International Journal of Clinical Obstetrics and Gynaecology

ISSN (P): 2522-6614
ISSN (E): 2522-6622
Indexing: Embase
Impact Factor (RJIF): 6.71

www.gynaecologyjournal.com
2025; 9(5): 255-259
Received: 09-08-2025
Accepted: 13-09-2025

Dr. Yogeshkumar Patel
M.S. (Obstetrics & Gynaecology) DIMAS, Germany, Assistant Professor, Department of Obstetrics & Gynaecology Zydus Medical College, Dahod, Gujarat, India

Corresponding Author:
Dr. Yogeshkumar Patel
M.S. (Obstetrics & Gynaecology) DIMAS, Germany, Assistant Professor, Department of Obstetrics & Gynaecology Zydus Medical College, Dahod, Gujarat, India

Comparative evaluation of vaginal misoprostol and intracervical cerviprime gel in labour induction

Yogeshkumar Patel

DOI: https://www.doi.org/10.33545/gynae.2025.v9.i5d.1717

Abstract
Background: The initiation of labour in humans is a natural biological process governed by multiple physiological mechanisms. While most pregnancies result in spontaneous onset of labour, certain maternal or fetal conditions may necessitate medical induction. Among the pharmacological options available, prostaglandin analogues have emerged as the most commonly used agents for inducing labour. This study was undertaken to compare the efficacy and safety of two such agents vaginal misoprostol and intracervical Cerviprime gel in facilitating labour induction.
Methods: A total of 100 pregnant women were enrolled and randomly assigned into two equal groups. Group I received 25 µg of misoprostol vaginally every six hours for a maximum of five doses, while Group II was administered 0.5 mg of intracervical Cerviprime gel. The maternal and fetal outcomes were assessed and compared between the groups. Parameters analyzed included the induction-to-delivery interval, requirement for oxytocin augmentation, mode of delivery, and adverse maternal or neonatal effects.
Results: The findings revealed a significantly shorter induction-to-delivery interval in the misoprostol group compared to the Cerviprime gel group. Moreover, the requirement for oxytocin augmentation was notably lower among women induced with misoprostol. Both groups exhibited comparable maternal and fetal safety profiles, with no statistically significant differences in Apgar scores or adverse neonatal outcomes.
Conclusion: Vaginal misoprostol was found to be a more effective and convenient agent for the induction of labour compared to intracervical Cerviprime gel. It demonstrated a shorter induction-to-delivery interval, required less oxytocin support, and was well-tolerated by both mother and fetus. Misoprostol's ease of use, cost-effectiveness, and stability make it a practical alternative, particularly in resource-limited settings.

Keywords: Apgar score, Misoprostol, cerviprime gel, labour induction, gestational hypertension, caesarean section, fetal distress.

Introduction
Labour induction is defined as the deliberate initiation of uterine contractions through medical or mechanical methods before the spontaneous onset of labour, with the objective of achieving vaginal delivery [1]. Approximately 5-25% of pregnancies require induction, as evidence suggests that timely delivery can improve maternal and fetal outcomes in selected cases [2].
In recent decades, there has been an increasing trend toward labour induction, primarily aimed at reducing pregnancy-related complications and improving perinatal outcomes. In developed nations, nearly one in four term deliveries occur following medical induction [3-5].
Prostaglandins play a pivotal role in the physiological process of cervical ripening and the initiation of labour. They modify the extracellular matrix of the cervix, enhance collagenase activity, and increase intracellular calcium concentrations within myometrial cells, thereby stimulating uterine contractions [3-4].
The U.S. Food and Drug Administration (FDA) revised the labeling for misoprostol in April 2002, clarifying that the drug is contraindicated for pregnancy only when used for the treatment or prevention of NSAID-induced ulcers [5]. Since then, misoprostol a prostaglandin E_1 (PGE_1) analogue has been widely evaluated for obstetric indications, particularly for cervical ripening and induction of labour. Cerviprime gel, on the other hand, contains prostaglandin E_2 (PGE_2) and is available as a 0.5 mg intracervical preparation for similar use.
Misoprostol (15-deoxy-16-hydroxy-16-methyl-PGE_1) was initially introduced as a therapeutic agent for peptic ulcer disease. However, following observations of its uterotonic properties,

Sanchez-Ramos (1993) first utilized it in obstetrics for managing various conditions, including induction of labour. Misoprostol is available in 25, 50, 100, and 200 µg tablet forms, while Cerviprime gel is supplied in a 2.5 ml syringe for intracervical application. In developing countries, the overall rate of labour induction remains lower than in high-income nations, largely due to concerns about failed inductions leading to cesarean delivery, drug-related complications, and economic constraints. Hence, there is a pressing need for effective, affordable, and safe pharmacological agents that can be utilized even in low-resource settings.

This study was therefore undertaken to compare the efficacy and safety of intravaginal misoprostol (25 µg) with intracervical Cerviprime gel (0.5 mg PGE_2) for the induction of labour at GMERS Medical College, Dharpur, Gujarat, between 2021 and 2023.

Aims and Objectives

The primary aim of this study was to evaluate and compare the effectiveness of two commonly used prostaglandin analogues Misoprostol (PGE_1) and Cerviprime gel (PGE_2) for the induction of labour.

The specific objectives were:

- To assess the efficacy of both agents in achieving successful induction and delivery.
- To compare ease of administration and clinical handling during induction.
- To evaluate the maternal and fetal outcomes, including the need for oxytocin augmentation, mode of delivery, and complications.
- To analyze cost-effectiveness and safety profiles of both drugs in a tertiary care hospital setting.

Materials and Methods

This randomized comparative clinical study was conducted over a period of two years, from 2021 to 2023, in the Department of Obstetrics and Gynaecology, GMERS Medical College, Dharpur, Gujarat. A total of 100 pregnant women requiring induction of labour were enrolled after obtaining informed consent and appropriate counselling.

Study Design

Participants were randomly assigned into two equal groups (Group A and Group B), each comprising 50 women. Randomization was carried out using sealed opaque envelopes to maintain allocation concealment. A predesigned proforma was used to record all relevant clinical and investigative data.

Inclusion Criteria

- Singleton live pregnancy with gestational age ≥ 28 weeks (viable pregnancy)
- Cephalic presentation
- Bishop's score ≥ 6

Cases requiring induction due to:

- Gestational hypertension
- Post-term pregnancy (≥ 41 weeks)
- Preterm premature rupture of membranes (PPROM)
- Rh incompatibility

Exclusion Criteria

- Gestation < 28 weeks or > 42 completed weeks
- Cephalopelvic disproportion (CPD)
- Malpresentation
- Any medical contraindication to induction
- Placental abruption
- Previous cesarean section or uterine scar
- Grand multiparity
- Pregnancy following infertility treatment

Method of Induction

After clinical examination and relevant investigations (including ultrasound), participants were assigned to one of the following groups:

- **Group A (Misoprostol group):** Received 25 µg misoprostol inserted vaginally every 6 hours, for a maximum of 5 doses or until adequate uterine contractions were achieved.
- **Group B (Cerviprime group):** Received 0.5 mg intracervical Cerviprime gel administered just below the internal os every 6 hours, with a maximum of 3 doses.

Monitoring and Labour Management

All patients were monitored according to standard labour ward protocols using non-stress testing (NST) and cardiotocography (CTG) to assess fetal well-being and uterine activity.

Adequate uterine contractions were defined as three contractions every 10 minutes, each lasting approximately 45 seconds. Incidences of tachysystole, hypertonus, and uterine hyperstimulation were recorded and managed as per clinical guidelines.

Additional medications such as antihypertensives, antibiotics, and intravenous fluids were administered when indicated.

The following parameters were recorded for all participants:-

- Time from induction to onset of labour
- Time from induction to rupture of membranes
- Induction-to-delivery interval
- Requirement for oxytocin augmentation
- Mode of delivery (vaginal or cesarean)
- Maternal complications (e.g., PPH, fever, nausea, diarrhoea)
- Neonatal outcomes, including Apgar score and need for resuscitation

Data Analysis

The data were tabulated and analyzed statistically. Quantitative variables were expressed as mean ± standard deviation (SD), and categorical variables as percentages. The Chi-square test and Student's t-test were applied where appropriate. A p-value < 0.05 was considered statistically significant

Results

A total of 100 pregnant women participated in the study and were randomly allocated into two equal groups of 50 each. Group A received *vaginal misoprostol (25 µg every 6 hours)*, and Group B received *intracervical Cerviprime gel (0.5 mg every 6 hours)*.

Demographic Characteristics

Most participants were between 20 and 35 years of age, with the highest proportion (60%) falling within the 20-25-year age group. Nulliparous women constituted 60% of the total study population, while multiparous women made up 40%.

Indications for Induction

The most frequent indication for induction was gestational hypertension (31%), followed by post-dated pregnancy (29%). Other indications included preterm premature rupture of membranes (PPROM), intrauterine growth restriction (IUGR), and chorioamnionitis. Rh isoimmunization was the least common reason for induction.

Induction to Onset of Labour

None of the participants in either group entered labour within the first two hours following induction.

However, a significant difference was observed in the proportion of women who entered labour within 6 hours:

Time Interval	Group A (Misoprostol)	Group B (Cerviprime)	Total
< 6 hours	40 (80%)	31 (62%)	71
> 6 hours	10 (20%)	19 (38%)	29
Total	50	50	100

The difference between the two groups was statistically significant (p<0.001), indicating that labour onset occurred earlier with misoprostol than with Cerviprime gel.

Induction-to-Delivery Interval

The mean induction-to-delivery interval was 11.23 hours in Group A and 18.5 hours in Group B.

Time Interval	Group A (N=50)	Group B (N=50)
< 12 hours	40%	16%
12-24 hours	44%	44%
> 24 hours	0%	14%

The difference was statistically significant (P=0.02), confirming that women induced with misoprostol delivered more rapidly than those given Cerviprime gel.

Mode of Delivery

The overall vaginal delivery rate was higher in the misoprostol group (88%) compared to the Cerviprime gel group (80%). Conversely, the cesarean section rate was lower in Group A (12%) than in Group B (20%).

However, the difference in delivery mode was not statistically significant.

Mode of Delivery	Group A	Group B	Total
Vaginal	44 (88%)	40 (80%)	84
Cesarean Section	6 (12%)	10 (20%)	16
Total	50	50	100

Requirement for Oxytocin Augmentation

In the misoprostol group, all patients reached the active phase of labour without oxytocin. In contrast, 62% of patients in the Cerviprime group required oxytocin augmentation to progress to active labour.

This difference was highly significant (p<0.001), suggesting superior uterotonic efficiency of misoprostol.

Indications for Cesarean Section

Indication	Group A (N=50)	Group B (N=50)
Non-progress of labour	6 (40%)	5 (45.6%)
Fetal distress	5 (33.3%)	2 (18.2%)
Abnormal uterine activity	4 (26.7%)	4 (36.3%)
Total Cases	15	11

Neonatal Outcomes (Apgar Scores)

Apgar scores at 1 and 5 minutes were comparable between both groups, with no significant statistical difference.

Apgar Score	Group A	Group B
< 7 at 1 minute	5 (10%)	4 (8%)
< 7 at 5 minutes	1 (2%)	2 (4%)
Total	6	6

Both groups demonstrated good neonatal outcomes, and no perinatal mortality was reported.

Maternal Complications

Minor maternal side effects such as fever, nausea, and diarrhea were more commonly observed in the misoprostol group.

Postpartum hemorrhage (PPH) occurred in 2 patients from each group, and all were successfully managed with uterotonic agents and blood transfusion when necessary.

Importantly, no maternal deaths were recorded during the study period.

Discussion

The present randomized comparative study evaluated the efficacy and safety of vaginal misoprostol versus intracervical Cerviprime gel for the induction of labour. The demographic parameters including maternal age, parity, and gestational age were comparable across both study groups, indicating that the populations were similar and suitable for comparison. These findings align with observations made in several other studies examining the same agents [8-10].

In this study, the majority of patients requiring induction belonged to the 21-25-year age group (60%), which is consistent with the results reported by Shivarudraiah and Palaksha (2012) [11]. The most frequent indications for induction were gestational hypertension (39%) and post-term pregnancy (31%), findings that parallel previous research outcomes by similar authors.

A significantly higher proportion of patients in the misoprostol group (80%) entered labour within six hours compared to 62% in the Cerviprime group (p<0.001). This demonstrates that misoprostol acts faster in initiating uterine contractions and achieving cervical ripening. Comparable outcomes have been reported in studies by Kudagi *et al*., Buser *et al*., Nunes *et al*., Belfrage *et al*., Neiger and Greaves, and Rozenberg *et al*., all of which concluded that misoprostol offers a shorter induction-to-onset interval than dinoprostone preparations [12-17].

The mean induction-to-delivery interval in our study was 11.23 hours for the misoprostol group and 18.5 hours for the Cerviprime group, a statistically significant difference (P=0.02). Similar observations were made by Nanda *et al*., who reported an interval of 13.3 hours with misoprostol versus 18.53 hours with dinoprostone [18].

Regarding the mode of delivery, vaginal birth was achieved in 88% of patients induced with misoprostol and 80% of those induced with Cerviprime gel. Although the difference was not statistically significant, the trend favored misoprostol. These findings are in line with those of Gupta *et al*., who found spontaneous vaginal delivery rates of 86% in the misoprostol group compared with 68% in the dinoprostone group [19].

The requirement for oxytocin augmentation was notably lower among women receiving misoprostol, confirming its superior uterotonic effect. This feature makes misoprostol particularly advantageous in settings with limited access to continuous monitoring or infusion facilities.

In terms of neonatal outcomes, no significant differences were

found between the two groups. The majority of newborns had Apgar scores >7 at both 1 and 5 minutes, demonstrating that both agents are equally safe for the fetus. Similarly, maternal complications were mild and manageable. Fever, nausea, and diarrhea were slightly more common in the misoprostol group, consistent with prior literature, but none of these adverse effects were severe or life-threatening.

The cesarean section rate was somewhat higher in the Cerviprime group (20%) than in the misoprostol group (12%), though not statistically significant. The primary indications for cesarean section in both groups included non-progression of labour, fetal distress, and abnormal uterine contractions.

When compared with other studies, our results affirm that misoprostol is more effective, faster-acting, and equally safe as Cerviprime gel for inducing labour. Furthermore, misoprostol is more cost-effective, does not require cold chain storage, and is easier to administer, making it especially beneficial in rural and resource-limited settings.

Conclusion

This comparative study demonstrated that vaginal misoprostol is a more effective agent for labour induction than intracervical Cerviprime gel. Misoprostol was associated with a shorter induction-to-delivery interval, higher rate of vaginal deliveries, and reduced need for oxytocin augmentation.

Although mild side effects such as fever, nausea, and diarrhea were observed in a few patients, they were transient and easily managed. Importantly, these adverse effects did not influence neonatal Apgar scores or overall perinatal outcomes.

In addition to its efficacy and safety, misoprostol offers several practical advantages it is cost-effective, thermostable (requiring no cold chain for storage), and easy to administer. These qualities make it especially suitable for low-resource and rural healthcare settings, where access to refrigeration and specialized staff may be limited.

Hence, misoprostol can be considered a safe, effective, and affordable option for labour induction, particularly in developing countries. However, larger-scale, multicentric studies with more rigorous designs are recommended to further validate these findings and minimize inter-observer variation.

Declaration by Authors

Ethical Approval

This study was reviewed and approved by the Institutional Ethics Committee.

Acknowledgment

The authors express their gratitude to the Department of Obstetrics & Gynaecology, GMERS Medical College, Dharpur, for providing necessary facilities and support during the study period.

Source of Funding

No external funding was received for this study.

Conflict of Interest

The authors declare no conflicts of interest.

Financial Support

Not available

References

1. Houghton Mifflin Company. Induction of Labour. In: The American Heritage Dictionary, 4th Ed. Boston, MA: Houghton Mifflin Harcourt; 2006, p. 1074.
2. Beischer NA. Maternal well-being during pregnancy. In: Beischer NA, Mackay EV, Colditz PB, editors. Obstetrics and the Newborn: An Illustrated Textbook. 3rd Ed. Philadelphia: Saunders; 1997, p. 449.
3. Witter FR. Prostaglandin E2 preparations for pre-induction cervical ripening. Clinical Obstetrics and Gynecology. 2000;43(3):469-474.
4. Arias F. Pharmacology of oxytocin and prostaglandins. Clinical Obstetrics and Gynecology. 2000;43(3):455-468.
5. American College of Obstetricians and Gynecologists (ACOG). New U.S. Food and Drug Administration labeling on Cytotec (Misoprostol) use and pregnancy. ACOG Committee Opinion. Washington, DC: ACOG; 1999, No. 283.
6. Cunningham FG, Leveno KJ, Bloom SL, Rouse DJ, Spong CY. Williams Obstetrics. 23rd Ed. New York: McGraw-Hill Education; 2010, p. 502.
7. Gregson S, Waterstone M, Norman I, Murrells T. A randomized controlled trial comparing low-dose vaginal misoprostol and dinoprostone vaginal gel for inducing labour at term. BJOG: An International Journal of Obstetrics & Gynaecology. 2005;112(4):438-444.
8. Sheela CN, Mhaskar A, George S. Comparison of vaginal and oral misoprostol with intracervical dinoprostone gel for induction of labour at term. Journal of Obstetrics and Gynaecology of India. 2007;57(4):327-330.
9. Sahu L, Chakraborty B. Comparison of prostaglandin E1 (Misoprostol) and prostaglandin E2 (Cerviprime) for labour induction. Journal of Obstetrics and Gynaecology of India. 2004;54(2):139-142.
10. Patil KP, Swamy MK, Rao RK. Oral misoprostol versus intracervical dinoprostone for cervical ripening and labour induction. Journal of Obstetrics and Gynaecology of India. 2005;55(2):128-131.
11. Murthy BK, Arkalgud MS. Misoprostol alone versus a combination of cerviprime and oxytocin for induction of labour. Journal of Obstetrics and Gynaecology of India. 2006;56(5):413-416.
12. Calder AA, Loughney AD, Weir CJ, Barber JW. Induction of labour in nulliparous and multiparous women: A multicentre, open-label study comparing intravaginal misoprostol with cerviprime. BJOG: An International Journal of Obstetrics & Gynaecology. 2008;115(10):1279-1288.
13. Özkan S, Caliskan E, Doger E, Yucesoy I, Ozeren S, Vural B. Comparative safety and efficacy of vaginal misoprostol versus cerviprime vaginal insert in term labour induction: A randomized trial. Archives of Gynecology and Obstetrics. 2009;280(1):19-24.
14. Cheng SY, Ming H, Lee JC. Titrated oral versus vaginal misoprostol for induction of labour: A randomized controlled trial. Obstetrics & Gynecology. 2008;111(1):119-125.
15. Muzonzini G, Hofmeyr GJ. Buccal or sublingual misoprostol for cervical ripening and labour induction. Cochrane Database of Systematic Reviews. 2004;(4):CD004221.
16. Colon I, Clawson K, Hunter K, Druzin ML, Taslimi MM. A prospective randomized clinical trial comparing oral stepwise misoprostol and vaginal misoprostol for inpatient cervical ripening. American Journal of Obstetrics and Gynecology. 2005;192(3):747-752.
17. Agarwal N, Gupta A, Kriplani A, Bhatla N. Six-hourly

vaginal misoprostol versus intracervical dinoprostone for cervical ripening and labour induction. Journal of Obstetrics and Gynaecology Research. 2003;29(3):147-151.
18. Garry D, Figueroa R, Kalish RB. Randomized controlled trial of vaginal misoprostol versus dinoprostone vaginal insert for labour induction. Journal of Maternal-Fetal & Neonatal Medicine. 2003;13(4):254-259

How to Cite This Article
Patel Y. Comparative evaluation of vaginal misoprostol and intracervical cerviprime gel in labour induction. International Journal of Clinical Obstetrics and Gynaecology. 2025;9(5):255-259.