Clinical and Experimental Obstetrics & Gynecology

Clin. Exp. Obstet. Gynecol. **2025**; 52(2): 26977
https://doi.org/10.31083/CEOG26977

Systematic Review

Comparison of Double Balloon Catheter and Dinoprostone Vaginal Insert in Induced Labor: A Meta-Analysis of 2267 Patients

Xiaomeng Zhou[1], Yun Wang[1,*]

[1]Department of Obstetrics and Gynecology, Hangzhou Women's Hospital, 310008 Hangzhou, Zhejiang, China
*Correspondence: yun-wang@ldy.edu.rs (Yun Wang)
Academic Editor: George Daskalakis
Submitted: 15 October 2024 Revised: 20 December 2024 Accepted: 30 December 2024 Published: 6 February 2025

Abstract

Background: Labor induction is a common procedure in obstetrics, with various methods employed to facilitate the process. This study aimed to compare the effects of labor induction using the double-balloon catheter (DBC) and dinoprostone (D), two widely used methods in clinical practice. **Methods**: Randomized controlled trials (RCTs) were identified from the Cochrane Library, SinoMed, PUBMED, and Embase up to March 2024. Two researchers independently screened and extracted the literature according to the inclusion and exclusion criteria. After evaluating the literature, Revman 5.4 software was used to analyze the data. The time to the onset of active labor and the rate of cesarean deliveries were the key outcomes. The secondary outcomes included assisted vaginal delivery, failure to progress rate, failed induction rate, incidence of nonreassuring fetal heart rate, neonatal asphyxia incidence, neonatal intensive care unit (NICU) admission rate, improvement in time to onset of active labor, time to vaginal delivery, Bishop score, need for oxytocin administration, presence of postpartum hemorrhage, vaginal delivery within 24 hours, and uterine hyperstimulation rate. **Results**: The total of 7 RCTs involving 2267 patients were included, with 1127 treated with DBC, and 1140 treated with D. Our meta-analysis showed no significant difference between the two groups in terms of cesarean delivery [odds ratio (OR) = 1.10, 95% confidence interval (95% CI): 0.91, 1.32, p = 0.34], time to onset of active labor [mean difference (MD) = 0.66, 95% CI: –4.72, 6.03, p = 0.81], presence of nonreasuring fetal heart, success rate of induction, improvement in Bishop score, rate of progress in labor, vaginal delivery rate within 24 hours, time to vaginal delivery, postpartum hemorrhage, and assisted vaginal delivery. Although the oxytocin administration rate (OR = 3.96, 95% CI: 3.18, 4.93, $p < 0.00001$) was lower, D was more likely to cause uterine hyperstimulation, leading to a higher rate of neonatal asphyxia (OR = 0.39, 95% CI: 0.18, 0.85, p = 0.02). **Conclusions**: Compared to DBC, D was more likely to cause uterine hyperstimulation, leading to a higher rate of neonatal asphyxia.

Keywords: double-balloon catheter; dinoprostone; induction of labor

1. Introduction

Induction of labor (IOL) is a common procedure for pregnant patients. It implies the use of artificial methods to promote cervical maturation and induce uterine contractions to achieve the goal of delivery. According to the National Vital Statistics report, in the United States, 31.9% of women underwent IOL in 2022 [1]. The plan of induction depends on the cervical Bishop score which was developed by Dr. Edward Bishop in 1964 [2]. It is comprised of fetal head station, cervical consistency, position, effacement and dilation. When the modified Bishop score is less than 7, preinduction cervical ripening—which involves utilizing pharmaceutical or mechanical methods to dilate, efface and soften the cervix—should be considered, with the exception of term premature rupture of fetal membranes (PROM) [3].

Cervical ripening is mainly divided into a mechanical or pharmaceutical option. Mechanical option for IOL uses physical effects to dilate the cervix. The mechanical option can stimulate the release of endogenous prostaglandins (PGs) from the cervix by increasing the separation of the amnion from the fetal-maternal interface [4]. Foley catheter and double-balloon catheter (DBC) are 2 of the most common mechanical methods used for cervical ripening [5]. The Foley catheter provides pressure at the internal cervical os, while the DBC, as a modified method, promotes cervical ripening by acting on both the internal and external cervix. Pharmacologic options include misoprostol (prostaglandin E1, PGE_1) and dinoprostone (D, prostaglandin E2, PGE_2). Both can increase the levels of prostaglandins (oral or intravaginal) in the body to induce uterine contractions. Both D vaginal gel and oral misoprostol, when used as a second cycle of induction after the failure of D vaginal insert, appear equally effective in achieving active labor and vaginal delivery, with no significant increase in adverse events [6]. Both mechanical and pharmacologic methods have been widely recognized for their safety and effectiveness in cervical ripening. However, there is still controversy about which cervical ripening option is better. Therefore, to compare the labor induction effects of the mechanical option and pharmacologic option, we performed a meta-analysis with DBC as the mechanical mode and D as the pharmacologic mode. Our study's objective was to give medical professionals further information regarding IOL.

2. Materials and Methods

2.1 Search Methods

This study was previously registered with PROSPERO (CRD42024619409) and followed Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines. Following the rules set forth by PRISMA, we compiled a list of all published randomized controlled trials (RCTs) that evaluated cervical ripening effects by contrasting the D with the DBC. The following electronic databases were perused to March 2024: Cochrane libraries (https://www.cochranelibrary.com/), Sino Med (http://www.sinomed.ac.cn), PubMed (https://pubmed.ncbi.nlm.nih.gov/), and EMBAS (https://www.embase.com). Search terms included "Double-balloon catheter", "Dinoprostone", "Induction of labor". Two independent researchers with expertise in obstetrics and gynecology systematically identified trials with full-text articles by screening the titles and abstracts, and discrepancies were resolved through discussion.

2.2 Selection and Exclusion Criteria

The selection criteria included: (1) RCTs published in English; (2) trials including women with live singleton pregnancies, cephalic presentation, intact fetal membranes, 3rd trimester pregnancies ($\geq$34 weeks), cervical Bishop score [2] $\leq$6; (3) intervention with either DBC and D. Only studies that utilized the controlled-release D vaginal insert (10 mg) in the D group were included to ensure consistency in intervention comparison; (4) pregnant patients with various clinical conditions, such as prolonged gestation, hypertension, diabetes, oligohydramnios, intrauterine growth restriction (IUGR), and suspected fetal macrosomia. We selected a gestational age of $\geq$34 weeks to focus on pregnancies that are sufficiently advanced to benefit from labor induction without the additional risk factors associated with preterm birth. This approach minimizes the potential confounding effects of preterm delivery on labor induction outcomes, while still addressing clinically relevant cases of late preterm pregnancies.

The exclusion criteria including: (1) unable to obtain full-text papers; (2) reviews, case reports, animal research or letters; (3) insufficient information for data extraction; (4) combined with other intervention, e.g., Foley catheter, misoprostol.

2.3 Selection of Studies and Data Extraction

According to the selection and exclusion criteria, two independent reviewers with expertise in obstetrics and gynecology systematically identified trials with full-text articles. Discrepancies were resolved through discussion. The study selection process was illustrated in a PRISMA diagram.

Recorded data included in the study: author, year of publication, administration route and dose of D, balloon volume (mL), outcomes, sample number, patient age, outcome indicators, and baseline Bishop score. Data were managed and extracted by NoteExpress (version 3.20; Aegean Software, Beijing, China) and Excel (version 14.4.0; Microsoft Corporation, Redmond, WA, USA).

The rate of cesarean deliveries and the incidence of hospital admission prior to the commencement of active labor were the main results. The secondary outcomes included assisted vaginal delivery, failure to progress, failed induction, presence of nonreassuring fetal heart rate, neonatal asphyxia, improvement in Bishop score, neonatal intensive care unit admission (NICU), time to vaginal delivery, need for oxytocin administration, postpartum hemorrhage incidence, uterine hyperstimulation rate, and vaginal delivery within 24 h. Active labor was defined as cervical dilation of at least 4 cm accompanied by regular and effective uterine contractions. In cases of uterine hyperstimulation, management involved discontinuing the catheter or vaginal insert, or reducing the oxytocin infusion rate. Neonatal asphyxia was defined as an Apgar score [7] of 7 or lower at either 1 minute or 5 minutes after birth, accompanied by umbilical artery blood pH $<$7.2.

2.4 Assessment of Risk of Bias

According to the Cochrane risk of bias tool for randomised trials (RoB 2.0, Cochrane Collaboration, Oxford, United Kingdom), the following biases were evaluated: selection bias (random sequence generation), attrition bias (incomplete outcome data), performance bias (blinding of personnel and participants), reporting bias (selective reporting), detection bias (blinding of outcome assessment), and other sources of bias [8].

2.5 Statistical Analysis

The data analysis program used was RevMan 5.4 (Cochrane Collaboration, Oxford, United Kingdom). The 95% confidence interval (95% CI) and odds ratio (OR) were used as the count data effect markers. The measurement data effect markers were the standard mean difference (SMD) or mean difference (MD) and the 95% CI. The heterogeneity was tested using the χ^2 test, and the degree of heterogeneity was assessed using the I^2 statistic. If no heterogeneity was observed, a fixed-effects model was used; if heterogeneity was present, sensitivity analysis, or descriptive analysis of the potential causes were conducted, and a random-effects model was employed. The choice between a fixed effect model and a random effect model depended on the degree of heterogeneity. Sensitivity analysis was employed to investigate the sources of heterogeneity through the methodical removal of individual trials. p values less than 0.05 were considered to be statistically significant.

Table 1. Characteristics of studies.

Trial	Intervention		Sample size DBC/D	Age (years)		Baseline Bishop score		Outcomes
	Double-balloon catheter (DBC)	Dinoprostone (D)		DBC	D	DBC	D	
Cromi *et al.* 2012 [13]	Cook cervical ripener balloon (50 mL/50 mL)	Controlled-release vaginal insert (10 mg)	105/103	34 (19–42)/33.6 ± 4.57	33 (20–45)/32.9 ± 4.98	2 (0–5)/2.05 ± 0.99	2 (0–5)/2.06 ± 1.00	①②③④⑤⑦⑧⑨⑩⑫⑬
Du *et al.* 2015 [10]	Cook cervical ripener balloon (80 mL/80 mL)	Controlled-release vaginal insert (10 mg)	76/79	28.45 ± 4.57	27.33 ± 3.29	3.38 ± 1.10	3.76 ± 1.36	①②③④⑤⑥⑦⑧⑨⑩⑪⑫⑬⑭
Wang *et al.* 2014 [14]	Cook cervical ripener balloon (80 mL/80 mL)	Controlled-release vaginal insert (10 mg)	67/59	27.9 ± 3.9	27.8 ± 3.4	2.4 ± 0.8	2.5 ± 0.7	①③⑤⑥⑦⑨⑩⑪⑫⑬⑭
Suffecool *et al.* 2014 [12]	Cook cervical ripener balloon (80 mL/80 mL)	Controlled-release vaginal insert (10 mg)	31/31	27.5 ± 6.4	28 ± 7.1	2 (0–5)/2.12 ± 1.22	2 (1–5)/2.23 ± 0.97	①②③④⑤⑧⑨⑬
Shechter-Maor *et al.* 2015 [11]	Cook cervical ripener balloon (unclear)	Times-release formulation Propess (10 mg)	26/26	28.5 (20–40)/28.89 ± 5.05	28.5 (18–39)/28.5 ± 5.3	-	-	①②⑤⑧⑩
Beckmann *et al.* 2020 [9]	Cook cervical ripener balloon (80 mL/80 mL)	vaginal gel (2 mg) or controlled-release vaginal tape (10 mg)	215/233	30 (26–34)/30 ± 1.45	30 (26–34)/30 ± 1.44	3 (2–4)/3 ± 0.36	3 (2–4)/3 ± 0.36	①②③④⑥
Diguisto *et al.* 2021 [15]	Cook cervical ripener balloon (80 mL/80 mL)	Times-release formulation Propess (10 mg)	607/609	31.1 ± 5.2	31.3 ± 5.1	3.2 ± 1.4	3.1 ± 1.4	①②③⑤⑥⑩⑪⑫⑬⑭

Note: data are displayed as number (%), median (range), or mean ± standard deviation (SD). ① Cesarean delivery rate; ② Assisted vaginal delivery rate; ③ Failure to progress rate; ④ Failed induction rate; ⑤ Nonreassuring fetal heart incidence rate; ⑥ Neonatal asphyxia incidence rate; ⑦ Improvement in Bishop Score; ⑧ Time to onset of active labor; ⑨ Time to vaginal delivery; ⑩ Oxytocin administration requiring rate; ⑪ Postpartum hemorrhage incidence rate; ⑫ Neonatal intensive care unit (NICU) admission rate; ⑬ Delivery within 24 h rate; ⑭ Uterine hyperstimulation rate.

3. Results

3.1 Description of Studies

The PRISMA flow diagram (Fig. 1) for this meta-analysis presents the detailed process of screening. The sum of 689 studies were found by initial screening. After duplicates were removed, a total of 408 studies were included. After the titles and abstracts were screened, 273 items were removed. A total of 8 studies were included as being RCTs. Other intervention, gestational age <34 weeks and animal trials were excluded. Finally, 7 studies [9–15] underwent meta-analysis after excluding papers without sufficient information for data extraction.

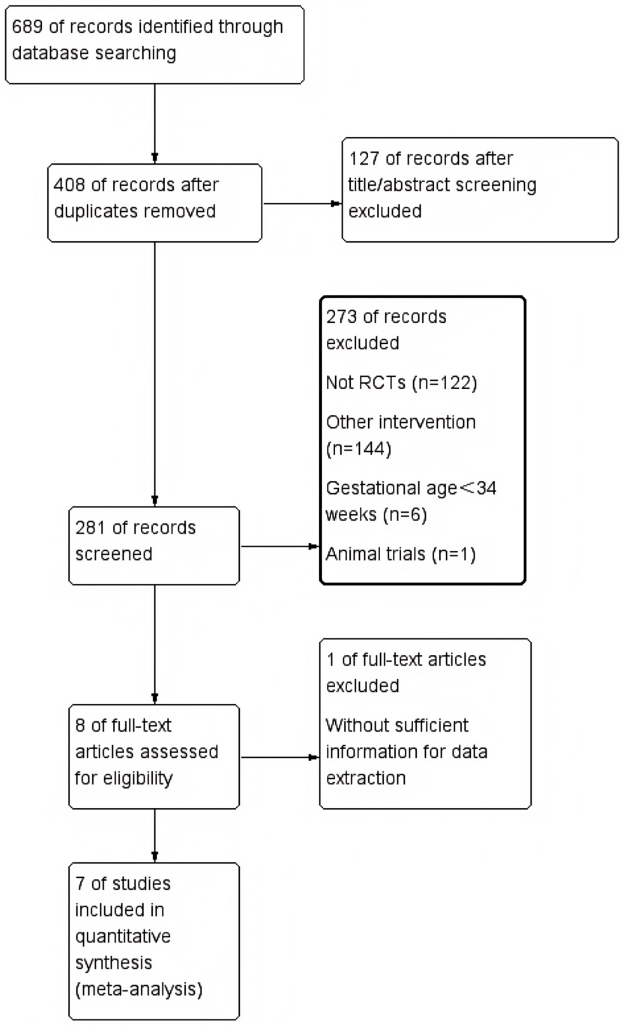

Fig. 1. The Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) flow diagram. RCTs, randomized controlled trials.

3.2 Study Characteristics

The primary information of 7 pooled studies is presented in Table 1 (Ref. [9–15]). Every study was published in English and identified through electronic data search. A total of 2267 patients were included, 1127 of whom were treated with DBC, while 1140 were treated with D.

3.3 Quality of Included Studies

The Jadad scale study indicated that low-quality literature had a score of $\leq$2, while high-quality literature had a score of $\geq$3. Studies with a Jadad score $\geq$3 were included. Fig. 2 is a summary of each included studies' risk of bias. A total of 7 trials with clear randomization and allocation methods were assessed as low risk. Because of the difference between the mechanical option and pharmaceutical option, a double-blind design is essentially impossible. The blinding of participants and personnel in all trials were judged as unclear risk. The data of all studies were complete. There was no selective reporting in any of the 7 RCTs.

3.4 Primary Outcomes

The primary outcomes were cesarean delivery rate and time to onset of active labor. All studies reported cesarean delivery rate, including 2267 patients (1127 in DBC group and 1140 in D group). The heterogeneity test yielded p = 0.63 and I^2 = 0% as findings. Consequently, the overall effect size was computed using a fixed effects model. The information showed that there was no statistically significant difference involving the two groups [OR = 1.10, 95% CI: (0.91, 1.32), p = 0.34] (Fig. 3). Time to beginning of active labor was observed in 4 studies including 441 participants (222 in the DBC group and 219 in the D group). Heterogeneity test findings demonstrated that $p < 0.00001$ and I^2 = 92%. Consequently, the overall effect size was determined using a random effects model. Based on the information provided, there was no statistically significant variation [MD = 0.66, 95% CI: (–4.72, 6.03), p = 0.81] involving the two groupings (Fig. 4). No a priori subgroup analyses were conducted for this outcome due to the absence of available data in the included studies. A sensitivity analysis based on the type of model showed consistent results (MD = 0.52, 95% CI: (–0.84, 1.88), p = 0.46, fixed model). Furthermore, sensitivity analysis was conducted by removing studies. After excluding the studies by Cromi *et al.* [13] and Suffecool *et al.* [12] on time to onset of active labor to avoid significant heterogeneity, there was a statistically significant variation [MD = 5.43, 95% CI: (3.23, 7.64), $p <$ 0.00001] involving the two groupings.

3.5 Secondary Outcomes

No statistically significant change was seen involving the 2 groups in the improvement to Bishop score [MD = –0.01, 95% CI: (–0.95, 0.94), p = 0.99] (Fig. 5). A sensitivity analysis based on the type of model showed consistent results [MD = 0.52, 95% CI: (–0.84, 1.88), p = 0.46, fixed model]. Furthermore, sensitivity analysis was conducted by removing studies. After excluding the study by Cromi *et al.* [13] on the improvement to Bishop score to avoid signifi-

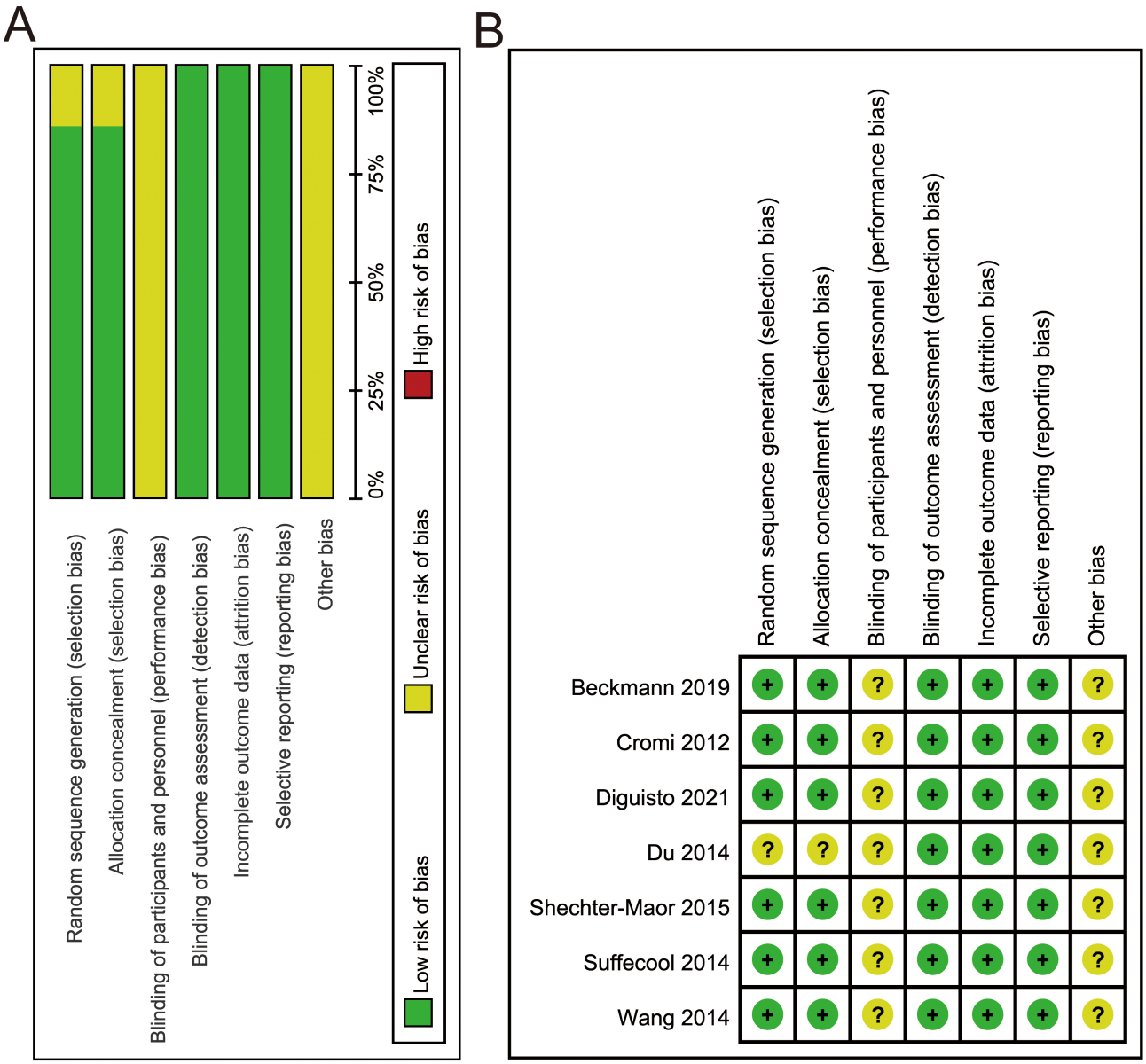

Fig. 2. Risk of bias graph. (A) A review of authors' judgments about each risk of bias item presented as percentages across all included studies. (B) A review of authors' judgments about each risk of bias item for each included study.

cant heterogeneity, there was a statistically significant variation [MD = 0.48, 95% CI: (0.12, 0.84), $p = 0.010$] involving the two groupings. However, compared to DBC group, the D group had a lower rate of oxytocin administration [OR = 3.96, 95% CI: (3.18, 4.93), $p < 0.00001$] (Fig. 6).

In contrast to the DBC group, the D group had a higher incidence rate of uterine hyperstimulation [OR = 0.16, 95% CI: (0.08, 0.32), $p < 0.00001$] (Fig. 7), and neonatal asphyxia [OR = 0.39, 95% CI: (0.18, 0.85), $p = 0.02$] (Fig. 8). However, no difference in nonreassuring fetal heart [OR = 0.72, 95% CI: (0.35, 1.49), $p = 0.38$] (Fig. 9) and NICU admission rate [OR = 1.20, 95% CI: (0.81, 1.78), $p = 0.36$] (Fig. 10) was observed between the 2 groups. A sensitivity analysis based on the type of model showed consistent results [OR = 0.74, 95% CI: (0.55, 1.01), $p = 0.06$, fixed model]. Furthermore, sensitivity analysis was conducted by removing studies. After excluding the studies by Du, Wang and Diguisto *et al.* [10,14,15] on the nonreassuring fetal heart to avoid significant heterogeneity, there was no statistically significant variation [OR = 0.74, 95% CI: (0.55, 1.01)] involving the two groupings.

There was no statistically significant difference between the 2 groups in failure to progress rate [OR = 1.25, 95% CI: (0.75, 2.10), $p = 0.40$] (Fig. 11), failed induction rate [OR = 1.09, 95% CI: (0.54, 2.20), $p = 0.80$] (Fig. 12), time to vaginal delivery [MD = 0.33, 95% CI: (–3.16, 3.81), $p = 0.85$] (Fig. 13), vaginal delivery within 24 h [OR = 1.26, 95% CI: (0.53, 2.98), $p = 0.60$] (Fig. 14), assisted vaginal

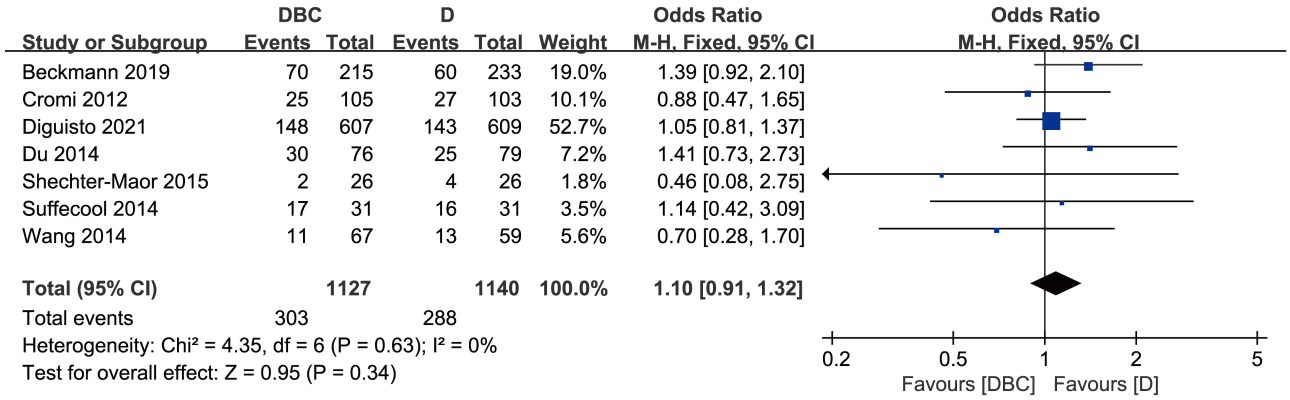

Fig. 3. Meta-analysis of cesarean delivery rate between double-balloon catheter (DBC) and dinoprostone (D). 95% CI, 95% confidence interval; M-H, Mantel-Haenszel.

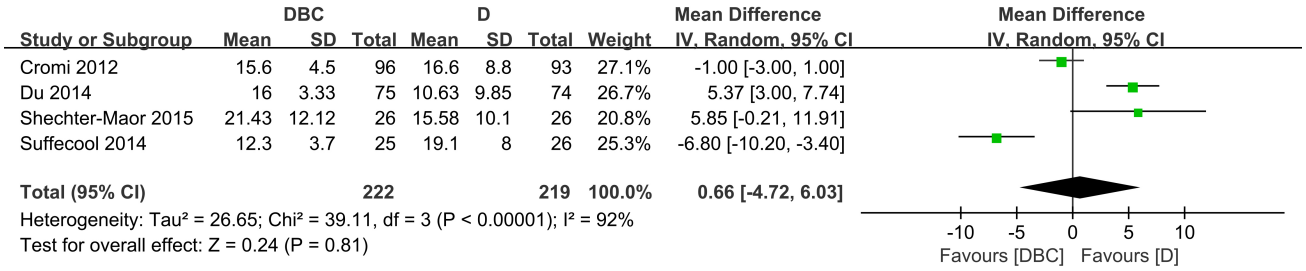

Fig. 4. Meta-analysis of time to onset of active labor between DBC and D. IV, inverse variance; SD, standard deviation.

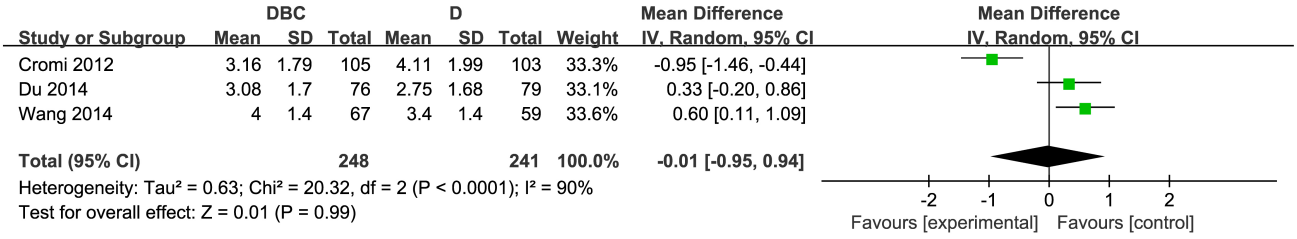

Fig. 5. Meta-analysis of Bishop score between DBC and D.

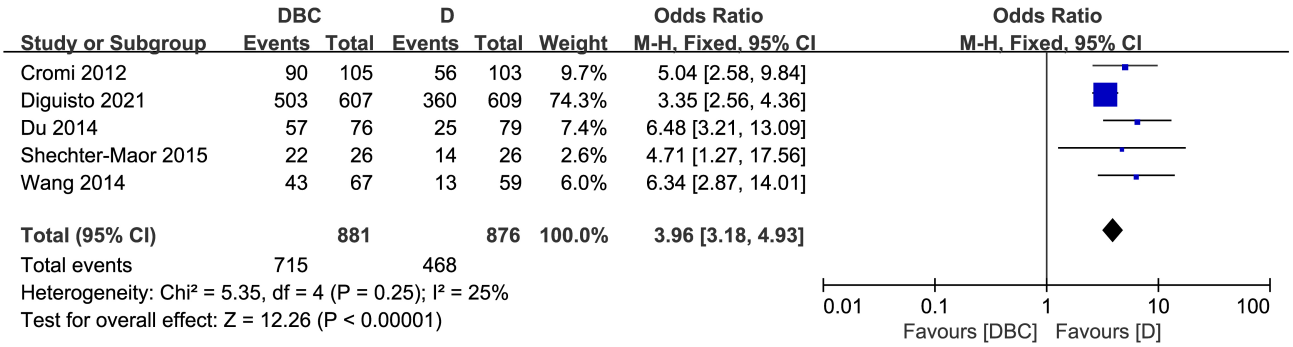

Fig. 6. Meta-analysis of oxytocin administration requiring rate between DBC and D.

delivery rate [OR = 0.83, 95% CI: (0.65, 1.06), $p = 0.13$] (Fig. 15), or postpartum hemorrhage incidence rate [OR = 0.80, 95% CI: (0.60, 1.09), $p = 0.16$] (Fig. 16). A sensitivity analysis based on the type of model for failure to progress rate [OR = 1.04, 95% CI: (0.82, 1.32), $p = 0.76$, fixed model], time to vaginal delivery [OR = 0.71, 95% CI: (–0.67, 2.09), $p = 0.31$, fixed model], and vaginal delivery within 24 h [OR = 0.82, 95% CI: (0.64, 1.04), $p = 0.11$, fixed model] showed consistent results. Furthermore, sensitivity analysis was conducted by removing studies. After exclud-

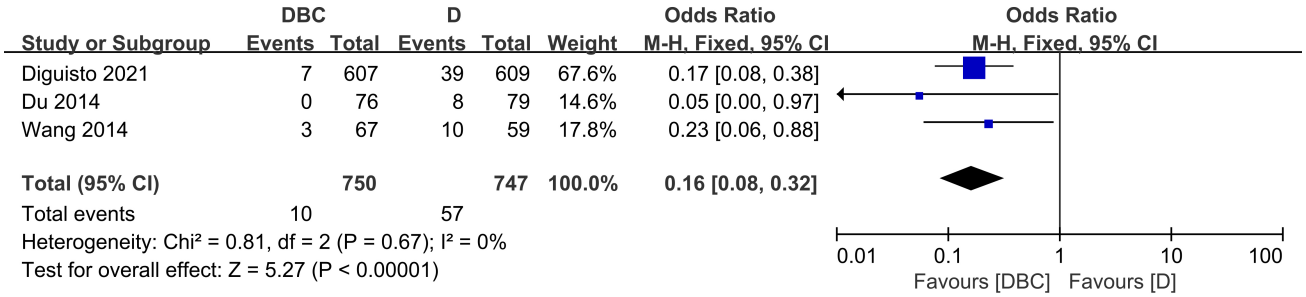

Fig. 7. Meta-analysis of uterine hyperstimulation rate between DBC and D.

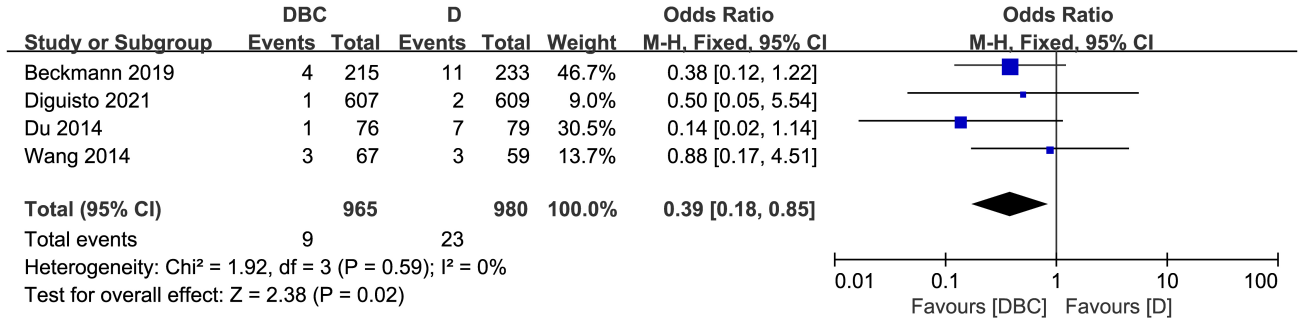

Fig. 8. Meta-analysis of neonatal asphyxia between DBC and D.

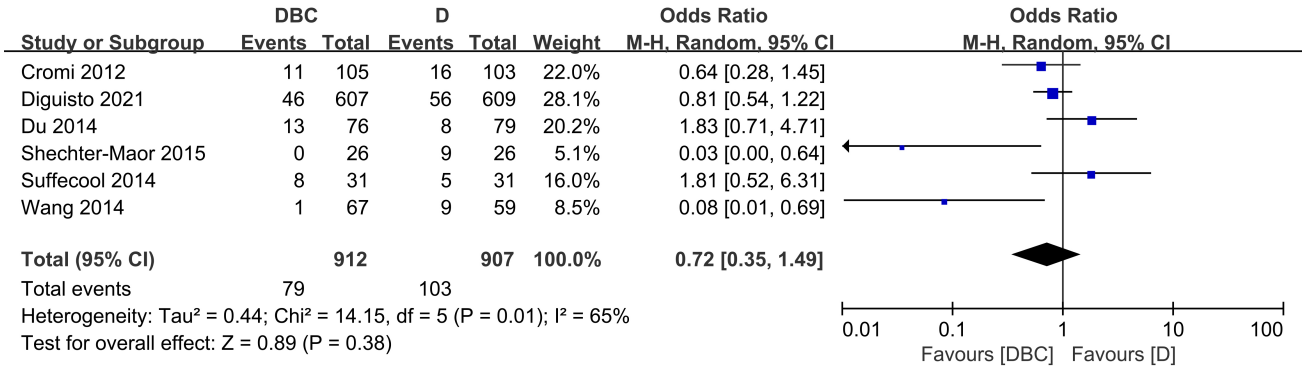

Fig. 9. Meta-analysis of the incidence of nonreassuring fetal heart a rate between DBC and D.

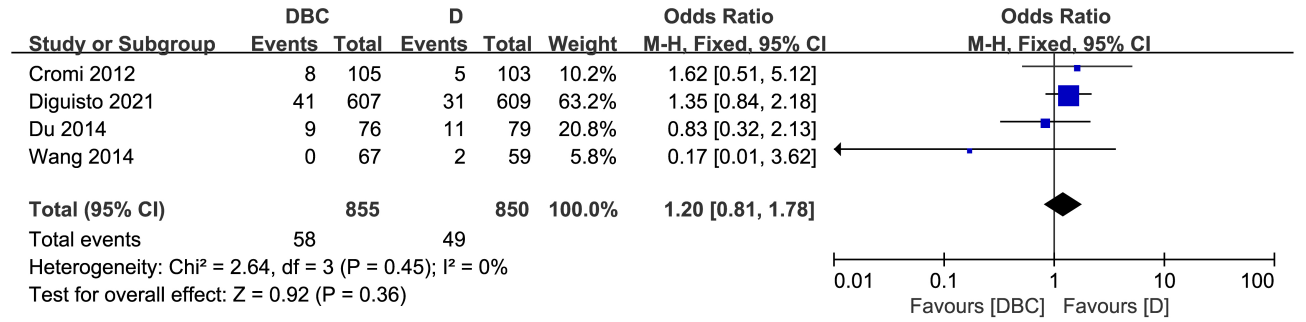

Fig. 10. Meta-analysis of NICU admission rate between DBC and D.

ing the study by Du *et al.* [10] on the failure to progress rate to avoid significant heterogeneity, there was no statistically significant variation [OR = 0.98, 95% CI: (0.71, 1.35), p = 0.90] involving the two groupings. After excluding the study by Du and Wang *et al.* [10,14] on the time to vaginal delivery to avoid significant heterogeneity, there was no statistically significant variation [MD = 0.05, 95% CI: (–1.67, 1.57), p = 0.95] involving the two groupings. Af-

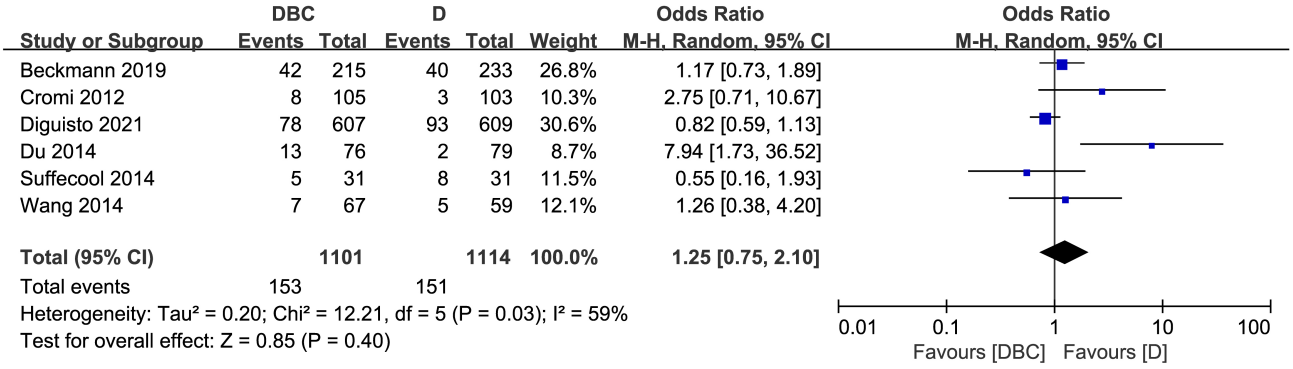

Fig. 11. Meta-analysis of failure to progress rate between DBC and D.

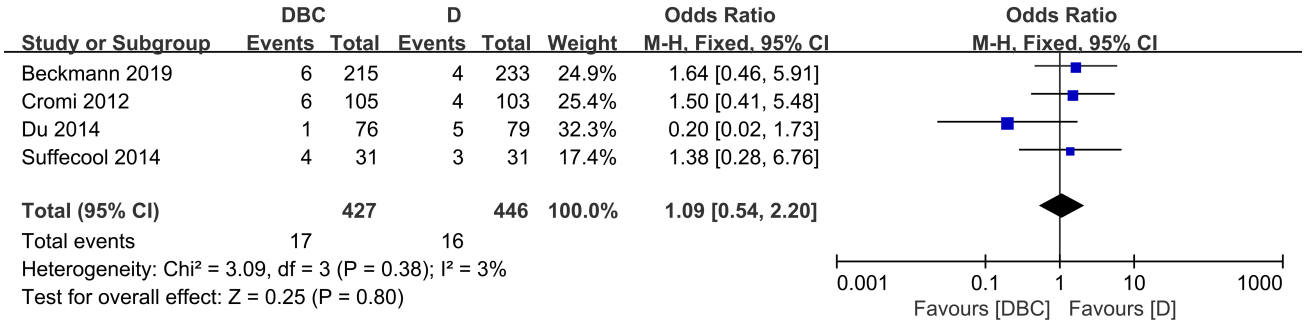

Fig. 12. Meta-analysis of failed induction rate between DBC and D.

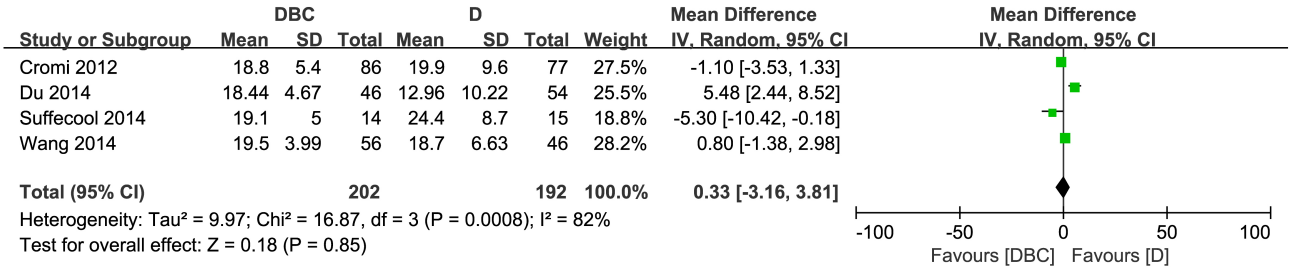

Fig. 13. Meta-analysis of time to vaginal delivery between DBC and D.

ter excluding the study by Cromi, Diguisto and Suffecool *et al.* [12,13,15] on the vaginal delivery within 24 h to avoid significant heterogeneity, there was no statistically significant variation [OR = 0.91, 95% CI: (0.57, 1.46), $p = 0.69$] involving the two groupings.

3.6 Publication Bias

The Begg's funnel plots of both the primary and secondary outcomes indicated that no publication bias existed (**Supplementary Figs. 1–14**).

4. Discussion

The findings of our meta-analysis comparing the labor induction effects of DBC and D provide valuable insights into the clinical management of labor induction. Overall, our analysis of 7 RCTs involving 2267 patients revealed no significant differences in primary outcomes such as cesarean delivery rate and time to onset of active labor between the DBC and D groups.

The process of cervical ripening including softening, effacement and dilatation is based on uterine contractile activity and immunologic effects [16]. By raising inflammatory mediators in the cervix and causing cervical remodeling, prostaglandins are essential for cervical ripening [17,18]. D, one of the major prostaglandin formulations is approved in many countries worldwide for cervical ripening. It takes action on the prostaglandin type E prostanoid (EP) family of receptors [19]. Also, D can modulate the inflammatory response by increasing the inflammatory mediators such as interleukin-8 (IL-8) and tumor necrosis factor-a (TNF-a) *in vivo* [20]. The first balloon used to dilate the cervix was revealed by Chiari *et al.* in 1855 [21]. The direct mechanical pressure by the balloon can increase the release of prostaglandins from the decidua and cervix [22]. DBC is

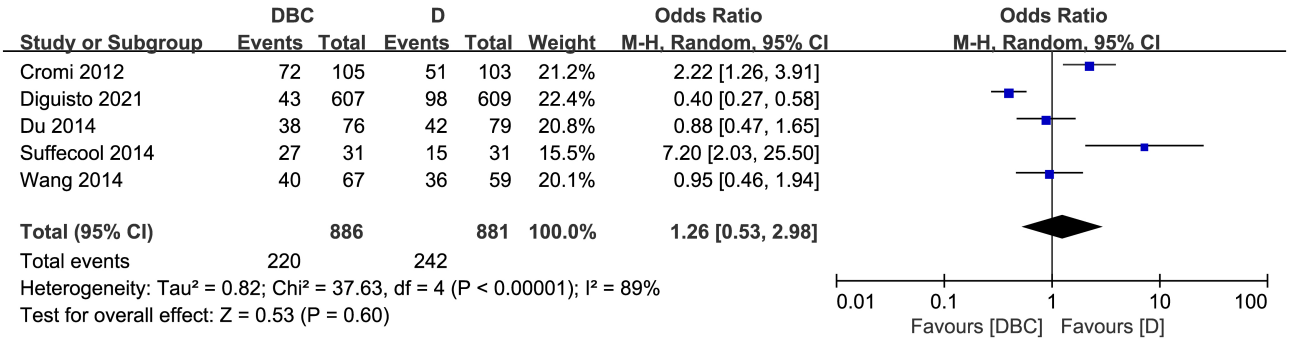

Fig. 14. Meta-analysis of vaginal delivery within 24 h between DBC and D.

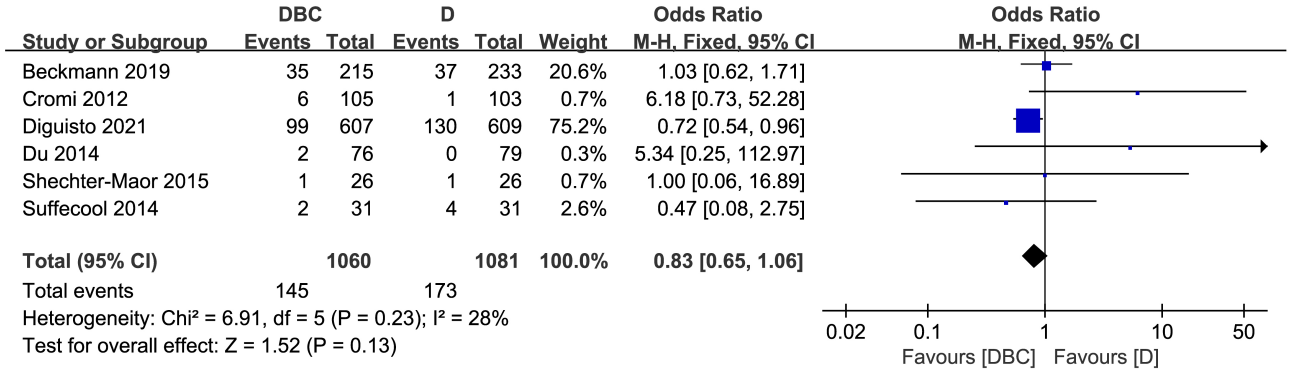

Fig. 15. Meta-analysis of assisted vaginal delivery rate between DBC and D.

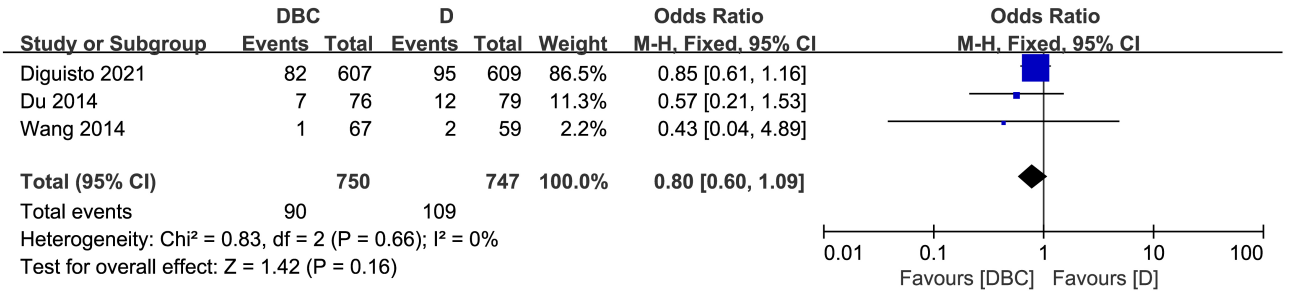

Fig. 16. Meta-analysis of postpartum hemorrhage incidence between DBC and D.

an improved version of the Foley catheter and is specifically designed for induction of labor. However, a meta-analysis reported that DBC and Foley catheter exhibit comparable efficacy, efficiency, safety, and patient satisfaction levels [5]. Both DBC and D are the most frequently used methods for cervical ripening. Under special circumstances, choosing between the two is not difficult. For example, the D vaginal insert group was associated with a higher rate of successful vaginal delivery within 24 hours as compared to DBC group in term nulliparous pregnancies, although it was also linked to a higher occurrence of nonreassuring fetal heart rate patterns [23]. However, for women without relevant contraindications, there is still much controversy over which method of cervical ripening is the best.

The results of our meta-analysis may provide some guidance. In this meta-analysis, we compared the labor induction effects between DBC and D. According to our research, there were no appreciable variations involving the 2 methods in most primary and secondary outcomes in terms of time to onset of active labor, success rate of induction, improvement to Bishop score, success rate of labor progress, time to vaginal delivery and vaginal delivery rate within 24 hours. The possible reason is that although D takes effect quickly, some patients may need an early removal due to the uterine hyperstimulation. Insufficient duration of drug action may lead to incomplete ripeness of the cervix. Our analysis revealed no discernible change in the time to onset of active labor between the DBC and D groups, suggesting that both methods are equally effective in initiating labor once the induction process has begun. Time to onset of active labor is a critical parameter in labor management, as delays in labor progression can in-

crease the risk of maternal and neonatal complications [24]. Our findings support the notion that both DBC and D are viable options for achieving timely labor onset. Timely onset of active labor is crucial for minimizing maternal and neonatal complications associated with prolonged labor induction [24]. The Bishop score is a widely used assessment tool for predicting the success of labor induction and is based on cervical dilation, effacement, consistency, position, and fetal station [2]. Moreover, our results regarding no discernible change in the improvement of Bishop score involving the two groups indicated that both DBC and D can effectively improve cervical ripeness, leading to successful labor induction. However, we observed that the oxytocin administration rate was lower in the D group in contrast to the DBC group. This may be attributed to the rapid onset of action of D, leading to fewer cases requiring additional oxytocin augmentation. This finding suggests that D may require less additional intervention to augment labor progress, which could have implications for resource utilization and patient satisfaction.

In terms of side effects, there was not a noticeable variation in the cesarean delivery rate, postpartum hemorrhage incidence rate, or assisted vaginal delivery rate between DBC and D. In our meta-analysis, we observed no discernible change in the cesarean delivery rate between the DBC and D groups. This result is in line with earlier researchers that have reported comparable rates of cesarean delivery following labor induction with mechanical and pharmacological methods [25]. Cesarean delivery rates are important outcomes in labor induction, as they reflect both maternal and fetal outcomes and are influenced by various factors, including the method of induction, maternal characteristics, and obstetric practices [26]. Compared to DBC, D was more likely to cause uterine hyperstimulation, leading to a higher rate of nonreasuring fetal heart and neonatal asphyxia. These findings are consistent with the pharmacological properties of D, which can induce strong and sometimes unpredictable uterine contractions [27]. Clinicians should weigh the potential benefits of reduced oxytocin use against the risks of uterine hyperstimulation when choosing between DBC or D for labor induction. However, there was not a noticeable variation in neonatal intensive care unit (ICU) admission rates involving the two groups. A possible reason is that neonatal asphyxia caused by uterine hyperstimulation is reversible [28]. Immediate conservative measures (remove medication or use of tocolytic agents) can be undertaken to reverse the uterine hyperstimulation state. The results suggest that when using D for cervical ripening, it is necessary to closely monitor uterine contractions and the changes of fetal heart rate. If regular contractions have already occurred, we suggest avoiding using D.

Our study has several strengths, including the inclusion of a large sample size from multiple RCTs and a comprehensive analysis of various labor induction outcomes. However, there are some limitations to consider in this study. Firstly, due to the obvious difference between the 2 interventions, blinding for participants or researchers cannot be implemented. The blinding of participants and personnel in all trials was judged as unclear risk. Secondly, the comparison of pain perception between the 2 methods by patients has not been revealed. Moreover, the included studies enrolled diverse patient populations, with some studies specifically focusing on women with prolonged gestation, hypertension, diabetes, oligohydramnios, IUGR, and/or suspected fetal macrosomia. However, the level of detail regarding these conditions varied, and some studies did not provide comprehensive information on all comorbidities. As a result, a precise classification of the populations could not be achieved, but we have provided a general description of the most common conditions observed across the studies. Therefore, more high-quality studies are needed for a future meta-analysis. Finally, the sensitivity analysis conducted in this study helped clarify the sources of heterogeneity, especially in outcomes like time to onset of active labor and improvement to Bishop score. These analyses provided more consistent and reliable conclusions by excluding studies that contributed to significant heterogeneity. However, for outcomes such as nonreassuring fetal heart rate and vaginal delivery within 24 hours, heterogeneity remained unaddressed, suggesting that future studies should focus on standardizing reporting methods to minimize variation.

5. Conclusions

DBC was equally effective as D in terms of success rate of induction, time to onset active labor, success rate of induction, improvement to Bishop score, success rate of progress, time to vaginal delivery, vaginal delivery rate within 24 hours, cesarean delivery rate, postpartum hemorrhage incidence rate, and assisted vaginal delivery rate, and incidence of nonreasuring fetal heart rate. Although the oxytocin administration rate was lower, D was more likely to cause uterine hyperstimulation, leading to a higher rate of neonatal asphyxia. Clinicians should consider individual patient factors and preferences when selecting the appropriate method for cervical ripening.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

XZ was responsible for conceptualization, data curation, formal analysis, investigation, methodology, project administration, resources, software, supervision, validation, and drafting the original manuscript. YW contributed to conceptualization, data curation, formal analysis, investi-

gation, methodology, resources, software, supervision, validation, and funding acquisition, as well as reviewing and editing the manuscript. Both authors have read and approved the final manuscript. Both authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

Acknowledgment

Not applicable.

Funding

This research received no external funding.

Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/CEOG26977.

References

[1] Osterman MJK, Hamilton BE, Martin JA, Driscoll AK, Valenzuela CP. Births: Final Data for 2022. National Vital Statistics Reports: from the Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System. 2024; 73: 1–56.

[2] Wormer KC, Bauer A, Williford AE. Bishop Score. In StatPearls [Internet]. StatPearls Publishing: Treasure Island (FL). 2024.

[3] Robinson D, Campbell K, Hobson SR, MacDonald WK, Sawchuck D, Wagner B. Guideline No. 432a: Cervical Ripening and Induction of Labour - General Information. Journal of Obstetrics and Gynaecology Canada. 2023; 45: 35–44.e1. https://doi.org/10.1016/j.jogc.2022.11.005.

[4] Wing DA, Farinelli CK. Abnormal labor and induction of labor. In Gabbe SG, Niebyl JR, Simpson JL, Landon MB, Galan HL, Jauniaux EM (eds.) Obstetrics: Normal and Problem Pregnancies (pp. 287–310). 6th edn. Elsevier Saunders: Philadelphia, PA. 2012.

[5] Liu X, Wang Y, Zhang F, Zhong X, Ou R, Luo X, *et al*. Double- versus single-balloon catheters for labour induction and cervical ripening: a meta-analysis. BMC Pregnancy and Childbirth. 2019; 19: 358. https://doi.org/10.1186/s12884-019-2491-4.

[6] Mancarella M, Costa Torro D, Moggio G, Bounous VE, Biglia N. Induction of labor with repeated prostaglandin administration after failure of dinoprostone vaginal insert: a retrospective study comparing dinoprostone and misoprostol. Minerva Obstetrics and Gynecology. 2024. https://doi.org/10.23736/S2724-606X.23.05414-3. (online ahead of print)

[7] AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON FETUS AND NEWBORN, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS COMMITTEE ON OBSTETRIC PRACTICE. The Apgar Score. Pediatrics. 2015; 136: 819–822. https://doi.org/10.1542/peds.2015-2651.

[8] Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, *et al*. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ (Clinical Research Ed.). 2019; 366: l4898. https://doi.org/10.1136/bmj.l4898.

[9] Beckmann M, Gibbons K, Flenady V, Kumar S. Induction of labour using prostaglandin E_2 as an inpatient versus balloon catheter as an outpatient: a multicentre randomised controlled trial. BJOG: an International Journal of Obstetrics and Gynaecology. 2020; 127: 571–579. https://doi.org/10.1111/1471-0528.16030.

[10] Du C, Liu Y, Liu Y, Ding H, Zhang R, Tan J. Double-balloon catheter vs. dinoprostone vaginal insert for induction of labor with an unfavorable cervix. Archives of Gynecology and Obstetrics. 2015; 291: 1221–1227. https://doi.org/10.1007/s00404-014-3547-3.

[11] Shechter-Maor G, Haran G, Sadeh-Mestechkin D, Ganor-Paz Y, Fejgin MD, Biron-Shental T. Intra-vaginal prostaglandin E2 versus double-balloon catheter for labor induction in term oligohydramnios. Journal of Perinatology. 2015; 35: 95–98. https://doi.org/10.1038/jp.2014.173.

[12] Suffecool K, Rosenn BM, Kam S, Mushi J, Foroutan J, Herrera K. Labor induction in nulliparous women with an unfavorable cervix: double balloon catheter versus dinoprostone. Journal of Perinatal Medicine. 2014; 42: 213–218. https://doi.org/10.1515/jpm-2013-0152.

[13] Cromi A, Ghezzi F, Uccella S, Agosti M, Serati M, Marchitelli G, *et al*. A randomized trial of preinduction cervical ripening: dinoprostone vaginal insert versus double-balloon catheter. American Journal of Obstetrics and Gynecology. 2012; 207: 125.e1–7. https://doi.org/10.1016/j.ajog.2012.05.020.

[14] Wang W, Zheng J, Fu J, Zhang X, Ma Q, Yu S, *et al*. Which is the safer method of labor induction for oligohydramnios women? Transcervical double balloon catheter or dinoprostone vaginal insert. The Journal of Maternal-Fetal & Neonatal Medicine. 2014; 27: 1805–1808. https://doi.org/10.3109/14767058.2014.880880.

[15] Diguisto C, Le Gouge A, Arthuis C, Winer N, Parant O, Poncelet C, *et al*. Cervical ripening in prolonged pregnancies by silicone double balloon catheter versus vaginal dinoprostone slow release system: The MAGPOP randomised controlled trial. PLoS Medicine. 2021; 18: e1003448. https://doi.org/10.1371/journal.pmed.1003448.

[16] Yellon SM. Immunobiology of Cervix Ripening. Frontiers in Immunology. 2020; 10: 3156. https://doi.org/10.3389/fimmu.2019.03156.

[17] Flis W, Socha MW. The Role of the NLRP3 Inflammasome in the Molecular and Biochemical Mechanisms of Cervical Ripening: A Comprehensive Review. Cells. 2024; 13: 600. https://doi.org/10.3390/cells13070600.

[18] Socha MW, Flis W, Pietrus M, Wartęga M, Stankiewicz M. Signaling Pathways Regulating Human Cervical Ripening in Preterm and Term Delivery. Cells. 2022; 11: 3690. https://doi.org/10.3390/cells11223690.

[19] Cheng H, Huang H, Guo Z, Chang Y, Li Z. Role of prostaglandin E2 in tissue repair and regeneration. Theranostics. 2021; 11: 8836–8854. https://doi.org/10.7150/thno.63396.

[20] Bakker R, Pierce S, Myers D. The role of prostaglandins E1 and E2, dinoprostone, and misoprostol in cervical ripening and the induction of labor: a mechanistic approach. Archives of Gynecology and Obstetrics. 2017; 296: 167–179. https://doi.org/10.1007/s00404-017-4418-5.

[21] Chiari J, Braun C, Spaeth J. Klinik der Geburtshilfe und Gynaekologie. Ealangen: Verlag von Ferdinand Enke. 1855.

[22] Levine LD. Cervical ripening: Why we do what we do. Seminars in Perinatology. 2020; 44: 151216. https://doi.org/10.1016/j.semperi.2019.151216.

[23] Li S, He H, Zheng W, Liu J, Chen C. Comparison of outcomes of labor induction with dinoprostone vaginal insert (PROPESS) and double balloon cook catheter in term nulliparous preg-

nancies. The Journal of Obstetrics and Gynaecology Research. 2025; 51: e16107. https://doi.org/10.1111/jog.16107.

[24] Laughon SK, Berghella V, Reddy UM, Sundaram R, Lu Z, Hoffman MK. Neonatal and maternal outcomes with prolonged second stage of labor. Obstetrics and Gynecology. 2014; 124: 57–67. https://doi.org/10.1097/AOG.0000000000000278.

[25] Lauterbach R, Ben Zvi D, Dabaja H, Zidan R, Justman N, Vitner D, *et al*. Vaginal Dinoprostone Insert versus Cervical Ripening Balloon for Term Induction of Labor in Obese Nulliparas-A Randomized Controlled Trial. Journal of Clinical Medicine. 2022; 11: 2138. https://doi.org/10.3390/jcm11082138.

[26] Ghafari-Saravi A, Chaiken SR, Packer CH, Davitt CC, Garg B, Caughey AB. Cesarean delivery rates by hospital type among nulliparous and multiparous patients. The Journal of Maternal-fetal & Neonatal Medicine. 2022; 35: 8631–8639. https://doi.org/10.1080/14767058.2021.1990884.

[27] Cañadas JV, González MT, Limón NP, Alguacil MS, Prieto MG, Riaza RC, *et al*. Intracervical double-balloon catheter versus dinoprostone for cervical ripening in labor induction in pregnancies with a high risk of uterine hyperstimulation. Archives of Gynecology and Obstetrics. 2021; 304: 1475–1484. https://doi.org/10.1007/s00404-021-06071-1.

[28] Chandraharan E, Ghi T, Fieni S, Jia YJ. Optimizing the management of acute, prolonged decelerations and fetal bradycardia based on the understanding of fetal pathophysiology. American Journal of Obstetrics and Gynecology. 2023; 228: 645–656. https://doi.org/10.1016/j.ajog.2022.05.014.