RESEARCH PAPER

Comparative Study of Vaginal Misoprostol versus Single Balloon Catheter for Pre-Induction Cervical Ripening: A Randomised Controlled Trial

Dr Shikha[1], Dr. Rajni Agarwal[2], Dr. Mridula Sharma[3], Dr. Kashish[4]

[1]Obstetrics and Gynaecology Resident, Rajshree Medical Research Institute, Bareilly
[2]HOD, Department of Obstetrics and Gynaecology, Rajshree Medical Research Institute, Bareilly
[3]Professor, Department of Obstetrics and Gynaecology, Rajshree Medical Research Institute, Bareilly
[4]Senior Resident, Department of General Medicine, PGIMS, Rohtak

ABSTRACT

Introduction: Pre-induction cervical ripening is a crucial determinant of successful induction of labour (IOL), particularly in women with an unfavourable cervix. Pharmacological agents such as vaginal misoprostol and mechanical methods like the single balloon (Foley) catheter are commonly used for cervical ripening. However, controversy persists regarding their relative efficacy and safety profiles.

Aim: To compare the efficacy and safety of vaginal misoprostol versus single balloon catheter for pre-induction cervical ripening in term primigravida women.

Materials and Methods: This randomised controlled trial was conducted in the Department of Obstetrics and Gynaecology at Rajshree Medical Research Institute, Bareilly, from April 2024 to November 2025. A total of 126 primigravida women with singleton live cephalic pregnancies between 37–42 weeks of gestation and Bishop score <4 were randomly allocated into two groups. Group A (n=63) received 25 μg vaginal misoprostol every 6 hours (maximum four doses).

Group B (n=63) underwent intracervical single balloon catheter insertion (30 mL balloon) for up to 24 hours. Primary outcomes included time to achieve Bishop score >8 and induction-to-delivery interval. Secondary outcomes included duration of labour stages, mode of delivery, maternal complications, Apgar score, and NICU admission. Statistical analysis was performed using Student's t-test and Chi-square test, with $p \leq 0.05$ considered statistically significant.

Results: Baseline demographic and obstetric characteristics were comparable between the two groups ($p>0.05$). The misoprostol group demonstrated a significantly shorter time to achieve Bishop score >8 and shorter induction-to-delivery interval compared to the balloon catheter group ($p<0.0001$). Duration of first stage of labour was significantly reduced in Group A. However, there was no statistically significant difference between the groups regarding mode of delivery, cesarean section rate, maternal complications including postpartum haemorrhage, Apgar scores at 1 and 5 minutes, or NICU admissions ($p>0.05$).

Conclusion: Both vaginal misoprostol and single balloon catheter are effective and safe methods for pre-induction cervical ripening. Vaginal misoprostol is associated with faster cervical ripening and shorter induction-to-delivery interval, whereas the single balloon catheter remains a reliable alternative with comparable maternal and neonatal outcomes.

Keywords: Cervical ripening, Induction of labour, Misoprostol, Foley catheter, Bishop score, Randomised controlled trial

How to cite this article: Shikha, Agarwal R, Sharma M, Kashish. Comparative Study of Vaginal Misoprostol versus Single Balloon Catheter for Pre-Induction Cervical Ripening: A Randomised Controlled Trial. Int J Drug Deliv Technol. 2026;16(6s): 318-323; DOI: 10.25258/ijddt.16.6s.35

Source of support: Nil

Conflict of interest: None

INTRODUCTION

Induction of labour (IOL) is one of the most frequently performed obstetric interventions worldwide and is undertaken when the benefits of delivery outweigh the

risks of continuing the pregnancy [1]. Globally, approximately 10–25% of pregnancies undergo induction, with higher rates reported in developed countries [2]. The increasing trend of IOL reflects changing obstetric practices aimed at reducing maternal and perinatal morbidity and mortality [3].

The success of IOL largely depends on the condition of the cervix at the time of induction. An unfavourable cervix, commonly assessed using the Bishop score, is associated with prolonged labour, increased requirement of oxytocin augmentation, and higher rates of failed induction and cesarean section [4]. A Bishop score of less than 6 generally indicates the need for cervical ripening before induction [5]. Effective pre-induction cervical ripening improves the likelihood of vaginal delivery and reduces obstetric complications [6].

Cervical ripening can be achieved by pharmacological, mechanical, or combined methods. Pharmacological methods primarily include prostaglandins such as prostaglandin E1 (misoprostol) and prostaglandin E2 (dinoprostone), while mechanical methods include transcervical balloon catheters and laminaria tents [7]. Among these, vaginal misoprostol and the Foley balloon catheter are widely used because of their effectiveness, availability, and cost-efficiency [8].

Misoprostol, a synthetic analogue of prostaglandin E1, acts by promoting cervical softening through collagen breakdown and stimulating uterine contractions via myometrial activation [9]. It is inexpensive, stable at room temperature, and easy to administer, making it particularly useful in resource-limited settings [10]. Vaginal administration provides sustained drug release and enhanced cervical effect compared to oral administration [11]. However, misoprostol is associated with adverse effects such as uterine tachysystole, hyperstimulation, meconium-stained liquor, and rarely uterine rupture, especially in women with previous uterine scars [12].

The Foley balloon catheter is one of the oldest mechanical methods used for cervical ripening. First described by Embrey and Mollison in 1967, it works by exerting direct pressure on the internal os, leading to mechanical dilatation and release of endogenous prostaglandins [13]. Mechanical methods are associated with lower rates of uterine hyperstimulation compared to pharmacological agents [14]. Additionally, they are considered safer in women with previous cesarean sections due to reduced risk of uterine rupture [15]. However, balloon catheter use may be associated with discomfort, longer induction-to-delivery intervals, and occasional need for oxytocin augmentation [16].

Several randomised controlled trials and meta-analyses have compared vaginal misoprostol with balloon catheter for cervical ripening. Some studies report shorter induction-to-delivery intervals and higher rates of vaginal delivery with misoprostol [17,18], while others demonstrate comparable efficacy between the two methods with fewer uterine hyperstimulation events in the balloon catheter group [19]. A few studies suggest no significant difference in cesarean section rates or neonatal outcomes between the two approaches [20]. The heterogeneity of results in existing literature creates uncertainty regarding the optimal method of cervical ripening, particularly in primigravida women with an unfavourable cervix.

Given the increasing rates of induction of labour and the need to minimise maternal and neonatal complications, it is important to identify an effective, safe, and resource-appropriate cervical ripening method. In developing countries, cost-effectiveness and safety are particularly relevant considerations. Therefore, the present study was undertaken to compare the efficacy and safety of vaginal misoprostol versus single balloon catheter for pre-induction cervical ripening in term primigravida women with an unfavourable cervix.

MATERIALS AND METHODS

Study Design and Participants

This randomised controlled trial was conducted in the Department of Obstetrics and Gynaecology at Rajshree Medical Research Institute, Bareilly, from April 2024 to November 2025. Institutional Ethics Committee approval was obtained prior to commencement of the study. Written informed consent was obtained from all participants.

A total of 126 primigravida women were enrolled. Inclusion criteria were: singleton live fetus in cephalic presentation, gestational age between 37 and 42 weeks, indication for induction of labour, and Bishop score <4. Women with known hypersensitivity to misoprostol or latex, placenta previa, placenta accreta spectrum, previous uterine surgery, malpresentation, cord prolapse, active genital herpes infection, chorioamnionitis, estimated fetal weight >4 kg, and significant renal or hepatic disease were excluded.

Sample size was calculated using Master 2.0 software for equivalence trial design, considering a mean difference of 4.37 hours in induction time with pooled standard deviation of 7.81 hours, alpha error of 5%, beta error of 20%, and power of 80%. The calculated sample size was 63 women in each group.

Participants were randomly allocated into two groups (Group A and Group B) using computer-generated block randomisation with equal allocation.

Intervention Protocol and Outcome Measures

Group A (n=63) received 25 µg vaginal misoprostol placed in the posterior fornix during digital examination.

The dose was repeated every 6 hours for a maximum of four doses or until adequate uterine contractions were established or Bishop score improved by at least two points.

Group B (n=63) underwent intracervical insertion of a 14-F Foley catheter under aseptic precautions using a speculum. The balloon was inflated with 30 mL sterile water after crossing the internal os. Gentle traction was maintained by securing the catheter to the medial thigh. The catheter was assessed every 6 hours for spontaneous expulsion. If not expelled, it was removed after 24 hours. Following expulsion or removal, oxytocin infusion was initiated as per institutional protocol.

Continuous fetal heart rate monitoring and partograph assessment were performed throughout labour.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using GraphPad Prism version 9.2.0. Continuous variables were expressed as mean ± standard deviation and compared using Student's t-test. Categorical variables were presented as frequencies and percentages and analysed using Chi-square test or Fisher's exact test as appropriate. A p-value ≤0.05 was considered statistically significant.

RESULTS

A total of 126 primigravida women were enrolled and equally randomised into two groups: Group A (Vaginal Misoprostol, n=63) and Group B (Single Balloon Catheter, n=63). The two groups were comparable in terms of mean maternal age, gestational age, initial Bishop score, and indications for induction (p>0.05) (table 1)

Table 1: Baseline Characteristics of Study Participants

Variables	Group A (Misoprostol) (n=63)	Group B (Balloon Catheter) (n=63)	p-value
Age (years), Mean ± SD	24.8 ± 3.2	25.1 ± 3.5	0.62
Gestational age (weeks), Mean ± SD	39.2 ± 1.1	39.1 ± 1.3	0.71
Initial Bishop Score, Mean ± SD	3.1 ± 0.8	3.0 ± 0.7	0.48
Indication for induction			
Postdated pregnancy	32 (50.8%)	30 (47.6%)	0.83
Gestational hypertension	18 (28.6%)	20 (31.7%)	
Oligohydramnios	13 (20.6%)	13 (20.6%)	

Successful cervical ripening was slightly higher in the misoprostol group; however, the difference was not statistically significant (p=0.29). The time required to achieve favourable Bishop score and the overall induction-to-delivery interval were significantly shorter in the misoprostol group (p<0.001). Oxytocin augmentation was required significantly more often in the balloon catheter group (p=0.002) (table 2)

Table 2: Induction Characteristics

Variables	Group A (n=63)	Group B (n=63)	p-value
Successful cervical ripening (Bishop ≥8), n (%)	56 (88.9%)	52 (82.5%)	0.29
Time to Bishop score >8 (hours), Mean ± SD	10.4 ± 3.2	13.8 ± 4.5	<0.001
Induction-to-delivery interval (hours), Mean ± SD	14.6 ± 4.8	18.9 ± 5.6	<0.001
Oxytocin augmentation required, n (%)	21 (33.3%)	38 (60.3%)	0.002

The majority of women in both groups delivered vaginally. Although the vaginal delivery rate was slightly higher in the misoprostol group, the difference in mode of delivery between the two groups was not statistically significant (p=0.54).

Table 3: Mode of Delivery

Mode of Delivery	Group A (n=63)	Group B (n=63)	p-value
Normal vaginal delivery	48 (76.2%)	45 (71.4%)	0.54
Instrumental delivery	5 (7.9%)	6 (9.5%)	
Cesarean section	10 (15.9%)	12 (19.1%)	

Uterine tachysystole was significantly more common in the misoprostol group (p=0.03). There was no statistically significant difference between the two groups with respect to postpartum haemorrhage, Apgar scores, or NICU admissions (p>0.05). Neonatal outcomes were comparable in both groups (table 4).

Table 4: Maternal and Neonatal Outcomes

Variables	Group A (n=63)	Group B (n=63)	p-value
Uterine tachysystole, n (%)	9 (14.3%)	2 (3.2%)	0.03
Postpartum haemorrhage, n (%)	4 (6.3%)	3 (4.8%)	0.70
Apgar score <7 at 1 min, n (%)	6 (9.5%)	5 (7.9%)	0.75
Apgar score <7 at 5 min, n (%)	2 (3.2%)	2 (3.2%)	1.00
NICU admission, n (%)	5 (7.9%)	6 (9.5%)	0.75

DISCUSSION

Induction of labour remains one of the most common obstetric interventions worldwide, and its success largely depends on cervical favourability at the time of induction [1–3]. Pre-induction cervical ripening plays a pivotal role in improving vaginal delivery rates and reducing maternal morbidity. The present study compared vaginal misoprostol and single balloon catheter for cervical ripening in primigravida women with unfavourable cervix.

In our study, both groups were comparable in terms of maternal age, gestational age, initial Bishop score, and indication for induction. This baseline homogeneity strengthens the internal validity of the study and reduces confounding bias. Similar comparability between groups has been reported in previous randomised trials comparing misoprostol and Foley catheter [17,18,20].

Efficacy of Cervical Ripening

Successful cervical ripening (Bishop score ≥8) was achieved in 88.9% of women in the misoprostol group and 82.5% in the balloon catheter group, though the difference was not statistically significant. This finding suggests that both methods are effective for pre-induction cervical ripening.

Misoprostol acts by promoting collagen degradation and enhancing myometrial contractility [9,11], whereas the balloon catheter causes mechanical dilatation and endogenous prostaglandin release [13,14]. Previous systematic reviews have reported comparable cervical ripening efficacy between pharmacological and mechanical methods [6,14].

Afolabi et al., observed similar success rates between intravaginal misoprostol and Foley catheter for cervical ripening [17]. Roudsari et al., also reported no significant difference in cervical ripening success between the two modalities [18]. Noor et al., demonstrated comparable Bishop score improvement with both methods [20]. These findings align with the results of the present study.

Induction-to-Delivery Interval

The mean time to achieve favourable Bishop score and induction-to-delivery interval were significantly shorter in the misoprostol group (p<0.001). This indicates that misoprostol facilitates faster onset of labour compared to mechanical methods.

The shorter induction-to-delivery interval with misoprostol has been reported in several studies. Wing and Gaffaney demonstrated that vaginal misoprostol accelerates cervical ripening and reduces induction time [9]. Tang et al., showed sustained vaginal absorption and effective uterotonic action of misoprostol, explaining its rapid clinical response [11]. Fox et al., in their meta-analysis, reported shorter labour duration with misoprostol compared to balloon catheter [19].

Similarly, Afolabi et al., and Roudsari et al., observed significantly shorter induction-to-delivery intervals in the misoprostol group [17,18]. The present findings are consistent with these observations.

Oxytocin Requirement

Oxytocin augmentation was required significantly more frequently in the balloon catheter group (60.3% vs

33.3%). Mechanical methods primarily promote cervical dilatation but may not consistently stimulate effective uterine contractions [14]. Consequently, adjunctive oxytocin is often necessary.

Ten Eikelder et al., reported increased oxytocin requirement in the Foley catheter group compared to misoprostol [8]. Henry et al., also noted higher augmentation rates with mechanical induction methods [16]. These findings are consistent with our results.

Mode of Delivery

Although vaginal delivery rate was slightly higher in the misoprostol group, the difference in mode of delivery between groups was not statistically significant. Cesarean section rates were comparable (15.9% vs 19.1%).

Previous literature has shown similar cesarean rates between mechanical and pharmacological induction methods. Mozurkewich et al., found no significant difference in cesarean delivery rates across various induction methods [6]. Fox et al., also reported comparable cesarean rates in their meta-analysis [19]. Noor et al., demonstrated similar cesarean section incidence between misoprostol and Foley catheter groups [20].

Thus, while misoprostol shortens labour duration, it does not significantly alter overall cesarean section rates compared to balloon catheter.

Maternal Complications

Uterine tachysystole was significantly higher in the misoprostol group (14.3% vs 3.2%). This is consistent with the pharmacological action of prostaglandins, which stimulate uterine contractions [10,12].

Cochrane reviews by Hofmeyr et al., and Alfirevic et al., have reported increased uterine hyperstimulation associated with misoprostol use compared to mechanical methods [10,12]. Mechanical methods are associated with lower rates of uterine tachysystole because they do not directly stimulate uterine contractions [14].

However, postpartum haemorrhage rates were comparable between the two groups, suggesting no significant difference in immediate maternal morbidity.

Neonatal Outcomes

Neonatal outcomes including Apgar score at 1 and 5 minutes and NICU admissions were comparable between the two groups. Despite increased uterine tachysystole with misoprostol, no significant adverse neonatal impact was observed.

Similar findings were reported by Roudsari et al., and Noor et al., where neonatal outcomes did not differ significantly between groups [18,20]. Meta-analyses have also shown no consistent difference in neonatal morbidity between misoprostol and Foley catheter methods [14,19].

Clinical Implications

Misoprostol offers advantages such as shorter induction time and reduced need for oxytocin augmentation. It is inexpensive, stable at room temperature, and easy to administer, making it particularly suitable in resource-limited settings [7,10]. However, it carries a higher risk of uterine tachysystole.

The balloon catheter, though associated with longer induction time and increased oxytocin requirement, demonstrates a safer uterine stimulation profile with lower incidence of hyperstimulation. It may therefore be preferred in women at risk of uterine rupture or when careful titration of contractions is desired [14,15].

Both methods demonstrate comparable vaginal delivery rates and neonatal outcomes, suggesting that choice of method may be individualised based on clinical context, resource availability, and maternal risk profile.

CONCLUSION

Both vaginal misoprostol and single balloon catheter are effective methods for pre-induction cervical ripening in primigravida women with an unfavourable cervix. In the present study, vaginal misoprostol was associated with a significantly shorter time to achieve favourable Bishop score and reduced induction-to-delivery interval. It also required less oxytocin augmentation compared to the balloon catheter. However, misoprostol was associated with a higher incidence of uterine tachysystole.

The mode of delivery, cesarean section rate, maternal complications such as postpartum haemorrhage, and neonatal outcomes including Apgar scores and NICU admissions were comparable between the two groups. Thus, while misoprostol offers the advantage of faster induction, the balloon catheter provides a safer uterine stimulation profile with lower risk of hyperstimulation. The choice of method may therefore be individualised based on maternal condition, institutional protocol, and resource availability.

REFERENCES

1. World Health Organization. WHO recommendations for induction of labour. Geneva: World Health Organization; 2011.
2. Martin JA, Hamilton BE, Osterman MJK, Driscoll AK, Drake P. Births: Final data for 2019. Natl Vital Stat Rep. 2021;70(2):01-51.
3. Middleton P, Shepherd E, Morris J, Crowther CA, Gomersall JC. Induction of labour at or beyond 37 weeks' gestation. Cochrane Database Syst Rev. 2020;7:CD004945.
4. Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol. 1964;24:266-268.

5. Laughon SK, Zhang J, Troendle J, Sun L, Reddy UM. Using a simplified Bishop score to predict vaginal delivery. Obstet Gynecol. 2011;117(4):805-811.
6. Mozurkewich EL, Chilimigras JL, Koepke ER, Keeton KL, King VJ. Methods of induction of labour: A systematic review. BMC Pregnancy Childbirth. 2011;11:84.
7. Cunningham FG, Leveno KJ, Bloom SL, Dashe JS, Hoffman BL, Casey BM, et al. Williams Obstetrics. 26th ed. New York: McGraw Hill; 2022.
8. Ten Eikelder MLG, Oude Rengerink K, Jozwiak M, De Leeuw JW, De Graaf IM, Van Pampus MG, et al. Induction of labour at term with oral misoprostol versus Foley catheter: A systematic review. BJOG. 2016;123(9):1462-1470.
9. Wing DA, Gaffaney CA. Vaginal misoprostol administration for cervical ripening and labour induction. Am J Obstet Gynecol. 1998;178(3):532-537.
10. Hofmeyr GJ, Gülmezoglu AM, Pileggi C. Vaginal misoprostol for cervical ripening and induction of labour. Cochrane Database Syst Rev. 2010;10:CD000941.
11. Tang OS, Schweer H, Seyberth HW, Lee SWH, Ho PC. Pharmacokinetics of different routes of misoprostol administration. Hum Reprod. 2002;17(2):332-336.
12. Alfirevic Z, Aflaifel N, Weeks A. Oral misoprostol for induction of labour. Cochrane Database Syst Rev. 2014;6:CD001338.
13. Embrey MP, Mollison BG. The use of Foley's catheter for cervical ripening. J Obstet Gynaecol Br Commonw. 1967;74:44-48.
14. Jozwiak M, Bloemenkamp KWM, Kelly AJ, Mol BWJ, Irion O, Boulvain M. Mechanical methods for induction of labour. Cochrane Database Syst Rev. 2012;3:CD001233.
15. American College of Obstetricians and Gynecologists. Practice Bulletin No. 107: Induction of labour. Obstet Gynecol. 2009;114(2 Pt 1):386-397.
16. Henry A, Madan A, Reid R, Tracy SK, Austin K, Welsh A, et al. Outpatient Foley catheter versus inpatient prostaglandin for induction of labour. BMC Pregnancy Childbirth. 2013;13:25.
17. Afolabi BB, Oyekan TO, Morhason-Bello IO. Intravaginal misoprostol versus Foley catheter for cervical ripening and induction of labour. Int J Gynaecol Obstet. 2004;86(3):263-267.
18. Roudsari FV, Ayati S, Ghasemi M, Moghaddam NA. Comparison of vaginal misoprostol with Foley catheter for cervical ripening. J Obstet Gynaecol Res. 2011;37(10):1362-1367.
19. Fox NS, Saltzman DH, Klauser CK, Peress D, Gutierrez CV, Rebarber A. Balloon catheter vs misoprostol for cervical ripening: Meta-analysis. Am J Obstet Gynecol. 2011;204(5):418.e1-418.e7.
20. Noor N, Ansari MA, Ali SM, Parveen S. Foley catheter versus vaginal misoprostol for labour induction. J Clin Diagn Res. 2015;9(6):QC05-QC08.