

Original Research Article

MATERNAL AND NEONATAL OUTCOMES FOLLOWING LABOR INDUCTION WITH DINOPROSTONE GEL VERSUS DINOPROSTONE VAGINAL PESSARY: A RANDOMIZED CLINICAL STUDY

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ABSTRACT

Background: Induction of labor is a common obstetric intervention, with prostaglandin E₂ (dinoprostone) widely used for cervical ripening. Both dinoprostone gel and vaginal pessary are employed, but comparative evidence regarding efficacy and fetomaternal outcomes is limited. **Objectives:** To compare the efficacy, maternal outcomes, and neonatal outcomes of labor induction using dinoprostone gel versus dinoprostone vaginal pessary in term pregnancies with an unfavorable cervix.

Material and Methods: In this randomized clinical study at a tertiary care center in Kolkata, 60 term pregnant women requiring labor induction were randomly assigned to receive either intracervical dinoprostone gel (0.5 mg, up to two doses; n=30) or a 10 mg controlled-release vaginal pessary (n=30). Primary outcomes included induction-to-delivery interval and induction success; secondary outcomes included mode of delivery, oxytocin requirement, maternal complications, and neonatal outcomes. Statistical significance was set at $p < 0.05$.

Results: Baseline characteristics and indications for induction were comparable. The induction-to-delivery interval was significantly shorter in the pessary group (9.0 ± 2.1 h) compared to the gel group (11.5 ± 2.4 h; $p = 0.004$). Delivery within 12 hours occurred in 70% of the pessary group versus 26.7% of the gel group ($p < 0.001$). Caesarean section rates were higher in the gel group (33.3% vs 3.3%; $p < 0.001$). Uterine tachysystole and fetal distress were more frequent with gel, whereas neonatal outcomes, including Apgar scores and resuscitation needs, were similar between groups.

Conclusion: Both dinoprostone gel and vaginal pessary are effective and safe for labor induction at term. However, vaginal pessary offers superior efficacy, with a shorter induction-to-delivery interval, higher induction success, and lower cesarean rates, without compromising maternal or neonatal safety.

Keywords: Labor induction, Dinoprostone gel, Dinoprostone vaginal pessary, Cervical ripening, Maternal outcome, Neonatal outcome.

INTRODUCTION

Induction of labor is a commonly performed obstetric intervention, defined as the artificial initiation of uterine contractions prior to the spontaneous onset of labor, with the aim of achieving vaginal delivery of the fetus and placenta. This intervention is undertaken only in pregnancies at or beyond the legal

limit of fetal viability and is indicated when the anticipated benefits of delivery outweigh the risks associated with continuation of pregnancy.^[1] Over the past two decades, the incidence of labor induction has shown a significant rise worldwide, reflecting changing obstetric practices, improved fetal surveillance, and increasing maternal and fetal indications for timely delivery.^[2-4]

Despite being undertaken with the objective of achieving vaginal birth, induction of labor is frequently associated with prolonged labor, increased need for augmentation, and a higher incidence of operative vaginal delivery and cesarean section, particularly in nulliparous women. One of the most important determinants of successful labor induction is cervical favorability, which is commonly assessed using the Bishop scoring system. A Bishop score of 6 or more is predictive of successful induction, whereas an unfavorable cervix is associated with higher rates of failed induction and operative delivery.^[5,6] Therefore, pre-induction cervical ripening plays a crucial role in improving induction outcomes.

Cervical ripening may be achieved using mechanical methods such as Foley catheter insertion or hygroscopic dilators, or pharmacological agents including prostaglandins. Among pharmacological agents, prostaglandins have a central role in cervical ripening and parturition due to their effects on collagen remodeling, cervical softening, and enhancement of myometrial contractility.^[7] Prostaglandin E2 (dinoprostone) is one of the most widely used agents for cervical ripening and labor induction and can be administered through various routes, including intracervical gel and controlled-release vaginal pessary.^[8]

Dinoprostone gel requires repeated dosing and frequent vaginal examinations, which may increase patient discomfort and the risk of infection. In contrast, the dinoprostone vaginal pessary offers sustained release of the drug over a prolonged period and has the advantage of easy removal in the event of uterine hyperstimulation or fetal heart rate abnormalities.^[9] However, studies comparing these two formulations have reported variable results with respect to induction-to-delivery interval, need for oxytocin augmentation, mode of delivery, and maternal and neonatal outcomes, possibly due to differences in dosing regimens, patient characteristics, and cervical status at induction.^[10]

Although dinoprostone gel and dinoprostone vaginal pessary are widely employed for induction of labor, there remains no clear consensus regarding the superiority of one formulation over the other, particularly in resource-constrained settings and across heterogeneous patient populations. Furthermore, region-specific data comparing maternal and neonatal outcomes following induction with these two formulations are limited. The present randomized clinical study was therefore conducted to compare the efficacy and fetomaternal outcomes of labor induction using dinoprostone gel and dinoprostone vaginal pessary, with the objective of generating evidence-based guidance for clinical practice.

MATERIALS AND METHODS

This randomized clinical study was conducted in the Department of Obstetrics and Gynaecology, Medical

College Hospital (MCH), Kolkata, over a period of 18 months from January 2018 to June 2019 after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to enrolment. A total of 60 term pregnant women admitted for induction of labor were included in the study, with the sample size calculated using the formula $4PQ(Z\alpha+Z\beta)^2/(P_1-P_2)^2$, where P was derived from previously published studies comparing dinoprostone gel and dinoprostone pessary, with P₁ and P₂ taken as 62 and 28 respectively [9, 10], and a significance level of 0.05. Based on this calculation, 60 women were considered adequate and were randomly allocated into two equal groups of 30 each using computer-generated random number tables.

Women were included if they had a singleton live pregnancy in cephalic presentation between 37 and 41 completed weeks of gestation, with intact membranes, a Bishop score of ≤ 6 , a history of two or fewer previous viable vaginal deliveries, and a medical or obstetric indication for induction of labor. Exclusion criteria included hypersensitivity to prostaglandins, favorable cervix (modified Bishop score ≥ 6), multiple pregnancy, malpresentation, non-reassuring fetal heart rate pattern, previous uterine scar, cephalopelvic disproportion, antepartum hemorrhage, and fetal congenital anomalies.

All participants underwent detailed antenatal evaluation including general and obstetric examination, and fetal well-being was assessed using cardiotocography. Pre-induction Bishop score was assessed by digital per vaginal examination and documented prior to administration of the induction agent. Group A received intracervical dinoprostone gel at a dose of 0.5 mg under aseptic precautions, following which the patient was kept in a recumbent position for at least 30 minutes. If labor did not ensue, a second dose was administered after 6 hours following reassessment and cardiotocography, with a maximum of two doses allowed. Group B received a 10 mg controlled-release dinoprostone vaginal pessary placed in the posterior vaginal fornix, after which the patient was advised to remain recumbent for at least 30 minutes. The pessary was removed after 12 hours or earlier if active labor commenced, membranes ruptured, or uterine hyperstimulation or fetal distress occurred.

Following administration of the induction agent, fetal heart rate was monitored every 20 minutes during the first hour and hourly thereafter until the onset of labor, while uterine activity, maternal vital parameters, and color of liquor were closely observed. Once active labor was established, labor progress was monitored using a partograph along with cardiotocographic monitoring as indicated. Oxytocin augmentation was initiated when required, starting at 2.5 mIU/min and increased by 2.5 mIU/min every 20 minutes until adequate uterine contractions of three contractions in 10 minutes were achieved, provided fetal heart rate remained reassuring. Artificial rupture of membranes was

performed during active labor when indicated. Induction failure was defined as failure to establish active labor after two doses of intracervical dinoprostone gel administered 6 hours apart within 24 hours, or after one dinoprostone vaginal pessary used for 12 hours.

Maternal outcomes assessed included induction-to-delivery interval, mode of delivery, need for oxytocin augmentation, and complications such as fetal distress, uterine tachysystole, meconium-stained liquor, postpartum hemorrhage, and precipitate labor. Neonatal outcomes were evaluated using Apgar scores at 1 and 5 minutes, need for neonatal resuscitation, and requirement for neonatal care unit admission. Both mothers and neonates were followed until discharge. Data were recorded and analyzed using Microsoft Excel software, with categorical variables compared using the Chi-square test or Fisher's exact test as appropriate. All statistical analyses were two-tailed, and a p value of less than 0.05 was considered statistically significant.

RESULTS

A total of 60 term pregnant women were enrolled in the study and randomly allocated into two equal groups: 30 women in the dinoprostone gel group and 30 women in the dinoprostone vaginal pessary group. The baseline demographic characteristics and indications for induction of labor are presented in Table 1. The majority of women in both groups

belonged to the 20–30-year age group, accounting for 63.3% in the dinoprostone gel group and 70.0% in the dinoprostone pessary group. Women aged less than 20 years constituted 13.3% and 10.0%, while those aged more than 30 years constituted 23.3% and 20.0% in the gel and pessary groups, respectively. Regarding parity, primiparous women constituted 33.3% of the dinoprostone gel group and 40.0% of the dinoprostone pessary group, whereas multiparous women constituted 66.7% and 60.0%, respectively. Religion-wise distribution was comparable between the two groups. Hindu women comprised 60.0% in the dinoprostone gel group and 66.7% in the dinoprostone pessary group, while Muslim women comprised 40.0% and 33.3%, respectively. Preeclampsia was the most common indication for induction of labor in both groups, accounting for 33.3% of cases in the gel group and 30.0% in the pessary group, followed by post-dated pregnancy (26.7% and 20.0%, respectively). Other indications included gestational hypertension, gestational diabetes mellitus, chronic hypertension, premature rupture of membranes, and Rh-negative pregnancy. The distribution of indications for induction of labor did not differ significantly between the two groups ($p > 0.05$ for all indications). Overall, no statistically significant differences were observed between the two groups with respect to baseline demographic characteristics or indications for induction of labor, indicating that the study groups were comparable at baseline.

Table 1: Baseline Characteristics and Indications of Labor Induction in PGE2 Gel vs PGE2 Pessary Groups

Variable / Indication	PGE2 Gel (n=30)	PGE2 Pessary (n=30)	Total (n=60)	p-value	
Age (years)	<20	4 (13.3%)	3 (10%)	7 (11.7%)	0.852
	20–30	19 (63.3%)	21 (70%)	40 (66.7%)	
	>30	7 (23.3%)	6 (20%)	13 (21.7%)	
Parity	Primipara	10 (33.3%)	12 (40%)	22 (36.7%)	0.592
	Multipara	20 (66.7%)	18 (60%)	38 (63.3%)	
Religion	Hindu	18 (60%)	20 (66.7%)	38 (63.3%)	0.592
	Muslim	12 (40%)	10 (33.3%)	22 (36.7%)	
Indications of Labor Induction	CHR HTN	2 (6.7%)	5 (16.7%)	7 (11.7%)	0.227
	GDM	4 (13.3%)	3 (10%)	7 (11.7%)	0.687
	GES HTN	4 (13.3%)	4 (13.3%)	8 (13.3%)	1.000
	PD - Post Dated	8 (26.7%)	6 (20%)	14 (23.3%)	0.541
	Pre-eclampsia	10 (33.3%)	9 (30%)	19 (31.7%)	0.781
	PROM	1 (3.3%)	0 (0%)	1 (1.7%)	0.313
	RH NEG	1 (3.3%)	3 (10%)	4 (6.7%)	0.300

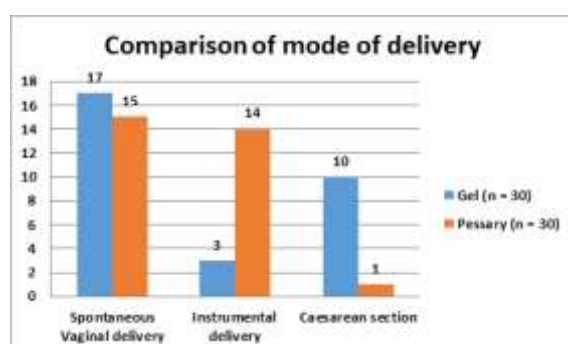
Efficacy outcomes of labor induction is shown in Table 2. The mean induction-to-delivery interval was significantly shorter in the dinoprostone vaginal pessary group compared to the dinoprostone gel group (9.0 ± 2.1 hours vs 11.5 ± 2.4 hours; $p = 0.004$). A significantly higher proportion of women in the pessary group achieved delivery within 12 hours (70.0%) compared to the gel group (26.7%) ($p < 0.001$). The requirement for oxytocin augmentation

was comparable between the two groups, with 33.3% of women in the gel group and 40.0% in the pessary group requiring augmentation, and the difference was not statistically significant ($p = 0.592$). Induction failure was observed in 10.0% of women in the gel group, whereas no cases of induction failure were recorded in the pessary group, and this difference was statistically significant ($p < 0.001$).

Table 2: Efficacy Outcomes of Labor Induction

Outcome	Gel (n = 30)	Pessary (n = 30)	p-value
Induction-to-delivery interval (hours, Mean ± SD)	11.5 ± 2.4	9.0 ± 2.1	0.004
Delivery ≤ 12 hours	8 (26.7%)	21 (70.0%)	< 0.001
Oxytocin augmentation required	10 (33.3%)	12 (40.0%)	0.592
Induction failure	3 (10.0%)	0 (0%)	< 0.001

Figure 1 shows the comparison of mode of delivery between the two groups. Spontaneous vaginal delivery occurred in 56.6% of women in the dinoprostone gel group and 50.0% in the dinoprostone vaginal pessary group. Instrumental delivery was more frequent in the pessary group (46.6%) compared to the gel group (10.0%). In contrast, the rate of caesarean section was significantly higher in the gel group (33.3%) than in the pessary group (3.3%). Overall, the distribution of mode of delivery differed significantly between the two groups ($p < 0.001$).

**Figure 1: Comparison of mode of delivery between the two groups**

Maternal complications observed during labor are presented in Table 3. Uterine tachysystole occurred in 6.7% of women in the dinoprostone gel group, while no cases were observed in the dinoprostone vaginal pessary group, and this difference was statistically significant ($p = 0.001$). Postpartum haemorrhage was reported in 10.0% of women in the gel group and 6.7% in the pessary group, with no statistically significant difference between the two groups ($p = 0.640$). Precipitate labor was observed only in the pessary group in two cases; however, this difference was not statistically significant ($p = 0.150$).

Table 3: Maternal Adverse Outcomes During Labor Induction

Complication	Gel (n = 30)	Pessary (n = 30)	p-value
Tachysystole	2 (6.7%)	0 (0%)	0.001
Postpartum haemorrhage	3 (10.0%)	2 (6.7%)	0.640
Precipitate labor	0	2	0.150

Neonatal outcomes in both study groups are summarized in Table 4. Fetal distress was observed in 16.7% of neonates in the dinoprostone gel group, whereas no cases were reported in the dinoprostone vaginal pessary group, and this difference was statistically significant ($p = 0.019$). Meconium-stained liquor occurred infrequently in both groups and did not differ significantly between them ($p =$

0.052). The mean Apgar scores at 1 minute and 5 minutes were comparable between the two groups, with no statistically significant differences observed ($p = 0.280$ and $p = 0.060$, respectively). The requirement for neonatal resuscitation was low in both groups and did not differ significantly ($p = 0.553$).

Table 4: Neonatal Outcomes Following Labor Induction

Outcome	Gel (n = 30)	Pessary (n = 30)	p-value
Fetal distress	5 (16.7%)	0 (0%)	0.019
Meconium-stained liquor	2 (6.7%)	1 (3.3%)	0.052 (NS)
Mean APGAR score (1 min)	8.18 ± 0.62	8.34 ± 0.58	0.280
Mean APGAR score (5 min)	9.36 ± 0.49	9.74 ± 0.44	0.060
Need for neonatal resuscitation	2 (6.7%)	1 (3.3%)	0.553

DISCUSSION

Induction of labor in women with an unfavorable cervix remains a clinical challenge, with the choice of induction agent significantly influencing labor outcomes. The present randomized clinical study

compared dinoprostone gel and dinoprostone vaginal pessary with respect to efficacy, mode of delivery, and maternal and neonatal outcomes.

In the current study, the induction-to-delivery interval was significantly shorter in the dinoprostone vaginal pessary group. This finding is consistent with

earlier reports demonstrating that controlled-release dinoprostone preparations provide sustained cervical ripening and continuous uterine stimulation, thereby reducing overall labor duration.^[11,12] The prolonged and steady release of prostaglandin E2 from the vaginal pessary may avoid fluctuations in drug concentration associated with repeated gel applications, contributing to more efficient labor progression. A significantly higher proportion of women in the pessary group delivered within 12 hours, and no cases of induction failure were observed in this group. Similar findings have been reported in previous randomized trials, where vaginal pessary use was associated with higher induction success rates and reduced need for repeat dosing.^[13,14] These observations suggest that dinoprostone vaginal pessary may be particularly advantageous in women with an unfavorable cervix.

Although the requirement for oxytocin augmentation was comparable between the two groups, the absence of induction failure in the pessary group indicates superior cervical ripening efficacy. Studies comparing different prostaglandin formulations have reported variable oxytocin requirements, largely influenced by parity and baseline cervical status.^[15] The mode of delivery differed significantly between the two groups in the present study. The caesarean section rate was higher in the dinoprostone gel group, whereas instrumental deliveries were more frequent in the pessary group. Previous studies have demonstrated that prolonged induction and failed cervical ripening are associated with increased caesarean delivery rates, particularly in nulliparous women.^[16,17] The lower caesarean rate observed with the vaginal pessary may therefore be attributed to improved induction efficiency and shorter labor duration.

Maternal complications were infrequent in both groups. Uterine tachysystole was observed only in the gel group and was statistically significant. Similar observations have been documented in studies reporting higher peak prostaglandin levels following repeated intracervical gel administration.^[18] In contrast, the vaginal pessary offers the advantage of rapid removal in the event of uterine hyperstimulation, which enhances its safety profile. Postpartum haemorrhage and precipitate labor were uncommon and did not differ significantly between the groups.

Neonatal outcomes were largely comparable. Although fetal distress was more frequently observed in the gel group, Apgar scores at 1 and 5 minutes and the need for neonatal resuscitation did not differ significantly. Several studies have reported similar neonatal safety profiles between different dinoprostone formulations when used under appropriate fetal monitoring.^[19,20] These findings indicate that both agents are safe with respect to short-term neonatal outcomes.

The strengths of this study include its randomized design, uniform induction protocol, and comprehensive assessment of both maternal and

neonatal outcomes. However, the study was limited by a relatively small sample size and its single-center nature, which may restrict generalizability. Long-term neonatal outcomes were also not assessed. Larger multicenter trials are warranted to further validate these findings and to evaluate cost-effectiveness and patient satisfaction, particularly in resource-limited settings.^[21,22]

CONCLUSION

Both dinoprostone gel and dinoprostone vaginal pessary are effective and safe methods for induction of labor at term in women with an unfavorable cervix. However, dinoprostone vaginal pessary was associated with a significantly shorter induction-to-delivery interval, a higher proportion of deliveries within 12 hours, and a lower rate of induction failure compared to dinoprostone gel. Although the overall need for oxytocin augmentation was similar between the two groups, the vaginal pessary demonstrated a more favorable mode of delivery profile with fewer caesarean sections. Maternal and neonatal outcomes were comparable, with no increase in adverse events.

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