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Original Article

Effectiveness and Outcome of Mifepristone and Misoprostol for Early Abortion — A Single-Centre Study

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ABSTRACT

Introduction: *About 56 million induced abortions occurred each year worldwide and about 1.2 million induced abortions occurred each year in Bangladesh. Maternal mortality in Bangladesh is 1.76 /1000 live birth, one fourth of these deaths are due to complication of induced abortion.* ***Objective:*** *To assess the effectiveness, outcome, and safety of use of combination of mifepristone and misoprostol in inducing early abortion in Gynae OPD of Dhaka National Medical Institute and hospital.* ***Methods & Materials:*** *This was a prospective cross sectional study of 70 outpatients seeking menstrual regulation (by MRM) within nine weeks (63 days) of a missed period was conducted at a Gynae OPD of Dhaka National Medical Institute and hospital from July 2023 to December 2023.* ***Results:*** *This study analyzed the demographic and clinical outcomes of first-trimester medical abortions in 70 participants, primarily young adults aged 19 to 29 (97.14%). Most were multigravid, with 41.43% in their second pregnancy. Expulsion typically occurred within 4 hours of treatment, with the highest success rates observed at earlier gestational stages—96.67% for pregnancies between 4 and 6 weeks, and 95.24% for 6 to 8 weeks. Side effects included per vaginal bleeding of variable amount (100%), uterine cramps (74.28%), nausea (35.71%), and fever (30%), with no cases of uterine rupture. Only three cases required surgical intervention due to failed medical abortions.* ***Conclusion:*** *This study demonstrates the high effectiveness and safety of medical abortions using mifepristone and misoprostol in the first trimester, particularly at earlier gestational stages.*

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INTRODUCTION

Medical abortion is a non-surgical method of terminating early pregnancies using medications like mifepristone and misoprostol. It's generally safe and effective, offering a convenient alternative to surgical procedures.

Mifepristone and misoprostol, when used in combination, have become a widely recognized and effective method for terminating early pregnancies. Mifepristone is a progesterone receptor antagonist that blocks the action of progesterone, a hormone essential for maintaining pregnancy. Misoprostol is a prostaglandin analog that induces uterine contractions, leading to the expulsion of the uterine contents. Despite a relatively high contraceptive prevalence rate (61%) compared to other developing countries, Bangladesh continues to exhibit low utilization of long-term or permanent contraceptive methods, resulting in a high discontinuation rate[1]. Globally, an estimated 56 million induced abortions occur annually, highlighting a significant public health concern worldwide[2].

Since its inception in 1979, Bangladesh's national family planning program has included menstrual regulation as a component. While precise figures are unavailable, indirect estimates indicate that over 1.2 million menstrual regulations and induced abortions occur annually within the country[3].

Mifepristone, an antiprogesterone, in conjunction with the prostaglandin analog misoprostol, constitutes an effective and well-tolerated regimen for terminating early pregnancies. This combination has demonstrated a favorable safety profile, making it a widely used option for women seeking medical abortion[4]. While government regulatory agencies typically stipulate a 600mg dosage of mifepristone for medical abortion regimens, the global standard in practice has become a significantly reduced dose of 200mg[5].

Mifepristone, a potent anti-progestin, is commonly used in early pregnancy termination. However, when administered alone, it can result in incomplete expulsion, occurring in approximately 20% of women[6]. The sequential administration of mifepristone followed by misoprostol, in varying dosage regimens, has been established as an effective, accessible, and patient-acceptable method for early pregnancy termination[7]. The regimen employed in our study aligns with the guidelines outlined by the World Health Organization (WHO)[8].

A recent survey conducted by Marie Stopes Bangladesh in 62 pharmacies across the country found that a significant portion of drug sellers and pharmacists were aware of medications used to induce medical abortions. Specifically, 51% of respondents indicated knowledge of these drugs, while 30% reported that their respective drug stores or pharmacies were actively selling them to the public[9].

Clinical research has shown that up to 49 days of gestation, a complete abortion rate of 87–96% can be achieved by administering 200 mg of mifepristone orally, followed 24 hours later by 800 mg of misoprostol oraly[10-13] Numerous large-scale randomized trials have demonstrated the equivalent effectiveness of regimens employing a lower dose of mifepristone[14,15].

OBJECTIVE

To assess the effectiveness, outcome and safety of the use of a combination of mifepristone and misoprostol in inducing early abortion in Gynae OPD of Dhaka National Medical Institute and Hospital.

METHODS AND MATERIALS

This was a prospective cross-sectional study of 70 outpatients seeking menstrual regulation (by MRM) within nine weeks (63 days) of a missed period conducted at a Gynae OPD of Dhaka National Medical Institute and Hospital from July 2023 to December 2023. All participants received 200 mg of oral mifepristone, followed by 800 µg of buccal misoprostol. Patients were randomly assigned to administer the buccal misoprostol at a healthcare facility or home 24 hours after the mifepristone intake. Follow-up was conducted after 1 day and again after 7 days. 7 days later Follow-up was conducted via ultrasonography to confirm complete expulsion. Treatment was considered unsuccessful if surgical evacuation was required for any reason.

Inclusion Criteria

1. Gestational Age: Women with a gestational age of less than 9 weeks (63 days).
2. Consent: Voluntary, informed consent obtained from the participant.
3. Medical History: No contraindications to mifepristone or misoprostol use, such as severe anemia, active bleeding, or known allergy to either medication.
4. Pregnancy Confirmation: Positive pregnancy test by USG.

Exclusion Criteria

1. Ectopic Pregnancy: Confirmed or suspected ectopic pregnancy.
2. Chronic Conditions: Severe chronic conditions that could interfere with the study or increase the risk of complications.
3. Medication Use: Current use of medications that could interact with mifepristone or misoprostol.
4. Previous Abortion: History of failed medical or surgical abortions.
5. Substance Abuse: Active substance abuse, including alcohol and drugs.

RESULTS

Table I presents the demographic characteristics of the study participants. The majority of cases (n=24, 34.29%) were young adults aged 19-24, followed by those aged 25-29 (n=19, 27.14%). A smaller proportion (n=15, 21.43%) were over 29, while only 12 cases (17.14%)

were under 12 years old. Regarding reproductive history, 17 cases (24.29%) reported having had a previous termination of pregnancy.

Table 1: Demographic Profile of our study cases(n=70)

Socio-demographic Profile	Frequency	Percentage
Age		
<18 years	12	17.14
19-24 years	24	34.29
25-29 years	19	27.14
>29 years	15	21.43
Previous history of Termination of Pregnancy (TOP)	17	24.29

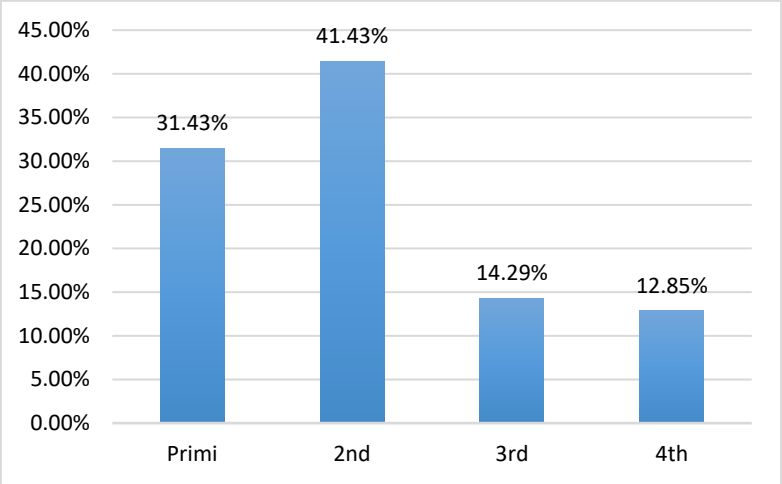

Figure – 1: Gravidity and Parity of Our Patients (*n*=70)

As depicted in **Figure 1**, the majority of our cases were multi-gravid, with 29 (41.43%) women being in their second pregnancy and 22 (31.43%) in their first. Additionally, 10 cases (14.29%) represented third pregnancies, while 9 cases (12.85%) were fourth pregnancies. At 12 months, 76% of patients reported being very satisfied with their outcome, 16% were satisfied, 4% were neutral, and 4% were dissatisfied.

Table II provides a detailed analysis of the time to first expulsion following the administration of mifepristone and misoprostol. Among the participants with a gestational age of less than 6 weeks, a significant majority (33 cases) experienced expulsion within 4 hours of treatment. Additionally, 12 cases demonstrated expulsion within the subsequent 4–24-hour period. For those with a gestational age between 6 and 9 weeks, the data revealed a similar pattern: 17 cases had expulsion within 4 hours, while 8 cases occurred within the 4–24-hour timeframe.

Table – II: Time of First Expulsion After Administration of Mifepristone and Misoprostol (*n*=70)

Gestational Age	Within 4 Hours	4-24 Hours
<6 weeks	33(47.14)	12(17.14)
>6-9weeks	17(24.29)	8 (11.43)

Table II presents the success rates of medical abortions at various gestational ages within the first trimester. Of the 30 cases, 21 were performed between 4 and 6 weeks, 19 between 6 and 8 weeks, and 19 at 8 weeks or later. The success rates were 96.67% (4-6 weeks), 95.24% (6-8 weeks), and 94.74% (8 weeks or later). Only three cases required surgical intervention due to failed medical abortions.

Table III: Success rate of medical abortion at different gestational ages in the first trimester (n=70)

Cases	4-6 Weeks	6-8 Weeks	8 Weeks Onward
Number of cases	30	21	19
Failure cases	1(3.33)	1(4.76)	1(5.26)
Success cases	29 (96.67)	20 (95.24)	18(94.74)

As shown in **Table IV**, the most common side effects among study participants were per vaginal bleeding of variable amount (100%, n=70) and uterine cramps (74.28%, n=52). Other reported side effects included nausea and vomiting (35.71%, n=22) and fever (30%, n=21). Importantly, no cases of uterine rupture were observed throughout the study period.

Table IV: Side effects of mifepristone and misoprostol

Side Effects	Frequency	Percentage
Per vaginal bleeding of variable amount	70	100
Uterine cramps	52	74.28
Fever	21	30
Nausea and vomiting	22	35.7
Ruptured uterus	0	0-

Of the three medical abortion failures documented in **Table V**, two cases (2.86%) resulted in ongoing pregnancies. The remaining case was classified as another type of failure.

Table – V: Type of Failure in Our Study Cases (*n*=70)

Types	Frequency	Percentage
Ongoing pregnancy	2	2.86
Nonviable pregnancy	0	-
Others	1	1.43

DISCUSSION

Our study presents a comprehensive analysis of the demographic and clinical outcomes associated with first-trimester medical abortions. The majority of participants were young adults aged 19 to 29 years (n=68, 97.14%), with a notable subset aged 19 to 24 years (n=24, 34.29%). A significant proportion of participants (n=17, 24.29%) had a history of previous pregnancy terminations, emphasizing key aspects of their reproductive history.

Regarding gravidity, most participants were multigravid, with 29 women (41.43%) experiencing their second pregnancy and 22 (31.43%) in their first. Additionally, 10 cases (14.29%) were in their third pregnancy, and 9 cases (12.85%) were in their fourth. These findings align with previous studies on the reproductive patterns of women seeking medical abortions[16].

In terms of time to expulsion following the administration of mifepristone and misoprostol, our data revealed that among participants with a gestational age under 6 weeks, the majority (33 cases) experienced expulsion within 4 hours, while 12 cases expelled between 4 to 24 hours. Similarly, for those between 6- and 9 weeks' gestation, 17 cases resulted in expulsion within 4 hours, with 8 occurring in the 4–24-hour range. This consistency in expulsion timing aligns with other relevant studies [17].

Our study also examined the success rates of medical abortions across different gestational ages. The highest success rates were observed in earlier stages, with 96.67% for those between 4 and 6 weeks and 95.24% for those between 6 and 8 weeks. Although the success rate slightly decreased to 94.74% for abortions performed at 8 weeks or later, the overall first-trimester success rate remained high. Only three cases (4.29%) required surgical intervention, which underscores the overall effectiveness of medical abortion in early pregnancy.

The most common side effects reported were per vaginal bleeding of variable amount (100%) and uterine cramps (74.28%), affecting 68 and 52 participants, respectively. Other less frequent side effects included nausea and vomiting (n=22, 35.71%) and fever (n=21, 30%). Notably, no cases of uterine rupture were observed, reinforcing the safety profile of this method.

Of the three cases where medical abortion failed, two resulted in ongoing pregnancies (2.86%), and one was classified as a different type of failure. This highlights the importance of further investigation into the causes of failure

and the potential for refining medical protocols to prevent such occurrences. Our findings regarding failure types are consistent with previous research[18].

Conclusion

The Use of the combination of mifepristone and misoprostol is safe and highly effective for medical termination of pregnancy in the early first trimester. It has a shorter induction abortion interval and, a high success rate, particularly in early gestational stages, requiring minimal surgical intervention and fewer side effects. The most common side effects were hemorrhage, uterine cramps, nausea, vomiting, and fever, but no cases of uterine rupture were observed. While the majority of participants experienced successful abortions, a small percentage encountered failures. It can also be used in scarred uterus with caution. However, a broad-based, well designed randomized study is hereby suggested for national policy formulation.

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