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RESEARCH ARTICLE

Comparative evaluation of transcervical Foley's catheter and intravaginal misoprostol for preinduction cervical ripening - a prospective study

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ABSTRACT

Objective: This study was conducted to compare the efficacy of intravaginal misoprostol and transcervical Foley's catheter in the cervical ripening and its effects on neonatal outcomes. **Method:** This was a prospective observational study conducted on 280 women for preinduction cervical ripening fulfilling inclusion criteria and giving consent for study. Patient was randomly assigned to either Foley's catheter group (Group A), and misoprostol (Group B). This study compared indications of labor, duration, and progression of labor, maternal outcomes and neonatal outcome in both groups. **Results:** Most of the women were primigravida most common indications being oligohydramnios + IUGR. In group B cervical ripening seen <6 hour was 42 (30%) and in group A was 26 (18.5%). Postripening Bishop's score 8 in group B and group A was in 58(41.43%) and 65 (46.43%). Artificial rupture of membrane was done in group A in 116 (83.86%) and 83 (59.29%) in group B and oxytocin in 46 (32.86%) and in group B 21 (15%). Mean ± SD of induction to delivery time in group A, group B was 18.9 ± 4 hrs, 16.2 ± 3.7 hrs respectively. Vaginal deliveries more in group A than group B was 91 (65%) and 74 (52.86). Groups A and B, maternal adverse effect was significantly different (p=0.020). NICU admission for birth asphyxia of group A was comparable to group B (p >0.05). **Conclusion:** Thus we conclude that though both methods are effective for preinduction cervical ripening. Intracervical Foley's catheter is safer and can be considered as an alternative mode.

Keywords: Misoprostol, preinduction, cervical ripening, Foley's catheter.

Induction of labour is defined as stimulation of uterine contractions before the spontaneous onset of labour with or without rupture of membranes [1]. It is a therapeutic option used for early delivery when the risk of continuing pregnancy is very high. Over the past few years, incidence of induction of labour to shorten the duration of pregnancy has increased all over the world. In developing countries, the rate of induction of labour has doubled. The incidence of deliveries by induction of labour as high as 20% have been reported in the United States of America and United Kingdom [2]. In an unpublished data from WHO Global Survey, it was estimated that 9.6% of the deliveries were induced. The African countries showed lower rates of deliveries by induction compared to Asian and Latin American countries and the highest incidence of 35% was reported from Sri Lanka [3]. Induction of labour has been recommended by various professionals when the risks of continuation of pregnancies are greater than the shortened duration of pregnancy. There are few specific indications for induction of labour. The clinicians should judge the requirement for induction as the interventions may cause discomfort to the expectant mothers and restrict their mobility. The induction of labour requires close monitoring of the mother and the baby and this put may put a strain in

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resource limited settings. Like any other interventions, induction of labour is not free from complications like bleeding, caesarean section, hyper stimulation and uterine rupture [4].

The ability of labour induction in a successful vaginal delivery is dependent on several factors and a favourable cervix is one of them. It has been reported that a successful induction resulting in vaginal delivery was observed in 97% multiparous and 76% nulliparous mothers and the success rate was higher in women with a ripe cervix [5]. The cervical ripening can be achieved by pharmacological and mechanical methods. The pharmacological methods include prostaglandin E2 (Dinoprostone) cervically and intravaginal or oral misoprostol. Misoprostol has shown a success rate comparable to that of oxytocin. The mechanical methods of cervical ripening include the use of a transcervical Foley's catheter or via hygroscopic dilators. Transcervical Foley's catheter has been reported to improve the Bishop's score and achieves better results when it is combined with oxytocin[6-10]. Hence, this study was conducted to compare the efficacy of intravaginal misoprostol and transcervical Foley's catheter in the cervical ripening at a tertiary care hospital and its effects on neonatal outcomes.

Materials and methods

This study was a hospital based prospective observational study, conducted in maternal and child health wing of rural tertiary care hospital of central India for a period of 18 months. Proper approval from local institutional ethics committee was taken prior to initiation of the study from November 2019 to May 2021. Women reporting to the labor room for induction of labor fulfilling inclusion criteria and giving consent for study were taken.

A total of 280 pregnant women more than 37 weeks of gestations, eligible for preinduction cervical ripening divided into two groups of 140 each were studied. Women was randomly assigned to either Foley's catheter group (Group A), and the misoprostol (Group B). By taking envelope method that contained the random group assignment. The envelope was assigned to a group by means of a random number table and assignment schedule was not known to participant. A total 280 identical envelopes was prepared using computer generated random number table.

Sample size calculation: The sample size was estimated by using the formula $N=2S2\ (Z\alpha+Z\beta)2\ /d2$. $Z\alpha$ and $Z\beta$ are constants. $Z\alpha$ is the standard normal variation at 95% confidence interval and considered as 1.96. $Z\beta$ is 0.84 at a power of 80%, d is the difference of mean which is taken as 0.25, while S is the standard deviation, which is assumed as 6, based on the review of literature. Using the aforementioned formula, the sample size was considered to be 140 in both the groups, to which 10% is added for nonresponse. Thus, to compare the efficacy of transcervical Foley's catheter and intravaginal misoprostol for preinduction of cervical ripening, 140 pregnant women fulfilling the inclusion criteria were recruited in each group. Overall, a total of 280 pregnant women were included in the study.

Inclusion criteria:

1) Singleton pregnancy
2) Vertex presentation
3) Reactive FHR in live fetus
4) Intact membrane
5) No previous uterine surgery
6) Bishops score less than 6
7) Absence of contraindication to vaginal delivery

Exclusion criteria:

1) Previous uterine or cervical surgery
2) Cephalo-pelvic disproportion
3) Antepartum haemorrhage
4) Hypersensitivity to prostaglandin
5) Chorioamnionitis
6) Non vertex presentation
7) Pyrexia, vaginal bleeding, unknown etiology
8) Latex allergy

At any point of time if women refused to continue with induction and augmentation of labor according to standard protocol she was withdrawn from study.

Data collection: After obtaining approval from the institutional ethics committee, women fulfilling the inclusion criteria and exclusion criteria were enrolled in the study. Informed written consent was obtained. Details of any pregnancy related complaints were obtained to decide inclusion/ exclusion in study. Last menstrual period was recorded and gestational age was calculated estimation was done. Maternal outcome like mode of delivery was noted. Fetal/neonatal outcome like birth weight, Apgar score, neonatal morbidity and mortality noted. Antenatal investigations were done according to routine departmental protocol. All pertinent study information was explained to study participants and they were informed that rejection or withdrawal from the study will not affect any medical service provide. Detailed history and physical examination and abdominal examination were done along with pelvic

examination. Abdominal examination was done to know the presentation, uterine tone and fetal heart rate. Per vaginal examination was done to assess the cervical ripening by the modified Bishop's score and to rule out cephalopelvic disproportion. Cardiotocograph (CTG) and obstetric scan is done to all patients to ascertain the fetal well being.

Two groups were created based on agent for preinduction cervical ripening.

Group A – women whose induction was done with transcervical Foley's 16 French catheter. Group B - women whose induction was done with intravaginal misoprostol 25 microgram 4 hourly. They were then been followed up for induction and augmentation of labor according to standard protocol.

In group A: Foley's catheter no. 16 F was used for cervical ripening in group A patients. Under aseptic conditions with patient lying in lithotomy position, through sponge holding forceps anterior lip of cervix was held and Foley's 16 French catheter was inserted into endocervical canal beyond internal os and balloon was inflated with 50-60 ml of normal saline. The catheter was strapped to the thigh with gentle traction. Catheter was being either removed at 12 hours or when it will be expelled spontaneously, it was removed earlier in case of onset of active labour, rupture of membranes, non reassuring cardiotocography.

In group B: All patient under this group was ripened by intravaginal misoprostol tablets under all aseptic condition, misoprostol tablets was placed 4 hourly in posterior fornix of vagina in transverse position by lubricating it with jelly, like this 2-3 doses was given. If effective cervical ripening was not established after 24 hrs of trial other method of cervical ripening can be used. In both groups, progress of labor was monitored by partogram in active stage of labor. Labor was augmented with oxytocin.

Post induction Bishop's score after 6 hours, induction delivery interval, mode of delivery, oxytocin requirement, maternal side effects and fetal outcome like Apgar score, birth weight, neonatal resuscitation, meconium stained liquor and NICU admission was recorded.

Statistical analysis: Statistical analysis was done by using descriptive and inferential statistics using chi square test and software used in the analysis were SPSS 27.0 version and GraphPad Prism 7.0 version and $p < 0.05$ is considered as level of significance.

Results

In this study most of the women who delivered were primigravida in group A was 112 (80%) and group B 110 (78.57%) followed by multigravida in group A was 28 (20%) and group B 30 (21.43%). The distribution of women according to their parity of group A was comparable to group B ($p > 0.05$).

In this study, the most common cause of indications of induction in this study was oligohydramnios + IUGR in group A 67(47.86) and group B 54 (38.57%) followed by postdate 24(17.14%) and 19(13.57%) respectively. Other indications of induction in group A and group B was hypertensive disorder of pregnancy 21 (15%) and 22 (15.71%), decreased fetal movement 11 (7.86%) and 25 (17.86%), GDM 7 (5%) and 16 (11.43%), thyroid abnormalities 10 (7.14%) and 8 (5.71%) respectively (table 1).

Table 1: Distribution of women according to their indications for induction

Indications for labour	Foley's	Misoprostol	χ2-value
Oligohydramnios + IUGR	67(47.86%)	54(38.57%)	13.07
Polyhydramnios	0(0%)	2(1.43%)	
Hypertensive disorder of pregnancy	21(15%)	22(15.71%)	p=0.041
Thyroid abnormalities	10(7.14%)	8(5.71%)	S
Decreased fetal movement	11(7.86%)	25(17.86%)	
Gestational diabetes mellitus	7(5%)	16(11.43%)	
Post dated	24(17.14%)	19(13.57%)	
Total	140(100%)	140(100%)	

Table 2: Distribution of women according to time required for ripening

Time required for ripening	Foley's	Misoprostol	χ2-value
<6 hrs	26(18.57%)	42(30%)	13.85
6-8 hrs	27(19.29%)	31(22.14%)	p=0.001,S
8-10 hrs	28(20%)	34(24.29%)	
10-12 hrs	30(21.43%)	26(18.57%)	
>12 hrs	29(20.71%)	7(5%)	
Total	140(100%)	140(100%)	

It was observed that in group B cervical ripening seen <6 hour was 42 (30%) and in group A was 26 (18.5%) which was statistically significant. Another observation that between 8-10 hours in group B and group A were 34 (24.29%) and 28 (20%) followed by between 6-8 hours was 31(22.14%) and 27 (19.29%), >12 hours was 7(5%) and 29(20.71%) respectively (table 2).

Pre ripening Bishop's score < 3 in group A and group B was 69 (49.29%) and 66(47.14%) followed by score 4 was in 49 (35%) and 50 (35.71%) respectively. The distribution of women according to their preripening Bishop's score of group A was comparable to group B ($p > 0.05$).

Postripening Bishops score 8 in Group B and Group A was in 58 (41.43%) and 65 (46.43%) followed by score 50

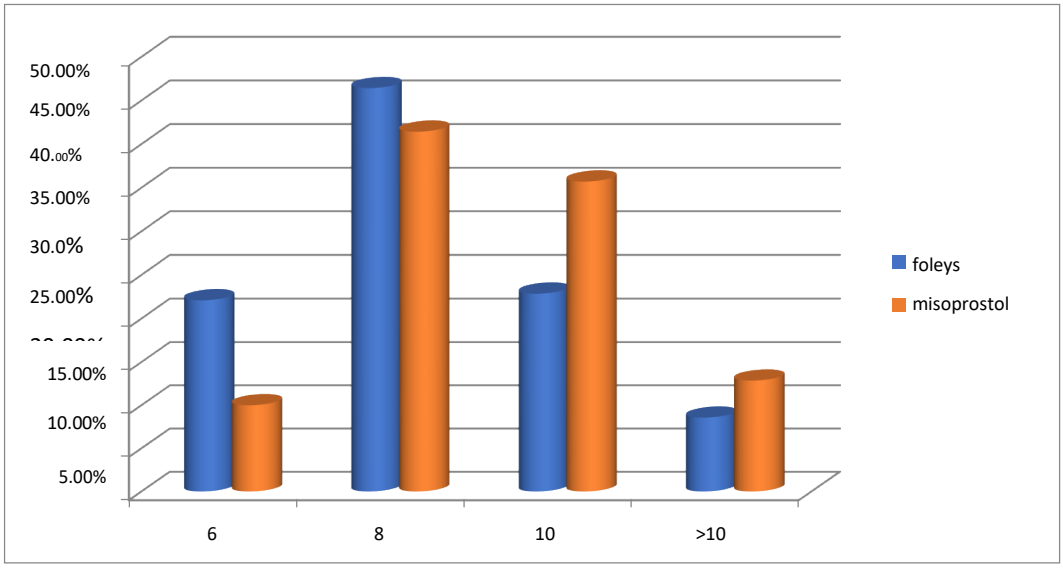

Figure 1: Distribution of women according to postripening Bishop's score

(35.71%) and 32 (22.86%) respectively. Post ripening Bishops score better in group B than group A (figure 1).

In most of delivered patients artificial rupture of membrane had done at 5-6 cm cervical dilatation in group A was 116 (83.86%) and 83 (59.29%) in group B. In this study, in group A after ripening of cervix still needed oxytocin for augmentation of labour for better cervical dilatation to delivered the baby was 46 (32.86%) and in group B 21 (15%). In this study, most of the women according to time from active labour to delivery in 10 hours in group B was 10 (7.14) and group A 4 (2.86%). Distribution of women according to time from active labour to delivery group A was comparable to group B (P>0.05). In this study, vaginal deliveries more in group A than group B was 91 (65%) and 74 (52.86%). Lower segment c-sections were more in group B than group A was 53 (37.86%) and 48 (34.29%). Instrumental deliveries were more in group B than group A. Distribution of women according to mode of delivery group A was comparable to group B (p> 0.05).

In majority of the patients in group B, excessive nausea and vomiting 21 (55.26%) followed by hyperstimulation during labour 9 (23.68%) only present in group B, diarrhea 7 (18.42 %), PPH 1 (2.63%). Meanwhile in group A excessive nausea and vomiting 12 (85.71%) followed by PPH 2 (14.29 %). Among the study groups A and B, maternal adverse effect was significantly different (p=0.020) (table 3). There were total 3 (14.92%) cases of PPH, which was mild in nature and was managed by uterotonics and none of them required any blood transfusion or surgical intervention. There were no cases of maternal mortality and uterine rupture.

Most of the women who delivered baby NICU admission in group A was 8 (5.71%) and group B 12 (8.57%). The distribution of women according to NICU admission for birth asphyxia of group A was comparable to group B (p >0.05) (table 4).

Table 3: Distribution of women according to maternal complications

Maternal complications	Foley's	Misoprostol	χ2-value
Hyper stimulation during labour	0(0%)	9(23.68%)	9.79
Excessive nausea and vomiting	12(85.71%)	21(55.26%)	p =
Diarrhoea	0(0%)	7(18.42%)	0.020, S
PPH	2(14.29%)	1(2.63%)	
Total	14(100%)	38(100%)	

Table 4: Distribution of women according to NICU admission for birth asphyxia

NICU admission	Foley's	Misoprostol	χ2-value
Yes	8(5.71%)	12(8.57%)	0.86
No	132(94.29%)	128(91.43%)	P=0.35,NS
Total	140(100%)	140(100%)	

Discussion

Based on the findings of this study it was found that increase in postinduction Bishop's score was earlier in intravaginal misoprostol than intracervical Foley's catheter. Misoprostol induction had a better rate of cervical dilatation and needed less frequent oxytocin for augmentation of labour as compared to Foley's group. Active labour to delivery, induction to delivery time was not significantly different in both groups. Lower segment caesarean sections and instrumental deliveries was more in misoprostol due to fetal distress. Neonatal and maternal complications were less in Foley's catheter as compared to intravaginal misoprostol. Thus we conclude that though both methods are effective for

pre-induction cervical ripening intracervical Foley's catheter is safer and can be considered as an alternative mode for preinduction cervical ripening.

In a similar study conducted by Tuuli MG et al [11] it was observed that the augmentation with oxytocin in nulliparous women was not significantly different in misoprostol and Foley's catheter group (80% vs 89.8%, p=0.12) but a significant difference was observed in multiparous women among both the groups (72% vs 84%, p=0.04).

In our study, most common indication for induction was oligohydramnios with IUGR. Adeniji O A et al [12] conducted similar study where the most common indication for induction in both the groups was postdated pregnancy (64% vs 67%).

In our study, misoprostol had a better cervical ripening time. This is similar to study conducted by Afolabi B et al [13] which reported that intravaginal misoprostol had better cervical ripening time than Foley's catheter.

In our study, postripening Bishop's score was better in misoprostol group. Adeniji et al performed a study in 2006, they reported that vaginal misoprostol was more effective to improve the scores of cervical length and consistency, while Foley's catheter was better to improve the cervical os dilatation score during the preinduction cervical ripening [12]. Tobowei TO and Oboro VO [14] conducted similar study reported that the intravaginal misoprostol was more effective than Foley's catheter for ripening of cervix.

In our study, hyperstimulation was seen only in misoprostol group. Nasreen Noor et al [15] did a similar study reported that the hyper stimulation of uterus was reported in 11.7% among misoprostol group while no similar complication was reported in Foley's catheter group. Roudsari F et al [16] study reported that the rate of complications among both the groups was not significantly different, but tachysystole (2%) and uterine hyper tonicity (2%) were seen in misoprostol group.

In our study, there was a significant difference among NICU admission among both groups with higher admission among misoprostol group. Adeniji OA et al [12] conducted a randomized study reported that 4 neonates from misoprostol group and 2 neonates from Foley's catheter group required supplemental oxygen during neonatal resuscitation.

Conclusion

Based on the findings of this study it was found that increase in postinduction Bishop's score was earlier in intravaginal misoprostol than intracervical Foley's catheter. Misoprostol induction had a better rate of cervical dilatation and needed less frequent oxytocin for augmentation of labour as compared to Foley's group. Active labour to delivery, induction to delivery time was not significantly different in both groups. Lower segment caesarean sections and instrumental deliveries was more in misoprostol due to fetal distress. Neonatal and maternal complications were less in Foley's catheter as compared to intravaginal misoprostol. Thus we conclude that though both methods are effective for preinduction cervical ripening intracervical Foley's catheter is safer and can be considered as an alternative mode for preinduction cervical ripening.

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