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**Original Research Article**

# Comparative study of mifepristone plus vaginal misoprostol versus vaginal misoprostol alone for second-trimester medical abortion

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## ABSTRACT

**Background:** Misoprostol is widely used for cervical ripening and uterine contractions, while mifepristone priming improves uterine sensitivity to prostaglandins and may enhance treatment efficiency. The present study compared the efficacy and safety of mifepristone plus vaginal misoprostol versus vaginal misoprostol alone for second-trimester termination of pregnancy (14-20 weeks).
**Methods:** This prospective comparative study included 150 women with singleton pregnancies between 14 and 20 weeks, allocated into two equal groups (n=75 each). Group 1 (Mife+Miso) received mifepristone 200 mg orally, followed after 36 hours by vaginal misoprostol 800 µg, then 400 µg vaginally every 3 hours up to four doses or until expulsion. Group 2 (Miso alone) received vaginal misoprostol 800 µg, followed by 400 µg every 3 hours up to four doses or until abortion occurred. Participants were monitored for expulsion, adverse effects, and complications; incomplete/failed abortions were managed with appropriate additional interventions.
**Results:** Baseline characteristics were comparable (mean age 24.43±5.13 vs 24.12±5.00 years; p=0.711). Complete abortion occurred in 90.7% of group 1 versus 65.3% of group 2 (p=0.0005), and overall success (complete abortion) remained significantly higher in group 1 (p=0.0004). The mean induction–abortion interval was significantly shorter with the combination regimen (7.38±2.60 vs 9.97±3.67 hours; p<0.001), with more women aborting within ≤8 hours (66.7% vs. 41.3%; p=0.003). The mean total misoprostol dose was lower in Group 1 (1413.33±368.10 vs. 1850.67±370.67 µg; p<0.001), and dose-category distribution differed significantly (p<0.001).
**Conclusions:** Mifepristone priming followed by vaginal misoprostol was more effective and faster than vaginal misoprostol alone for second-trimester medical abortion.

**Keywords:** Second-trimester abortion, Mifepristone, Misoprostol, Induction-abortion interval, Medical termination of pregnancy

## INTRODUCTION

Second-trimester abortion, commonly defined as termination after the first trimester and before fetal viability, represents a smaller but clinically important proportion of abortion care. Although most abortions occur in the first trimester, second-trimester procedures account for a disproportionate share of abortion-related morbidity because of larger uterine size, advanced placental development, greater cervical resistance and higher probability of retained products or bleeding.[1] The World Health Organization emphasizes that safe abortion care should be evidence based, timely and supported by trained providers, because delays in access and unsafe procedures remain preventable contributors to maternal morbidity and mortality.[2]

Medical abortion has become increasingly important in the second trimester because it avoids instrumentation of the gravid uterus and can be implemented in settings where highly skilled surgical services for dilation and evacuation are limited. Misoprostol, a prostaglandin E1 analogue,

induces uterine contractions and cervical softening and can be administered by vaginal, sublingual or buccal routes. Vaginal administration offers sustained uterotonic activity and is widely used in institutional protocols. However, misoprostol alone may be associated with prolonged induction, higher cumulative dose, fever, chills, gastrointestinal symptoms and increased need for repeat dosing or surgical completion.[3]

Mifepristone is a progesterone-receptor antagonist that produces functional progesterone withdrawal, decidual breakdown, cervical ripening and enhanced myometrial sensitivity to prostaglandins. When administered before misoprostol, it biologically prepares the cervix and uterus for expulsion, thereby improving the efficiency of the subsequent prostaglandin phase. Contemporary guidelines from the World Health Organization and Society of Family Planning recommend mifepristone 200 mg followed by repeated misoprostol doses as the preferred medication regimen for abortion at and beyond 14 weeks when mifepristone is available; misoprostol-only regimens remain alternatives where mifepristone is unavailable.[4]

Several randomized trials and cohort studies have demonstrated that mifepristone-misoprostol regimens shorten the induction-to-expulsion interval and reduce the total misoprostol requirement compared with misoprostol alone.[5-7] Nevertheless, reported outcomes differ by gestational age, dose, route, interval between drugs and institutional thresholds for defining failure or incomplete abortion. In India, where access to second-trimester abortion has been shaped by the Medical Termination of Pregnancy Act and subsequent amendments, locally generated data are needed to guide regimen selection in tertiary and peripheral centres. The present study compared mifepristone plus vaginal misoprostol with vaginal misoprostol alone for second-trimester termination of pregnancy, focusing on complete abortion rate, induction-abortion interval, total misoprostol dose, side effects and requirement for additional procedures.

## METHODS

This prospective comparative study was conducted in the Department of Obstetrics and Gynaecology, Al Ameen Medical College and Hospital, Vijyapura, Karnataka, India. The study was conducted over a planned period from November 2023 to 2026, during which consecutive eligible women requesting second trimester abortion were enrolled and followed up until completion of the termination procedure and immediate post-abortion outcome assessment.

### *Inclusion criteria*

Women were included in the study if they met all the criteria like gestational age between 14 and 20 weeks, based on menstrual history, clinical examination and ultrasound; asingle live intrauterine fetus; indications for termination of pregnancy fulfilling the provisions of the MTP act (e.g. failure of contraception, fetal anomalies, medical or social indications), and certified by the required number of registered medical practitioners; closed cervical os with no evidence of active vaginal bleeding at the time of recruitment.

### *Exclusion criteria*

Women with contraindications to the study drugs, multiple pregnancy, suspected ectopic pregnancy, placenta previa, active labour, significant medical contraindication or previous uterine surgery were excluded as per institutional protocol.

A total of 150 women were included and allocated into two equal groups of 75 each.

The Mife+Miso group received mifepristone 200 mg orally on day 1. After a 36-hour interval, women were admitted or shifted to the labour ward and received vaginal misoprostol 800 micrograms in the posterior fornix under aseptic precautions, followed by 400 micrograms vaginally every 3 hours up to a maximum of four repeat doses or until expulsion of fetus and placenta.

The Miso group received vaginal misoprostol 800 micrograms as the initial dose, followed by 400 micrograms every 3 hours up to four repeat doses or until abortion occurred.

All women were monitored for uterine activity, vital signs, vaginal bleeding, pain, side effects and complications. Complete abortion was defined as expulsion of fetus and placenta without need for surgical evacuation. Incomplete abortion included retained fetus or placenta requiring additional treatment, while failure referred to non-expulsion despite completion of the protocol. Additional procedures included oxytocin augmentation, instrumental evacuation or rescue medical induction, depending on clinical assessment. Follow-up ultrasonography was performed to confirm complete evacuation when indicated.

Data were entered into a master chart and analysed using descriptive and inferential statistics. Continuous variables were expressed as mean and standard deviation and compared using the independent samples t test. Categorical variables were summarized as frequencies and percentages and compared using the chi-square test or Fisher's exact test where appropriate. A p value less than 0.05 was considered statistically significant.

## RESULTS

The study included 150 women, 75 in each treatment arm. The groups were comparable with respect to age, gestational age, gravidity and indication for termination, allowing outcome differences to be interpreted in relation to the intervention regimen.

**Table 1: Baseline demographic and obstetric characteristics.**

| Variables | Mife+Miso group (n=75) | Miso Group (n=75) | Test statistic | P value |
|---|---|---|---|---|
| **Mean age (years)** | 24.43±5.13 | 24.12±5.00 | t=-0.371 | 0.71$^{NS}$ |
| **Age 21-25 years, N (%)** | 30 (40.0) | 32 (42.7) | Chi$^2$=0.290 | 0.96$^{NS}$ |
| **Primigravida, N (%)** | 24 (32.0) | 20 (26.7) | Chi$^2$=1.216 | 0.87$^{NS}$ |
| **Mean gestational age (weeks)** | 17.63±1.67 | 17.77±1.61 | t=-0.547 | 0.58$^{NS}$ |
| **GA 17-18 weeks, N (%)** | 41 (54.7) | 44 (58.7) | Chi$^2$=0.580 | 0.74$^{NS}$ |
| **Unwanted pregnancy, N (%)** | 51 (68.0) | 54 (72.0) | Chi$^2$=0.419 | 0.81$^{NS}$ |

Values are mean ± SD or N (%). NS- non-significant.

**Table 2: Abortion outcome and overall success.**

| Outcomes | Mife+Miso group (n=75), N (%) | Miso group (n=75), N (%) | Test statistic | P value |
|---|---|---|---|---|
| **Complete abortion** | 68 (90.7) | 49 (65.3) | Chi square test=15.345 | 0.0005* |
| **Incomplete abortion** | 7 (9.3) | 20 (26.7) | | |
| **Failure** | 0 (0.0) | 6 (8.0) | | |
| **Success** | 68 (90.7) | 49 (65.3) | Chi square test=12.587 | 0.0004* |
| **Failure/incomplete** | 7 (9.3) | 26 (34.7) | | |

Values are represented as N (%); * denotes significant (p<0.05).

**Table 3: Induction-abortion interval.**

| Variables | Mife+Miso group (n=75), N (%) | Miso group (n=75), N (%) | Test statistic | P value |
|---|---|---|---|---|
| **Mean interval (hours)** | 7.38±2.60 | 9.97±3.67 | t=-5.003 | <0.001* |
| **≤8** | 50 (66.7) | 31 (41.3) | Chi square test =11.552 | 0.003* |
| **>8-12** | 20 (26.7) | 28 (37.3) | | |
| **>12** | 5 (6.7) | 16 (21.3) | | |

Values are shown as mean ± SD or N (%); * denotes significant (p<0.05).

**Table 4: Total misoprostol dose requirement.**

| Variables | Mife+Miso group (n=75), N (%) | Miso group (n=75), N (%) | Test statistic | P value |
|---|---|---|---|---|
| **Mean dose (micrograms)** | 1413.33±368.10 | 1850.67±370.67 | t=-7.250 | <0.001* |
| **≤1200** | 39 (52.0) | 10 (13.3) | Chi square test =39.326 | <0.001* |
| **1201-1600** | 26 (34.7) | 21 (28.0) | | |
| **1601-2000** | 8 (10.7) | 31 (41.3) | | |
| **>2000** | 2 (2.7) | 13 (17.3) | | |

Values are shown as mean ± SD or N (%); *denotes significant (p<0.05).

**Table 5: Safety profile and additional procedures.**

| Variables | Mife+Miso group (n=75), N (%) | Miso group (n=75), N (%) | Test statistic | P value |
|---|---|---|---|---|
| **No side effects** | 62 (82.7) | 52 (69.3) | Chi square test =2.961 | 0.085$^{NS}$ |
| **Any side effect** | 13 (17.3) | 23 (30.7) | | |
| **No additional procedure** | 68 (90.7) | 59 (78.7) | Chi square test =3.287 | 0.070$^{NS}$ |
| **Additional procedure required** | 7 (9.3) | 16 (21.3) | | |
| **Major complication** | 0 (0.0) | 0 (0.0) | - | - |

Values are represented as N (%); NS-Non-Significant.

**Table 6: Association between gestational age category and induction outcome.**

| Gestational age (weeks) | Success, N (%) | Failure/incomplete, N (%) | Test statistic |
|---|---|---|---|
| **14-16** | 16 (84.2) | 3 (15.8) | Chi Square=6.322, p=0.04* |
| **17-18** | 71 (83.5) | 14 (16.5) | |
| **19-20** | 30 (65.2) | 16 (34.8) | |

Values are represented as N (%); *: denotes significant.

A total of 150 women were included (75 per group). The mean age was comparable between the Mife+Miso group (24.43±5.13 years) and the Miso group (24.12±5.00 years; p=0.71). Most participants were aged 21-25 years (40.0% vs. 42.7%), and primigravidae constituted 32.0% vs. 26.7% (p=0.87). Mean gestational age was similar (17.63±1.67 vs. 17.77±1.61 weeks; p=0.58), and the commonest indication was unwanted pregnancy (68.0% vs. 72.0%; p=0.81), confirming baseline comparability (Table 1).

Complete abortion occurred in 68/75 (90.7%) women in the Mife+Miso group compared with 49/75 (65.3%) in the Miso group (p=0.0005). Incomplete abortion was lower in the combination arm (7/75, 9.3%) than in the misoprostol-only arm (20/75, 26.7%), and failure was seen only in the Miso group (6/75, 8.0%). When dichotomised, overall success remained significantly higher with mifepristone pretreatment (90.7% vs. 65.3%; p=0.0004) (Table 2).

The mean induction–abortion interval was significantly shorter with the combination regimen (7.38±2.60 hours) compared with misoprostol alone (9.97±3.67 hours; p<0.001). Abortion within ≤8 hours occurred in 50/75 (66.7%) in the Mife+Miso group versus 31/75 (41.3%) in the Miso group (p=0.003). A prolonged interval >12 hours was more common with misoprostol alone (21.3%) than with combination therapy (6.7%) (Table 3).

Women receiving mifepristone pretreatment required a significantly lower mean total misoprostol dose (1413.33±368.10 µg) than those receiving misoprostol alone (1850.67±370.67 µg; p<0.001). A low dose requirement ≤1200 µg was achieved in 52.0% of the Mife+Miso group but only 13.3% of the Miso group, whereas high-dose categories 1601-2000 µg and >2000 µg were more frequent in the misoprostol-only arm (41.3% and 17.3%, respectively). The dose distribution differed significantly between groups (p<0.001) (Table 4).

Side effects were reported less frequently in the Mife+Miso group (13/75, 17.3%) compared with the Miso group (23/75, 30.7%), though this difference was not statistically significant (p=0.085). Additional procedures were needed in 7/75 (9.3%) women in the combination group versus 16/75 (21.3%) in the misoprostol-only group (p=0.070), showing a non-significant trend favoring the combination regimen. No major complications were observed in either group (Table 5).

Gestational age showed a significant association with induction outcome: among failures/incomplete outcomes, a larger proportion occurred at higher gestational ages, especially 19-20 weeks, compared to 14-16 weeks. In contrast, successful outcomes were more frequently observed in the 17-18-week category. The association between gestational age category and outcome was statistically significant (p=0.04) (Table 6).

## DISCUSSION

The present study demonstrates that mifepristone followed by vaginal misoprostol is more effective and efficient than vaginal misoprostol alone for second-trimester medical abortion between 14 and 20 weeks. Baseline variables were comparable between the groups, including mean age, gravidity, gestational age and indications for termination. This comparability strengthens the interpretation that the significant differences in complete abortion rate, induction-abortion interval and misoprostol dose were attributable mainly to the treatment regimen rather than baseline imbalance.

The principal efficacy finding was the significantly higher complete abortion rate in the Mife+Miso group (90.7%) compared with the Miso group (65.3%). This is biologically plausible because mifepristone induces functional progesterone withdrawal, decidual separation and cervical ripening before the prostaglandin stimulus is introduced.[8] The uterus therefore responds to misoprostol in a more coordinated and efficient manner. The observed difference is consistent with the randomized trial by Ngoc et al.9 which showed that pretreatment with mifepristone produced more than twice the likelihood of complete uterine evacuation within 15 hours compared with misoprostol alone. In a study done by Saharan et al.10 the second trimester abortion rate was higher in Mife+Miso as compared to Miso alone group (90 vs. 70%; p<0.05). Recent guideline panels have also concluded that mifepristone before misoprostol is the most effective medication approach for gestations between 14 and 27 weeks.[11]

The induction-abortion interval was significantly shorter with the combination regimen. The mean interval of 7.38 hours in the Mife+Miso arm compares favourably with published intervals of approximately 7-10 hours for combination regimens. In a study done by Chavhan et al the induction abortion interval was significantly shorter in Mife+Miso group when compared to Miso group (7.8±2.3 vs 11.6±3.1 hours; p<0.05).[12] In a study done by Arora et al.13 the mean induction abortion interval was shorter in Mife+Miso group as compared to Miso group (10.7 hrs vs. 19.12 hrs). The shorter interval in the present study has

practical value in a high-volume tertiary hospital because it reduces bed occupancy, time in pain, emotional distress and nursing workload. The category analysis further reinforces this finding: 66.7% of women in the combination arm aborted within 8 hours compared with 41.3% with misoprostol alone.

A second major advantage was the significant reduction in cumulative misoprostol dose. Women receiving mifepristone required a mean of 1413 micrograms compared with 1851 micrograms in the misoprostol-only arm. In a study done by Akkenapally et al the requirement of misoprostol dose was lower in Mife+Miso group as compared to Miso group (1046 mcg vs. 1610 mcg).[14] In another study done by Soren et al.15 the misoprostol dose requirement was lower in Mife+Miso group as compared to Miso group (1081.48 µg vs. 1675.67 µg).

Over half of the combination group completed abortion with 1200 micrograms or less, while larger doses were more frequent with misoprostol alone. This finding is clinically relevant because misoprostol-related adverse effects such as fever, chills, nausea, vomiting and diarrhoea are dose dependent. Although the side-effect difference in this study did not reach statistical significance, side effects were numerically lower in the Mife+Miso group (17.3% vs. 30.7%), supporting the concept that mifepristone may improve tolerability by reducing prostaglandin exposure. Likewise, in a study done by Aiob et al the complications were less in Mife+Miso group as compared to the Miso group (1.7% vs. 10.0%, p=0.031).[16]

The need for additional procedures was also lower in the combination group (9.3% vs. 21.3%), although the difference approached but did not reach statistical significance. This trend is important because additional procedures such as instrumental evacuation, oxytocin augmentation or repeat induction increase cost, patient anxiety and resource use. Larger studies have frequently reported fewer surgical evacuations with mifepristone-misoprostol regimens, especially when success is defined within clinically meaningful time frames.[17] The lack of statistical significance in the present cohort may reflect the sample size and relatively low number of such events rather than absence of a true clinical difference.

The results align with contemporary recommendations. WHO guidance supports repeated misoprostol doses at gestations at and beyond 14 weeks and recommends combined mifepristone-misoprostol regimens when available. The Society of Family Planning recommends mifepristone 200 mg orally 24-48 hours before misoprostol, followed by misoprostol 400 micrograms every 3 hours by vaginal, sublingual or buccal route; when mifepristone is unavailable, misoprostol alone is recommended.[18] Although the present protocol used an 800 microgram vaginal loading dose followed by 400 micrograms every 3 hours, the findings are consistent with the central principle of these guidelines: mifepristone pretreatment enhances the performance of misoprostol.

The present study has several strengths. It used a prospective comparative design, equal group sizes and objective outcomes such as complete abortion, induction-abortion interval and total drug dose. The study also adds locally relevant Indian data to a field in which protocols and access vary across institutions. However, limitations should be considered. The study was conducted at a single centre and excluded women with previous uterine surgery, limiting generalizability to scarred uteri. Side effects were analysed as present or absent rather than graded by severity, and patient satisfaction, pain scores, cost data and length of hospital stay were not fully evaluated. The sample size was adequate for major efficacy outcomes but may have been insufficient for rare safety outcomes and additional procedures.

Overall, the study supports mifepristone plus vaginal misoprostol as the preferred regimen for second-trimester medical abortion where mifepristone is available. Misoprostol alone remains an important option in settings where mifepristone is unavailable, unaffordable or contraindicated; however, counselling should emphasize the possibility of a longer induction, higher cumulative dose and greater need for additional interventions. Future multicentre studies with standardized dosing, detailed adverse-effect reporting and cost-effectiveness assessment would further strengthen policy and institutional protocols.

However, certain limitations should be acknowledged. Random allocation and blinding were not incorporated, and therefore selection bias cannot be completely excluded. The study excluded women with previous uterine surgery; consequently, findings should not be generalized to scarred uteri, where misoprostol dosing requires greater caution. Minor side effects were recorded categorically rather than by severity, and outcomes such as pain score, duration of hospital stay, cost per patient and patient satisfaction were not measured in detail. In addition, the study was conducted in a single tertiary hospital, so multicentre validation would strengthen external applicability.

The findings nevertheless provide useful local evidence for practice. In settings where both drugs are available, mifepristone pretreatment should be incorporated into routine second-trimester medical abortion protocols because it improves success, reduces the induction period and lowers misoprostol exposure. Misoprostol alone continues to have a role where mifepristone is unavailable, unaffordable or contraindicated; however, women should be counselled that the process may require more doses, may take longer and may have a higher probability of incomplete abortion or additional procedures. Such counselling is essential for informed consent and for setting realistic expectations.

## CONCLUSION

Mifepristone 200 mg followed by vaginal misoprostol was superior to vaginal misoprostol alone for second-trimester medical abortion in this prospective comparative study. The combination regimen achieved a higher complete abortion rate, shorter induction-abortion interval and lower total misoprostol requirement, with no major complications. These findings support the use of mifepristone-misoprostol as the preferred protocol for second-trimester termination where mifepristone is accessible, while misoprostol-only regimens should be reserved for situations where mifepristone is unavailable or contraindicated.

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