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Systematic review

Double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction: a systematic review and meta-analysis of randomised controlled trials

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Background Induction of labour has become an increasingly common procedure. Ripening methods, including mechanical devices and pharmacological agents, improve the success rate of labour induction.

Objective To compare the efficacy and safety of the double-balloon catheter with prostaglandin E2 agents used for labour induction.

Search strategy We searched electronic sources from MEDLINE, Embase and Web of Science, the Cochrane Library Database of Systematic Reviews, and ClinicalTrials.gov website.

Selection criteria Only randomised controlled trials comparing the PGE2 agents with the double-balloon catheter for cervical ripening and labour induction in women with unfavourable cervices were included in the analysis.

Data collection and analysis The main outcomes included the vaginal delivery rate within 24 hours and risk of caesarean section. We calculated relative risks and mean differences using fixed- and random-effects models.

Main results Nine studies (1866 patients) were included in this systematic review. Both the double-balloon catheter and PGE2 agents were comparable with regard to rate of caesarean section (RR 0.92; 95% CI 0.79, 1.07), vaginal delivery within 24 hours (RR 0.95; 95% CI 0.78, 1.16) and maternal adverse events, but the risk of excessive uterine activity (RR 10.02; 95% CI 3.99, 25.17) and need for neonatal intensive care unit admissions (RR 1.31; 95% CI 1.01, 1.69) were significantly increased in women who received PGE2 agents.

Conclusions The double-balloon catheter demonstrated greater safety and cost-effectiveness than PGE2 agents for cervical ripening and labour induction. The efficacy profiles of both methods were similar.

Keywords Cervical ripening, double-balloon catheter, induction of labour, prostaglandin E2.

Tweetable abstract Double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction

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Introduction

Induction of labour is an increasingly common procedure and more than 22% (roughly one of five) of all pregnant women had their labour induced.[1] The goal of labour induction is to achieve vaginal delivery by ripening the cervix and stimulating uterine contractions before the spontaneous onset of labour.

The unripe cervix is a major impediment to the success of labour induction and vaginal delivery.[2,3] To maximise the success rate, various ripening methods are available, including mechanical devices and pharmacological options. A mechanical device was first described with laminaria tents; more recently, the standard Foley urinary catheter, as well as a specifically designed double-balloon catheter, has also been used successfully.[4,5] The catheter is introduced through the cervical canal to reach the extra-amniotic space and then inflated to modify the cervical status and to keep the catheter in place. Regarding pharmacological methods, prostaglandin E2 (PGE2) administered intracervically or intravaginally has been demonstrated to be an effective ripening agent.

Recent clinical trials comparing the safety and efficacy profile of the double-balloon catheter with various forms of prostaglandin E2 agents, mainly vaginal and intracervical gels, vaginal tablets and dinoprostone vaginal inserts, demonstrated that the double-balloon catheter was associated with fewer episodes of uterine hyperstimulation, without modifying the incidence of caesarean section or vaginal delivery within 24 hours.[6–9] Given the frequency of labour induction and the growing body of research regarding the optimal method of cervical ripening, the knowledge of even small differences between induction methods could be useful to guide clinical practices. The present meta-analysis of randomised controlled trials was conducted to compare the effectiveness and safety profile of the mechanical method of a double-balloon catheter with the locally applied PGE2 agents used for cervical ripening and labour induction.

Methods

Data sources and search strategy

This review was performed and reported in accordance with the preferred reporting items in systematic review and meta-analysis (PRISMA).[10]

We searched several electronic sources from inception to June 2015: MEDLINE, Embase and Web of Science. Medical subject headings and free word combinations using Boolean logic of the following search items were used: induction of labour, cervical ripening, double-balloon catheter, and prostaglandin E2 (Appendix S1). We also manually retrieved references of all relevant articles and review papers to locate additional studies. Experts were contacted for further studies and data. Additionally, the Cochrane Library Database of Systematic Reviews and ClinicalTrials.gov website were searched to identify additional ongoing or complete trials.

Institutional review board approval was not requested because this is a systematic review and meta-analysis based on published studies and no new subjects were recruited.

Study selection and data extraction

Only randomised controlled trials appeared in English-language publications and those comparing the locally applied PGE2 agents versus the transcervical double-balloon catheter, with or without intravenous oxytocin for cervical ripening and induction of labour in women with unfavourable cervices in the third trimester of pregnancy were included in the analysis.

Inclusion criteria for the studies were singleton pregnancies with live fetuses in vertex presentation, intact membranes, and unfavourable cervices. We excluded studies in which the patients in the comparison groups also received other induction methods concurrently with the transcervical double-balloon catheter or locally applied PGE2 preparations, such as oxytocin, other prostaglandins. As both PGE2 agents and the double-balloon catheter were followed by oxytocin administration in labour process at many institutions as a routine induction procedure, we did not exclude studies in which oxytocin was given after the double-balloon catheter was removed or after the last dose regimen of PGE2 agents. Additionally, for studies with more than two intervention groups, we only extracted data for the double-balloon catheter and PGE2 agent comparison groups. Studies were excluded if they appeared only as abstracts or the full texts could not be obtained after contacting with the authors.

Two reviewers (J.L.O., Y.M.D.) independently reviewed the full articles for final selection in accordance with inclusion/exclusion criteria. We developed a data extraction sheet, piloted it on randomly selected studies, and refined it appropriately. Two investigators (L.Y.Z., B.H.J.), who used the standardised data extraction sheet, extracted the following data independently: study characteristics (authors, years of publication, country), patient characteristics (including maternal age, gestational age, parity, Bishop score, indications for induction), induction methods (volume and placement time of the double-balloon catheter, PGE2 preparations and dosing regimen, oxytocin administration procedure), and treatment outcome measures.

We discussed all discrepancies and involved a third independent reviewer if the discrepancies could not be resolved.

Selection of outcomes

The outcome measures included in our meta-analysis presented the efficacy and safety profile of each intervention. The main outcomes, which were selected before we retrieved individual studies, included the rate of achieving vaginal delivery within 24 hours after the initiation of ripening and the proportion of patients who underwent caesarean section. We also included secondary outcomes with regard to efficacy of induction methods: ripening-to-delivery interval, interval time between beginning of the ripening and initiation of active labour, rate of vaginal delivery and assisted vaginal birth, proportion of patients who went into active labour during ripening process, need for oxytocin administration, and indications for caesarean section. In addition, there were some secondary safety outcomes: the incidence of excessive uterine activity (including uterine hyperstimulation, tachysystole, and hypertonus), neonatal outcomes (5-minute Apgar score of <7, umbilical artery blood PH <7.0, rate of admission to the neonatal intensive care unit, and birthweight).We also recorded the number of cases of maternal and neonatal adverse events: postpartum haemorrhage, placental abruption, amniotomy, regional anaesthesia, uterine atony, macrosomia, etc.

As some of the clinical outcome measures were not described specifically or were defined differently in various

studies, we depended on the definitions used by the authors of the studies. Not all studies evaluated each of the outcome measures; therefore, we included specific outcomes based on a various number of studies in our meta-analysis.

Quality assessment

Two independent investigators evaluated the methodological quality of included studies by assessing the risk of bias in accordance with the Cochrane collaboration's tool.[11] In brief, the risk of bias was assessed by answering the questions about the following features of studies with 'Yes' (low risk of bias), 'No' (high risk of bias) or 'Unclear' (lack of information or uncertainty over the potential bias): random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Blinding of participants was excluded from the risk of bias assessment since it was impossible in these trials. Possible sources of 'other bias' were determined by consensus of the investigators.

Statistical analysis

All statistical analyses were carried out using the Review Manager software package (REVMAN, version 5.3; The Nordic Cochrane Center, Copenhagen, Denmark). We calculated estimates of relative risks (RRs) and 95% confidence intervals (CIs) for dichotomous outcomes using fixed- and random-effects models. The mean differences (MDs) and 95% CIs were calculated for continuous variables. For studies that only reported medium and range time to delivery, the mean and standard deviation were calculated using a standard formula recommended by Cochrane Handbook.[11]

A random effect model was used whenever there was evidence of significant clinical heterogeneity. The heterogeneity of the estimates of RRs and MDs was examined by Cochrane's Q test. This was a chi-square test with the degrees of freedom equal to number of studies minus one, and it tested the null hypothesis that the within-study effect estimates were homogeneous across studies. The I^2 index was used to measure the extent of true heterogeneity and can be interpreted as the percentage of the total variability in a set of effect estimates that result from differences between studies. A probability value of <0.1 or an I^2 $>50\%$ indicated statistical differences in the analyses of heterogeneity.

To visually explore heterogeneity, we generated a Forest plot to demonstrate RRs, MDs and relative 95% CIs for individual studies. We performed subgroup analyses to investigate the potential sources of heterogeneity. Additionally, sensitivity analysis was conducted to assess the influence of each individual study on the pooled estimates and to evaluate whether the overall estimates were dominated by one single study.

Only three studies conducted an intention-to-treat (ITT) analysis. There was lack of outcome data for patients excluded from the relative intervention group in the remaining studies; therefore, our analyses were based on the patients who received the interventions as allocated by the study group.

Results

Study characteristics

Figure 1 summarised the identification and selection process. Of the 152 studies, nine articles were included in the systematic review and meta-analysis.[5–9,12–15] Details of the characteristics of the included individual studies are demonstrated in Table S1. A total of 1866 participants were enrolled in these trials, 887 of them in the locally applied PGE2 agents group and 846 in the mechanical method group. The number of women recruited in the PGE2 agents group ranged from 26 to 413, with comparison groups generally having a similar number.

The inclusion criteria varied across the records, some studies included only the primiparous,[8,13] whereas others recruited those who were primiparous or multiparous. Several studies excluded women with twin pregnancy, pre-eclampsia, oligohydramnios, or history of caesarean section;[5,7–9,12–14] others did not exclude them.[6] In addition, there were differences between studies with regard to the minimal gestational ages and maximal Bishop scores used for inclusion criteria. The values of gestational ages and Bishop scores were $\geq$34, $\geq$36 or $\geq$37 weeks and $\leq$4 or $\leq$6, respectively. Despite various differences in the inclusion and exclusion criteria, most of the studies recruited patients with a singleton pregnancy, vertex presentation, intact membranes and reassuring fetal heart rate tracing.

There were significant heterogeneity in terms of PGE2 preparations (intravaginal pessary, intravaginal tablet, intracervical or intravaginal gel), dosing regimens (0.5–12 mg), and volumes of the double-balloon catheter (50/50 ml, 80/80 ml, and 100/100 ml). In several studies, PGE2 agents were repeatedly given unless there was the onset of labour, non-reassuring fetal heart rate patterns, up to 12–24 hours, attaining a favourable Bishop score, or excessive uterine contractions. Removal of intravaginal pessary PGE2 occurred after rupture of amniotic membranes, onset of labour, or non-reassuring fetal heart rate (FHR) tracing. We found similarity points through studies in the timing of discontinuation of the double-balloon catheter: after it expelled spontaneously or a maximum of 12 hours' placement.

There were also considerable differences with regard to the guidelines for oxytocin administration in labour

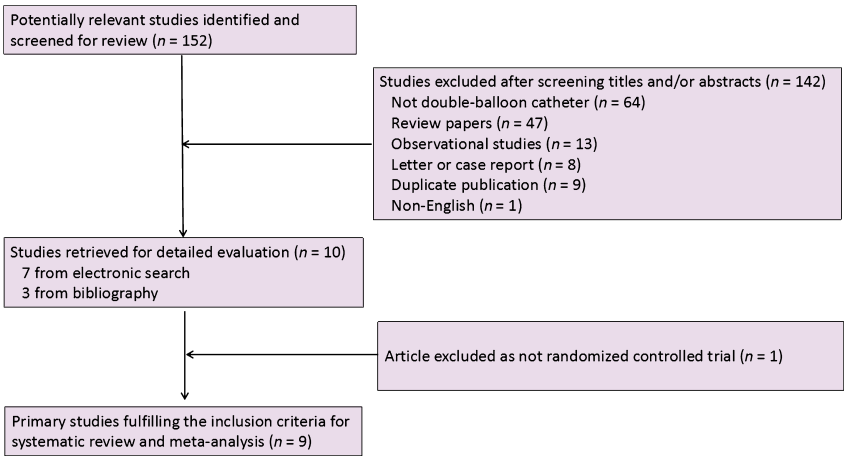

Figure 1. Flow diagram of reviewed articles.

induction and augmentation after cervical ripening had been achieved. The choice of primary outcomes significantly differed across the studies, and three of them did not state the main end points. The definitions of excessive uterine activity (hyperstimulation, tachysystole and hypertonus) were consistent for most of the studies. However, in some trials, the same outcomes had different descriptions partly because there was lack of standard definitions. For example, failed induction was defined as women who did not progress into active labour after 12 hours of oxytocin infusion, a second Bishop score of ≤4, amniotomy could not be performed 4 hours later after double-balloon catheter removal, or labour was not established within 48 hours after the first PGE2 administration; therefore, as could be expected, there was considerable heterogeneity in the study design and protocol.

Quality assessment

Overall, the methodological assessment of included studies was of good quality. Both random sequence generation and adequate allocation concealment were performed in four of nine studies.[6,9,13,14] Two studies[7,8] did not describe the method of randomisation clearly and three studies[5,12,15] did not adequately conduct the concealed allocation. Blinding of participants, personnel and outcome assessment were not likely to influence the outcomes of interest. Attrition and selective reporting bias was detailed in four trials.[8,12–14] The overall large proportion of studies with low risk of bias reflects the relatively high quality of the reporting.

Comparison results

For the primary efficacy outcome, our meta-analysis yielded a nonsignificantly decreased proportion of women who achieved vaginal delivery within 24 hours in the locally applied PGE2 arm (RR 0.95; 95% CI 0.78, 1.16; Figure 2) compared with the double-balloon catheter group. Use of locally applied PGE2 agents resulted in an increased rate in women who went into active labour during the ripening process (RR 1.62; 95% CI 1.28, 2.06; Table 1) and did not significantly shorten the interval of time between initiation of cervical ripening and active phase of labour (MD –0.26; 95% CI –3.45, 2.92), decrease the likelihood of failed ripening (RR 0.82; 95% CI 0.47, 1.41) or improve the Bishop score changes (MD 0.27; 95% CI –0.85, 1.40). Compared with the double-balloon catheters, PGE2 agents were associated with a reduced need for oxytocin administration in the process of labour induction and augmentation (RR 0.62; 95% CI 0.49, 0.78). No statistical differences between the two groups were noted with respect to the rate of women who achieved vaginal deliveries (RR 1.02; 95% CI 0.97, 1.08), the need for assisted vaginal births (RR 1.10; 95% CI 0.84, 1.45) or the interval of time between initiation of induction and delivery (MD 0.03; 95% CI –1.43, 1.50).

Eight of nine studies investigated the primary safety outcome of incidence of caesarean section, and the pooled data did not demonstrate a difference between the PGE2 agents and double-balloon catheter groups (RR 0.92; 95% CI 0.79, 1.07; Figure 2). We found no statistical differences between the two groups in terms of the indications for caesarean section, including failed induction and non-reassuring fetal heart rate patterns, but we found PGE2 agents did decrease the rate of failure to process (RR 0.64; 95% CI 0.43, 0.95), which caused the intervention of caesarean section.

Compared with mechanical methods, PGE2 agents resulted in a higher risk of excessive uterine activity (uterine hyperstimulation, tachysystole and hypertonus) with or without accompanied non-reassuring fetal heart rate patterns (RR 10.02; 95% CI 3.99, 25.17; Figure 3).

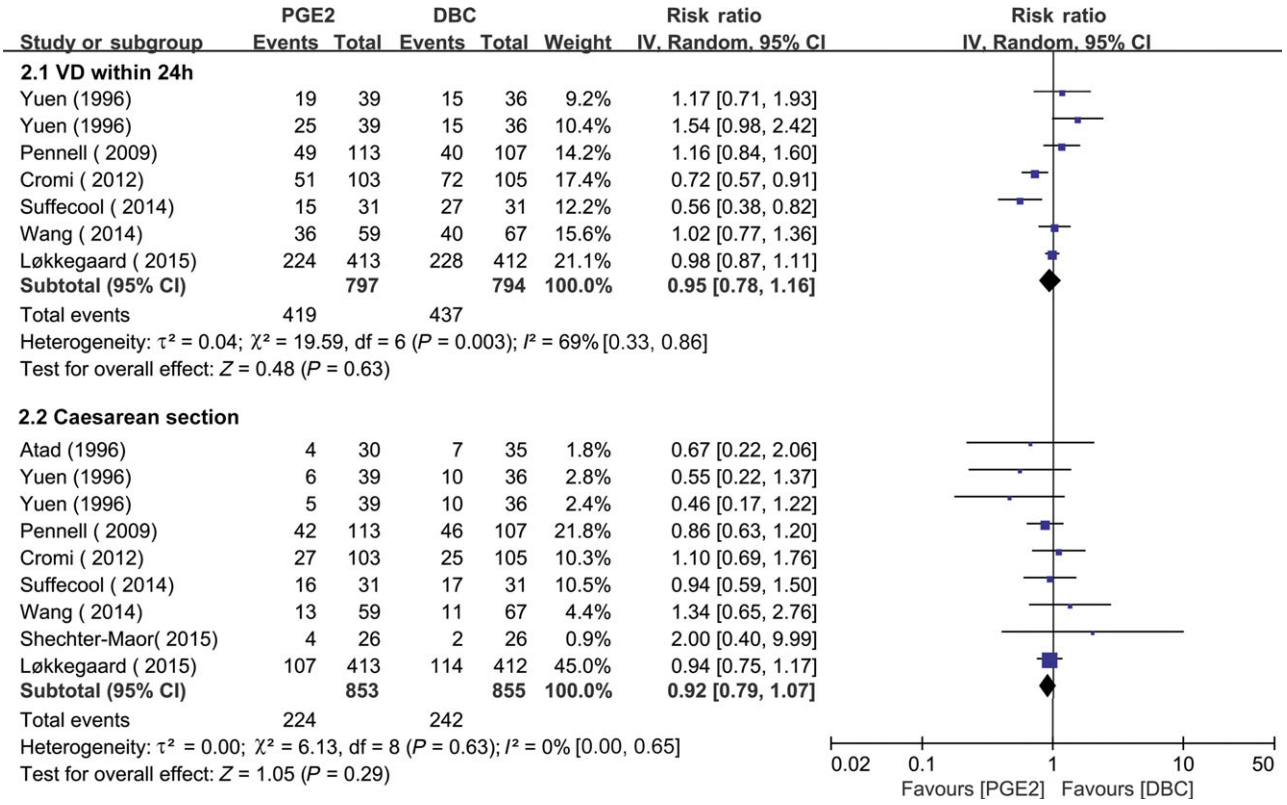

Figure 2. Forest plot showing the use of prostaglandin E2 (PGE2) agents versus the double-balloon catheter (DBC) for the cervical ripening and labour induction on the likelihood of (2.1) vaginal delivery (VD) within 24 hours and (2.2) caesarean section.

With respect to adverse maternal events, we recorded no significant difference with regard to placental abruption, vaginal bleeding during the ripening process, maternal fever, need for antibiotics, uterine atony, precipitous delivery, birth canal injury or re-hospitalisation.

Additionally, in studies investigating the pooled neonatal outcomes, we found cervical ripening and labour induction with PGE2 agents increased the risk of needing to be admitted to the neonatal intensive care unit (RR 1.31; 95% CI 1.01, 1.69; Figure 3). Cord blood gases were worse in the PGE2 agents group than in the comparison group with a lower umbilical artery blood pH. We also recorded that the incidence of neonatal umbilical artery blood pH <7.0 was higher in the PGE2 agents group (RR 2.80; 95% CI 1.19, 6.62). The incidence of a 5-minute Apgar score <7, the rate of macrosomia, newborn asphyxia, and birthweight difference were similar in the comparison groups.

Heterogeneity

No considerable heterogeneity was noted with respect to induction-to-delivery time, rate of active labour during ripening, rate of vaginal delivery, assisted vaginal delivery, caesarean section and failed induction, indications for caesarean section, uterine hyperstimulation, neonatal outcomes and need for local anaesthesia.

There was significant heterogeneity noted among studies for the rate of vaginal delivery within 24 hours, the time to active labour, need for oxytocin infusion, rate of any PPH, and incidence of amniotomy. Subgroup analyses based on patient characteristics did not result in significant improvement in heterogeneity.

Sensitivity analyses were performed by sequential omission of each study and analyses of the overall impact on the pooled results. The omission of any individual study did not change the outcomes for the important estimates that were analysed in this meta-analysis, except for the pooled outcome of NICU admission rate (Table S2).

Discussion

Main findings

This comprehensive meta-analysis compared the clinical efficacy and safety profile of transcervical double-balloon catheters (Atad Ripener Device or Cook Cervical Ripener Balloon) with locally applied PGE2 preparations (gels, tablets and pessaries) for cervical ripening and labour induction in women with unfavourable cervices during the

Table 1. Meta-analysis of outcome measures of studies comparing PGE2 agents with double-balloon catheter

Outcome measures	Studies (No. of participants)	PGE2 *n/N*	DBC *n/N*	Relative risk (95% CI)
Vaginal delivery	8 (1708)	630/853	619/855	1.02 (0.97, 1.08)
Active labour during ripening	3 (484)	110/240	70/244	1.62 (1.28, 2.06)
Assisted vaginal delivery	6 (1517)	94/764	83/753	1.10 (0.84, 1.45)
Failed ripening	4 (270)	36/133	45/137	0.82 (0.47, 1.41)
Oxytocin infusion	4 (1211)	224/601	343/610	0.62 (0.49, 0.78)
Indications for caesarean delivery				
Failed induction	4 (640)	14/325	22/315	0.62 (0.32, 1.19)
Failure to process	5 (766)	34/384	53/382	0.64 (0.43, 0.95)
Non-reassuring FHR	5 (766)	56/384	41/382	1.27 (0.85, 1.89)
Excessive uterine activity	6 (809)	46/401	3/408	10.02 (3.99, 25.17)
PPH >500 ml	2 (346)	49/172	42/174	1.10 (0.80, 1.53)
PPH >1000 ml	2 (428)	19/216	13/212	1.43 (0.72, 2.84)
Placental abruption	2 (346)	1/172	0/174	2.84 (0.12, 69.01)
Amniotomy	2 (951)	220/472	287/479	0.70 (0.48, 1.02)
Vaginal bleeding during ripening	1 (150)	1/78	0/72	2.77 (0.12, 66.02)
Maternal fever	1 (220)	20/113	18/107	1.05 (0.59, 1.88)
Antibiotics	1 (220)	19/113	26/107	0.69 (0.41, 1.17)
Uterine atony	1 (160)	3/78	2/72	1.38 (0.24, 8.05)
Precipitous delivery	1 (126)	3/59	1/67	3.41 (0.36, 31.87)
Birth canal injury	1 (126)	5/59	1/67	5.68 (0.68, 47.22)
Rehospitalisation	1 (220)	10/113	4/107	2.37 (0.77, 7.32)
Regional anaesthesia	2 (346)	114/139	112/133	0.97 (0.88, 1.08)
Neonatal outcomes				
5-minutes Apgar score <7	5 (1441)	8/719	5/722	1.44 (0.55, 3.77)
Macrosomia	3 (322)	10/160	14/162	0.73 (0.34, 1.58)
Umbilical artery blood PH <7.0	3 (484)	16/193	6/203	2.80 (1.19, 6.62)
Newborn asphyxia	2 (346)	4/172	5/174	0.86 (0.24, 3.08)

CI, confidence interval; DBC, double-balloon catheter; NICU, neonatal intensive care unit; PGE2, prostaglandin E2; PPH, postpartum haemorrhage.

third trimester of pregnancy. Our analyses demonstrated that both the double-balloon catheter and PGE2 agents were comparable with regard to rate of caesarean section, vaginal delivery within 24 hours and maternal adverse events, but the risk of excessive uterine activity and need for NICU admission were significantly increased in women who received PGE2 agents compared with the double-balloon catheter.

We have made a considerable effort to include all relevant randomised controlled trials and the validity of this meta-analysis is supported by the use of a comprehensive literature search, independent inclusion process and data extraction, and rigorous methodological quality assessment.

Strengths and limitations

Some limitations of this meta-analysis should be acknowledged. First, it was not possible to blind participants or researchers to the type of intervention in these trials, as the intervention of transcervical double-balloon catheters and various preparations of locally applied PGE2 agents required different actions by the attendants or clinicians. Therefore, there was potential bias that might be introduced by the awareness of ripening methods. Furthermore, we found diversities across studies in the inclusion/exclusion criteria of participants (maternal age, gestational age, body mass index, gravidity, parity, baseline Bishop score, indication for labour induction, history of caesarean section, and existing pregnancy complication), PGE2 preparation and dosage, volume of the double-balloon catheter, study design and protocol (indication for discontinuation of the catheter and pharmacological agent, time allowed for intervention, regimen of PGE2, induction protocol for oxytocin administration), definitions of measurements and outcomes (failed ripening, failed labour induction, failure to process, active labour, hyperstimulation, tachysystole, etc.), and methodological quality of studies. We did find considerable heterogeneity in the primary efficacy outcome of vaginal deliveries in 24 hours and in the secondary efficacy outcomes of need for oxytocin augmentation and induction, which demonstrated that the studies included in consideration were not sufficiently homogeneous to provide that accurate pooled estimates. Despite the heterogeneity, the random effects model (in which each study is regarded as estimating a different effect) that was used did

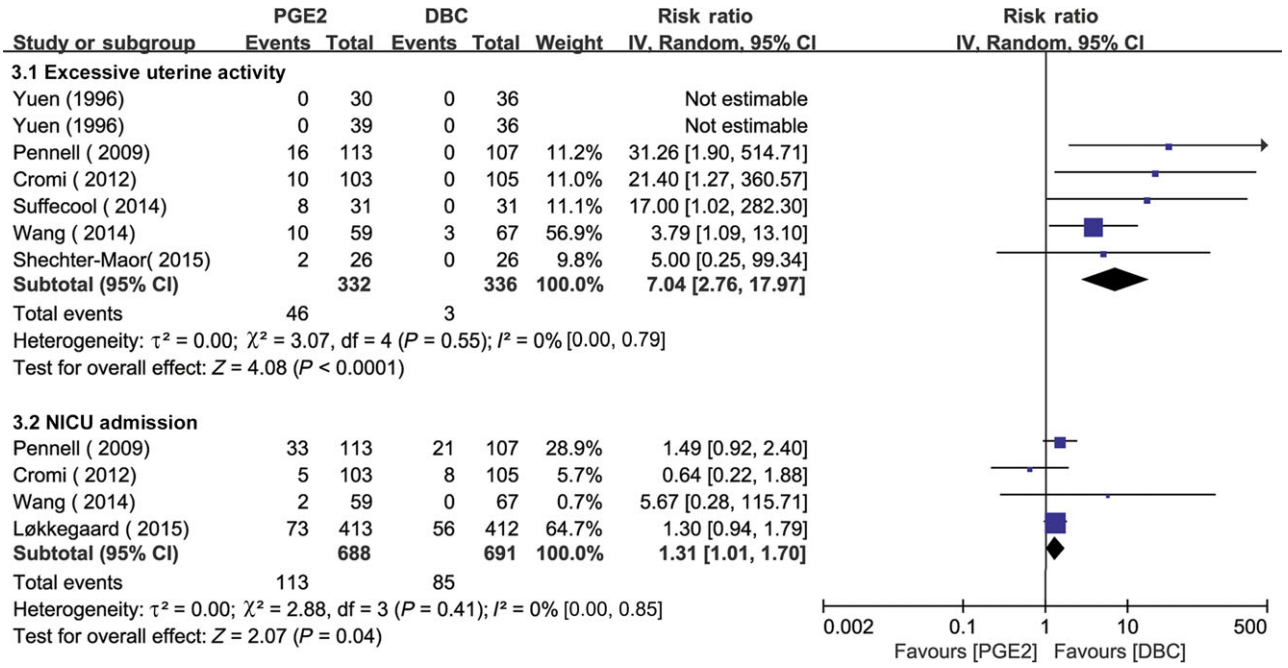

Figure 3. Forest plot showing the use of prostaglandin E2 (PGE2) agents versus the double-balloon catheter (DBC) for the cervical ripening and labour induction on the likelihood of (3.1) excessive uterine activity and (3.2) neonatal intensive care unit (NICU) admission.

not find differences in 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 randomisation 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 appeared in non-English languages or only in abstracts.

Interpretation

A Cochrane review in 2012 comparing all forms of prostaglandins with various mechanical dilations (including Atad and Foley catheters) demonstrated that mechanical methods resulted in similar caesarean section rates and a lower risk of hyperstimulation, and did not increase the overall number of women not delivered within 24 hours.[16] In this meta-analysis, we included both data from the four studies[5,8,9,15] that had been cited by that Cochrane review and data from five additional studies[6,7,12–14] on the comparison of the double-balloon catheter with PGE2 agents; all of the five studies were published after the Cochrane review analysis. The Cochrane meta-analysis conducted comparisons of Atad and Foley catheters with various prostaglandins (intracervical or intravaginal PGE2, and oral or vaginal misoprostol), as the Foley catheter and double-balloon catheter were relatively similar interventions for cervical ripening and labour induction. Salim et al. who compared the double-balloon catheter with the Foley catheter, reported that both catheters were equally efficacious for labour induction.[17] However, they also found that an increased number of adverse events and more operative deliveries were caused by the double-balloon catheter. In contrast, the findings from Hoppe et al.[18] suggested that the double-balloon catheter was more effective than single-balloon catheter for pre-induction cervical ripening and achieving vaginal delivery. Therefore, comparisons in terms of efficacy and safety between the two types of catheters still need to be confirmed in more randomised trials, and we could not simply consider the two mechanical methods as similar interventions, and the pooled outcome data about them should be interpreted cautiously. In this meta-analysis, we focused on the comparison between the double-balloon catheter and locally applied PGE2 agent to supply direct clinical recommendations to guide institutional induction protocol.

All prostaglandins, including PGE2 agents, even in low doses, are known to cause uterine rupture with possible catastrophic consequences due to their high risk of uterine hyperstimulation, particularly in women with a history of caesarean section or previous uterine surgery.[19] In this meta-analysis we note that the double-balloon catheter is associated with a significantly reduced risk of excessive uterine activity and this mechanical method is especially advantageous for patients in whom uterine

hyperstimulation should be avoided, such as those with intrauterine growth restriction, pre-eclampsia, oligohydramnios, post-term pregnancy, and chronic diseases. In these women with varying degrees of placental insufficiency, the reduction in risk of hyperstimulation may lead to a lower rate of caesarean section for non-reassuring fetal heart patterns, decreased incidence in fetal acidaemia, and reduced risk of NICU admission. Trials included in this meta-analysis recruited women with or without a history of caesarean section or previous uterine surgery, and we noted no detailed data for the subgroup of women with a history of caesarean section. Mechanical methods may theoretically have the potential to reduce the risk of uterine rupture, due to the lower risk of hyperstimulation compared with PGE2 agents. More studies are warranted to assess the potential benefits of this induction method in women with history of caesarean section.

Data on patient overall satisfaction and discomfort associated with the double-balloon catheter and PGE2 agents are sparse. Only two studies reported on patients' satisfaction and discomfort associated with insertion of cervical ripening devices and labour induction process, both consistently demonstrating that women in the double-balloon catheter group experienced more discomfort with insertion but less pain during the entire ripening phase compared with those receiving PGE2 agents.[8,12] These disparities did not translate into a significant difference. Suffecool et al.[8] and Pennell et al.[13] compared the cost-effectiveness of the mechanical method of double-balloon catheter with that of PGE2 preparations and found that the cost of double-balloon catheters was significantly lower than that of pharmaceuticals. This, together with the savings related to reduced risk of NICU admission, makes the double-balloon catheter a more cost-effective and more desirable method for cervical ripening and labour induction.

Conclusion

This meta-analysis supports the premise that the double-balloon catheter is as effective as locally applied PGE2 agents in cervical ripening and labour induction. It is less likely to induce excessive uterine activity and has a lower risk of NICU admission, It should be considered a good alternative to conventional pharmacological methods for cervical ripening and labour induction. It is noteworthy that the evidence is highly relevant to current clinical practice, as prostaglandin E analogues, other than mechanical methods, are the main cervical ripening methods recommended by national and international guidelines on labour induction.[1,20] To improve the quality of care given to pregnant women with unfavourable cervices needing cervical ripening and labour induction, future studies should encompass a larger sample size and should focus on assessing the safety issues of the double-balloon catheter in women with a history of caesarean section or previous uterine surgery. Furthermore, patient perception and satisfaction with different methods used for cervical ripening and labour induction process should be assessed carefully.

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

JLO, YMD conceived the review, carried out data gathering and analysis, drafted the article, and were responsible for the integrity of the paper. LYZ, BHJ carried out data extraction and interpretation of data, and revised the article. LNC provided subsequent writing and editing support in developing ensuing drafts. All authors contributed to the overall report structure and concepts.

Details of ethics approval

This study was exempted from ethics approval as it did not involve human subjects.

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None.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Search strategy for Medline.

Table S1. Characteristics of included studies.

Table S2. Sensitivity analysis for main safety and effectiveness measurements. ■

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