REVIEW ARTICLE

A meta-analysis and systematic review of the effect of dinoprostone in full term pregnancy labor induction

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*Zhongren Hu, Fangbin Lai, Qiwei Lin and Yu Zhang**

Department of Obstetrics,Zhangzhou Hospital Affiliated to Fujian Medical University, ZhangZhhou, 353000, China

***For Correspondence:** Email: *zhangyu39251761@163.com*; Phone: 0596-2082030

Abstract

This meta-analysis comprehensively evaluates Dinoprostone's efficacy and safety in full-term labor induction through systematic review of 11 studies from Cochrane, PubMed, Medline, Embase, WeiPu, and Google Scholar databases. The search strategy included key terms such as dinoprostone, prostaglandin E2, cervical ripening, and labor induction, applied across both Chinese and English literature. The analysis demonstrated significant advantages in vaginal delivery rates within 24 hours (OR=0.66, 95%CI:0.55-0.81, P<0.0001) with acceptable heterogeneity (I^2=33%, P=0.14). Neonatal outcomes favored Dinoprostone, showing reduced incidence of 1-minute Apgar scores <7 (OR=0.64, 95%CI:0.48-0.84, P=0.002). Comparative analysis revealed Dinoprostone's longer medication-to-delivery interval but superior safety profile versus Misoprostol, particularly in 5 min Apgar scores. These findings provide robust evidence for clinical decision-making regarding prostaglandin-based labor induction protocols *(Afr J Reprod Health 2025; 29 [10]: 195-206)*

Keywords: Dinoprostone;Obstetrics and Gynecology;cervical ripening promotion;full-term pregnancy labor induction;Meta-analysis

Résumé

Cette méta-analyse évalue de manière exhaustive l'efficacité et la sécurité du dinoprostone dans l'induction du travail à terme, à travers une revue systématique de 11 études issues des bases de données Cochrane, PubMed, Medline, Embase, WeiPu et Google Scholar. La stratégie de recherche a inclus des mots-clés tels que dinoprostone, prostaglandine E2, maturation cervicale et induction du travail, appliqués à la littérature en anglais et en chinois. L'analyse a démontré des avantages significatifs concernant les taux d'accouchement par voie vaginale dans les 24 heures (OR = 0,66, IC95 % : 0,55-0,81, P < 0,0001) avec une hétérogénéité acceptable (I^2 = 33 %, P = 0,14). Les résultats néonatals ont favorisé le dinoprostone, montrant une diminution de l'incidence des scores d'Apgar <7 à 1 minute (OR = 0,64, IC95 % : 0,48-0,84, P = 0,002). L'analyse comparative a révélé que le dinoprostone présentait un intervalle plus long entre l'administration du médicament et l'accouchement, mais un profil de sécurité supérieur à celui du misoprostol, en particulier pour les scores d'Apgar à 5 minutes. Ces résultats fournissent des preuves solides pour la prise de décision clinique concernant les protocoles d'induction du travail à base de prostaglandines. *(Afr J Reprod Health 2025; 29 [10]: 195-206).*

Mots-clés: Dinoprostone;Obstétrique et gynécologie;promotion de la maturation cervicale;induction du travail à terme;Méta-analyse

Introduction

Induction of labour at term pregnancy is meant to achieve natural labour using drugs[1]. Induction of labor at term is one of the most used methods in obstetrics and gynecology to manage high-risk pregnancies[2-4]. Induction of labor is recommended to reduce complications in pregnant women when systemic maternal conditions such as severe diabetes, hypertension, or kidney disease are present; or when fetal factors such as suspected fetal distress, placental dysfunction, stillbirth, or severe fetal malformations are identified. Induction is also indicated in cases of prolonged pregnancy or premature rupture of membranes[5-6]. Some contraindications to use of labor induction include placenta previa, umbilical cord prolapse, fetal malposition, previous history of uterine surgery, and abnormal soft birth canal conditions[7].

Induction of labor at full term involves six well-established clinical approaches. Among pharmacological methods, intravenous oxytocin is commonly used to stimulate uterine contractions and promote cervical ripening. Additionally, diazepam may be employed for its dual effects—providing sedation and inhibiting catecholamine

release, both of which can enhance uterine contractility. Mechanical techniques involve artificial membrane dilation for cervical opening beyond 3cm with engaged fetal head, and membrane stripping in non-infected cases[9]. Physiological interventions feature castor oil consumption - where intestinal hydrolysis of ricinoleic acid triggers reflexive uterine contractions - alongside breast stimulation that activates the hypothalamic-pituitary pathway to release endogenous oxytocin[10]. These methods, each with distinct mechanisms and clinical considerations, constitute the fundamental armamentarium for labor induction in contemporary obstetrical practice.

Cervical maturity is a key determinant of successful labor induction. Initiating induction when the cervix is unfavorable or immature can result in prolonged labor and increased risk of complications. The Bishop score continues to be regarded as the gold standard for evaluating cervical maturity in clinical practice, serving as a key predictor of successful labor induction outcomes. This scoring system evaluates five key parameters: cervical dilation, effacement, consistency, position, and fetal station. Each parameter is scored from 0 to 2 or 3, with the total score ranging from 0 to 13. A score above 6 generally indicates cervical maturity and predicts favorable response to labor induction. The components collectively assess the cervix's readiness for childbirth, where higher scores correlate with greater induction success rates[11]. Dinoprostone is a medicine that belongs to the prostaglandin E2 group. It comes in several forms, such as vaginal tablets, vaginal suppositories, gels, and rectal suppositories. It has been approved by both the U.S. Food and Drug Administration (FDA) and the China Food and Drug Administration for use in the third trimester of pregnancy to help soften and open the cervix, making it easier to start labor when induction is needed[12]. It delivers a sustained and stable release rate of 0.3 mg/h, incorporating a unique recovery mechanism for belt termination. While E2 suppositories offer operational convenience and high reproducibility, their clinical application is limited by high cost and stringent storage requirements at temperatures below -20°C.

Current evidence is still inconclusive about the specific effects of prostaglandin E2 on cervical changes and labor outcomes in pregnant women. This meta-analysis brings together both domestic and international studies and applies rigorous statistical methods to provide a comprehensive assessment of its efficacy, safety, and cost-effectiveness. Objective of present investigation is to systematically compare Dinoprostone and Misoprostol for term labor induction across critical obstetric parameters, thereby establishing evidence-based clinical guidance.

Methods

Literature search

Various search engines including PubMed, Medline, Embase, Weipu, and Google Scholar were accessed. The clinical research related to Dinoprostone in the treatment of full-term pregnancy labor induction was reviewed. The retrieval time was from the establishment of the database to August 25, 2021. The English and chinese database was searched by the combination of Dinoprostone, prostaglandin E2, cervical ripening and induced labor.

Literature inclusion and exclusion criteria

Inclusion criteria: The randomized controlled trials exploring the efficacy of Dinoprostone in the treatment of full-term pregnancy labor induction; II, the research objects which included, the head position of a single child, and the gestational period was 38-42 weeks; III, the experimental group was the Dinoprostone group. Suppository was placed in the posterior curvature of the vagina of the pregnant woman, and it was continuously released at 0.3 mg/L for 12h; IV, the observation indicators were fully described and the data extraction was feasible.

Exclusion criteria: Studies were excluded if they met any of the following criteria: (I) non-randomized trials; (II) descriptive research, studies with infeasible data extraction, or unclear reporting of sample data; and (III) studies in which the research population, methodology, or drug dosage form did not meet the inclusion criteria.

Observation indicators

The following indicators were analyzed: the number of vaginal delivery cases with medication for 24h, 12h, the time interval from medication to delivery,

the number of medications to promote cervical ripening. Apgar score less than 7 points, and the number of neonates with 5-minute Apgar score less than seven points.

Data extraction

A standardized Excel table was created, and the required data were independently extracted by two experts using an integrated data sheet. In cases of disagreement, a consensus was reached through discussion. The extraction criteria included the research topic, author, year of publication, and details regarding the study population.

Quality evaluation and bias risk assessment

This study used the Jadad scale, a quality evaluation standard method to evaluate the for allocation, blinding, and integrity of data research results. The above five aspects were judged as "high risk bias", "low risk bias", or "unclear". The included studies were classified into two categories, low quality studies (1-3 points) and high-quality studies (4-7 points). They were independently evaluated by two experts according to the above criteria.

Statistical methods

The efficacy and safety of Dinoprostone on full-term pregnancy labor induction were analyzed using Rev Man 5.3. When P>0.01 and I2<50%, the fixed effect model was used for meta-analysis. When P<0.01 and I2>50%, the random-effects model was used. Continuous variables were represented by mean difference (MD) and its 95% CI. The dichotomous variables were expressed by odds ratio (OR) and 95% CI. Heterogeneity between the results was assessed by $\chi 2$ test and I2 test.

Results

Search results and basic information of included documents

A total of 191 literatures and 58 journals were obtained from computer retrieval database. After 42 republished papers, 31 unqualified papers, and 15 were excluded for other reasons, total of 161 studies were included. After 47 articles were excluded because of their unqualified titles and abstracts, 114 articles remained. After literature review, 8 studies with incomplete observational indicators and four studies with non-full-term pregnancy labor induction were excluded. Eleven articles were obtained for meta-analysis of this study[13-23] (Figure 1). Among the 11 articles that met the inclusion criteria, all were small-sample studies ranging from 84 to 369, and all subjects were over 20 years old. The number of cases, intervention measures, and observational indicators of patients in experimental and control group were described in detail in 11 articles (Table 1).

The results of evaluating the risked bias of the involved data

The Cochrane data base of systematic reviews 5.0 was evaluated for the risk ratio by plotting the graphed results (Figure 2A and Figure 2B). Among the 11 studies included in this study, research objects in 7 literatures were randomly grouped, those in 3 literatures were selected using computer random number table method.

Meta-analysis results of the efficacy of Dinoprostone for full-term pregnancy labor induction

A total of 10 literatures were evaluated (Figure 3A) for the number of vaginal delivery cases after 24h of medication, no difference was noted among studies (P = 0.14, I2 = 33%).But statistical difference between the experimental and the control group was seen (OR = 0.66, 95% CI: 0.55, 0.81, P <0.0001). By sensitivity analysis, the randomized exclusion of the two studies had no considerable effect on the combined effect size.

A total of 7 studies were examined (Figure 3B) for the number of vaginal delivery cases after 12h of medication. After medication, there was obvious heterogeneity between the selected articles (P<0.0001, I2=79%). A random-effects model was applied for the meta-analysis. The results indicated no statistically significant difference between the two groups. Sensitivity analysis, performed by sequentially excluding two studies, demonstrated no substantial impact on the overall effect size.

Six studies were analyzed (Figure 3C) for the time interval from medication to delivery.

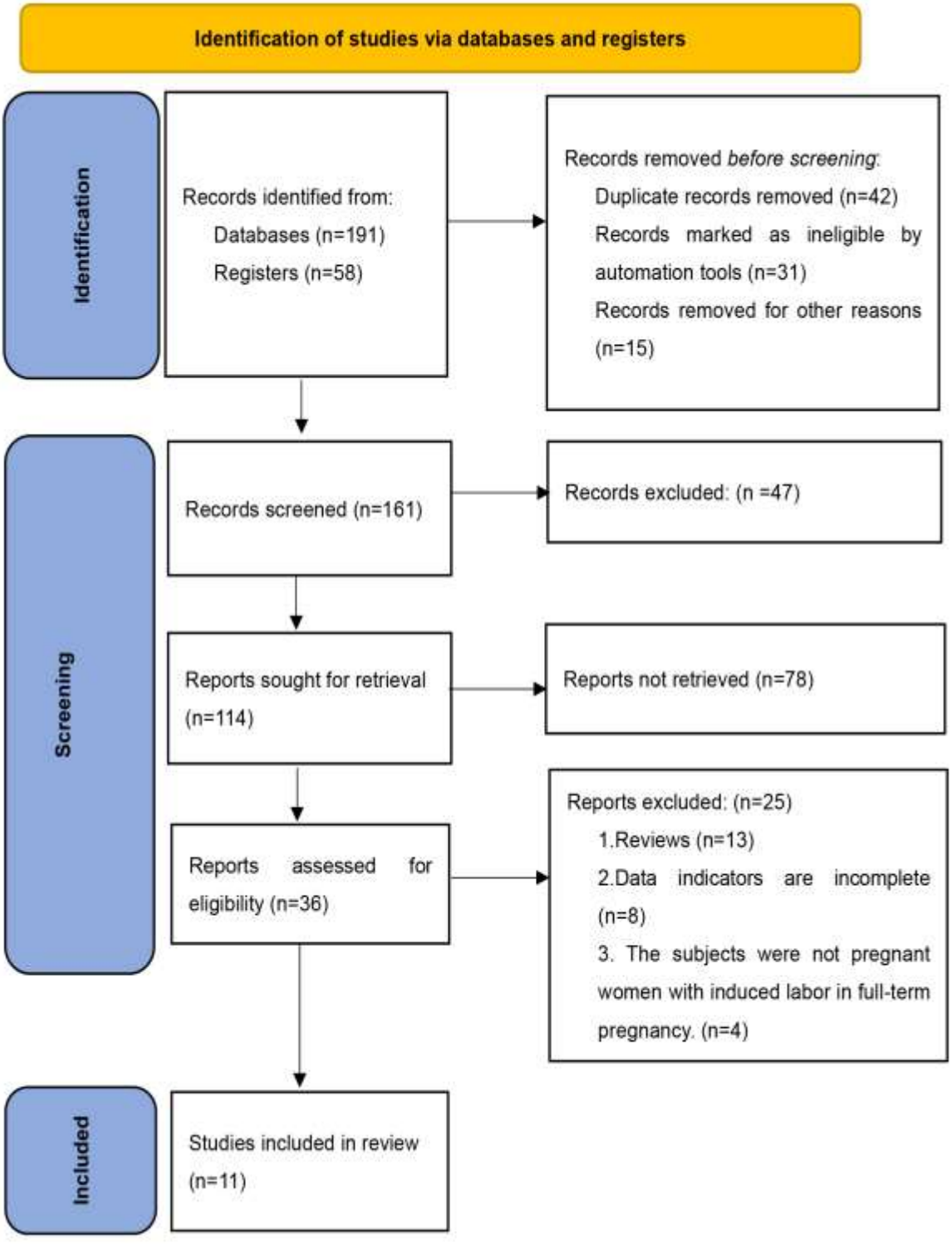

Figure 1: Retrieval flowchart

Table 1: Basic information of the included studies

Author	Year	Case number		Interventions		Observation indexes
		Experimental group	Control group	Experimental group	Control group	
Bartha (13)	2000	100	100	Dinoprostone	Misoprostol	a, d, g, h, i
Bolnick (14)	2004	58	64	Dinoprostone	Misoprostol	a, b, c, d, e, g, h, i
De Bonrostro (15)	2019	99	99	Dinoprostone	Misoprostol	e, f, h, i
Garry (16)	2003	89	97	Dinoprostone	Misoprostol	a, b, c, d, f, g,, h, i
Meyer (17)	2005	42	42	Dinoprostone	Misoprostol	a, d
Nunes (18)	1999	94	95	Dinoprostone	Misoprostol	a, b, c, d, h, i
Papanikolaou (19)	2004	83	80	Dinoprostone	Misoprostol	a, b, c, f, d, g, h, i
Rozenberg (20)	2001	185	184	Dinoprostone	Misoprostol	e, h, i
Sanchez (21)	1998	115	108	Dinoprostone	Misoprostol	a, b, d, g, h, i
Wing (22)	1997	98	99	Dinoprostone	Misoprostol	a, c, e, f, h, i
Young (23)	2020	172	172	Dinoprostone	Misoprostol	a, b, d, e, h, i

a, the number of vaginal delivery cases after 24h of medication; b, the number of vaginal delivery cases after 12h of medication; c, time interval from medication to delivery; d,number of pregnancies through cesarean; e, number of gastrointestinal reactions; f, number of abnormal cases of fetal heart rate monitoring; g, number of abnormal contractions; h, newborns with 1-minute Apgar score less than 7; i, neonates with 5-minute Apgar score less than 7 points.

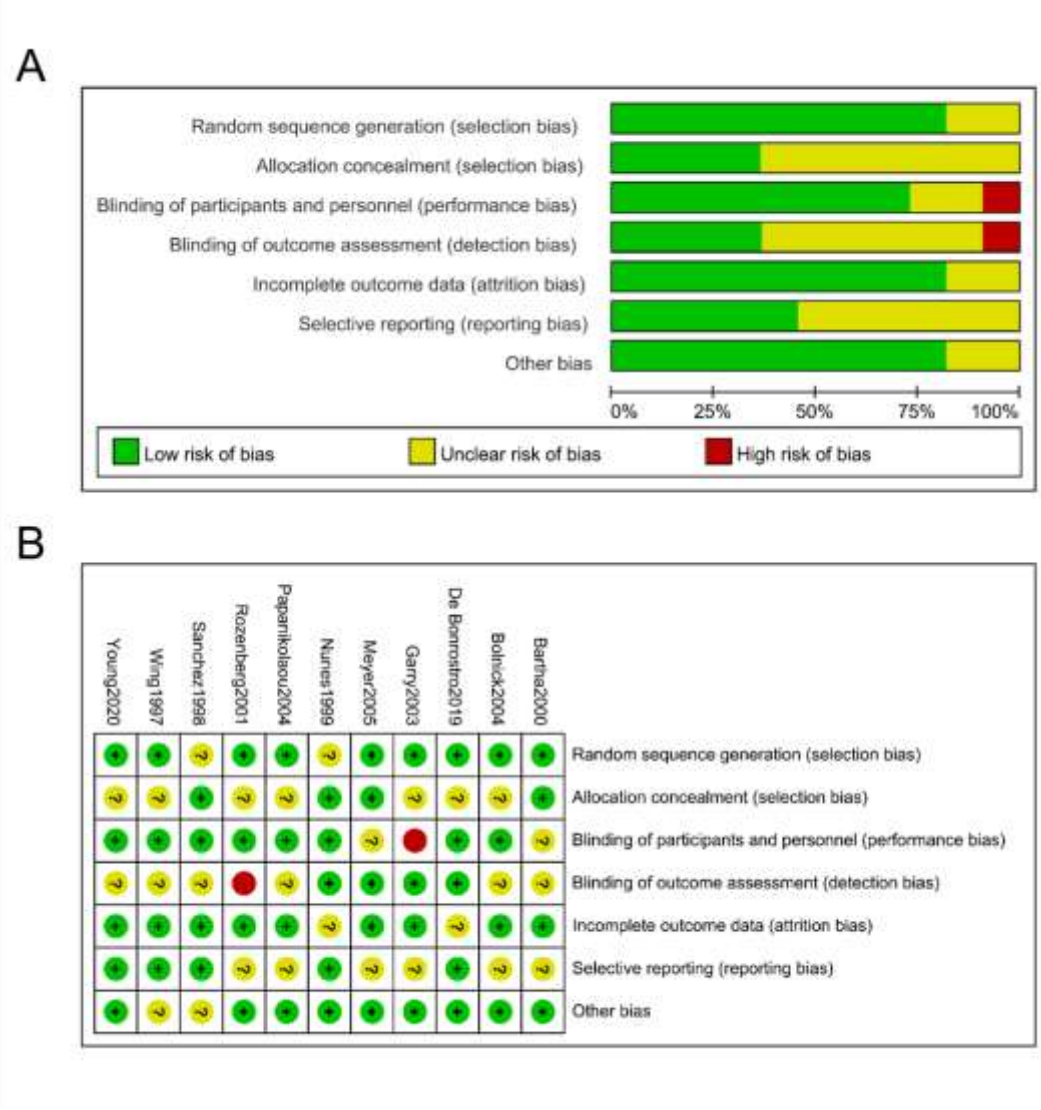

Figure 2: Risk of bias. (A) Proportion of included risk bias evaluation results; (B) Distribution of multiple risk of bias evaluation results corresponding to the included studies

The results showed huge variation among the groups (MD = 1.02, 95% CI: 0.11, 1.94, P = 0.03).After sensitivity analysis, the random exclusion of two studies had no considerable effect on the overall heterogeneity.

Seven articleswere scrutinized (Figure 3D) for number of pregnancies through cesarean, and there was diversity among the studies (P=0.002, I2=71%). A random effects model was used for Meta-analysis. The results showed no statistical difference between both groups (OR = 1.36, 95% CI: 0.75, 2.47, P = 0.31).After sensitivity analysis, the random exclusion of two studies had no considerable effect on the overall heterogeneity.

Meta-analysis results of the safety of Dinoprostone for full-term pregnancy labor induction

Overall 3 articles were explored (Figure 4A)for the number of gastrointestinal reactionsand there was difference in the included studies (P = 0.26, I2 = 26%).The results showed no statistical difference between the two groups. (OR = 1.45, 95% CI: 0.96, 2.18, P = 0.08).

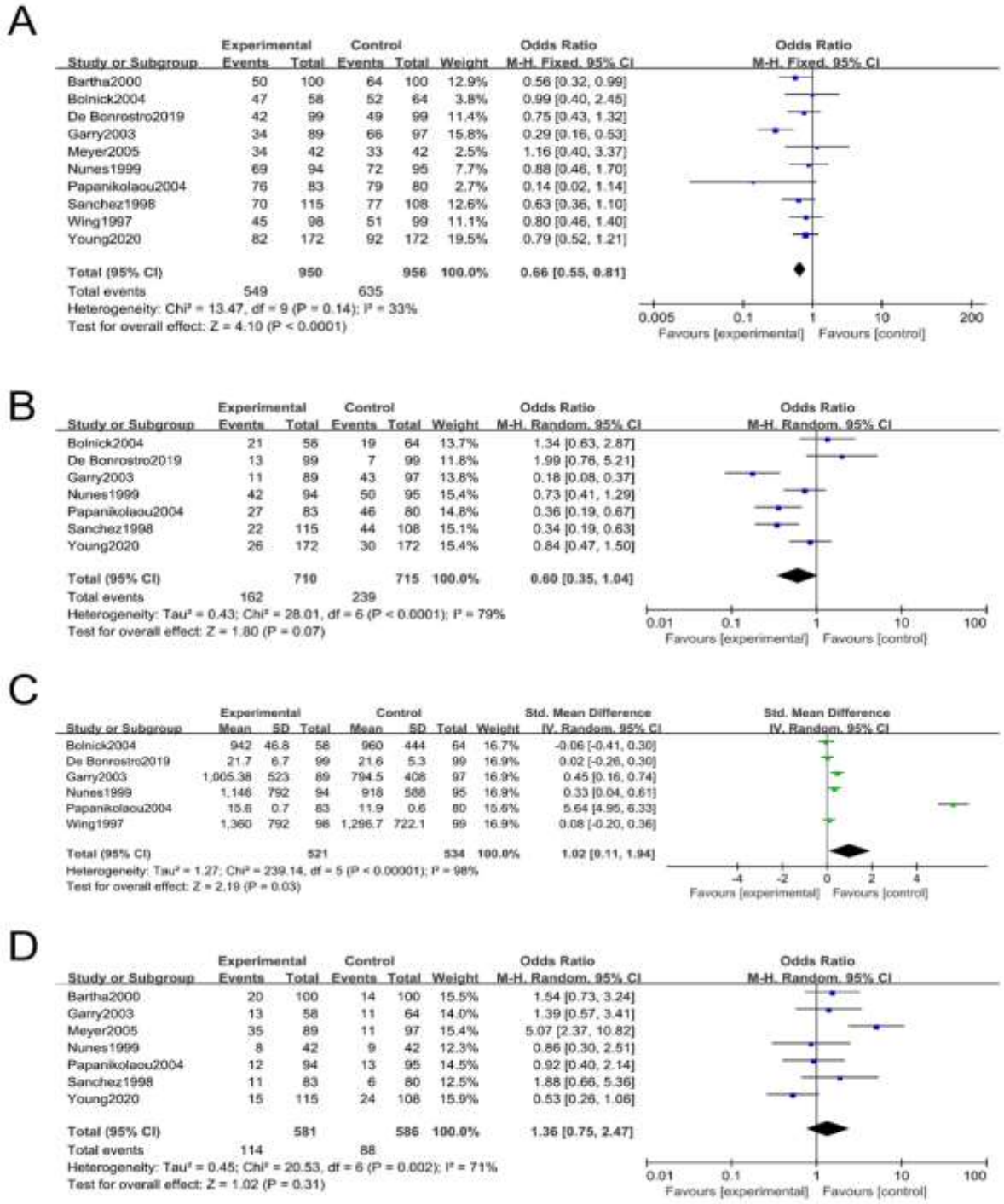

Figure 3: Forest plot of the efficacy of Dinoprostone for full-term pregnancy labor induction. (A) the number of vaginal delivery cases after 24h of medication; (B) the number of vaginal delivery cases after 12h of medication; (C) the time interval from medication to delivery; (D) the number of pregnancies through cesarean.

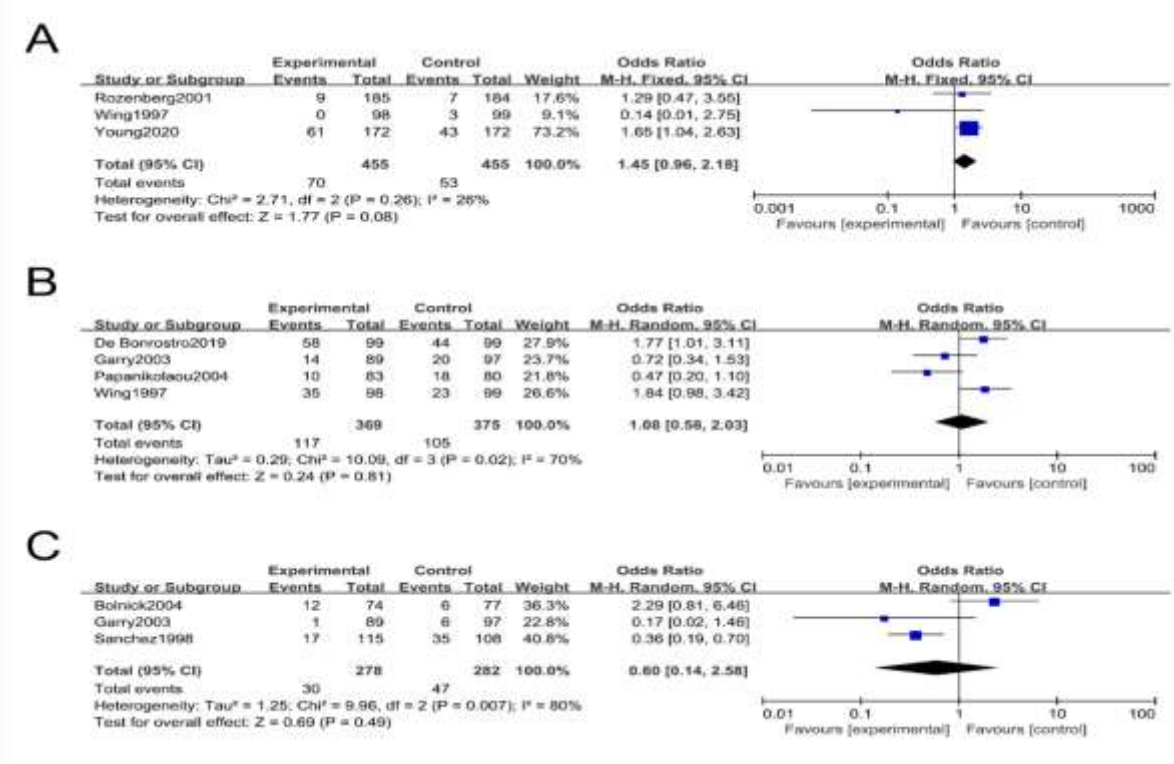

Figure 4: Forest plot of the safety of Dinoprostone for full-term pregnancy labor induction. (A) the number of gastrointestinal reactions; (B) the number of abnormal cases of fetal heart rate monitoring; (C) the number of abnormal contractions.

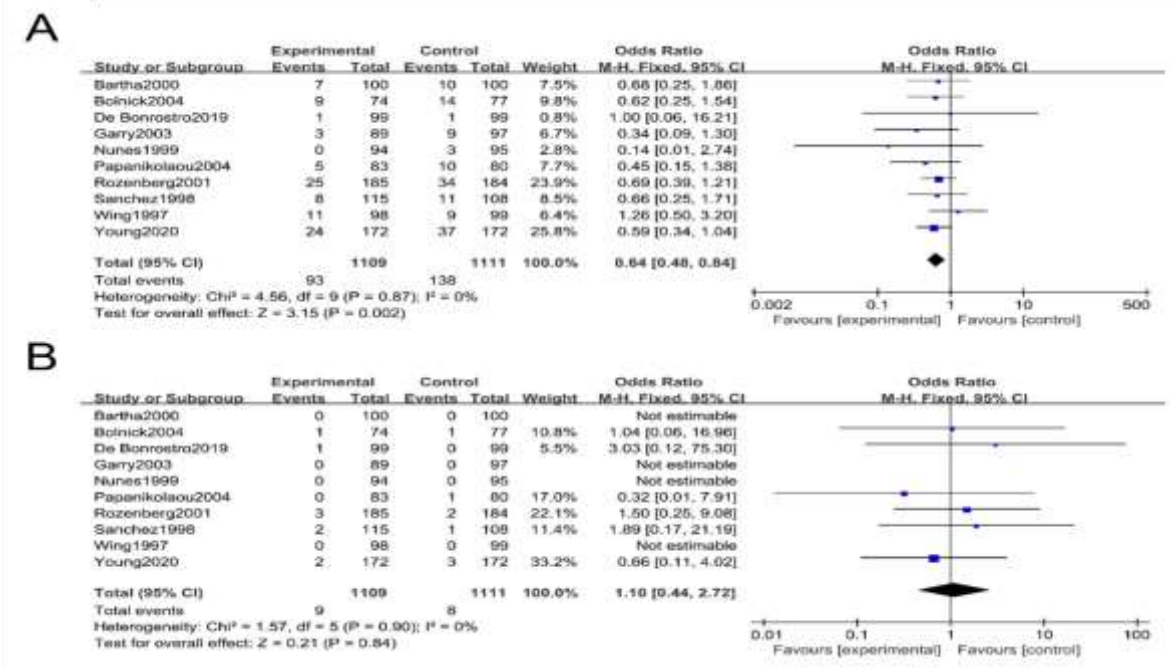

Figure 5: Forest plot of Apgar score evaluation. (A) newborns with 1-minute Apgar score less than 7; (B) neonates with 5-minute Apgar score less than 7 points**.**

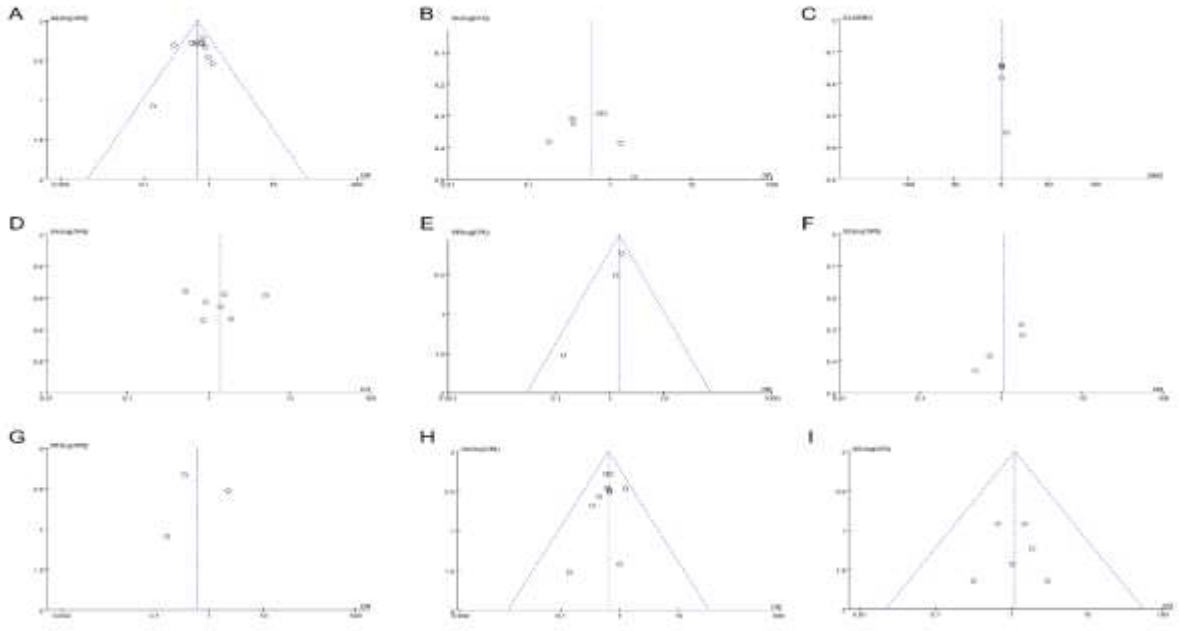

Figure 6: Funnel plot. (A) the number of vaginal delivery cases after 24h of medication; (B) the number of vaginal delivery cases after 12h of medication; (C) the time interval from medication to delivery; (D) the number of pregnancies through cesarean; (E) the number of gastrointestinal reactions; (F) the number of abnormal cases of fetal heart rate monitoring; (G) the number of abnormal contractions; (H) newborns with 1-minute Apgar score less than 7; (I) neonates with 5-minute Apgar score less than 7 points.

We selected four research papers (Figure 4B) for abnormal cases of fetal heart rate monitoring, and heterogeneity was noted in the included studies(P = 0.02, I^2 = 70%).A random effects model was used. The results differed radically (OR = 1.08, 95% CI: 0.58, 2.03, P = 0.81).

Three articles were selected (Figure 4C) for the number of abnormal contractions.There was obvious difference among the studies (P = 0.007, I^2 = 80%).A random effects model was used for Meta-analysis.

Meta-analysis results of Apgar score evaluation

Ten articles were taken for analysis (Figure 5A) for newborns with 1-minute Apgar score less than 7. There were no variations among the studies (P=0.87, I2=0%).Meta-analysis was carried out using a fixed-effects model, and the results showed difference dramatically (OR = 0.64, 95% CI: 0.48, 0.84, P = 0.002).After sensitivity analysis, the random exclusion of two studies had no considerable effect on overall heterogeneity.

We explored ten articles(Figure 5B) for neonates with 5-minute Apgar score less than 7 points. No difference was seen in the studies (P=0.90, I^2=0%).Meta-analysis was performed using a fixed-effect model, and no statistical difference was observed between both groups (OR = 1.10, 95% CI: 0.44, 2.72, P = 0.84).

Publication bias results

Funnel plot showed that the circles were relatively concentrated, suggesting high accuracy of research and no bias in publication (Figure 6)

Discussion

Cervical maturity is the most important factor in pregnant women with full-term pregnancy who may require induction for maternal or fetal indications. To assess cervical readiness, methods such as the Bishop score, vaginal ultrasound, and delivery prediction tools are used, with the Bishop score being the most widely applied by clinicians. Unlike natural cervical maturation, medically facilitated

cervical ripening does not trigger uterine contractions or overstimulation, does not impair uterine blood flow, does not cause rupture of membranes, and does not adversely affect subsequent pregnancies[24-26]. Traditional methods of inducing labor promote cervical ripening primarily by stimulating uterine contractions. However, this approach may lead to maternal fatigue and place the fetus in a compromised condition, increasing the risk of intrauterine hypoxia[27-28]. Prostaglandins play a crucial role in cervical ripening by altering the composition of the cervical extracellular matrix, leading to softening and relaxation of the cervix. They also facilitate cervical dilatation, stimulate uterine smooth muscle contractions, and promote cervical effacement[29-32].

Dinoprostone is a natural prostaglandin (PG), prescribed in all stages of pregnancy which has a contraction effect, but the sensitivity of the uterus to prostaglandin E2 in each stage is inconsistent, and the full-term uterine reaction is most sensitive[33-36]. The present meta-analysis assessed the effectiveness and safety of dinoprostone and misoprostol for labor induction in full-term pregnancies. Effectiveness outcomes included the number of vaginal deliveries within 12 hours and 24 hours, the time interval between drug administration and delivery, and the rate of cesarean sections. The results of meta-analysis showed that there was a substantial difference between the two groups from medication to delivery (P<0.05), which was consistent with the results of Varaklis *et al*.[37].
The number of gastrointestinal symptoms such as nausea, vomiting, and diarrhea, the number of abnormal fetal heart monitoring, uterine contractions, the number of newborns with 5-minute Apgar score less than 7 were used as safety indicators.The meta-analysis results showed that the number of neonates with 5-minute Apgar score less than 7 in the Dinoprostone group was less than that in the Misoprostol group, which was statistically different (P<0.05).In addition, there was no statistical difference in other safety indicators. Wang *et al*.[38] compared the effects and safety of Misoprostol, controlled-release Dinoprostone, and oxytocin in full-term pregnancy labor induction and stated that no statistical difference in the controlled-release of two drugs could be found and the results are consistent with present study.

All included studies were published articles, and the funnel plot demonstrated that the overall data were relatively concentrated. The circles in most studies were essentially symmetrical, indicating high study accuracy and no significant evidence of publication bias. In summary, dinoprostone and misoprostol were found to be equally effective for labor induction in full-term pregnancies. However, to shorten the waiting time for pregnant women and alleviate psychological stress, further optimization of dinoprostone dosing regimens may be warranted. This study, through a meta-analysis, confirmed the significant advantages of dinoprostone in full-term induction of labor. Its core value is reflected in three dimensions: in terms of clinical efficacy, the significant increase in vaginal delivery rate within 24 hours (OR = 0.66) and the improvement in the 1-minute Apgar score of the newborn (OR = 0.64) jointly verified the dual benefit mechanism of this drug - it not only effectively promotes cervical ripening through prostaglandin E2 receptors, but also avoids the adverse effects of excessive uterine stimulation on fetal oxygenation. The novelty of this study lies in the application of network meta-analysis for the first time to quantitatively compare the time–effect relationship of different prostaglandin preparations. The findings revealed that although dinoprostone has a slower onset of action, its “mild and continuous” pharmacokinetic profile aligns well with the natural course of physiological labor, which may account for its lower incidence of adverse neonatal outcomes. Nevertheless, this study has certain limitations, including the relatively small proportion of Asian populations represented in the included literature, which may limit the generalizability of the results to East Asian parturients. These findings have clear guiding significance for clinical practice: obstetric guidelines should place more emphasis on the precise matching of drug selection and cervical Bishop score, and for primiparas with a Bishop score of ≤ 6, dinoprostone can be used as the first choice to balance efficacy and safety. Future research should aim to address two key issues: (i) racial and ethnic differences in response to prostaglandin preparations, and (ii) the optimal synergistic approach for combining pharmacological agents with mechanical cervical ripening methods.

Conclusion

This meta-analysis demonstrates that the time interval from dinoprostone administration to delivery is longer compared with misoprostol. However, the study has several limitations. First, the strict inclusion criteria resulted in a limited number of eligible studies and a relatively small sample size. Second, inconsistencies in drug regimens and timing of administration introduced potential heterogeneity, the sources of which could not be fully determined. Future research should involve larger sample sizes and well-designed, long-term randomized controlled trials to validate and strengthen the conclusions of this meta-analysis.

Authors' contributions

ZRH and YZ conceptualised this study. ZRH, FBLandQWL worked on theliterature review. ZRH and YZ worked on the data analysis and interpretation of results. All authors worked on the discussion of the findings. All the authors read and approved the final manuscript.

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Declaration of conflicting interests

The authors declare no competing interests.

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