Gemeinsamer Bundesausschuss

Kriterien zur Bestimmung der zweckmäßigen Vergleichstherapie

und

Recherche und Synopse der Evidenz zur Bestimmung der zweckmäßigen Vergleichstherapie nach § 35a SGB V

und

Schriftliche Beteiligung der wissenschaftlich-medizinischen Fachgesellschaften und der Arzneimittelkommission der deutschen Ärzteschaft (AkdÄ) zur Bestimmung der zweckmäßigen Vergleichstherapie nach § 35a SGB V

Vorgang: 2021-B-007 (Misoprostol)

Stand: März 2021

I. Zweckmäßige Vergleichstherapie: Kriterien gemäß 5. Kapitel § 6 VerfO G-BA

Misoprostol [zur Geburtseinleitung] **Kriterien gemäß 5. Kapitel § 6 VerfO**	
Sofern als Vergleichstherapie eine Arzneimittelanwendung in Betracht kommt, muss das Arzneimittel grundsätzlich eine Zulassung für das Anwendungsgebiet haben.	Siehe Übersicht „II. Zugelassene Arzneimittel im Anwendungsgebiet“
Sofern als Vergleichstherapie eine nicht-medikamentöse Behandlung in Betracht kommt, muss diese im Rahmen der GKV erbringbar sein.	Eipollösung Amniotomie Ballonkatheter Hygroskopische Dilatatoren
Beschlüsse/Bewertungen/Empfehlungen des Gemeinsamen Bundesausschusses zu im Anwendungsgebiet zugelassenen Arzneimitteln/nicht-medikamentösen Behandlungen	Es liegen keine Beschlüsse vor
Die Vergleichstherapie soll nach dem allgemein anerkannten Stand der medizinischen Erkenntnisse zur zweckmäßigen Therapie im Anwendungsgebiet gehören.	Siehe systematische Literaturrecherche

II. Zugelassene Arzneimittel im Anwendungsgebiet

Wirkstoff **ATC-Code** **Handelsname**	**Anwendungsgebiet** (Text aus Fachinformation)
Zu bewertendes Arzneimittel:	
Misoprostol	Angusta® wird zur Geburtseinleitung angewendet
Hypophysenhinterlappenhormone	
Oxytocin H01BB02 z.B. Oxytocin PANPHARMA 3 I. E./1 ml Injek-tionslösung	Vor der Geburt: – Geburtseinleitung aus medizinischen Gründen am Termin – primäre und sekundäre Wehenschwäche – Wehenstimulierung (Oxytocin-Belastungstest)
Prostaglandin E2	
Dinoproston G02AD02 MINPROSTIN®	Medizinisch indizierte Geburtseinleitung bei Schwangeren am Termin oder nahe am Termin mit ausreichender Geburtsreife der Cervix uteri (Bishop-Score 4 und größer) und Einlingsschwangerschaft

Quellen: AMIS-Datenbank, Fachinformationen

Gemeinsamer Bundesausschuss

Abteilung Fachberatung Medizin

Recherche und Synopse der Evidenz zur Bestimmung der zweckmäßigen Vergleichstherapie nach § 35a SGB V

Vorgang: 2021-B-007 (Misoprostol)

Auftrag von:	Abt. AM
Bearbeitet von:	Abt. FB Med
Datum:	17. Februar 2021

Inhaltsverzeichnis

Abkürzungsverzeichnis

ARM	Artificial rupture of membranes
AWMF	Arbeitsgemeinschaft der wissenschaftlichen medizinischen Fachgesellschaften
CI	Confidence interval
CS	Caesarean section
EASI	Extra-amniotic saline infusion
ECRI	ECRI Guidelines Trust
FHR	Fetal heart rate
G-BA	Gemeinsamer Bundesausschuss
GIN	Guidelines International Network
GoR	Grade of Recommendations
HR	Hazard Ratio
IMN	Isosorbide mononitrate
IOL	Induction of labour
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
KI	Konfidenzintervall
LoE	Level of Evidence
MS	Membrane sweeping
NICE	National Institute for Health and Care Excellence
NZ	New Zealand
OR	Odds Ratio
PG	Prostaglandine
PGE2	Prostaglandin E2
PROM	Pre-labour rupture of membranes
RCT	Randomised Controlled Trial
RR	Relatives Risiko
SIGN	Scottish Intercollegiate Guidelines Network
SOGC	Society of Obstetricians and Gynaecologists of Canada
TPROM	Term pre-labour rupture of membranes
TRIP	Turn Research into Practice Database
WHO	World Health Organization

1 Indikation

Anwendungsgebiet laut Beratungsanforderung: zur Geburtseinleitung.

2 Systematische Recherche

Es wurde eine systematische Literaturrecherche nach systematischen Reviews, Meta-Analysen und evidenzbasierten systematischen Leitlinien zur Indikation *Geburtseinleitung* durchgeführt. Der Suchzeitraum wurde auf die letzten 5 Jahre eingeschränkt und die Recherche am 20.01.2021 abgeschlossen. Die Suche erfolgte in den aufgeführten Datenbanken bzw. Internetseiten folgender Organisationen: The Cochrane Library (Cochrane Database of Systematic Reviews), MEDLINE (PubMed), AWMF, ECRI, G-BA, GIN, NICE, TRIP, SIGN, WHO. Ergänzend erfolgte eine freie Internetsuche nach aktuellen deutschen und europäischen Leitlinien. Die detaillierte Darstellung der Suchstrategie ist am Ende der Synopse aufgeführt.

In einem zweistufigen Screening wurden die Ergebnisse der Literaturrecherche bewertet. Die Recherche ergab 337 Quellen. Im ersten Screening wurden auf Basis von Titel und Abstract nach Population, Intervention, Komparator und Publikationstyp nicht relevante Publikationen ausgeschlossen. Zudem wurde eine Sprachrestriktion auf deutsche und englische Quellen vorgenommen. Im zweiten Screening wurden die im ersten Screening eingeschlossenen Publikationen als Volltexte gesichtet und auf ihre Relevanz und methodische Qualität geprüft. Dafür wurden dieselben Kriterien wie im ersten Screening sowie Kriterien zur methodischen Qualität der Evidenzquellen verwendet. Basierend darauf, wurden insgesamt 11 Quellen eingeschlossen. Es erfolgte eine synoptische Darstellung wesentlicher Inhalte der identifizierten Referenzen.

3 Ergebnisse

3.1 G-BA Beschlüsse/IQWiG Berichte

Es liegen keine relevanten G-BA Beschlüsse/IQWiG Berichte zur Fragestellung vor.

3.2 Cochrane Reviews

Finucane EM et al., 2020 [3].

Membrane sweeping for induction of labour.

Fragestellung

To assess the effects and safety of membrane sweeping for induction of labour in women at or near term (≥ 36 weeks gestation).

Methodik

Population:

- Pregnant women carrying a live fetus at or near term (≥ 36 weeks gestation)

Intervention:

- Amniotic membrane sweeping

Komparator:

- No treatment/sham treatment or other methods listed on predefined list of labour induction methods (vaginal/intracervical prostaglandins; intravenous oxytocin +/- amniotomy; amniotomy only; vaginal/oral misoprostol; mechanical methods including extraamniotic Foley catheter; differing frequencies of amniotic membrane sweeping)

Endpunkte:

- primary outcomes:
    - maternal: spontaneous onset of labour; induction of labour (defined as the process of artificially stimulating the uterus to start labour); caesarean section; spontaneous vaginal birth; uterine hyperstimulation with/without fetal heart rate (FHR) changes; maternal death or serious maternal morbidity (i.e. uterine rupture, admission to intensive care unit, septicaemia)
    - neonatal: neonatal death or serious neonatal perinatal morbidity (i.e. neonatal sepsis, seizures, birth asphyxia defined by trialists, neonatal encephalopathy, disability in childhood)
- secondary outcomes:
    - maternal: instrumental vaginal birth; epidural analgesia; postpartum haemorrhage (as defined by the trial authors); uterine rupture (all clinically significant ruptures of unscarred or scarred uteri); augmentation of labour (defined as “the process of stimulating the uterus to increase the frequency, duration and intensity of contractions after the onset of spontaneous labour”)
    - neonatal: Apgar score less than seven at five minutes; neonatal encephalopathy; perinatal death

- measures of satisfaction: woman's satisfaction; cost

Recherche/Suchzeitraum:

- We searched the Cochrane Pregnancy and Childbirth's Trials Register (25 February 2019), ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP) (25 February 2019), and reference lists of retrieved studies.

Qualitätsbewertung der Studien:

- Cochrane approach / GRADE

Ergebnisse

Anzahl eingeschlossener Studien:

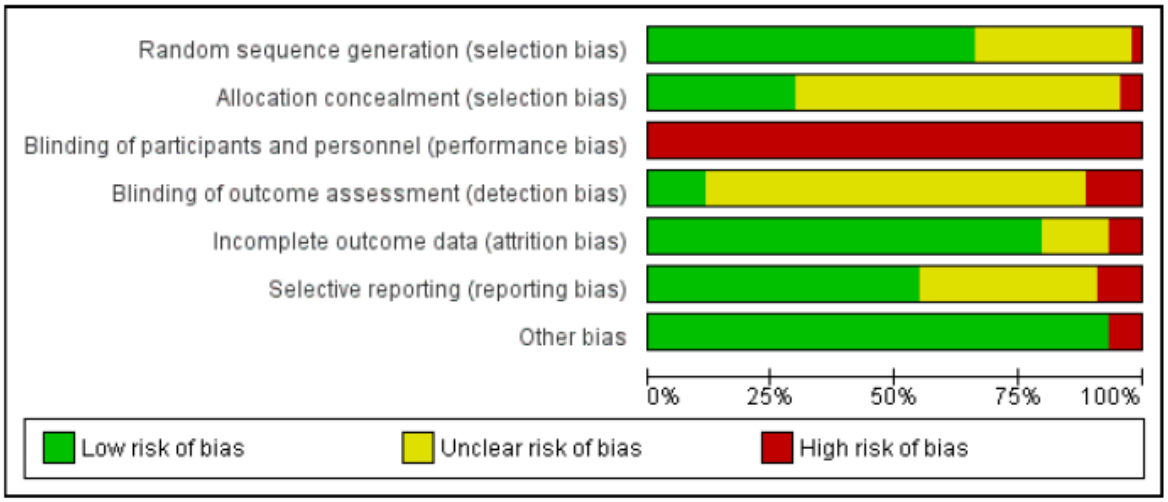
- We included 44 studies (20 new to this update), reporting data for 6940 women and their infants.
- Six studies (n = 1284) compared membrane sweeping with more than one intervention and were thus included in more than one comparison.

Charakteristika der Population:

- Three studies (n = 482) only included nulliparous women; five studies (n = 817) included multiparous women only; thirty-five studies (n = 5567) included mixed parity
- Three studies (n = 473) included only women with a history of a caesarean section; twelve studies (n = 1600) excluded women with a history of caesarean section or a uterine scare; nine studies (n = 1740) included only women with an unfavourable cervix; four studies (n = 574) excluded women with a closed cervix
- Inclusion criteria for gestational age varied among studies

Qualität der Studien:

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Studienergebnisse (main results):

- **Membrane sweeping versus vaginal/intracervical prostaglandins (4 studies, 480 women)**:

  There may be little to no difference between groups for the outcomes:
  - spontaneous onset of labour (aRR, 1.24, 95% CI 0.98 to 1.57, 3 studies, 339 participants, low-certainty evidence);
  - induction (aRR 0.90, 95% CI 0.56 to 1.45, 2 studies, 157 participants, low-certainty evidence);
  - caesarean (aRR 0.69, 95% CI 0.44 to 1.09, 3 studies, 339 participants, low-certainty evidence);
  - spontaneous vaginal birth (aRR 1.12, 95% CI 0.95 to 1.32, 2 studies, 252 participants, low-certainty evidence);
  - maternal death or serious morbidity (aRR 0.93, 95% CI 0.27 to 3.21, 1 study, 87 participants, low-certainty evidence);
  - neonatal perinatal death or serious morbidity (aRR 0.40, 95% CI 0.12 to 1.33, 2 studies, 269 participants, low-certainty evidence).
- **Membrane sweeping versus intravenous oxytocin +/- amniotomy (1 study, 104 women)**:

  There may be little to no difference between groups for:
  - spontaneous onset of labour (aRR 1.32, 95% CI 88 to 1.96, 1 study, 69 participants, low-certainty evidence);
  - induction (aRR 0.51, 95% CI 0.05 to 5.42, 1 study, 69 participants, low-certainty evidence);
  - caesarean (aRR 0.69, 95% CI 0.12 to 3.85, 1 study, 69 participants, low-certainty evidence);
  - maternal death or serious morbidity was reported on, but there were no events.
- **Membrane sweeping versus vaginal/oral misoprostol (2 studies, 160 women):**

  There may be little to no difference between groups for:
  - caesareans (RR 0.82, 95% CI 0.31 to 2.17, 1 study, 96 participants, low-certainty evidence).

- We found no studies that compared membrane sweeping with amniotomy only or mechanical methods.
- Three studies, providing data for 675 women, reported that women indicated favourably on their experience of membrane sweeping with one study reporting that 88% (n = 312) of women questioned in the postnatal period would choose membrane sweeping in the next pregnancy.
- Two studies reporting data for 290 women reported that membrane sweeping is more cost-effective than using prostaglandins, although more research should be undertaken in this area.

Anmerkung/Fazit der Autoren

Membrane sweeping may be effective in achieving a spontaneous onset of labour, but the evidence for this was of low certainty. When compared to expectant management, it

potentially reduces the incidence of formal induction of labour. Questions remain as to whether there is an optimal number of membrane sweeps and timings and gestation of these to facilitate induction of labour.

De Vaan MDT et al., 2019 [1].

Mechanical methods for induction of labour.

Fragestellung

To determine the effectiveness and safety of mechanical methods for third trimester (> 24 weeks' gestation) induction of labour in comparison with prostaglandin E2 (PGE2) (vaginal and intracervical), low-dose misoprostol (oral and vaginal), amniotomy or oxytocin.

Methodik

Population:

- Pregnant women due for third trimester induction of labour, carrying a viable fetus

Intervention/Komparator:

- specific mechanical methods (balloon catheter, laminaria tents or extra-amniotic saline infusion EASI) compared with prostaglandins (different types, different routes) or with oxytocin
- single balloon compared to a double balloon
- addition of prostaglandins or oxytocin to mechanical methods compared with prostaglandins or oxytocin alone
- for this update, we chose only to include low-dose misoprostol (defined as ≤ 50 µg every ≥ 4 hours) as evidence suggests low-dose misoprostol is superior to high-dose misoprostol regarding safety outcomes and being equally effective (Alfirevic 2014; Hofmeyr 2010)

Endpunkte:

- primary outcomes: vaginal delivery not achieved within 24 hours (from start cervical ripening); uterine hyperstimulation with fetal heart rate (FHR) changes; caesarean section; serious neonatal morbidity or perinatal death (e.g. seizures, birth asphyxia defined by trialists, neonatal encephalopathy, disability in childhood); serious maternal morbidity or death (e.g. uterine rupture, admission to intensive care unit, septicaemia)
- secondary outcomes: cervix unfavourable/unchanged after 12 to 24 hours; oxytocin augmentation; complications (e.g. uterine hyperstimulation without FHR changes, uterine rupture, epidural analgesia, instrumental vaginal delivery, meconium-stained liquor, Apgar score less than 7 at 5 minutes, neonatal intensive care unit (NICU) admission, neonatal encephalopathy, perinatal death, disability in childhood etc.), measures of satisfaction (woman/caregiver not satisfied)

Recherche/Suchzeitraum:

- For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register, ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP), and reference lists of retrieved studies (9 January 2018). We updated the search in March 2019 and added the search results to the awaiting classification section of the review.

Qualitätsbewertung der Studien:

- Cochrane approach / GRADE

Ergebnisse

Anzahl eingeschlossener Studien:

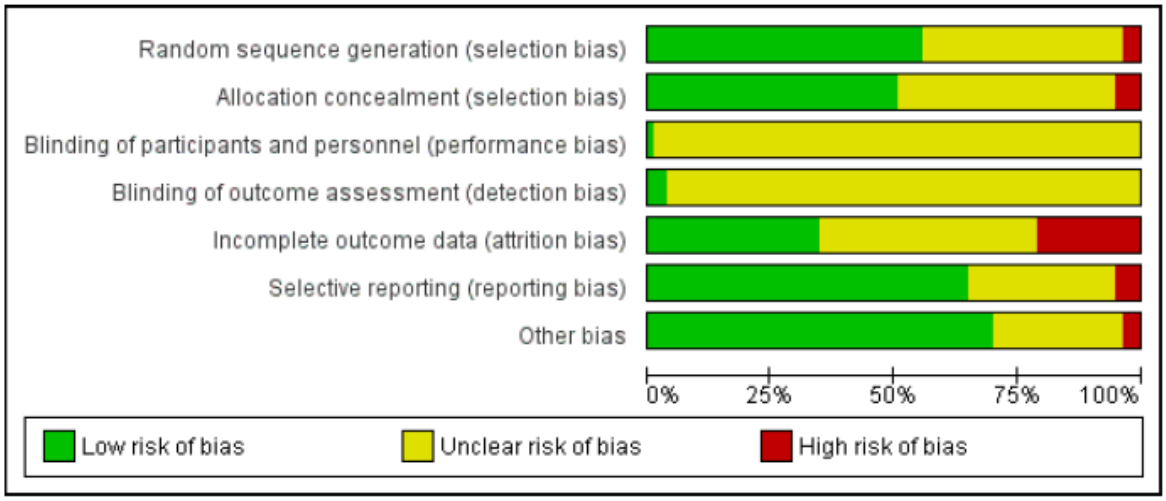
- This review update includes a total of 113 trials (22,373 women) contributing data to 21 comparisons.

Charakteristika der Population:

- Most studies included both nulliparous and multiparous women
- Most studies excluded women with a past history of caesarean section
- The majority of studies included women with a gestational age beyond 37 weeks

Qualität der Studien:

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Studienergebnisse (main results):

- **Balloon versus vaginal PGE2**: There may be little or no difference in vaginal deliveries not achieved within 24 hours (average risk ratio (RR) 1.01, 95% confidence interval (CI) 0.82 to 1.26; 7 studies; 1685 women; IQ = 79%; low-quality evidence) and there probably is little or no difference in caesarean sections (RR 1.00, 95% CI 0.92 to 1.09; 28 studies; 6619 women; moderate-quality evidence) between induction of labour with a balloon catheter and vaginal PGE2. A balloon catheter probably reduces the risk of uterine hyperstimulation with fetal heart rate (FHR) changes (RR 0.35, 95% CI 0.18 to 0.67; 6 studies; 1966 women; moderate-quality evidence), serious neonatal morbidity or perinatal death (RR 0.48, 95% CI 0.25 to 0.93; 8 studies; 2757 women; moderate-quality evidence) and may slightly reduce the risk of a NICU admission (RR 0.82, 95% CI 0.65 to 1.04; 3647 women; 12 studies; low-quality evidence). It is uncertain whether there is a difference in serious maternal morbidity or death (RR 0.20, 95% CI 0.01 to 4.12; 4 studies; 1481 women) or five-minute Apgar score < 7 (RR 0.74, 95% CI 0.49 to 1.14; 4271 women; 14 studies) because the quality of the evidence was found to be very low and low, respectively.

- **Balloon versus low-dose vaginal misoprostol**: It is uncertain whether there is a difference in vaginal deliveries not achieved within 24 hours between induction of labour with a balloon catheter and vaginal misoprostol (RR 1.09, 95% CI 0.85 to 1.39; 340 women; 2 studies; low-quality evidence). A balloon catheter probably reduces the risk of uterine hyperstimulation with FHR changes (RR 0.39, 95% CI 0.18 to 0.85; 1322 women; 8 studies; moderate-quality evidence) but may increase the risk of a caesarean section (average RR 1.28, 95% CI 1.02 to 1.60; 1756 women; 12 studies; IQ = 45%; low-quality evidence). It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death (RR 0.58, 95% CI 0.12 to 2.66; 381 women; 3 studies), serious maternal morbidity or death (no events; 4 studies, 464 women), both very low-quality evidence, and five-minute Apgar score < 7 (RR 1.00, 95% CI 0.50 to 1.97; 941 women; 7 studies) and NICU admissions (RR 1.00, 95% CI 0.61 to 1.63; 1302 women; 9 studies), both low-quality evidence.
- **Balloon versus low-dose oral misoprostol**: A balloon catheter probably increases the risk of a vaginal delivery not achieved within 24 hours (RR 1.28, 95% CI 1.13 to 1.46; 782 women, 2 studies, and probably slightly increases the risk of a caesarean section (RR 1.17, 95% CI 1.04 to 1.32; 3178 women; 7 studies; both moderate-quality evidence) when compared to oral misoprostol. It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes (RR 0.81, 95% CI 0.48 to 1.38; 2033 women; 2 studies), serious neonatal morbidity or perinatal death (RR 1.11, 95% CI 0.60 to 2.06; 2627 women; 3 studies), both low-quality evidence, serious maternal morbidity or death (RR 0.50, 95% CI 0.05 to 5.52; 2627 women; 3 studies), very low-quality evidence, five-minute Apgar scores < 7 (RR 0.71, 95% CI 0.38 to 1.32; 2693 women; 4 studies) and NICU admissions (RR 0.82, 95% CI 0.58 to 1.17; 2873 women; 5 studies), both low-quality evidence.
- **Combination balloon and low dose misoprostol versus misoprostol alone** (seven trials involving 1422 women): No differences found for primary outcomes. Secondary outcomes: A balloon catheter combined with misoprostol probably reduces the risk of an unfavourable cervix after 24 hours when compared to misoprostol alone (RR 0.27, 95% CI 0.08 to 0.94; 140 women; 1 study) and the risk of uterine hyperstimulation without FHR changes when compared to misoprostol alone (RR 0.53, 95% CI 0.32 to 0.90; 982 women; 4 studies). A balloon catheter combined with misoprostol may reduce the risk of NICU admission when compared to misoprostol alone (RR 0.57, 95% CI 0.36 to 0.91; 1246 women; 6 studies). No differences were found for other secondary outcomes.

Anmerkung/Fazit der Autoren

Low- to moderate-quality evidence shows mechanical induction with a balloon is probably as effective as induction of labour with vaginal PGE2. However, a balloon seems to have a more favourable safety profile. More research on this comparison does not seem warranted.

Moderate-quality evidence shows a balloon catheter may be slightly less effective as oral misoprostol, but it remains unclear if there is a difference in safety outcomes for the neonate. When compared to low-dose vaginal misoprostol, low-quality evidence shows a balloon may be less effective, but probably has a better safety profile. Future research could be focused more on safety aspects for the neonate and maternal satisfaction.

Most of the studies included in the review examined a balloon and compared it with either vaginal PGE2 or with vaginal or oral misoprostol. A smaller number of studies examined a balloon versus either intracervical PGE2 or oxytocin. Since the last update, no more studies

have been published about induction of labour with a Laminaria tent or with EASI. None of the included studies examined the combination of a mechanical method with amniotomy.

In the updated search of 19 March 2019, an additional 38 trial reports were added to the list of studies awaiting classification for consideration in the next update. The references have been assessed but not incorporated into the review. Only seven of these trials are likely to contribute data for this review and are mainly small trials. The authors imputed the data for these trials and this resulted in no changes in terms of the direction or strength of the evidence. These studies will be fully incorporated at the next update.

Kommentare zum Review

- Zur Fragestellung Ballonkatheter versus orales Misoprostol siehe auch Kemper et al. [4]. Zur Fragestellung Ballonkatheter und Misoprostol versus Misoprostol allein siehe auch Ornat et al. [7].
- Zur Fragestellung Ballonkatheter versus vaginales PGE2 (Dinoproston) siehe auch Liu et al. [5].

Smith CA et al., 2017 [9].

Acupuncture or acupressure for induction of labour.

Fragestellung

To determine the effectiveness and safety of acupuncture and acupressure for third trimester cervical ripening or induction of labour.

Methodik

Population:

- Pregnant women carrying a viable fetus due for third trimester induction of labour

Intervention/Komparator:

- Manual, laser, or electro-acupuncture or acupressure compared with placebo, no treatment, sham acupuncture/acupressure, or any other method on a predefined list of methods of labour induction (vaginal prostaglandins; intracervical prostaglandins; intravenous oxytocin; amniotomy; intravenous oxytocin with amniotomy; vaginal misoprostol; oral misoprostol; mechanical methods including extraamniotic Foley catheter; membrane sweeping; extraamniotic prostaglandins; intravenous prostaglandins; oral prostaglandins; mifepristone; oestrogens with or without amniotomy; corticosteroids; relaxin; hyaluronidase; castor oil, bath, and/or enema)

Endpunkte:

- primary outcomes: vaginal delivery not achieved within 24 hours; uterine hyperstimulation with fetal heart rate (FHR) changes; caesarean section; serious neonatal morbidity or perinatal death (e.g. seizures, birth asphyxia defined by trialists, neonatal encephalopathy, disability in childhood); serious maternal morbidity or death (e.g. uterine rupture, admission to intensive care unit, septicaemia)
- secondary outcomes: cervix unfavourable/unchanged after 12 to 24 hours; oxytocin augmentation; complications (e.g. uterine hyperstimulation without FHR changes, uterine rupture, epidural analgesia, instrumental vaginal delivery, meconium-stained liquor etc.); measures of satisfaction (woman/caregiver not satisfied); acupuncture-

specific outcomes (i.e. use of other induction methods, time from trial intervention to the birth of the baby, length of labour, spontaneous vaginal delivery)

Recherche/Suchzeitraum:

- We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 November 2016), PubMed (1966 to 25 November 2016), ProQuest Dissertations & Theses (25 November 2016), CINAHL (25 November 2016), EMBASE (25 November 2016), the WHO International Clinical Trials Registry Portal (ICTRP) (3 October 2016), and bibliographies of relevant papers.

Qualitätsbewertung der Studien:

- Cochrane approach / GRADE

Ergebnisse

Anzahl eingeschlossener Studien:

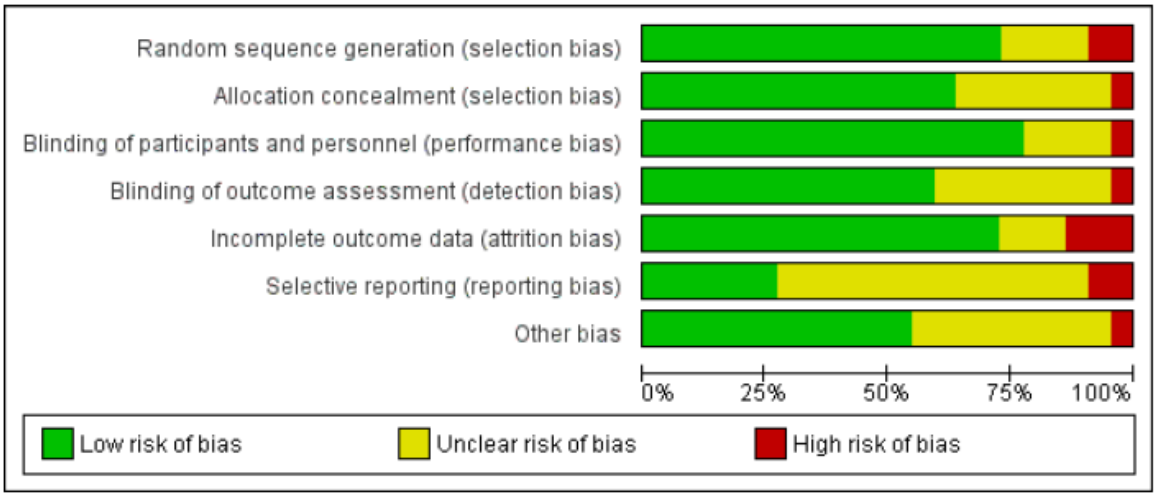
- This review update includes 22 trials (3456 women)
- Trials using manual or electro-acupuncture were compared with usual care (eight trials, 760 women), sweeping of membranes (one trial, 207 women), or sham controls (seven trials, 729 women)
- Trials using acupressure were compared with usual care (two trials, 151 women) or sham controls (two trials, 239 women).

Charakteristika der Population:

- 10 trials recruited nulliparous women only; 10 trials recruited both nulliparous and primiparous women; parity was unclear in 2 trials
- 6 trials included only women who were post-date (> 40 weeks gestational age); 7 studies included women both under and over 40 weeks gestational age; 3 studies included only women less than 40 weeks gestational age

Qualität der Studien:

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Studienergebnisse (main results):

- **Acupuncture versus usual care**: There was no clear difference in caesarean sections between groups (average RR 0.77, 95% CI 0.51 to 1.17, eight trials, 760 women; low-quality evidence). There was an increase in cervical maturation for the acupuncture (electro) group compared with control (MD 1.30, 95% CI 0.11 to 2.49, one trial, 67 women) and a shorter length of labour (minutes) in the usual care group compared to electro-acupuncture (MD 124.00, 95% CI 37.39 to 210.61, one trial, 67 women).
- **Acupuncture versus sweeping of fetal membranes**: One trial of acupuncture versus sweeping of fetal membranes showed no clear differences between groups in caesarean sections (RR 0.64, 95% CI 0.34 to 1.22, one trial, 207 women, moderate-quality evidence), need for augmentation, epidural analgesia, instrumental vaginal birth, Apgar score < 7 at 5 minutes, neonatal intensive care admission, and postpartum bleeding greater than 500 mL.
- **Acupressure versus usual care**: There was no evidence of benefit from acupressure in reducing caesarean sections compared to usual care (RR 1.02, 95% CI 0.68 to 1.53, two trials, 151 women, moderate-quality evidence). There was no evidence of a clear benefit in reduced epidural analgesia, Apgar score < 7 at 5 minutes, admission to neonatal intensive care, time from trial intervention to birth of the baby, use of other induction methods, and spontaneous vaginal birth.

Anmerkung/Fazit der Autoren

Overall, there was no clear benefit from acupuncture or acupressure in reducing caesarean section rate. The quality of the evidence varied between low to high. Few trials reported on neonatal morbidity or maternal mortality outcomes. Acupuncture showed some benefit in improving cervical maturity, however, more well-designed trials are needed. Future trials could include clinically relevant safety outcomes.

West HM et al., 2017 [11].

Methods of term labour induction for women with a previous caesarean section.

Fragestellung

To assess the benefits and harms associated with different methods used to induce labour in women who have had a previous caesarean birth.

Methodik

Population:

- Pregnant women with a live fetus, who have had a previous caesarean section, requiring induction of labour in the third trimester of pregnancy

Intervention/Komparator:

- All methods of cervical ripening or labour induction including: prostaglandin medication (including oral or vaginal PGE2 and misoprostol); mifepristone; mechanical methods (including Foley catheters and double-balloon catheters); oxytocin, or placebo compared with placebo or any other method were included.

Endpunkte:

- primary outcomes: vaginal delivery not achieved within 24 hours (or period specified by trial authors); uterine hyperstimulation with fetal heart rate (FHR) changes;

caesarean section; serious neonatal morbidity or perinatal death (e.g. seizures, birth asphyxia defined by trialists, neonatal encephalopathy, disability in childhood); serious maternal morbidity or death (e.g. uterine rupture, admission to intensive care unit, septicaemia)

- secondary outcomes: cervix unfavourable/unchanged after 12 to 24 hours; oxytocin augmentation; complications (e.g. uterine hyperstimulation without FHR changes, uterine rupture, epidural analgesia, instrumental vaginal delivery, meconium-stained liquor etc.), measures of satisfaction (woman/caregiver not satisfied)

Recherche/Suchzeitraum:

- We searched Cochrane Pregnancy and Childbirth's Trials Register (31 August 2016) and reference lists of retrieved studies.

Qualitätsbewertung der Studien:

- Cochrane approach / GRADE

Ergebnisse

Anzahl eingeschlossener Studien:

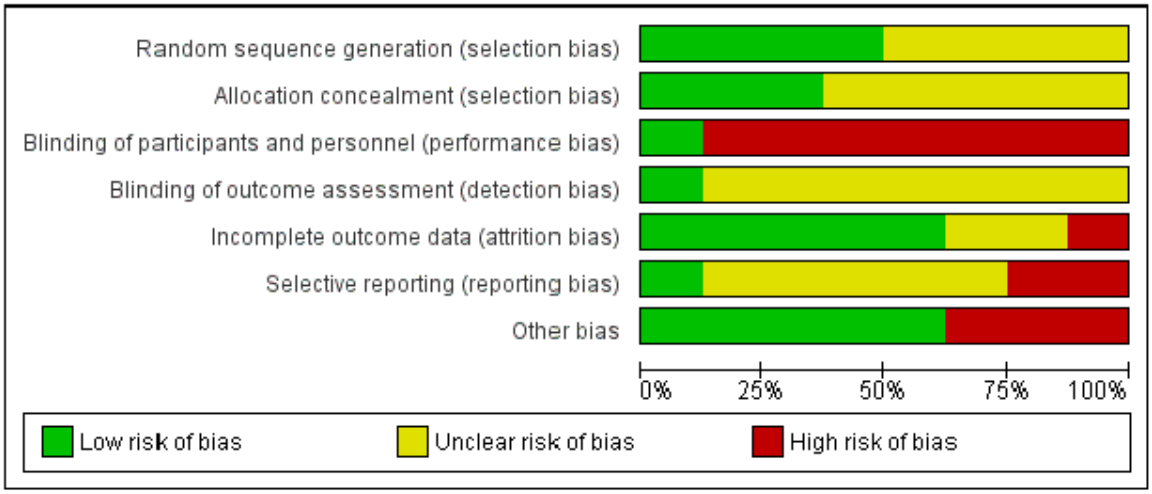
- Eight studies (data from 707 women and babies) are included in this updated review

Charakteristika der Population:

- All participants were women with a prior caesarean section
- All studies looked at induction at term, or approaching term
- The gestational age at which women were eligible and the indications for induction of labour varied between the studies

Qualität der Studien:

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



Studienergebnisse (main results):

- **Vaginal PGE2 versus intravenous oxytocin** (one trial, 42 women): no clear differences for caesarean section (risk ratio (RR) 0.67, 95% confidence interval (CI) 0.22 to 2.03, evidence graded low), serious neonatal morbidity or perinatal death (RR 3.00, 95% CI 0.13 to 69.70, evidence graded low), serious maternal morbidity or death (RR 3.00, 95%

CI 0.13 to 69.70, evidence graded low). Also no clear differences between groups for the reported secondary outcomes. The GRADE outcomes vaginal delivery not achieved within 24 hours, and uterine hyperstimulation with fetal heart rate changes were not reported.

- **Vaginal misoprostol versus intravenous oxytocin** (one trial, 38 women): this trial stopped early because one woman who received misoprostol had a uterine rupture (RR 3.67, 95% CI 0.16 to 84.66) and one had uterine dehiscence. No other outcomes (including GRADE outcomes) were reported.
- **Foley catheter versus intravenous oxytocin** (one trial, subgroup of 53 women): no clear difference between groups for vaginal delivery not achieved within 24 hours (RR 1.47, 95% CI 0.89 to 2.44, evidence graded low), uterine hyperstimulation with fetal heart rate changes (RR 3.11, 95% CI 0.13 to 73.09, evidence graded low), and caesarean section (RR 0.93, 95% CI 0.45 to 1.92, evidence graded low). There were also no clear differences between groups for the reported secondary outcomes. The following GRADE outcomes were not reported: serious neonatal morbidity or perinatal death, and serious maternal morbidity or death.
- **Double-balloon catheter versus vaginal PGE2** (one trial, subgroup of 26 women): no clear difference in caesarean section (RR 0.97, 95% CI 0.41 to 2.32, evidence graded very low). Vaginal delivery not achieved within 24 hours, uterine hyperstimulation with fetal heart rate changes, serious neonatal morbidity or perinatal death, and serious maternal morbidity or death were not reported.
- **Oral mifepristone versus Foley catheter** (one trial, 107 women): no primary/GRADE outcomes were reported. Fewer women induced with mifepristone required oxytocin augmentation (RR 0.54, 95% CI 0.38 to 0.76). There were slightly fewer cases of uterine rupture among women who received mifepristone, however this was not a clear difference between groups (RR 0.29, 95% CI 0.08 to 1.02). No other secondary outcomes were reported.
- **Vaginal isosorbide mononitrate (IMN) versus Foley catheter** (one trial, 80 women): fewer women induced with IMN achieved a vaginal delivery within 24 hours (RR 2.62, 95% CI 1.32 to 5.21, evidence graded low). There was no difference between groups in the number of women who had a caesarean section (RR 1.00, 95% CI 0.39 to 2.59, evidence graded very low). More women induced with IMN required oxytocin augmentation (RR 1.65, 95% CI 1.17 to 2.32). There were no clear differences in the other reported secondary outcomes. The following GRADE outcomes were not reported: uterine hyperstimulation with fetal heart rate changes, serious neonatal morbidity or perinatal death, and serious maternal morbidity or death.

Anmerkung/Fazit der Autoren

RCT evidence on methods of induction of labour for women with a prior caesarean section is inadequate, and studies are underpowered to detect clinically relevant differences for many outcomes. Several studies reported few of our prespecified outcomes and reporting of infant outcomes was especially scarce. The GRADE level for quality of evidence was moderate to very low, due to imprecision and study design limitations.

Meta-analysis was not possible because studies compared different methods of labour induction. All included studies had at least one design limitation (i.e. lack of blinding, sample attrition, other bias, or reporting bias).

High-quality, adequately-powered RCTs would be the best approach to determine the optimal method for induction of labour in women with a prior caesarean birth. However,

such trials are unlikely to be undertaken due to the very large numbers needed to investigate the risk of infrequent but serious adverse outcomes (e.g. uterine rupture). Observational studies (cohort studies), including different methods of cervical ripening, may be the best alternative. Studies could compare methods believed to provide effective induction of labour with low risk of serious harm, and report the outcomes listed in this review.

3.3 Systematische Reviews

Padayachee L et al., 2020 [8].

Oral misoprostol for induction of labour in term PROM: a systematic review.

Fragestellung

To assess the efficacy of oral misoprostol for induction of labour (IOL) in the context of term pre-labour rupture of membranes (TPROM), and to assess pregnancy outcomes following the administration of oral misoprostol.

Methodik

Population:

- Singleton cephalic term pregnancies (> 36 weeks gestation) with confirmed rupture of membranes and no spontaneous labour at the time of membranes rupture, in mothers with no contraindications to vaginal delivery

Intervention:

- oral misoprostol for labour induction

Komparator:

- placebo / no treatment
- other methods of labour induction

Endpunkte:

- „efficacy“, „pregnancy outcomes“ (keine genaueren Angaben bzgl. vordefinierter Endpunkte)

Recherche/Suchzeitraum:

- systematic search of multiple electronic databases (Ovid Medline, EMBASE, PubMed, and Cochrane) from database inception to February 6, 2019; reference lists of included articles were hand-searched

Qualitätsbewertung der Studien:

- modifizierte Jadad-Skala

Ergebnisse

Anzahl eingeschlossener Studien:

- 12 RCT (1489 singleton pregnancies)

Charakteristika der Population:

- 924 participants (63,9 %) were primiparous

Qualität der Studien:

- Study quality ranged from moderate to high quality

Table 2. Quality assessment of included articles using the Jadad scoring system

Study	Randomized	Appropriately randomized	Blinded	Appropriately blinded	Present withdrawals/ dropouts	Inclusion and exclusion criteria	Adverse effects	Described statistical analysis	Total
Ayaz et al. (2008)[13]	1	0	0	0	0	1	1	1	4
Crane et al. (2003)[14]	1	1	0	0	1	1	1	1	6
Kruit et al. (2016)[15]	1	1	0	0	1	1	1	1	6
Lo et al. (2003)[16]	1	1	1	1	0	1	1	1	7
Mbaluka et al. (2014)[17]	1	1	0	0	0	1	1	1	5
Mozurkewich et al. (2003)[18]	1	1	0	0	1	1	1	1	6
Nagpal et al. (2009)[19]	1	1	0	0	0	1	1	1	5
Ngai et al. (2000)[20]	1	1	0	0	1	1	1	1	6
Ngai et al. (1996)[21]	1	1	1	1	1	1	1	1	8
Pourali et al. (2018)[22]	1	1	0	0	1	1	1	1	6
Shetty et al. (2002)[23]	1	1	0	0	0	1	1	1	5
Thangathai and Kasthuri (2016)[24]	1	0	0	0	0	1	1	1	4

Studienergebnisse:

- **Oral misoprostol versus PGE2 vaginal gel:**
  - Two trials involving a total of 144 women compared oral misoprostol given every 4 hours with 24-hour observation followed by PGE2 gel and showed a higher incidence of vaginal birth in the misoprostol group (pooled relative risk ratio [RR] 1.33, 95% confidence interval [CI] 1.10−1.61).
  - A separate trial comparing misoprostol to PGE2 gel with no observation period found no difference in the incidence of vaginal birth (average RR 1.00, 95% CI 0.85−1.19).
- **Oral misoprostol versus oxytocin infusion:**
  - Two trials involving a total of 405 women compared oral misoprostol every 6 hours with intravenous oxytocin infusions. One study found a slightly higher rate of cesarean delivery in the misoprostol group (20.1% misoprostol vs. 19.9% oxytocin), and the other found no difference in mode of delivery between the two groups.
  - Four additional trials compared misoprostol to oxytocin at different doses and time periods. None of these trials reported a statistically significant difference in mode of delivery.
  - A pooled meta-analysis combined the data from Mozurkewich et al. and Thangathai and Kasthuri assessing the relative risk of vaginal delivery using 100 µg of misoprostol every 6 hours compared to low-dose intravenous oxytocin. There was no statistically significant difference in the relative risk of vaginal delivery when comparing both interventions (pooled RR 1.18, 95% CI 0.81−1.73).
- **Oral Misoprostol versus Foley balloon catheter:**
  - One trial compared oral misoprostol every 4 hours with a single-balloon catheter and found no significant difference in the cesarean delivery rate between the study groups (RR 0.77, 95% CI 0.44−1.35).
- **Hyperstimulation:**
  - The incidence of hyperstimulation with misoprostol was investigated in 8 of the 12 trials and did not differ based on type of labour induction agent used.

Anmerkung/Fazit der Autoren

One main limitation of this study was the inability to conduct a more robust pooled analysis owing to the heterogeneity of misoprostol doses found in the literature.

Oral misoprostol appears to be a safe alternative for induction of labour in TPROM pregnancies. However, standardized dose and frequency protocols need to be established to achieve labour but avoid side effects such as hyperstimulation.

Kommentare zum Review

Die Qualitätsbewertung der Primärliteratur wurde anhand der Jadad-Skala vorgenommen. Diese Bewertung ermöglicht keine umfassende Einschätzung des Verzerrungspotenzials.

Keine der Studien mit einer höheren Qualität berichtete statistisch signifikante Ergebnisse.

Ten Eikelder MLG et al., 2016 [10].

Induction of labor using a foley catheter or misoprostol: a systematic review and meta-analysis.

Fragestellung

To assess the safety and effectiveness profile of the Foley catheter for cervical ripening compared with different dosage and administration regimes of misoprostol.

Methodik

Population:

- Pregnant women who were scheduled for third trimester induction of labor, with an unfavorable cervix, a viable fetus in cephalic presentation and no prior cesarean delivery

Intervention:

- Foley catheter

Komparator:

- misoprostol (any dose, any administration route)

Endpunkte:

- main outcomes for safety: hyperstimulation, meconium stained liquor, cesarean delivery for nonreassuring FHR, vaginal instrumental delivery for nonreassuring FHR, postpartum haemorrhage, arterial umbilical cord pH of less than 7,05, Apgar score of less than 7, neonatal intensive care admission, neonatal mortality
- main outcomes for effectiveness of induction of labor: total cesarean delivery rate, cesarean delivery for failure to progress first stage, total vaginal instrumental deliveries.

Recherche/Suchzeitraum:

- We searched the Cochrane Library, Pubmed, EMBASE and Web of Science (from January 1, 1980 to February 12, 2016)

Qualitätsbewertung der Studien:

- Cochrane approach

Ergebnisse

Anzahl eingeschlossener Studien:

- 22 RCT (reporting on 5015 women)

- Comparison 1 (Foley catheter versus misoprostol, all dosages and administration routes): 17 studies (including a total of 4234 women)
  - 13 studies compared Foley catheter to 25 µg vaginal misoprostol; three studies compared Foley catheter to 50 µg vaginal misoprostol; one study compared Foley catheter to 50 µg oral misoprostol.
- Comparison 2 (Foley catheter and misoprostol versus misoprostol alone): 7 studies (total of 1073 women)
  - Five studies compared 25 µg vaginal misoprostol with the concurrent use of a Foley catheter to 25 µg vaginal misoprostol alone; one study compared Foley catheter with concurrent use of 100 µg oral misoprostol to 100 µg oral misoprostol alone; one study compared Foley catheter with concurrent use of 100 µg oral misoprostol to 100 µg oral misoprostol alone.

Charakteristika der Population:

- Comparison 1: Two studies included patients with intact and ruptured membranes, whereas 15 studies included only patients with intact membranes.
- Comparison 2: Six studies included only women with intact membranes, whereas this feature was unknown in one study.

Qualität der Studien:

Study	A	B	C	D	E	F	G
Barrilleaux 2002	+	+	+	+	?	+	+
Carbone 2013	+	+	+	+	+	+	+
Chavakula 2015	+	+	+	+	+	+	+
Chung 2003	+	+	+	+	?	+	+
Eikelder 2015	+	+	+	+	+	+	+
Filho 2010	+	+	+	+	?	+	?
Gelisen 2004	+	+	+	+	+	+	+
Greybush 2001	+	+	+	+	+	?	+
Hill 2009	+	+	+	+	?	+	+
Jozwiak 2013	+	+	+	+	+	+	+
Kandil 2012	-	-	+	+	-	+	+
Kashanian 2005	?	?	+	+	?	?	+
Lanka 2014	+	+	+	+	+	+	+
Noor 2015	?	?	+	+	?	+	+
Oliveira e Oliveira 2010	+	+	+	+	+	+	+
Owolabi 2005	+	+	+	+	?	+	+
Prager 2008	+	+	+	+	+	+	+
Roudsari 2011	?	?	+	+	+	+	+
Rust 2001	+	+	+	+	?	+	+
Sciscione 2001	+	+	+	+	-	-	+
Sheikher 2009	?	?	+	+	-	-	?
Sujata 2012	+	+	+	+	-	?	?

Table S1. Risk of bias. A = random sequence generation (selection bias). B = Allocation concealment (selection bias). C = Blinding of women and personnel (performance bias). D = Blinding of outcome assessment (detection bias). E = Incomplete outcome data (attrition bias). F = Selective reporting (reporting bias). G = Other bias.

Studienergebnisse:

- **Comparison 1: Foley catheter versus misoprostol, all dosages and administration routes:**
  - Hyperstimulation (i.e., more than 3 contractions per 10 minutes with FHR changes) was documented in 12 studies (3591 women) and occurred in 2.1% in the Foley catheter group compared to 3.9% in the misoprostol group (RR, 0.54; 95% CI, 0.37-0.97)
  - Presence of meconium stained liquor was reported in ten studies (3387 women) and did not differ significantly between Foley induction and misoprostol (11.3% vs. 13.0%; RR, 0.86; 95% CI, 0.72-1.03)

- Nonreassuring FHR as a reason for cesarean delivery was reported in nine studies (3269 women) and was less often in the Foley catheter group (5%) than in the misoprostol group (7%) (RR, 0.72; 95% CI, 0.55-0.95)
- Vaginal instrumental delivery for nonreassuring FHR was reported in three studies with 2362 women (5% vs. 6%; RR, 0.77; 95% CI, 0.55-1.06).
- Neonatal intensive care unit admission was reported in 11 studies (3370 women) and did not differ between the two groups (3.7% vs. 3.9%; RR, 0.99; 95% CI, 0.71-1.38).
- Other neonatal outcomes such as arterial pH and neonatal mortality were reported infrequently.
- Total cesarean delivery rates were 25.6% (539 of 2106 women) in the Foley catheter group and 22.0% (469 of 2128 women) in the misoprostol group (RR, 1.16; 95% CI, 1.00-1.34; random-effects I^2, 35%). Funnel plot of the included studies showed asymmetry indicating possible risk of bias. Sensitivity analysis for studies with a low risk of bias (nine studies, 3181 women) showed a comparable result in the Foley catheter group vs. the oral misoprostol group (RR, 1.15; 95% CI, 1.01-1.31; fixed-effects I^2, 0%).
- Failure to progress as a reason for cesarean delivery was reported in eight studies (3090 women) and did not differ significantly (11% vs. 8%; RR, 1.29; 95% CI, 0.88-1.90).
- There were fewer vaginal instrumental deliveries in the Foley catheter group (10.0% vs. 13.6%; RR, 0.74; 95% CI, 0.60-0.91; seven studies, 2789 women).

- **Comparison 2: Foley catheter and misoprostol versus misoprostol alone:**
  - In the combination group, there was less uterine hyperstimulation (16.6% vs. 23.3%; four studies, 666 women; RR, 0.71; 95% CI, 0.52-0.97).
  - Nonreassuring FHR as a reason for cesarean delivery was reported in three studies (439 women) and did not differ significantly between groups (14% vs. 18% of all cesarean deliveries performed; RR, 0.79; 95% CI, 0.56-1.11).
  - Neonatal outcomes such as Apgar score, arterial pH and neonatal mortality were not reported.
  - Total cesarean delivery rates were 34% vs. 34% (seven studies, 1073 women; RR, 1.01; 95% CI, 0.86-1.19)
  - Failure to progress as a reason for cesarean delivery was reported in four studies (508 women) (17% vs. 13%; RR, 1.27; 95% CI, 0.88-1.81)
  - Vaginal instrumental deliveries did not differ between groups (17% vs. 12.5%; two studies, 218 women; RR, 1.33; 95% CI, 0.70-2.51).

Anmerkung/Fazit der Autoren

Based on the present findings, Foley catheter seems to have a better safety profile than misoprostol, but numbers are too low to draw definite conclusions. All studies were underpowered to answer questions about the safety profiles of the induction methods.

Our meta-analysis demonstrates that Foley catheter gives less hyperstimulation compared to misoprostol (any dose, any administration route), and there were fewer vaginal instrumental deliveries with a Foley catheter. Furthermore, the Foley catheter resulted in fewer cesarean deliveries for nonreassuring FHR than misoprostol, with a comparable total cesarean deliveries rate. Foley catheter with misoprostol compared to misoprostol alone resulted in less hyperstimulation than misoprostol alone, whereas there was no difference in cesarean delivery rate.

3.4 Leitlinien

Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (DGGG), 2020 [2].

Weitere federführende Fachgesellschaften: Österreichische Gesellschaft für Gynäkologie und Geburtshilfe (OEGGG), Schweizerische Gesellschaft für Gynäkologie und Geburtshilfe (SGGG)

Geburtseinleitung (S2k-Leitlinie, AWMF-Registernummer 015-088)

Zielsetzung/Fragestellung

Darstellung der verschiedenen Methoden zur Geburtseinleitung mit ihren Vor- und Nachteilen sowie Risiken

Methodik

Disclaimer: Die Leitlinie erfüllt nicht ausreichend die methodischen Anforderungen. Aufgrund ihrer Relevanz für den deutschen Versorgungskontext, wird die Leitlinie jedoch ergänzend dargestellt.

Grundlage der Leitlinie

- Repräsentatives Gremium, jedoch scheinbar keine Patientenvertretung;
- Interessenkonflikte und finanzielle Unabhängigkeit dargelegt;
- Literatursuche in PubMed durch Leitlinienautoren, jedoch keine systematische Suche, Auswahl und Bewertung der Evidenz;
- Formale Konsensusprozesse dargelegt; kein externes Begutachtungsverfahren, nur Prüfung durch Vorstände der beteiligten Fachgesellschaften;
- Empfehlungen der Leitlinie sind eindeutig und die zugrundeliegende Evidenz ist im Hintergrundtext beschrieben;
- Gültigkeit und Verfahren zur Aktualisierung beschrieben.

Recherche/Suchzeitraum:

- Keine Angaben zu Suchzeitraum und -methodik
- Keine Ergebnisdarstellung der Literatursuche

LoE

- Keine Evidenzgraduierung dargelegt (von den Autoren wurde keine Bewertung der Studien und Beurteilung des Evidenzgrads durchgeführt)

GoR

Tabelle 5: Graduierung von Empfehlungen (deutschsprachig)

Beschreibung der Verbindlichkeit	Ausdruck
Starke Empfehlung mit hoher Verbindlichkeit	Soll / Soll nicht
Einfache Empfehlung mit mittlerer Verbindlichkeit	Sollte / Sollte nicht
Offene Empfehlung mit geringer Verbindlichkeit	Kann / Kann nicht

Tabelle 7: Einteilung zur Zustimmung der Konsensusbildung

Symbolik	Konsensusstärke	Prozentuale Übereinstimmung
+++	Starker Konsens	Zustimmung von > 95% der Teilnehmer
++	Konsens	Zustimmung von > 75-95% der Teilnehmer
+	Mehrheitliche Zustimmung	Zustimmung von > 50-75% der Teilnehmer
-	Kein Konsens	Zustimmung von < 51% der Teilnehmer

Sonstige methodische Hinweise

- Sollten fachliche Aussagen nicht als Handlungsempfehlungen, sondern als einfache Darlegung Bestandteil der Leitlinie sein, werden diese als „Statements“ bezeichnet

Mechanische Geburtseinleitung

4.1.1 Eipollösung

Konsensbasierte Empfehlung 4.E27	
Expertenkonsens	Konsensusstärke +++
Eine Eipollösung am Termin kann den Schwangeren angeboten werden.	

Evidenzbasis:

- 1 Cochrane Review (Finucane 2020, vgl. [3]); 1 systematische Übersichtsarbeit mit Meta-Analyse (Avdiyovski 2019)

4.1.2 Amniotomie

Konsensbasierte Empfehlung 4.E28	
Expertenkonsens	Konsensusstärke +++
Die Amniotomie soll nicht als alleiniges Verfahren zur Geburtseinleitung erfolgen.	

Evidenzbasis:

- alleinige Anwendung: „nur wenig solide Evidenz aus überwiegend älteren Publikationen (Bricker 2000, Cochrane Review). Alleinige Anwendung wird in verschiedenen Leitlinien nicht empfohlen (WHO 2011, Leduc 2013)“
- Kombination der Amniotomie mit Oxytocin: „Datenlage nicht zufriedenstellend (Howarth 2001, Cochrane Review)“

4.1.3 Ballonkatheter

Konsensbasiertes Statement 4.S2	
Expertenkonsens	Konsensusstärke +++
Ballonkatheter (Einzel- und Doppelballonkatheter) sind ein wirksames Verfahren zur Zervixreifung und Geburtseinleitung bei unreifem Zervixbefund.	

Konsensbasiertes Statement 4.S3	
Expertenkonsens	Konsensusstärke +++
Die Rate an uterinen Überstimulationen ist im Vergleich zu den Prostaglandinen bei der Verwendung mit Ballonkathetern geringer.	

Konsensbasiertes Statement 4.S4	
Expertenkonsens	Konsensusstärke +++
Die sequentielle Geburtseinleitung von Ballonkathetern und Prostaglandinen ist vor allem bei Erstgebärenden mit unreifem Zervixbefund wirksam.	

Konsensbasiertes Statement 4.S5	
Expertenkonsens	Konsensusstärke +++
Die simultane Geburtseinleitung von Ballonkathetern und Oxytocin oder Prostaglandinen ist wirksam und führt zu einem kürzeren Einleitung-Geburt-Intervall als die alleinige Verwendung eines Verfahrens.	

Evidenzbasis:

- Effektivität Ballonkatheter zur Geburtseinleitung: 1 systematische Übersichtsarbeit (Alfirevic 2016)
- Vergleich Ballonkatheter vs. Prostaglandine: 1 Cochrane Review (de Vaan 2019, vgl. [1]); 3 systematische Übersichtsarbeiten (Ten Eikelder 2016, vgl. [10]; Liu 2019, vgl. [5]; Zhu 2018)
- Sequentielle Anwendung Ballonkatheter und Misoprostol: 2 Kohortenstudien (Kehl 2016; Kehl 2019); 1 prospektive Fall-Kontroll-Studie (Ande 2012)
- Simultane Anwendung Ballonkatheter und Oxytocin oder Prostaglandine: 2 systematische Übersichtsarbeiten (Gallagher 2019; Ornat 2020, vgl. [7]); 1 RCT (Chowdhary 2019)
- Zufriedenheit der Gebärenden mit Ballonkatheter: 1 RCT (Kehl 2013)

4.1.4 Hygroskopische Dilatatoren

Konsensbasierte Empfehlung 4.E29	
Expertenkonsens	Konsensusstärke +++
Zervixdilatatoren können zur Geburtseinleitung bei einem unreifen Zervixbefund verwendet werden.	

Evidenzbasis:

- „Erfahrungen liegen v.a. bei Abortinduktion in frühen Schwangerschaftswochen vor (Diedrich 2020, klinische Empfehlungen)“
- Sicherheit von Zervixdilatatoren: 2 Beobachtungsstudien (Saad 2020, Gupta 2018); 1 RCT (Saad 2019)

Medikamentöse Geburtseinleitung

4.2.1 Oxytocin

Konsensbasierte Empfehlung 4.E30	
Expertenkonsens	Konsensusstärke +++
Oxytocin soll bei einem unreifen Zervixbefund nicht zur Geburtseinleitung verwendet werden.	

Konsensbasierte Empfehlung 4.E31	
Expertenkonsens	Konsensusstärke +++
Oxytocin kann bei einem reifen Zervixbefund zur Geburtseinleitung verwendet werden. Die Kombination mit einer Amniotomie erhöht die Wahrscheinlichkeit einer vaginalen Entbindung.	

Evidenzbasis:

- Keine Anwendung bei unreifem Zervix aufgrund der höheren Rate an Kaiserschnitten und längeren Einleitung-Geburt-Intervallen im Vergleich zu Ballonkatheter und Prostaglandinen: 4 Cochrane Reviews (Jozwiak 2012; Alfirevic 2009; Alfirevic 2014; Hofmeyr 2010)
- Kombination Oxytocin mit Amniotomie: 3 RCT (Selo-Ojeme 2009; Gagnon-Gervais 2009; Tan 2013)

4.2.2 Prostaglandin E2 (Dinoproston)

Konsensbasierte Empfehlung 4.E32	
Expertenkonsens	Konsensusstärke +++
Die vaginale Applikation von Prostaglandin E2 zur Geburtseinleitung bei unreifem Zervixbefund ist geeignet und wirksam und sollte der intrazervikalen Gabe vorgezogen werden.	

Evidenzbasis:

- Intrazervikale Gabe von Dinoproston ist technisch aufwendiger und weniger effektiv als vaginale Gabe: 1 Cochrane Review (Boulvain 2008)

4.2.3 Prostaglandin E1-Analoga (Misoprostol)

Konsensbasierte Empfehlung 4.E33	
Expertenkonsens	Konsensusstärke +++
Bis zum Erhalt einer neuen Zulassung zur Geburtseinleitung soll über den Off-Label-Use aufgeklärt werden.	

Konsensbasiertes Statement 4.S6	
Expertenkonsens	Konsensusstärke +++
Misoprostol ist das wirksamste Medikament zur Geburtseinleitung bei einem unreifen Zervixbefund.	

Konsensbasierte Empfehlung 4.E34	
Expertenkonsens	Konsensusstärke +++
Die Applikation von Misoprostol sollte oral erfolgen.	

Konsensbasiertes Statement 4.S7	
Expertenkonsens	Konsensusstärke +++
Misoprostol-Dosierungen von 25 µg gelten auch bei vaginaler Applikation als sicher.	

Konsensbasiertes Statement 4.S8	
Expertenkonsens	Konsensusstärke +++
Misoprostol in einer Dosierung von 50 µg oral entspricht dem Sicherheitsprofil einer vaginalen Applikation von 25 µg.	

Konsensbasiertes Statement 4.S9	
Expertenkonsens	Konsensusstärke +++
Eine Nebenwirkung wie eine uterine Überstimulation führt nicht zwangsläufig zu einem pathologischen CTG, einem Kaiserschnitt und/oder einem schlechten kindlichen Outcome.	

Konsensbasiertes Statement 4.S10	
Expertenkonsens	Konsensusstärke +++
Orales/vaginales Misoprostol in einer Dosierung von ≥ 50 µg pro Tablette führte zwar im Vergleich zu Placebo zu mehr Überstimulationen, die Rate an Verlegungen in die Kinderklinik war jedoch nicht verschieden.	

Konsensbasierte Empfehlung 4.E35	
Expertenkonsens	Konsensusstärke +++
Erstgaben von > 50 µg und Einzelgaben von > 100 µg sollten vermieden werden.	

Konsensbasiertes Statement 4.S11	
Expertenkonsens	Konsensusstärke +++
Eigenhändiges Zerstückeln von Tabletten höherer Dosierung und/oder Auflösen von Tabletten in Flüssigkeit und Gabe von bestimmten Trinkmengen sind aufgrund der Ungenauigkeit der Stabilität und Wirkstoffkonzentration zu vermeiden. Eine korrekte Herstellung durch eine Apotheke ist deshalb unabdingbar.	

Evidenzbasis:

- Vergleich Misoprostol vs. Dinoproston: 1 Cochrane Review (Alfirevic 2014); 1 systematische Übersichtsarbeit (Austin 2010); 1 systematische Übersichtsarbeit mit Netzwerkmetaanalyse (Chen 2016)

Zustand nach Sectio caesarea

6.4.2 Methoden der Geburtseinleitung bei Zustand nach Sectio caesarea

Konsensbasiertes Statement 6.S17	
Expertenkonsens	Konsensusstärke +++
Bei reifem Zervixbefund (Bishop-Score ≥ 6) stellt eine Geburtseinleitung nach vorherigem Kaiserschnitt mittels Oxytocin und Amniotomie eine risikoarme Methode dar.	

Konsensbasiertes Statement 6.S18	
Expertenkonsens	Konsensusstärke +++
Bei unreifem Zervixbefund (Bishop-Score < 6) stellt die Geburtseinleitung nach vorherigem Kaiserschnitt mittels Prostaglandin E2 (Dinoproston) eine risikoarme Methode dar, auch wenn das Risiko für eine Uterusruptur erhöht ist.	

Konsensbasiertes Statement 6.S19	
Expertenkonsens	Konsensusstärke +++
Die Geburtseinleitung mit mechanischen Methoden (transzervikaler Ballonkatheter, Amniotomie) ist mit einem niedrigeren Uterusruptur-Risiko als mit Prostaglandinen assoziiert.	

Konsensbasierte Empfehlung 6.E52	
Expertenkonsens	Konsensusstärke +++
Misoprostol soll im dritten Trimenon nicht zur Geburtseinleitung bzw. Zervixreifung nach vorherigem Kaiserschnitt oder einer Operation, die mit einer Eröffnung des Cavum uteri einhergegangen ist, eingesetzt werden.	

Evidenzbasis:

- Vergleich Uterusrupturrate bei spontanem Wehenbeginn vs. Geburtseinleitung mit Oxytocin bei vorangegangener Kaiserschnittentbindung: 1 Beobachtungsstudie (Landon 2004)
- Vergleich Uterusrupturrate und perinatale Mortalität bei Geburtseinleitung mit Prostaglandinen vs. nicht-medikamentösen Verfahren bei vorangegangener Kaiserschnittentbindung: 1 Beobachtungsstudie (Landon 2004)
- Risiken von Dinoproston bzw. Ballonkatheter nach vorherigem Kaiserschnitt: 4 Kohortenstudien (Haas 2014; Schmitz 2013; Kehl 2016; Huisman 2019); 1 systematische Übersichtsarbeit (Kehl 2016)
- „vorhandene Evidenz beruht vorrangig auf Kohortenstudien mit zu geringer Fallzahl, weshalb die Beantwortung der Fragen nach dem sichersten Einleitungsverfahren bei Zustand nach Kaiserschnitt nicht eindeutig beantwortet werden kann (West 2017, Cochrane Review, vgl. [11])“
- „Empfehlung gegen den Einsatz von Misoprostol zur Geburtseinleitung bei Zustand nach Kaiserschnitt beruht auf kleinen Studien, die jedoch übereinstimmend ein erhöhtes Risiko für das Auftreten einer Uterusruptur zeigten (Aslan 2004; Wing 1998; Plaut 1999; Bennett 1997)“

Multidisciplinary Clinical Guidelines Panel, 2019 [6].

Developed by members of New Zealand College of Midwives, Royal Australian and New Zealand College of Obstetrics and Gynaecology (RANZCOG), Royal Australasian College of Physicians, along with representatives of consumer groups and Midwifery and Obstetrics from around NZ

Induction of Labour in Aotearoa New Zealand

Zielsetzung/Fragestellung

This guideline provides the most recent research evidence for clinical conditions where induction of labour (IOL) at term would be considered, and for methods of cervical ripening and starting induction of labour. A multidisciplinary Panel assessed quality of evidence and made recommendations, considering the Aotearoa New Zealand (NZ) context.

Methodik

Grundlage der Leitlinie

- Repräsentatives Gremium;
- Finanzielle Unabhängigkeit dargelegt; von der Autorenschaft wurden keine potentiellen Interesskonflikte gemeldet, die genaue Art der Abfrage ist in der Leitlinie jedoch nicht dargelegt.
- Systematische Suche, Auswahl und Bewertung der Evidenz;
- „The Panel (…) formulated recommendations by consensus“, Konsensusprozesse sind nicht dargelegt; externes Begutachtungsverfahren dargelegt;
- Empfehlungen der Leitlinie sind eindeutig und die Verbindung zu der zugrundeliegenden Evidenz ist explizit dargestellt;
- Regelmäßige Überprüfung der Aktualität gesichert.

Recherche/Suchzeitraum:

- Searches for indications and methods for induction of labour were conducted using the Cochrane Database of Systematic Reviews, and databases PubMed, MeSH and Google Scholar. In addition, the registries clinicaltrials.gov and Australian New Zealand Clinical Trials Registry were searched to identify any ongoing clinical trials focused on IOL.
- Search dates were limited from 01/01/2014 - 03/12/2018 to ensure any updated information from the 2014 National Consensus IOL Guideline was identified. If searching new terms, the timeline was open.
- The initial search was for Cochrane reviews. If not found, the search was limited to systematic reviews and meta-analyses, followed by RCTs. If not found, then observational studies were used.
- Selection criteria included papers written in English, where the ideal countries for published material were from populations most similar to New Zealand (Australia, United Kingdom, Canada, United States of America).
- Tabellarische Darstellung der Suchresultate (Anzahl und Art der Publikationen) für die verschiedenen Fragestellungen.

LoE

Table 2. National Institute of Clinical Health and Excellence levels of evidence and categories of papers (NICE 2008)

Level of evidence	Category of paper
1	Meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a low risk of bias
2	Systematic reviews of case–control or cohort studies, or well conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion, formal consensus

GoR

Table 3. GRADE quality rating for evidence and strength of recommendations (Guyatt 2008)

GRADE rating of quality of evidence
High Quality - Further research is very unlikely to change our confidence in the estimate of effect Moderate Quality - Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate Low Quality - Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate Very Low Quality - Any estimate of effect is very uncertain *Note: RCTs start at High Quality, cohort and case-control studies start at Low Quality, and case series and expert opinion are Very Low Quality. Confidence in the evidence may be decreased for several reasons including study limitations, inconsistency of results, indirectness of evidence, imprecision and reporting bias; and may be increased if the magnitude of the treatment effect is very large, if there is evidence of a dose-response relation, or if all plausible biases would decrease the magnitude of an apparent treatment effect.*
GRADE rating of strength of recommendations
Strong Conditional Good practice point (GPP) *Note: Recommendations can be in favour of or against a practice*

Notes

The GRADE system (Guyatt 2008) classifies the quality of evidence in one of four levels (see Table 2), and offers two grades of recommendations (see Table 3).

- Level 1 evidence: Includes meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a low risk of bias.
- Recommendations: When the desirable effects of an intervention clearly outweigh the undesirable effects, or clearly do not, guideline panels offer 'strong' recommendations. When the trade-offs are less certain—either because of low quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced— they offer 'conditional' recommendations.
- Practice Points: When recommendations are based on low or very low quality evidence, the guideline panel offers practice points, or important things to consider for clinical practice.

Throughout this guideline, the Clinical Guidelines Panel has included practice points aimed at encouraging further understanding and discussion about the diverse beliefs, traditions and aspirations held by many women, their partners, family and whānau.

Membrane sweeping at term for reducing the need for induction of labour

Membrane sweeping

Recommendation	Level of evidence	Strength of recommendation
Consider offering membrane sweeping at term to reduce the frequency of pregnancy continuing beyond 41 weeks' gestation.	Level 1; Moderate quality	Conditional
Practice Point		
If offering membrane sweeping, consider performing from around 39 weeks' gestation.		

Evidenzbasis:

- Einsatz der Eipollösung zur Geburtseinleitung: 1 Cochrane Review (Boulvain 2005)

Methods of cervical ripening

Cervical ripening

Recommendations	Level of evidence	Strength of recommendation
Offer cervical ripening with prostaglandins to women with unfavourable cervix, to improve the chance of vaginal birth within 24 hours, compared to oxytocin alone.	Level 1; moderate quality	Conditional
For PGE2 for cervical ripening, offer either vaginal gel or controlled-release pessary, as both methods are comparable to achieve vaginal birth in 24 hours, and for risk of caesarean section.	Level 1; moderate quality	Conditional
Offer oral misoprostol for cervical ripening, to reduce the risk of caesarean section.	Level 1; moderate quality	Conditional
Offer balloon catheter for cervical ripening, to reduce the risk of uterine hyperstimulation with fetal heart rate changes, compared to prostaglandins.	Level 1; moderate evidence	Conditional
For single-balloon catheter, inflate greater than 30 mL (and not more than manufacturer recommendation), to increase the chance of vaginal birth in 24 hours, compared to 30mL or less.	Level 1; moderate quality	Conditional
Practice Points		
Consider offering membrane sweeping concurrent with cervical ripening.		
For cervical ripening with PGE2 vaginal gel: Decide initial dose based on parity and Bishop score. If nulliparous and BS≤4, consider 2mg; otherwise consider 1mg. Decide subsequent dose based on cervical change – if none, consider 2mg; otherwise consider 1mg. Use as per manufacturer's instructions.		
For cervical ripening with PGE2 controlled-release vaginal pessary: Pessary may have higher risk of uterine tachysystole and hypertonus compared to vaginal gel. Use as per manufacturer's instructions.		
For cervical ripening with PGE1 analogue (misoprostol): Vaginal administration may have higher risk of adverse outcomes compared to oral administration. If using misoprostol, low-dose (25 micrograms) two-hourly in oral solution is recommended. See Appendix E for suggested protocols.		

Consider using balloon catheter for cervical ripening where induction of labour is indicated in setting of previous caesarean section.

<u>Evidenzbasis</u>

- Vergleich vaginales Misoprostol vs. vaginales PGE2: 1 Cochrane Review (Hofmeyr 2010)
- Vergleich orales Misoprostol vs. vaginales Misoprostol bzw. orales Misoprostol vs. vaginales PGE2: 1 Cochrane Review (Alfirevic 2014)
- Einsatz Prostaglandine zur Geburtseinleitung: 1 systematische Übersichtsarbeit mit Netzwerkmetaanalyse (Alfirevic 2015)
- Vergleich mechanische Methoden (Ballonkatheter) vs. Prostaglandine: 1 Cochrane Review (Jozwiak 2012); 2 RCT (Eikelder 2016, Mundle 2017)
- Methoden zur Geburtseinleitung bei Frauen mit vorherigem Kaiserschnitt: 1 Cochrane Review (West 2017, vgl. [11])

Methods of induction of labour

Induction of labour methods

Practice Points
To start induction of labour once cervix is favourable, consider offering the combination of artificial rupture of membranes and intravenous oxytocin infusion, to increase chance of vaginal birth within 24 hours.
The timing and order of performing artificial rupture of membranes and starting intravenous oxytocin infusion to be individualised and negotiated between the woman, her Lead Maternity Carer, the hospital midwife and the obstetrician.
Offer either low- or high-dose oxytocin protocol, as both methods are comparable to achieve vaginal birth in 24 hours, and risk for caesarean section.
Usual time interval to increase dose of oxytocin is approximately 20 minutes.

Evidenzbasis:

- Vergleich Amniotomie in Kombination mit Oxytocin vs. Plazebo oder andere Methoden: 1 Cochrane Review (Howarth 2001)

4 Detaillierte Darstellung der Recherchestrategie

Cochrane Library - Cochrane Database of Systematic Reviews (Issue 01 of 12, January 2021) am 19.01.2021

#	Suchfrage
1	MeSH descriptor: [Labor, Induced] explode all trees
2	(labo*r* NEAR/3 induc*):ti,ab,kw
3	#1 OR #2
4	#3 with Cochrane Library publication date from Jan 2016 to present, in Cochrane Reviews

Systematic Reviews in Medline (PubMed) am 19.01.2021

#	Suchfrage
1	Labor, Induced[mh]
2	(labor[tiab] OR labors[tiab] OR laboring[tiab] OR labour[tiab] OR labours[tiab] OR labouring[tiab]) AND induc*[tiab]
3	#1 OR #2
4	(#3) AND (((Meta-Analysis[ptyp] OR systematic[sb] OR ((systematic review [ti] OR meta-analysis[pt] OR meta-analysis[ti] OR systematic literature review[ti] OR this systematic review[tw] OR pooling project[tw] OR (systematic review[tiab] AND review[pt]) OR meta synthesis[ti] OR meta-analy*[ti] OR integrative review[tw] OR integrative research review[tw] OR rapid review[tw] OR umbrella review[tw] OR consensus development conference[pt] OR practice guideline[pt] OR drug class reviews[ti] OR cochrane database syst rev[ta] OR acp journal club[ta] OR health technol assess[ta] OR evid rep technol assess summ[ta] OR jbi database system rev implement rep[ta]) OR (clinical guideline[tw] AND management[tw]) OR ((evidence based[ti] OR evidence-based medicine[mh] OR best practice*[ti] OR evidence synthesis[tiab]) AND (review[pt] OR diseases category[mh] OR behavior and behavior mechanisms[mh] OR therapeutics[mh] OR evaluation study[pt] OR validation study[pt] OR guideline[pt] OR pmcbook)) OR ((systematic[tw] OR systematically[tw] OR critical[tiab] OR (study selection[tw]) OR (predetermined[tw] OR inclusion[tw] AND criteri* [tw]) OR exclusion criteri*[tw] OR main outcome measures[tw] OR standard of care[tw] OR standards of care[tw]) AND (survey[tiab] OR surveys[tiab] OR overview*[tw] OR review[tiab] OR reviews[tiab] OR search*[tw] OR handsearch[tw] OR analysis[ti] OR critique[tiab] OR appraisal[tw] OR (reduction[tw] AND (risk[mh] OR risk[tw]) AND (death OR recurrence))) AND (literature[tiab] OR articles[tiab] OR publications[tiab] OR publication [tiab] OR bibliography[tiab] OR bibliographies[tiab] OR published[tiab] OR pooled data[tw] OR unpublished[tw] OR citation[tw] OR citations[tw] OR database[tiab] OR internet[tiab] OR textbooks[tiab] OR references[tw] OR scales[tw] OR papers[tw] OR datasets[tw] OR trials[tiab] OR meta-analy*[tw] OR (clinical[tiab] AND studies[tiab]) OR treatment outcome[mh] OR treatment outcome[tw] OR pmcbook)) NOT (letter[pt] OR newspaper article[pt])) OR Technical Report[ptyp]) OR (((((trials[tiab] OR studies[tiab] OR database*[tiab] OR literature[tiab] OR publication*[tiab] OR Medline[tiab] OR Embase[tiab] OR

#	Suchfrage
	Cochrane[tiab] OR Pubmed[tiab])) AND systematic*[tiab] AND (search*[tiab] OR research*[tiab]))) OR ((((((((((HTA[tiab]) OR technology assessment*[tiab]) OR technology report*[tiab]) OR (systematic*[tiab] AND review*[tiab])) OR (systematic*[tiab] AND overview*[tiab])) OR meta-analy*[tiab]) OR (meta[tiab] AND analyz*[tiab])) OR (meta[tiab] AND analys*[tiab])) OR (meta[tiab] AND analyt*[tiab]))) OR (((review*[tiab]) OR overview*[tiab]) AND ((evidence[tiab]) AND based[tiab]))))))
5	((#4) AND ("2016/01/01"[PDAT] : "3000"[PDAT]) NOT "The Cochrane database of systematic reviews"[Journal]) NOT (animals[MeSH:noexp] NOT (Humans[mh] AND animals[MeSH:noexp]))
6	(#5) NOT (retracted publication [pt] OR retraction of publication [pt])

Leitlinien in Medline (PubMed) am 19.01.2021

#	Suchfrage
1	Labor, Induced[mh]
2	(labor[tiab] OR labors[tiab] OR laboring[tiab] OR labour[tiab] OR labours[tiab] OR labouring[tiab]) AND induc*[tiab]
3	#1 OR #2
4	(#3) AND (Guideline[ptyp] OR Practice Guideline[ptyp] OR guideline*[Title] OR Consensus Development Conference[ptyp] OR Consensus Development Conference, NIH[ptyp] OR recommendation*[ti])
5	(#4) AND ("2016/01/01"[PDAT] : "3000"[PDAT])
6	(#5) NOT (retracted publication [pt] OR retraction of publication [pt])

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Beteiligung von AkdÄ und Fachgesellschaften nach §35a Abs. 7 SGB V i.V.m. VerfO 5. Kapitel § 7 Abs. 6

2021-B-007

Kontaktdaten

Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (DGGG)

Deutsche Gesellschaft für Hebammenwissenschaft (DGHWi)

Indikation gemäß Beratungsantrag

Wird zur Geburtseinleitung angewendet.

Was ist der Behandlungsstandard unter Berücksichtigung der vorliegenden Evidenz bei der "*Geburtseinleitung*"? Wie sieht die Versorgungspraxis in Deutschland aus?

Der Behandlungsstandard wird von der AWMF-Leitlinie Geburtseinleitung (Registernummer 015-088) vorgegeben. In Deutschland werden 20-25 % aller Geburten eingeleitet. Eine Geburtseinleitung wird aufgrund verschiedener medizinischer Indikationen oder auch auf Wunsch durchgeführt. Es stehen dabei verschiedene mechanische (z. B. Amniotomie, Eipollösung, Ballonkatheter) und medikamentöse Verfahren (z. B. Oxytocin, Prostaglandine) zur Verfügung. Naturheilkundliche Verfahren werden zwar von vielen Schwangeren gewünscht, es liegen jedoch keine ausreichenden Evidenzen vor, um spezifische Empfehlungen abzugeben.

Gibt es Kriterien für unterschiedliche Behandlungsentscheidungen bei der „*Geburtseinleitung*" die regelhaft berücksichtigt werden? Wenn ja, welche sind dies und was sind in dem Fall die Therapieoptionen?

Es gibt verschiedene Kriterien, die bei der Entscheidung für eine Behandlung respektive einer speziellen Einleitungsmethode berücksichtigt werden müssen. Verschiedene Faktoren beeinflussen den Erfolg einer Geburtseinleitung günstig oder ungünstig. Zu den Faktoren, die eine Geburtseinleitung günstig beeinflussen, gehören ein reifer Zervixbefund, eine Vaginalgeburt in der Anamnese und ein vorzeitiger Blasensprung. Vor allem die Zervixreife, die klinisch beurteilt und anhand des Bishop Score wiedergegeben wird, ist eine der wichtigsten Prädiktoren für eine erfolgreiche Geburtseinleitung und sollte daher erhoben und dokumentiert werden. Zu den ungünstigen Faktoren einer Geburtseinleitung gehören dementsprechend ein niedriger Bishop Score, Nulliparität, ein hoher Body Mass Index, ein vorangegangener Kaiserschnitt und ein niedriges Gestationsalter.

Im Fall einer unreifen Zervix sind mechanische Methoden wie die Ballonkatheter und Prostaglandine zu favorisieren, da diese nicht nur zu einer Weheninduktion, sondern auch zu einer Zervixreifung führen. Bei einer reifen Zervix kann dahingegen auch eine Einleitung mit Oxytocin, einem Wehenmittel, erfolgen. Nach vorherigem Kaiserschnitt soll andererseits unabhängig von der Zervixreife auf die Geburtseinleitung mit dem synthetischen Prostaglandin-E1-Analogon Misoprostol verzichtet werden.

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