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Effectiveness of Vaginal Misoprostol Compared to Oral Misoprostol in the Medical Management of Missed Abortion During First Trimester of Pregnancy

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Abstract

Background: Missed abortion is a common complication (1-5% of pregnancies) involving the retention of a non-viable embryo or fetus within utero. Diagnosis relies on ultrasound, revealing halted development and absent fetal heartbeat. If untreated it poses emotional distress and infection risk. Treatment options are surgical evacuation or medical management with abortifacients. Vaginal misoprostol is preferred for higher efficacy and quicker results, while oral misoprostol is more convenient but slightly less effective with longer treatment times. Both the rotes offer non-invasive alternatives to surgery, in management option of missed abortion. ***Objective:*** To compare the effectiveness of vaginal misoprostol over oral misoprostol in the medical management of missed abortion during the first trimester of pregnancy. ***Methods:*** The randomized controlled trial (RCT) was carried in the Department of Obstetrics and Gynecology, Institute of Child and Mother Health (ICMH), Matuail, Dhaka. The sampling method was random selection according to the availability of the patients. Data were collected from women aged 18-35 years. Patients diagnosed with missed abortion through ultrasonography (USG) and received medical management with vaginal misoprostol were considered as group I (n=36), while those received oral misoprostol comprised as group II (n=36). The outcome of termination of pregnancy in between group I and II were measured. The descriptive and inferential analysis was carried out using SPSSv26. p-value < 0.05 was considered as statistically significant. ***Results:*** This study found that vaginal misoprostol was significantly more effective than oral misoprostol, with a success rate of 80.6% compared to 55.6% (p=0.042). Vaginal misoprostol also required fewer doses and shorter induction-expulsion times (p=0.028, p=0.004). Surgical intervention was needed less frequently in the vaginal group (19.4% vs. 44.4%, p=0.042). Adverse effects differed, with more nausea/vomiting and fever in the oral group and more severe cramps and diarrhea in the vaginal group. Hemoglobin levels decreased similarly in both groups. The duration of bleeding favored vaginal misoprostol, but patient satisfaction significantly favored it as well (75.0% vs. 44.5%, p=0.029). ***Conclusion****:* Vaginal misoprostol is more effective than oral misoprostol in the medical management of missed abortion during the first trimester of pregnancy.

Keywords: Missed Abortion, Vaginal Misoprostol, Oral Misoprostol, Effectiveness.

INTRODUCTION

Early pregnancy loss or first trimester missed abortion is defined as a nonviable, intrauterine pregnancy with either an empty gestational sac or a gestational sac containing an embryo or fetus without fetal heart activity within the first 12 weeks of gestation.[1] Early pregnancy loss is frequent, with 10% of all clinically recognized pregnancies experiencing it. Approximately 80% of all incidences of miscarriage occur during the first trimester.[2] The management of early pregnancy loss encompasses various approaches, including expectant, medical and surgical methods, all demonstrating high rates of successful product of

conception evacuation with rare serious complications. Surgical evacuation, as a primary choice, offers faster and more predictable complete evacuation, with a success rate approaching 99%.[3] However, medical management remains a reasonable option for different types of pregnancy failure. Serious complications, such as clinically significant intrauterine adhesion formation, hemorrhage and infection, are infrequent and comparable across treatment modalities. Hemorrhage-related hospitalization rates are similar, while infection rates are generally low. Antibiotic prophylaxis, particularly a single preoperative dose of doxycycline, is recommended for surgical management to prevent postoperative infection. Patient preference should guide the choice of intervention, given the absence of clear superiority between expectant, medical or surgical approaches.[4] In the management of early pregnancy loss, medical approaches offer a viable option for women without specific complications like infection, severe anemia, or bleeding disorders who prefer to avoid surgical intervention. These medical methods, typically involving misoprostol-based regimens, have shown efficacy in reducing the time to expulsion and increasing the rate of complete tissue expulsion compared to expectant management.[5] The efficacy and safety of misoprostol alone for missed abortion have been established in numerous studies. However, the route of administration of misoprostol and success rates have varied among these studies. Misoprostol can be administered orally, sublingually or vaginally and it functions by stimulating uterine smooth muscle contraction and promoting cervical ripening. The most suitable route and optimal dose of misoprostol for the management of missed abortion have not been definitively determined. [6-9] Vaginal misoprostol peaks in plasma after 70–80 minutes and lasts 6 hours. Direct access to uterine muscles through the cervix and medication transfer from vaginal veins to arterioles may causes quicker onset of action.[10] Oral administration of misoprostol in solution is generally preferred by women due to the reduced need for vaginal examinations. Misoprostol has a 20–40-minute half-life when taken orally. The drug's plasma concentration peaks 30 minutes after administration and steadily falls, clearing the system within 120 minutes. A literature study found that oral and vaginal administration are equally effective. [11,12] Vaginal misoprostol is favored over oral administration in the management of missed abortion due to several advantages. It is associated with higher effectiveness in inducing uterine contractions and cervical ripening, leading to a faster onset of action typically within 70-80 minutes. Vaginal administration minimizes the risk of gastrointestinal side effects and may offer better outcomes.[13] Moreover, the direct access to uterine muscles through the cervix and rapid clearance from the bloodstream make vaginal misoprostol a practical and well-tolerated option for many women undergoing this procedure. [11,12] The oral route of misoprostol has drawbacks including reduced bioavailability and a greater likelihood of gastrointestinal side effects. While there are numerous researches comparing oral and vaginal misoprostol for missed abortion, the available studies have produced conflicting results making it a topic of ongoing debate.

MATERIALS AND METHODS

This randomized controlled trial (RCT) was conducted in the Department of Obstetrics and Gynecology at the Institute of Child and Mother Health (ICMH), Matuail, Dhaka, Bangladesh, over a 12-month period from July 2022 to June 2023. The study included women with ultrasonographically confirmed first-trimester missed abortion who attended the inpatient and outpatient departments of the hospital. Ethical approval was obtained from the Institutional Review Board of ICMH before commencement of the study and written informed consent was obtained from all participants prior to enrollment. A total of 72 eligible women aged 18–35 years with singleton pregnancies of less than 12 weeks' gestation were recruited through simple random sampling. Sample size was calculated using the formula described by Zhong, resulting in 36 participants in each treatment arm with 95% confidence level and 90% study power. Participants were randomly allocated into two equal groups by lottery method using colored cards. The intervention group (Group I, n = 36) received 400 µg of vaginal misoprostol inserted into the posterior fornix after moistening with normal saline, whereas the control group (Group II, n = 36) received 400 µg of oral misoprostol with water. Up to three doses were administered at six-hour intervals according to the study protocol.

Women with inevitable abortion, gestational age greater than 12 weeks, multiple gestation, previous cervical dilatation, severe anemia (hemoglobin <8 g/dL), bleeding disorders, bronchial asthma, or hemodynamic instability were excluded from the study. Baseline demographic and obstetric characteristics, including age, educational status, occupation, body mass index, gravidity, gestational age, blood pressure and previous abortion history, were recorded using a pretested semi-structured questionnaire. Participants were monitored clinically for uterine contractions, vaginal bleeding, expulsion of products of conception, adverse effects and vital signs. The primary outcome was complete uterine evacuation confirmed by ultrasonography on the 14th day, defined as endometrial thickness ≤15 mm without retained echogenic products. Secondary outcomes included induction-to-expulsion interval, number of misoprostol doses required, need for surgical evacuation, blood loss, change in hemoglobin concentration, duration of post-abortal bleeding, adverse effects and patient satisfaction. Venous blood samples (5 mL) were collected at follow-up for hemoglobin estimation. Data were entered and analyzed using IBM SPSS Statistics version 26.0. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Between-group comparisons were performed using the

unpaired Student's t-test for continuous variables and Chi-square or Fisher's exact test for categorical variables, as appropriate. A p-value of less than 0.05 was considered statistically significant. The confidentiality of all participants was maintained throughout the study by assigning unique identification numbers and restricting access to study data.

RESULTS

A total of 72 pregnant women aged 18–35 years with a first-trimester diagnosis of missed abortion were enrolled in this study. Participants were equally allocated into two treatment groups: Group I (vaginal administration of misoprostol, n = 36) and Group II (oral administration of misoprostol, n = 36). Baseline socio-demographic, obstetrical, and clinical characteristics were compared between the two groups to ensure comparability before treatment.

Table 1: Comparison of the participants according to socio-demographic characteristics

Socio-demographic variables	Group I (n = 36)	Group II (n = 36)	*p* value
Age (years)			
<20 years	6 (16.7%)	8 (22.2%)	0.855[a]
21–30 years	22 (61.1%)	20 (55.6%)	
>30 years	8 (22.2%)	8 (22.2%)	
Mean ± SD	25.94 ± 5.03	25.69 ± 4.77	0.829[c]
Educational qualification			
Primary	5 (13.9%)	7 (19.4%)	0.256[a]
SSC	25 (69.4%)	18 (50.0%)	
HSC and above	6 (16.7%)	11 (30.6%)	
Occupation			
Housewife	28 (77.8%)	31 (86.1%)	0.523[b]
Student	4 (11.1%)	1 (2.8%)	
Service holder	4 (11.1%)	4 (11.1%)	
Monthly family income			
<15,000 BDT	8 (22.2%)	3 (8.3%)	0.280[a]
15,000–25,000 BDT	20 (55.6%)	24 (66.7%)	
>25,000 BDT	8 (22.2%)	9 (25.0%)	

[a]Chi-square test; [b]Fisher's exact test; [c]Unpaired t-test.

Table 1 demonstrates that the socio-demographic characteristics of the participants were comparable between the vaginal and oral misoprostol groups. The majority of women in both groups were aged 21–30 years (61.1% in Group I vs. 55.6% in Group II), with a mean age of 25.94 ± 5.03 years and 25.69 ± 4.77 years, respectively (p=0.829). Most participants had completed secondary school (SSC) education, accounting for 69.4% of Group I and 50.0% of Group II, while relatively fewer women had primary education or higher secondary education and above. Housewife was the predominant occupation in both groups (77.8% vs. 86.1%) and more than half of the participants reported a monthly family income between 15,000 and 25,000 Bangladeshi Taka. No statistically significant differences were observed between the two groups regarding age, educational status, occupation or monthly family income (p>0.05), indicating that both treatment groups were socio-demographically comparable at baseline.

Table 2: Comparison of the participants according to obstetrical characteristics

Obstetrical characteristics	Group I (n = 36)	Group II (n = 36)	*p* value
Gestational age (weeks)	**8.86 ± 1.22**	**9.03 ± 1.36**	0.587[c]
Gravida			
Primigravida	6 (16.7%)	9 (25.0%)	0.471[b]
Multigravida	30 (83.3%)	27 (75.0%)	
History of abortion			
No	25 (69.4%)	26 (72.2%)	1.000[a]
Yes	11 (30.6%)	10 (27.8%)	

[a]Chi-square test; [b]Fisher's exact test; [c]Unpaired t-test.

Table 2 presents the obstetrical characteristics of the study participants. The mean gestational age at diagnosis of missed abortion was 8.86 ± 1.22 weeks in the vaginal misoprostol group and 9.03 ± 1.36 weeks in the oral misoprostol group with no statistically significant difference (p=0.587). Most participants in both groups were multigravida, representing 83.3% in Group I and 75.0% in Group II, whereas primigravida women accounted for 16.7% and 25.0%, respectively. Approximately one-third of participants had a previous history of abortion (30.6% in Group I and 27.8% in

Group II), while the majority had no such history. None of the obstetrical variables differed significantly between the two treatment groups (p>0.05), confirming that the groups were well matched before intervention.

Table 3: Comparison of the participants according to BMI and Blood pressure

Body mass index and Blood Pressure	Group I (n = 36)	Group II (n = 36)	p value
BMI (Mean ± SD)	23.51 ± 3.03	23.71 ± 3.16	0.779 [c]
SBP (Mean ± SD)	106.94 ± 10.64	103.61 ± 9.60	0.167 [c]
DBP (Mean ± SD)	77.22 ± 7.41	78.33 ± 3.78	0.426 [c]

[c] unpaired t test was done to measure the level of significance

Table 3 compares baseline clinical characteristics between the two study groups. The mean body mass index (BMI) was 23.51 ± 3.03 kg/m² in the vaginal misoprostol group and 23.71 ± 3.16 kg/m² in the oral misoprostol group (p=0.779). Similarly, the mean systolic blood pressure was 106.94 ± 10.64 mmHg in Group I and 103.61 ± 9.60 mmHg in Group II (p=0.167), while the mean diastolic blood pressure was 77.22 ± 7.41 mmHg and 78.33 ± 3.78 mmHg, respectively (p=0.426). No statistically significant differences were observed in BMI or blood pressure measurements between the two groups demonstrating that baseline physiological characteristics were comparable before treatment initiation.

Table 4: Comparison of the participants according to the effectiveness of vaginal and oral misoprostol

Effectiveness	Group I (n = 36)	Group II (n = 36)	p value
Success			
Successful	29 (80.6)	20 (55.6)	0.042 [a]
Failure	7 (19.4)	16 (44.4)	
Number of Doses			
First	3 (8.3)	0 (0.0)	0.028 [b]
Second	25 (69.4)	17 (47.2)	
Third	8 (22.2)	19 (52.8)	
Induction-Expulsion Time			
< 6 hours	3 (8.3)	0 (0.0)	<0.001 [b]
6-18 hours	26 (72.2)	4 (11.1)	
> 18 hours	7 (19.4)	32 (88.9)	
Mean ± SD	14.69 ± 5.54	22.69 ± 2.79	<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

There was significant variation in effectiveness between vaginal and oral misoprostol groups in this study. The success rate was higher in the vaginal group (80.6%) compared to the oral group (55.6%) (p=0.042). The oral group (52.8%) required three doses in a higher percentage compared to the vaginal group (22.2%), which was statistically significant (p=0.028). The induction-expulsion time was significantly shorter for the vaginal group (14.69 ± 5.54) compared to the oral group (22.69 ± 2.79) (<0.001).

Table 5: Comparison of the participants according to the need of surgical intervention of vaginal and oral misoprostol

Surgical intervention	Group I (n = 36)	Group II (n = 36)	p value
Surgical intervention			
Not needed	29 (80.6)	20 (55.6)	0.042 [a]
Needed	7 (19.4)	16 (44.4)	

[a] Chi square test was done to measure the level of significance

In this study, the need for further surgical intervention was significantly higher in the oral route group (44.4%) compared to the vaginal route group (19.4%) of misoprostol (p = 0.042).

Table 6: Comparison of the participants according to the side effects of vaginal and oral misoprostol

Adverse effects	Group I (n = 36)	Group II (n = 36)	p value
Nausea/vomiting	8 (22.7)	13 (36.1)	0.300 [a]
Fever	8 (22.7)	13 (36.1)	0.300 [a]
Severe lower abdominal cramp	10 (27.8)	8 (22.2)	0.786 [a]
Diarrhoea	5 (13.9)	3 (8.3)	0.710 [a]
Drop of Hb ≥ 1g/dl	10 (27.8)	13 (36.1)	0.614 [a]

[a] Chi square test was done to measure the level of significance

Participants in the oral misoprostol group had greater rates of nausea/vomiting (36.1%), fever (36.1%) and hemoglobin decrease (≥ 1g/dl 36.1%). The vaginal misoprostol group had more severe lower abdominal cramp (27.8%) and diarrhoea (13.9%).

Mean haemoglobin concentration of pre- and post-induction of vaginal and oral misoprostol group.

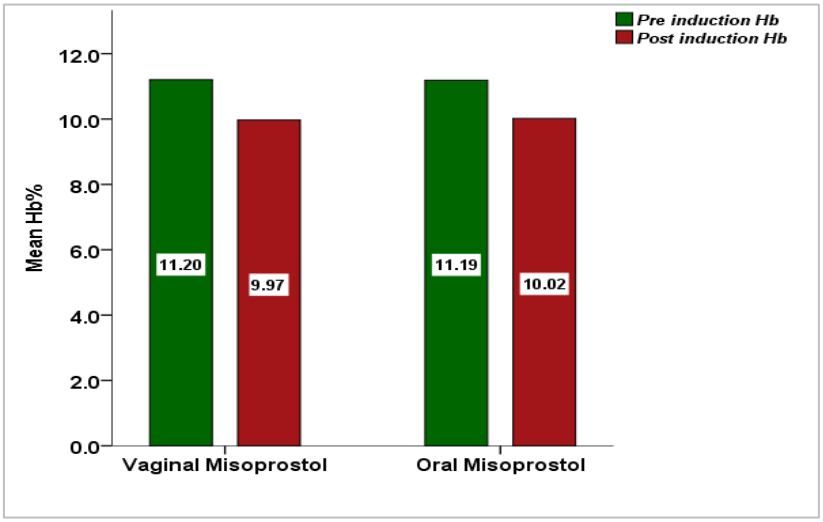

Figure I: Bar diagram showing the mean Hb level of different group before and after administration of vaginal and oral misoprostol.

The graph shows that both the vaginal (from 11.20 to 9.97) and oral (from 11.19 to 10.02) misoprostol groups had a drop in Hb values due to bleeding after misoprostol administration.

Table 7: Comparison of the participants according to Hb% changes by group

Hb%	Group I (n = 36)	Group II (n = 36)	p value
Hb% before administration	11.20 ± 1.52	11.18 ± 1.61	0.964 [c]
Hb% after administration	9.96 ± 2.08	10.01 ± 1.43	0.906 [c]
Hb% reduction (post-administration)	1.23 ± 1.83	1.16 ± 1.24	0.857 [c]

[c] Unpaired t-test was done to measure the level of significance

The comparison of pre-administered and post-administered hemoglobin percentages for vaginal and oral misoprostol is presented in the table. Both treatments showed similar effects on hemoglobin changes as indicated by non-significant p-values (>0.05) for all measurements.

Table 8: Comparison of the participants according to the blood loss following vaginal and oral misoprostol

Bleeding	Group I (n = 36)	Group II (n = 36)	p-value
Amount of bleeding in ml (within 24 hours)			
Mean ± SD	96.60 ± 10.2	76.80 ± 8.20	<0.001[c]
Duration of bleeding (Follow up at day 14)			
Brief (<5 days)	4 (11.1)	5 (13.9)	0.324 [b]
Average (5-10 days)	26 (72.2)	20 (55.6)	
Prolonged (>10 days)	6 (16.7)	11 (30.6)	

[c] Unpaired t-test and [b] Fisher's exact test was done to measure the level of significance

The amount of bleeding in first 24 hours was significantly higher in group I (96.60 ± 10.2) compared to group II (76.80 ± 8.20) (p<0.001). Prolonged bleeding was higher among group II (30.6%) compared to group I (16.7%) whereas average bleeding was higher in group I (72.2%) compared to group II (55.6%) which was not statistically significant (p=0.324) on day 14th follow up.

Table 9: Comparison of the participants according to the satisfaction of vaginal and oral misoprostol

Satisfaction	Group I (n = 36)	Group II (n = 36)	p-value
Satisfied	27 (75.0)	16 (44.5)	0.029 [a]
Neutral	5 (13.9)	12 (33.3)	
Unsatisfied	4 (11.1)	8 (22.2)	

[a] Chi square test was done to measure the level of significance

Table 9 illustrates the distribution of study participants' satisfaction levels regarding vaginal and oral misoprostol. Group I (75.0%) had a higher proportion of satisfied participants compared to Group II (44.5%) and the difference is statistically significant (p = 0.029).

DISCUSSION

The management of missed abortion during the first trimester of pregnancy is a critical aspect of women's healthcare. This clinical trial offers crucial insights into the comparative efficacy of vaginal and oral misoprostol for managing first-trimester missed abortions. The study, including 72 pregnant women attending the Institute of Child and Mother Health (ICMH) in Dhaka, revealed significant differences between the two administration routes. The study carefully controlled socio-demographic and obstetric parameters in both groups to reduce confounding results. No significant differences were seen in age, education, occupation, income, para, gravida, gestational age or abortion history. BMI and blood pressure were similar. In this study vaginal misoprostol exhibited a significantly higher success rate (80.6%) compared to oral misoprostol (55.6%), with a p-value of 0.042. The vaginal group also required fewer three-dose regimens (22.2% vs. 52.8% in the oral group, p=0.028). Reduced dosing in the vaginal group may contribute to its higher success rate. Ayres-de-Campos et al. [14] observed that vaginal misoprostol can completely evacuate 56.8% of patients; 14.9% require only one dose. They noticed that vaginal misoprostol induces full evacuation in missed abortions with low dosages. It treats such cases safely and effectively with most patients having successful outcomes and manageable side effects like this study.[14] Marwah et al. [6] found both vaginal and oral methods safe and effective with higher comfort levels in the vaginal group (92%) compared to the oral group (74%) (p=0.032). Vaginal ejection was faster at 10.87 hours, while oral expulsion took 13.24 hours. Treatment acceptance was high in both groups (76% in Group A and 70% in Group B), mirroring our study's results.[6] In this study vaginal misoprostol significantly shortened the induction-expulsion time (14.63 ± 5.54 hours vs. 22.69 ± 2.73 hours in the oral group, p=<0.001), suggesting potential advantages in expediting the abortion process. Rita and Kumar [10] observed that vaginal misoprostol had shorter induction-expulsion times and a greater success rate (80%) than oral (36%), indicating that it is more effective for this purpose.[10] In this study, a statistically significant difference was observed in the need for surgical intervention following treatment with oral and vaginal routes of misoprostol. The requirement for surgery was lower in the vaginal group (19.4%) compared to the oral group (44.4%). Souizi et al.,[9] compared three administration routes of misoprostol, vaginal use demonstrated a significantly higher success rate for complete abortion, making it a viable alternative to curettage, whereas oral and sublingual routes were less successful in achieving complete abortion.[9] In this study oral misoprostol was associated with higher rates of nausea/vomiting (36.1%), fever (36.1%) and haemoglobin drop by ≥1g/dl (36.1%). Vaginal misoprostol led to more severe lower abdominal cramps (27.8%) and diarrhoea (13.9%). Vaginal misoprostol is typically favored because to its less systemic adverse effects, as lower doses can be employed compared to oral delivery. This decreases the risk of gastrointestinal problems, such as diarrhoea and nausea, which are more typically associated with the oral route. Some studies found that vaginal misoprostol had less adverse effects than oral misoprostol for missed abortions, including abdominal pain, bleeding, headaches and dizziness/weakness. [15-17] In this study, the amount of bleeding in first 24 hours was significantly higher in group I (96.60 ± 10.2) compared to group II (76.80 ± 8.20) (p<0.001). Overall, the duration of bleeding was comparable, although oral misoprostol users reported longer bleeding episodes (more than 10 days). Notably, vaginal misoprostol achieved higher patient satisfaction (75.0%) compared to oral (44.5%) (p = 0.029), underscoring its clinical advantages. Marwah et al. found that both vaginal (92%) and oral (74%) misoprostol methods were effective, safe and well-tolerated with manageable side effects.[6] Vaginal administration led to faster expulsion (10.87 hours) than oral (13.24 hours). In cases of treatment failure, most had permeable cervixes before surgery. Both methods were well-received with a 76% acceptance rate for vaginal and 70% for oral administration.[6] This study suggests that vaginal misoprostol has higher efficacy rates, shorter

induction-expulsion times, less surgical intervention and improved patient satisfaction.

CONCLUSIONS

The findings of this study suggest that vaginal misoprostol has higher efficacy rates, shorter induction-expulsion times, less surgical intervention, less side effects and improved patient satisfaction.

Limitations Of the Study

This study had some limitations as well-

- The study was conducted in a single tertiary hospital; therefore, the results of the study may not fully reflect the exact status of the broader population.
- Study sample was limited and could not be increase due to financial constraints.
- Short follow-up duration missed the long-term outcomes.
- Achieving blinding in a study with apparent treatment routes was not done.

Therefore, the study findings cannot be generalized to the entire population.

Recommendations

In the light of the findings of the present study, it is recommended:

1) Promote vaginal misoprostol as the preferred choice in clinical practice guidelines for first-trimester missed abortion management.
2) Encourage further research, cost-effectiveness analysis and quality assurance for optimal care.

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