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Second Trimester Medical Abortion with Two Sequential Doses of Mifepristone Followed by Catheter Plus Misoprostol Versus Single Dose of Mifepristone Followed by Catheter with Misoprostol

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A B S T R A C T

Introduction- Although the majority of abortions occur in the first trimester, 13% are conducted during the second trimester worldwide due to delayed diagnosis of foetal defects and failure to identify an unwanted pregnancy in the first trimester. The present study was conducted to compare the effect of two sequential doses of mifepristone followed by catheter plus Misoprostol versus single dose of mifepristone followed by catheter with misoprostol in second trimester abortion.

Material and methods- The present comparative study was conducted at Dept of Obst & Gynae SMGS hospital for a study period of one year among 100 pregnant women who wants to get abortion in second trimester. Patients were divided into two groups GROUP A (50 patients) in which women were given two sequential doses of mifepristone followed by catheter plus Misoprostol and GROUP B (50 patients) in which women were given single dose of mifepristone followed by catheter with misoprostol. The Statistical Package for Social Sciences (SPSS for Windows version 25) was used to do the statistical analysis. Every statistical test was conducted at a significance threshold of $p > 0.05$ and was two-sided.

Results- In both groups, the predominant indication was foetal congenital abnormalities (88% in Group A compared to 86% in Group B). No statistically significant variation in indication distribution was seen ($p = 0.747$). The majority of patients in both groups exhibited a closed, uneffaced cervix, signifying an unfavourable cervical condition prior to therapy. In Group A (2-dose), 88% had a closed cervix, compared to 92% in Group B (1-dose). A minor percentage in both groups exhibited marginally more favourable results (cervix accommodating one finger with early effacement). Although not statistically significant ($p = 0.067$). Group A (2-dose mifepristone) had a significantly reduced Induction-to-Abortion Interval (IAI) (mean 3.54 ± 1.89 hours compared to 5.39 ± 2.09 in Group B; $p = 0.012$), and required fewer misoprostol doses on average (1.98 vs 2.37; $p = 0.02$). Both regimens were predominantly safe; however, Group B (1-dose) exhibited marginally elevated rates of mild problems such as fever, diarrhoea, and haemorrhage.

Conclusion – This comparative study concludes that administering two consecutive doses of mifepristone, followed by catheter induction and misoprostol, is a more efficacious. The two-dose regimen markedly decreases the induction-to-abortion duration and the necessary misoprostol dosage while preserving a favourable complication profile.

Keywords: Second trimester abortion, Mifepristone, Misoprostol, Cervical ripening, Induction-to-abortion interval

INTRODUCTION

The Medical termination of pregnancy Act (Act No. 34 of 1971) has been defined in its opening lines as 'An Act to provide for the termination of certain pregnancies by registered medical practitioners and for matters connected therewith or incidental thereto'. Passed by Parliament on August 10, 1971.The purpose of this act was to define the situations and circumstances in which safe abortion could be legally performed and to empower medical practitioners and institutions

delivering this service.[1] The incidence of MTP in INDIA is estimated to be 2.84 per 1000 women of reproductive years (15–49 years) out of which Second-trimester abortions account for 13% of all terminations.[2]

Unwanted pregnancies, contraceptive failure, financial or personal limitations, worries about maternal or foetal health, foetal abnormalities or genetic illnesses, or situations such as rape or incest are a few indications for choosing MTP.[3] In second trimester amongst the mechanical methods, Foleys induction and hygroscopic dilators (Dilapan-S) are the most commonly used methods and modern medical methods include induction with mifepristone and misoprostol, or with misoprostol alone. [4]

Mifepristone, an antiprogestin, enhances myometrial sensitivity and promotes cervical ripening, whereas misoprostol, a prostaglandin E1 analog, triggers uterine contractions to evacuate fetal tissue. Research has demonstrated the efficacy of the mifepristone-misoprostol regimen compared to misoprostol alone, resulting in decreased continuing pregnancy rates and shorter induction-to-abortion durations [5-10].

The conventional protocol typically comprises 200 mg of mifepristone, succeeded 36–48 hours later by misoprostol in split doses. Evidence suggests that 200 mg is equally efficacious as 600 mg when administered in combination, with both 1-day and 2-day intervals between the medicines demonstrating comparable efficacy [11,12]. Although certain studies investigated concurrent administration, findings indicated increased misoprostol demands and extended expulsion durations. Therefore, a 24 to 48-hour delay between mifepristone and misoprostol is the recommended regimen [13].

The ideal dose method for misoprostol is still under discussion. Protocols utilizing 800 mcg followed by 400 mcg every three hours are prevalent; however, recent studies indicate that reduced dosages (200 mcg every 3–4 hours) may demonstrate comparable efficacy with an advantageous safety profile, especially in scarred uteri. The notion of "unlimited dosing" within 48 hours following mifepristone administration has demonstrated elevated success rates and tolerability, hence diminishing the necessity for surgical evacuation [14,15].

In this context, our study seeks to assess the efficacy, safety, and expulsion duration of two sequential doses of mifepristone followed by catheter insertion with misoprostol compared to the standard single-dose mifepristone followed by catheter and misoprostol in second-trimester medical abortions. This comparison may yield significant insights for optimizing dosage regimens, enhancing abortion results, and reducing complications.

MATERIAL AND METHODS

The present comparative study was conducted at Dept of Obst & Gynae SMGS hospital for a study period of one year among pregnant women who want to get abortion in second trimester. Ethical clearance for conducting the research was taken from institutional ethics of college and hospital. Informed consent form was signed from patients after explaining them the complete procedure of the study.

Through convenient sampling a total 100 patients who want to get abortion in second trimester were selected on the basis of inclusion and exclusion criteria.

Inclusion criteria

- Patients who are willing to give consent for the study.
- 14 weeks till 24-week period of gestation
- Age 18 to 45 years.

Exclusion criteria

- Patients who are unwilling to give consent for the study.
- Patients with prior 2 or more uterine surgeries
- Comorbidities like heart disease, uncontrolled hypertension, uncontrolled diabetes
- Contraindication to mifepristone or misoprostol like chronic adrenal failure or on any immunosuppressants.
- Disseminated Intravascular Coagulation
- Severe Anaemia

Patients were divided into two groups-

GROUP A (50 patients) in which women were given two sequential doses of mifepristone followed by catheter plus Misoprostol

GROUP B (50 patients) in which women were given single dose of mifepristone followed by catheter with misoprostol
The critical outcome reported was ongoing pregnancy. The secondary outcomes included safety issues such as serious maternal complications (excessive bleeding due to incomplete expulsion necessitating surgical evacuation of the retained products of conception, blood transfusion, uterine rupture or cervical laceration, pelvic infection), patient acceptability

(whether patients would opt for the same method again), satisfaction (whether patients were satisfied with the method) and side effects (e.g., nausea, vomiting, diarrhoea and fever).

All quantifiable data were examined for normality, and the Mann-Whitney test (for skewed or ordinal data) and Student's paired t test (for normally distributed data) were used to compare means. Descriptive statistics, either the mean ± SD or the median, were used to present the data. The Chi-Square test was used to examine the relationship between the two groups in category or categorized data. The Statistical Package for Social Sciences (SPSS for Windows version 25) was used to do the statistical analysis. Every statistical test was conducted at a significance threshold of $p > 0.05$ and was two-sided.

RESULTS

Table 1 compares the baseline characteristics between the two study groups (n = 50 each). The average age, parity, gestational age, BMI, and haemoglobin levels exhibited no significant differences (all p-values > 0.05), affirming that the two groups were demographically and clinically equivalent at baseline. The majority of women were between 16 and 20 weeks of gestation. The distribution of parity and history of prior caesarean sections was uniform.

Table 1 Baseline characteristics

Parameter	Group A	Group B	p-value
Mean age in years ± SD	27.65 ± 4.49	26.97 ± 4.43	0.282
Mean parity ± SD	0.73 ± 0.89	0.73 ± 0.90	0.353
Range	0–4	0–4	
Nullipara + Primigravida	50% (25)	49% (25)	
Multipara without previous CS	35% (18)	43% (22)	
Multipara with previous CS	15% (7–8)	7% (3–4)	
Mean gestation in weeks ± SD	18.14 ± 2.07	18.19 ± 1.98	0.871
Range (weeks)	13–21	13–21	
13 to 16 weeks	18% (9)	13% (7)	
16+ to 20 weeks	82% (41)	87% (43)	
Mean BMI (kg/m²) ± SD	25.12 ± 2.49	24.62 ± 2.99	0.124
Range	18.3–32.0	18.7–34.7	
Mean hemoglobin (gm/dl) ± SD	10.17 ± 1.09	10.03 ± 1.20	0.310
Range	8–13.9	8–13.9	

Table 2 shows the indications for abortion as stipulated by the provisions of the MTP Act. In both groups, the predominant indication was foetal congenital abnormalities (88% in Group A compared to 86% in Group B). Other factors, including unintended pregnancy, severe maternal health issues, and contraceptive failure, were less prevalent. No statistically significant variation in indication distribution was seen (p = 0.747), indicating that both groups experienced similar clinical conditions for second-trimester abortions.

Table 2 Indications for Abortion

Indication	Group A	Group B	p-value
Life-threatening medical disorders	1% (0–1)	2% (1)	0.747
Unwanted pregnancy	8% (4)	11% (6)	
Fetal congenital malformations	88% (44)	86% (43)	
Contraception failure	3% (1–2)	1% (0–1)	

Table 3 shows the cervical status prior to the intervention. The majority of patients in both groups exhibited a closed, uneffaced cervix, signifying an unfavourable cervical condition prior to therapy. In Group A (2-dose), 88% had a closed cervix, compared to 92% in Group B (1-dose). A minor percentage in both groups exhibited marginally more favourable results (cervix accommodating one finger with early effacement). Although not statistically significant (p = 0.067).

Table 3 Initial Cervical Findings (Day 1, Before Mifepristone)

Cervical Status	Group A	Group B	p-value
Cervix (external os) closed and uneffaced	88% (44)	92% (46)	0.067
Cervix (external os) admitting 1 finger and early effaced	12% (6)	8% (4)	

Table 4 shows the comparison of outcomes of second trimester abortion. Group A (2-dose mifepristone) had a significantly reduced Induction-to-Abortion Interval (IAI) (mean 3.54 ± 1.89 hours compared to 5.39 ± 2.09 in Group B; p = 0.012), and required fewer misoprostol doses on average (1.98 vs 2.37; p = 0.02). On Day 3, cervical status indicated superior advancement in Group A, with a greater number of patients attaining favourable cervical modifications. Group B experienced a somewhat reduced hospital stay (6.64 vs 6.98 days; p = 0.02).

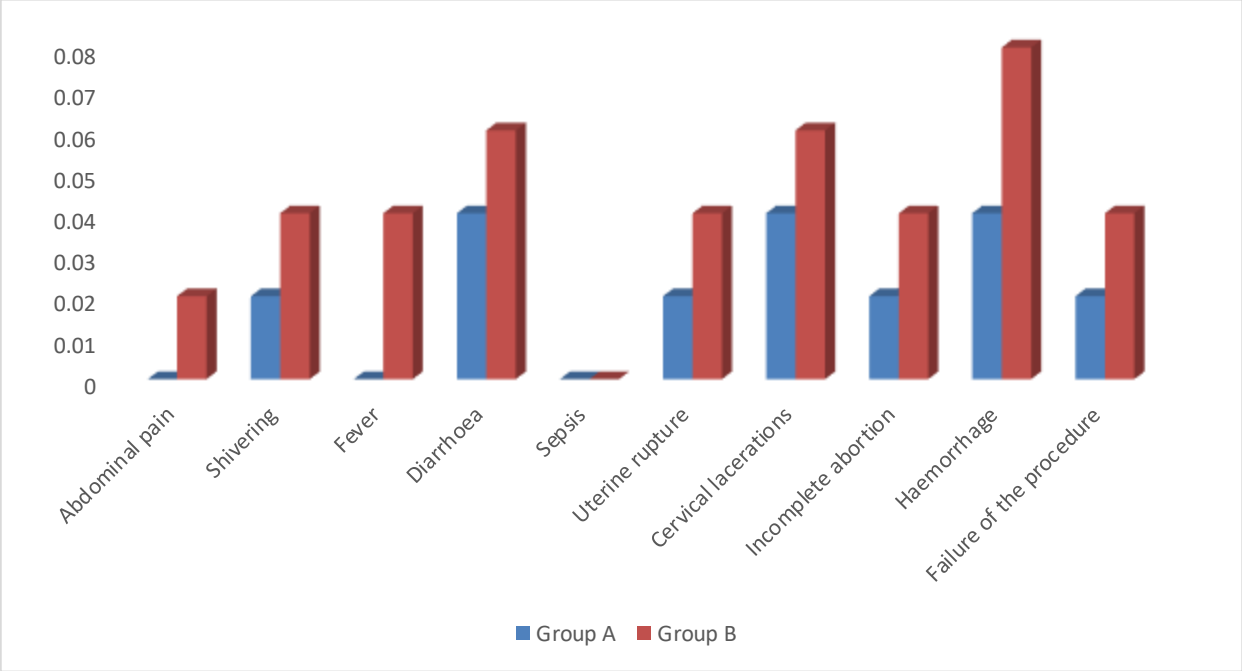
Table 4 Comparison of outcomes of second trimester abortion

Outcomes		Group A	Group B	P value
Mean IAI		3.54±1.89	5.39±2.09	0.012
Mean number of misoprostol dose required		1.98±0.87	2.37±1.87	0.02
Subsequent cervical findings on day 3	Cervix closed and uneffaced	30 (60)	45 (90)	0.001
	Cervix admitting 1 finger and early effaced	20 (40)	15 (10)	
Mean number of hospital days		6.98±2.3	6.64±1.7	0.02

Table 5, graph 1 shows maternal side effects and problems. Both regimens were predominantly safe; however, Group B (1-dose) exhibited marginally elevated rates of mild problems such as fever, diarrhoea, and haemorrhage. Uterine rupture, however infrequent, was observed in 1 patient from Group A and 2 patients from Group B. Incomplete abortion and cervical lacerations were somewhat more prevalent in Group B.

Table 5 Comparison of complications between two groups

Complications	Group A	Group B
Abdominal pain	0	1 (2)
Shivering	1 (2)	2 (4)
Fever	0	2 (4)
Diarrhoea	2 (4)	3 (6)
Sepsis	0	0
Uterine rupture	1 (2)	2 (4)
Cervical lacerations	2 (4)	3 (6)
Incomplete abortion	1 (2)	2 (4)
Haemorrhage	2 (4)	4 (8)
Failure of the procedure	1 (2)	2 (4)



Graph 1 Comparison of complication rate among two groups

DISCUSSION

Second-trimester abortion is an essential aspect of reproductive healthcare, especially in instances of foetal malformations, maternal health threats, or socio-economic considerations recognised post-first trimester. Although essential, second-trimester abortion presents greater therapeutic challenges than first-trimester termination, frequently linked to elevated complication rates, extended expulsion durations, and heightened mental suffering.[2] The present study was conducted to compare the effect of two sequential doses of mifepristone followed by catheter plus Misoprostol versus single dose of mifepristone followed by catheter with misoprostol in second trimester abortion.

In the present investigation, the two-dose mifepristone cohort (Group A) demonstrated a markedly reduced induction-to-abortion interval (3.54 ± 1.89 hours) in contrast to the single-dose cohort (Group B) (5.39 ± 2.09 hours). This discovery corresponds with the findings of Prodan N et al , who indicated that extending the gap between mifepristone and misoprostol, together with optimising the priming dose, diminished expulsion durations.[16] Furthermore, a randomised trial conducted by Ngoc NTN et al demonstrated that the administration of mifepristone prior to misoprostol markedly enhanced the efficiency of abortion, particularly when given for a duration beyond 24 hours.[17]

The average number of misoprostol doses needed was fewer in the two-dose group, corroborating the findings of Tang OS et al, who observed that a well-primed cervix diminishes the necessity for prostaglandin doses and related side effects.[18] Minimising misoprostol exposure may be particularly advantageous for individuals with a history of uterine surgery, due to the established risk of uterine rupture associated with excessive prostaglandin use. [19]

On Day 3, cervical condition was more advantageous in Group A, as a greater number of patients attained partial dilatation. This corroborates earlier study by Blum J et al. (2007), which indicated that several doses of mifepristone yield enhanced cervical ripening relative to single-dose protocols.[20]

The complication rates in both groups were minimal, with only minor adverse effects noted, including fever and diarrhoea. These occurrences were more prevalent in the single-dose group, while not statistically significant. The occurrence of uterine rupture was minimal however evident in both cohorts, aligning with previous case studies (Silva C et al).[21] The utilisation of a Foley catheter in conjunction with pharmacologic drugs likely facilitated improved cervical preparedness and less mechanical resistance during expulsion, as indicated by Ngo et al. [17]

The prevalence of foetal abnormality as the reason for abortion in both groups (86%-88%) indicates current trends in prenatal screening and diagnosis. According to data from the WHO and the Guttmacher Institute, enhanced access to second-trimester ultrasounds and abnormality scans has resulted in an increase in medically necessary abortions beyond 13 weeks.

Notwithstanding the encouraging results, this study possesses limitations. The study was performed at a singular tertiary care facility with a somewhat small sample size. The non-randomized allocation and open-label approach may result in selection and observer bias. Future investigations should examine long-term reproductive results, cost-effectiveness, and patient-reported satisfaction metrics related to two-dose procedures.

CONCLUSION

This comparative study illustrates that administering two consecutive doses of mifepristone, followed by catheter induction and misoprostol, is a more efficacious and comparably safe approach for second-trimester medical abortion than the single-dose strategy. The two-dose regimen markedly decreases the induction-to-abortion duration and the necessary misoprostol dosage while preserving a favourable complication profile. This protocol may improve patient experience, alleviate provider workload, and maximise resource utilisation in healthcare environments. These findings endorse the use of sequential mifepristone dosing as a preferred method in second-trimester abortion methods, particularly when prompt and effective uterine evacuation is sought.

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