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# Comparison of Effectiveness of Sublingual Versus Vaginal Misoprostol Use for Labour Induction at Term Pregnancy

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## ABSTRACT

**Background**:
Labour induction is a common obstetric intervention to facilitate vaginal delivery when prolonged pregnancy poses risks to maternal or fetal health. Misoprostol, a prostaglandin E1 analogue, is widely used for cervical ripening and labour induction, but the optimal route of administration remains debated. This study aimed to compare the efficacy and safety of sublingual versus vaginal misoprostol in term pregnancies.

**Methodology**:
A randomized prospective trial was conducted at IIMSR, Lucknow (2023–2025), involving 128 term pregnancies. Participants were randomly assigned to the sublingual (Group A, n=64) or vaginal (Group B, n=64) misoprostol group. Misoprostol (25 mcg) was administered every 4 hours, up to six doses, unless active labour occurred. Primary outcomes included vaginal delivery within 24 hours and induction-to-delivery interval, while secondary outcomes assessed cesarean rates, neonatal morbidity, and adverse drug effects. Statistical analysis was performed using SPSS 23.0, with a significance threshold of $p<0.05$.

**Results:**
In the present study, labour induction was more frequent after 37 weeks (68.75% vaginal vs. 57.81% sublingual). G1P0L0 was the most common parity in both groups. Higher misoprostol doses were required in the vaginal group. Cesarean rates were comparable (64.06% vaginal vs. 62.50% sublingual), and neonatal complications, mainly respiratory distress, were similar (53.13% vs. 51.56%). Maternal side effects were more frequent in the sublingual group (64.06% vs. 53.12%).

**Conclusion**:
We concluded that, both sublingual and vaginal misoprostol are effective for labour induction. The choice of route should be individualized based on patient preference, clinical conditions, and resource availability.

**Keywords:** Misoprostol, labour induction, sublingual route, vaginal route, term pregnancy.

## 1. INTRODUCTION

Induction of labour is a commonly performed obstetric intervention for achieving vaginal delivery when early delivery is more beneficial than prolonged pregnancy.[1] The success of induction is influenced by various factors, including cervical

favorability, parity, and the method used for induction.[2] In obstetric care, several pharmacological agents are available; among them, misoprostol which is a synthetic prostaglandin $E_1$ analogue has gained more attention and prevalent acceptance due to its efficacy, room temperature stability and cost-effectiveness.[3,4,5]

Misoprostol can be administered via several routes oral, sublingual, buccal, vaginal, and rectal each differing in terms of pharmacokinetics, bioavailability, and clinical outcomes.[6] Traditionally, misoprostol has been administered vaginally as a labor induction drug because of its local effects and sustained uterotonic effects.[7] However, sublingual administration offers higher peak plasma concentrations, faster absorption, and ease of administration without a vaginal examination, enhancing maternal comfort and reducing infection risks.[8,9]

Although, numerous studies have shades light on, the various routes of administration for misoprostol, the optimal route to balance efficacy and safety for both mother and fetus remains controversial.[10,11,12,13] This debate especially observes at term pregnancy, where early and effective induction is critical, comparative data on sublingual versus vaginal misoprostol remains insufficient and sometimes conflicting. To address this gap, we conducted this study to compare the effectiveness of sublingual and vaginal misoprostol in labour induction at term pregnancy.

## 2. METHODOLOGY

This randomized prospective study was conducted in the Department of Obstetrics and Gynecology at IIMSR, Lucknow, over a duration of 18 months. The present study included pregnant women between 37 to 40 weeks of gestation who required induction of labor. Participants included both primigravida and multigravida women with a cephalic presentation, adequate pelvis, reassuring fetal heart tracing, a Bishop score of less than 6, and no contraindications for vaginal delivery. Women with a previous cesarean section, malpresentation, multiple pregnancies, asthma or other contraindications to prostaglandins, or cephalopelvic disproportion were excluded from this study.

Based on the above inclusion and exclusion criteria, a total of 128 participants were selected and randomly assigned into two equal groups.

- **Group A**: This group consisted of 64 participants who received 25 micrograms of misoprostol sublingually.
- **Group B:** In this group we included, 64 participants who received 25 micrograms of misoprostol vaginally, with the tablet placed in the posterior fornix of the vagina.

At the time of enrollment, informed written and verbal consent was obtained from all participants. A detailed clinical assessment was performed, which included per abdomen, per speculum, and per vaginal examinations. Baseline investigations were conducted, and non-stress testing (NST) was carried out to confirm fetal well-being prior to induction. Misoprostol was administered every four hours for a maximum of six doses within a 24-hour period, provided the participant had not entered active labor. Uterine contractions and cervical changes were monitored every four hours or as clinically indicated. Further doses were withheld once contractions of moderate intensity were established defined as three contractions in ten minutes, each lasting 35 to 40 seconds or if the participant entered active labor, indicated by cervical dilation of 5 cm or more, in accordance with the WHO next generation partograph. Induction was deemed to have failed if labor did not progress within four hours after the final dose of misoprostol.

The primary outcomes measured in the study included the percentage of women who achieved vaginal delivery within 24 hours of induction and the induction-to-delivery interval. Secondary outcomes included the cesarean section rate due to fetal distress, the number of misoprostol doses required before labor augmentation with oxytocin, and neonatal outcomes such as meconium aspiration, intrapartum fetal death, and prolonged NICU stay. Additionally, any side effects related to the use of misoprostol including uterine hyperstimulation, tachysystole, nausea, vomiting, and diarrhea were documented and analysed.

Statistical analysis:

## 3. RESULTS

In the present study, a total of 128 participants were included and evenly divided into two groups i.e., Group A and Group B, each carries 64 participants. We found that, the majority of participants in both groups were between 38 to 40 weeks of gestation. In the vaginal group, 68.75% were in this range compared to 57.81% in the sublingual group. On the other hand, 31.25% in the vaginal group and 42.19% in the sublingual group were between 37 weeks and 37 weeks + 6 days (Table 1).

**Table 1: Showing cross tabulation of route of induction and period of gestation**

| Period Of Gestation | Per Vaginal | Per Vaginal% | Sublingual | Sublingual% |
|---|---|---|---|---|
| 37 Week-37 week+ 6 days | 20 | 31.25% | 27 | 42.19% |
| 38 WEEK-40 WEEK | 44 | 68.75% | 37 | 57.81% |
| Total | 64 | 100.00% | 64 | 100.00% |

**Table 2: Showing total dose of misoprostol given in per vaginal and sublingual group.**

In the present study, more participants in the sublingual group required two doses (40.6%) compared to the vaginal group (20.3%). A single dose was more effective in the vaginal group (29.7% vs. 23.4%). Overall, dose distribution between groups showed no significant difference (p = 0.099), as presented in Table 2.

| Total Dose Of Misoprostol Given | Per Vaginal (n, %) | Sublingual (n, %) | Total (n, %) | Chi sqaure | p value |
|---|---|---|---|---|---|
| 1 Dose | 19 (29.7%) | 15 (23.4%) | 34 (26.6%) | 6.278 | 0.099 |
| 2 Dose | 13 (20.3%) | 26 (40.6%) | 39 (30.5%) | | |
| 3 Dose | 21 (32.8%) | 15 (23.4%) | 36 (28.1%) | | |
| 4 Dose | 11 (17.2%) | 8 (12.5%) | 19 (14.8%) | | |
| **Total** | **64 (100.0%)** | **64 (100.0%)** | **128 (100.0%)** | | |

Our study outcomes observed that, the rate of caesarean section was similar between the vaginal (64.06%) and sublingual (62.50%) groups, with no significant difference in mode of delivery (p = 0.855), as noted in the following Table 3.

**Table 3: Showing cross tabulation of route of induction and mode of delivery.**

| Mode of Delivery | Per Vaginal (n., %) | Sublingual (n, %) | Chi square | p value |
|---|---|---|---|---|
| C-Section | 41 (64.06%) | 40 (62.50%) | 0.034 | 0.855 |
| FTNVD | 23 (35.94%) | 24 (37.50%) | | |
| **Total** | **64 (100.00%)** | **64 (100.00%)** | | |

Our investigation showed that, fetal distress was the most common indication for caesarean section in both groups, higher in the vaginal group (39.02%) than the sublingual group (25%). Non-reactive NST was also more frequent in the sublingual group (42.5% vs. 26.83%). Other indications varied slightly, with no significant difference overall (p = 0.057), as observed in Table 4.

**Table 4: Showing cross tabulation of route of induction and indication of C-section.**

| Indication Of C-Section | Per Vaginal | Per Vaginal% | Sublingual | Sublingual % | Chi Square | P Value |
|---|---|---|---|---|---|---|
| Fetal distress | 16 | 39.02% | 10 | 25.00% | 17.42 | 0.057 |
| Fetal tachycardia | 4 | 9.76% | 3 | 7.50% | | |
| Meconium | 0 | 0.00% | 3 | 7.50% | | |
| MSL / Fetal distress | 1 | 2.44% | 1 | 2.50% | | |
| MSL + Non-reactive NST | 6 | 14.63% | 3 | 7.50% | | |
| Non-reactive NST (combined) | 11 | 26.83% | 17 | 42.50% | | |
| Non-progress of labour | 3 | 7.32% | 3 | 7.50% | | |
| Total | 41 | 100.00% | 40 | 100.00% | | |

In the current study, Table 5 shows that, neonatal outcomes were similar in both groups, with complications seen in 53.13% of the Per Vaginal group and 51.56% of the Sublingual group (p = 0.524).

**Table-5: Distribution of neonatal outcome and cross tabulation of route of induction and type of neonatal outcome.**

| **Neonatal Outcome** | **Per Vaginal (n, %)** | **Sublingual (n, %)** | **Chi sqaure** | **p value** |
|---|---|---|---|---|
| None | 30 (46.88%) | 31 (48.44%) | 0.914 | 0.524 |
| Issues | 34 (53.13%) | 33 (51.56%) | | |
| **Total** | **64 (100.00%)** | **64 (100.00%)** | | |
| **Neonatal Complication** | **Per Vaginal (n, %)** | **Sublingual (n, %)** | **Chi sqaure** | **p value** |
| Meconium Aspiration Syndrome | 10 (29.41%) | 7 (21.21%) | 7.354 | 0.118 |
| NEC (Necrotizing Enterocolitis) | 0 (0.00%) | 3 (9.09%) | | |
| Prolonged NICU Stay | 10 (29.41%) | 8 (24.24%) | | |
| Respiratory Distress Syndrome | 11 (32.35%) | 15 (45.45%) | | |
| Uneventful | 3 (8.82%) | 0 (0.00%) | | |
| **Total** | **34 (100.00%)** | **33 (100.00%)** | | |

We demonstrated that, maternal side effects were more frequent in the sublingual group (64.06%) than in the vaginal group (53.12%), with diarrhea being the most common in both. Unique to the sublingual group were cases of uterine hyperstimulation, tachysystole, and stomach cramps (Table 6).

**Table 6: Distribution based on maternal side effects and cross tabulation of route of induction and types of maternal side effect.**

| Maternal side effects (Present) | **Per vaginal** | **Per vaginal%** | **Sublingual** | **Sublingual%** | | |
|---|---|---|---|---|---|---|
| | 34 | 53.12% | 41 | 64.06% | | |
| **Maternal Side Effect** | **Per Vaginal** | **Per Vaginal%** | **Sublingual** | **Sublingual%** | **Chi Square** | **P value** |
| Diarrhoea | 12 | 35.29% | 14 | 34.15% | 7.788 | 0.072 |
| Dizziness | 4 | 11.76% | 0 | 0.00% | | |
| Fever | 5 | 14.71% | 3 | 7.32% | | |
| Nausea | 9 | 26.47% | 7 | 17.07% | | |
| Stomach cramp | 0 | 0.00% | 4 | 9.76% | | |
| Uterine hyperstimulation | 0 | **0.00%** | 3 | **7.32%** | | |
| Uterine tachysystole | 0 | **0.00%** | 4 | **9.76%** | | |
| Vomiting | 4 | 11.76% | 6 | 14.63% | | |
| Total | 34 | 100.00% | 41 | 100.00% | | |

According to Table 7, the mean induction-to-delivery interval was slightly shorter in the sublingual group (7.55 hours) than in the vaginal group (7.98 hours), but the difference was not statistically significant (p = 0.533).

**Table 7: Showing Induction to delivery interval in per vaginal and sublingual group.**

| Induction To Delivery Interval | **N** | **Mean (hours)** | **Std dev.** | **t value** | **p value** |
|---|---|---|---|---|---|
| Per vaginal | 64 | 7.984 | 2.357 | 0.626 | 0.533 |
| Sublingual | 64 | 7.546 | 1.011 | | |

## 4. DISCUSSION

This study evaluated the comparative efficacy and safety of sublingual and vaginal misoprostol for labor induction, adding to the body of evidence that both routes are effective and well-tolerated. In similar with previous studies [1–6], our results showed that misoprostol, a synthetic prostaglandin E1 analogue, is a widely used pharmacologic agent for cervical ripening due to its cost-effectiveness, stability at room temperature, and reliable clinical outcomes.

A total of 128 patients were divided equally into sublingual and vaginal misoprostol groups. The majority of participants were primigravidas, with most inductions occurring after 37 weeks of gestation. The mean total dose of misoprostol

administered did not differ significantly between groups, suggesting comparable dosing requirements. Although the sublingual group showed a slightly shorter induction-to-delivery interval (7.54 hours) compared to the vaginal group (7.98 hours), the difference was not statistically significant, echoing similar trends observed by Singh P, et al., (2019) [14] and Zahran F, et al., (2009) [15].

Cesarean delivery rates were nearly identical in both groups (64.06% for vaginal vs. 62.50% for sublingual), consistent with prior findings by Jain V, et al., (2016) and Gupta et al. (2015) [16,17] Indications for cesarean section varied slightly: fetal distress was more common in the vaginal group, while non-reactive NST was more frequent in the sublingual group, possibly reflecting pharmacokinetic differences.

Maternal side effects, including gastrointestinal symptoms, were slightly more frequent in the sublingual group (64.06%) compared to the vaginal group (53.12%), though not statistically significant, aligning with observations by Chawla et al. (2014) and Arora et al. (2013). [18,19] Neonatal outcomes were comparable between groups, supporting findings from Feitosa et al. (2006) and Bartusevicius et al. (2006) [20,21].

Although more women in the vaginal group required higher doses (3 or 4 doses), this did not reach statistical significance. The pharmacokinetic advantage of sublingual administration, with rapid absorption and higher peak plasma concentrations [8,9] [von Hertzen H,][ Mukherjee AA.], may explain the trend toward fewer doses and shorter labor duration.

These findings underscore the clinical flexibility of using either route. While the sublingual route offers convenience and potentially faster results, the vaginal route remains a reliable option, especially in settings where systemic side effects need to be minimized. Thus, the choice can be tailored to patient preference and clinical settings, as supported by Tang et al. (2004), [22] Shetty et al. (2002) [23] and others. [6-11]

## 5. CONCLUSION

The present study concluded that, both sublingual and vaginal misoprostol are feasible methods for labor induction at term, with similar efficacy and safety profiles. Further research is needed to improve dosing strategies and examine long-term maternal and neonatal outcomes.

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