



## Original Research Article

# Oral 600 µg misoprostol vs manual vacuum aspiration (MVA) for the management of incomplete abortion- A randomized controlled trail

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## ABSTRACT

**Introduction:** Approximately one in five recognized pregnancies are spontaneously miscarried in the first trimester and an additional 22% end in induced abortion. Incomplete abortion occurs when there are retained products of conception (POC) after induced abortion (whether by unsafe or safe methods) or after spontaneous abortion, also known as miscarriage. Some women may resort to self-induction. These conditions increase the likelihood that women will experience abortion complications and will seek treatment for incomplete terminations. Incomplete abortion can be treated with expectant management, which allows for spontaneous evacuation of the uterus, or active management, using surgical or medical methods. Expectant management is not preferred by many providers due to its relatively low efficacy and the fact that the time interval to spontaneous expulsion is unpredictable.

**Materials and Methods:** The study was performed in a Durgapur Steel plant hospital, a tertiary care Hospital in West Bengal, India. The institute caters a huge area, both rural and urban. The study was done between 1st January 2019 to 31st October 2020.

Study population was drawn from patients attended OPD and patients admitted with incomplete abortions, either of spontaneous or, induced etiology in the Dept. Of Obst, & Gynae, Durgapur Steel plant hospital. A total of 80 women were randomised to either a single dose of 600 micrograms of oral misoprostol or MVA. **Result:** 160 women were recruited to the trial, of which 80 women were grouped into misoprostol group & another 80 to MVA group. Immediately after abortion, all the patients were available & data collected from all the patients. But during next follow-up after 1-2 wk, 33 in the MVA group & 27 in the misoprostol group did not come (Lost to follow up n=33) for follow-up. So, approximately 41% (33) of participants in MVA group & 34% (27) in the misoprostol group were lost to follow-up.

In our study both MVA & Misoprostol groups had similar age distribution. Mean age in MVA group 23.5 years ( $\pm 4.5$ ) and in MISO group 23.4 Years ( $\pm 4.8$ ).

**Conclusion:** For treatment of first-trimester uncomplicated incomplete abortion, both manual vacuum aspiration and 600 µg oral misoprostol are safe, effective, and acceptable treatments.

However, misoprostol appears to be somewhat better option than MVA, in regards to availability, low cost of therapy, less pain, less need of expert manpower or specialised instruments.

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## 1. Introduction

Approximately one in five recognized pregnancies are spontaneously miscarried in the first trimester<sup>1</sup> and an additional 22% end in induced abortion.<sup>2</sup> Incomplete

abortion occurs when there are retained products of conception (POC) after induced abortion (whether by unsafe or safe methods) or after spontaneous abortion, also known as miscarriage.<sup>3</sup> Some women may resort to self-induction. These conditions increase the likelihood that women will experience abortion complications and will

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seek treatment for incomplete terminations.<sup>4</sup> Incomplete abortion can be treated with expectant management, which allows for spontaneous evacuation of the uterus, or active management, using surgical or medical methods. Expectant management is not preferred by many providers due to its relatively low efficacy and the fact that the time interval to spontaneous expulsion is unpredictable.<sup>5</sup>

Until recently, the treatment for incomplete abortion has usually been surgery of some kind (dilatation and curettage [D + C] or manual vacuum aspiration [MVA]). While these treatments are effective, they require specialised equipment and skills. Furthermore, they subject the woman to the dangers of a surgical procedure—trauma, perforations, infections, bleeding due to instrumentation, and reactions to anaesthesia. If women live in a long distance from medical facilities and do not have access to dependable transportation, they may be required to remain at the hospital for an extended period, which can be inconvenient and costly for both patient and facility. It is particularly inconvenient in some parts of the world, where many women are immune-compromised (mainly due to HIV infection), as the risk of sepsis argues against lengthy period of waiting.

Finally, in all settings, women may be anxious to feel like the abortion process is ‘finished’ so that they can get this generally painful event behind them. Such women may not want to ‘wait and watch’.

Many studies have indicated that the uterotonic and cervical ripening properties of the prostaglandin E1 analogue misoprostol make it a safe and highly effective method of evacuating the uterus in cases of incomplete abortion, in comparison to surgical methods (such as manual vacuum aspiration).<sup>6</sup>

Misoprostol stability at room temperature and low cost could make it an ideal treatment in low-resource settings, as well; it should prove safe and effective in such locales. The present study is designed to fill an important gap in the research by testing misoprostol for incomplete abortion at a regional hospital with a large rural catchment area in a low-income country.

The 600 µg dose and oral route of misoprostol administration were chosen instead of the vaginal route as past studies shown that many women found vaginal administration more invasive and less acceptable than oral use, and there was an unconfirmed possibility that this route may be associated with greater rates of infection.

Misoprostol is effective in emptying the uterus because of its ability to induce uterine contractions and to soften the cervix. Misoprostol for treatment of incomplete abortion has been well documented in women presenting with uterine size less than or equal to a pregnancy of 12 weeks since last menstrual period (LMP).<sup>5</sup>

Misoprostol has not been associated with long-term effects on women’s health, and prolonged or serious side

effects are virtually nonexistent. Women and providers find misoprostol for treatment of incomplete abortion to be highly acceptable. Many women reported that they would choose misoprostol again if they need treatment for incomplete abortion in the future. Research in low resource settings in several countries has indicated that over 90% of women were “very satisfied” or “satisfied” with misoprostol treatment.<sup>7</sup>

Another aspect is that, misoprostol for post-abortion care (PAC) would decrease the burden on tertiary health care facilities because of its low cost. It has an additional benefit of being highly acceptable to women as it is less invasive. It would also limit the burden on busy gynaecologists as well as reducing the need for surgical equipment, sterilization and anaesthesia.

With these facts in mind, the present study is formulated, to compare different aspects of treatment of incomplete abortion by oral 600 µg misoprostol and manual vacuum aspiration in a busy teaching hospital in eastern India.

## 2. Materials and Methods

The study was performed in a Durgapur Steel plant hospital, a tertiary care Hospital in West Bengal, India. The institute caters a huge area, both rural and urban. The study was done between 1st January 2019 to 31<sup>st</sup> October 2020.

Study population was drawn from patients attended OPD and patients admitted with incomplete abortions, either of spontaneous or, induced etiology in the Dept. of Obst, & Gynae, Durgapur Steel plant hospital. A total of 80 women were randomised to either a single dose of 600 micrograms of oral misoprostol or MVA.

The sample size of 160 women 80 in each study arm, was not based on a power calculation but rather was meant to ensure an optimum number of participants to allow the benefits and drawbacks of the approach to present them fully within one year. The sample, nonetheless, was large enough to provide 77% power to detect a difference (one tailed) of 4.5% or greater in the effectiveness of the treatments, assuming 99% effectiveness for MVA.

Randomization was performed by computer-generated random code, created in blocks of ten at Durgapur Steel plant hospital office. The code was used by employee of our hospital who were not part of the research team as a basis for sealing cards in consecutively numbered envelopes; the cards read either ‘Misoprostol’ or ‘MVA’. When a new participant was enrolled in the study, site staff opened the next envelope in the numbered series and the woman had received the treatment specified therein.

Approximately 160 patients were selected for this study after an informed consent as per parameters cited above.

Women who met the above requirements were given a full description of the study and asked if they would like to participate.

Those who gave written informed consent were randomly assigned to one of the two study regimens using sequentially numbered envelopes. Women who were unable to read the consent form had the form read to them in their native language. Those who did not wish to participate were given standard treatment and care.

Those received misoprostol were admitted in the ward for 24- 48 hours to deal with any heavy episode of bleeding that might occur. Later, they were discharged and scheduled to return to the hospital for follow-up care after 1-2 wk. Women were also informed that they had every right to return to the hospital or contact the study providers at any time if they had additional concerns. Those women who were randomised to surgical treatment with MVA were managed according to the standard of care at the hospital, using 'verbal anaesthesia' (i.e. reassurance) alone during the procedure. The pain was assessed by Likert Scale.<sup>8</sup>

Each woman was requested to return to the hospital 1-2 wk after treatment. If the abortion was found to be complete at the follow-up visit, the woman was released from the study. If the abortion was still incomplete, the woman was offered the choice between an additional follow-up visit in 1 week with no further intervention during this period or immediate surgical evacuation. If after the additional week of follow up the abortion was still not complete, the woman underwent D & E.

Statistical analyses were done applying standard and appropriate statistical tests (for example, Chi-square tests used for categorical data and t tests for continuous data) with standard statistical software (IBM SPSS Statistics).

### 3. Result

160 women were recruited to the trial, of which 80 women were grouped into misoprostol group & another 80 to MVA group. Immediately after abortion, all the patients were available & data collected from all the patients. But during next follow-up after 1-2 wk, 33 in the MVA group & 27 in the misoprostol group did not come (Lost to follow up n=33) for follow-up. So, approximately 41% (33) of participants in MVA group & 34% (27) in the misoprostol group were lost to follow-up.

In our study both MVA & Misoprostol groups had similar age distribution. Mean age in MVA group 23.5 years ( $\pm$  4.5) and in MISO group 23.4 Years ( $\pm$  4.8). (Table 1)

Regarding Obstetric history- In our study 65% in MISO group & 58.75% in MVA group were Primi-Gravida. Both the groups were comparable in regard to the number of previous miscarriages. Almost two third patients in both the groups had no previous history of any miscarriage.

Because many of the patients were not sure about their LMP, a clinical examination & assessment of the size of the uterus is necessary. The majority of patients presented with an 8 – 10 wk size gravid uterus.(Table 2)

When the women who returned for follow-up at 1–2 weeks were analyzed, 92.45% of women assigned to misoprostol and 95.8% of women assigned to MVA had a completed abortion following use of their allocated treatment alone. 4 women in the misoprostol group and 1 in the manual vacuum aspiration group required an additional re-evacuation of the uterus after the initial treatment (Table 3).

The rate of complications was higher in the manual vacuum aspiration group. In that group, 3 women experienced bleeding from cervical trauma during treatment (although no women needed more than a single cervical suture), and 6 women had pelvic infection at follow-up, requiring additional antibiotics. In the misoprostol group, only 5 women experienced a complication (Table 4).

Most of the women in both groups didn't report any adverse effects at all, although fever & shivering were significantly more in the MVA group.(Table 5)

Bleeding ranged from mild, for about two-thirds of women, to moderate for another third. Few women enrolled in the study had severe bleeding at the first visit.

In the 6 hours following treatment, bleeding was the most common symptom reported by women in the 2 study groups.

When women were asked to rate the maximum pain they experienced, most reported that the maximum pain was mild or moderate. Women in the MVA group rated their pain significantly higher than those receiving misoprostol, only 20% in the misoprostol group have experienced moderate to severe pain, as compared to 41.25% in the MVA group. (Table 6)

Interestingly, for maximum bleeding following treatment, the opposite was found, with women in the misoprostol group rating their bleeding significantly greater than those receiving manual vacuum aspiration. (Almost 30% in the misoprostol group have moderate to severe bleeding, as compared to only 16.25% in the MVA group).(Table 6)

Table 7 shows women's reports of overall satisfaction when assessed at their follow-up visits. Regardless of the treatment they received, 70-80% of women indicated that they were either "very satisfied" or "satisfied" with their experience.

### 4. Discussion

This study shows that 600 mg oral misoprostol is as effective as manual vacuum aspiration for the treatment of incomplete abortion and, in so doing, suggests that the medical management of this condition may be feasible and successful in less-developed countries.

Rates of complications and reported adverse effects were infrequent in both treatment groups. Pelvic infection was observed in 4 woman receiving misoprostol and 6 receiving manual vacuum aspiration, and each of these

**Table 1:** Distribution of patients

	<b>MVA</b>	<b>MISO</b>	
Primi/ Multi	47(58.75%) / 33 (41.25%)	52(65%) / 24 (35%)	P=0.406 (*Chi-square test)
Previous one miscarriage	15(18.75%)	19 (23.75%)	P=0.335 (*Chi-square test)
H/O Recurrent Miscarriage (≥2)	5(6.25%)	9 (11.25%)	P=0.335 (*Chi-square test)
H/O Previous Induced Abortion	12(15%)	15(18.75%)	P=0.331(*Chi-square test)

**Table 2:** Distribution as per size of uterus on clinical examination (wk)

	<b>MVA</b>	<b>MISO</b>	<b>Grand Total</b>	
<8 wk	19(23.75%)	27(33.75%)	46(57.5%)	X <sup>2</sup> =2.274
8-10 wk	57(71.25%)	48(60%)	105(65.62%)	DF=2
>10 wk	4(5%)	5(6.25%)	9(5.62%)	*P=0.321

**Table 3:** Clinical outcome

	<b>MVA (n= 47)</b>	<b>Misoprostol (n = 53)</b>	<b>RR (95% CI) &amp; P value</b>
Success	45 (95.8%)	49 (92.45%)	RR=0.965(0.87-1.06) P=0.482
Total Failure*	2 (4.2%)	4 (7.5%)	RR=2.186(0.4-11.34) P=0.351
Need for repeat evacuation	1 (2.1%)	4 (7.5%)	
Other causes of failure**	1 (2.1%)	0 (0)	

(\*Failure means those patients, in whom abortion was not completed by allotted treatment. \*\*This woman bled heavily during the MVA, and the clinician therefore used sharp curettage to complete it.)

**Table 4:** Complications in two groups

	<b>MVA (n= 80)</b>	<b>Misoprostol (n = 80)</b>	<b>* RR, 95% CI &amp; P Value</b>
Infection	6 (7.5%)	4 (5%)	RR=0.667 (0.19 – 2.27) P=0.517
Cervical trauma	3 (3.75%)	0	RR=0.143(0.007-2.72) P=0.195
Blood transfusion	3 (3.75%)	1(1.25%)	RR= 0.333 (0.03 – 3.13) P=0.336
Total Complications	12 (15%)	5 (6.25%)	RR=0.417 (0.15- 1.12) P=0.085

\*Assuming MVA as control group

**Table 5:** Women's experiences on the day of treatment

<b>Adverse effects reported by women</b>	<b>MVA (n= 80)</b>	<b>Misoprostol (n = 80)</b>	<b>* RR, 95% CI &amp; P Value</b>
None	49(61.25%)	56(70%)	RR=1.142 (0.91 – 1.43) P=0.246
Backache, headache	15(18.75%)	13(16.25%)	RR=0.867 (0.44-1.7) P=0.677
Dizziness, weakness, malaise	10(12.5%)	8(10%)	RR=0.8 (0.33 – 1.92) P= 0.617
Fever, shivering	16(20%)	3(3.75%)	RR= 0.187 (0.06- 0.62) P=0.006

\*Assuming MVA as control group

**Table 6:** Symptoms

	<b>MVA</b>			<b>Miso</b>			
<b>Blood Loss</b>	Mild	Moderate	Severe	Mild	Moderate	Severe	*P = 0.092
	83.75%	15%	1.25%	70%	25%	5%	
<b>Pain</b>	Mild	Moderate	Severe	Mild	Moderate	Severe	*P = 0.01
	58.75%	35%	6.25%	80%	18.75%	1.25%	

**Table 7:** Satisfaction with method

	MVA (n= 47)	Misoprostol (n = 53)	
Very Satisfied	17 (36%)	32(60.4%)	<b>*P=0.024</b>
Satisfied	16 (34%)	9 (17%)	$X^2= 11.25$
Neutral	2 (4.25%)	6 (11.3%)	df= 4
Unsatisfied	9 (19%)	4(7.5%)	
Very Unsatisfied	3 (6.75%)	1 (3.8%)	

infections were successfully treated with antibiotics. (This low rate probably reflects the use of routine antibiotics for all women). Compared with their manual vacuum aspiration counterparts, women receiving misoprostol reported significantly less pain but more bleeding at the time of the procedure.

Irrespective of the method they received, women were generally satisfied with their treatment.

For low-resource settings, this study suggests that misoprostol may have a number of advantages over manual vacuum aspiration.

1. Firstly, misoprostol appears to be a much more flexible treatment. For manual vacuum aspiration, a definite diagnosis of both abortion status and gestation needs to be made. The same may not be true of misoprostol. A review of the known failures in this study demonstrates that, while all 4 failures in the misoprostol group were attributable to failure of the drug, 1 of the 2 failures in the manual vacuum aspiration group were due to inaccurate clinical diagnosis, causing profuse bleeding, which could not be controlled by MVA, so curettage used to complete the evacuation.
2. The second benefit of misoprostol is its ease of use. Manual vacuum aspiration requires a specific piece of equipment along with a trained operator. Even in a training centre such as DSP Main Hospital, manual vacuum aspiration kits or trained surgical providers may be unavailable sometimes. Misoprostol, however, is readily available at low cost (approximately Rs.50 for a 600 $\mu$ g tablet) in local pharmacies and could be safely administered by midlevel providers. Access to misoprostol treatment, therefore, may be greater than that of manual vacuum aspiration.

In our study, clinical examination, rather than ultrasonography, was used to diagnose an incomplete abortion, as is the usual practice in India. The failure to correctly diagnose gestational age on initial clinical examination is a reality of clinical practice in many parts of the world. Indeed, the fact that there was no significant excess of failures in the misoprostol group suggests that 600  $\mu$ g oral misoprostol may be equally effective at slightly later gestations. This study suggests that both methods can be safely offered to women without unnecessary recourse to ultrasound examination, which is expensive and dependent on skilled providers.

The major weakness of this trial is the low rate of attendance at the follow-up visit. The low rate of follow up was recognized early in the study, and numerous attempts were made to improve it. Despite these efforts, which included a review of the quality of counselling offered to women before and just after treatment, nearly 40% of the study participants did not return to the hospital for follow-up care.

The low rate of return is not that surprising, given that induced abortion is highly stigmatized in India. Indeed, to receive any formal treatment for an abortion (whether induced or spontaneous) can be seen as shameful, and this may have inhibited women from attending their follow-up visits, irrespective of whether they had a manual vacuum aspiration or misoprostol. The discomfort of having a manual vacuum aspiration may also have discouraged women in that group from re-attending, through fear of needing to undergo a further surgical technique. In the misoprostol group, the ease of simply swallowing 1 tablets (or 3 tablets 200  $\mu$ g) may have led to less anxiety; hence, the finding that they were significantly more likely to return for follow-up.

In low-resource, third world countries, such as India, where abortion rates are very high, inexpensive and easy-to-use treatments are badly needed, and the introduction of misoprostol could greatly benefit both women and providers.

Post-abortion care based on misoprostol treatment requires minimal technical skill and is ideal for rural health centres with limited facilities. Provided that clinicians can correctly assess whether the internal cervical os is open or not, they can safely administer misoprostol. Manual vacuum aspiration requires more equipment and more advanced staff and is therefore better suited to larger health centres for use as second-line therapy.

Future studies should address the appropriate application of misoprostol-based post-abortion care outside of tertiary level facilities, as well as the development of home follow-up via simple symptom checklists to assist women in determining whether they need to return to a hospital after treatment. If we can develop practical training programs and treatment protocols for use in rural areas, then the use of misoprostol could potentially lead to a major reduction in abortion-related maternal morbidity and mortality.

## 5. Conclusion

For treatment of first-trimester uncomplicated incomplete abortion, both manual vacuum aspiration and 600  $\mu\text{g}$  oral misoprostol are safe, effective, and acceptable treatments.

However, misoprostol appears to be somewhat better option than MVA, in regards to availability, low cost of therapy, less pain, less need of expert manpower or specialised instruments.

Based on availability of each method and the wishes of individual women, either option may be presented to women for the treatment of incomplete abortion.

Misoprostol & MVA both methods can be safely offered to women without unnecessary recourse to ultrasound examination, which is expensive and dependent on skilled providers.

For developing countries like India, both the methods can provide a solution for treatment of incomplete abortion safely and misoprostol is more suitable for use in rural health care facilities.

Misoprostol for post-abortion care (PAC) would decrease the burden on tertiary health care facilities because of its low cost.

## 6. Sources of Funding

None.

## 7. Conflict of Interest

The authors declare that there is no conflict of interest.

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