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ORIGINAL ARTICLE

Controlled-release dinoprostone insert versus Foley catheter for labor induction: a meta-analysis

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Abstract

Objective: To compare the effectiveness and safety of controlled-release dinoprostone insert with Foley catheter balloon for cervical ripening and labor induction.
Methods: PubMed, Cochrane Central Register of Controlled Trials, Web of Science, and China Knowledge Resource Integrated Database were searched. Only randomized controlled trials comparing controlled-release dinoprostone insert with Foley catheter balloon were included. Risk ratio (RR) or mean difference (MD) with 95% confidence interval (CI) was calculated.
Results: Six studies were included with 731 women received dinoprostone insert and 722 Foley catheter. Time from induction to delivery was significantly shortened in dinoprostone insert group compared to Foley catheter group (MD 5.73 h, 95% CI 1.26–10.20). There were no significant differences in vaginal delivery within 24 h (RR 0.75, 95% CI 0.43–1.30) or cesarean section (RR 0.94, 95% CI 0.80–1.12) between two ripening methods. Dinoprostone insert was related with increased rate of excessive uterine contraction (RR 0.07, 95% CI 0.03–0.19), but less oxytocin use (RR 1.86, 95% CI 1.25–2.77) when compared with Foley catheter.
Conclusions: Induction of labor with controlled-release dinoprostone insert seems to be more effective than Foley catheter. However, the former method causes excessive uterine contraction more frequently.

Keywords

Dinoprostone insert, Foley catheter, labor induction, meta-analysis

History

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Introduction

Induction of labor is one of the most common obstetric interventions. Nowadays in developed countries, nearly one-fourth of all infants are delivered following labor induction [1]. For the patient with an unripe cervix, induction of labor is often associated with reduced effectiveness and increased risk of cesarean delivery, which promotes the cervical ripening agents to be investigated.

Historically, there are mechanical and pharmacological methods used to artificially ripen the cervix before labor induction. Mechanical methods (laminaria tent, various types of balloon catheter, and extra-amniotic saline infusion), developed initially to ripen the cervix, are thought to work by physically dilating the cervix and stimulating the release of endogenous prostaglandins. Pharmacological ripening agents include oxytocin administration and various forms of exogenous prostaglandin delivered orally or vaginally. During the past two decades, pharmacological methods have superseded the mechanical interventions and become the first-line agents for labor induction. Nevertheless, the increasingly reported side effects of exogenous prostaglandins have suggested the obstetricians to reconsider the application of mechanical methods. In 2012, an updated Cochrane review of 71 randomized controlled trials (RCTs) compared various mechanical methods with no treatment, prostaglandins or oxytocin for cervical ripening [2]. The study found no differences in the risks of not achieving vaginal delivery within 24 h or cesarean section, but there was a reduced risk of hyperstimulation with fetal heart rate changes when mechanical methods were compared with vaginal prostaglandin E2 (dinoprostone). Similar results were observed in the comparison of Foley catheter balloon versus vaginal dinoprostone.

Generally, prostaglandin E2 is available as a tablet, gel or a controlled-release vaginal insert for cervical ripening and labor induction. Due to the rapidity and ease of removal when uterine hyperstimulation is occurred or active labor is established, the dinoprostone insert has become the preferred vehicle for delivering prostaglandin E2 [3]. In order to search for the optimal method for induction of labor, many investigators have conducted clinical trials to compare the efficacy and safety of Foley catheter balloon with dinoprostone insert. However, the results have reached no consensus. In addition, the aforementioned Cochrane review did not include the comparison of Foley catheter balloon to dinoprostone insert for cervical ripening.

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In view of these, we carried out this meta-analysis of RCTs to compare the effectiveness and safety of dinoprostone insert with Foley catheter balloon in women with an unfavorable cervix.

Methods

Search strategy

The electronic databases utilized in our literature search included PubMed, Cochrane Central Register of Controlled Trials, Web of Science, and China Knowledge Resource Integrated Database. The following MeSH terms and text words were used: ''Foley'', ''catheterization'', ''balloon dilatation'', ''mechanical dilatation'', ''dinoprostone'', ''prostaglandins'', ''prostaglandin E2'', ''propess'', ''induction'', ''labor induced'', and ''cervical ripening''. The ''AND'' or ''OR'' operator was used to combine these terms in varying combinations. Article language was limited to English and Chinese. The latest search was conducted on 30 June 2015. Two authors independently reviewed the titles and abstracts identified in the search. All references cited in the articles were also searched by hand to identify additional publications. Investigators and experts in the field of obstetrics were contacted to ensure that all relevant studies were identified.

Study selection

All stages of study selection, data extraction and quality assessment were done independently by two reviewers. Any discrepancies between the two reviewers were resolved by discussion or arbitration by a third reviewer. For inclusion in the meta-analysis, a study had to fulfill the following criteria: (1) RCTs; (2) compared controlled-release dinoprostone vaginal insert with Foley catheter balloon for cervical ripening and labor induction; and (3) reported on at least one of the outcomes mentioned below. If two or more trials from the same institution were identified, the most recent or the most informative was selected, unless they were reports from different time periods or if the data of overlapping patients could be subtracted. All other forms of prostaglandin E2 (e.g. tablet, gel) were not included in the current meta-analysis. Retrospective studies, reviews and case reports were excluded. Cohen's kappa statistic was used to assess chance-corrected agreement between reviewers (SPSS version 18.0, SPSS Inc., Chicago, IL) [4].

Data extraction and quality assessment

For each study, the following data were extracted using standardized data extraction forms: the first author's last name, publication year, country, study design, study interval, and the criteria for participant inclusion. The primary outcomes of this meta-analysis were cesarean section rate, vaginal delivery within 24 h, and time from induction to delivery. The secondary outcomes included other maternal parameters and neonatal outcomes. Excessive uterine activity in this study was defined as tachysystole, hypertonus, and hyperstimulation. The data of oxytocin administration in each study were extracted only after study agent removal. The methodological quality of the included studies was assessed according to the criteria specified by the Cochrane Collaboration [5].

Statistical analysis

We performed this study in accordance with the Statement of Preferred Reporting Items for Systematic Reviews and Meta-Analyzes [6]. The outcomes were pooled as estimate of the overall effect for the meta-analysis conducted using Review Manage, version 5.1.0 (The Cochrane Collaboration, 2011). For dichotomous variables, the risk ratio (RR) for each study was aggregated in Mantel–Haenszel method to obtain a pooled RR with a corresponding 95% confidence interval (CI). Analysis of continuous variables was done by calculating the mean difference (MD) with the corresponding 95% CI in inverse variance method. If studies reported continuous data as median and/or range values, the standard deviation was calculated using statistical algorithms by Hozo et al. [7]. All outcomes in this meta-analysis were assessed for clinical and statistical heterogeneity. Clinical heterogeneity was discussed when appropriate and possible. The Cochran's Q test and I^2 statistic were used to assess statistical heterogeneity among studies [8]. For Q test, $p < 0.1$ was considered to represent a significant difference. As we previously described [9], if there was a significant heterogeneity, the random effects model would be used; otherwise, the fixed-effect model would be chosen. Forest plots were constructed with $p < 0.05$ considered to be statistically significant. Publication bias was evaluated by constructing a funnel plot with visual assessment of asymmetry. If there was no bias, the plot should resemble a symmetrical inverted funnel. Conversely, an asymmetrical and skewed shape indicated the presence of bias.

Results

Trial flow

A total of 251 potential articles were identified from literature searches. After selection, six studies matched the inclusion criteria and were suitable for our meta-analysis [10–15]. The flow diagram in Figure S1 details the selection process. A total of 1453 subjects were analyzed, of which 722 (49.7%) received Foley catheter balloon and 731 (50.3%) dinoprostone insert. On review of the study selection and data extraction, there was excellent agreement between reviewers ($\kappa = 0.93$).

Study characteristics

The study characteristics are summarized in Table 1. There were no significant differences between two groups with respect to maternal age, body mass index, gestational age, and baseline Bishop score ($p > 0.05$). The balloon volumes in each study ranged from 30 mL to 80 mL, and the maximal time from study agent placement to removal varied between 12 h and 48 h. Foley catheter was used for mechanical labor induction in five studies [10,11,13–15], while a double balloon catheter was applied in one study by Cromi et al. [12]. The methodological quality assessment based on the Cochrane risk of bias was presented in Table S1. Overall, the studies included in our analysis were of moderate quality.

Cesarean section

All studies in our analysis reported the data regarding cesarean section. When six studies were pooled, 193

Table 1. Characteristics of the studies.

Study	Year	Country	Study design	Study interval	Foley catheter *n* (mL/h)	Dinoprostone *n* (mg/h)	Inclusion criteria	Primary outcome
Cromi et al. [10]	2011	Italy	Single-center RCT	2008–2010	133 (50/24)	132 (10/24)	GA $\geq$ 34 wk, singleton gestation, vertex presentation, intact membranes, unfavorable cervix (Bishop score $\leq$6), and reassuring fetal heart tracing on admission	Vaginal delivery within 24 h
Zheng et al. [11]	2011	China	Single-center RCT	2009	64 (80/24)	62 (10/24)	Singleton term pregnancy, vertex presentation, intact membranes, unfavorable cervix (Bishop score $<$ 6), and medically indicated for labor induction	Undefined
Cromi et al. [12]	2012	Italy	Single-center RCT	2010–2011	105 (50, 50/12)	103 (10/24)	GA $\geq$ 34 wk, singleton gestation, vertex presentation, intact membranes, unfavorable cervix (Bishop score $\leq$6), and reassuring fetal heart tracing on admission	Vaginal delivery within 24 h
Wang et al. [13]	2012	China	Single-center RCT	2010	128 (80/24)	124 (10/24)	Singleton term pregnancy, vertex presentation, intact membranes, unfavorable cervix (Bishop score $<$ 6), and medically indicated for labor induction	Undefined
Jozwiak et al. [14]	2013	Netherlands	Multi-center RCT	2009–2010	107 (30/48, twice)	119 (10/24)	Singleton term pregnancy, vertex presentation, intact membranes, unfavorable cervix (Bishop score $<$ 6), and no prior cesarean section	Cesarean section rate
Edwards et al. [15]	2014	USA	Multi-center RCT	2010–2013	185 (30/12)	191 (10/12)	GA $\geq$ 36 wk, singleton gestation, vertex presentation, intact membranes, unfavorable cervix (dilation less than 3 cm; if 2 cm, less than 80% effaced), and no contraindication to labor or either study agent	Time from induction to delivery

RCT, randomized controlled trial; GA, gestation age.

(26.9%) patients in Foley catheter group and 207 (28.5%) in dinoprostone insert group experienced cesarean section. Due to the non-significant heterogeneity across studies ($p = 0.47$, $I^2 = 0\%$), fixed-effect model was used. The meta-analysis showed that there was no significant difference in cesarean section rate between two groups (RR 0.94, 95% CI 0.80–1.12, $p = 0.50$) (Figure 1).

Vaginal delivery within 24 h

Five included studies [10–13,15] provided the information about vaginal delivery within 24 h. Overall, 236 (38.4%) women in Foley catheter group and 277 (45.3%) in dinoprostone insert group achieved vaginal delivery within 24 h. Random effects model was applied due to the significant heterogeneity among studies ($p < 0.01$, $I^2 = 94\%$). Our pooling results revealed no significant difference in this outcome between two groups (RR 0.75, 95% CI 0.43–1.30, $p = 0.31$) (Figure 2).

Time from induction to delivery

Data of induction to delivery interval were described in five studies [10–14]. There was a significant heterogeneity among studies ($p < 0.01$, $I^2 = 95\%$). Meta-analysis on random effects model showed that time from induction to delivery was significantly shorter in dinoprostone insert group compared with Foley catheter group (MD 5.73 h, 95% CI 1.26–10.20, $p = 0.01$) (Figure 3).

Secondary outcomes

Our meta-analysis found that improvement in Bishop score was significantly greater in patients receiving dinoprostone insert (MD −0.89, 95% CI −1.12 to −0.67, $p < 0.01$), and that oxytocin was administrated less frequently when dinoprostone insert was used than when Foley catheter was applied for cervical ripening (RR 1.86, 95% CI 1.25–2.77, $p < 0.01$). However, there was a significantly increased risk of excessive uterine activity in dinoprostone insert group (RR 0.07, 95% CI 0.03–0.19, $p < 0.01$). No significant differences were observed between two groups with respect to epidural analgesia (RR 1.24, 95% CI 0.94–1.63, $p = 0.13$), or meconium staining (RR 0.92, 95% CI 0.63–1.34, $p = 0.65$). There were also no significant differences between the groups for neonatal outcomes (birth weight, 5-min Apgar score < 7, umbilical artery blood pH < 7, and admission to the neonatal intensive care unit) (Table 2).

Publication bias

The funnel plot, constructed on the basis of cesarean section rate, indicated no publication bias (Figure S2).

Discussion

The results of our meta-analysis suggest that induction of labor with controlled-release dinoprostone insert is associated with reduced time to delivery and oxytocin use, but with increased risk of excessive uterine activity when compared to

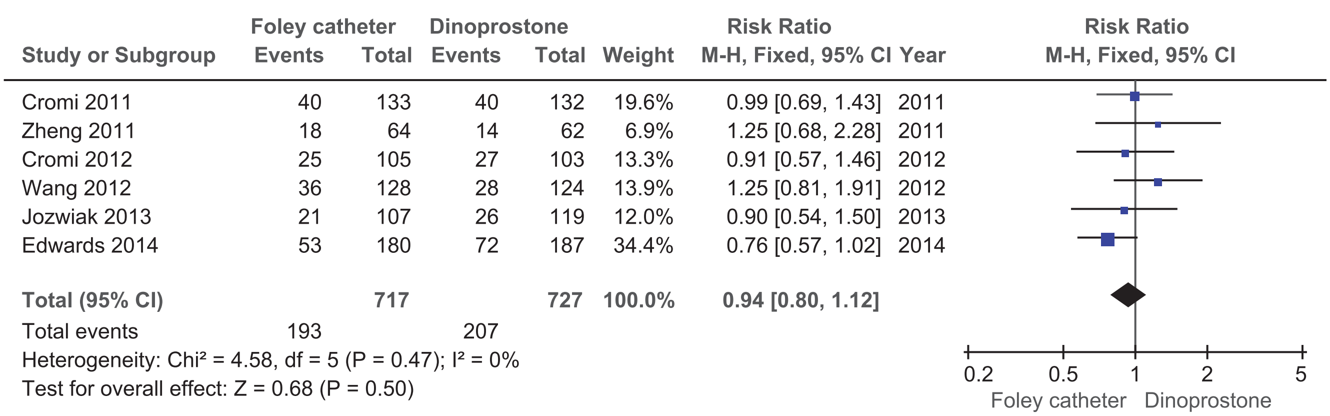
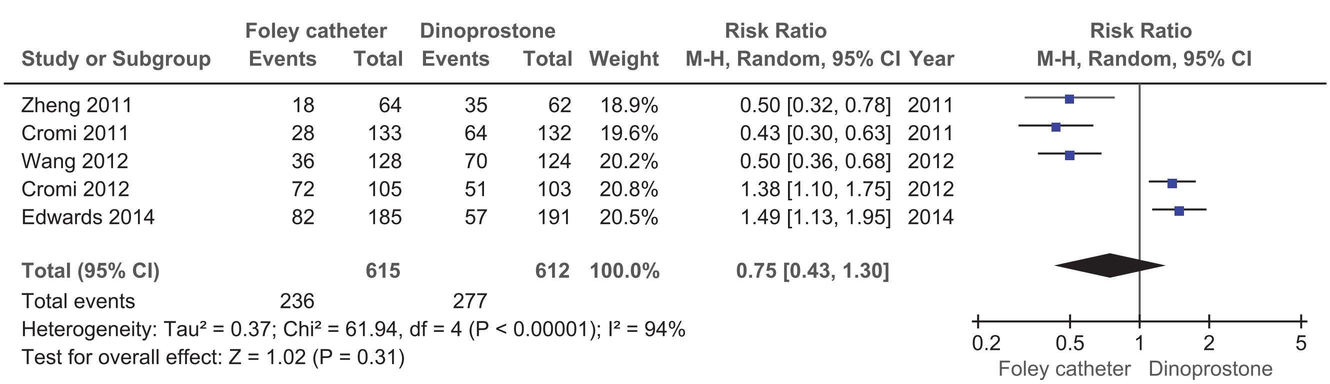


Figure 1. Forest plot of cesarean section rate.



induction of labor with Foley catheter balloon. The two methods were comparable in terms of cesarean section rate, vaginal delivery within 24 h, and neonatal outcomes.

When pregnant women are interviewed as to their expectations regarding childbirth, one of the main hopes for their labor is short duration [16]. A questionnaire-based study assessing how women perceived their birth experience in the setting of labor induction suggested that a long time delay between the start of the induction and the delivery played a significant role in patient dissatisfaction with the birth process [17]. In addition, a lengthy labor is directly associated with increased risks of maternal chorioamnionitis, postpartum fever, and neonatal infection [18,19]. Therefore, the time for cervical ripening should be taken into consideration when a method for induction of labor is chosen. A recent meta-analysis comparing Foley catheter balloon with locally applied prostaglandins for cervical ripening showed no difference in induction to delivery interval between two groups [20]. Similar results were observed in two of the included studies of this analysis [12,14]. In contrast, Suffecool et al. [21] declared that induction of labor with the double-balloon catheter was associated with a shorter time to delivery compared to dinoprostone insert. It has to be mentioned that in that study there was a confounding factor because oxytocin infusion was started 6 h after placement of the catheter. Of the included studies, one by Edwards et al. [15] also declared that cervical ripening with Foley catheter had a shorter time to delivery. However, three included studies [10,11,13] in this analysis reported that a shorter time from induction to delivery was found in dinoprostone insert group. Our pooling results showed a mean reduction of 5.73 h in induction to delivery interval for ripening with insert, which indicates that dinoprostone insert is more effective than Foley catheter for labor induction. With regard to vaginal delivery that was achieved in 24 h, three studies [10,11,13] in our analysis were in favor of dinoprostone insert, whereas two [12,15] in favor of Foley catheter. Our results of meta-analysis revealed no statistically significant difference between groups, but a trend in favor of dinoprostone insert (45.3% versus 38.4%), which implies a potential superiority over Foley catheter.

The effectiveness and the safety are equally important factors when evaluating a cervical ripening method. Therefore, an ideal ripening agent should offer the best balance of these two factors, with minimal side effects. It is believed that the rate of cesarean section occurred while the ripening agent is *in situ* might be the most objective indication of the treatment safety [10]. A recent meta-analysis comparing intra-vaginal misoprostol versus Foley catheter for labor induction observed no difference in cesarean delivery rate [22]. Also, the largest RCT by Jozwiak et al. [23] found that use of a Foley catheter resulted in a comparable cesarean section rate when compared with the use of prostaglandin E2 gel. Our meta-analysis showed similar finding, indicating that ripening with dinoprostone insert could shorten time to delivery without increasing cesarean delivery rate compared to ripening with Foley catheter.

It is noted that the largest trial by Jozwiak et al. [23] recorded two serious adverse events in the prostaglandin E2 gel group (one uterine perforation and one uterine rupture). In the present analysis, we observed no serious maternal and neonatal adverse events in either of the two groups. Nevertheless, our study simultaneously showed that use of

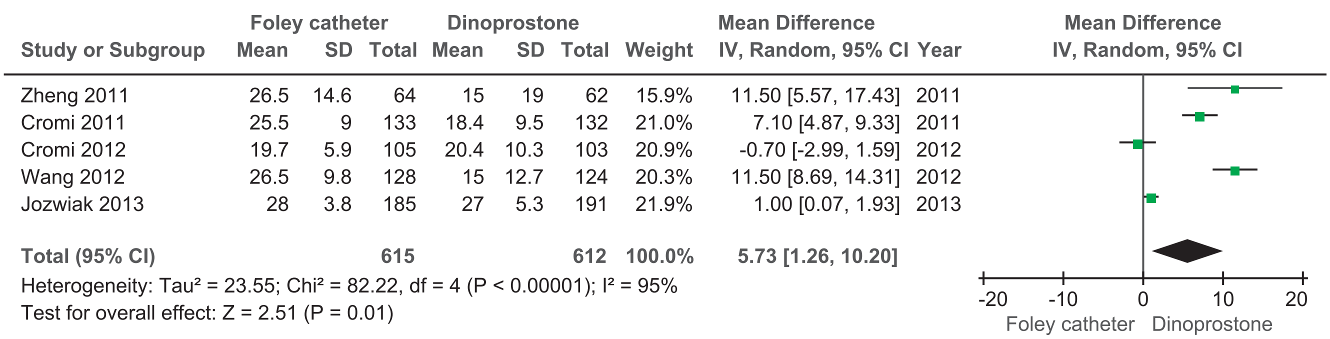


Figure 3. Forest plot of time from induction to delivery.

Table 2. Summary of secondary outcomes of meta-analysis.

Outcome	No. of studies	Participants FC	Participants DI	Heterogeneity	Overall effect size	95% CI	p
Improvement in Bishop score	4 [10–13]	430	421	$p = 0.66$, $I^2 = 0\%$	MD −0.89	−1.12, −0.67	<0.01
Excessive uterine activity	6 [10–15]	722	731	$p = 0.13$, $I^2 = 42\%$	RR 0.07	0.03, 0.19	<0.01
Oxytocin administration	6 [10–15]	722	731	$p < 0.01$, $I^2 = 97\%$	RR 1.86	1.25, 2.77	<0.01
Epidural analgesia	4 [10,12,14,15]	530	545	$p < 0.01$, $I^2 = 90\%$	RR 1.24	0.94, 1.63	0.13
Meconium-stained fluid	3 [11,13,15]	377	377	$p = 0.25$, $I^2 = 28\%$	RR 0.92	0.63, 1.34	0.65
Birth weight (g)	5 [10–13,15]	615	612	$p = 0.56$, $I^2 = 0\%$	MD −36.71	−82.05, 8.62	0.11
5-min Apgar score <7	6 [10–15]	722	731	$p = 0.67$, $I^2 = 0\%$	RR 0.77	0.31, 1.90	0.57
Umbilical artery blood pH <7	4 [10,12,14,15]	530	545	$p = 0.54$, $I^2 = 0\%$	RR 1.25	0.38, 4.11	0.72
NICU admission	4 [10,12,14,15]	530	545	$p = 0.61$, $I^2 = 0\%$	RR 0.88	0.61, 1.27	0.49

FC, Foley catheter; DI, dinoprostone insert; CI, confidence interval; MD, mean difference; RR, risk ratio; NICU, neonatal intensive care unit.

dinoprostone insert could increase the rate of uterine contraction abnormalities, along with reduced oxytocin use. This is in concordance with other studies that was designed to assess the effectiveness and the safety between mechanical methods and other preparations of prostaglandin [2,20,22,23].

It is reported that uterine contractions become apparent after the first hour of prostaglandin E2 administration [24]. Consequently, the phases of cervical ripening and start of labor often occur simultaneously after the use of prostaglandins. In contrast, Foley catheters ripen the cervix with little uterine activity, and most deliveries initiate only after a formal process of induction is begun [10]. The increased rate of oxytocin use in catheter group may reflect the different nature of two ripening agents, which might partially explain why ripening with dinoprostone insert in this analysis needed shorter time to delivery compared to ripening with Foley catheter. However, owing to the frequent occurrence of uterine contractions, widespread applications of dinoprostone insert are often restricted. On the contrary, ripening with a Foley catheter that causes rare uterine contraction, is associated with less pain [25], and could be a good alternative for women with a previous cesarean birth requiring labor induction [26].

Further advantages of Foley catheter involve easy storage and low cost. We did not perform cost-effectiveness analysis of ripening methods because of the limited studies focusing on this issue. However, we presume that savings in oxytocin use, manpower and ancillary expenses that are associated with shortened time spent in labor may counterbalance the high cost of dinoprostone insert.

There are some limitations in our analysis, which deserve discussion. First, we observed considerable heterogeneity between the analyzed studies. Clinical heterogeneities principally include the experience of study agent placement, the types of catheter, the volumes of balloon after inflation, the maximal times from study agent placement to removal, and the inclusion/exclusion criteria in each study. We did not perform subgroup analysis for these heterogeneities because of the limited studies in this analysis. There are evidences that a higher volume Foley (60 or 80 ml) is more effective than one of 30 ml [27,28], and that a 24-h Foley catheter is less effective than a 12-h Foley catheter [10]. One of the included studies compared dinoprostone insert with double-balloon catheter rather than Foley catheter for induction of labor [12]. In view of the previous findings that these two catheters used for cervical ripening were comparable in effectiveness and side effects [25,29], we decided to include this study in our meta-analysis. Despite the clinical heterogeneities mentioned above, we still observed balanced groups when we compared interstudy baseline population characteristics. Statistical heterogeneities among studies were significant, and could not be eliminated by sensitivity analysis. As a result, most pooled outcome measures were determined using a random effects model, which has taken those heterogeneities into account. Second, in this analysis we selected the eligible studies only from those published in English or Chinese language, which might introduce publication bias. However, this bias is not supported by the funnel plot.

In conclusion, our meta-analysis shows that induction of labor with controlled-release dinoprostone insert seems to be more effective when compared to induction of labor with Foley catheter. However, the dinoprostone insert causes excessive uterine contraction more frequently.

Declaration of interest

The authors report no declarations of interest.

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Supplementary material available online