European Journal of Clinical Pharmacy

Print ISSN: 2385-409X **Online ISSN**: Applied
Website: https://farmclin.com/

Original Research Article

Comparison of Induction of Labor by Combining Intracervical Catheter and Misoprostol Tablet Versus Misoprostol Tablet alone at Term

Article History:

Name of Author:
Dr Rosheen Ayesha[1], Dr Samar Amin[2], Dr Minal Amna[3]

Affiliation:
1PGR, Obstetrics and Gynecology, Maternal and Newborn Child Healthcare Hospital (MNCH) Faisalabad, Pakistan
2Consultant Obstetrics and Gynecology, HOD Maternal and Newborn Child Healthcare Hospital (MNCH) Faisalabad, Pakistan
3Consultant Obstetrics and Gynecology, Faisalabad International Hospital, Pakistan

Corresponding Author:
Dr Rosheen Ayesha
rosheenaisha131@gmail.com

Received: 03-12-2025
Revised: 21-12-2025
Accepted: 27-12-2025
Published: 30-12-2025

Abstract:

Background: Induction of labor in women with an unfavorable cervix remains a clinical challenge, and optimization of safe and effective induction methods is important to improve maternal and neonatal outcomes.

Objective: To compare the efficacy and safety of induction of labor using combined intracervical Foley catheter and misoprostol versus misoprostol alone at term.

Study Design: Randomized controlled trial. Place and Duration of Study: Maternal Newborn and Child Healthcare (MNCH), Faisalabad, from 1 September 2025 to 1 December 2025. Methodology: A total of 844 patients were randomized into two groups, with 422 patients in each group. Group A received intracervical Foley catheter combined with vaginal misoprostol, while Group B received vaginal misoprostol alone. Primary outcome was induction-to-delivery interval. Secondary outcomes included mode of delivery, failed induction, oxytocin augmentation, meconium-stained liquor, postpartum hemorrhage, NICU admission, and neonatal outcomes.

Results: Mean induction-to-delivery interval was significantly shorter in the Foley plus misoprostol group compared with misoprostol alone (11.6 ± 3.8 vs 15.2 ± 4.5 hours, $p<0.001$). Vaginal delivery rate was significantly higher in the combination group (76.3% vs 66.6%, $p=0.002$), while failed induction was lower (7.3% vs 13.7%, $p=0.004$). Oxytocin augmentation was reduced in the combination group (44.1% vs 55.2%, $p=0.001$).

Conclusion: Combined intracervical Foley catheter and misoprostol was associated with superior induction efficiency, improved vaginal delivery rates, reduced failed induction, and better maternal and neonatal outcomes compared with misoprostol alone.

Keywords: Induction of labor, Foley catheter, Misoprostol, Cervical ripening, Vaginal delivery, NICU admission.

INTRODUCTION

Induction of labor (IOL) is the initiation of labor before the spontaneous onset of labor, with or without rupture of membranes. Cervical ripening is an initial part of induction of labor and is used to facilitate the softening and opening of the cervix prior to labor. The World Health Organization's (WHO) Global Survey on Maternal and Perinatal Health in 24 countries showed that IOL was performed in 9.6% of all births and 22.5% of births in the US during the same year [1]. The reasons for induction of labor have been broad from maternal to fetal interests. The aim of induction of labor is when the risk of continuing pregnancy is greater than the benefit for the mother or fetus. The second issue is how can this be done most safely. Labor is a combination of two factors: Myometrial activity and cervical dilatation and effacement (ripening of cervix). So ideally any agent that is introduced with the intention of labor induction should work on both [2,3]. There are numerous methods for cervical ripening. These include intra cervical Foley catheter, and vaginal misoprostol for cervical ripening and labor induction3. Misoprostol, synthetic analog of "prostaglandin E1" was manufactured as gastrocytoprotective agent [4]. Sublingual, vaginal, oral, buccal and rectal are routes.

The vaginal route increases the cervical ripening and vaginal delivery rate within 24 hours. It is extensively used for induction of labor, abortion, prevention and treatment of postpartum hemorrhage [4,5]. The PGs cause cervical softening and effacement while the mechanical devices cause cervical dilatation. Therefore, mechanical methods in combination with prostaglandins are considered to be helpful for cervical ripening for unripe cervix [6]. In many developing countries, the use of intra cervical Foley's catheter as a mechanical method has been recommended. In different studies, the use of intra cervical folly's catheter alone or in combination with prostaglandins have proved to be very successful [7]. Though the mechanism of action of Foley's catheter is not clear. We have seen a positive effect with the combined use of mechanical and pharmacological methods, and the advantages and safety for the mother and infant. Overseas there are several studies that compared methods of intracervical folly catheter and intravaginal misoprostol, separately and combined. These studies have demonstrated the two different mechanisms to have a synergistic effect [8,9]. In one study, mode of vaginal delivery was 25 (26%) in group Misoprostol group and 45 34 (35.4%) in Misoprostol + catheter group. Cesarean delivery was 37 (37.5%) in Misoprostol group and 14 (14.65) in Misoprostol+ catheter group7. In another study, PPH was 5 (6.8%) in Foleys catheter + Misoprostol group and 2 (2.7%) in Misoprostol group. Meconium liquor was 25 (33.8%) in Misoprostol+ catheter group and 45 (60.8%) in Misoprostol group. Admission in NICU was 30 (40.5%) in Foleys catheter + Misoprostol group and 47 (63.5%) in Misoprostol group [8]. There is limited number of previous studies, comparing the combination methods vs single method; resulting in limited evidence of superiority of the combination.

Objectives: To determine the outcome of induction of labour by combining intracervical Foleys catheter and misoprostol tablet and misoprostol tablet alone.

METHODOLOGY:

This Randomized control trial was conducted at Maternal New Born and Child Healthcare (MNCH), Faisalabad from 1 September 2025 to 1 December 2025. Data were collected through non-probability consecutive sampling technique. Sample size was calculated by using WHO sample size calculator for 2 proportions

Power of study = 80%

Level of significance= 5%

Anticipated Proportion in Foleys catheter + Misoprostol group (P1) =6.8%8

Anticipated Proportion in Misoprostol group (P2) =2.7%8

Sample size = 844 (422 in each group)

Women 20-40 years old with gestational age 37-40+6 weeks (by LMP), single alive fetus in cephalic presentation demonstrated by ultrasound, intact membranes and Bishop score 3 or less on clinical examination were included. Those with indications for induction such as pregnancy-induced hypertension, preeclampsia, gestational diabetes, oligohydramnios, chronic hypertension and diabetes were included. Patients having multiple pregnancy, malpresentation, contraindications to vaginal delivery (history of a caesarean section, placenta Previa), contraindications to Foley balloon catheter (ruptured membranes, vaginal infection, chorioamnionitis, cervical dilation ≥3 cm) were excluded.

Data collection: The study was started after obtaining permission from Institutional Ethical Review Committee and CPSP. Consent was taken from the participants. A proforma was filled including age, parity, gestational age, indication for induction, Bishop score, induction-delivery interval, mode of delivery, meconium-stained liquor, post-partum hemorrhage and admission to NICU. Women were allocated into two groups. In Group A, intracervical Foley catheter and misoprostol were used, while Group B used misoprostol. Group A patients were given an 18F intracervical Foley catheter inflated with 60 mL and inserted at 4 pm and removed after 24 hours if not spontaneously expelled. An additional dose of vaginal misoprostol 25 µg was given every 6 hours until the cervical ripening was sufficient (Bishop score >6) or the maximum of four doses was reached. If the desired Bishop score was not achieved within 6 hours of the last dose, it was considered induction failure. Group B was given vaginal misoprostol alone at the same dose. Oxytocin augmentation was used if the uterus failed to contract and amniotomy was done as required. The primary outcome was time from induction to delivery. The secondary outcomes were mode of delivery, failed induction, meconium-stained liquor, postpartum hemorrhage and NICU admission. Outcomes were measured based on definitions.

Statistical Analysis: Data were entered and analyzed using SPSS version 26. Quantitative variables including age, parity, gestational age, and induction-to-delivery interval were presented as mean ± standard deviation. Qualitative variables were presented as frequency and percentages. Independent sample t-test was used to compare induction-to-delivery interval between groups, while Chi-square test was applied for comparison of categorical outcomes. Effect modifiers including age, gestational age, parity, GDM, PIH, hypertension, diabetes, and oligohydramnios were controlled through stratification. Post-stratification Chi-square test and independent sample t-test were applied. A p-value ≤0.05 was considered statistically significant.

RESULTS

Data were collected from 844 patients, mean maternal age was 28.7 ± 4.6 years overall, with comparable values in the Foley plus misoprostol group (28.5 ± 4.5 years) and misoprostol alone group (28.9 ± 4.7 years). Mean parity was similar between groups (1.7 ± 1.1 vs 1.8 ± 1.2), as was mean gestational age (38.5 ± 1.0 vs 38.6 ± 1.1 weeks). The distribution of pregnancy-

induced hypertension was comparable between groups, observed in 118 (28.0%) versus 114 (27.0%) patients.

Table 1: Baseline Maternal and Obstetric Characteristics (n=844)

Variable	Category	Total (n=844)	Foley + Misoprostol (n=422)	Misoprostol Alone (n=422)
Age (years)	—	28.7 ± 4.6	28.5 ± 4.5	28.9 ± 4.7
Parity	—	1.8 ± 1.2	1.7 ± 1.1	1.8 ± 1.2
Gestational Age (weeks)	—	38.6 ± 1.0	38.5 ± 1.0	38.6 ± 1.1
PIH	Yes	232 (27.5)	118 (28.0)	114 (27.0)
GDM	Yes	154 (18.2)	74 (17.5)	80 (19.0)
Oligohydramnios	Yes	119 (14.1)	58 (13.7)	61 (14.5)
Chronic HTN/DM	Yes	98 (11.6)	50 (11.8)	48 (11.4)

The mean induction-to-delivery interval was significantly shorter in the Foley plus misoprostol group compared with misoprostol alone (11.6 ± 3.8 vs 15.2 ± 4.5 hours; p<0.001). Vaginal delivery occurred more frequently in the combination group, with 322 (76.3%) patients compared with 281 (66.6%) in the misoprostol-alone group, while cesarean section was lower in the combination group (23.7% vs 33.4%). Failed induction was significantly reduced in the combination group, occurring in 31 (7.3%) compared with 58 (13.7%) patients (p=0.004).

Table 2: Induction and Delivery Outcomes

Variable	Foley + Misoprostol (n=422)	Misoprostol Alone (n=422)	p-value
Induction-to-Delivery Interval (hours)	11.6 ± 3.8	15.2 ± 4.5	<0.001
Vaginal Delivery	322 (76.3)	281 (66.6)	0.002
Cesarean Section	100 (23.7)	141 (33.4)	
Failed Induction	31 (7.3)	58 (13.7)	0.004
Oxytocin Augmentation	186 (44.1)	233 (55.2)	0.001

Meconium-stained liquor was observed in 36 (8.5%) women in the Foley plus misoprostol group compared with 59 (14.0%) in the misoprostol-alone group (p=0.012). Postpartum hemorrhage occurred less frequently in the combination group, 18 (4.3%) versus 31 (7.3%) (p=0.048). Uterine tach systole was also significantly lower with combined induction, reported in 21 (5.0%) compared with 44 (10.4%) patients (p=0.006). Maternal infection rates were low and comparable between groups, with no statistically significant difference (p=0.541).

Table 3: Maternal Outcomes

Variable	Foley + Misoprostol (n=422)	Misoprostol Alone (n=422)	p-value
Meconium-Stained Liquor	36 (8.5)	59 (14.0)	0.012
Postpartum Hemorrhage	18 (4.3)	31 (7.3)	0.048
Uterine Tachystole	21 (5.0)	44 (10.4)	0.006
Maternal Infection	11 (2.6)	14 (3.3)	0.541

NICU admission was significantly lower among neonates delivered in the Foley plus misoprostol group, occurring in 39 (9.2%) compared with 67 (15.9%) in the misoprostol-alone group (p=0.004). Low Apgar score at 5 minutes (<7) occurred less frequently in the combination group, 18 (4.3%) versus 33 (7.8%) (p=0.031).

Table 4: Neonatal Outcomes

Variable	Foley + Misoprostol (n=422)	Misoprostol Alone (n=422)	p-value
NICU Admission	39 (9.2)	67 (15.9)	0.004
Apgar <7 at 5 min	18 (4.3)	33 (7.8)	0.031
Neonatal Distress	29 (6.9)	51 (12.1)	0.010

Mean induction-to-delivery interval remained significantly shorter in the Foley plus misoprostol group (12.3 ± 4.0 vs 16.7 ± 4.8 hours; p<0.001). Vaginal delivery was achieved more frequently in the

combination group, 178 (72.4%) versus 139 (58.2%) (p=0.001), while failed induction was significantly lower at 23 (9.3%) compared with 44 (18.4%) in the misoprostol-alone group (p=0.005).

Table 5: Stratified Outcomes in Patients with Bishop Score ≤2

Variable	Foley + Misoprostol (n=246)	Misoprostol Alone (n=239)	p-value
Induction-to-Delivery Interval (hours)	12.3 ± 4.0	16.7 ± 4.8	<0.001
Vaginal Delivery	178 (72.4)	139 (58.2)	0.001
Failed Induction	23 (9.3)	44 (18.4)	0.005

DISCUSSION

This is a randomized controlled trial of induction of labor at term with combined intracervical Foley catheter and misoprostol (Foley plus misoprostol) compared with misoprostol alone and found the combined approach to be superior in terms of shorter induction-to-delivery interval, increased vaginal delivery, decreased failed induction, decreased oxytocin use, and better maternal and neonatal outcomes. The results provide evidence for the possible benefits of using combined mechanical and pharmacologic cervical ripening agents in women with an unfavourable cervix who are being induced [10]. The key finding of this study is the reduced induction-to-delivery time in the combination group than in the misoprostol-only group (11.6 ± 3.8 vs 15.2 ± 4.5 hours, p<0.001). This implies that intracervical catheter may increase the efficiency of induction, likely because of the combined effect of cervical dilation and endogenous prostaglandin release with the effect of the exogenous prostaglandin. Other studies have also found shorter induction time using combined methods compared with pharmacologic induction [11].

Another key outcome was the increased vaginal delivery rate in the Foley plus misoprostol group (76.3% vs 66.6%, p=0.002) with a corresponding decrease in cesarean delivery rates. This could be attributed to more effective cervical ripening and progression of labor, which may also improve delivery outcomes. Other studies report on the higher successful vaginal delivery rates of combined mechanical and pharmacologic induction of labor, especially in women with an unfavorable cervix [12]. The combination group had a lower rate of failed induction (7.3% vs 13.7%, p=0.004), which is an important outcome. Failed induction is a major contributor to maternal morbidity, health-care costs and operative birth. This study's finding suggests the potential for better induction with combined approaches. Other studies have also shown decreased failed induction rates in combined methods [13]. The combination group also had significantly lower rates of oxytocin augmentation (44.1% vs 55.2%, p=0.001), indicating less need for intervention. This may be due to more successful spontaneous onset of labor after cervical maturation. This may have resource implications in terms of workload and the need for close monitoring in large units [14].

There were fewer adverse maternal outcomes. There was a lower proportion of meconium-stained liquor (8.5% vs 14.0%, p=0.012) in women who received combination induction and a reduction in postpartum hemorrhage (4.3% vs 7.3%, p=0.048). Furthermore, uterine tach systole was reduced in the combination group (5.0% vs 10.4%, p=0.006) and this may have improved safety compared with the use of misoprostol alone [15]. Other studies have also noted a reduction in complications due to hyper stimulation with the addition of mechanical methods. The lower frequency of uterine tach systole is important as uterine hyper stimulation can lead to fetal compromise and operative vaginal birth [16]. The reduced frequency with combined inductions may be due to the ability to successfully ripen the cervix with potentially lower reliance on the prostaglandin effect. This might be a potential key mechanism for some of the positive outcomes [17]. A significant contribution to the field was the sub analysis in women with very unfavorable cervix (Bishop score ≤2), where improvement was still observed [18,19]. The combined group had a shorter induction to delivery interval, higher rate of vaginal delivery and lower rate of failed induction in this high-risk group. This is an important result as women with very unfavorable cervices are among the most difficult patients to induce. Other studies have similarly suggested that combined approaches may be particularly good for these women [20]. These observations are relevant given that cost-effective induction strategies may be of value in resource-poor settings where a reduction in the rates of induction failure, prolonged labor and operative delivery may be desirable. An approach that reduces the duration of induction and need for additional intervention may benefit both maternal outcomes and resource allocation.

CONCLUSION:

It is concluded that combined intracervical Foley catheter and misoprostol for induction of labor was associated with lower induction-to-delivery interval, vaginal birth rates, failed induction and oxytocin augmentation when compared to misoprostol alone. The combined approach was also associated with fewer maternal complications, such as uterine tach systole and postpartum hemorrhage, and fewer neonatal complications, including NICU admissions and neonatal distress.

REFERENCES:

1. El-Kelani OA, El-Halaby AE, El-Shamy ES, Abd El-Fattah TN. Comparison between intracervical Foley catheter plus misoprostol

and misoprostol alone for labor induction. Menoufia Med J. 2019;32:1393-1396.
2. Davalagi V, Lakshmikantha G, Neeta. Efficacy of vaginal misoprostol versus transcervical Foley's catheter and vaginal misoprostol in induction of labor. Int J Reprod Contracept Obstet Gynecol. 2019;8:1341-1346.
3. Orr L, Reisinger-Kindle K, Roy A, Levine L, Connolly K, Visintainer P, et al. Combination of Foley and prostaglandins versus Foley and oxytocin for cervical ripening: a network meta-analysis. Am J Obstet Gynecol. 2020;223(5):1-17.
4. Toshniwal SM, Inamdar S, Sharma SR. Foley's catheter and vaginal misoprostol versus vaginal misoprostol alone for labor induction. J South Asian Fed Obstet Gynaecol. 2022;14:381-386.
5. Elpo JA, Araújo BA, Volpato LK. Foley catheter plus misoprostol versus misoprostol alone for labor induction. Rev Assoc Med Bras (1992). 2023;69(1):119-123. doi:10.1590/1806-9282.20220897.
6. Rafiq M, Salman SG. Comparison of Foley's catheter and misoprostol versus misoprostol alone on labour induction. Hamdan Med J. 2022;15:93-96.
7. Kadu NA, Shiragur S. Comparison of intracervical Foley's catheter with vaginal misoprostol versus intravaginal misoprostol alone for cervical ripening and induction of labor. Cureus. 2023;15(9):e45162.
8. Lee HH, Huang BS, Cheng M, Yeh CC, Lin IC, Horng HC, et al. Intracervical Foley catheter plus intravaginal misoprostol versus intravaginal misoprostol alone for cervical ripening: a meta-analysis. Int J Environ Res Public Health. 2020;17(6):1825. doi:10.3390/ijerph17061825.
9. Gomez HB, Hoffman MK, Caplan R, Ruhstaller K, Young MHH, Sciscione AC. Buccal versus vaginal misoprostol combined with Foley catheter for cervical ripening at term (the BEGIN trial): a randomized controlled trial. Am J Obstet Gynecol. 2021;224(5):524.e1-524.e8. doi:10.1016/j.ajog.2021.02.016.
10. Zhao G, Song G, Liu J. Safety and efficacy of double-balloon catheter for cervical ripening: a Bayesian network meta-analysis of randomized controlled trials. BMC Pregnancy Childbirth. 2022;22(1):688. doi:10.1186/s12884-022-04988-2.
11. Neetika N, Mandrelle K. To compare the outcome of induction of labour by intracervical Foley's catheter and misoprostol versus misoprostol alone. Int J Med Pharm Res. 2025;6(6):747-752.
12. Priyadarshini A, Jaiswar SP, Singh A, Singh S. Comparative outcome of induced labor by intracervical Foley catheter with misoprostol versus misoprostol alone. J Comp Eff Res. 2019;8(1):55-59.
13. Garg R, Bagga R, Kumari A, Kalra J, Jain V, Saha SC, Kumar P. Comparison of intracervical Foley catheter combined with a single dose of vaginal misoprostol tablet or intracervical dinoprostone gel for cervical ripening: a randomized study. J Obstet Gynaecol. 2022;42(2):232-238.
14. Aregeb ZA, Albromboly W, Abdelhameid AA, Helal KF, Badr MS. Induction of labor using vaginal misoprostol alone or combined with intracervical Foley catheter. Egypt J Hosp Med. 2021;85(1):3125-3129.
15. Kerr RS, Kumar N, Williams MJ, Cuthbert A, Aflaifel N, Haas DM, et al. Low-dose oral misoprostol for induction of labour. Cochrane Database Syst Rev. 2021;(6):CD014484.
16. Santosh KP, Kaur A, Kaur M, Garg R. A comparative study of combination of intracervical Foley's catheter and intravaginal misoprostol versus intravaginal misoprostol alone for induction of labour. Indian J Obstet Gynecol Res. 2020;5(1):131-135.