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Treatment Response and Safety Profile of Combined Intravaginal Misoprostol and Intracervical Foley Catheter in Second-Trimester Missed Abortion

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ABSTRACT

Introduction: Second-trimester missed abortion is associated with increased risks of hemorrhage, infection, prolonged induction, and incomplete expulsion. Misoprostol is widely used for medical management; however, the addition of an intracervical Foley's catheter may enhance cervical ripening and improve treatment outcomes. **Aim of the Study:** To determine the treatment response and safety profile of combined intravaginal Misoprostol and intracervical Foley's catheter in the management of second-trimester missed abortion. **Methods & Materials:** This single-arm descriptive study was conducted in the Department of Obstetrics and Gynecology, Institute of Child and Mother Health (ICMH), Matuail, Dhaka, between January 2023 and June 2024. A total of 53 women aged 18–35 years with missed abortion between 13 and 24 weeks of gestation received 400 µg intravaginal Misoprostol combined with an intracervical Foley's catheter. Treatment outcomes included successful expulsion, induction–expulsion interval, Misoprostol dose requirement, need for surgical intervention or additional uterotonics, blood transfusion, and adverse effects. Data were analyzed using descriptive statistics and presented as frequency, percentage, mean, and standard deviation. **Results:** The mean age and gestational age were 26.13 ± 5.16 years and 16.92 ± 2.02 weeks, respectively. Successful expulsion was achieved in 51 participants (96.2%), while 2 (3.8%) had failed expulsion. The mean induction–expulsion interval was 13.27 ± 3.83 hours, with most participants (58.5%) achieving expulsion within 12–18 hours. Among successful cases, the mean number of Misoprostol doses required was 2.98 ± 0.65, and most participants (58.8%) required three doses. Surgical intervention and additional oxytocin were required in 2 participants (3.8%) each. Overall, 24 participants (45.3%) experienced at least one side effect, most commonly nausea/vomiting (13.2%) and diarrhea (11.3%). Blood transfusion was required in 4 participants (7.5%). **Conclusion:** Combined intravaginal Misoprostol and intracervical Foley's catheter demonstrated a high rate of successful expulsion with a favorable induction–expulsion interval, low requirement for surgical intervention, and an acceptable safety profile in women with second-trimester missed abortion.

Keywords: *Misoprostol, Foley catheter, Abortion*

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INTRODUCTION

Missed abortion, defined as the retention of a non-viable pregnancy within the uterus without spontaneous expulsion, remains a common and clinically significant complication of pregnancy worldwide. Globally, unintended pregnancy and pregnancy loss impose a substantial public health burden, particularly in low- and middle-income countries where access to timely obstetric care is often limited.[1] In Bangladesh, hospital-based studies have similarly documented a considerable prevalence of miscarriage and missed abortion among women presenting for obstetric care, with maternal age, prior pregnancy loss, and environmental factors identified as important contributors.[2,3] Second-trimester missed abortion, in particular, poses greater management challenges than first-trimester loss, given the more advanced gestational tissue, the less favorable cervix, and the higher risk of complications such as hemorrhage, infection, and incomplete evacuation if not managed promptly and effectively.[4,5] Management options for second-trimester missed abortion include medical, surgical, and expectant approaches, each carrying distinct risks and resource requirements.[6] Surgical evacuation, while effective, requires anesthesia, skilled personnel, and carries procedural risks such as uterine perforation and cervical trauma, making it less accessible in many resource-limited settings. Consequently, medical management using Misoprostol, a synthetic prostaglandin E1 analogue, has become widely adopted for its efficacy, low cost, and ease of administration.[7,8,9] However, Misoprostol used alone is sometimes associated with prolonged induction-to-expulsion intervals, incomplete expulsion, and the need for repeated dosing, prompting interest in adjunct mechanical methods to improve outcomes.[10] The intracervical Foley's catheter, traditionally used for cervical ripening in labor induction, has increasingly been explored in combination with Misoprostol for second-trimester pregnancy termination. Its proposed mechanism involves direct mechanical pressure on the internal cervical os, promoting local prostaglandin release and progressive cervical softening and dilation, which is thought to act synergistically with the pharmacological effect of Misoprostol. By providing continuous mechanical dilation of the cervix alongside the pharmacological action of Misoprostol, this combined approach has been reported to shorten induction-to-expulsion time, reduce the number of Misoprostol doses required, and lower the need for surgical intervention in several comparative studies.[11,12,13,14] Despite this growing body of comparative evidence, dedicated reporting of the treatment response and safety profile of the combined method itself, independent of a comparator arm, remains limited, particularly from South Asian clinical settings such as Bangladesh where resource constraints make efficient, well-tolerated regimens especially valuable.[15] Given this gap, a focused description of clinical outcomes with the combined intravaginal Misoprostol and intracervical Foley's catheter approach can help clinicians in similar settings anticipate expected success rates, timelines, and adverse effects when

counseling and managing patients with second-trimester missed abortion. Therefore, the study aimed to determine the treatment response and safety profile of combined intravaginal Misoprostol and intracervical Foley's catheter in the management of second-trimester missed abortion.

METHODS & MATERIALS

This single-arm descriptive study was conducted in the Department of Obstetrics and Gynecology, Institute of Child and Mother Health (ICMH), Matuail, Dhaka, between January 2023 and June 2024. Fifty-three women aged 18-35 years, admitted with a diagnosis of missed abortion between 13 and 24 weeks of gestation and fulfilling the eligibility criteria, were enrolled by simple random sampling; inclusion required hemodynamic stability and willingness to provide written informed consent, while women with a previous caesarean section, incomplete or inevitable abortion, axillary temperature above 37.5°C, hypertensive disorder, bronchial asthma, heart disease, hypersensitivity to prostaglandins, coagulation disorder or anticoagulant use, cervical growth, hemoglobin below 8.5 g/dl, multiple pregnancy, or infected vaginal discharge were excluded. Each participant received 400 µg intravaginal Misoprostol together with an intracervical Foley's catheter, with the induction-expulsion interval, number of Misoprostol doses required, need for surgical intervention or additional uterotonic, mode of placental delivery, blood transfusion requirement, and adverse effects recorded on a preformed semi-structured questionnaire following relevant obstetric and medical history-taking; successful expulsion was defined as complete expulsion of conception without surgical intervention, and failure was defined as non-termination despite a maximum of five 400 µg doses of Misoprostol requiring surgical evacuation. Data were analyzed using SPSS version 26, with descriptive statistics (frequency, percentage, and mean ± SD) used to summarize qualitative and quantitative variables as appropriate. Ethical clearance was obtained from the Institutional Review Board of ICMH, Matuail, Dhaka, and written informed consent was taken from all participants after explaining the study in the local language, with confidentiality maintained and participation kept voluntary throughout.

RESULTS

This study reports treatment response and safety outcomes for 53 women with second-trimester missed abortion who received combined intravaginal Misoprostol and intracervical Foley's catheter at the Department of Obstetrics and Gynecology, Institute of Child and Mother Health (ICMH), Matuail, Dhaka. This cohort represents the combined-treatment arm of a parent randomized controlled trial (registration/reference as applicable); outcomes are reported descriptively for this arm.

Table I

Baseline characteristics of study participants (*n*=53).

Characteristics (n=53)	Frequency (n)	Percentage (%)
Age (years), Mean ± SD	26.13 ± 5.16	
Gestational age (weeks), Mean ± SD	16.92 ± 2.02	
Gestational age group		
13–18 weeks	40	75.5
19–24 weeks	13	24.5
Gravida		
Primigravida	19	35.85
Multigravida	34	64.15
Menstrual cycle		
Regular	46	86.79
Irregular	7	13.21

Values are expressed as frequency with percentage, or as Mean ± SD.

The mean age of participants was 26.13 ± 5.16 years, and the mean gestational age at presentation was 16.92 ± 2.02 weeks. Most participants (75.5%) presented between 13 and 18 weeks of gestation. The majority were multigravida (64.15%) with a regular menstrual cycle (86.79%).

Table II

Treatment response — expulsion outcome, induction–expulsion interval, and misoprostol dose requirement (*n*=53).

Treatment response parameter (n=53)	Frequency (n)	Percentage (%)
Successful expulsion of conception	51	96.2
Failed expulsion	2	3.8
Induction–expulsion interval		
< 6 hours	0	0.0
6–12 hours	15	28.30
12–18 hours	31	58.49
> 18 hours	7	13.21
Mean ± SD (hours)	13.27 ± 3.83	
Doses of misoprostol required for successful expulsion (n=51)[a]		
2 doses	11	21.6
3 doses	30	58.8
4 doses	10	19.6
Mean ± SD	2.98 ± 0.648	

[a] *Dose data reported among participants who achieved successful expulsion (n=51).*

Successful expulsion of conception was achieved in 51 of 53 participants (96.2%), with only 2 (3.8%) experiencing failed expulsion. Most participants (58.49%) expelled within 12–18 hours of induction, with a mean induction–expulsion interval of 13.27 ± 3.83 hours. Among those with successful expulsion, the majority (58.8%) required 3 doses of misoprostol, with a mean of 2.98 ± 0.648 doses.

Table III
Need for surgical intervention and adjunct measures (*n*=53).

Parameter (n=53)	Frequency (n)	Percentage (%)
Surgical intervention needed	2	3.8
D&C (of those needing intervention, n=2)[a]	1	50
Evacuation of uterus (n=2)[a]	1	50
Uterine massage needed	0	0.0
Additional uterotonic (oxytocin) required	2	3.8

[a] *Percentages for intervention type are calculated among the 2 participants who required surgical intervention.*

Surgical intervention was required in only 2 participants (3.8%), one requiring dilatation and curettage and one requiring evacuation of the uterus. No participant required uterine massage, and additional uterotonic (oxytocin) was needed in 2 participants (3.8%).

Table IV
Safety profile — adverse effects, hemoglobin, and blood transfusion requirement (*n*=53).

Safety parameter (n=53)	Frequency (n)	Percentage (%)
Any side effect experienced	24	45.3
Nausea/vomiting	7	13.2
Diarrhea	6	11.3
Psychological upset	4	7.5
Fever	4	7.5
Hemoglobin (g/dL), Mean ± SD	10.82 ± 0.89	
Blood transfusion needed	4	7.5

Values are expressed as frequency with percentage, or as Mean ± SD.

Overall, 24 participants (45.3%) experienced at least one side effect. The most common were nausea/vomiting (13.2%) and diarrhea (11.3%), followed by psychological upset and fever (7.5% each). The mean hemoglobin level was 10.82 ± 0.89 g/dL, and blood transfusion was required in 4 participants (7.5%).

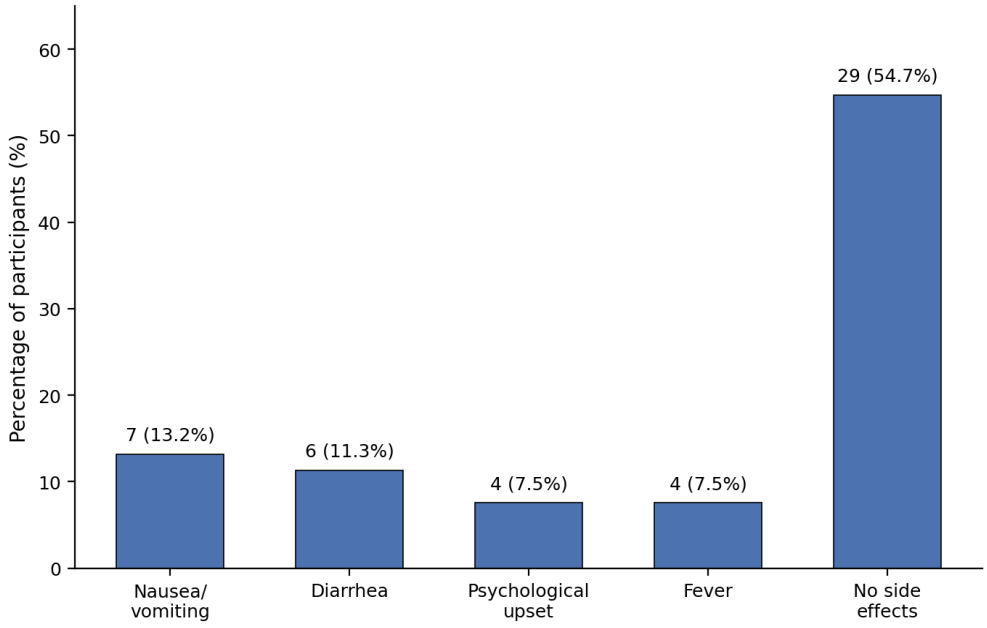

Figure 1 Distribution of side effects among participants (*n*=53).

Nearly half of the participants (45.3%) reported no side effects. Among those who did, nausea/vomiting and diarrhea were the most frequently reported, and no severe or life-threatening adverse events were recorded.

DISCUSSION

This study evaluated the treatment response and safety profile of combined intravaginal Misoprostol and intracervical Foley's catheter in 53 women with second-trimester missed abortion, reporting outcomes descriptively for this treatment arm drawn from a parent randomized controlled trial conducted at ICMH, Matuail, Dhaka. Second-trimester missed abortion carries a substantial physical and psychological burden, and identifying a management strategy that is both effective and well-tolerated remains an important clinical priority, particularly in low-resource settings where prolonged induction-to-expulsion intervals can strain hospital capacity and patient wellbeing.

The mean age of participants in our study was 26.13 ± 5.16 years, with a mean gestational age of 16.92 ± 2.02 weeks at presentation, and the majority (64.15%) were multigravida. These baseline characteristics were comparable to those reported by Mahajan et al., who studied a similar population undergoing mid-trimester pregnancy termination in India.[11] Ait-allah et al. also reported a

broadly similar demographic profile among women undergoing combined Foley catheter and Misoprostol induction for midtrimester abortion, supporting that any differences in outcomes across studies are unlikely to be driven by baseline demographic variation.[12]

Regarding treatment response, our study found a high successful expulsion rate of 96.2% (51/53), with a mean induction-expulsion interval of 13.27 ± 3.83 hours. This success rate was higher than that reported by Ait-allah et al., who found a 92% success rate with the combined Foley-Misoprostol approach in women with an unfavorable cervix.[12] Similarly, Kaur et al. reported a mean induction-delivery interval of 14.58 ± 6.67 hours in their combined-treatment group, closely comparable to our finding.[13] In contrast, Rezk et al. observed a longer mean induction-to-abortion interval in their combined-method cohort, suggesting that variation in Foley balloon volume, misoprostol dosing interval, and gestational age range across studies can meaningfully affect expulsion time.[16] The mean number of misoprostol doses required for successful expulsion in our cohort was 2.98 ± 0.648. This was lower than the requirement described by Agarwal et al., where the largest proportion of patients needed three 200 mcg doses (600 mcg total) to achieve successful abortion, and is consistent with Dickinson and Evans, who found a regimen of 400 mcg vaginal misoprostol every 6 hours to be among the most efficient dosing schedules for second-trimester termination.[17,18]

For surgical intervention and adjunct measures, only 3.8% (2/53) of our participants required surgical evacuation, and none needed uterine massage. This rate was lower than that reported by Ait-allah et al., where manual removal of retained products was required more often in the misoprostol-alone arm than in the combined arm of their trial, and is broadly consistent with Kaur et al., who concluded that the Foley catheter-Misoprostol combination lowered the need for additional intervention compared with Misoprostol alone.[12,13] The meta-analysis by Lee et al. similarly supports that combined mechanical-pharmacological cervical ripening is associated with a lower rate of failed induction requiring surgical rescue than pharmacological methods alone.[19]

With respect to safety, 45.3% of our participants experienced at least one side effect, most commonly nausea/vomiting (13.2%) and diarrhea (11.3%), with no severe adverse events recorded. This side-effect profile is consistent with that reported by Hashemi et al. and Saleh et al., both of whom described mild, self-limiting gastrointestinal and febrile symptoms as the predominant adverse effects of Misoprostol-based regimens.[20,21] The mean hemoglobin level in our cohort was 10.82 ± 0.89 g/dL, and blood transfusion was required in only 7.5% (4/53) of participants. This finding aligns with Ait-allah et al., who also reported a low transfusion requirement in their combined-treatment group.[12] However, our finding differs from that of Yüce et al., who reported significantly higher postoperative hemoglobin levels in their combined-method group compared with the Misoprostol-alone group, suggesting that the magnitude of hemoglobin preservation with combined therapy may vary with baseline anemia prevalence and blood-loss assessment methods across settings.[22]

Taken together, our findings support that combined intravaginal Misoprostol and intracervical Foley's catheter achieves a high rate of successful expulsion within a clinically favorable time frame, with a low requirement for surgical intervention, additional uterotonics, or blood transfusion, and a tolerable, largely self-limiting side-effect profile. These findings are broadly consistent with existing literature, though variation in magnitude across studies reflects differences in population characteristics, gestational age range, and treatment protocol, underscoring the value of standardized protocols in future multicentre studies. As this analysis describes a single treatment arm without a concurrent comparator, causal claims about the relative superiority of the combined method cannot be drawn from these data alone; nonetheless, the consistency of our findings with prior comparative studies strengthens confidence in the combined approach as a favorable option for managing second-trimester missed abortion in similar clinical settings.

LIMITATION

The main limitation of this study was its small sample size and single-arm design without a concurrent comparison group, which limits the generalizability and comparative interpretation of the findings.

CONCLUSION

This study found that the combination of intravaginal Misoprostol and an intracervical Foley's catheter is effective for expelling tissues in women with second-trimester missed abortion. Most participants experienced successful expulsion within a reasonable timeframe and required minimal surgical intervention, suggesting the treatment's effectiveness. Although some mild adverse effects were reported, there were no severe complications. Overall, this approach appears to be a safe and effective option, though the findings should be considered preliminary due to the lack of a comparison group.

RECOMMENDATION

The combined use of intravaginal Misoprostol and an intracervical Foley's catheter may be a viable option for managing second-trimester missed abortion, given its high success rate and reduced need for surgery. Careful patient selection and monitoring are crucial to address potential complications. Future research should focus on larger randomized controlled trials to compare this approach with Misoprostol alone and assess factors like dosing schedules, induction–expulsion time, patient acceptability, and longer-term outcomes.

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