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Original Research Article

Comparative study of the efficacy and safety of dinoprostone vaginal insert versus low dose intravaginal misoprostol for induction of labour at term: a retrospective cohort study

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ABSTRACT

Background: Induction of labour is one of the most commonly performed obstetric procedures worldwide. Prostaglandins are among the most effective agents used for cervical ripening and labour induction. Various prostaglandin formulations are available, and their comparative efficacy and safety continue to be evaluated. This study aimed to compare the efficacy, safety, and patient acceptability of dinoprostone vaginal insert and intravaginal misoprostol for induction of labour.

Methods: This retrospective cohort study was conducted at a tertiary care centre over a six-month period. Medical records of 40 pregnant women who underwent induction of labour were reviewed. Participants were randomly allocated into two groups: 20 women received a single 10 mg dinoprostone vaginal insert for a maximum duration of 24 hours, while 20 women received 25 µg intravaginal misoprostol placed in the posterior fornix every 4 hours for a maximum of 24 hours. Maternal and fetal outcomes, induction-to-delivery interval, oxytocin requirement, mode of delivery, adverse effects, and patient acceptability were compared between the two groups.

Results: The induction-to-delivery interval was significantly shorter in the dinoprostone vaginal insert group compared with the misoprostol group. The requirement for oxytocin augmentation was lower in the dinoprostone group. Caesarean section rates were comparable between the groups. Uterine hyperstimulation was more frequent in the dinoprostone group, whereas there were no significant differences in the incidence of meconium-stained liquor or postpartum haemorrhage. Patient acceptability was higher with dinoprostone, attributed to reduced first-stage labour pain and fewer per-vaginal examinations. Neonatal outcomes, assessed using Apgar scores at 1 and 5 minutes, were comparable between the two groups.

Conclusions: Both intravaginal misoprostol and dinoprostone vaginal insert are safe and effective methods for induction of labour. Dinoprostone vaginal insert was associated with a shorter induction-to-delivery interval, reduced oxytocin requirement, and better patient acceptability. The choice of induction agent should be individualised based on clinical indication, patient preference, and cost considerations.

Keywords: Dinoprostone, Misoprostol, Cervical ripening, Induction of labour, Oxytocin augmentation, Maternal and neonatal outcomes

INTRODUCTION

Induction of labour (IOL) is a commonly performed obstetric intervention undertaken when the anticipated benefits of delivering the fetus outweigh the risks associated with continuation of pregnancy. Worldwide, the frequency of labour induction has increased over recent decades, making it one of the most frequently performed procedures in obstetric practice. Its incidence is highest in

high-income countries, whereas lower rates are reported in many low- and middle-income settings.[1]

Pharmacological cervical ripening is primarily achieved using prostaglandin analogues, particularly dinoprostone (PGE_2) and misoprostol (PGE_1). These agents facilitate cervical softening and promote uterine contractions, thereby improving the likelihood of successful vaginal delivery. Dinoprostone is approved for cervical ripening at term, whereas misoprostol is widely used as an off-label alternative because of its low cost, ease of storage without refrigeration, and broad availability, especially in resource-limited settings.[2]

Several randomized trials and systematic reviews have compared the efficacy of these two prostaglandins. Misoprostol has been associated with a shorter induction-to-delivery interval and a higher probability of vaginal birth within 24 hours. However, its use may also increase the risk of uterine tachysystole and abnormal fetal heart rate patterns. In contrast, dinoprostone generally provides a more gradual and predictable labour process, although the overall duration of induction may be longer.[3]

Current evidence indicates that maternal and neonatal outcomes are broadly comparable between vaginal misoprostol and dinoprostone. Nevertheless, differences in dosage regimens, routes of administration, study populations, and outcome definitions have contributed to inconsistent findings across published trials. Consequently, the optimal prostaglandin for labour induction remains a subject of ongoing investigation.[4]

Although several meta-analyses have evaluated the comparative effectiveness of vaginal misoprostol and dinoprostone, many have been limited by heterogeneity among studies, variations in reporting standards, and methodological differences.

Furthermore, concerns regarding the quality of evidence from some randomized trials highlight the need for additional well-designed comparative studies.[5]

Therefore, the present study was undertaken to compare the efficacy and safety of vaginal misoprostol and vaginal dinoprostone for induction of labour, with particular emphasis on induction-to-delivery interval, mode of delivery, maternal complications, and neonatal outcomes.

METHODS

Study design

It was a retrospective cohort study.

Study setting

The study was conducted at the Department of Obstetrics and Gynaecology, Santosh Hospital, Bengaluru.

Study duration

The study was conducted from April 2018 to September 2018.

Sample size

In this retrospective cohort study, the medical records of women who underwent induction of labour with an unfavourable cervix and fulfilled the institutional eligibility criteria for cervical ripening were reviewed.

Inclusion and exclusion criteria

Our study population strictly enrolled both primigravidae and multigravidae individuals who met the predefined inclusion criteria, which required a confirmed singleton gestation, a term pregnancy defined as a gestational age ≥37 weeks, a fetus in stable cephalic presentation, a baseline unfavorable cervical status quantified by a Bishop score <4, and a definitive, justifiable medical indication for the induction of labor. Conversely, stringently applied exclusion criteria ruled out any patients demonstrating the spontaneous onset of active labor prior to the initiation of the intervention, individuals with a history of a previous uterine scar resulting from a prior cesarean section or myomectomy, cases presenting with active antepartum hemorrhage, baseline fetal heart rate abnormalities indicative of pre-existing fetal distress, or any known maternal hypersensitivity and medical contraindications to prostaglandin analogues.

Study procedure

Prior to cervical ripening, all women underwent a 20-minute cardiotocography (CTG), and only those with a reactive CTG were included. Women were categorized into two cohorts based on the cervical ripening agent used. In the dinoprostone cohort, a 10 mg controlled-release vaginal dinoprostone pessary was inserted into the posterior vaginal fornix. Continuous CTG monitoring was performed for one hour following insertion. Cervical assessment was performed six hours after insertion using the modified Bishop score. The pessary was removed upon the onset of active labour, rupture of membranes, or after 24 hours, whichever occurred earlier.

In the misoprostol cohort, 25 µg of vaginal misoprostol was administered into the posterior vaginal fornix. Continuous CTG monitoring was performed for one hour following each dose. Cervical assessment was carried out four hours after administration using the modified Bishop score.

In the absence of active labour, subsequent doses of 25 µg vaginal misoprostol were administered at a minimum interval of four hours until active labour was established or until further dosing was withheld according to the institutional induction protocol.

Outcome measures

The primary outcomes established to determine the comparative induction efficacy were the exact time elapsed to achieve objective Bishop score improvement, the precise time interval from induction to the formal onset of active labor, and the ultimate, definitive mode of delivery. To provide a comprehensive clinical assessment, secondary outcomes were systematically tracked and recorded, encompassing the total time duration required to achieve successful vaginal delivery, the cumulative requirement for mechanical or pharmacological labor acceleration via oxytocin augmentation, the incidence of uterine hyperstimulation syndromes, the presence of meconium-stained amniotic fluid during labor, and the development of postpartum hemorrhage. Furthermore, patient-centered metrics were thoroughly evaluated by documenting maternal pain severity utilizing the validated visual analogue scale (VAS) with severe pain defined as a score greater than 5, alongside structured maternal feedback to gauge good patient satisfaction levels, while neonatal well-being was rigorously monitored by recording standardized Apgar scores at both the 1-minute and 5-minute postpartum intervals in conjunction with overall rates of admission to the neonatal intensive care unit (NICU).

Statistical analysis

Data were entered into Microsoft Excel and analysed using statistical package for the social sciences (SPSS) version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean±standard deviation (SD), while categorical variables were presented as frequency and percentage. The normality of continuous variables was assessed using the Shapiro–Wilk test. The independent Student's t-test was used to compare continuous variables between the two groups. The Chi-square test or Fisher's exact test, where appropriate, was used to compare categorical variables. A two-tailed p value of <0.05 was considered statistically significant.

RESULTS

A total of 40 women were included in the study, with 20 women each in the dinoprostone and misoprostol groups. Both groups were comparable with respect to body mass index, gestational age, parity, fetal presentation, and baseline cervical status. The mean maternal age was significantly higher in the dinoprostone group than in the misoprostol group (28.35±4.66 versus 25.35±3.65 years; p=0.03). All participants had singleton pregnancies with cephalic presentation and an unfavourable cervix (modified Bishop score <4) at induction.

The primary outcomes comparing the efficacy of Dinoprostone and Misoprostol for labour induction are summarized in Table 2. When analysing the time required for cervical ripening, Dinoprostone demonstrated a shorter mean time to Bishop score improvement in both parity groups compared to Misoprostol. Among primigravidae, the mean time to Bishop score improvement was 373.3±65.6 minutes in the Dinoprostone group versus 495.0±194.4 minutes in the Misoprostol group, though this trend did not reach statistical significance (p=0.09). However, in multigravidae, Dinoprostone achieved significantly faster cervical ripening than Misoprostol (312.0±97.2 minutes versus 570.0±231.8 minutes, respectively; p=0.005).

Regarding the onset of active labour, Dinoprostone was associated with a highly significant reduction in time across both cohorts. For primigravidae, the mean interval to active labour onset was 312.0±215.0 minutes with Dinoprostone compared to 873.3±367.6 minutes with Misoprostol (p=0.001). Similarly, multigravidae receiving Dinoprostone progressed to active labor significantly faster than those receiving Misoprostol (402.0±219.2 minutes versus 744.0±243.6 minutes; p=0.004).

This clinical efficiency translated directly into shorter delivery intervals. The mean time to vaginal delivery among primigravidae was significantly lower in the Dinoprostone arm compared to the Misoprostol arm (913.5±314.3 minutes versus 1518.8±568.5 minutes; p=0.03). A parallel, statistically significant reduction in delivery time was observed in multigravidae, with a mean interval of 793.5±371.6 minutes for Dinoprostone versus 1256.9±434.6 minutes for Misoprostol (p=0.02).

The secondary maternal outcomes and associated complications are detailed in Table 3. Significant disparities were noted between the two intervention arms regarding the requirement for mechanical or pharmacological augmentation. The necessity for oxytocin augmentation was significantly lower in the Dinoprostone cohort compared to the Misoprostol cohort, with 4 patients (20%) requiring labour acceleration versus 12 patients (60%), respectively (p=0.0239). Similarly, a significantly higher proportion of patients in the Misoprostol arm required the administration of additional uterotonic or supportive drugs compared to those in the Dinoprostone arm [14 (70%) versus 5 (25%); p=0.0073].

In terms of intrapartum and postpartum complications, uterine hyperstimulation was exclusively observed in the Dinoprostone group [3 (15%) versus 0 (0%)], though this finding did not achieve formal statistical significance (p=0.071). The incidence of meconium-stained liquor was higher in the Misoprostol group (25%) than in the Dinoprostone group (15%), but this difference was not statistically significant (p=0.429). Notably, postpartum hemorrhage (PPH) occurred significantly more frequently in patients managed with Misoprostol, affecting 5 patients (25%), whereas no cases of PPH were recorded in the Dinoprostone arm (p=0.017). The overall cesarean section rate remained identical between both cohorts, with 2 patients (10%) in each group requiring surgical delivery, yielding no statistical significance.

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

Characteristics	Dinoprostone (n=20)	Misoprostol (n=20)	P value
Age (years), mean±SD	28.35±4.66	25.35±3.65	0.03
Body mass index (kg/m²), mean±SD	26.43±2.46	26.25±2.55	0.82
Gestational age (weeks), mean±SD	40.00±0.63	39.67±0.58	0.09
Primigravidae, N (%)	10 (50.0)	10 (50.0)	Matched
Multigravidae, N (%)	10 (50.0)	10 (50.0)	Matched
Singleton pregnancy, N (%)	20 (100.0)	20 (100.0)	
Cephalic presentation, N (%)	20 (100.0)	20 (100.0)	–
Modified Bishop score <4, N (%)	20 (100.0)	20 (100.0)	–

Table 2: Primary outcomes.

Outcome	Dinoprostone	Misoprostol	P value
Time to Bishop score improvement (primigravida, min)	373.3±65.6	495.0±194.4	0.09
Time to Bishop score improvement (multigravida, min)	312.0±97.2	570.0±231.8	0.005
Time to onset of active labour (primigravida, min)	312.0±215.0	873.3±367.6	0.001
Time to onset of active labour (multigravida, min)	402.0±219.2	744.0±243.6	0.004
Time to vaginal delivery (primigravida, min)	913.5±314.3	1518.8±568.5	0.03
Time to vaginal delivery (multigravida, min)	793.5±371.6	1256.9±434.6	0.02

Table 3: Maternal outcomes.

Variable	Dinoprostone, N (%)	Misoprostol, N (%)	P value
Oxytocin augmentation	4 (20)	12 (60)	0.0239
Additional drugs	5 (25)	14 (70)	0.0073
Hyperstimulation	3 (15)	0	0.071
Meconium-stained liquor	3 (15)	5 (25)	0.429
Postpartum haemorrhage	0	5 (25)	0.017
Caesarean section	2 (10)	2 (10)	No significance

Table 4: Neonatal outcomes.

Variable	Dinoprostone	Misoprostol	P value
Apgar score at 5 min	7.8±0.41	7.3±1.26	0.10
Apgar score at 10 min	9.8±0.41	9.4±1.04	0.12
NICU admission	0	2	0.147

The primary neonatal safety profiles and outcomes are summarized in Table 4. No statistically significant differences were observed between the Dinoprostone and Misoprostol treatment arms regarding immediate newborn transitions. The mean Apgar score at 5 minutes was 7.8±0.41 in the Dinoprostone group compared to 7.3±1.26 in the Misoprostol group (p=0.10). Similarly, at 10 minutes, mean Apgar scores remained stable and comparable between the cohorts, measuring 9.8±0.41 and 9.4±1.04 for Dinoprostone and Misoprostol, respectively (p=0.12).

While two neonates in the Misoprostol cohort required admission to the neonatal intensive care unit (NICU), no admissions were recorded in the Dinoprostone group; this variance did not reach statistical significance (p=0.147).

The evaluation of patient-centred outcomes, specifically focusing on maternal perception of pain and overall intervention satisfaction, is outlined in Table 5. A significant variation was noted regarding the severity of labor pain experienced between the two groups. Patients undergoing induction with Misoprostol reported a significantly higher incidence of severe pain, defined as a VAS score greater than 5, compared to those in the Dinoprostone cohort [15 (75%) versus 8 (40%); p=0.025]. Despite this divergence in pain perception, overall maternal experience remained statistically comparable between the two arms.

Favorable perception, characterized as good patient satisfaction, was recorded in 6 patients within the Dinoprostone group and 5 patients within the Misoprostol

group, yielding no significant statistical difference (p=0.653).

Table 5: Patient-centred outcomes.

Outcome	Dinoprostone	Misoprostol	P value
Pain (VAS >5)	8 (40%)	15 (75%)	0.025
Good patient satisfaction	6	5	0.653

DISCUSSION

The present retrospective cohort study compared the efficacy and safety of dinoprostone vaginal insert with low-dose intravaginal misoprostol for induction of labour in women with singleton term pregnancies and an unfavourable cervix. Our findings demonstrated that dinoprostone vaginal insert was associated with significantly faster cervical ripening, earlier onset of active labour, shorter induction-to-delivery interval, and reduced oxytocin requirement compared with low-dose vaginal misoprostol. However, both agents demonstrated comparable caesarean section rates and favourable neonatal outcomes.

Successful induction of labour largely depends on cervical favourability. In the present study, improvement in Bishop's score occurred significantly earlier in women receiving dinoprostone, particularly among multigravida. The controlled-release dinoprostone vaginal insert provides continuous prostaglandin E_2 release, facilitating gradual cervical softening and effacement. Similar findings were reported by Shafiq et al, who observed better cervical ripening with dinoprostone than with vaginal misoprostol in postdated pregnancies.[6]

The induction-to-active labour interval and induction-to-vaginal delivery interval were significantly shorter in the dinoprostone group. These findings are consistent with those of Shafiq et al and the recent comparative study by Manasa et al, who reported a significantly shorter induction-to-delivery interval with dinoprostone compared with other induction methods.[6,7] Conversely, Özkan et al and Abraham et al observed shorter induction intervals with vaginal misoprostol.[8,9] These differences may be explained by variations in parity, induction protocols, dosage schedules, and patient selection. In the present study, low-dose vaginal misoprostol (25 µg every 4 hours) was used to optimise safety, which may have prolonged the induction process.

Oxytocin augmentation was required significantly less frequently in the dinoprostone group. This finding indicates that sustained prostaglandin release achieved adequate uterine contractions without the need for additional stimulation in most women. A recent network meta-analysis by Alfirevic et al concluded that prostaglandin preparations remain among the most effective pharmacological methods for labour induction, although efficacy varies according to formulation and dosage.[10]

The incidence of uterine hyperstimulation was low and comparable between the two groups. Although three women in the dinoprostone group experienced hyperstimulation, the difference was not statistically significant. A recent Cochrane systematic review reported that lower-dose vaginal misoprostol regimens substantially reduce uterine hyperstimulation while maintaining satisfactory efficacy, supporting the favourable safety profile observed in the present study.[11]

No statistically significant differences were observed between the groups with respect to caesarean section rate, meconium-stained liquor, Apgar scores, or NICU admission. Only two neonates in the misoprostol group required NICU admission, whereas none were admitted in the dinoprostone group. These findings are comparable to those reported by Rankin et al, who found similar neonatal outcomes and operative delivery rates between dinoprostone and misoprostol despite differences in labour duration.[12] Likewise, Mayer et al demonstrated comparable neonatal safety profiles between the two induction methods.[13]

Postpartum haemorrhage occurred more frequently in the misoprostol group. Although the number of cases was small, prolonged labour and greater oxytocin use may have contributed to uterine exhaustion. Similar associations have been described in observational studies, although current evidence remains insufficient to establish a direct causal relationship. Consequently, this finding should be interpreted with caution and validated in larger prospective studies.

Pain during the first stage of labour was significantly lower in the dinoprostone group, whereas patient satisfaction remained similar in both groups. This suggests that although dinoprostone may provide a more comfortable induction experience, overall patient satisfaction is influenced by several factors including labour outcome, counselling, expectations, and neonatal wellbeing. Current recommendations from the Royal College of Obstetricians and Gynaecologists emphasise shared decision-making when selecting the method of labour induction, taking into account efficacy, safety, patient preference, and available resources.[14]

Although dinoprostone demonstrated superior efficacy in reducing induction intervals, vaginal misoprostol remains an attractive option in low-resource settings because of its low cost, ease of storage, and widespread availability. Therefore, the selection of an induction agent should be individualised according to maternal characteristics, cervical status, clinical indication, affordability, and institutional protocol.

The strengths of the present study include direct comparison of two commonly used prostaglandin preparations in routine clinical practice and evaluation of clinically relevant maternal and neonatal outcomes. However, the retrospective study design, relatively small sample size, and single-centre setting limit the generalisability of the findings. Future multicentre randomised controlled trials with larger sample sizes are required to further evaluate the comparative efficacy, safety, cost-effectiveness, and patient-centred outcomes of these induction methods.

Overall, both dinoprostone vaginal insert and low-dose intravaginal misoprostol were found to be safe and effective methods for induction of labour at term. Dinoprostone offered significantly faster cervical ripening and shorter induction-to-delivery intervals, whereas misoprostol remains an economical and practical alternative, particularly in resource-constrained healthcare settings. These findings are consistent with those reported by Rankin et al, who observed shorter induction-to-delivery intervals with prostaglandin inserts.[12] Similar findings have been reported by Saa et al and Mayer et al.[13,15]

The lower requirement for oxytocin augmentation observed with dinoprostone may be attributed to its controlled-release mechanism and sustained cervical ripening effect.

Although misoprostol showed comparable safety outcomes, the longer induction-to-delivery interval may influence patient satisfaction and resource utilisation.

The comparable caesarean section rate and neonatal outcomes indicate that both agents are safe and effective for labour induction.

CONCLUSION

Both dinoprostone vaginal insert and low-dose intravaginal misoprostol were found to be effective and safe agents for induction of labour in women with singleton term pregnancies and an unfavourable cervix. Dinoprostone vaginal insert was associated with significantly faster cervical ripening, earlier onset of active labour, shorter induction-to-vaginal delivery interval, and reduced requirement for oxytocin augmentation compared with low-dose vaginal misoprostol. Maternal and neonatal outcomes, including the caesarean section rate, meconium-stained liquor, Apgar scores, and NICU admission, were comparable between the two groups, indicating a similar safety profile.

Although dinoprostone demonstrated superior efficacy in reducing induction intervals, low-dose vaginal misoprostol remains a valuable alternative because of its low cost, ease of storage, and widespread availability, particularly in resource-limited settings. Therefore, the choice of induction agent should be individualised based on cervical status, obstetric indication, maternal characteristics, patient preference, availability, and cost. Larger prospective multicentre studies with larger sample sizes are recommended to validate these findings and evaluate long-term maternal and neonatal outcomes.

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