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Comparative study of oral versus vaginal misoprostol 25 mcg for induction of labour at term in a Medical College Hospital in South India – Prospective Study

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Abstract

Objective of the study is to compare the safety and efficacy of oral versus vaginal misoprostol 25mcg for induction of labour at term and to assess perinatal out come.

Materials and Method: Study was conducted in the department of Obstetrics and Gynecology (OBG) at P K Das Institute of Medical Sciences, Vaniamkulam. It was a one year study. It is a comparative prospective study on 300 patients admitted at term for safe confinement. The patients were divided into 2 groups – 150 in each – 25 mcg oral misoprostol / 25mcg vaginal.

Results: There is no statistically significant association between parity and route of administration of drug. There is statistically significant association between Premature Rupture of Membranes (PROM) and route of administration of drug.

In oral group- 66.6 % had Induction Delivery interval between 8-12 hrs and in vaginal group – 68% had Induction Delivery interval between 8-12hrs.

In oral group - 100 % had 2 repeat doses. In vaginal group - 90% had 2 repeat doses.

In oral group, 80% had normal delivery. Only 6.66% had LSCS.

In vaginal group, 73.33% had normal delivery. 13.33% had LSCS.

In oral group, 96.66% had no NICU admission. In vaginal group, 97.33% had no NICU admission.

Among the oral group of those patients who had atonic Post Partum Hemorrhage (PPH), three required blood transfusions.

Conclusion: In our study, oral misoprostol 25mcg is as effective as vaginal misoprostol 25mcg for induction of labour at term with minimal maternal and fetal complications.

Keywords: Induction of labour, Misoprostol, Maternal complication, Fetal complication.

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Introduction

Induction of labour is done to initiate uterine contraction prior to their spontaneous onset.(1) About 20% of pregnant women will have labour induced for variety of reasons.

Induction of labour involves the use of some methods (Mechanical, Pharmacological or Surgical) on a pregnant uterus that has crossed the period of viability to result in the onset of uterine contractions & hopefully end in vaginal delivery of a healthy baby. Mechanical methods of induction of labour are among the oldest methods to initiate labour.(2) Most hospital statistics have shown that induction rates have gone up drastically. Pharmacological methods used for induction of labour include prostaglandins (PGE2), Misoprostol (PGE1) Mifepristone & Relaxin.(3) In the absence of a ripe cervix, a successful vaginal delivery is less likely. Various methods of induction of labour have been used, but prostaglandins still remain a preferred method for cervical ripening and labour induction.(4) Misoprostol is well absorbed by oral route with peak plasma concentration achieved earlier than vaginal route.(5)

Induction of labour at term in the presence of an unfavorable cervix leads to failed induction &increased cesarean section rates. The use of prostaglandin preparations with or without oxytocin infusion is widely used for labour induction. Prostaglandin preparations reduce induction time and reduces risk of failed induction.

Misoprostol is cheap and requires no special storage arrangement. Misoprostol can be used by various routes like vaginal, sublingual and oral.(6) Misoprostol when used vaginally can result in uterine hyperstimulation.(7) Women with decreased fetal movements but with a reassuring nonstress test had safe delivery with vaginal route when used for induction of labour.(8)

When used in low doses Misoprostol is as effective as dinoprostone.

Objective of the study

1. To compare the safety and efficacy of oral versus vaginal misoprostol 25mcg for induction of labour at term.
2. To assess perinatal outcome.

Materials and Method

The present study was conducted in the department of OBG at P K Das Institute of Medical Sciences, Vaniamkulam for a period of 1 year. This is a comparative prospective study on 300 patients admitted

at term for safe confinement. They were divided into 2 groups - 150 in each group – 25mcg oral misoprostol / 25mcg vaginal.

Inclusion criteria - Primigravida or multi gravida with singleton pregnancy / Twins
Cephalic presentation
Term patients
PROM
Bishop score < 5
Reactive Non Stress Test (NST)

Exclusion criteria - Scarred uterus
Malpresentations
Known allergy to prostaglandins
Gand multipara
Intrauterine growth restriction
Cervical dilatation > 3cm
Uterine contractions > 3/10 min
Cephalopelvic disproportion (CPD).

Written informed consent for induction of labour, route of drug administration, side effects of the drug and possible maternal / fetal complications were taken on admission. Investigations reviewed and repeated if necessary before induction. Patients were reassessed again. Clinical examination with per abdomen examination done to confirm lie, presentation, gestational age, estimated fetal weight and liquor. Vaginal examination was done to assess Bishop score and to rule out CPD. Admission NST was done and made sure it was reactive. NST repeated before induction and after each insertion of misoprostol.

Group 1 received oral 25mcg misoprostol every 4 hourly to a maximum of 6 doses after maternal and fetal monitoring.

Group 2 received vaginal misoprostol 25mcg. Tablet was moistened with normal Saline and inserted into the posterior fornix of vagina. Subsequent doses were administered 4th hourly and Bishop score noted before every administration. Maternal and fetal parameters were assessed by partogram. Drug was repeated every 4th hourly till adequate uterine contractions were achieved (3 C/10") or cervical dilatation (> 3cm) with maximum of 6 doses.

Complications like tachysystole, hypertonus & uterine hyperstimulation were monitored. If any of the above conditions occur, no further drug was given. Labour was managed according to labour room protocols. Once delivery is achieved, duration of induction – delivery interval, mode of delivery, meconium staining liquor, Apgar score, maternal side effects of drug with nausea, vomiting, diarrhea and shivering were noted. Need of oxytocin augmentation was noted. Finally number of doses required for induction was also analysed. Incidence of postpartum haemorrhage & rupture uterus was also analysed.

Results

This was a comparative prospective study on 300 patients at term for induction of labour. The patients were divided into 2 groups – 150 in each group – 25mcg oral / 25mcg vaginal misoprostol was given.

Table 1: Parity

Parity	Oral		Vaginal	
	No.	%	No.	%
Primi	90	60	92	61.3
Multi	60	40	58	38.6
Total	150	100.0	150	100.0

P = 0.81 (P value > 0.05). Hence it is non-significant. There is no statically significant association between parity and route of administration of drug.

Table 2: PROM

PROM	Oral		Vaginal	
	No.	%	No.	%
	120	80	100	66.6
Total	150	100	150	100

P Value = 0.009 (P Value < 0.05). Hence it is significant. There is statistically significant association between PROM and route of administration of drug.

Table 3: Induction – Delivery Interval

1 – D Interval	Oral		Vaginal	
< 8 hrs	No.	%	No.	%
	20	13.3	2	1.3
8 – 12 hrs	100	66.6	102	68
>12 hrs	30	20	46	30.6
Total	150	100.0	150	100.0

In oral group- 13.3% had 1-D interval <8hrs. 66.6 % 1- D interval between 8-12 hrs.20% I-D interval >12hrs.

In vaginal group – 1.3% had I-D interval < 8 hrs. 68% had I-D interval between 8-12hrs.30.6% had I-D interval > 12hrs.

Table 4: No. of repeat doses

No. of repeat doses	Oral		Vaginal	
	No.	%	No.	%
2	150	100	135	90
3	0	0	15	10
6	0	0	0	0
Total	150	100	150	100.0

In oral group - 100 % had 2 repeat doses.
In vaginal group - 90% had 2 repeat doses, 10% had 3 repeat doses.
In both the groups, none received 6 doses.

Table 5: Mode of delivery

Mode of delivery	Oral		Vaginal	
	No.	%	No.	%
FTND	120	80	110	73.33
Instrumental	40	26.66	20	13.33
LSCS	10	6.66	20	13.33
Total	150	100.0	150	100.0

In oral group, 80% had normal delivery. 26.66% had instrumental delivery. Only 6.66% had LSCS.

In vaginal group, 73.33% had normal delivery. 13.33% had instrumental delivery and 13.33% had LSCS.

Table 6: NICU admission

NICU admission	Oral		Vaginal	
	No.	%	No.	%
No	145	96.66	146	97.33
Yes	5	3.33	4	2.66
Total	150	100	150	100

In oral group, 96.66% had no NICU admission. Only 3.33% had NICU admission.

In vaginal group, 97.33% had no NICU admission. Only 2.66% had NICU admission.

Discussion

Misoprostol is an efficacious and cost effective alternative to various other drugs used for induction of labour.[9] This study was conducted on 300 patients who were admitted at term for induction of labour. They were divided into 2 groups – 150 in each group – 25mcg oral / 25mcg vaginal misoprostol.

Study shows that both the routes are safe and effective for induction of labour and can be alternatively used. Observations noted among the oral group were multigravida responds better with multiple doses. If induction was done for PROM with oral, they had successful vaginal delivery. Induction – active phase was long, but active – delivery phase was short. Multiple doses were needed in majority. Oxytocin augmentation was needed in majority (140 patients out of 150). Good Apgar score & less NICU admission needed in oral group.[10]

There were no maternal side effects with oral group. Incidence of PPH was low, except one case with traumatic PPH and needed internal iliac ligation and blood transfusion. Various studies of misoprostol have shown that oral misoprostol is safer in terms of incidence of uterine hyperstimulation and fetal distress.[11] Compared to vaginal misoprostol, oral is safer and has the lowest rate of caesarean section.[12] In vaginal group, also, complications were less and vaginal misoprostol found to be effective; except PROM cases where oral misoprostol responds better. There were no cases of rupture uterus in both the groups.

Women has to be given information about what is not known and what is known regarding methods of induction in order to participate fully in decision making.[13] Misoprostol may be the best prostaglandin for induction of labour.[14] WHO has incorporated recommendations to use misoprostol in induction of labour, prevention and treatment of postpartum haemorrhage and management of spontaneous and induced abortion.[15]

Conclusion

In our study, oral misoprostol 25mcg is as effective as vaginal misoprostol 25mcg for induction of labour at term with minimal maternal and fetal complications.

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