

# Intracervical Foley catheter balloon versus dinoprostone insert for induction cervical ripening

## A systematic review and meta-analysis of randomized controlled trials

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### Abstract

**Background:** Successful labor induction depends on the cervical status at the time of induction. Currently, both a Foley catheter and a dinoprostone insert are used for effective cervical ripening. This study compared the efficacy and safety of the intracervical Foley catheter and dinoprostone insert for cervical ripening to achieve successful labor induction.

**Methods:** PubMed, Embase, and the Cochrane Library were searched from January 2000 to February 2017 for relevant articles. Only published randomized, controlled trials comparing the dinoprostone insert with the Foley catheter were included.

**Results:** Eight trials including 1191 women who received the intracervical Foley catheter balloon and 1199 who received the dinoprostone insert were used for this study. There was no significant difference between the 2 groups regarding the induction-to-delivery (I-D) interval in a random effect model (mean difference, 0.71 hours; 95% confidence interval [CI], -2.50 to 3.91;  $P = .67$ ). The highly significant heterogeneity ( $I^2 = 97\%$ ) could be explained by the subgroup analysis of the type of Foley catheter and balloon volume. There was no significant difference between the 2 methods regarding the cesarean delivery rate (relative risk, 0.91; 95% CI, 0.78–1.07;  $P = .24$ ), Apgar score, or side effects, including maternal infection rate, postpartum hemorrhage, and hyperstimulation. No obvious publication bias was found.

**Conclusions:** According to the cesarean delivery rate, the intracervical Foley catheter balloon was as efficient as the dinoprostone insert. A moderate balloon volume (30 mL) and higher dose of dinoprostone ( $\geq 6$  mg) were related to shorter I-D intervals. Additionally, there was no significant difference between the two methods regarding maternal or neonatal safety.

**Abbreviations:** CI = confidence interval, CS% = cesarean section rate, I-D interval = induction to delivery interval, IQR = interquartile range, MD = mean difference, N = number of studies, Ph =  $P$ -value of heterogeneity, RR = relative risk.

**Keywords:** dinoprostone, Foley catheter balloon, induction, meta-analysis

## 1. Introduction

Labor induction has become more widespread in most countries during the past decade,<sup>[1]</sup> with 20% to 30% of all deliveries worldwide involving induced labor.<sup>[2–4]</sup> Successful labor induc-

tion depends on the cervical status at the time of induction. It is predicted that patients with a poor Bishop score will have an unacceptably high rate of induction failure.<sup>[5]</sup> However, a variety of methods, including mechanical and pharmacologic methods, are available for cervical ripening.

Mechanical methods (laminaria tent, various types of balloon catheters, and extra-amniotic saline infusion) that were initially developed to ripen the cervix are thought to work by physically dilating the cervix and stimulating the release of endogenous prostaglandins. Pharmacologic ripening agents include oxytocin administration and various forms of exogenous prostaglandin administered orally or vaginally. Currently, prostaglandin E2 preparations (Prostin1, Cervidil1, Propess1) are the preferred choices in many countries.<sup>[6–10]</sup> However, the best method of labor induction is unknown.

To determine the optimal method of labor induction, investigators have conducted many clinical trials that have compared the efficacy and safety of the Foley catheter balloon with the dinoprostone insert. However, the results have not led to a consensus. Therefore, we performed a meta-analysis to compare the efficacy and safety of the intracervical Foley catheter and the dinoprostone insert for cervical ripening for successful labor induction.

## 2. Methods

This study was developed in accordance with the Cochrane Handbook for Systematic Reviews of Interventions. All statistical

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analyses were performed using data reported in previously published studies. Ethical approval and informed consent were not required.

### 2.1. Search strategy

We performed a systematic literature search of PubMed, Embase, and the Cochrane Library from 2000 to February 2017. The following MeSH terms and text words were used: "Delivery," "Deliveries," "Obstetric," "Obstetric," "Parturition," "Birth," "Births," "Childbirth," "Childbirths," "labor," "Induced," "Induction," "Abortion," "Cervical," "Ripenings," "Prostaglandin," "Prostaglandins," "Prostanoids," "Prostanoid," "Endoperoxides," "Analogues," "PGE," "ProstaglandinsE," "Alprostadil," "PGE1," "Dinoprostone," "PGE2," "PGE2?alpha," "Prostenon," "Misoprostol," "Novo?Misoprostol," "misoprostol?acid," "propress," "water?bag," "water?balloon," "bladder," "Foley," "Foley?Catheter," "seaweed?stick," "laminaria," "laminaria?tent," "RCT," "randomised," "Clinical," "Controlled," and "Trial\*." The "AND" or "OR" operator was used to combine these terms in varying combinations. The article language was limited to English. The latest search was conducted on February 28, 2017. Two authors (JHX and JQL) independently reviewed the titles and abstracts identified during the search. Any disagreement was resolved by discussion or by involving a 3rd assessor (FC). No protocol was developed for this review.

### 2.2. Study selection

Inclusion criteria were as follows: primigravida;  $\geq 37$  and  $< 42$  weeks of gestation; singleton pregnancy; cephalic presentation; Bishop score  $\leq 3$ ; intact membranes; intracervical Foley catheter balloon for cervical ripening and labor induction; dinoprostone insert for cervical ripening and labor induction; study reported both primary outcomes (cesarean delivery rate and induction-to-delivery [I-D] interval); and study reported a randomized, controlled trial. Exclusion criteria were as follows: literature published as letters, editorials, abstracts, reviews, case reports, or expert opinions; experiment was in vitro or in vivo but not based on patients; no cesarean delivery rate and I-D interval mentioned; and repeated and similar studies. Cohen kappa statistic was used to assess the chance-corrected agreement between reviewers (SPSS version 18.0; SPSS Inc, Chicago, IL).<sup>[11]</sup>

### 2.3. Data extraction

We designed a form to extract data (Appendix 1 of the supplementary data, <http://links.lww.com/MD/C638>). For eligible studies, 2 review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, a 3rd review author (FC) was consulted. The following clinical data were extracted for each trial: the first author's last name; publication year; country; study design; study interval; and criteria for participant inclusion. The primary outcomes of this meta-analysis were cesarean delivery rate and I-D interval. The secondary outcomes included other maternal parameters and neonatal outcomes. When an article only included the median and interquartile range (IQR), we used a formula (when data distribution was close to normal:  $IQR = 1.35 \times \text{standard deviation}$ ) to calculate the estimated mean and corresponding 95% confidence interval (CI).

### 2.4. Assessment of risk of bias

Two review authors (LZ and CZ) independently assessed the risk of bias for each study using the following information outlined in the Cochrane Handbook for Systematic Reviews of Interventions<sup>[12]</sup>: whether blinding was implemented for participants, staff, and outcome assessments; what proportion of subjects completed follow-up; and whether there was evidence of selective reporting of outcomes. Any disagreement was resolved by discussion or by involving a third assessor (FC).

### 2.5. Data synthesis and statistical analysis

We performed a statistical analysis using Review Manager software (RevMan 5.3). The primary outcomes were cesarean delivery rate and I-D interval of the intracervical Foley catheter balloon compared with the dinoprostone insert. Relative risk (RR) and 95% CI were used to measure the cesarean delivery rate. Cases of maternal or neonatal adverse events were also recorded. Heterogeneity among studies was measured by the  $I^2$  test. The latent publication bias was assessed by a funnel plot and Egger linear regression test. All statistical tests were 2-tailed, and  $P < .05$  was considered statistically significant. All analyses were conducted using Review Manager software version 5.3 (The Cochrane Collaboration) and STATA statistical software package version 12.0 (Stata Corporation, College Station, TX).

## 3. Results

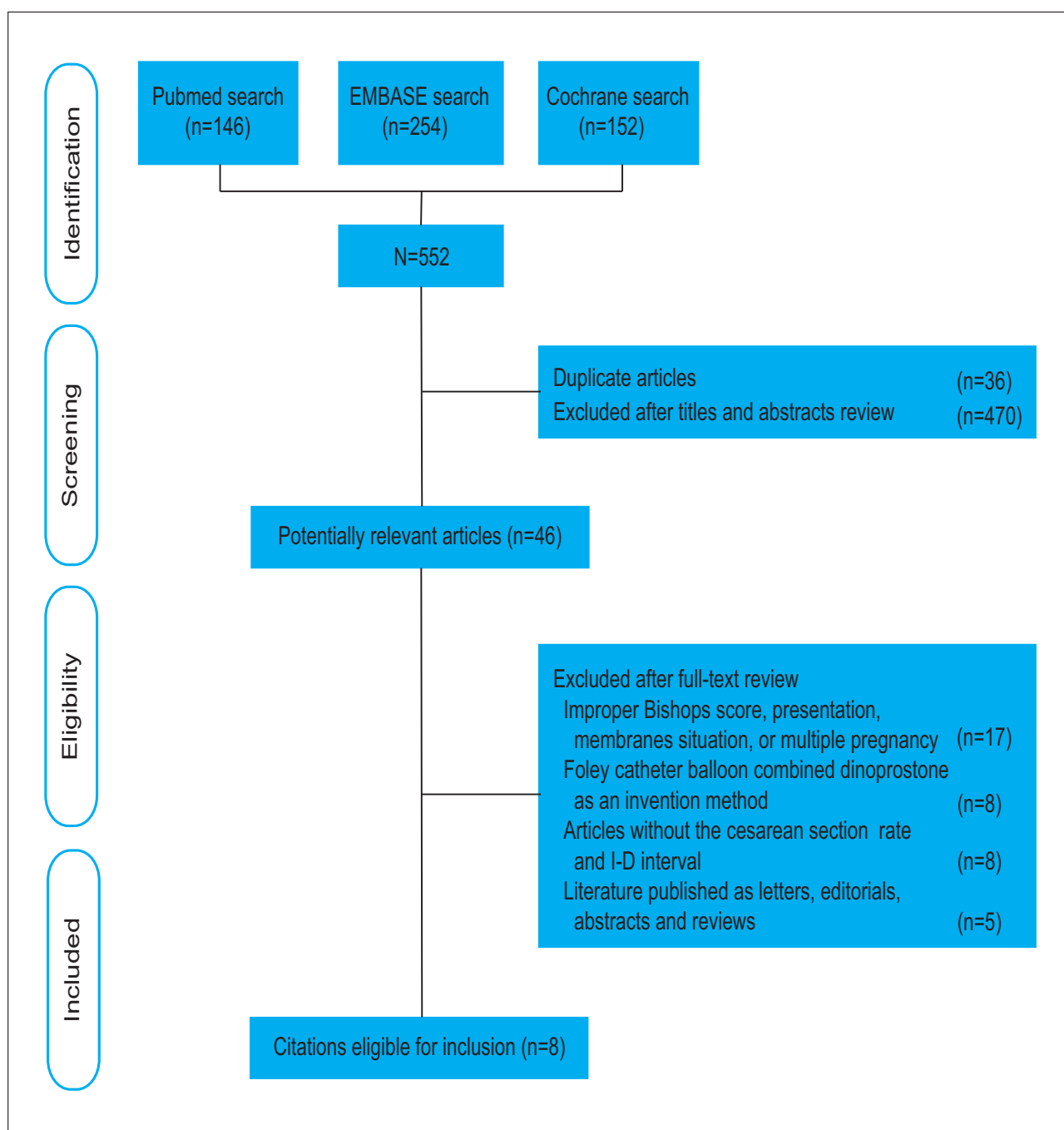
### 3.1. Search results

A total of 552 potential articles were identified from the literature searches. After selection, 8 studies matched the inclusion criteria and were suitable for our meta-analysis.<sup>[13–20]</sup> The flow diagram in Figure 1 shows the selection process. A total of 2390 cases were analyzed; 1191 (49.8%) patients received a Foley catheter balloon and 1199 (50.2%) received a dinoprostone insert. A review of the study selection and data extraction indicated excellent agreement between reviewers ( $k = 0.821$ ).

### 3.2. Study characteristics and quality assessment

Study characteristics are summarized in Table 1. There were no significant differences between the 2 groups regarding maternal age, body mass index, gestational age, and baseline Bishop score. Study sample sizes ranged from 70 to 824. Two studies involved white populations.<sup>[16,17]</sup> The remaining studies involved Asian populations.<sup>[13–15,18–20]</sup> The type of Foley catheter used in each study ranged from 14F to 22F. The methodologic quality assessment based on the Cochrane risk of bias is presented in Figures 2 and 3. Overall, the studies included in our analysis were of moderate quality.

**3.2.1. Cesarean delivery.** All studies in our analysis reported data regarding cesarean delivery. Two hundred thirty-two (19.5%) patients in the intracervical Foley catheter balloon group and 256 (21.4%) in the dinoprostone insert group had a cesarean delivery. Due to the low heterogeneity across studies ( $I^2 = 15\%$ ), a fixed-effect model was used. No significant differences were found between groups regarding the cesarean delivery rate (RR, 0.91; 95% CI, .78–1.07;  $P = .24$ ) (Fig. 4).



**Figure 1.** Flow chart for the selection of records. The search strategy identified 552 citations. Titles and abstracts were reviewed. Forty-six potential articles were retrieved and evaluated. Finally, 8 randomized, controlled trials appeared to be eligible.

### 3.3. Time from the start of intervention to birth

Data regarding the I-D interval were described in eight studies.<sup>[13–20]</sup> Due to the significant heterogeneity across studies ( $I^2=97\%$ ), a random-effect model was used. The pooled mean difference of the studies had no statistical significance ( $P=.67$ ) (Fig. 5).

### 3.4. Subgroup analysis

Based on the high heterogeneity of the I-D interval analysis, we conducted a subgroup analysis by stratifying the pooled data

according to year (2010 or after vs before 2010), study region (Asian vs white), sample size ( $\geq 200$  vs  $< 200$ ), type of Foley catheter (14F vs 18F vs 22F), balloon volume (30 mL vs 50 mL), and dinoprostone dose ( $< 3$  mg vs  $\geq 3$  mg and  $< 6$  mg vs  $\geq 6$  mg) (Table 2).

According to Table 2, heterogeneity of each subgroup decreased only during the dinoprostone dose analysis ( $I^2=93\%$ ;  $I^2=95\%$ ). In addition, the results of the subgroups were different but logical. When a low dose of dinoprostone ( $< 3$  mg) was used for comparison, the Foley catheter resulted in a shorter I-D interval (mean difference,  $-5.06$  hours; 95% CI,  $-10.12$  to

**Table 1****Main characteristics of all the studies included in the meta-analysis.**

Study	Year	Country	Study design	Study interval	No. of patients	Foley catheter	PGE2	Inclusion criteria	Primary outcome
Deshmukh et al <sup>[13]</sup>	2011	India	Single-center RCT	3 y	200/200	Unknown	Unknown	Primigravida ≥37 wk gestation Singleton pregnancy Cephalic presentation Bishop score ≤3 Intact membranes	Improvement in Bishop score
Mansour Ghanaie et al <sup>[14]</sup>	2013	Iran	Single-center RCT	2 y	121/118	22–30 mL	0.5–2.0 mg	Primiparous ≥37 wk, <42 wk gestation Singleton pregnancy Cephalic presentation Bishop score ≤3 Intact membranes	Time to active phase
Laddad et al <sup>[15]</sup>	2013	India	Single-center RCT	1 y	200/200	Unknown	Unknown	Primigravida ≥37 wk gestation Singleton pregnancy Cephalic presentation Bishop score ≤3 Intact membranes	Induction to delivery interval
Jozwiak et al <sup>[16]</sup>	2011	The Netherlands	Multi-center RCT	1 y	412/412	Unknown/30 mL	10 mg	Primigravida >37 wk gestation Singleton pregnancy Cephalic presentation Bishop score ≤5 Intact membranes	Cesarean section rates
Jozwiak et al <sup>[17]</sup>	2013	The Netherlands	Multi-center RCT	1 y	107/109	Unknown/30 mL	3–6 mg	Primiparous ≥37 wk, <42 wk gestation Singleton pregnancy Cephalic presentation Bishop score ≤5 Intact membranes	Caesarean section rates
Al-Taani <sup>[18]</sup>	2004	Jordan	Single-center RCT	1 y	72/75	18–50 mL	3–6 mg	Primiparous ≥37 wk, <42 wk gestation Singleton pregnancy Cephalic presentation Bishop score ≤5 Intact membranes	Time from induction to delivery
Moini et al <sup>[19]</sup>	2003	Iran	Single-center RCT	1 y	35/35	22–30 mL	0.5 mg	Primiparous ≥37 wk, <42 wk gestation Singleton pregnancy Cephalic presentation Bishop score ≤5 Intact membranes	Change in Bishop score
Niromanesh et al <sup>[20]</sup>	2002	Iran	Single-center RCT	1 y	45/45	14–30 mL	3–6 mg	Primiparous ≥37 wk, <42 wk gestation Singleton pregnancy Cephalic presentation Bishop score <5 Intact membranes	Change in Bishop score

Foley catheter, type of Foley catheter/balloon volume.

–0.01;  $P < .05$ ). Conversely, a high dose of dinoprostone (>6 mg) resulted in a shorter I-D interval (mean difference, 11.00 hours; 95% CI, 8.92–13.08;  $P < .00001$ ). When the dose of dinoprostone was between 3 and 6 mg, there was no significant difference between the 2 methods regarding the I-D interval (mean difference, 0.85 hours; 95% CI, –4.37 to 6.07;  $P = .75$ ). This indicated that the dose of dinoprostone was negatively related to the I-D interval, and that the individual study<sup>[21]</sup> had a great impact on total heterogeneity due to its high dose of dinoprostone (10 mg). However, the heterogeneities were still high, suggesting other confounding factors.

Therefore, subgroup analyses were repeated without including the study by Marta, and a further decrease in heterogeneity was found for the Foley catheter type ( $I^2 = 93\%$ ) (Table 3) and balloon volume analyses ( $I^2 = 88\%$ ) (Table 3). Although the heterogeneity was not largely reduced, the results for each subgroup varied widely. Interestingly, the Foley catheter balloon with a small diameter (14F) or large diameter (22F) had a shorter I-D interval than the dinoprostone insert (14F: mean difference –2.50 hours; 95% CI, –4.26 to –0.74;  $P < .005$ ; 22F: mean difference, –5.06 hours; 95% CI, –10.12 to –0.01;  $P < .05$ ) (Table 3). However, the Foley catheter balloon with a moderate

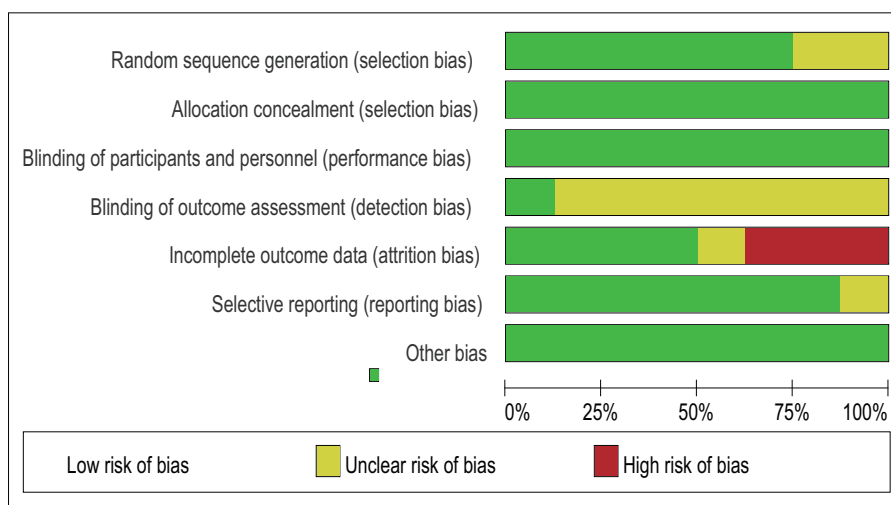


Figure 2. Risk of bias graph. The review authors' judgments of each risk of bias item are presented as percentages.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Deshmukh 2011	+	+	+	?	+	?	+
Ghanaie 2013	?	+	+	?	-	+	+
Manisha 2013	+	+	+	?	+	+	+
Marta 2011	+	+	+	?	-	+	+
Marta 2013	+	+	+	+	+	+	+
MIAI 2004	+	+	+	?	?	+	+
Moini 2003	+	+	+	?	+	+	+
Niromanesh 2002	?	+	+	?	-	+	+

Figure 3. Risk of bias summary. The review authors' judgments of each risk of bias item for each included study.

diameter (18F) had a longer I-D interval (mean difference, 4.00 hours; 95% CI, 2.97–5.03;  $P < .00001$ ) (Table 3). This illogic result was believed to be due to the small sample effects (only 1 study was included in the 2 subgroups), and the mechanical compression of the Foley catheter balloon on the cervix was mainly dependent on balloon volume. Moderate balloon volume (30mL) was more efficient than large balloon volume (50 mL) regarding the I-D interval (30 mL: mean difference, -3.40 hours; 95% CI, -6.76 to -0.04;  $P < .05$ ; 50 mL: mean difference, 4.00 hours; 95% CI, 2.97–5.03;  $P < .00001$ ) (Table 3). It was suggested that the dose of dinoprostone and balloon volume were the main causes of heterogeneity.

3.5. Secondary outcomes

Cases of maternal or neonatal adverse events were recorded, and no significant difference was found between 2 groups (Table 4). There was no significant difference between the 2 methods regarding Apgar score and side effects such as maternal infection rate, postpartum hemorrhage, and hyperstimulation.

3.6. Sensitivity analysis

To determine the stability of our results, a sensitivity analysis was performed. We conducted a metatrim analysis of the cesarean delivery rate. The metatrim analysis is a rank-based data augmentation technique that estimates the number and outcomes of missing studies and adjusts the meta-analysis to incorporate the missing theoretical studies. No data point was filled, which meant that the result was stable. According to the multivariate analysis and the univariate analysis, no significant changes were detected between the previous RR and new RR for the cesarean delivery rate. The new RR was pooled using the remaining studies after we deleted 1 individual study at a time. However, regarding the I-D interval, a new pooled significant mean difference (0.40; 95% CI, 0.31–0.49) indicated that the I-D interval was longer for the dinoprostone insert group when the study by Mansour Ghanaie et al was not included.<sup>[14]</sup> Therefore, this study might have affected the stability of this meta-analysis.

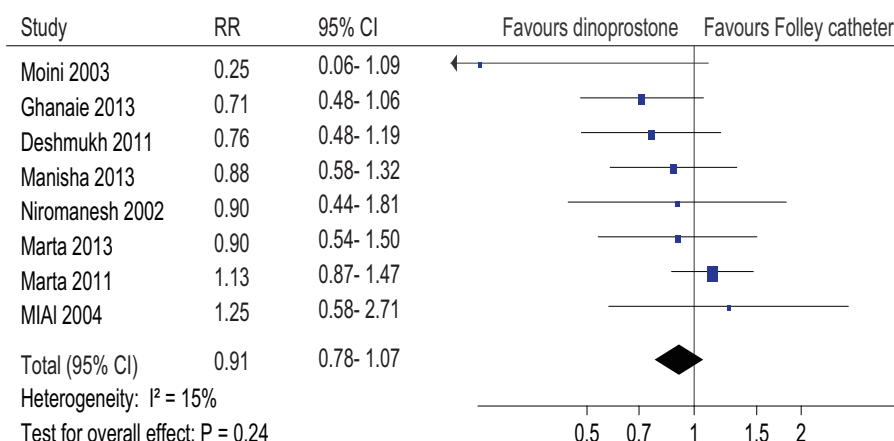


Figure 4. Forest plot of the cesarean delivery rate. RR, relative risk.

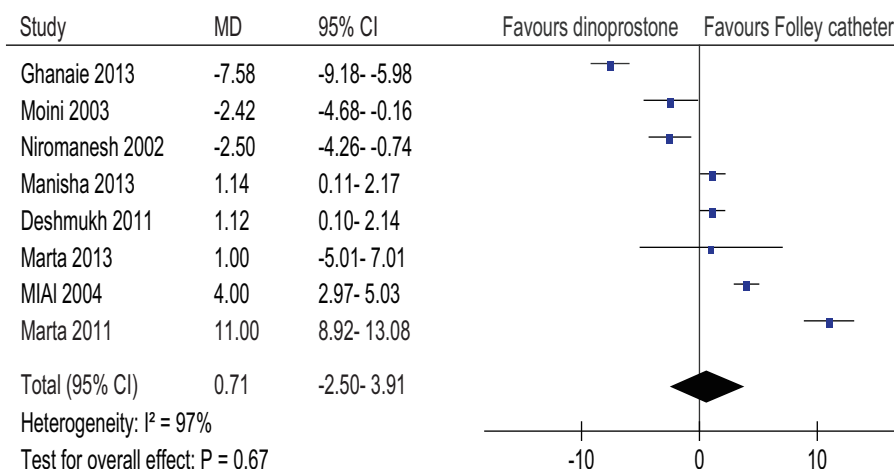


Figure 5. Forest plot of the induction-to-delivery interval. MD, mean difference.

Table 2

Subgroup analyses on I-D interval\*.

	N	MD (95% CI)/h	P	$I^2$ , %	Ph
Overall	8	0.71 (-2.50, 3.91)	.67	97	<.01
Year					
≥2010	3	4.55 (-3.09, 12.19)	.24	97	<.01
<2010	5	-1.44 (-5.39, 2.52)	.48	98	<.01
Study region					
Asian	6	-0.98 (-4.03, 2.06)	.53	97	<.01
Caucasian	2	6.41 (-3.35, 16.18)	.20	89	<.01
Sample size					
≥200	4	1.38 (-3.98, 6.75)	.61	98	<.01
<200	4	-0.02 (-4.29, 4.26)	.99	94	<.01
Type of Foley catheter					
14F	1	-2.50 (-4.26, -0.74)	<.01	-	-
18F	2	7.44 (0.58, 14.30)	.03	97	<.01
22F	2	-5.06 (-10.12, -0.01)	.05	93	<.01
Balloon volume, mL					
30	5	-0.14 (-6.94, 6.65)	.97	98	<.01
50	1	4.00 (2.97, 5.03)	<.01	-	-
Dinoprostone dose, mg					
<3	2	-5.06 (-10.12, -0.01)	.05	93	<.01
≥3, <6	3	0.85 (-4.37, 6.07)	.75	95	<.01
≥6	1	11.00 (8.92, 13.08)	<.01	-	-

MD= mean difference, N=the number of studies, Ph=*P*-value of heterogeneity.

\* Data of "no mention" group are excluded in the form.

**Table 3****Subgroup analyses on I-D interval excluded 1 outlier study\*.**

	N	MD (95% CI)/h	P	I <sup>2</sup> , %	Ph
Overall	7	0.80 (−3.67, 2.07)	.59	96	<.01
Year					
≥2010	2	1.14 (0.12, 2.15)	.03	0	.96
<2010	5	−1.44 (−5.39, 2.52)	.48	98	<.01
Study region					
Asian	6	−0.98 (−4.03, 2.06)	.53	97	<.01
Caucasian	1	1.00 (−5.01, 7.01)	.74	–	–
Sample size					
≥200	3	−1.73 (−6.41, 2.95)	.47	98	<.01
<200	4	−0.02 (−4.29, 4.26)	.99	94	<.01
Type of Foley catheter					
14F	1	−2.50 (4.26, −0.74)	<.01	–	–
18F	1	4.00 (2.97, 5.03)	<.01	–	–
22F	2	−5.06 (−10.12, −0.01)	.05	93	<.01
Balloon volume, mL					
30	4	−3.40 (−6.76, −0.04)	.05	88	<.01
50	1	4.00 (2.97, 5.03)	<.01	–	–
Dinoprostone dose, mg					
<3	2	−5.06 (−10.12, −0.01)	.05	93	<.01
≥3, <6	3	0.85 (−4.37, 6.07)	.75	95	<.01

MD=mean difference, N=the number of studies, Ph=*P*-value of heterogeneity.

\*Data of "no mention" group are excluded in the form.

**3.7. Publication bias**

The funnel plot (Fig. 6) and Harbord modified test for small study effects ( $P=.140$ ) on the cesarean delivery rate indicated no publication bias. According to the funnel plot (Fig. 7) and Egger test for small study effects ( $P=.221$ ), no publication bias was found for the I-D interval.

**4. Discussion**

Labor induction is one of the most common interventions in clinical obstetrics.<sup>[22]</sup> Although numerous studies have been conducted to compare ripening methods, no agreement has been universally achieved. The cesarean delivery rate, I-D interval, maternal complications, and neonatal outcomes need to be considered for ideal ripening. Many outcomes can be used to assess the effectiveness of induction methods. Cesarean delivery, which is surgery, is not acceptable to many pregnant women. Therefore, we chose the cesarean delivery rate as the primary outcome. As was expected, the cesarean delivery rate was similar for both groups, indicating further similarities between the 2 methods. Furthermore, low heterogeneity suggested credibility of the results ( $I^2=15\%$ ;  $P=.24$ ).

When pregnant women were interviewed about their expectations regarding childbirth, one of the main hopes was a short duration of labor.<sup>[23]</sup> Therefore, the time required for cervical ripening should be taken into consideration when selecting a method of labor induction. Three of the studies included (Mansour Ghanaie et al,<sup>[14]</sup> Moini et al,<sup>[19]</sup> and Niromanesh et al<sup>[20]</sup>) in this analysis claimed that the dinoprostone insert was associated with shorter time to delivery than the intracervical Foley catheter balloon. However, four of the studies included (Deshmukh et al,<sup>[13]</sup> Laddad et al,<sup>[15]</sup> Jozwiak et al,<sup>[16]</sup> and Al-Taani<sup>[18]</sup>) in this analysis reported that a shorter time to delivery was found with the use of an intracervical Foley catheter balloon. Jozwiak et al<sup>[17]</sup> showed no difference between the 2 groups regarding the I-D interval. Our pooled results showed high heterogeneity ( $I^2=97\%$ ), and the subgroup analysis suggested that a moderate balloon volume (30 mL) and higher dose of dinoprostone ( $\geq 6$  mg) were related to shorter I-D intervals.

Efficacy and safety are equally important factors when evaluating a cervical ripening method. Therefore, an ideal ripening agent should offer the best balance of these 2 factors and minimal side effects. Our meta-analysis also pooled outcomes of

**Table 4****Cases of maternal or neonatal adverse events in Foley catheter balloon group and dinoprostone insert group.**

Variable	No. of studies	Data type	Effect measure	No. of cases/total number		Effective index (95% CI)	Heterogeneity, I <sup>2</sup> , %
				In Foley catheter balloon group	In dinoprostone insert group		
Hyperstimulation	3	Dichotomous	RR	11/563	13/571	0.85 (0.39, 1.87)	36
Postpartum hemorrhage	3	Dichotomous	RR	36/590	52/602	0.70 (0.47, 1.06)	0
Maternal partum infection	3	Dichotomous	RR	43/639	59/645	0.74 (0.51, 1.07)	0
1 min Apgar $\leq 7$	4	Dichotomous	RR	58/628	73/637	0.81 (0.58, 1.12)	0
5 min Apgar $\leq 7$	5	Dichotomous	RR	43/1111	50/1120	0.87 (0.59, 1.29)	0

N=the number of studies, RR=relative risk.

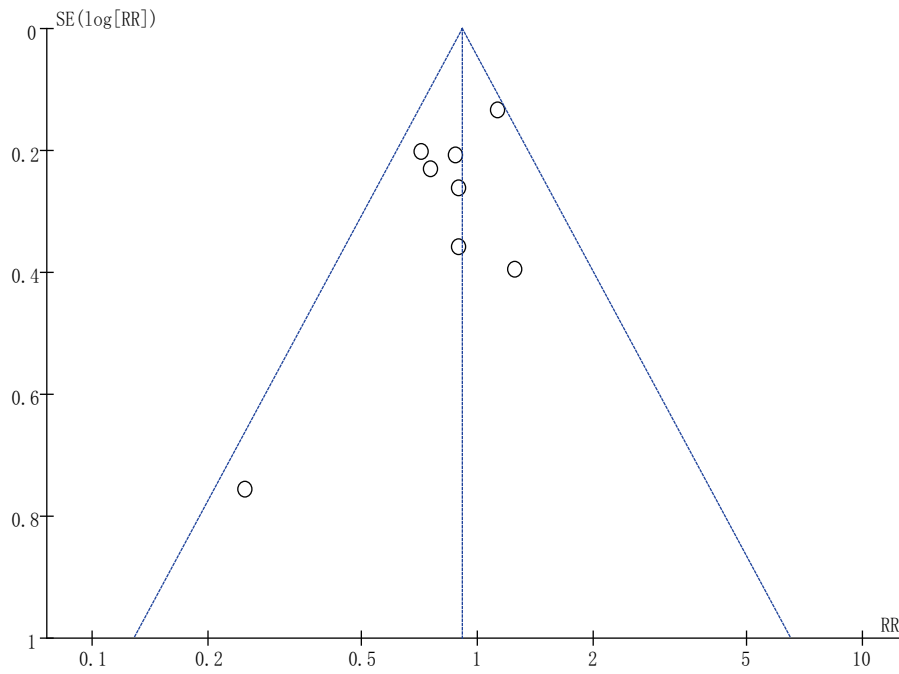


Figure 6. Funnel plot of the cesarean delivery rate.

maternal complications, including hyperstimulation, postpartum hemorrhage, and maternal partum infection. No significant difference was found between the 2 groups. However, compared to prostaglandin E2, Foley catheters have additional advantages such as wide availability, easy storage, and low cost. A cost-effectiveness analysis of ripening methods was not performed

because of limited data. However, the lower costs associated with oxytocin use, required personnel, and ancillary expenses might counterbalance the high cost of the dinoprostone insert method.<sup>[24]</sup> No significant differences were observed between the 2 groups regarding neonatal outcomes, including Apgar scores at 1 and 5 minutes.

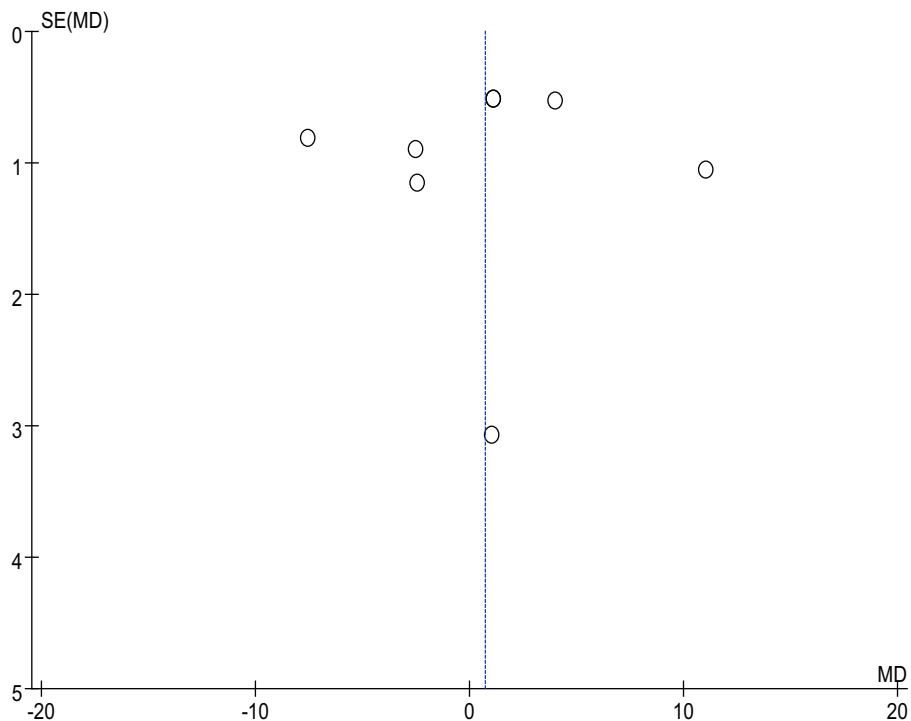


Figure 7. Funnel plot of the induction-to-delivery interval.



#### 4.1. Comparisons with similar systematic reviews

Researchers were able to reach a consensus regarding efficacy. They concluded that both methods have comparable efficacy. Jozwiak et al conducted a meta-analysis that included 3 individual studies that suggested comparable cesarean delivery rates (RR, 0.94; 95% CI, 0.73–1.21).<sup>[17]</sup> Wang et al conducted a meta-analysis that included 6 individual studies and reached the same conclusion (RR, 0.94; 95% CI, 0.80–1.21).<sup>[24]</sup> However, regarding the I-D interval, the results were inconsistent. A recent meta-analysis conducted by Vaknin showed no difference between I-D intervals for those using the Foley catheter balloon and those using the prostaglandin insert for cervical ripening.<sup>[25]</sup> In contrast, the results of the study by Wang et al indicated that the I-D interval was significantly shorter for the dinoprostone insert group compared to Foley catheter group (mean difference, 5.73 hours; 95% CI, 1.26–10.20),<sup>[24]</sup> which indicated that the dinoprostone insert was more effective than the Foley catheter for labor induction. Our research indicated that this could not be generalized and that time depended on the balloon volume and dose of dinoprostone.

Regarding maternal and neonatal complications, no significant difference was found between the 2 groups in our study. In the present analysis, McMaster et al observed similar results regarding maternal and neonatal adverse events, including maternal infection, chorioamnionitis, endometritis, and neonatal infection.<sup>[26]</sup> Wang et al observed no significant differences between the two groups regarding epidural analgesia, meconium staining, and neonatal complications (low birth weight, 5-minute Apgar score <7, umbilical artery blood pH <7, and admission to the neonatal intensive care unit); however, a significantly increased risk of excessive uterine activity in the dinoprostone insert group was reported (RR, 0.07; 95% CI, 0.03–0.19;  $P < .01$ ).<sup>[24]</sup>

#### 4.2. Limitations

There were some limitations to our analysis that deserve discussion. First, we observed considerable heterogeneity between the studies when analyzing the I-D interval. Although we performed a subgroup analysis and analyzed the dose of dinoprostone and balloon volume, heterogeneity did not decrease to a reasonable range. There was evidence that a Foley catheter balloon with a higher balloon volume (60 or 80 mL) was more effective than a volume of 30 mL,<sup>[27,28]</sup> which was inconsistent with the results of our subgroup analysis. However, no randomized, controlled trials proved this theory. Second, during this analysis, we selected eligible studies only from those published in English, which might have caused publication bias. However, this bias was not supported by the funnel plot.

#### 5. Conclusion

According to the cesarean delivery rate, an intracervical Foley catheter balloon was as efficient as a dinoprostone insert for inducing cervical ripening. A moderate balloon volume (30 mL) and higher dose of dinoprostone ( $\geq 6$  mg) were related to shorter I-D intervals. In addition, there was no significant difference between the 2 methods regarding maternal or neonatal safety.

#### Author contributions

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