

Original Article**A Comparison of Using Oral Misoprostol and Manual Vacuum Aspiration (MVA) in the First Trimester Incomplete Abortion**

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Abstract:

Background: Misoprostol, a synthetic prostaglandin E1 analogue, may work as an alternative to manual vacuum aspiration (MVA) in incomplete abortion, which is easy to administer orally, and helps to increase access to post abortion care. **Objective:** To compare the effectiveness, safety and acceptability by the patients of using oral misoprostol therapy and manual vacuum aspiration technique for the treatment of incomplete abortion in the first trimester of pregnancy. **Methods:** This cross-sectional study was conducted in Department of Obstetrics & Gynaecology, Sir Salimullah Medical College & Mitford Hospital, Dhaka, Bangladesh, between January and July of 2016. A total of 200 patients (women with incomplete abortion ≤ 12 weeks) were enrolled in the study. 100 Patients were randomly selected and treated with oral misoprostol 600mcg (group I), while the other 100 were treated with manual vacuum aspiration (MVA) (group II). They were followed up for 1-3 days before discharge. Participants were asked to return to the clinic for follow-up after 1 week. In follow-up visit, if abortion was not found complete, an immediate surgical evacuation was performed. **Results:** The mean age of the participants were 28.59 ± 10.44 and 28.24 ± 9.40 in group I and II respectively. In group I, 94% had complete abortion, while 6% had incomplete abortion or continued pregnancy. However, in group II, 100% had complete abortion ($P > 0.05$). Per vaginal normal and heavy bleeding were 35% and 12% in group I, while 9% and 1% in group II respectively ($P < 0.001$). Pain, nausea, vomiting and gastrointestinal issues were more observed in group I than that of group II ($P < 0.001$). However, incidence of fever, headache and vertigo were similar in both groups ($P < 0.001$). In group I, 98% stated that the treatment was 'satisfactory/very satisfactory', while in group II, 99% found the procedure 'satisfactory/very satisfactory'. The difference between the groups is not statistically significant ($P > 0.05$). In group I, 98% stated that they would select this method again, if needed and recommend it to a friend or relative, while in group II, 88% stated that they would choose this method again and 86% would like to recommend to a friend or relative. The difference between the groups is statistically significant ($P < 0.001$). **Conclusion:** Our data suggest that oral misoprostol therapy can be used effectively ensuring safety and patients' satisfaction for treatment of incomplete abortion in the first trimester as compared to manual vacuum aspiration technique.

Keywords: Incomplete abortion, post abortion care, oral misoprostol, manual vacuum aspiration.

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Introduction:

Early pregnancy failure, or loss of an intrauterine pregnancy within the first trimester is a major public health problem throughout the world. It has been estimated that over 10-20% pregnancies end

up in spontaneous abortion and 80% of all these occur before 12 gestational weeks¹. An estimated 21.6 million unsafe abortions took place worldwide and unsafe abortion related deaths were 47,000 in 2008, almost all in developing countries². In

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Bangladesh, a developing country of South Asian region, many women have abortions initiated by “backstreet abortionists” and then present to a health care facility with an incomplete abortion, as because spontaneous and induced abortions are usually impossible to distinguish; all women in this situation are treated as if illegally induced³. However, unsafe induced abortions hardly meet officially prescribed circumstances and safeguards; they are aggravated by unhygienic conditions, dangerous interventions or incorrect administration of medication. Although unsafe abortions are preventable, they continue to pose undue risks to a woman’s health and may endanger her life^{2,3}. The current treatment of choice in the first trimester is manual vacuum aspiration (MVA)^{3,4}. This simple technique makes use of a syringe to produce the vacuum for a suction curettage. It is highly effective at uterine evacuation causing less pain and less bleeding and can be used in an outpatient setting^{4,5}. However, in low-resource settings, access to surgical methods may be difficult due to a scarcity of trained providers, sterile surgical facilities, and/or inadequate transportation to reach the centers where surgical procedures are performed^{3,5}. Nevertheless, misoprostol, a synthetic prostaglandin E1 analogue, may work as an alternative to manual vacuum aspiration, that is inexpensive, easy to administer orally, and stable at room temperature. Previous studies of misoprostol for incomplete abortion have used a wide range of diagnostic criteria, doses, and routes and reported success rates between 13% and 100%⁶⁻¹⁰. In Bangladesh, hospitalizations for abortion related complications are very common. Methods for unsafe abortion range from insertion of objects into the reproductive tract, to ingestion of pharmaceutical and homeopathic medications, to use of vacuum aspiration or D&C equipment by informally trained providers^{5,11-13}. Approximately 70,000 women annually are estimated to present to hospitals and clinics with abortion related complications^{5,11,12}. A recent study from Bangladesh suggested that providing women with life-saving treatment for abortion related complications costs the health sector 1.6 million US dollars annually in incremental costs alone¹¹. The analysis also showed wide variations in incremental health system costs of providing care for moderate abortion complications, referring to those requiring uterine evacuation but no other surgical care from US \$10 at the primary care level to US \$50 at the tertiary care level¹¹. Therefore,

we were curious to identify means of making care for abortion related complications both more cost-efficient for the health system and higher quality for the patient. Under the circumstances, misoprostol could save many lives annually by providing a treatment that can be administered at even the most basic rural health center. Hence, the present study was designed to evaluate and compare the effectiveness, safety and acceptability by the patients of using oral misoprostol and manual vacuum aspiration (MVA) technique for the treatment of incomplete abortion in the first trimester of pregnancy.

Methods:

This cross-sectional study was conducted in Department of Obstetrics & Gynaecology, Sir Salimullah Medical College & Mitford Hospital, Dhaka, Bangladesh, between January and July of 2016. We used convenient sampling technique. Sample size was determined by the formula for estimating the difference between the two-population proportions with level of significance 5% and power 80% for one-sided test.

Inclusion criteria:

1. Patients with a diagnosis of incomplete abortion with gestational age ≤ 12 weeks, as determined by a reliable menstrual history and/or pelvic examination on day one of study;
2. No severe active per vaginal bleeding (as defined by change of two fully soaked sanitary pads hourly for two consecutive hours);
4. No signs of infection (temp $> 37.5^{\circ}\text{C}$, pulse > 110 per minute, or foul-smelling discharge);
5. No known hypersensitivity to misoprostol;
6. Women willing to return for follow up.

Exclusion Criteria:

1. Patients in poor general health (e.g. chronic ill health or patients may need resuscitation back-up);
2. Patients with severe per vaginal bleeding;
3. Patients have signs of any infection;
4. Patients with known allergy to misoprostol.

Women with incomplete abortion admitted into the hospital was approached. After fulfilling the inclusion and exclusion criteria, a total of 200 patients were enrolled in the study. Among them, 100 Patients were randomly selected and treated with oral misoprostol 600mcg (group I), while

the rest of the patients were treated with manual vacuum aspiration (MVA) (group II). After taking written informed consent from the patient or her legal guardian, initial evaluation was done by history taking and doing clinical examination and recorded in the preformed data collection sheet. Pelvic examination and ultrasonography of the lower abdomen was done. A complete blood count was done at that time. Women who were assigned to the surgical arm received immediate manual vacuum aspiration (MVA) under local anaesthesia. Analgesics and antibiotics were given if needed. They were followed up for 1-3 days before discharge. All participants were asked to return to the clinic after 1 week later to confirm their clinical status. In the event of continued heavy bleeding, an enlarged uterus, the women were referred for ultrasound and follow-up care. If continued incomplete abortion was determined by clinical exam or by ultrasound in either of the study arms, women were given the option of an immediate surgical evacuation or returning for additional follow-up 1 week later to see if expulsion would have occurred spontaneously.

Data were analyzed using SPSS (Statistical Package for the Social Science) version 16.0. (SPSS Inc, Chicago, IL, USA). Continuous data were expressed as mean $\pm$ SD, while dichotomous data were expressed as percentage. Comparison between groups were done by unpaired t-test, while categorical data were analyzed with Chi-square (χ^2) test. P value <0.05 was considered as statistically significant.

Results:

The mean age of the participants was 28.59 $\pm$ 10.44 and 28.24 $\pm$ 9.40 in group I and II respectively. In group I, 94% had complete abortion, while 6% had incomplete abortion or continued pregnancy. However, in group II, 100% had complete abortion. There was no difference in effectiveness between the procedures ($p>0.05$) (Table-I). Pervaginal normal and heavy bleeding were 35% and 12% in group I, while 9% and 1% in group II respectively; the difference is statistically significant ($P<0.001$). Pain, nausea, vomiting and gastrointestinal issues were more observed in group I than that of group II; the differences were statistically significant ($P<0.001$). However, incidence of fever, headache and vertigo were similar in both groups and no statistically significant difference was found ($P<0.001$) (Table-II). In group I, 98%

stated that the treatment was 'satisfactory/very satisfactory', while in group II, 99% found the procedure 'satisfactory/very satisfactory'. The difference between the groups is statistically significant ($p>0.05$). In group I, 98% stated that they would select this method again, if needed and recommend it to a friend or relative, while in group II, 88% stated that they would choose this method again and 86% would like to recommend to a friend or relative. The difference between the groups is statistically significant ($p<0.001$) (Table-III).

Table I: Type of abortion and efficacy of Misoprostol vs. MVA in study population (n=200)

	Group I	GROUP II	P value
	Percentage	Percentage	
Types of abortion			
Spontaneous abortion	96	95	0.944 ^{NS} 0.874 ^{NS}
Induced abortion	4	5	
Procedural efficacy			
Complete abortion	94	100	0.09 ^{NS}
Incomplete abortion/ ongoing pregnancy	6	0	

NS = Non-significant; P value determined by Chi-square (χ^2) test.

Table II: Side effects of misoprostol vs. MVA in study population (n=200)

Side effects	Group I	GROUP II	P value
	Percentage	Percentage	
Normal bleeding	35	09	<0.001**
Heavy bleeding	12	01	<0.001**
Spotting	31	51	<0.001**
Pain/cramps	54	24	<0.001**
Fever/chills	04	02	0.02 ^{NS}
Nausea	16	03	<0.001**
Vomiting	07	01	<0.01**
Headache	08	09	0.74 ^{NS}
Gastrointestinal issues	15	04	<0.001**
Vertigo	04	03	0.07 ^{NS}

NS = Non-significant; ** = Significant; P value determined by Chi-square (χ^2) test.

Table III: Acceptability of treatment in study population(n=200)

Acceptability of treatment	Group I	GROUP II	P value
	Percentage	Percentage	
Satisfactory/very satisfactory	98	99	0.944 ^{NS}
Unsatisfactory/very unsatisfactory	02	01	0.144 ^{NS}
Would select this method again, if needed	98	88	<0.001**
Would recommend this method to a friend/relative	98	86	<0.001**

NS = Non-significant; ** = Significant; P value determined by Chi-square (χ^2) test.

Discussion:

The mean age of group I and group II patients were 28.59 ± 10.44 years and 28.24 ± 9.40 years respectively. There was no significant difference in age distribution among the groups. Gronlund et al.¹⁴ found the mean age of group I and group II patients, 32.0(range 20-46) years and 32.1(range 20-45) years respectively. Weeks et al.¹⁵ found the mean age of their patients to be 23.7 ± 5.4 years in group I & 23.7 ± 5.4 years in group II. Shochet et al.¹⁶ reported the mean age of their patients to be 28.1 ± 7.2 years in group I & 28.7 ± 7.3 years in group II.

Shochet et al.¹⁶ also reported about the difficulty of treatment in their study population of group I, as 95.4% stated that the treatment was 'not at all difficult/a little difficult' and 04.6 % stated that the treatment was 'difficult/very difficult' and in group II, 97.4% stated that the treatment was 'not at all difficult/a little difficult' and 02.6 % stated that the treatment was 'difficult/very difficult'. Weeks et al.¹⁵ reported the tolerability of pain of their study population of group I, 11.3% had no pain & 81.1% had very tolerable pain and 07.5% had not tolerable pain and in group II, 06.1% had no pain & 85.7% had very tolerable pain and 08.2% had not tolerable pain, which are similar to the findings of our study.

Shochet et al.¹⁶ reported similar figure about the acceptability of treatment of their study population of group I, 98.5% stated that the treatment was 'satisfactory/ very satisfactory' and 1.5% stated that the treatment was 'unsatisfactory/ very unsatisfactory' and in group II, 98.1% stated that the treatment was 'satisfactory/ very

satisfactory' and 01.9% stated that the treatment was 'unsatisfactory/ very unsatisfactory'. Weeks et al.¹⁵ also reported similar figure about the acceptability of treatment of their study population of group I, as 94.2% stated that the treatment was 'satisfactory/ very satisfactory' and 05.8 % stated that the treatment was 'unsatisfactory/ very unsatisfactory' and in group II, 94.7% stated that the treatment was 'satisfactory/ very satisfactory' and 05.3% stated that the treatment was 'unsatisfactory/ very unsatisfactory'.

Shochet et al.¹⁶ reported similar figure about the selection of the treatment again, if needed of their study population of group I and group II, 97.6% vs 87.8% respectively. Weeks et al.¹⁵ reported similar figure about the selection of the treatment again if needed: in group I and group II - 96.2% vs 90.5% respectively.

However, Shochet et al.¹⁶ reported about whether recommending the treatment to a friend, as group I and group II opined: 97.6% vs 85.8% respectively. Weeks et al.¹⁵ reported almost similar figure i.e. group I and group II - 96.2% vs 92.0% respectively.

Conclusion:

Our data suggest that oral misoprostol can be used effectively ensuring safety and patients' satisfaction for treatment of incomplete abortion in the first trimester as compared to manual vacuum aspiration (MVA) technique. In a resource-poor country like Bangladesh, using misoprostol may be considered in post abortion care as an easy method to administer, requiring no surgical skills, that ultimately helps to increase access to post abortion care.

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Ethical approval issue: The study was approved by the Ethics Review Committee of Bangladesh College of Physicians and Surgeons (BCPS), Dhaka, Bangladesh.

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