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**Original Research Article**

# Evaluation of vaginal and sublingual routes of misoprostol in induction of labor

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## ABSTRACT

**Background:** Labor induction is used to initiate uterine contractions. Various misoprostol administration routes demonstrate differing pharmacokinetics and efficacy. Optimal route is selected considering factors like onset of action, side effects, patient comfort, and neonatal outcomes. Objectives were to study the response of sublingual and vaginal routes of misoprostol for induction of labor and compare both the routes for induction of labor.
**Methods:** A randomized prospective study was conducted from May 2023 to October 2024 at Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, UP. Participants were assigned to either sublingual or vaginal misoprostol (25 mcg every 4 hours, up to five doses), stopped at 4 cm dilation or if adverse effects occurred. Oxytocin was given if needed. Labor progress, induction-to-delivery time, doses, patient preference, and side effects were recorded.
**Results:** The present study on labor induction with sublingual and vaginal misoprostol showed no significant differences in demographic factors, gravidity, parity, or gestational period between the groups. Bishop scores improved significantly after three doses of misoprostol. The sublingual group had a shorter labor duration and required fewer doses, supporting its quicker induction efficiency. No significant differences were found in adverse effects, mode of delivery, failure rates, or neonatal outcomes but individualized care is essential.
**Conclusions:** This study highlighted that both sublingual and vaginal misoprostol are effective for labor induction, with sublingual route offering faster results but higher risks, suggesting that the choice of route should be based on patient-specific factors.

**Keywords:** Induction of labor, Maternal complications, Misoprostol, Perinatal complications, Sublingual, Vaginal

## INTRODUCTION

Induction of labor is used to induce or augment uterine contractions, helping facilitate vaginal delivery when pregnancy risks threaten the mother or baby.[1,2] It is crucial for preventing complications like post-term pregnancy, preeclampsia, IUGR, fetal demise, and PROM.[1,3]

Globally, labor induction has increased due to better prenatal screening and detection of pregnancy complications.[4] In the US, the induction rate rose to 22.5% by 2006, reflecting a significant increase from the 1990s.[5] While lower in developing countries, some healthcare centers report rates like those in developed nations due to improved access to care.[6]

Several routes of misoprostol administration such as oral, vaginal, buccal, and sublingual are studied for their efficacy in labor induction, each demonstrating unique pharmacokinetics.[7] Vaginal misoprostol is often preferred for its sustained uterotonic effect, promoting regular contractions over time. However, vaginal administration can cause discomfort due to repeated examinations and carries a higher risk of hyperstimulation, which may necessitate continuous fetal monitoring to ensure fetal well-being.[8-10]

Despite these benefits, key concerns include the potential for uterine hyperstimulation, fetal distress, and the need for emergency cesarean delivery, which must be carefully evaluated when comparing these routes.[10,12]

Labor can be induced using various methods, depending on the clinical situation, the readiness of the cervix, and the patient's preferences. One commonly used method involves prostaglandins, such as misoprostol or inopportune, administered vaginally or orally to ripen the cervix and stimulate uterine contractions.

This study addresses the comparative effectiveness and safety of sublingual versus vaginal misoprostol for labor induction. Both routes offer distinct benefits and challenges, and their careful evaluation is essential to inform clinical practice. By analyzing outcomes such as the time to labor onset, maternal satisfaction, neonatal health, and incidence of complications, this research aims to provide evidence-based recommendations for healthcare providers. This study was designed on objective to study the response of sublingual and vaginal routes of misoprostol for induction of labor and compare both the routes of misoprostol administration for induction of labor.

***Aim and objective***

To study the response of sublingual and vaginal routes of misoprostol for induction of labor and compare both the routes of misoprostol administration for induction of labor.

## METHODS

The study employed a randomized, prospective design, ethically approved, to compare the outcomes of sublingual versus vaginal routes of misoprostol for labor induction. Randomization ensured an unbiased division into two groups for fair analysis.

Participants were included in the study if the met with the criteria of pregnant women aged between 18 to 30 years, gestational age between 37 to 42 weeks, singleton pregnancy, no contraindications for vaginal delivery and vertex presentation

Participants were excluded from the study if they refused to provide consent, had suspected cephalo-pelvic disproportion, a history of cesarean section or previous uterine surgery, multiple gestations, malpresentation (e.g., breech or transverse lie), chorioamnionitis or signs of infection, evidence of fetal distress, allergy to, or contraindications for, misoprostol, meconium-stained amniotic fluid, placenta previa and history of poor obstetric outcomes

All eligible individuals were approached upon their admission to the labor ward. The study's purpose, procedures, potential risks, and benefits were thoroughly explained. Those who agreed to participate provided written informed consent prior to enrolment. Participants underwent a comprehensive clinical assessment, including demographic details, obstetric history, and any existing medical conditions. Physical examinations and routine laboratory investigations (hemoglobin, blood group, Rh typing, glucose, TSH, viral infection screening, and urinalysis) were performed. Ultrasound and Doppler studies assessed fetal well-being and placental function. Upon admission, the Bishop score was recorded to evaluate cervical favorability.

Participants were randomized into two groups: group I received 25 µg misoprostol sublingually every 4 hours (max five doses), while group II received the same dose vaginally, followed by 30 minutes of supine rest. Dosing was stopped upon reaching active labor (cervical dilation ≥4 cm) or upon adverse events. Amniotomy was performed if labor failed to progress.

If labor did not commence after the final dose, oxytocin infusion was initiated after 4-6 hours. Labor was monitored using a partograph, recording uterine contractions, cervical changes, fetal descent, and labor duration. Side effects such as hyperstimulation or fetal distress were managed symptomatically.

After delivery, participants received postpartum and contraceptive counselling. Their comfort with the assigned drug administration route was qualitatively assessed, and follow-up visits were scheduled within 1-2 weeks for recovery monitoring and further support.

## RESULTS

A total of 80 women were recruited after meeting inclusion and exclusion criteria. These were randomized into two equal groups to receive sublingual (group 1) and vaginal misoprostol (group 2). There were no dropouts in the study. The demographic features, indications for induction and pre-induction scores were comparable between the two groups.

The demographic comparison between the two misoprostol administration groups revealed no statistically significant differences (Table 1). Participants in the vaginal group had a mean height of 159 cm (SD=8.89) and a mean weight of 69.7 kg (SD=12.28), while those in the sublingual group averaged 161.1 cm in height (SD=11) and 64.8 kg in weight (SD=12.86).

Body mass index (BMI) analysis further supported this similarity, with mean BMI values of 27.8±5.83 in the vaginal group and 25.4±6.2 in the sublingual group. The BMI distribution did not significantly differ between the two groups ($\chi^2$=2.45, p=0.484). Similarly, random blood glucose levels showed no statistical variation ($\chi^2$=2.67, p=0.264).

**Table 1: Baseline sociodemographic parameters between two groups.**

| Parameters | Group A | Group B | P value |
|---|---|---|---|
| | Sublingual group N (%) | Vaginal group N (%) | |
| **Age (years)** | | | |
| 18-21 | 1 (2.50) | 3 (7.50) | 0.163 |
| 22-25 | 16 (40) | 22 (55) | |
| 26-30 | 23 (57.50) | 15 (37.50) | |
| **Religion** | | | |
| Muslim | 7 (17.5) | 10 (25.00) | 0.648 |
| Hindu | 25 (62.5) | 23 (57.50) | |
| Others | 8 (20) | 7 (17.50) | |
| **Socieconomic status** | | | |
| Lower | 13 (32.50) | 15(37.50) | 0.779 |
| Lower middle | 10 (25.00) | 10 (25.00) | |
| Upper middle | 6 (15.00) | 5 (12.50) | |
| Upper lower | 10 (25.00) | 7 (17.5) | |
| Upper | 1 (2.50) | 3 (7.5) | |
| **BMI** | | | |
| <18.5 | 4 (10.00) | 3 (7.5) | 0.484 |
| 18.5-24.9 | 14 (35) | 9 (22.5) | |
| 25-29.9 | 14 (35) | 15 (37.5) | |
| >30 | 8 (20) | 13 (32.5) | |
| **Gravida** | | | |
| G1 | 15 (37.5) | 20 (50) | 0.094 |
| G2 | 14 (35) | 13 (32.5) | |
| G3 | 7 (17.5) | 7 (17.5) | |
| G4 | 4 (10) | 0 (0) | |

**Table 2: Bishop score comparison between two groups.**

| Parameters | Group A | Group B | P value |
|---|---|---|---|
| | Sublingual group N (%) | Vaginal group N (%) | |
| **Initial Bishop score** | | | |
| 0 | 8 (20) | 11 (27.5) | 0.641 |
| 1 | 12 (30) | 14 (35) | |
| 2 | 10 (25) | 9 (22.5) | |
| 3 | 10 (25) | 6 (15) | |
| **Bishop score after 3 doses** | | | 0.035 |
| 3 | 1 (2.5) | 9 (22.5) | |
| 4 | 9 (22.5) | 12 (30) | |
| 5 | 8 (20) | 8 (20) | groups A |
| 6 | 13 (32.5) | 8 (20) | |
| 7 | 6 (15) | 3 (7.5) | |
| 8 | 3 (7.5) | 0 (0) | |

Bishop scoring between the two misoprostol administration groups revealed no statistically significant differences. Across both groups, the most common dose category was 3 doses, with 29 participants, while the least common were 1 dose and 5 doses, with 12 and 8 participants, respectively. A chi-squared test yielded a value of 34.8 with a p value of <0.001, signifying a statistically significant difference in the distribution of doses between the two groups.

These results suggest that the route of misoprostol administration has a notable impact on the number of doses required for successful labor induction. The sublingual group generally required fewer doses, highlighting its potential efficiency compared to the vaginal route as shown by Table 2.

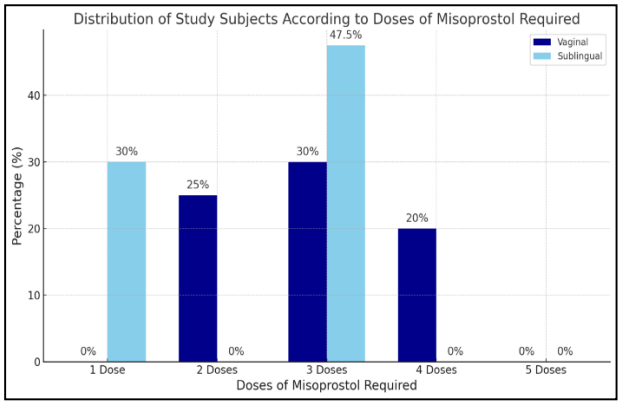


**Figure 1: Doses required between two groups.**

Assessment of labor duration indicated a noticeable difference between the two administration methods. Participants in the sublingual group experienced shorter labors, with a mean duration of 5±0.906 hours, compared to 6.7±1.18 hours in the vaginal group ($\chi^2$=13.6, p=0.001). Additionally, the sublingual route required significantly fewer doses for effective induction (p<0.001) as shown in Figure 1.

When evaluating labor durations between 6 and 12 hours, 7.5% of primigravida and 10% of multigravida women in the sublingual group successfully delivered, compared to 3.8% and 7.5%, respectively, in the vaginal group. In the 13–18-hour window, the sublingual route continued to show a higher success rate in primigravida women (11.3%) than the vaginal route (8.8%). However, among multigravida women, the vaginal group slightly outperformed the sublingual group (22.5% versus 21.3%). Importantly, no inductions exceeded 18 hours in either group, highlighting the general effectiveness of misoprostol in promoting timely delivery regardless of administration route as shown in Table 3.

**Table 3: Time interval comparison between two groups, from initiation of labor to active phase and delivery represented by mean, SD, t-value and p values**

| Parameters | Route | Gravida | Mean (SD) | t-value | P value |
|---|---|---|---|---|---|
| **Time interval from initiation of induction to onset of active phase of labor** | Sublingual | Primi | 13.13 (0.855) | 2.024 | 0.9564 |
| | | Multi | 13.08 (0.899) | | |
| | Vaginal | Primi | 16.75 (1.54) | 2.0243 | 0.69380 |
| | | Multi | 17.25 (1.515) | | |
| **Time interval from active phase to delivery** | Sublingual | Primi | 5.066 (0.78) | 2.0244 | 0.7234 |
| | | Multi | 4.96 (0.873) | | |
| | Vaginal | Primi | 6.625 (1.316) | 2.024394 | 0.747607 |
| | | Multi | 6.75 (1.5) | | |
| **Time interval from onset of labor till delivery** | Sublingual | Primi | 18.2 (0.86) | 2.0262 | 0.9123 |
| | | Multi | 18.08333 (1.12) | | |
| | Vaginal | Primi | 23.375 (1.17) | 2.024394 | 0.616155 |
| | | Multi | 24 (1.660) | | |

In the 1-3-hour window following the onset of the active labor phase, no primigravida women delivered in either group, whereas 5% of multigravida women did in both. Between 3 and 5 hours, delivery rates were higher in the sublingual group (12.5% for primigravida and 22.5% for multigravida) compared to the vaginal group (5% and 15%, respectively).

For labor exceeding 5 hours, the vaginal group reported more deliveries- 15% in primigravida and 10% in multigravida- than the sublingual group (6.3% and 3.8%, respectively). In total labor duration, no deliveries were observed under 12 hours in either group. For the 12-18-hour range, multigravida women in the vaginal group had a slightly higher delivery rate (13.8%) than those in the sublingual group (12.5%). Among primigravida women, the sublingual group had a higher proportion of deliveries (8.8%).

During the 19-24-hour interval, both gravidity categories experienced more deliveries in the sublingual group- 10.0% (primigravida) and 18.8% (multigravida)- versus 11.3% and 15.0% in the vaginal group. In durations beyond 24 hours, only the vaginal group reported deliveries among primigravida women (8.8%), with no such instances in the sublingual group. While these findings suggest faster labor progression with the sublingual route, particularly in early stages, none of the observed differences were statistically significant.

Adverse events such as fever, nausea, and tachysystole occurred at comparable rates across both groups, with no statistically significant differences. The requirement for oxytocin augmentation was notably higher in the vaginal group (62.5%) than in the sublingual group (17.5%), a statistically significant difference (p<0.001), indicating a possible advantage of sublingual misoprostol in reducing the need for additional uterotonic support.

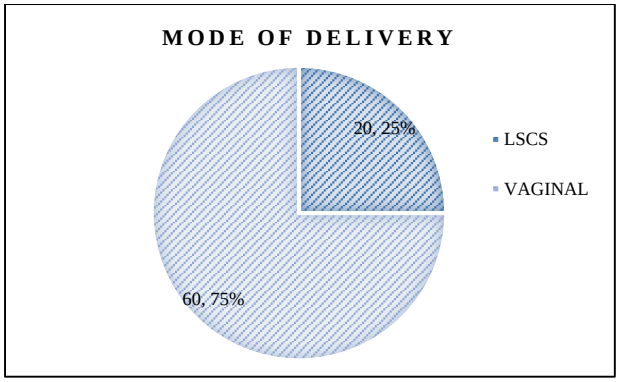


**Figure 2: Mode of delivery between two groups.**

Mode of delivery was not significantly influenced by the route of misoprostol administration (p=0.606), nor were there significant differences in failure rates- 17.5% in the vaginal group and 27.5% in the sublingual group (p=0.284) as shown in Figure 2. Neonatal outcomes, including sex distribution, APGAR scores at 1 and 5 minutes, and NICU admission rates, were similar between the two groups, supporting the safety of both administration routes.

## DISCUSSION

Misoprostol, a synthetic prostaglandin E1 analogue, has shown significant potential as an agent for inducing labor. It is affordable, does not require refrigeration, and has a favorable safety profile at lower doses. Its versatility in administration- whether orally, vaginally, sublingually, buccally, or rectally- adds to its practicality. Moreover, misoprostol is effective in facilitating cervical softening and triggering uterine contractions. Clinical use has included dosages ranging from 25 to 200 micrograms.

The present study found that the predominant age group for vaginal misoprostol was 20–24 years (45%, mean age 24.9±3.19), while the sublingual group was mostly 25-29 years (65%, mean age 26.0±2.52), with no statistically significant difference between the two ($\chi^2$=5.57, p=0.134). These findings align partially with Wolf et al and Gülmezoglu, who reported higher mean ages of 28.2 and 27.1 years, respectively.[13,14] Conversely, Conti-Harandi and Kaur reported lower averages around 23 years. Religious distribution was balanced (40% Muslim, 60% Hindu; $\chi^2$=0.208, p=0.648), and no significant influence on outcomes was observed, consistent with previous studies by Alfirevic et al.[15] Socioeconomic status also showed no significant variation between groups ($\chi^2$=1.76, p=0.779), supporting findings from DebBarma and others that induction outcomes remain consistent across economic backgrounds, although Amini noted cost-related preferences.

Anthropometric comparisons showed no significant difference in height or weight between groups, with the vaginal group averaging 159 cm and 69.7 kg, and the sublingual group 161.1 cm and 64.8 kg. BMI analysis revealed no significant differences either (mean BMI: vaginal 27.8±5.83, sublingual 25.4±6.2; $\chi^2$=2.45, p=0.484). While some studies like Sharma and Joshi reported BMI-related variations in drug absorption or labor duration, the overall consensus suggests that anthropometric parameters do not significantly affect the success of misoprostol-induced labor.

The present study found no significant differences in random blood sugar levels ($\chi^2$=2.67, p=0.264), TSH levels ($\chi^2$=1.13, p=0.288), gravidity, parity, abortions, or number of living children between sublingual and vaginal misoprostol groups, indicating effective randomization. While some studies, like those by Kumar et al noted that pregestational or gestational diabetes significantly impacted induction outcomes, our results align with studies by Patel, Singh, and Chawla, which found no such association.[16] Similarly, our findings on thyroid function and hemoglobin levels echo those of Rahimi-Sharbaf et alwho found no significant influence of misoprostol route on these parameters.[17] The physiological responses in pulse rate were consistent across groups (p=0.992), though blood pressure differed significantly (SBP p=0.031, DBP p=0.002), suggesting a potential route-specific effect. Baseline Bishop scores showed no statistical difference ($\chi^2$=1.68, p=0.641), while post-third dose scores did ($\chi^2$=12, p=0.035), indicating a stronger cervical ripening effect with one route.

Gestational age distribution was perfectly uniform ($\chi^2$=0.00, p=1.00), supporting the robustness of our randomization. Labor duration analysis revealed significant differences favoring sublingual misoprostol, with a shorter average time to delivery (5±0.906 hours) compared to the vaginal group (6.7±1.18 hours; $\chi^2$=13.6, p=0.001). This finding aligns with studies by Pergialiotis and Nautiyal, who observed faster labor with sublingual administration.[18] However, Jahromi and Sunda reported no major timing differences, suggesting individual variability.[19] The cumulative evidence from the present study and comparable research indicates that while baseline demographics and physiological measures are largely unaffected by the route of misoprostol, sublingual administration may offer improved efficiency in cervical ripening and labor progression.

The present study demonstrated that sublingual misoprostol significantly shortened the time from labor onset to delivery (18.1±3.12 hours) compared to vaginal administration (23.75±3.79 hours; p<0.001), requiring fewer doses (p<0.001) and less oxytocin augmentation (17.5% versus 62.5%; p<0.001). These findings align with Wolf et al, Milani et al, and Nautiyal et al, who noted enhanced efficiency and faster induction with sublingual misoprostol.[13,18,20] While Hofmeyr and Gülmezoglu emphasized the effectiveness of vaginal misoprostol, they also cautioned about dose-related risks. Our results further indicate no significant differences in adverse effects, failure rates, mode of delivery, APGAR scores, or NICU admissions, suggesting both administration routes are

comparably safe. These safety outcomes are consistent with studies by DebBarma, supporting the use of sublingual misoprostol without compromising maternal or neonatal health.[21]

The route of misoprostol administration did not influence neonatal sex distribution or TSH and hemoglobin levels, reinforcing findings by Alfirevic.[15] Moreover, the mode of delivery was not significantly different across groups (p=0.606), echoing results from Nautiyal, Jahromi, and Sunda, who found similar cesarean and complication rates across routes.[18] Although some variability exists in the literature- particularly regarding oxytocin use and time to delivery- our data support sublingual misoprostol as a potentially more efficient method for labor induction. These findings highlight the importance of tailoring induction strategies to patient profiles, balancing efficacy with safety, and considering institutional protocols for optimal outcomes.

## CONCLUSION

Misoprostol by both routes sublingual and vaginal had successful induction and vaginal delivery rates. The sublingual route led to a faster onset and shorter time interval from onset to delivery. This makes it preferable in conditions where faster induction to delivery is desired like preeclampsia, severe preeclampsia, eclampsia and delivery of second twin among few cases where rapid labor induction is needed. However, it also carries a higher risk of uterine hyperstimulation, requiring careful monitoring. Misoprostol by the vaginal route offers a slower, more controlled induction and is the preferable choice in cases like grand multiparty, cardiac disorders, severe anemia and resource poor settings. With a lesser risk of hyperstimulation makes it a safer choice. However, this route of misoprostol is associated with maternal dehydration and ketosis.

The decision between the two routes should be patient-centered, considering factors like indication for induction, maternal health, and institutional resources. Clinicians should educate patients on both options to support informed decision-making. Standardized guidelines can further aid in selecting the appropriate method based on clinical needs and available resources.

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