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ORIGINAL ARTICLE

Comparison of oral versus vaginal misoprostol for medical management of early fetal demise at Akhtar Saeed Trust Hospital, Lahore.

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ABSTRACT… Objective: To compare the efficacy, safety, and clinical outcomes of oral versus vaginal misoprostol for medical management of first-trimester missed abortion at Akhtar Saeed Trust Hospital, Lahore. **Study Design:** Randomized Controlled Trial. **Setting:** Akhtar Saeed Trust Hospital, Lahore. **Period:** 15 November 2024 to 15 February 2025. **Methods:** A total of 110 female patients aged 18–45 years with a confirmed diagnosis of first-trimester missed abortion (gestational age <14 weeks) were enrolled. Participants were randomly assigned into two groups: Group A received oral misoprostol (400µg every six hours, up to three doses), and Group B received vaginal misoprostol (400µg soaked in normal saline, every six hours, up to three doses). Primary outcomes included treatment efficacy (complete uterine evacuation within 24 hours) and the need for surgical evacuation. Secondary outcomes included the mean time to expulsion and adverse effects such as bleeding, pain, vomiting, fever, and diarrhea. Data were analyzed using SPSS version 25.0, with a chi-square test used to compare efficacy between groups. **Results:** The efficacy of vaginal misoprostol (93.1%) was significantly higher than oral misoprostol (75.0%) (p=0.009). The mean time to expulsion was shorter in the vaginal group (10.87±2.0 hours) compared to the oral group (13.24±2.0 hours). The need for surgical evacuation was significantly higher in the oral group (25.0%) than in the vaginal group (6.9%) (p=0.009). Adverse effects, including bleeding, abdominal pain, vomiting, fever, and diarrhea, were comparable between groups, with no statistically significant differences. **Conclusion:** Vaginal misoprostol is more effective, results in faster expulsion, and significantly reduces the need for surgical evacuation compared to oral misoprostol. Given its superior clinical outcomes, vaginal misoprostol should be considered the preferred method for the medical management of first-trimester missed abortion.

Key words: First-trimester Abortion, Misoprostol, Missed Abortion, Medical Management, Oral Misoprostol, Vaginal Misoprostol.

INTRODUCTION

Early fetal demise, often known as missed miscarriage or abortion, is treated with drugs to evacuate non-viable pregnancy tissue.[1] The gold standard for managing early fetal demise is surgical evacuation, which is both rapid and highly effective when conducted by an experienced provider in an appropriate environment.[2] Expectant management is associated with adverse effects/complications, including uncertainty in expulsion timing and reliance on surgical backup. Therefore, there is increasing interest in using medical methods to promote gentle, non-traumatic cervical dilation, separation of pregnancy products, and expulsion.[3]

By adopting a medical approach, significant resource savings can be realized, eliminating the need for routine curettage. Misoprostol, a PGE1 analog, is commonly used for pregnancy termination despite being considered an 'off-label' use. It is practical, affordable, and does not require injections, making it a preferred choice. While it is effective through both oral and vaginal routes, the majority of women choose the oral route to bypass the discomfort of vaginal examinations.[4]

Misoprostol is often used. Oral or vaginal misoprostol can treat early fetal death. Both methods induce pregnant tissue ejection.[5] A

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study reported that both routes demonstrated high efficacy (vaginal: 92%, oral: 74%, p = 0.032), safety, and patient acceptability, with side effects that were tolerable. The mean time to expulsion was longer in the oral group (13.24 hours) compared to the vaginal group (10.87 hours).[6] In another study, 14 women (17.7%) in the vaginal treatment group required surgical evacuation, while 5 women (6.7%) in the oral misoprostol group needed surgical intervention.[7]

The requirement for evacuation and curettage was less in the oral group (20 women, 40%) than in the vaginal group (30 women, 60%) (p = 0.046). In the vaginal group, the most common complications were excessive bleeding (5 women, 10%), vomiting (3 women, 6%), excessive abdominal pain (3 women, 6%), and diarrhea (1 woman, 2%). In the oral group, excessive abdominal pain was the most frequently reported side effect (4 women, 8%), followed by excessive bleeding (3 women, 6%), fever (2 women, 4%), and diarrhea (1 woman, 2%).[8] Oral misoprostol resulted in more frequent systemic side effects (shivering, diarrhea, vomiting, and pyrexia) at a rate of 44.5%, compared to 20% with vaginal misoprostol.[9] In a local study, oral misoprostol proved effective in 84% of patients, while 22 patients (16%) experienced ineffectiveness. In contrast, the vaginal group showed an effectiveness rate of 91%, with 12 patients (9%) being ineffective. No significant difference in efficacy was noted between the two routes.[10]

The rationale behind this study is based on the limited local data available on the efficacy of oral versus vaginal misoprostol administration. The route of administration may vary depending on the healthcare provider, the patient's needs, and clinical circumstances. Some studies indicate that the efficacy of both routes is comparable. It is vital to consult with a healthcare expert to discuss the route of administration, taking into account the patient's medical history, gestational age, and any contraindications. This study is designed to compare the efficacy of misoprostol administered via the vaginal and oral routes for managing first-trimester missed abortion. The approach that leads to better outcomes, fewer interventions, and reduced adverse effects will be recommended for routine use.

METHODS

This randomized controlled trial was conducted at Akhtar Saeed Trust Hospital, Lahore, over a period of three months (15 November '24 to 15 February '25) following approval from the Institutional Ethical Review Committee(IRB Approval No. M-24/214/-DPT). Inclusion Criteria: A total of 110 female patients, aged 18–45 years, with a confirmed diagnosis of first-trimester missed abortion (gestational age <14 weeks) on ultrasonography were enrolled. Participants were allocated into two groups using a lottery method: Group A received oral misoprostol, while Group B received vaginal misoprostol. The study utilized a non-probability consecutive sampling technique.

The exclusion criteria for this study include any degree of cervical dilatation, excessive uterine bleeding, hemoglobin concentration below 9 g/dL, and hemodynamic instability. Patients with blood pressure exceeding 160/90 mmHg, a history of inflammatory bowel disease, asthma, liver disease, or contraindications to misoprostol use will also be excluded. Additionally, those with a deranged coagulation profile, signs or symptoms of infection, or a history of anticoagulant use or bleeding disorders will not be eligible. Other exclusion factors include any prior medical or surgical intervention to terminate the current pregnancy and cases of molar pregnancy.

Eligible women were admitted to the hospital, and baseline investigations, including ultrasonographic confirmation of missed abortion, were performed. Women with Rh-negative blood type received prophylactic anti-D immunoglobulin (50µg intramuscularly). Patients in Group A were administered 400µg of oral misoprostol every six hours for a maximum of three doses. Patients in Group B received 400µg of misoprostol intravaginally (soaked in normal saline) every six hours for a maximum of three doses.

Throughout the study, all participants were closely monitored for vital signs, vaginal bleeding, and expulsion of products of conception (POCs). The

occurrence of drug-related adverse effects was also documented. Expulsion was assessed at each dosing interval, and in cases where POCs were expelled, gross examination was conducted. If incomplete expulsion was suspected, additional doses were administered until complete abortion was achieved or the maximum dosage was reached.

The primary outcome, treatment efficacy, was defined as complete evacuation of the uterus within 24 hours, confirmed via ultrasonography, with an endometrial thickness of <9mm. Surgical evacuation was performed in cases of heavy vaginal bleeding, severe pain, infection, or failure of medical management beyond 24 hours. Women were also given the option to request surgical evacuation at any stage if they preferred not to wait for spontaneous expulsion.

Following complete abortion or surgical evacuation, patients were observed for six hours before discharge. All women received prophylactic antibiotics and analgesics for five days. A follow-up visit was scheduled 14 days post-discharge, during which patients underwent a bimanual pelvic examination and ultrasonography to confirm complete evacuation. Any patient who initially achieved expulsion but later presented with excessive bleeding, retained POCs, infection, or severe pain was reassessed and underwent surgical evacuation if necessary.

Data collection and analysis were conducted using SPSS version 25.0. For quantitative variables, such as age, mean and standard deviation were computed, and for qualitative variables, like treatment efficacy, frequencies and percentages were reported. The chi-square test was applied to compare the efficacy of oral and vaginal misoprostol. Additionally, stratification was performed by age, parity, and BMI, and post-stratification chi-square tests were used to identify any potential confounders. A p-value of <0.05 was considered statistically significant.

RESULTS

In Table-I We divided age into two groups: 18–30 years and 31–45 years. A total of 49 participants (44.5%) fell within the younger age group, while the majority, 61 individuals (55.5%), were in the 31–45 years category with 31.54+7.67 years as mean age. Regarding parity, the majority of participants, 93 women (84.5%), had 1–3 previous pregnancies, while 17 women (15.5%) had a parity of more than 3. The mean parity was 1.85 ± 1.42 pregnancies, indicating that most women had experienced at least one pregnancy prior to the study. Participants' body mass index (BMI) was categorized into two groups: BMI between 18–30 kg/m^2 and BMI greater than 30 kg/m^2. The majority of women, 78 (70.9%), had a BMI in the 18–30 range, which includes those classified as normal weight and overweight. In contrast, 32 women (29.1%) had a BMI greater than 30, classifying them as obese. The mean BMI was 27.54 ± 4.61 kg/m^2, reflecting a population that included normal weight, overweight, and obese individuals. The mean gestational age at the time of intervention was 9.66 ± 2.30 weeks, suggesting that most cases occurred during the first trimester. This is significant for assessing the effectiveness of misoprostol, which is often used for early pregnancy loss management.

In Table-II The time to expulsion of POCs following misoprostol administration was also evaluated. The mean time to expulsion was 12.41 hours, with a standard deviation of 2.43 hours. This suggests that, on average, complete expulsion occurred within a relatively predictable timeframe following treatment initiation. The findings highlight that the duration required for complete expulsion remained within an acceptable clinical range, reinforcing the effectiveness of the treatment protocol used.

The study compared the clinical outcomes of two groups of participants: Group-A, who received oral misoprostol, and Group-B, who received vaginal misoprostol. The key aspects analyzed included treatment efficacy, the need for surgical evacuation, time to expulsion, and adverse effects such as bleeding, abdominal pain, vomiting, fever, and diarrhea.

The efficacy of misoprostol was significantly different between the two groups. In Group-A, 39

out of 52 participants (75.0%) achieved complete expulsion within 24 hours, while in Group-B, 54 out of 58 participants (93.1%) had successful outcomes. The difference was statistically significant (p=0.009), indicating that vaginal misoprostol was more effective in achieving complete expulsion of the products of conception compared to oral administration. Similarly, the need for surgical evacuation was higher in the oral misoprostol group, with 13 participants (25.0%) requiring surgical intervention compared to only 4 participants (6.9%) in the vaginal misoprostol group. This difference was also statistically significant (p=0.009), reinforcing that vaginal misoprostol is more effective in reducing the need for surgical evacuation.

The time required for complete expulsion of the products of conception was shorter in Group-B than in Group-A. The mean time to expulsion was 13.24 ± 2.0 hours in the oral misoprostol group, whereas in the vaginal misoprostol group, it was 10.87 ± 2.0 hours. This indicates that the vaginal route led to a faster expulsion process, reducing the waiting period for patients undergoing medical management.

Adverse effects of misoprostol, including bleeding, abdominal pain, vomiting, fever, and diarrhea, were also evaluated. Bleeding was reported in 5 participants (9.6%) in Group-A and 5 participants (8.6%) in Group-B, with no statistically significant difference between the two groups (p=0.856). Abdominal pain was observed in 4 participants (7.7%) in Group-A and 2 participants (3.4%) in Group-B, but this difference was not statistically significant (p=0.328). Vomiting occurred in 2 participants (3.8%) in Group-A and 6 participants (10.3%) in Group-B. Although the occurrence was slightly higher in the vaginal group, the difference was not statistically significant (p=0.190). Fever was recorded in 2 participants (3.8%) in Group-A, while no cases were observed in Group-B. The absence of fever in the vaginal group was not statistically significant (p=0.132). Diarrhea was reported in 3 participants (5.2%) in Group-B, whereas no cases were recorded in Group-A. Although diarrhea was only reported in the vaginal group, the difference was not statistically significant (p=0.096).

The comparative analysis of clinical data between two groups (Group-A and Group-B) across various effect modifiers reveals significant differences in certain variables, with varying implications for efficacy. Age (18-30 years): The analysis demonstrates a strong association between age and efficacy. In the 18-30 years age group, the efficacy of the treatment was significantly higher in Group-B, with 70% of patients experiencing a positive outcome, compared to just 30% in Group-A (p = 0.000). This suggests that the treatment is more effective in younger patients, particularly in Group-B. Age (31-45 years): In contrast, for patients aged 31-45 years, the treatment efficacy is similar across both groups, with 50.9% of Group-A and 49.1% of Group-B patients experiencing a positive outcome. The p-value of 0.960 indicates no significant difference between the two groups in this age category, implying that age does not play a major role in determining efficacy for this group.

Parity (1-3): Parity, or the number of previous pregnancies, also appears to be a factor influencing efficacy. Among those with 1-3 children, 41% of Group-A and 59% of Group-B patients experienced efficacy, with a p-value of 0.022. This suggests that higher efficacy was observed in Group-B for women with 1-3 pregnancies. On the other hand, for women with a parity greater than 3, there was no significant difference between groups (p = 0.156), with both groups showing similar efficacy outcomes (46.7% in Group-A and 53.3% in Group-B).

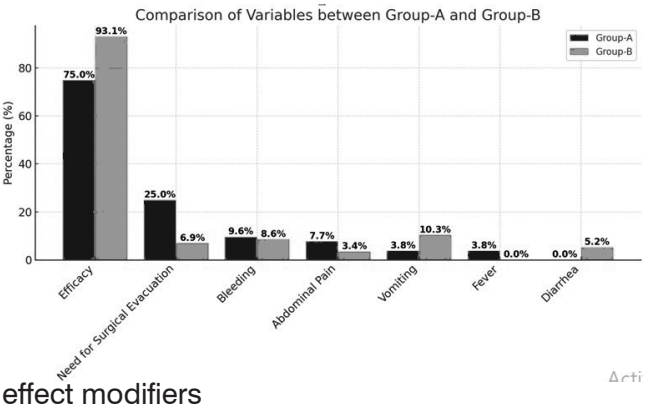
BMI (18-30): Body mass index (BMI) also influences the efficacy of treatment. In the BMI 18-30 category, Group-B showed a higher efficacy rate (58.1%) compared to Group-A (41.9%) with a p-value of 0.018, indicating statistical significance. This suggests that patients with a BMI between 18 and 30 may benefit more from the treatment in Group-B. However, for those with a BMI greater than 30, efficacy between the two groups was similar, with no significant difference (p = 0.249), indicating that BMI may not be as influential in the treatment outcomes for obese patients.

The findings indicate that vaginal misoprostol is more effective, results in faster expulsion, and significantly reduces the need for surgical evacuation compared to oral misoprostol. The adverse effects were similar in both groups, with no statistically significant differences in bleeding, abdominal pain, vomiting, fever, or diarrhea. Although vomiting and diarrhea were more commonly reported in the vaginal group, fever was observed only in the oral group. Overall, the results suggest that vaginal misoprostol provides better clinical outcomes and should be considered a preferred method for the medical management of early pregnancy loss.

Variable	Group	Frequency	Percent
Age	18-30	49	44.5
	31-45	61	55.5
Parity	1-3	93	84.5
	>3	17	15.5
BMI	18-30	78	70.9
	>30	32	29.1

Table-I. Demographic information of the participants

Comparative analysis of Clinical data of both groups according to variable according to various



effect modifiers

DISCUSSION

In our study, we compared the efficacy and safety of oral versus vaginal misoprostol for first-trimester missed abortion management. We observed that vaginal misoprostol was significantly more effective (93.1%) than oral misoprostol (75.0%) ($p = 0.009$), with a faster mean expulsion time (10.87 vs. 13.24 hours) and a lower need for surgical evacuation (6.9% vs. 25.0%, $p = 0.009$). Adverse effects were similar between both groups. Our results align with findings from multiple studies that highlight the superior efficacy of vaginal misoprostol.

Variable	Group	Group-A (Count %)	Group-B (Count %)	Total (Count %)	P-Value
Efficacy	Yes	39 (75.0%)	54 (93.1%)	93 (84.5%)	0.009
	No	13 (25.0%)	4 (6.9%)	17 (15.5%)	
Need for Surgical Evacuation	Yes	13 (25.0%)	4 (6.9%)	17 (15.5%)	0.009
	No	39 (75.0%)	54 (93.1%)	93 (84.5%)	
Bleeding	Yes	5 (9.6%)	5 (8.6%)	10 (9.1%)	0.856
	No	47 (90.4%)	53 (91.4%)	100 (90.9%)	
Abdominal Pain	Yes	4 (7.7%)	2 (3.4%)	6 (5.5%)	0.328
	No	48 (92.3%)	56 (96.6%)	104 (94.5%)	
Vomiting	Yes	2 (3.8%)	6 (10.3%)	8 (7.3%)	0.190
	No	50 (96.2%)	52 (89.7%)	102 (92.7%)	
Fever	Yes	2 (3.8%)	0 (0.0%)	2 (1.8%)	0.132
	No	50 (96.2%)	58 (100.0%)	108 (98.2%)	
Diarrhea	Yes	0 (0.0%)	3 (5.2%)	3 (2.7%)	0.096
	No	52 (100.0%)	55 (94.8%)	107 (97.3%)	

Table-II. Comparative analysis of Clinical data of both groups

Variable	Efficacy	Group-A (Count %)	Group-B (Count %)	Total (Count %)	Chi-Square p-value
Age (18-30)	Yes	12 (30.0%)	28 (70.0%)	40 (100.0%)	0.000
	No	9 (100.0%)	0 (0.0%)	9 (100.0%)	
Age (31-45)	Yes	27 (50.9%)	26 (49.1%)	53 (100.0%)	0.960
	No	4 (50.0%)	4 (50.0%)	8 (100.0%)	
Parity (1-3)	Yes	32 (41.0%)	46 (59.0%)	78 (100.0%)	0.022
	No	11 (73.3%)	4 (26.7%)	15 (100.0%)	
Parity (>3)	Yes	7 (46.7%)	8 (53.3%)	15 (100.0%)	0.156
	No	2 (100.0%)	0 (0.0%)	2 (100.0%)	
BMI (18-30)	Yes	26 (41.9%)	36 (58.1%)	62 (100.0%)	0.018
	No	12 (75.0%)	4 (25.0%)	16 (100.0%)	
BMI (>30)	Yes	13 (41.9%)	18 (58.1%)	31 (100.0%)	0.249
	No	1 (100.0%)	0 (0.0%)	1 (100.0%)	

Majeed et al. (2025) performed a meta-analysis of 10 randomized controlled trials (RCTs) involving 1,142 patients, which found that vaginal misoprostol resulted in a higher success rate (RR: 0.85, P = 0.004), a shorter induction-to-expulsion interval (MD: 4.95 hours, P = 0.0001), and greater patient satisfaction. These findings reinforce our study, demonstrating greater efficacy, a shorter expulsion time, and fewer surgical evacuations with vaginal misoprostol.

Similarly, C.R. & C.A. (2023)[12] reported comparable efficacy rates (91.7% vaginal vs. 75% oral, p = 2.400), reinforcing our conclusion that vaginal misoprostol is more effective. The Cochrane review by Lemmers et al (2019)[13] also supports our findings, showing that vaginal misoprostol is comparable to surgical evacuation in managing early pregnancy failure. This is reflected in our study, where vaginal misoprostol significantly reduced the need for surgical intervention.

While our results are consistent with many studies, some contradictory findings exist in the literature. Aman et al. (2022)[14] reported that vaginal misoprostol had higher efficacy (91%) than oral misoprostol (84%), but the difference was not statistically significant. This contrasts with our study, where the difference was statistically significant (p = 0.009). The lack of statistical significance in Aman et al.'s[14] study may be due to a larger sample size (n=274) diluting minor differences, variations in misoprostol dosages, or differences in inclusion criteria. Roy et al[15] (2024) found no significant difference in efficacy between oral (82.3%) and vaginal (80%) misoprostol, and surprisingly, a higher need for curettage in the vaginal group (42.8% vs. 34.3% in oral group). This contradicts our finding that surgical evacuation was more frequent in the oral group (25.0%) than in the vaginal group (6.9%). Possible explanations for these differences include differences in patient populations, dosing regimens, and definitions of treatment success. Roy et al.'s[15] study focused on medical termination of pregnancy (MTP), while ours specifically addressed missed abortion. Variations in gestational age and cervical readiness may influence success rates. The study by Roy et al[15] used 400µg every 4 hours up to five doses, whereas our protocol used 400µg every 6 hours for a maximum of three doses. Higher dosing frequency in the vaginal group may have led to increased uterine hyperstimulation, resulting in higher surgical intervention rates. Additionally, Roy et al. did not differentiate between complete expulsion confirmed by ultrasound and clinical observation, potentially affecting reported efficacy rates.

Our findings suggest that vaginal misoprostol should be the preferred route for first-trimester missed abortion due to its higher efficacy, faster expulsion time, and reduced need for surgical evacuation. However, individual patient

preferences and tolerability must also be considered. Some studies, such as Majeed et al[11] (2025), report higher nausea and vomiting rates in oral misoprostol users, which may be a deciding factor for certain patients.

Although our findings align with most literature, variations in results highlight the need for standardized protocols for misoprostol administration. Future studies should compare different dosing regimens to optimize efficacy and minimize side effects, evaluate patient preferences and acceptability in real-world clinical settings, and assess long-term reproductive outcomes following different misoprostol administration routes.

CONCLUSION

Our study confirms that vaginal misoprostol is more effective than oral misoprostol for managing first-trimester missed abortion, reducing the need for surgical evacuation and leading to faster expulsion. While most literature supports our findings, discrepancies in some studies highlight the need for further research into dosing strategies, patient selection, and treatment protocols.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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1	**Zermina Azhar:** Data collection, analysis, paper writing.
2	**Shereen Sukhan:** Data collection, paper writing.
3	**Fatima Khalid:** Discussion writing, review of manuscript.
4	**Iqra Ajmal:** Review of manuscript.
5	**Ridda Fatima:** Data entry and literature review.
6	**Naheed Jamal Faruqi:** Data entry and literature review.