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Comparison of Vaginal vs Oral Misoprostol for Induction of Labor at Term Gestation

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Abstract: To compare efficacy and safety of 50 microgram misoprostol vaginally with oral route for induction of labor at term gestation. Total 100 women with term gestation, with bishop score <= 4 with various indications for induction of labor were randomized. 50 cases were given 50microgram of misoprostol vaginally and another group 50 microgram misoprostol orally, four hourly (maximum 6 doses) or till the women went into active labor. Statistical analysis was done. It was found that in vaginal misoprostol group induction delivery interval was significantly less (10.2hr vs 16.45hr). Successful induction was significantly higher (90% vs 75%) than oral group within 24hrs of induction. As far as dose required is concerned in vaginal group 40.25% women needed only 2 doses for delivery in contrast to 35.25% in oral group with maximum 6 doses were required.
Keywords: misoprostol, women, Vaginal, Oral.

INTRODUCTION

Induction of labor at term with unfavourable cervix is associated with increased risk of failed induction and cesarean section. Conventional methods for cervix ripening (oxytocin, foley's catheter) are being used since long but have their own merits and demerits. Thus there is a need for more efficient agent with lesser limitations [1].

Prostaglandins are new drug of interest in this field. Out of all prostaglandins PGE1 and PGE2 have been tried for induction of labor. PGE2 is being used as gel and is used intra-cervical or vaginally but is expensive and needs refrigeration.

Whereas PGE1's synthetic analogues misoprostol which is originally used as gastroprotective agent, its use in cervical ripening and induction of labor is now tried worldwide. It has advantage of being cheap, stable at room temperature and easy to administer by various routes i.e. vaginal, oral, sublingual and rectal. Absorption by oral route is erratic at the same time it is more rapid than vaginally administered misoprostol reaching peak serum concentrations within 30 mins compared to one hour with vaginal route. Oral misoprostol is eliminated rapidly (2-3 hrs) than vaginal (>=4 hrs). thus, vaginal route seems to be more efficacious than oral and should result in shorter induction delivery interval and reduced need for oxytocin augmentation [2].

MATERIALS AND METHODS

All women with term gestation who was admitted in labor room at Nalanda Medical College and Hospital, Patna between Jan 2015 to Dec 2017 with various indications for induction of labor were randomly included in the study after informed written consent.

Total 105 women with term pregnancy, singleton pregnancy, cephalic presentation, no fetal congenital malformation, normal fetal heart rate pattern, bishop score(<=4) and ruptured membrane of <4 hrs duration were taken in the study.

Women with cephalopelvic disproportion Bishop Score >4, placenta previa or unexplained vaginal bleeding, previous Cesarean section/or other uterine surgery, carcinoma cervix, chorioamnionitis or any contraindication to use of prostaglandins e.g. hypersensitivity, asthma, etc. were excluded. Out of 105 women, 5 were excluded and hence only 100 women could be studied.

Detailed history, systemic and local examination of 50 women was tried with vaginal misoprostol inserted vaginally in posterior fornix and 50 women with oral misoprostol.

Table-1: Characteristics and indications for labor induction

	Oral misoprostol group	Vaginal misoprostol group
1.age (years)	25 (20-40)	25 (20-40)
2.gestation (weeks)	37-42	37-42
3.indication for induction		
Hypertensive disorder	42 (84%)	43 (86%)
Intrauterine growth retardation	5 (10%)	4 (8%)
Oligohydramnios	2 (4%)	3 (6%)
Diabetes mellitus	1 (2%)	0 (0%)

Progress at labor was monitored especially for uterine contractions, its frequency, intensity and duration. Fetal heart rate and other fetal and maternal complications like nausea, vomiting, diarrhea, distress was considered and managed symptomatically with antiemetics, IV fluids etc.

Women was considered in 'active labor' if she had 3 uterine contractions in 10 mins lasting for >= 60 seconds and with good intensity. Both oral and vaginal tablets were repeated every 4 hourly till either she went in active labor or maximum six doses of tablets have been consumed. Once she went into active labor no further tablets were given orally or vaginally.

If women did not go into active labor 4 hours after 6th dose- induction of labor was said to be a "failure". Once labeled as "failure" and there was no obstetric indication to terminate the pregnancy by LSCS, then augmentation with oxytocin was done and labor was monitored in the same way [3].

During the course of induction uterus was said to be hypertonic if uterine contractions lasted for >120 secs, tachysystole if >6 contractions per 10 mins for 2 consecutive 10 minutes or hyperstimulation if either or both hypertonus tachysystole associated with abnormal fetal heart rate pattern occurred then vaginal tablet from posterior fornix removed and no oral or vaginal dose was given any more. Terbutaline 0.25mg was given IV or SC. Fetal heart rate was monitored by fetal Doppler. If abnormal fetal heart rate detected then before proceeding to LSCS, ARM done and Cesarean section was decided on the basis of obstetrical indication.

After delivering both mother and neonate were observed throughout the hospital stay for any complication especially neonate admission.

The main measure of efficacy was successful induction i.e. number of women who achieved active labor within 24hrs of induction and their induction delivery interval. Other measures were number of deliveries within 24 hrs, total dose of misoprostol/oxytocin required for delivery and mode of delivery.

The measures of safety included the uterine tachysystole, uterine hypertonus, abnormal fetal heart tracings, incidence of meconium passage and the neonatal outcome. Baseline data included maternal age, socio-economic status, parity, gestation, indication for induction and pre-induction cervical score.

Finally women who had received misoprostol vaginally were grouped as vaginal group and those who received orally were grouped as oral group (fig 1).

RESULTS

The successful induction rate was 90.40% in vaginal group and about 74.5% in oral group (table 2) which is statistically significant.

Induction to active labor induction was significantly shorter in vaginal group in comparison to oral group. At the same time greater number of women delivered within 24hrs of induction by vaginal misoprostol than with oral. Women not delivered within 24hrs of induction by oral group and labeled as failure. All failures achieved active labor with median dose of (range 10-18mU/min) of oxytocin.

Greater number of women delivered with 2 doses of vaginal misoprostol (40%) whereas in oral group about 10% required 6 doses to go into active labor. While in vaginal misoprostol maximum dose required was 5 tabs in 3 cases i.e. about 5.7%.

Lesser fetal heart rate abnormality were observed with vaginal than with oral misoprostol. Incidence of uterine contractile abnormalities was more with vaginal misoprostol.

Majority of women in both groups (86/100) delivered vaginally but overall incidence of vaginal births being significantly greater in vaginal groups 46/50 vs 37/50 in oral group. Cesarean section rate was significantly more in oral group (25% vs 10%) and most common indication for cesarean section was fetal distress in both the groups.

Schematic representation of women studied

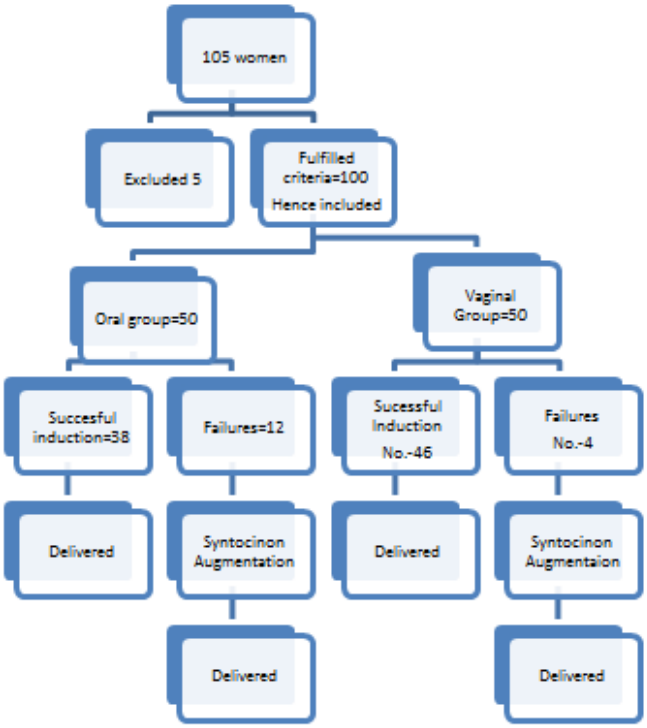

Fig-1

Table-2: Mode of delivery

Mode of delivery	Oral group (n=50)	Vaginal group (n=50)
1.vaginal	37(74%)	47(94%)
(a)normal	35(70%)	45(90%)
(b)forceps	2(4%)	2(4%)
2.lscs	13(26%)	3(6%)
indications for lscs		
(a)fetal distress	12(24%)	3(6%)
(b)cervical dystocia	0(0%)	0(0%)
(c)maternal distress	1(2%)	0(0%)

Neonatal outcome in both groups was good as all the neonates were born alive with APGAR score of 8,9 at 1 and 5 mins.

DISCUSSION

Misoprostol is a drug of choice for induction of labor. Vaginal misoprostol is an effective cervical ripening agent and labor inducing drug. In our study successful induction of labor with 50 microgram vaginal misoprostol was higher as compared to oral and shorter induction delivery by 10 hrs.

Vaginal misoprostol is absorbed rapidly and eliminated slowly from body making it available for action for a longer duration as compared to oral misoprostol. In our study more women (90.4% vs 72.5%) delivered within 24hrs in vaginal group [4].

Most important point in using misoprostol is excessive uterine contraction and sometime uterine rupture in both LSCS scar and unscarred uterus. But the complication is dose related. Higher the dose more is uterine stimulation but shorter is the induction delivery interval with use of 50 microgram of misoprostol the incidence of uterine contractile abnormalities have been reported to be about 4.9%. One uterine rupture was reported with scarred and none with unscarred uterus.

In observation despite the higher incidence of uterine contractile abnormalities with vaginal route it does not increase in cesarean section rate. LSCS rate in our oral group was significantly more 25.5% vs 9.5% which is consistent with How Hy *et al*.[2] and Shetty *et al*[4].

Commonest indication for LSCS in our study was fetal distress irrespective of route used for misoprostol. Fetal distress contributed 2.4% with oral and 1.2% with vaginal use. Misoprostol and its use by vaginal and oral route does not adversely affect neonatal and maternal outcome.

Table-3: Neonatal outcome

	Oral group (n=50)	Vaginal group (n=50)
1.birth weight	2.8 (1.5-4.0)	2.8 (1.5-4.0)
2.apgar score at 1 min	8 (0-10)	8 (0-10)
3.apgar score at 5 minutes	9 (0-10)	9 (0-10)
4.meconium staining of liquor	1	1
5.fetal heart abnormality	10	5
6.admission to nicu	3	0
7.live birth	50/50	50/50
8.still birth	0	0

Two neonates from oral groups required NICU admission.

CONCLUSION

Vaginal administration of 50 microgram misoprostol is highly effective cervical ripening and labor inducing agent than oral misoprostol but its use demands close monitoring for uterine contractile abnormalities.

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