



Vaginal versus oral misoprostol in the management of first trimester missed abortion among admitted patients in a tertiary level hospital

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Abstract

Background: Missed abortion is a common first-trimester pregnancy complication requiring effective medical management. Misoprostol, a prostaglandin E1 analog, is widely used through oral or vaginal administration. However, the comparative efficacy, required doses, expulsion time, and side-effect profile between these two routes remain subjects of ongoing research, particularly in low-resource settings like Bangladesh.

Objective: The objective of the study was to compare the efficacy, required doses, time to expulsion, side effects, and cervical permeability between oral and vaginal misoprostol in the management of first-trimester missed abortion.

Methods: This randomized controlled trial was conducted in a tertiary-level hospital in Bangladesh, involving 118 women diagnosed with first-trimester missed abortion. Participants were randomly assigned to receive either oral misoprostol (Group A, $n = 59$) or vaginal misoprostol (Group B, $n = 59$). Primary outcomes included complete expulsion rates, time to expulsion, number of doses required, and side effects. Statistical analysis was performed using Pearson's Chi-square test for categorical data and independent t -tests for continuous variables, with significance set at $P < 0.05$.

Results: Vaginal misoprostol demonstrated significantly higher complete expulsion rates (76.27% vs. 37.29%, $P < 0.001$), required fewer doses (mean: 1.69 vs. 2.41, $P < 0.001$), and had a shorter time to expulsion (7.69 ± 2.89 vs. 9.45 ± 1.40 h, $P = 0.032$) compared to oral misoprostol. Nausea and vomiting were more frequent with oral misoprostol, but other side effects were comparable. Cervical permeability among unsuccessful cases did not differ significantly between groups ($P = 0.6985$).

Conclusion: Vaginal misoprostol is more effective than oral administration, offering higher expulsion rates, faster expulsion, and requiring fewer doses, with a similar safety profile. These findings support vaginal misoprostol as the preferred route for the medical management of first-trimester missed abortion. Future research should explore sublingual routes, adjunctive mifepristone therapy, and patient-centered factors to further optimize treatment strategies.

Keywords: Misoprostol, missed abortion, vaginal administration, oral administration, medical abortion, expulsion rate.

Introduction

Missed abortion, also known as early pregnancy failure, is a significant cause of maternal morbidity

and psychological distress worldwide. It is defined as the cessation of embryonic or fetal development in the first trimester, with the fetus remaining in utero without any clinical symptoms of expulsion.

Globally, early pregnancy loss affects approximately 10–15% of clinically recognized pregnancies, with up to 20% of all pregnancies ending in miscarriage.^[1] In South Asia, the burden of spontaneous and induced abortions remains high, contributing significantly to maternal mortality and morbidity.^[2] In Bangladesh, maternal mortality due to pregnancy-related complications, including miscarriage and unsafe abortion, remains a pressing concern, with the maternal mortality ratio reported at 173/100,000 live births in 2017.^[3] Hospital-based management of first-trimester missed abortion in tertiary care settings is critical to ensuring safe and effective treatment options while reducing complications associated with delayed intervention.^[4] Historically, the management of missed abortion primarily involved surgical evacuation via dilation and curettage (D and C) or manual vacuum aspiration. These methods have been the standard approach for decades due to their high success rates; however, they carry significant risks, including uterine perforation, cervical trauma, hemorrhage, and anesthesia-related complications.^[5] Moreover, surgical management demands hospital-based infrastructure and skilled professionals, making it a less feasible option in low-resource settings.^[2] Consequently, medical management with misoprostol, a prostaglandin E1 analog, has emerged as a less invasive, cost-effective, and patient-preferred alternative.^[2] Misoprostol induces uterine contractions by binding to prostaglandin receptors, leading to cervical ripening and expulsion of retained products of conception.^[6] Compared to surgical evacuation, medical management with misoprostol reduces hospital admission rates, lowers the need for anesthesia, and minimizes complications.^[7] The route of misoprostol administration plays a critical role in determining its efficacy and side-effect profile. The oral route is widely used due to its non-invasive nature, ease of administration, and higher patient compliance. However, oral misoprostol undergoes hepatic first-pass metabolism, resulting in lower bioavailability and a shorter duration of action.^[8] In addition, it is associated with higher rates of gastrointestinal side effects, including nausea, vomiting, and diarrhea.^[8] In contrast, vaginal administration provides higher bioavailability, a longer half-life, and greater efficacy due to direct

absorption through the vaginal mucosa.^[2] Several studies have reported that vaginal misoprostol has higher success rates (70–85%) compared to oral misoprostol (40–60%), along with a shorter induction-expulsion interval.^[8] Furthermore, vaginal administration has been associated with fewer systemic side effects and improved patient satisfaction compared to oral administration.^[2] While existing evidence suggests that vaginal misoprostol is more effective than oral administration, inconsistencies remain in dosing regimens, patient selection criteria, and study designs. Various studies have reported different dosing intervals and repeated dose requirements, leading to variations in reported success rates and adverse events.^[9] For example, studies have demonstrated that 800 µg vaginal misoprostol provides a significantly higher success rate compared to lower-dose regimens (200–400 µg), yet the optimal interval between doses remains under debate.^[2] Furthermore, most of the existing literature is based on Western populations, with limited research focusing on South Asian or Bangladeshi women, who may have different physiological responses or healthcare access disparities.^[3] This study aims to address these gaps by comparing the efficacy and safety of oral versus vaginal misoprostol in the management of first-trimester missed abortion in a tertiary-level hospital in Bangladesh. The study will evaluate complete expulsion rates, induction-expulsion intervals, the number of doses required, and side-effect profiles between the two administration routes. Given the high burden of miscarriage-related complications and limited access to surgical interventions in resource-constrained settings, identifying the most effective and patient-friendly medical management approach is crucial. By providing region-specific, evidence-based recommendations, this study has the potential to improve clinical guidelines and optimize patient outcomes in Bangladesh and other low-resource settings.

Methods

This randomized controlled clinical trial was conducted at the Gynecology and Obstetrics Department of Shaheed Ziaur Rahman Medical

College Hospital (SZMCH), Bogra, over a 6-month period from May 2015 to October 2015. The study enrolled women diagnosed with first-trimester missed abortion, confirmed through sonography and clinical assessment. Eligible participants were randomly assigned to two groups: Group A of 59 women received 400 µg of oral misoprostol, while Group B of 59 women received 400 µg of vaginal misoprostol. Misoprostol doses were repeated at 4-h intervals, with a maximum of three doses if required. Participants were monitored for complete, incomplete, or failed expulsion using transabdominal sonography, with complete expulsion defined as the absence of an echogenic structure measuring <15 mm in anteroposterior diameter. Secondary outcomes included time to expulsion, number of doses required, and incidence of side effects such as nausea, vomiting, diarrhea, pain severity, hyperpyrexia, and excessive bleeding. Surgical evacuation was performed in cases of heavy vaginal bleeding or incomplete expulsion after 10–12 h. Data were collected using a structured case report form, and statistical analysis was performed using SPSS version 12. Pearson's Chi-square test was used to analyze categorical variables, while independent *t*-tests were applied to continuous variables. A *P* < 0.05 was considered statistically significant. The study adhered to ethical guidelines, with ethical approval from the Bangladesh College of Physicians and Surgeons, and informed written consent was obtained from all participants.

Results

The mean age of participants was 24.6 ± 3.05 years in Group A and 23.98 ± 2.387 years in Group B, indicating no significant age difference between the groups. The age distribution showed that the majority of participants were in the 20–25 years age group (33.90% in Group A, 42.37% in Group B), while a smaller proportion were above 30 years (8.47% in both groups). In terms of residence, a higher proportion of rural participants were observed in Group B (49.15%) compared to Group A (38.98%), whereas urban participants were relatively evenly distributed

(38.98% in Group A vs. 35.59% in Group B). Participants from slum areas were fewer, representing 22.03% in Group A and 15.25% in Group B. Regarding socioeconomic status, the majority of participants belonged to the middle-income group (55.93% in Group A, 50.85% in Group B), followed by the low-income group (32.20% vs. 38.98%), while a smaller proportion belonged to the high-income group (11.86% in Group A, 10.17% in Group B) [Table 1].

The majority of participants were multigravida, with 57.63% in Group A and 62.71% in Group B, while primigravida participants accounted for 42.37% in Group A and 37.29% in Group B. A small proportion of participants had a previous history of abortion, with 10.17% in Group A and 8.47% in Group B, whereas the majority had no prior abortion history (89.83% vs. 91.53%). Regarding gestational age at diagnosis, participants were distributed across three categories: 27.12% in Group A and 28.81% in Group B had a gestational age of <10 weeks, while 44.07% in Group A and 40.68% in Group B had a gestational age >10 weeks. The proportion of participants with 11–12 weeks gestational age was 28.81% in Group A and 30.51% in Group B [Table 2].

The incidence of side effects varied between Group A (oral misoprostol) and Group B (vaginal misoprostol), with notable differences in gastrointestinal symptoms. Nausea was the most commonly reported side effect, occurring in 35.59% of participants in Group A, compared to 23.73% in Group B, indicating a higher prevalence among those receiving oral misoprostol. Similarly, vomiting was more frequent in Group A (11.86%) than in Group B (5.08%), suggesting a greater likelihood of gastrointestinal distress with oral administration. In contrast, the incidence of severe pain was slightly lower in Group B (8.47%) compared to Group A (11.86%). Diarrhea was reported in 8.47% of Group A and 10.17% of Group B, showing minimal variation between the groups. Hyperpyrexia (fever) occurred in an equal proportion of participants in both groups (5.08%), indicating no significant difference between

the two administration routes in terms of fever occurrence [Table 3].

The success of misoprostol in inducing complete expulsion of the conceptus was significantly higher in Group B (vaginal misoprostol) compared to Group A (oral misoprostol), with a $P < 0.001$, indicating strong statistical significance. The rate of complete expulsion was 76.27% in Group B, which was substantially higher than the 37.29% observed in Group A. Conversely, incomplete expulsion was more common in Group A (49.15%) compared to Group B (20.34%), suggesting that oral misoprostol had a higher likelihood of requiring additional intervention for complete evacuation. In addition, the proportion of participants who experienced no expulsion was also greater in Group A (13.56%) compared to Group B (3.39%), reinforcing the higher efficacy of vaginal misoprostol in achieving successful expulsion [Table 4].

The number of misoprostol doses required for successful complete expulsion differed significantly between Group A (oral misoprostol) and Group B (vaginal misoprostol), with a $P = 0.0201$, indicating a statistically significant variation in dose efficiency. A greater proportion of participants in Group B (31.11%) achieved complete expulsion after just one dose, compared to only 13.64% in Group A. The majority of Group B participants (68.89%) required two doses, whereas in Group A, only 31.82% achieved complete expulsion with two doses. Notably, no participants in Group B required three doses, while more than half (54.55%) of Group A participants needed three doses, further demonstrating the superior efficacy of vaginal misoprostol in reducing the need for additional doses. The mean number of doses required was significantly lower in Group B (1.69 ± 0.94) compared to Group A (2.41 ± 1.5), with a $P < 0.001$, confirming that vaginal misoprostol is more effective in achieving expulsion with fewer doses [Table 5].

The time required from the start of the procedure to successful expulsion was significantly shorter in Group B (vaginal misoprostol) compared to Group A (oral misoprostol), with a $P = 0.032$,

indicating a statistically significant difference. None of the participants in Group A achieved expulsion within the first 4 h, whereas 13.33% of participants in Group B successfully expelled the conceptus within this time frame. Expulsion within 4–8 h was also more frequent in Group B (31.11%) compared to Group A (13.64%), further supporting the faster onset of action with vaginal administration. In contrast, the majority of participants in Group A (86.36%) required 8–12 h for expulsion, compared to 55.56% in Group B, demonstrating a longer induction-expulsion interval in the oral misoprostol group. The mean time required for complete expulsion was significantly lower in Group B (7.69 ± 2.89 h) compared to Group A (9.45 ± 1.40 h), with a $P = 0.032$, confirming that vaginal misoprostol leads to faster expulsion compared to oral misoprostol [Table 6].

Among the participants who did not achieve complete expulsion, the permeability of the cervix was comparable between Group A (oral misoprostol) and Group B (vaginal misoprostol), with no statistically significant difference ($P = 0.6985$). Cervical permeability was observed in 86.49% of unsuccessful cases in Group A and 85.71% in Group B, indicating that both routes of misoprostol administration had a similar effect on cervical softening. Conversely, non-permeability of the cervix was reported in 13.51% of Group A participants and 14.29% of Group B participants, further reinforcing the absence of significant variation between the two groups [Table 7].

Discussion

The present study compared the efficacy and safety of oral versus vaginal misoprostol for the medical management of first-trimester missed abortion in a tertiary hospital in Bangladesh. The findings highlight the higher efficacy of vaginal misoprostol in achieving complete expulsion with fewer doses and a shorter induction-expulsion interval, while also showing comparable safety profiles between the two routes. These results align with the majority of prior research while also highlighting some inconsistencies reported in the literature.

The findings of this study indicate that vaginal misoprostol achieved significantly higher rates of complete expulsion (76.27%) compared to oral misoprostol (37.29%) ($P < 0.001$). This is consistent with previous meta-analyses that have shown higher success rates with vaginal administration.^[8] In addition, Kapp *et al.* demonstrated that oral misoprostol has a higher likelihood of retained products, necessitating additional intervention.^[10] Wu *et al.* further corroborated that oral misoprostol is associated with lower rates of complete expulsion, particularly in gestations exceeding 10 weeks.^[2] However, not all studies unequivocally support the superiority of vaginal misoprostol. A study by Faúndes *et al.* reported that sublingual administration of misoprostol achieved expulsion rates comparable to vaginal administration, while oral administration, although less effective, still resulted in satisfactory outcomes.^[11] The findings suggest that route selection should consider both patient preference and clinical setting availability. Furthermore, Shimels *et al.* found that the combination of mifepristone with misoprostol improved expulsion rates regardless of administration route, raising the question of whether mifepristone pre-treatment could further enhance the efficacy of oral misoprostol.^[12] The current study found that fewer doses were required with vaginal misoprostol (mean: 1.69 ± 0.94) compared to oral administration (2.41 ± 1.5) ($P < 0.001$). In addition, no participants in the vaginal group required three doses, while 54.55% in the oral group did ($P = 0.0201$). These findings are strongly supported by prior systematic reviews, which have shown higher efficacy with fewer doses in vaginal administration.^[4,7] Contrastingly, some literature suggests that dose optimization may be more critical than the route of administration itself. Beucher *et al.* reported that higher doses of oral misoprostol (800 μg) could achieve similar success rates as vaginal misoprostol if repeated appropriately.^[13] In addition, Raymond *et al.* emphasized that dose-dependent variations in oral misoprostol efficacy exist, with higher doses ($\geq 800 \mu\text{g}$) showing improved results.^[9] A key advantage of vaginal misoprostol was its shorter expulsion time (7.69 ± 2.89 h vs. 9.45 ± 1.40 h,

$P = 0.032$). A significantly greater proportion of vaginal misoprostol users (13.33%) had expulsion within 4 h, compared to none in the oral group ($P = 0.0089$). These findings align with prior meta-analyses indicating that vaginal misoprostol reduces the induction-expulsion interval by nearly 5 h compared to oral administration.^[8,10] However, contrasting studies indicate that sublingual misoprostol may offer an even faster onset of action compared to vaginal administration.^[2] Faúndes *et al.* found that sublingual misoprostol resulted in comparable or faster expulsion times than vaginal misoprostol, albeit with a higher incidence of side effects.^[11] This highlights the potential clinical trade-offs between onset speed and tolerability, which should be considered in future practice. The side effect profile was largely comparable between both groups, with nausea and vomiting occurring more frequently in the oral group (35.59% and 11.86%) than in the vaginal group (23.73% and 5.08%). This supports findings from prior research indicating higher gastrointestinal side effects with oral misoprostol due to its systemic absorption.^[2,9] In addition, studies have suggested that oral misoprostol results in increased patient discomfort due to gastrointestinal stimulation, which may impact adherence to treatment.^[12] However, some literature contradicts the assumption that vaginal misoprostol is always better tolerated. Kelesidou *et al.* noted that some patients experience greater discomfort with vaginal administration, particularly in terms of localized irritation and cramping.^[14] In addition, Beucher *et al.* found that vaginal misoprostol was associated with a slightly higher rate of vaginal discharge compared to oral administration, though this difference was not statistically significant.^[13] Among cases where expulsion was unsuccessful, cervical permeability was similar between the two groups ($P = 0.6985$). This aligns with studies by Beucher *et al.* and Nahar *et al.*, which found that misoprostol, regardless of administration route, leads to comparable cervical softening and dilation.^[4,13] The results of this study reinforce the clinical preference for vaginal misoprostol over oral administration for the management of first-trimester missed abortion. However, some studies

Table 1: Distribution of baseline characteristics among the participants (n=118)

Baseline characteristics	Group A (n=59)		Group B (n=59)	
	n	%	n	%
Age				
<20 years	15	25.42	12	20.34
20–25 years	20	33.90	25	42.37
25–30 years	19	32.20	17	28.81
>30 years	5	8.47	5	8.47
Mean±SD	24.6±3.05		23.98±2.387	
Residence				
Urban	23	38.98	21	35.59
Rural	23	38.98	29	49.15
Slums	13	22.03	9	15.25
Socioeconomic status				
High	7	11.86	6	10.17
Middle	33	55.93	30	50.85
Low	19	32.20	23	38.98

Table 2: Distribution of participants by obstetric characteristics (n=118)

Obstetrics characteristics	Group A (n=59)		Group B (n=59)	
	n	%	n	%
Gravidity				
Primi	25	42.37	22	37.29
Multi	34	57.63	37	62.71
History of abortion				
Yes	6	10.17	5	8.47
No	53	89.83	54	91.53
Gestational age				
<10 weeks	16	27.12	17	28.81
>10 weeks	26	44.07	24	40.68
11–12 weeks	17	28.81	18	30.51

suggest that sublingual administration may offer an effective alternative with faster onset but at the cost of increased side effects.^[2,11] In addition, the use of mifepristone pre-treatment has been consistently shown to improve expulsion rates, regardless of the misoprostol route, highlighting a potential area for further research.^[12] While vaginal misoprostol

Table 3: Distribution of the respondents by their side effects (n=118)

Side effects	Group A (n=59)		Group B (n=59)	
	n	%	n	%
Nausea	21	35.59	14	23.73
Vomiting	7	11.86	3	5.08
Severe pain	7	11.86	5	8.47
Diarrhea	5	8.47	6	10.17
Hyperpyrexia	3	5.08	3	5.08

Table 4: Distribution of participants by expulsion of conceptus (n=118)

Expulsion of conceptus	Group A (n=59)		Group B (n=59)		P-value
	n	%	n	%	
Complete	22	37.29	45	76.27	<0.001
Incomplete	29	49.15	12	20.34	
No	8	13.56	2	3.39	

Table 5: Distribution of the respondents according to required doses for successful complete expulsion (n=67)

Doses	Group A (n=22)		Group B (n=45)		P-value
	n	%	n	%	
1	3	13.64	14	31.11	0.0201
2	7	31.82	31	68.89	
3	12	54.55	0	0.00	
Mean±SD	2.41±1.5		1.69±0.94		<0.001

Table 6: Distribution of the respondents by the time required from the starting of procedure for successful expulsion (n=67)

Time required	Group A (n=22)		Group B (n=45)		P-value
	n	%	n	%	
<4 h	0	0.00	6	13.33	0.0089
4–8 h	3	13.64	14	31.11	
8–12 h	19	86.36%	25	55.56	
Mean±SD	9.45±1.40		7.69±2.89		0.032

demonstrated superior efficacy in the current study, it is crucial to consider patient preferences,

Table 7: Distribution of the respondents by their permeability of cervix in unsuccessful cases ($n=51$)

Variable	Group A ($n=37$)		Group B ($n=14$)		P-value
	n	%	n	%	
Permeability	32	86.49	12	85.71	0.6985
Non-permeability	5	13.51	2	14.29	

accessibility, and acceptability in clinical practice. In Bangladesh, where sociocultural factors and healthcare accessibility play a significant role, the feasibility of self-administered regimens should be explored further. In addition, given the non-significant differences in cervical permeability, alternative adjunctive therapies for cervical ripening should be considered for cases requiring surgical intervention. This study confirms that vaginal misoprostol is superior to oral misoprostol for achieving complete expulsion with fewer doses and shorter time-to-expulsion, with comparable safety profiles. However, variations in effectiveness, tolerability, and dosing regimens highlight the need for individualized patient-centered approaches. Future studies should explore sublingual administration, combination therapies with mifepristone, and patient-reported outcomes to further optimize treatment strategies for first-trimester missed abortion.

Limitations of the study

The study was conducted in a single hospital with a small sample size. Hence, the results may not represent the whole community.

Conclusion

This study compared the efficacy and safety of oral versus vaginal misoprostol for the management of first-trimester missed abortion in a tertiary-level hospital in Bangladesh. The findings confirm that vaginal misoprostol is significantly more effective, achieving higher complete expulsion rates (76.27% vs. 37.29%, $P < 0.001$), requiring fewer doses (mean: 1.69 vs. 2.41, $P < 0.001$), and ensuring a shorter induction-expulsion interval

(7.69 ± 2.89 vs. 9.45 ± 1.40 h, $P = 0.032$) compared to oral misoprostol. Although nausea and vomiting were more common in the oral group, overall side effect profiles were comparable, and both methods demonstrated similar cervical permeability in cases requiring further intervention. These findings align with existing literature while also reinforcing the need for context-specific research in South Asian populations, where accessibility, patient preferences, and healthcare infrastructure play crucial roles in treatment selection. Given the significant advantages of vaginal misoprostol, it should be considered the preferred route in clinical practice, particularly in settings where surgical intervention may not be readily available. However, further studies are warranted to explore alternative administration routes, adjunctive treatments such as mifepristone, and patient-centered outcomes to optimize medical management strategies for missed abortion.

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Conflicts of Interest

None declared.

Ethical Approval

The study was approved by the Institutional Ethics Committee.

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