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A comparative study of oral V/S vaginal misoprostol for induction of labor conducted at Karwar institute of medical science, Karwar, Karnataka

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Abstract

Objective: To study the efficacy of 50 µg of Misoprostol tablet for induction of labor, oral v/s vaginal route.
Methods: 100 women, at term gestation, with various indication for induction of labor with Bishop's score of ≤4 were included. After deciding, 50 women received 50 µg orally and 50 women received 50 µg vaginally every fourth hourly (maximum of 6 doses) or till they went into active labor.
Results: After statistical analysis it was found that in vaginal misoprostol route the induction to delivery interval was significantly less compared to oral misoprostol group (9.5 v/s 160).
It was also found that the required dose of drug in vaginal route is less compared to oral route (40% of women need only 2 doses in vaginal group compared to 35% of oral group were 6 doses required).
Conclusion: For induction of labor vaginal misoprostol is always more effective compared to oral route.

Keywords: Misoprostol, vaginal misoprostol, oral misoprostol, labor induction

Introduction

Labor induction with unfavourable cervix is always met with failure and also increased incidence of C-section. Various agents and methods had been used with own merits and demerits. Presently prostaglandins is getting advantage for labor induction over other agents especially PGE_1 and PGE_2.
Prostaglandin E_2 is more often used as gel (cerviprime) and it is more expensive. But PGE_1 is a synthetic prostaglandins originally used as anti-secretary drug for gastro-protective purpose [4]. Presently the drug is used as labor inducing agent by the obstetrician worldwide [5]. The drug is cheap, stable at room temperature, easy to administer by oral, rectal and vaginal route. The absorption by oral route is rapid erratic, reaching peak in 30 minutes and compared to one hour in vaginal route. The elimination of the drug occurs in 2 hours in oral as compared to 4 hours in vaginal route. Hence the vaginal route is more safer and the induction delivery interval is reduced with less complication compared to oral route.

Methods and materials

This study is undertaken to compare 50 µg of misoprostol oral with vaginal route. At the beginning 106 women at term included in the study group. Accordingly every women received one tablet of misoprostol. The route of administration was selected randomly. The tablet is repeated every fourth hour to maximum of 6 doses.

All women who were admitted to the labor room of Karwar Medical College, Karwar, with various indication for labor induction were included in the study randomly. An informed consent was taken before the study protocol.

Initial study group included 106 women at term. The following selection criteria were made-singleton pregnancy, cephalic presentation, no fetal congenital malformation, reactive fetal heart tracing, Bishop Score ≤4 and rupture of membrane less than 4hours of duration. Exclusion criteria includes women with Bishop score >4, cephalo pelvic disproportion, placenta previa/abruption, previous LSCS or other uterine surgery, active herpes simplex infection, chorioamnionitis, carcinoma cervix, and contradictions for the use of prostaglandins like asthma, hypersensitivity and PID. Out of 106 women under the study 6 were excluded due to the above exclusion criteria.

After detailed history and thorough clinical examination the women was given 50 µg misoprostol tablets orally and categorized. Similarly next selected woman the labor was inducted with 50µg of misoprostol inserted vaginally in the post fornix and categorized. The progress of labor was monitored carefully, monitoring uterine contractions that is:- intensity, frequency, regularity and duration. Similarly fetal well-being is monitored carefully. And any untowered complications was noted and treated immediately (nausea, vomiting, diarrohea, distress most often seen). All women with above complications treated with IV fluids, anti-emetics etc. The women was said to be in active labor when '3' uterine contractions is present in every 10 minutes lasting for ≥ 60 seconds with good intensity. In both oral and vaginal group, misoprostol tablets were repeated every 4^{th} hourly till the woman went into active labor or 6 doses of tablets have been given. Once the patient attained active labor no further doses were given. If the women doesn't start the active labor 4 hours after the 6^{th} dose of the tablet, the induction of labor is said to be failed. After the failed induction if there is no immediate indication for LSCS labor was augmented with oxytocin and observed.

During the process if there were no signs of hyper-stimulation like: contraction for more than 120 seconds or if more than 6 contractions per 10 minutes or if associated with abnormal fetal heart pattern the induction was abandoned and the tablet in the posterior fornix of vagina is removed and if necessary terbutaline 0.25 mg is given sub-cutaneously. Further ARM was done and vaginal delivery was tried if there was no emergency obstetric indication for LSCS. A observational note was made regarding the mode of delivery, intra-partum, postpartum, maternal/fetal complications. Both mother and baby were observed throughout the stay in the hospital.

The intention of the observation is to measure the efficacy of oral v/s vaginal route of misoprostol for induction of labor that is the total number of women who attained active labor within 24 hours of induction and also their induction to delivery interval. We also measure the total dose of misoprostol required for delivery and mode of delivery. The other data included maternal age parity, socioeconomic status, indication for induction and Bishop's score.

Statistical analysis and result

After the data collection and the study materials were analyzed and tabulated to arrive at the conclusion. In the present study out of 106 women 100 were taken for induction of labor. 50 women received 50µg of misoprostol orally and other 50 received vaginally. Six women were excluded from the study group because of the following reasons:- active herpes simplex (1 women), premature rupture of the membrane (3 women), undiagnosed breech (2 women); Maternal demographic factors and indications for labor were compared and analyzed (table-1). The commonest indication for induction of labor was hypertensive

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disease of pregnancy both in vaginal and oral group. The successful induction rate was 80% in case of vaginal group and 69.5% in oral group, which is statistically significant (table-2).

Table 1: Shows the demographic characteristics and indications for induction of labor in the present study (Expressed as median or percentage)

Demography		
Age (years)	25 (20-40)	26 (20-40)
Primigravida	30 (60.75%)	26 (48%)
Duration of pregnancy (weeks)	39 (37-42)	39 (37-42)
	Oral misoprostol group N=50	Vaginal misoprostol group N=50

Indication for induction:		
Pregnancy with hypertension	42 (84%)	46 (92%)
IUGR	4 (8%)	3 (6%)
Oligohydramnios	2 (4%)	1 (2%)
Diabetes mellitus	2 (4%)	0 (0%)

Induction to active labor interval also was analyzed. It was shorter in vaginal group compared to oral group (median 6.5 hours v/s 9 hours). Similarly induction to delivery interval also shorter in vaginal group compared to oral group (9.6 hours v/s 16 hours). The study also shows greater number of women delivered within 24 hours with vaginal misoprostol induction compared to oral misoprostol. (Table-2)

Table 2: Outcome of labor induction (values represented as median or percentage)

	Oral misoprostol group N=50	**Vaginal misoprostol group N=50**
Successful induction	35 (69.5%)	43 (80%)
Failures	15 (30.5%)	7 (20%)
Induction-active labor interval	9 hours	6.5 hours
Induction-delivery within 24 hours	16 hours	9.6 hours
Number delivered within 24 hours	34	43
Median dose required	6	3
Hyperstimulation	1	0
Uterine rupture	0	0

It was found lesser fetal heart abnormalities with vaginal misoprostol group compared to oral misoprostol group (Table-3). The majority women in the present study gave birth vaginally in both the groups but the incidence of LSCS was more with oral misoprostol induction. (Table-4) Commonest indication for casearen section was fetal distress in both oral and vaginal group.

Table 3: Dose of misoprostol required

Total dose of misoprostol		**Oral group**		**Vaginal group**	
Number of tablets	**In µg**	**Delivered**	**Not delivered**	**Delivered**	**Not delivered**
1	50	4	-	5	-
2	100	11	-	16	-
3	150	6	-	12	-
4	200	4	-	7	-
5	250	7	-	6	-
6	300	3	15	-	4
Total		50		50	

Table 4: Neonatal outcome

Parameters	Oral group N=50	Vaginal group N=50
Birth weights (in kg)	2.75 (1.5 to 4)	2.8 (1.5 to 4)
APGAR at 1 minute	8	8
APGAR at 5 minute	9	9
Meconium staining	2	1
Fetal heart changes	9	6
Live birth	50	50
Still birth	0	0

The neonatal outcome in both the group was good with the median APGAR score 8, 9 at 1 and 5 minutes respectively (Table-4). Two neonates required NICU admission for low birth weight with RDS (Table-4).

Table 5: Mode of delivery

Mode of delivery	Oral misoprostol group N=50	Vaginal misoprostol group N=50
Vaginal	35	46
Normal	33	42
Forceps	2	4
C-section	15	4

Discussion

Misoprostol is the drug with significant use for induction of labor. Vaginal misoprostol is the best route of administration for both cervical ripening and induction of labor. In the present study, labor induction with 50 µg of misoprostol by vaginal route results in greater number of vaginal deliveries compared to oral route of misoprostol (86.5% v/s 69.5%). Shetty at all [4] reported lower failure with 50 µg of vaginal misoprostol as compared to oral route and also reported shorter induction to delivery interval. Biswajith C *et al*. [1] observed 100% success rate with both oral and vaginal 50µg of misoprostol.

The vaginal misoprostol is absorbed rapidly and slowly eliminated from the body hence, greater concentration of the drug will be available at any time in the body compared to oral route. This results in greater number of women delivering within 24 hours of induction. The main disadvantage of the drug is the hyper-stimulation of the uterus with its adverse effects like uterine rupture and fetal asphyxia. The above complication is always dose related. The reported contractile abnormality with 50 µg of misoprostol vaginally, varies with different study. Jindal *et al*. [6] reported 9%, Wing DA *et al*. [7] reported 12%. In our study, the reported incidence of uterine contractile abnormalities was 10%. Despite increased incidence of uterine contractile abnormality there was no drastic increase in rate of LSCS in the present study. The LSCS rate is significantly more with oral misoprostol group compared to vaginal misoprostol group (24.5% v/s 9.2%). The commonest indication for LSCS was fetal distress in both oral and vaginal group.

Finally misoprostol and its regular use by vaginal and oral route does not adversely affect the neonatal and maternal outcome [5, 6].

Conclusion

Misoprostol by vaginal route is definitely, highly effective compared to oral route as a cervical ripener and labor inducing agent which demands careful monitoring of uterine abnormality throughout the labor.

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