ORIGINAL RESEARCH PAPER
Volume - 11 | Issue - 08 | August - 2022 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

PREINDUCTION CERVICAL RIPENING IN TERM PREGNANT WOMEN WITH ORAL MISOPROSTOL AND FOLEY CATHETER - A COMPARATIVE STUDY

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ABSTRACT

Background and objectives: Preinduction cervical ripening and induction of labour is practised in over 30% of pregnancies on account of various reasons. Studies shows inconsistent results comparing the safety and efficacy of cervical ripening agents. The objective of this study is to compare the safety and efficacy of 50 µg oral misoprostol and intra-cervical Foley's catheter in term women with Bishop's score <4. **Methods:** This prospective longitudinal study was done in 220 women (110 in each group). Either Foley catheter (18F, 30 ml) with extra-amniotic saline infusion (0.9%, 250 ml) or 50µg of oral misoprostol every four hours (maximum of three doses) were allotted randomly. For women in Foley catheter group, if the Bishop's score <6 after 18 hours or spontaneous expulsion, 50 µg of oral misoprostol was given (maximum of two doses). If failed to attain the Bishop score >6, the membrane was ruptured artificially or given oxytocin. Change in Bishop Score, mode of delivery, induction to delivery interval, maternal and fetal comlications were compared. **Findings:** The Foley catheter women was associated with a greater change in Bishop's score (M=1.90 vs M=1.30), with a mean difference of 0.6 (p=0.00). Caesarean section (32.73%, relative risk 1.71, 95% CI 1.072 - 2.74, p=0 • 021) and vaginal instrumental delivery (32.73%, relative risk 9, 95% CI = 1.160 - 69.8, p=0.019) was significantly more common in the misoprostol group. The misoprostol group had shorter induction- vaginal birth interval with a mean difference of 5.31 hours (p=0.002) and vaginal birth within 12 hours (p=0.006). In the misoprostol group, failed induction rate was significantly high (15.5 % vs 4.5%, relative risk 3.4, 95% CI 1.3 - 8.89, p=0.007). There was no statisticaly siginificant difference in ocurrence of other matenal and fetal complications. **Interpretation:** In women with an unfavourable cervix at term, Foley catheter with extra-amniotic saline infusion was found to be better choice for preinduction cervical ripening.

KEYWORDS

Preinduction cervical ripening; Oral misoprostol; Foley catheter; Change in Bishop's score; Induction of labour; Induced delivery

INTRODUCTION

Cervical ripening and induction of labour is a common practice in many parts of the world and is practised in over 20% of pregnancies in developed countries [1-2]. According to American College of Obstetricians and Gynaecologists, Induction of labour is undertaken when, in the opinion of the physician, the risks of delivery to the mother or the foetus or both are less than the risk of continuing the pregnancy [2]. Induction of labour is the process of artificially stimulating the uterus to start labour and is usually performed by administering prostaglandins or oxytocin to the pregnant woman or by rupturing the amniotic membranes manually [3]. The success of this commonly practised obstetric procedure is highly dependent on the condition of the cervix, and it is well known that an unfavourable cervix is associated with many adverse maternal and fetal outcomes [1-2, 4].

WHO recommends the following cervical ripening and induction agents; oral misoprostol, low-dose vaginal misoprostol, low doses of vaginal prostaglandins, intravenous oxytocin, amniotomy and balloon catheter, individually or in combinations [3]. The risks and favourable outcomes associated with each of the agents vary [3-4].

Oral misoprostol tablets and trans-cervical Foley catheterisation are the most widely used low-cost cervical ripening and induction agents in low resource settings [5]. WHO recommends 25g of Oral misoprostol 2-hourly for induction of labour [3]. When misoprostol and other prostaglandins are contraindicated or are not available, WHO recommends the combination of balloon catheter plus oxytocin as an alternative method of cervical ripening and induction of labour [3], these interventions are highly important in low resource settings where an augmentation of the labour process and reduction of maternal and neonatal mortality and morbidity is highly essential. The ideal cervical ripening and induction agents would result in significant changes in Bishop's score and relatively shorter duration of induction to delivery time without causing risk to mother and foetus and also with low rates of caesarean section [5]. Despite the wide availability of pharmacological methods, trans-cervical Foley catheterisation is still in practice, with or without the infusion of saline solution or prostaglandins into the extra-amniotic space [9].

Studies comparing these two methodd are limited in number and the protocols followed in those are different. The Foley balloon cervical ripening method may have considerable safety benefits for the mother and foetus, although there is conflicting evidence as to its effect on the speed of induction. Both methods are promising, but the relative risks and benefits of the two methods for labour induction among women with low Bishop's score have yet to be established in low resource settings. Given the limited number of studies comparing the induction agents to changes in Bishop's score and inconsistencies in the outcomes of using various induction agents, it is decided to study the safety and efficacy of the most commonly used two induction agents – oral misoprostol and intra-cervical Foley's catheter in term women with low Bishop's score (Score <4).

MATERIALS AND METHOD

This prospective comparative study was carried out in the Department of Obstetrics and Gynecology, TDMC Medical College, Alappuzha after approval by the Ethics Committee and a written informed consent was obtained from all participants. Inclusion criteria were term women (37 - 42 weeks of gestation) with Bishop's score <4, singleton gestation, cephalic presentation, reactive fetal heart rate pattern, intact membranes and the presence of globaly accepted indications for induction. The Exclusion criteria were; cervical dilatation of 3 cm or a Bishop score of 5, uterine contractions at a rate of >8/h, an estimated fetal weight of 4500g or evidence of cephalopelvic disproportion, an estimated fetal weight of <2000g as assessed by ultrasonography, placenta-previa or unexplained vaginal bleeding, breech presentation, active herpes simplex, previous cesarean delivery or history of uterine incision, evidence of chorioamnionitis as determined by maternal temperature 100.4°F and the presence of either uterine tenderness or foul-smelling amniotic fluid, or both, any moderate or severe pre-existing medical disease, such as cardiovascular disease or chronic renal failure, any contraindications to the use of prostaglandins, such as glaucoma or sickle cell disease.

Each woman was assigned to receive a cervical ripening agent of Foley catheter with an extra-amniotic saline infusion (N=110) or oral misoprostol (N=110). The choice of cervical ripening agents was based on the discretion of the concerned primary physician and was given according to our hospital protocol. Bishop's score of each subject was assessed and recorded prior to administration of agents.

In women assigned to the Foley catheter with extra-amniotic saline infusion, an 18 F Foley catheter was inserted into the endo-cervical canal under direct vision by doing a per speculum examination. The catheter was advanced into the endo-cervical canal. Once it passed the internal os, the balloon was filled with 30 ml of sterile water and 250 ml of lukewarm normal saline (0.9%) was infused into extra-amniotic space at a rate of 30 drops per minute. Then the end of the catheter was tied, and the catheter taped to the inner-thigh to maintain traction. Foley catheter was expected to fall spontaneously, or if this did not happen after 18 hours, the catheter was removed, and the Bishop's score was assessed again. Immediate following such expulsion, or

when the Bishop score attained a value of >6, for the acceleration of labour the membrane was ruptured artificially, or oxytocin was begun if necessary. If the Bishop score remains less than six after18 hours or spontaneous expulsion, 50 µg of oral misoprostol were given (maximum two doses).

The women assigned to the oral Misoprostol group received 50 µg of oral misoprostol initially after assessing Bishop's score. Repeated the dose every 4 hours if the patients did not start contractions and a total of three doses were given. Bishop's score was reassesed after 3 doses, or when recorded the contractions. In women who did not have spontaneous labour after 6 hours of the last dose of misoprostol or alternatively when the Bishop score attain a value of >6, for an acceleration of labour, the membrane was ruptured artificially, or oxytocin was begun if necessary. Each subject undergoes NST after one hour of administration of each dose, and she was allowed to ambulate with intermittent fetal heart rate (FHR) test assessment every 30 minutes.

In both these groups subsequent doses were withheld if the regular uterine contraction was established (at least 1 in 10 minutes regularly), tachysystole (6 contractions in 10 minutes), hyper uterine stimulation or non-reassuring FHR or rupture of membranes occurred. Pitocin augmentation was given until the contractions are adequate (3 contractions, 35 -40 seconds over 10 minutes). Patient and baby were monitored till discharge from the hospital.

Our primary objective was to evaluate the success of pre-induction cervical ripening by assessing the primary outcome measure, i.e. change in Bishop Score. For women in the Foley catheter group, that was defined as the difference between initial cervical examination and examination at the time of extrusion. In contrast, for the misoprostol group, it was the difference between initial examination and Bishop Score assigned after the last dose of oral misoprostol. Secondary outcome measures include the interval from the administration of the cervical ripening agent to the vaginal delivery, need for oxytocin augmentation, mode of delivery, the incidence of tachy-systole and hyper-stimulation syndrome (defined as six contractions in 10 minutes, in two consecutive 10 minutes periods), postpartum haemorrhage, shoulder dystocia, unplanned hysterectomy, chorioamnionitis, uterine rupture, thick meconium and 5-minute Apgar score <7 and NICU admission of the baby and the patients was monitored till discharge.

A study conducted by Sheikher et al., (2009) in Govt. Medical College, Jammu, India found that the change in the mean Bishop's Score was 4.0±0.2 and 3.9±0.3 respectively for oral misoprostol and Foley catheter group [15], so the sample size for this study was calculated as 102 women in each group (80% power and p = 0.05).

Data were analysed using SPSS Version 23. All qualitative variables were summarised as frequencies and percentages and quantitative variables as mean with standard deviation for normally distributed data. In the univariate and multivariate analysis, the Chi-Square tests and Fisher's exact test were used to compare categorical variables, and Student's t-test was used for comparison of continuous variables.

RESULTS

A total of 1150 mothers were screened from February 2019 to August 2020 and 110 women were randomely alloted to each group who met inclusion criteria. Demographic characteristics (Table 1) and the indications for cervical ripening (Table 2) were comparable between two groups.

Table 1 Demographic characteristics

Parameter	Oral misoprostol	Foley catheter
Sample size	N = 110	N = 110
Age	25.20 ± 3.97	24.80 ± 4.37
Body mass index	23.27 ± 1.83	22.02 ± 1.79
Parity		
0	77 (70.00%)	77 (70.00%)
1	29 (26.36 %)	26 (23.64%)
2	4 (3.64%)	7 (6.36%)
Gestational age		
Early term	65 (59.09%)	82 (74.55%)
Full term	45 (40.91%)	28 (25.45%)
Antenatal Exercise	8 (7.3%)	18 (16.4)
Booking status	106 (96%)	107 (97.3)
Mean preinduction Bishop's score	3.03 ± 1.02	2.41 ± 1.05

Table 2 Indications for induction

Indication for Induction	Oral misoprostol	Foley catheter
Gestational Diabetes Mellitus	43 (39.1%)	29 (26.36 %)
Late term	19 (17.3%)	9 (8.2%)
Gestational Hypertension	15 (13.6%)	13 (11.8%)
Oligamnios	14 (12.7%)	18 (16.4%)
Fetal growth retardation	11 (10%)	29 (26.36 %)
Decreased fetal movement	7 (6.4%)	5 (4.55%)
Acute fatty liver of pregnancy	1 (0.91%)	0
Abnormal Doppler	0	4 (3.6%)
Overt Diabetes Mellitus	0	2 (1.8%)
Rh –ve blood group	0	1 (0.91%)

The Misoprostol group was associated with a change in Bishop score M=1.30 (SD= 1.462) and in the Foley catheter group, it was higher M=1.9 (SD= 1.075). The independent samples t-test was associated with a statistically significant effect, t= -3.467, p=0.001 (Table 3). Thus the pregnant women induced with Foley catheter were associated with a greater change in BISHOP score than Misoprostol group.

Table 3: Change in Bishop Score

Bishop score	Oral misoprostol	Foley catheter	p value
Mean pre-induction score	3.03 ± 1.02	2.41 ± 1.05	
Mean post-induction score	4.29 ± 1.47	4.31 ± 0.85	
Mean change in score	1.3 ± 1.46	1.9 ± 1.075	0.001

Along with the induction agent, 70.9% of women in the misoprostol group and 65.5% women in the Foley catheter group got Oxytocin infusion to augment the labour and the difference between this groups were not statistically significant p=0.385 (Table 4)

Table 4: Need for oxytocin augmentation

Variable	Misoprostol	Foley catheter	p value
Oxytocin augmentation	78 (70.9%)	72 (65.5%)	0.385

The misoprostol group (N=74) was associated with shorter duration of cervical ripening to vaginal birth interval M=20.26 (SD= 10.71) compared with the Foley catheter group M=25.57 (SD= 10.41) and the difference were statistically significant (t= -3.198, p=0.002). In the misoprostol group, 23 (31.1%) of 74 women had vaginal delivery within 12 hours compared with 12 (13.5%) of 89 women in the Foley catheter group and the difference between this groups were statistically significant at p=0 · 006. But the relationship between the method of cervical ripening and vaginal birth within 24 hours was not statistically significant (p=0.19). Similarly, the misoprostol group (N=110) was associated with shorter induction-delivery interval M=22.10 (SD= 10.75) than the Foley catheter group M=25.97 (SD= 12.56) and the difference were statistically significant (t= -2.457, p=0.015). Thus the pregnant women induced with misoprostol were associated with lower induction-delivery interval than the Foley catheter group (Table 5).

In the misoprostol group, 17 (15.5 %) women had failed induction compared with 5 (4.5%) in the Foley catheter group and the difference was statistically significant, p=0.007 (Table 5). Caesarean section rate was high (32.73%) in the misoprostol group compared with Foley catheter group (19.09%), with a statistically significant difference between groups, p=0.021 (Table 5). Spontaneous vaginal birth was more common among those induced with Foley catheter (88%) compared with misoprostol group (59.09%), and the difference was statistically significant at p=0.001. Vaginal instrumental delivery was significantly more common in the misoprostol group (32.73%) than in the Foley catheter group (0.91%), with p value 0.019 (Table 5).

Table 5: Induction-delivery interval and mode of delivery

Variable	Oral misoprostol	Foley catheter	p value
Cervical ripening to vaginal birth interval	20.26 ±10.71	25.57 ± 10.41	0.002
Induction-Delivery Interval	22.11 ± 10.75	25.97 ± 12.56	0.015
Vaginal Delivery within 12 hours	23 (31.1%)	12 (13.5%)	0.006
Vaginal Delivery within 24 hours	45 (60.8%)	45 (50.6%)	0.19

Failed Induction	17 (15.5%)	5 (4.5%)	0.007
Caesarean section	36 (32.73%)	21 (19.09%)	0.021
Spontaneous vaginal birth	65 (59.09%)	88 (80%)	0.001
Vaginal instrumental	9 (32.73%)	1 (0.91%)	0.019

Maternal complications like birth injury, postpartum haemorrhage, maternal pyrexia, uterine hyper stimulation and maternal infection was reported in study population. Apart from maternal infection, the rate of occurrences of other maternal complications was less in the Foley catheter group. But, difference in the incidence of those complications across study group was not statistically significant (Table 6).

Table 6: Maternal Complications

Variable	Misoprostol	Foley catheter	p value
Birth injury	7 (6.4%)	5 (4.5%)	0.553
Maternal pyrexia	6 (5.5%)	1 (0.91%)	0.122
Postpartum haemorrhage	8 (7.3%)	2 (1.8%)	0.101
Uterine hyperstimulation	4 (3.6%)	0	0.119
Maternal infection	1 (0.91%)	2 (1.8%)	1

Only shoulder dystocia, meconium-stained liquor and fetal distress were reported across both groups and none of the neonatal complications listed were not statistically significant. No statistical difference were noted between the groups on account of APGAR score <7 at 1 minute and 10 minutes. In the misoprostol group, 15 (13.6%) neonates got admitted in NICU compared with 11 (10.0%) neonates in the Foley catheter group and the difference were not statistically significant, p=4.04 (Table 7).

Table 7: Neonatal outcomes

Variable	Misoprostol	Foley catheter	p value
Shoulder dystocia	1 (0.91%)	1 (0.91%)	1
Meconium-stained liquor	6 (5.5%)	3 (2.7%)	0.499
Fetal distress	14 (12.7%)	12 (10.9%)	0.676
1 minute APGAR score <7	1 (0.9%)	1 (0.9%)	1
5 minutes APGAR score <7	1 (0.9%)	0 (0%)	1
NICU admissions	15 (13.6%)	11 (10.0%)	0.404

DISCUSSION

This prospective longitudinal study was done to compare the efficacy of the most commonly used pre-induction cervical ripening agents such as oral misoprostol and intra-cervical Foley's catheter in term women with low Bishop's score (Score <4). This study reveals that, in women with an unfavourable cervix (Bishop's score <4) at term, pre-induction cervical ripening with Foley catheter with extra-amniotic saline infusion has many advantages over oral misoprostol in terms of safety and effectiveness.

It is found that, the pregnant women induced with Foley catheter were associated with a greater change in Bishop's score than oral misoprostol group and the difference were statistically significant. However, similar study done by Goonewardene et al., (2014) fount no difference between groups [88]. Seemingly, women induced with oral misoprostol had significantly short hours of induction to active phase interval and the mean difference was 4.88 hours. The misoprostol group was associated with significant reduction in the cervical ripening - vaginal birth interval with a mean difference of 5.31 hours.

Similarly, statistically significant shorter cervical ripening- delivery interval with a mean difference of 3.87 hours was observed in oral misoprostol group. Accordingly, vaginal birth and total delivery within the first 12 hours occurred more often after oral misoprostol, whereas the relationship between the method of cervical ripening and vaginal birth and total delivery within 24 hours was not statistically significant. This finding is corroborated with the result of similar studies done in in the Netherlands [12]. Due to longer hours of labour, women in Foley catheter group are more likely to be dissatisfied [13].

WHO and the Cochrane Collaboration established that delivery within 24 hours of the start of induction is considered as one of the key indicator to measure the effectiveness of methods of cervical ripening and labour induction agents [3, 7]. Even so, the main goal of preinduction cervical ripening and labour induction is to achieve safe vaginal delivery for both mother and child in order to reduce the risk of various complications associated with labour. Thus, delivery with more than 24 hours is acceptable, provided the trade-off between risk and benefit to both mother and baby allow such a delay and the chances of safe spontaneous and vaginal delivery overweight the complications [3, 12].

Though, the preinduction cervical ripening with Foley catheter is significantly associated more cervical ripening to vaginal birth interval, number of caesarian delivery was significantly less compared to the use of oral misoprostol. The proportion of women who had caesarean section was lower in Foley catheter group and the difference between groups was statistically significant and the result is similar to the findings of Goonewardene et al., (2014) [88]. Aghideh et al (2013) and Ten Eikelder et al., (2016) found no significant difference in the rate of caesarean section between the misoprostol group and the Foley catheter group [14, 12]. Similarly, vaginal instrumental delivery was also significantly more common in the misoprostol group than in the Foley catheter group with the relative risk of 9. This result is complementary to the result of Ten Eikelder et al., (2016) [12] and Aghideh et al (2013)[14]. Additionally, the rate of spontaneous vaginal birth was significantly higher among those induced with Foley catheter compared with misoprostol group. Hence, Foley catheter is found to be better choice for preinduction cervical ripening.

This finding is contradictory to the result of a recent study [12]. One of the possible reasons is that, Ten Eikelder et al., (2016) included women with Bishop score less than six as inclusion criteria [12], whereas women with Bishop score less than four were considered in this study. In addition to that, rate of failed induction was significantly higher in the misoprostol group with a relative risk of 3.4. In concordance, higher rate of caesarean sections were recorded in the oral misoprostol group.

Maternal complications like birth injury, postpartum hemorrhage, maternal pyrexia, uterine hyper stimulation and maternal infection was reported in study population. Apart from maternal infection, the rate of occurrences of other maternal complications was less in the Foley catheter group. But, difference in incidence of those complications across study group was not statistically significant. Use of prostaglandin such as oral misoprostol might have risk of uterine hyper stimulation and subsequent birth asphyxia, such risk is rare in women induced with mechanical methods [12]. Though there were four reported cases of uterine hyper stimulation in oral misoprostol group and none in Foley catheter group, the incidence was not statistically significant and the result correspond to the finding of other studies [12].

Although it is customary to associate the transcervical Foley catheter with higher incidence of chorioamnionitis, no single case was reported in this study and this result is consistent with other studies [88]. The possible reason for not reporting this complication may be because of concurrent administration of prophylactic antibiotic along with Foley catheter insertion. Hospital stay after delivery was almost equal and the difference was not significant across both groups.

Neonatal complications associated pre-induction cervical ripening agents used did not show any significant difference between two groups. Only shoulder dystocia, meconium-stained liquor and fetal distress were reported across both groups and none of the neonatal complications listed were not statistically significant. Overall, those getting oral misoprostol did not have higher rates of fetal distress, and in fact had slightly higher rates than Foley group. In short, preinduction cervical ripening with Foley catheter is equally safe as oral misoprostol on account of both maternal and fetal complications. In consistent with other studies, there was no statistical association between method of cervical ripening and Apgar score less than at 1 minute and 10 minutes [12, 88]. Accordingly, rate of NICU admission did not have any association with agents used. This result is comparable to the findings of Ten Eikelder et al., (2016) [12]. Thus both agents are safe for neonates.

Major findings of this study were contradictory to the result of PROBAAT II study of Ten Eikelder et al., (2016) [12]. The possible reasons for these conflicting results may be the difference in the protocol followed in the administration of ripening agents. Ten Eikelder et al., (2016) included women with Bishop score less than six as inclusion criteria [12], whereas women with Bishop score less than four were considered in this study. Another notable difference was in this study, the Foley catheter was left in place for 18 hours, whereas in PROBAAT II study, Foley catheter was removed only after 48 hours. In this study, along with 30 ml Foley catheter, 250 ml of lukewarm normal saline (0.9%) was infused into extra-amniotic space at a rate of

30 drops per minute and it was not in PROBAAT II study. Additionally, if the Bishop score remains less than six after 18 hours or spontaneous expulsion, 50 µg of oral misoprostol will be given (maximum two doses). In PROBAAT II study, no misoprostol was administered.

CONCLUSION

Oral misoprostol and Foley catheterisation are the most widely used low-cost labour induction agents in low resource settings. A comparaticve study of those agents were done with the objective of assessing the changes in Bishop's score and the obstetrical outcomes such as mode of delivery, maternal and fetal complications. Women in the Foley catheter were significantly associated with a greater change in Bishop's score than Misoprostol group. In the misoprostol group, more women had caesarean section and instrumental delivery compared with the Foley catheter group. However the misoprostol group was associated with significant reduction in the cervical ripening to vaginal birth interval. Along with that, vaginal birth within the first 12 hours occurred more often in oral misoprostol women. There was no statisticaly siginificant difference in ocurrence of matenal and fetal comlications. In short, for women with an unfavourable cervix at term, Foley catheter was found to be better choice for preinduction cervical ripening.