A comparative study of sublingual and vaginal low-dose misoprostol for induction of labor

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**INTRODUCTION**

Labor induction is a clinical intervention that has the potential to confer major benefits to the mother and newborn. It is defined as an intervention designed to artificially initiate uterine contractions on a pregnant uterus that has crossed the period of viability, leading to progressive dilatation and effacement of the cervix and vaginal birth of healthy baby.[1] Induction of labor is a common obstetric procedure as around 20% of all deliveries are preceded by labor induction.[2]

The prostaglandins (PGs) are a group of physiologically active lipid compounds having diverse hormone-like effects in animals. One of them is misoprostol which is inexpensive, stored easily, and not affected by ambient temperature, and needs no refrigeration, in comparison with the other PGs. It has minimal side effects on cardiovascular system and bronchial tree smooth muscles; hence, it can be safely used in hypertensive and asthmatic patients.

Induction of labor with PGs offers the advantage of promoting cervical ripening while stimulating myometrial contractility. The American College of Obstetricians and Gynecologists has reaffirmed the use of misoprostol as a drug for induction of labor due to its proven safety and efficacy.[3]

The present study has been undertaken to compare the safety and efficacy of vaginal and sublingual misoprostol for induction of labor in women requiring induction in the Department of Obstetrics and Gynaecology in Rohilkhand Medical College and Hospital, Bareilly (UP).

**Introduction:** Labor induction is a common obstetric procedure done to initiate uterine contractions for the purpose of vaginal delivery. Misoprostol (prostaglandins E1) is a popularly used cervical ripening and inducing agent.

**Materials and Methods:** We conducted a study on induction of labor with misoprostol on antenatal patients with medical or obstetric indication who presented in the Department of Obstetrics and Gynaecology, Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh, India. **Aim and Objectives:** The aim was to compare the safety and efficacy of sublingual versus vaginal misoprostol. Maternal and neonatal outcomes were analyzed. **Result:** There was no significant difference in the demographic characteristics between the two groups. The main indication for induction in both groups was pregnancy-induced hypertension. Incidence of cesarean section was not significantly different in the two groups. **Conclusion:** There was no significant difference in maternal complications between the two groups. Sublingual misoprostol is as effective and safe as vaginal misoprostol for induction of labor at term.

**KEY WORDS:** Induction of labor, misoprostol, sublingual, vaginal
Aim
The aim of the study was to compare both the safety and efficacy of low-dose misoprostol by two different routes that are sublingual and vaginal.

Objectives
The objectives of the study were (1) to compare induction to delivery intervals between sublingual and vaginal routes of misoprostol administration; (2) to evaluate maternal and fetal outcomes after sublingual and vaginal routes of administration.

MATERIALS AND METHODS
The present study was a randomized prospective study carried out in the Department of Obstetrics and Gynaecology, Rohilkhand Medical College and Hospital, Bareilly (UP), from 2014 to 2015. The permission for the same was obtained from the hospital ethical committee, Rohilkhand Medical College and Hospital, Bareilly (UP). Consent in written was obtained from all the patients who participated in the study.

Inclusion Criteria
The following criteria were included in the study:
• Live singleton pregnancy of gestation age 37–40 weeks with medical and obstetrics indication for induction of labor
• Both primigravida and multigravida
• Cephalic presentation
• Reassuring fetal heart tracing
• Bishop score <6.

Exclusion Criteria
The following criteria were excluded from the study:
• Previous cesarean delivery
• Malpresentation
• Multiple pregnancy
• Known contraindication to use of PGs (asthma)
• Cranio Pelvic Disproportion (CPD).

The patients were divided into two groups: Groups A and B patients who received 25 µg misoprostol sublingually were considered in the Group A, and those who received 25 µg misoprostol vaginally were considered in the Group B [Table 1].

Demographic details such as age, parity, gestational age, and indication for induction were noted. In all these patients, the cervical status was assessed using Bishop’s score before induction. Repeat Bishop’s was assessed before every repeat dose.

Labor was managed according to labor room protocol (partographically) for decision regarding oxytocin augmentation, artificial rupture of membrane (ARM), and administration of labor analgesia. Primary outcome was measured by vaginal deliveries achieved and induction to delivery interval [Table 2]. Secondary outcome was measured by including incidence of cesarean section for fetal distress, incidence of failed induction, occurrence of side effects such as hyperstimulation, tachysystole, fever, nausea, and vomiting. Neonatal outcomes were assessed by Apgar score and neonatal intensive care unit (NICU) admission. Failed induction was diagnosed when women did not go into labor or cervix was not favorable enough for ARM at the end of induction protocol; birth asphyxia was defined by Apgar score ≤3 or requirement of ventilation.

OBSERVATIONS
In both the groups, age characteristics were found to be similar.

On comparing the indications for induction, there were 18 (18%) cases of pregnancy-induced hypertension in the sublingual group and 23 (23%) in the vaginal group. None of the cases of eclampsia were found in the sublingual group whereas 21% cases were found in the vaginal group, 2% and 8% cases of gestational diabetes were found in sublingual and vaginal group respectively 0.25% cases of postdated pregnancy were found in sublingual and vaginal group. only 1 case of polyhydramnios was reported in vaginal group and 45% cases of premature rupture of membrane was found in sublingual group.

There was no significant difference in Bishop’s score in the sublingual and vaginal groups [Table 3].

There was no significant difference in relation to augmentation of labor in the sublingual and vaginal groups. Furthermore, there was no significant difference in cases in relation to mode of delivery in the sublingual and vaginal groups.

There was no significant difference between sublingual and vaginal misoprostol with an average induction delivery interval in relation to primigravida ($P = 0.0838$). Average induction delivery interval in multigravida was in $8.61 \pm 3.16$ h in the sublingual group and $11.55 \pm 5.35$ h in the vaginal group. This was highly significant.

In Group A, in which misoprostol was used sublingually for induction of labor, 2% had maternal complications. In Group B, in which misoprostol was used vaginally for induction of labor, 2% had maternal complications (vomiting and precipitate labor).

There was no significant difference in cases in weight of the babies in the sublingual and vaginal groups. About 100% of babies were alive in both Groups A and B.

DISCUSSION
In the present study, a total number of cases of sublingual (Group A) mean dose of misoprostol for delivery was $2.65 \pm 1.07$ and in cases of vaginal (Group B) required mean dose for delivery was $3.5 \pm 1.25$.

In this result is consistent with the study done by Feitosa et al. that mean dose in the sublingual group was $2.8 \pm 1.2$ and in the vaginal group the mean dose was $2.6 \pm 1.2$. Furthermore, the study by Prabha et al. showed similar result since mean
A comparative study of sublingual and vaginal low-dose misoprostol for induction of labor

Amrin et al. A comparative study of sublingual and vaginal low-dose misoprostol for induction of labor

The number of doses required was more in vaginal as compared to the sublingual group. This is mostly because pharmacokinetics is different in sublingual versus vaginal administration of misoprostol. For sublingual administration, the onset of action is 11 min and duration of action is 3 h. For vaginal administration, the onset of action is 20 min and duration of action is 4 h; it is clear by the pharmacokinetics that the time of onset is short in sublingual misoprostol. More number of cases in the vaginal group required oxytocin augmentation in the present study, similar to other studies. In the present study, 80% of antenatal women in the sublingual group were delivered vaginally which was comparable to other studies.

The mean induction to vaginal delivery interval in the present study in comparison to other studies shows that there is a significant reduction in the induction to vaginal delivery interval with sublingual misoprostol [Table 4]. The difference is statistically highly significant ($P = 0.00001$), indicating that sublingual route of administration leads to lesser induction to delivery intervals as compared to vaginal. It was found that 7% of babies in the sublingual group and 15% in the vaginal group had 5 min Apgar score <7 [Table 5]. The difference was not statistically significant ($P = 0.1577$). In the present study, 8% of cases required admission to NICU in the sublingual group. In the previous studies such as Yasmeen et al. and Prabha et al., NICU admissions were almost comparable. About 2% of cases from the sublingual group developed side effects such as nausea, vomiting, and fever, whereas vaginal group 2% of cases developed vomiting and precipitate labor [Table 6].

CONCLUSIONS

Women who received sublingual misoprostol, experienced shorter induction to delivery intervals, and required fewer doses of misoprostol their requirement of oxytocin augmentation were much less than those who received vaginal misoprostol. Sublingual misoprostol could be more acceptable to the patients and could be an attractive option for induction of labor at term. Sublingual misoprostol has an added advantage over vaginal misoprostol in cases of PROM. Sublingual misoprostol is as effective and safe as vaginal misoprostol for induction of labor at term.

REFERENCES


