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Dr. Farida Yesmin
Medical Officer, Obstetrics & Gynecology, Mugda Medical College and Hospital, Dhaka, Bangladesh

Dr. Nahreen Akhtar Professor, Department of Fetomaternal Medicine, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh

Dr. Janty Mojumder
Medical Officer, Obstetrics & Gynecology, Shaheed Suhrawady Medical College and Hospital, Dhaka, Bangladesh

Dr. Israt Jahan Ripa
Medical Officer, Obstetrics & Gynecology, Mugda Medical College and Hospital, Dhaka, Bangladesh

Dr. Nargis Islam
Registrar, Obstetrics & Gynecology, 300 Beded Hospital, Khanpur, Narayangoj, Bangladesh

Dr. Syeda Sayeeda Professor, Department of Fetomaternal Medicine, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh

Dr. Tabassum Parveen
Professor & Chairman, Department of Fetomaternal Medicine, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh

Corresponding Author:
Dr. Farida Yesmin
Medical Officer, Obstetrics & Gynecology, Mugda Medical College and Hospital, Dhaka, Bangladesh
E-mail:
farida106ssmc35@gmail.com

Effectiveness of mifepristone with foley's catheter versus foley's catheter alone for termination of pregnancy with prior cesarean section

Farida Yesmin, Nahreen Akhtar, Janty Mojumder, Israt Jahan Ripa, Nargis Islam, Syeda Sayeeda and Tabassum Parveen

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Abstract
Background: Termination of pregnancy in the second trimester presents significant challenges in modern obstetric practice, with risks exceeding those of first-trimester termination. It remains a common procedure, primarily due to congenital anomalies and intrauterine fetal death, contributing substantially to the number of abortions or induced deliveries. This study aimed to determine the effectiveness of Mifepristone with intracervical Foley's catheter for termination of pregnancy at second trimester with history of prior cesarean section in comparison with intracervical Foley's catheter alone.
Methods: This randomized controlled trial was conducted at the Department of Feto-maternal Medicine of Bangabandhu Sheikh Mujib Medical University (BSSMU), Dhaka, Bangladesh from September 2022 to August 2023. Seventy women with singleton pregnancies (14-28 weeks, one/two cesarean sections) were enrolled purposively at BSMMU, randomized into two groups: experimental (Mifepristone and Foley's catheter) and control (Foley's catheter only). Data was analyzed via SPSS 26.0.
Results: Successful abortion or delivery occurred in 82.9% of cases in the experimental group compared to 60% in the control group, showing a statistically significant difference (P=0.034). The mean induction-to-abortion or delivery interval was significantly shorter in the experimental group (54.12 hours) than in the control group (64.11 hours; P=0.033). Although side effects were less frequent in the experimental group (8.6%) compared to the control group (14.3%), the difference was not statistically significant (P=0.708).
Conclusion: The combination of Mifepristone and intracervical Foley's catheter significantly improved second-trimester abortion or delivery success rates, reduced induction-to-abortion/delivery intervals, and resulted in fewer complications compared to intracervical Foley's catheter alone.

Keywords: Cesarean section, intracervical foley's catheter, mifepristone, pregnancy termination

Introduction

Fetal anomaly screening is intensively conducted during the second trimester, and if anomalies incompatible with life are detected, termination may be recommended. In 1-5% of pregnancies, termination is necessary due to absent fetal heart rate [1]. Delays in diagnosing fetal anomalies, along with logistical and financial challenges in completing invasive tests during the first trimester, contribute to the continued need for second-trimester termination [2]. Termination remains one of the most common surgical procedures in obstetrics and gynecology, with approximately 50 million procedures worldwide each year [3]. The surgical approach for second-trimester pregnancy termination accounts for nearly two-thirds of major complications, including perforation, hemorrhage, cervical lacerations, and infections [2]. Hoopman *et al*. (2014) highlighted that due to higher morbidity and maternal mortality after the first trimester, medical termination is the preferred method [3]. In Bangladesh, the prevalence of cesarean section is 67.4%, with rates highest among South and Southeast Asian women. The cesarean section prevalence in Bangladesh has more than doubled compared to earlier national statistics and is over six times higher than the WHO recommendations [4]. Hoopman *et al*. (2014) reported that medical induction is typically used for pregnancy termination after the first trimester, with Mifepristone significantly shortening the induction interval [3]. Mifepristone, a synthetic 19-nor steroid, binds strongly to the progesterone receptor, inhibiting its effect. It is affordable, stable at room temperature, and has a long shelf life, making it the only anti-progestin approved for abortion induction. Mifepristone undergoes hepatic oxidative metabolism, primarily excreted through feces [2].

Mifepristone increases the likelihood of mid-trimester abortion within 24 to 48 hours while reducing the incidence of hysterotomy. It lowers the uterine contraction threshold and promotes cervical ripening by inhibiting progesterone receptors. When combined with or without labor augmentation, Mifepristone is a safe, efficient, economical, and convenient induction agent for abortion in women with scarred uteri [3]. Failed labor induction and prolonged induction-to-delivery intervals lead to increased hospitalization costs, maternal and perinatal anxiety, and a higher risk of adverse outcomes when vaginal delivery is not achieved timely [5]. The intracervical Foley catheter disrupts the integrity of the amnion-chorion and myometrium, releasing prostaglandins and cytokines that alter collagen and extracellular matrix, making the uterus more susceptible [6]. During physiological labor onset, cervical ripening occurs before myometrial contractions begin. The intracervical Foley's catheter promotes cervical ripening without inducing uterine contractions, while prostaglandins affect both cervical ripening and uterine contractions simultaneously [7]. Amrutha *et al*. [8] concluded that while Foley's catheter is a safe, effective, simple, and low-cost method for an unfavorable cervix, it does not fully satisfy women or caregivers. Mifepristone pretreatment, which serves a dual role in both cervical ripening and labor induction, shows comparable efficacy to Foley's catheter. Mechanical and pharmacological cervical ripening agents operate through different mechanisms, and their combined use may have a synergistic effect [5].

Methodology

This randomized controlled trial was conducted at the Department of Feto-maternal Medicine, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from September 2022 to August 2023. A total of 70 women with singleton pregnancies, who required pregnancy termination between 14 to 28 weeks of gestation and had a history of one or two previous cesarean sections, were included in the study. Convenient and purposive sampling techniques were used for sample selection. All women admitted to BSMMU were selected and randomized into two groups using a lottery method. The experimental group (35 women) received Mifepristone and an intracervical Foley's catheter, while the control group (35 women) received only the intracervical Foley's catheter. Women with 14-28 weeks of pregnancy, a history of 1 or 2 cesarean sections, and medical termination indication were included if they met any of the following: fetal congenital anomalies incompatible with life, severe maternal illness (e.g., pre- eclampsia, chronic kidney disease), or fetus diagnosed with beta- thalassemia major or other genetic disorders via Amniocentesis or CVS. Informed consent was obtained. This study excluded women with a history of 3 or more cesarean sections, low-lying or central placenta praevia, multiple pregnancies, preterm rupture of membranes, myomectomy, classical cesarean section, bronchial asthma, hemorrhagic disorders, liver disease, latex/Mifepristone hypersensitivity, labor pain, or scar tenderness. Ethical approval was obtained, and data were analyzed using SPSS 26.0.

Results

In this study, the age distribution between the experimental and control groups was similar, with mean ages of 27.4 and 29.5 years, respectively, and no statistically significant difference ($p>0.05$). The majority of participants in both groups had one previous cesarean section, and their obstetric histories were comparable, with no significant statistical difference ($p>0.05$). The distribution of gestational ages was also similar, with most cases in both groups between 23 to 28 weeks of gestation. The primary reason for pregnancy termination in both groups was multiple fetal congenital anomalies, and there was no significant difference between the groups in terms of the indications for termination ($p>0.05$). In our study, the successful abortion rate was significantly higher in the Mifepristone and intracervical catheter group (82.9%) compared to the intracervical catheter alone group (60%), with a statistically significant difference (p = 0.034). The complications observed in both groups were similar, with no statistically significant difference ($p>0.05$). Regarding post-abortion/delivery complications, excessive hemorrhage occurred in 6.9% of the experimental group and 14.3% of the control group, with no significant difference ($p>0.05$). Retained placenta occurred in 3.4% of the experimental group and 9.53% of the control group, with no significant difference (p = 0.794). Post-abortion bleeding in both groups was managed with uterine massage, oxytocin infusion, and per rectal misoprostol administration. In our study, single-unit blood transfusion was required for 6.9% of participants in the experimental group and 9.5% in the control group, with no statistically significant difference. There was also no significant difference in the management of retained placenta. The mean duration from induction to abortion was significantly shorter in the Mifepristone and intracervical catheter group compared to the intracervical catheter alone group (p = 0.033), with a 95% CI of
1.7 to 18.3 hours. Induction failure occurred in 20 participants (8 from the experimental group, 12 from the control group), with 8 (40%) requiring hysterotomy or cesarean section due to scar tenderness and 12 (60%) needing additional methods, such as catheterization or prostaglandin E2 gel.

Discussion

In this study, the mean age in the Mifepristone and intracervical catheter group was 27.37±5.27 years, while in the catheter-only group, it was 29.54±5.43 years, with no statistically significant difference (p = 0.094). Similarly, in Amrutha *et al*.'s study [8], the mean age in the Mifepristone group was 23.06±2.85 years, and in the Foley's group was 23.04±2.72 years. The obstetric profiles of both groups were comparable, with 80% in the combined group and 74.3% in the Foley's catheter group having had a previous cesarean section, with no significant difference (p = 0.773). Gestational age at termination was similar in both groups, with 62.9% in the combined group and 71.4% in the catheter-only group at 23 to 28 weeks.

Table 1: Distribution of respondents by number of previous cesarean deliveries.

Cesarean section	Experimental (N=35)		Control (N=35)		P-Value
	n	%	n	%	
One cesarean section	28	80.0%	26	74.3%	0.773
Two cesarean sections	7	20.0%	9	25.7%	

A chi-square test was done to measure the level of significance

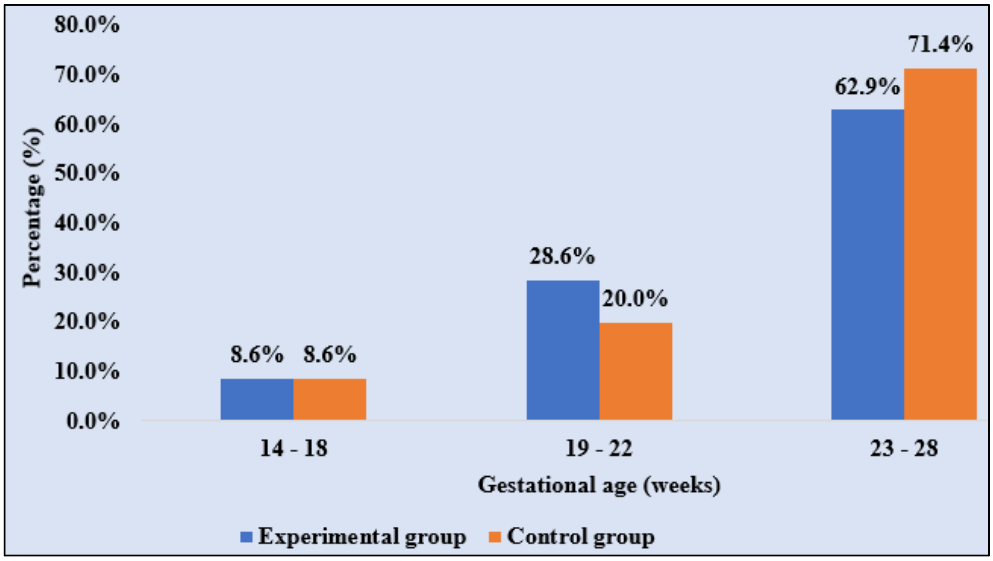

Fig 1: Bar chart showed distribution of respondents according to gestational age.

Table 2: Distribution of respondents according to indication of termination of pregnancy.

Indications	Experimental	Control	P-Value
	N (%)	N (%)	
Multiple congenital anomalies	10 (28.6)	9 (25.7)	[a]1.000
Hydrops fetalis	5 (14.3)	4 (11.4)	[b]1.000
Intrauterine fetal death	2 (5.7)	3 (8.6)	[b]1.000
Fetal CNS anomalies	4 (11.4)	5 (14.3)	[b]1.000
Fetal renal anomaly with oligohydramnios	5 (14.3)	6 (17.1)	[b]1.000
Fetal abdominal wall defect	2 (5.7)	2 (5.7)	[b]1.000
Skeletal dysplasia	3 (8.6)	4 (11.4)	[b]1.000
Fetal hemoglobinopathy	1 (2.9)	1 (2.9)	[b]1.000
Pre-eclampsia with severe features	3 (8.6)	1 (2.9)	[b]0.603

a: Chi-Square test and b: Fisher's Exact test was done.

Table 3: Abortion outcome of the study subjects.

Abortion outcome	Experimental		Control		P-Value
	N	%	N	%	
Successful abortion	29	82.90%	21	60.00%	[a]0.034[S]
Induction failure	6	17.10%	14	40.00%	[a]0.034[S]
Complications developed (excessive bleeding, retained placenta)	3	8.60%	5	14.30%	[b]0.708[NS]

a: Chi-Square test and b: Fisher's Exact test was done to determine the level of significance, S= Significant, NS= Not significant

Table 4: Distribution by complications in both groups.

Complications	Experimental		Control		P-Value
	N	%	N	%	
Excessive post-abortion/delivery hemorrhage	2	6.90%	3	14.30%	0.794
Retained placenta	1	3.40%	2	9.50%	0.794

Fisher's exact test was done to measure the level of significance

Table 5: Distribution of respondents according to management of complications.

Management of complications	Experimental		Control		P-Value
	N	%	N	%	
Excessive post-abortion/delivery hemorrhage-blood transfusion	2	6.90%	2	9.50%	1
Need for uterine message and utero tonics	1	3.40%	1	4.80%	1
Retained placenta requiring evacuation and curettage	1	3.40%	1	4.80%	1
Manual removal of placenta	0	0.00%	1	4.80%	0.315

Fisher's exact test was done to measure the level of significance

Table 6: Comparison of induction to abortion/delivery interval between the two groups.

Induction	Group		P-Value	95% CI
	Experimental (N=29) (Mean ±SD)	Control (N=21) (Mean ±SD)		
Abortion/delivery interval (hours)	54.12±16.66	64.11±18.05	0.033	9.99 (1.7-18.3)

Mann-Whitney U test was done

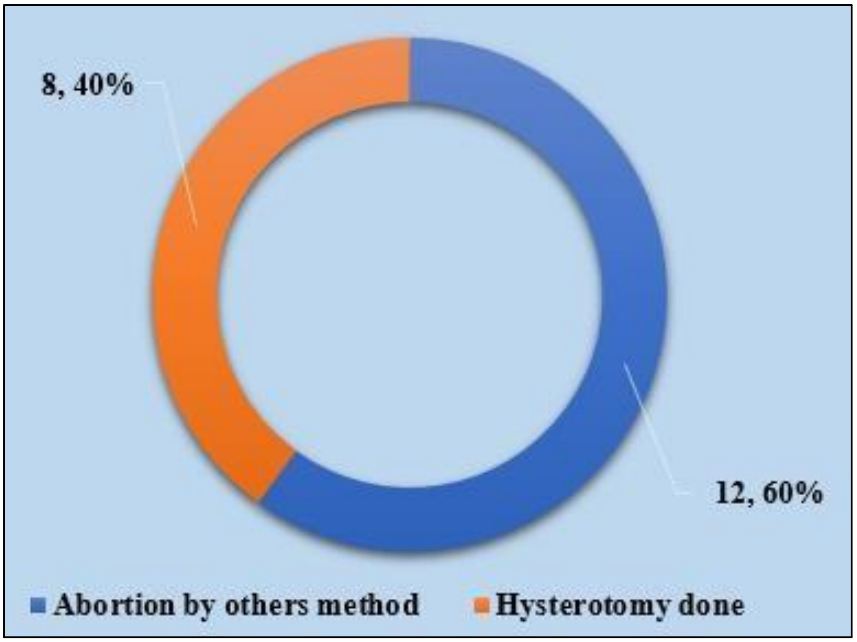

Fig 2: Outcome of failed induction participants of both groups

In contrast, Chikkagowdra *et al.* [9] observed most medical terminations occurred in pregnancies between 18-24 weeks. This discrepancy may be due to anomaly scans being performed between 18 to 22 weeks in our clinical practice, and the majority of terminations in our study were for fetal congenital anomalies, thus the higher proportion of participants in the 23-28-week group. In this study, the indications for termination of pregnancy were similar in both the experimental and control groups, with the majority of participants undergoing termination due to fetal multiple congenital anomalies. The difference was not statistically significant (p>0.05). Chikkagowdra *et al.* [9] found that 50% of terminations were due to fetal anomalies, which aligns with the findings of this study. The induction-to-abortion interval was significantly shorter in the combined group (54.12±16.66 hours) compared to the Foley's catheter-only group (64.11±18.05 hours) with a p-value of 0.033 (95% CI: 1.7 to 18.3). This result is consistent with Ranjan *et al.* [6], who reported a significant difference in induction-to-delivery intervals in their study, with 20.68±4.82 hours in the combined group versus 25.65±9.75 hours in the Foley's catheter-only group (p< 0.05). Similar findings were also observed in studies by Dahiya *et al.* [10] and Kushumam *et al.* [11]. In our study, the successful abortion rate was significantly higher in the Mifepristone and catheter group (82.9%) compared to the catheter-only group (60%), with a p-value of 0.034 (< 0.05). Similar findings were reported by Amrutha *et al.* [8], who observed a 72% success rate in the combined group and 64% in the catheter-only group. Our results were also consistent with those of Chikkagowdra *et al.* [9] and Hapangama and Neilson [12]. Chikkagowdra *et al.* [9] found lower failure rates with Mifepristone, while Hapangama *et al.* [12] reported fewer cesarean sections due to failed induction in Mifepristone-treated women. Although uterine rupture, hemorrhage, and hysterotomy/hysterectomy are uncommon serious complications of second-trimester pregnancy termination [13], our study excluded failed induction cases in the complication analysis, and the majority of participants experienced no major complications in either group. In our study, significant post-abortion/delivery bleeding occurred in 6.9% of cases in the combined group and 14.3% in the Foley's group, with no statistically significant difference (P=0.794). Retained placenta was observed in 3.5% of the combined group and 9.5% of the Foley's group, with no significant difference (P=0.794). Similar results were reported by Amrutha *et al.* [8], who found post-partum hemorrhage in 6% of the Foley's group and 4% in the Mifepristone group, with no significant difference (P=0.245). Allanson *et al.* [14] found higher rates of retained placenta, 26.5% in the catheter group and 18.3% in the Mifepristone-Misoprostol group, compared to our study. This discrepancy could be due to the different study populations, with Allanson's study involving nulliparous patients and the use of Misoprostol, while our study involved multiparous patients with scarred uteri and used intracervical Foley's catheter combined with Mifepristone. Although no significant difference in maternal complications was observed between the two groups, the risks and incidence of complications associated with second-trimester medical termination of pregnancy remain an important aspect of clinical decision-making and should be carefully considered when counseling patients [15]. Our study found that using the combined method of Mifepristone and intracervical Foley's catheter resulted in a higher successful abortion/delivery rate with fewer side effects or complications, which is consistent with findings in other studies [1, 2]. Additionally, the combination of Mifepristone and Foley's catheter significantly shortened the induction to abortion interval compared to the Foley's catheter alone group, with the decrease in duration likely attributable to Mifepristone use.

Conclusion & Recommendation

In the present study, the combination of Mifepristone and intracervical Foley's catheter was found to be more effective than using the Foley's catheter alone. The success rate of abortion was higher in the combined group (82.9% compared to 60%), and the time from induction to abortion/delivery was shorter (54.12 hours versus 64.11 hours) in the combined group, with both differences being statistically significant. Therefore, this combined regimen can be recommended for successful abortion/delivery in patients with a previous cesarean scar. Both methods of induction in women with a previous cesarean section were found to be safe, simple, and effective. A larger study examining the safety and efficacy of Mifepristone in patients with scarred uteri would further support its use in daily obstetric care.

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