Thieme

Outpatient Induction of Labor – Are Balloon Catheters an Appropriate Method?

Ambulante Geburtseinleitung – sind Ballonkatheter eine geeignete Methode?

Authors
Werner Rath[1], Patrick Stelzl[2], Sven Kehl[3]

Affiliations
1 Medizinische Fakultät, Gynäkologie und Geburtshilfe, Universitätsklinikum Schleswig-Holstein, Campus Kiel, Kiel, Germany
2 Universitätsklinik für Gynäkologie, Geburtshilfe und Gynäkologische Endokrinologie, Kepler Universitätsklinikum, Johannes Kepler Universität Linz, Linz, Austria
3 Frauenklinik, Universitätsklinikum Erlangen, Erlangen, Germany

Key words
outpatient/inpatient induction of labor/cervical priming, balloon catheter, prostaglandins, efficacy, safety

Schlüsselwörter
ambulante/stationäre Geburtseinleitung/Zervixpriming, Ballonkatheter, Prostaglandine, Effektivität, Sicherheit

received 25.4.2020
accepted after revision 6.11.2020

Bibliography
Geburtsh Frauenheilk 2021; 81: 70–80
DOI 10.1055/a-1308-2341
ISSN 0016-5751

Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Correspondence
Univ.-Prof. Dr. med. Dr. h. c. Werner Rath
Medizinische Fakultät Gynäkologie und Geburtshilfe, Universitätsklinikum Schleswig-Holstein, Campus Kiel
Arnold-Heller-Straße 3, 24105 Kiel, Germany
Werner.Rath@uksh.de

Deutsche Version unter:
https://doi.org/10.1055/a-1308-2341

ABSTRACT

As the number of labor inductions in high-income countries has steadily risen, hospital costs and the additional burden on obstetric staff have also increased. Outpatient induction of labor is therefore becoming increasingly important. It has been estimated that 20–50 % of all pregnant women requiring induction would be eligible for outpatient induction. The use of balloon catheters in patients with an unripe cervix has been shown to be an effective and safe method of cervical priming. Balloon catheters are as effective as the vaginal administration of prostaglandin E_2 or oral misoprostol. The advantage of using a balloon catheter is that it avoids uterine hyperstimulation and monitoring is less expensive. This makes balloon catheters a suitable option for outpatient cervical ripening. Admittedly, intravenous administration of oxytocin to induce or augment labor is required in approximately 75 % of cases. Balloon catheters are not associated with a higher risk of maternal and neonatal infection compared to vaginal PGE_2. Low-risk pregnancies (e.g., post-term pregnancies, gestational diabetes) are suitable for outpatient cervical ripening with a balloon catheter. The data for high-risk pregnancies are still insufficient. The following conditions are recommended when considering an outpatient approach: strict selection of appropriate patients (singleton pregnancy, cephalic presentation, intact membranes), CTG monitoring for 20–40 minutes after balloon placement, the patient must be given detailed instructions about the indications for immediate readmission to hospital, and 24-hour phone access to the hospital must be ensured. According to reviewed studies, the balloon catheter remained in place between 12 hours (“overnight”) and 24 hours. The most common reason for readmission to hospital was expulsion of the balloon catheter. The advantages of outpatient versus inpatient induction of cervical ripening with a balloon catheter were the significantly shorter hospital stay, the lower costs, and higher patient satisfaction, with both procedures having been shown to be equally effective. Complication rates (e.g., vaginal bleeding, severe pain, uterine hy-

perstimulation syndrome) during the cervical ripening phase are low (0.3–1.5%); severe adverse outcomes (e.g., placental abruption) have not been reported. Compared to inpatient induction of labor using vaginal PGE_2, outpatient cervical ripening using a balloon catheter had a lower rate of deliveries/24 hours and a significantly higher need for oxytocin; however, hospital stay was significantly shorter, frequency of pain during the cervical ripening phase was significantly lower, and patients' duration of sleep was longer. A randomized controlled study comparing outpatient cervical priming with a balloon catheter with outpatient or inpatient induction of labor with oral misoprostol would be of clinical interest.

ZUSAMMENFASSUNG

Mit der steigenden Rate an Geburtseinleitungen in den Industrieländern steigen auch die Krankenhauskosten und die Mehrbelastung des geburtshilflichen Personals. Daher kommt der ambulanten Geburtseinleitung zunehmende Bedeutung zu. Schätzungsweise sind 20–50% aller Schwangeren mit Notwendigkeit zur Geburtseinleitung für ein ambulantes Vorgehen geeignet. Die Anwendung von Ballonkathetern bei unreifer Zervix ist eine effektive und sichere Methode zum Zervixpriming. Die Vorteile gegenüber lokal appliziertem Prostaglandin E_2 und oralem Misoprostol liegen bei vergleichbarer Effizienz vor allem in der Vermeidung uteriner Überstimulierungen und dem geringeren Überwachungsaufwand. Ballonkatheter stellen daher eine geeignete Option zur ambulanten Zervixreifung dar. Allerdings ist zur Weheninduktion/-verstärkung in durchschnittlich 75% der Fälle Oxytocin intravenös erforderlich. Ein höheres Infektionsrisiko für Mutter und Kind im Vergleich zu vaginalem Prostaglandin E_2 besteht nicht. Geeignet zum ambulanten Zervixpriming mit dem Ballonkatheter sind vor allem Schwangere mit niedrigem Risiko (z. B. Terminüberschreitung, Gestationsdiabetes). Bei Hochrisikoschwangeren ist die Datenlage unzureichend. Wichtige Voraussetzungen für ein ambulantes Vorgehen sind: strenge Selektion geeigneter Schwangerer (Einlingsschwangerschaft, Schädellage, intakte Fruchtblase), ein CTG-Monitoring 20–40 Minuten nach der Einlage, Instruktionen an die Schwangere hinsichtlich der Notwendigkeit zur umgehenden Wiedervorstellung in der Klinik sowie die Gewährleistung eines 24-Stunden-Kontakts zur Klinik. Die Liegedauer des Ballonkatheters lag in Studien zwischen ca. 12 Stunden („über Nacht“) und 24 Stunden und bis zu 24 Stunden. Der häufigste Grund für eine Wiederaufnahme in die Klinik war die Expulsion des Ballonkatheters. Die Vorteile einer ambulanten versus einer stationären Zervixreifung mit Ballonkathetern sind die signifikant kürzere Hospitalisierungsdauer, die niedrigeren Kosten und die hohe Zufriedenheit der Schwangeren bei vergleichbarer Effizienz beider Vorgehensweisen. Die Komplikationsrate (z. B. vaginale Blutungen, starke Schmerzen, uterines Hyperstimulationssyndrom) während der Zervixreifungsphase ist gering (0,3–1,5%), schwere Komplikationen (z. B. vorzeitige Plazentalösung) wurden nicht beobachtet. Im Vergleich zur stationären Geburtseinleitung mit vaginalem PGE_2 war mit Ballonkathetern die Rate vaginaler Geburten/24 Stunden geringer und die Notwendigkeit zur Oxytocin-Gabe signifikant höher, allerdings die Hospitalisierungsdauer signifikant kürzer, die Häufigkeit an Schmerzen während der Zervixreifungsphase signifikant geringer und die Schlafdauer der Schwangeren länger. Von klinischem Interesse wäre eine randomisierte kontrollierte Studie zum Vergleich von ambulantem Zervixpriming mit Ballonkathetern versus einer ambulanten oder stationären Geburtseinleitung mit oralem Misoprostol.

Introduction

In the last 20 years, labor induction rates have almost doubled in high-income countries, with reported rates of 23.2% in the USA in 2014 [1], 24% in Australia in 2015 [2], 29.4% in the United Kingdom in 2016/2017 [3] and 21.8% in Germany in 2017 [4]. In Germany, medication is used to induce labor in more than 95% of cases.

According to a nation-wide survey in Germany 2013 (542 hospitals), the majority (66%) reported that they used oral misoprostol for cervical ripening and only 1.8% used balloon catheters [5]. This survey is currently being updated.

The advantages of prostaglandin E_2 (PGE_2) and misoprostol are their high efficacy (e.g., the rate of vaginal deliveries/24 hours) in patients with an unripe cervix (Bishop Score [BS] < 6) because of the pharmacological synergism between cervical ripening and its myometrium-stimulating effect. But these two effects of prostaglandins (PG) cannot easily (or at all) be separated from each other [6].

The disadvantages of PG are the unpredictable onset of action (e.g., 2 mg vaginal PGE_2 gel unterine contractions may occur from < 1 to > 10 h after administration), making it almost impossible to control the onset of action; the lack of evidence-based recommendations for monitoring (CTG); and the unpredictable variation and high rates of uterine hyperstimulation (polysystoles, uterine hypertonia, uterine hyperstimulation syndrome) which ranges from 3 to 20% [7]. Uterine hyperstimulation syndrome may occur in 1.8–7.2% of cases following the administration of 1–2 mg vaginal PGE_2 gel, 3 mg vaginal PGE_2 tablets or a 10 mg vaginal PGE_2 pessary [7].

The frequency of uterine hyperstimulation syndrome following the administration of misoprostol depends on the dose. The mean frequency for oral misoprostol administered in a single dose of ≤ 50 µg is 3% [8]. It is associated with a risk of fetal hypoxia, particularly in cases with intrauterine growth restriction/pregnancies with limited placental function.

Inducing uterine contractions when the cervix is still unripe does not accelerate the birth; instead, it places additional stress on the fetoplacental unit due to contraction-related uterine hypoperfusion and reduces acceptance of the method among pregnant women (painful contractions).

One strategy which is increasingly being propagated is to only start inducing contractions after sufficient cervical ripening [9].

Transcervical balloon catheters are an effective method for cervical ripening without inducing significant uterine contractions and have no systemic maternal side-effects [10, 11]. The effort and costs of monitoring are significantly lower compared to monitoring following PG administration. In a Cochrane review published in 2019 [12], the risk of uterine hyperstimulation syndrome with balloon catheters was found to be significantly lower than after administering vaginal PGE_2 (RR 0.35; 95% CI: 0.18–0.67) or vaginal misoprostol (RR 0.39; 95% CI: 0.18–0.85). According to this Cochrane review, the data on oral misoprostol are less clear.

A network meta-analysis published in 2016 (96 randomized controlled studies [RCTs], n = 17 387) found that the frequency of uterine hyperstimulation was significantly lower with the Foley catheter compared to vaginal PGE_2 or after the administration of different doses of vaginal or oral misoprostol [13]. Another meta-analysis, also published in 2016 (9 RCTs, n = 1866), found a 10-times higher frequency of uterine hyperstimulation after vaginal PGE_2 administration compared to double balloon catheter placement, even though the two methods were similarly effective (rate of vaginal deliveries/24 hours) and had similar caesarean section rates [14]. In a systematic review performed in 2017 [15], uterine hyperstimulation (2.7%) and pathological CTG (10.8%) occurred almost exclusively in the context of labor induction/augmentation using intravenous oxytocin.

However, the need for intravenous oxytocin was significantly higher in patients treated with a balloon catheter compared to patients who received vaginal PGE_2 (RR 1.54; 95% CI: 1.35–1.76), vaginal misoprostol (RR 1.62; 95% CI: 1.38–1.90) or oral misoprostol (RR 1.28; 95% CI: 1.09–1.49) [12].

There were no significant differences in patient satisfaction between Foley/double balloon catheters and vaginal PGE_2 gel [16], vaginal PGE_2 pessary [17] and oral misoprostol [18].

The findings on the risk of infection from placement of a "foreign body" in the uterus are contradictory [12, 19, 20]. It is important to note that the administration of PGE_2 also requires repeated vaginal manipulation/applications which could also potentially increase the risk of infection.

In contrast to the meta-analysis by Heinemann et al. [19], who reported a significantly higher rate of maternal infections (chorioamnionitis, endomyometritis), following the use of a Foley catheter compared to drug-based methods of inducing labor, two subsequent meta-analyses [12, 20] came to the conclusion that use of a Foley catheter did not significantly increase the frequency of chorioamnionitis (7.2 vs. 7.2%), endometritis (3.8 vs. 3.5%), or neonatal infections (3.2 vs. 3.6%) compared to locally applied PGE_2 [20].

Because of its efficacy and safety, balloon catheters are a suitable method for cervical ripening/induction of labor [21] and therefore represent a promising option for outpatient induction of labor.

Compared to inpatient induction of labor, outpatient induction is associated with higher patient satisfaction (home environment, support of partner and family), more sleep, no increase in the level of anxiety [22–25], less work for obstetric staff [26] and a reduction of hospital costs [27, 28].

On the other hand, the important issue is the safety of this outpatient method for mother and infant.

This review looks at the current status of outpatient versus inpatient cervical priming/induction of labor using balloon catheters and compares the use of balloon catheters in an outpatient setting with inpatient application of PGE_2.

Review

Comparison of outpatient with inpatient cervical ripening using a balloon catheter (▸ Table 1)

A Cochrane review published in 2013 included 4 randomized controlled studies (n = 1439) on outpatient versus inpatient induction of labor, 3 of which used vaginal prostaglandin E_2 (PGE_2) and one (n = 111) which used Foley catheters. The data of all 4 studies were insufficient and did not permit any statement to be made about the efficacy and safety of outpatient induction of labor [29]. This Cochrane review included an RCT in which cervical ripening was carried out using a Foley catheter (12 Charrière [Ch], filling volume 30 ml) in 61 pregnant women on an outpatient basis and in 50 pregnant women in an inpatient setting. Reasons for inducing labor were post-term pregnancy in the majority of cases; all patients had a median initial BS of 3 and a singleton pregnancy in vertex presentation [30]. The catheter was placed in the evening and a CTG was carried out for 20 minutes after placement; if the results of the CTG were normal, the pregnant woman was discharged home until 6 a.m. the next morning after being given detailed written information on how to proceed. The subsequent induction of labor was done by intravenous administration of oxytocin.

There were no significant differences between the groups with regard to improvement in the Bishop Score (primary outcome criterion), maximum oxytocin dose, rate of caesarean sections, and perinatal outcomes. The inpatient hospital stay was significantly ($p < 0.001$) shorter (by 9.6 hours), and patient satisfaction determined using a visual analog scale was higher in the outpatient setting. 8% of outpatient pregnant women were readmitted to hospital ahead of schedule for premature rupture of membranes or start of contractions; there were no cases of uterine hyperstimulation in either of the groups. The limitations of this study are the imprecise data on the length of time the balloon catheter was left in place, the rate of catheter expulsions, and the oxytocin dose/amount of oxytocin required as well as the inadequate statistical power with regard to complications after catheter placement in an outpatient setting (e.g., intrauterine fetal death (IUFD), placental abruption, umbilical cord prolapse) and neonatal outcome.

A retrospective case-control study investigated a total of 615 pregnant women with an unripe cervix who underwent cervical ripening with a Foley catheter (16 Ch, filling volume 30 ml), the majority because of post-term pregnancy (41%), gestational diabetes (16.6%) or oligohydramnios (11.3%). Women were treated either on an outpatient (n = 300) or inpatient (n = 315) basis [31]. Induction of contractions was subsequently carried out by intravenous administration of oxytocin and early artificial rupture of membranes. The catheter remained in place for approx. 12 hours (from the evening until the next morning).

▶ **Table 1** Comparison of use of balloon catheters for cervical ripening/induction of labor in patients with an unripe cervix: outpatient versus inpatient use.

Author/ Year	No. of outpatients/ inpatients	Study	Primary outcome criteria	Main indication for induction	Outcome
Sciscione AL 2001[+]	61/50	randomized	Improvement of BS during balloon placement	elective, PTP	**Primary outcome criterion:** no significant differences **Significant:** shorter hospital stay (– 9,6 h), lower costs
Mc Kenna 2004[+]	300/315	retrospective case-controlled	Rate of vaginal deliveries Febrile morbidity	PTP, pre-eclampsia	**Primary outcome criteria:** no significant differences **Significant:** shorter hospital stay, lower costs
Wilkinson C 2015[+]	33/15	randomized controlled	Oxytocin requirement Caesarean section rate	PTP	**Primary outcome criteria:** lower oxytocin use, lower caesarean section rate
Kruit H 2016[*]	204/281	prospective cohorts	Caesarean section rate Maternal/neonatal infection	PTP	**Primary outcome criteria:** no significant differences **Significant:** longer induction-to-delivery interval **Median: 1842 vs. 1486 min**
Policiano C 2017[*]	65/65	randomized controlled	Improvement of BS during balloon placement	PTP	**Primary outcome criterion:** no significant differences **Significant:** ▪ shorter induction-to-delivery interval (38.2 vs. 44.9 h) ▪ shorter hospital stay (– 10 h) ▪ lower caesarean section rate due to failure to progress in labor (3 vs. 17 %)

[+] Duration of balloon placement: approx. 12 h ("overnight")

[*] Duration of balloon placement: up to 24 h

Abbreviations: BS = Bishop Score, PTP = post-term pregnancy

There was no significant difference between groups with regard to the induction-to-delivery interval or the overall rate of caesarean sections. However, the number of caesarean sections because of failure to progress in labor was significantly higher in the group which had outpatient cervical priming (39.7 vs. 31.2 %; $p < 0.001$) compared to inpatient cervical priming, while the percentage of c-sections carried out because of fetal distress was significantly higher in the inpatient group (14.5 vs. 11.1 %, $p < 0.001$). The hospital stay of the outpatient group was significantly shorter (2.5 ± 1.4 vs. 3.5 ± 3.0 days, $p < 0.001$). There were no significant differences with regard to maternal febrile morbidity (6.4 vs. 10.3 %, $p = 0.08$) or the rate of neonatal infections (2.3 vs. 4.8 %, $p = 0.13$). Outpatient cervical ripening resulted in cost savings amounting to a total of $165 000. However, the retrospective design of the study, possible selection bias, and the lack of data about the subsequent procedures used to induce labor and the method-related infections limits the validity of this study.

To determine the safety of outpatient catheter use, the data of 1905 pregnant women who underwent cervical ripening with a Foley catheter (16 Ch, filling volume 30 ml) in hospital with an observation period of 2 hours following catheter placement and the catheter remaining in place for approx. 10–12 hours (placement was done in the early evening and the catheter remained in place until 6 a. m. the next morning) were evaluated in a retrospective electronic analysis. Inclusion criteria were unripe cervix, singleton pregnancy, cephalic presentation and ≥ 37th week of gestation. The most common indications for induction of labor were post-term pregnancy > 41st week of gestation (40 %), elective induction of labor (25 %), gestational diabetes (12 %) and fetal indications such as intrauterine growth restriction (13 %). A total of 5 caesarean sections had to be carried out during the entire time between placement of the catheter and 6 a. m. the following morning, 2 of them because of pathological CTG during the 2-hour observation period but none for this indication during the rest of the time in which the catheter remained in place. There were no cases of placental abruption in this period. The authors came to the conclusion that, provided strict selection criteria were used, placement of a Foley catheter in a low-risk cohort represented a safe method for outpatient cervical ripening [32].

The safety of balloon catheters (Foley and double balloon catheters, filling volume 30–80 ml) for outpatient cervical priming was evaluated in 2017 in a systematic review [33]. A total of 26 RCTs and cohort studies of pregnant women with cephalic presentation, a live fetus, and unripe cervix were investigated (number of pregnant women = 8292). Induction of labor was carried out on an outpatient or inpatient basis in high-risk (including previous caesarean section) and low-risk pregnancies. Primary outcome criteria were complications in the period between placement of the balloon catheter and its expulsion. In the majority of cases (> 90 %), women were induced for post-term pregnancy.

The prevalence of pain following catheter placement was 0.26%, the rate of artificial rupture of membranes was 0.04%, the vaginal bleeding rate was 0.07%, and balloon dislocation occurred in 0.07% of cases. Polysystole occurred in 1 : 4812 pregnant women and uterine hypertonia in 1 : 3707 pregnant women.

The limitations of this systematic review are the heterogeneity of the studies (study design, intervention methods, demographic differences), the lack of standardization of outcome criteria, the lack of information on complications occurring between expulsion of the catheter and readmission to hospital of patients treated on an outpatient basis, and the insufficient differentiation between high-risk and low-risk cohorts with regard to complication rates.

In accordance with Sciscione et al. [32], the authors came to the conclusion that outpatient cervical ripening with balloon catheters is a safe method in low-risk pregnancies.

A randomized pilot study of 48 low-risk pregnant women with unripe cervix (BS ≤ 6) and post-term pregnancy treated with placement of a double balloon catheter (filling volume 70–80 ml), with the catheter remaining in place for approx. 12 hours and CTG monitoring carried out for 20 minutes after placement, showed no significant differences between outpatient and inpatient cervical ripening with regard to efficacy (rate of vaginal deliveries), c-section rate, maternal morbidity, and neonatal outcome. The amount of oxytocin required was almost 24% lower in the outpatient group than in the comparison group. This was attributed to the fact that pregnant women are “more relaxed in their home environment” and the probability that labor will start spontaneously is higher. Acceptance of outpatient cervical ripening was very high among pregnant women and obstetric staff (90%) [24]. The limitations of this study are its low case numbers and insufficient statistical power, particularly with regard to possible complications and neonatal outcomes.

A retrospective cohort study from Finland published in 2016 [34] included a total of 485 pregnant women with uncomplicated singleton pregnancy, intact membranes, cephalic presentation, gestational age ≥ 37th week of gestation and a BS < 6. Cervical ripening was carried out by placement of a Foley catheter (22 Ch, filling volume 40–50 ml) either as an outpatient (n = 204) or inpatient (n = 281) procedure. In 90% of cases, post-term pregnancy was the reason for inducing labor. After receiving written information about the procedure, undergoing vaginal and ultrasound examination and CTG monitoring for 20 minutes, patients were discharged home with the stipulation that they must return to hospital in the event of vaginal bleeding, fever, rupture of membranes or decreased fetal movements or at the latest 24 hours after placement of the catheter. Patients with a BS ≥ 6 then underwent amniotomy and, where necessary, received intravenous oxytocin; patients with a BS < 6 received vaginal misoprostol under continuous CTG monitoring. The main reason for contacting the hospital was expulsion of the catheter (59.3%).

No cases of severe vaginal bleeding, severe pain, placental abruption, IUFD or signs of infection were noted in patients treated on an outpatient basis; only 8.9% of the pregnant women had an unripe cervix (BS < 6) following expulsion/removal of the balloon catheter.

There were no significant differences between nulliparae and multiparae in both groups with regard to caesarean section rate, oxytocin administration to augment labor, intrapartum or postpartum infections, postpartum bleeding, or neonatal outcome. The induction-to-delivery interval was significantly longer in the group of pregnant women treated on an outpatient basis (median: 1842 minutes) compared to the group of women who remained in hospital (median: 1486 minutes, p < 0.001). This was attributed to the fact that pregnant women treated on an outpatient basis were allowed to stay at home even after expulsion of the catheter. Caesarean section for fetal distress occurred significantly more often in nulliparae treated on an inpatient basis (48.4 vs. 25%, p = 0.007); caesarean section because of failure to progress in labor occurred significantly more often in the outpatient group (63 vs. 43.8%, p = 0.02). However, multivariate regression analysis found that outpatient cervical ripening was not associated with c-section rates. 85.3% of women in the outpatient group were satisfied with the procedure used; there are no comparable data for women in the inpatient group.

The limitations of this study are a lack of randomization and possible selection bias caused by the disproportionate assignment of pregnant women with post-term pregnancy to the inpatient group.

In another randomized study [35] of 130 pregnant women with singleton pregnancy, cephalic presentation, BS < 6, post-term pregnancy > 41st week of gestation and other medical indications for inducing labor, women were randomized into outpatient or inpatient groups to undergo cervical ripening with a Foley catheter (16 Ch, filling volume 50 ml), with 65 women in each group. The catheter was left in place for 24 hours. Reasons to induce labor included post-term pregnancy (60%) and high-risk pregnancies (e.g., hypertension, diabetes). Subsequent induction of labor was done by administering oxytocin in cases with a BS of ≥ 6 or applying vaginal misoprostol in cases with a BS < 6.

The primary outcome criterion of the study was improvement of the Bishop Score during the cervical ripening phase using a balloon catheter. In this respect, there were no statistically significant differences between both groups (mean improvement of BS: 3.4 vs. 2.9), and the cervical length measured on ultrasound was also similar. The only statistically significant differences between the two groups were the mean induction-to-delivery interval (38.2 vs. 44.9 hours), the lower c-section rate for failure to progress in labor (3 vs. 17%, p = 0.02) and the mean inpatient stay (23.4 vs. 35.5 hours, p < 0.001) in favor of outpatient cervical ripening. The rate of vaginal deliveries was also slightly higher in the outpatient group compared to the inpatient group (72 vs. 62%, p = 0.19). No complications were observed during the cervical ripening phase using a balloon catheter. The limitations of this study are its lack of statistical power because of the limited number of cases for secondary outcome criteria (including induction-to-delivery interval, mode of delivery, complications). The authors stated that outpatient cervical ripening with a balloon catheter is an efficient and safe method which does not increase maternal morbidity.

A randomized controlled study which included 129 pregnant women (multiparae, ≥ 39th week of gestation, cervical dilatation < 3 cm and normal CTG) reported that use of a Foley catheter (14 Ch, filling volume 30 ml) treated on an outpatient basis (duration of catheter placement: 12 hours) did not result in a significant

▶ **Table 2** Comparison of labor induction by outpatient balloon catheter placement with inpatient administration of vaginal PGE_2 gel in patients with an unripe cervix.

Author/Year	No. of pts. in balloon/ PGE_2 group	Study	Primary outcome criterion	Main indication for labor induction	Results
Henry A 2013	50/51	randomized	Rate of vaginal deliveries/12 h after admission to labor ward Stay in hospital prior to delivery	PTP	**Primary outcome criteria:** (significant) ▪ Rate of vaginal deliveries/12 h: 28 vs. 53% ▪ Duration of hospital stay: 21 vs. 32 h **Significant:** ▪ More oxytocin required: 88 vs. 59% ▪ Hours of sleep: 5.8 vs. 3.4 h ▪ Pain during cervical ripening: 26 vs. 58%
Beckmann M 2020	215/233	randomized, controlled	Overall neonatal morbidity	PTP	**Primary outcome criterion:** no significant differences **Significant:** ▪ Lower overall neonatal morbidity for nulliparae: 20.4 vs. 31% (p = 0.032) ▪ Multiparae: higher c-section rate: 17.2 vs. 5.1% (p = 0.045)

Abbreviations: BS = Bishop Score, PTP = post-term pregnancy, pts. = patients

decrease in the mean interval between admission to the labor ward and delivery compared to inpatient treatment (Foley catheter and concomitant administration of oxytocin) (12.4 vs. 13.5 hours) [36].

Balloon catheter versus prostaglandins for outpatient induction of labor (▶ Table 2)

Local application of prostaglandin E_2 and oral and vaginal misoprostol have also been used in numerous studies on outpatient induction of labor [26, 37, 38]. Because of the unpredictable occurrence of uterine hyperstimulation, the standard method recommended in guidelines when using PG is to induce labor in an inpatient setting [39]. There are currently only a few studies which have compared cervical priming/induction of labor with PG in an inpatient setting with cervical priming/induction of labor with a balloon catheter in an outpatient setting.

In a prospective randomized study of 101 pregnant women (singleton pregnancy, cephalic presentation, > 37th week of gestation, BS < 7), cervical ripening/induction of labor was either performed as an outpatient procedure using a Foley catheter (n = 50, 16 Ch, filling volume 30 ml) or by administering 2 mg vaginal PGE_2 gel to nulliparae or 1 mg to multiparae (n = 51) [40]. CTG monitoring for 30 minutes after placement was mandatory. The catheter remained in place "overnight" until about 7 a. m. the following morning (more exact information is not provided). In the majority of cases, induction of labor was for post-term pregnancy or gestational diabetes, hypertensive pregnancy disorders or cholestasis of pregnancy. Primary outcome criteria were the rate of vaginal deliveries within 12 hours after admission to the labor ward and the duration of hospital stay. When cervical ripening was carried out as an outpatient procedure using a Foley catheter, the duration of hospital stay before delivery was significantly shorter (21.3 vs. 32.4 hours, p = 0.001), the rate of vaginal deliveries within 12 hours significantly lower (28 vs. 53%, p = 0.01), and the need for oxytocin significantly higher (88 vs. 59%, p = 0.01) compared to the group of inpatient women treated with PGE_2. The pain perception rate was found to be significantly lower after outpatient procedures (26 vs. 58%, p = 0.003) and the amount of sleep the patients had was significantly longer (5.8 vs. 3.4 hours, p < 0.001). There were no significant differences between groups with regard to frequency of fever, pathological CTG, postpartum bleeding, or perinatal outcomes; the uterine hyperstimulation rate was 0 with the Foley catheter and 4% for PGE_2.

The limitations of this study are the insufficient number of pregnant women included in the study (originally planned as n = 240), which resulted in an insufficient statistical power for all of the study's secondary outcome criteria, and a lack of data about complications during the cervical ripening phase, the precise duration of balloon catheter placement, and the priming effect (BS).

The authors did not subsequently make any explicit recommendations for or against either of the procedures.

Another randomized controlled multicenter study was published in 2020 [41]. It evaluated 215 pregnant women who underwent outpatient cervical ripening using a balloon catheter (double balloon, filling volume 80 ml) and 233 pregnant women who underwent inpatient cervical ripening and received either 2 mg vaginal PGE_2 gel or a 10 mg vaginal PGE_2 pessary. Inclusion criteria were low-risk pregnancies (elective induction of labor, post-term pregnancy or advanced maternal age ≥ 40 years) and a BS < 7. After placement, CTG monitoring was carried out for 30 minutes. The catheter remained in place for approx. 12 hours. Subsequent procedures used to induce labor consisted of amniotomy, where possible, or intravenous oxytocin or another application of PGE_2. Primary outcome criterion of the study was overall neonatal morbidity.

There was no statistically significant difference in the overall neonatal morbidity between the two groups (18.6 vs. 25.8%, RR 0.77; 95% CI: 0.51–1.02; p = 0.07). The rates of operative deliveries, fetal distress and perinatal outcomes also did not differ sta-

tistically significantly between groups. However, a subgroup analysis found a significantly lower overall neonatal morbidity in nulliparae treated with placement of a balloon catheter compared to administration of PGE_2 (20.4 vs. 31.0%, p = 0.032), in particular, a lower frequency of antibiotic administration to neonates and arterial umbilical cord values of < 7.10. The rate of caesarean sections in nulliparae was similarly high in both groups (38.2 vs. 31.1%); however, in the group of multiparae, it was significantly higher in those who had balloon catheter placement compared to the group of multiparae treated with PGE_2 (17.2 vs. 5.1%; p = 0.045). Of the group of women who underwent placement of a balloon catheter for cervical ripening with a mean time spent at home of 12 hours, 13.5% had to be readmitted to hospital earlier because of pain, expulsion of the balloon, or contractions. The inpatient stay of women who had balloon catheter placement was significantly shorter (p = 0.039).

The authors commented their results as follows: they attributed the relative difference in caesarean section rates between nulliparae and multiparae to the reduced mechanical effect of the balloon catheter in multiparae resulting from the decreased cervical dilation associated with a lower endogenous prostaglandin release from the cervical tissue. Previous caesarean section was an exclusion criterion in this study, and it does therefore not explain the comparatively high rate of caesarean sections. The higher acidosis rate after PGE_2 administration was explained by the more common frequency of uterine hyperstimulation compared to the balloon catheter group, while the comparatively higher frequency of antibiotic administration to neonates was attributed to the more frequent vaginal examinations in the PGE_2 group which are associated with a higher risk of infection.

The authors commented that outpatient cervical ripening using a balloon catheter offers better results for nulliparae than inpatient induction of labor using vaginal PGE_2, but this does not apply to multiparae.

A randomized controlled study from Australia (OBLIGE trial, ACTRN 12616000739415) is currently recruiting pregnant women up until December 2020 (planned number of patients: n = 1552), who will either undergo outpatient cervical ripening with a balloon catheter (duration of catheter placement 18–24 hours) or inpatient treatment with vaginal PGE_2 gel/PGE_2 pessary. Inclusion criteria are singleton pregnancy, cephalic presentation, gestational age ≥ 37th week of gestation, intact membranes, BS < 7 and distance to hospital ≤ 1 hour. Primary outcome criterion of this multicenter study is the rate of caesarean sections. It is hypothesized that the caesarean section rate will be lower following outpatient balloon catheter use than after administration of PGE_2 in an inpatient setting [42].

A cost-effectiveness analysis was recently carried out in the Netherlands [28], based on data obtained from the PROBAAT II trial [43]. This randomized controlled study showed that there were no significant differences with regard to the rates of caesarean section, postpartum bleeding. and perinatal outcomes between labor induction using 50 µg oral misoprostol every 4 hours and labor induction with a Foley catheter (filling volume 30 ml) followed by amniotomy/intravenous administration of oxytocin in pregnant women at term with an unripe cervix. The cost analysis was based on an evaluation of 924 pregnant women in the misoprostol and 921 in the balloon catheter group. The mean overall hospital costs of both procedures were roughly comparable. However, cervical ripening using a Foley catheter in an outpatient setting resulted in significant cost savings of an average of € 981/pregnant woman in this low-risk cohort.

Discussion

As the labor induction rates have continually risen in high-income countries, the hospital costs and the burden on obstetric staff have also increased. The satisfaction of pregnant women and self-determination/self-regulation is also becoming more and more important in obstetrics. Inducing labor when the cervix is still unripe is often associated with long induction-to-delivery intervals, which are stressful for pregnant women and increase the costs. That is why outpatient procedures to induce labor are attracting much greater interest again. But this also raises questions about the safety of this approach for mother and baby. It is estimated that 20–50% of all pregnant women requiring induction of labor could be eligible for outpatient procedures [44].

Prostaglandin E_2, misoprostol and balloon catheters are the most commonly used approaches investigated in studies [26, 37, 38]. A Cochrane review carried out in 2010 (28 studies, n = 2610) came to the conclusion that the data on outpatient procedures to induce labor are insufficient with regard to the efficacy and safety of procedures [45]. A Cochrane review published in 2013 relating to the same issue [29] which included 4 RCTs (n = 1439), 3 of which used vaginal PGE_2 and one which used a Foley catheter (n = 111), came to similar conclusions. A more recent Cochrane review published in 2017 [46] included 34 RCTs (n = 5028) with 11 different methods for outpatient induction of labor. Although the overall risk of severe complications was low, there was insufficient evidence on which method of outpatient induction of labor should be preferred in terms of efficacy and safety. It should be noted, however, that this review did not include any studies of balloon catheters.

Comparison of PGE_2 with balloon catheter

The key advantage of using PG (PGE_2, misoprostol) is their high efficacy (rate of vaginal deliveries/24 hours) because of the pharmacological synergism of cervical ripening and induction of labor, two effects which cannot be clinically separated from one another [6]. The disadvantages of using PG are that they are difficult to control because the onset of action is unpredictable; they need to be applied repeatedly, which potentially increases the risk of infection, the costs of monitoring are higher; and, above all, they are associated with an unpredictable occurrence of uterine hyperstimulation, most often polysystoles in up to 20% of cases [7], which do not lead to labor progress. Uterine hyperstimulation syndrome may result in fetal hypoxia caused by acute hypoperfusion of the fetoplacental unit.

A total of 425 pregnant women were included in the currently largest randomized controlled study on outpatient and inpatient induction of labor using vaginal PGE_2 gel (1 mg for multiparae, 2 mg for nulliparae), with the majority of women being induced because of post-term pregnancy (outpatients n = 215; inpatients n = 210) [47]. After an initial 40-minute monitoring phase, 21.9%

(47/215) were not discharged home because of contractions, pathological CTG, or because the patient had changed her mind and did not want to be discharged home. Of the remaining 168 pregnant women in this group, 38.1% (n = 64) had to be admitted to hospital early because of contractions, premature rupture of membranes or anxiety, leaving only 48.3% (104/215) of all pregnant women in the study who remained at home until the next morning. The uterine hyperstimulation rate was 3% [47]. The authors stated that vaginal PGE_2 gel is not a suitable method for outpatient induction of labor. As a consequence of their study, the authors have switched their procedure to outpatient cervical ripening using a balloon catheter [48].

With the off-label use of Foley catheters (filling volume: 30–60 ml) and the use of double balloon catheters (filling volume: 80 ml) which have been approved for labor induction (duration of catheter placement ranging from 12 to 24 hours) methods are available which are as effective as vaginal PGE_2 gel in achieving cervical ripening [49], but which are not associated with an increased risk of uterine hyperstimulation [6]. The uterine hyperstimulation rate after catheter placement is reported to be between 0 and 0.4% [50 – 52]. This is significantly lower than the reported rates for vaginal PGE_2 gel.

Other relevant advantages of balloon catheters compared to PGE_2/misoprostol for the induction of labor in women with unripe cervix are the lower costs of monitoring and the associated reduction in staffing hours and the ease of storage at room temperature compared to PGE_2 [37]. The results of cost-effectivness analyses are controversial [10, 53, 54].

In 14–33% of cases, use of a balloon catheter alone led to the development of uterine contractions during cervical ripening, while 67–86% of cases required intravenous administration of oxytocin to induce/augment labor [6]. In the largest randomized, controlled study carried out to date (PROBAAT trial, n = 824), the use of oxytocin to augment contractions was necessary in 86% of cases treated with a Foley catheter and in 59% of women treated with vaginal PGE_2 ($p < 0.0001$) [49]. Uterine hyperstimulation after placement of a balloon catheter occurred almost exclusively following subsequent administration of oxytocin in 2.0–2.7% of pregnant women [15, 49].

Problems do occasionally occur when placing balloon catheters. For inserting a double ballon catheter the cervical canal should be patent for at least 6 mm [6], up to 4% of pregnant women may experience mostly slight pain when the catheter is inserted [15].

According to the findings of a systematic review [33], the estimated prevalence in a low-risk cohort during the cervical ripening phase was 0.26% for pain/discomfort, 0.07% for vaginal bleeding, 0.07% for dislocation of the balloon catheter, 0.04% for artificial rupture of membranes, and 0.01% for pathological CTG; there were no reported cases of umbilical cord prolapse. However, because of the substantial heterogeneity of the studies and the selection bias, these results should be interpreted with caution. They differ from those reported by Kruit et al. [34], who observed higher rates of pain (2%), vaginal bleeding (1.5%) and artificial rupture of membranes (2%) after placement of a balloon catheter.

It is also important to point out the potential risk of umbilical cord prolapse, an event that has been reported in individual cases [41]. Other serious complications such as placental abruption or intrauterine fetal death have not occurred according to an extensive analysis of the data [32].

Comparison between outpatient and inpatient cervical ripening using balloon catheters

Comparative studies which evaluated outcomes of outpatient and inpatient cervical ripening with balloon catheters have been very heterogeneous, particularly with regard to the study design (controlled randomized studies versus retrospective cohort studies), the primary outcome criteria (cf. ▶ **Tables 1** and **2**), the type and use of balloon catheters (Foley versus double balloon catheter, filling volume 30–80 ml, with or without traction, duration of placement 12–24 hours) and the obstetric approach (different monitoring protocols, different methods to induce labor with oxytocin/amniotomy, vaginal PGE_2, misoprostol). In two studies, a distance to the obstetric hospital of > 30–60 minutes was an exclusion criterion [30, 41]. In almost all of the studies, the initial BS was ≤ 6; in 5 studies, the period the balloon catheter remained in situ was approx. 12 hours (“overnight”) [24, 25, 30, 31], while in 3 studies the catheter remained in place for up to 24 hours [35, 42]. It is generally thought that balloon catheters can remain in situ for up to 3 days without increasing the risk [13, 43, 50, 55].

The most common indications for induction of labor were elective, post-term pregnancy > 41st week of gestation, suspicion of fetal macrosomia, and gestational diabetes; 2 studies also included high-risk pregnancies (e.g., preeclampsia, gestational hypertension, IUGR) [21, 35] or previous caesarean section [34]. In the majority of studies, it was pointed out that an outpatient procedure can only be justified in low-risk pregnancies.

CTG monitoring for 20–40 minutes after placement of the catheter was mandatory in all studies. Some studies also carried out sonography to determine fetal position and amniotic fluid volumes and to exclude placenta previa [30, 34]. This approach increases the safety and affects the selection of pregnant women considered suitable for an outpatient procedure.

Written informed consent of the pregnant woman was also mandatory. This included providing information to the patient about the circumstances which would require her to contact the hospital or return to hospital for readmission. Accordingly, the patient must be informed about the following risks: painful contractions, fever, vaginal bleeding, rupture of membranes, reduced fetal movements, difficulty in urinating, expulsion of the balloon catheter.

In the currently largest prospective cohort study [34], expulsion of the catheter during a period of up to 24 hours after placement was the most common reason (59.3%) for contacting the hospital, followed by contractions (6.9%), premature rupture of membranes (2%), and vaginal bleeding (1.5%). The observation that only 8.9% still had an unripe cervix (BS < 6) at the time of readmission to hospital is clinically important.

Several studies have pointed out that 24-hour contact to the hospital must be ensured for patients having outpatient induction of labor [24, 30, 34, 41], while other studies did not provide any information on this point [25, 34, 35].

▶ **Table 3** Approach for outpatient induction of labor using a balloon catheter.

▪ **Indication:** only low risk pregnancies; e.g., post-term pregnancy ≥ 41st week of gestation; indication must be confirmed by a consultant
▪ **Pre-procedure discussion:** information about potential pain, bleeding, premature rupture of membranes, expulsion of the catheter
▪ Informed consent
▪ **Prior to placement:** cervical status (BS < 6), sonography (placental location, amniotic fluid volume, fetal position), CTG for 30 min
▪ **E. g., at 8 : 00 p. m.:** placement of double balloon catheter (80 ml) or Foley catheter (50 ml); fixation, poss. sonographic control, CTG → monitored in hospital for approx. 2 h → normal CTG → discharged home
▪ **Before being discharged:** instructions (oral/written): immediate readmission for vaginal bleeding, rupture of membranes, fever, severe pain, contractions every 5–10 min, balloon expulsion
▪ Ensure hospital can be contacted easily (telephone number)
▪ **E. g., at 8 : 00 a. m.:** readmission: cervical status, CTG, temperature → removal of the balloon → BS > 6 intravenous oxytocin → BS ≤ 6 e.g., oral misoprostol

▶ **Table 4** Inclusion criteria for outpatient induction of labor with a balloon catheter.

▪ Pregnant woman's preference for outpatient procedure, age > 18 years
▪ Gestational age ≥ 37 + 0 weeks of gestation
▪ Singleton pregnancy, cephalic presentation
▪ No low-lying placenta/placenta previa
▪ Low risk: e.g., no preeclampsia/underlying maternal disease, no previous caesarean section, negative group B Strep swab test
▪ Normal lab test at admission
▪ No fever (temperature < 37.6 °C ear thermometer)
▪ Normal CTG
▪ Good communiation with the patient, patient's compliance, pregnant woman can return to hospital within a short time

▶ **Table 3** provides a summary of the procedure for outpatient induction of labor using balloon catheters and ▶ **Table 4** summarizes the inclusion criteria of the different studies.

As regards primary outcome criteria such as improvement of the BS, vaginal delivery rate, frequency of caesarean sections, and infection rates, there was no significant difference between outpatient and inpatient cervical ripening with balloon catheters. Similarly, there were no significant differences between the two procedures in terms of the need for oxytocin, uterine hyperstimulation rate (n = 0) and neonatal outcome. This indicates that both approaches are equally effective and safe.

The findings on caesarean section rates due to failed induction or failure to progress to labor in the different studies are contradictory [30, 31, 35] as are the results for the induction-to-delivery interval [34, 35]. The studies consistently found that the outpatient procedure significantly decreased the time spent in hospital by up to 10 hours and that pregnant women were highly satisfied with the outpatient procedure for cervical ripening. Between 6.7 and 13.5 % of cases had to return to hospital earlier than planned because of severe pain, contractions, or premature rupture of membranes [24, 30, 34, 41]; other studies did not provide any information on this point [25, 30, 34]. Some study protocols required readmission to hospital in the event of expulsion of the balloon catheter [24, 35, 41], while others did not [25, 30, 34]. The balloon expulsion rate may significantly be influenced by the filling volume of the balloon and the length of time it remained in place; however, only a few studies provided any precise data on this issue. The expulsion rate of balloons which remained in place for 12–24 hours and had a filling volume of 80 ml (double balloon) was 10.2 and 33.3 %, respectively [24, 41], while the expulsion rate of Foley catheters left in place for up to 12 hours with a filling volume of 40–50 ml was 59.3 % [34]. Only one study reported cost savings in favor of the outpatient procedure [31]. Despite the differences between the studies in terms of their different evaluation criteria, patient satisfaction with outpatient cervical priming was high, although patients complained of discomfort during catheter placement, irrespective of the approach chosen (inpatient vs. outpatient) [24, 30, 35].

Comparison of outpatient balloon catheter and inpatient prostaglandin E_2

When outpatient balloon catheters were compared with inpatient administration of vaginal PGE_2 gel, the rate of vaginal deliveries within 12 hours after readmission to the labor ward was significantly lower (28 vs. 53 %, p = 0.01) and the need for oxytocin was significantly higher (88 vs. 59 %, p < 0.01) in the group treated with a balloon catheter; while overall neonatal morbidity for nulliparae and multiparae was comparable. The stay in hospital was shorter and pain during the cervical ripening phase was lower in the outpatient group, and pregnant women in the outpatient group had more hours of sleep (cf. ▶ **Table 2**). The aim of a currently recruiting RCT in Australia is to compare both procedures with regard to caesarean section rates (primary outcome criterion) [42].

While a cost-effectiveness analysis carried out in 101 pregnant women (Foley catheter: n = 50, vaginal PGE_2 gel: n = 51) to evaluate the induction of labor in women with an unripe cervix showed no significant differences between both groups with regard to hospital costs [56], an extensive cost-effectiveness analysis carried out in the Netherlands comparing the use of Foley catheters (n = 921) with oral misoprostol (n = 924) administered at a dose of 50 µg every 4 hours in a low-risk cohort found that hospital costs were only lower if outpatient cervical priming with a balloon catheter continued until the start of contractions [28]. Based on the results of the PROBAAT II trial [43] and the non-significant differences between Foley catheters and oral misoprostol with regard to uterine hyperstimulation rates [12], it would be worth comparing the use of both methods for outpatient induction of labor.

Because of insufficient data and a lack of evidence, outpatient induction of labor is only discussed in passing in international guidelines.

The 2011 WHO guideline [57] spoke against outpatient induction of labor because the lack of sufficient data. The 2013 NICE guideline [58] commented "Induction of labour should only be carried out in an outpatient setting, if safety and support procedures are in place", and the ACOG Practice Bulletin No. 107 2009/19 [59] only promotes outpatient induction of labor after careful selection of pregnant women with a preference given to mechanical methods.

Conclusion

The use of a balloon catheter in low-risk pregnancies (e.g., postterm pregnancy) with an unripe cervix and no contractions is an effective and safe method for outpatient preinduction cervical ripening. It is not associated with a higher risk of infection compared to prostaglandins. Important preconditions for outpatient procedures are the strict selection of suitable pregnant women, CTG monitoring for 20–40 minutes after catheter placement, detailed instructions given to the pregnant woman instructing her about the signs which would make an immediate return to hospital imperative, and 24-hour phone access to the hospital. Outpatient preinduction cervical ripening with a balloon catheter results in significantly shorter hospital stays, reduces hospital costs, and has a higher patient satisfaction compared to inpatient procedures.

The goal of a future randomized controlled study with adequate statistical power should be to evaluate the method's safety, patient acceptance and cost-effectiveness, particularly compared to oral misoprostol administered in an outpatient setting to be able to make evidence-based recommendations for clinical practice.

Conflict of Interest

The authors declare that they have no conflict of interest.

References

[1] Hamilton BE, Martin JA, Osterman MJ et al. National vital statistics reports. Natl Vital Stat Rep 2015; 64: 1–64

[2] Ministry of Health. Report on Maternity 2015. Wellington: Ministry of Health; 2017

[3] Stephenson E, Burakati A, Simpson I et al. Foley catheter for induction of labour: a UK observational study. J Obstet Gynecol 2019. doi:10.1080/01443615.2019.1676213

[4] IQTIG: Institut für Qualitätssicherung und Transparenz im Gesundheitswesen. Basisauswertung zum Erfassungsjahr 2017. Geburtshilfe. 2018. Accessed April 14, 2020 at: https://iqtigorg/downloads/auswertung/2017/16n1gebh/QSKH-16 ns-GEBH-2017-BUAW-V02–2018-08-01.pdf

[5] Voigt F, Goecke TW, Najjari L et al. Off-label use of misoprostol for labor induction in Germany: a national survey. Eur J Obstet Gynecol Reprod Biol 2015; 187: 85–89

[6] Rath W, Kehl S. Renaissance des transzervikalen Ballonkatheters zur Zervixreifung und Geburtseinleitung. Geburtshilfe Frauenheilkd 2015; 75: 1130–1139

[7] Rath W, Pecks U. Medikamentöse Geburtseinleitung. 2. vollst. aktualisierte Auflage. Bremen, London, Boston: Uni Med; 2010

[8] Rath W. Misoprostol zur Geburtseinleitung – eine aktuelle Übersicht. Frauenarzt 2014; 55: 346–353

[9] Norman JE, Stock S. Intracervical Foley catheter for induction of labour. Lancet 2011; 378: 2054–2055

[10] Sciscione AC. Methods of cervical ripening and labour induction. Clin Obstet Gynecol 2014; 57: 369–376

[11] Wing DA, Lockwood CJ, Barss VA. Techniques for ripening the unfavourable cervix prior th induction 2014. Accessed March 15, 2020 at: www.uptodate.com

[12] de Vaan MD, ten Eikelder ML, Jozwiak M et al. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2019; (10): CD001233

[13] Chen W, Xue J, Peprah MK et al. A systematic review and network meta-analysis comparing the use of Foley catheters, misoprostol, and dinoprostone for cervical ripening in the indication of labour. BJOG 2016; 123: 346–354

[14] Du YM, Zhu LY, Cui LN et al. Double-balloon catheter versus prostaglandin E_2 for cervical ripening and labour induction: a systematic review and meta-analysis of randomised controlled trials. BJOG 2017; 124: 891–899

[15] Gommers JSM, Diederen M, Wilkinson C et al. Risk of maternal, fetal and neonatal complications associated with the use of the transcervical balloon catheter in induction of labour: A systematic review. Eur J Obstet Gynecol Reprod Biol 2017; 218: 73–84

[16] Penell CE, Henderson JJ, O'Neill MJ et al. Induction of labour in nulliparous women with an unfavourable cervix: a randomized trial comparing double and single balloon catheters and PGE_2 gel. BJOG 2009; 116: 1443–1452

[17] Shechter-Maor G, Haran G, Sadeh-Mestechkin D et al. Intravaginal prostaglandin E_2 versus double-balloon catheter for labour induction in term oligohydramnions. J Perinat 2015; 35: 95–98

[18] Kehl S, Welzer G, Erhard A et al. Women's acceptance of a double-balloon device as an additional method for induction labour. Eur J Obstet Gynecol Reprod Biol 2013; 168: 30–35

[19] Heinemann J, Gillen G, Sanchez-Ramos I et al. Do mechanical methods of cervical ripening increase infectious morbidity? A systematic review. AJOG 2008; 199: 177–187

[20] Mc Master K, Sanchez-Ramos L, Kaunitz AM. Evaluation of a transcervical Foley catheter as a source of infection: a systematic review and meta-analysis. Obstet Gynecol 2015; 126: 539–551

[21] Solone M, Shaw KA. Induction of labour with an unfavourable cervix. Curr Opin Obstet Gynecol 2020; 32: 107–112

[22] Turnbull D, Adelson P, Oster C et al. Psychosocial outcome of a randomized controlled trial of outpatient cervical priming for induction of labour (OPRA study). Birth 2013; 40: 75–80

[23] Howard K, Gerars K, Adelson P et al. Women's preferences for inpatient and outpatient priming for labour induction: a discrete choice experiment. BMC Health Services Res 2014; 14: 330

[24] Wilkinson C, Adelson P, Turnbull D. A comparison of inpatient with outpatient balloon catheter cervical ripening: a pilot randomized controlled trial. BMC Pregnancy Childbirth 2015; 15: 126

[25] Henry A, Madan A, Reid R et al. Outpatient Foley catheter versus inpatient prostaglandin E_2 gel for induction of labour: a randomised trial. BMC Pregnancy Childbirth 2013; 13: 25

[26] Leopold B, Sciscione A. Is there a place for outpatient preinduction cervical ripening? Obstet Gynecol Clin North Am 2017; 44: 583–591

[27] Gelber S, Sciscione A. Mechanical methods of cervical ripening and labor induction. Clin Obstet Gynecol 2006; 49: 642–657

[28] Ten Eikelder M, van Baaren GJ, Oude Regerink K et al. Comparing induction of labour with oral misoprostol or Foley catheter at term: cost-effectiveness analysis of a randomised controlled multi-centre non-inferiority trial. BJOG 2018; 125: 375–383

[29] Kelly AJ, Alfirevic Z, Ghosh A. Outpatient versus inpatient induction of labour for improving birth outcomes. Cochrane Database Syst Rev 2013; (11): CD007372

[30] Sciscione A, Muenaty M, Pollock M et al. Transcervical Foley catheter for preinduction cervical ripening in an outpatient versus inpatient setting. Obstet Gynecol 2001; 98: 751–756

[31] Mc Kenna DS, Duke JM. Effectiveness and infectious morbidity of outpatient cervical ripening with a Foley catheter. J Reprod Med 2004; 49: 28–32

[32] Sciscione A, Bedder CL, Hoffman MK et al. The timing of adverse events with Foley catheter preinduction cervical ripening: Implications for outpatient use. Am J Perinatol 2014; 31: 781–786

[33] Diederen M, Gommers JSM, Wilkinson C et al. Safety of the balloon catheter for cervical ripening in outpatient care: complications during the period from insertion to expulsion of a balloon catheter in the process of labour induction: a systematic review. BJOG 2018; 125: 1086–1095

[34] Kruit H, Heikinheimo O, Ulander V-M et al. Foley catheter induction of labor as an outpatient procedure. J Perinatol 2016; 36: 618–622

[35] Policiano C, Pimenta M, Martins D et al. Outpatient versus inpatient cervical priming with Foley catheter: a randomized trial. Eur J Obstet Gynecol Reprod Biol 2017; 210: 1–6

[36] Kuper SG, Jank VC, George DR et al. Outpatient Foley catheter for induction of labour in parous women: a randomized controlled trial. Obstet Gynecol 2018; 132: 94–101

[37] Rath W. Outpatient induction – how safe? J Perinat Med 2009; 37: 461–467

[38] Goonewardene M. Cervical ripening and induction of labour: Inpatient of outpatient, oral misoprostol or Foley catheter? Ceylon Med J 2017; 62: 117–120

[39] Tsakiridis I, Mamopoulos A, Apostolos A et al. Induction of labor: An overview of guidelines. Obstet Gynecol Surv 2020; 75: 61–72

[40] Henry A, Madan A, Reid R et al. Outpatient Foley catheter versus inpatient prostaglandin E_2 gel for induction of labour: a randomized trial. BMC Pregnancy Childbirth 2013; 13: 25

[41] Beckmann M, Gibhons K, Flenady V et al. Induction of labour using prostaglandin E_2 as an inpatient versus balloon catheter and an outpatient: a multicentre randomized controlled trial. BJOG 2020; 127: 571–579

[42] Wise MR, Mariott J, Battin M et al. Outpatient balloon catheter vs. inpatient prostaglandin for induction of labour (OBLIGE): a randomised controlled trial. Trials 2020; 21: 190

[43] Ten Eikelder MLG, Rengerink KO, Jozwiak M et al. Induction of labour at term with oral misoprostol versus a Foley catheter (PROBAAT-II): a multicentre randomised controlled non-inferiority trial. Lancet 2016; 387: 1619–1628

[44] Farmer KC, Schwartz WJ, Rayburn WF et al. A costminization analysis for intracervical prostaglandin E_2 for cervical ripening in an outpatient versus inpatient setting. Clin Therap 1996; 18: 747–756

[45] Dowswell T, Kelly AJ, Livio S et al. Different methods for the induction of labour in outpatient settings. Cochrane Database Syst Rev 2010; (8): CD007701

[46] Vogel JP, Osoti AO, Kelly AJ et al. Pharmacological and mechanical interventions for labour induction in outpatient settings. Cochrane Database Syst Rev 2017; (9): CD007701

[47] Wilkinson C, Bryce R, Adelson P et al. A randomised controlled trial of outpatient compared with inpatient cervical ripening with prostaglandin E_2 (OPRA study). BJOG 2015; 122: 94–106

[48] Wilkinson C, Turnbull D. Authors' reply re: A randomised controlled trial of outpatient compared to inpatient cervical ripening with prostaglandin E_2 (OPRA study). BJOG 2016; 123: 2050. doi:10.1111/1471-0528.14045

[49] Jozwiak M, Oude Rengerink KO, Benthem M et al. Foley catheter versus vaginal prostaglandin E_2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. Lancet 2011; 378: 2095–2103

[50] Jozwiak M, Bloemenkamp KWM, Kelly AJ et al. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2012; (3): CD001233

[51] Cromi A, Ghezzi F, Uccello S et al. A randomized trial of pre induction cervical ripening dinoprostone vaginal insert versus double-balloon catheter. AJOG 2012; 207: 125e1–125e7

[52] Du C, Liu Y, Liu Y et al. Double-balloon catheter vs. dinoprostone vaginal insert for induction of labor with an unfavorable cervix. Arch Gynecol Obstet 2015; 291: 1221–1227

[53] Lim SY, Kim H, Kim CH et al. The effect of a Foley catheter balloon on cervical ripening. J Obstet Gynaecol 2013; 33: 830–838

[54] van Baaren GJ, Jozwiak M, Opmeer B et al. Cost-effectiveness of induction of labour at term with a Foley catheter compared to vaginal prostaglandin E_2 gel (PROBAAT-trial). BJOG 2013; 120: 987–995

[55] Ekele IA, Isak AY. Cervical ripening: how long can the Foley catheter safety remain in the cervical canal? Afr J Reprod Health 2002; 6: 98–102

[56] Austin K, Chambers GM, de Ahren Lovrenzo R et al. Cost-effectiveness of term induction of labour using inpatient prostaglandin gel versus outpatient Foley catheter. Austr NZJ Obstet Gynaecol 2015; 55: 440–445

[57] WHO. WHO recommendations for induction of labour. Accessed April 14, 2020 at: http://whqlibdoc.who.int.hg/2011

[58] Induction of labour: evidence update 2013: a summary of selected new evidence relevant to NICE clinical guideline 70, Induction of labour' (2008). London: National Institute for Health and Care Excellence; 2013

[59] ACOG Practice Bulletin No. 107. 2009 (reaffirmed 2019). Induction of labour. Obstet Gynecol 2009; 114: 386–397