REVIEW ARTICLE

Double-balloon catheter vs dinoprostone (PGE-2) insert for labour induction: A meta-analysis of 2493 pregnancies

DOI: 10.29063/ajrh2023/v27i4.10

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Abstract

Induction of labor (IOL) is the stimulation of the uterus during pregnancy to begin the onset of labour. Nearly two of five pregnancies require IOL. We compared the effectiveness of double-balloon catheter (DBC) with dinoprostone (PGE-2) insert for labour induction from previous studies. We included randomized controlled trials (RCTs) that compared the safety and efficacy of DBC to PGE-2. To evaluate the studies, we utilized the Cochrane tool for risk of bias assessment. The rates of vaginal birth and cesarean section were the primary outcomes. We included ten RCTs in this meta-analysis with a total sample of 2493 singleton pregnancies. After 24 hours, there was no significant difference in the delivery rates between DBC and PGE-2 s [R.R=1.08, 95% CI, (0.77, 1.52), *P.value*=0.65], and the rate of cesarean delivery [R.R=1.03, 95% CI, (0.90; 1.18), *P.value*=0.65]. The DBC showed a significantly higher oxytocin use rate compared to the PGE-2 group [R.R=1.77, 95% CI, (1.41; 2.32), *P.value*<0.0001]. In the PGE-2 group, there was a significantly higher risk of uterine hyperstimulation, tachysystole, and umbilical artery PH levels below 7. There was no significant difference in the efficacy between the PGE-2 and DBC in terms of delivery rate in 24 hours and the rate of cesarean delivery except for a slight BISHOP score improvement with DBC. However, DBC showed a higher rate of oxytocin use compared to the PGE-2, the DBC seems to be safer with a lower risk of umbilical artery PH < 7, uterine hyperstimulation, and tachysystole incidence than PGE-2. *(Afr J Reprod Health 2023; 27 [4]: 84-95).*

Keywords: Double-balloon catheter, (DBC), dinoprostone, (PGE-2), labor induction, meta-analysis

Résumé

L'induction du travail (IOL) est la stimulation de l'utérus pendant la grossesse pour déclencher le début du travail. Près de deux grossesses sur cinq nécessitent une IOL. Nous avons comparé l'efficacité du cathéter à double ballonnet (DBC) avec l'insert de dinoprostone (PGE-2) pour l'induction du travail à partir d'études précédentes. Nous avons inclus des essais contrôlés randomisés (ECR) comparant l'innocuité et l'efficacité de la DBC à la PGE-2. Pour évaluer les études, nous avons utilisé l'outil Cochrane pour l'évaluation du risque de biais. Les taux d'accouchement vaginal et de césarienne étaient les critères de jugement principaux. Nous avons inclus dix ECR dans cette méta-analyse avec un échantillon total de 2493 grossesses uniques. Après 24 heures, il n'y avait pas de différence significative dans les taux d'accouchement entre DBC et PGE-2 s [R.R = 1,08, IC à 95 %, (0,77, 1,52), P.value = 0,65], et le taux d'accouchement par césarienne [R.R =1,03, IC à 95 %, (0,90 ; 1,18), valeur P = 0,65]. Le DBC a montré un taux d'utilisation d'ocytocine significativement plus élevé par rapport au groupe PGE-2 [R.R = 1,77, IC à 95 %, (1,41 ; 2,32), valeur P> 0,0001]. Dans le groupe PGE-2, il y avait un risque significativement plus élevé d'hyperstimulation utérine, de tachysystolie et de niveaux de PH de l'artère ombilicale inférieurs à 7. Il n'y avait pas de différence significative dans l'efficacité entre le PGE-2 et le DBC en termes de taux d'accouchement en 24 heures. et le taux d'accouchement par césarienne à l'exception d'une légère

amélioration du score BISHOP avec DBC. Cependant, le DBC a montré un taux d'utilisation d'ocytocine plus élevé que le PGE-2, le DBC semble être plus sûr avec un risque plus faible de PH de l'artère ombilicale < 7, d'hyperstimulation utérine et d'incidence de tachysystolie que le PGE-2. *(Afr J Reprod Health 2023; 27 [4]: 84-95).*

Mots-clés: Cathéter à double ballonnet, (DBC), dinoprostone, (PGE-2), déclenchement du travail, méta-analyse

Introduction

Labour induction (IOL) is the process of stimulating uterine contractions before the beginning of labor to facilitate vaginal birth[1]. Induction of labour is performed at a rate of over 20% in the United States, UK, and Australia, with some hospitals reaching as high as 40%. By contrast, lower rates are obtainable in in Latin America (11.4%) , Asia (12.1%), and Africa (4.4%)a[2]. Historically, inducing labour was carried out to prevent the progression of pathological disorders that might endanger the mother or baby, such as preeclampsia or intrauterine growth restriction[3]. In general, labour induction is undertaken when it is determined that the risks to the fetus or the mother posed by continuing the pregnancy are more significant than the risks posed by delivering the baby as planned[4]. Although there are strong arguments supporting the use of labor induction for several situations, it is not strongly recommended for women who have diabetes, twin pregnancies, suspected fetal macrosomia, or oligohydramnios, according to Mozurkewich *et al*.[5]. Since then, there has been much debate regarding whether and how to induce labor. There is no universally accepted benchmark; instead, there is a wide range of clinical criteria.

The results of a clinical assessment of cervical ripeness (cervical inducibilty) should go into the decision as to whether or not to induce labour and which procedure will serve as the best delivery option. Suppose the cervix is in a favorable position (A Bishop score of 8 or greater). In that case, an oxytocin infusion via an IV and an amniotomy is suggested next steps in the birthing process[6]. Cervical ripening is essential to boost the chance of a successful induction if the cervix is not in a favorable position[6]. Cervical ripening techniques may be divided into two main groups: mechanical and pharmaceutical[7-10].

When using a mechanical approach, pressure is applied inside the cervical canal to cause dilatation. Cervical remodeling is made more accessible by releasing prostaglandins in response to the local pressure. The most common mechanical dilation methods are Foley catheters and transcervical double-balloon catheter (DBC)[11]. The DBC provides a method for dilatation between the external and internal cervical os that is superior to the unilateral pressure of a single balloon catheter[12].

It is well-established that a higher induction failure rate is linked to a low Bishop score. When the Bishop score is under 6, medical intervention to hasten cervical ripening is necessary before labour may begin[13,14]. Medical options for cervical ripening range from progesterone (PG) preparations and oxytocin to estrogens and mifepristone[13,14]. The Food and Drug Administration (FDA) has given its approval for the use of prostaglandin E2 (PGE-2) to induce labor[15]. Binding to EP1-4 G protein-coupled receptors (GPCRs) causes various responses in cells and tissues, with the specificity of these responses depending on the EP subtype and the expression pattern. These receptors may modulate prostaglandin E2's efficacy during pregnancy; E2 increases cervical dilatation, effacement, and softening, most likely due to increased collagenase release[16]. PGE2 may be given vaginally as a suppository, gel, or implant[17-19]. The controlled-release PGE-2 insert is now one of the most popular methods of administering prostaglandin E2 since it can be removed quickly and easily after labour has begun[20]. The last meta-analysis comparing DBC and PGE-2, the DBC to the PGE-2 implant, observed no significant changes in cervical ripening[21]. Recent randomized controlled studies have shown that DBC are effective and safe alternatives to PGE-2[22,23].

This meta-analysis and systematic review aimed to update the existing evidence and assess how far the DBC are safe and efficient compared to PGE-2 for inducing labor.

Methods

This meta-analysis was carried out according to the guidelines of the Cochrane Handbook and then reported in accordance with the Preferred Reporting

Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[24].

Inclusion and exclusion criteria

We included only the studies that fulfilled the following PICOs criteria: Patients: Singleton pregnancies undergoing labor induction, Intervention: DBC, Comparator: PGE-2 as a vaginal insert, Outcomes: Cesarean section rates and birth within 24 hours were the primary outcomes. The intraoperative and postoperative complications and the outcomes for neonates are the other types of outcomes, Study design: Randomized controlled trials. Only studies on humans originally published in English were considered for this review. Studies that used other forms of PGE-2 (such as gel or suppository), a Foley catheter as a replacement, a history of cesarean section, no control group, a case report, or a conference abstract were not included.

Literature search

In September 2022, we searched five online databases: Cochrane Library, PubMed, SCOPUS, Web of Science, and EMBASE. The following keywords were used to find relevant studies: "dual-balloon catheter," "cervical-ripening balloon," "balloon dilatation," "PGE-2," and "prostaglandins E2". Additionally, we manually searched the bibliographies of all applicable trials. Disagreements were settled via a team discussion.

Study selection

Two steps of eligibility screening were conducted by two authors separately. First, the eligibility of the titles and abstracts was assessed. After screening abstracts that matched the inclusion criteria in the meta-analysis, a full-text examination was performed to determine which studies would ultimately be included.

Quality assessment

Completely independently, two authors assessed the potential for bias in the included research. The risk of bias was assessed according to the Cochrane Handbook for randomized controlled trials. These guidelines covered seven distinct areas, which were as follows: generation of random sequences, concealment of allocations, blinding of both participants and result assessment, selective reporting of outcomes, inadequate data on outcomes, and any other biases. The possibility of bias in each of the included studies was either deemed to be low, high, or unclear[25].

Data extraction

The following information was obtained from each of the studies that were included: Baseline data include the sample size, the maternal age (in years), the gestational age (in weeks), the body mass index (BMI), the proportion of nulliparas pregnancies, and the BISHOP score at the time of induction, and the summary included studies consist of study arms, trial registration, inclusion criteria, main outcomes, and conclusion. Also, we extracted outcomes data, which include the percentage of pregnancies that result in a cesarean section and the rate of births that take place within 24 hours; other outcomes include postoperative complications (including materno-fatal infections, uterine hyperstimulation, chorioamnionitis, post-partum hemorrhage, tachysystole, asphyxia, and respiratory distress syndrome as well as neonatal outcomes (include umbilical artery PH<7.1, NICU admission, 5 min Apgar score<7, umbilical artery PH, macrosomia >4000mg, head circumference in cm, birth weight in grams).

Statistical analysis

Review Manager (RevMan), version 5.4, was utilized in order to carry out the statistical analysis. Findings were considered to be statistically significant if the P-value was less than 0.05. For continuous data, the data were put together as a mean difference (M.D). For dichotomous data, the data were pooled as a risk ratio (R.R), all with a 95% confidence interval (CI) through the Mantel–Haenszel statistical method. At first, we assumed that the trials did not have a significant heterogeneity by using the fixed-effects model. Otherwise, the random-effects model was used to pool heterogeneous data. The Chi-square test and the I-square test were used in order to conduct our statistical analysis of the data's level of heterogeneity. If the chi-square P-value was less than 0.1, it showed that there was a statistically significant difference between the groups. The I-

square test was used in order to ascertain the level of heterogeneity that existed among studies.

Results

Search results

Our search method yielded 792 results. After titles and abstracts screening, we identified 18 studies for full-text screening. As shown in Figure 1, this systematic review included 10 of these studies, all were included in the meta-analysis[22,23,26-33].

Baseline characteristics of the included studies

We included ten RCTs in our meta-analysis with a total sample of 2493 singleton pregnancies. The maternal age in all studies was relatively similar, ranging between 27 and 34 years. In all included trials, the gestational age was more than 38 weeks. Regarding BMI, all studies were less than 30 kg/m2, except Lauterbach *et al*.[22]. The nulliparous percentage ranged between 50% and 100%. The least BISHOP score was one in Lauterbach *et al*.; in other studies, it ranged between 2 and 6. Oxytocin was applied with DBC by Devillard *et al*. Further details are shown in *supplementary table 1*.

Quality assessment results

In terms of randomization, all included studies were judged as having a low risk of bias, except for two studies in which the randomization method was unclear[27,30]. Allocation concealment was the same as randomization with one more exception; Bhide *et al*. 2020 also unclear[31]. All studies had a minimal risk of bias regarding the blinding of participants and outcome assessment. Regarding the attrition bias, Lauterbach et al. 2022 demonstrated a high risk of bias[22], while shecter-maor *et al*. showed an unclear risk[28], and the risk in the other studies was low. Reporting bias was low in all studies, except in shecter-maor *et al*. was unclear[28]. Lastly, other biases were detected in four studies[22,23,31,33].

Outcomes

1. Primary outcomes

The delivery rate in 24 hours

The pooled analysis of 8 trials with a total sample size of 2393 did not show a significant difference between DBC and PGE-2 as follows [R.R=1.08, 95%CI, (0.77; 1.52), *P=0.65*], and the data was heterogenous (P<0.00001, I2=94%), and this heterogeneity couldn't be resolved. (*Figure3)*

Cesarean delivery rate

PGE-2 group and DBC showed no statistically significant differences as follows [R.R=1.03, 95% CI, (0.90; 1.18), *P.value*=0.65], and the results was homogenous (P=0.72, I2=0). The data were pooled from all studies with a sample of 2493. *Figure 4*

2. Other outcomes

Oxytocin use percentage

According to data from five trials totaling 935 participants, the DBC showed a significantly higher oxytocin use rate compared to the PGE-2 group as follows [R.R=1.77, 95% CI, (1.41; 2.23), P.value<0.0000] and the data were heterogeneous (P=0.008, I2=71%), and this heterogeneity couldn't be resolved. *Figure 5*

Umbilical artery PH < 7 percentage

The incidence of umbilical artery PH < 7 was lower in DBC group than the PGE-2 group [R.R=0.55, 95% CI, (0.31; 0.7), *P.value*=0.04], and the data were homogenous (P=0.11, I2=47%). The combined data set included 1774 participants from five studies. *Figure 6A*

Uterine hyperstimulation incidence

The pooled analysis of five studies with 1969 pregnancies showed that the DBC group had significantly less uterine hyperstimulation than the PGE-2 group [R.R=0.17, 95% CI, (0.1; 0.3), *P.value*<0.00001], and the data were homogenous (P=0.19, I2=34%). *Figure 6B*

Tachysystole incidence

The incidence of tachysystole was shown to be statistically lower in the DBC group compared to the PGE-2 group, as determined by a pooled analysis of four studies, including a total sample size of 486 as follows [R.R=0.13, 95% CI (0.06; 0.32), *P.value*<0.00001], and the data were homogenous (P=0.66, I2=0). *Figure 6C*

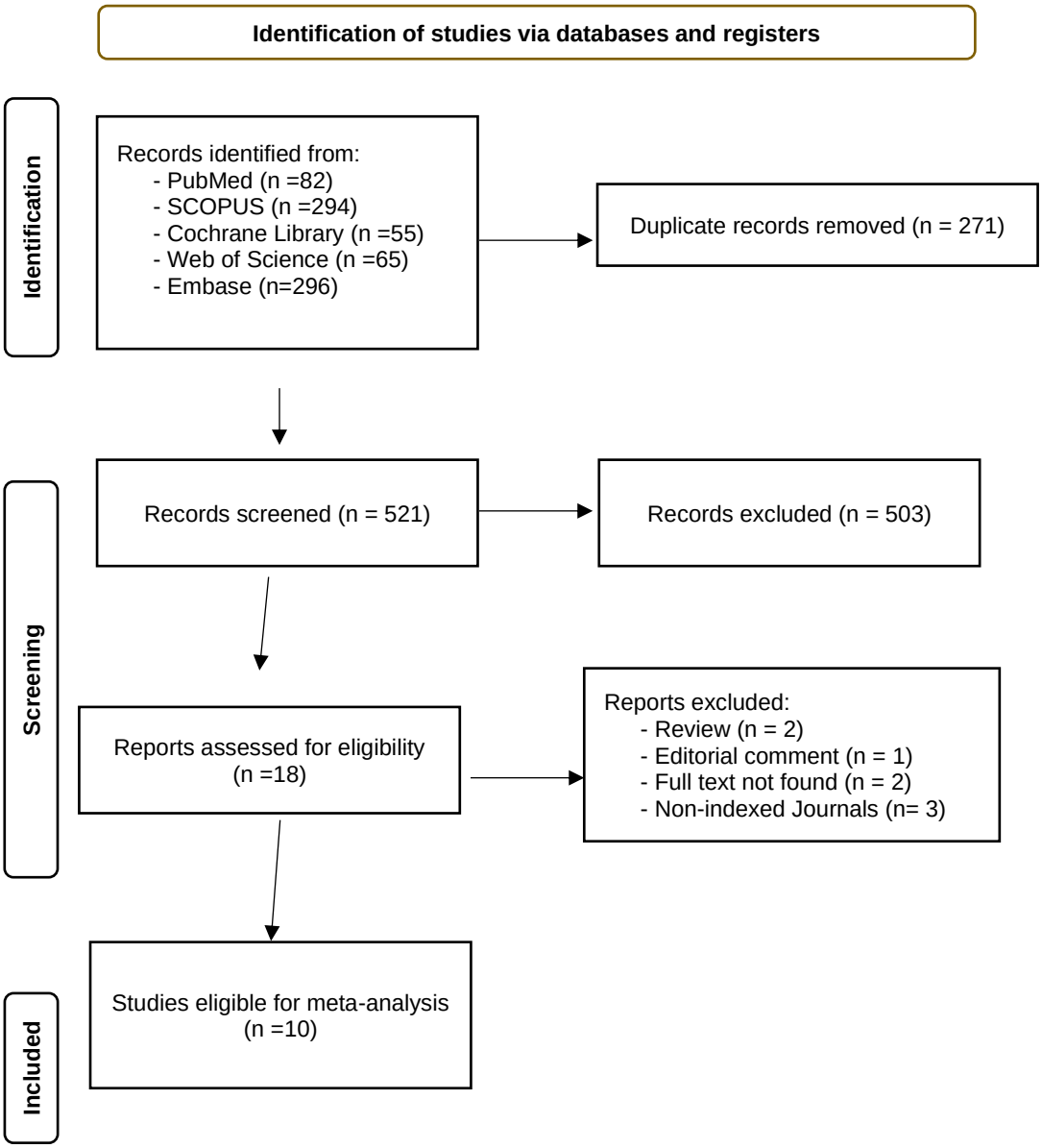

Figure1: PRISMA 2020 flow diagram for new systematic reviews, which includes searches of databases

Other operation-related outcomes

Regarding Improvement in BISHOP score, compared to the DBC group, the PGE-2 group showed no significant improvement [M.D=-0.03, 95% CI (-1.06; 0.99), *P.value*=0.95], but the data was heterogenous (P<0.00001, I2=93%), and the heterogeneity resolved by excluding Cromi et al. 2018. After resolving heterogeneity, BISHOP improvement in DBC group was significantly increased compared to PGE-2 group as follows [M.D=0.48, 95% CI, (0.12; 0.84), *P.value*=0.01], and the data were homogeneous (P=0.46, I2=0).

However, no significant difference was detected between the PGE-2 and DBC groups for the onset of active labor, cesarean indications such as labor arrest, induction failure, non-favorable heart rate (FHR), time to vaginal birth or time to delivery (all deliveries), the time between cervical ripening balloon and IOL, time to active labor in hours, and epidural analgesia use. *supplementary Table 2*

Other neonatal outcomes

There was an insignificant difference between the PGE-2 group and the DBC group regarding

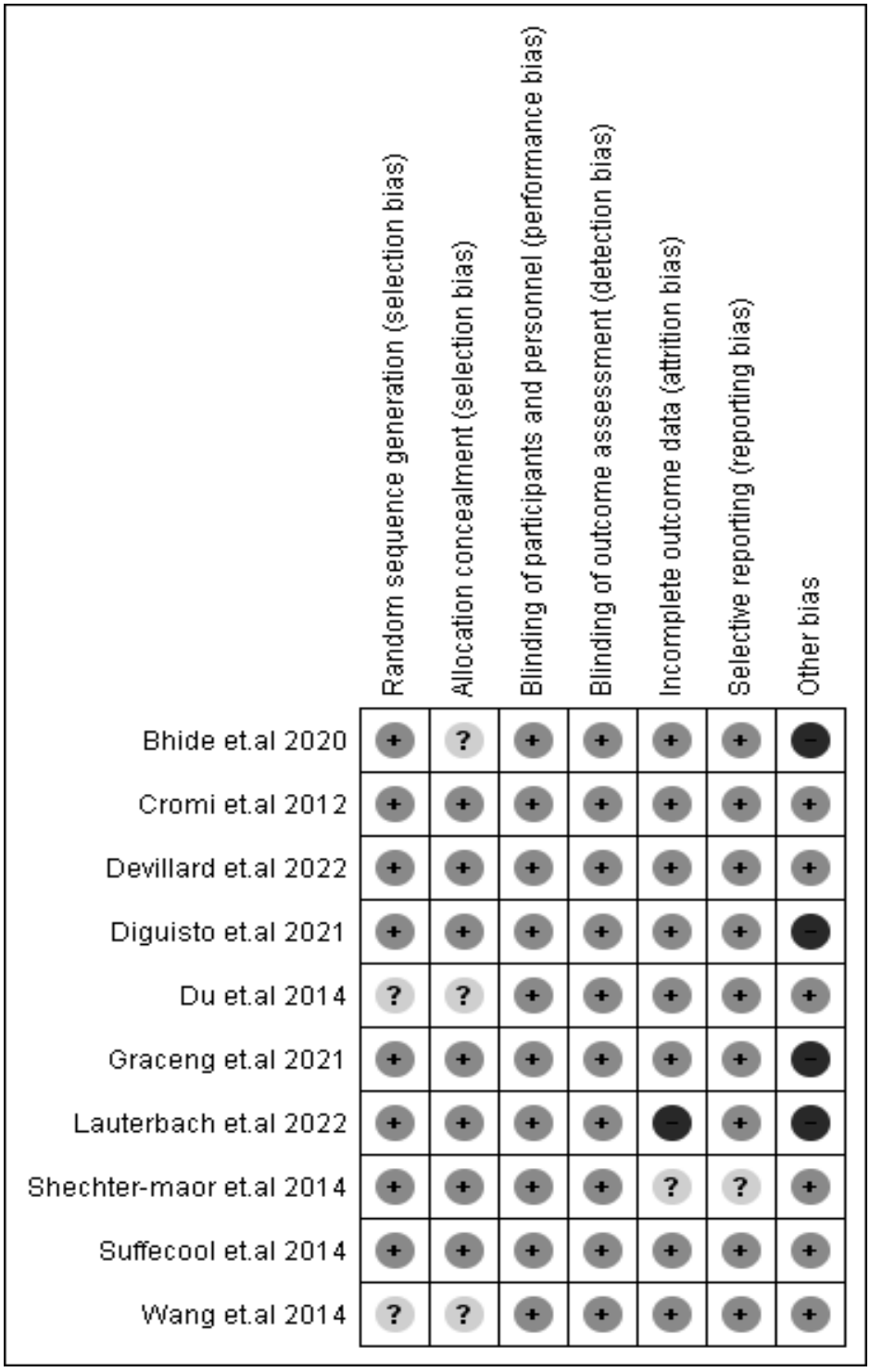

Figure 2: Summary of the risk of bias

umbilical artery PH, NICU admission, 5-minute Apgar score < 7, birth weight in grams, macrosomia > 4000mg, or head circumference in cm. *Supplementary Table 2*

Other intraoperative and postoperative complications

There was an insignificant difference between the PGE-2 group and the DBC regarding fatal maternal

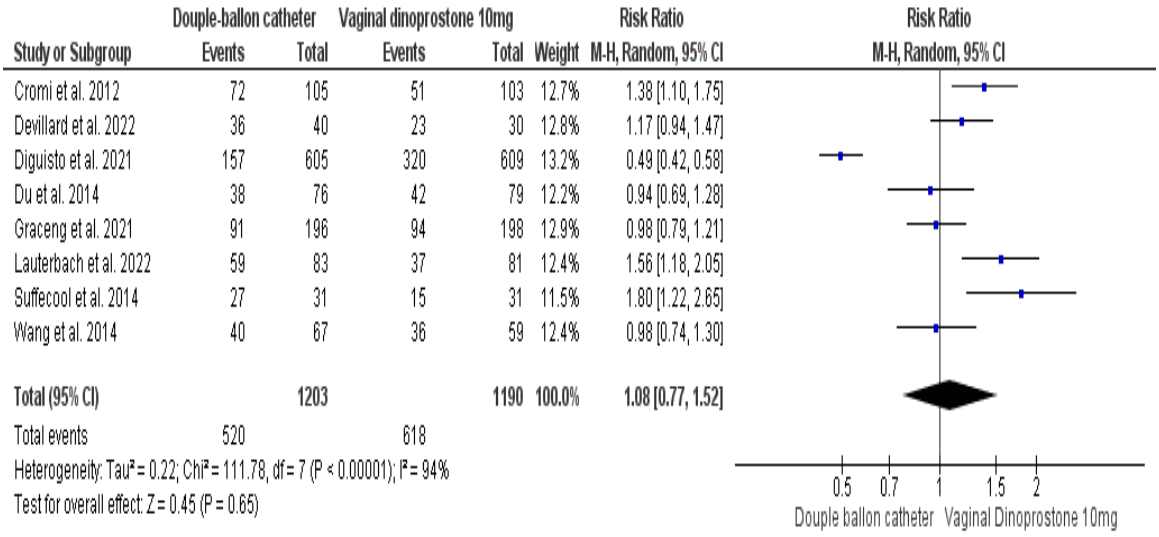

Figure 3: The delivery rate in 24 hours

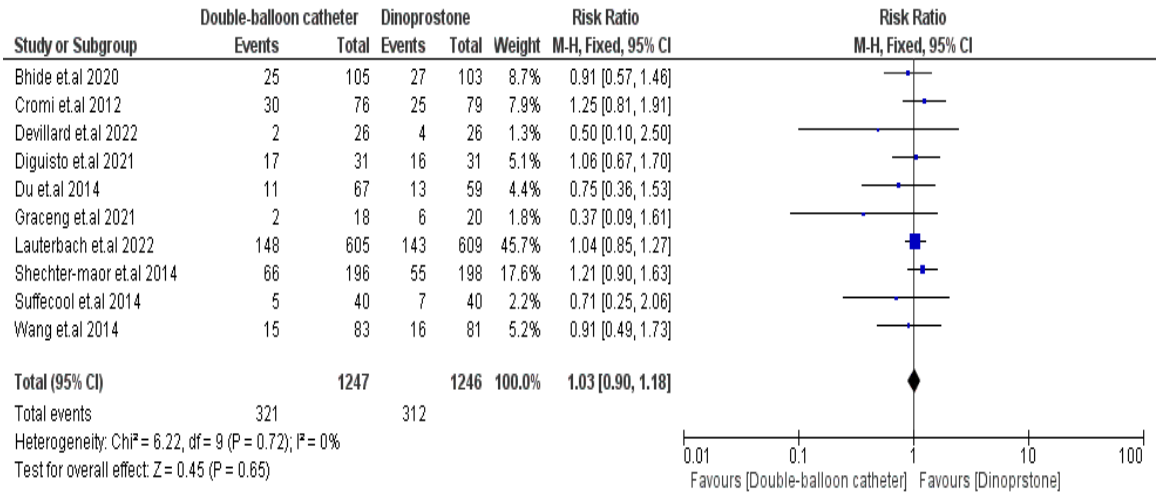

Figure 4: Cesarean delivery rate

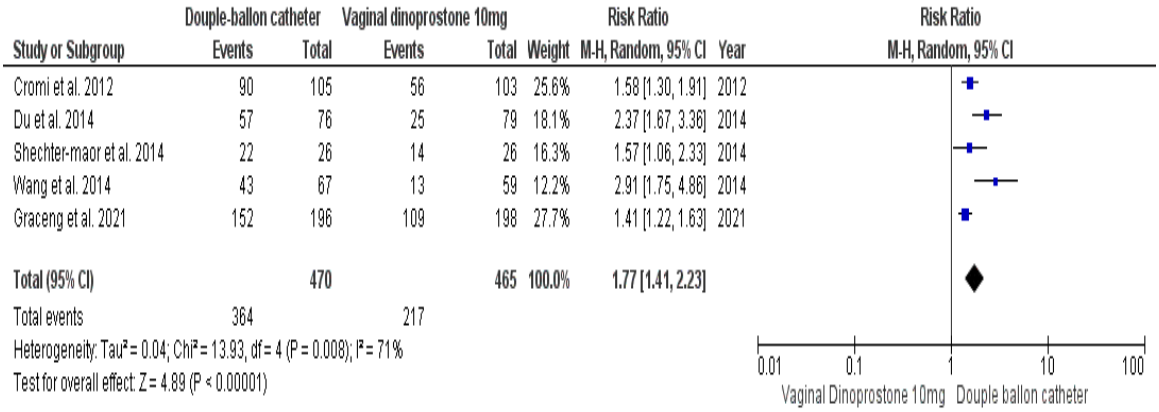

Figure 5: Oxytocin use rate

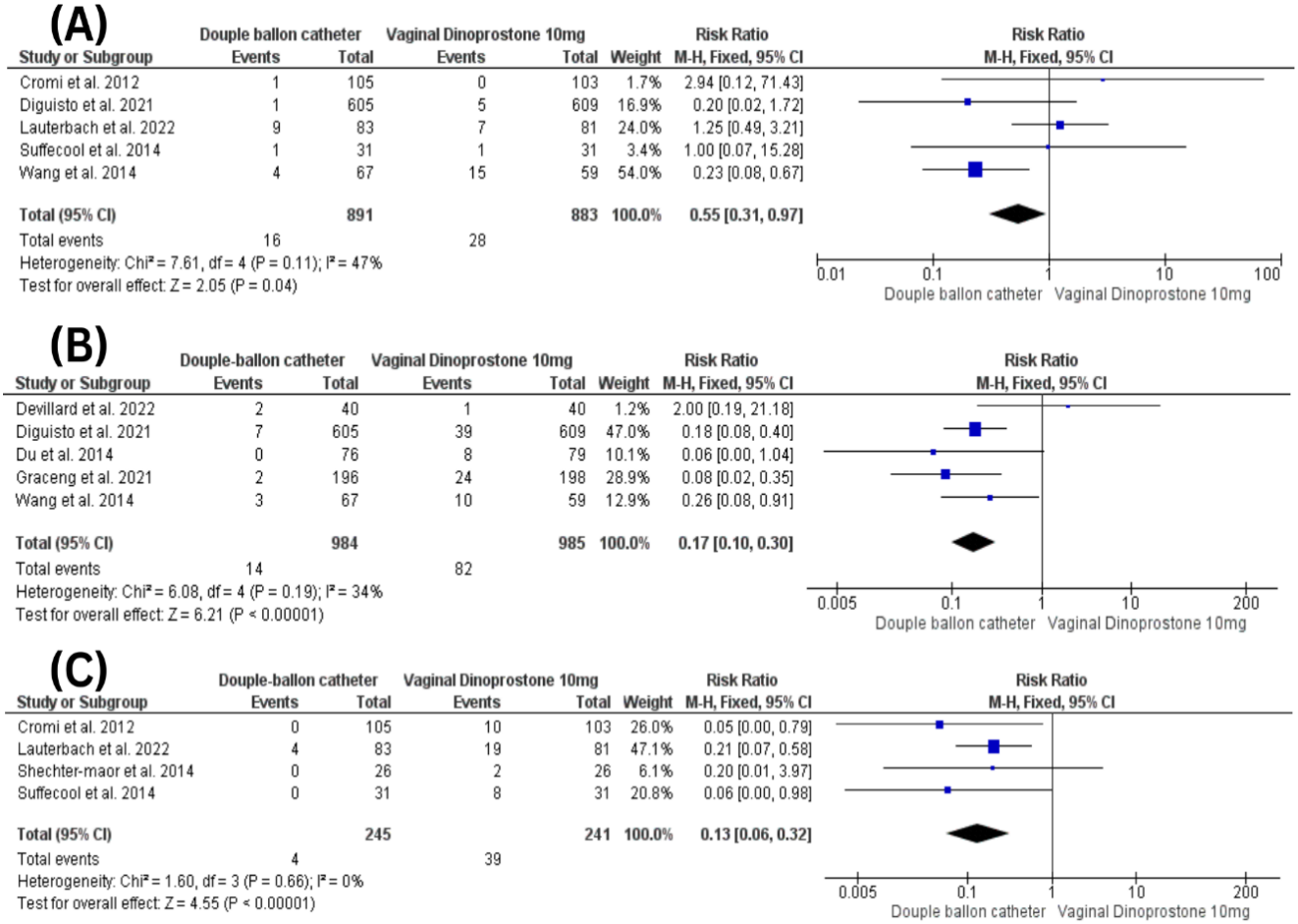

Figure 6: (A) Umbilical artery PH < 7 percentage, (B) Uterine hyperstimulation incidence, and (C) Tachysystole incidence

infections, chorioamnionitis, postmortem hemorrhage, hypoxia, or respiratory distress syndrome before, during, or after delivery. *Supplementary Table 2*.

Discussion

This meta-analysis aimed to compare DBC and PGE-2 in terms of their ability to induce labor in singleton pregnancies successfully and to assess any potential risks associated with using either method. There was no significant difference between DBC and PGE-2 in the rate of delivery within 24 hours. Also, PGE-2 did not significantly differ from DBC in cesarean delivery rate. However, DBC showed a considerably higher oxytocin use percentage compared PGE-2 group. While the PGE-2 group had a greater incidence of uterine hyperstimulation, tachysystole, and umbilical artery PH < 7 than the DBC group. No significant difference was found between both groups in the onset of active labor. Regarding BISHOP score improvement, the DBC improvement was higher than the PGE-2 group.

Indications for cesarean birth didn't significantly differ in the PGE-2 and DBC groups. Both vaginal delivery time and overall birth time did not change between the PGE-2 and DBC groups. No statistically significant difference was seen between the PGE-2 and DBC groups in the time between the cervical ripening balloon and the IOL, the number of hours it took for labor to begin, or the need for an epidural for pain management.

The most recent meta-analysis comprised five studies totaling 603 singleton pregnancies[21]. They found that the percentage of women who gave birth vaginally within 24 hours was not significantly differed between the DBC group and

the PGE-2 group. Also, the results of our meta-analysis revealed that there was not a significant difference between the two groups. Regarding the indication for cesarean delivery, the findings in the last meta-analysis and our study were comparable. They demonstrated an insignificant difference between the PGE-2 and DBC groups. Also, the results were similar regarding the significance of reducing oxytocin usage in the PGE-2 group. Moreover, both studies showed that the newborn outcomes were comparable: the PGE-2 group had a significantly higher umbilical artery PH <7, while the other outcomes showed insignificant differences between the groups. Also, the time to delivery and to vaginal delivery and the onset of active labor were insignificant in both studies. Additionally, the percentage of uterine hyperstimulation and tachysystole, in which PGE-2 has been demonstrated to carry a greater risk than a DBC. Also, we analyzed the improvement in the BISHOP score, which showed an insignificant difference before resolving heterogeneity, but with the homogenous data, the DBC group showed a significantly higher improvement.

Patients may receive PGE-2 as an implant or use it as a gel or suppository. The uterus is cleansed by this suppository. It is advised to use a suppository with 20 mg / three hours until delivery occurs. The doctor must discontinue the drug if the delivery does not occur within 24 hours or there are serious side effects[34,35]. The endocervical gel and the vaginal inserts encourage the ripening of the cervical mucosa. Although the technique requires more vaginal inspections, cervical gel allows for a faster release than the vaginal insert. PGE2 should be inserted into the posterior fornix every six hours until labor is induced, defined as the onset of regular, painful contractions. Medication delivery also should stop if there are no contractions within 24 hours or significant side effects, such as membrane rupture or hyperstimulation[17].

Regarding the administration of suppositories, patients need to be carefully monitored for any side effects, most notably pyrexia, and the patient's PGE-2 treatment has to be stopped immediately if any significant side effects appear. Additional procedures, like dilation and curettage, are occasionally needed to complete a prostaglandin E2 suppository removal [36]. Also, for gel and insert administration, uterine activity, fetal health, and cervical dilatation need monitoring. Medical professionals should check for uterine hyperstimulation, persistent contractions, and fetal discomfort. When these or other adverse effects appear, the PGE-2 must be stopped[37]. Additionally, a previous network meta-analysis showed that the efficacy of PGE-2 doesn't differ much from DBC, and the cost and application of DBC and PGE-2 were relatively similar, but with a greater safety profile for DBC[38].

Our study has some strong points. We included only randomized controlled trials, which gave more trustable evidence. Our meta-analysis's sample size was much higher than the last meta-analysis. Also, most included studies showed high quality, and we extracted and analyzed all the available outcomes. However, we have some limitations. One of these is that we found substantial heterogeneity in analyses, which may be attributable to variations in the inclusion and exclusion criteria for individuals across studies.

Conclusion

We conclude that there is no significant difference in the efficacy between the PGE-2 and DBC in terms of delivery rate in 24 hours and the rate of cesarean delivery except for a slight BISHOP score improvement with DBC. However, DBC shows a higher rate of oxytocin use compared to the PGE-2, the DBC seems to be safer with a lower risk of umbilical artery PH < 7, uterine hyperstimulation, and tachysystole incidence than PGE-2. Larger and well-designed trials are required to confirm the results of these two methods on labor induction, and to compare DBC with other induction methods.

Data availability

The corresponding author can provide the data used to support the study's results upon request.

Conflict of interest

The authors have no conflicts of interest to disclose.

Authors' contributions

Conception and design: all the authors. Acquisition of data: A.M. E, H.A.F, R.A.E, A.A.M, F.R.S and, S.A.M Analysis and interpretation of data: S.E.M, R.H, N.S.E, S.M.A, N.H.A, S.A.S, H.H.A, E.A.I,A.M.O Drafting of manuscript: , R.K.M,

S.J.F, H.I.H, S.A.S, W.H.T Reviewing and editing: all the authors.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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