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Original Research Article

Evaluating the outcomes of sublingual and vaginal misoprostol for labor induction

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ABSTRACT

Background: To evaluate and compare the effectiveness, safety, and outcomes of 25 µg sublingual versus 25 µg vaginal misoprostol used for induction of labor at term.
Methods: This retrospective observational study was conducted from May 2021 to October 2022. To analysed the records of 200 antenatal patients who were in their third trimester, specifically beyond 37 weeks of gestation. The study identified case files of patients who received induction of labor through sublingual versus vaginal misoprostol for various indications. The data collection process involved a thorough examination of the case record form, capturing essential details such as patients age, parity, clinical presentations, examination findings, and results from clinical assessments and ultrasonography. Additionally, it included pre-induction CTG readings, Bishop scores, the method of administering tablet misoprostol, the quantity of tablets utilized, modes of delivery, fetal and maternal outcomes, any complications encountered, and NICU admissions.
Results: Vaginal delivery occurred in 90% of the vaginal group and 88% of the sublingual group. The mean induction-to-delivery interval was slightly shorter in the vaginal group. Oxytocin augmentation was more frequently required with sublingual misoprostol. Adverse effects such as fever, nausea, and diarrhea were occurring slightly more in the sublingual group without statistical significance. Non-reassuring cardiotocography was the leading indication for caesarean section. Neonatal outcomes showed no significant difference.
Conclusions: Both sublingual and vaginal misoprostol are equally effective and safe for term induction. The route may be individualized according to patient preference and clinical suitability.

Keywords: Labour, Oxytocin, Sublingual misoprostol, Vaginal misoprostol

INTRODUCTION

Induction of labor is a commonly performed obstetric procedure undertaken when the benefits of delivery outweigh the risks of continuing pregnancy.[1] The ideal induction agent should be safe, inexpensive, stable at room temperature, and effective in achieving vaginal delivery within a reasonable time frame while minimizing maternal and fetal complications. Labor induction is indicated in various maternal and fetal conditions such as prelabor rupture of membranes (PROM), hypertensive disorders of pregnancy, oligohydramnios, post-term pregnancy, intrahepatic cholestasis, diabetes mellitus, and other medical complications where continuation of pregnancy poses risk. Induction methods are broadly classified into mechanical and pharmacological techniques. Mechanical approaches include membrane stripping, artificial rupture of membranes, and insertion of intracervical catheters or dilators. Pharmacological agents primarily include prostaglandins such as dinoprostone (PGE_2) and misoprostol (PGE_1).[2]

Misoprostol, a synthetic prostaglandin E1 analogue, fulfills most of these criteria. It promotes cervical ripening and stimulates uterine contractions through increased intracellular calcium release. Because of its stability at room temperature, low cost, and multiple routes of administration, it has become widely used in low-resource settings.

Different routes oral, sublingual, vaginal, and buccal yield variable absorption and pharmacodynamic effects. The American College of Obstetricians and Gynecologists (ACOG) has endorsed the use of misoprostol for labor induction, recognizing its efficacy and acceptable safety profile.[3-5]

The vaginal route allows slower, sustained release, while the sublingual route ensures rapid systemic absorption and higher peak concentrations.[6] However, the optimal route for term induction remains debated.

This study compares sublingual versus vaginal misoprostol for induction of labor at term, evaluating efficacy, maternal side effects, and neonatal outcomes.

Objectives of study was to compare the safety and efficacy of sublingual vs. vaginal misoprostol for induction of labor at term. To monitor and compare the fetomaternal outcome of the use of sublingual v/s vaginal misoprostol.

METHODS

This retrospective observational study was conducted using the records of 200 antenatal patients who were beyond 37 weeks of gestation.

Inclusion criteria

Primigravida and 2nd gravida patients with ≥37 weeks of gestation, singleton pregnancy, Bishops score ≤5, vertex presentation, reactive CTG on admission, patients fulfilling the above criteria were included in the study

Exclusion criteria

Patients with H/O previous caesarean section, CPD, malpresentation, multiple gestations, any medical or surgical disorder contraindicated for use of Misoprostol, multigravida and ≤37 weeks of gestation, intrauterine death, congenital anomalies.

Methodology

The retrospective observational study analysing the cases of Induction of Labor was performed from May 2021 to October 2022 at Department of Obstetrics and Gynecology at Dr. M. K. Shah Medical College and Research Center, Ahmedabad, after receiving ethical approval. Women received 25µg misoprostol via either the sublingual or vaginal route, repeated every six hours up to four doses or until active labor began. Oxytocin augmentation was administered if contractions remained inadequate. Data on maternal age, parity, indication for induction, Bishop score, dosage required, induction-delivery interval, mode of delivery, and maternal and neonatal outcomes were recorded.

Outcome measures of study

A correlation between age, parity, clinical indication, USG findings, mode of induction, induction to delivery time, and feto-maternal outcomes was analyzed.

All case records were divided into groups based on Vaginal mode versus Sublingual mode of induction, and the induction to delivery time was observed (with a minimum of 24 hours and a maximum of 48 hours).

The indications for induction of labor and pre-induction Bishop scores were correlated.

The total dose of tablet Misoprostol administered was studied.

Delivery outcomes were described.

Complications during the intrapartum and postpartum periods were also described.

Statistical analysis

Data were analyzed using SPSS version 19. Continuous variables were expressed as mean ± SD; categorical data were represented as percentages. Statistical significance was determined at a confidence level of 95% with p-value <0.05 was considered statistically significant.

RESULTS

A total of 200 antenatal women were analyzed 100 in the vaginal misoprostol group (Group A) and 100 in the sublingual misoprostol group (Group B).

Table 1: Distribution of women according to age.

Age groups (in years)	Group	
	Sublingual	Vaginal
≤20	16 (16%)	12 (12%)
21-25	55 (55%)	58 (58%)
26-30	25 (25%)	20 (20%)
≥30	4 (4%)	10 (10%)
Total	100	100

Table 2: Distribution of women according to parity.

Parity	Sublingual	Vaginal
Primigravida	30	40
2nd gravida	70	60
Total	100	100

Most participants in both groups were aged 21–25 years, comprising over half of the study population. A smaller proportion of women were younger than 20 years or older than 30 years

With respect to parity, second gravidae represented the majority (70% in Group B and 60% in Group A), while the remainder were primigravida Table 2.

Table 3, the most frequent indication for induction of labor in both groups was hypertensive disorder of pregnancy, followed by gestational diabetes mellitus, oligohydramnios, and premature rupture of membranes (PROM). Other less common indications included post-dated pregnancy, intrahepatic cholestasis of pregnancy, and Rh isoimmunization. The distribution of indications was similar across both groups, indicating comparability between study arms.

Table 3: Comparison of Indication for induction of labour in both groups.

Indication for induction of labour	Group A per vaginal	Group B sublingual
Premature rupture of membrane	10	20
Hypertensive disorder	21	21
Oligohydroamnios	10	11
Gestational diabetes mellitus	15	18
Postdated pregnancy	8	9
Intrahepatic cholestasis of pregnancy	15	10
Rh-isoimmunization	15	17
0-3	50	58
>3-<6	50	42

Table 4: Number of misoprostol dose given for induction and oxytocin required for augmentation.

Total dose of misoprostol	Intravaginal	Sublingual
1	25	31
2	42	43
3	23	15
4	10	11

Table 4, Most women required two doses of misoprostol to achieve effective labor induction in both groups. The requirement for oxytocin augmentation was slightly higher in the vaginal group (70%) compared with the sublingual group (50%), though this difference did not reach statistical significance (p>0.05).

Table 5, The majority of women achieved vaginal delivery in both groups 90% in the vaginal group and 88% in the sublingual group.

A higher proportion of vaginal deliveries occurred within 24 hours of induction in Group A (74%) than in Group B (60%), but this difference was not statistically significant.

Table 5: Clinical outcomes of induction in both groups.

Outcome	Group A per vaginal	Group B sublingual	P value
Vaginal delivery ir fever than 24 hour	74	60	
Need for oxytocin	70	50	0.09
Vaginal delivery	90	88	
LSCS	10	11	

Table 6: Maternal adverse effects.

Adverse effects	Group A (n=100) per vaginal	Group B (n=100) sublingual	P value
GIT effects	7	10	
Pyrexia	5	3	
Headache	2	0	
Tachycardia	2	3	0.23
Tachysystole/ Hyperstimulation	4	2	
Total	20	18	

Table 7: Neonatal outcome.

Outcome	Group A per vaginal	Group B sublingual
Maconium passage	13	15
NICU admission	10	6
APGAR Score <7 at 5 min	0	1
Perinatal death	0	0
Total	23	22

The overall rate of caesarean delivery was comparable (10% vs. 11%).

Table 6 the most frequently encountered side effects were gastrointestinal disturbances (nausea, vomiting, diarrhea) and pyrexia. Gastrointestinal effects were slightly more common in the sublingual group (10%) compared to the vaginal group (7%), whereas pyrexia was marginally higher in the vaginal group. Other adverse reactions such as headache, tachycardia, and uterine hyperstimulation were rare and showed no significant intergroup difference (p>0.05).

Table 7, neonatal assessment revealed comparable outcomes between both groups. Meconium-stained liquor was observed in 13% of Group A and 15% of Group B. NICU admission rates were 10% and 6% respectively,

while Apgar scores below 7 at 5 minutes occurred in only one neonate in the sublingual group.

There were no perinatal deaths reported in either group.

Table 8: Indications for caesarean delivery.

Fetal complications	Group A (n=100) per vaginal	Group B (n=100) sublingual
Fetal distress+ MSL	10	6
NRCTG (non reassurin cardiotocography)	18	15

Table 9: Third stage of labour complications.

Complications of third stage of labour	Group A (n=100) per vaginal	Group B (n=100) sublingual
Postpartum hemorrhage	7	4
Cervical tear	2	1
Complete perineal tear	0	0
Vulval hematoma	0	0
Total	9	5

Table 8, the most common reason for caesarean delivery in both groups was non-reassuring cardiotocography (NRCTG), followed by fetal distress with meconium-stained liquor. The distribution of caesarean indications did not differ significantly between the two routes of misoprostol administration.

Table 9, during the third stage of labor, postpartum hemorrhage (PPH) was the most frequent complication occurring in 7% of women in Group A and 4% in Group B.

Minor cervical tears were reported in 2% and 1% respectively, with no cases of perineal tear or vulvar hematoma in either group.

DISCUSSION

Main finding

This retrospective study compared the efficacy and safety of 25 µg sublingual versus 25 µg vaginal misoprostol for induction of labor at term. Both groups were comparable with respect to maternal age, parity, and indications for induction. The most common reason for induction in this study was hypertensive disorder of pregnancy, followed by gestational diabetes mellitus and PROM.

The results demonstrated that the rate of vaginal delivery was similar between the two routes 90% in the vaginal group and 88% in the sublingual group. A majority of patients required two doses of misoprostol for effective induction, and the need for oxytocin augmentation was slightly higher among those receiving vaginal misoprostol.

These findings align with previous reports by Caliskan et al and Parimkayala et al who also observed similar induction success rates with both routes.[7,8]

The preinduction Bishop score exhibited comparable results across both groups. In a study involving two groups, fifty women in group A and fifty-eight women in group B recorded a Bishop score of less than 3. Additionally, 50 women in group A and 42 women in group B fell within the Bishop score range of 3 to 6.8 Malik and colleagues conducted a study involving 100 first-time mothers with singleton pregnancies at term who experienced pre-labor rupture of membranes and had an unfavourable Bishop score.[9]

Comparison with other studies

The findings of this study are consistent with research by Shetty et al who reported comparable vaginal delivery rates within 24 hours between sublingual and vaginal misoprostol groups.[10] Similarly, Deepika et al observed a 66% vaginal delivery rate following sublingual administration, while Dorr et al reported 84.9% vaginal deliveries with a low rate of failed inductions.[11,12] Ayati et al found that 71.8% of women delivered after two doses of sublingual misoprostol, supporting the rapid and efficient action of the sublingual route.[13]

In this study, meconium-stained liquor (MSL) was slightly more common in the sublingual group. However, there was no significant difference in neonatal outcomes such as Apgar score, NICU admission, or perinatal mortality. The most frequent indication for caesarean delivery in both groups was non-reassuring cardiotocography (NRCTG), which is comparable to the findings reported by Malik et al and Shetty et al.[9,10]

Maternal safety

Adverse effects were generally mild and transient. Gastrointestinal symptoms (nausea, vomiting, diarrhea) and fever were the most frequent side effects, occurring more often with sublingual administration but without statistical significance. Tachysystole and hyperstimulation were slightly more frequent with vaginal administration, which may be attributed to prolonged mucosal absorption leading to sustained uterine activity. Similar trends have been reported in other studies comparing these two routes. Postpartum complications were minimal. Postpartum hemorrhage (PPH) was the most common third-stage complication, slightly higher in the vaginal group. No cases of severe morbidity or mortality were noted, reinforcing the safety of both methods.

Neonatal safety

Neonatal outcomes, including Apgar scores and NICU admissions, were comparable between both groups. Only one neonate in the sublingual group had an Apgar score below 7 at 5 minutes, and no perinatal deaths were

reported. This suggests that the choice of misoprostol route does not significantly affect neonatal morbidity. Similar conclusions were drawn by Deepika et al and Malik et al who also found no significant differences in fetal outcomes between routes.[9,14]

Strengths and limitations

A major strength of this study is the direct comparison between two commonly used routes of low-dose misoprostol administration under uniform clinical settings, providing real-world insights into their effectiveness. However, the retrospective nature of the study limits control over confounding variables and data uniformity. Additionally, the sample was restricted to term, low-risk pregnancies, which may not reflect outcomes in high-risk or preterm populations.

Interpretation

The findings suggest that both routes of misoprostol sublingual and vaginal are equally effective and safe for labor induction at term. The sublingual route may offer practical advantages such as ease of administration, faster onset, and better patient comfort. Meanwhile, the vaginal route ensures steady absorption and sustained uterotonic effect. Hence, the choice of route may be tailored based on patient preference, clinical scenario, and provider experience.

CONCLUSION

Both sublingual and vaginal misoprostol (25µg) are safe and effective for term induction of labor. The vaginal route offers a slightly shorter induction-delivery interval, whereas the sublingual route provides faster onset and easier administration. There is no significant difference in mode of delivery, maternal adverse effects, or neonatal outcomes. Thus, either route may be selected based on patient preference and clinical context.

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