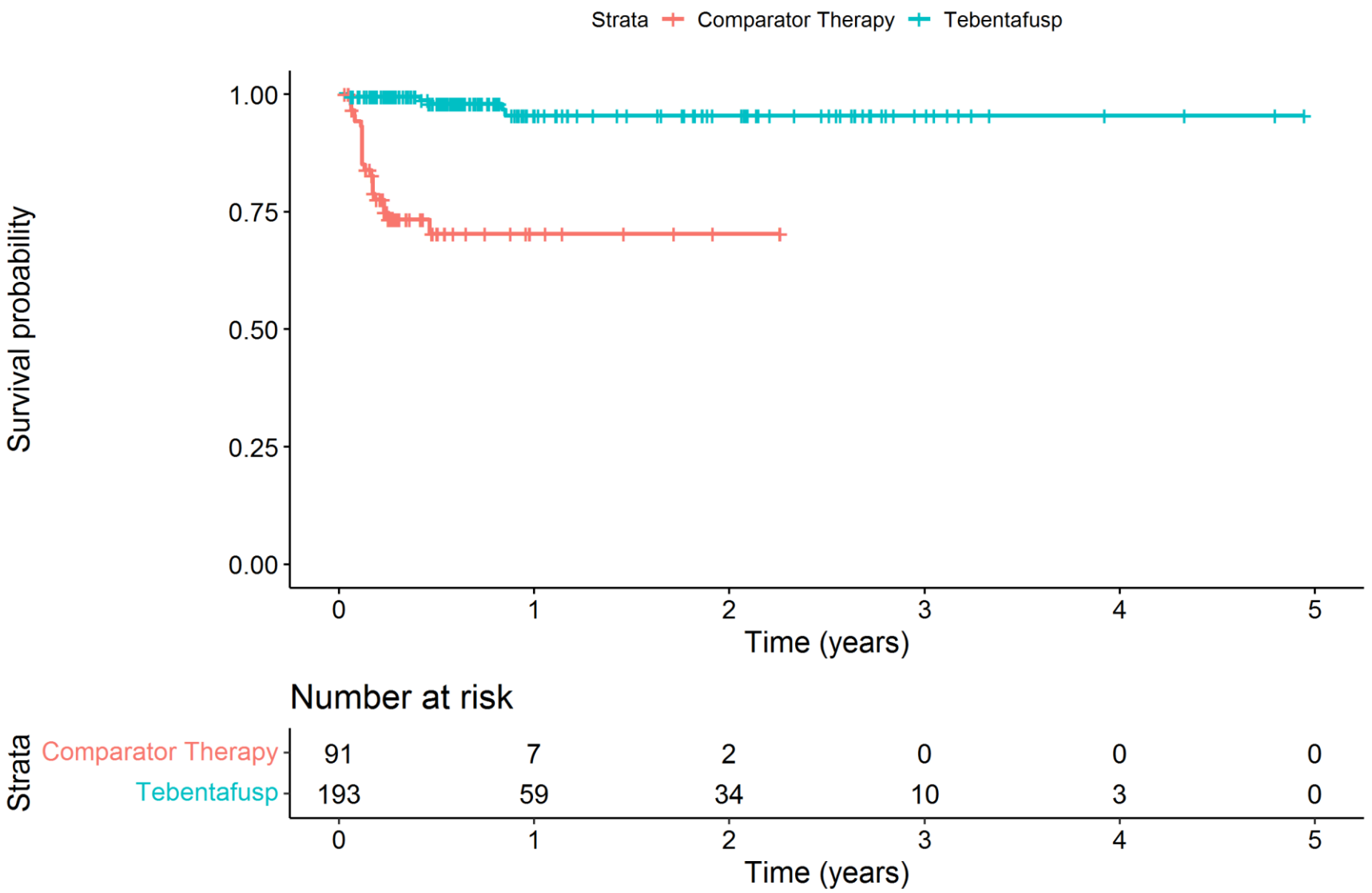
61.18 Endokrine Erkrankungen- Nicht-Nordamerika



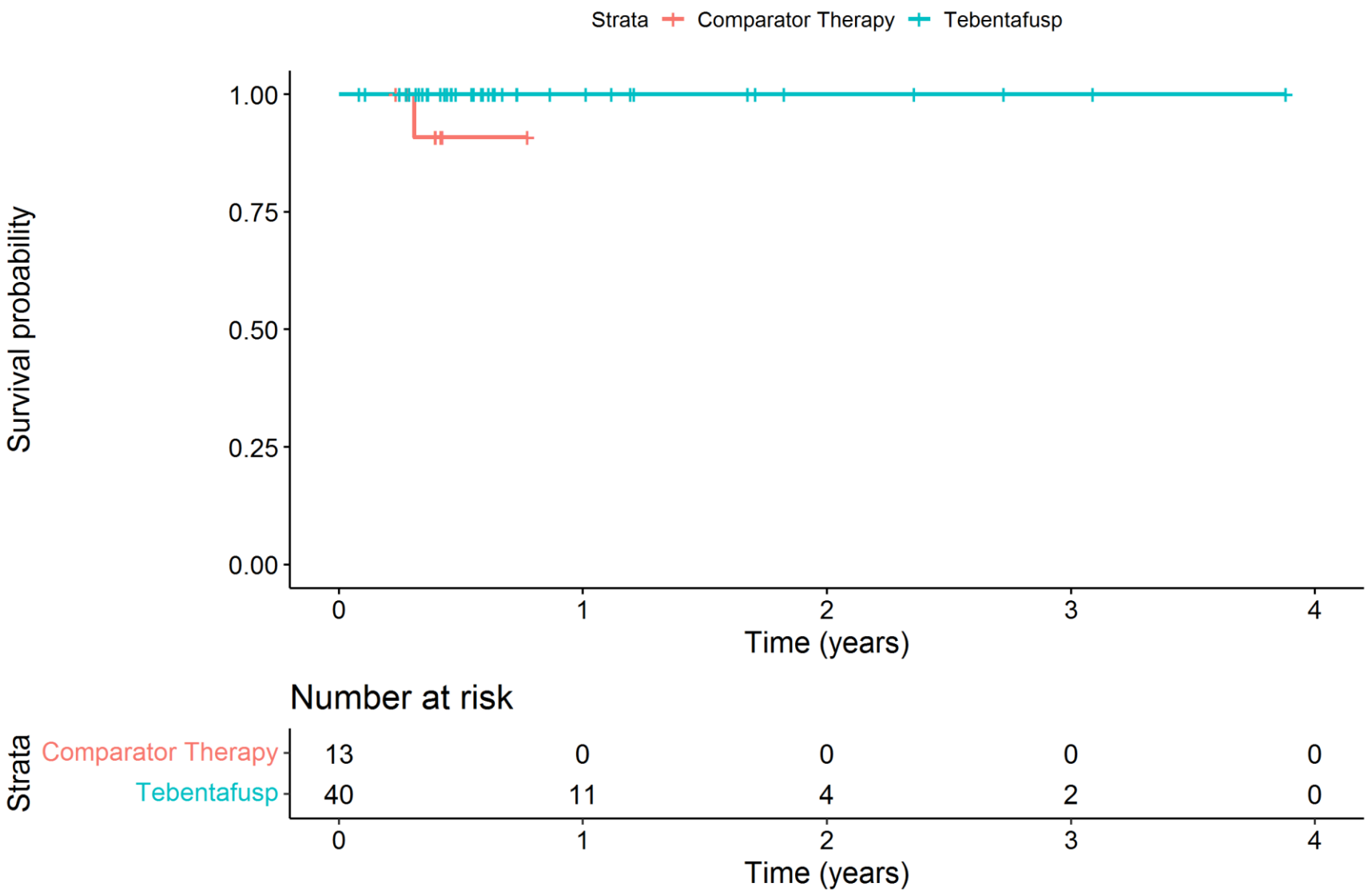
61.19 Endokrine Erkrankungen- Dacarbazin



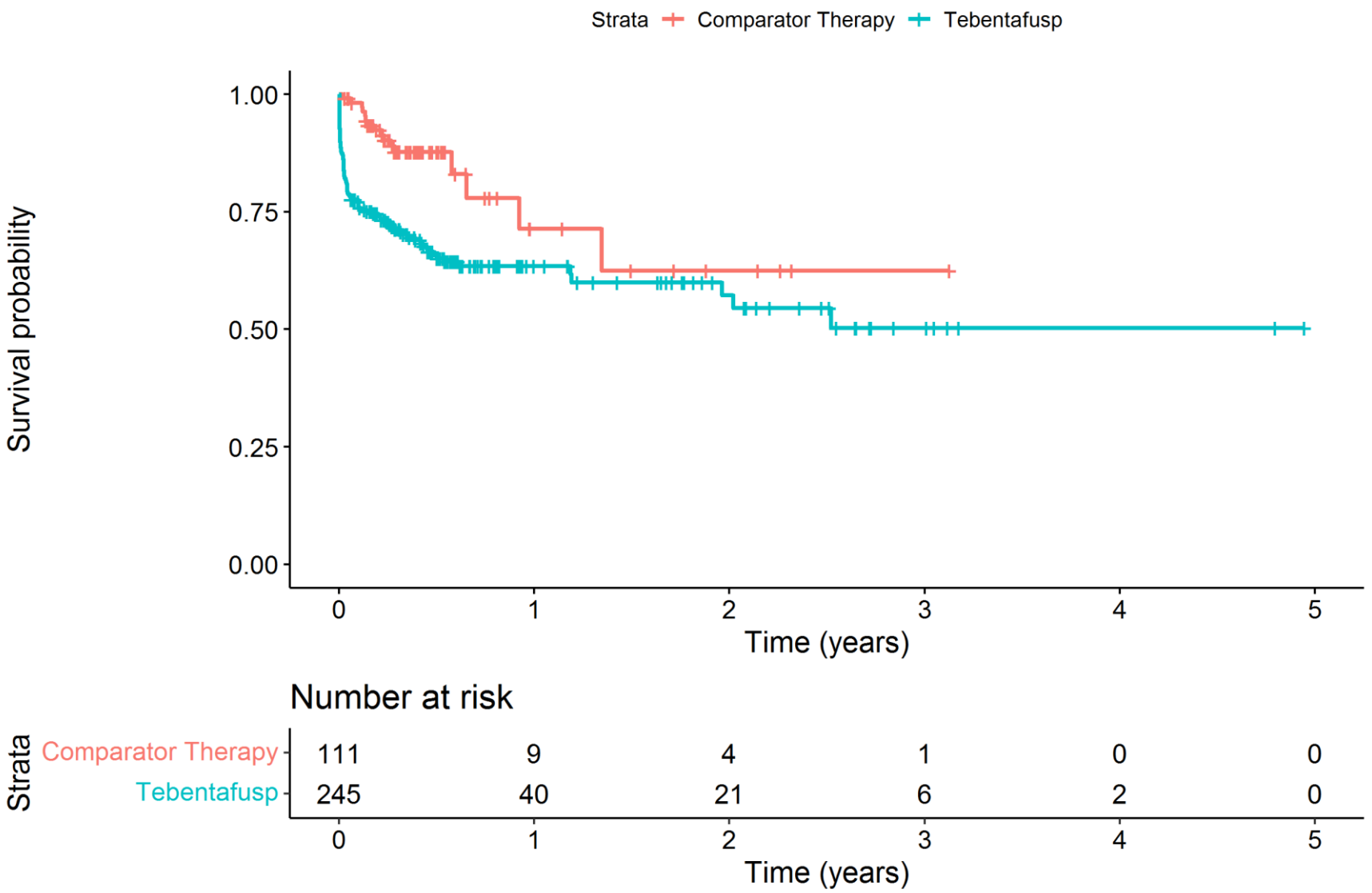
61.20 Endokrine Erkrankungen- Pembrolizumab



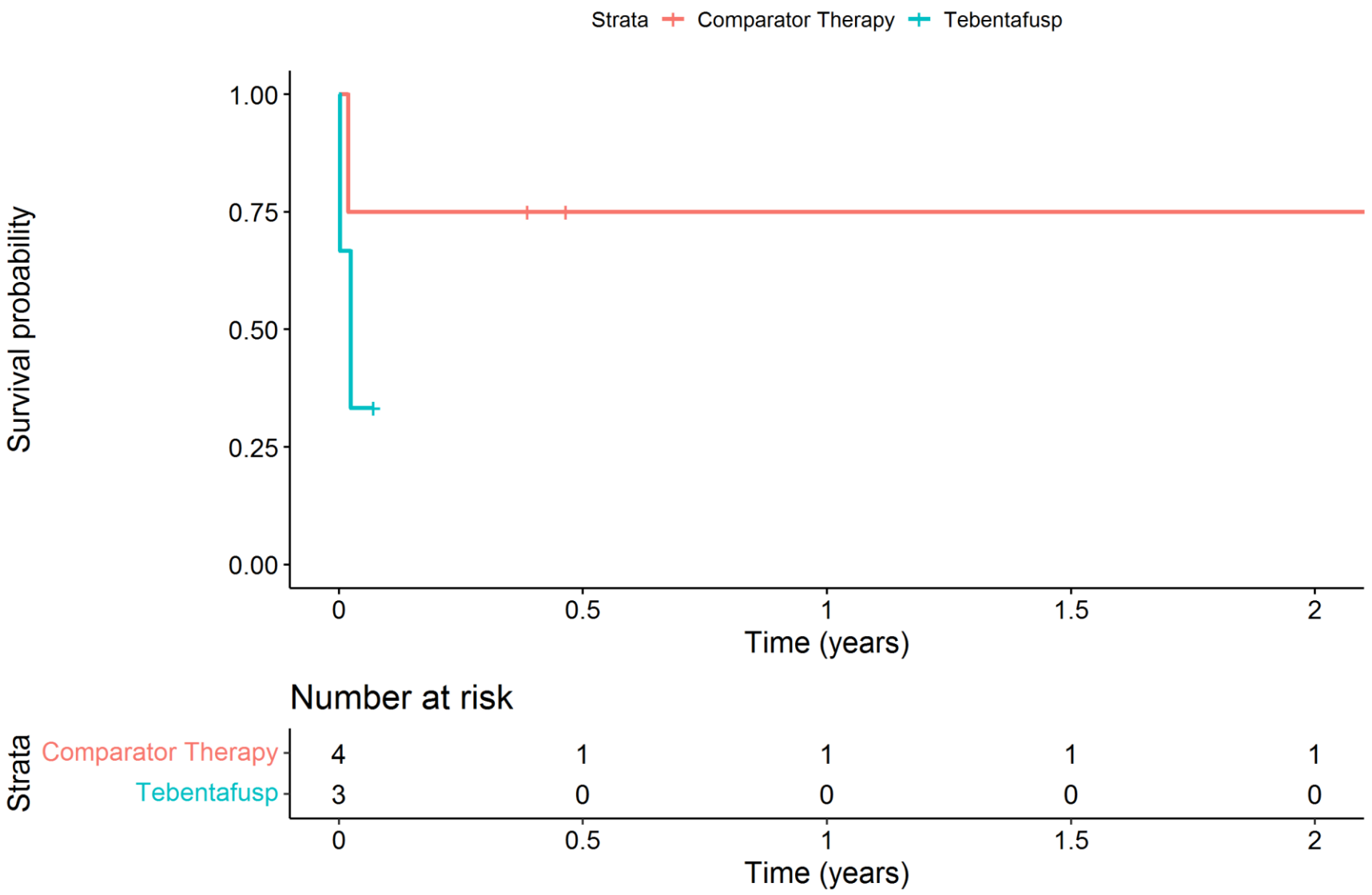
61.21 Endokrine Erkrankungen- Ipilimumab



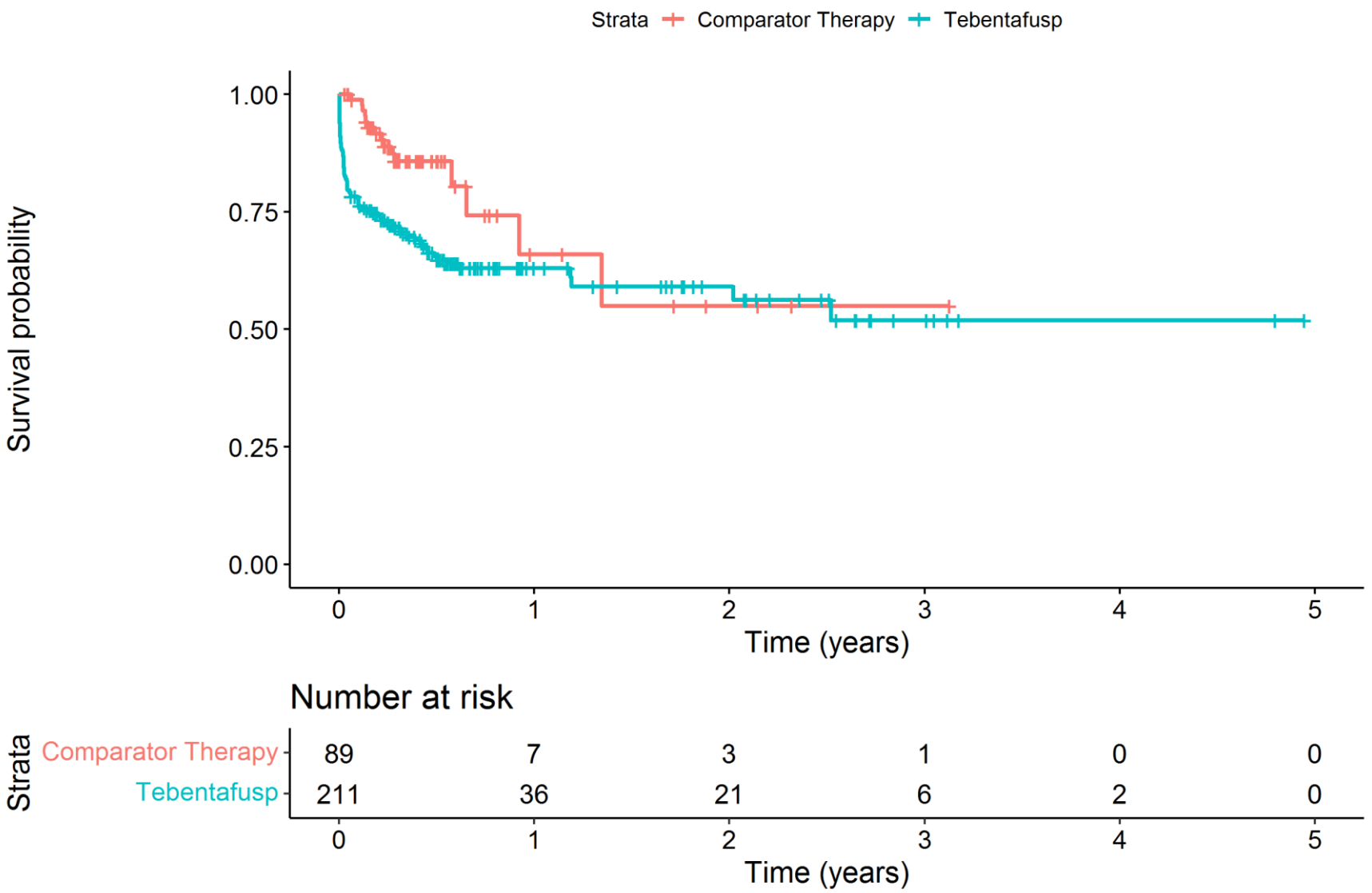
61.22 Augenerkrankungen- Gesamt



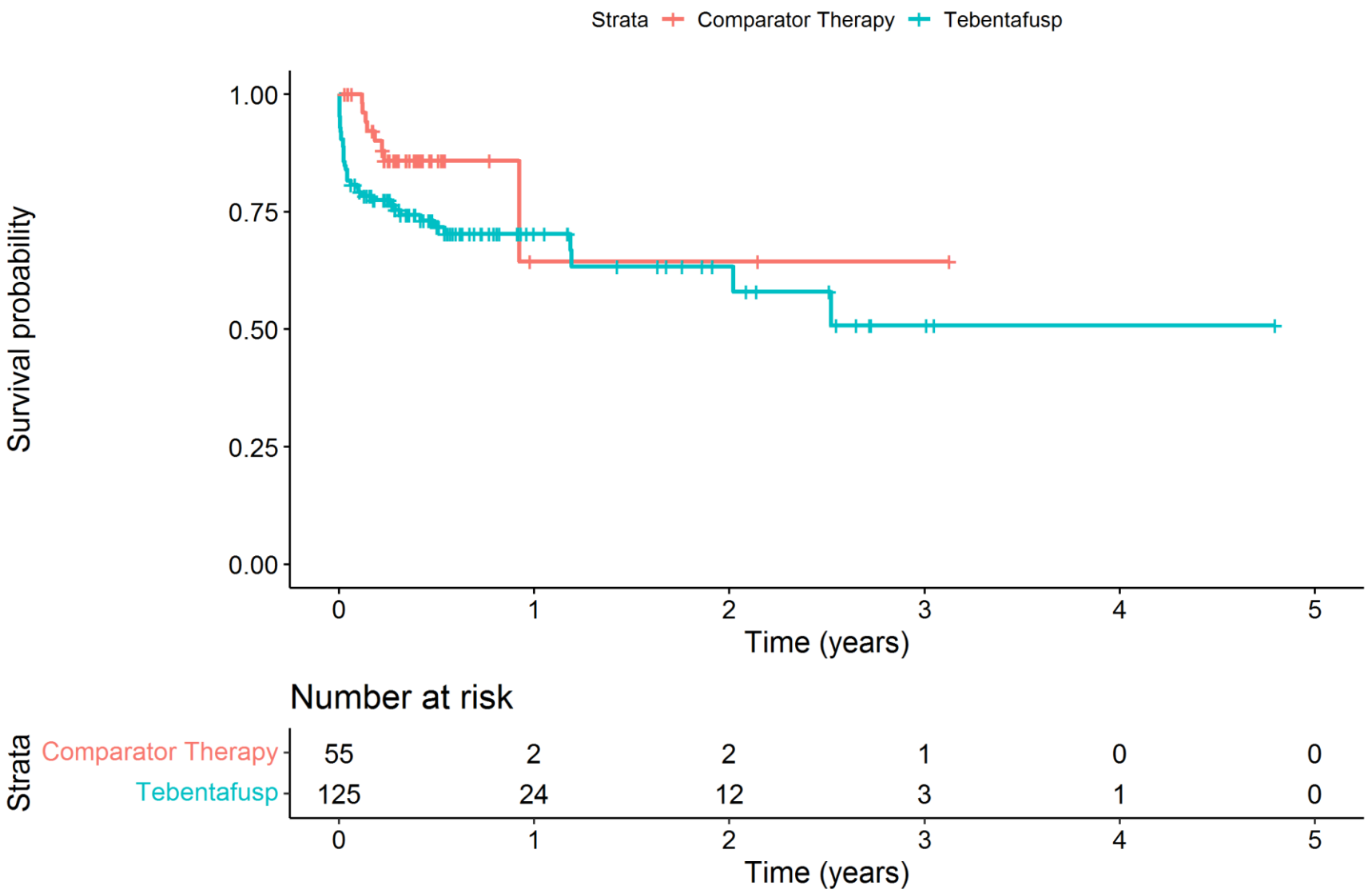
61.23 Augenerkrankungen- Hispanisch



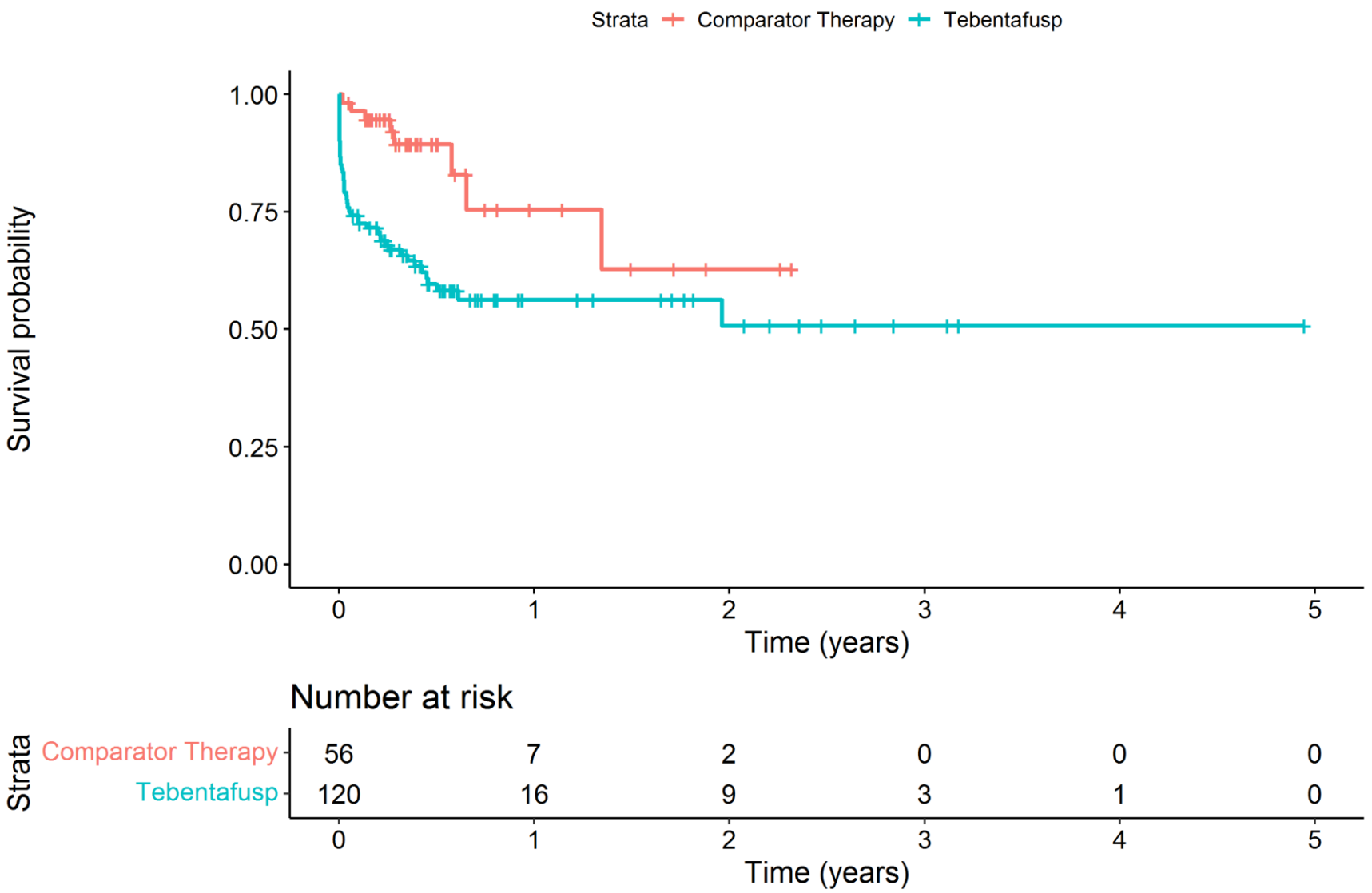
61.24 Augenerkrankungen- Nicht-hispanisch



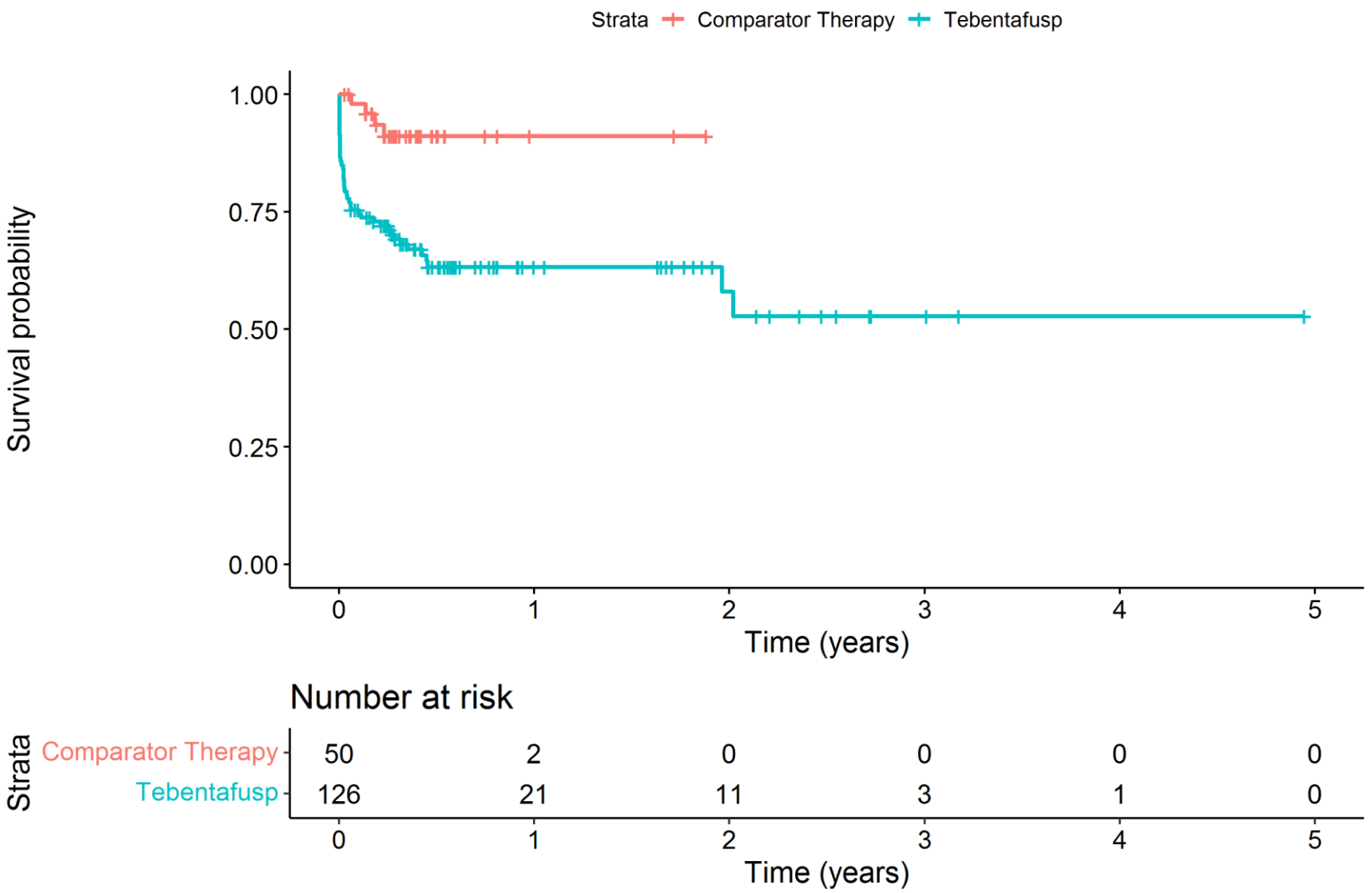
61.25 Augenerkrankungen- Männlich



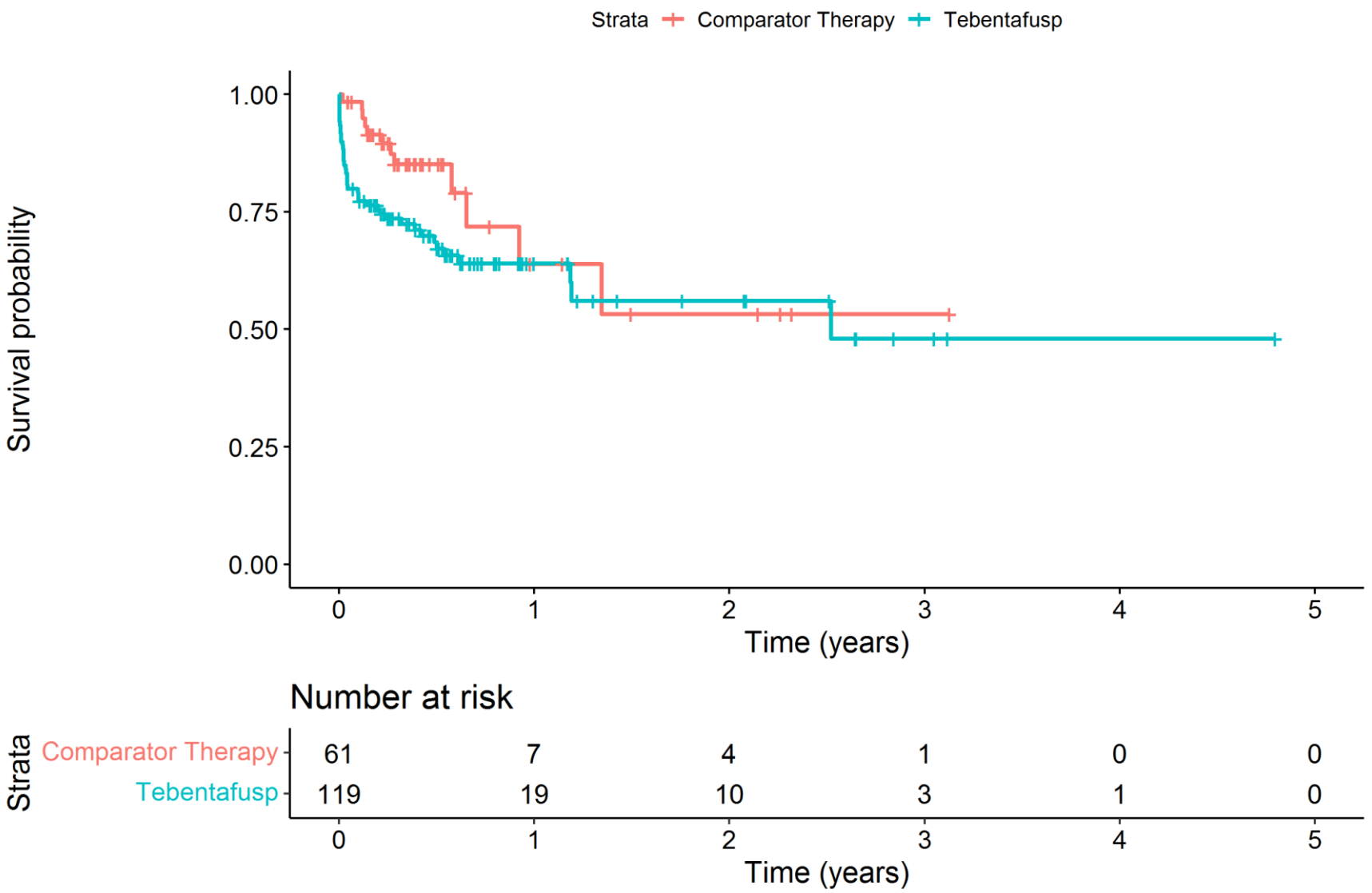
61.26 Augenerkrankungen- Weiblich



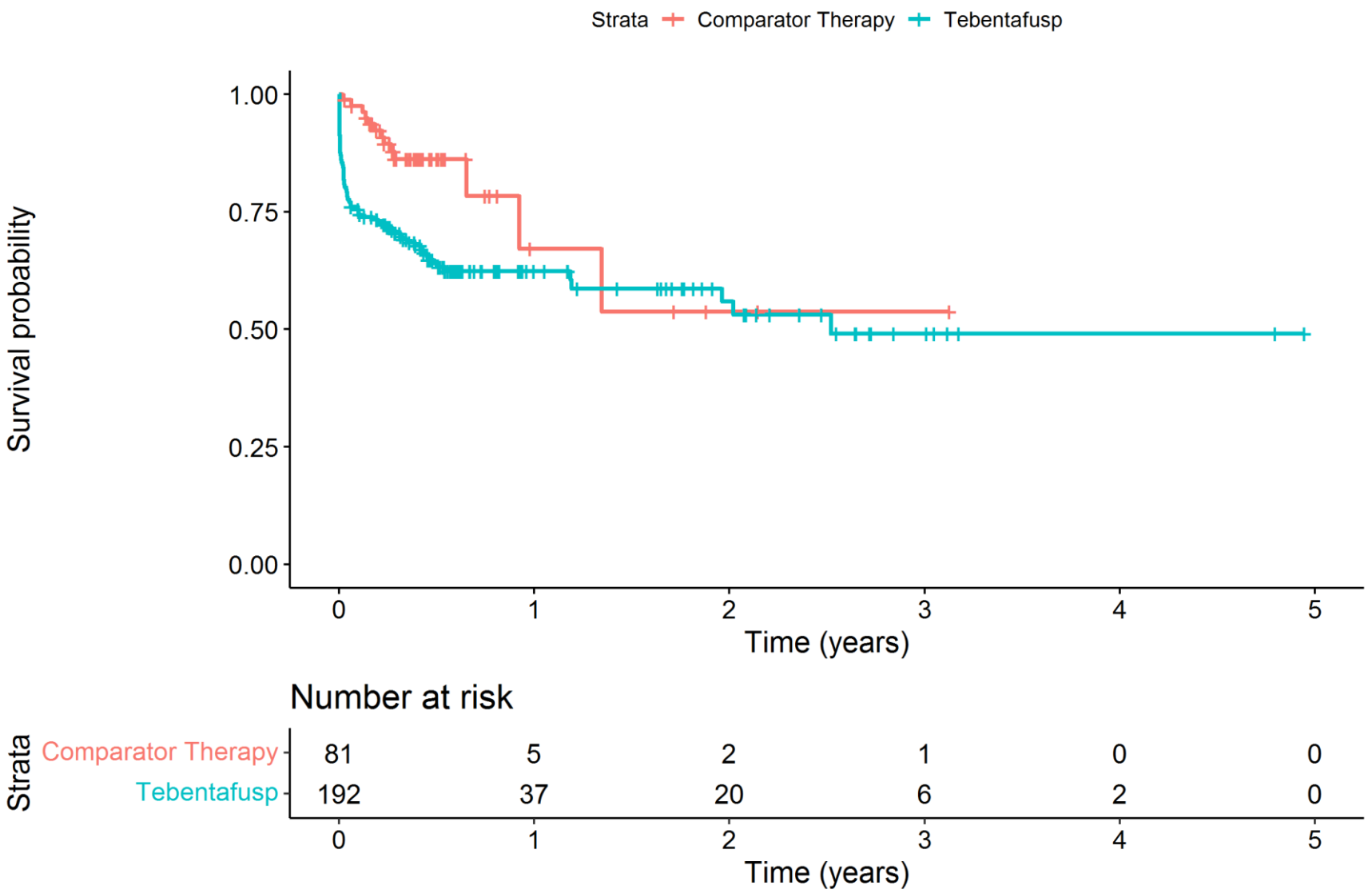
61.27 Augenerkrankungen- <65



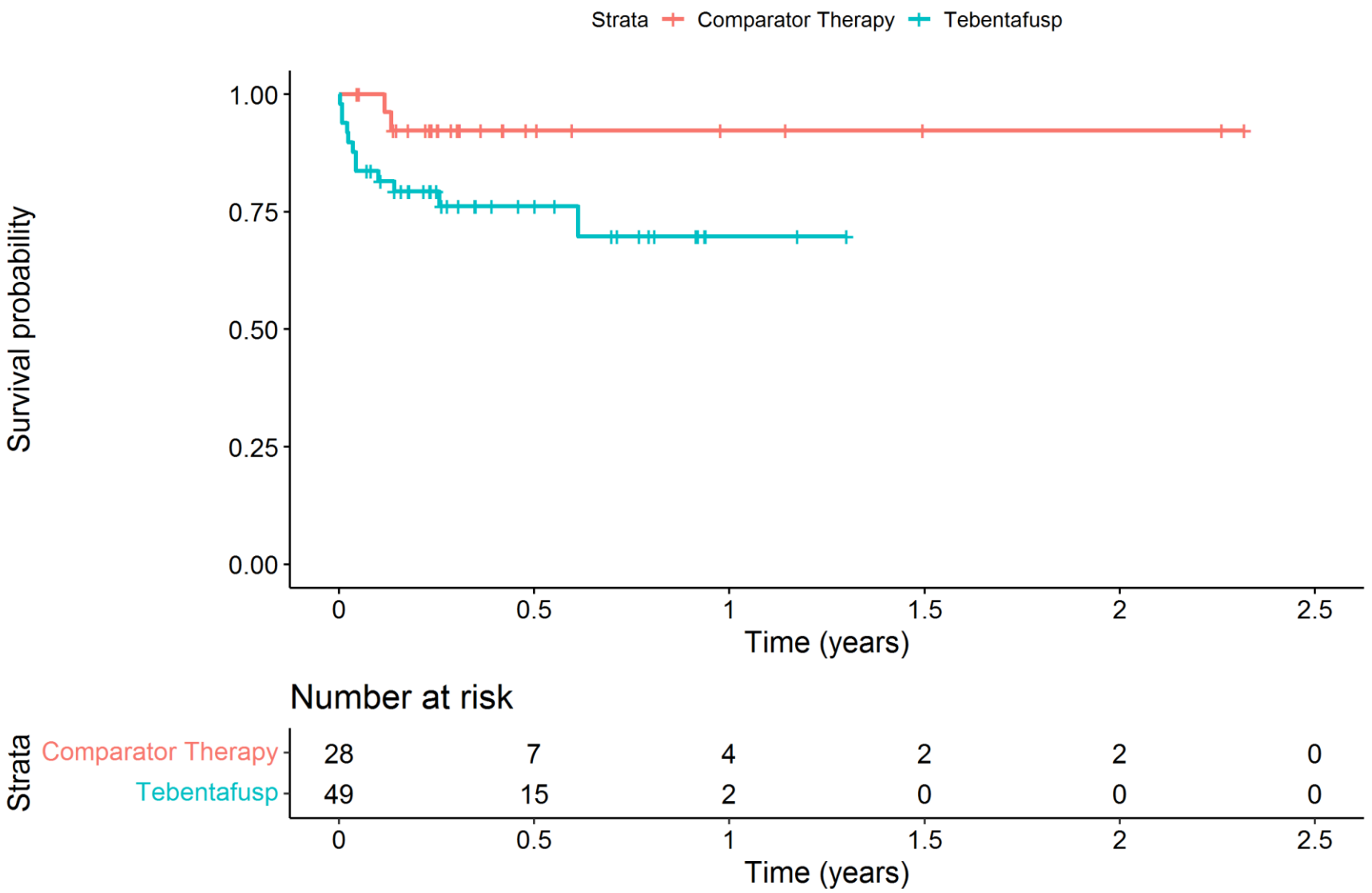
61.28 Augenerkrankungen- ≥65



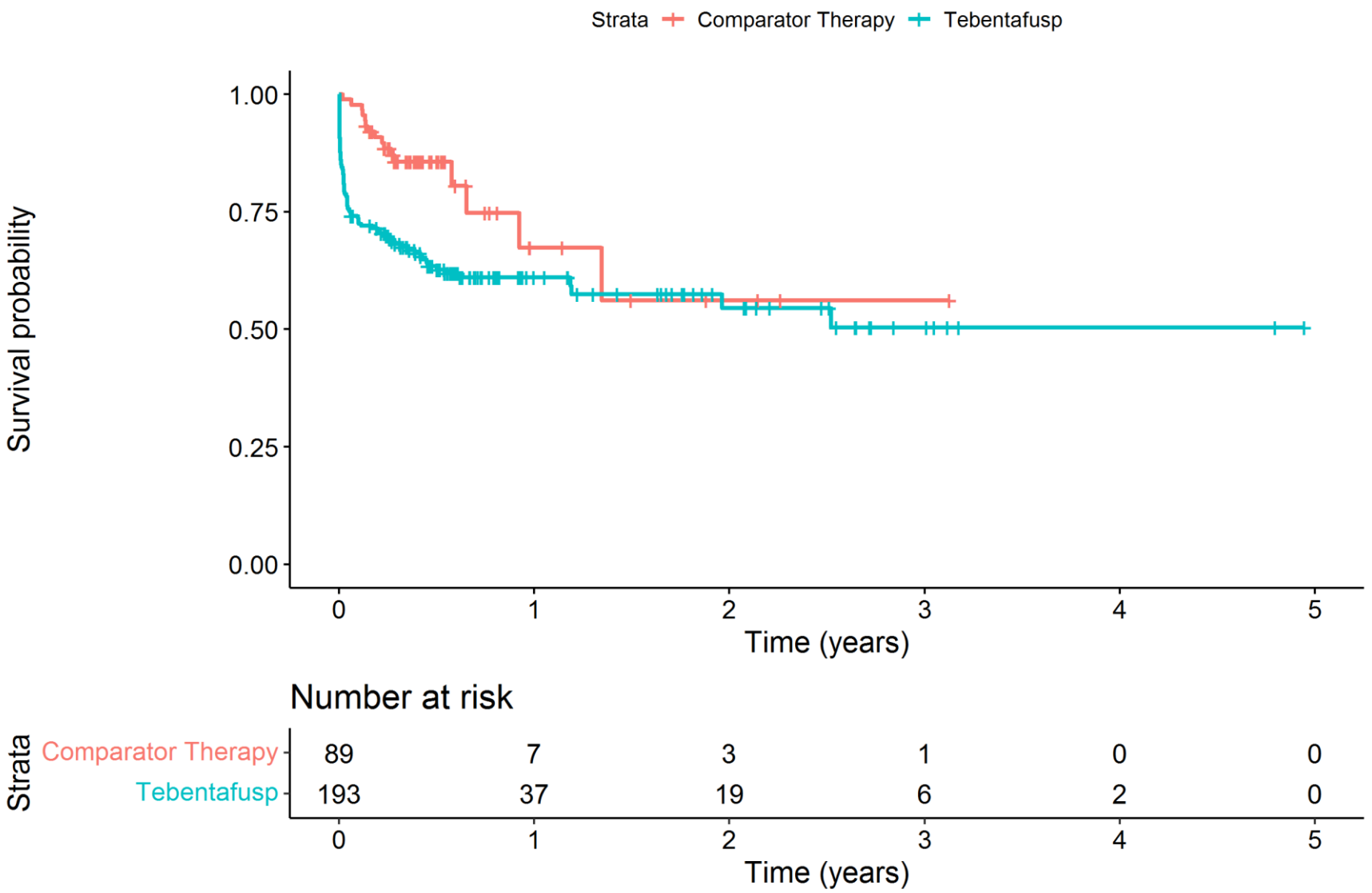
61.29 Augenerkrankungen- ECOG 0



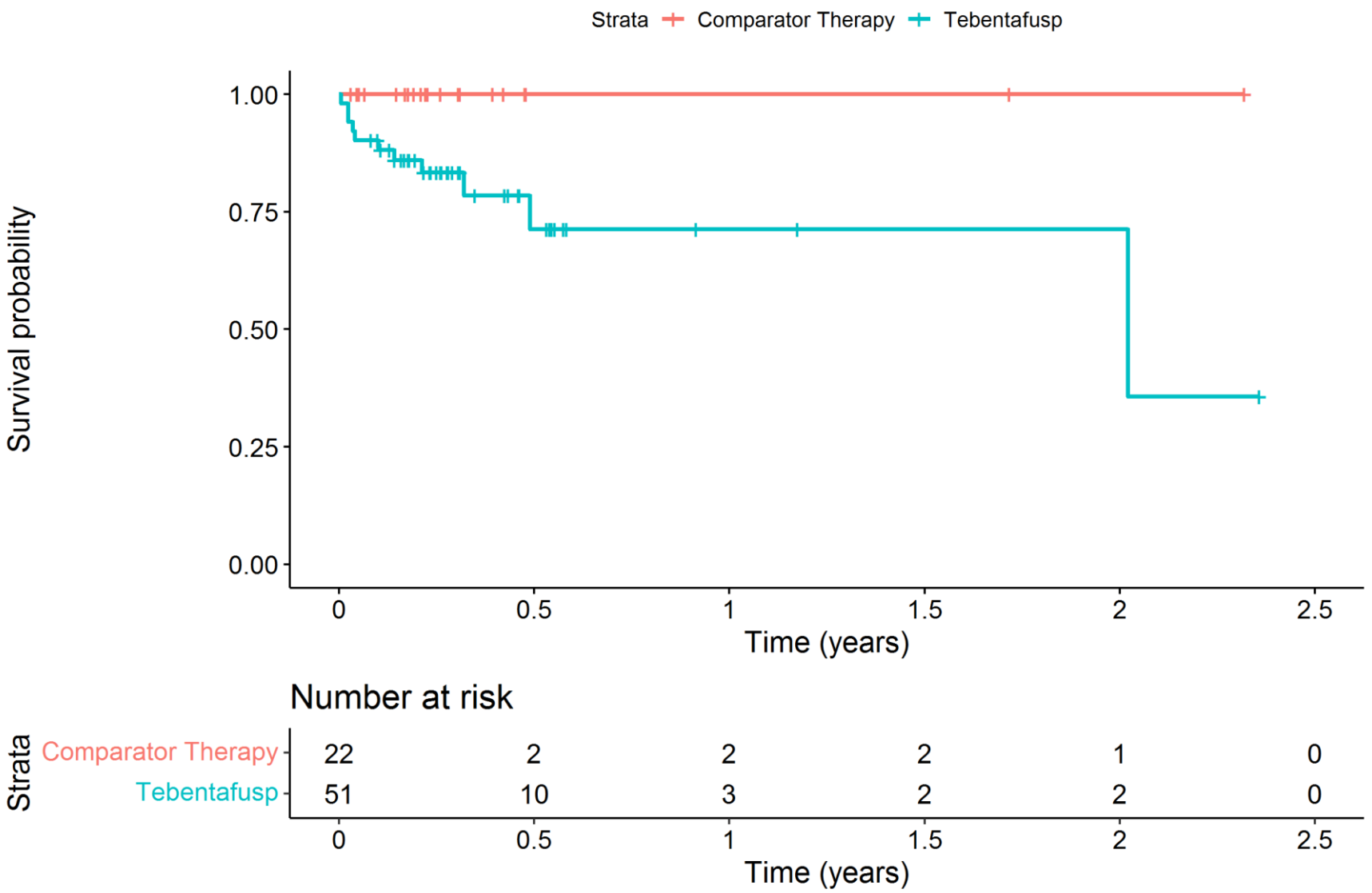
61.30 Augenerkrankungen- ECOG 1



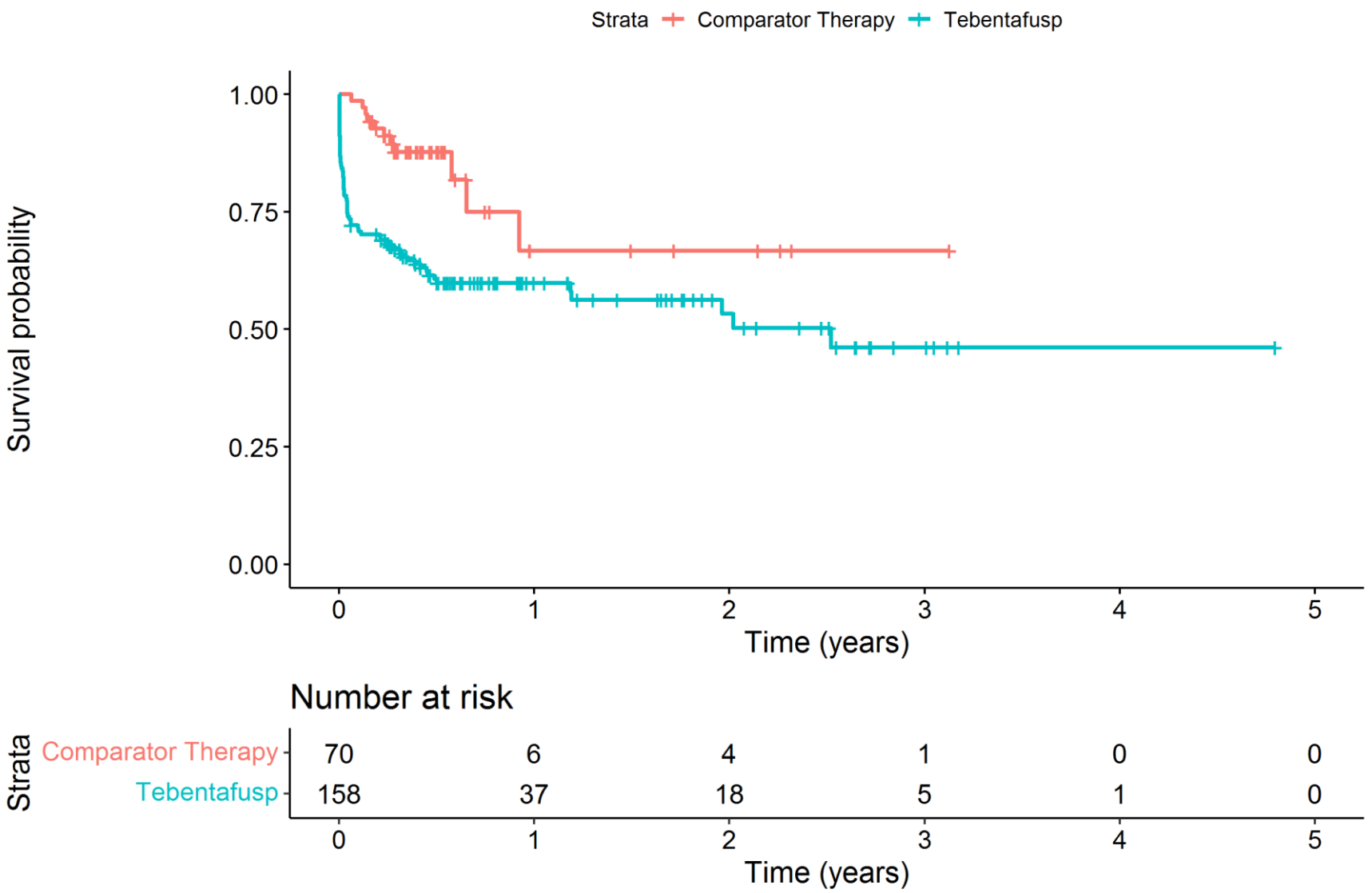
61.31 Augenerkrankungen- ALP ≤ ULN



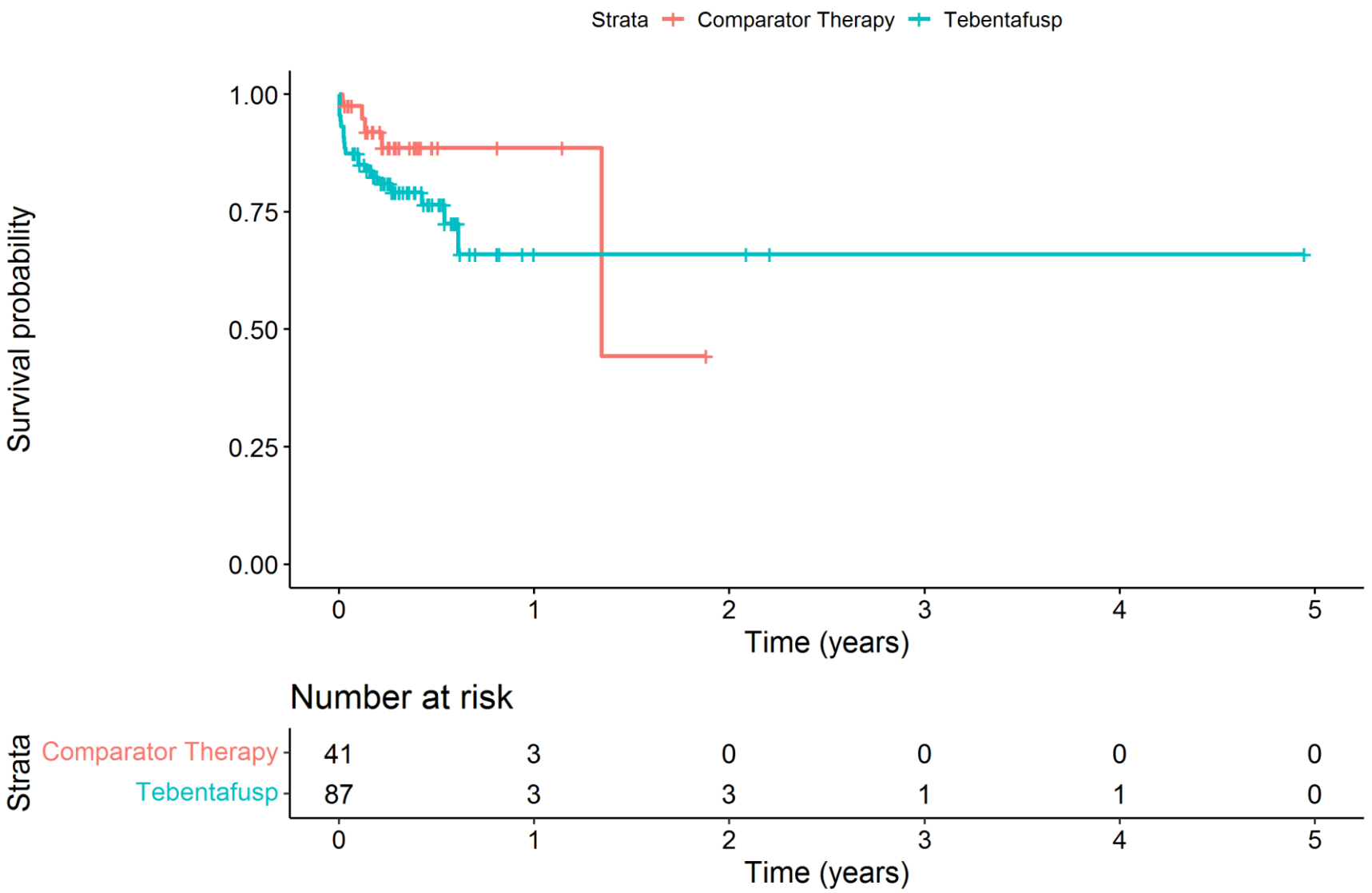
61.32 Augenerkrankungen- ALP > ULN



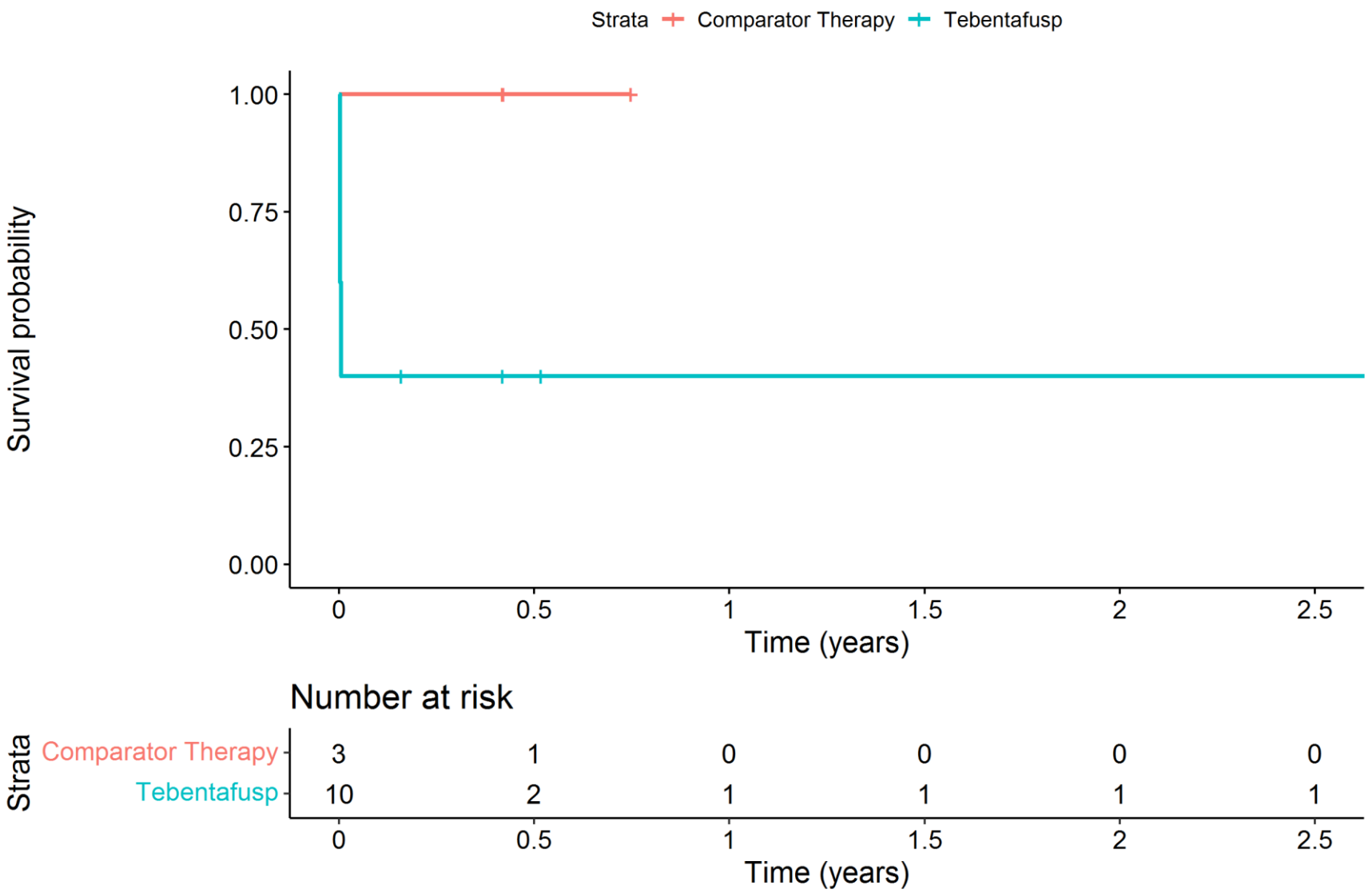
61.33 Augenerkrankungen- LDH =< ULN



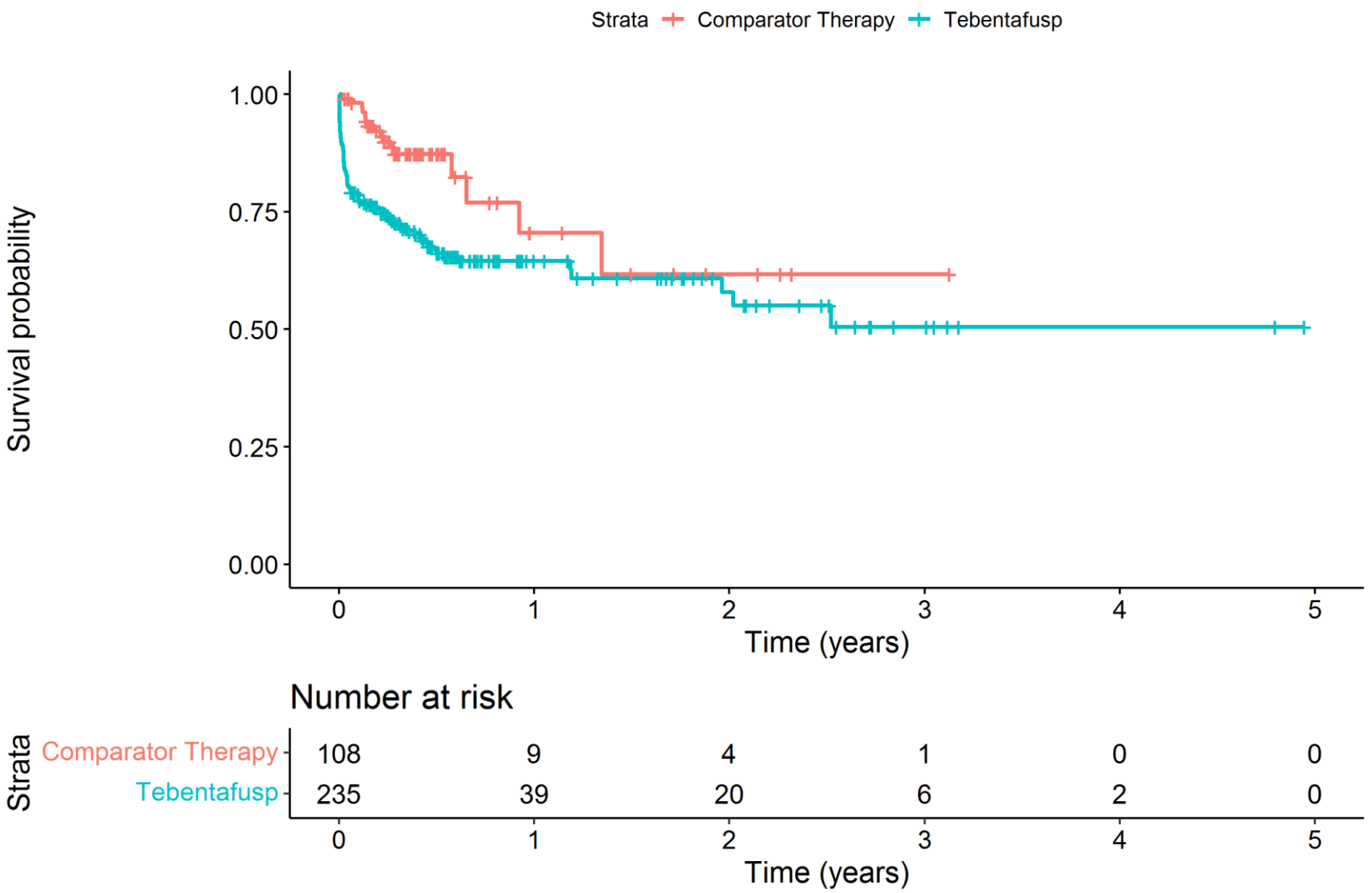
61.34 Augenerkrankungen- LDH > ULN



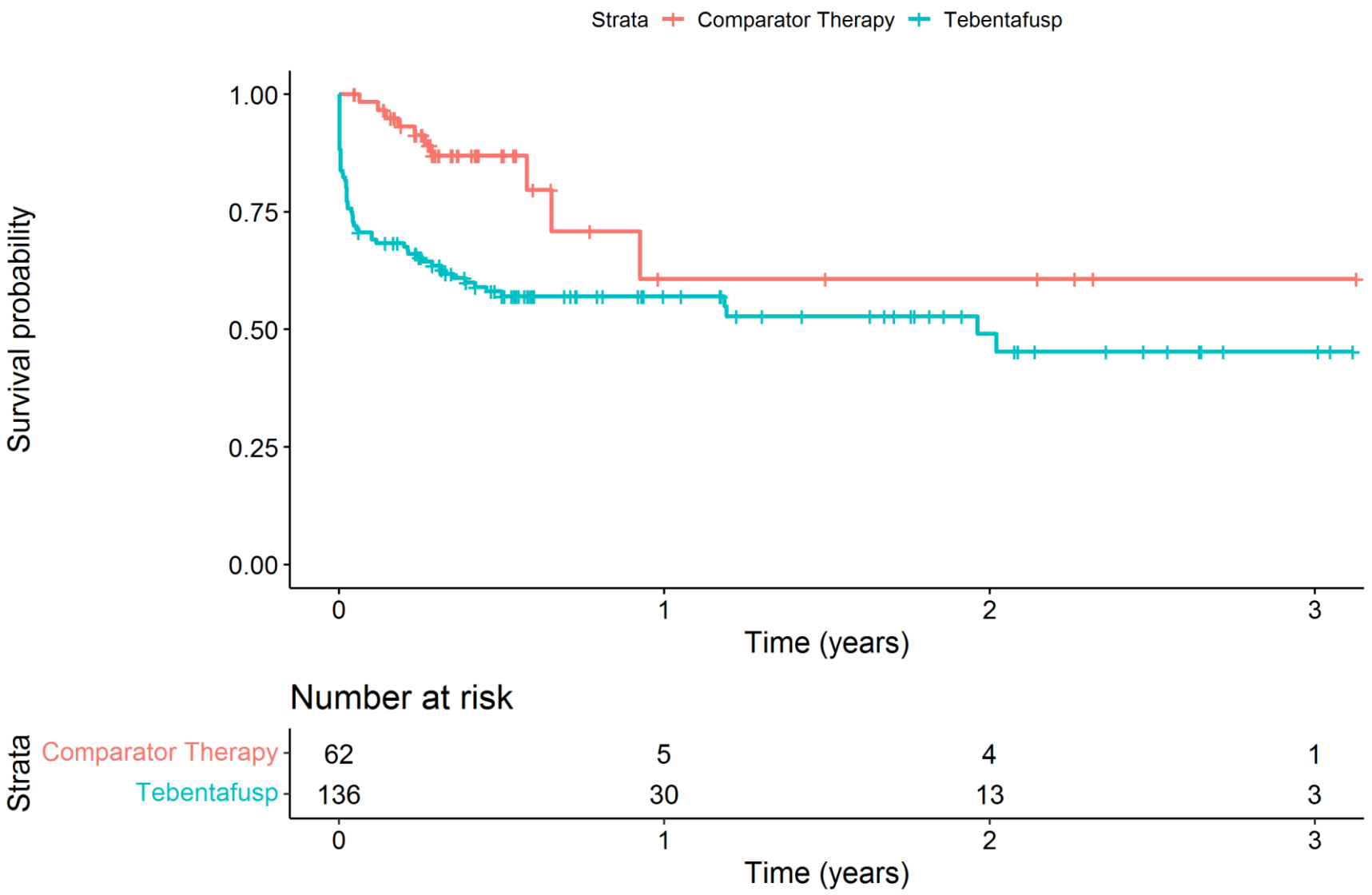
61.35 Augenerkrankungen- Vorherige Therapie adjuvant/neoadjuvant



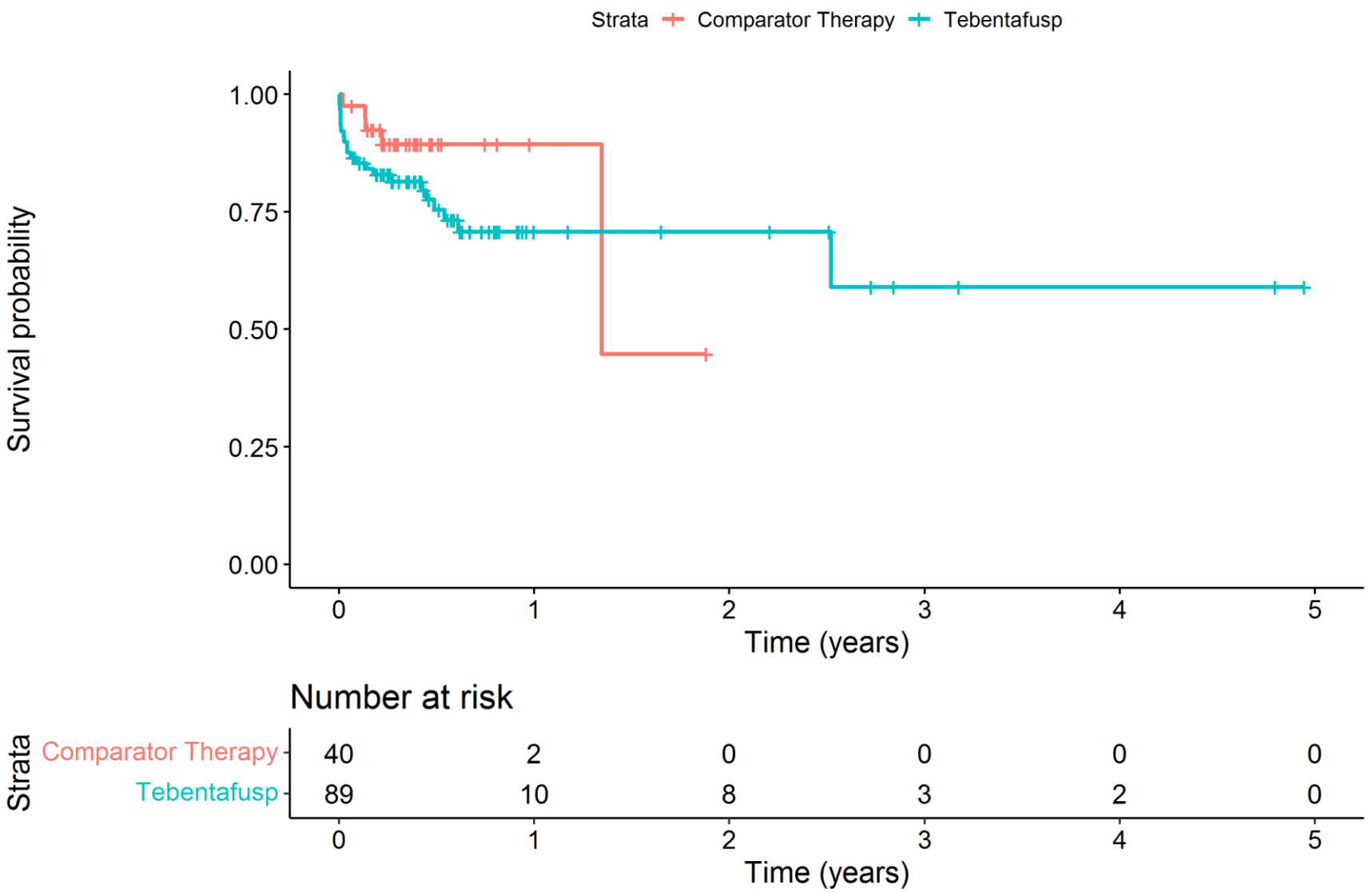
61.36 Augenerkrankungen- Keine Vorherige Therapie adjuvant/neoadjuvant



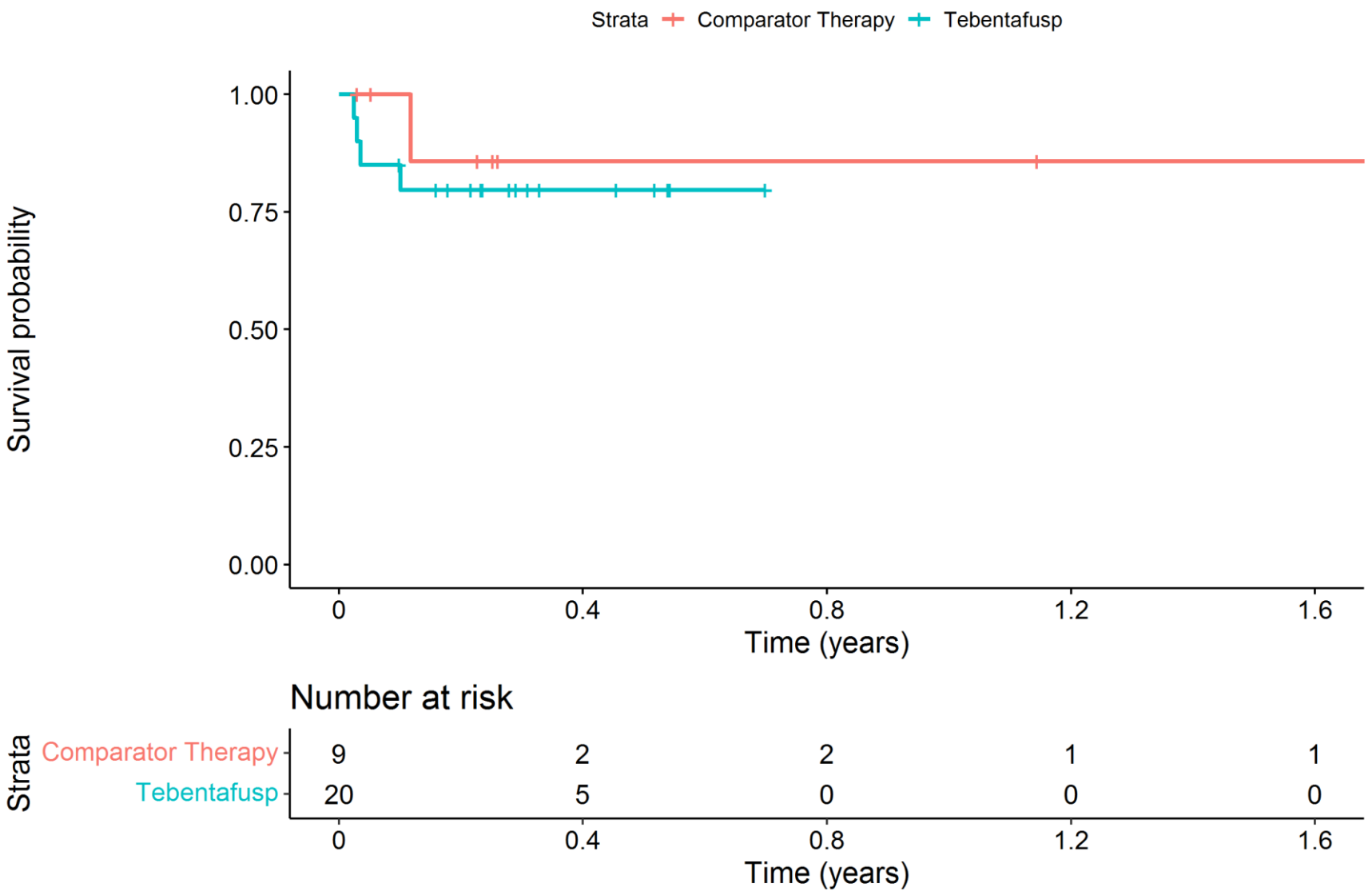
61.37 Augenerkrankungen- Läsion ≤ 3cm



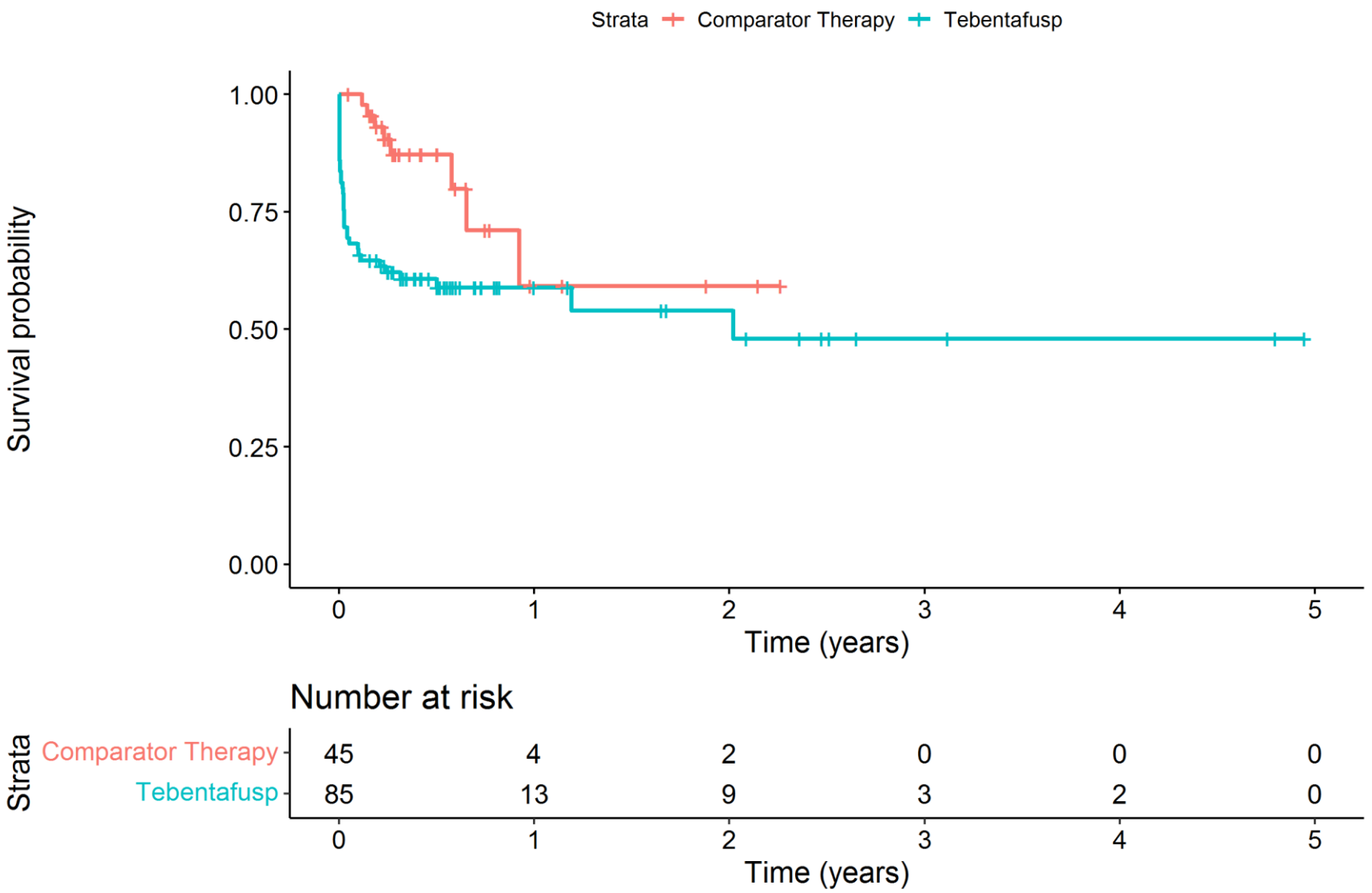
61.38 Augenerkrankungen- Läsion 3,1-8,0 cm



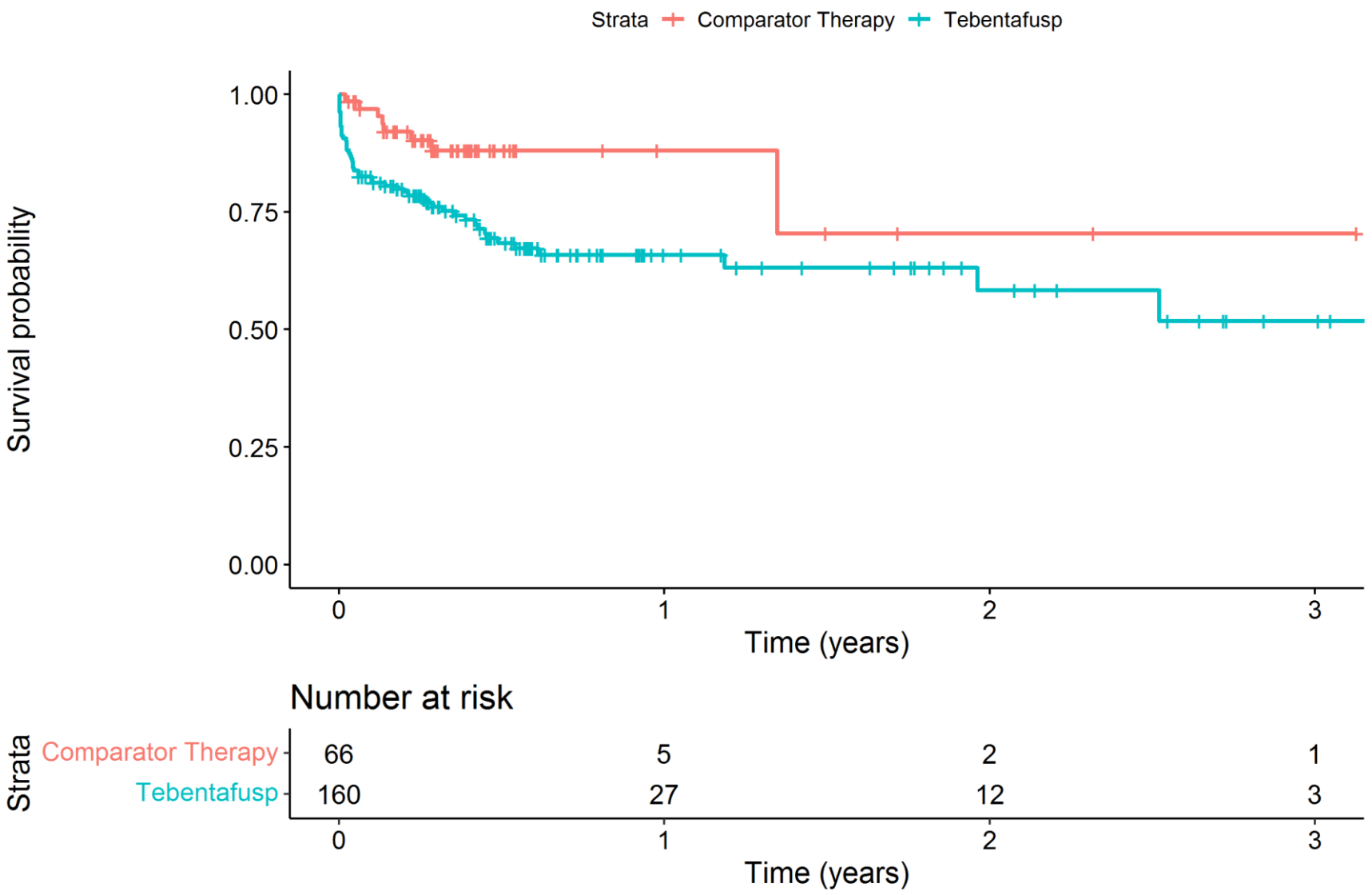
61.39 Augenerkrankungen- Läsion ≥8,1 cm



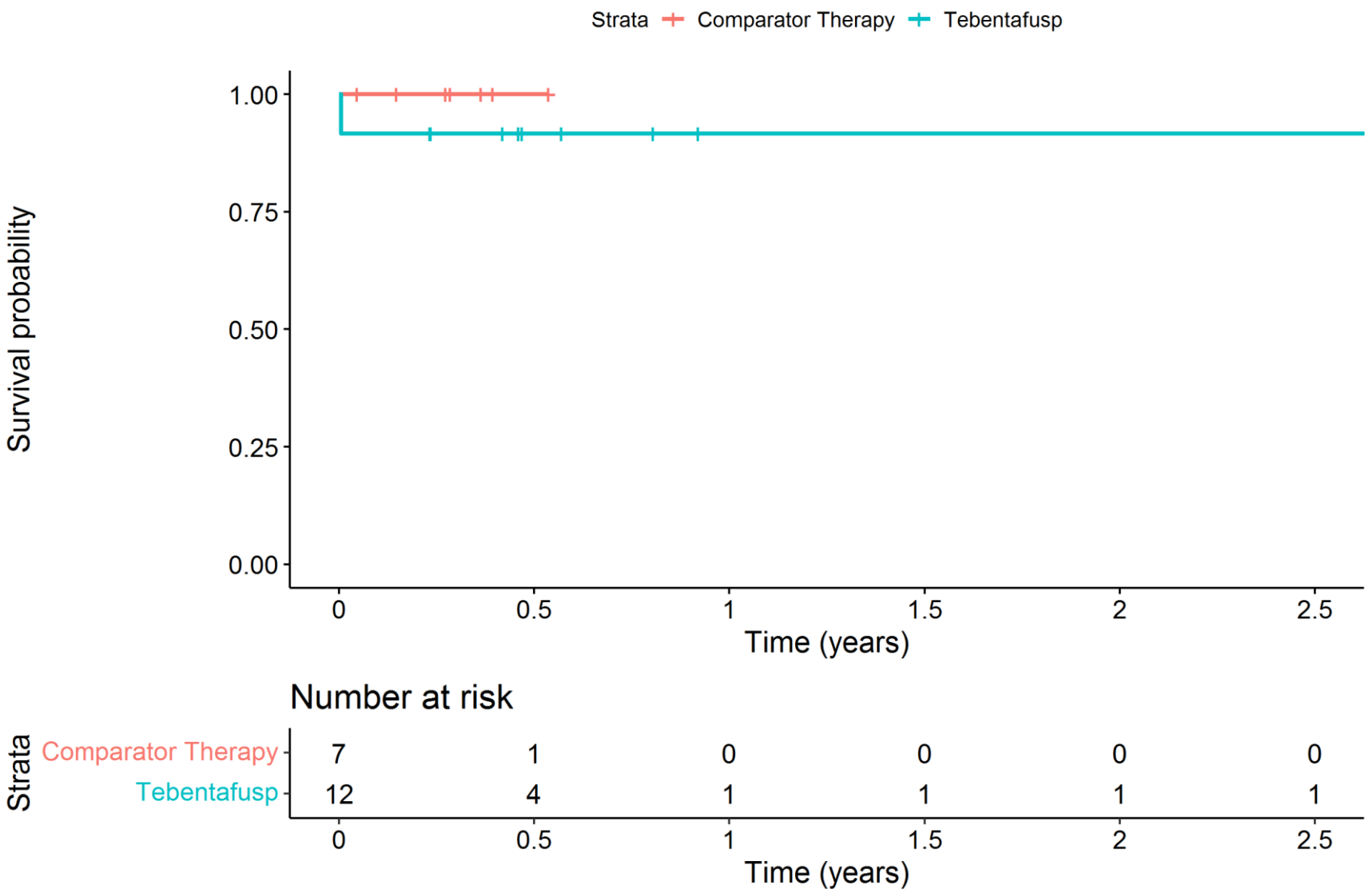
61.40 Augenerkrankungen- Nordamerika



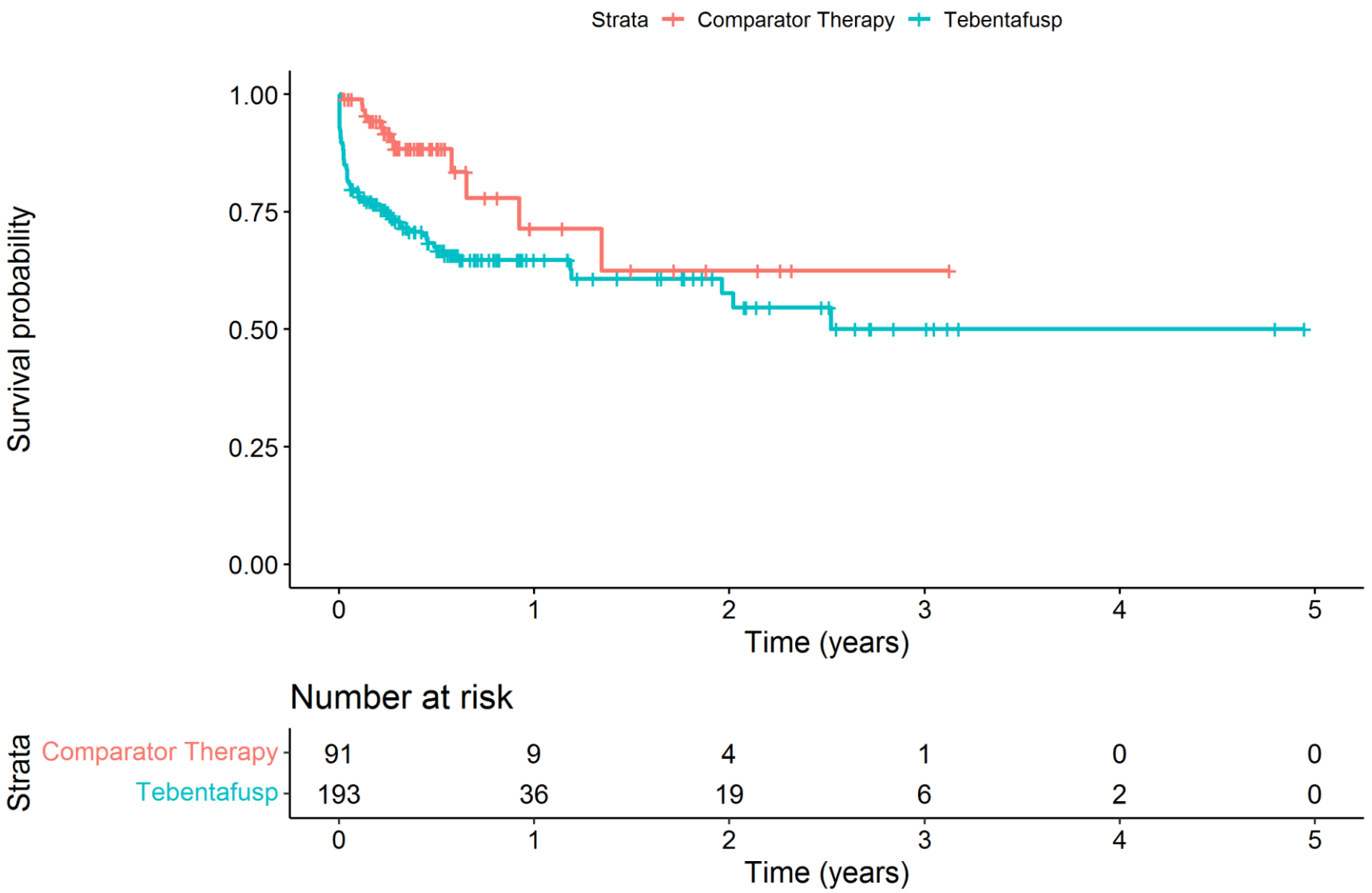
61.41 Augenerkrankungen- Nicht-Nordamerika



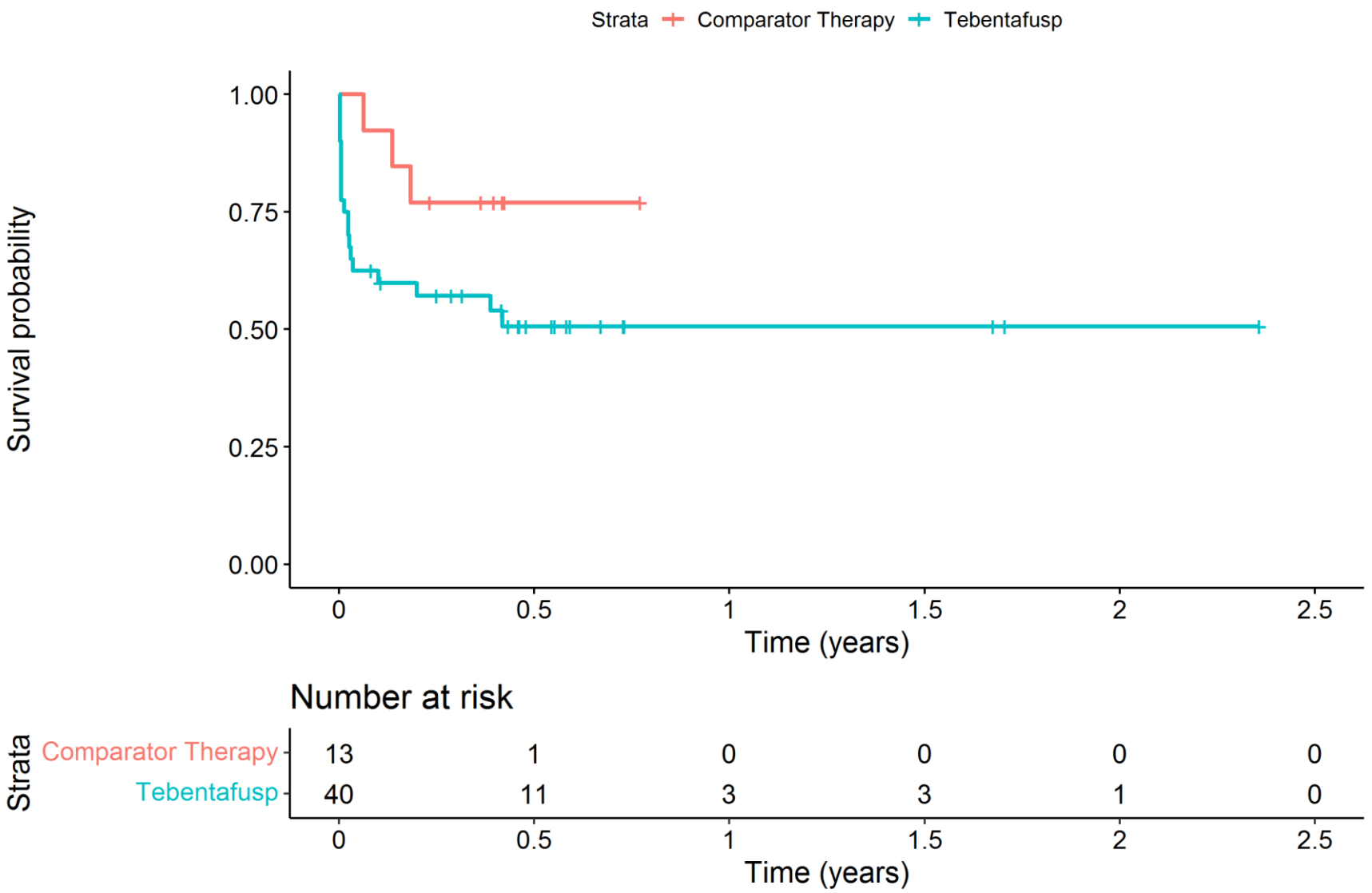
61.42 Augenerkrankungen- Dacarbazin



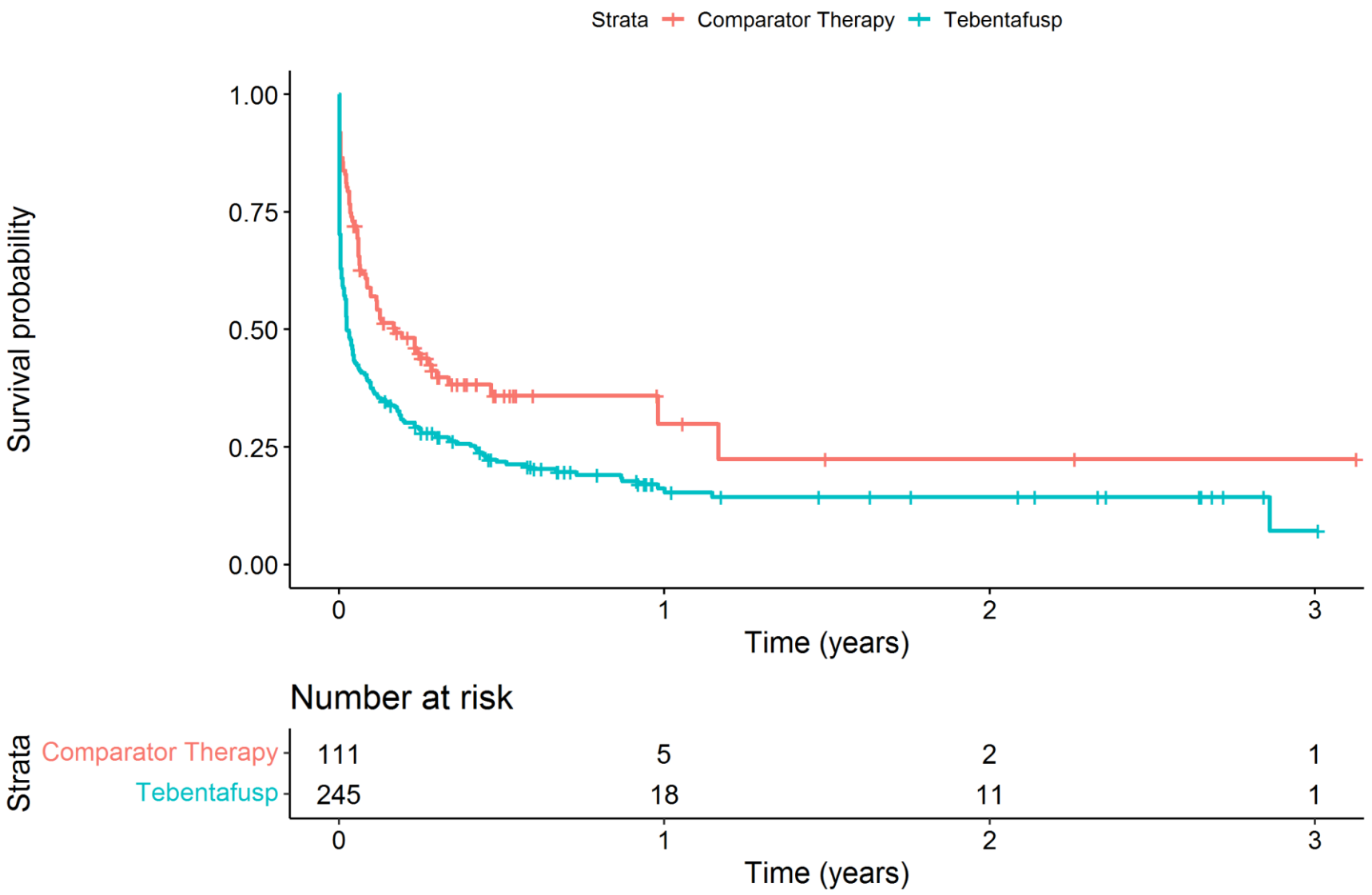
61.43 Augenerkrankungen- Pembrolizumab



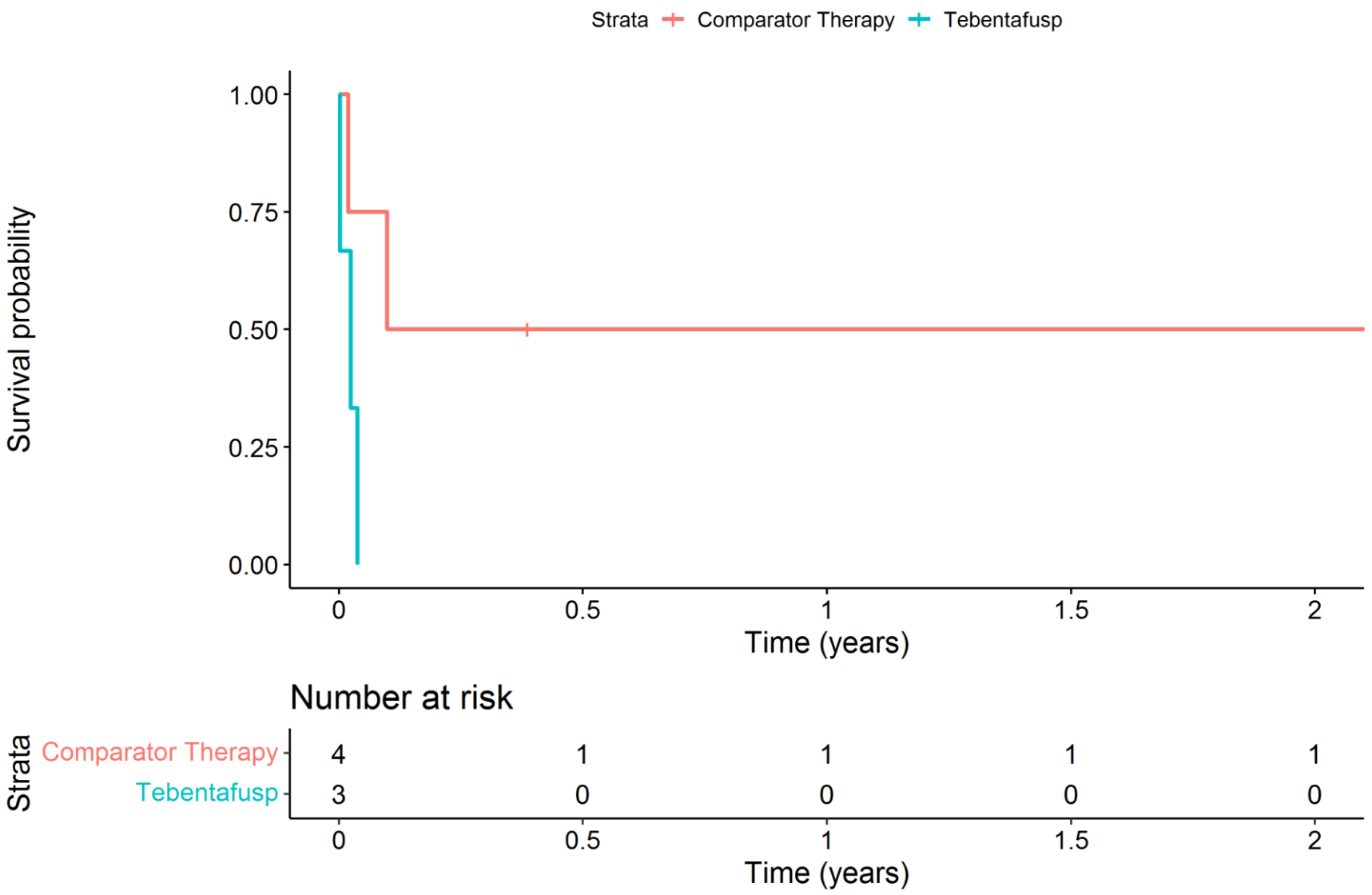
61.44 Augenerkrankungen- Ipilimumab



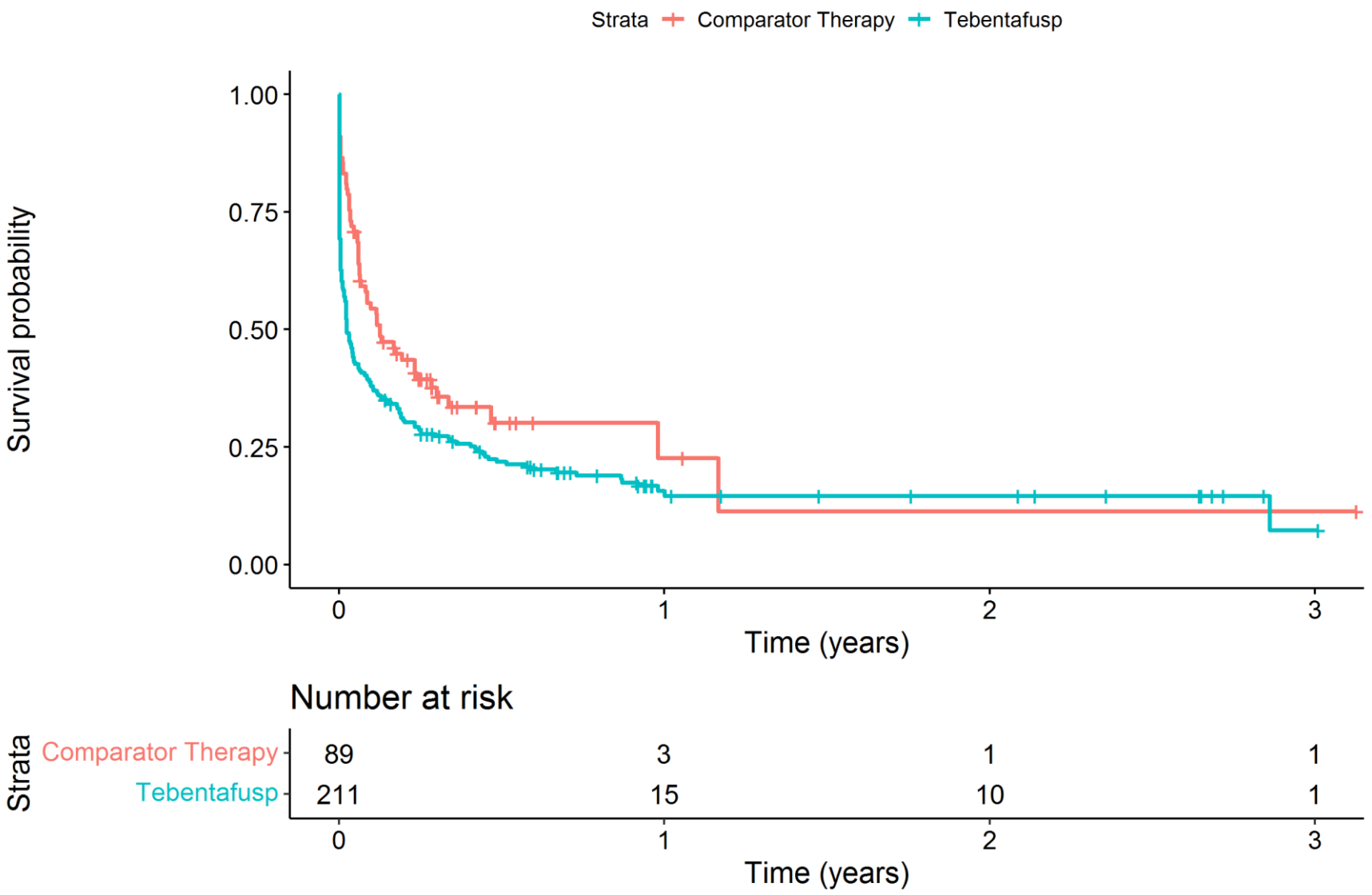
61.45 Erkrankungen des Gastrointestinaltrakts- Gesamt



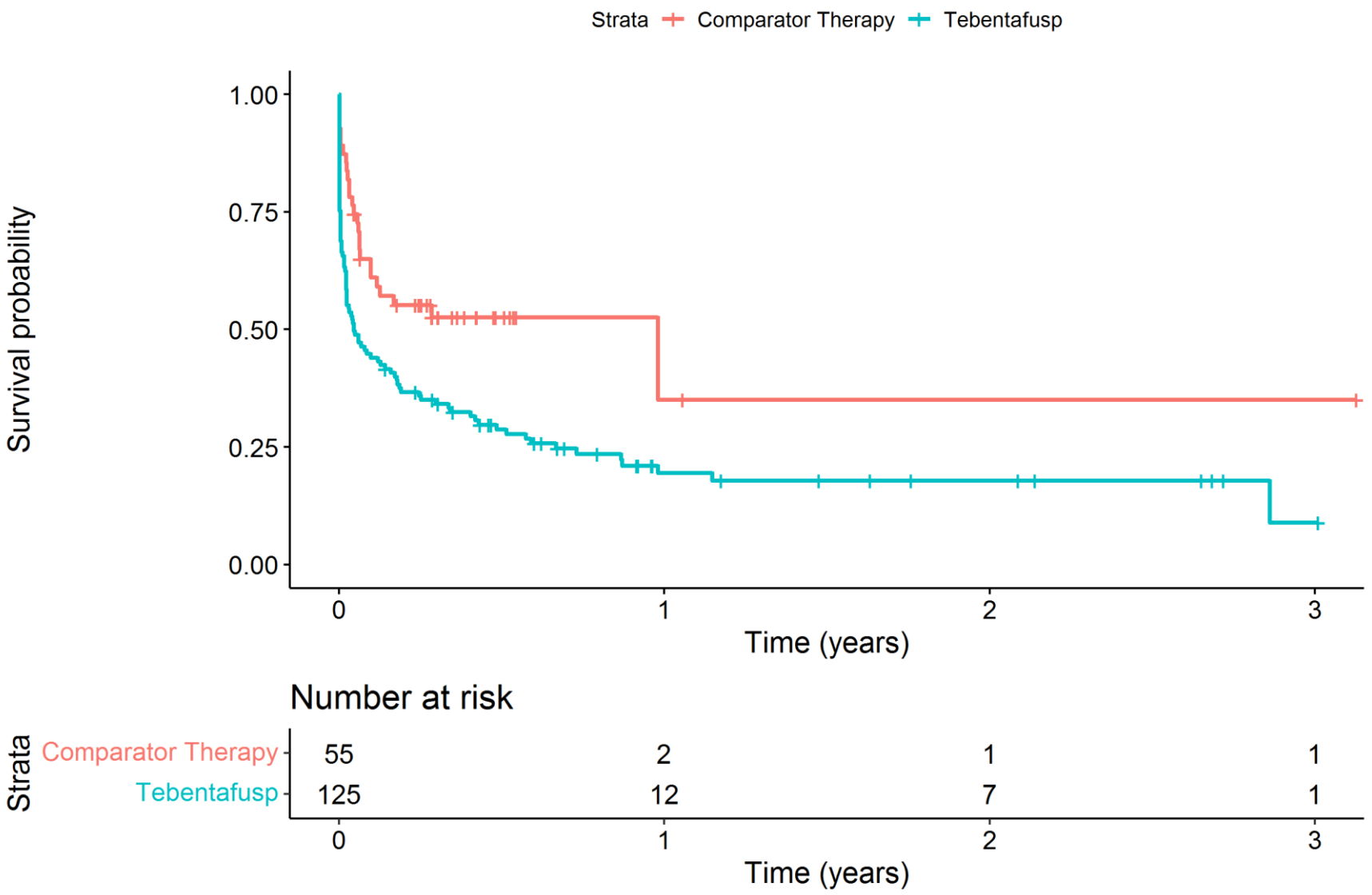
61.46 Erkrankungen des Gastrointestinaltrakts- Hispanisch



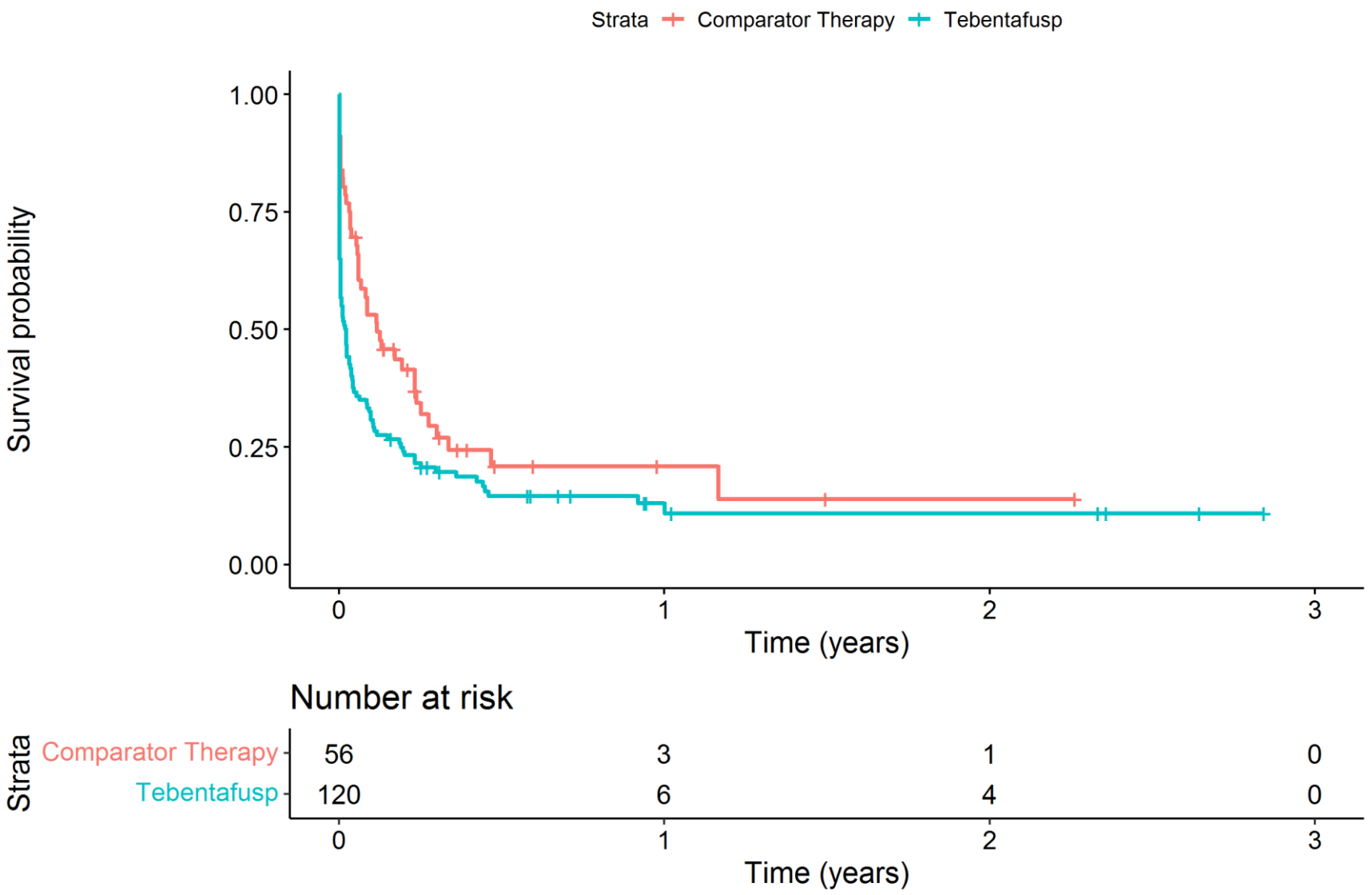
61.47 Erkrankungen des Gastrointestinaltrakts- Nicht-hispanisch



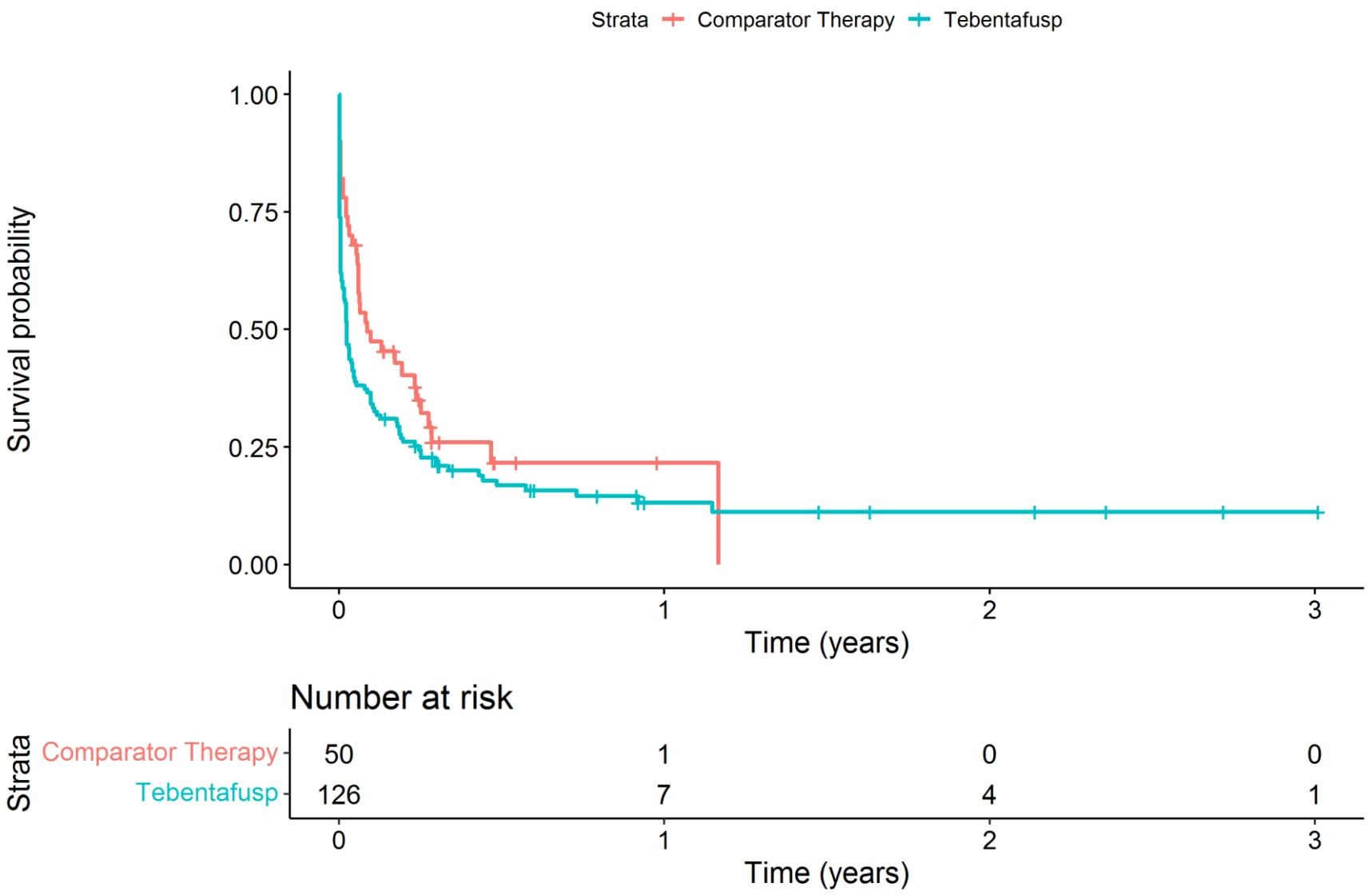
61.48 Erkrankungen des Gastrointestinaltrakts- Männlich



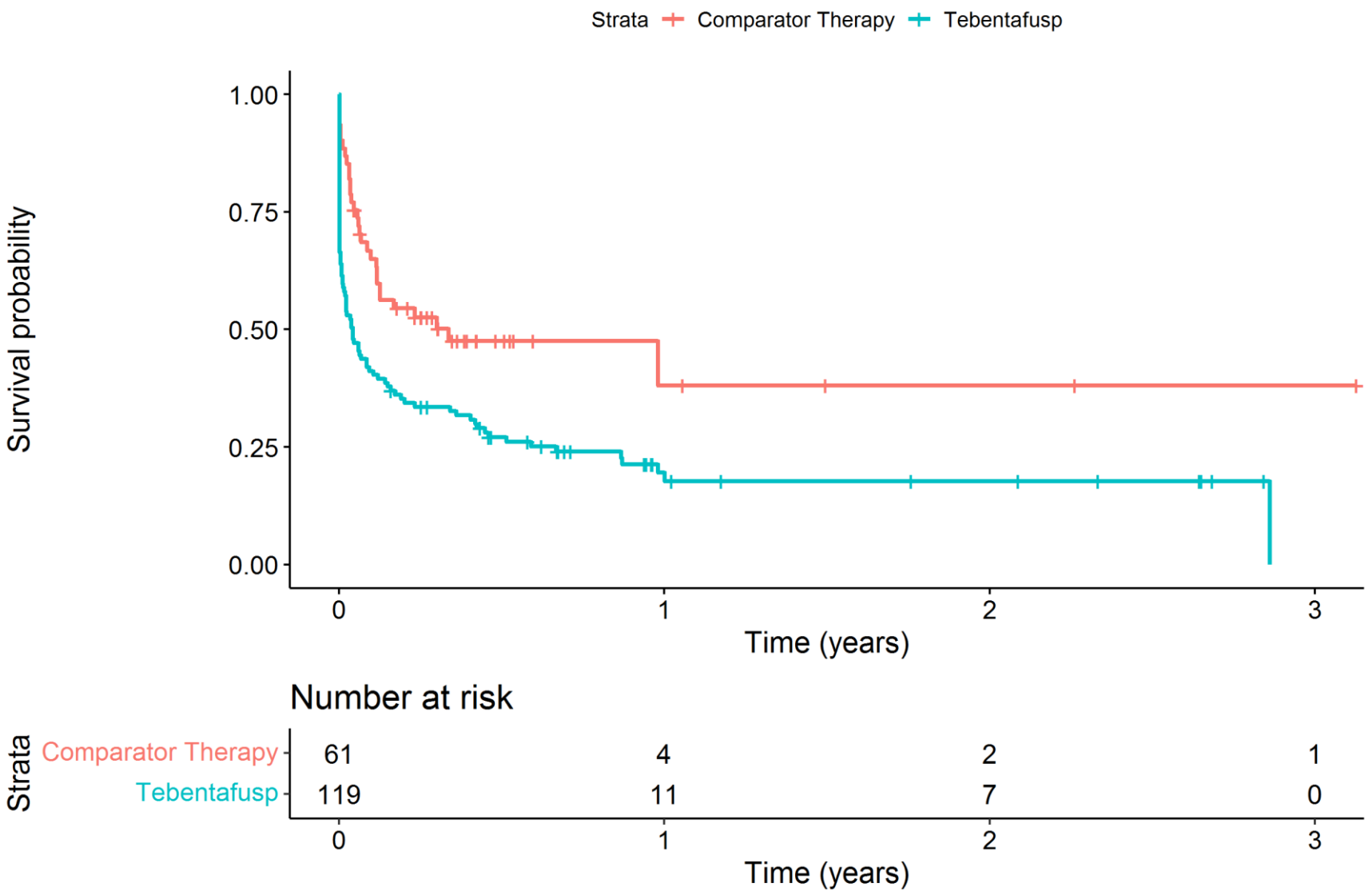
61.49 Erkrankungen des Gastrointestinaltrakts- Weiblich



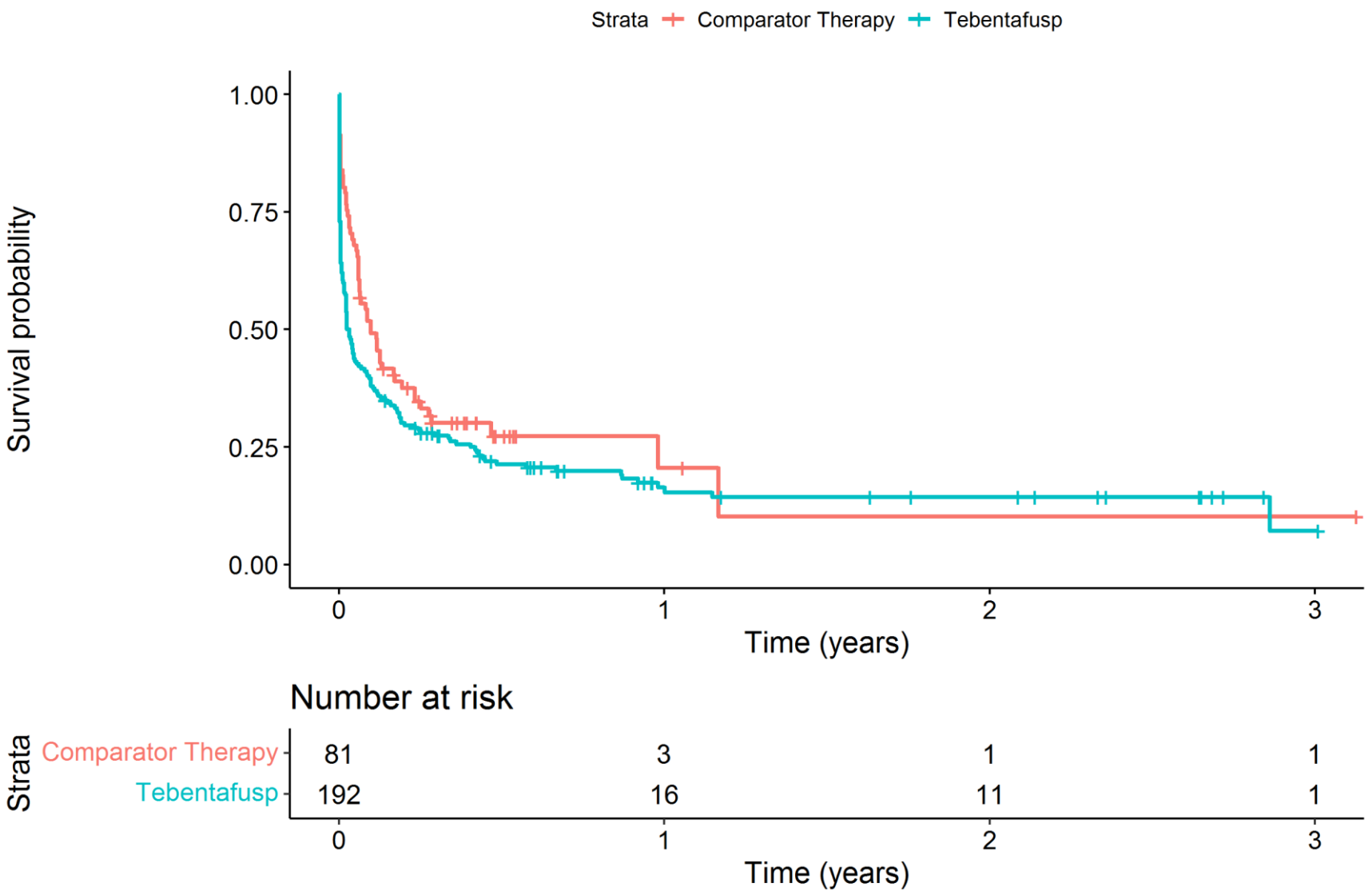
61.50 Erkrankungen des Gastrointestinaltrakts- <65



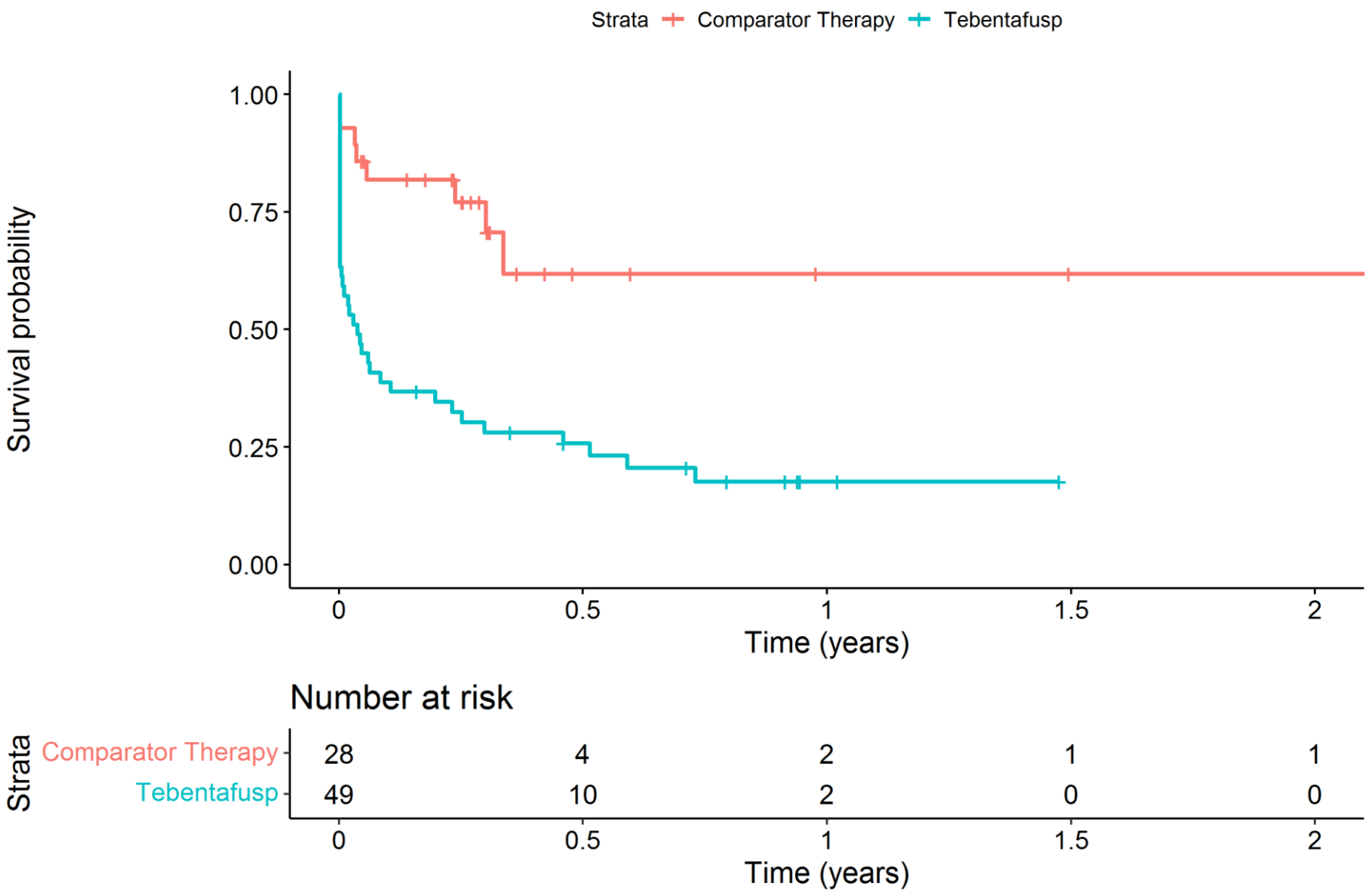
61.51 Erkrankungen des Gastrointestinaltrakts- ≥65



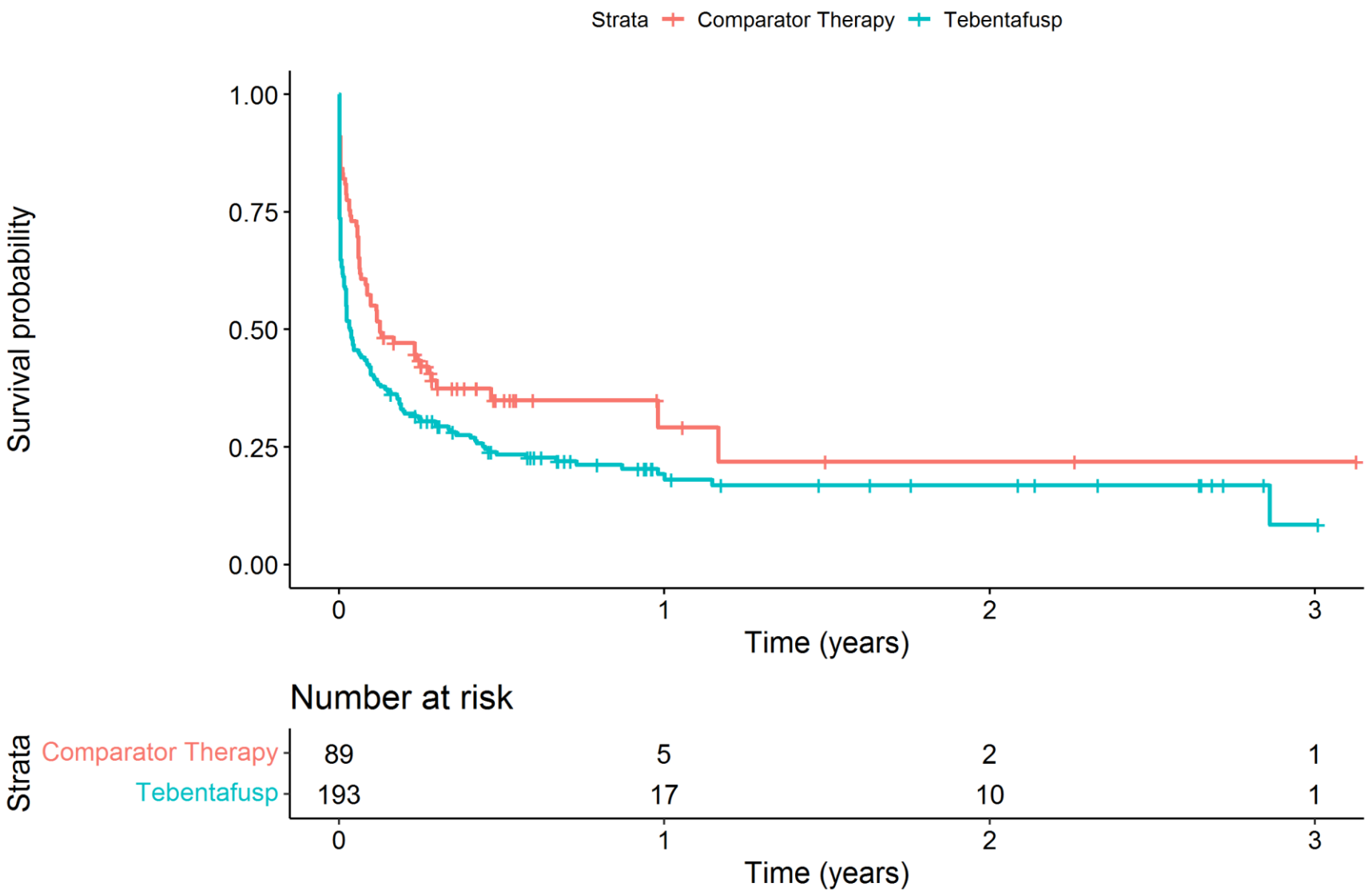
61.52 Erkrankungen des Gastrointestinaltrakts- ECOG 0



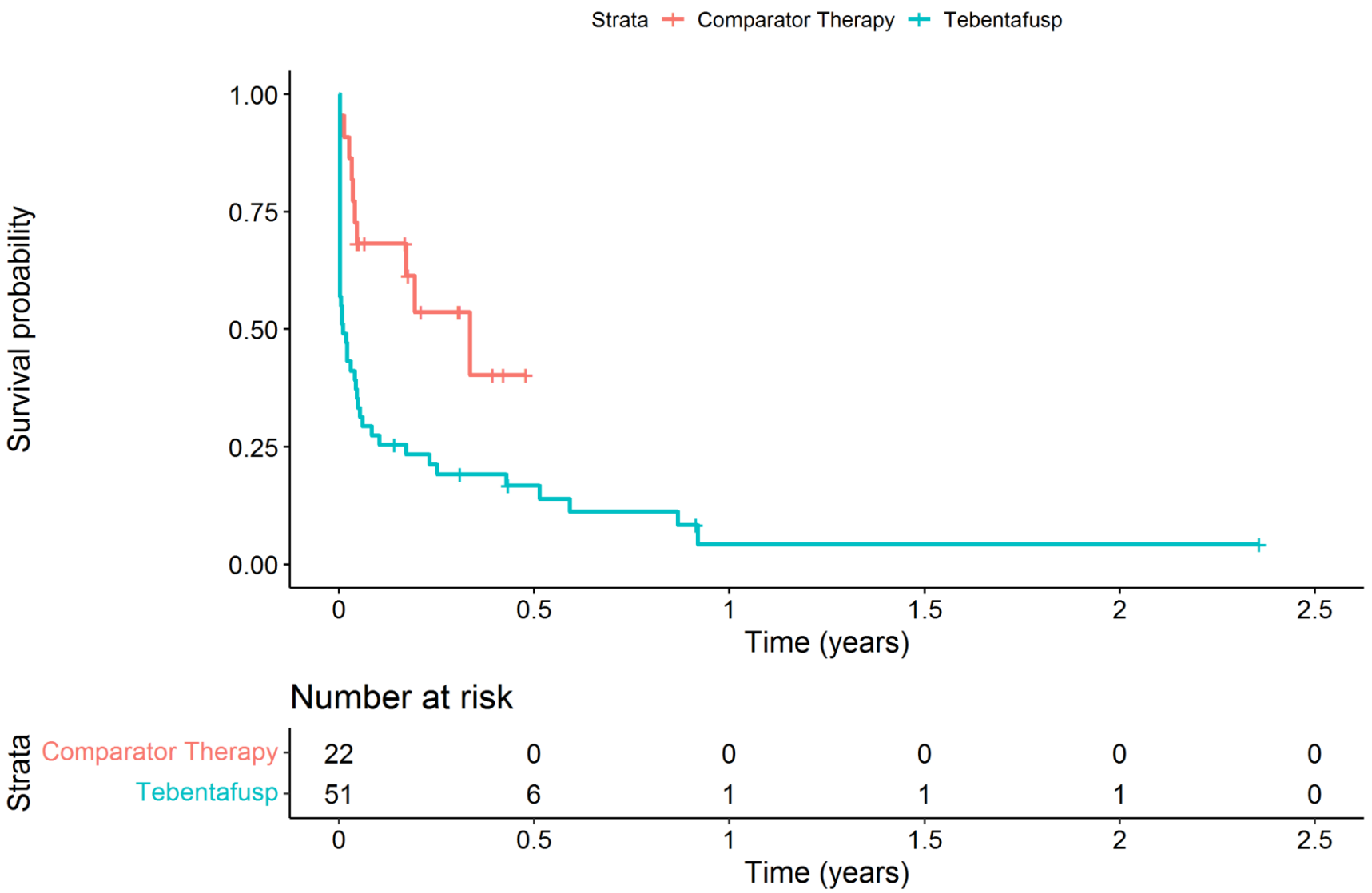
61.53 Erkrankungen des Gastrointestinaltrakts- ECOG 1



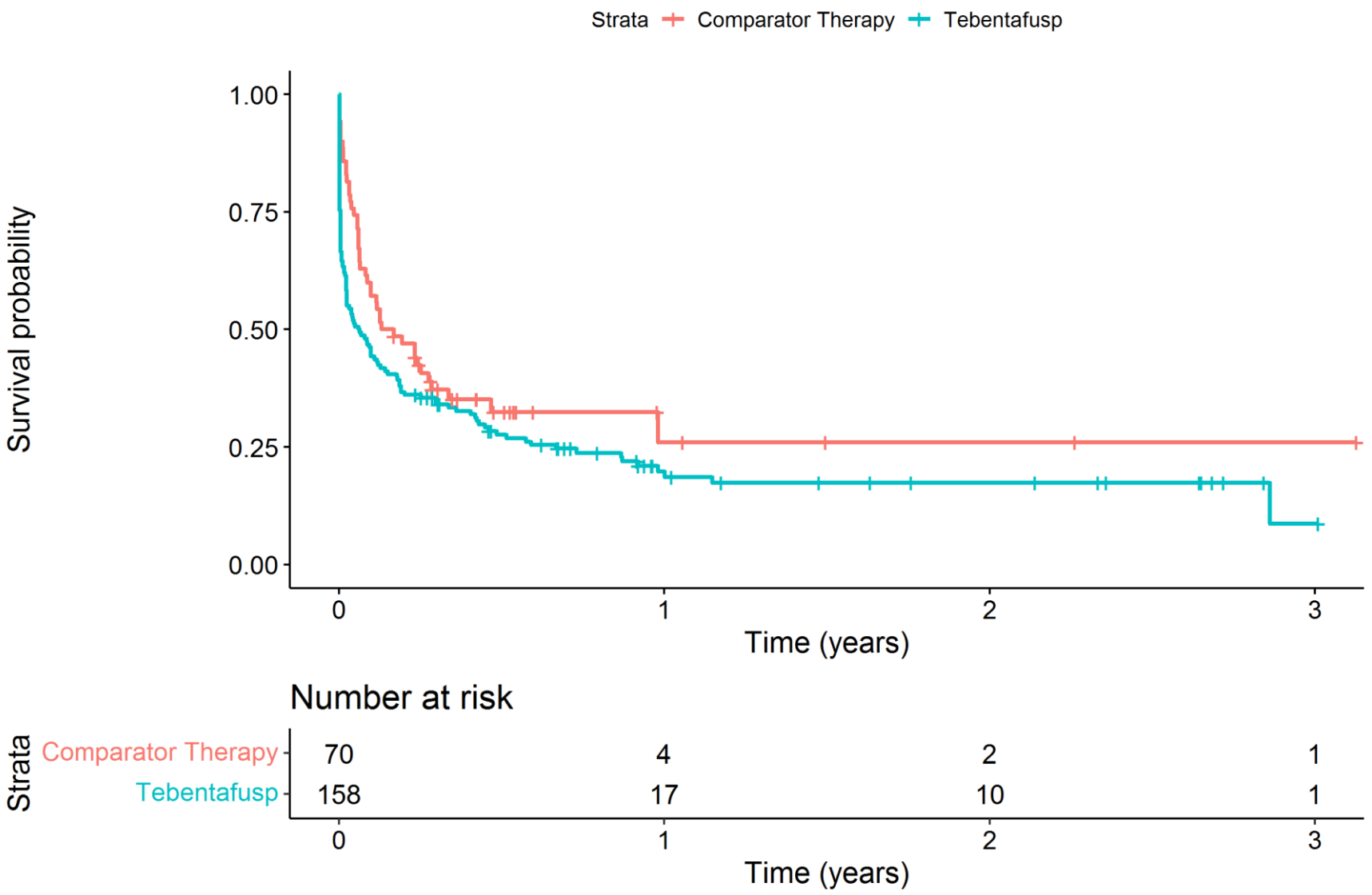
61.54 Erkrankungen des Gastrointestinaltrakts- ALP ≤ ULN



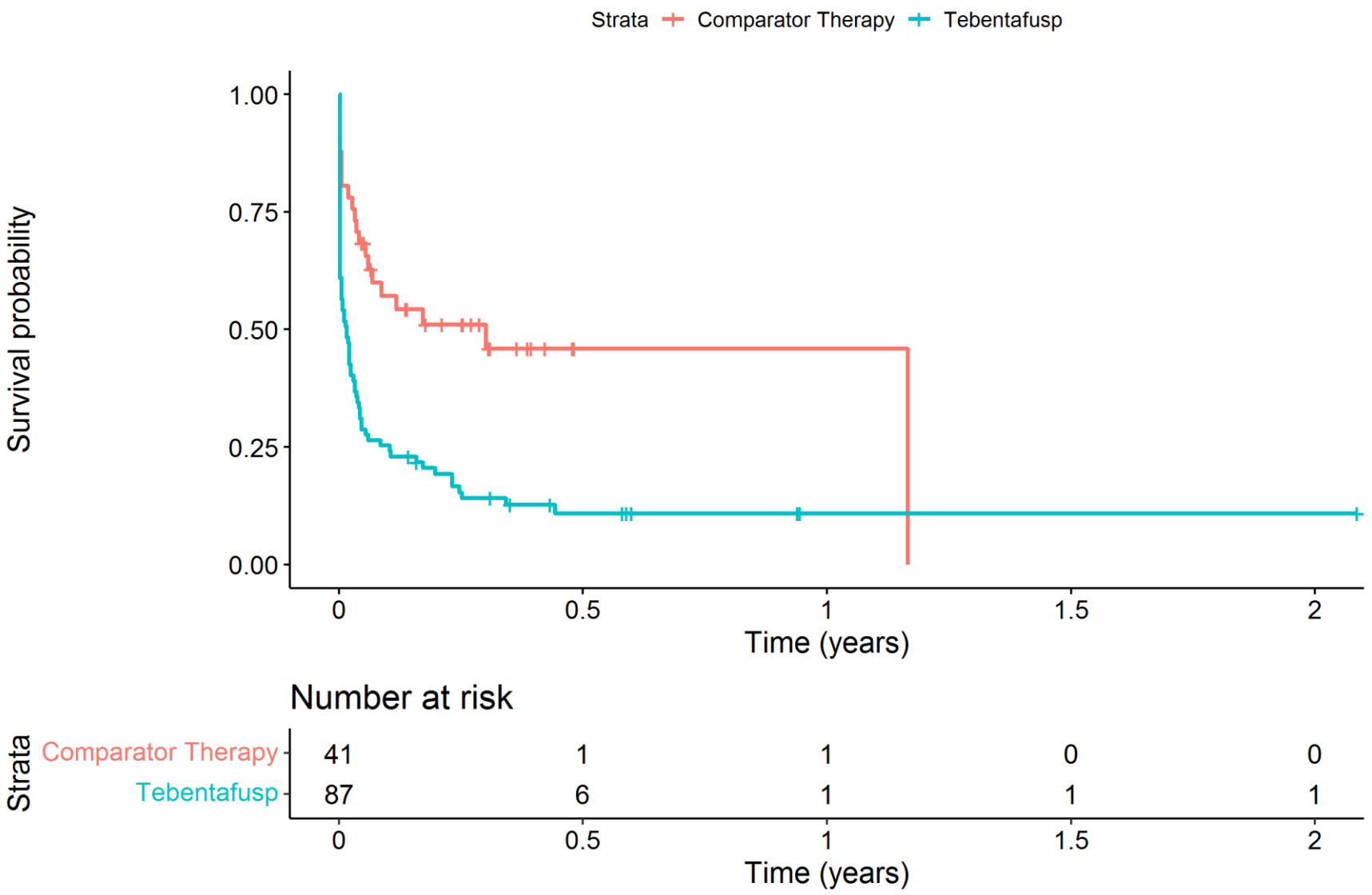
61.55 Erkrankungen des Gastrointestinaltrakts- ALP > ULN



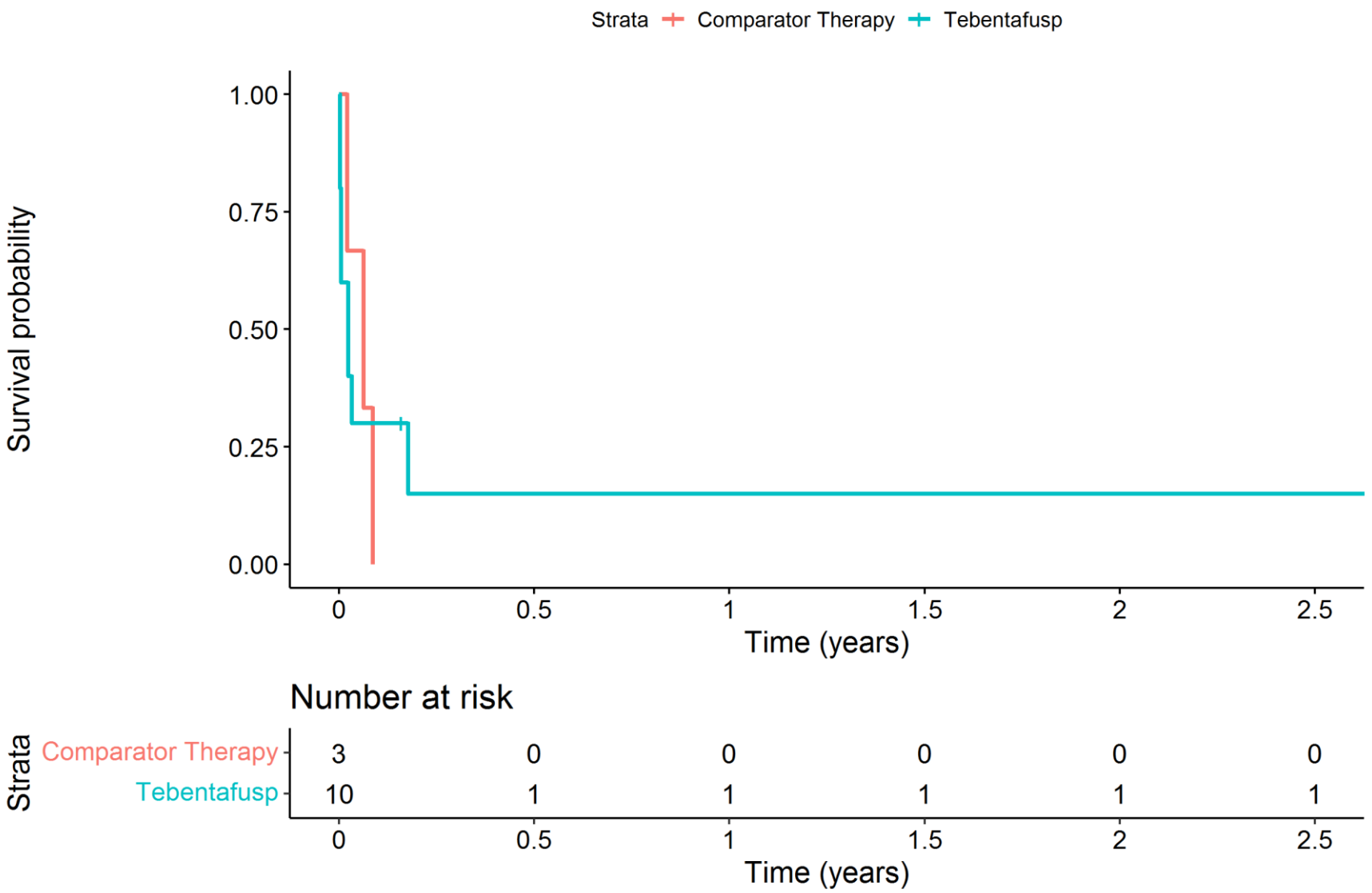
61.56 Erkrankungen des Gastrointestinaltrakts- LDH =< ULN



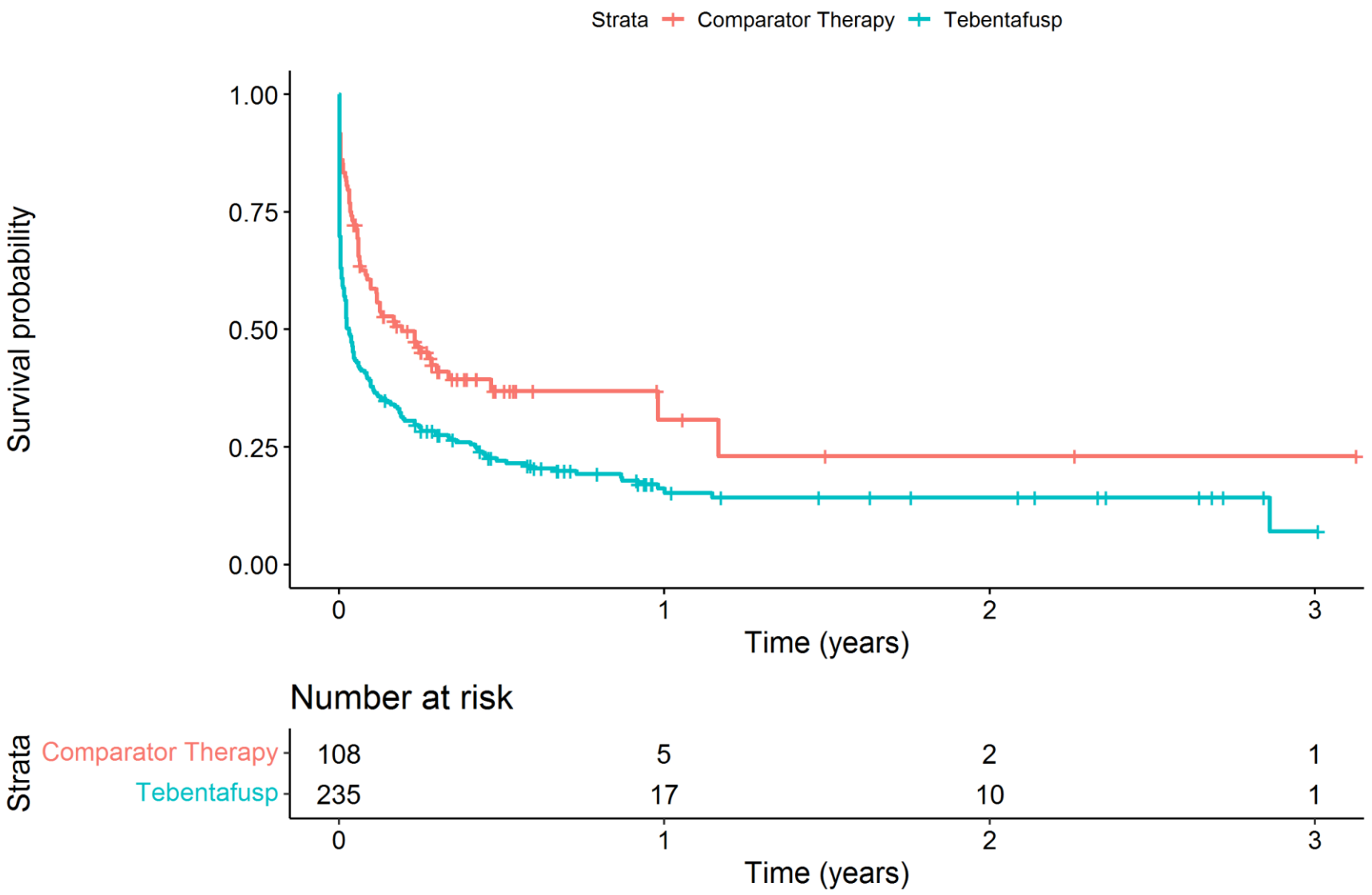
61.57 Erkrankungen des Gastrointestinaltrakts- LDH > ULN



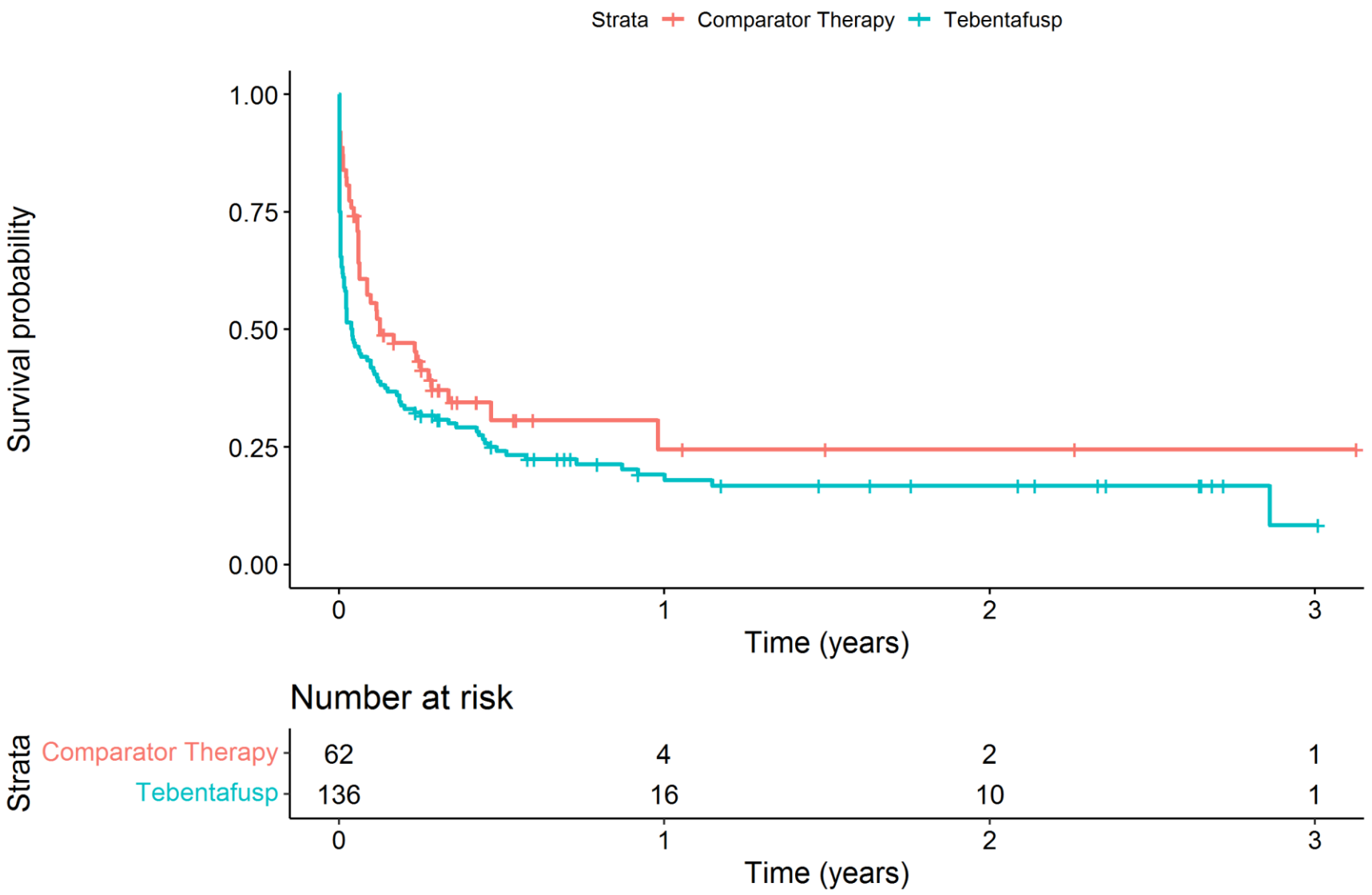
61.58 Erkrankungen des Gastrointestinaltrakts- Vorherige Therapie adjuvant/neoadjuvant



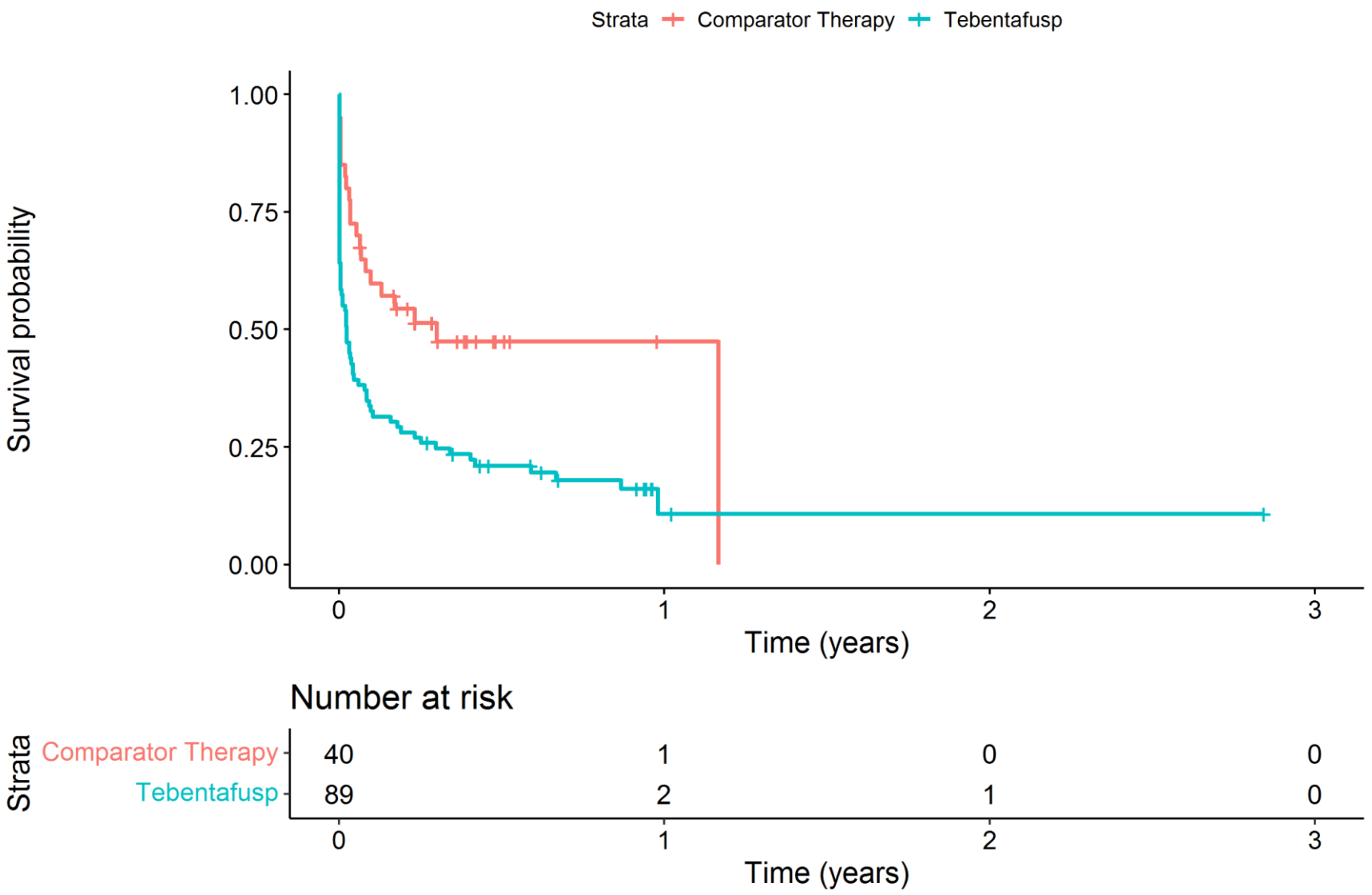
61.59 Erkrankungen des Gastrointestinaltrakts- Keine Vorherige Therapie adjuvant/neoadjuvant



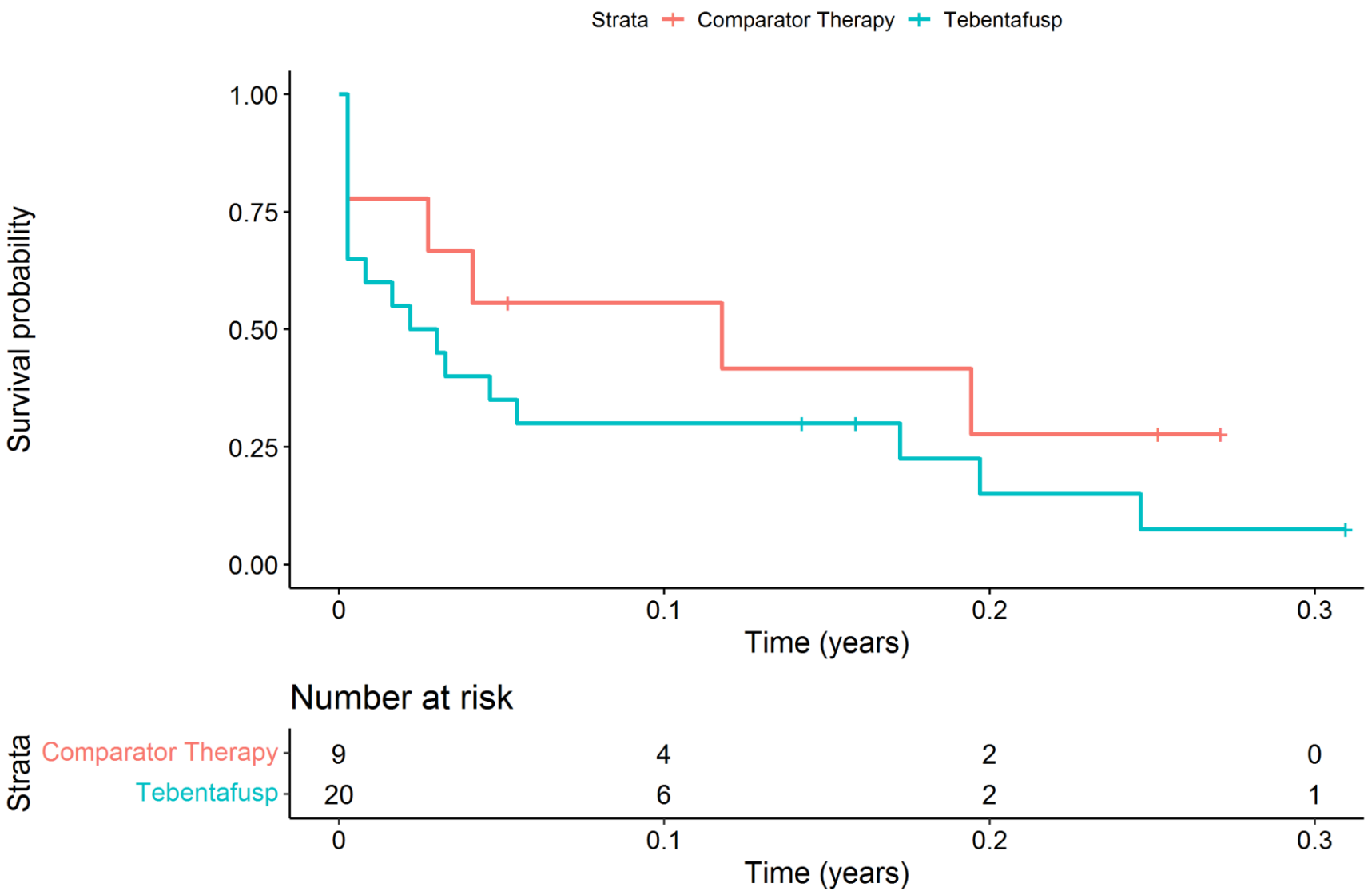
61.60 Erkrankungen des Gastrointestinaltrakts- Läsion ≤ 3cm



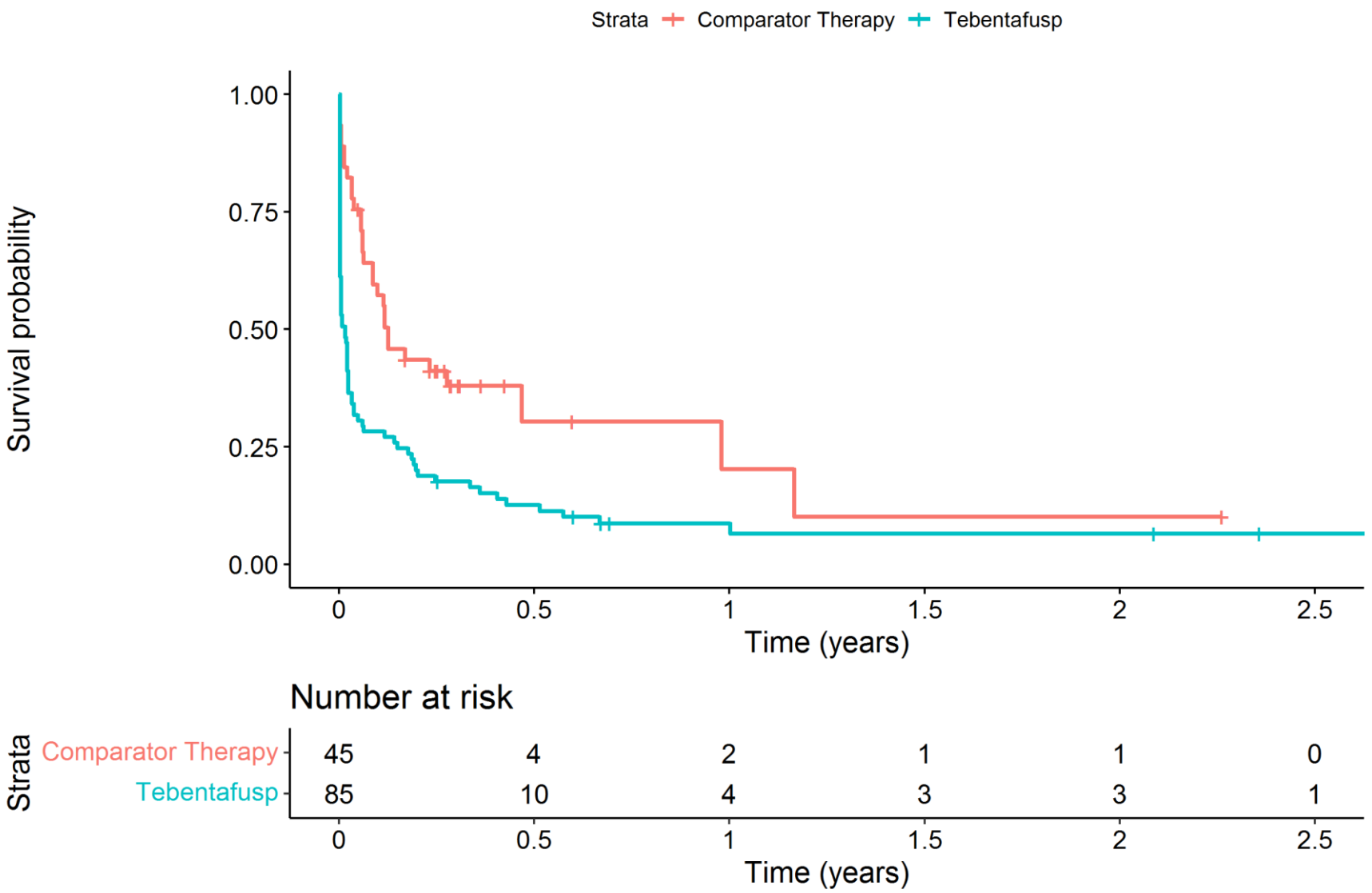
61.61 Erkrankungen des Gastrointestinaltrakts- Läsion 3,1-8,0 cm



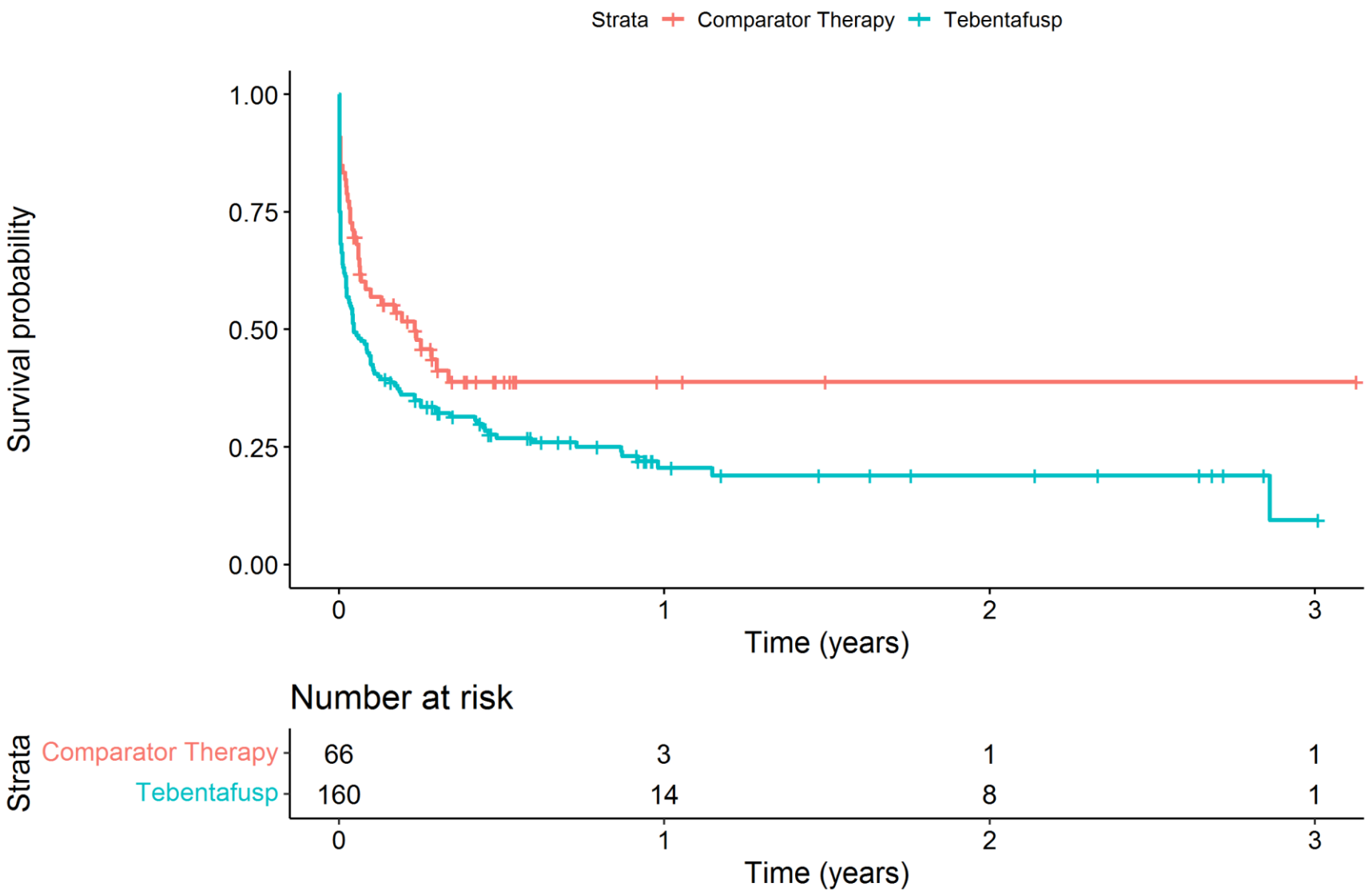
61.62 Erkrankungen des Gastrointestinaltrakts- Läsion ≥8,1 cm



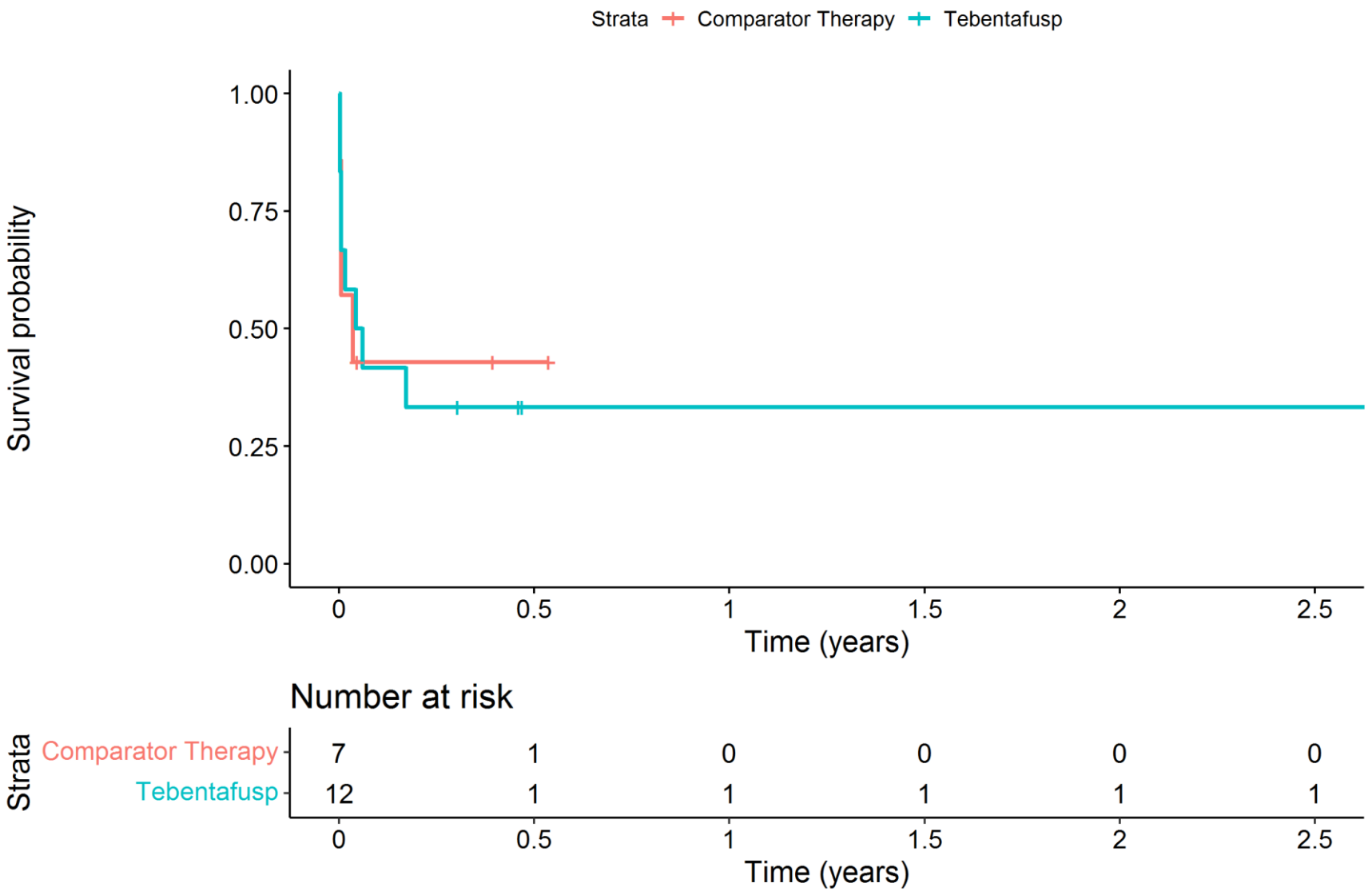
61.63 Erkrankungen des Gastrointestinaltrakts- Nordamerika



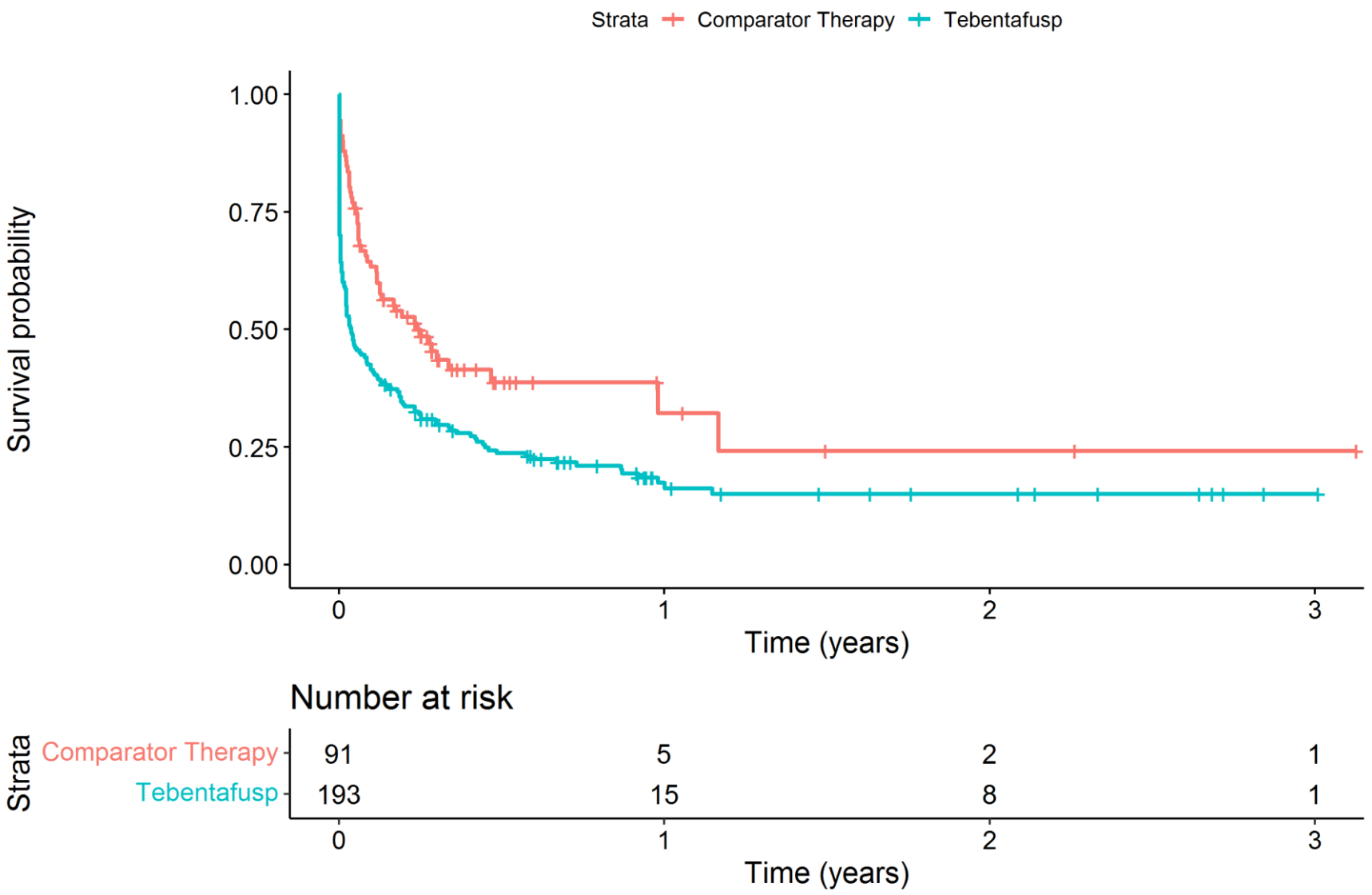
61.64 Erkrankungen des Gastrointestinaltrakts- Nicht-Nordamerika



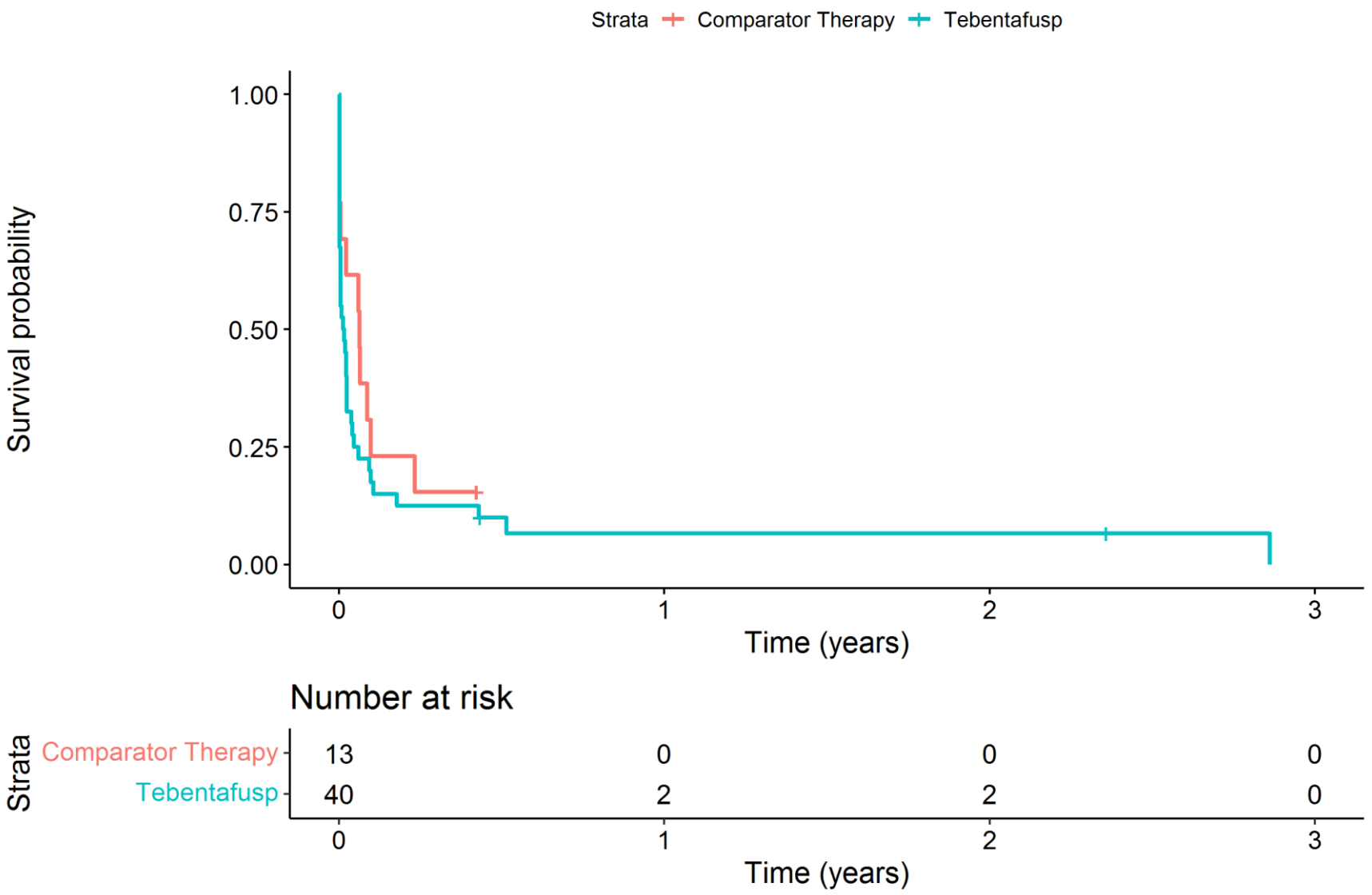
Erkrankungen des Gastrointestinaltrakts- Dacarbazin



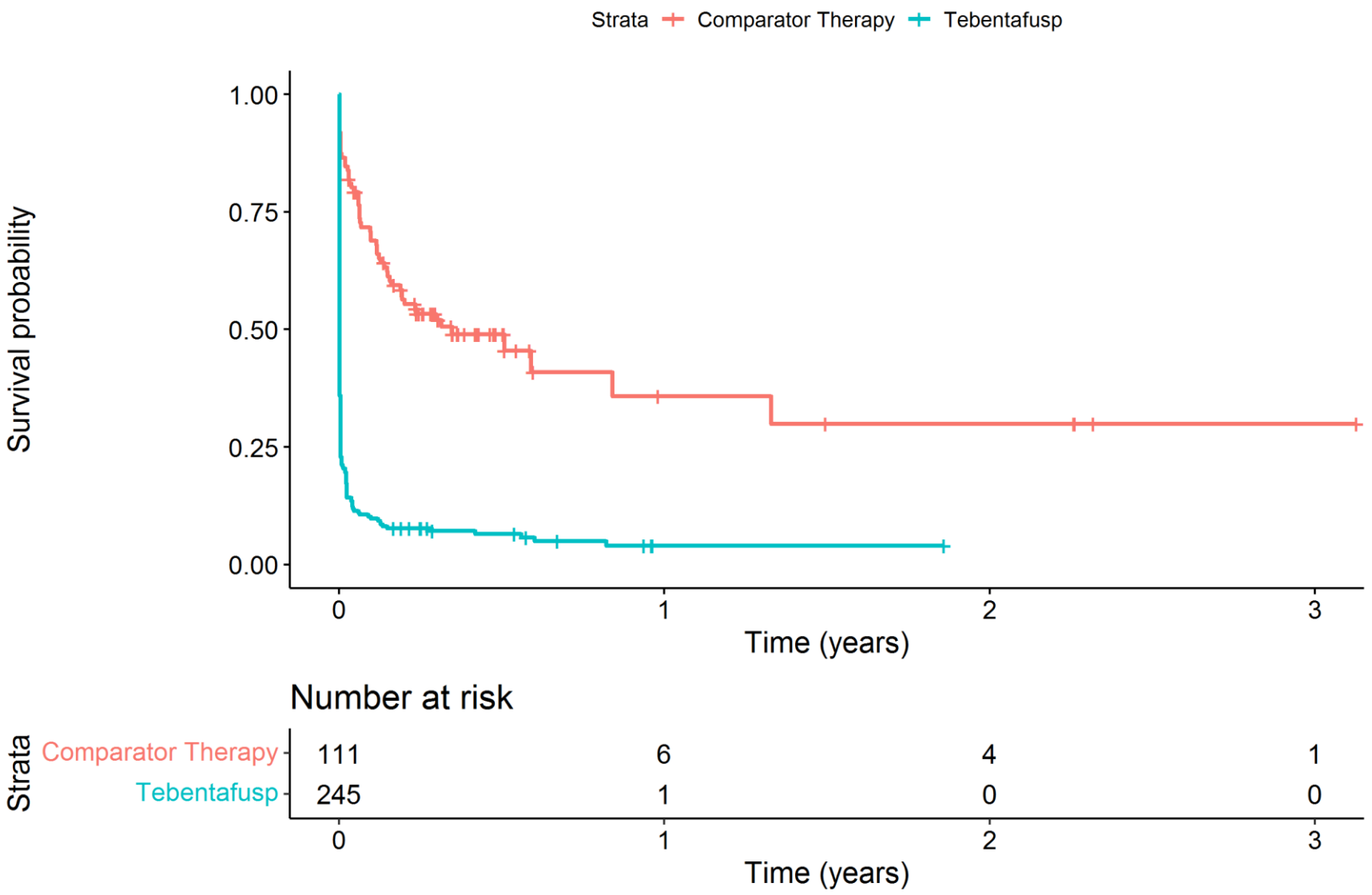
61.65 Erkrankungen des Gastrointestinaltrakts- Pembrolizumab



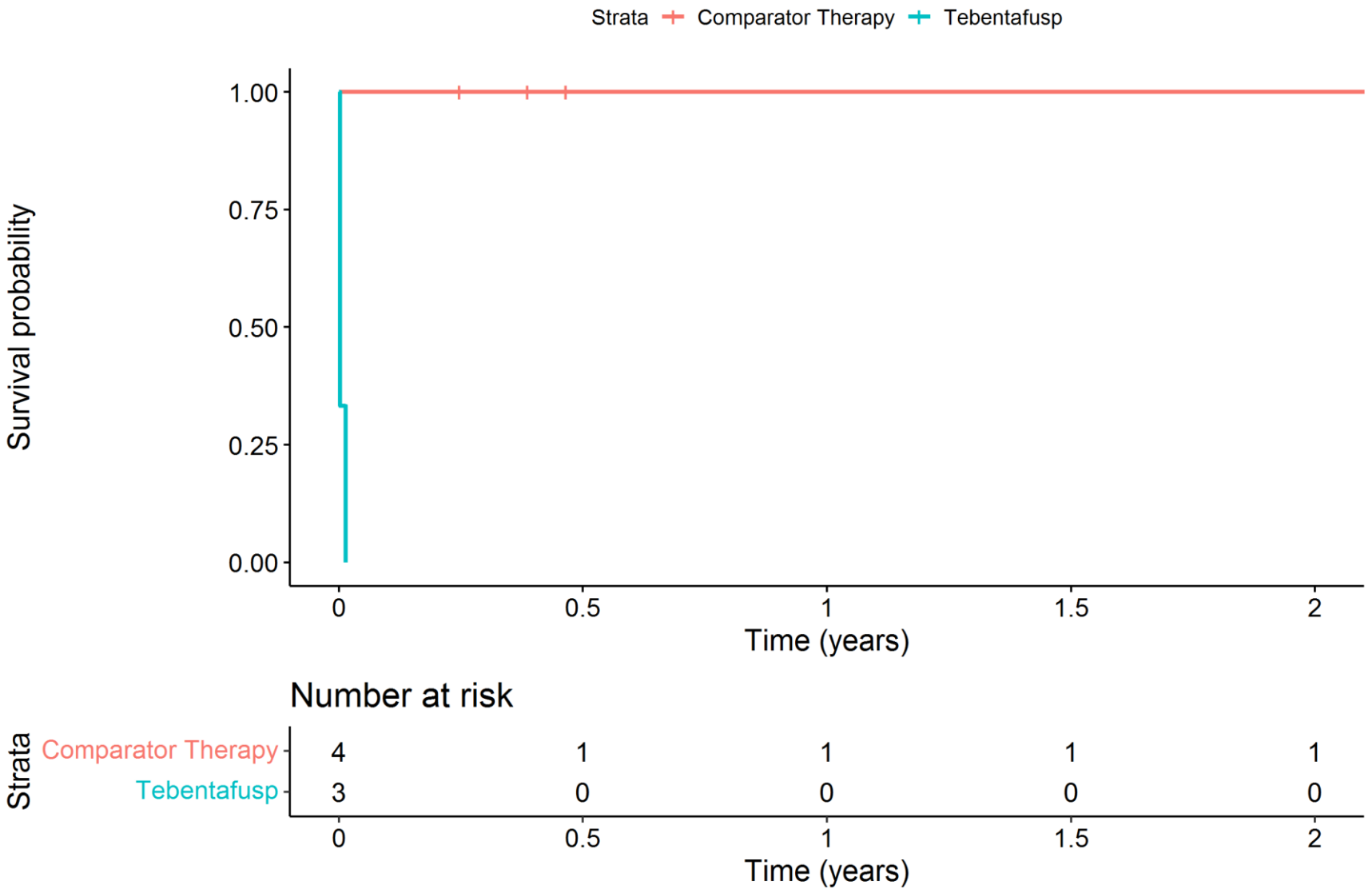
61.66 Erkrankungen des Gastrointestinaltrakts- Ipilimumab



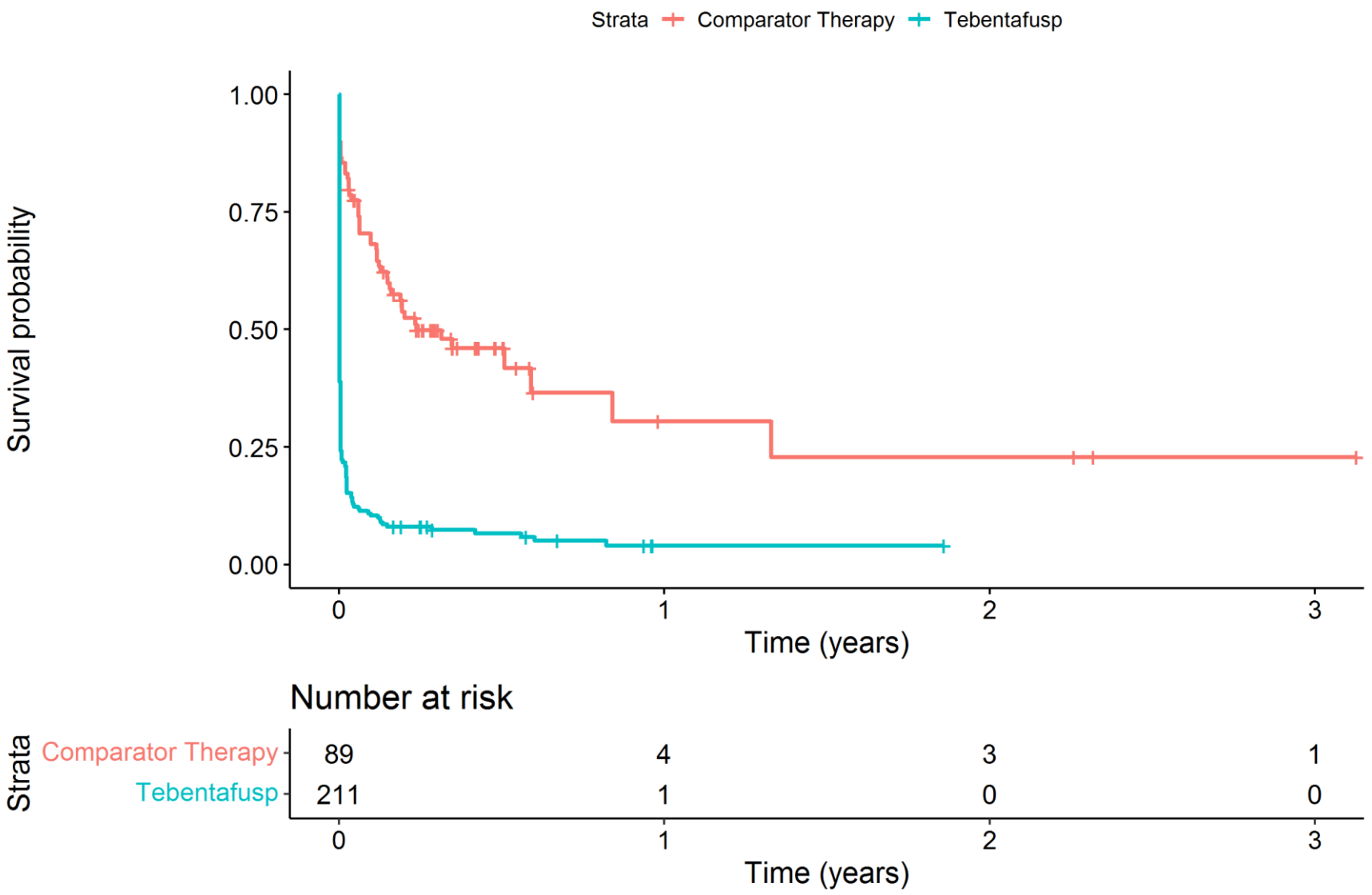
61.67 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Gesamt



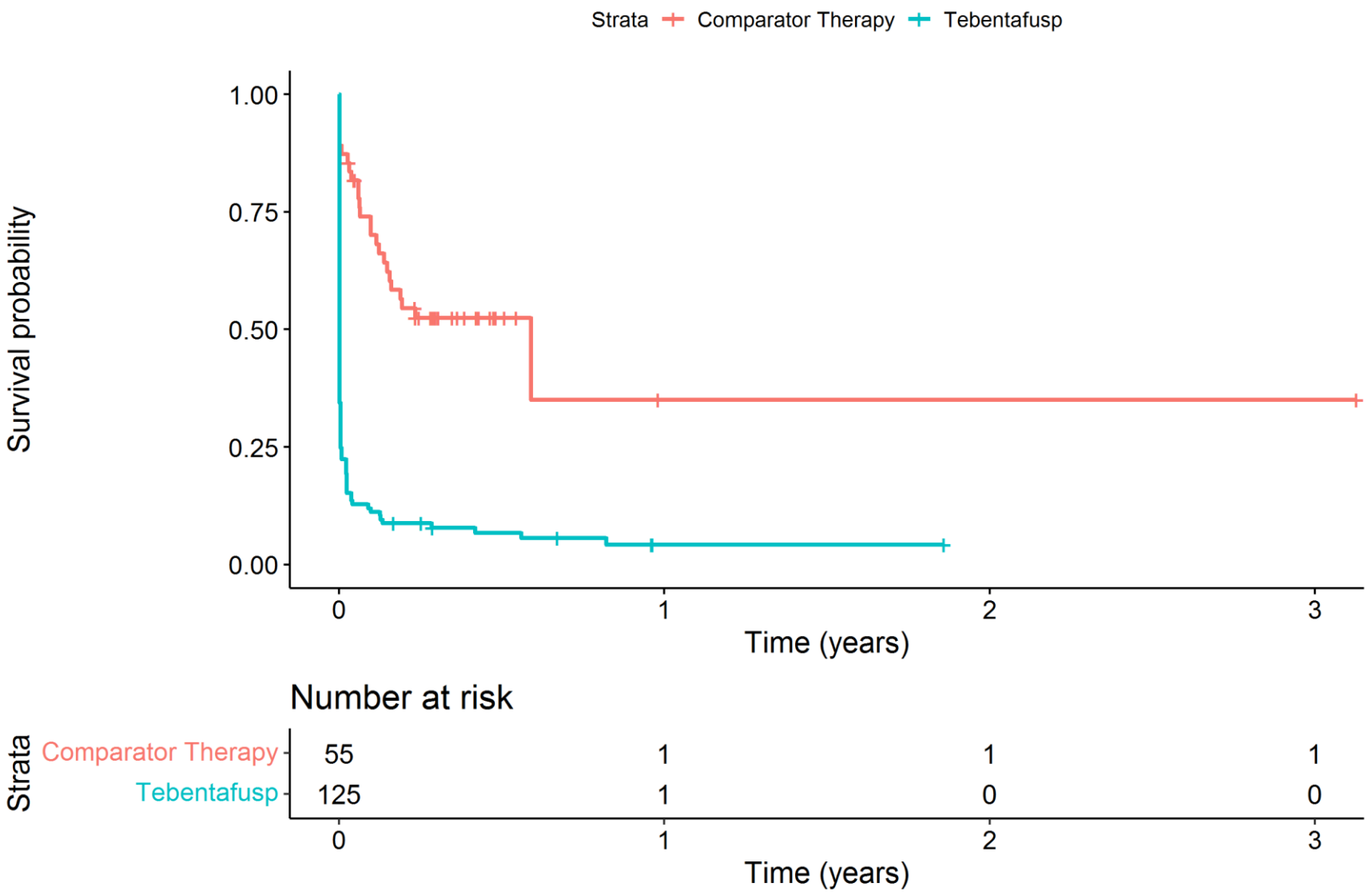
61.68 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Hispanisch



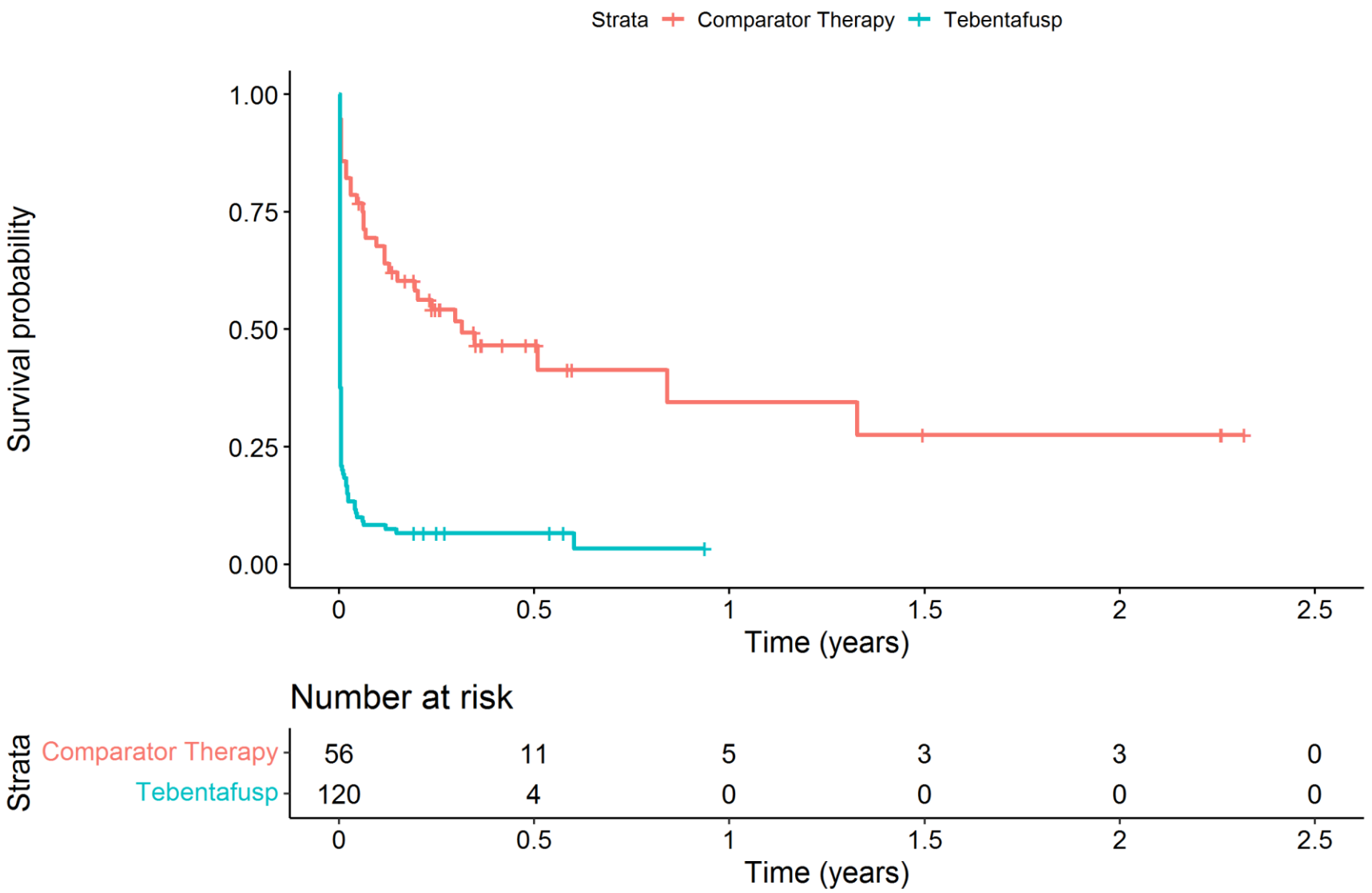
61.69 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nicht-hispanisch



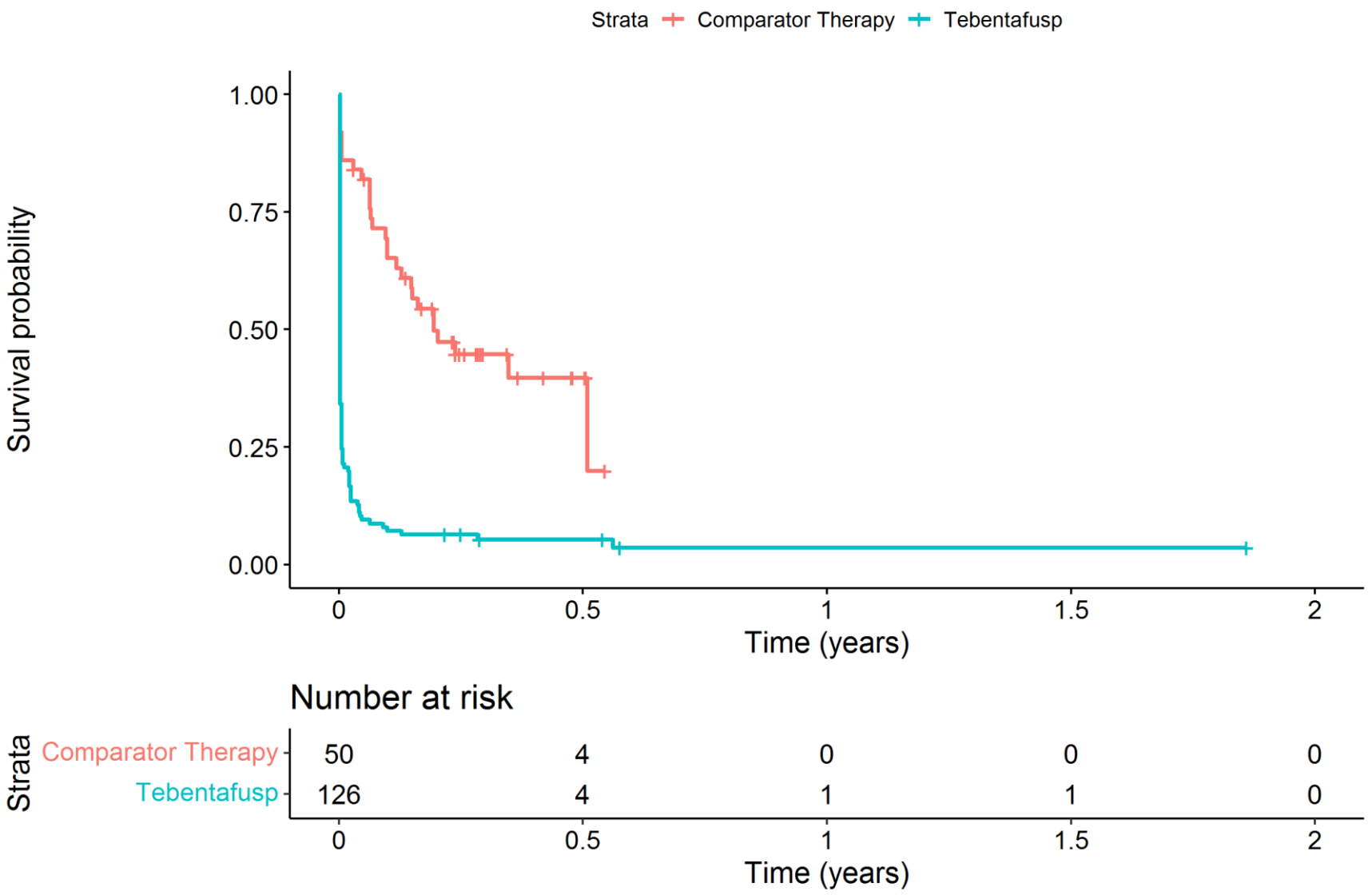
61.70 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Männlich



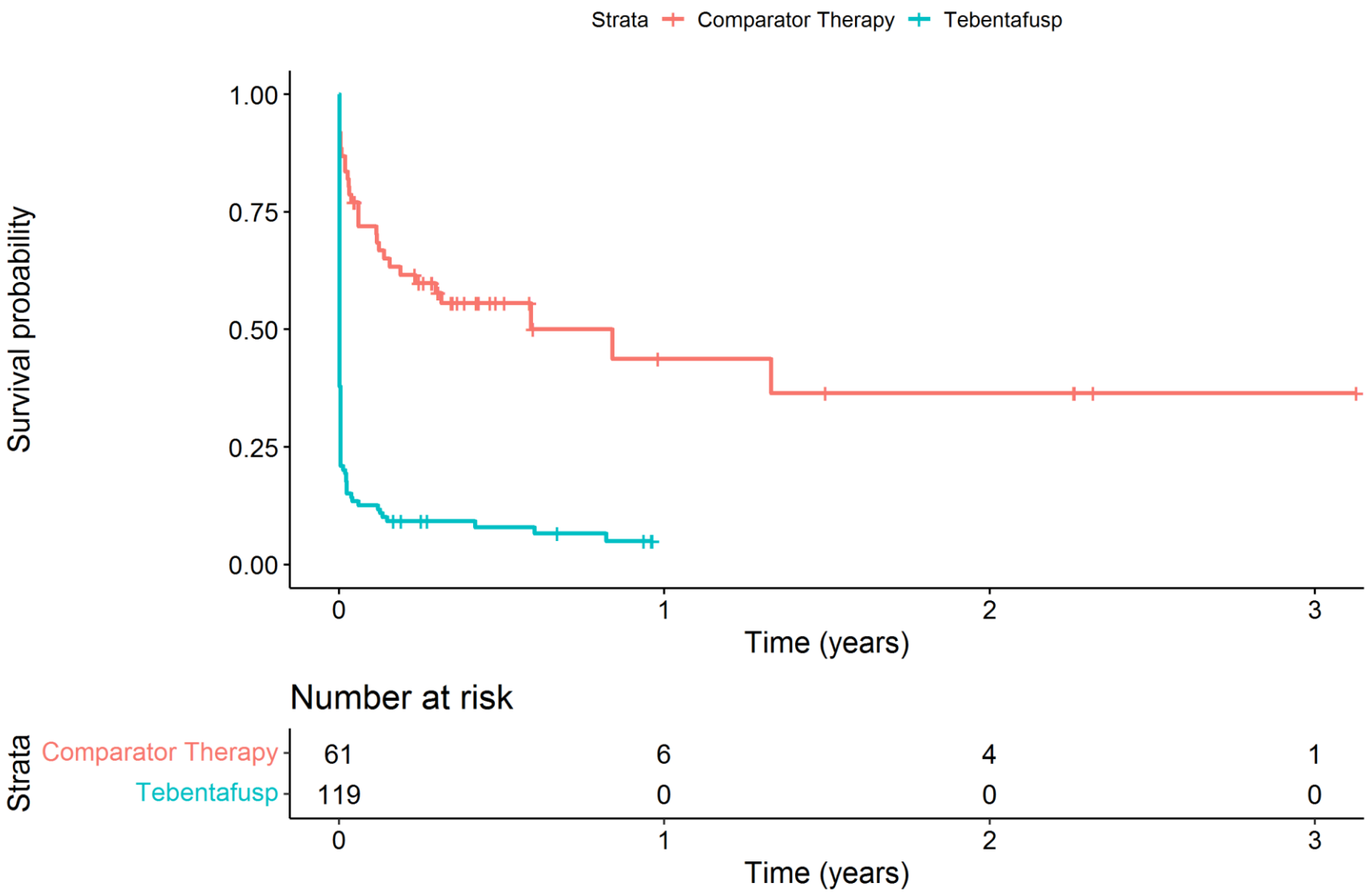
61.71 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Weiblich



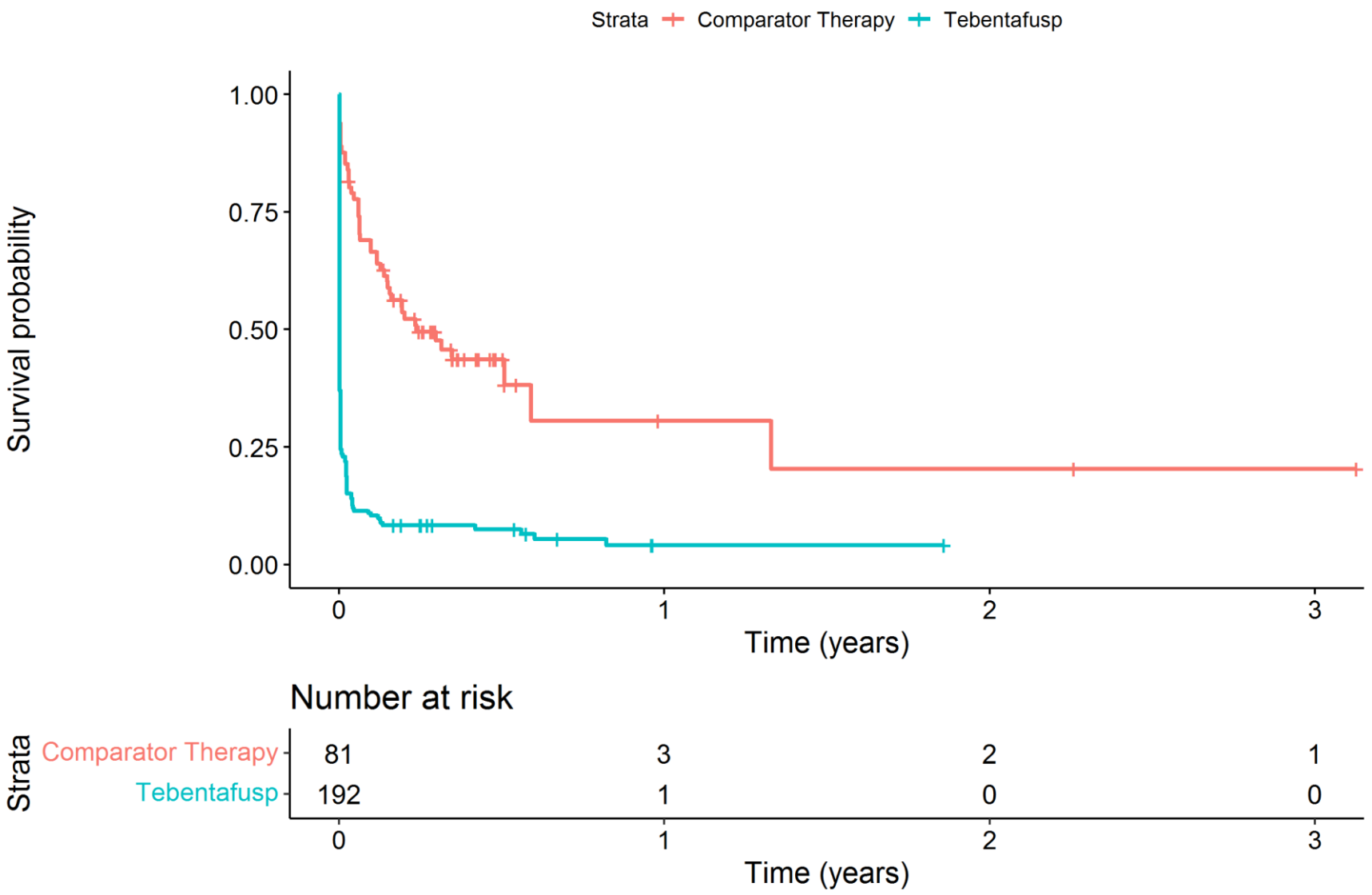
61.72 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- <65



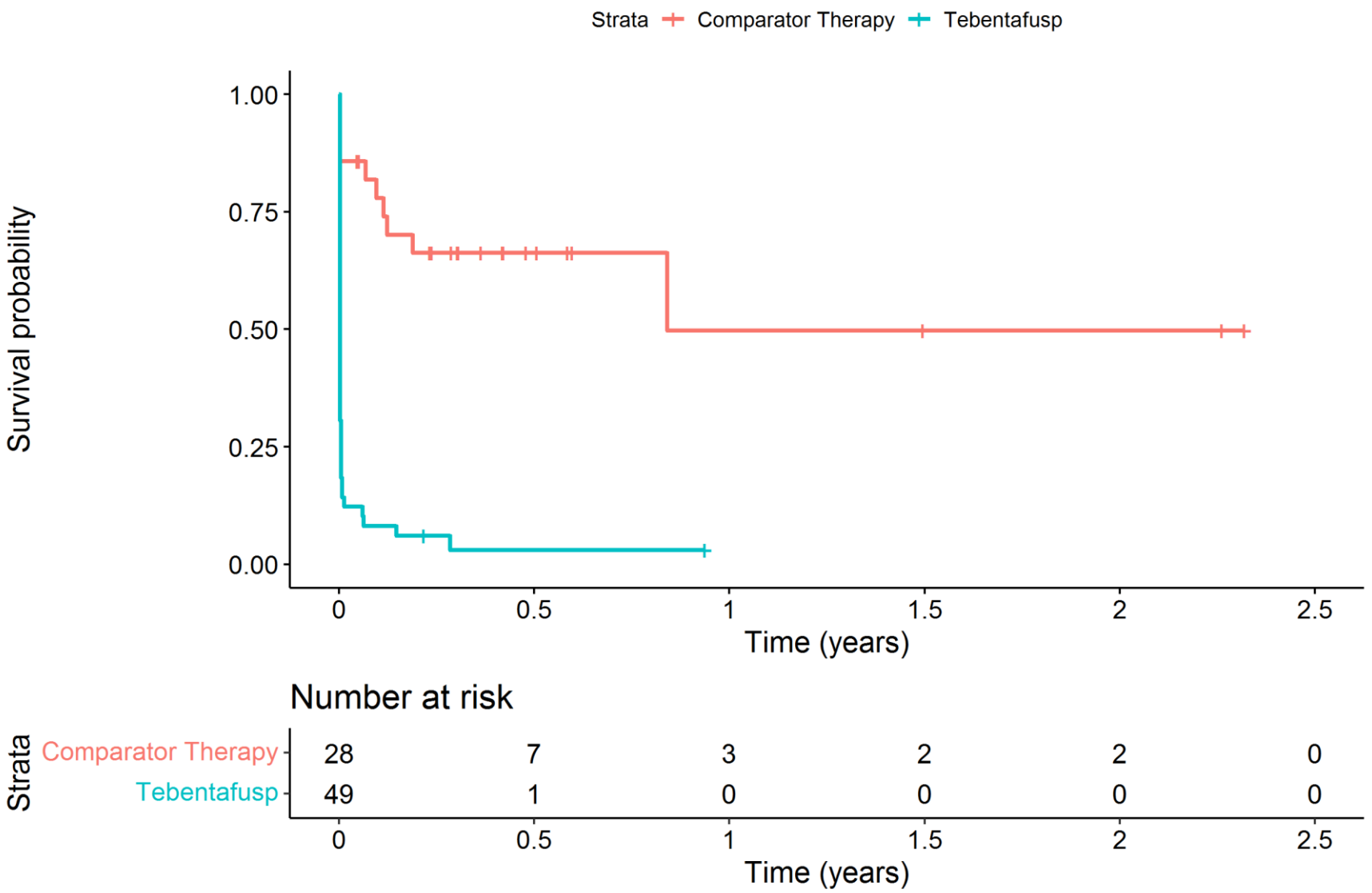
61.73 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ≥65



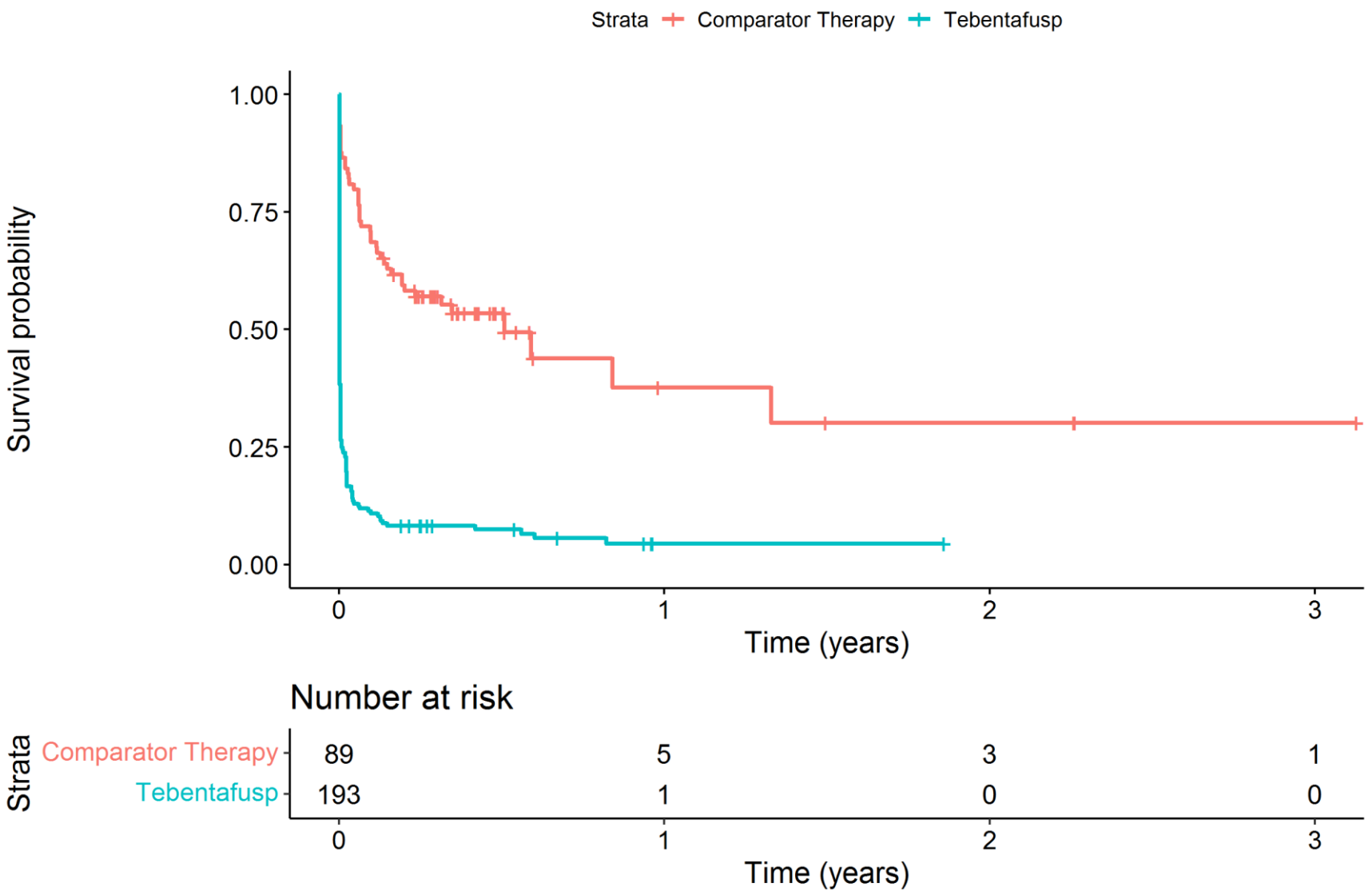
61.74 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ECOG 0



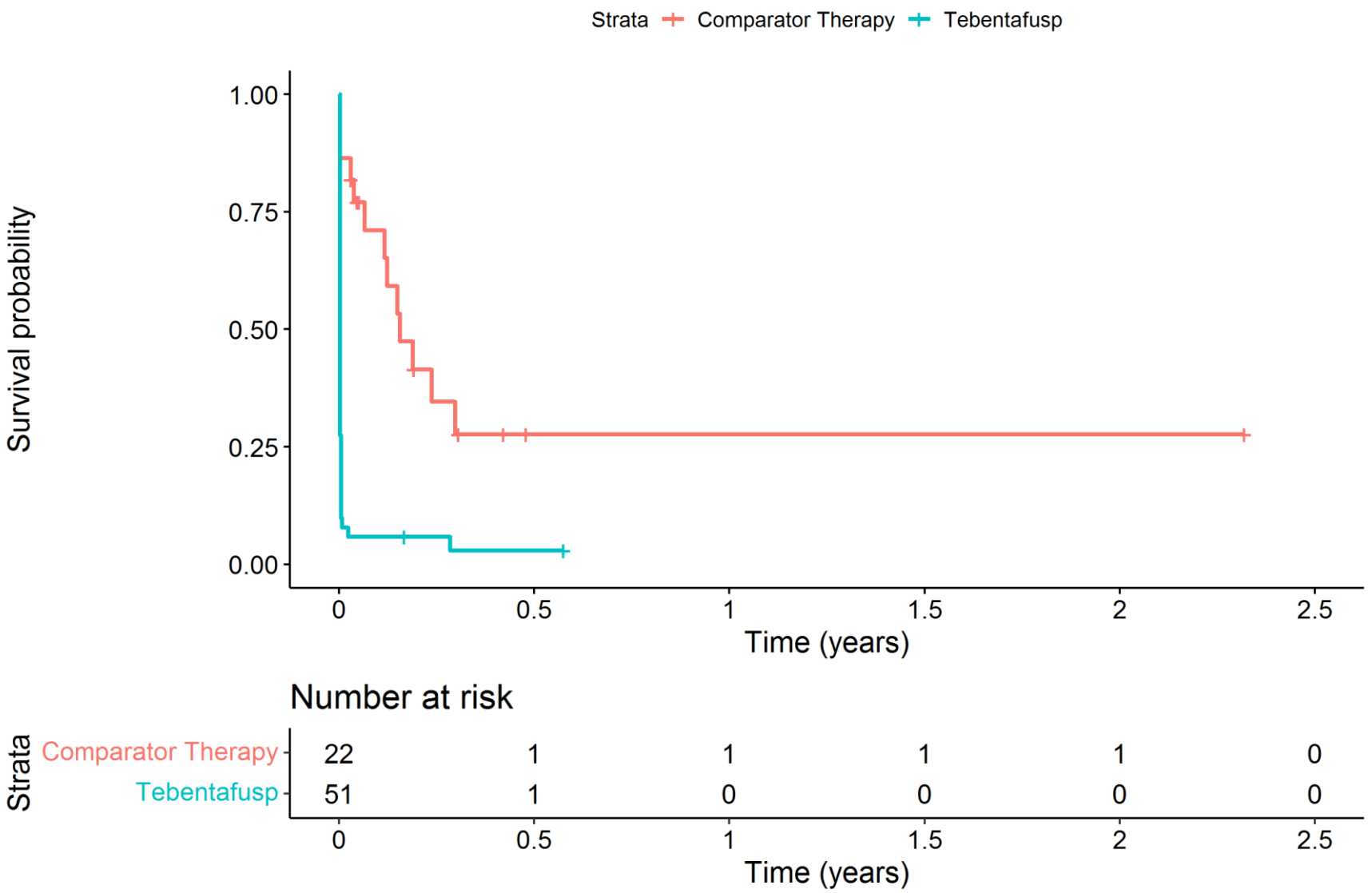
61.75 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ECOG 1



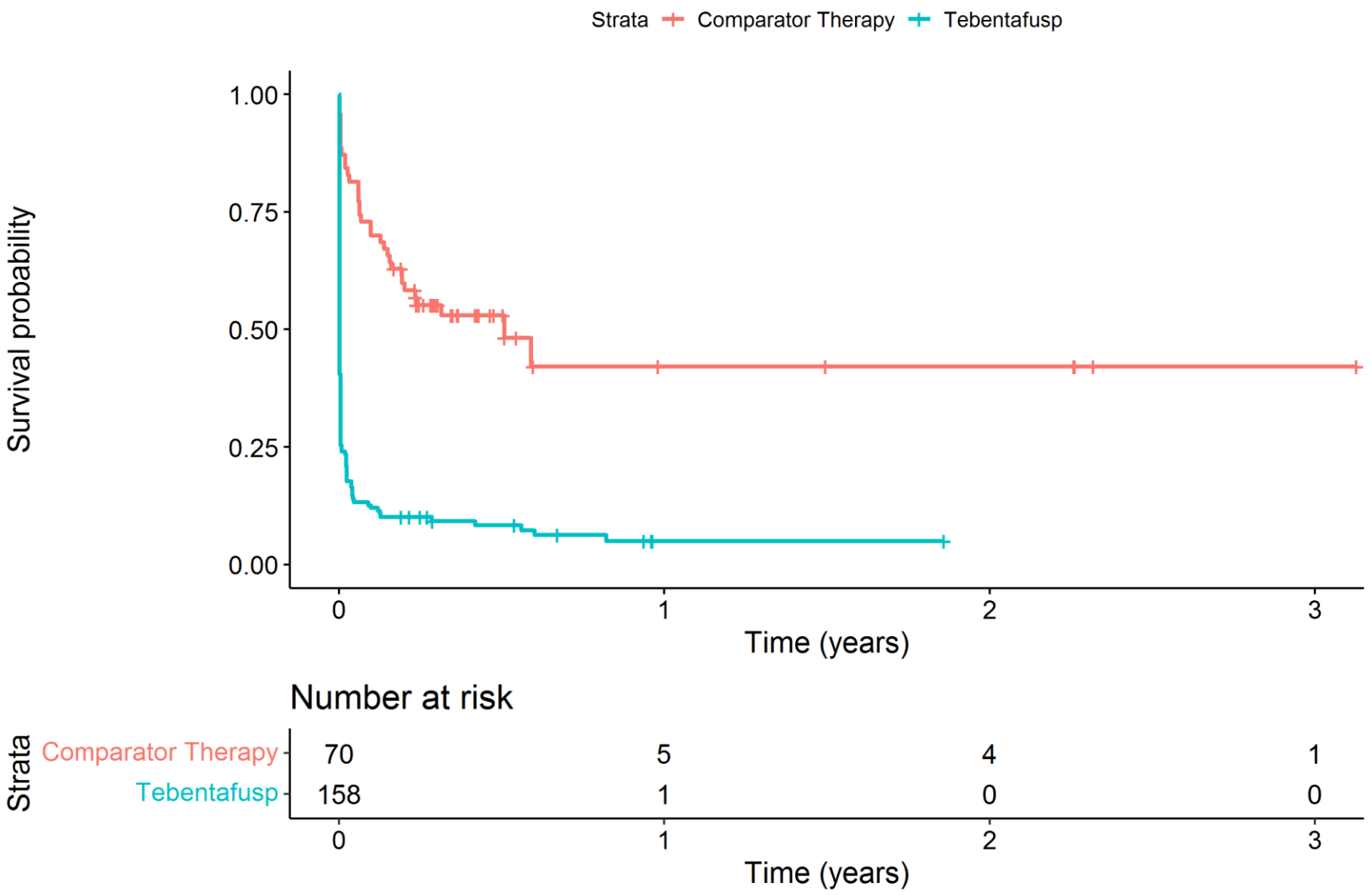
61.76 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ALP ≤ ULN



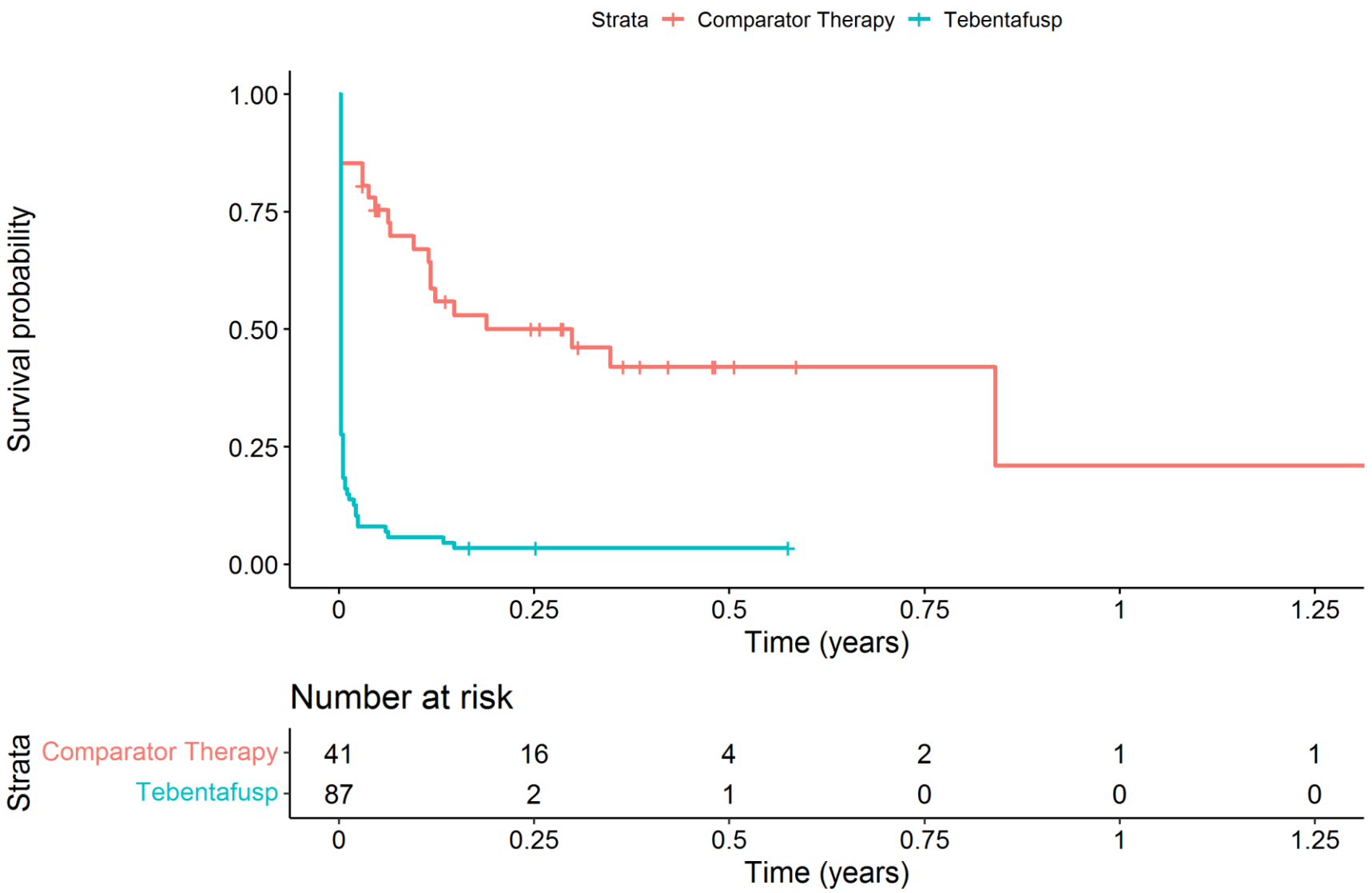
61.77 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ALP > ULN



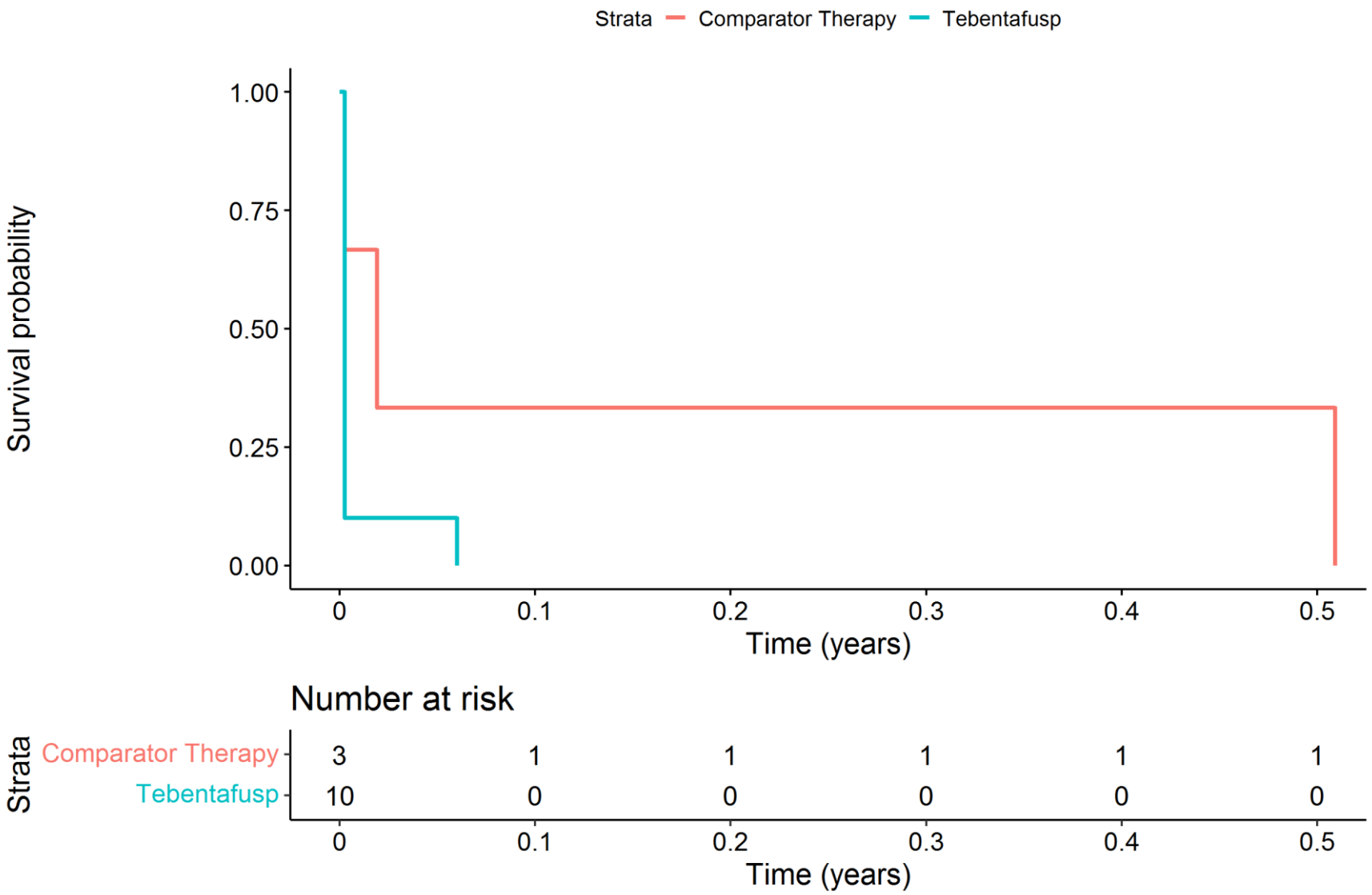
61.78 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- LDH =< ULN



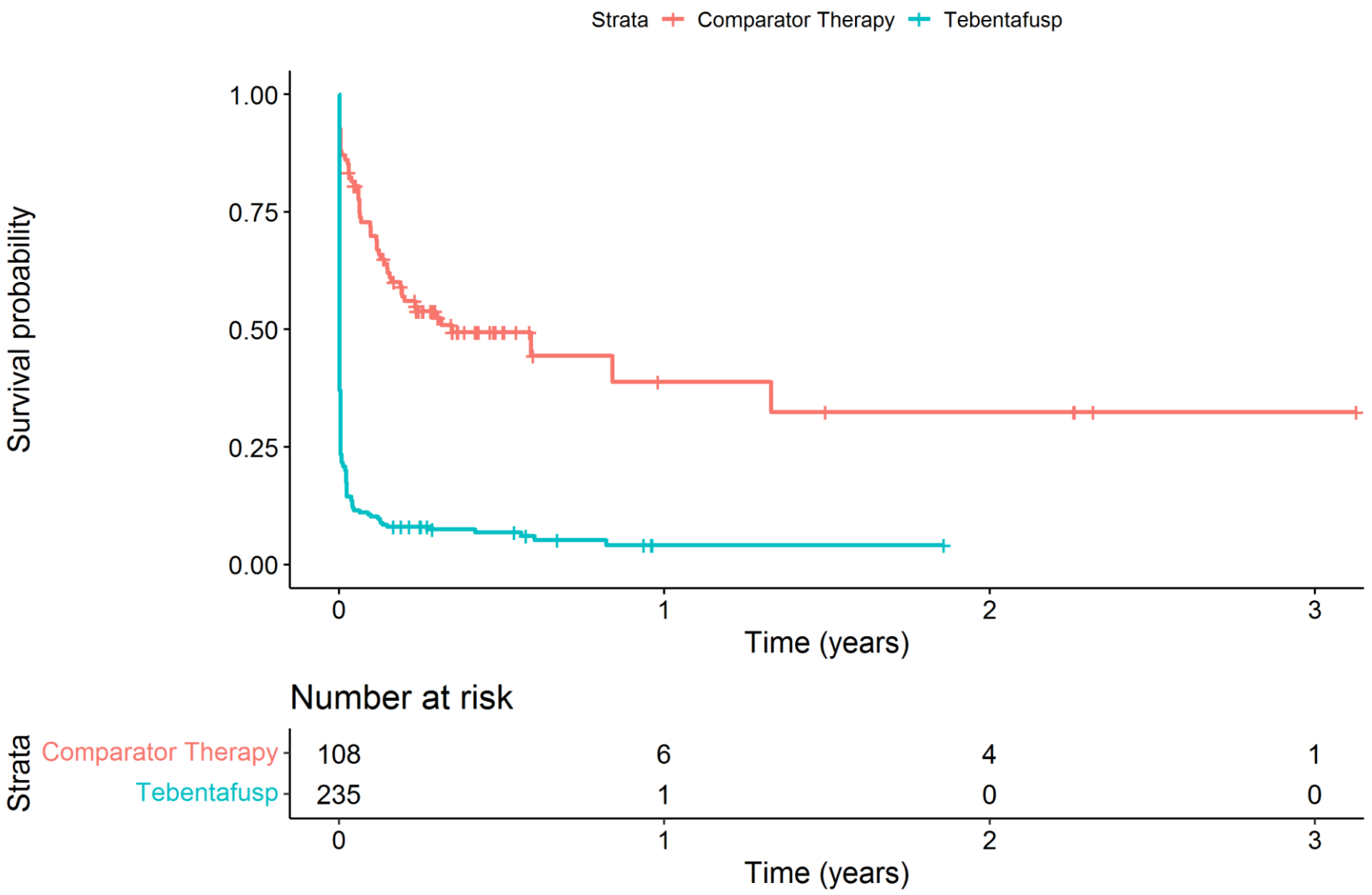
61.79 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- LDH > ULN



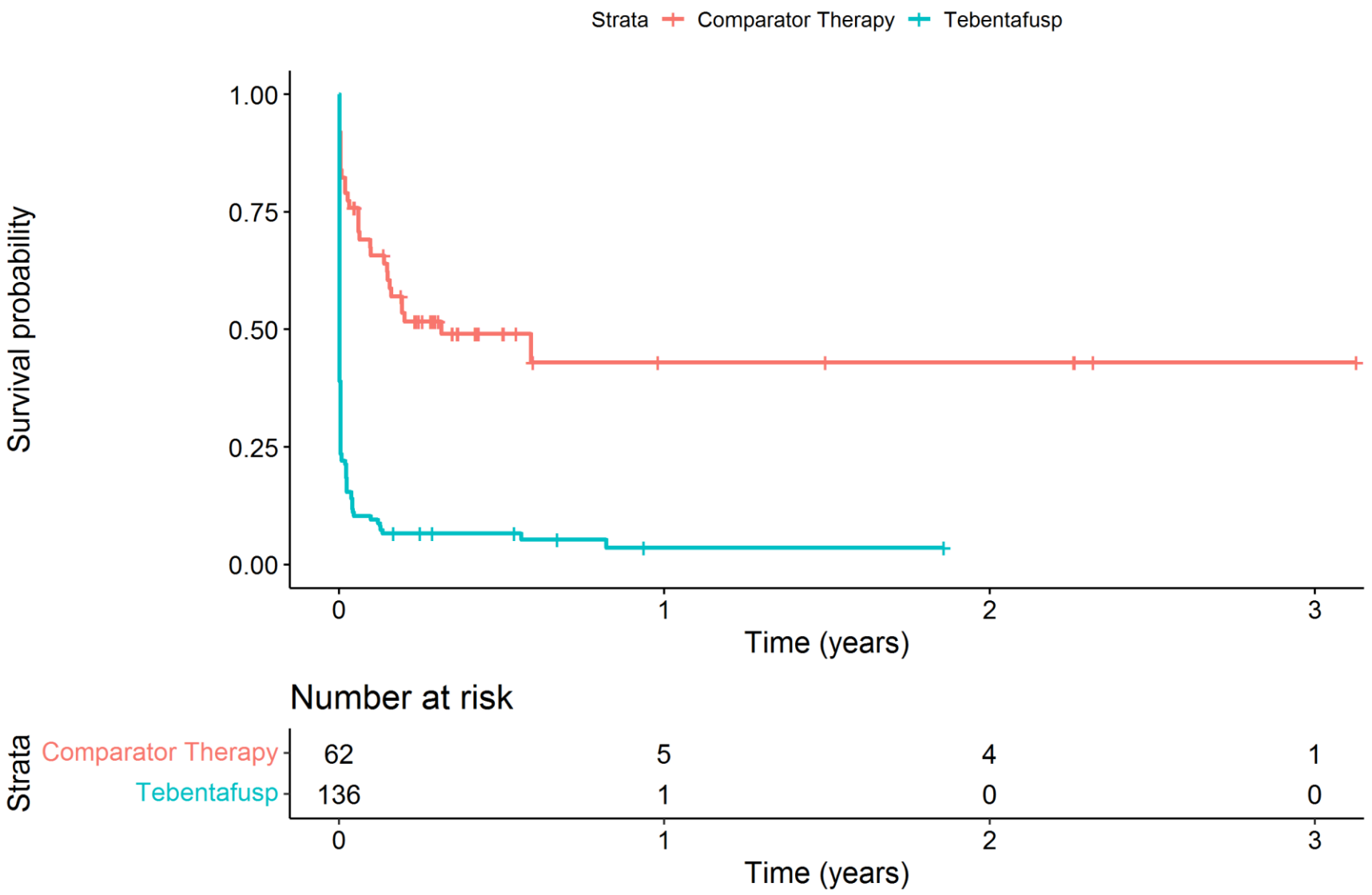
61.80 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Vorherige Therapie adjuvant/neoadjuvant



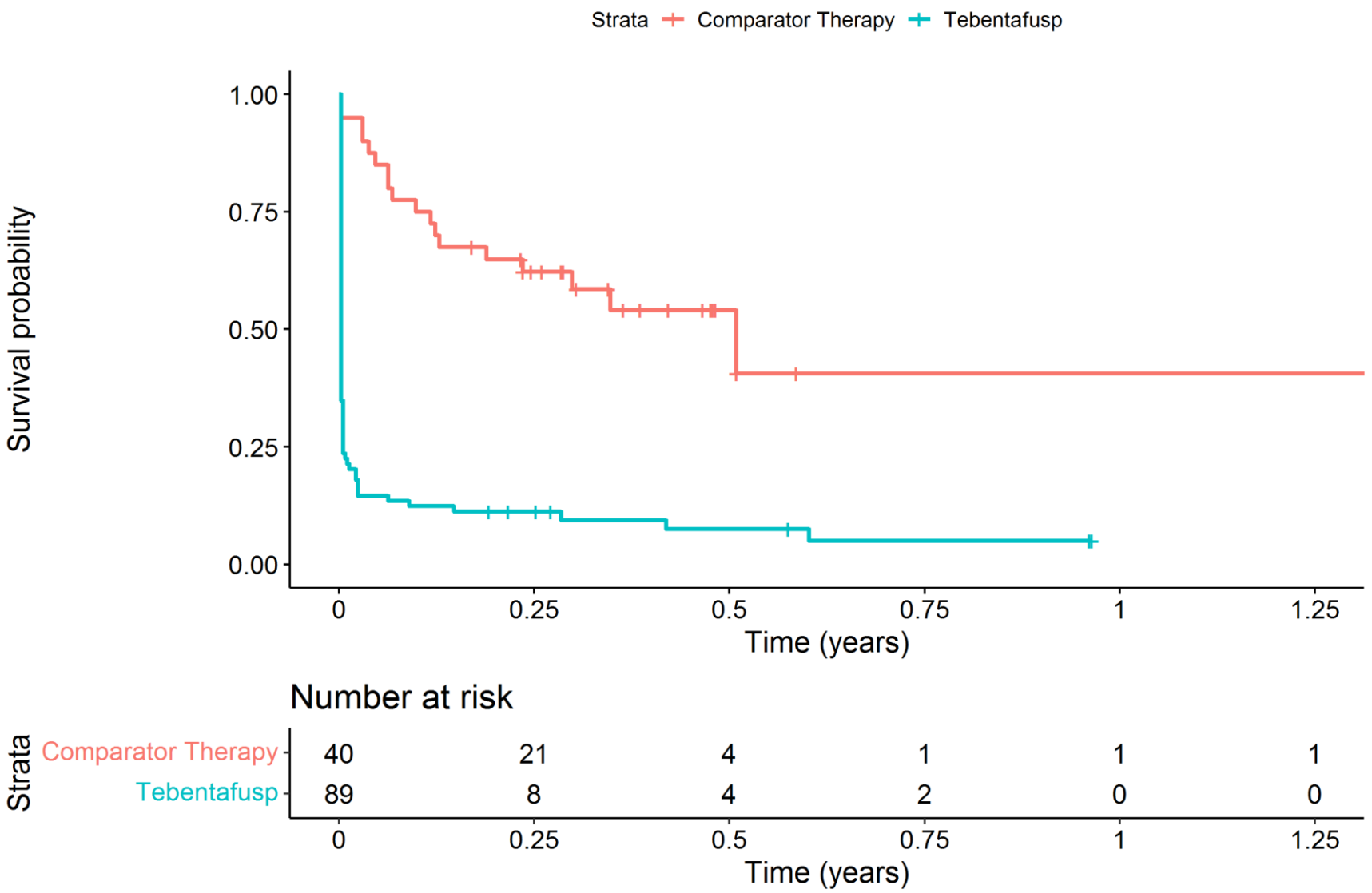
61.81 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Keine Vorherige Therapie adjuvant/neoadjuvant



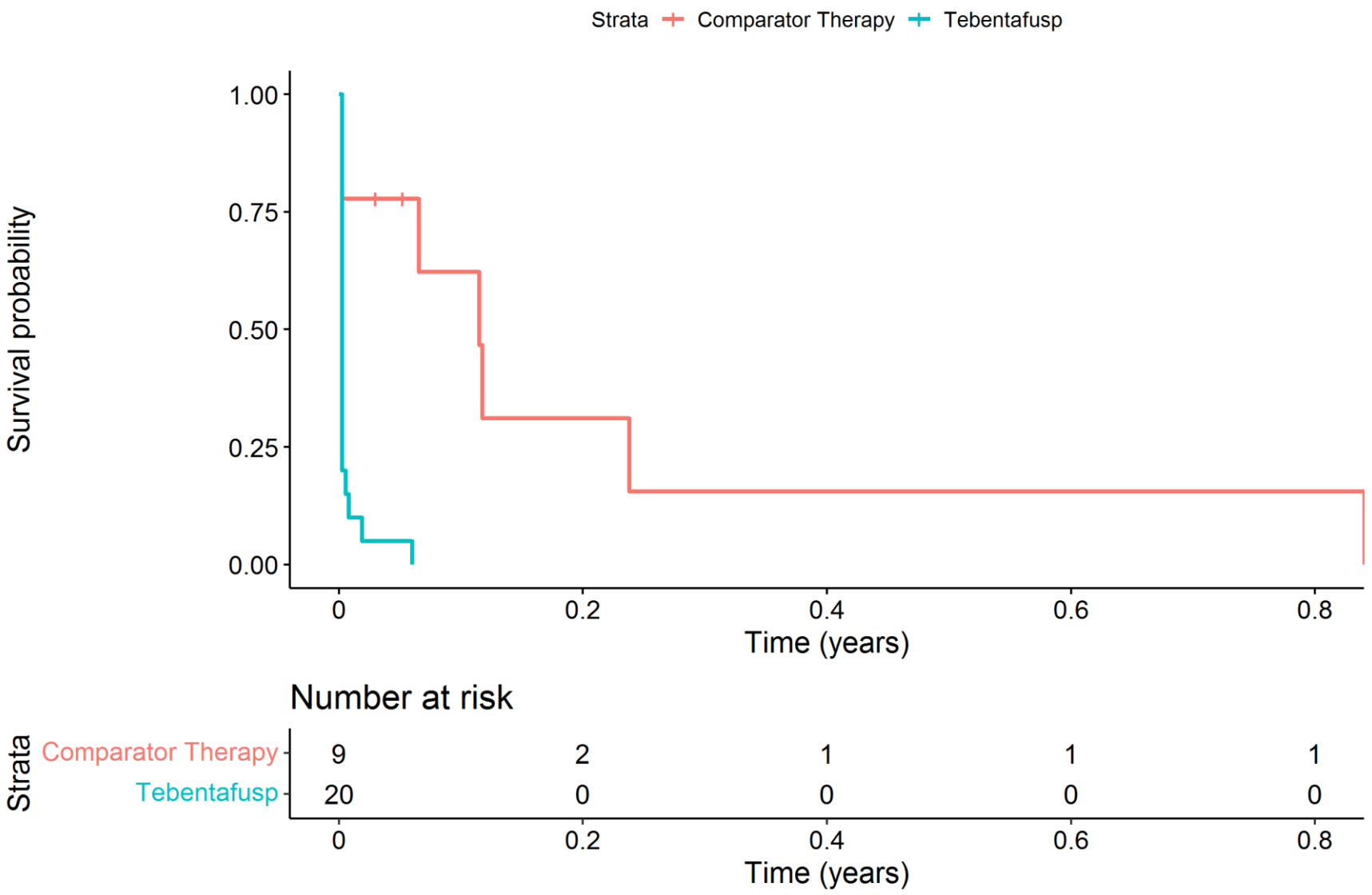
61.82 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion ≤ 3cm



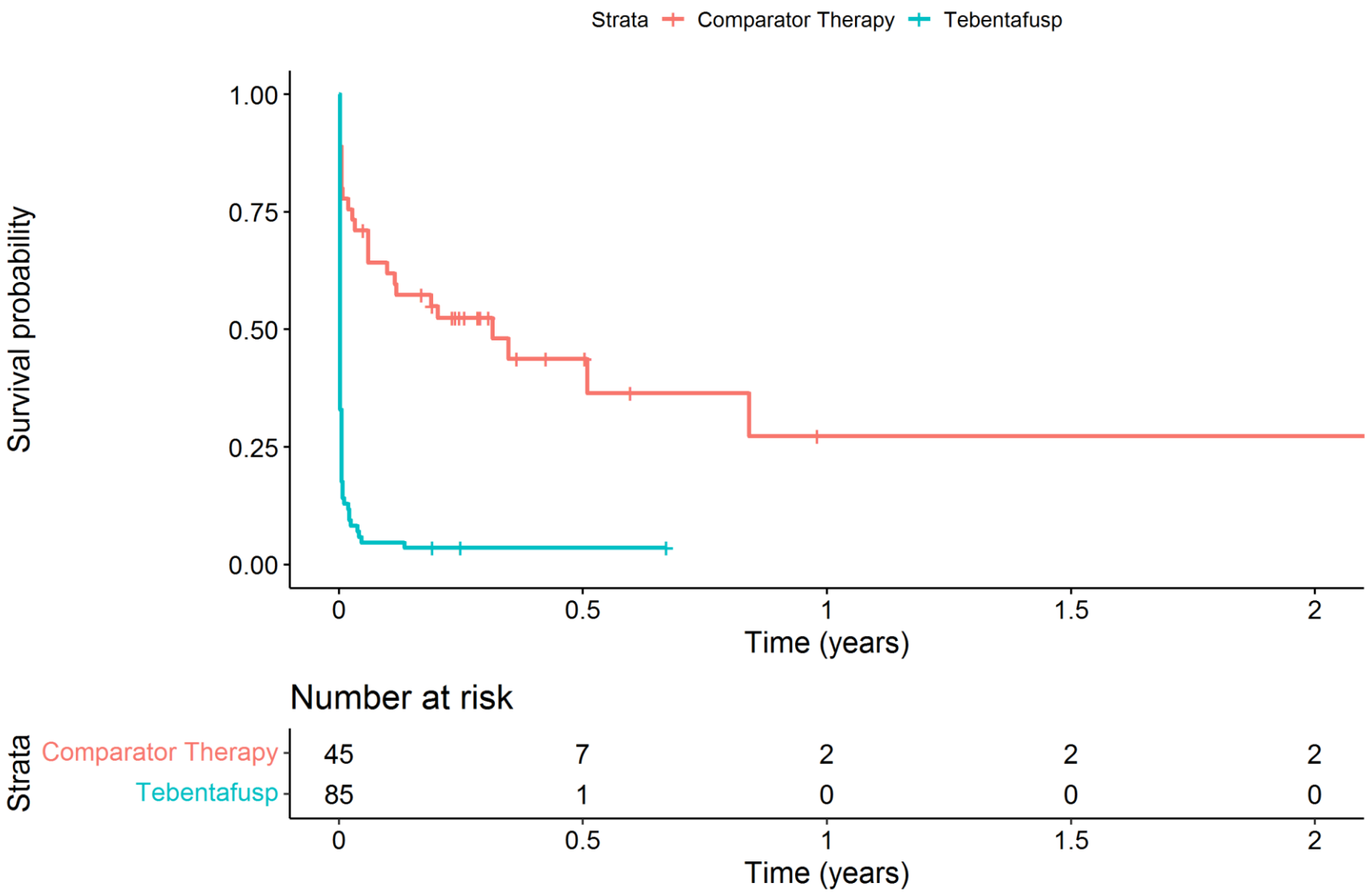
61.83 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion 3,1-8,0 cm



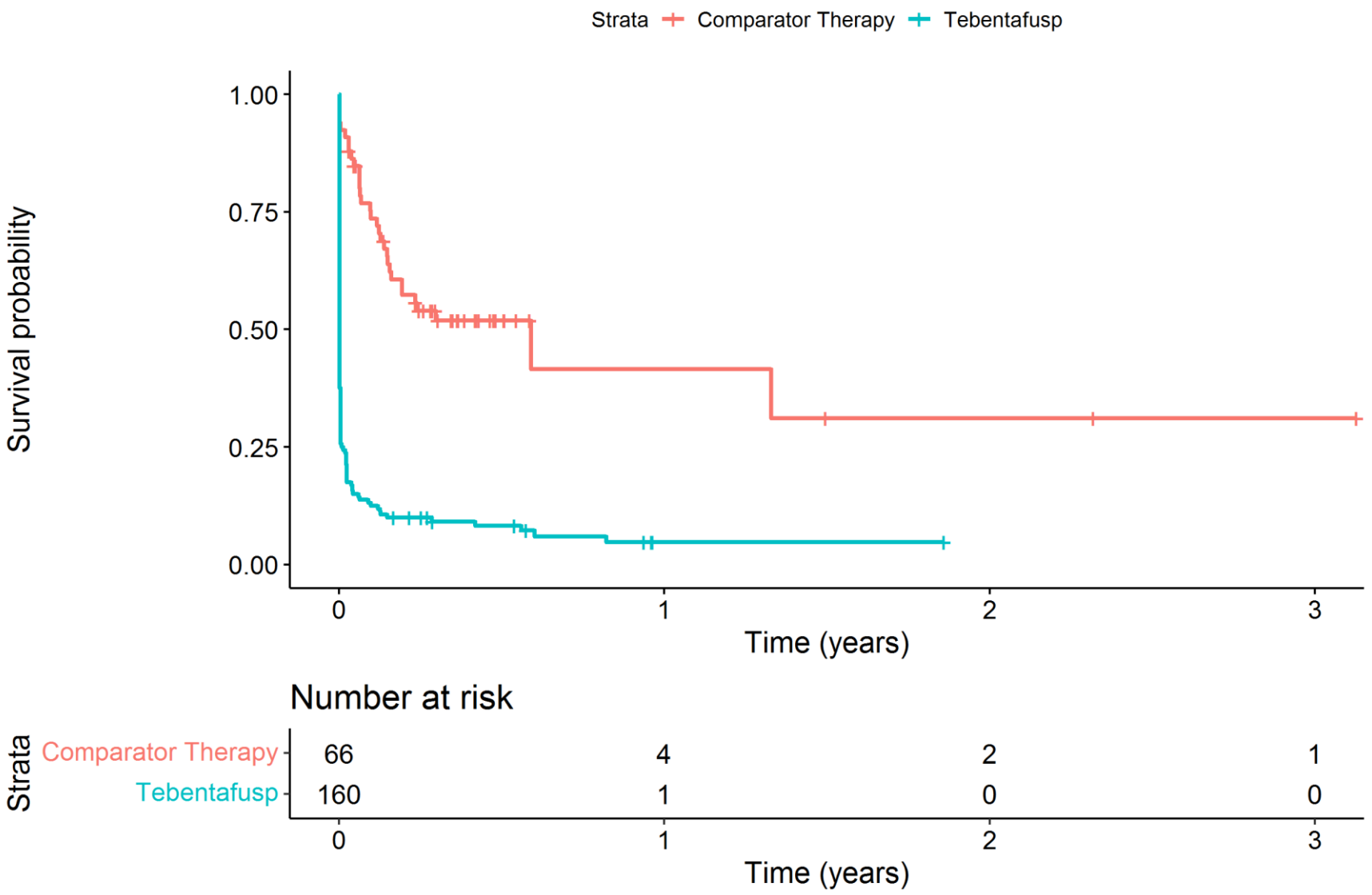
61.84 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion ≥8,1 cm



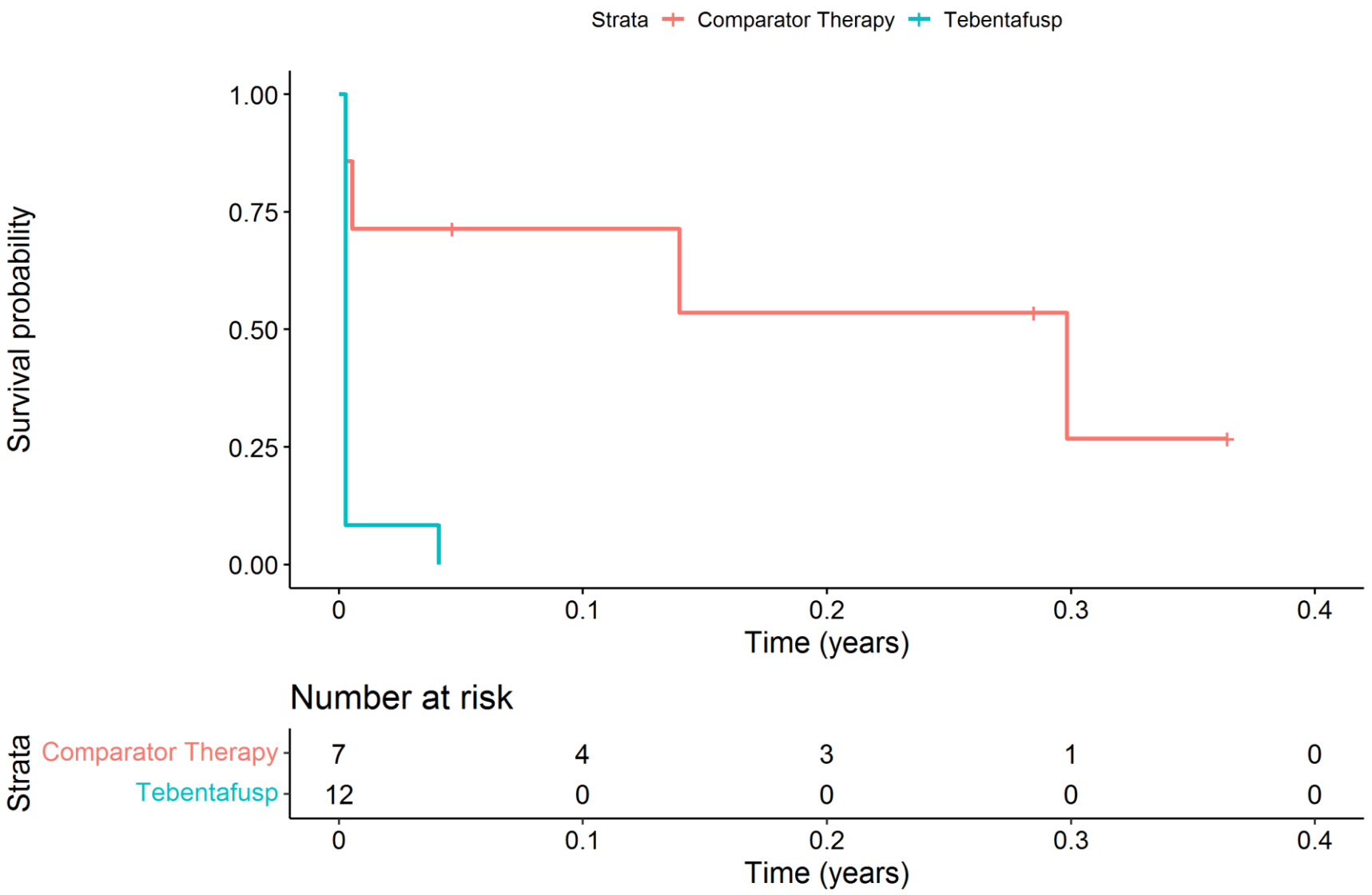
61.85 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nordamerika



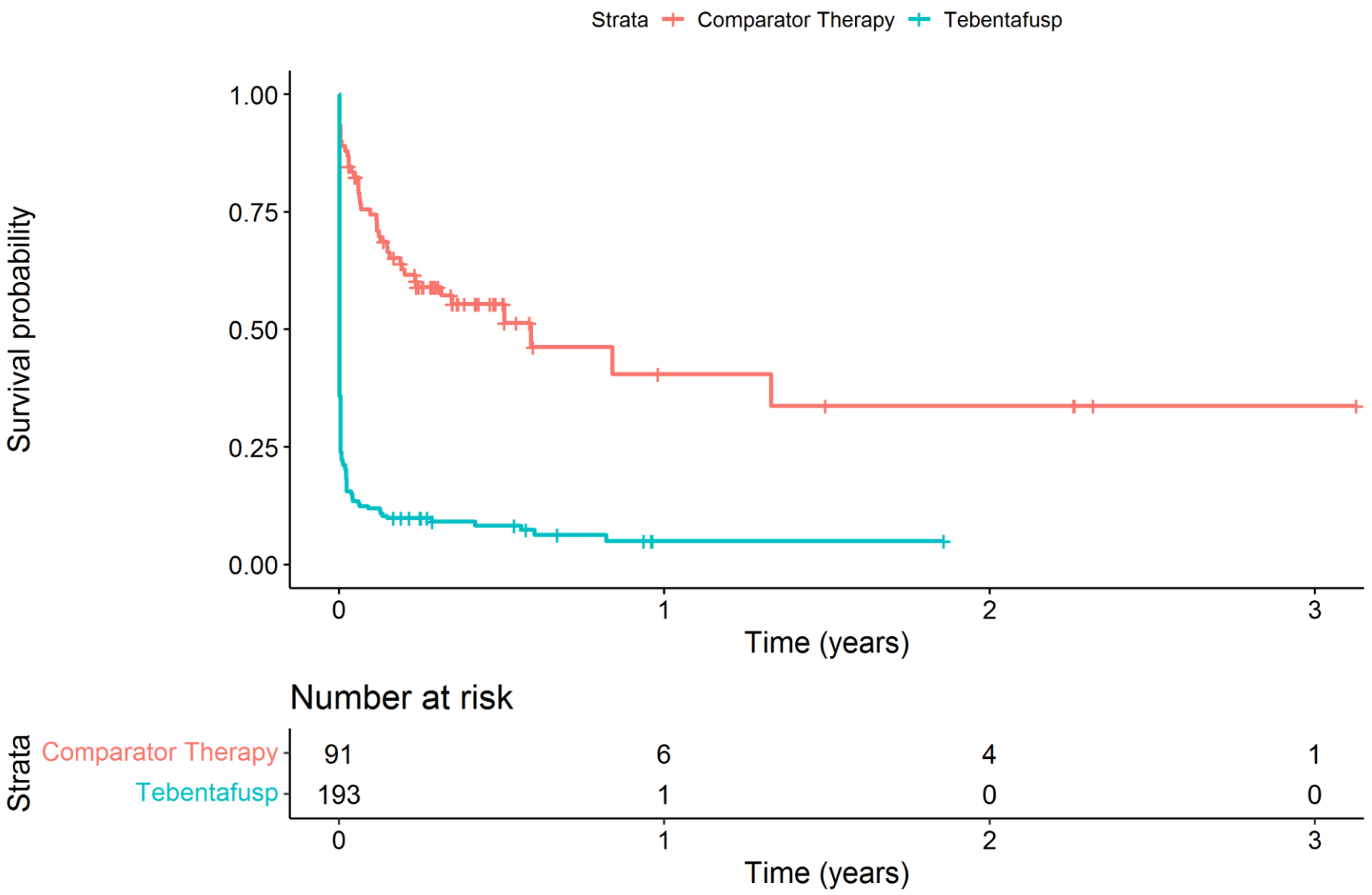
61.86 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nicht-Nordamerika



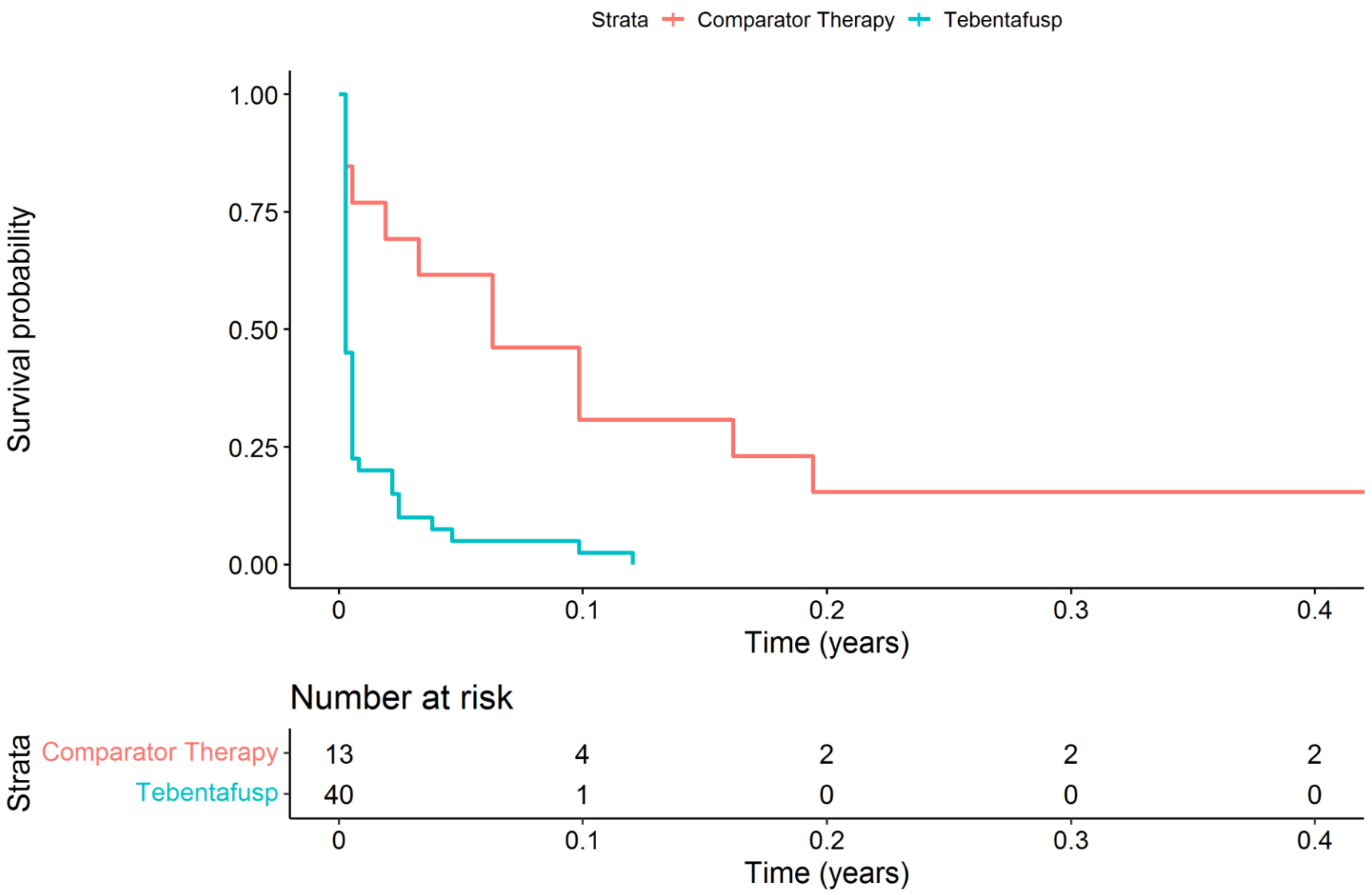
61.87 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Dacarbazin



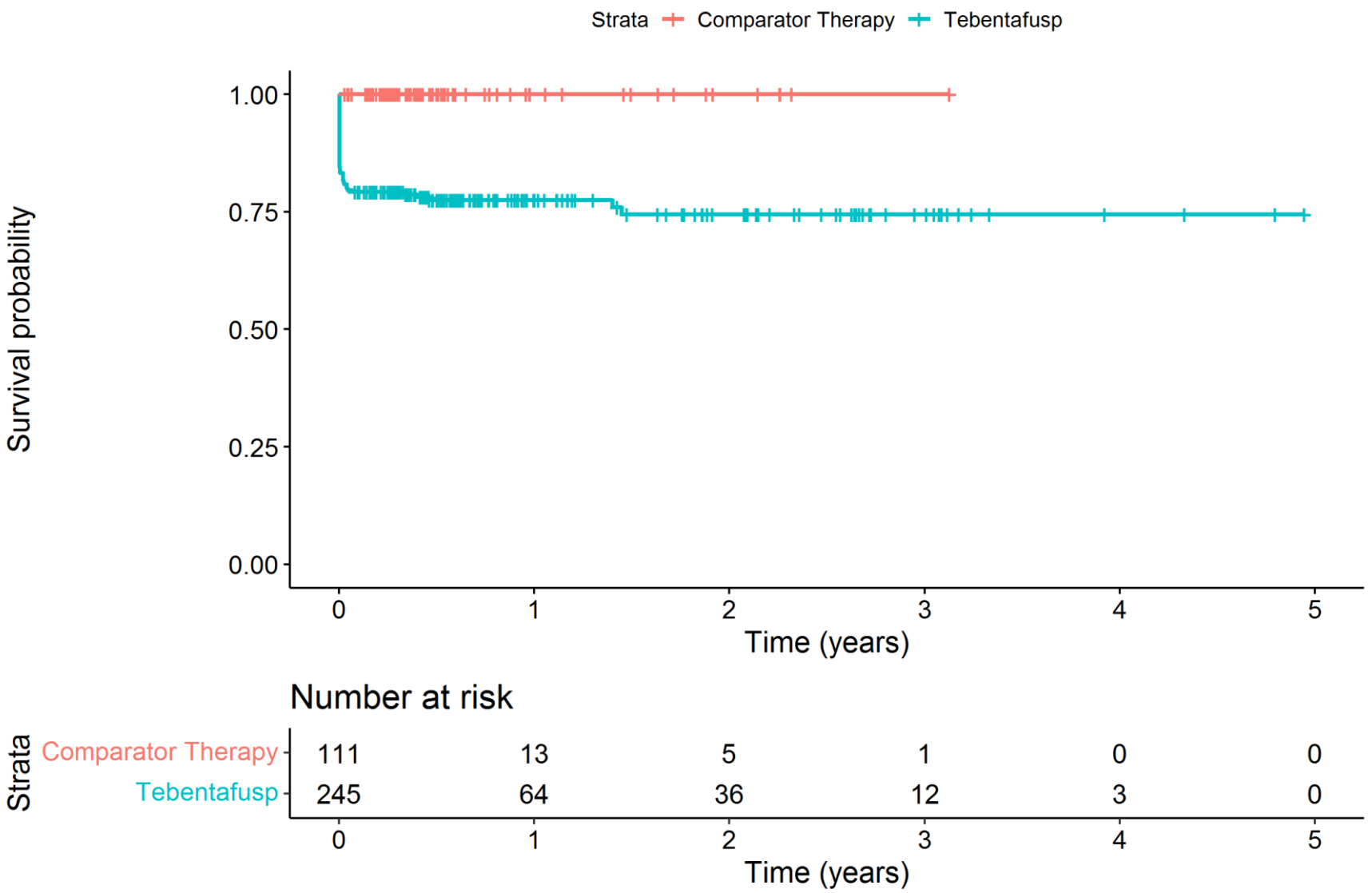
61.88 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Pembrolizumab



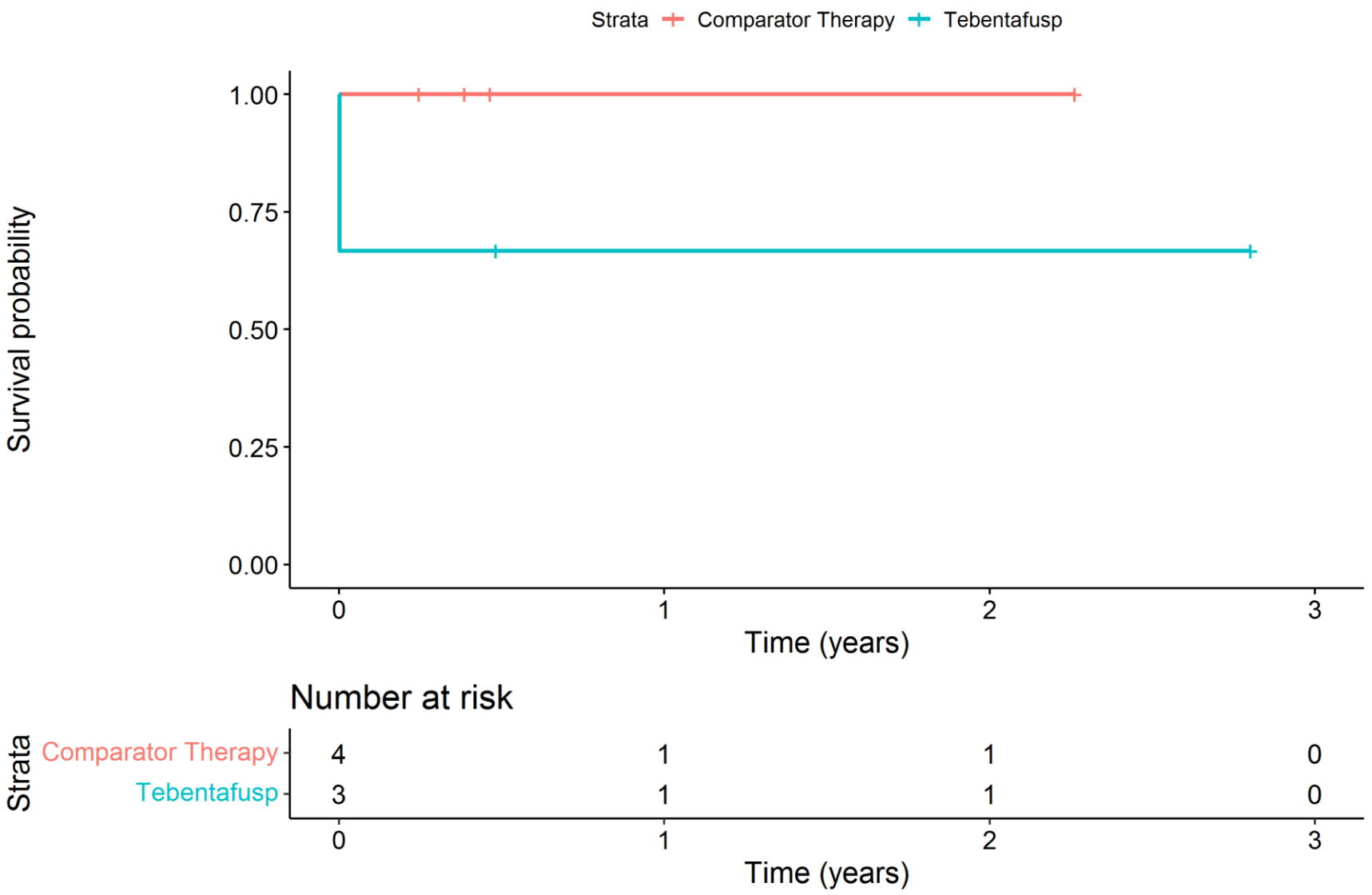
61.89 Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Ipilimumab



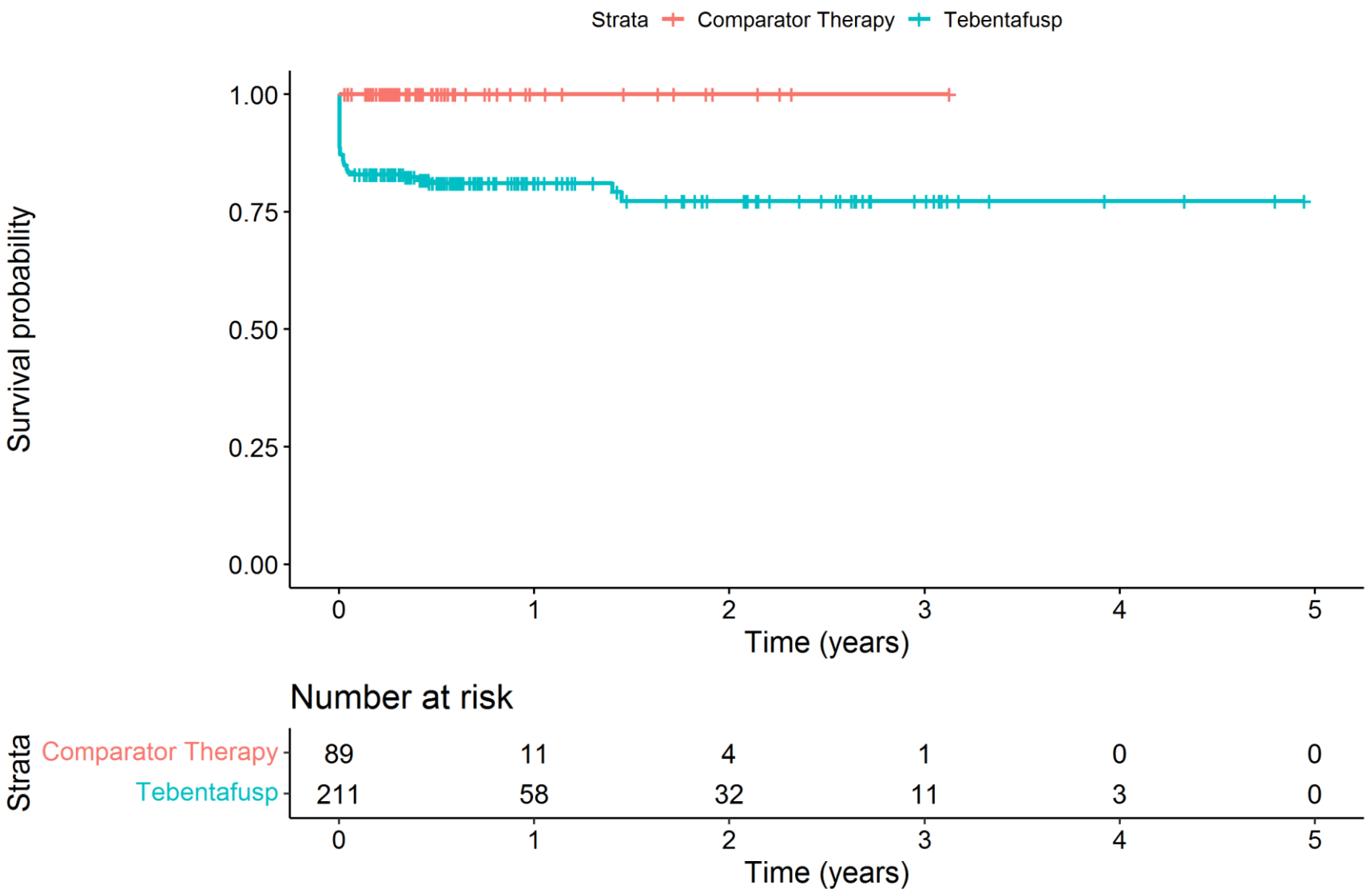
61.90 Erkrankungen des Immunsystems- Gesamt



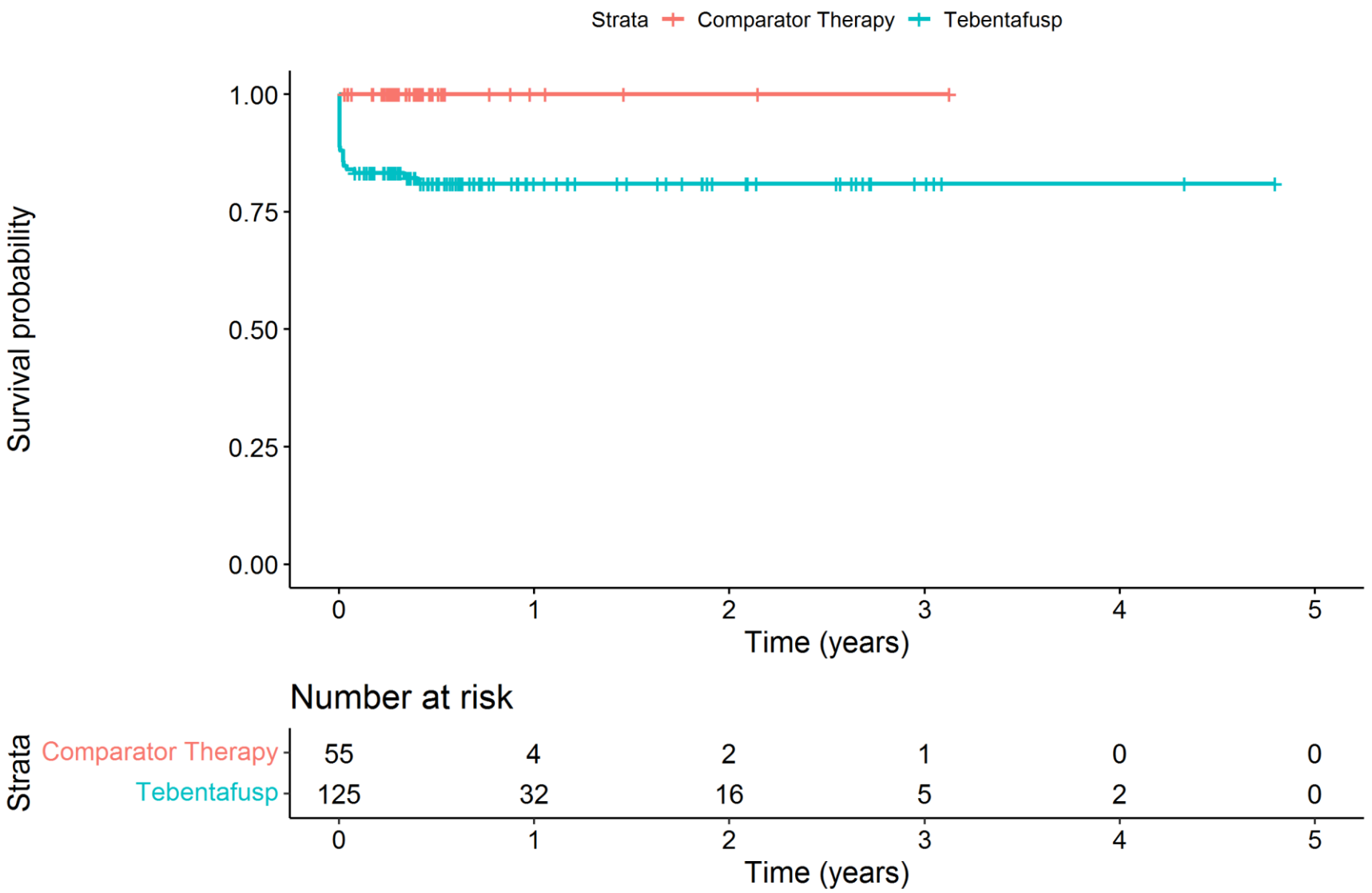
61.91 Erkrankungen des Immunsystems- Hispanisch



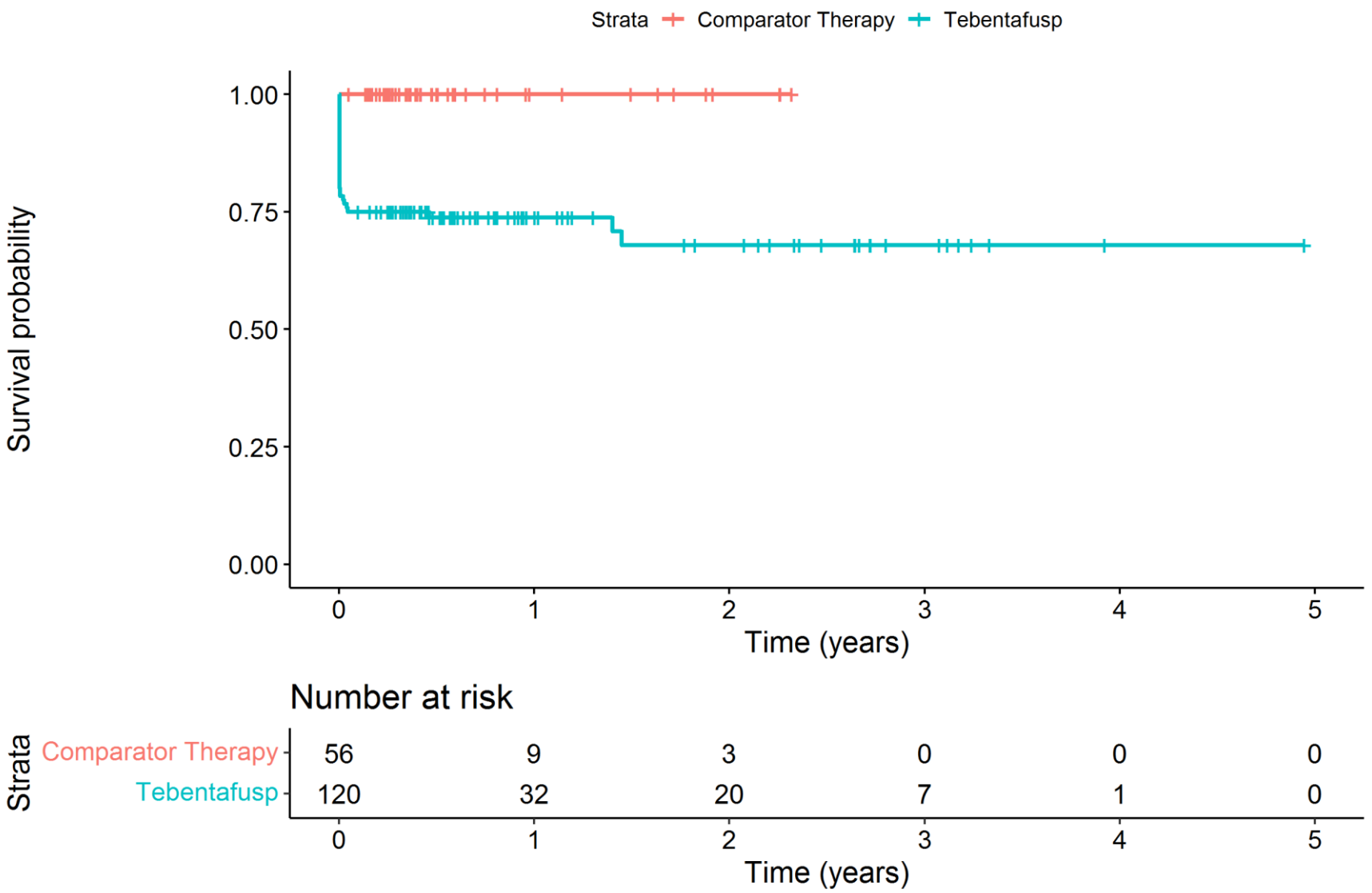
61.92 Erkrankungen des Immunsystems- Nicht-hispanisch



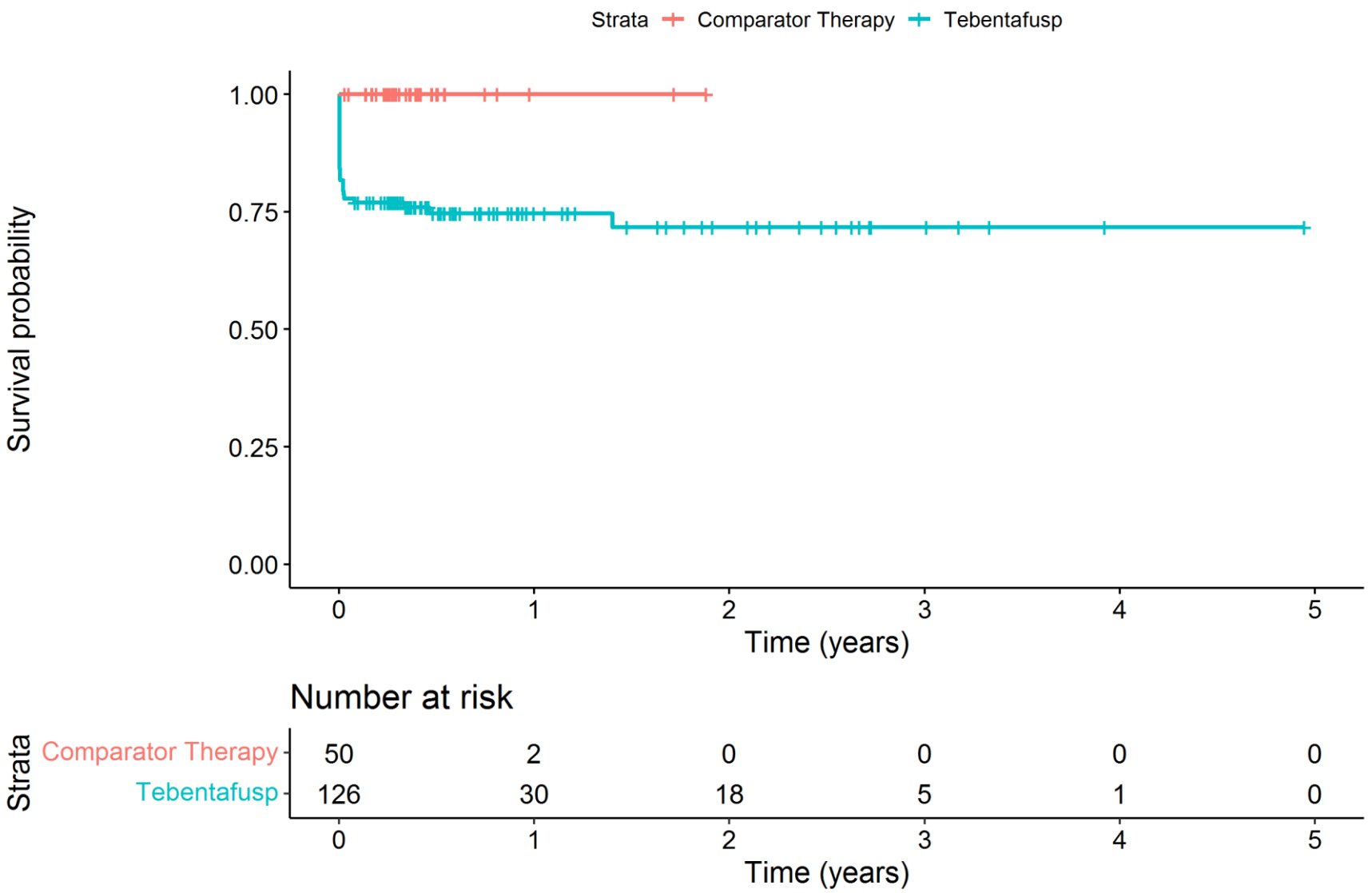
61.93 Erkrankungen des Immunsystems- Männlich



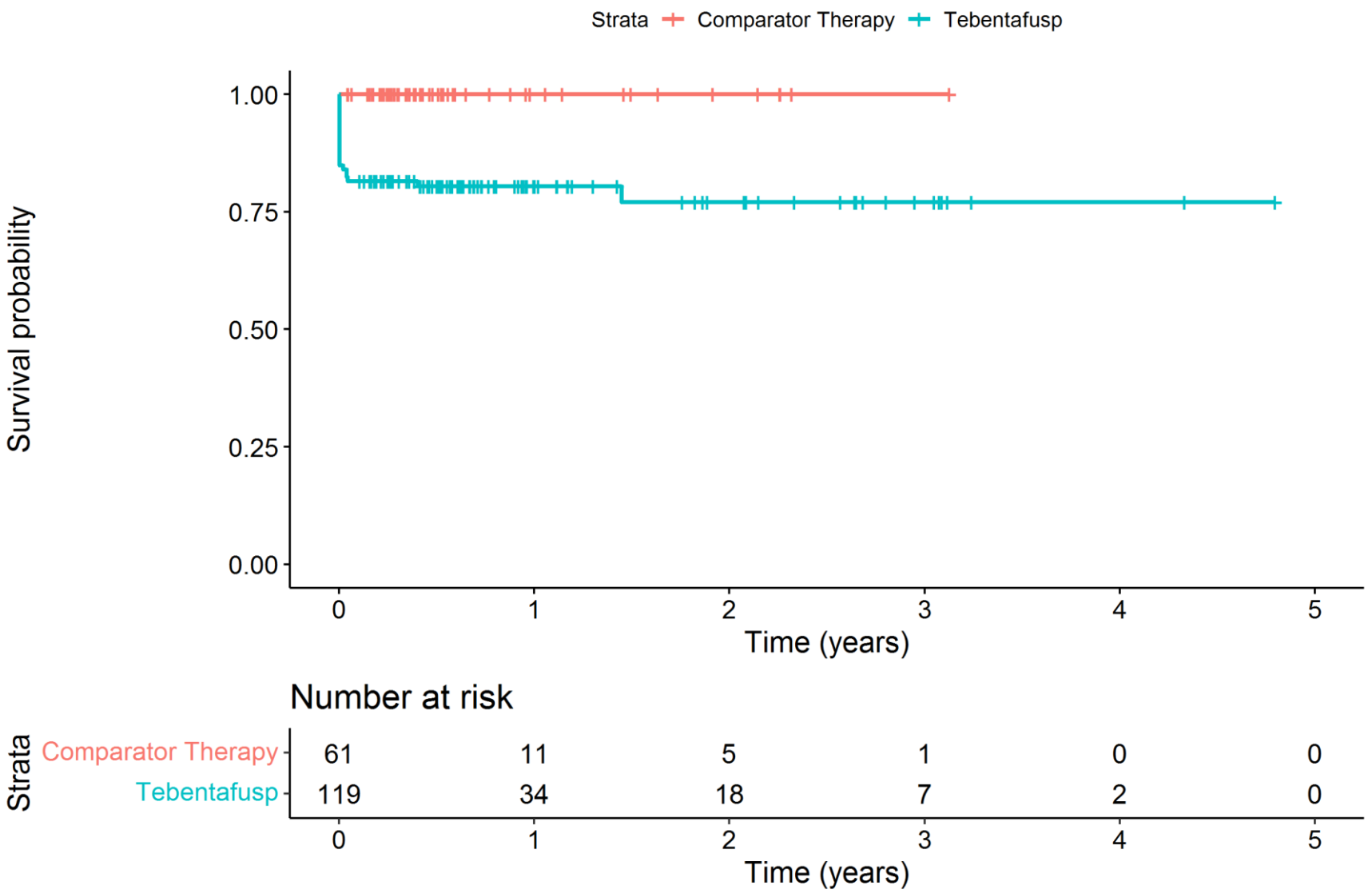
61.94 Erkrankungen des Immunsystems- Weiblich



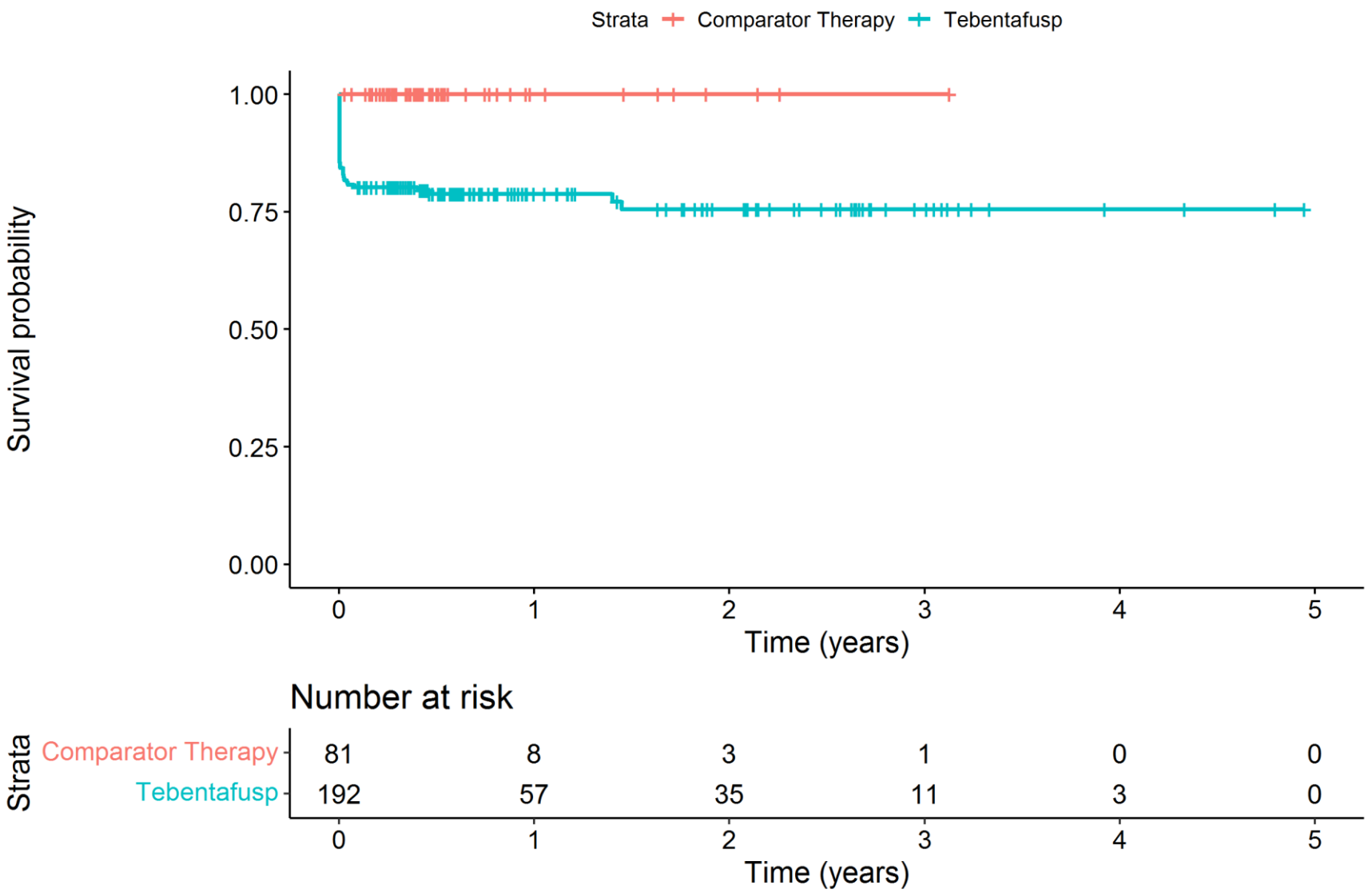
61.95 Erkrankungen des Immunsystems- <65



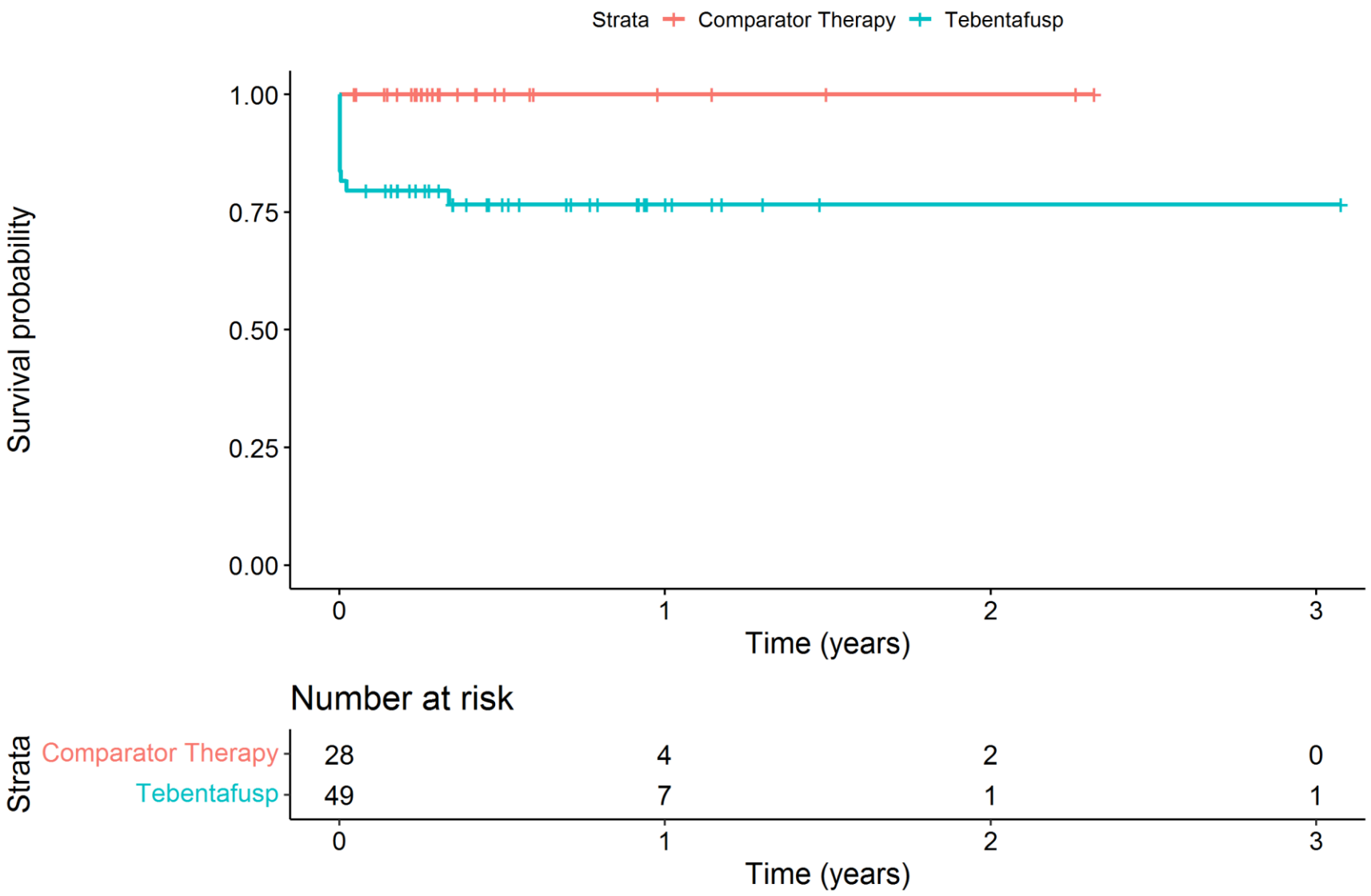
61.96 Erkrankungen des Immunsystems- ≥65



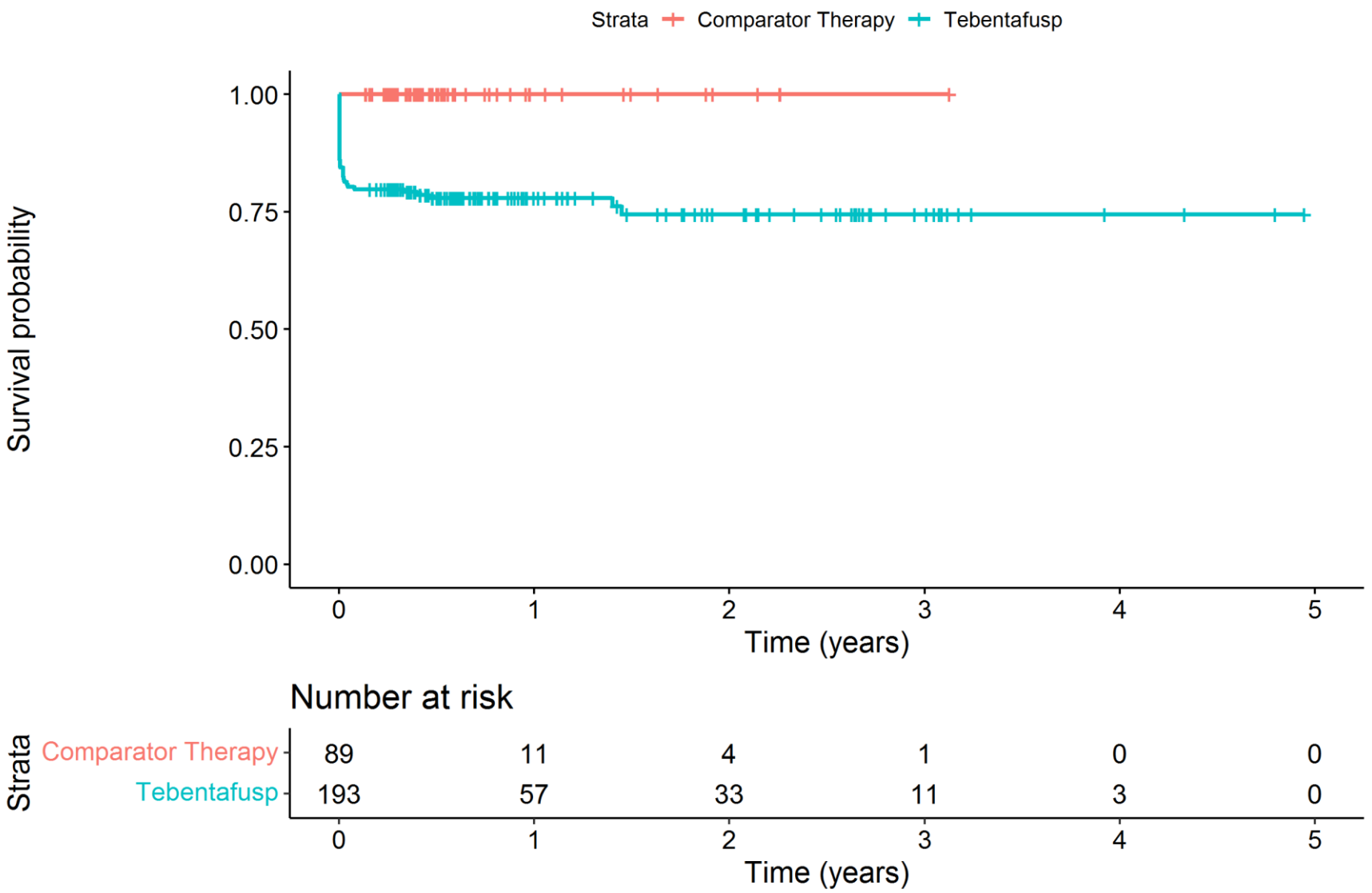
61.97 Erkrankungen des Immunsystems- ECOG 0



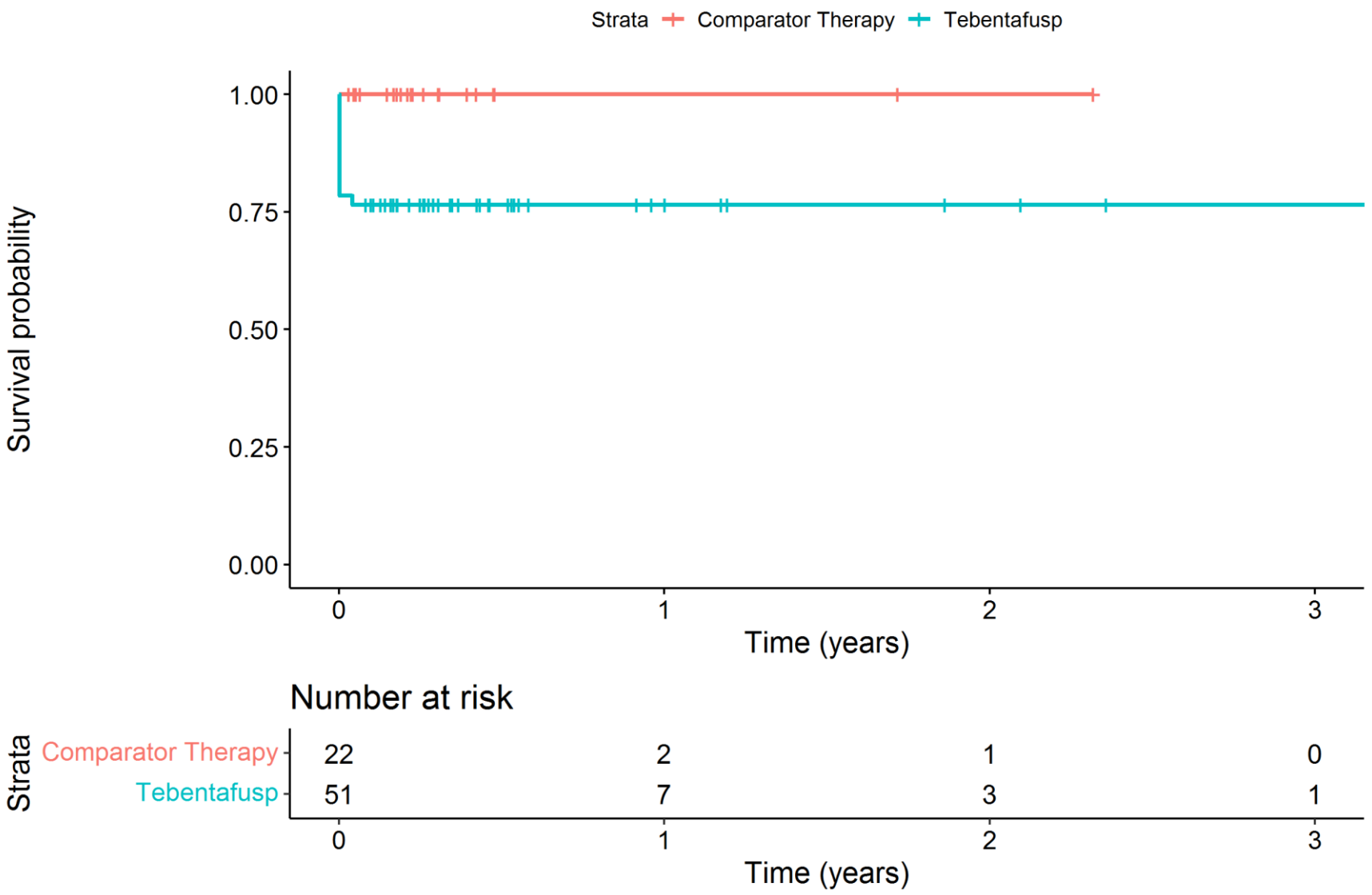
61.98 Erkrankungen des Immunsystems- ECOG 1



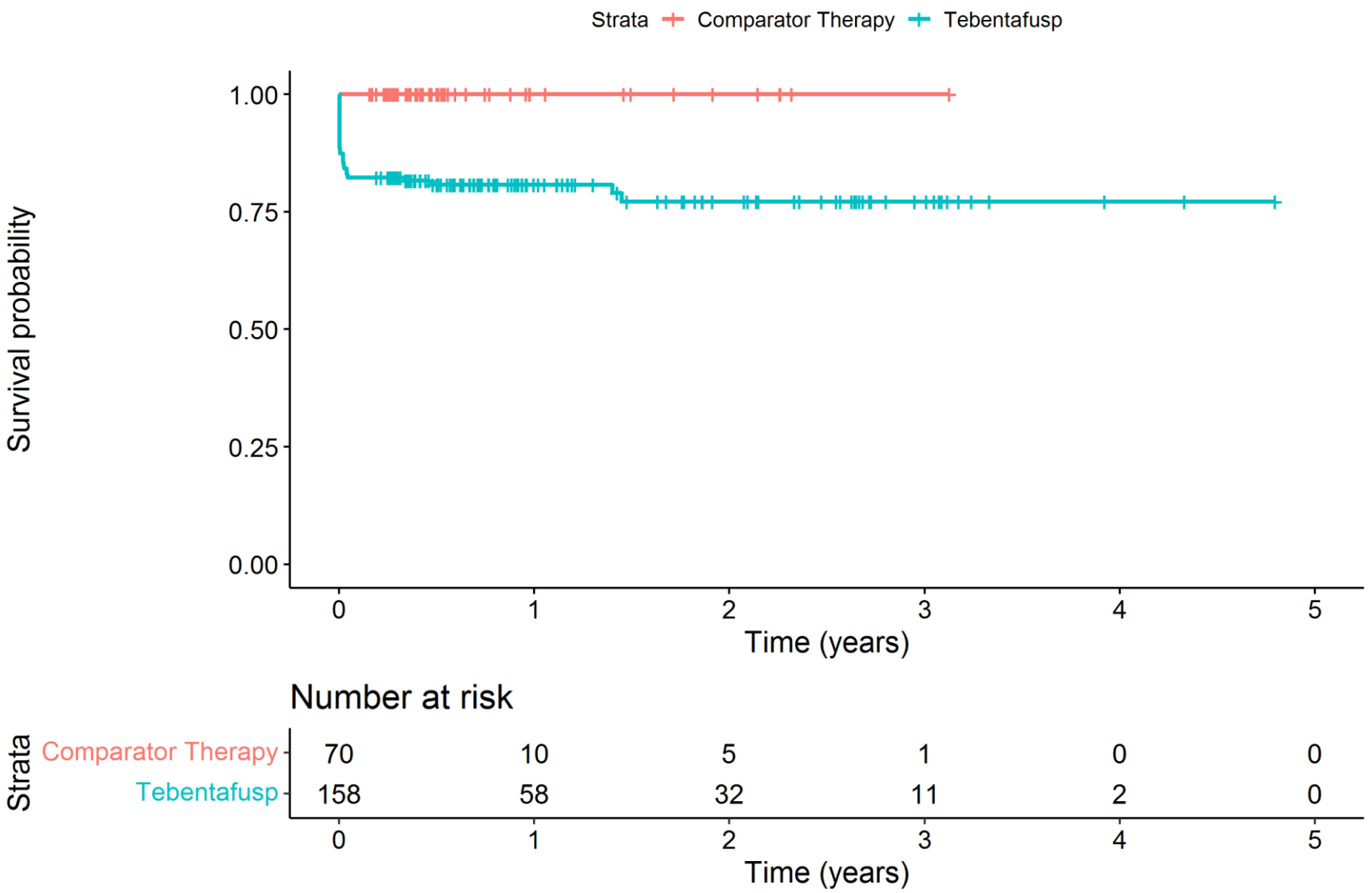
61.99 Erkrankungen des Immunsystems- ALP ≤ ULN



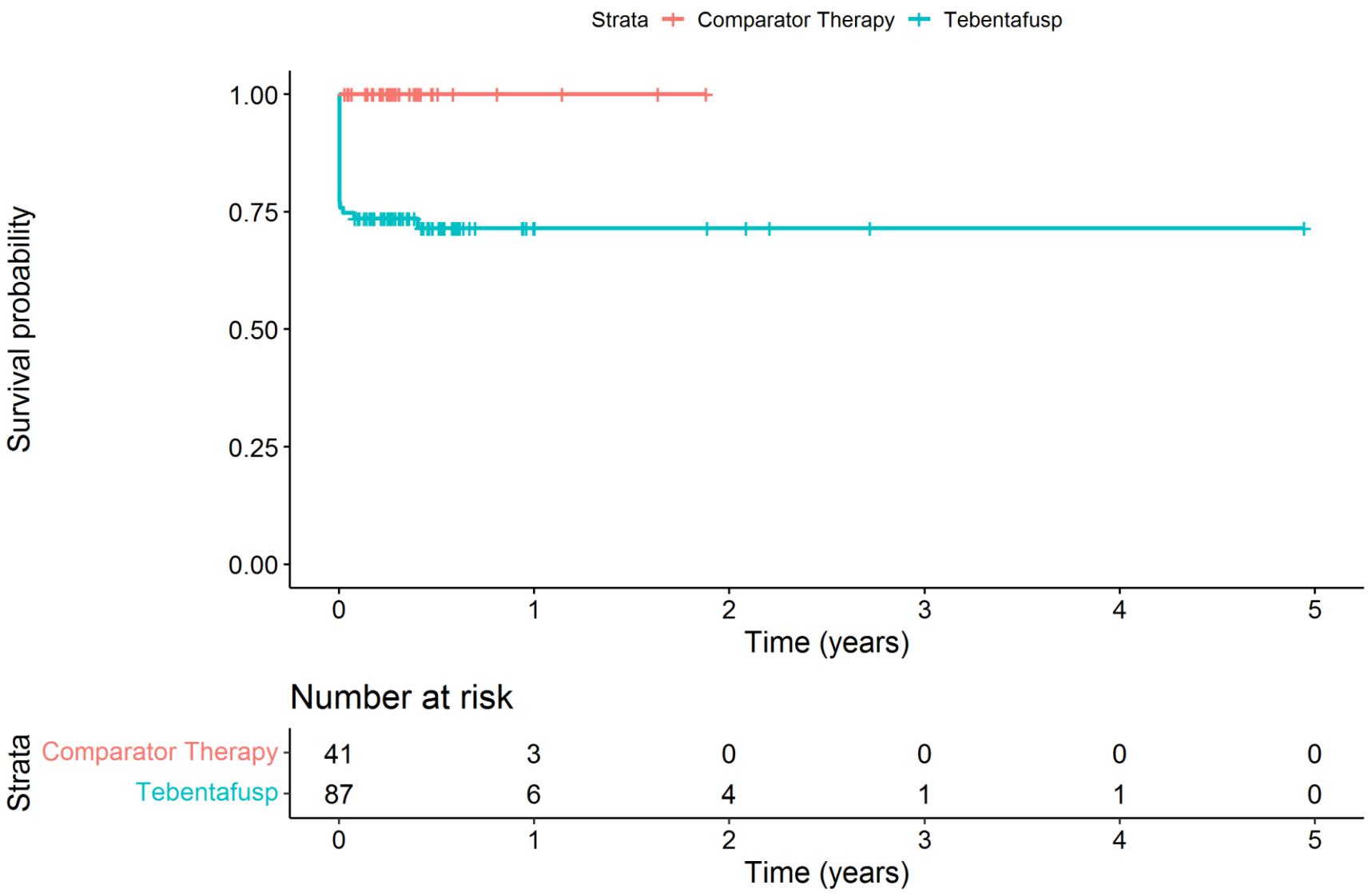
61.100 Erkrankungen des Immunsystems- ALP > ULN



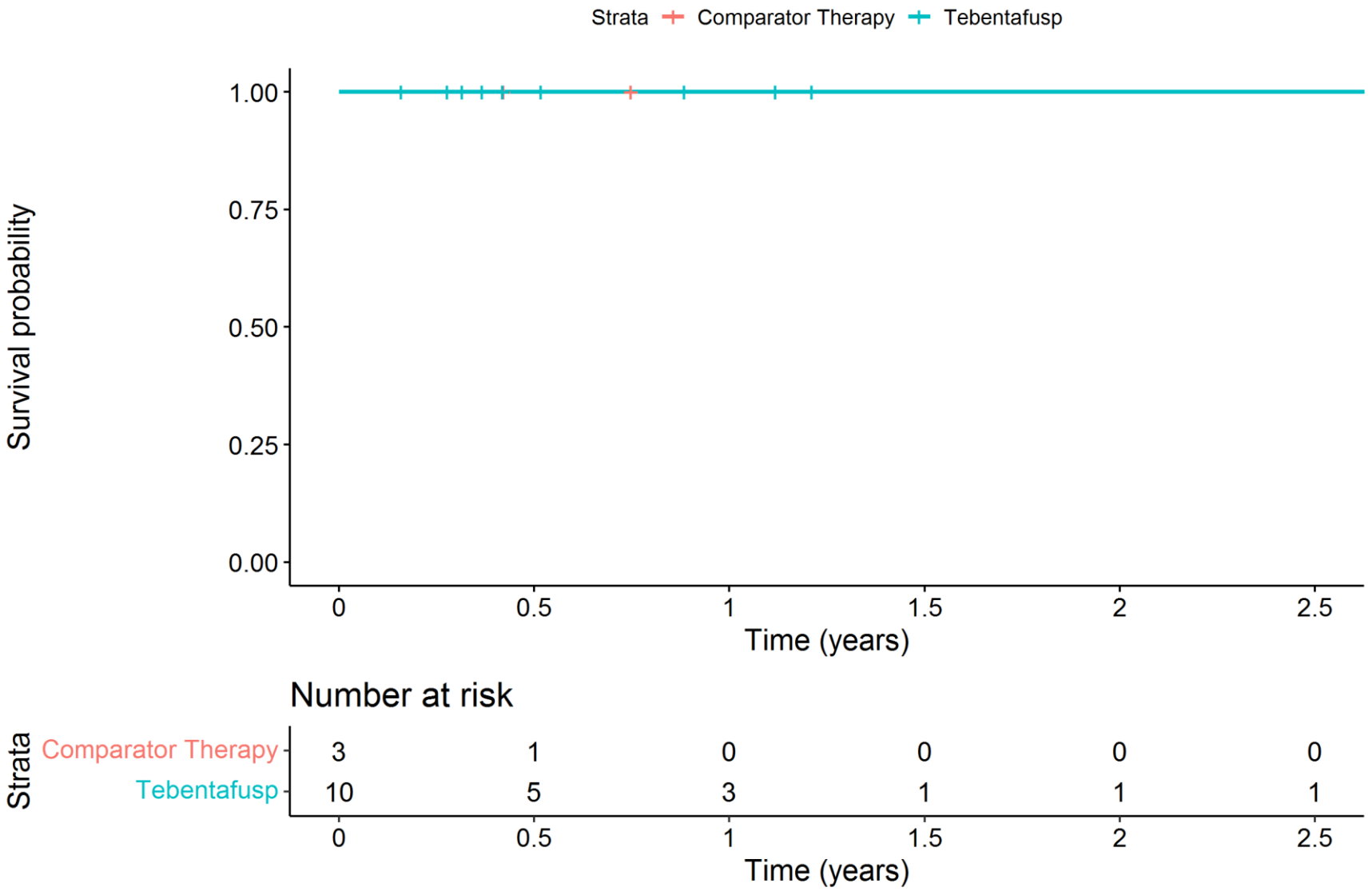
61.101 Erkrankungen des Immunsystems- LDH =< ULN



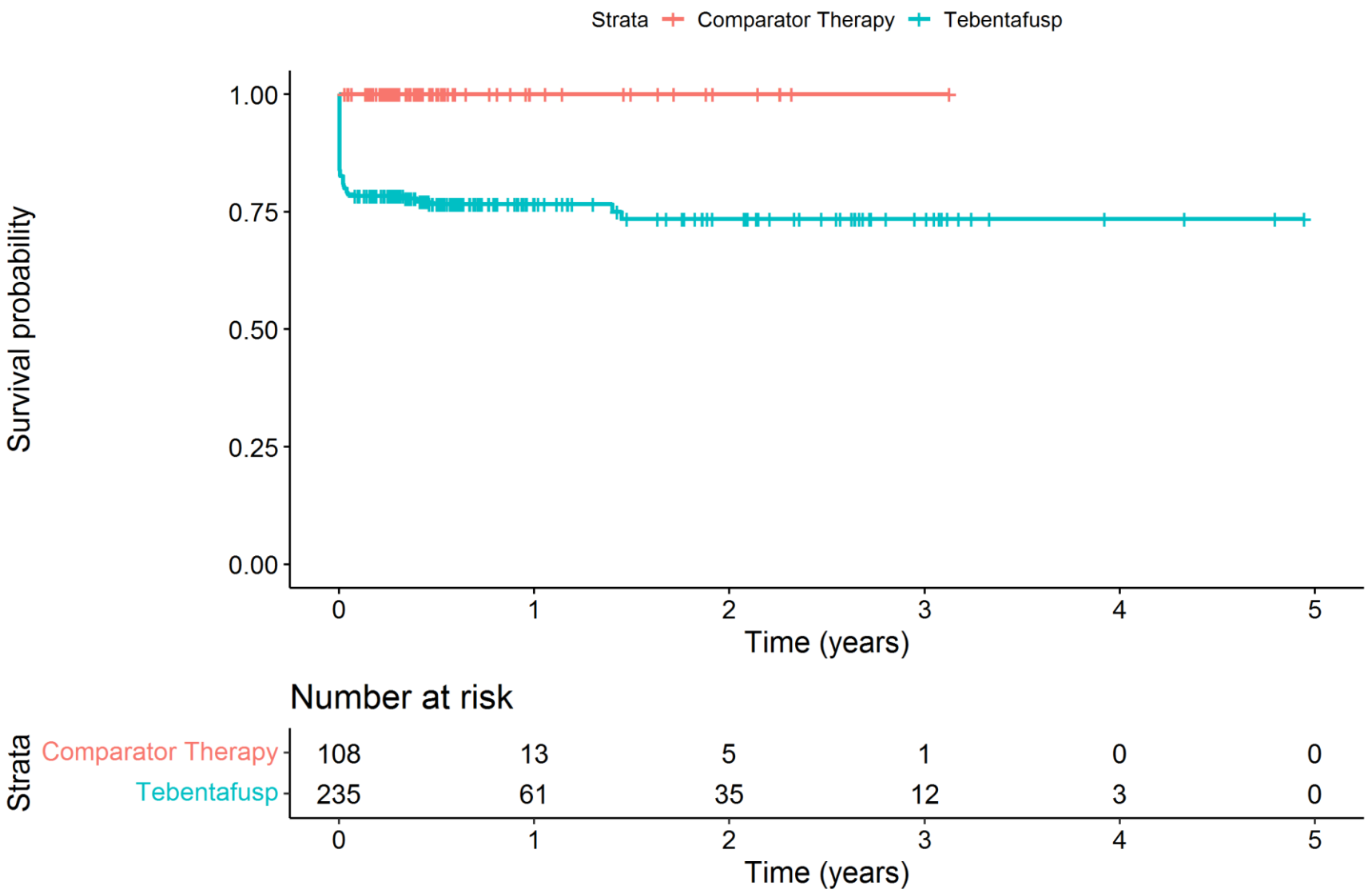
61.102 Erkrankungen des Immunsystems- LDH > ULN



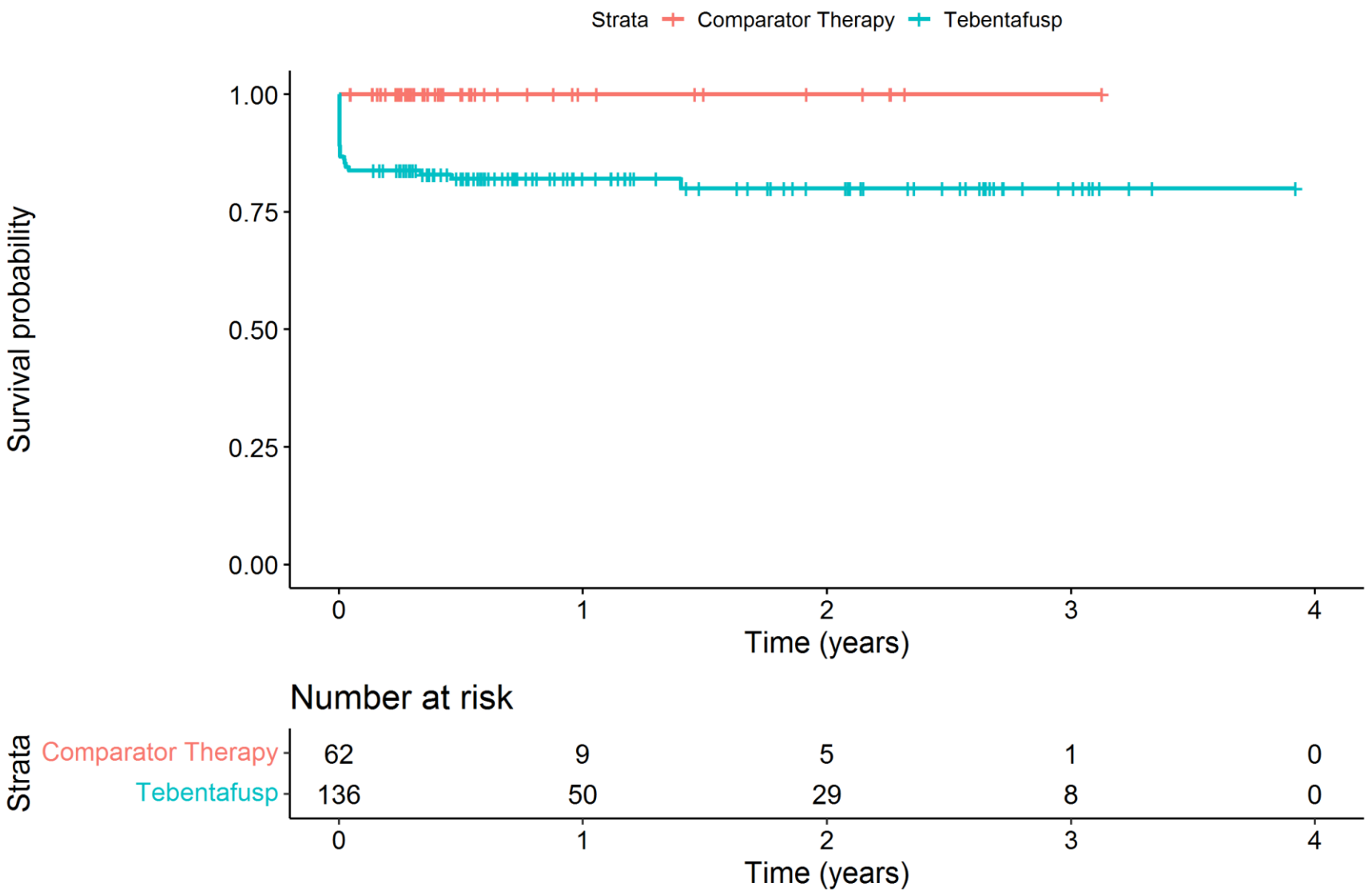
61.103 Erkrankungen des Immunsystems- Vorherige Therapie adjuvant/neoadjuvant



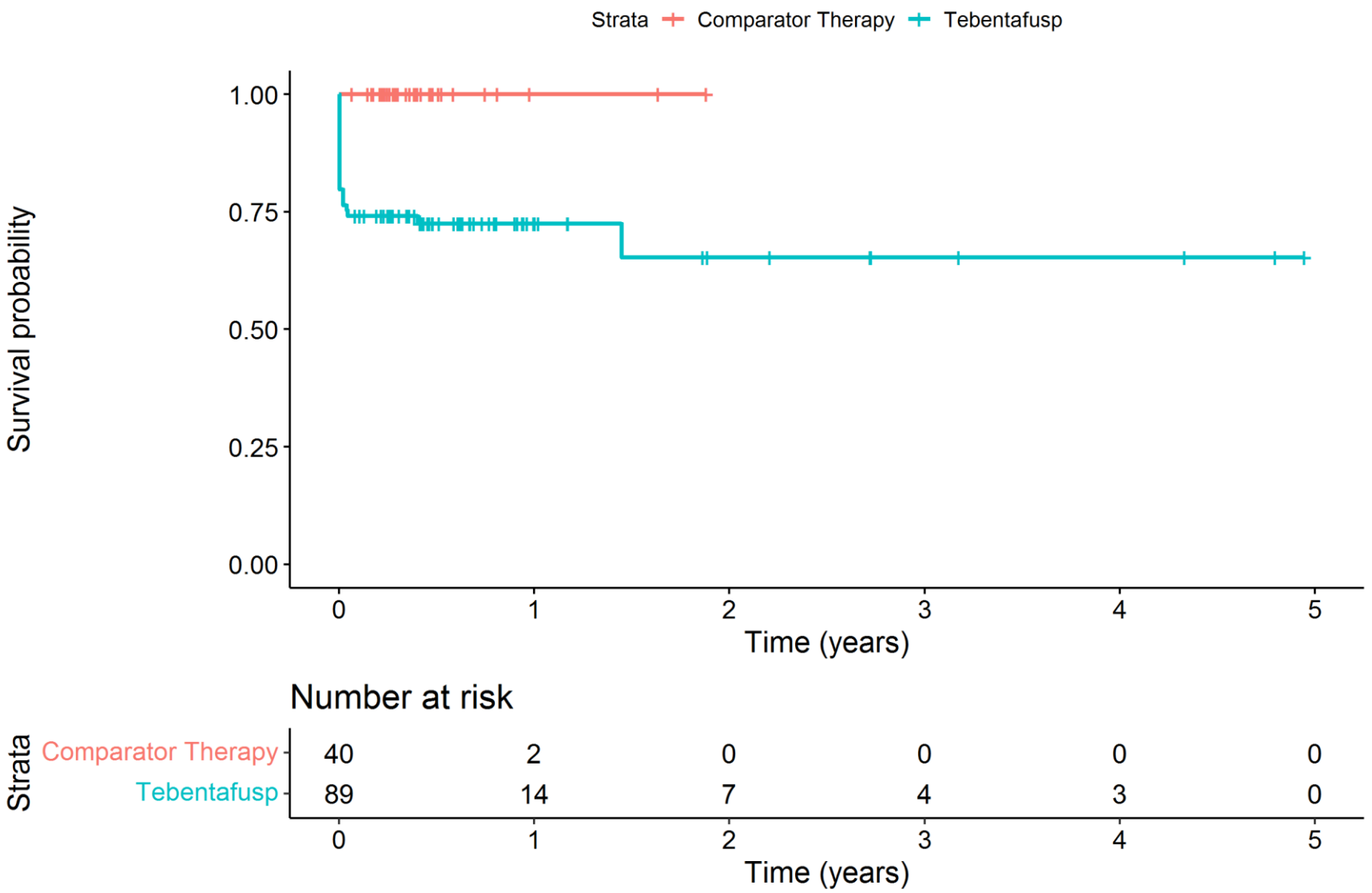
61.104 Erkrankungen des Immunsystems- Keine Vorherige Therapie adjuvant/neoadjuvant



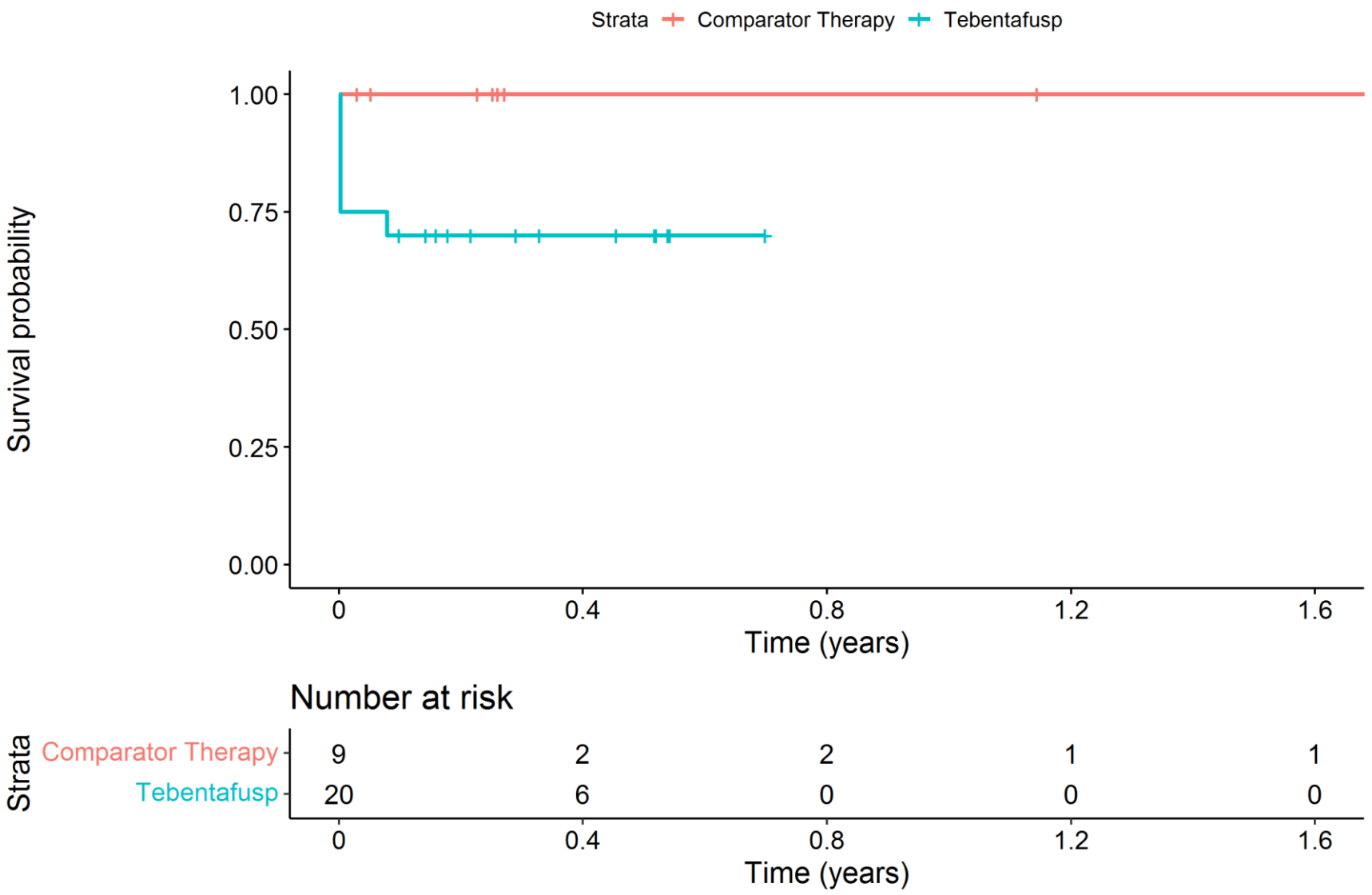
61.105 Erkrankungen des Immunsystems- Läsion ≤ 3cm



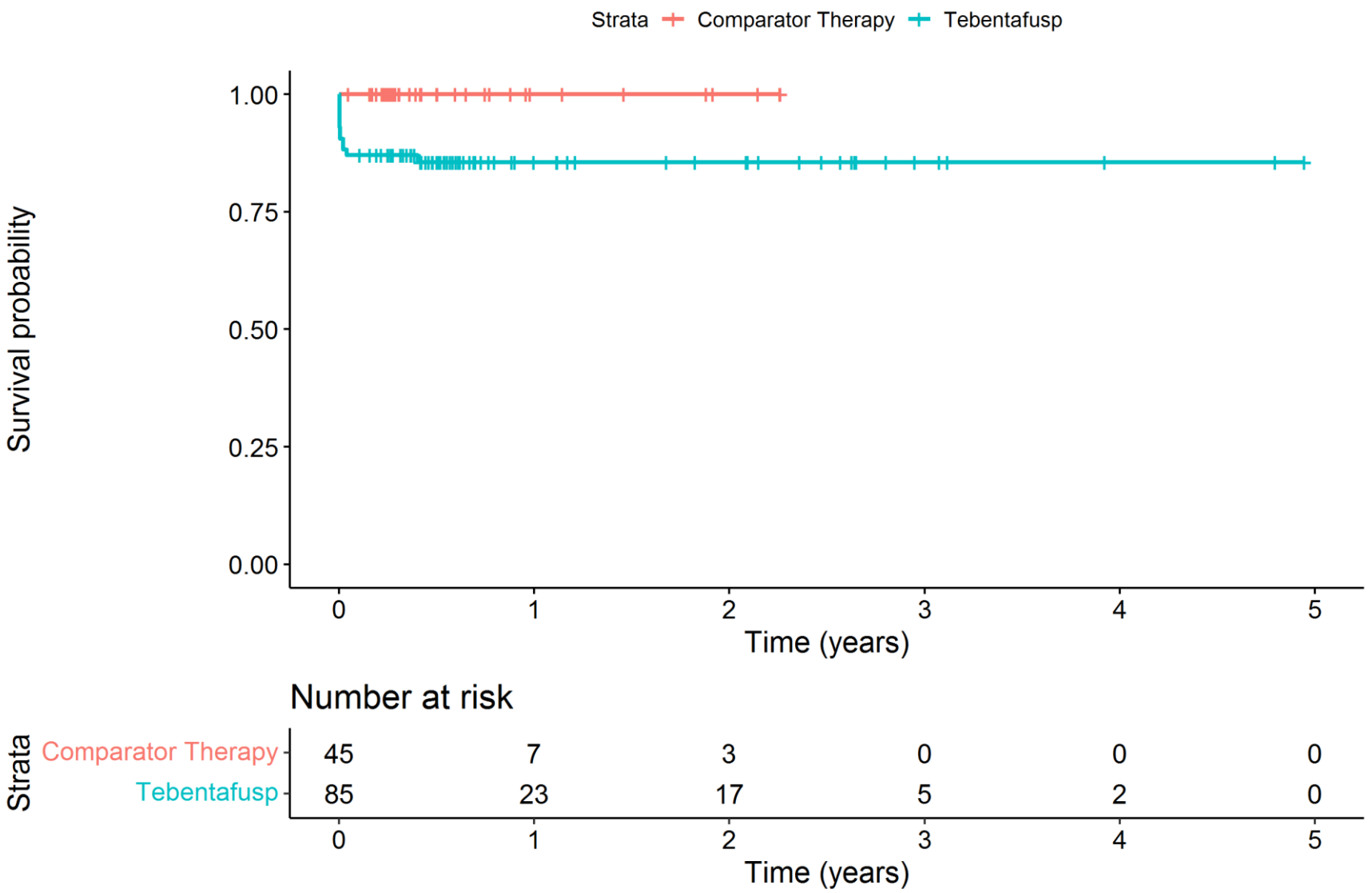
61.106 Erkrankungen des Immunsystems- Läsion 3,1-8,0 cm



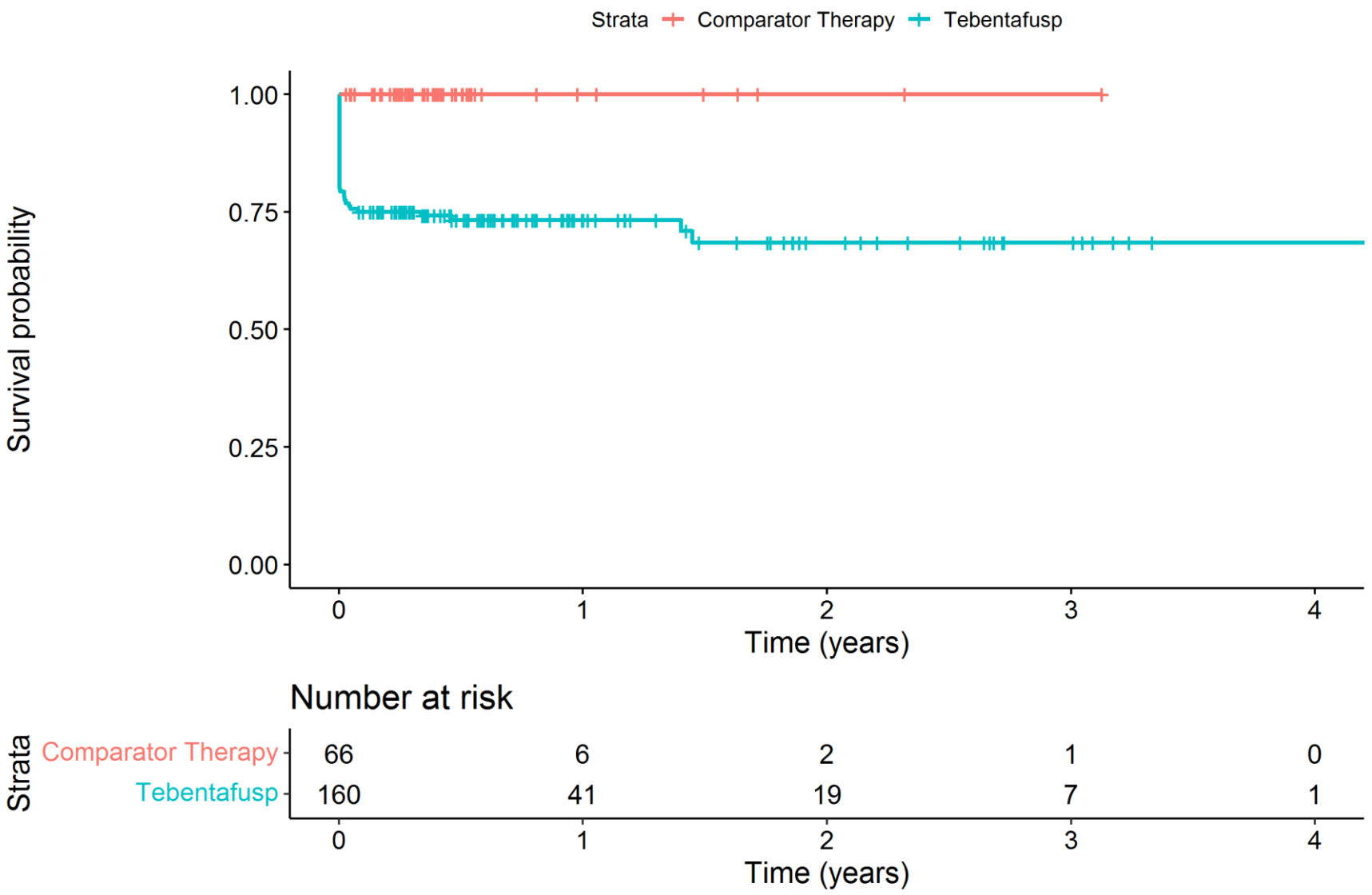
61.107 Erkrankungen des Immunsystems- Läsion ≥8,1 cm



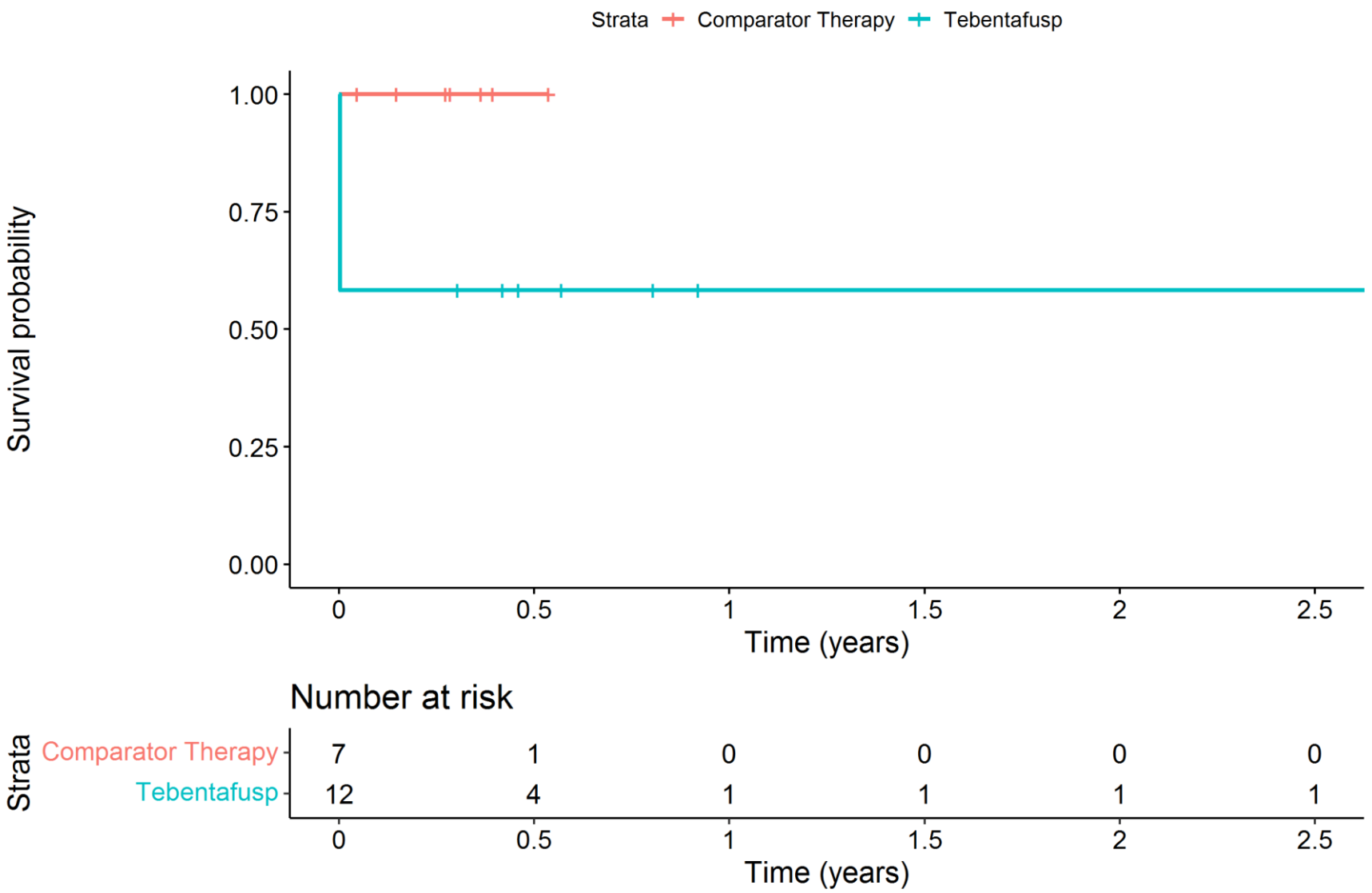
61.108 Erkrankungen des Immunsystems- Nordamerika



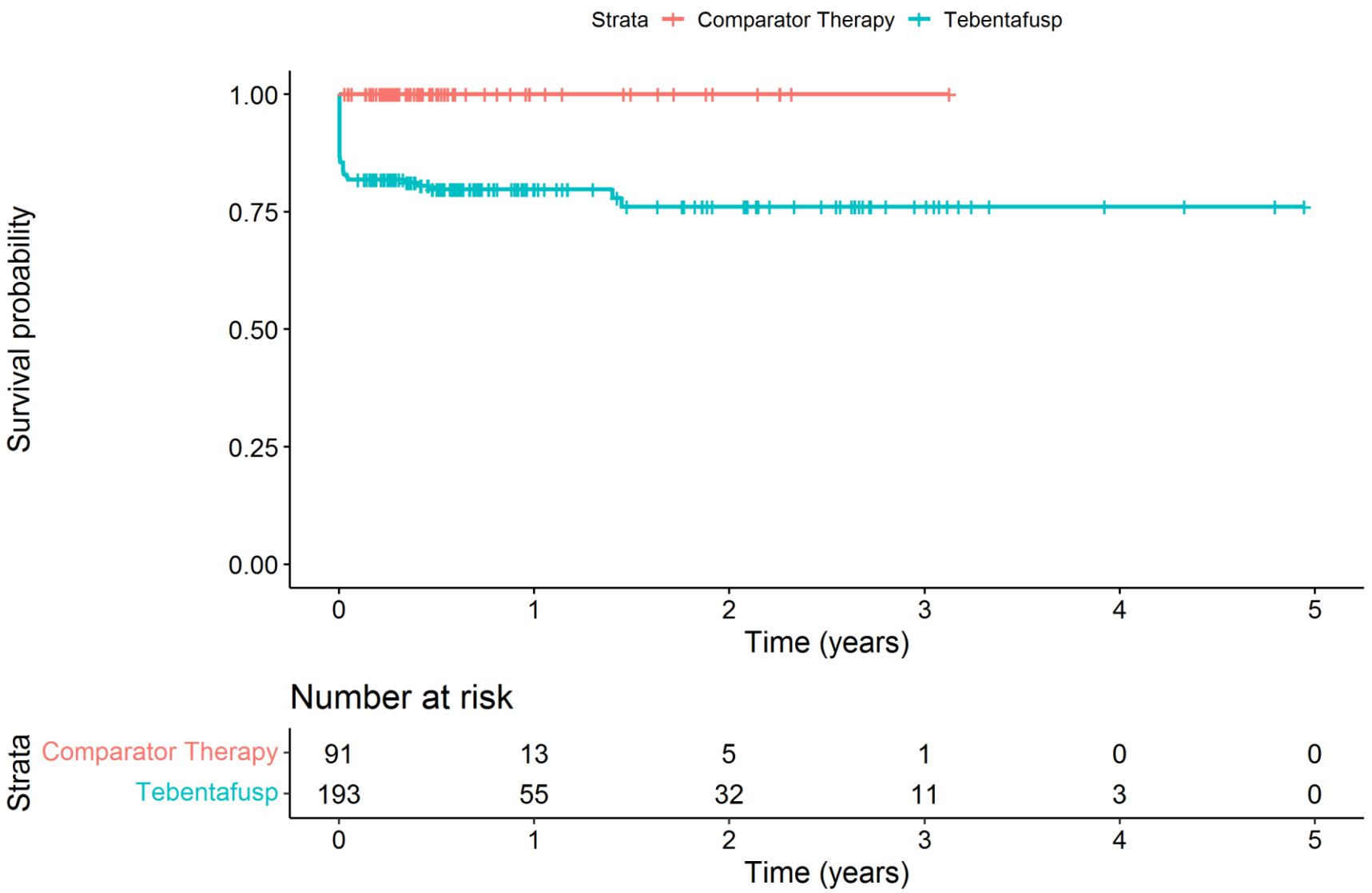
61.109 Erkrankungen des Immunsystems- Nicht-Nordamerika



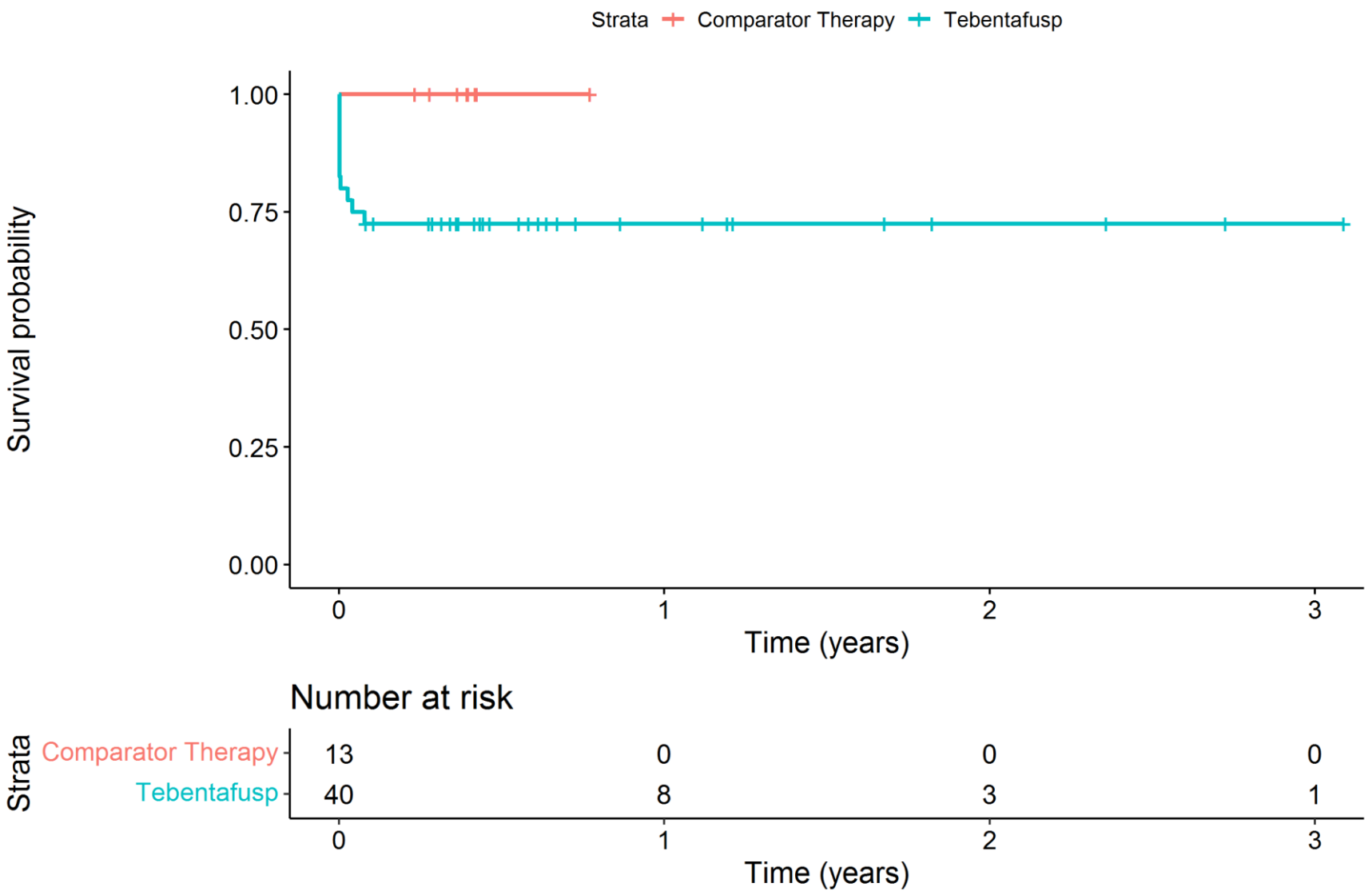
61.110 Erkrankungen des Immunsystems- Dacarbazin



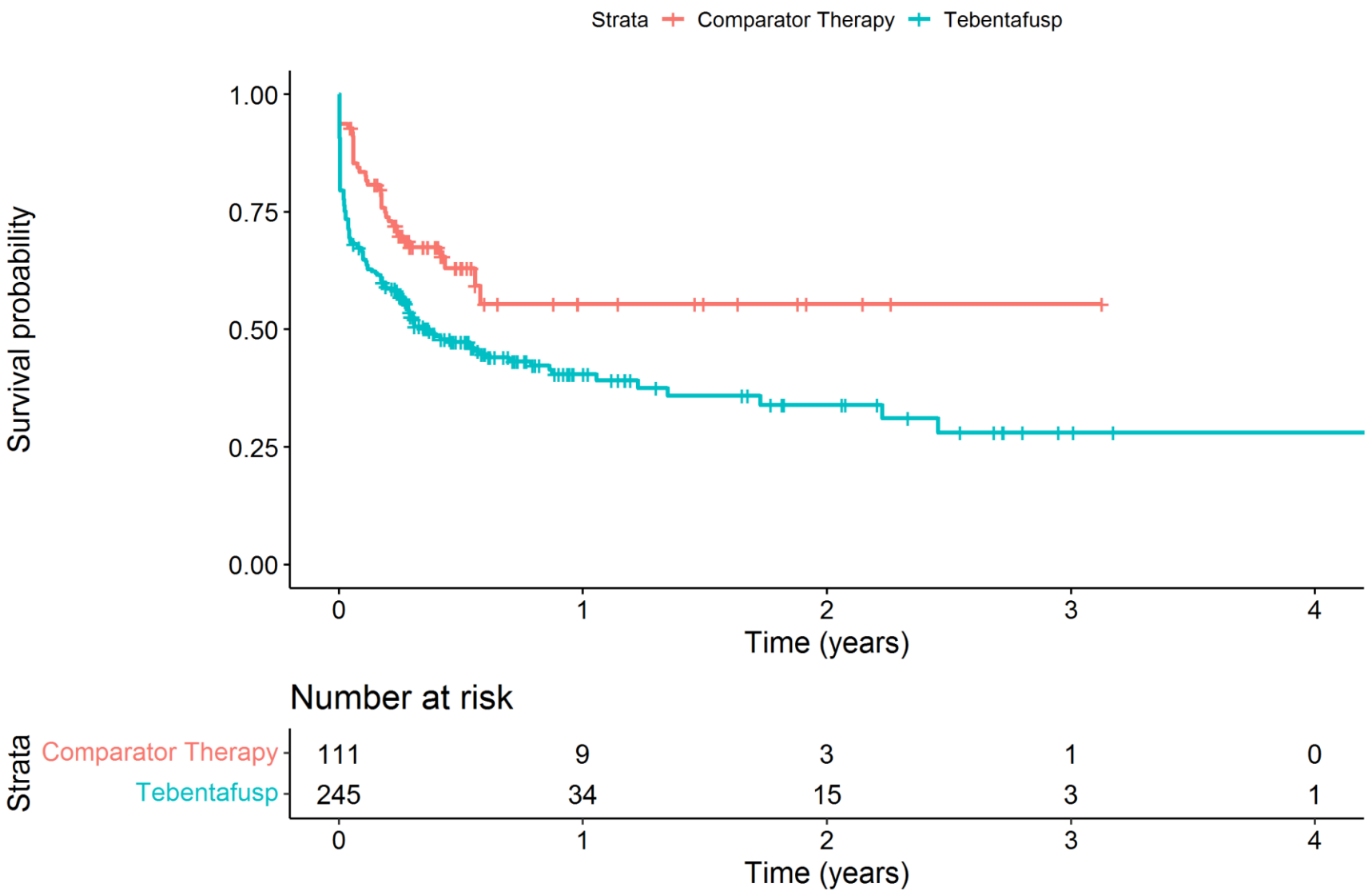
61.111 Erkrankungen des Immunsystems- Pembrolizumab



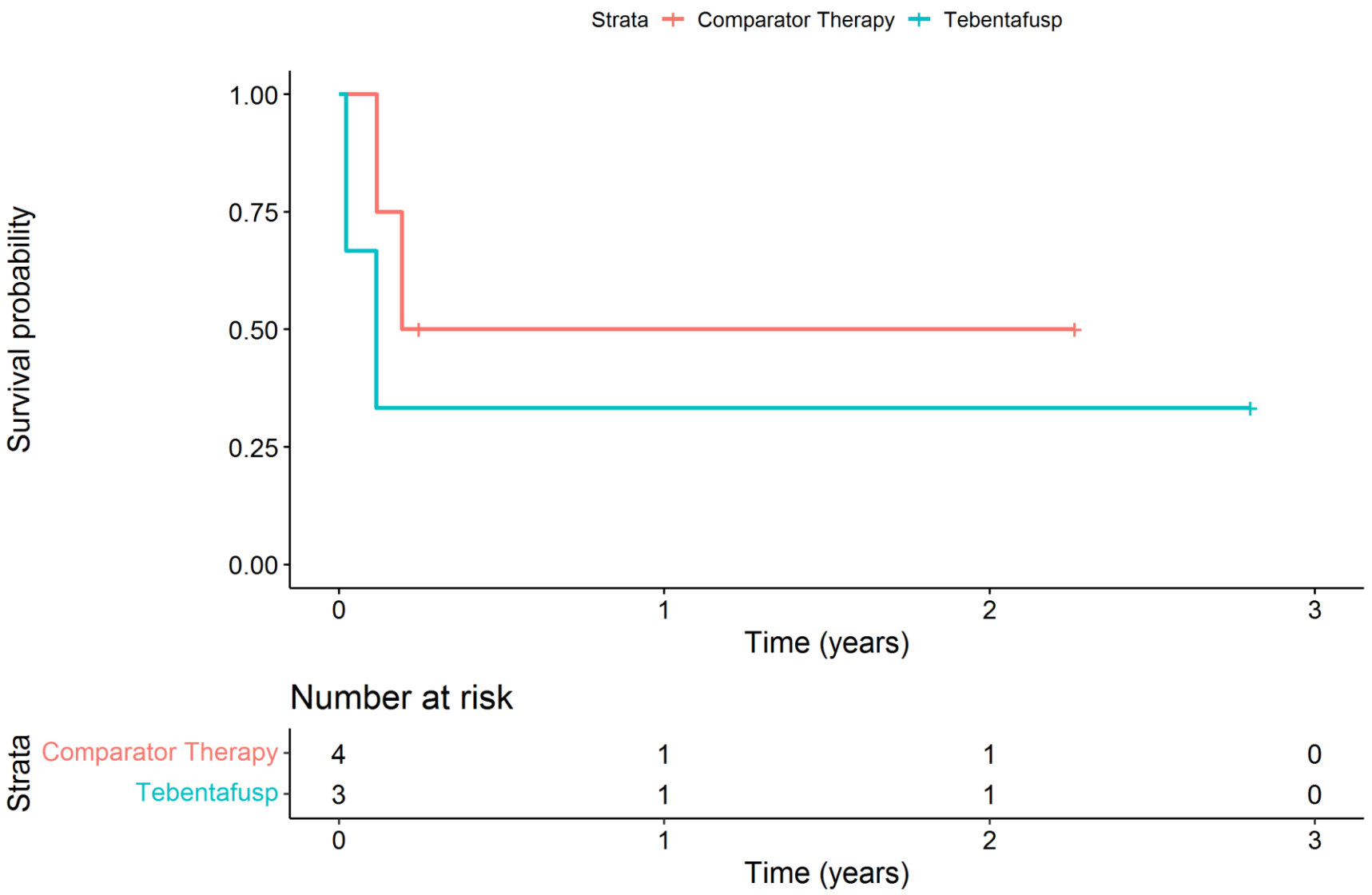
61.112 Erkrankungen des Immunsystems- Ipilimumab



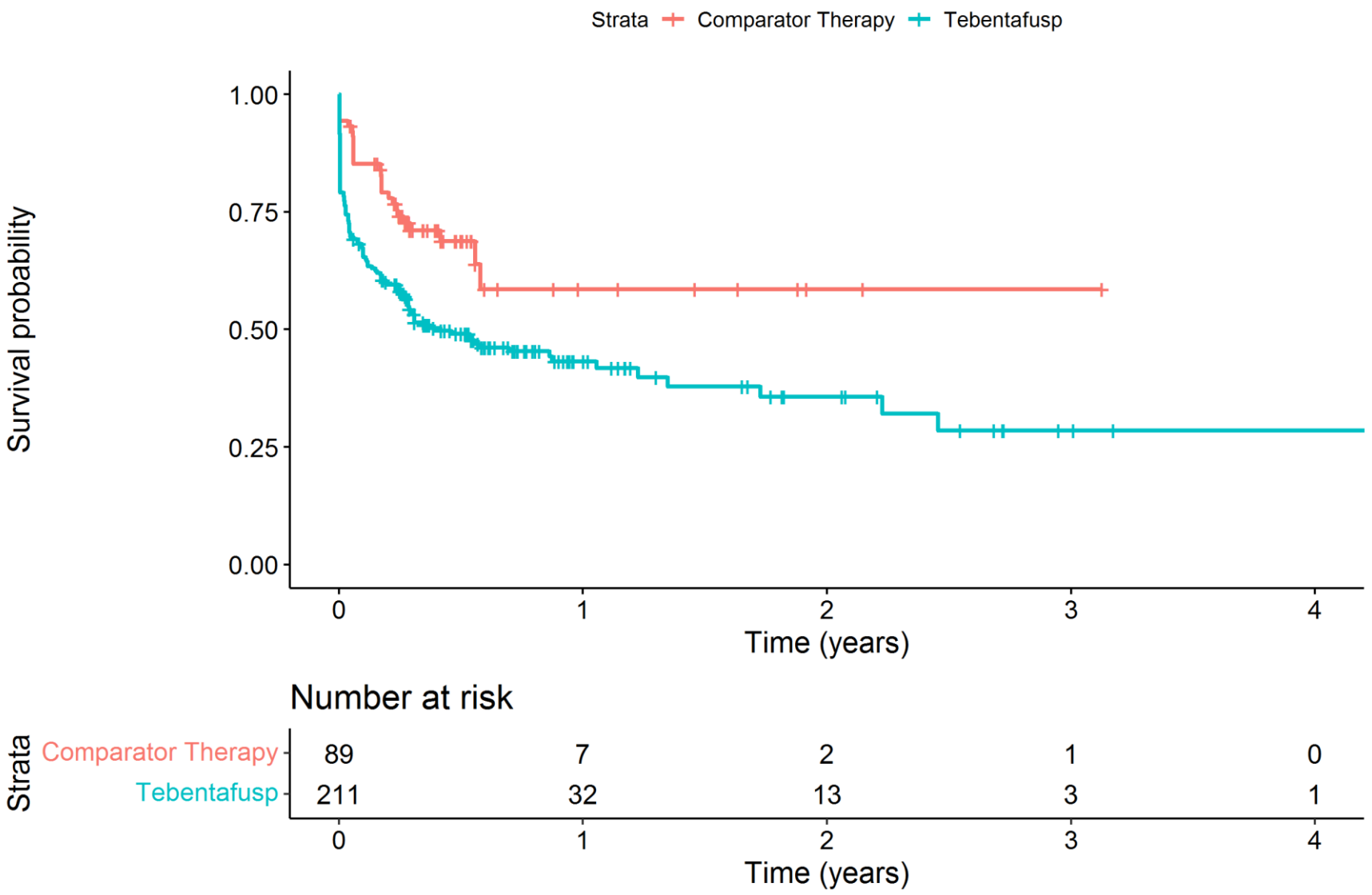
61.113 Untersuchungen - Gesamt



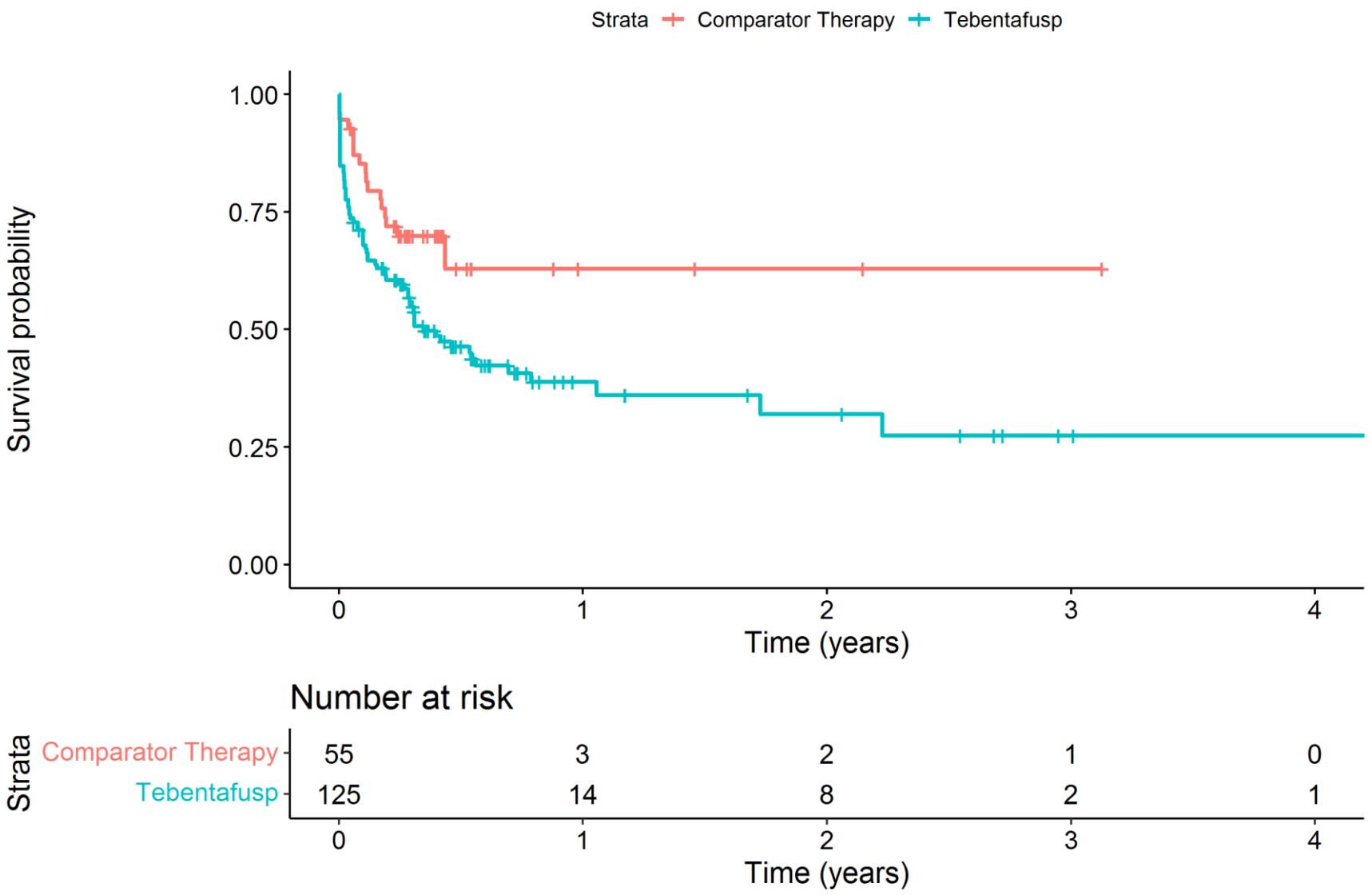
61.114 Untersuchungen - Hispanisch



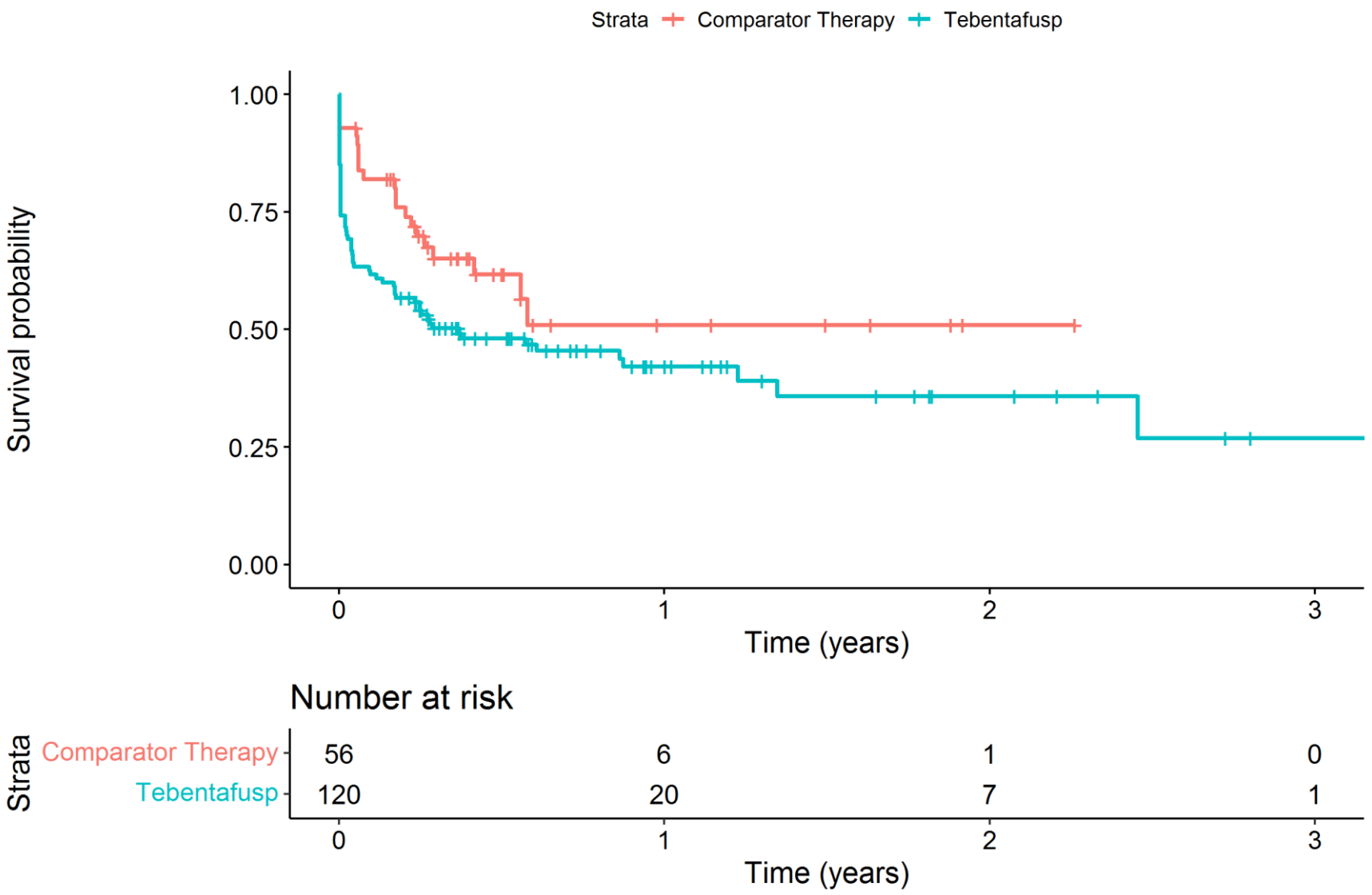
61.115 Untersuchungen - Nicht-hispanisch



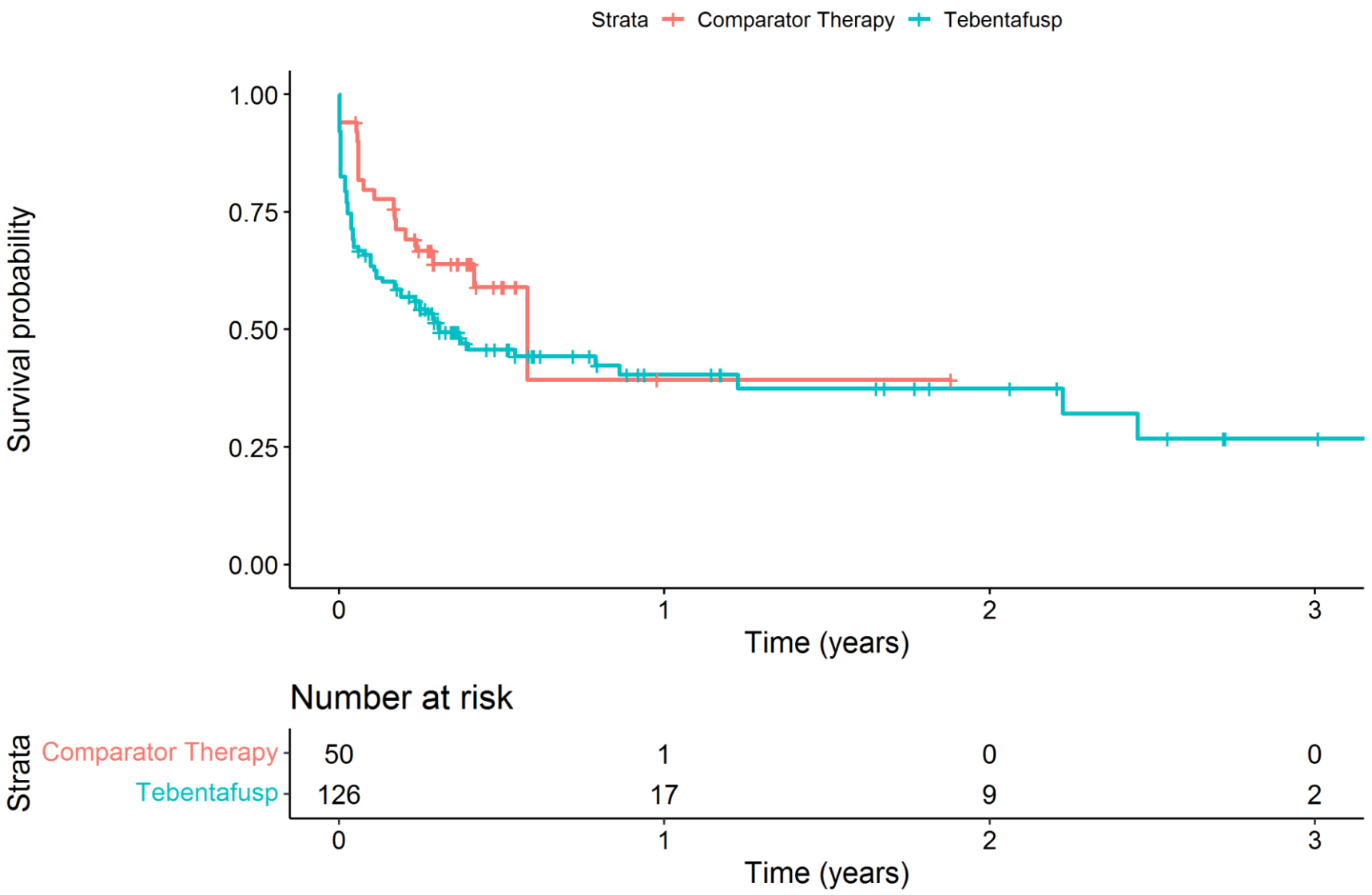
61.116 Untersuchungen - Männlich



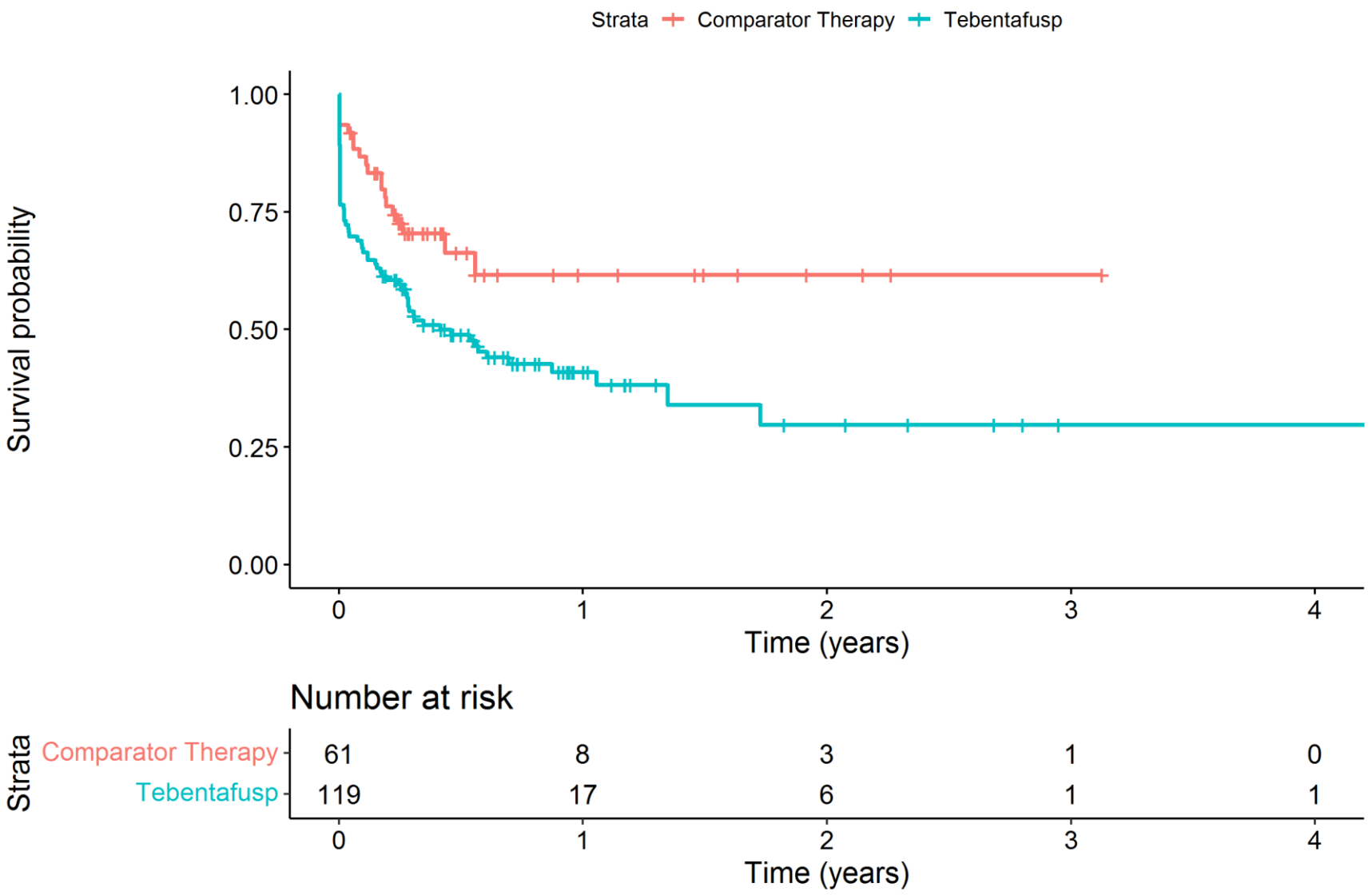
61.117 Untersuchungen - Weiblich



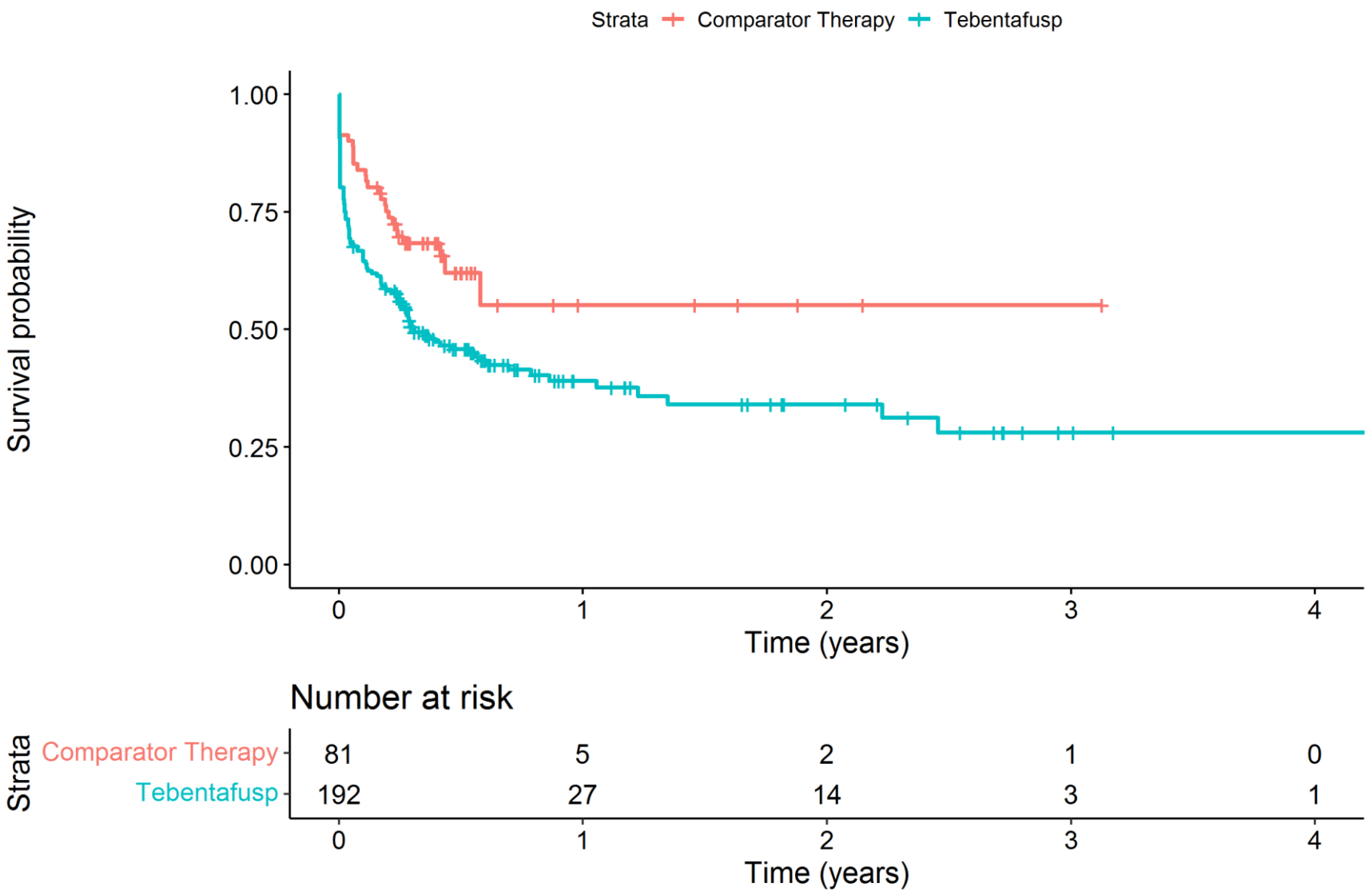
61.118 Untersuchungen - <65



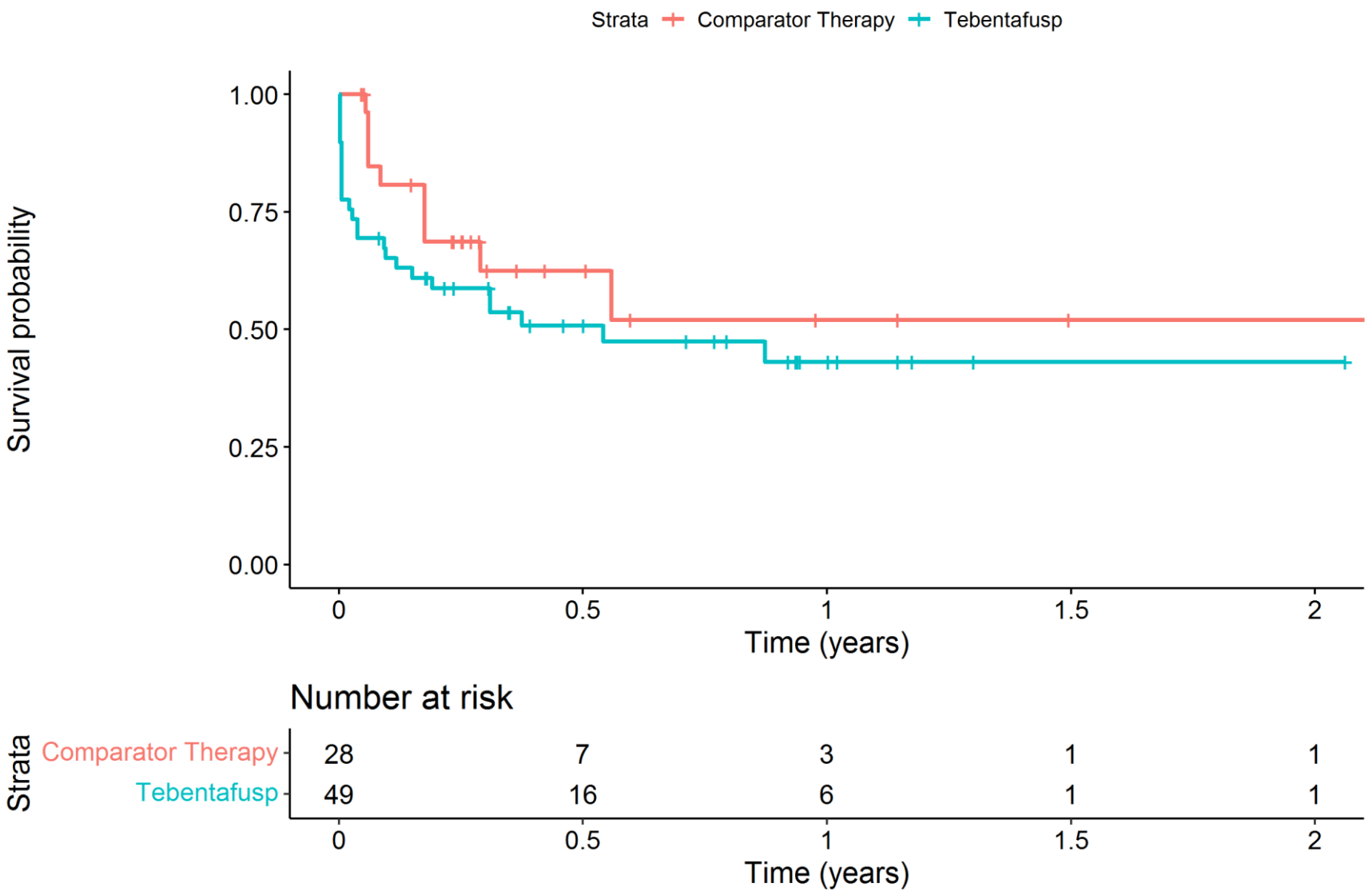
61.119 Untersuchungen - ≥65



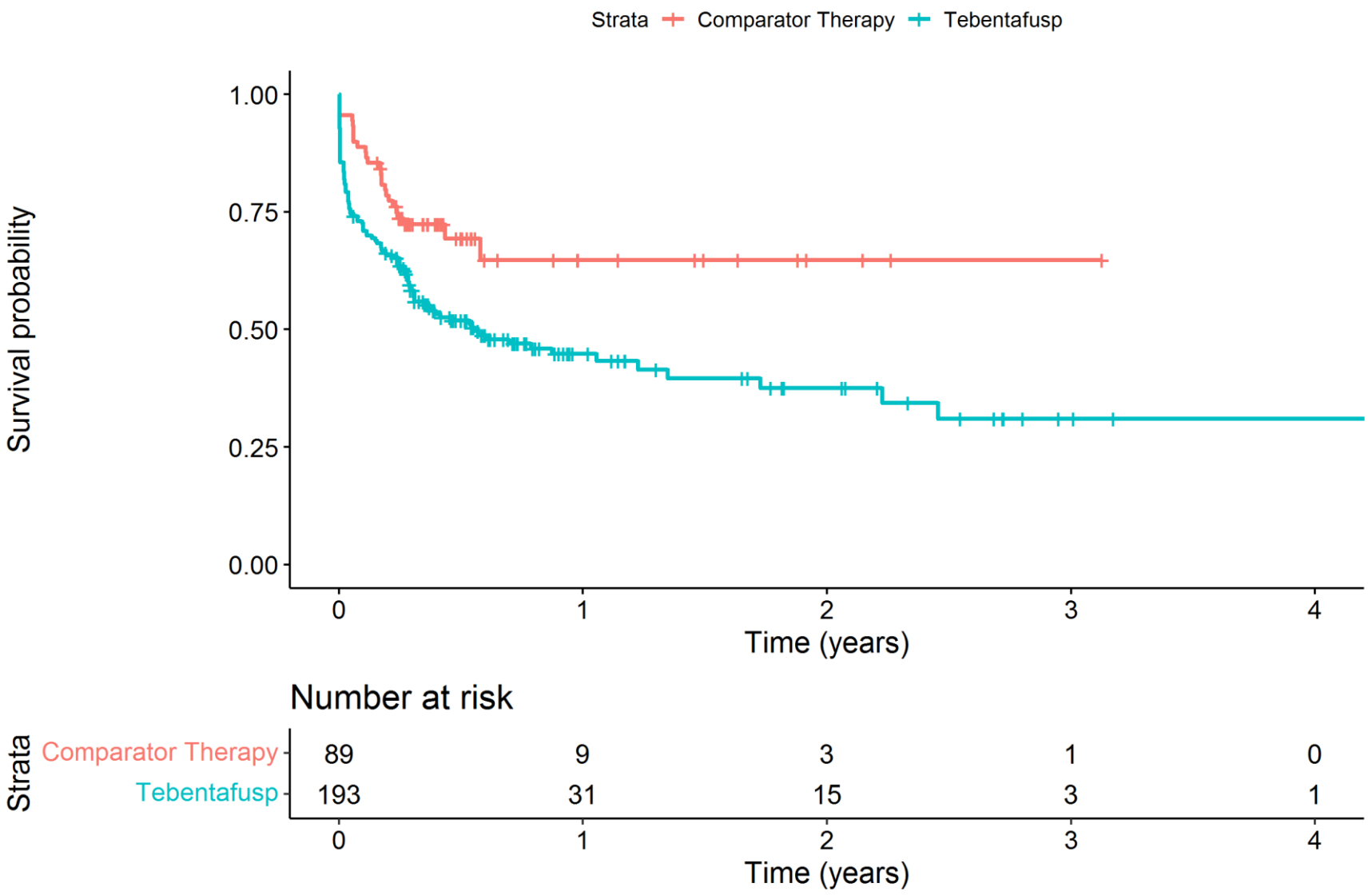
61.120 Untersuchungen - ECOG 0



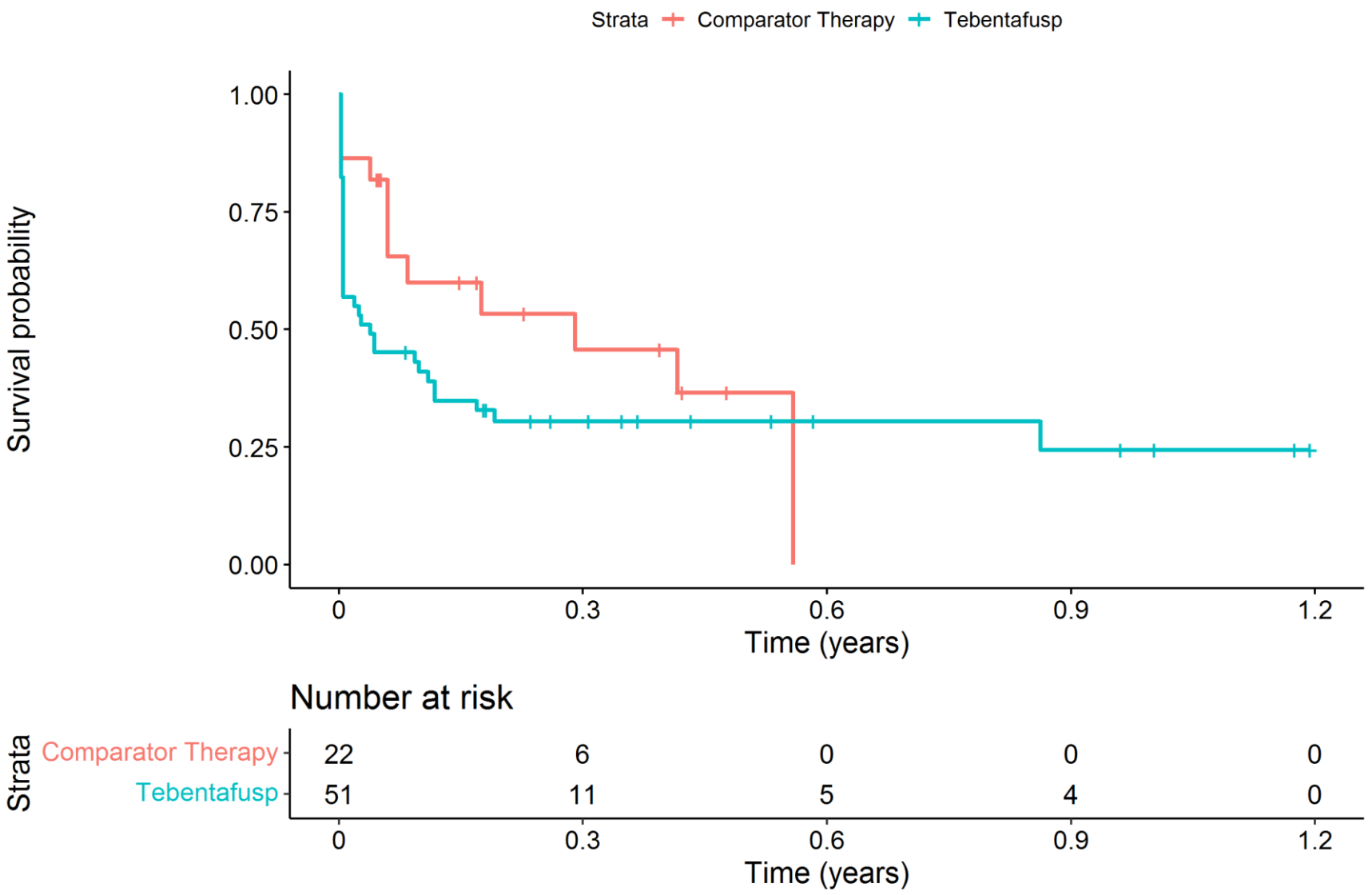
61.121 Untersuchungen - ECOG 1



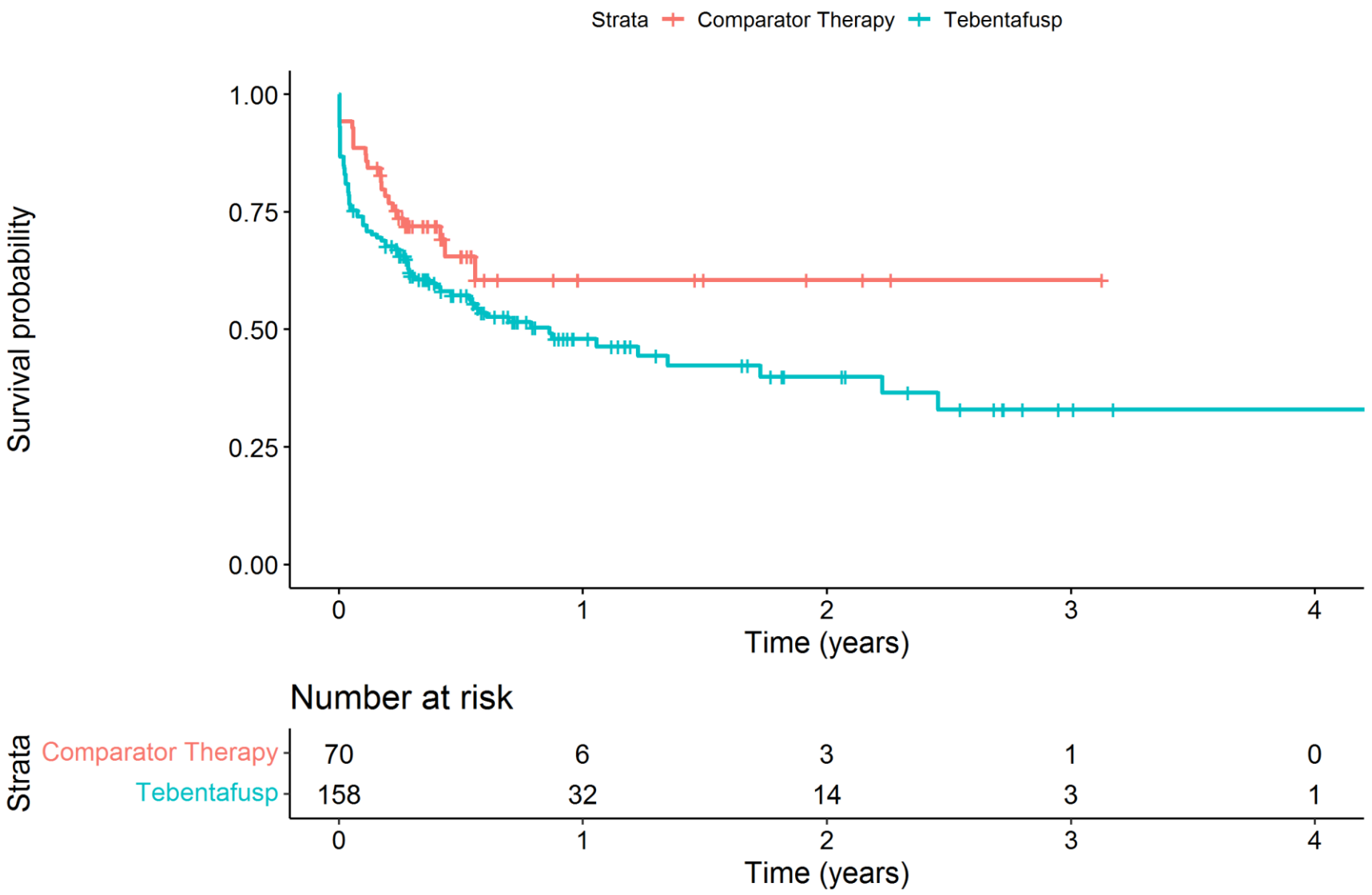
61.122 Untersuchungen - ALP ≤ ULN



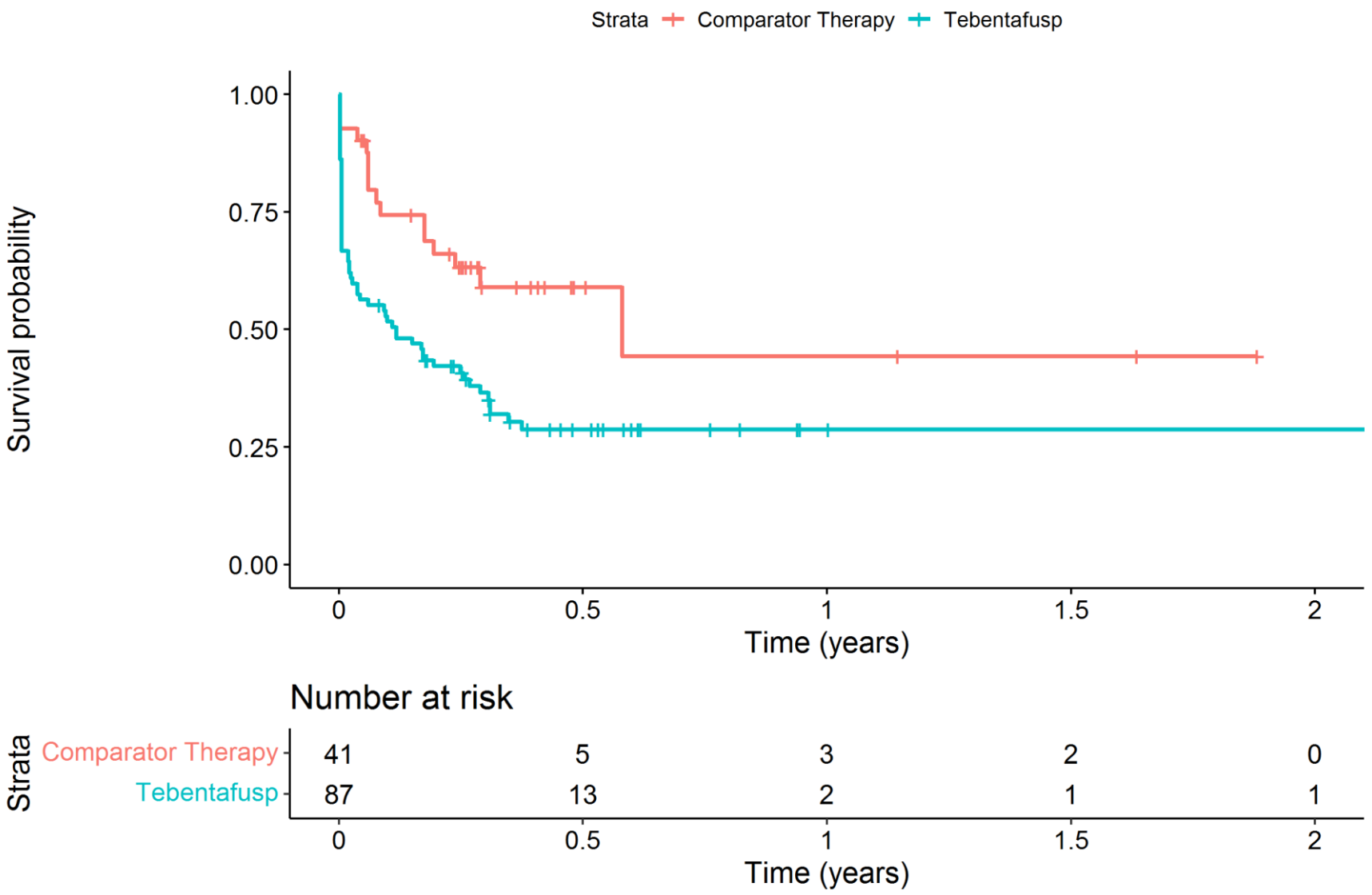
61.123 Untersuchungen - ALP > ULN



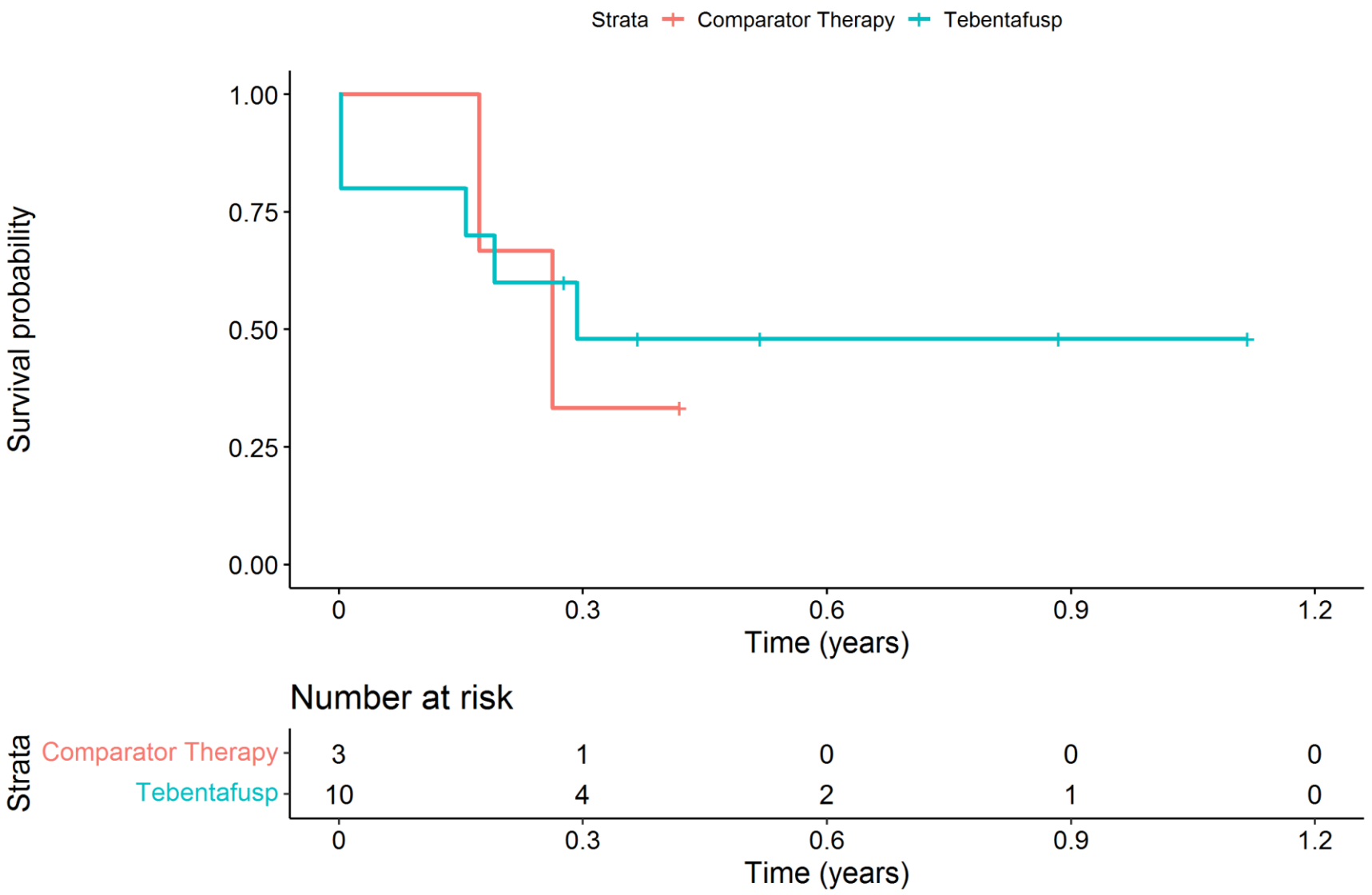
61.124 Untersuchungen - LDH =< ULN



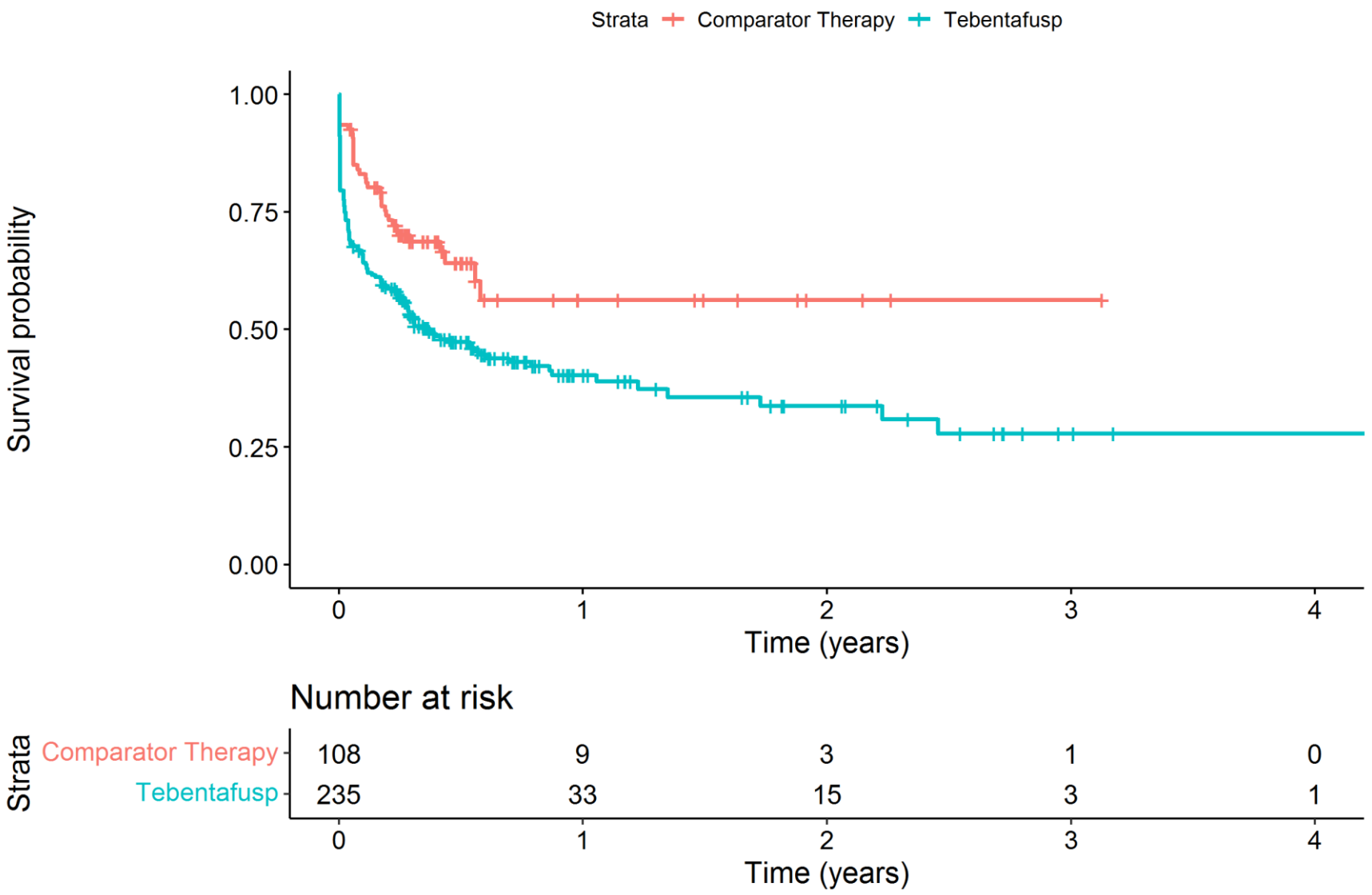
61.125 Untersuchungen - LDH > ULN



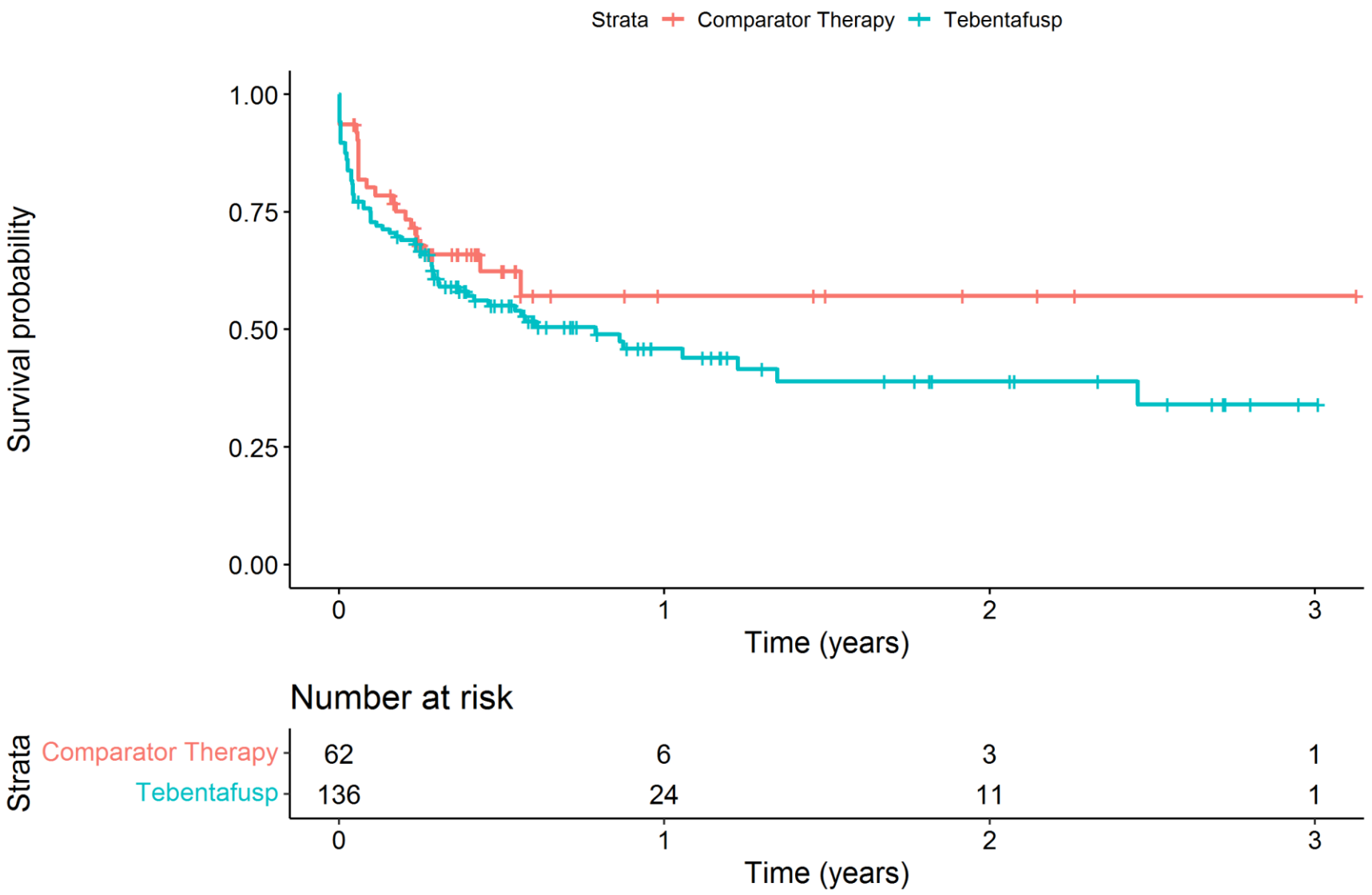
61.126 Untersuchungen - Vorherige Therapie adjuvant/neoadjuvant



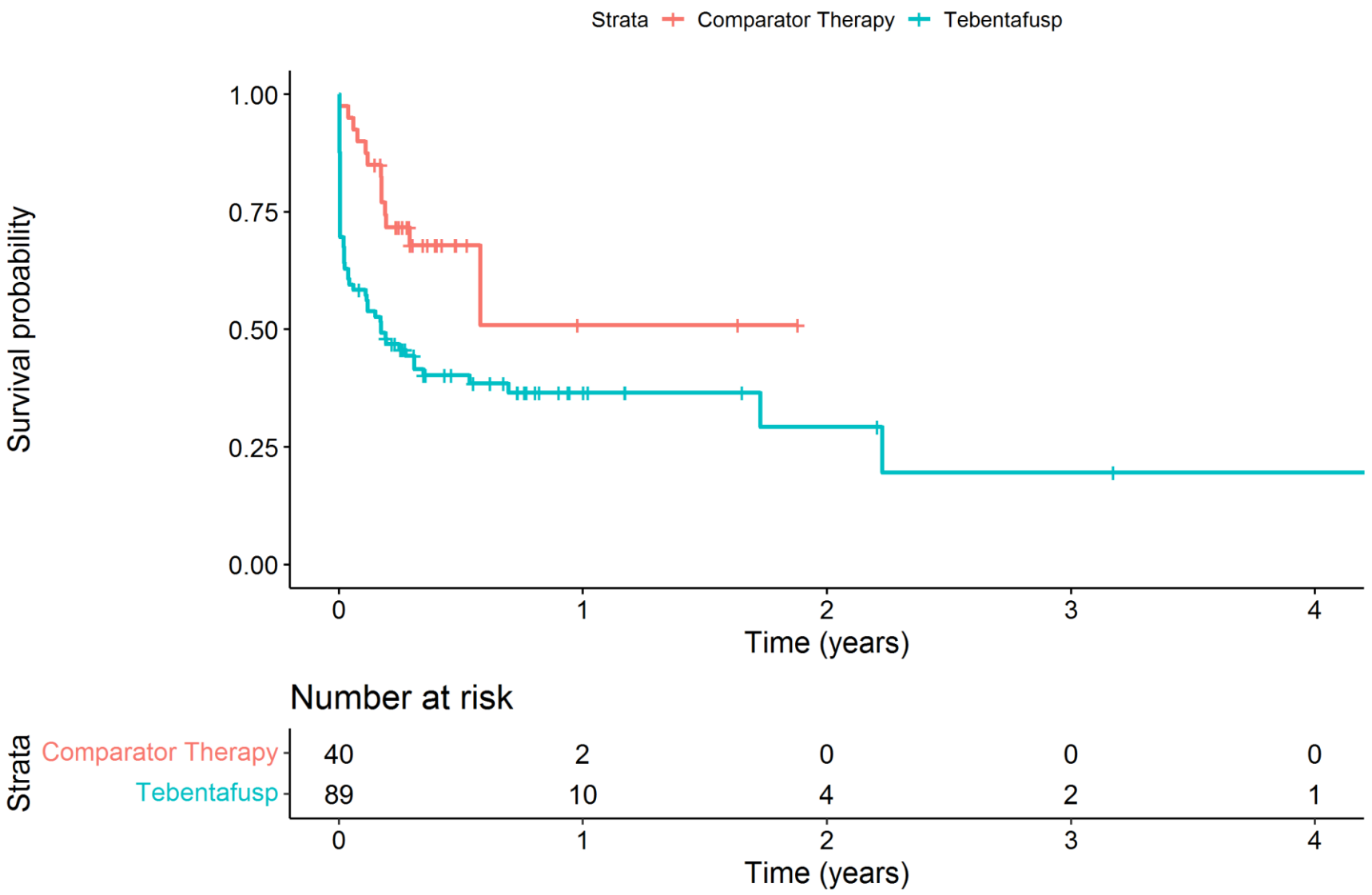
61.127 Untersuchungen - Keine Vorherige Therapie adjuvant/neoadjuvant



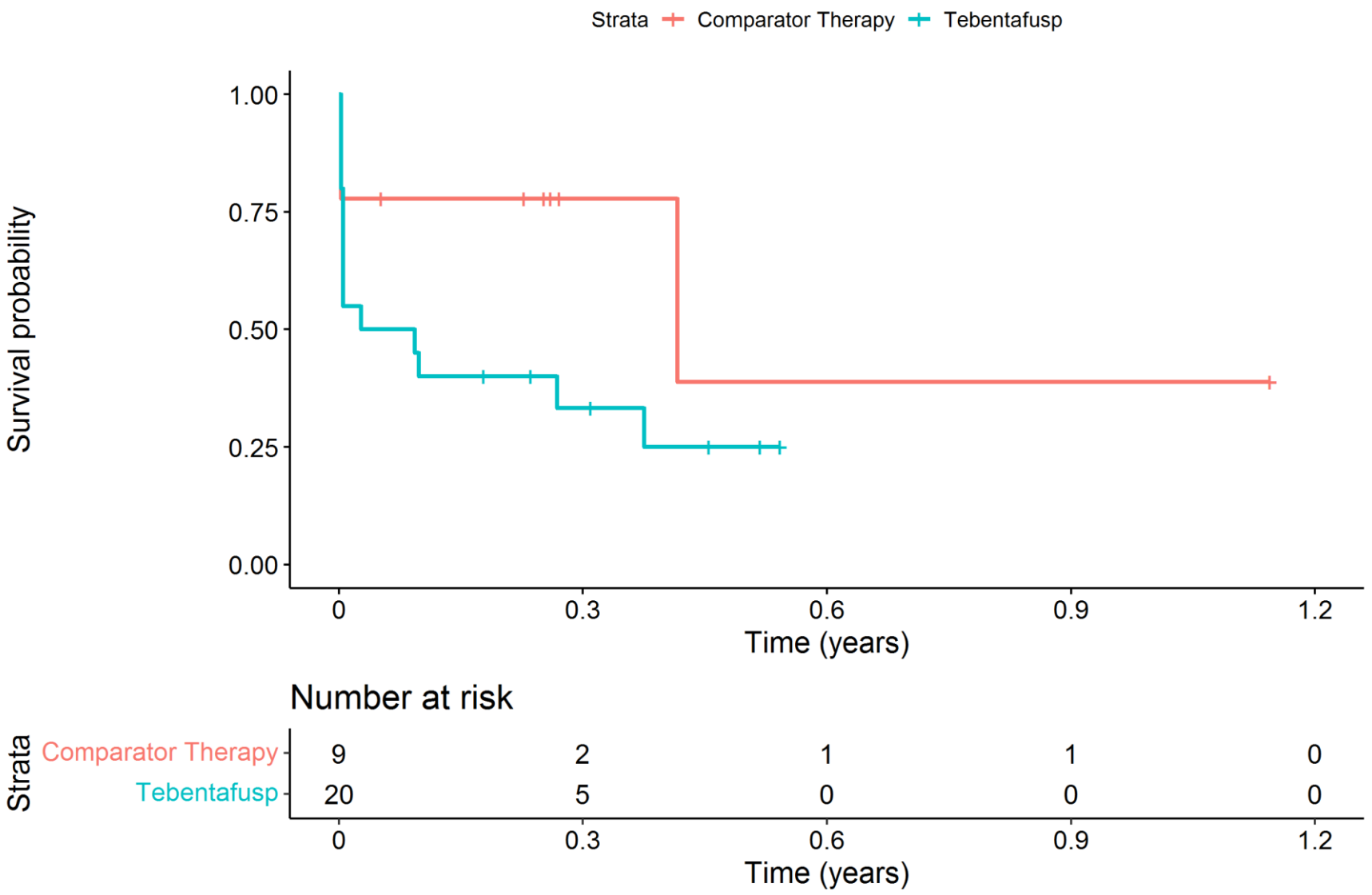
61.128 Untersuchungen - Läsion ≤ 3cm



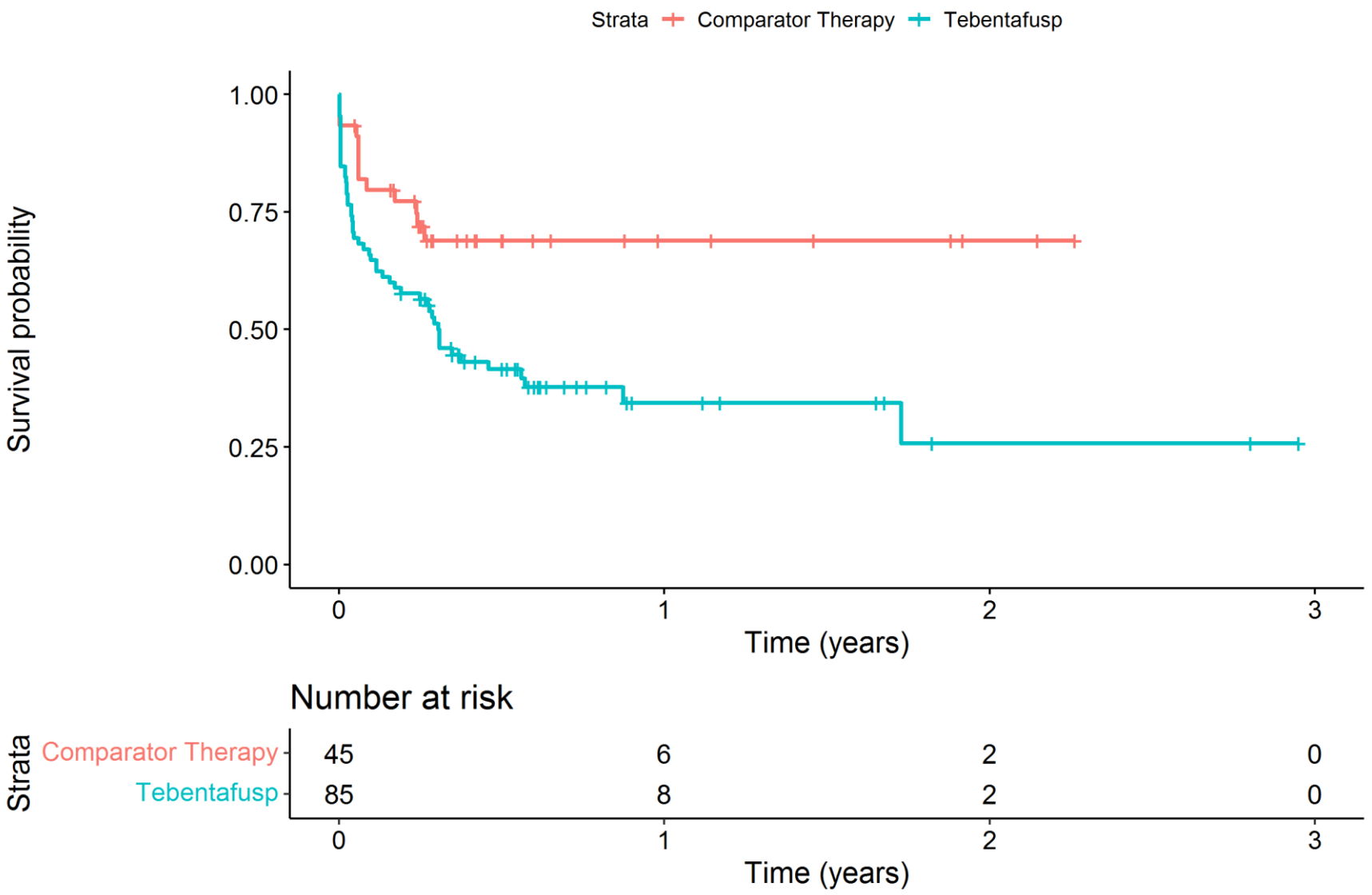
61.129 Untersuchungen - Läsion 3,1-8,0 cm



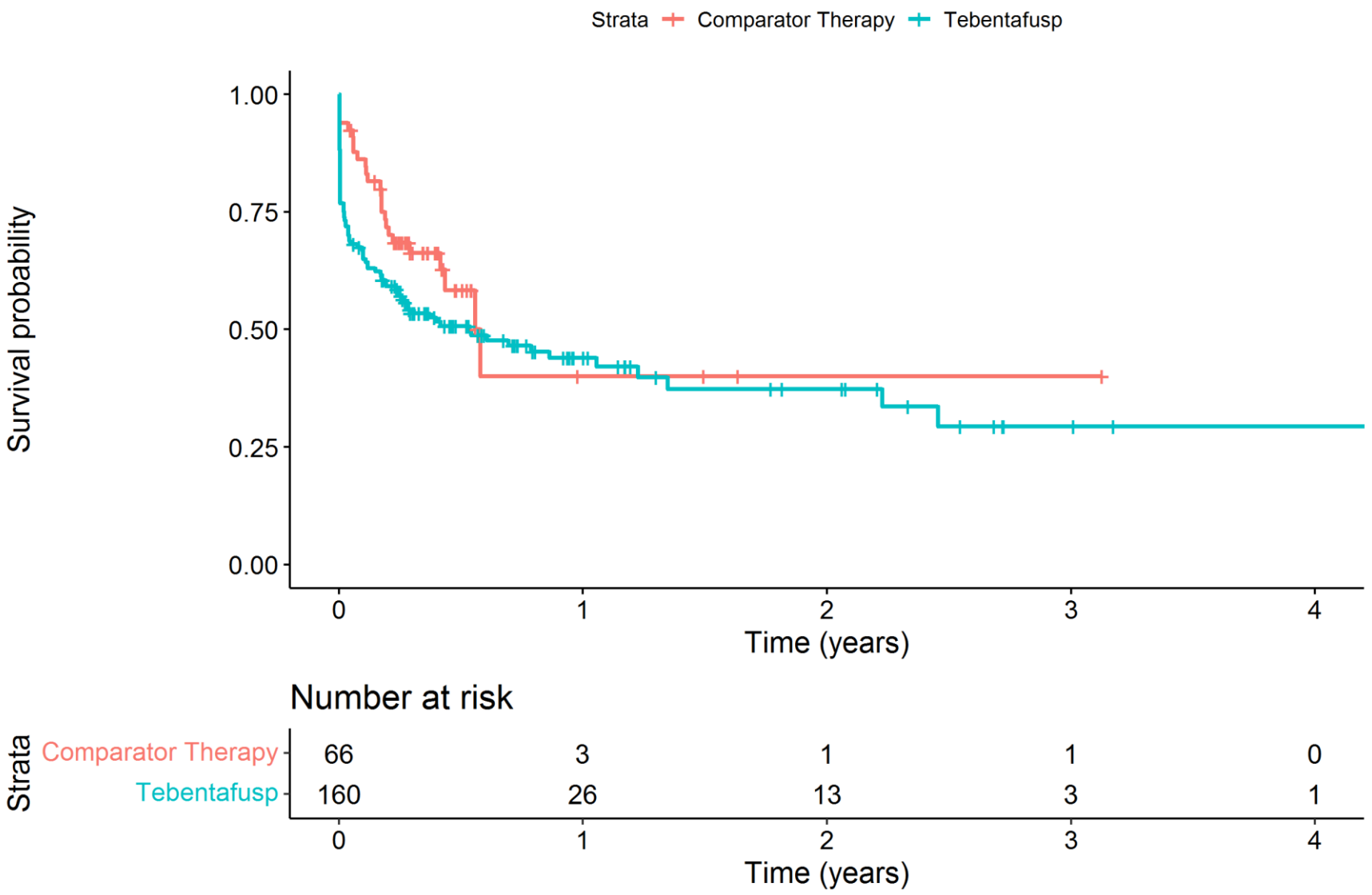
61.130 Untersuchungen - Läsion ≥8,1 cm



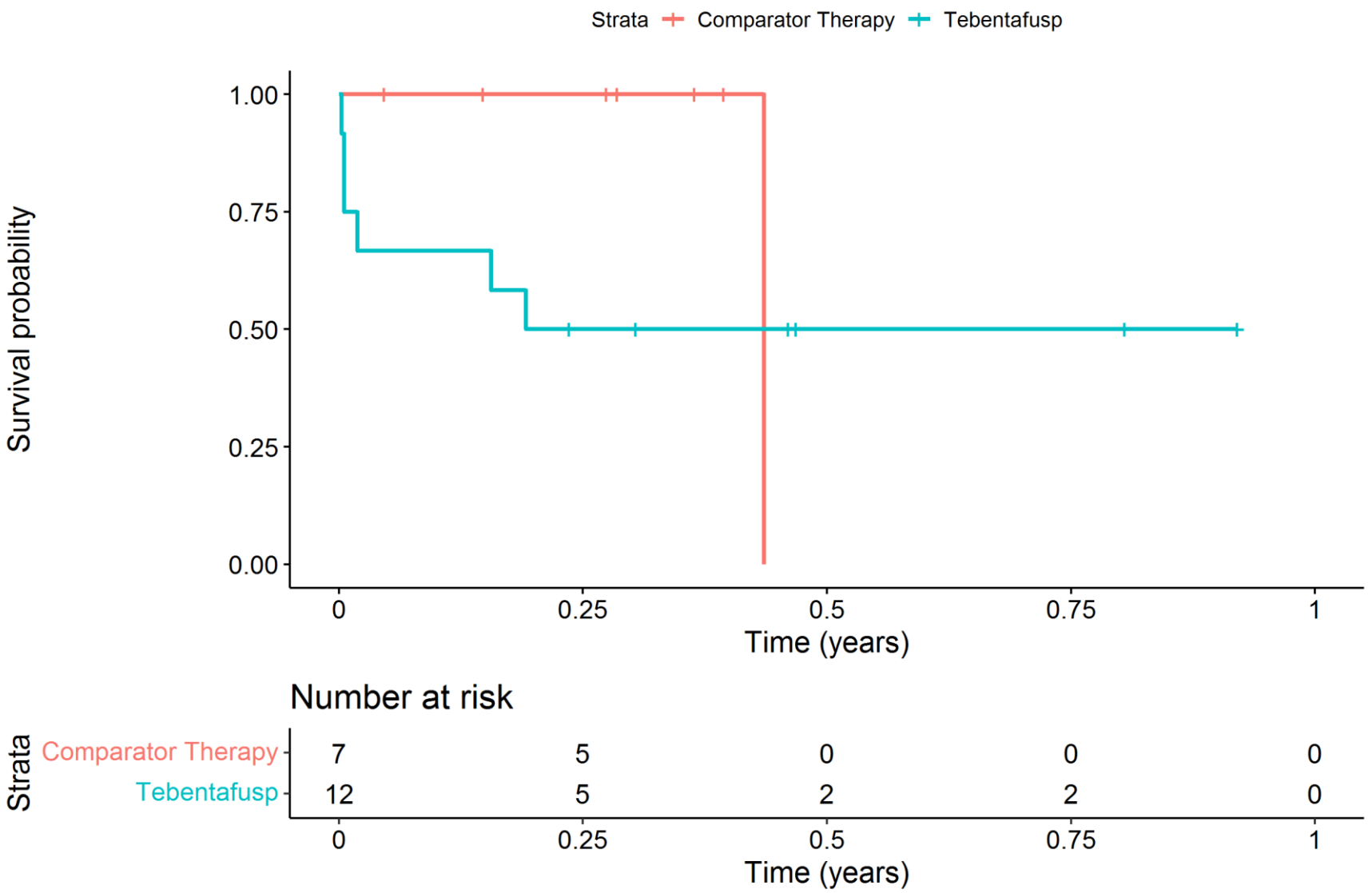
61.131 Untersuchungen - Nordamerika



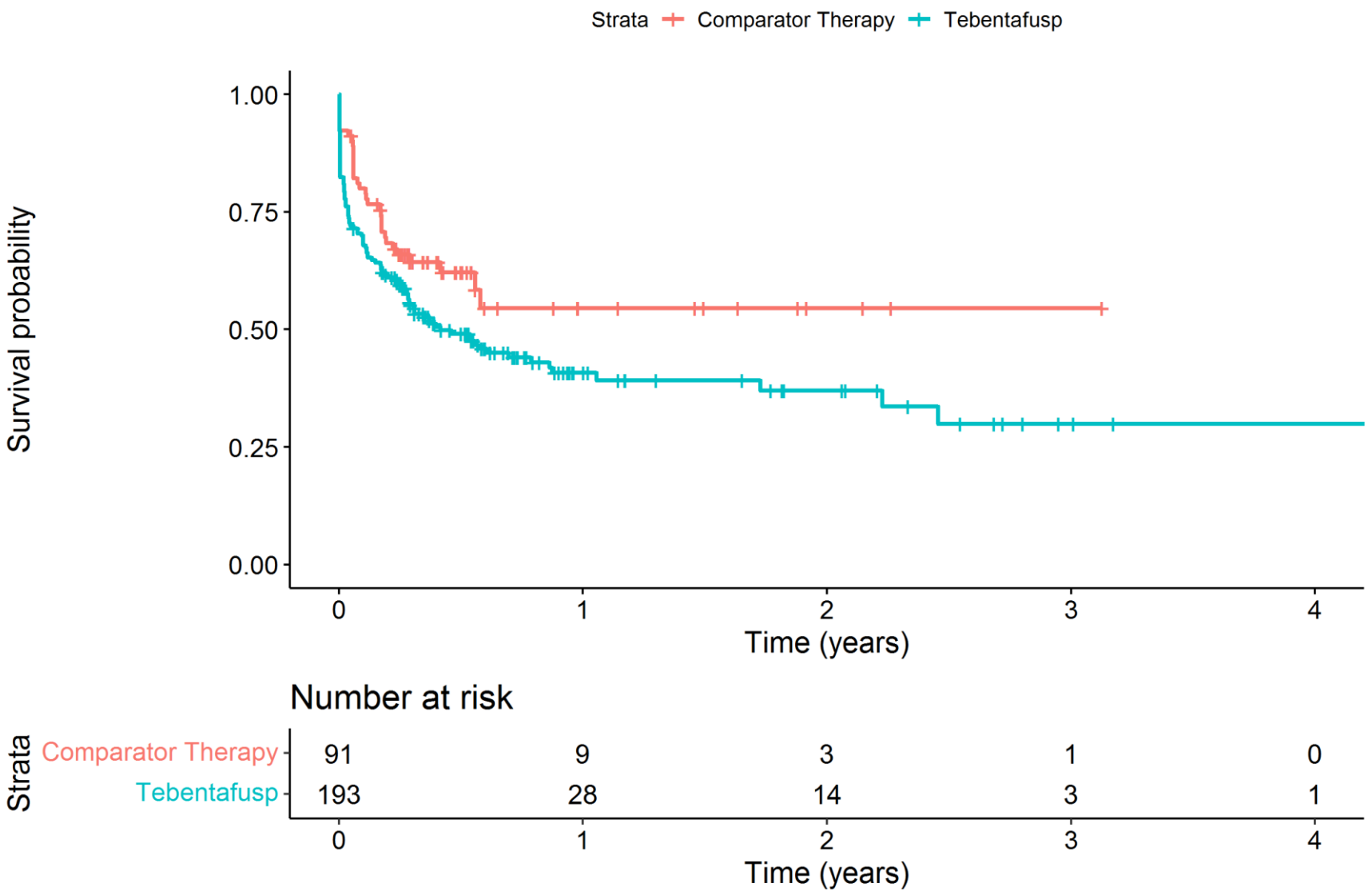
61.132 Untersuchungen - Nicht-Nordamerika



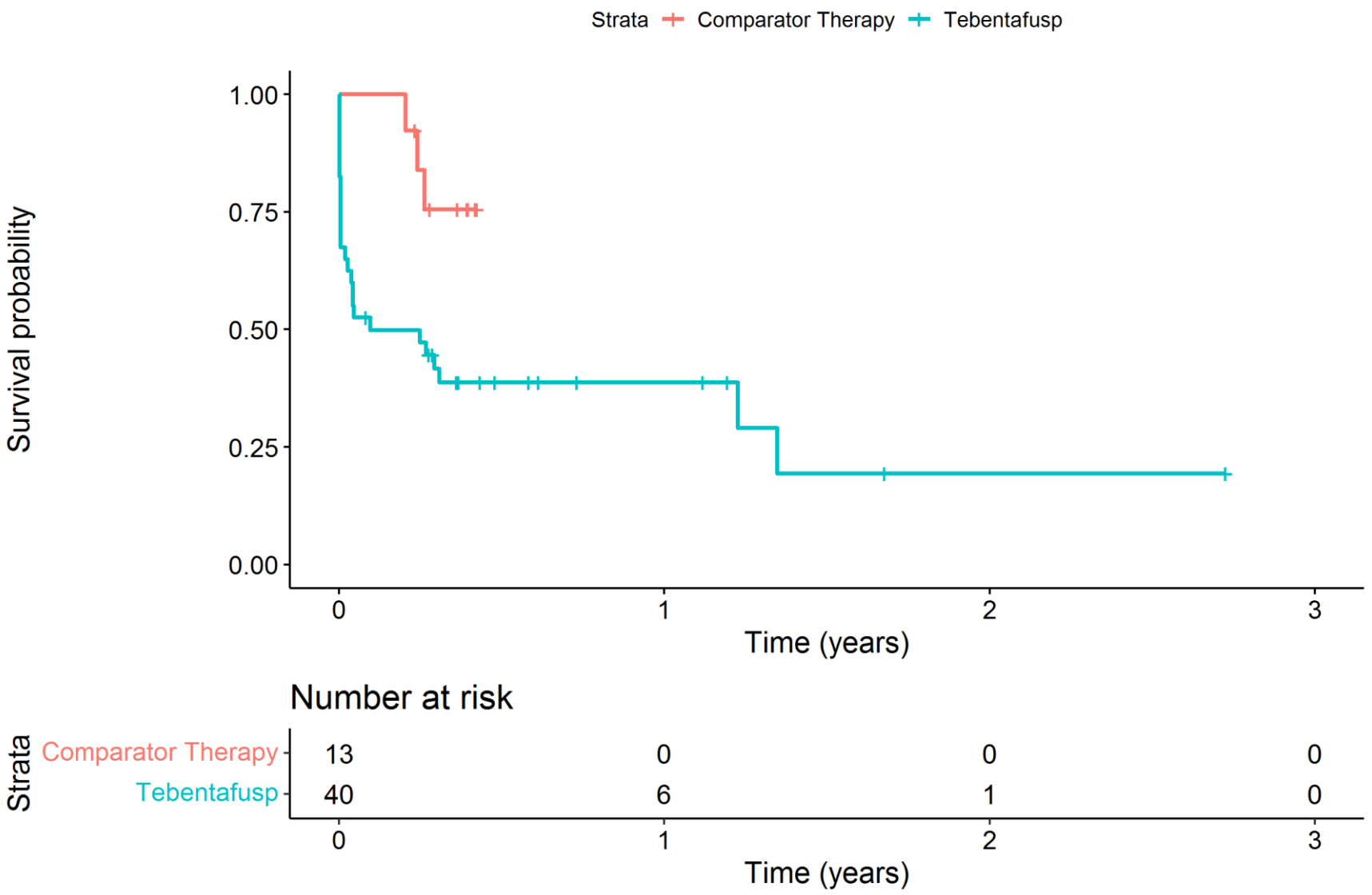
61.133 Untersuchungen - Dacarbazin



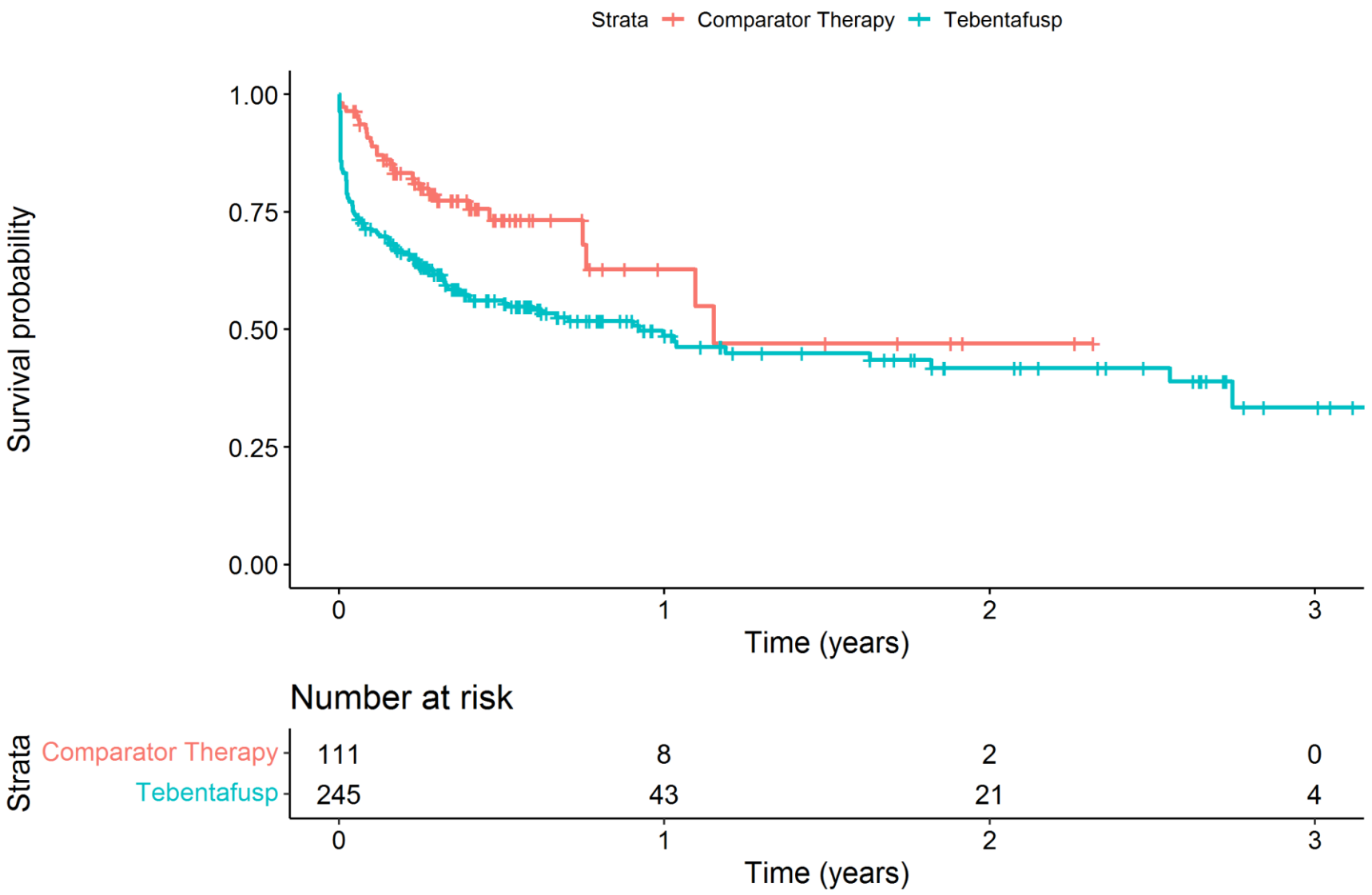
61.134 Untersuchungen - Pembrolizumab



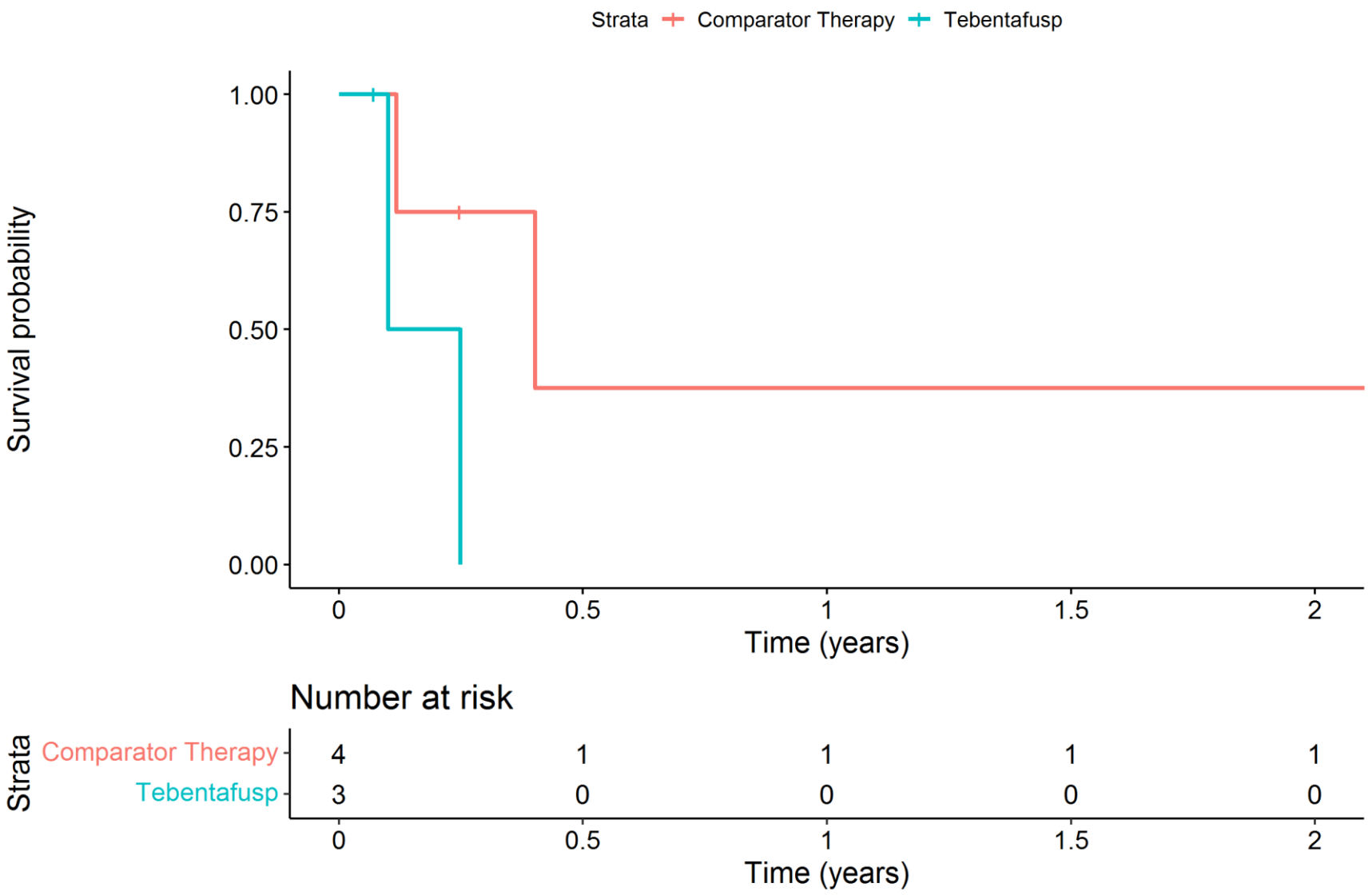
61.135 Untersuchungen - Ipilimumab



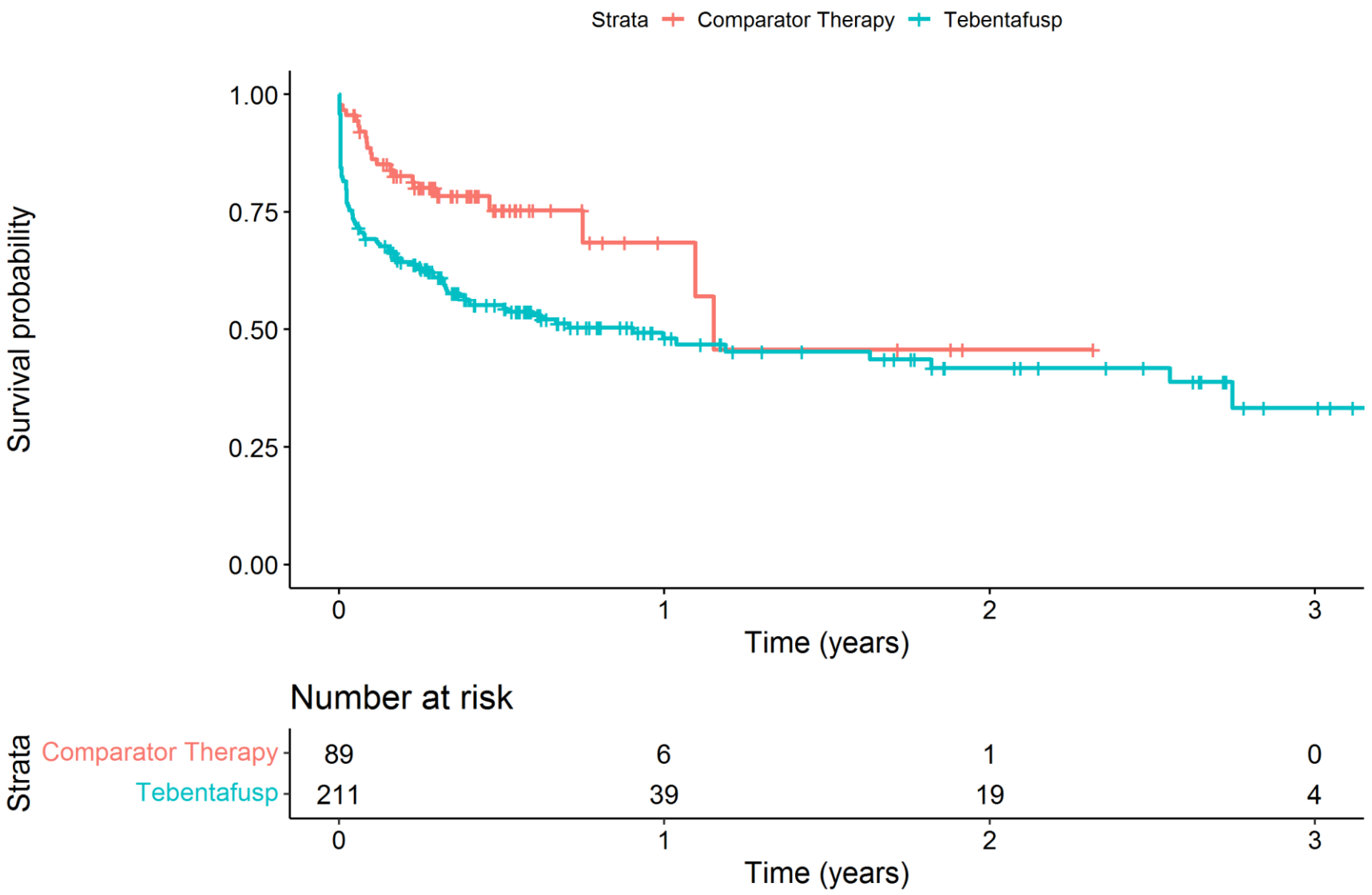
61.136 Stoffwechsel- und Ernährungsstörungen- Gesamt



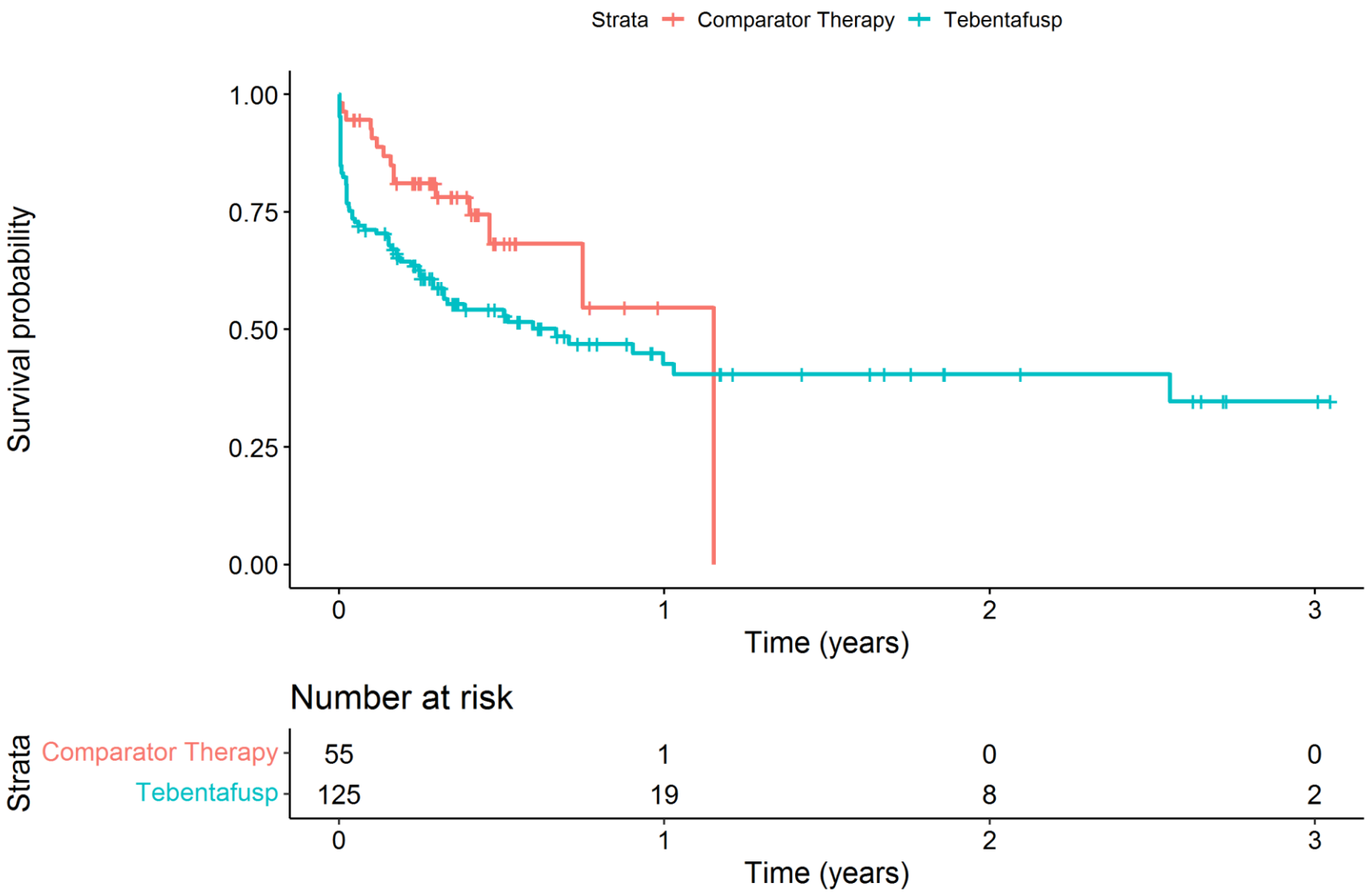
61.137 Stoffwechsel- und Ernährungsstörungen- Hispanisch



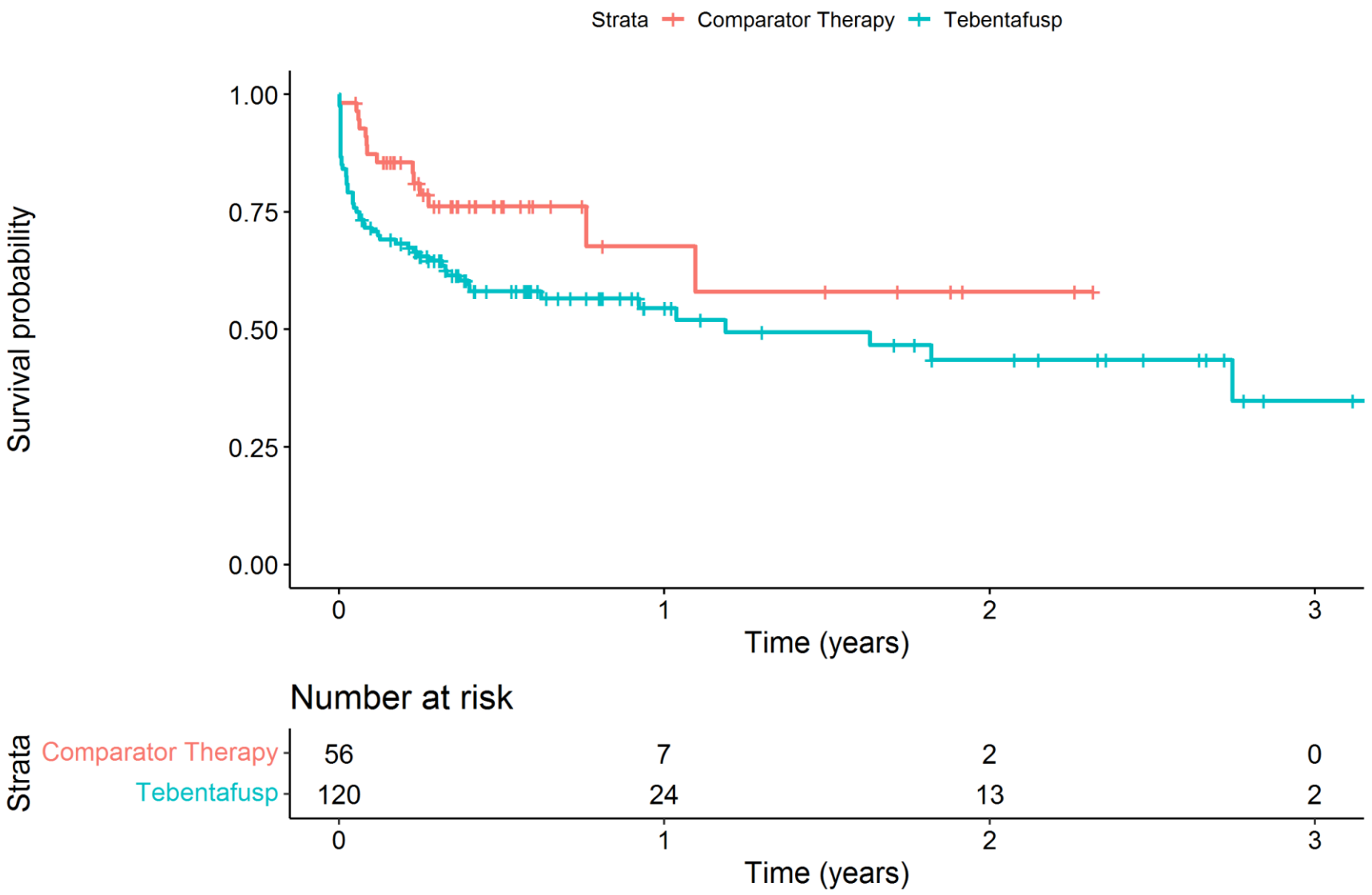
61.138 Stoffwechsel- und Ernährungsstörungen- Nicht-hispanisch



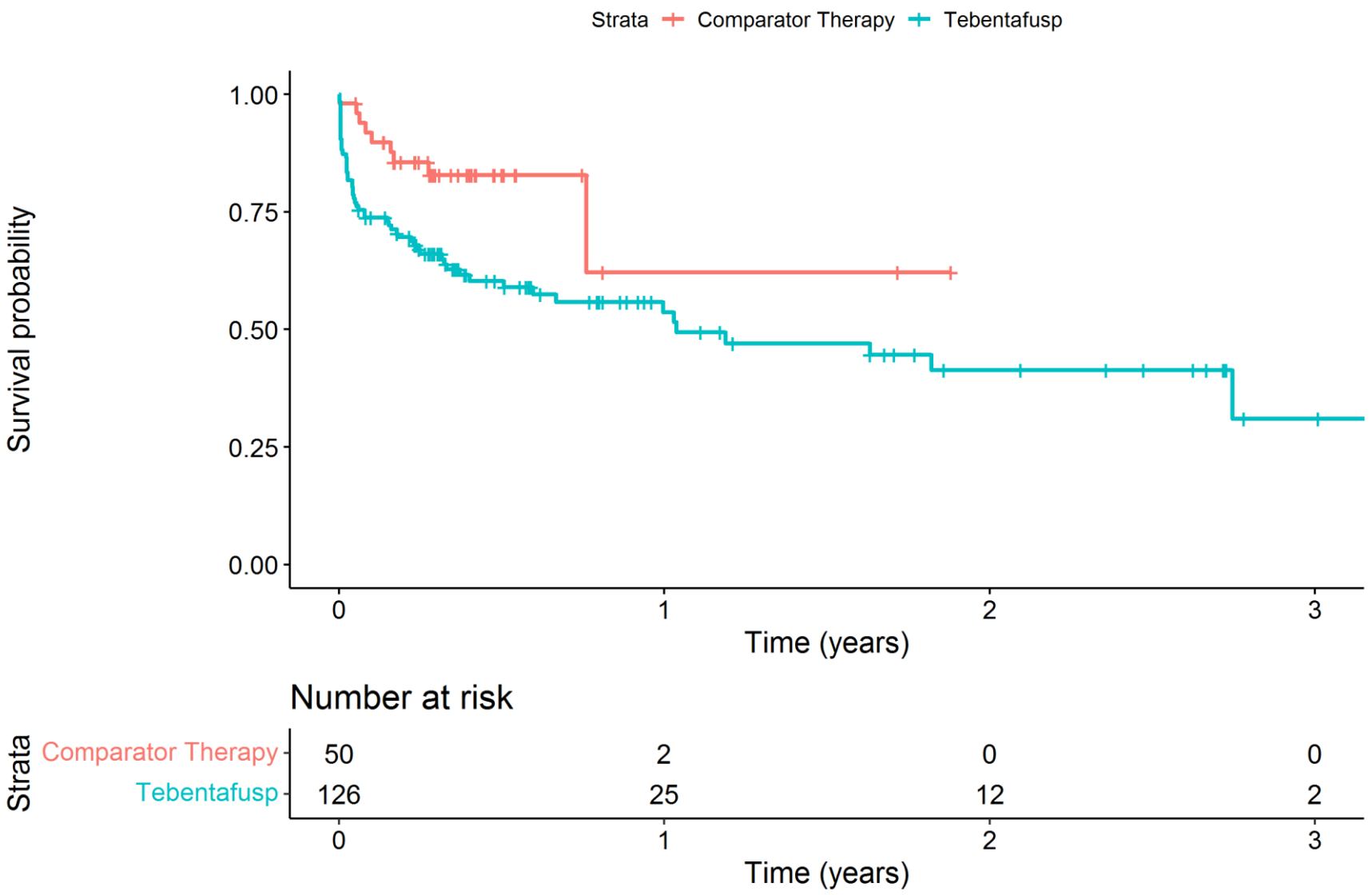
61.139 Stoffwechsel- und Ernährungsstörungen- Männlich



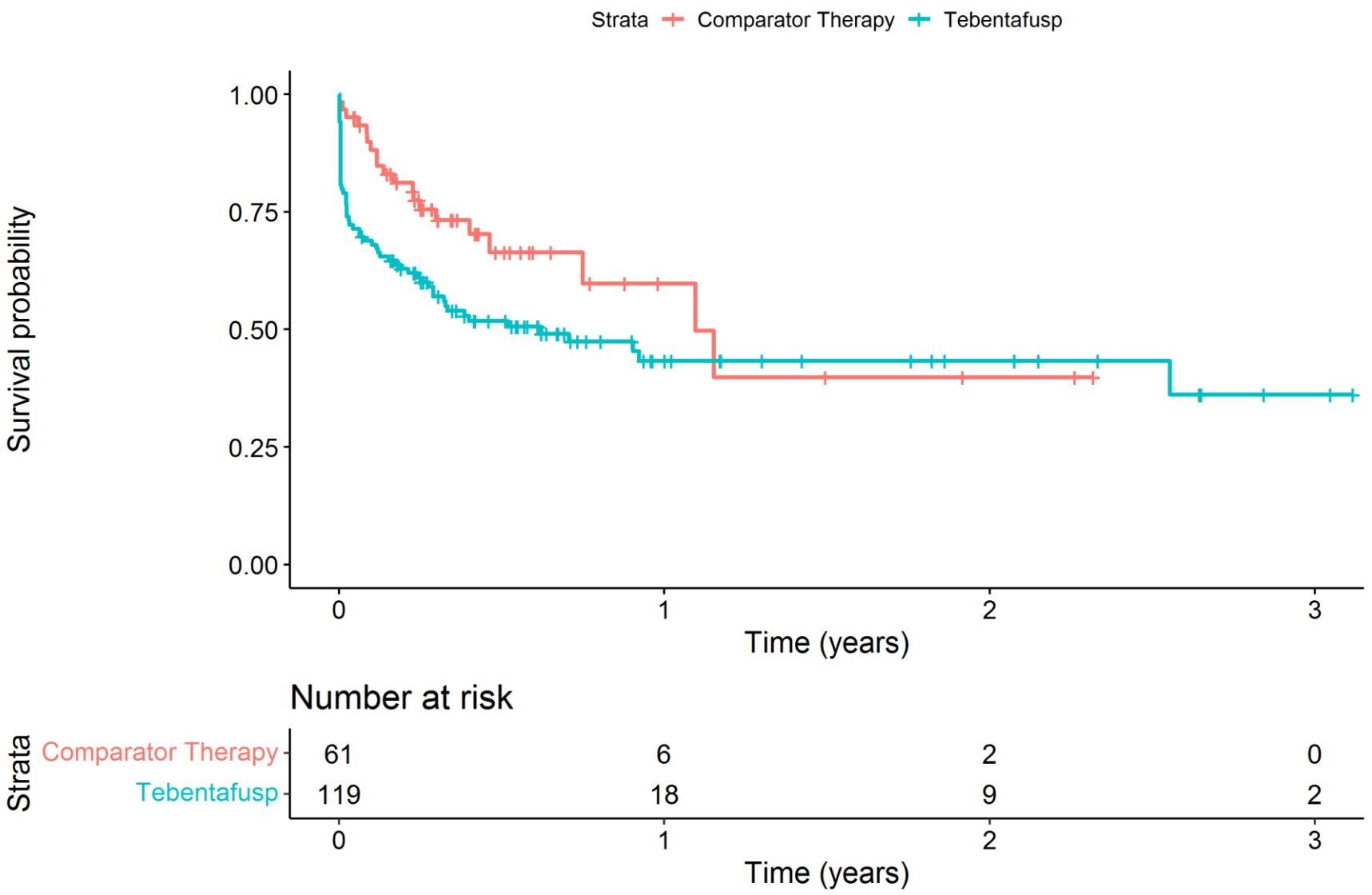
61.140 Stoffwechsel- und Ernährungsstörungen- Weiblich



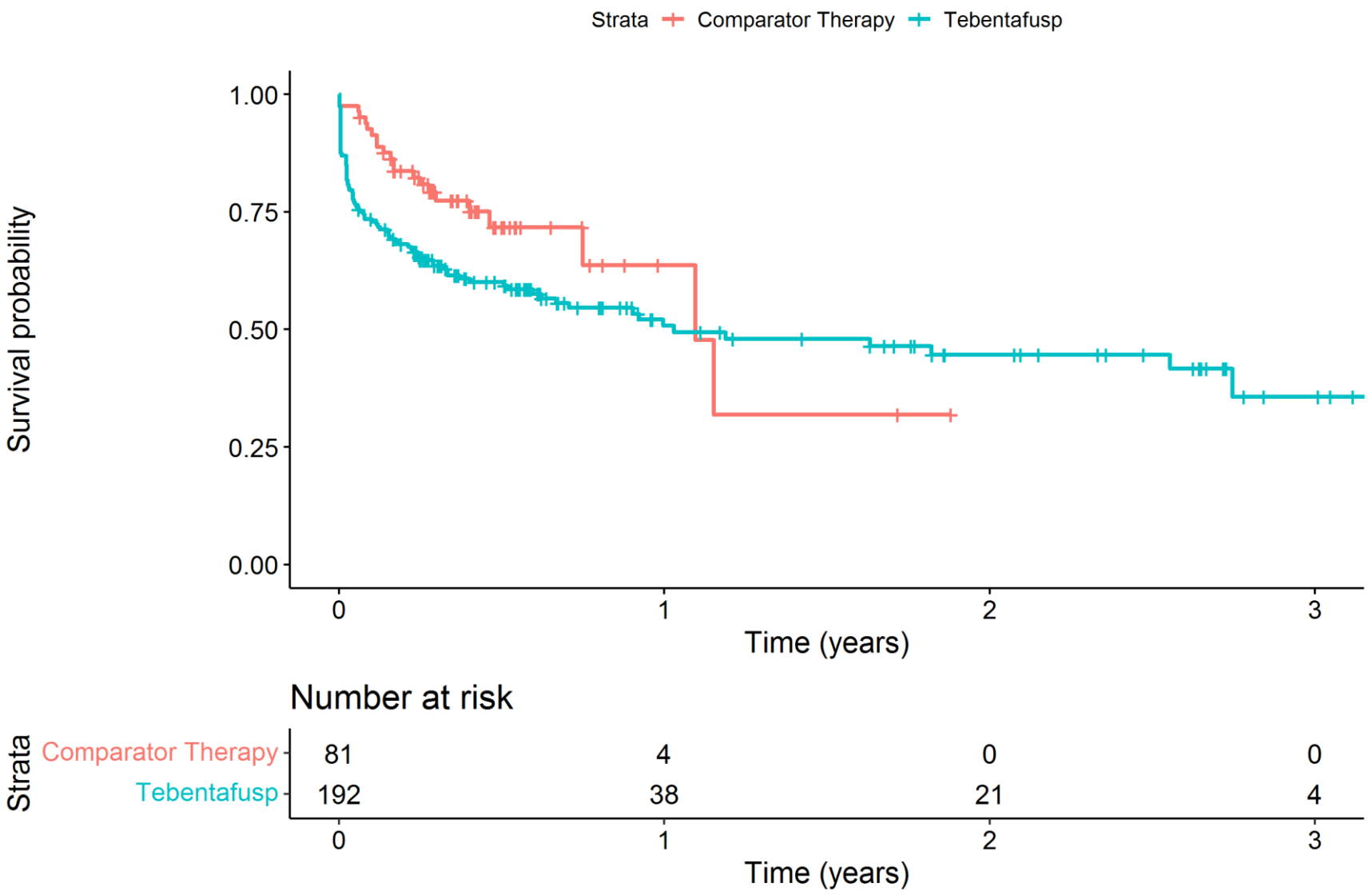
61.141 Stoffwechsel- und Ernährungsstörungen- <65



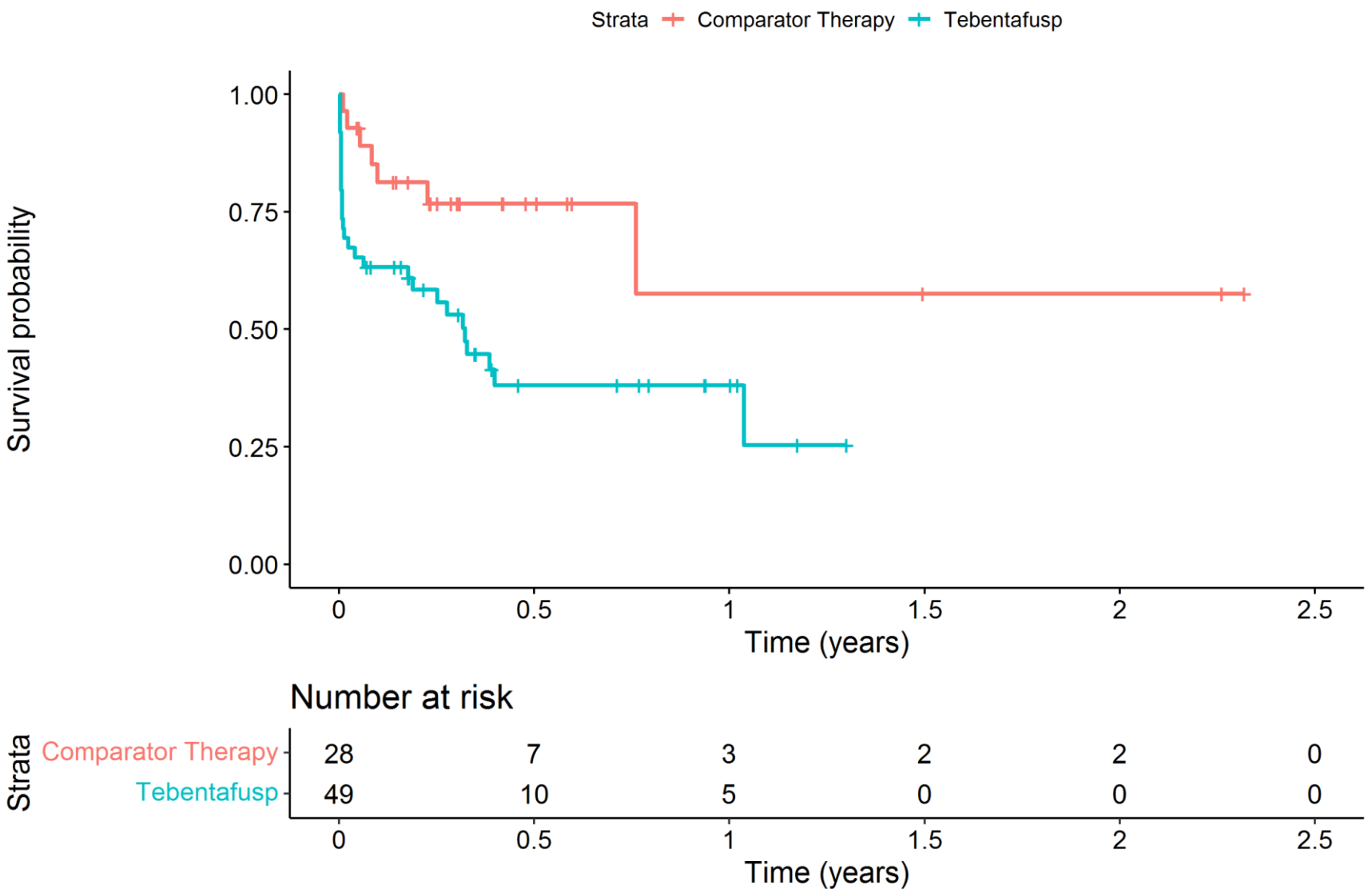
61.142 Stoffwechsel- und Ernährungsstörungen- ≥65



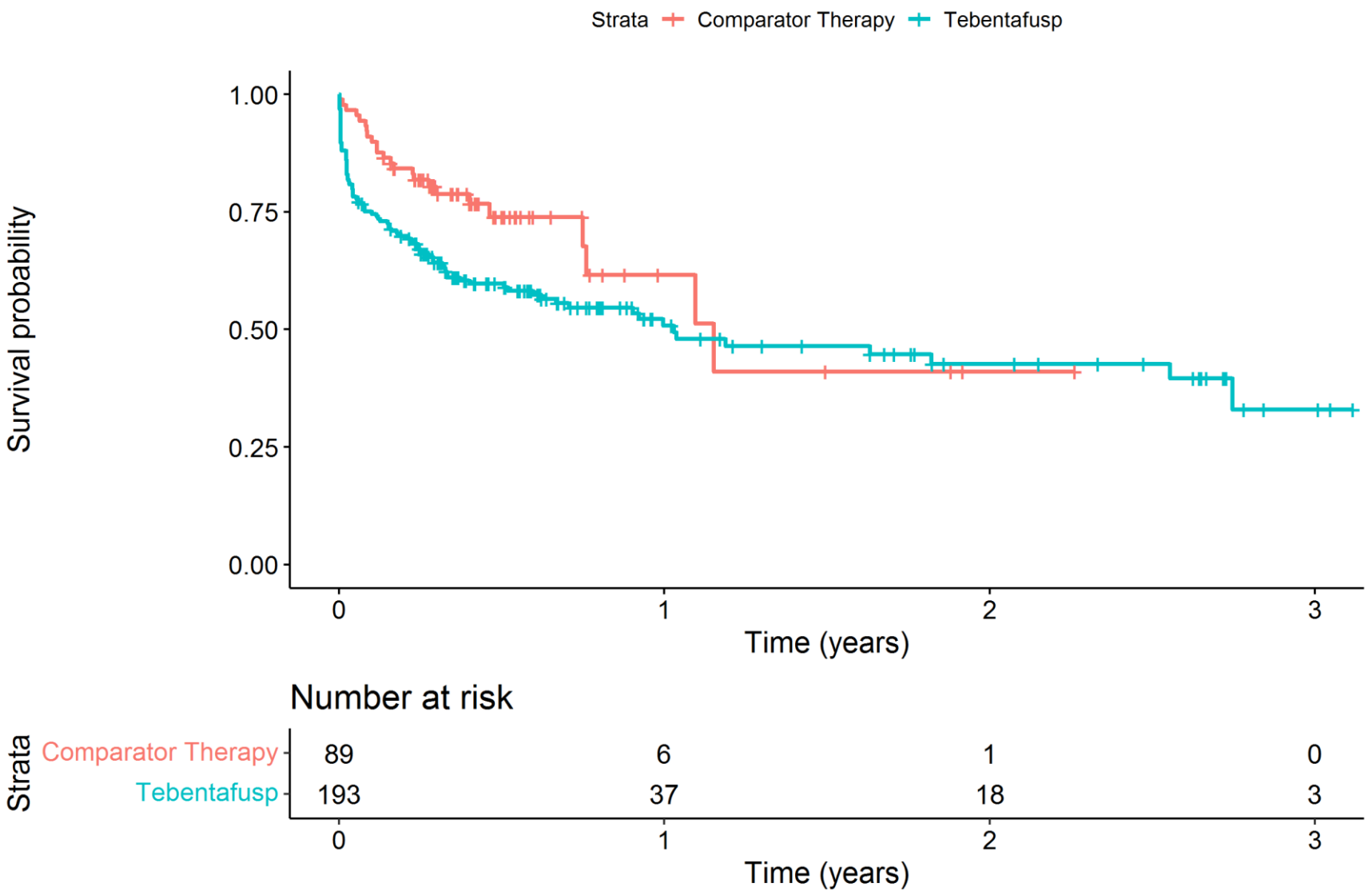
61.143 Stoffwechsel- und Ernährungsstörungen- ECOG 0



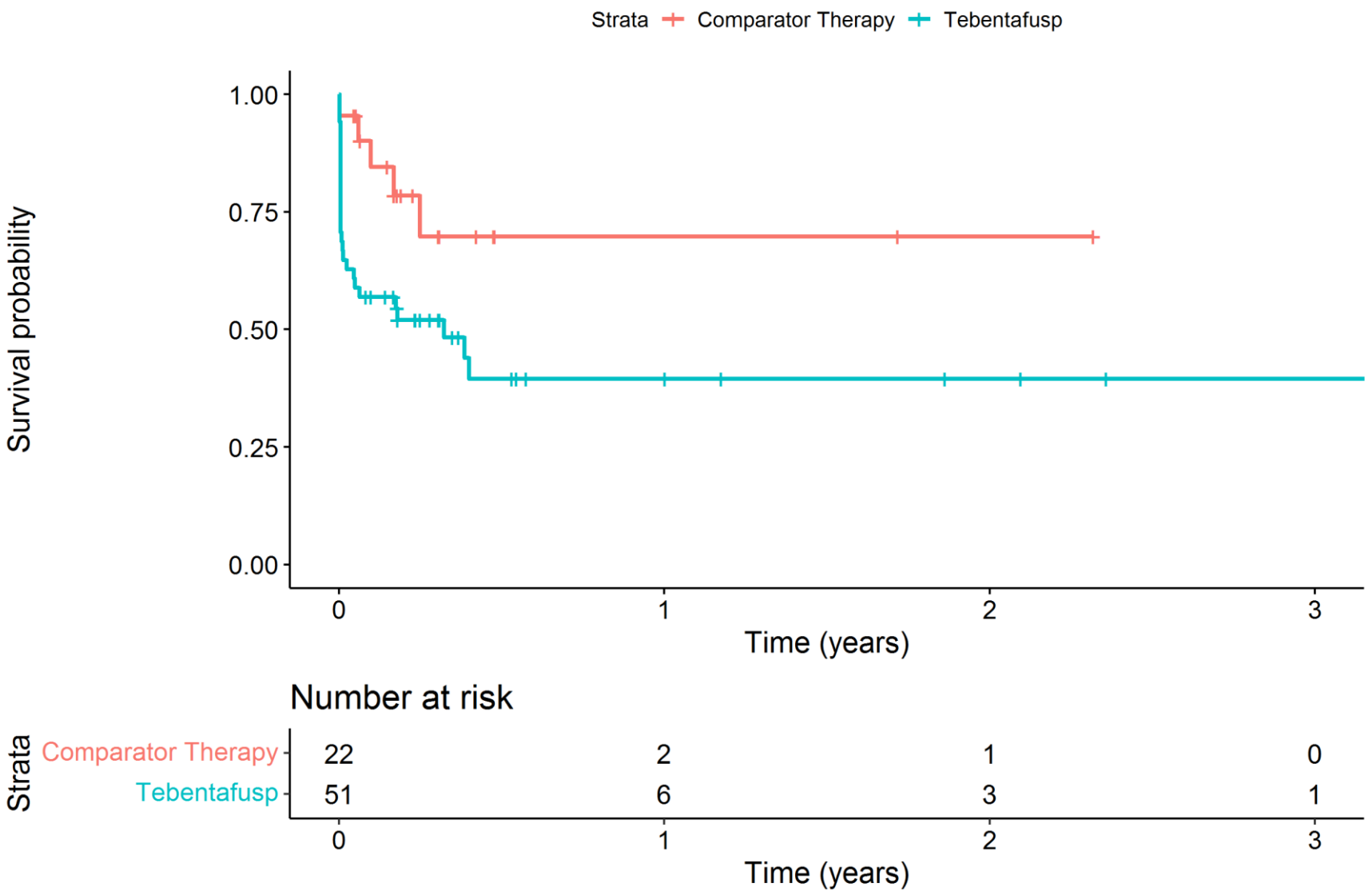
61.144 Stoffwechsel- und Ernährungsstörungen- ECOG 1



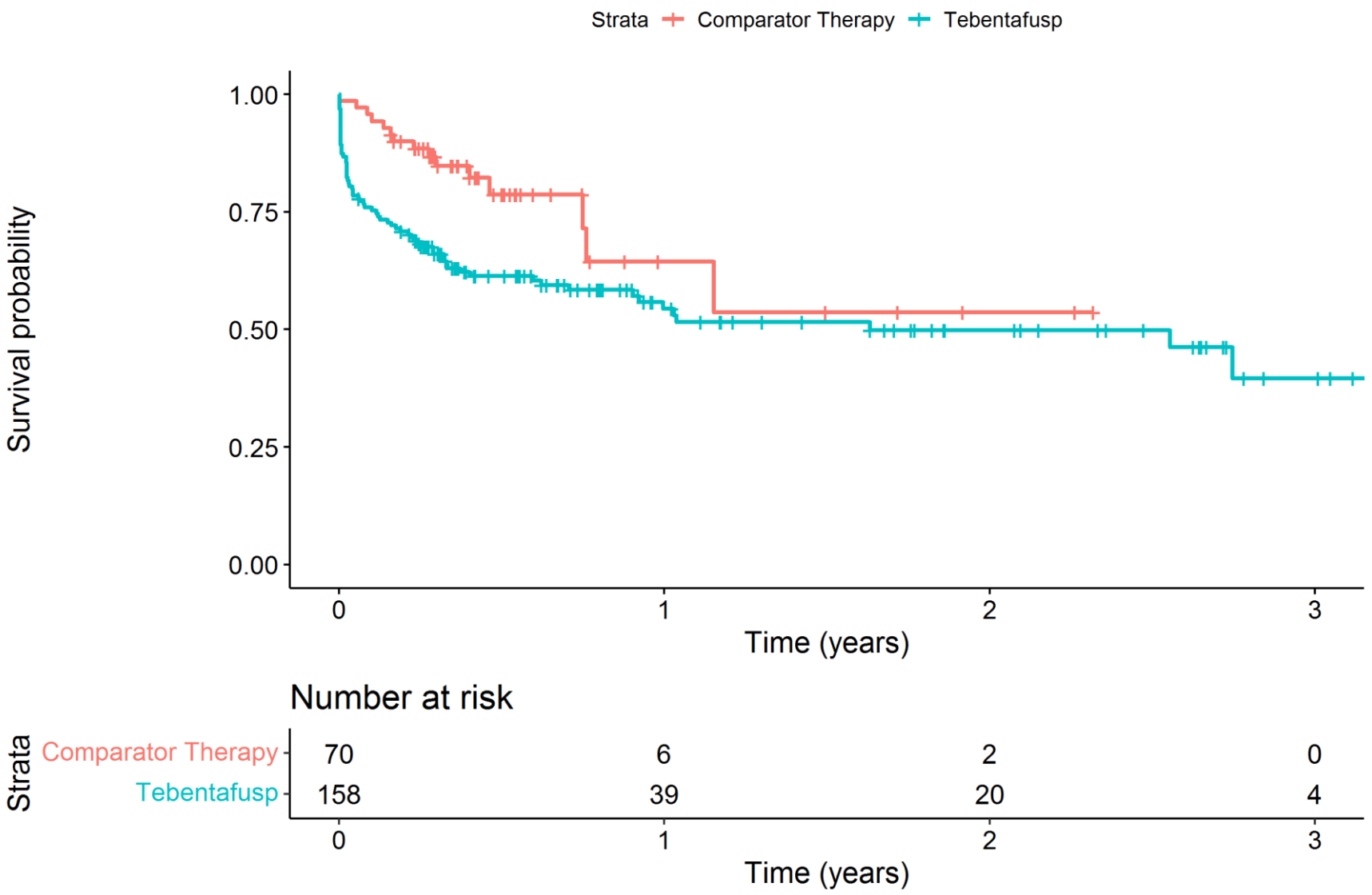
61.145 Stoffwechsel- und Ernährungsstörungen- ALP ≤ ULN



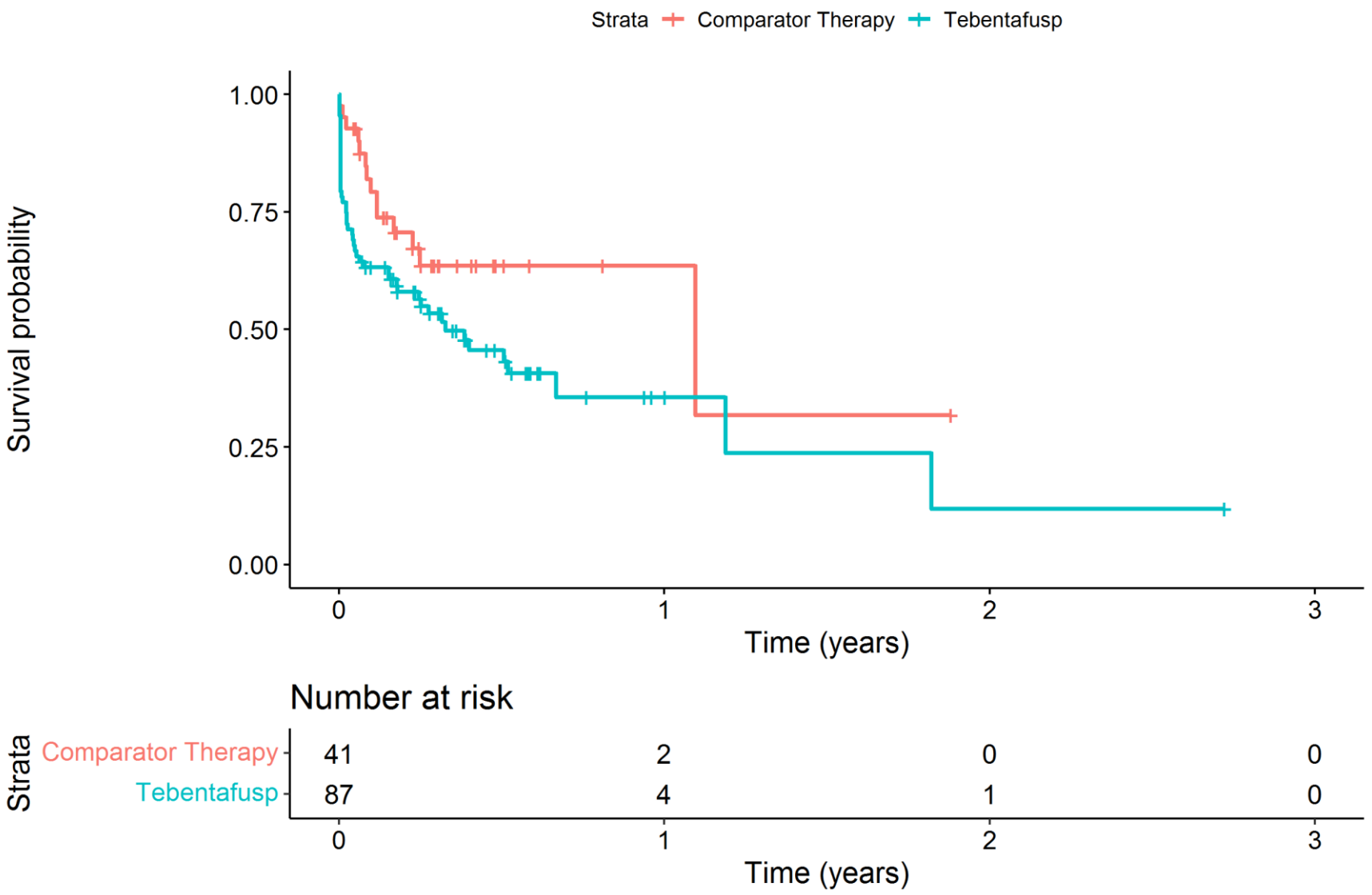
61.146 Stoffwechsel- und Ernährungsstörungen- ALP > ULN



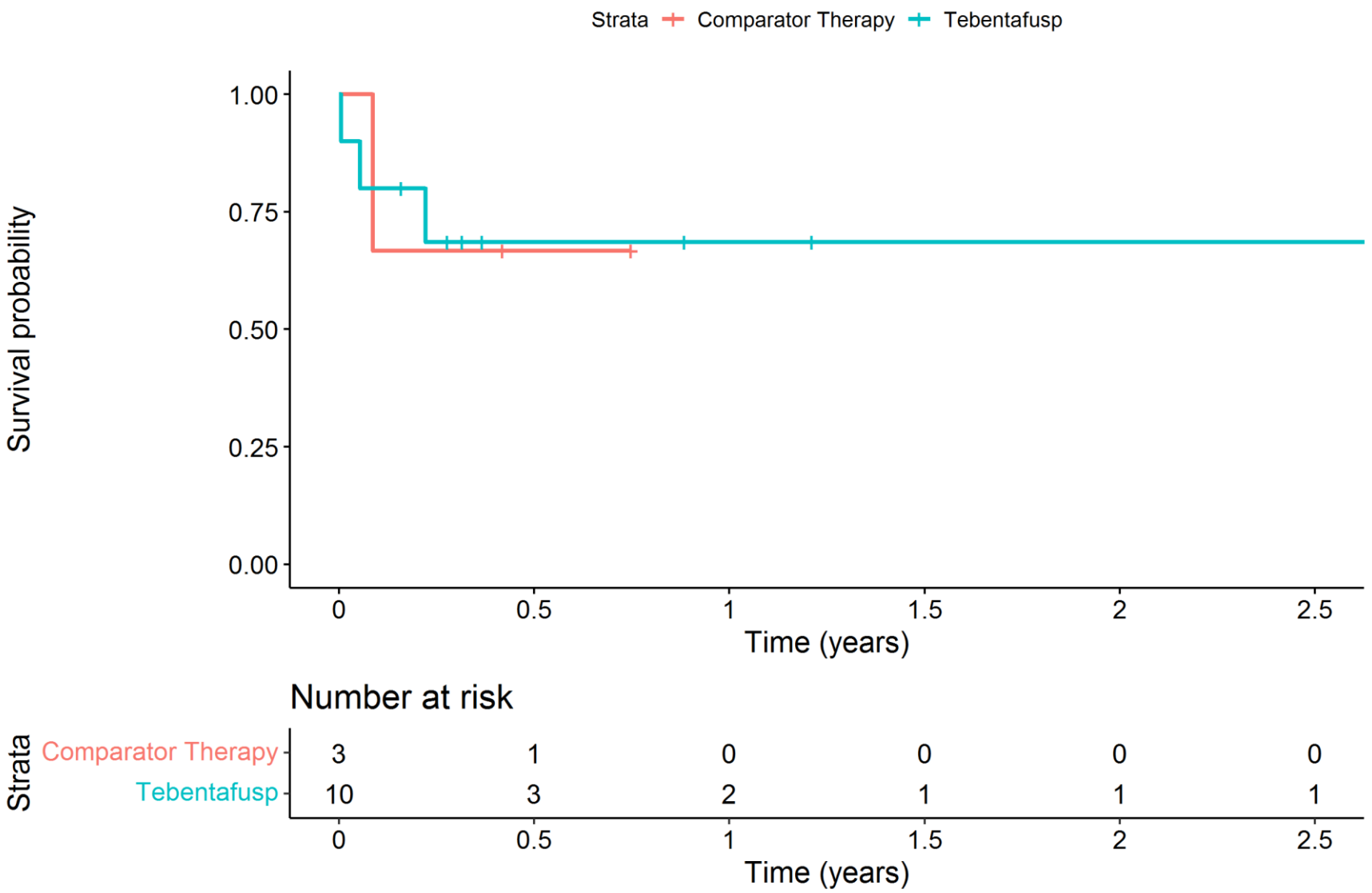
61.147 Stoffwechsel- und Ernährungsstörungen- LDH =< ULN



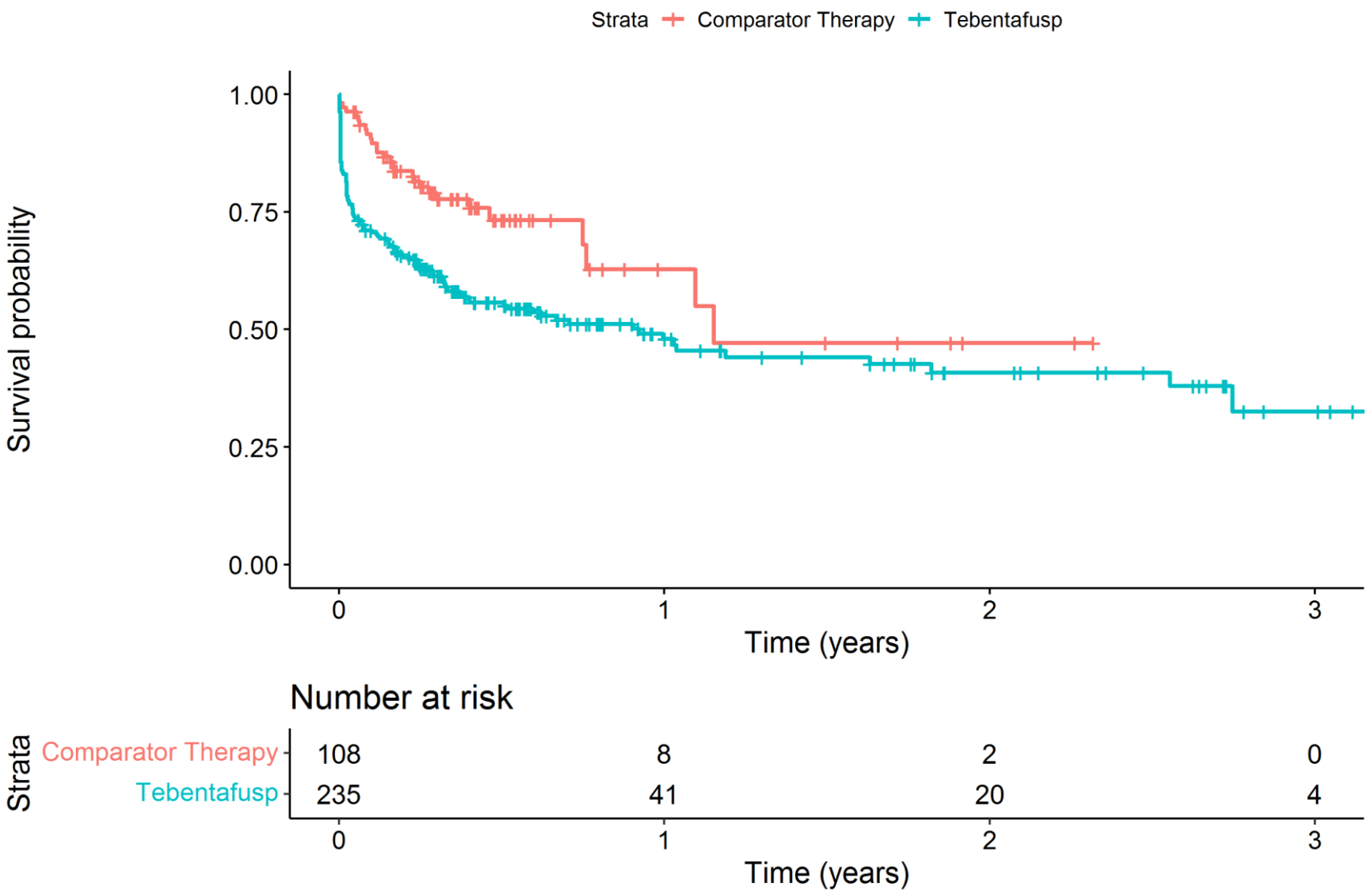
61.148 Stoffwechsel- und Ernährungsstörungen- LDH > ULN



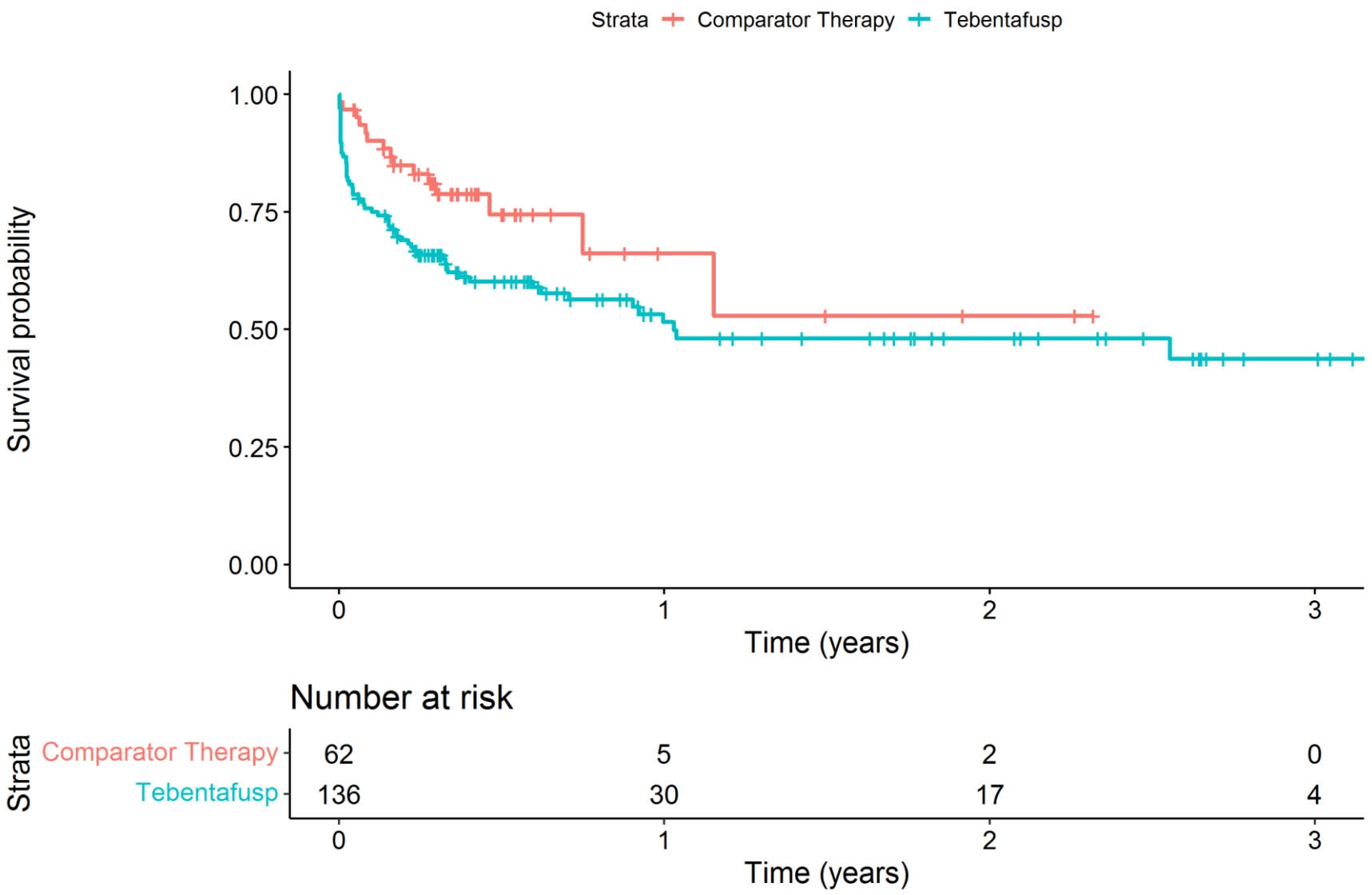
61.149 Stoffwechsel- und Ernährungsstörungen- Vorherige Therapie adjuvant/neoadjuvant



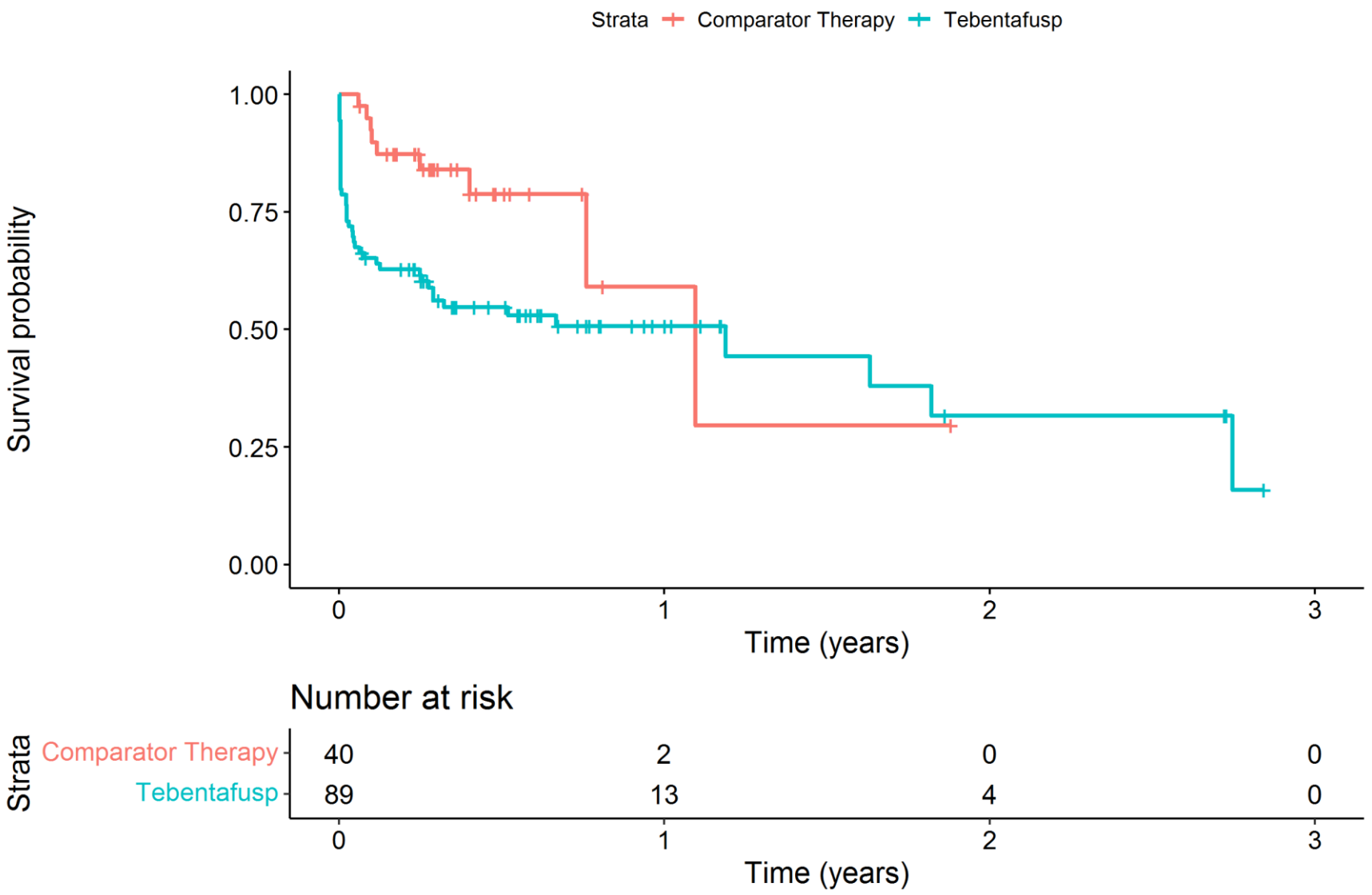
61.150 Stoffwechsel- und Ernährungsstörungen- Keine Vorherige Therapie adjuvant/neoadjuvant



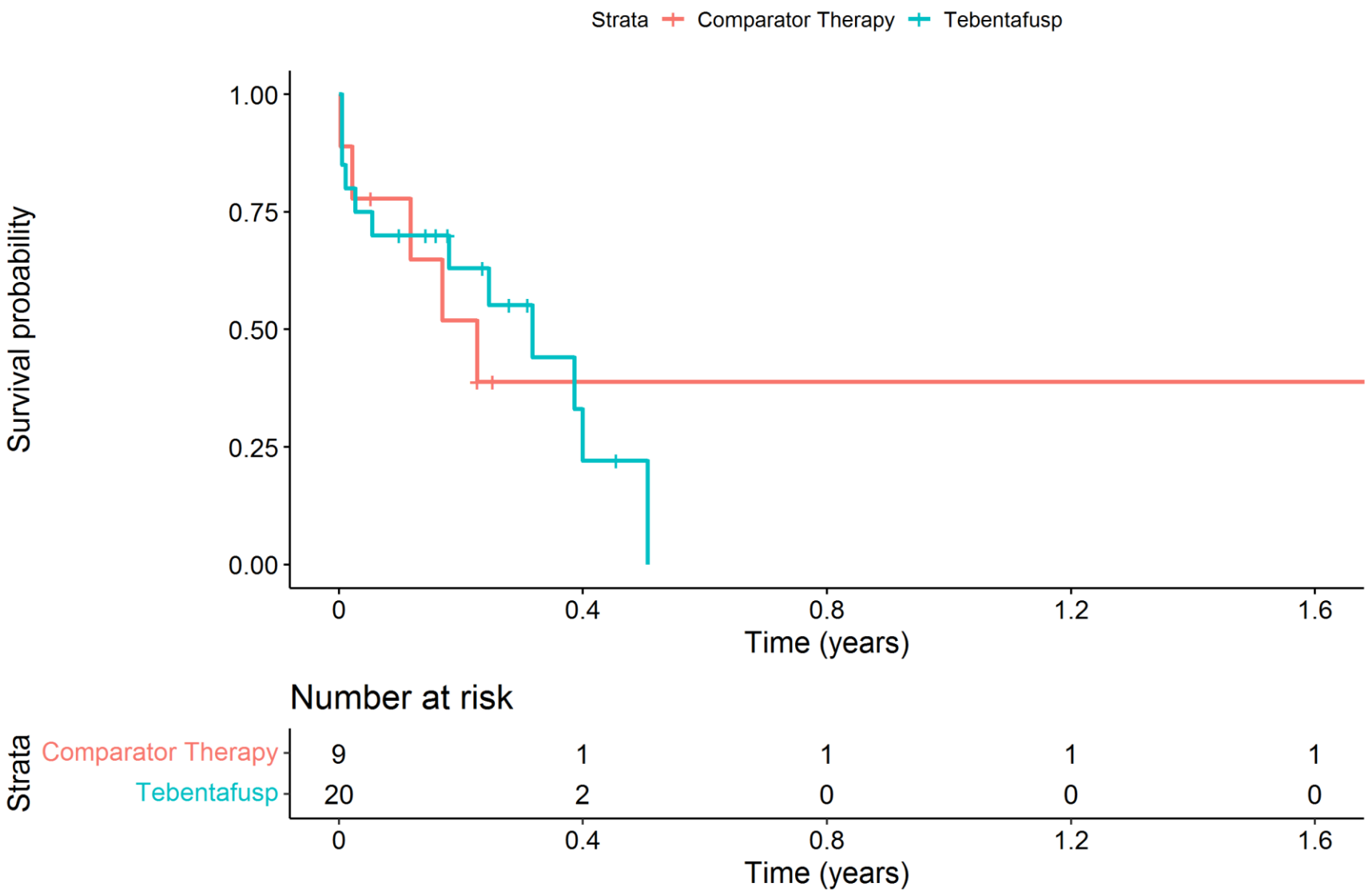
61.151 Stoffwechsel- und Ernährungsstörungen- Läsion ≤ 3cm



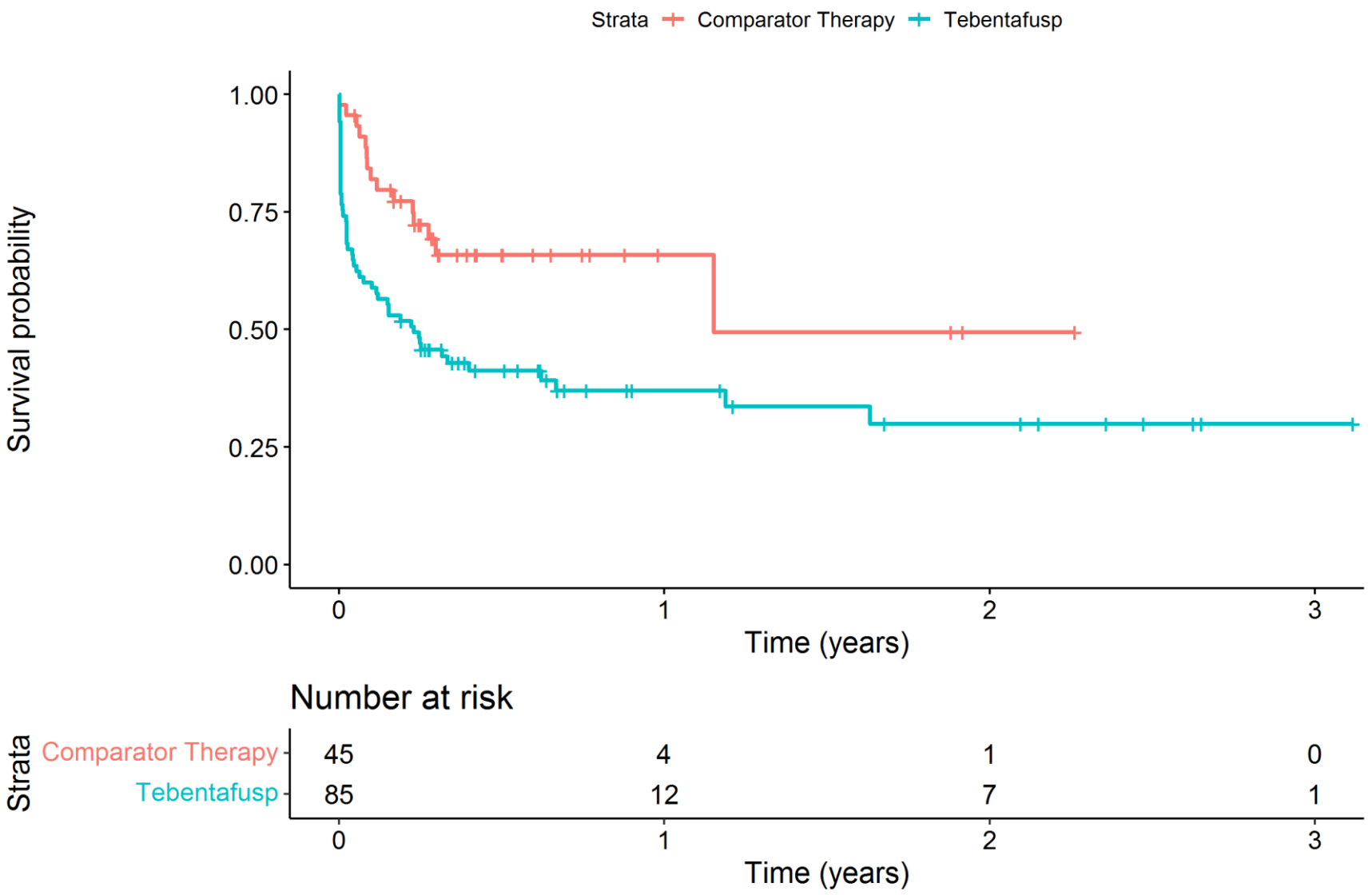
61.152 Stoffwechsel- und Ernährungsstörungen- Läsion 3,1-8,0 cm



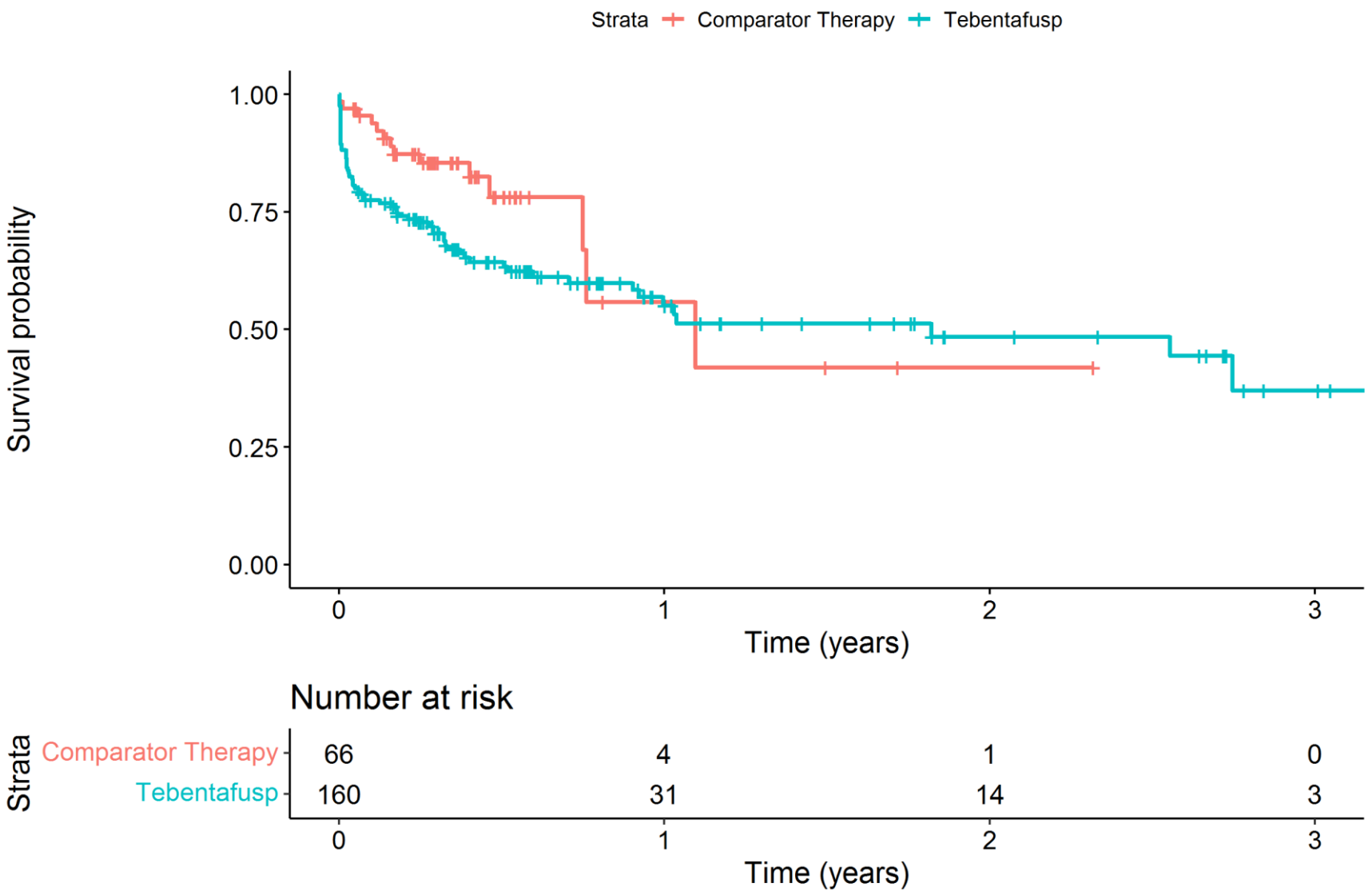
61.153 Stoffwechsel- und Ernährungsstörungen- Läsion ≥8,1 cm



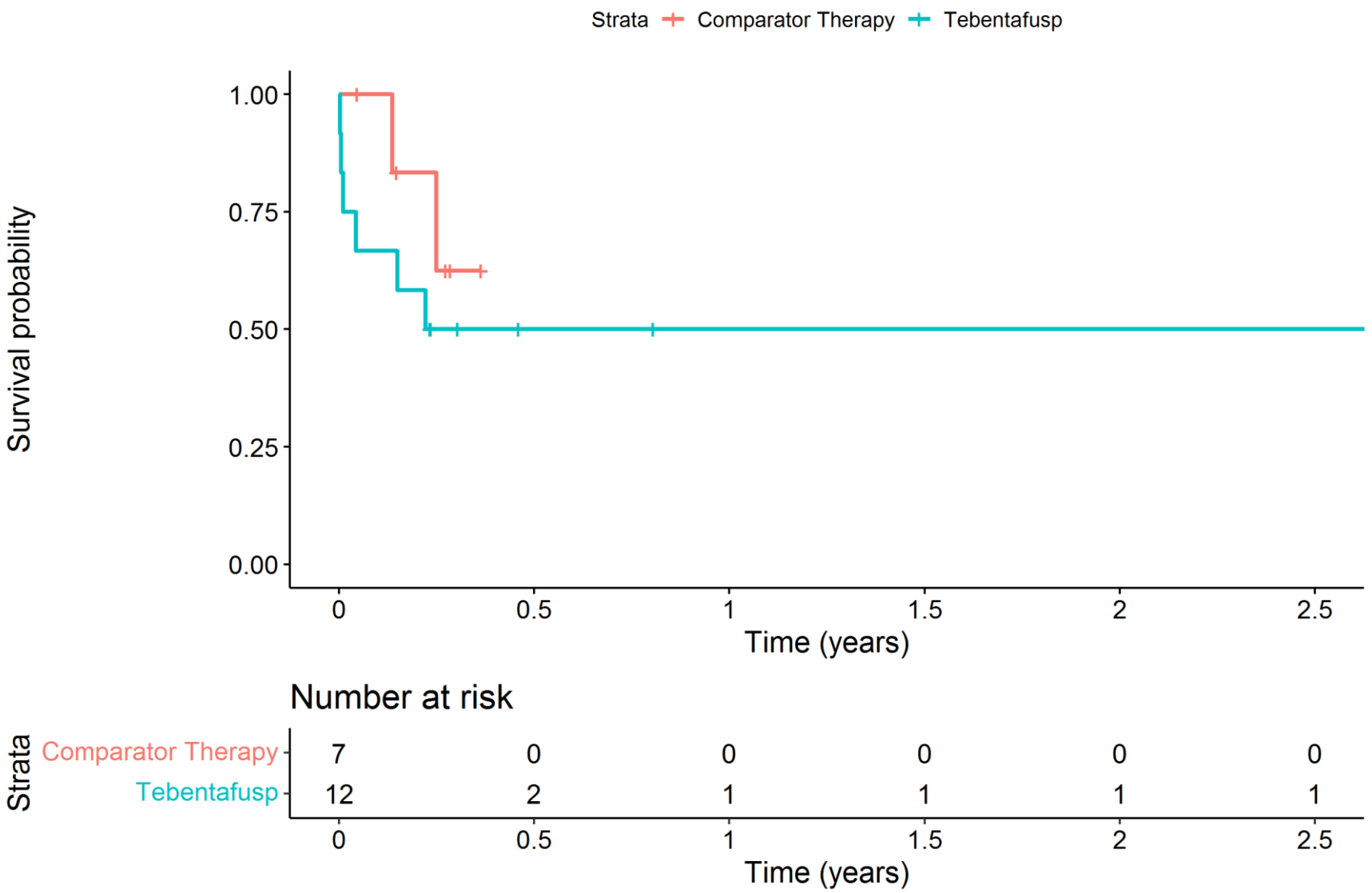
61.154 Stoffwechsel- und Ernährungsstörungen- Nordamerika



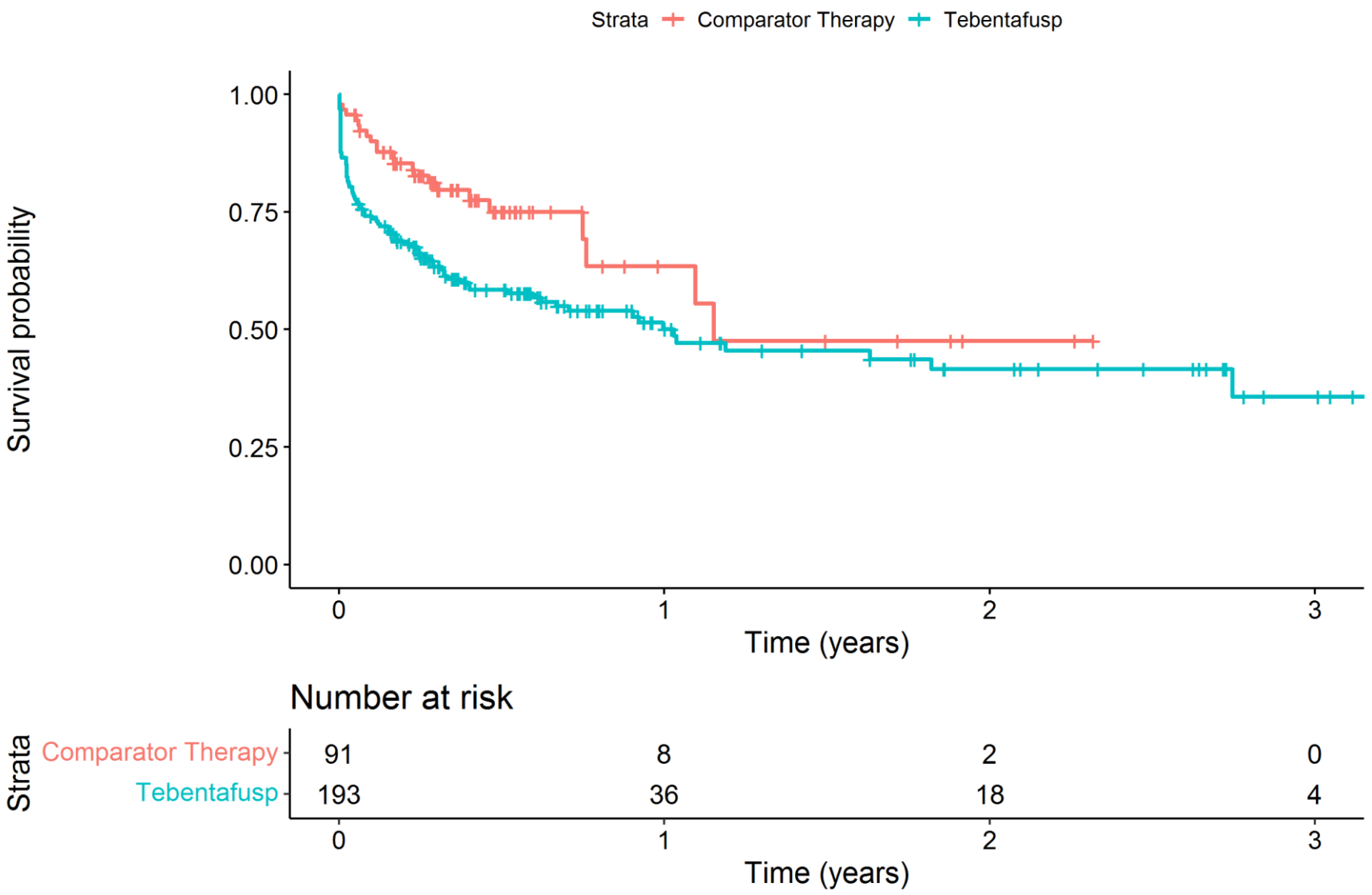
61.155 Stoffwechsel- und Ernährungsstörungen- Nicht-Nordamerika



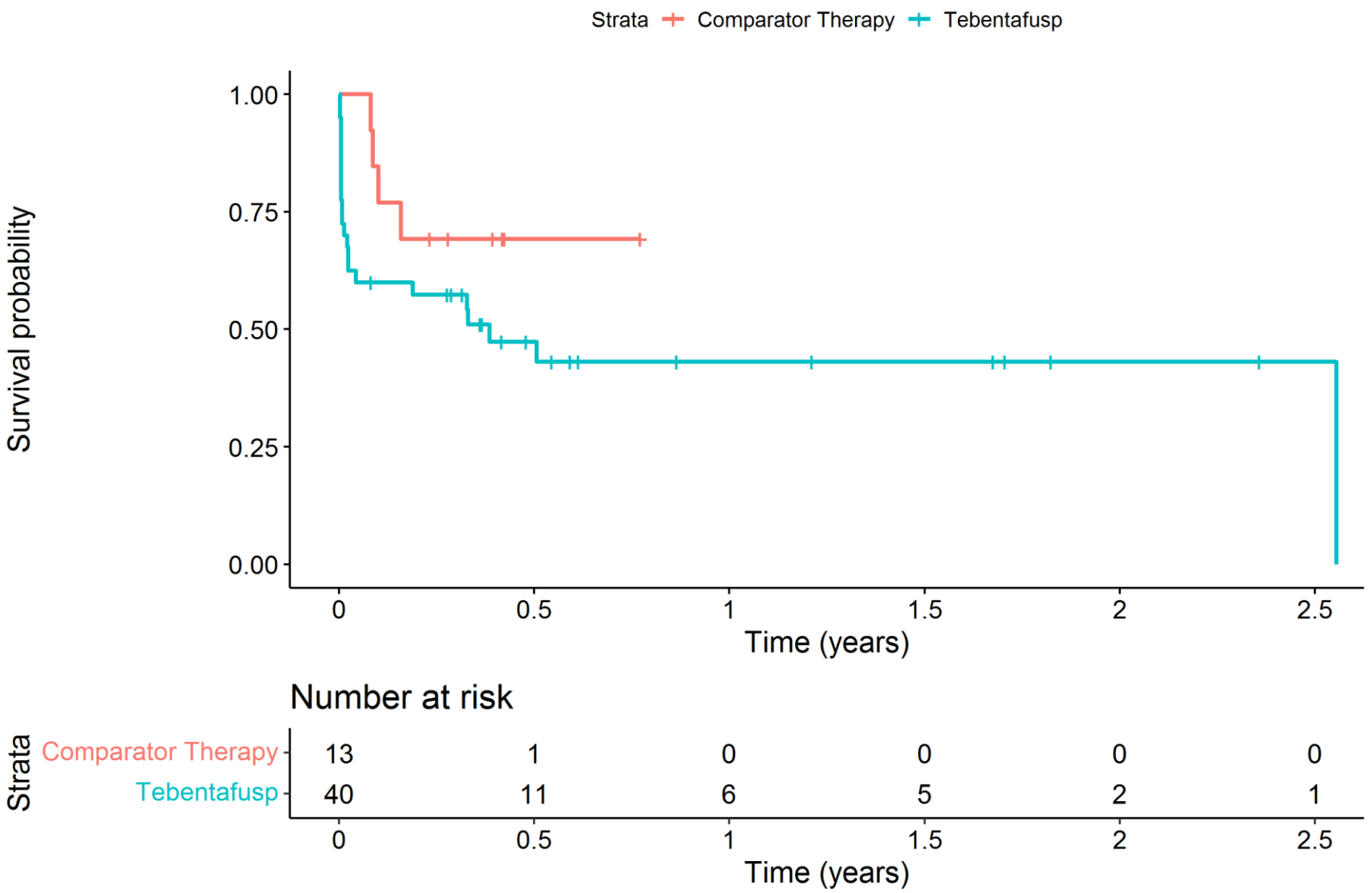
61.156 Stoffwechsel- und Ernährungsstörungen- Dacarbazin



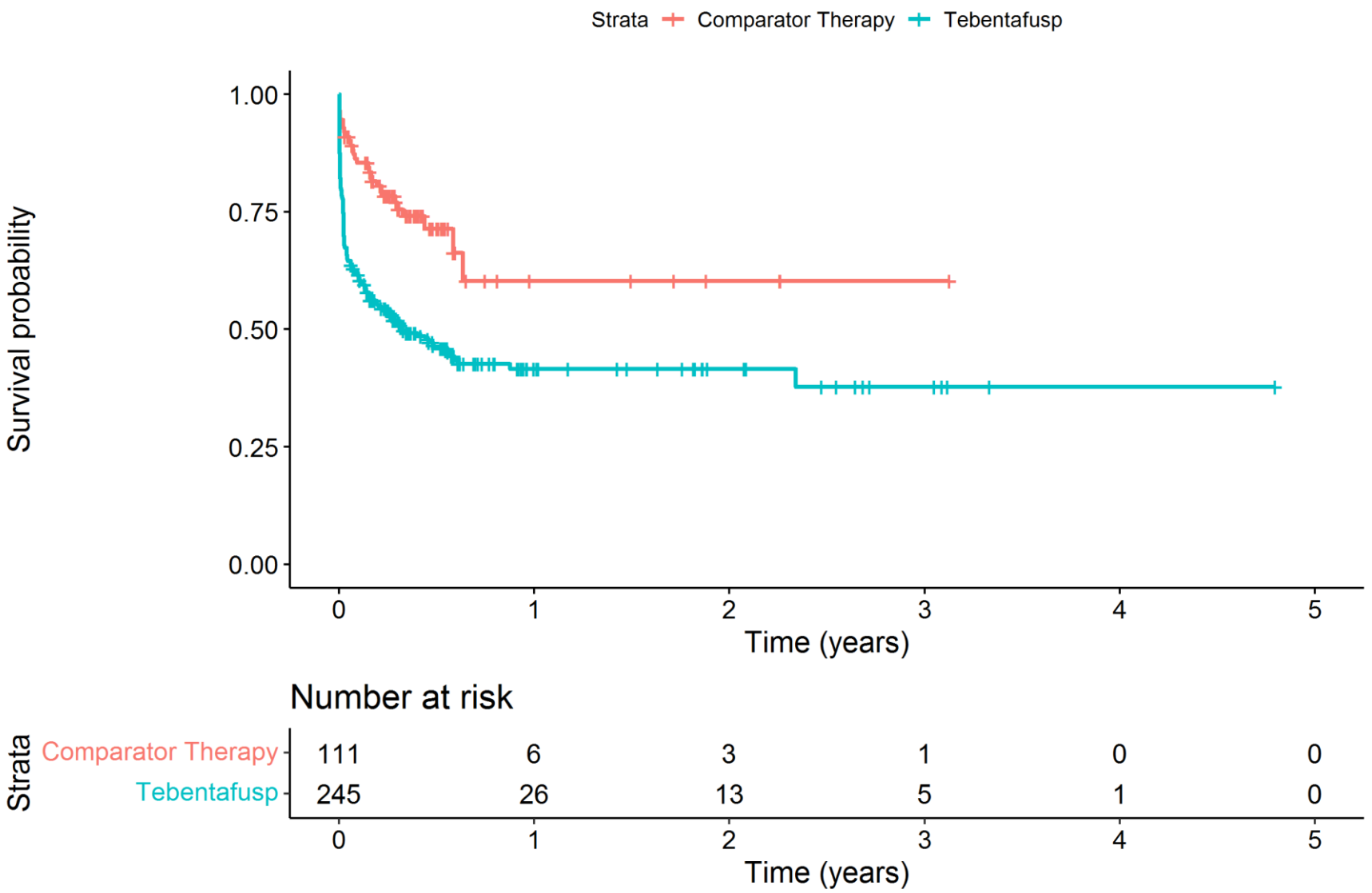
61.157 Stoffwechsel- und Ernährungsstörungen- Pembrolizumab



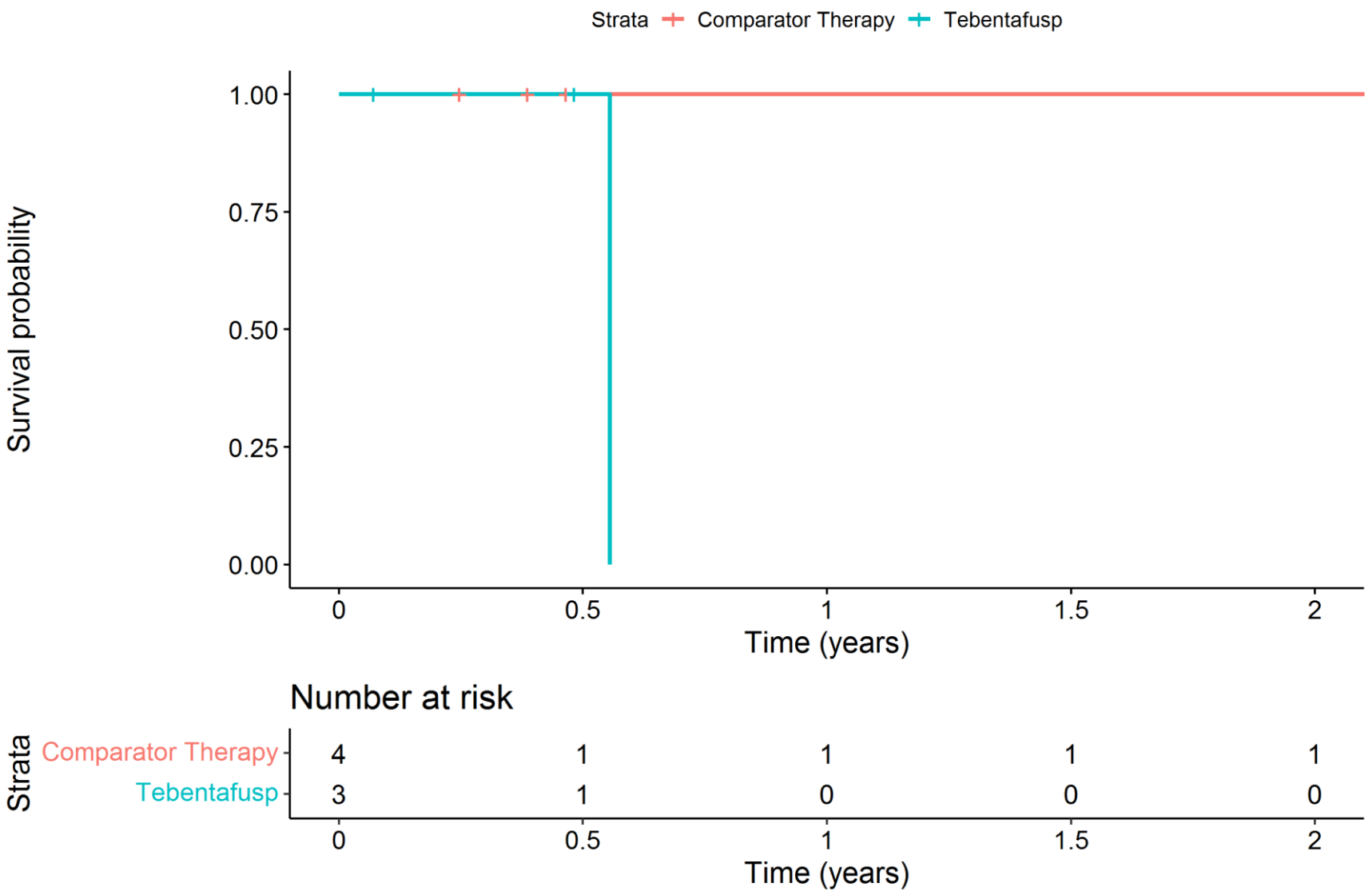
61.158 Stoffwechsel- und Ernährungsstörungen- Ipilimumab



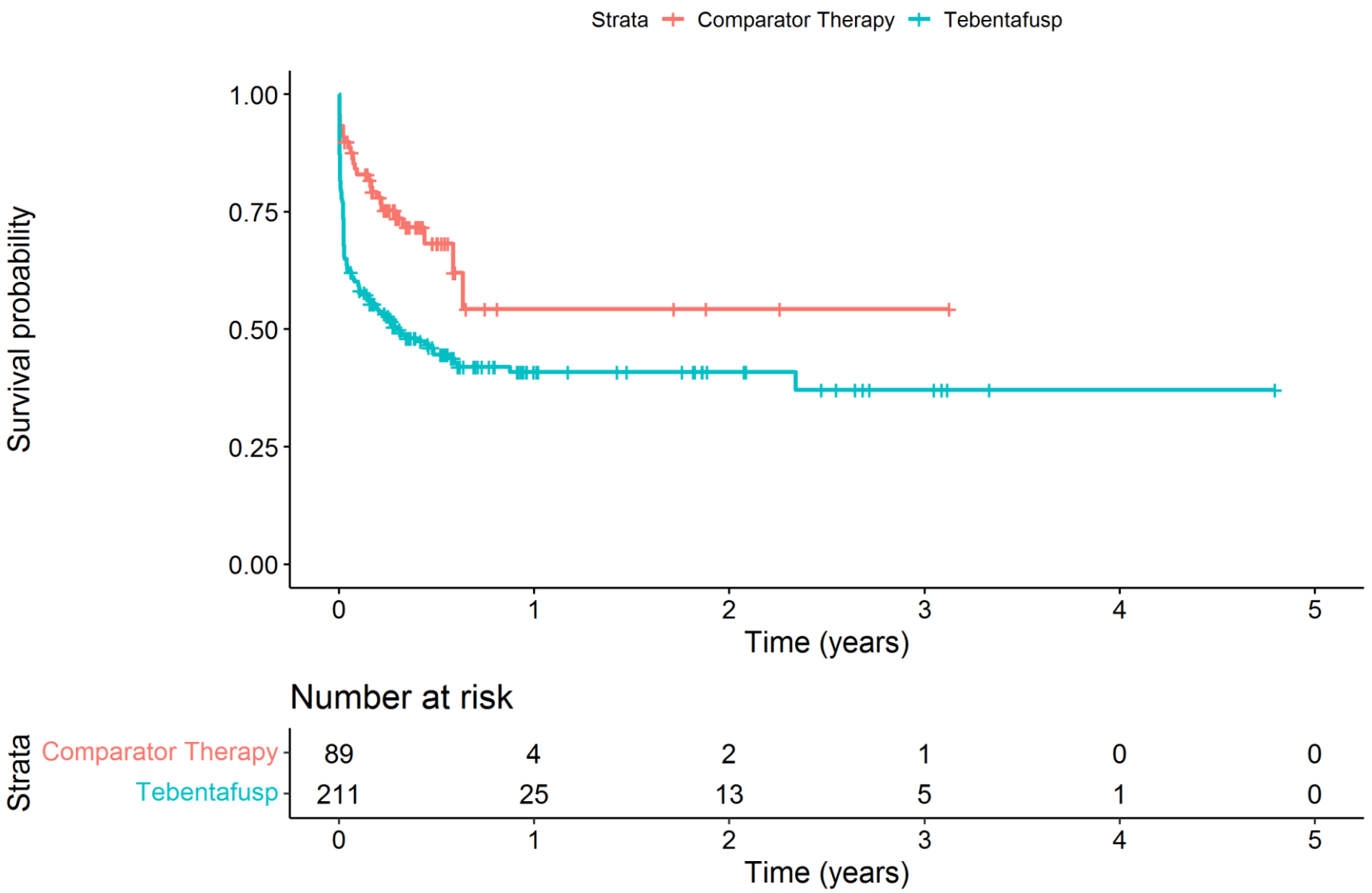
61.159 Erkrankungen des Nervensystems- Gesamt



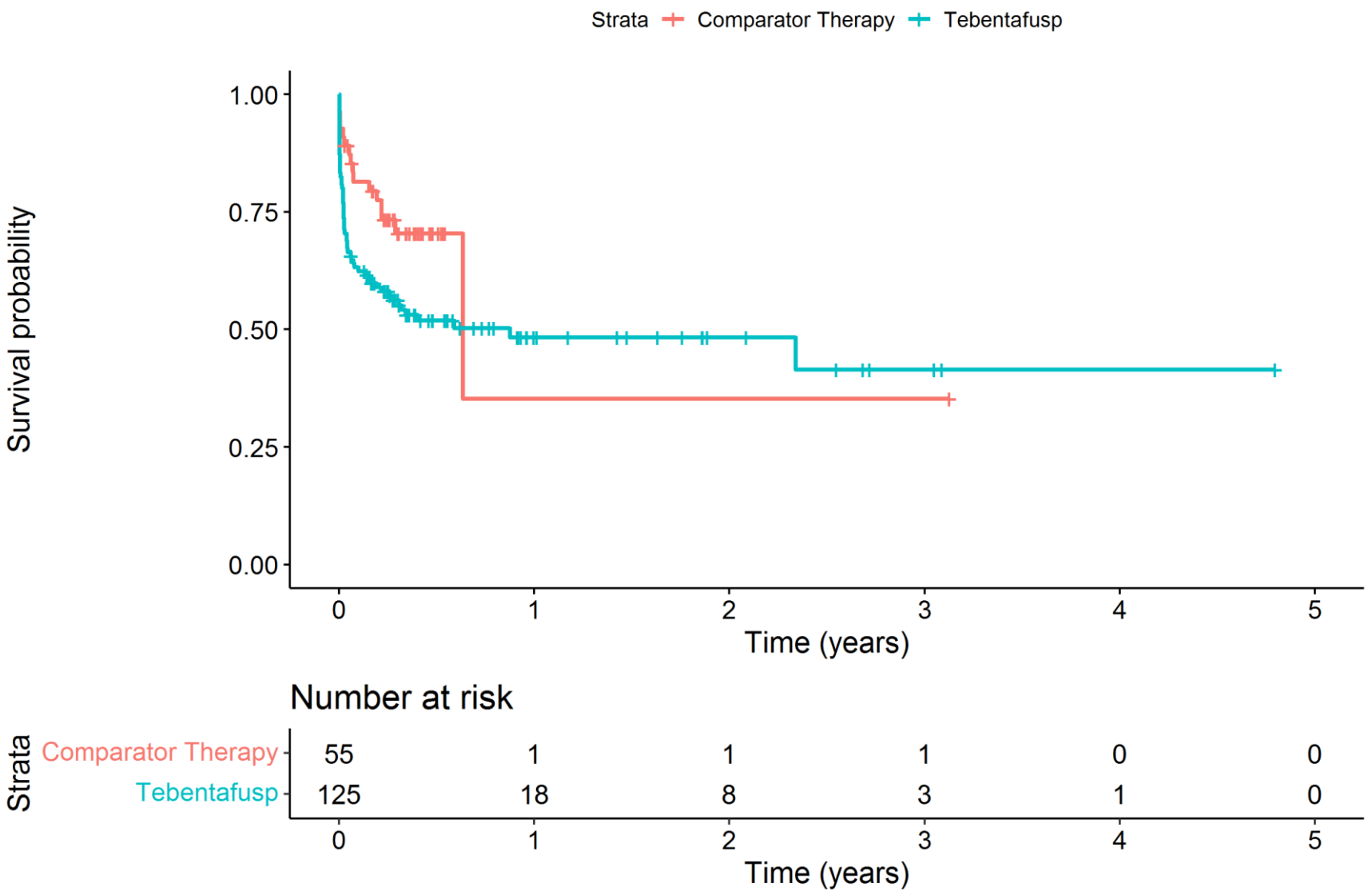
61.160 Erkrankungen des Nervensystems- Hispanisch



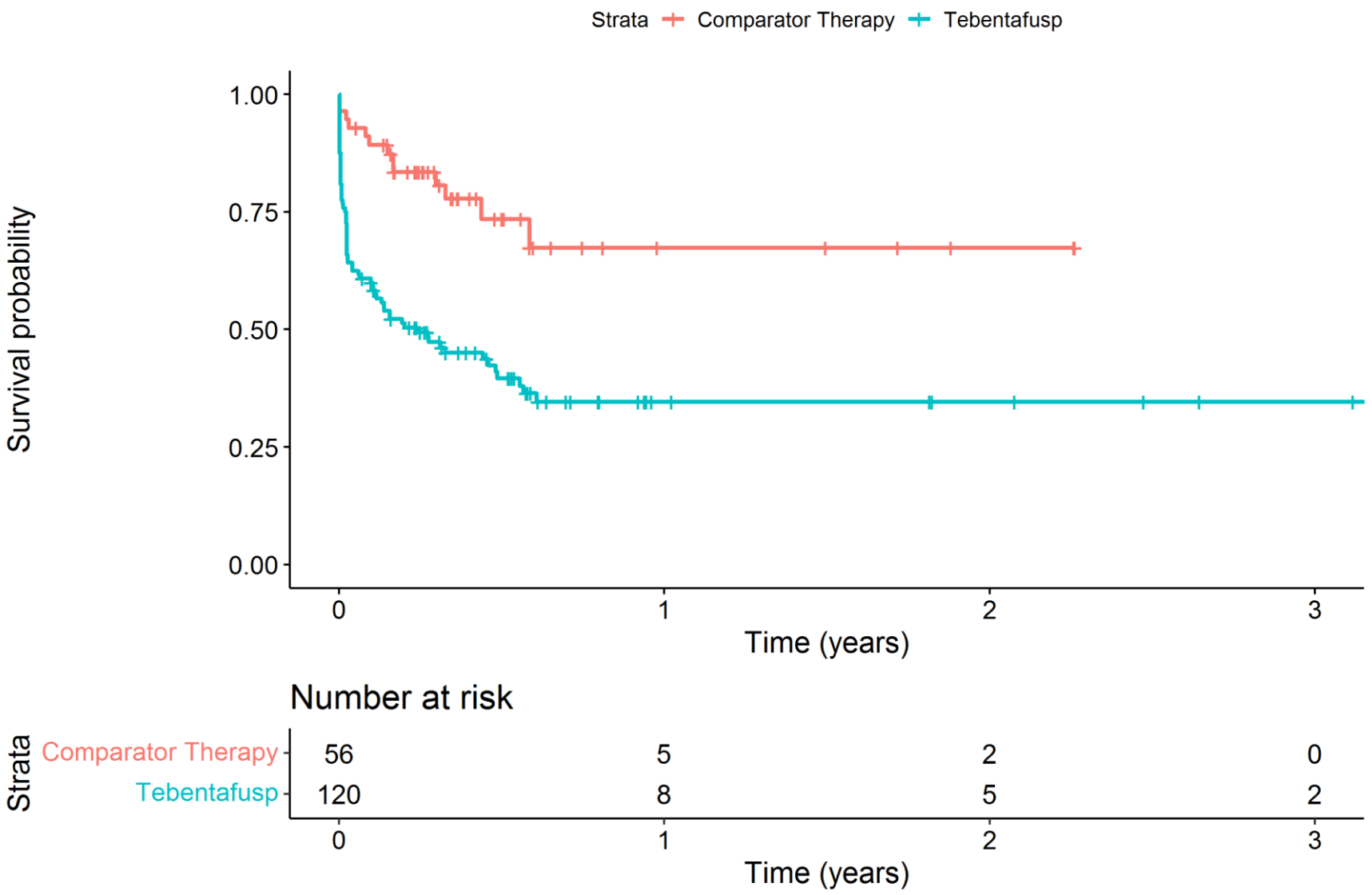
61.161 Erkrankungen des Nervensystems- Nicht-hispanisch



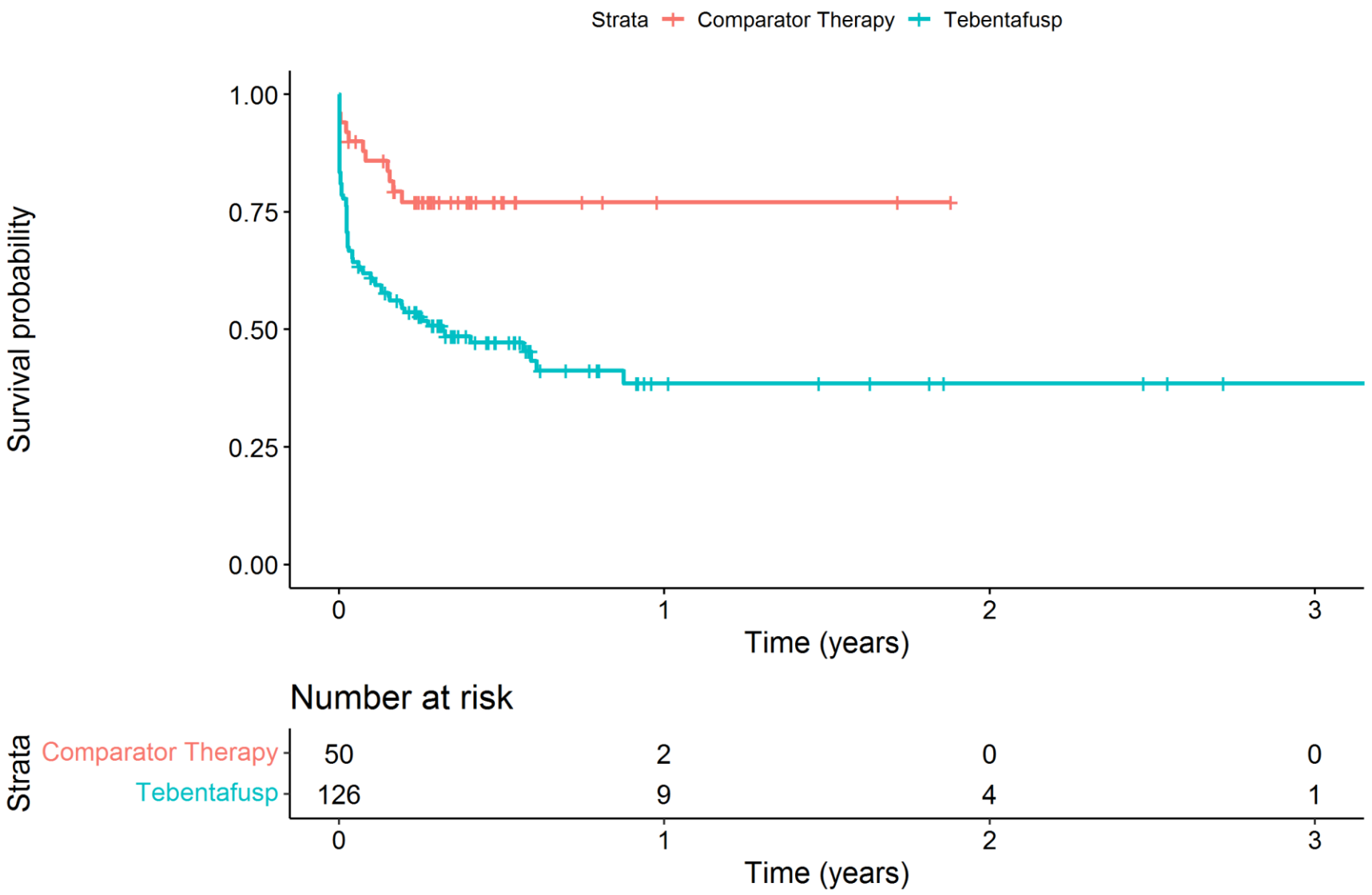
61.162 Erkrankungen des Nervensystems- Männlich



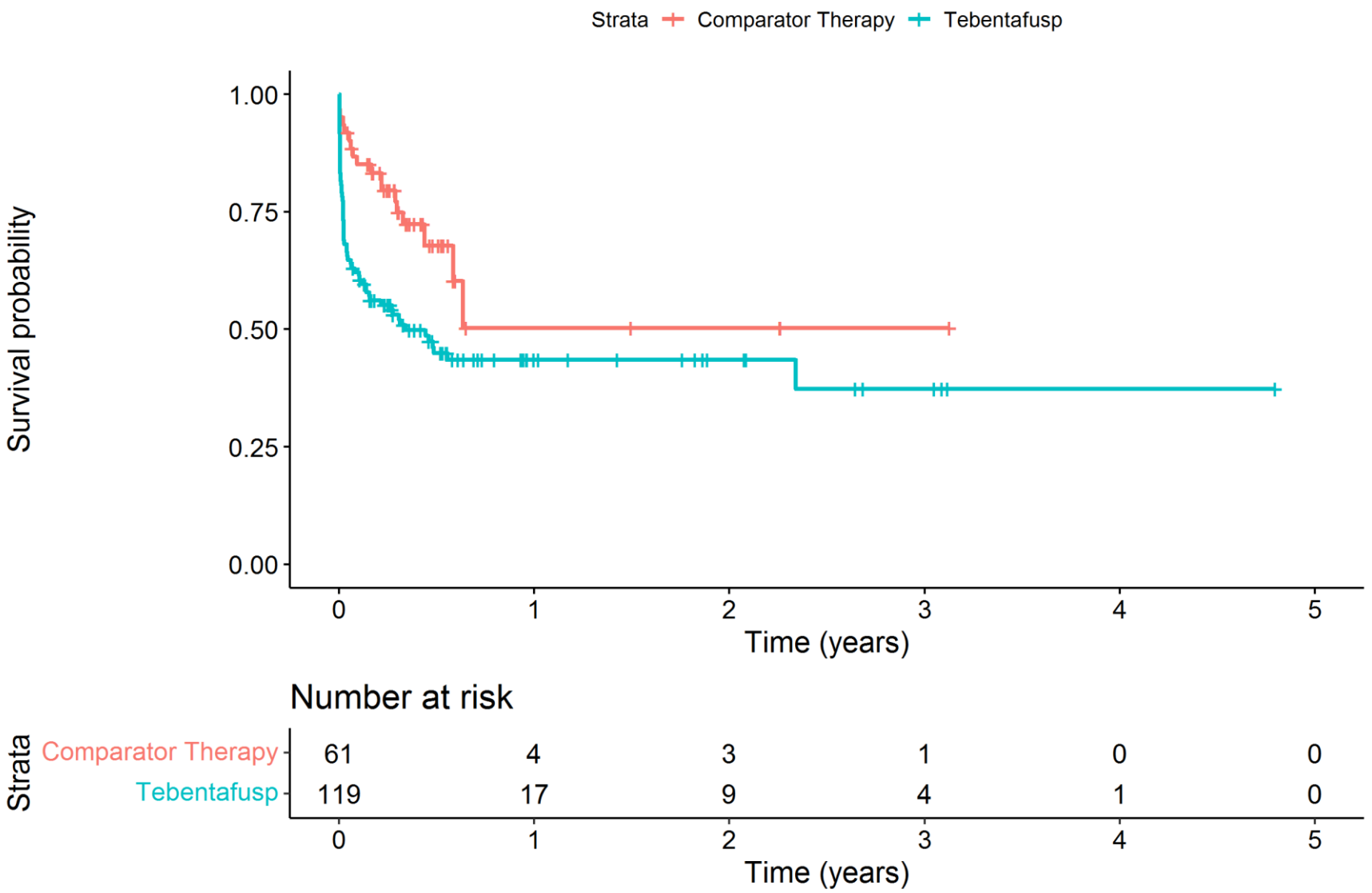
61.163 Erkrankungen des Nervensystems- Weiblich



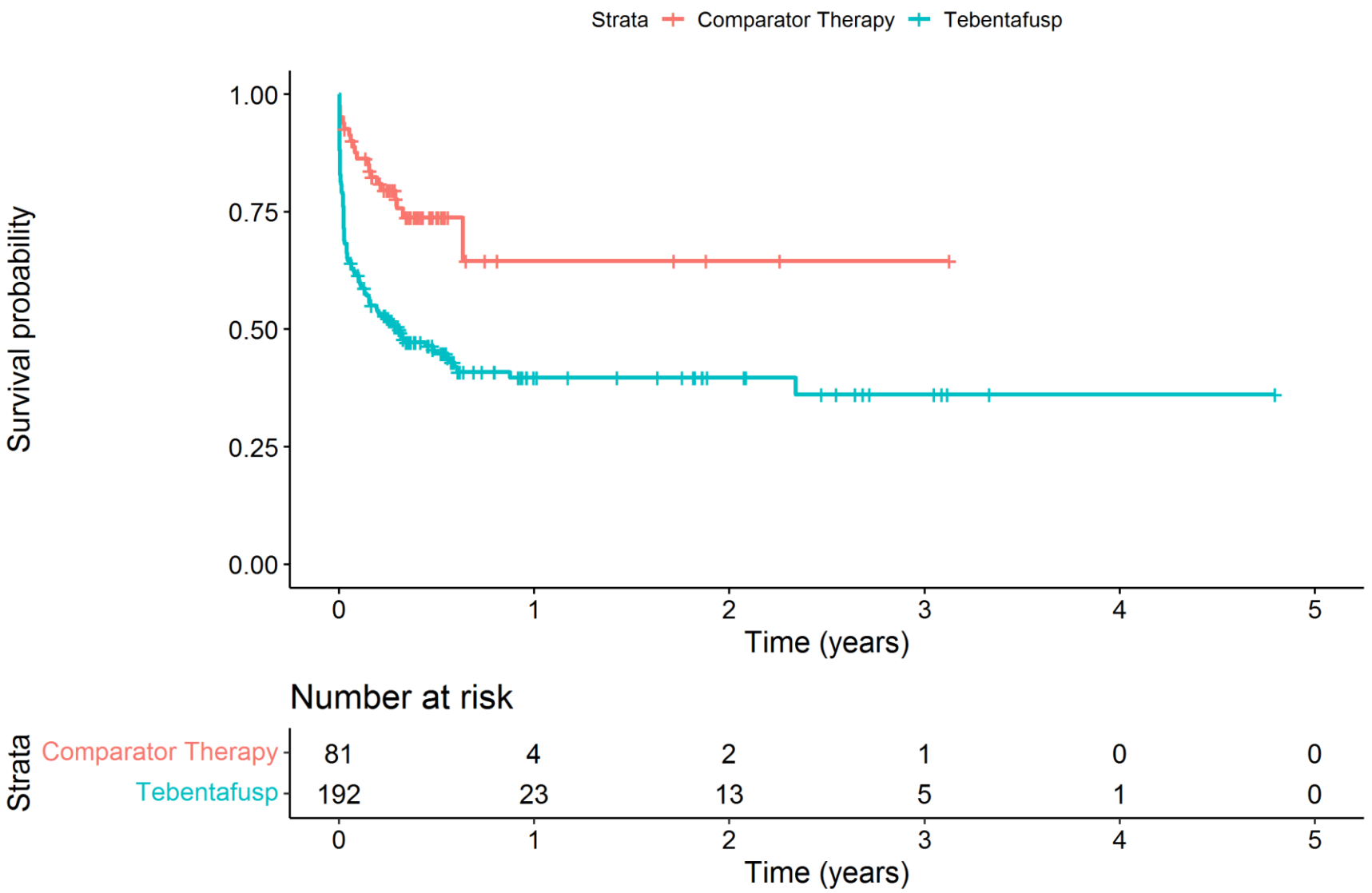
61.164 Erkrankungen des Nervensystems- <65



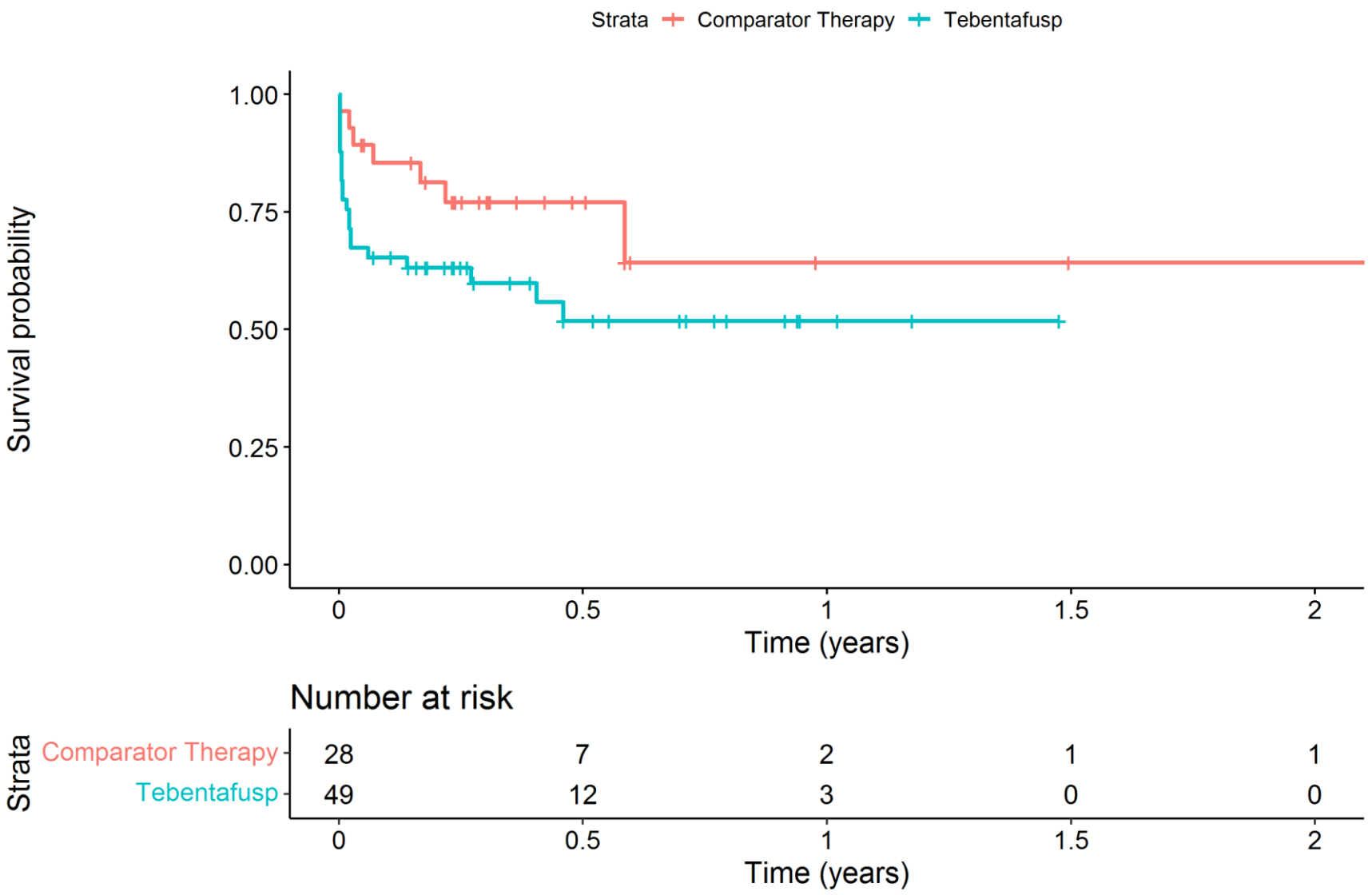
61.165 Erkrankungen des Nervensystems- ≥65



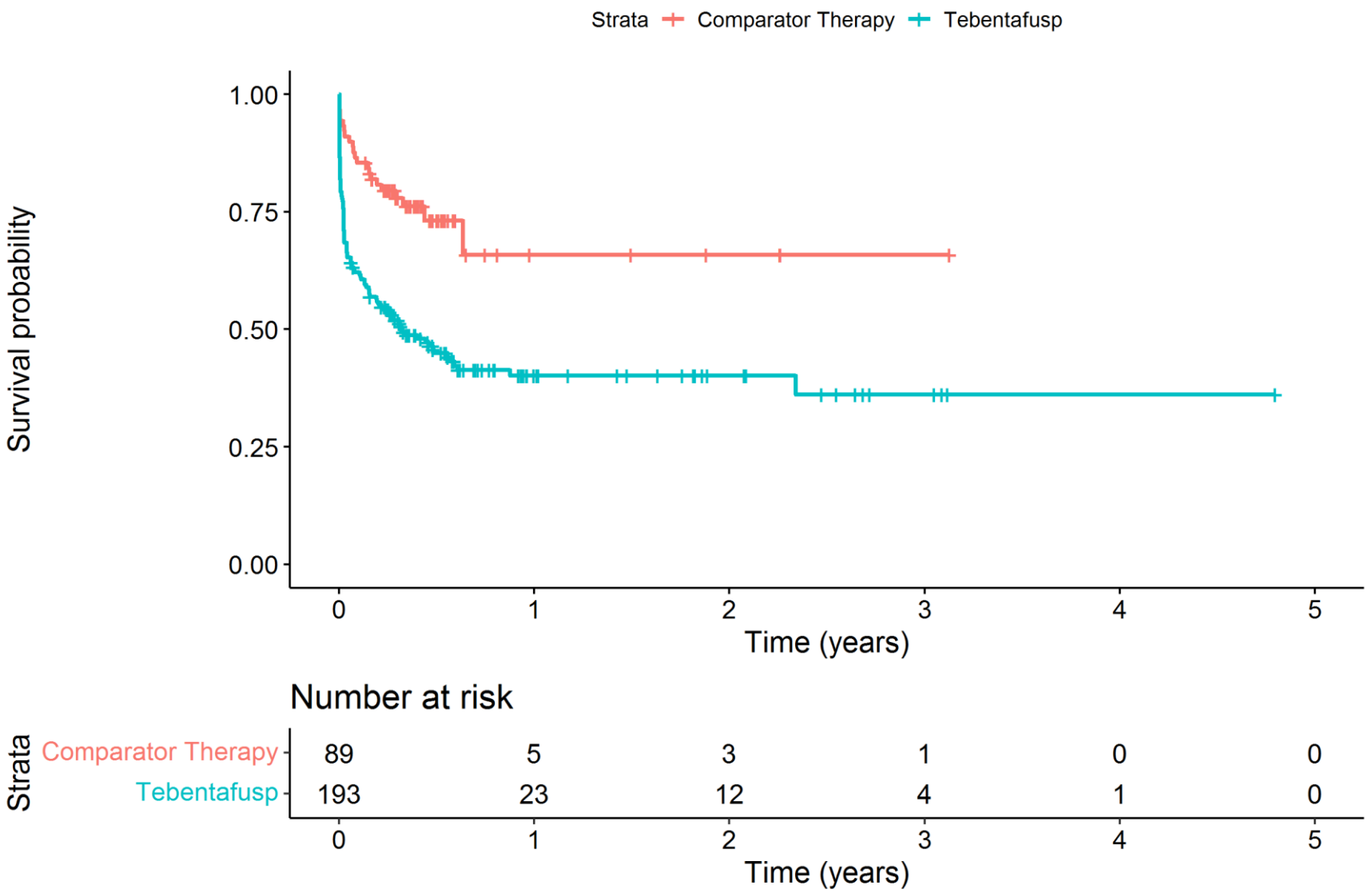
61.166 Erkrankungen des Nervensystems- ECOG 0



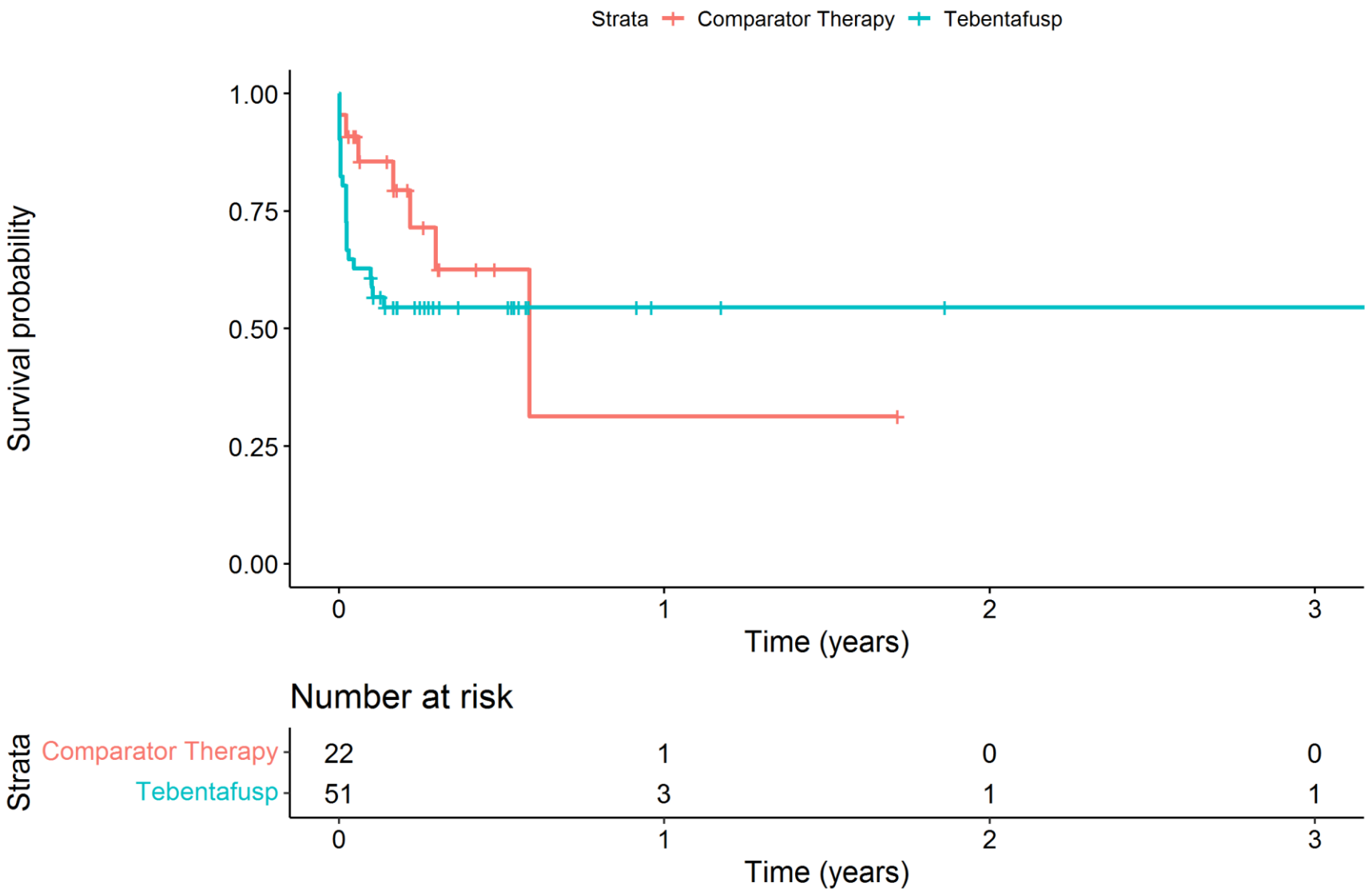
61.167 Erkrankungen des Nervensystems- ECOG 1



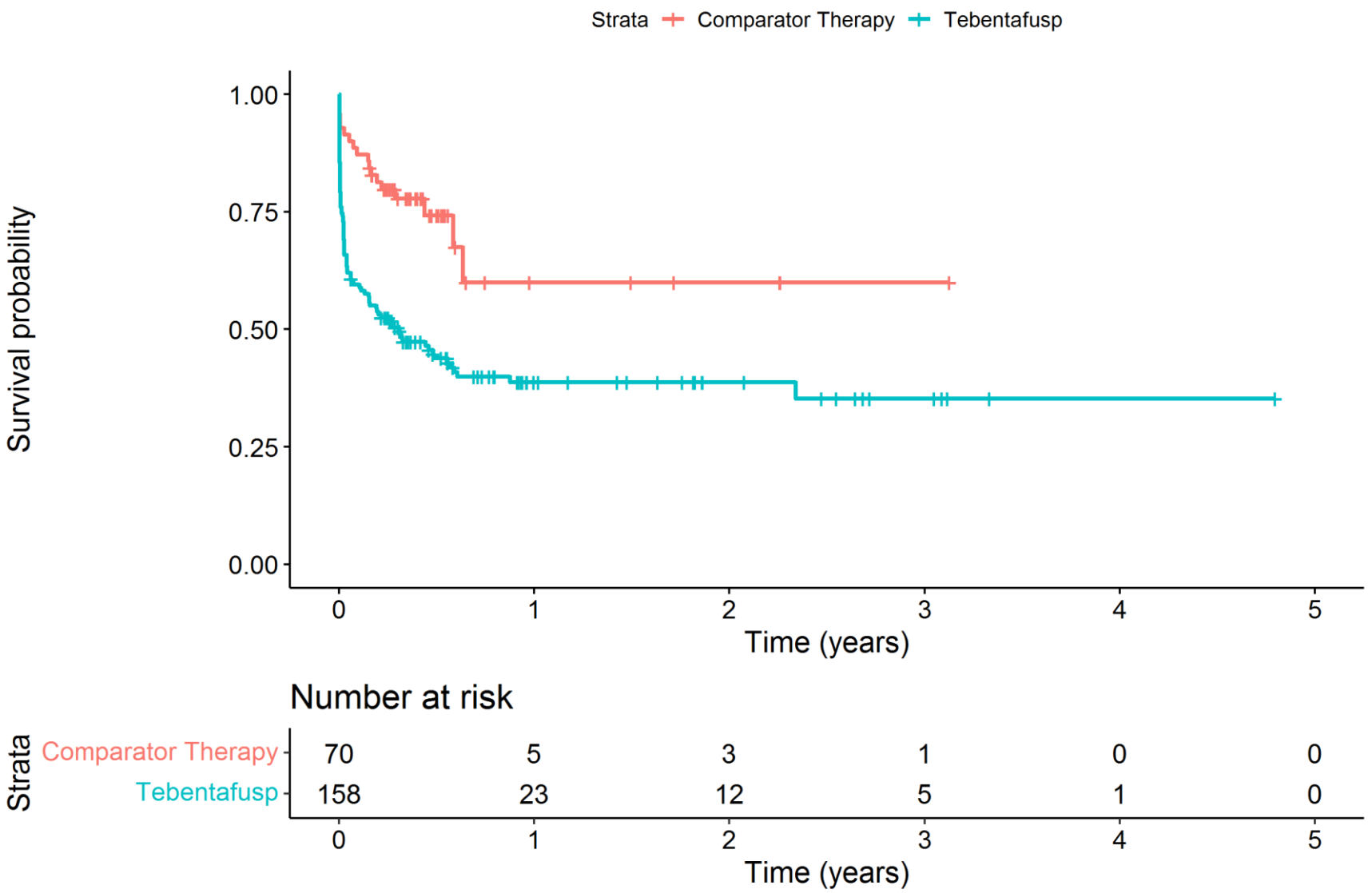
61.168 Erkrankungen des Nervensystems- ALP ≤ ULN



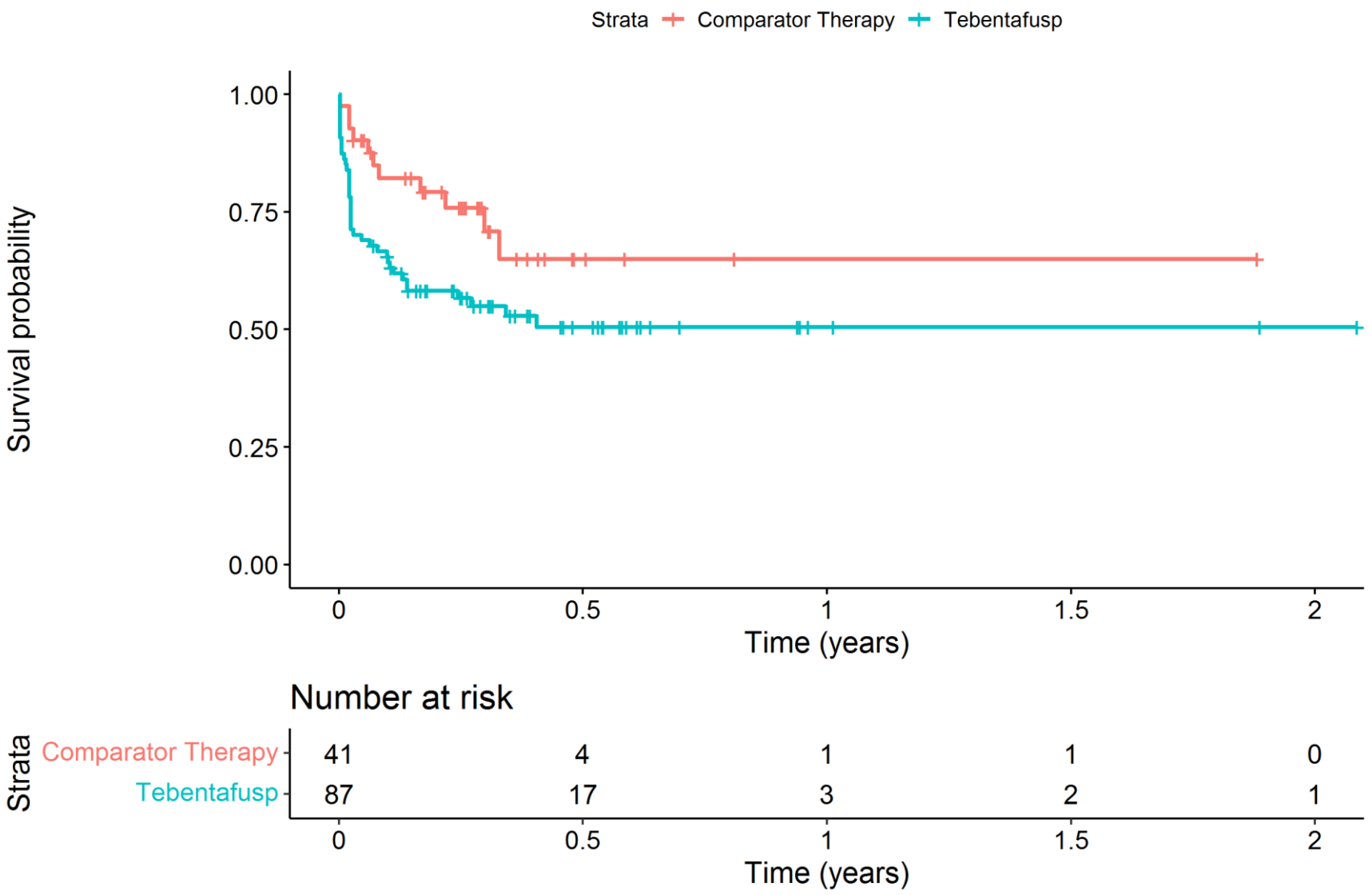
Erkrankungen des Nervensystems- ALP > ULN



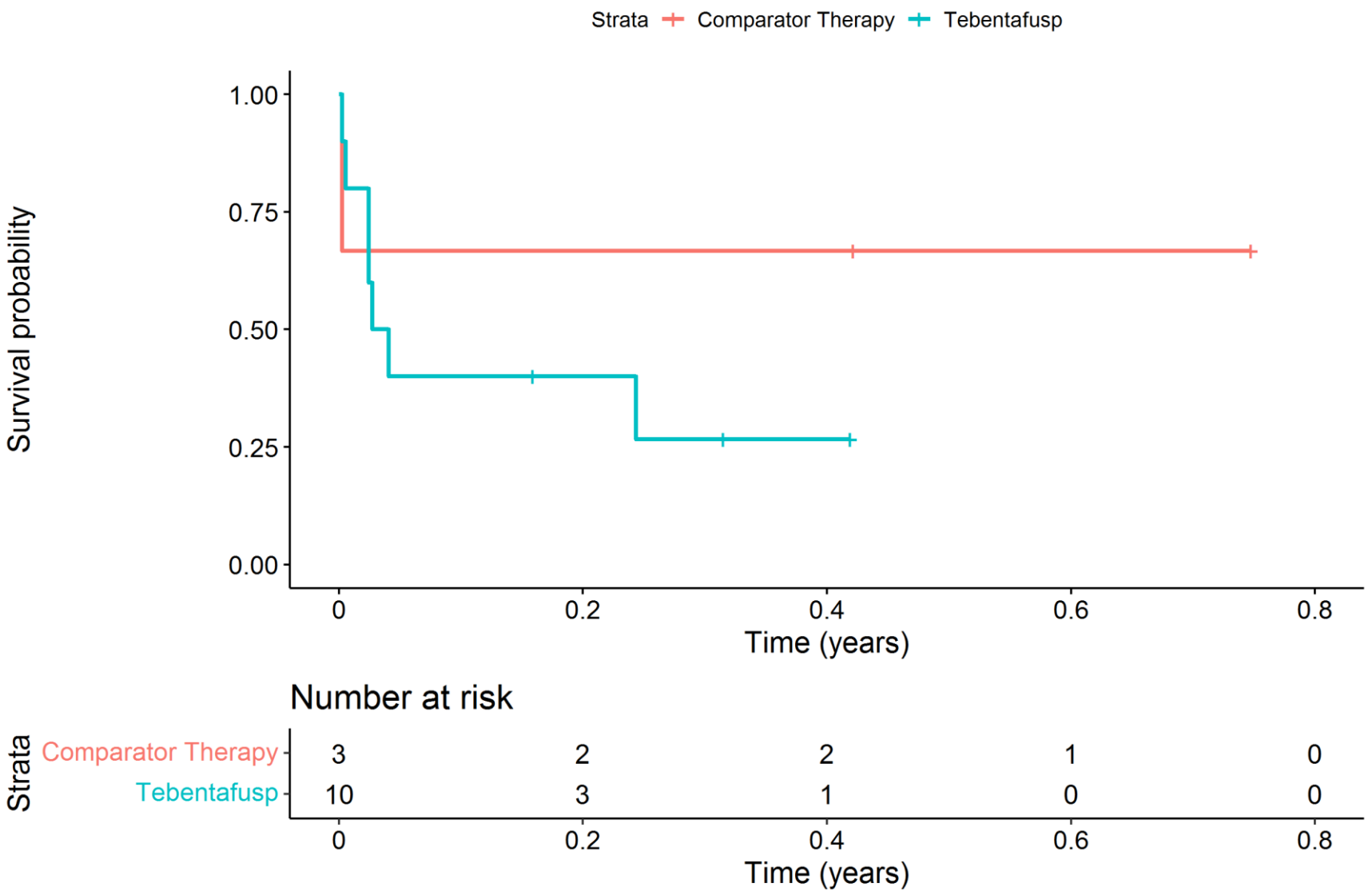
61.169 Erkrankungen des Nervensystems- LDH =< ULN



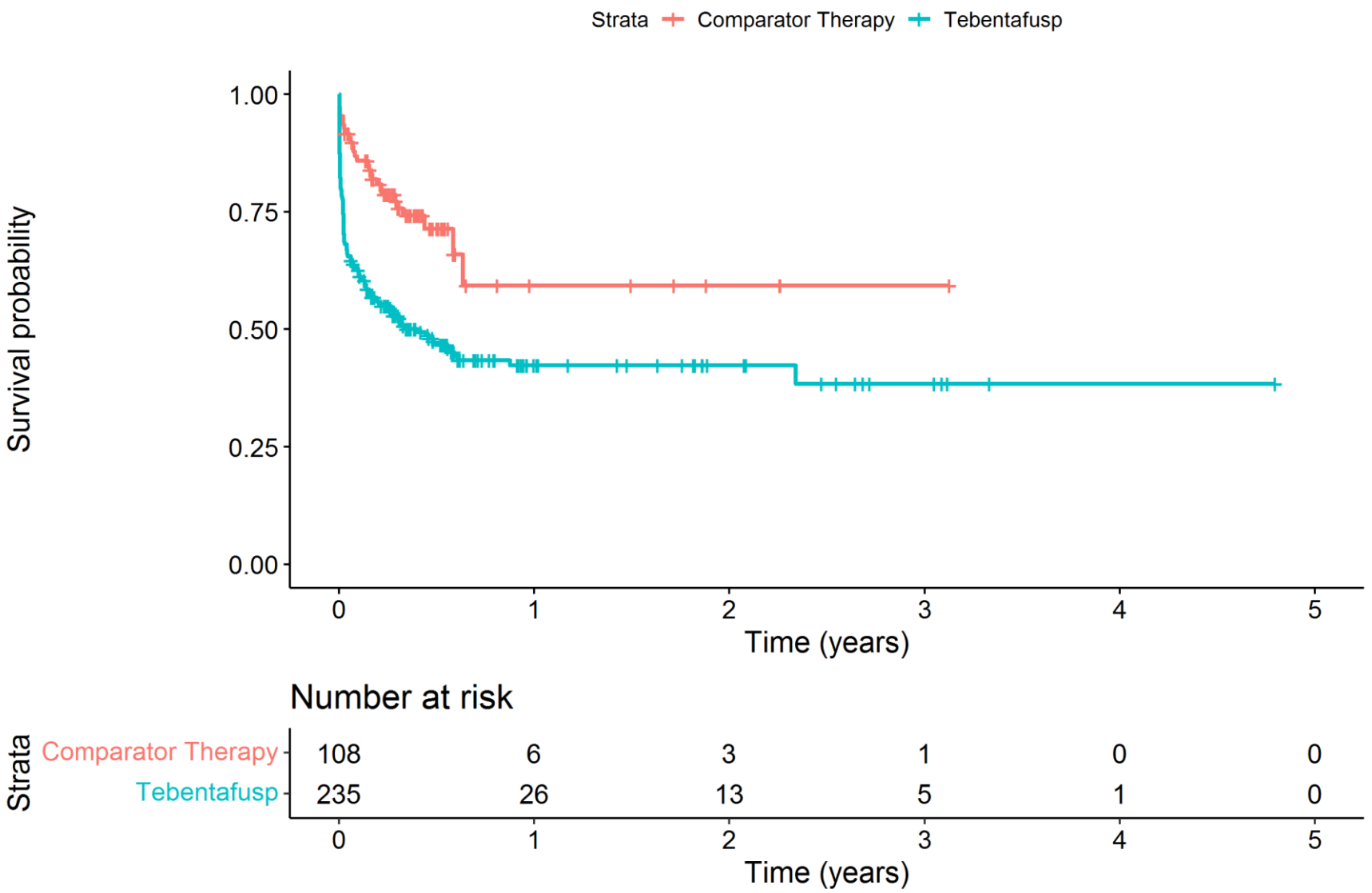
61.170 Erkrankungen des Nervensystems- LDH > ULN



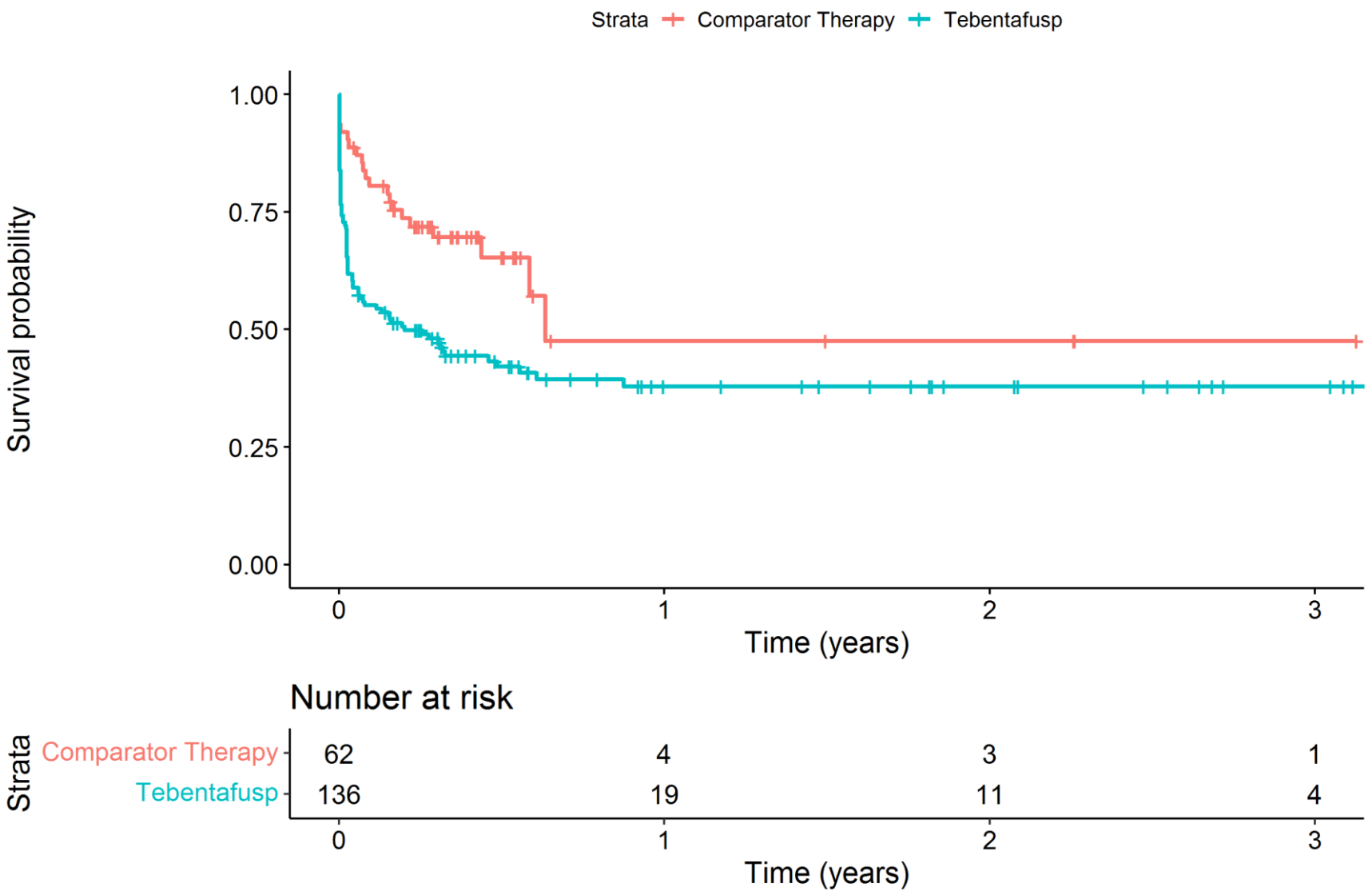
61.171 Erkrankungen des Nervensystems- Vorherige Therapie adjuvant/neoadjuvant



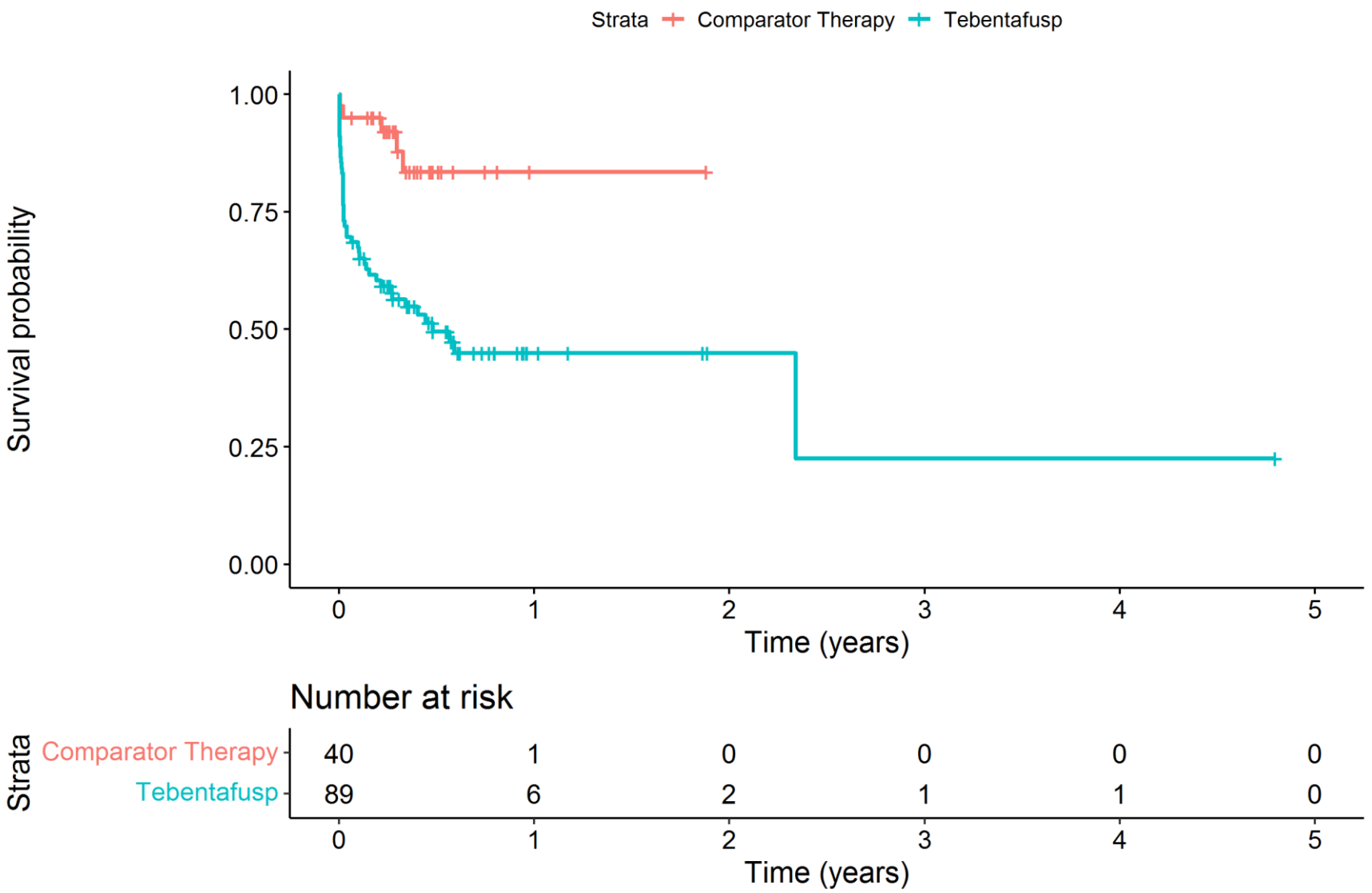
61.172 Erkrankungen des Nervensystems- Keine Vorherige Therapie adjuvant/neoadjuvant



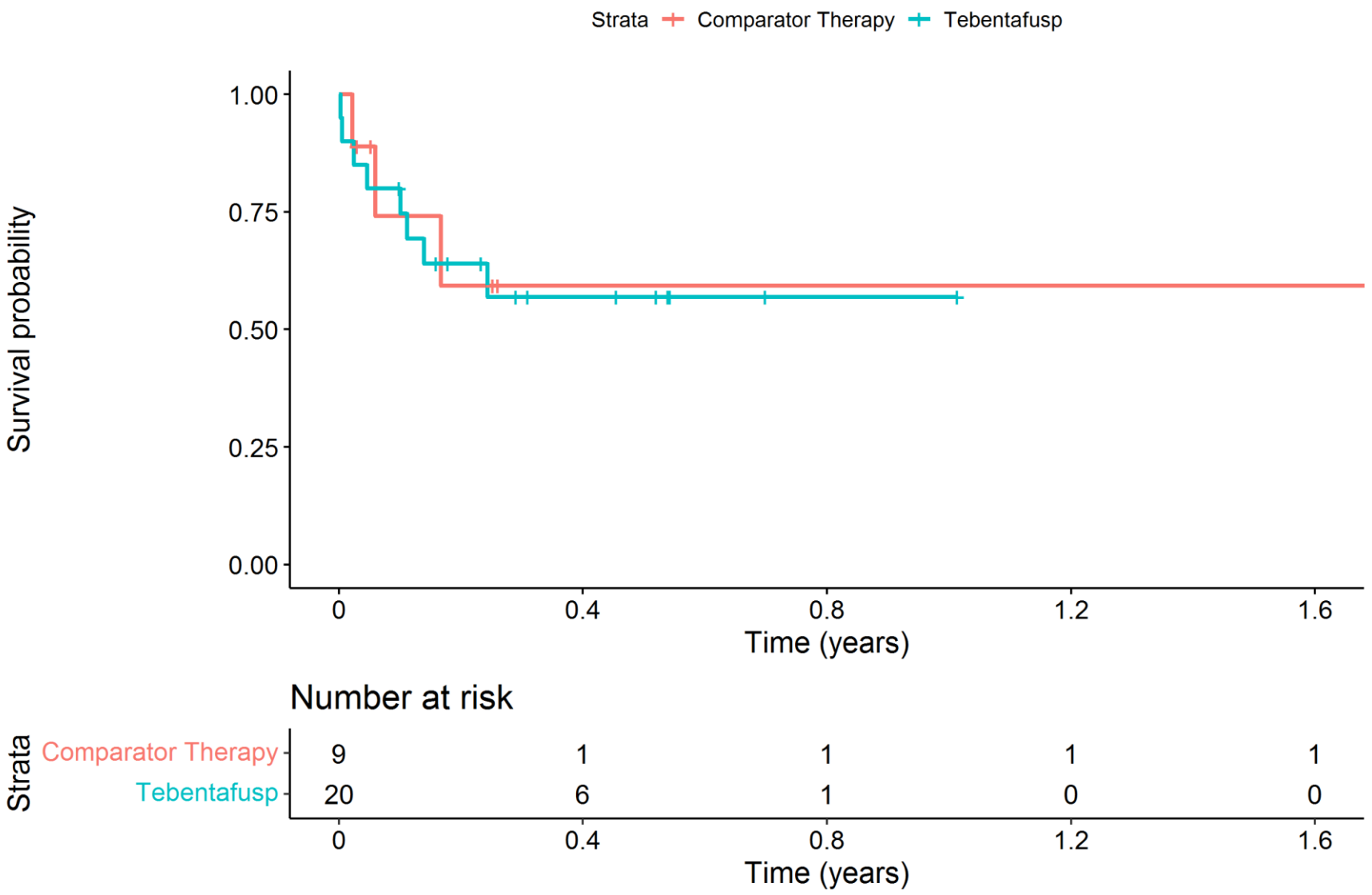
61.173 Erkrankungen des Nervensystems- Läsion ≤ 3cm



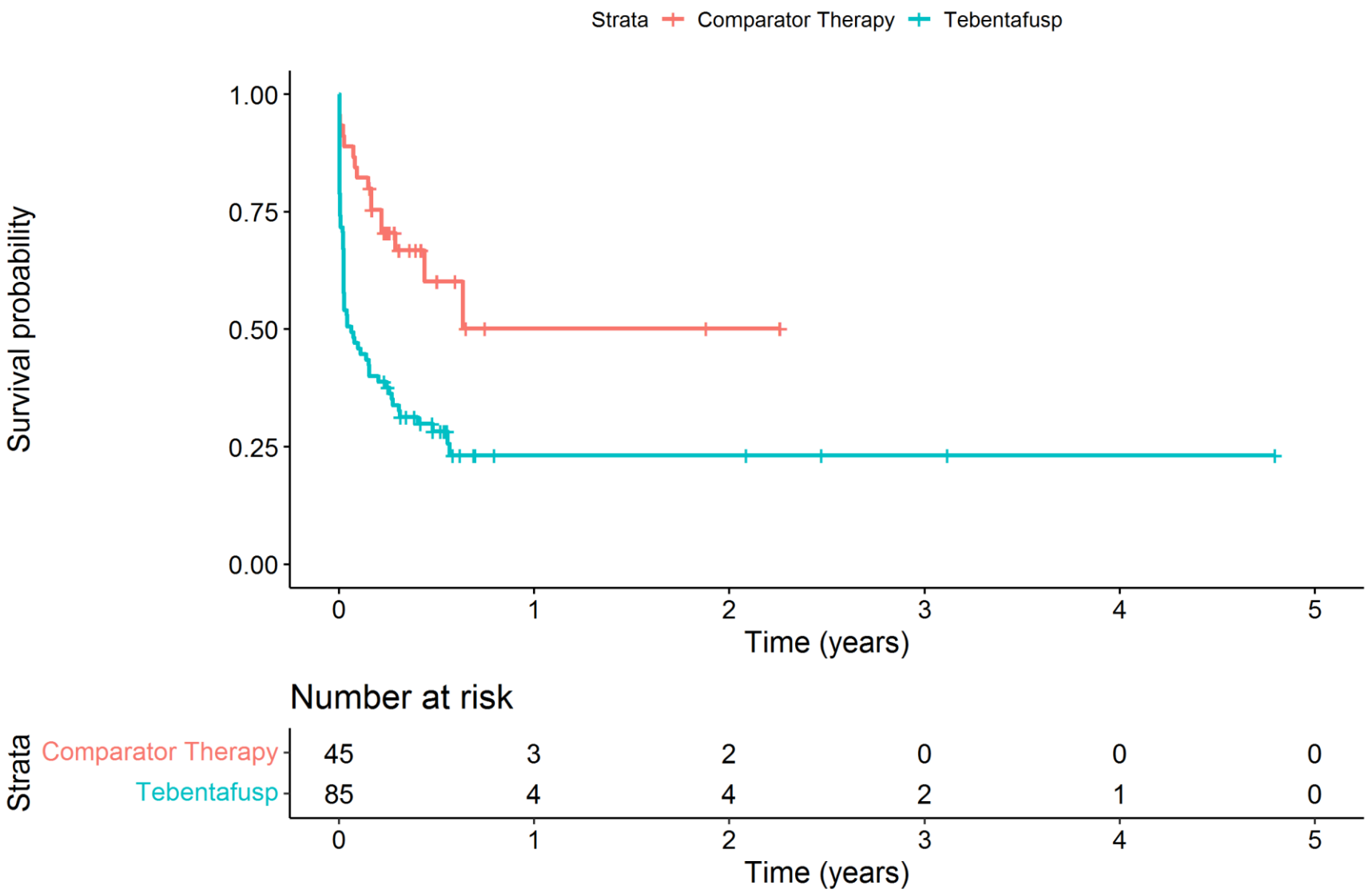
61.174 Erkrankungen des Nervensystems- Läsion 3,1-8,0 cm



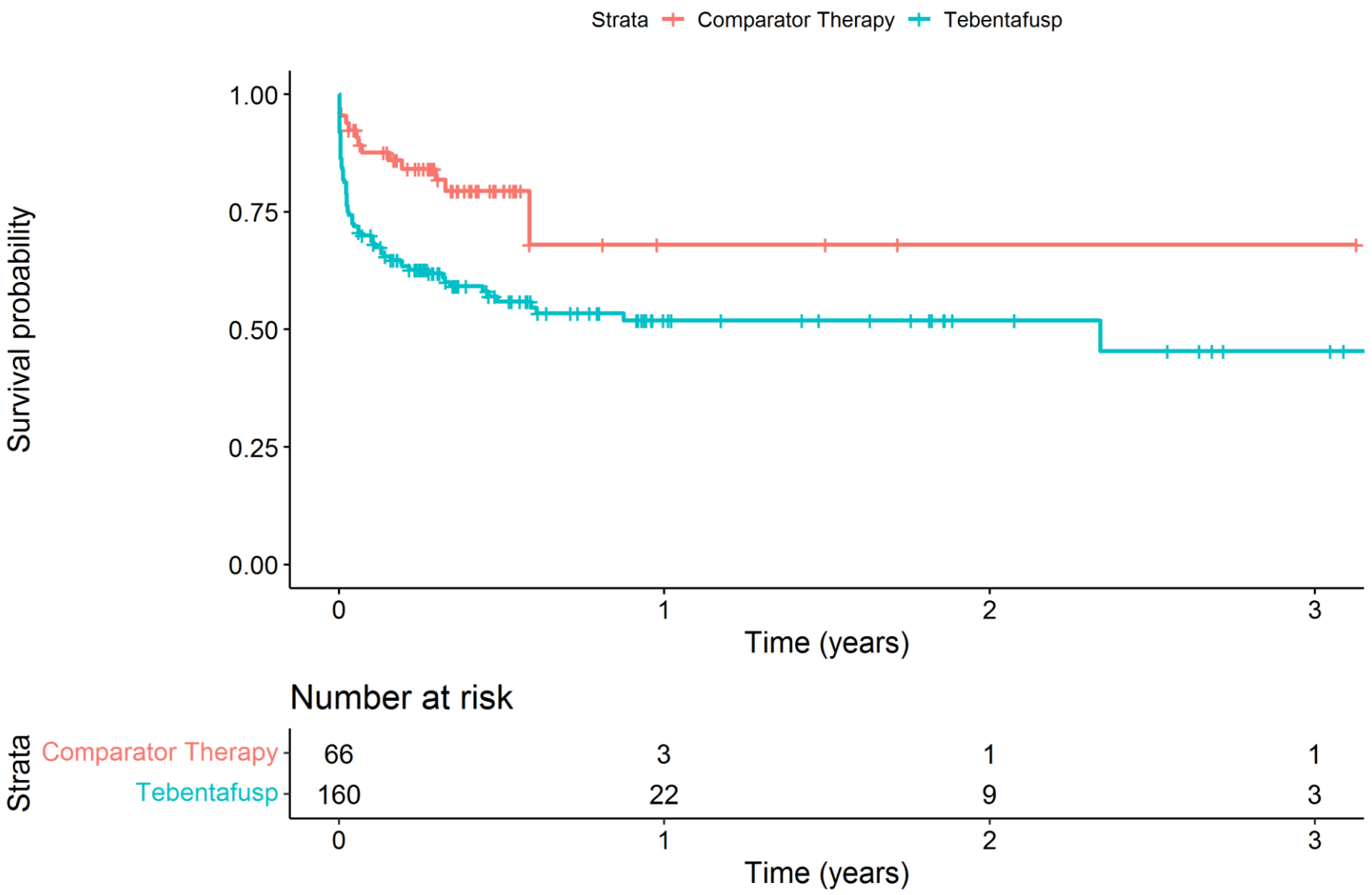
61.175 Erkrankungen des Nervensystems- Läsion ≥8,1 cm



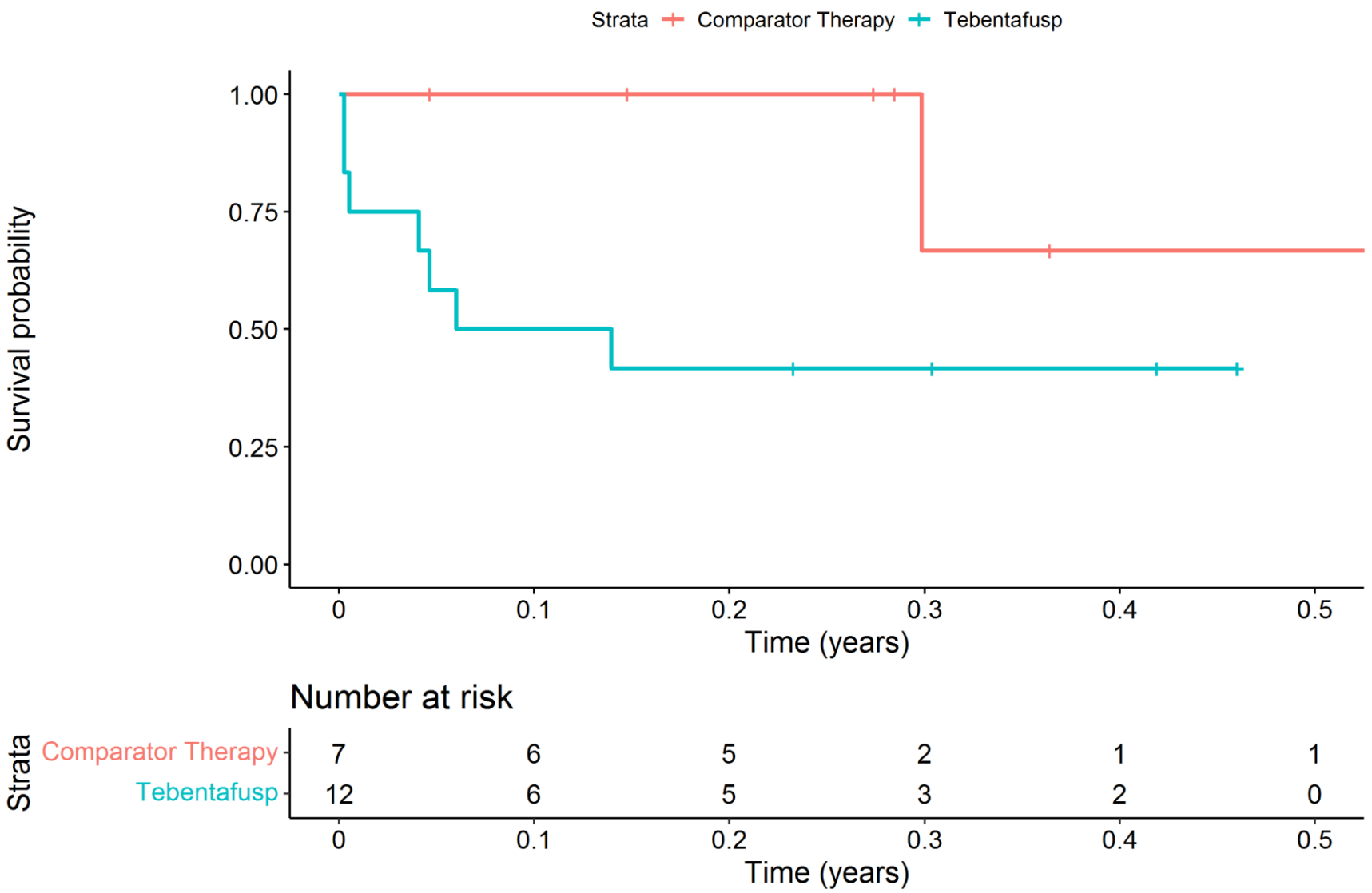
61.176 Erkrankungen des Nervensystems- Nordamerika



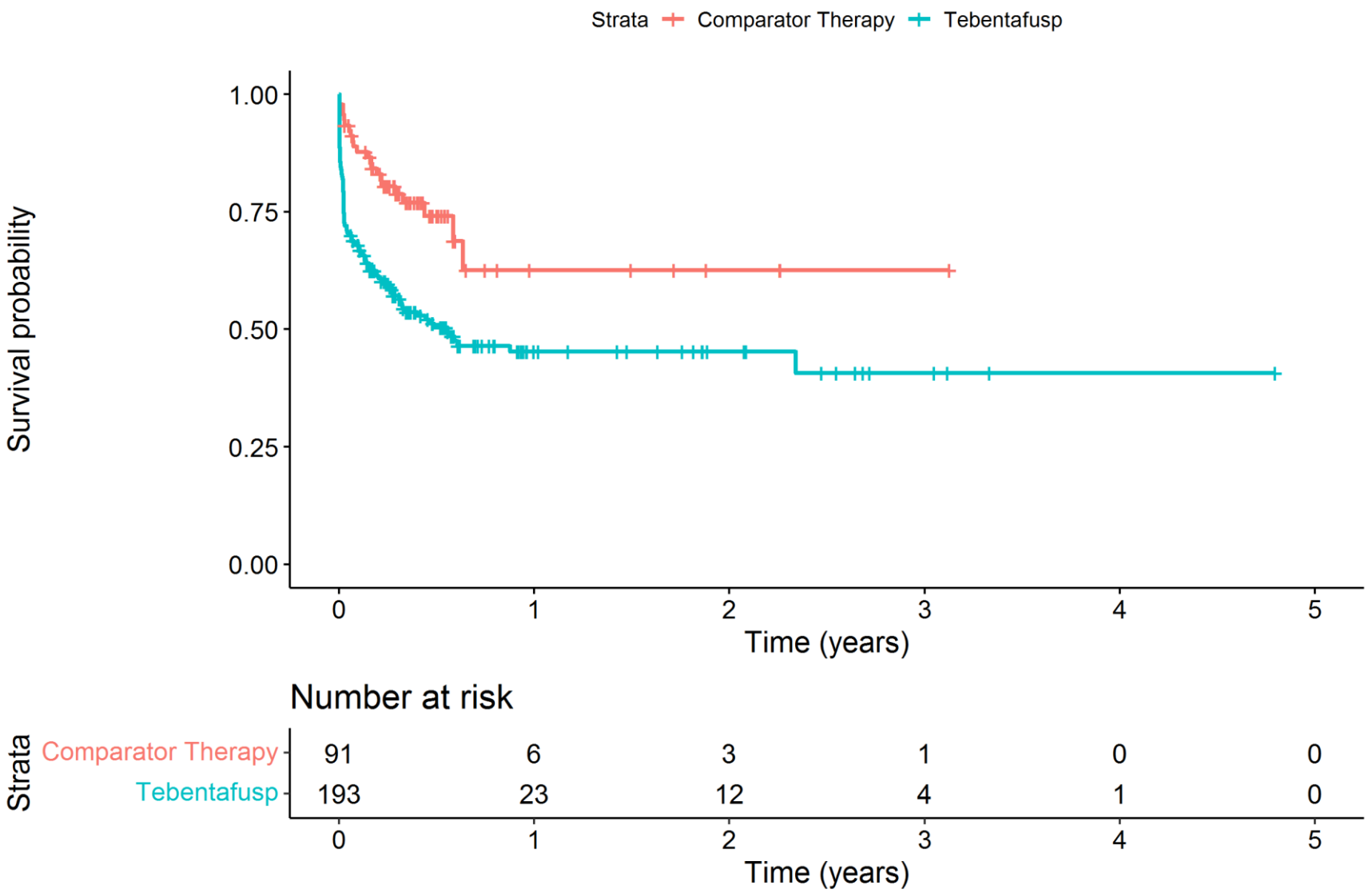
61.177 Erkrankungen des Nervensystems- Nicht-Nordamerika



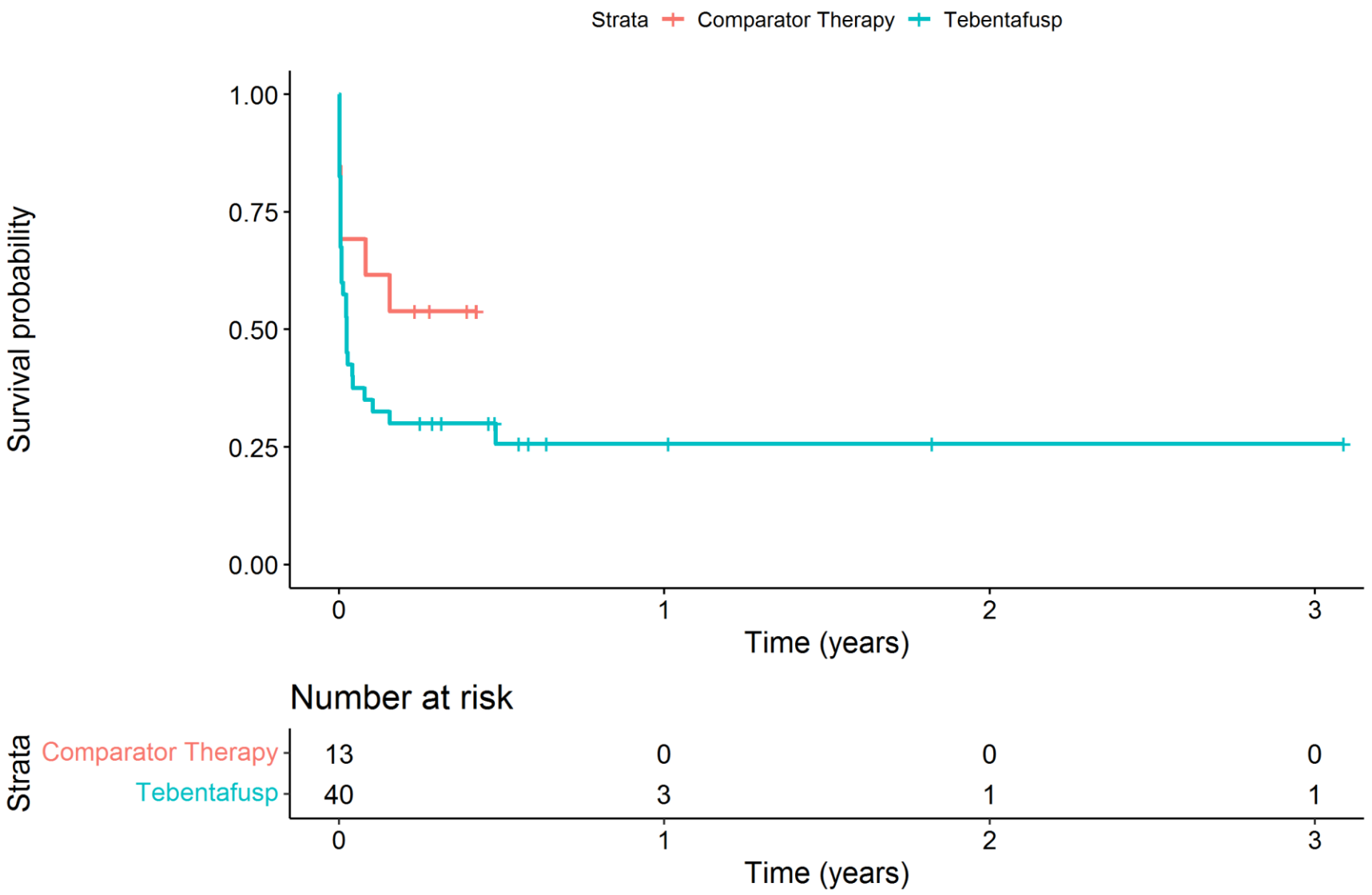
61.178 Erkrankungen des Nervensystems- Dacarbazin



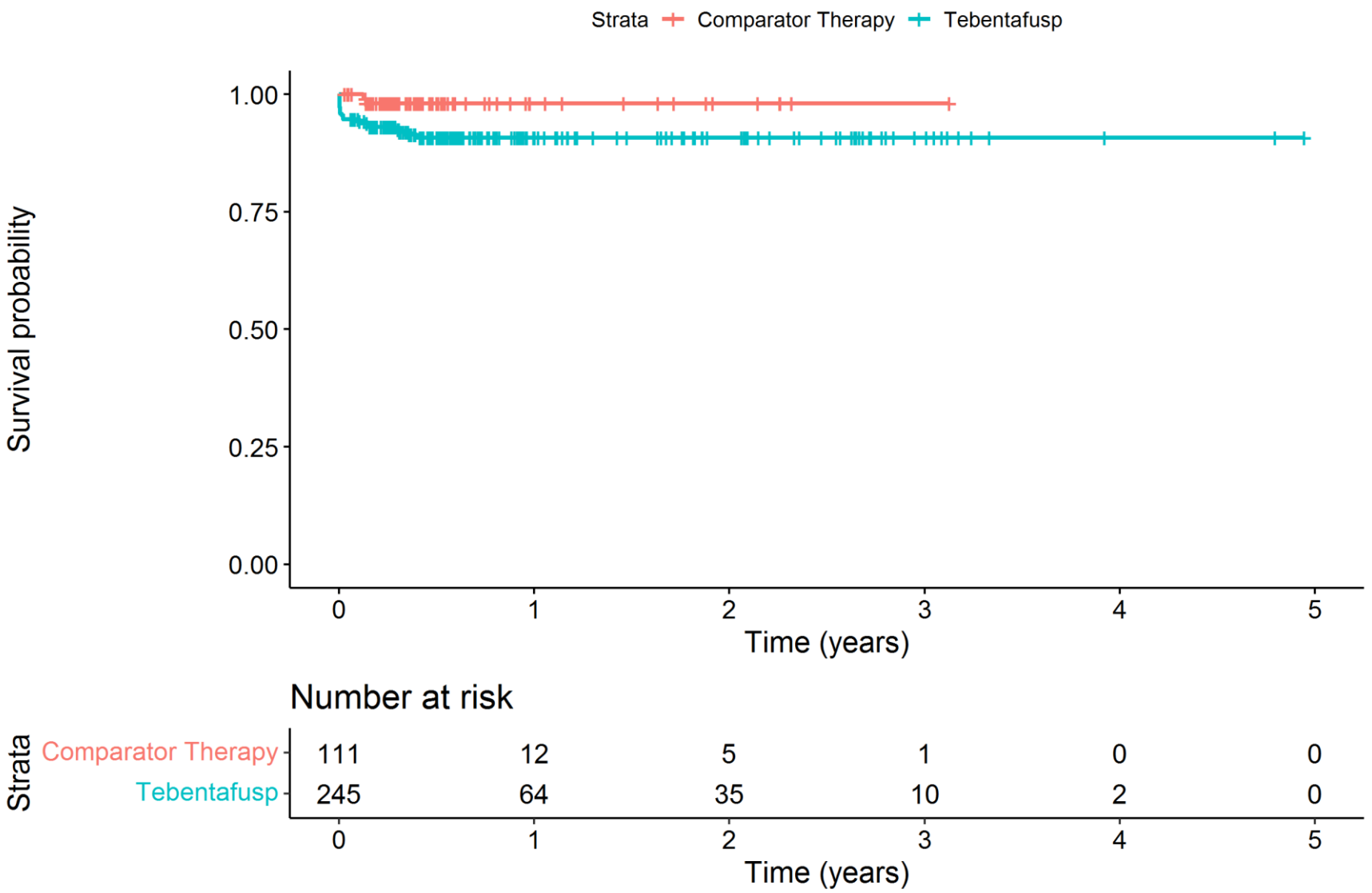
61.179 Erkrankungen des Nervensystems- Pembrolizumab



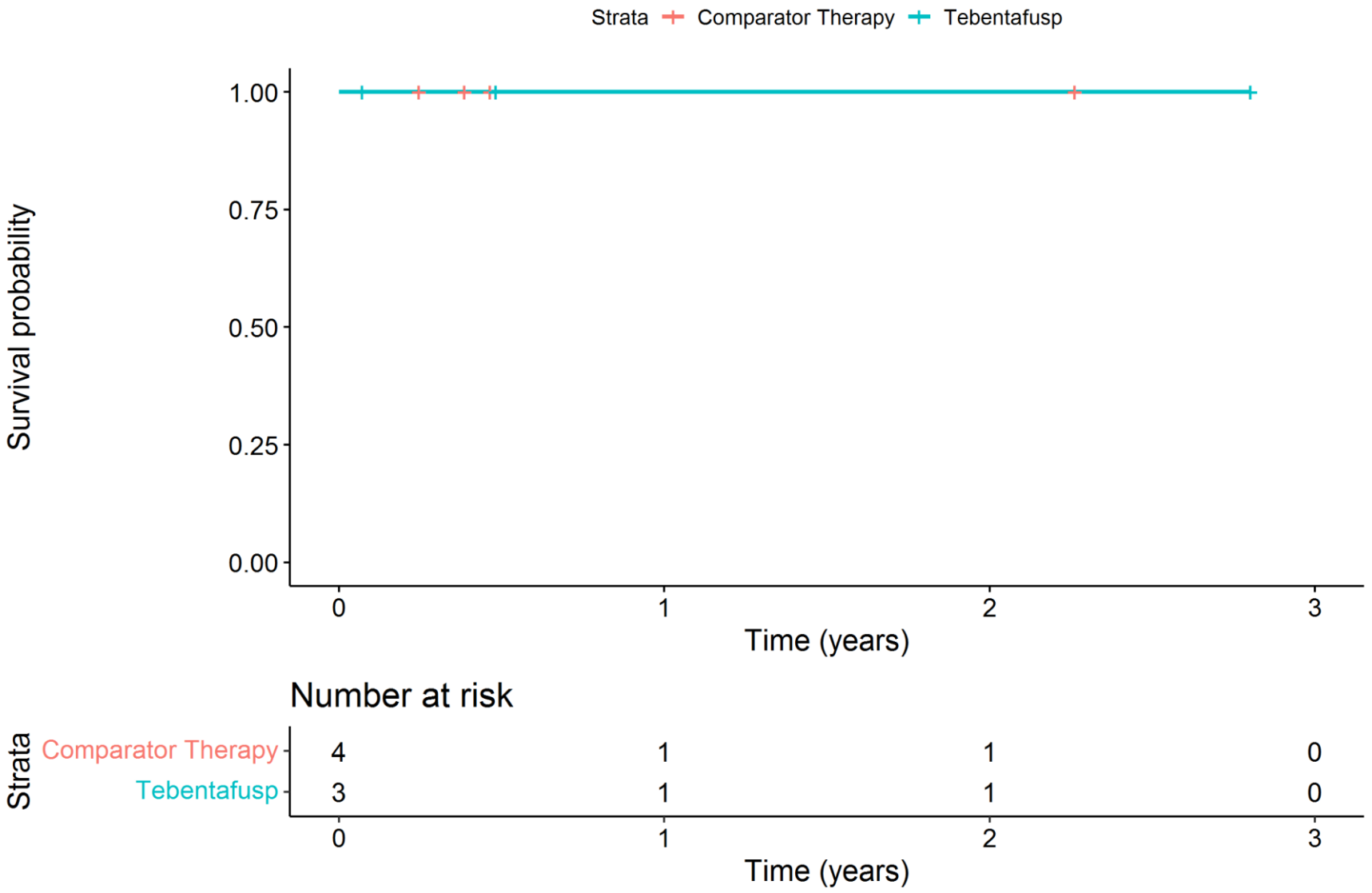
61.180 Erkrankungen des Nervensystems- Ipilimumab



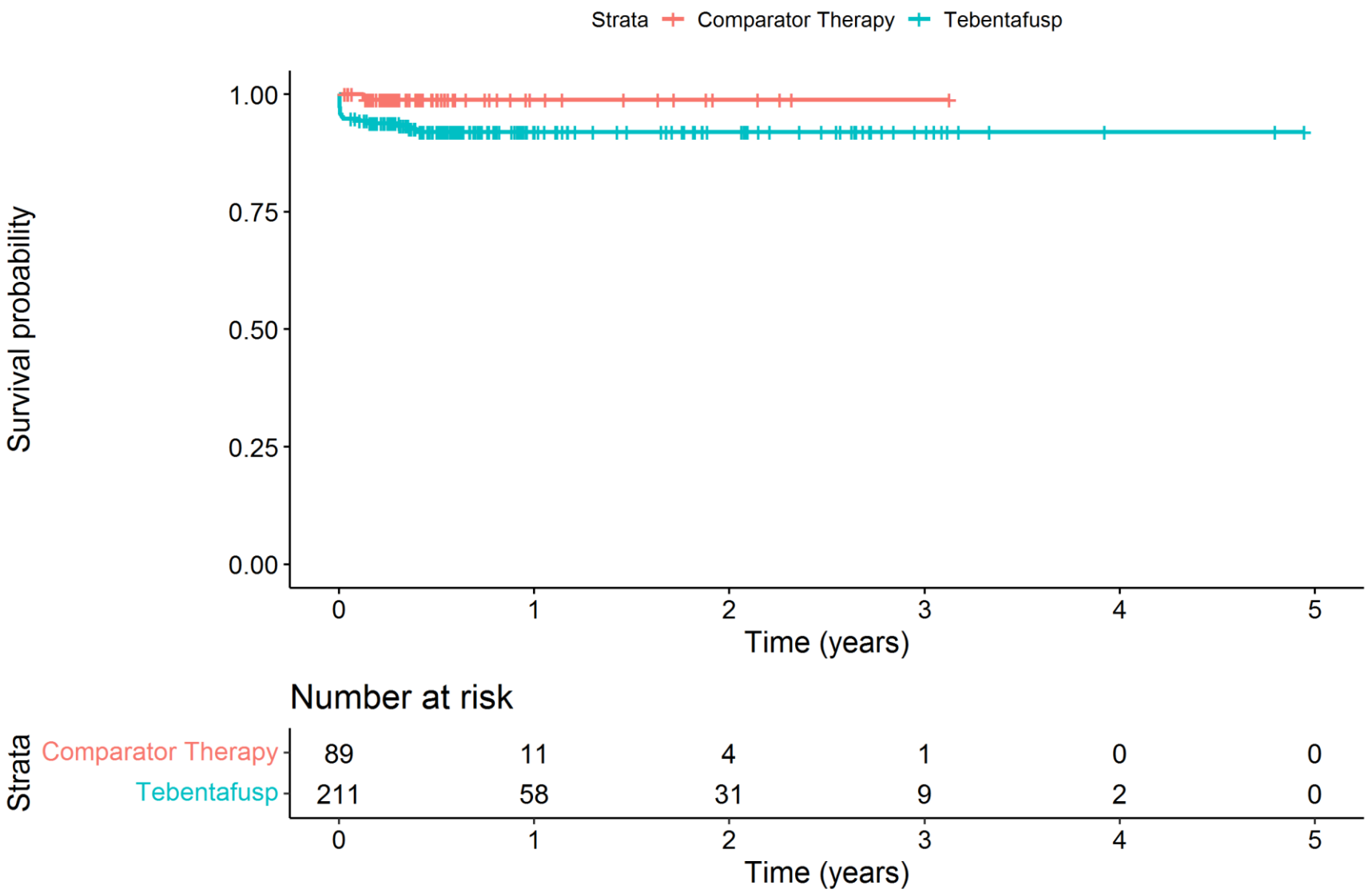
61.181 Erkrankungen der Geschlechtsorgane und der Brustdruese- Gesamt



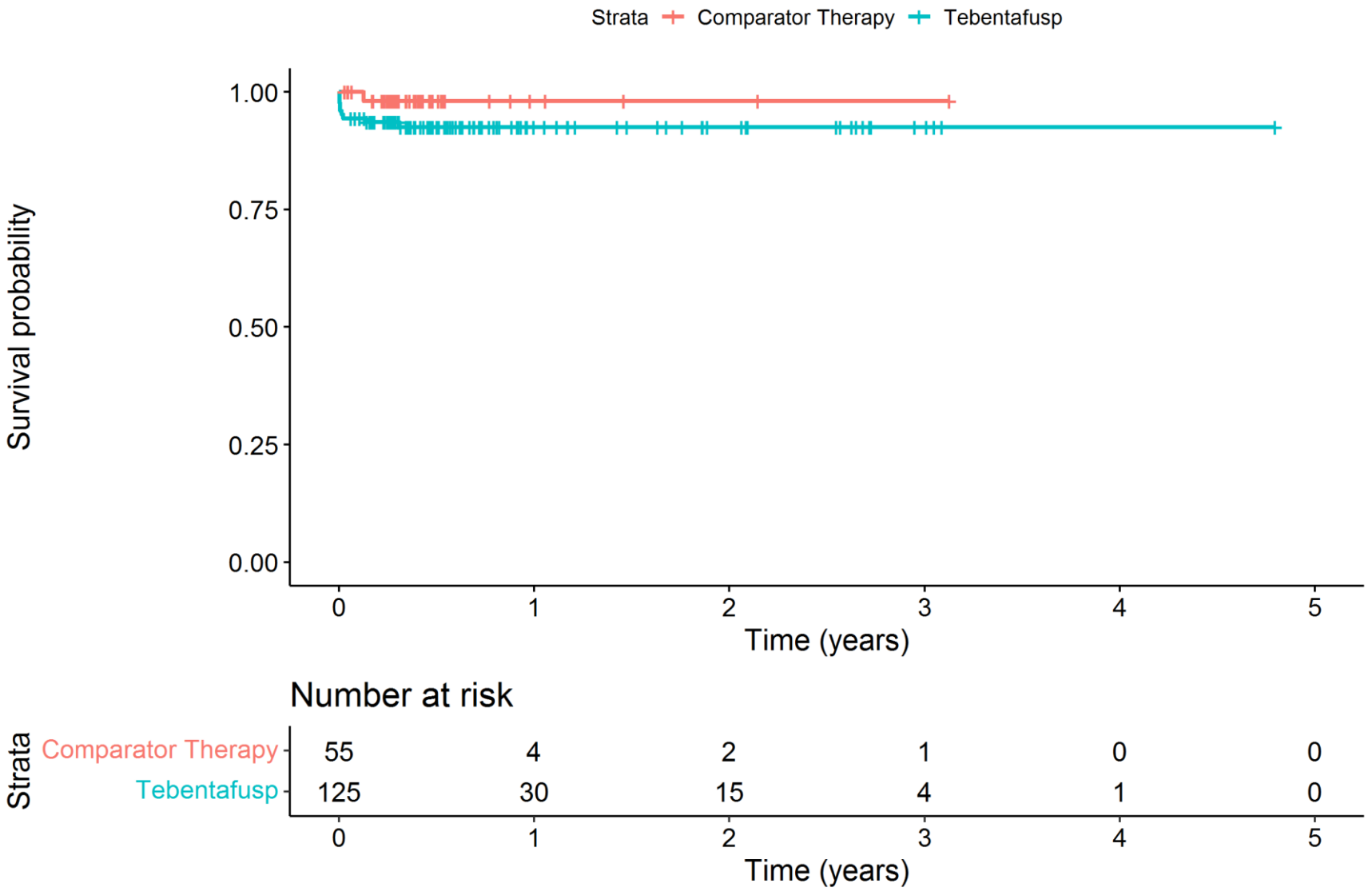
61.182 Erkrankungen der Geschlechtsorgane und der Brustdruese- Hispanisch



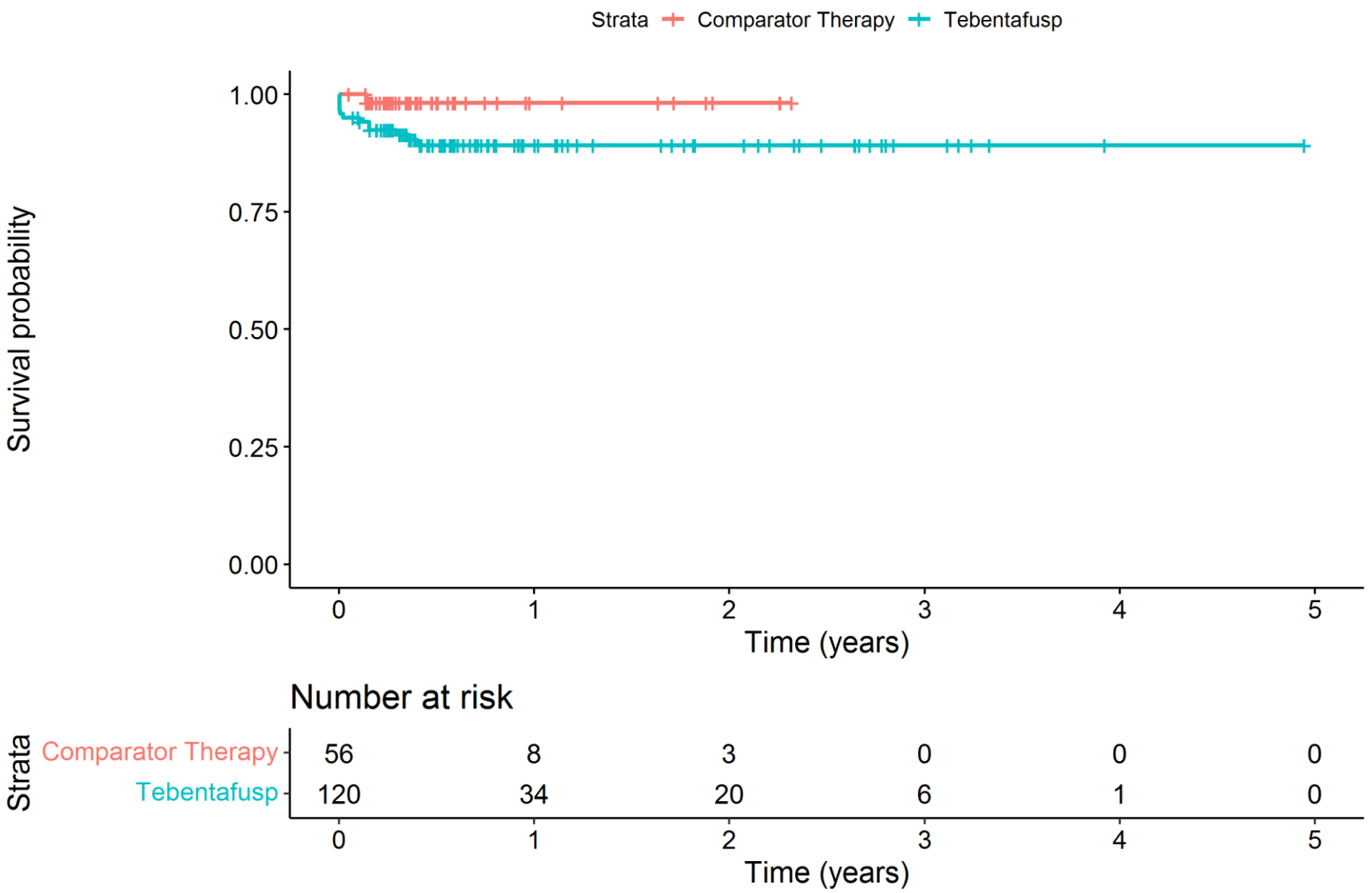
61.183 Erkrankungen der Geschlechtsorgane und der Brustdruese- Nicht-hispanisch



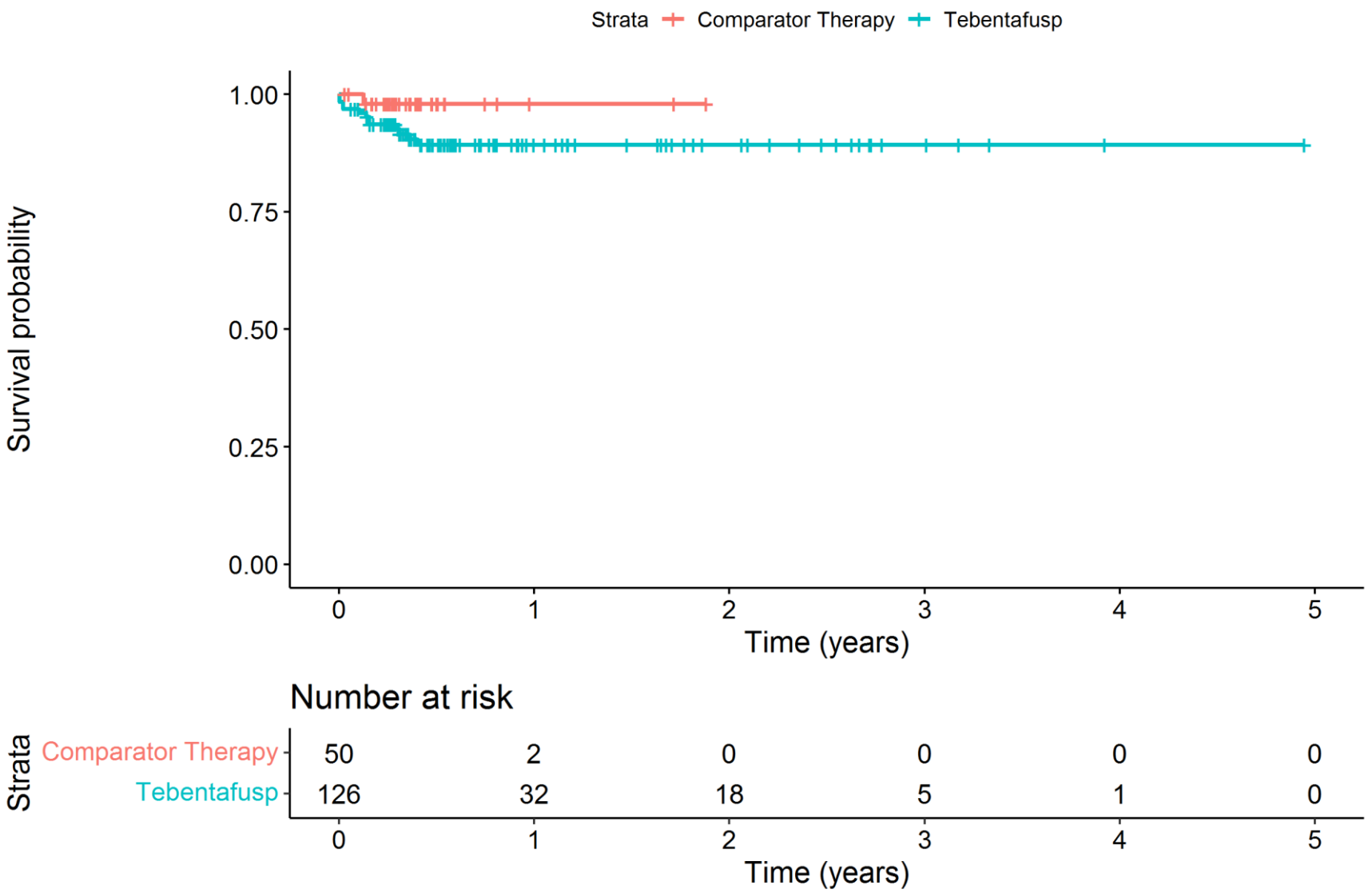
61.184 Erkrankungen der Geschlechtsorgane und der Brustdruese- Männlich



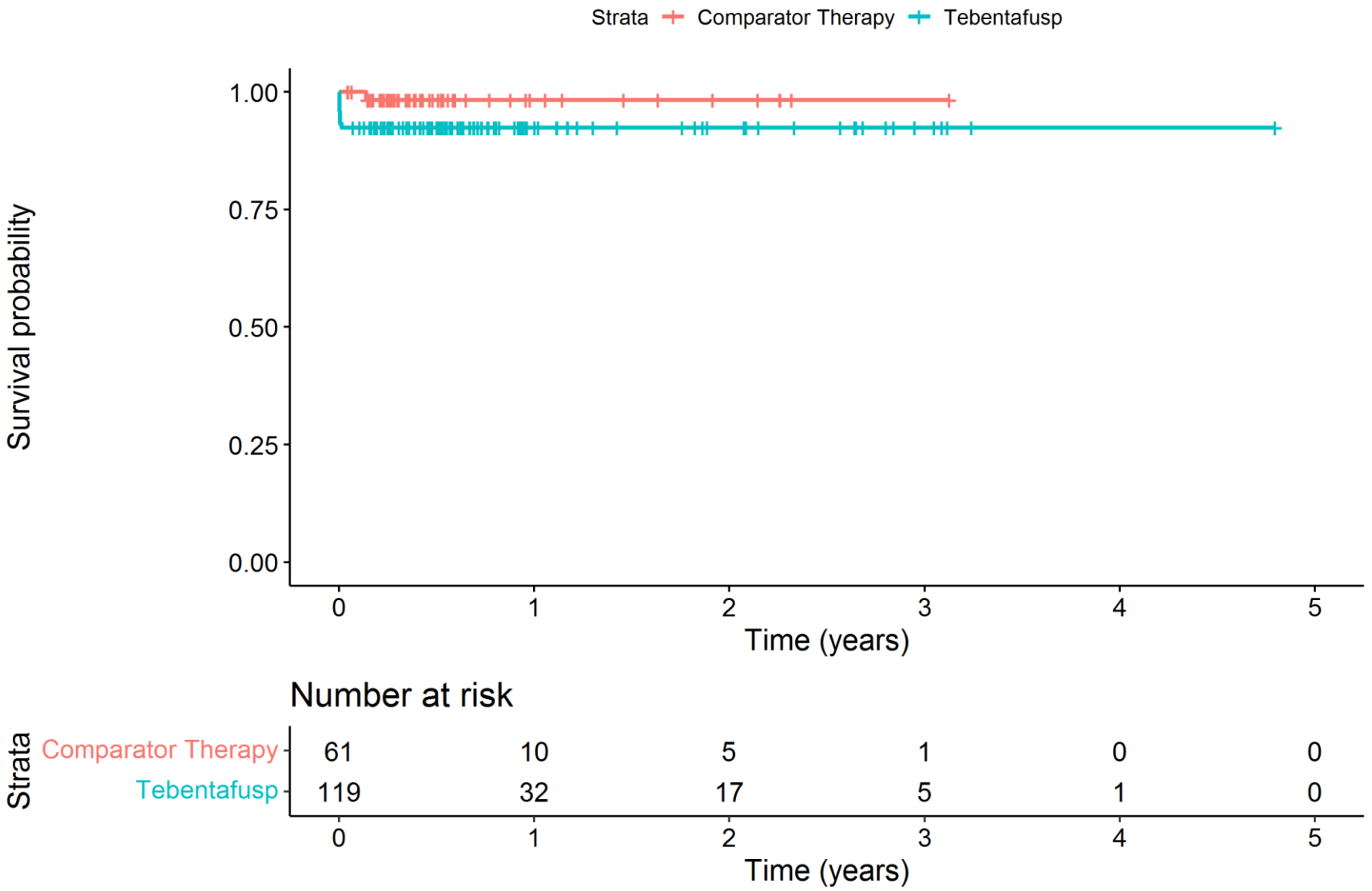
61.185 Erkrankungen der Geschlechtsorgane und der Brustdruese- Weiblich



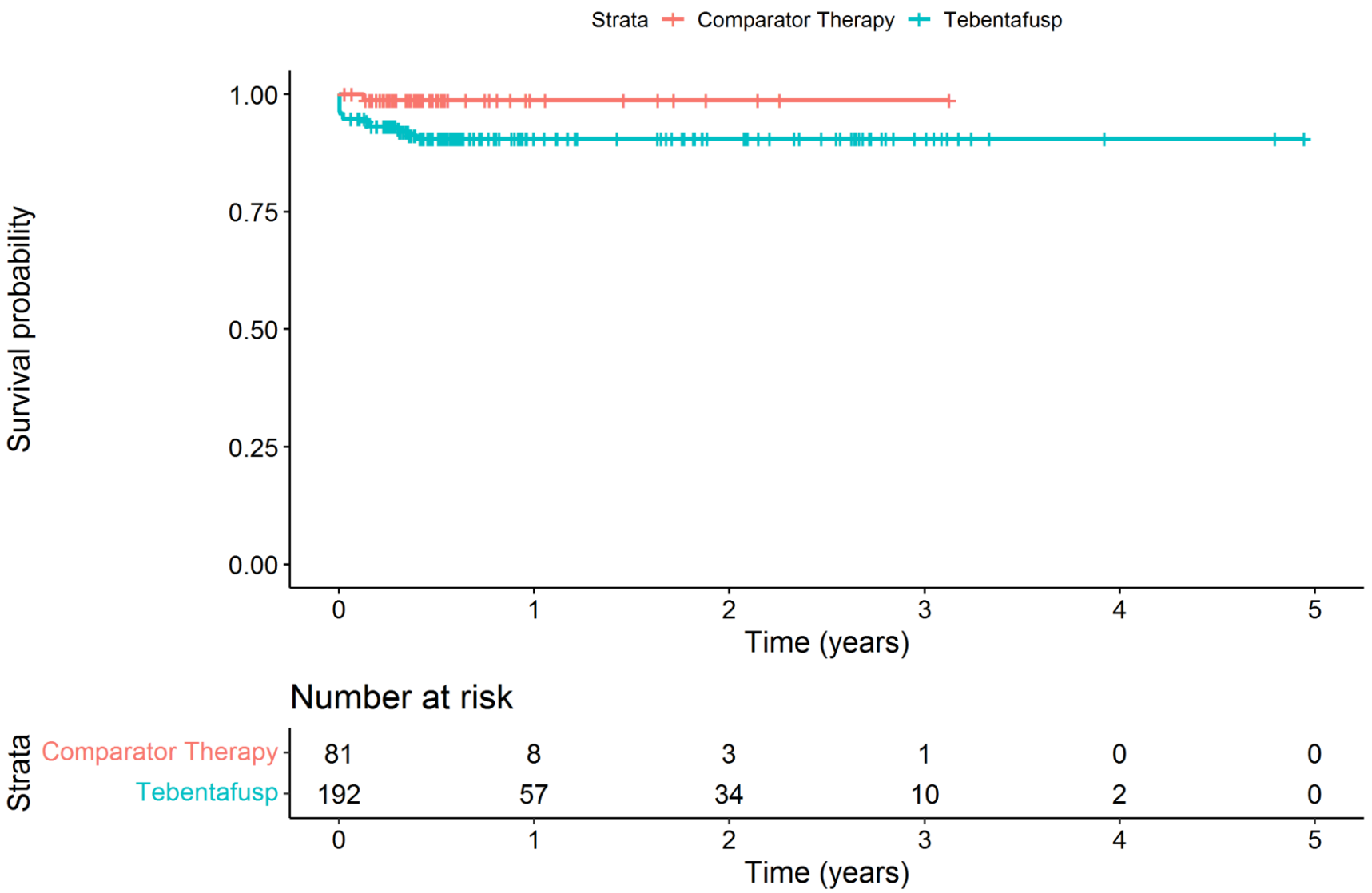
61.186 Erkrankungen der Geschlechtsorgane und der Brustdruese- <65



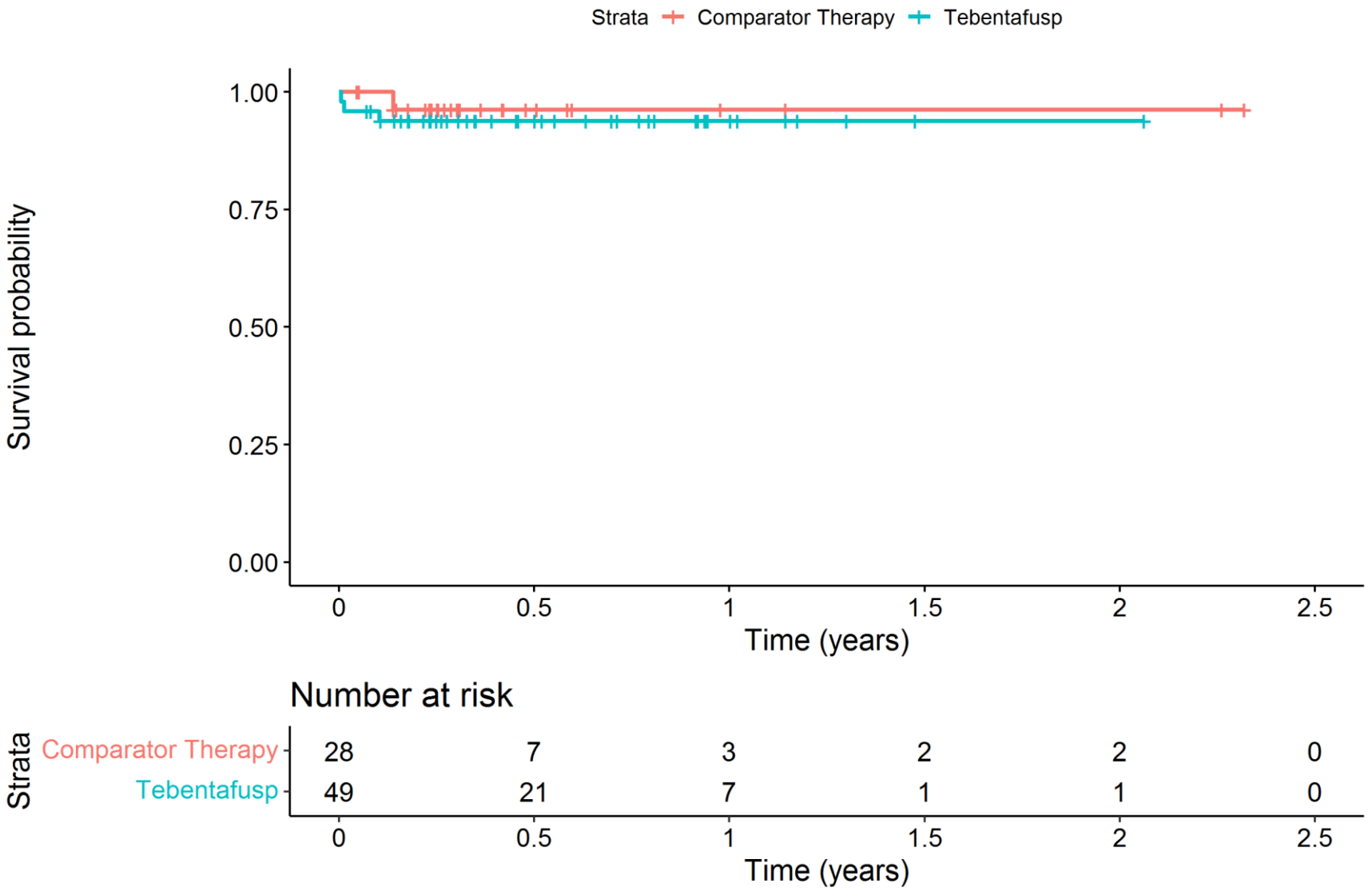
61.187 Erkrankungen der Geschlechtsorgane und der Brustdruese- ≥65



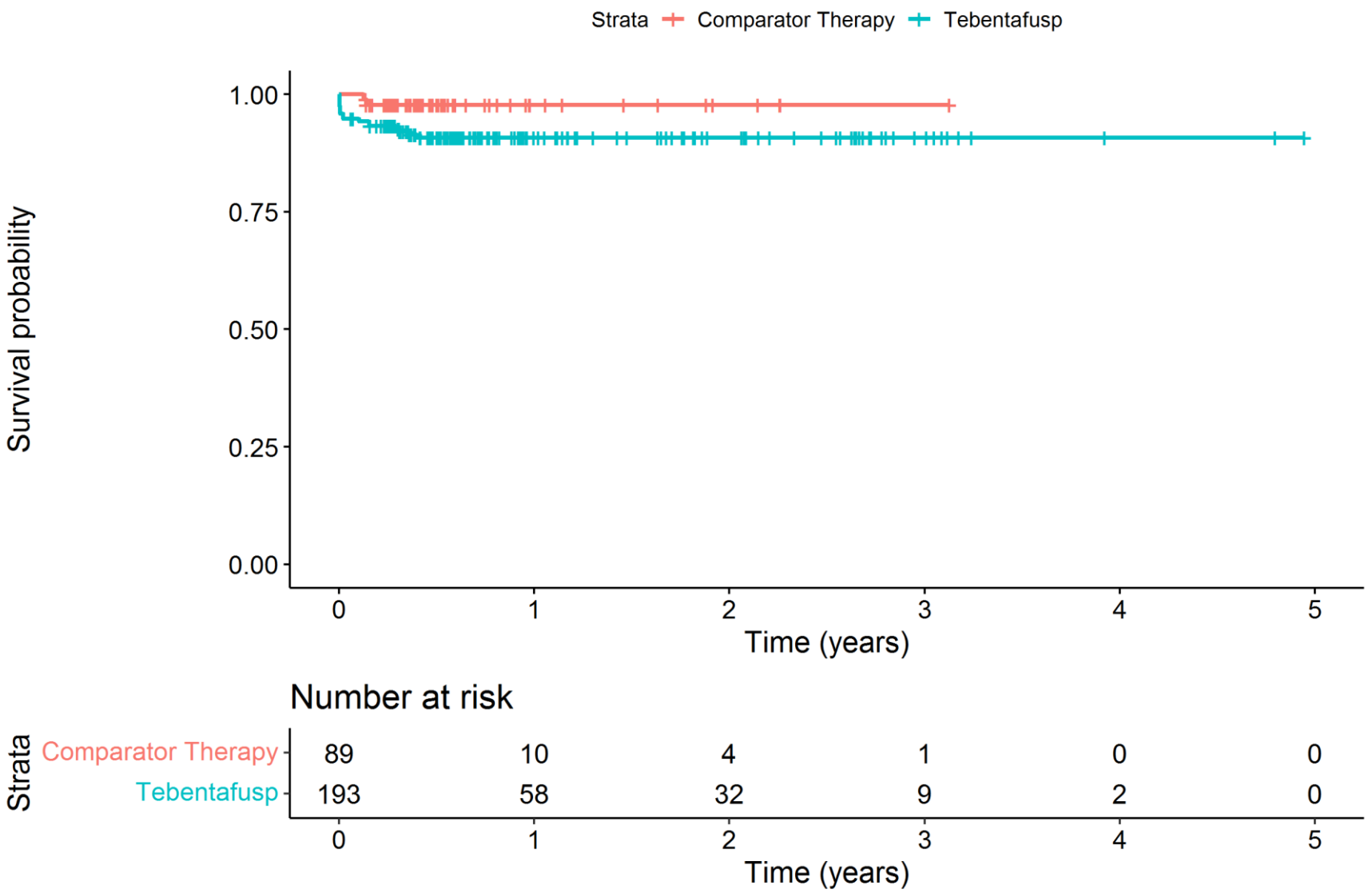
61.188 Erkrankungen der Geschlechtsorgane und der Brustdruese- ECOG 0



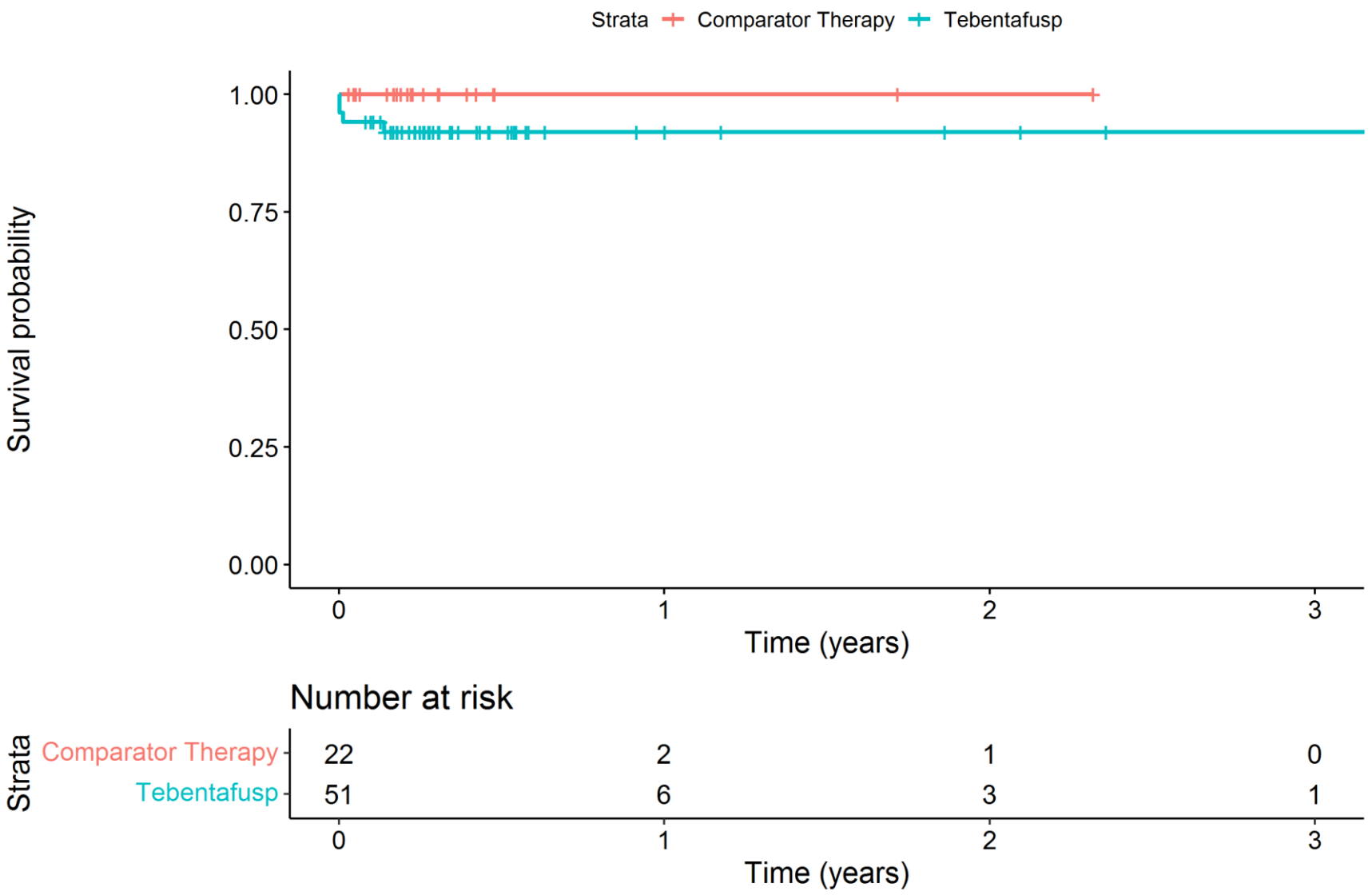
61.189 Erkrankungen der Geschlechtsorgane und der Brustdruese- ECOG 1



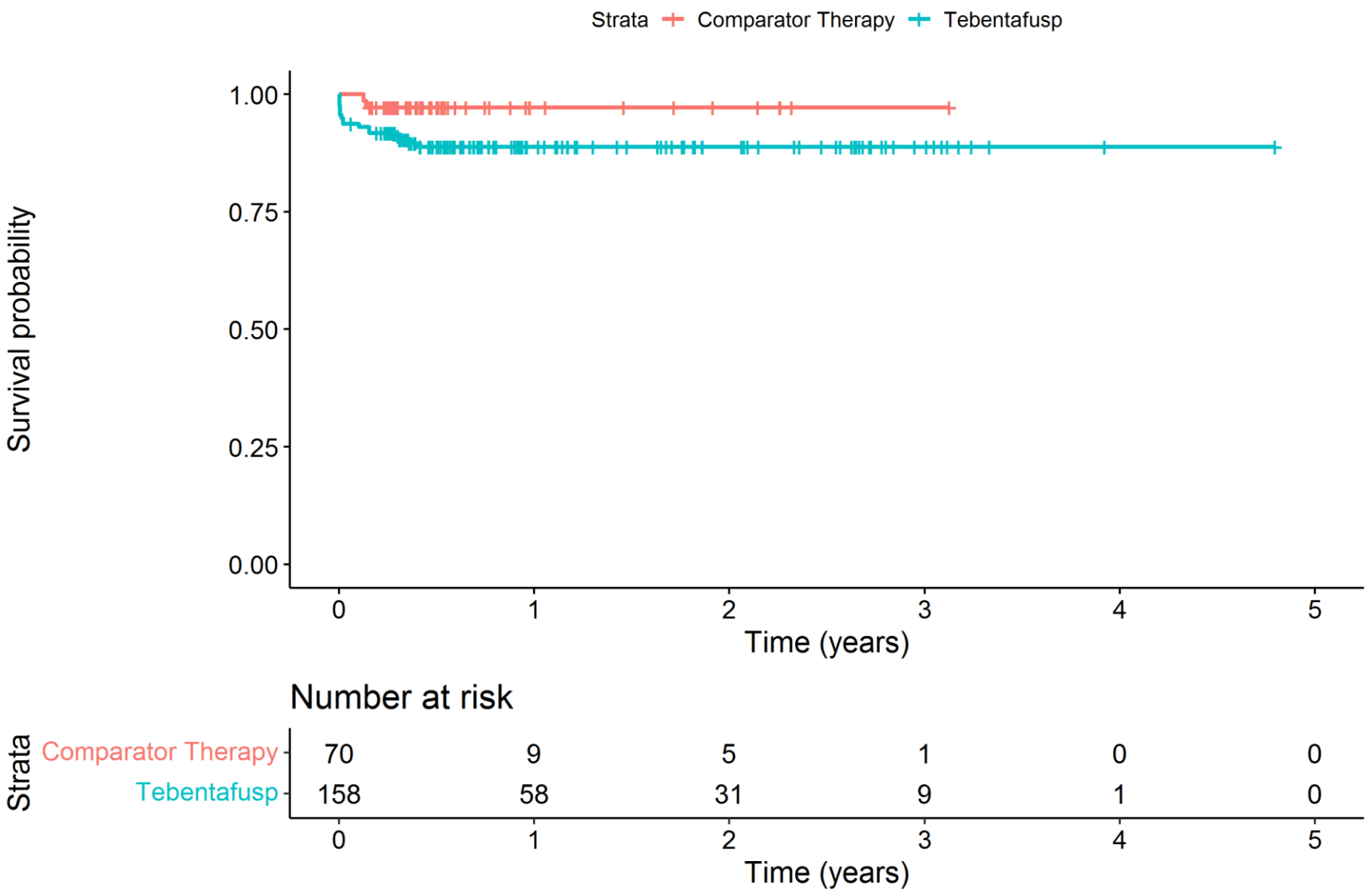
61.190 Erkrankungen der Geschlechtsorgane und der Brustdruese- ALP ≤ ULN



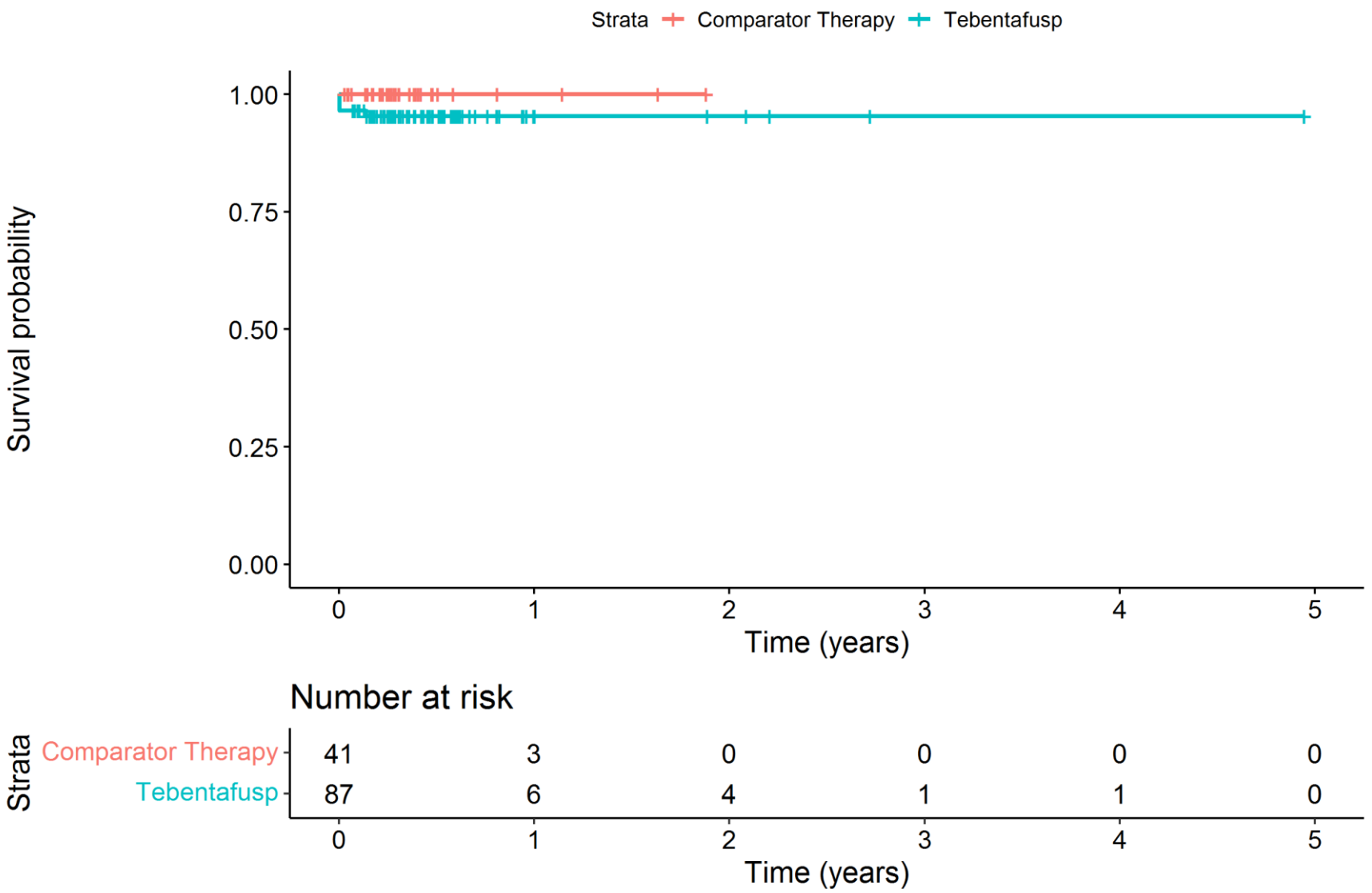
61.191 Erkrankungen der Geschlechtsorgane und der Brustdruese- ALP > ULN



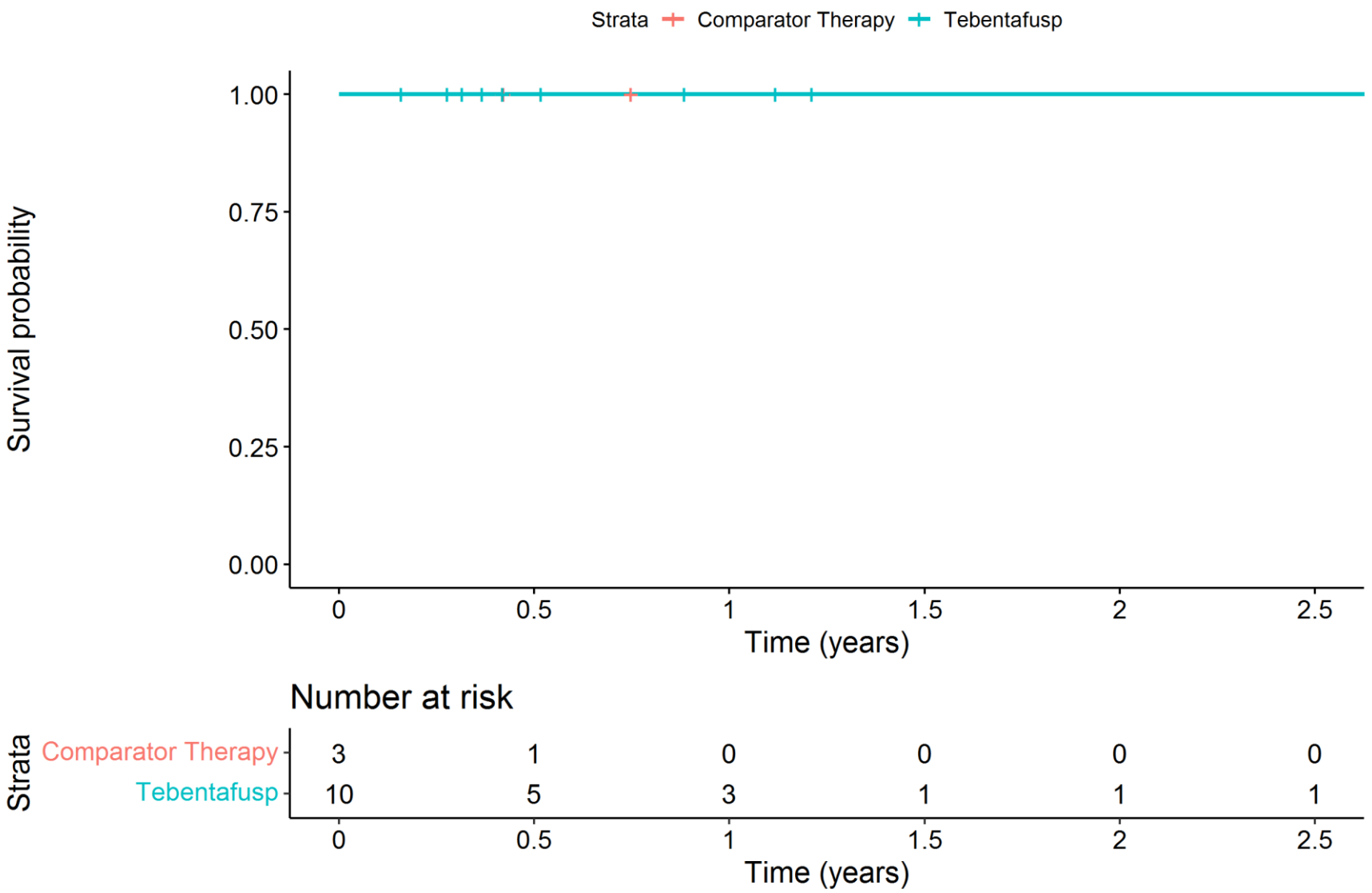
61.192 Erkrankungen der Geschlechtsorgane und der Brustdruese- LDH =< ULN



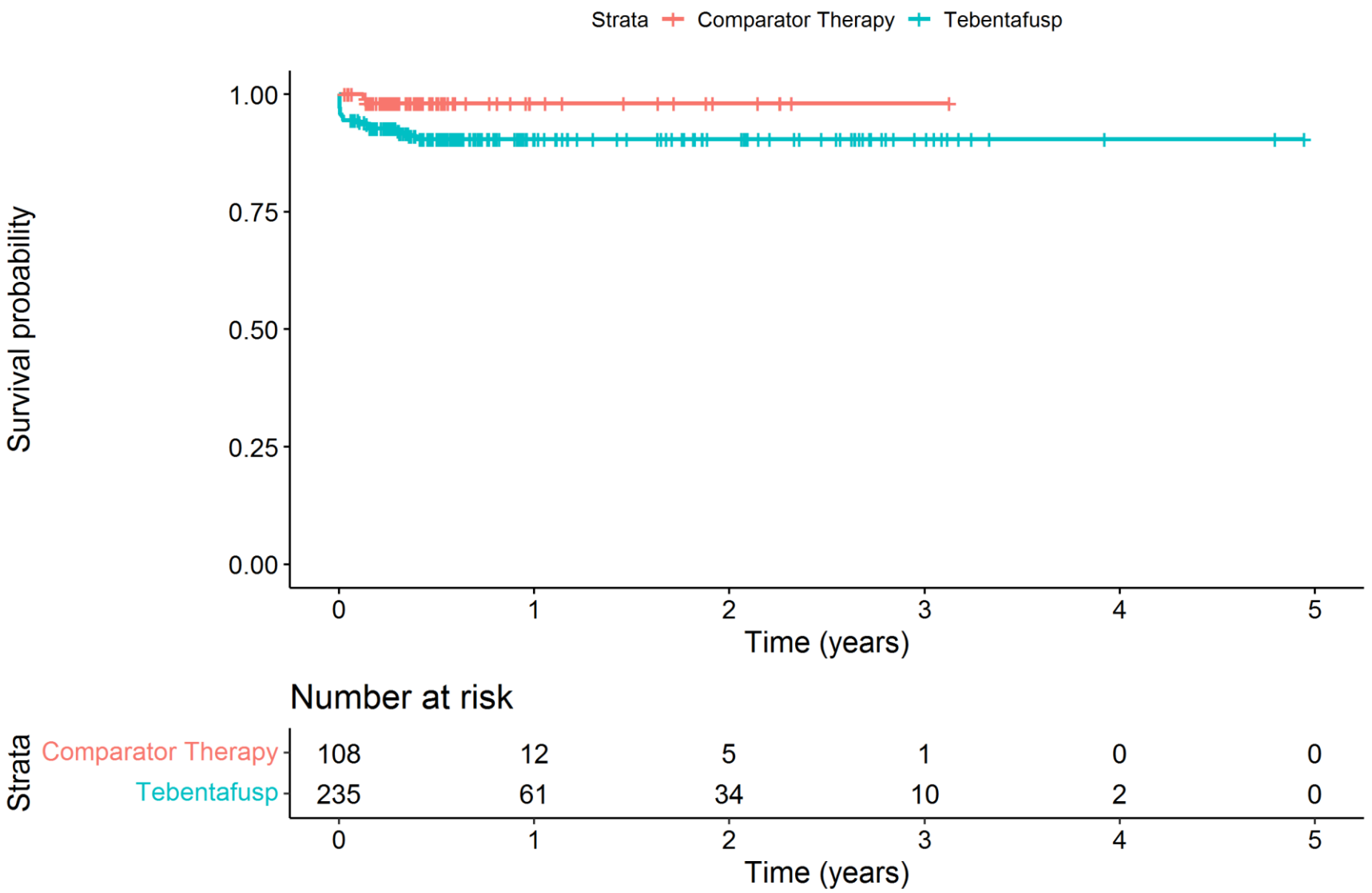
61.193 Erkrankungen der Geschlechtsorgane und der Brustdruese- LDH > ULN



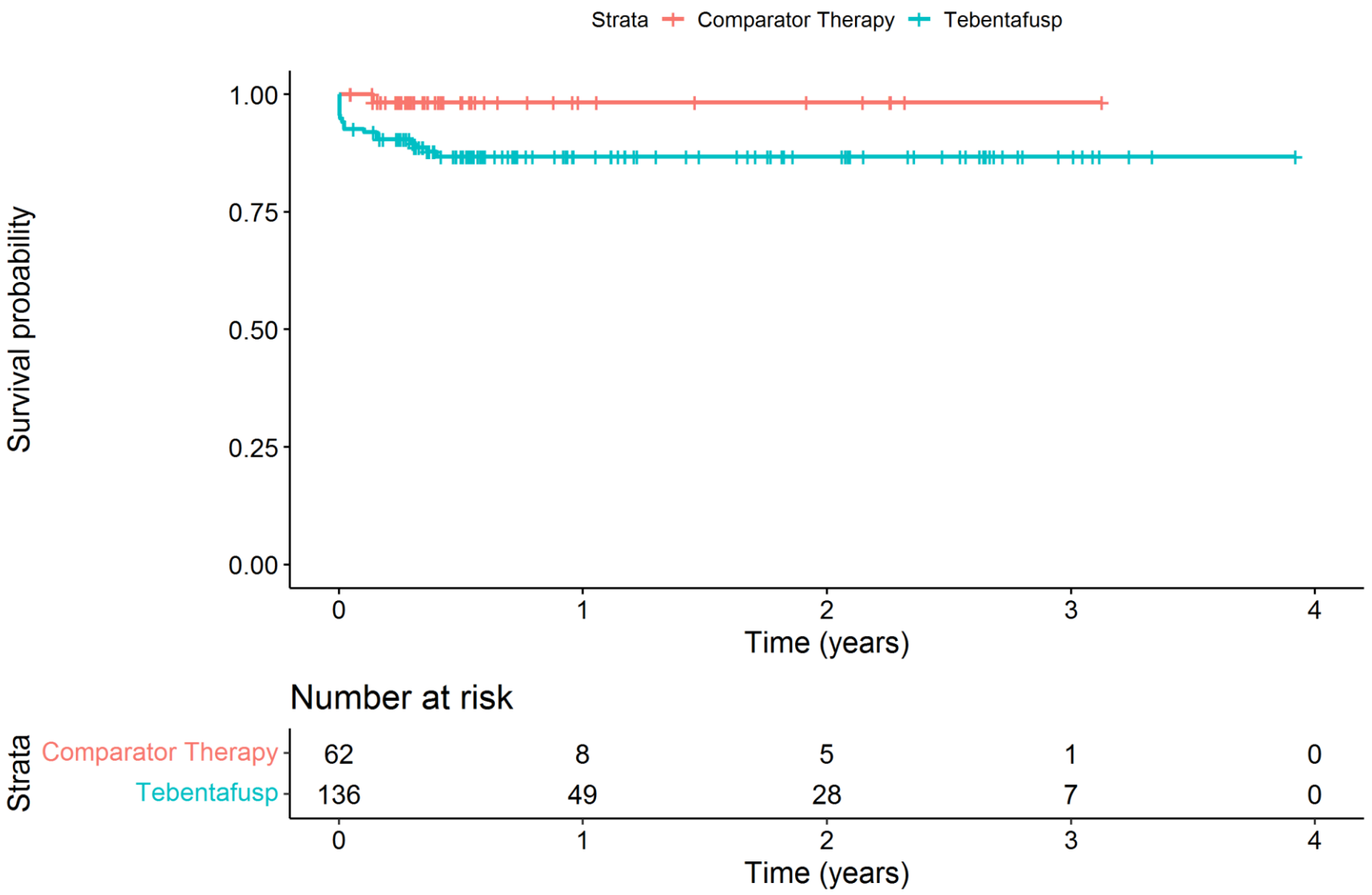
61.194 Erkrankungen der Geschlechtsorgane und der Brustdruese- Vorherige Therapie adjuvant/neoadjuvant



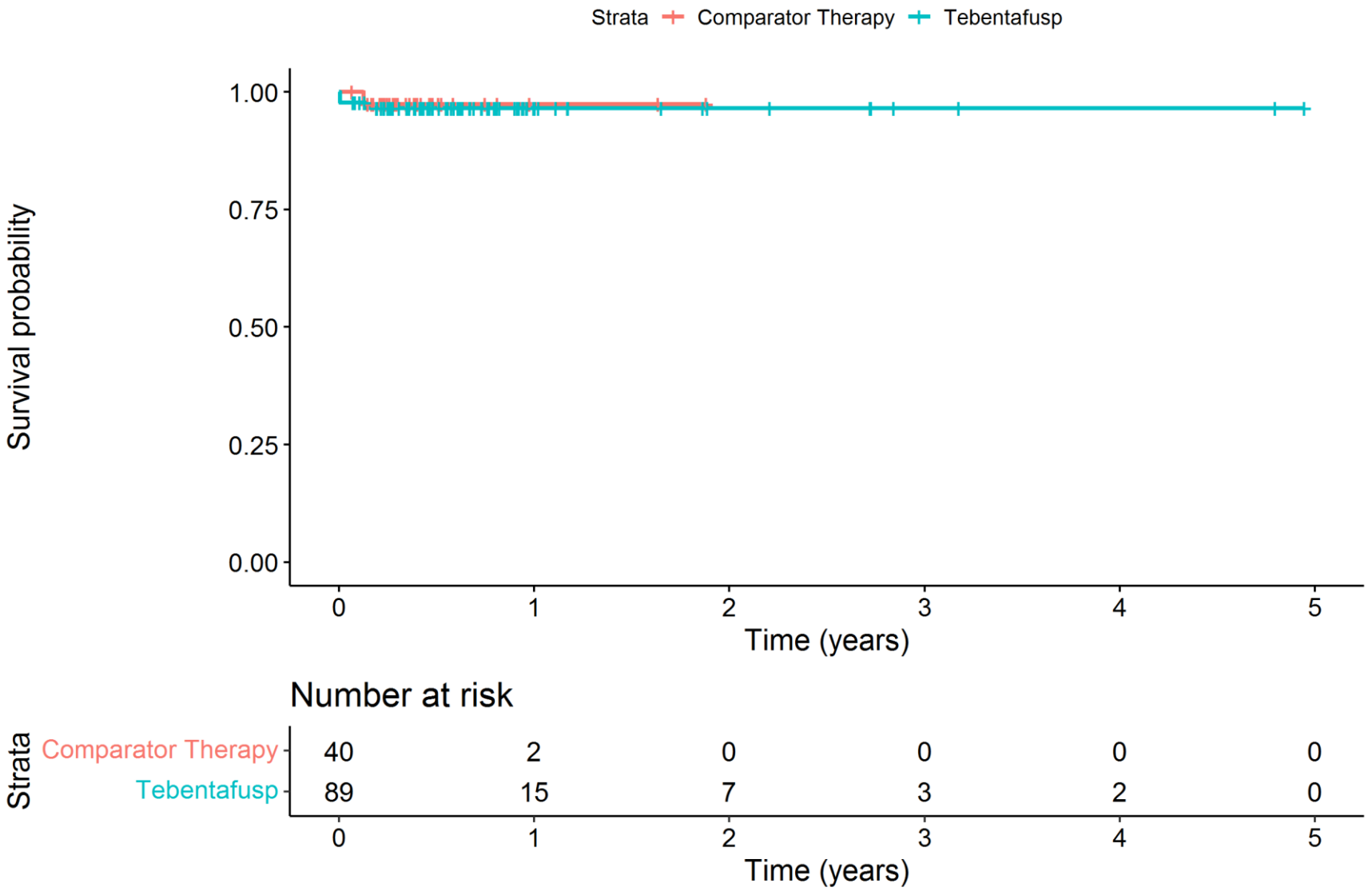
61.195 Erkrankungen der Geschlechtsorgane und der Brustdruese- Keine Vorherige Therapie adjuvant/neoadjuvant



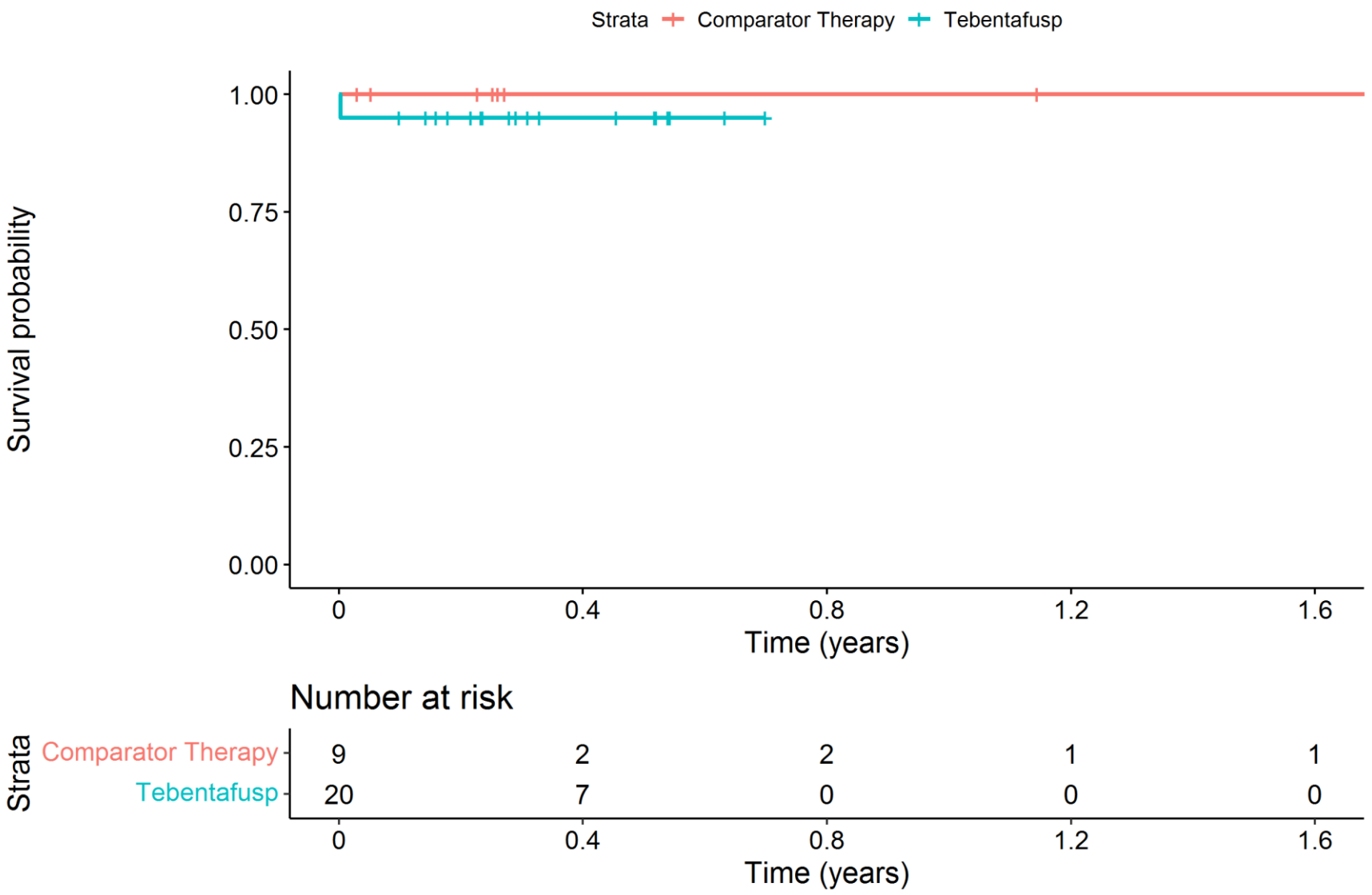
61.196 Erkrankungen der Geschlechtsorgane und der Brustdruese- Läsion ≤ 3cm



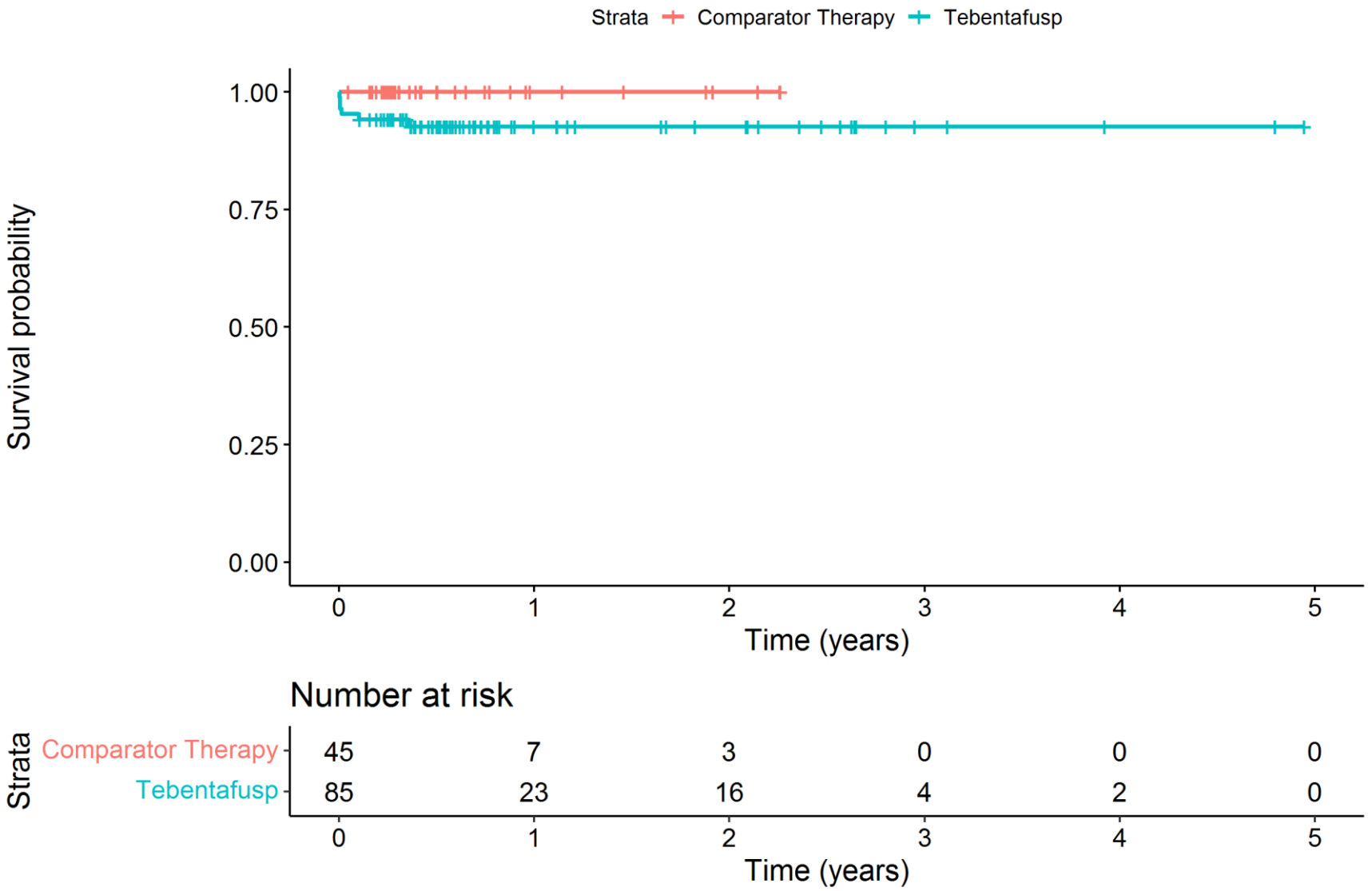
61.197 Erkrankungen der Geschlechtsorgane und der Brustdruese- Läsion 3,1-8,0 cm



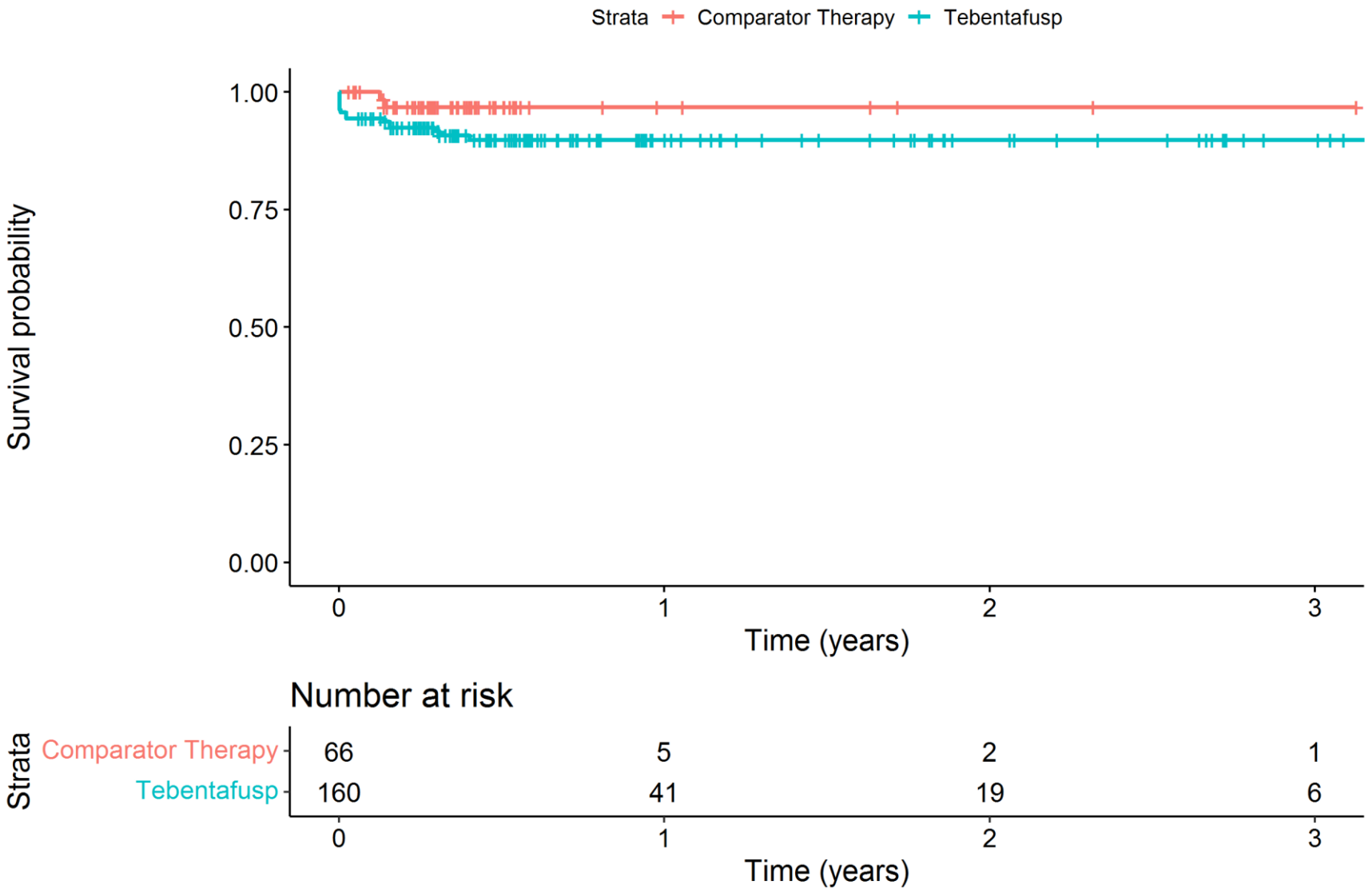
61.198 Erkrankungen der Geschlechtsorgane und der Brustdruese- Läsion ≥8,1 cm



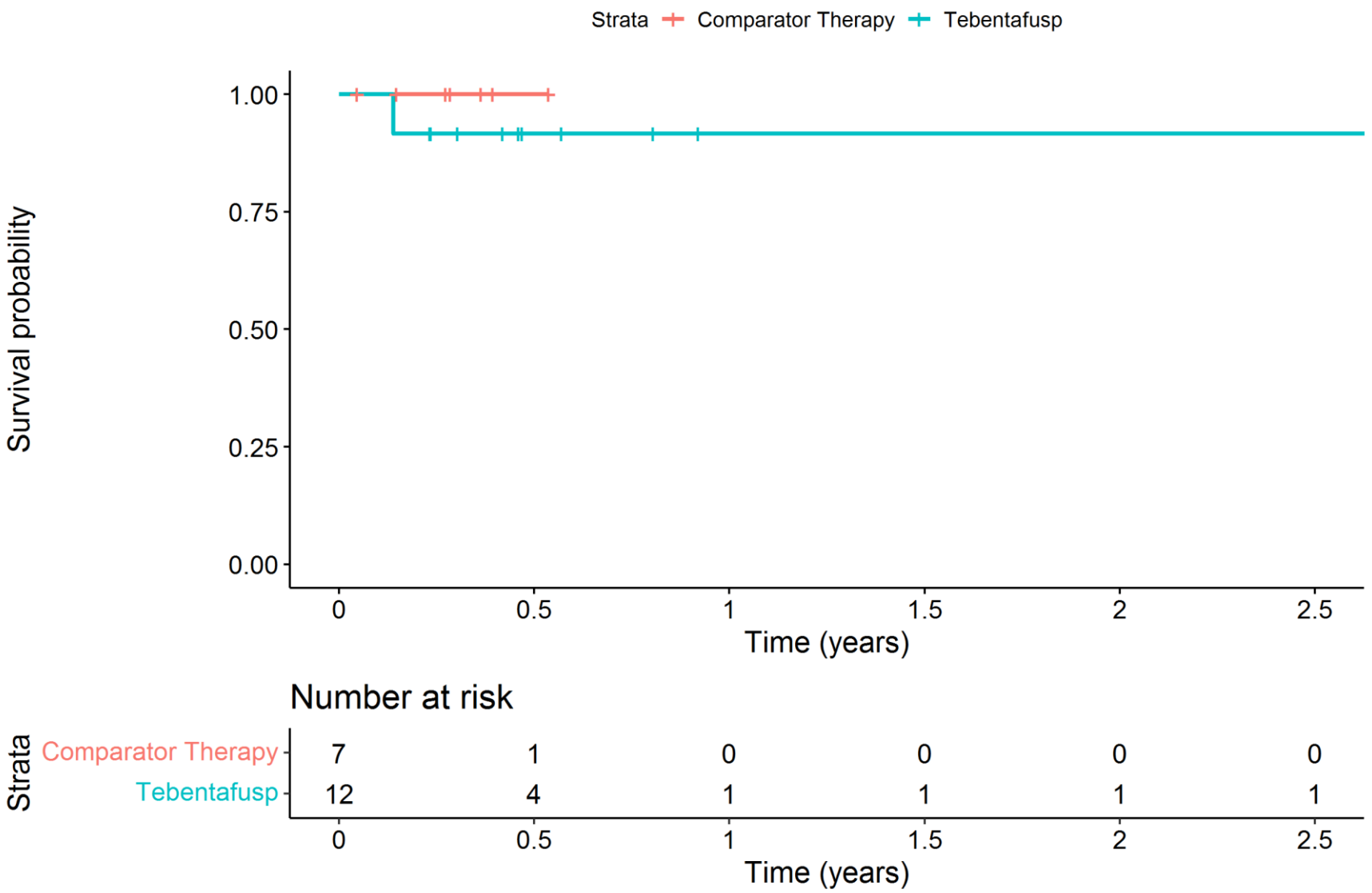
61.199 Erkrankungen der Geschlechtsorgane und der Brustdruese- Nordamerika



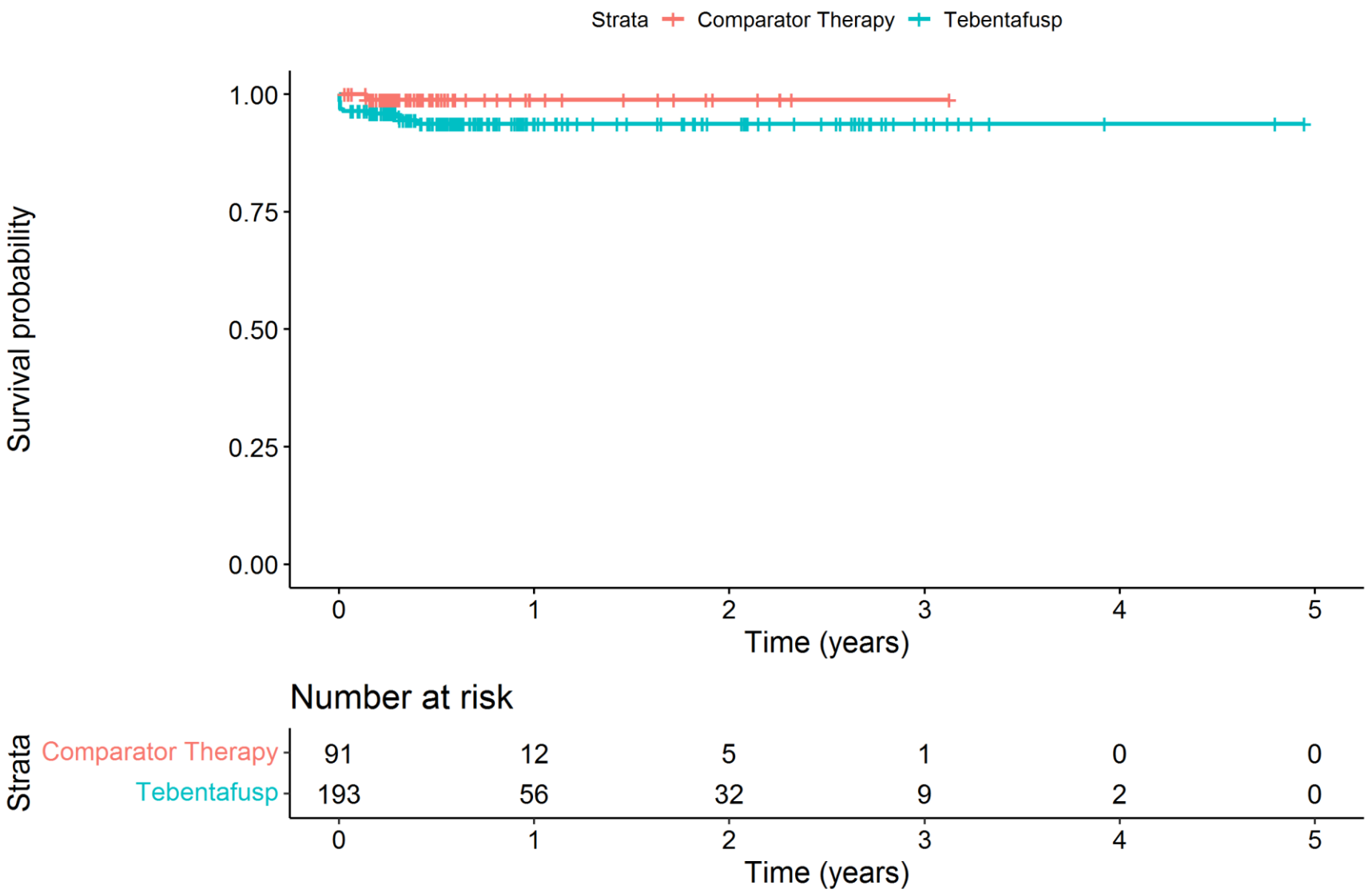
61.200 Erkrankungen der Geschlechtsorgane und der Brustdruese- Nicht-Nordamerika



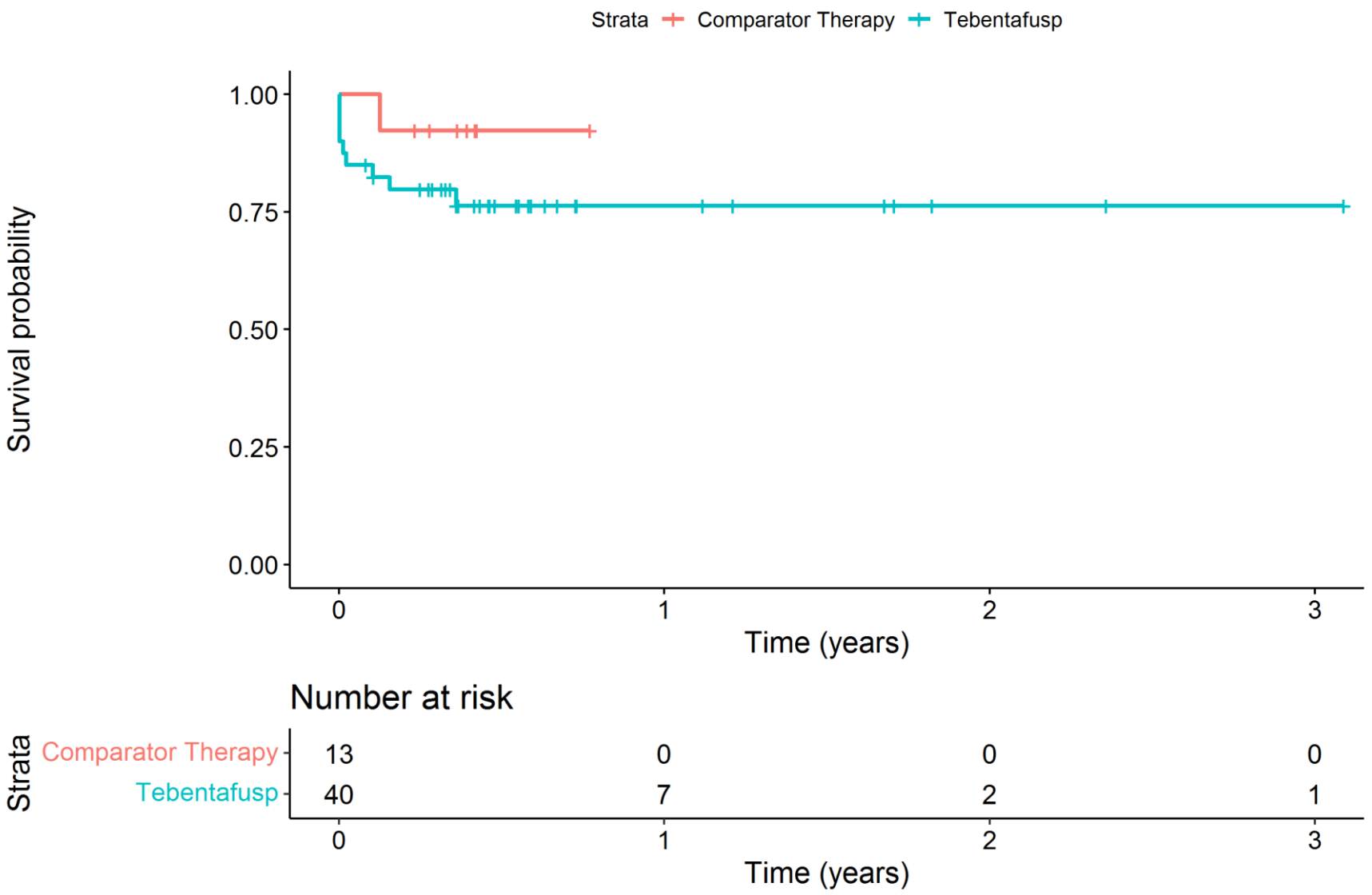
61.201 Erkrankungen der Geschlechtsorgane und der Brustdruese- Dacarbazin



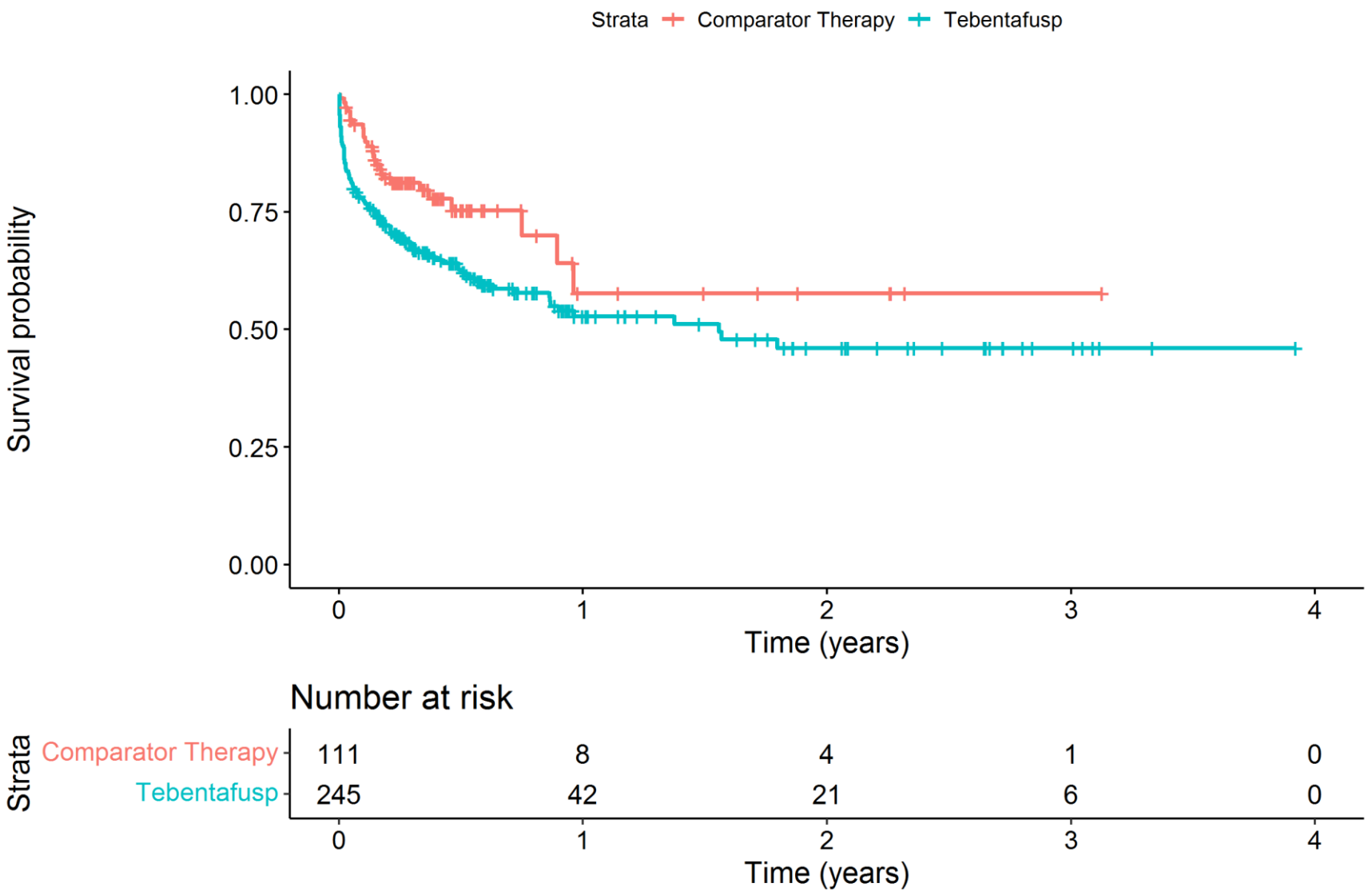
61.202 Erkrankungen der Geschlechtsorgane und der Brustdruese- Pembrolizumab



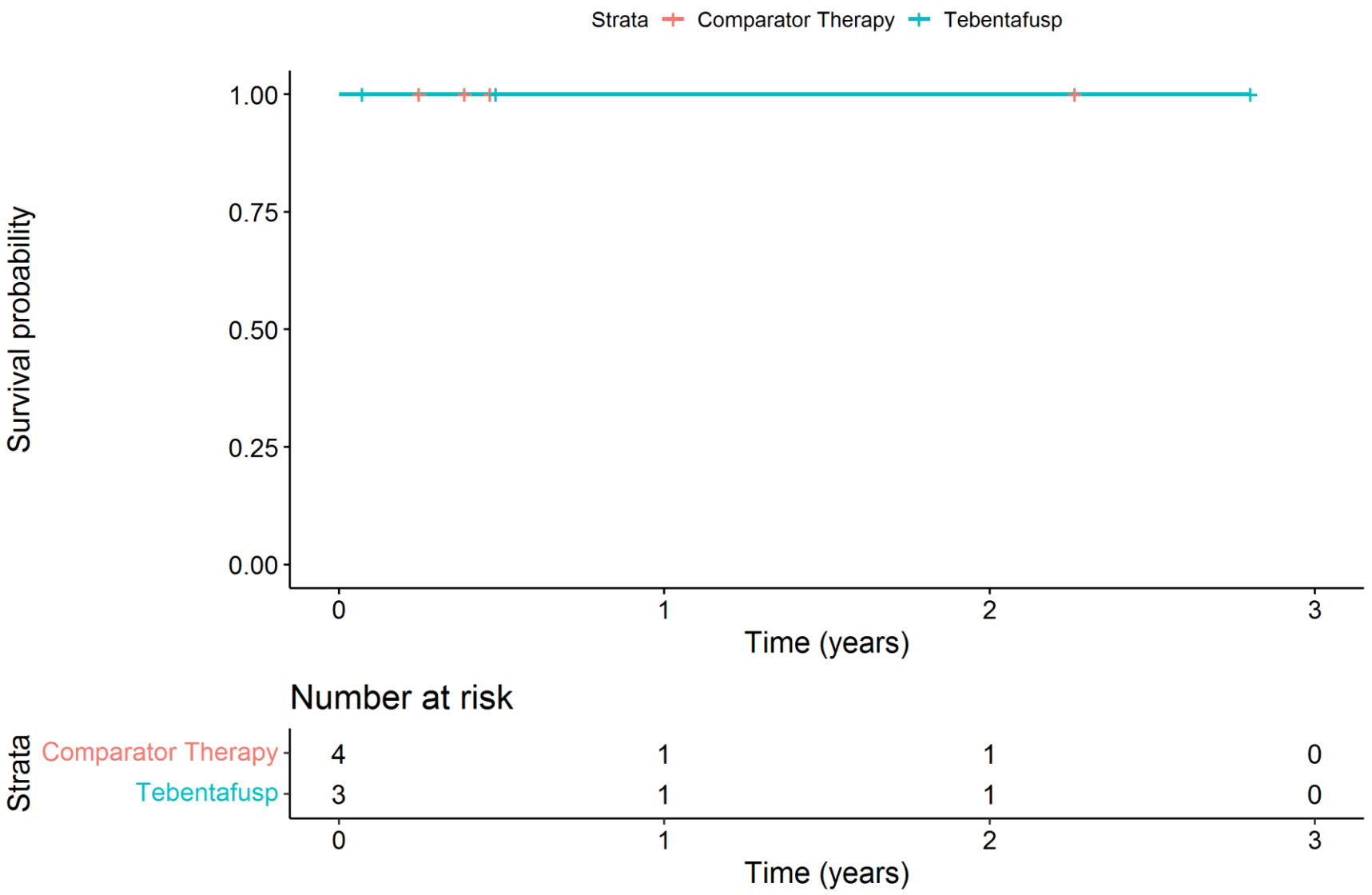
61.203 Erkrankungen der Geschlechtsorgane und der Brustdruese- Ipilimumab



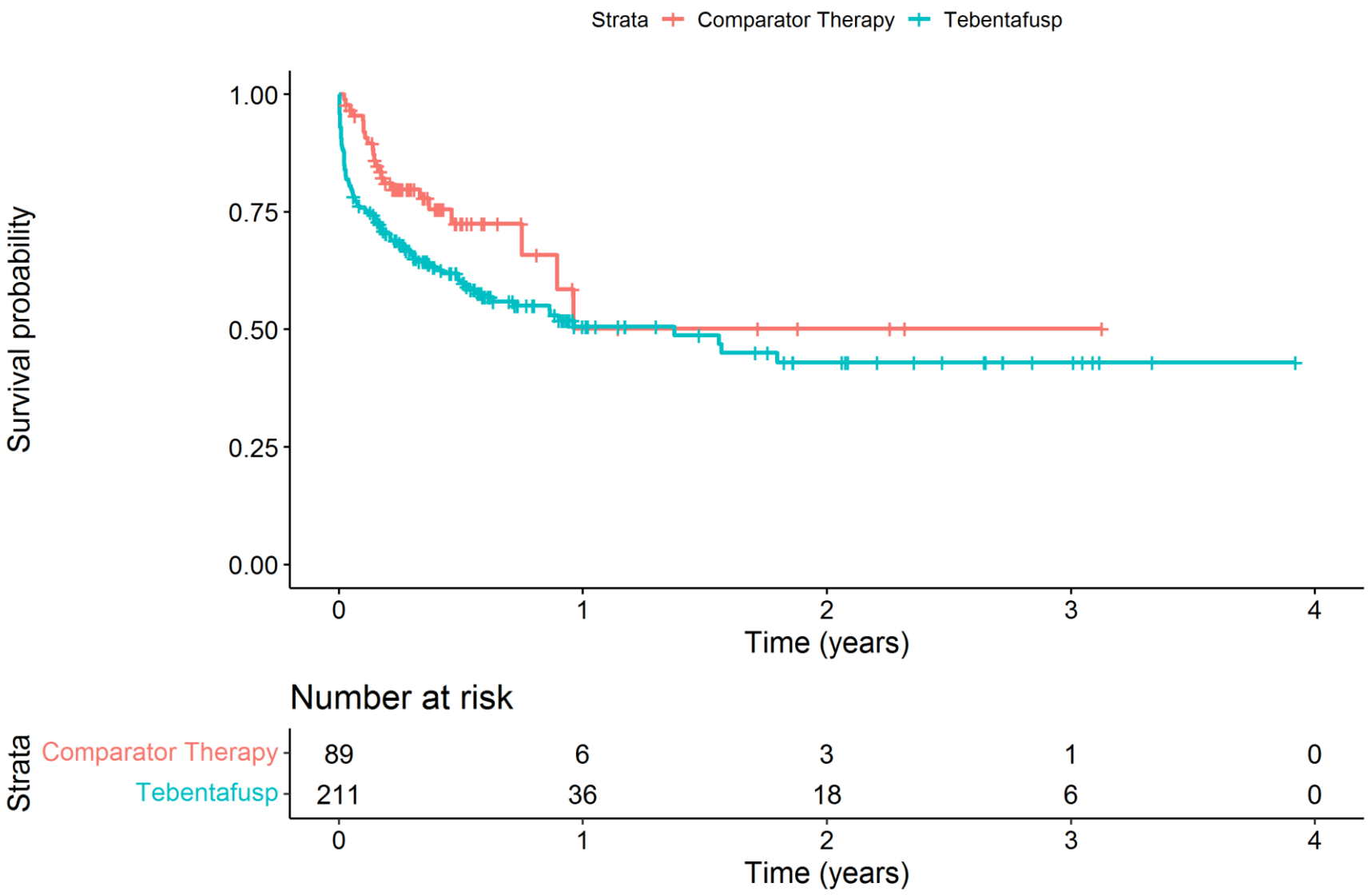
61.204 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Gesamt



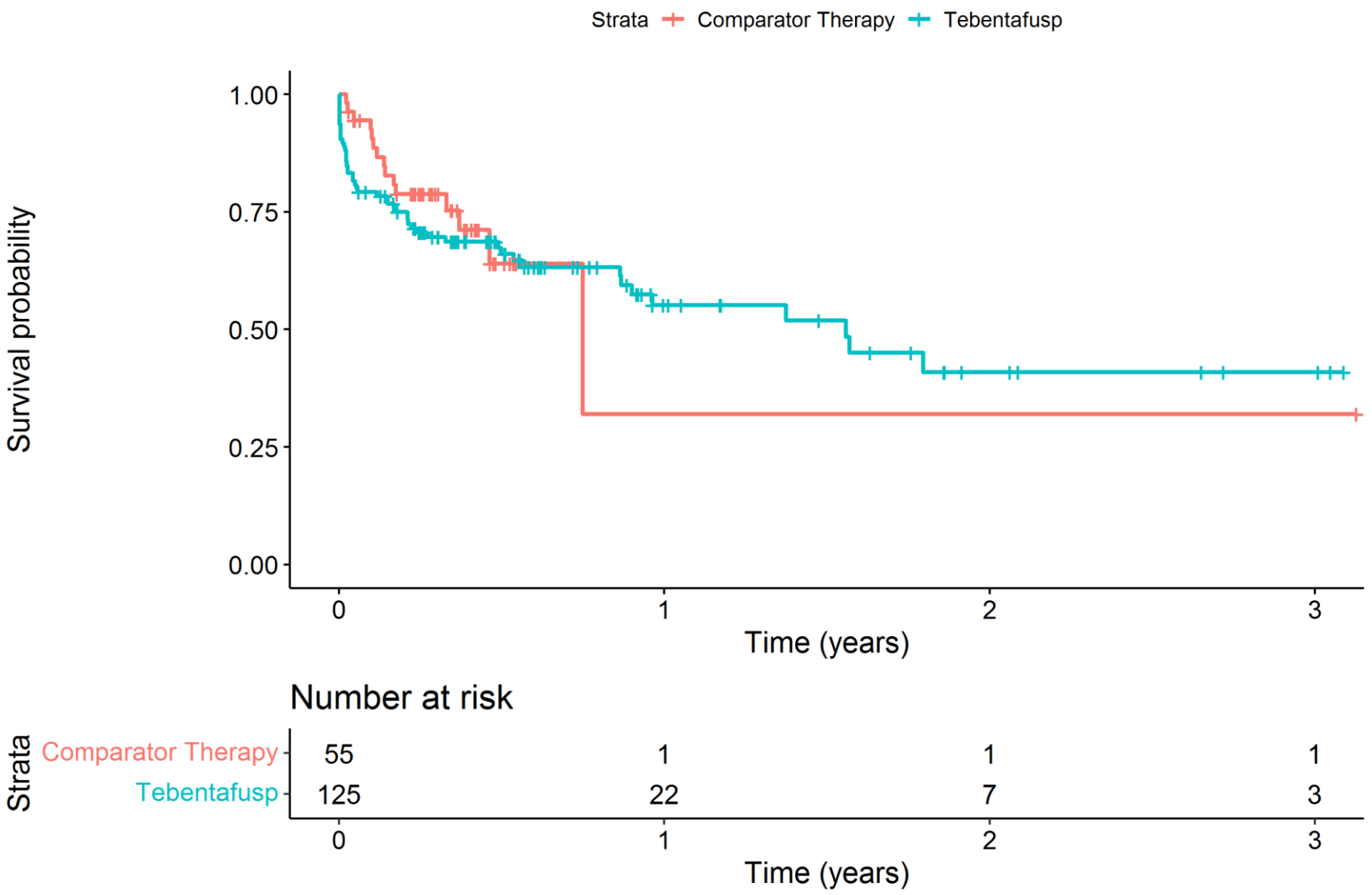
61.205 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Hispanisch



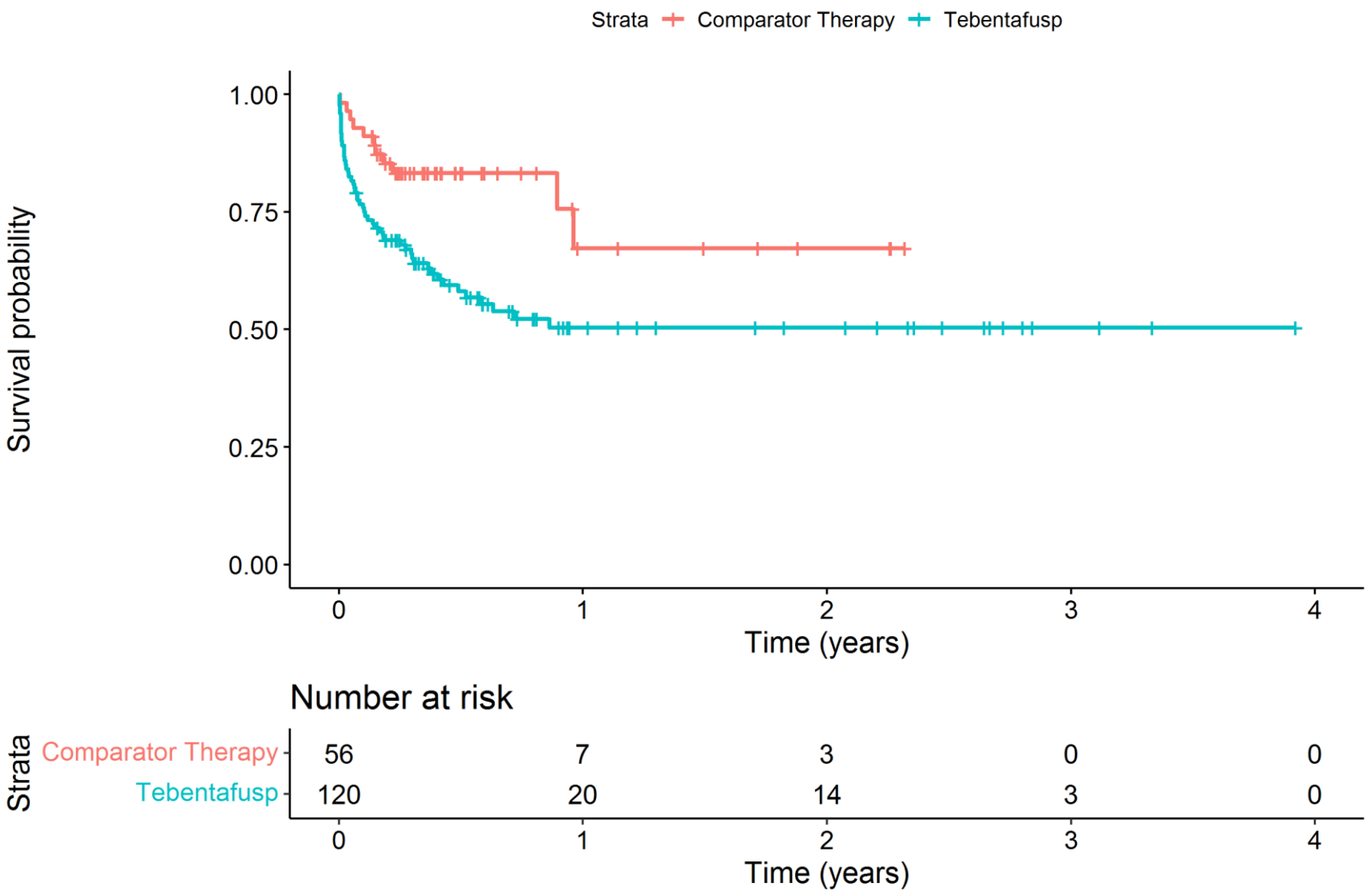
61.206 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nicht-hispanisch



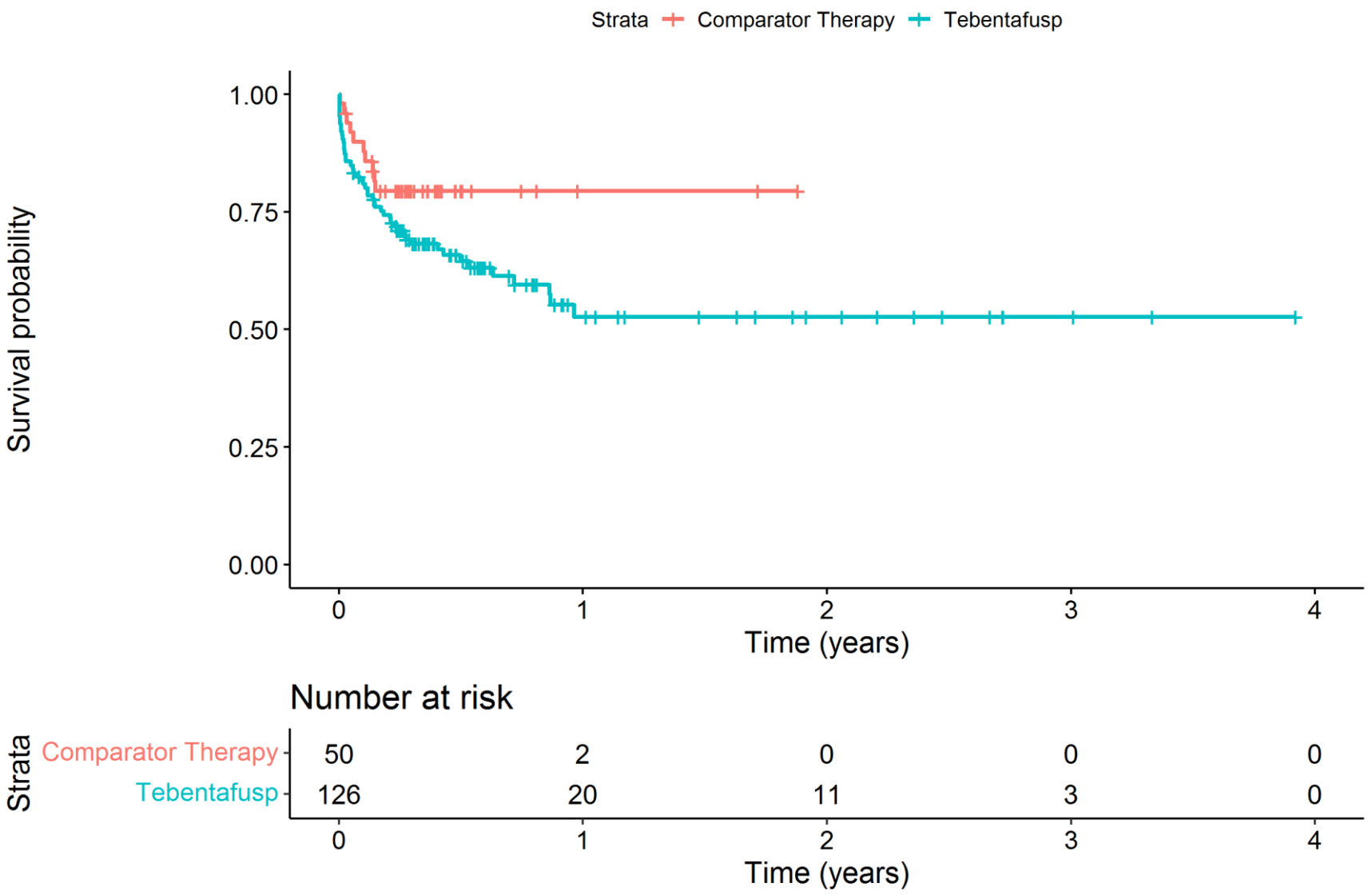
61.207 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Männlich



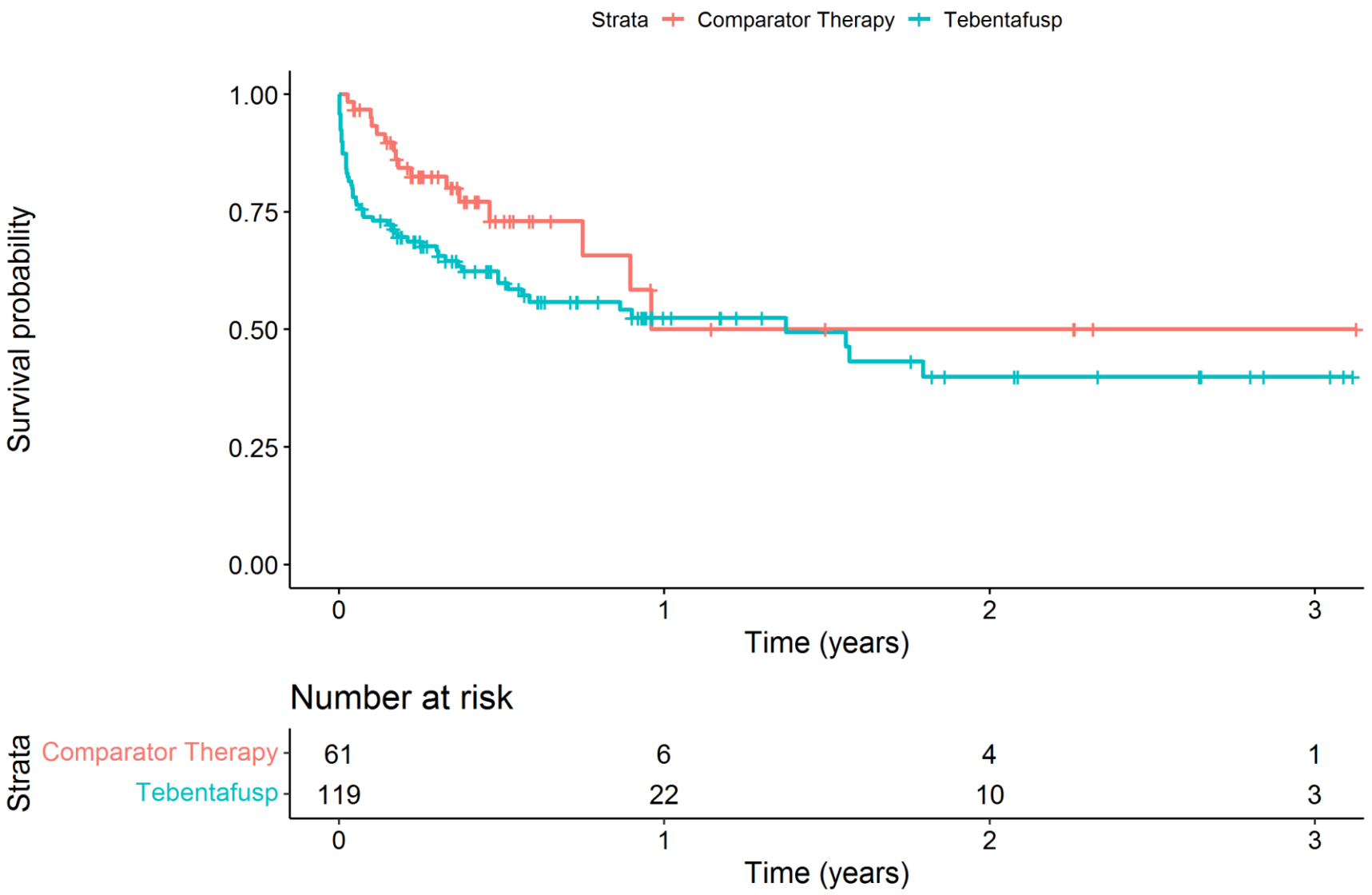
61.208 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Weiblich



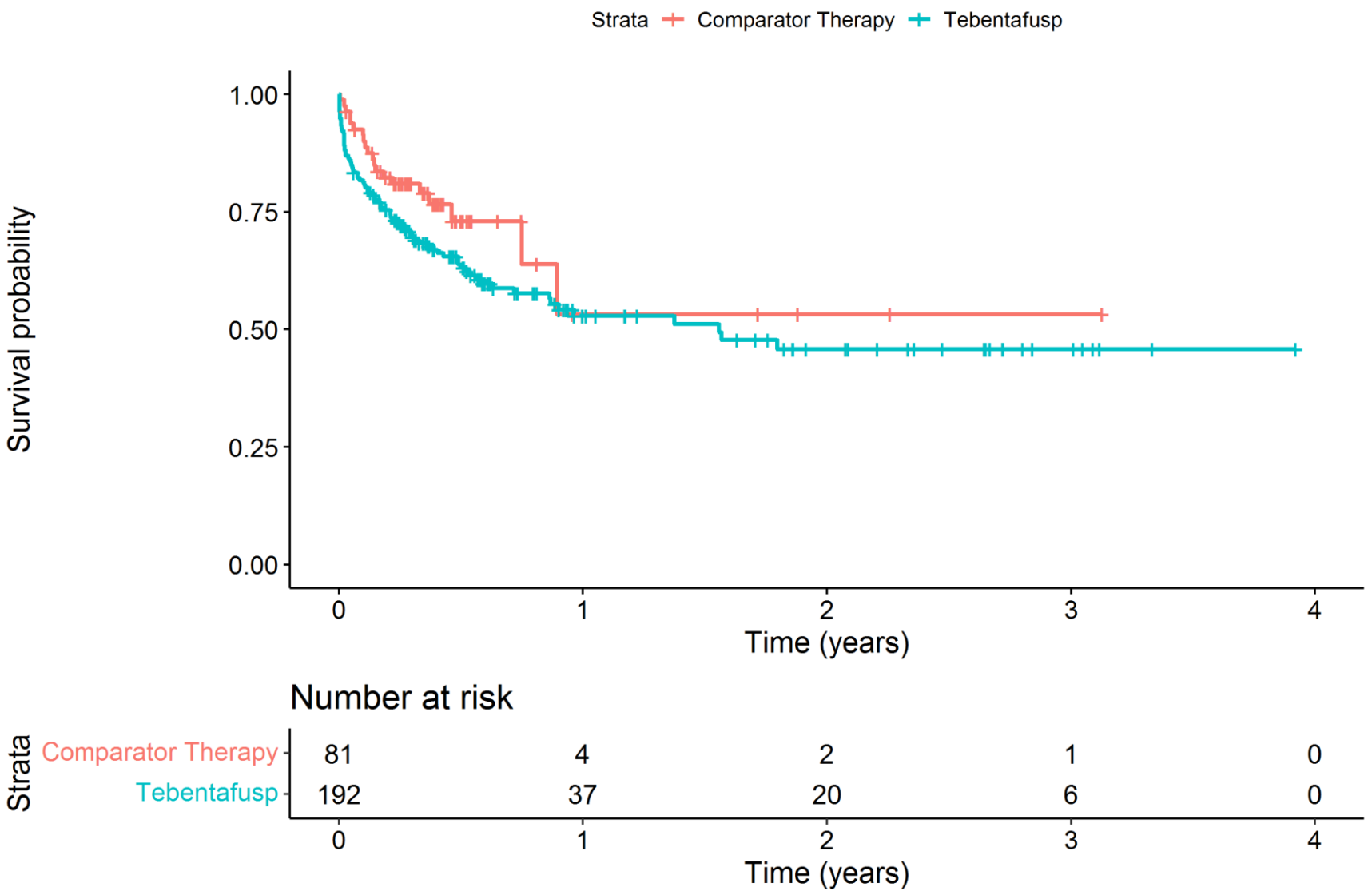
61.209 Erkrankungen der Atemwege, des Brustraums und Mediastinums- <65



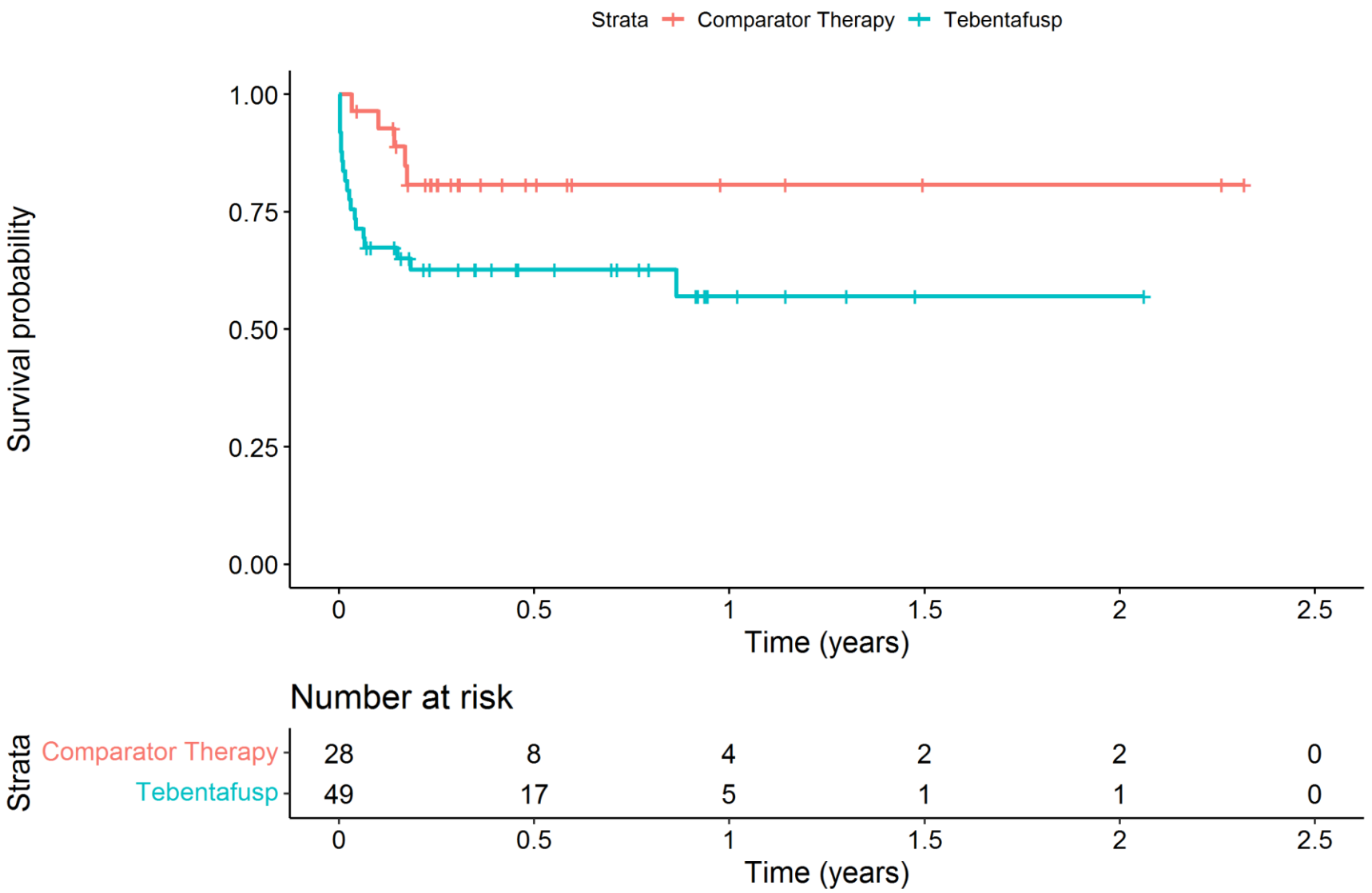
61.210 Erkrankungen der Atemwege, des Brustraums und Mediastinums- ≥65



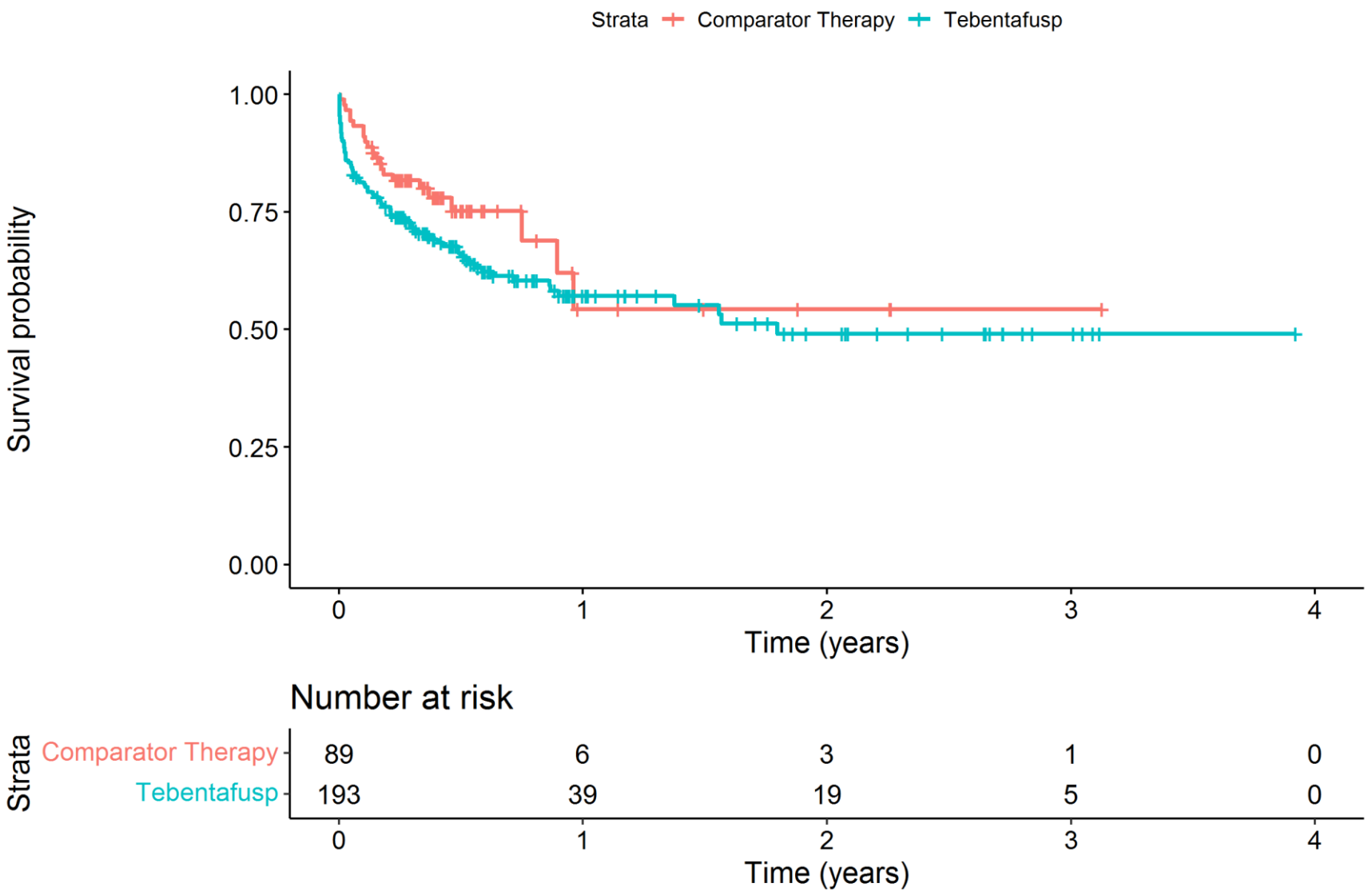
61.211 Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 0



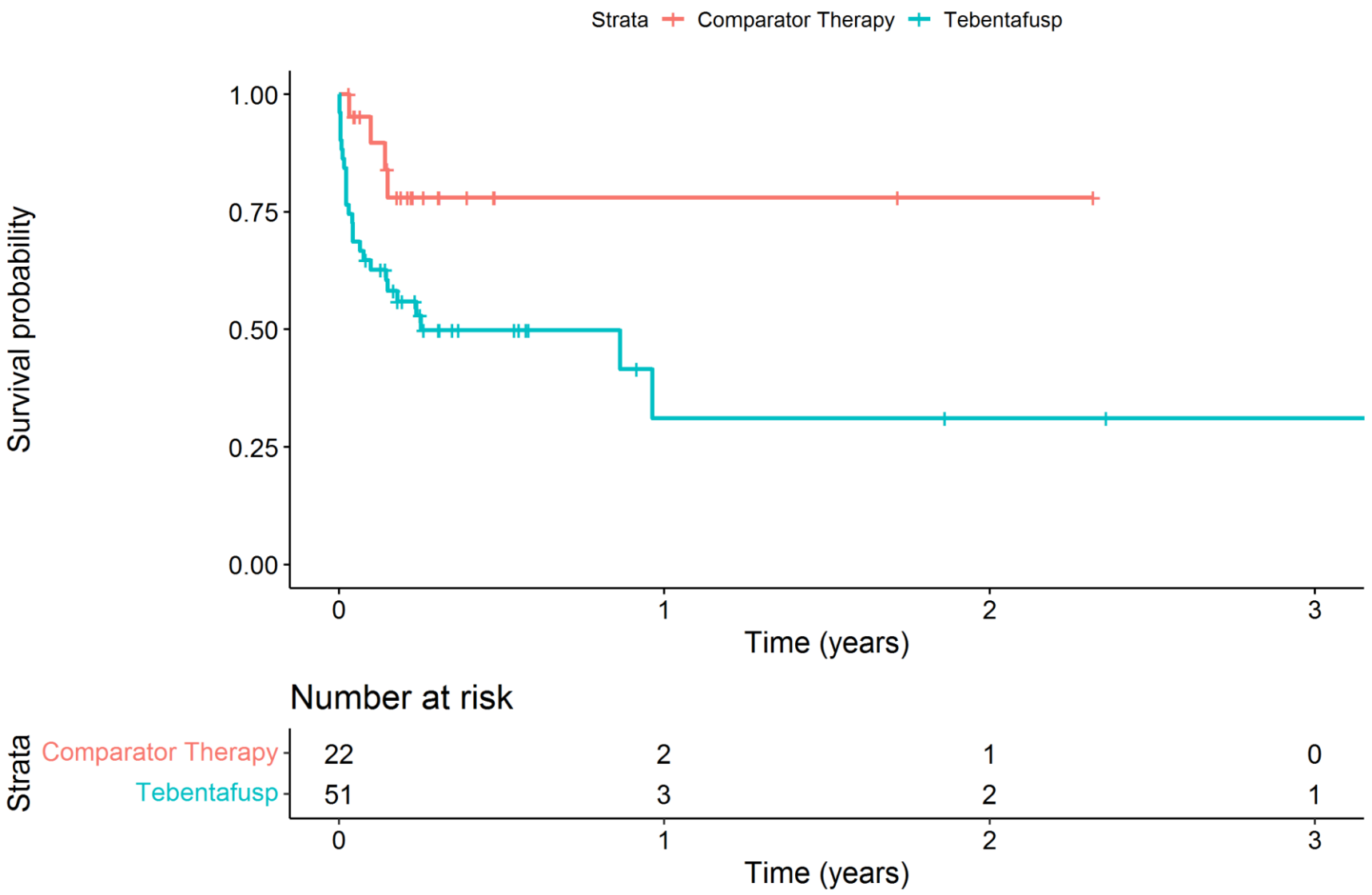
61.212 Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 1



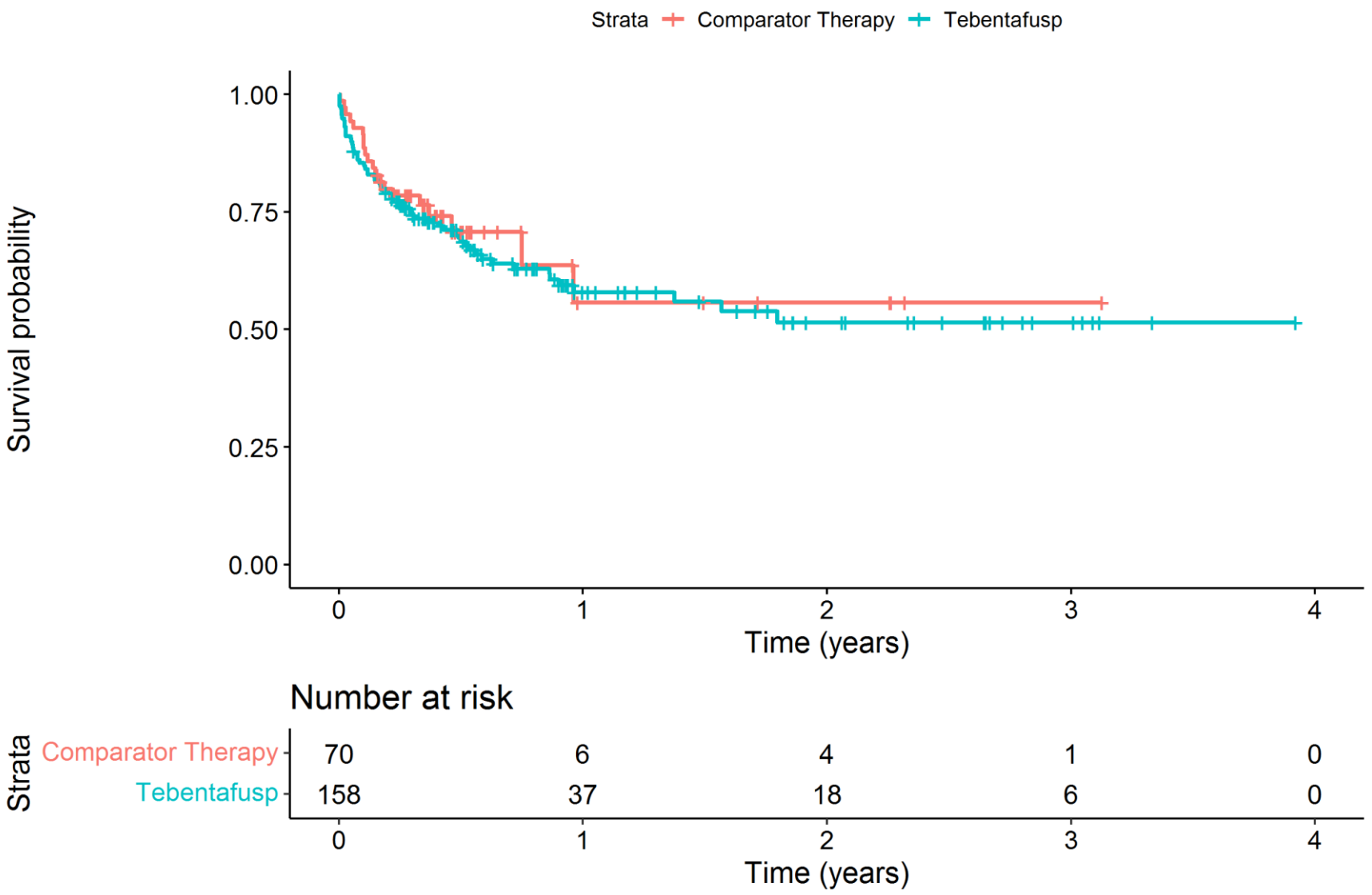
61.213 Erkrankungen der Atemwege, des Brustraums und Mediastinums- ALP ≤ ULN



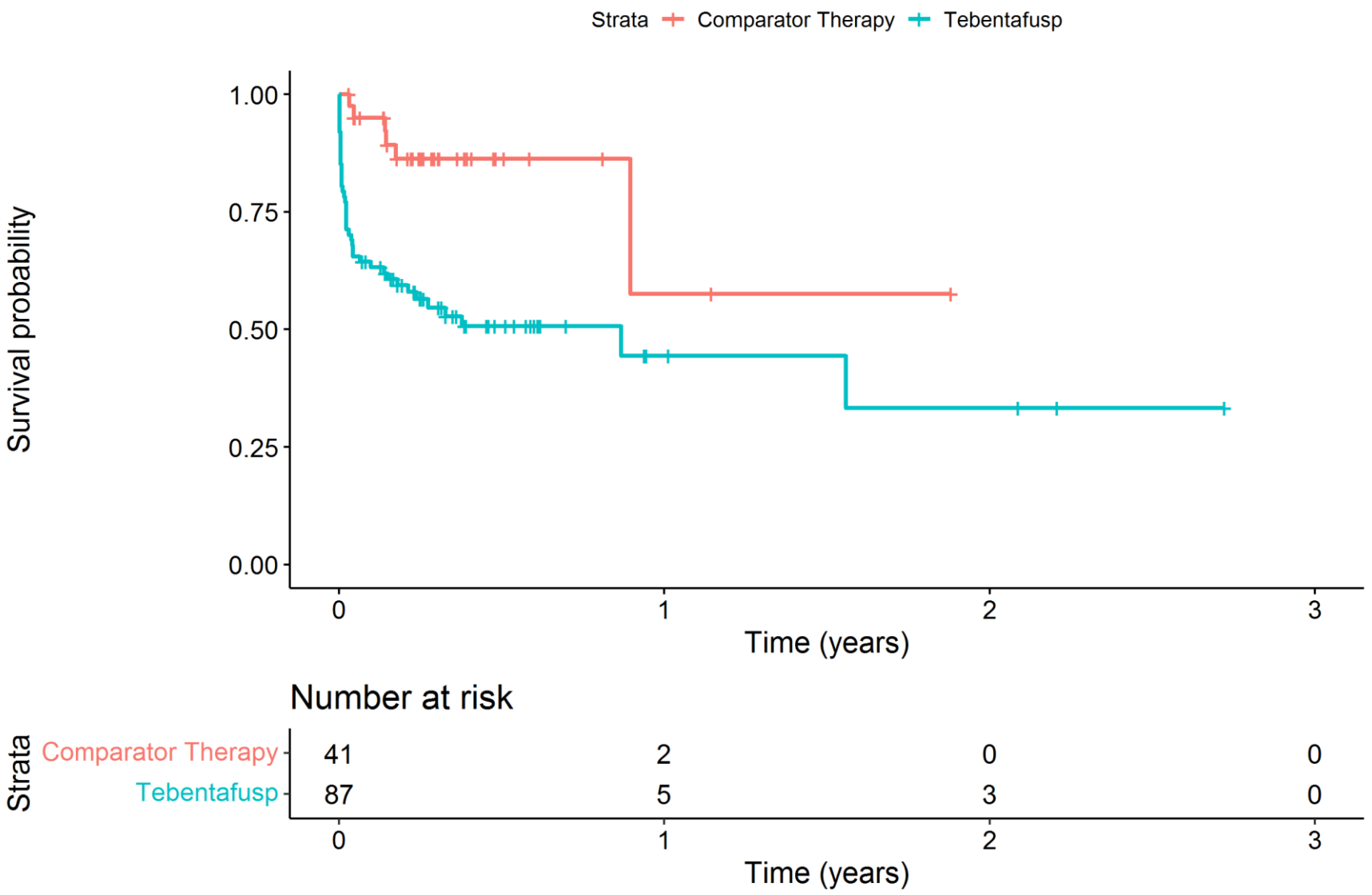
61.214 Erkrankungen der Atemwege, des Brustraums und Mediastinums- ALP > ULN



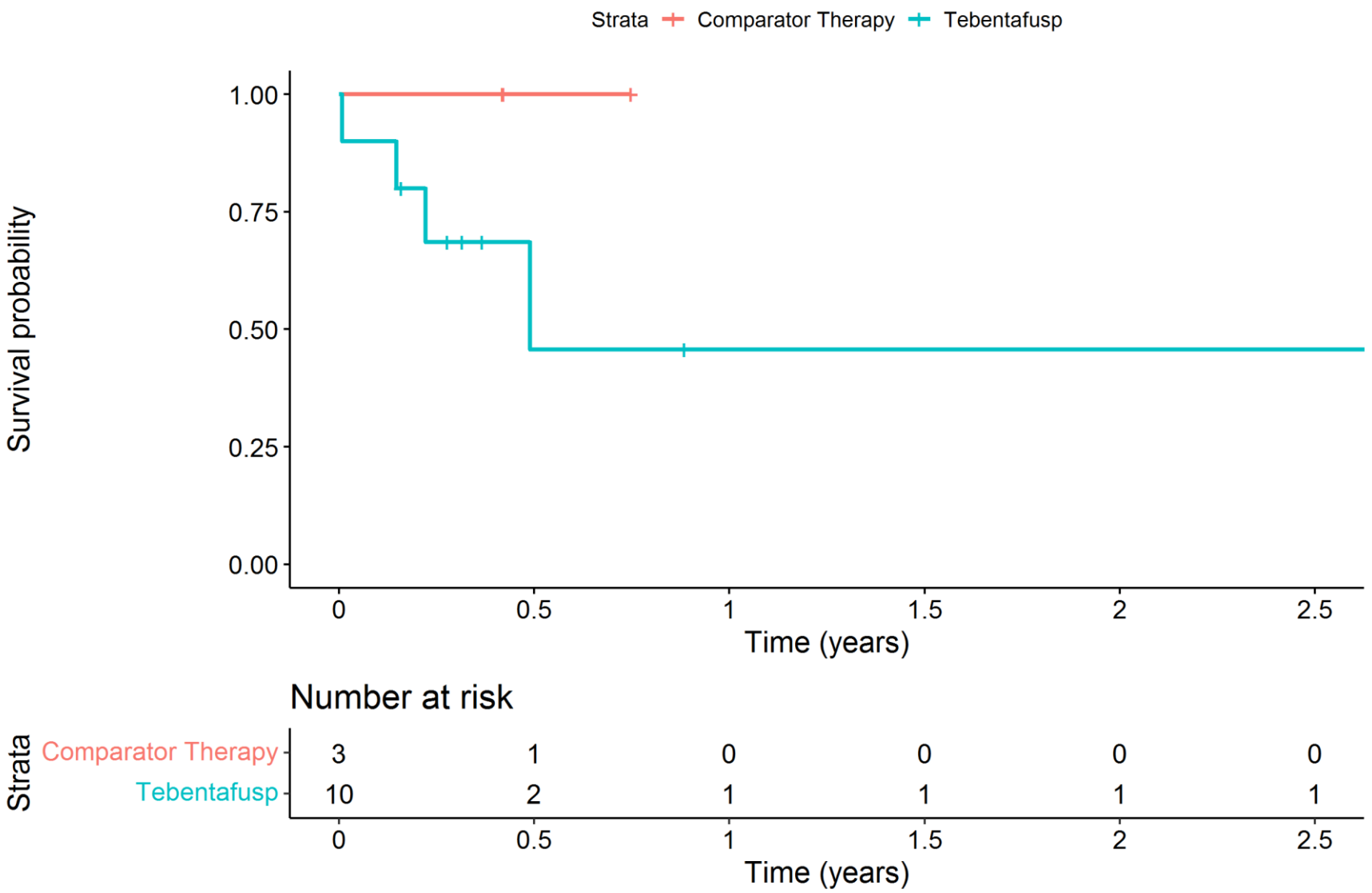
61.215 Erkrankungen der Atemwege, des Brustraums und Mediastinums- LDH =< ULN



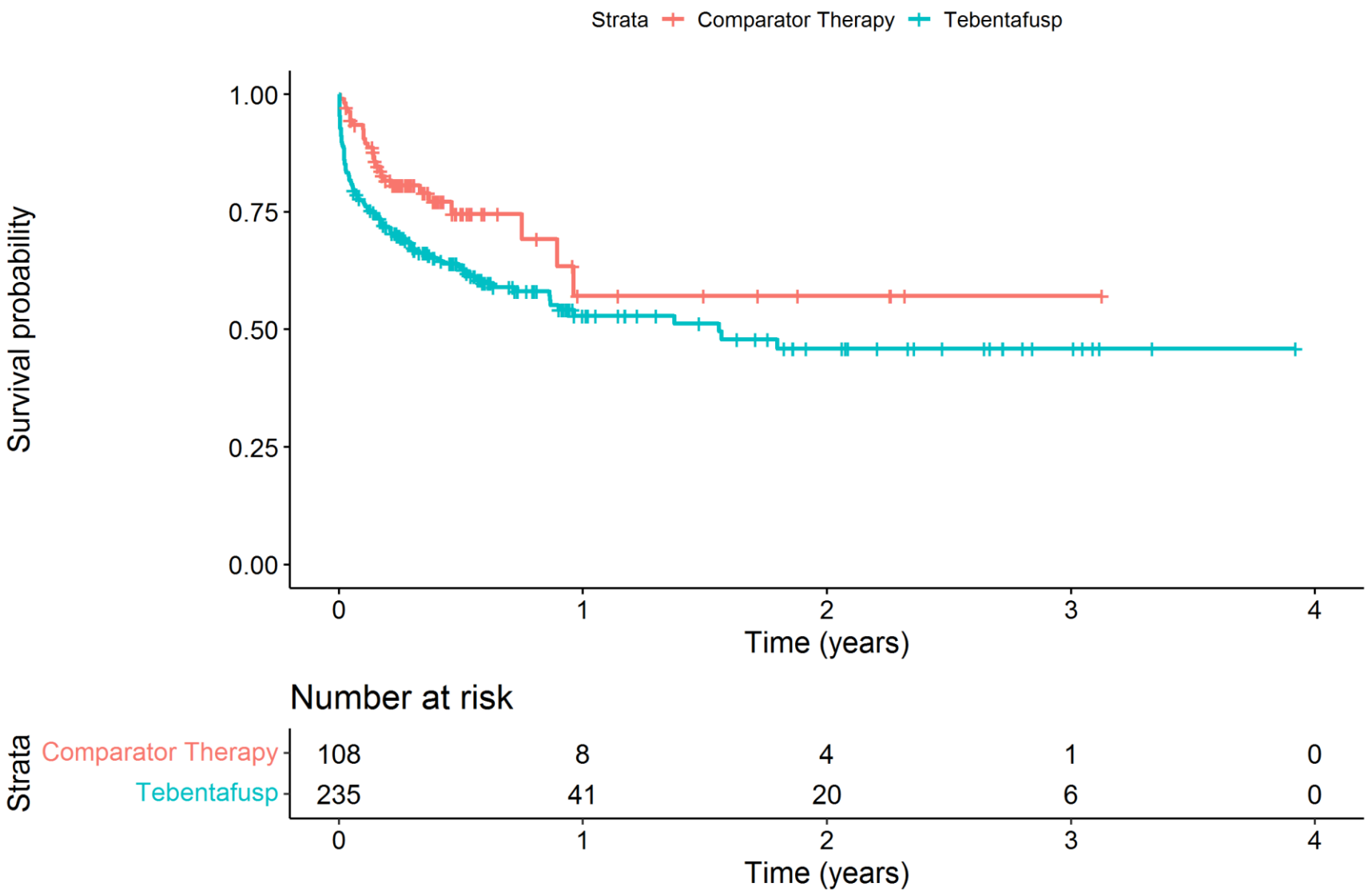
61.216 Erkrankungen der Atemwege, des Brustraums und Mediastinums- LDH > ULN



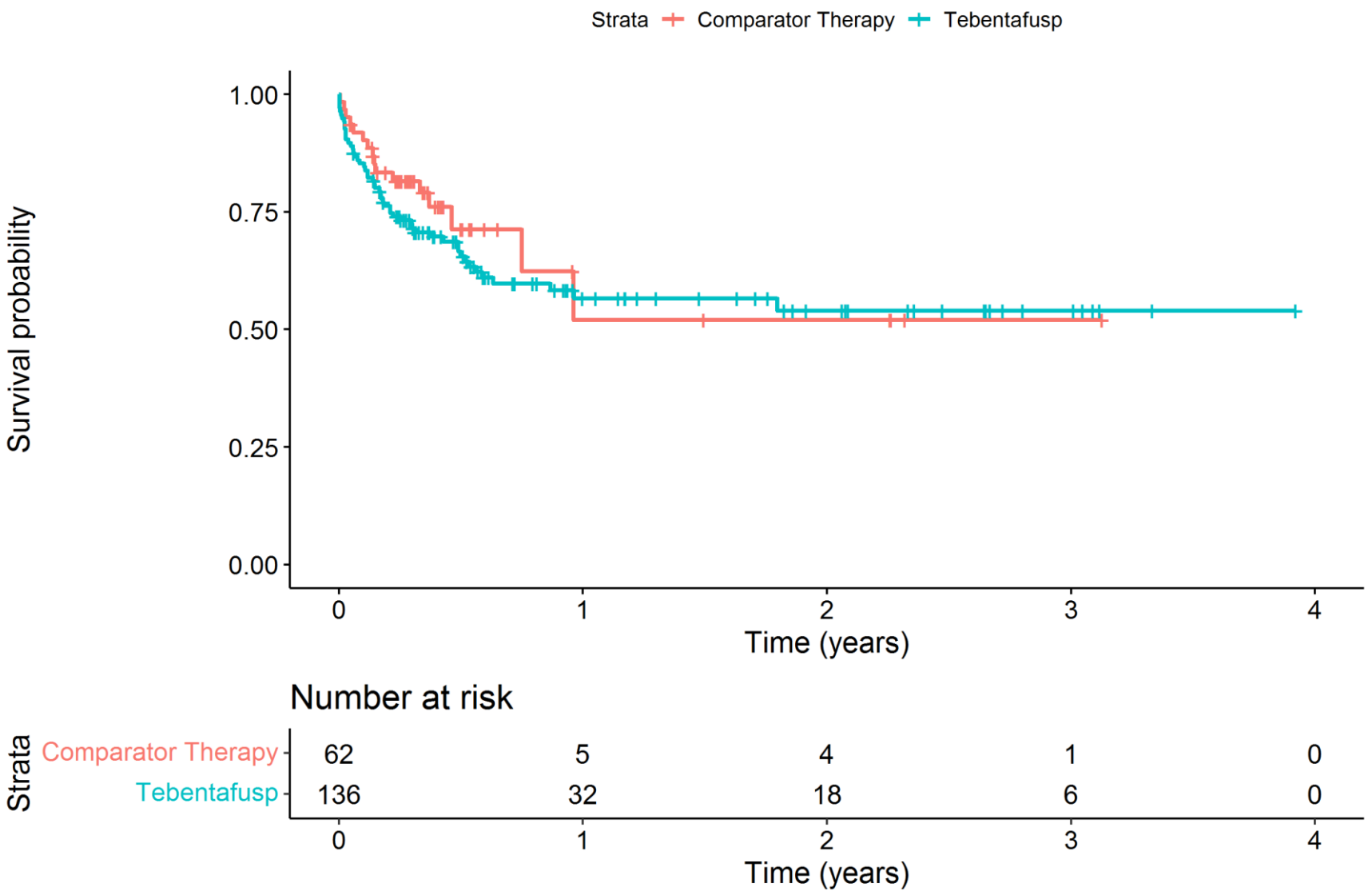
61.217 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Vorherige Therapie adjuvant/neoadjuvant



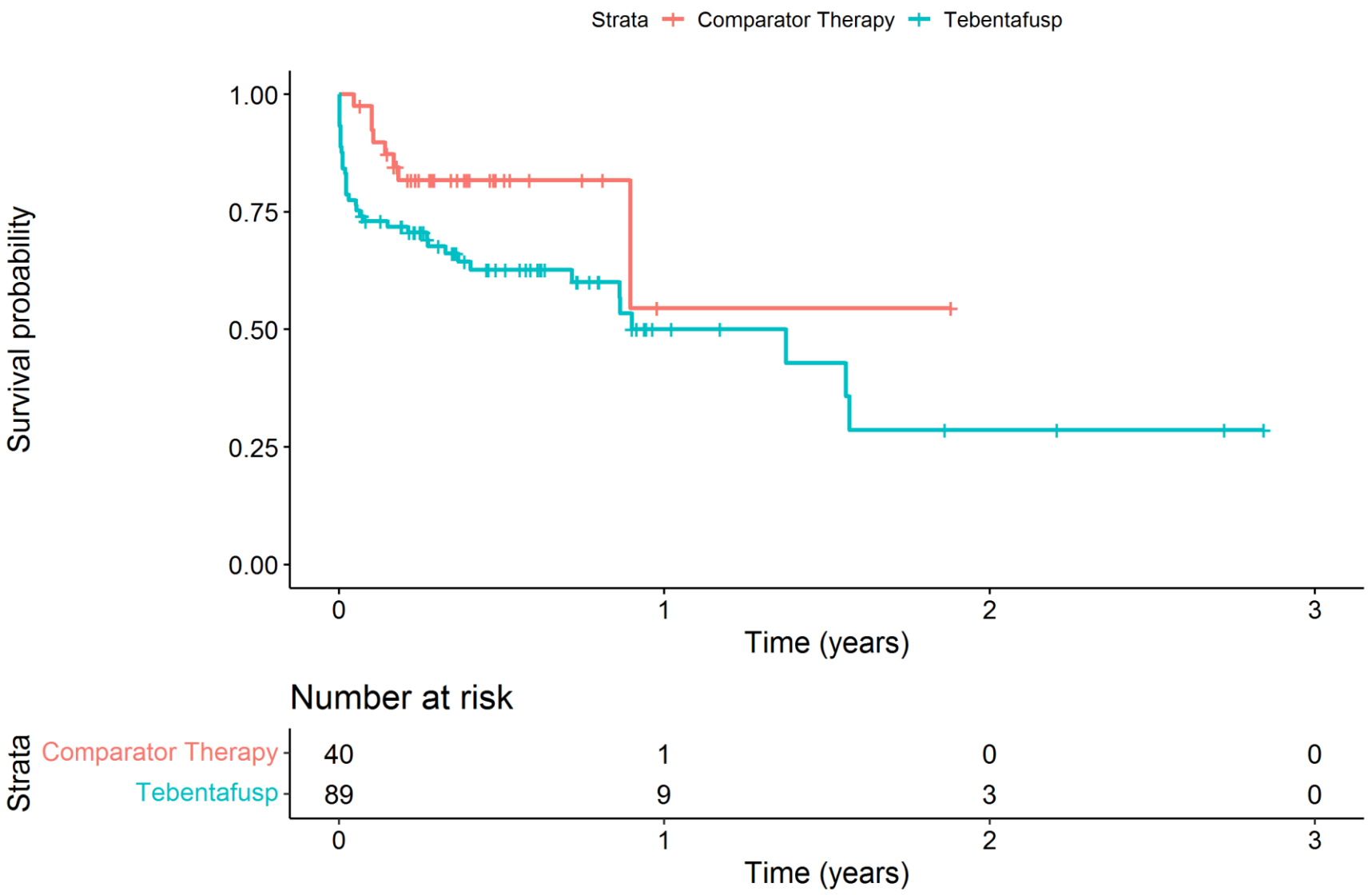
61.218 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Keine Vorherige Therapie adjuvant/neoadjuvant



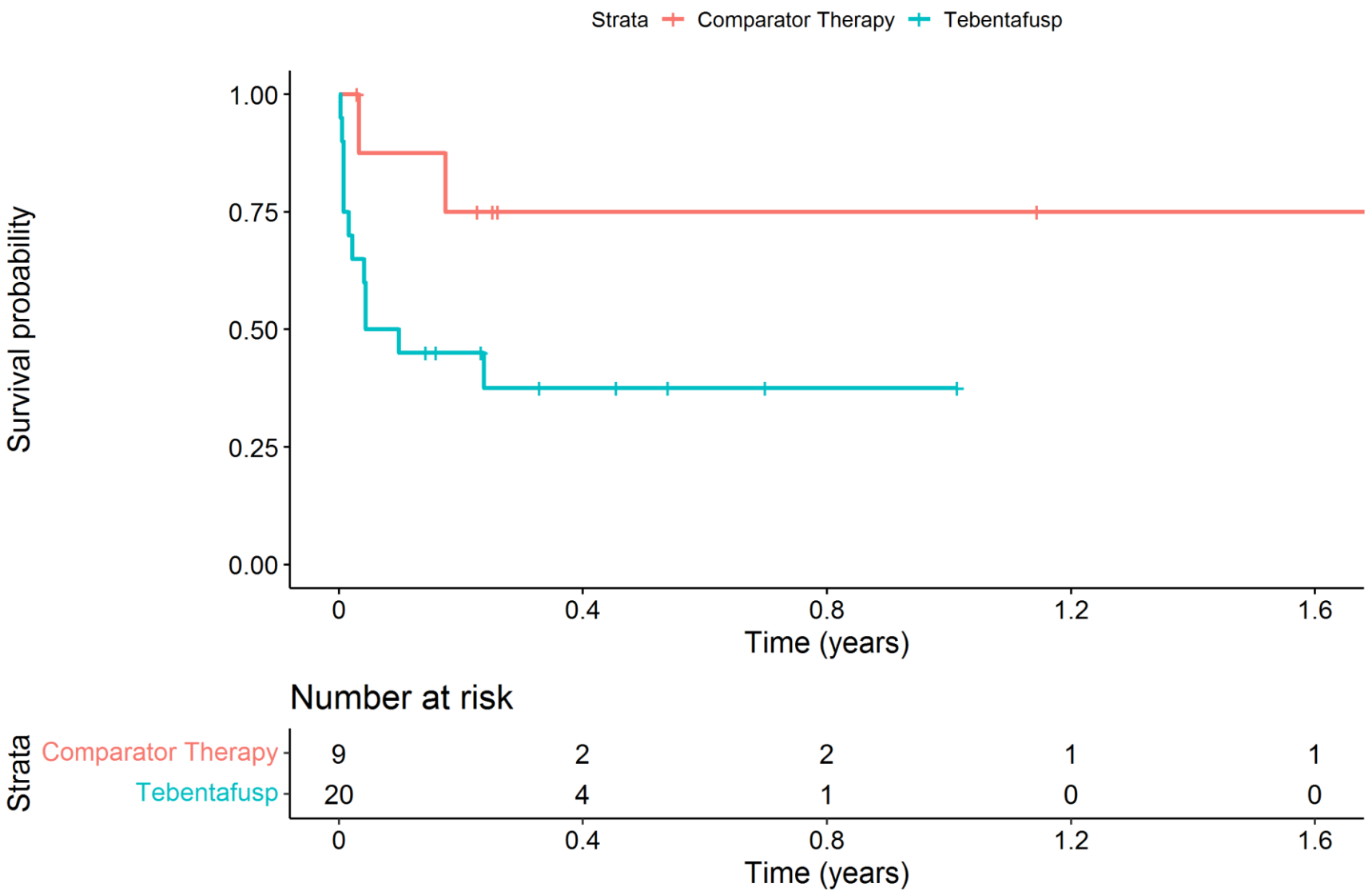
61.219 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion ≤ 3cm



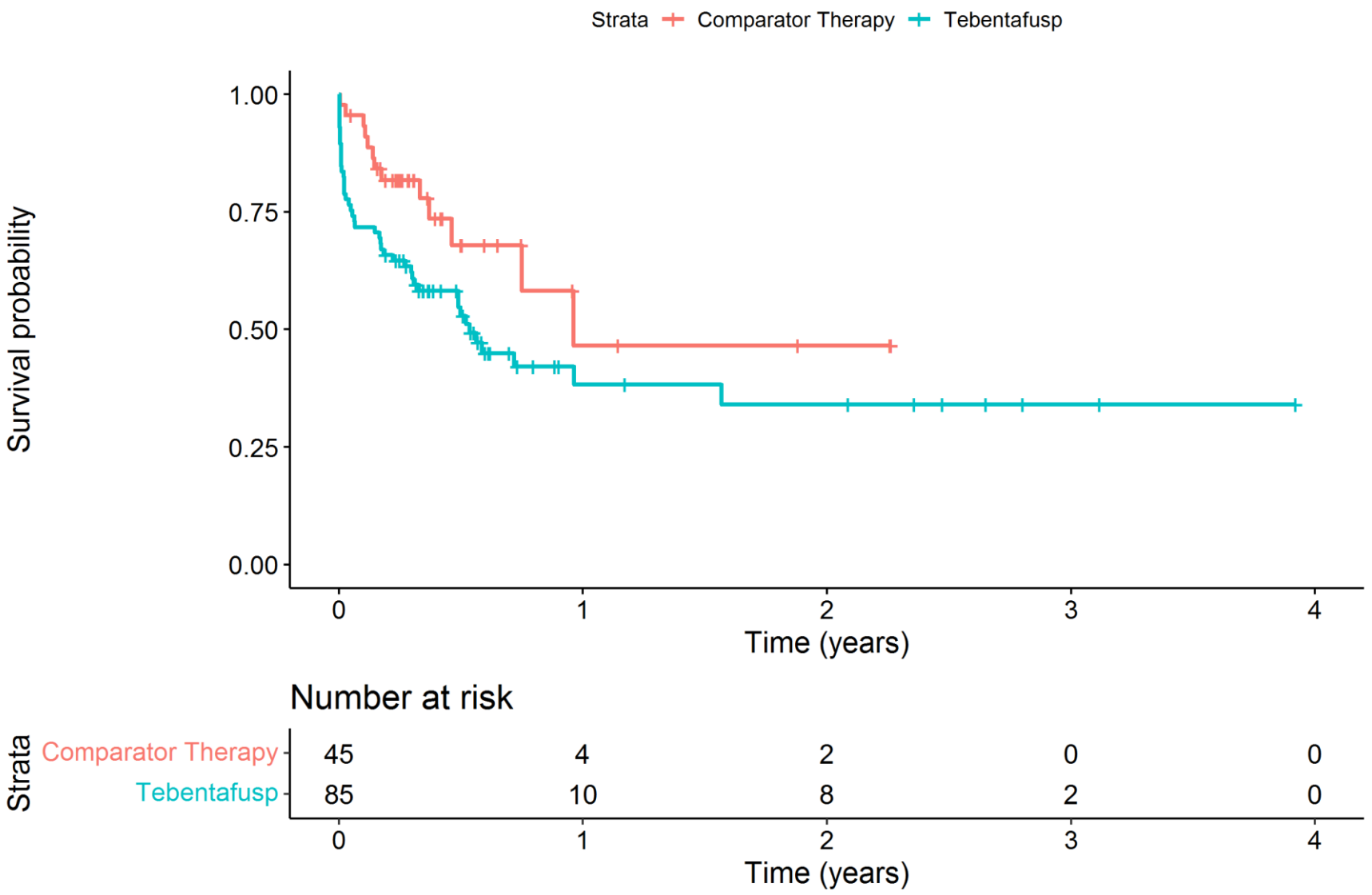
61.220 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion 3,1-8,0 cm



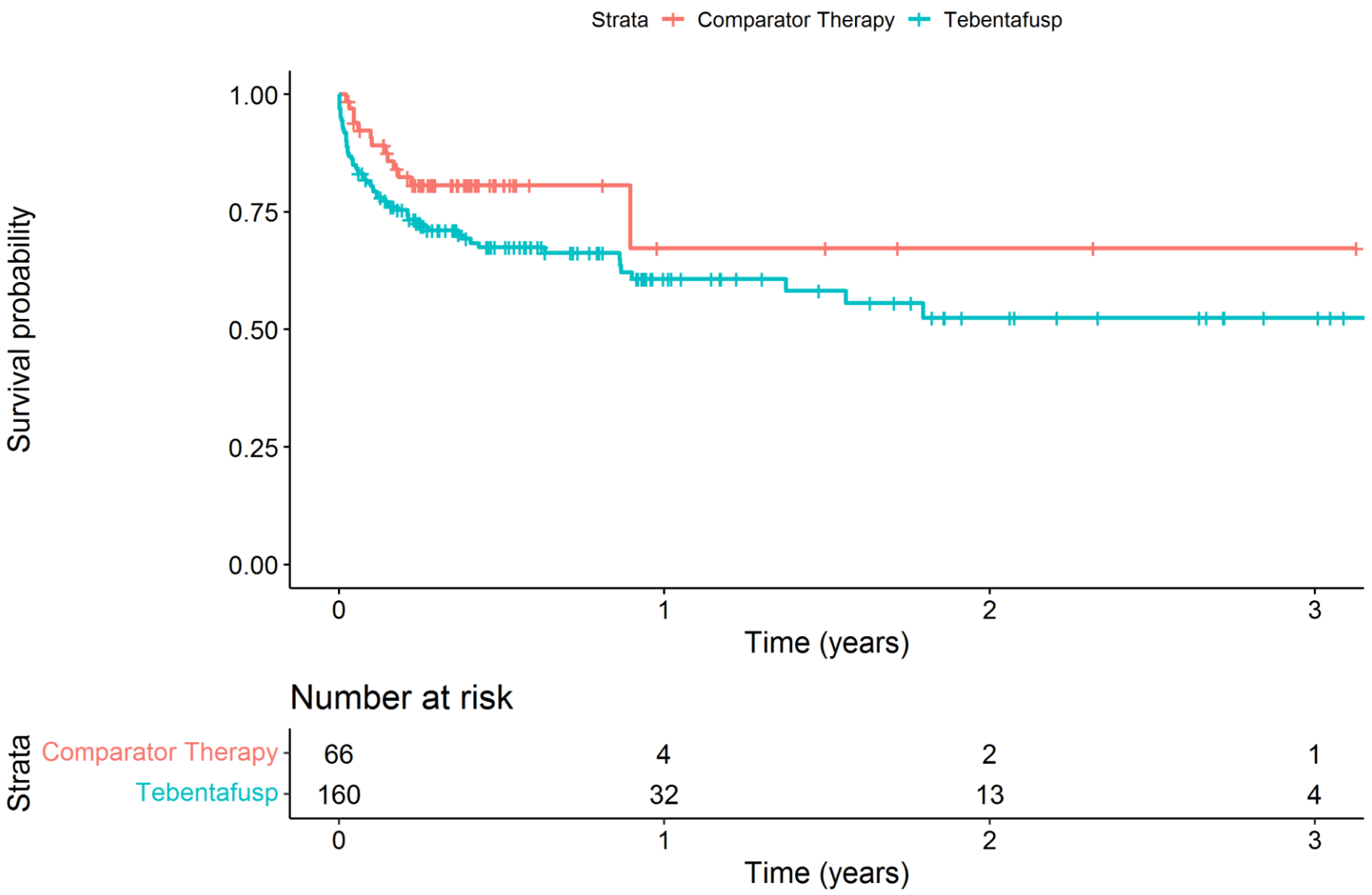
61.221 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion ≥8,1 cm



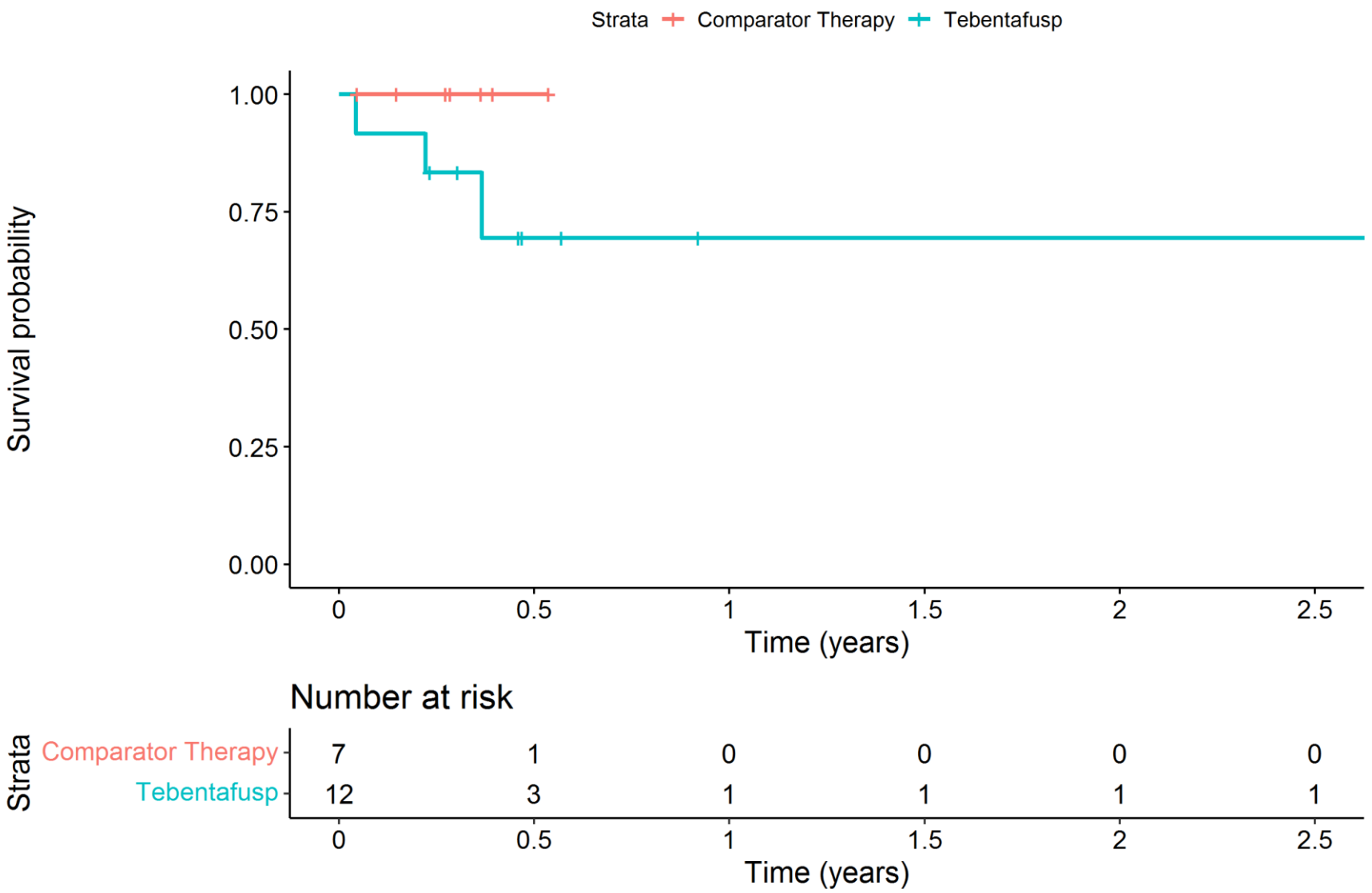
61.222 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nordamerika



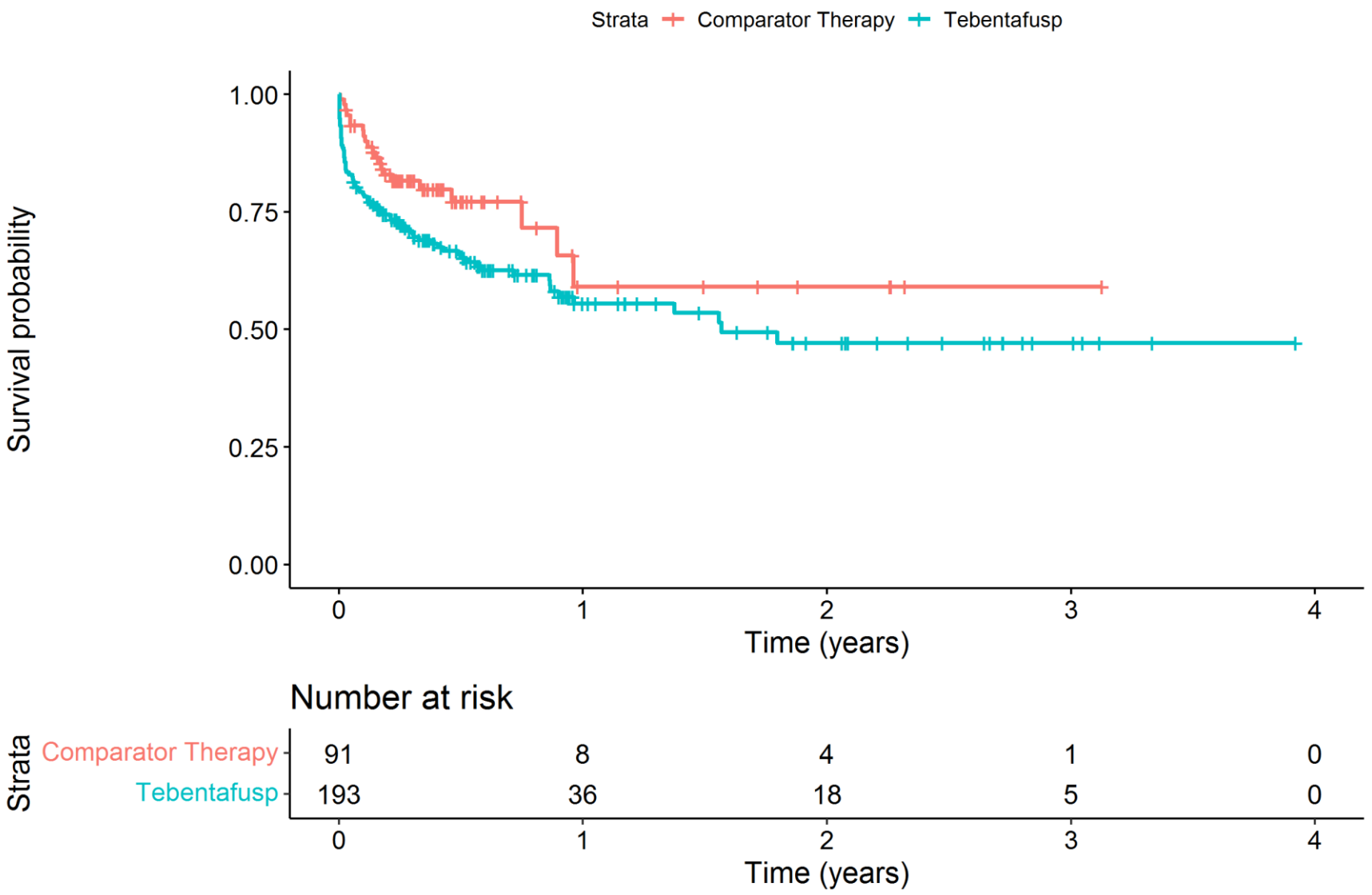
61.223 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nicht-Nordamerika



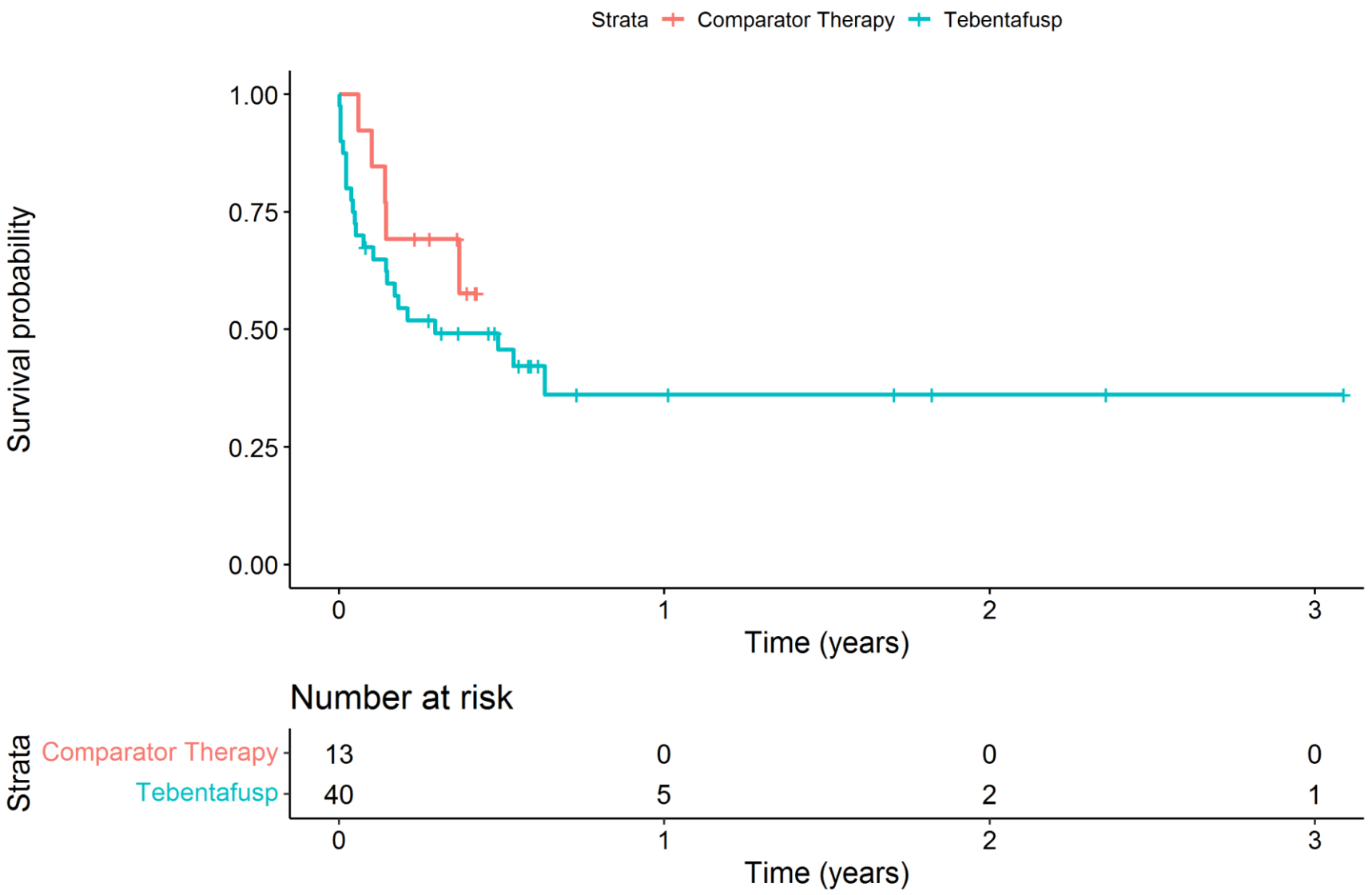
61.224 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Dacarbazin



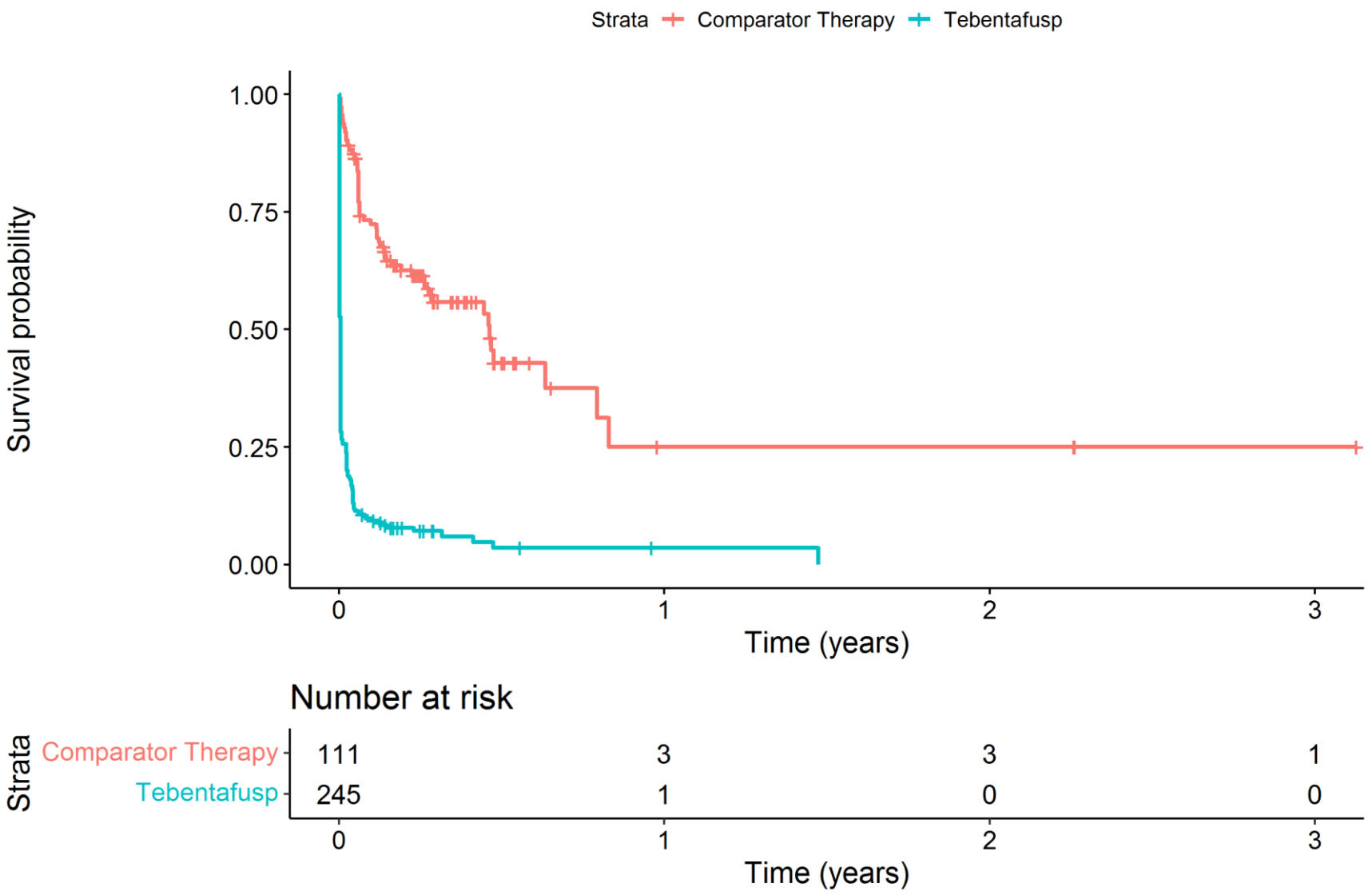
61.225 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Pembrolizumab



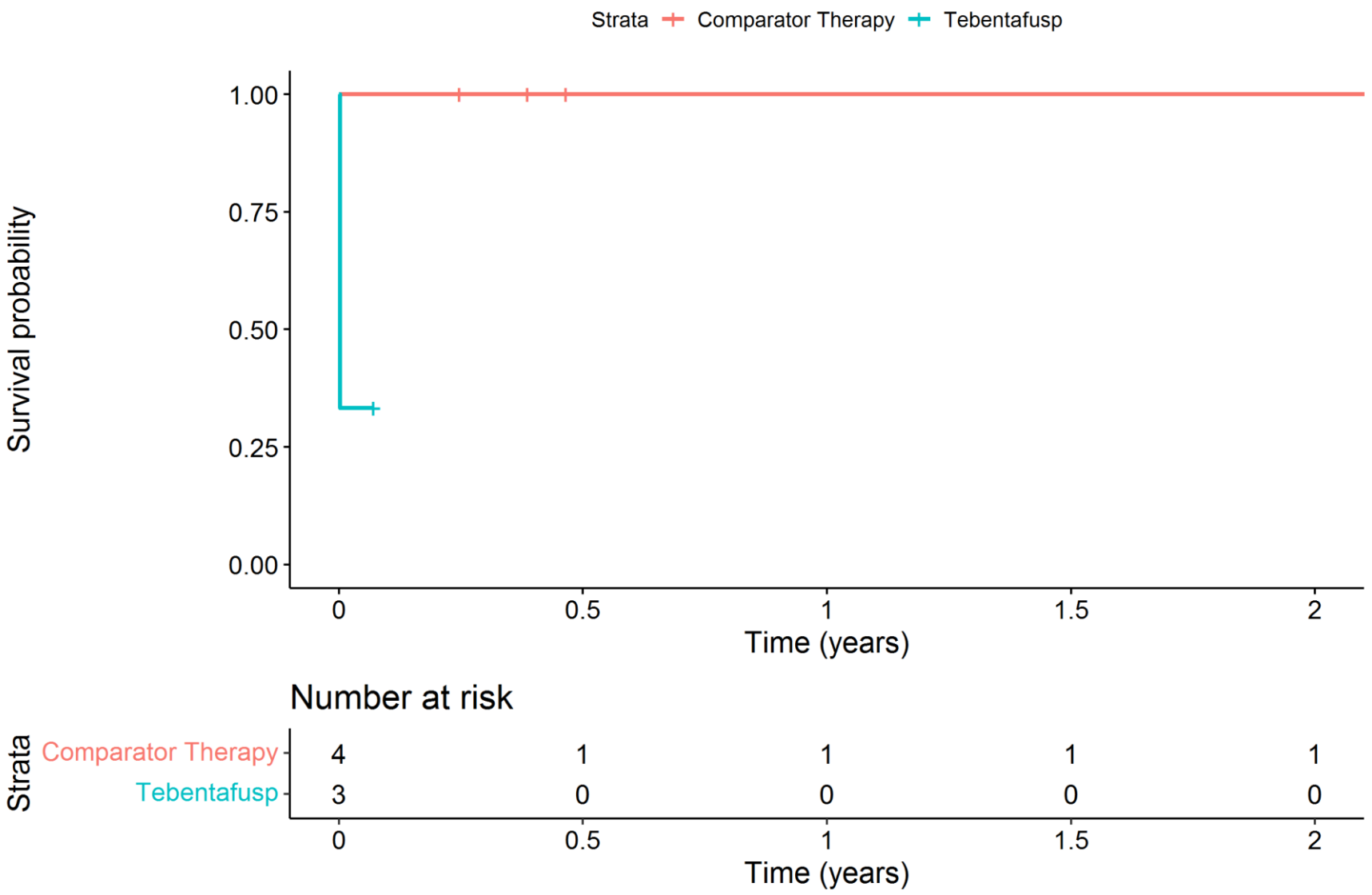
61.226 Erkrankungen der Atemwege, des Brustraums und Mediastinums- Ipilimumab



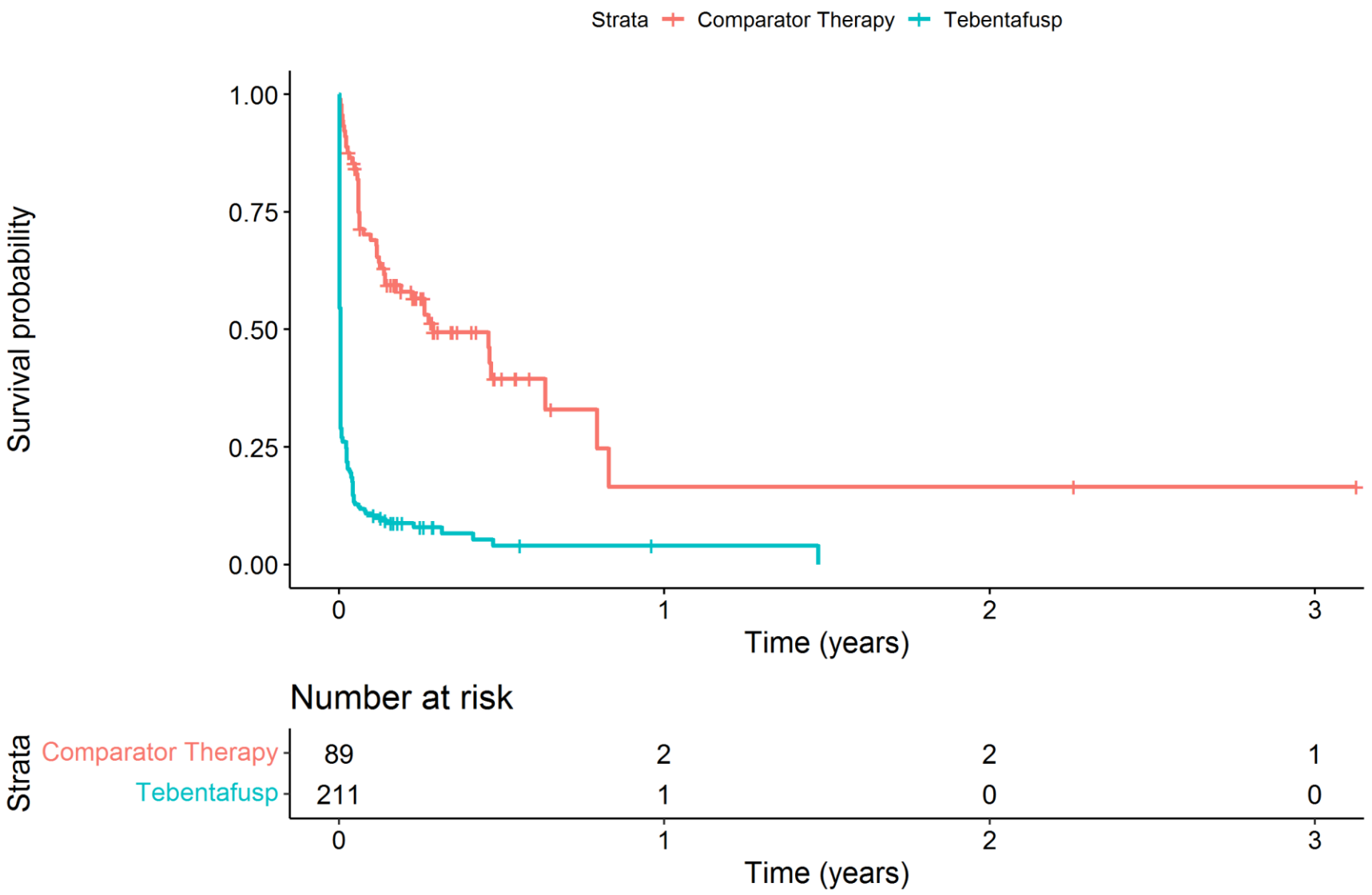
61.227 Erkrankungen der Haut und des Unterhautgewebes- Gesamt



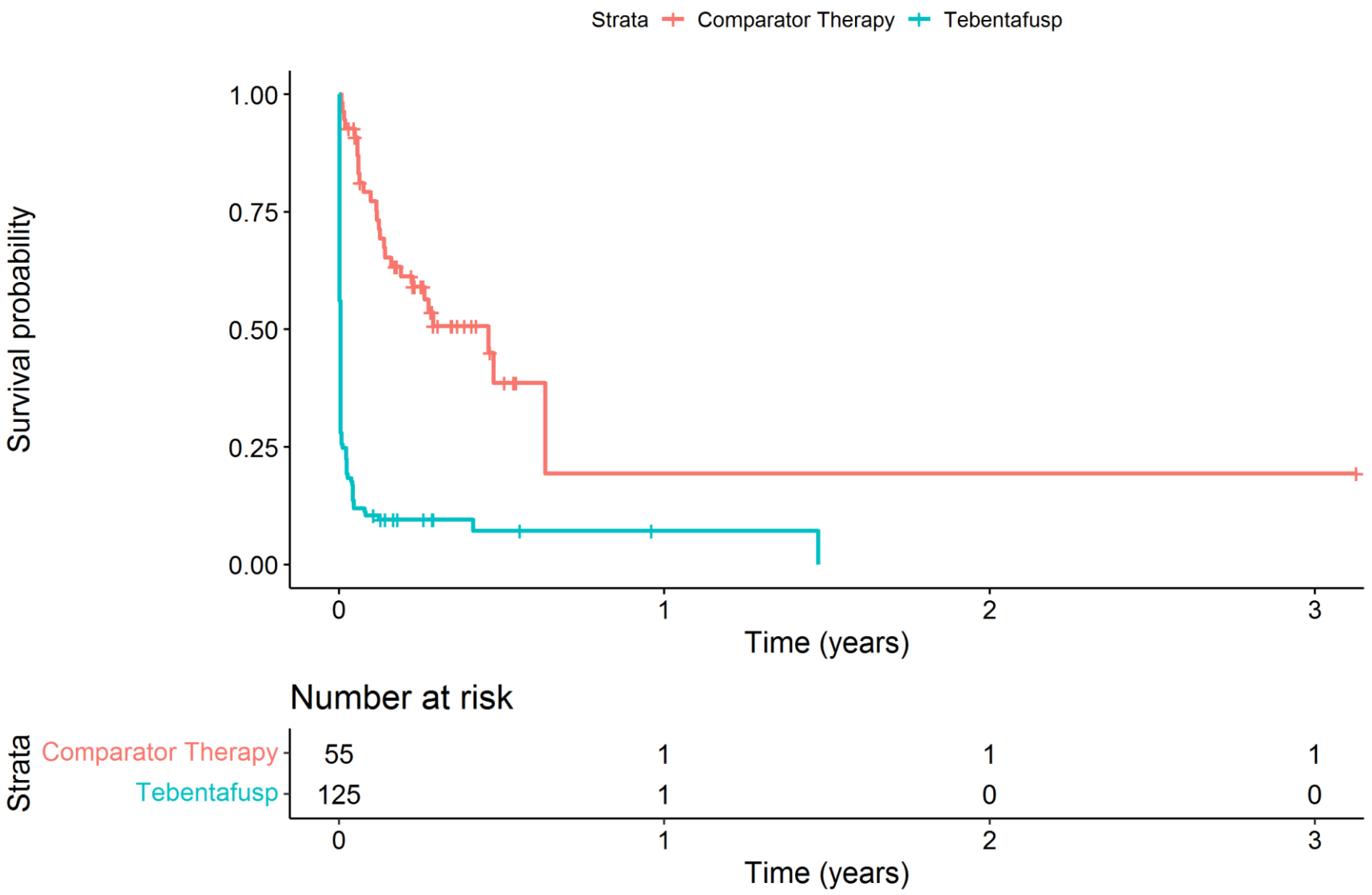
61.228 Erkrankungen der Haut und des Unterhautgewebes- Hispanisch



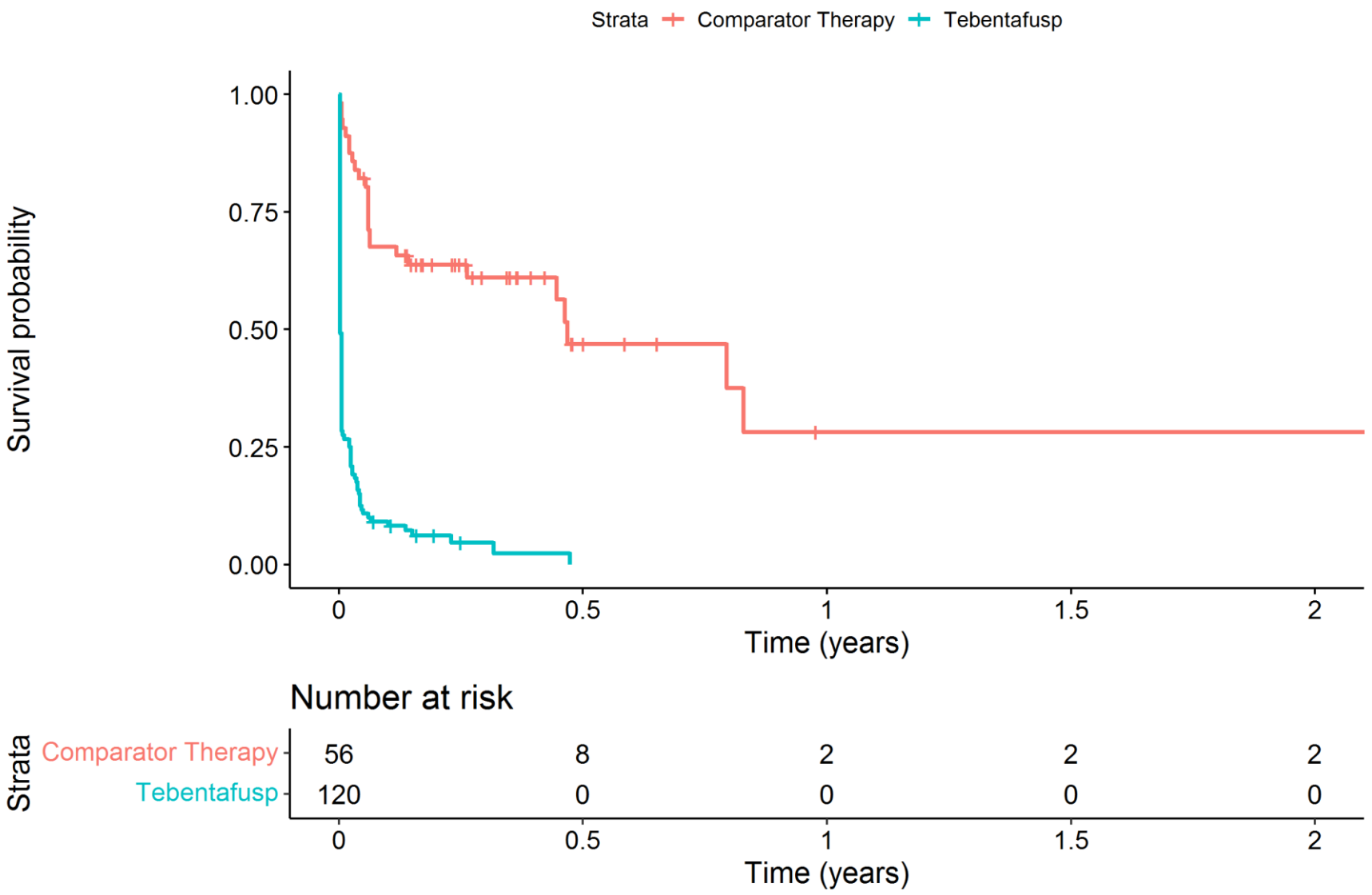
61.229 Erkrankungen der Haut und des Unterhautgewebes- Nicht-hispanisch



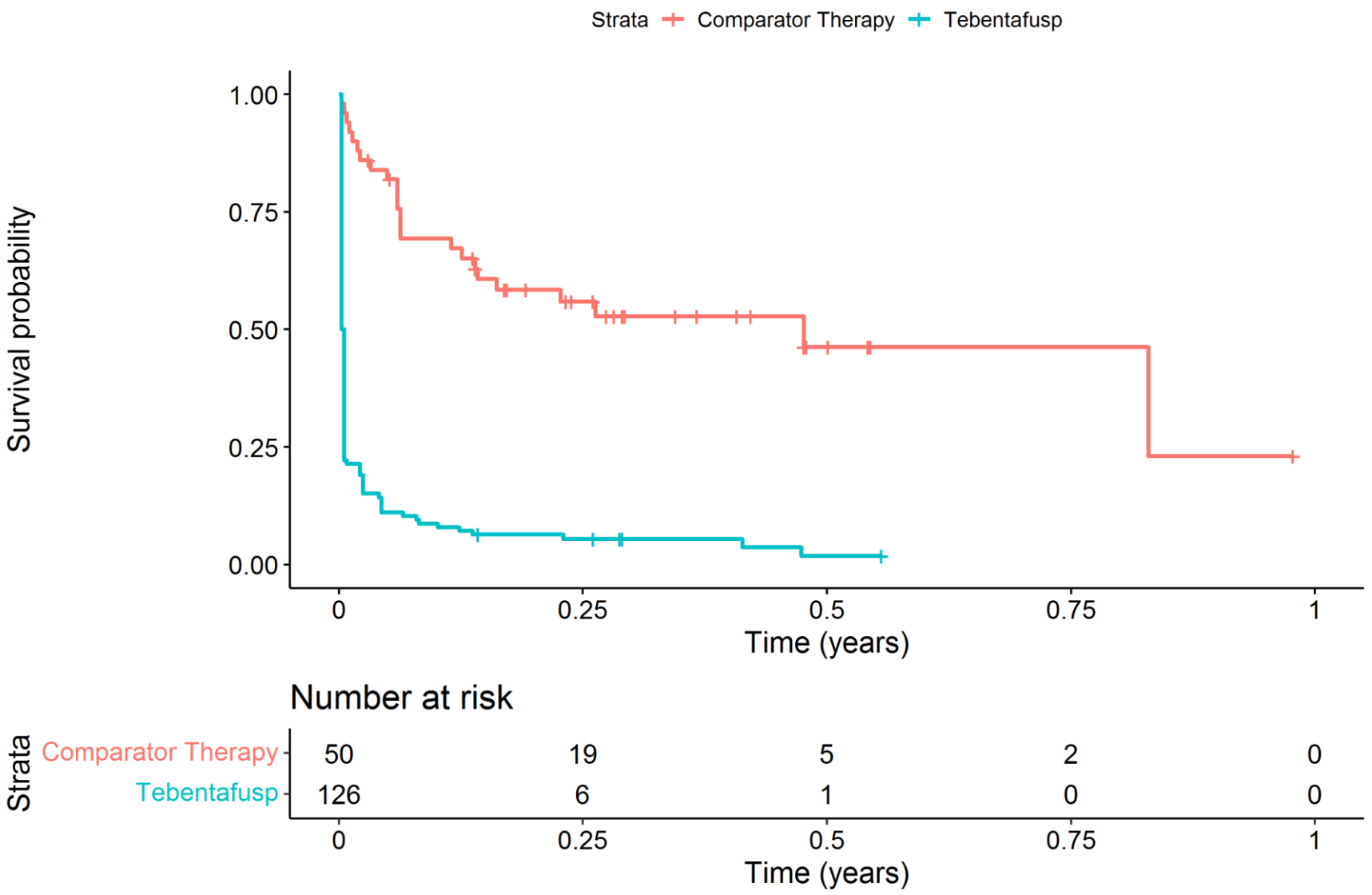
61.230 Erkrankungen der Haut und des Unterhautgewebes- Männlich



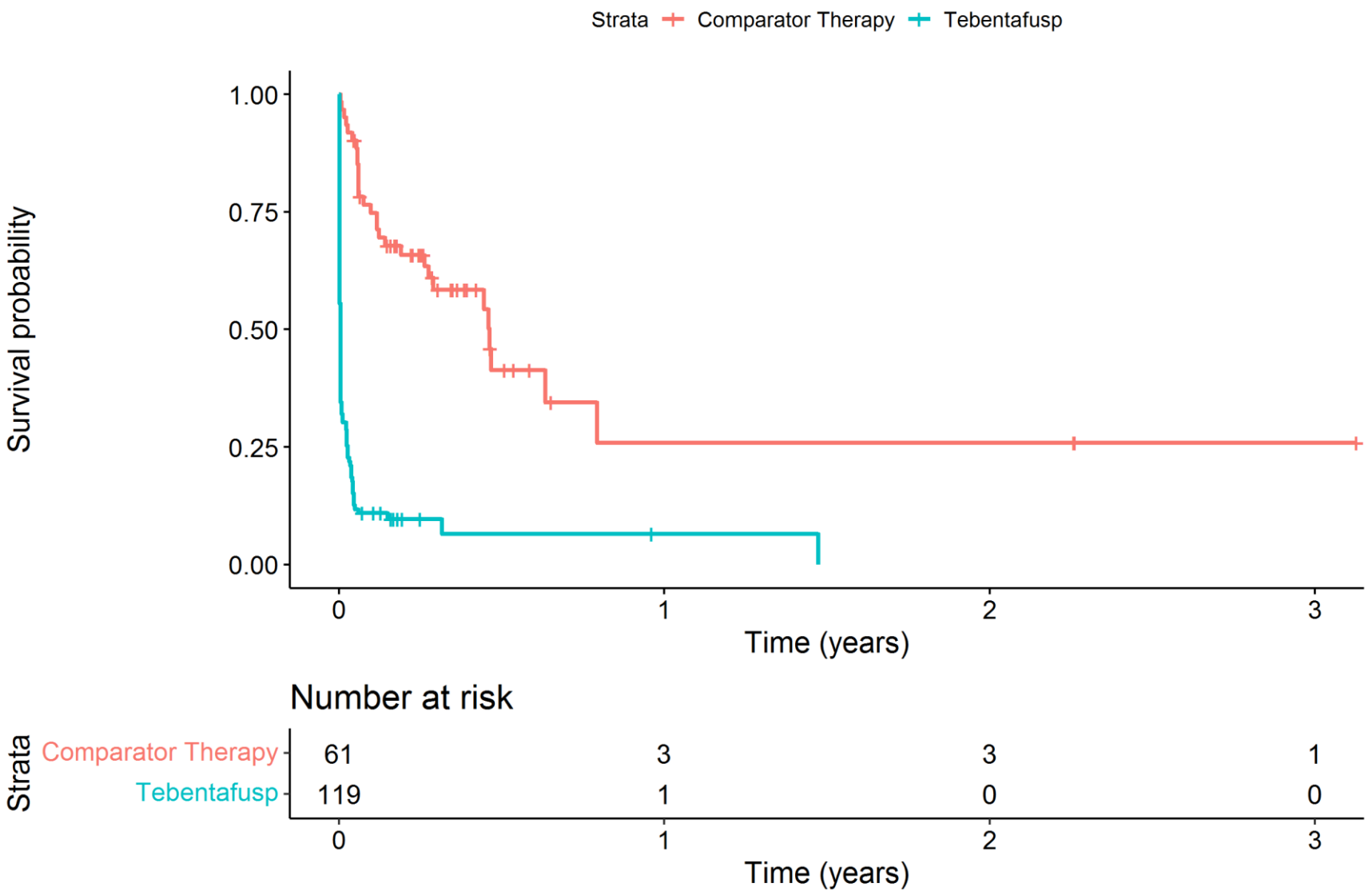
61.231 Erkrankungen der Haut und des Unterhautgewebes- Weiblich



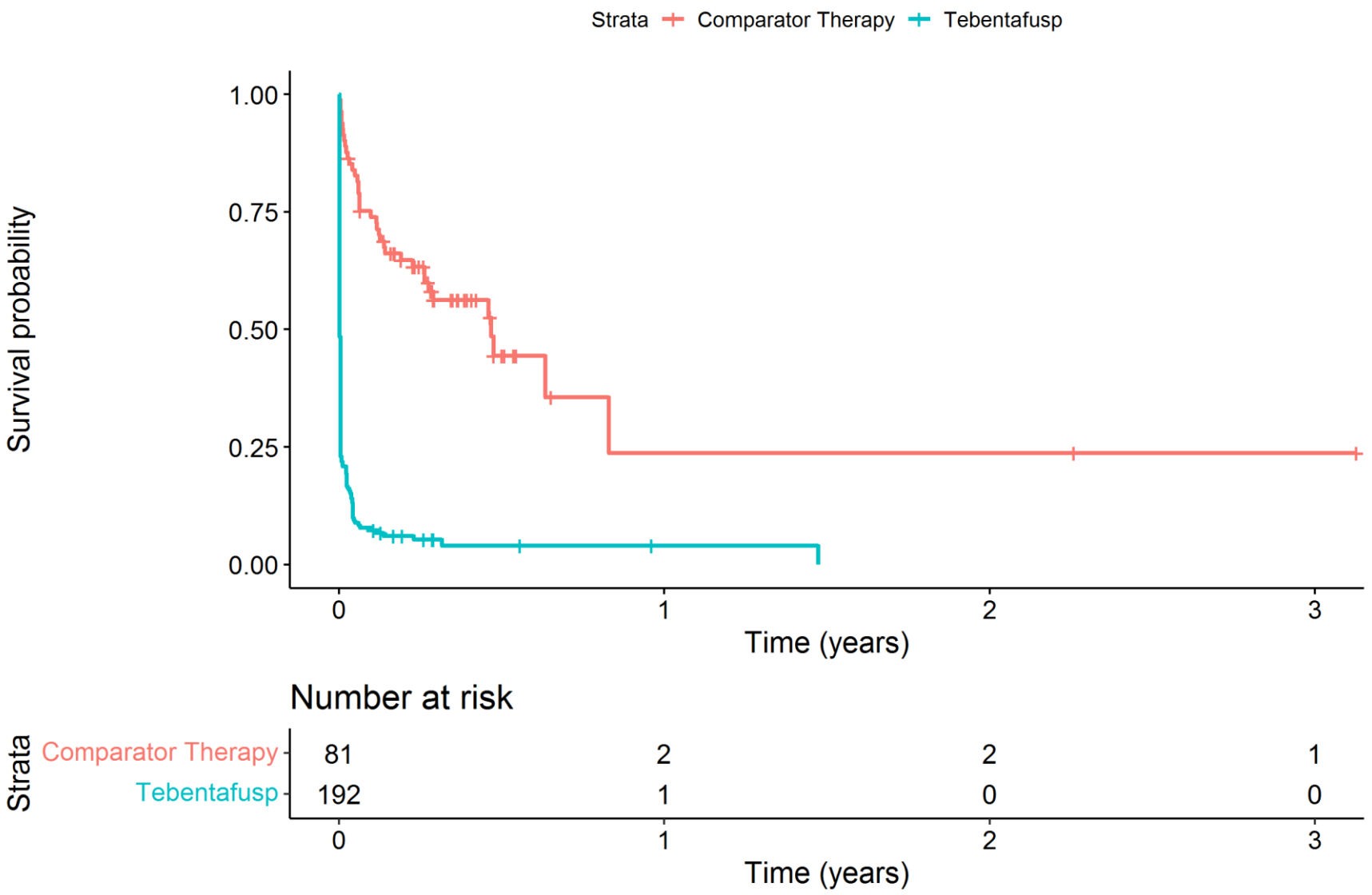
61.232 Erkrankungen der Haut und des Unterhautgewebes- <65



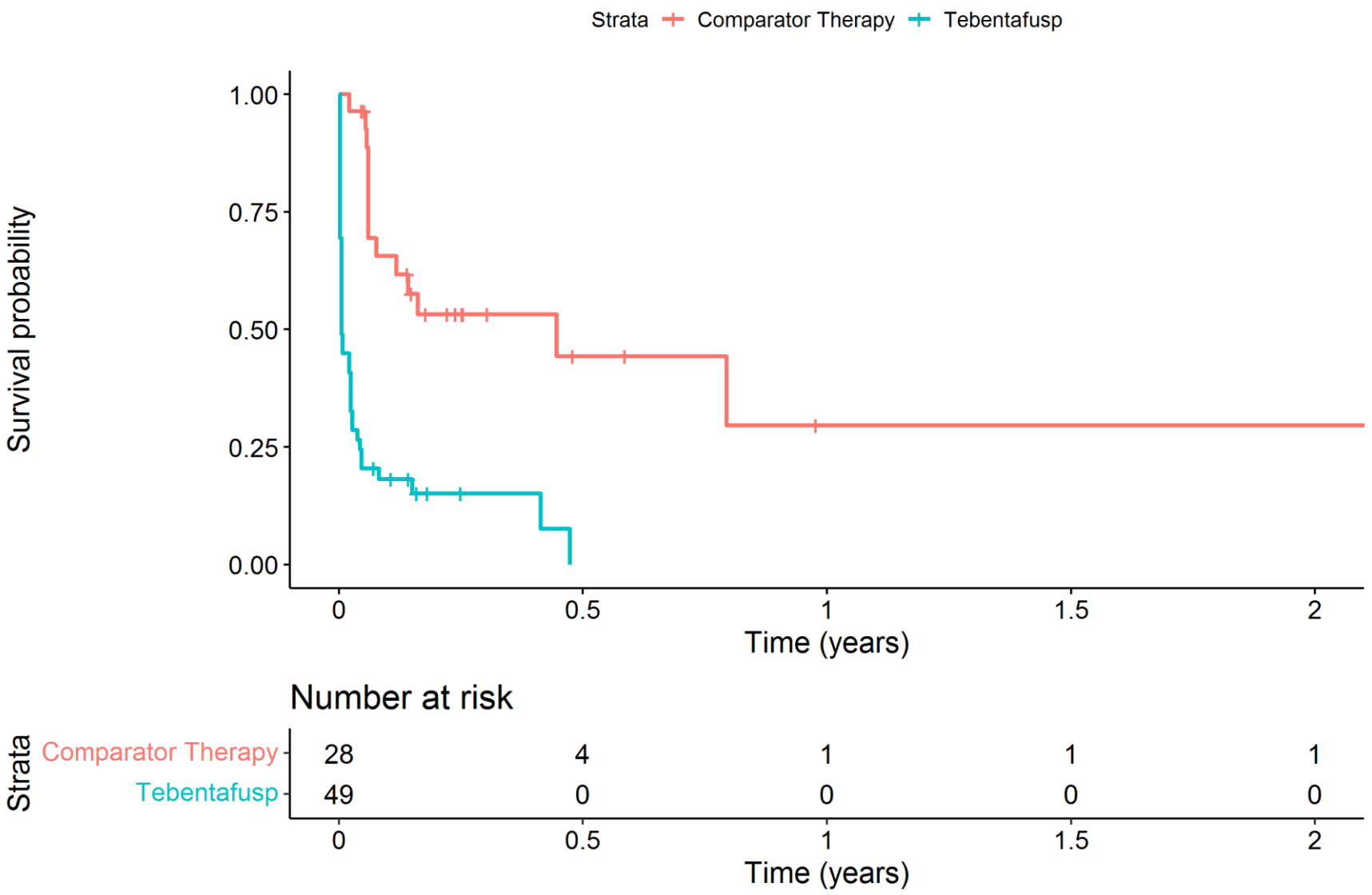
61.233 Erkrankungen der Haut und des Unterhautgewebes- ≥65



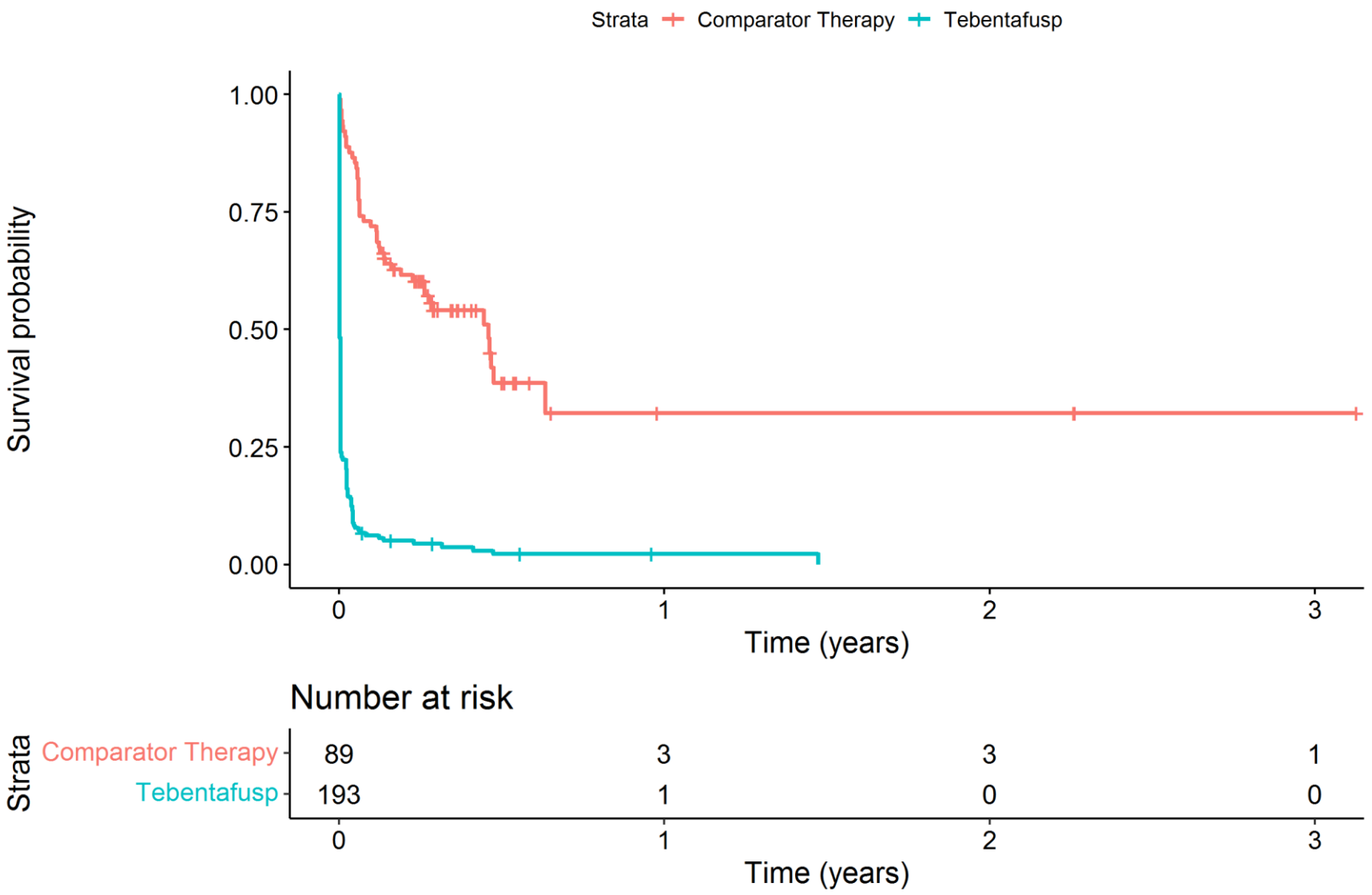
61.234 Erkrankungen der Haut und des Unterhautgewebes- ECOG 0



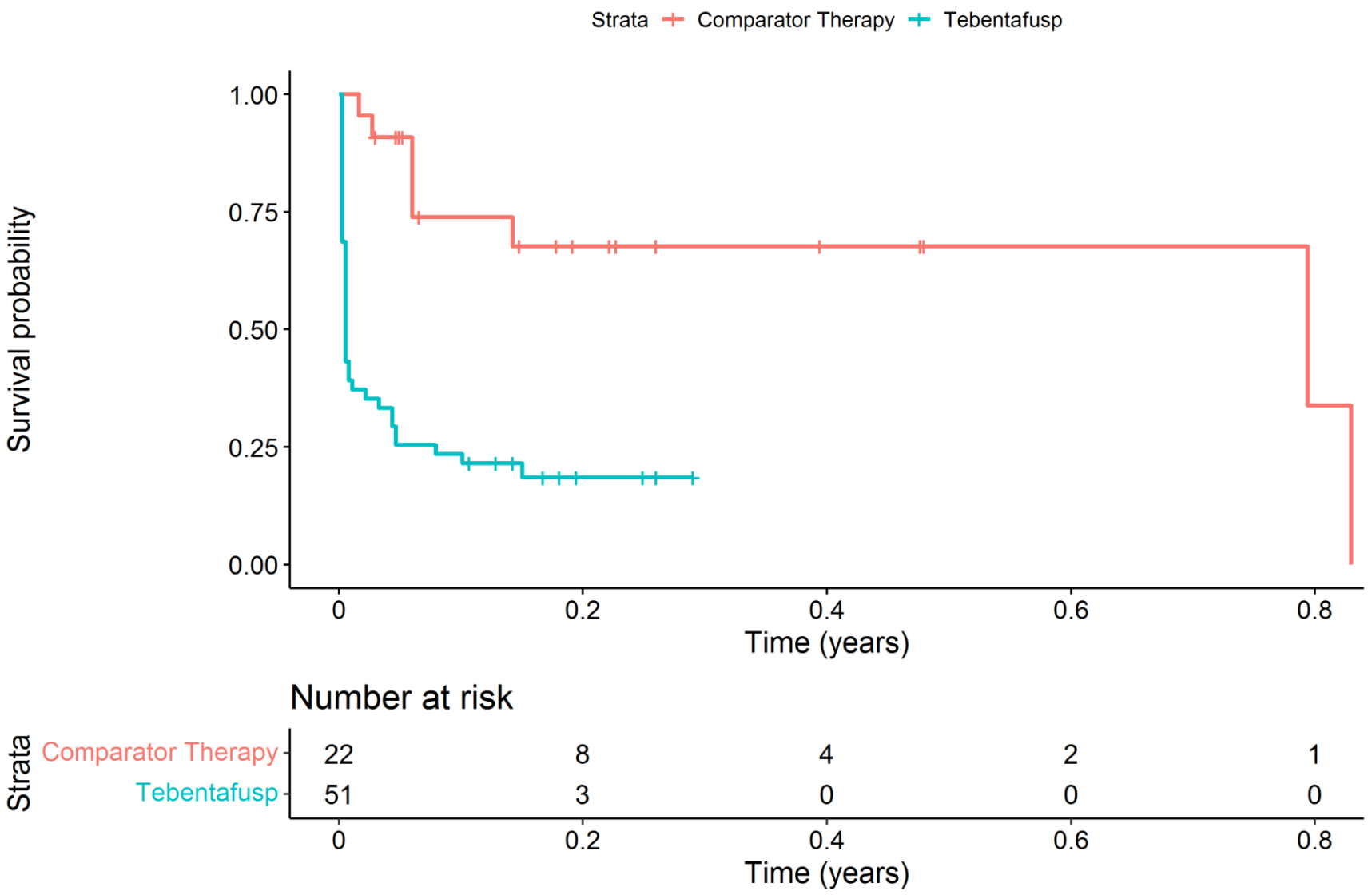
61.235 Erkrankungen der Haut und des Unterhautgewebes- ECOG 1



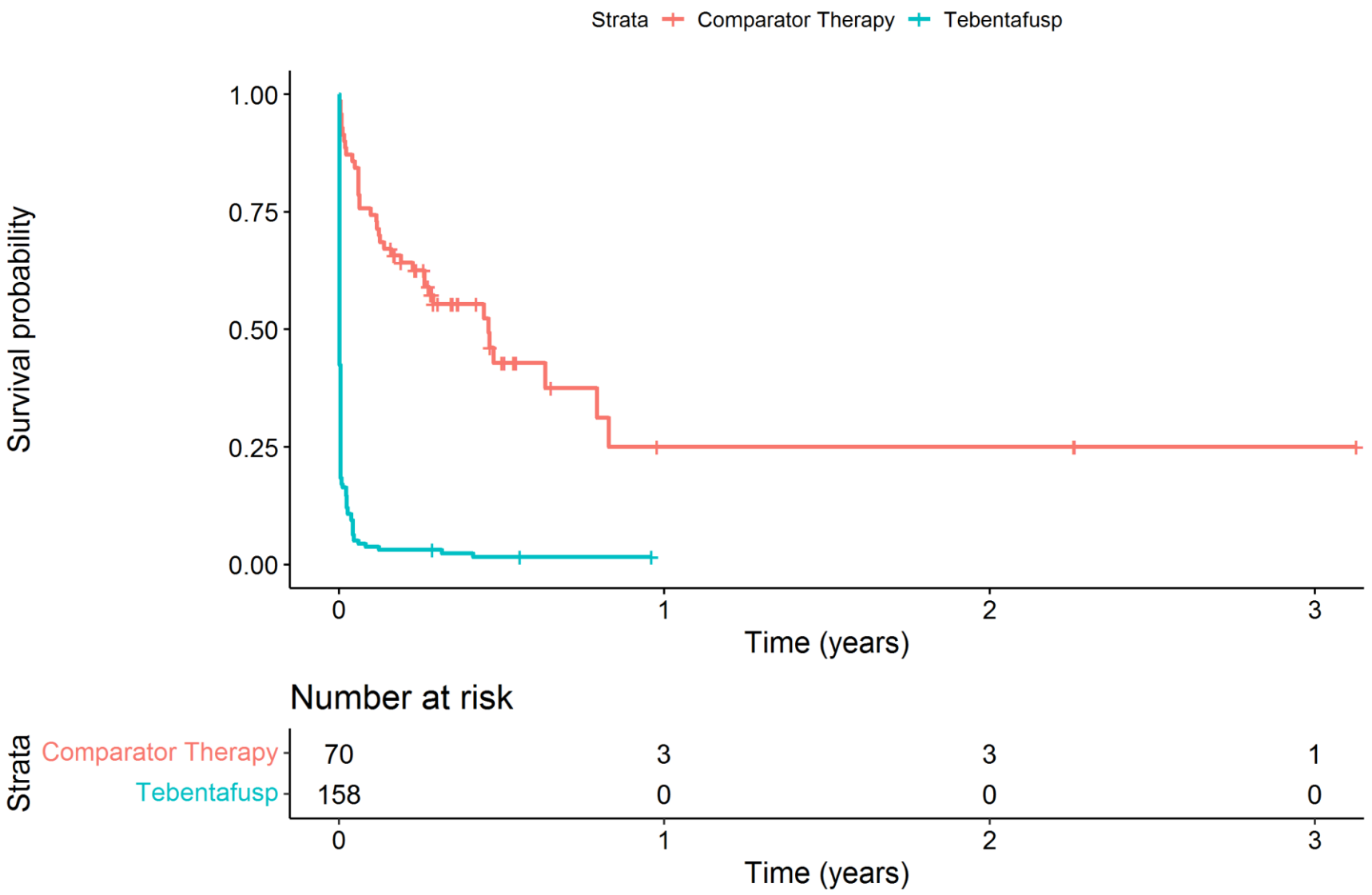
61.236 Erkrankungen der Haut und des Unterhautgewebes- ALP ≤ ULN



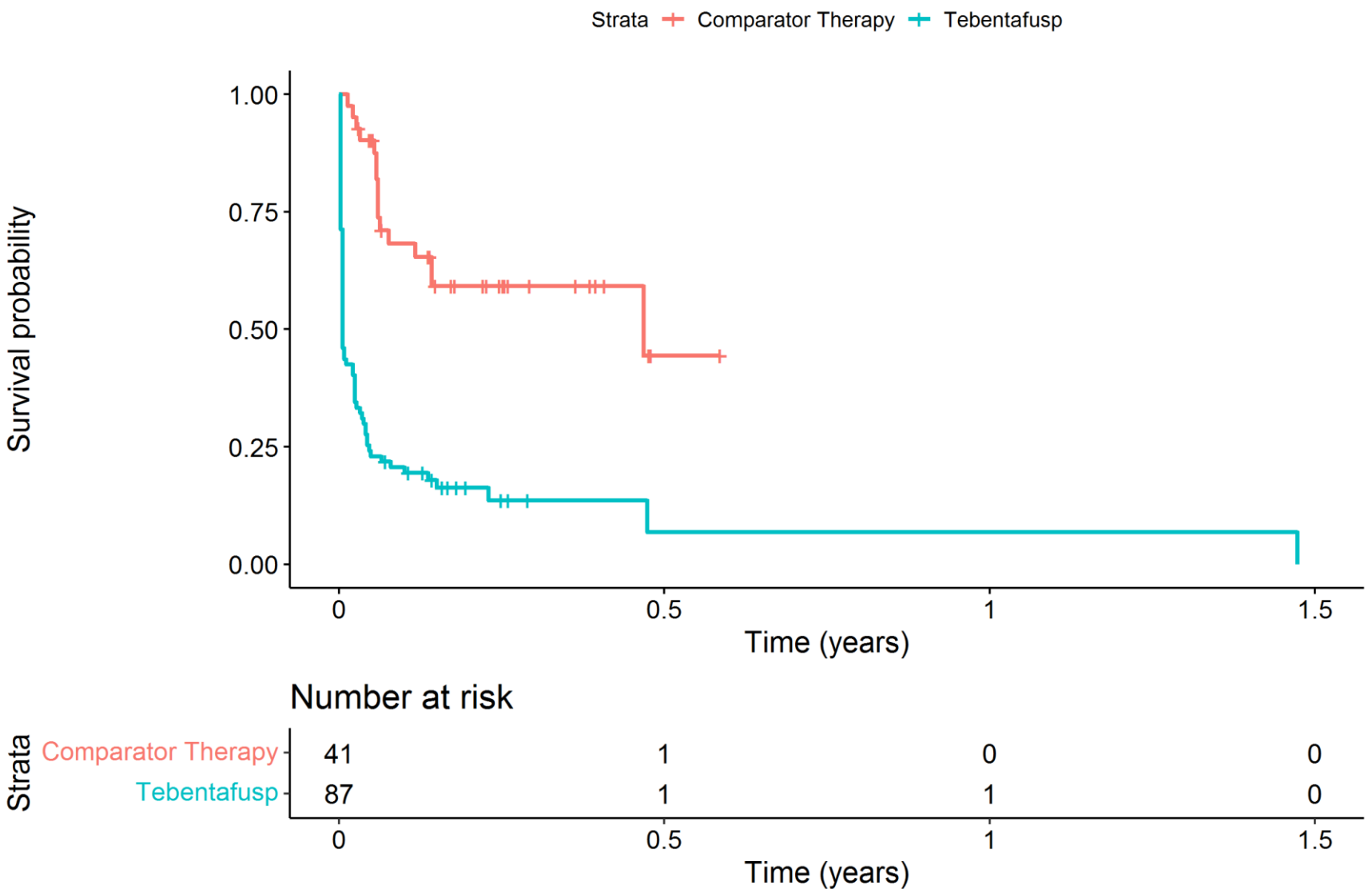
61.237 Erkrankungen der Haut und des Unterhautgewebes- ALP > ULN



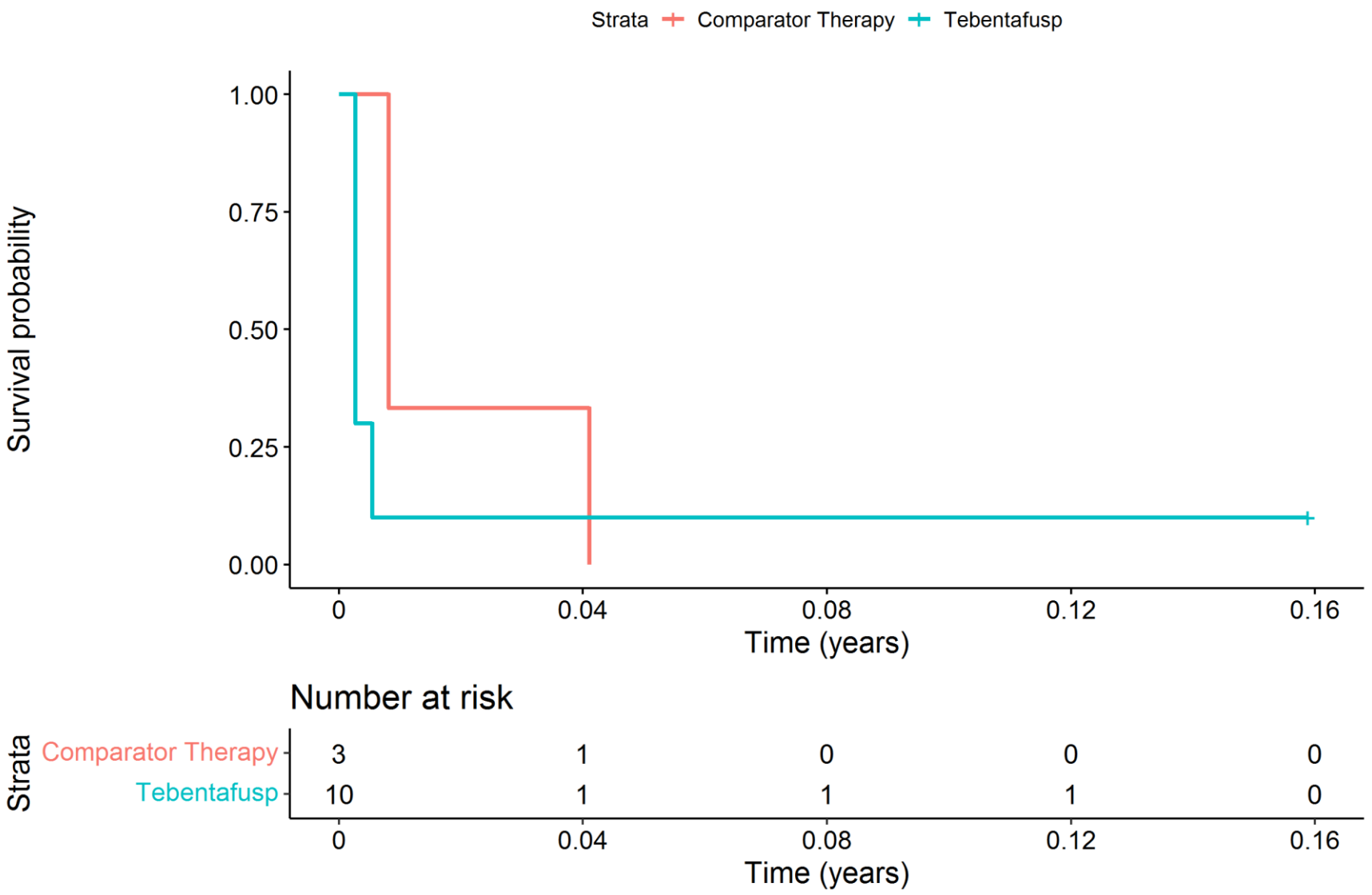
61.238 Erkrankungen der Haut und des Unterhautgewebes- LDH =< ULN



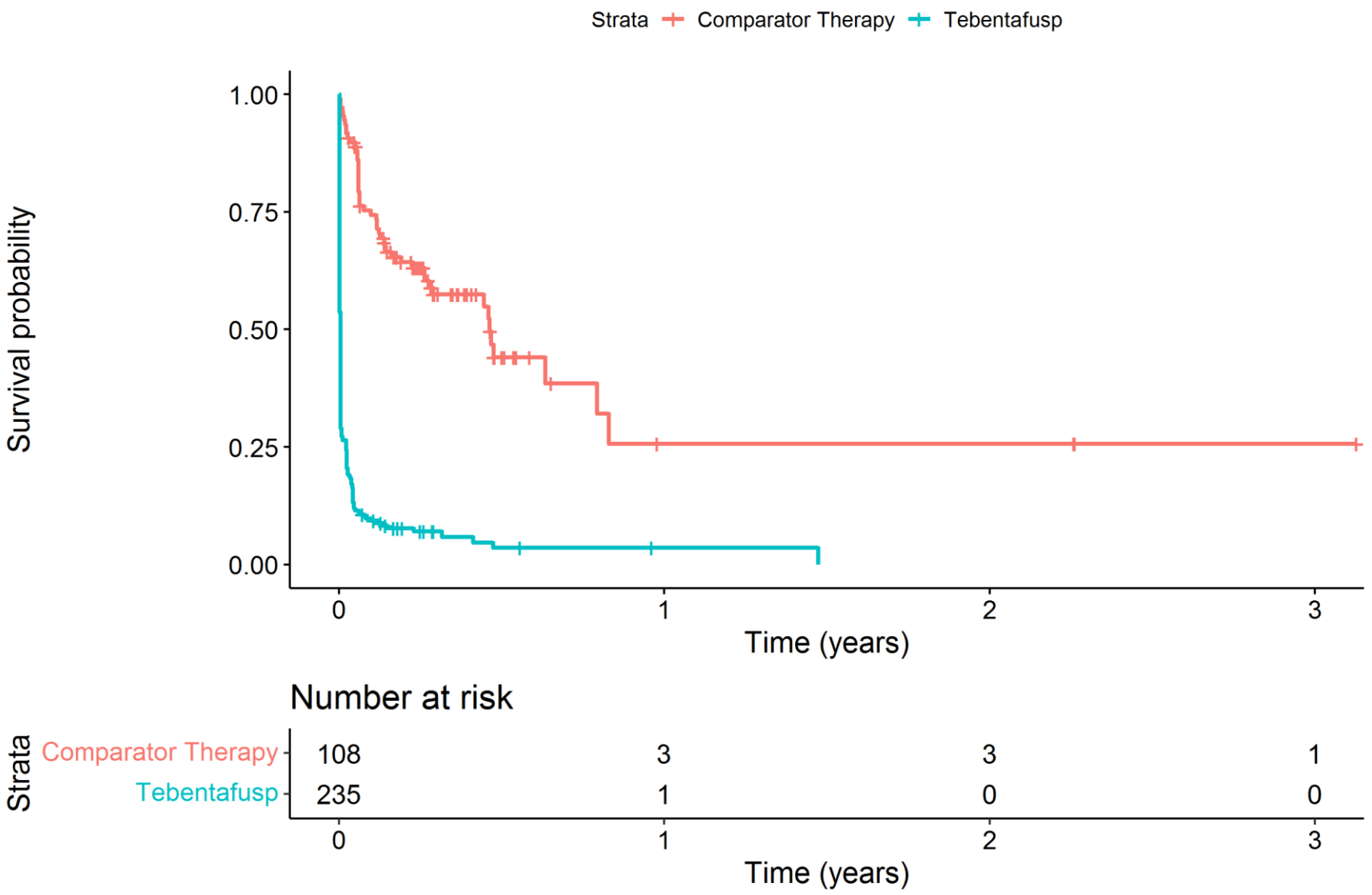
61.239 Erkrankungen der Haut und des Unterhautgewebes- LDH > ULN



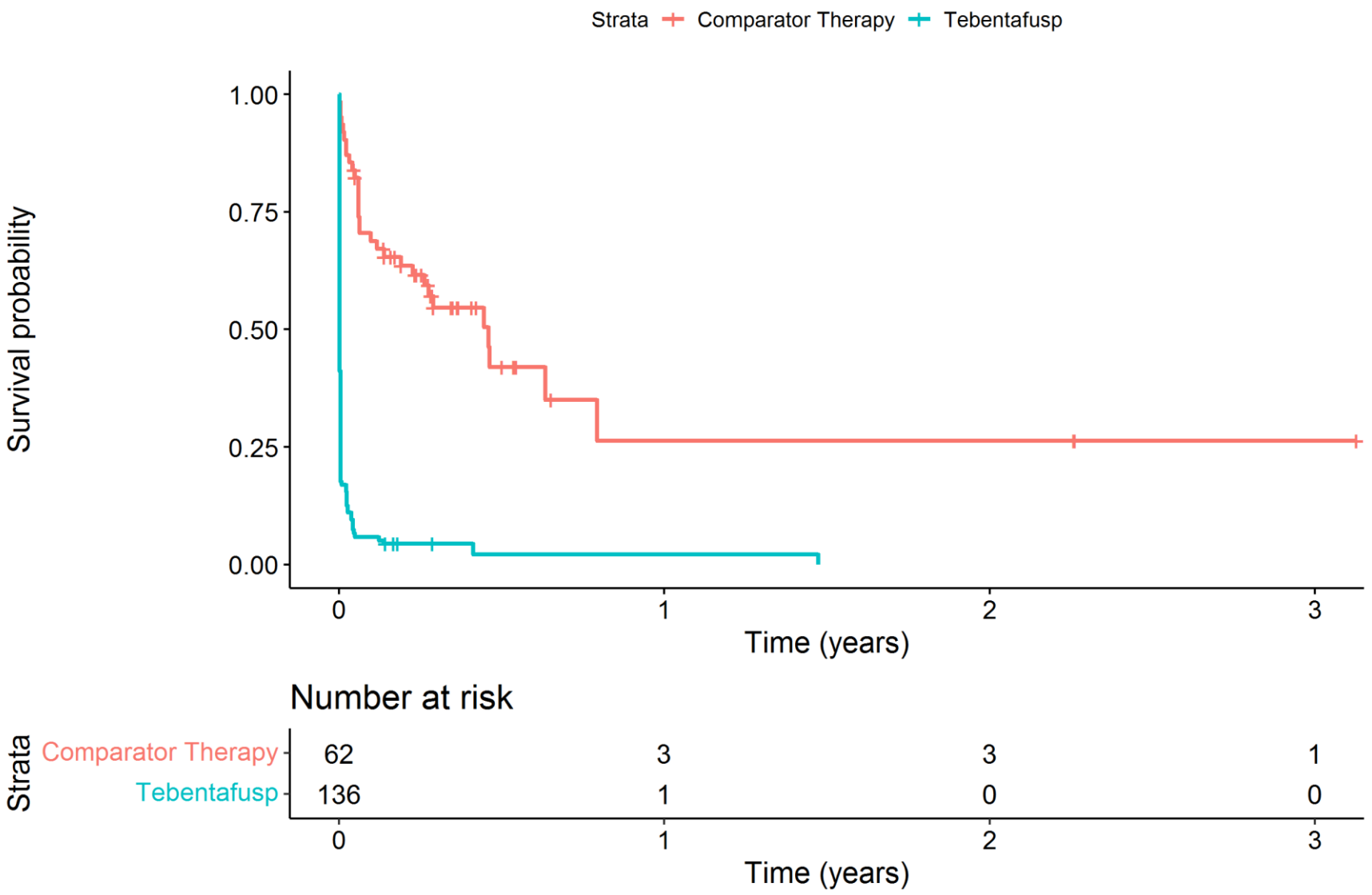
61.240 Erkrankungen der Haut und des Unterhautgewebes- Vorherige Therapie adjuvant/neoadjuvant



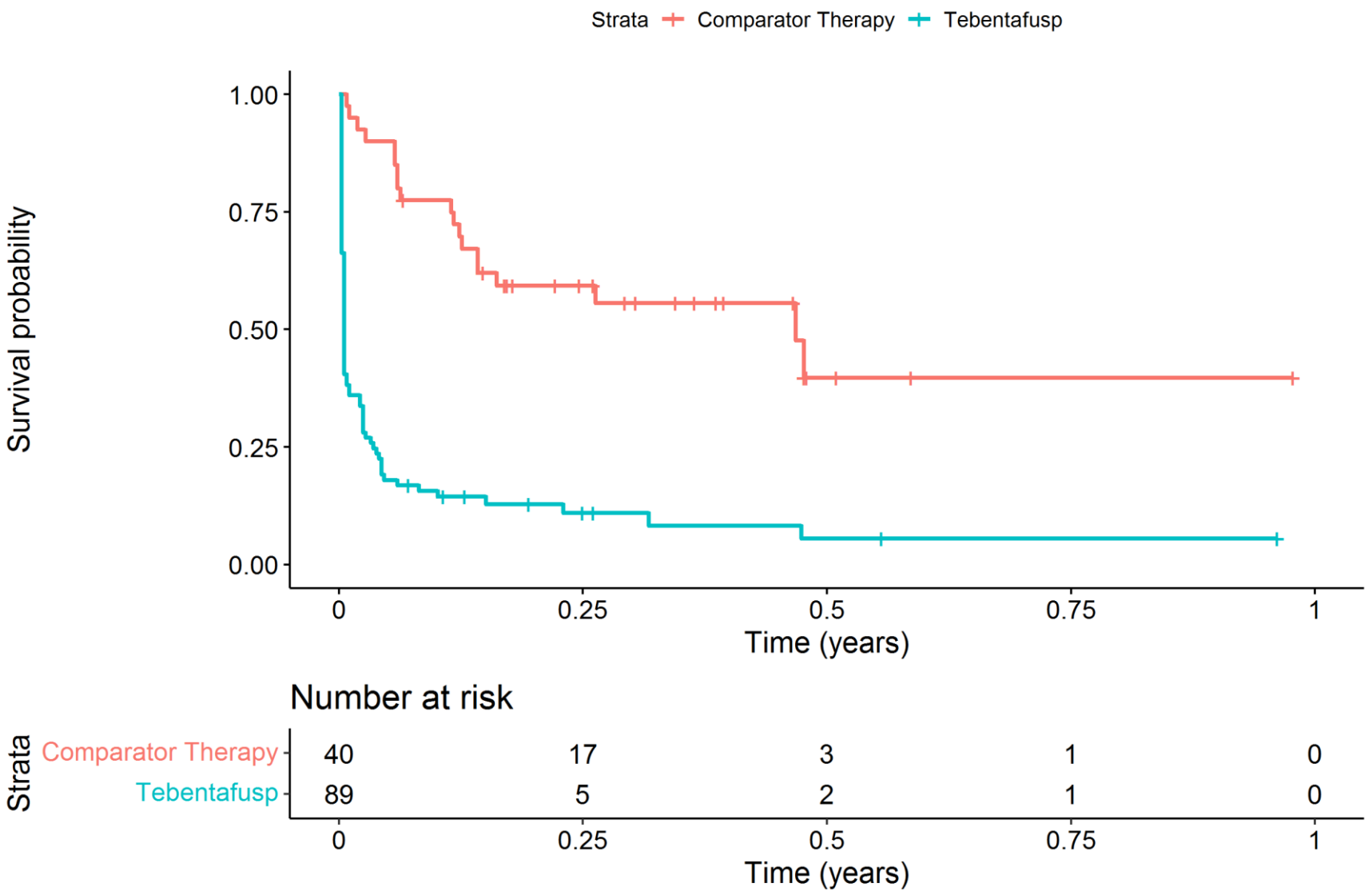
61.241 Erkrankungen der Haut und des Unterhautgewebes- Keine Vorherige Therapie adjuvant/neoadjuvant



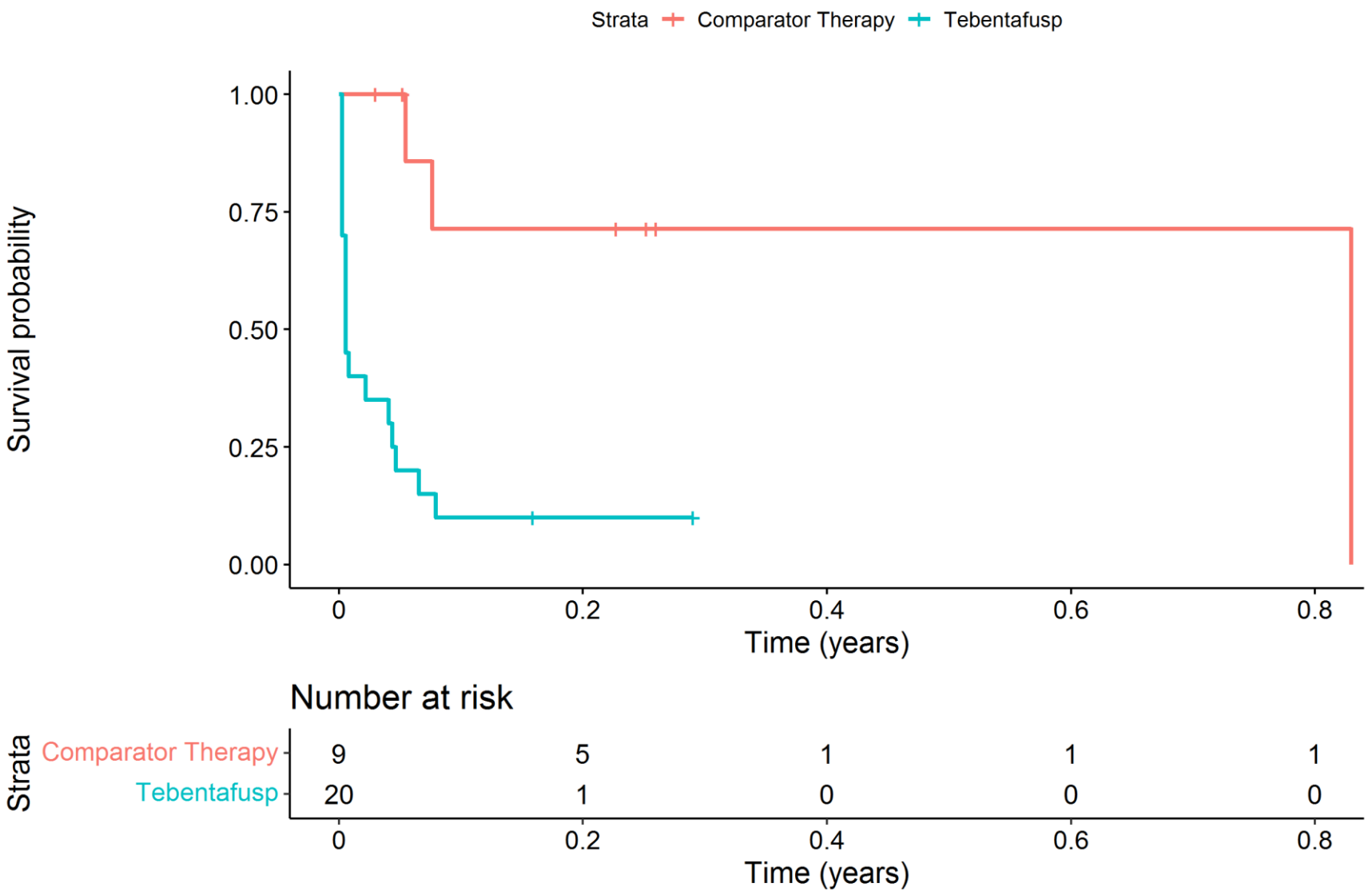
61.242 Erkrankungen der Haut und des Unterhautgewebes- Läsion ≤ 3cm



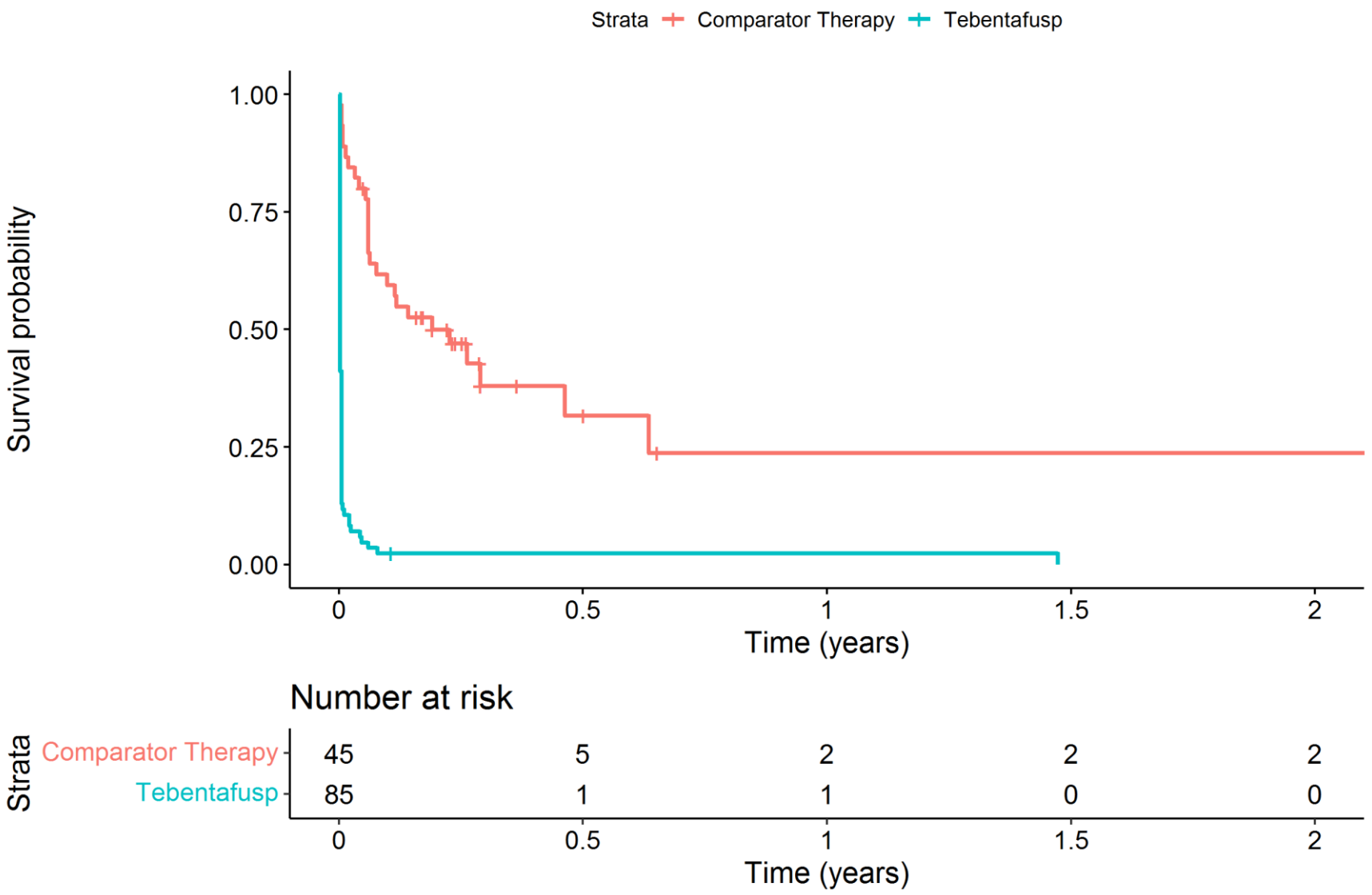
61.243 Erkrankungen der Haut und des Unterhautgewebes- Läsion 3,1-8,0 cm



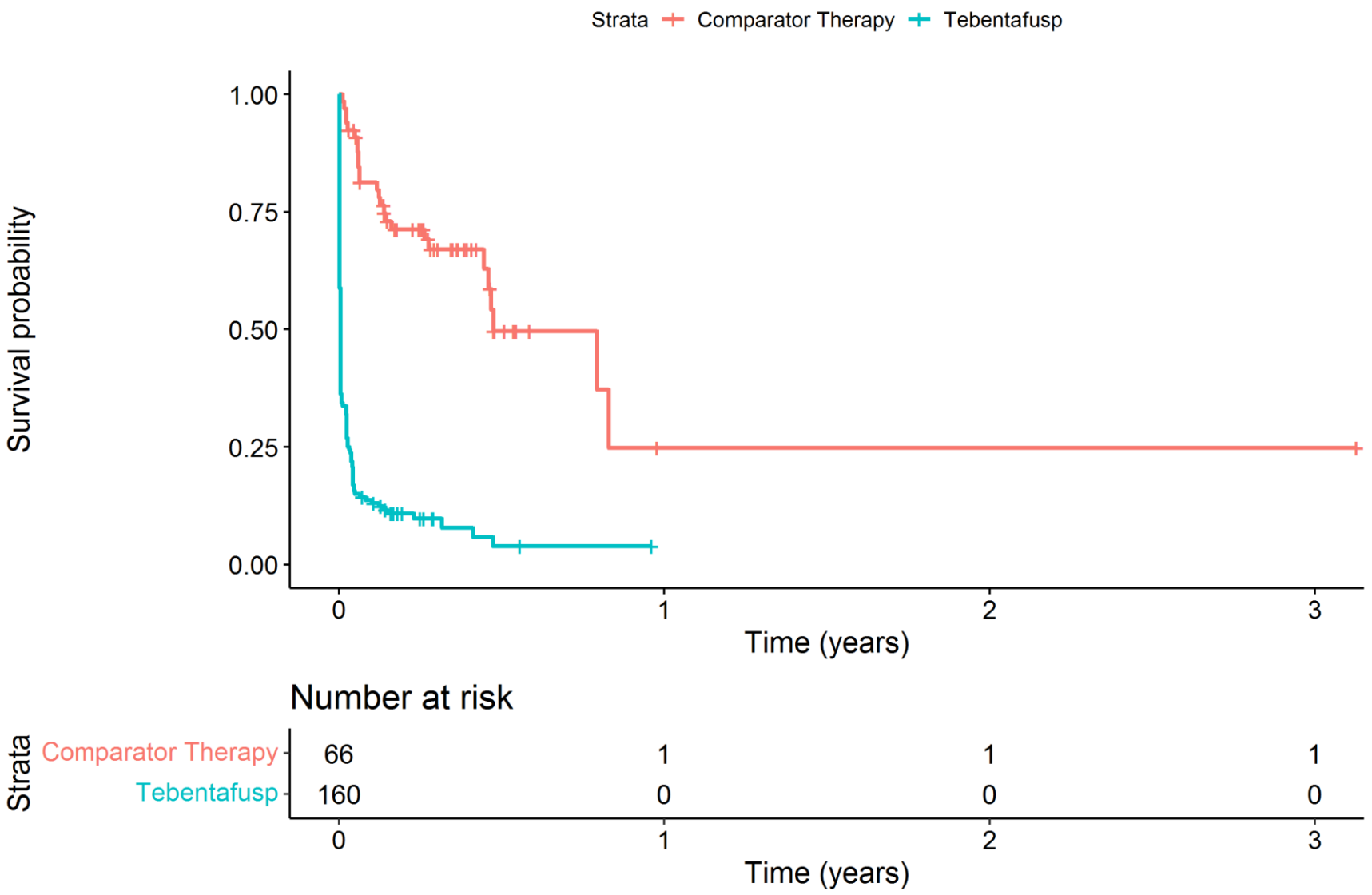
61.244 Erkrankungen der Haut und des Unterhautgewebes- Läsion ≥8,1 cm



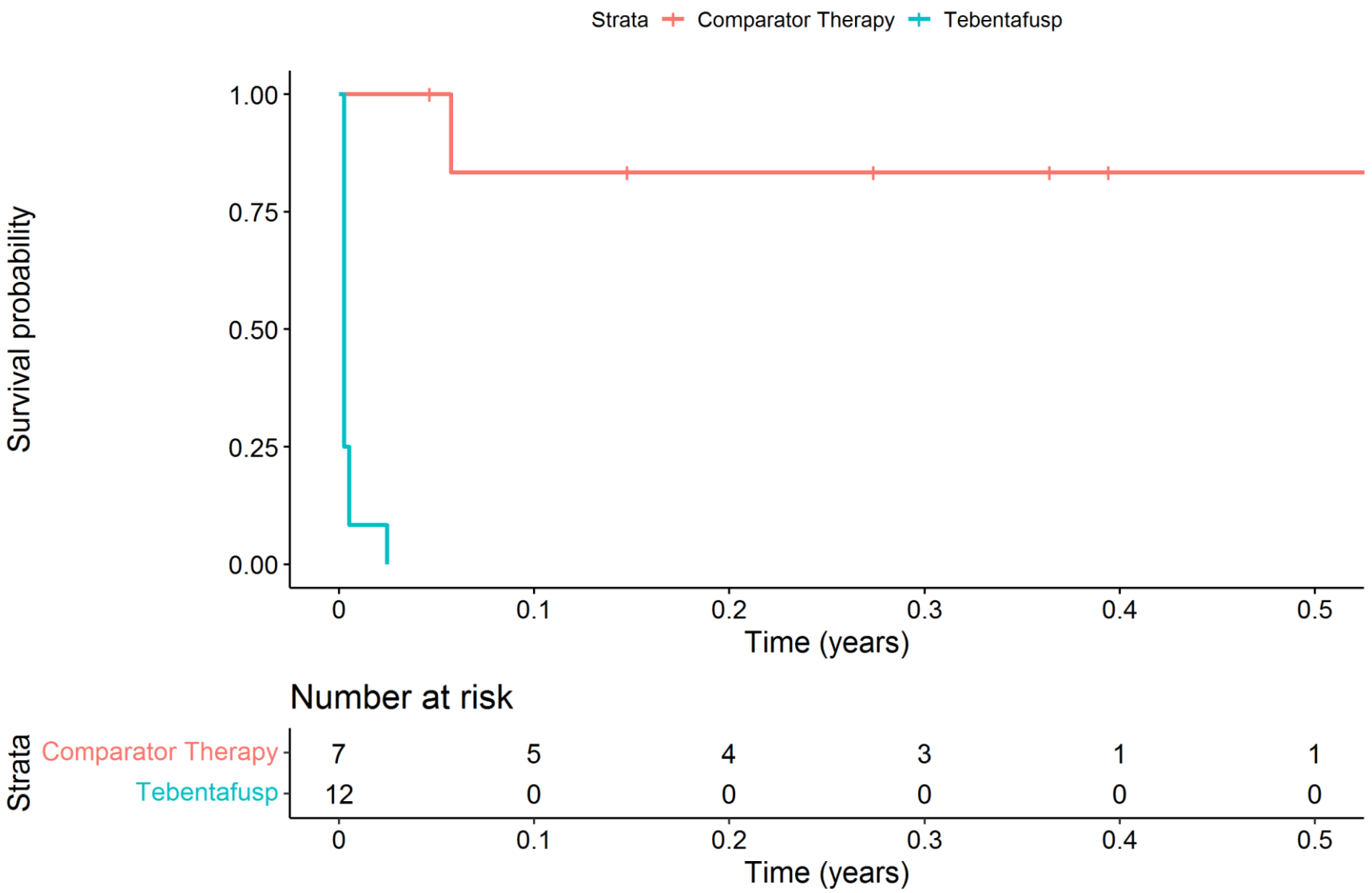
61.245 Erkrankungen der Haut und des Unterhautgewebes- Nordamerika



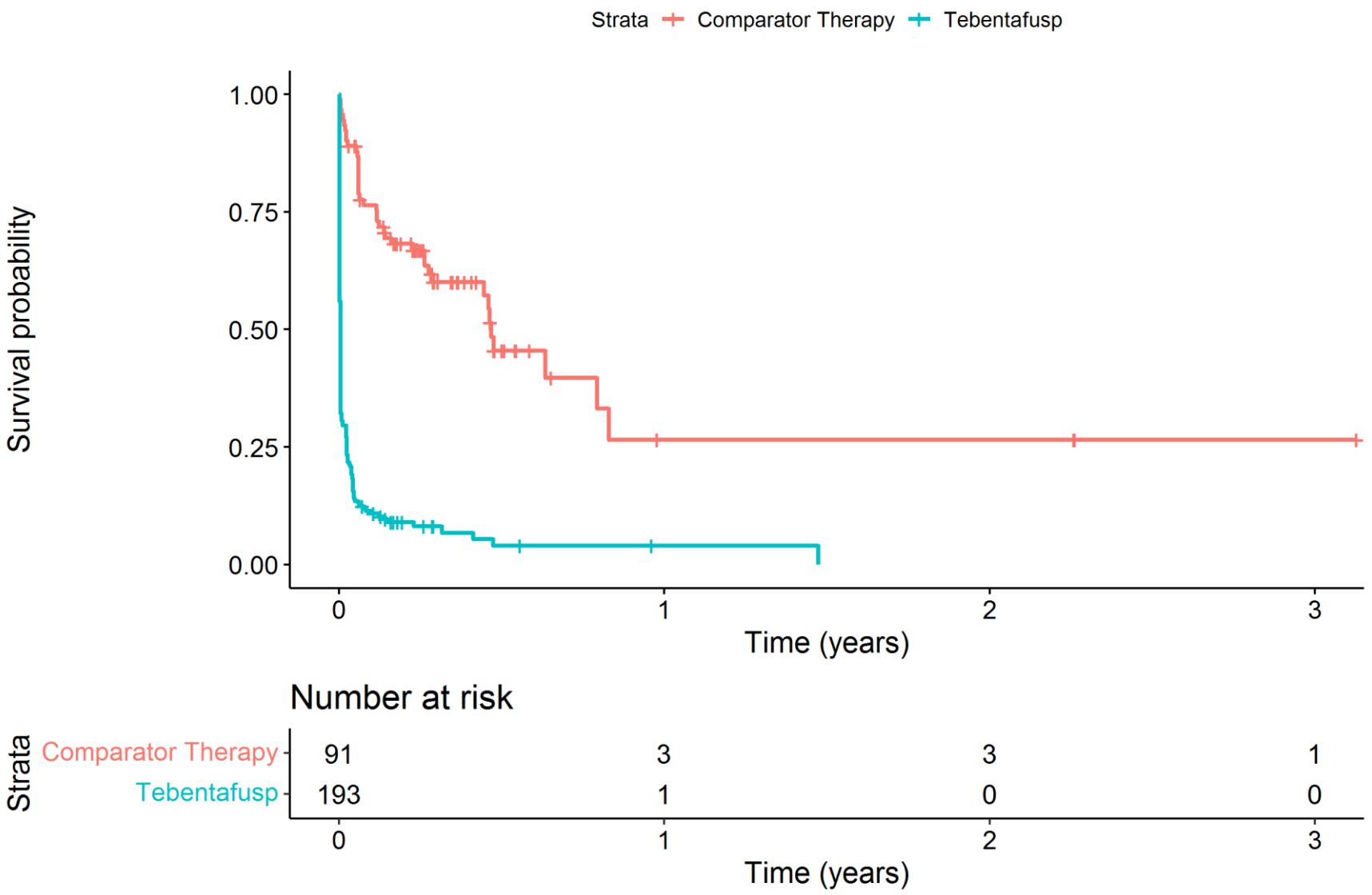
61.246 Erkrankungen der Haut und des Unterhautgewebes- Nicht-Nordamerika



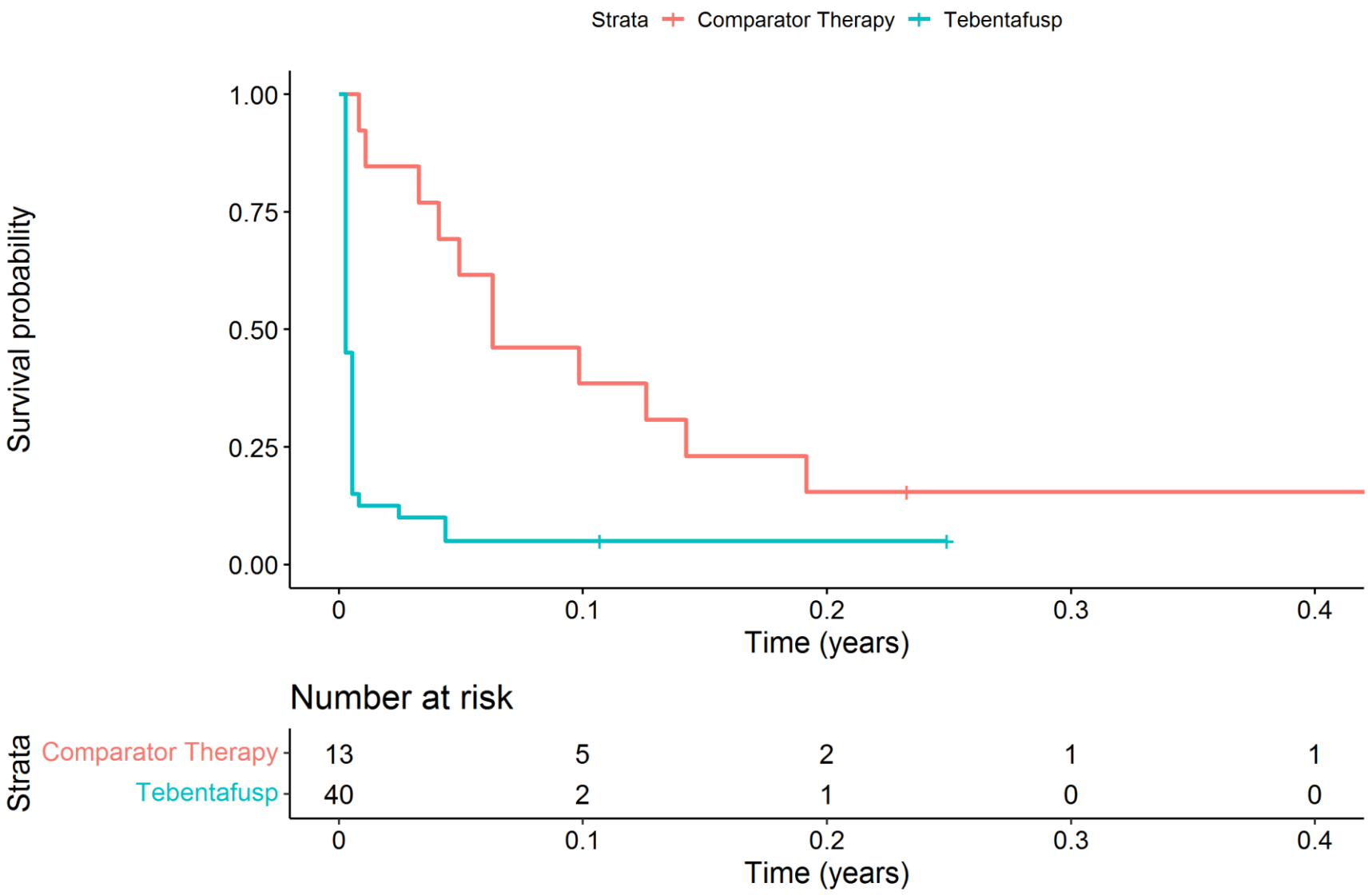
61.247 Erkrankungen der Haut und des Unterhautgewebes- Dacarbazin



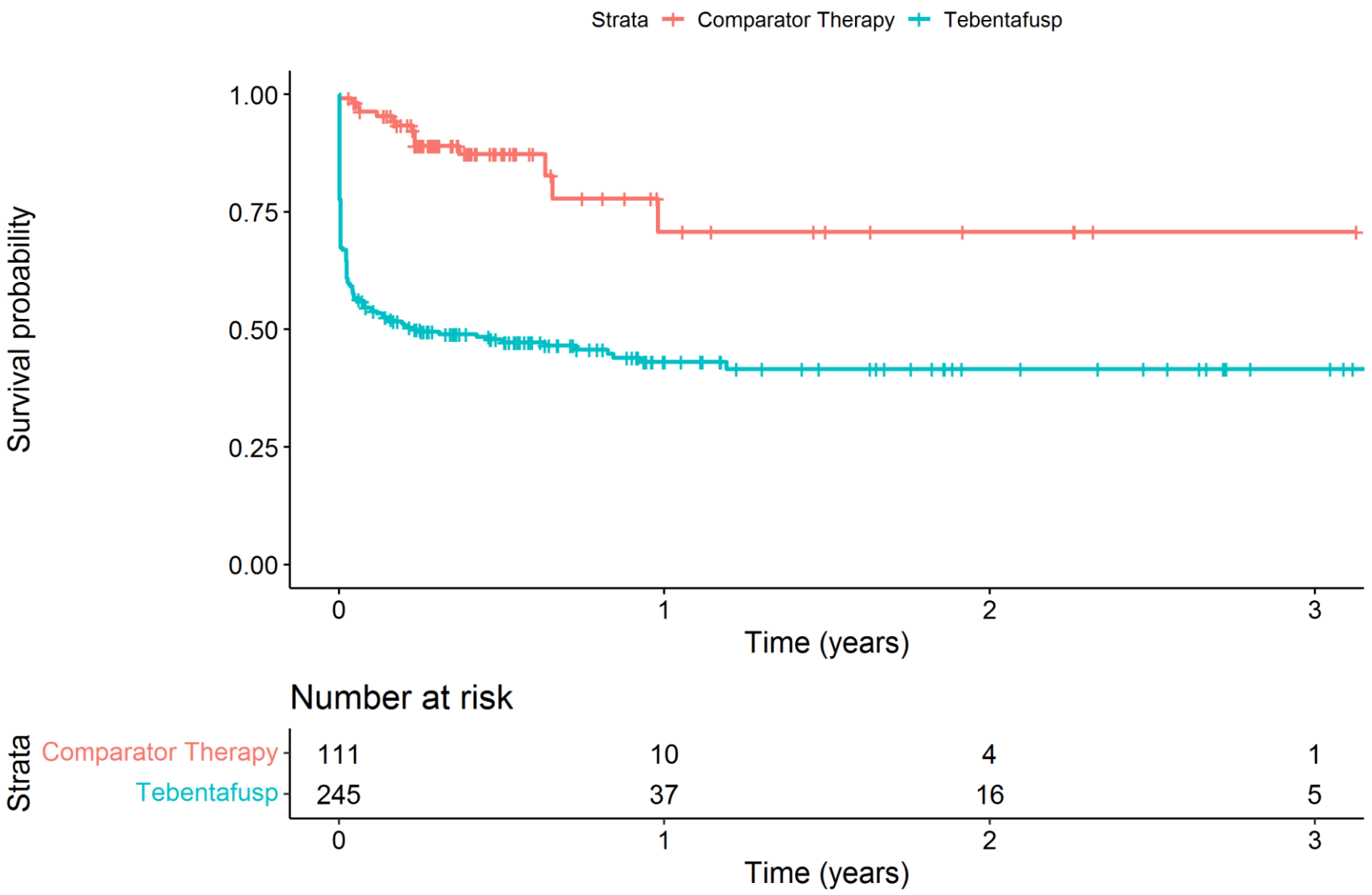
61.248 Erkrankungen der Haut und des Unterhautgewebes- Pembrolizumab



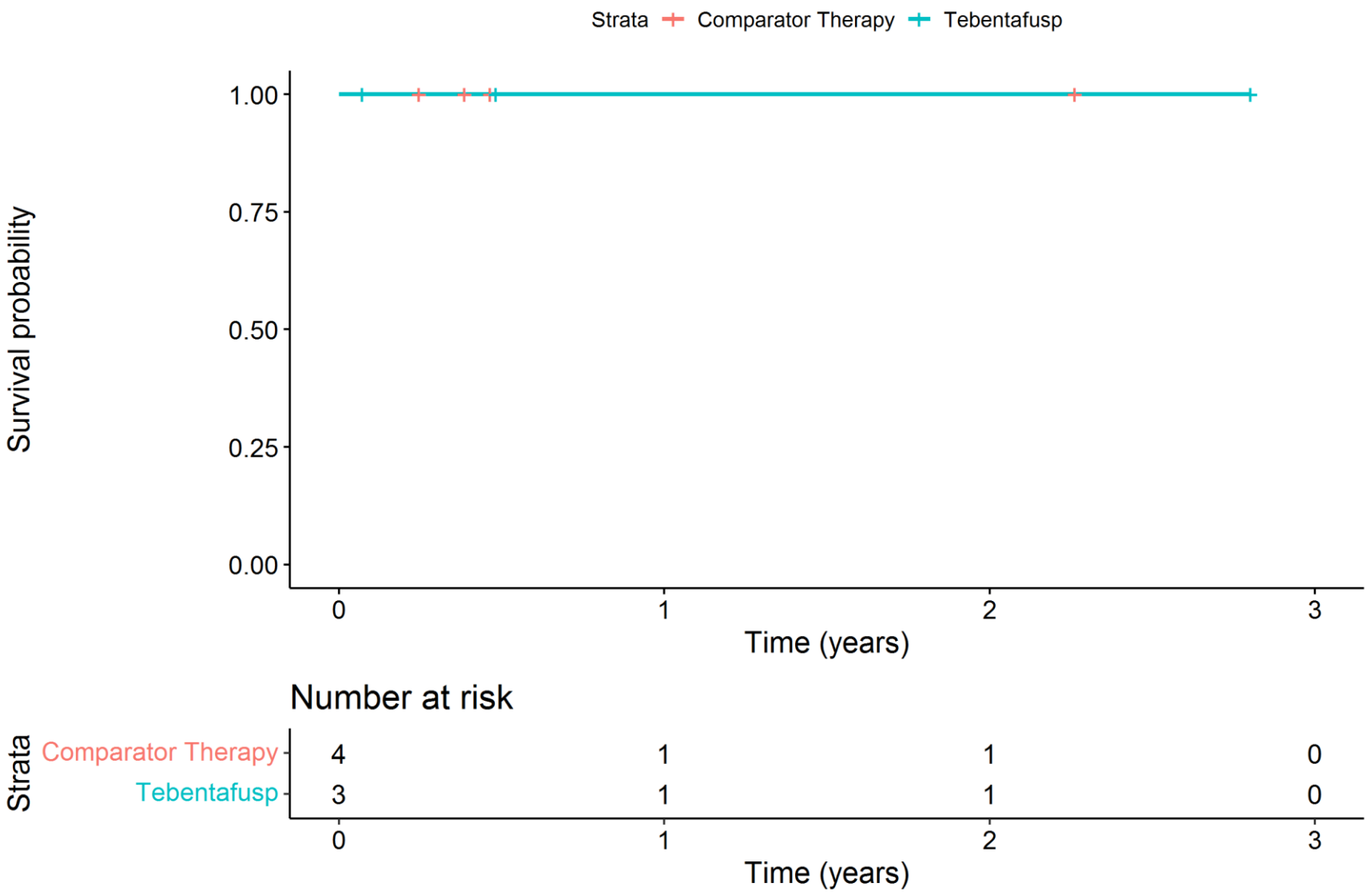
61.249 Erkrankungen der Haut und des Unterhautgewebes- Ipilimumab



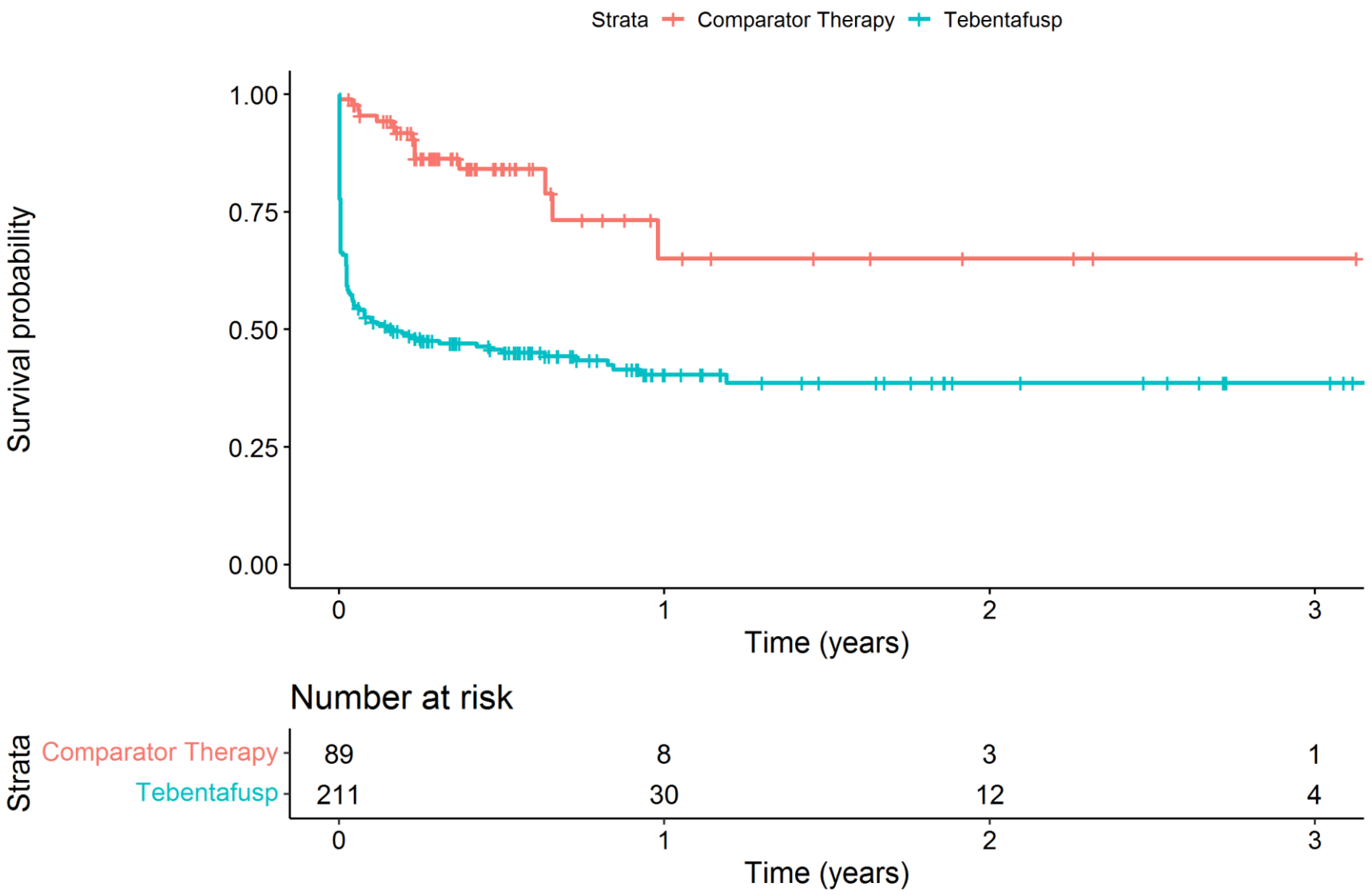
61.250 Gefäßerkrankungen- Gesamt



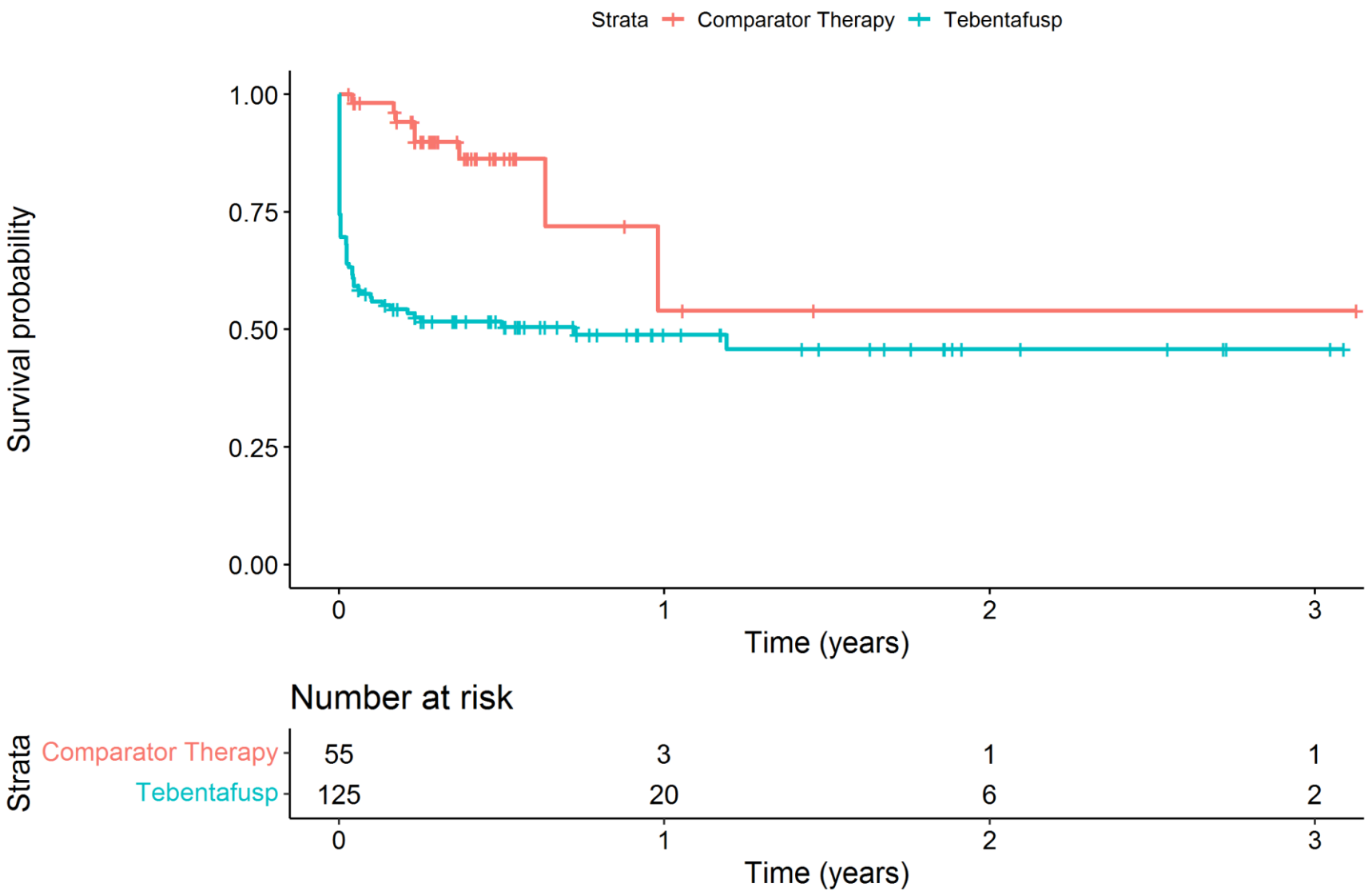
61.251 Gefäßerkrankungen- Hispanisch



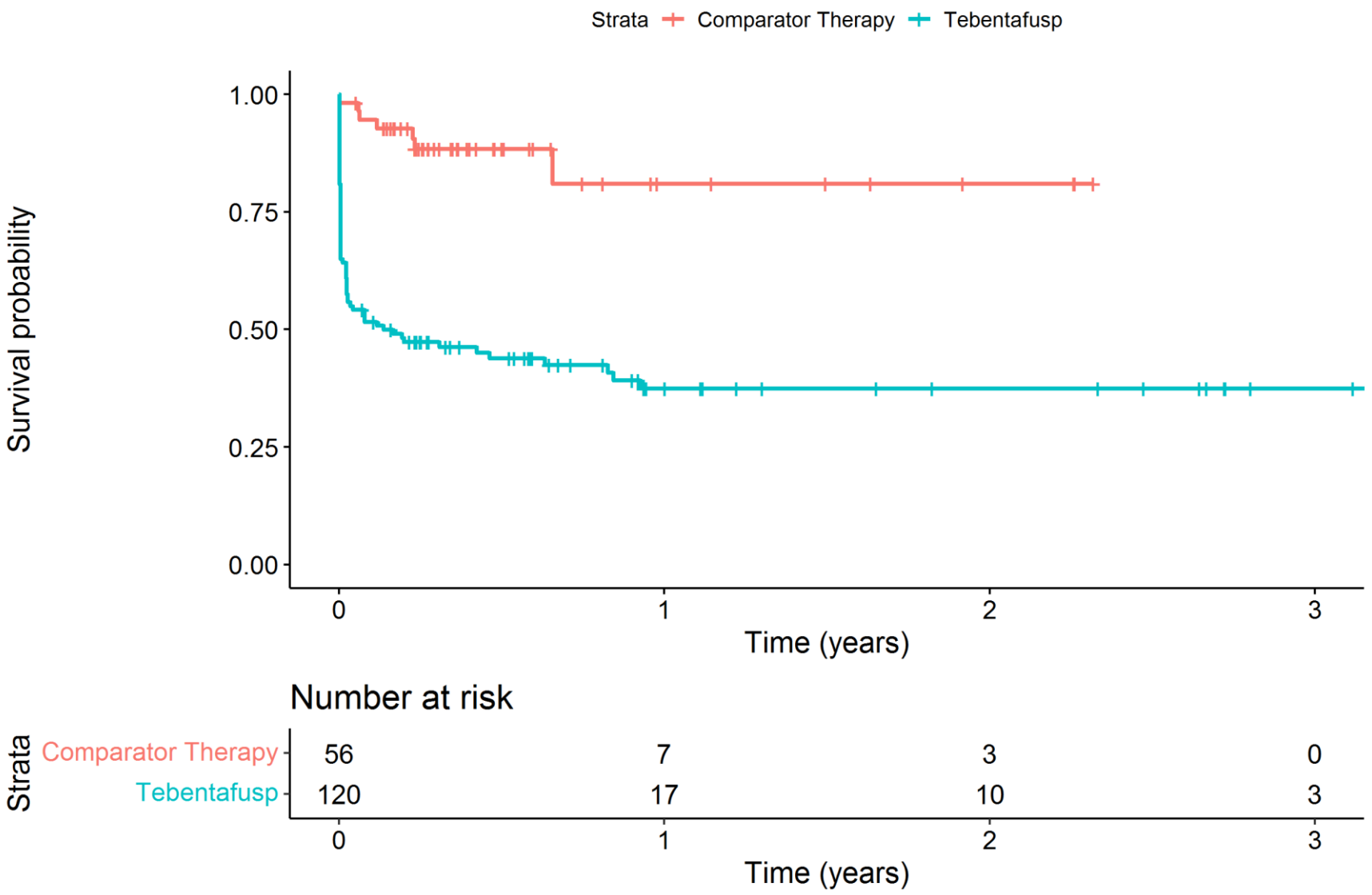
61.252 Gefäßerkrankungen- Nicht-hispanisch



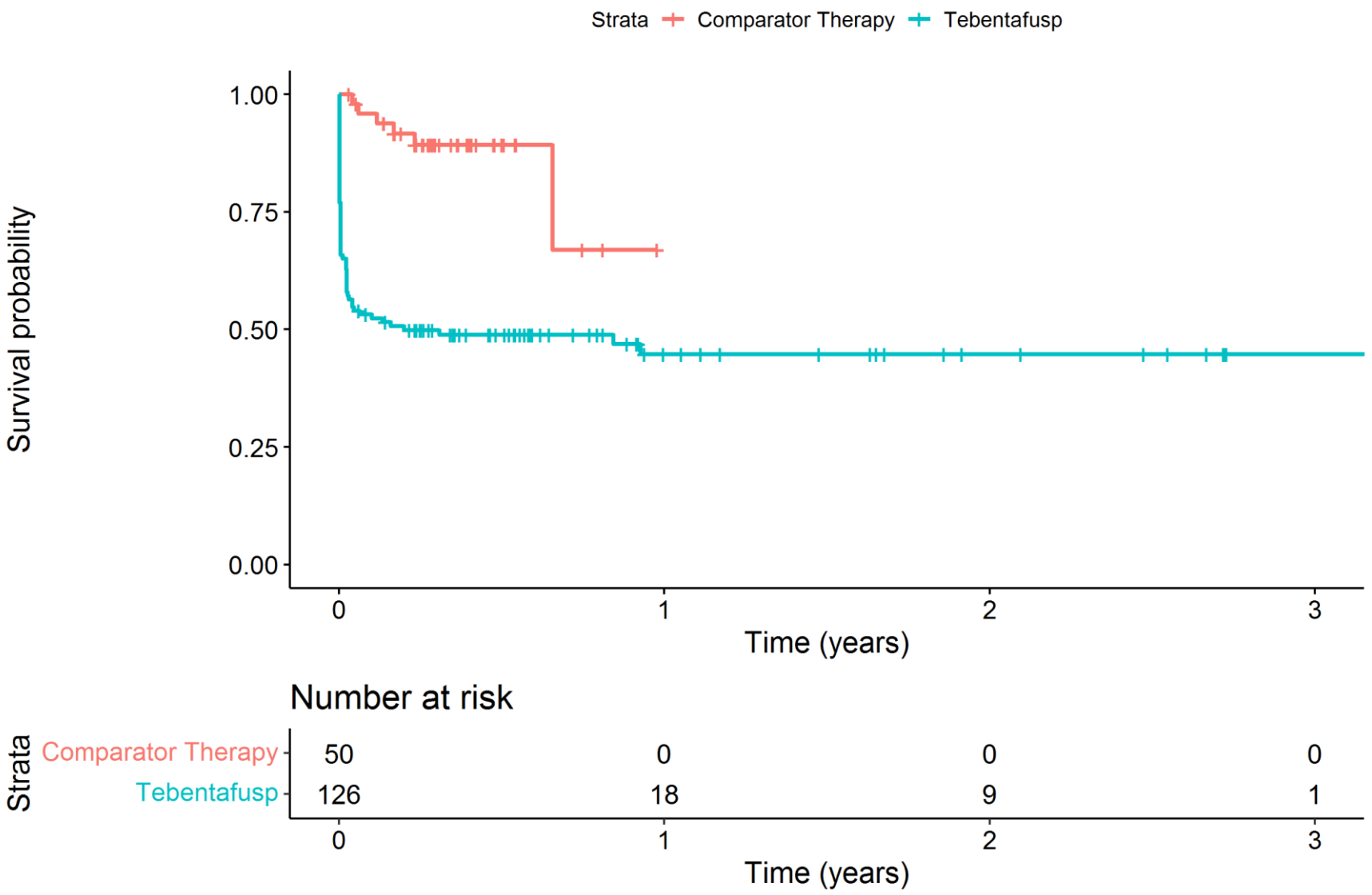
61.253 Gefäßerkrankungen- Männlich



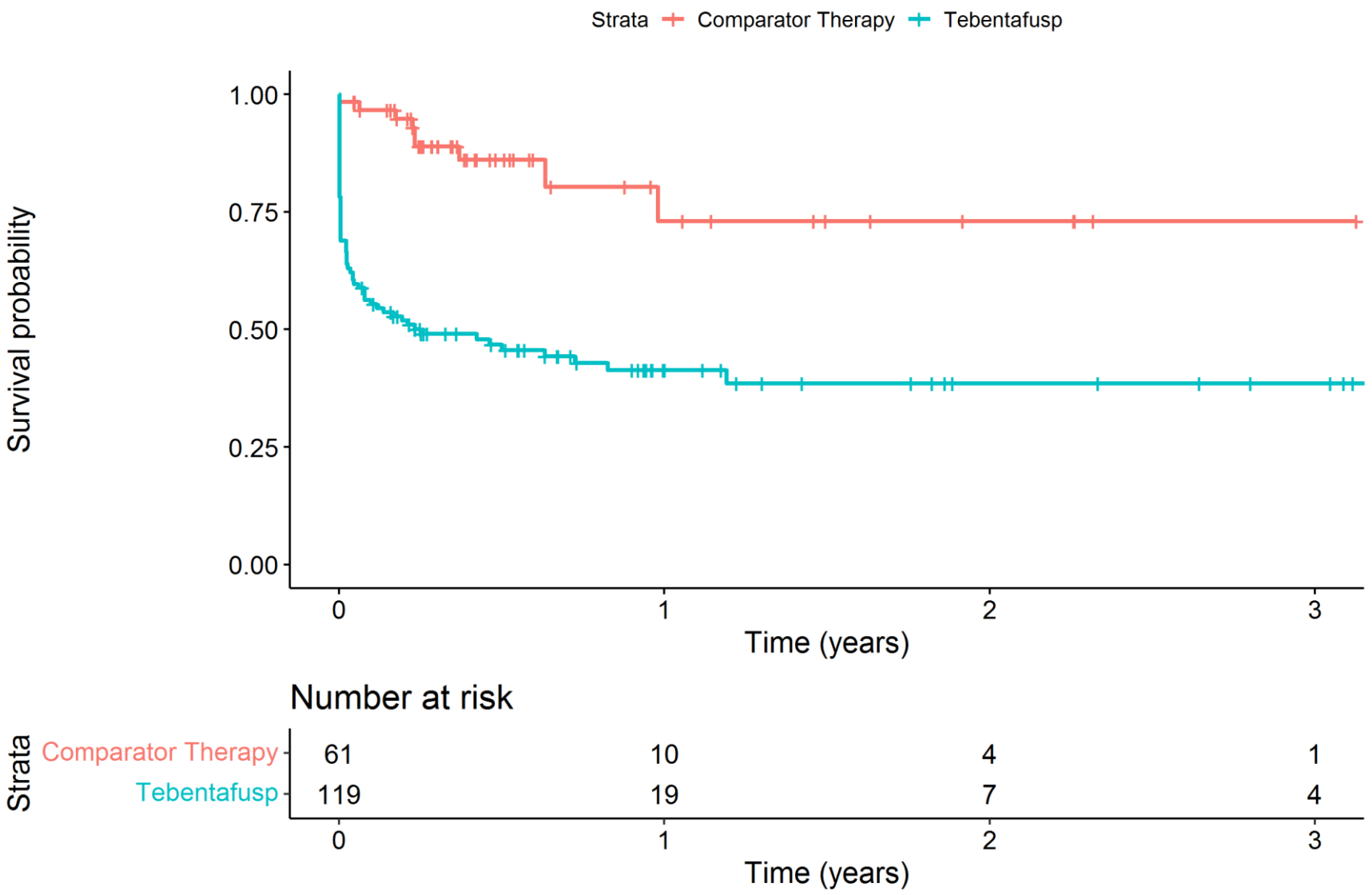
61.254 Gefäßerkrankungen- Weiblich



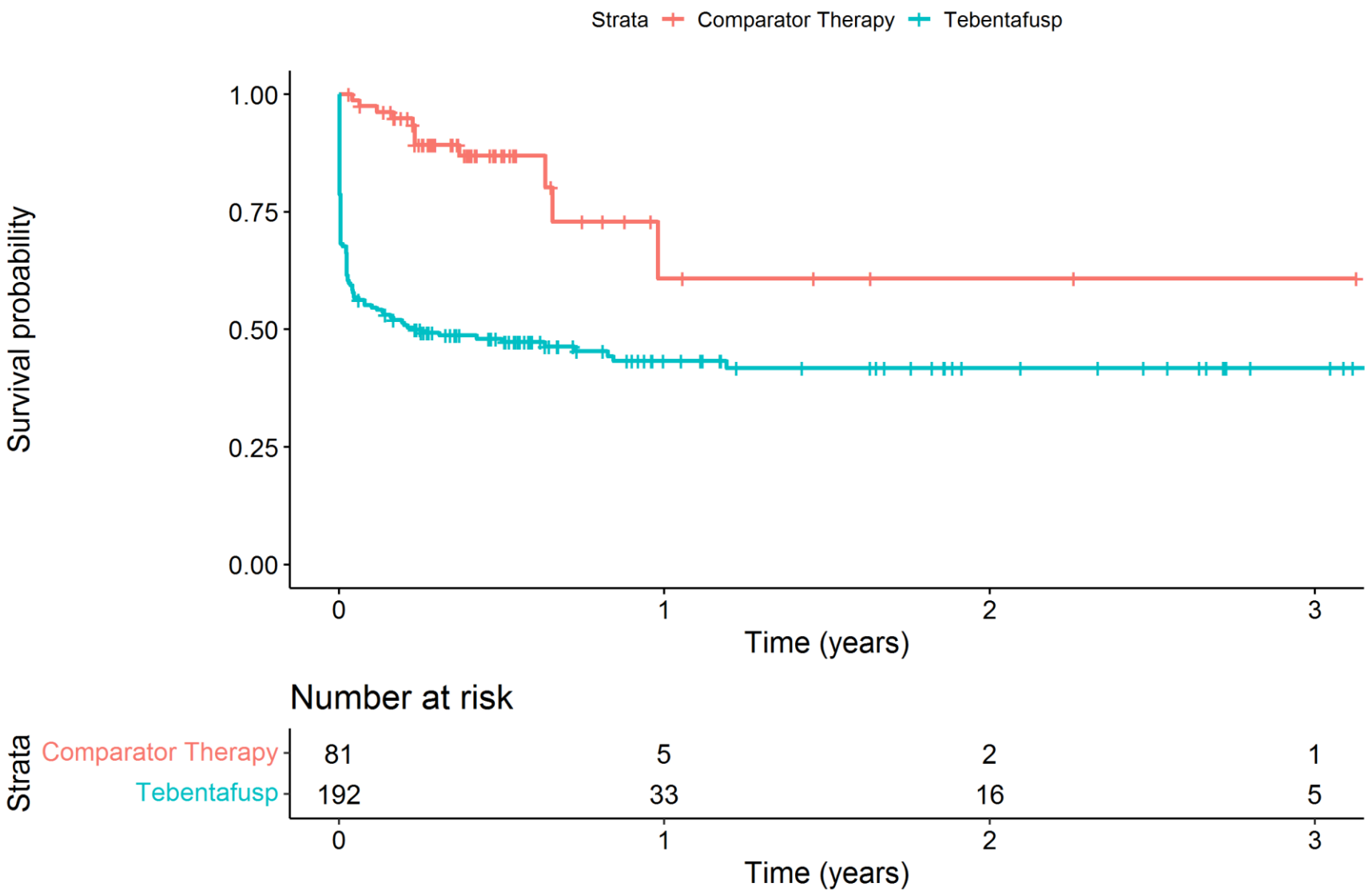
61.255 Gefäßerkrankungen- <65



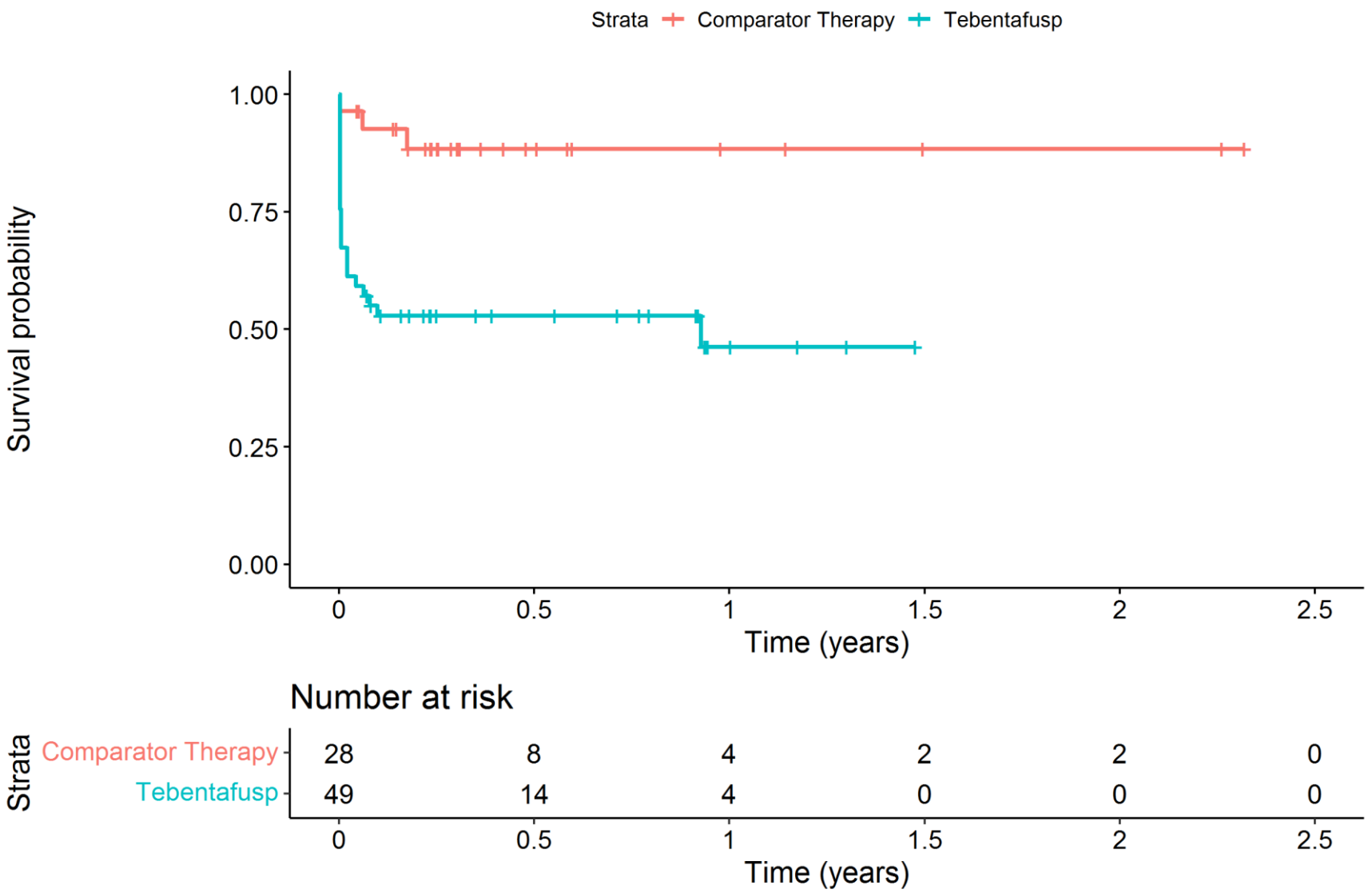
61.256 Gefäßerkrankungen- ≥65



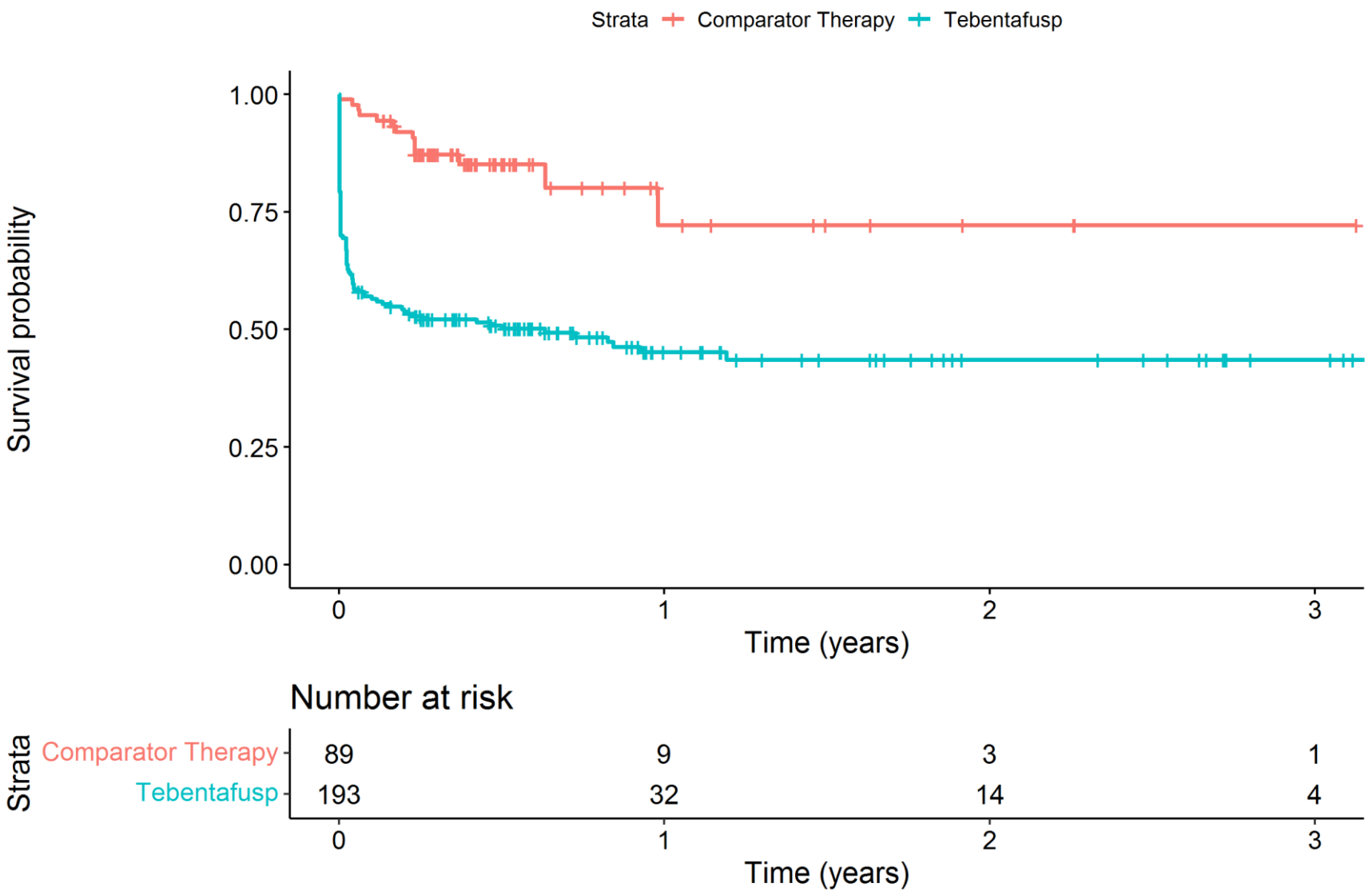
61.257 Gefäßerkrankungen- ECOG 0



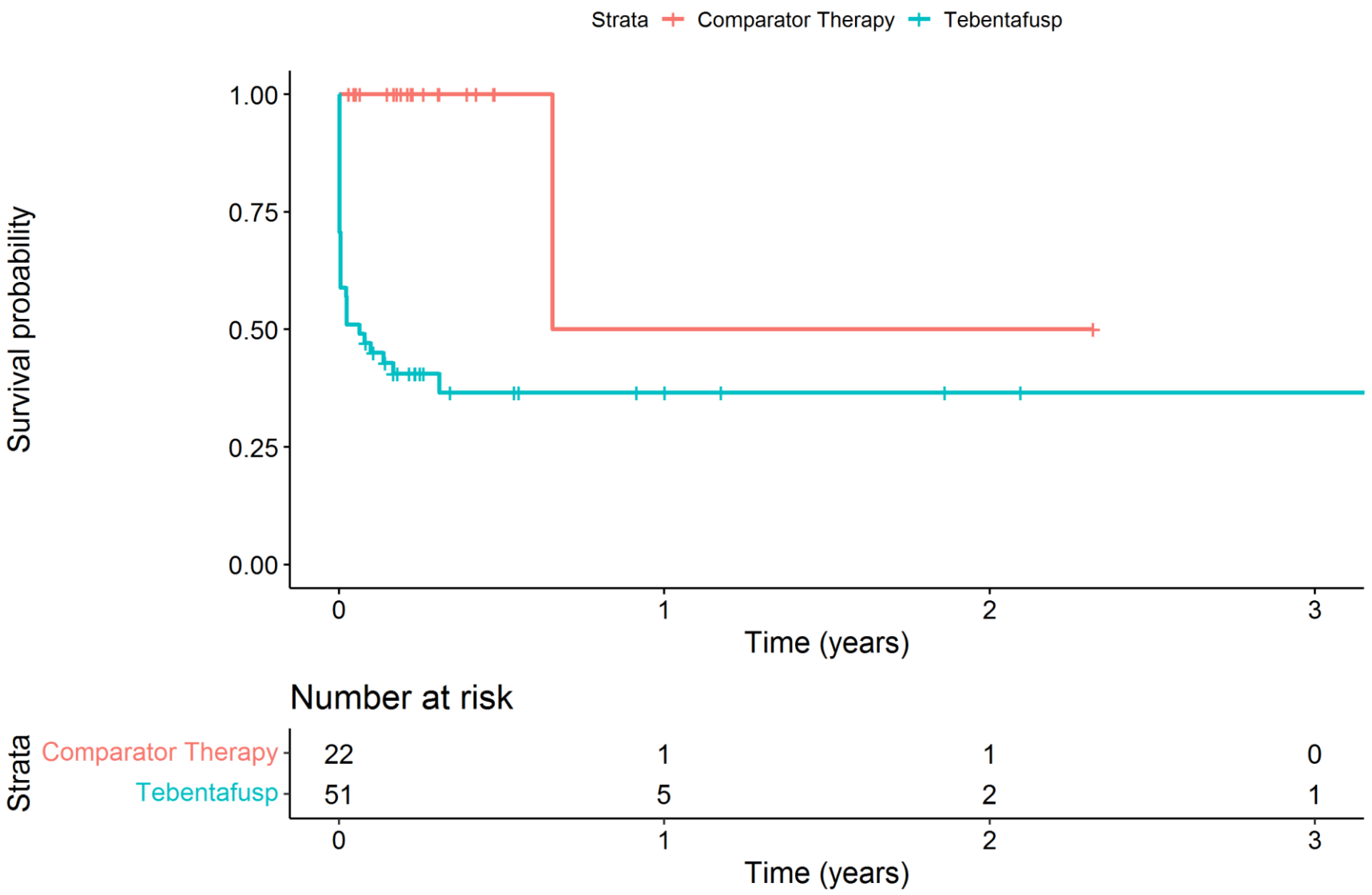
61.258 Gefäßerkrankungen- ECOG 1



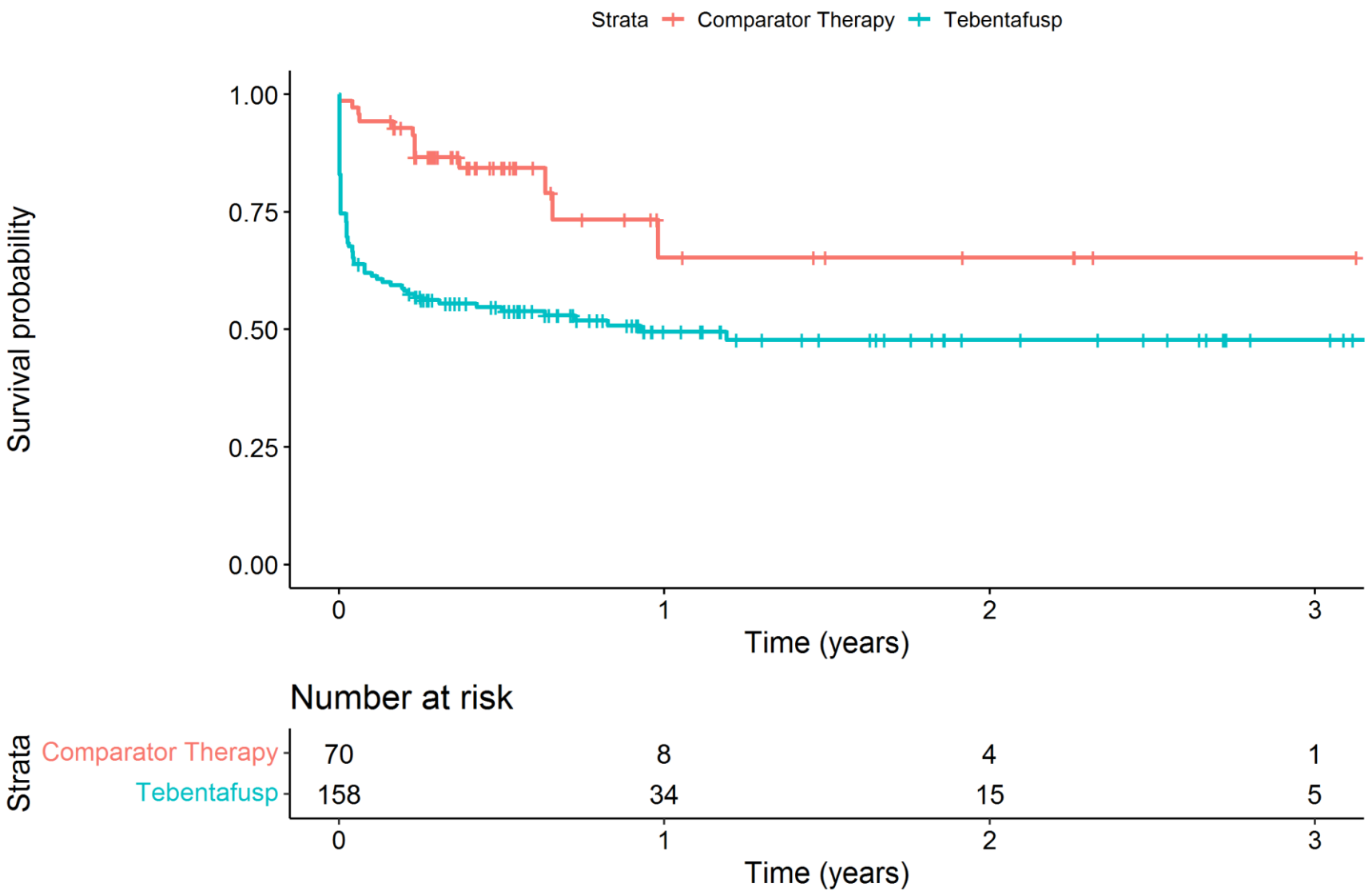
61.259 Gefäßerkrankungen- ALP ≤ ULN



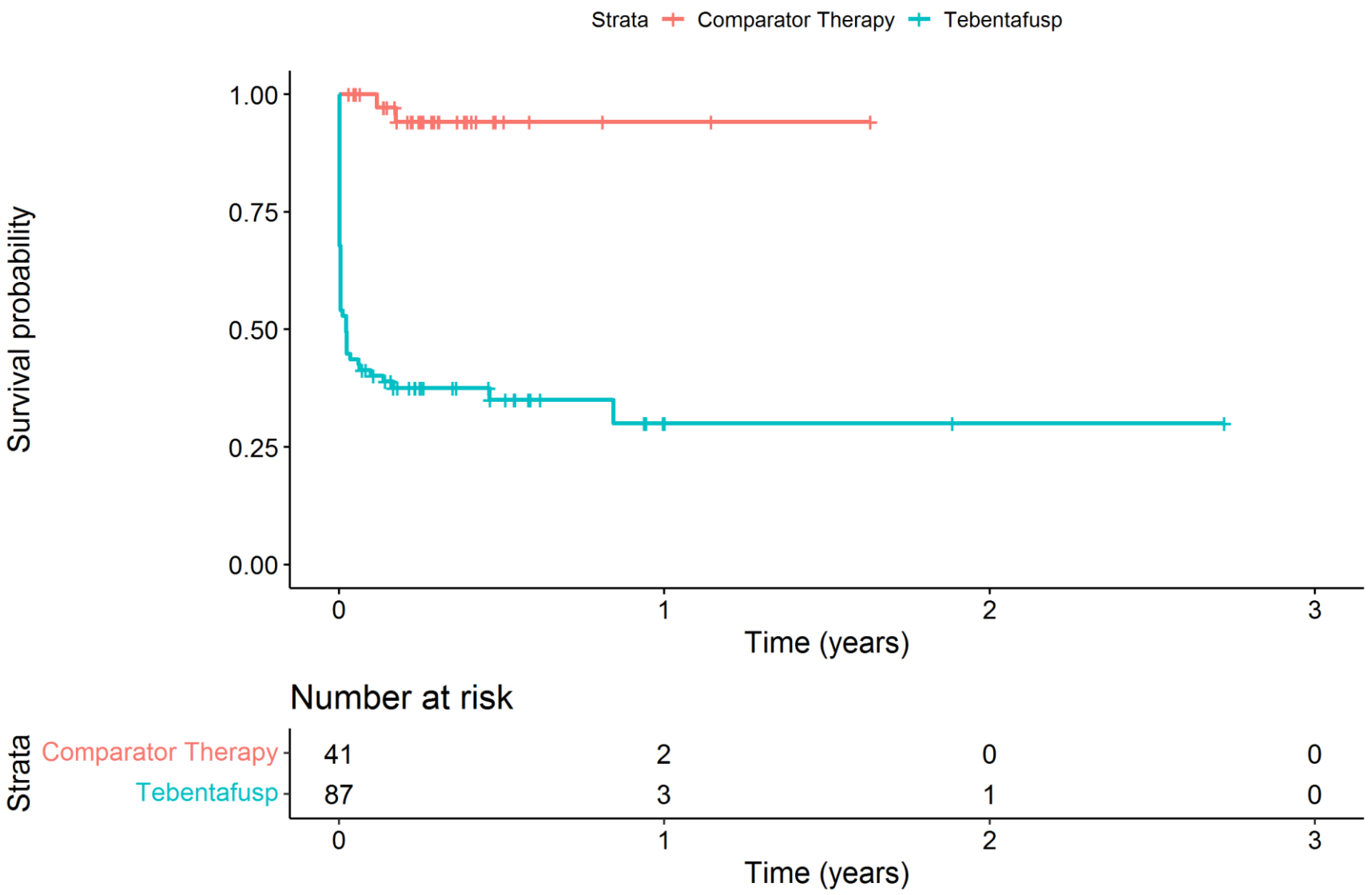
61.260 Gefäßerkrankungen- ALP > ULN



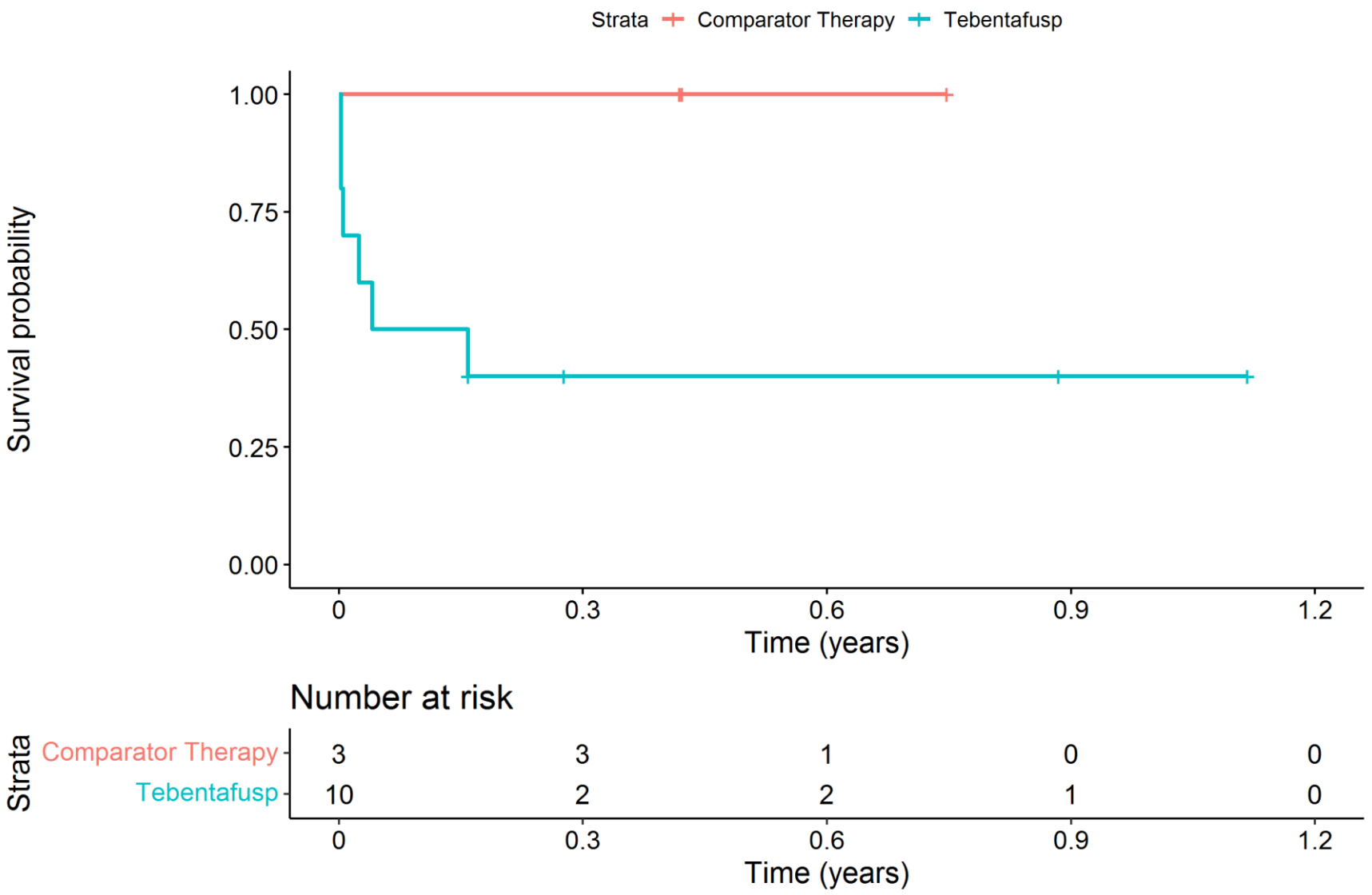
61.261 Gefäßerkrankungen- LDH =< ULN



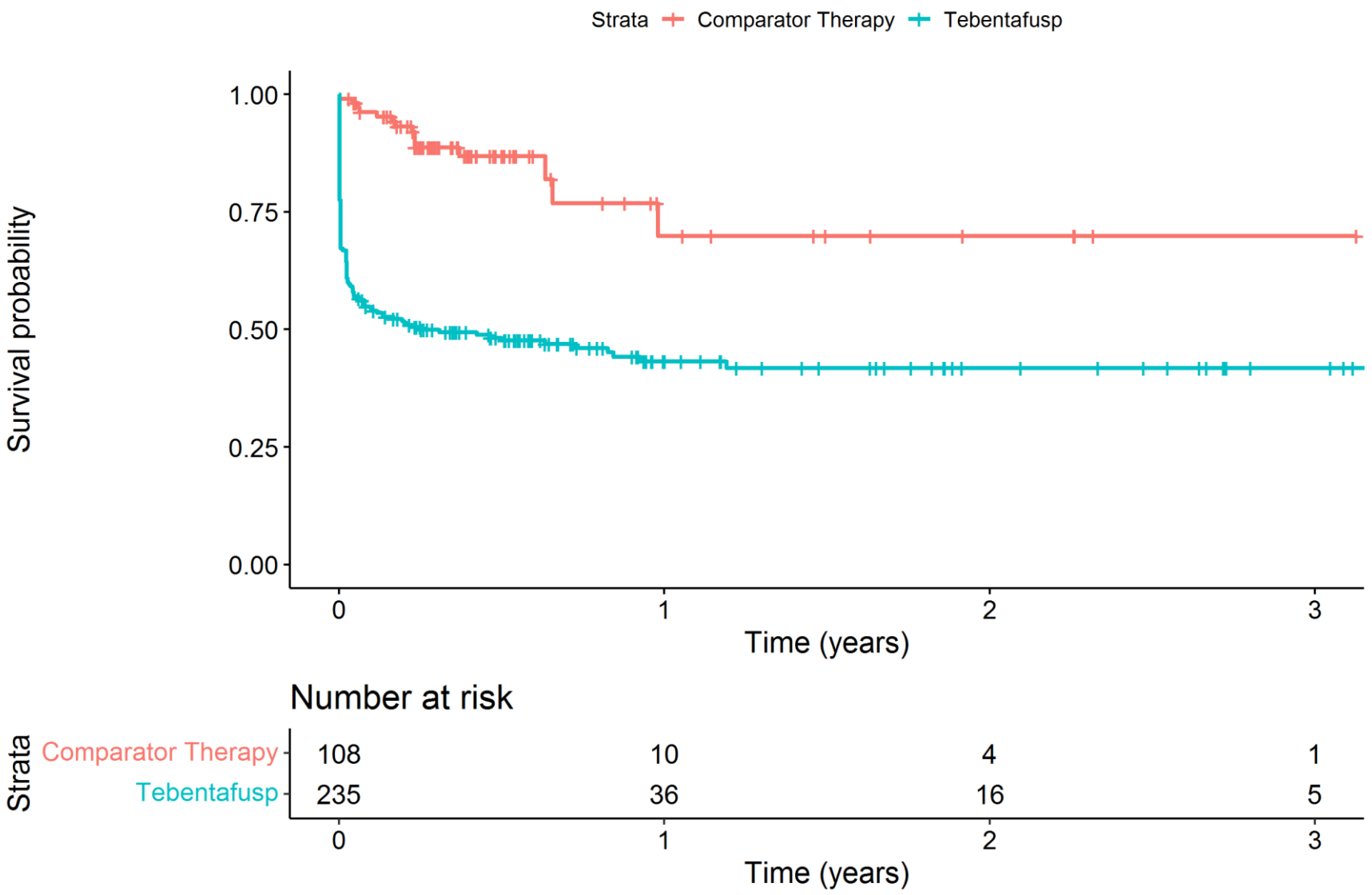
61.262 Gefäßerkrankungen- LDH > ULN



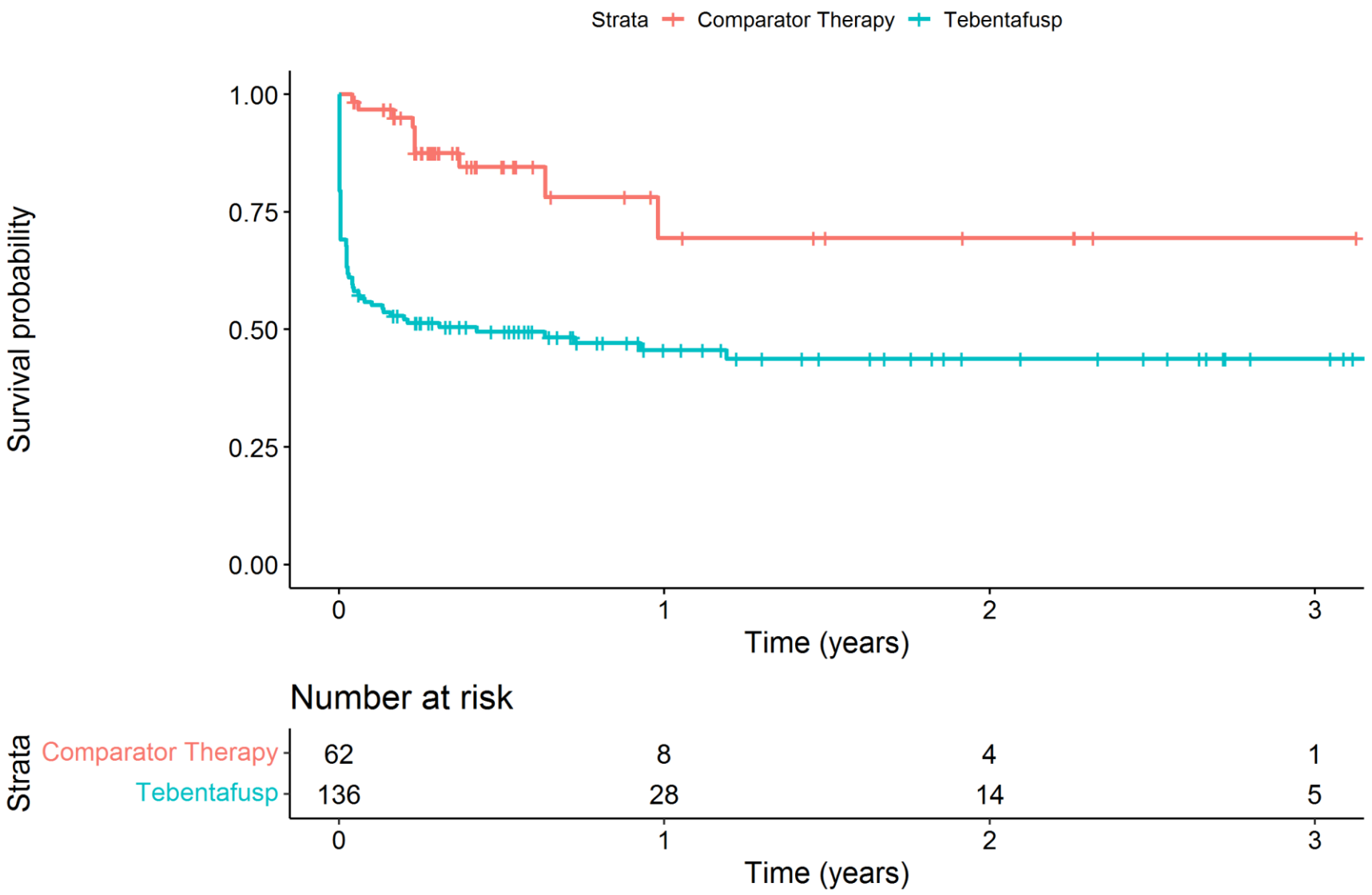
61.263 Gefäßerkrankungen- Vorherige Therapie adjuvant/neoadjuvant



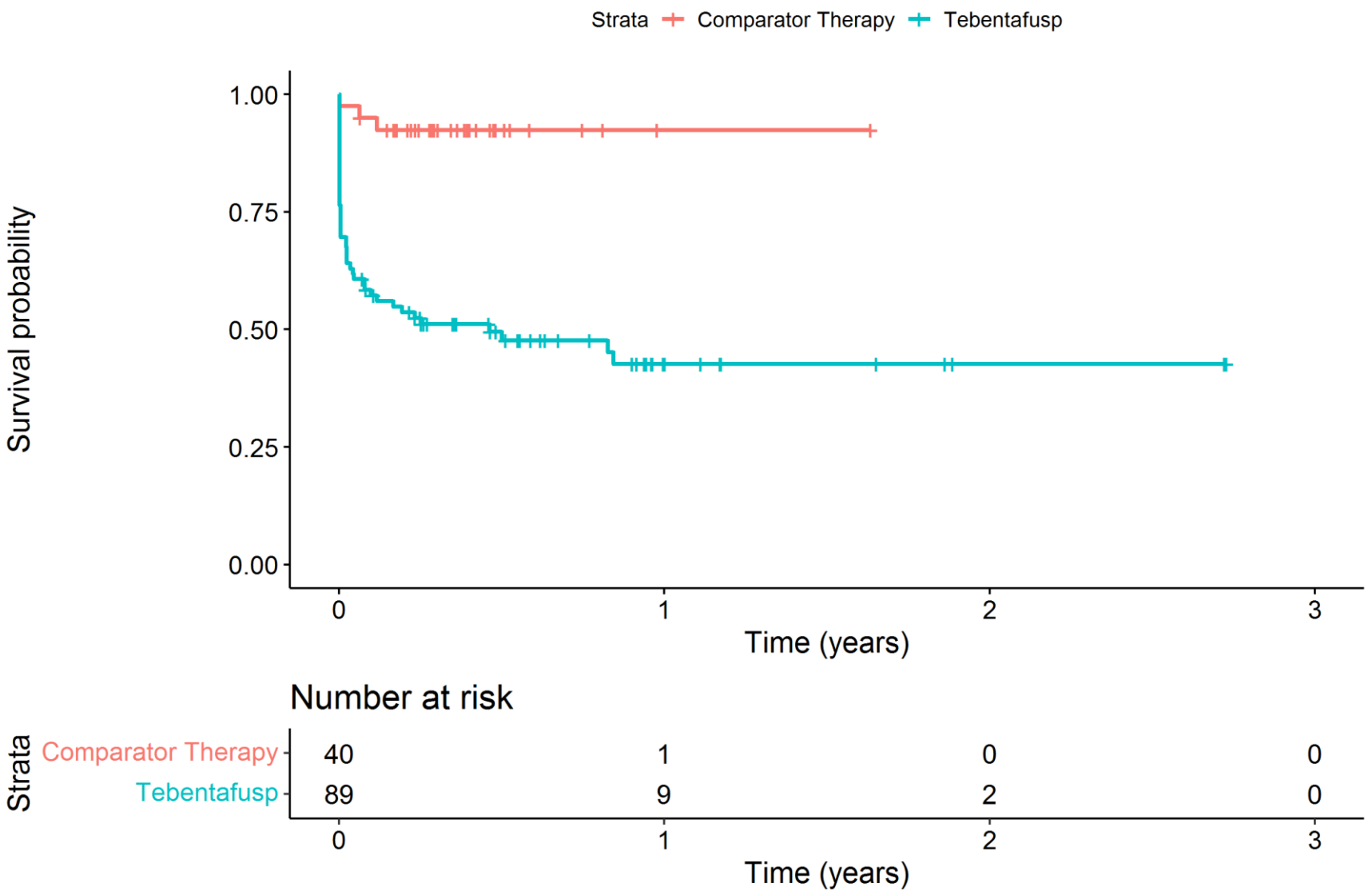
61.264 Gefäßerkrankungen- Keine Vorherige Therapie adjuvant/neoadjuvant



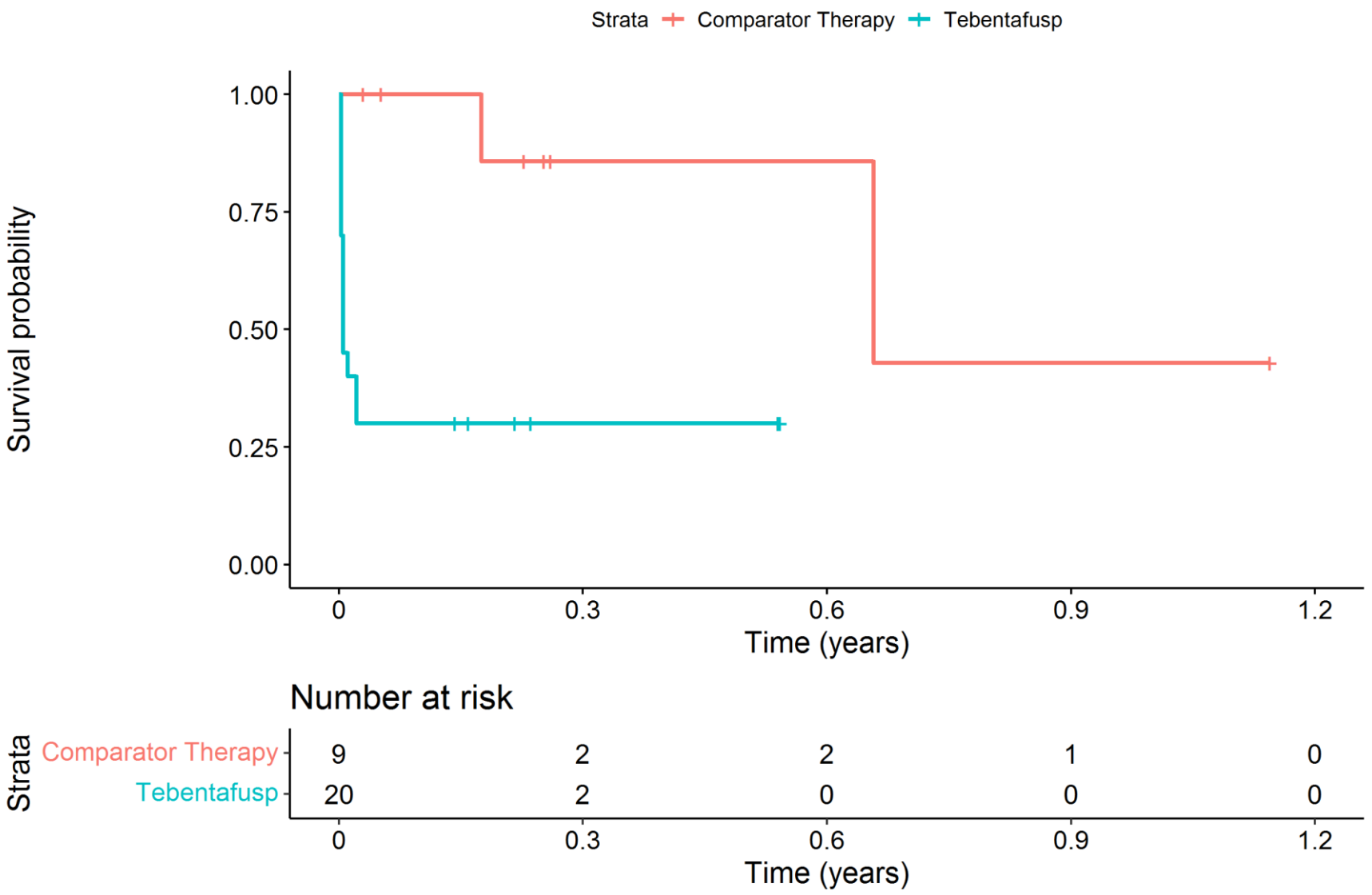
61.265 Gefäßerkrankungen- Läsion ≤ 3cm



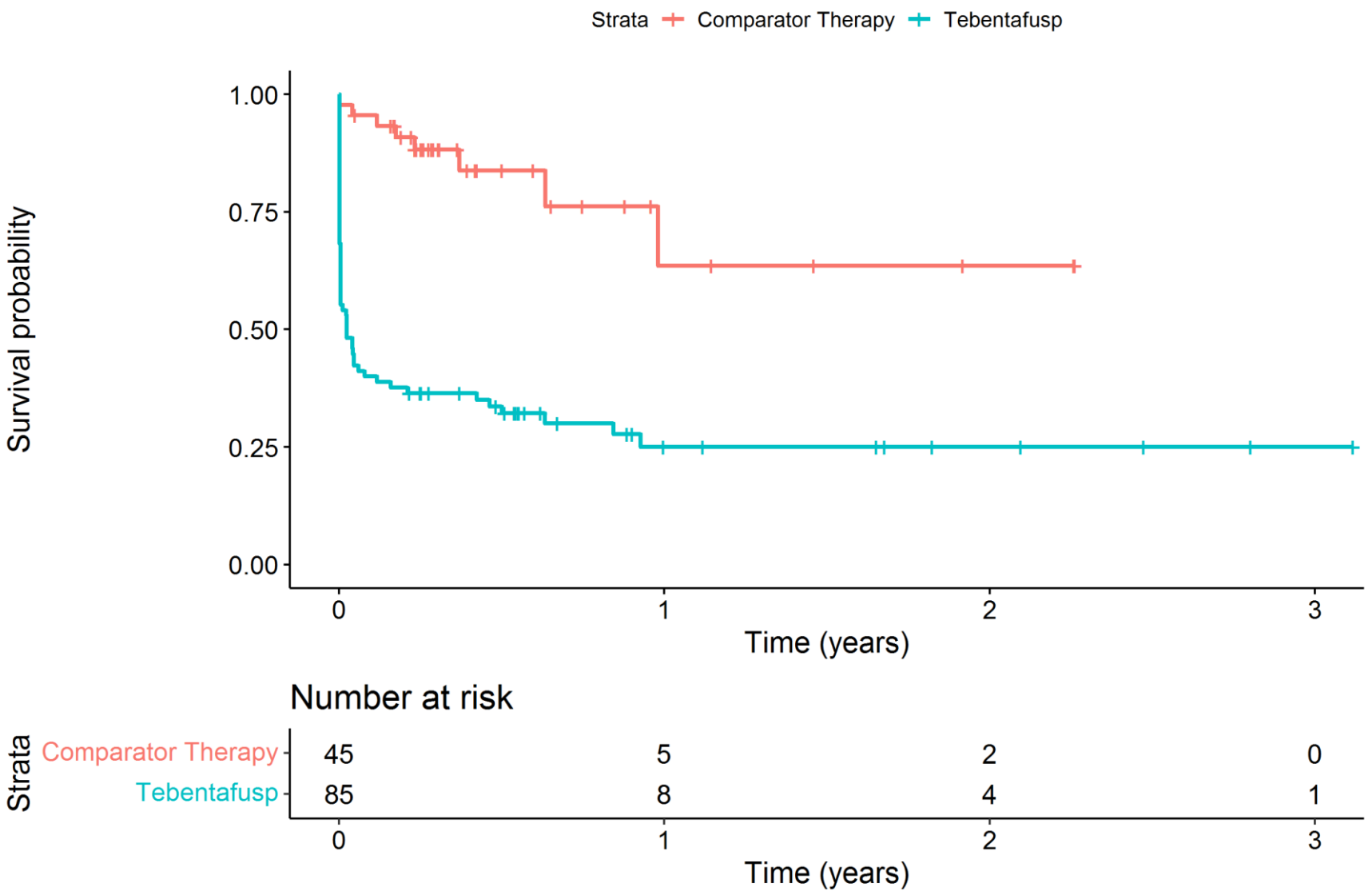
61.266 Gefäßerkrankungen- Läsion 3,1-8,0 cm



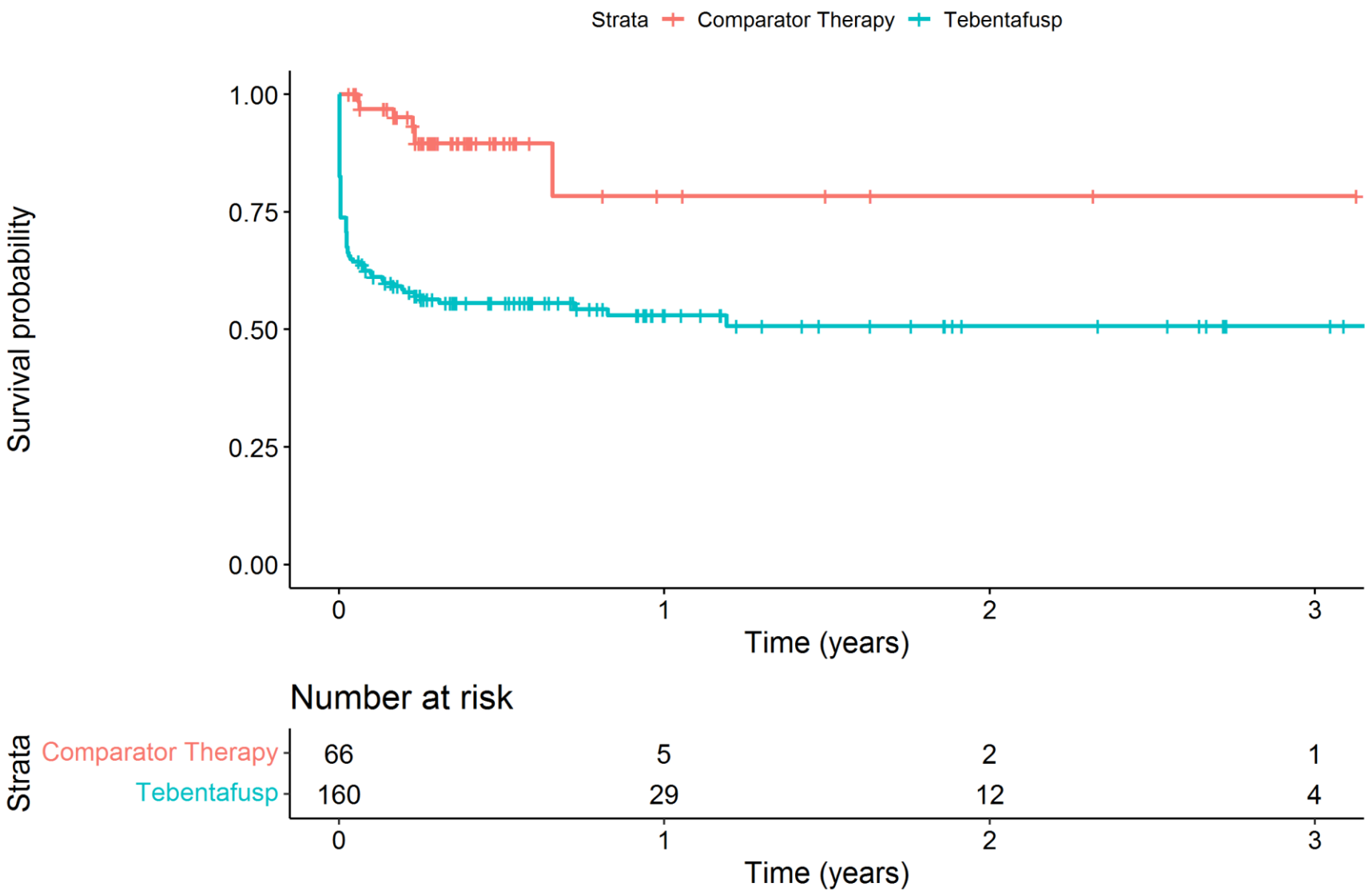
61.267 Gefäßerkrankungen- Läsion ≥8,1 cm



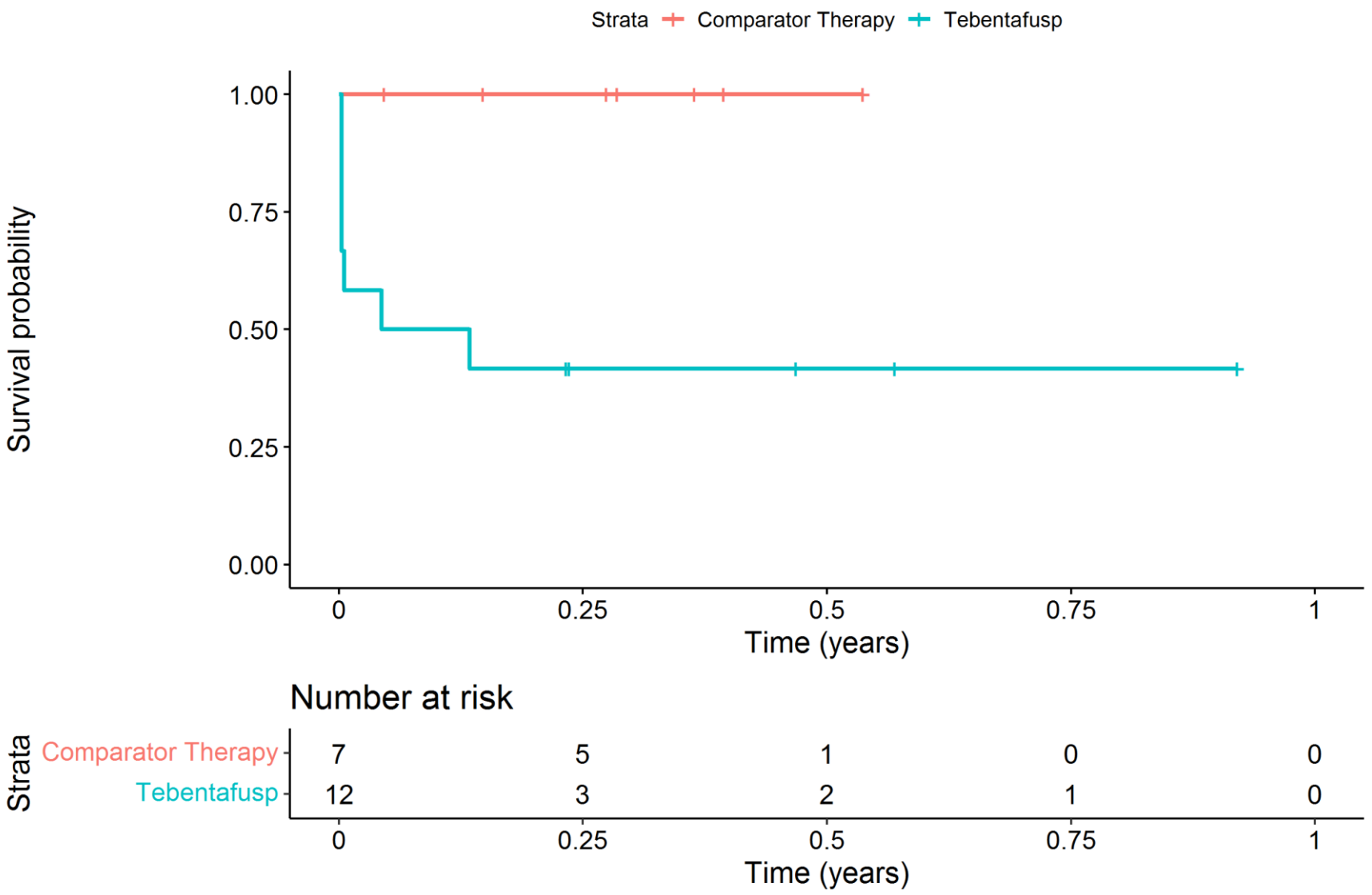
61.268 Gefäßerkrankungen- Nordamerika



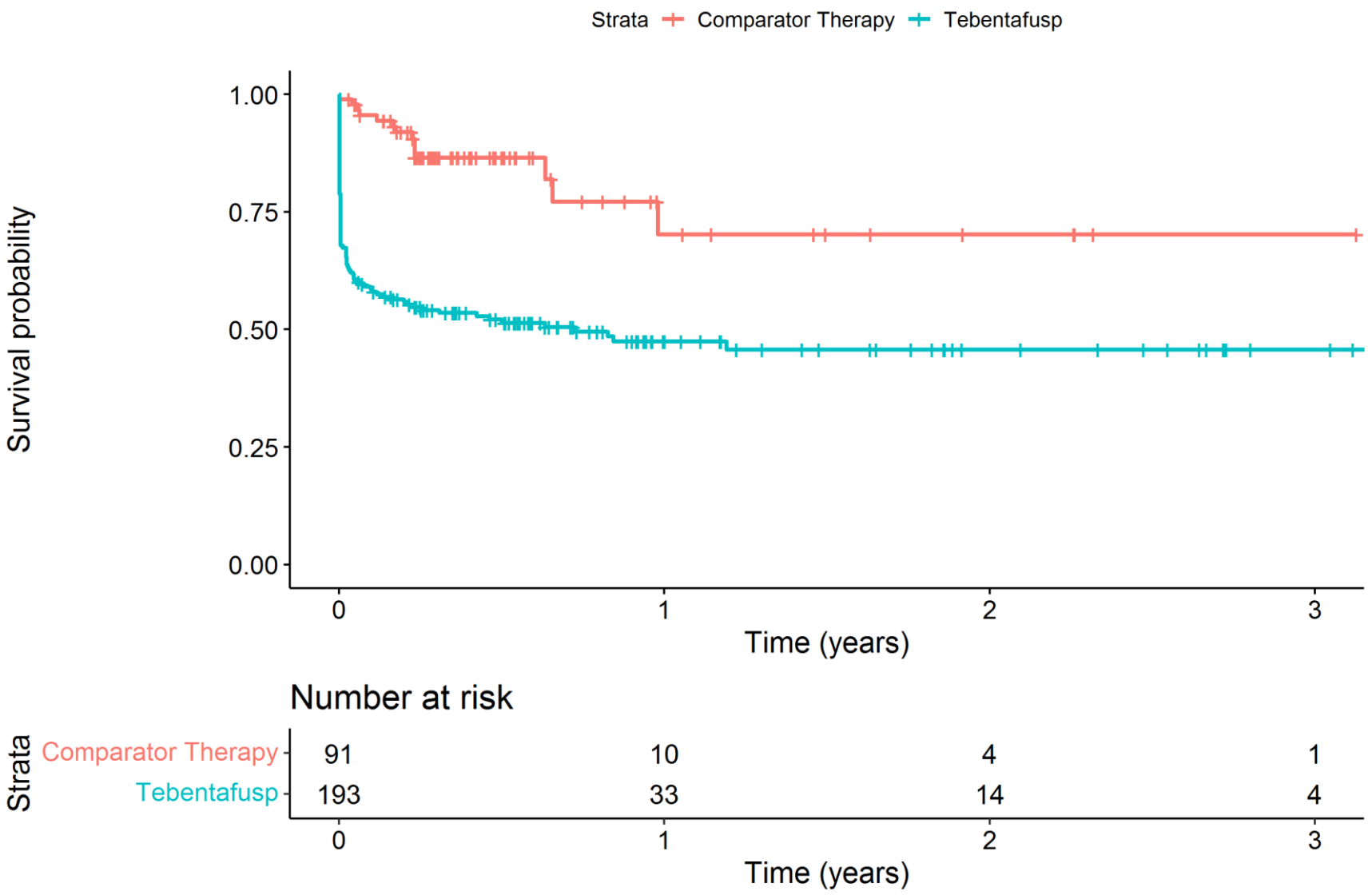
61.269 Gefäßerkrankungen- Nicht-Nordamerika



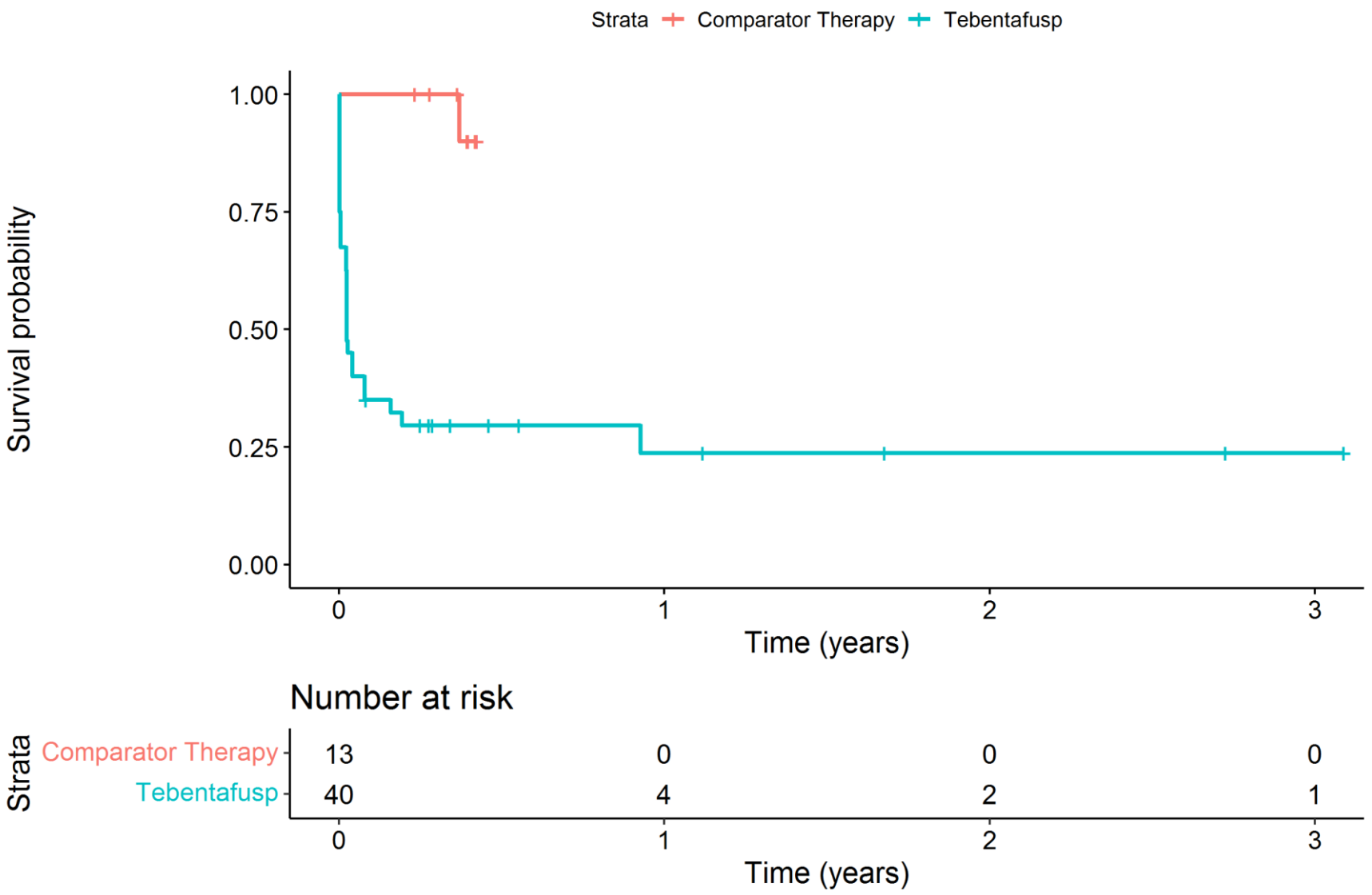
61.270 Gefäßerkrankungen- Dacarbazin



61.271 Gefäßerkrankungen- Pembrolizumab

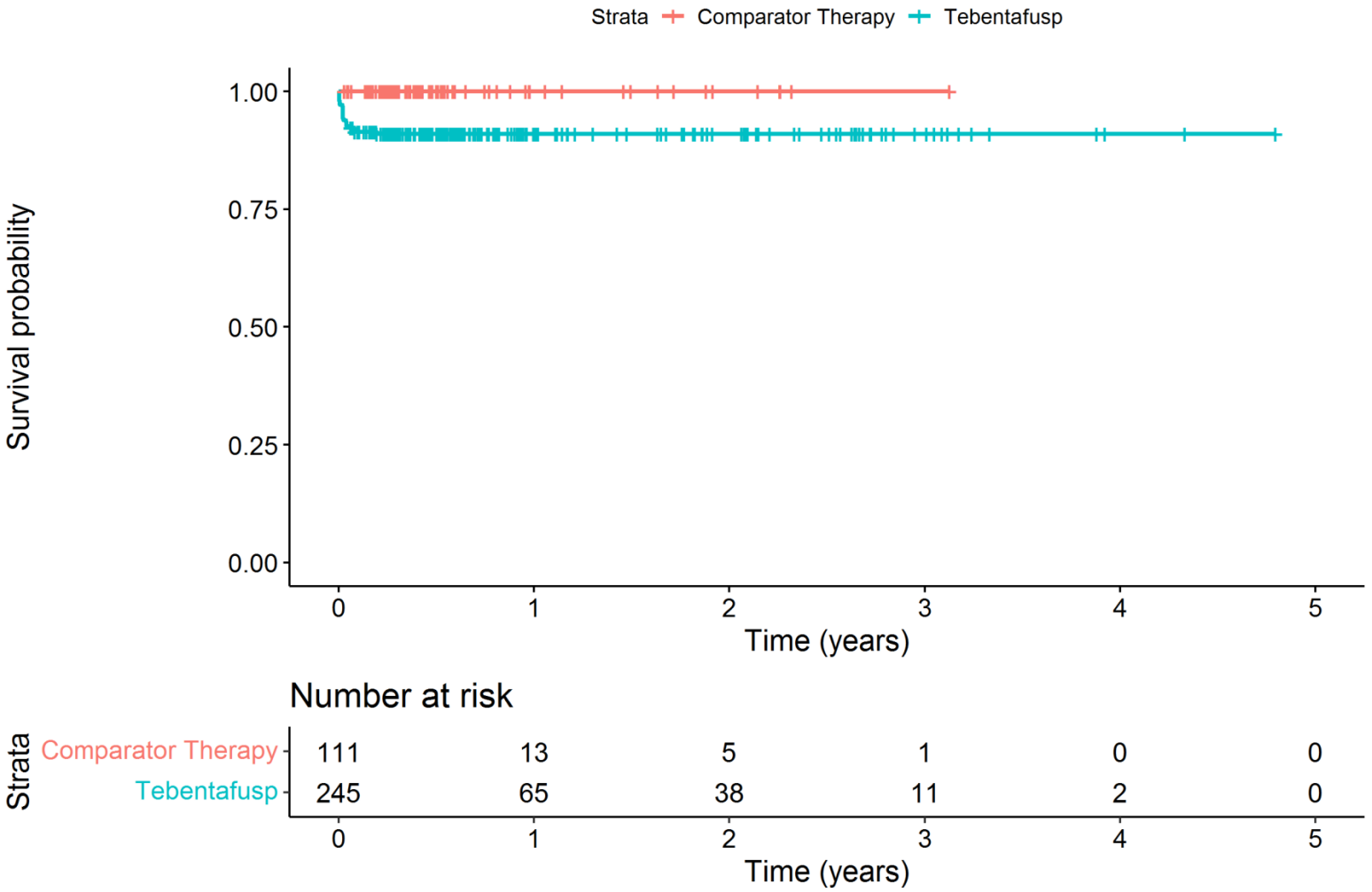


61.272 Gefäßerkrankungen- Ipilimumab

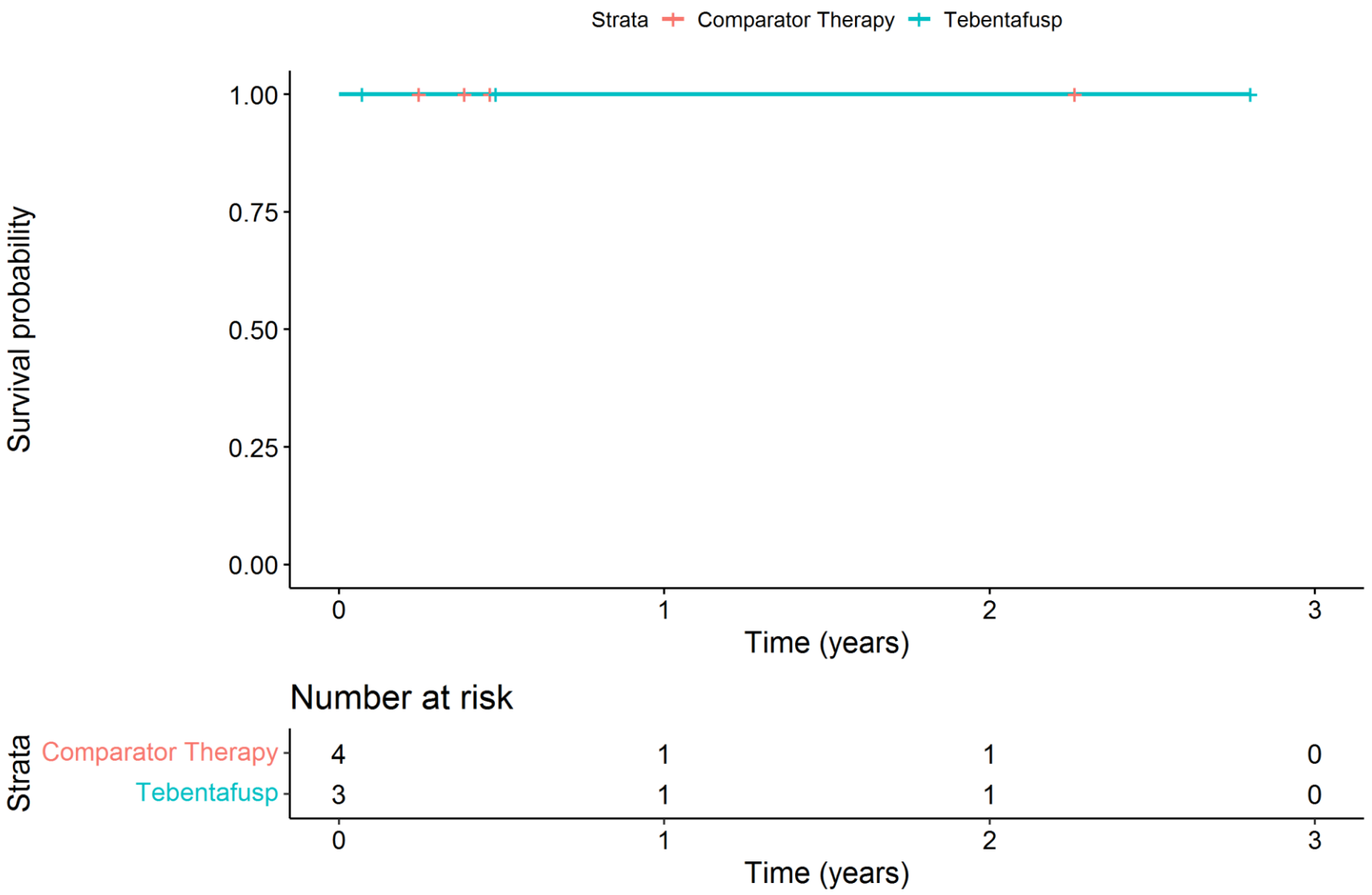


62 UEs (PT) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-327)

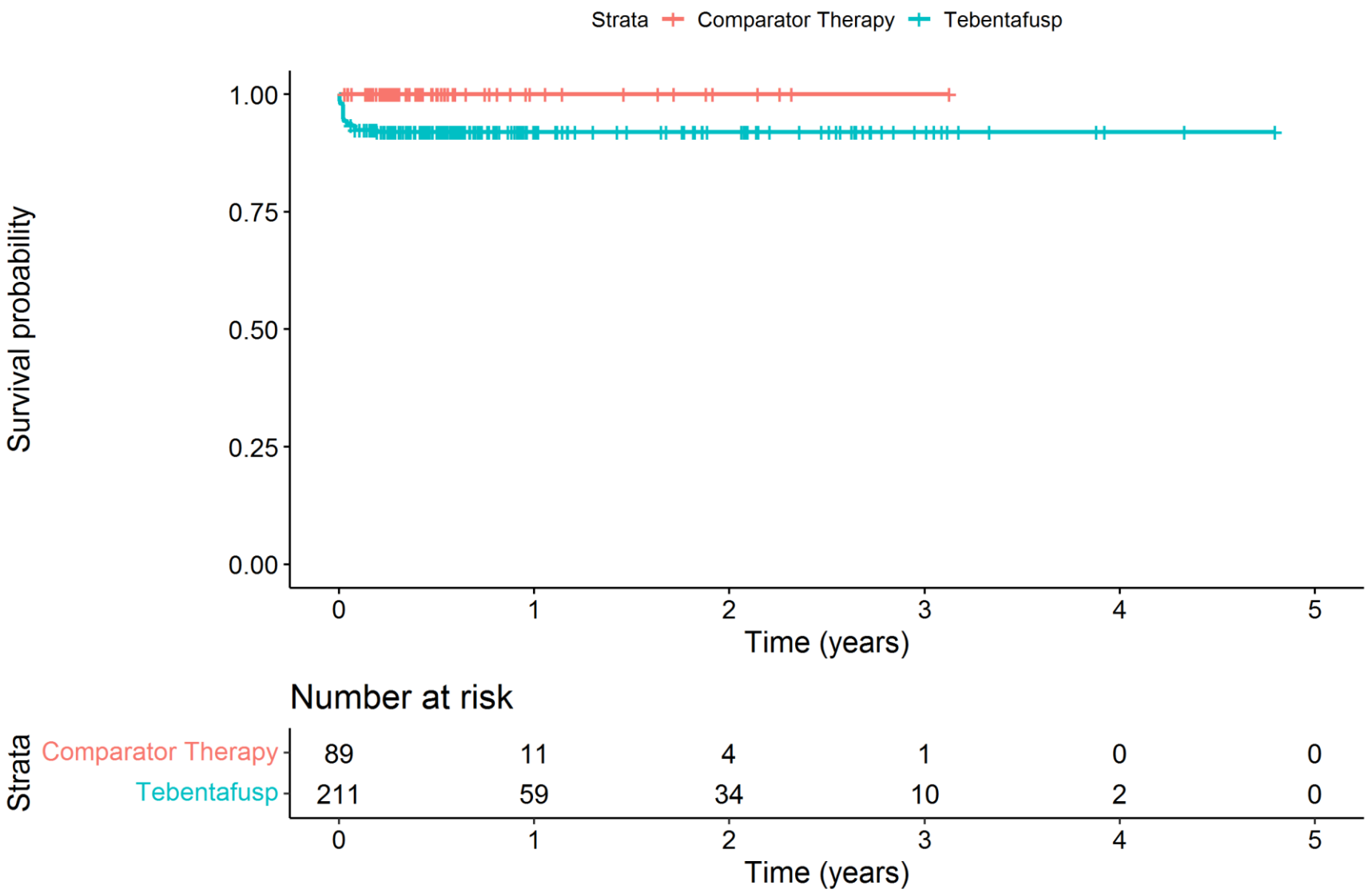
62.1 Hautausschlag - Gesamt



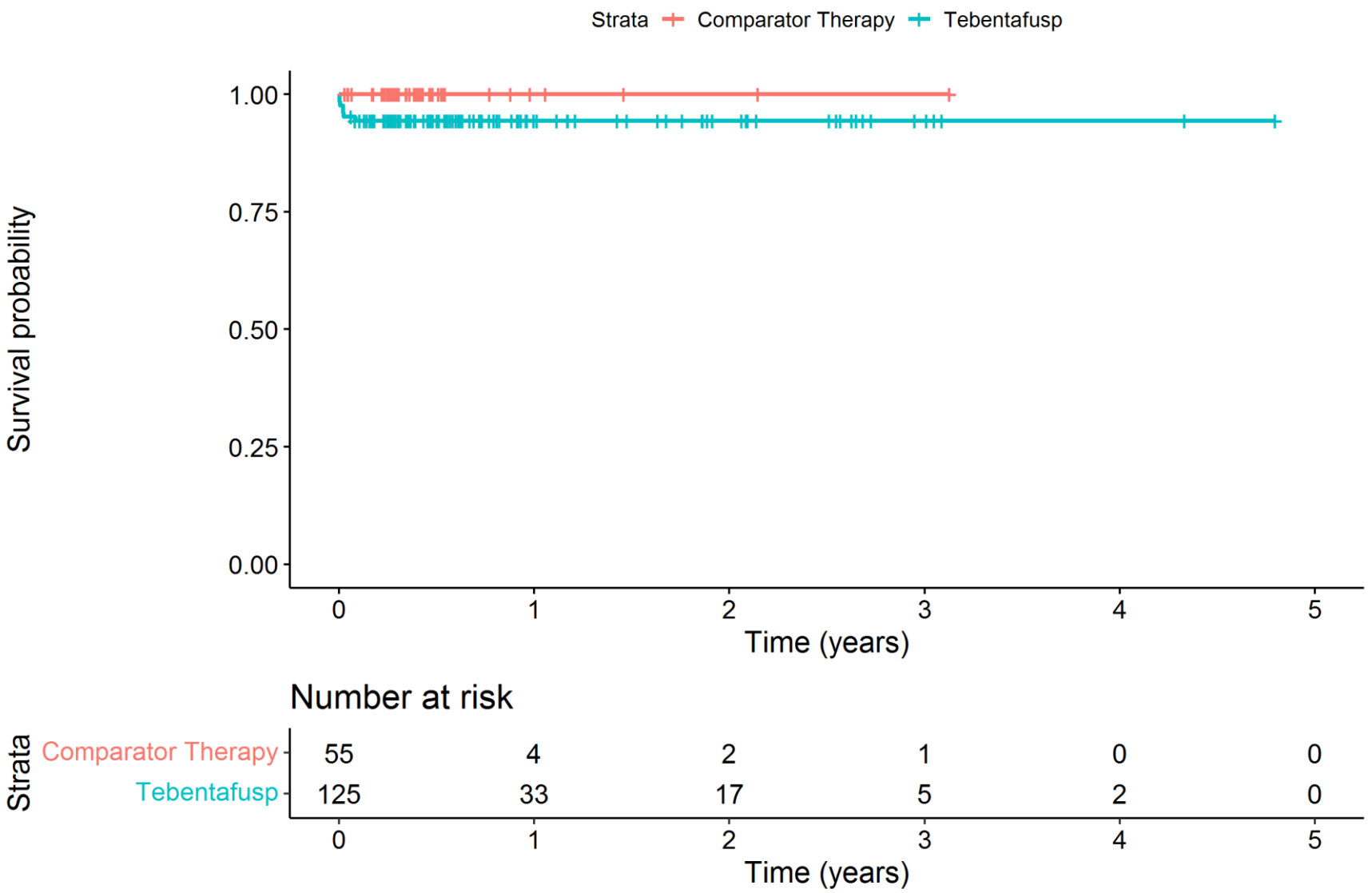
62.2 Hautausschlag - Hispanisch



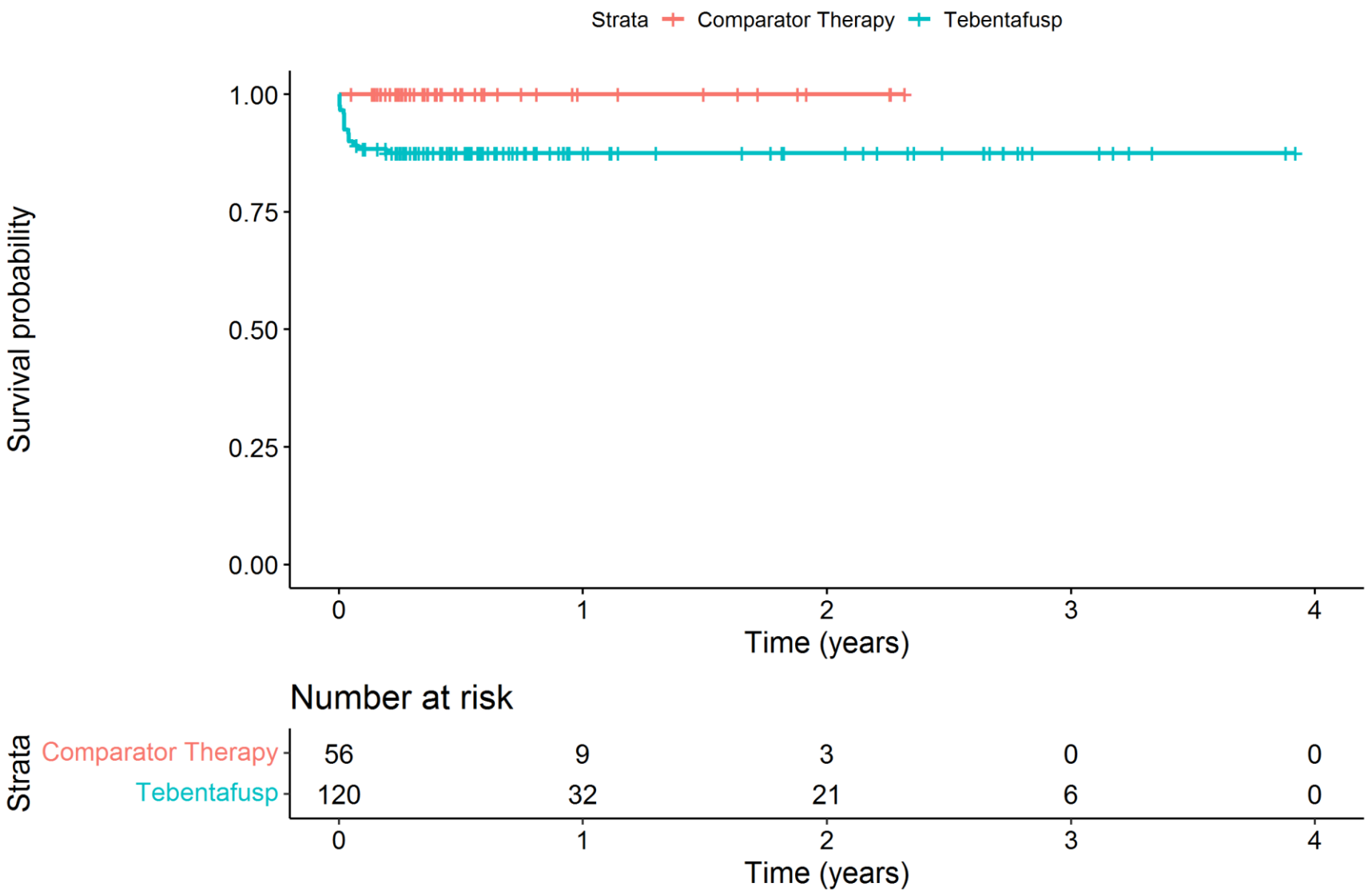
62.3 Hautausschlag - Nicht-hispanisch



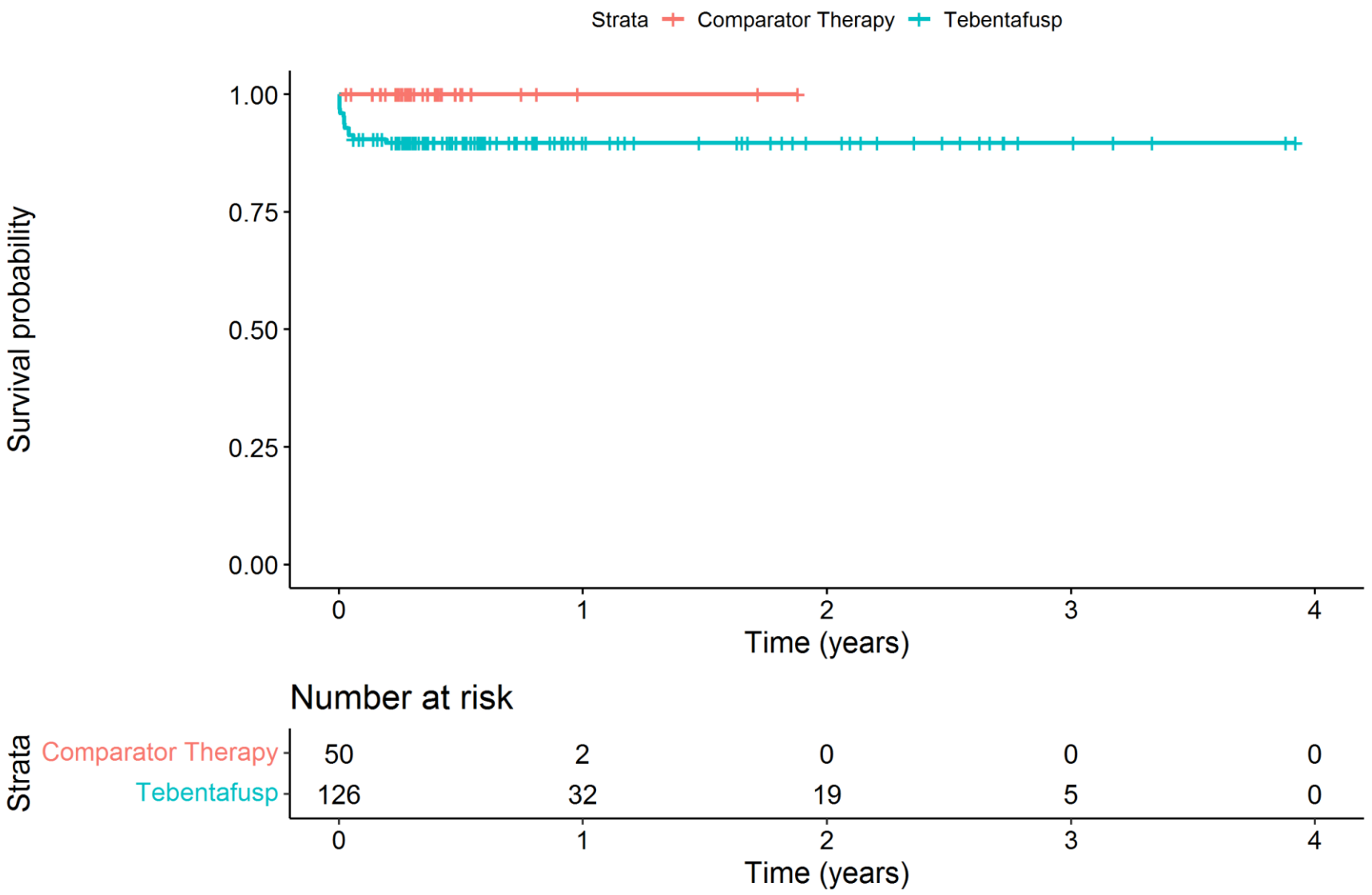
62.4 Hautausschlag - Männlich



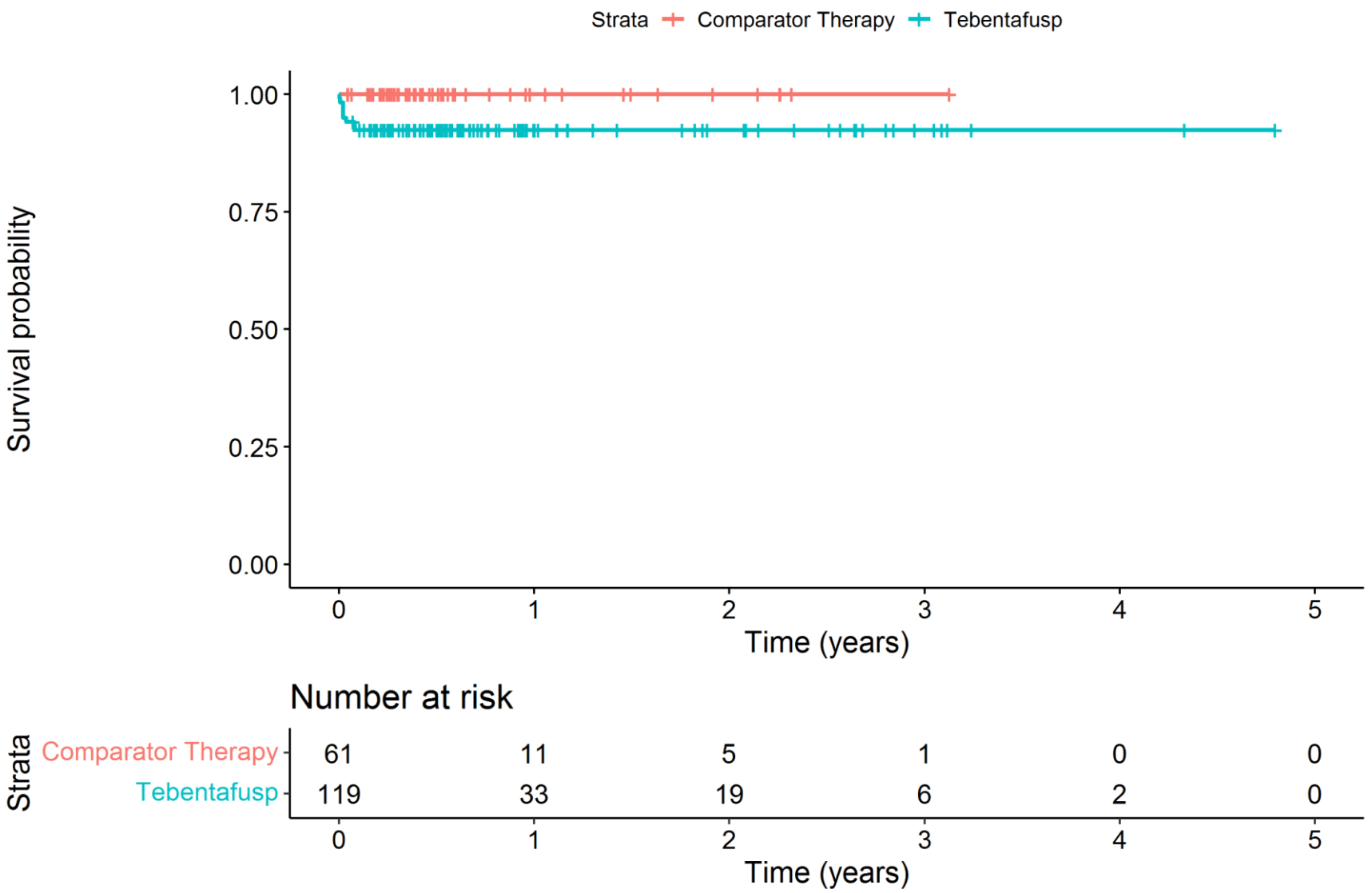
62.5 Hautausschlag - Weiblich



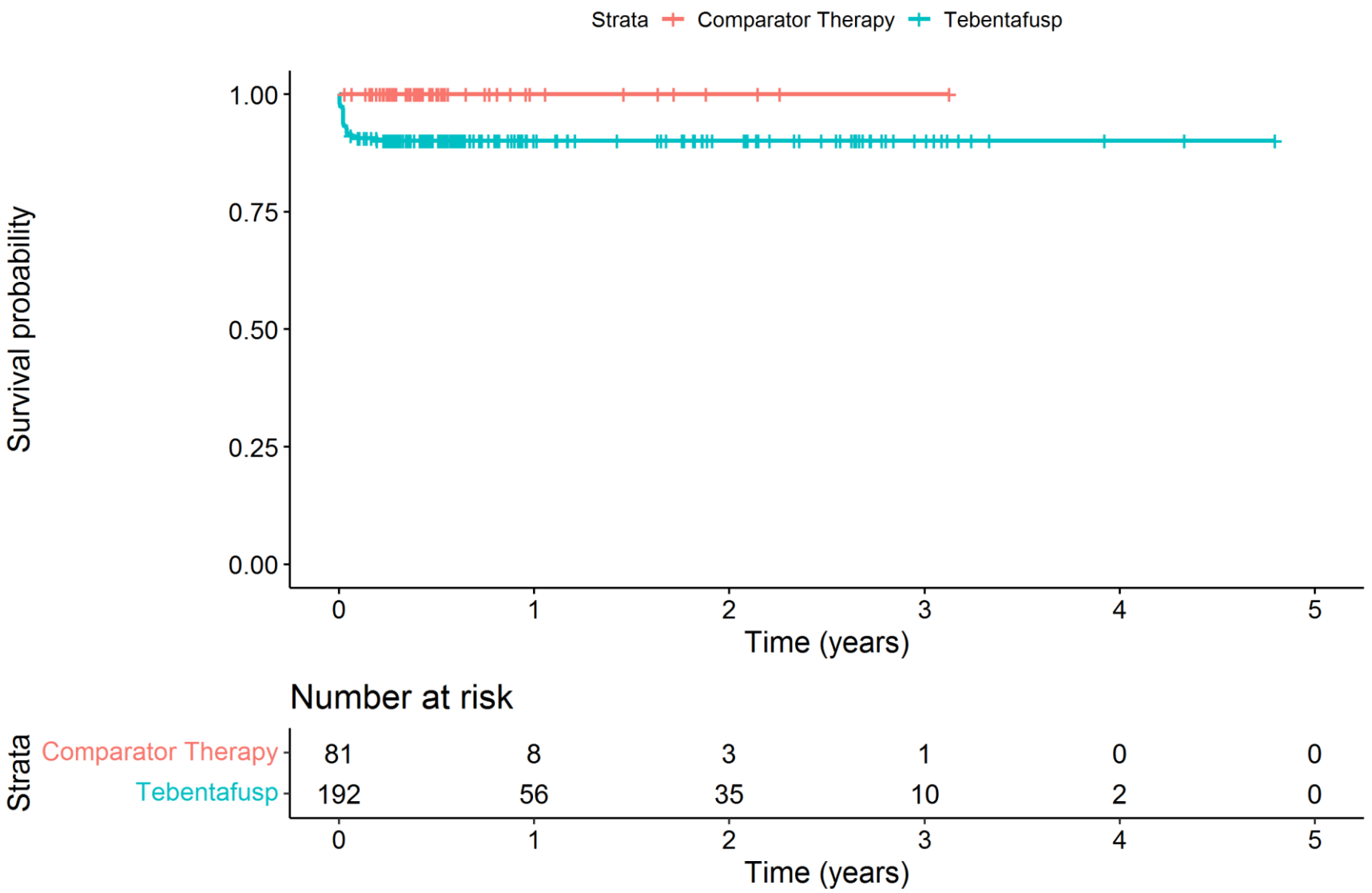
62.6 Hautausschlag - <65



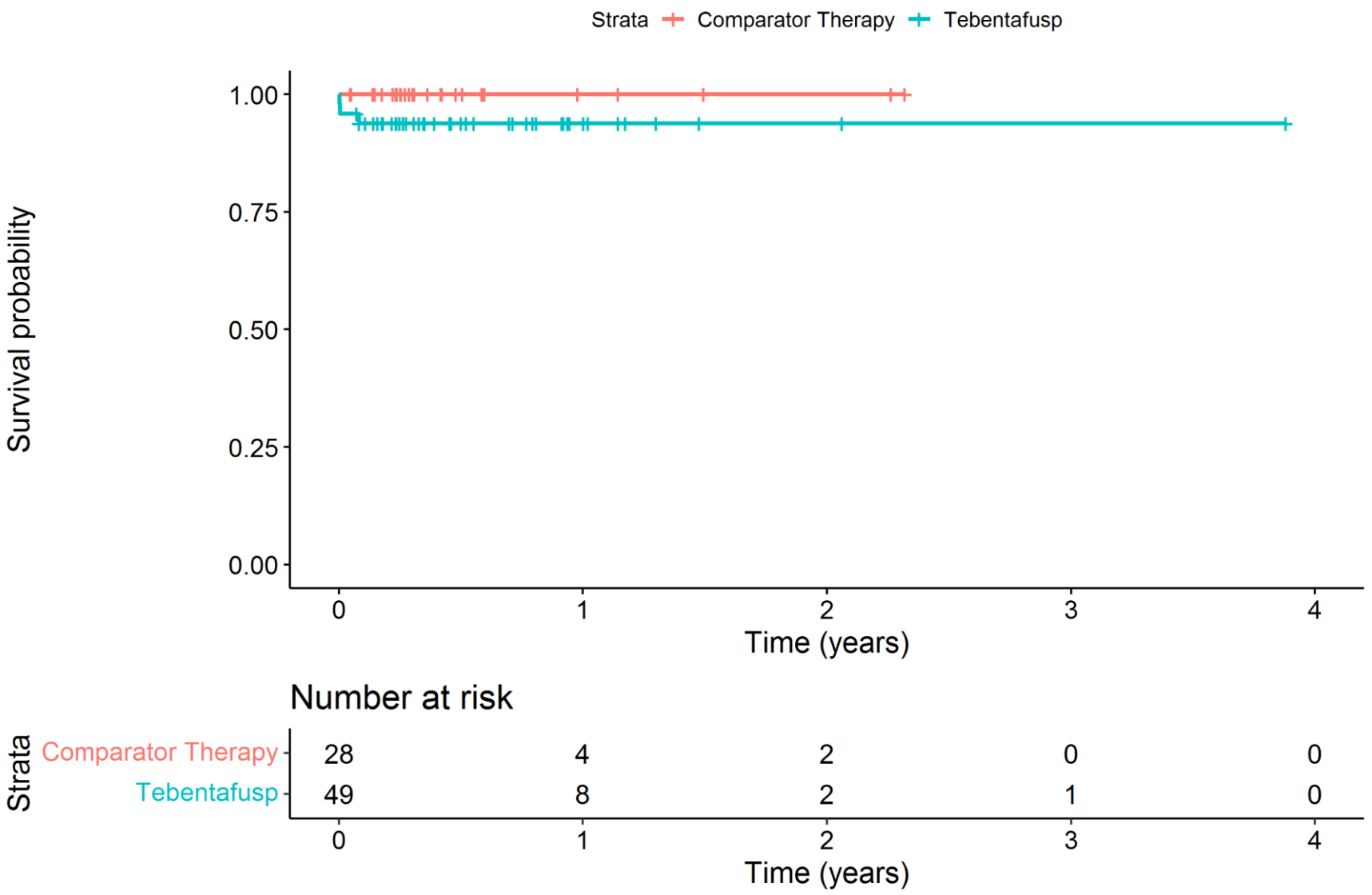
62.7 Hautausschlag - ≥65



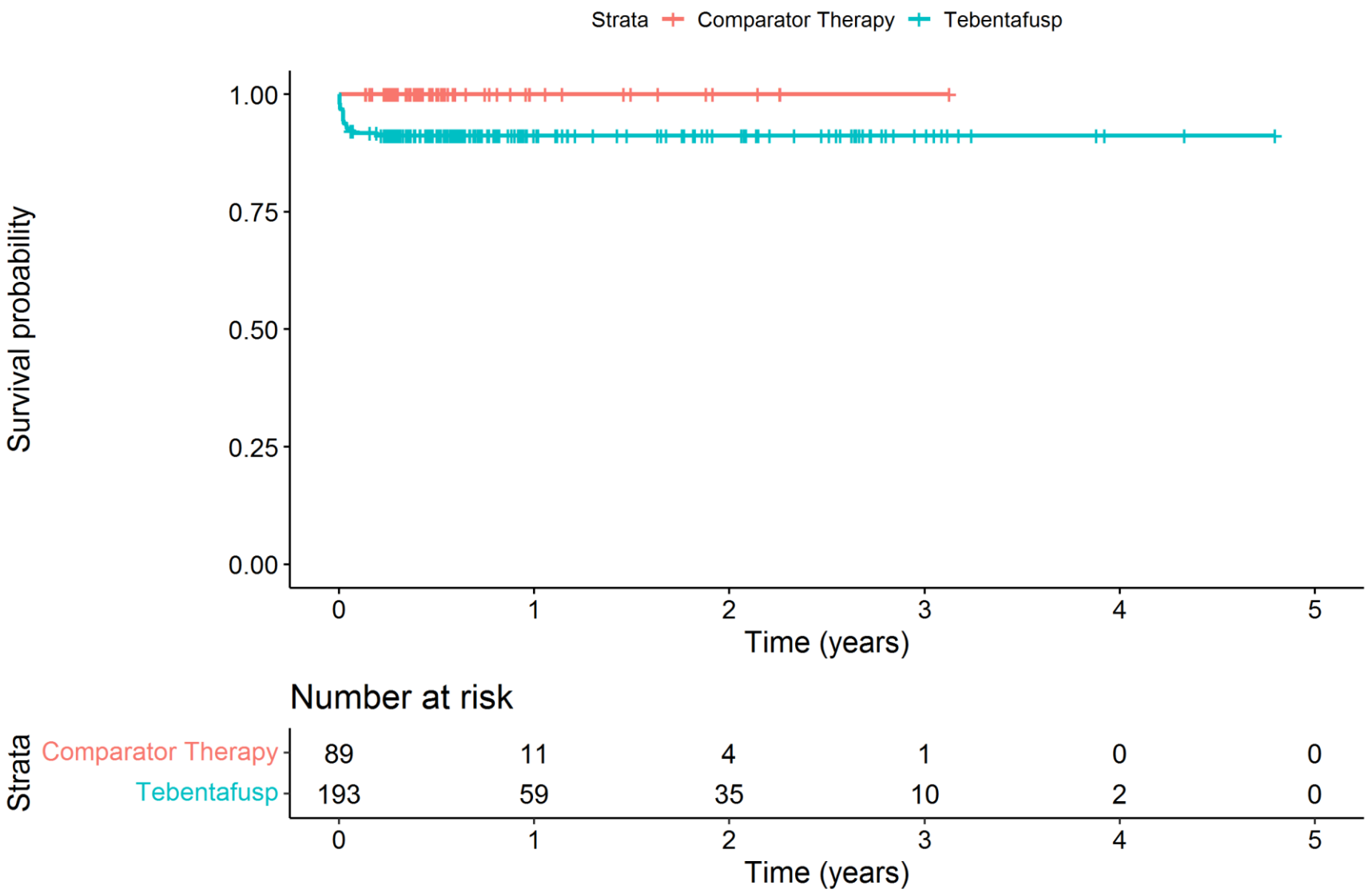
62.8 Hautausschlag - ECOG 0



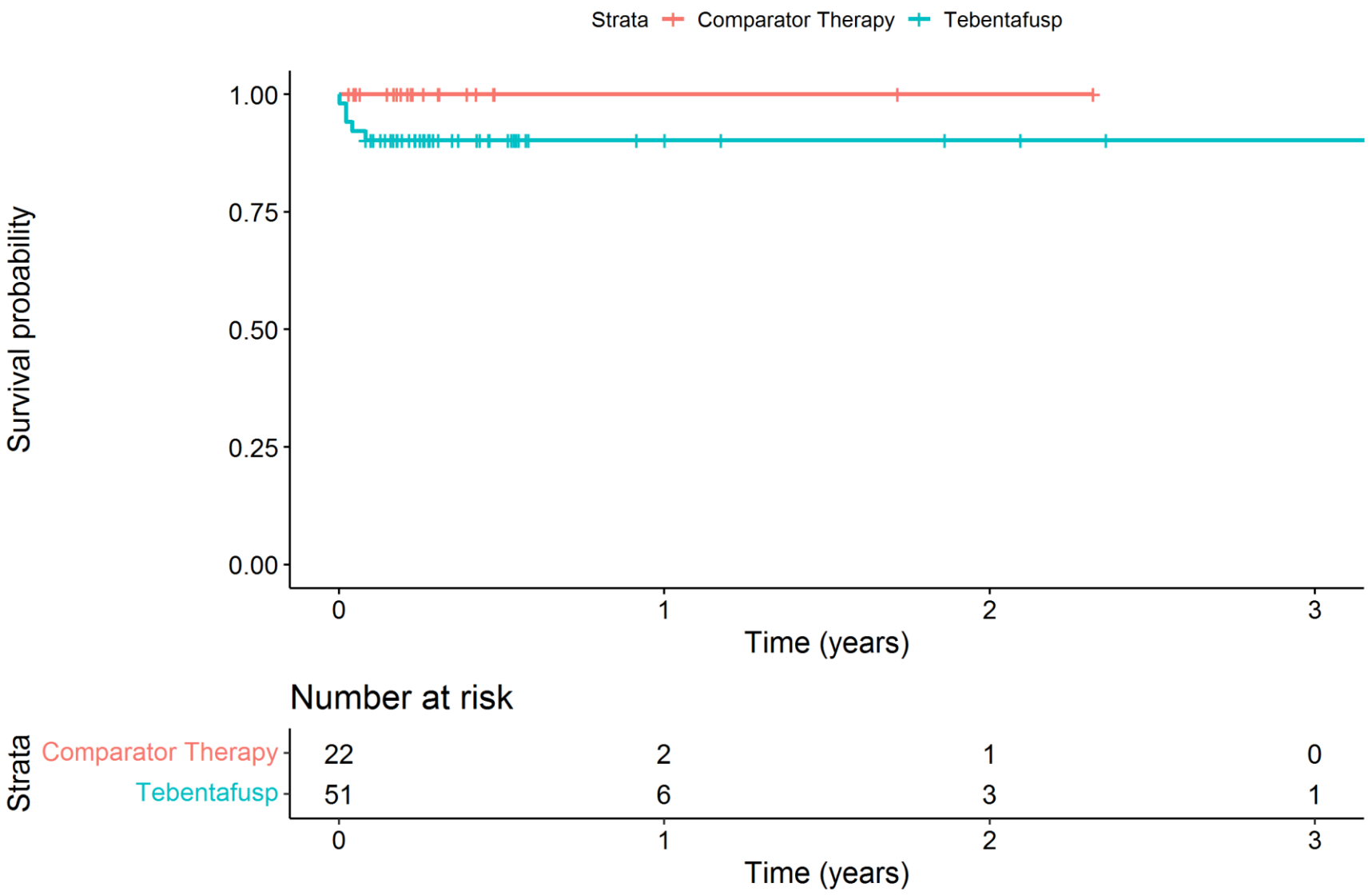
62.9 Hautausschlag - ECOG 1



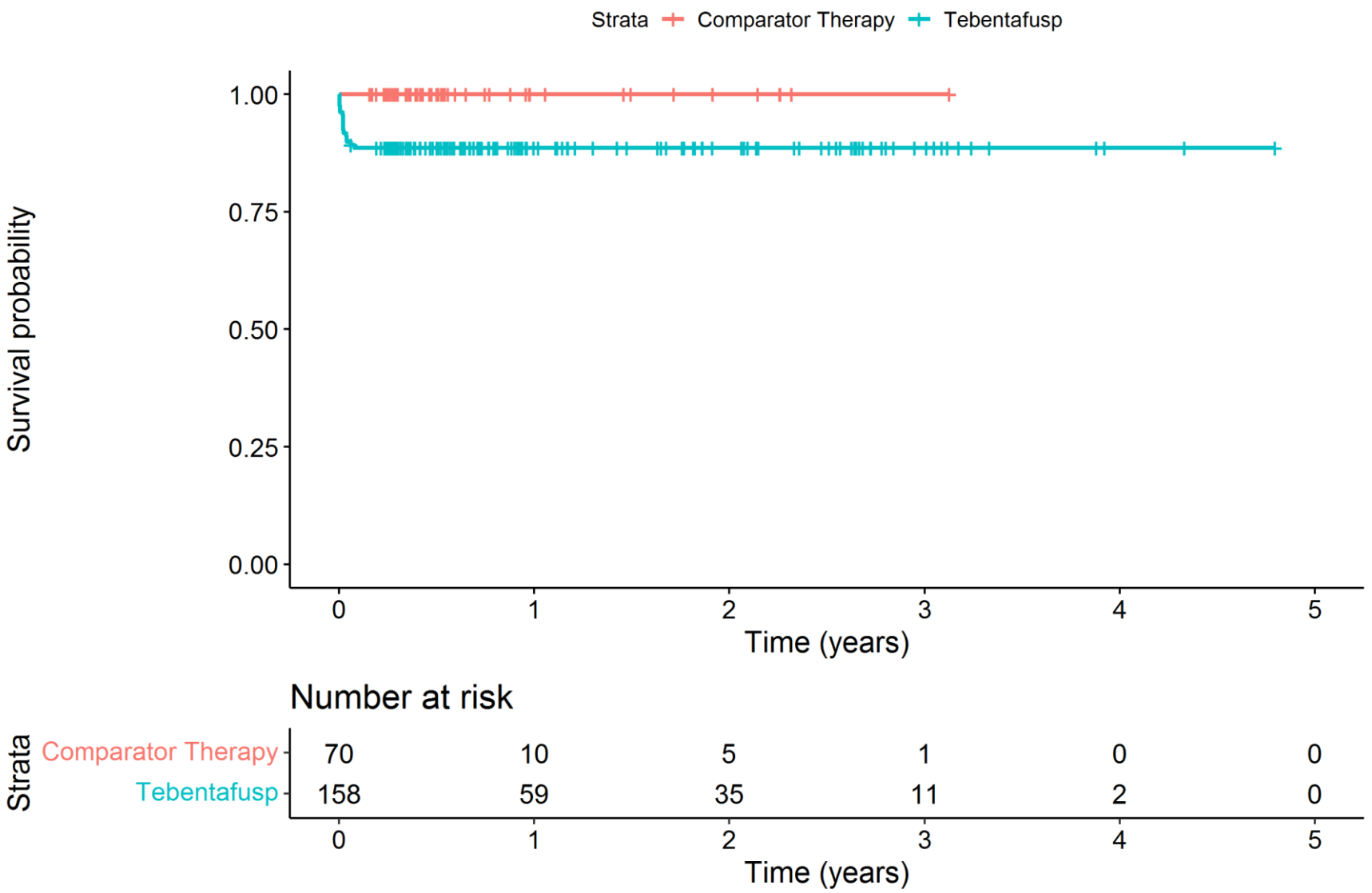
62.10 Hautausschlag - ALP ≤ ULN



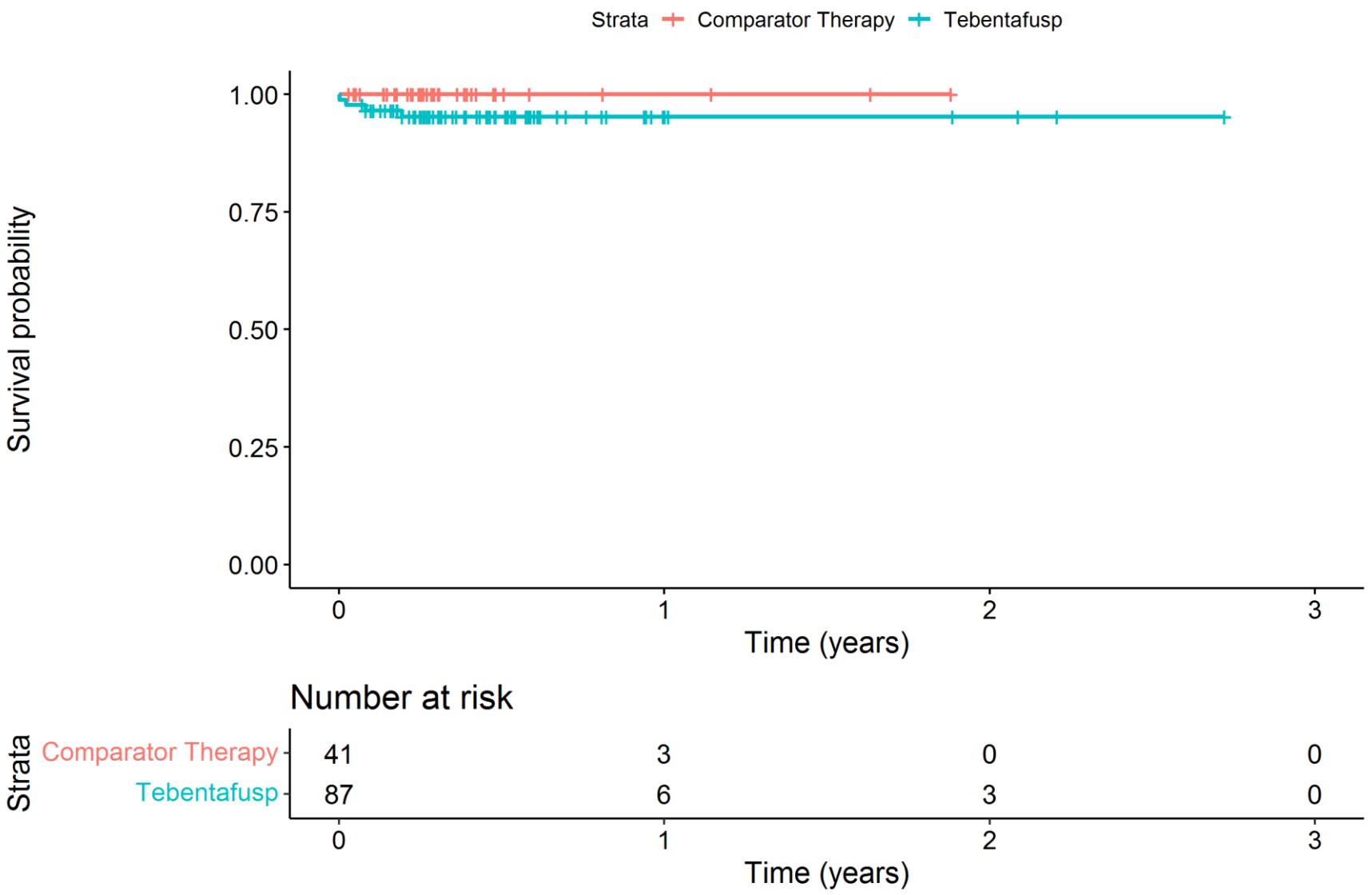
62.11 Hautausschlag - ALP > ULN



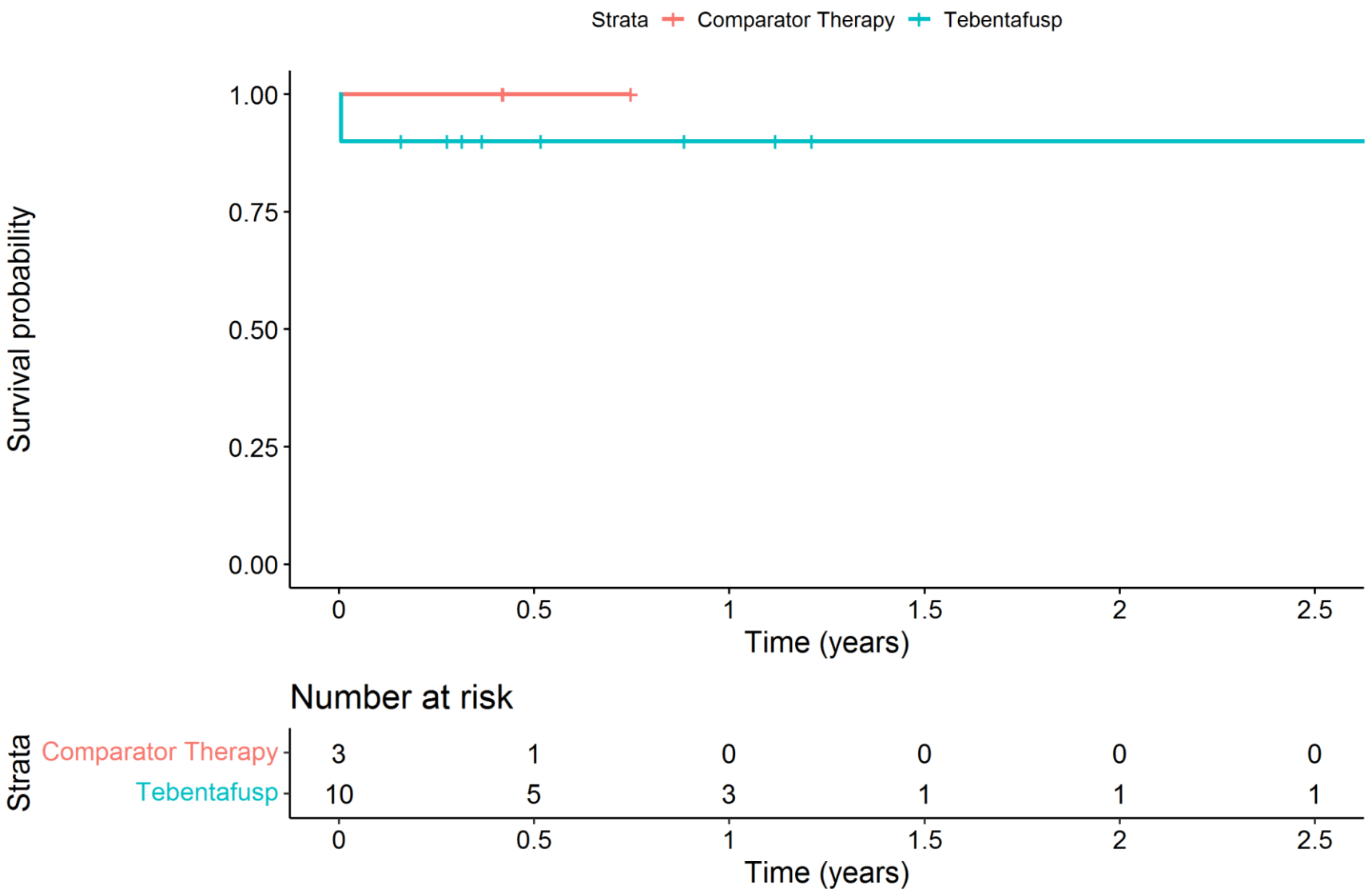
62.12 Hautausschlag - LDH =< ULN



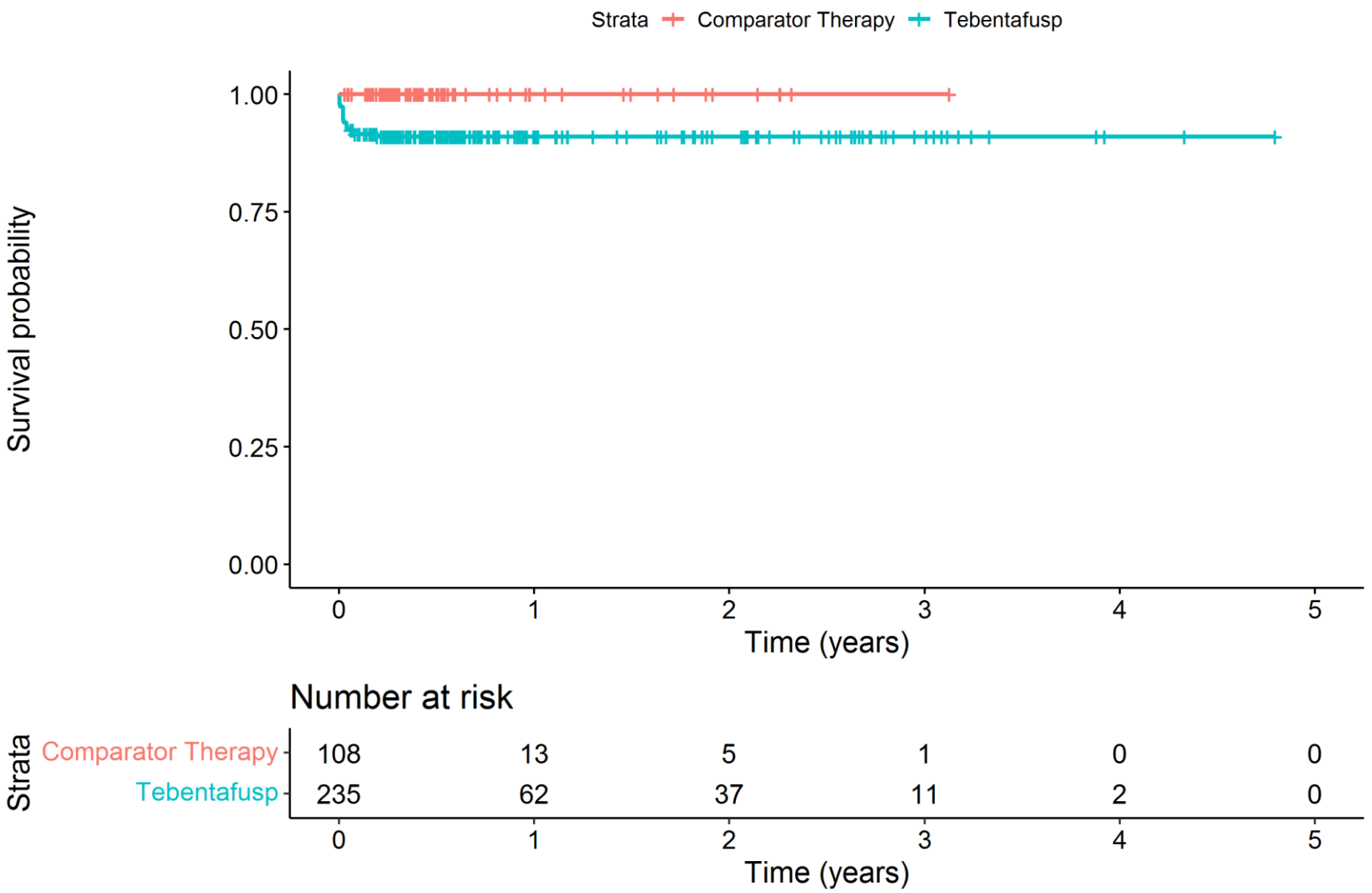
62.13 Hautausschlag - LDH > ULN



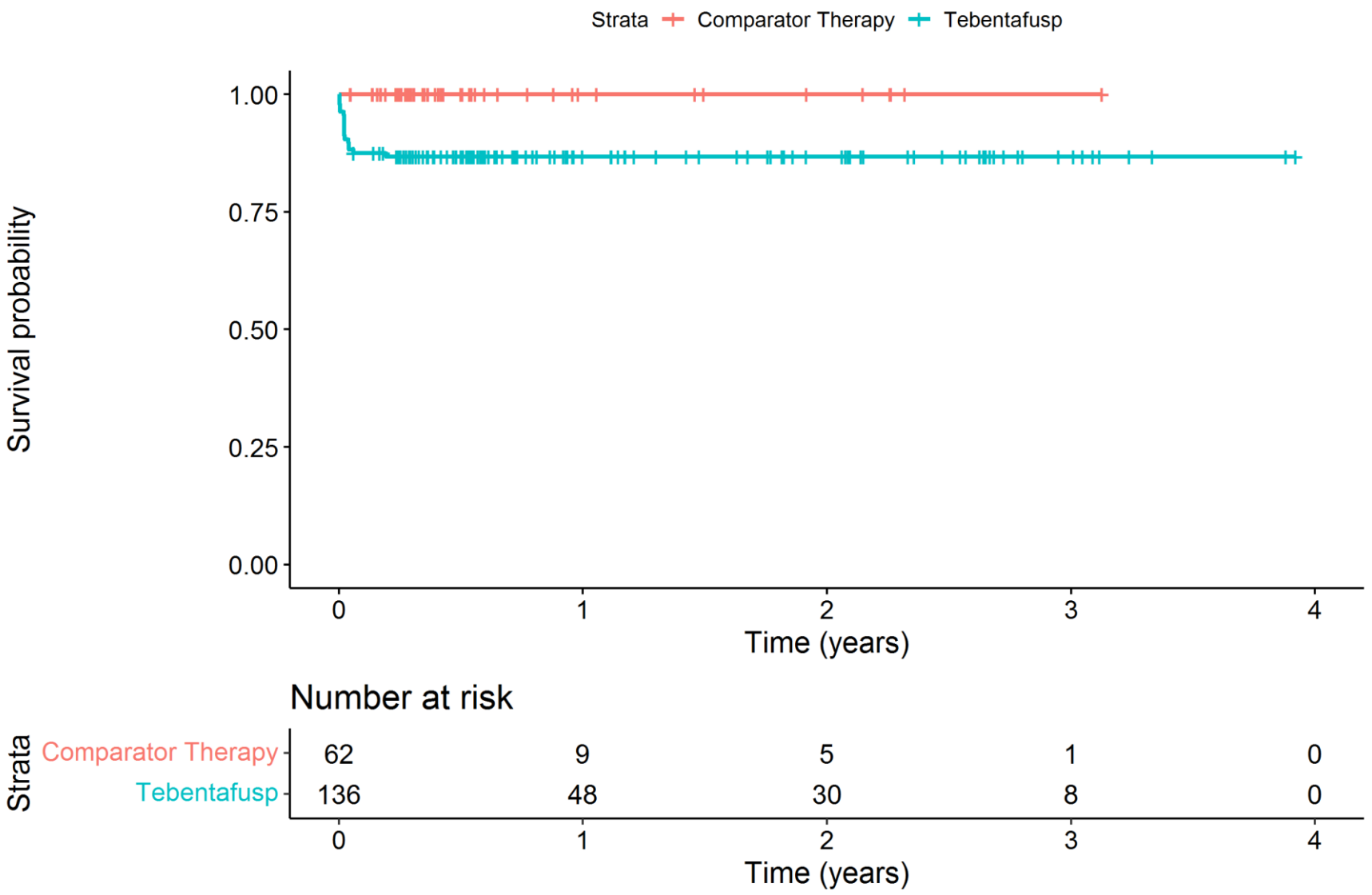
62.14 Hautausschlag - Vorherige Therapie adjuvant/neoadjuvant



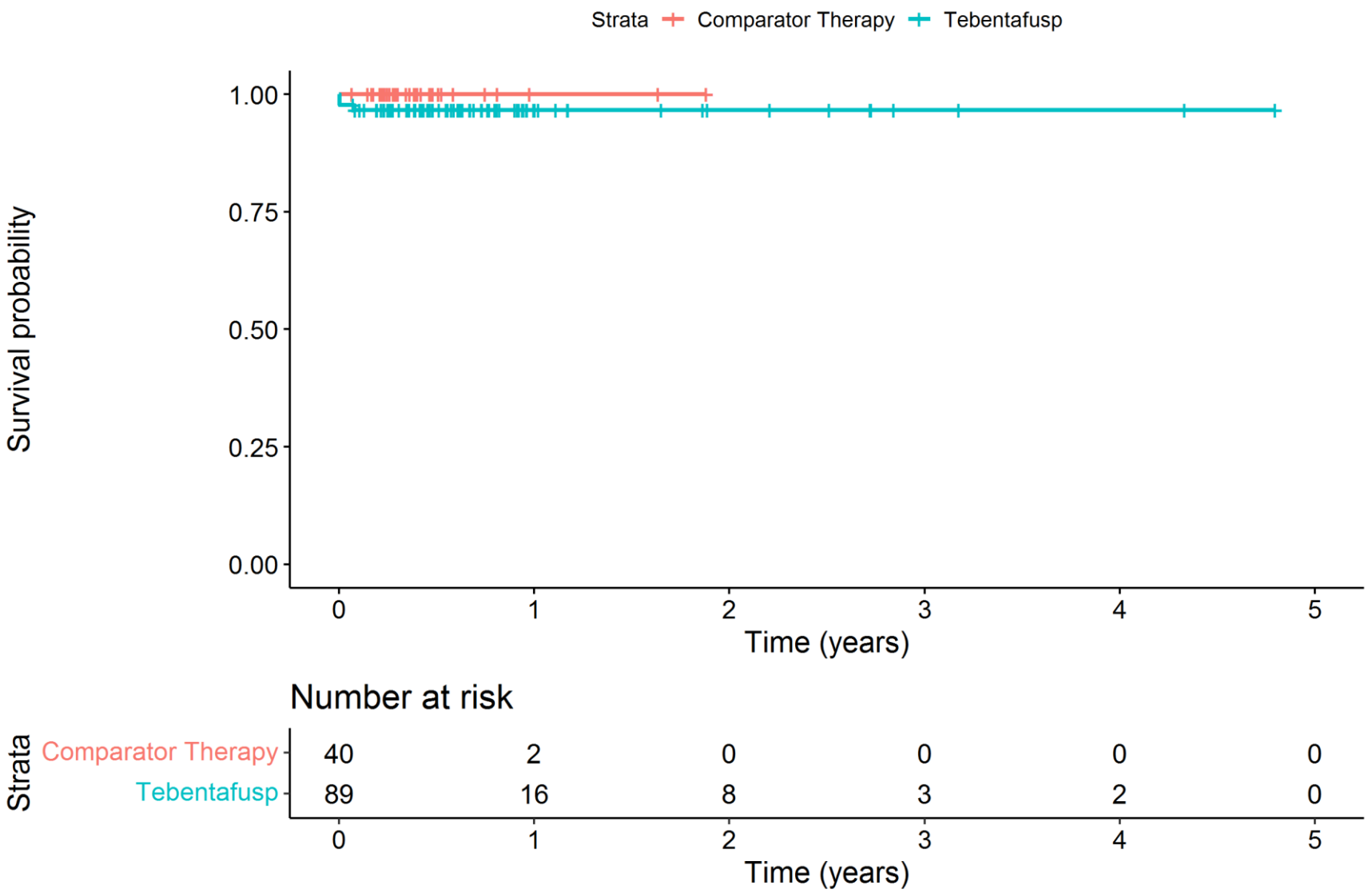
62.15 Hautausschlag - Keine Vorherige Therapie adjuvant/neoadjuvant



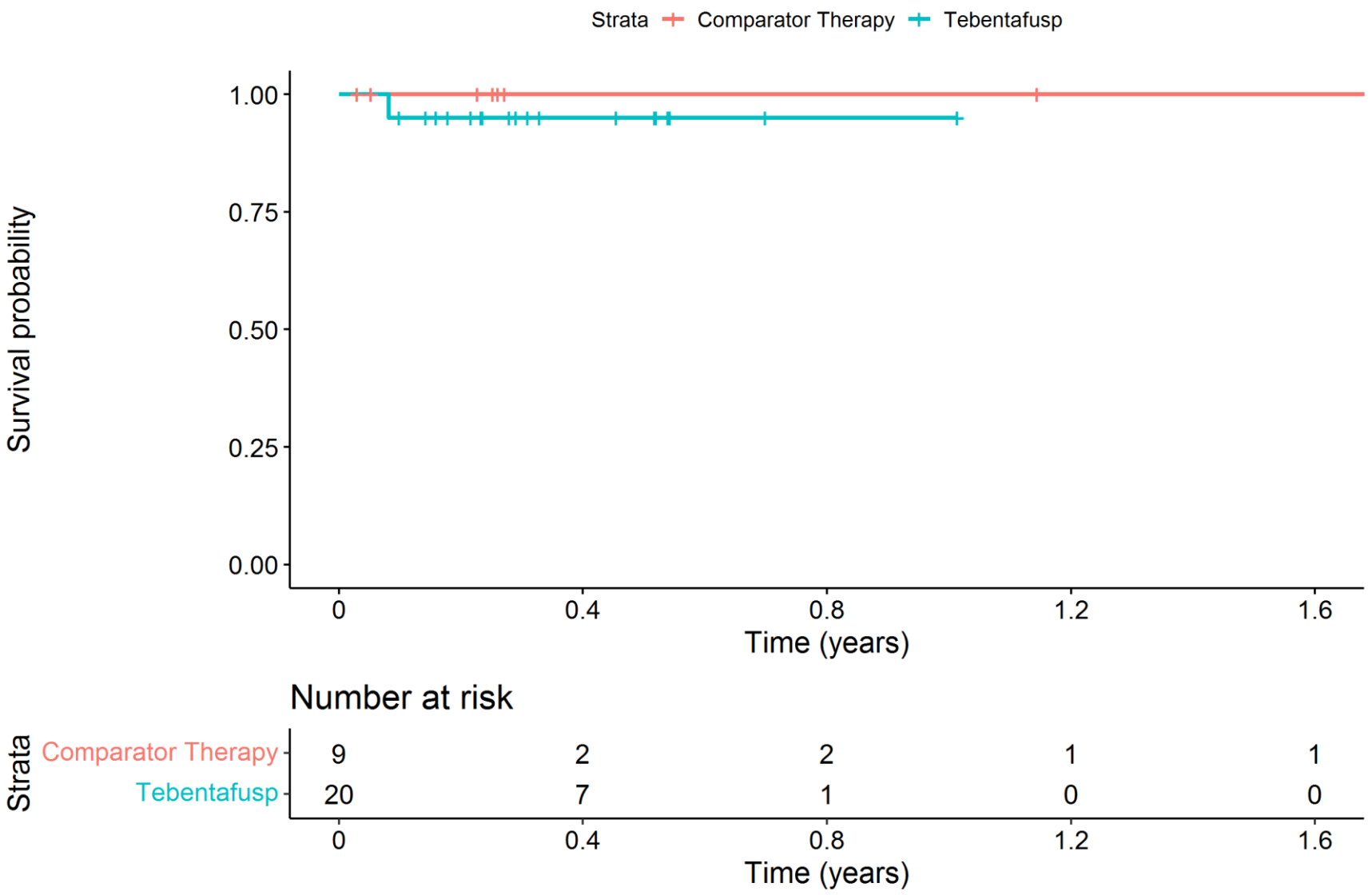
62.16 Hautausschlag - Läsion ≤ 3cm



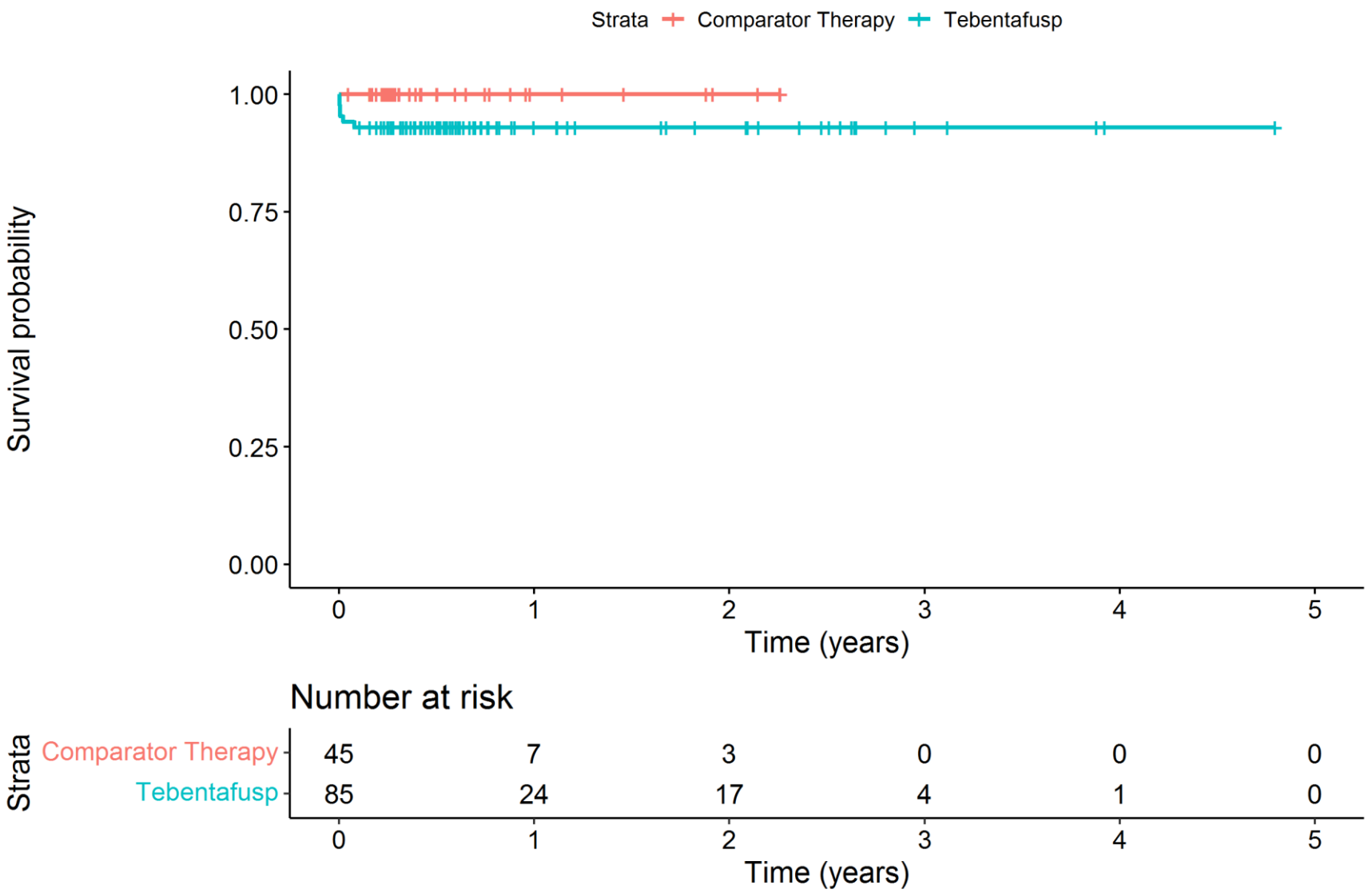
62.17 Hautausschlag - Läsion 3,1-8,0 cm



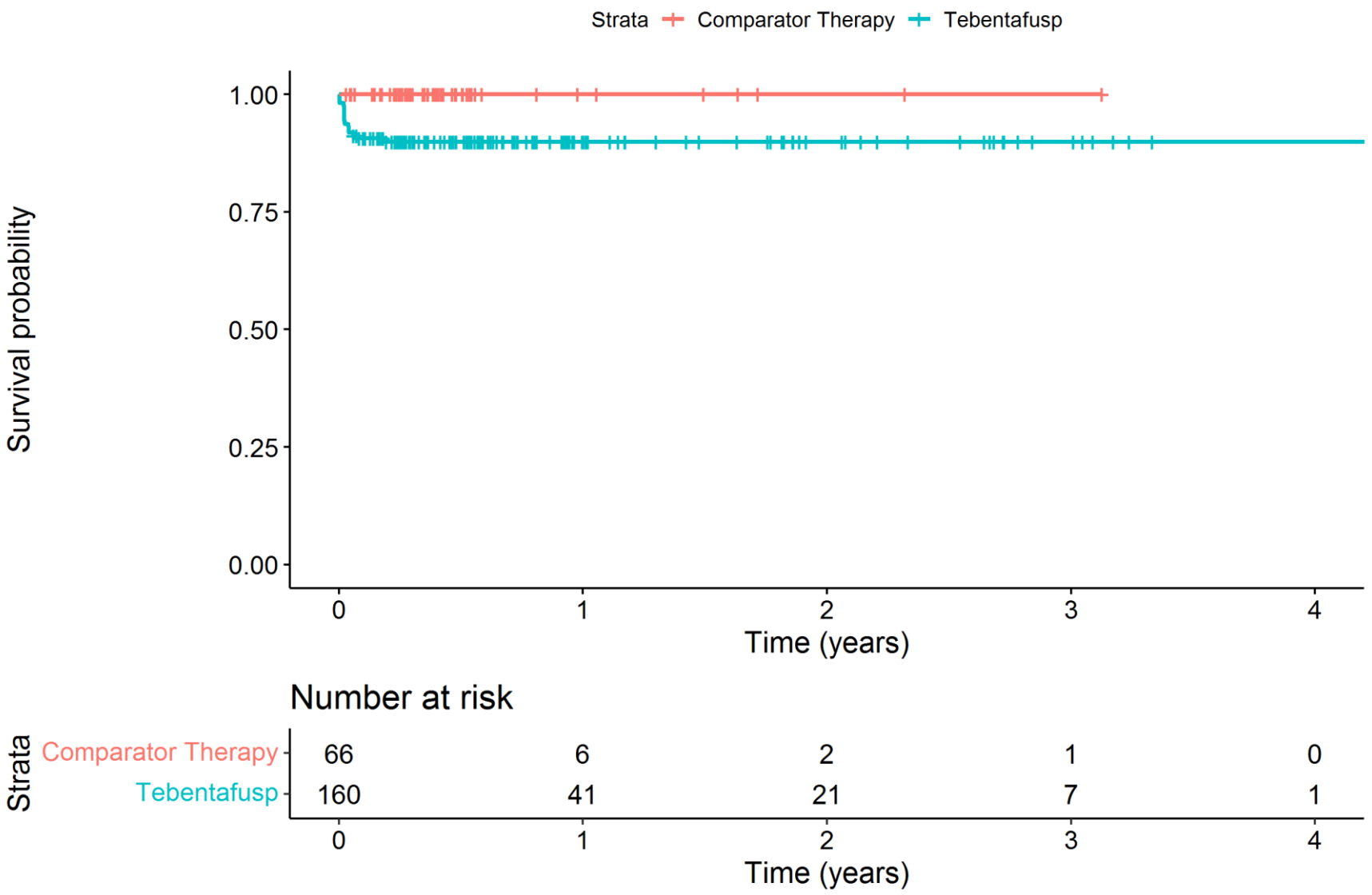
62.18 Hautausschlag - Läsion ≥8,1 cm



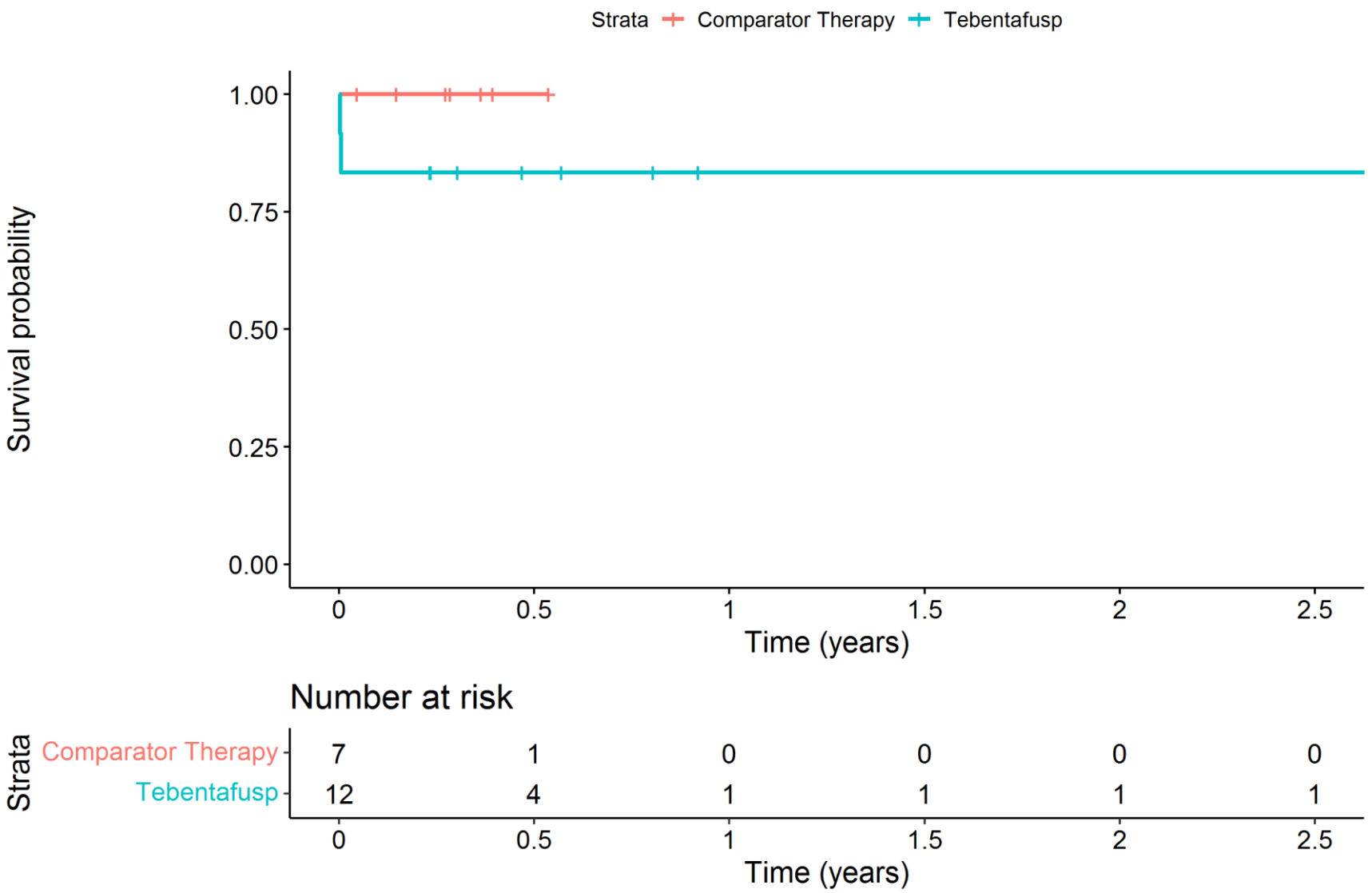
62.19 Hautausschlag - Nordamerika



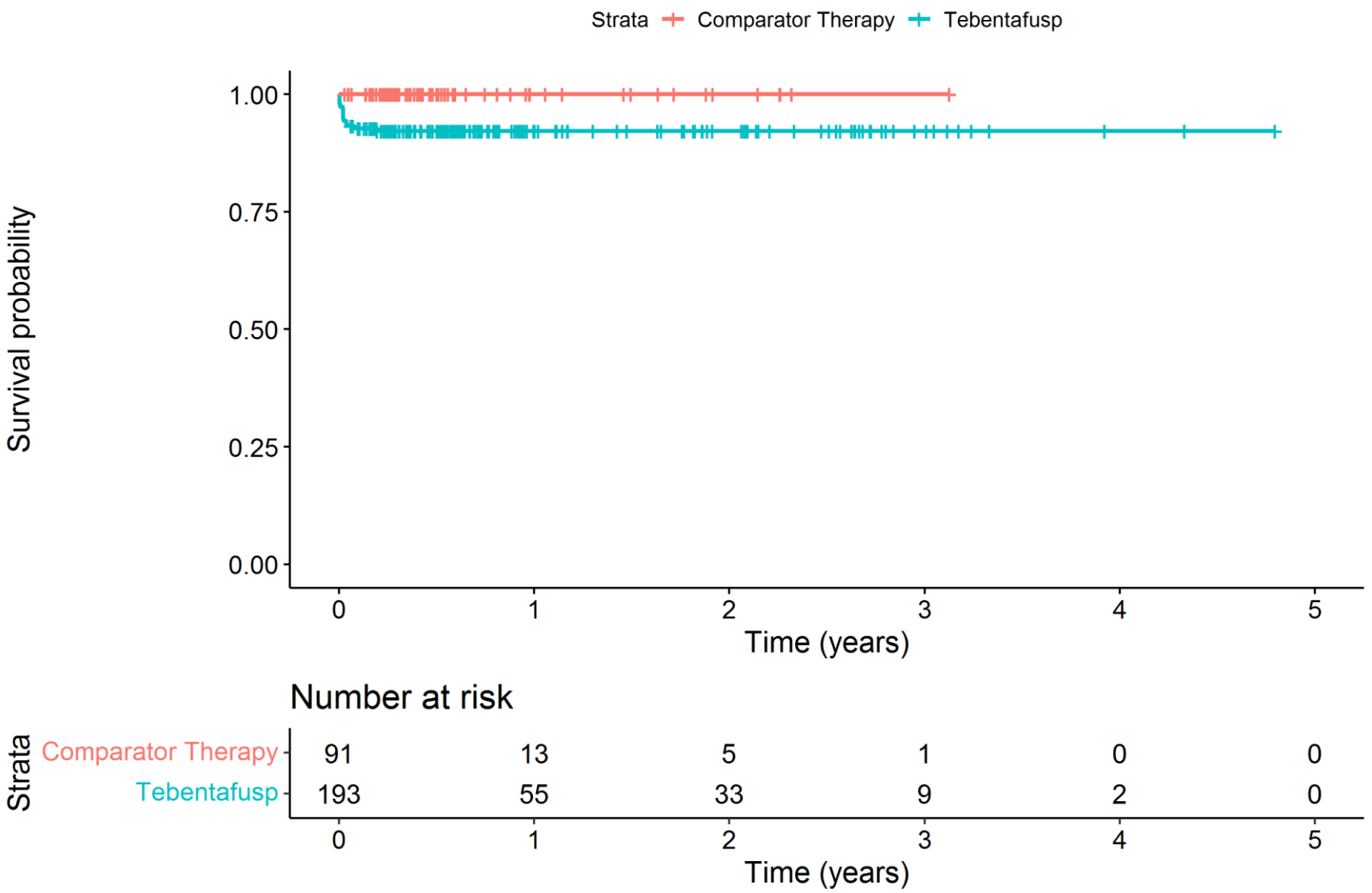
62.20 Hautausschlag - Nicht-Nordamerika



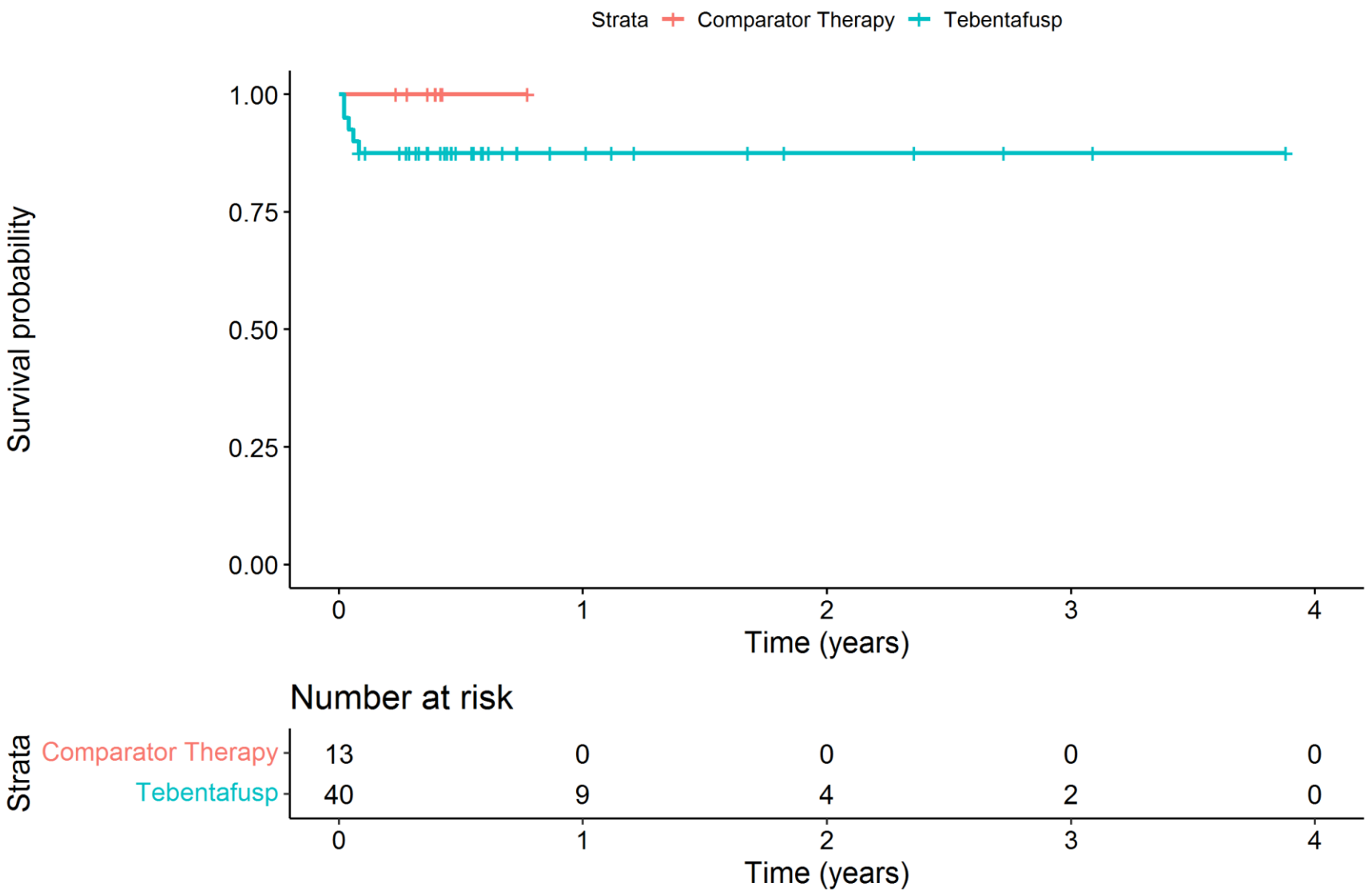
62.21 Hautausschlag - Dacarbazin



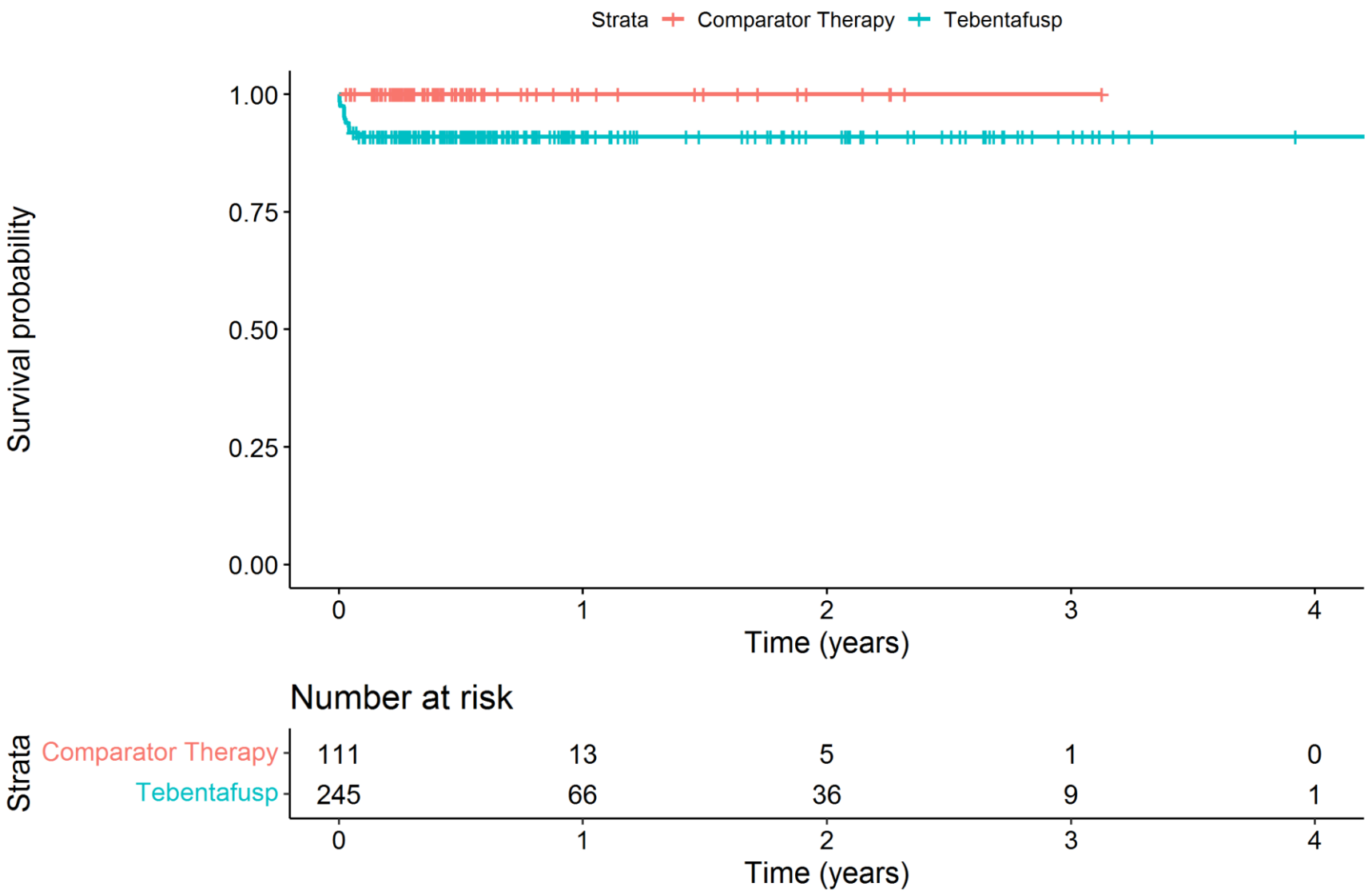
62.22 Hautausschlag - Pembrolizumab



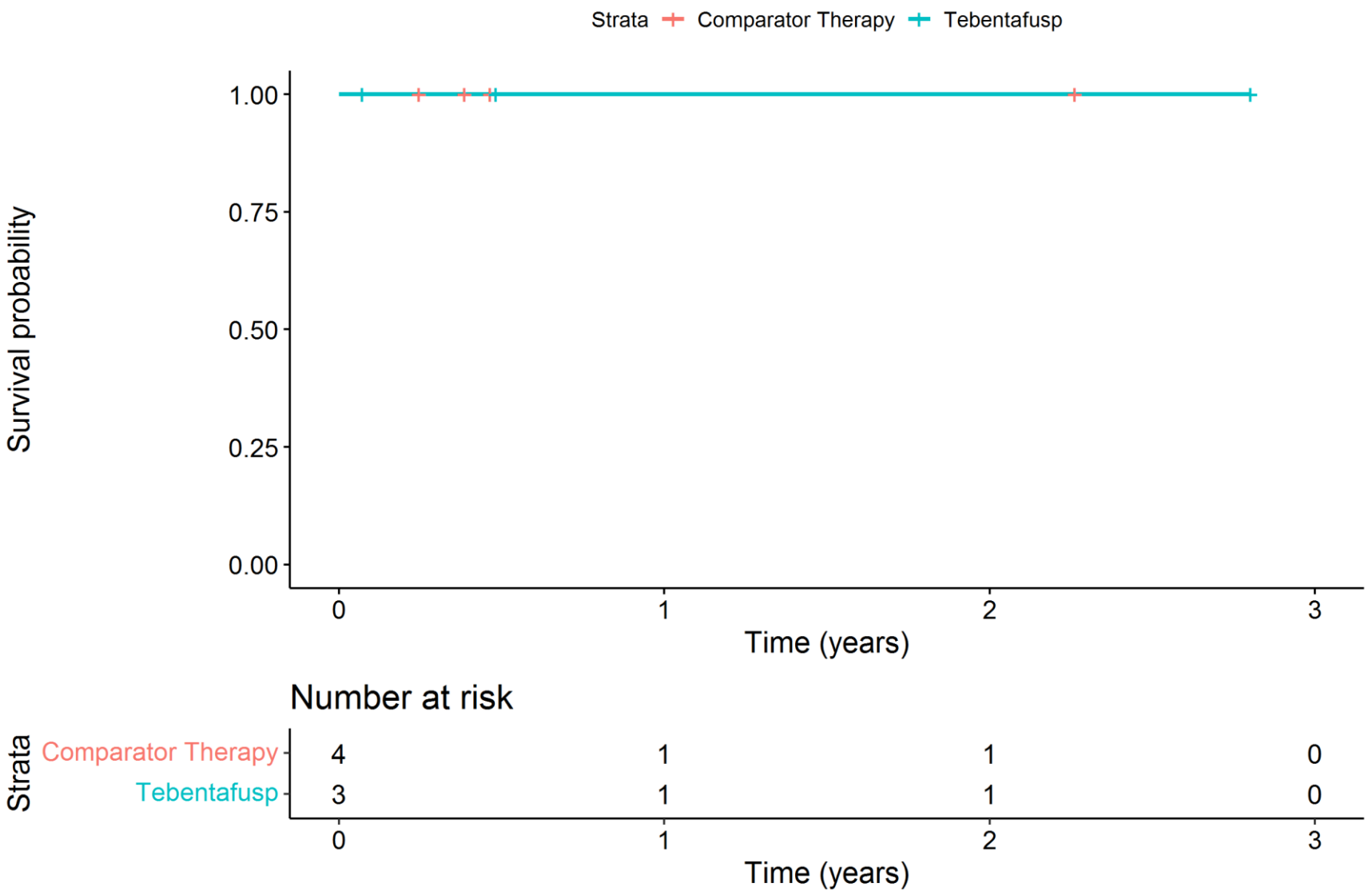
62.23 Hautausschlag - Ipilimumab



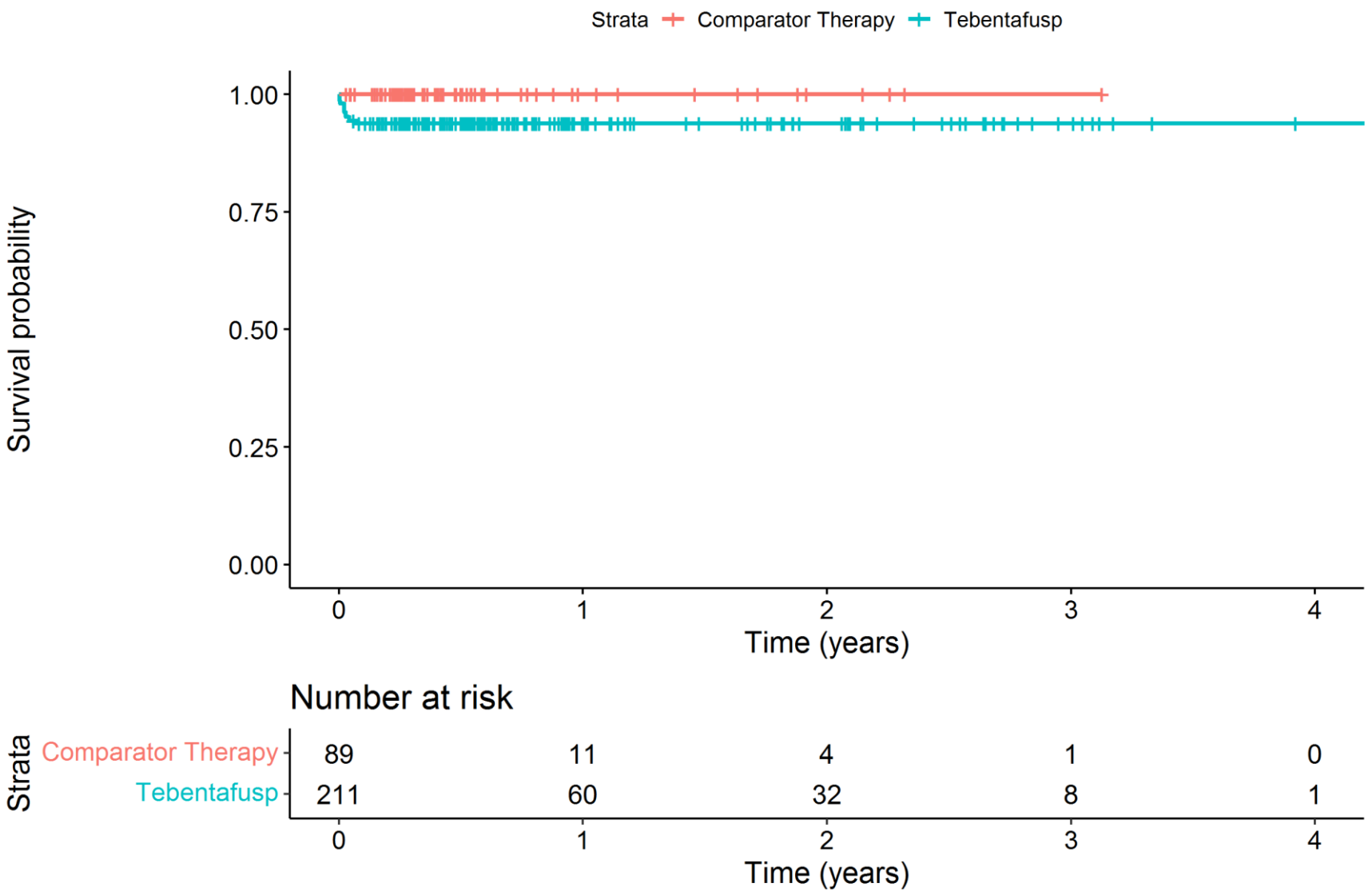
62.24 Makulo-papulöser Hautausschlag- Gesamt



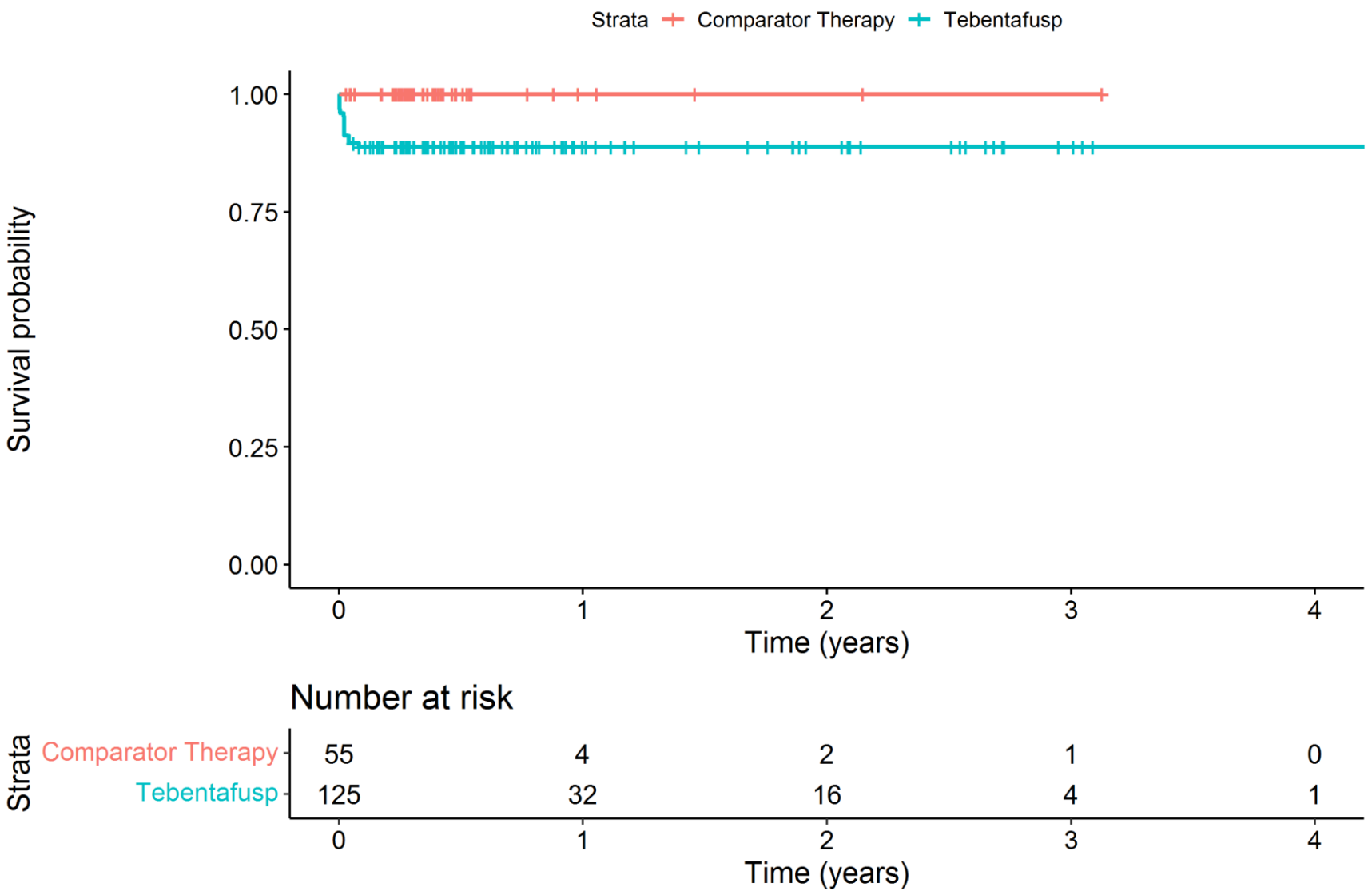
62.25 Makulo-papulöser Hautausschlag- Hispanisch



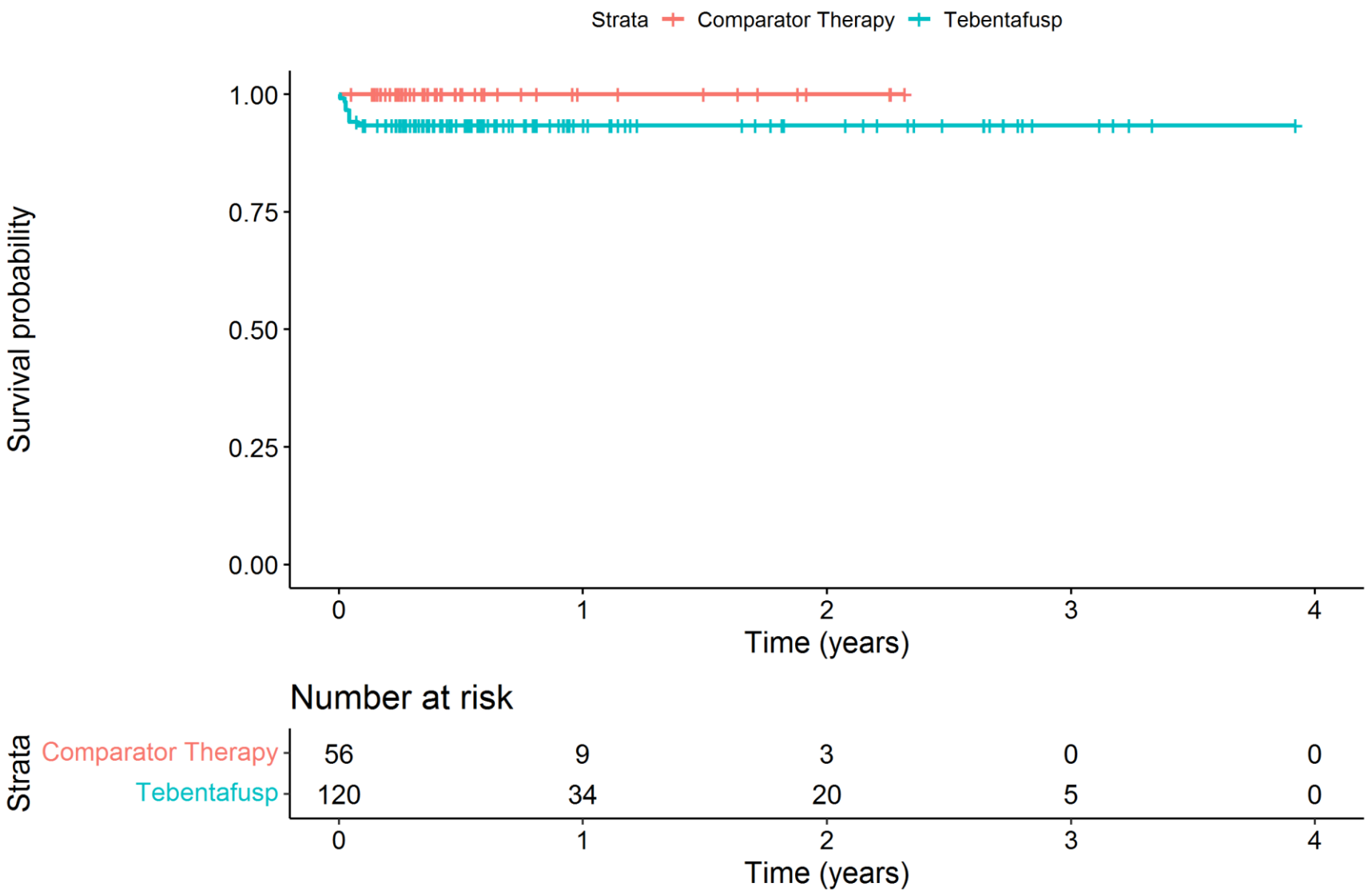
62.26 Makulo-papulöser Hautausschlag- Nicht-hispanisch



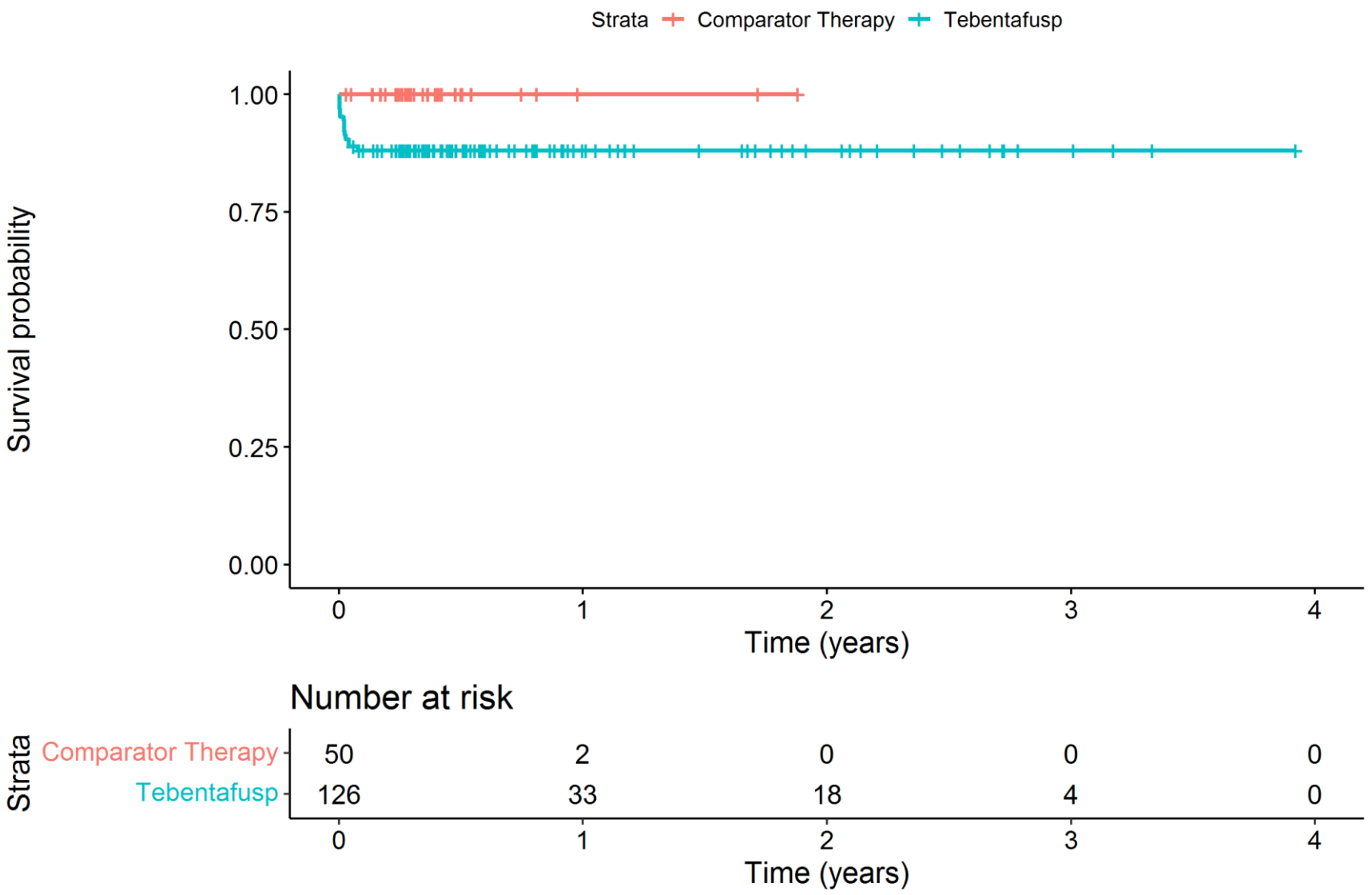
62.27 Makulo-papulöser Hautausschlag- Männlich



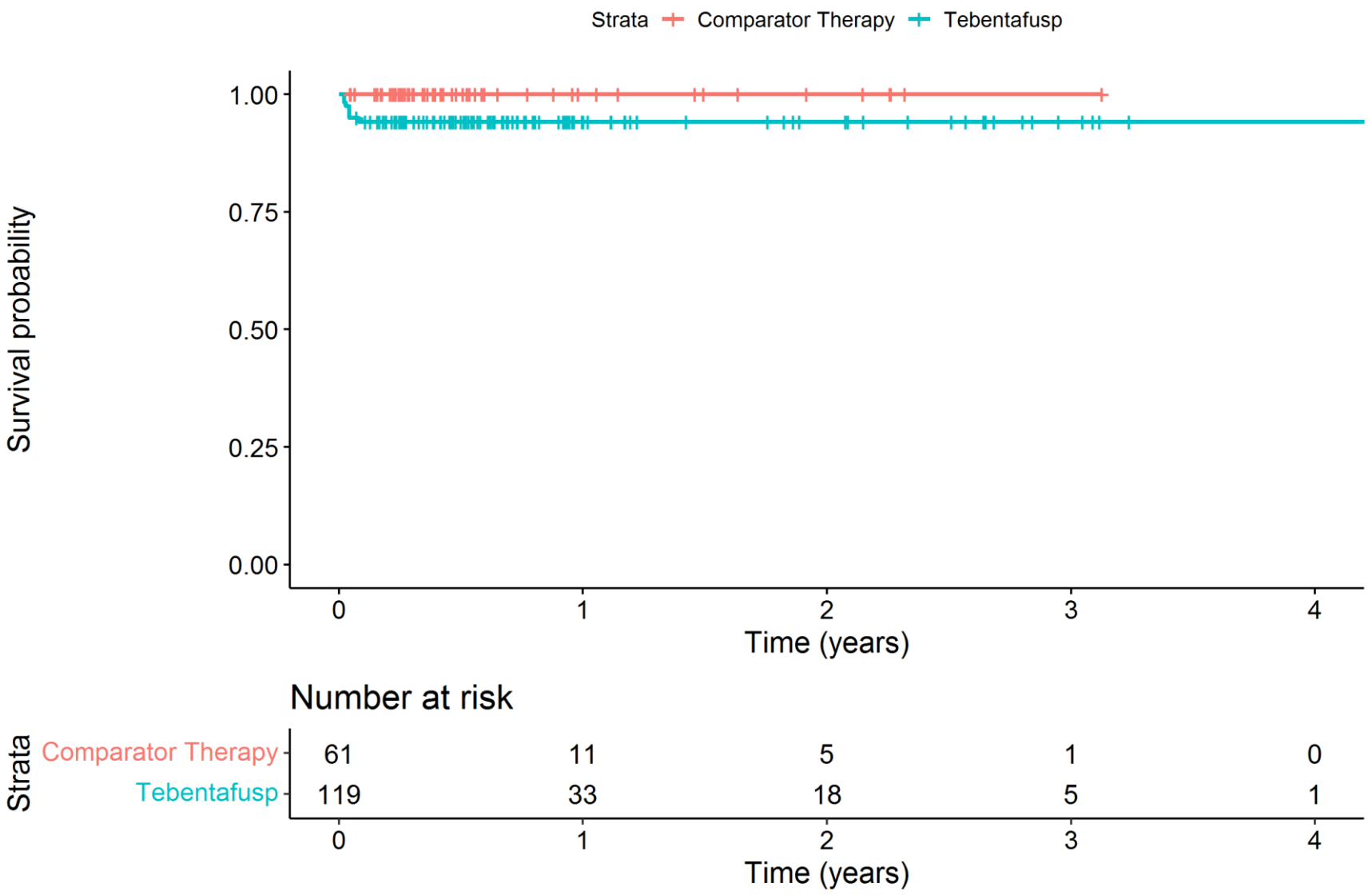
62.28 Makulo-papulöser Hautausschlag- Weiblich



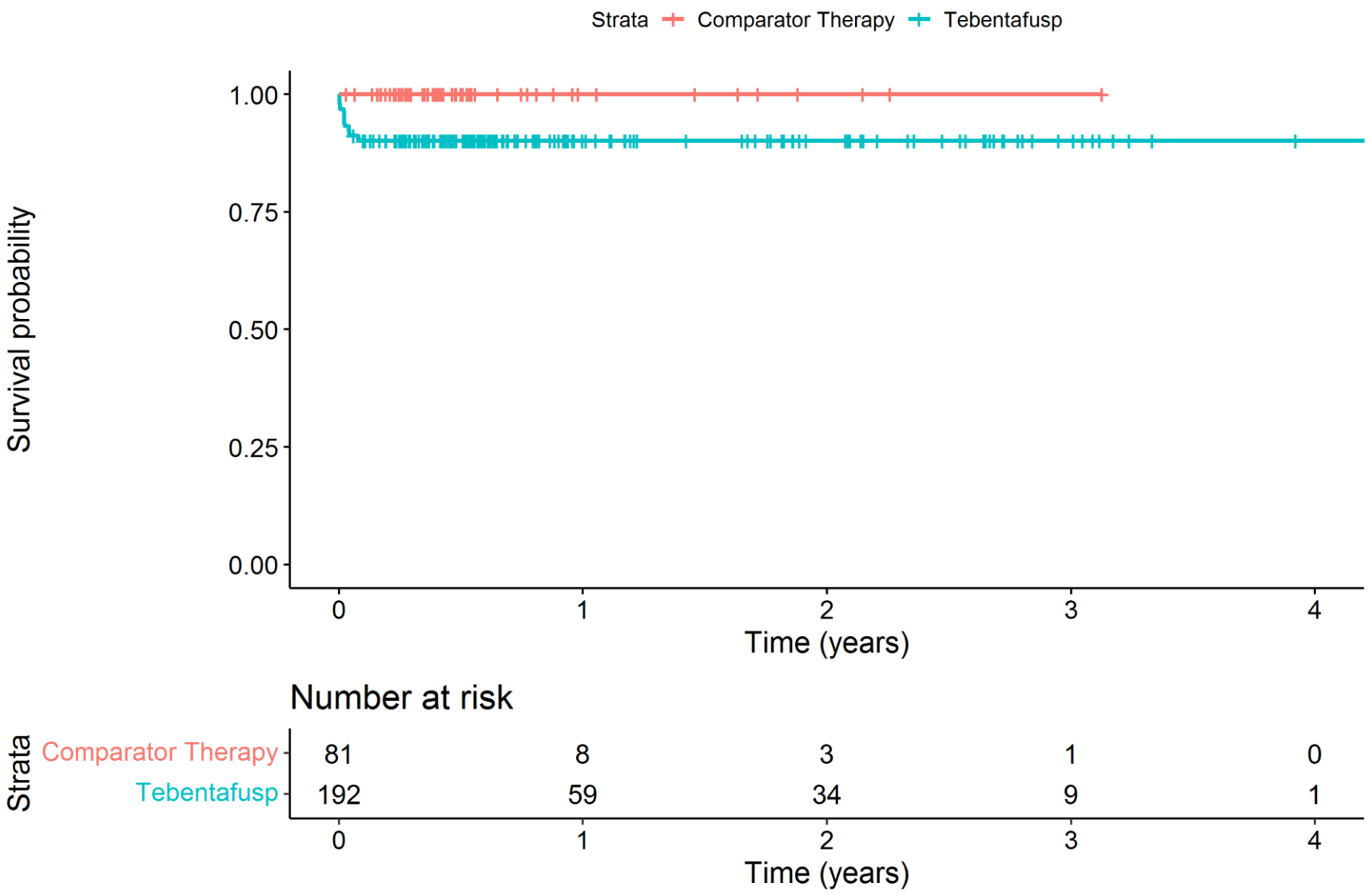
62.29 Makulo-papulöser Hautausschlag- <65



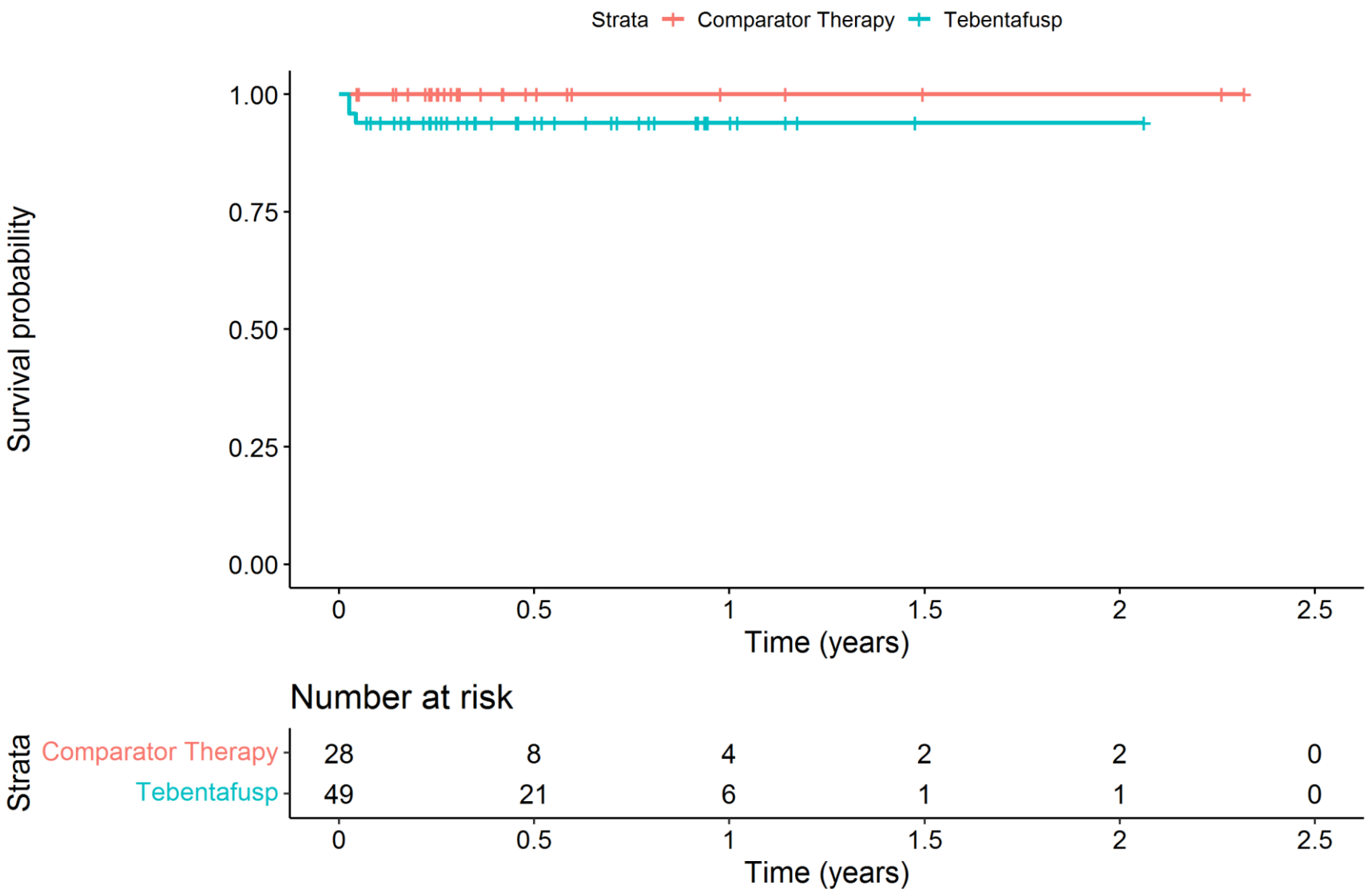
62.30 Makulo-papulöser Hautausschlag- ≥65



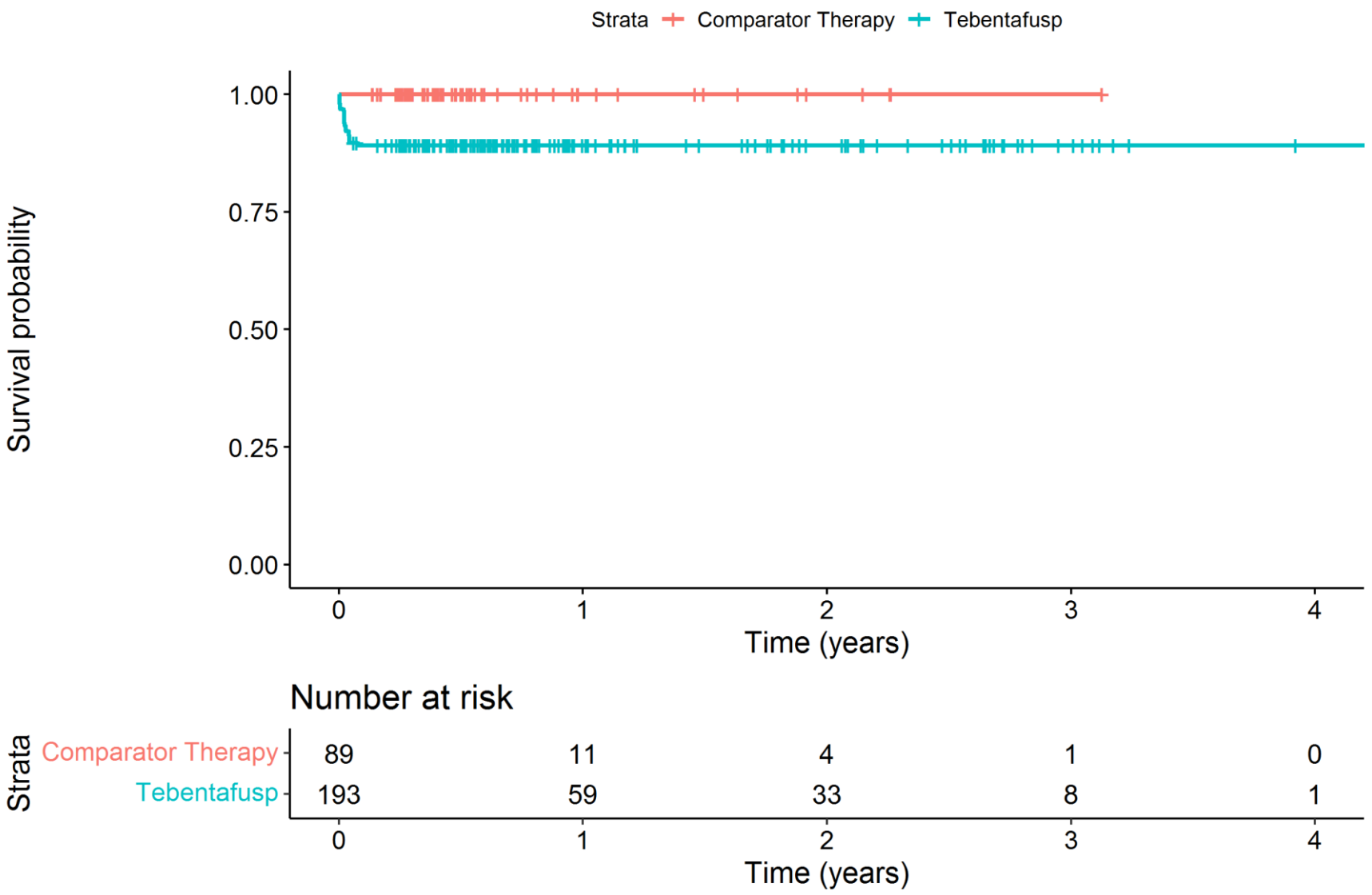
62.31 Makulo-papulöser Hautausschlag- ECOG 0



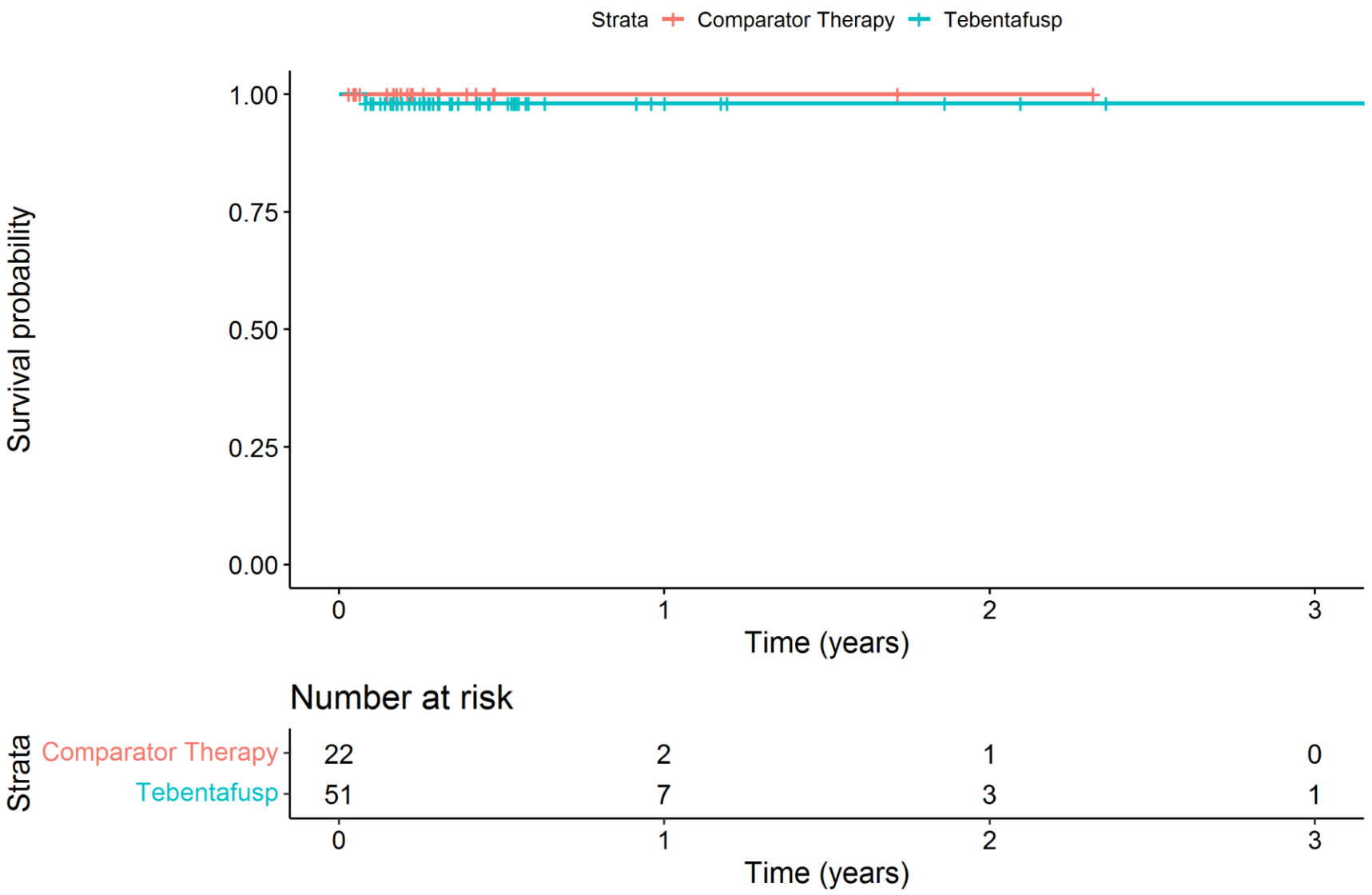
62.32 Makulo-papulöser Hautausschlag- ECOG 1



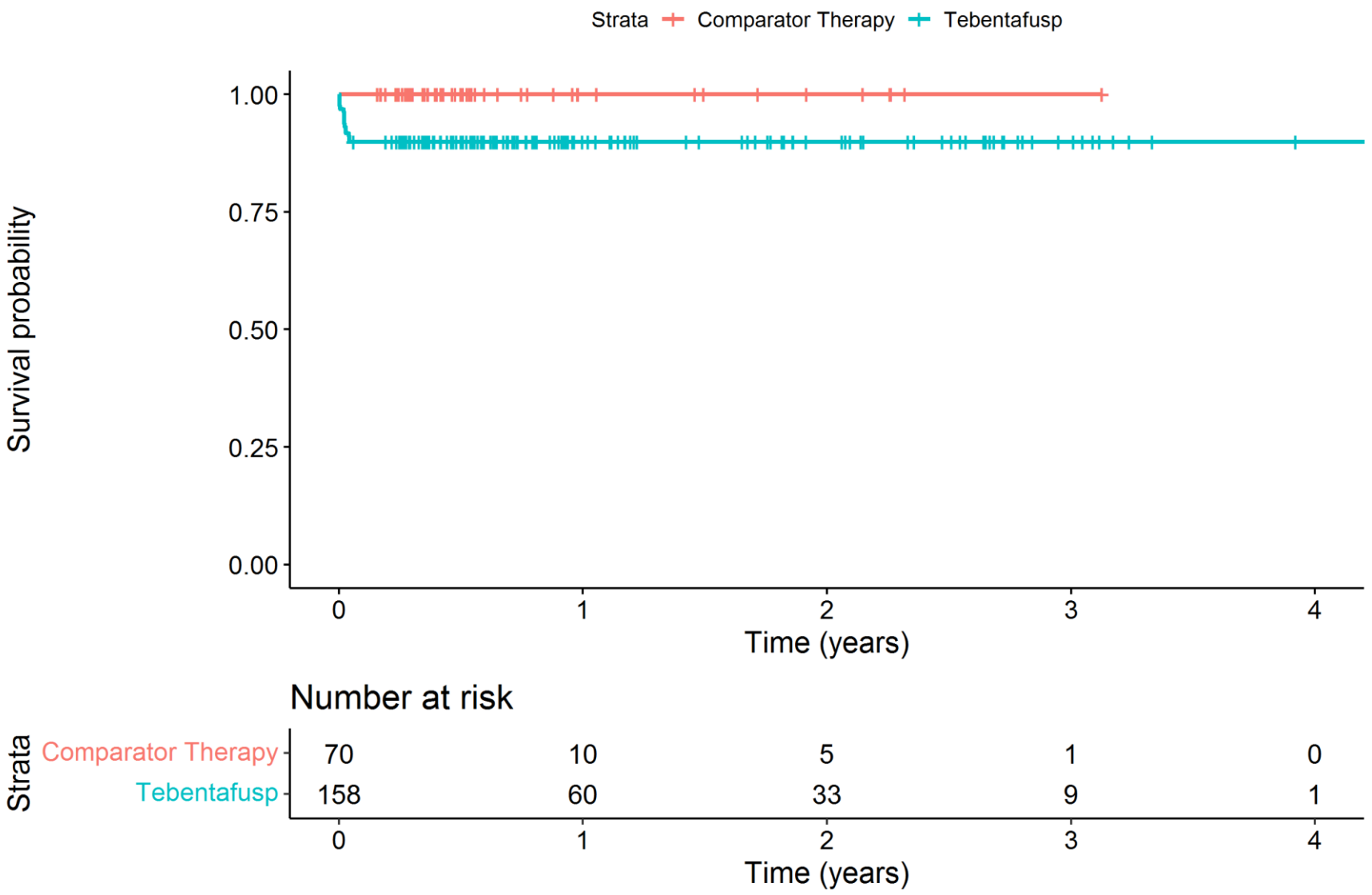
62.33 Makulo-papulöser Hautausschlag- ALP ≤ ULN



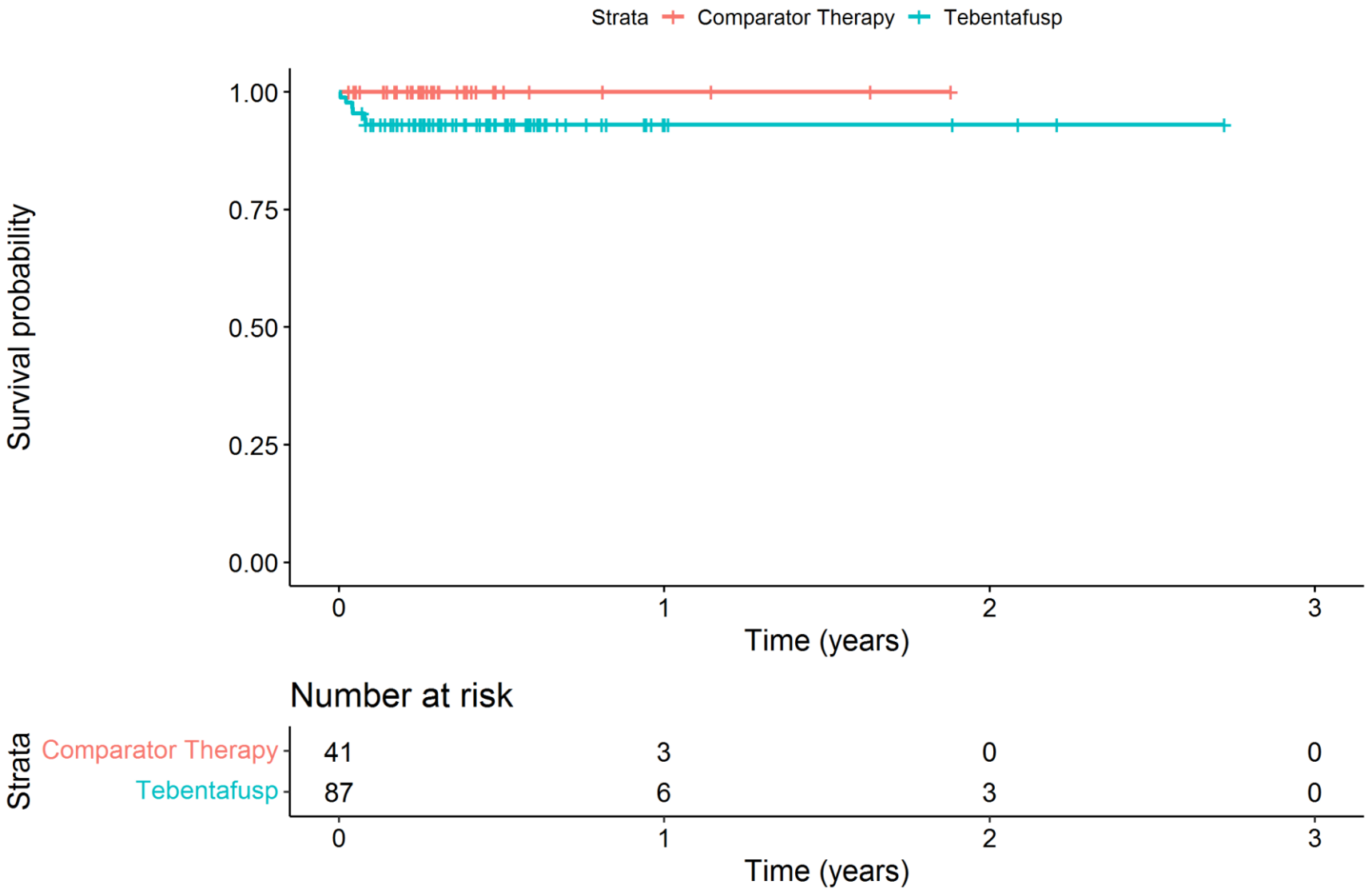
62.34 Makulo-papulöser Hautausschlag- ALP > ULN



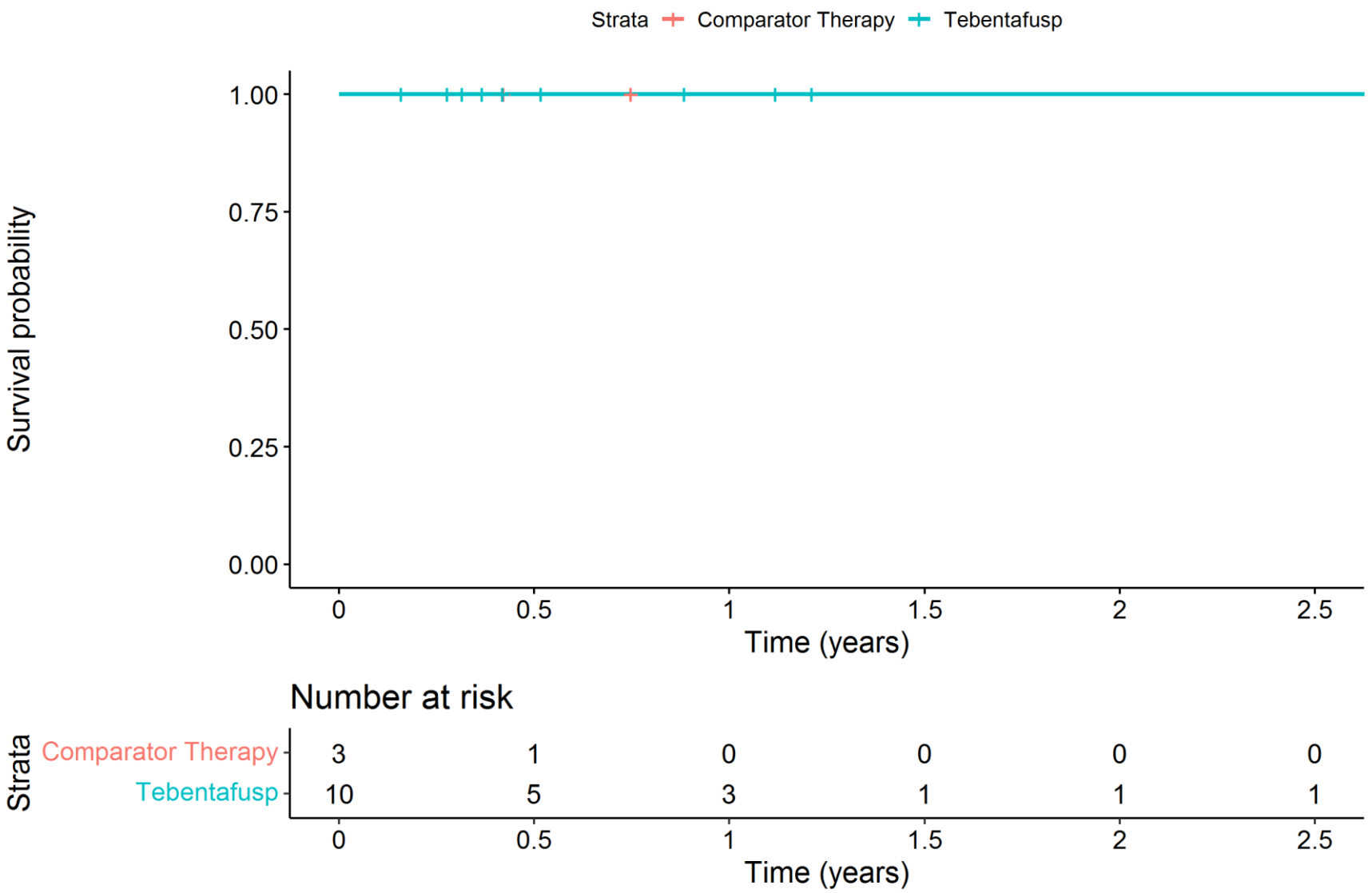
62.35 Makulo-papulöser Hautausschlag- LDH =< ULN



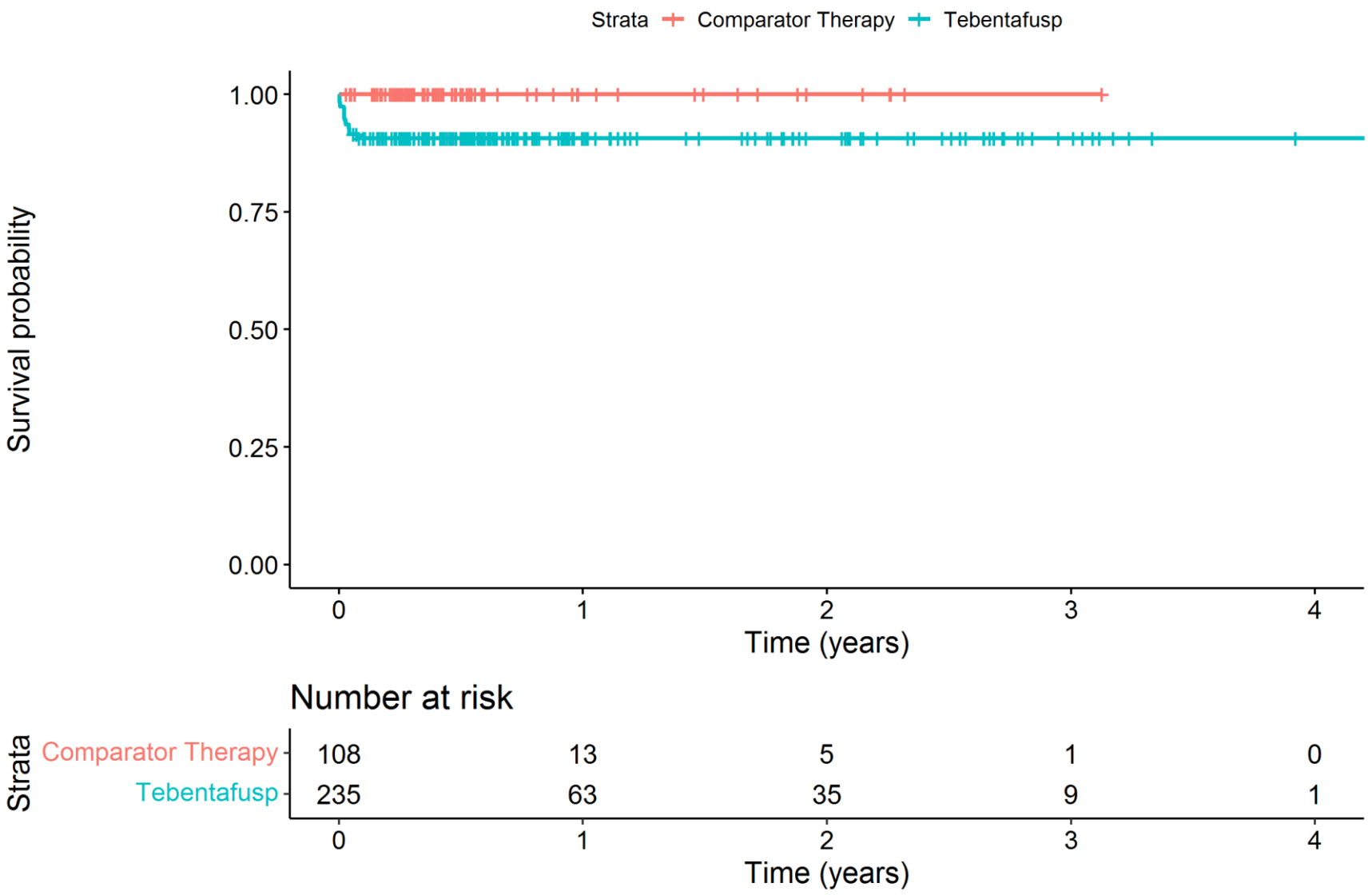
62.36 Makulo-papulöser Hautausschlag- LDH > ULN



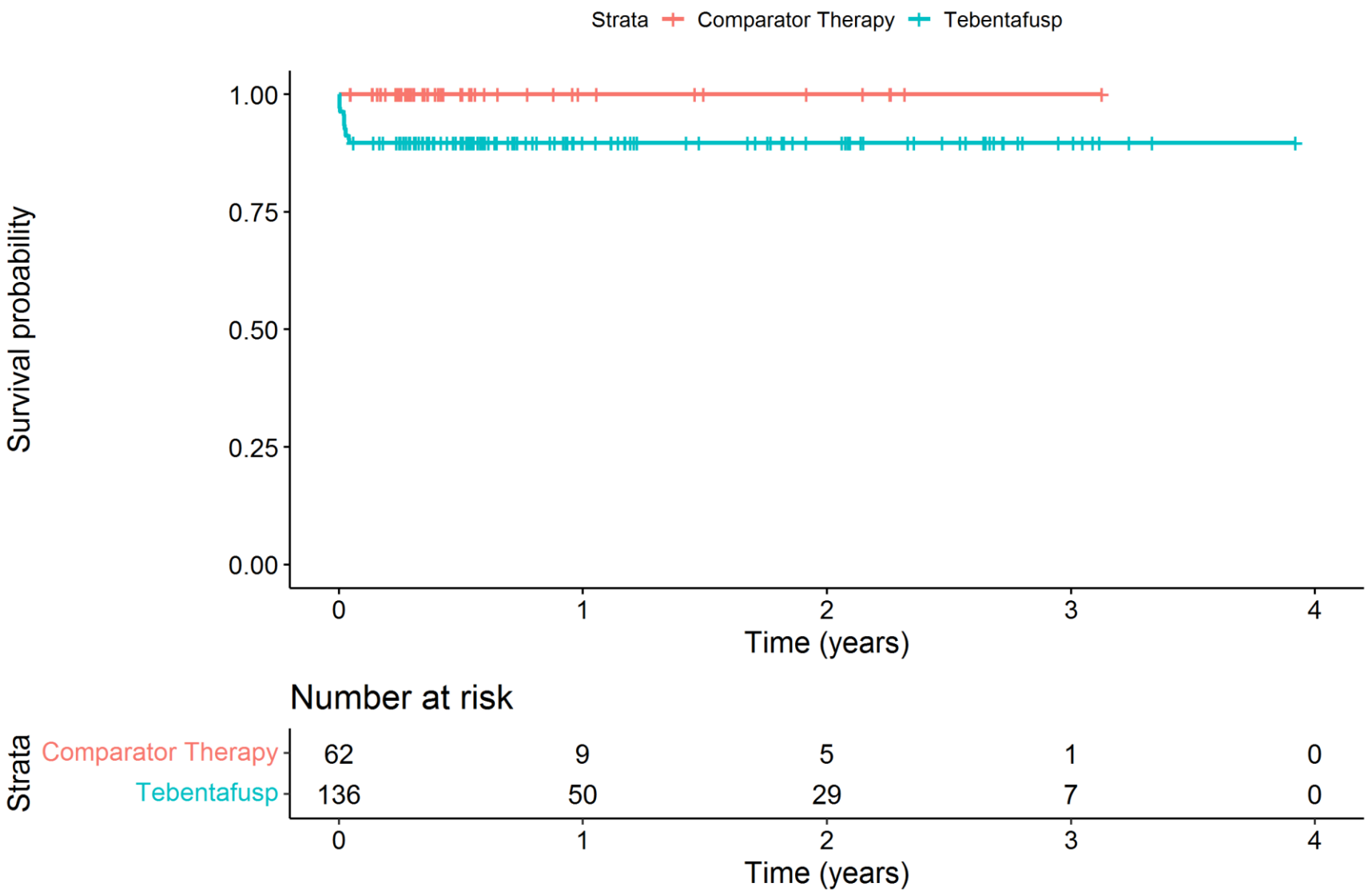
62.37 Makulo-papulöser Hautausschlag- Vorherige Therapie adjuvant/neoadjuvant



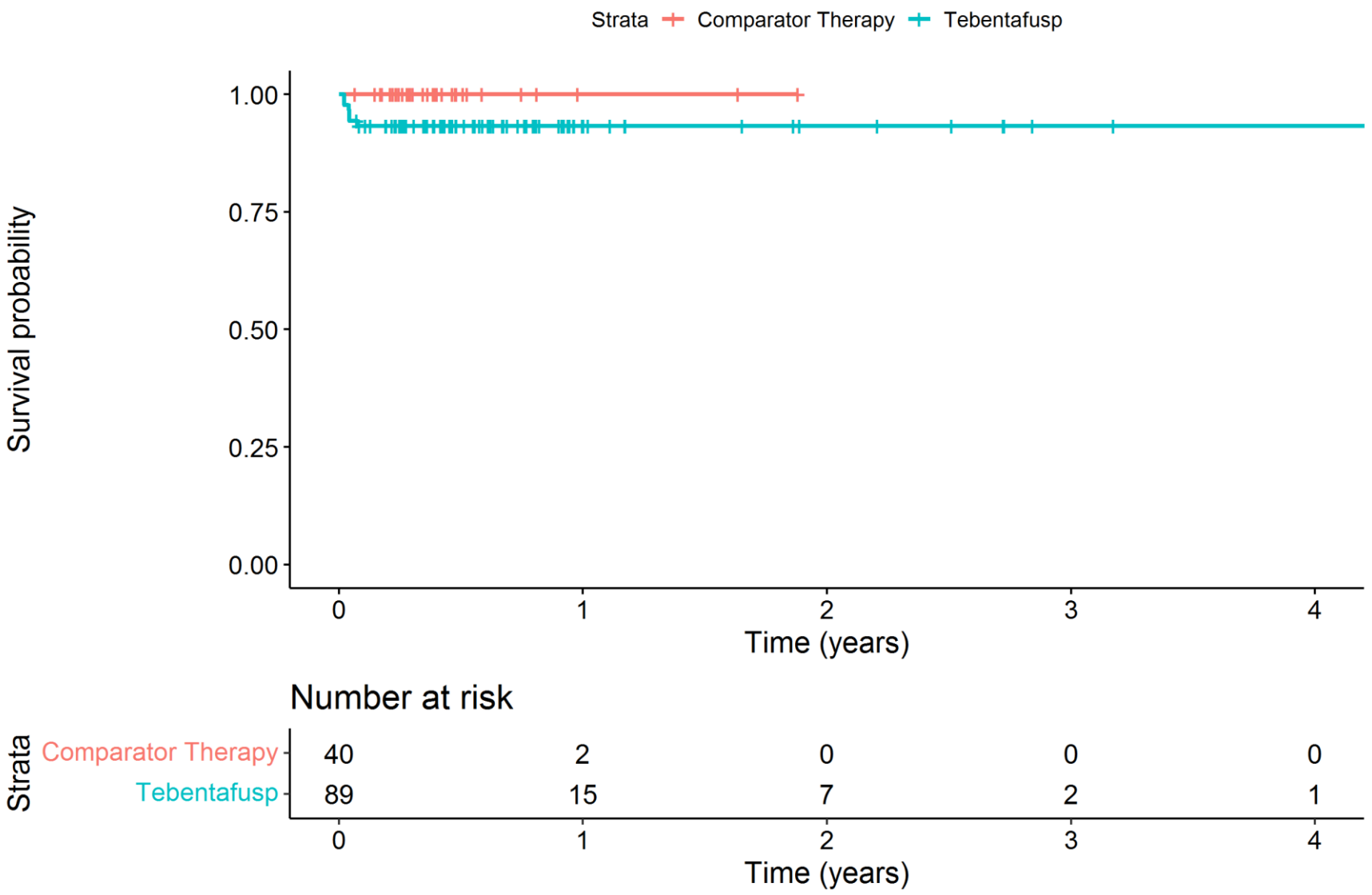
62.38 Makulo-papulöser Hautausschlag- Keine Vorherige Therapie adjuvant/neoadjuvant



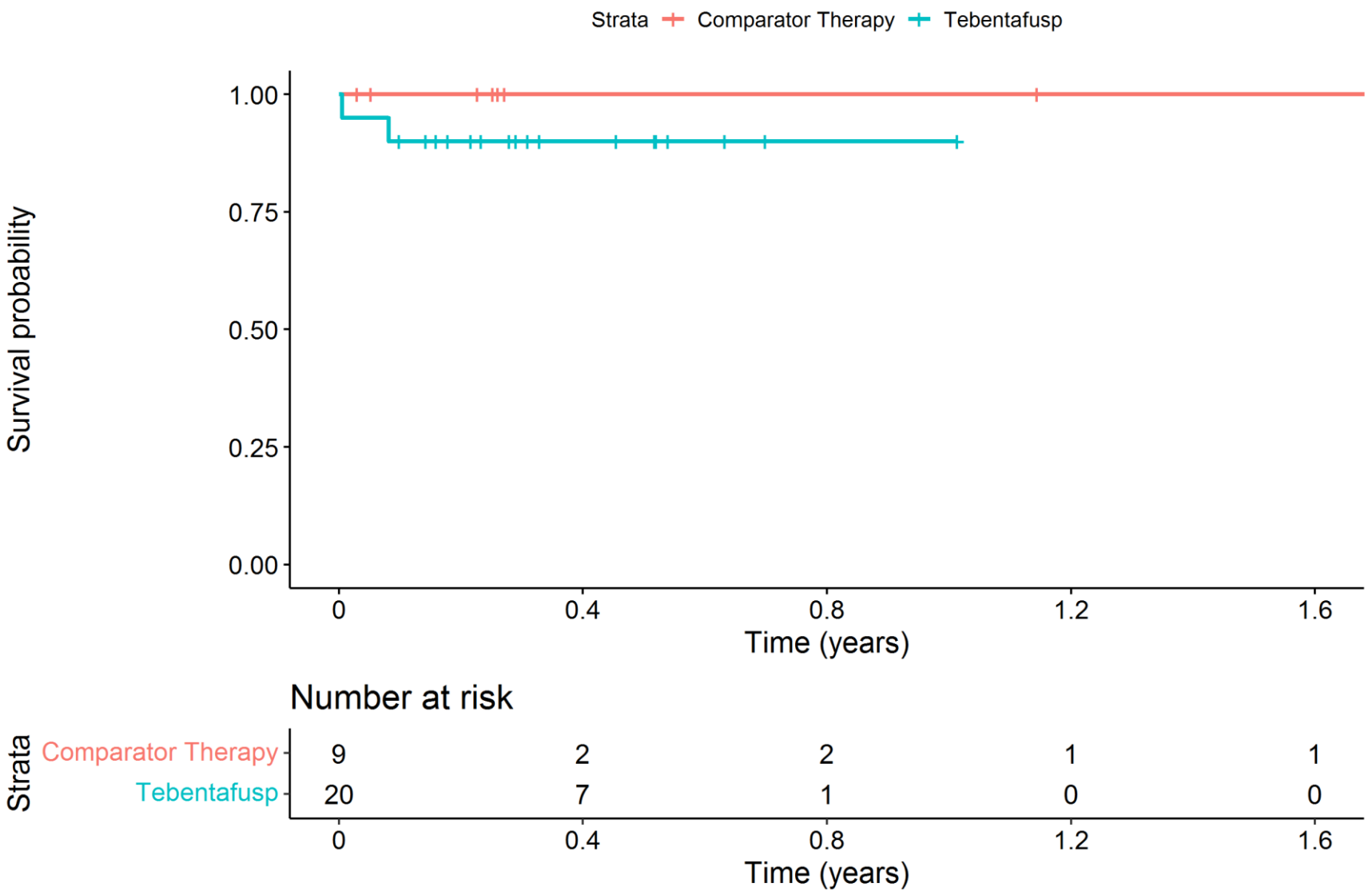
62.39 Makulo-papulöser Hautausschlag- Läsion ≤ 3cm



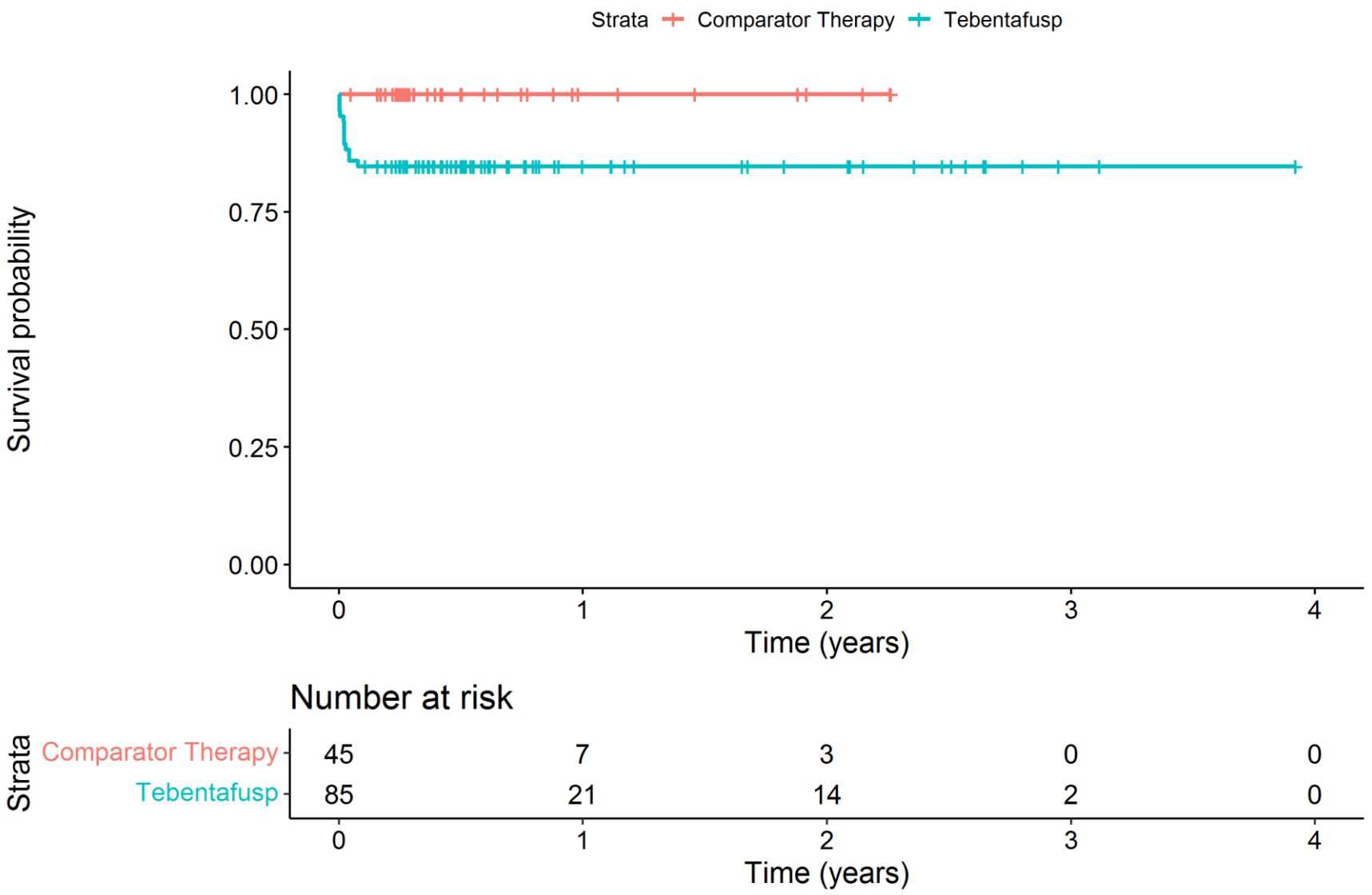
62.40 Makulo-papulöser Hautausschlag- Läsion 3,1-8,0 cm



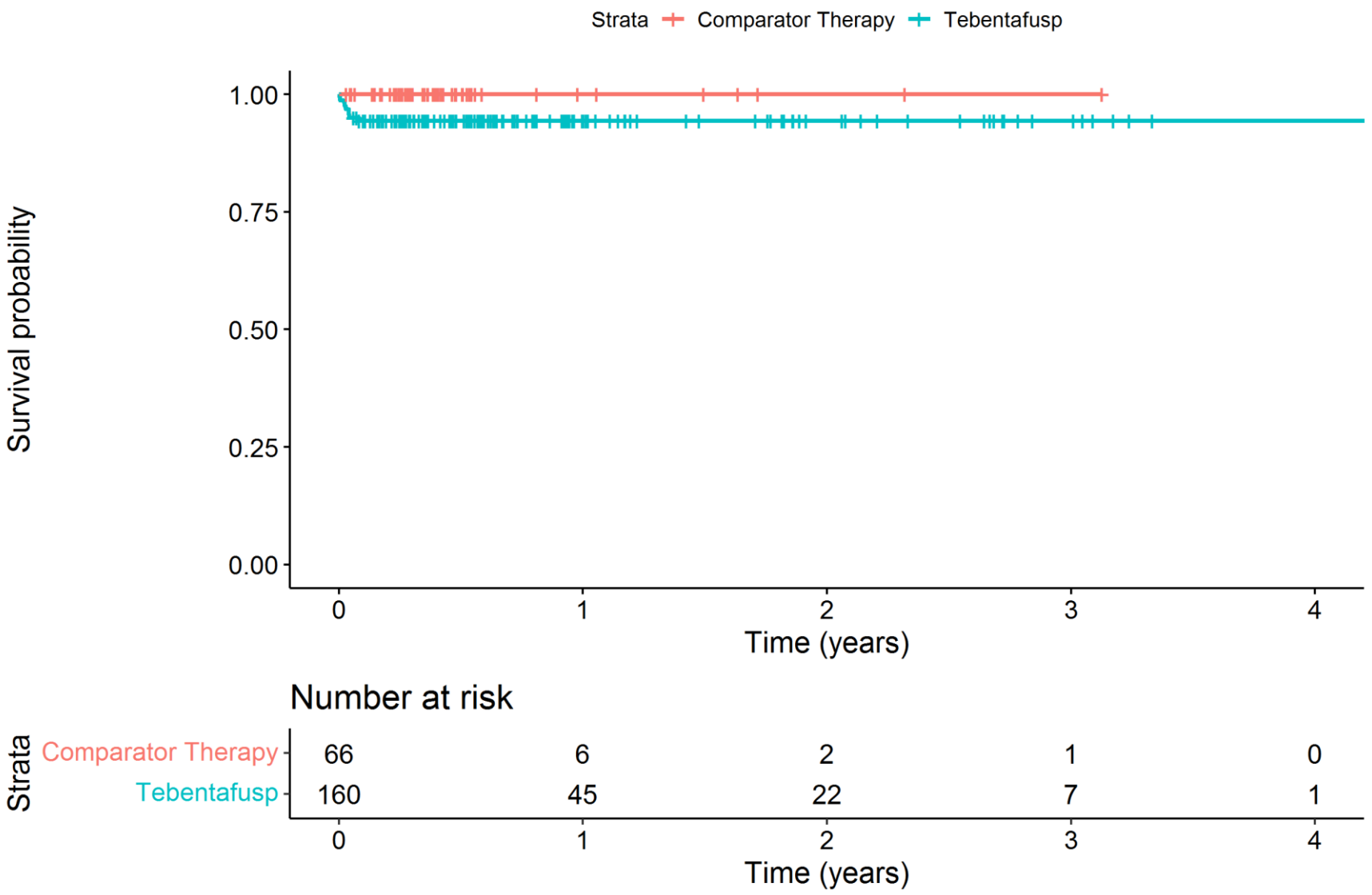
62.41 Makulo-papulöser Hautausschlag- Läsion ≥8,1 cm



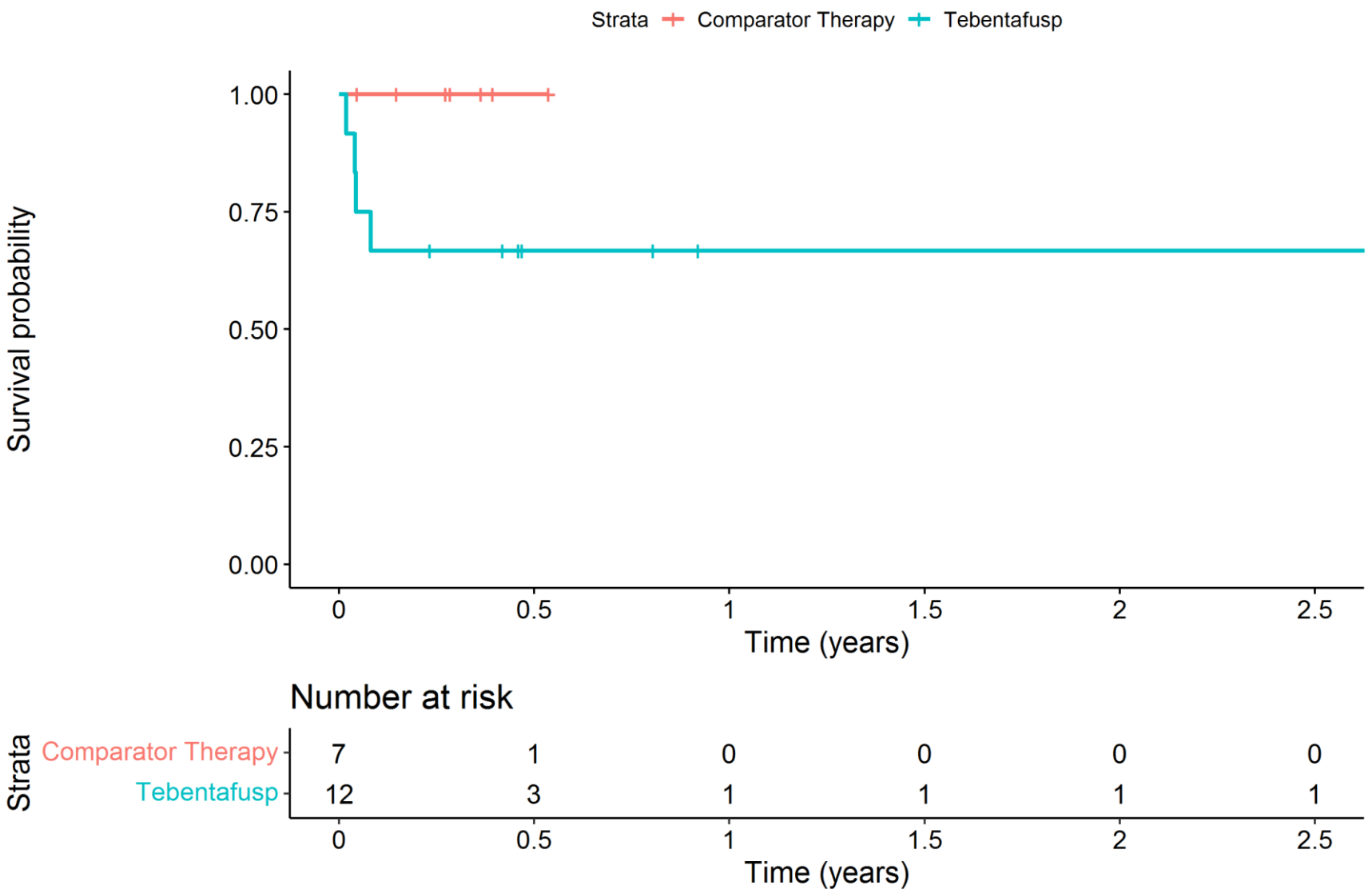
62.42 Makulo-papulöser Hautausschlag- Nordamerika



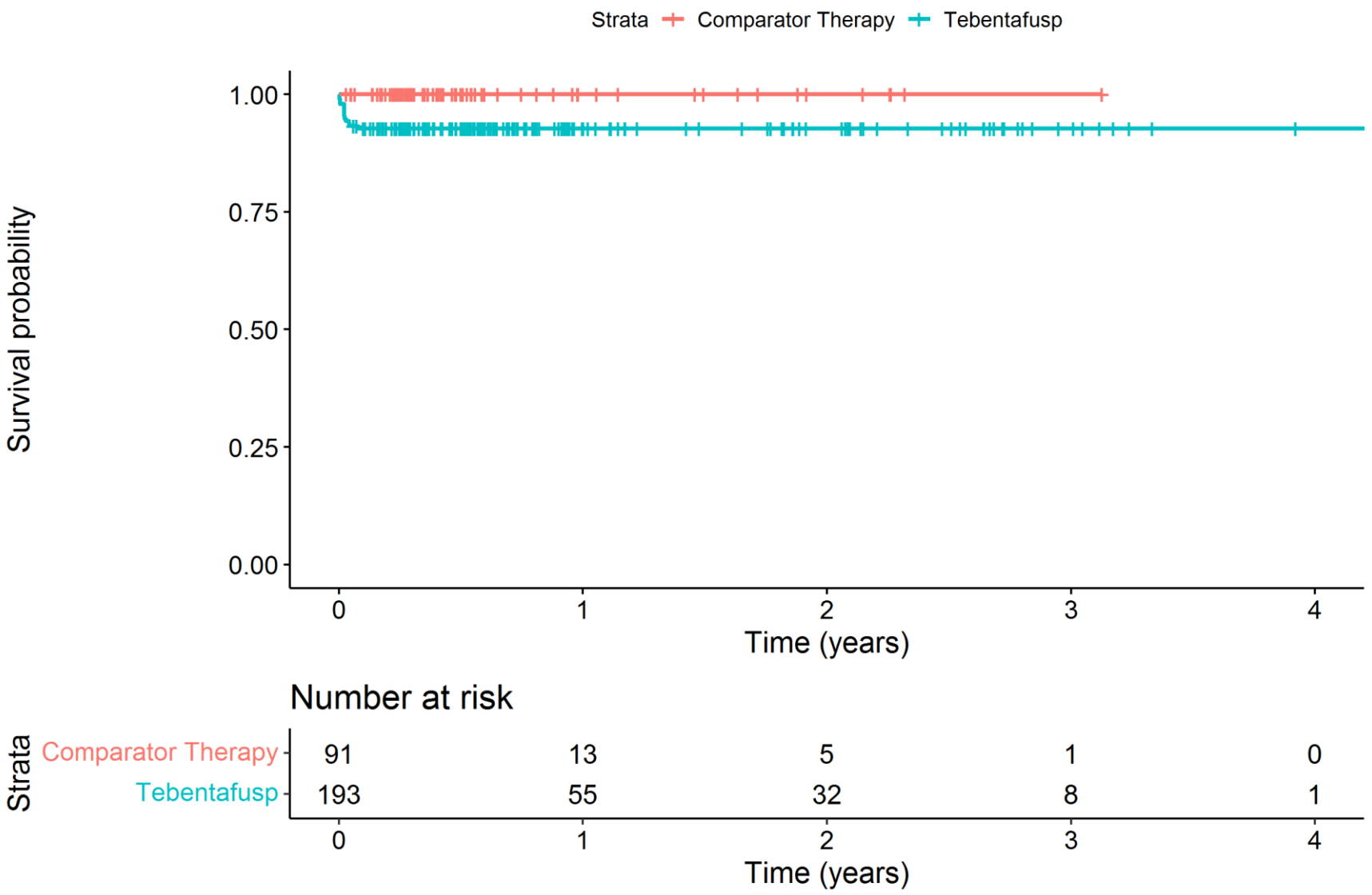
62.43 Makulo-papulöser Hautausschlag- Nicht-Nordamerika



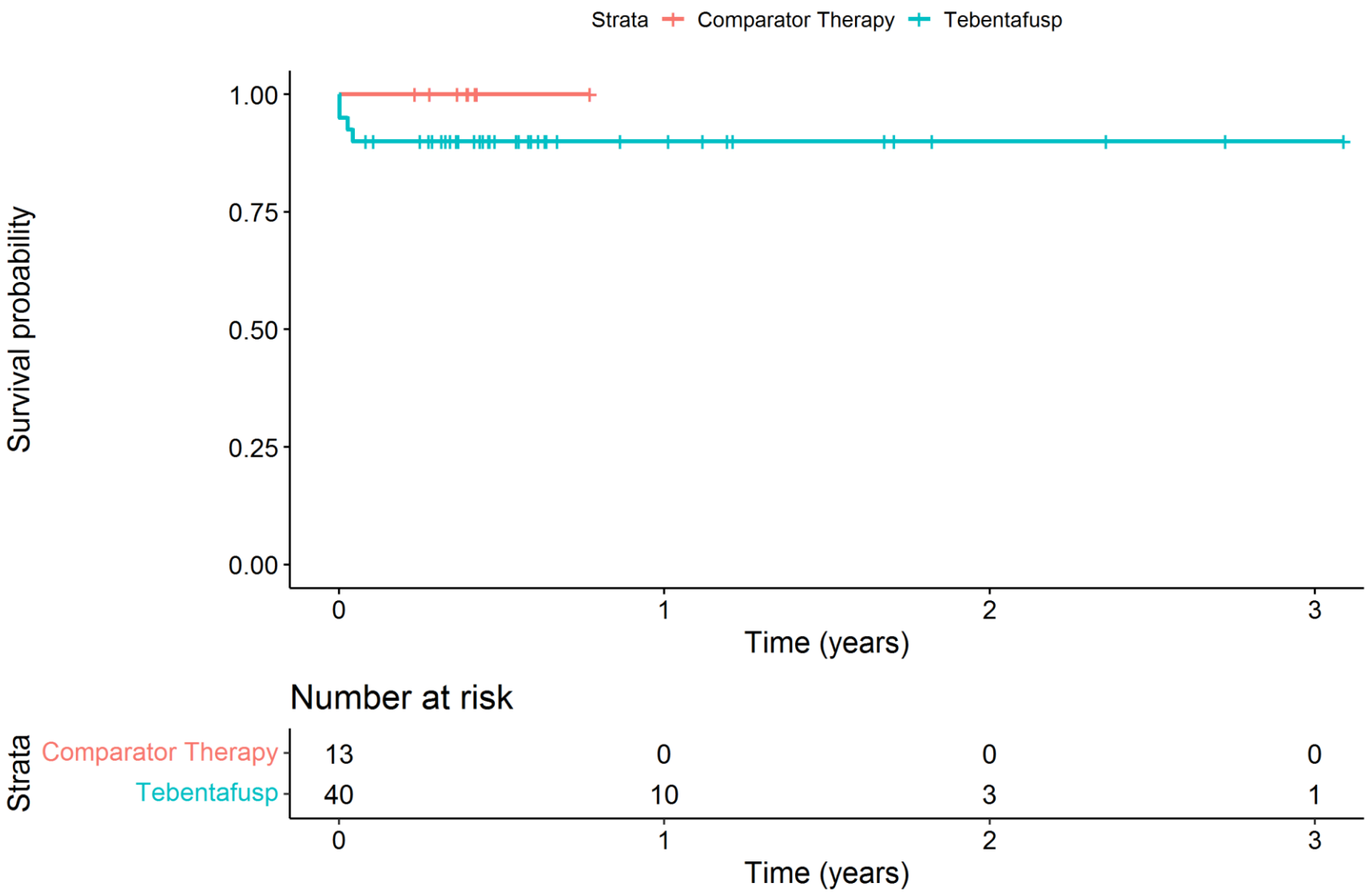
62.44 Makulo-papulöser Hautausschlag- Dacarbazin



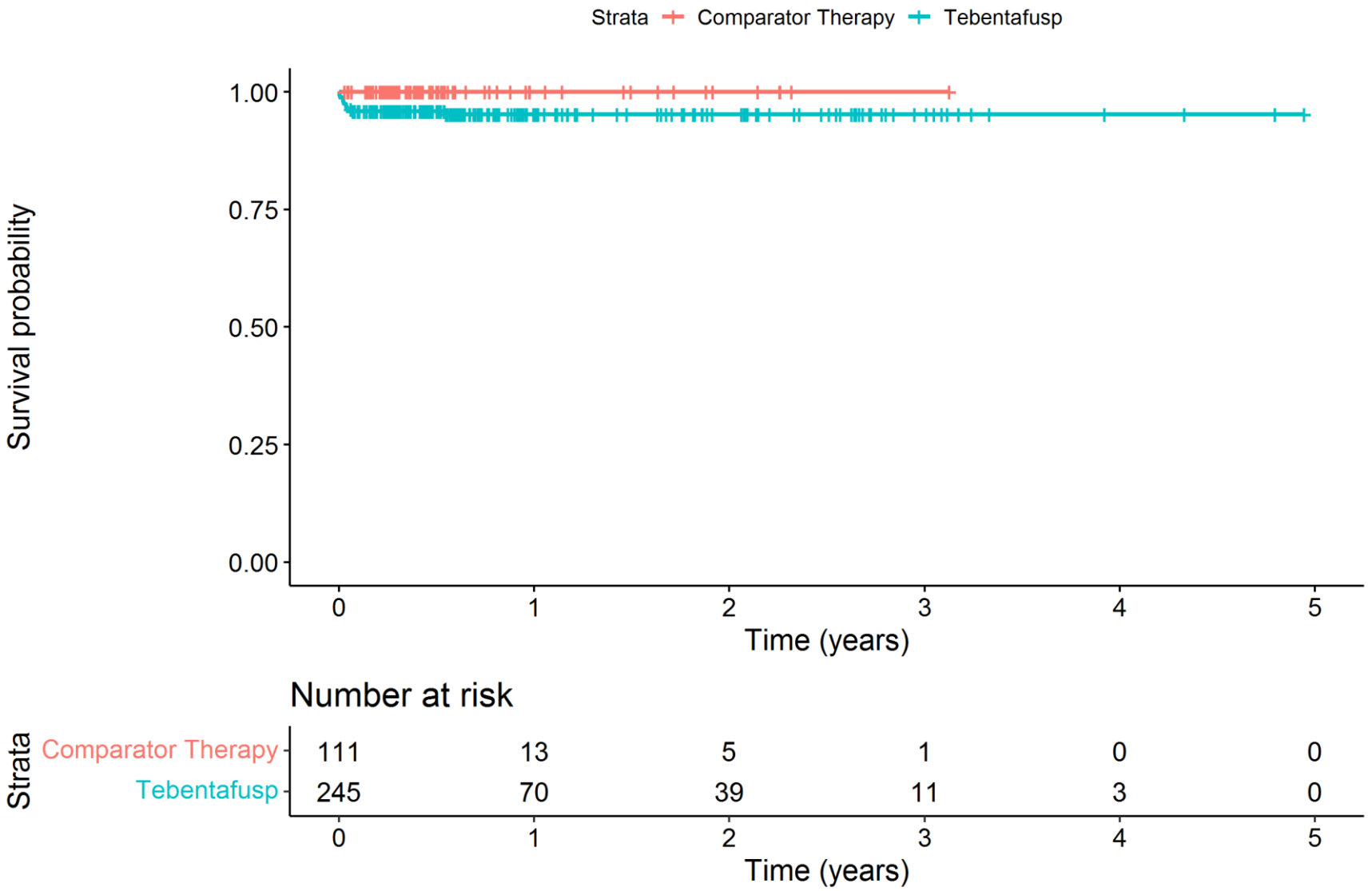
62.45 Makulo-papulöser Hautausschlag- Pembrolizumab



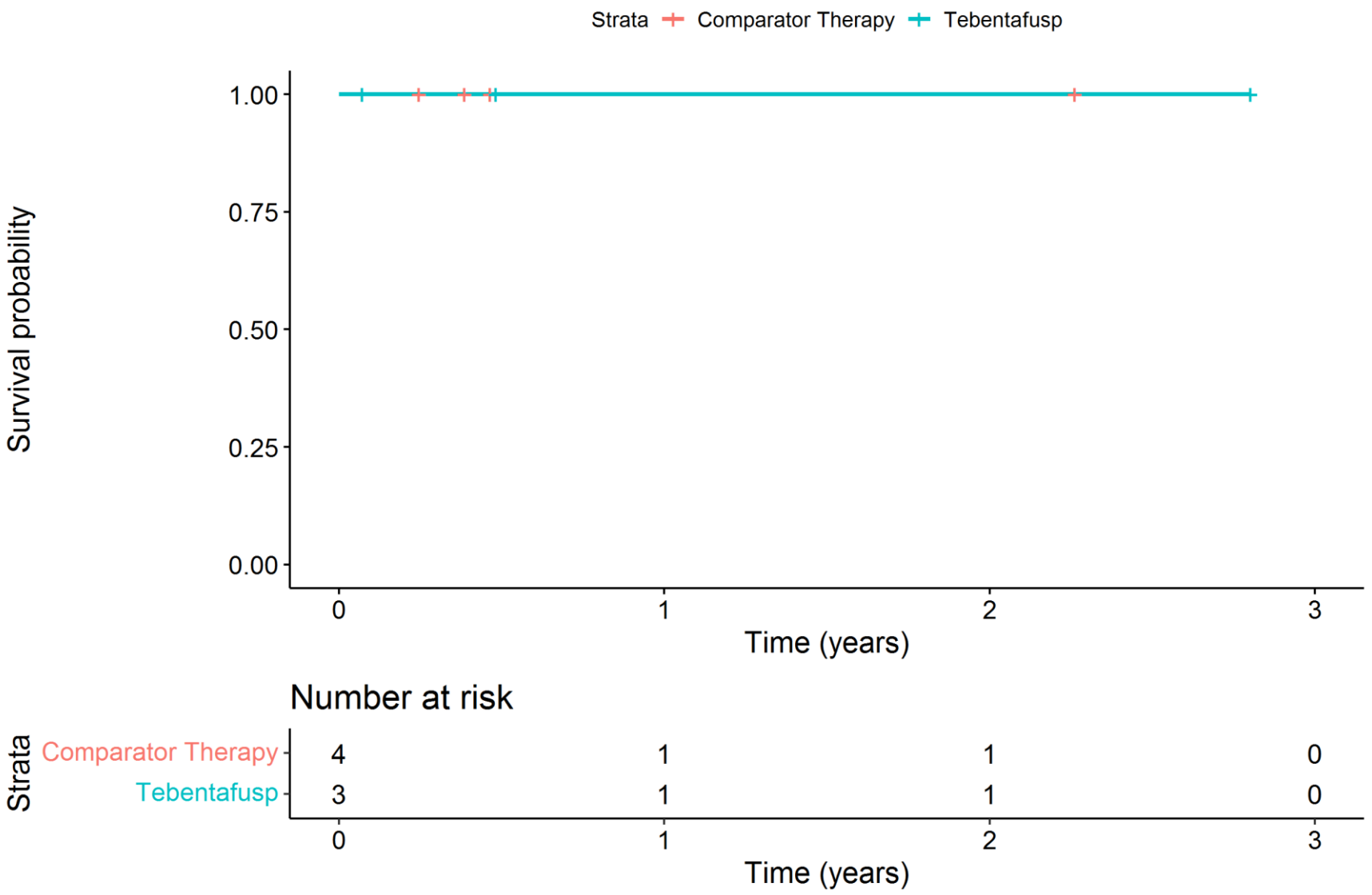
62.46 Makulo-papulöser Hautausschlag- Ipilimumab



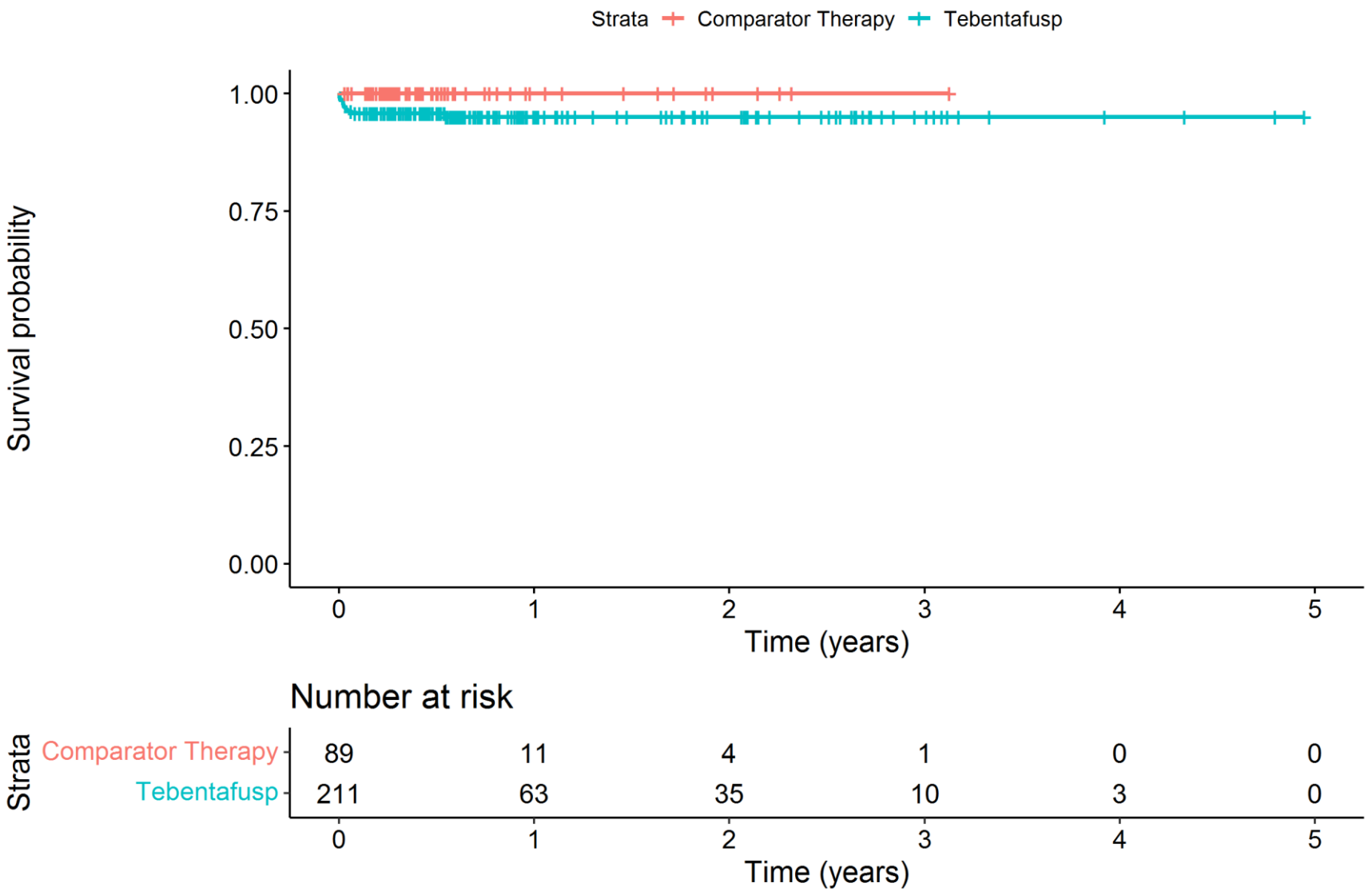
62.47 Pruritus - Gesamt



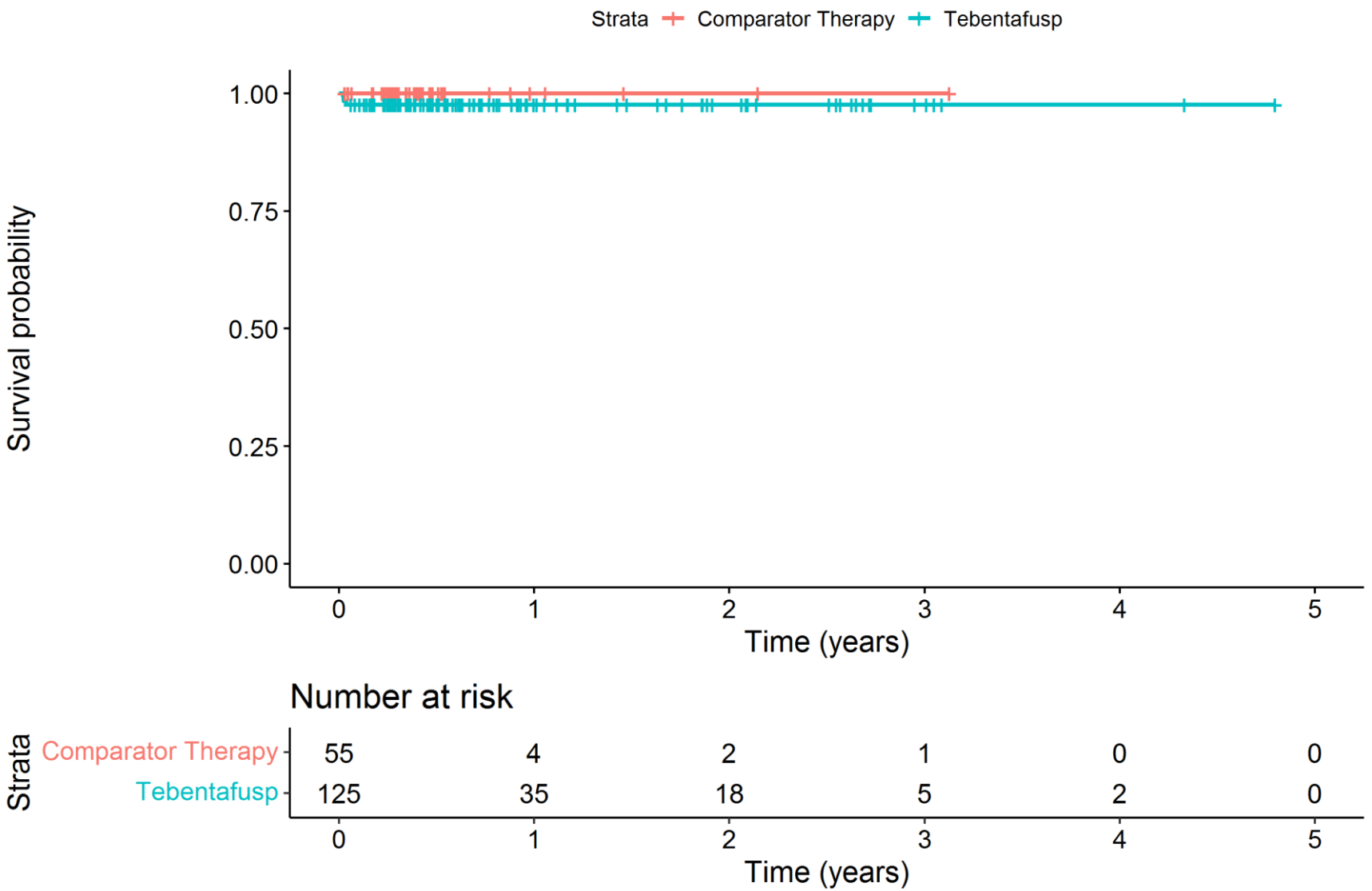
62.48 Pruritus - Hispanisch



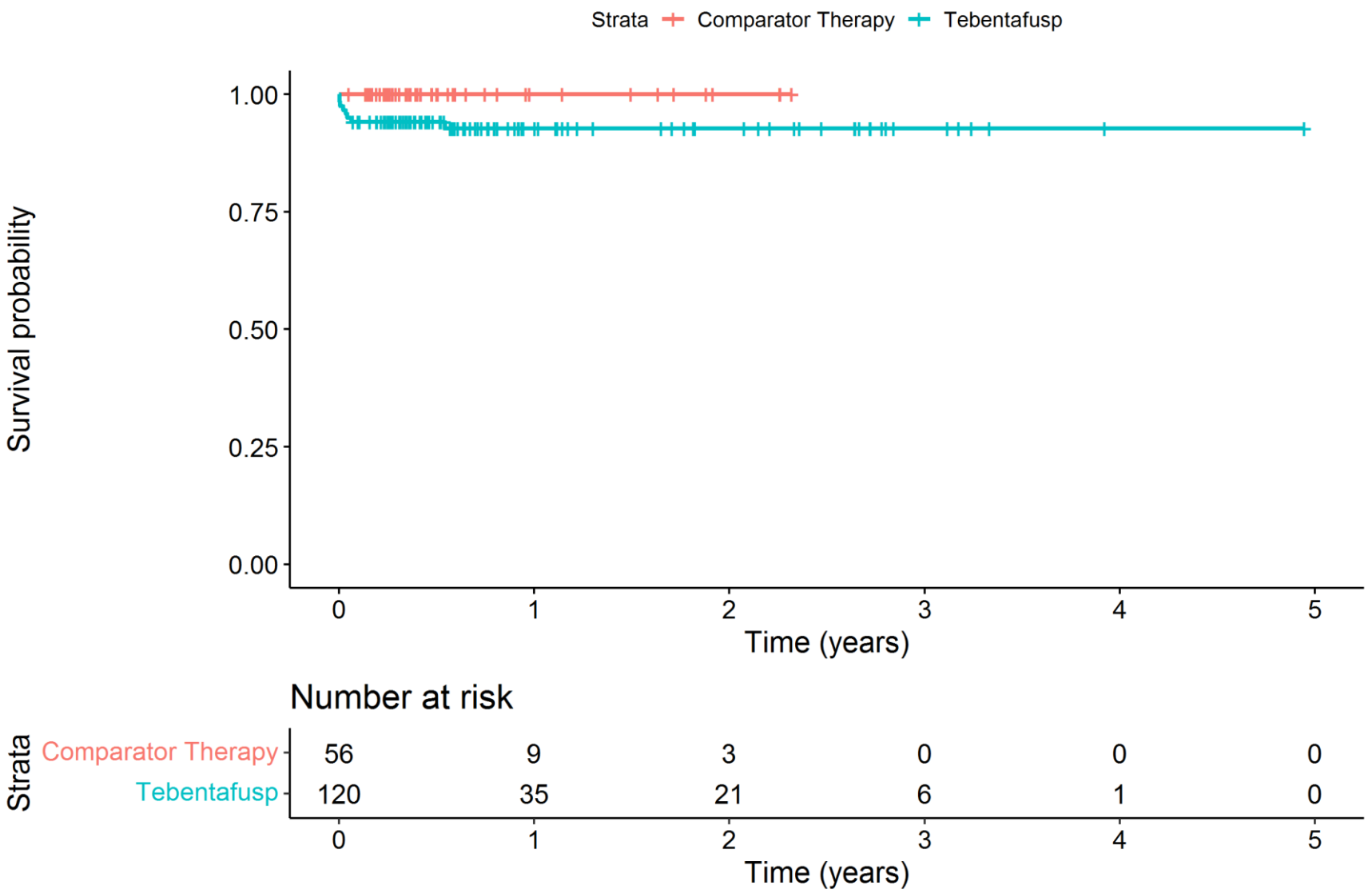
Pruritus - Nicht-hispanisch



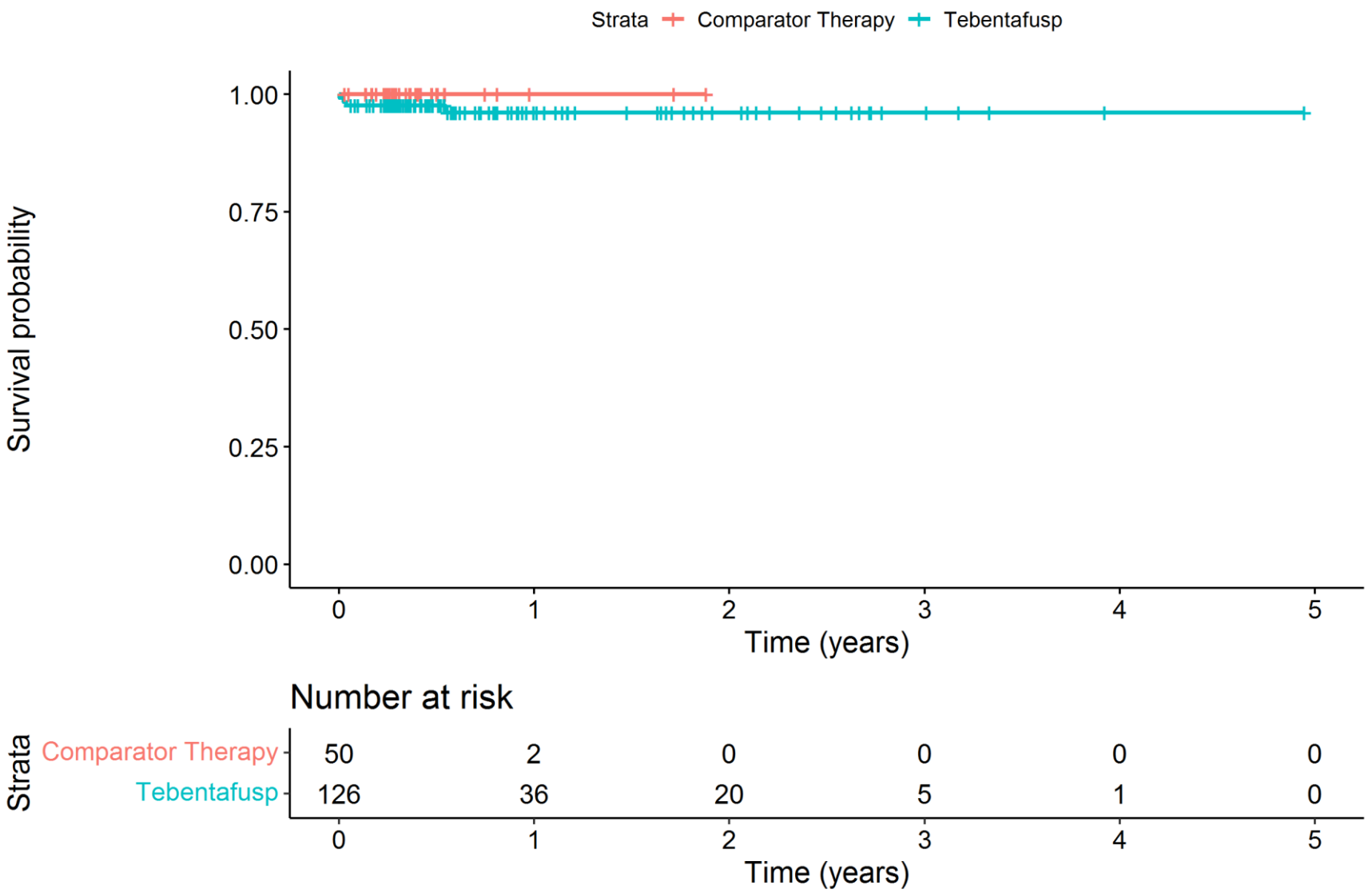
Pruritus - Männlich



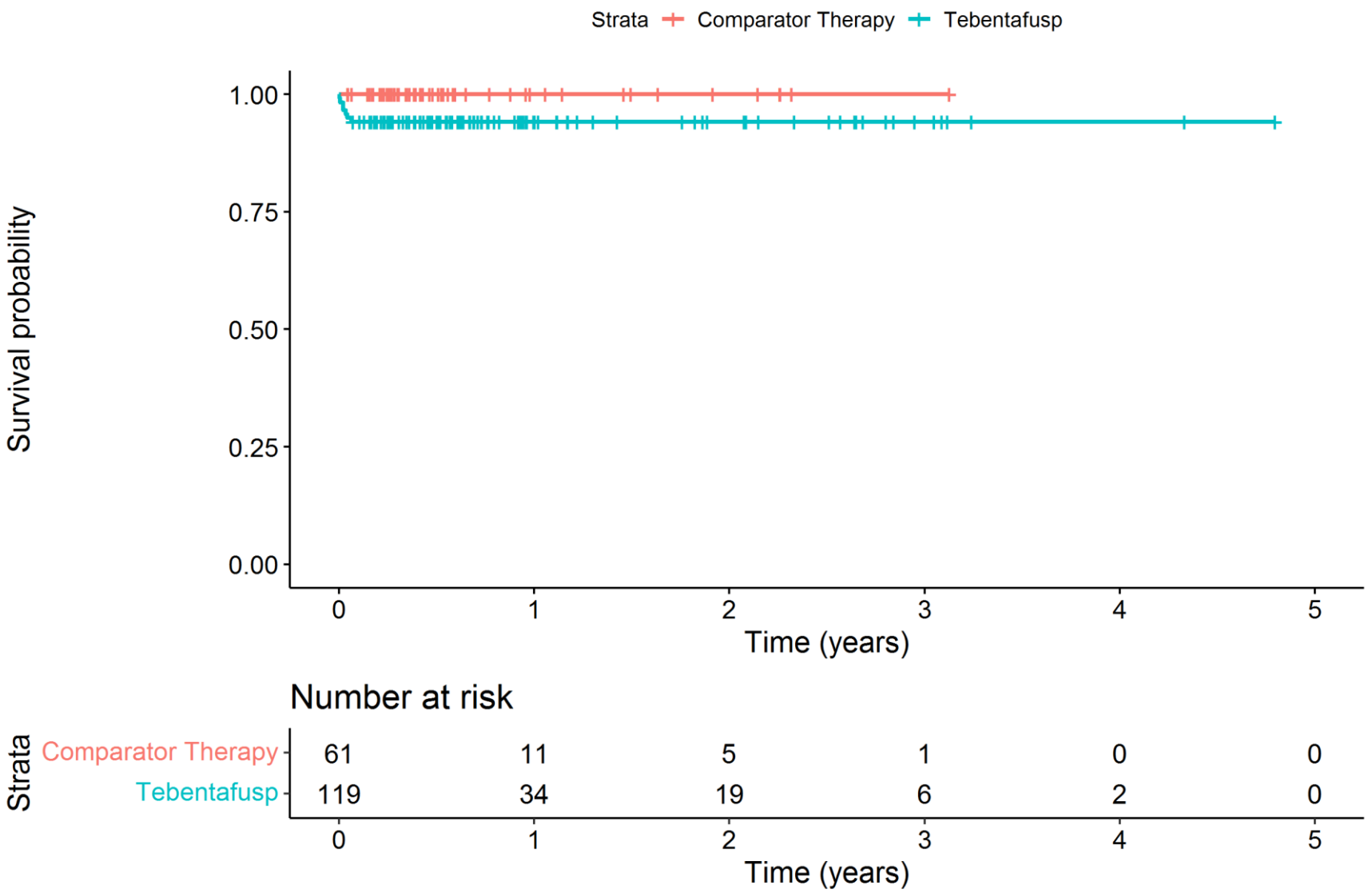
62.49 Pruritus - Weiblich



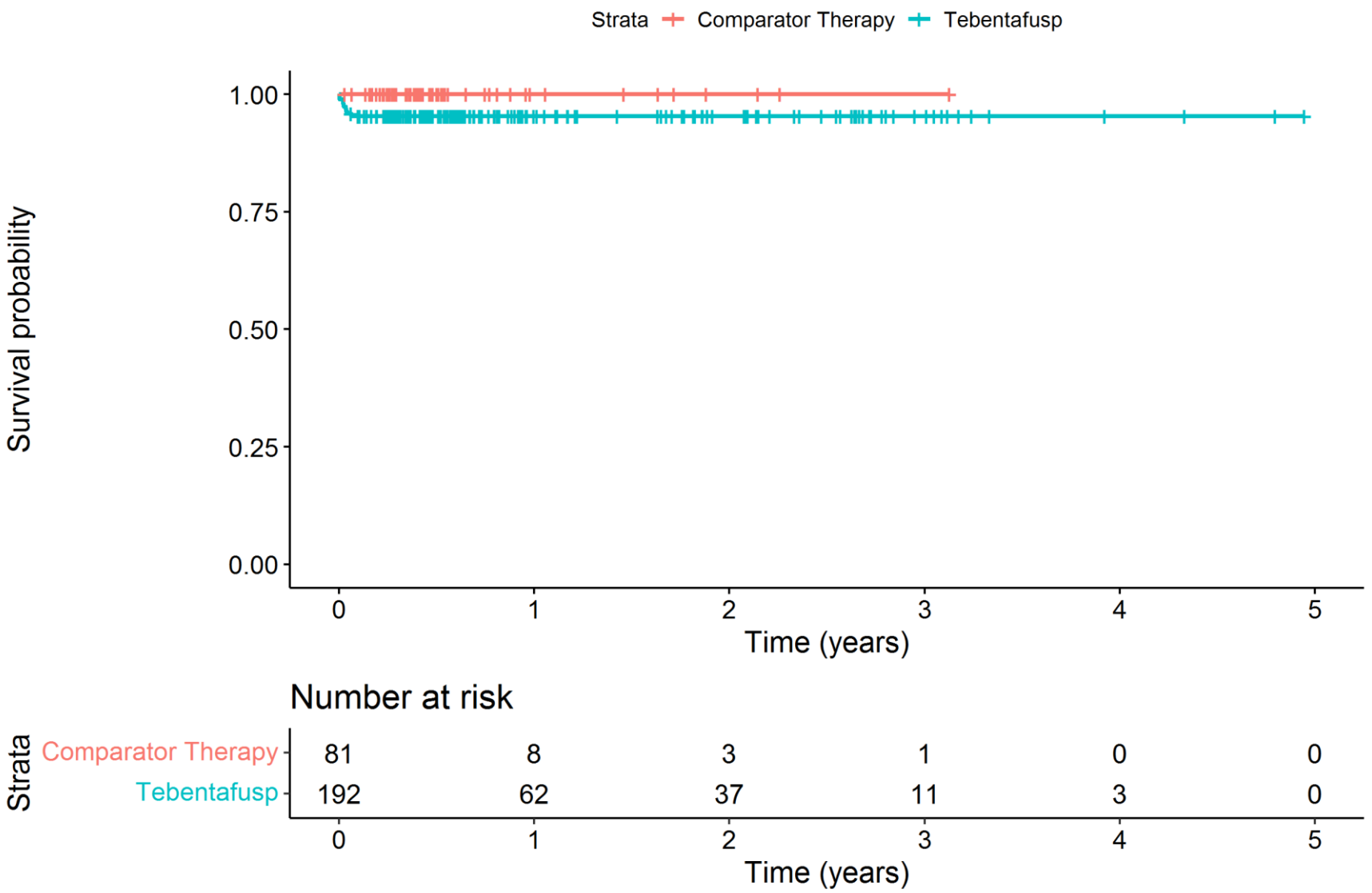
62.50 Pruritus - <65



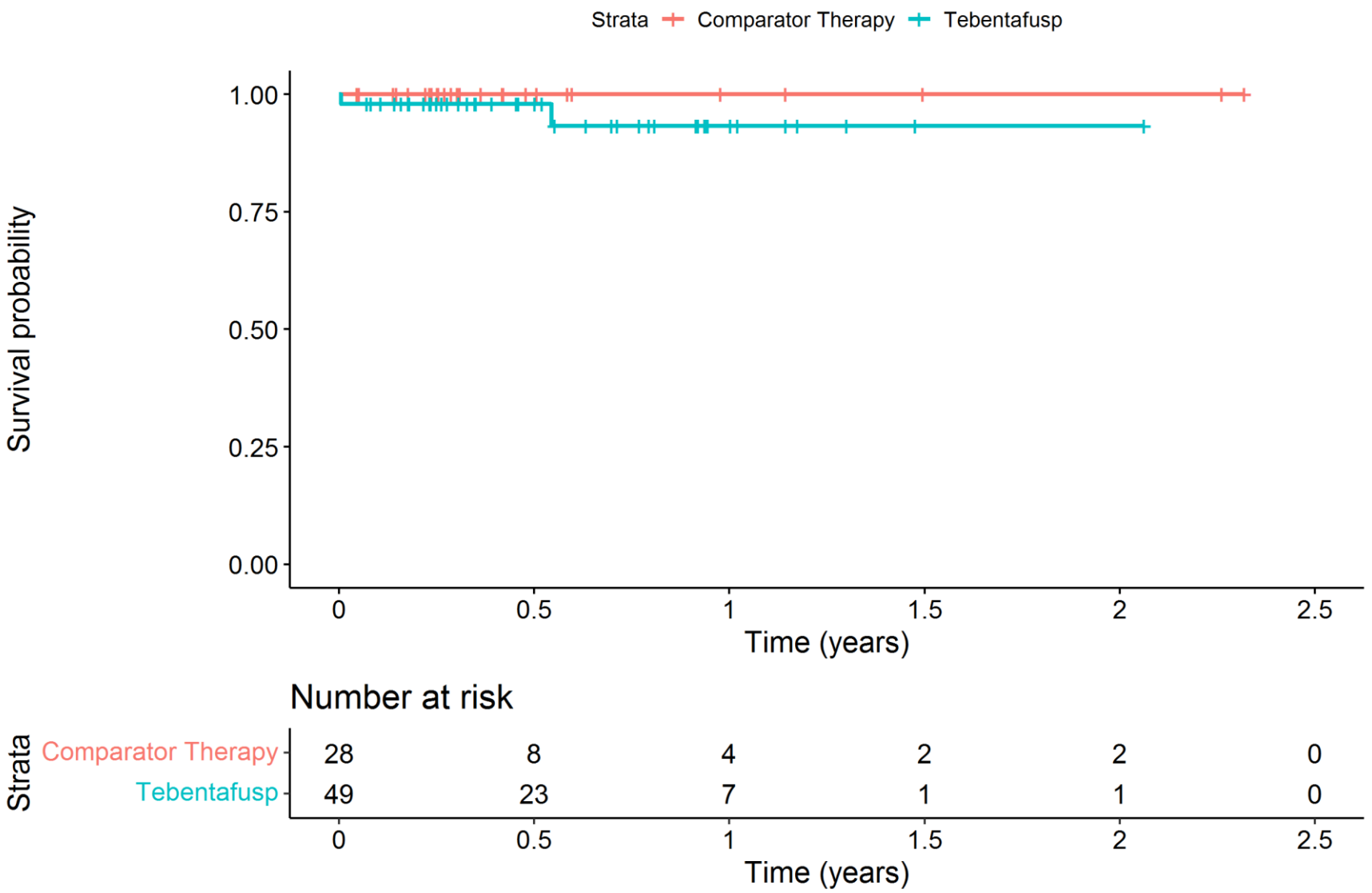
62.51 Pruritus - ≥65



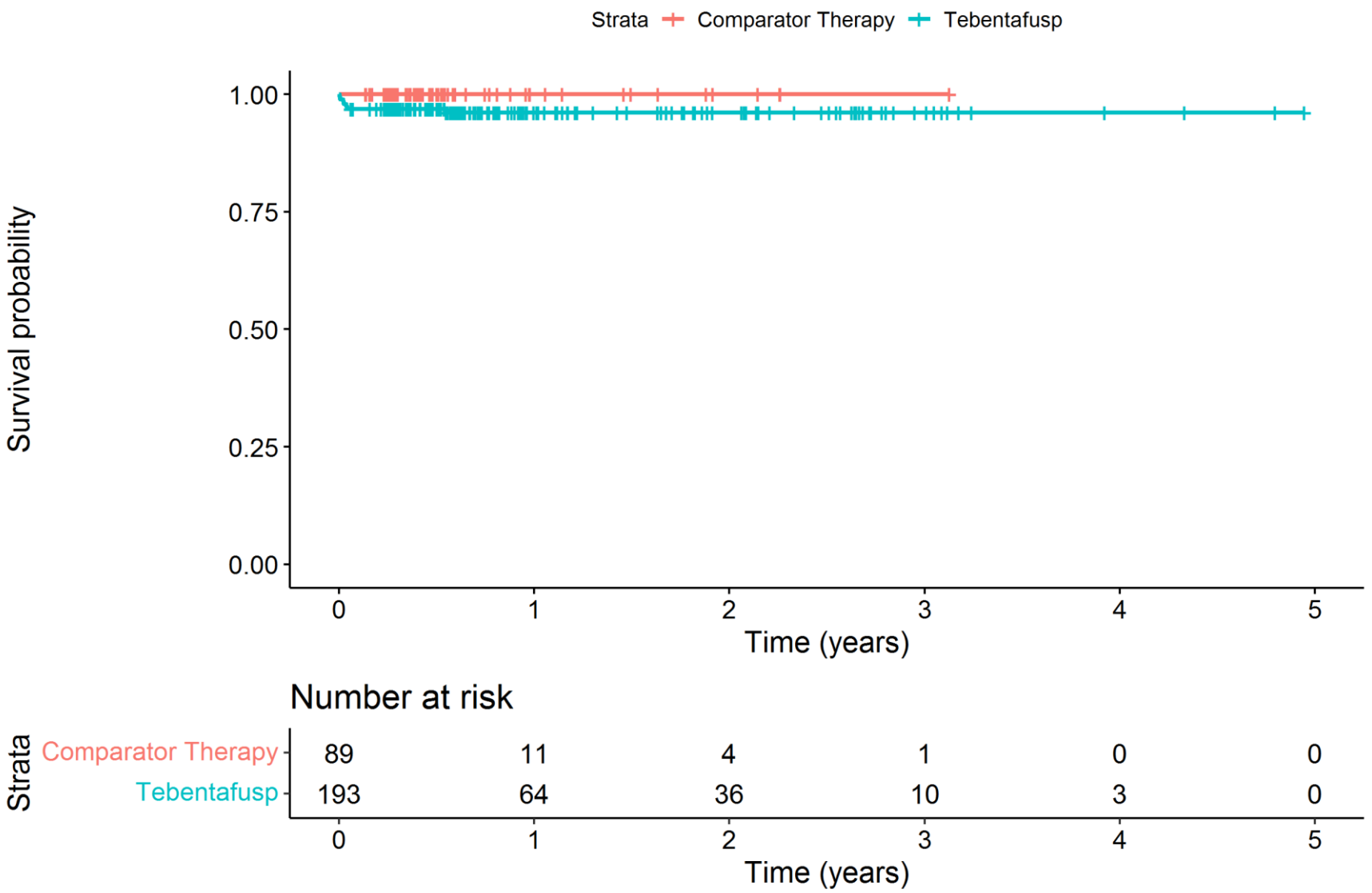
62.52 Pruritus - ECOG 0



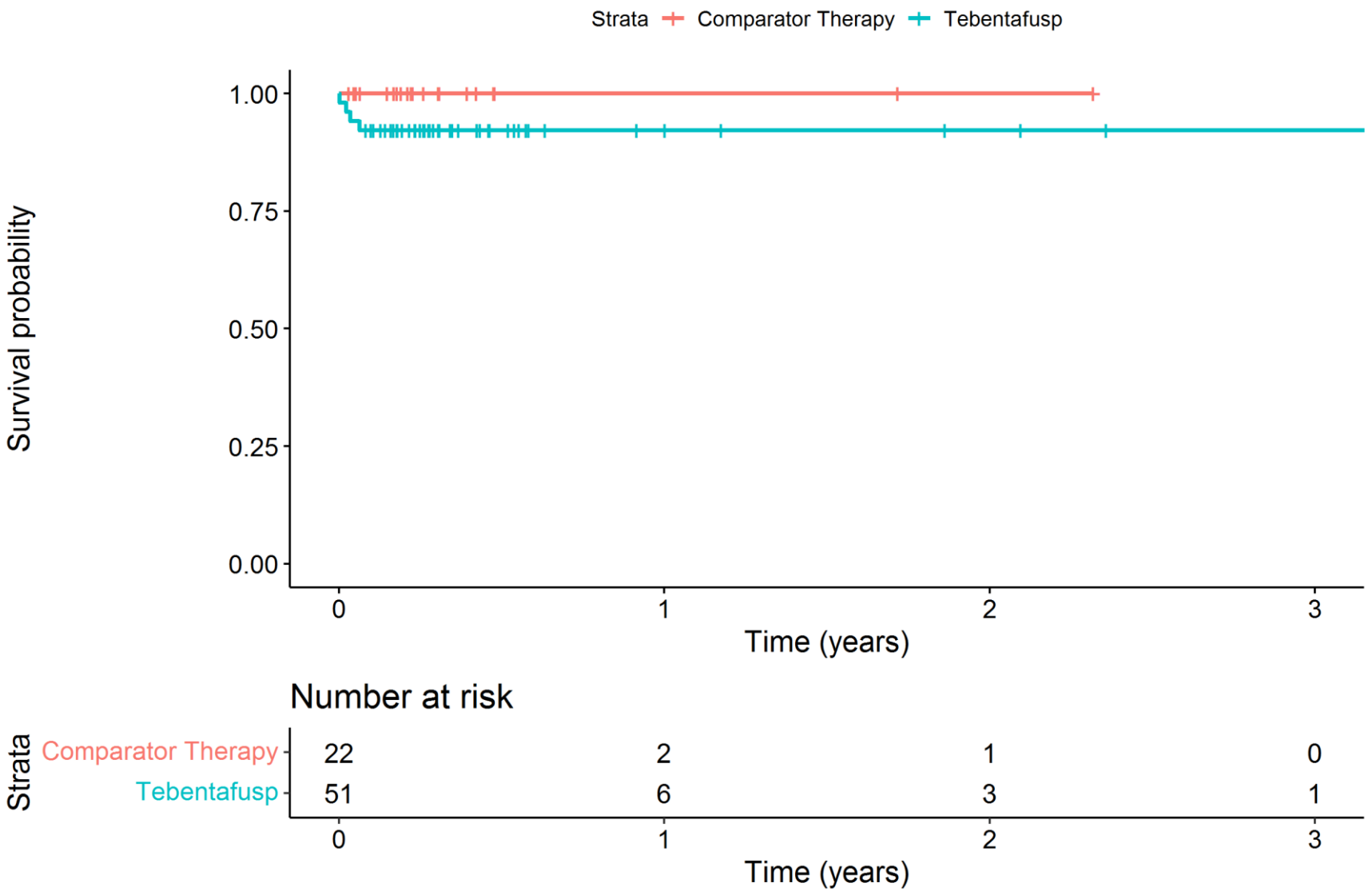
62.53 Pruritus - ECOG 1



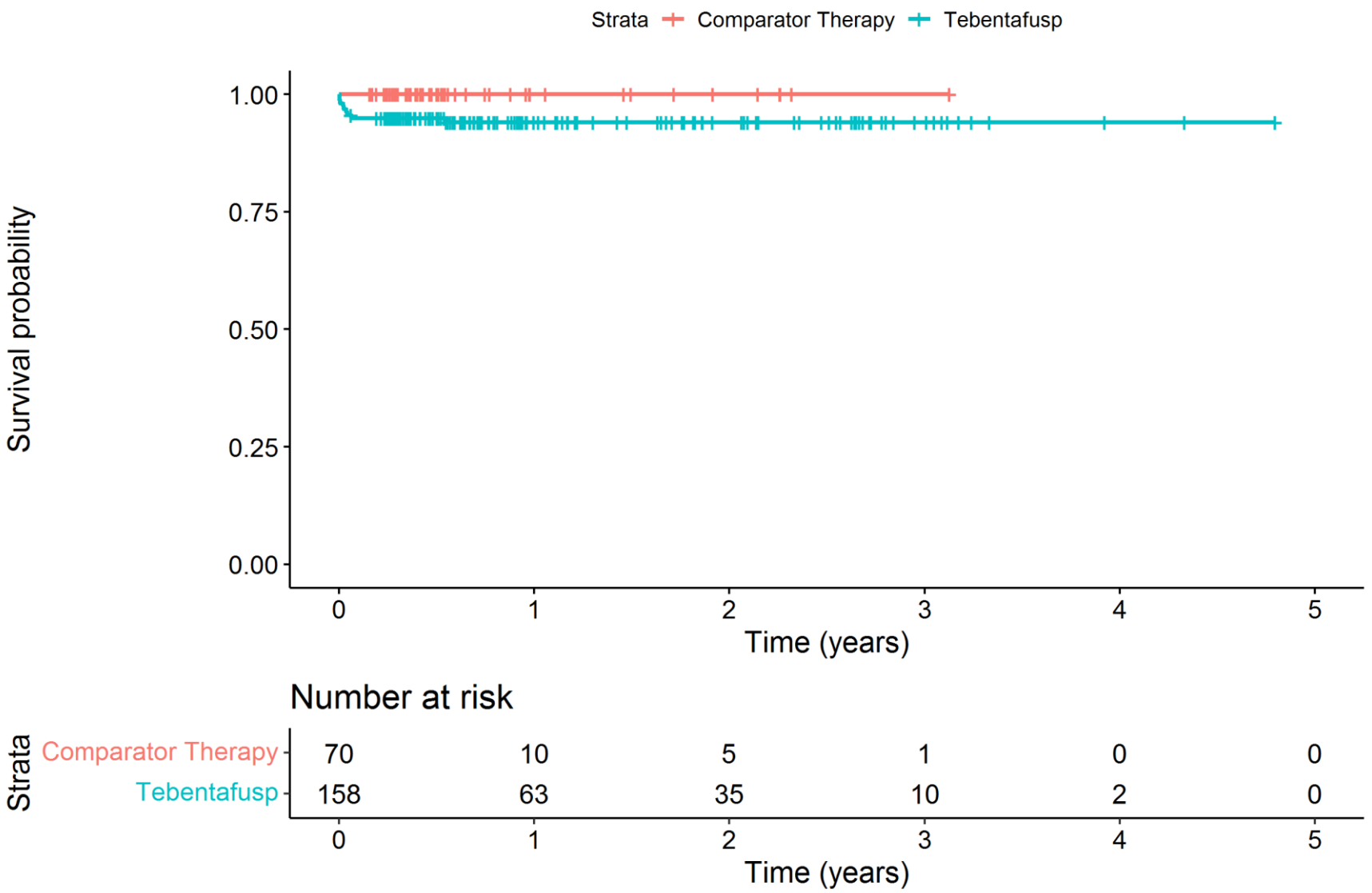
62.54 Pruritus - ALP ≤ ULN



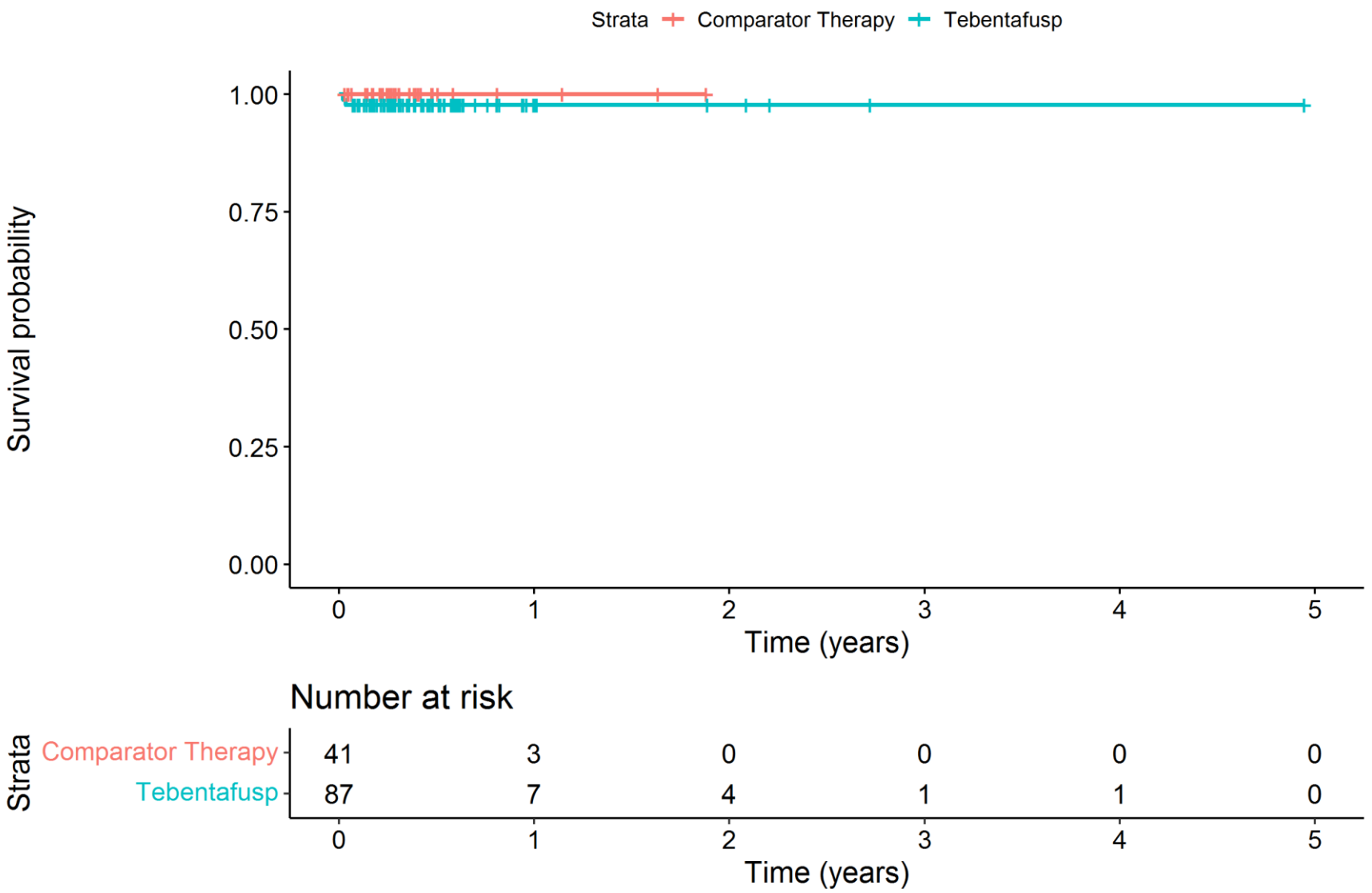
Pruritus - ALP > ULN



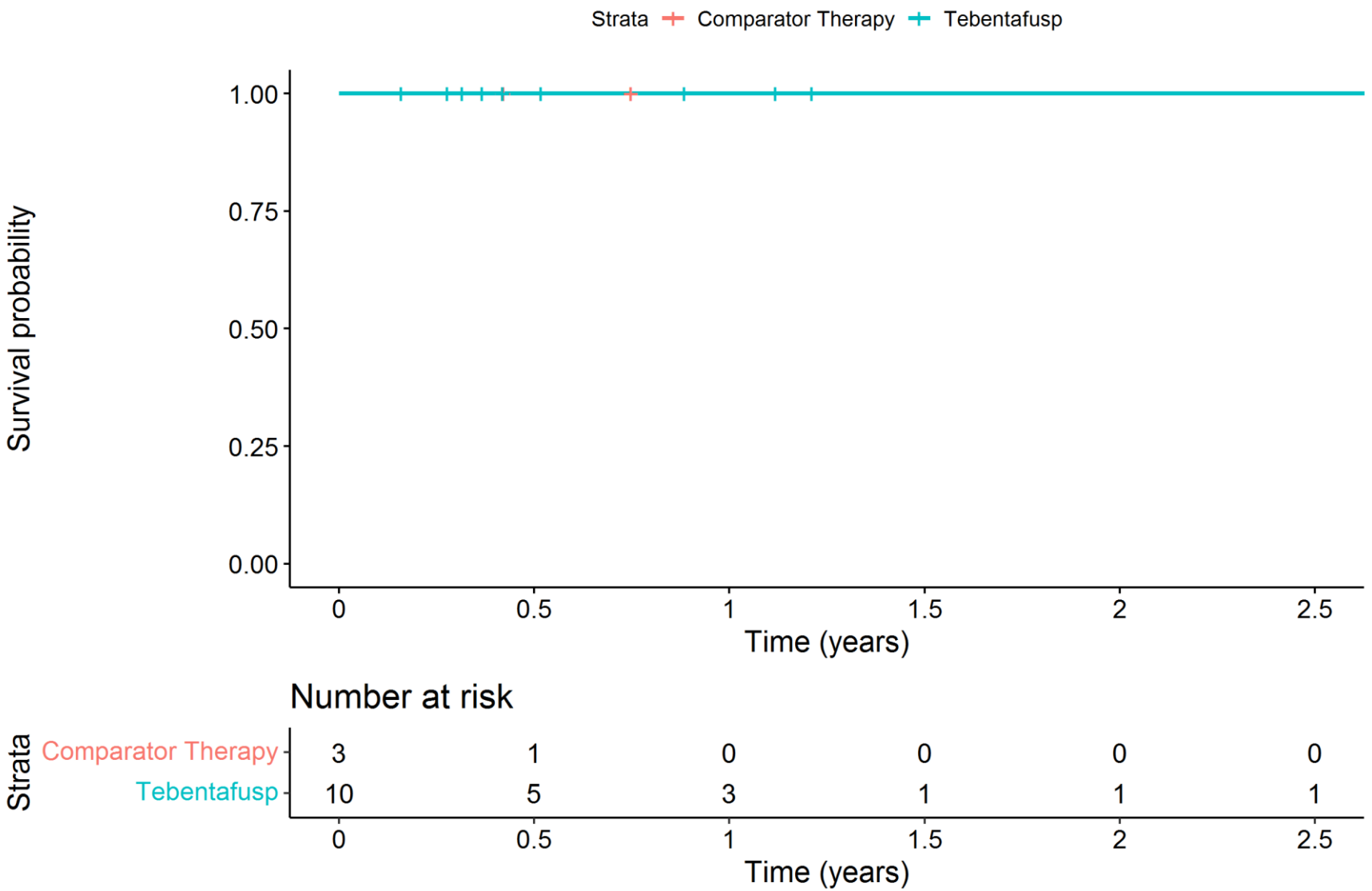
62.55 Pruritus - LDH =< ULN



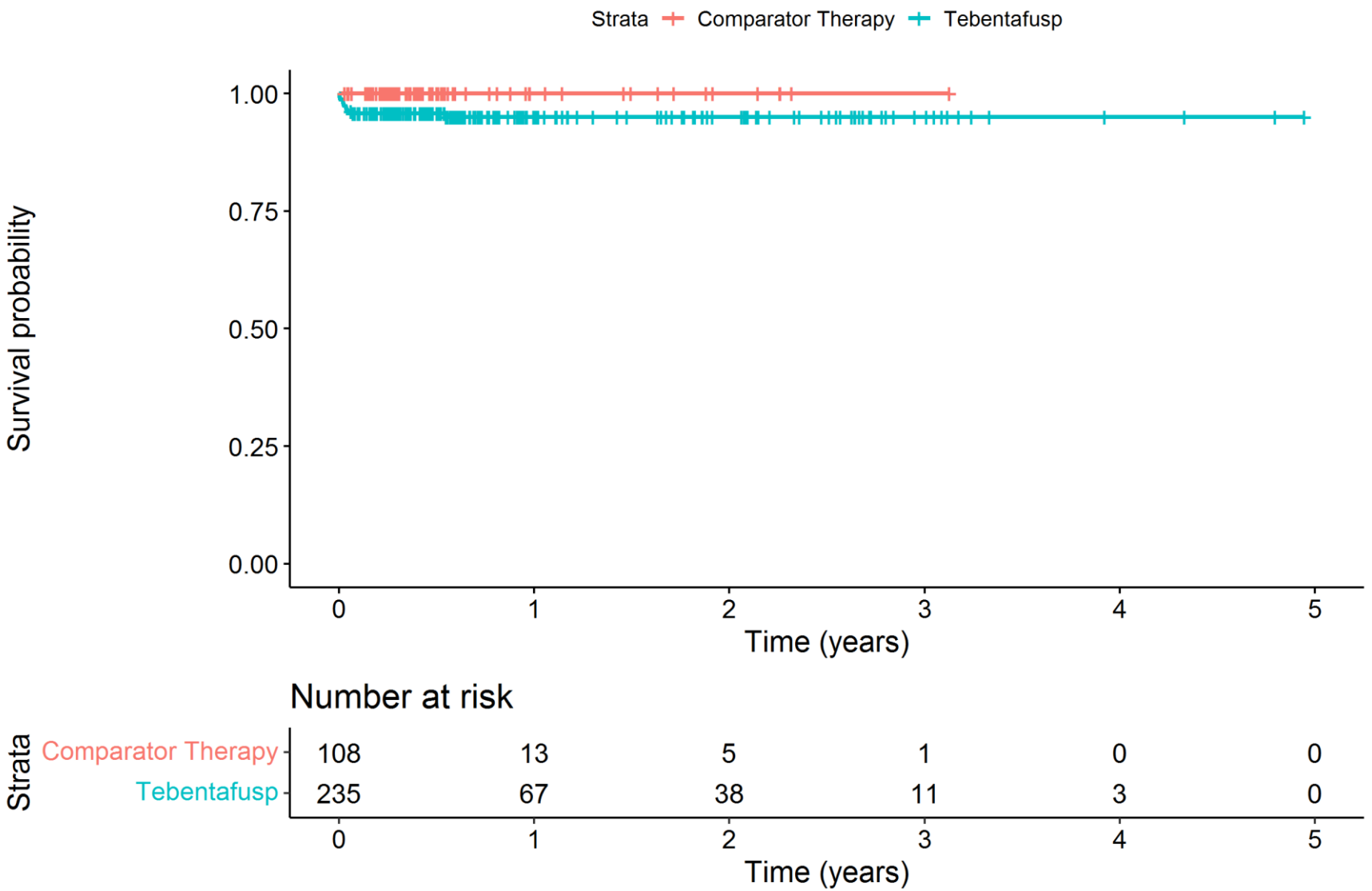
62.56 Pruritus - LDH > ULN



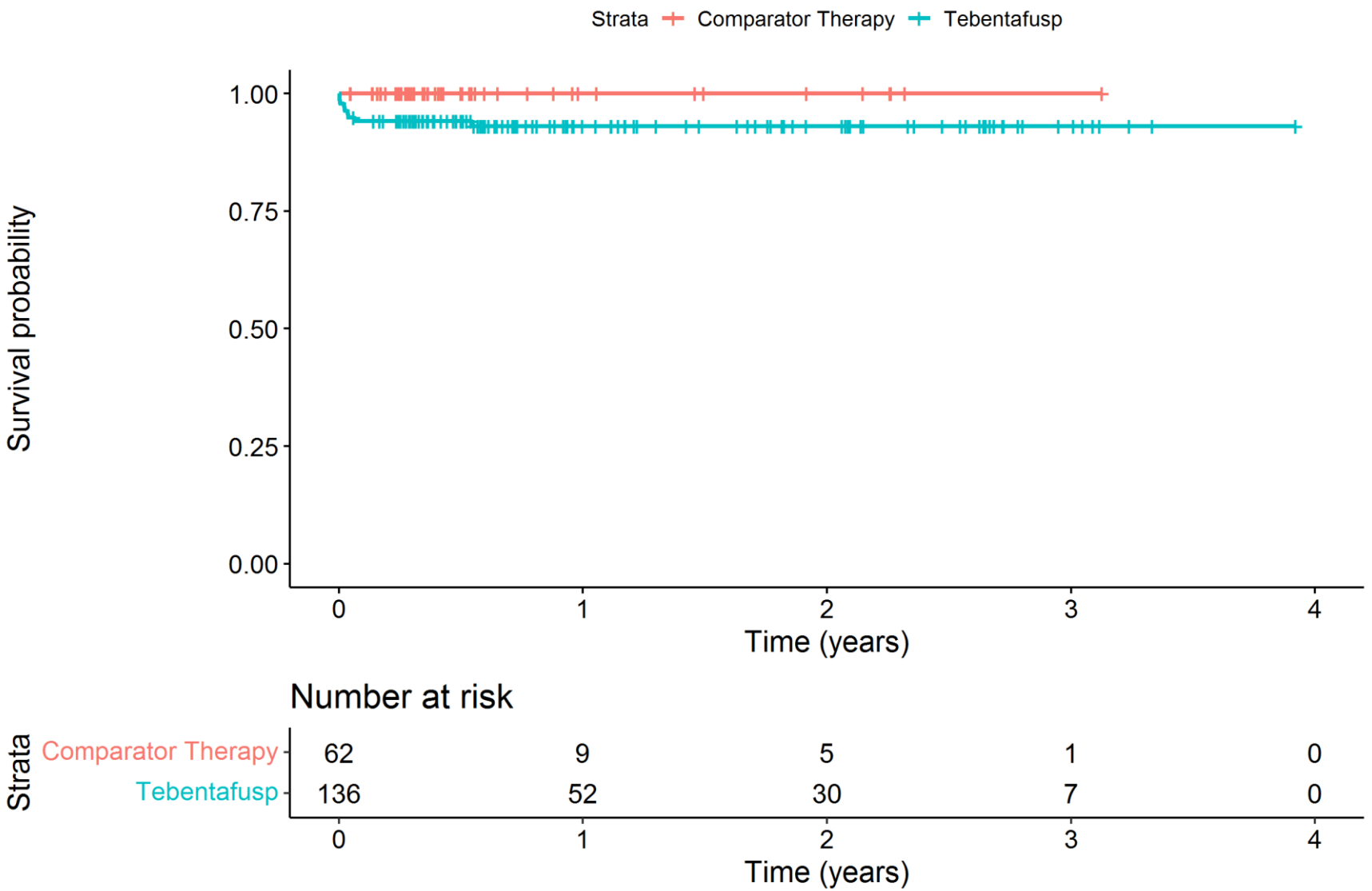
Pruritus - Vorherige Therapie adjuvant/neoadjuvant



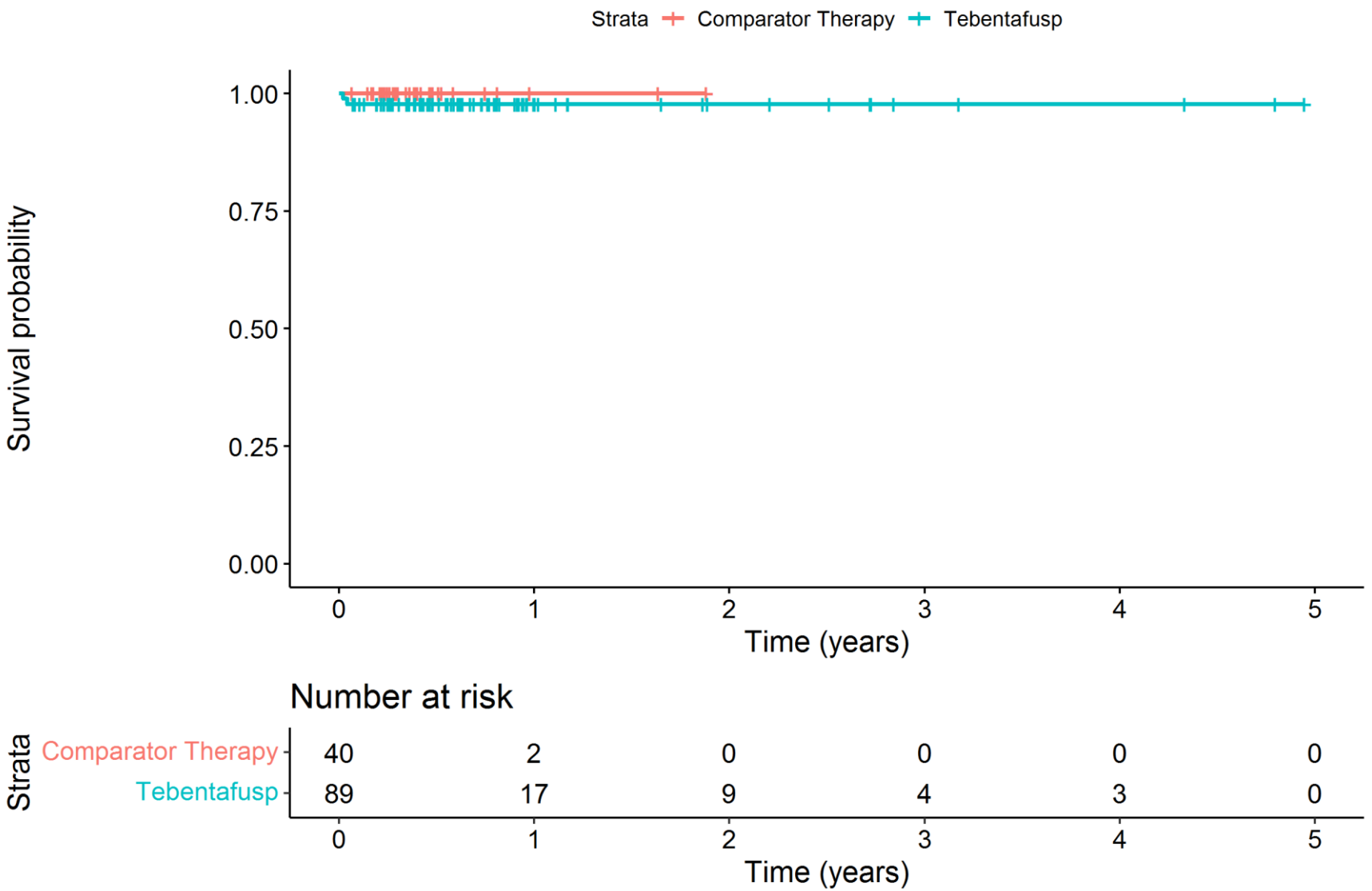
Pruritus - Keine Vorherige Therapie adjuvant/neoadjuvant



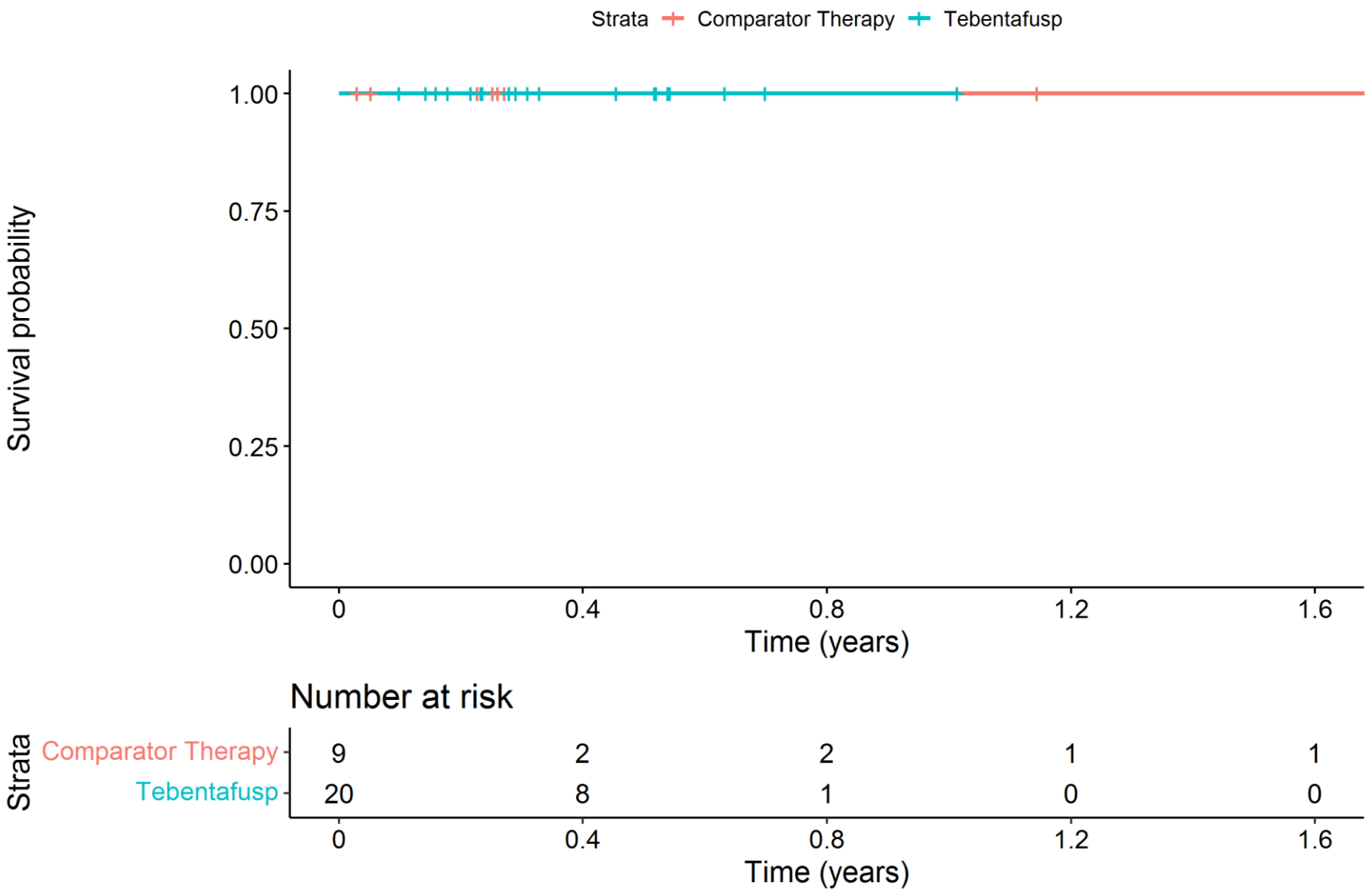
Pruritus - Läsion ≤ 3cm



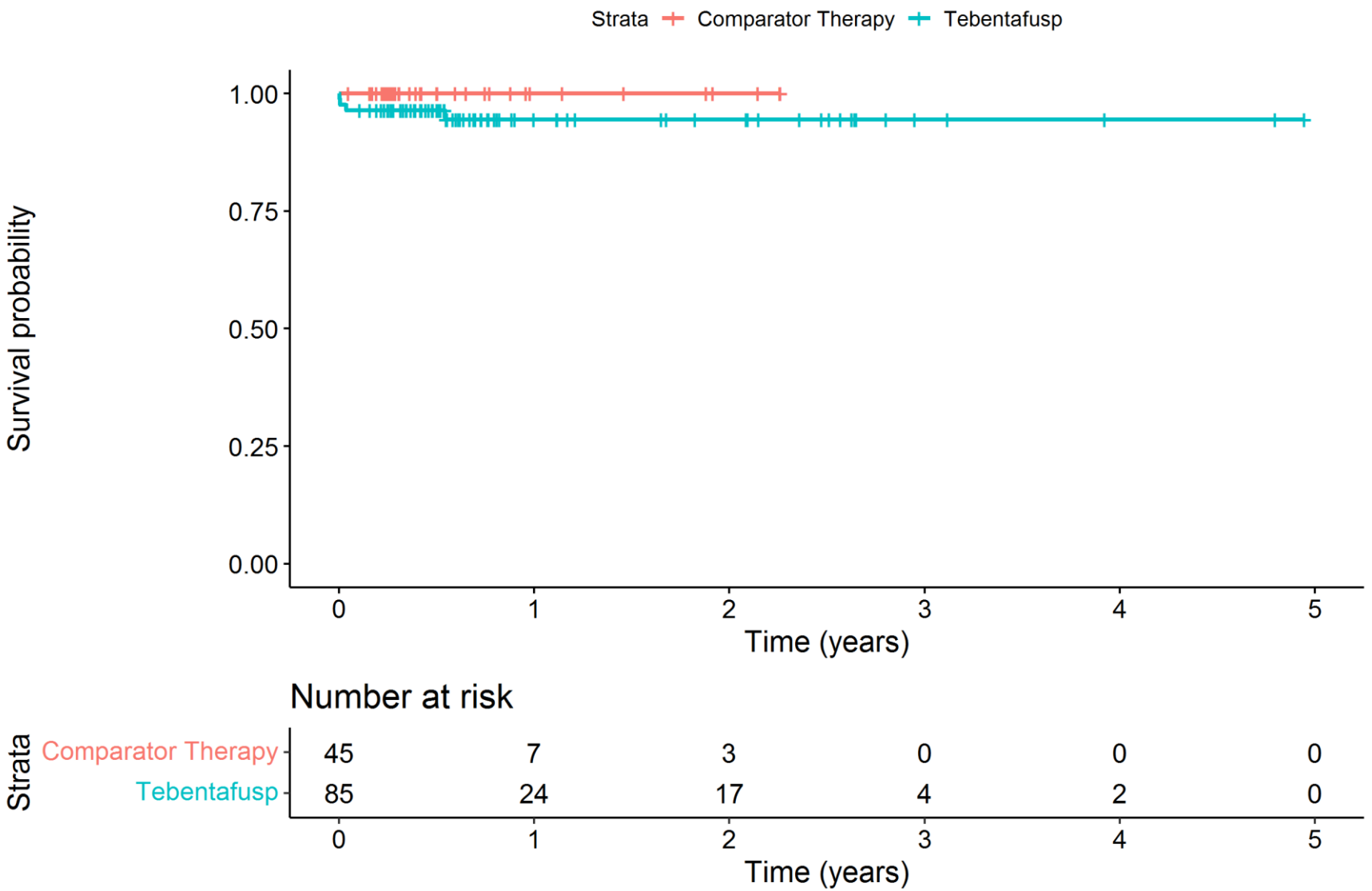
Pruritus - Läsion 3,1-8,0 cm



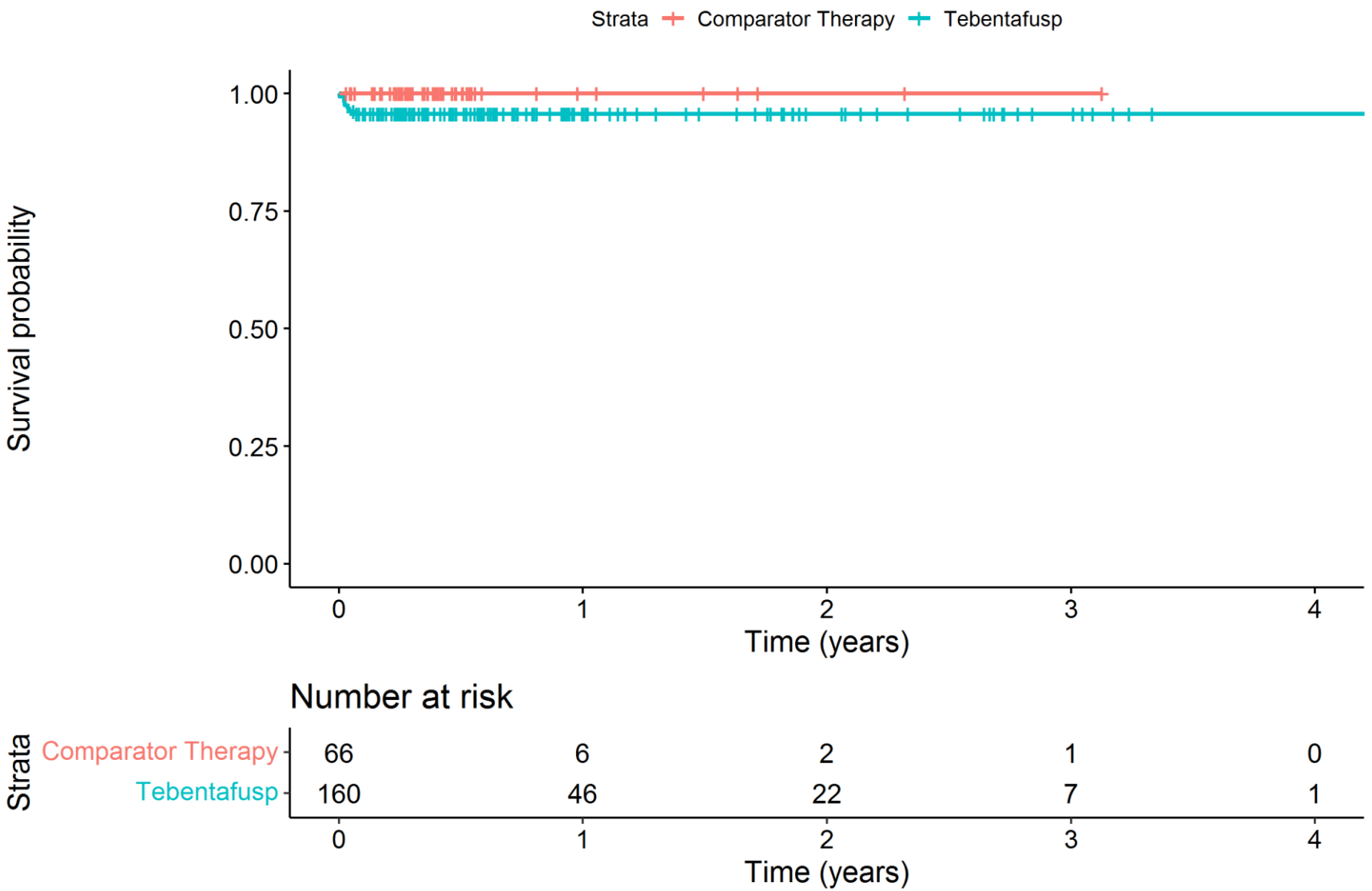
Pruritus - Läsion ≥8,1 cm



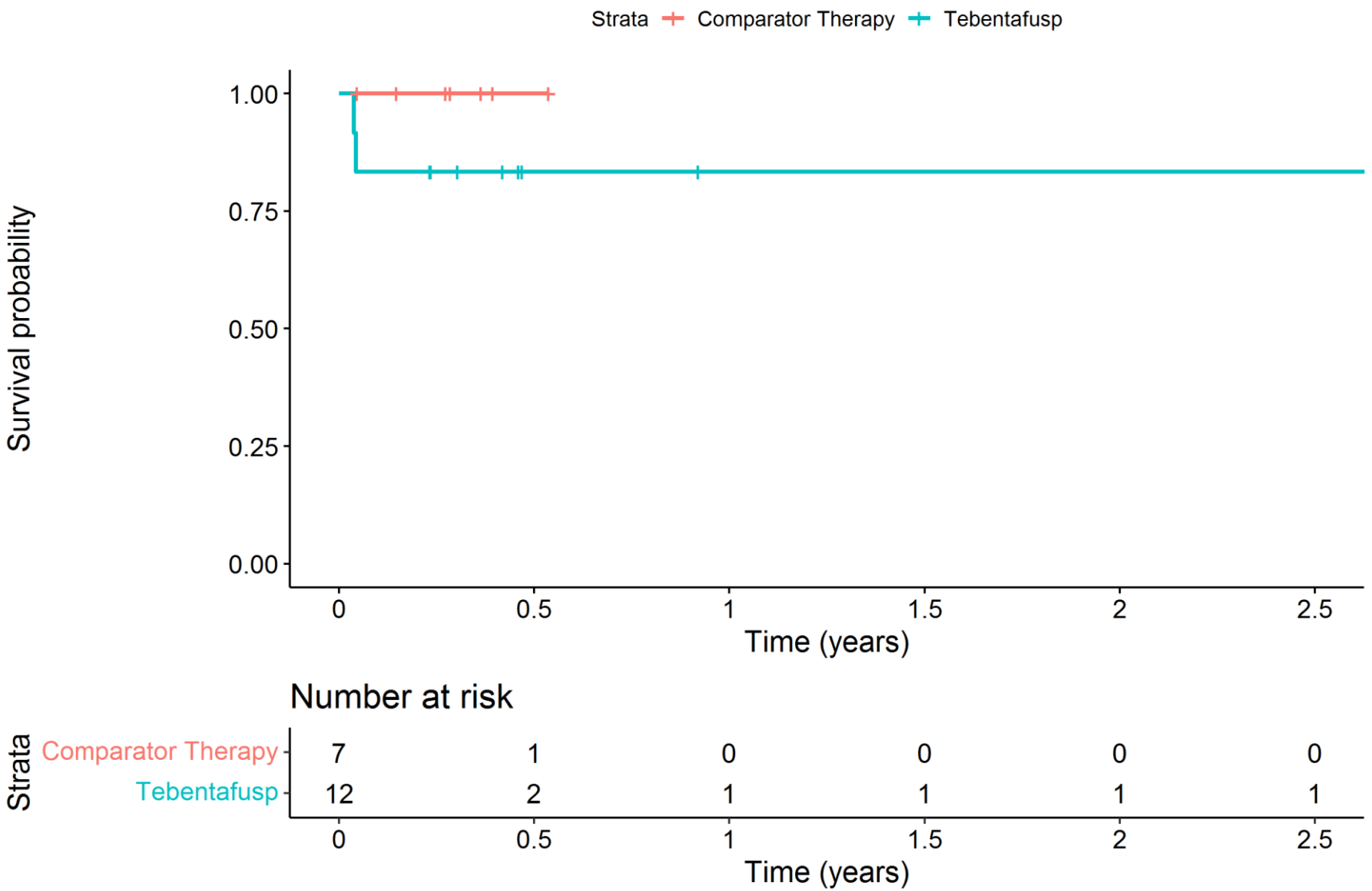
Pruritus - Nordamerika



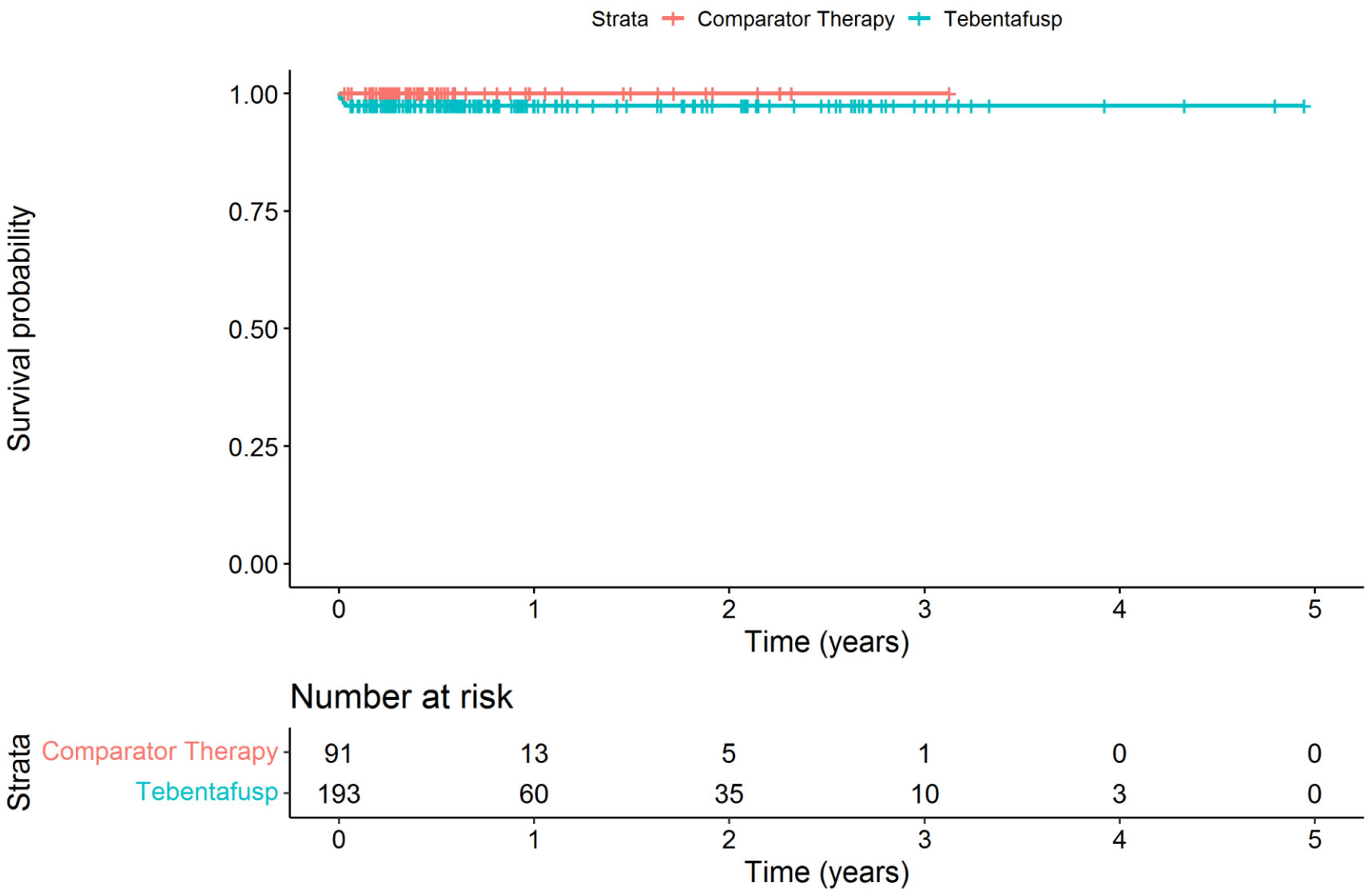
Pruritus - Nicht-Nordamerika



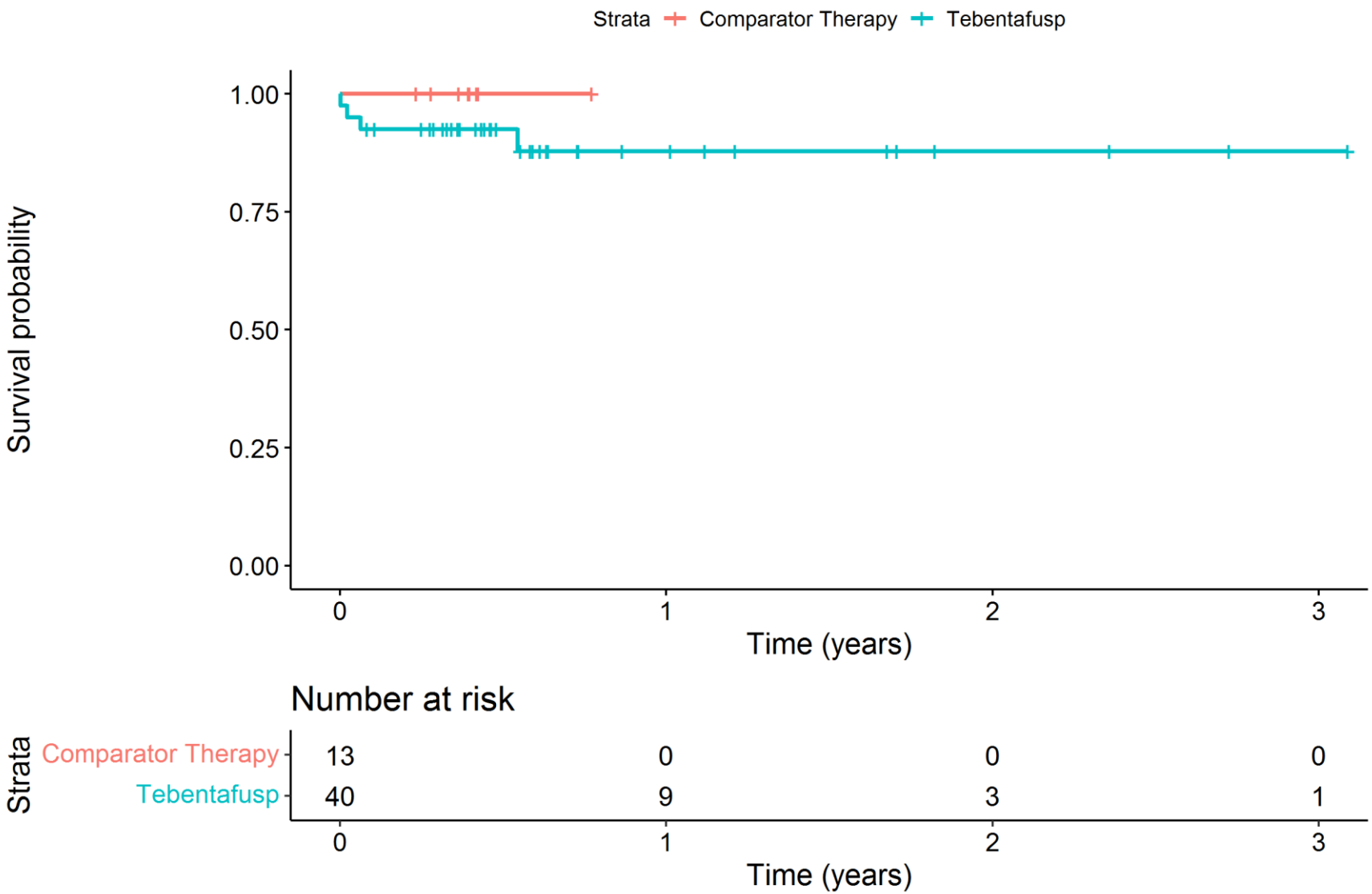
Pruritus - Dacarbazin



Pruritus - Pembrolizumab

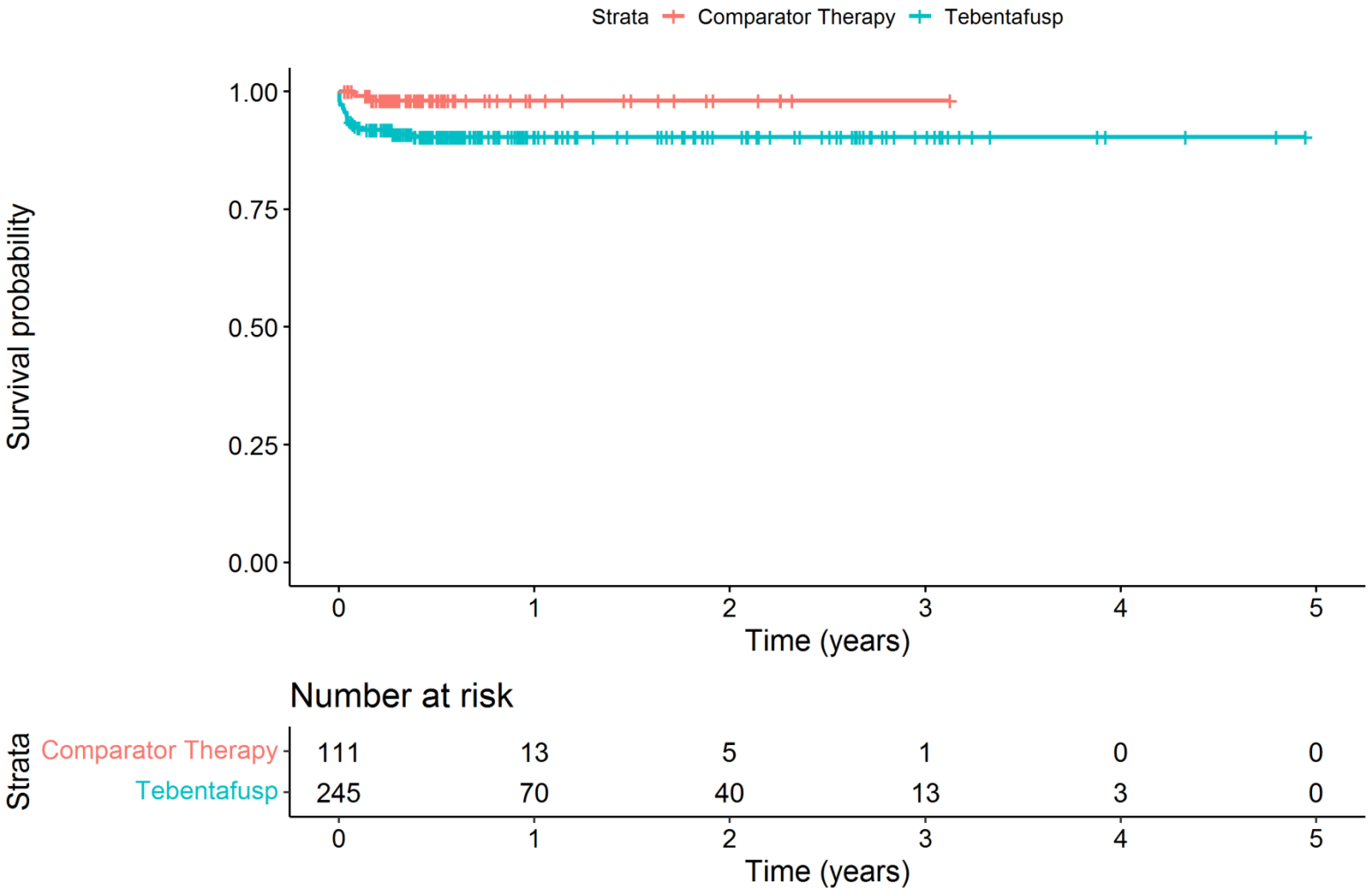


Pruritus - Ipilimumab

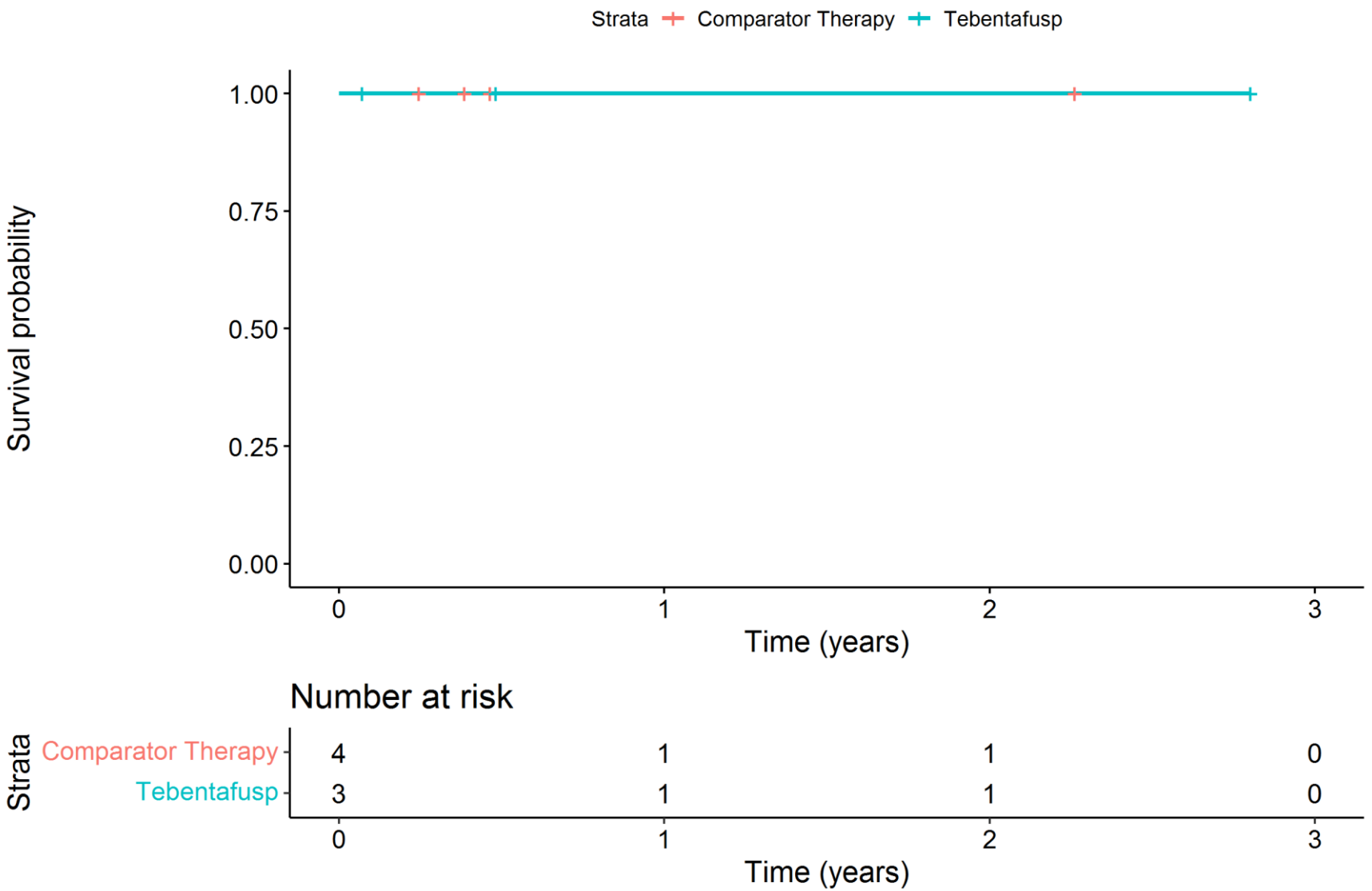


63 UEs (SOC) des Grades ≥ 3, die bei ≥ 1 % der Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-327)

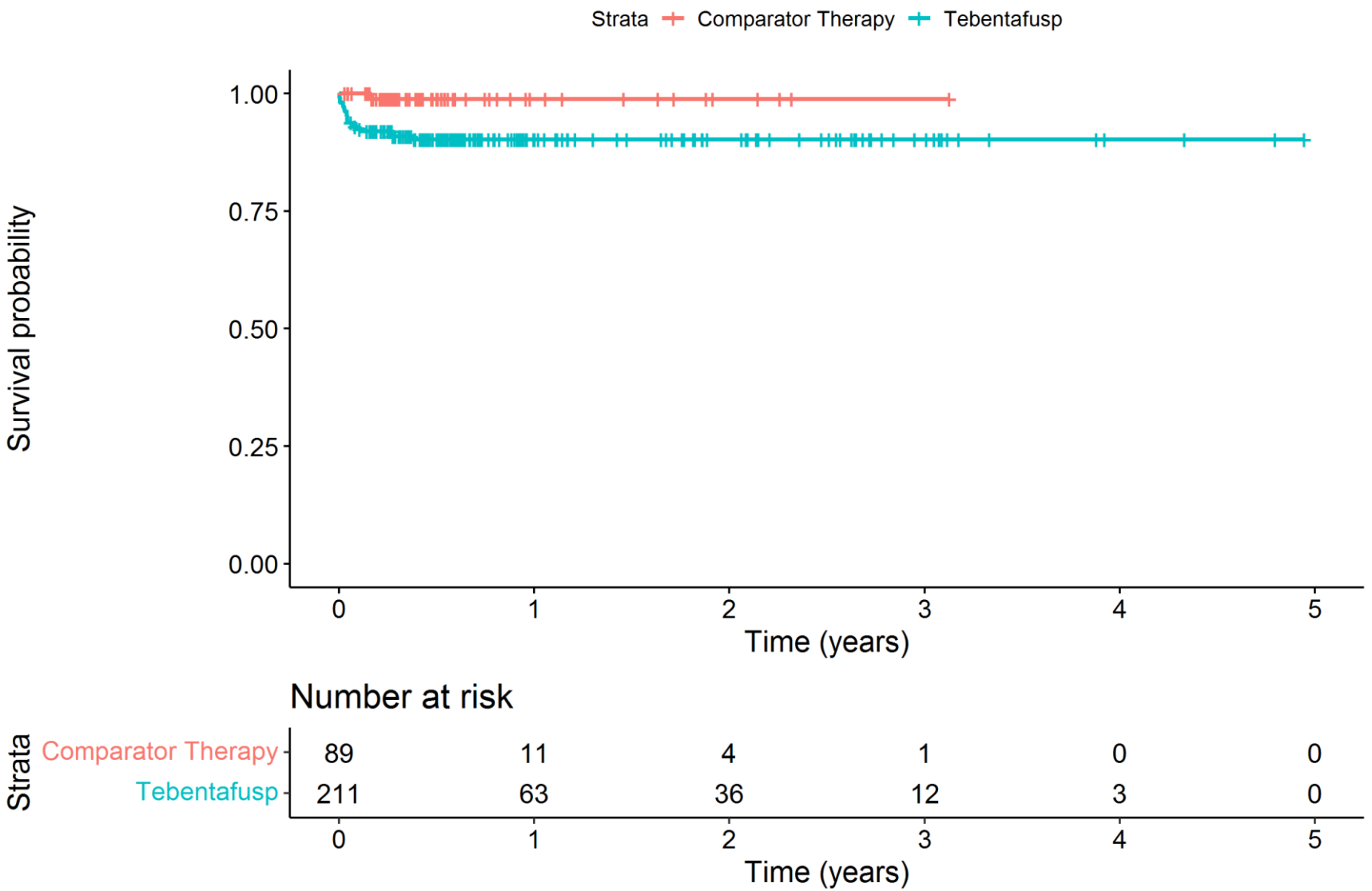
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Gesamt



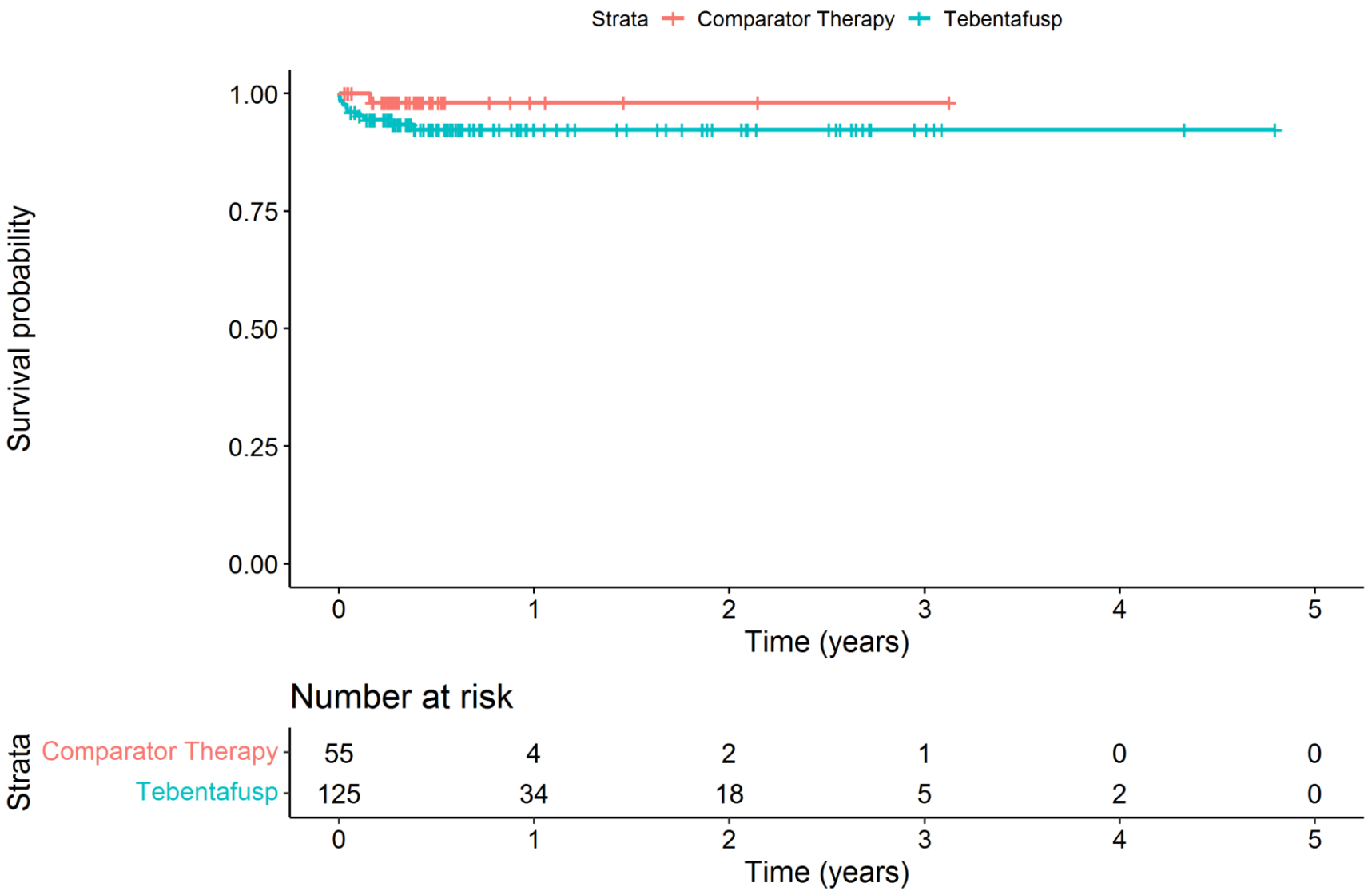
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Hispanisch



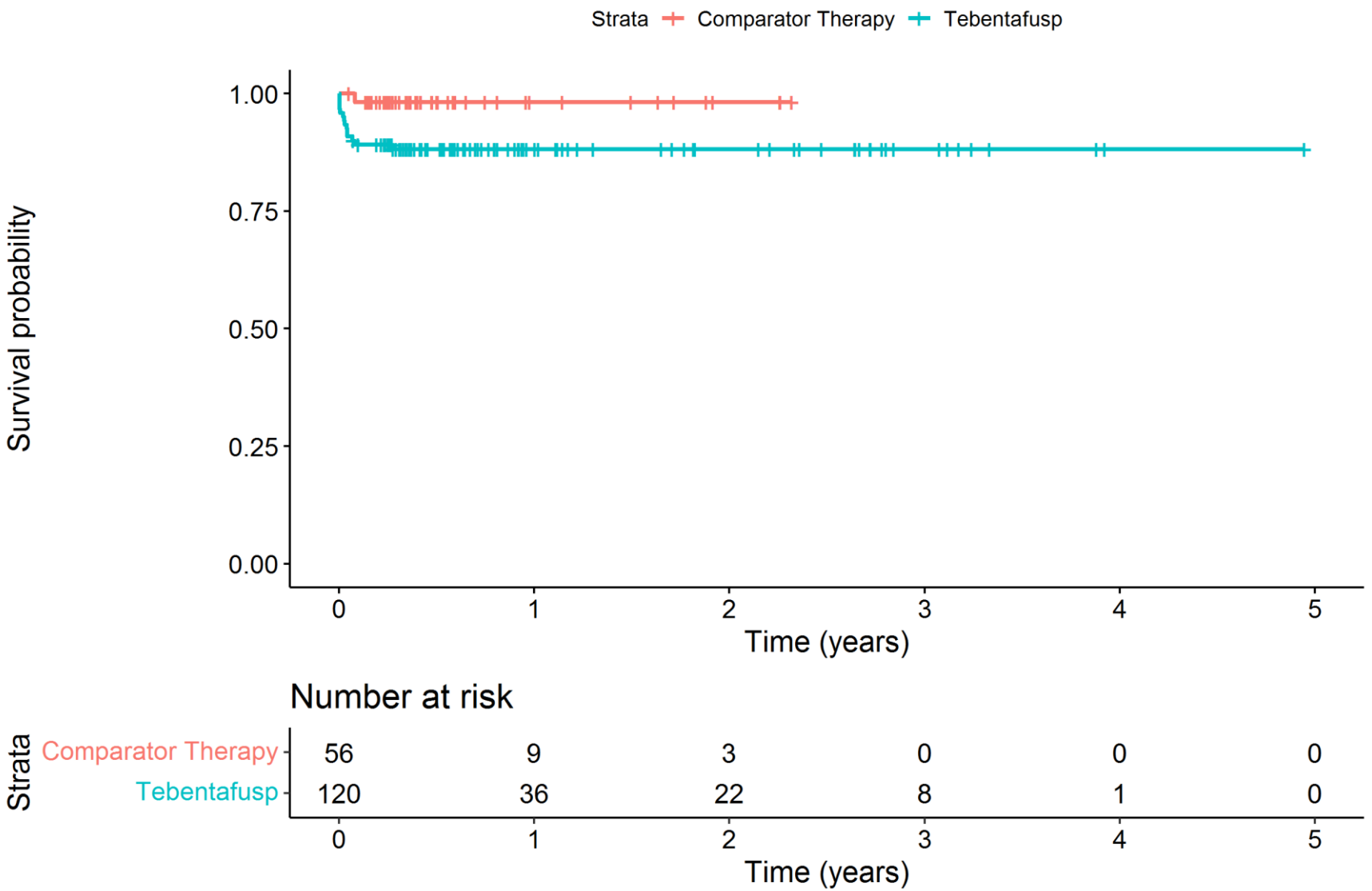
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nicht-hispanisch



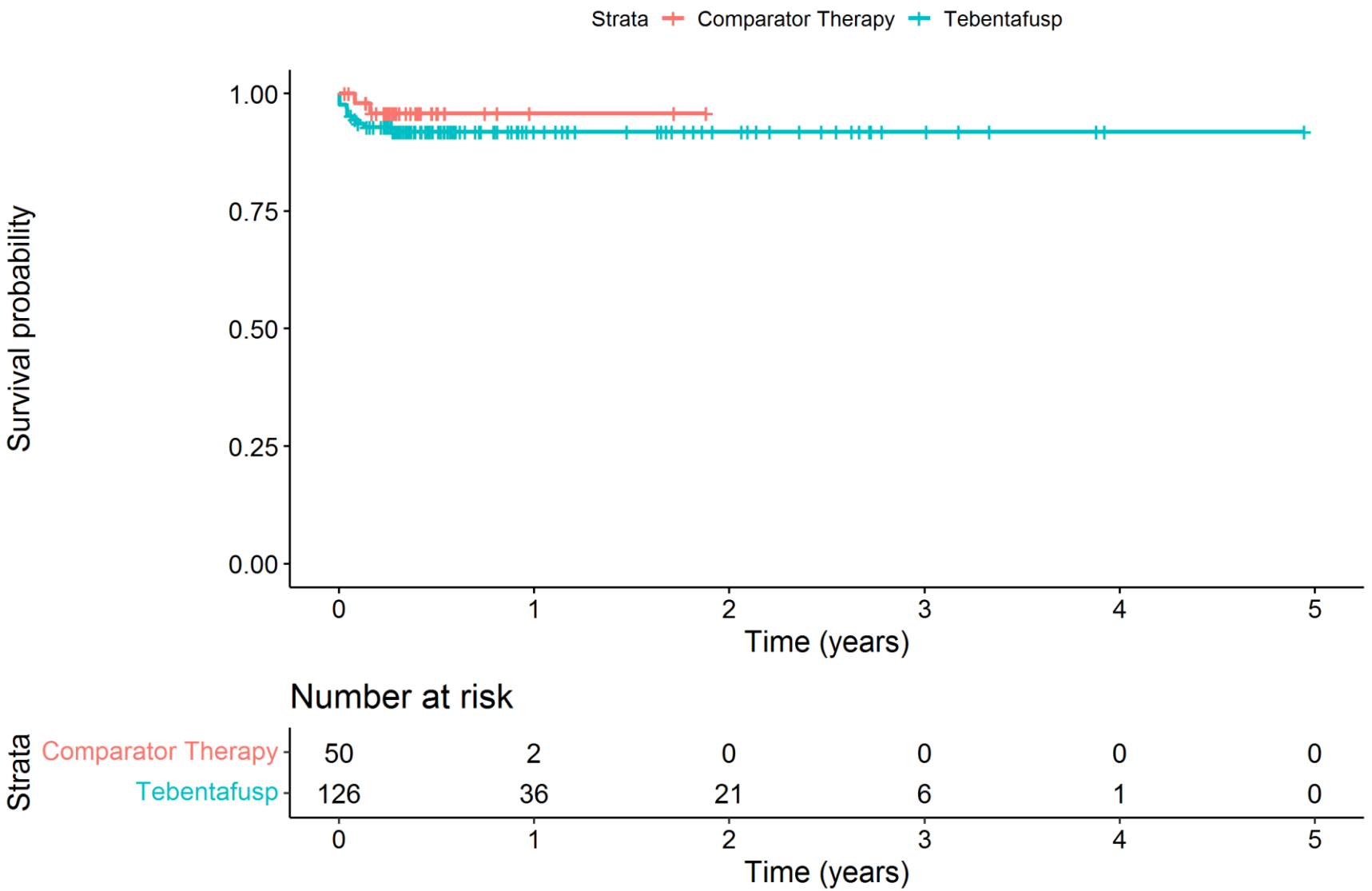
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Männlich



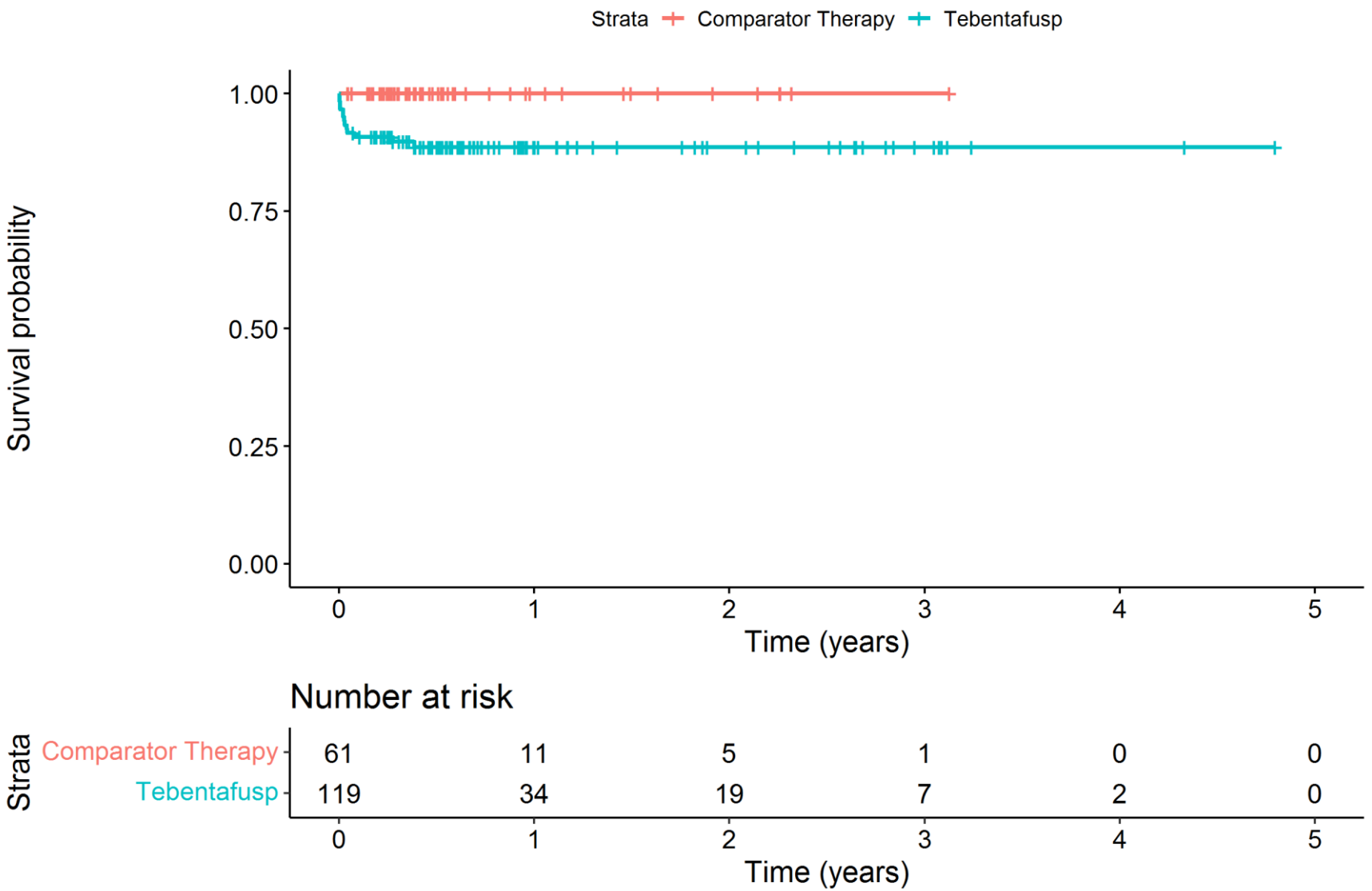
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Weiblich



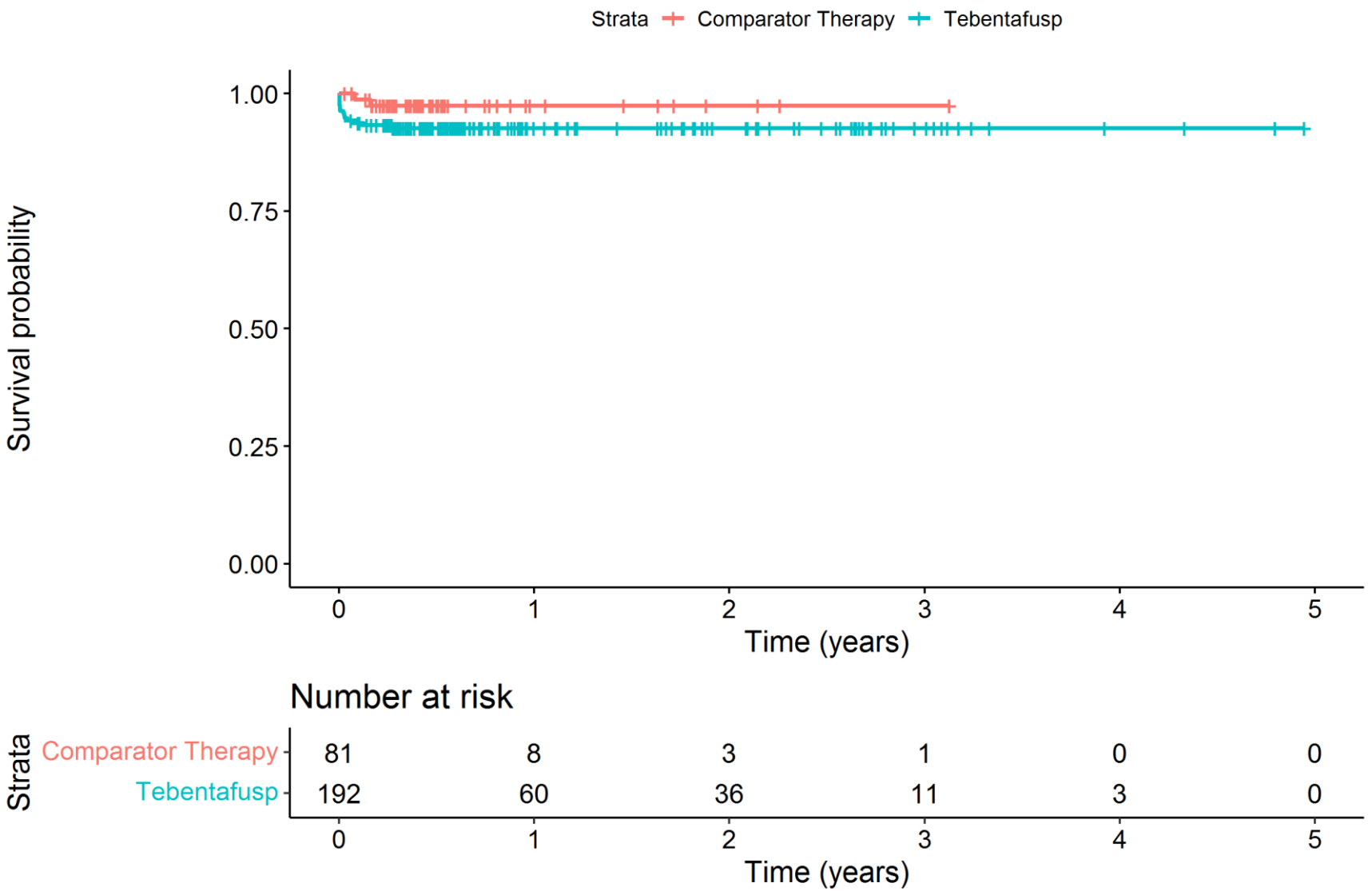
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- <65



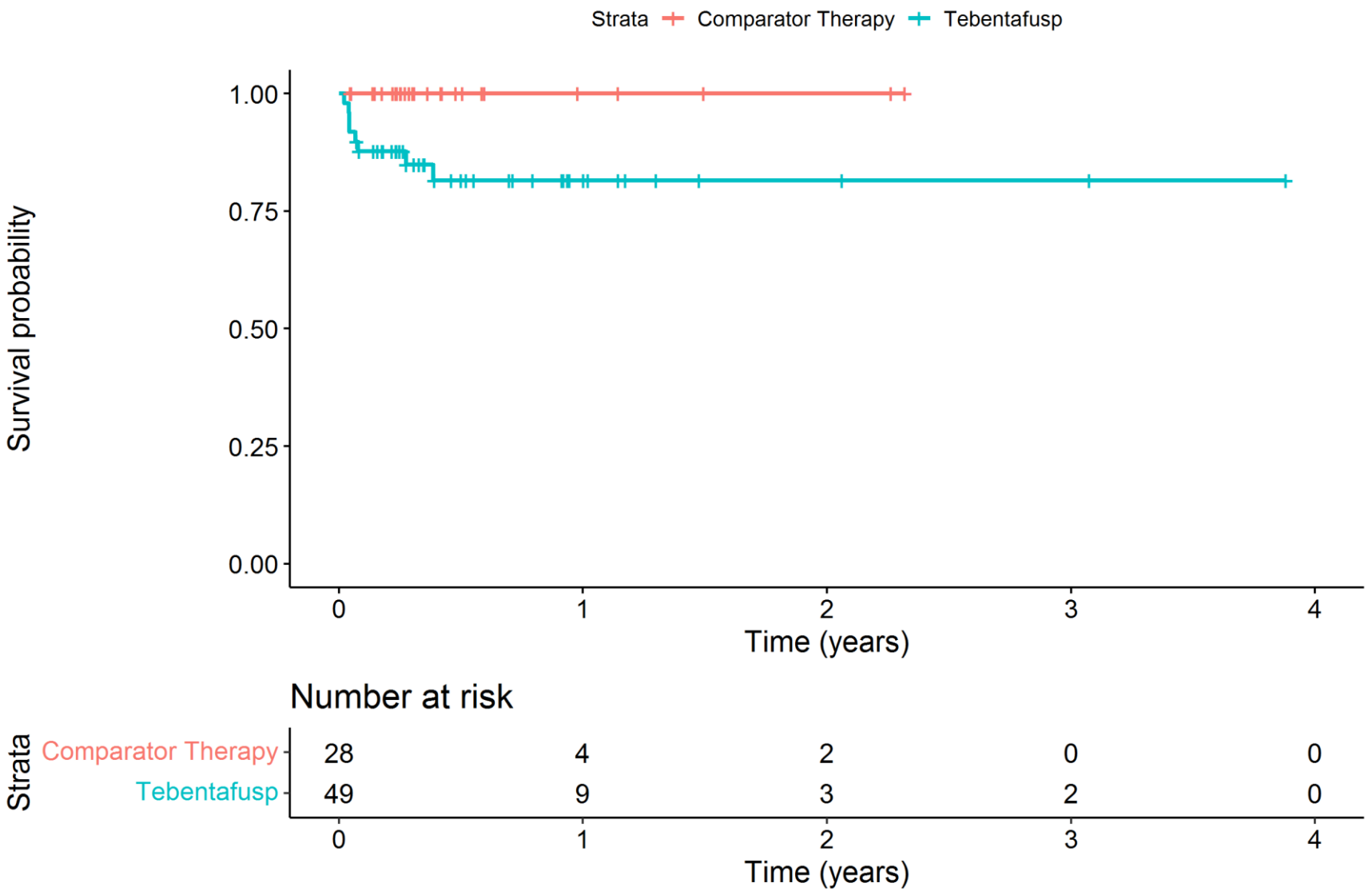
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ≥65



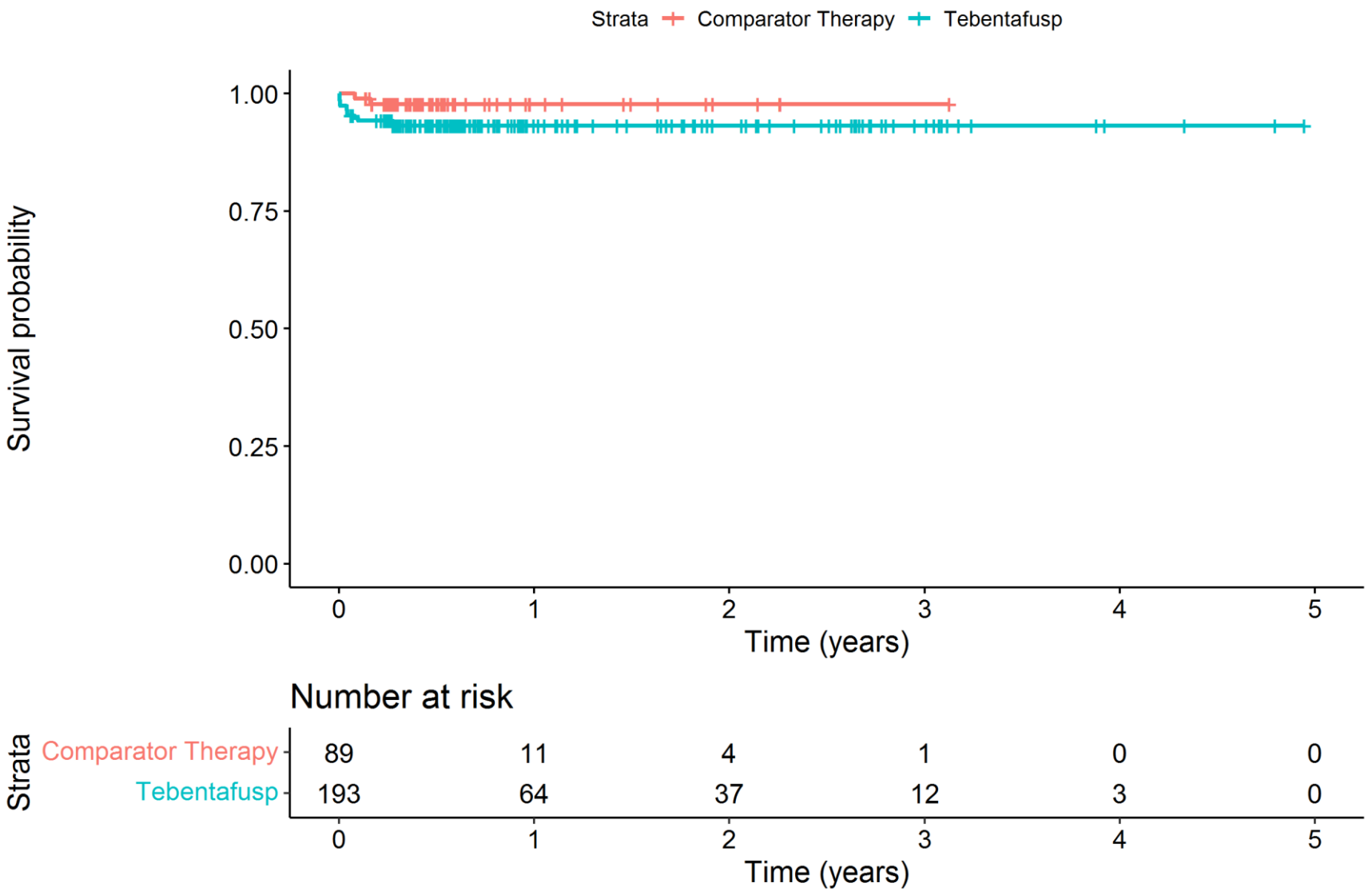
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ECOG 0



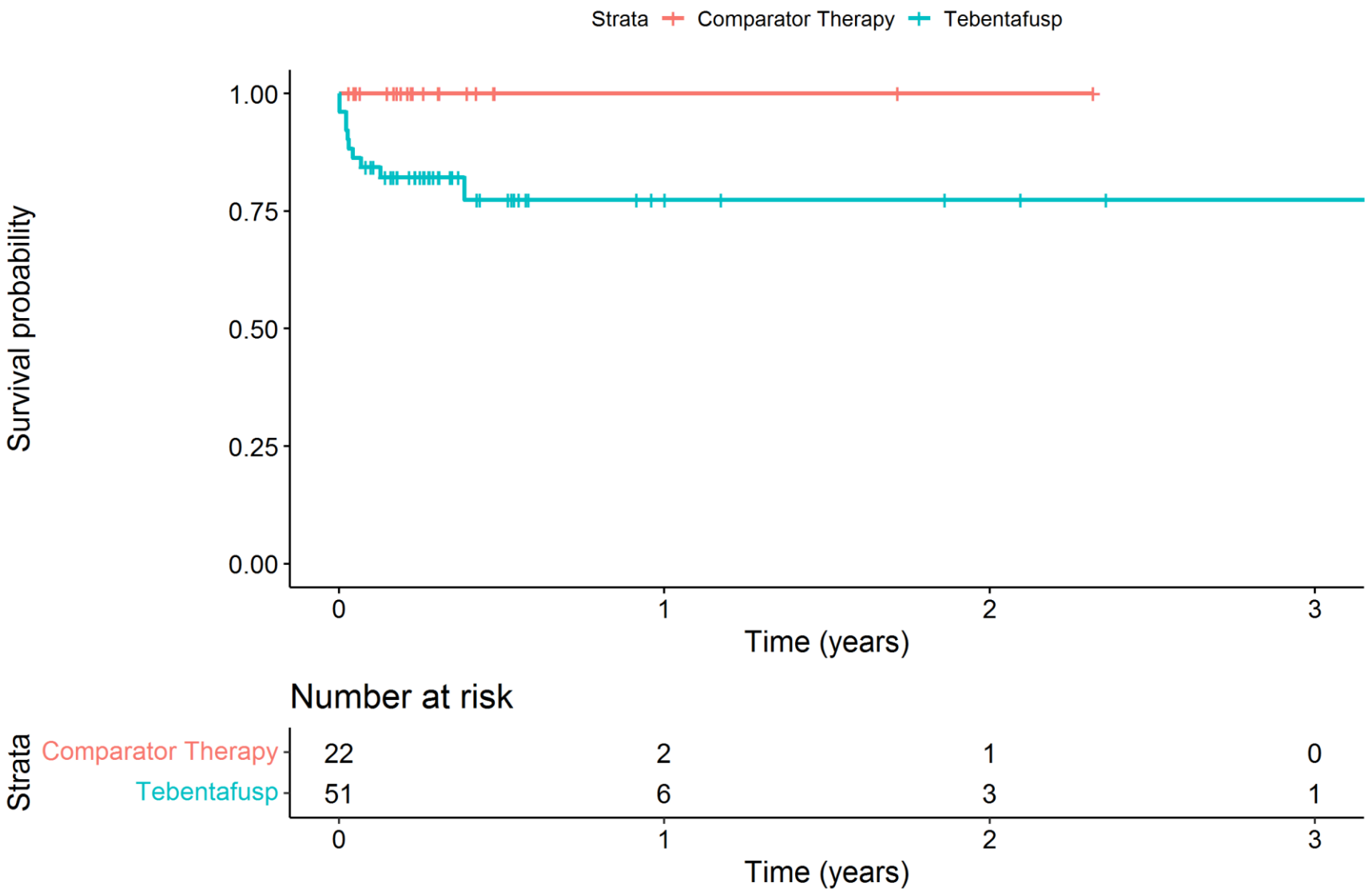
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ECOG 1



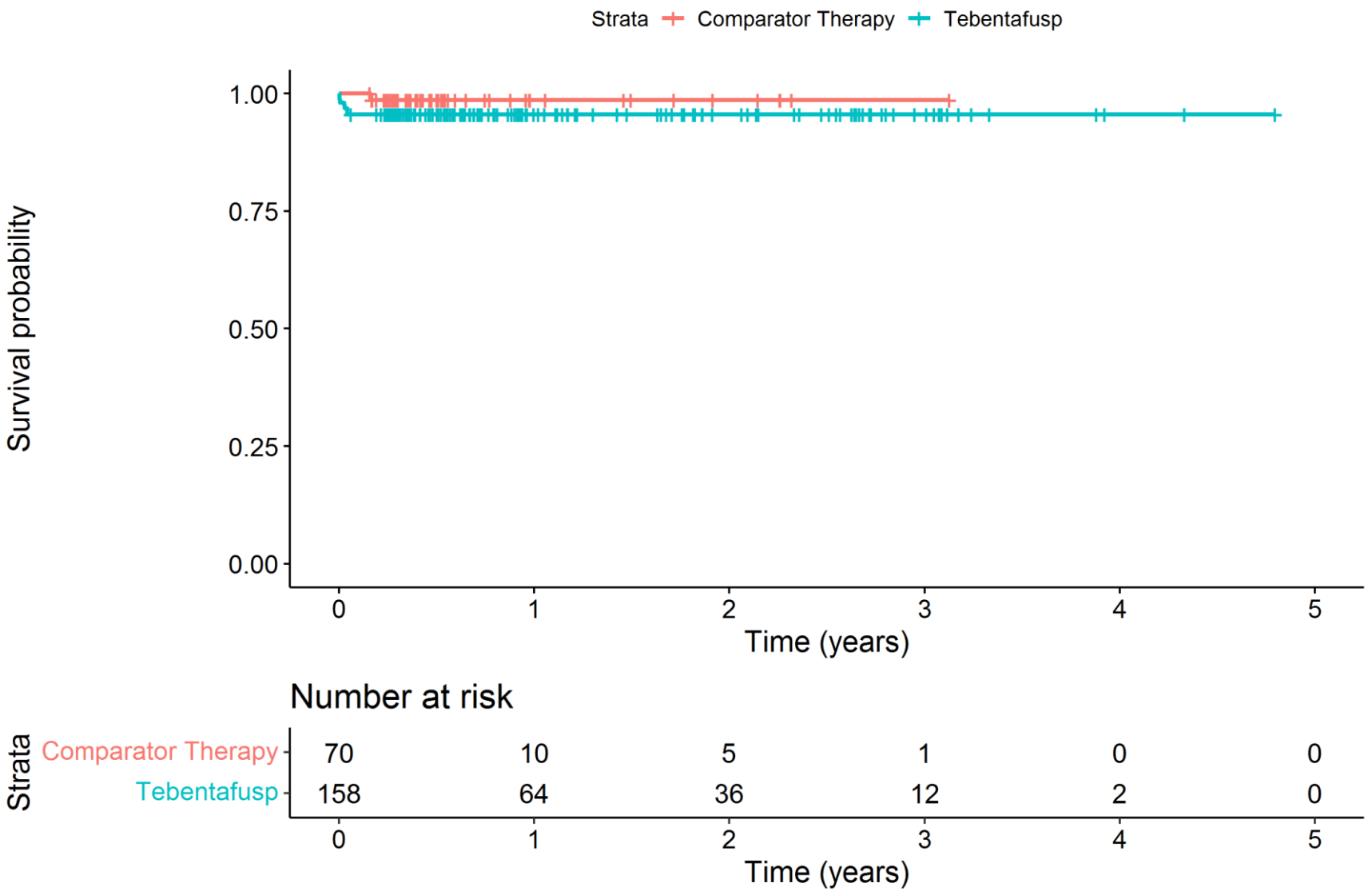
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ALP ≤ ULN



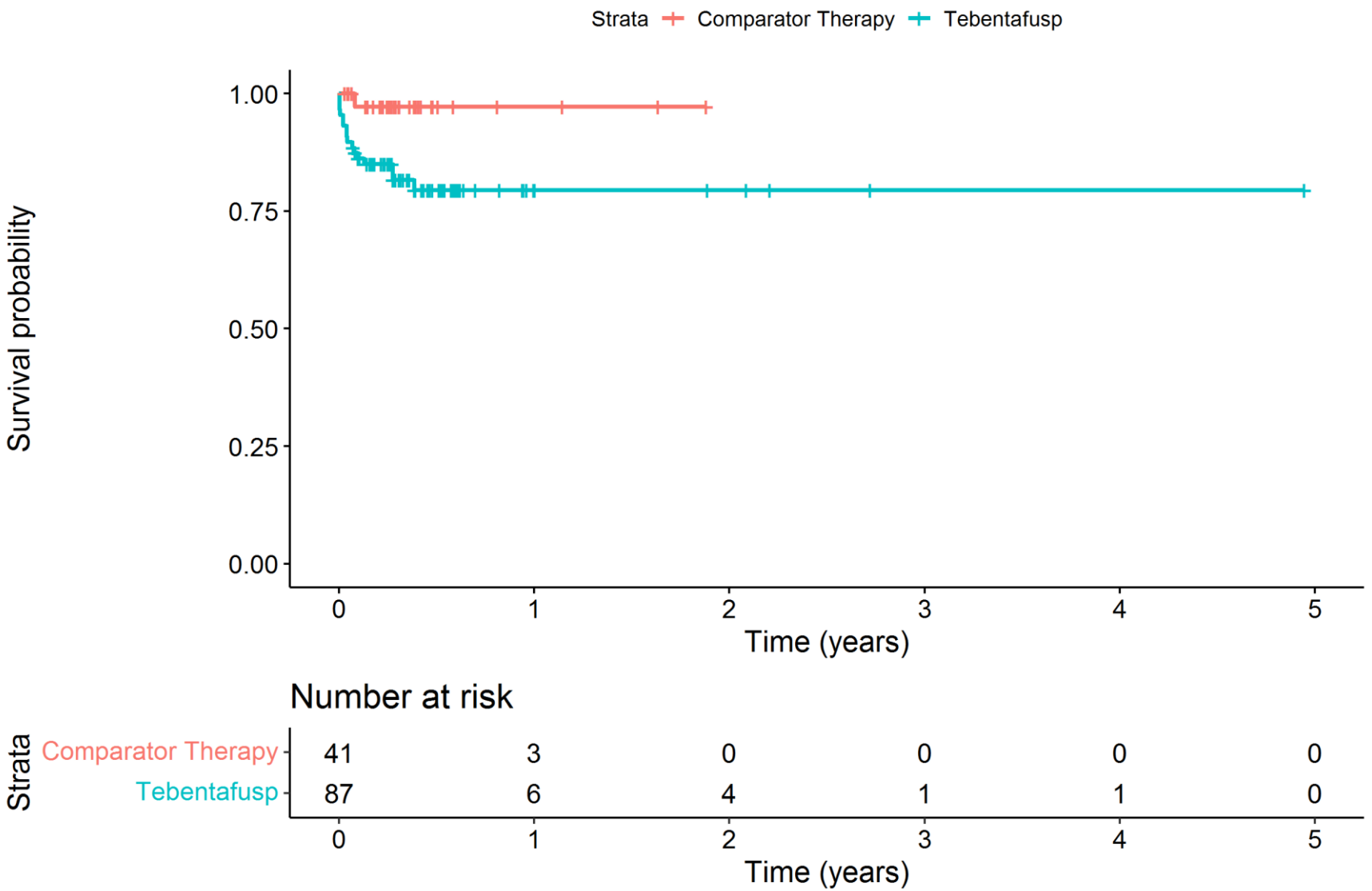
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- ALP > ULN



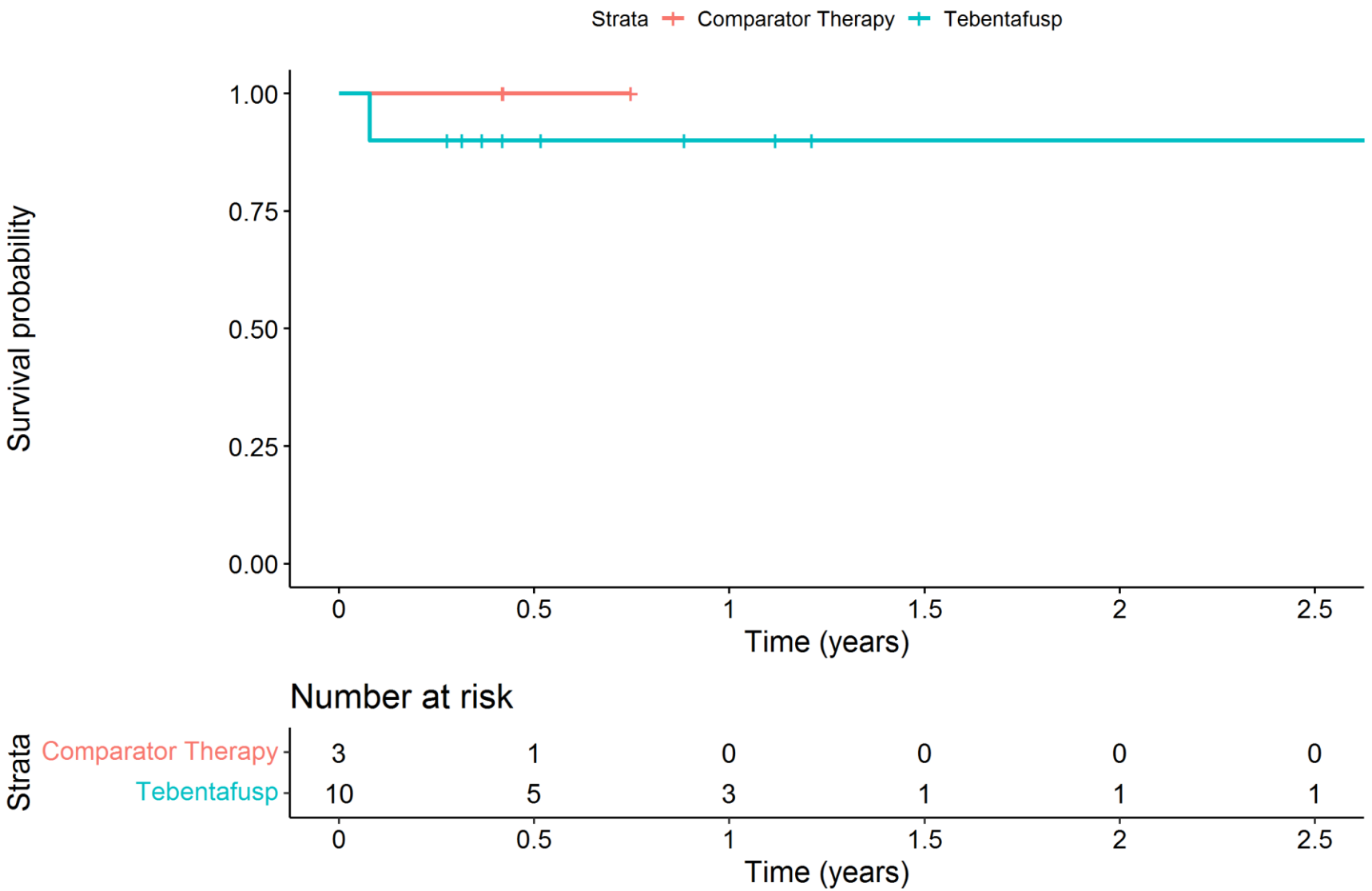
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- LDH =< ULN



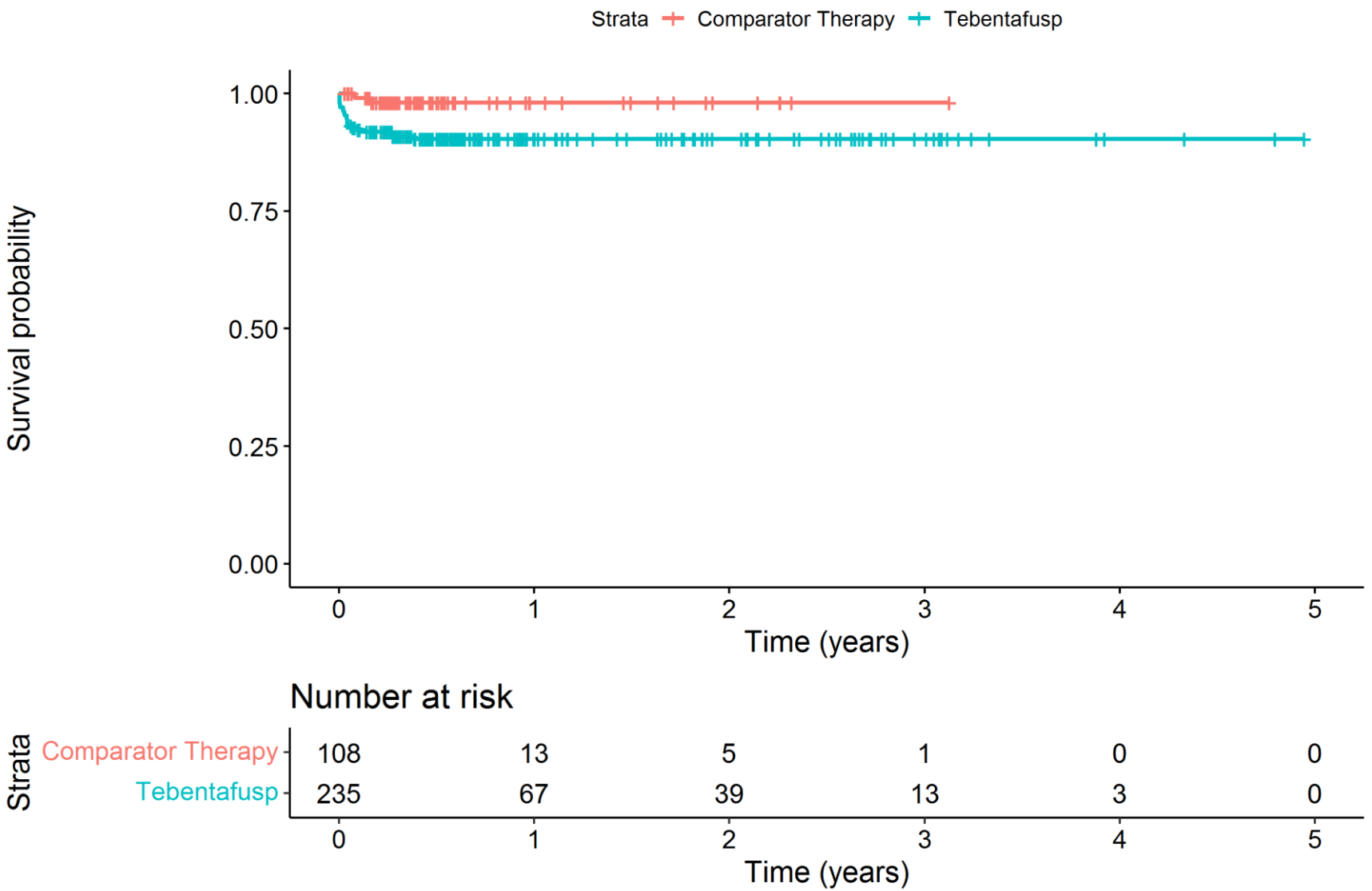
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- LDH > ULN



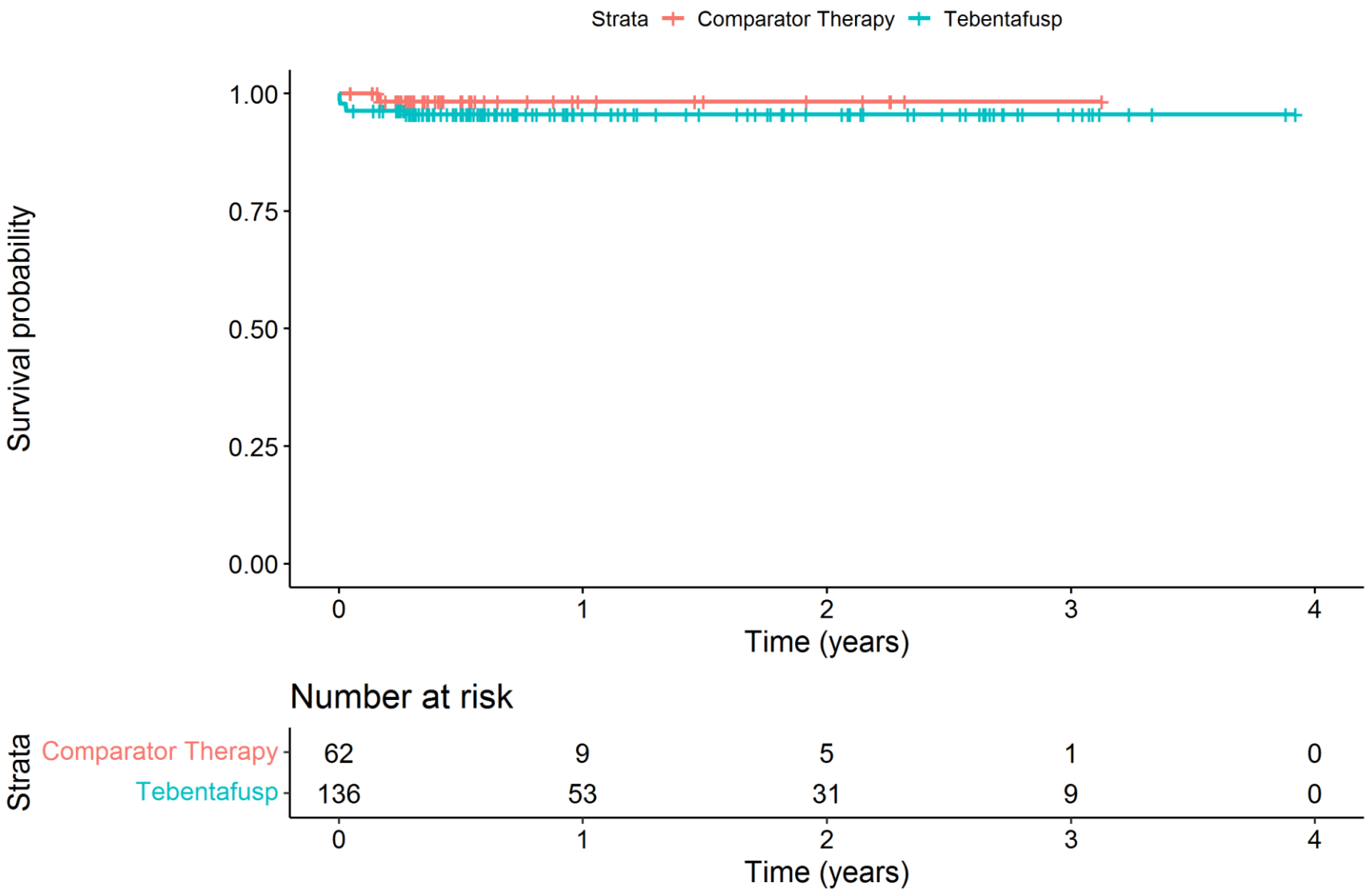
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Vorherige Therapie adjuvant/neoadjuvant



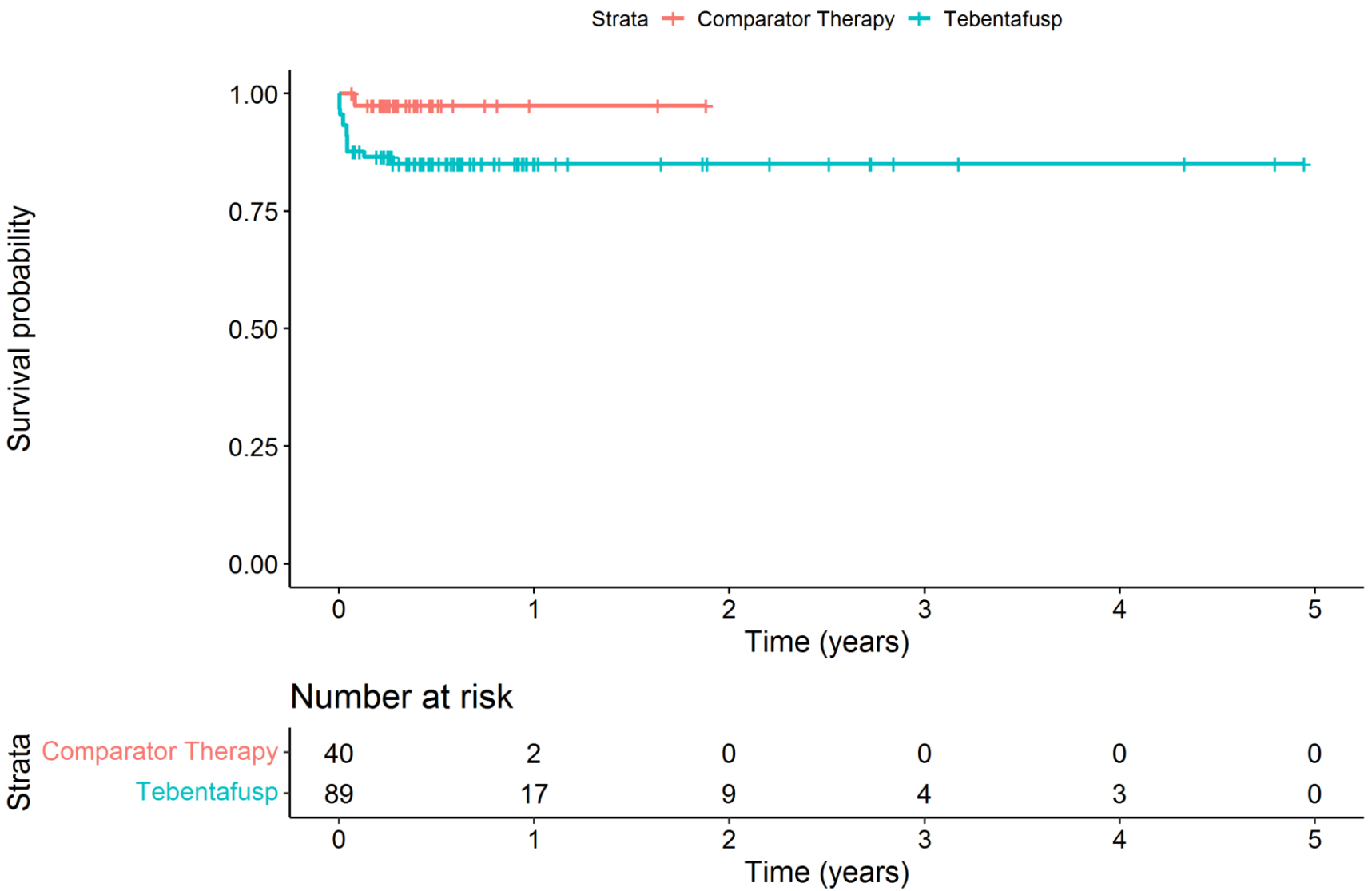
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Keine Vorherige Therapie adjuvant/neoadjuvant



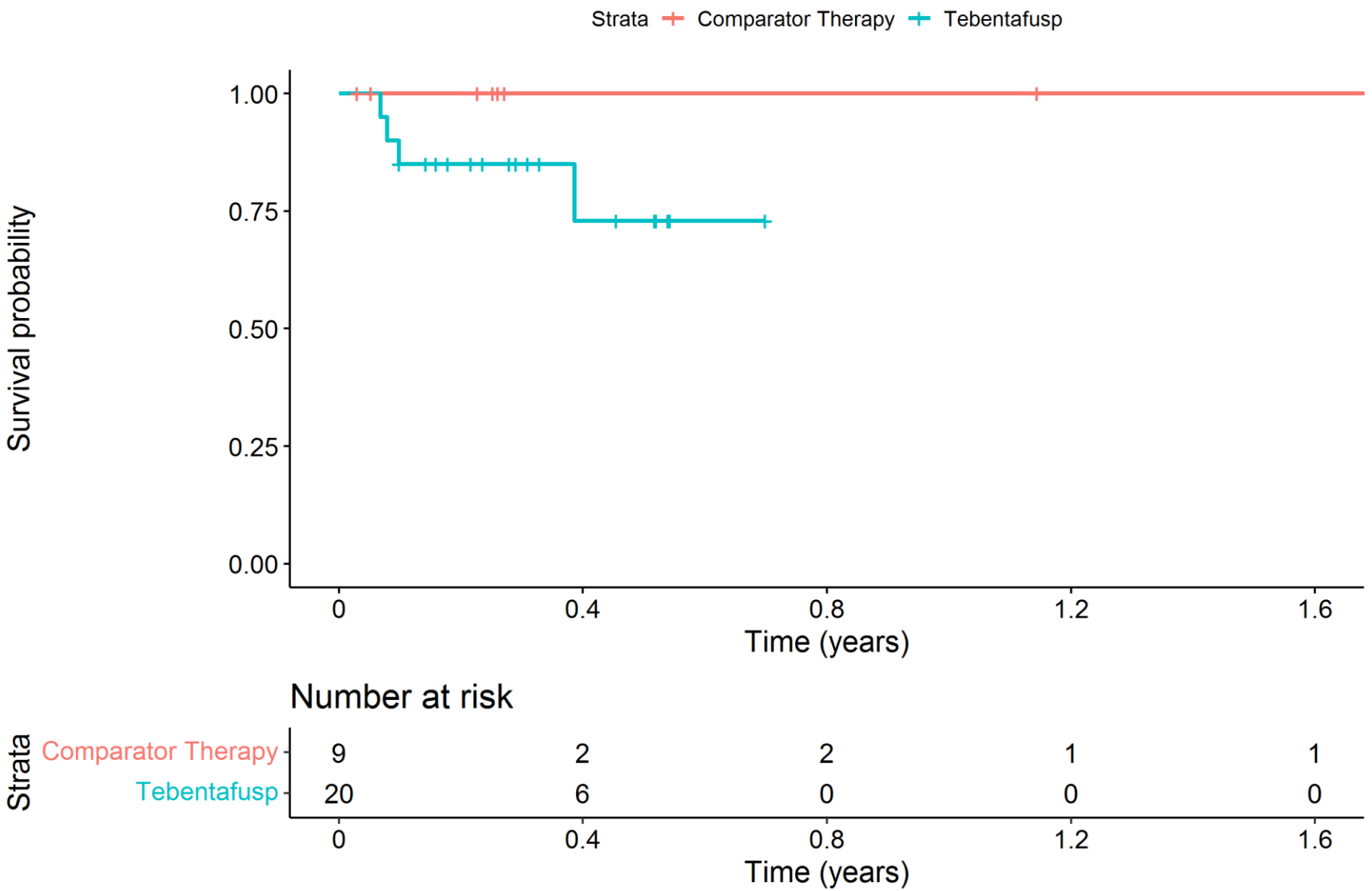
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion ≤ 3cm



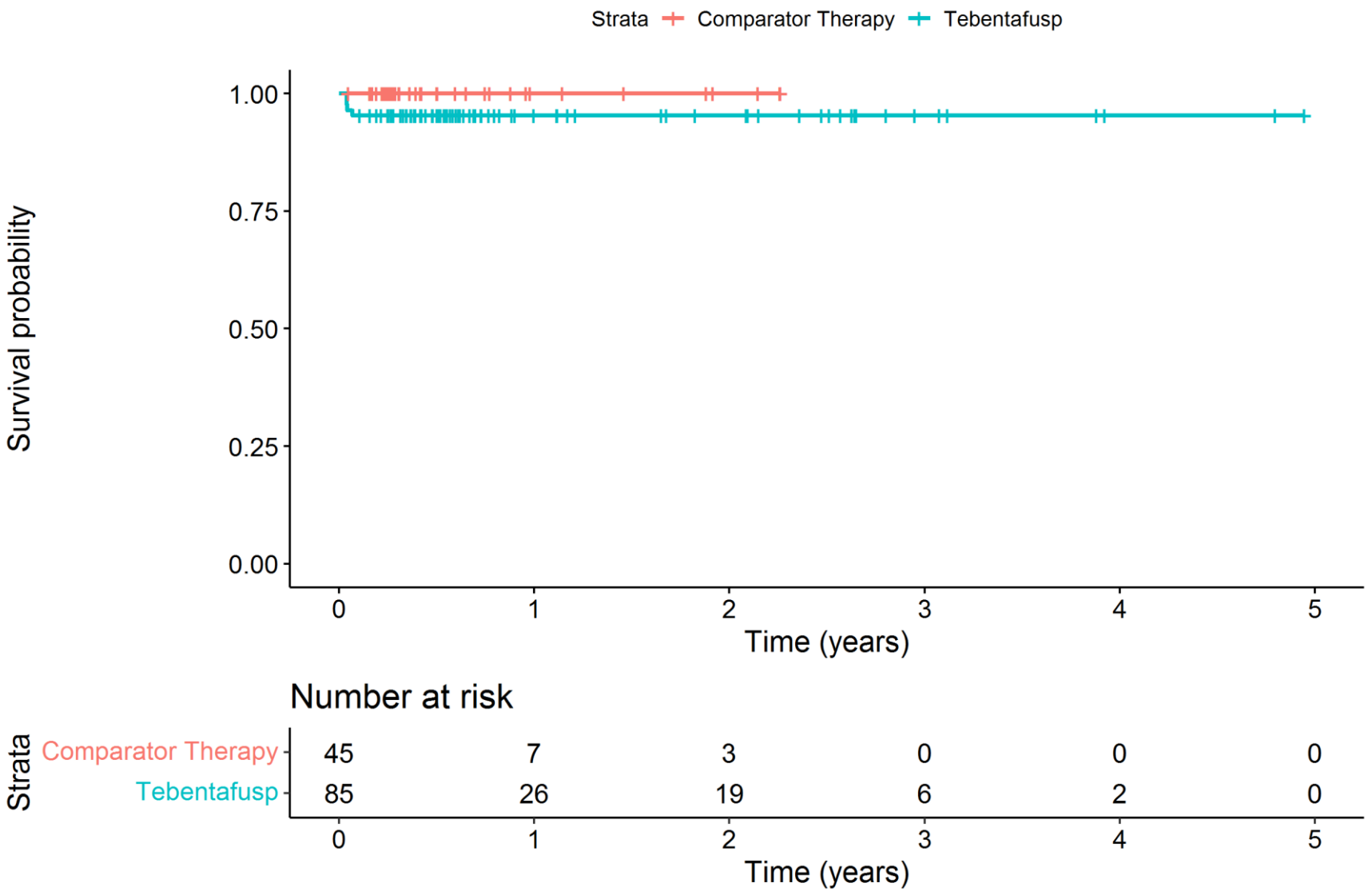
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion 3,1-8,0 cm



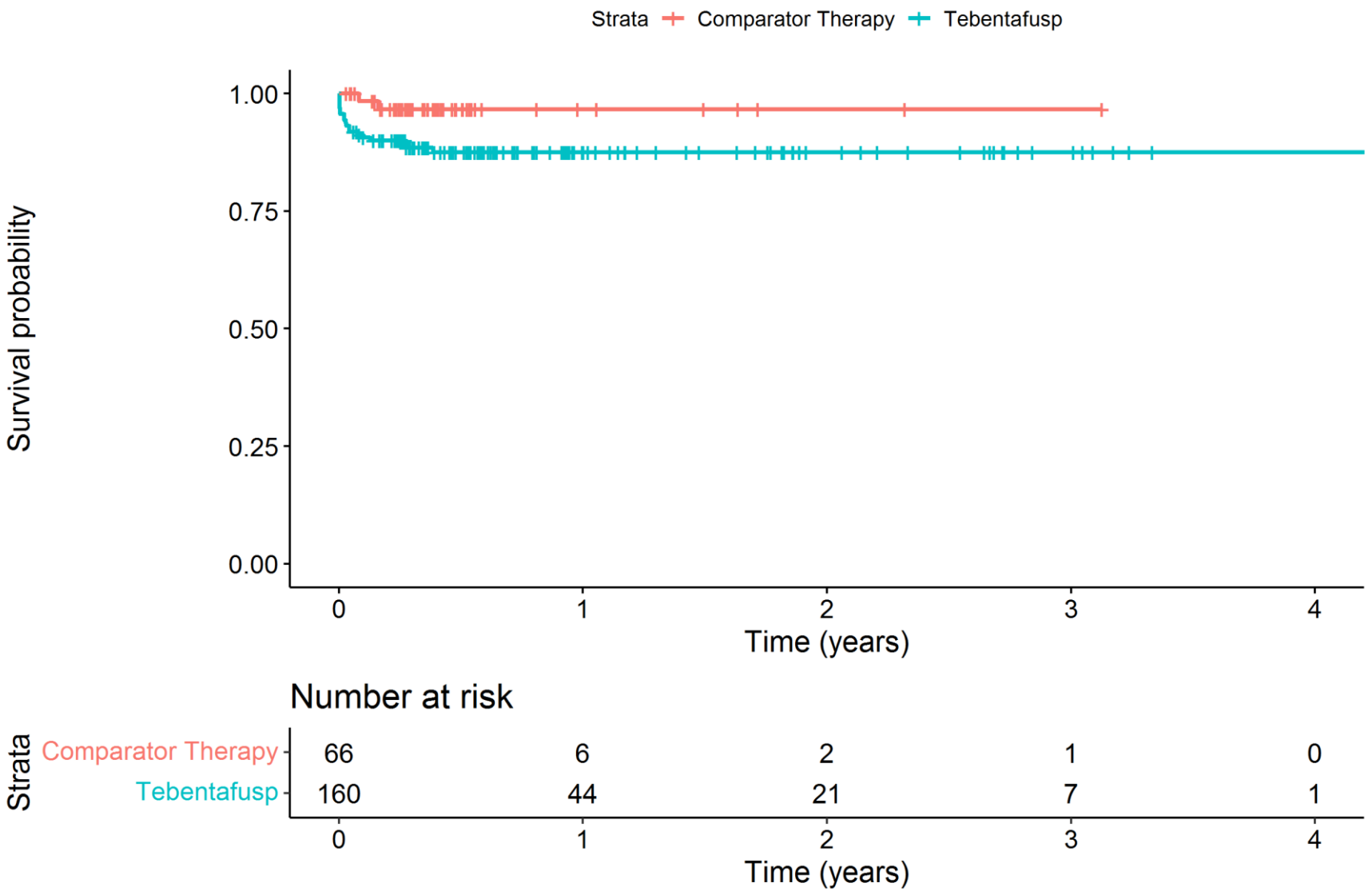
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Läsion ≥8,1 cm



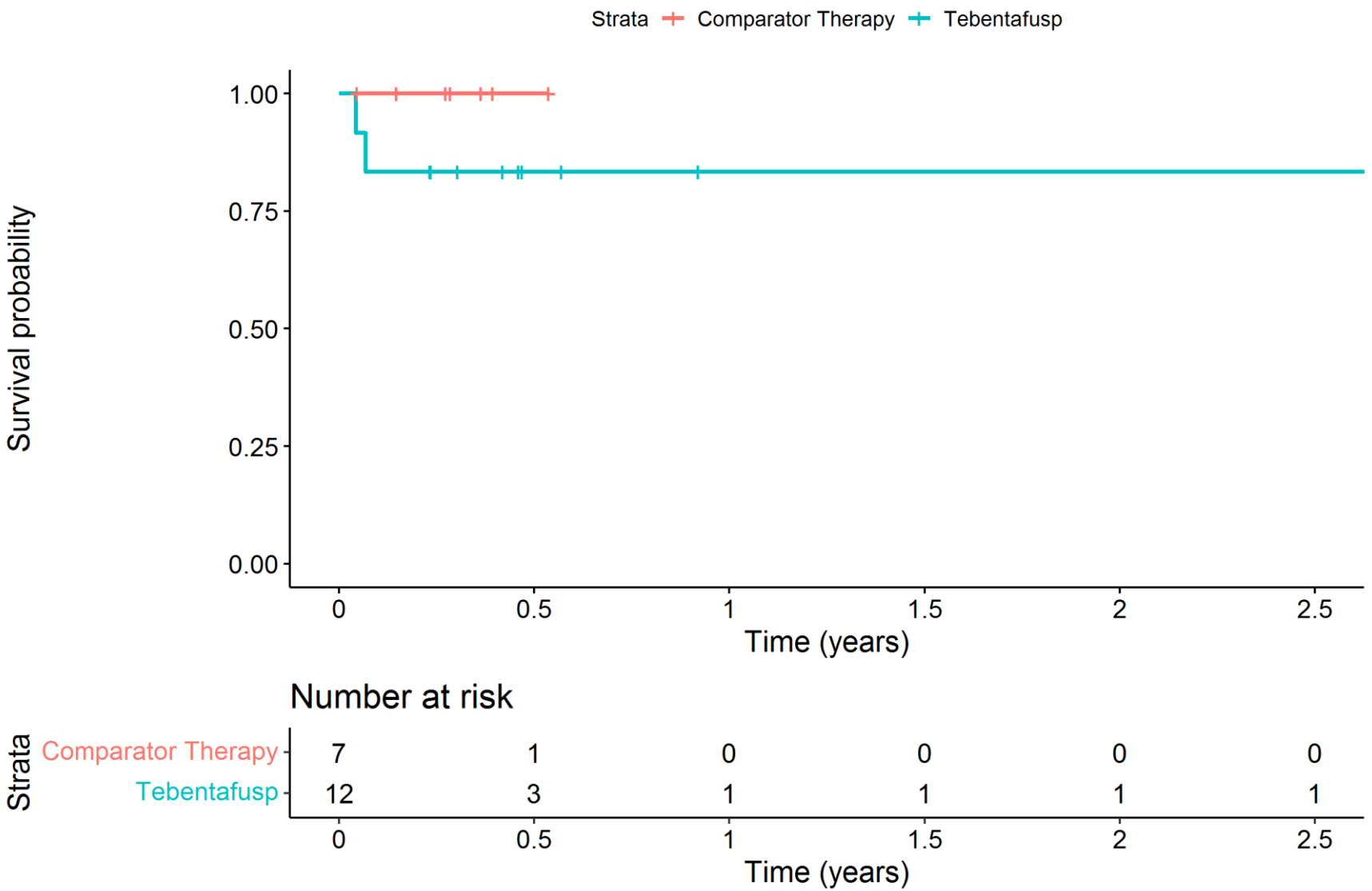
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nordamerika



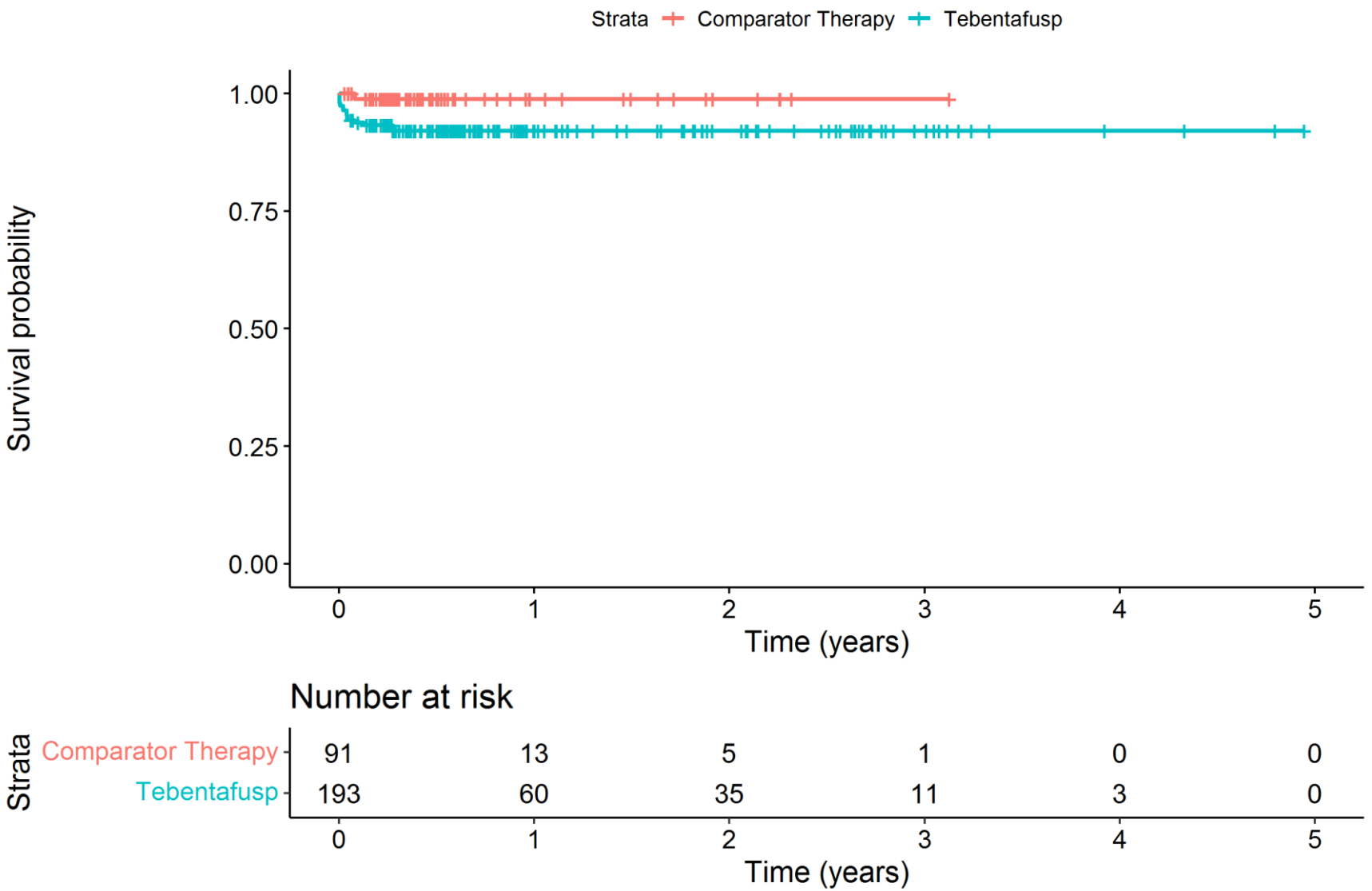
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Nicht-Nordamerika



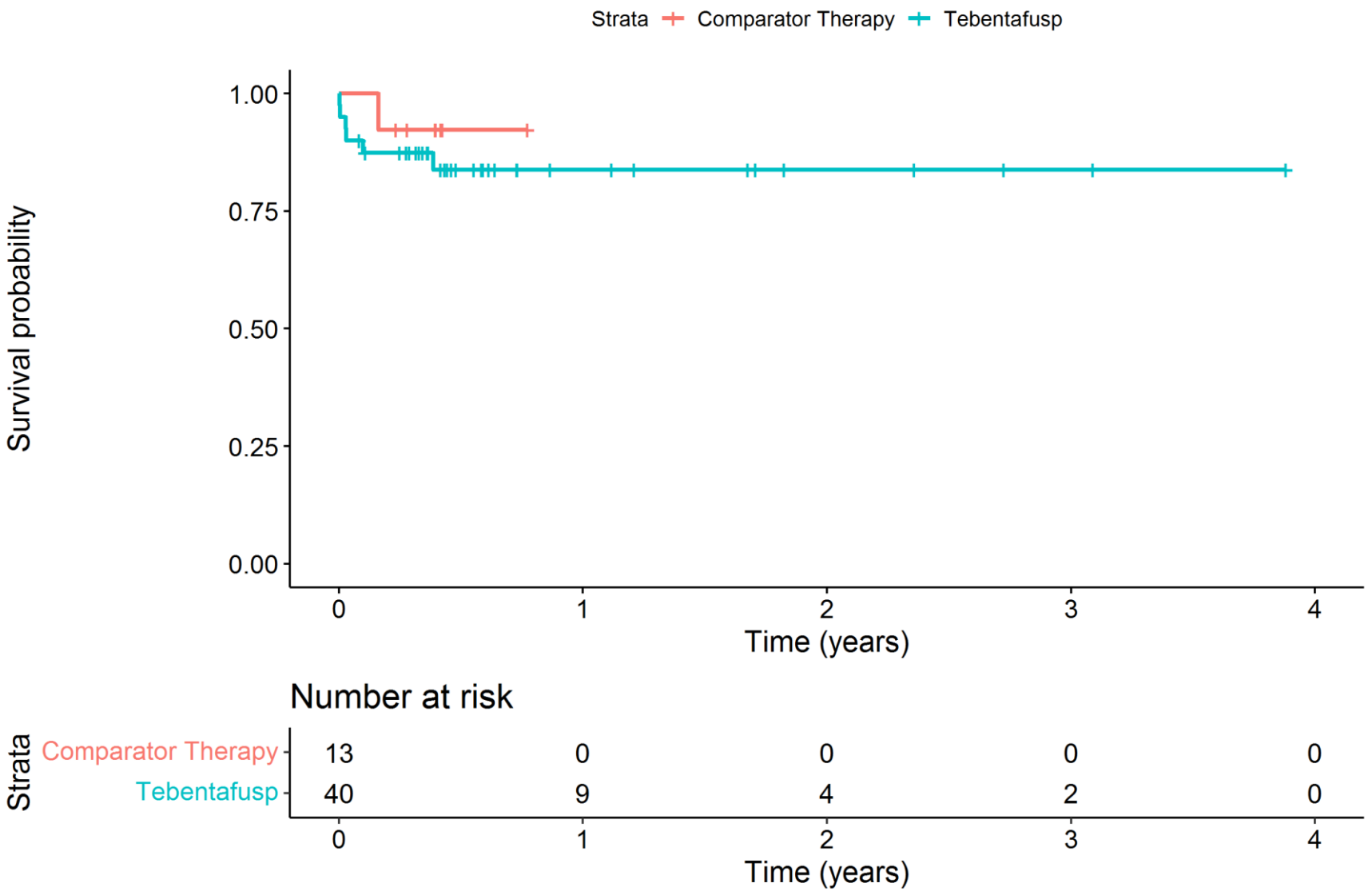
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Dacarbazin



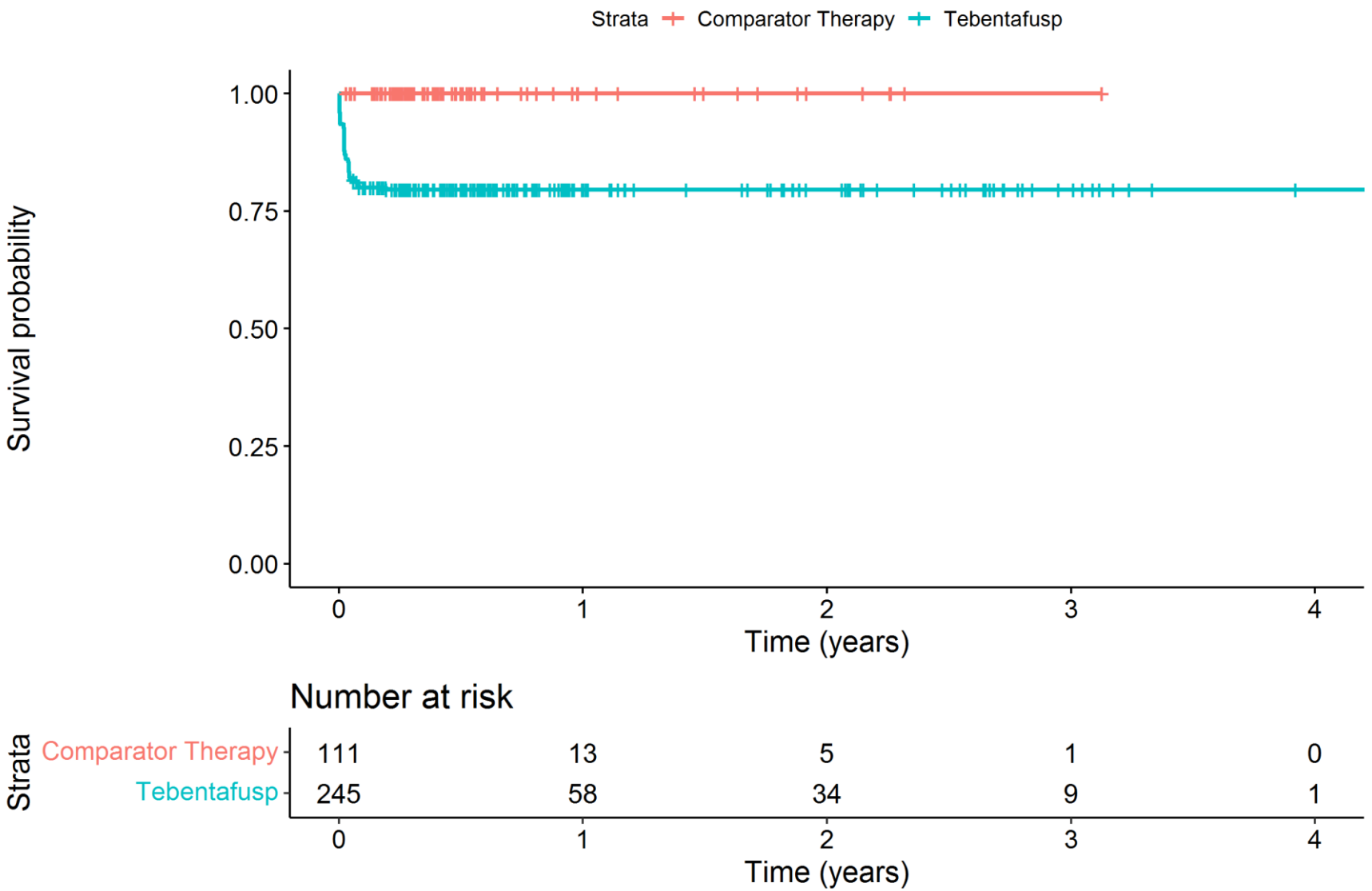
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Pembrolizumab



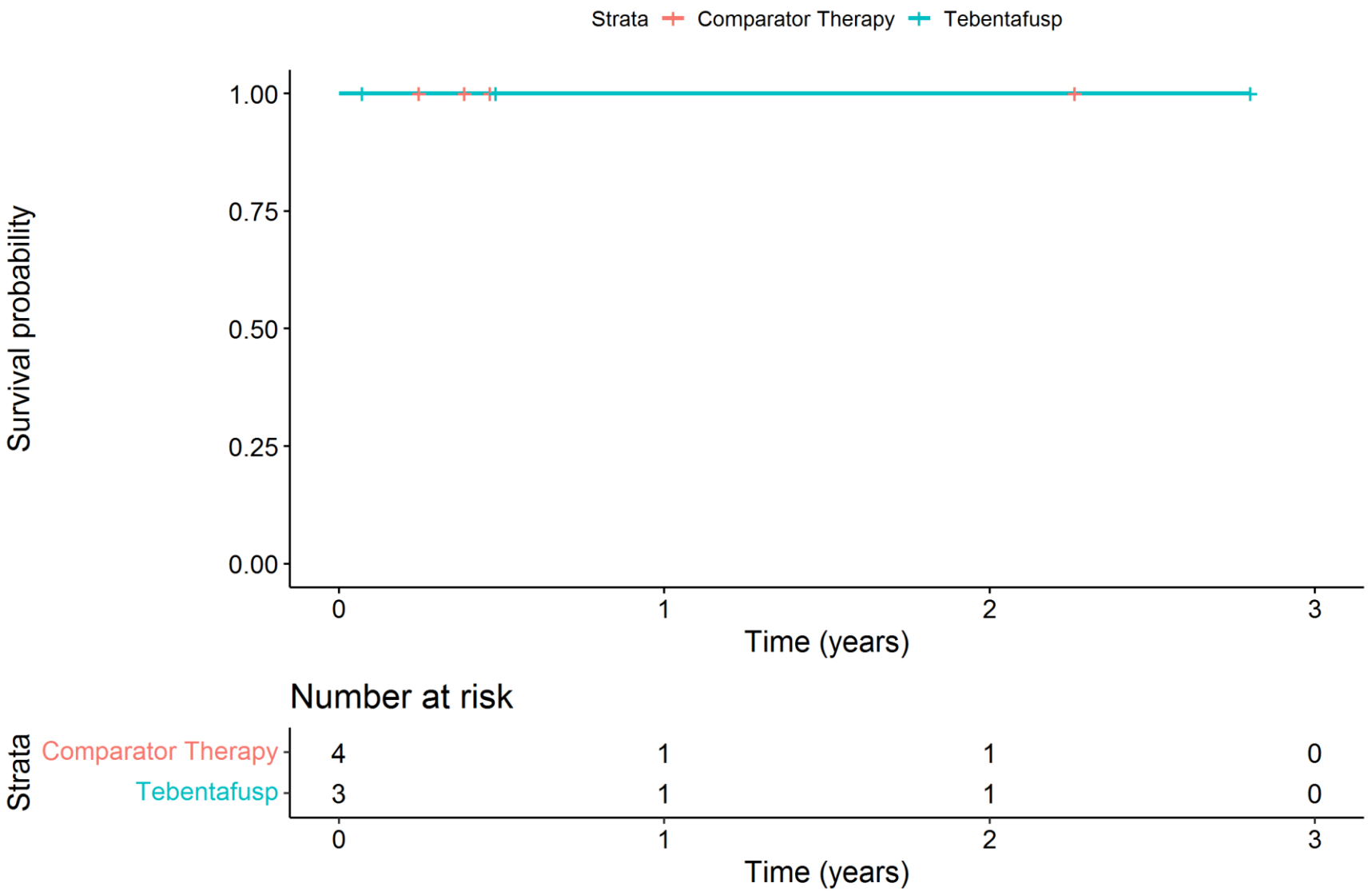
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort- Ipilimumab



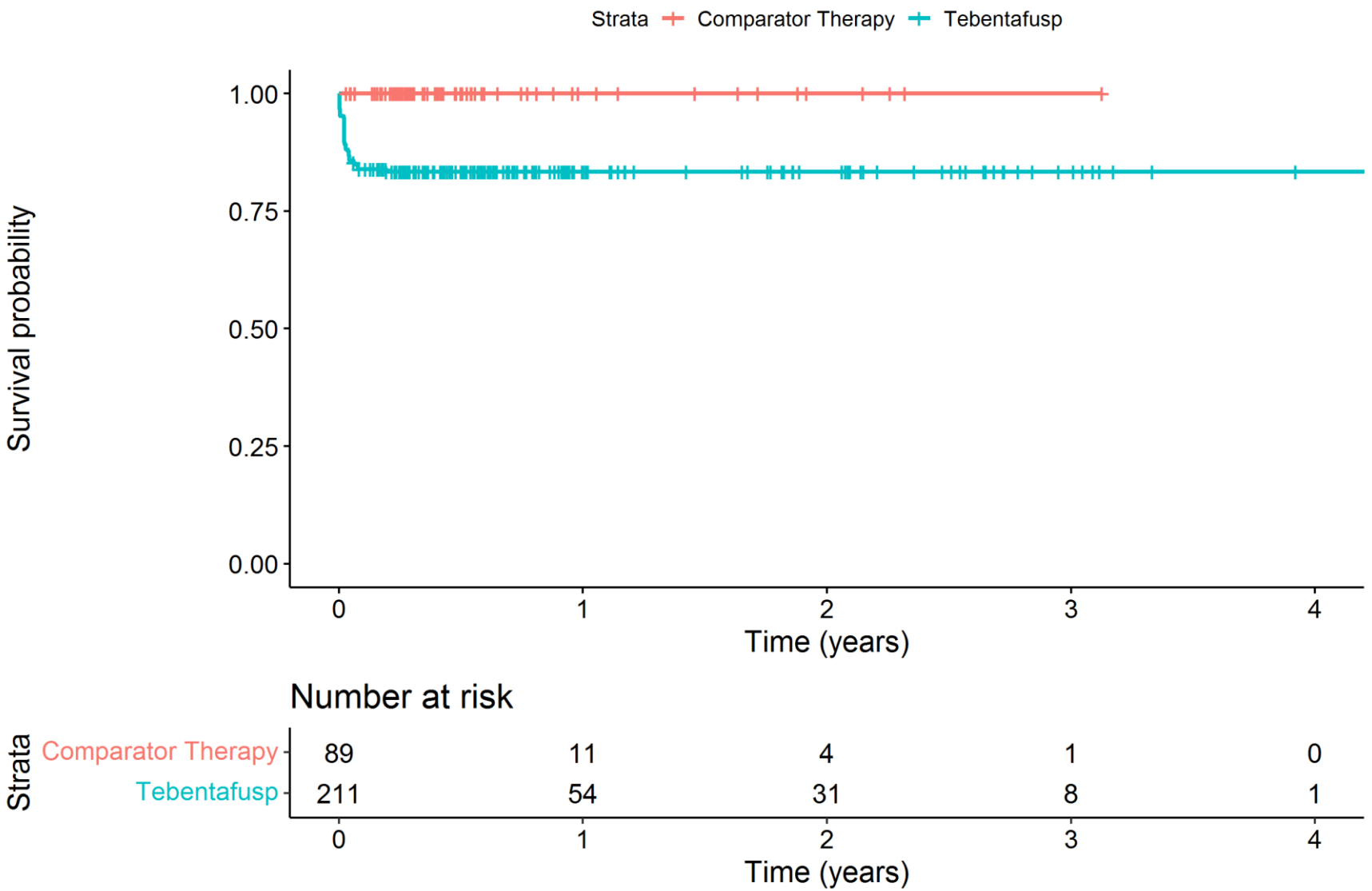
Erkrankungen der Haut und des Unterhautgewebes- Gesamt



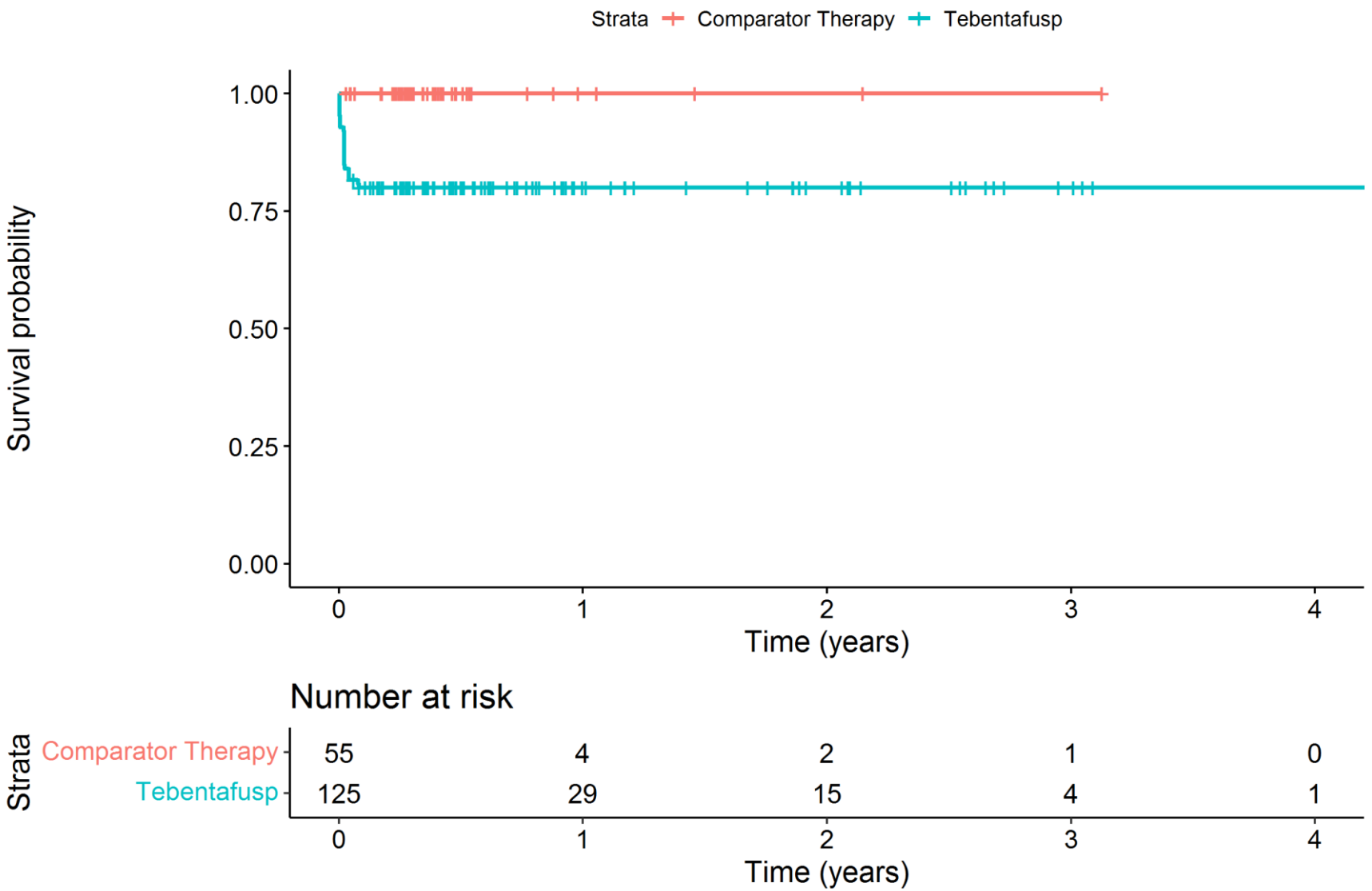
Erkrankungen der Haut und des Unterhautgewebes- Hispanisch



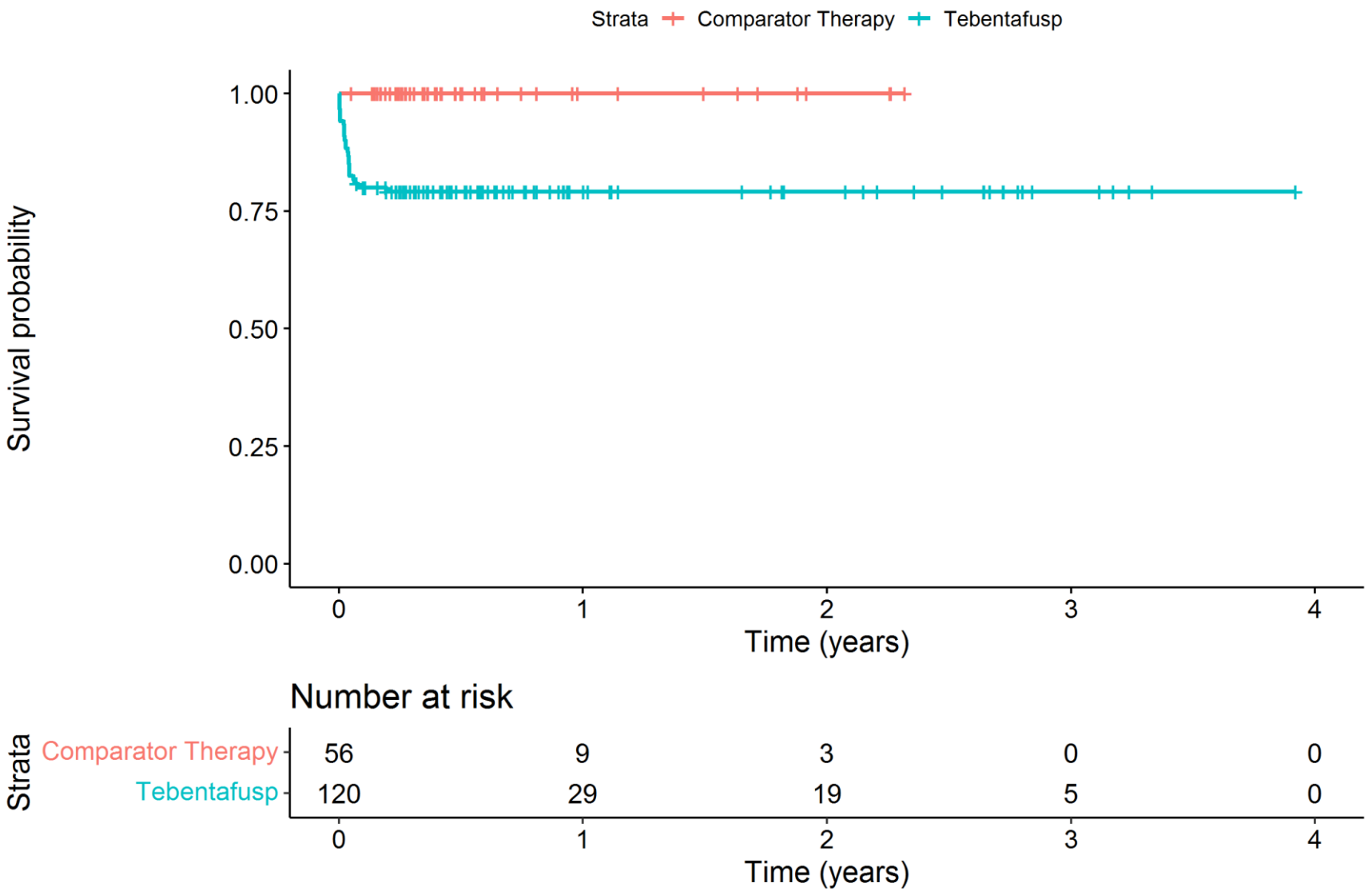
Erkrankungen der Haut und des Unterhautgewebes- Nicht-hispanisch



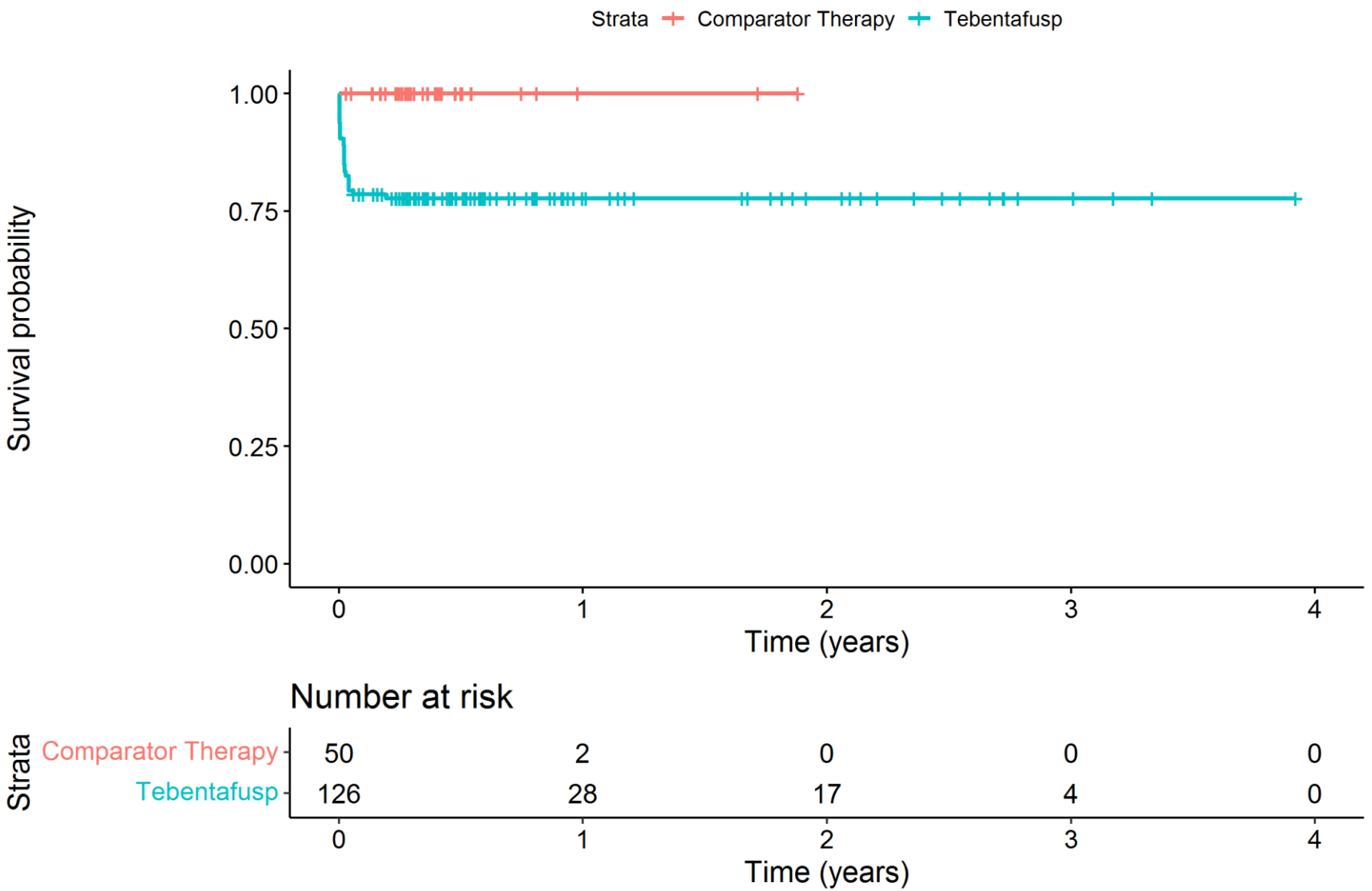
Erkrankungen der Haut und des Unterhautgewebes- Männlich



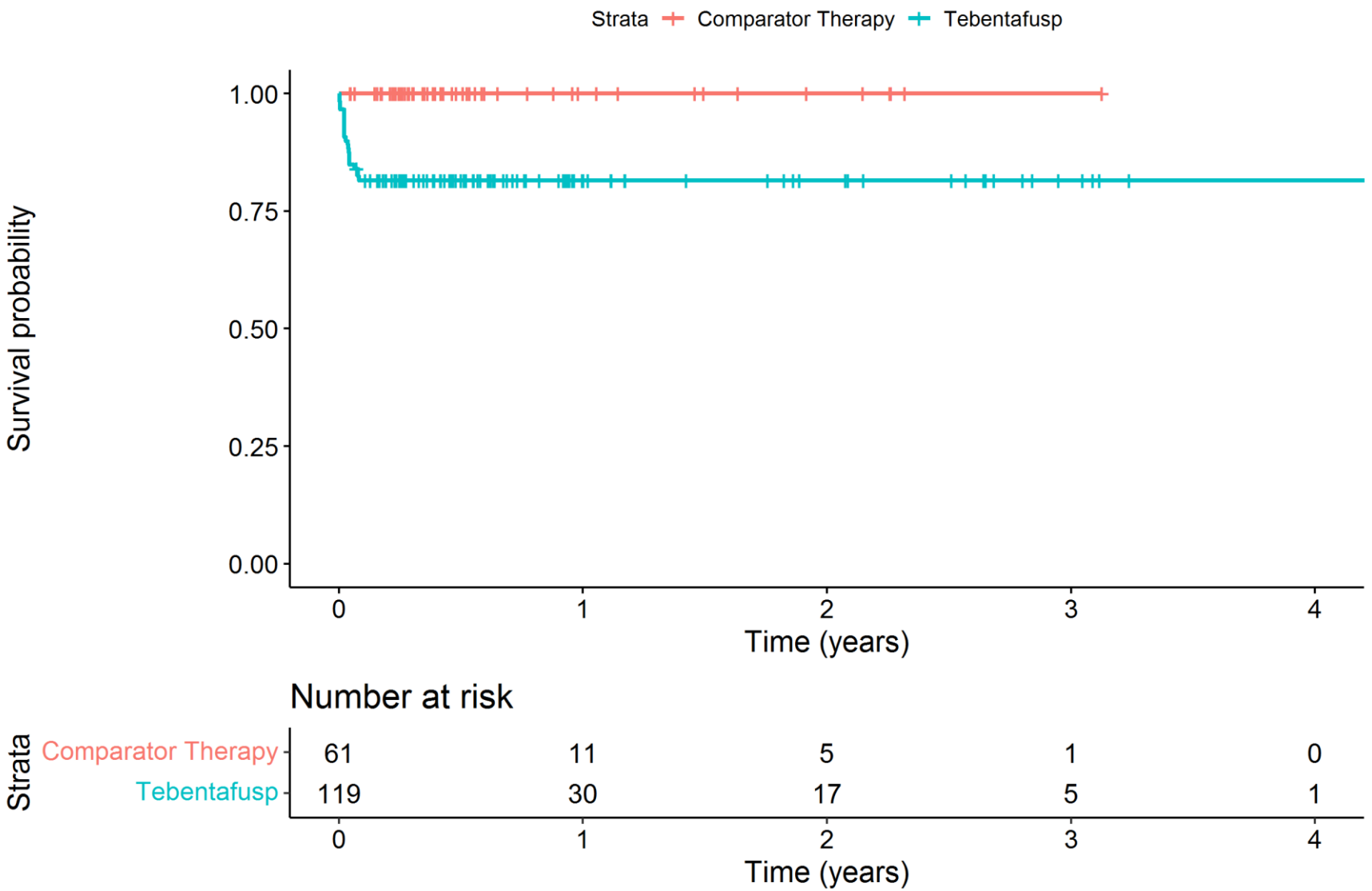
Erkrankungen der Haut und des Unterhautgewebes- Weiblich



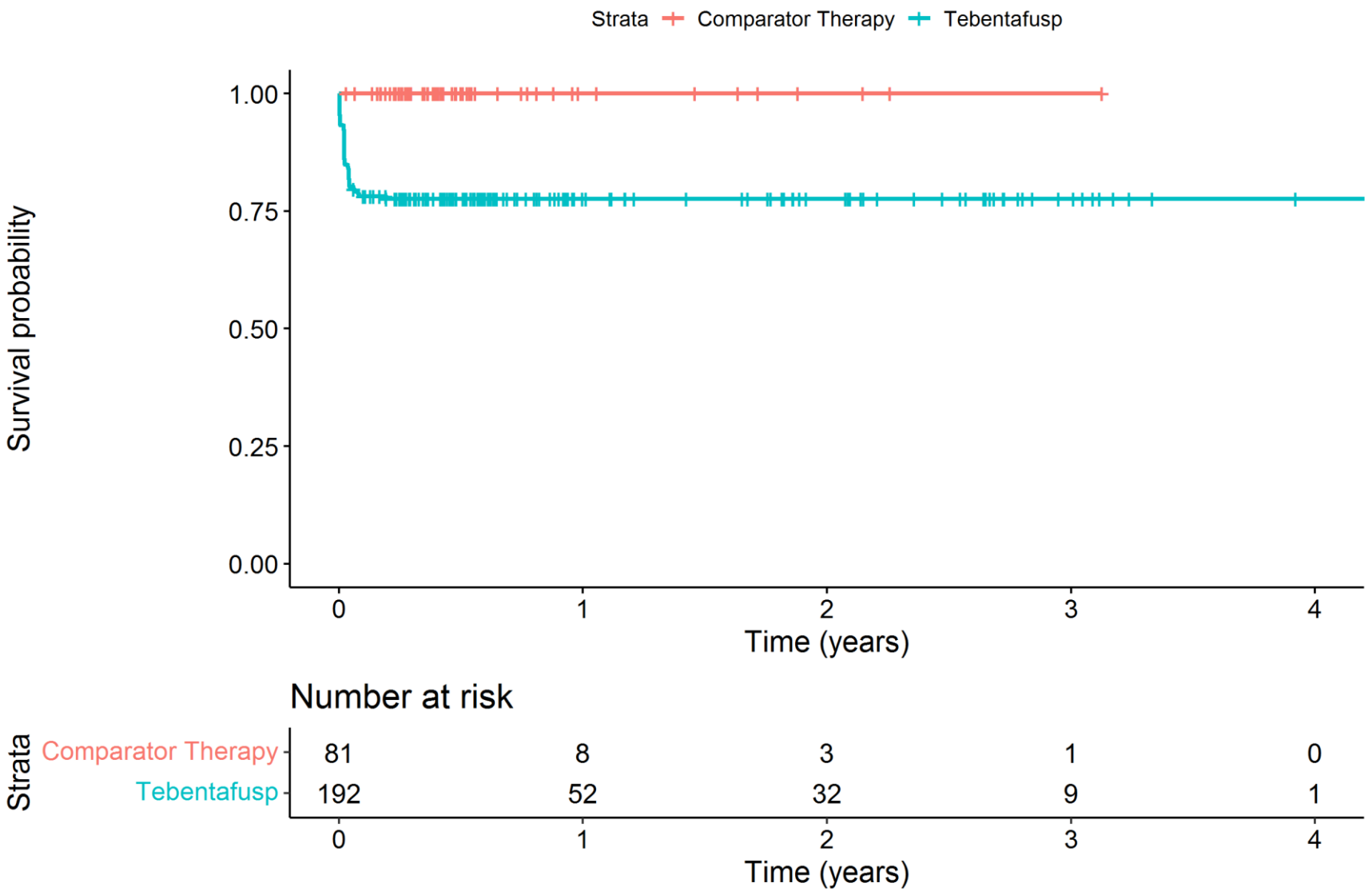
Erkrankungen der Haut und des Unterhautgewebes- <65



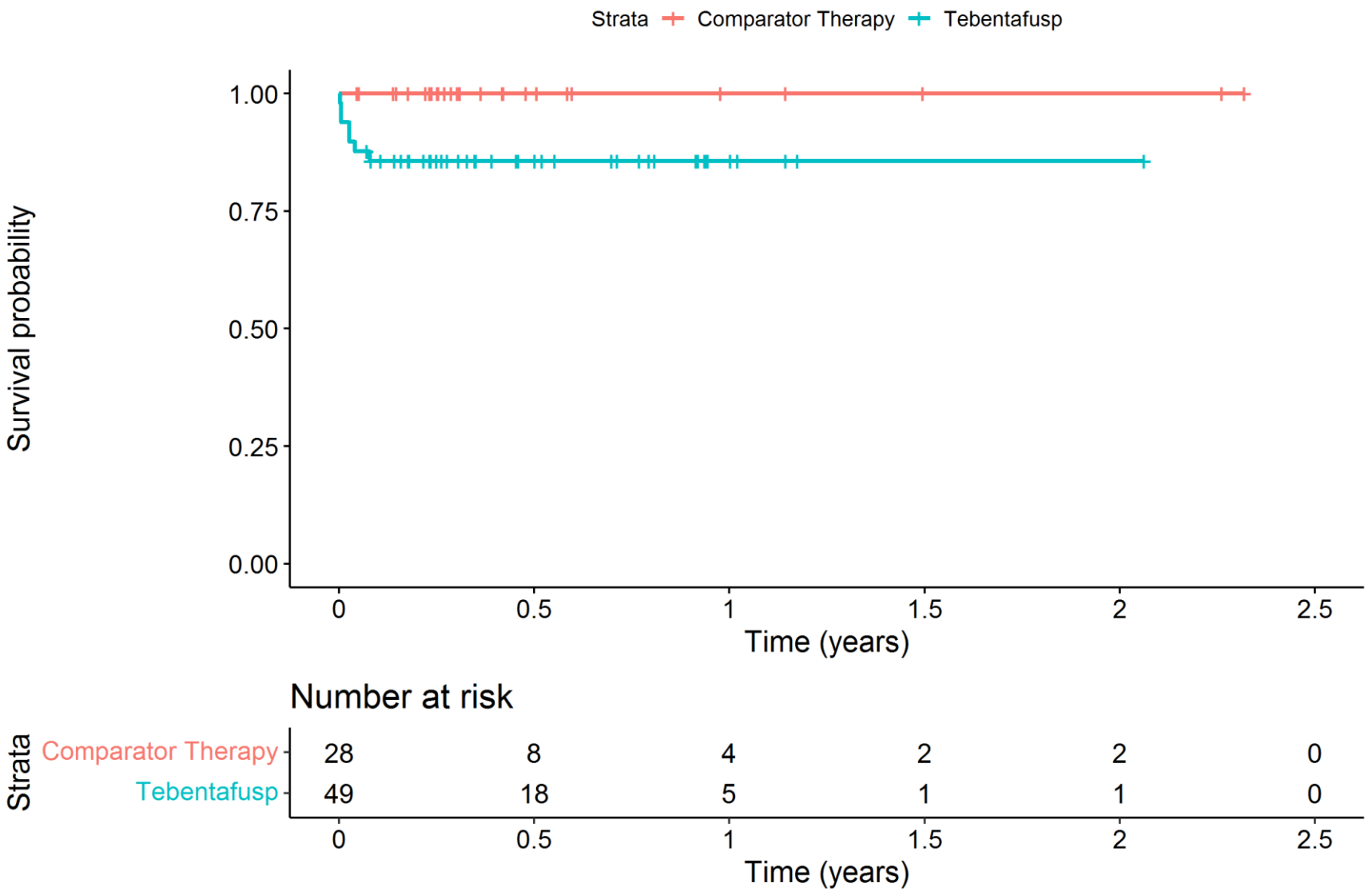
Erkrankungen der Haut und des Unterhautgewebes- ≥65



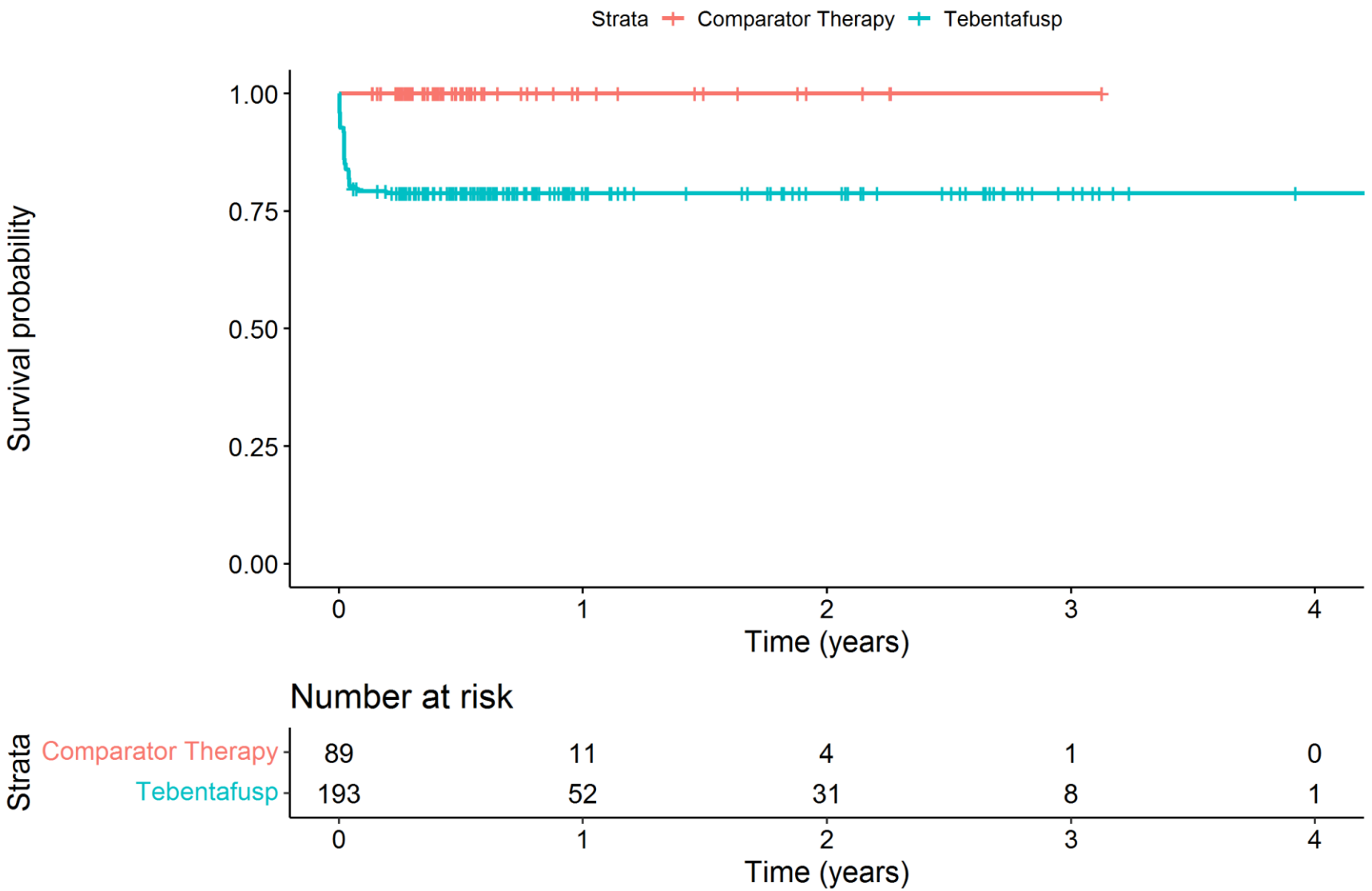
Erkrankungen der Haut und des Unterhautgewebes- ECOG 0



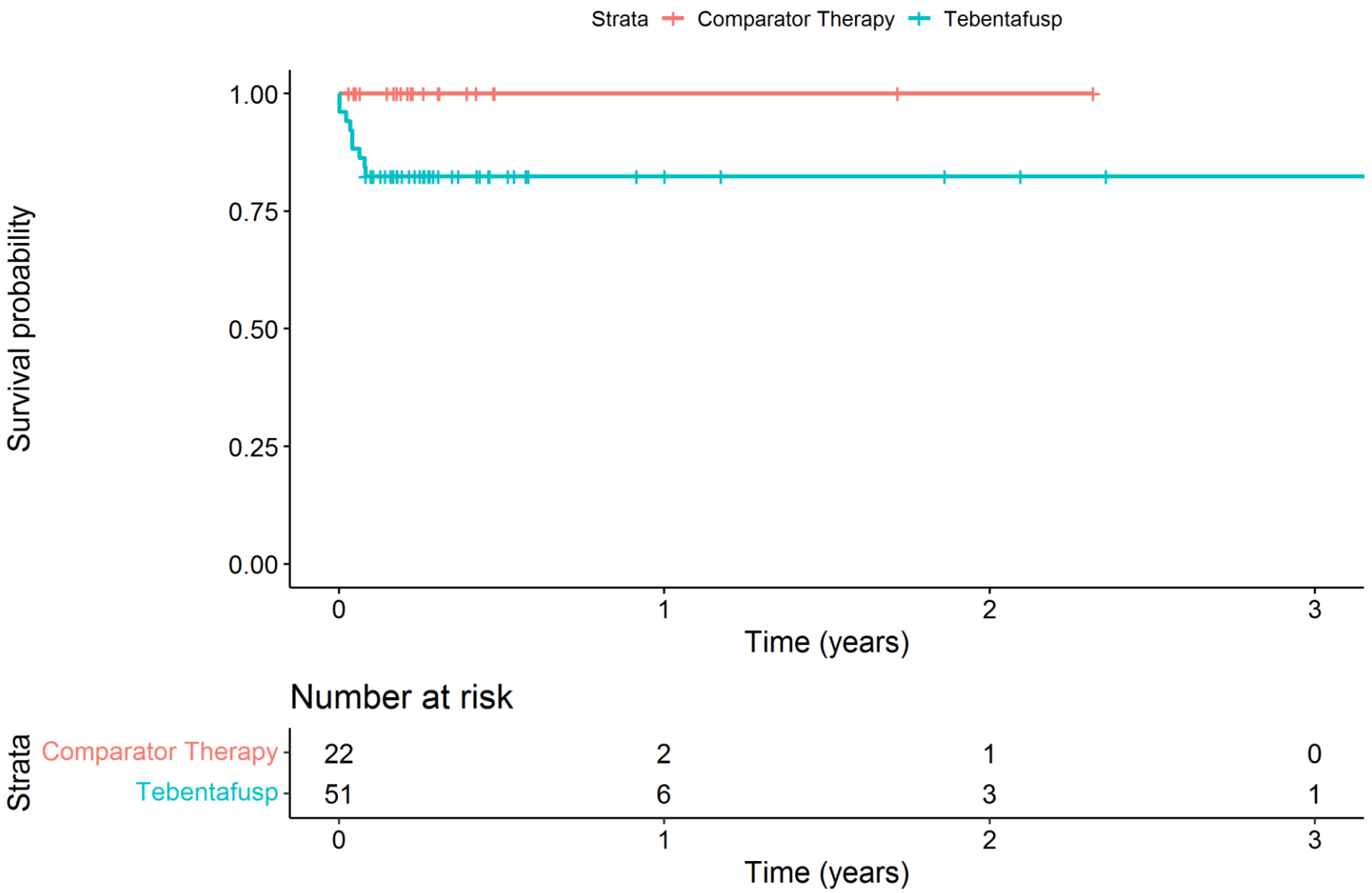
Erkrankungen der Haut und des Unterhautgewebes- ECOG 1



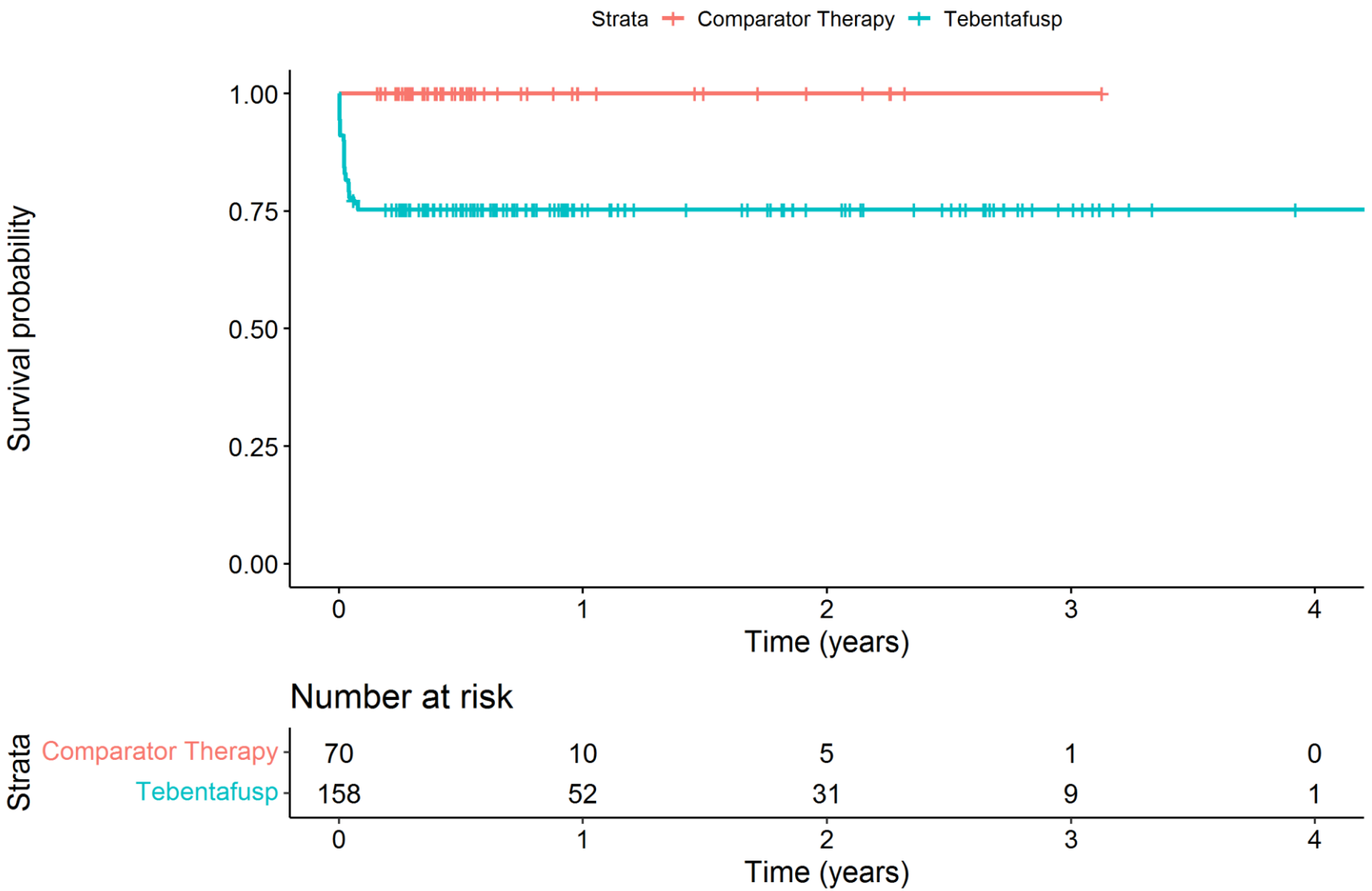
Erkrankungen der Haut und des Unterhautgewebes- ALP ≤ ULN



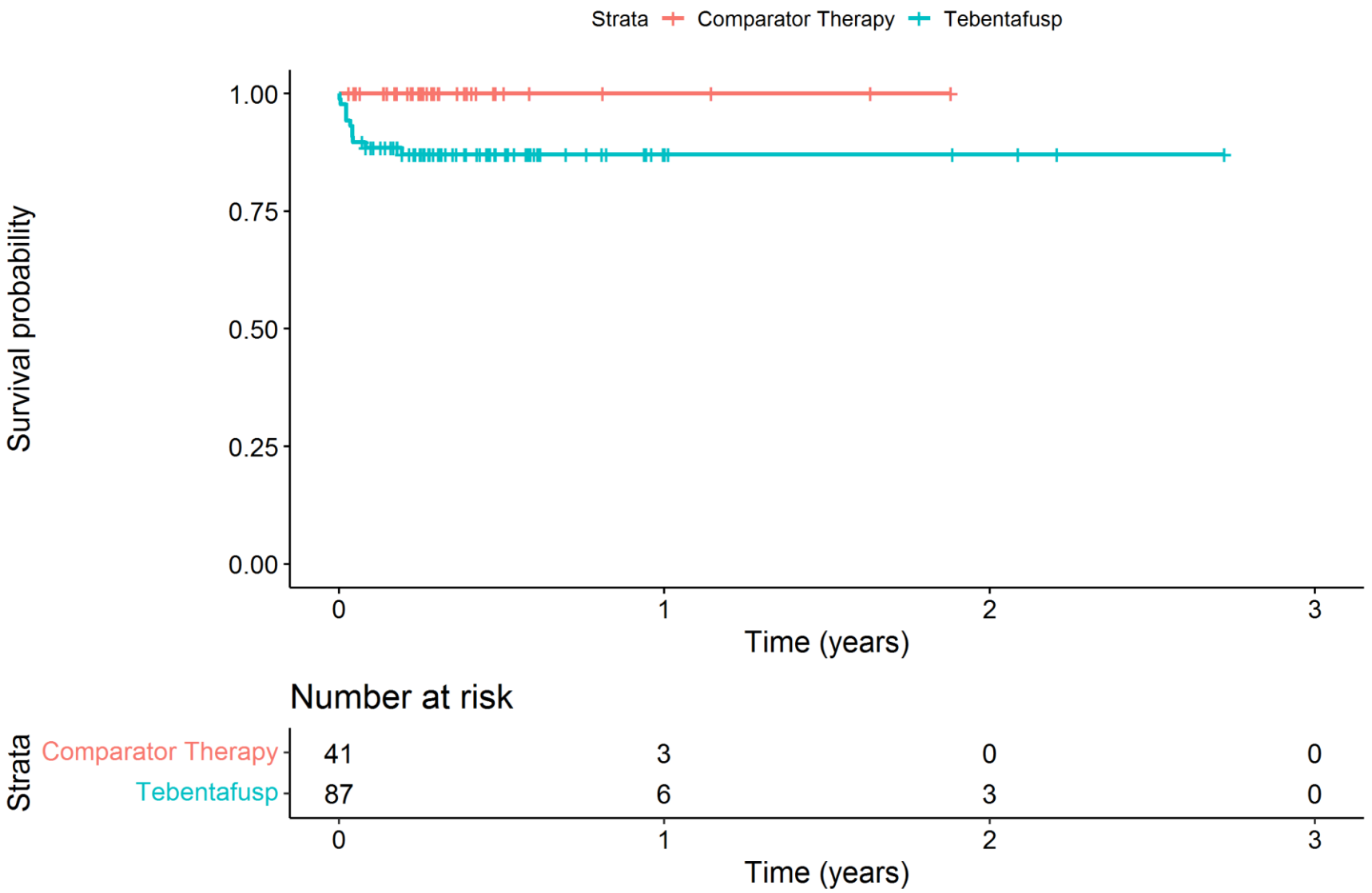
Erkrankungen der Haut und des Unterhautgewebes- ALP > ULN



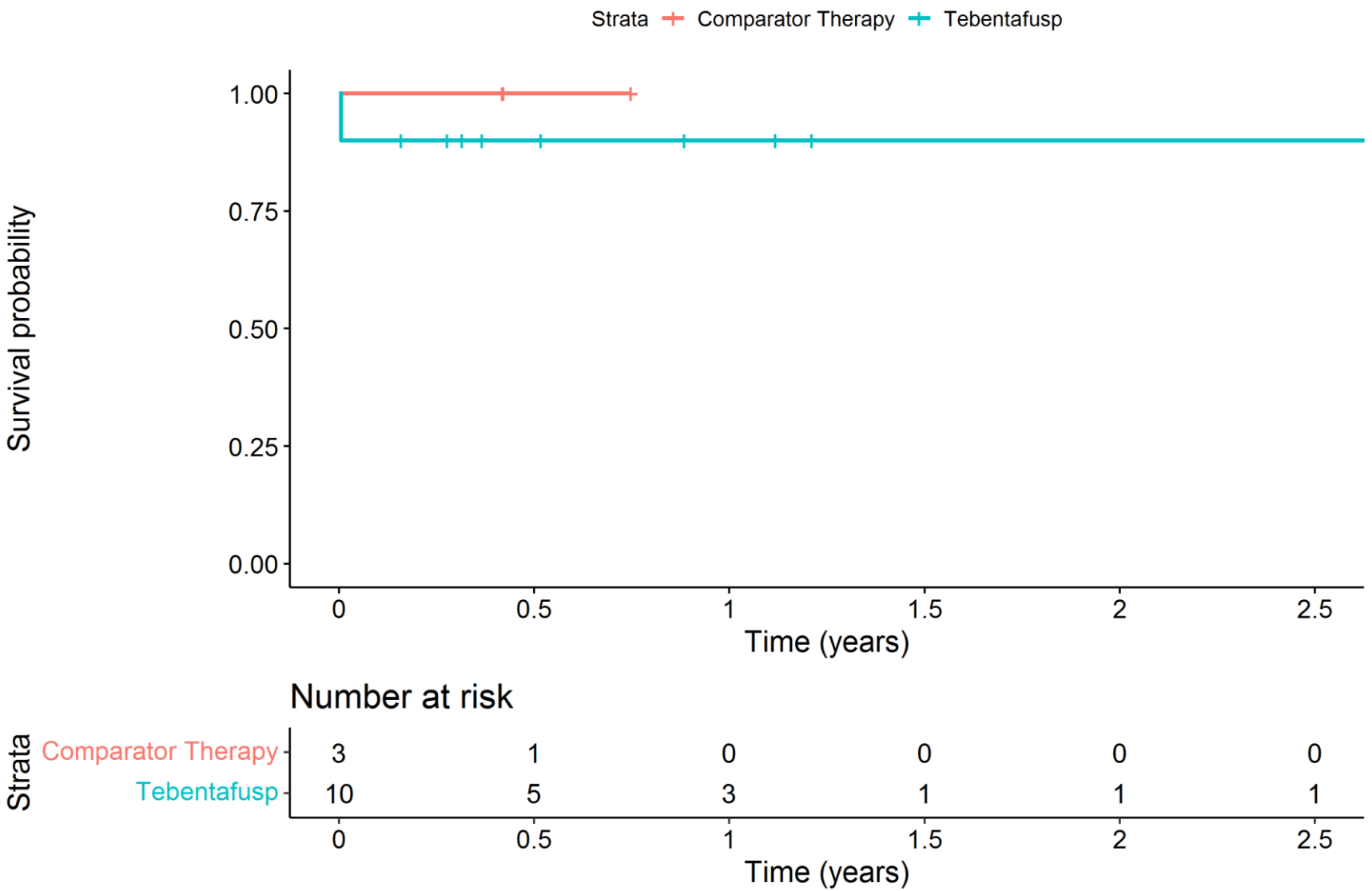
Erkrankungen der Haut und des Unterhautgewebes- LDH =< ULN



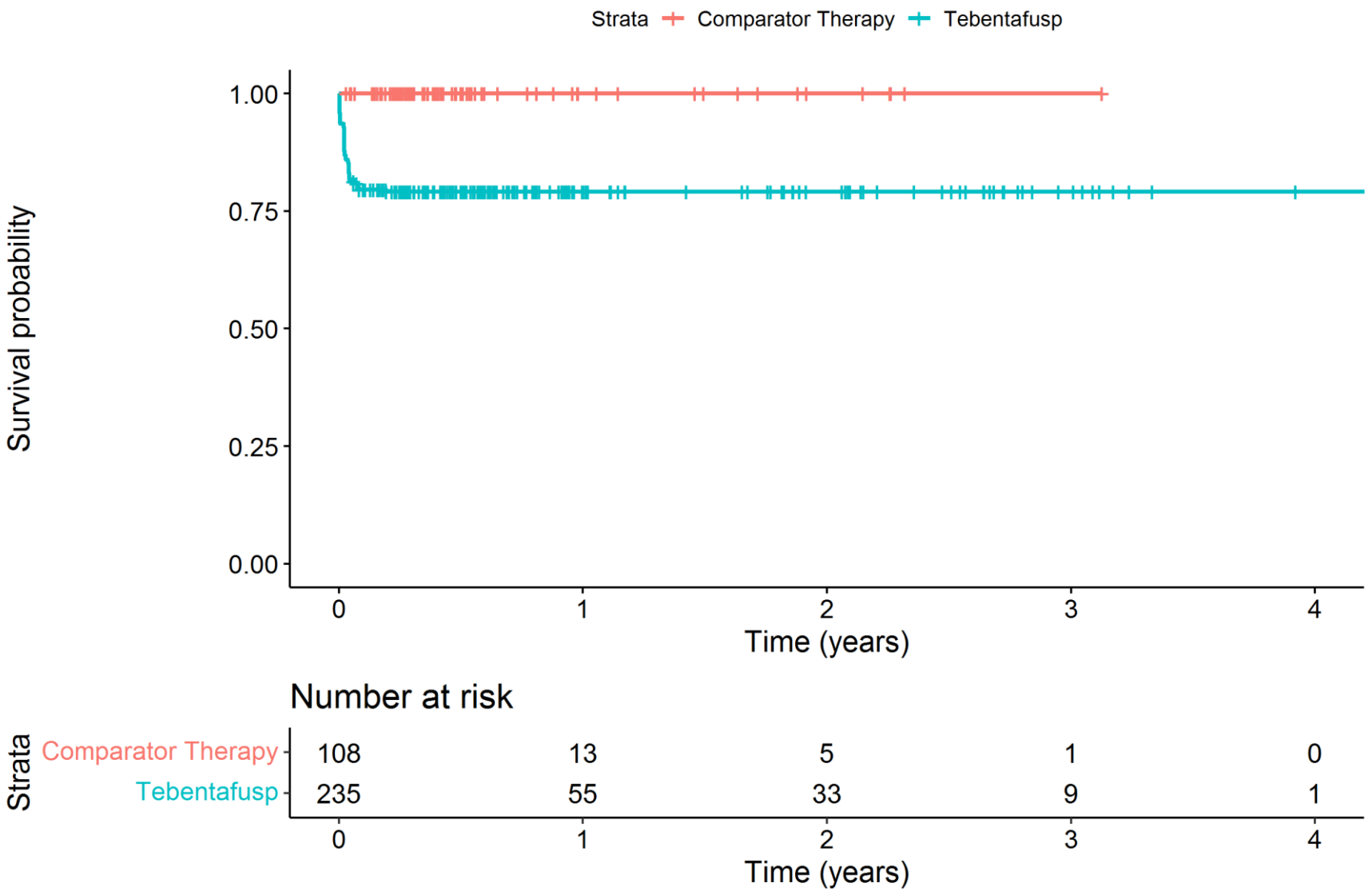
Erkrankungen der Haut und des Unterhautgewebes- LDH > ULN



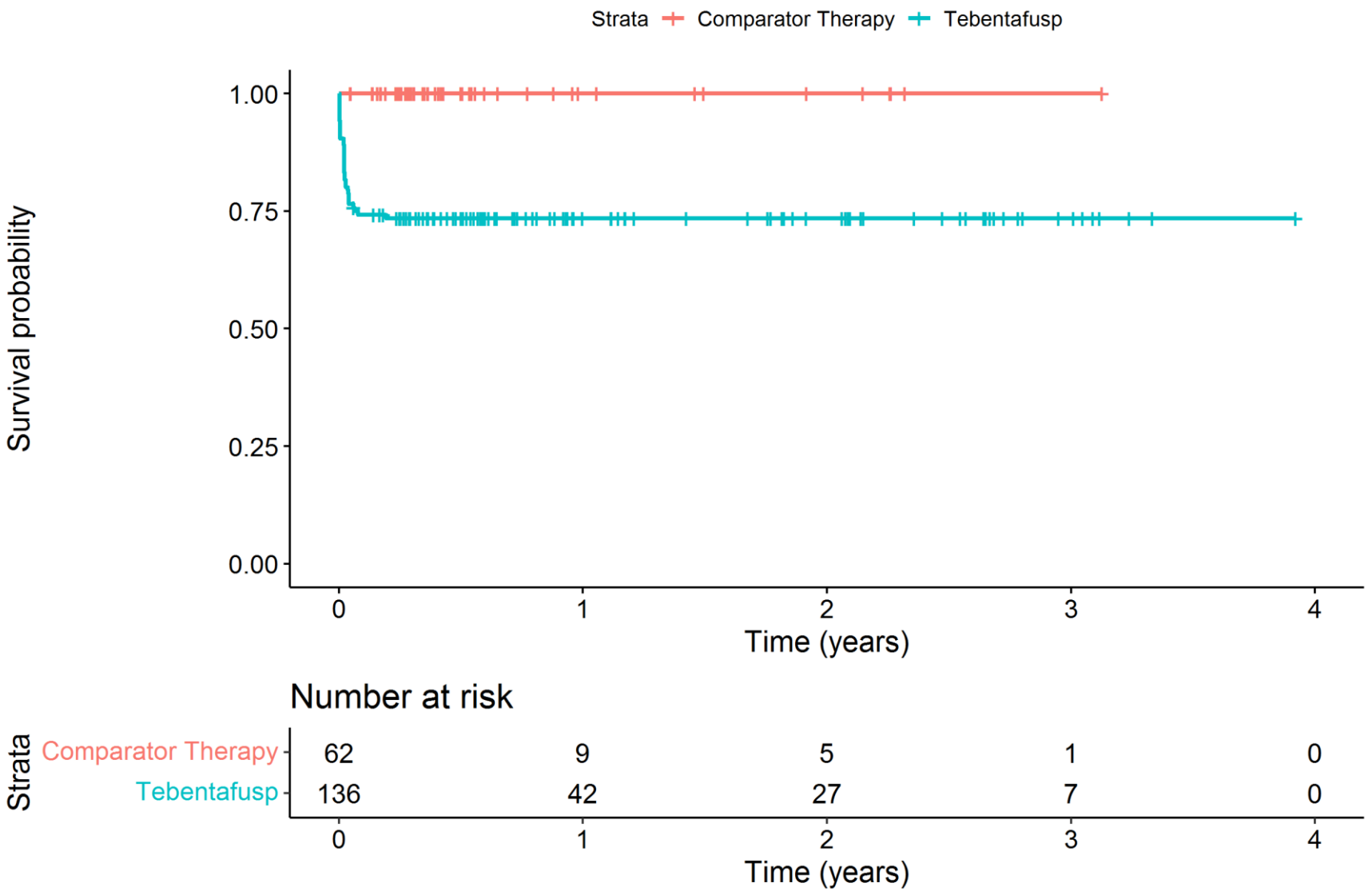
Erkrankungen der Haut und des Unterhautgewebes- Vorherige Therapie adjuvant/neoadjuvant



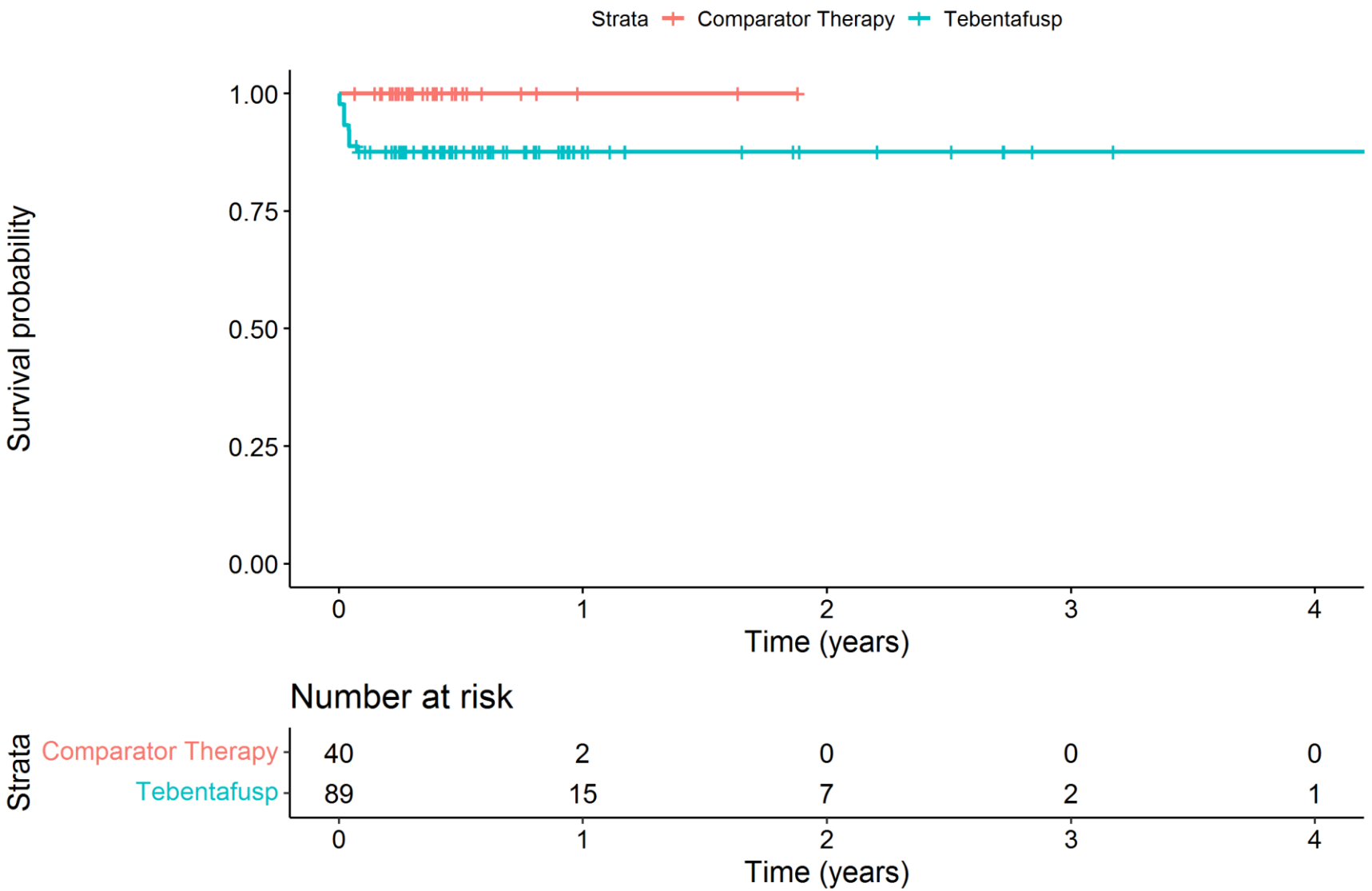
Erkrankungen der Haut und des Unterhautgewebes- Keine Vorherige Therapie adjuvant/neoadjuvant



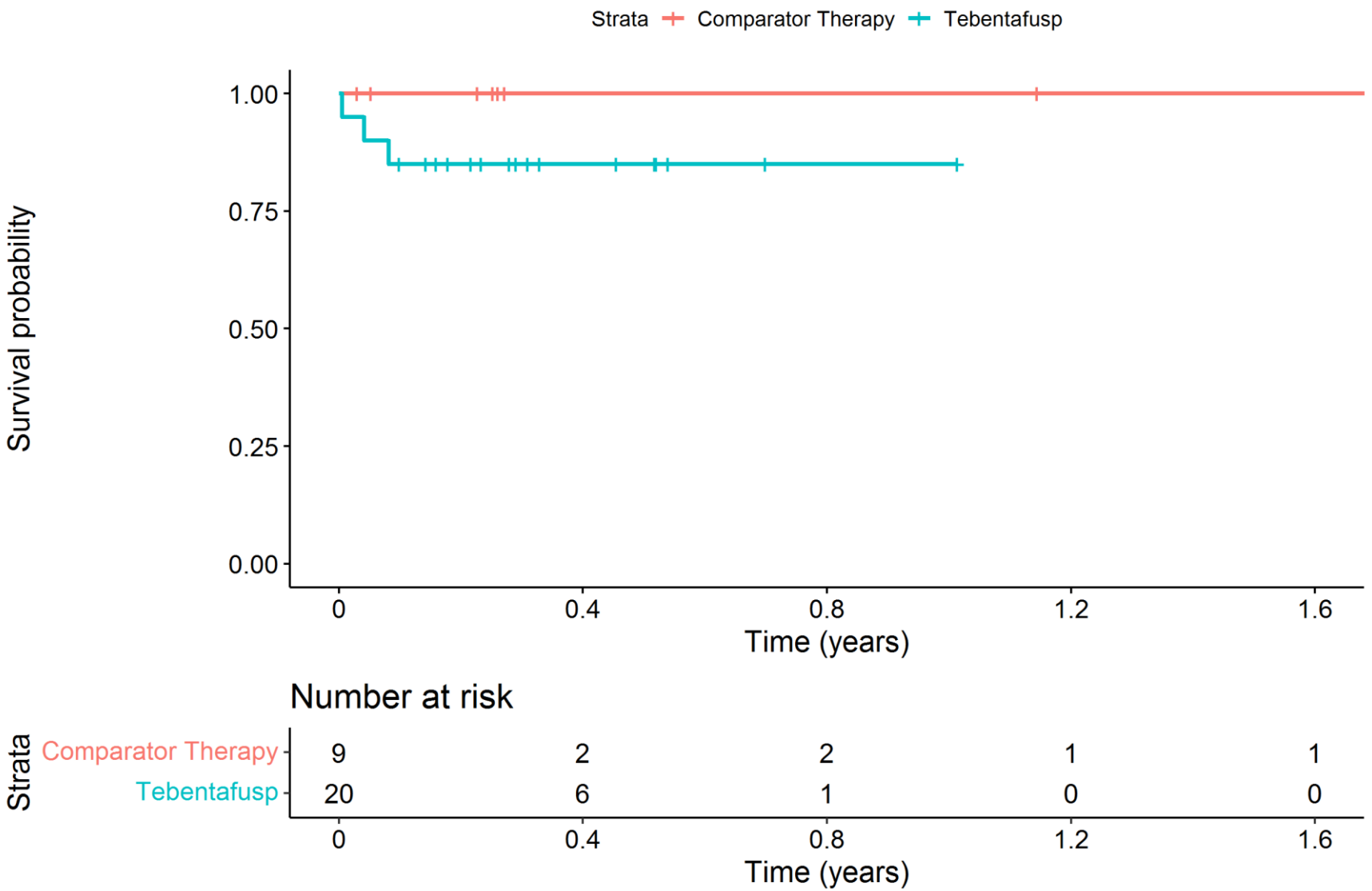
Erkrankungen der Haut und des Unterhautgewebes- Läsion ≤ 3cm



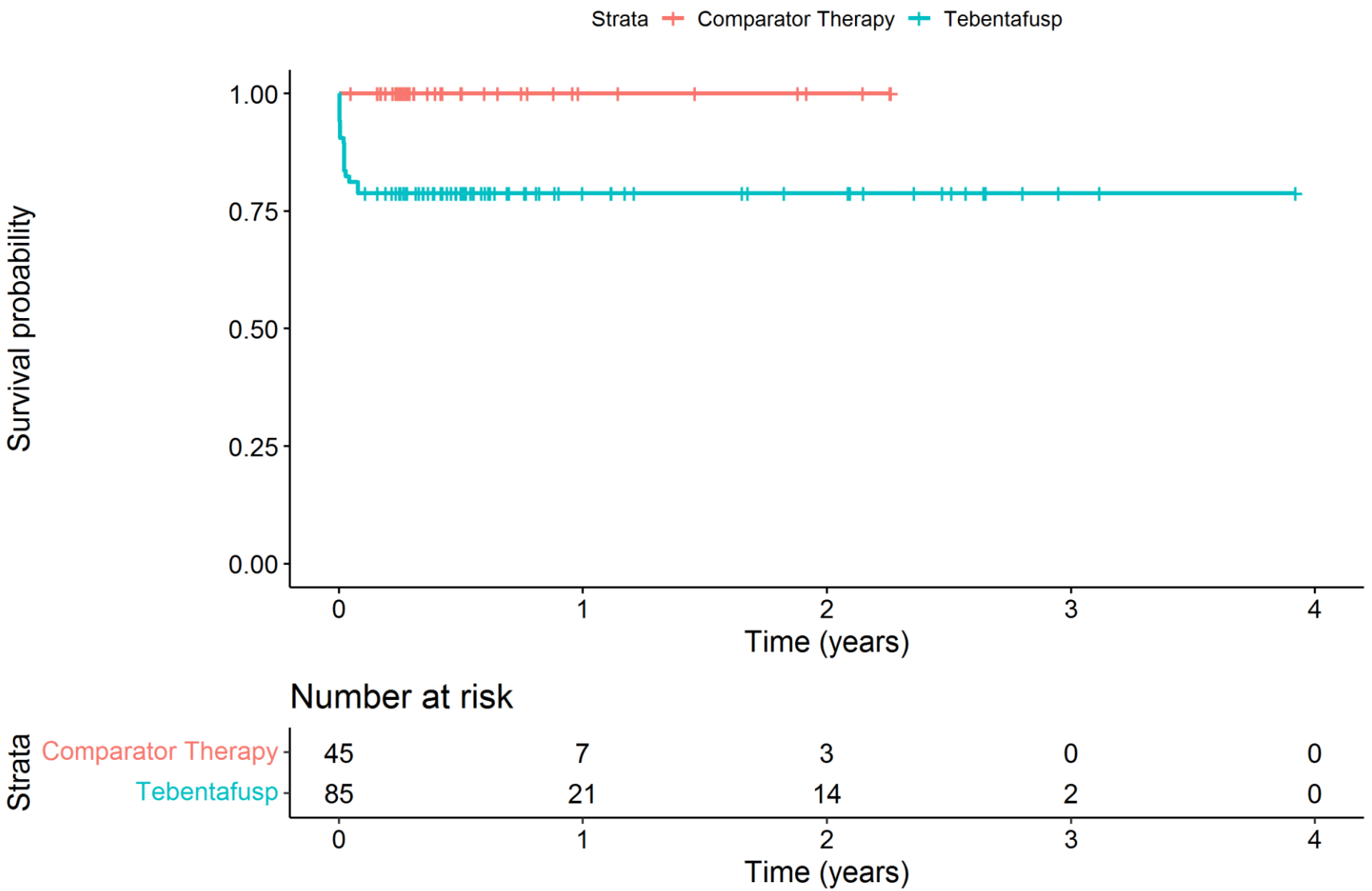
Erkrankungen der Haut und des Unterhautgewebes- Läsion 3,1-8,0 cm



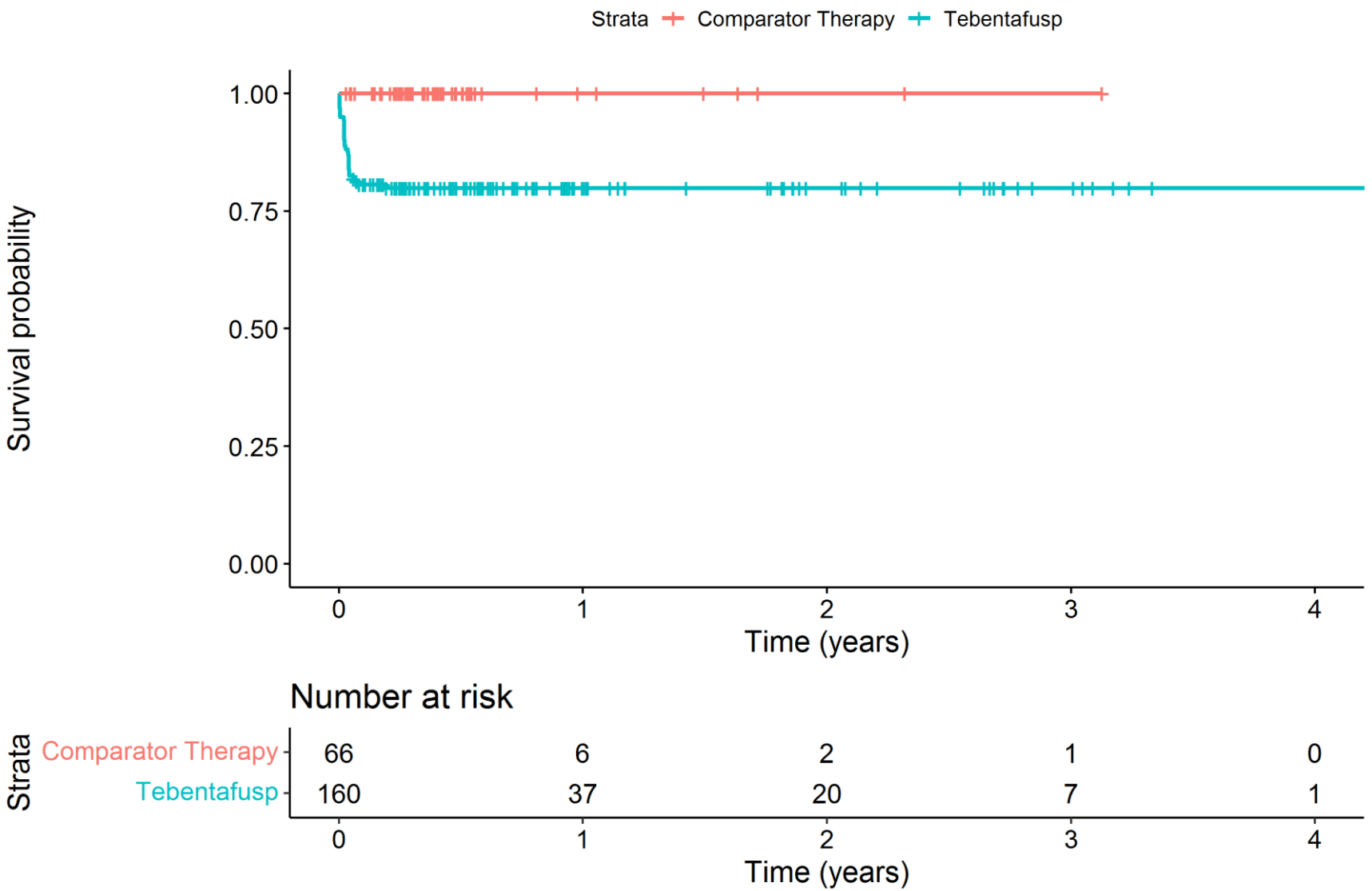
Erkrankungen der Haut und des Unterhautgewebes- Läsion ≥8,1 cm



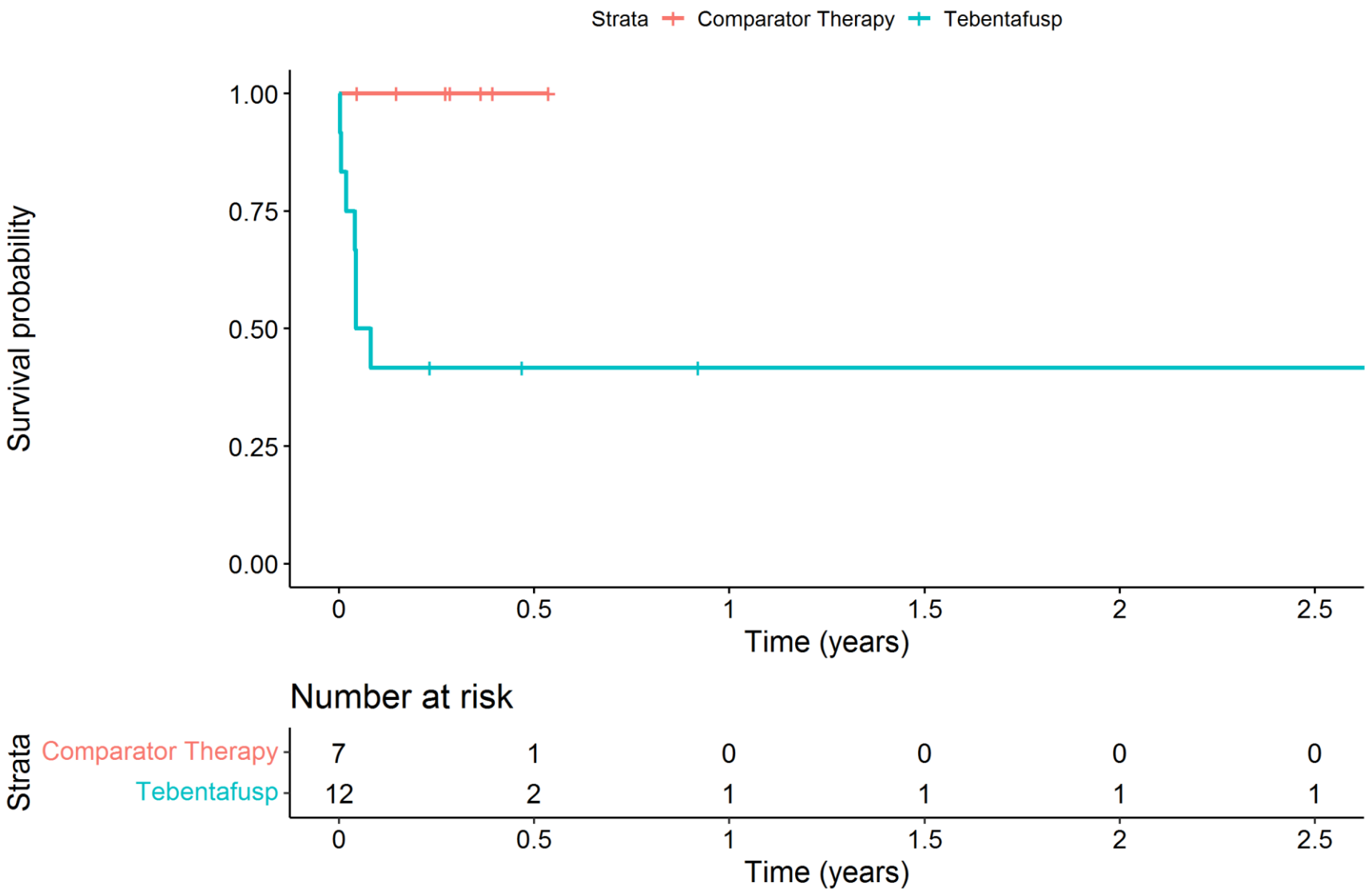
Erkrankungen der Haut und des Unterhautgewebes- Nordamerika



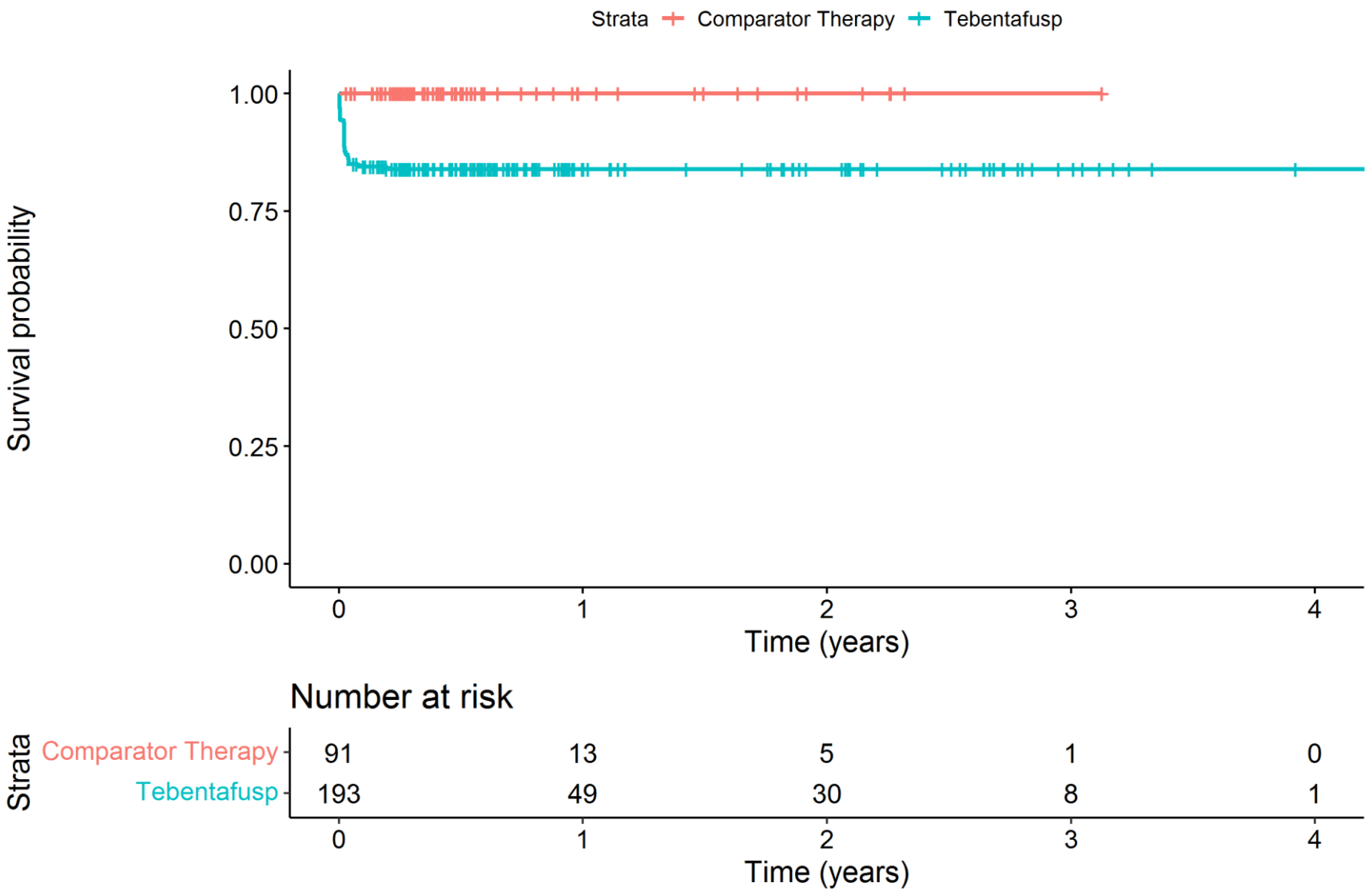
Erkrankungen der Haut und des Unterhautgewebes- Nicht-Nordamerika



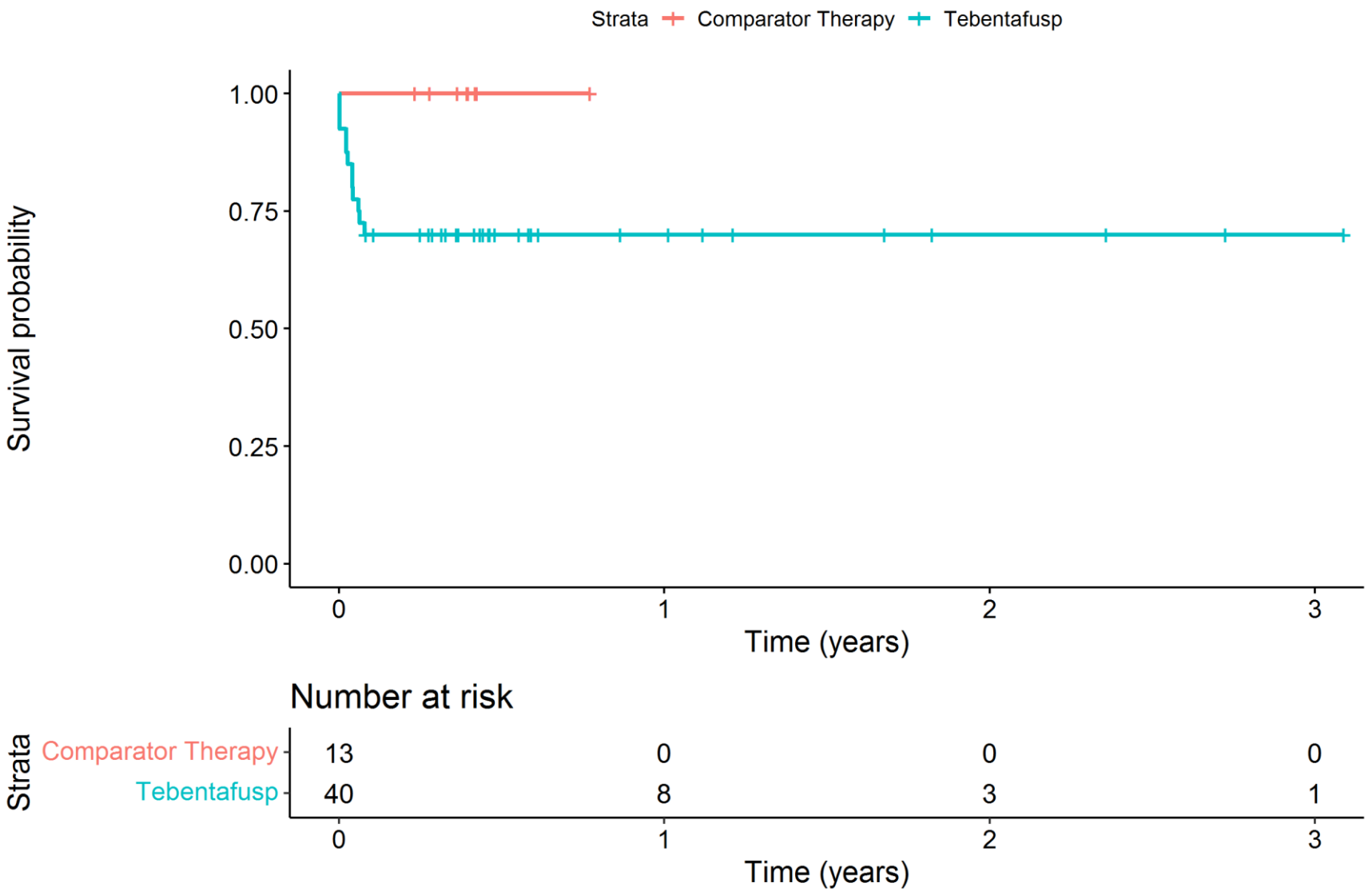
Erkrankungen der Haut und des Unterhautgewebes- Dacarbazin



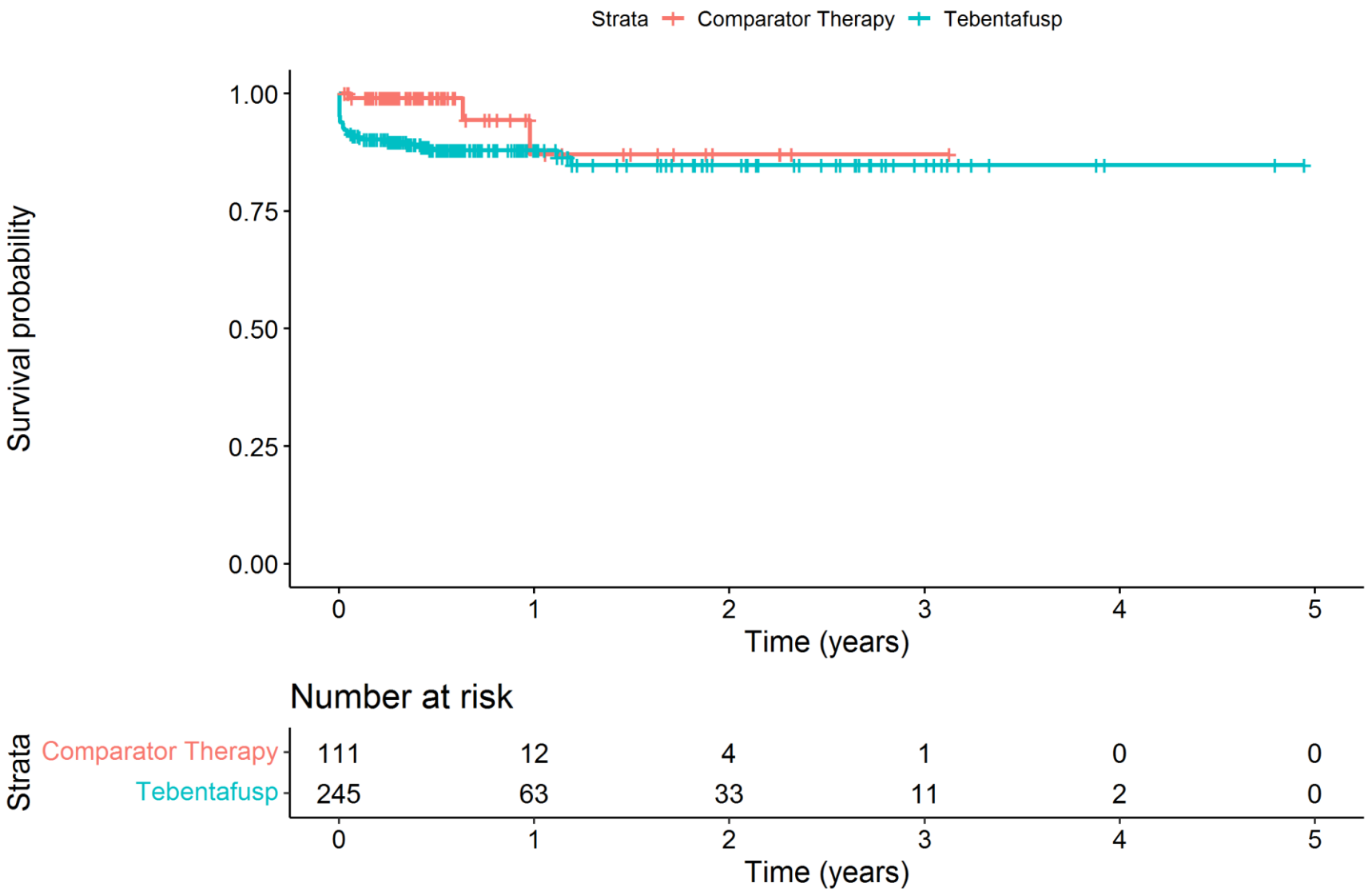
Erkrankungen der Haut und des Unterhautgewebes- Pembrolizumab



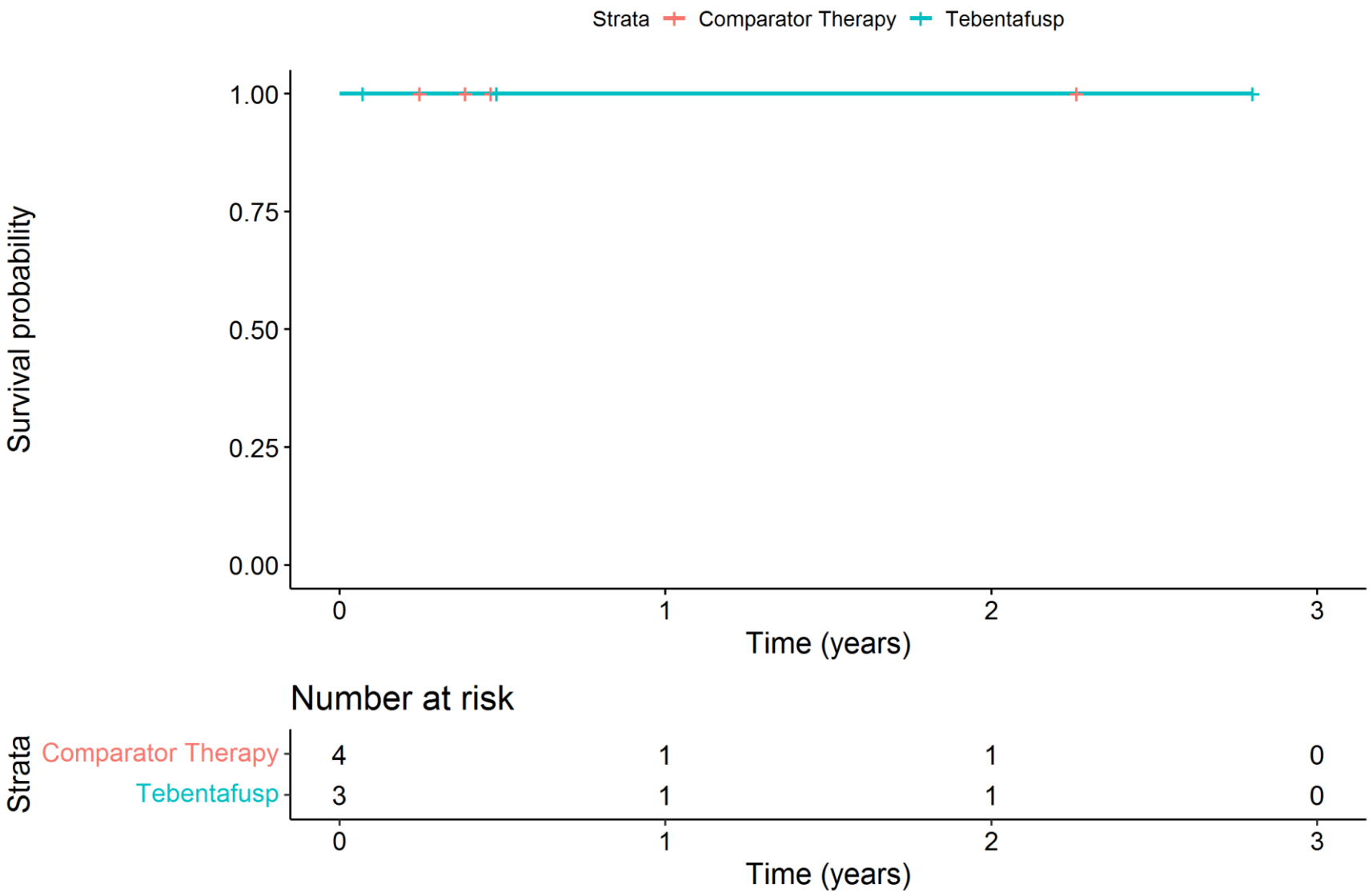
Erkrankungen der Haut und des Unterhautgewebes- Ipilimumab



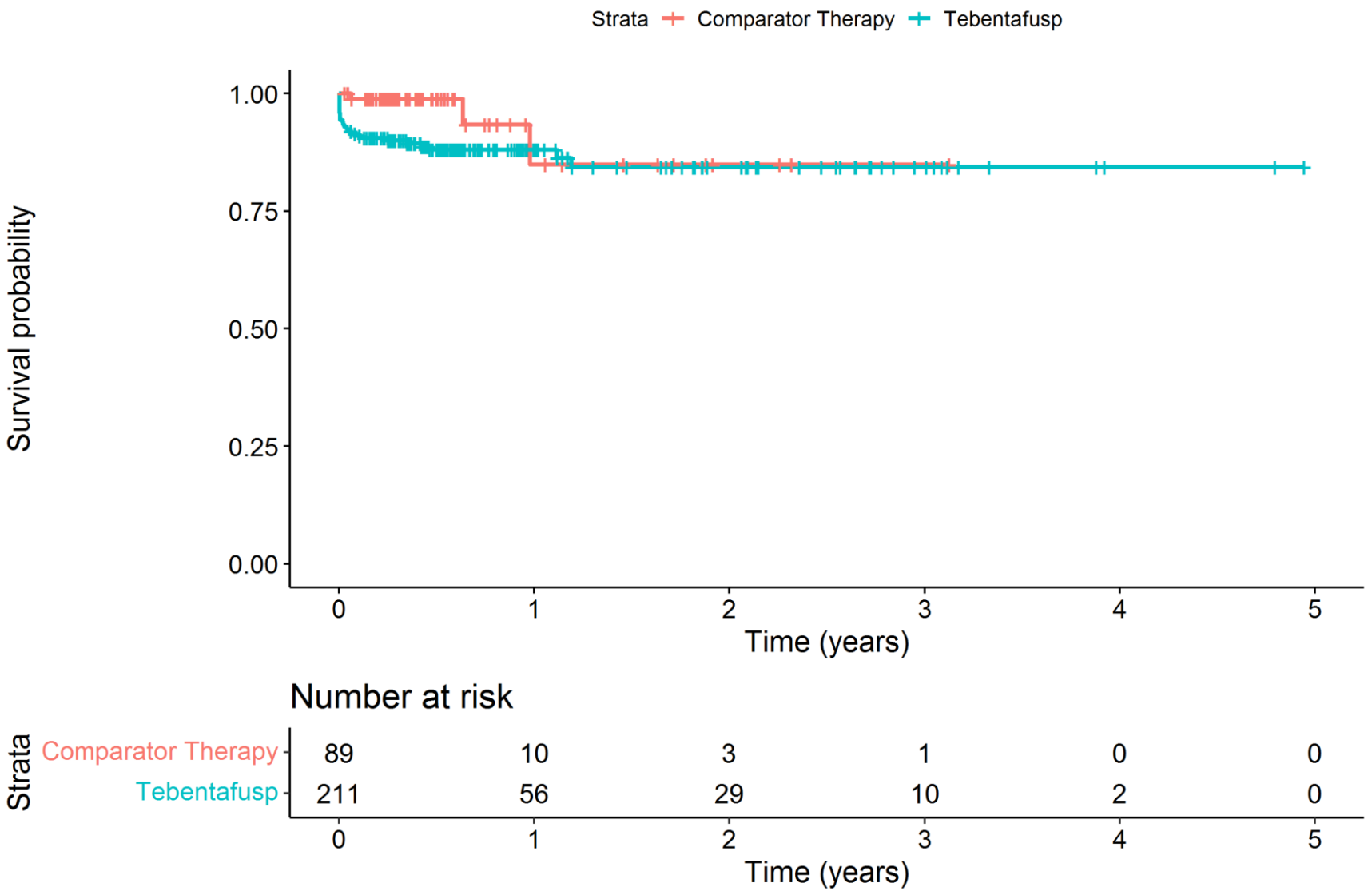
Gefäßerkrankungen- Gesamt



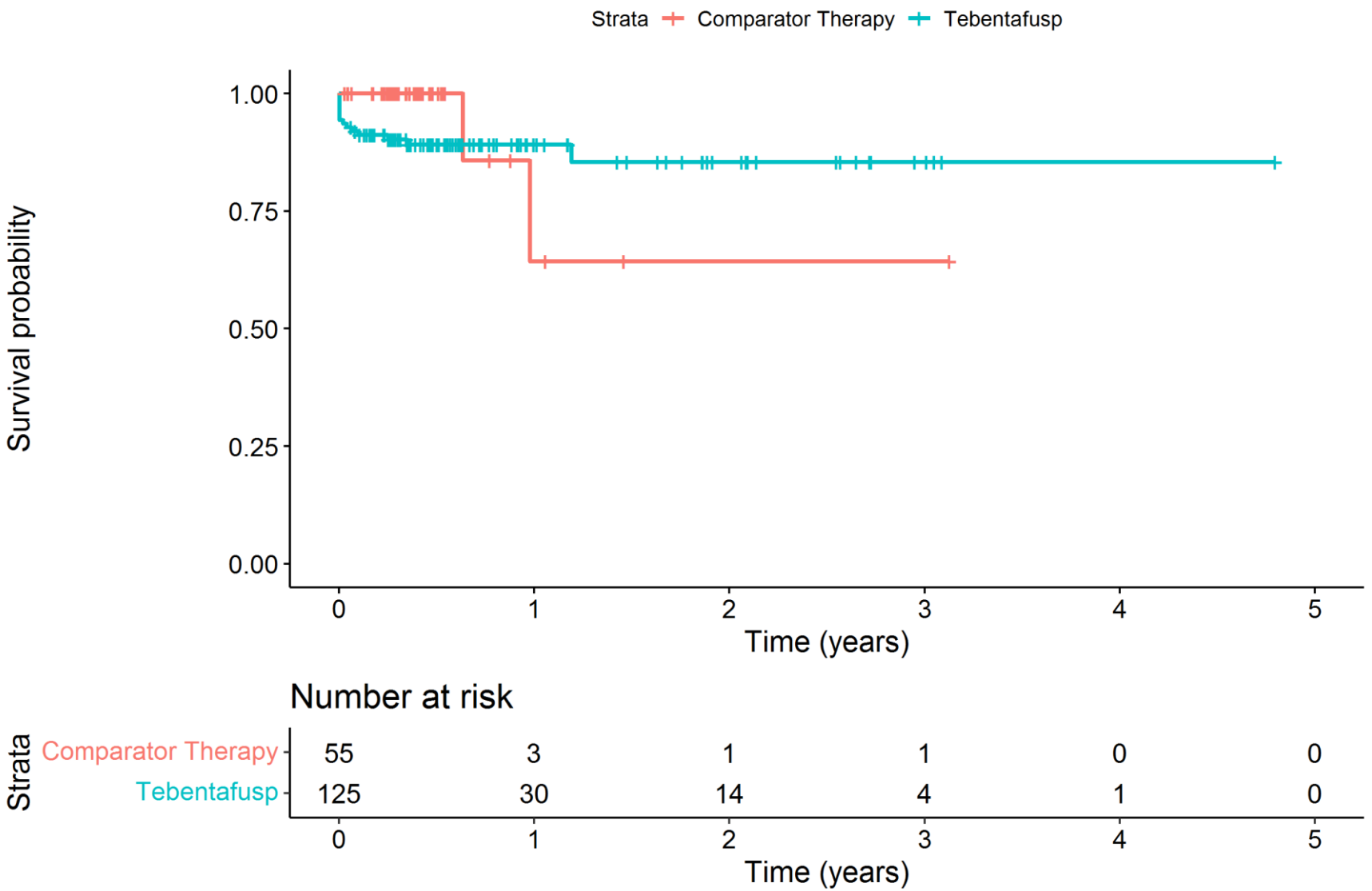
Gefäßerkrankungen- Hispanisch



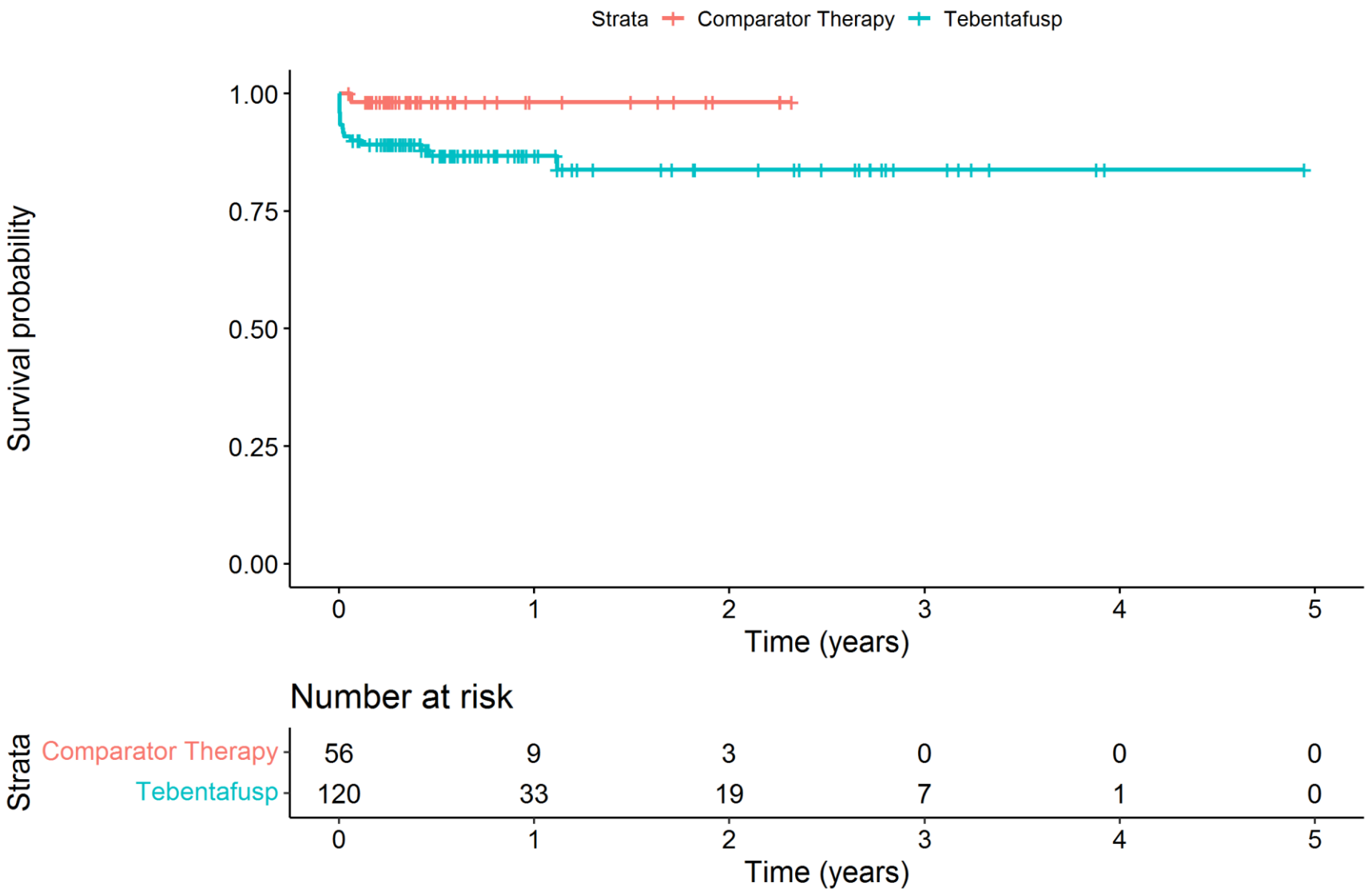
Gefäßerkrankungen- Nicht-hispanisch



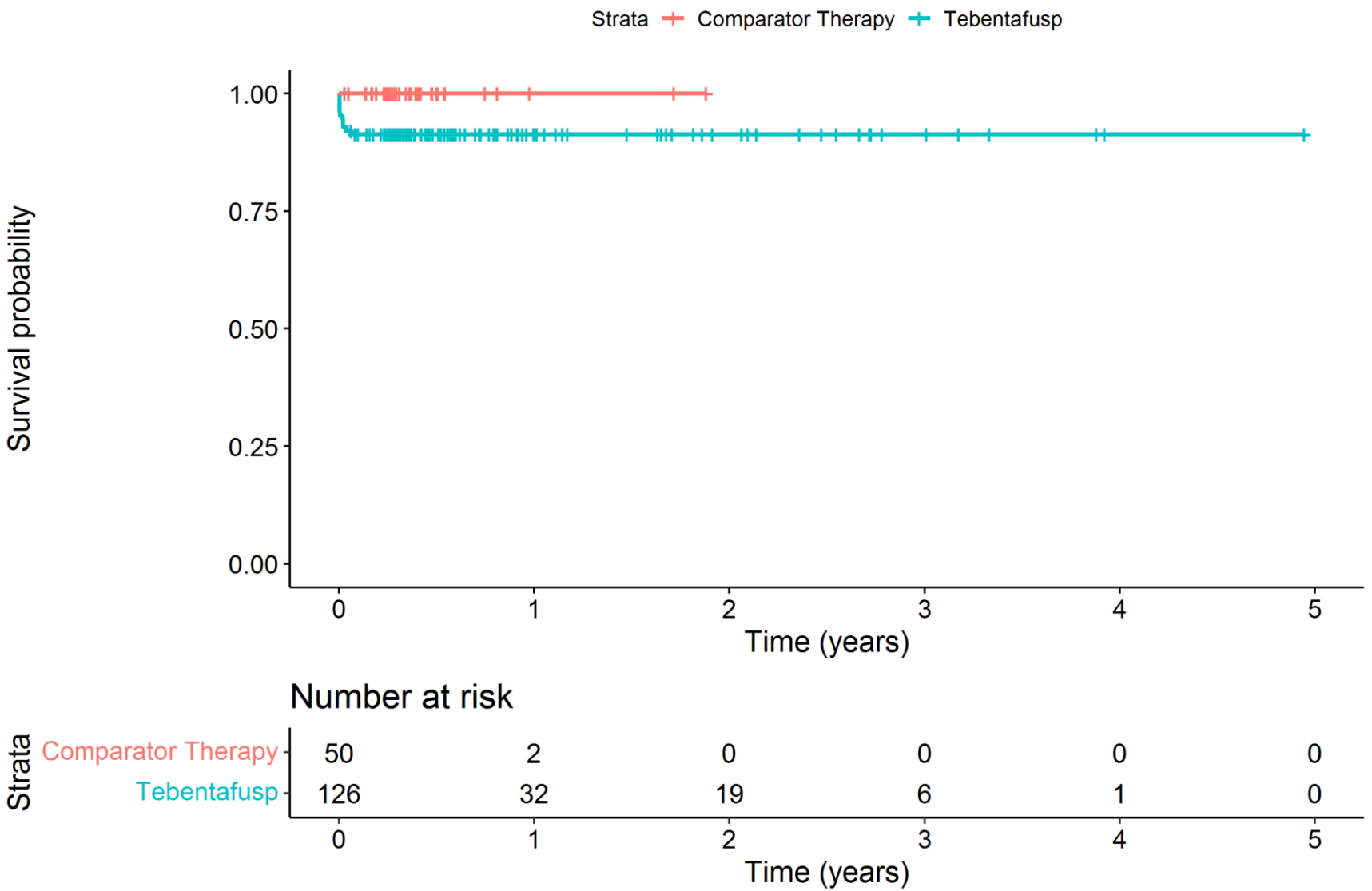
Gefäßerkrankungen- Männlich



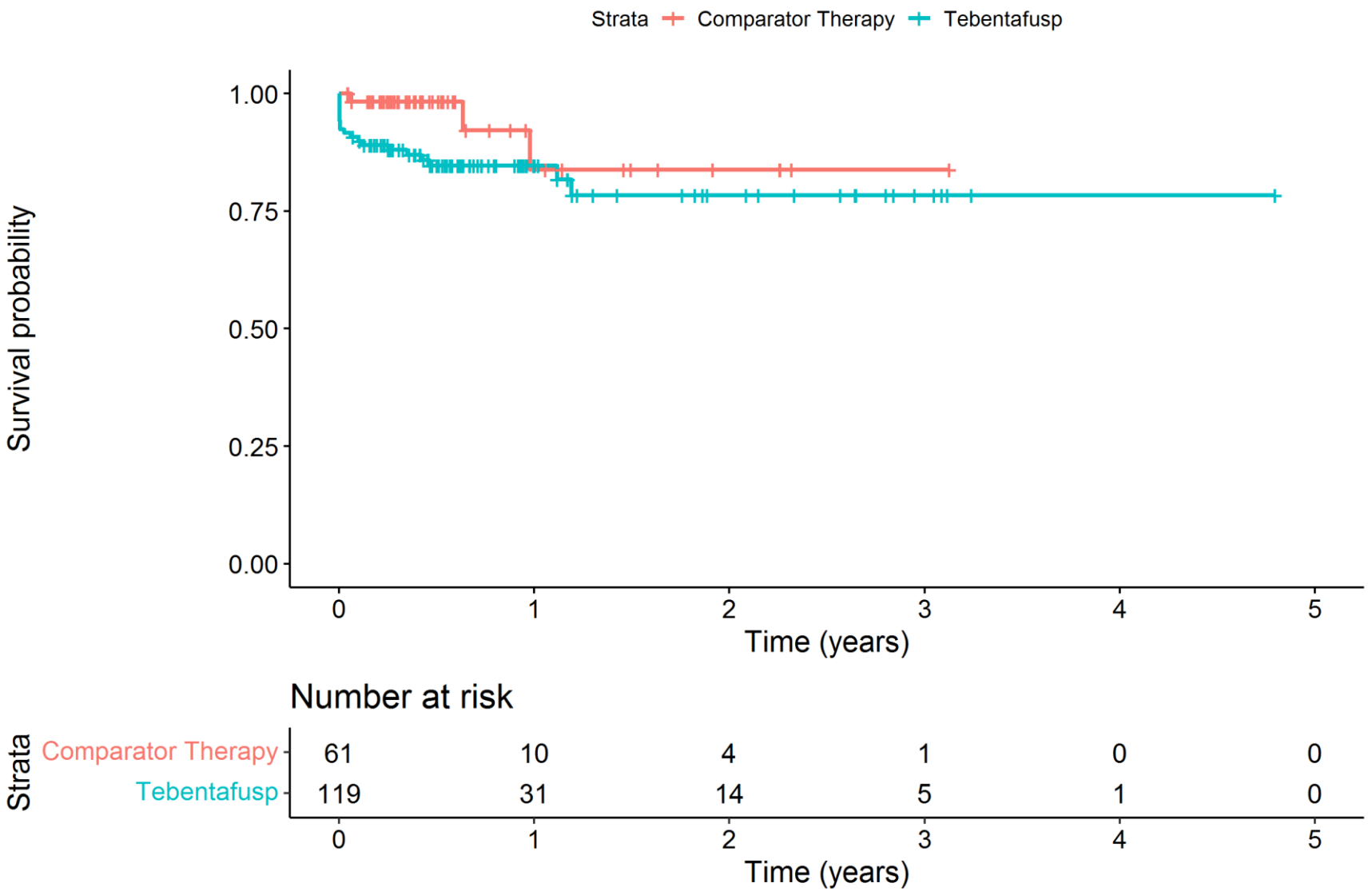
Gefäßerkrankungen- Weiblich



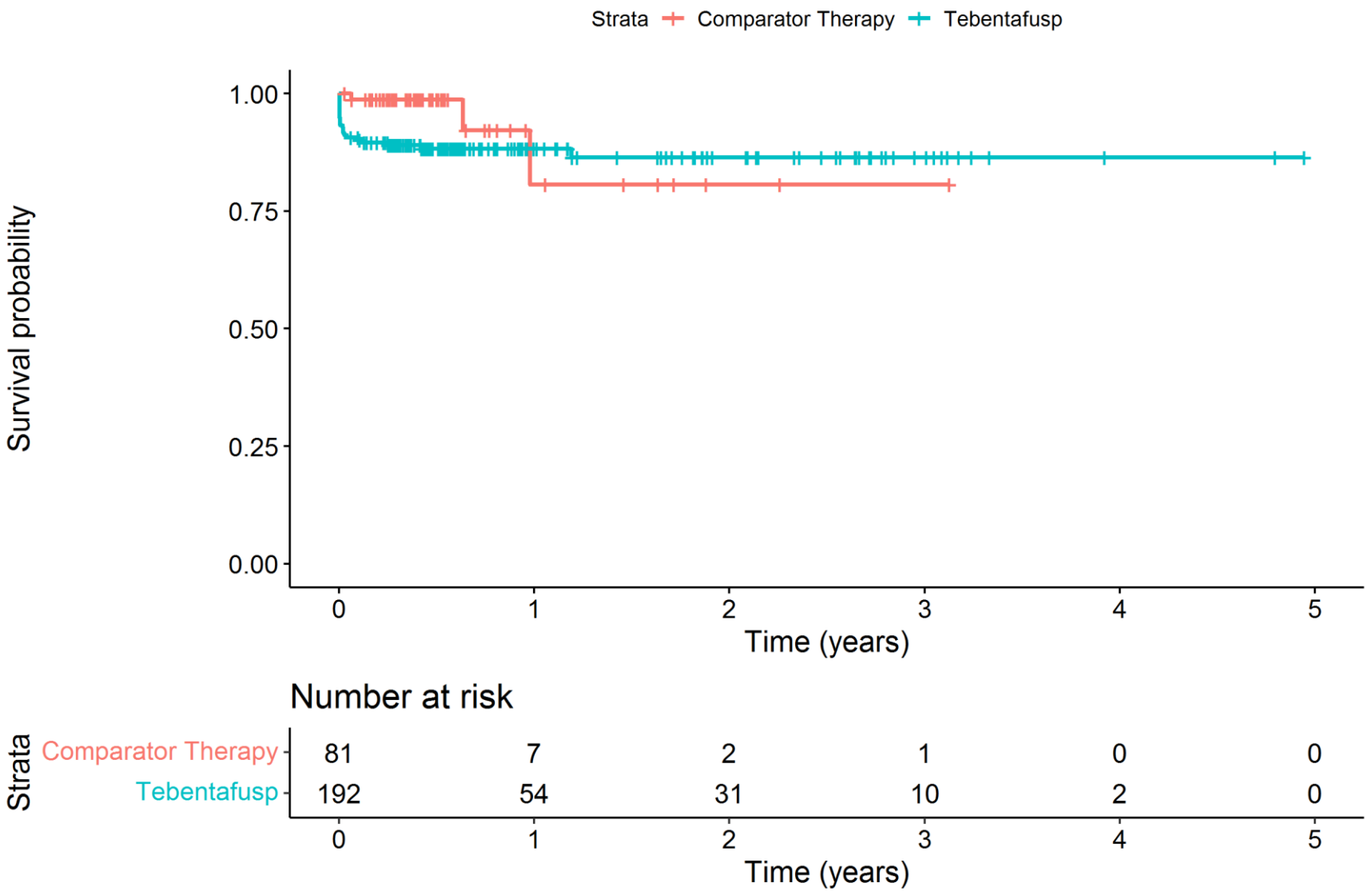
Gefäßerkrankungen- <65



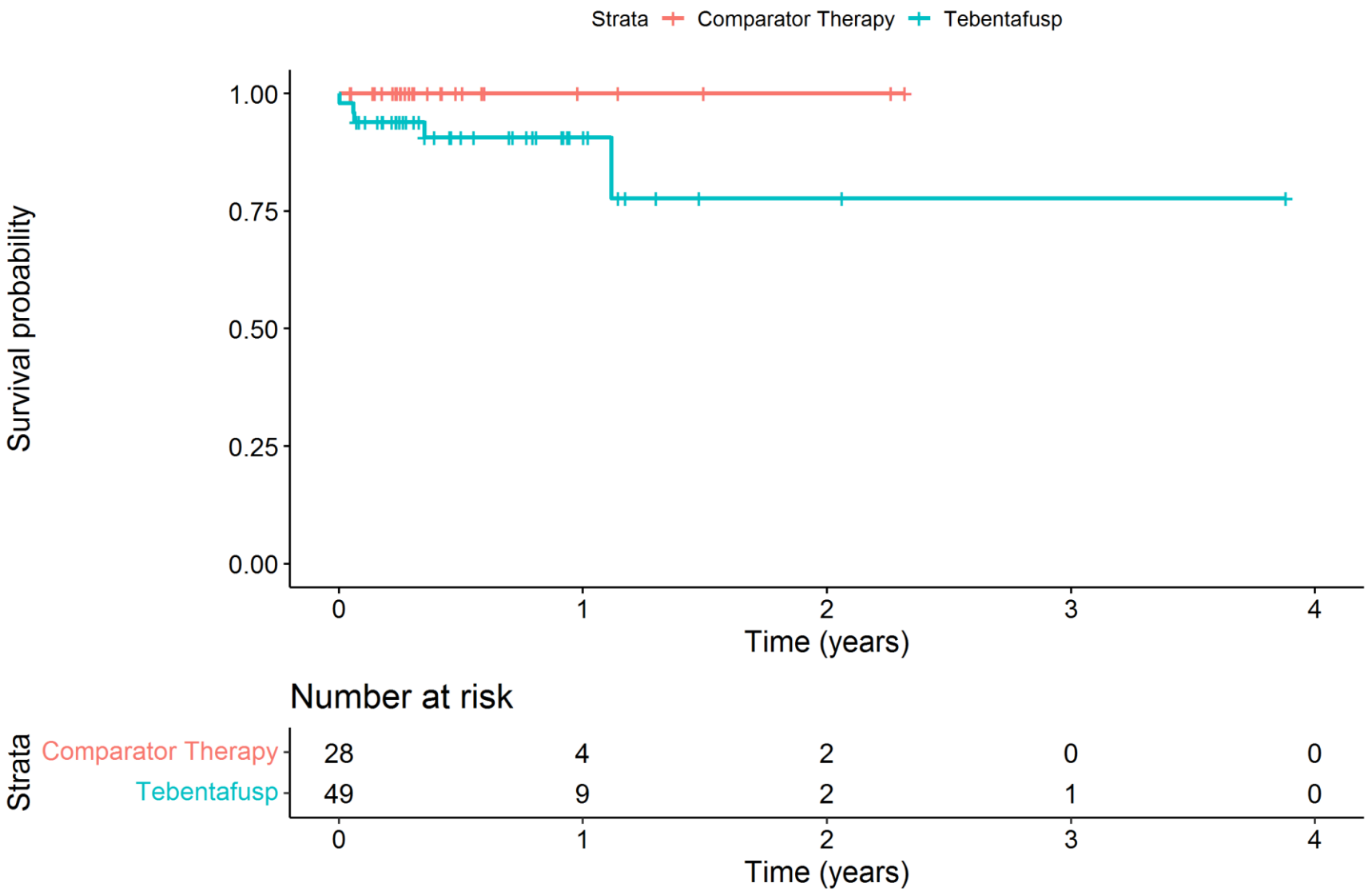
Gefäßerkrankungen- ≥65



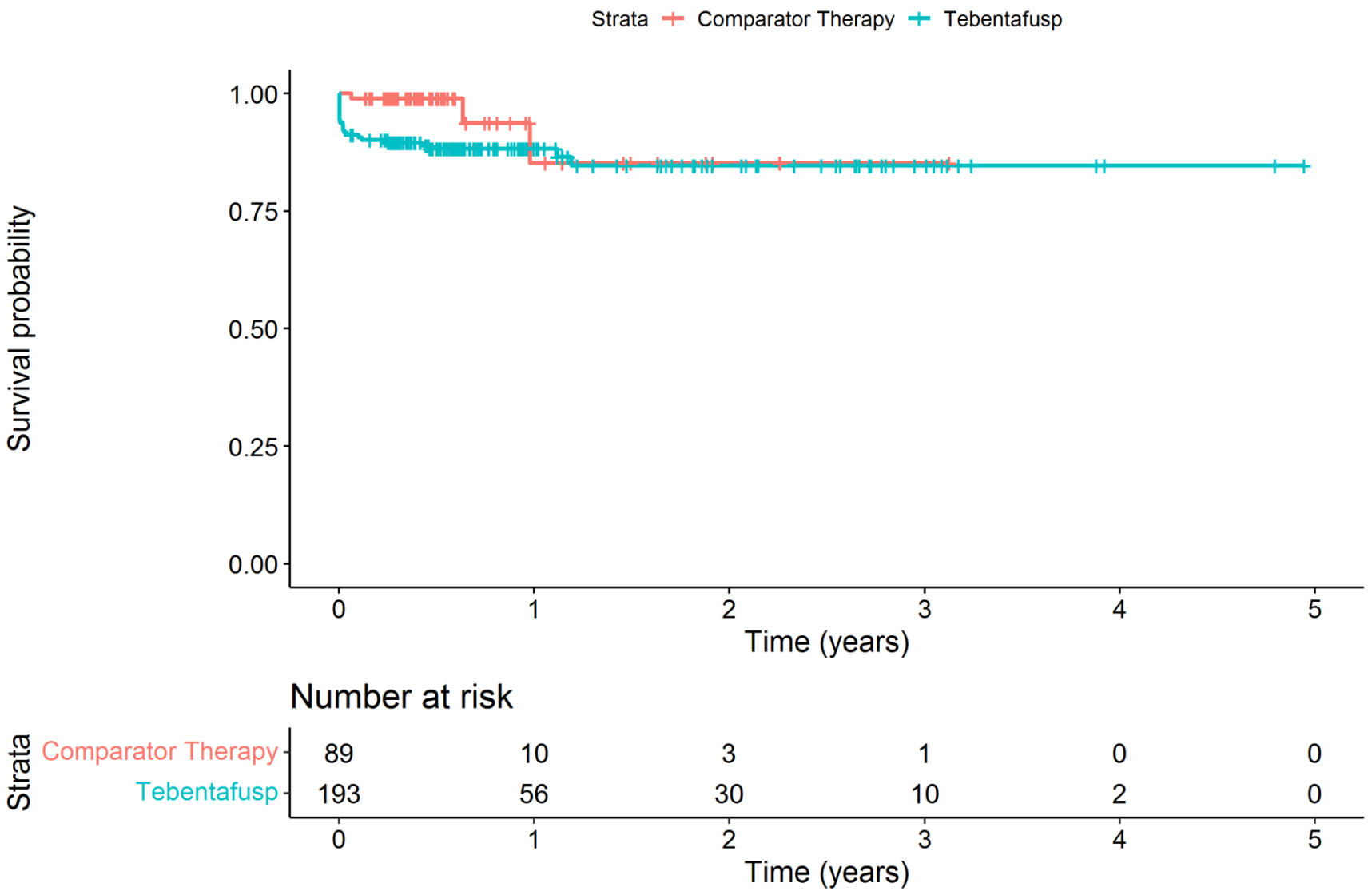
Gefäßerkrankungen- ECOG 0



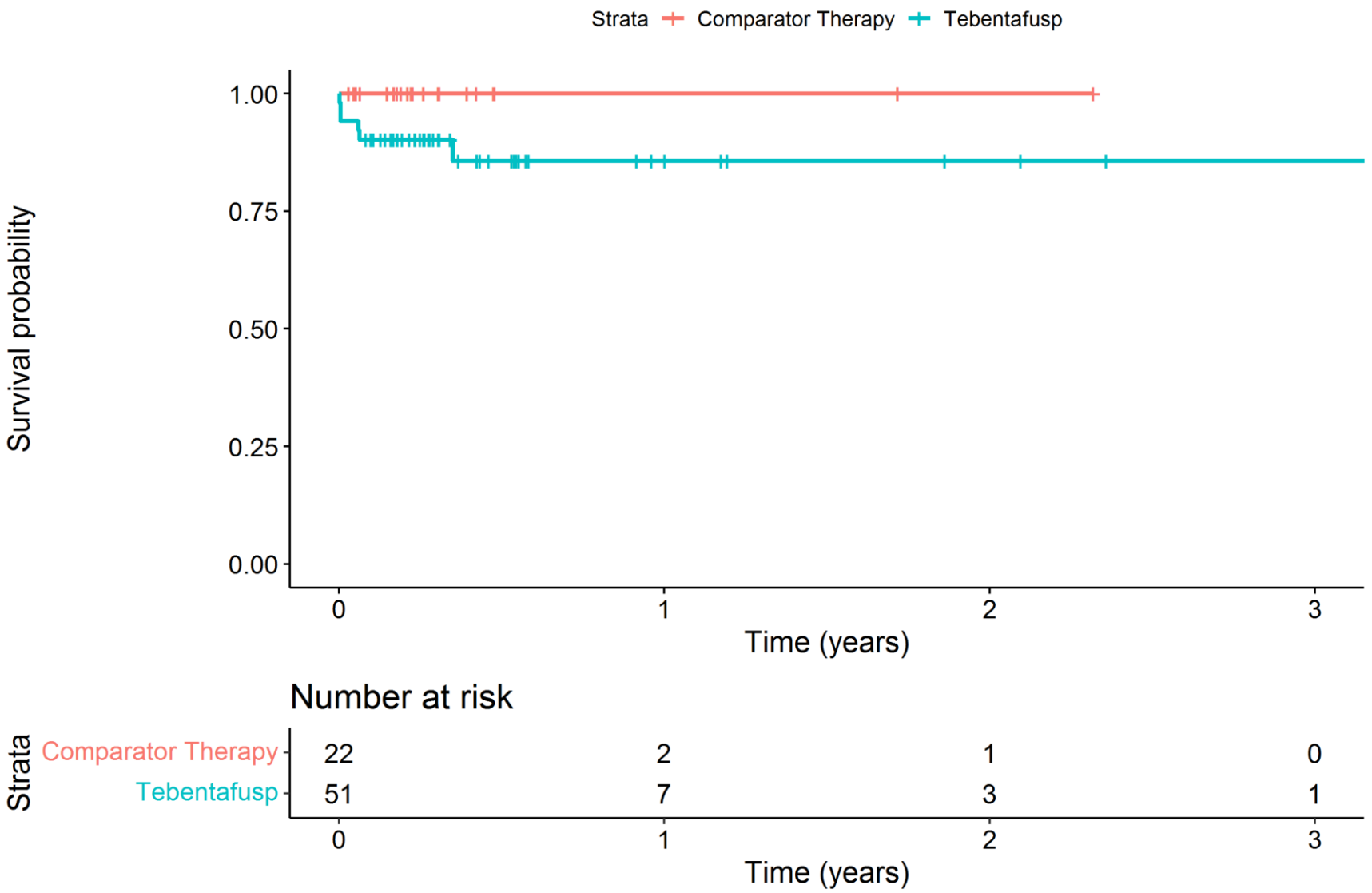
Gefäßerkrankungen- ECOG 1



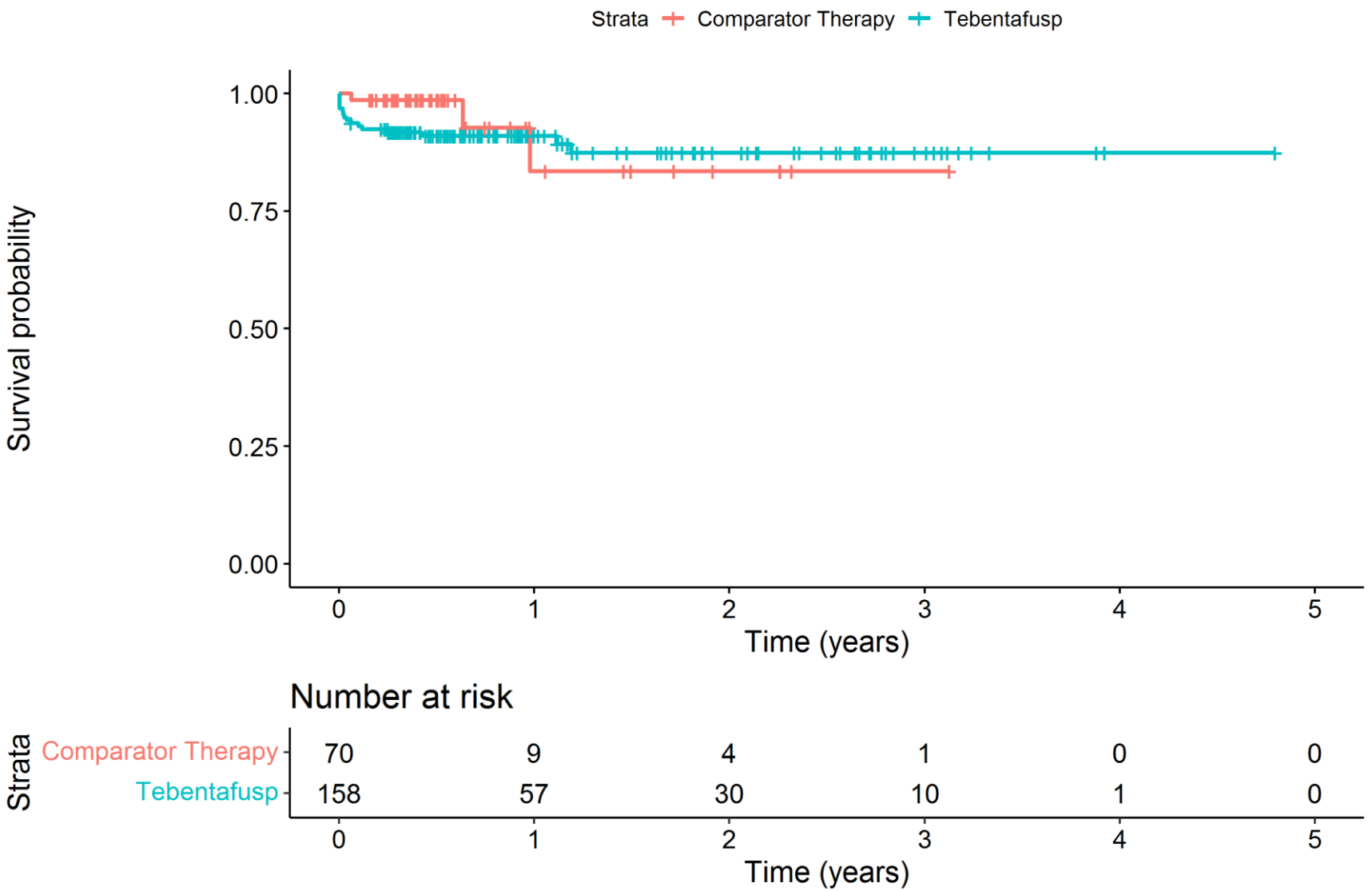
Gefäßerkrankungen- ALP ≤ ULN



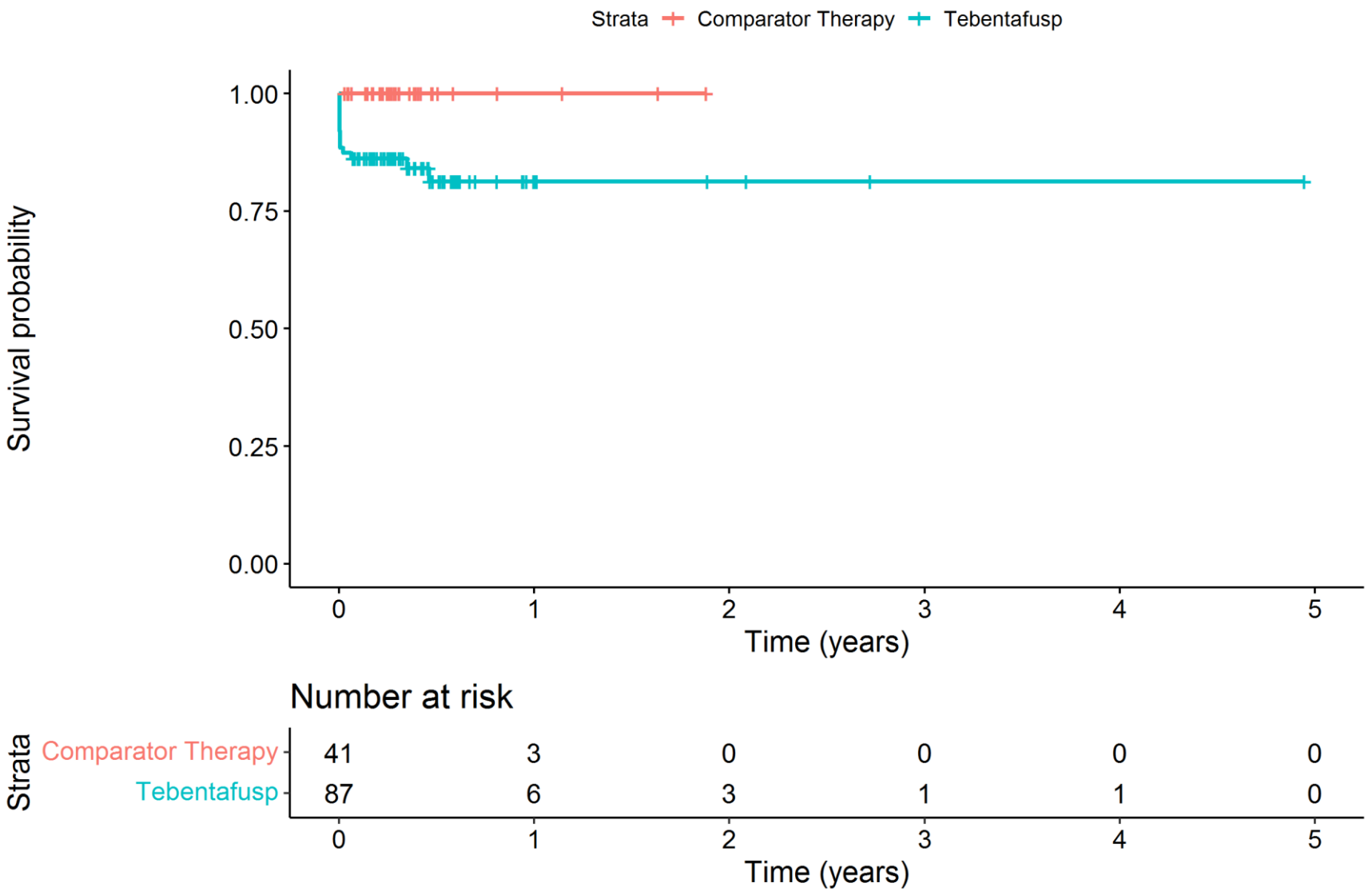
Gefäßerkrankungen- ALP > ULN



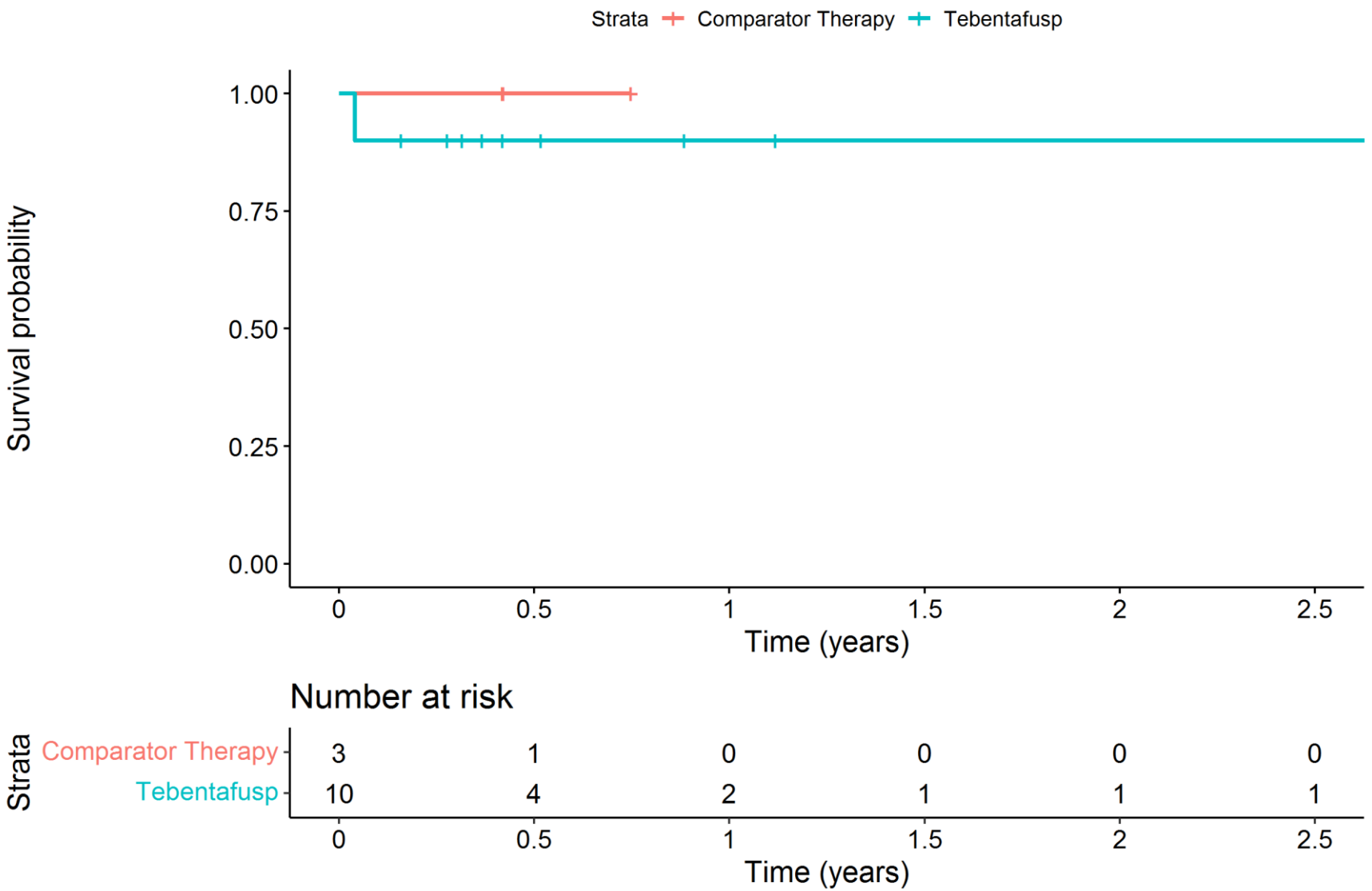
Gefäßerkrankungen- LDH =< ULN



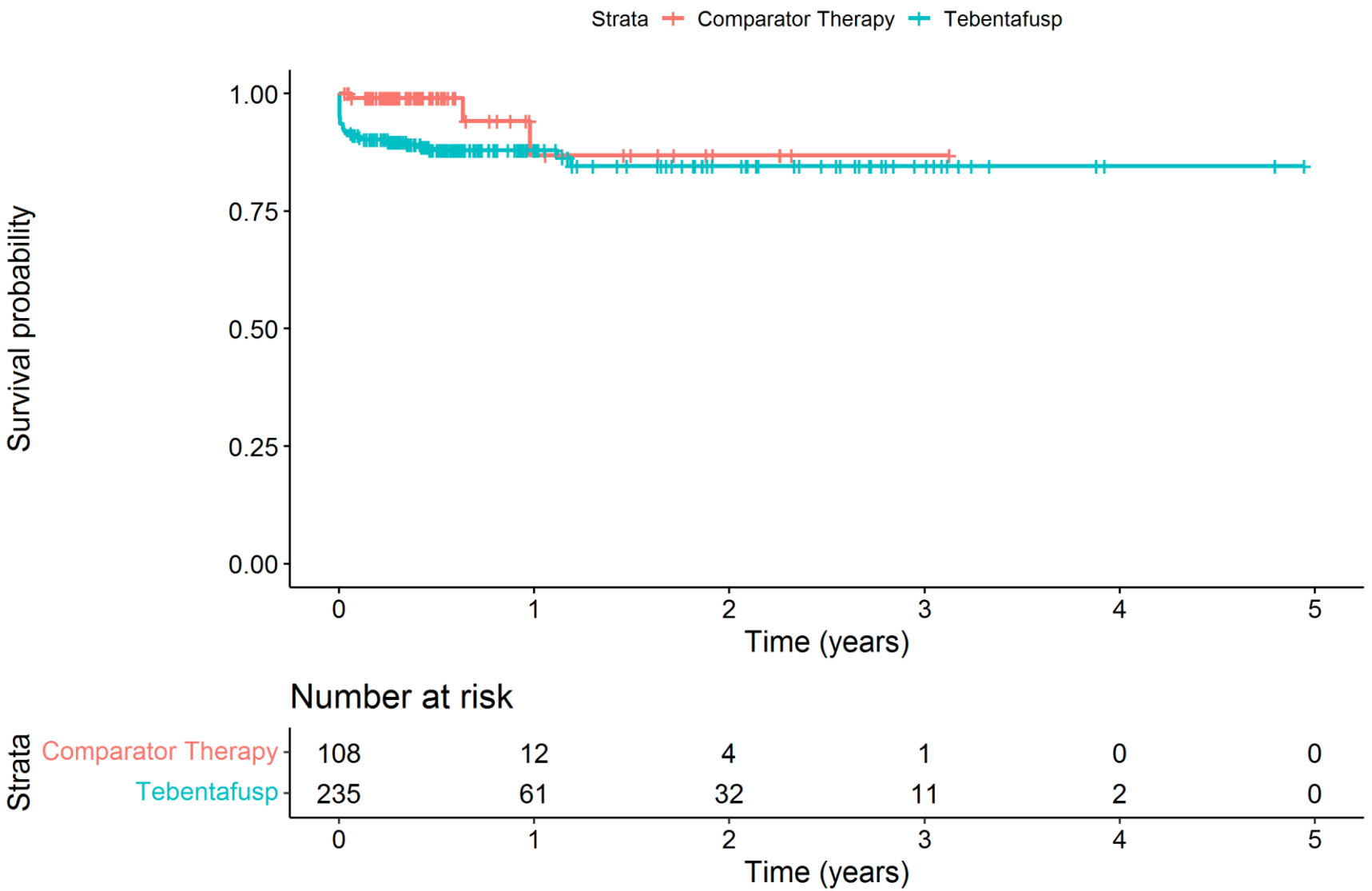
Gefäßerkrankungen- LDH > ULN



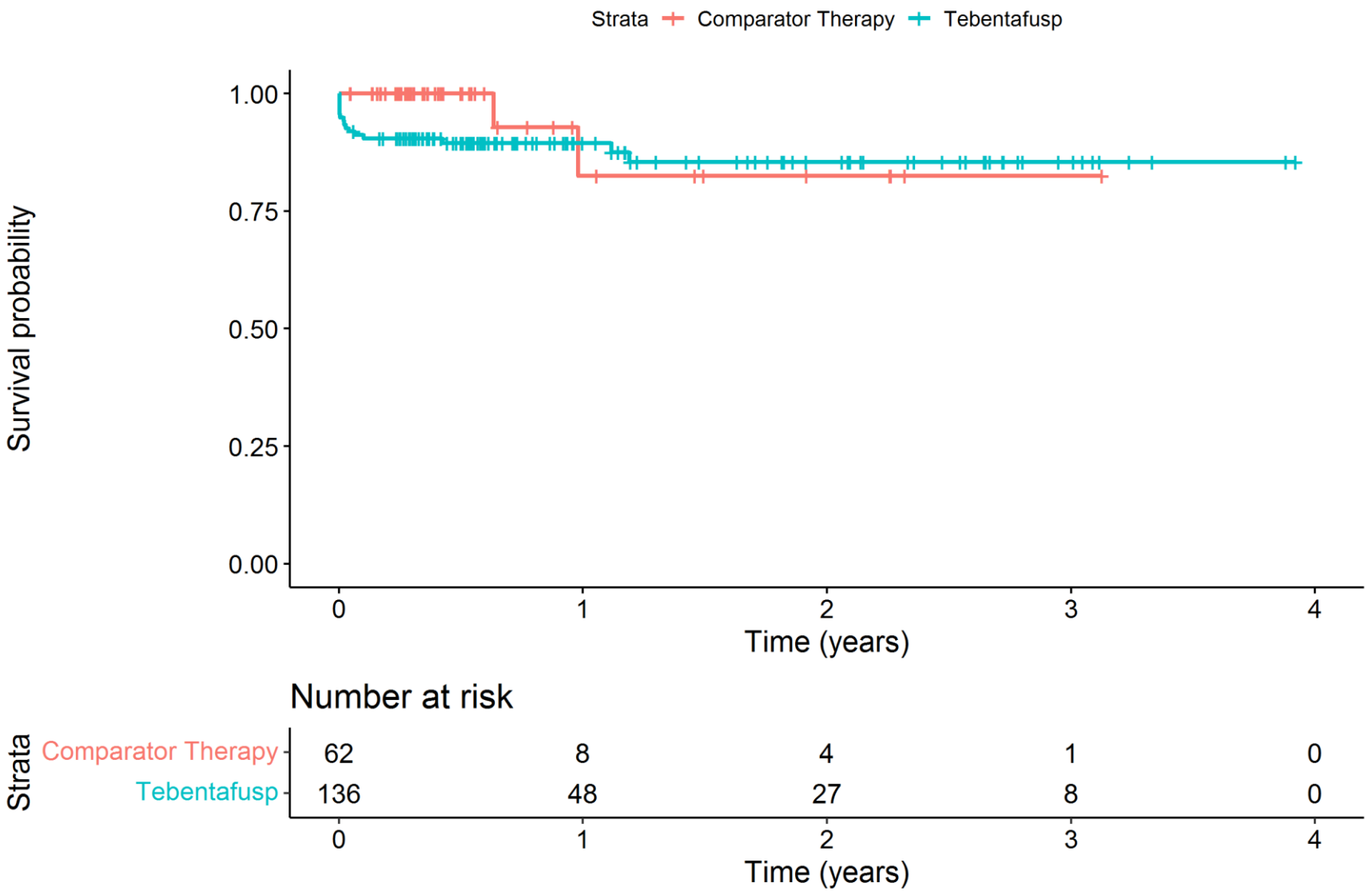
Gefäßerkrankungen- Vorherige Therapie adjuvant/neoadjuvant



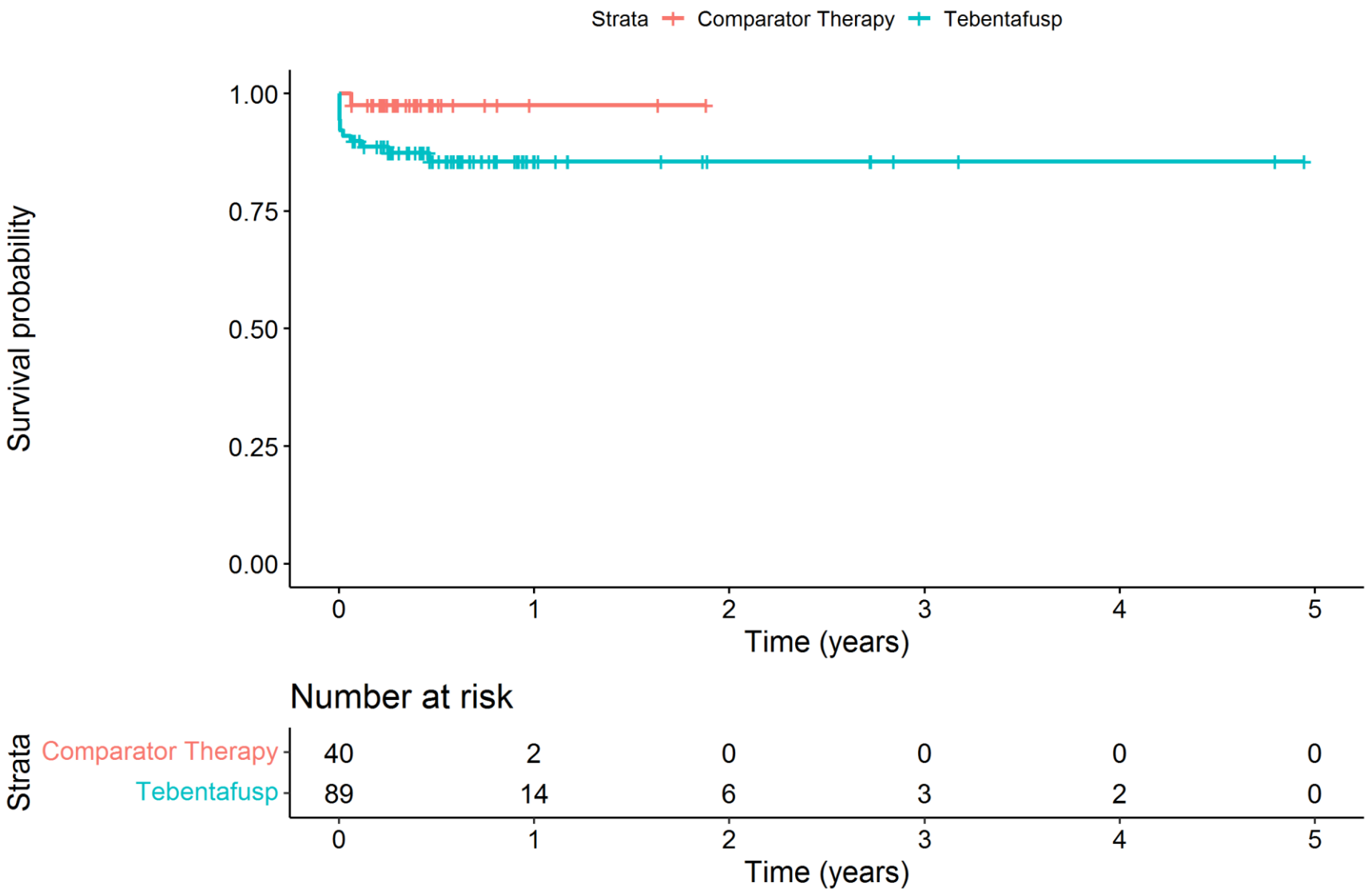
Gefäßerkrankungen- Keine Vorherige Therapie adjuvant/neoadjuvant



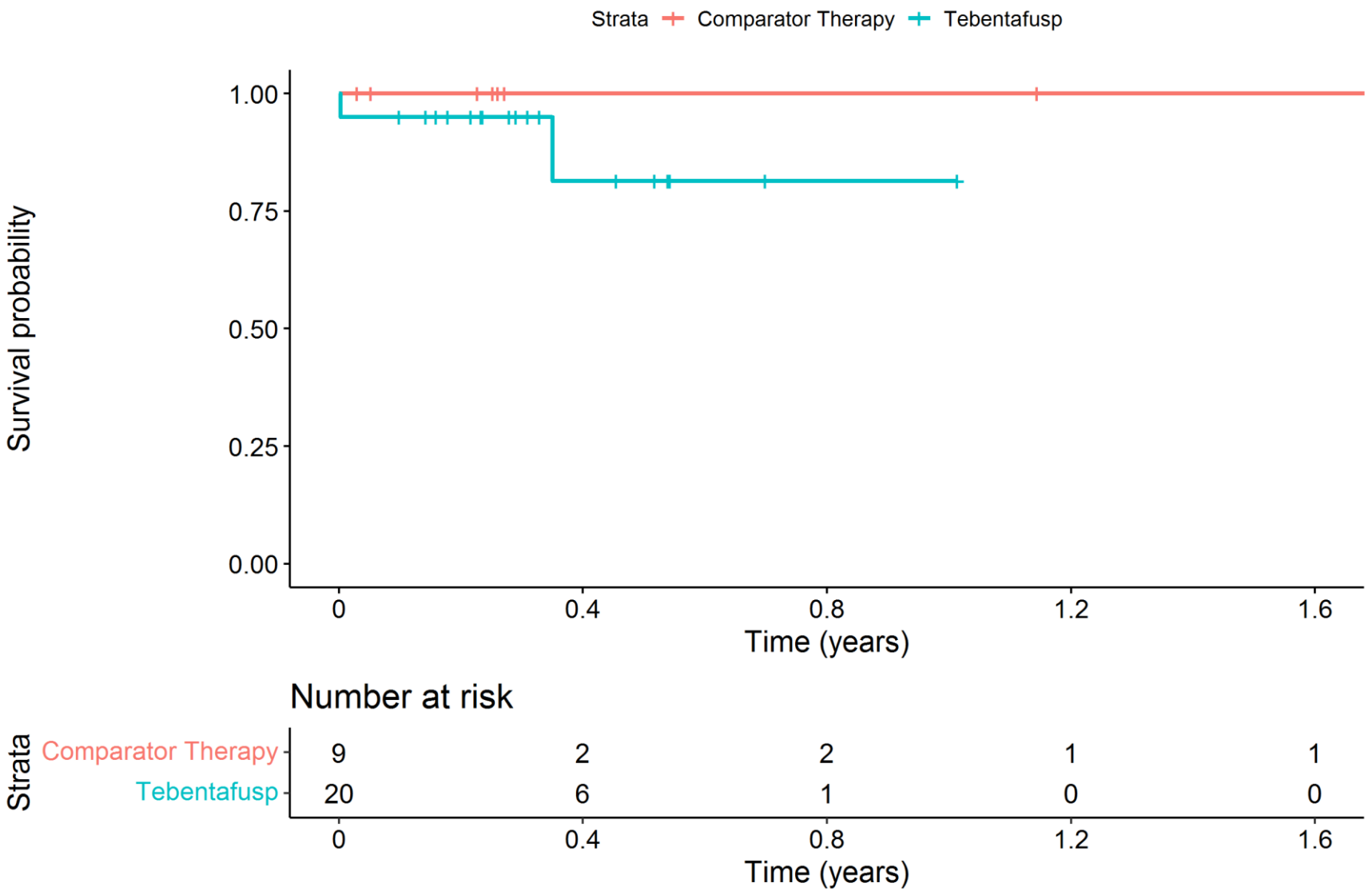
Gefäßerkrankungen- Läsion ≤ 3cm



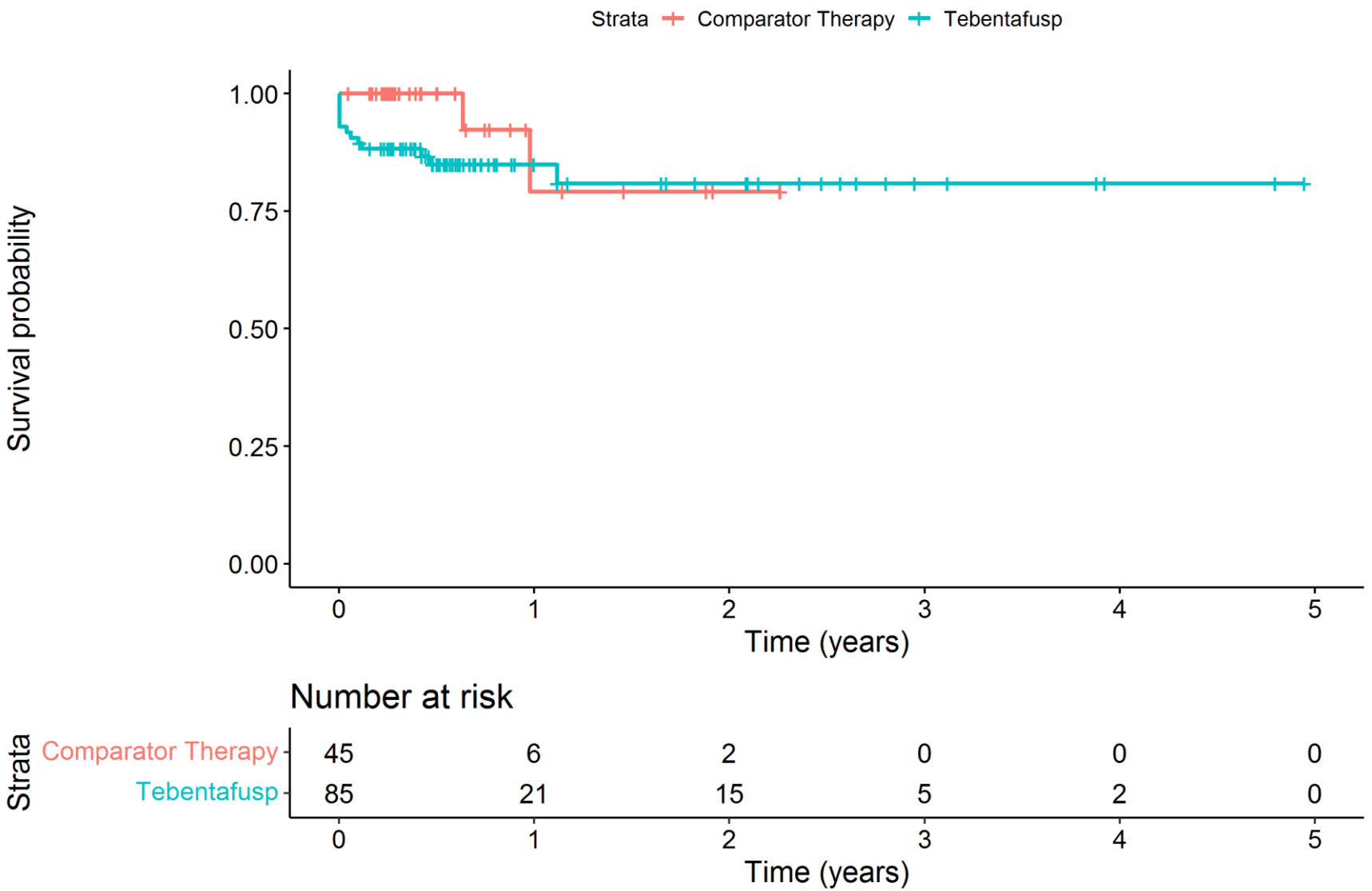
Gefäßerkrankungen- Läsion 3,1-8,0 cm



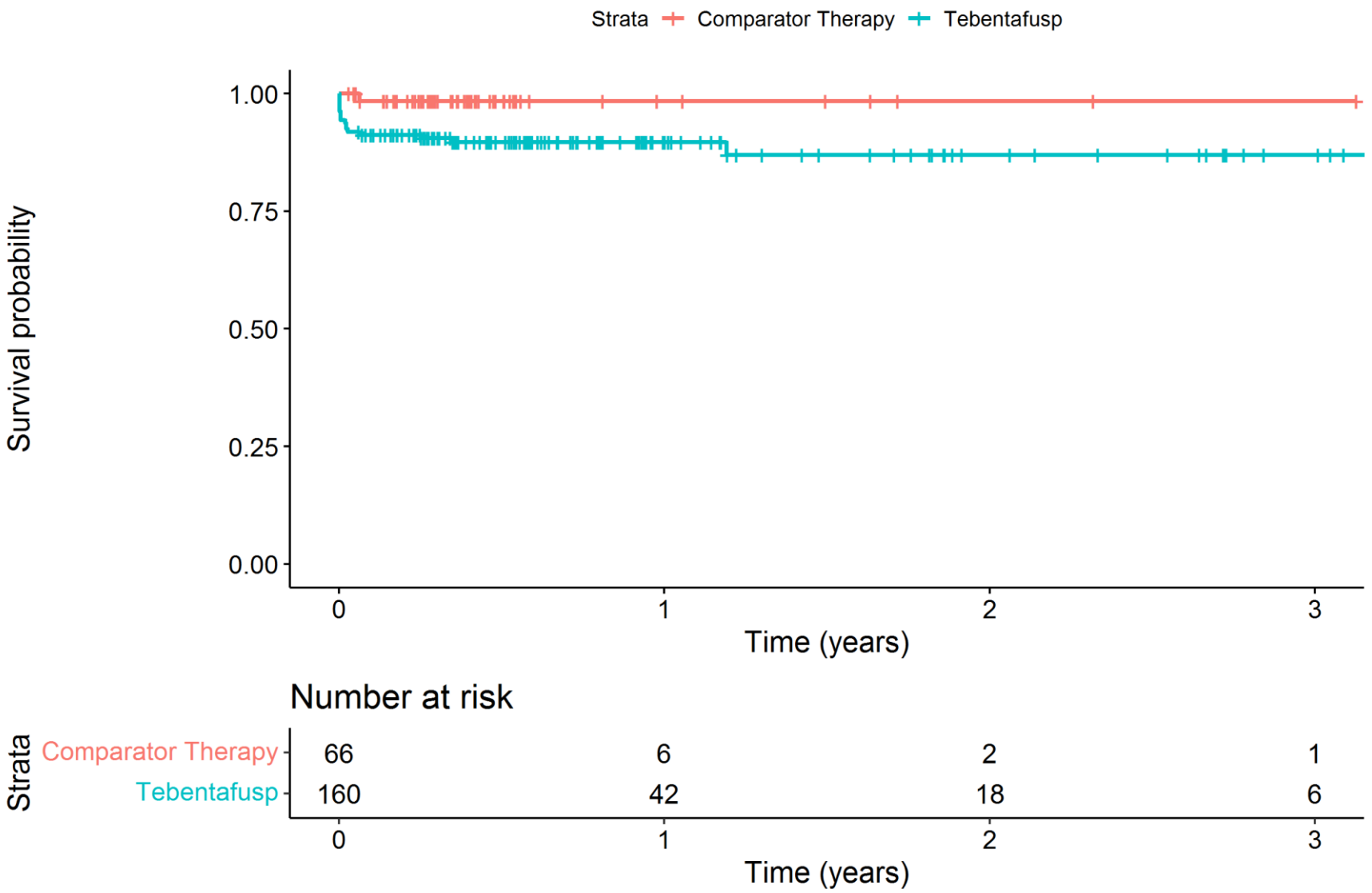
Gefäßerkrankungen- Läsion ≥8,1 cm



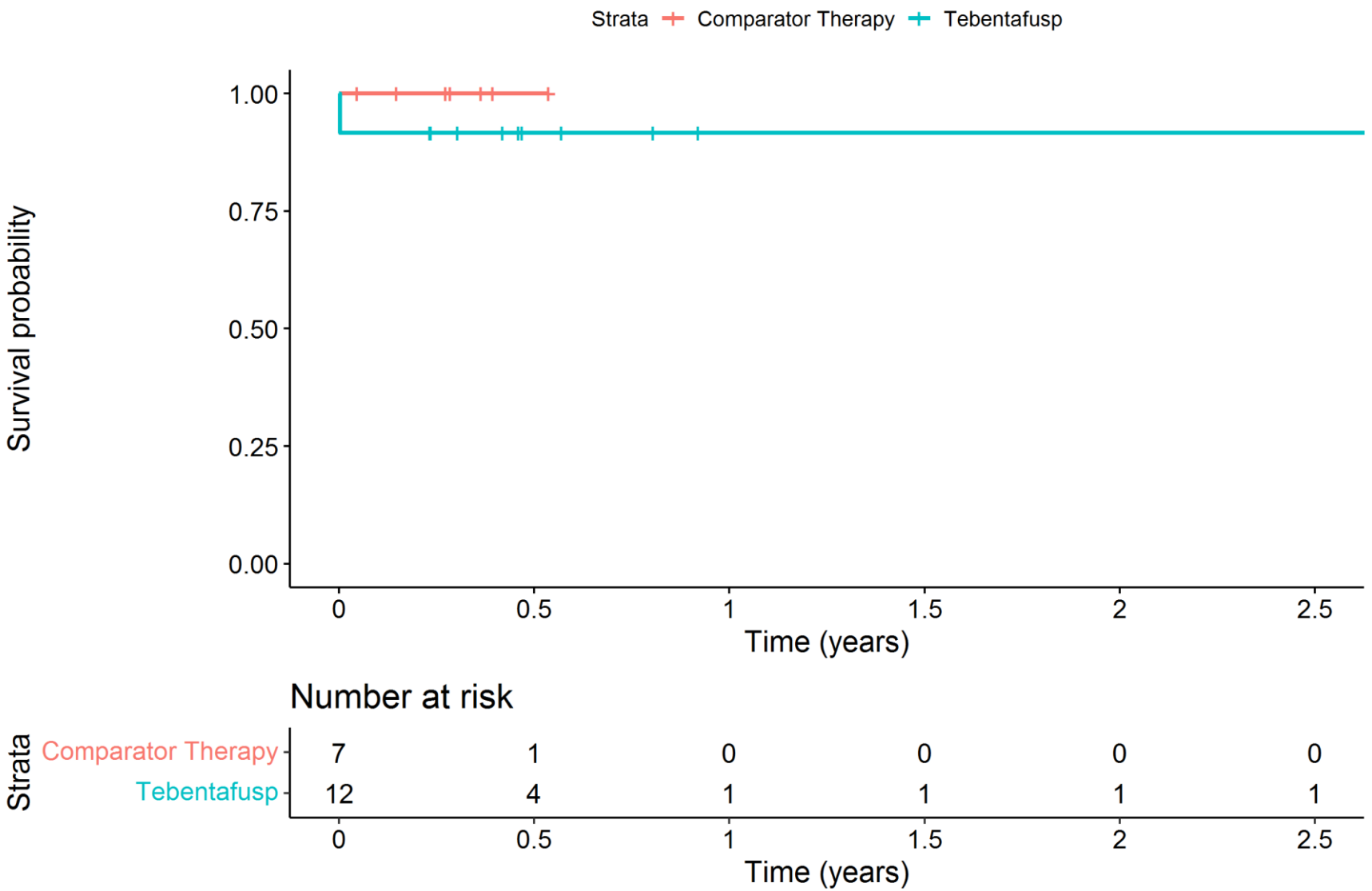
Gefäßerkrankungen- Nordamerika



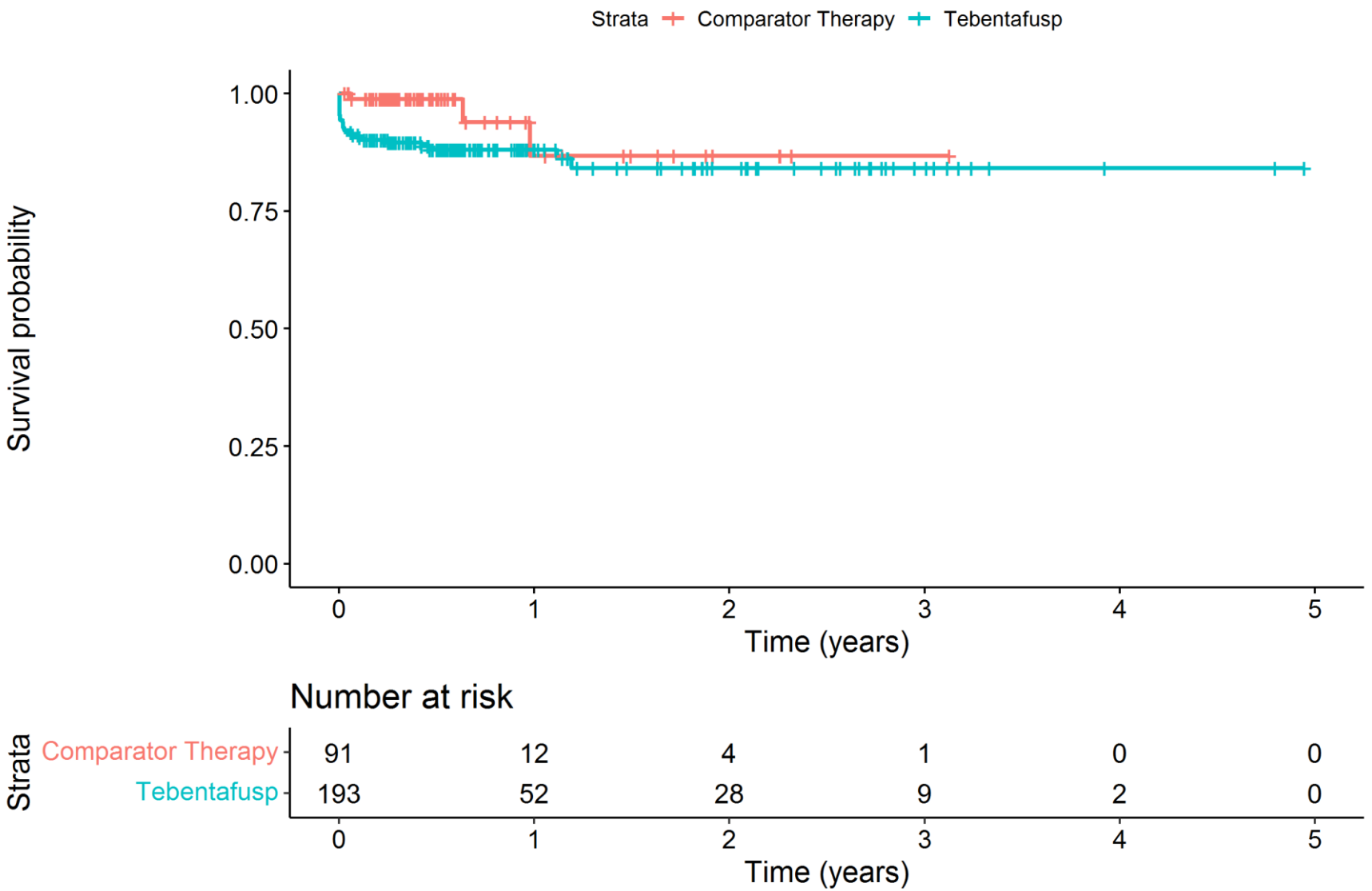
Gefäßerkrankungen- Nicht-Nordamerika



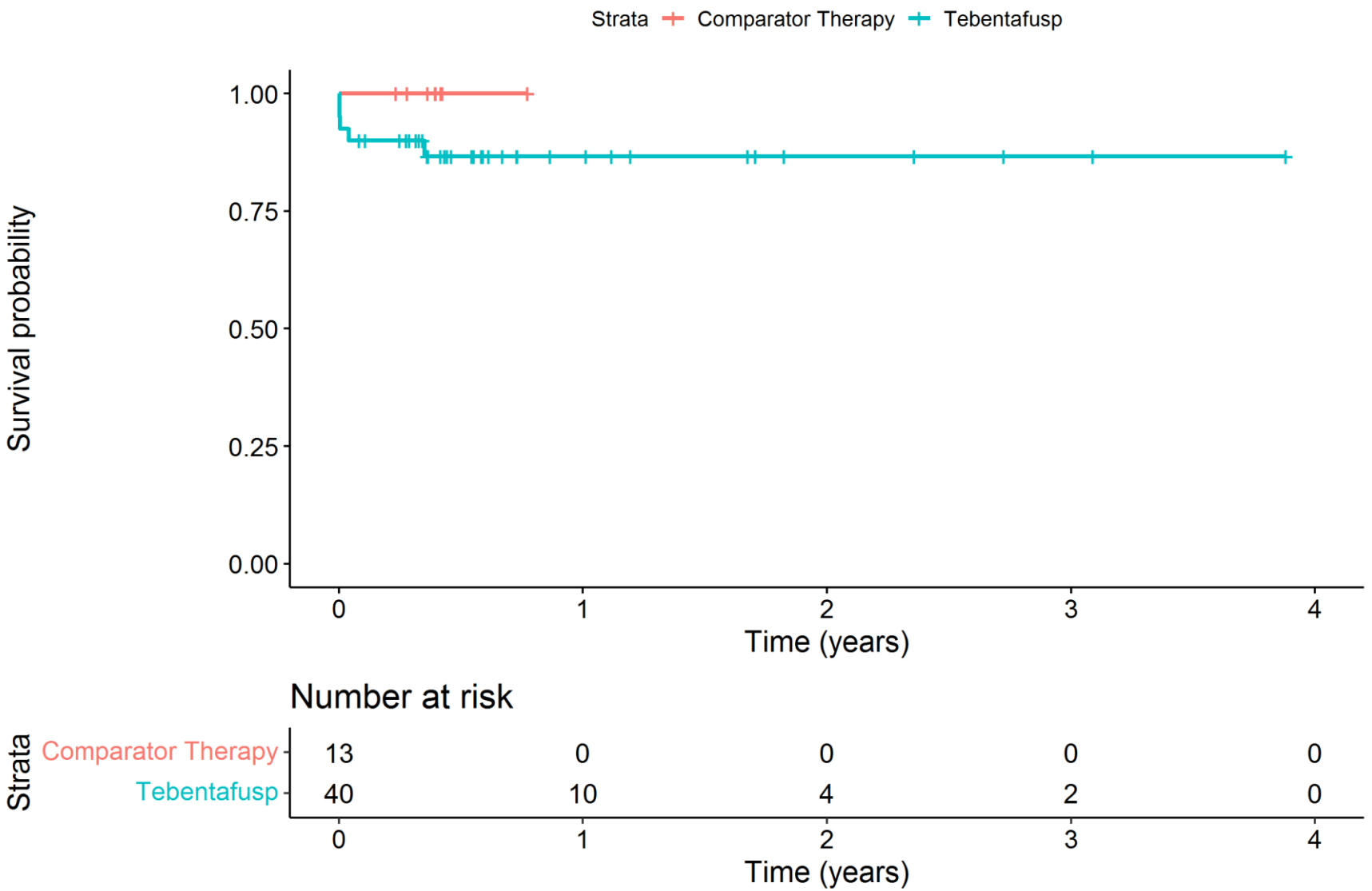
Gefäßerkrankungen- Dacarbazin



Gefäßerkrankungen- Pembrolizumab

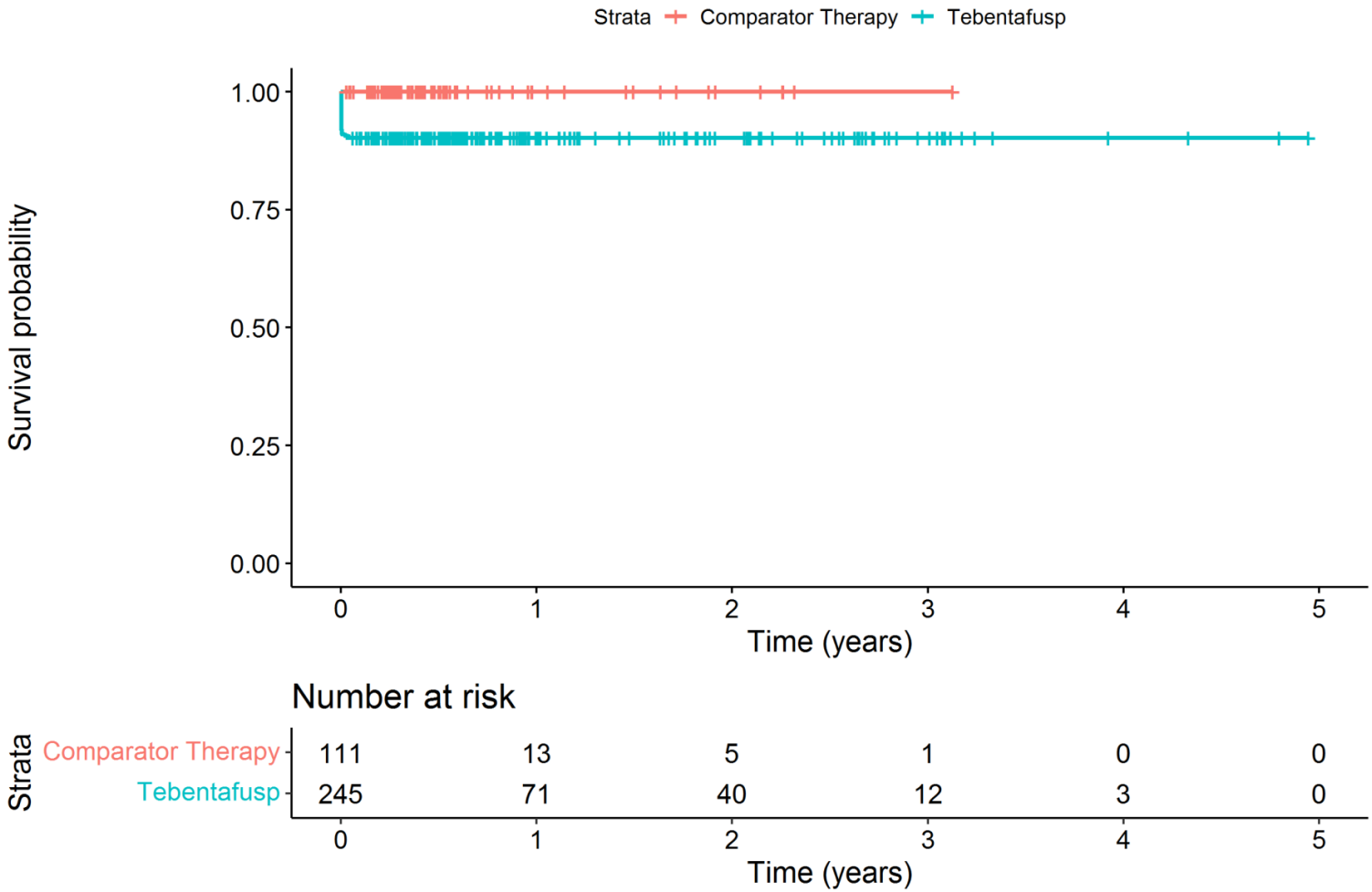


Gefäßerkrankungen- Ipilimumab

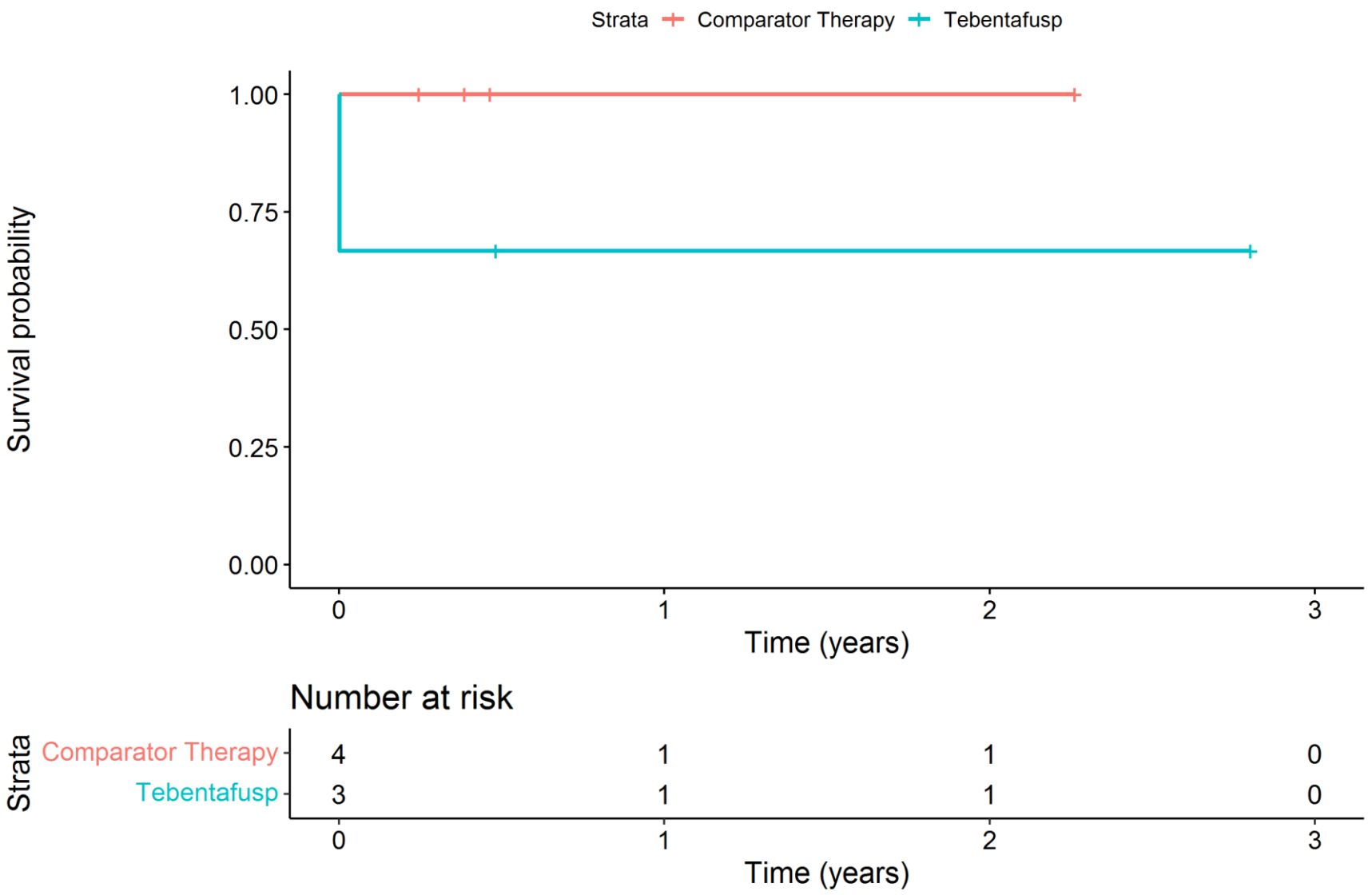


64 SUEs (PT) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-339)

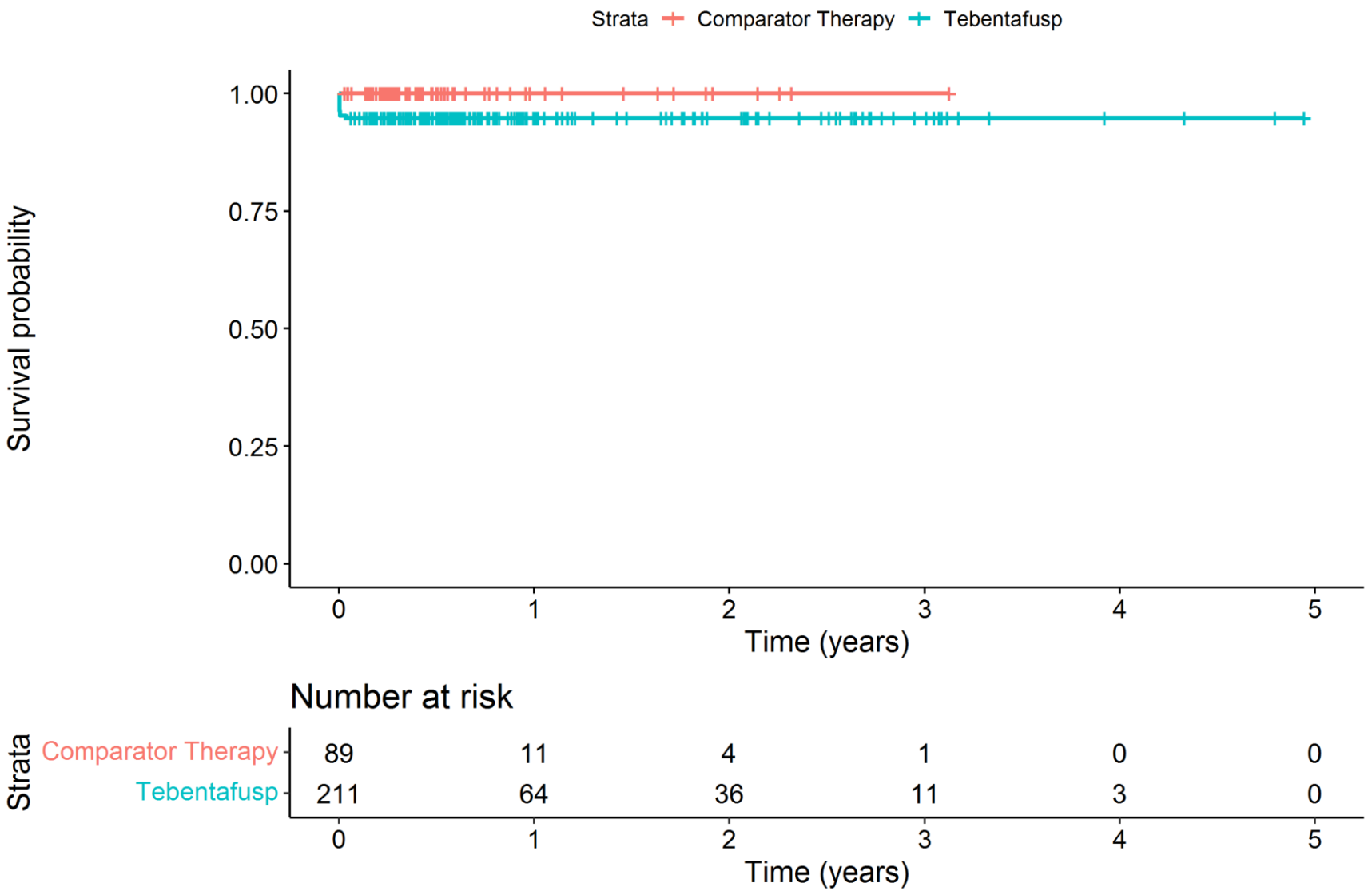
Zytokin-Freisetzungssyndrom- Gesamt



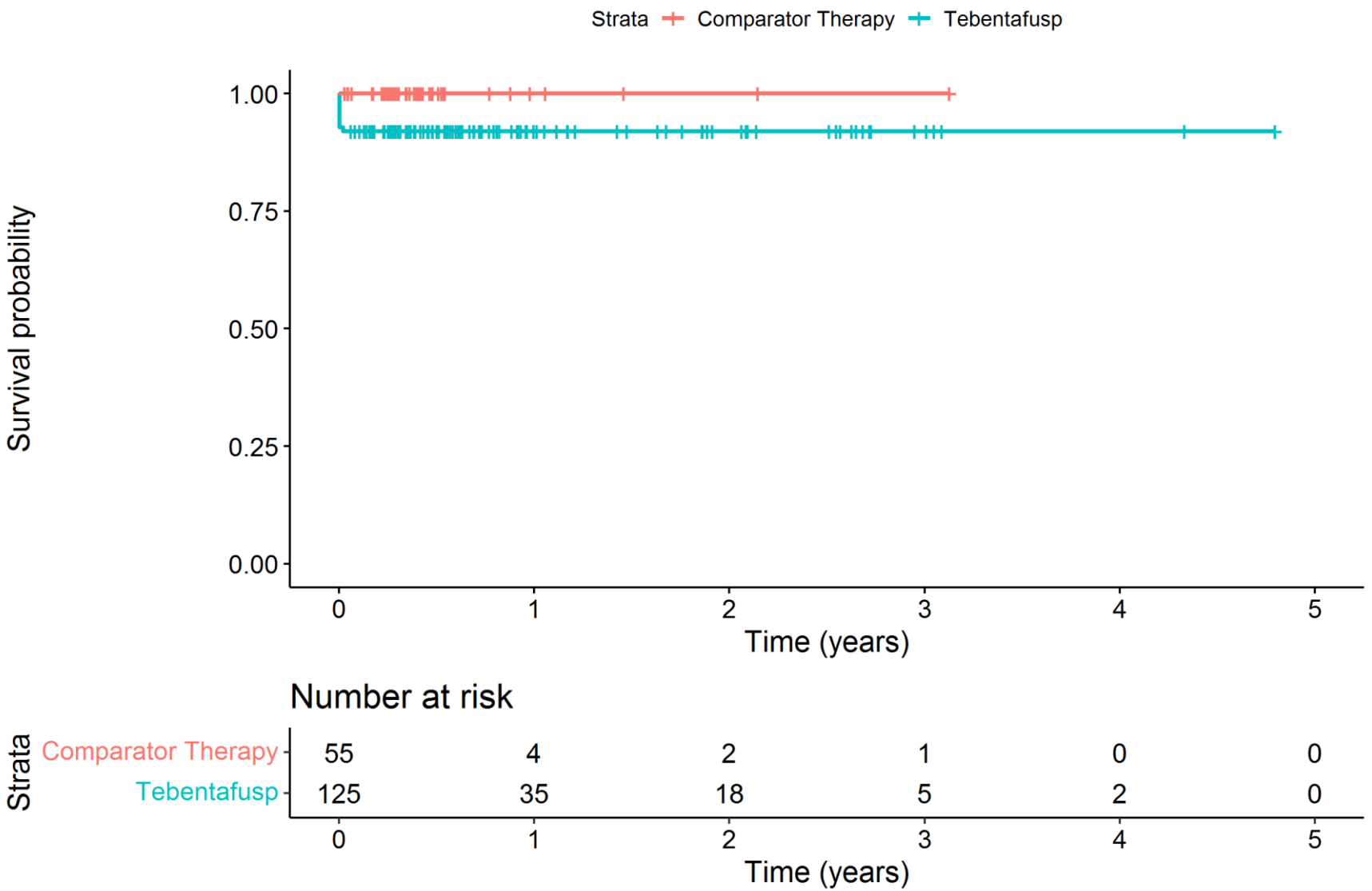
64.1 Zytokin-Freisetzungssyndrom- Hispanisch



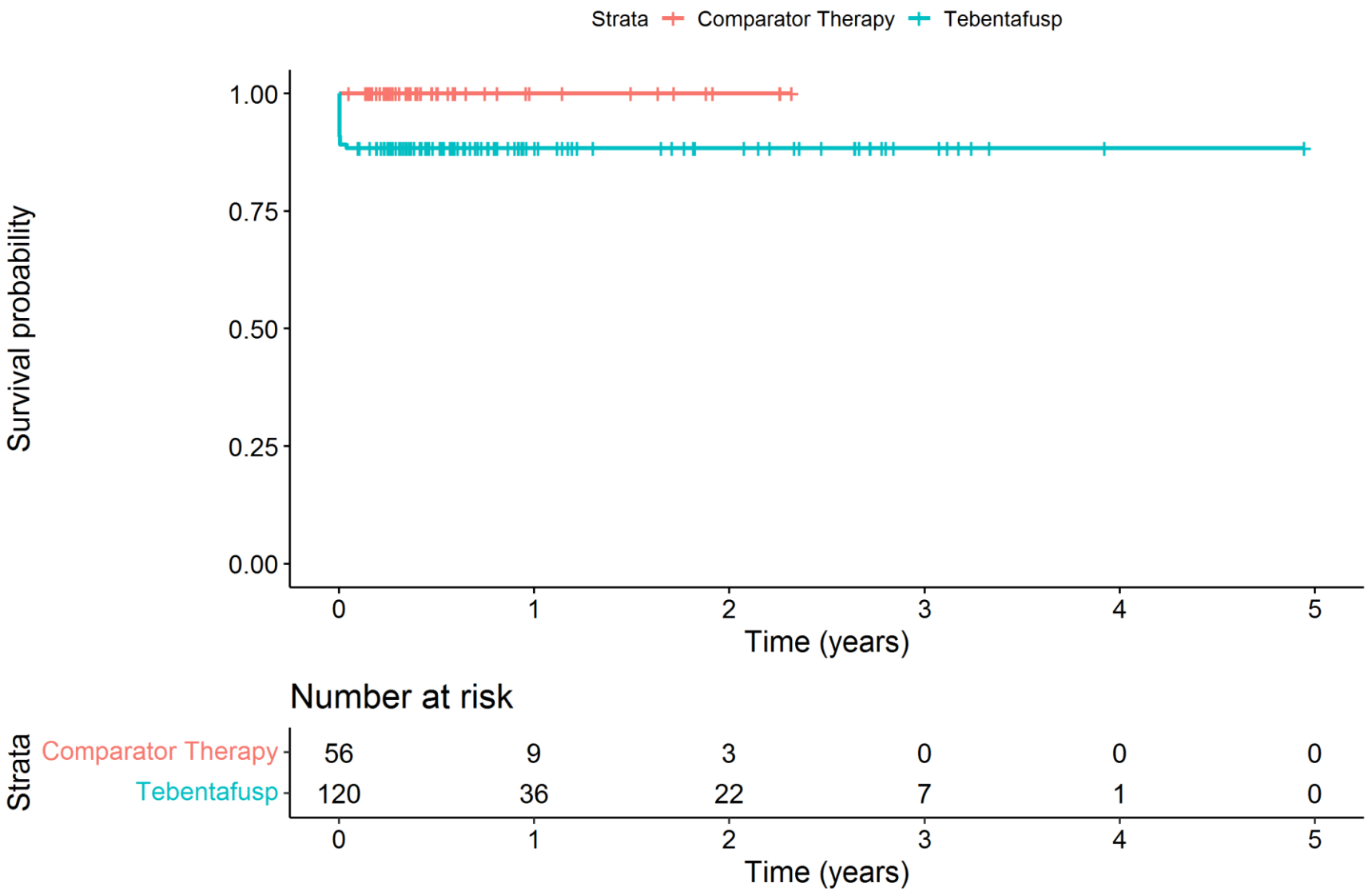
Zytokin-Freisetzungssyndrom- Nicht-hispanisch



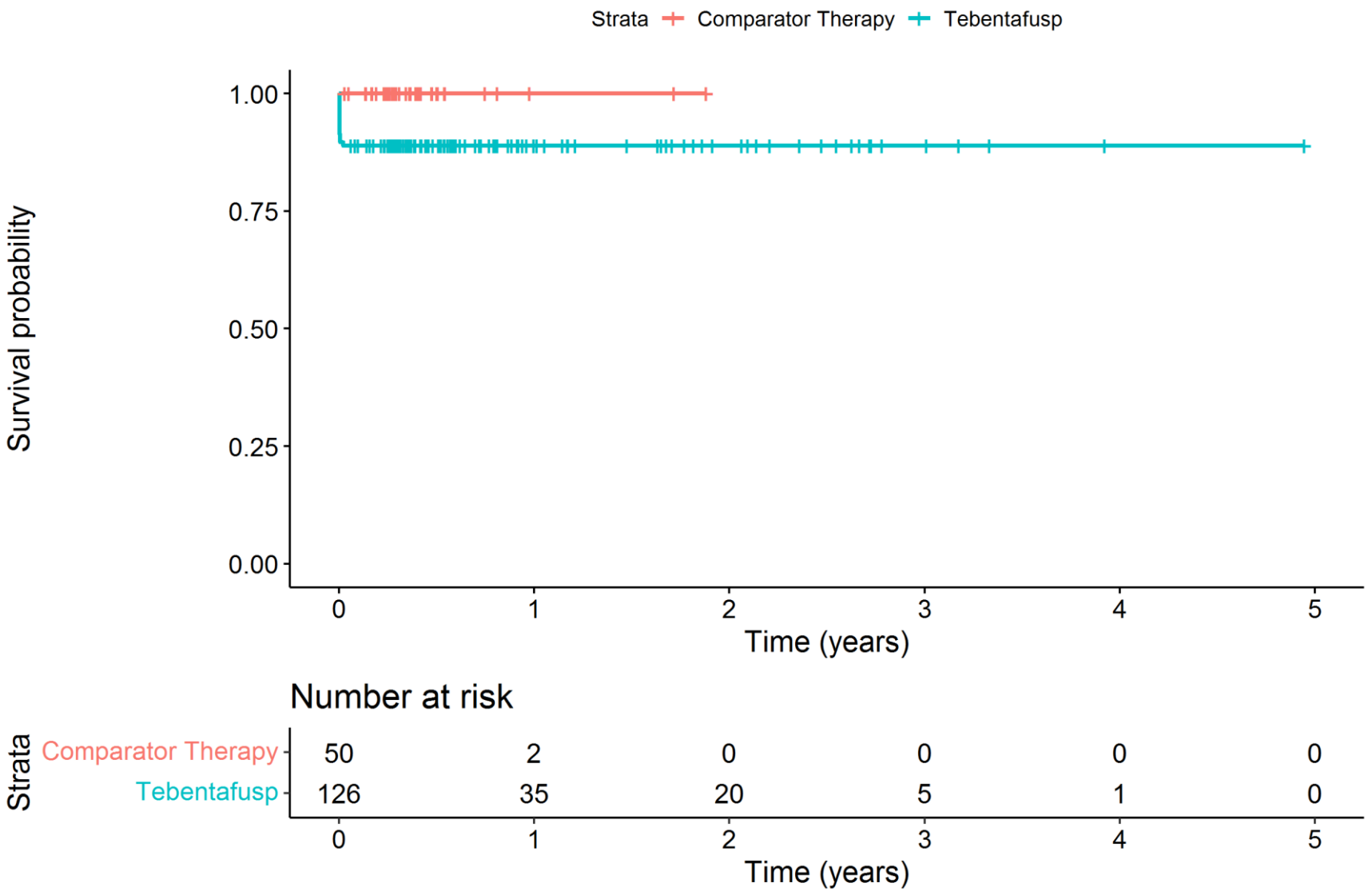
Zytokin-Freisetzungssyndrom- Männlich



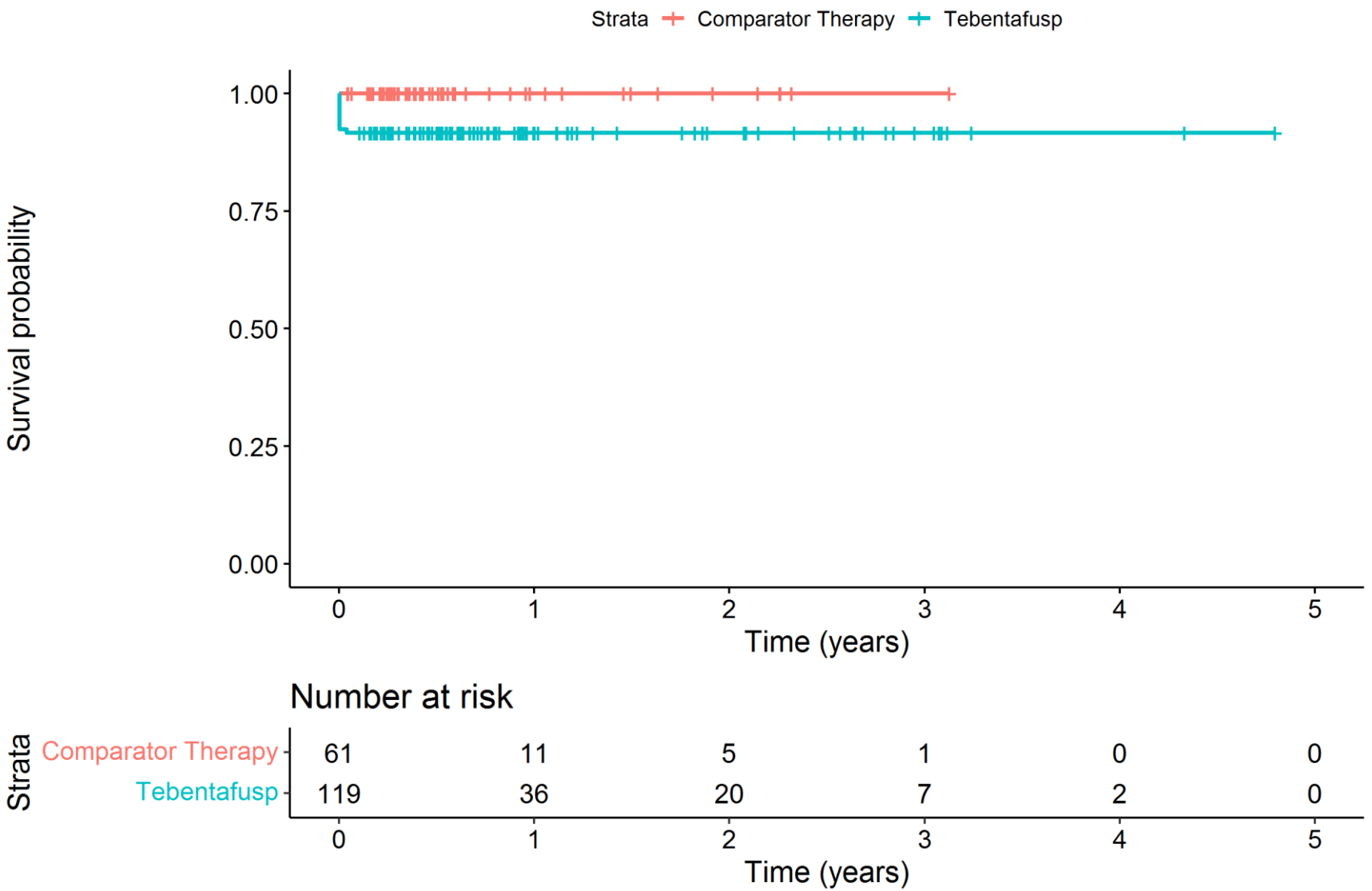
Zytokin-Freisetzungssyndrom- Weiblich



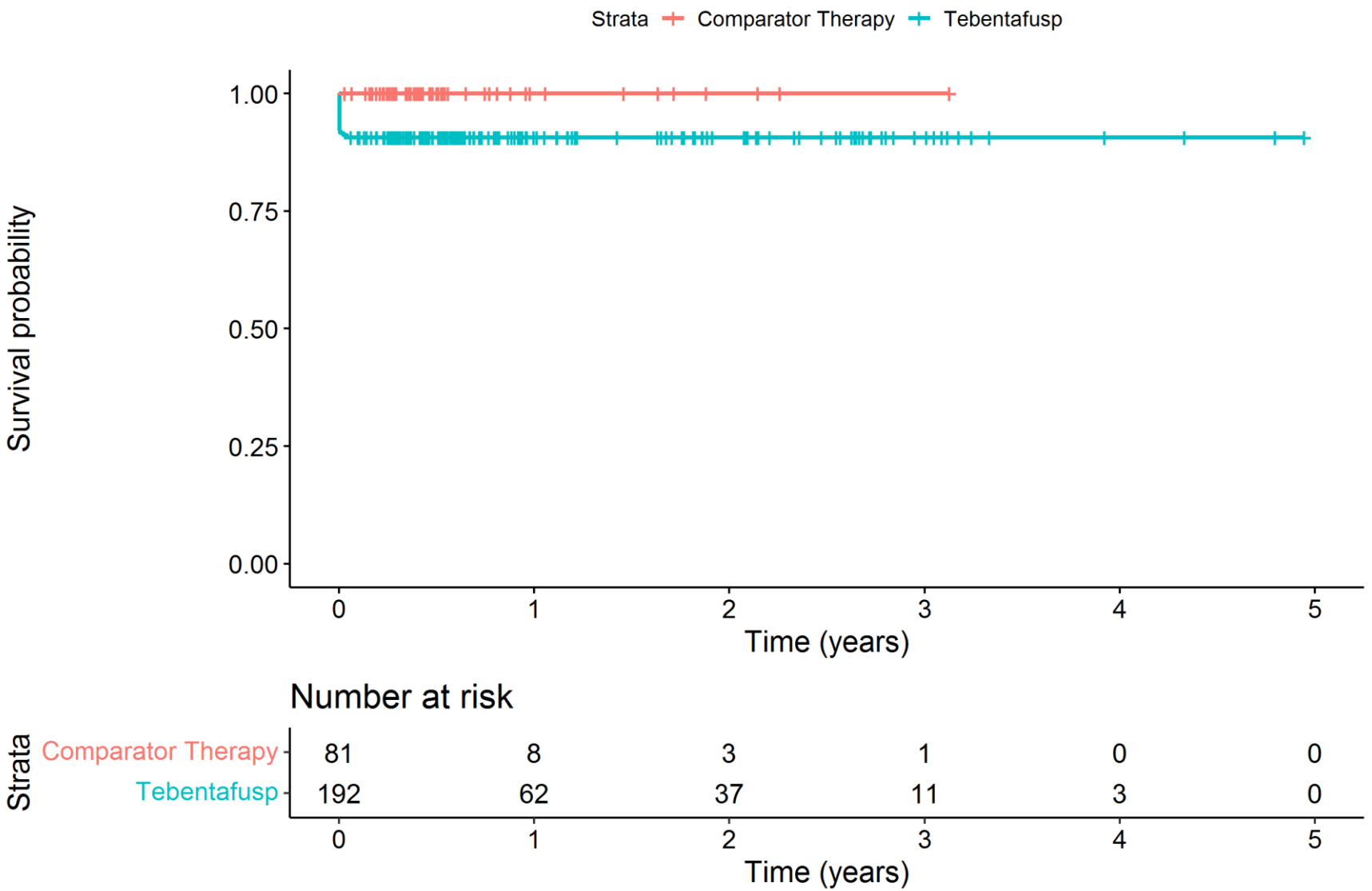
Zytokin-Freisetzungssyndrom- <65



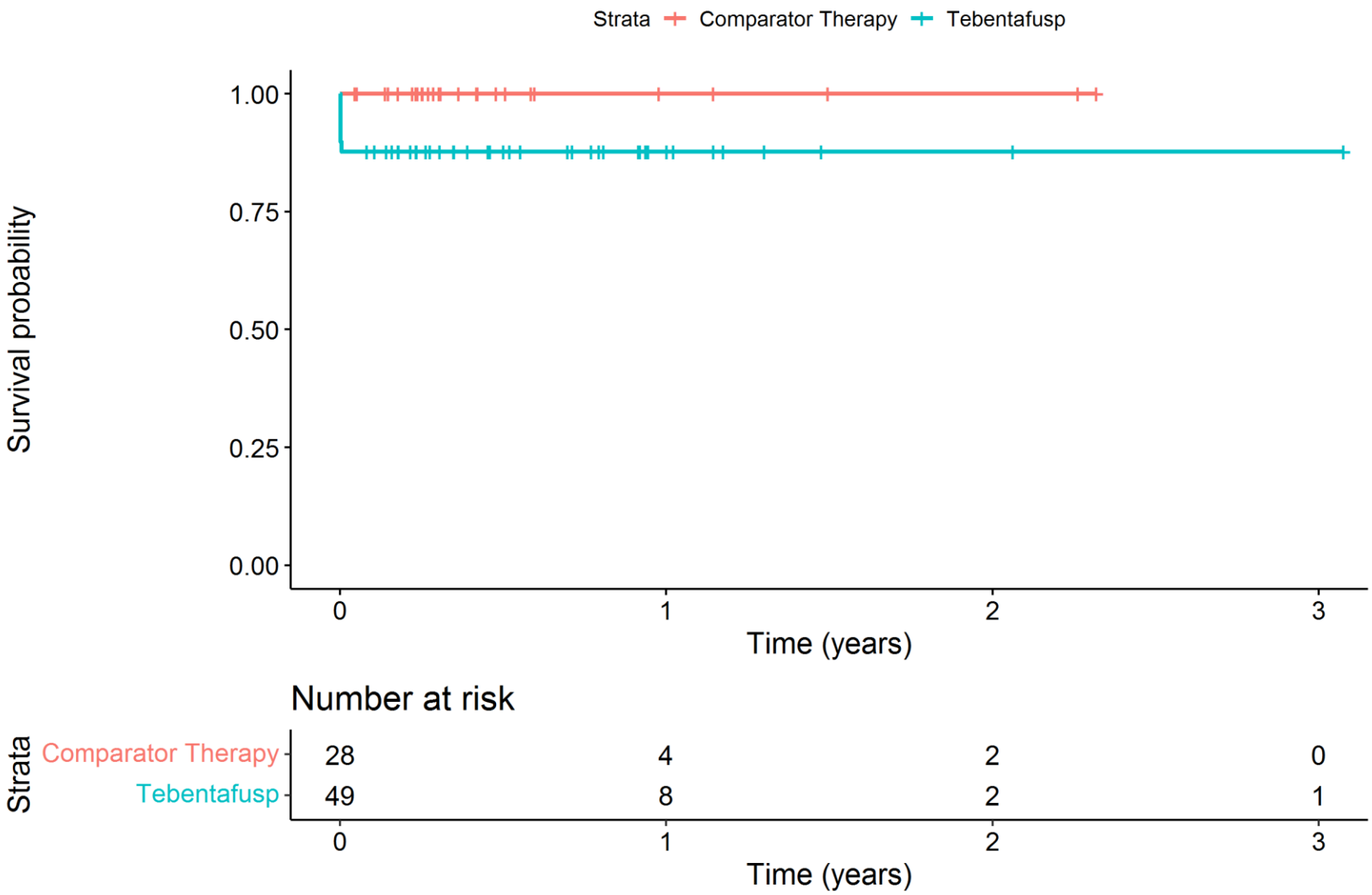
Zytokin-Freisetzungssyndrom- ≥65



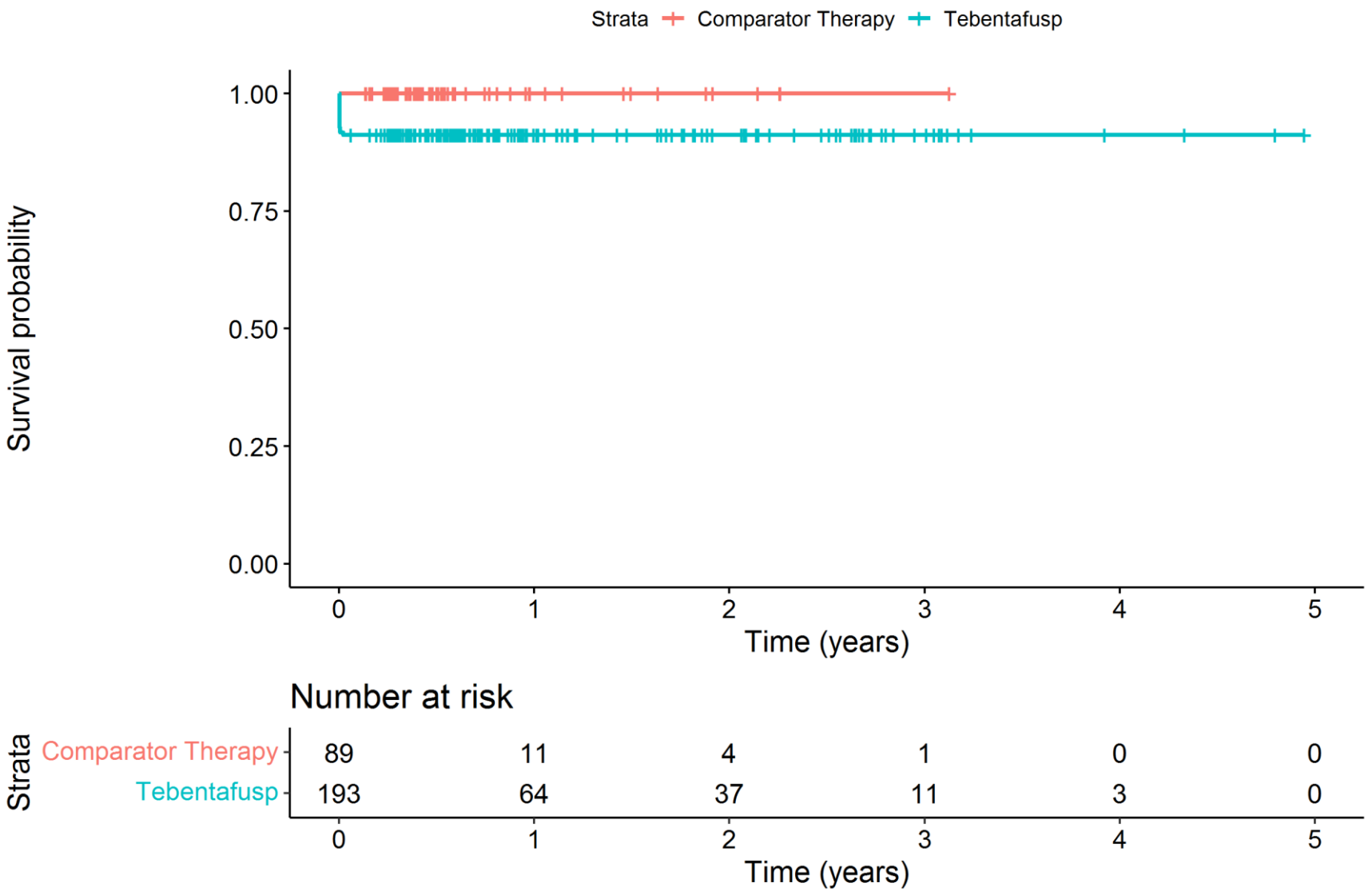
Zytokin-Freisetzungssyndrom- ECOG 0



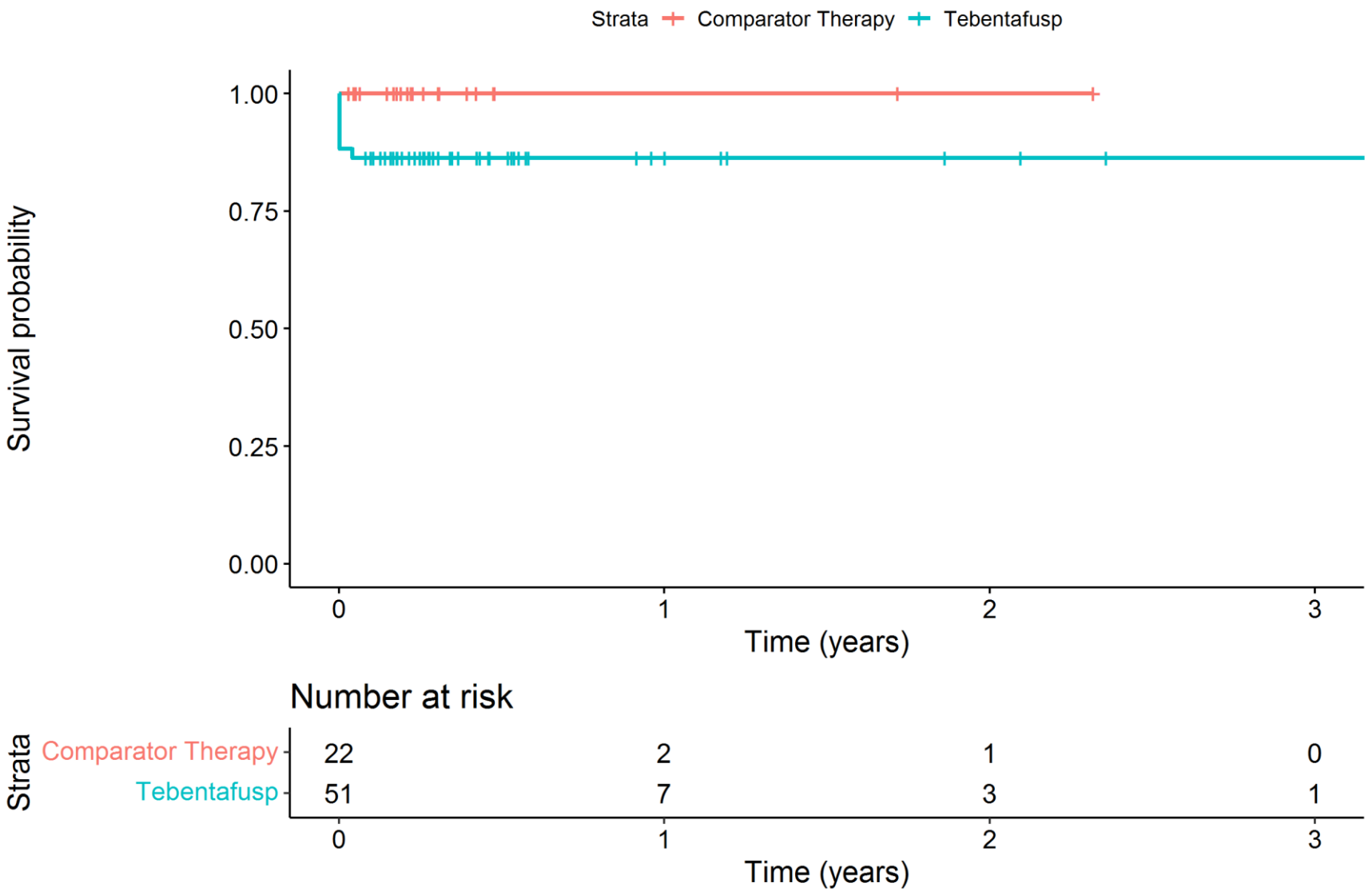
Zytokin-Freisetzungssyndrom- ECOG 1



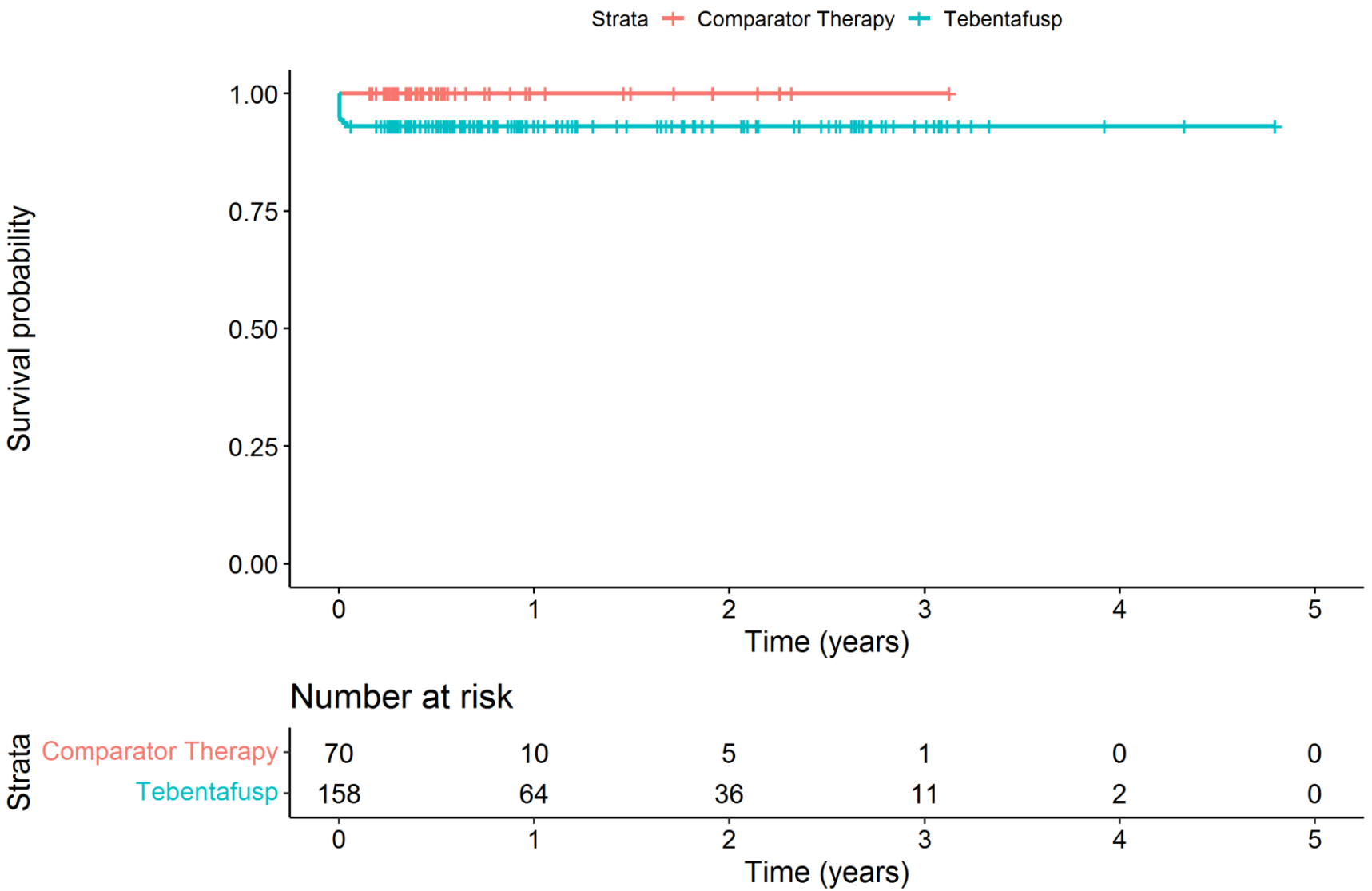
Zytokin-Freisetzungssyndrom- ALP ≤ ULN



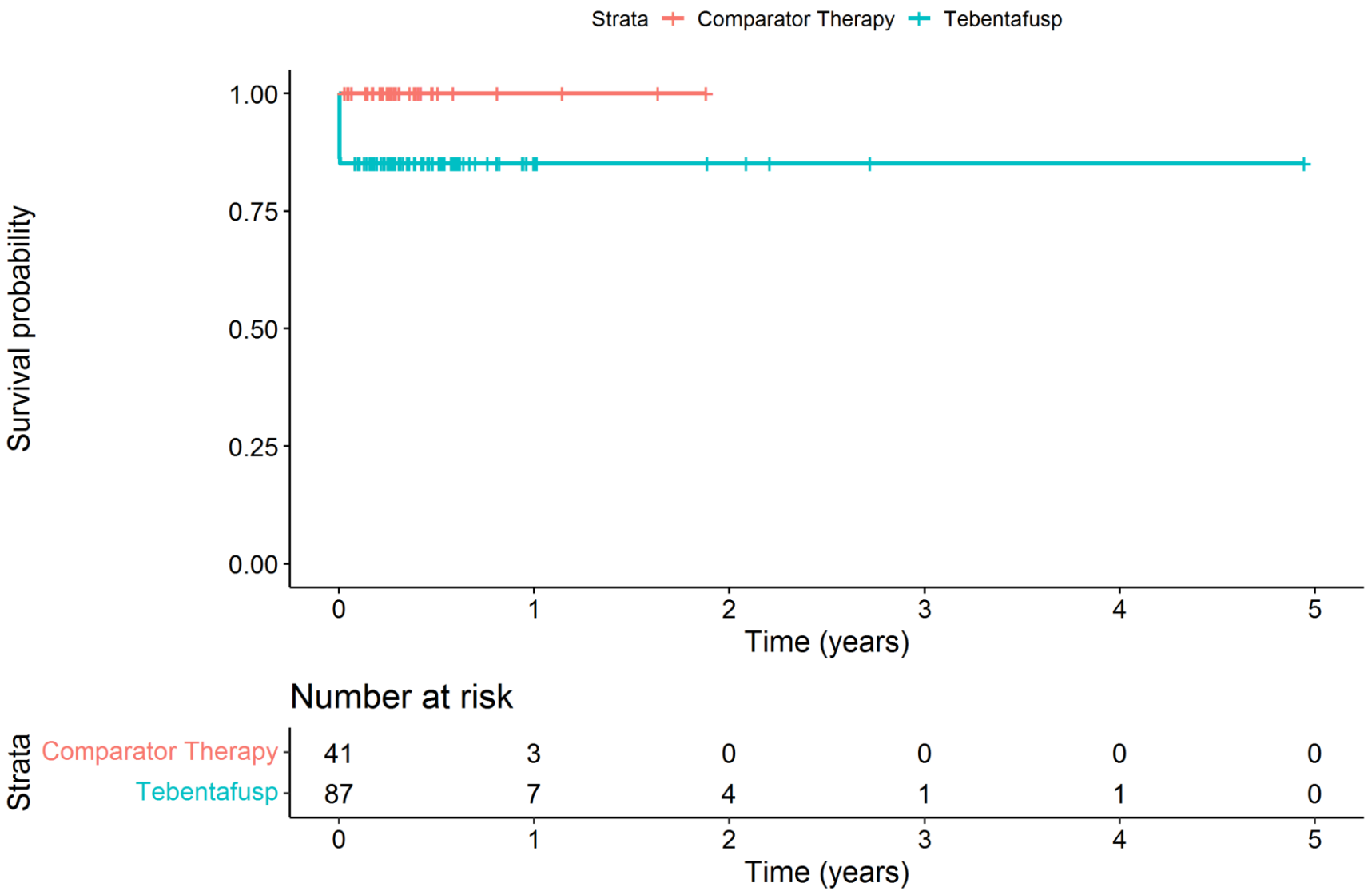
Zytokin-Freisetzungssyndrom- ALP > ULN



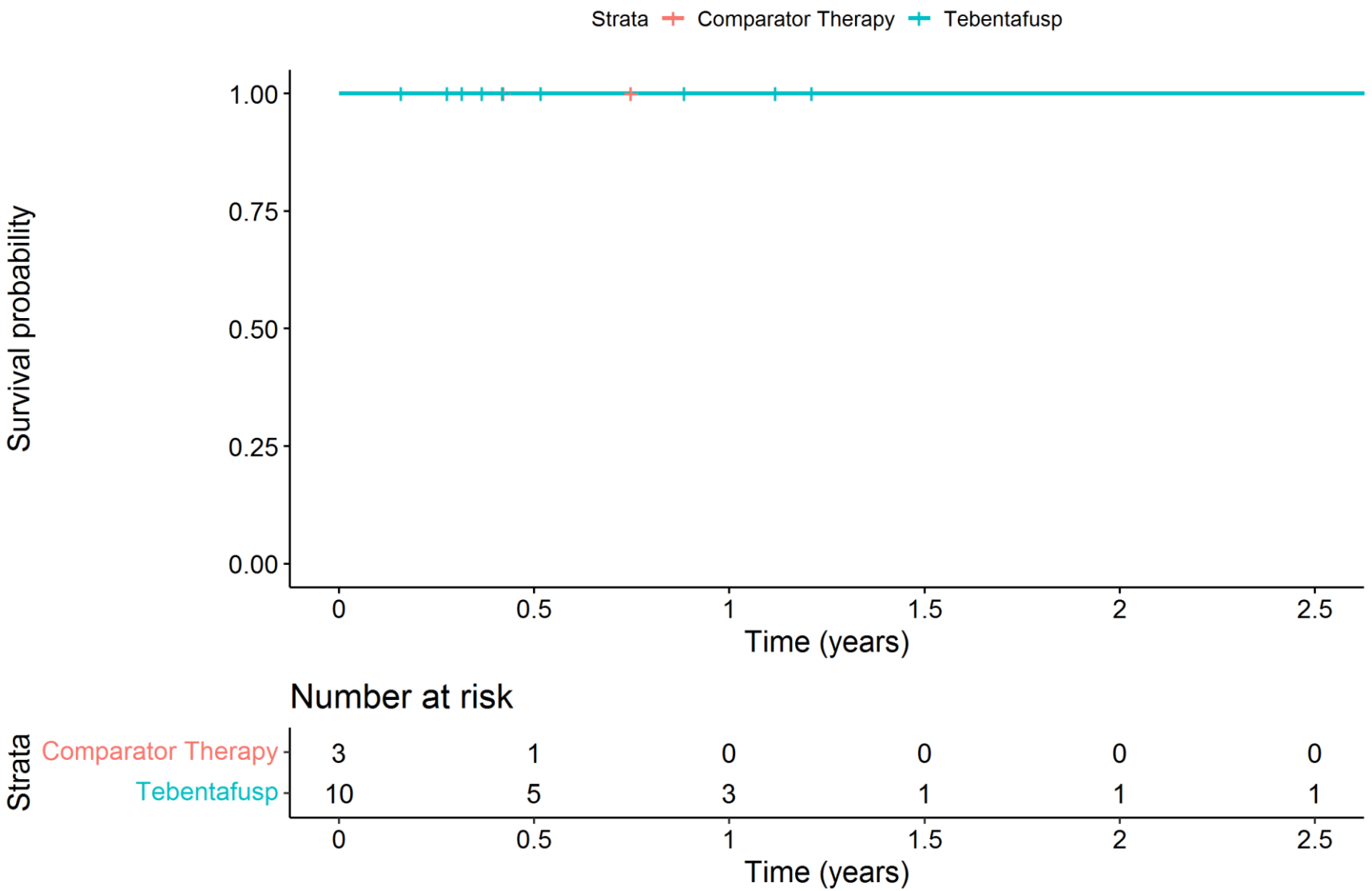
Zytokin-Freisetzungssyndrom- LDH =< ULN



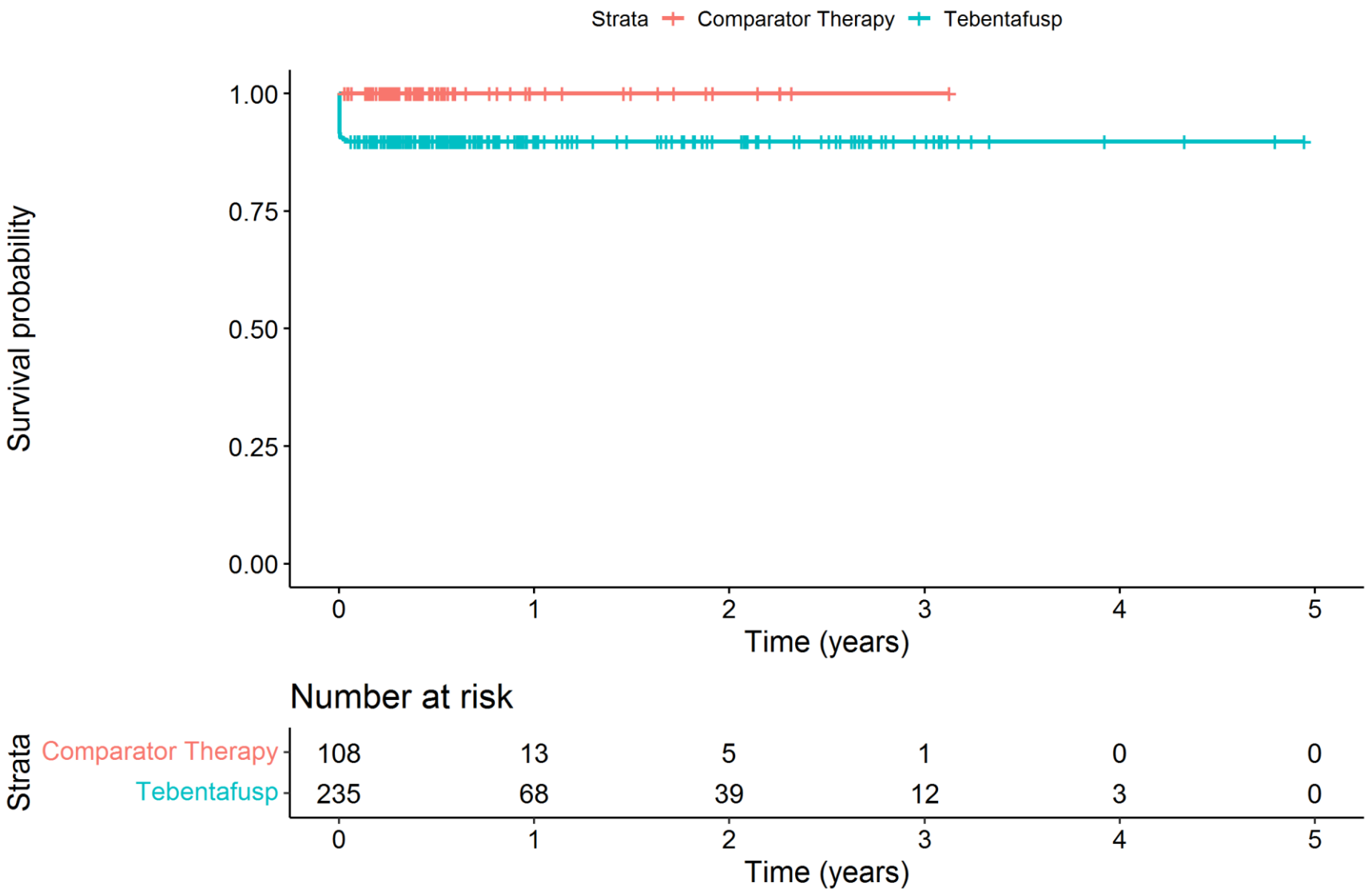
Zytokin-Freisetzungssyndrom- LDH > ULN



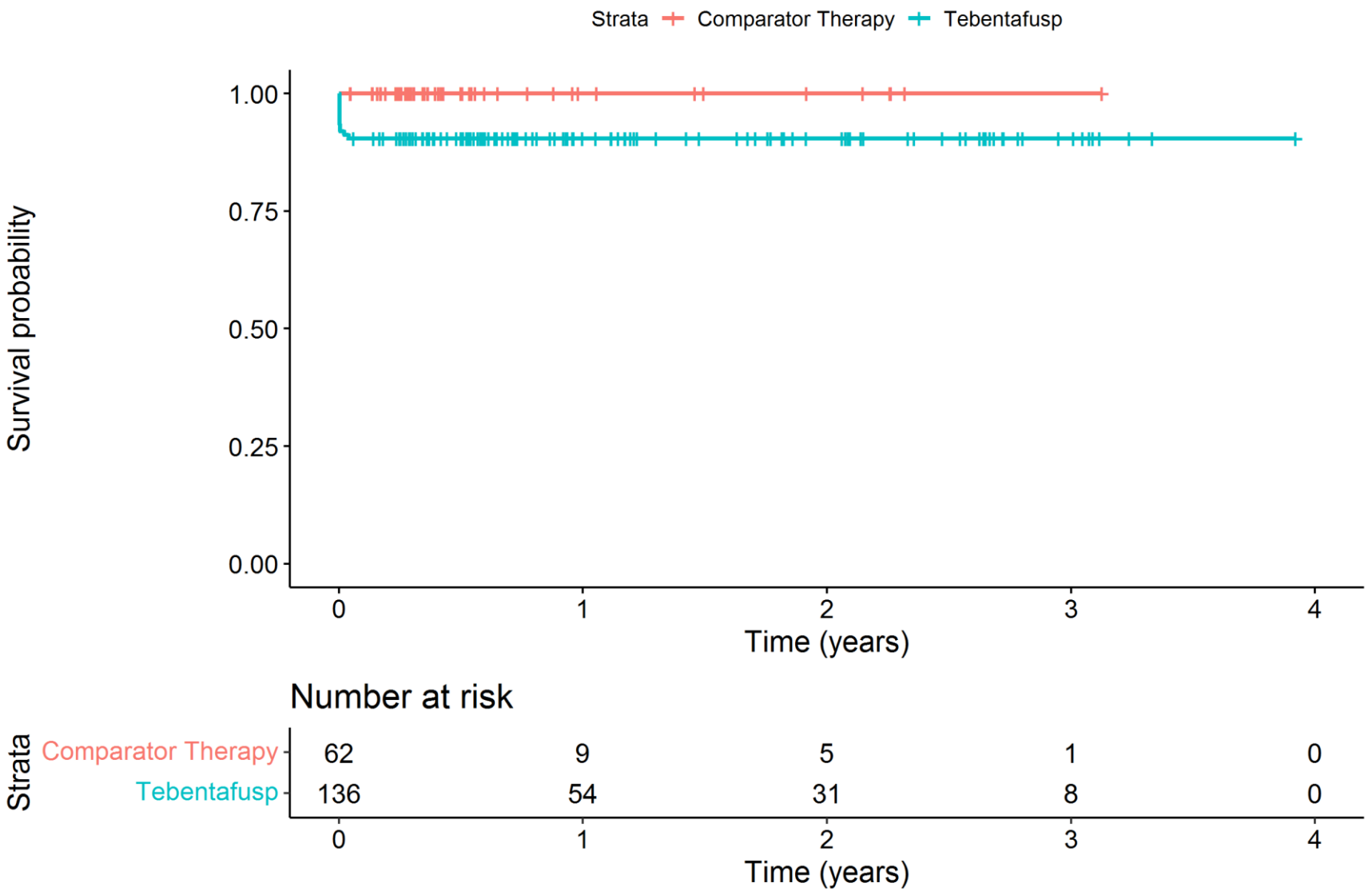
Zytokin-Freisetzungssyndrom- Vorherige Therapie adjuvant/neoadjuvant



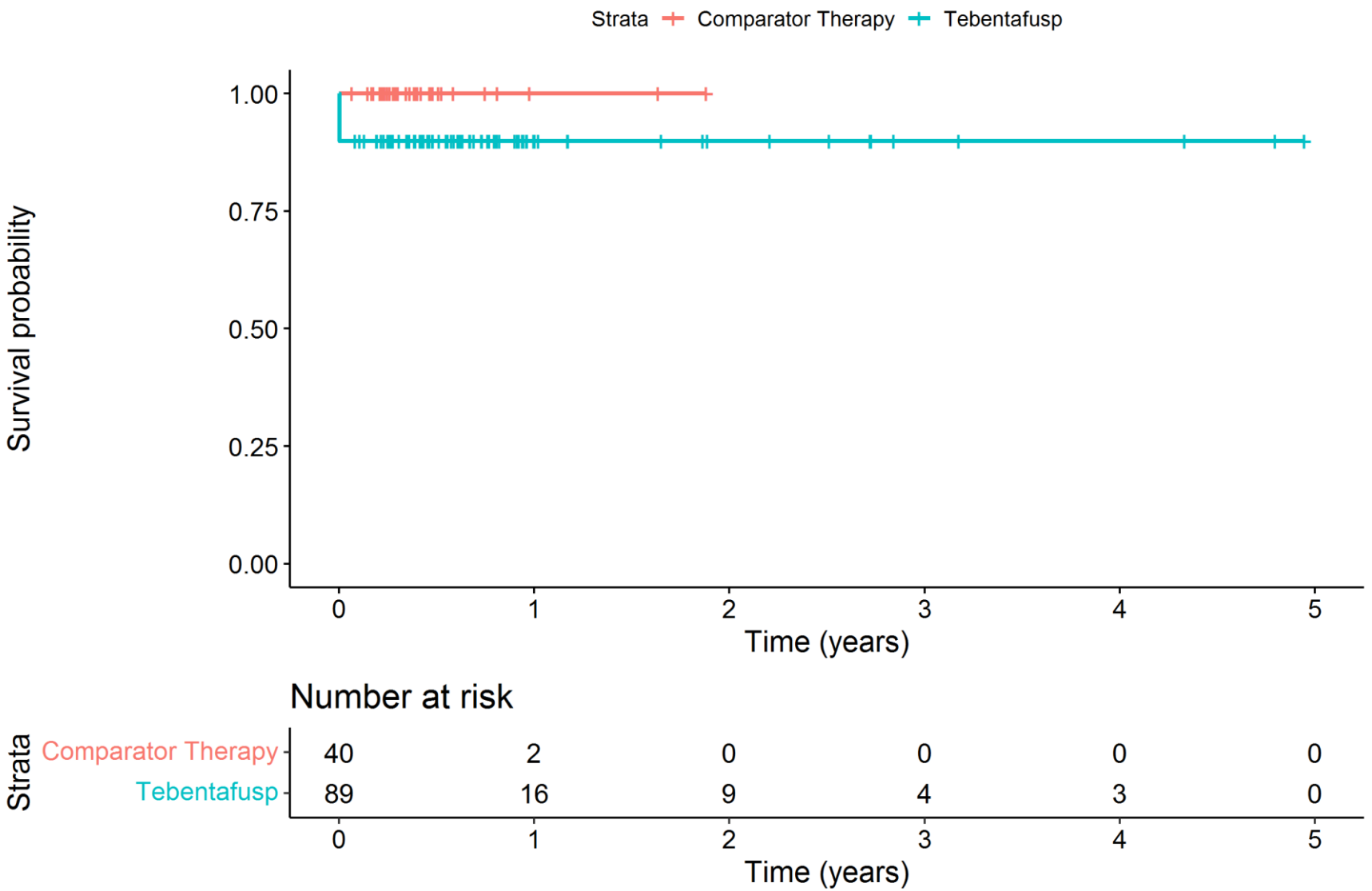
Zytokin-Freisetzungssyndrom- Keine Vorherige Therapie adjuvant/neoadjuvant



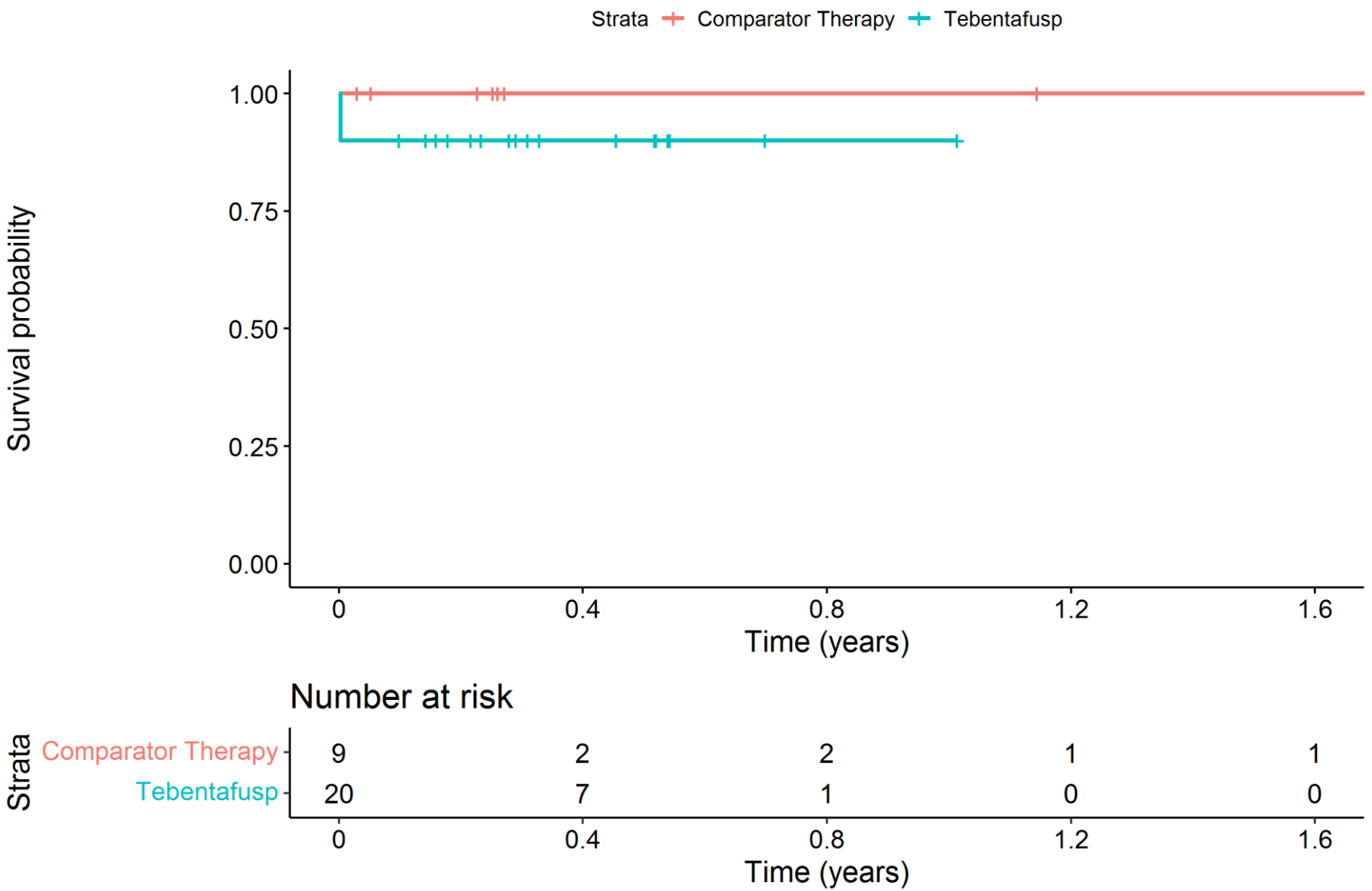
Zytokin-Freisetzungssyndrom- Läsion ≤ 3cm



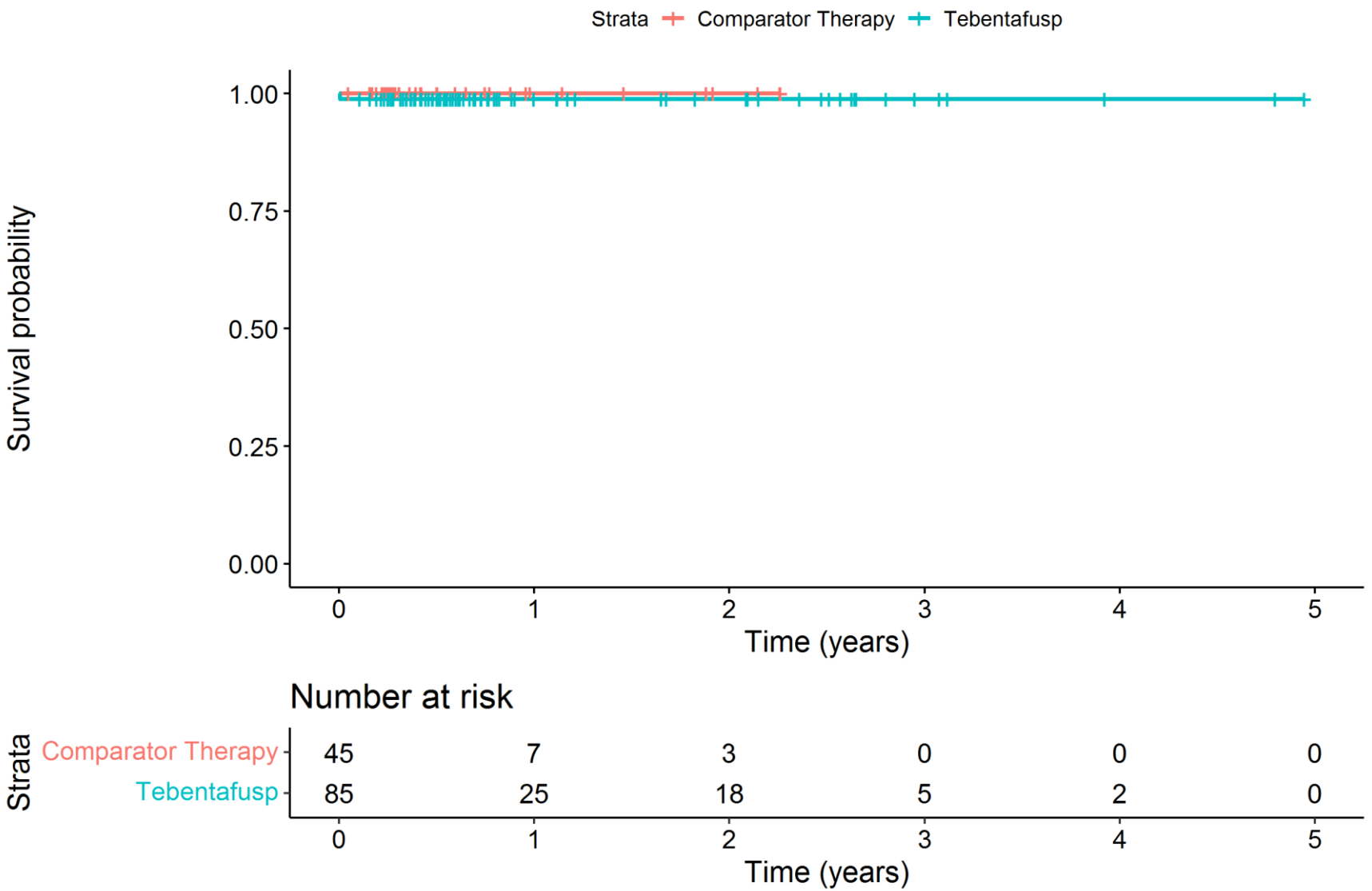
Zytokin-Freisetzungssyndrom- Läsion 3,1-8,0 cm



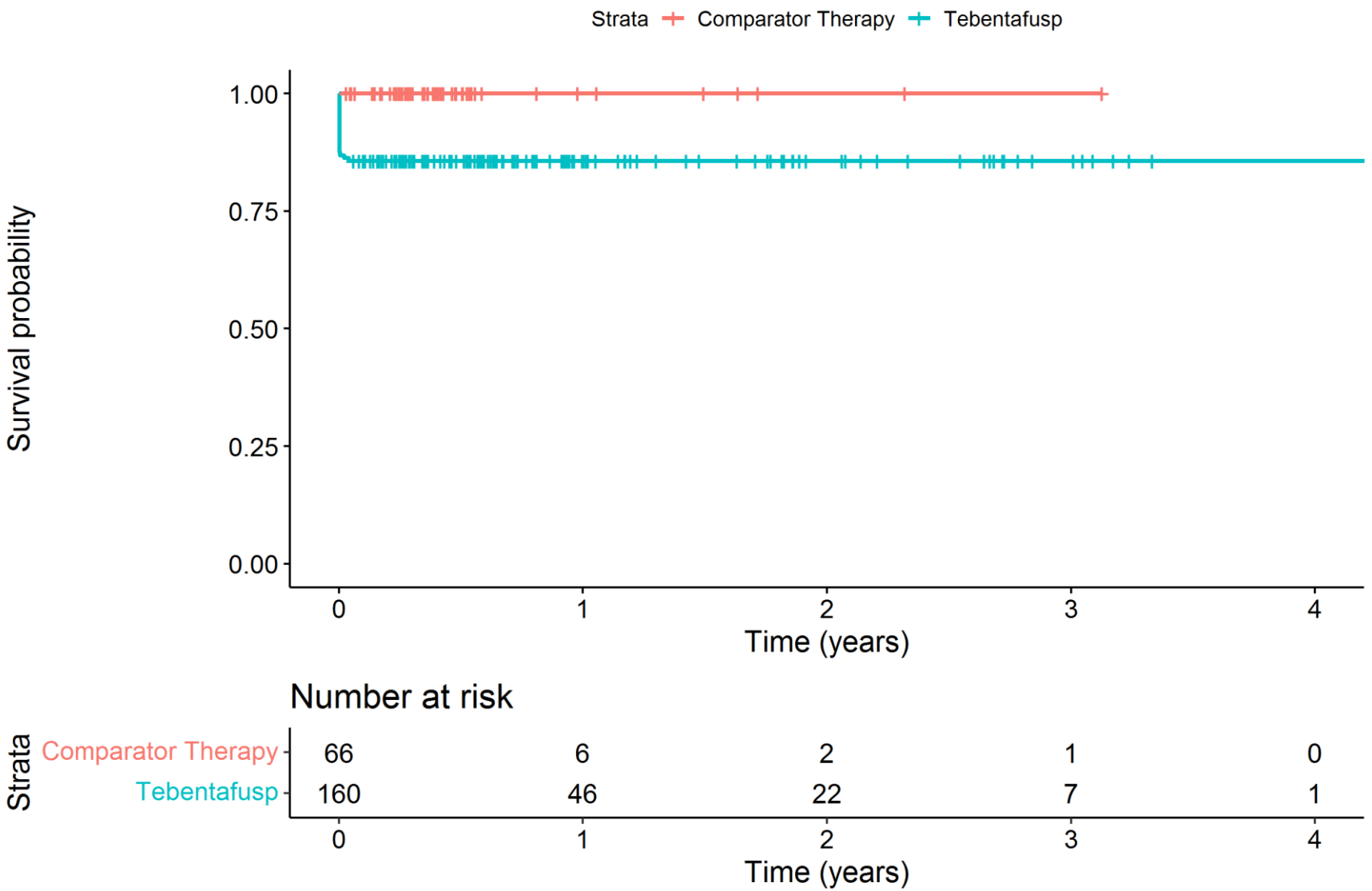
Zytokin-Freisetzungssyndrom- Läsion ≥8,1 cm



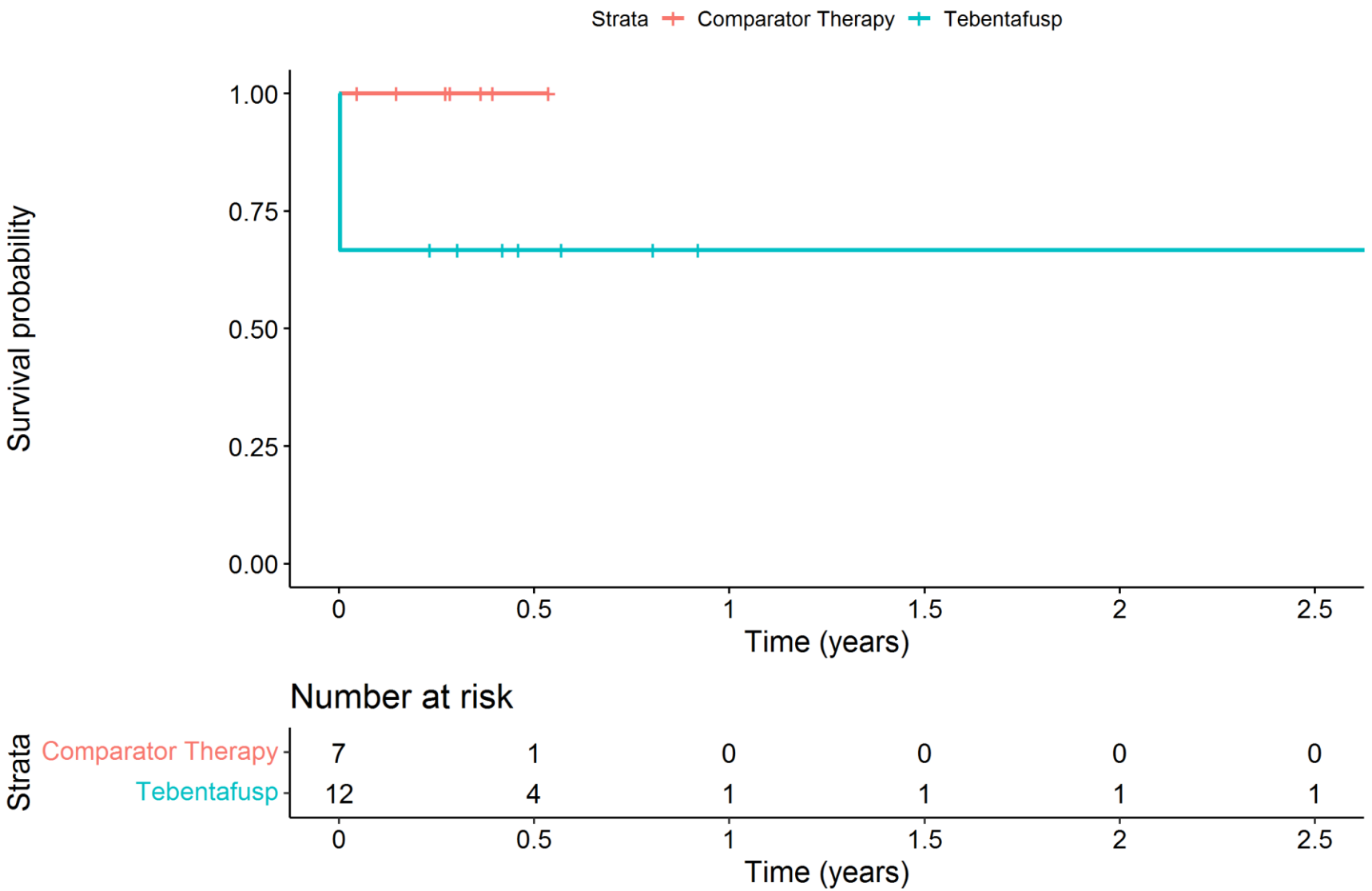
Zytokin-Freisetzungssyndrom- Nordamerika



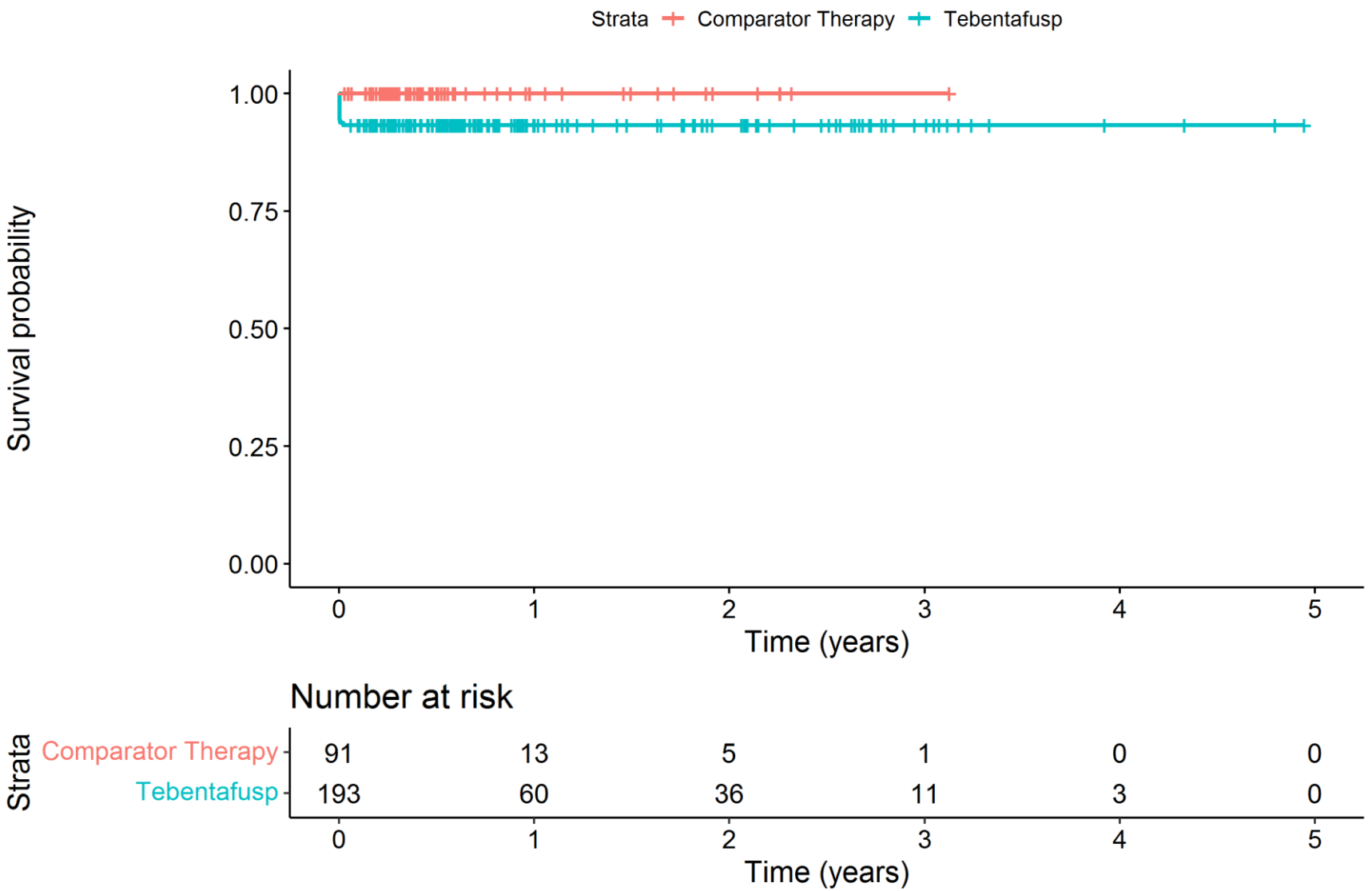
Zytokin-Freisetzungssyndrom- Nicht-Nordamerika



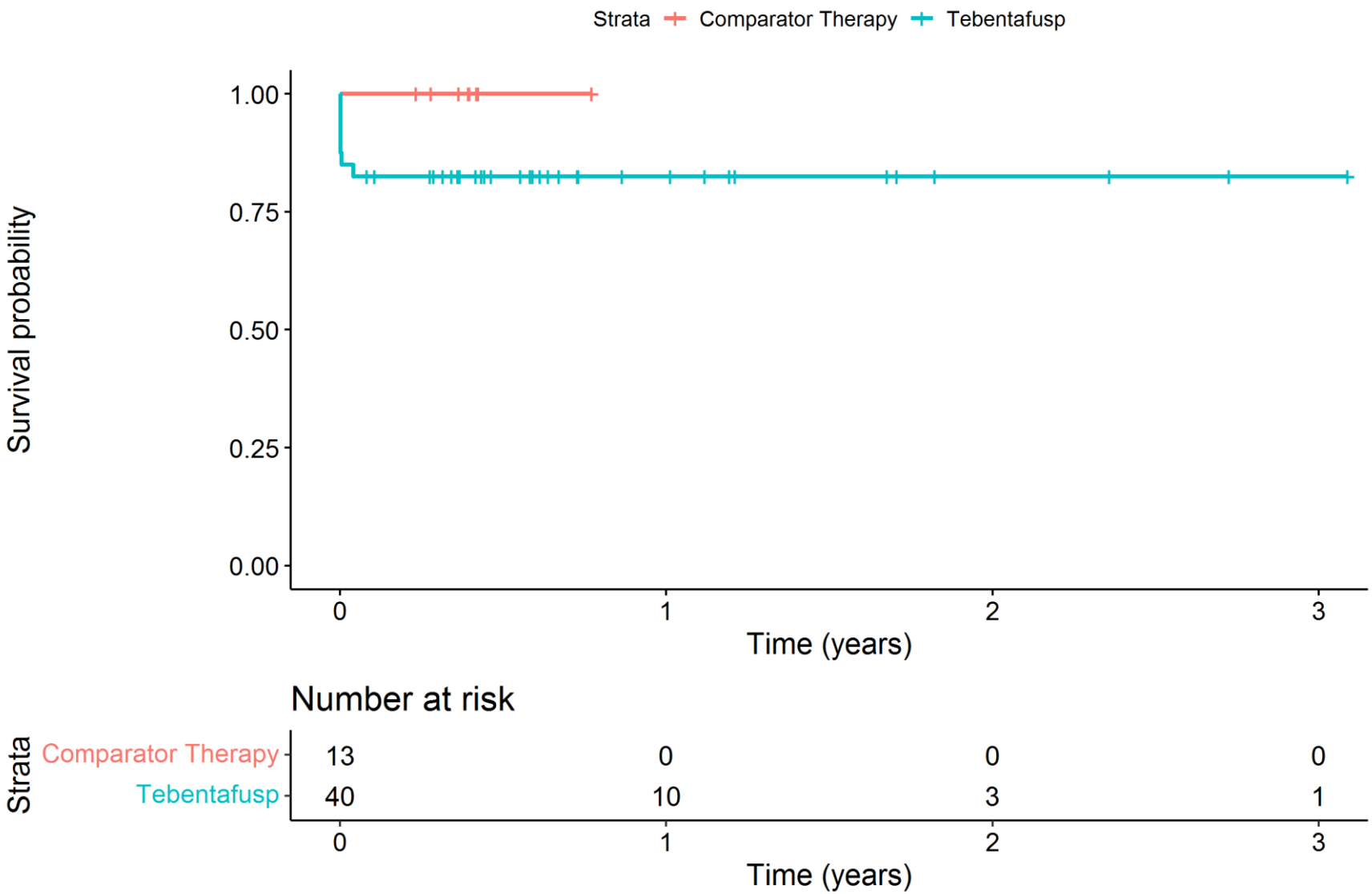
Zytokin-Freisetzungssyndrom- Dacarbazin



Zytokin-Freisetzungssyndrom- Pembrolizumab

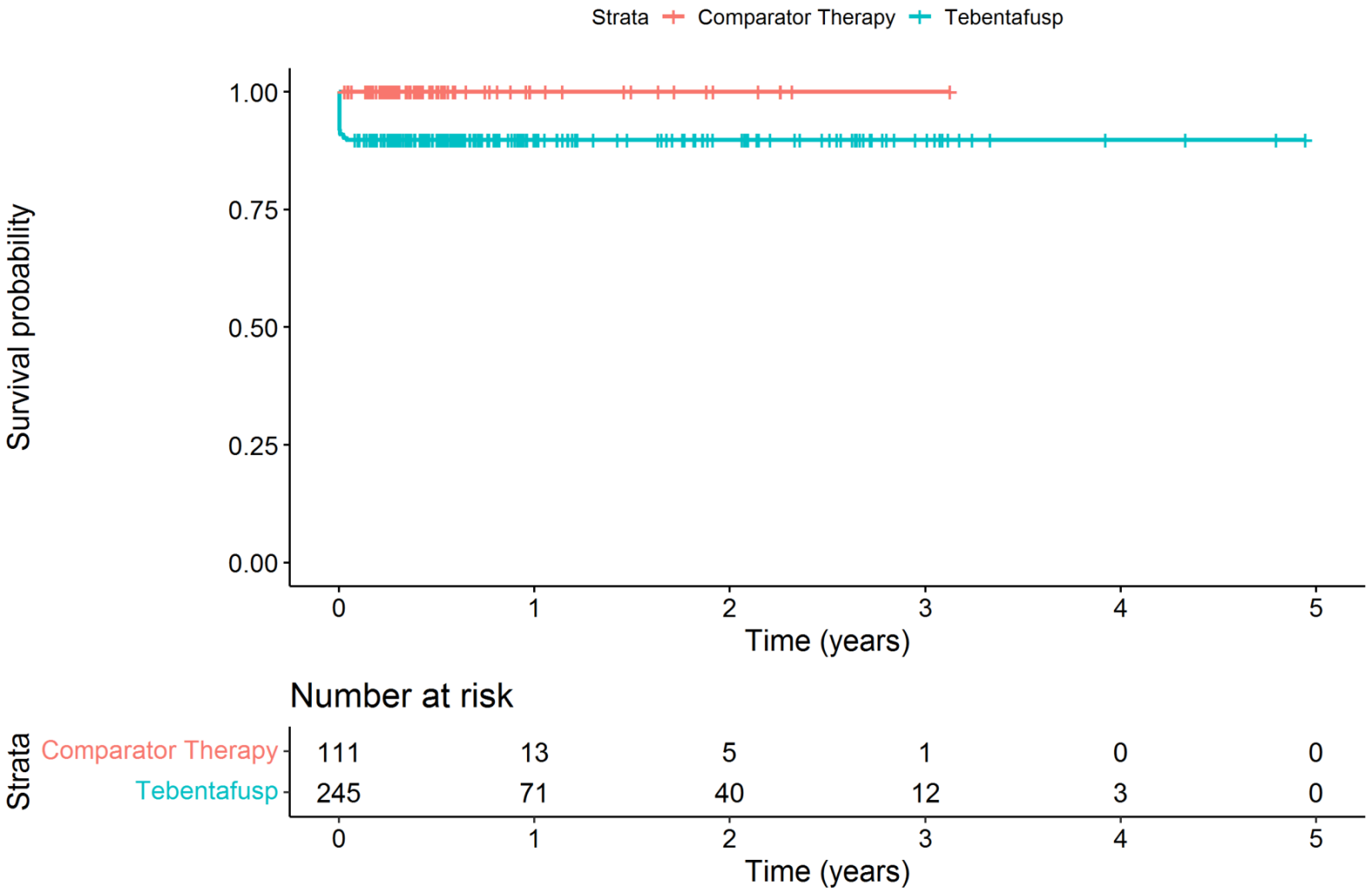


Zytokin-Freisetzungssyndrom- Ipilimumab

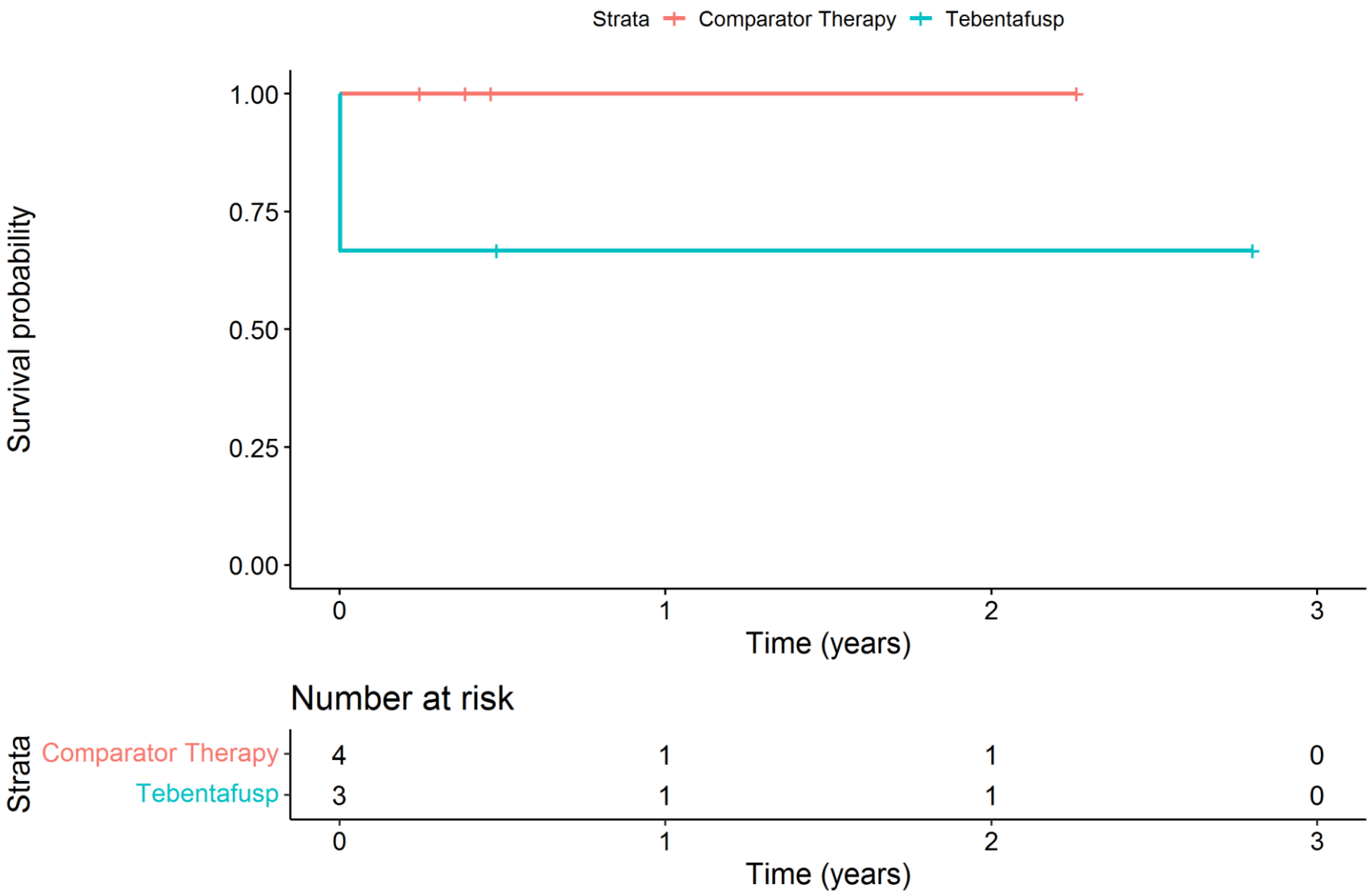


65 SUEs (SOC) die bei ≥ 2 Patienten in einem Behandlungsarm auftraten (ab Tabelle 4-339)

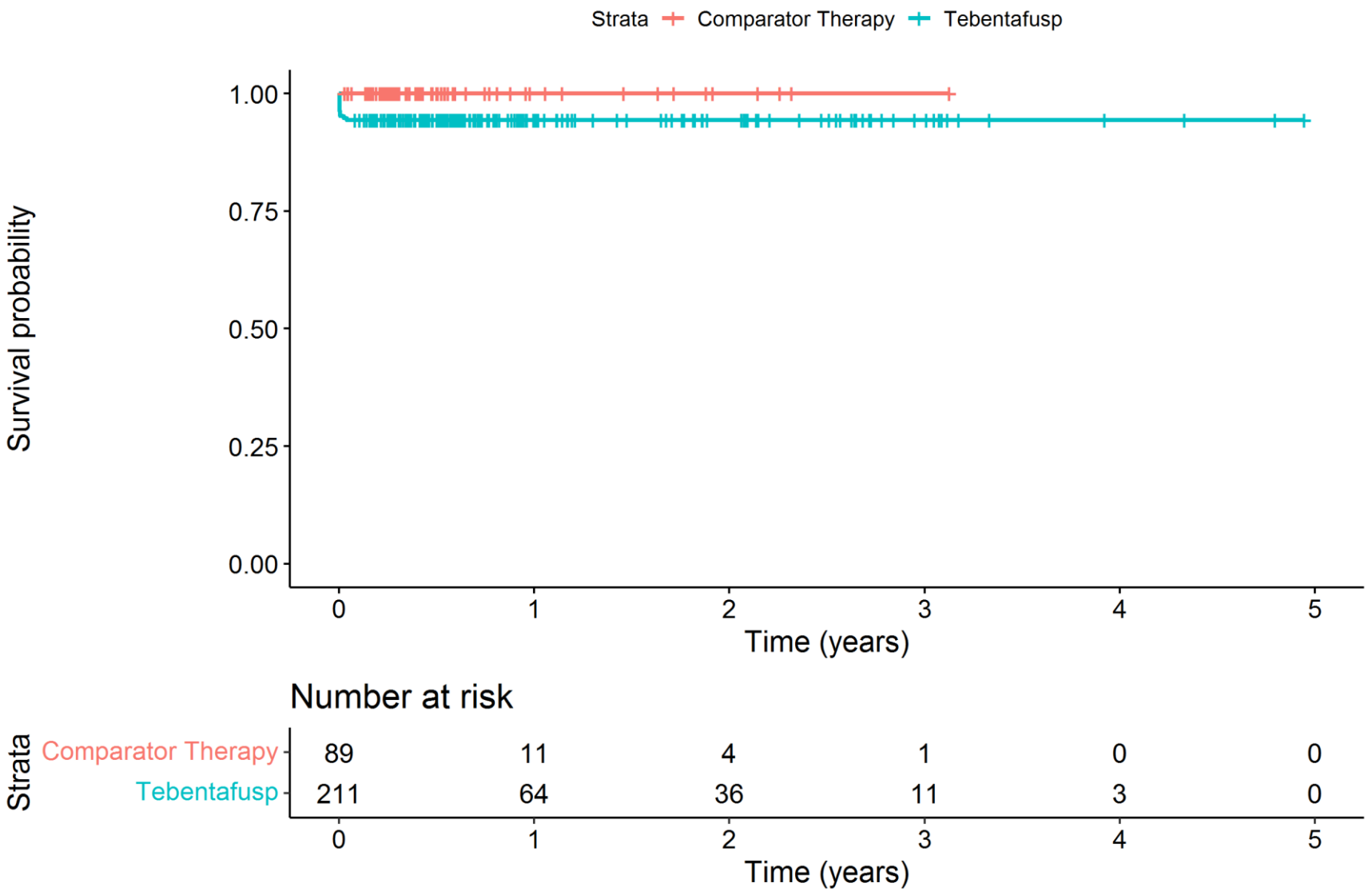
Erkrankungen des Immunsystems- Gesamt



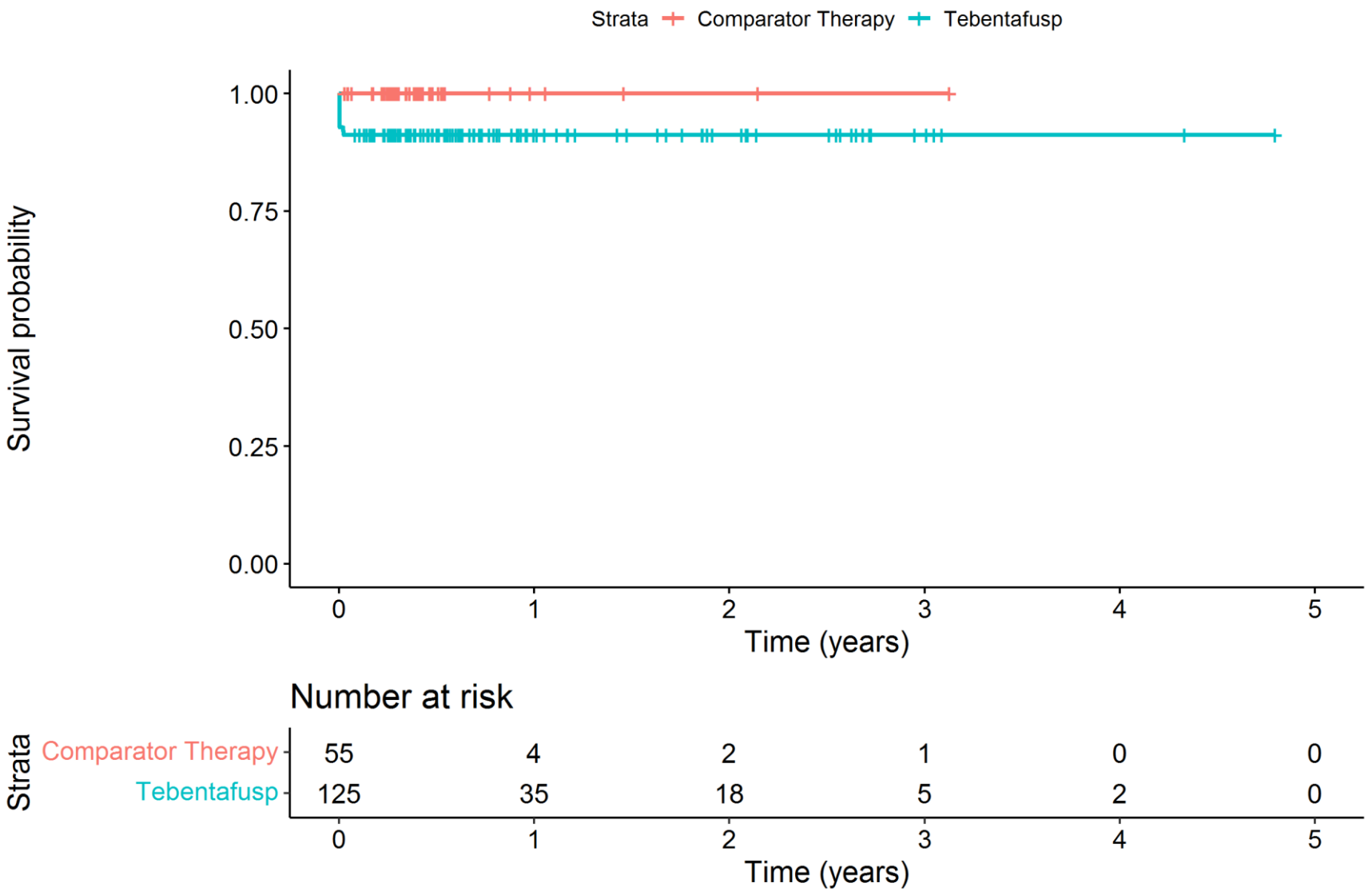
Erkrankungen des Immunsystems- Hispanisch



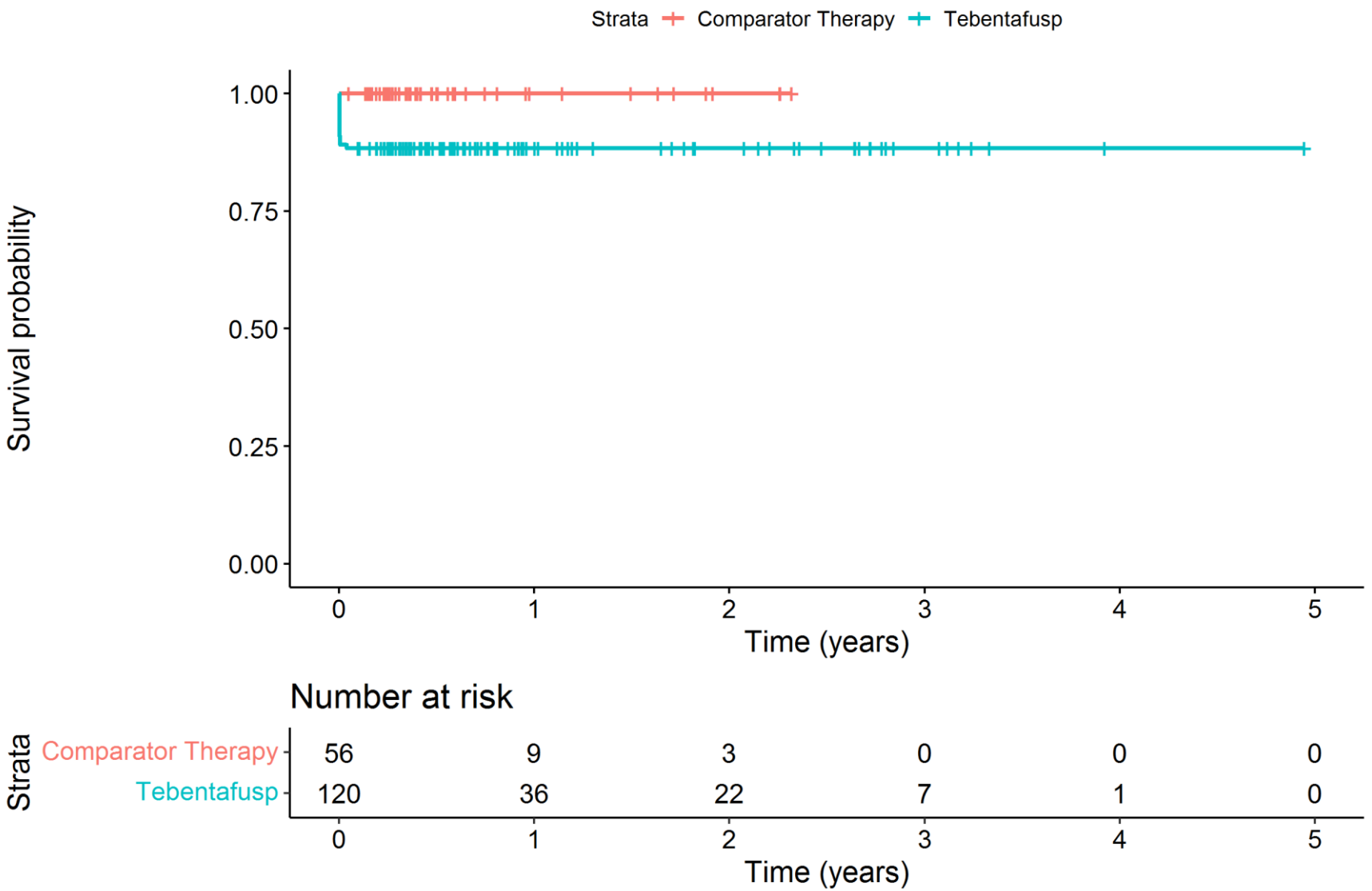
Erkrankungen des Immunsystems- Nicht-hispanisch



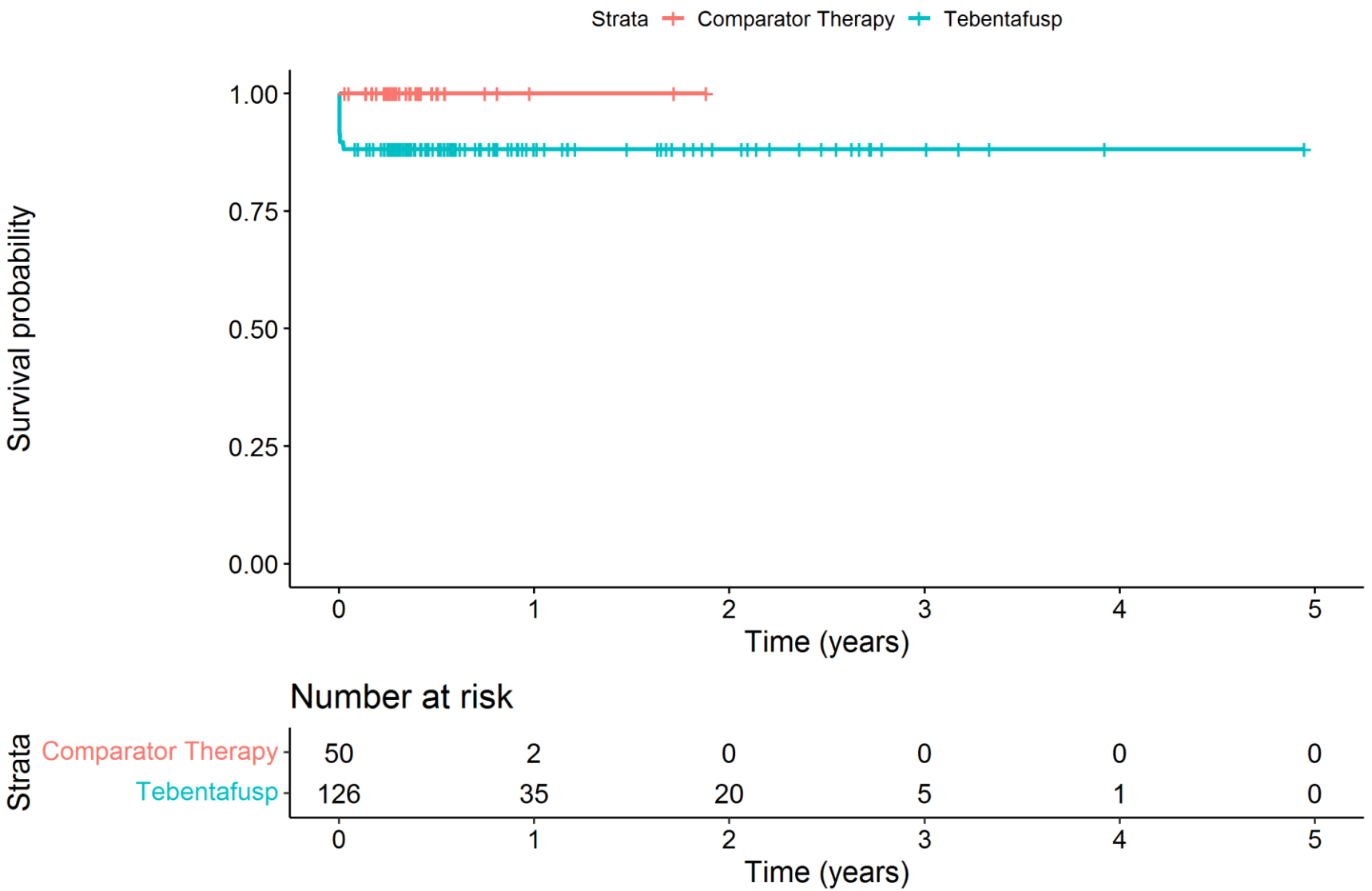
Erkrankungen des Immunsystems- Männlich



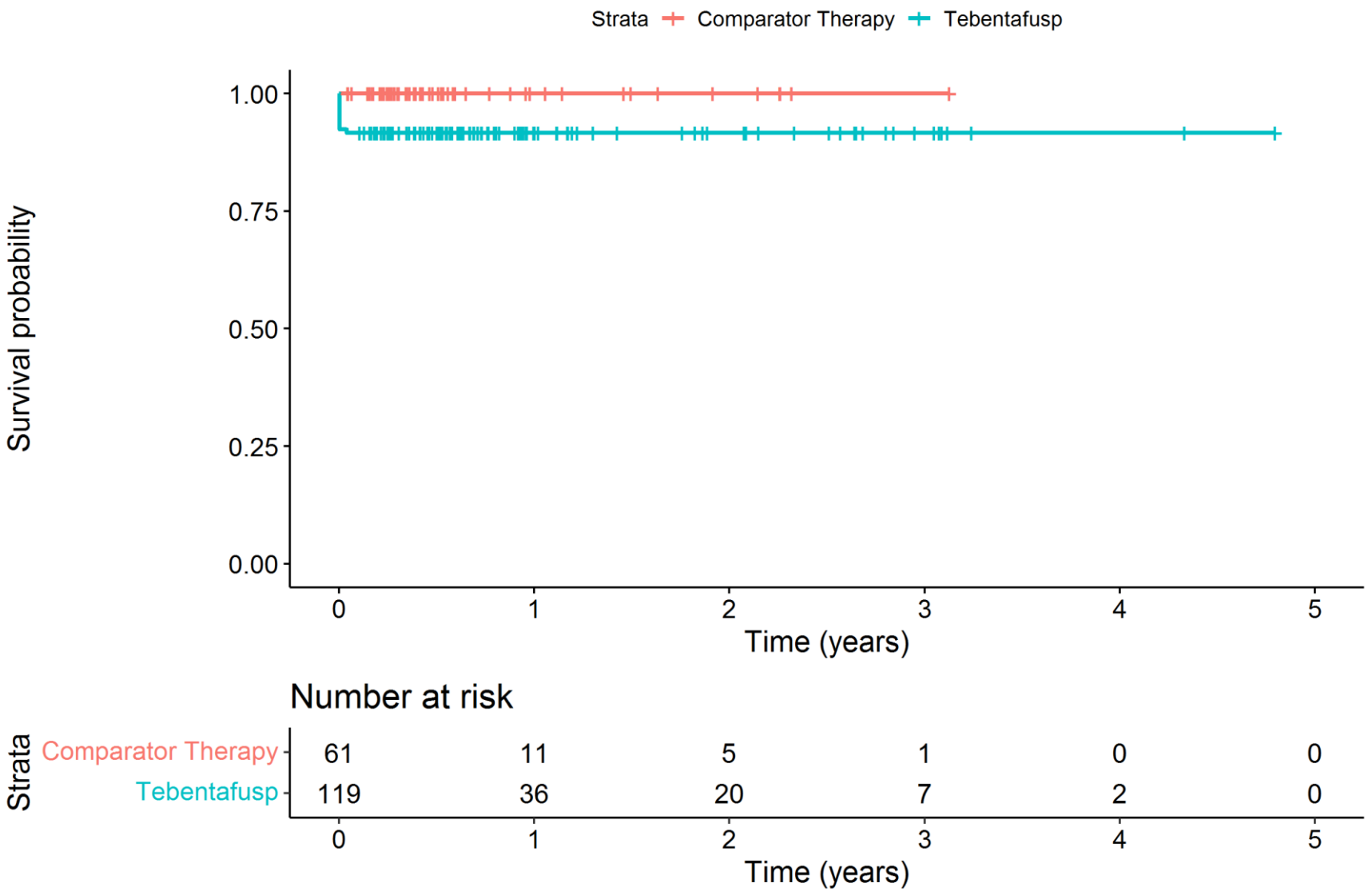
Erkrankungen des Immunsystems- Weiblich



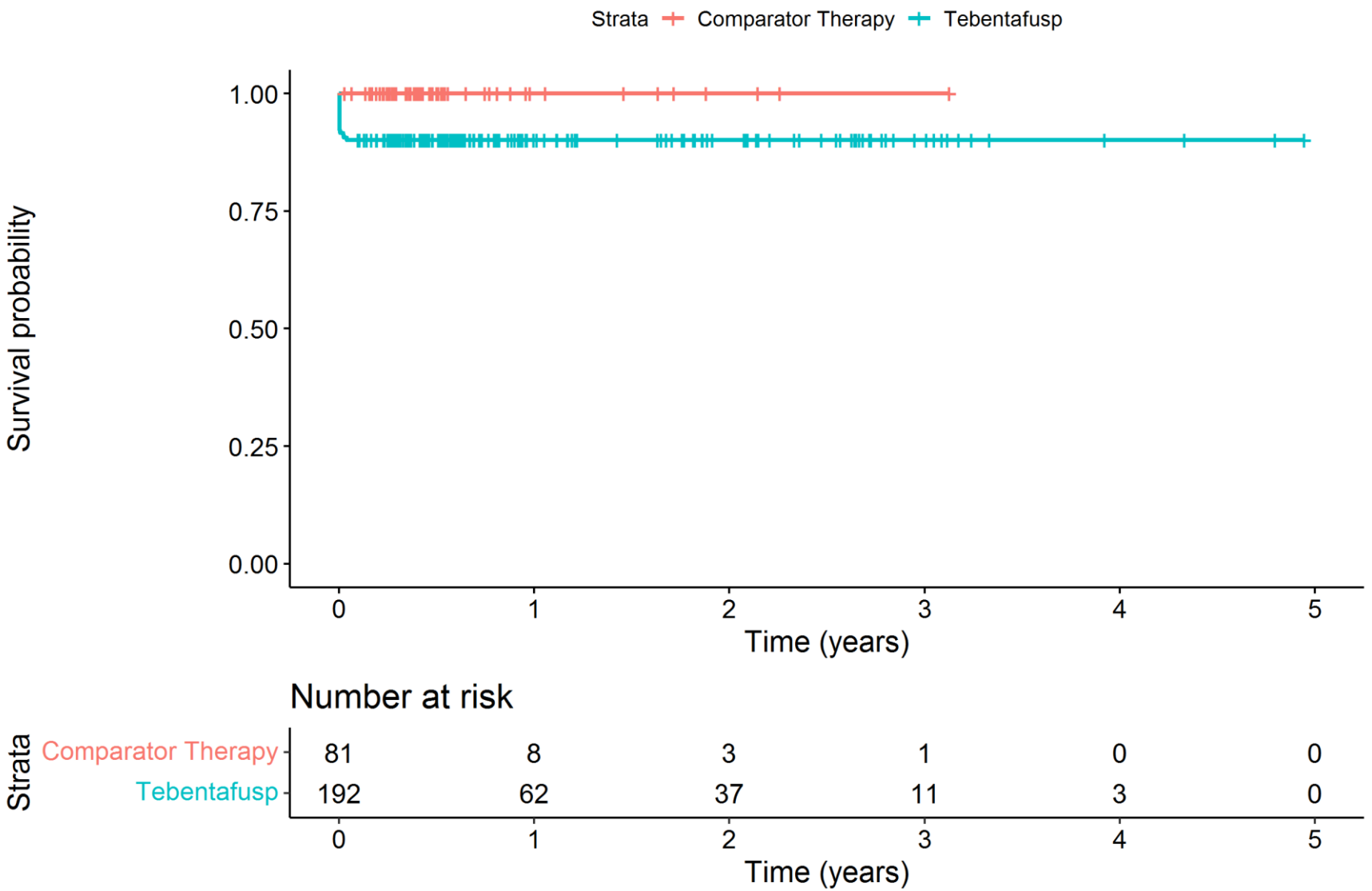
Erkrankungen des Immunsystems- <65



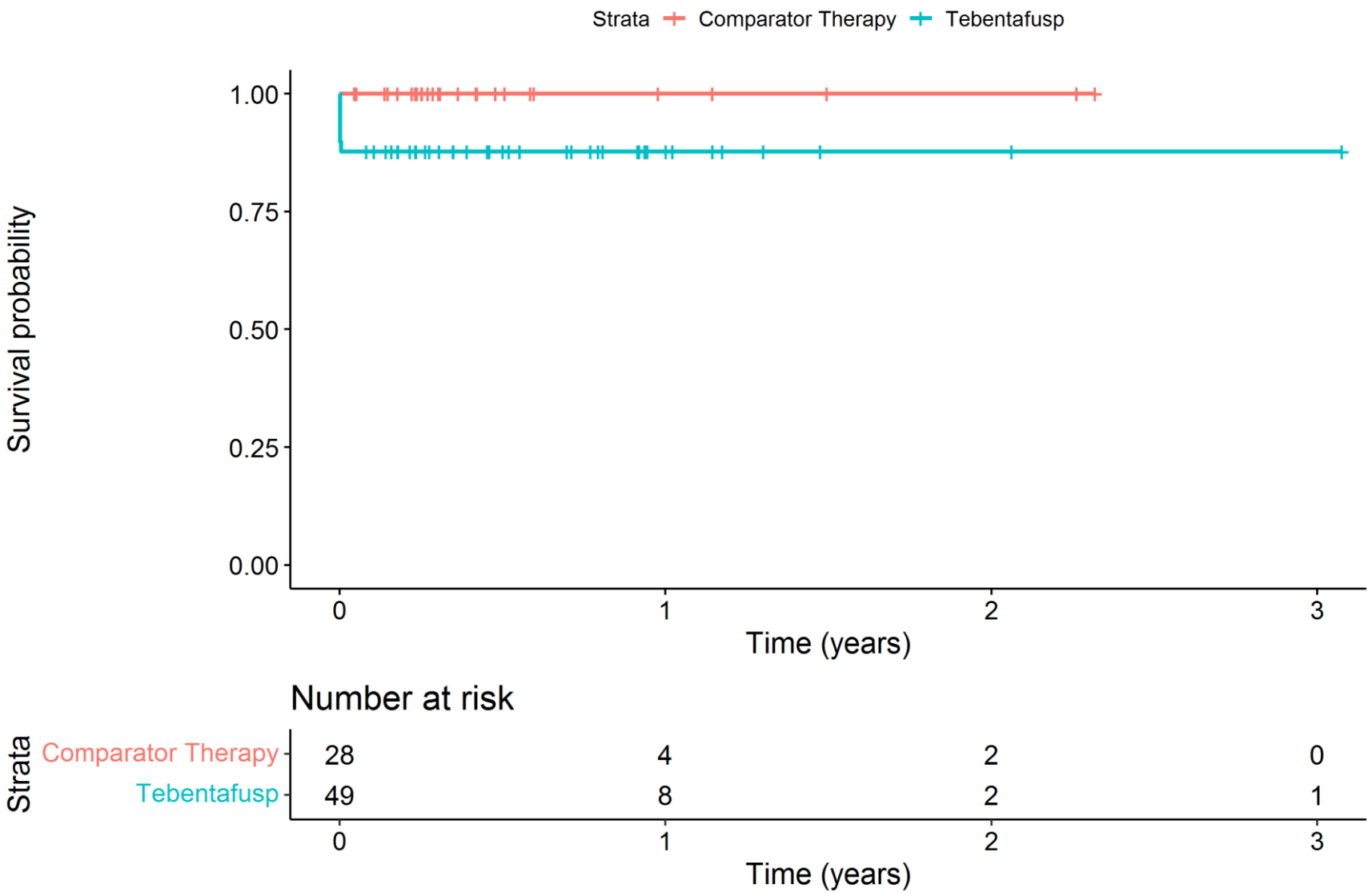
Erkrankungen des Immunsystems- ≥65



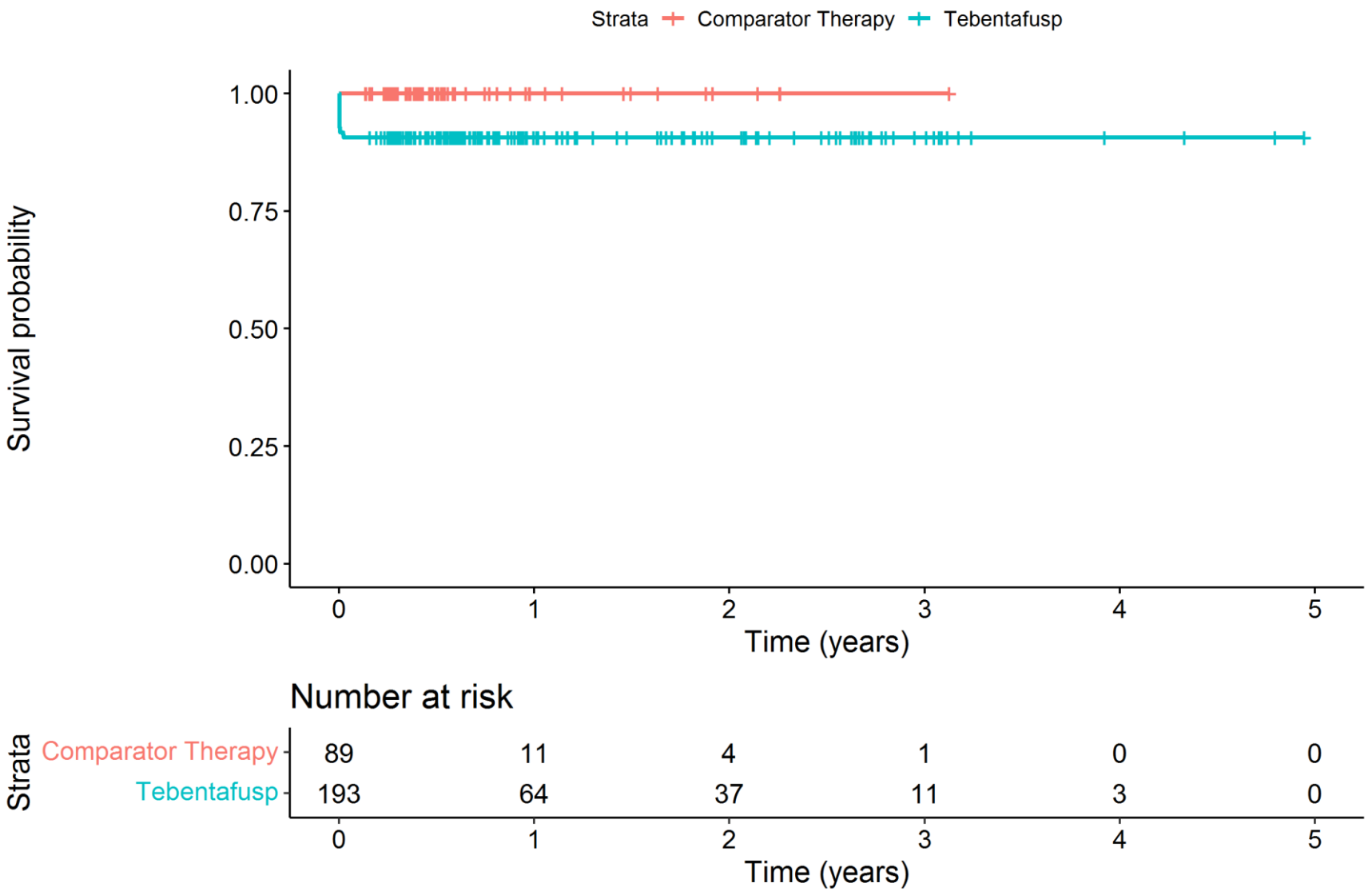
Erkrankungen des Immunsystems- ECOG 0



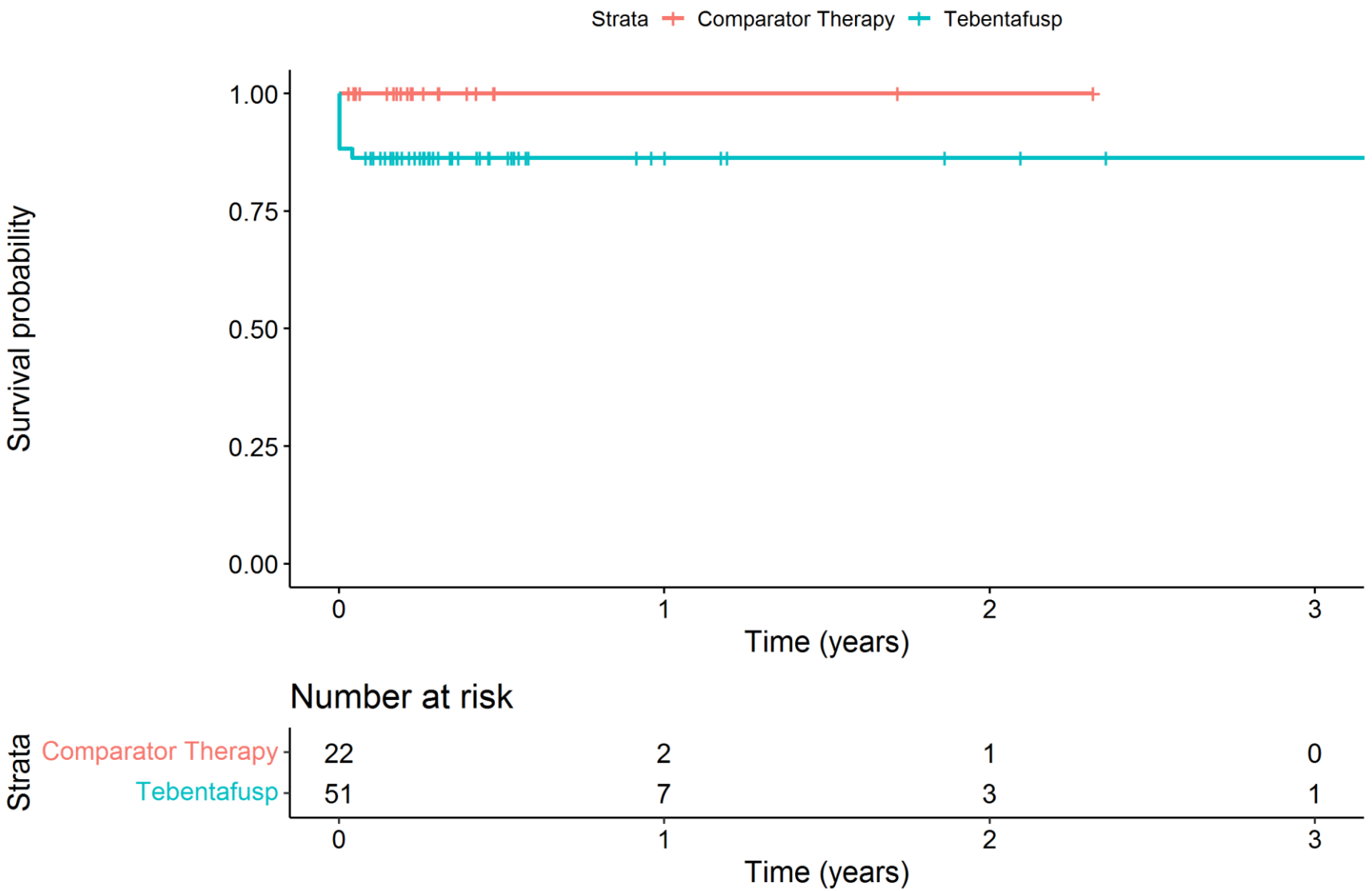
Erkrankungen des Immunsystems- ECOG 1



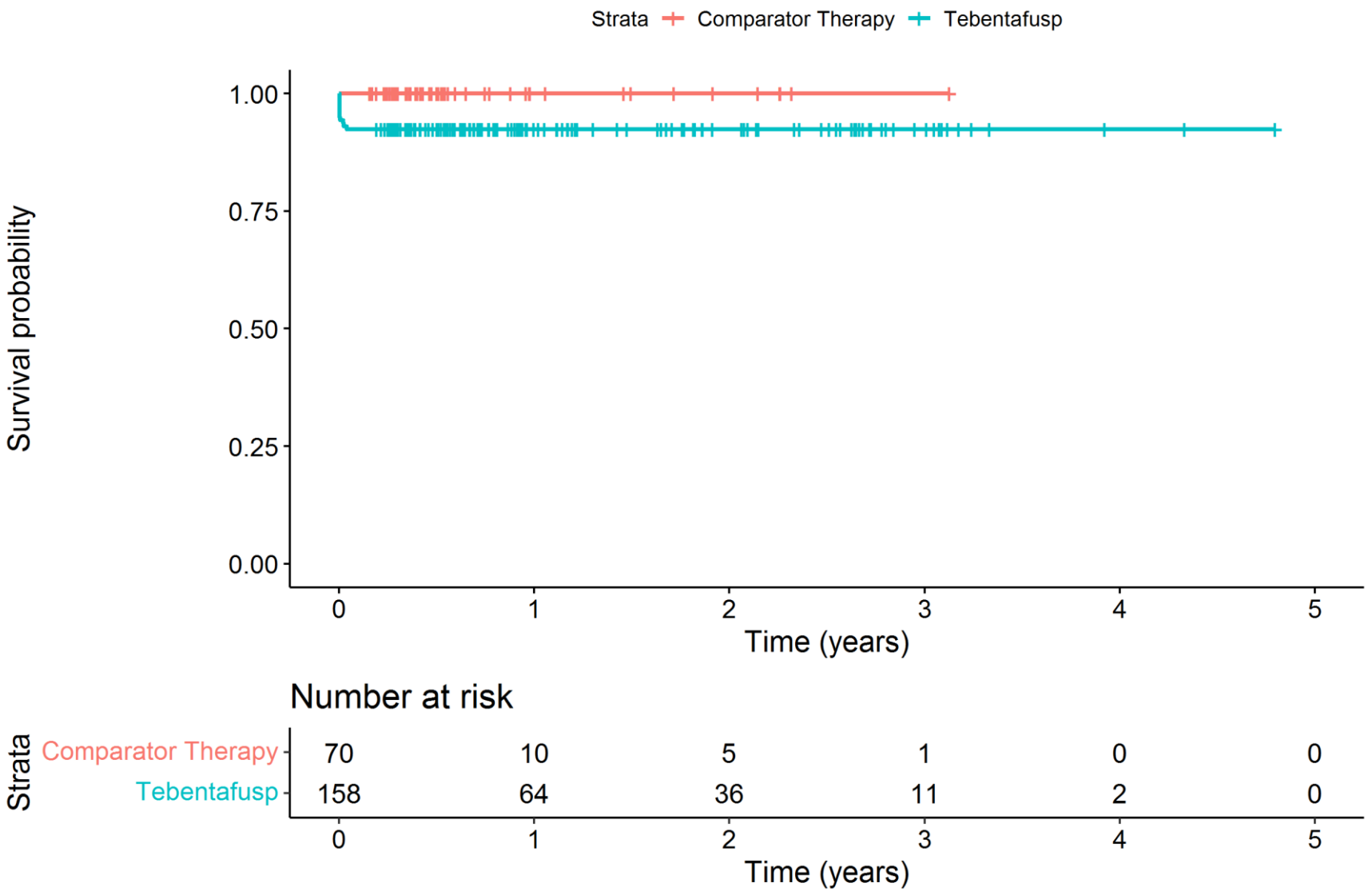
Erkrankungen des Immunsystems- ALP ≤ ULN



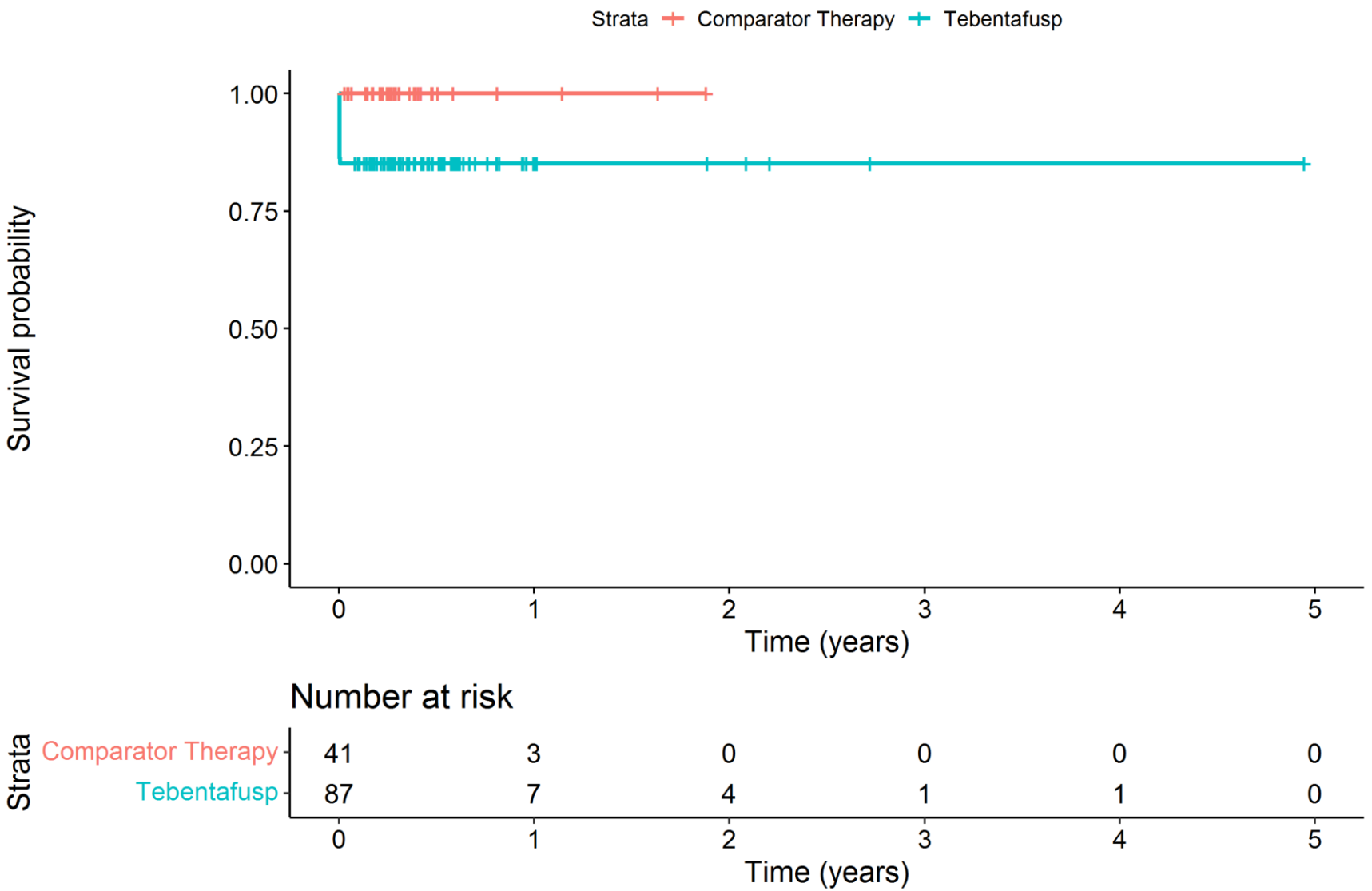
Erkrankungen des Immunsystems- ALP > ULN



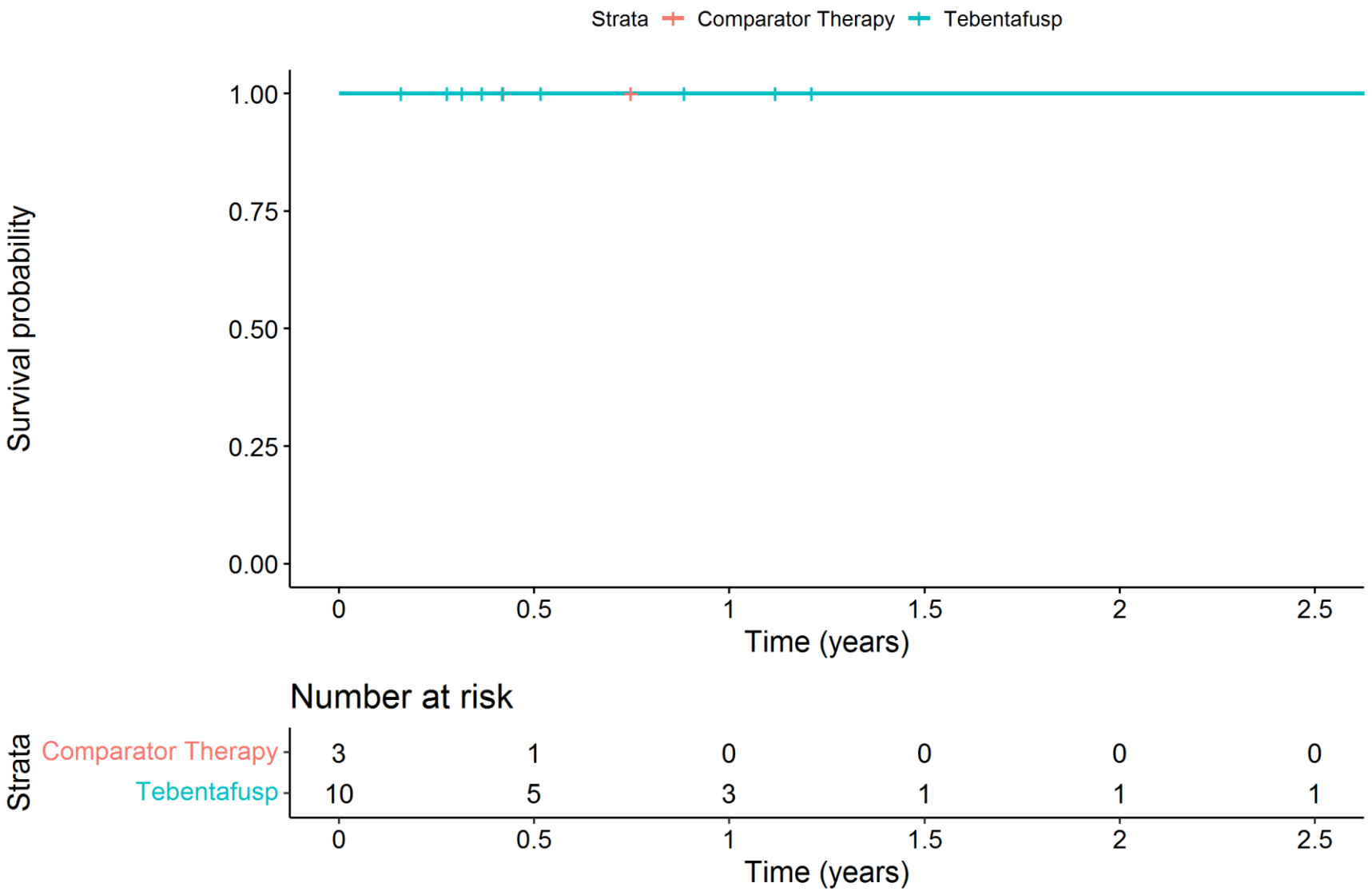
Erkrankungen des Immunsystems- LDH =< ULN



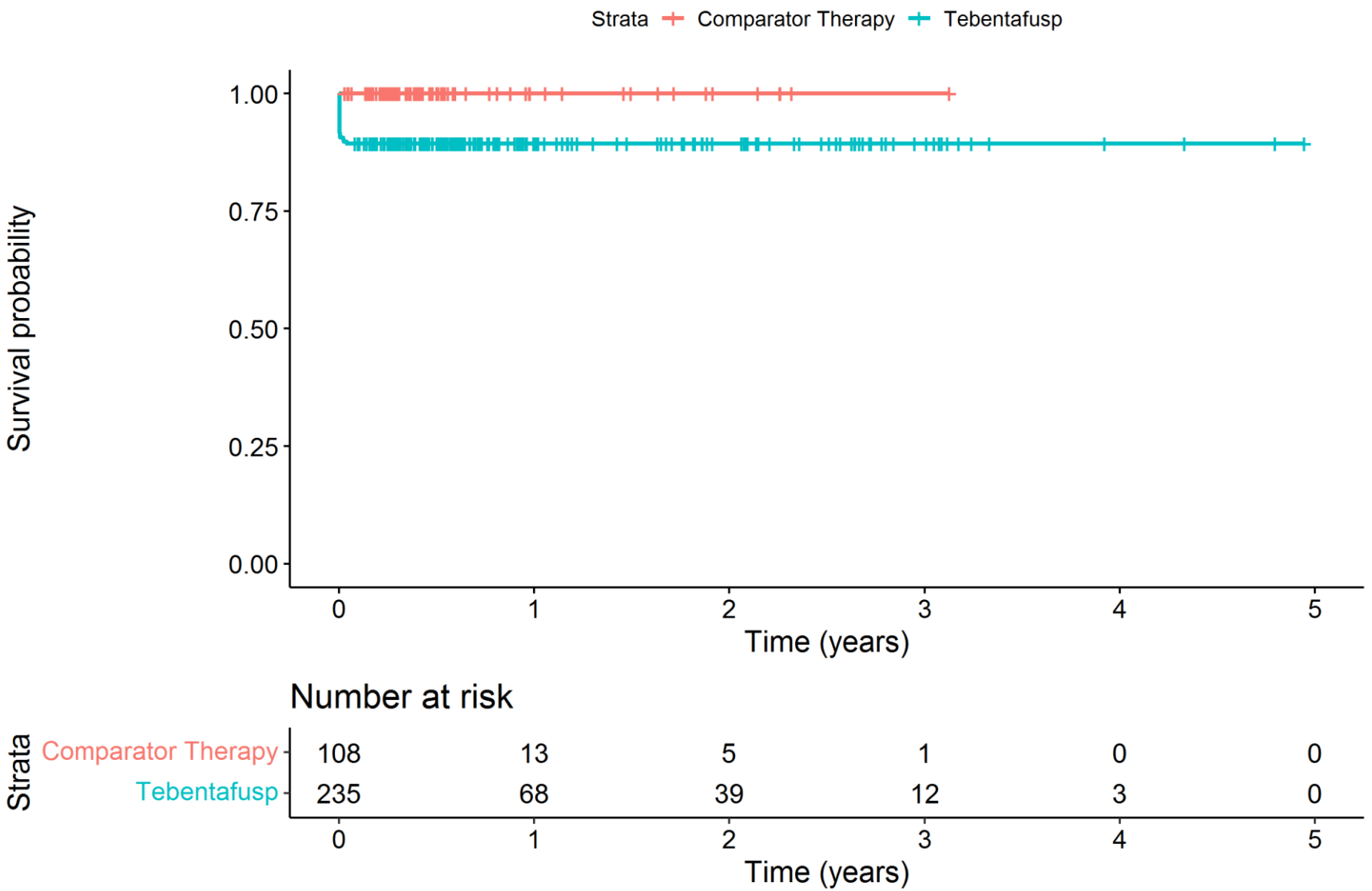
Erkrankungen des Immunsystems- LDH > ULN



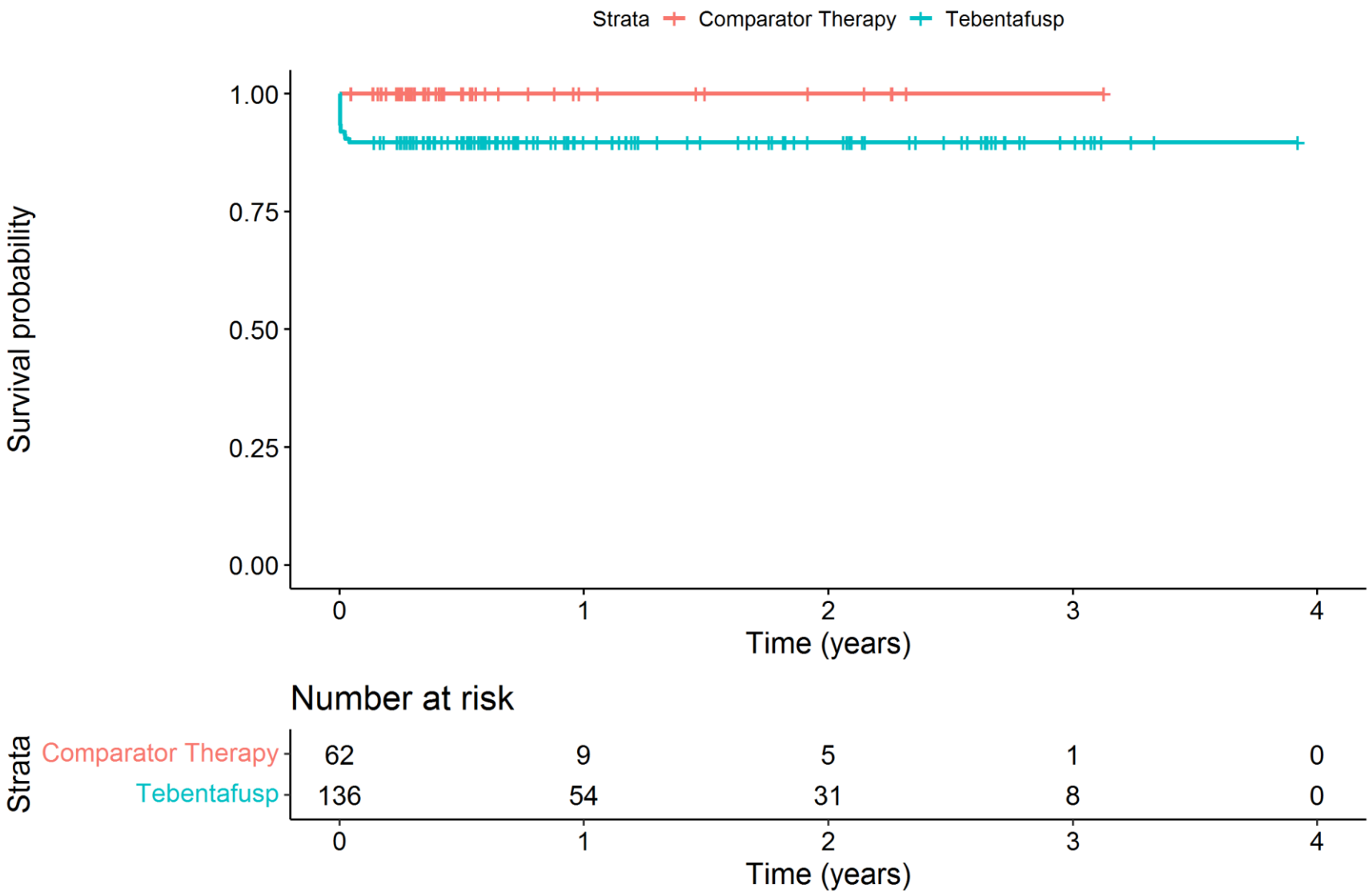
Erkrankungen des Immunsystems- Vorherige Therapie adjuvant/neoadjuvant



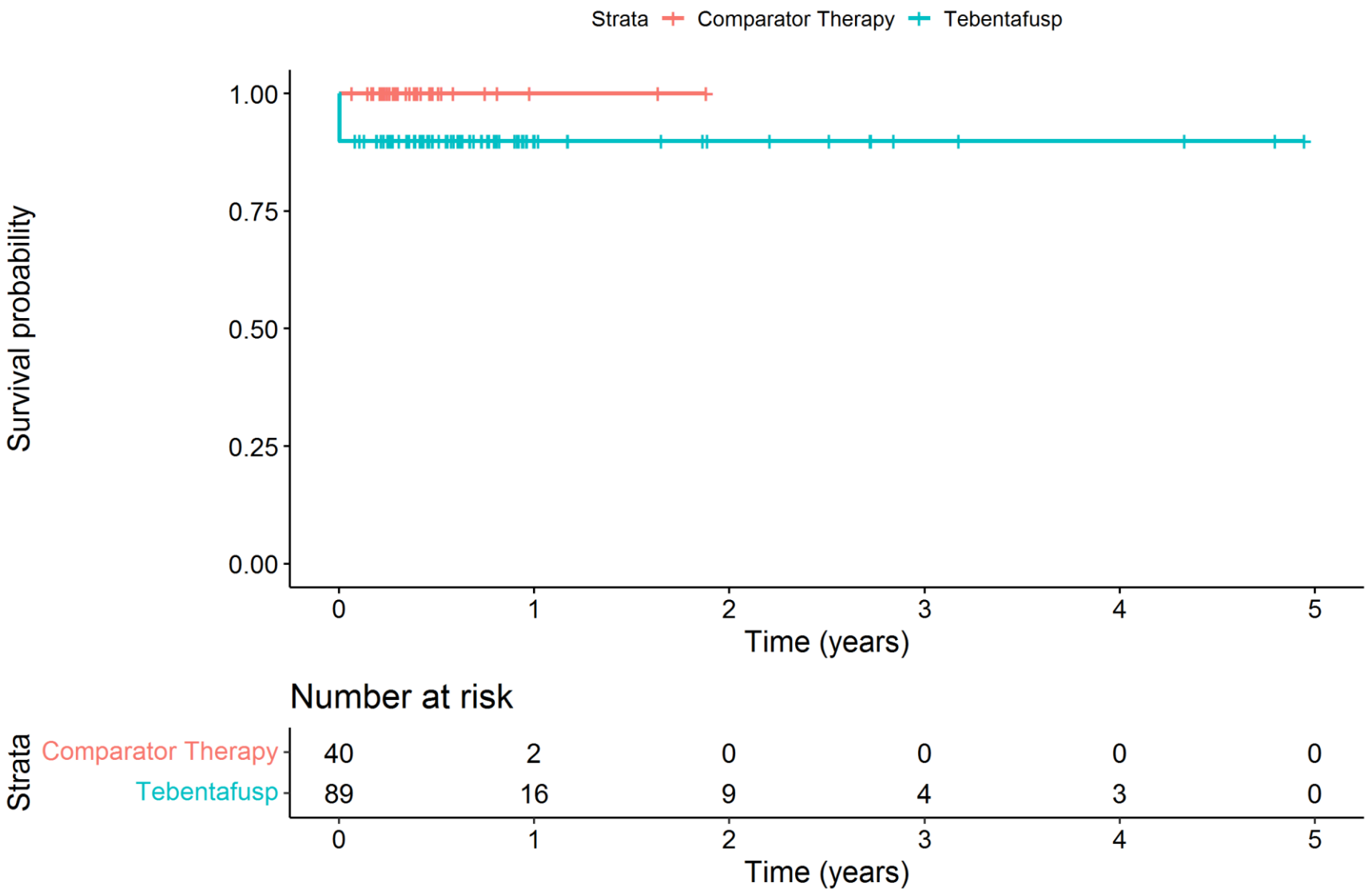
Erkrankungen des Immunsystems- Keine Vorherige Therapie adjuvant/neoadjuvant



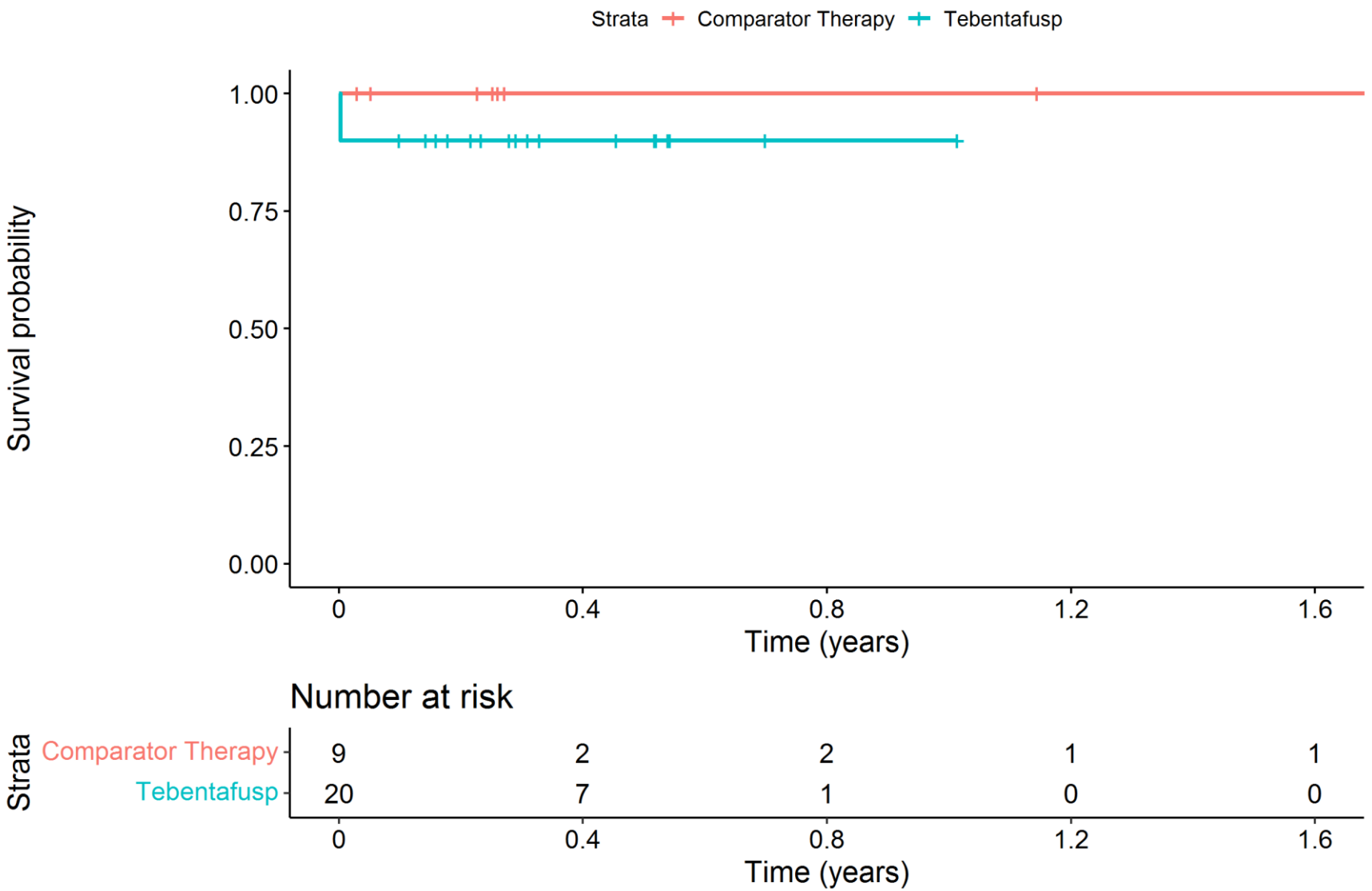
Erkrankungen des Immunsystems- Läsion ≤ 3cm



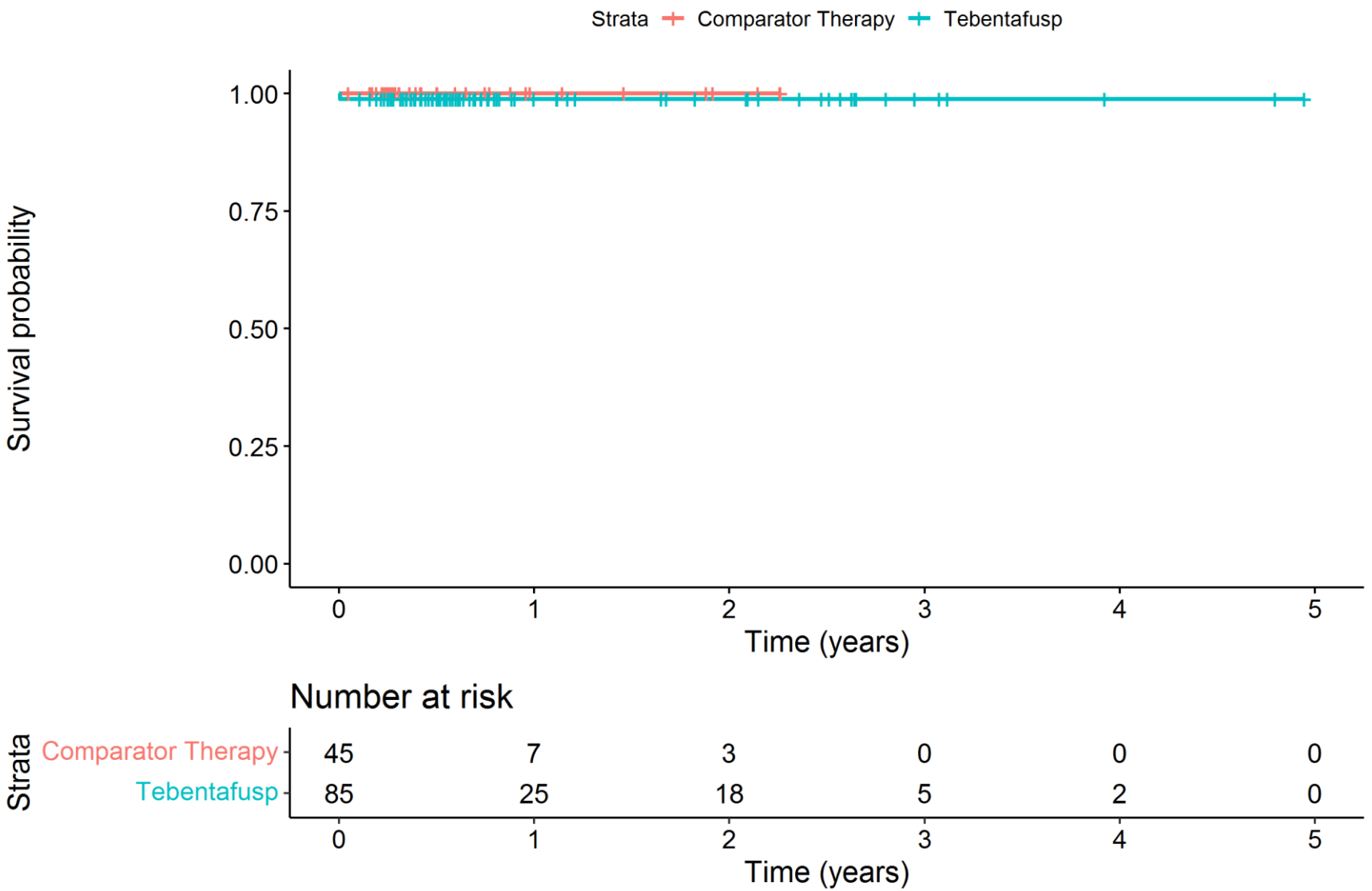
Erkrankungen des Immunsystems- Läsion 3,1-8,0 cm



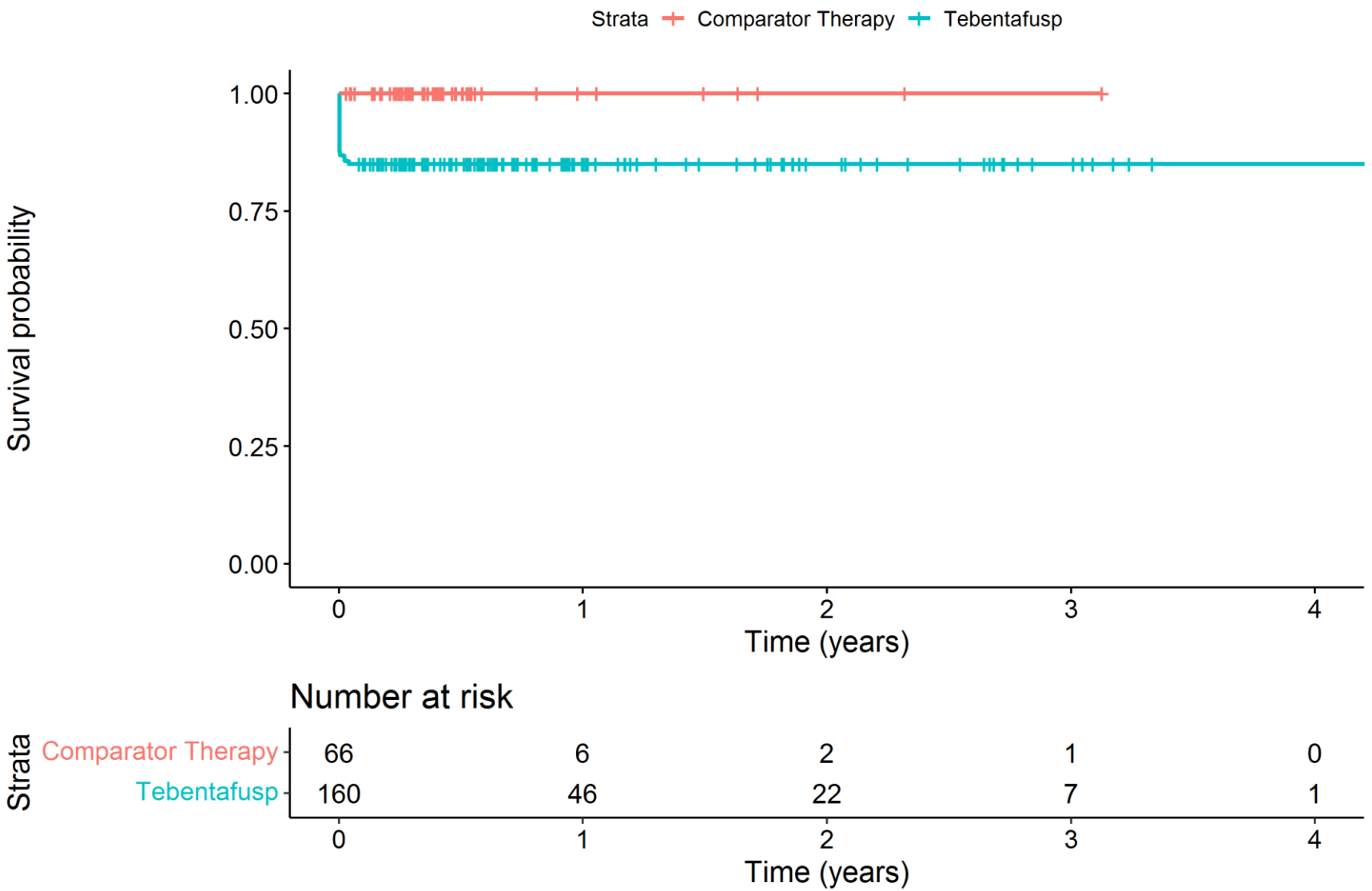
Erkrankungen des Immunsystems- Läsion ≥8,1 cm



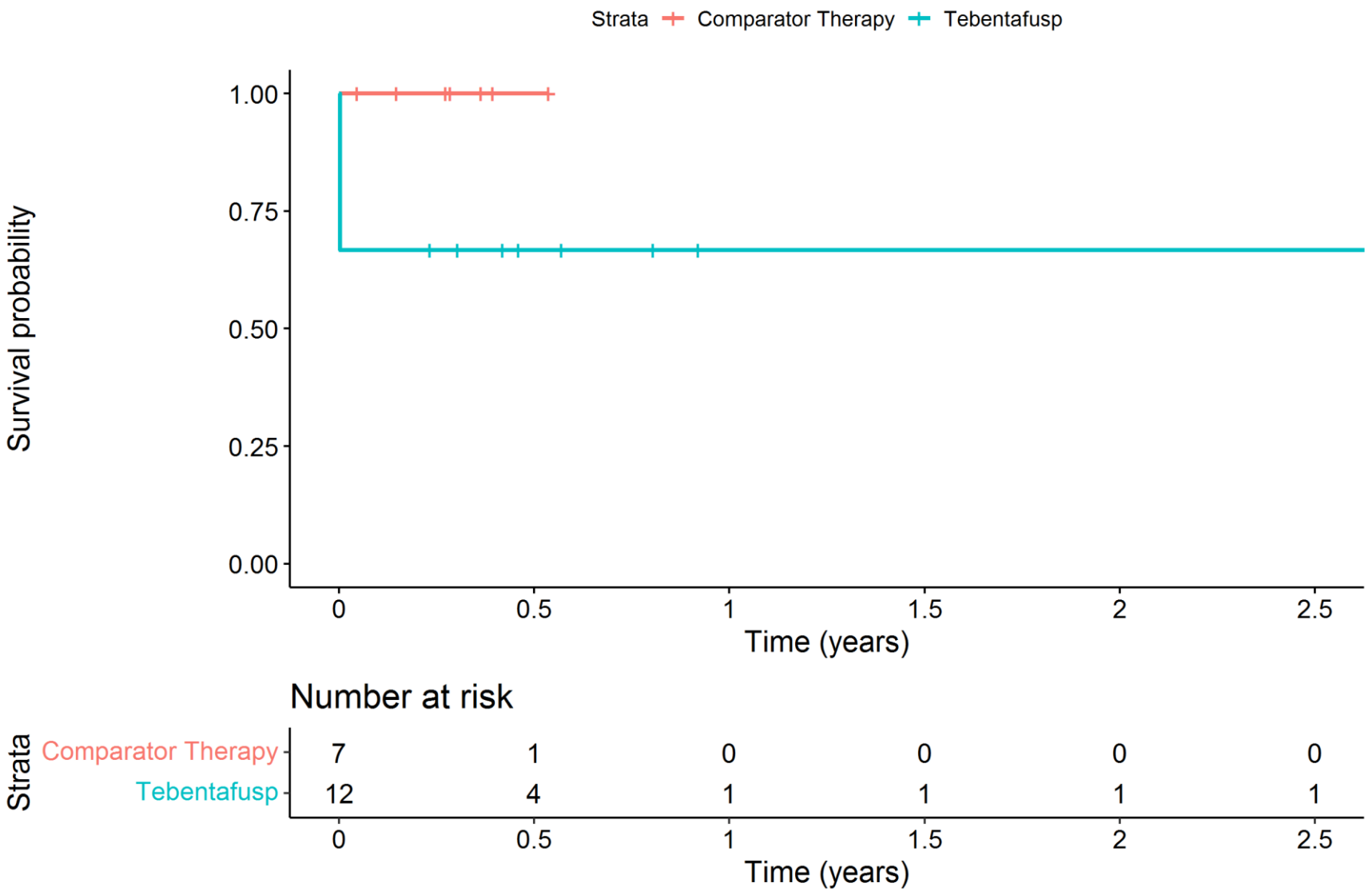
Erkrankungen des Immunsystems- Nordamerika



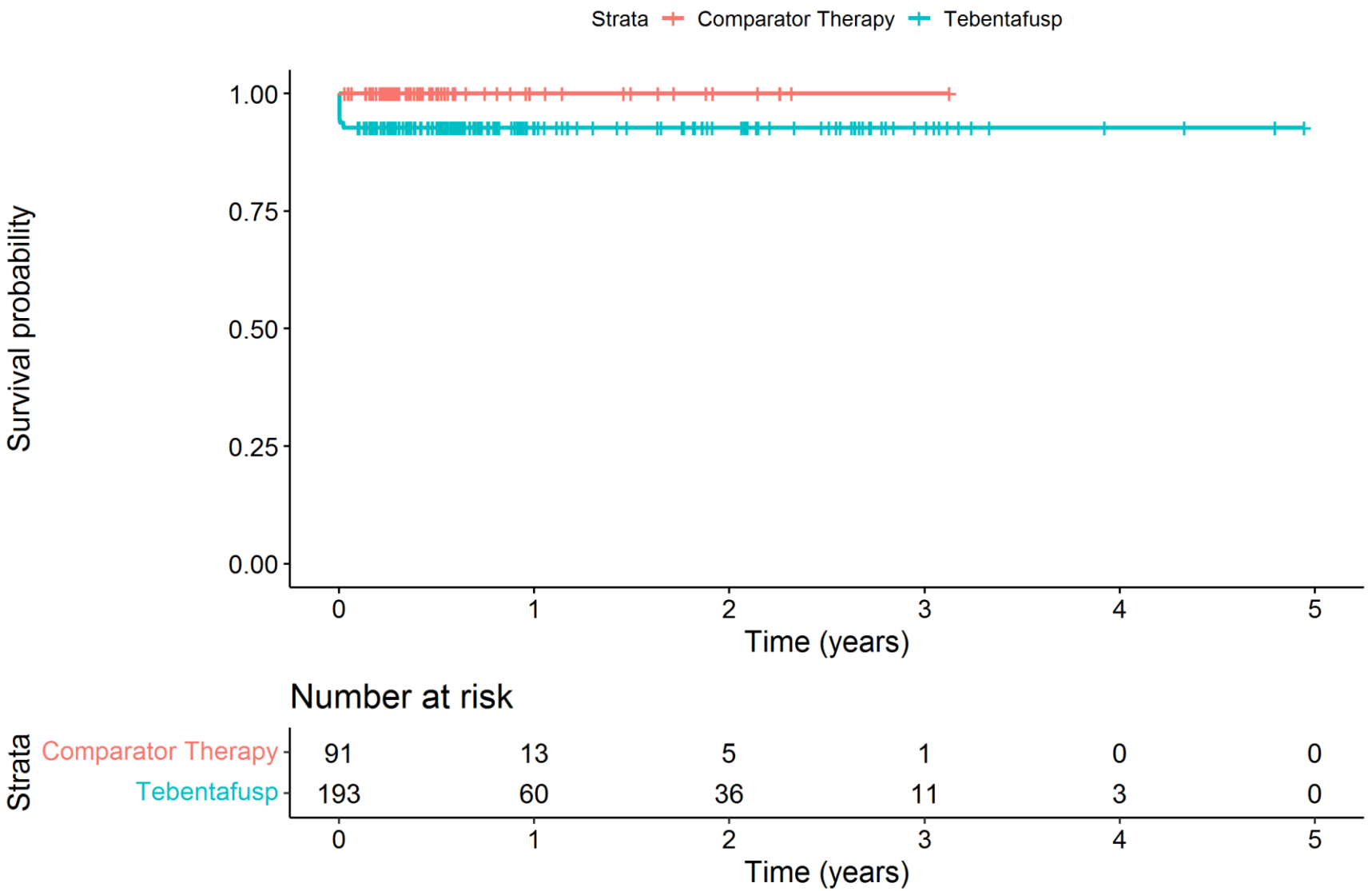
Erkrankungen des Immunsystems- Nicht-Nordamerika



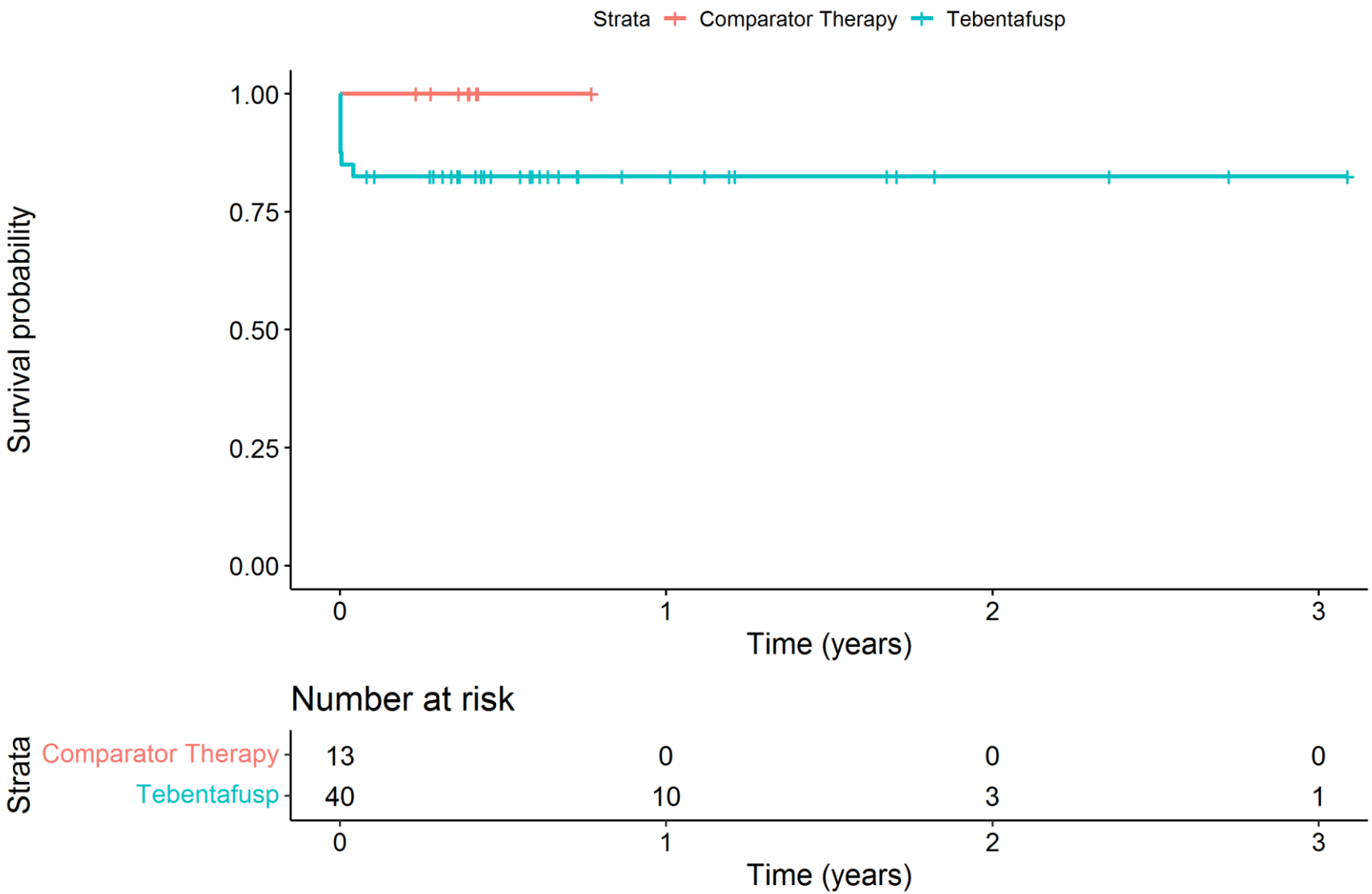
Erkrankungen des Immunsystems- Dacarbazin



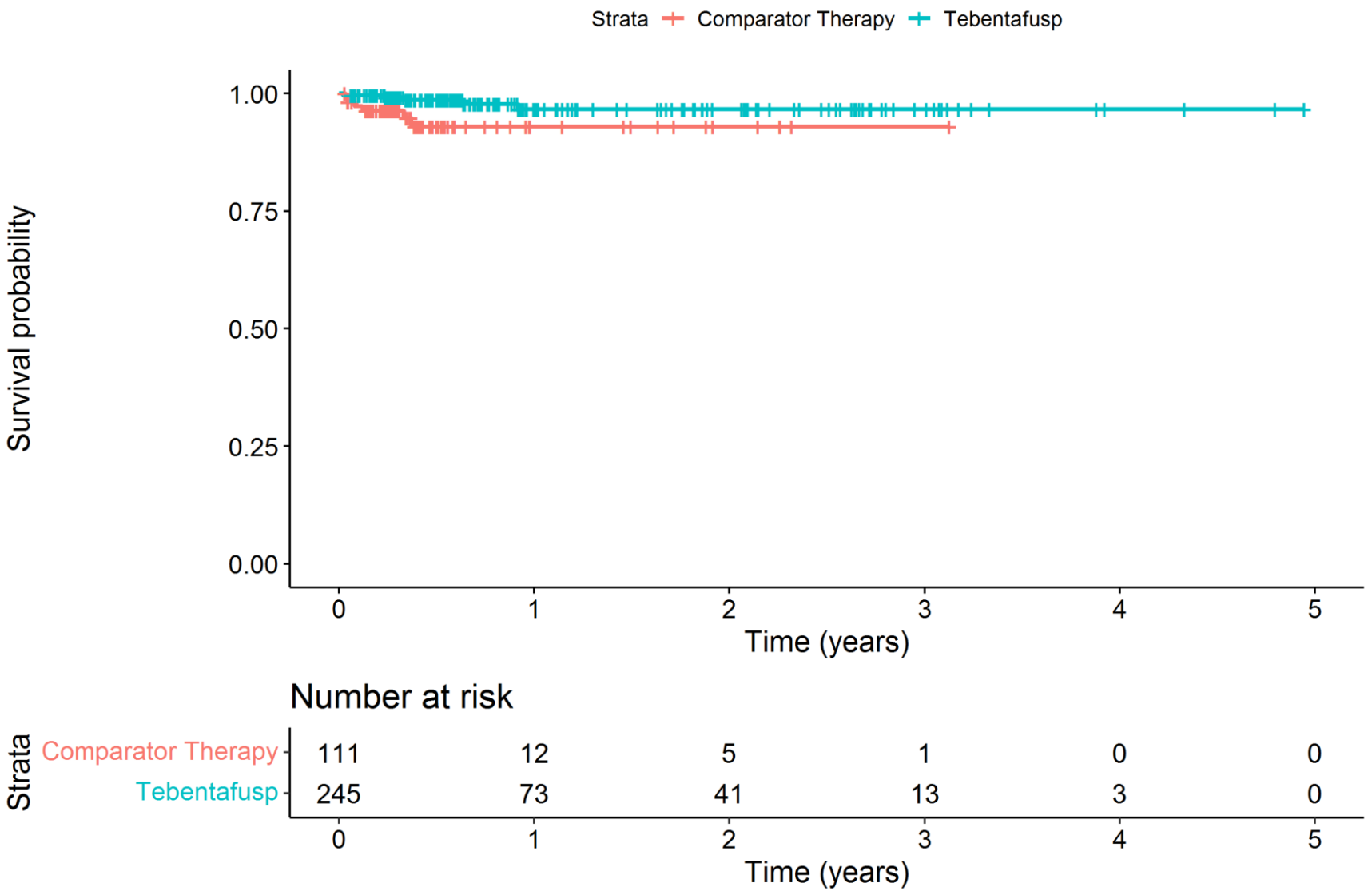
Erkrankungen des Immunsystems- Pembrolizumab



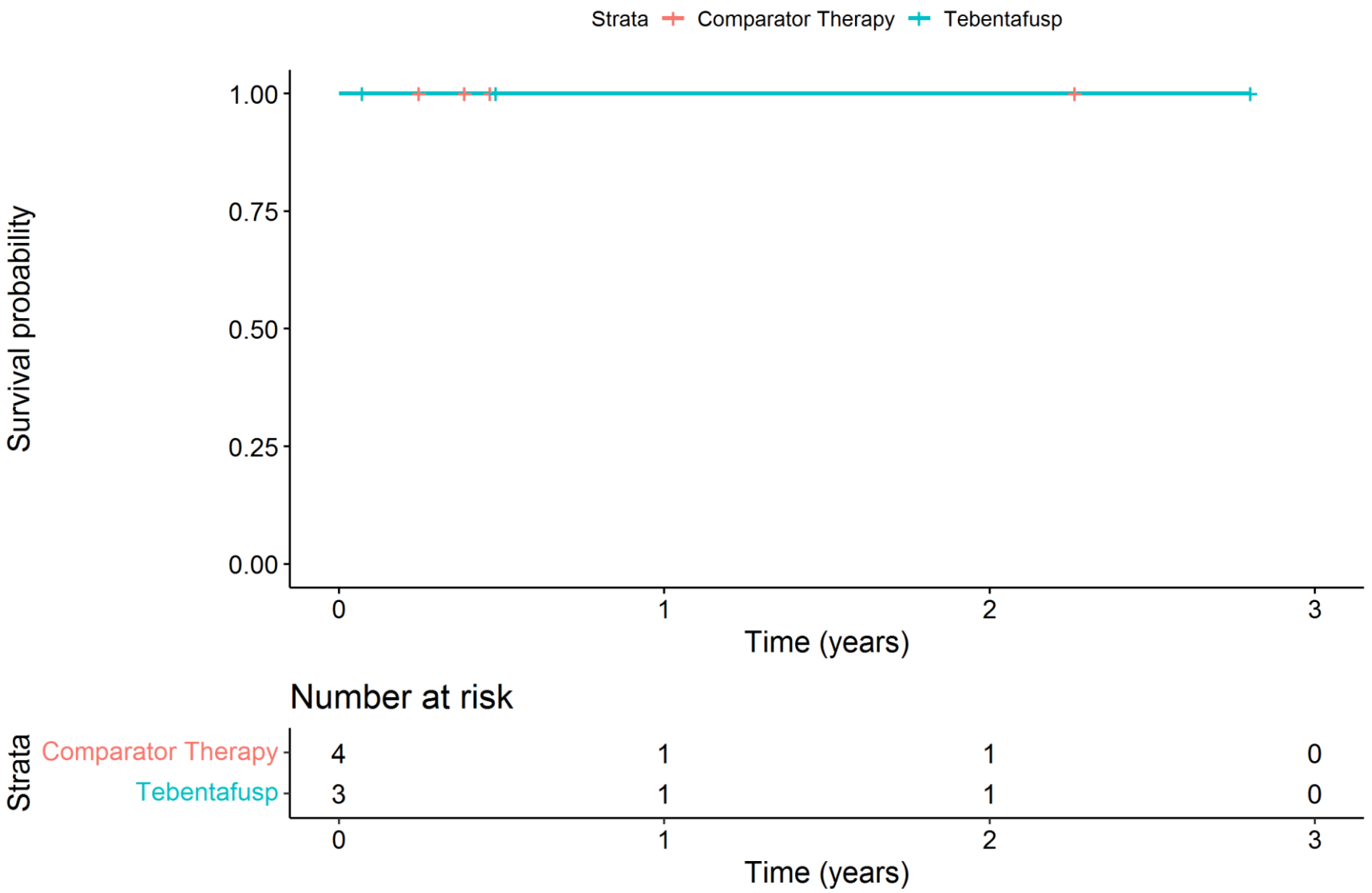
Erkrankungen des Immunsystems- Ipilimumab



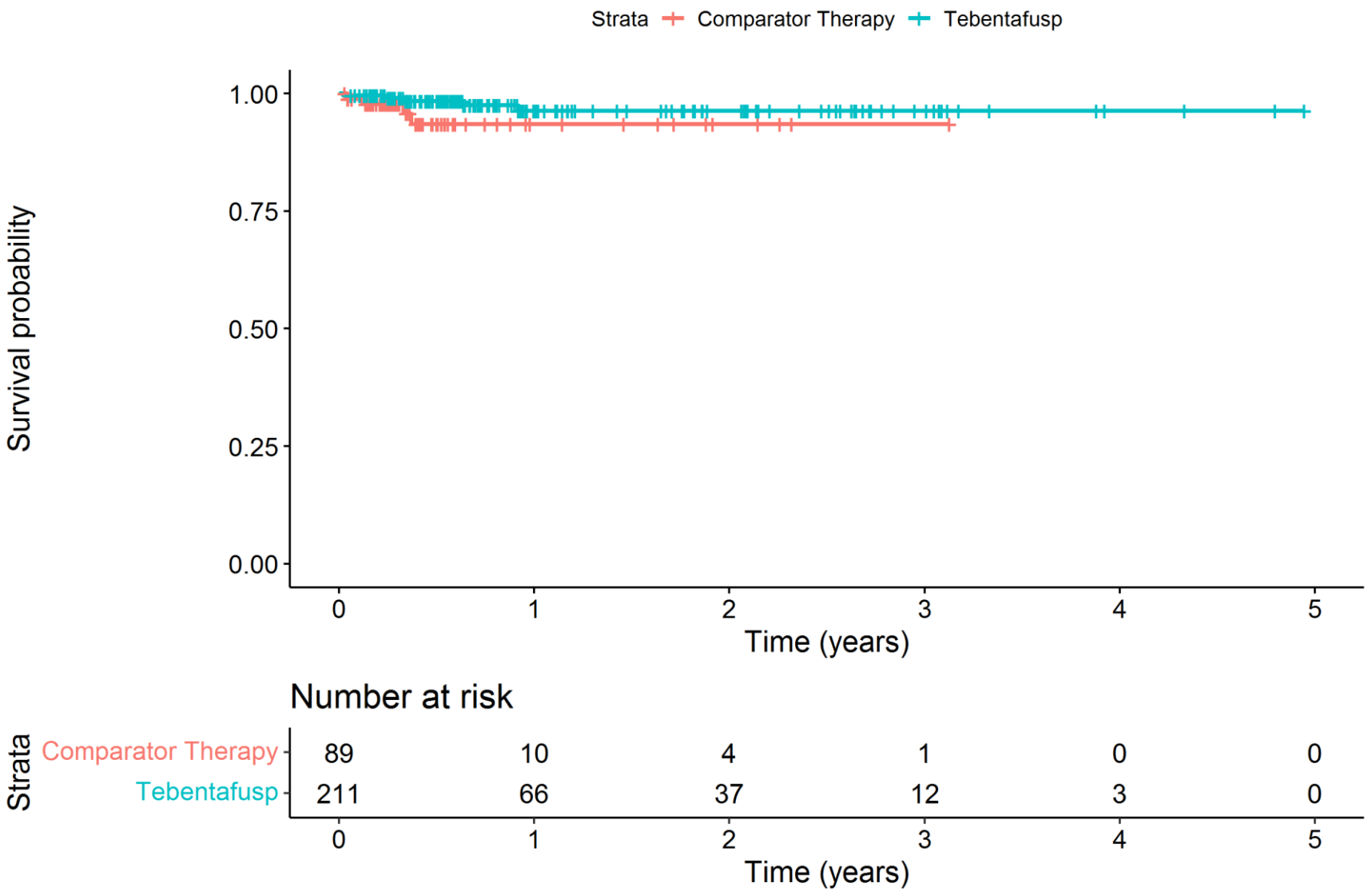
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Gesamt



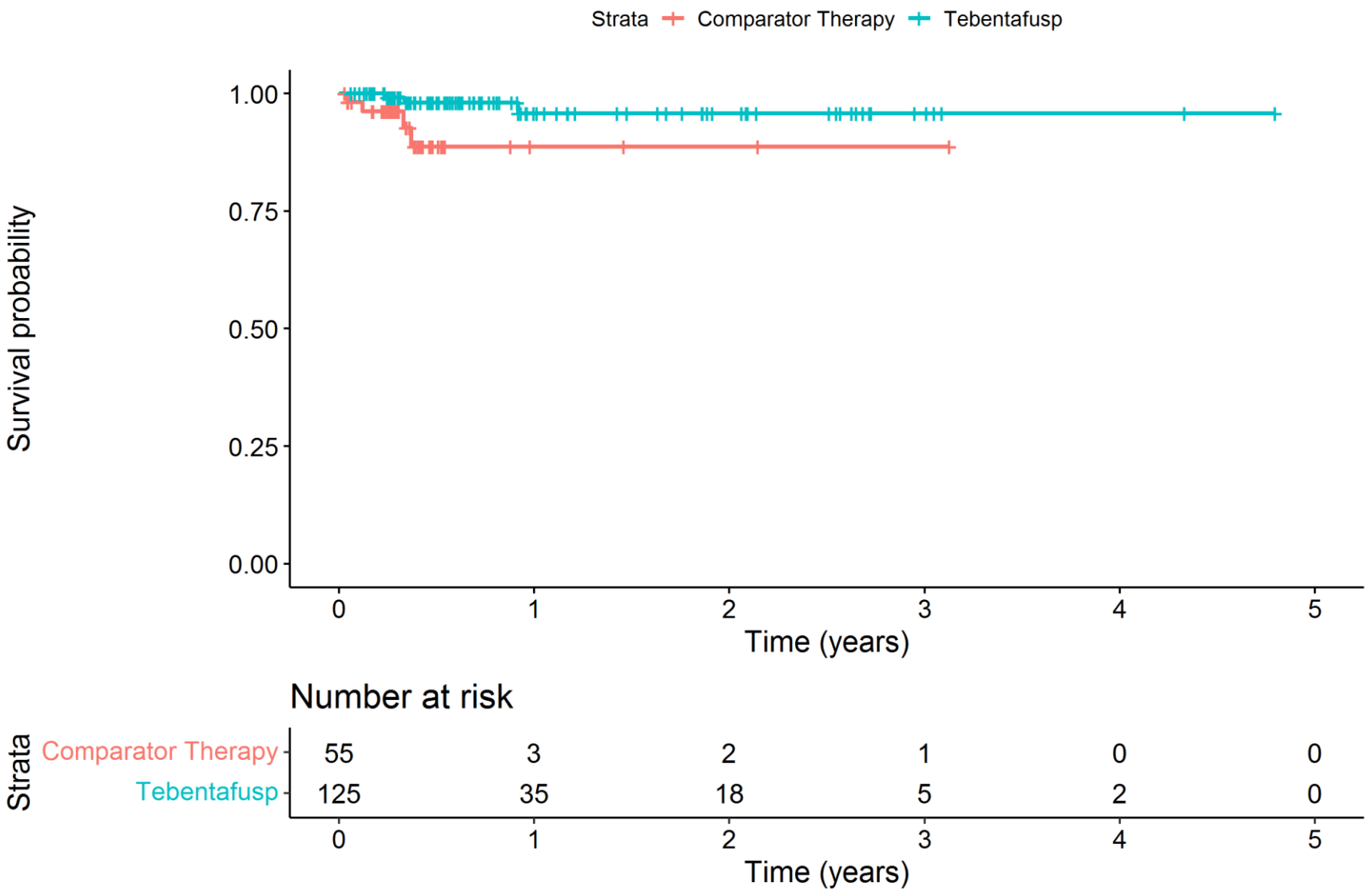
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Hispanisch



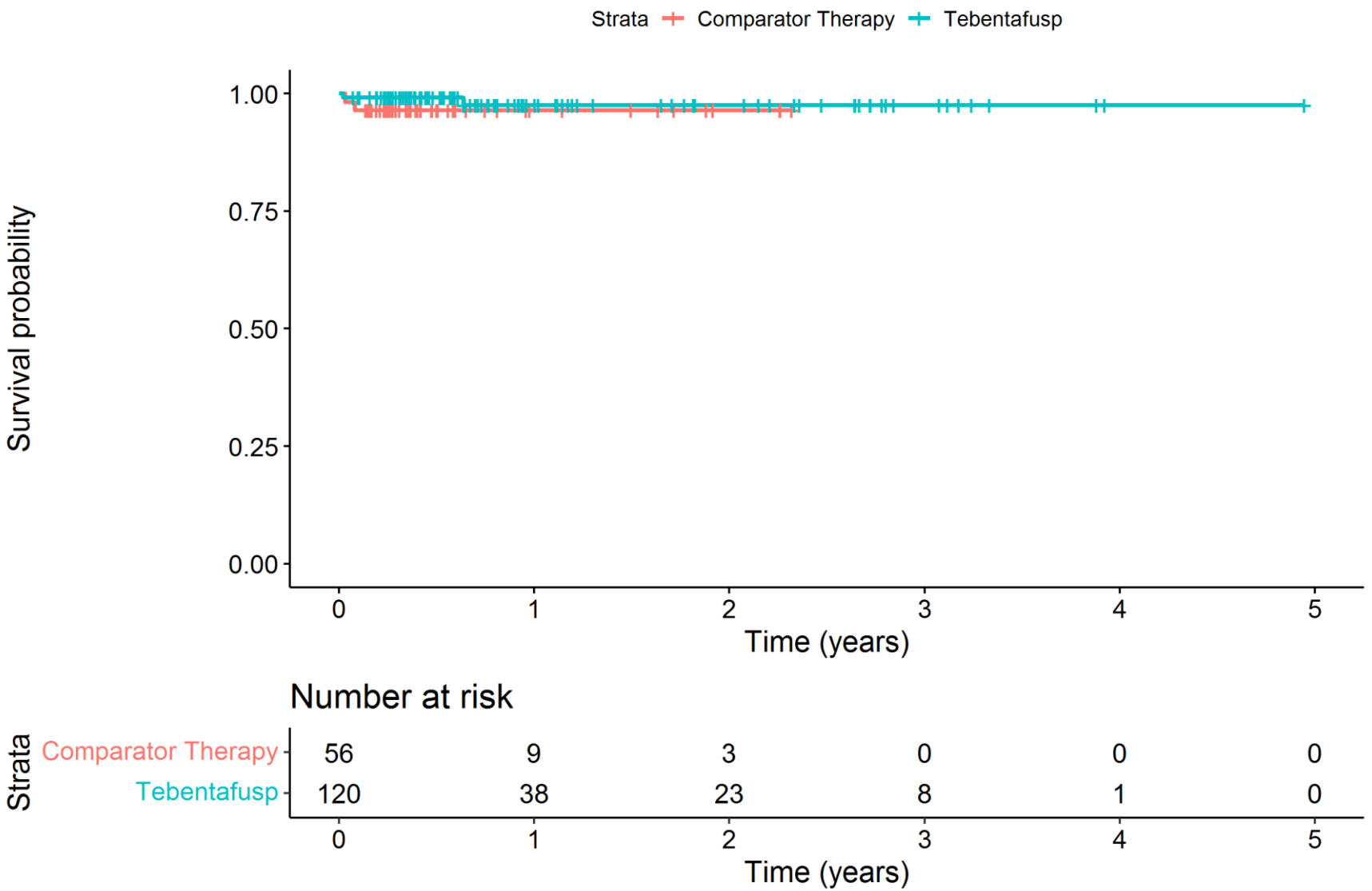
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nicht-hispanisch



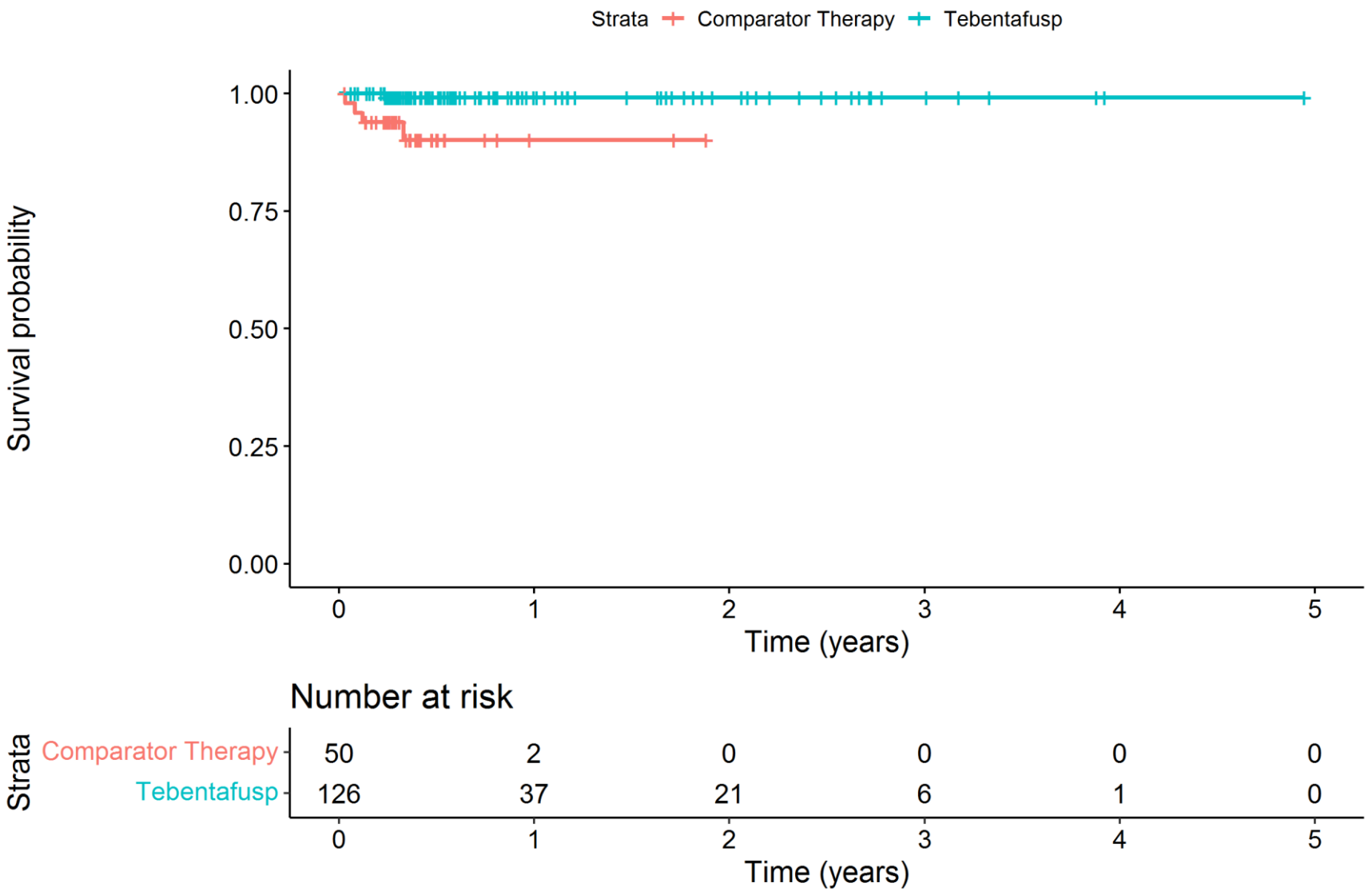
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Männlich



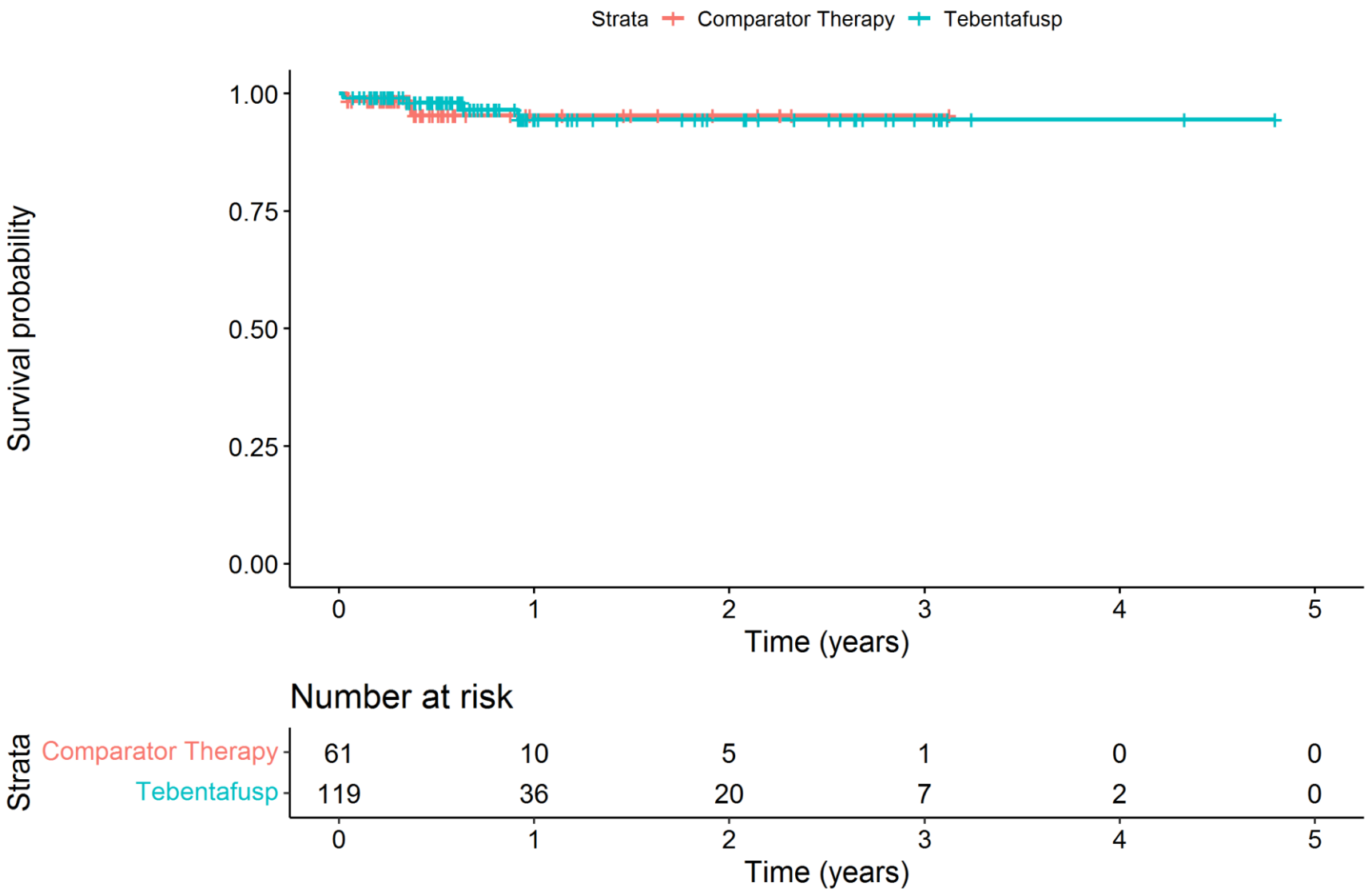
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Weiblich



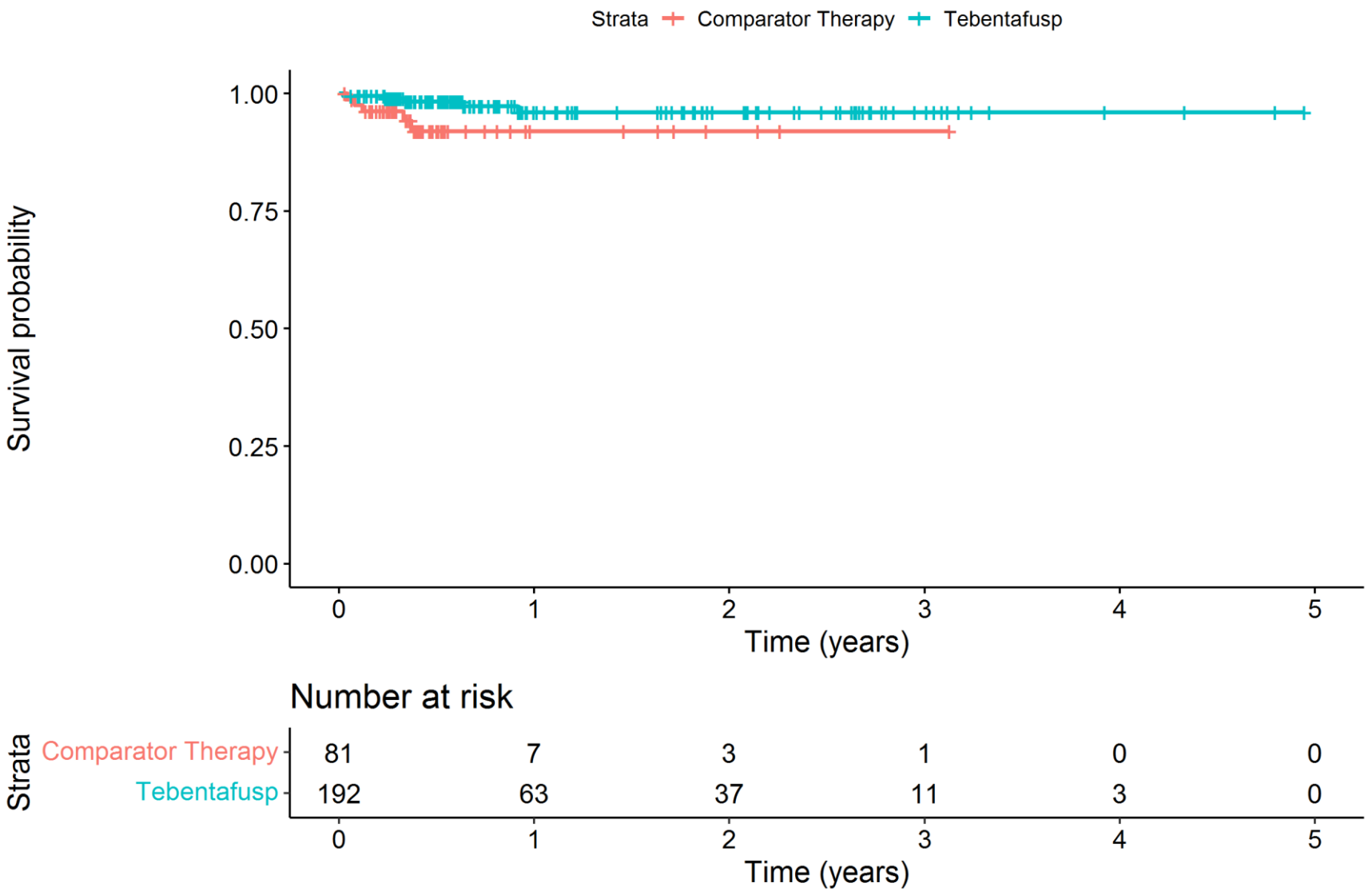
Erkrankungen der Atemwege, des Brustraums und Mediastinums- <65



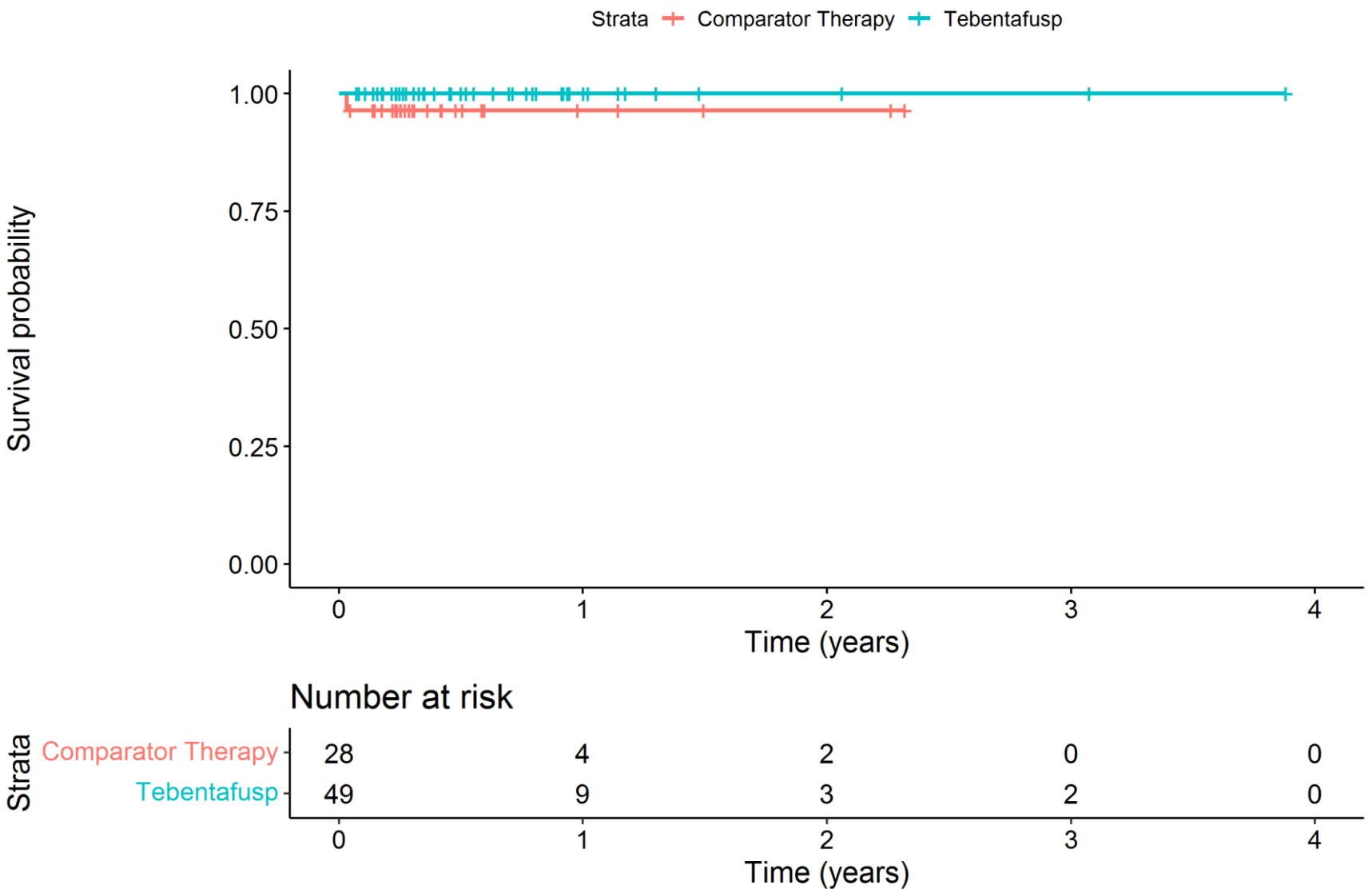
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ≥65



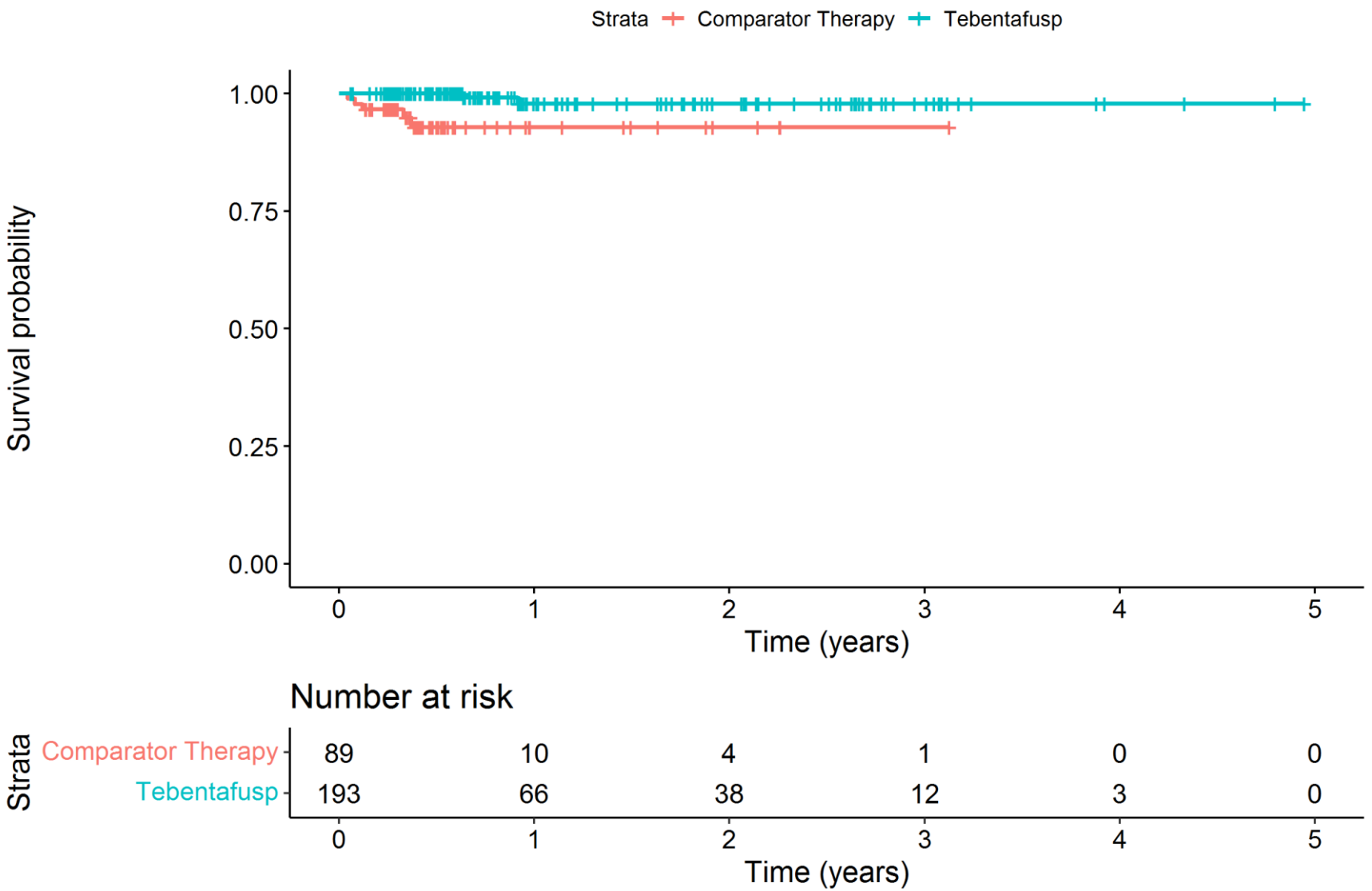
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 0



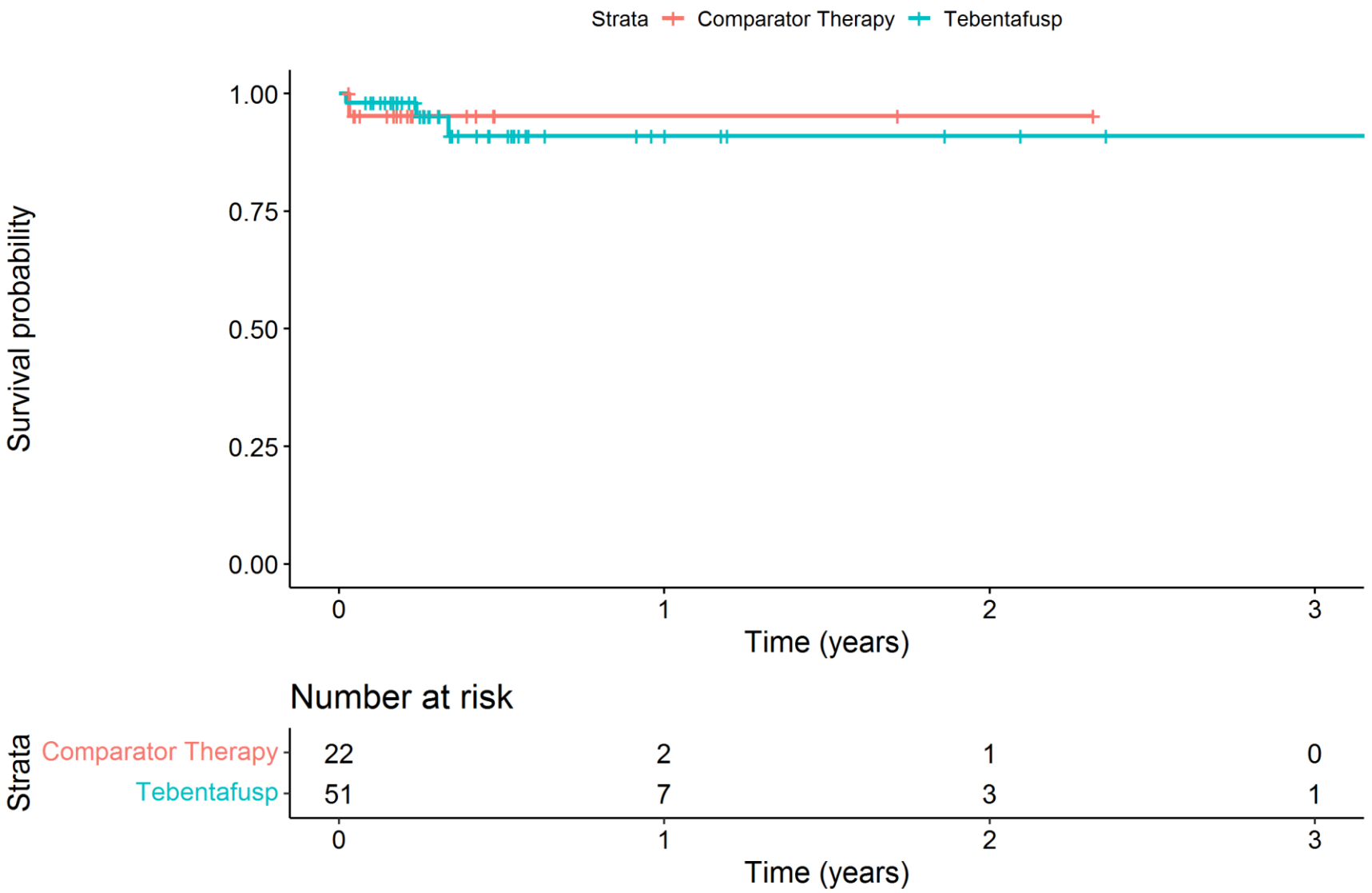
Erkrankungen der Atemwege, des Brustraums und Mediastinums- ECOG 1



Erkrankungen der Atemwege, des Brustraums und Mediastinums- ALP ≤ ULN



Erkrankungen der Atemwege, des Brustraums und Mediastinums- ALP > ULN



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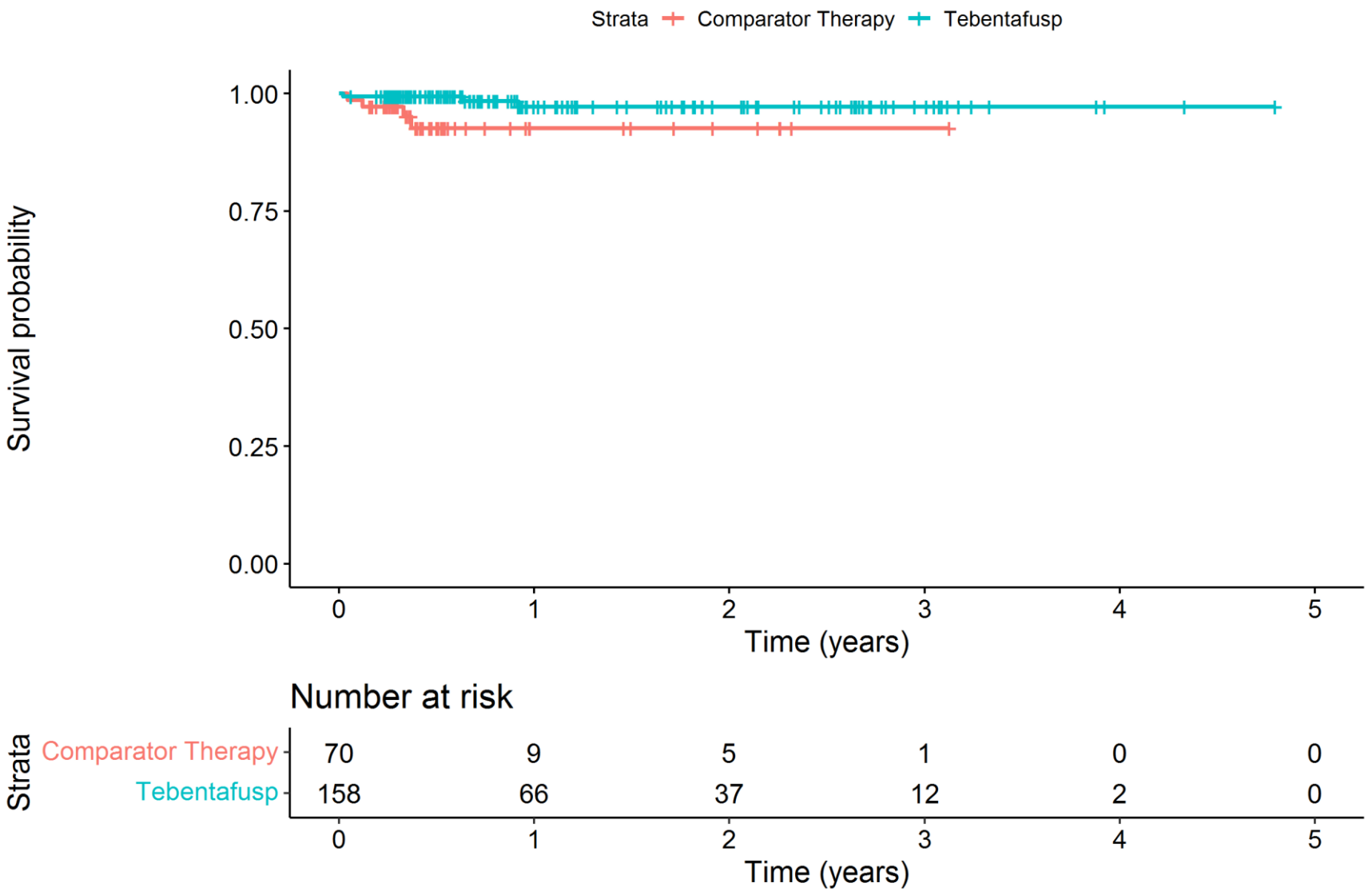
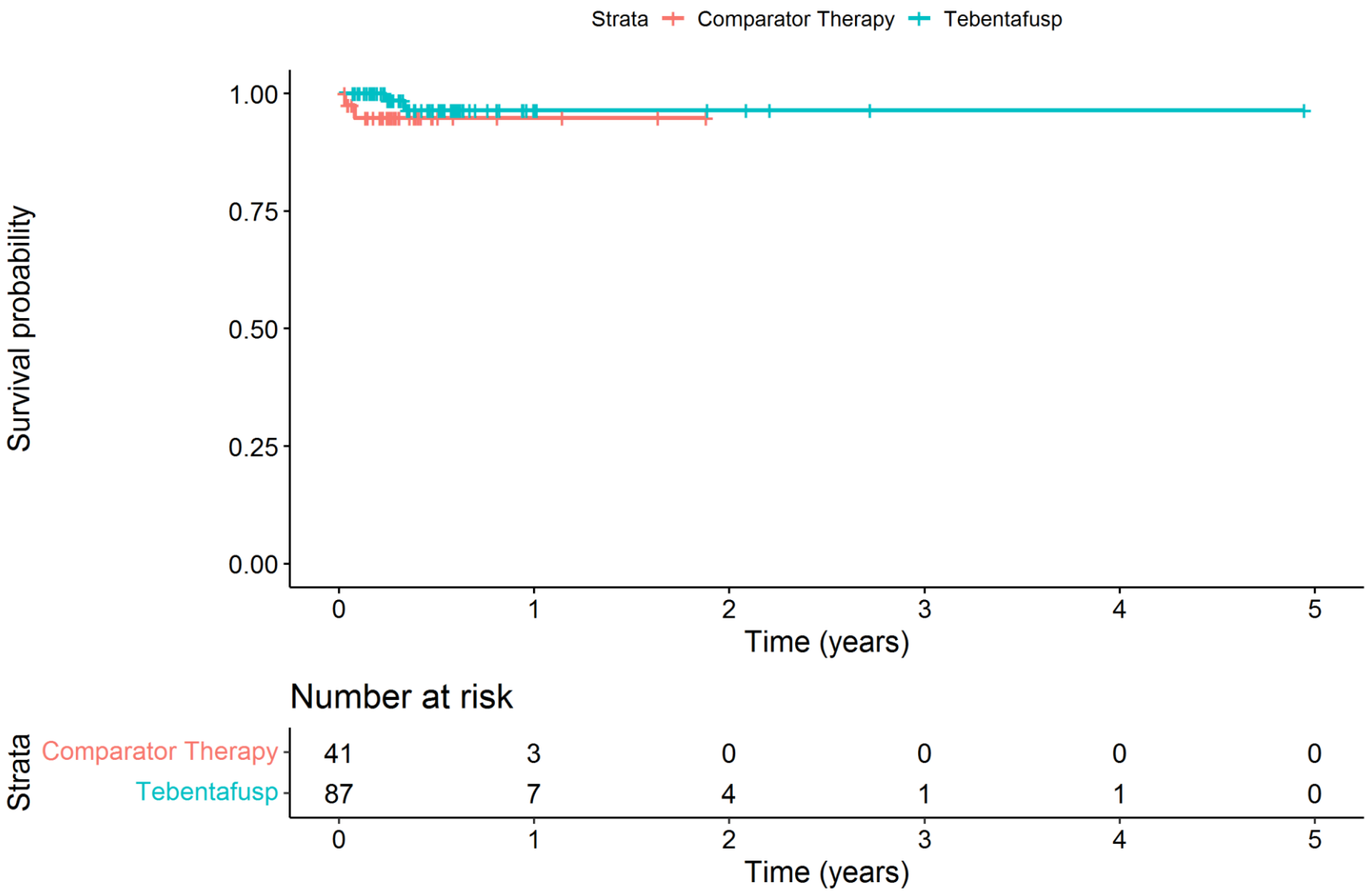
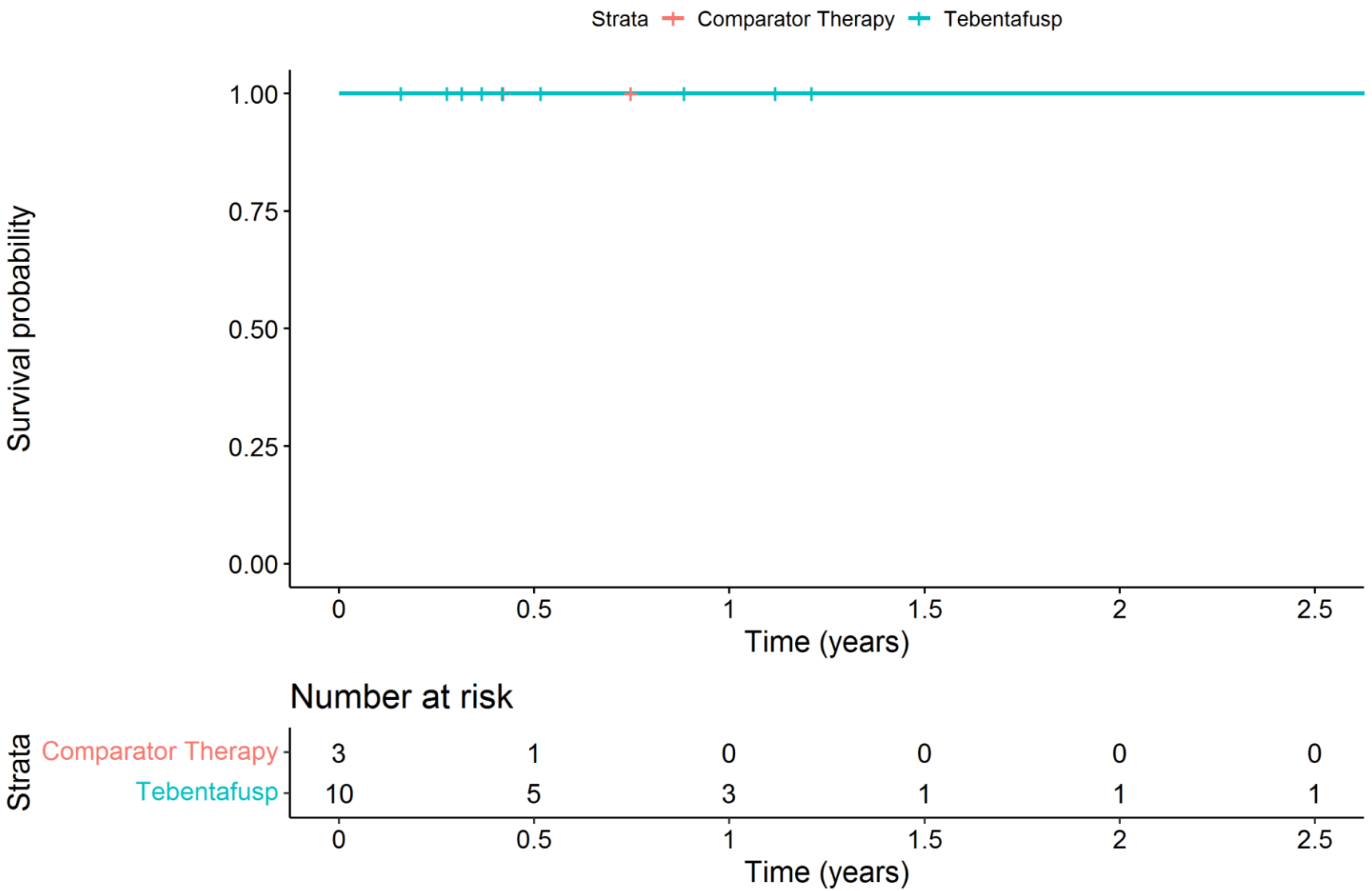


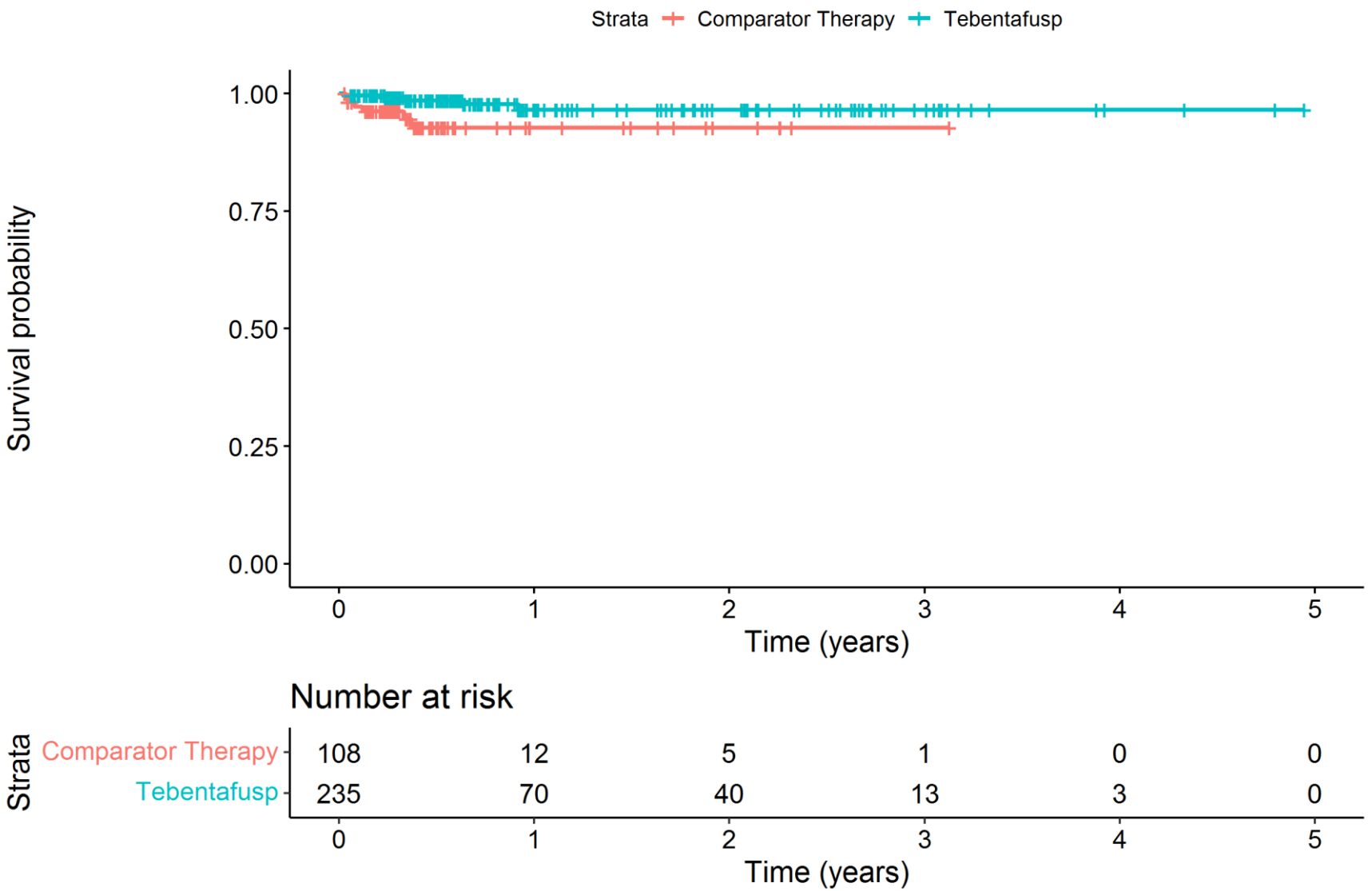
Erkrankungen der Atemwege, des Brustraums und Mediastinums- LDH > ULN



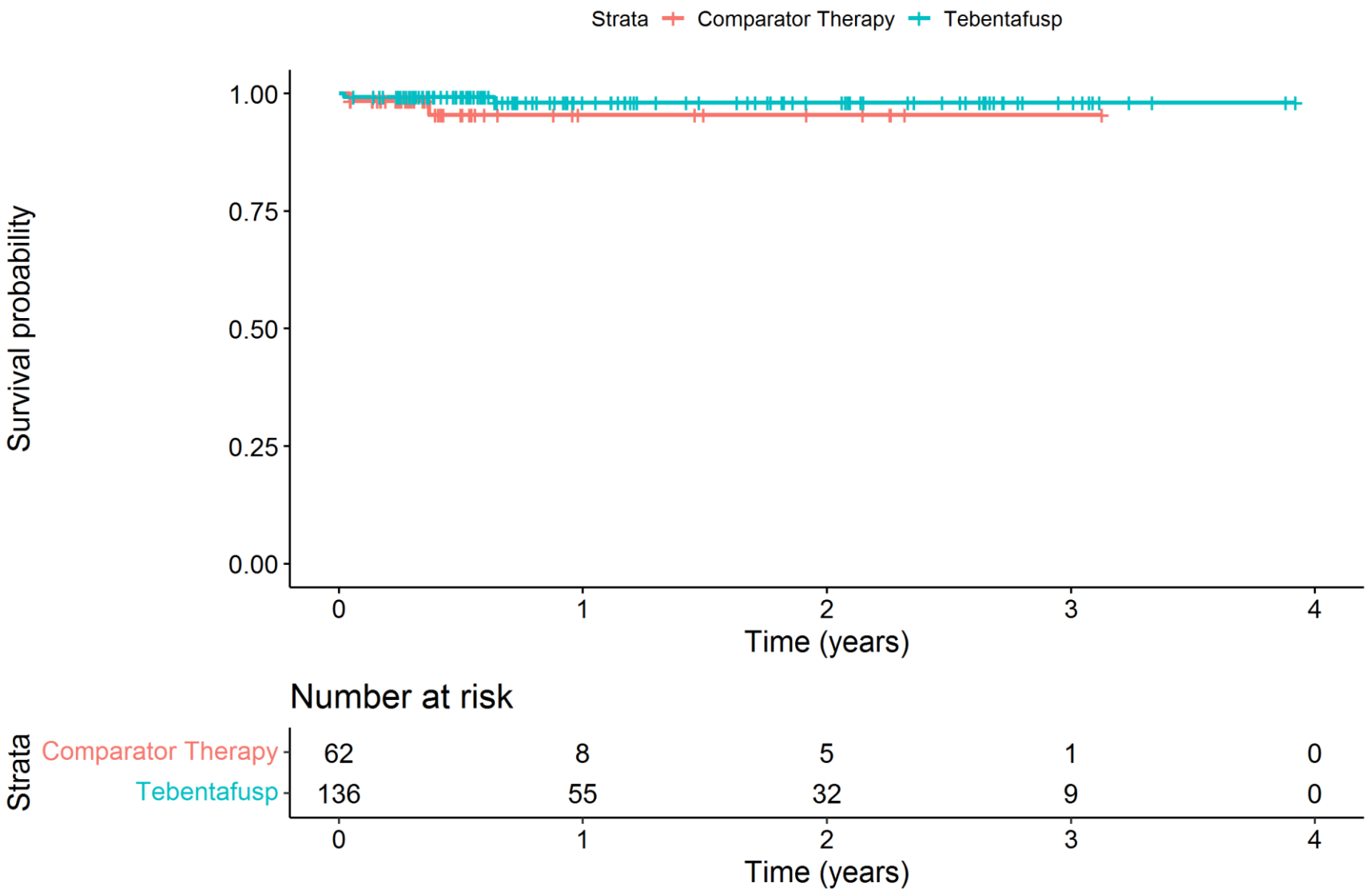
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Vorherige Therapie adjuvant/neoadjuvant



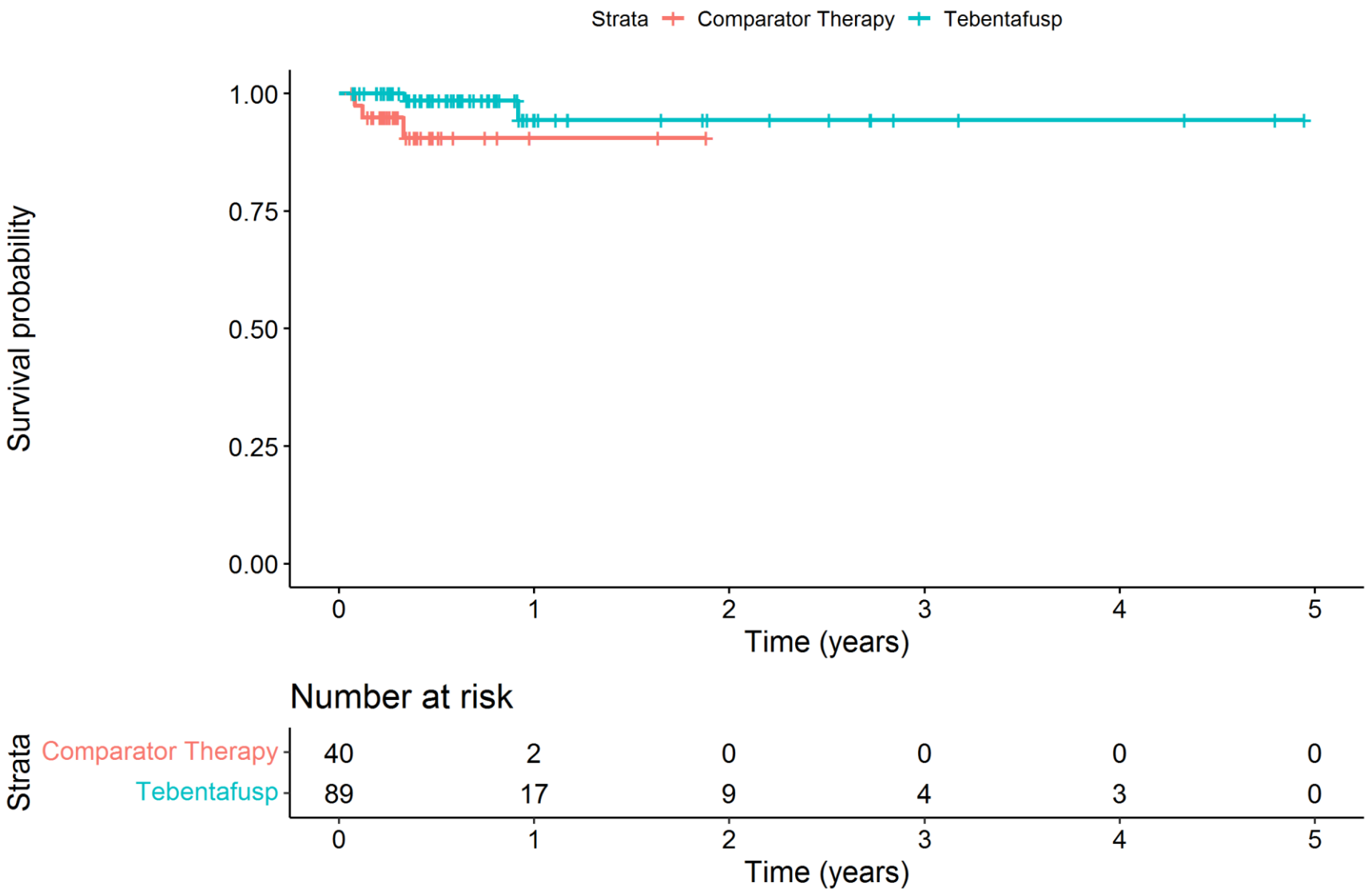
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Keine Vorherige Therapie adjuvant/neoadjuvant



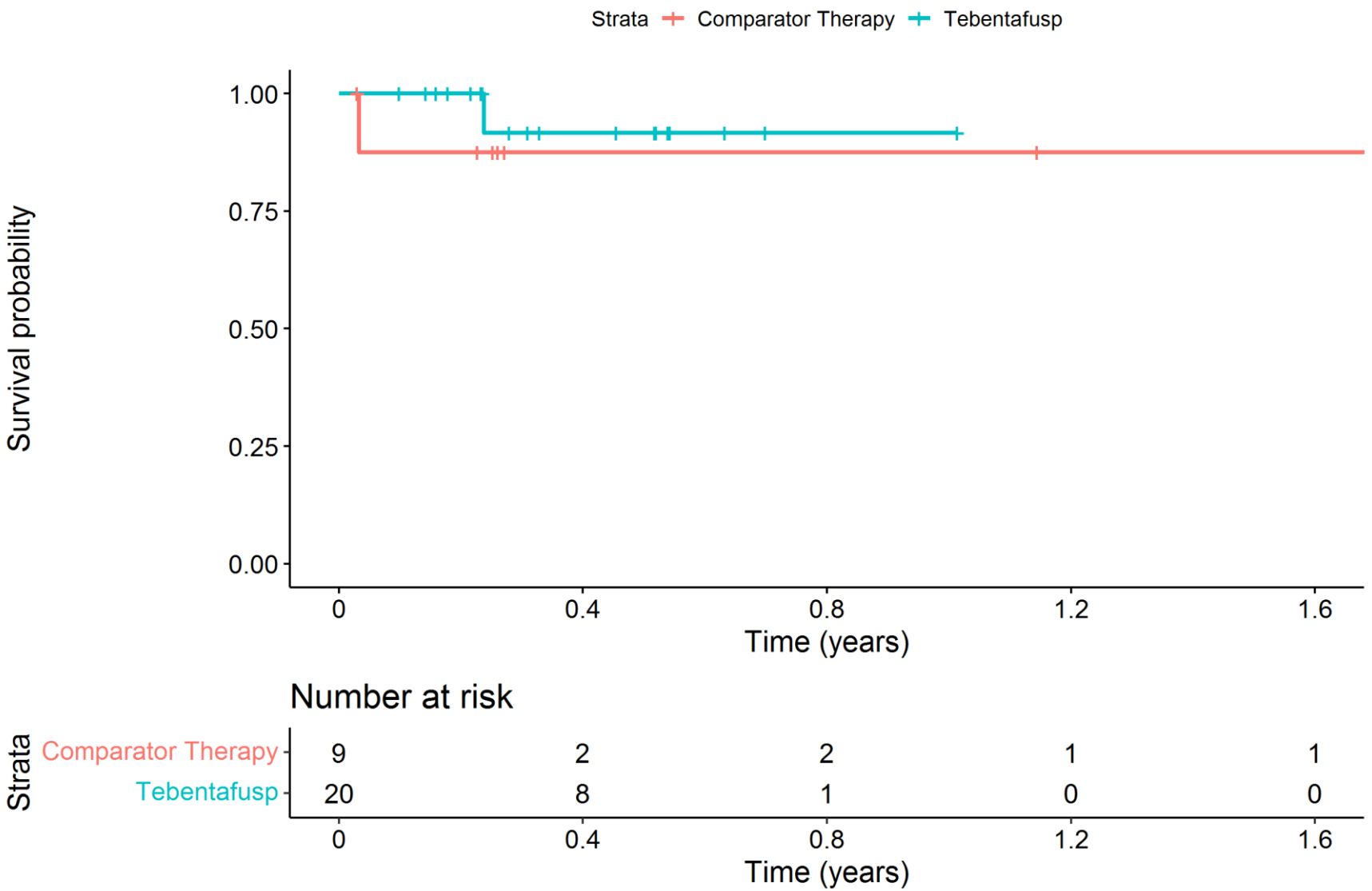
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion ≤ 3cm



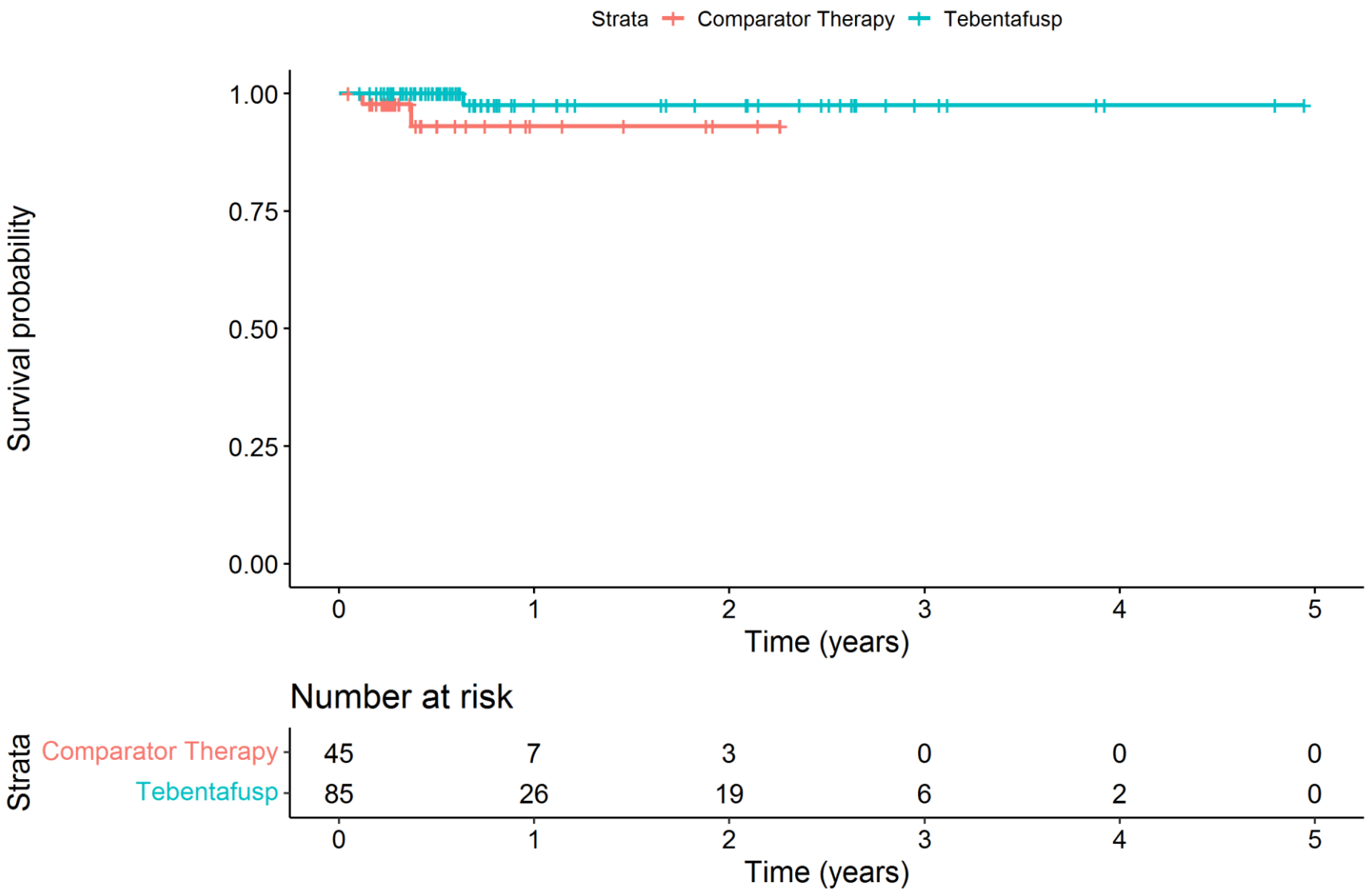
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion 3,1-8,0 cm



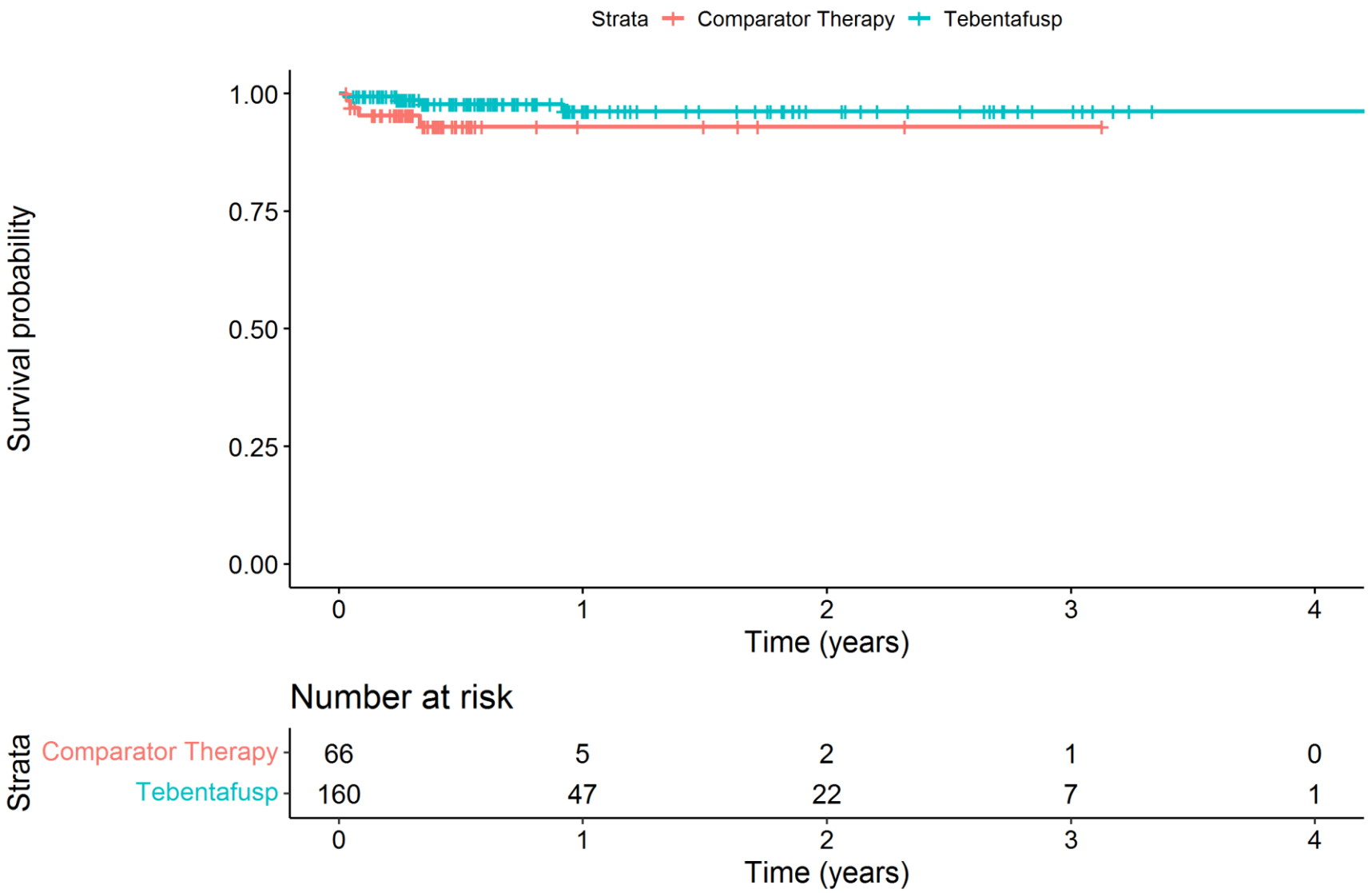
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Läsion ≥8,1 cm



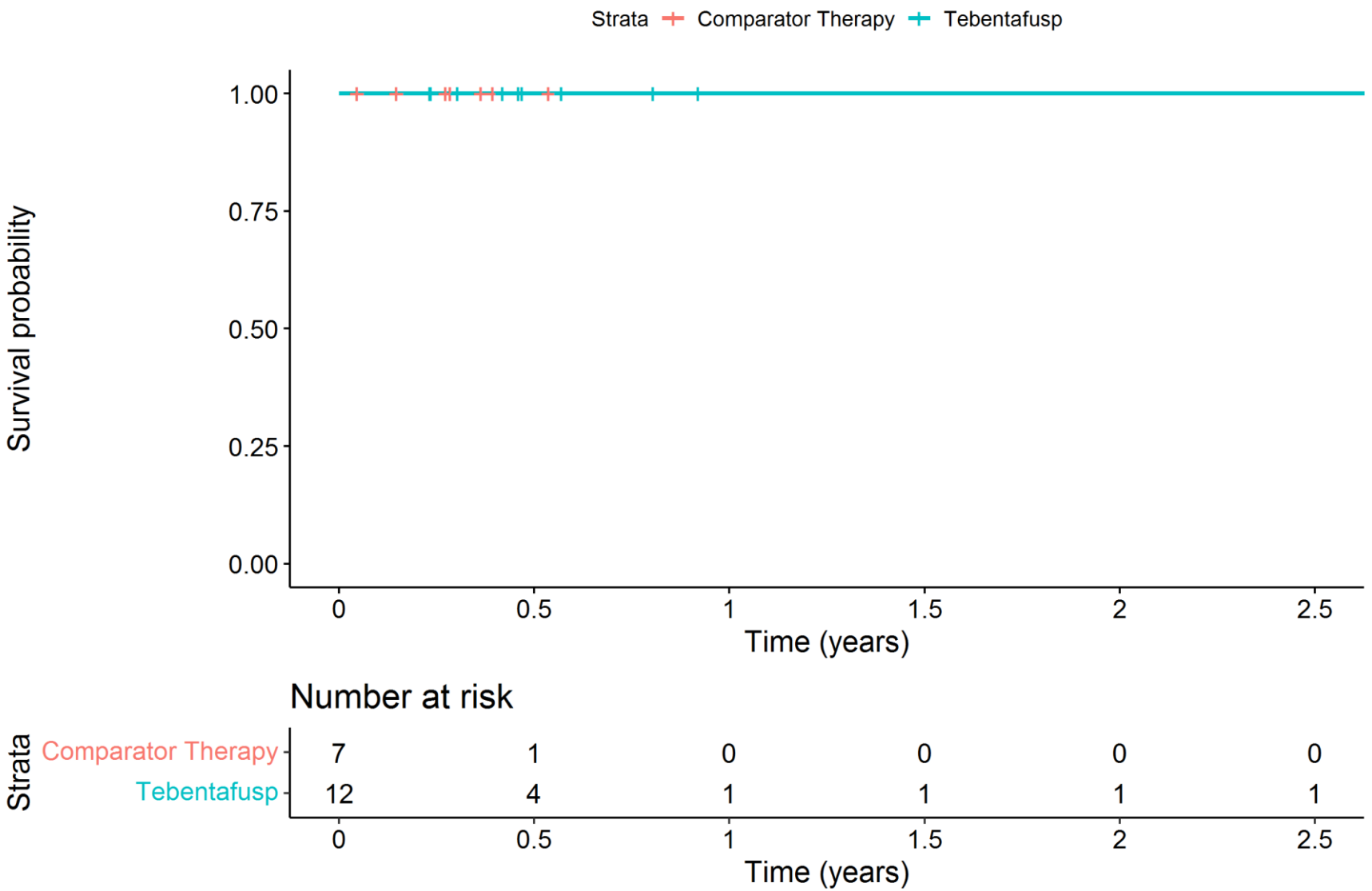
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nordamerika



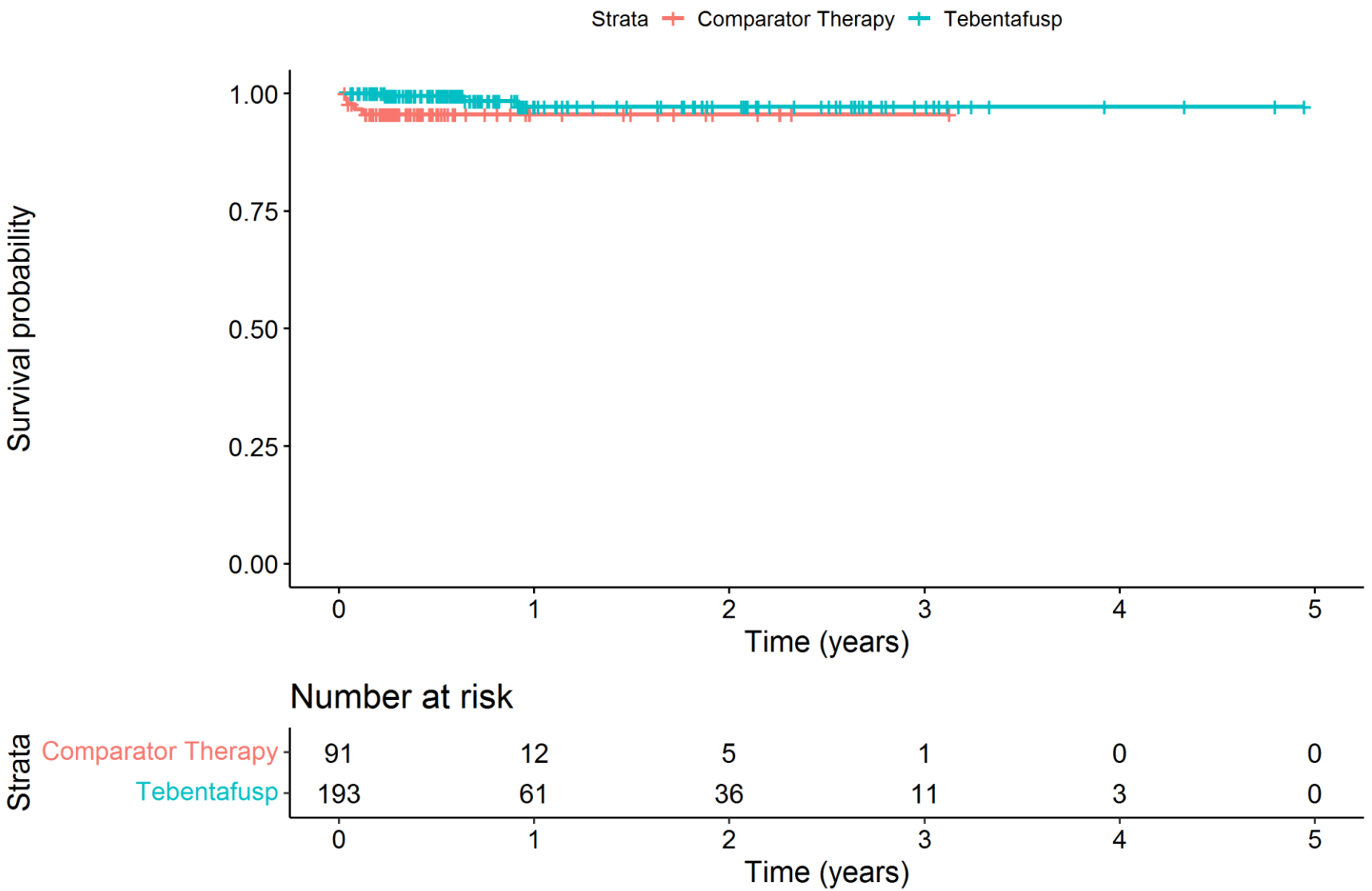
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Nicht-Nordamerika



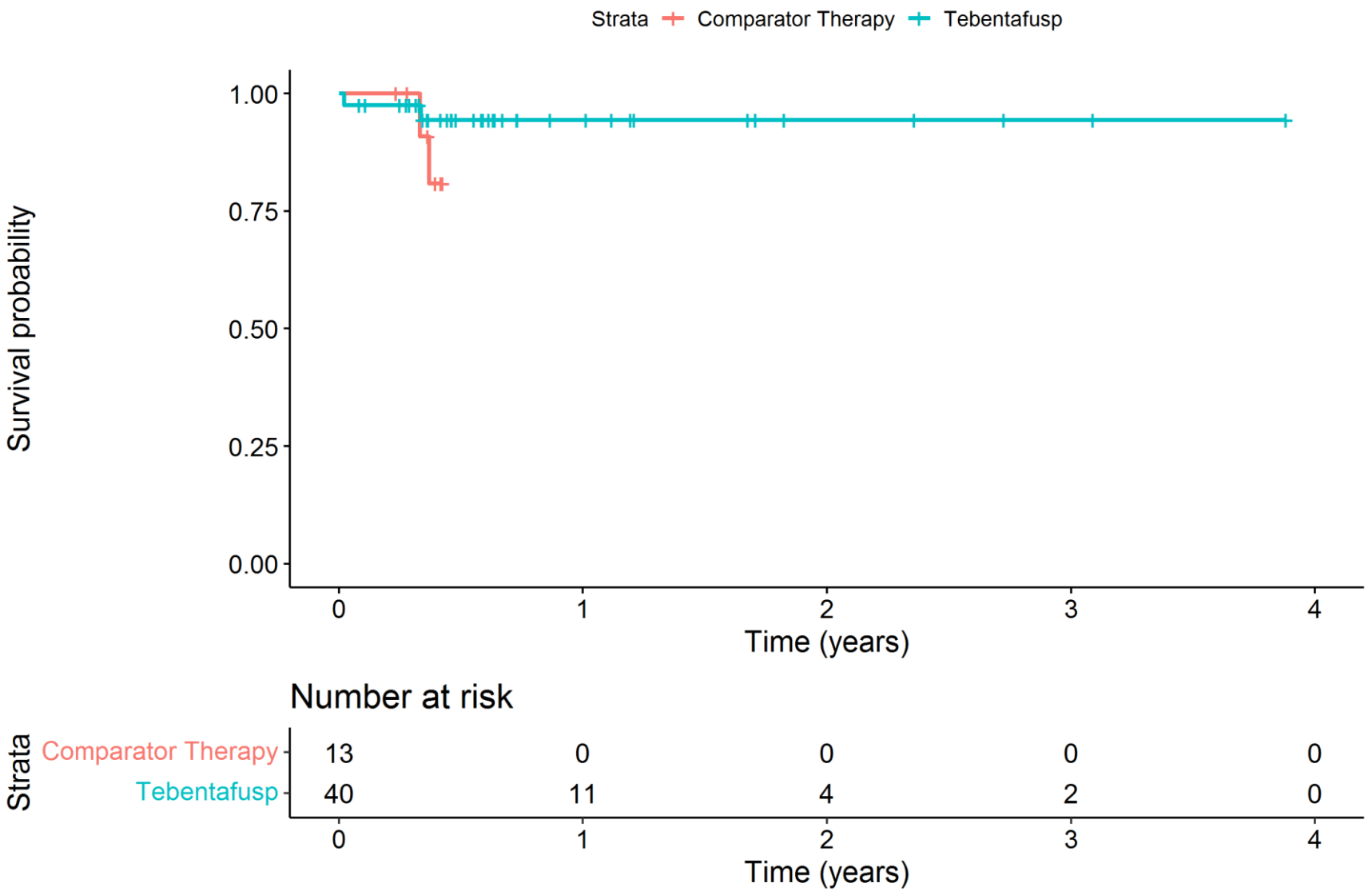
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Dacarbazin



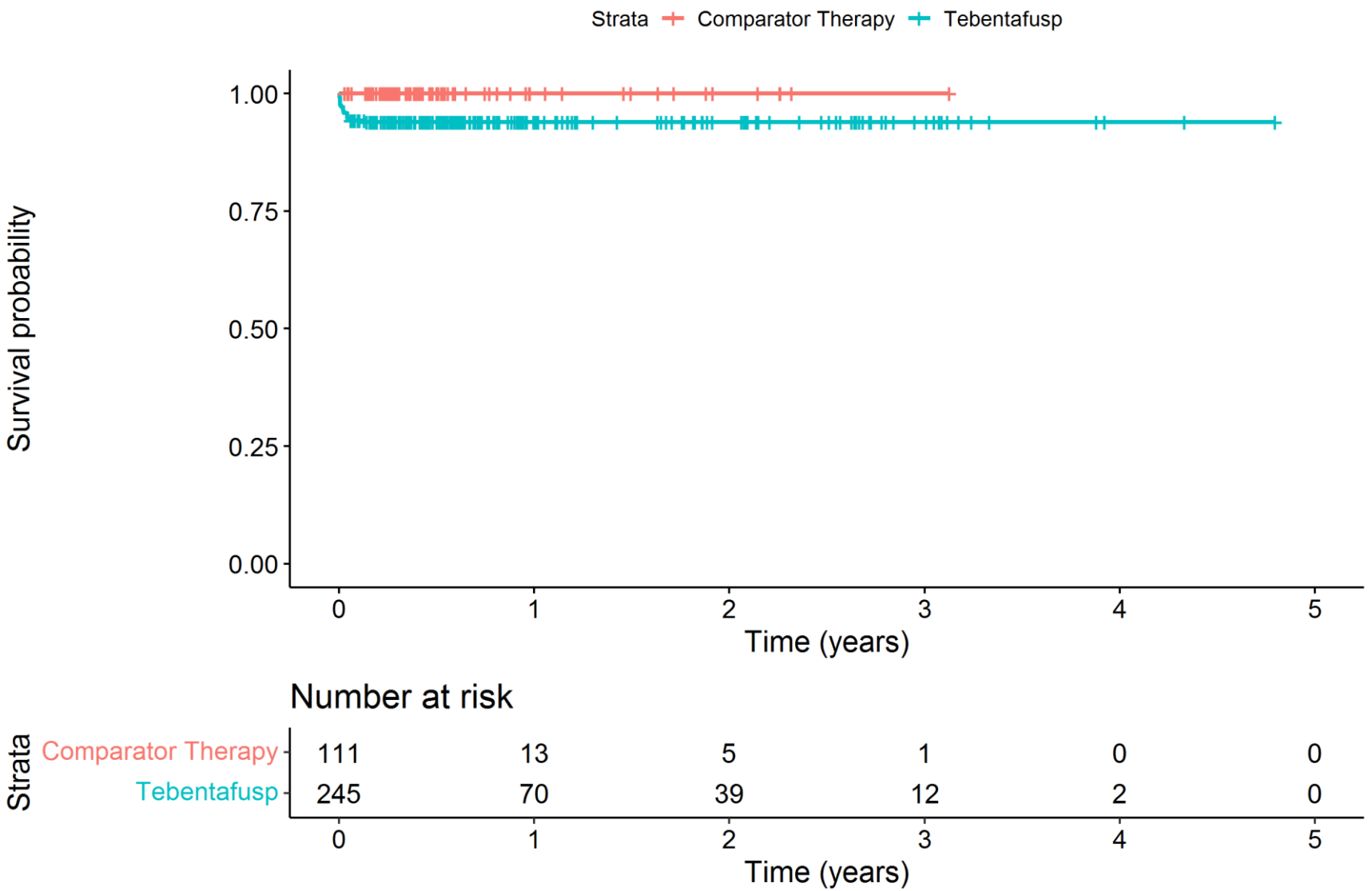
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Pembrolizumab



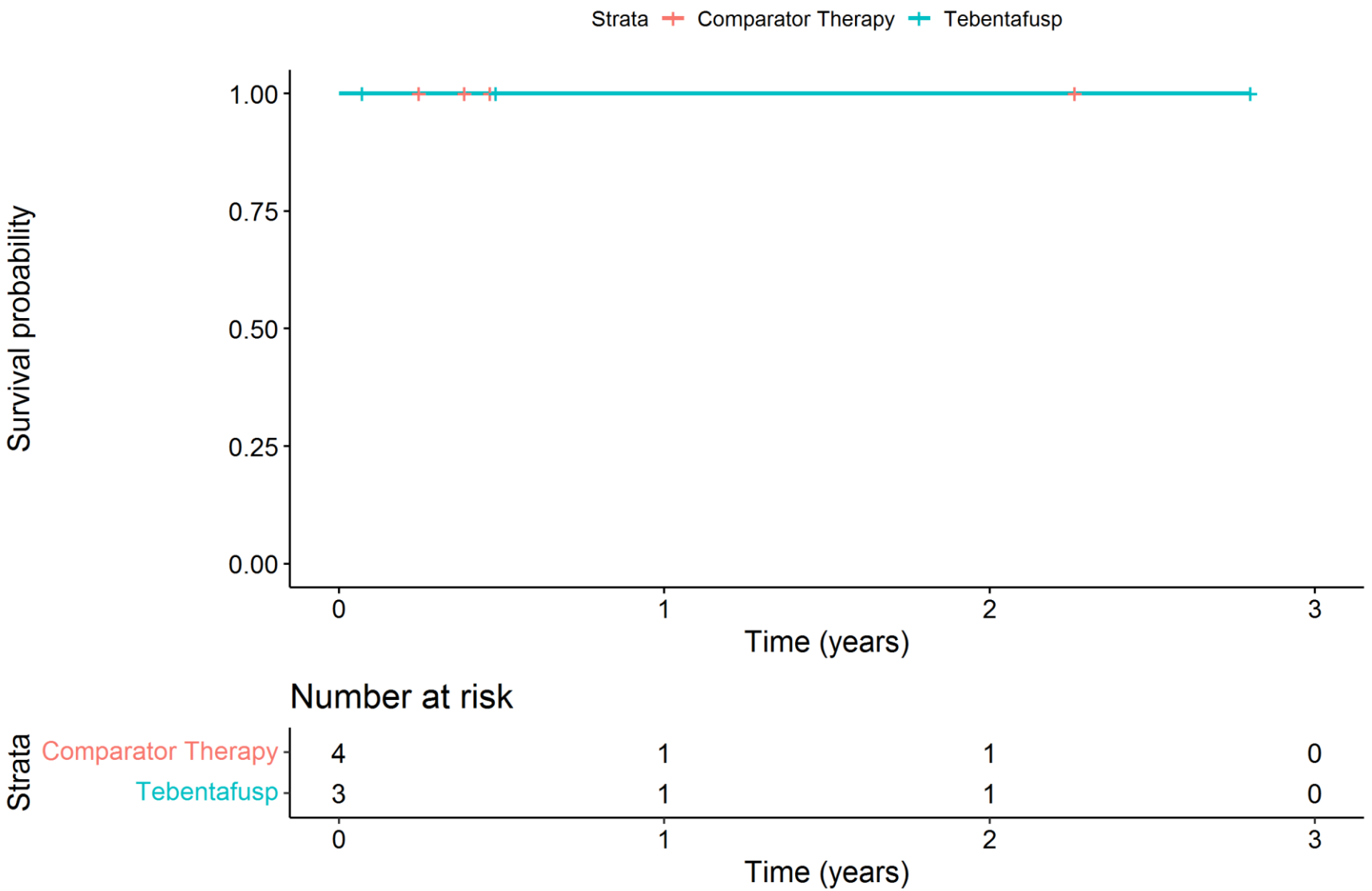
Erkrankungen der Atemwege, des Brustraums und Mediastinums- Ipilimumab



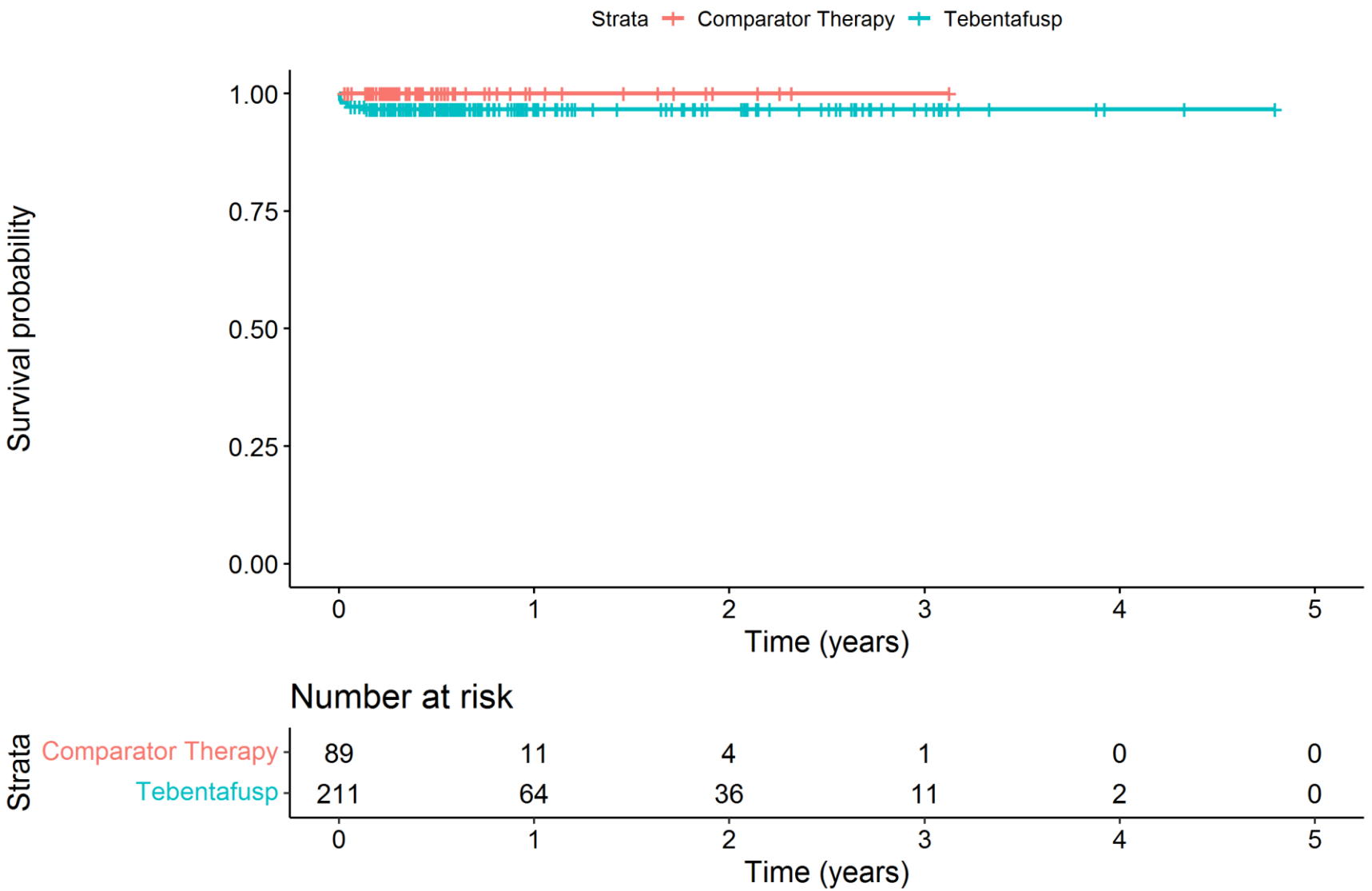
Erkrankungen der Haut und des Unterhautgewebes- Gesamt



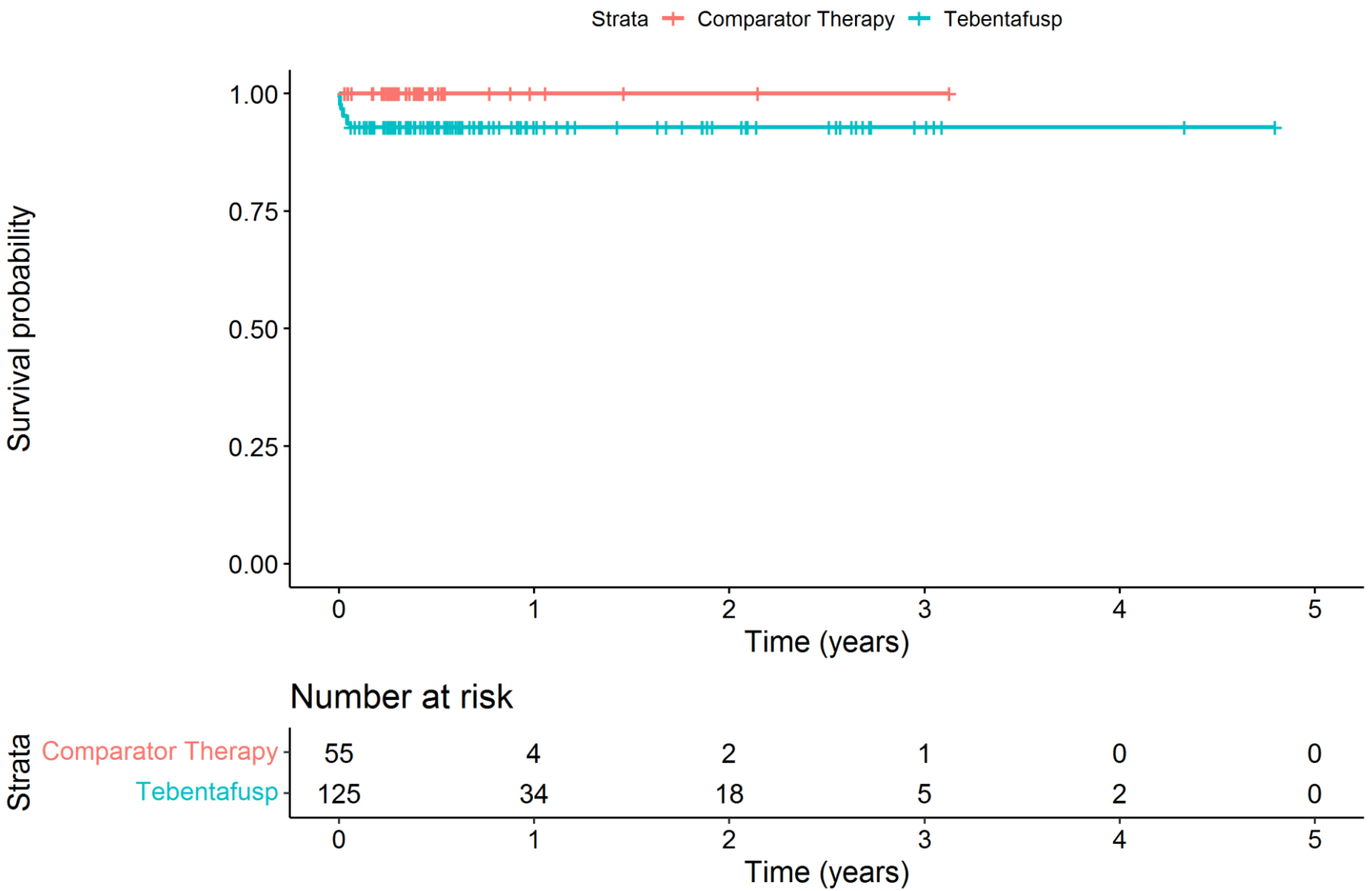
Erkrankungen der Haut und des Unterhautgewebes- Hispanisch



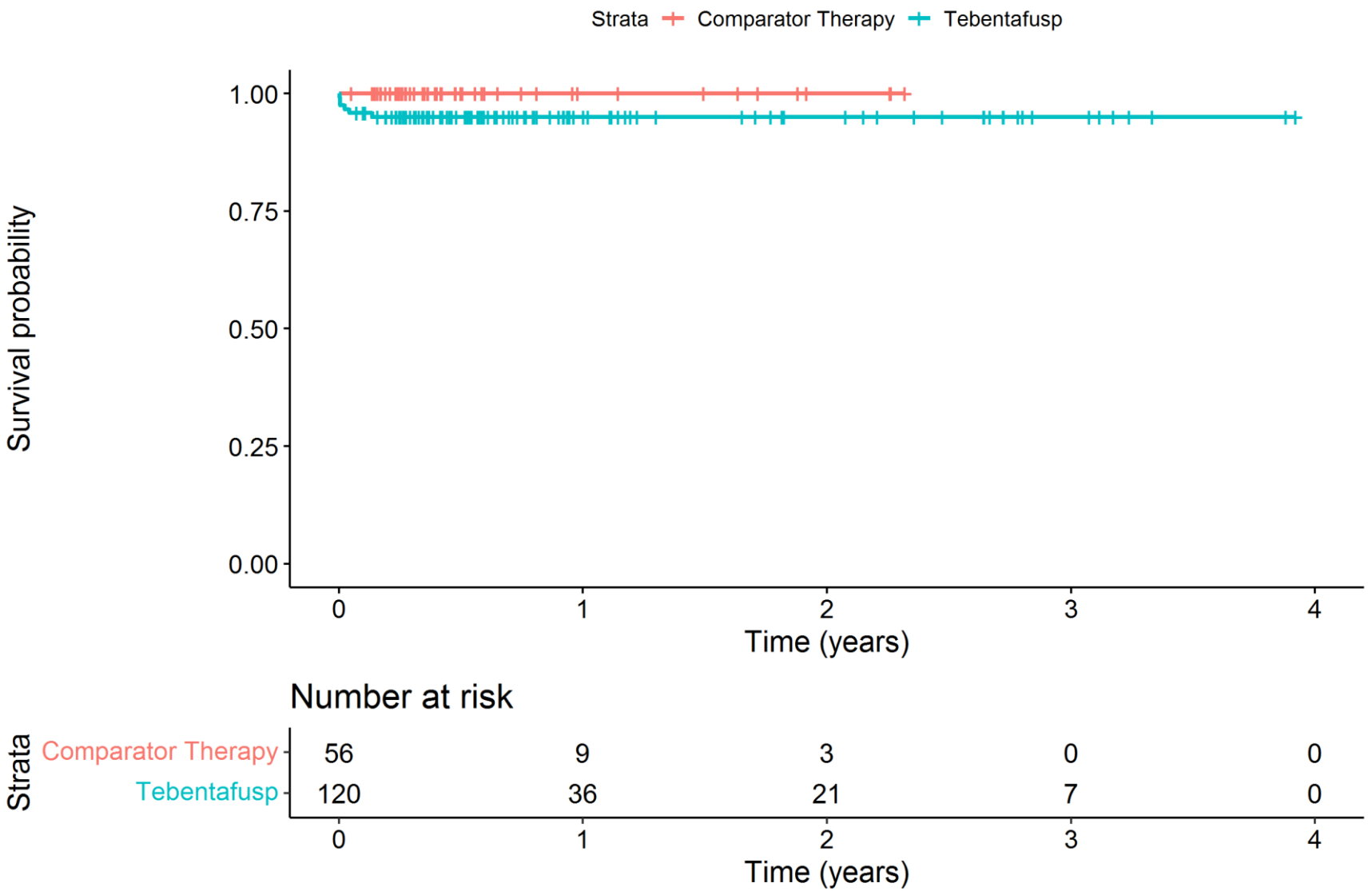
Erkrankungen der Haut und des Unterhautgewebes- Nicht-hispanisch



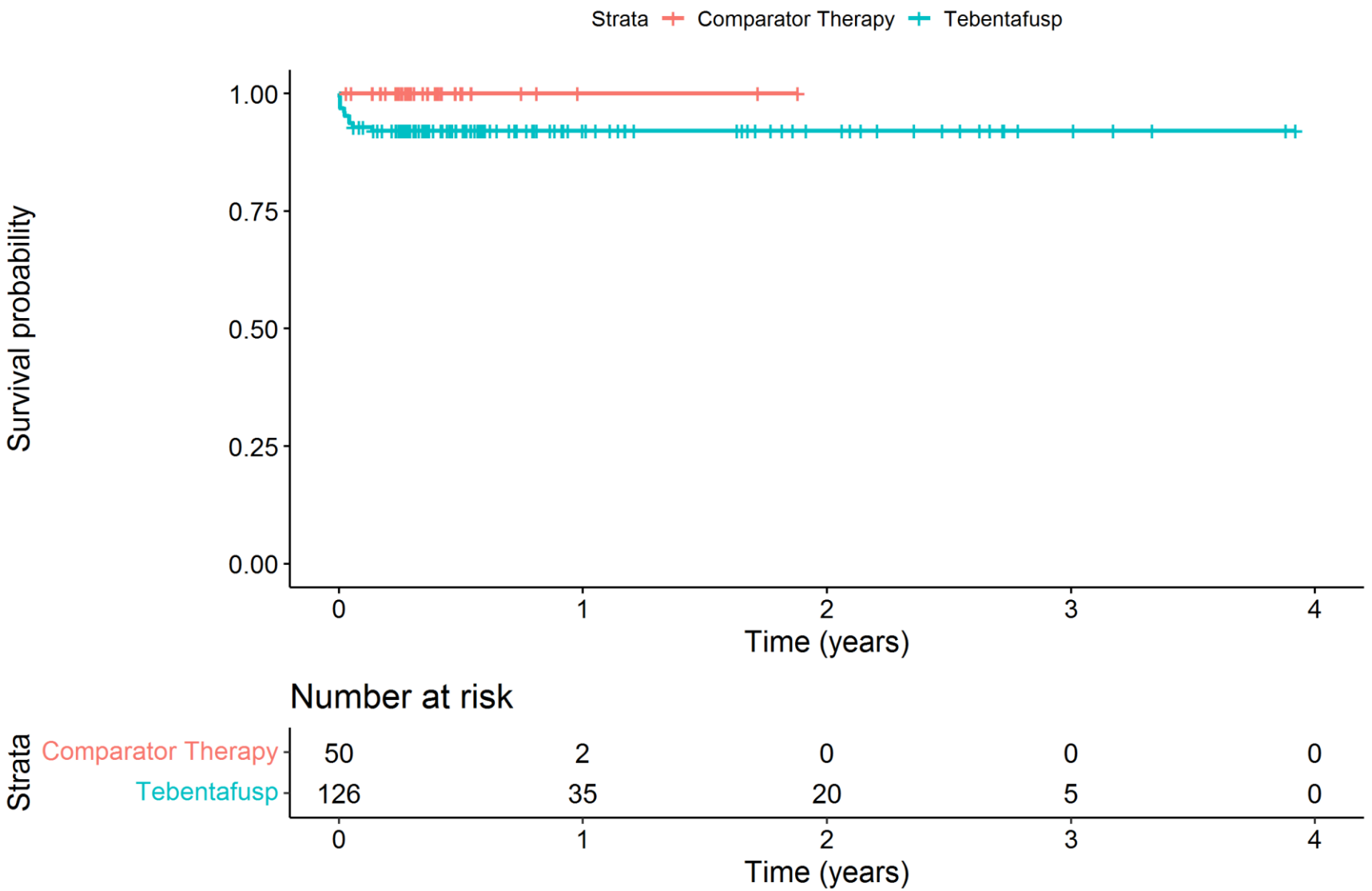
Erkrankungen der Haut und des Unterhautgewebes- Männlich



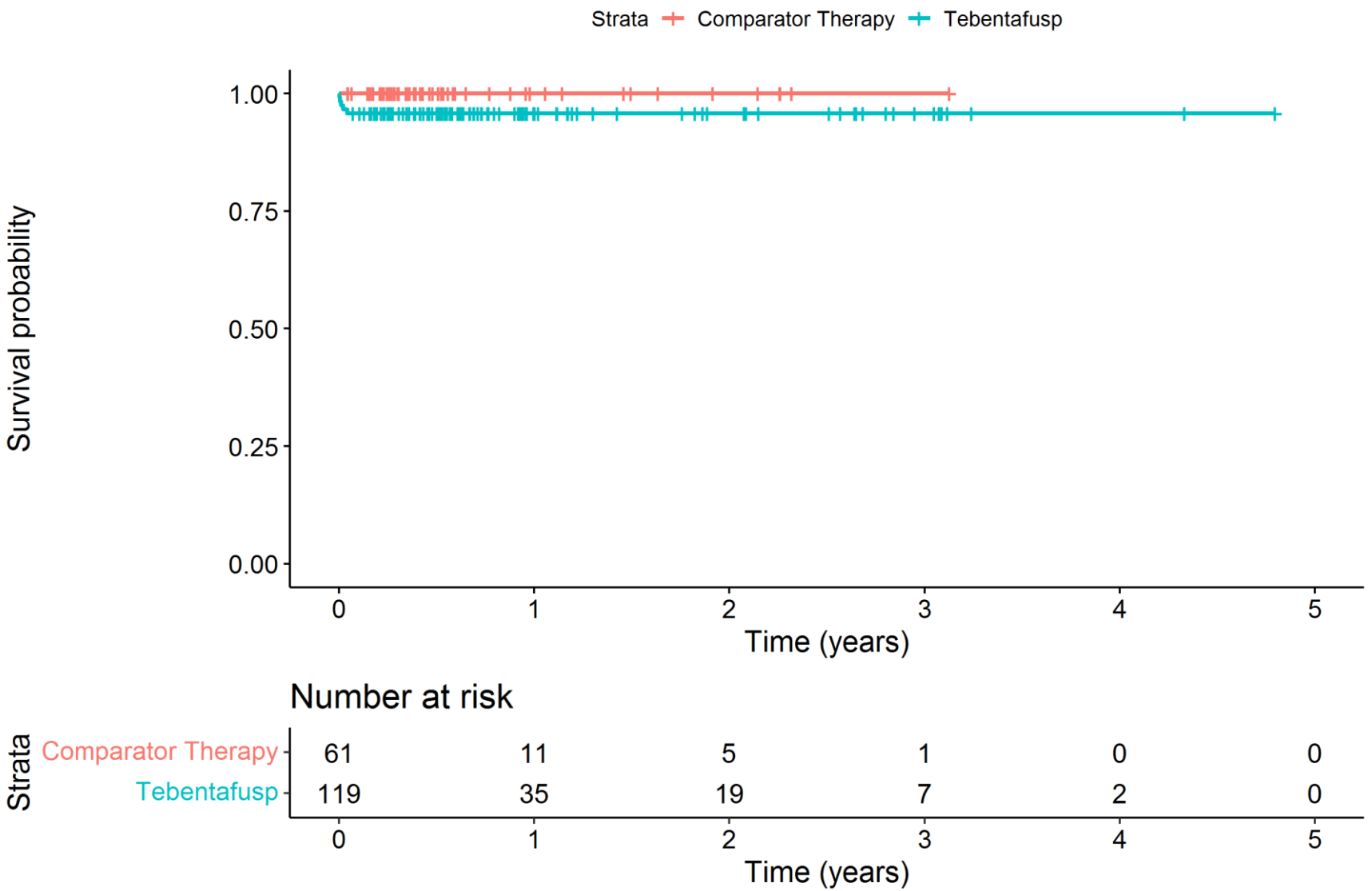
Erkrankungen der Haut und des Unterhautgewebes- Weiblich



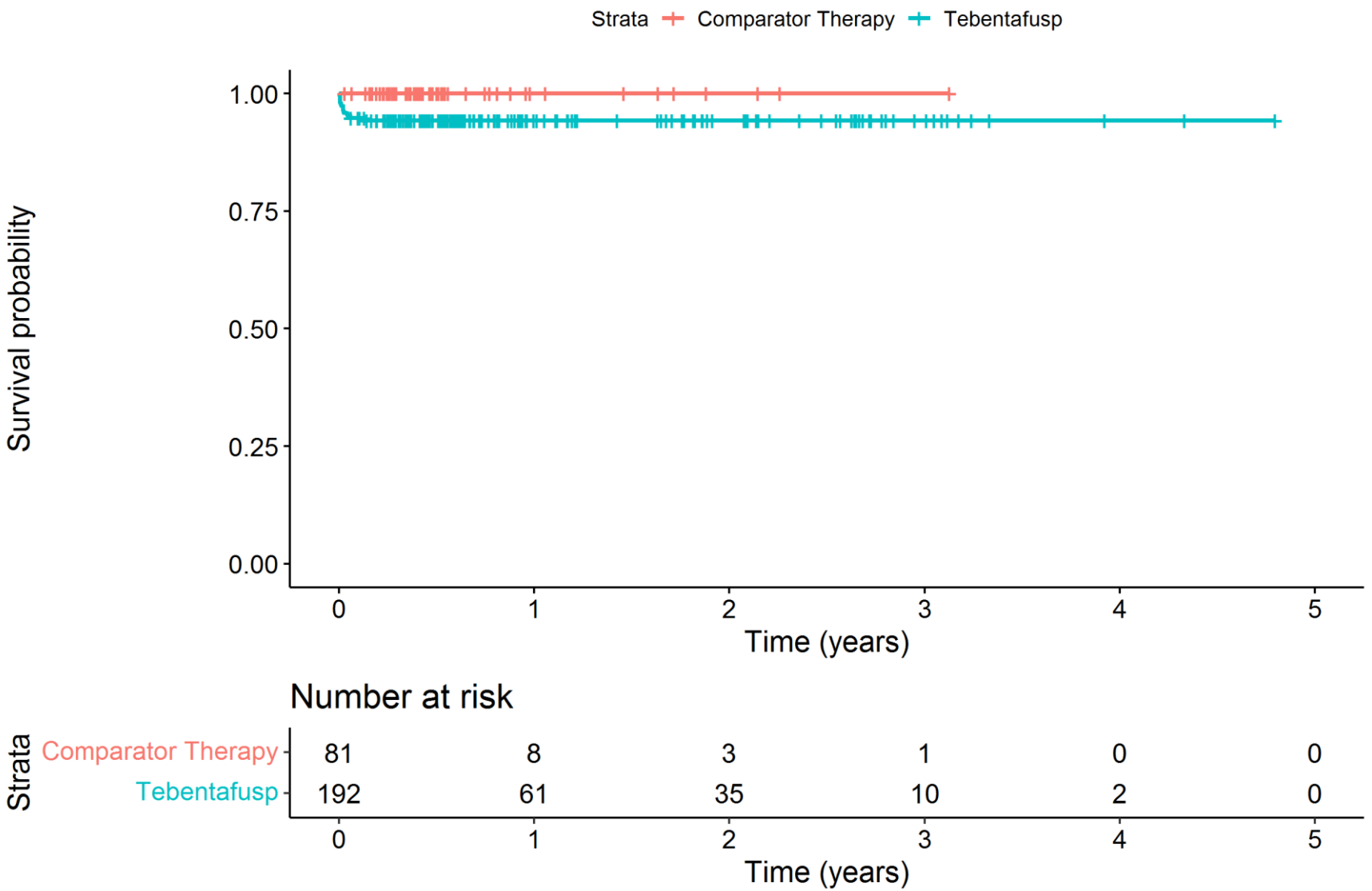
Erkrankungen der Haut und des Unterhautgewebes- <65



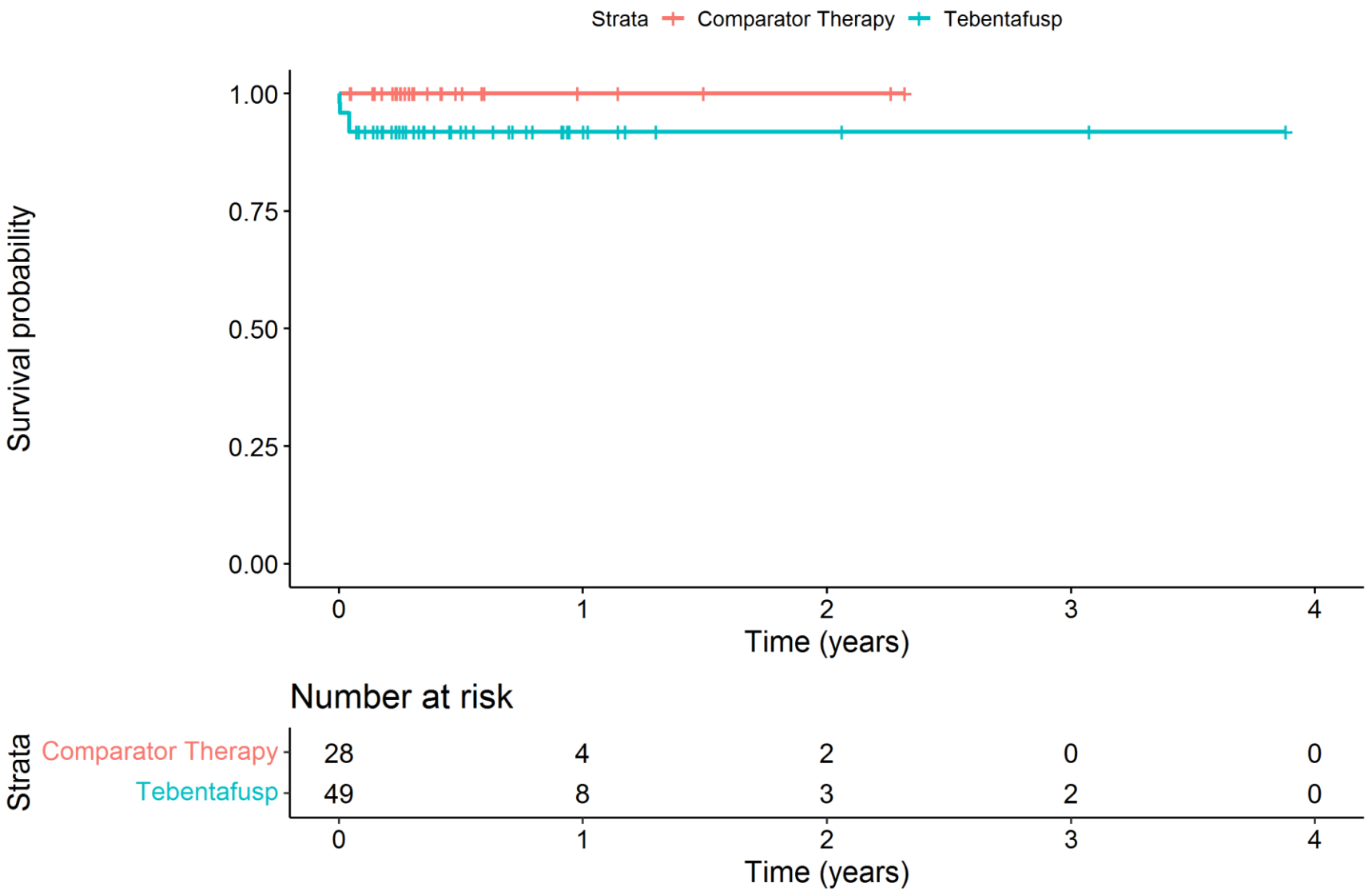
Erkrankungen der Haut und des Unterhautgewebes- ≥65



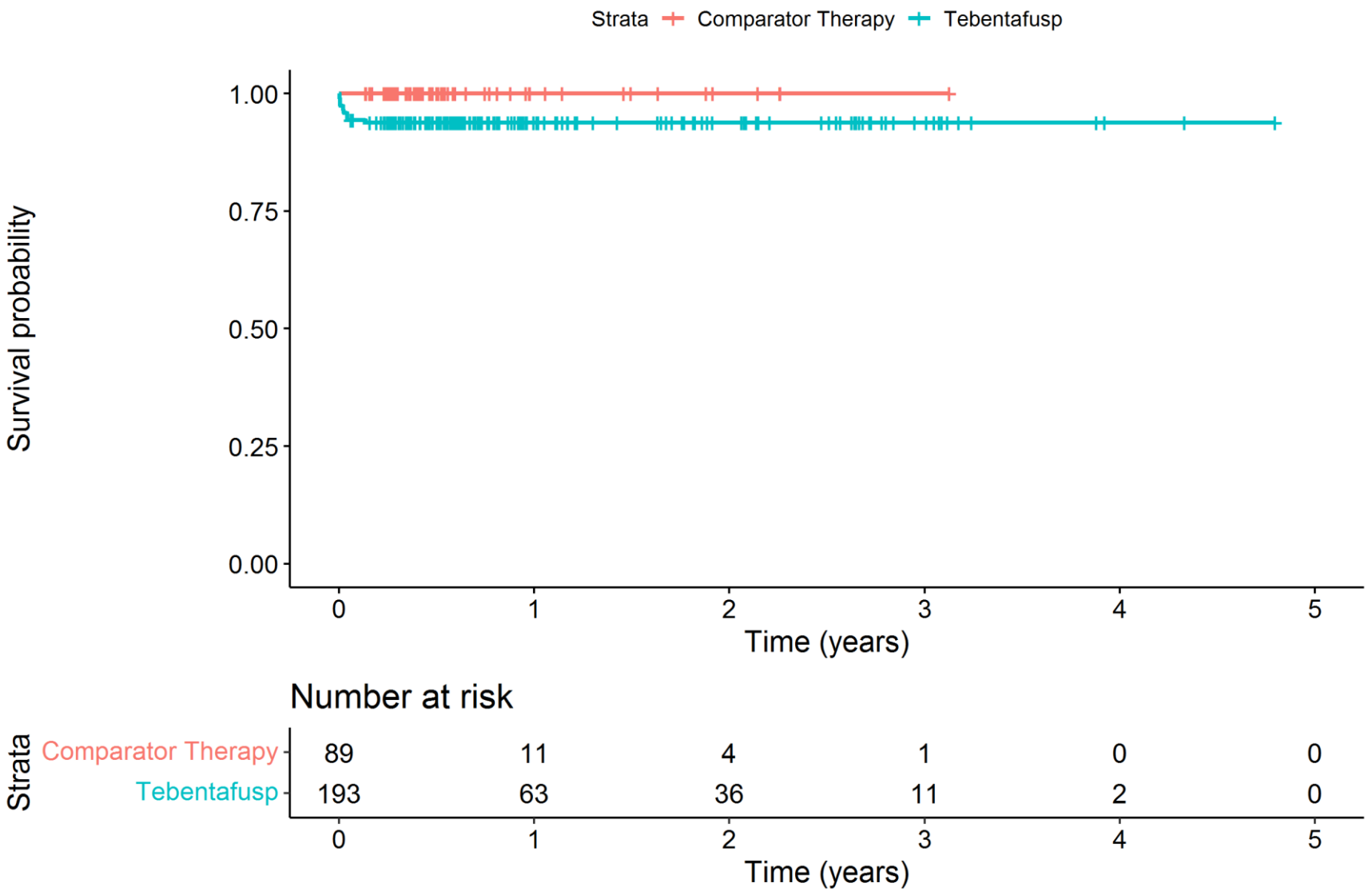
Erkrankungen der Haut und des Unterhautgewebes- ECOG 0



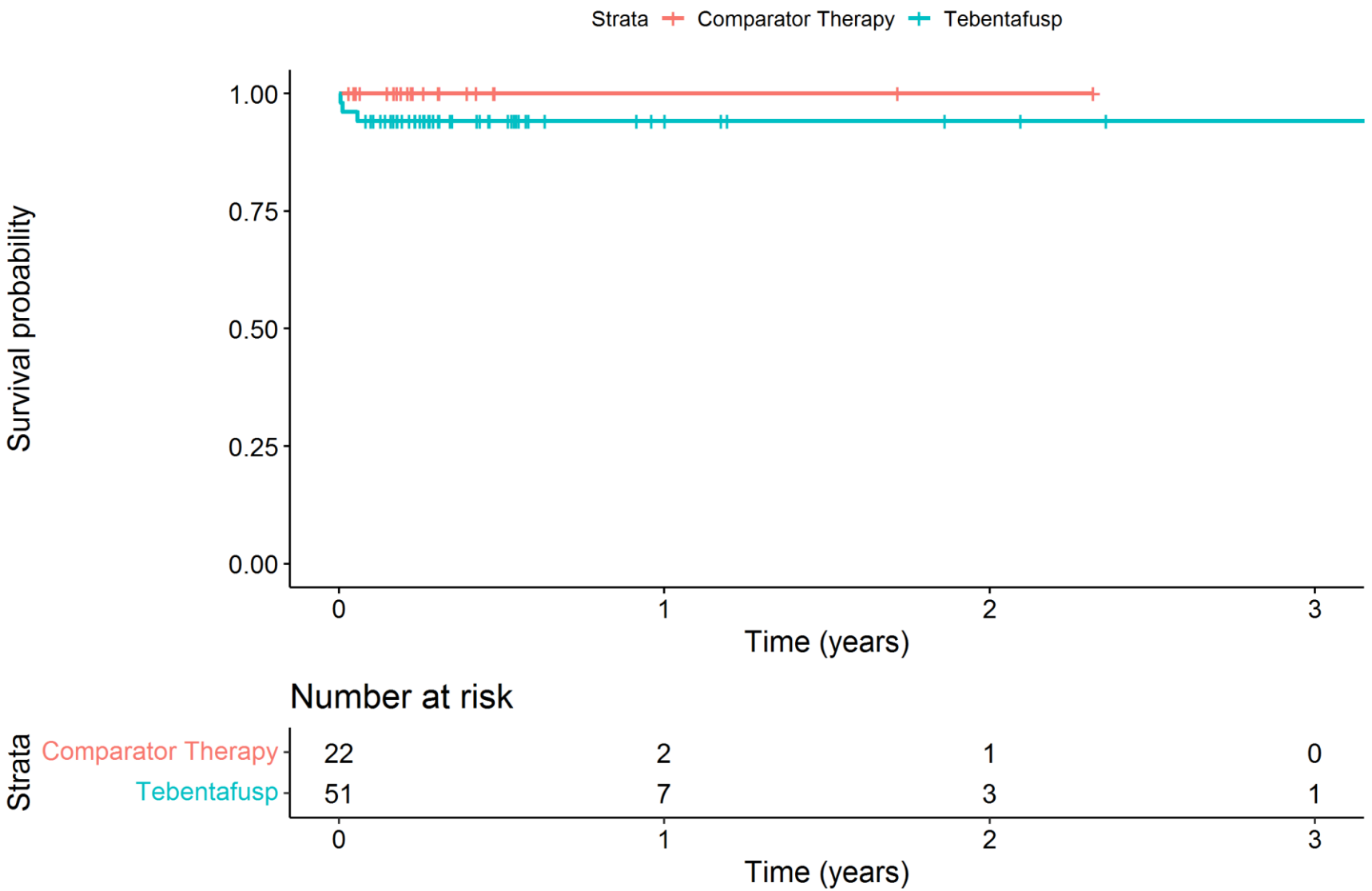
Erkrankungen der Haut und des Unterhautgewebes- ECOG 1



Erkrankungen der Haut und des Unterhautgewebes- ALP ≤ ULN



Erkrankungen der Haut und des Unterhautgewebes- ALP > ULN



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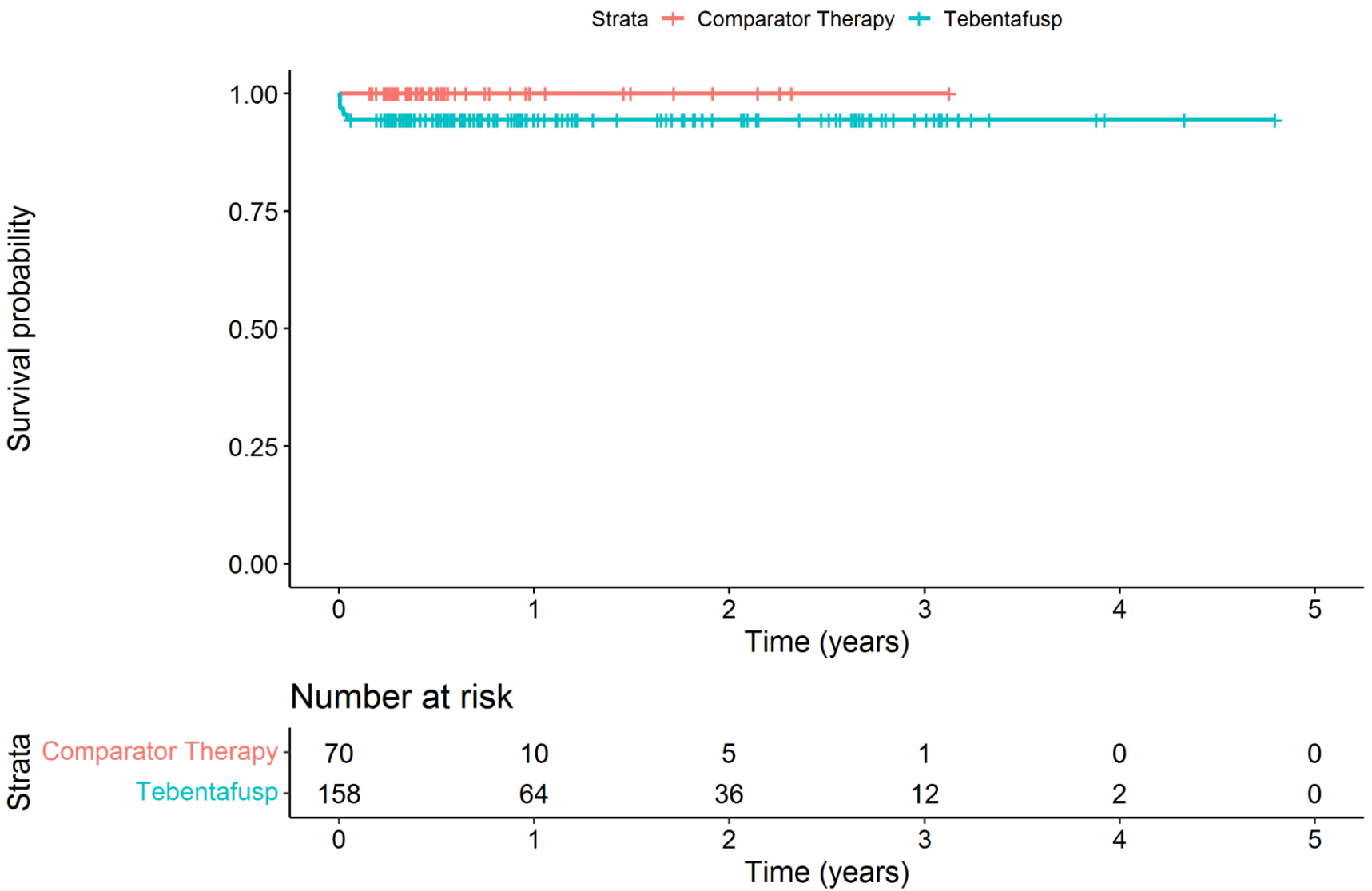
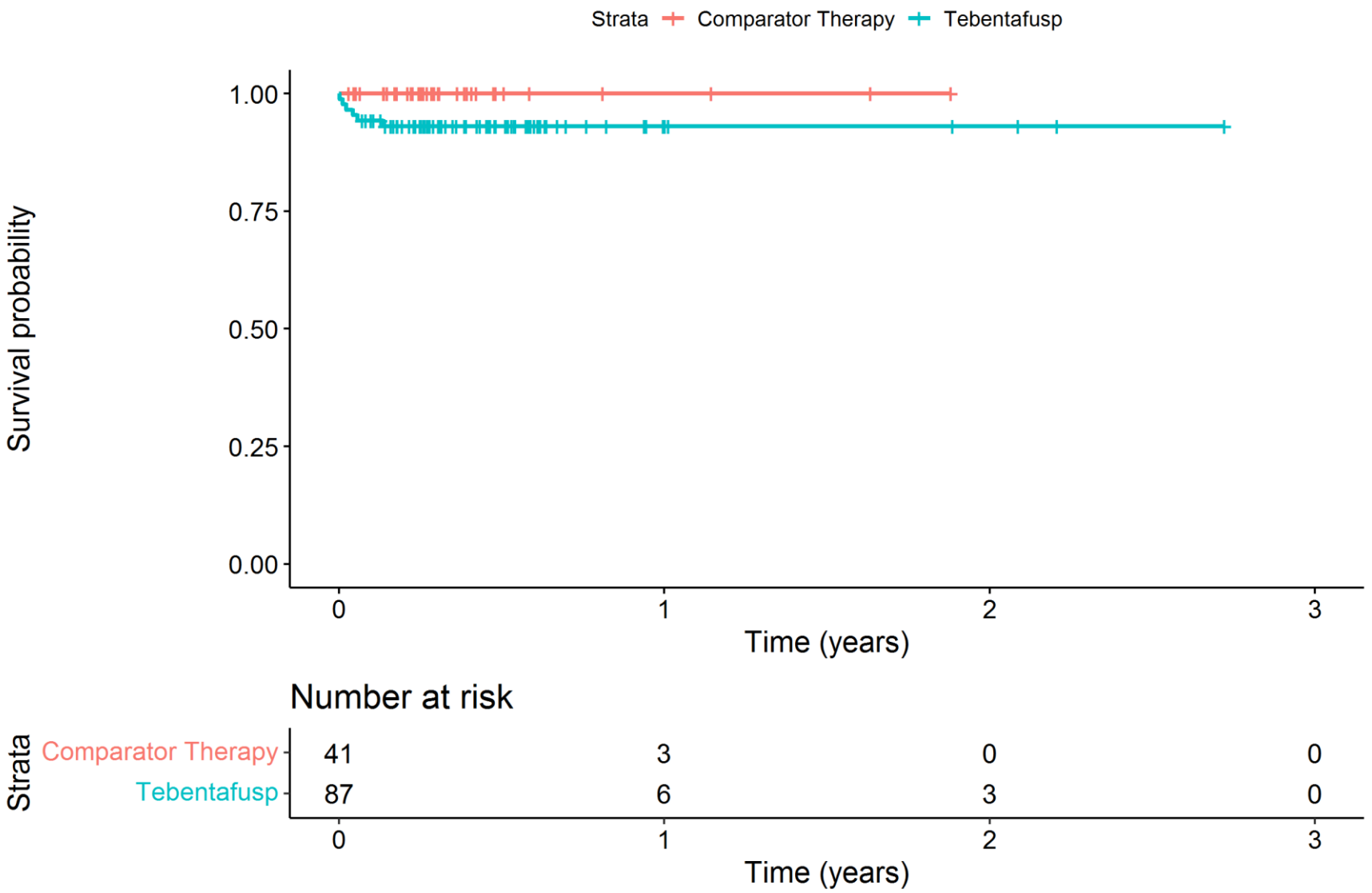
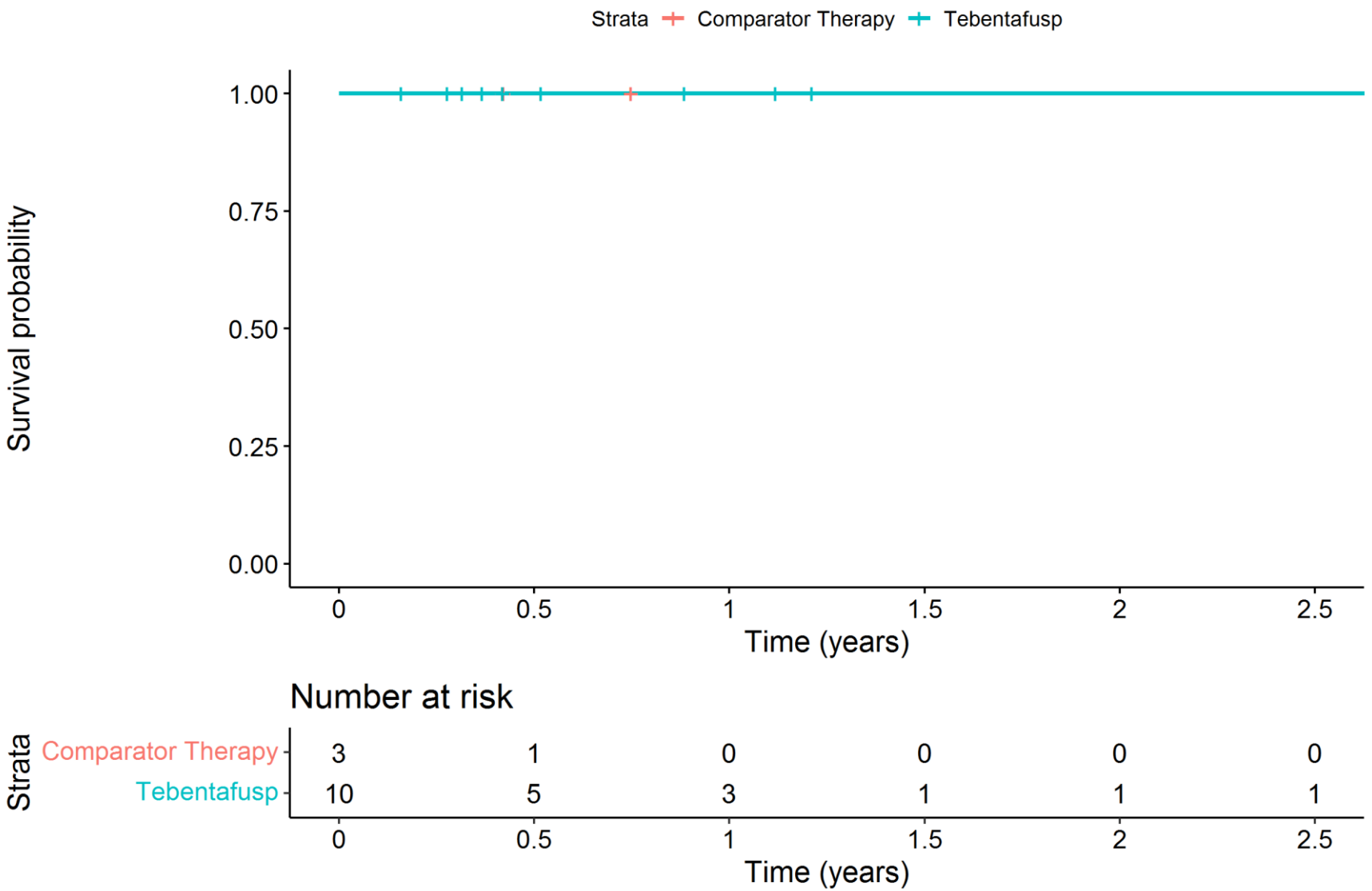


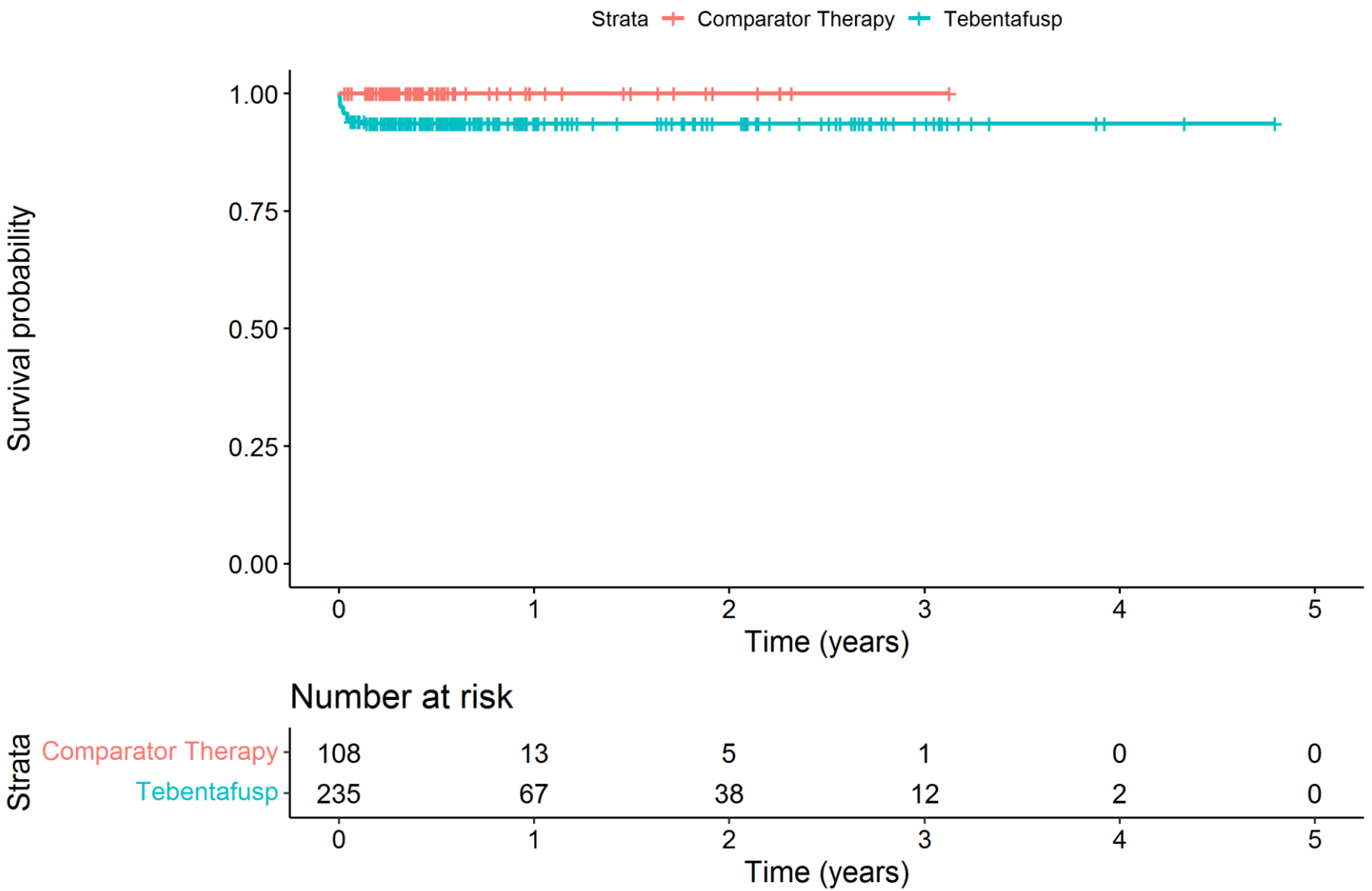
Erkrankungen der Haut und des Unterhautgewebes- LDH > ULN



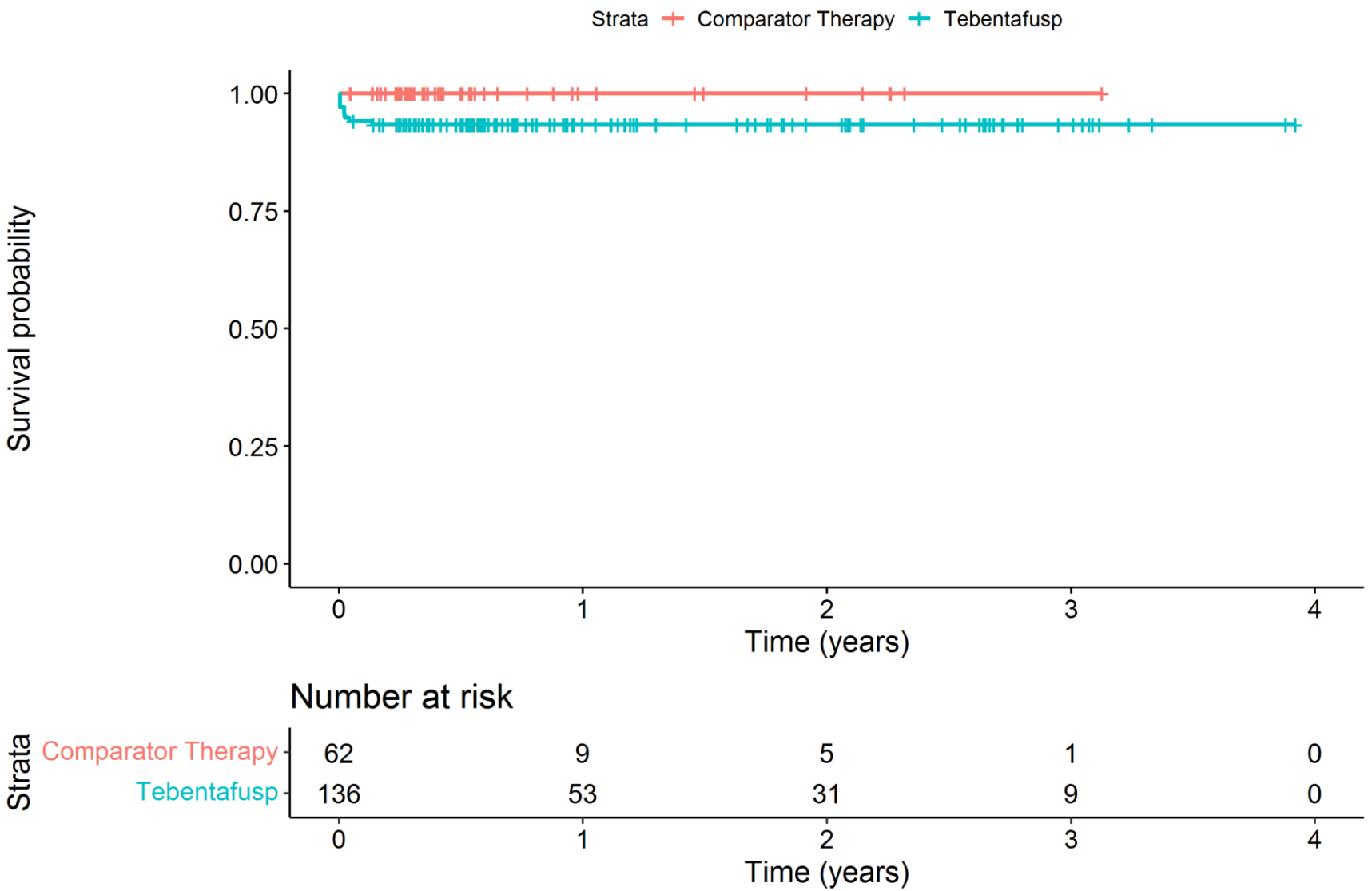
Erkrankungen der Haut und des Unterhautgewebes- Vorherige Therapie adjuvant/neoadjuvant



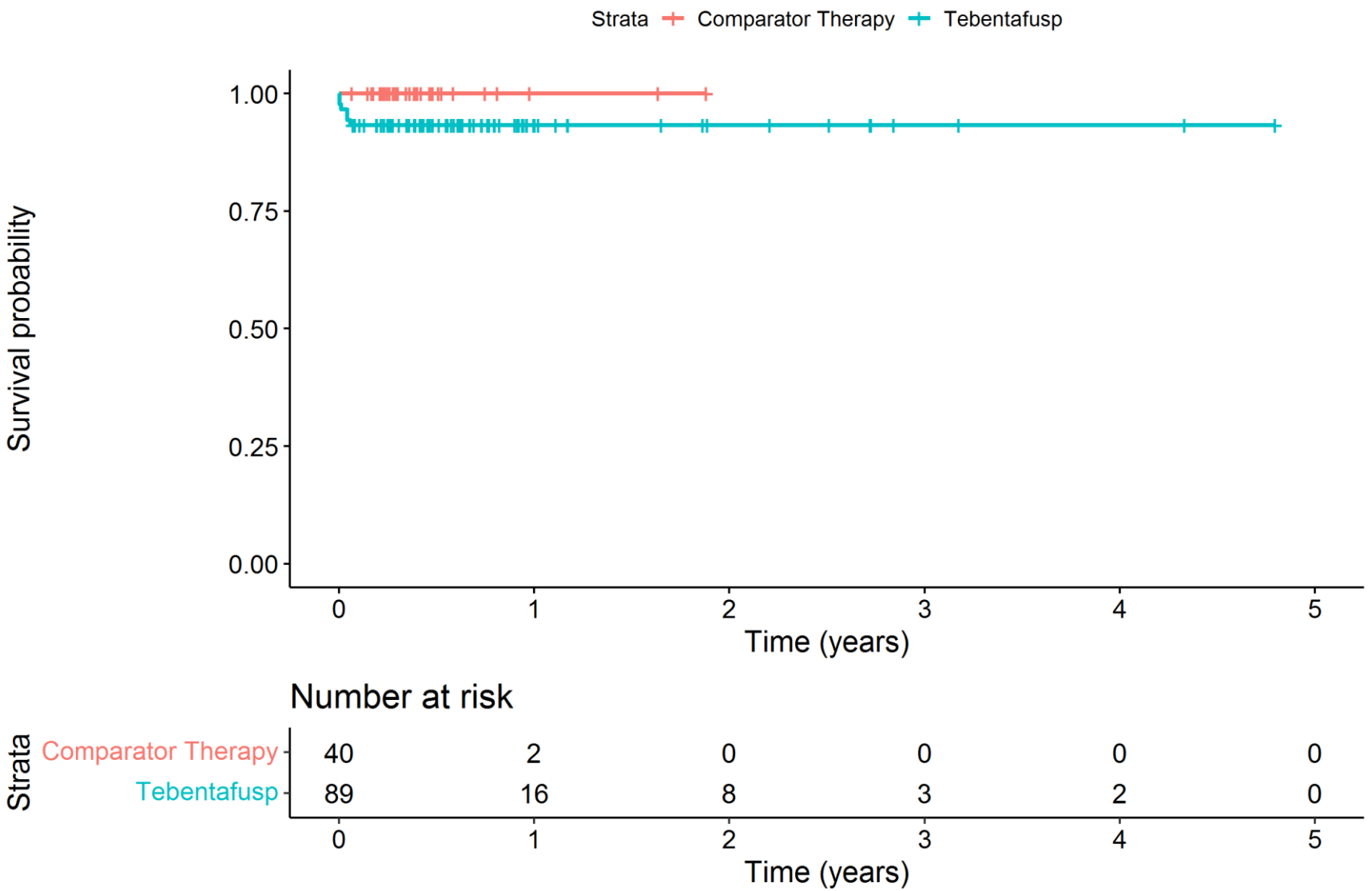
Erkrankungen der Haut und des Unterhautgewebes- Keine Vorherige Therapie adjuvant/neoadjuvant



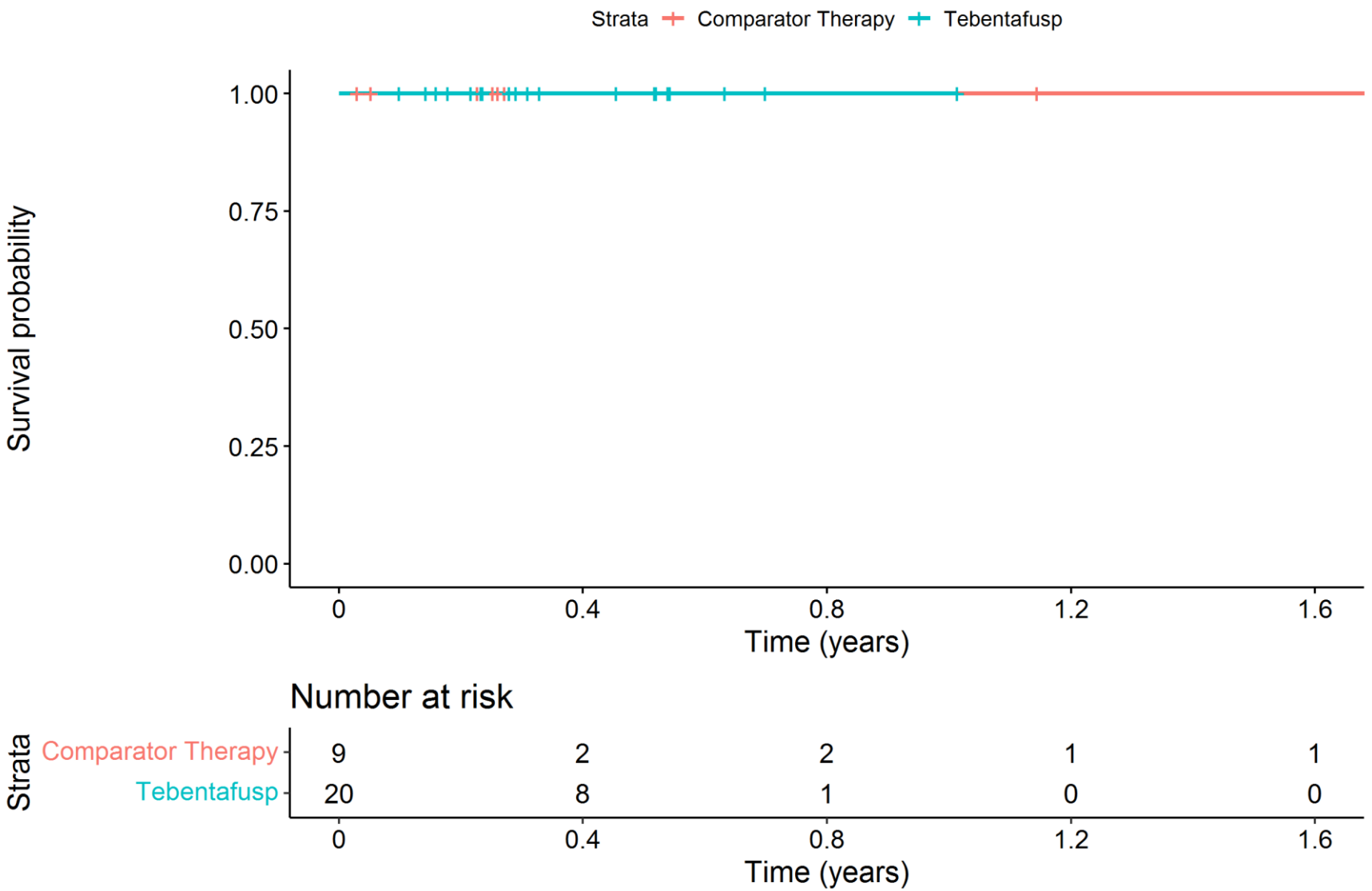
Erkrankungen der Haut und des Unterhautgewebes- Läsion ≤ 3cm



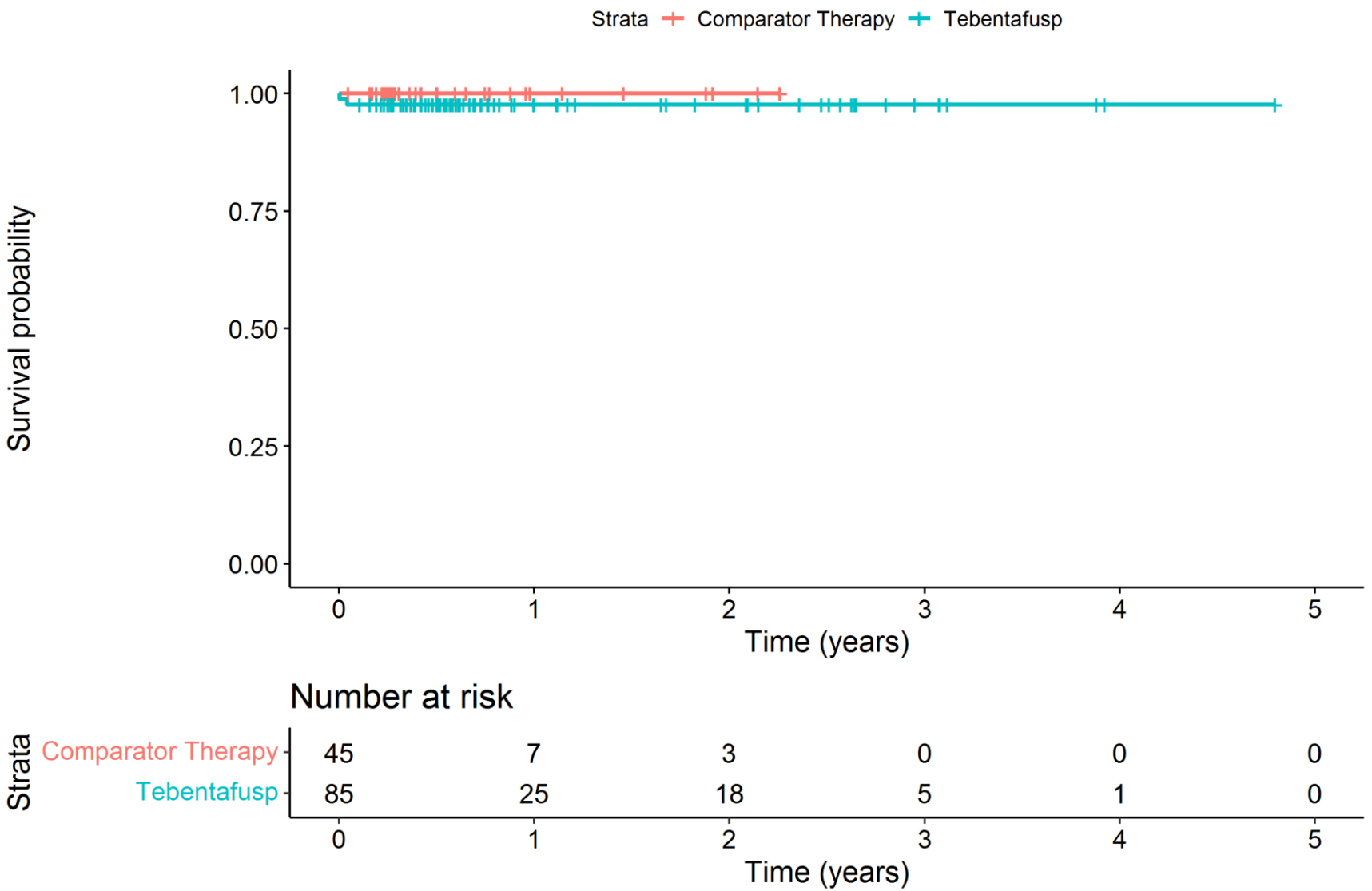
Erkrankungen der Haut und des Unterhautgewebes- Läsion 3,1-8,0 cm



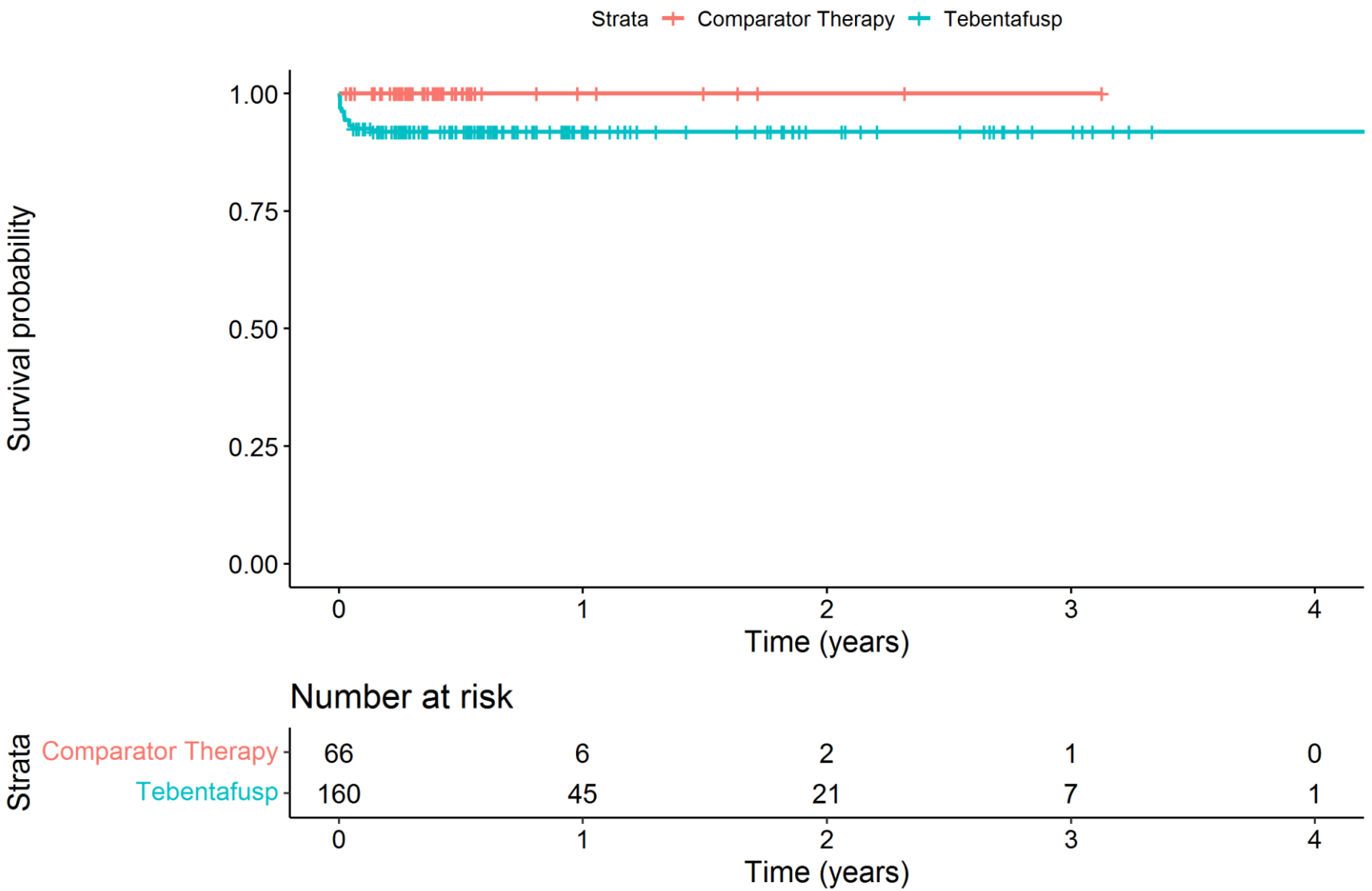
Erkrankungen der Haut und des Unterhautgewebes- Läsion ≥8,1 cm



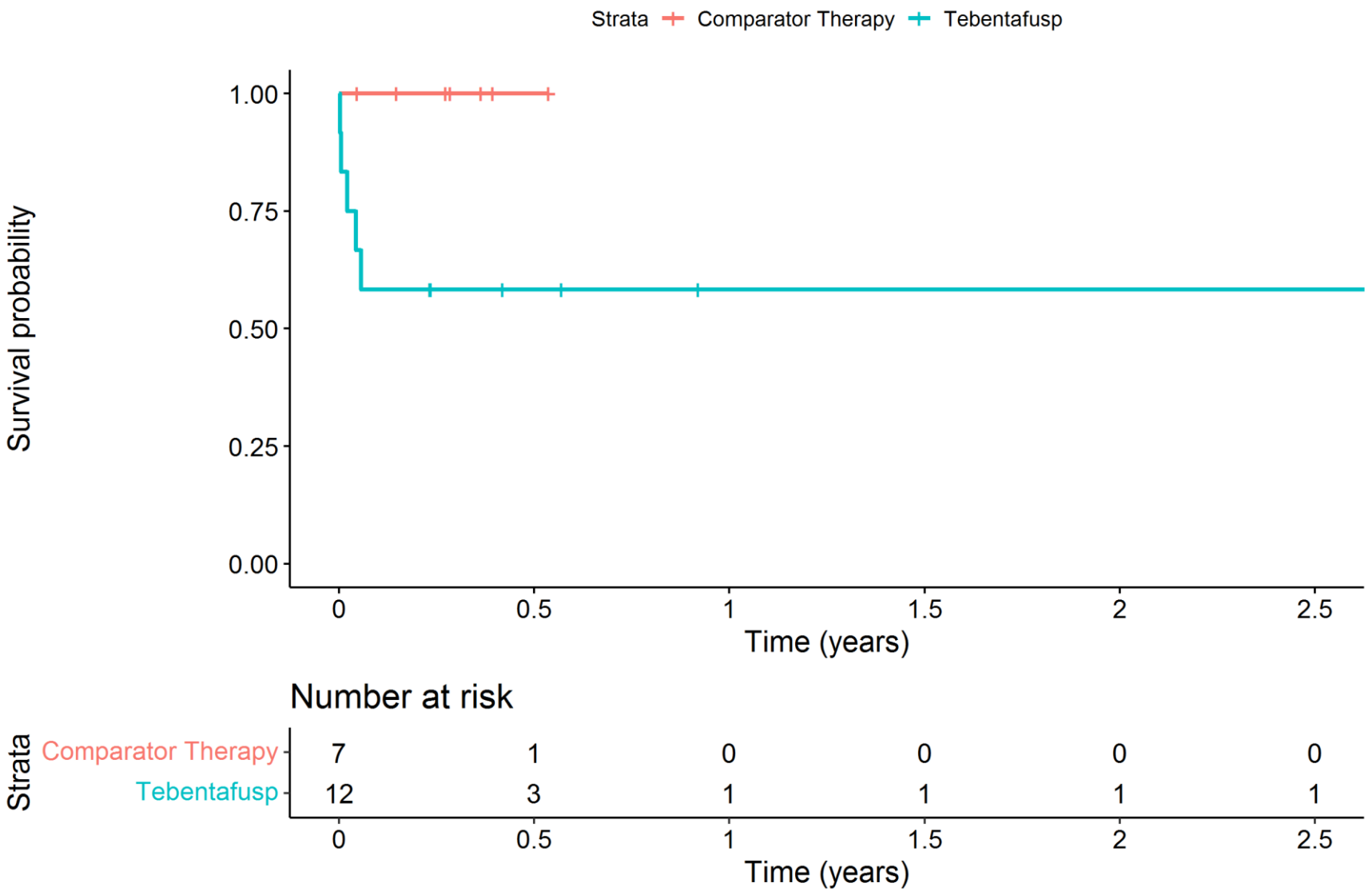
Erkrankungen der Haut und des Unterhautgewebes- Nordamerika



Erkrankungen der Haut und des Unterhautgewebes- Nicht-Nordamerika



Erkrankungen der Haut und des Unterhautgewebes- Dacarbazin



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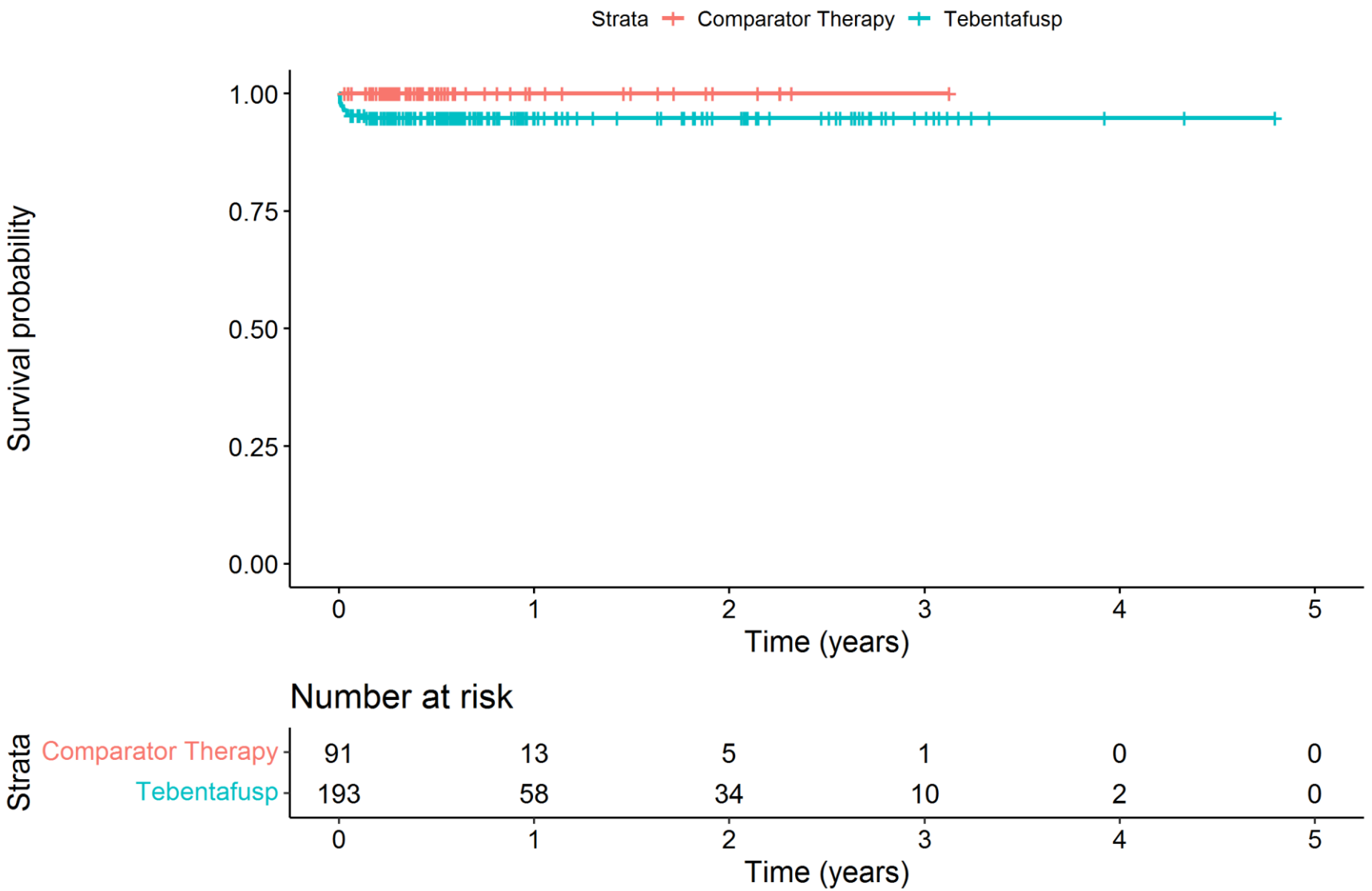

Erkrankungen der Haut und des Unterhautgewebes- Ipilimumab