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ORIGINAL ARTICLE

Comparison of Maternal and Fetal Outcomes in Induction of Labor Using Misoprostol Versus Foley's Catheter in Term Pregnancies

ASIFA MAJID[1], AZRA RASHID[2], AFSHIN AMAN[3], SAIMA NOREEN[4], ANIKAH KANWAL[5], TAHIRA AKHTAR[6]
[1]*Senior Registrar in Gynecology and Obstetrics Princes Mansour Military Hospital, Taif, KSA*
[2]*Specialist in Gynecology and Obstetrics, Khorfakkan Hospital, Sharjha, UAE*
[3]*Demonstrator in Department of Biochemistry, Sheikh Zayed Medical College/Hospital, Rahim Yar Khan*
[4]*Senior Registrar in Department of Gynecology and Obstetrics Jinnah Hospital, Lahore*
[5] *Senior Registrar in Department of Gynecology and Obstetrics Jinnah Hospital, Lahore*
[6]*Assistant Professor in Department of Gynecology and Obstetrics Gujranwala Medical College Gujranwala*
Correspondence to: Saima Noreen, Email: drsaimanoreen@yahoo.com

ABSTRACT

Background: The induction of labor is a widely practiced obstetric intervention when continuation of pregnancy poses greater risks than delivery. Various methods are used for cervical ripening, with misoprostol and Foley's catheter being among the most common.

Objectives: To compare maternal and fetal outcomes in induction of labor using misoprostol versus Foley's catheter in term pregnancies.

Study Design & Setting: A randomized controlled trial was conducted at the Department of Obstetrics and Gynecology Jinnah Hospital, Lahore.

Methodology: A total of 120 term pregnant women requiring induction were randomly allocated into two groups: Misoprostol group (n = 60) and Foley's catheter group (n = 60). Baseline demographics, Bishop scores, and indications for induction were recorded. Misoprostol 25 µg was administered vaginally at 4-hour intervals up to a maximum of 6 doses, while a 16–18 French Foley's catheter balloon was inserted in the comparator group. Primary outcomes were induction-to-delivery interval and mode of delivery. Secondary outcomes included need for oxytocin augmentation, maternal complications, neonatal Apgar scores, NICU admissions, and perinatal mortality. Data were analyzed using SPSS version 25, with $p < 0.05$ considered significant.

Results: The mean induction-to-delivery interval was significantly shorter in the Misoprostol group (9.6 ± 3.1 hours) compared to the Foley's catheter group (12.4 ± 3.8 hours, $p < 0.001$). Vaginal delivery occurred more frequently with misoprostol (80.0% vs. 63.3%), while cesarean section was higher in the Foley's group (36.7% vs. 20.0%, $p = 0.048$). Maternal and neonatal complications were comparable between groups.

Conclusion: Misoprostol demonstrated superior efficacy in achieving shorter induction-to-delivery interval and higher vaginal delivery rates compared to Foley's catheter, with similar safety profiles.

Keywords: Cesarean section, Foley's catheter, Induction of labor, Misoprostol, Neonatal outcome, Vaginal delivery

INTRODUCTION

Induction of labor (IOL) is a common obstetric intervention intended to initiate uterine contractions and effect vaginal delivery when continuing pregnancy poses greater risk than delivery. Indications range from post-dated pregnancy and hypertensive disorders to fetal growth restriction and premature rupture of membranes.[1,2] IOL is certainly one of the most frequently performed obstetric procedures in the world: recent data indicate a percentage of induction of up to 35.5% in Sri Lanka, 24.5% in the United States, and from 6.8 to 33% in Europe. Reported IOL rates vary widely between regions and health systems, reflecting differences in maternal demographics, clinical policies, and availability of induction agents and equipment.[3,4]

Etiology and pathophysiology underlying the need for induction often relate to maternal or fetal compromise. Maternal hypertensive disorders, diabetes, post-term pregnancy, and infections can create an intrauterine environment where the balance of risks favors delivery.[5,6] From a physiologic perspective, labor initiation requires cervical ripening—remodeling of collagen and extracellular matrix—and activation of myometrial contractility mediated by hormonal and inflammatory pathways.[7] Cervical readiness is the single most important determinant of successful induction; an unripe cervix predicts longer inductions and greater likelihood of operative delivery.[8]

Current management strategies for IOL focus on cervical ripening followed by augmentation. Pharmacologic options include prostaglandins (such as misoprostol and dinoprostone) which promote cervical softening and uterine contractions, and oxytocin infusion for augmentation.[10] Mechanical methods—most commonly the transcervical Foley's catheter—achieve ripening by direct mechanical pressure and local prostaglandin release.[11] Each approach has advantages and tradeoffs: misoprostol is inexpensive and effective but carries risk of hyperstimulation; Foley's catheter is simple and associated with lower systemic effects but may require more time or adjunctive oxytocin.[12]

Comparing maternal and fetal outcomes between misoprostol and Foley's catheter in term pregnancies is therefore clinically relevant to inform safe, evidence-based induction protocols.

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MATERIALS AND METHODS

The study was a randomized controlled trial conducted at the Department of Obstetrics and Gynecology of Jinnah Hospital, Lahore from January 2023 to June 2023. After approval from the Institutional Review Board and written informed consent, a total of 120 women with singleton, cephalic, term pregnancies (≥37 and ≤41 weeks) requiring induction of labor for standard obstetric indications were enrolled and randomly allocated equally to two groups (Misoprostol group, n = 60; Foley's catheter group, n = 60). Women with previous uterine surgery (including cesarean section), non-vertex presentation, multiple gestation, known hypersensitivity to prostaglandins, placenta previa, active genital infection, fetal compromise requiring immediate delivery, or severe medical disorders that precluded expectant management were excluded. Sample size was calculated for comparison of two proportions with $\alpha = 0.05$ and power = 80%; assuming an anticipated successful vaginal delivery rate of 80% in the Misoprostol group versus 55% in the Foley group, the required sample was 54 patients per arm. To allow for dropouts and protocol deviations the sample size was rounded to 60 patients per group, giving a total of 120 patients. Randomization was performed using computer-generated random numbers in blocks of four and allocation was concealed in sequentially numbered opaque envelopes which were opened only at the time of intervention. Baseline demographic and obstetric variables were recorded. Cervical status was assessed using the Bishop score at enrollment. The Misoprostol group was managed with vaginal misoprostol 25 µg placed in the posterior fornix and

repeated every 4 hours up to a maximum of 6 doses or until active labor (regular painful contractions with cervical dilatation ≥4 cm) was achieved. The Foley's catheter group had a 16–18 French Foley's catheter inserted transcervically with the balloon inflated to 30–50 mL of sterile saline and gentle traction applied; the catheter was left in situ for up to 12 hours or until expulsion, after which oxytocin augmentation was started if needed. Oxytocin for augmentation in either group was started according to a standard hospital protocol when indicated and was titrated until an adequate contraction pattern was observed.

Maternal monitoring was continuous cardiotocography during active induction and intermittent vital signs observation as per protocol; uterine hyperstimulation and fetal heart rate abnormalities were predefined and managed according to institutional guidelines. Primary outcomes were mode of delivery and induction-to-delivery interval; secondary outcomes included need for oxytocin augmentation, uterine hyperstimulation, maternal complications (fever, postpartum hemorrhage, infection), neonatal Apgar scores at 1 and 5 minutes, and neonatal intensive care unit admission.

Data were entered and analyzed using SPSS version 25. Continuous variables were presented as mean ± standard deviation and compared using Student's t-test or Mann–Whitney U test as appropriate; categorical data were shown as frequencies and percentages and compared using chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS

The baseline demographic and obstetric characteristics of both groups were comparable. The mean maternal age was 27.4 ± 4.8 years in the Misoprostol group and 27.9 ± 5.2 years in the Foley's catheter group. Gravidity and parity distribution were similar, with nulliparous women constituting 46.7% in the Misoprostol group and 43.3% in the Foley's catheter group. The mean gestational age at induction was also nearly the same in both groups (39.1 ± 1.0 vs. 39.0 ± 1.1 weeks), and the baseline Bishop score did not differ significantly (3.7 ± 1.2 vs. 3.6 ± 1.3). These findings confirm that both groups were homogeneous at baseline, as given in Table 1. In terms of primary maternal outcomes, the mean induction-to-delivery interval was significantly shorter in the Misoprostol group (9.6 ± 3.1 hours) compared to the Foley's catheter group (12.4 ± 3.8 hours, $p < 0.001$). Vaginal delivery was achieved in 80.0% of women in the Misoprostol group compared to 63.3% in the Foley's catheter group, while the rate of cesarean section was higher in the Foley's group (36.7%) than in the Misoprostol group (20.0%), and this difference was statistically significant ($p = 0.048$). Oxytocin augmentation was required more frequently among Foley's catheter patients (58.3%) than Misoprostol patients (36.7%, $p = 0.02$), as given in Table 2.

Table 1: Baseline Demographic and Obstetric Characteristics of Study Participants (n = 120)

Variable	Misoprostol Group (n = 60)	Foley's Catheter Group (n = 60)	p-value
Maternal age	27.4 ± 4.8	27.9 ± 5.2	0.62
Gravidity	2.3 ± 1.4	2.1 ± 1.2	0.49
Nulliparous (%)	28 (46.7%)	26 (43.3%)	0.72
Gestational age	39.1 ± 1.0	39.0 ± 1.1	0.68
Baseline Bishop Score	3.7 ± 1.2	3.6 ± 1.3	0.81

Table 2: Primary Maternal Outcomes

Outcome	Misoprostol Group (n = 60)	Foley's Catheter Group (n = 60)	p-value
Induction-to-delivery interval (hours)	9.6 ± 3.1	12.4 ± 3.8	<0.001
Vaginal delivery	48 (80.0%)	38 (63.3%)	0.048
Cesarean section	12 (20.0%)	22 (36.7%)	0.048
Need for oxytocin augmentation	22 (36.7%)	35 (58.3%)	0.02

Maternal complications were generally infrequent in both groups. Uterine hyperstimulation was observed in 10.0% of the Misoprostol group and 3.3% of the Foley's catheter group, though the difference was not statistically significant. Postpartum hemorrhage occurred in 5.0% of women in the Misoprostol group and 6.7% in the Foley's group. Maternal fever was documented in 6.7% and 5.0% of patients, respectively, while genital tract infections occurred in 3.3% of the Misoprostol group and 8.3% of the Foley's group. None of these differences reached statistical significance, as given in Table 3. Neonatal outcomes were also broadly comparable between the two groups. The mean birth weight was 3.01 ± 0.42 kg in the Misoprostol group and 3.05 ± 0.39 kg in the Foley's catheter group. Apgar scores below 7 at 1 minute were seen in 13.3% of neonates in the Misoprostol group and 16.7% in the Foley's group, while at 5 minutes, the corresponding figures were 3.3% and 6.7%, respectively. NICU admissions were slightly higher in the Foley's catheter group (11.7%) compared to the Misoprostol group (8.3%), but without statistical significance. Perinatal mortality was identical, with one case (1.7%) in each group, as given in Table 4.

Table 3: Maternal Complications

Complication	Misoprostol Group (n = 60)	Foley's Catheter Group (n = 60)	p-value
Uterine hyperstimulation	6 (10.0%)	2 (3.3%)	0.14
Postpartum hemorrhage	3 (5.0%)	4 (6.7%)	0.69
Maternal fever	4 (6.7%)	3 (5.0%)	0.69
Genital tract infection	2 (3.3%)	5 (8.3%)	0.24

Table 4: Neonatal Outcomes

Neonatal Outcome	Misoprostol Group (n = 60)	Foley's Catheter Group (n = 60)	p-value
Mean birth weight	3.01 ± 0.42	3.05 ± 0.39	0.58
Apgar score <7 at 1 min	8 (13.3%)	10 (16.7%)	0.61
Apgar score <7 at 5 min (%)	2 (3.3%)	4 (6.7%)	0.40
NICU admission	5 (8.3%)	7 (11.7%)	0.54
Perinatal mortality	1 (1.7%)	1 (1.7%)	1.00

DISCUSSION

Induction of labor is a common obstetric intervention performed when continuation of pregnancy poses risks to the mother or fetus. It accounts for a considerable proportion of deliveries worldwide, with rising rates in both developed and developing countries.[13] Comparing their outcomes is essential to guide evidence-based practice and optimize maternal and neonatal safety. In our study, the mean induction-to-delivery interval was significantly shorter in the Misoprostol group (9.6 ± 3.1 hours) compared to the Foley's catheter group (12.4 ± 3.8 hours, $p < 0.001$), and vaginal delivery was achieved in 80.0% of women with misoprostol versus 63.3% with Foley's catheter. These findings are consistent with Yashvantsinh et al. (2025), who also reported a shorter induction-to-delivery interval in the misoprostol group (9.4 ± 2.1 vs. 12.6 ± 3.5 hours, $p < 0.001$). In their study, vaginal delivery occurred in 82% with misoprostol compared to 74% with Foley's catheter, although the difference did not reach statistical significance ($p = 0.19$). Our results align closely with these outcomes, confirming the efficiency of misoprostol in reducing labor duration and improving vaginal delivery rates, as shown by the comparable 80% versus 63.3% difference in our trial.

Similarly, Noor et al. (2015) observed a shorter induction-to-delivery interval in the misoprostol group (14.03 ± 7.61 vs. 18.40 ± 8.02 hours, $p < 0.01$) and a higher rate of vaginal delivery (76.7% vs. 56.8%) compared with Foley's catheter. These findings resonate strongly with our study, where misoprostol was also superior both in reducing time to delivery and in achieving spontaneous vaginal births. Shafqat et al. (2023) reported that with misoprostol, 85.1% of women delivered spontaneously, and cesarean section was required in only 10.68%. These results

mirror our findings of 80.0% vaginal deliveries and a lower cesarean rate in the misoprostol group (20.0% vs. 36.7%), further reinforcing the reliability of misoprostol in improving delivery outcomes.

Our study demonstrated that cesarean section was significantly higher in the Foley's catheter group (36.7% vs. 20.0%, p = 0.048), which is in line with Agarwal et al. (2017), where the cesarean section rate was significantly higher with Foley's catheter compared to misoprostol (p < 0.05). Comparable results were reported by Kumar et al. (2019), who found a vaginal delivery rate of 85% with misoprostol and 70% with Foley's catheter, with Foley being associated with longer induction-to-delivery time (18.12 hours vs. 12.35 hours). Likewise, Chavakula et al. (2015) reported that misoprostol reduced cesarean section rates (15.2% vs. 29.6%) and required less oxytocin augmentation (60.9% vs. 85.2%, p = 0.007), which supports our observation of lower oxytocin use in the misoprostol group (36.7% vs. 58.3%, p = 0.02).

In terms of maternal complications, uterine hyperstimulation was seen in 10.0% of our misoprostol group versus 3.3% in Foley's catheter group, though not statistically significant. Yashvantsinh et al. (2025) reported similar findings, with uterine hyperstimulation being significantly higher with misoprostol (12% vs. 2%, p = 0.01). Noor et al. (2015) also reported hyperstimulation as more frequent with misoprostol. By contrast, Chavakula et al. (2015) and Beyrami et al. (2024) documented lower rates of tachysystole overall, with only one case occurring in their misoprostol group. These differences may reflect variations in misoprostol dosage, administration route, and monitoring practices across studies.

Regarding neonatal outcomes, we found no significant differences between groups, with NICU admissions being 8.3% in the misoprostol group and 11.7% in the Foley's catheter group. This finding is consistent with Yashvantsinh et al. (2025), who reported 14% NICU admissions in the misoprostol group compared to 10% in the Foley's group (p = 0.42). Noor et al. (2015) and Shafqat et al. (2023) also reported comparable neonatal outcomes between groups, with most neonates having favorable Apgar scores and limited need for NICU care. Similarly, Agarwal et al. (2017) observed no significant difference in neonatal birth weight or Apgar scores at 1 and 5 minutes between misoprostol and Foley's catheter. While Beyrami et al. (2024) noted higher adverse neonatal outcomes with oral misoprostol compared to combination therapy, our findings indicate that misoprostol alone remained safe when used vaginally, with only 3.3% neonates having Apgar <7 at 5 minutes.

Overall, our results highlight that misoprostol is associated with significantly shorter induction-to-delivery interval, higher rates of vaginal delivery, lower cesarean section rate, and reduced requirement of oxytocin compared to Foley's catheter, with comparable neonatal outcomes. These findings are consistent with multiple national and international studies including those by Yashvantsinh et al. (2025), Noor et al. (2015), Shafqat et al. (2023), Chavakula et al. (2015), Kumar et al. (2019), and Agarwal et al. (2017), thereby affirming the role of misoprostol as a more effective and reliable method of induction of labor at term.

The study was a randomized controlled trial with adequate sample size and well-defined inclusion and exclusion criteria. Standardized protocols for both interventions minimized bias in clinical practice. Maternal and neonatal outcomes were comprehensively assessed, providing a holistic comparison of efficacy and safety. However, it was conducted at a single center, which may limit generalizability. Blinding was not possible due to the nature of interventions. Longer follow-up of neonatal outcomes beyond the immediate postnatal period was not performed.

CONCLUSION

Misoprostol was associated with shorter induction-to-delivery interval and higher rates of successful vaginal delivery compared to Foley's catheter. Both methods were safe with low complication rates. Misoprostol may therefore be considered a more effective option for induction of labor at term.

REFERENCES

1. Coates D, Makris A, Catling C, Henry A, Scarf V, Watts N, Fox D, Thirukumar P, Wong V, Russell H, Homer C. A systematic scoping review of clinical indications for induction of labour. Plos one. 2020 Jan 29;15(1):e0228196.
2. McCarthy CM, Meaney S, McCarthy M, Conners N, Russell N. Induction of labor: reviewing the past to improve the future. AJOG global reports. 2022 Nov 1;2(4):100099.
3. Agarwal S, D'Souza R, Dy J. Induction of labour in patients with prior caesarean births or uterine surgery. Best Practice & Research Clinical Obstetrics & Gynaecology. 2022 Mar 1;79:95-106.
4. Marconi AM. Recent advances in the induction of labor. F1000Research. 2019 Oct 30;8:F1000-aculty.
5. Turner JM, Mitchell MD, Kumar SS. The physiology of intrapartum fetal compromise at term. American journal of obstetrics and gynecology. 2020 Jan 1;222(1):17-26.
6. Romero R, Gotsch F, Pineles B, Kusanovic JP. Inflammation in pregnancy: its roles in reproductive physiology, obstetrical complications, and fetal injury. Nutrition reviews. 2007 Dec 1;65(suppl_3):S194-202.
7. Megli CJ, Coyne CB. Infections at the maternal–fetal interface: an overview of pathogenesis and defence. Nature Reviews Microbiology. 2022 Feb;20(2):67-82.
8. Kramer MS, Rouleau J, Baskett TF, Joseph KS. Amniotic-fluid embolism and medical induction of labour: a retrospective, population-based cohort study. The Lancet. 2016 Oct 21;368(9545):1444-8.
9. Campbell K, Hobson SR, MacDonald WK, Sawchuck D, Wagner B. Guideline no. 432a: cervical ripening and induction of labour–general information. Journal of Obstetrics and Gynaecology Canada. 2023 Jan 1;45(1):35-44.
10. Shahabuddin Y, Murphy DJ. Cervical ripening and labour induction: a critical review of the available methods. Best Practice & Research Clinical Obstetrics & Gynaecology. 2022 Mar 1;79:3-17.
11. Saunders SJ, Saunders R, Wong T, Saad AF. Out-of-Hospital cervical ripening with a synthetic hygroscopic cervical dilator may reduce hospital costs and cesarean sections in the United States—a cost-consequence analysis. Frontiers in Public Health. 2021 Jun 18;9:689115.
12. Carlson N, Ellis J, Page K, Dunn Amore A, Phillippi J. Review of evidence-based methods for successful labor induction. Journal of midwifery & women's health. 2021 Jul;66(4):459-69.
13. Kruit H, Place K, Väyrynen K, Orden MR, Tekay A, Vääräsmäki M, Uotila J, Tihtonen K, Rinne K, Mäkikallio K, Heinonen S. Comparison of balloon catheter, oral misoprostol, or combination of both for cervical ripening in late-term and post-term nulliparous women: A Finnish randomized controlled multicenter pilot trial. Acta Obstetricia et Gynecologica Scandinavica. 2025 Feb;104(2):389-99.
14. Yashvantsinh M, Heena P, Ketan T, Lomabhai S. Comparative Evaluation of Maternal and Fetal Outcomes in Induction of Labor Using Foley Catheter Versus Misoprostol in Term Pregnancie: Prospective Randomized Controlled Trial. Journal of Heart Valve Disease. 2025 Jul 22;30:174-8.
15. Noor N, Ansari M, Ali SM, Parveen S. Foley catheter versus vaginal misoprostol for labour induction. International journal of reproductive medicine. 2015;2015(1):845735.
16. Shafqat T, Zeb L, Fatima SS, Bhittani R. Maternal and fetal outcomes in women undergoing induction of labor with low dose vaginal misoprostol. Pakistan Journal of Medical Sciences. 2023 Sep;39(5):1307.
17. Zheng R, Du L, Zhu X, Zhang X, Han W, Yang Z. Clinical comparison of vaginal misoprostol combined with a foley balloon versus vaginal misoprostol alone for inducing labor: a prospective cohort study. BMC Pregnancy and Childbirth. 2025 Mar 15;25(1):295.
18. Chavakula PR, Benjamin SJ, Abraham A, Londhe V, Jeyaseelan V, Mathews JE. Misoprostol versus Foley catheter insertion for induction of labor in pregnancies affected by fetal growth restriction. International Journal of Gynecology & Obstetrics. 2015 May 1;129(2):152-5.
19. KUMAR G, NAIR A. Assessment of fetomaternal outcome following common induction methods (Foley's catheter, dinoprostone and misoprostol) for induction of labor in low risk women with term pregnancy. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 2024;14(1):146-51.
20. Beyrami S, Noorzadeh M, Naemi M. Safety and efficacy of combined oral misoprostol and Foley catheter treatment in comparison with oral misoprostol alone for labor induction: a randomized clinical trial study. Biomedical Research and Therapy. 2024 Oct 31;11(10):6852-8.
21. Agarwal M, Kose V. Comparative study of vaginal misoprostol and intra cervical Foley's catheter for pre-induction cervical ripening at term. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 2017 Apr 1;6(4):1283-8.

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