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COMPARISON OF EFFICACY OF ORAL VERSUS VAGINAL MISOPROSTOL FOR FIRST TRIMESTER MISSED MISCARRIAGES

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ABSTRACT

Background: Missed miscarriage is a common early pregnancy complication requiring timely and effective management. Misoprostol is widely used for medical treatment, but the optimal route of administration remains debated.
Objective: To compare the efficacy of oral versus vaginal misoprostol in the management of first-trimester missed miscarriage.
Methodology: This comparative cross-sectional study was conducted at the Maternity and Child Health Centre, Pakistan Institute of Medical Sciences, from 20-10-2025 to 03-04-2026, including 122 women aged 18–40 years with ultrasound-confirmed missed miscarriage (≤12 weeks gestation), allocated into oral (n=61) and vaginal (n=61) misoprostol groups. Participants received 800 µg misoprostol every 6 hours for a maximum of three doses. Complete expulsion was confirmed by transabdominal ultrasonography 24-hours after passage of pregnancy tissue, defined as endometrial thickness <15 mm with no retained products of conception. Data were analyzed using SPSS version 27. Chi-square test was applied for efficacy comparison, with $p \leq 0.05$ considered significant.
Results: Baseline characteristics were comparable between groups (all $p>0.05$). Vaginal misoprostol achieved a significantly higher complete expulsion rate than oral misoprostol (91.8% vs. 75.4%, p=0.018). More women in the vaginal group achieved complete expulsion after the first dose (52.5% vs. 29.5%, p=0.031). The vaginal route resulted in a shorter mean time to expulsion (8.3±1.9 vs. 10.4±2.2 hours, p=0.001) and required fewer doses (1.8±0.7 vs. 2.5±0.6, p=0.003). Nausea and vomiting were less frequent with vaginal administration (14% vs. 32%, p=0.011), whereas abdominal pain and fever were comparable ($p>0.05$). Stratified analyses by age and gestational age showed no significant effect modification (all $p>0.05$).
Conclusion: Vaginal misoprostol is more effective, faster, and better tolerated than oral misoprostol for first-trimester missed miscarriage, though both remain safe options.

Keywords: Missed miscarriage, Misoprostol, Oral route, Vaginal route.

INTRODUCTION

Missed miscarriage, or silent miscarriage, is when the embryo or fetus has died but is not expelled from the uterus, no signs or symptoms of miscarriage, and is typically found through ultrasound with no fetal heartbeat. The incidence of

miscarriage is estimated as around 15.3% for all known pregnancies and about 23 million pregnancies succumb to miscarriage each year worldwide, with nearly 10% of miscarriages being missed [1,2]. There is variability among populations, with one study finding missed miscarriage accounted for 36.2% of all miscarriage cases [3]. True burden is difficult to estimate in Pakistan due to limited epidemiological data as well as inadequate evaluation of pregnancy losses and lack of awareness, timely diagnosis and appropriate management of the same [4].

In the case of missed miscarriage, the embryo/fetus is no longer viable, but the pregnancy tissue remains in the uterus because it is not expelled naturally. Hormonal and inflammatory mechanisms are involved in this process. A decrease in progesterone could result in poor uterine contractions, and inflammation and damage to the decidual tissue may also contribute to poor tissue expulsion [5,6]. Prostaglandins are important because they help to evoke uterine contractions and to modulate inflammatory response, which is needed during the removal of retained products of conception [6]. But if the prostaglandin activity is too high, there may be complications including heavy bleeding and incomplete miscarriage, making it important to have proper medical supervision [7].

Treatment for missed miscarriage may be expectant, medical, or surgical and depends on the clinical status of the woman, the fetal stage, and her wishes. Spontaneous expulsion of pregnancy tissue can be expected and may be appropriate for selected patients, but will generally require a longer waiting period [8]. Medical management, typically by misoprostol alone or in combination with the drug mifepristone, is an effective non-invasive approach. Mifepristone and misoprostol have been shown to have higher complete uterine evacuation rates and fewer surgical interventions than misoprostol alone [10]. Surgical treatment (typically uterine curettage) can be provided quickly and definitively, but can also result in infection, uterine damage, and intrauterine adhesion, which can impact future pregnancies [10]. Thus, the choice of treatment should be individualised, taking into account efficacy, possible complications and patient preference.

Misoprostol is a synthetic prostaglandin E_1 analogue that causes uterine contractions and ripens the cervix by stimulating the prostaglandin receptors and thus promotes uterine evacuation [11]. It is a clinically effective compound, but its efficacy depends on its method of administration. The vaginal route of misoprostol results in higher bioavailability, lesser first-pass hepatic metabolism, longer duration of action and higher rates of complete uterine evacuation compared to the oral route [12]. Oral misoprostol on the contrary, it suffers from first pass metabolism and is less available in plasma, with more gastrointestinal side effects including nausea and diarrhoea [11]. A study report that a success rate of oral misoprostol was 75% and vaginal route 91.7% complete expulsion of products of conception. Oral misoprostol had a mean induction to expulsion hours of 10.5 hours and vaginal was 8 hours. The general acceptance to treatment was good using both of the routes i.e.,70% using oral route and 76% using vaginal route [13]. While the vaginal route is more effective, patient acceptability, accessibility and clinical context should also be taken into account for the route of administration.

There are multiple international studies that have compared oral and vaginal misoprostol for the treatment of first trimester missed miscarriage, but treatment practices, patient differences, and clinical and health care resources could affect treatment outcomes in different settings. There is limited local, evidence-based data, especially from tertiary care hospitals with standard dose regimens, in Pakistan. Moreover, because of the discrepancies in patient acceptance, treatment efficacy and side-effect severity, the local population should be further investigated. Thus, the current study was designed to provide a contemporary evidence on the comparative effectiveness and safety of oral and vaginal Misoprostol in the Pakistani women with missed miscarriage in first trimester of pregnancy so as to provide context-specific data to aid in evidence-based clinical decision making.

MATHODOLOGY

This comparative, cross-sectional study conducted at the Maternity and Child Health Centre Pakistan Institute of Medical Sciences from 20-10-2025 to 03-04-2026, including 122 pregnant women, after obtaining approval from hospital IRB committee under reference No: F-5-2/2024(ERRC)/PIMS; dated: 17/10/2025. The sample size was calculated through WHO sample size calculator, keeping the success rate of oral misoprostol for complete expulsion of products of conception was 75% and for vaginal route was 91.7% [13], confidence level of 95% and 5% margin of error. Non-probability consecutive sampling technique were used for patients' selection.

The inclusion criteria were patients of age 18-40 years, gestational age $\leq$ 12 weeks and have missed miscarriage conformed on ultrasound. However, Women with previous scars, having anaemia, presenting with chronic disease and have multiple pregnancy was excluded.

First trimester missed miscarriage was defined as a condition in which the embryo or fetus had ceased to develop or had died before 12 weeks of gestation without immediate clinical signs of pregnancy loss. Ultrasound diagnosis was established when the crown–rump length was greater than 7 mm with absent embryonic cardiac activity, or when the gestational sac measured ≥25 mm without a yolk sac or embryo. Misoprostol was used as a synthetic prostaglandin E1 analogue for termination of pregnancy. Complete expulsion of the products of conception was confirmed by transabdominal ultrasound performed 24 hours after expulsion, demonstrating an endometrial thickness of less than 15 mm.

The hypothesis for this study is vaginal misoprostol had better outcomes than oral misoprostol for first trimester missed miscarriage in terms of complete expulsion of product of conception. All women diagnosed with a first trimester missed miscarriage via ultrasound and fulfilling the inclusion criteria were included in the study after taking informed consent. In group A, patients receiving 800 µg of misoprostol per oral every six hours, with a maximum of three doses was included. Whereas in group B patients receiving 800 µg of misoprostol per vaginal every six hours, up to a maximum of three doses were included.

Data was collected using a self-administered questionnaire, including demographic details such as age, gravidity and parity. Complete expulsion of the products of conception (POCs) was defined as complete evacuation of the uterine cavity confirmed by transabdominal ultrasonography performed 24 hours after the reported passage of pregnancy tissue. Complete expulsion was considered present when the endometrial thickness was <15 mm with no retained products of conception requiring additional medical or surgical intervention. Incomplete expulsion was defined as the persistence of retained products of conception on transabdominal ultrasonography (endometrial thickness ≥15 mm and/or visible retained intrauterine tissue) requiring additional medical treatment or surgical evacuation. The primary outcome of the study was the rate of complete expulsion following treatment with oral or vaginal misoprostol. The primary outcome was complete expulsion of POCs, as confirmed by transabdominal ultrasonography 24 hours after the reported passage of pregnancy tissue.

Data was analysis through SPSS Version27. Descriptive statistics was calculated for quantitative and qualitative variables. Qualitative variables like efficacy in terms of complete expulsion and gestational age was measured in terms of frequency and percentages. Quantitative variables like age and parity will be measured in terms of mean and standard deviation. Both groups will be compared by chi square test for efficacy (complete expulsion of product of conception). Effect modifiers like age, gestational age and parity will be stratified by using post stratified chi square test. p-value ≤ 0.05 will be considered significant.

RESULTS

A total of 122 patients fulfilling the inclusion criteria were enrolled in the study and equally divided into two groups: oral misoprostol (n = 61) and vaginal misoprostol (n = 61). The baseline demographic and clinical characteristics were comparable between the oral and vaginal misoprostol groups. The mean age (27.8 ± 4.5 vs 26.9 ± 4.2 years, p = 0.54), distribution across age groups (p = 0.81), mean gestational age (9.2 ± 1.4 vs 9.1 ± 1.5 weeks, p = 0.67), gestational age categories (p = 0.88), and mean parity (2.1 ± 1.2 vs 2.0 ± 1.1, p = 0.63) showed no statistically significant differences between the two groups (table 1).

Table 1: Baseline Demographic and Clinical Characteristics (n = 122)

Variable	Oral (n=61)	Vaginal (n=61)	p-value
Age (years, Mean ± SD)	27.8 ± 4.5	26.9 ± 4.2	0.54
Age Group 18–25	18 (29.5%)	20 (32.8%)	0.81
Age Group 26–33	28 (45.9%)	27 (44.3%)	
Age Group 34–40	15 (24.6%)	14 (22.9%)	
Gestational Age (weeks)	9.2 ± 1.4	9.1 ± 1.5	0.67
≤8 weeks	26 (42.6%)	25 (41.0%)	0.88
9–12 weeks	35 (57.4%)	36 (59.0%)	
Parity (Mean ± SD)	2.1 ± 1.2	2.0 ± 1.1	0.63

Treatment success was assessed according to the predefined ultrasonographic criteria for complete and incomplete expulsion described in the Methodology. The rate of complete expulsion was significantly higher in the vaginal

misoprostol group compared to the oral group (91.8% vs 75.4%), while incomplete expulsion was more frequent with oral administration (24.6% vs 8.2%). This difference was statistically significant (p = 0.018), indicating that vaginal is more effective than oral misoprostol (table 2).

Table 2: Comparison misoprostol of Treatment Efficacy

Outcome	Oral (n=61)	Vaginal (n=61)	Total (n=122)	p-value
Complete Expulsion	46 (75.4%)	56 (91.8%)	102 (83.6%)	0.018
Incomplete Expulsion	15 (24.6%)	5 (8.2%)	20 (16.4%)	

The number of doses required to achieve complete expulsion differed significantly between the two treatment groups (p = 0.031). More than half of the women in the vaginal misoprostol group achieved complete expulsion after the first dose (52.5%) compared with only 29.5% in the oral group. Conversely, a greater proportion of women in the oral group required a third dose than those in the vaginal group (18.0% vs. 9.8%) table 3.

Table 3: Number of Misoprostol Doses Required for Complete Expulsion

Number of doses required	Oral (n = 61)	Vaginal (n = 61)	p-value
After 1st dose	18 (29.5%)	32 (52.5%)	0.031
After 2nd dose	17 (27.9%)	18 (29.5%)	
After 3rd dose	11 (18.0%)	6 (9.8%)	

The mean time to expulsion was significantly shorter in the vaginal misoprostol group compared to the oral group (8.3 ± 1.9 hours vs 10.4 ± 2.2 hours), with a highly significant difference (p = 0.001). Additionally, the vaginal route required significantly fewer doses to achieve complete expulsion (1.8 ± 0.7 vs 2.5 ± 0.6, p = 0.003). These findings indicate that vaginal misoprostol is more efficient than oral misoprostol (table 4).

Table 4: Time to Expulsion and Number of Misoprostol Doses Required

Variable	Route of Administration	Mean ± SD (hours)	p-value
Time to Expulsion	Oral Misoprostol	10.4 ± 2.2	0.001
	Vaginal Misoprostol	8.3 ± 1.9	
Number of Misoprostol Doses Required	Oral Misoprostol	2.5 ± 0.6	0.003
	Vaginal Misoprostol	1.8 ± 0.7	

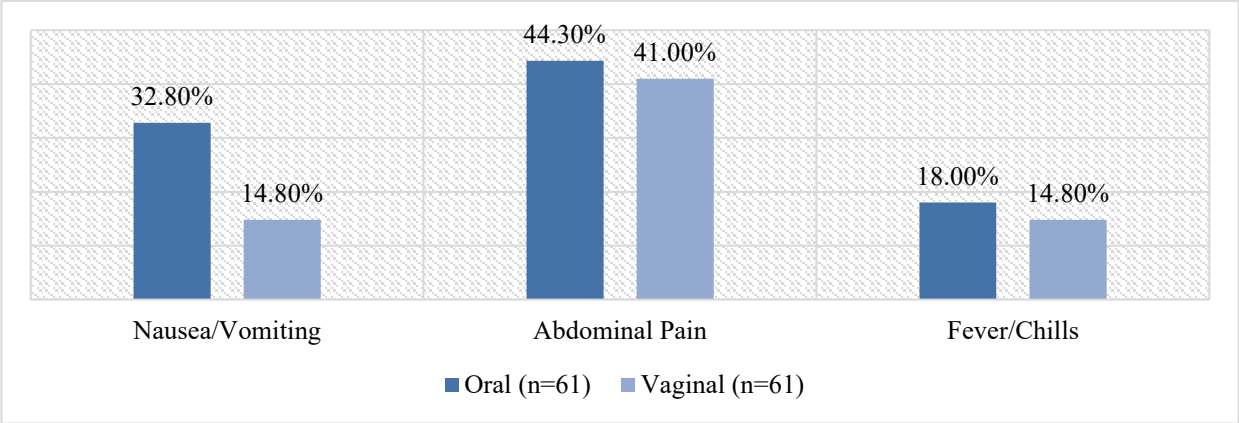
Stratified analysis was performed to evaluate the effect of age, gestational age, and parity on treatment efficacy. Vaginal misoprostol consistently showed higher success rates across all subgroups. However, these differences were not statistically significant after stratification (p > 0.05), indicating that these variables did not significantly modify treatment outcomes (table 5).

Table 5: Stratification of Treatment Efficacy by Age and Gestational Age

Variable	Category	Oral Success n/N (%)	Vaginal Success n/N (%)	p-value
Age (years)	18–25	13/18 (72.2%)	18/20 (90.0%)	0.08
	26–33	21/28 (75.0%)	25/27 (92.6%)	0.06
	34–40	12/15 (80.0%)	13/14 (92.9%)	0.09
Gestational Age	≤8 weeks	19/26 (73.1%)	22/25 (88.0%)	0.07
	9–12 weeks	27/35 (77.1%)	33/36 (91.7%)	0.06

Adverse effects were more frequently observed in the oral misoprostol group. Nausea and vomiting were reported in 32% of patients in the oral group compared to 14% in the vaginal group, which was statistically significant (p = 0.011). Other side effects such as abdominal pain and fever showed no statistically significant difference between the two groups (figure 1). No cases of diarrhea were reported in either group during the study period.

Figure 1: Comparison of Side Effects



DISCUSSION

The current study has contrasted the effectiveness of oral and vaginal misoprostol in the treatment of first trimester missed miscarriage and has shown that vaginal administration is much more effective, quicker and better tolerated than oral route. These results align with most of the published evidence and reinforce the evidence to support the use of vaginal misoprostol in clinical practice.

When it comes to baseline characteristics, both groups of the current study were similar regarding age, gestational age, and parity, as mean ages were about 26-28 years of age, and gestational age was about 9 weeks. This finding is in agreement with other studies, where most of the respondents were reproductive age (between 18 to 35 years) and gestational age less than 12 weeks [14]. A higher degree of similarity boosts our findings' external validity and comparability.

In terms of efficacy, the complete expulsion rate of our study was found to be significantly higher in the vaginal misoprostol group (91.8% vs. 75.4% in the oral group). Now these findings are broadly similar to those that were previously reported where the vaginal administration of misoprostol was more successful with rates ranging from 76.3 to 91.7 compared with the lesser rates of oral administration (37.3 to 64.9) [15]. Another study has demonstrated higher success rate with vaginal misoprostol (87.6 per cent) compared with oral (64.9 per cent), thus confirming that the vaginal route is superior to the oral route [12]. The consistently higher success rates when given vaginally may be due to its pharmacokinetic advantage with higher uterine concentrations.

The complete expulsion rate was significantly higher in the vaginal Misoprostol group compared to the oral group (91.8% vs. 75.4%). Additionally, fewer doses were needed to complete expulsion and the time to expulsion was significantly shorter for vaginal administration. The results are similar to those of previous studies, which achieved greater success and a faster rate of uterine emptying using misoprostol vaginally [12,16]. This is probably due to its increased bioavailability, prolonged uterine exposure and lack of first pass hepatic metabolism, which allows continued uterotonic activity.

Regarding safety, the group that took the oral misoprostol experienced significantly more nausea and vomiting than the group that took the vaginal misoprostol, while the amount of abdominal pain and fever was similar. During the study period, no diarrhea cases were reported in either treatment groups. These results are similar to previously reported differences in gastrointestinal side effects between oral and vaginal use of misoprostol, with the former having a higher rate of side effects because of first-pass hepatic metabolism, and the overall safety profiles of the two routes being similar [12,17,18]. However, both routes were safe, though vaginal misoprostol was better tolerated and had fewer gastrointestinal side effects.

Our stratified analysis showed that success rates were higher in all age and gestational age groups with use of vaginal misoprostol but these differences were not statistically significant. Other study reports similar findings indicating that there is not a significant influence of other demographic and clinical characteristics such as age, parity and gestational age on treatment outcomes [19,20]. This means that women with a vagina are better off than all others.

Vaginal misoprostol is usually more effective than rectal misoprostol, but in certain studies, there was no difference between the two routes and the route used depends upon patient preference and clinical situation [21,22]. Given the potential, oral misoprostol might still be used in settings where vaginal delivery is either not acceptable or not possible. Thus, it is essential to have a patient-centred approach for clinical decision-making.

The overall findings of this study are quite congruent with the current literature, and this indicates that vaginal Misoprostol is more effective, requires fewer doses, quicker expulsion, and has fewer gastrointestinal side effects than oral Misoprostol. The results are consistent with the use of misoprostol vaginae as the first line drug for treatment of missed miscarriages and the importance of individual care [23-25]

There are some limitations to this study. It set was performed in a single tertiary care center, and was non-probability sampling technique with a fairly small number of samples, which might restrict the generalizability of the findings. Furthermore, treatment results were only evaluated at short-term follow-up, hence long-term outcomes, e.g., subsequent fertility and patient satisfaction were not analysed. Yet, the study offers important local evidence with a consistent misoprostol dosage and post intervention analysis. Our results are consistent with those of earlier international research, indicating that vaginal Misoprostol is effective in the treatment of first trimester missed miscarriage. Larger trials and longer follow-up of a multicenter randomized controlled trial are required to validate these results and assess long-term outcomes of the procedure and of the patient.

CONCLUSION

Conclusively, vaginal misoprostol seems to be more effective and efficient than oral misoprostol in the treatment of first-trimester missed miscarriage. It is linked with increased chances of total expulsion, reduced time to uterine evacuation, and increased tolerability with fewer gastrointestinal side effects. Although both of the routes are safe and acceptable in general, the vaginal route provides more predictable clinical results. Nevertheless, patient preference, comfort, and clinical circumstances must also be taken into account to provide a patient-centered approach to care.

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