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Sublingual Versus Vaginal Misoprostol For Induction Of Labour At Term

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Objective*: To compare the efficacy of sublingual with vaginal misoprostol for induction of labour in primigravida at term.*
Study Design*: Randomized controlled trial.*
Place and Duration of Study*: Department of Obstetrics and Gynaecology V.S.S. Medical College &Hospital ,Burla, Odisha.*
Methodology*: The study included 102 primigravidaswith singleton pregnancy at term, havingunfavourable Bishop score with no contraindication of induction of labour, vaginal delivery or misoprostoluse. The cases were randomized into two equal groups, A and B. Women in the group A were given 25 µg of misoprostolvaginaly at an interval of 4 hours to a maximum of 6 doses while patients in the group B were prescribed the medicine sublingually (25 µg, 4 hourly, maximum of 6 doses). Induction to delivery interval, mode of delivery and fetomaternal complications were main outcome measures of the study.*
Results*: In the sublingual misoprostol group (B), 92% women delivered within 12 hours of induction while 84% of subjectsdelivered in this time period in vaginal group (A, p < 0.05). There was no failed induction in either group. Regarding dosage,64% of women delivered with 2-3 dose in group B while only 32% delivered with 4-5 dose in group A (p < 0.05). Thefrequency of vaginal delivery was 92% in group B versus 80% in group A, while rate of caesarean section was 8% in thegroup B and 20% in the group A, which is statistically insignificant. No significant fetomaternal complications were seen inboth groups.*
Conclusion*: The efficacy of sublingual misoprostol in the dosage of 25 µg was comparable to 25 µg vaginal dose for theinduction of labour in the primigravida at term with unfavorable bishop score.*
Key words*: Misoprostol, Labour induction, Primigravida, Sublingual, vaginal administration*

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I. Introduction

The artificial initiation of uterine activity in a quiescent uterus in pregnancy beyond 28 weeks of gestation or before the onset of spontaneous labourthat aims to secure a vaginal delivery is called as induction of labour (IOL). The incidence of IOL has been reported to be 50% in 1993 (2) and has further increased due to PIH, postdatism, IUGR and congenital malformations.

Exogenously administered Prostaglandins are relatively newer Pharmacological agents used for IOL. Initially PGE2 gel was used intracervically but due to its high cost and cold storage problems, it is being replaced by newer PGE1 tablets for effective and safe induction.

Misoprostol (PGE1) tablets acts as effective myometrial stimulant, is quiet stable in vivo and is rapidly absorbed orally and vaginally. Furthermore, it is cost-effective as compared to the commercial dinoprostone prostaglandin preparations for the induction of labour in women with an unfavourable cervix. This agent is especially relevant for a country like INDIA with scarce economic resources and high temperature. However, the safest and most effective dosage and route of administration of the drug is generally not yet agreed.Recent studies have found that sublingual administration of misoprostol is very effective for induction of labour. AlsoWHO in 2010 in Geneva crafted a protocol in which oral and vaginal misoprostol for IOL.

Therefore, the aim of the present study was to compare the efficacy and safety of sublingual with vaginal misoprostol for induction of labour in primigravidae at term as it provides less inconvience to the patient and bypasses the1st pass metabolism at the same time. In addition causes less nausea and more patient satisfaction.

AIMS AND OBJECTIVE

1)To compare efficacy of 25 mcg of sublingual vs vaginal administration of Misoprostol for labor induction
2) To compare induction delivery interval
3) To compare the maternal complications
4) To compare the Fetal outcome

II. Matreial And Methods

The study was conducted on 102 pregnant women at term in deptt of obst. & Gynae, VSS medical college and Hospital, burlasambalpur over a period of one year. After getting full informed consent, the subjects were randomly assigned to two groups viz : vaginal misoprostol (Group-a), and sublingual misoprostol (Group-b) A detailed history followed by general physical examination was done to rule out any cardio-respiratory, hepatic and renal disease, obstetrical examination included P/A – for fundal height, lie, presentation and fetal heart sound. P/V - examination was done for assessing bishop's score and pelvis. Routine biochemical investigations include ABO/ Rh, Hb, BT, CT, Urine examination and obstetrical USG was done.

INCLUSION CRITERIA:

1) favorable Bishop score
2) Single live intrauterine gestation
3) Intact membrane
4) Cephalic presentation
5) >/= 37 weeks pregnancy
6) Sonographic weight evaluation less than 4000g

Exclusion criteria:

1) Twin pregnancy
2) Other fetus presentations
3) Previous uterine scars
4) Cephalopelvic disproportions
5) Any medical disorder like cardiac disease or asthma
6) AFI < 5
7) Premature rupture of membrane
8) Antepartum haemorrhage

Procedure: By means of a computer-generated randomization table, 102 cases were randomized into two equal groups, A and B. Women in the group A were given 25 µg of misoprostol vaginaly at an interval of 4 hours to a maximum of 6 doses while patients in the group B were prescribed the medicine sublingually (25 µg, 4 hourly, maximum of 6 doses). Fetal auscultation every 15 min was performed during labor in all patients, before, during, and after contractions. The uterine activity was clinically assessed every 30 min. During whole intrapartum period strict monitoring of fetal heart rate rhythm was done & uterine activity was monitored for tachysystole, hypertonus& hyper stimulation syndrome. Induction of labour was considered to have failed when cervix was unfavourable for amniotomy after 24 hours or after 5 doses of misoprostol and cesarean section was performed

III. Results

In the sublingual misoprostol group (B), 92% women delivered within 12 hours of induction while 84% of subjects delivered in this time period in vaginal group (A, $p < 0.05$). (table 1)

Induction Delivery Interval(table 1)

Time (hrs)	Group A VAGINAL Misoprostol	Group B SUBLINGUAL Misoprostol	P value
< 12	43 (84%)	**47 (92%)**	< 0.05
12 - 24	3 (5 %)	2 (4 %)	< 0.05
> 24	5 (11%)	2 (4%)	<0.05

There was no failed induction in either group.

Regarding dosage, 64% of women delivered with 2-3 dose in group B while only 32% delivered with 4-5 dose in group A ($p < 0.05$). (table 2)

Distribution of Cases according to Total Dosage of Misoprostol(table 2)

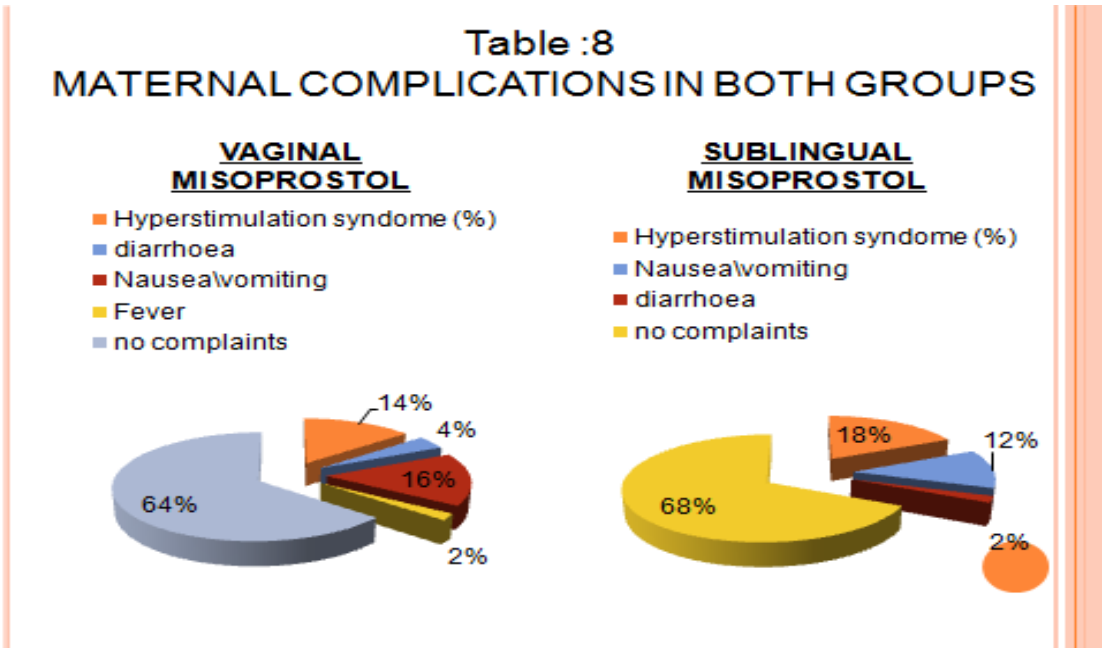
No. of Doses	Total Dosage of Misoprostol	Group A VAGINAL Misoprostol	Group B SUBLINGUAL Misoprostol
1	25mcg	3	4
2	50mcg	9	**17**
3	75mcg	**19**	**21**
4	100mcg	**17**	8
5	125mcg	2	1
6	150mcg	1	0

The frequency of vaginal delivery was 92% in group B versus 80% in group A, while rate of caesarean section was 8% in the group B and 20% in the group A, which is statistically insignificant.

Clinical outcomes of induction in both groups(table 3)

ITEMS	VAGINAL MISOPROSTOL	SUBLINGUAL MISOPROSTOL	P VALUE
Oxcytocin use (%)	32 (50.9)	**28 (49.2)**	0.855
Induction failure (%)	3 (5.3)	2 (3.17)	0.910
VAGINAL DELIVERY (OVERALL)	80%	**92%**	**0.044**
Spontaneous vaginal delivery (%)	69 %	**85 %**	**0.042**
LOW FORCEPS	6%	3%	0.76
VENTOUS	5 %	4 %	0.78
Cesarean section (%)	**20 %**	8%	**< 0.05**

No significant fetomaternal complications were seen in both groups.



Fetal complication intabulated form

ITEMS	VAGINAL MISOPROSTOL	SUBLINGUAL MISOPROSTOL	P VALUE
Still birth	1	0	-
Apgar < 7 at 5 min	4	1	< 0.05
NICU admission (%)	5 (8.8)	4 (6.3)	0.734

Statistical Analysis

The data was analysis with the help of computer software SPSS120 for windows. The data represented as percentage as well as mean & SD as being appropriate. Statistically significant difference were evaluated using Chi square test. A p value of <.05 was considered as statistically significant.

IV. Discussion

IOL is an integral component of any maternity practice and is often taken up in the interest of mother and fetus. The present study demonstrated comparable efficacy and safety of 25mg of misoprostol sublingually to 25mg vaginal dose for induction of labour in women at term. Elhassan also concluded the safety and efficacy of 50 µg misoprostol sublingual while comparing it with oral and vaginal route. FEITOSA FE et al in 2006 studied the effect of 25mcg s/l misoprostol in singleton term pregnancy and concluded thatactive labor occurred in 100% of cases after misoprostol administration.The mean (+/ -SD) induction-to-labor interval was 4.8(+/ -3.8 hrs. Interval from induction-to-delivery varied from 8 to 31 hours with 95% of the deliveries occurring in the first 24 hours with 75% of vaginal deliveries. The frequency of tachysystole was 12.5%. The women did not present relevant side effects nor were there any neonatal complications which corresponds to the result of our study. FurtherZahrane et al 2004 randomized double blind placebo controlled clinical study, using the same inclusion criteria as us, found that sublingual Misoprostol resulted in a shorter induction to delivery interval, more women delivered within 24h of induction and fewer patients required Oxcytocin augmentation compared with those using vaginal Misoprostol ,The same finding as our study groups. Wolf described that 100 µg of sublingual misoprostol was more effective than 50 µg of sublingual misoprostol but the incidence of tachysystole and uterine hyperstimulation syndrome was higher with that dose.

In our study ,the sublingual route doesn't increase cesarean section rate compared to vaginal route 8% vs 20% as in study by Feitosa et al 2006 showed a non significant but considerable difference between cesarean section rate due to fetal distress in both groups (15% vs 5% respectively vaginal and sublingual misoprostol) .In contradiction with the literature our sublingual group experienced more **hyperstimulation** syndrome (11% vs 3.5%), statistically significant But Zahrane et al 2004 findings showed that sublingual route is greater safety than vaginal route.Elhassan et al. 2007 also concluded the increased safety and efficacy of 50 µg misoprostol sublingual while comparing it with oral and vaginal route.

No baby in Group B needed NICU admission, clearly ruling out any adverse affect of the drug on the neonate's health even though one baby in each of the other two groups needed NICU admission but discharged in healthy condition. Careful monitering of labour is essential for reducing neonatal complications.

V. Conclusion

There is no doubt that IOL confers benefit in various material & fetal conditions. Our present study emphasized thatSublingual Misoprostol is as safe and efficient as vaginal Misoprostol in the induction of labor in viable term pregnancies at doses of 25 mcg.It reduces the cesarean rate with increase in vaginal delivery and has better fetal outcome than vaginal route. Therefore, sublingual misoprostol may be an option for induction of labour in selected patients.

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