European Journal of Clinical Pharmacy
Print ISSN: 2385-409X, **Online ISSN**: 3105-0409
Website: https://farmclin.com/

Comparative Efficacy of Oxytocin and Dinoprostone Vaginal Insert for Labor Induction in Term Multiparous Women with an Unfavorable Cervix.

Article History:

***Received**:* 03-09-2025
***Revised**:* 28-11-2025
***Accepted**:* 11-12-2025
***Published**:* 24-12-2025

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Abstract: **Objective:** To compare the efficacy of intravenous oxytocin and dinoprostone vaginal insert in terms of successful vaginal delivery for induction of labor in term multiparous women presenting with an unfavorable cervix. **Study Design and Setting:** Randomized controlled trial. Place and duration of study: MCH Unit II, Department of Obstetrics and Gynecology, Pakistan Institute of Medical Sciences (PIMS), Islamabad, from July 2024 to December 2024. **Methodology:** A total of 200 term multiparous women (37–41 weeks gestation) with Bishop score ≤6 were included and randomized into two groups: Group O (receiving intravenous oxytocin infusion), and Group D (receiving a 10 mg dinoprostone vaginal insert). The primary outcome was set as successful vaginal delivery within 24 hours of induction. Secondary outcomes were the induction-to-delivery interval, need for augmentation, uterine hyperstimulation, and neonatal outcomes (including 5-minute Apgar score and NICU admission). **Results:** The primary outcomes showed that successful vaginal delivery was significantly higher in Group D compared to Group O (78% vs 62%, p=0.01). The results of secondary outcomes showed a significantly shorter induction-to-delivery interval (10.38±1.82 vs 13.83±2.88 hours, p<0.001) and significantly lower need for augmentation (28% vs 54%, p<0.001) in Group D compared to Group O. No statistically significant differences were observed in uterine hyperstimulation (p=0.14), 5-minute Apgar score <7 (p=0.58), or NICU admissions (p=0.62). **Conclusion:** Dinoprostone vaginal insert is more effective than intravenous oxytocin for labor induction, offering a shorter induction-to-delivery interval and higher rates of vaginal delivery in term multiparous women presenting with an unfavorable cervix.

Keywords: Cervical ripening, Cesarean section, Dinoprostone, Labor, Multiparity, Oxytocin.

INTRODUCTION

Induction of labor (IOL) is one of the most frequently performed interventional procedures in modern obstetric practice to mitigate the maternal or fetal risks associated with continued gestation. The technique involves the deliberate initiation of uterine contractions prior to their spontaneous onset, to accomplish vaginal delivery (VD). The rate of IOL in high-income countries is approximately 25%, whereas this rate is comparatively lower in low- and middle-income countries (LMICs).1,2

Common indications for IOL include post-term pregnancy, gestational diabetes mellitus (GDM), hypertensive disorders, intrauterine growth restriction (IUGR), oligohydramnios, premature rupture of membranes (PROM), and maternal or fetal compromise. The success of labor induction is largely dependent on cervical favorability, assessed by using Bishop score, where a score of ≤6 is taken as unfavorable for successful VD after induction.3 An unfavorable cervix, characterized by being closed, posterior, firm, and uneffaced (Bishop score of ≤6), is associated with prolonged labor, increased cesarean section (CS) rates, chorioamnionitis, and postpartum hemorrhage.3,4 Adequate cervical ripening prior to IOL is therefore necessary to facilitate the process.5

IOL is generally more successful in multiparous women due to prior cervical and uterine changes; however, an unfavorable cervix can pose significant challenges even in this group, including failed induction, prolonged induction-to-delivery interval,

and increased maternal morbidity. The selection of the most effective cervical ripening and induction agent therefore remains critical in optimizing maternal and fetal outcomes.6

The two most prevalent pharmacological agents used for IOL are the intravenous (IV) oxytocin and dinoprostone (prostaglandin E2) vaginal insert.

Oxytocin is a synthetic nonapeptide analogue of the endogenous posterior pituitary hormone that acts directly on myometrial receptors to stimulate uterine contractions. It has been the cornerstone of labor induction and augmentation for several decades and is widely favored for its rapid onset, easy IV titration, and cost-effectiveness. However, its principal limitation lies in minimal cervical ripening activity, rendering it less effective in the presence of an unfavorable cervix. When used alone, it often requires prolonged infusion, leading to extended induction-to-delivery intervals and increased risks of uterine tachysystole. Consequently, higher rates of failed induction and CS have been reported with oxytocin, highlighting the need for prior cervical ripening.7

Dinoprostone, on the other hand, is a prostaglandin analogue (prostaglandin E2) that acts to promote cervical ripening by enhancing collagen degradation, increasing cervical compliance, and stimulating uterine contractions. The drug offers a dual advantage of cervical ripening and uterine stimulation, thereby helping to improve the Bishop score; however, it is associated with a potential risk of uterine hyperstimulation.8,9

The commercially available vaginal inserts of dinoprostone provide a slow, sustained release over 12–24 hours, allowing a gradual and controlled cervical maturation. The sustained release vaginal inserts also confer the advantage of rapid cessation of drug delivery in case of uterine hyperstimulation or fetal distress, offering a significant safety benefit in clinical practice.10

The clinical benefits and limitations of these two strategies for IOL underscore the importance of comparisons between these two approaches; however, this comparison is sparse, especially in the specific population of multiparous women with an unfavorable cervix. PIMS, Islamabad, is a resource-limited tertiary care hospital which serves patients not only from the urban population but also from nearby suburban areas.

This study was therefore planned to compare the efficacy and safety of IV oxytocin versus dinoprostone vaginal insert for IOL in term multiparous women with an unfavorable cervix. The outcomes of this study will offer evidence-based insights for obstetric practices and help in the judicious selection of an induction agent to ensure maternal and neonatal safety, minimize CS rates, and optimize the utilization of limited healthcare resources.

METHODOLOGY

This randomized controlled trial was conducted at MCH Unit II, Department of Obstetrics and Gynecology, PIMS, Islamabad, from July 2024 to December 2024 after getting approval from ethical review committee of the hospital.

Sample size was calculated based on the anticipated VD rate of 55.3% in the dinoprostone group and 34% in the oxytocin group.11 With a two-sided α of 0.05 and 80% power, the required sample size was 82 participants per group (total n = 164). However, to account for some anticipated dropouts, we enrolled 100 patients in each group (Total n =200).

A total of 200 term pregnant women, aged 20–40 years and gestational age between 37–41 weeks were enrolled in the study. The women had to be with parity ≥1 (multiparous), singleton pregnancies in cephalic presentation, with an unfavorable cervix (Bishop score ≤6) and an indication for labor induction (such as post-dates pregnancy, gestational hypertension, or decreased fetal movements).

The exclusion criteria consisted of patients with previous CS, placenta previa, fetal distress, multiple pregnancy, malpresentation, ruptured membranes, or any contraindication to VD. A written informed consent was obtained from each patient prior to inclusion.

All the relevant demographic and clinical data was recorded for each woman. Participants were then randomly allocated into two equal groups (n=100 each) using a computer-generated randomization sheet. Women in Group O received IV oxytocin infusion starting at 2 mU/min, and increased incrementally every 30 min until adequate uterine contractions (3–5 contractions per 10 minutes) were achieved, while women in Group D received a controlled-release dinoprostone vaginal insert (10 mg), which was placed in the posterior fornix for up to 12 hours or until the achievement of active labor.

Fetal monitoring was continued during this period using cardiotocography. Maternal vital signs and uterine activity were kept under close observation. Oxytocin augmentation was allowed in Group D if adequate contractions were not achieved after removal of the vaginal insert.

The primary outcome of the study was set as successful VD within 24 hours of induction. Secondary outcome measures included the induction-to-delivery interval (IDI), need for augmentation, incidence of uterine hyperstimulation, and neonatal outcomes including 5-minute Apgar score and NICU admission.

Statistical analysis was performed using SPSS version 26. Descriptive statistics were employed to present the

study variables where quantitative variables were expressed as mean ± standard deviation (SD), while qualitative variables were expressed as frequency and percentage. Chi-square test was used to compare the categorical variables, and independent t-test for continuous variables between the two groups. A p-value ≤0.05 was considered statistically significant for all the comparisons.

RESULTS

The mean age of women in this study was 30.19±5.73 years with a range of 20-40 years. The mean GA was 38.85±1.33 weeks ranging from 37 to 41 weeks. The group wise demographics and clinical characteristics are shown in Table-I.

Table-I: Demographics and baseline clinical characteristics n= 200

Demographics and baseline clinical variables	Group O (n=100)	Group D (n=100)	p-value
Age (Mean ± SD) years	29.75±5.92	30.62±5.52	0.28
Gestational age (Mean ± SD) weeks	39.03±1.34	38.69±1.33	0.07
Parity (Mean ± SD)	2.26±0.79	2.37±0.86	0.35
Bishop score (Mean ± SD)	4.34±0.78	4.40±0.79	0.59

The results of primary outcomes of this study showed that the number of successful VD was significantly higher in Group D compared to Group O (p=0.01), as shown in Table-II.

Table-II: Primary maternal outcome. n =200

Primary outcomes		Group O (n=100)	Group D (n=100)	p-value
Mode of delivery	**Successful vaginal delivery n (%)**	62 (62)	78 (78)	0.01
	Cesarean section n (%)	38 (38)	22 (22)	

The results of secondary outcomes showed that the IDI and need for augmentation were significantly lower in Group D compared to Group O (p<0.001 for both). However, no significant difference was present between the groups regarding maternal and neonatal outcomes including Uterine Hyperstimulation (p=0.14), 5-min Apgar <7 (p=0.58) and NICU admission (p=0.62), as shown in Table-III.

Table-III: Secondary maternal and neonatal outcomes. n =200

Study variables	Group O (n=100)	Group D (n=100)	p-value
Maternal outcomes			
IDI*	13.83±2.88	10.38±1.82	<0.001
Need for augmentation n (%)	54 (54)	28 (28)	<0.001
Uterine hyperstimulation n (%)	6 (6)	12 (12)	0.14
Neonatal outcomes			
5-min Apgar <7 n (%)	8 (8)	6 (6)	0.58
NICU admission n (%)	10 (10)	8 (8)	0.62

Induction-to Delivery interval*

DISCUSSION

The primary outcomes showed that dinoprostone is significantly more effective than oxytocin in providing successful VD within 24 hours of induction (p=0.01). The drug also offered significantly shorter IDI (p<0.001) and reduced need for augmentation (p<0.001). Dinoprostone caused uterine hyperstimulation in more cases; however, this difference was not statistically significant (p=0.14). Similarly, no statistically significant difference was observed regarding neonatal outcomes including 5-minute Apgar score <7 (p=0.58), or NICU admissions (p=0.62), indicating that this improved efficacy did not compromise maternal and neonatal safety.

These results are aligned with previous studies conducted to evaluate the efficacy of pharmacological agents used for cervical ripening and labor induction. Several studies have assessed the efficacy of oxytocin and dinoprostone independently, whereas a few have directly compared these agents, especially in term multiparous women with an unfavorable cervix.

In a multicenter study by Wei Y et al. involving 1,408 late-term pregnancies, dinoprostone was compared with oxytocin for labor induction. Dinoprostone demonstrated significantly lower overall CS rates; however, oxytocin was suggested as a viable alternative when dinoprostone is unavailable.12 Similarly, Antonazzo P et al. conducted a trial with 94 women with unfavorable cervix and reported an overall higher VD rate and a lower CS rate with dinoprostone insert compared to oxytocin (55.3% vs. 34.0% and 44.7% vs. 66%, respectively).11

In contrast, Buyuk GN et al. compared dinoprostone

vaginal insert and IV oxytocin for IOL in term multiparous women (Bishop score ≤6). The IDI was comparable between groups; however, CS rates were significantly higher with dinoprostone (15.6% versus 9.3%, $p<0.05$), suggesting oxytocin as a more appropriate option for cervical ripening in term multiparous women.13

The evidence was further supported by Dogan GO et al. in a case-control study in term pregnancies with unripe cervices. Dinoprostone alone was compared with dinoprostone combined with low-dose oxytocin and showed no difference in rate of CS ($p=0.084$) or the incidence of adverse events including tachysystole and uterine hyperstimulation ($p>0.05$). However, combination therapy significantly shortened the active phase and IDI ($p=0.04$), supporting its use for expediting labor induction.14

Likewise, Shahi P et al. compared different methods of labor induction including dinoprostone, oxytocin infusion and foley catheter insertion. In this study conducted with Indian population, dinoprostone was the one with the highest VD rate (76%) and the lowest IDI (10.2 ± 2.8 hours) followed by oxytocin. However, the group combining two methods was more effective than single approach. There was no significant difference among the groups regarding neonatal safety including Apgar scores ≥7 at 5 min. and NICU admission.15

However, some studies have reported contrasting findings. Erasto E et al. evaluated oxytocin, dinoprostone, misoprostol, and balloon catheter for labor induction, in a Tanzanian cohort. Oxytocin yielded the highest spontaneous vaginal delivery (SVD) rate (95%) with the shortest median delivery time (5.42 hours). There was also significantly lower maternal blood loss ($p<0.001$), and superior neonatal outcomes ($p<0.01$) with oxytocin compared to other methods. Hence, the oxytocin was established as the most effective and safest induction agent.16

To synthesize the available evidence shared by different studies, Chang TA et al. conducted a meta-analysis including 9 trials comparing dinoprostone and oxytocin for IOL in term women and found VD rates of 84.2% and 79.8% respectively. No statistically significant differences were identified in major parameters of efficacy including VD (RR=1.05; 95% CI: 0.95–1.16), CS (RR=0.84; 95% CI: 0.52–1.35), or IDI between groups. These findings therefore suggested that oxytocin is a feasible alternative in women with an unfavorable cervix.17

The variation observed in findings across different studies may be ascribed to differences in patient populations, study settings, and varying induction protocols. Dinoprostone exerts its effect primarily through cervical ripening by biochemical remodeling, and offers a distinct advantage in women with an unfavorable cervix, as seen in our study and several other studies with similar pool of patients. In contrast, oxytocin primarily stimulates uterine contractions and may be more effective in populations with relatively favorable cervical conditions or those with different obstetric characteristics.18 Additionally, variations in parity, baseline Bishop score, and availability of required resources in the given medical facility may further influence outcomes and explain the observed inconsistencies across studies.

In short, the findings of our study and studies conducted previously demonstrate dinoprostone as an efficient and clinically favorable option for IOL in this subset of patients compared to the traditional options used for this purpose.

This study was conducted at a single tertiary care center with a relatively limited sample size. These factors may affect the generalizability of the findings at the national level. Additionally, future studies should assess the long-term maternal and neonatal outcomes not assessed in our study to strengthen this evidence.

CONCLUSION

Dinoprostone vaginal insert is more effective than IV oxytocin for induction of labor in term multiparous women presenting with an unfavorable cervix. The drug offers higher rates of successful VD, shorter IDI, and reduced need for augmentation without increasing adverse maternal or neonatal outcomes. These results support the use of dinoprostone, particularly in resource-limited settings, where optimizing labor outcomes and reducing CS rates are essential. The use of these study findings may help in clinical decision-making and improve obstetric care practices and patient outcomes.

Conflict of Interest:
No.
Disclaimer:
No..

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