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COMPARATIVE EVALUATION OF MATERNAL AND PERINATAL OUTCOMES FOLLOWING DIFFERENT METHODS OF LABOUR INDUCTION IN TERM PREGNANCIES: A PROSPECTIVE OBSERVATIONAL STUDY FROM A TERTIARY CARE CENTER IN NORTH INDIA

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Abstract

Background: Induction of labour is a common obstetric intervention aimed at improving maternal and perinatal outcomes when continuation of pregnancy poses risks. Various pharmacological and mechanical methods are used, each with differing efficacy and safety profiles.

Objectives: To comparatively evaluate the maternal and perinatal outcomes associated with different methods of labour induction in term pregnancies.

Methods: A prospective observational study was conducted at a tertiary care hospital in North India from January 2013 to September 2013, including 188 term pregnant women undergoing induction of labour. Participants were grouped based on the induction method used: misoprostol (n=78), dinoprostone (n=60), and Foley catheter (n=50). Maternal outcomes (induction-to-delivery interval, mode of delivery, complications) and perinatal outcomes (birth weight, Apgar score, NICU admission) were compared. Statistical analysis was performed using SPSS version 25.0, with $p<0.05$ considered significant.

Results: Baseline characteristics were comparable across groups. The mean induction-to-delivery interval was significantly shorter in the misoprostol group compared to dinoprostone and Foley catheter groups ($p<0.001$). Vaginal delivery rates were highest with misoprostol (71.8%) but did not differ significantly across groups. Cesarean section rates were higher in the Foley catheter group, though not statistically significant. Maternal complications, including uterine hyperstimulation and postpartum hemorrhage, were comparable. Perinatal outcomes, including Apgar scores and NICU admissions, showed no significant differences among groups.

Conclusion: All three methods of labour induction demonstrated comparable maternal and perinatal outcomes. Misoprostol was associated with a shorter induction-to-delivery interval, making it an efficient option. Selection of induction method should be individualized based on clinical context and resource availability.

Keywords: Labour induction; Misoprostol; Dinoprostone; Foley catheter; Maternal outcomes; Perinatal outcomes

Introduction

Induction of labour (IOL) is a commonly performed obstetric intervention defined as the artificial initiation of uterine contractions before the spontaneous onset of labour, with the aim of achieving vaginal delivery when continuation of pregnancy poses risks to the mother or fetus [1]. Globally, the rate of labour induction has been steadily increasing, with estimates suggesting that approximately 20–30% of pregnancies in high-income countries undergo induction, reflecting evolving obstetric practices and improved access to healthcare services [2]. The World Health Organization (WHO) recommends that induction of labour should be undertaken only when there is a clear medical indication and when the benefits outweigh the potential risks [3].

In low- and middle-income countries, including India, the burden of maternal and perinatal morbidity remains significant, and timely induction of labour plays a crucial role in reducing adverse outcomes associated with post-term pregnancies, hypertensive disorders, and intrauterine growth restriction [4]. However, the choice of induction method varies widely depending on resource availability, clinician preference, cervical favorability, and institutional protocols. Commonly used methods include pharmacological agents such as prostaglandins (e.g., misoprostol, dinoprostone), mechanical methods like Foley catheter, and combined approaches [5].

Each method of labour induction has its own efficacy profile and associated risks. Prostaglandins are widely used due to their effectiveness in cervical ripening and initiation of uterine contractions but may be associated with uterine hyperstimulation and fetal distress [6]. Mechanical methods, such as Foley catheter insertion, are considered safer in certain high-risk scenarios due to a lower risk of hyperstimulation, though they may be less effective in achieving timely delivery [7]. Oxytocin infusion remains an important adjunct for augmentation but is rarely used as a primary method in an unfavorable cervix [8]. The comparative evaluation of these methods in terms of maternal outcomes (such as mode of delivery, duration of labour, complications) and perinatal outcomes (such as Apgar scores, NICU admission, and perinatal morbidity) is essential for optimizing clinical decision-making.

In the Indian context, variability in patient characteristics, late presentation, and limited standardized protocols across healthcare settings further complicate the selection of the most appropriate induction method [9,10]. Despite the widespread use of different induction techniques, there remains a lack of robust prospective data from tertiary care centers in North India comparing their effectiveness and safety in a real-world clinical setting. Most existing studies are either retrospective or limited by small sample sizes, heterogeneous populations, or lack of standardized outcome measures.

Given these considerations, there is a clear need for a well-designed prospective study to systematically compare maternal and perinatal outcomes associated with different methods of labour induction in term pregnancies. Such evidence would help guide clinicians in selecting the most appropriate method tailored to patient characteristics, thereby improving maternal and neonatal outcomes while minimizing complications.

Therefore, the present study aims to comparatively evaluate the maternal and perinatal outcomes associated with different methods of labour induction in term pregnancies in a tertiary care hospital setting in North India.

Methodology

Study Design: This study was conducted as a hospital-based prospective observational study.

Study Setting: The study was carried out in the Department of Obstetrics and Gynecology of a tertiary care teaching hospital in North India, which caters to a large population of both urban and rural patients and serves as a referral center for high-risk pregnancies.

Study Duration: The study was conducted over a period of one year, from January 2013 to September 2013.

Study Population: The study population comprised pregnant women admitted to the labour ward for induction of labour at term gestation (≥37 weeks), fulfilling the eligibility criteria during the study period.

Inclusion Criteria

- Pregnant women with singleton pregnancy at term (≥37 weeks of gestation)
- Cephalic presentation
- Indication for induction of labour (medical or obstetric)
- Bishop score indicating need for induction (unfavorable or favorable cervix)
- Willingness to participate and provide informed consent

Exclusion Criteria

- Previous cesarean section or uterine surgery
- Multiple pregnancy
- Non-cephalic presentation
- Placenta previa or vasa previa
- Known contraindications to vaginal delivery
- Fetal congenital anomalies incompatible with life
- Refusal to participate

Sample Size: The sample size was calculated based on the expected difference in successful vaginal delivery rates among different induction methods, considering findings from previous studies. Assuming a proportion of successful vaginal delivery of approximately 70% with standard methods, a confidence level of 95%, and an absolute precision of 7%, the sample size was calculated using the formula:

$$n = \frac{Z^2 \times p \times q}{d^2}$$

Where:

($Z = 1.96$) (for 95% confidence level)

($p = 0.70$), ($q = 0.30$)

($d = 0.07$)

The calculated sample size was approximately 165. Considering a 10–15% margin for attrition or incomplete data, the final sample size was increased to 188 participants.

Sampling Technique: A consecutive sampling technique was employed, wherein all eligible pregnant women meeting the inclusion criteria during the study period were enrolled until the required sample size of 188 was achieved.

Data Collection Tools & Procedure: Data were collected using a predesigned, pretested, semi-structured case record form. On admission, detailed history, clinical examination, and obstetric assessment including Bishop score were recorded. Participants were categorized into groups based on the method of labour induction used, such as pharmacological methods (misoprostol or dinoprostone), mechanical methods (Foley catheter), or combination methods, as per institutional protocol and clinician discretion. Continuous maternal and fetal monitoring was performed throughout labour. Labour progression, need for augmentation, mode of delivery, and any intrapartum complications were documented. Neonatal outcomes were recorded immediately after delivery, including Apgar scores and need for NICU admission.

Study Variables: The independent variable was the method of labour induction (pharmacological, mechanical, or combined methods). Dependent variables included maternal outcomes such as induction-to-delivery interval, mode of delivery (vaginal, instrumental, cesarean section), and maternal complications (e.g., uterine hyperstimulation, postpartum hemorrhage, infection), as well as perinatal outcomes including birth weight, Apgar scores at 1 and 5 minutes, need for neonatal resuscitation, NICU admission, and perinatal morbidity.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 16.0. Descriptive statistics were used to summarize baseline characteristics. Continuous variables were expressed as mean ±standard deviation, while categorical variables were presented as frequencies and percentages. Comparative analysis between different induction methods was performed using Chi-square test or Fisher's exact test for categorical variables and one-way ANOVA or Kruskal–Wallis test for continuous variables, as appropriate. A p-value of <0.05 was considered statistically significant.

Ethical Considerations: Written informed consent was obtained from all participants prior to enrollment. Confidentiality of patient information was strictly maintained. The study adhered to the ethical principles outlined in the Declaration of Helsinki, ensuring respect for autonomy, beneficence, non-maleficence, and justice.

Results

A total of 188 term pregnant women undergoing induction of labour were included in the study and categorized into three groups based on the method used: misoprostol (41.5%), dinoprostone (31.9%), and Foley catheter (26.6%). Baseline demographic and obstetric characteristics were comparable across the three groups, with no statistically significant differences observed (Table 1).

Table 1: Baseline Characteristics of Study Participants by Induction Method (n = 188)

Variable	Misoprostol (n=78)	Dinoprostone (n=60)	Foley Catheter (n=50)	p-value
Mean age (years)	25.8 ± 3.6	26.1 ± 3.9	25.5 ± 3.7	0.68
Primigravida (%)	46 (59.0)	34 (56.7)	27 (54.0)	0.82
Mean gestational age (weeks)	38.9 ± 1.1	39.0 ± 1.0	38.8 ± 1.2	0.54
Mean Bishop score	3.2 ± 1.1	3.4 ± 1.2	3.1 ± 1.0	0.47
Indication: Postdated (%)	34 (43.6)	26 (43.3)	22 (44.0)	0.99

The mean induction-to-delivery interval was significantly shorter in the misoprostol group compared to dinoprostone and Foley catheter groups ($p<0.001$), indicating faster labour progression

(Table 2). Although the rate of vaginal delivery was highest in the misoprostol group (71.8%), followed by dinoprostone and Foley catheter groups, the difference was not statistically significant. Similarly, cesarean section rates were higher in the Foley catheter group, but this difference did not reach statistical significance.

Table 2: Labour and Delivery Outcomes by Induction Method

Outcome	Misoprostol (n=78)	Dinoprostone (n=60)	Foley Catheter (n=50)	p-value
Mean induction-delivery interval (hours)	11.2 ± 3.8	13.5 ± 4.1	15.1 ± 4.5	<0.001*
Vaginal delivery (%)	56 (71.8)	40 (66.7)	30 (60.0)	0.28
Instrumental delivery (%)	6 (7.7)	5 (8.3)	4 (8.0)	0.98
Cesarean section (%)	16 (20.5)	15 (25.0)	16 (32.0)	0.29

*Statistically significant

Maternal complications were comparable across all groups (Table 3). Uterine hyperstimulation was observed more frequently with misoprostol; however, the difference was not statistically significant. The incidence of postpartum hemorrhage and maternal fever was similar across groups.

Table 3: Maternal Complications by Induction Method

Complication	Misoprostol (n=78)	Dinoprostone (n=60)	Foley Catheter (n=50)	p-value
Uterine hyperstimulation (%)	9 (11.5)	5 (8.3)	1 (2.0)	0.08
Postpartum hemorrhage (%)	5 (6.4)	4 (6.7)	3 (6.0)	0.98
Maternal fever (%)	6 (7.7)	4 (6.7)	3 (6.0)	0.94

Perinatal outcomes did not differ significantly among the three induction methods (Table 4).

Table 4: Perinatal Outcomes by Induction Method

Outcome	Misoprostol (n=78)	Dinoprostone (n=60)	Foley Catheter (n=50)	p-value
Mean birth weight (kg)	2.9 ± 0.4	3.0 ± 0.5	2.8 ± 0.4	0.22
Apgar <7 at 1 min (%)	10 (12.8)	8 (13.3)	7 (14.0)	0.97
Apgar <7 at 5 min (%)	4 (5.1)	3 (5.0)	3 (6.0)	0.96
NICU admission (%)	9 (11.5)	8 (13.3)	7 (14.0)	0.91

Mean birth weight, Apgar scores, and NICU admission rates were comparable, indicating similar neonatal safety profiles. Among cesarean deliveries, fetal distress was the most common indication (42.6%), followed by failed induction and non-progress of labour (Table 5).

Table 5: Indications for Cesarean Section

Indication	Frequency (n=47)	Percentage (%)
Fetal distress	20	42.6
Failed induction	15	31.9
Non-progress of labour	12	25.5

Overall, while misoprostol was associated with a significantly shorter induction-to-delivery interval, maternal and perinatal outcomes were broadly comparable across the different methods of labour induction.

Discussion

The present prospective observational study comparatively evaluated maternal and perinatal outcomes associated with different methods of labour induction in term pregnancies. The key findings indicate that while misoprostol was associated with a significantly shorter induction-to-delivery interval, the overall rates of vaginal delivery, cesarean section, maternal complications, and perinatal outcomes were comparable across misoprostol, dinoprostone, and Foley catheter groups.

The significantly shorter induction-to-delivery interval observed with misoprostol in this study is consistent with existing literature, which highlights its potent uterotonic effect and efficacy in cervical ripening [6]. Studies have demonstrated that misoprostol results in faster labour progression compared to dinoprostone and mechanical methods due to its pharmacodynamic properties and sustained uterine activity [5,11]. This finding has important clinical implications in high-volume tertiary care settings where reducing labour duration can improve patient flow and resource utilization.

Although the rate of vaginal delivery was highest in the misoprostol group, the difference among the groups was not statistically significant. This aligns with previous comparative studies that have shown similar success rates of vaginal delivery across different induction methods when appropriately selected [7,10]. The slightly higher cesarean section rate observed in the Foley catheter group, although not statistically significant, may be attributed to slower cervical ripening and prolonged labour, which can increase the likelihood of failed induction.

Maternal complications, including uterine hyperstimulation, postpartum hemorrhage, and intrapartum fever, were comparable across the groups. While uterine hyperstimulation was more frequently observed in the misoprostol group, the difference did not reach statistical significance. This trend has been consistently reported in earlier studies, where prostaglandins, particularly misoprostol, were associated with a higher incidence of uterine tachysystole compared to mechanical methods [6,10]. However, careful dosing and continuous monitoring can mitigate these risks effectively. The comparable rates of postpartum hemorrhage and maternal fever across groups further support the safety of all induction modalities.

Perinatal outcomes, including Apgar scores and NICU admissions, were also similar across the study groups, indicating that none of the induction methods adversely affected neonatal outcomes. These findings are in agreement with prior studies, which have demonstrated comparable neonatal safety profiles across different induction techniques when conducted under proper supervision [2,11]. The lack of significant differences in perinatal outcomes reinforces the clinical acceptability of all three methods in term pregnancies.

The predominance of fetal distress as the leading indication for cesarean section in this study is consistent with established obstetric patterns [1]. This underscores the importance of vigilant

intrapartum fetal monitoring irrespective of the induction method used. Failed induction and non-progress of labour were also important contributors, particularly in patients with an unfavorable cervix at baseline.

From a clinical and public health perspective, the findings suggest that while misoprostol offers the advantage of a shorter induction-to-delivery interval, the overall maternal and perinatal outcomes are comparable across methods. Therefore, the choice of induction method should be individualized based on patient characteristics, cervical status, clinical indication, and resource availability. In low-resource settings, misoprostol offers advantages of cost-effectiveness, stability, and ease of administration, whereas mechanical methods such as Foley catheter may be preferable in selected high-risk cases due to a lower risk of uterine hyperstimulation.

The strengths of this study include its prospective design, adequate sample size, and conduct in a tertiary care setting, enhancing external validity. Standardized data collection and monitoring protocols further strengthen the reliability of findings.

However, certain limitations must be acknowledged. Being a single-center study, generalizability may be limited. The non-randomized allocation of induction methods introduces potential selection bias. Additionally, residual confounding due to unmeasured clinical variables cannot be excluded. Future multicentric randomized controlled trials with larger sample sizes are recommended to provide more definitive evidence.

Conclusion

This prospective study demonstrates that different methods of labour induction—misoprostol, dinoprostone, and Foley catheter—have comparable maternal and perinatal outcomes in term pregnancies. Misoprostol was associated with a significantly shorter induction-to-delivery interval, indicating greater efficiency in achieving labour, while rates of vaginal delivery, cesarean section, maternal complications, and neonatal outcomes were similar across all groups. These findings suggest that no single induction method is universally superior in terms of safety and overall outcomes. Therefore, the choice of induction method should be individualized based on patient characteristics, cervical status, clinical indication, and institutional protocols. In resource-limited settings, misoprostol may be preferred due to its cost-effectiveness and ease of use, whereas mechanical methods may be advantageous in selected high-risk cases. Further large-scale, multicentric randomized studies are recommended to validate these findings and support the development of standardized clinical guidelines for labour induction.

Declarations

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Conflict of Interest: The authors declare no conflict of interest.

Consent: Written informed consent was obtained from all participants prior to inclusion in the study.

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References

1. Cunningham FG. Williams obstetricia. InWilliams obstetricia 2000 (pp. 1254-1254).
2. Vogel JP, Souza JP, Gülmezoglu AM. Patterns and outcomes of induction of labour in Africa and Asia: a secondary analysis of the WHO global survey on maternal and neonatal health. PloS one. 2013 Jun 3;8(6):e65612.

3. World Health Organization. WHO recommendations for induction of labour. Geneva: WHO; 2011.
4. Government of India. India Newborn Action Plan (INAP). Ministry of Health and Family Welfare.
5. Ten Eikelder ML, Neervoort F, Rengerink KO, Jozwiak M, De Leeuw JW, De Graaf I, van Pampus MG, Franssen M, Oudijk M, van der Salm P, Woiski M. Induction of labour with a Foley catheter or oral misoprostol at term: the PROBAAT-II study, a multicentre randomised controlled trial. BMC pregnancy and childbirth. 2013 Mar 19;13(1):67.
6. Hofmeyr GJ, Gülmezoglu AM, Pileggi C, Cochrane Pregnancy and Childbirth Group. Vaginal misoprostol for cervical ripening and induction of labour. Cochrane Database of Systematic Reviews. 1996 Sep 1;2013(1).
7. Jozwiak M, Oude Rengerink K, Benthem M, et al. Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. The Lancet. 2011 Dec 17;378(9809):2095-103.
8. Alfirevic Z, Kelly AJ, Dowswell T. Intravenous oxytocin alone for cervical ripening and induction of labour. Cochrane Database of Systematic Reviews. 2009(4).
9. National Health Mission. Guidelines for antenatal care and skilled attendance at birth by ANMs/LHVs/SNs. Government of India; 2010.
10. Jozwiak M, Oude Rengerink K, Benthem M, et al. Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. Lancet. 2011 Dec 17;378(9809):2095-103.
11. Wing DA, Brown R, Plante LA, Miller H, Rugarn O, Powers BL. Misoprostol vaginal insert and time to vaginal delivery: a randomized controlled trial. Obstetrics & Gynecology. 2013 Aug 1;122(2 PART 1):201-9.