Original Research Paper

Volume-8 | Issue-6 | June-2018 | PRINT ISSN No 2249-555X

Gynecology

A COMPARISON OF SUBLINGUAL WITH VAGINAL ADMINISTRATION OF MISOPROSTOL FOR INDUCTION OF LABOR AT TERM

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ABSTRACT

Background: To compare the efficacy and safety of sublingual route of misoprostol with vaginal route of administration.
Methods: This study was conducted at Department of Obstetrics and Gynecology, Alluri Sitarama Raju Academy of Medical Sciences, Eluru, India. 50 cases each with a singleton term pregnancy and a live fetus requiring induction of labor were allocated to sublingual and vaginal administration of misoprostol. Outcome measures related to labor and maternal and fetal side effects were compared between the two groups and evaluated using Chi square test and t-test.
Results: The sublingual route of misoprostol was associated with a reduced risk of failed induction, reduced induction to delivery interval. The incidence of cesarean sections, major side effects and vaginal delivery were similar in both the group. Neonatal outcomes of both groups were comparable.
Conclusions: The sublingual route of administration of misoprostol is comparable in efficacy and safety to the vaginal route for induction.

KEYWORDS : Induction of labour, Misoprostol, Sublingual

INTRODUCTION

Induction of labour can be defined as an intervention intended to artificially initiate uterine contractions resulting in progressive effacement and dilatation of cervix.1There are various methods of induction of labour. 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.

Amongst the various techniques available for induction of labor, Prostaglandins remain the single most effective means of achieving cervical ripening and inducing labor and have been administered through various routes. Pharmacological studies suggest that sublingual route might be the optimal route of administration for PGE1 analogue misoprostol 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.2-5This has generated an interest in the sublingual route for labor induction. Because of easy administration, less frequent need for vaginal examination, greater freedom of position and the possibility of its convenient use despite vaginal bleeding or ruptured membranes make sublingual route a better alternative.

Various studies have found that sublingual administration of misoprostol is also effective for induction of labour.6-8 This study was designed to compare the efficacy and safety of tablet misoprostol 25 µg administered sublingually with that of routinely employed tablet misoprostol 25 µg administered vaginally for induction of labor at term.

MATERIALAND METHODS

This study was conducted at Department of Obstetrics and Gynecology, Alluri Sitarama Raju Academy of Medical Sciences, Eluru, Andhra Pradesh, India over a one-year period. The study included 100 subjects. There were 50 cases each in both the groups i.e. sublingual and vaginal

Inclusion criteria

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

Exclusion criteria

- Multiple Pregnancies
- Para ≥ 4
- Malpresentation,
- Antepartum hemorrhage
- Previous uterine scar
- Severe oligohydramnios (AFI < 5);
- Polyhydramnios (AFI > 25cm)
- Non reassuring fetal heart rate pattern
- IUGR
- Cephalopelvic disproportion
- Renal and hepatic disease
- Hypersensitivity to prostaglandins
- Chorioamnionitis& hyperthermia > 38°c

METHODOLOGY

100 pregnant women of more than 37 weeks gestation requiring induction of labour for any obstetrical and medical indication were selected for the study either from antenatal ward or emergency admission to labour room. All these cases were admitted for induction of labour by misoprostol either by sublingual route or vaginal route.These cases were randomized into Group A and Group B. Group A included the antenatal women receiving 25µgms misoprostol sublingually. Group B includes the antenatal women receiving 25µgms misoprostol vaginally in the posterior fornix. The dose is scheduled to be repeatedonce in every 4 hours if necessary, that is, if regular uterine contractions have not started within 4 hours of first dose.

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. Informed consent was taken from the patient for induction. Women were allotted for either of two groups by means of non-probability convenience means of sampling. In women selected to receive sublingual misoprostol (Group A) 25 mcg of misoprostol was placed below the tongue and were instructed not to swallow the drug. Further doses were administered at 4 hours interval depending on the patients' response to a maximum of six doses. In women selected to receive vaginal misoprostol (Group B), 25 mcg of misoprostol was placed in posterior fornix. 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 labor, partogram were maintained and fetal 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 cesarean section in each group was calculated and the indication for the same was recorded.

Fetal outcome measures included APGAR scores at 1minute and 5 minutes, passage of meconium and NICU admission. Number of babies with APGAR score of < 7 at 1 minute and 5 minutes in either group was recorded. Number of babies that passed meconium in either group was recorded. Number of babies requiring NICU admission in each group was recorded.

STATISTICALANALYSIS :

The data was analyzed with the help of computer software SPSS version 12.0 for windows. Statistically significant differences were evaluated using t- test & Chi square test. P value of <0.05 was considered as statistically significant.

RESULTS :

Of hundred pregnant women recruited for the study, 50 women received sublingual misoprostol and 50 women received per vaginal misoprostol.

A comparative study containing 100 pregnant women (>37 weeks) undergoing induction of labor;

- 50 patients in group A (Sublingual misoprostol)
- 50 patients in group B (per vaginal misoprostol)

Table 1 : Demographic profile

Variable	Sublingual misoprostol	Vaginal misoprostol
Mean Maternal age	23.88±3.5 yr	23.08±3.42 yr
Gravida		
Primi Gravida	35(70%)	40(80%)
Second Gravida	13(26%)	7(14%)
Third Gravida	2(4%)	3(6%)
Gestational age		
40- 42 weeks	29(58%)	33(66%)
37-40 Weeks	21(42%)	17(34%)
Indication for induction		
Past dates	29(58%)	34(68%)
PROM	8(16%)	1(2%)
Mild PIH	10(20%)	9(18%)
Severe PIH	1(2%)	1(2%)
Oligohydramnios	2(4%)	5(10%)
BISHOP'S score		
0-3	17(34%)	21(42%)
4-6	33(66%)	29(58%)

In this study, mean age in group A & B was almost comparable. 70% in group A & 80% in group B were primigravida. Various indications for induction were mentioned in Table 1, out of which past dates and mild PIH were common indications. Bishop's score in both groups was comparable but statistically insignificant with p-value of 0.49.

Table 2 : Outcome of induction

Variable	Sublingual misoprostol	Vaginal misoprostol	p-value
Doses required for induction			
1	19(38%)	14(28%)	p-value 0.001, statistically significant
2	17(34%)	18(36%)	
3	10(20%)	12(24%)	
4	1(2%)	3(6%)	
5	1(2%)	2(4%)	
6	2(4%)	1(2%)	
Augmentation with oxytocin	10(20%)	14(28%)	
Induction delivery interval			
≤ 12 hrs	28(56%)	21(42%)	
12-24 hrs	15(30%)	23(46%)	P-value 0.25
≥ 24 hrs	7(14%)	6(12%)	
Average IDI	14.14hrs	14.74 hrs	

In this study, 38% in sublingual group & 28% in vaginal group required single dose for induction. After 3doses, labour was induced in almost 90% cases in both groups. Augmentation with oxytocin was required lesser in sublingual group (20%) as compared to the vaginal group (28%). The averageinduction delivery interval in group A & group B is comparable.As the sample size in small, the distribution of cases in relation to induction delivery interval is statistically insignificant (table 2).

Table 3 :Labour outcome& complications

Variable	Sublingual misoprostol	Vaginal misoprostol	p- value
Mode of delivery			
Labour normal	31(62%)	29(58%)	Statistically insignificant , p-value > 0.05
Outlet Forceps	4(8%)	2(4%)	
Ventouse	1(2%)	1(2%)	
Cesarean Section	14(28%)	18(36%)	
Indication for LSCS			
Fetal Distress	13(26%)	15(30%)	
Failed Induction	1(2%)	3(6%)	
Tachysystole	4%	2%	p-value >0.05 statistically insignificant
Nausea & vomiting	4%	2%	
Non reassuring FHR	15(30%)	14(28%)	
Meconium stained liquor	14%	24%	
5min APGAR < 7	2%	2%	
Admission to NICU	6%	18%	
Neonatal death	0	2	
Patient's acceptability	41(82%)	31(62%)	

In present study, 72% of antenatal women in sublingual group & 64% in group B were delivered as labour normal. Cesarean section is slightly higher in vaginal group than sublingual with common indication in both being fetal distress.

Uterine tachysystole is more common with sublingual misoprostol. There is more incidence of meconium stained liquor, NICU admission rate, perinatal morbidity and mortality with vaginal group in this study. Sublingual route had higher patient acceptability rate than vaginal route.

DISCUSSION

In present study, majority of the cases about 38% were delivered with single dose ofsublingual misoprostol.It was statistically significant (p-value 0.001). In Feitosa et al9 only 21% of antenatal women were delivered with single dose of sublingual misoprostol ,in Shetty et al10 study 71%& in Samuel B wolf et al11 study 60%. The total number of doses of sublingual misoprostol required for delivery were 2.1. In Feitosa et al study, was 2.8 & in Shetty et al,Samuel B et alstudies 1.5 & 1.7 respectively. In present study total number of doses of vaginal misoprostol required for delivery were 2.2, In Bartusevicius etal12 study and Feitosa et al study the total number of doses of vaginal misoprostol required for delivery were 1.3 and 2.6 respectively.

The average latent period in group A was 6.07 hours where as in group B it was 7.26 hours.In present study number of women required oxytocin for the delivery in Group A were 20 % & 51.3 % in Eraycaliskanet al13 study respectively.In present study number of women required oxytocin for the delivery in Group B were 28 % whereas in Sheela et al14 it was 23%.72 % of antenatal women in Group A were delivered as labour normal which was comparable to 65.5% in MORAES filho et al15 study. 28 % of cases of Group A were delivered with cesarean section where as in Feitosa et al study it was 43 %.In present study, 64 % of antenatal women in Group B were

delivered as labour normal which was comparable to 69% of Feitosa et al study.

Maternal side effects like nausea and vomiting in Group A were 4 % & in Feitosa et al study it was 12 %. Uterine hyperstimulation (Tachysystole) pattern was present in Group A in about 2 % of cases which was equal to 1.7% in MORAES et al group & in group B, tachysystole was present in about 4 % cases, which was almost equal to 3.2 % in MORAES et al study.

The average induction delivery interval in Group A was 14.14 hours, which was comparable with 12 hours of Eraycaliskan et al study& in Group Bit was 14.74 hours which was almost equal to that in Ratna Khatri et al16 study.The number of women delivered within 12 hours& 24 hours in Group A were 56%& 86%, where in Feitosa et al study it was 32%& 81 % respectively.88% of antenatal women in Group B were delivered within 24 hours which was almost equal to 79%of Feitosa et al study.

Babies with 5 minute APGAR score <7 in Group A were 2% which was less than 3.4 percent in MORAES et al study & in Group B it was 2%.In group A,14% of cases had meconium stained liquor which was more when compared to 5.2 % of MORAES et al study& in group B, it was 24 % which was almost equal to A Bartsevicius et al study of 27 %.The patient's acceptability in sublingual misoprostol group 82%,was almost equal toNassar AH et al17 study 80.3% & in vaginal misoprostol group its was 62 % , almost equal to 63.9 % in Nassar AH et al study.

CONCLUSION

Misoprostol is effective in induction of labor both with sublingual and vaginal routes. Sublingual route has significantly less induction time delivery interval. Number of doses required in sublingual group was lesser compared to pervaginal group. Only few patients had minor side effects in both groups. No major side effects were reported. Administration by sublingual group avoids repeated vaginal examination. Sublingual route seems to have better efficacy than vaginal Misoprostol, seems to be acceptable to patients and is an option to be considered to induce labour at term.

REFERENCES

1) Induction of labour: evidence-based clinical guideline number 9. London (UK): Royal College of Obstetricians and Gynaecologists Press; 2001
2) Tang OS, Schweer H, Seyberth HW, Lee SW, Chung Ho P. Pharmacokinetics of different routes of administration of misoprostol. Hum. Reprod. 2002;17(2):332-6.
3) Tang OS, Gemzell-Danielsson K, Ho P C. Misoprostol: Pharmacokinetic profiles, effects on the uterus and side effects. Int J GynaecolObstet. 2007;99:160-7.
4) Aronsson A, Bygdeman M, Gemzell-Danielsson K. Effects of misoprostol on uterine contractility following different routes of administration. Hum Reprod. 2004;19(1):81-4.
5) Tang OS, Schweer H, Seyberth HW, Lee SW, Chung Ho P. Pharmacokinetics of repeated doses of misoprostol. Hum. Reprod. 2009;24(8):1862-9.
6) Bartusevicius A, Barcaite E, Nadisauskiene R. Oral, vaginal and sublingual misoprostol for induction of labor. Int J Gynaecol Obstet. 2005;91(1):2-9.
7) Feitosa FEL, Sampaio ZS, Alencar CA Jr, Amorim MMR, Passini R Jr. Sublingual versus vaginalmisoprostol for induction of labour. Int J Gynaecol Obstet. 2006;94:91-5.
8) Bartusevicius A, Barcaite E, Krikstolaitis R, Gintautas V, Nadisauskiene R. Sublingual compared with vaginal misoprostol for labour induction at term: a randomised controlled trial. BJOG. 2006;113:1431-7.
9) Feitosa et al. Misoprostol 50 µ gms sublingual versus vaginally for labour induction at term: a randomized study. Gynecolobstet invest 2005 : 59:155– 161.
10) Shetty A, et al Sublingual misoprostol for the induction of labor at term. Am J Obstet Gynecol. 2002;186(1):72-6
11) Wolf SB, et al Sublingual misoprostol for labor induction: a randomized clinical trial. ObstetGynecol 2005;105:365–71.
12) BartusevicusA,etal,Sublingual compared with vaginal misoprostol for labour induction at term: a randomised controlled trial. BJOG 2006;113:1431–1437
13) Caliskan E, et al Labour induction post term with 25 micrograms vs. 50 micrograms of intravaginal misoprostol. Int J Gynecol Obstet. 2003;81:249–55.
14) Ayati Sheela et al. / IJPR (2014), 13 (1): 299-304, Vaginal Versus Sublingual Misoprostol for Labor Induction at Term and Post Term: a Randomized Prospective Study.
15) MORAES et al, sublingual versus vaginal Misoprostol for induction of term pregnancies .Rew. Bras. Gynecol. Obstet, Jan 2005, Vol. 27, No. 1, p.24-31 ISSN 01000-7203.
16) Ratna Khatri et al. Oral: Vaginal Misoprostol:Which route for induction of term labor Nepal journal of OBG,2007;2(1):23-28.
17) Nassar A, et al,Arandomised comparison of patient satisfaction with vaginal and sublingual misoprostol for induction of labour at term. BJOG 2007;114:1215–1221