International Journal of Reproduction, Contraception, Obstetrics and Gynecology
*Mishra R et al. Int J Reprod Contracept Obstet Gynecol. 2025 Oct;14(10):3430-3436*
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20253088

**Original Research Article**

# Comparative study between 25 µg vaginal misoprostol and PGE2 gel for induction of labour at term

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**Received:** 30 July 2025
**Revised:** 08 September 2025
**Accepted:** 10 September 2025

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## ABSTRACT

**Background:** Labour induction is a critical aspect of obstetric care, significantly affecting maternal and neonatal outcomes. Prostaglandins such as PGE2 gel facilitate cervical ripening and uterine contractions. Misoprostol, a prostaglandin E1 analogue, has shown promising results in achieving vaginal delivery within 24 hours. This study aims to compare these agents to provide clearer guidance on the safer and more effective option for labour induction. To compare the effectiveness and safety of 25 µg vaginal misoprostol versus 0.5 mg PGE2 gel for induction of labour at or beyond 37 weeks of gestation in terms of efficacy, foeto-maternal outcomes, and complications.
Objectives include comparing induction-to-delivery intervals, caesarean rates, and foeto-maternal outcomes between the two drugs.
**Methods:** A single-centre, randomised, open-label clinical trial was conducted in a tertiary care centre's Obstetrics and Gynaecology department. A total of 176 women were randomised: Group A received 25 µg misoprostol every 4 hours (up to five doses), and Group B received 0.5 mg PGE2 gel every 6 hours (up to three doses). Outcomes included induction-to-delivery time, labour onset, need for augmentation, and maternal and neonatal outcomes.
**Results:** Both groups were similar in age, parity, and Bishop scores. Misoprostol led to quicker labour onset (6.5 vs. 8.5 hours) and required less oxytocin (15.9% vs. 45.5%). Delivery mode and neonatal outcomes were comparable.
**Conclusions:** Misoprostol proved more effective, with shorter induction-to-delivery intervals and less need for augmentation. It is cost-effective, stable at room temperature and offers similar maternal and neonatal safety compared to PGE2 gel.

**Keywords:** Misoprostol, PGE2 gel, Labour, Maternal, Neonatal

## INTRODUCTION

Effective management of labour induction is a critical component of obstetric care, profoundly impacting both maternal and neonatal health.[1]

This can be achieved through the application of both mechanical and pharmacological methods.[2] Pharmacological cervical ripening is frequently achieved through the use of prostaglandins. The dual action of these methods is a notable advantage over mechanical methods, as they not only dilate the cervix but also strengthen uterine contractions.[3] Prostaglandins have been extensively employed to accelerate cervical ripening and induce labour, with prostaglandin E2 (PGE2) gel being one of the most frequently employed options.[4] Numerous studies have shown that PGE2 gel can effectively decrease the incidence of caesarean sections without increasing the risk of maternal or neonatal morbidity.[5]

Misoprostol has gained recognition as a viable alternative for induction. Recent meta-analyses underscore its

efficacy, especially in enabling vaginal delivery within 24 hours.[6,7] Although multiple studies have compared pharmacological and mechanical methods, there has been limited direct comparison between misoprostol and PGE2 gel, especially regarding their use in labour induction for women at or beyond 37 weeks of gestation. This lack of comparative data leaves a significant gap in our understanding of which agent might offer superior safety and efficacy outcomes.

This study seeks to address this gap by directly looking at how vaginal misoprostol and PGE2 gel work to start labour. The primary focus is on assessing the effectiveness of each agent in terms of the duration from induction to delivery and the rates of caesarean sections. By providing a direct comparison, this research aims to offer valuable insights that could guide clinical decisions and improve labour induction practices, ultimately benefiting both mothers and their babies.

### *Aim*

To evaluate the efficacy and safety of 25 µg vaginal misoprostol and 0.5 mg PGE2 gel for labour induction in women, with an emphasis on drug efficacy, foetal and maternal outcomes, and drug-related complications at or beyond 37 weeks of gestation.

### *Objectives*

*Primary objective*

To estimate and compare the induction-to-delivery duration between 25 µg vaginal misoprostol and 0.5 mg PGE2 gel used for labour induction.

*Secondary objective*

To estimate and compare the caesarean section rates following labour induction using 25 µg vaginal misoprostol versus 0.5 mg PGE2 gel.

To assess and compare foetal and maternal outcomes after labour induction using 25 µg vaginal misoprostol versus 0.5 mg PGE2 gel.

## METHODS

### *Study design*

This single-centre, randomised, controlled clinical intervention trial with an open-label design was done in the Obstetrics and Gynaecology department of DVVPF's Medical College and Hospital, Ahilyanagar, Maharashtra, from July 2024 to December 2024, subsequent to permission from the institutional ethics committee. Informed consent was obtained in writing from all individuals prior to their inclusion in the study. The patient cohort was categorised into two groups: Group A, which included 88 patients administered 25 µg of Misoprostol vaginally, and Group B, consisting of 88 patients who got 0.5 mg of PGE2 gel vaginally.

### *Inclusion criteria*

The study included women with singleton pregnancies who had a gestational age of 37 weeks or more, were not in labour, and presented with a cephalic presentation. Induction of labour was considered in cases of post-term pregnancy, early rupture of membranes, gestational diabetes mellitus, pre-eclampsia, oligohydramnios, gestational hypertension, intrauterine foetal demise, and foetal growth restriction. Thus, labour was induced for either maternal or obstetric indications.

### *Exclusion criteria*

Women who were in the latent or active phase of labour, those with multi-foetal gestations, abnormal foetal presentations or abnormal foetal lies were excluded from the study. Patients with a previous history of caesarean section, an estimated foetal weight of more than 4000 grams, or those suffering from cardiopulmonary or other systemic diseases were also not considered. Additionally, women with unexplained vaginal bleeding, such as antepartum haemorrhage, were excluded.

The trial also excluded women who had difficulties from glaucoma, asthma, heart, liver, renal, or adrenal cortical insufficiency, or those with a history of hypersensitivity to misoprostol, prostaglandins, or any excipients in the medication.

### *Randomised allocation design*

Eligible women (n=176) were randomly assigned (1:1) to 25 µg vaginal misoprostol or PGE2 gel groups using computer-generated numbers. Informed consent was obtained after explaining the study's purpose, procedures, risks, and potential complications. Labour induction commenced only after participants fully understood all pertinent information.

### *Method of administration*

Written informed assent was obtained upon admission to the labour room. Bishop's scoring was implemented subsequent to a comprehensive physical examination and medical history. A 20-minute non-stress test was administered, and uterine contractions were monitored. If the non-stress test was reactive and contractions were absent, induction was performed using either 25 µg of misoprostol or PGE2 gel. Women in group A were administered a 25 µg misoprostol tablet into the posterior vaginal fornix every 4 hours, with a maximum of five doses. A maximum of three doses of 0.5 mg PGE2 gel were administered to women in group B into the posterior vaginal fornix every six hours. When the woman attained the active phase of labour (cervical dilation >4 cm and contractions every 3/10 minutes), induction agents were

discontinued. If contractions were insufficient, labour augmentation was achieved by infusing oxytocin at a maximal dose of 32 miu/min or achieving three contractions every 10 minutes. The women were observed every 30 minutes for the progression of labour and any adverse effects. Vaginal examinations were conducted at 4-hour intervals to evaluate labour progress. Abnormal labour was defined by the establishment of clear and specific criteria.

*Latent phase*

Progress failure was defined as no advancement for 24 hours in primigravida and 14 hours in multigravida.

*Active phase*

Progress failure was defined as the absence of additional cervical dilation beyond 4 cm or the lack of foetal head descent despite 2 hours of strong uterine contractions.

*Second stage*

In primigravida, progress failure was defined as the absence of foetal head descent for 2 hours, and 1 hour in multigravida, despite the presence of sufficient contractions. Apgar scores were recorded at delivery.

***Outcomes measured***

The primary outcomes were the efficacy and safety of misoprostol in comparison to PGE2 gel. Key variables included the induction-to-delivery interval, as well as the rates of caesarean births and vaginal deliveries. Postpartum haemorrhage, uterine rupture, premature membrane rupture, uterine tachysystole with or without FHR alterations, and medication side effects, including fever, trembling, nausea, vomiting, and diarrhoea, were among the adverse effects on the mother. The negative consequences on the foetus included newborn mortality, admission to the neonatal intensive care unit (NICU), non-reassuring heart rate (FHR), and Apgar scores of less than 7 at 1 and 5 minutes.

The foetal heart rate was intermittently monitored every hour prior to the onset of labour and every 30 minutes during labour. If abnormalities such as persistent decelerations, foetal tachycardia (heart rate exceeding 160 beats per minute), foetal bradycardia (heart rate below 100 beats per minute), or reduced short-term variability (less than 5 beats per minute) were detected, continuous electronic foetal monitoring was implemented.

The absence of labour onset within 24 hours of induction was considered a failure of induction. The occurrence of six or more contractions within 10 minutes was referred to as tachysystole. Foetal tachycardia, late decelerations, or reduced beat-to-beat variability were the results of hyperstimulation, which was defined by tachysystole and increased contraction intensity and duration.

***Statistical analysis***

The data that was collected was organised in an Excel spreadsheet and analysed using Microsoft Excel, Epi Info, and SPSS software version 20.0. The mean and standard deviation were computed for variables that were routinely distributed, while categorical variables were summarised using frequency and percentage. P values were computed at an alpha level of 0.05 to account for type I error, and the Fisher exact test, Chi-square test, and T-test were employed to conduct statistical analysis.

## RESULTS

The study compared Group A and Group B across several obstetric parameters, with notable findings highlighting distinctions in baseline characteristics, induction protocols, labour dynamics, maternal outcomes, and neonatal outcomes.

**Table 1: Distribution according to baseline characteristics between Group A and Group B.**

| Statistic | Group A (n=88) | Group B (n=88) |
|---|---|---|
| **Age distribution** | | |
| <20 years (N) | 20 | 10 |
| 20–30 years (N) | 50 | 50 |
| >30 years (N) | 18 | 28 |
| Mean age (years) | 25.2±3.6 | 25.8±3.2 |
| **Std. deviation (age)** | 3.6 | 3.2 |
| **Gestational age distribution** | | |
| 37–38+6 weeks (N) | 28 | 22 |
| 39–40+6 weeks (N) | 45 | 50 |
| 41–41+6 weeks (N) | 15 | 16 |
| Mean gestational age (weeks) | 39.6±0.5 | 39.5±0.6 |
| Std. deviation (GA) | 0.5 | 0.6 |
| **Pre-induction bishop score** | | |
| <6 | 35 (39.77%) | 30 (34.09%) |
| >6 | 53 (60.23%) | 58 (65.91%) |

The patient population was divided into two groups: Group A, which consisted of 88 patients who were administered 25 µg of vaginal Misoprostol, and Group B, which consisted of 88 patients who were administered 0.5 mg of vaginal PGE2 gel. The mean age of the patients in both groups was statistically comparable, with the majority falling within the 20-30 age range (25.2±3.6 years vs. 25.8±3.2 years), as illustrated in Table 1. The gestational ages of both groups were similar, with 39.6±0.5 weeks and 39.5±0.6 weeks, respectively. Group A and Group B had primigravida rates of 62.5% and 56.8%, respectively (p=0.5399), indicating no statistically significant difference. The pre-induction Bishop scores did not exhibit any significant disparity between the two groups (p=0.5399). (Table 1).

**Table 2: Comparison of the number of doses required for induction between Group A and Group B, along with oxytocin augmentation.**

| Category | Group A (n=88) | % Group A | Group B (n=88) | % Group B |
|---|---|---|---|---|
| **Number of doses required** | | | | |
| One dose / single application | 28 | 31.38% | 74 | 84.09% |
| Two doses/2nd application | 33 | 37.22% | 13 | 14.77% |
| Three doses/3rd application | 14 | 16.23% | 1 | 1.14% |
| Four doses | 11 | 12.33% | - | - |
| Five doses | 2 | 2.38% | - | - |
| **Augmentation by oxytocin** | | | | |
| Oxytocin required | 14 | 15.9% | 40 | 45.5% |
| Oxytocin not required | 74 | 84.1% | 48 | 54.5% |

**Table 3: Comparison of induction-to-onset of labor and induction-to-delivery intervals between Group A and Group B.**

| Time interval (hours) | Group A | %Group A | Group B | % Group B |
|---|---|---|---|---|
| **Induction to onset of labour** | | | | |
| 0-6 | 44 | 50.0% | 30 | 34.1% |
| 7-12 | 44 | 50.0% | 40 | 45.5% |
| 13-18 | 0 | 0.0% | 8 | 9.1% |
| 19-24 | 0 | 0.0% | 10 | 11.4% |
| >24 | 0 | 0.0% | 0 | 0.0% |
| Total | 88 | 100% | 88 | 100% |
| Median (Range) | 6.5 (1–11) | | 8.5 (1–20) | |
| **Induction to delivery interval** | | | | |
| 0–6 | 2 | 2.5% | 2 | 2.4% |
| 7-12 | 12 | 14.8% | 11 | 13.1% |
| 13-24 | 46 | 56.8% | 39 | 46.4% |
| >24 | 21 | 25.9% | 32 | 38.1% |
| Total | 81 | 100% | 84 | 100% |
| Mean±SD | 20.08±8.24 | | 23.19±9.59 | |

**Table 4: Comparison according to mode of delivery between Group A and Group B.**

| Mode of delivery | Group A (n=88) | % | Group B (n=88) | % |
|---|---|---|---|---|
| **Spontaneous vaginal** | 81 | 92.0% | 84 | 95.5% |
| **Operative vaginal** | 0 | 0.0% | 0 | 0.0% |
| **C-Section** | 7 | 8.0% | 4 | 4.5% |
| **Total** | 88 | 100% | 88 | 100% |

**Table 5: Comparison of caesarean section characteristics between Group A and Group B.**

| Category | Group A (n=7) | Group B (n=4) |
|---|---|---|
| **Indication** | | |
| Failure of induction | 2 (28.6%) | 2 (50%) |
| Foetal distress | 3 (42.9%) | 1 (25%) |
| NPOL | 1 (14.3%) | 1 (25%) |
| Meconium | 1 (14.3%) | 0 |
| **Gravida score** | | |
| Primigravida | 7/55 = 12.72 | 4/50=8 |
| Multigravida | 3/33 = 9.09 | 0 |
| **Bishops score** | | |
| <6 | 5/35 = 14.28% | 3/30=10% |
| >6 | 5/53 = 9.43 | 1/58 = 1.72% |

**Table 6: Comparison of maternal outcomes between Group A and Group B.**

| Associated events | Group A (n=88) | % | Group B (n=88) | Percentage |
|---|---|---|---|---|
| Perineal lacerations | 1 | 1.1% | 0 | 0.0% |
| Vomiting | 2 | 2.3% | 4 | 4.5% |
| Nausea | 8 | 9.1% | 12 | 13.6% |
| Arrested labour | 0 | 0.0% | 0 | 0.0% |
| Pyrexia | 2 | 2.3% | 0 | 0.0% |
| Postpartum haemorrhage (PPH) | 2 | 2.3% | 2 | 2.3% |
| Prolonged labour | 0 | 0.0% | 0 | 0.0% |
| Precipitate labour | 0 | 0.0% | 0 | 0.0% |
| Uterine hyper stimulation | 0 | 0.0% | 0 | 0.0% |
| Cervical tear | 0 | 0.0% | 2 | 2.3% |
| Perineal tear | 2 | 2.3% | 0 | 0.0% |

**Table 7: Comparison of neonatal outcomes between Group A and Group B.**

| Nature of liquor | Mode of delivery | NICU stay (No) | NICU stay (Yes) | Total | VD - NICU stay | LSCS - NICU stay |
|---|---|---|---|---|---|---|
| **Group A** | | | | | | |
| Clear | 81 (VD)/6 (LSCS) | 77 | 10 | 87 | 9 | 1 |
| Meconium-stained | 0 (VD)/1 (LSCS) | 0 | 1 | 1 | 0 | 1 |
| Total (Group A) | 81 (VD)/7 (LSCS) | 77 | 11 | 88 | 9 | 2 |
| **Group B** | | | | | | |
| Clear | 84 (VD)/4 (LSCS) | 80 | 8 | 88 | 6 | 2 |
| Meconium-stained | 0 | 0 | 0 | 0 | 0 | 0 |
| Total (Group B) | 84 (VD)/4 (LSCS) | 80 | 8 | 88 | 6 | 2 |

Patients in Group A required a larger number of doses than those in Group B (p=0.00001). Nevertheless, the necessity for oxytocin augmentation was significantly lower in Group A (15.9%) than in Group B (45.5%) (P=0.00001) (Table 2). The onset of labour was significantly faster in Group A (6.5 hours vs. 8.5 hours, p<0.046) (Table 3). Additionally, 50% of patients delivered within 12 hours, compared to 45.5% in Group B (Table 3). Although Group A had a marginally shorter induction-to-delivery interval (20.08±8.24 hours) than Group B (23.19±9.59 hours), the difference was not statistically significant (P=0.1314). (Table 3).

The incidence of caesarean sections was marginally higher in Group A (8% vs. 4.5%), but the difference was not statistically significant (P=0.5355) (Table 4). Vaginal delivery rates were 92% in Group A and 95.5% in Group B. The primary reason for Caesarean sections was foetal distress, which was the cause of 3 cases in Group A (42.9%) and 1 case in Group B (25%). There was one patient in each cohort who did not progress with labour induction. (Table 5).

Adverse maternal outcomes were infrequent. Group A reported slightly higher rates of perineal tears (2.3%) and pyrexia (2.3%), while Group B reported more cases of cervical tears (2.3%). Vomiting and nausea were more prevalent in Group B. Two women in both groups developed postpartum haemorrhage (Table 6).

The two groups did not exhibit any substantial variation in the mean birth weight or APGAR scores at 1 minute and 5 minutes. (Table 7).

## DISCUSSION

The efficacy and safety of 25 µg Misoprostol (Group A) versus PGE2 gel (Group B) for labour induction were evaluated in this randomised controlled trial. The results underscore the importance of prostaglandins in the promotion of cervical dilatation and the initiation of labour.

Prostaglandins are a technique that is both widely acknowledged and advanced for labour induction.[8] Among these, PGE2 gel remains a commonly used agent; however, misoprostol has emerged as a potent cervical ripening alternative.[9] Misoprostol's advantages include its cost-effectiveness and its ability to remain stable at room temperature. Its affordability over PGE2 gel makes it particularly suitable for resource-limited settings.[10]

This study included 176 women, with comparable maternal demographics across both groups. Most participants were aged 20-30 years, the mean age of Group

A was 25.2±3.6 years, while Group B had a mean age of 25.8±3.2 years. The parity distribution was also comparable, with 62.5% primigravida in Group A and 56.8% in Group B. There were no significant differences in pre-induction Bishop scores (p=0.5390), consistent with findings by Wing et al and Frank et al.[11,12]

Group A (misoprostol) demonstrated superior efficacy in labour induction. Labour onset occurred significantly Group A completed the task at a faster pace (6.5 hours vs. 8.5 hours, p<0.046). Furthermore, 50% of women in Group A encountered labour onset within 12 hours, while 45.5% of women in Group B (PGE2 gel) did. Despite the fact that the induction-to-delivery interval was shorter in Group A (20.08±8.24 hours) than in Group B (23.19±9.59 hours), the differential was not statistically significant (P=0.1314), which is in accordance with the results of EJ Langenegger et al.[13] It is important to note that a higher percentage of women in Group A accomplished vaginal delivery within 24 hours (95% vs. 85%), which is consistent with the findings of Murthy BK et al.[14]

These results are consistent with the results of research conducted by Özkan S et al and Cheng SY et al.[15,16]

Oxytocin augmentation was significantly reduced in Group A (15.9% vs. 45.5%, p<0.00001), highlighting misoprostol's efficacy as an induction agent. However, women in Group A required a higher number of doses compared to Group B (P<0.00001), a trend also reported by Parmar et al.[17] The rates of vaginal delivery were similar, with 92% in Group A and 95.5% in Group B. The caesarean section rate in Group A was 8%, compared to 4.5% in Group B; however, this difference was not statistically significant (P=0.5355). This finding aligns with the observations made by Wing et al who similarly reported no significant disparity between the groups.[11] Parmar et al observed a caesarean rate of 6% in the Misoprostol group (Group A), in contrast to 22% in the PGE2 gel group (Group B).[17] In this study, caesarean deliveries were primarily linked to foetal distress. The observations are corroborated by the findings of Sahu Latika et al and Murthy Bhaskar et al.[18,19]

The two groups exhibited comparable neonatal outcomes, including equivalent mean birth weights and APGAR scores at 1 and 5 minutes. No significant differences in neonatal complications were observed, consistent with the results of Parmar et al.[17] However, a slightly higher occurrence of meconium-stained liquor was noted in Group A (misoprostol group), a trend also documented by Hofmeyr GJ et al though this variation was not statistically significant.[20]

Both groups experienced negligible maternal adverse effects. In Group A (misoprostol group), 15% of patients experienced fever with chills, while no gastrointestinal side effects were reported. Conversely, 5% of women in Group B (PGE2 gel group) reported nausea, vomiting, and diarrhoea.

Uterine contraction abnormalities are a significant concern when using Misoprostol, as evidenced by prior research conducted by Wing et al and Hofmeyr et al.[20,21] These abnormalities are frequently associated with the administration of higher doses of Misoprostol (50 µg or more), whether orally or vaginally. The occurrence of meconium-stained liquor and caesarean deliveries has also been documented in numerous studies, which are attributed to foetal distress in women who are receiving elevated vaginal concentrations of Misoprostol.[21] Nevertheless, tachysystole was not observed with misoprostol or PGE2 gel, and the difference in caesarean section rates between the two groups was not statistically significant in our study.

Despite its efficacy, misoprostol is not universally approved for labour induction. Concerns remain regarding its higher doses, these have been linked to uterine hyperstimulation and rupture, as documented in the research conducted by Chitta Charon et al, Joy et al, and Kamal et al.[22-24] Vaginal misoprostol regimens, as employed in this study, are considered safer and more effective than oral regimens, which carry a higher risk of complications. However, as emphasized by Kamal et al and others, a faster induction method is not necessarily better for childbirth.[24,25]

Future research should focus on refining dosing regimens to enhance both safety and efficacy.

## CONCLUSION

This study establishes that low-dose (25µg) vaginal misoprostol is a safe, cost-effective, and more efficient agent for labour induction compared to $PGE_2$ gel, offering shorter induction-to-delivery intervals and reduced need for oxytocin augmentation without compromising maternal or neonatal outcomes. By confirming its comparable safety profile and highlighting its affordability and ease of storage, our findings advance understanding by positioning misoprostol as a practical and accessible alternative, particularly in resource-limited settings. This contributes to the growing body of evidence supporting misoprostol as a preferred induction method and underscores the need for continued research to optimize dosing strategies for broader, safe clinical application.

Our study demonstrates that 25µg vaginal misoprostol is a more effective labour induction agent than PGE2 gel, offering notable clinical and practical benefits. Misoprostol was linked to shorter induction-to-delivery intervals, a faster onset of labour, and a significantly lower requirement for oxytocin augmentation. However, it necessitated a greater number of doses to achieve effective induction compared to PGE2 gel. Despite this, the overall clinical outcomes, including delivery mode and maternal and neonatal outcomes, the two groups exhibited comparable results, with no statistically significant differences identified.

*Funding: No funding sources*
*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Mishra R, Shinde S, Gavali U, Aher G. Comparative study between 25 µg vaginal misoprostol and PGE2 gel for induction of labour at term. Int J Reprod Contracept Obstet Gynecol 2025;14:3430-6.