International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Cervical Ripening in Postdate Pregnancies in Emergency Settings: A Comparative Evaluation of Misoprostol and Foley's Catheter

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OPEN ACCESS

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Received: 19-11-2025
Accepted: 10-12-2025
Available online: 18-12-2025

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ABSTRACT

Background: Postdate pregnancies are associated with increased risks of maternal and neonatal complications, particularly in emergency settings where timely labour induction becomes critical. Among available methods, vaginal misoprostol and intracervical Foley catheter are widely used for cervical ripening, but their comparative efficacy and safety remain areas of ongoing clinical interest.
Aim: This study aimed to evaluate and compare the effectiveness, safety, and maternal–neonatal outcomes of vaginal misoprostol and Foley catheter in inducing labour among women with postdate pregnancies.
Methods: A non-randomized control study was conducted over 18 months in a tertiary care hospital. A total of 100 postdate pregnant women (≥40 to ≤42-week gestation) with unfavourable cervix (Bishop score <5) were divided into two equal groups: Group 1received 25 mcg vaginal misoprostol every 4 hours (max 75 mcg), and Group 2 underwent cervical ripening with intracervical Foley catheter. Labour progression, oxytocin requirement, mode of delivery, labour duration, and neonatal outcomes were assessed.
Results: The mean duration of labour was significantly shorter in the misoprostol group (9.19 hours) compared to the Foley group (16.49 hours). All patients in the misoprostol group delivered without oxytocin, whereas 78% of the Foley group required augmentation. Vaginal delivery rates were slightly higher in the Foley group (84% vs. 74%), with cesarean section more often performed for fetal distress in the misoprostol group. NICU admissions and APGAR scores were comparable but slightly more favourable in the Foley group.
Conclusion: Misoprostol demonstrated faster induction and reduced need for oxytocin, making it more time-efficient. However, Foley's catheter was associated with better neonatal tolerance and a slightly higher vaginal delivery rate. Individualized selection based on maternal risk profile is recommended for optimal outcomes in postdate pregnancies requiring induction.

Keywords*: Postdate pregnancy, cervical ripening, labour induction, misoprostol, Foley catheter, maternal outcomes, neonatal outcomes.*

INTRODUCTION

Postdate pregnancy, also referred to as prolonged pregnancy, is defined as a gestational duration extending beyond 40 weeks but not exceeding 42 weeks from the first day of the last menstrual period, in the absence of labour onset. It is distinct from post-term pregnancy, which begins after 42 completed weeks of gestation [1]. Globally, the incidence of post-dated pregnancy ranges from 5% to 10%, with slightly higher rates reported in low- and middle-income countries like India, largely due to delayed antenatal registration and limited access to early ultrasound-based dating[2].

Post-dated gestation is associated with increased maternal and perinatal risks. For mothers, complications include prolonged labor, increased rates of operative vaginal delivery, higher incidence of cesarean section, and postpartum haemorrhage. Fetuses are at risk of meconium aspiration syndrome, oligohydramnios, macrosomia, birth asphyxia, and in

severe cases, stillbirth or neonatal death [3, 4]. To mitigate these risks, timely and effective induction of labour (IOL) becomes essential—particularly when the cervix is unfavourable for spontaneous labour.

Cervical ripening is a critical preparatory step before initiating uterine contractions in labour induction. The effectiveness of IOL is heavily influenced by cervical favourability, usually assessed by the Bishop score. When the Bishop score is ≤5, indicating an unripe cervix, pharmacological or mechanical interventions are required to facilitate ripening and improve induction outcomes [1].

Among pharmacological options, misoprostol, a synthetic prostaglandin E1 analog, is widely used due to its dual action in promoting cervical softening and uterine contractions. When administered vaginally in low doses (e.g., 25 mcg every 4–6 hours), it has demonstrated high efficacy, though its use is associated with a potential risk of uterine tachysystole and fetal distress if not carefully monitored [5, 1].

In contrast, mechanical methods such as intracervical Foley's catheter achieve ripening by exerting direct pressure on the cervix and stimulating endogenous prostaglandin release. Foley's catheter is particularly favoured in women with previous cesarean scars or contraindications to prostaglandins, owing to its lower risk of uterine hyperstimulation [6, 7]. Although both misoprostol and Foley catheter have been individually studied, the literature reveals inconsistent findings regarding their comparative performance, especially in real-world emergency settings where post-dated pregnancies are often referred late without prior antenatal care. Most earlier trials were conducted under elective, controlled conditions with booked cases and homogeneous populations [8, 9]. There remains a lack of clinical data reflecting high-volume tertiary care centers where emergency induction is more common and patient profiles are more variable.

Therefore, this study aimed to compare the efficacy, safety, and maternal-neonatal outcomes of vaginal misoprostol versus intracervical Foley's catheter in cervical ripening among postdate pregnant women presenting in emergency settings at a tertiary referral hospital.

MATERIALS AND METHODS

Study Design and Setting: This study was a hospital-based, prospective, non-randomized control study conducted in the Department of Obstetrics and Gynaecology at GMERS Medical College and Civil Hospital, Sola, Ahmedabad. The study spanned 18 months, from March 2023 to August 2024, and included women with postdate pregnancies requiring labor induction.

Inclusion and Exclusion Criteria:

Women were considered eligible for participation if they:

- Had a confirmed singleton pregnancy between 40+0 and 42+0 weeks of gestation,
- Had a cephalic presentation, and
- Had a Bishop score ≤5 at the time of assessment.

Women were excluded if they had:

- Malpresentation, intrauterine fetal demise, or multiple gestation,
- Major fetal anomalies or scarred uterus (e.g., previous cesarean),
- Pre-labor rupture of membranes (PROM),
- Significant maternal comorbidities (e.g., severe pre-eclampsia, uncontrolled diabetes, intrahepatic cholestasis of pregnancy),
- Or if they did not provide informed consent.

Sample Size:

The study included a total of 100 postdate pregnant women, divided equally into two groups of 50 participants each. The sample size was determined based on previous literature comparing the outcomes of misoprostol and Foley catheter use for cervical ripening, and was considered sufficient to evaluate key maternal and neonatal outcomes within the scope of a single-center study.

Group Allocation

Participants were allocated into two equal groups based on the induction method used:

- Group 1 (n=50): Vaginal Misoprostol
- Group 2 (n=50): Intracervical Foley's Catheter

Assignment was done based on clinician discretion and patient suitability, as randomization was not employed in this study.

Induction Protocol

Group 1 – Misoprostol Group

Each patient received 25 mcg of vaginal misoprostol placed in the posterior vaginal fornix under aseptic precautions. The dose was repeated every 4 hours up to a maximum of three doses (75 mcg total) over a 12-hour period, based on cervical response and uterine activity.

- If the Bishop score improved to >5 within this period, patients were allowed to progress in spontaneous labour.
- If not, oxytocin augmentation (10 mU/min) was initiated for up to 6 hours.
- Failure to achieve adequate cervical change (≤1 cm/hour in primigravida or ≤1.5 cm/hour in multigravida) after 18 hours resulted in cesarean section.
- *Group 2 – Foley's Catheter Group*
- A 16 Fr Foley catheter was inserted through the cervical canal and the balloon inflated with 50 mL of sterile saline. Traction was maintained by securing the catheter to the inner thigh.
- Patients were monitored for 12 hours.
- If the Bishop score was still ≤5, oxytocin was administered in the same dosage as above for up to 6 hours.
- Lack of labour progression prompted delivery by cesarean section, using the same criteria as in the misoprostol group.

In both groups, maternal and fetal monitoring was carried out continuously during the induction and labour process. Decisions for cesarean section were based on standardized criteria including fetal distress, meconium-stained liquor, or non-progression of labour.

Data Collection Tools

Clinical and demographic data were collected using structured case forms. Key outcome measures included:

- Modified Bishop Score (pre- and post-induction),
- Duration of labor (from induction to delivery),
- Need for oxytocin augmentation,
- Mode of delivery (vaginal or cesarean),
- Indication for cesarean section (if any),
- APGAR scores at 1, 5, and 10 minutes,
- NICU admission rates, and
- Neonatal birth weight.

Ethical Clearance

Prior to initiating the study, ethical approval was obtained from the Institutional Ethics Committee (IEC) of GMERS Medical College and Civil Hospital, Ahmedabad (Approval Date: 23/02/2023). All participants provided written informed consent, and the study adhered to the principles outlined in the Declaration of Helsinki for ethical research involving human subjects.

RESULTS

Patient Demographics

Among the 100 women admitted for induction of labour due to postdate pregnancy, the majority (88%) were emergency cases, while only 12% were previously booked. Most participants belonged to the 26–30 years age group (60%), followed by 20–25 years (37%) and 31–35 years (3%). Regarding obstetric history, second gravidas constituted 50%, third gravidas 33%, and primigravidas 17%.In the misoprostol group (n=50), the majority were second gravidas (62%), followed by third (24%) and primigravidas (14%). The Foley group (n=50) had a slightly different distribution, with third gravidas accounting for 42%, second gravidas 38%, and primigravidas 20%. Gestational age was comparable between groups, with 95% of all patients presenting between 40 and 40+6 weeks and only 5% beyond 41 weeks.

Mode of Delivery

Vaginal delivery was achieved in 74% of the misoprostol group compared to 84% in the Foley catheter group. Cesarean sections were required in 26% and 16% respectively. (Figure 1) In the misoprostol group, fetal distress (53.8%) and meconium-stained liquor (46.2%) were the main indications for cesarean delivery. Among Foley patients, non-progression of labor (75%) and fetal distress (25%) were predominant indications. (Figure 2)

Duration of Labor

The average duration of labor was shorter in the misoprostol group, with a mean of 9.19 ± 2.1 hours, compared to 16.49 ± 1.9 hours in the Foley group (Figure 3). Among primigravidas, the mean duration was 10.14 hours with misoprostol versus 16.95 hours with Foley. In multigravidas, the figures were 9.02 and 16.38 hours respectively.

Oxytocin Augmentation

None of the patients in the misoprostol group required oxytocin augmentation. In contrast, 78% of patients in the Foley group did. Among the Foley subgroup, those who progressed spontaneously (without oxytocin) had longer mean labor durations (18.72 hours) compared to those who received augmentation (16.15 hours), which is also depicted in Figure 4.

A Chi-square test confirmed a highly significant difference in oxytocin requirement between groups ($\chi^2 = 60.7$, $p < 0.001$), showing a distinct uterotonic advantage with misoprostol (Figure 5).

Neonatal Outcomes

APGAR scores at 1, 5, and 10 minutes were slightly higher in the Foley group:

1. 1 min: Misoprostol = 9.04, Foley = 9.84
2. 5 min: Misoprostol = 9.68, Foley = 9.92
3. 10 min: Misoprostol = 9.90, Foley = 9.96

Descriptive trends favored Foley (Figure 6), though differences were minimal.

NICU admission was necessary in 12% of neonates from the misoprostol group and 8% from the Foley group. Delayed cry was the leading cause in both arms, with one case of TTN (Transient Tachypnea of the Newborn) noted in the misoprostol group only (Figure 7).

The Chi-square test showed no statistically significant difference in NICU admissions between groups ($\chi^2 = 0.10$, $p = 0.75$).

Birth Weight

Mean fetal birth weights were similar across groups: 3.02 kg in the misoprostol group and 3.04 kg in the Foley group. There was no significant difference between them.

Bishop Score Progression

Baseline Bishop scores were comparable (Misoprostol: 3.0; Foley: 3.15). After 12 hours, all misoprostol patients had delivered. In contrast, Foley group scores improved to an average of 5.46.

BMI and Labor Duration

The mean BMI in both groups was comparable (Misoprostol: 24.31; Foley: 24.79). A weak correlation was observed between BMI and duration of labor ($r \approx 0.1$), suggesting no significant impact of BMI on labor outcomes in either group.

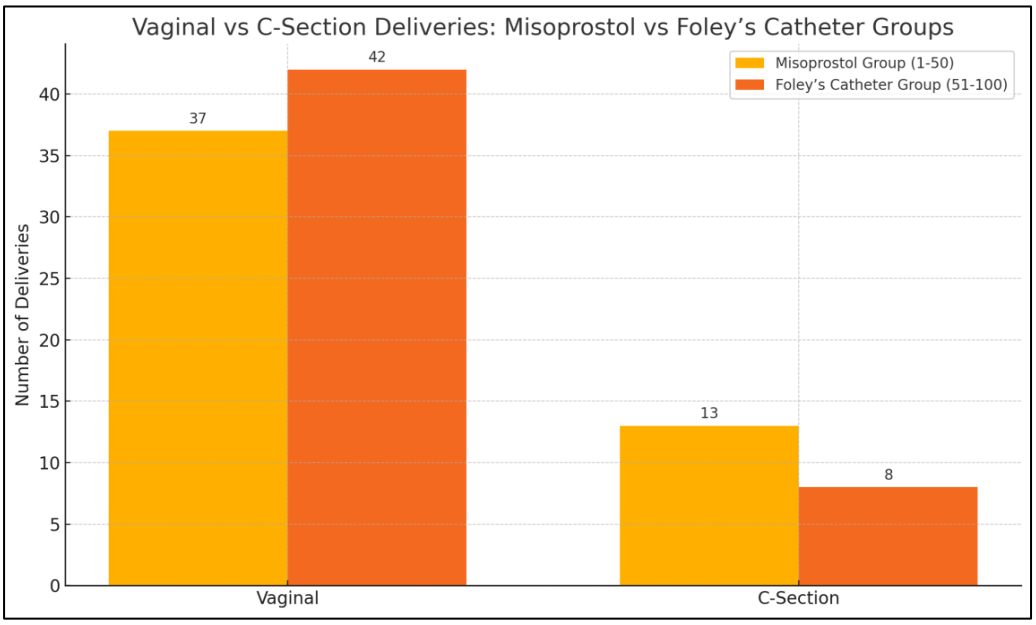

Figure 1: *Comparison of mode of delivery between Misoprostol and Foley's catheter groups.*

The graph illustrates the number of vaginal and cesarean deliveries in both induction groups. Vaginal delivery was more common in both groups, with a higher frequency observed in the Foley's catheter group (n=42) compared to the Misoprostol group (n=37). Cesarean sections were slightly more frequent in the Misoprostol group (n=13) than in the Foley's catheter group (n=8).

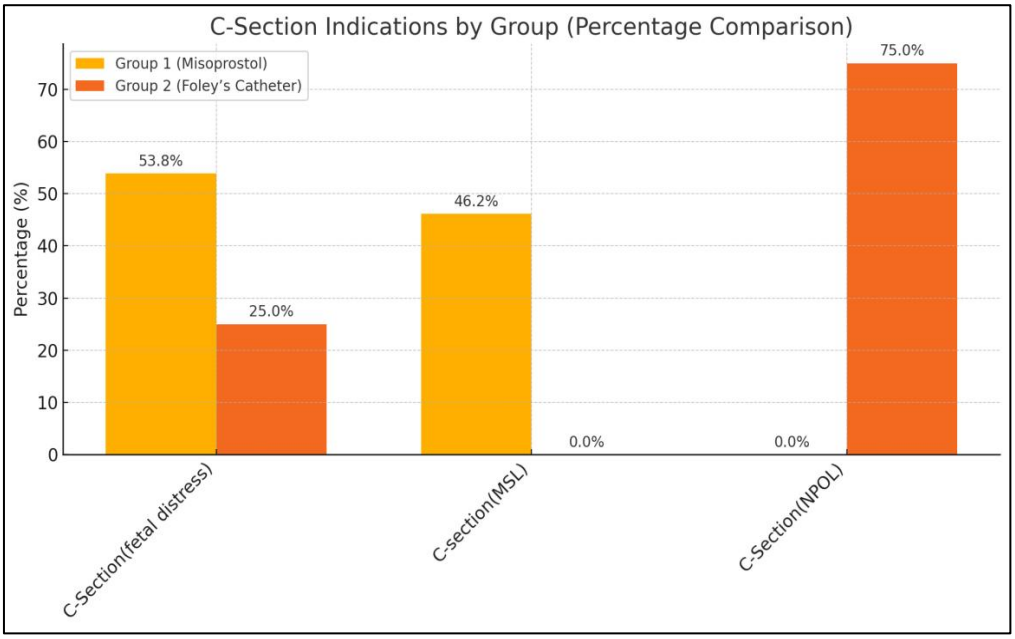

Figure 2:*Distribution of indications for cesarean section among Misoprostol and Foley's catheter groups (percentage-wise).*Among patients who underwent cesarean delivery, the most common indication in the Misoprostol group was fetal distress (53.8%), followed by meconium-stained liquor (MSL) (46.2%). In contrast, the Foley's catheter group had a predominant indication of non-progression of labor (NPOL) (75.0%), with fewer cases attributed to fetal distress (25.0%) and none due to MSL. These patterns suggest differing labor dynamics and fetal tolerance profiles between the two induction methods.

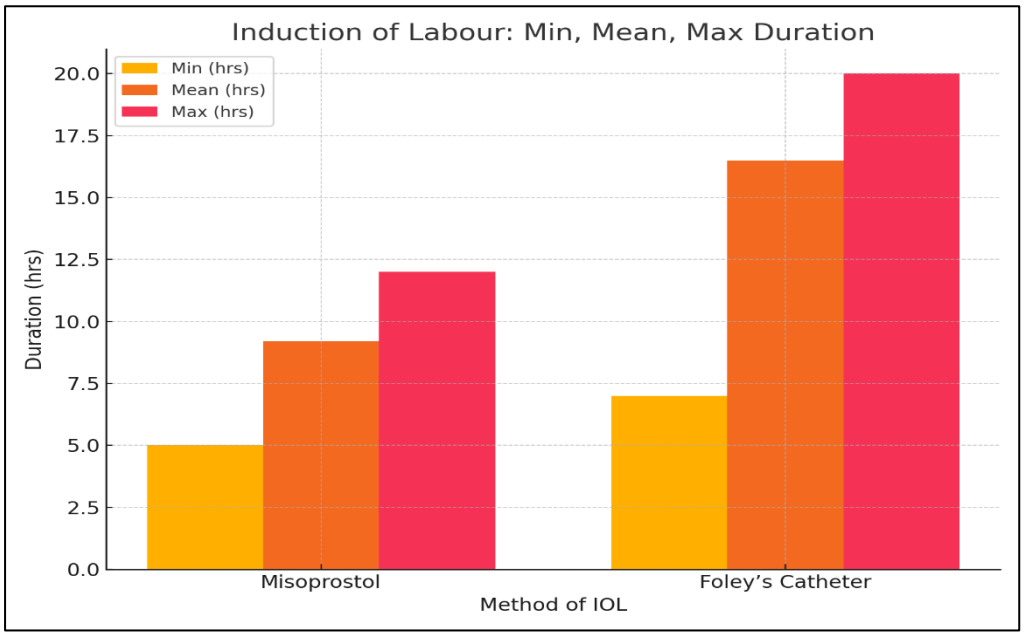

Figure 3: *Minimum, mean, and maximum induction-to-delivery intervals by method of labor induction.* This bar chart compares the labor duration (in hours) among women induced with Misoprostol versus Foley's catheter. The mean duration was shorter in the Misoprostol group (9 hours) compared to the Foley group (16.6 hours). Similarly, minimum and maximum durations were lower with Misoprostol (5.15 to 12.20 hours) than with Foley's catheter (7.20 to 20.15 hours), indicating a faster onset of labor and delivery in patients induced with Misoprostol.

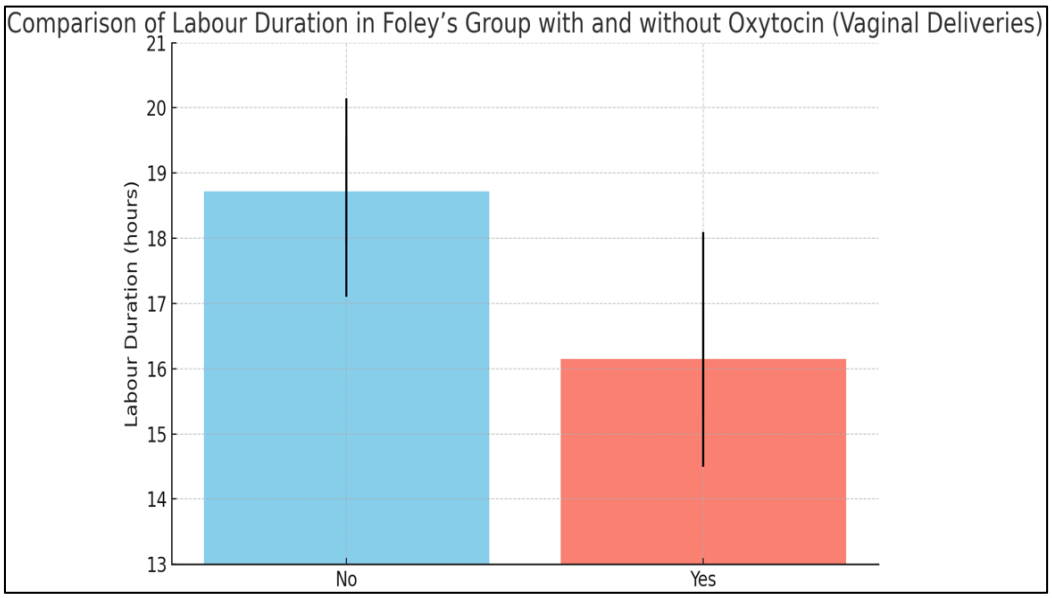

Figure 4: *Comparison of Labour Duration in Foley's Group with and without Oxytocin Augmentation (Vaginal Deliveries Only).* The graph shows that patients who did not require oxytocin had a longer mean labour duration (18.72 ± 0.83 hours) compared to those who required oxytocin (16.15 ± 0.86 hours)

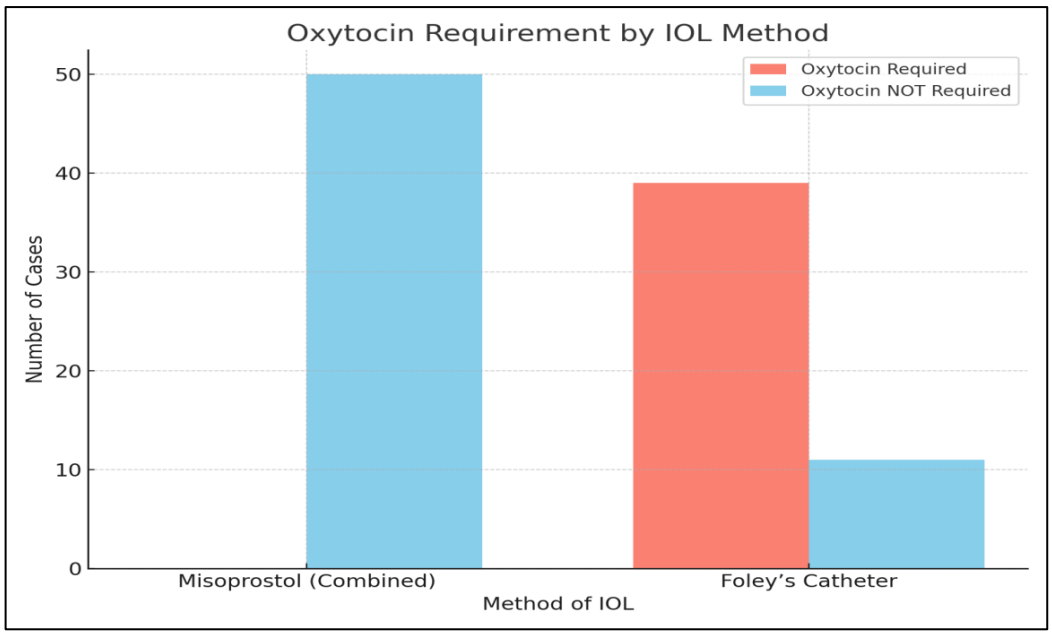

Figure 5: *Oxytocin Requirement by Method of Induction of Labour (IOL).* A significantly higher proportion of patients in the Foley's catheter group (78%) required oxytocin augmentation compared to none in the misoprostol group. Chi-square analysis revealed a highly significant association between the method of IOL and need for oxytocin ($\chi^2 = 60.7$, $p < 0.001$), underscoring the stronger uterotonic effect of misoprostol.

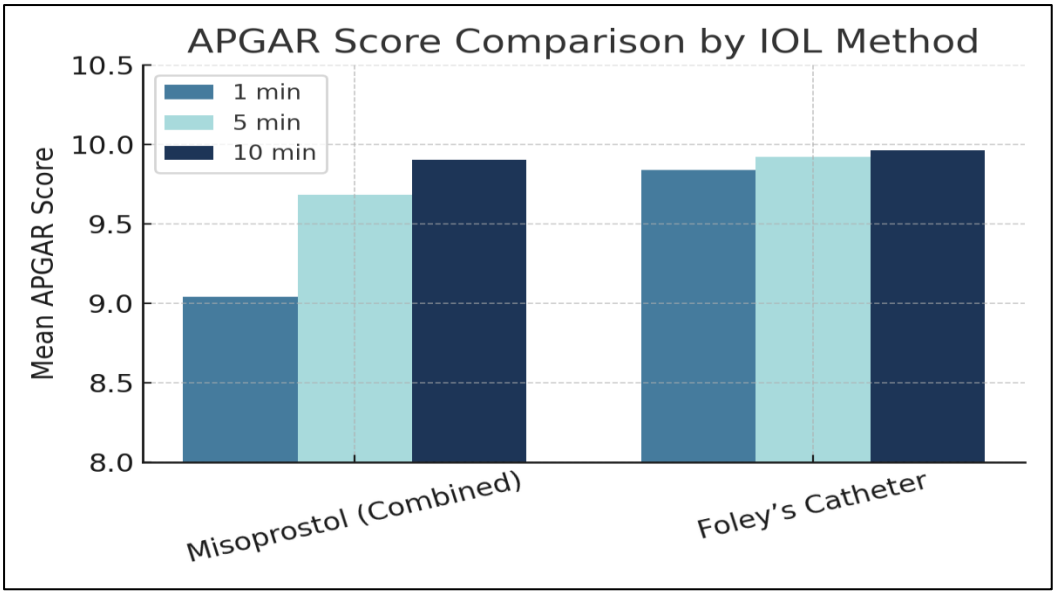

Figure 6:*Mean APGAR Scores at 1, 5, and 10 Minutes by Method of Induction.* The bar graph compares neonatal APGAR scores between the Misoprostol and Foley's catheter groups. At 1 minute, scores were slightly higher in the Foley group. By 5 and 10 minutes, both groups showed nearly equal and optimal scores, reflecting good neonatal outcomes in both induction methods.

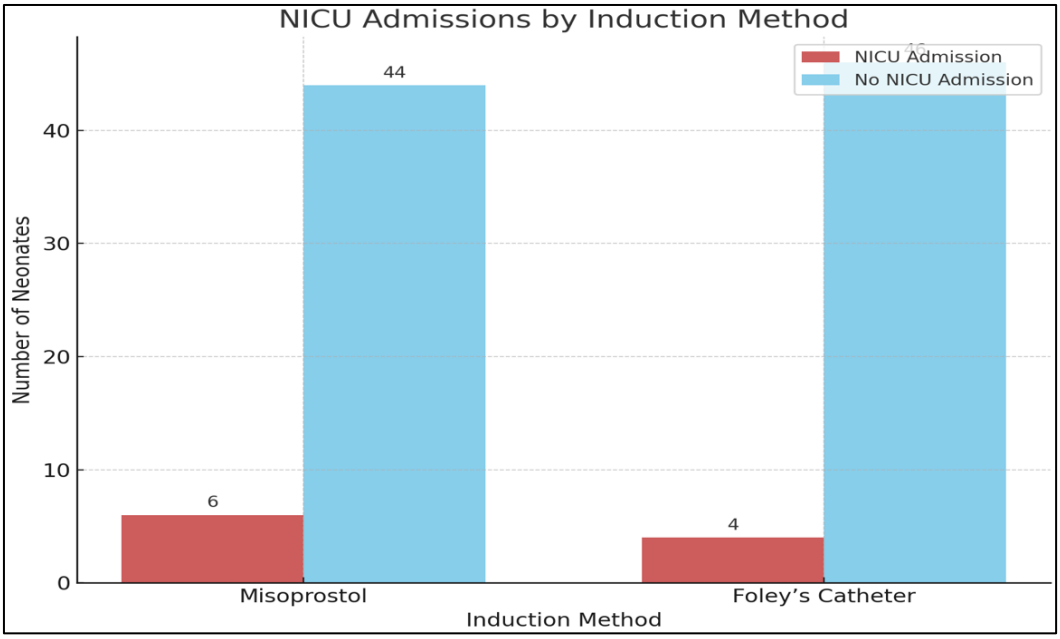

Figure 7:NICU admissions among neonates delivered following induction with Misoprostol vs Foley's catheter.NICU admission was required in 6 neonates (12%) from the Misoprostol group and 4 neonates (8%) from the Foley group.The most common indication was delayed cry, with one case of TTN reported only in the Misoprostol group.Statistical analysis using the Chi-square test did not show a significant difference between the groups ($\chi^2 = 0.10$, $p = 0.75$).

DISCUSSION

In this prospective non-randomised control study of 100 post-date pregnant women, we compared the outcomes of cervical ripening using vaginal misoprostol versus intracervical Foley catheter. The key findings in our cohort were: a markedly shorter induction-to-delivery interval in the misoprostol group, a much lower requirement for oxytocin augmentation, a slightly higher vaginal-delivery rate in the Foley group (though non-significant), and comparable neonatal outcomes (NICU admissions, APGAR). Below we discuss these findings in the context of existing literature, interpret their implications, and review the strengths and limitations of our work.Our data showed mean labour duration of ~9.2 hours in the misoprostol group versus ~16.5 hours in the Foley catheter group. This difference aligns with earlier reports: for example, a randomized trial found misoprostol produced a mean induction-to-vaginal delivery time of 17.3 h

compared to 20.2 h with Foley catheter (p = 0.016) in term/post-term pregnancies [10]. Similarly, a meta-analysis reported intravaginal misoprostol significantly shortened the induction-delivery interval compared with mechanical methods[11].The shorter interval in our misoprostol arm likely reflects its direct cervical and myometrial prostaglandin effect, leading to more rapid cervical ripening and uterine activity.

However, some studies found no significant difference between methods: Tuuli et al. reported median time to 10 cm of 12 h vs 14.2 h for misoprostol vs Foley respectively (p = 0.19)[12]. Our findings therefore support the advantage of misoprostol in reducing induction-to-delivery time in the post-date emergency context.A prominent finding was that none of the misoprostol group required oxytocin augmentation, whereas 78% of the Foley group did — a difference confirmed by Chi-square ($\chi^2 = 60.7$, $p < 0.001$). This result is consistent with previous observations: studies comparing misoprostol vs Foley generally report higher oxytocin requirement in mechanical ripening arms[13]. This suggests misoprostol may provide sufficient uterotonic stimulus alone in many cases of post-date induction in women with unfavourable cervix. From a resource-utilisation perspective, this has implications for labor ward staffing, oxytocin monitoring, and cost.

Also,In our study, the vaginal delivery rate was 74% in the misoprostol group and 84% in the Foley group, but the difference was not statistically significant ($\chi^2 = 0.964$, $p = 0.326$). This echoes findings from larger trials: for example, one RCT found that although misoprostol achieved shorter time to delivery, rates of cesarean section did not differ significantly between groups[10].This suggests that while misoprostol accelerates labour, it may not inherently alter the risk of cesarean delivery in post-date settings. Importantly, the slightly higher vaginal delivery rate in our Foley cohort may reflect selection bias, given the non-randomised design and clinician-driven allocation.Neonatal outcomes were also found, favourable in both groups: NICU admission was 12% in the misoprostol arm and 8% in the Foley arm ($\chi^2 = 0.10$, $p = 0.75$), indicating no statistically significant difference. Mean APGAR scores at 1, 5 and 10 minutes were marginally higher in the Foley arm but clinically similar. These findings are consistent with previous reports: for example, a study comparing misoprostol to Foley found no significant difference in neonatal morbidity or APGAR scores[14].This reassures that in a post-date setting, misoprostol — despite its more rapid induction effect — does not appear to compromise neonatal condition compared to mechanical ripening.

Interpretation & Clinical Implications

Collectively, our results suggest that in post-date pregnancies requiring emergency induction, vaginal misoprostol offers the advantages of shorter labour and minimal oxytocin requirement, while mechanical ripening with a Foley catheter offers a similarly safe neonatal profile and may marginally favour vaginal delivery rates (significantly in our sample). Given these findings, a tailored approach is warranted: for example, in women where shorter labour is critical (scarred uterus absent, minimal risk of hyperstimulation), misoprostol may be preferred. In women with higher risk of uterine rupture or in resource-limited settings where oxytocin monitoring is constrained, the Foley catheter may remain a safe choice.

Strengths

- The study was done in a real-world tertiary referral emergency setting, capturing patients often excluded from elective trials.
- Equal group sizes (n=50 each) and standardized protocols for induction enhance internal validity.
- Key outcomes (duration, oxytocin use, delivery mode, neonatal status) were clearly defined and practically relevant to obstetric practice in India.

Limitations

- Non-randomised design introduces allocation bias: clinician discretion may have influenced group assignment based on perceived risk profile.
- Single-centre study with post-date population only limits generalisability to other induction contexts (e.g., PROM, pre-labour rupture).
- Labour management (e.g., timing of oxytocin initiation, decision thresholds for cesarean) may vary between clinicians and could confound results.
- While neonatal outcomes were comparable, long-term neonatal morbidity (beyond NICU admission) was not assessed.

Future Implications

Future multicentre randomised trials in Indian settings are warranted, examining not only induction-to-delivery intervals but long-term maternal and neonatal outcomes, cost-effectiveness, and patient-centred metrics (e.g., maternal satisfaction, pain, experience). Additionally, investigations into combined protocols (e.g., Foley plus misoprostol) may further optimise induction in late-term pregnancies[15].

Conflict of Interest

The authors declare that they have no conflict of interest related to this study.

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