The Renaissance of Transcervical Balloon Catheters for Cervical Ripening and Labour Induction

Renaissance des transzervikalen Ballonkatheters zur Zervixreifung und Geburtseinleitung

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Abstract
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Due to rising rates of labour induction in industrialised countries, safe and effective methods of induction have once again become a focus of interest and research. Prostaglandins are effective for cervical ripening and induction of uterine contractions. They do, however, cause overstimulation of the uterus in up to 20 % of cases, sometimes causing changes in fetal heart rate. Transcervical balloon catheters provide an alternative to prostaglandins for labour induction and have been used for this purpose for almost 50 years. This induction method has experienced a recent renaissance in clinical practice that is reflected in an annually rising number of publications on its use. Balloon catheters allow gentle ripening of the cervix without causing uterine overstimulation. The two catheters available are the Foley catheter (off-label use) and the double balloon catheter, which is licensed for use in induction of labour. Both are as effective as prostaglandins, and do not increase the risk of infection to mother or child. Catheter induction also requires less monitoring compared to prostaglandins resulting in improved patient satisfaction. Balloon catheters provide a useful and promising option to achieve vaginal delivery despite failed prostaglandin induction. Intravenous oxytocin is nevertheless required in up to 85 % of cases for adequate induction/augmentation of contractions. Balloon catheters, vaginal PGE_2 and misoprostol are equally effective in the context of an unripe/unfavourable cervix, the rate of uterine hyperstimulation being significantly lower, and the need for oxytocin significantly higher for catheters. Balloon catheters are increasingly being used in combination or sequentially with oral/vaginal misoprostol, although there is currently inadequate published data on the subject. International guidelines recommend the use of balloon catheters for labour in-

Zusammenfassung
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Angesichts steigender Raten in den Industrieländern ist die Frage nach effektiven und sicheren Methoden der Geburtseinleitung wieder in den Fokus des Interesses gelangt. Prostaglandine sind effektiv zur Zervixreifung und Weheninduktion, weisen aber auch in bis zu 20 % der Fälle uterine Überstimulierungen mit und ohne fetale Herzfrequenzveränderungen auf. Eine Alternative ist der seit fast 50 Jahren zur Geburtseinleitung angewandte transzervikale Ballonkatheter, der – wie jährlich steigende Publikationszahlen zeigen – eine Renaissance erfahren hat. Ballonkatheter ermöglichen eine schonende Zervixreifung ohne uterine Überstimulierungen. Zur Verfügung stehen der Foley-Katheter (off-label use) und der für die Geburtseinleitung zugelassene Doppelballonkatheter, die so effektiv sind wie Prostaglandine, das Infektionsrisiko für Mutter und Kind nicht erhöhen und bei im Vergleich zu Prostaglandinen geringerem Überwachungsaufwand eine gute Akzeptanz bei den Schwangeren aufweisen. Nach frustraner Geburtseinleitung mit Prostaglandinen sind Ballonkatheter eine vielversprechende Option, noch eine vaginale Geburt zu erreichen. Zur Weheninduktion/-verstärkung ist allerdings in bis zu 85 % der Fälle Oxytocin intravenös erforderlich. Hinsichtlich der Effizienz weisen Ballonkatheter und vaginales PGE_2 sowie Misoprostol bei unreifer Zervix keine signifikanten Unterschiede auf, die Rate uteriner Überstimulierungen ist signifikant niedriger, der Oxytocinbedarf signifikant höher. Zunehmend häufiger wird der Ballonkatheter in Kombination oder sequenziell mit oralem/vaginalem Misoprostol eingesetzt, allerdings ist die Datenlage bisher unzureichend. Internationale Leitlinien empfehlen die Anwendung des Ballonkatheters zur Geburtseinleitung bei unreifer Zervix (auch nach vorangegangener Sectio caesarea) als Alternative zu

duction with an unripe cervix (also following previous caesarean section) as an alternative to prostaglandins, particularly when these are not available or are contraindicated.

Prostaglandinen, insbesondere dann, wenn diese nicht zur Verfügung stehen oder kontraindiziert sind.

Introduction
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In industrialised countries rates of induction of labour have almost doubled in the past 10 years, e.g. the current induction rate in the Netherlands is 33% [1] and in Germany (2013) 22% of which 98% were medical inductions [2].

The advantage of the prostaglandin E_1 analogue misoprostol and prostaglandin E_2 (PGE_2) is their efficiency (e.g. rate of vaginal deliveries in 24 hours) when the cervix is unfavourable (Bishop score [BS] < 6). This is a result of pharmacological synergism between cervix ripening and myometrium stimulating effects [3], the two effects being clinically indistinguishable from one another. The main disadvantage of prostaglandins is a variable rate (3–20%) of associated uterine hyperstimulation, which may cause changes in fetal heart rate and thus constitutes a risk factor for fetal hypoxia (e.g. in the context of IUGR with reduced placental reserves) [4].

When the cervix is unfavourable induction of uterine contractions does not accelerate the progress of labour; it worsens fetoplacental perfusion during contractions and patient satisfaction is reduced e.g. through induction of painful contractions. A commentary from the Lancet notes that increasing numbers of clinicians favour the strategy of commencing induction of contractions only once the cervix is ripe [5].

Thus in recent years NO-donors and mechanical induction methods (balloon catheters and cervical dilators such as Lamicel or Dilapan-S) have been the focus of interest (see reviews in [6–8]). NO-donors are currently not recommended in international guidelines due to insufficient literature on their use.

Placement of a transcervical balloon catheter induces cervical ripening without causing significant uterine contractions or systemic side effects in mothers [7,8]. Therefore much less monitoring is required during labour compared to prostaglandin induction.

It has been postulated that mechanical stretching by the catheter balloon causes increased release of endogenous prostaglandins e.g. from myometrium and amnionic cells [9], which in turn cause cervical ripening. A recent prospective study found that cervical ripening was triggered by a local inflammatory reaction; significantly raised levels of interleukin-6 and interleukin-8, metalloproteinase-8, hyaluronic acid synthetase and NO synthetase were found on immunohistochemistry of cervical tissue following balloon insertion [10].

Balloon catheters have been used for labour induction as far back as the 1890s. Embrey and Mollison rediscovered the method in 1967 using it in combination with extraamniotic prostaglandins (see review in [11]). Since then numerous studies have been performed worldwide, mostly using the Foley catheter.

Developed by Atad in 1990, the double balloon catheter was expected to provide improved results. It was hoped that the simultaneous application of pressure to the inner and outer cervical openings would cause even more effective cervical ripening compared to the single balloon catheter. The double balloon catheter is now commercially available and licensed for cervical ripening (labour induction) and may be in place for up to 12 hours; prostaglandins, current or planned, and low-lying placenta/placenta praevia are some of the contraindications to its use. Important

to note is that according to the manufacturer's warning, the safety and effectiveness of the double balloon catheter for cervical ripening has not been shown in the context of previous isthmus-transverse caesarean section and its use is therefore contraindicated after previous caesarean section. This problem is the subject of a subsequent, independent publication of the authors and will therefore not be discussed further here.

Expulsion of the double balloon catheter usually occurs at a cervical dilation of about 4 cm.

In recent years there has been a veritable renaissance of balloon catheter use for labour induction with almost two thirds of the literature on the subject from the past 15 years having been published in the last 5 years. Combinations of medical and mechanical methods have been studied in particular. This review article aims to provide an overview of the current evidence on labour induction using balloon catheters.

Implementation in Clinical Practice
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Comparison of Foley catheter vs. double balloon catheter

We identified 4 randomised trials comparing Foley and double balloon catheters for labour induction [12–15]. The results are somewhat contradictory (● Table 1). In 3 studies the Foley catheter was shown to have significant advantages [12, 14, 15], in two other studies the double balloon catheter was more effective [13, 16]. Taking all available data into account, no significant difference between the two catheters has been clearly demonstrated. All studies note the better cost-effectiveness of the Foley catheter; the double balloon catheter has the major advantage of being licensed for labour induction.

Balloon filling

The filling volume of the double balloon is up to 80 ml. Various trials have studied the effectiveness of different filling volumes when using the Foley catheter. Three randomised studies compared a filling volume of 30 ml with 60 ml [17] and 80 ml [18, 19] (● Table 2). All three studies were included in a recently published systematic review and meta-analysis by Berndl et al. [20]. Although there was no significant difference in caesarean section rate (RR 0.82; 95% CI 0.48–1.41) the likelihood of a favourable cervix (not uniformly defined) was greater with larger filling volumes (RR 1.72; 95% CI 1.46–2.04), and the rate of women not delivered within 24 hours was significantly reduced (RR 0.70; 95% CI 0.54–0.90). Another randomised study examined whether traction to the Foley catheter influences rate of cervical dilatation (filling volume 30 ml, weighted traction using a 1000 ml fluid-filled bag; n = 60). Time to cervical opening was significantly reduced in the weighted traction group (by approx. 3 hours) without an increased rate of pain perception following balloon insertion [21]. In the above mentioned study by Kashanian et al. [19], 500-ml-weighted traction had no additional effect (● Table 2).

Premature rupture of membranes

Balloon catheters are not used or are removed when membranes rupture prematurely; alternatively the catheter remains in situ

Table 1 Randomised controlled trials of Foley catheter vs. double balloon catheter.

Lead author	Year	n	Foley catheter (F)	Double balloon catheter (DB)	Significant findings	
Pennell CE [12]	2009	320 (nulliparae)	Filling vol.: 30 ml in situ time 12 h	80 ml 12 h or PGE$_2$ vaginal gel	Induction to delivery time (h, median) F: 23.2 DB: 24.5 PGE$_2$: 23.8	p = 0.043
					Perceived as painful (pain score ≥ 4) (%) F: 36 DB: 55 PGE$_2$: 63	p < 0.001
Solt I [13]	2009*	200	n/a	n/a	Caesarean section rate in nulliparae (%) F: 40 DB: 20	p = 0.02
					Balloon removal to delivery time (nulliparae) (h) F: 22.6 DB: 14.6	p = 0.05
					Bishop score after balloon removal (nulliparae) F: 3.4 ± 2.0 DB: 4.4 ± 1.9	p = 0.02
Salim R [14]	2011	293	Filling vol.: 60 ml in situ time 12 h	80 ml 12 h	Rate of vacuum extraction or c-section (%) F: 14.4 DB: 25.7	p = 0.02
Mei-Dan E [15]	2012	188	Filling vol.: 30 ml in situ time 12 h + extraamniotic NaCl 50 ml/h	80 ml 12 h	Balloon insertion to expulsion time (h) F: 6.9 ± 4.2 DB: 10.1 ± 4.7	p = 0.001
					Induction to delivery time (h) F: 19.6 ± 11.4 DB: 23.4 ± 15.5	p = 0.03
Mei-Dan E [16]	2014	186	Filling vol.: 30 ml + extraamniotic NaCl 50 ml/h in situ time 12 h	80 ml + extraamniotic NaCl 50 ml/h 12 h	Caesarean section rate (%) F: 20 DB: 8.3	p = 0.05
					Induction to delivery time (h, median) F: 15.8 DB: 14.3	p = 0.04

* published as abstract only

Table 2 Randomised controlled trials comparing various filling volumes.

Lead author	Year	n	Standard filling volume (SF)	Greater filling volume (GF)	Significant results	
Levy R [18]	2004	203	30 ml	80 ml	Cervical dilatation ≥ 3 cm to cervical ripening (%) SF: 52.4 GF: 76.0	p < 0.001
					Vaginal delivery rate in 24 h in nullipara (%) SF: 49.0 GF: 71.4	p < 0.05
					Oxytocin augmentation in nullipara (%) SF: 90.4 GF: 69.3	p < 0.05
Kashani-an M [19]	2009	270	30 ml with traction	80 ml without traction	Bishop score ≥ 9 (%) SF: 38.9 GF: 83.3	p < 0.001
					Vaginal deliveries (%) SF: 83.3 GF: 90.0	p < 0.001
Delaney S [17]	2010	192	30 ml	60 ml	Vaginal delivery rate in 24 h (%) SF: 14.0 GF: 26.0	p < 0.04
					Cervical dilatation at balloon expulsion SF: 3 cm GF: 4 cm	p < 0.01

Table 3 Labour induction: Foley catheter vs. vaginal PGE$_2$ gel: PROBAAT-study (randomised, controlled, multicentre, n = 824) [28].

Criteria (selected)	0.5 mg PGE$_2$ vaginal gel (n = 408)	Foley catheter (n = 412)	p-value
Caesarean section rate (%)	20	23	NS
Caesarean due to failure to progress in the 1st stage of labour (%)	8	12	0.021
Operative delivery due to fetal distress (%)	18	12	0.0218
Induction to delivery time (median, h)	18	29	< 0.0001
Oxytocin augmentation (%)	59	86	< 0.0001
Uterine hyperstimulation (tachysystole/contractions lasting > 3 min) (%)	3	2	NS
Uterine rupture/perforation (n)	2	0	NS
Suspected maternal infection (intrapartum fever and commencement of antibiotics) (%)	3	1	0.035
Neonatal admission (%)	20	12	0.0019

NS = not significant

for a maximum of 12 hours during the 1st stage of labour [8]. The Foley catheter (filling volume 30 ml) was compared to vaginal misoprostol (25 µg 4-hourly or 50 µg 6-hourly) in a retrospective observational study of 122 pregnant women with premature rupture of membranes ≥ 36 SSW [22]. The median induction to delivery time was significantly shorter for the Foley catheter group (736 vs. 1354 min) though use of oxytocin for augmentation of labour was significantly higher; caesarean section rates were comparable (36.3 vs. 39.4%). The incidence of chorioamnionitis (defined as intrapartum fever with need for antibiotics or anatomical/pathological evidence of chorioamnionitis) was significantly lower in Foley catheter patients (11.5%) compared to those receiving vaginal misoprostol (27.3%); notably, it is well known that frequent vaginal manipulations increase the risk of infection.

A recent retrospective cohort study of 129 women with premature rupture of membranes close to term showed the rate of chorioamnionitis (not defined by the authors) non-significantly increased in Foley catheter patients compared to those with intravenous oxytocin/vaginal misoprostol (30.2 vs. 16.3% respectively, p = 0.066); the multivariate regression analysis found nulliparity and measurement of intrauterine pressure (both twice as common in the Foley catheter group) to be independent risk factors for chorioamnionitis, though method of induction was not [23].

A multicentre randomised trial of the use of Foley catheter in the context of premature rupture of membranes near term (FOLCROM trial) is currently underway [24].

Risk of infection

Whether the placement of a "foreign body" into the uterus increases the risk of infection or not is currently a topic of debate, the evidence being astoundingly sparse and contradictory. Recent review articles either do not mention infection risk at all [6, 7] or quote the two meta-analyses noted below. According to available literature there has not been a single reported case of serious infection or sepsis associated with balloon catheters used for labour induction, though it should be noted that studies have been conducted almost exclusively on women with intact membranes [8].

The meta-analysis by Heinemann et al. 2008 [25] that included 30 randomised controlled trials (n = 4468) comparing the Foley catheter to medical methods of induction found a significantly increased rate of maternal infections (7.6 vs. 5.0%, pooled OR: 1.50; 95% CI 1.07–2.09). Infection was defined as fever, endomyometritis or chorioamnionitis. The rate of chorioamnionitis was significantly raised (7.6 vs. 3.7%, pooled OR: 2.05; 95% CI 1.22–

3.44), rates of endomyometritis non-significantly raised (5.1 vs. 3.2%, pooled OR: 1.42; 95% CI 0.74–2.97). There are no randomised studies of prophylactic antibiotic use in this context to date. The 2012 Cochrane review (33 trials using the Foley catheter) concluded that in view of the limited number of trials and differing criteria for infections, there is no evidence that balloon catheters increase infection risk. The authors do warn though, that the results should be interpreted with caution [26].

A detailed analysis of the infectious morbidity within the trials included was not performed in the Cochrane review.

Interestingly, a recent multicentre study from the Netherlands showed that placement of an intrauterine pressure catheter did not increase infection risk up to 3 weeks postpartum when compared to external tocometry (8.8 vs. 10.4% respectively [27]).

Another large Dutch multicentre trial (n = 824) compared the Foley catheter to vaginal PGE$_2$ gel [28]. Suspected intrapartum infection (defined as body temperature ≥ 38 °C and commencement of broad spectrum antibiotics) was diagnosed in 1% of patients with Foley catheter and 3% with vaginal PGE$_2$ (p = 0.035), and the rate of neonatal admission was significantly higher following PGE$_2$ (20 vs. 12%, p = 0.002, ● Table 3).

In conclusion it can be assumed that the placement of a balloon catheter is not associated with increased infection risk, particularly when compared to repeated vaginal application of prostaglandins.

Failed induction with prostaglandin/misoprostol

Notwithstanding differing definitions of the term "failed induction" [26, 29, 30], balloon catheters are a promising option in this setting, though research evidence is insufficient. 75% of women delivered vaginally when a Foley catheter was used following failed induction with 3 mg PGE$_2$ vaginal tablet (no evidence of labour onset after 2–3 applications) [31], and after failure of 50 µg vaginal misoprostol – applied 6-hourly to the unripe cervix (no evidence of labour onset after 24 hours) – 93 of 112 women (83%) delivered vaginally [32].

In our view, women who have failed induction with prostaglandins and who still wish to deliver vaginally should be offered further induction with a balloon catheter. The decision should be made together with the patient and on an individual basis, considering all potential risks and benefits.

Patient satisfaction

Patient satisfaction with balloon catheters vs. medical induction is not addressed in existing reviews/meta-analyses [7, 8, 26, 33, 34] or current guidelines. Only Penell et al. 2009 [12], whose pre-

viously mentioned randomised study was included in the 2012 Cochrane review [22], state finding no significant difference in overall satisfaction among women induced with Foley catheter, double balloon catheter or PGE$_2$ vaginal gel.

A very recent comparative study of double balloon catheter and 10 mg PGE$_2$ vaginal insert in oligohydramnios at term has come to a similar conclusion: Although balloon catheter placement was significantly more unpleasant than the vaginal insert, no significant difference was found in patient satisfaction between the two methods [35].

Patient satisfaction was the focus of a prospective, randomised trial in which oral misoprostol alone was compared to a combination of oral misoprostol plus double balloon catheter for labour induction in 122 women [36]. Findings were as follows: There was no significant difference in patient satisfaction between the two methods; women were not bothered by the insertion of the double balloon catheter or its presence subsequently; significantly more women in the combination group would choose the same method of induction in a subsequent pregnancy or would recommend it to others; the birth experience, assessed using a standardized questionnaire on postpartum mental state which provides a total score for birth experience (Salmon's item list), was positive in both groups but significantly better in the combination group compared to misoprostol alone.

A pre-publication study from Israel [37] found that patient satisfaction (calculated using a 10 point scale) was significantly lower in obese pregnant women (body mass index > 30) compared to non-obese women (BMI ≤ 30, 5.95 ± 3.14 vs. 7.85 ± 2.7; p = 0.009). It has been recognised that this important criterion of labour induction with balloon catheters compared to other methods needs further research and two current randomised studies (oral misoprostol vs. Foley catheter) in the Netherlands [38] and the USA [39] address the issue.

Of relevance to clinical practice is the observation that the insertion of a Foley catheter using a speculum is significantly more often experienced as painful by patients (visual analogue scale) compared to digital insertion. However, once again, overall satisfaction with the method was not affected [40].

Balloon Catheter vs. Prostaglandin E$_2$
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Balloon catheters alone only lead to effective uterine contractions during cervical ripening 15–33% of the time; in 67–85% of cases intravenous oxytocin (mostly commenced concurrently with balloon insertion or after balloon expulsion using various dosing schedules) is necessary for augmentation of labour [41, 42].

Previous studies/meta-analyses comparing balloon catheters and prostaglandins for labour induction have focussed almost exclusively on differing filling volumes using the Foley catheter.

The most recent Cochrane review, which includes 23 randomised studies, provides an overview of published data on balloon catheter vs. prostaglandins (PGE$_2$ and misoprostol) [26]. The results (❍ Table 4) are in general agreement with a meta-analysis by Vaknin et al. from 2010 [43] as well as two subsequently published randomised controlled trials [12, 44], so that in 2011 Henderson et al. are able to conclude that in nulliparae and multiparae with unfavourable cervix, transcervical balloon catheter is preferable to PGE$_2$ with respect to safety, cost, patient satisfaction and length of labour [45].

Table 4 Labour induction: balloon catheter vs. prostaglandins (prostaglandin E$_2$, misoprostol). Results of 2012 Cochrane review [26].

▶ tendency to increased rate of women not delivered within 24 h: 48 vs. 38% (RR 1.26; 95% CI 0.94–1.68)
▶ no significant difference in caesarean section rate: 27 vs. 25% (RR 1.01; 95% CI 0.90–1.13)
▶ no significant difference in cervical ripening (cervix unfavourable after 12–24 h): 37 vs. 39% (RR 0.96; 95% CI 0.70–1.34)
▶ significantly higher rate of need for augmentation of labour with oxytocin: 75 vs. 80% (RR 1.51; 95% CI 1.15–1.97)
▶ significantly lower rate of uterine hyperstimulation with fetal heart rate changes: 0.4 vs. 3% (RR 0.19; 95% CI 0.08–0.43)

Jozwiak M et al. Cochrane Database Syst Rev 2012; 3: CD001233.
Comparable results in: Vaknin Z et al. AJOG 2010 (meta-analysis [43])

Balloon catheter vs. PGE$_2$ vaginal gel

The largest randomised, controlled trial to date on the subject (PROBAAT-trial) compared the Foley catheter (filling volume 30 ml + amniotomy and i.v. oxytocin on catheter expulsion or BS > 6 dependant on uterine activity) to PGE$_2$ vaginal gel (1 mg initially, repeated after 6 h then twice daily, initial dose in nulliparae 2 mg) in 824 women with unfavourable cervix (BS < 6) [28]. Results are shown in ❍ Table 3. The authors of a meta-analysis that takes these results into account as well as the results of two other recent randomised trials using PGE$_2$ vaginal gel in controls [12, 44] conclude the following:

▶ No significant difference in caesarean section rate, however with Foley catheter caesarean more often indicated because of failure to progress; lower rates due to fetal distress.
▶ Longer induction to birth times for Foley catheter compared to PGE$_2$, possibly due to delayed commencement of oxytocin and/or amniotomy only after catheter expulsion (e.g. at night) (also compare with [7]).
▶ With Foley catheter, significantly lower rate of uterine hyperstimulation in the meta-analysis (RR 0.44; 95% CI 0.21–0.9) but not in the PROBAAT-trial (2 vs. 3%, p = 0.36); no significant effect on neonatal outcome (5-minute Apgar score, umbilical cord pH).

The unanimously stated advantages of balloon catheters compared to PGE$_2$ in clinical practice are less need for monitoring during the first stage of labour, simple storage at room temperature and lower cost [6, 7, 24].

The latest cost-effectiveness analysis on the PROBAAT-trial data [46] that included costs of labour ward admission, those for additional medication and regional anaesthesia, for the induction method itself and for the delivery showed no significant differences in cost between Foley catheter and vaginal PGE$_2$ for induction with unfavourable cervix.

Balloon catheter vs. PGE$_2$ vaginal insert

Four randomised trials together including 824 patients have compared the Foley [47] and double balloon catheters [41, 42, 48] with 10 mg PGE$_2$ vaginal insert (insertion time up to 24 h) for labour induction with unfavourable cervix (Bishop score ≤ 6) (❍ Table 5). Cromi et al. 2011 [47] left the Foley catheter in situ for either 12 or 24 hours and on catheter expulsion gave oxytocin intravenously. There were no significant differences between the methods for caesarean section rate or effectiveness of cervical ripening after 12 and 24 hours; the rate of uterine hyperstimulation was however significantly lower with Foley catheter (0 vs. 6.1%). Rate of vaginal deliveries in 24 hours was only 21% for Fo-

Table 5 Randomised, controlled trials: balloon catheter vs. PGE$_2$ vaginal insert.

Lead author	Year	n	Balloon catheter	10 mg PGE$_2$ vaginal insert	Significant findings	
Cromi A [47]	2011	397	Foley (F) filling volume: 50 ml in situ time: A: 24 h B: 12 h	24 h	Vaginal delivery rate in 24 h (%) Foley A: 21.0 Foley B: 59.8 PGE$_2$: 48.5	p = 0.0001
					Oxytocin augmentation (%) Foley A: 81.2 Foley B: 81.8 PGE$_2$: 53.8	p = 0.05
Cromi A [41]	2012	208	Double balloon (DB) filling volume: 80 ml in situ time: 12 h	24 h	Vaginal delivery rate in 24 h (%) DB: 68.6 PGE$_2$: 49.5	p = 0.007
					Oxytocin augmentation (%) DB: 85.7 PGE$_2$: 54.4	p < 0.0001
					Uterine hyperstimulation (%) DB: 0 PGE$_2$: 9.7	p < 0.0007
Du C [42]	2014	155	Double balloon (DB) filling volume: 80 ml in situ time: 12 h	24 h	Oxytocin augmentation (%) DB: 75 PGE$_2$: 53.2	p < 0.001
					Uterine hyperstimulation (%) DB: 0 PGE$_2$: 10.1	p < 0.007
Suffecool K [49]	2014	62	Double balloon (DB) filling volume: 80 ml in situ time: 12 h	12 h	Induction to delivery time (h) DB: 19.1 ± 5.0 PGE$_2$: 24.4 ± 8.7	p = 0.05
					Vaginal delivery rate in 24 h (%) DB: 87.1 PGE$_2$: 47.4	p = 0.002

ley catheter in situ for 24 hours compared to 59.5 % for Foley catheter in situ for 12 hours and 48.5 % for PGE$_2$ vaginal insert (p < 0.001), a clinically relevant finding. The results of the two randomised prospective comparative studies of double balloon catheter vs. 10 mg PGE$_2$ vaginal insert (insertion time up to 24 hours) were in agreement, finding no significant difference in caesarean rate between the methods but a significantly greater need for oxytocin and lower rate of uterine hyperstimulation with the double balloon catheter without affecting neonatal outcome. Rate of vaginal deliveries in 24 hours differed between the two studies: While Cromi et al. 2012 [41] showed a significantly higher rate with the double balloon catheter (68.6 vs. 49.5 %), Du et al. 2014 [42] did not (50 vs. 53.2 %).

A recently published randomised trial in 62 nulliparae with unfavourable cervix (BS < 6) compared the double balloon catheter (filling volume 80 ml, in situ for up to 12 hours, oxytocin intravenously 6 hours after catheter insertion) to a 10 mg PGE$_2$ vaginal insert (insertion time up to 12 hours) [48]. Average induction to delivery time was significantly shorter for the double balloon catheter than for PGE$_2$ vaginal insert (17.9 vs. 26.7 hours) and rate of vaginal deliveries in 24 hours was significantly higher (87.1 vs. 47.4 %) with similar caesarean rates (51.6 vs. 54.8 %) and no significant differences in neonatal outcome. Uterine hyperstimulation occurred at a rate of 25.8 % with PGE$_2$ vaginal insert compared to 0 % for the double balloon catheter.

A shortened induction to birth interval is meaningful since it correlates closely with patient satisfaction with the method of induction [49].

Balloon Catheter vs. Misoprostol
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Balloon catheter vs. vaginal misoprostol
Numerous studies have investigated the use of Foley catheters (filling volume 30–50 ml) vs. vaginal misoprostol (25 µg 3–6-hourly). A recently published meta-analysis of 10 randomised studies conducted between 2001 and 2012 (n = 1520) summarises the results [50]. More recently data from the 2014 PROBAAT-M study have been published [50] (○ **Table 6**). 129 women (BS 0–5) were treated either with Foley catheters (filling volume 30 ml) or with vaginal misoprostol (25 µg 4-hourly, maximum 3 doses/24 h); when the Bishop score was ≥ 6 amniotomy was performed and intravenous oxytocin commenced with dosing according to the strength of contractions. The main findings of the PROBAAT-M study that differ with those of the meta-analysis are a longer induction to delivery time and a non-significantly raised incidence of uterine hyperstimulation for the Foley catheter. The authors offer no explanation for these findings. The findings of the meta-analysis are in general agreement with that of Fox et al. published in 2011 [33] (9 trials, n = 1603), although 4 of these trials used 50 µg vaginal misoprostol 4- to 6-hourly. Interestingly the average induction to delivery time between study groups did not differ significantly (Fox et al.) There was also no significant difference in the incidence of chorioamnionitis (RR 1.13; 95 % CI 0.61–2.09).

Balloon catheter vs. oral misoprostol
To date there are few trials comparing the Foley catheter to oral misoprostol for labour induction and patient numbers are small

Table 6 Labour induction: Foley catheter vs. vaginal misoprostol.

Meta-analysis 2014 (10 studies, n = 1520)			
Significant findings	Oxytocin for induction/augmentation of labour	RR (95% CI) 1.74 (1.30–2.32)	
	Uterine hyperstimulation	RR (95% CI) 0.39 (0.26–0.60)	
	Uterine hyperstimulation syndrome*	RR (95% CI) 0.39 (0.24–0.61)	
No significant difference	Caesarean rate, postpartum haemorrhage, chorioamnionitis/endomyometritis, 5-minute Apgar < 7		
PROBAAT-M Study (n = 56)	**25 μg misoprostol (n = 64)**	**Foley catheter (n = 65)**	**p-value**
Caesarean section rate (%)	17	25	0.29
Caesarean due to failure to progress in the 1st stage of labour (%)	3	14	0.03
Induction to delivery time (median, h)	25	36	< 0.001
Oxytocin augmentation (%)	50	82	< 0.001
Uterine hyperstimulation (%)	2	4	0.59
Arterial umbilical cord pH < 7.10 (%)	9	10	1.00

Jozwiak M et al. Am J Perinatol 2014; 31: 145 [50]

* uterine hyperstimulation (polysystole and/or prolonged uterine contraction) with pathological fetal heart rate

[51, 52]. Advantages of oral misoprostol over the application vaginally – at similar dosage – are lower rates of uterine hyperstimulation, better neonatal outcome (5-minute Apgar < 7 [53]), better patient acceptance and lower infection risk through avoidance of vaginal manipulation.

There are currently two studies underway comparing the Foley catheter (filling volume 30 ml) with oral misoprostol (50 μg 4-hourly or 25 μg 2-hourly). Primary endpoints of the first (PROBAAT-II Study [38]), which plans to include 1860 patients, are neonatal outcome (umbilical cord pH ≤ 7.05 or 5-minute Apgar < 7) and postpartum haemorrhage (blood loss ≥ 1000 ml). The single primary endpoint of the second trial, with an intended study population of 620 women with preeclampsia, is vaginal delivery rate in 24 hours [39].

Combined or Sequential Use of Balloon Catheters and other Uterine Stimulants
▼

Since balloon catheters cause cervical ripening but in the majority of cases not contractions, they have been combined with numerous other methods of uterine stimulation. The vaginal delivery rate in 24 hours was not increased by intravenous oxytocin commenced simultaneously with Foley catheter insertion during the 1st stage of labour compared to Foley catheter alone (46 vs. 45% [54]). Also, there was no significant difference in median induction to delivery time between study groups receiving fixed vs. increasing doses of intravenous oxytocin following balloon insertion (23.7 vs. 19.2 hours) [55].

Balloon Catheter Combined with Extra-amnionic Salt Infusion (EASI)
▼

A comparative study of the Foley catheter plus extra-amniotic salt infusion vs. double balloon catheter alone showed significant advantages for the combined approach: The time between balloon insertion and expulsion was reduced as was induction to delivery time in the Foley catheter + salt infusion group [15]. A follow-on study by the same investigators [16] compared the Foley and double balloon catheters, both in combination with EASI. The results are summarised in ○ **Table 1**. On comparison of the double balloon catheter with and without EASI, again significant advantages were found for the combined approach [56]: shorter

balloon insertion to delivery time (14.2 vs. 20.45 h, p < 0.001) and a higher rate of balloon expulsion (68.5 vs. 51%, p = 0.04).

Balloon catheter and misoprostol simultaneously
More recent randomised trials have focused on the combination of balloon catheter and misoprostol vs. misoprostol alone for labour induction. A 2012 Cochrane review [26] including 8 studies published before January 2012 (n = 1295) summarises this data. Findings were a significantly increased vaginal delivery rate in 24 hours (RR 0.45; 95% CI 0.25–0.71) for the combination method without an effect on the caesarean section rate, as well as a reduced incidence of uterine hypersimulation (RR 0.59; 95% CI 0.35–0.78) for the combined method. Evidence on the incidence of the uterine hyperstimulation syndrome is however conflicting. Results of randomised studies since 2012 are shown in ○ **Table 7**. In their prospective, randomised trial Kehl et al. compared the double balloon catheter (in situ time up to 24 hours) plus oral misoprostol 50 μg (repeated after 4 and 8 hours, increased to 100 μg as required) to oral misoprostol alone in a study population of 122 women [57]. The primary outcome of the study was failure of induction, which was defined as no vaginal delivery within 48 hours. There were significantly fewer induction failures in the control group (9.3 vs. 21.7%, p = 0.07) as well as a significantly shorter median induction to delivery time (15.3 vs. 20.8 hours).

In 3 further randomised trials conducted in the past 2 years, the combination of Foley catheter plus vaginal misoprostol (25 μg 4-hourly) vs. vaginal misoprostol alone lead to significantly shorter induction to delivery times, a significant reduction in uterine hyperstimulation and meconium stained liquor and less need for oxytocin [58–60] compared to misoprostol alone. Vaginal misoprostol given 6 hours after Foley catheter insertion was more effective than vaginal misoprostol alone [61] (○ **Table 7**).

Overall, the combination of balloon catheter and vaginal misoprostol results in a reduction of uterine hyperstimulation (with or without fetal heart rate changes), and no significant differences in chorioamnionitis rates or neonatal outcome when compared to misoprostol alone. However because of low case numbers and the heterogeneity of available trials, the evidence is still insufficient for a general recommendation of the combination approach for clinical practice.

Balloon catheter and misoprostol sequentially
Until recently no trial had studied the use of double balloon catheters with sequential oral misoprostol. A multicentre, random-

Table 7 Balloon catheter plus misoprostol vs. misoprostol alone for labour induction with unfavourable cervix. Results of recent randomised, controlled trials.

Author, year	Number of patients (n)	Intervention	Control	Significant findings
Kehl et al. 2011 [57]	122	Double balloon catheter (up to 24 h) + 50 µg misoprostol p. o. (dose increase to 100 µg possible)	50 µg misoprostol p. o. (dose increase to 100 µg possible)	Induction to delivery time (median): 15.3 vs. 20.8 hours Induction failure: 9.3 vs. 21.2%
Ande et al. 2012 [61]	100	Foley catheter + 50 µg vaginal misoprostol following catheter insertion	50 µg vaginal misoprostol (6-hourly)	Vaginal delivery rate in 12 hours: 92.5 vs. 60% Caesarean section: 20 vs. 40%
Carbone et al. 2013 [58]	123	Foley catheter + 25 µg vaginal misoprostol (4-hourly)	25 µg vaginal misoprostol (4-hourly)	Induction to delivery time (median): 15.3 vs. 18.3 hours Cervical dilatation rate (median): 13.7 vs. 17.1 hours
Ugwu et al. 2013 [59]	150	Foley catheter + 25 µg vaginal misoprostol (4-hourly)	25 µg vaginal misoprostol or Foley catheter alone	1st stage of labour approx. 3 hours shorter Oxytocin: 40 vs. 17.5 vs. 25.6%
Lanka et al. 2014 [60]	126	Foley catheter + 25 µg vaginal misoprostol (4-hourly)	25 µg vaginal misoprostol (4-hourly)	Uterine hyperstimulation: 7.9 vs. 39.7% Meconium stained liquor: 6.3 vs. 27%
Kehl et al. 2015 [62]	326	Double balloon catheter, after 24 h 50 µg misoprostol p. o. (100 µg possible)	50 µg misoprostol p. o. (100 µg possible)	Induction to delivery time (median): 32.4 vs. 22.5 hours Total misoprostol dose 100 vs. 200 µg

ised, controlled trial of 326 pregnant women with unfavourable cervix and various induction indications has now been published [62]. Induction was either with double balloon catheter (in situ time up to 12 hours) followed by oral misoprostol 50 µg 24 hours after catheter insertion (repeat doses after 4 and 8 hours with the possibility of increasing dose to 100 µg after 24 hours), or oral misoprostol alone with the same dosing schedule. Primary endpoints were induction to delivery time and vaginal delivery rate in 48 hours. There was a non-significant difference in caesarean section rate (21.6 vs. 29.8%). Independent of parity, the median induction to delivery time for the combination group was significantly longer than for oral misoprostol alone (32.4 hours vs. 22.5 hours; p = 0.004). However this difference was not statistically significant when comparing primiparae and multiparae. There were no significant differences in vaginal delivery rate in 48 hours (79.5 vs. 84.9%) or need for oxytocin. The number of misoprostol applications was however significantly fewer, and the total misoprostol dose significantly lower in the combination group. The double balloon catheter alone lead to effective contractions in 23.3% of cases. Whether better results would be achieved by giving oral misoprostol immediately after catheter removal or not, remains to be studied.

Comment on Current Guidelines
▼

According to WHO recommendations from 2011 [63] balloon catheters are recommended for labour induction and are approximately as efficient as vaginal prostaglandins (PGE$_2$, misoprostol) (moderate quality of evidence, strong recommendation). A combination of balloon catheter and oxytocin is recommended as an alternative when prostaglandins (including misoprostol) are not available or are contraindicated (low quality evidence, weak recommendation). The balloon catheter is also mentioned as an option for labour induction after previous caesarean section (no recommendation grade stated).
According to the 2008 RCOG guidelines (update 2014 [64]) balloon catheters should not be used routinely for labour induction with unfavourable cervix, and their use after previous caesarean section should be studied in clinical trials.

The 2009 ACOG guidelines [65] recommend the Foley catheter as a sensible and effective alternative to prostaglandins for cervical ripening/labour induction (grade A recommendation). Its use is mentioned an option for outpatient induction.
The 2013 Canadian guidelines (SOGC) [66] advocate the balloon catheter as an acceptable method of labour induction following previous caesarean section (I-B) and for outpatient induction (II-B), with the double balloon catheter as second-line option. The guidelines draw attention to the greater need for oxytocin when using balloon catheters as well as lower rates of uterine tachysystole without increased risk of maternal (chorioamnionitis, endometritis) or neonatal infections.
In Germany there are no recommendations or guidelines on this subject.

Conclusion
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Induction of labour using balloon catheters has experienced a renaissance in recent years and the method is now part of many international guidelines. The statistics presented in this paper confirm that, just as with the more established prostaglandins, labour can be successfully induced using balloon catheters. The pros and cons of the balloon catheter compared to prostaglandins are shown in ● **Table 8**.
The two catheters available for use are the Foley catheter, which is cheaper, and the double balloon catheter, which has the advantage of being licensed for use in labour induction. Combining medical induction with the use of balloon catheters is a particularly interesting option that results of a number of trials currently underway are expected to provide more detailed information on in future.

Conflict of Interest
▼

Sven Kehl: Presentation fee and travel costs (COOK Medical).

Table 8 Advantages and disadvantages of balloon catheters compared to prostaglandin E_2/misoprostol.

Pros	Cons
▶ single application	▶ greater need for oxytocin augmentation
▶ no uterine hyperstimulation → less risk to the fetus	▶ potentially increased infection risk compared to oral prostaglandin
▶ less monitoring required	▶ lower vaginal delivery rate in 24 h* in multiparae
▶ cheaper than prostaglandin E_2	
▶ no need for special storage (e.g. cold chain)	

* Jozwiak M et al. Cochrane Database Syst Rev 2012; 8: CD001233 [26]

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