OPEN ACCESS

Scholars International Journal of Obstetrics and Gynecology

Abbreviated Key Title: Sch Int J Obstet Gynec
ISSN 2616-8235 (Print) | ISSN 2617-3492 (Online)
Scholars Middle East Publishers, Dubai, United Arab Emirates
Journal homepage: https://saudijournals.com

Original Research Article

Maternal Safety and Side Effects of Mifepristone with Misoprostol Versus Intracervical Foley's Catheter in Mid-Trimester Missed Abortion with Scarred Uterus

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DOI: https://doi.org/10.36348/sijog.2025.v08i10.004 | **Received:** 08.08.2025 | **Accepted:** 06.10.2025 | **Published:** 10.10.2025

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Abstract

Background: Management of mid-trimester missed abortion in women with a scarred uterus poses unique challenges. Both pharmacological and mechanical methods are used. Misoprostol is widely used for second-trimester termination, while Foley's catheter aids cervical ripening through prostaglandin and oxytocin release. The combination of mifepristone and misoprostol has been shown to reduce the induction-to-abortion interval compared to Foley's catheter alone. This study aimed to compare the maternal safety, effectiveness, and side-effect profile of these two methods in women with mid-trimester missed abortion and a scarred uterus. ***Methods:*** This comparative observational study was conducted in the Department of Obstetrics & Gynaecology, Dhaka Medical College Hospital (DMCH), Dhaka, Bangladesh, including 80 women with missed abortion and prior cesarean section. Participants were divided into two groups: Group A (n = 40) received combined mifepristone and misoprostol, and Group B (n = 40) received Foley's catheter alone. ***Results:*** The mean age was comparable between groups (27.0 ± 4.1 vs. 27.2 ± 4.0 years). Mean gestational age was significantly lower in Group A (16.2 ± 2.6 weeks) than Group B (23.1 ± 2.0 weeks). Success rates were high in both groups (97.5% vs. 95.0%, p=0.558). The mean induction–expulsion interval was significantly shorter in Group A (10.1 ± 2.1 hours) compared to Group B (18.5 ± 2.9 hours, p<0.0001). Surgical interventions were rarely required, with manual vacuum aspiration being the only method used. Side effects differed between groups: Group A experienced nausea/vomiting (50.0%) and fever (19.4%), while Group B reported psychological upset (8.3%) and mild pain (19.4%). ***Conclusion:*** Mifepristone with misoprostol was more effective in reducing induction–expulsion time compared to Foley's catheter, with different but tolerable side effect profiles in both groups.

Keywords: Mid-trimester abortion, Scarred uterus, Mifepristone, Misoprostol, Foley's catheter, Maternal safety.

INTRODUCTION

Abortion is defined as the termination of pregnancy (TOP) by any means before the fetus attains viability. Currently, fetal viability is considered to be reached at 23–24 weeks of gestation. The second trimester, or mid-trimester, spans from 13 to 28 weeks and is further subdivided into early (13–20 weeks) and late (20–28 weeks) mid-trimester abortion [1].

Abortions remain one of the most commonly performed gynecological procedures worldwide, yet

they continue to pose a significant health problem in developing countries, contributing to considerable maternal morbidity and mortality. The World Health Organization (WHO) has reported that approximately 53 million unplanned pregnancies are terminated annually, with abortion-related deaths accounting for nearly 20% of maternal mortality globally [2]. Among these, second-trimester termination of pregnancy (TOP) is particularly controversial [3].

Mid-trimester uterine evacuation may be indicated electively for fetal or pregnancy-related complications, or for maternal medical conditions [4]. Although second-trimester abortions account for only 10–15% of induced abortions, they are responsible for nearly two-thirds of major complications [2]. Advances in ultrasonography and prenatal diagnostic techniques have led to earlier detection of fetal abnormalities, thereby increasing the number of women requiring mid-trimester termination [5]. Indications for second-trimester abortion include maternal conditions such as pre-eclampsia, placental abruption, and certain respiratory, hepatic, or cardiac disorders, as well as fetal anomalies incompatible with life [6].

Several methods are available for second-trimester termination, including intrauterine instillation of abortifacients, systemic agents, and dilatation and evacuation. However, instillation methods and surgical evacuation carry significant risks, prompting exploration of safer alternatives [7]. The Foley catheter, first described for termination in 1833 by Krause [8], was later reported by Embrey and Mollison in 1967 to achieve a 94% success rate in 100 women [9]. Its mechanism involves direct cervical dilatation and stimulation of endogenous prostaglandin release, further enhanced by traction. Compared with dinoprostone pessary, the Foley catheter has shown superior efficacy, is economical, and has been widely adopted in many developing countries [10].

Mifepristone, a norethindrone derivative with potent antiprogestin activity, blocks progesterone receptors, promotes cervical softening, induces uterine contractions, and increases sensitivity to prostaglandins [7]. Misoprostol, a prostaglandin E1 analogue, acts on myometrial receptors to induce uterine contractions and cervical ripening [11]. FIGO recommends vaginal, sublingual, or buccal misoprostol (200 µg every 4–6 hours for fetal demise), and for surgical preparation: 400 µg vaginally at 13–19 weeks, with additional modalities beyond 19 weeks [12]. Vaginal misoprostol is considered more effective and better tolerated than the oral route, with fewer side effects [13]. While effective, the optimal regimen, route, and dose of misoprostol remain debated [14]. Combination regimens of oral mifepristone followed 36–48 hours later by misoprostol (oral or vaginal) have been shown to shorten induction-to-delivery time and reduce procedure-related pain compared to prostaglandin-only protocols [7].

The primary concern in obstetric practice remains identifying a method that is effective, safe, cost-efficient, and associated with minimal induction-to-expulsion time and side effects. Therefore, the present study aimed to compare the maternal safety, effectiveness, and side effect profile of mifepristone with misoprostol versus intracervical Foley's catheter in women with mid-trimester missed abortion and a scarred uterus.

METHODOLOGY & MATERIALS

This comparative observational study was conducted in the Department of Obstetrics & Gynaecology, Dhaka Medical College Hospital (DMCH), Dhaka, Bangladesh, from April 2020 to September 2021. The study enrolled 80 women with a scarred uterus from a previous cesarean section, who were diagnosed with missed abortion and admitted to the Department of Obstetrics & Gynaecology for management. Participants meeting the selection criteria were divided into two groups:

Group A: Women who received a combination of oral mifepristone and vaginal misoprostol.

Group B: Women who were managed with an intracervical Foley catheter alone.

These were the following criteria for eligibility as study participants:

Inclusion Criteria

- Women with gestational age between 13 and 28 weeks.
- Women diagnosed with missed abortion.
- Women with a previous Caesarean section.
- Patients who provided written informed consent to participate.

Exclusion Criteria

- Women with pre-existing medical conditions such as heart disease, uncontrolled hypertension, bronchial asthma, or coagulation disorders.
- Patients receiving anticoagulant therapy or corticosteroids.
- Women with hemoglobin levels below 8 g/dl.
- Known hypersensitivity to mifepristone or misoprostol.

Drug dosage:

Dose of mifepristone: 200 mg per oral [15].

Dose of misoprostol: 200 – 400 mcg per vaginally [15].

Time duration: After 24 hours of mifepristone administration, misoprostol was administered 3 hourly intervals till expulsion [16].

Table 1: The guideline of WHO 2018 medical management

Gestational Age	No. of Scar	Mifepristone	Misoprostol (after 24 hours of mifepristone)	Duration of Misoprostol
13-24 wks	one scar	200 mg per orally (Single dose)	400 mcg (2 tab) per vaginally	2 tab every 3 hourly till expulsion
13-24 wks	more than one scar	200 mg per orally (Single dose)	200 mcg (1 tab) per vaginally	1 tab every 3 hourly till expulsion
24-28 wks	one or more than one scar	200 mg per orally (Single dose)	200 mcg (1 tab) per vaginally	1 tab every 3 hourly till expulsion

Data Collection Procedure:

Written informed consent was obtained from all participants after explaining the study objectives and procedures. Relevant obstetric and medical history, along with clinical information, were collected using a pre-designed semi-structured questionnaire. A thorough clinical examination was conducted, and laboratory investigations were performed according to standard protocols. Participants were non-randomly allocated into two intervention groups. Group A (n = 40) 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). Group B (n = 40) was 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 fetal expulsion. Patients were closely monitored at three-hour intervals for vital signs, abdominal pain, uterine contractions, vaginal bleeding, and overall clinical status. Vaginal blood loss was estimated using fully soaked pads. All maternal side effects, including nausea, vomiting, fever, pain, discomfort, and psychological upset, were systematically recorded. 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. Follow-up continued until complete fetal expulsion. Data on induction-to-expulsion time, number of misoprostol doses, complications, side effects, and failed induction were recorded on individual data sheets for comparison between groups.

Statistical Analysis:

Data were systematically entered into a pre-formatted data collection form. Quantitative variables were expressed as mean ± standard deviation, and qualitative variables as frequency and percentage. Associations between outcome variables were analyzed using Chi-square tests, while the mean induction-to-abortion time was compared using unpaired t-tests. A p-value < 0.05 was considered statistically significant. All analyses were performed using SPSS version 26 (Statistical Package for Social Sciences). The study received ethical approval from the Institutional Review Committee of Dhaka Medical College Hospital (DMCH).

RESULTS

Table 2: Socio-demographic, obstetrical, and clinical characteristics of the study population (N = 80)

Variables	Group A		Group B	
Age (years)	**N=40**	**P(%)**	**N=40**	**P(%)**
≤ 25 years	18	45.0	14	35.0
26–30 years	14	35.0	20	50.0
> 30 years	8	20.0	6	15.0
Mean ± SD	27.0 ± 4.1		27.2 ± 4.0	
Gestational age (weeks)				
13–18 weeks	34	85.0	0	0.0
19–24 weeks	6	15.0	28	70.0
> 24 weeks	0	0.0	12	30.0
Mean ± SD	16.2 ± 2.6		23.1 ± 2.0	
Parity				
Primipara	29	72.5	28	70.0
Multipara	11	27.5	12	30.0
Hb level (g/dl)	9.4 ± 0.4		9.3 ± 0.3	
Blood transfusion				
Needed	2	5.0	0	0.0
Not needed	38	95.0	40	100.0

Table 2 shows that the mean age of women was comparable between the two groups (27.0 ± 4.1 vs. 27.2 ± 4.0 years). In Group A, the majority (45.0%) were ≤25 years, while in Group B, half (50.0%) were in the 26–30 years category. The mean gestational age differed significantly between groups (16.2 ± 2.6 weeks in Group

A vs. 23.1 ± 2.0 weeks in Group B). Regarding parity, primipara women predominated in both groups (72.5% in Group A vs. 70.0% in Group B). The mean hemoglobin level was similar across groups (9.4 ± 0.4 g/dl vs. 9.3 ± 0.3 g/dl). Blood transfusion was required in a small proportion of cases in Group A (5.0%), whereas none of the participants in Group B required transfusion.

Table 3: Number of misoprostol doses required for successful induction

Number of Doses Needed	**Number**	**Percentage**
Second dose	8	19.44%
Third dose	33	83.33%
Fourth dose	9	22.22%

This table shows the distribution of participants according to the number of misoprostol doses required for induction. A second dose was needed in 8 women (19.44%). The majority required a third dose (33 cases, 83.33%), while 9 women (22.22%) required a fourth dose for successful induction.

Table 4: Effectiveness and induction–expulsion time among study participants

Variables	**Group A**		**Group B**		**p-value**
Effectiveness	**N=40**	**P(%)**	**N=40**	**P(%)**	
Successful	39	97.5	38	95.0	0.558
Failure	1	2.5	2	5.0	
Induction–Expulsion Time					
≤ 6 hours	0	0.0	0	0.0	
7–12 hours	34	85.0	1	2.5	< 0.0001
13–18 hours	6	15.0	16	40.0	0.0128
> 18 hours	0	0.0	23	57.5	
Mean ± SD	10.1 ± 2.1		18.5 ± 2.9		< 0.0001

This table presents the effectiveness of induction and the induction–expulsion interval in the two groups. The success rate was high in both groups, with 97.5% in Group A and 95.0% in Group B, and the difference was not statistically significant (p = 0.558). The mean induction–expulsion time was significantly shorter in Group A (10.1 ± 2.1 hours) compared to Group B (18.5 ± 2.9 hours) (p < 0.0001). The majority of women in Group A (85.0%) delivered within 7–12 hours, while in Group B, most required more than 18 hours (57.5%). A higher proportion in Group B also delivered between 13–18 hours (40.0% vs. 15.0% in Group A), showing a statistically significant difference (p = 0.0128).

Table 5: Surgical and additional interventions required in study patients

Variables	**Group A**		**Group B**		**p-value**
Surgical intervention	**N=40**	**P(%)**	**N=40**	**P(%)**	
Not needed	39	97.5	38	95.0	0.558
Needed	1	2.5	2	5.0	
Type of Surgical Intervention					
MVA	1	100	2	100	
Uterine massage					
Required	1	2.5	0	0.0	0.317
Not required	39	97.5	40	100	
Additional uterotonic (Oxytocin)					
Required	1	2.5	3	7.5	0.307
Not required	39	97.5	37	92.5	

Table 5 summarizes the need for surgical and supportive interventions following induction. The majority of women in both groups did not require surgical intervention (97.5% in Group A vs. 95.0% in Group B), with only a few cases requiring intervention (2.5% vs. 5.0%, p = 0.558). In all cases where surgical management was necessary, manual vacuum aspiration (MVA) was performed. Uterine massage was required in a single case in Group A (2.5%), while none required it in Group B (p = 0.317). Additional uterotonic support with oxytocin was given more frequently in Group B (7.5%) compared to Group A (2.5%), though the difference was not statistically significant (p = 0.307).

Table 6: Distribution of side effects among study respondents

Side effects	Group A		Group B	
	N=40	P(%)	N=40	P(%)
Nausea/ Vomiting	18	50.0	0	0
Fever	7	19.4	0	0
Shivering	2	5.6	0	0
Psychological Upset	0	0	3	8.3
Mild Pain	0	0	7	19.4
Discomfort	0	0	2	5.6

Table 6 shows the occurrence of side effects following induction in both groups. In Group A, the most frequently reported side effect was nausea/vomiting (50.0%), followed by fever (19.4%) and shivering (5.6%). No cases of psychological upset, mild pain, or discomfort were observed in this group. In contrast, Group B reported no cases of nausea/vomiting, fever, or shivering. Instead, participants experienced psychological upset (8.3%), mild pain (19.4%), and discomfort (5.6%).

DISCUSSION

This study compared the efficacy of oral mifepristone combined with vaginal misoprostol versus intracervical Foley's catheter for mid-trimester abortion in women with a scarred uterus at Dhaka Medical College Hospital. A total of 80 women were enrolled and equally divided into Group A (mifepristone–misoprostol) and Group B (Foley's catheter). Notable differences were observed between the two methods in terms of outcomes.

The mean age of participants was comparable between the two groups (27.0 ± 4.1 years in Group A vs. 27.2 ± 4.0 years in Group B). Similar findings were reported by Mahajan *et al.,* where the mean age was 22.63 ± 2.47 years in the combined (misoprostol and Foley) group and 23.27 ± 2.3 years in the misoprostol group [17]. This aligns with the results of Subha *et al.,* who reported a mean age of 23.4 ± 4.1 years [18].

The mean gestational age differed significantly between groups, being 16.2 ± 2.6 weeks in Group A versus 23.1 ± 2.0 weeks in Group B. Mahajan *et al.,* reported mean gestational ages of 16.87 ± 1.73 weeks in the combined group and 17.09 ± 1.8 weeks in the misoprostol group [17], which was consistent with Shrivastava *et al.,* who observed 17+7 weeks in the misoprostol group and 17.8+6.2 weeks in the combined group [19].

In terms of parity, the majority of women in the present study were primiparous (71.25%), with multiparous women accounting for 28.75%. This distribution is comparable to findings by Afsheen et al., who reported 44.3% nulliparous, 32.2% primiparous, and 23.5% multiparous participants [13]. Mahajan *et al.,* also found a similar distribution, with 48.33% nulliparous, 41.67% primiparous, and 10% multiparous [17].

The success rate was high in both groups, with 97.5% in the mifepristone–misoprostol group. Previous studies have reported similar efficacy: Fonseca *et al.,* (88.88%) [7], Allahbadia *et al.,* (98%) [20], Agarwal *et al.,* (97%) [21], Dickinson *et al.,* (76%) [22], and Bebbington *et al.,* (87%) [23], indicating consistently high effectiveness across different populations. In the Foley catheter group, the success rate was 95.0%, which is in line with Fonseca *et al.,* (83.3%) [7], Bhathena *et al.,* (92%) [24], Bebbington *et al.,* (76%) [23], and Prachasilpchai *et al.,* (75%) [25]. Mahajan *et al.,* reported a success rate of 96.67% in both combined and misoprostol groups with no major complications [17], and Rezk *et al.,* observed a similar success rate of 96% without significant adverse events [26].

The mean induction-to-expulsion time was significantly shorter in Group A (10.1 ± 2.1 hours) compared to Group B (18.5 ± 2.9 hours, $p < 0.0001$). In the mifepristone–misoprostol group, 85% of women delivered within 7–12 hours, while the majority in the Foley group required more than 18 hours (57.5%). For women undergoing mid-trimester abortion with a Foley's catheter, Fonseca *et al.,* reported a mean interval of 20.11 hours [7], while Bhathena *et al.,* observed a slightly longer duration of 28 hours [24]. Bebbington *et al.,* reported an even longer interval of 33 hours [23], and Prachasilpchai *et al.,* documented a shorter mean interval of 18 hours [25]. In contrast, studies using the pharmacological approach with the mifepristone–misoprostol combination generally reported longer induction-to-abortion intervals. Allahbadia *et al.,* documented a mean interval of 35 hours [20], whereas Agarwal *et al.,* reported an interval of up to 59 hours [21] Mahajan *et al.,* found 18.31 ± 1.95 hours in the combined group and 21.90 ± 2.62 hours in the misoprostol group [17], which aligns with Shabana *et al.,*(15.6 ± 4.9 hours vs. 21.9 ± 5.4 hours, $p < 0.05$) [27] and Rezk *et al.,*(8.16 ± 1.52 hours vs. 12.76 ± 1.63 hours, $p < 0.001$) [26,27]. In some studies, differences were not statistically significant, such as Toptas *et al.,* (11.33–17.25 hours vs. 9.50–15.33 hours; $p = 0.14$) [28] and Farzana *et al.,* (9.34 ± 0.605 hours vs. 10.65 ± 0.622 hours; $p > 0.05$) [29].

Regarding side effects, the most common in the mifepristone–misoprostol group was nausea/vomiting

(50.0%), followed by fever (19.4%) and shivering (5.6%). In contrast, the Foley catheter group experienced psychological upset (8.3%), mild pain (19.4%), and discomfort (5.6%). Fonseca *et al.,* reported pain, nausea, and vomiting in 100%, 55.55%, and 38.88% of women in the Foley group, and in 100%, 22.22%, and 16.66% in the mifepristone–misoprostol group [7]. Mahajan *et al.,* observed that 88.33% of women had no complications, with mild events such as diarrhea (71.43%) and fever (28.57%) in the remainder [17]. Side effects reported by Allahbadia *et al.,* using ethacridine lactate included fever (6%), vomiting (2%), rigors (5%), and hemorrhage (2%) [20]; by Jain and Mishell using misoprostol: fever (11%), vomiting (4%), diarrhea (4%) [30]; and by Herabutya *et al.*: fever (41%), vomiting (15%), diarrhea (20%) [31].

Overall, these findings demonstrate that both mifepristone–misoprostol and Foley catheter methods are effective for mid-trimester termination in women with a scarred uterus, with the pharmacological combination showing a shorter induction-to-expulsion interval and a slightly higher success rate, consistent with previously published studies.

Limitations of the Study

This study has several limitations. First, the sample size was relatively small and recruited from a single tertiary care center, which may limit the generalizability of the findings. Second, participants were non-randomly allocated to the intervention groups, introducing potential selection bias. Third, the study relied on clinical observation and self-reported side effects, which may be subject to reporting bias.

CONCLUSION AND RECOMMENDATIONS

Mifepristone combined with misoprostol is an effective and safe method for the management of mid-trimester missed abortion in women with a scarred uterus, achieving a shorter induction–expulsion interval compared to intracervical Foley's catheter. Both methods were associated with high success rates and minimal need for surgical intervention. The side effect profiles differed between groups: gastrointestinal and febrile symptoms were more common with mifepristone-misoprostol, whereas psychological discomfort and mild pain predominated with Foley catheter use. Overall, both approaches are viable options, but mifepristone-misoprostol may offer advantages in terms of rapid completion of abortion and reduced intervention time.

Further study with a prospective and longitudinal study design, including a larger sample size, needs to be done to validate the findings of this study.

Funding: No funding sources.

Conflict of Interest: None declared.

Ethical Approval: This study was ethically approved.

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