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Original Research Article

A study to compare combination of Foley's catheter with misoprostol versus mifepristone with misoprostol in second trimester abortion

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ABSTRACT

Background: Second trimester abortion, which is the interruption of pregnancy between 13 and 28 weeks of gestation, accounts for roughly 10–15% of all induced abortions worldwide. Although second trimester procedures are less common than first trimester ones, they account for an unequal share of abortion-related complications and maternal health issues due to the later gestational age at which they are performed. Typical reasons for second trimester abortions include fetal abnormalities found during standard ultrasounds, intrauterine fetal death, and maternal health concerns like severe hypertension, heart disease, or mental health disorders.
Methods: Study was carried out at Department of Obstetrics and Gynecology, R.N.T. Medical College, Udaipur (Rajasthan). Study period: April 2024 to March 2025.
Results: Findings indicate that a method-wise comparison of two protocols for second trimester abortion—Foley catheter with Misoprostol and Mifepristone with Misoprostol, involving 33 participants each. The average interval from induction to abortion was notably reduced in the Foley group (11.27±3.36 hours) in contrast to the Mifepristone group (29.75±3.92 hours), with a p-value of 0.0, reflecting strong statistical significance. The median induction time was 10.4 hours for Foley and 29.1 hours for Mifepristone, with the overall induction time varying from 5.1 to 18.2 hours in the Foley group and 24.2 to 37.6 hours in the Mifepristone group.
Conclusions: To conclude, the Foley catheter combined with misoprostol is a quicker and more economical approach, making it especially appropriate for low-resource environments or scenarios that require reduced induction times. Conversely, mifepristone combined with misoprostol offers a more thorough and dependable uterine evacuation, minimizing the requirement for surgical procedures.

Keywords: Second trimester abortion, Foley's catheter, Misoprostol

INTRODUCTION

Second trimester abortion, defined as the termination of pregnancy between 13 and 28 weeks of gestation, constitutes approximately 10–15% of all induced abortions globally. Despite being less frequent than first trimester procedures, second trimester terminations are responsible for a disproportionate share of abortion-related complications and maternal morbidity due to the advanced gestational age at which they occur.[1] Common indications for second trimester abortion include fetal anomalies detected during routine ultrasounds, intrauterine fetal demise, and maternal health conditions such as severe hypertension, cardiac disease, or psychiatric illness. Socioeconomic barriers and lack of early access to reproductive services can also lead to delayed decisions regarding termination.[2] Second trimester abortions, though comprising a smaller percentage of total abortions, carry significant clinical, social, and policy relevance. Globally, approximately 10–15% of abortions occur during the second trimester, often driven by delayed pregnancy detection, socioeconomic barriers, or identification of fetal

anomalies.[3] In low-resource countries, second trimester abortions contribute disproportionately to maternal mortality. A lack of trained providers, stigma, and limited access to health facilities often result in delayed care or unsafe abortion practices. The World Health Organization emphasizes scaling up access to safe mid-trimester abortion services to address these preventable deaths.[4]

In South Asia, including India and Nepal, second trimester abortions are frequently linked to sociocultural constraints, limited reproductive education, and logistical delays. For example, a retrospective study in Nepal found that 38% of women undergoing second trimester abortion were nulliparous, and the leading cause for termination was maternal mental health concerns.[5]

In the United States, second trimester abortions have declined as a proportion of total procedures—from 21% in the 1970s to around 7% by 2019. this decline masks significant disparities: women with limited access to abortion services, including those facing geographic or legal restrictions, are more likely to seek care later in pregnancy.[6] Furthermore, in regions affected by restrictive laws following the Dobbs v. Jackson Women's Health ruling, travel distance and provider scarcity have delayed access, resulting in higher proportions of second trimester procedures.[7] Objective of study was to compare the efficacy of Foley's bulb induction with misoprostol and mifepristone with misoprostol in second trimester MTP by mean induction to abortion interval and maternal complications.

METHODS

This study was conducted at Department of Obstetrics and Gynaecology, R.N.T. Medical College, Udaipur (Rajasthan). Study duration from April 2024 to March 2025.

Study design

This study is a randomized controlled trial with a parallel-group design, in which participants are assigned in equal allocation to the intervention groups. It is conducted as a superiority trial of means, aiming to compare the average outcomes between groups to determine whether one intervention demonstrates superior effectiveness over the other.

Place of study

The study was conducted in the Department of Obstetrics and Gynaecology at R.N.T. Medical College, Udaipur.

Study population

All patients admitted to the labor room who required termination of pregnancy in the second trimester were included in the study.

Sample size

Sample size is calculated according to randomised control trial comparing medical and mechanical method for early mid-trimester abortion, where 60 women were randomised in two groups.

Group 1 received the medical method alone, consisting of mifepristone 200 mg followed 48 hours later by vaginal misoprostol 400 mg administered every 4 hours. Group 2 received a combined medical and mechanical method, which included the use of a transcervical Foley catheter inflated with 60 ml of normal saline in addition to the medical regimen.

Aims and objectives

The objectives of the study are to compare the efficacy of Foley's bulb induction with misoprostol versus mifepristone with misoprostol in second-trimester medical termination of pregnancy by assessing the mean induction-to-abortion interval, and to evaluate maternal complications associated with both methods.

Inclusion criteria

Patients of Singleton pregnancies,13 to 24 gestational weeks and those fulfils the indications defined in the MTP amendment of India 2021.

Exclusion criteria

Patient in the process of abortion, Multiple gestation, underlying medical conditions like cardiac disease, diabetes mellitus, bronchial asthma, Scarred uterus and known maternal allergy to prostaglandins or previous adverse reactions.

Methodology of study

Sixty-six pregnant women admitted to the labour room for second-trimester medical termination of pregnancy who fulfilled the inclusion and exclusion criteria were selected for the study. Ultrasound examination was used to confirm gestational age and assess eligibility. The selected patients were advised to be admitted to the labour ward and remain in the hospital until termination of pregnancy was achieved, and a complete evaluation of each patient was performed at the time of admission. Detailed medical and obstetric history, along with examination findings, were recorded.

Patients were assigned to one of the two groups on admission. In Group A, induction was performed using Foley's bulb inflation followed by intravaginal misoprostol 400 mg after insertion, with additional doses of 400 mg intravaginal misoprostol administered every 4 hours up to a maximum of four doses. In Group B, induction was carried out using oral mifepristone 200 mg followed by 400 mg intravaginal misoprostol after 24

hours, with subsequent doses of 400 mg vaginal misoprostol given every 4 hours up to a maximum of four doses. The outcome was assessed by measuring the time interval from induction to expulsion of the conceptus to calculate the induction-to-abortion interval.

Statistical analysis

Data were entered into Microsoft Excel data sheet and analysed using SPSS 22 version software.

RESULTS

The table 1 reveals that largest proportion of participants belonged to the age group of 18–25 years, accounting for 43.9% of the total study population. This is followed by the 26–30 years group comprising 34.8%. Only 21.2% of participants were above 30 years of age. This indicates that the majority of women undergoing second trimester abortion in the present study were young adults, which may be reflective of early reproductive age-related decisions or circumstances leading to termination.

Table 1: Frequency and percentage distribution of age of study participants (n=66).

Age group (in years)	Frequency (f)	Percentage (%)
18–25	29	43.9
26–30	23	34.8
Above 30	14	21.2
Total	66	100.0

The table 2 shows that the highest number of women undergoing second trimester abortion were third gravida (28.8%), followed by second gravida (27.3%). Primigravida (G1) women accounted for 19.7%, and only 7.6% of participants were in their fifth or higher pregnancy. The findings suggest that most women had prior reproductive experiences, indicating a possible history of complications or need-based decisions in later pregnancies.

Table 2: Frequency and percentage distribution of gravida of study participants (n=66).

Gravida	Frequency (f)	Percentage (%)
G1 (primigravida)	13	19.7
G2	18	27.3
G3	19	28.8
G4	11	16.7
>G4	5	7.6
Total	66	100.0

The table 3 shows that the majority of women undergoing second trimester abortion in this study were between 17–20 weeks of gestation, accounting for 59.1% of participants. The remaining 40.9% were in the 13–16-week range. This distribution suggests that second trimester terminations tend to be more commonly required during the later part of the mid-trimester. This could be attributed to late detection of fetal anomalies, delayed decision-making, or referral timings, which are often more prevalent in the 17–20-week window.

Table 3: Frequency and percentage distribution of gestational age of study participants (n=66).

Gestational age	Frequency (f)	Percentage (%)
13–16 weeks	27	40.9
17–20 weeks	39	59.1
Total	66	100.0

The Figure 1 shows that half of the participants (50%) underwent abortion upon maternal request under legal provisions. Fetal anomalies were the second most common indication, found in 34.8% of the cases, indicating that structural or genetic abnormalities detected during anomaly scans remain a significant reason for second trimester terminations. Intrauterine fetal death (IUFD) was observed in 9.1% and an hydramnios in 6.1% of the cases. These findings highlight that while maternal choice plays a major role, medical and fetal indications still account for a substantial proportion of second trimester abortions.

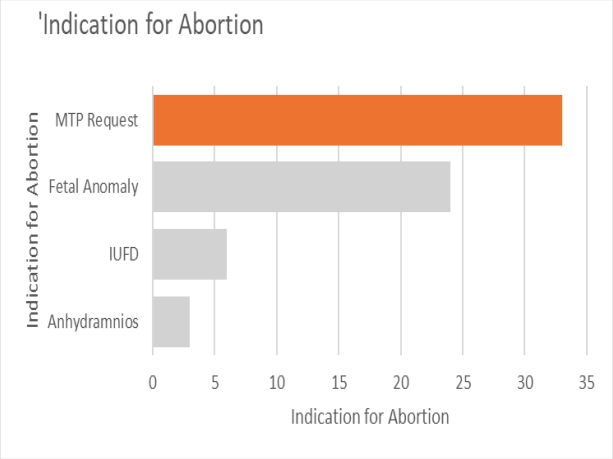

Figure 1: Frequency and percentage distribution of indication for abortion (n=66).

The most commonly reported side effect was abdominal pain, observed in 19.7% overall, with slightly more in the Mifepristone group (21.2%) than the Foley group (18.2%). Bleeding and vomiting were mild; bleeding was more common in Mifepristone group and vomiting was more common in Foley Group. One case of diarrhoea was reported in the Foley group, while no such case was seen in the Mifepristone group. A majority of participants in both groups (66.7% in Foley and 69.7% in Mifepristone) experienced no side effects, confirming the tolerability of both regimens. Table 5 provides a method-wise comparison of two regimens used for second trimester abortion—Foley catheter with Misoprostol and Mifepristone with Misoprostol, each with 33 participants.

The mean induction-to-abortion interval was significantly shorter in the Foley group (11.27±3.36 hours) compared to the Mifepristone group (29.75±3.92 hours), with a p-value of 0.000, indicating high statistical significance. The median induction time was 10.4 hours for Foley and 29.1 hours for Mifepristone, and the overall induction time ranged from 5.1–18.2 hours in the Foley group and 24.2–37.6 hours in the Mifepristone group. In terms of efficacy, complete expulsion was achieved in all patients (100%) in the Mifepristone group, while 3 patients (9.1%) in the Foley group had incomplete abortion requiring surgical evacuation. The average number of misoprostol doses required was slightly higher in the Foley group (~2.39 doses) versus the Mifepristone group (~2.09 doses), suggesting better uterine priming with Mifepristone.

Table 4: Method-wise comparison of side effects observed (n=66).

Side effect	Foley + misoprostol (n=33)	Mifepristone + misoprostol (n=33)	Total (n=66)
Abdominal pain	6 (18.2%)	7 (21.2%)	13 (19.7%)
Vaginal bleeding	1 (3.0%)	2 (6.06%)	3 (4.5%)
Vomiting	3 (9.1%)	1 (3.0%)	4 (6.1%)
Diarrhoea	1 (3.0%)	0 (0%)	1 (1.5%)
None	22 (66.7%)	23 (69.7%)	45 (68.2%)

Table 5: Comparison between foley + misoprostol and mifepristone + misoprostol regimens (n=66).

Parameter	Foley + misoprostol (n=33)	Mifepristone + misoprostol (n=33)	Statistical significance
Mean induction to abortion interval	11.27±3.36 h	29.75±3.92 h	P=0.000 (highly significant)
95% confidence interval (mean)	4.68-17.86 h	22.08-37.43 h	
Median induction time (h)	10.4	29.1	
Range (minimum–maximum)	5.1-18.2 h	24.2-37.6 h	
Interquartile range (IQR)	~4.3	~6.0	
Complete expulsion	30 (90.9%)	33 (100%)	
Average misoprostol doses used	~2.39 doses	~2.09 doses	
Side effects observed	Abdominal pain (18.2%), bleeding (3.0%), vomiting (9.1%), diarrhoea (3.0%)	Abdominal pain (21.2%), bleeding (6.06%), vomiting (3.0%)	
Complications	1 blood transfusions, 3 method failure	2 blood transfusions, no failure	
Need for additional procedure (S and E)	3 cases (9.1%)	None	
No side effects reported	22 (66.7%)	23 (69.7%)	
No complications observed	29 (87.9%)	31 (93.9%)	

When evaluating side effects, pain was the most common symptom in both groups (18.2% in Foley, 21.2% in Mifepristone). Vomiting occurred in 9.1% of Foley cases and 3.0% of Mifepristone cases. One case of diarrhoea was noted in the Foley group. A majority of participants experienced no side effects—66.7% in the Foley group and 69.7% in the Mifepristone group.

As for complications, the Foley group had 1 case of blood transfusion and 3 method failures, whereas the Mifepristone group had 2 cases requiring transfusion but no failures. No participants in either group experienced severe complications like uterine rupture or sepsis. In conclusion, while Foley + Misoprostol was significantly faster, Mifepristone + Misoprostol provided higher expulsion completeness and eliminated the need for surgical intervention, highlighting the clinical strengths of both regimens depending on context.

DISCUSSION

Second trimester abortion remains a critical component of reproductive healthcare, especially in cases involving fetal anomalies, intrauterine fetal demise, or maternal request under legal indications. The optimal method for termination during this period must be effective, safe, rapid, and well tolerated. In this study, we compared two widely used protocols—Foley's catheter with misoprostol and mifepristone with misoprostol—to assess their relative

efficacy, safety profile, and associated complications in second trimester MTP.

Efficacy based on induction-to-abortion interval

In the present research, the induction-to-abortion interval (IAI) was notably shorter in the Foley's catheter combined with misoprostol group (mean: 11.27±3.36 hours) when compared to the mifepristone with misoprostol group (29.75±3.92 hours), achieving high statistical significance ($p<0.001$). This implies that the Foley catheter's mechanical action, which directly expands the cervix and stimulates endogenous prostaglandin release, results in faster expulsion. Comparable results have been documented in multiple clinical studies. Manku (2024) noted a notably reduced IAI in the Foley group (6.66±1.1 hrs) compared to the mifepristone group (9.42±2.69 hrs), validating the benefit of mechanical priming in shortening expulsion time.[8] Fonseca and Sah similarly found a significantly shorter IAI in the Foley group (20.11 hrs) versus the mifepristone group (54.77 hrs), with equivalent safety profiles.[9]

In a similar vein, Sangeetha reported a mean IAI of 10.35 hours for the Foley group compared to 10.68 hours for the mifepristone group, indicating faster results with mechanical approaches and proposing it as a cost-effective choice in low-resource environments.[10]

Finally, Kusumam et al showed that even in patients given mifepristone in both groups, those who received vaginal misoprostol experienced a shorter IAI (14.6 hrs) compared to those given Foley with extra-amniotic saline (18.4 hrs), further validating the influence of pharmacological versus mechanical timing on the expulsion interval.[11] Both methods are effective; however, the Foley catheter combined with misoprostol consistently results in a reduced induction-to-abortion interval, making it preferable in urgent clinical situations or when early expulsion is prioritized.

Completeness of abortion

In the current study, complete expulsion was achieved in 100% of cases in the mifepristone + misoprostol group, compared to 90.9% in the Foley + misoprostol group, where three patients required suction and evacuation due to retained products. This suggests that while the Foley method may offer faster expulsion, mifepristone pretreatment enhances the reliability and completeness of abortion, likely due to its action on endometrial decidual breakdown and improved cervical softening.

This finding is strongly supported by multiple studies Swathi et al observed a 96% complete abortion rate in the mifepristone group compared to 80% in the misoprostol-only group, along with fewer retained placenta cases and a shorter hospital stay, indicating the superiority of mifepristone in achieving full expulsion.[12] Beishen further demonstrated that using moistened misoprostol with mifepristone resulted in 96–98% success rates, regardless of whether dry or wet tablets were used, indicating that the route and combination both significantly enhance abortion completeness.[13]

Vani and Pranavi compared mifepristone + misoprostol with misoprostol alone and observed fewer incomplete expulsions and a significantly higher rate of complete abortion in the combined regimen group, emphasizing the role of mifepristone in improving procedural success.[14] In conclusion, although both regimens are effective for second trimester abortion, the addition of mifepristone to misoprostol enhances the completeness of abortion, reduces the need for surgical evacuation, and improves the overall reliability of the procedure.

Misoprostol dose requirements

This study demonstrated that the mifepristone + misoprostol group required fewer doses of misoprostol (~2.09 doses) compared to the Foley + misoprostol group (~2.39 doses). This difference, although modest, is clinically significant. It suggests that mifepristone enhances uterine sensitivity to prostaglandins and facilitates better cervical priming, thereby reducing the number of misoprostol doses required to induce complete abortion.

Consistent with these findings, Swathi et al reported that the mean misoprostol requirement in the mifepristone group was significantly lower (596±28.28 mcg) than in the misoprostol-only group (1148 ± 160.66 mcg), highlighting the drug-sparing effect of mifepristone.[12] Similarly, Sium et al found that a two-day interval between mifepristone and misoprostol led to significantly fewer misoprostol doses and faster expulsions than a one-day interval, supporting the efficiency of optimal mifepristone timing.[15]

In another randomized trial, Beishen demonstrated that combining mifepristone with either dry or moistened misoprostol tablets achieved high success with significantly reduced misoprostol exposure, reinforcing the additive benefits of combined regimens.[13]

Side effect

The present study found that both abortion regimens—Foley catheter with misoprostol and mifepristone with misoprostol—were generally well tolerated by patients, with more than 66% of participants in each group reporting no side effects. The most frequently observed adverse event was abdominal pain (19.7%), followed by vomiting (6.1%), bleeding (4.5%), and diarrhoea (1.5%), all of which were mild and managed symptomatically. These findings are consistent with those reported by Fonseca and Sah, who also observed a similar side effect profile, with abdominal pain being the most common complaint and a higher pain intensity associated with the Foley catheter group compared to the mifepristone group.[9] Likewise, Manku found that although the Foley catheter combined

with misoprostol led to faster abortion induction and reduced misoprostol dose requirements, it also resulted in higher discomfort levels than the mifepristone-based regimen.[16]

Furthermore, Kusumam et al compared mifepristone–misoprostol to mifepristone with Foley-based extra-amniotic saline infusion and observed that the mifepristone–misoprostol group had a higher rate of side effects, though the overall safety profile remained acceptable in both regimens.[17] Similarly, Gupta et al reported that the simultaneous use of mifepristone and misoprostol resulted in fewer gastrointestinal symptoms and a lower frequency of abdominal cramping than misoprostol alone, underscoring the improved tolerability of the combination regimen.[18] Lastly, a study by Kshetri et al on early pregnancy termination with oral mifepristone and sublingual misoprostol reported a similarly low incidence of side effects, confirming the consistency of this profile across gestational ages.[19]

Complications

In the present study, both abortion regimens showed a low overall complication rate, with no cases of sepsis, uterine rupture, or injury in either group. method failure occurred in 9.1% of cases in the Foley + misoprostol group, while no failures were observed in the mifepristone group. Blood transfusion was required in 1 case in the Foley group and 2 cases in the mifepristone group. Overall, 90.9% of all participants had no complications, reflecting a high safety profile for both approaches.

A similar low complication profile was reported by Sangeetha noted that 26% of patients in the Foley group had incomplete abortions compared to 10% in the mifepristone group, while 4% experienced method failure with Foley. Importantly, there were no major adverse outcomes, reinforcing the relative safety of both protocols.[10] In a retrospective review by Manku, 100% success was achieved in the Foley + misoprostol group, though the authors cautioned that nulliparous women and those with a lower Bishop Score had a higher risk of delayed response and complications such as incomplete expulsion.[16]

Yesmin et al, studying women with previous caesarean sections, found that adding mifepristone to Foley catheter significantly reduced complications, including the need for transfusion and surgical evacuation, without increasing the risk of scar rupture or infection.[20] Lastly, El-Refaey and Templeton highlighted the safety of mifepristone-misoprostol combinations in second trimester abortions, showing no increase in severe complications, even when administered via different prostaglandin routes. Their results supported its use in clinical protocols seeking low-risk, high-completion methods.[21] In conclusion, while both regimens are safe, the mifepristone + misoprostol regimen demonstrates a lower incidence of method failure and complications, supporting its preference in clinical practice for reliable and complication-free second trimester abortions.

Overall efficacy and comparative evaluation

When evaluating overall efficacy, the present study reveals that both Foley + misoprostol and mifepristone + misoprostol are effective regimens for second trimester abortion. distinct strengths were observed in each approach. The Foley group showed a significantly shorter induction-to-abortion interval (11.27±3.36 hrs), making it ideal in settings where time is a critical factor. On the other hand, the mifepristone group demonstrated superior completeness of abortion (100%), lower misoprostol dose requirements, and fewer surgical interventions—highlighting its reliability, patient comfort, and reduced procedural burden.

These findings are consistent with Fonseca and Sah, who concluded that although the Foley catheter led to faster expulsion (mean 20.11 hrs vs 54.77 hrs), the mifepristone group required fewer repeat doses and had higher patient satisfaction.[9] Kusumam et al also emphasized the higher 6- and 12-hour expulsion rates in the mifepristone-misoprostol group, despite the longer overall abortion duration, underlining its effectiveness when complete uterine evacuation is prioritized.[11]

Sium et al provided additional insight by showing that optimizing the timing of mifepristone (using a 2-day interval before misoprostol) enhanced both efficacy and speed, making it more adaptable to patient needs and facility scheduling.[15] Meanwhile Yesmin et al concluded that while Foley catheter methods are more cost-effective and faster, the risk of method failure and retained products is marginally higher compared to mifepristone-based regimens, especially in women with prior reproductive complications or low parity.[20] In summary, Foley + misoprostol may be preferred in resource-limited or time-sensitive contexts due to its shorter abortion duration, while mifepristone + misoprostol offers higher procedural success, reduced need for surgical interventions, and better patient tolerance, making it a clinically superior and more comprehensive regimen when available.

In conclusion, this comparative study highlights that while both Foley catheter with misoprostol and mifepristone with misoprostol are effective and safe methods for second trimester abortion, their strengths differ. Foley catheter offers a shorter induction-to-abortion interval, making it suitable for quicker terminations, particularly in low-resource or time-sensitive settings. mifepristone with misoprostol demonstrates superior outcomes in terms of complete expulsion rates, fewer required doses of misoprostol, reduced need for surgical evacuation, and a better overall side effect profile. These findings align with existing literature and underscore the importance of individualizing abortion protocols based on patient needs, institutional resources, and clinical priorities. Further large-scale, multicenter studies are recommended to

validate these findings and optimize second trimester abortion care.

Limitations

The study has several limitations. The small sample size of 66 participants limits the generalizability of the findings to the wider population. Being a single-centre study conducted in a tertiary care hospital, the results may not be applicable to rural or lower-resource settings. In addition, there was no long-term follow-up to assess delayed complications, future fertility outcomes, or patient satisfaction after abortion. Blinding was not feasible due to the nature of the interventions, which may have introduced observer bias in outcome assessment. Furthermore, the study did not include a cost-effectiveness analysis, which is an important consideration for decision-making in low-resource settings.

CONCLUSION

Foley catheter with misoprostol is a faster and cost-effective method, making it particularly suitable in low-resource settings or situations demanding shorter induction times. On the other hand, mifepristone with misoprostol provides a more complete and reliable uterine evacuation, reducing the need for surgical intervention. The choice between regimens should be guided by clinical context, drug availability, patient preference, and institutional resources. Both methods contribute meaningfully to safe second trimester abortion care when applied appropriately.

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