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Original Research Article

Termination of Unwanted Pregnancy by Medication (Mifepristone and Misoprostol)

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Abstract

***Introduction*:** Menstrual regulation, or the evacuation of the uterus of a woman at risk of being pregnant is done to ensure a state of no pregnancy, was introduced in Bangladesh in the 1970s in the context of a restrictive abortion law, in part to reduce maternal morbidity and mortality associated with unsafe abortion. ***Objectives*:** The study is designed to see the efficacy, safety and acceptability of uterine evacuation by medication using oral mifepristone and buccal misoprostol. ***Methods*:** All the patients attending the outpatient department. Of obstetrics & gynaecology in DNMCH during the study period seeking for MRM unwanted pregnancy. Of them 100 cases were selected purposively according to inclusion and exclusion criteria. Success was defined as medical abortion. ***Results*:** The oral misoprostol-mifepristone regimen, used by 100 women with a gestational age below 63 days, had a success rate of 92.0%. Ninety two percent patients were completely evacuated and Eight percent patients were incompletely evacuated. ***Conclusion*:** An evidence based regimen of 200 mg of mefipristone orally followed by home use of 800 mcg of buccal misoprostol 24hr later is safe and effective up to 9 weeks (63 days) of pregnancy. Further the need of aspiration for any reason was low and hospitalization was rare.

Keywords: Termination, Unwanted Pregnancy, Mifepristone, Misoprostol.

INTRODUCTION

Menstrual regulation, or the evacuation of the uterus of a woman at risk of being pregnant is done to ensure a state of nonpregnancy, was introduced in Bangladesh in the 1970s in the context of a restrictive abortion law, in part to reduce maternal morbidity and mortality associated with unsafe abortion [1, 2]. The introduction of menstrual regulation also coincided with the Bangladesh Liberation War, during which 200,000-400,000 Bangladeshi women were the victims of war violence, the new government allowed abortions for those who had become pregnant [3]. Menstrual regulation (MR) has been part of Bangladesh's national family planning program since 1979. MR is a procedure that usually uses manual vacuum aspiration (MVA) to safely establish nonpregnancy after a missed period. Physicians are permitted to perform menstrual regulation up to 10 weeks of amenorrhea and midlevel providers (family welfare visitors or nurses and paramedics) up to eight weeks of amenorrhea [2-4]. In a recent study, Bangladeshi women faced a range of socioeconomic barriers that affected their access to menstrual regulation services and contributed to delays in obtaining these services [5]. In that study, cost, social stigma and fear of the procedure was identified as the main obstacles to obtaining safe menstrual regulation services. Low levels of education and lack of awareness of menstrual regulation services also affect safety access. As a result, they go for unsafe abortion. According to a recent study, more than 231,000 women were treated for complications of unsafe abortion and menstrual regulation in 2010 [6]; Because not all women develop complications reported for treatment, the true number of women experiencing complications from menstrual regulation and unsafe abortion is expected to be much higher. This barrier and complications can be overcome by using oral medications like using mifepristone and misoprostol as a method of menstrual regulation with medication in place of surgical procedure like MVA. Mifepristone is anti-progesterone. Mifepristone ends a pregnancy by blocking the receptors of the hormone

progesterone, causing the lining of the uterine walls to shed similar to during one's menstrual cycle. It also increases prostaglandin levels and dilates the cervix, facilitating abortion. Mifepristone is given orally as a single dose of 200 microgram tablet [7]. Misoprostol is a prostaglandin E1 analogue. It causes uterine contractions irrespective of weeks of gestation. The overall success rate of medical abortion using mifepristone-buccal misoprostol regimen is 98.3% up to 9 weeks of gestation [7]. All women who use mifepristone experience bleeding and cramping; both symptoms are normal and part of the medical abortion process. Other potential but not threatening side effects include nausea, headache, vomiting, diarrhea, dizziness, back pain, tiredness, mild fever and chills. These side effects lessen by the third day after taking mifepristone and are usually gone within two weeks. Occasionally serious adverse events, like hospitalization for excessive hemorrhage or need of blood transfusions, may happen. Use in multiple gestation, multiple scarred uterus, increase maternal age, advance weeks of gestation increases the rate of failure, that is incomplete evacuation.

MATERIALS AND METHODS

Study Design: The study was a cross-sectional hospital based descriptive study.

Place of Study: This study was carried out in outpatient Department of Obstetrics & Gynaecology, Dhaka National Medical College Hospital. Dhaka, Bangladesh.

Study Period: Six months-from (July, 2017 to December, 2017).

Sample Size: Sample size was=100.

Study Population: All the patients attending the inpatient and outpatient Department of Obstetrics & Gynaecology in DNMCH during the study period seeking for MRM (unwanted pregnancy) and attend with complication having MR. Of them 100 cases selected purposively according to inclusion and exclusion criteria.

Inclusion Criteria:

- Women agree to participate in this study.
- Uterine size upto 9 weeks of pregnancy.

Exclusion Criteria:

1. History of amenorrhoea for more than 9 weeks.
2. Suspected ectopic pregnancy.
3. Suspected molar pregnancy.
4. Serious medical problems that may complicate abortion procedure.
5. Cannot come or not reliable for, follow-up appointment.
6. Does not have an access to telephone, transportation and back up medical care.
7. Diagnosed as a patient of bleeding disorder.
8. Known history of allergy to any prostaglandins.
9. History of previous 3 caesarean section.

Method of Data Collection:

Inform written consent was taken from the patient. All patients were interviewed by using a preformed questionnaire containing socio demographic and relevant information about the study topic. General medical conditions of the patients were evaluated through history, physical examination and help of investigation and subsequently the diagnosis was confirmed. All these information was collected and was recorded in a pre-designed data collection sheet.

Procedure Followed:

After taking history with particular attention to aspects relevant to this study, clinical examinations were carried out. Informed written consent was taken from the patient after detailed explanation of the purpose of study. After a detailed history taking general, physical &obstetric examination was performed. Gestational age was established from the history & by USG. By per vaginal examination size of the uterus, cervix & all the fornix was assessed. Eligible patient was offered tab mifepristone & tab misoprostol to terminate her pregnancy. After proper counseling regarding the side effects of these drugs she was prescribed to take tab Mifepristone 200 mg orally by one dose at home and then after 24 hours tab misoprostol 800 mcg (4 tab) buccaly (patients were taken 2 tab in each cheek for half an hour then swallowed any pill fragment). Patients came to the hospital if any severe adverse effects occur. Otherwise she came after 14 days for follow up visit when repeat UsG was done to see the result. If there was incomplete expulsion then she was offered MVA to complete the abortion.

Data Analysis:

Statistical package for the social science (SPSS) version 22.0 for windows was used to analyze the data. Categorical variables were expressed as propotion (percentage) and numerical data were expressed as means (standard deviation) and ranges. Different tables were constructed according to findings.

RESULTS

Table-1: Age distribution of the patients (n=100)

Age group	Number	Percentage (%)
<20 years	14	14.0
21-30 years	26	62.0
31-40 years	24	24.0
Total	20	100.0
Mean±SD	26.42±5.91	
Range	(16-40) years	

Table-1 shows the age distribution of the study patients. Among 100 patients, highest frequency 62% patients were in the age 21-30 years, 14.0% patients were

below 20 years. Minimum age was 16 and maximum age was 40 years. Mean±SD of age was 26.42+5.91 years. 26% were graduate and above and 12% were the primary level. Above table showed the occupational distribution of the study respondents, 68% were housewife, 24% were student and 8% patients were service holder.

Table-2: Distribution of the study subjects by type of parity (n=100)

Parity	Frequency	Percentage (%)
Nulliparous	26	26.0
Primiparous	10	10.0
Multiparous	64	64.0
Total	**100**	**100.0**

Table-2 shows the type of parity, maximum (64%) participants were multiparous, 26.0% were nulliparous and 10.0% participants were primiparous.

Table-3: Distribution of the study subjects according to duration of pregnancy by USG (n=100)

Duration of pregnancy (weeks)	Frequency	Percentage (%)
5	2	2.0
6	38	38.0
7	42	42.0
8	12	12.0
9	6	6.0
Total	**100**	**100.0**

Table-3 shows, distribution of the respondents according to duration of pregnancy. Maximum (42%) participants had duration of pregnancy of 7 weeks and 38% participants had duration of 6 weeks.

Table-4: Distribution of the study subjects according to reason behind MRM (n=100)

Reason for MRM	Frequency	Percentage (%)
Unwanted pregnancy/ Unplanned pregnancy	46	46.0
Contraceptive failure	54	54.0
Total	**100**	**100.0**

Table-4 shows, distribution of the respondents according to reason behind seeking MRM. Maximum (54%) participants had contraceptive failure and rest of the patients had (46%) unwanted pregnancy/unplanned pregnancy.

Table-5: Distribution of the study participants by mode of delivery (n=74)

Mode of delivery	Frequency	Percentage (%)
NVD	46	62.2
Caesarean section	28	37.8
Total	**74**	**100.0**

Above table-5 showed the mode of delivery, maximum (62.2%) had NVD and 37.8% participants had previous caesarean delivery.

Table-6: Distribution of the study participants by complications (n=100)

	Completeness of procedure		Total
	Complete evacuation/ expulsion (n=92)	Incomplete evacuation/ expulsion (n=8)	
Excessive bleeding	0	6(75.0%)	6(6.0%)
Infection	0	2(25.0%)	2(2.0%)
Uterine scar dehiscence	0	0	
No complications	92(100.0%)	0	92(92.0%)
Total	**92(100.0%)**	**8(100.0%)**	**100(100%)**

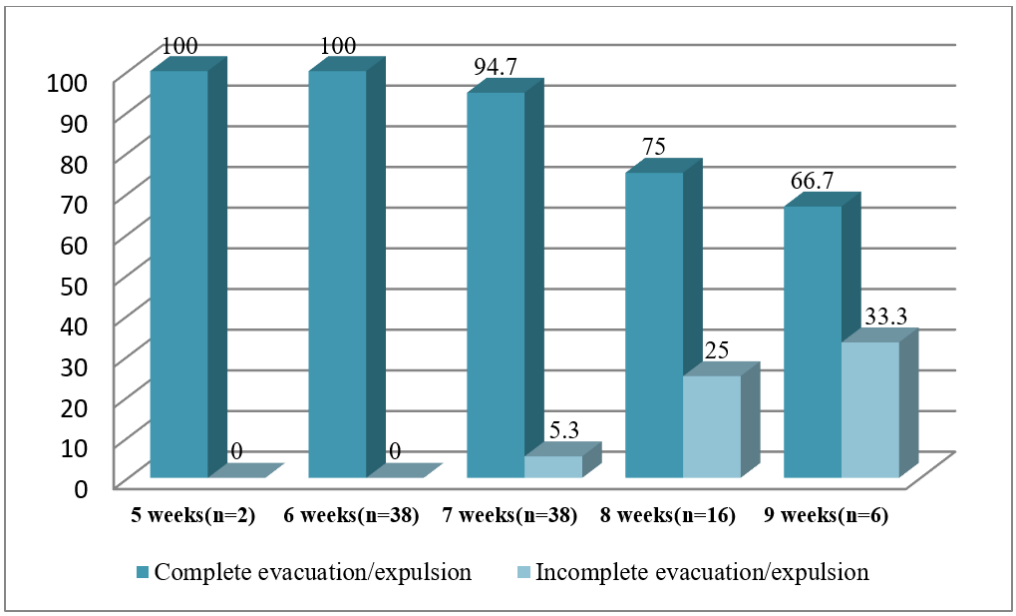

Fig-1: Bar diagram showing the completeness of procedure with gestational age.

Above table-6 showed the complication of study participants, among 8 patients of incomplete evacuation, 75% had excessive bleeding, 25% developed infection. Ninety two percent patients had complete expulsion and did not suffer from any complications other than mild side effects, like- nausea and abdominal cramp.

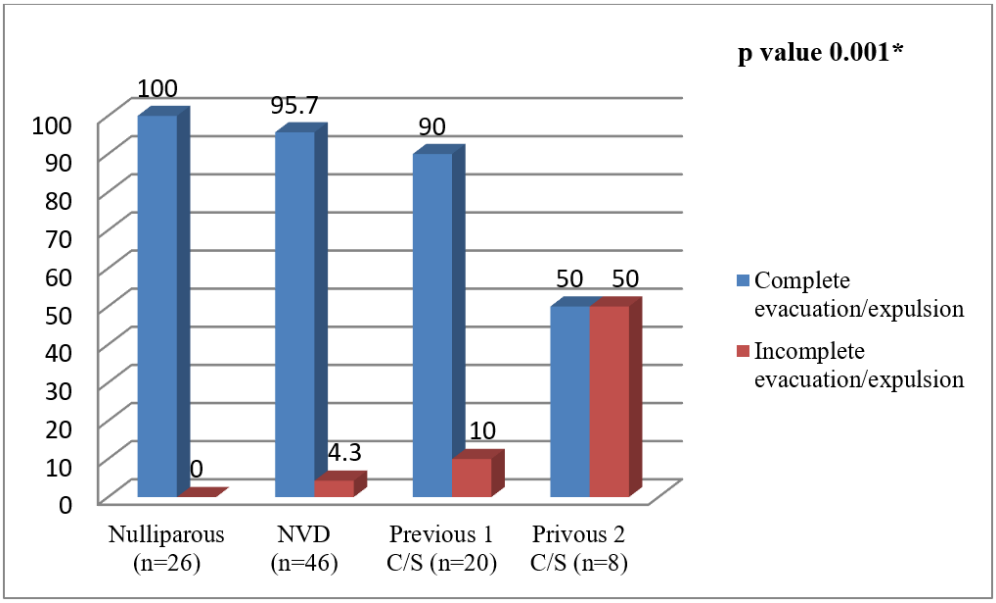

Fig-2: Bar diagram showing the completeness of procedure with obstetric history

DISCUSSION

This cross-sectional hospital based descriptive study was conducted among 100 patients who attended the outpatient Department of Obstetrics & Gynecology in DNMCH during the study period seeking for MRM up to 9 weeks of pregnancy. The study was aimed to assess the efficacy of MRM in terms of completeness of procedure and success rate. Medical abortion offers great potential for improving abortion access and safety, as it requires less extensive infrastructure than surgical abortion. Also there is, no need for anesthesia and operation theater facilities, and maintains patient's need of privacy. The disadvantages would be that the women requires at least two visits to the hospital, unpredictable outcome in few patients, longer duration of bleeding, and potential risk of fetal malformation if it fails to cause abortion. The factors that may prevent the women from accepting the medical method of termination of pregnancy is the abdominal cramps and heavy bleeding, duration of bleeding (average 7-10 days), and the need to follow-up after 2 weeks for clinical examination and sologrophy. We conducted this study to find the efficacy

of the regime, 200 mg of mifepristone (orally) and 800 microgram of misoprostol administered (buccally) 24 hours later. In present study, among 100 patients, highest frequency, 62% of patients were in the age 21-30 years, 14.0% patients were below 20 yrs. Minimum age 16 and maximum age was 40 years. Most of the subjects, 68% were housewife, 24% were student and 8% patients were service holder. In regards to duration of pregnancy maximum 42% participants had duration of pregnancy of 71 weeks, 38% participants had duration of 6 weeks and only 6% patients had duration of gestational 9 weeks. A similar study done by Kailash *et al.*, [8] revealed that maximum number of women 28(32.9%) belonged to the age. group of 25-29, followed by 21 (24.7%) of age group of 30-34 years. There were 59 (69.7%) women with fetal gestational age of 40-49 days followed by 21 (24.7%) women with 30-39 days. Mean gestational age was 41.5 days. A research work done by Fjerstad *et al.*, [7] revealed that the mean age of mifepristone was the women using the regimen with buccal administration 25.8 years. Mean reported gestational age was 47 days (range 21-59 days). Fjershad *et al.*, [7] documented the overall success rate of medical abortion using buccal misoprostol was 98.3%. The study explored whether. There was a trend toward decreased effectiveness with increased gestational age by examining effectiveness by gestational age cohorts in weeks separately for all pregnancies and for singleton pregnancies. However, for all I pregnancies, the success rate (99.1%) at gestations below the median (44 days) was significantly higher than the success rate (97.6 %) at gestations of 44 days and higher. These findings were comparable with our study [7] in present study, among 8 unclear patients, all patients underwent MVA procedure, 75% suffered from excessive bleeding, 50% patients needed hospital admission and blood transfusion and 25% suffered from infection, and they also needed hospital admission for control of infection. There is no scar dehiscence. Ninety two percent patients had successful abortion and did not suffer from any complications other than mild side effects, like- nausea and abdominal cramp. In Kailash *et al.*, [8] in present study, women with gestational age <63 days (9 weeks) were considered. The success rate (defined as the nonsurgical evacuation of the products of conception), of oral Mifepristone and buccal Misoprostol was found to be 92%. In a study done by Pirruccello *et al.*, [9] focused on regimen, efficacy, and acceptability and future directions in 2003 and revealed 92-99% of success rates at 49 days gestation. The authors also mentioned that newer regimens and alternative route of drug administration could improve the result, as future direction. Intravaginal administration of Misoprostol is associated with significantly more prostaglandin-related side effects [9]. Shrivastava in 2006 performed similar research in Nepal Medical College, Nepal, and assessed the safety, and efficacy [10]. In her prospective study, Misoprostol was used vaginally and the success rate was 92.6% [10]. Vaginal bleeding and uterine cramping (usually heavier than with menstruation) are expected [10]. Kathleen *et al.*, in 2011 performed a similar research with misoprostol administered vaginally, and the success rate was 80 % [11] recently, sublingual administration of Misoprostol has been studied for medical abortion and cervical priming. The Misoprostol tablet is very soluble and can be dissolved in 20 minutes when it is put under the tongue. The peak concentration is achieved about 30 minutes after sublingual route, whereas following vaginal administration, it takes 75 minutes. Therefore, it appears that the sublingual has the quickest onset of action. This is due to rapid absorption through the sublingual mucosa as well as avoidance of first pass metabolism via the liver for oral route. The abundant blood supply under the tongue and the relatively neutral pH in the buccal cavity may be contributing factor [12] our study also showed a significant (P=0.004) association between gestational age and success rate Failure of abortion was found in women with higher gestational age as compared to those with lower gestational age [13]. Found women undergoing MTP experienced minimum 4 days and maximum 9 days of vaginal bleeding. None of the women reported heavy bleeding and none required a transfusion. The higher incidence of vaginal bleeding is related to the dose and duration of exposure to the drug. In a research done by Schiff *et al.*, two days after receiving Mifepristone, intravaginal administration of Misoprostol 800 mcg, with mean gestational age of 43 days, resulted in heavy bleeding in 13.3% of the women undergoing MTP [14]. Uterine cramping and abdominal pain, in our study, were experienced for two days Lasting up to 6 days for few women. El-Refaey *et al.*, conducted a randomized trial to compare oral and intravaginal routes of Misoprostol administration among women at ≤ 63 days' gestation showing that oral Misoprostol group had higher rates of gastrointestinal side effects, 70% had nausea, 44 % had vomiting, and 36 % had diarrhea [15]. Chuni and Chandrashekhar [15] conducted a study on 112 women for MTP of 63 days duration with oral mifepristone 200 mg followed by oral misoprostol 400 mcg 48 h apart. The rates of complete abortion were 92.8%, 83%, and 80% in the <49 days group, 50-59 days group, and 57-63 days group, respectively. A study in Nepal [16] reveals that unintended pregnancies amongst married couples are common. Given the circumstances - in which young women have relatively less power than men in fertility decision making, and are often pressured by their mothers-in-law or other relatives to get pregnant immediately after marriage to secure their marital relationship or to avoid marital breakdown. It was an open-ended questionnaire was given to the study population to evaluate the reason for seeking MRM and patients satisfaction. However, all women who responded to the particular question have given different reasons for abortion. Maximum 54% participants had contraceptive failure rest of the patients 46% unwanted pregnancy/unplanned pregnancy. In present study 86% patients were satisfied and 14% patients were unsatisfied. Among satisfied patients all of them had complete evacuation with bleeding <7 days with mild pain and no other complications. Among unsatisfied

patients, 6(42.9%) had incomplete evacuation with prolong duration of bleeding and 6(42.9%) patients had complete evacuation with prolong duration of bleeding. Infection rate was low 2(14.3%) and there was no scar dehiscence. Alam *et al.*, [17] done a similar study demonstrate, most of the women (92%) were satisfied with use of pills for their menstrual regulation. Providers faced initial challenges and concerns, particularly related to the additional counseling requirements and lack of control over the final outcome, but became more confident after successful use of the medication regimen.

CONCLUSION

In conclusion, an evidence-based regimen of mifepristone 200 mg orally followed by misoprostol 800 mcg buccally 24hr later is safe and effective through 63 days (9wks.) of estimated gestational age. It is an acceptable and safe method and has only few minor side effects. This study reinforces the safety, efficacy and acceptability of the evidence-based regimen for medical abortion and contributes to the evidence against restrictions that require use of the FDA-approved regimen. The patients were comfortable with buccal tablets of misoprostol. Access to safe abortion is limited in our country because of legal restrictions, administrative and financial barriers, and lack of adequately trained providers. This regimen is better alternative to surgical evacuation.

Limitations of this Study

The present study had the following limitations. There should be kept in mind while deciding on the implication of the findings of the study.

(a) Short study period.
(b) Sample technique was purposive.
(c) Single centered study

RECOMMENDATIONS

- The efficacy of misoprostol may vary depending upon gestational age, the route of administration, or the frequency of dosing. Research is required to determine a lower dose of misoprostol might be used with comparable efficacy.
- Further study required to dose adjustment in case of scared uterus.
- RCT should be done in multicenter to see the efficacy of different route of administration of misoprostol.

Conflict of Interest: None.

Source of Fund: None.

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