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Evaluation of Oral versus Vaginal Misoprostol for Induction of Labour: A Comparative Study.

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ABSTRACT

Background: Induction of labor is the artificial initiation of labor before its spontaneous onset for the purpose of delivery of the feteplacental unit using mechanical or pharmacologic methods.The success of labor induction depends on the cervical status at the time of induction. About 20% of pregnant women will have labour induced for variety of reasons. **Methods:**This was a comparative prospective study on 90 patients at term for induction of labour. The patients were categorized into two groups – Group A and Group B in each group – 25mcg oral / 25mcg vaginal misoprostol was given. **Results:** The mean age of patients was 27.42±8.6 years in oral group A, 25.52±6.23 years in in the vaginal group B (p=0.48). The mean period of gestation was 38.23±11.24 weeks in the oral group A, 38.87±12.02 weeks in in the vaginal group B (p=0.58). The mean Bishop was 3.43±0.73 in oral group A, and 3.51±0.49 in the vaginal group B (p= 0.37). **Conclusion:** Induction of labor, 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, 25 mcg Misoprostol, Oral route and vaginal route.

INTRODUCTION

Induction of labor is the artificial initiation of labor before its spontaneous onset for the purpose of delivery of the feteplacental unit using mechanical or pharmacologic methods.[1] The success of labor induction depends on the cervical status at the time of induction. About 20% of pregnant women will have labour induced for variety of reasons. It is generally predicted that the patients with a poor Bishop's score have unacceptably higher rates of failure of induction.[2] The prostaglandin that has been the agent of choice for labour induction is prostaglandin E2 (PGE2 or dinoprostone). The use of misoprostol, a synthetic PGE1 analogue commonly used as a gastric cytoprotective agent, was first reported in 1987 for the induction of labour in cases of intrauterine fetal death in the third trimester.[3] Since then, there has been an increasing interest in its use for labour induction at term. 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.[4] 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.[5] 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.[6] Misoprostol is well absorbed by oral route with peak plasma concentration achieved earlier than vaginal route.[7] 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.[8] Misoprostol when used vaginally can result in uterine hyperstimulation.[9] Women with decreased fetal movements but with a reassuring nonstress test had safe delivery with vaginal route when used for induction of labour.[10] When used in low doses Misoprostol is as effective as dinoprostone. Aim of the present study was to compare the safety and

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efficacy of misoprostol 25 mcg when administered in equivalent doses orally and vaginally for induction of labour at term.

MATERIALS & METHODS

This study was conducted in the Department of Obstetrics and Gynaecology, Nimra Institute of Medical Sciences, Nimra Nagar, Ibrahimpatnam, Jupudi, Vijayawada, Andhra Pradesh. A total of 90 pregnant women at term in department of Obstetrics and Gynecology, Nimra Institute of Medical Sciences, during the period of eighteen months i.e., from November 2016 to May 2018. Ethical committee approval was taken. After getting full informed consent, the subjects were randomly assigned into two groups:

Group A: 45 pregnant women received oral 25mcg misoprostol- every four hourly to a maximum of six doses after maternal and fetal monitoring.

Group B: 45 pregnant women 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. Routine biochemical investigations include RBS, ABO/ Rh, Hb, BT, CT, Urine examination and obstetrical USG was done.

RESULTS

This study was conducted in the Department of Obstetrics and Gynaecology, Nimra Institute of Medical Sciences. This was a comparative prospective study on 90 patients at term for induction of labour. The patients were categorized into two groups – Group A and Group B in each group – 25mcg oral / 25mcg vaginal misoprostol was given. [Table1] Shows the demographics with regard to age, period of gestation, parity, Bishop Score and indication for induction of labor were similar in all the three groups. The mean age of patients was 27.42±8.6 years in oral group A, 25.52±6.23 years in in the vaginal group B (p=0.48). The mean period of gestation was 38.23±11.24 weeks in the oral group A, 38.87±12.02 weeks in in the vaginal group B (p=0.58). The mean Bishop was 3.43±0.73 in oral group A, and 3.51±0.49 in the vaginal group B (p= 0.37).

Table 1: Demographic charateristics of subjects

Variablels	Group A	Group B	P-value
Maternal age in year	27.42±8.6	25.52±6.23	0.48
Period of gestation in weeks	38.23±11.24	38.87±12.02	0.58
Pre-induction Bishop score	3.43±0.73	3.51±0.49	0.37

Table 2: Shows the Parity of subjects

Parity	Oral (n=45)		Vaginal (n=45)	
	No.	%	No.	%
Primi	28	62.2	29	64.4
Multi	17	37.8	16	35.6
Total	45	100	45	100

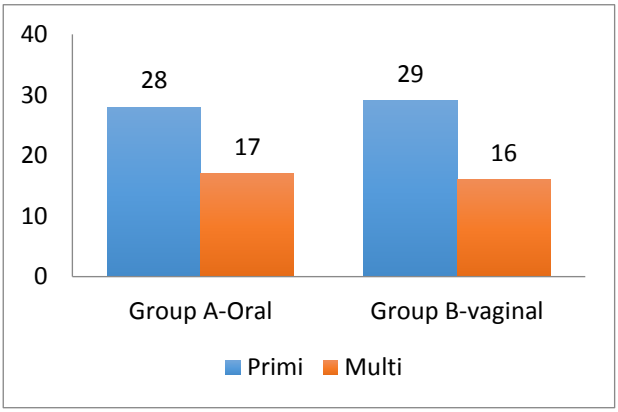

Figure 1: Shows the Parity of subjects.

[Table 2 & Figure 1] Shows the statistically not significant association between parity and route of administration of drug P=0.68 (P value > 0.05).

Table 3: Shows the Prom of subjects.

Variable	Oral (n=45)		Vaginal (n=45)	
	No.	%	No.	%
PROM	35	77.8	30	66.7
Total	45	100	45	100

[Table 3] Shows the statistically significant association between PROM and route of administration of drug P= 0.001 (P Value < 0.05).

Table 4: Shows the Induction – Delivery Interval of subjects

1–D Interval	Oral (n=45)		Vaginal (n=45)	
	No.	%	No.	%
< 8 hrs	7	15.6	3	6.7
8 – 12 hrs	28	62.2	31	68.9
>12 hrs	10	22.2	11	24.4
Total	45	100	45	100

[Table 4] Shows the oral group A- 15.6% had 1-D interval <8hrs, 62.2 % 1- D interval between 8-12 hrs and 22.2% I-D interval >12hrs. Similarly, In vaginal group B – 3.0% had I-D interval < 8 hrs. 68.9% had I-D interval between 8-12hrs and 24.4% had I-D interval > 12hrs.

Table 5: Shows the No. of repeat doses in the subjects.

No. of repeat doses	Oral (n=45)		Vaginal (n=45)	
	No.	%	No.	%
2	45	100	38	84.4
3	0	0.0	7	15.6
6	0	0.0	0	0.0
Total	45	100	45	100

[Table 5] Shows the oral group A - 100 % had 2 repeat doses. In vaginal group B - 84.4 % had 2 repeat doses, 15.6 % had 3 repeat doses. In both the groups A & B, none of them received 6 doses.

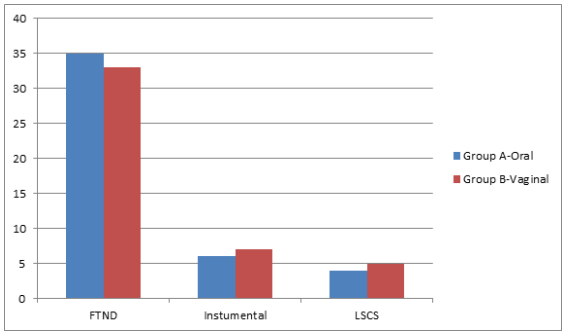

Figure 2: Shows the Mode of delivery.

[Figure 2] Shows the oral group A, 35 (77.8 %) had normal delivery. 06(13.3 %) had instrumental delivery and Only 04(8.9 %) had LSCS. Similarly, In vaginal group B, 33(73.33%) had normal delivery. 07(15.6 %) had instrumental delivery and 05(11.1 %) had LSCS.

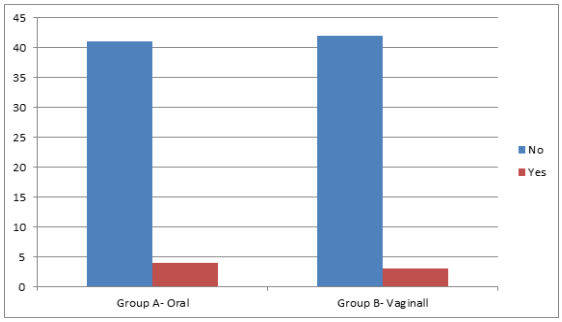

Figure 3: Shows the NICU admission.

[Figure 3] Shows the oral group A, 41(91.1 %) had no NICU admission and Only 04(8.9 %) had NICU admission. Similarly, In vaginal group B, 42(93.3%) had no NICU admission and Only 03(6.7 %) had NICU admission.

DISCUSSION

The use of prostaglandin E1 analogue, Misoprostopl for induction of labor has been quite promising. It is inexpensive can be stored at room temperature, has minimal side effects at low doses, can be administered with ease by various routes like oral, sublingual, vagina, buccal and rectal and more importantly acts to promote cervical ripening and uterine contractions. Doses ranging from 25 mcg to 200 mcg have been used but doses more than 50 mcg is associated with uterine contraction abnormalities, meconium passage and uterine rupture.[11] There are several studies comparing oral and vaginal misoprostol as well as sublingual and vaginal misoprostol for labor induction.[12-15] The mean age, parity period of gestation and the initial Bishop score was similar in all the two groups. This distribution was similar to previous studies by Shetty et al studies.[16] Oral-group A and vaginal-group B shows that in both the routes are safe and effective for induction of labour and can be alternatively used. Observations noted among the oral group A were multigravida responds better with multiple doses. If induction was done for PROM with oral group A, 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. Good Apgar score & less NICU admission needed in oral group A.[17] There were no maternal side effects with oral group A. 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.[18] Compared to vaginal misoprostol, oral is safer and has the lowest rate of caesarean section.[19] In vaginal group B, 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.[20] Misoprostol may be the best prostaglandin for induction of labour.[21] WHO has incorporated recommendations to use misoprostol in induction of labour, prevention and treatment of postpartum haemorrhage and management of spontaneous and induced abortion.[22] Thus, present study shows that the fetal outcome results were also comparable in both the groups A & B. Maternal side effects were also same in the both groups and similar findings were seen in studies by Benette et al and Shetty et al.[16,23]

CONCLUSION

In conclusion, this study shows that for induction of labor, oral misoprostol 25mcg is as effective as

vaginal misoprostol 25mcg for induction of labour at term with minimal maternal and fetal complications. The number of dosage required is less; induction delivery interval is less, less incidence of failed induction and less rate of Cesarean section. Neonatal outcome and maternal side effects are comparable in both the groups.

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