

RESEARCH ARTICLE

Outcome of Combined Mifepristone and Misoprostol Versus Misoprostol Alone in the Management of First Trimester Abortion

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Abstract

Background: Early abortion is a frequent pregnancy complication, occurring in 10- 20% of clinically diagnosed pregnancies. Abortion can cause heavy bleeding, infection, anxiety, sadness, and post traumatic stress disorder (PTSD).

Aim: This study compares mifepristone and misoprostol for first-trimester abortion against misoprostol alone.

Methods: Approval of the protocol was taken by the Institutional Ethical Committee of ICMH, Matuail, Dhaka before the commencement of the study. This Randomised Controlled Trial was conducted Department of Obstetrics & Gynaecology, Institute of Child and Mother Health, Matuail, Dhaka on 70 women with first trimester abortion with prefixed specific inclusion and exclusion criteria. Participants were divided into Group A and Group B based on offered intervention. Group A received 200mg mifepristone and misoprostol 800µg orally and group B received only misoprostol 800µg orally. The expected primary outcome was successful expulsion of conception. The secondary outcome included number of doses for successful expulsion, time interval between first dose and spontaneous expulsion and side effects. Data were processed manually and analyzed with the help of SPSS Version 26.0. Quantitative data were expressed in mean and standard deviation; and comparison was done between the groups by independent sample “t” test. Qualitative data were expressed in frequency and percentage; and comparison was done between groups by Chi-square / Fisher’s Exact test. A probability value of <0.05 is considered statistically significant.

Result: In regard to the observed results, it was shown that Group A exhibited a higher rate of successful expulsion of conceptions (77.8%) compared to Group B (50%). The average number of doses required for effective expulsion in Group A was found to be lower (2.19±0.69) compared to Group B (3.41±2.53%). The duration of successful expulsion was found to be shorter in group A (14.28±3.84) compared to group B (20.93±5.67). Combination group exhibited a low incidence of maternal problems (33.3%). The duration

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of hospitalization was notably shorter in group A. All relationships exhibited statistical significance at a significance level of $p < 0.05$.

Conclusion: Combined regimen of mifepristone and misoprostol appears to be a more effective, safer, and efficient approach for first-trimester pregnancy terminations compared to using misoprostol alone.

1. Introduction

“Abortion is the termination of pregnancy by any means before the foetus is sufficiently developed to survive. (Malhotra, N., et al.2018). First trimester abortion is one of the most common complication of pregnancy occurring in 10-20% of clinically recognized pregnancies (American College of Obstetricians and Gynecologists, 2018). There are two main type of First trimester Abortion include incomplete abortion and missed abortion that require medical intervention (Chu, J.J., et al.2020). A Missed abortion, also known as a delayed or silent abortion is diagnosed when non-viable pregnancy is identified on USG scan during first 12^{6/7} weeks of gestation (American College of Obstetricians and Gynecologists, 2018). Often women who have missed abortion are asymptomatic or have small amount of vaginal bleeding or pain before the diagnosis is made. All pregnancy tissue is retained in the uterus in a missed abortion. By contrast an incomplete abortion is diagnosed when pregnancy tissue have been partly expelled by the uterus (Chu, J.J., et al.2020). If women do not abort spontaneously they will undergo medical or surgical treatment in order to remove the product of conception from the uterus (Van den Berg, J., et al.2019). According to ACOG (American college of obstetricians and Gynecologists) & RCOG (Royal College of obstetricians and Gynecologists) advantage of medical treatment is safe, effective and acceptable alternative and it is used in off-label for several obstetric and gynecologic indications (Van den Berg, et al.2019). Surgical evacuation also might be preferable in other situations, including the presence of medical comorbidities such as severe anemia, bleeding disorders, or cardiovascular disease. Many women prefer surgical evacuation to expectant or medical treatment because it provides more immediate completion of the process with less follow-up (American College of Obstetricians and Gynecologists, 2018). Medical management for early pregnancy loss can be considered in women without infection, haemorrhage, severe anemia, or bleeding disorders who want to shorten the time to complete expulsion but prefer to avoid surgical evacuation. Mifepristone is the only Anti progestin approved for

the induction of abortion. It is a 19 norsteroid which bind with high affinity to the progesterone receptor thus inhibiting the effect of progesterone. The blocking the progesterone receptors by mifepristone results in vascular damage, decidual necrosis and bleeding which lead to cervical softening, increased uterine sensitivity to PG and conversion of the quiet pregnant uterus into an organ of spontaneous activity with maximal effect of 36-48 hours (Gemzell-Danielsson., et al.2008). For other indication such a labour induction in case of fetal death after the first trimester and also for the medical termination of viable pregnancy (Van den Berg, J., et al.2019). Misoprostol is a Synthetic PGE1 analogue which induces cervical ripening as well as strong uterine contractions and leads to expulsion of a pregnancy (Bhaskar et al., 2018). However, misoprostol is not always effective and 15-40% of women require an additional dose of misoprostol, thus prolonging the duration of treatment. To augment the effect of Misoprostol, a steroidal anti progesterone called mifepristone is sometimes used in combination. The reported effectiveness of combination treatment with mifepristone and misoprostol for the medical management of first trimester abortion in proving previous clinical trial has ranged from 64% to 84% (Chu, J.J., et al.2020.). Other trials found that pretreatment with misoprostol plus mifepristone did not improve success rates. Due to these conflicting results this study is designed to compare of outcome of combined mifepristone and misoprostol with misoprostol alone in the management of first trimester abortion, in order to have a ripe, dilated cervix and expulsion of product of conception.

2. Methodology

Study design: It was a Randomized Controlled trial (RCT).

Study place: The study was conducted in the Department of Obstetrics & Gynaecology, Institute of Child and Mother Health, Matuail, Dhaka.

Study period: The study was conducted for 12 months (January 2023-December 2023).

Study Population: All patients with first trimester abortion, admitted in Department of Obstetrics and

Gynaecology, Institute of Child & Mother Health, Matuail Dhaka for expulsion of the product of conception and fulfilling the inclusion and exclusion criteria were enrolled as study population.

Sampling technique: Random sampling technique was applied to enroll the subjects.

2.1 Patients Selection Criteria

Inclusion criteria:

1. Women with first trimester abortion with a period of gestation up to 12 weeks (Ultrasonography diagnosis).
2. Haemodynamically stable women.
3. Afebrile.
4. Willingness and ability to sign the informed consent.

Exclusion criteria:

- Patients age less than 16 years.
- Hemodynamic instability.
- Signs of infection.
- Contraindications for mifepristone or misoprostol.
- Potential interaction between study medication and other medication.
- Known case of clotting disorder.
- Use of anticoagulants
- Presence of cardiovascular disease

Study procedure: All patients in this study were admitted to the Department of Obstetrics and Gynecology, Institute of Child & Mother Health, Matuail, Dhaka. Detailed history, general, and gynecological examinations were carried out. The demographic characteristics of each patient was assessed including age, body weight, gravidity, parity, history of previous miscarriages, and gestational age that was determined by last menstrual period. Investigations were conducted for each patient including complete blood picture, renal function tests, liver function tests, Blood grouping. Rh typing and coagulation profile. Informed written consent was obtained from the patients or guardians after full explanation of the purpose of the study. They were informed of their right to withdraw from the study. Seventy women with first trimester abortion satisfying the inclusion and exclusion criteria were selected in this study.

Grouping of the sample: Both of the groups in this study were selected by lottery. Each patient/ guardian was offered two sealed envelope containing folded piece of paper bearing letter A or B and was requested to pick up one of these. Those who picked A were selected for group- A and those who picked B were selected for group-B.

Intervention: In Group A 200mg mifepristone was given on empty stomach in such a way that mifepristone was placed orally for half an hour than swallowed. After 24 hours two doses of misoprostol 400µg were given orally 4 hours apart. In Group B only two doses of misoprostol 400µg were given orally, 4 hours apart. If no tissue is lost after 24 hours two more doses of oral misoprostol 400 µg (4 hour apart) were given to both group approximately 24 hours after the first course. After 2 weeks, complete, incomplete or no expulsion were documented by trans abdominal ultrasound. Regular monitoring of patients for blood pressure, pulse, temperature at 4 hourly interval were carried out. Patients were observed for abdominal pain, uterine contractions and vaginal bleeding. Rh-negative women were given 150 microgm of anti D immunoglobulin. Surgical evacuation was performed in case of heavy vaginal bleeding or when trans abdominal ultrasound did not document a complete expulsion after 2 weeks. The primary outcome evaluated drug induced complete or incomplete evacuation. Secondary outcome evaluated dose, time interval, patient satisfaction, complications, side effects and costs. All relevant findings were recorded in a pre-designed data collection sheet designed for the study.

Data collection: Patients were selected from the department of Obstetrics and Gynaecology, Institute of Child and Mother Health, Matuail, Dhaka. After explaining the study objectives, informed written consent was taken. Structured questionnaire was filled up regarding the clinical history and laboratory findings already in hand. Abdominal ultrasonogram was carried out for all cases, which was supervised by expert supervisor.

Methods of collection of data: Sample was selected through simple random sampling method from patients with first trimester abortion. History and physical examination of each patient were taken and recorded. A questionnaire was filled up by the investigator which will contain information about particulars of the patient including Age, socioeconomic condition, smoking, alcohol and drug history, other co-morbidities and

presenting complains such as abdominal pain, p/v bleeding, vomiting, anorexia, jaundice. Laboratory and radiological investigation were also recorded.

Data processing and analysis Data were processed manually and analyzed with the help of SPSS (Statistical package for social sciences) Version 26.0. Quantitative data were expressed in mean and standard deviation; and comparison was done between the groups by independent sample “t” test. Qualitative data were expressed in frequency and percentage; and comparison was done between groups

by Chi-square (χ^2). A probability value of <0.05 ($p<0.05$) was considered statistically significant.

3. Results

This RCT was conducted on all patients with first trimester abortion, admitted in Department of Obstetrics and Gynaecology, Institute of Child & Mother Health, Matuail, Dhaka. In this study participants who were treated with combined mifepristone and misoprostol were included in Group-A & those who were treated with misoprostol alone were included in Group-B.

Table 1. Distribution of the participants according to sociodemographic characteristics

Age	Group A (n=36)	Group B (n=34)	P Value
18-28	26 (52%)	24 (48%)	^a 0.880 ^{ns}
>28	10 (40%)	10 (50%)	
Mean \pm SD	26.33 \pm 6.35	24.94 \pm 5.35	^b 0.326 ^{ns}
Median (min-max)	24 (18-42)		

Data expressed as frequency (percentage) mean \pm SD, median (min-max), a= chi-square test, b= independent sample t-test ns=non-significant.

In Group A: 52% of participants are in the age range of 18-28 (26 out of 36). The mean age of Group A participants is 26.33 years with a standard deviation (SD) of 6.35. In Group B: 48% of participants are in

the age range of 18-28 (24 out of 34). The mean age of Group B participants is 24.94 years with a standard deviation (SD) of 5.35.

Table 2. Distribution of the participants according to chief complaints

Variables	Group A (n=36)	Group B (n=34)	P Value
Amenorrhoea for (weeks)			
Mean \pm SD	9.39 \pm 2.72	10.06 \pm 2.95	^b 0.328 ^{ns}
Median (min-max)	10 (5-12)		
Presenting complaints			
Lower abdominal pain	4 (11.1%)	7 (20.6%)	0.
P/V bleeding	8 (22.2%)	3 (8.8%)	^a 0.209 ^{ns}
Pain + bleeding	24 (66.7%)	24 (70.6%)	

The duration of amenorrhoea is presented in terms of mean (average) values, standard deviations (SD),

and the median duration along with the minimum and maximum values observed.

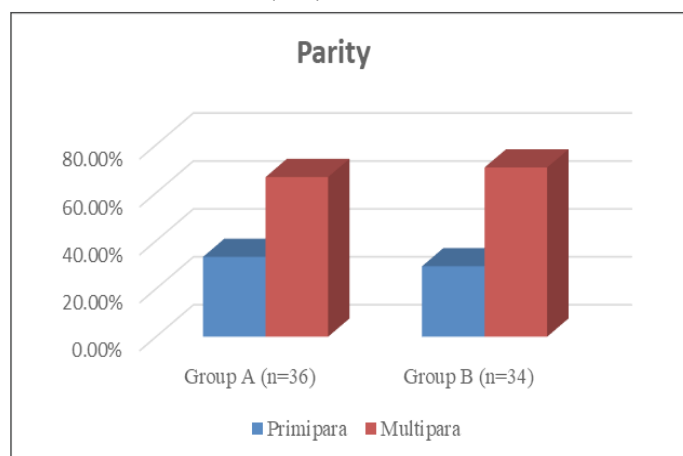


Figure 1. Distribution of the participants according to parity

The study compared parity between Group A (n=36) and Group B (n=34). In Group A, 12 participants (33.3%) were primipara, while 24 participants (66.6%) were multipara. In Group B, 10 participants (29.4%) were primipara and 24 participants (70.6%) were

multipara. The P value for the difference in parity between the two groups was 0.940, indicating no significant difference (ns) between Group A and Group B.

Table 3. Distribution of the participants according to past obstetric history of multipara patients

Past obstetric history	Group A (n=24)	Group B (n=24)	P Value
Vaginal delivery	24 (100%)	20 (87%)	^c 0.233 ^{ns}
Instrumental delivery	0	2 (4.3%)	
Caesarean delivery	0	2 (8.7%)	

In Group A, 24 participants (100%) have a history of vaginal delivery, while in Group B, 20 participants (87%) have also had vaginal deliveries. Instrumental delivery: In Group A, there are no participants who have experienced instrumental delivery, while in Group B, 2 participants had a history of instrumental delivery. Caesarean delivery: In Group A there are no participants with a history of caesarean delivery and Group B had 2 participants.

Table 4. Distribution of the participants according to general examination

Variables	Group A (n=36)	Group B (n=34)	P value
Anemia			
Absent	28 (77.8%)	22 (64.7%)	^c 0.283 ^{ns}
(+)	8 (22.2%)	9 (26.5%)	
(++)	0	2 (5.9%)	
(+++)	0	1 (2.9%)	
Pulse	75.28±4.31	75.35±3.44	^b 0.936 ^{ns}
SBP	106.47±8.86	104.41±10.27	^b 0.377 ^{ns}
DBP	71.12±8.24	70.91±8.05	^b 0.917 ^{ns}

There was no statistically significant difference of anemia status, pulse, SBP and DBP between two groups.

Table 5. Distribution of the participants according to per speculum examination

Variables	Group A (n=36)	Group B (n=34)	P value
Internal OS			
Close	21 (58.3%)	19 (55.9%)	a0.836 ^{ns}
Open	15 (41.7%)	15 (44.1%)	
Bleeding through OS			
Absent	6 (16.7%)	3 (8.8%)	c0.736 ^{ns}
Present	29 (80.6%)	30 (88.2%)	
Scanty	1 (2.8%)	1 (2.9%)	

Data expressed as frequency (percentage) a= chi-square test

c= Fisher's Exact test ns=non- significant

No statistical difference was seen in both groups in terms of per specular examination

Table 6. Distribution of the participants according to bimanual examination

Variables	Group A (n=36)	Group B (n=34)	P value
Uterus Size	10.50±2.17	11.0±1.72	^b 0.422 ^{ns}
Cervical length	2.58±0.55	2.88±0.48	^b 0.022 ^s
Cervical consistency			
Firm	21 (58.3%)	17 (50%)	^a 0.484 ^{ns}
Soft	15 (41.7%)	17 (50%)	

Data expressed as frequency (percentage) and mean ±SD

The mean uterus size is provided for both groups, along with their respective standard deviations (SD).

The p-value for this variable is 0.422, indicating no statistically significant difference. Cervical length was bigger in group B than group A which was statistically significant (p<0.022). There was no

statistical difference in terms of cervical consistency between two groups.

The study also categorized the participants based on specific gestational conditions and the presence of echogenic structures. Anembryonic gestation was observed in 10% of the cases. Missed abortion

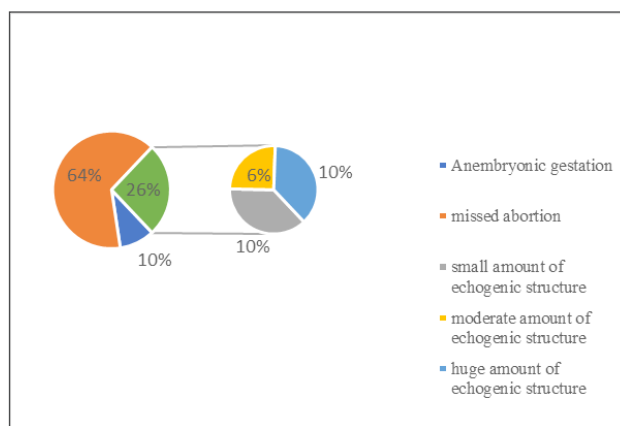


Figure 2. Sonographic findings of women with first trimester abortion

occurred in 64% of the participants. 26% presented the cases, while a moderate amount was present in with incomplete abortion. Among them; a small amount of echogenic structure was found in 10% of the cases, while a huge amount of echogenic structure was noted in 10% of the cases.

Table 7. Distribution of the participants according to outcome parameters

Variables	Group A (n=36)	Group B (n=34)	P value
Successful expulsion of retained product of conception confirmed by USG			
Yes	28 (77.8%)	17 (50%)	a0.015s
No	8 (22.2%)	17 (50%)	
Number of doses of misoprostol for successful expulsion of retained product of conception			
Mean±SD	2.19±0.69	3.41±2.53	b0.023s
Time interval between first dose and successful expulsion of retained product of conception in hours			
Mean±SD	14.28±3.84	20.93±5.67	b0.001s

In Group A, 77.8% of participants had a successful expulsion, while 22.2% did not. In Group B, 50% of participants had a successful expulsion, while 50% did not. The difference was statistically significant (p=0.015). It was seen that significantly less dose was needed for successful expulsion in group A than group B. Time interval of first dose and successful expulsion was significantly less in group A than group B.

Table 8. Distribution of the participants according to side effects

Maternal complications	Group A (n=36)	Group B (n=34)	P value
Yes	12 (33.3%)	22 (58.8%)	^a 0.032 ^s
No	24 (66.7%)	12 (41.2%)	

Group B had more maternal complications (58.8%) than group A (33.3%).

Table 9. Distribution of the participants according to side effects

Side effects	Group A (n=12)	Group B (n=22)	P value
Vomiting	2 (33.3%)	4 (66.7%)	^a 0.354 ^{ns}
Diarrhea	1 (33.3%)	2 (66.7%)	^a 0.522 ^{ns}
Severe pain	2 (33.3%)	4 (66.7%)	^a 0.354 ^{ns}
Hyperpyrexia	0	1 (100%)	^a 0.300 ^{ns}
Excessive blood loss	5 (50%)	5 (50%)	^a 0.922 ^{ns}
Headache	2 (25%)	6 (75%)	^a 0.112 ^{ns}

Although patients of group B suffered from more side effects than group a but there was no statistical significance.

Table 10. Distribution of the participants according to requirement of blood transfusion

Blood transfusion	Group A (n=36)	Group B (n=34)	P value
Yes	1 (14.3%)	6 (85.7%)	a0.044s
No	35 (55.6%)	28 (44.4%)	
Total hospital admission days			
Mean±SD	0.85±0.36	1.05±0.47	b0.049s

Group B needed more blood transfusion (85.7%) than group A. Even hospital stay was significantly less in group A. All associations were statistically significant (p<0.05).

4. Discussion

A Randomized Controlled Trial (RCT) took place in the Department of Obstetrics and Gynaecology at the Institute of Child & Mother Health in Dhaka. The study focused on patients undergoing first-trimester abortions, and meeting specific inclusion and exclusion criteria were selected for the study. They were then divided into two groups: Group A: received a combination of 200mg mifepristone and misoprostol 800µg, while Group B received only misoprostol 800µg orally. The mean age of the participants was approximately 25.66 years with a standard deviation of 5.88. Both groups had similar age distributions, indicating that the age range was consistent among the participants in both Group A and Group B. The participants presented with an average amenorrhea duration in group A about 9.39 weeks with a standard deviation of 3.72 and in group B about 10.06 weeks with a standard deviation of 2.95. Regarding past obstetric history, it appears that there was a difference between the groups. In Group A, all participants had a history of previous vaginal deliveries. Meanwhile, in Group B, 87% had previous vaginal deliveries, and a smaller percentage, around 8.7%, had prior caesarean deliveries and 4.3% had prior instrumental deliveries. These obstetric characteristics were somewhat reflective of the studies included in Abubeker et al., (2020). The general examination findings indicated that more than half of the participants in both groups were non-anemic. However, Group B had a higher proportion of anemic participants compared to Group A. Despite this difference, statistical analysis revealed no significant variation in anemia status between the two groups. The mean size of the uterus was similar in both groups, averaging around 10-11 weeks, with no statistically significant difference noted in uterine size between Group A and Group B. These parameters were similar as Wingo et al., (2020). In the per speculum examination, it was observed that approximately 58.3% of group A and 55.9% of Group B's participants had a closed internal os. Bleeding through the os was present in roughly 80.6% of Group A's subjects and about 88.2%, in the participants of Group B. A statistically significant difference (with a p-value of 0.022) was identified in the cervical length between the two groups. This difference suggested that Group B had a longer cervix compared to Group A. Additionally, more than half of the participants in each group had a firm cervix. The outcomes between the two groups

showed differences in the successful expulsion of the conceptus. Group A exhibited a higher rate of successful expulsion at 77.8% compared to 50% in Group B. "Complete expulsion was achieved more (about 80%) in women treated with a combination of mifepristone and misoprostol versus women treated with misoprostol alone".---this was the conclusive findings of the study by Van den Berg et al., (2014) ; Hamel et al., (2021) which supported our findings. Additionally, the mean number of doses required for successful expulsion was lower in Group A (2.19 ± 0.69) compared to Group B (3.41 ± 2.53). Jain et al., (2002); Chu et al., (2020) found similar finding that only 14% of the combination group required further increasing doses to achieve success. The time required for spontaneous expulsion was also notably less in Group A (14.28 ± 3.84) compared to Group B (20.93 ± 5.67). Wingo et al., (2020) also found that use of combination drug requires less time to expulsion than misoprostol alone group. The comparison between the groups revealed that Group B experienced a higher incidence of maternal complications at 58.8%, whereas Group A had a lower incidence at 33.3% which has shown a similar prevalence by the study Hamel et al., (2021). Additionally, Group B required more blood transfusions, with 85.7% of participants needing this intervention, compared to Group A. Moreover, the hospital stay was significantly shorter for participants in Group A compared to Group B which was also supported by the findings of Dunford and Fyfe, (2018). These differences in maternal complications, the need for blood transfusions, and hospital stay were all statistically significant (with a p-value less than 0.05). It's also worth noting that while patients in Group B suffered more side effects than those in Group A, this difference did not reach statistical significance. Van den Berg et al., (2014) opposed our findings, they found the hemorrhage to be more in combination group. But Ngoc et al., (2011) supported our findings fully. These findings indicate that the method used in Group A resulted in a higher success rate for conceptus expulsion, requiring fewer doses and less time for expulsion compared to the method used in Group B.

5. Conclusion

The combined use of mifepristone and misoprostol for pregnancy termination demonstrated significant advantages over the use of misoprostol alone. The study revealed that with the combined intervention, patients experienced higher rates of successful

expulsion of the conceptus, requiring fewer doses and less time for successful expulsion compared to only misoprostol. The combination group had a lower incidence of maternal complications, a reduced need for blood transfusions, and shorter hospital stays. These suggests that the combined regimen is more effective and efficient in inducing expulsion in first-trimester abortions.

Limitations

Reduce sample size compared to calculated sample was taken due to time constrain in academic calendar

Single center study

Short follow-up period

Recommendations

Long-Term Follow-up

Multi-center study

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