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COMPARISON OF SAFETY, EFFICACY, AND FETOMATERNAL OUTCOMES FOLLOWING INDUCTION OF LABOUR WITH VAGINAL MISOPROSTOL VERSUS DINOPROSTONE GEL IN PRIMIGRAVIDA: A RANDOMIZED CONTROLLED TRIAL

Obstetrics & Gynaecology

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ABSTRACT

Background: Induction of labour (IOL) is one of the most frequently performed obstetric interventions worldwide, with increasing utilization in both developed and developing countries. Pharmacological cervical ripening agents, particularly prostaglandin analogues such as misoprostol and dinoprostone, play a pivotal role in facilitating labour induction, especially in primigravida women with an unfavourable cervix. However, the optimal agent balancing efficacy, safety, and fetomaternal outcomes remains debated. **Objectives:** To compare the safety, efficacy, and fetomaternal outcomes of vaginal misoprostol versus intracervical dinoprostone gel for induction of labour in term primigravida women. **Methods:** This randomized controlled trial was conducted at a tertiary care teaching hospital in Rajasthan from May to July 2025. Fifty term primigravida women with a Bishop score ≤5 and a valid indication for induction were randomly allocated into two groups: vaginal misoprostol (25 µg every 4 hours, maximum two doses) or intracervical dinoprostone gel (0.5 mg every 6 hours, maximum two doses). Primary outcomes included induction-to-delivery interval and need for oxytocin augmentation. Secondary outcomes included mode of delivery, maternal complications, neonatal outcomes, and NICU admissions. **Results:** The induction-to-delivery interval was significantly shorter in the misoprostol group (8.68 ± 2.90 hours) compared to the dinoprostone group (14.66 ± 3.18 hours; $p < 0.001$). Oxytocin augmentation was required significantly less frequently in the misoprostol group (36%) than in the dinoprostone group (80%; $p = 0.002$). Mode of delivery, Bishop score improvement, maternal complications, neonatal birth weight, Apgar scores, and NICU admissions were comparable between groups. **Conclusion:** Both misoprostol and dinoprostone are safe and effective agents for labour induction in term primigravida women. Misoprostol demonstrates superior efficacy in terms of shorter induction-to-delivery interval and reduced need for oxytocin augmentation, making it a cost-effective and practical alternative, particularly in resource-limited settings.

KEYWORDS

Induction of labour, Misoprostol, Dinoprostone, Primigravida, Fetomaternal outcome

INTRODUCTION

Induction of labour (IOL) refers to the artificial initiation of uterine contractions before the spontaneous onset of labour, with the objective of achieving vaginal delivery when the benefits of early delivery outweigh the risks of continuing the pregnancy.[1] Over the past three decades, the global rate of labour induction has increased substantially, reflecting changes in obstetric practice, improved fetal surveillance, and broader indications for intervention.[2] In high-income countries, approximately one-quarter of all deliveries occur following induction, whereas in low- and middle-income countries (LMICs), induction rates range between 10% and 15, with considerable regional variation.[3] In India, the reported prevalence of labour induction is approximately 12.1%, with higher rates observed in tertiary care centres due to increased institutional deliveries, improved referral systems, and adherence to standardized obstetric protocols.[4] Rajasthan has similarly witnessed a rise in medically indicated labour induction, particularly among primigravida women, who often present with unfavourable cervical conditions at term.[5]

The cervix plays a crucial role in the success of labour induction. Cervical ripening involves biochemical and structural changes including collagen remodelling, increased water content, and inflammatory mediator release, resulting in cervical softening, effacement, and dilation. The Bishop score remains the most widely accepted clinical tool to assess cervical favourability, with a score ≤5 indicating an unfavourable cervix and the need for cervical ripening prior to induction.[6]

Pharmacological methods using prostaglandins are widely employed for cervical ripening and labour induction. Prostaglandin E1 (misoprostol) and Prostaglandin E2 (dinoprostone) analogues are the most commonly used agents. Dinoprostone gel has long been considered the standard pharmacological agent due to its physiological similarity to endogenous prostaglandins and favourable safety profile. However, its high cost, need for cold-chain storage, and repeated dosing requirements limit its utility in resource-constrained settings.[7-8]

Misoprostol, a synthetic PGE1 analogue initially approved for gastric ulcer prophylaxis, has emerged as an effective alternative for labour induction due to its uterotonic properties, low cost, stability at room temperature, and ease of administration.[9] Numerous clinical trials and meta-analyses have demonstrated its efficacy in cervical ripening and labour induction. However, concerns regarding uterine hyperstimulation, tachysystole, and potential fetal compromise-especially with higher doses-have necessitated cautious dosing and monitoring.[10]

Primigravida women represent a particularly vulnerable group for induction-related complications due to higher rates of prolonged labour, failed induction, and operative delivery. Despite the widespread use of both misoprostol and dinoprostone, there remains limited region-specific data from Indian tertiary care settings directly comparing their safety, efficacy, and fetomaternal outcomes in primigravida patients under standardized protocols.[11]

Given the rising burden of labour induction and the need for cost-effective, safe, and efficient induction strategies, this randomized controlled trial was undertaken to compare vaginal misoprostol and intracervical dinoprostone gel in term primigravida women, with a focus on induction efficiency, maternal safety, and neonatal outcomes.

AIM AND OBJECTIVES

Aim

To compare the safety, efficacy, and fetomaternal outcomes following induction of labour using vaginal misoprostol versus dinoprostone gel in term primigravida women.

Objectives

1. To compare the induction-to-delivery interval between misoprostol and dinoprostone.
2. To assess changes in Bishop score following induction in both groups.
3. To compare the requirement for oxytocin augmentation.
4. To evaluate maternal and neonatal outcomes associated with each induction agent.

MATERIALS AND METHODS

Study Design And Setting

This randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology, Mathura Das Mathur Hospital, attached

to Dr. S. N. Medical College, Jodhpur, Rajasthan, India.

Study Duration May 2024 to July 2025.

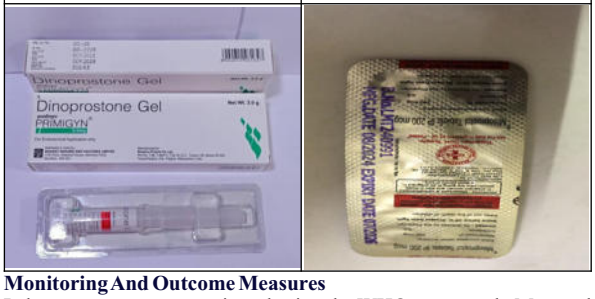
Sample Size
A total of 50 participants were enrolled, with 25 women allocated to each group. Sample size calculation was performed assuming a power of 90% and alpha error of 0.05, based on expected differences in induction-to-delivery interval.

Inclusion Criteria
- Primigravida
- Term pregnancy
- Live singleton fetus
- Bishop score ≤5
- Indication for induction (post-dated pregnancy, hypertensive disorders, GDM, mild oligohydramnios)

Exclusion Criteria
- Multifetal pregnancy
- Malpresentation
- Abnormal fetal heart rate patterns
- Cephalopelvic disproportion
- Ruptured membranes
- Previous uterine surgery
- Placenta previa

Randomization And Intervention
Participants were randomized using block randomization into two groups:

Group B (Dinoprostone group):	Group A (Misoprostol group)
Intracervical dinoprostone gel 0.5 mg every 6 hours, maximum two doses.	Vaginal misoprostol 25 µg every 4 hours, maximum two doses.



Monitoring And Outcome Measures
Labour progress was monitored using the WHO partograph. Maternal vitals, uterine contractions, and fetal heart rate were continuously observed. Artificial rupture of membranes was performed at 4 cm cervical dilatation if indicated.

Primary outcomes included induction-to-delivery interval and oxytocin augmentation. Secondary outcomes included mode of delivery, maternal complications, neonatal Apgar scores, birth weight, NICU admission, and duration of NICU stay.

Statistical Analysis
Data were analyzed using SPSS version 22.0. Continuous variables were expressed as mean ± SD and compared using the Student's t-test. Categorical variables were expressed as percentages and analyzed using the chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS
The demographic characteristics, including age, residence, education, socioeconomic status, booking status, and gestational age, were comparable between the two groups, with no statistically significant differences (p > 0.05).

Table 1: Induction To Delivery Interval Between Groups

Variable	Misoprostol (n=25) Mean ± SD	Dinoprostone (n=25) Mean ± SD	t-value	p-value
Induction to Delivery Interval (hours)	8.68 ± 2.90	14.66 ± 3.18	6.949	0.000

The mean induction-to-delivery interval was significantly shorter in the misoprostol group (8.68 ± 2.90 hours) compared to the dinoprostone group (14.66 ± 3.18 hours; p < 0.001).

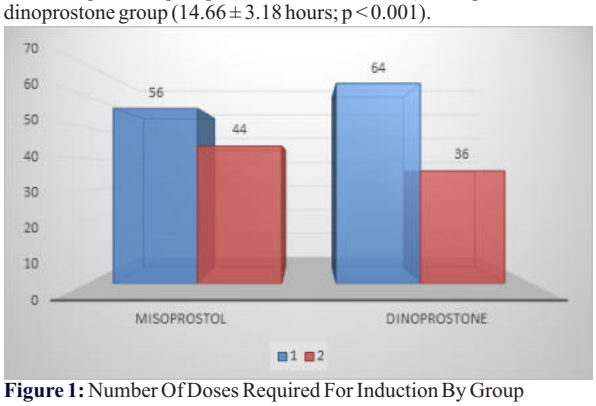


Figure 1: Number Of Doses Required For Induction By Group

Oxytocin augmentation was required in 36% of women in the misoprostol group versus 80% in the dinoprostone group (p = 0.002).

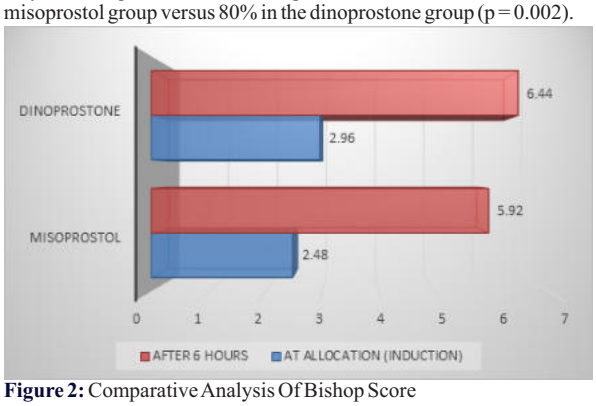


Figure 2: Comparative Analysis Of Bishop Score

Both groups had similar dose requirements, with 56% of Misoprostol and 64% of Dinoprostone participants requiring only one dose, while 44% and 36% required two doses, respectively.

The mode of delivery did not differ significantly between groups, with vaginal delivery rates of 80% in the misoprostol group and 76% in the dinoprostone group. Caesarean section rates were comparable.

Maternal complications, including hyperstimulation, postpartum haemorrhage, tachysystole, and gastrointestinal side effects, did not differ significantly between groups. Neonatal outcomes, including birth weight, Apgar scores at 1 and 5 minutes, NICU admission, and duration of NICU stay, were also comparable.

DISCUSSION
The present randomized controlled trial demonstrates that both vaginal misoprostol and intracervical dinoprostone gel are effective and safe agents for labour induction in term primigravida women. The significantly shorter induction-to-delivery interval and reduced need for oxytocin augmentation observed with misoprostol highlight its superior efficacy in initiating and sustaining labour.

In the present study, a highly statistically significant difference was observed in the induction-to-delivery interval between the misoprostol and dinoprostone groups (t-value = 6.949, p = 0.000). The mean interval was significantly shorter in the misoprostol group (8.68 ± 2.90 hours) compared to the dinoprostone group (14.66 ± 3.18 hours), suggesting that misoprostol facilitates a more rapid progression from induction to delivery, while Papanikolaou et al. (2004)[12] reported a mean duration of 11.9 hours for misoprostol compared to 15.5 hours for dinoprostone (p < 0.001), with significantly more women delivering within 12 and 24 hours in the misoprostol group. Likewise, Pandis et al. (2001)[9] found that misoprostol reduced the median induction-to-delivery time to 14.6 hours compared to 19.0 hours with dinoprostone (p = 0.0014). Supporting studies by Unni et al. (2025)[13], Biswas (2015)[14], and Dulewad et al. (2021)[15] further confirmed this trend. Unni et al. found a mean interval of 15.2 hours for misoprostol versus 18.3 hours for dinoprostone (p < 0.001); Biswas observed 8.13 vs. 14.32 hours (p < 0.001); and Dulewad reported 12.26 vs. 16.15 hours (p < 0.001), all favoring misoprostol. The comparable

rates of vaginal delivery, maternal complications, and neonatal outcomes suggest that misoprostol does not compromise safety when used in low-dose regimens with appropriate monitoring.

The absence of significant differences in neonatal Apgar scores and NICU admissions further supports the neonatal safety of both agents. The slight increase in uterine hyperstimulation observed with misoprostol aligns with existing literature but did not translate into adverse neonatal outcomes in this study. Given its low cost, ease of storage, and superior induction efficiency, misoprostol offers substantial advantages in resource-limited settings such as public tertiary care hospitals in India.

CONCLUSION

Both vaginal misoprostol and dinoprostone gel are safe and effective for induction of labour in term primigravida women with unfavourable cervices. Misoprostol is associated with a significantly shorter induction-to-delivery interval and reduced need for oxytocin augmentation, without compromising maternal or neonatal safety. Misoprostol may therefore be considered a preferable induction agent in appropriately monitored clinical settings, particularly in low-resource environments.

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