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Original Research Article

Efficacy of vaginal Misoprostol versus transcervical Foley's catheter and vaginal Misoprostol in induction of labor

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ABSTRACT

Background: The objective is to compare the efficacy of vaginal Misoprostol versus transcervical Foley's catheter and vaginal Misoprostol.
Methods: A prospective study analyzing the comparative efficacy of intravaginal instillation of Misoprostol in two groups (tablet Misoprostol 50μg alone and combination of intracervical Foley's catheter and tablet Misoprostol 50μg) carried out in the labour room on 300 subjects (150 subjects in each group), from May 2013 to November 2015.
Results: The common gestational age at the time of induction was 36-40 weeks and the most common indication was premature rupture of membrane. In both the groups, most of the cases delivered within 12 hours. present results show that statistically significant number of cases delivered vaginally within 12 hours with the group using Misoprostol plus Foley's catheter as compared to the group using Misoprostol alone. Cesarean section rate was 12.67% in Misoprostol group and 10.67% in Misoprostol plus Foley's catheter group. Incidence of failure of induction was similar in both the groups. The incidence of babies with Apgar score less than 8/10 at 5 minutes and incidence of early neonatal death were similar in both the groups.
Conclusions: Addition of intracervical Foley's catheter to vaginal Misoprostol for induction of labor in subjects with unfavorable cervices reduces the Induction-Delivery interval without added side effects or complications to the mother and fetus.

Keywords: Labor induction, Misoprostol, Transcervical Foley's catheter

INTRODUCTION

Labor is that beautiful gift of nature, which plays a central role in the perpetuation of this creation. It is a multifactorial process involving myometrial contractions, cervical ripening and dilatation then expulsion of fetus and placenta in an orderly manner. Induction of labor is defined as deliberate initiation of labor to achieve vaginal delivery when continuation of pregnancy presents a threat to the life or wellbeing of the mother or fetus or both. The rate of induction of labor has greatly increased in the last decade.[1,2] The indications of induction of labor have encompassed wide horizons ranging from maternal (both medical and obstetric conditions) to fetal conditions. Infact induction is indicated when the benefits to either the mother or fetus outweighs those of continuing the pregnancy. The second question is how best this can be accomplished in the safest manner. Labor basically is a sum up of two components: Myometrial contraction and cervical dilatation and effacement (ripening of cervix). Therefore, any agent introduced with the aim of inducing labor should ideally act on both. Prostaglandins have proved their worth on basis of these criteria and surpassed all other agents in vogue for induction of labor. Prostaglandins are now recognized to be important intermediaries in several aspects of human reproduction.

This physiological agent has now been converted into a pharmacological tool. Different Prostaglandin analogues have been tried and tested for this purpose. Misoprostol, a PGE_1 analogue has been the latest drug to be experimented upon. Misoprostol has clearly outlined the shortcomings of already available drugs for induction of labor. It is stable at room temperature, cheap and more effective but is associated with more risk.[3]

The purpose of this study is to compare and evaluate the role of vaginal Misoprostol alone versus combination of vaginal Misoprostol and intra-cervical Foley's catheter for cervical ripening.

METHODS

This was a prospective study analyzing the comparative efficacy of intravaginal instillation of Misoprostol in two groups (tablet Misoprostol 50µg alone and combination of intracervical Foley's catheter and tablet Misoprostol 50µg) carried out in the labor room on 300 subjects (150 subjects in each group), from May 2013 to November 2015.

Inclusion criteria

- Singleton gestation
- Vertex presentation
- Gestation >34 week
- Bishop's score <6
- IUFD (intrauterine fetal death)
- PET (pre-eclamptic toxemia)
- Post term pregnancy
- PROM (premature rupture of membrane).

Exclusion criteria

- Placenta previa
- Negative LAT (labour admission test)
- Known allergy to Misoprostol
- Severe IUGR (intrauterine growth restriction)
- Previous uterine scar
- Severe oligohydramnios.

A total of 300 subjects were admitted to the labour room. A detailed history was taken to exclude any contraindications for induction with Misoprostol. General examination, systemic examination and a thorough obstetric examination were done to identify and select patients suitable for induction.

A baseline NST was done for at least 10 minutes to exclude any abnormal fetal heart rate patterns which could suggest already existing compromised state of the fetus-in-utero. Routine investigations and an obstetric ultrasound was done to check for fetal wellbeing in addition to other parameters like gestational age, placental site including grading and liquor volume. The patients were grouped in 2 categories according to randomization number.

Group A: Tablet Misoprostol 50µg
Group B: Tablet Misoprostol 50µg plus Foley's catheter (No. 18).

After selection informed consent was taken explaining the need of induction and hazards associated with the drug and the process of induction. The patient was examined to assess the Bishop's score and according to randomization number, subject was either induced with Tablet Misoprostol 50µg or combined Tab Misoprostol 50µg plus Foley's catheter number 18 with normal saline instillation of 30cc. The patient was kept in lateral position for half an hour.

For subjects assigned to Group A, the Tablet Misoprostol 50µg was placed intravaginally in the posterior fornix of vagina every 6 hourly for a maximum of 4 doses.

For subjects to Group B, first Foley's catheter 18F was inserted intracervically with visualization of the cervix by sterile speculum examination. Effort was made to avoid contact of catheter with the vagina or ectocervix and to perform the procedure with sterile technique. After proper placement was ensured, the catheter balloon was inflated with 30cc of sterile normal saline solution. Traction was applied to the catheter until the balloon was taut against the internal cervical os. The catheter was then taped with traction to the inner thigh of the patient until spontaneous expulsion. Then Tablet Misoprostol 50µg placed intravaginally in the posterior fornix of the vagina every 6 hourly for a maximum of 4 doses. Complaints of patients, vital signs, uterine contractions and fetal heart rate patterns were monitored. The second and third stages were managed as usual. Apgar score and meconium aspiration were noted in neonates.

The following were outlined as the principal outcomes of present study in which present results were tabulated.

Outcome studies

Primary outcome

- Induction-delivery interval in both groups.

Secondary outcome

- Number of successful vaginal delivery
- Need for caesarean section
- Need for instrumental delivery
- Side effect of Misoprostol
- Neonatal outcome-meconium staining of amniotic fluid, 1- and 5-min Apgar score, neonatal ICU admission, early neonatal death
- Maternal complications.

RESULTS

The common age of cases requiring induction was between 21-25 years. Most of them were nullipara. The common gestational age at the time of induction was 36-40 weeks. The most common indication for induction was premature rupture of membrane. Most of the cases requiring induction had unfavourable Bishop's score (<5).

Majority of cases delivered after second instillation of Misoprostol in both the groups (88.67% in Misoprostol alone and 97.34% in Misoprostol plus Foley's catheter group). Cesarean section rate was 12.67% in Misoprostol group and 10.67% in Misoprostol plus Foley's catheter group. The common indications for Cesarean section were fetal distress and thick meconium stained liquor in both the groups.

Table 1: Indications for induction of labour.

Indications	Group A (Misoprostol alone) (n=150) Subjects	Group B (Misoprostol + Foley's catheter) (n=150) Subjects
PROM	87 (58.00%)	77 (51.34%)
Postdatism	40 (26.67%)	30 (20.00%)
Hypertensive disorders	11 (7.33%)	23 (15.33%)
Oligohydramnios	10 (6.67%)	8 (5.33%)
IUFD	2 (1.33%)	11 (7.33%)
Miscellaneous	0 (0.00%)	1 (0.67%)

Incidence of failure of induction was similar in both the groups (10.52% in Misoprostol alone group and 12.50% in Misoprostol plus Foley's catheter group). In both the groups, the most common maternal side effects was fever and rigor. The common fetal complication was abnormal fetal heart rate patterns and meconium passage. The incidence of babies with Apgar score less than 8/10 at 5 minutes and the incidence of early neonatal death were similar in both the groups.

Table 2: Distribution of the subjects according to pre-induction bishop's score.

Bishop score	Group A (Misoprostol alone) (n=150) Subjects	Group B (Misoprostol + Foley's catheter) (n=150) Subjects
0-1	1 (0.67%)	2 (1.33%)
2-3	43 (28.67%)	72 (48.00%)
4-5	101 (67.33%)	74 (49.34%)
6-7	5 (3.33%)	2 (1.33%)

Present results show statistically significant (p value=0.0093) number of subjects delivered vaginally within 12 hours in group using Misoprostol plus Foley's catheter, as compared to group using Misoprostol alone, means induction-delivery interval is less (<12 hours) in more number of patients [131 (87.33%)] in Misoprostol plus Foley's catheter group.

Table 3: Induction delivery interval.

Induction to delivery interval	Group A (Misoprostol alone) (n=150) Subjects	Group B (Misoprostol + Foley's catheter) (n=150) Subjects	P value
< 12 hours	115 (76.67%)	131 (87.33%)	0.0093
12-24 hours	32 (21.33%)	16 (10.67%)	0.011
> 24 hours	03 (2.00%)	03 (2.00%)	1

Number of subjects delivering between 12-24 hours showed statistically significant difference (p value=0.011) showing that Misoprostol group in comparison with Misoprostol plus Foley's catheter group has more number of subjects delivering between 12-24 hours. In both the groups, three subjects were undelivered at the end of 24 hours.

Table 4: Dose of Misoprostol required.

Number of doses required	Group A (Misoprostol alone) (n=150) Subjects	Group B (Misoprostol + Foley's catheter) (n=150) Subjects	P value
1 dose	80 (53.34%)	92 (61.34%)	0.62
2 doses	53 (35.33%)	54 (36.00%)	
3 doses	15 (10.00%)	02 (1.33%)	0.08
4 doses	02 (1.33%)	02 (1.33%)	

Majority of the cases delivered after second instillation of Misoprostol in both groups (88.67% in Misoprostol alone and 97.34% in Misoprostol plus Foley's catheter group) (p=0.62). 11.33% cases in Misoprostol group needed more than two doses while 2.66% of subjects in Misoprostol plus Foley's catheter group needed more than two instillations of Misoprostol (p=0.08), which appears to be statistically significant.

The incidence of failed induction was 1.33% in both the groups and this was seen in subjects of premature rupture of membrane. All these subjects underwent Cesarean section.

Table 5: Distribution of subjects according to mode of delivery.

Mode of delivery	Group A (Misoprostol alone) (n=150) Subjects	Group B (Misoprostol + Foley's catheter) (n=150) Subjects	P value
Vaginal delivery	131 (87.33%)	128 (85.33%)	
Instrumental delivery (forceps/vacuum)	0 (0%) 0/0	5 (3.33%) 3 (2%) / 2 (1.33%)	0.0731
Cesarean section	19 (12.67%)	16 (10.67%)	0.59
Exploratory laparotomy	0 (0%)	1 (0.67%)	

Table 6: Side effects and complications.

Maternal	Group A (Misoprostol alone) (n=150) Subjects	Group B (Misoprostol + Foley's catheter) (n=150) Subjects	P value
Fever	3 (2%)	4 (2.67%)	
Rigor	5 (3.33%)	4 (2.67%)	
Bowel disturbance (diarrhea)	2 (1.33%)	1 (0.67%)	0.56
Abnormal uterine contractions	3 (2%)	1 (0.67%)	
Tachysystole	2 (1.33%)	0 (0%)	
Hypertonic contractions	0 (0%)	0 (0%)	
Hyperstimulation syndrome	1 (0.67%)	1 (0.67%)	
PPH	3 (2%)	4 (2.67%)	
Atonic	0 (0%)	0 (0%)	
Traumatic	3 (2%)	4 (2.67%)	
Rupture of uterus	0 (0%)	1 (0.67%)	
Total	16 (10.67%)	15 (10%)	
Fetal	**Group A (Misoprostol alone) (n=148) Subjects**	**Group B (Misoprostol + Foley's catheter) (n=139) Subjects**	**P value**
Abnormal fetal heart rate	13 (8.78%)	12 (8.63%)	
Bradycardia	1 (0.68%)	1 (0.72%)	
Deceleration	12 (8.11%)	11 (7.91%)	
Late	6 (4.05%)	7 (5.04%)	
Variable	0 (0.00%)	0 (0.00%)	
Early	4 (2.70%)	2 (1.44%)	0.45
Persistent fetal tachycardia	2 (1.35%)	1 (0.72%)	0.599
Meconium stained liquor	12 (8.11%)	6 (4.32%)	0.185
Thin	2 (1.35%)	1 (0.72%)	
Thick	10 (6.7%)	5 (3.60%)	0.23
Total	25 (16.89%)	18 (12.95%)	
Neonatal	**Group A (Misoprostol alone) (n=148) Subjects**	**Group B (Misoprostol + Foley's catheter) (n=139) Subjects**	**P value**
Apgar score less than 8/10 at 5 minutes	3 (2.03%)	2 (1.44%)	0.703
Admission to NICU	5 (3.38%)	4 (2.88%)	0.808
Early neonatal death	2 (1.35%)	1 (0.72%)	0.599

As shown Table 5, there was no statistically significant difference in vaginal delivery rate in the two groups. Cesarean section rate was 12.67% in Misoprostol group and 10.67% in Misoprostol plus Foley's catheter group.

One multiparous subject (previous one full term vaginal delivery) in Misoprostol plus Foley's catheter group had uterine rupture following a single instillation of Misoprostol with intracervical Foley's insertion for IUFD.

She underwent an exploratory laparotomy which revealed a rent on the right side of lower uterine segment of 2cm in size which was repaired. So, the overall success rate in terms of successful vaginal delivery were similar in the two groups.

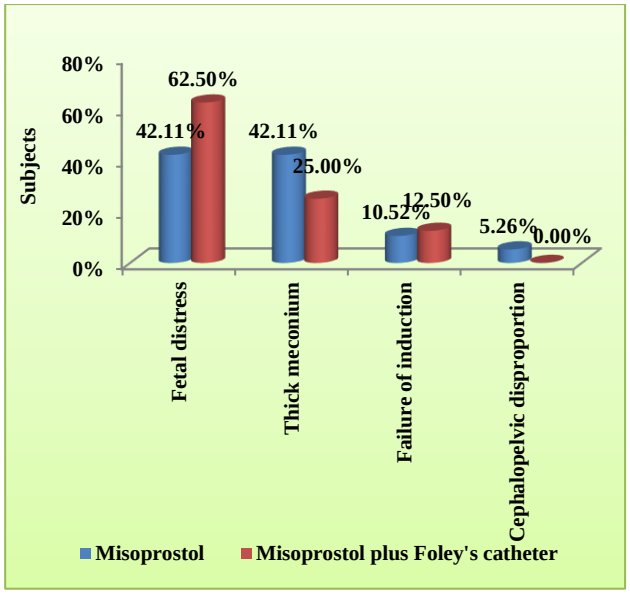

Figure 1: Distribution of subjects according to indication for cesarean section.

Figure 1 shows that the most common indication for Cesarean section was fetal distress and thick meconium stained liquor in both the groups. Fetal distress in both the groups was comparable. There was difference in the incidence of thick meconium staining of liquor in the two groups-42.11% in the Misoprostol alone group versus 25% in the Misoprostol plus Foley's catheter group, though the p value (0.239) was not statistically significant. The failure of induction rates were similar. The rate of Cesarean section due to failure of induction are very less in both the groups (10.52% in Misoprostol group and 12.50% in Misoprostol plus Foley's catheter group).

DISCUSSION

The need to deliver a patient with unripe cervix, to induce labour, to increase the efficiency of labour are frequent problems to Obstetricians. Several methods have been mentioned in the literature for cervical ripening. These are stripping of membranes, oxytocin, prostaglandins, mifepristone, mechanical dilators like Foleys balloon catheter, extra amniotic fluid infusion etc. Among all these prostaglandins are found to be very useful in cervical ripening and induction of labor. Although PGE_2 has been used for long for ripening at term PGE_1 (misoprostol) has been tried recently. The advantage of misoprotol is that it is cheaper and unlike PGE2 it doesnot require refrigeration. Misoprostol is extensively absorbed and undergoes rapid de-esterification to its free acid (Misoprostol acid) which is responsible for its clinical activity. Used in both oral and vaginal routes systemic bioavailability of vaginally administered Misoprostol is three times higher than that of orally administered Misoprostol.[5,6] Foleys balloon catheter causes cervical ripening by mechanical dilatation of cervix and by releasing Prostaglandin from amniotic membranes.[7] Spontaneous expulsion of catheter correlates with 2-3cm dilatation of cervix. Induction to delivery interval within 12 hours is 87% in group B compared to 76% in group A which is of paramount significance. The meconium staining in liquor of present study group (Misoprostol plus Foley's catheter) was 4.32% which was comparable to 6.4% noted in Scott Barrileaux et al (2002) study, while the incidence of the same in Chung's study was 16.3% (probably because they repeated vaginal Misoprostol at short intervals).[8,9] Present study has shown improved rate of vaginal delivery as shown in Table 7.

Table 7: Mode of delivery.

Mode of delivery	Present study		Chung JH et al[9]	
	Group A (Misoprostol alone) (n=150)	Group B (Misoprostol + Foley's catheter) (n=150)	Group A (Misoprostol alone) (n=49)	Group B (Misoprostol + Foley's catheter) (n=43)
Vaginal delivery	87.33%	85.33%	63.3%	58.1%
Instrumental delivery	0%	3.33%	-	-
Cesarean section	12.67%	10.67%	36.7%	41.9%

As shown in Table 8, there was a high rate of fetuses with Apgar score less than 8/10 at 5 minutes in Chung JH who used frequent doses of Misoprostol (25µg) every 3 hours.[9] However, the side effects and complications are comparable between both the groups. Lesser doses of Misoprostol used with intracervical Foley's catheter appears to be an advantage to decrease the risks involved with Misoprostol which leads to a safe delivery of the fetus with minimal maternal risks.[10]

Table 8: Distribution of cases according to neonatal complications.

Author		Apgar score <8/10 at 5 minutes
Chung JH et al[9]	Group A	10.2%
	Group B	9.3%
Present study	Group A	2.03%
	Group B	1.44%

CONCLUSION

Addition of intracervical Foley's catheter with 30 ml saline to vaginal Misoprostol for induction of labour in subjects with unfavourable cervices reduces the Induction-Delivery interval without added side effects or complications to the mother and fetus.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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