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Original Research Article

Comparative effectiveness of mifepristone with misoprostol versus intracervical Foley's catheter in mid-trimester missed abortion with scarred uterus

Rubab Sarmin[1], Maliha Tasnim[2], Sharif Mohammad Towhid Tarif[3], Mahzabin Husain[4], Jannatul Ferdous Chowdhury[5], Effat Aziz[6], Tasnia Sultana[7], Salma Akter[8]*

[1]Department of Obstetrics and Gynecology, Sir Salimullah Medical College, Mitford Hospital, Dhaka, Bangladesh
[2]Department of Obstetrics and Gynecology, Chittagong Medical College and Hospital, Chittagong, Bangladesh
[3]Department of Otolaryngology and Head Neck Surgery, Sir Salimullah Medical College, Mitford Hospital, Dhaka, Bangladesh
[4]National Institute of Burn and Plastic Surgery, Dhaka, Bangladesh
[5]Department of Obstetrics and Gynecology, Sarkari Karmachari Hospital, Dhaka, Bangladesh
[6]Department of Obstetrics and Gynecology, East West Medical College, Dhaka, Bangladesh
[7]Department of Obstetrics and Gynecology, Ad-Din Akij Medical College, Khulna, Bangladesh
[8]Department of Obstetrics and Gynecology, 250 Bedded General Hospital, Sirajganj, Bangladesh

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***Correspondence:**
Dr. Salma Akter,
E-mail: salmafmc12@gmail.com

ABSTRACT

Background: Second-trimester pregnancy termination carries higher risks than first-trimester procedures, making pharmacologic methods preferable. Misoprostol is widely used, while intracervical Foley's catheter aids cervical ripening and stimulates prostaglandin/oxytocin release. Combined mifepristone and misoprostol have been shown to shorten induction-to-abortion time compared to Foley's catheter alone. This study aimed to evaluate the effectiveness of combined mifepristone and misoprostol versus intracervical Foley's catheter for mid-trimester missed abortion in women with a scarred uterus.
Methods: This quasi-experimental study was conducted at the department of gynecology and obstetrics, Dhaka Medical College Hospital, including 72 women aged 18-35 years with missed abortion and prior cesarean section. Participants were divided into two groups: group I (n=36) received combined mifepristone and misoprostol, and group II (n=36) received Foley's catheter alone.
Results: Group I had a lower mean gestational age (16.2±2.6 versus 23.1±2.0 weeks), higher abortion success rate (97.2% versus 94.4%), shorter induction-expulsion time (7-12 hours in 86.1% versus >18 hours in 58.3%), and fewer surgical interventions (2.8% versus 5.6%) compared to group II. Side effects were more frequent in group I (55.6% versus 27.8%). All differences were statistically significant ($p<0.05$).
Conclusions: Combined mifepristone and misoprostol is more effective than Foley's catheter alone for mid-trimester missed abortion in scarred uterus, yielding higher success rates and shorter induction-expulsion times.

Keywords: Foley's catheter, Mifepristone, Misoprostol, Scarred uterus, Second-trimester abortion

INTRODUCTION

Abortion is defined as the termination of pregnancy (TOP) before the fetus reaches viability, currently acknowledged to occur at around 23-24 weeks of gestation. The second trimester, spanning from 13 to 28 weeks, is further divided into an early phase (13-20 weeks) and a late phase (20-28 weeks).[1] A "missed abortion" refers to the clinical scenario

in which the products of conception remain within the uterus without spontaneous expulsion, with an estimated incidence of approximately 15% among clinically diagnosed pregnancies.[2]

Over recent decades, rising cesarean delivery rates have been paralleled by an increase in pregnancy terminations, creating a distinct subgroup of women with prior uterine scars who may require second-trimester TOP.[3] This is clinically significant, as women with previous cesarean sections face an elevated risk of uterine rupture, a complication with a reported incidence of <1% but nonetheless a serious concern in obstetric practice.[4] Termination of pregnancy in the second trimester among women with prior cesarean sections is therefore a complex and high-risk procedure, necessitating specialized care and careful consideration of both maternal safety and procedural efficacy.[5]

Globally, more than one-third of pregnancies are unintended, and approximately 20% end in termination. Of these, 10-15% occur during the second trimester, accounting for over two-thirds of severe abortion-related complications.[6] Advances in medical abortion techniques have markedly improved safety and accessibility, with drug-induced regimens emerging as effective alternatives to surgical methods. The combined use of mifepristone and misoprostol has proven particularly successful, typically achieving expulsion within 6-9 hours while minimizing surgical risks.[7]

Mifepristone, a synthetic anti-progesterone introduced in 1982, sensitizes the myometrium to prostaglandins, facilitates cervical ripening, and interrupts pregnancy by antagonizing progesterone activity. Its effects peak 36-48 hours after administration and are commonly followed by the use of misoprostol, a prostaglandin analogue, to complete the abortion process.[8] Misoprostol is widely adopted due to its cost-effectiveness, stability at room temperature, ease of administration (oral, vaginal, sublingual, or rectal), and proven efficacy in inducing uterine contractions and cervical ripening.[9-12] Nevertheless, misoprostol use is associated with side effects in up to 30% of cases, and concerns about uterine rupture remain particularly relevant in women with uterine scarring.

While mifepristone-misoprostol combination regimens are endorsed by the American College of Obstetricians and Gynecologists (ACOG) and the Royal College of Obstetricians and Gynaecologists (RCOG), access to mifepristone is limited in many resource-constrained settings due to high cost and availability issues.[13-15] As a result, misoprostol alone is frequently used despite the risks. The challenge is further compounded in low- and middle-income countries, where cesarean sections are often performed under suboptimal conditions, such as traditional techniques and single-layer uterine closures, which increase the likelihood of uterine rupture and reduce the applicability of international guidelines.[16]

Given these concerns, particularly in resource-limited settings, there is a pressing need to explore safer alternatives to misoprostol for second-trimester TOP in women with prior cesarean sections agents that can provide comparable efficacy while minimizing risks of uterine rupture.

METHODS

This quasi-experimental study was conducted in the department of obstetrics and gynecology, Dhaka Medical College Hospital (DMCH), Dhaka, Bangladesh, from April 2020 to September 2021. The study enrolled women with a gestational age of 13 to 28 weeks, all with a scarred uterus from a previous cesarean section, who were diagnosed with missed abortion and admitted to the department of obstetrics and gynecology for management. Participants meeting the selection criteria were divided into two groups: group I: Women who received a combination of oral mifepristone and vaginal misoprostol. Group II: Women who were managed with an intracervical Foley catheter alone.

These were the following criteria for eligibility as study participants:

Inclusion criteria

Women gestational age from 13-28 weeks. Women with missed abortion. Women having undergone a prior cesarean section. Patients giving informed written consent.

Exclusion criteria

Hemodynamically unstable. Inevitable or incomplete abortion. Known case of heart disease, uncontrolled hypertension, bronchial asthma or coagulation disorder. On anti-coagulant or corticosteroid. Hemoglobin <8 gm%. Known hypersensitivity to mifepristone or misoprostol.

Drug dosage

Dose of mifepristone: 200 mg per oral (World Health Organization, 2019b).[17]

Dose of misoprostol: 200-400 µg per vaginally (World Health Organization, 2019b).[17]

Time duration: After 24 hours of mifepristone administration, misoprostol should be administered 3 hourly intervals till expulsion.[18]

Data collection procedure

Written informed consent was obtained after being informed about the study objectives and procedures. Relevant obstetric and medical history, along with clinical information, were obtained using a pre-designed semi-structured questionnaire. A thorough clinical examination was conducted for all participants, and laboratory

investigations were performed as per standard protocols. Subjects were allocated non-randomly into two intervention groups: 36 women received oral mifepristone (200 mg single dose) followed 24 hours later by intravaginal misoprostol (400 µg every 3 hours, up to a maximum of four doses), while 36 women were managed with an intracervical self-retaining bi-channel Foley catheter (16 Fr), inserted under sterile conditions, with the balloon inflated (30-50 ml) and traction applied until spontaneous expulsion. Patients were closely monitored at three-hour intervals for vital signs, abdominal pain, uterine contractions, vaginal bleeding, and overall clinical status, with vaginal blood loss estimated using fully soaked pads. Rh-negative women received 300 µg of anti-D immunoglobulin. Surgical evacuation was performed in cases of excessive bleeding or incomplete expulsion after two weeks, and all participants were followed until complete fetal expulsion. Data on induction-to-expulsion time, doses of mifepristone and misoprostol, complications, and failed induction were recorded on individual data sheets for comparison between the two groups.

Table 1: The guideline of WHO 2018 medical management.

Gestational age (weeks)	No. of scar	Mifepristone	Misoprostol (after 24 hours of mifepristone)	Duration of misoprostol
13-24	One scar	200 mg per orally (Single dose)	400 µg (2 tab) per vaginally	2 tab every 3 hourly till expulsion
13-24	More than one scar	200 mg per orally (Single dose)	200 µg (1 tab) per vaginally	1 tab every 3 hourly till expulsion
24-28	One or more than one scar	200 mg per orally (Single dose)	200 µg (1 tab) per vaginally	1 tab every 3 hourly till expulsion

Statistical analysis

All data were recorded systematically in a pre-formatted data collection form. Quantitative data were expressed as mean and standard deviation, and qualitative data were expressed as frequency distribution and percentage. Chi-square tests were applied to assess associations between outcome variables of missed abortion management across the two groups, while unpaired t-tests were used to compare the mean induction-to-abortion time between the groups. A p value <0.05 was considered significant. Statistical analysis was performed by using SPSS 26 (Statistical Package for Social Sciences). This study was ethically approved by the institutional review committee of Dhaka Medical College Hospital (DMCH)

RESULTS

This quasi-experimental study was conducted at the department of obstetrics and gynecology, Dhaka Medical College Hospital, Dhaka, Bangladesh.

Table 2: Comparison of the participants according to age by two groups.

Age (in years)	Group I (n=36)	Group II (n=36)	P value
≤25	16 (44.4)	13 (36.1)	
26-30	13 (36.1)	18 (50.0)	0.484[a]
>30	7 (19.4)	5 (13.9)	
Mean±SD	27.0±4.1	27.2±4.0	0.797[c]

[a]Chi square test and [c]unpaired t test was done to measure the level of significance, Figure within parentheses ( ) indicates percentage.

The study enrolled 72 women aged 18-35 years with missed abortion and a scarred uterus. Participants were divided equally into two groups: group I, treated with oral mifepristone and vaginal misoprostol (n=36), and group II, managed with an intracervical Foley's catheter (n=36). The study's findings are presented in the following graphs and tables

Table 3: Comparison of the participants according to their gestational age and parity.

Obstetrical characteristics	Group I (n=36)	Group II (n=36)	P value
Gestational age (in weeks)			
13-18	31 (86.1)	0 (0.0)	<0.0001[b]
19-24	5 (13.9)	25 (69.4)	
>24	0 (0.0)	11 (30.6)	
Mean±SD	16.2±2.6	23.1±2.0	<0.001[c]
Para			
Primipara	26 (72.2)	25 (69.4)	0.795[a]
Multipara	10 (27.8)	11 (30.6)	

[a]Chi square test, [b]Fisher's exact test and [c]unpaired t test was done to measure the level of significance. Figure within parentheses ( ) indicates percentage.

Table 2 shows that in two groups (group I and group II), there was no significant difference in age distribution (p=0.484). The percentages of participants aged ≤25 years, 26-30 years, and >30 years were 44.4%, 36.1%, and 19.4% in group I, and 36.1%, 50.0%, and 13.9% in group II, respectively. The mean age in group I was 27.0±4.1 years, and in group II, it was 27.2±4.0 years, with no significant difference (p=0.797).

Table 3 shows that in two groups, the gestational age differed significantly, with a mean of 16.2±2.6 weeks in group I and 23.1±2.0 weeks in group II (p<0.001). Regarding parity, there was no significant difference between the groups, with 72.2% primiparous participants in group I and 69.4% in group II (p=0.795). Multiparous individuals accounted for 27.8% in group I and 30.6% in group II.

Table 4: Comparison of the participants according to Hb level and need of blood transfusion after procedure.

Hb level and blood transfusion	Group I (n=36)	Group II (n=36)	P value
Hb (Mean±SD)	9.4±0.4	9.3±0.3	0.369[b]
Blood transfusion			
Needed	2 (5.6)	0 (0.0)	0.493[c]
Not needed	34 (94.4)	36 (100.0)	

[b]unpaired t test and [c]Fisher's Exact test were done to measure the level of significance. Figure within parentheses ( ) indicates percentage.

Table 4 presents the comparison of hemoglobin (Hb) levels and blood transfusion requirements between group I and group II. The mean Hb level was comparable between the two groups (9.4±0.4 gm/dl in group I versus 9.3±0.3 gm/dl in group II, p=0.369). Blood transfusion was required in 2 patients (5.6%) from group I, while none of the patients in group II required transfusion; however, this difference was not statistically significant (p=0.493).

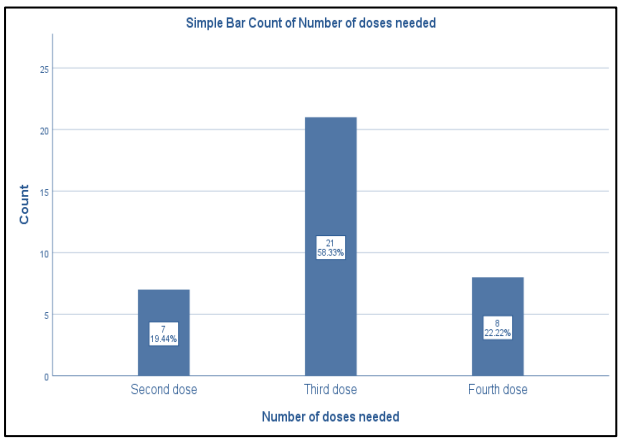

Figure 1: Number of misoprostol doses needed for complete expulsion of product of conception in group I (group I: oral mifepristone and vaginal administration of misoprostol).

Figure 1 displays that, majority 58.33% of the respondents taking misoprostol needed 3 doses, 22.22% needed 4 doses and only 19.44% were completed with 2 doses.

Table 5 compares the effectiveness of two methods for inducing abortion: oral mifepristone with vaginal misoprostol (group I) and intracervical Foley's catheter (group II). Successful outcomes were achieved in 97.2% of group I and 94.4% of group II patients, a difference that was statistically significant (p=0.042). Failure rates were 2.8% in group I and 5.6% in group II. The induction-expulsion interval also showed significant variation between groups. No cases fell within the ≤6 hours category for either group. In the 7-12 hours range, 86.1% of group I achieved expulsion compared with only 2.8% of group II. For the 13-18 hours range, 13.9% of group I and 38.9% of group II were observed. Notably, none of the patients in group I required more than 18 hours, whereas 58.3% of group II did. The mean induction-expulsion time was significantly shorter in group I (10.1±2.1 hours) compared to group II (18.5±2.9 hours; p<0.001).

Table 5: Comparison of the participants according to the effectiveness of mifepristone, misoprostol together and intracervical Foley's catheter alone.

Effectiveness	Group I (n=36)	Group II (n=36)	P value
Success			
Successful	35 (97.2)	34 (94.4)	0.042[a]
Failure	1 (2.8)	2 (5.6)	
Induction-expulsion time			
≤6 hours	0 (0.0)	0 (0.0)	<0.001[b]
7-12 hours	31 (86.1)	1 (2.8)	
13-18 hours	5 (13.9)	14 (38.9)	
>18 hours	0 (0.0)	21 (58.3)	
Mean±SD	10.1±2.1	18.5±2.9	<0.001[c]

[a]Chi square test, [b]Fisher's exact test and [c] unpaired t test was done to measure the level of significance. Figure within parentheses ( ) indicates percentage.

Table 6: Comparison of the participants according to the need of surgical intervention, uterine massage and additional uterotonic agent (oxytocin) between two groups.

Surgical intervention	Group I (n=36)	Group II (n=36)	P value
Surgical intervention			
Not needed	35 (97.2)	34 (94.4)	0.042[a]
Needed	1 (2.8)	2 (5.6)	
Surgical intervention			
MVA	1 (100.0)	2 (100.0)	
D and C	0 (0.0)	0 (0.0)	
Repair of scar	0 (0.0)	0 (0.0)	
Hysterotomy	0 (0.0)	0 (0.0)	
Hysterectomy	0 (0.0)	0 (0.0)	
Uterine massage			
Required	1 (2.8)	0 (0.0)	1.00[b]
Not required	35 (97.2)	36 (100.0)	
Additional uterotonic (oxytocin)			
Required	1 (2.8)	3 (8.3)	0.614[b]
Not required	35 (97.2)	33 (91.7)	

[a]Chi square test and [b]Fisher's exact test was done to measure the level of significance. Figure within parentheses ( ) indicates percentage.

Table 6 compares the outcomes of surgical intervention and additional management measures between group I and group II for missed abortion. Surgical intervention was required in 2.8% of participants in group I and 5.6% in group II, showing a significant difference (p=0.042). All surgical procedures in both groups involved manual vacuum aspiration (MVA), with no cases requiring dilation and curettage (D andC), scar repair, hysterotomy, or hysterectomy. Uterine massage was needed in 2.8% of participants in group I, while none required it in group II. Additional uterotonic therapy with oxytocin was administered to 2.8% of participants in group I and 8.3% in group II, showing a non-significant trend (p=0.614).

Table 7: Comparison of the participants according to presence of side effect between two groups.

Side effects	Group I (n=36)	Group II (n=36)	P value
Present			0.017[a]
Nausea/vomiting Fever Shivering Psychological upset Mild pain Discomfort	20 (55.6)	10 (27.8)	
Absent			
Nausea/vomiting fever shivering psychological upset mild pain discomfort	16 (44.4)	26 (72.2)	

[a] Chi square test was done to measure the level of significance. Figure within parentheses ( ) indicates percentage.

Table 7 summarizes the side effects observed in the two study groups. Side effects, including nausea/vomiting, fever, shivering, psychological upset, mild pain, and discomfort, were reported in 55.6% of patients in group I compared to 27.8% in group II, a difference that was statistically significant (p=0.017). Conversely, absence of side effects was noted in 44.4% of group I and 72.2% of group II patients.

Table 8: Side effects among the respondents.

	N	%
Side effects in mifepristone and misoprostol group		
Nausea/vomiting	18	50.0
Fever	7	19.4
Shivering	2	5.6
Side effects in intracervical Foley's catheter group		
Psychological upset	3	8.3
Mild pain	7	19.4
Discomfort	2	5.6

Table 8 outlines the distribution of specific side effects in both groups. In the mifepristone and misoprostol group, the most common side effect was nausea/vomiting, affecting 50% of patients, followed by fever (19.4%) and shivering (5.6%). In contrast, the intracervical Foley's catheter group reported psychological upset in 8.3% of patients, mild pain in 19.4%, and discomfort in 5.6%.

DISCUSSION

Managing missed abortion during the second trimester is critical for safeguarding women's health. This study compared the efficacy of oral mifepristone combined with vaginal misoprostol versus intracervical Foley's catheter in women with a scarred uterus at Dhaka Medical College Hospital. Seventy-two women were enrolled, equally divided into group I (mifepristone and misoprostol) and group II (Foley's catheter), revealing notable differences in outcomes between the two approaches.

Socio-demographic and obstetric characteristics were carefully controlled to minimize confounding. No significant differences were observed in age, parity, or hemoglobin levels between groups. However, gestational age differed significantly, with group I showing a lower mean gestational age compared to group II, consistent with findings by Ranjan et al., where the mean gestational age in the mifepristone-misoprostol group was 22.72±3.4 weeks versus 23.42±3.8 weeks in the Foley's catheter group.[5]

Blood transfusion requirements were low in both groups, with 5.6% of participants in group I needing transfusion, while none in group II required it, showing no statistically significant difference. This minor discrepancy may be due to variations in the severity of complications or treatment efficacy, aligning with findings by Wood et al.[19]

In terms of abortion induction, group I achieved a higher success rate than group II, with statistical significance. This difference likely reflects variations in the mechanisms of action and pharmacological efficiency between the two methods. Similar efficacy has been reported by Tahir et al, who observed complete abortion in 96.7% of women with a scarred uterus using the combined regimen.[11]

Regarding dosing, most participants in group I required three doses of misoprostol, highlighting inter-individual variability influenced by gestational age, uterine responsiveness, and physiological differences. A smaller proportion required four doses, and the fewest needed only two, consistent with Sharma et al., who reported a mean misoprostol dose of 2.48, ranging from one to five doses, with over half achieving expulsion after two doses.[7] Lin et al also recommended 400 µg vaginal misoprostol every 3-6 hours as the most effective second-trimester regimen.[20]

The induction-expulsion time differed significantly between groups. In group I, most participants achieved expulsion within 7-12 hours, whereas the majority in group II required 13-18 hours or more than 18 hours. The

mean induction-expulsion time was significantly shorter in the combined mifepristone-misoprostol group, supporting findings by Sharma et al, who reported a median expulsion time of 6-9 hours using this regimen.[7]

Surgical intervention was required less frequently in group I, with both groups undergoing manual vacuum aspiration (MVA) when necessary and no cases requiring laparotomy. Additional uterotonic agents, such as oxytocin, were more frequently administered in group II, although not significantly so.

Side effect profiles differed between groups. In group I, side effects including nausea, vomiting, fever, and shivering were more common, likely due to pharmacological action and individual tolerance. Previous studies also reported gastrointestinal and systemic side effects with vaginal misoprostol administration, such as abdominal pain, bleeding, headaches, and dizziness.[21-23] In contrast, participants in the Foley's catheter group reported psychological upset, mild pain, and local discomfort, reflecting procedural-related discomfort rather than pharmacological effects. Ali et al similarly noted pain and vaginal bleeding as common adverse effects with Foley's catheter insertion, which may reduce maternal satisfaction.[24]

Overall, the combined use of oral mifepristone and vaginal misoprostol demonstrated higher efficacy, shorter induction-expulsion time, and fewer surgical interventions, albeit with a higher incidence of systemic side effects compared to intracervical Foley's catheter. The findings support the use of the pharmacological regimen as a safe and effective method for managing second-trimester missed abortions in women with a scarred uterus, consistent with previous studies.

This study has certain limitations. First, it was conducted in a single tertiary care hospital, which may limit the generalizability of the findings to the broader population. Second, the sample size was relatively small and could not be expanded further due to financial constraints. Finally, the short follow-up period did not allow assessment of long-term outcomes. Therefore, the results should be viewed with caution and may not apply to the wider population.

CONCLUSION

This study shows that among the women treated with oral mifepristone and vaginal misoprostol and those managed with an intracervical Foley's catheter, age distribution and parity were comparable. However, those receiving mifepristone with misoprostol had a lower mean gestational age, achieved a higher success rate, required fewer doses for induction, and experienced a significantly shorter induction–expulsion interval. Surgical intervention was less frequent with this regimen, although manual vacuum aspiration was required in both approaches. Side effects such as nausea, vomiting, fever, and shivering were more common with mifepristone and misoprostol, whereas psychological upset, mild pain, and discomfort were more often reported with Foley's catheter. Overall, the combined use of oral mifepristone and vaginal misoprostol appears to be a more effective and preferable option for managing second-trimester missed abortion in women with a scarred uterus.

Further research using a prospective, longitudinal study design with a larger sample size, incorporating cost-effectiveness analyses and quality assurance assessments, is needed to validate the findings of this study and enhance clinical practice.

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