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Original Research Article

Effectiveness of combined use of misoprostol with intracervical catheter for induction of labour: a randomized control trial

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ABSTRACT

Background: Labor induction methods are continuously evolving to ensure safer and more effective outcomes for both mother and neonate. The present study aimed to assess the effectiveness and safety of combined use of misoprostol with intracervical catheter for labor induction.
Methods: This single-blinded, parallel-group randomized control trial conducted at Shaheed Suhrawardy Medical College, Dhaka, Bangladesh, included 200 women with term gestation and Bishop score ≤6. Participants were divided into two groups: the intervention group (group B) received misoprostol juice and Foley's catheter, while the control group (group A) received misoprostol in the posterior fornix.
Results: In Group A, 58% had vaginal deliveries, while in Group B, 65% had vaginal deliveries. Group B experienced a longer mean length of labor in the 1st stage (13.25±1.095) compared to Group A (12.98±1.982, p=0.008). The 3rd stage was shorter for Group B (10.00±0.000) than Group A (12.02±2.469, p<0.001). The most common induction reason was labor pain with an unfavorable cervix (31 in Group A and 33 in Group B). Group B had a higher percentage of inductions at less than 12 hours and a lower percentage at more than 24 hours. Neonatal outcomes were generally better for Group B. The Cox regression hazard model showed a lower likelihood of positive outcomes in Group B (hazard ratio 0.337, 95% CI 0.243-0.469, p=0.000), indicating a statistically significant difference between the groups.
Conclusions: The combined use of misoprostol with Foley's catheter for labor induction is safe and effective, resulting in shorter labor duration and higher rates of vaginal delivery compared to misoprostol alone.

Keywords: Catheter, Effectiveness, Induction, Intracervical, Misoprostol

INTRODUCTION

The rate of cesarean section is higher compared to vaginal delivery in various parts of the world.[1] It has been well documented that there are many complications associated with cesarean deliveries in resource-poor settings such as Bangladesh, including potentially life-threatening complications such as hemorrhage, surgical complications, and placenta accreta.[2,3] To reduce unnecessary cesarean sections, induction of delivery plays an important role. Therefore, there has been a significant increase in the rate of labour induction, which is usually performed when the risk of continuing a pregnancy outweighs the benefits of delivery. Labour induction is a frequently used method in the management of high-risk pregnancies. Currently, both mechanical and medical methods have been applied for cervical ripening in women with an unfavorable cervix. Mechanical methods aim to promote cervical ripening and the onset of labour by dilating the cervix. Hygroscopic and osmotic dilators are

effective, but they may be associated with an increase in maternal infection and are rarely used in term labour induction.[1] The most commonly used mechanical device for labour induction is the Foley catheter balloon, which acts not only as a mechanical dilator of the cervix but also as a stimulator of endogenous prostaglandin release from the fetal membranes. Cervical ripening has a close relationship with the success rate of vaginal delivery, so methods of cervical ripening that ripen the cervix in a short period of time play an important role in modern obstetrics.[4] Several methods have been mentioned in the literature for cervical ripening, including stripping of membranes, oxytocin, prostaglandins, mifepristone, mechanical dilators such as the Foley balloon catheter, extra-amniotic fluid infusion, and more.[5] Among all these methods, prostaglandin PGE2 is very useful in cervical ripening and induction of labour.[6] PGE1 (misoprostol) has also been used for the ripening of the cervix at term. The advantage of misoprostol is that it is cheaper, stable at room temperature, and has a good effect it is frequently used in obstetrics and gynecology for termination of pregnancy, especially in the third trimester.[7] Ideally, these agents used for induction should mimic spontaneous labour without causing excessive uterine activity.[8] Intravaginal use of misoprostol, transcervical insertion of Foley's catheter, and insertion of prostaglandin gel are the most common methods used when the cervix is unfavorable, where with a ripe cervix, oxytocin may be administered intravenously.[9-11] Due to the mentioned benefits, it is frequently used in obstetrics and gynecology for the termination of pregnancy, especially in the third trimester. In one study, two methods of cervical ripening and labour induction with vaginal misoprostol and Foley catheter were compared, with the results showing that the success rate in the misoprostol group was higher than the Foley catheter group.[11] Fekrat et al evaluated three methods of cervical ripening and labour induction with vaginal misoprostol and Foley catheter and the combination of these two methods, reporting that vaginal misoprostol was more effective than the other two methods.[11] According to a study by Kashanian et al, the use of a Foley catheter with varying balloon volumes was found to be a safe and effective method for cervical ripening and labour induction when compared to oxytocin.[12] The study concluded that the use of a Foley catheter may reduce the duration of labour and increase the number of deliveries within 24 hours, with larger balloon volumes potentially improving these effects. This finding is supported by other studies and a combined method of using both Foley catheter and oxytocin was found to result in a shorter induction to delivery time without increasing labour complications.[13-15] In a study by Dewan comparing the use of a Foley catheter for induction of labour in postdated pregnancies to the sweeping of membranes in prolonged pregnancy, it was found that the use of a Foley catheter resulted in a safe vaginal delivery with a short induction to the delivery interval in the Foley group. Additionally, another study found that the use of repeated small doses of misoprostol for cervical ripening resulted in a high rate of vaginal delivery, shorter induction-delivery interval, lower incidence of failed induction, less need for oxytocin augmentation, fewer maternal side effects, and fewer NICU admissions.[8] Foley catheter is also widely used in developing countries for pre-induction cervical ripening due to their affordability.[9]

In this study we aimed to assess the effectiveness and safety of the combined use of misoprostol and intracervical catheter for induction of labour.

METHODS

This study was a single-blinded, parallel-group, randomized control trial conducted in the gynecology and obstetrics department of Shaheed Suhrawardy Medical College, Dhaka, Bangladesh. The study population consisted of pregnant women at term with singleton pregnancy and an indication for induction of labour, as determined by a Bishop score of 6 or less. The study was conducted from July 2021 to June 2022, with participants providing written informed consent and receiving clearance from the local ethics review committee.

The sample was collected and allocated according to a computer-generated simple random sampling technique. Participants were randomly divided into two groups, group A and group B each having 100 patients, with group A, or the control group receiving 25 ml of misoprostol juice for 4 doses with 2 hours interval, and group B or the intervention group receiving Foleys catheter insertion with 2 doses of 25 ml misoprostol juice given orally for 2 hours

The primary outcome was induction delivery interval and secondary outcomes included the number of successful vaginal deliveries, need for instrumental delivery, the need for caesarean section, side effects of misoprostol, neonatal outcome, and maternal complications.

Statistical analysis

Data were analysed using SPSS software and statistical significance was determined with a p value of less than 0.05.

RESULTS

The largest proportion of participants in both groups was in the 25 to 30-year age range (50% in group A and 64% in group B), followed by those in the 30 to 35-year age range (32% in group A and 22% in group B). The majority of participants in both groups were housewives (66% in group A and 82% in group B) with secondary education (80% in group A and 100% in group B). The majority of participants in both groups were in the upper socioeconomic status category (80% in group A and 74% in group B), and most participants in both groups follow Islam (94% in both groups) (Table 1).

Most participants of both groups had regular menstrual cycles (96% in group A and 94% in group B). A higher

proportion of participants in group B used contraceptives (50%) compared to group A (38%), and a higher proportion of participants in group B had regular ante-natal check-ups (84%) compared to group A (88%). In terms of Bishop score, the majority of participants in both groups had a score of 4 to 5 (64% in group A and 68% in group B). The majority of women in group A (42/100) stayed an additional 4 days in the hospital, while group B had most women (55/100) stay 0 additional days. Both groups had a minority of women stay 1 or 2 additional days.

Table 1: Socio-demographic characteristics of study population.

Baseline clinical profiles	Group A (n=100)	Group B (n=100)
Age group		
Less than 25 years	8	10
25 to 30 years	50	64
30 to 35 years	32	22
More than 35 years	10	4
Occupation		
Housewife	66	82
Working lady	34	18
Educational status		
Primary	2	0
Secondary	80	100
Socioeconomic status		
Middle	20	26
Upper	80	74
Religion		
Islam	94	94
Hindu	6	6

The proportion of participants with anemia was similar in both groups (68% in group A and 70% in group B, with a p value of 0.76). A higher proportion of participants in group B had edema (14%) compared to group A (8%), but the difference was not statistically significant (p value =0.175). Both groups had 2 participants with raised temperatures, with a p value of 1. The proportion of participants with SFH at 38 weeks was similar in both groups (100% in group A and 98% in group B). A higher proportion of participants in group A had not engaged in pregnancy (4%) compared to group B (0%), with a statistically significant difference (p value =0.043). The proportion of participants with inadequate liquor was similar in both groups (4% in group A and 6% in group B, with a p value of 0.516). The mean pulse rate was 85.65±3.135 in group A and 84.35±3.286 in group B, with a statistically significant difference (p value =0.006). The mean SBP and DBP were similar in both groups, with p values of 0.548 and 0.503, respectively. The mean weight was 56.60±2.462 in group A and 56.30±2.186 in group B, with a p value of 0.363. The mean FHS was 136.64±4.525 in group A and 133.18±5.225 in group B, with a statistically significant difference (p value =0.007) (Table 3).

The results showed that 18% of group A had a firm per vaginal cervix consistency while 82% had a medium consistency, whereas 6% of group B had a firm consistency and 94% had a medium consistency (p value =0.009). 80% of group A had a midline per vaginal cervix position, while 20% had a posterior position, 70% of group B had a midline position and 30% had a posterior position (p value =0.102). In terms of PV cervix effacement, 40% of group A had 30%, 12% had 40%, and 48% had 50% effacement, while 34% of group B had 30%, 2% had 40%, and 64% had 50% effacement (p value =0.007). 96% of group A had a station of the presenting part at 2 and 4% at 3, while 98% of group B had a station at 2 and 2% at 3 (p value =0.407). 98% of group A had an intact membrane, and 2% had a ruptured membrane, while 100% of group B had an intact membrane and 0% had a ruptured membrane (p value =0.155) (Table 4).

Group B had a longer mean length of labour in the 1st stage (13.25±1.095) compared to group A (12.98±1.982) with a p value of 0.008. In the 2nd stage, there was no significant difference in the mean length of labour between the two groups (group B: 1.00±0.000, group A: 1.02±0.153, p value: 0.282). However, the 3rd stage had a shorter mean length of labour in group B (10.00±0.000) minutes compared to group A (12.02±2.469) minutes with a p value of <0.001 (Table 5).

Table 2: Baseline clinical profiles of study population.

Baseline clinical profiles	Group A (n=100)	Group B (n=100)
Age menarche		
11 years	14	16
12 years	62	58
13 years	22	24
14 years	2	2
Menstrual period		
3 to 4 days	2	0
4 to 5 days	6	40
5 to 6 days	56	56
5 to 7 days	22	32
6 to 7 days	10	6
More than 7 days	4	2
Gravida		
Primigravida	68	72
Multigravida	32	28
Para		
0	70	76
1	28	24
2	2	0
Bishop score		
0 to 1	4	4
2 to 3	32	28
4 to 5	64	68
Additional duration of hospital stay		
0 day	25	55
1 day	30	8
2 days	3	2
4 days	42	35
Menstrual cycle		
Regular	96	94
Irregular	4	6
Use contraceptive		
Yes	38	50
No	62	50
Ante-natal check		
Regular	88	84
Irregular	12	16

Table 3: Distribution of participants by physical examination findings among the study population.

Clinical findings	Group A (n=100)	Group B (n=100)	P value
Anemia	68	70	0.76
Edema	8	14	0.175
Raised temp	2	2	1
36 weeks SFH	0	2	0.159
38 weeks SFH	100	98	
Not engaged pregnancy	4	0	0.043
Inadequate liquor	4	6	0.516
Mean±SD clinical parameters			
Pulse	85.65±3.135	84.35±3.286	0.006
SBP	141.0±11.55	142.0±11.93	0.548
DBP	95.0±12.268	96.2±13.01	0.503
Weight	56.60±2.462	56.30±2.186	0.363

Continued.

Clinical findings	Group A (n=100)	Group B (n=100)	P value
FHS	136.64±4.525	133.18±5.225	0.007

Table 4: Findings of per vaginal examination among the study population.

Variables	Group A n=100	Group B n=100	P value
Per vaginal cervix consistency			
Firm	18	6	0.009
Medium	82	94	
PV cervix position			
Midline	80	70	0.102
Posterior	20	30	
PV cervix effacement			
30	40	34	0.007
40	12	2	
50	48	64	
Station presenting part			
2	96	98	0.407
3	4	2	
Membrane			
Intact	98	100	0.155
Ruptured	2	0	

Table 5: Mean±SD length of labour at different stages among the study population.

Length of labour	Mean±SD	P value
1st stage (in hours)		
Group B	13.25±1.095	0.008
Group A	12.98±1.982	
2nd stage (in hours)		
Group B	1.00±0.000	0.282
Group A	1.02±0.153	
3rd stage (in minutes)		
Group B	10.00±0.000	<0.001
Group A	12.02±2.469	

Table 6: Distribution of participants by indication for induction.

Indication	Group A	Group B
Post-dated pregnancy	30	31
Labor pain with an unfavorable cervix	31	33
PIH	12	13
GDM	18	13
Oligohydramnios	9	10

The most common indication for induction in both groups was labour pain with an unfavorable cervix (31 in group A and 33 in group B), followed by post-dated pregnancy (30 in group A and 31 in group B). The incidence of pregnancy induced hypertension (PIH) was 12 in group A and 13 in group B, and that of gestational diabetes mellitus (GDM) was 18 in group A and 13 in group B. The least common indication was oligohydramnios, with 9 in group A and 10 in group B.

Table 7: Interval between the inductions to delivery.

Interval	Group A	Group B
Less Than 12 hours	10	28
12 to 24 hours	60	55
More Than 24 hours	30	17

Data shows majority in both group A (60/100) and group B (55/100) had an interval between 12-24 hours, but group B had higher percentage of inductions at less than 12 hours, and a lower percentage of inductions at more than 24 hours compared to group A.

Table 8: Maternal and neonatal outcomes parameters.

Safety parameters	Group a	Group b
Mode of delivery		
Vaginal delivery	58	65
Caesarean section	42	35
Maternal outcomes		
Chills	4	0
Fever	4	2
Normal	92	98
Neonatal outcomes		
NICU admission	2	0
Transient tachycardia	6	2
Low APGAR	6	2
Normal	94	98

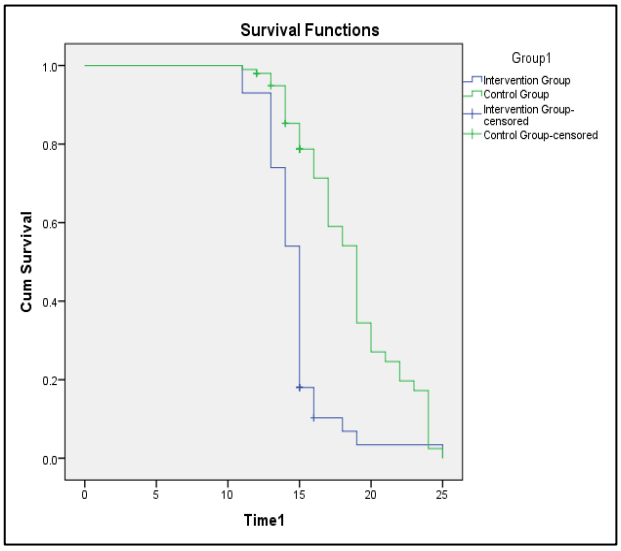

Figure 1: Comparison of cumulative Kaplan-Meier curve between the groups.

Table 9: Cox regression hazard model.

	P value	Hazard ratio	95.0% CI for HR	
			Lower	Upper
Group B	0.000	0.337	0.243	0.469

The mode of delivery for group A was vaginal delivery for 58 patients and caesarean section for 42 patients, while for group B, it was vaginal delivery for 65 patients and caesarean section for 35 patients. Cesarean section for patients of both group was selected as the delivery method for a variety of reasons, including failure to induction. Chills were reported in 4 patients in group A and none in group B. Fever was reported in 4 patients in group A and 2 patients in group B. 92 patients in group A and 98 patients in group B had normal outcomes. For neonatal outcomes, 2 neonates in group A were admitted to NICU while none in group B. Transient tachycardia was reported in 6 neonates in group A and 2 neonates in group B. Low APGAR score was reported in 6 neonates in group A and 2 neonates in group B. The normal outcome was reported in 94 neonates in group A and 98 neonates in group B.

In the Cox regression hazard model, the hazard ratio of the intervention group was 0.337 with a 95.0% confidence interval ranging from 0.243 to 0.469 and a p value of 0.000. This means that the likelihood of a positive outcome (as defined by the study) was lower in group B compared to group A. The p value of 0.000 indicates that the difference between the two groups was statistically significant.

DISCUSSION

Several studies have compared the efficacy of combining mechanical and pharmacologic methods for cervical ripening.[11,13] Jozwiak et al found the combination of a Foley balloon and intracervical prostaglandin E1 gel to be more effective in improving the Bishop's score and resulted in fewer failed inductions compared to prostaglandin E1 gel alone.[13] The incidence of uterine hyperstimulation, which is often thought to be elevated by misoprostol administration, was low.[14] The use of a Foley catheter for inducing labour is safe, successful, and cost-effective and is used with additional induction agents to decrease delivery time.[15] Although pharmacologic methods are growing in popularity, the trans-cervical balloon with or without EASI is still a well-established means of cervical ripening and dilatation.[16] Mechanical methods can dilate the cervix but may also increase prostaglandin and/or oxytocin release by causing localized inflammation, while prostaglandin preparations promote both cervical remodelling and uterine activity.[17] In recent years, there has been a significant increase in the rate of labour induction.[18] This is usually performed when the risks of continuing the pregnancy outweigh the benefits of delivery. Indications for labour induction include immediate conditions such as severe preeclampsia or ruptured membranes with chorioamnionitis, as well as common medical and obstetric indications like membrane rupture without labour, gestational hypertension, postdated pregnancy, oligohydramnios, non-reassuring fetal status, intrauterine growth restriction, chronic hypertension, and diabetes.[19] Cervical ripening plays a crucial role in the success of vaginal delivery. Various methods are used for labour induction, but none are free of medical risks, so labour should only be induced if the risk of continuing the pregnancy outweighs the risk of induction.[1] Cervical ripening in pregnant women with an unripe cervix can be achieved through mechanical, surgical, or pharmacologic means.[20] The most common protocol for pre-induction cervical ripening is intracervical instillation of prostaglandin (PGE2-dinoprostone gel). However, this method requires refrigeration for storage, is contraindicated for patients with asthma or prostaglandin allergies, incurs a high risk of hyperstimulation, and is relatively expensive.[15] This has led to the exploration of alternative methods, such as mechanical cervical ripening through the insertion of an intracervical Foley catheter. This method overcomes the limitations of dinoprostone but has not been widely used due to the fear of induction failure and infection risk. However, recent studies have shown that Foley catheter insertion is more promising with proper aseptic precautions.[15] Additionally, the combination of a Foley catheter with intracervical prostaglandin E1 gel is more effective in improving the Bishop's score and leading to fewer failed inductions compared to prostaglandin E1 gel alone.[13] The incidence of uterine hyperstimulation, which is often thought to be elevated by misoprostol administration, is low with this combination.[14] The Foley catheter has proven to be a safe, effective, and economical means of inducing labour, and its use with other induction agents has shown promise in reducing the total time to delivery.[15] Despite the increasing popularity of pharmacological methods, the use of trans-cervical balloons with or without EASI remains a well-established means of cervical ripening and dilation.[16] Mechanical methods not only dilate the cervix but may also increase prostaglandin and/or oxytocin release by causing localized inflammation, while prostaglandin preparations work to promote cervical remodelling and uterine activity.[17] This study aims to compare the use of vaginal misoprostol tablets alone versus a combination of misoprostol juice and Foley catheter for cervical ripening and induction of labour. The rate of labour induction has risen significantly in recent years, and achieving a vaginal delivery for women requiring induction is a major challenge for obstetricians.[18] Labour is induced when the risks of continuing the pregnancy are greater than the benefits of delivery, and common medical and obstetric indications include preeclampsia, ruptured membranes with chorioamnionitis, postdated pregnancy, non-reassuring fetal status, and more.[19] Cervical ripening has a close relationship with the success of vaginal delivery, and while various methods exist, none are without medical risks.[20] As a result, labour should only be induced when the risk of allowing the pregnancy to continue outweighs the risk of induction.[1] For women with an unripe cervix, cervical ripening can be achieved through mechanical, surgical, or pharmacological means.[20] Intracervical

prostaglandin instillation (PGE2-dinoprostone gel) is a common protocol, but it must be refrigerated, contraindicated in patients with asthma or allergies to prostaglandins, carries a high risk of hyperstimulation, and has a relatively high cost.[15] As a result, the search for an ideal cervical ripening agent continues, leading to the exploration of alternatives such as mechanical methods like intracervical Foley catheter insertion.[15] However, the use of the Foley catheter has been limited by the fear of induction failure and the risk of infection.[15] Recent studies have shown that the proper use of aseptic precautions can make the use of the Foley catheter more promising.[15] The goal of induction of labour is to achieve vaginal delivery through the stimulation of uterine contractions and to reduce the rate of cesarean delivery.[19] The benefits of labour induction must be weighed against potential maternal or fetal risks.[20] This study aims to review current methods for cervical ripening and induction of labour, summarize their effectiveness based on evidence-based research, and outline safe clinical use guidelines for various induction methods.

Due to the COVID-19 pandemic, the study population had a limited sample size. The study was conducted at a single center and only included patients admitted to the hospital, making it unable to provide a comprehensive overview of the situation in the country. Further research on a larger scale is necessary to reach a definitive conclusion. Additionally, the study was conducted at a tertiary care hospital, which may not accurately reflect the conditions at primary or secondary centers.

CONCLUSION

The combination of misoprostol and Foley's urinary catheter has been proven to be both safe and effective for inducing labour. In the interventional group, vaginal delivery was more common compared to the control group. Moreover, the frequency of caesarean sections was lower in both the interventional and control groups. The number of patients with failed induction was also lower in both groups. Furthermore, the maternal outcomes indicated fewer complications in the interventional group compared to the control group.

Recommendations

In order to improve maternal and newborn health, the following recommendations are proposed: 1) Increase awareness through counselling during antenatal care and the intranatal period. 2) Improve technical support by providing training, increasing midwife support, and ensuring availability of necessary machinery such as CTG and instruments. 3) Ensure proper selection of cases and timely decision making, with prompt identification of complications. 4) Engage the media to raise awareness and promote public engagement. 5) Involve government policy makers to develop and implement effective policies that support maternal and newborn health.

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