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Original Research Article

Comparison between dinoprostone intracervical gel and dinoprostone vaginal pessary for induction of labor at term in primigravida with poor Bishop's score

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ABSTRACT

Background: Dinoprostone is widely used for cervical ripening in form of intracervical gel and sustained-release vaginal pessary. This study compared the effectiveness of intracervical dinoprostone gel and vaginal dinoprostone pessary for induction of labor (IOL) in term primigravida with a modified Bishop score of <6.
Methods: This prospective randomized comparative study conducted over 12 months (April 2025-March 2026) at Tirath Ram Shah Hospital, Delhi. 42 primigravida (37-40 weeks) with singleton cephalic pregnancies, Bishop score <6 was randomized into two groups (n=21 each) using sealed envelope method. Group A received intracervical dinoprostone gel, while Group B received vaginal dinoprostone pessary. Participants assessed for cervical ripening according to Bishop score changes at 6, 12, 18, and 24hr, induction-to-delivery interval, need for oxytocin, mode of delivery, and maternal and neonatal outcomes.
Results: The gel group showed greater improvement Bishop score at 6 and 12 hours (p=0.008 and p=0.006, respectively) and higher proportion of women achieving favorable Bishop score (>6) at 6 hours (p=0.004). The induction-to-delivery interval (13.75±4.75 vs. 25.89±7.87 hours; p=0.003) and induction-to-active labor interval (10.55±3.67 vs. 19.61±7.10 hours; p=0.001) were shorter in gel group. CS rate was significantly lower with gel than pessary (47.6% vs. 81.0%; p=0.01). Gel resulted in faster cervical ripening, shorter induction-to-delivery interval, lower caesarean section rate, while maintaining comparable maternal and neonatal safety.
Conclusions: Intracervical dinoprostone gel was more effective for IOL in term primigravida with unfavorable cervix.

Keywords: Propess, Intracervical gel, Bishops score

INTRODUCTION

Induction of labor (IOL) is artificial initiation of uterine contractions before the spontaneous onset of labor to achieve vaginal delivery when continuation of pregnancy poses greater risk to the mother or fetus. The incidence of induced labor is 9.6% worldwide.[1] In India, the rates are widely variable depending on private/government facility and nonteaching or teaching/tertiary care hospitals, ranging from 6.5 % to 23.9%.[2] Successful induction depends on several factors, including parity, gestational age, cervical favorability assessed by the modified Bishop score, and the method of induction used. Failure of induction is associated with prolonged labor, increased need for operative delivery, postpartum hemorrhage (PPH), chorioamnionitis, and increased maternal and neonatal morbidity.

Cervical ripening is a crucial determinant of successful labor induction. Pharmacological methods of cervical ripening include oxytocin and prostaglandins, among which dinoprostone (prostaglandin E_2) remains one of the

most widely used and recommended agents, because it closely mimics the physiological process of cervical ripening.[3] Dinoprostone is available as an intracervical gel and as a controlled-release vaginal pessary.

Both formulations are approved for IOL by USFDA and the Drug Controller General of India. Although controlled-release pessary offers advantages such as continuous drug release, ease of administration and retrieval. Its higher cost and requirement for cold-chain storage may limit its routine use, particularly in resource-constrained settings. In contrast, intracervical dinoprostone gel is widely available, relatively inexpensive and extensively used in clinical practice.

Modified Bishop's score is a pre-labor scoring system used to predict outcome of IOL. Modified Bishop score with less than 6 points indicates that the cervix is unfavorable for induction, and the probability for vaginal delivery is very low.[4] This study aimed to compare the efficacy of dinoprostone controlled release vaginal pessary vs dinoprostone intracervical gel for IOL in Primigravida patients with poor Bishop's score (<6).

METHODS

After obtaining ethical committee approval, this prospective randomized comparative study was conducted in the Department of Obstetrics and Gynecology, Tirath Ram Shah Hospital, Delhi, over a period of 12 months from April 2025 to March 2026 in term primigravida aged 21-40 years admitted for IOL.

The inclusion criteria for the study were primigravida women with singleton pregnancies at term (37-40 weeks of gestation), calculated according to the last menstrual period (LMP) and confirmed by first-trimester ultrasonography (USG), with vertex presentation, reactive cardiotocography (CTG), and a modified Bishop's score of less than 6.

The exclusion criteria were women with a history of previous lower segment caesarean section (LSCS) or any previous uterine surgery, severe medical disorders such as severe cardiac or renal disease, contracted pelvis or suspected cephalopelvic disproportion (CPD), and premature rupture of membranes (PROM).

The sample size was calculated assuming the expected mean and standard deviation (SD) of the meantime (in hours) based on the study by Tempe et al the induction-to-delivery time was approximately 19.72±11.18 hours for the intracervical gel group and 12.53±6.57 hours for the vaginal pessary group.[5] A total of 42 eligible participants were enrolled.

The 42 participants were randomly divided into two equal groups by simple randomization using sealed envelope method. After confirming eligibility and obtaining written informed consent, each participant selected a sealed envelope containing the group allocation.

Group A: Dinoprostone intracervical gel (0.5 mg) and Group B: Dinoprostone controlled-release vaginal pessary (10 mg).

Before induction, all participants underwent baseline clinical assessment including uterine activity, CTG, and modified Bishop score assessment.

Women in Group A received 0.5 mg intracervical dinoprostone gel. Repeat doses were administered every six hours if required, up to a maximum of three doses, until a favorable cervix was achieved or labor commenced. Women in Group B received a single 10 mg controlled-release dinoprostone vaginal pessary inserted high in the posterior vaginal fornix. The pessary was removed after 24 hours or earlier if active labor developed, uterine hyperstimulation occurred, or a non-reassuring fetal heart rate pattern was detected.

Modified Bishop score was reassessed at 6, 12, 18, and 24 hours after initiation of induction. Continuous electronic fetal monitoring was performed for 20 minutes following prostaglandin administration, followed by CTG every two hours until the active phase of labor. Active labor was defined as cervical dilatation of ≥5 cm with at least three regular uterine contractions in 10 minutes. Induction failure was defined as failure to achieve a Bishop score ≥6 and failure to establish regular uterine contractions after 24 hours of dinoprostone administration.

Primary outcome measured

Change in modified Bishop's score at 6 hours, 12 hours, 18 hours, and 24 hours after dinoprostone application. Induction-to-delivery interval, i.e., time taken from initiation of induction until delivery.

Secondary outcome measured

Induction to active phase interval, interval between active phase and normal delivery, need for oxytocin augmentation after the onset of the active phase of labor. Outcome of induction in terms of mode of delivery (normal vaginal delivery/cesarean section). Maternal adverse effects such as uterine hyperstimulation and PPH. Fetal adverse effects like Meconium-stained liquor and fetal distress, at birth outcome-a. APGAR SCORE at 1 min, 5 min, need for NICU admission and birth weight.

Data were entered into Microsoft excel and analyzed using statistical package for the social sciences (SPSS) version 16.0. Comparisons between groups were performed using Student's t test for continuous variables and the Chi-square test for categorical variables. A $p<0.05$ was considered statistically significant.

RESULTS

The baseline demographic and obstetric characteristics were comparable between 2 groups. Most participants in the study belonged to the 26-30 years age group (47.6%), followed by those aged >31 years (31.0%) and 21-25 years (21.4%). The mean body mass index was 24.62±0.92 kg/m² in the gel group and 24.14±1.19 kg/m² in the pessary group (p=0.15). Most women were between 37 and 39 weeks of gestation, and distribution of socioeconomic status was similar between groups (p>0.05).

The most common indication for IOL was intrahepatic cholestasis of pregnancy (38.1%), followed by gestational diabetes mellitus (23.8%). Other indications included deranged Doppler (16.7%), fetal growth restriction (14.3%), hypertensive disorders (9.5%), and postdated pregnancy (9.5%) (p>0.05).

In the present study, the mean Bishop's score at baseline (0 hours) was comparable between the dinoprostone gel group (2.33±1.56) and the pessary group (1.86±1.62), with no statistically significant difference (p=0.33).

At 6 hours, the gel group demonstrated a significantly higher mean Bishop's score (5.26±2.10) compared to the pessary group (3.57±1.72), and this difference was statistically significant (p=0.008). Similarly, at 12 hours, the bishop's score remained significantly higher in the gel group (6.85±2.64) than in the pessary group (4.59±1.46), with a statistically significant difference (p=0.006).

However, at later time intervals, the difference between the groups was not statistically significant. At 18 hours, although the mean Bishop's score was higher in the gel group (6.00±2.16) compared to the pessary group (5.38±1.85), the difference was not significant (p=0.58). At 24 hours, the pessary group showed a higher mean Bishop's score (6.42±2.77) compared to the gel group (4.50±0.70), but this difference was also not statistically significant (p=0.36). This suggests that although the gel acts faster initially, most participants were delivered in the gel group, whereas the pessary demonstrates delayed cervical ripening.

The mean induction-to-active phase interval was significantly shorter in the gel group than in the pessary group (10.55±3.67 vs. 19.61±7.10 hours; p=0.001). Similarly, the mean induction-to-delivery interval was significantly shorter with intracervical dinoprostone gel (13.75±4.75 vs. 25.89±7.87 hours; p=0.003). However, the duration of active labor was comparable between the two groups (2.52±1.24 vs. 2.14±0.90 hours; p=0.58).

Oxytocin augmentation was required in 12 (57.1%) women in the gel group and 18 (85.7%) women in the pessary group.

Although the requirement was higher in the pessary group, the difference was not statistically significant (p=0.087).

Regarding delivery outcomes, the caesarean section rate was significantly higher in the pessary group than in the gel group (81.0% vs. 47.6%; p=0.01). Fetal distress was the most common indication for caesarean delivery in both groups, followed by failed induction, with no statistically significant difference in the indications for caesarean section (p=0.50).

Table 1: Baseline demographic and obstetric characteristics of the study participants.

Variables	Gel group, (n=21)	Pessary group, (n=21)	Total, (n=42)	P value	Statistical significance
Age group (in years)					
21-25	6 (28.6%)	3 (14.3%)	9 (21.4%)		
26-30	11 (52.4%)	9 (42.9%)	20 (47.6%)	0.21	Not significant
>31	4 (19.0%)	9 (42.9%)	13 (31.0%)		
BMI (kg/m²)	24.62±0.92	24.14±1.19	-	0.15	Not significant
Socioeconomic status	Majority upper middle class	Majority upper middle class	-	0.50	Not significant
Gestational age (in weeks)					
37-39	13 (61.9%)	13 (61.9%)	26 (61.9%)	0.62	Not significant
>39	8 (38.1%)	8 (38.1%)	16 (38.1%)		

Table 2: Change in Bishop score.

Bishop scores	Gel group		Pessary group		P value
	Mean	SD	Mean	SD	
Bishop score-0 hr	2.33	1.56	1.86	1.62	0.33
Bishop score-6 hr	5.26	2.10	3.57	1.72	0.008
Bishop score-12 hr	6.85	2.64	4.59	1.46	0.006
Bishop score-18 hr	6.00	2.16	5.38	1.85	0.58
Bishop score-24 hr	4.50	0.70	6.42	2.77	0.36

Table 3: Proportion of patients achieving a favorable cervix (≥6) at different time intervals.

Time interval (after induction)	Change in Bishop score	Method of induction		P value
		Gel group	Pessary group	
6 hours n=19 for gel n=21 for pessary group	<6	9 (47.4%)	19 (90.5%)	0.004
	≥6	10 (52.6%)	2 (9.5%)	
12 hours n=13 for gel group n=17 for pessary group	<6	5 (38.5%)	12 (70.6%)	0.08
	≥6	8 (61.5%)	5 (29.4%)	
18 hours n=4 for gel group n=13 for pessary group	<6	2 (50%)	7 (53.8%)	0.66
	≥6	2 (50%)	6 (46.2%)	
24 hours n=2 for gel group n=12 for pessary group	<6	2 (100%)	5 (41.7%)	0.23
	≥6	0 (0%)	7 (58.3%)	

Table 4: Comparison of labor induction outcomes.

Parameters	Dinoprostone gel, mean±SD	Dinoprostone pessary, mean±SD	P value
Induction to active phase interval (hours)	10.55±3.67	19.61±7.10	0.001
Induction to vaginal delivery interval (hours)	13.75±4.75	25.89±7.87	0.003
Active phase to delivery interval (hours)	2.52±1.24	2.14±0.90	0.58
Oxytocin augmentation required	12 (57.1%)	18 (85.7%)	0.087

Table 5: Comparison between indications of LSCS.

Indication for LSCS	Gel group, (n=10)	Pessary group, (n=17)	Total, (n=27)
2nd stage arrest	1 (10.0%)	2 (11.8%)	3 (11.1%)
Failed induction	2 (20.0%)	5 (29.4%)	7 (25.9%)
Fetal distress	3 (30.0%)	8 (47.1%)	11 (40.7%)
Hyperstimulation	1 (10.0%)	0 (0.0%)	1 (3.7%)
MSL in early labor	3 (30.0%)	1 (5.9%)	4 (14.8%)
NPOL	0 (0.0%)	1 (5.9%)	1 (3.7%)
Total	10 (100%)	17 (100%)	27 (100%)

Table 6: Comparison between mode of delivery.

Mode of delivery	Gel group, (n=21)	Pessary group, (n=21)	Total, (n=42)
LSCS	10 (47.6%)	17 (81%)	27 (64.3%)
Normal vaginal delivery	5 (23.8 %)	4 (19%)	9 (21.4%)
Vacuum delivery	6 (28.6%)	0 (0%)	6 (14.3%)
Total	21	21	42

*Chi-Square: 7.92, p=0.01, statistically significant

Adverse maternal outcomes were rare in both groups. One case of hyperstimulation was observed in the gel group, and one case of PPH was observed in the pessary group. Overall, both methods were safe with minimal maternal complications. The incidence of fetal distress was identical in both groups (33.3%), while meconium-stained liquor (14.3%) was slightly higher in the gel group. However, the overall fetal outcomes were comparable, indicating similar safety profiles.

All neonates had an APGAR score of 8 at 1 minute. At 5 minutes, most neonates had scores of 9, with comparable distribution in both groups. NICU admission was required in 23.8% of cases in both groups, showing no difference in neonatal outcomes. The mean birth weight was 2.98±0.39 kg in the gel group and 2.99±0.40 kg in the pessary group, with no statistically significant difference (p=0.94), indicating comparability between the groups.

DISCUSSION

The success of IOL largely depends on cervical favorability. Prostaglandin E2 preparations are widely used for cervical ripening. However, there remains variability in the efficacy of different formulations,

necessitating comparative evaluation. Our study demonstrated intracervical dinoprostone gel resulted in significantly faster cervical ripening during the first 12 hours, shorter induction-to-active labor and induction-to-delivery intervals, and a lower caesarean section rate compared with the dinoprostone pessary.

Most participants in the study belonged to the 26-30 years age group (47.6%), followed by those aged >31 years (31.0%) and 21-25 years (21.4%), mean age 24.58±3.33 years in gel group and 25.25±3.84 years in the pessary group (p=0.21). Das et al observed a statistically significant difference in age distribution between the two groups (p=0.04).[6]

The most common indication for IOL was Intrahepatic Cholestasis of Pregnancy (IHCP), followed by gestational diabetes mellitus. Studies done by Tempe et al and Senthilvel et al found out postdated pregnancy was most common indication.[5,7]

At 6 hours, gel group demonstrated higher mean Bishop's score compared to the pessary group (p=0.008). Similarly, at 12 hours, the bishop's score remained higher in the gel group than in the pessary group (p=0.006). However, at later time intervals (at 18 and 24 hr), the difference between the groups was not statistically significant. This suggests that although the gel acts faster initially, most participants were delivered in the gel group, whereas the pessary demonstrates delayed cervical ripening. While the study done by Fathima et al observed significantly higher Bishop's scores in the pessary group at 12 hours (p=0.002) and 18 hours (p=0.0001).[8] Nivethitha et al found that a final Bishop's score of 7-9 was achieved in a significantly higher proportion of women in the vaginal insert group (36%) compared to the gel group (16%) (p=0.01).[9]

Different studies have used varying cut-offs to define an unfavorable cervix, such as ≤6 by Mukhopadhyay et al ≤8 by Ottinger et al and ≤4 by Fabio Fachinetti et al.[10-12]

Regarding proportion of women achieving favorable bishops score>6 higher proportion of participants in the dinoprostone gel group achieved a favorable Bishop score (≥6) at 6 hours compared to the pessary group (52.6% vs 9.5%), and this difference was statistically significant (p=0.004). At 12 hours, among the remaining participants, 61.5% in the gel group and 29.4% in the pessary group achieved a Bishop score (>6). However, this difference was not statistically significant (p=0.08). Furthermore, at 18 hours (p=0.66) and 24 hours (p=0.23), no statistically significant difference was observed between the two groups. These findings suggest that the gel demonstrates earlier efficacy. Tempe et al reported significantly greater improvement in Bishop score at 6 hours with the pessary (mean 3.65) compared to the gel (mean 2.310).[5]

The mean induction-to-vaginal delivery interval was significantly shorter in the dinoprostone gel group (13.75±4.75 hours) than in the pessary group (25.89±7.87 hours) (p=0.003). These findings are consistent with the meta-analysis conducted by Sanchez-Ramos et al which demonstrated that women receiving dinoprostone vaginal inserts had a lower likelihood of achieving vaginal delivery within 12 hours of prostaglandin application (OR 0.55, 95% CI 0.39-0.79).[13] Senthilvel et al reported a slightly shorter mean induction-to-delivery interval in the gel group (18.6 hours) compared to the pessary group (19.2 hours).[7] Additionally, Kumari et al study conducted at Delhi, observed a shorter induction-to-delivery interval with gel than with a pessary.[14]

The mean time from induction to the active phase of labor was significantly shorter in the dinoprostone gel group (10.55±3.67 hours) compared to the pessary group (19.61±7.10 hours), (p=0.001). In contrast to the present study, Tempe et al demonstrated that 90.6% of women in the pessary group achieved active labor, compared with 41.5% in the gel group.[5] However, Malik et al reported no statistically significant difference between the two methods regarding induction-to-active phase intervals between the gel and pessary groups among primigravida women (gel vs pessary 13.38±4.35 hours vs 14.00±7.01 hours, respectively).[15]

Oxytocin augmentation was required in 57.1% of participants in the dinoprostone gel group and 85.7% in the pessary group (p=0.087), suggesting relatively slower initiation of adequate uterine contractions with the pessary in the early phase. Similarly, Das et al reported oxytocin requirement in 59% of women in the gel group and 65% in the pessary group.[6]

The rate of LSCS was significantly higher in the pessary group (81.0%) compared to the gel group (47.6%), (p=0.01). Tempe et al reported a higher proportion of vaginal deliveries in the pessary group (83%) compared to the gel group (67.9%), (p=0.088).[5] The most common indication for LSCS in both groups was fetal distress (40.7%), followed by failed IOL (25.9%). In gel group, fetal distress (30%) and MSL in early labor (30%) was most common indication for LSCS, followed by failed induction (20%). Whereas in the pessary group 47.1% LSCS was due to fetal distress followed by failed induction (29.4%).

Adverse maternal outcomes were rare in both groups. One case of uterine hyperstimulation was observed in the dinoprostone gel group. One case of postpartum hemorrhage (PPH) was noted in the pessary group.

The incidence of fetal distress was identical in both groups (33.3%), whereas meconium-stained liquor (MSL) was slightly higher in the gel group (14.3%) than in the pessary group (9.5%). Thupakula et al observed a higher incidence of meconium-stained liquor in the vaginal insert group (12%) compared to the gel group (4%).[16] NICU admission was required in 23.8% of neonates in both the dinoprostone gel and pessary groups. The mean birth

weight was 2.98±0.39 kg in the dinoprostone gel group and 2.99±0.40 kg in the pessary group (p=0.94).

An important practical finding of the present study was the difference in cost between the two induction methods. The cost of a dinoprostone vaginal pessary in India is approximately ₹2707, whereas each intracervical dinoprostone gel costs around ₹271, making the pessary nearly ten times more expensive than the gel preparation. Furthermore, the vaginal pessary requires uninterrupted cold-chain storage to maintain drug stability, which may be difficult in resource-limited settings. These considerations make intracervical dinoprostone gel an attractive alternative in developing countries where cost-effectiveness is an important determinant of treatment selection.

Limitations

The study was conducted at a private hospital with a relatively small sample size, which may have limited the power to detect differences in both methods. Blinding was not feasible because of the nature of the interventions. Nevertheless, because previous studies have reported conflicting results regarding the comparative efficacy of the two formulations, larger multicenter randomized controlled trials are required to establish the optimal prostaglandin preparation for labor induction in this population.

CONCLUSION

The intracervical dinoprostone gel was substantially more cost-effective and avoided the need for cold-chain storage required for the vaginal pessary, making it a practical option in resource-limited settings. Based on findings of this study, intracervical dinoprostone gel may be considered an effective, safe and economical agent for IOL in term primigravida women with an unfavorable cervix.

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