

Efficacy and safety of Intravaginal Misoprostol versus Intracervical Foley's catheter for Cervical Ripening

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ABSTRACT

Introduction: The purpose was to compare the efficacy and safety of the intravaginal Misoprostol versus intracervical Foley's catheter for cervical ripening and labor inductions.

Methods: A prospective Randomized controlled trial done among pregnant women requiring induction of labor at the United Mission Hospital, Tansen, Nepal. Primary outcome was proportion of women achieving change in cervical ripening and time required achieving it.

Results: One hundred women were randomly assigned to receive intravaginal Misoprostol (n=50) or intracervical Foley's catheter (n=50). Catheter group showed statistically significant change in Bishop Score than Misoprostol (P <0.037). Oxytocin augmentation (16% vs 58%, P <0.001) and Caesarean delivery (20% vs 28%) were lower in misoprostol group, compared to Foley's catheter group.

Conclusions: Intracervical Foley's Catheter is a cheap and equally effective method with less complication for cervical ripening as compared with intravaginal Misoprostol.

Key words: *Misoprostol, Foley's Catheter, Cervical ripening.*

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INTRODUCTION

Cervical ripening refers to the process of preparing the cervix for induction of labor by promoting effacement and dilation as measured by Bishop Score. The most important factor in predicting the outcome of induction of labor is the state of the cervix. Labor induction at Bishop score <4 led to increased rates of caesarean section, oxytocin infusion, maternal fever, fetal asphyxia at birth.^{1,2,3} It is now well accepted that ripening the cervix by a variety of methods serves to decrease induction failure.^{4,5,6,7,8}

Misoprostol (Cytotec) is a synthetic PGE1 analog marketed for prevention and treatment of NSAID induced gastric and duodenal ulcers.^{4,13} But various studies^{9,10,11,12} including Cochrane reviewers¹⁰ have found that it is effective for cervical ripening and found a higher incidence of vaginal delivery within 24 hours with less use of oxytocin augmentation and lower rate of caesarean section when used intravaginally.

Transcervical Foley catheter for cervical ripening was first described by Embrey and Mollison.^{9,14} Since then various studies^{15,16,17} has documented that it is as effective as various prostaglandin preparations for ripening. In a larger, randomized trial, they found that the Foley catheter was more effective and more economical than PGE2 gel for providing pre-induction ripening.⁹

The purpose of this study was to compare the relevance, efficacy and safety of intravaginal misoprostol and the intracervical placement of a Foley balloon catheter for pre-induction cervical ripening in patients with unfavourable cervix.

METHODS

The study was conducted in the Maternity ward of United Mission Hospital, Tansen, Nepal after conjoint Ethical Review Board, Nepal Health Research Council and Department of Drug Administration, Nepal approval was received. United Mission is a semi-tertiary hospital located in western hilly area of Nepal with about 1500 deliveries taking place each year. Between April 1, 2008 to August 30, 2008, all inpatients admitted for induction of labor were invited to participate in the study. Inclusion criteria

included all singleton, more than 28 week gestation with vertex presentation and Bishop Score <5. Excluded were those patients with a rupture of membrane, ante-partum hemorrhage, active genital herpes infection, placenta previa and known allergy to Foley's catheter or misoprostol.

After written informed consent was obtained, the patients were randomized by sealed envelope method to the Intracervical Foley catheter or Intravaginal Misoprostol group. Envelope preparation was performed by computer-generated randomization, and the envelopes were sealed by a research nurse. The Bishop score was determined by Resident on duty or Principal Investigator in the Maternity ward. Any adverse maternal or fetal events were documented by the on-call resident staff. Management of the preinduction ripening and induction of labor were conducted by resident physician or principal investigator in consultation with the attending obstetrician.

Intravaginal Misoprostol application: Hospital protocol for the use of prostaglandins was placement of 50 mcg tablet at the posterior fornix. Repeated dose were administered only after 6 hours when no change noted in Bishop Score. The maximum doses to be given were 4 doses (200 mcg) or upto 24 hours.

Intracervical Foley's catheter: A 16 Fr Foley's catheter was passed through the cervix to few centimeters beyond the internal os. Balloon was inflated with 30 ml of distilled water. To produce some degree of traction the Foley catheter was pulled and taped in the inner side of the thigh with adhesive tapes. Once the Foley was extruded, Bishop's scoring was done and recorded by the principal investigator.

Primary outcome measure was to evaluate the success of preinduction cervical ripening, so the main observation was 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 the misoprostol group, it was difference between initial examination and Bishop Score assigned with the last dose of misoprostol.

Secondary outcome measures included interval to achieve a ripe cervix, interval from start of induction to delivery, augmentation requirements, route or mode of delivery, uterine contractile abnormalities, FHR disturbances, delivery outcomes in terms of Apgar score at 1 and 5 minutes, need for or type of resuscitation and the need for neonatal admission. Student *t* test, Pearson Chi-square and Fisher's exact test were used to statistically compare the two groups. Difference with a *P* value <0.05 were considered statistically significant.

RESULTS

A total of 100 patients were randomized to receive either intravaginal misoprostol (misoprostol group) or an intracervical Foley's balloon catheter (catheter group).

Characteristics	Foley's catheter (n=50)	Misoprostol (n=50)	P value
Age (Years), mean, SD	24.04 (±5.14)	24.38 (±6.19)	.766
Parity, mean	1.42	1.44	.842
Primiparous	29	28	.842
Multiparous	21	22	.840
Gestational age (Wks), mean, SD	41.74 (±0.68)	40.86 (±2.77)	.028
Baseline(Pre-induction) Bishop's score	2.9 (±1.09)	4 (±1.19)	<0.001
Primiparous	2.66 (±1.07)	3.79 (±1.37)	.001
Multiparous	3.24 (±1.04)	4.27 (±0.88)	.001
Indications			
Post dates	41	35	
Pregnancy Induced Hypertension	2	6	
Electives	4	5	
Oligohydramnios	3	4	

Table 1: Demographic characteristics of the patients.

Significant change in Bishop Score was noted in the women in Foley' catheter group (*p* value 0.037) compared to Misoprostol group. More patients in the catheter group required oxytocin for induction and/or augmentation of labor than in the misoprostol treated group (58% vs 16%, *p* <0.001). The number of patients requiring 1-2 doses of misoprotol was 78%. There was no significant difference between the two groups with respect to spontaneous and operative delivery (Table 2). The indications for caesarean section did not differ significantly between the two groups (*p* >0.05) (Table 2).

	Foley group (n=50)	Misoprostol group (n=50)
Change in Bishop score, mean (SD)	4.4 (±1.52)	3.6 (±1.85)
Primiparous	4.5 (±1.61)	3.5 (±2.08)
Multiparous	4.1 (±1.43)	3.8 (±1.56)
Cervical ripening time (min), mean(SD)	691.70 (±455.43)	549.92 (±399.55)
Primiparous	812.41 (±461.87)	649.57 (±434.85)
Multiparous	525.00 (±399.01)	422.82 (±314.93)
Induction to Delivery interval (min), mean (SD)	1505.10 (±736.36)	1293.72 (±881.35)
Primiparous	1648.48 (±710.28)	1578.57 (±980.2)
Multiparous	1307.09 (±742.41)	931.18 (±575.55)
Oxytocin Infusion needed	29	8
Primiparous	18/29	7/28
Multiparous	11/21	1/22
Mode of Delivery		
Spontaneous Vaginal Delivery	33	38
Instrumental Vaginal Delivery	3	2
Caesarean Delivery	14	10
Indications for Caesarean Delivery		
Non-progress	10	9
Fetal distress	2	1
Others	2	0

Table 2: Comparing differences in terms of change in cervical ripening, delivery interval, need of oxytocin infusion, and mode of delivery in both groups.

The induction to delivery interval in the misoprostol group 1293.72 ± 881.35 minutes compared with 1505.10 ± 736.36 minutes in the catheter group which was not significantly shorter (*P* value 0.19). In terms of complications, meconium passage occurred more in the misoprostol group than in the catheter group (20% vs 8%, *P* value 0.084) (Table 3).

	Foley's catheter (n=50)	Misoprostol (n=50)	Pval
Tachysystole	1	0	NS
Uterine hypertonus	0	0	-
Hyperstimulation syndrome	0	0	-
Meconium passage	4	10	.084
Primi	2	5	
Multi	2	5	
Others (Nausea, vomiting, fever, precipitate labor)	0	0	-
Non-reassuring FHR	2	1	NS
Post partum hemorrhage	0	4	NS
Primi	0	3	
Multi	0	1	
Failed inductions	3	3	NS

Table 3 : Comparing the maternal complication in both groups.

*NS Not Significant

Neonatal outcomes were similar in both groups. Other parameters including the median 1- or 5- min Apgar

scores and requirement for admissions into the neonatal care unit showed no difference between the two groups ($P>0.05$).

	Foley's catheter (n=50)	Misoprost (n=50)
Birth weight, gm, mean (SD)	2939.1 (\pm 427.70)	2910.4 (\pm 5
Apgar <7 at 1 min	7	10
Apgar <7 at 5 min	0	2
Baby Resuscitation	0	2
Baby admission	3	8

Table 4: Comparing the neonatal complications in both groups

DISCUSSION

Misoprostol is an effective agent for cervical ripening before oxytocin induction of labor. The misoprostol therapy group in this study demonstrated significantly less need for oxytocin augmentation and shorter mean induction to delivery interval whereas Foley's catheter group had significant higher change in Bishop score, low meconium passage compared to misoprostol group ($P<0.001$).

Intravaginal misoprostol was associated with shorter interval to achieve an 'inducible' cervical score, with 78% of the patients in this group requiring 1-2 doses only, similar to Adeniji and Owolabi studies.²⁰ The findings from this study demonstrate that, intravaginal misoprostol and intracervical Foley's catheter were equally effective as pre-induction cervical ripening agents and within the limited scope of this study, both have comparable safety profile.

The time needed for cervical ripening was similar between the two groups 11.5 vs 9.1 hours in Foley's and Misoprostol group, respectively, which is comparable to other studies, Sciscione⁹, Owolabi.²⁰ Foley's catheter was associated with increased number of women needing augmentation with oxytocin, 58% vs. 16%. This was statistically significant when compared with Misoprostol

($P<0.001$). Several other studies have also found increase need of oxytocin for the augmentation when using Foley for ripening and induction.^{9,20}

Foley's catheter group had higher rate of caesarean delivery, 28% vs. 20%, as compared to misoprostol but this differences was not statistically significant. This finding was similar with Owolabi study²⁰, where 28.3% vs 18.3% had caesarean section in the Foley's and Misoprostol group respectively. In contrast, Sciscione⁹ showed higher rate caesarean delivery in misoprostol group, 37.8% vs. 31.8% as compared to Foley catheter. The most common indications were non-progress of labor.

There was no incidence of tachysystole and hyperstimulation in this study while using 50 mcg dose of intravaginal misoprostol. This is one of the main concerns of the researchers when using misoprostol at different doses and routes.^{4,9,13} Four women in this group had post-partum hemorrhage due to atony uterus and perineal tear compared to catheter group, which was managed appropriately. There was no incidence of infection in catheter group in this study as observed in several studies.²¹

This report highlights the ability of the intracervical Foley's catheter to serve as a pre-induction ripening agent, with women in this report requiring more oxytocin infusions in catheter group. Misoprostol, however acts as a ripening agent and an induction agent, with more women entering labor without added oxytocin. Misoprostol's dual role in induction offers the small advantage of less nursing time in preparation and delivery of oxytocin. However, the associated increase in meconium passage, low Apgar score and baby admissions, combined with lack of significant time benefit or decrease in the caesarean delivery rate, minimize that advantage. There are obvious limitations in this study like small sample size, attending physicians couldn't be blinded to type of ripening agent used and moreover, 50 mcg Misoprostol was presently not available, thus each 100 mcg Misoprostol was divided into two along its demarcation line, using a pill cutter, and subtle fetal heart rate abnormality could have been missed because of lack of continuous electronic Fetal heart rate monitoring.

CONCLUSION

Maternal and perinatal outcome in this study have shown no difference confirming the efficacy and safety of both methods. This study has demonstrated the effectiveness of intravaginal Misoprostol compared with intracervical Foley's catheters as a pre-induction cervical ripening agent and further demonstrated additional advantages of a shorter duration of cervical ripening, induction to delivery interval, and reduced oxytocin requirement for induction of labor with intravaginal Misoprostol. Though the route of delivery and labour complications were similar with both methods, Intravaginal Misoprostol was associated with more meconium passage, low Apgar scores, and more number of babies needing hospital admissions.

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