Induction of labour : Foley catheter revisited

Jozwiak, M.

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FOLEY CATHETER VERSUS 25 µg VAGINAL MISOPROSTOL: RANDOMISED CONTROLLED TRIAL (PROBAAT-M STUDY) AND SYSTEMATIC REVIEW AND META-ANALYSIS OF LITERATURE

Marta Jozwiak, Mieke ten Eikelder,
Katrien Oude Rengerink, Christianne de Groot,
Hanneke Feitsma, Marc Spaanderman,
Mariëlle van Pampus, Jan Willem de Leeuw,
Ben Willem Mol, Kitty Bloemenkamp

American Journal of Perinatology 2013; Apr 5

ABSTRACT

Objectives: To assess effectiveness and safety of Foley catheter versus vaginal misoprostol for term induction of labour.

Study Design: This trial randomly allocated women with singleton term pregnancy to 30-mL Foley catheter or 25-µg vaginal misoprostol tablets. Primary outcome was caesarean delivery rate. Secondary outcomes were maternal and neonatal morbidity and time to birth. Additionally, a systematic review was conducted.

Results: Fifty-six women were allocated to Foley catheter, 64 to vaginal misoprostol tablets. Caesarean delivery rates did not differ significantly (25% Foley versus 17% misoprostol; relative risk [RR] 1.46, 95% confidence interval [CI] 0.72 to 2.94), with more caesarean deliveries due to failure to progress in the Foley group (14% versus 3%; RR 4.57, 95% CI 1.01 to 20.64). Maternal and neonatal outcomes were comparable. Time from induction to birth was longer in the Foley catheter group (36 hours versus 25 hours; $p < 0.001$). Meta-analysis showed no difference in caesarean delivery rate and reduced vaginal instrumental deliveries and hyperstimulation in the Foley catheter group. Other outcomes were not different.

Conclusion: Our trial and meta-analysis showed no difference in caesarean delivery rates and less hyperstimulation with fetal heart rate changes and vaginal instrumental deliveries when using Foley catheter, thereby supporting potential advantages of the Foley catheter over misoprostol as ripening agent.

INTRODUCTION

In developed countries around 20 to 30% of all births are induced.[1-3] Although labour induction is a common obstetric procedure, it is associated with a higher risk of complications compared with spontaneous labour. Despite numerous reports comparing the safety and efficacy of different induction techniques, there is still no consensus on which method is preferable.[4-7]

Mechanical methods, with Foley catheter being the most commonly used currently, are among the oldest methods of labour induction. Foley catheters work through mechanical dilation, resulting in the release of natural prostaglandins from the cervix.[8] In recent decades mechanical methods have largely been replaced by pharmacologic methods, such as prostaglandin E2 and prostaglandin E1 analogues. Their mechanism of action is twofold. Prostaglandins ripen the cervix directly by enzymatic collagen degradation and increase of water content in the extracellular matrix. Indirectly, they stimulate the myometrium and thereby induce contractions.[9,10]

Although Foley catheters have partly been replaced by prostaglandins, the catheters have several potential advantages over pharmacologic methods. They are relatively inexpensive, easy to store, and easy to remove when necessary. We recently showed that, compared with intravaginal prostaglandin E2 gel, use of a Foley catheter for the induction of labour results in similar caesarean delivery rates with fewer maternal and neonatal side effects.[11] Meta-analysis revealed a lower rate of hyperstimulation and a reduction of postpartum haemorrhage.[11]

Misoprostol, a prostaglandin E1 analogue, is one of the prostaglandins most frequently used for labour induction worldwide, mainly due to its low cost and easy storage.[12] Although not approved by the Food and Drug Administration for induction of labour, misoprostol is recommended by the American College of Obstetricians and Gynecologists, The British Royal College of Obstetricians and Gynaecologists, as well as the International Federation of Gynecology and Obstetrics (FIGO) and the World Health Organization.[4,5,13] In the Netherlands, however, this pharmacologic agent is rarely used for cervical ripening.[6]

Current literature comparing Foley catheter to misoprostol shows similar success rates of labour induction, with fewer cases of uterine hyperstimulation with and without fetal heart rate changes[9,14,15] and a comparable caesarean section rate when a Foley catheter is used.[14] However, randomized controlled trials are underpowered to investigate the estimators of interest, and meta-analyses are performed with studies using different dosing regimens of misoprostol, and are therefore not generally applicable.

Different prostaglandin analogues and dosing regimens seem to have different side effects. Therefore, in this PROBAAT-M trial, parallel to our main study the PROBAAT trial, we compared the effectiveness and safety of Foley catheter to 25 µg vaginal misoprostol. Additionally we performed a meta-analysis of this comparison to gather as much information as possible on the effectiveness and safety of Foley catheters versus 25 µg misoprostol for term cervical ripening and labour induction.

METHODS

Trial Design

This was an open-label randomized controlled trial comparing Foley catheter with 25 µg vaginal misoprostol for induction of labour at term in women with an unfavourable cervix. This pilot study was conducted parallel to the main PROBAAT study. As vaginal prostaglandin E2 gel was the most frequently used method for induction of labour in women with an unfavourable cervix, the goal of the main study was to investigate the effectiveness and safety of Foley catheter versus prostaglandin E2 gel.[11] We performed the current study parallel to the main PROBAAT study, and according to a parallel protocol (PROBAAT-M) together with a study comparing 10-mg slow-release vaginal prostaglandin E2 inserts (PROBAAT-P). The results of the latter study will be published separately. At the time of the study, vaginal misoprostol was only used in four participating hospitals in the Netherlands. The protocol was approved by the Ethics Committee of the Academic Medical Centre Amsterdam (MEC 08/310) and the institutional review boards of participating hospitals. The trial was registered with the Netherlands Trial Register (NTR 1646).

Participants

Women over 18 years of age with a term pregnancy and an unfavourable cervix (Bishop score < 6) requiring induction of labour were eligible for the study. Exclusion criteria were prior caesarean delivery, nonvertex presentation of the fetus, ruptured membranes, a hypersensitivity for one of the products used for induction, or a lethal congenital anomaly of the fetus.

Outcomes

The main outcome was caesarean delivery. Secondary outcomes included maternal and neonatal morbidity and time from the start of induction to birth. These are described in detail in the main trial.[11]

Sample Size

As described previously, this pilot study was conducted parallel to the PROBAAT study, within the same time frame. We randomized for the comparison Foley catheter versus all pharmacologic methods until power in the prostaglandin E2 gel study was reached. We did not calculate a separate sample size for the current study. The study was ended in May 2010 at the time the main study's power was reached. No analysis of data was done prior to the end of the study.

Randomisation and Blinding

Women were informed about the study by their obstetrician, when the need for induction of labour occurred. After informed consent, women were enrolled by the attending physician, midwife, or research nurse at the labour ward on the day of induction. Randomization occurred through a Web-based randomization

program. The randomization sequence was computer generated and was composed out of variable blocks of two and four, which could not be viewed by the recruiter, nor by the trial coordinator when the trial was ongoing. Women were randomized between Foley catheter and vaginal misoprostol in a 1:1 ratio.

Due to the nature of the intervention, neither the caregiver nor the patient were blinded.

Intervention

The interventions are described in detail in the main study.[11] In short, a Foley catheter filled with 30 mL sterile saline or water was introduced transcervically in women in the Foley catheter group. The protocol advised to examine women at the same 4-hour intervals as women in the misoprostol group.

In the misoprostol group women were treated with 25-µg tablets, inserted into the posterior vaginal fornix every 4 hours, with a maximum of 3 doses in 24 hours. Doses were withheld when there were 3 or more contractions in 10 minutes or in case of a nonreassuring fetal heart rate tracing.

If upon examination the Bishop score was ≥6, amniotomy was performed, and oxytocin was started according to local protocol if contractions or progress were deemed inadequate.

Statistical Methods

Data were analyzed according to the intention-to-treat principle. Normally distributed data are presented as means with standard deviation; skewed distributions are presented as medians with interquartile ranges. For categorical data, the treatment effect is presented as relative risks (RRs) with 95% confidence intervals (CIs). The chi-square test was used to calculate *p* values; when the expected cell count was < 5, Fisher exact test was used. For continuous data with a non-normal distribution, the Mann-Whitney *U* test was used. For time to delivery data, Kaplan-Meier survival curves were constructed and log-rank tests and according *p* values calculated. Further details are described in detail in the main article.[11]

Meta-Analysis

We searched the Cochrane Collabouration's trial registry from January 1966 to January 2013, and Medline and EMBASE from January 2012 till January 2013, the latter because the Cochrane Collabouration's trial registry is updated only four times a year. Our search was expanded till 2013 to include articles that are already online but not yet published in print.

We used the following terms: (Balloon Dilation OR mechanical methods OR mechanical method OR mechanical dilation OR mechanical dilatation OR mechanical dilations OR mechanical dilatations OR balloon OR foley* OR Catheterization OR Catheterisation OR catheter OR catheters OR catheter*) AND (prostaglandin E1 OR PGE1 OR PGE-1 OR misoprostol OR Abortifacient Agents, Nonsteroidal

OR ((Nonsteroidal OR "Non-Steroidal") AND Abortifacient) OR Alprostadil OR Prostaglandin E1α OR PGE1α OR Prostaglandin E1 OR Lipo-PGE1 OR Lipo PGE1 OR Edex OR Viridal OR Prostavasin OR Prostin VR OR Minprog OR Prostine VR OR Vasaprostan OR Caverject OR Sugiran).

All randomized clinical trials comparing Foley catheter to 25 µg vaginal misoprostol for cervical ripening in singleton pregnancies with a viable fetus in vertex presentation, intact membranes, and an unfavourable cervix were eligible. Two reviewers (M.J., M.E.) independently assessed all studies identified by the search for inclusion. Any disagreement was resolved through discussion or, in case of persisting disagreement, a third author (K.B.) was consulted.

The treatment outcome measures sought were all outcome measures reported in the PROBAAT-M trial, with caesarean delivery being the primary outcome measure. Studies were excluded if they did not report any of the predefined outcome measures. We attempted to contact the authors of studies that were only reported as abstract or did not report the predefined outcome measures. Two review authors (M.J., M.E.) independently assessed the methodological quality of the studies, using the Cochrane Collabouration's tool for methodological assessment of studies.[16] None of the trials were excluded on the basis of methodological assessment, but sensitivity analysis was performed excluding poor quality studies. Publication bias was investigated through visual inspection of funnel plots, which were constructed for all outcomes with 10 or more studies.

All statistical analyses were performed in Review Manager software.[17] We present the results as summary RR with 95% CIs, as we sought only dichotomous data. We assessed heterogeneity in each meta-analysis using the T^2, I^2, and chi-square statistics. Heterogeneity was regarded as substantial if $I^2 > 30\%$ and either $T^2 > 0$ or $p < 0.10$ in the chi-square test for heterogeneity. We used a fixed-effects model for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect. When statistical heterogeneity was substantial, we used a random-effects model for pooling.

We performed a subgroup analysis of studies in which Foley catheters were compared with 25 µg vaginal misoprostol every 4 hours, as this is the dose that was used in the current study and has been recommended before by FIGO.[13] Statistical significance was defined as $p < 0.05$.

RESULTS

Trial Results

Between February 2009 and May 2010, we included 120 women in four centers, 56 of whom were allocated to the Foley catheter group and 64 to the misoprostol group (Figure 1). Baseline characteristics were much the same (Table 1). Hypertensive disorders and post term pregnancy were listed most often as the reason for induction (Table 1).

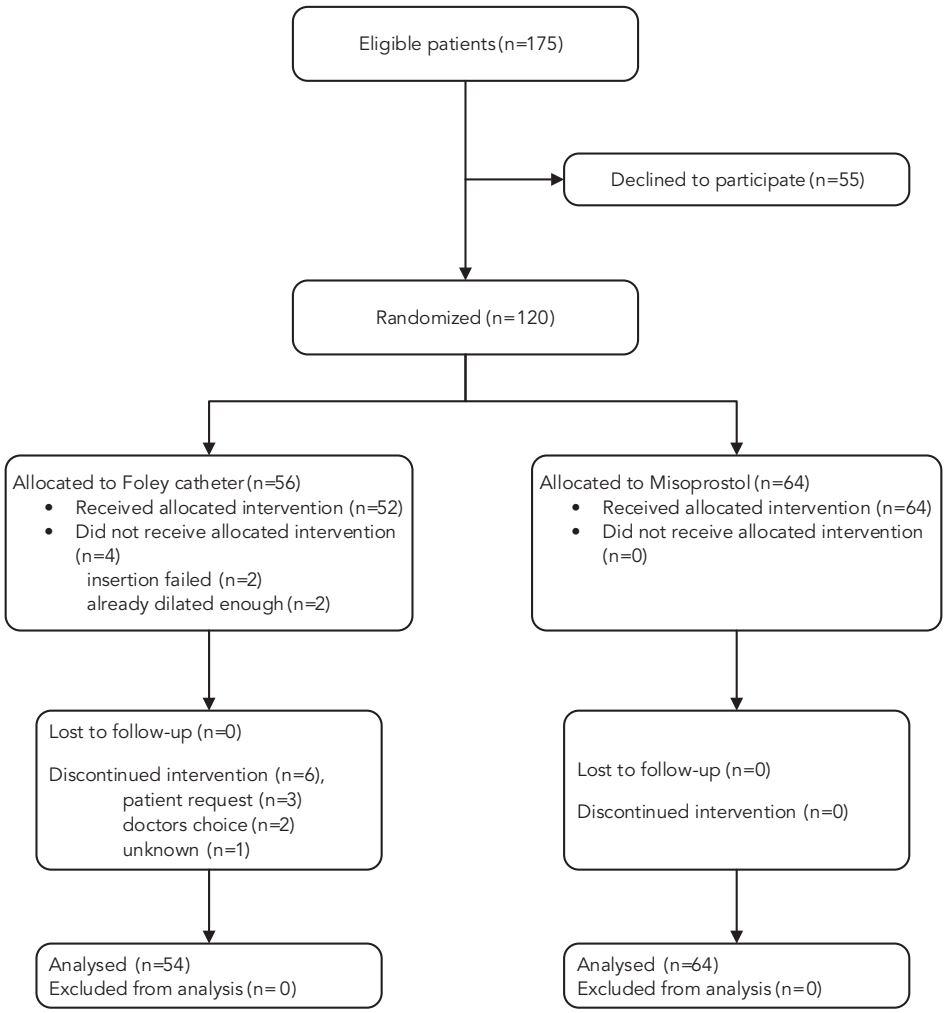


Figure 1. Patient flow diagram

The primary outcome, caesarean delivery, was available for all women. Caesarean delivery rates did not differ significantly between the groups (25% (14/56) Foley catheter group vs. 17% (11/64) misoprostol group; RR 1.46, 95% CI 0.72-2.94). Significantly more caesarean deliveries were performed for failure to progress in the first stage of labour in the Foley catheter group. There was a non significant decrease in vaginal instrumental deliveries in the Foley catheter (Table 2). The median time from the start of induction to birth was longer in the Foley catheter group.

Maternal and neonatal outcomes are presented in Table 3. No significant differences between the treatment groups were noted for these outcomes. No serious adverse events were recorded.

Table 1. Baseline Characteristics

	Foley catheter (N=56)	misoprostol (N=64)
Maternal age (years)*	31.0 (5.0)	32.3 (5.2)
Ethnic origin		
Caucasian	44 (79%)	50 (78%)
Non-Caucasian	12 (21%)	12 (19%)
Unknown / missing	0	2 (3%)
BMI†	25.9 (21.8-29.6)§	24.6 (22.4-27.8)ǁ
Parity		
0	37 (66%)	41 (64%)
1	9 (16%)	12 (19%)
≥2	10 (18%)	11 (17%)
Bishop score		
0	12 (21%)	11 (17%)
1	9 (16%)	14 (22%)
2	21 (38%)	19 (30%)
3	9 (16%)	11 (17%)
4	4 (7%)	5 (8%)
5	1 (2%)	4 (6%)
Gestational age (weeks)†	39.1 (38.1-41.1)	39.8 (38.4-41.2)
Indications for induction of labour‡		
Hypertensive disorders	11 (20%)	29 (45%)
Post term pregnancy	15 (27%)	23 (36%)
IUGR	6 (11%)	5 (8%)
Psychosocial = elective	9 (16%)	9 (14%)
Insulin dependent diabetes	5 (9%)	6 (9%)
Oligohydramnios	1 (2%)	2 (3%)
Other	13 (23%)	6 (9%)

*mean+ SD, †median+ IQR, ‡more than one option possible, §13% (n=7) missing values, ǁ11% (n=7) missing values

Meta-Analysis Results

We identified 102 citations in the Cochrane collaboration's trial registry, 17 in Medline and 46 in EMBASE. After removal of duplications, 144 citations remained. Of these, 103 were excluded based on the title, because they either did not investigate labour induction or used other induction agents. Of the 41 abstracts reviewed, 27 more studies were excluded, because they applied a different dose or route of administration of misoprostol. The full text articles of the remaining 15 were screened, and another three were excluded because they did not fulfill our inclusion criteria: one was a crossover trial, one included women with a caesarean scar (although this was an exclusion criterion of the trial itself), and one was a duplicate (Figure 2). We excluded three more trials, as after contacting the authors of the three trials, data were still not available.[18-20] Counting the current trial, 10 trials were included in this meta-analysis.[21,22,23,25,26,27,28,29,30] The overall methodological quality was reasonable for seven trials and poor for three (Table 4).

Table 2. Delivery Outcomes

	Foley catheter (N=56)	misoprostol (N=64)	RR (95% CI)	p-value
Mode of delivery				
Spontaneous	34 (61%)	35 (55%)	1.11 (0.82-1.51)	0.51
Vaginal instrumental	8 (14%)	18 (28%)	0.51 (0.24-1.08)	0.07
Caesarean section	14 (25%)	11 (17%)	1.46 (0.72-2.94)	0.29
Indication for caesarean section				
Failure to progress in 1st stage	8 (14%)	2 (3%)	4.57 (1.01-20.64)	0.03
Failure to progress in 2nd stage	0 (0%)	1 (2%)	NA	1.00
Fetal distress	6 (11%)	8 (13%)	0.86 (0.32-2.32)	0.76
Maternal reason	0 (0%)	0 (0%)	NA	NA
Elective	0 (0%)	0 (0%)	NA	NA
Indication for vaginal instrumental delivery				
Failure to progress in 2nd stage	2 (4%)	7 (11%)	0.33 (0.07-1.51)	0.17
Fetal distress	6 (11%)	11 (17%)	0.62 (0.25-1.58)	0.31
Maternal complication	0	0	NA	NA
Oxytocin augmentation	46 (82%)	32 (50%)	1.64 (1.25-2.16)	<0.001
Time from start induction to birth (hours)*	36 (29-61)†	25.4 (14-35)	NA	<0.001

*median+ IQR, †2% missing values (n=1)

Six studies investigated 25 µg vaginal misoprostol administered every 4 hours. In one study misoprostol was administered every 3 hours, and in three studies every 6 hours (Table 4).

The overall caesarean delivery rate did not differ statistically between the groups, nor did the risk of vaginal instrumental delivery. Oxytocin was used more often in the Foley catheter group. Hyperstimulation, both without and with nonreassuring fetal heart rate tracing, was seen less often in the Foley catheter group. We did not find any significant differences in the other outcomes (Table 5).

The subgroup analysis of studies comparing Foley catheter with 25 mcg misoprostol every four hours including data of the current trial showed comparable caesarean delivery rates, a reduction in vaginal instrumental deliveries, a reduction in hyperstimulation with fetal heart rate changes, significantly more oxytocin use in the Foley catheter group (figure 3a and 3b), and no differences in the remaining maternal and neonatal outcomes (data not shown).[22,23,25,29,30]

As only the outcome 'caesarean delivery' for the comparison Foley catheter versus 25 mcg vaginal misoprostol- all dosing schedules, was the result of meta-analysis of 10 or more studies, this is the only outcome a funnel plot was constructed for (Figure 4). Visual inspection of the plot does not show asymmetry. Other outcomes were all based on less than ten studies, and therefore the power of the funnel plot asymmetry test would be too small. Publication bias in this case can unfortunately not be excluded, also on the basis of funnel plots. Sensitivity analysis, excluding poor quality studies, did not

Table 3. Maternal and Neonatal outcome

	Foley catheter (N=56)	misoprostol (N=64)	RR (95% CI)	p-value
Analgesics				
Pethidine	5 (12%)	11 (21%)	0.57 (0.22-1.52)	0.25
Epidural	19 (45%)	17 (32%)	1.41 (0.84-2.36)	0.19
Other	3 (7%)	1 (2%)	3.79 (0.41-35.09)	0.32§
Maternal intrapartum infection				
Temp. ≥38 °C during labour	6 (11%)	1 (2%)	6.86 (0.85-55.24)	NA
Suspected intrapartum infection*	4 (7%)	0 (0%)	NA	NA
Post partum haemorrhage (>1000 cc)	3 (5%)	3 (5%)	1.14 (0.24-5.44)	1.00§
Post partum blood transfusion (Y/N)	0 (0%)	1 (2%)	NA	1.00§
Other maternal complication				
Hyperstimulation	2 (4%)	1 (2%)	2.29 (0.21-24.54)	0.59
Uterine rupture	0 (0%)	0 (0%)	NA	NA
Apgar Score 5 min <7	0	2 (3%)	NA	0.50
Arterial pH <7.10	5 (10%)†	5 (9%)‡	1.20 (0.37-3.92)	1.00
Neonatal admission				
Regular nursery	10 (18%)	15 (23%)	0.76 (0.37-1.56)	0.45
Intensive care	2 (4%)	1 (2%)	2.29 (0.21-24.54)	0.60
Reason for admission				
Suspected infection	5 (9%)	3 (5%)	1.91 (0.48-7.61)	0.47
Asphyxia	0 (0%)	1 (2%)	NA	1.00§
Dysmaturity[l]	3 (5%)	5 (8%)	0.69 (0.17-2.74)	0.72
Hypoglycaemia	0 (0%)	4 (6%)	NA	0.12
IRDS¶	0 (0%)	0 (0%)	NA	NA
Meconium aspiration	1 (2%)	0 (0%)	NA	NA
Other/Unknown	2 (4%)	5 (8%)	0.46 (0.09-2.27)	0.45
Length of admission (days) median(IQR)	2 (0-3)	1 (0-3)	NA	0.46

*body temperature during labour ≥38 °C AND start of broad spectrum antibiotics due to suspected infection, †13%, (n=7) missing values, ‡8% (n=5) missing values, §Fisher's exact test, [l]generally defined as birth weight below 5th centile, ¶infant respiratory distress syndrome

change the conclusions, however the relative risk for caesarean delivery rate changed direction (RR 0.98, 95%CI 0.66-1.46).

DISCUSSION

In this trial comparing Foley catheter to 25 µg vaginal misoprostol, we found that caesarean delivery rates and vaginal instrumental deliveries were not different, but more caesarean deliveries were performed for failure to progress in the first stage after induction with a Foley catheter. When using a Foley catheter, the time from start of induction to birth was significantly longer, and oxytocin augmentation was required more often. Maternal and neonatal secondary outcomes, including postpartum haemorrhage and pH < 7.10, did not differ significantly between

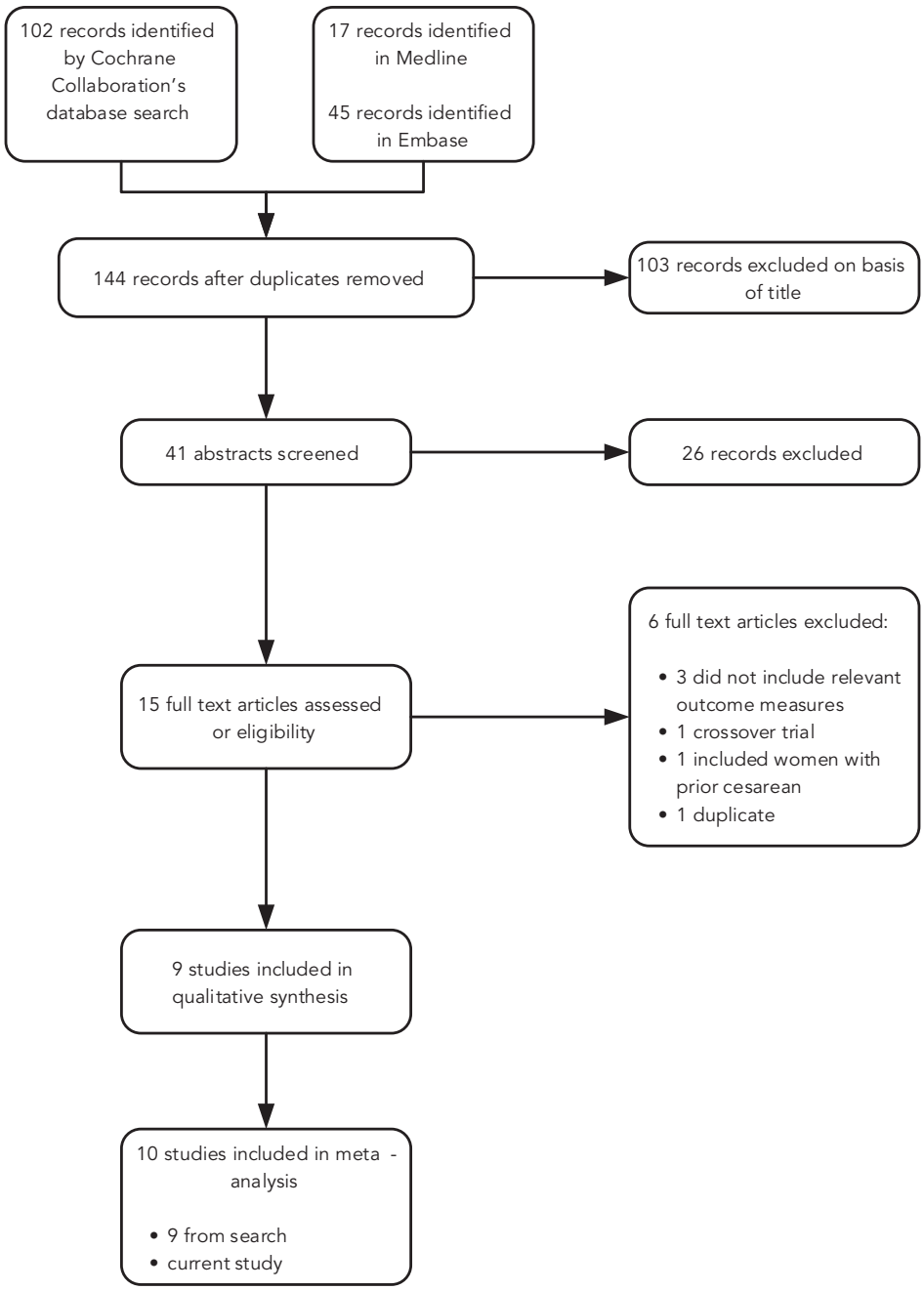


Figure 2. Flow diagram systematic review

Table 4. Characteristics of Studies Included in Meta-analysis

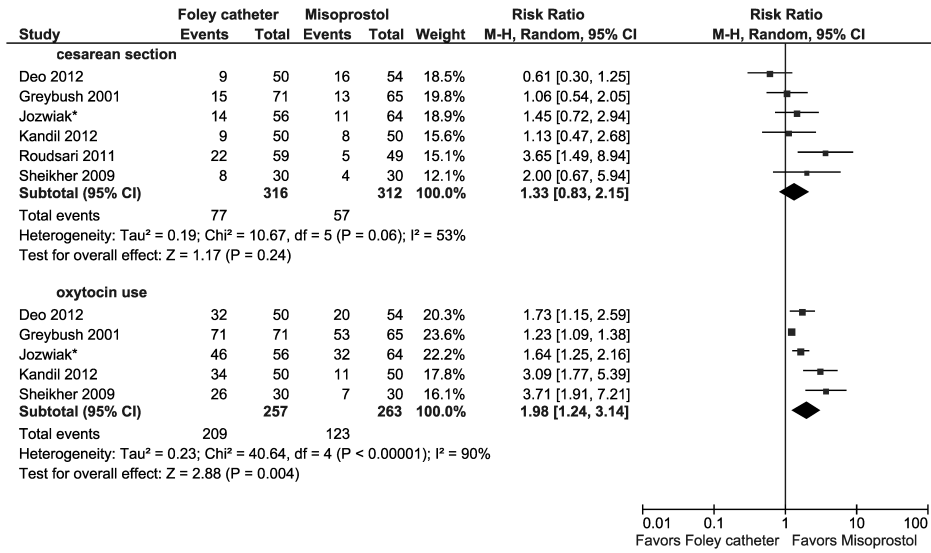
Study	Participants	Interventions	Primary Outcome	Risk of bias
Chung 2003[21]	GA* ≥28 wks BS† < 7	Foley catheter 30 mL (*n*=54) Misoprostol 25 µg every 3 h (*n*=49)	Vaginal delivery rate	Moderate Sequence generation: adequate Allocation concealment: adequate ITT‡: yes Reporting bias: yes; not all prespecified outcomes reported
Deo 2012[22]	Term BS† < 6	Foley catheter 30 mL (*n*=50) Misoprostol 25 µg every 4 h (*n*=54)	Change in BS	Moderate Sequence generation: adequate Allocation concealment: adequate ITT‡: no; protocol violations excluded Reporting bias: yes; no fetal outcomes reported
Greybush 2001[23]	GA* not specified BS < 6	Foley catheter 50 mL (*n*=71) Misoprostol 25 µg every 4 h (*n*=65)	Ripening to delivery time	Low Sequence generation: adequate Allocation concealment: adequate ITT‡: yes Reporting bias: no
Kandil 2012[25]	GA* > 41 wk BS† < 4	Foley catheter 30 mL (*n*=50) Misoprostol 25 µg every 4 h (*n*=50)	Induction to delivery interval	High Sequence generation: inadequate Allocation concealment: none ITT:‡ no Reporting bias: no
Moraes 2010[26]	Term BS† < 6	Foley catheter 30 mL (*n*=121) Misoprostol 25 µg every 6 h (*n*=119)	Successful induction <48 h	Low Sequence generation: adequate Allocation concealment: adequate ITT‡: yes Reporting bias: no
Oliveira 2010[27]	Term BS† < 5	Foley catheter 30 mL (*n*=80) Misoprostol 25 µg every 6 h (*n*=80)	BS > 5 after 48 h	Low Sequence generation: adequate Allocation concealment: adequate ITT‡: yes Reporting bias: no
Prager 2008[28]	Term BS† < 7	Foley catheter 50 mL (*n*=198) Misoprostol 25 µg every 6 h (*n*=199)	Induction to delivery interval	Low Sequence generation: adequate Allocation concealment: adequate ITT‡: yes (missing data *n*=4) Reporting bias: no
Roudsari 2011[29]	Term BS† < 7	Foley catheter 50 mL (*n*=59) Misoprostol 25 µg every 4 h (*n*=49)	Time from start induction to delivery	High Sequence generation: unkown Allocation concealment: unknown ITT‡: no Reporting bias: unclear
Sheikher 2009[30]	Term BS† < 5	Foley catheter 35 mL (*n*=30) Misoprostol 25 µg every 4 h (n=30)	Failed induction after 24 h	High Sequence generation: unkown Allocation concealment: unknown ITT‡: no Reporting bias: unclear

*GA= Gestational age, †BS = Bishop Score, ‡ITT=intention-to-treat

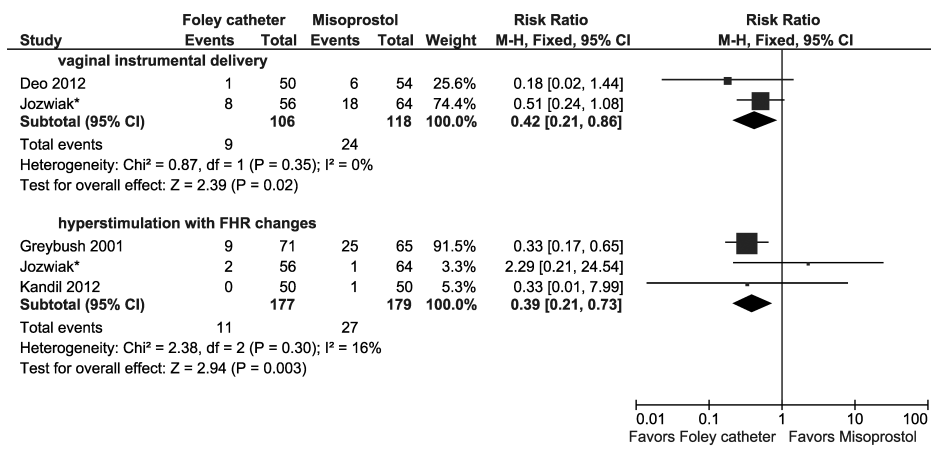
Table 5. Meta-analysis Foley catheter versus 25 mcg vaginal misoprostol - all dosing schedules

Outcome	Studies	Total participants	Foley catheter events/total	Misoprostol events/total	Statistical Method for pooling	RR [95% CI]
Caesarean delivery	10	1520	230/769	187/751	M-H*, random effect	1.24 [0.94-0.63]
Vaginal instrumental delivery	3	621	38/304	57/317	M-H*, random effect	0.64 [0.35-1.17]
Oxytocin use	7	783	321/391	196/392	M-H*, random effect	1.74 [1.30-2.32]
uterine hyperstimulation without FHR changes	3	363	21/184	51/179	M-H*, Fixed effect	0.39 [0.26-0.60]
uterine hyperstimulation with FHR changes	6	1096	21/550	52/546	M-H*, Fixed effect	0.39 [0.24-0.61]
epidural analgesia	4	756	256/379	232/377	M-H*, random effect	1.02 [0.82-1.26]
Post partum haemorrhage	1	120	3/56	3/64	no meta-analysis	1.14 [0.24-5.44]
(suspected) intrapartum infection/chorio-amnionitis	4	720	25/358	23/362	M-H*, Fixed effects	1.09 [0.63-1.86]
endo(myo)metritis	3	463	4/231	3/232	M-H*, Fixed effect	1.19 [0.31-4.63]
econium stained amniotic fluid	6	1008	63/512	82/496	M-H*, Fixed effects	0.75 [0.56-1.02]
Apgar score <7 after 5 min	4	580	5/287	5/293	M-H*, Fixed effect	1.03 [0.35-3.04]
NICU admission	6	1016	26/509	28/507	M-H*, Fixed effects	0.89 [0.54-1.49]

*M-H: Mantel-Haenszel



A * current study



B * current study

Figure 3. Meta-analysis Foley catheter versus 25 µg vaginal misoprostol every 4 hours with (A) random effects, and (B) fixed effects

the groups. Although we did not find any differences in primary and secondary outcomes, these results should be interpreted cautiously, due to the small numbers. Although the numbers were small, our trial was a valuable contribution to meta-analysis. In meta-analysis, we found that Foley catheter compared with 4 hourly vaginal administration of 25 µg misoprostol yielded comparable caesarean delivery rates, reduced rates of vaginal instrumental deliveries and of hyperstimulation, and increased oxytocin use.

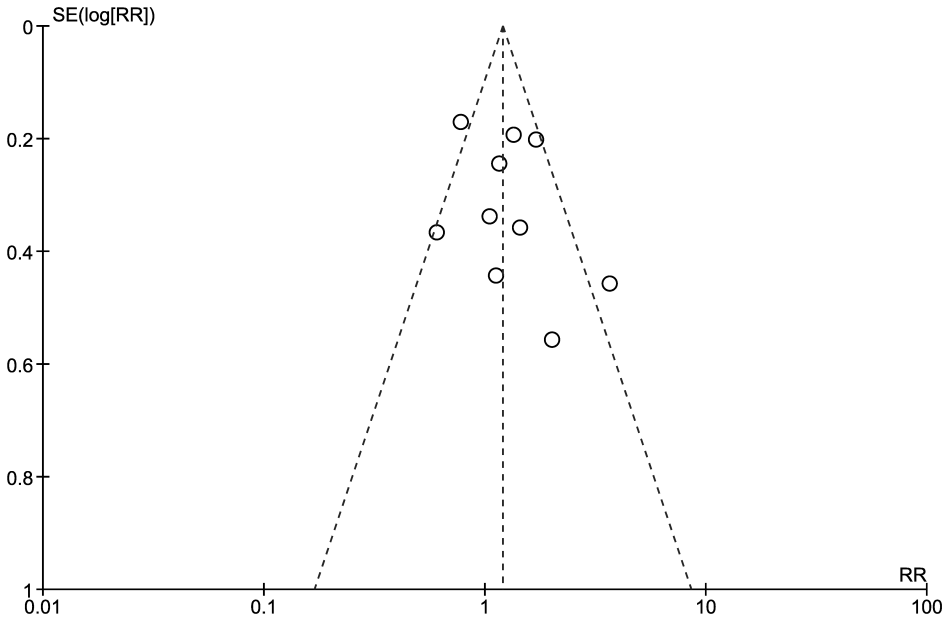


Figure 4. Funnel plot caesarean delivery

To our knowledge, this is the first meta-analysis that separately compares the most prevailing dose of misoprostol, 25 µg vaginally, to Foley catheter. Previous reviews comparing Foley catheters to misoprostol included different doses and dosing schedules.[14,31] As different dosing regimens are likely to affect the efficacy and safety of the induction agent, it is important to review them separately.

Our meta-analysis included 10 studies comparing Foley catheter to 25 µg vaginal misoprostol. Six studies, with a total of 628 participants, dosed the misoprostol every 4 hours. In these six trials, misoprostol was compared with a Foley catheter filled with 30 mL in three studies, 35 mL in one study, and 50 mL in two studies. Even though there is some evidence that a higher volume in the Foley balloon is more effective,[32,33] we have chosen to include all six studies in our subgroup analysis. Despite this, the total number of women is still too small to make definitive conclusions about safety of the two methods. Excluding the studies with a higher balloon volume did not change our conclusions regarding the primary outcome.

Although the total caesarean delivery rate in the current trial did not differ significantly, the rate of caesarean deliveries for failure to progress was higher in the Foley catheter group, with a very wide confidence interval (1.01 to 20.6). In the protocol, we did not define failure to progress in the first stage, as there is no commonly accepted definition of failure to progress in the first stage after induction of labour. A recent study, which aimed to find an objective definition of failed induction or failure to progress in the first stage of labour, concluded that it

is reasonable to avoid deeming labour induction a failure in the latent phase until oxytocin has been administered for at least 12 hours after membrane rupture. Additionally, 40% of women with a latent phase after membrane rupture longer than 12 hours deliver vaginally if allowed longer oxytocin infusion.[34]

When reviewing the cases of women undergoing caesarean delivery due to failure to progress in the first stage, we found that in three of the eight cases, the caesarean delivery was performed within 12 hours from rupture of membranes. Our hypothesis is that if more time was allowed, these women might have had the opportunity to deliver vaginally.

Oxytocin is used significantly more often when a Foley catheter is employed. This indicates that Foley catheter does not primarily cause contractions, but merely ripens the cervix. Foley catheters enable the separation of cervical ripening and actual labour induction. This could be an advantage, especially in case of induction with intrauterine growth restriction or oligohydramnios, where the fetus may have decreased tolerability for contractions.

Cervical ripening before induction of contractions could also decrease the need for fetal monitoring during ripening, which can enable outpatient use and consequent cost reduction of labour induction. Several researchers have studied inpatient versus outpatient cervical ripening using a Foley catheter. No significant differences were found in mode of delivery or maternal and neonatal morbidity comparing in- and outpatient ripening. However, a significant decrease in hospitalization time and costs was found when ripening was applied in an outpatient setting.[35,36] Adequately powered studies are needed to confirm the safety of outpatient Foley catheter use for cervical ripening.

The use of misoprostol in women with a prior caesarean delivery has been questioned, because several case reports and a randomized controlled trial, which was stopped prematurely due to safety concerns, suggested an increased risk of uterine rupture.[37-41]Foley catheters do not seem to cause contractions during the ripening phase and could therefore be a good alternative for labour induction in women with a history of caesarean delivery. Although retrospective data on Foley catheter use in these women suggest that it is safe,[42,43] prospective data on the comparison of methods for cervical ripening in this group of women are scarce. Therefore, we are currently investigating Foley catheter for induction in women with a prior caesarean delivery in a large prospective cohort (PROBAAT-S study).

In conclusion, Foley catheter compared with 25 µg vaginal misoprostol administered every 4 hours has comparable effectiveness on vaginal delivery rates, but a longer induction to delivery interval. However, there is a lower risk of hyperstimulation with fetal heart rate changes and a lower risk of vaginal instrumental delivery, which gives the Foley catheter potential benefits.

ACKNOWLEDGMENTS

We would like to sincerely thank the women who participated in this study. We also thank the residents, research team, and staff at the delivery wards of all participating hospitals for their engagement in this study. Furthermore we would like to acknowledge Annemarie van der Velden, Librarian at Groene hart Ziekenhuis in Gouda, for helping us with the literature search.

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