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Study of Sublingual versus Intravaginal Misoprostol for Induction of Labour at a Tertiary Hospital

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Abstract
Background: *Induction of labor is its intentional initiation before spontaneous onset, with the aim of vaginal birth which is safe for mother and newborn. Misoprostol has been extensively investigated for use in cervical ripening and labour induction. It has several potential advantages such as stable at room temperature, relatively inexpensive, and can be administered by several routes (oral, vaginal, sublingual, and buccal). The present study was carried out to study the effectiveness and safety of 25 µg tablets of misoprostol sublingually every 6 h for the induction of term labor, compared with the same dose administered vaginally.* ***Material and Methods:*** *Present study was conducted in patients required termination of pregnancy. 100 pregnant women of satisfying inclusion & exclusion criteria, requiring induction of labour for any obstetrical and medical indication were selected for the study. Patients were randomized into two groups as group A received 25 µg misoprostol sublingually& group B received 25 µg misoprostol vaginally. The data was analyzed with SPSS version 23. Statistically significant differences were evaluated using t- test & Chi square test. P value of <0.05 was considered as statistically significant.* ***Results:*** *Maximum patients from sublingual misoprostol group required 50 µg dose to progress into active labour (44%) while maximum patients from vaginal misoprostol group required 75 µg dose to progress into active labour (46%). Though when number of doses were compared, difference was not statistically significant. Modified Bishop's Score at time of induction was comparable in both groups. Tachysystole, hypertonus, hyperstimulation & non reassuring FHR were noted in present study. These adverse events were comparable in both groups. Non reassuring FHR was noted in 7 & 8 patients in sublingual & vaginal misoprostol group respectively. Caesarean section was required in 24% & 22% patients in sublingual & vaginal misoprostol group respectively. Fetal distress was most common indication in both groups. Mean induction to vaginal delivery interval was not statistically significant. Nausea/vomiting was more common in sublingual misoprostol group (6%) compared to vaginal misoprostol group (2%). NICU admission was required in 10 % & 8% neonates in sublingual & vaginal misoprostol group respectively & difference was not statistically significant. No stillbirth or neonatal mortality was noted in present study.*
Conclusion: *A low dose of 25 µg sublingual or vaginal misoprostol are equally safe and effective methods for labor induction in women with unfavorable cervix in third trimester of pregnancy. Also, majority of the women do not need any oxytocin augmentation of labor.*

Keywords: *induction of labour, misoprostol, vaginal, sublingual*

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I. Introduction

Induction of labor is its intentional initiation before spontaneous onset, with the aim of vaginal birth which is safe for mother and newborn. The common indications for induction of labor include pre-labor rupture of membranes, gestational hypertension, oligohydramnios, non-reassuring fetal status, post-term pregnancy, and various maternal medical conditions such as chronic hypertension and diabetes.[1]

Misoprostol, a PGE1 analogue, was developed and marketed as an oral medication for prevention and treatment of nonsteroidal anti-inflammatory drug (NSAID) induced upper GI ulcers. The effects of misoprostol are dose dependent and it includes cervical softening and dilation, contraction of uterus, nausea, vomiting, diarrhea, fever and chills.[2]

Misoprostol has been extensively investigated for use in cervical ripening and labour induction. It has several potential advantages such as stable at room temperature, relatively inexpensive, and can be administered by several routes (oral, vaginal, sublingual, and buccal).[3] These properties make misoprostol a useful agent for

induction of labour, particularly in settings in which the use of prostaglandin E2 is not possible because of a lack of availability, a lack of facilities for storage, or financial constraints.

Sublingual misoprostol has additional advantages, which include its easier administration, greater freedom of position after insertion and avoidance of repeated vaginal examinations.[4] Sublingual route might be the optimal route of administration because the avoidance of the first pass hepatic circulation would yield bioavailability similar to that achieved with the vaginal route along with an earlier onset of action and a prolonged activity. The present study was carried out to study the effectiveness and safety of 25 µg tablets of misoprostol sublingually every 6 h for the induction of term labor, compared with the same dose administered vaginally.

II. Material And Methods

Present study was conducted at Department of Obstetrics and Gynecology, Anugrah Narayan Magadh medical college & Hospital,Gaya(Bihar) over a period of 24 months (From January 2017 to December 2018). The study was approved by institutional ethics committee. Study population was in patients required termination of pregnancy.

Inclusion criteria

Informed consent of the pt.

- Full term pregnancy (>37 weeks gestation)
- Live foetus
- Singleton pregnancy
- Cephalic presentation
- Unfavourable cervix (Bishop's score <6)
- Reassuring faetal heart tracing
- Absence of uterine contractions

Exclusion criteria

- Multiple Pregnancies
- Parity ≥ 4
- Malpresentation,
- Antepartum haemorrhage
- Previous uterine scar
- Oligohydramnios (AFI < 5);
- Polyhydramnios (AFI > 25cm)
- Non reassuring faetal heart rate pattern
- IUGR
- Cephalopelvic disproportion
- Maternal renal and hepatic disease
- Hypersensitivity to prostaglandins
- Chorioamnionitis& hyperthermia > 38°c

100 pregnant women of satisfying inclusion & exclusion criteria, requiring induction of labour for any obstetrical and medical indication were selected for the study. Informed consent was taken from the patient for induction. A thorough history and clinical examinations was done. Demographic data such as age, parity, height, weight was recorded. Reason for induction and Bishop's score at the time of induction was recorded.

These cases were randomized into Group A and Group B.

1. Group A received 25 µgms misoprostol sublingually. Tablet misoprostol was placed below the tongue and were instructed not to swallow the drug.
2. Group B received 25µgms misoprostol vaginally in the posterior fornix.

The dose is scheduled to be repeated once in every 4 hours if necessary, that is, if regular uterine contractions have not started within 4 hours of first dose. Further doses were administered at 4 hours interval depending on the patients' response to a maximum of six doses.

Once the patient went into active labour, partogram were maintained and faetal heart sounds were monitored strictly. Number of doses of misoprostol administered to each woman in both the groups was recorded. Induction to delivery interval time was recorded in all patients. Number of patients who required oxytocin augmentation in both the groups was recorded. Percentage of patients going for caesarean section in each group was calculated and the indication for the same was recorded.

Fetal outcome such as APGAR scores at 1minute and 5 minutes, passage of meconium and NICU admission were recorded. The data was analyzed with SPSS version 23. Statistically significant differences were evaluated using t- test & Chi square test. P value of <0.05 was considered as statistically significant.

III. Results

Patients selected for study were divided into two groups A & B for sublingual & vaginal misoprostol (50 patients each). Maximum patients from sublingual misoprostol group required 50 µg dose to progress into active labour (44%) while maximum patients from vaginal misoprostol group required 75 µg dose to progress into active labour (46%). Though when number of doses were compared, difference was not statistically significant.

Table-1: Distribution of cases according to total dosage of misoprostol

No of doses	Total dosage of misoprostol	Group A Sublingual misoprostol (n = 50)	Group B Vaginal misoprostol (n = 50)	p value
1	25 µg	4 (8%)	2 (4%)	
2	50 µg	22 (44%)	19 (38%)	
3	75 µg	18 (36%)	23 (46%)	
4	100 µg	3 (6%)	1 (2%)	
5	125 µg	2 (4%)	3 (6%)	
6	150 µg	1 (2%)	2 (4%)	
Number of doses (mean ± SD)		2.91 ± 1.38	3.10 ± 1.28	0.721

Modified Bishop's Score at time of induction was comparable in both groups. Tachysystole, hypertonus, hyperstimulation & non reassuring FHR were noted in present study. These adverse events were comparable in both groups. Non reassuring FHR was noted in 7 & 8 patients in sublingual & vaginal misoprostol group respectively. Caesarean section was required in 24% & 22% patients in sublingual & vaginal misoprostol group respectively. Fetal distress was most common indication in both groups. Mean induction to vaginal delivery interval was not statistically significant. Nausea/vomiting was more common in sublingual misoprostol group (6%) compared to vaginal misoprostol group (2%).

Table 2. Comparison of labour outcomes

Characteristics	Group A Sublingual misoprostol (n = 50)	Group B Vaginal misoprostol (n = 50)	p value
Modified Bishop's Score at time of induction			
≤ 3	18 (36%)	15 (30%)	
4-6	16 (32%)	17 (34%)	
>6	16 (32%)	18 (36%)	
Adverse events, n (%)			
Tachysystole	1 (2%)	1 (2%)	
Hypertonus	1 (2%)	0	
Hyperstimulation	0	1 (2%)	
Non reassuring FHR	7 (14%)	8 (16%)	
Mode of delivery, n (%)			
Spontaneous vaginal delivery	32 (64%)	34 (68%)	0.192
Instrumental delivery	6 (12%)	5 (10%)	
Caesarean section	12 (24%)	11 (22%)	
Induction–vaginal delivery interval (mean ± SD in hours)	18.42 ± 3.5	19.05 ± 3.2	0.221
Vaginal delivery within 24 hours, n (%)	21 (42%)	19 (38%)	
Oxytocin augmentation	14 (28%)	16 (32%)	
Failed induction	2 (8%)	1 (2%)	
Indication for LSCS			
Fetal Distress	7 (14%)	8 (16%)	
Failed Induction	2 (8%)	1 (2%)	
Non-progress of labour	3 (8%)	2 (4%)	
Maternal adverse effects			
Nausea/vomiting	3 (6%)	1 (2%)	
Fever	0	1 (2%)	
Diarrhea	1 (2%)	0	
Postpartum hemorrhage	1 (2%)	1 (2%)	

NICU admission was required in 10 % & 8% neonates in sublingual & vaginal misoprostol group respectively & difference was not statistically significant. No stillbirth or neonatal mortality was noted in present study.

Table 3: Neonatal outcome

Neonatal complications	Group A Sublingual misoprostol (n = 50)	Group B Vaginal misoprostol (n = 50)	p value
NICU admission	5 (10%)	4 (8%)	0.322
Birth asphyxia	2 (4%)	3 (6%)	
Resuscitation at birth	5 (10%)	5 (10%)	
Neonatal jaundice	7 (14%)	4 (8%)	

IV. Discussion

The ideal method for induction of labour chosen should achieve quick onset of labour, low incidence of failure to induce labour, should not cause an increase in perinatal morbidity and also prevent an increase in cesarean section or instrumental delivery rate as compared to spontaneous labour.[5]

Evidence on misoprostol for induction of labour at term was derived from three systematic reviews *(17–19)* which include a large number of randomized controlled trials.[6-8] Cochrane Reviews have concluded that oral misoprostol is more effective than placebo and at least as effective as vaginal dinoprostone for induction of labor with doses not exceeding 50 μg; similarly, while vaginal misoprostol is more effective than other conventional methods, low-dose oral misoprostol is preferable.[6,7] WHO and FIGO recommend the use of oral (25 μg, at two-hour intervals) or vaginal (25 μg, at six-hour intervals) misoprostol for the induction of labor.[9,10]

Although induction of labor is associated with an increased rate of cesarean delivery independent of parity, the effect is most pronounced in nulliparous women with unfavorable cervices.[11] Patients required termination of pregnancy, should have been screened for trial of labour. As compared to caesarean delivery , vaginal delivery has less chances of infective morbidity, did not require general or spinal anaesthesia, provide early ambulation and early discharge, results in better bonding and early breast feeding.[12]

The dose requirement for misoprostol in the sublingual misoprostol group was reported to be more as compared to the vaginal misoprostol group in other studies, although the difference was less appreciable in the present study.[13,14] Augmentation with oxytocin was required in 28% & 32% patients in sublingual & vaginal misoprostol group respectively. Another Indian study bt Sheela et al noted similar findings.[15]

Siwatch S et al,[15]. noted that mean induction delivery were similar in both vaginal misoprostol and sublingual misoprostol groups (16.17 ± 5.96 hours vs 15.25 ± 5.03 hours). Mean number of doses of misoprostol required for induction of labor was similar in vaginal misoprostol group and sublingual misoprostol group (1.81 ± 0.84 vs 2.05 ± 0.98). In present study we noted similar findings.[16]

Akare and Patel[17] conducted a study with a singleton post-term pregnancy and a live fetus requiring induction of labor were allocated to sublingual and vaginal administration of misoprostol. They noted that the sublingual route of misoprostol was associated with a reduced risk of failed induction, reduced time from initiation to induction, reduced induction to delivery interval and a higher incidence of maternal and fetal side effects. However, the differences were not statistically significant.

In a study by Rahman H et al,.[18] noted that the mean induction-to-vaginal delivery interval and the number of women who delivered within 24 hours was similar in the oral and vaginal misoprostol groups, with no difference in CS rates and neonatal outcomes. Similar findings were noted in present study.

An ideal inducing agent must be effective, non- invasive, economical, and safe to mother and fetus. It must achieve labor in shortest possible time, with lower incidence of failure to achieve vaginal delivery and with no increase in perinatal morbidity. We did not noticed any significant difference between sublingual & vaginal misoprostol, for induction of labour. Still sublingual misoprostol has advantage of being a non- invasive route.

Present study limitations were small sample size, lack of a placebo group and lack of blinding after randomization. Multicentric studies with larger number of women are needed to achieve a statistical power sufficient to compare the occurrence of infrequent events.

V. Conclusion

A low dose of 25 μg sublingual or vaginal misoprostol are equally safe and effective methods for labour induction in women with unfavourable cervix in third trimester of pregnancy. Also, majority of the women do not need any oxytocin augmentation of labour.

Conflict of Interest: None to declare
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