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Original Research Article

Combination of foley catheter and vaginal misoprostol compared with vaginal misoprostol alone for cervical ripening and induction of labour

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ABSTRACT

Background: Induction of labour in women with an unfavourable cervix remains a common obstetric challenge. The addition of a transcervical Foley catheter may enhance cervical ripening through mechanical dilatation and endogenous prostaglandin release, thereby improving labour outcomes. This study compared the effectiveness and safety of Foley catheter combined with vaginal misoprostol versus vaginal misoprostol alone for cervical ripening and induction of labour in term pregnancies.
Methods: This prospective, comparative, hospital-based interventional study included 50 women with singleton term pregnancies, vertex presentation, intact membranes, and Bishop score ≤5. Participants were randomly allocated to vaginal misoprostol alone (n=25) or Foley catheter combined with vaginal misoprostol (n=25). Induction outcomes, mode of delivery, and neonatal outcomes were compared.
Results: The combination group had a significantly shorter induction-to-delivery interval (15.3±6.5 vs. 18.3±8.7 hours; p=0.03) and time to complete cervical dilatation (13.7±5.9 vs. 17.1±8.7 hours; p=0.03). Delivery within 24 hours was higher with combination therapy (80% vs. 64%). Birth weight, Apgar scores, and neonatal intensive care unit admissions showed no significant differences.
Conclusions: Foley catheter combined with vaginal misoprostol effectively shortens labour induction without increasing maternal or neonatal complications and is a safe alternative to vaginal misoprostol alone.

Keywords: Cervical ripening, Foley catheter, Induction of labour, Misoprostol, APGAR

INTRODUCTION

Induction of labour is one of the most commonly performed obstetric interventions and is indicated when the benefits of delivery outweigh the risks of continuing pregnancy. Common indications include postdated pregnancy, hypertensive disorders of pregnancy, oligohydramnios, and other maternal or fetal conditions requiring timely delivery. The success of labour induction depends largely on the condition of the cervix at the time of induction. An unfavourable cervix, usually defined by a Bishop score of ≤5, is associated with prolonged labour, failed induction, increased oxytocin requirement, and a higher likelihood of operative delivery.[1,2]

Various pharmacological and mechanical methods are available for cervical ripening. Misoprostol, a synthetic prostaglandin E1 analogue, is widely used because it is effective, inexpensive, and easy to administer. Vaginal misoprostol promotes cervical ripening and stimulates uterine contractions, making it an established method for labour induction. However, when used alone in women with an unfavourable cervix, induction may be prolonged and may require additional doses or oxytocin augmentation.[3]

Mechanical cervical ripening with a transcervical Foley catheter has also been shown to be an effective method. The Foley catheter produces cervical dilatation by direct mechanical pressure and stimulates the release of endogenous prostaglandins. Compared with pharmacological methods, it has a lower risk of uterine hyperstimulation and can be used safely in selected patients. Previous studies have suggested that combining a Foley catheter with vaginal misoprostol may produce a synergistic effect, resulting in faster cervical ripening and a shorter induction-to-delivery interval without increasing maternal or neonatal complications.[4]

Although several studies have compared pharmacological and mechanical methods of induction, evidence regarding the effectiveness of combination therapy in the Indian population remains limited.[5] Further evaluation is required to determine whether combining a Foley catheter with vaginal misoprostol improves labour outcomes while maintaining maternal and neonatal safety.

Therefore, the present study was undertaken to compare the effectiveness of Foley catheter combined with vaginal misoprostol versus vaginal misoprostol alone for cervical ripening and induction of labour in term pregnancies with an unfavourable cervix. The study also evaluated the induction-to-delivery interval, time to complete cervical dilatation, mode of delivery, and maternal and neonatal outcomes.

METHODS

Study design and setting

This prospective, comparative, hospital-based interventional study was conducted over a period of six months (Dec-2025 to June-2026) in the Department of Obstetrics and Gynaecology, NRI Institute of Medical Sciences, Visakhapatnam. The study compared the effectiveness of Foley catheter combined with vaginal misoprostol with vaginal misoprostol alone for cervical ripening and induction of labour in term pregnancies with an unfavourable cervix.

Study population

Pregnant women admitted for induction of labour during the study period were screened for eligibility. After obtaining written informed consent, eligible participants were enrolled and randomly allocated into two equal groups (n = 25 each). Group A received vaginal misoprostol alone, while Group B received a transcervical Foley catheter in combination with vaginal misoprostol.

Inclusion criteria

Pregnant women aged 18–40 years. Singleton pregnancy with vertex presentation. Gestational age ≥37 completed weeks. Intact membranes. Bishop score ≤5. Indication for induction of labour, including postdated pregnancy, mild oligohydramnios, gestational hypertension, preeclampsia, chronic hypertension, gestational diabetes mellitus, or elective induction.

Exclusion criteria

Previous caesarean section or other uterine surgery. Premature rupture of membranes. Multiple gestation. Antepartum haemorrhage. Active labour at admission. Known hypersensitivity to prostaglandins. Contraindications to vaginal delivery.

Study procedure

Following enrolment, participants were randomly allocated into two groups. Group A received vaginal misoprostol for cervical ripening and induction of labour according to the institutional protocol. Group B underwent insertion of a transcervical Foley catheter under aseptic precautions followed by vaginal misoprostol administration. Labour progress was monitored using standard obstetric protocols until delivery. Maternal and fetal well-being were assessed throughout labour.

Outcome measures

The primary outcome was the induction-to-delivery interval. Secondary outcomes included time to complete cervical dilatation, mode of delivery, requirement for oxytocin augmentation, maternal complications, neonatal birth weight, Apgar scores at 1 and 5 minutes, and neonatal intensive care unit admission.

Statistical analysis

Data were entered into Microsoft Excel and analysed using SPSS statistics version 25.0. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were presented as frequencies and percentages. Relative risks with 95% confidence intervals were calculated for categorical outcomes. A p-value of <0.05 was considered statistically significant.

Ethical considerations

The study protocol was approved by the Institutional Ethics Committee of NRI Institute of Medical Sciences before commencement of the study. Written informed consent was obtained from all participants prior to enrolment.

RESULTS

A total of 50 pregnant women meeting the eligibility criteria were enrolled and randomly allocated into two groups: Group A (Foley catheter combined with vaginal misoprostol, n=25) and Group B (vaginal misoprostol alone, n=25). All participants completed the study and were included in the final analysis.

The baseline demographic and obstetric characteristics of the two groups were comparable. The mean maternal age was 26.4±4.8 years in the combination group and 25.9±5.1 years in the misoprostol-alone group. The mean gestational age was 39.1±1.0 weeks and 39.0±1.1 weeks, respectively. The median Bishop score at admission was 3 (2–5) in both groups. The indications for induction of labour were similarly distributed between the groups (Table 1).

Table 1: Baseline demographic and obstetric characteristics.

Characteristic	Foley + Misoprostol (n=25)	Misoprostol (n=25)
Maternal age (years), N (%)		
20-25	6 (24.0)	7 (28.0)
26-30	13 (52.0)	11 (44.0)
31-35	6 (24.0)	7 (28.0)
Mean ± SD	26.4±4.8	25.9±5.1
Gestational age (weeks), N (%)		
37-38	2 (8.0)	3 (12.0)
38-39	6 (24.0)	6 (24.0)
39-40	14 (56.0)	13 (52.0)
≥40	3 (12.0)	3 (12.0)
Mean ± SD	39.1±1.0	39.0±1.1
Admission Bishop score, N (%)		
2	6 (24.0)	8 (32.0)
3	11 (44.0)	8 (32.0)
4	6 (24.0)	6 (24.0)
5	2 (8.0)	3 (12.0)
Median (IQR)	3 (2–5)	3 (2–5)

Women receiving Foley catheter combined with vaginal misoprostol had a significantly shorter induction-to-delivery interval (15.3±6.5 vs. 18.3±8.7 hours; p=0.03) and time to complete cervical dilatation (13.7±5.9 vs. 17.1±8.7 hours; p=0.03) compared with those receiving vaginal misoprostol alone. Although a greater proportion of women in the combination group delivered within 24 hours (80.0% vs. 64.0%), the difference was not statistically significant (p=0.09) (Table 2).

The rate of vaginal delivery was higher in the combination group (68%) than in the misoprostol-alone group (60%), while caesarean delivery occurred in 32% and 40% of women, respectively. However, these differences were not statistically significant (Table 2).

Table 2: Comparison of induction and delivery outcomes.

Outcome	Foley + Misoprostol (n=25)	Misoprostol (n=25)	Effect Size (95% CI)	P value
Induction to delivery time (hrs)	15.3±6.5	18.3±8.7	−3.1 (−5.9 to −0.3)	0.03*
Induction to complete dilatation time (hrs)	13.7±5.9	17.1±8.7	−3.5 (−6.7 to −0.4)	0.03*
Delivery within 24hrs	20 (80%)	16 (64%)	1.25 (0.90–1.70)	0.09
Vaginal delivery	17 (68%)	15 (60%)	1.13 (0.76–1.68)	0.56
Caesarean delivery (overall)	8 (32%)	10 (40%)	0.80 (0.39–1.66)	0.56

*Significant

Eighteen women (72%) in the combination group and 23 women (92%) in the misoprostol-alone group required a second dose; however, this difference was not statistically significant (p=0.13). The requirement for a third dose was significantly lower in the combination group than in the misoprostol-alone group (6 [24%] vs. 17 [68%]; p=0.002).

Similarly, only one woman (4%) in the combination group required a fourth dose compared with seven women (28%) in the misoprostol-alone group, and this difference was statistically significant (p=0.049).

None of the women in the Foley catheter plus vaginal misoprostol group required more than four doses, whereas one woman (4%) in the misoprostol-alone group required more than four doses; this difference was not statistically significant (p=1.00) (Table 3)

Table 3: Number of vaginal misoprostol doses required for cervical ripening.

Number of Misoprostol Doses	Foley + Vaginal Misoprostol (n=25)	Vaginal Misoprostol Alone (n=25)	P value
1 dose	25 (100%)	25 (100%)	—
2 doses	18 (72%)	23 (92%)	0.13
3 doses	6 (24%)	17 (68%)	0.002
4 doses	1 (4%)	7 (28%)	0.049
>4 doses	0 (0%)	1 (4%)	1.00

Neonatal outcomes were comparable between the two groups. Mean birth weight, Apgar scores at 1 and 5 minutes, and the frequency of neonatal intensive care unit admission did not differ significantly. No increase in adverse neonatal outcomes was observed with the use of combination therapy (Table 4).

Table 4: Neonatal outcomes.

Outcome	Foley + Misoprostol (n=25)	Misoprostol (n=25)	Relative risk (95% CI)	P value
Birth weight (g)	2829±494	2801±504	—	0.76
1-min Apgar score	8 (2, 9)	8 (2, 9)	—	0.55
5-min Apgar score	9 (8, 9)	9 (8, 9)	—	0.86
Admission to NICU	4 (16%)	6 (24%)	—	0.73

DISCUSSION

The present prospective comparative interventional study compared the effectiveness of Foley catheter combined with vaginal misoprostol versus vaginal misoprostol alone for cervical ripening and induction of labour in women with term pregnancies and an unfavourable cervix. The study demonstrated that combination therapy significantly shortened the induction-to-delivery interval and the time to achieve complete cervical dilatation without increasing maternal or neonatal complications. Although vaginal delivery rates were higher in the combination group, the difference was not statistically significant. The baseline demographic and obstetric characteristics were comparable between the two groups, including maternal age, gestational age, Bishop score and indications for induction. This indicates that both groups were well matched, thereby reducing the influence of confounding variables on the study outcomes. Similar baseline comparability has been reported in previous randomized controlled trials evaluating combined mechanical and pharmacological methods for labour induction.[5,6]

A significant reduction in the induction-to-delivery interval was observed in the combination group (15.3±6.5 hours) compared with the vaginal misoprostol group (18.3±8.7 hours; p=0.03). Likewise, the time required to achieve complete cervical dilatation was significantly shorter with combination therapy. These findings are consistent with those of Rust et al who demonstrated that transcervical Foley catheter combined with vaginal misoprostol resulted in a shorter induction process than vaginal misoprostol alone.[6] Similar findings were reported by Chung et al who concluded that combination therapy accelerated cervical ripening and labour progression compared with either method alone.[7] The probable explanation is the synergistic action of mechanical cervical dilatation by the Foley catheter and biochemical cervical ripening induced by misoprostol, leading to earlier onset of effective uterine contractions. Although delivery within 24 hours and vaginal delivery rates were higher in the combination group, the differences were not statistically significant. Similarly, the caesarean section rate was lower in the combination group (32%) than in the misoprostol-alone group (40%), although this difference did not reach statistical significance. These observations are comparable with those reported by Levine et al who found that combined mechanical and pharmacological methods improved labour efficiency without significantly altering caesarean delivery rates.[8] Likewise, Gibson et al observed that the use of a Foley catheter was associated with effective cervical ripening while maintaining similar operative delivery rates.[9]

While all women in both groups received the initial dose of misoprostol, the proportion requiring subsequent doses progressively decreased in the combination group. Although the requirement for a second dose was lower in the Foley catheter group (72% vs. 92%), the difference was not statistically significant. However, the need for a third dose (24% vs. 68%; p=0.002) and a fourth dose (4% vs. 28%; p=0.049) was significantly reduced in the combination group, indicating more effective cervical ripening with the combined mechanical and pharmacological approach.[10] These findings are comparable with those reported by Elpo et al who demonstrated that women receiving Foley catheter combined with vaginal misoprostol had a significantly lower requirement for second, third, and fourth misoprostol doses than those receiving vaginal misoprostol alone, reflecting a more efficient induction process. No increase in neonatal morbidity was observed with combination therapy, indicating that shortening the induction process did not compromise neonatal safety.

These findings are in agreement with the Cochrane systematic review by Hofmeyr et al which concluded that vaginal misoprostol is an effective agent for labour induction and that combining mechanical methods does not adversely affect neonatal outcomes.[11] Similarly, Levine et al. reported no significant differences in neonatal outcomes between combination therapy and pharmacological induction alone. Overall, the present study supports the use of Foley catheter combined with vaginal misoprostol as a safe and effective method for cervical ripening and induction of labour. The combination significantly reduced the induction-to-delivery interval without increasing maternal or neonatal complications, suggesting that it may be considered a valuable alternative to vaginal misoprostol alone in women with an unfavourable cervix. This study has certain limitations. The relatively small sample size and single-centre design may limit the generalisability of the findings to broader obstetric populations. The study was conducted over a relatively short period, and therefore longer-term maternal and neonatal outcomes could not be assessed. Larger, multicentric studies with longer follow-up are warranted to confirm these findings and establish the wider applicability of the combined Foley catheter and vaginal misoprostol approach.

CONCLUSION

In women with term pregnancies and an unfavourable cervix, the combination of a transcervical Foley catheter with vaginal misoprostol significantly reduced the induction-to-delivery interval and time to complete cervical dilatation compared with vaginal misoprostol alone. Combination therapy also reduced the requirement for repeated doses of misoprostol, while maternal and neonatal outcomes remained comparable between the groups. These findings suggest that Foley catheter combined with vaginal misoprostol is an effective and safe approach for cervical ripening and labour induction in appropriately selected women with an unfavourable cervix.

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