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Comparison of Vaginal Misoprostol and Foley Catheter for Cervical Ripening

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Abstract: ***Objectives**: To compare the efficacy and safety of intravaginal misoprostol with transcervical foley catheter for cervical ripening. **Material And Methods**: The present study was a prospective study and was conducted in the Department of Obstetrics and Gynaecology in collaboration with the Department of Paediatrics, J.N.M.C.H., A.M.U., Aligarh during 2013-2014 after getting approval from Institutional Ethics Committee. One hundred and four women with term gestation, with Bishop score < 4 with various indications for labour induction were randomly divided into two groups. In Group I, 25 µg of misoprostol tablet was placed intravaginally, 4 hourly up to maximum 6 doses. In Group II , Foley catheter 16F, inflated with 50 cc of sterile saline , was placed through the internal os of the cervix. Statistical analysis was done using SPSS software. **Results**: Two groups were similar in view of their demographic characteristics. The induction to delivery interval (mean ± SD) in women induced with intravaginal misoprostol was 14.03 ± 7.61 hours of transcervical Foley catheter was 18.40 ± 8.02 hours. Misoprostol is associated with a shorter induction to delivery interval. The rate of vaginal delivery was 76.7% Vs 56.8% in misoprostol and Foley catheter group respectively which was significantly higher in misoprostol group (p<0.001). Neonatal outcome was similar in both the groups. **Conclusion**: The use of Foley catheter is as effective as misoprostol for cervical ripening, but less effective in triggering spontaneous labour. Misoprostol is associated with a shorter induction to delivery interval and it increases the rate of vaginal delivery in cases of unripe cervix at term.*

Keywords: Cervical Ripening, Labour Induction, Foley Catheter

1. Introduction

In the recent decade, acknowledgement of the cervix as a functional organ is one of the major advances in reproductive physiology. The cervix must remain closed during pregnancy to maintain pregnancy, yet open during parturition. Its activity must be performed at the right time, in right sequence and within reasonable period of time. The process that co-ordinates these activities in labour is an equal mixture of uterine contractions, cervical effacement and dilatation.

In1964,Bishop introduced numeric scoring system to quantify physical examination of cervix. Bishop score consists of summation of five observations dealing with conditions of dilatation, effacement, consistency, position of the cervix as well as station of presenting part. Of all the parameters dilatation weighs the most in importance and position of cervix weighs the least in determining predictability of score(1). When a high score is present, it is assumed that those changes that constitute cervical ripening have occurred and no further attempts to ripen the cervix are needed. Cervical ripening would be especially beneficial in patients with cervical score less than 4. The physical and biochemical changes in the uterine cervix which normally precede the onset of parturition, are referred to as ripening and seem to be essential for normal labour and delivery. When cervix is unfavourable, cervical ripening is recommended to increase the likelihood of successful induction(2). A potential effect of induction of labour with an unripe cervix lead to high rate of induction failure and caesarean delivery(3).

Ripening of the cervix may be achieved by both pharmacological and non-pharmacological (mechanical) methods. The pharmacological preparation includes the prostaglandins. Two different preparations of prostaglandins are available, one is prostaglandin E2 (PGE2) or dinoprostone which is unstable at room temperature and requires refrigeration. The other is prostaglandin E1 (PGE1) analogue misoprostol, which has also been evaluated for possible use in cervical ripening and induction of labour. Vaginal misoprostol is currently widely used for ripening of cervix and induction of labour, however, there are ongoing trials regarding optimal dose, dosing regimen and route of administration. Non-pharmacological method includes the transcervical use of foley catheter for cervical ripening and induction of labour. Embrey and Mollison first described using a transcervical Foley catheter for cervical ripening(4).Foley catheter appears to induce labour not only through direct mechanical dilatation of cervix but also by stimulating endogenous release of prostaglandin. Thus, ripening of the cervix is merely the first step that is sometimes necessary in induction of labour. However, currently available studies are underpowered to estimate the advantages and disadvantages of Foley catheter and misoprostol. In view of the scarce evidence on the subject we conducted this study comparing the effectiveness and safety of intravaginal misoprostol with transcervical Foley catheter for cervical ripening.

2. Material and Methods:

The present study was a prospective study and was conducted in the Department of Obstetrics and Gynaecology in collaboration with the Department of Paediatrics, J.N.M.C.H., A.M.U., Aligarh during 2013-2014 after getting approval from Institutional Ethical Committee. A total of one hundred and four (104) women requiring indicated induction of labour with an unfavourable cervix (Bishop score ≤ 4) were included in the study after informed consent. Women were randomly divided into two groups. 60 women induced with intravaginal misoprostol as group I and 44 women induced with transcervical Foley catheter as group II. They were selected from the patients attending antenatal clinic (ANC), outpatient department (OPD) and patients admitted in the hospital. The two groups were comparable with respect to maternal age, parity, gestational and preinduction Bishop score. Demographic and clinical data were collected at routine antenatal visits . Inclusion criteria

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was singleton gestation, more than or equal to 37 weeks of gestation with intact membranes and Bishop score ≤ 4. We excluded the cases with rupture of membranes, chorioamnionitis, antepartum haemorrhage, cervical dilation > 2.5 cm, contracted pelvis polyhydramnios, indication for immediate delivery and previous uterine surgery (for Group I)In Group I, 25 mcg of misoprostol tablet was placed intravaginally, 6 hourly for maximum 6 doses. In the presence of spontaneous and frequent contractions (>40-45 seconds every 3minutes), the next dose was not administered. If there was no effective uterine contractions after the sixth dose, then it was considered as failure of induction by the concerned method. In Group II, 18 F Foley catheter was inserted into the endocervical canal under direct vision by doing a perspeculum examination. The catheter was advanced into the endocervical canal. Once past the internal os, the balloon was filled with 50 ml of sterile saline solution and the catheter was taped to the inner-thigh to maintain traction.The catheter was checked for extrusion of the balloon from the cervix every 6 hours by cervical examination and the catheter was remain in place until the balloon was expelled spontaneously and labour augmentation was done by artificial membrane rupture or oxytocin drip, whichever is indicated. The primary outcome measures were postinduction Bishop score and induction to delivery interval . Secondary outcome measures includes uterine contractile abnormalities , meconium stained liquor, mode of delivery , maternal and neonatal outcome, neonatal birth weight and Apgar score. Any maternal or fetal complication was also recorded. The data was tabulated and analysed. All the results were expressed as mean±standard deviation**.** Students 't' test and chi–square test were used to determine the significance of differences between them.

3. Results

A total of one hundred and four (104) women were included in the study. They were randomly divided into two groups. 60 women induced with intravaginal misoprostol as group I and 44 women induced with transcervical Foley catheter as group II. Maternal baseline characterstics were similar between the two groups in terms of age, parity, gestational age and preinduction Bishop score. **Table- I** The two groups were comparable with respect to indications for induction of labour as shown in **Table-II**

As shown in **Table III**, the preinduction and postinduction Bishop score (mean ± SD) in women induced with intravaginal misoprostol was 2.52 ± 0.77 and 7.43 ± 1.90 while that in women induced with transcervical Foley catheter was 2.34 ± 0.67 and 7.45 ± 1.26 respectively. Both the groups were comparable with respect to cervical ripening ($p > 0.05$). The induction to delivery interval (mean ± SD) in women induced with intravaginal misoprostol was 14.03 ± 7.61 hours while that of women induced with transcervical Foley catheter was 18.40 ± 8.02 hours. The induction to delivery interval in misoprostol group was significantly shorter than that in Foley catheter group ($p < 0.01$).

As depicted in **Table-IV**, the rate of vaginal delivery was 46 women (76.7%) and 25 women (56.8%) while 14 women (23.3%) and 19 women (43.2%) delivered through caesarean section in misoprostol and Foley catheter group respectively. The rate of vaginal delivery was significantly more in misoprostol group as compared to Foley catheter group ($p < 0.05$). The caesarean section rate was more in Foley catheter group as compared to misoprostol group and the results were statistically significant ($p < 0.05$).

The birth weight (Mean±SD) was 2.79 ± 0.43 kg and 2.91 ± 0.53 kg in misoprostol and Foley catheter group. The difference in the birth weight between the two study groups was statistically not significant ($p > 0.05$). The Apgar score at 1minute and 5 minute (Mean±SD) was 7.80 ± 0.77 Vs 7.91 ± 0.33 and 8.92 ± 0.38 Vs 8.98 ± 0.15 in misoprostol and Foley catheter group respectively. Statistically there was no significant difference in the Apgar score between the two groups at 1 and 5 minute ($p > 0.05$).

4. Discussion

The use of cervical ripening agents prior to conventional methods of induction is now a standard practice. Until now different methods for labour induction are used. In literature, contradictory results are reported regarding efficacy and safety of the induction methods. Therefore in this study, we compared the efficacy and safety of 25 µg vaginal misoprostol with transcervical Foley catheter for preinduction cervical ripening. The results of present study show that the rate of cervical ripening was same with both the agents. Our study is in accordance to the studies of Sciscione et al.[5] and Chung et al.[6], who also reported no differences between Foley catheter and intravaginal misoprostol for cervical ripening. Fekrat et al.[7] evaluated three methods of cervical ripening with vaginal misoprostol and Foley catheter and the combination of these two methods and they reported that vaginal misoprostol was more effective than other two methods. Hofmeyr et al.[8] evaluated intravaginal misoprostol and other conventional intravaginal prostaglandins and showed that the misoprostol is more effective for cervical ripening . Our findings are against the results of these studies, the most important cause for this may be lower dose of misoprostol (25 µg) used in our study compared with their studies. The study of Adeniji et al.[9] recommends a maximum dose of 50 µg every 6 hours for cervical ripening.

The results of present study show that induction to delivery interval was significantly shorter in misoprostol group as compared to Foley catheter group. Sheikher et al.[10] also found shorter induction delivery interval in vaginal misoprostol group compared to Foley catheter group. The shorter induction delivery interval in misoprostol group could be explained on the basis of greater oxytocic effect on uterus via vaginal route due to direct access to myometrium by cervical canal. Our study is not in accordance with Prager et al.[11], who found that induction to delivery interval was significantly shorter in Foley catheter group as compared to misoprostol and PGE2.

In our study, women undergoing vaginal delivery were significantly more in misoprostol group as compared to Foley catheter group and women undergoing caesarean section were .Our study is in harmony with Moraes Filho et al.[12] who also noticed significantly more vaginal delivery in misoprostol group. Roudsari et al.[13] found that the rate of

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vaginal delivery was significantly more in Foley catheter group as compared to misoprostol group . Our results were not in harmony with the findings of Adeniji et al.[9] who did not found any significant difference in the mode of delivery between the two groups.

In this study, there was a tendency towards more frequent caesarean section in response to foetal distress among women administered misoprostol. This finding is in agreement with most of the studies that have demonstrated a higher incidence of hyperstimulation associated with foetal distress in women induced with misoprostol. Both the groups were comparable in terms of meconium amniotic fluid as an indication of caesarean section. Statistically there was no significant difference in the Apgar score between the two groups at1 and 5 minute **.**Similar results were obtained by Moraes Filho et al.[12] and Roudsari et al.[13] and our present study support these results . Like most of the studies, the two groups in our study were comparable in terms of NICU admission.

5. Conclusion

The results of the present study suggest that both the modes of induction are safe and effective. Misoprostol is associated with a shorter induction to delivery interval and it increases the rate of vaginal delivery in cases of unripe cervix at term. The potential advantages of transcervical Foley catheter over misoprostol are reversibility, easy availability and lack of local and systemic serious side effects. However, further studies with larger sample size would be of sufficient power to assess significant adverse maternal and neonatal complications.

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Table I: Demographic Profile

Parameters		*Group I(n= 60) (Misoprostol)*	*Group II(n=44) (Foley Catheter)*	*'p' value*
Age (years) (Mean ±SD)		25.1 ± 2.8	25.6 ± 4.1	>0.05
Gravidity	Primi	41.7%	31.8%	>0.05
	Multi	58.3%	68.2%	>0.05
Gestational age(weeks) (Mean ±SD)		39.1 ± 1.4	39.4 ± 1.2	>0.05

Table II: Indication for Induction Of Labour

Indication for induction	Group I (Misoprostol)		Group II (Foley Catheter)		'p' value
	n	%	n	%	
≥ 40 weeks	29	48.3	27	61.3	>0.05
Oligohydramnios	11	18.3	08	18.2	>0.05
Preeclampsia	11	18.3	04	09.1	>0.05
IUGR	07	11.7	04	09.1	>0.05

Table III: Bishop Score in Group I and Group II

Parameters	*Group I(n=60) (Misoprostol)*	*GroupII(n=44) (Foley Catheter)*	*'p' value*
Preinduction Bishop score	2.52 ± 0.77	2.34 ± 0.67	>0.05
Postinduction Bishop score	7.43 ± 1.90	7.45 ± 1.26	>0.05
Induction to active phase interval (hrs) (Mean ± SD)	11.6 ± 5.21	11.8 ± 5.82	>0.05
Induction to delivery interval(hrs)(Mean ± SD)	14.03 ± 7.61	18.40 ± 8.02	< 0.01

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Table IV: Comparison of Mode of Delivery

Mode of delivery	Group I (Misoprostol)		Group II (Foley Catheter)		Total		‘ p’ value
	n	%	n	%	n	%	
Vaginal delivery	46	76.7	25	56.8	71	68.3	<0.05
Caesarean delivery	14	23.3	19	43.2	33	31.7	<0.05
Total	60	100.0	44	100.0	104	100.0	

Table V: Neonatal Outcome in Group I and Group II

Parameters	*Group I(n=60) (Misoprostol)*	*GroupII(n=44) (Foley Catheter)*	*‘p’ value*
Birth weight (kg) (Mean ± SD)	2.79 ± 0.43	2.91 ± 0.53	>0.05
Apgar score (at 1 min) Mean ± SD	7.80 ± 0.77	7.91 ± 0.33	>0.05
Apgar score (at 5 min) Mean ± SD	8.92 ± 0.38	8.98 ± 0.15	>0.05
NICU admission	13.3%	13.6%	>0.05
Meconium aspiration syndrome	8.3%	9.1%	>0.05

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