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REVIEW

Double-balloon catheter versus dinoprostone insert for labour induction: a meta-analysis

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Abstract

Objective To assess the efficacy and safety of a double-balloon catheter versus dinoprostone insert for labour induction.

Study design PubMed, MEDLINE, Embase, ClinicalTrials.gov, and the Cochrane Central Register of Clinical Trials databases were searched from 1985 to April 2018. Randomized controlled trials that compared a double-balloon catheter and dinoprostone insert for cervical ripening were identified. Eligible study populations consisted of women with singleton pregnancies that had any indication for labour induction and were randomly assigned to undergo induction with a double-balloon catheter or dinoprostone insert. The main outcomes were incidence of vaginal delivery within 24 h and caesarean section, and neonatal outcomes.

Results Five randomized trials (603 women; 305 with a double-balloon catheter and 298 with a dinoprostone insert) were eligible for inclusion. No differences were observed between the two groups in terms of vaginal delivery within 24 h [relative risk (RR) 1.21, 95% confidence interval (CI) 0.93–1.59] and incidence of caesarean section (RR 0.99, 95% CI 0.77–1.27). Compared with the double-balloon catheter, the dinoprostone insert was associated with a reduced need for oxytocin administration in the process of labour induction (RR 1.95, 95% CI 1.45–2.62). However, there was a higher incidence of excessive uterine activity (RR 0.17, 95% CI 0.06–0.54) and neonatal umbilical cord arterial blood pH < 7.1 (RR 0.36, 95% CI 0.15–0.84) in the dinoprostone insert group.

Conclusion This review showed that the efficacy of labour induction using both the double-balloon catheter and dinoprostone insert was similar. However, the double-balloon catheter seemed to be a safer method.

Keywords Double-balloon catheter · Dinoprostone insert · Induction of labour · Meta-analysis

Introduction

Induction of labour is an increasingly common obstetric intervention [1]. The goal of labour induction is to achieve vaginal delivery by ripening the unfavourable cervix and promoting the spontaneous onset of labour without adverse effects for mother or neonate [2]. The unripe cervix is a major impediment faced by obstetricians.

Many methods have been used for labour induction, mainly including pharmacologic options or mechanical devices [3, 4]. However, the optimal method of cervical ripening is still unknown. Commonly used mechanical options include the standard Foley urinary catheter and specifically designed double-balloon catheter [5]. The catheter slowly dilates the cervix by introducing a small amount of fluid into the extra-amniotic space [6]. The insertion of a Foley catheter into the cervical canal is one of the more commonly used mechanical methods and its use dates back to the 1960s [7]. The technique is more cost-effective compared with other mechanical methods [5], and the balloon is inflated with 30–80 ml of sterile saline [6, 7]. However, most double-balloon catheters are filled with 80 ml in the uterine balloon and 80 ml in the vaginal balloon [8, 9], making it easier to quantify the technique for comparison with other methods. Pharmacological ripening agents include oxytocin, misoprostol, and prostaglandins delivered orally or vaginally [10]. Due to the rapidity and ease of removal when active labour is established, the controlled-release dinoprostone insert has become the preferred vehicle for delivering prostaglandin E2 [11]. Recent clinical trials have been designed to compare the efficacy and safety of the double-balloon catheter with

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the dinoprostone insert to determine the optimal method of labour induction [12–14]. However, there is still no consensus. Accordingly, we performed this meta-analysis of randomized controlled trials (RCTs) to compare the effectiveness and safety of the double-balloon catheter with the dinoprostone insert in women with an unripe cervix.

Materials and methods

Search strategy

We attempted to conform to PRISM guidelines in the report of this meta-analysis and aimed to identify all published peer-reviewed, randomized and quasi-randomized controlled trials that assessed the effects of labour induction by comparing the double-balloon catheter with the controlled-release dinoprostone insert.

A literature search was performed using PubMed, MEDLINE, Embase, and Cochrane Central Register of Clinical Trials databases from 1985 to April 2018. The free-text search terms ("double-balloon catheter" or "cervical ripening balloon" or "balloon dilatation") combined with ("dinoprostone" or "prostaglandins E2" or "prostaglandins" or "Propess") were used. Manual searches of bibliographies of all relevant trials and review articles were also performed. Differences of opinion were resolved after team discussion. Data were extracted using predesigned tables. The search was restricted to studies conducted in humans and published in English.

Study selection

Inclusion and exclusion criteria for study selection were predefined.

We included: (1) studies of singleton gestations in women admitted for cervical ripening; (2) reports of intervention comparing the double-balloon catheter and dinoprostone insert for labour induction; (3) RCT written reports, such as a journal publication, thesis, or monograph; (4) sufficient information after data extraction.

We excluded: (1) use of the Foley catheter as a substitute; (2) other form of dinoprostone, e.g., gel, tablet; (3) previous caesarean delivery; (4) case report; (6) absence of a control group; (7) inability to measure data synthesis.

Assessment of risk of bias

The risk of bias was evaluated according to the Cochrane Handbook guidelines for RCTs, which contained seven specific domains (random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and "other issues"). All included trials were classified as "low", "unclear", or "high" risk of bias according to the criteria.

Data collection

Only data eligible as per our inclusion criteria were collected. Recorded data variables were as follows: first author's name, year of publication, source of publication, country of origin, study design (factorial, parallel, crossover, other), type of blinding (open, double blind), number of intervention groups, intervention regimen, total number of individuals and number of incident cases for each treatment group, mean age in each group, baseline characteristics, duration of intervention, and funding source.

Statistical analysis

The principal summary measures were relative risk (RR) and mean difference (MD) with 95% confidence interval (CI) for measurement of the effect of the double-balloon catheter versus dinoprostone insert on labour induction. Heterogeneity among the studies was estimated using the Mantel–Haenszel Q statistics. Because such tests of heterogeneity were relatively insensitive, $p < 0.10$ was considered significant. If significant heterogeneity was not observed, then only the fixed-effects result was reported. Otherwise, a random-effects model was used.

As the characteristics and outcomes reported differed among studies in the meta-analysis, the analysis included trials without missing data. All analysis was performed with Cochrane software, Review Manager Version 5.3.

Results

A total of 179 reports were identified through the electronic searches. After title and/or abstract screening, a total of 162 trials were excluded. Only 17 reports appeared to be potentially relevant for the aim of this review. Of these, three trials were not randomized, five were excluded for prostaglandin gel or tablet, one for protocol, one for non-English, and two for second analysis. The flow diagram of the literature search for this systematic review is shown in Fig. 1.

Finally, five publications fulfilled our inclusion criteria and were analysed in this meta-analysis [12–16]. We restricted our analysis to a homogenous group of participants selected from the five trials. Methodological quality assessment was evaluated for each trial (Fig. 2). Two of five studies reported that the methods of randomization were unclear [15, 16]. However, these five studies did not clearly describe blinding of the participants or investigators.

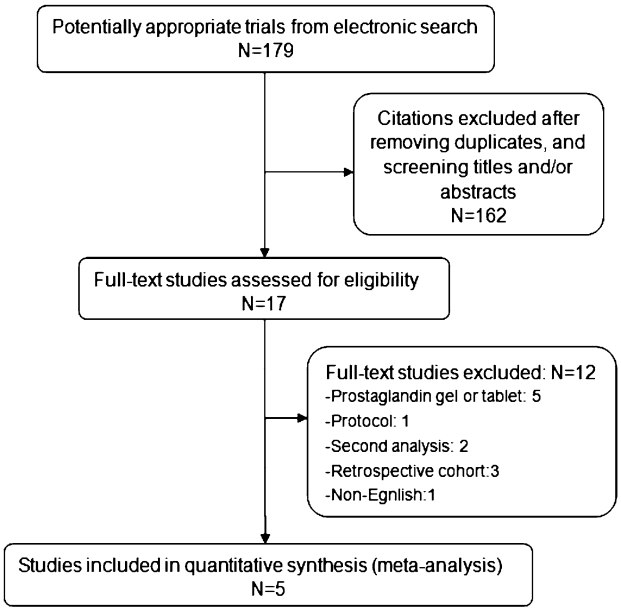

Fig. 1 Flow of information through the different phases of the review

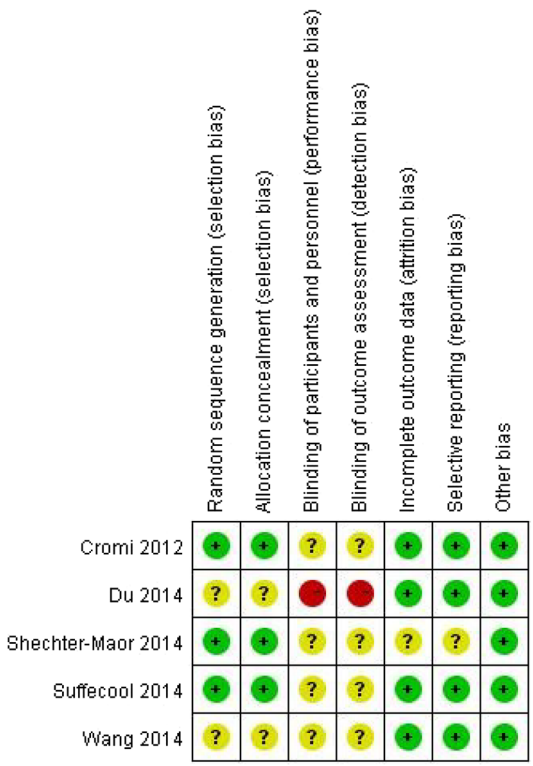

Fig. 2 Risk of bias summary: author judgements on each risk of bias item in each included study

The characteristics of the five eligible trials included in the meta-analysis are shown in Table 1. The sample size ranged from 26 to 105, with a total of 603 women. Of these five trials, one used a uterine and vaginal balloon that were both inflated with 50 ml of saline [12], one did not report the inflation volume [14], and the others used 80 ml of saline [13, 15, 16]. Meanwhile, all included articles used a 10-mg controlled-release dinoprostone vaginal insert.

Four of five studies reported the primary efficacy outcome of vaginal delivery within 24 h [12, 13, 15, 16]. Our meta-analysis showed a non-significant increase in the proportion of women who achieved vaginal delivery within 24 h in the double-balloon catheter group compared with those in the dinoprostone group (RR 1.21, 95% CI 0.93–1.59; Fig. 3). Oxytocin was administrated less frequently when the dinoprostone insert was used than when the double-balloon catheter was used for labour induction and augmentation (RR 1.95, 95% CI 1.45–2.62; Table 2). However, there was a significantly higher risk of excessive uterine activity in the dinoprostone insert group (RR 0.17, 95% CI 0.06–0.54). No statistical differences between the two groups were observed with respect to the rate of women who went into active labour (RR 0.92, 95% CI 0.74–1.15), total vaginal deliveries (RR 0.97, 95% CI 0.86–1.09), the need for assisted vaginal birth (RR 1.77, 95% CI 0.69–4.54), or the time to vaginal delivery (MD 0.24, 95% CI − 3.45–3.94).

For the primary safety outcome of incidence of caesarean section, our meta-analysis yielded a decreased proportion in the double-balloon catheter group, compared with the dinoprostone group, although it was statistically non-significant (RR 0.99, 95% CI 0.77–1.27; Fig. 4). We found no statistical differences between the two groups in terms of indications for caesarean section, including failed induction (RR 0.92, 95% CI 0.41–2.04), failure to progress (RR 1.75, 95% CI 0.65–4.70), and non-reassuring foetal heart rate tracing (RR 0.92, 95% CI 0.42–2.06).

Additionally, we found that the incidence of neonatal umbilical cord arterial blood pH < 7.1 was significantly higher in the dinoprostone group (RR 0.36, 95% CI 0.15–0.84). There were no significant differences between the two groups in the incidence of a 5-min Apgar score < 7, the rate of macrosomia, admission to the neonatal intensive care unit, and birth weight (Table 2).

Discussion

The differences in the incidence of caesarean section and vaginal delivery within 24 h between the two methods of labour induction were not significant. The results of our meta-analysis suggest that induction of labour with the controlled-release dinoprostone insert is associated with reduced oxytocin use, but with increased risk of excessive uterine activity when compared to induction of labour with the double-balloon catheter. Although the incidence of neonatal umbilical cord arterial blood pH < 7.1 was slightly

Table 1 Characteristics of included studies

Study	Inclusion criteria	Double-balloon catheter (dose)	Dinoprostone (dose)	Maternal age (year ± SD)
Cromi [12]	A singleton gestation Vertex presentation Bishop score ≤ 6 Intact membranes Gestation age ≥ 34 weeks Reassuring fetal heart tracing on admission	Cook cervical ripener balloon (50 ml/50 ml) *N* = 105	Controlled-release vaginal insert (10 mg) *N* = 103	DBC: 34 (19–42) D: 33(20–45) (range)
Du [15]	Same as Cromi [12] Except: Gestation age ≥ 37 weeks	Cook cervical ripener balloon (80 ml/80 ml) *N* = 76	Controlled-release vaginal insert (10 mg) *N* = 79	DBC: 28.45 ± 4.57 D: 27.33 ± 3.29
Shechter-maor [14]	Oligohydramnios Bishop score ≤ 6 A singleton, term gestation (≥ 37 weeks) Cephalic presentation Intact membranes	Cook cervical ripener balloon (not mentioned) *N* = 26	Times-release formulation PGE2 Propess (10 mg) *N* = 26	DBC: 28.5 (20–40) D: 28.5(18–39) (range)
Suffecool [13]	Nulliparous pregnant Older with term singleton gestations Vertex presentation Bishop score ≤ 6 Intact membranes	Cook cervical ripener balloon (80 ml/80 ml) *N* = 31	Controlled-release vaginal insert (10 mg) *N* = 31	DBC: 27.5 ± 6.4 D: 28 ± 7.1
Wang [16]	Same as Shechter-maor [14]	Cook medical (80 ml/80 ml) *N* = 67	Controlled-release vaginal insert (10 mg) *N* = 59	DBC: 27.9 ± 3.9 D: 27.8 ± 3.4

DBC double-balloon catheter, *D* dinoprostone, *SD* standard deviation

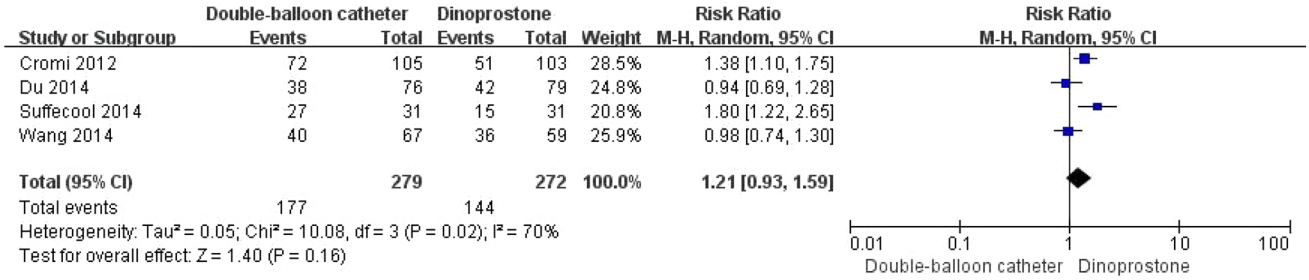

Fig. 3 Comparison of the rate of delivery within 24 h

higher in the dinoprostone insert group than in the double-balloon catheter group, there were no differences between the two groups in term of other neonatal outcomes, such as the 5-min Apgar score < 7, neonatal intensive care unit admission, and macrosomia.

Some limitations of this meta-analysis should be acknowledged. First, it was hard to blind participants or researchers to the type of intervention in these trials, as the use of transcervical double-balloon catheters and dinoprostone vaginal inserts required different preparations and actions by the clinicians. Therefore, no studies clearly described the methods of blinding. Furthermore, we found diversity across studies in the inclusion/exclusion criteria for participants (maternal age, gestational age, body mass index, gravidity, parity, baseline Bishop score, indication for labour induction, and existing pregnancy complication), volume of the double-balloon catheter, study design (indication for discontinuation of the catheter and pharmacological agent, time allowed for intervention, regimen of prostaglandin E2, induction protocol for oxytocin administration), definitions of measurements and outcomes (failed ripening, failed labour induction, failure to progress, active labour, hyperstimulation, etc.), and methodological quality of studies. We did find considerable heterogeneity in the primary efficacy outcome of vaginal deliveries in 24 h and in the secondary efficacy outcome of need for oxytocin augmentation, which demonstrated that the studies included were not sufficiently homogeneous to provide accurate pooled estimates. Despite

Table 2 Meta-analysis of outcome measures of studies comparing double-balloon catheter with dinoprostone insert

Outcome measures	Number of studies	Heterogeneity	Overall effect size	95% CI	*p*
Onset of active labor	3	$p=0.05$, $I^2=66\%$	RR 0.92	0.74, 1.15	0.48
Oxytocin administration	4	$p=0.03$, $I^2=67\%$	RR 1.95	1.45, 2.62	<0.01
Excessive uterine activity	2	$p=0.36$, $I^2=0\%$	RR 0.17	0.06, 0.54	0.002
Time to onset of active labor	3	$p<0.01$, $I^2=93\%$	MD −0.18	−6.74, 5.12	0.79
Time to vaginal delivery	4	$p=0.002$, $I^2=80\%$	MD 0.24	−3.45, 3.94	0.90
Time to delivery	2	$p=0.001$, $I^2=91\%$	MD −4.37	−11.91, 3.17	0.26
Vaginal-overall	4	$p=0.42$, $I^2=0\%$	RR 0.97	0.86, 1.09	0.64
Assisted vaginal delivery	4	$p=0.24$, $I^2=29\%$	RR 1.77	0.69, 4.54	0.24
Indications for cesacrean delivery					
Fetal distress	4	$p=0.06$, $I^2=61\%$	RR 0.92	0.42, 2.06	0.81
Failed induction	3	$p=0.26$, $I^2=26\%$	RR 0.91	0.41, 2.04	0.83
Failure to progress	4	$p=0.04$, $I^2=64\%$	RR 1.75	0.65, 4.70	0.27
Neonatal outcomes					
Birth weight	4	$p=0.38$, $I^2=2\%$	MD 24.62	−53.45, 100.68	0.54
Macrosomia	2	$p=0.51$, $I^2=0\%$	RR 1.53	0.69, 3.41	0.30
5-min Apgar score < 7	4	$p=0.47$, $I^2=0\%$	RR 0.77	0.21, 2.82	0.70
Umbilical artery blood pH < 7.1	3	$p=0.24$, $I^2=39\%$	RR 0.32	0.15, 0.84	0.02
NICU admission	3	$p=0.35$, $I^2=4\%$	RR 0.95	0.51, 1.77	0.87

CI confidence interval, *MD* mean difference, *RR* risk ratio, *NICU* neonatal intensive care unit

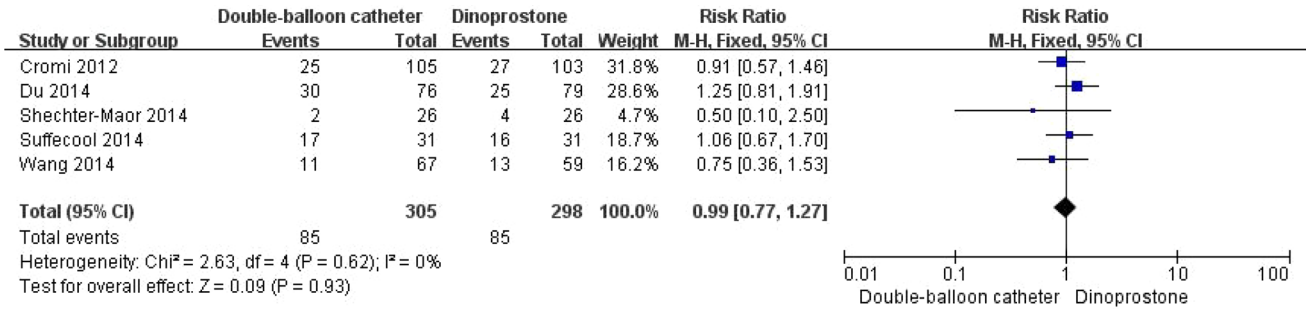

Fig. 4 Comparison of the indications for caesarean section

the heterogeneity, the random-effects model (in which each study is regarded as estimating a different effect) that was used did not show differences in the pooled estimated outcomes with sequential removal of any specific study. In addition, we did not conduct an intention-to-treat analysis because there was a lack of outcome data for patients who were excluded after randomization before initiation of treatment and for participants who did not receive prespecified intervention in a large number of studies. Other limitations were that we restricted our search sources to English-language studies and excluded results that were published in any other language or if only abstracts were available.

Although our study was strictly confined to randomized trials with consistent results and minimal heterogeneity, the sample size of the trials included in this analysis was not very large, and the results were more likely affected by the trials with larger sample sizes. Only two of five reported the rate of uterine hyperstimulation, but none described the definition of excessive uterine activity and the time of occurrence before or after oxytocin infusion [15, 16]. Therefore, it was hard to judge these two methods of labour induction according to this factor. The relative paucity of data indicates that there is an urgent need to conduct further high-quality studies focusing on comparisons of methods of labour induction.

Conclusion

Based on a limited number of RCTs, we found no significant differences in cervical ripening between use of the double-balloon catheter and dinoprostone insert. Large and well-designed studies are needed in future to confirm the effect of the two methods on labour induction. However, the dinoprostone insert group in our meta-analysis was associated with a higher incidence of excessive uterine activity and neonatal umbilical cord arterial blood pH < 7.1. Therefore, the induction of labour with the double-balloon catheter seems to be safer.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no confict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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