Scholars Journal of Applied Medical Sciences
Abbreviated Key Title: Sch J App Med Sci
ISSN 2347-954X (Print) | ISSN 2320-6691 (Online)
Journal homepage: https://saspublishers.com

OPEN ACCESS

Obs & Gynaecology

Study on Misoprostol in Case of Missed Abortion

Dr. Fawzia Zaman[1*], Dr. Jesmine Akter[2], Dr. Zinat Ara Ferdousi[3], Dr. Shabeen Afreen[4], Dr. Nasreen Afreen[5]

[1]Associate Professor (Obs & Gynae), Colonel Maleque Medical College, Manikgonj, Bangladesh
[2]Assistant Professor (Obs & Gynae), Colonel Maleque Medical College, Manikgonj, Bangladesh
[3]Assistant Professor (Gynae), Dhaka Medical College and Hospital, Dhaka, Bangladesh
[4]Associate Professor (Obs & Gynae), Dhaka Medical College and Hospital, Dhaka, Bangladesh
[5]Associate Professor, Sher-e-Bangla Medical College, Barishal, Bangladesh

DOI: https://doi.org/10.36347/sjams.2024.v12i10.006 | **Received:** 29.08.2024 | **Accepted:** 05.10.2024 | **Published:** 08.10.2024

***Corresponding author:** Dr. Fawzia Zaman
Associate Professor (Obs & Gynae), Colonel Maleque Medical College, Manikgonj, Bangladesh

Abstract **Original Research Article**

Background: Misoprostol and manual vacuum aspiration (MVA) are both effective treatments for incomplete abortion. Misoprostol, a medication that induces uterine contractions, is often preferred for its non-invasive nature and ease of administration. MVA, a surgical method, involves removing retained products of conception using suction. Studies suggest that while MVA has a higher success rate and faster recovery, misoprostol is a cost-effective, accessible option with fewer complications, though it may require follow-up treatment in some cases. ***Objective:*** In this our main goal is to assess the efficiency of misoprostol versus manual vacuum aspiration for the treatment of incomplete abortion. ***Method:*** This hospital based randomized controlled trial study was conducted in in-patient patient Department of Obstetrics and Gynaecology, Chittagong Medical College and Hospital from October 2007 to September 2008. A total of 128 women between the age of 15 to 40 years with diagnosis of first trimester uncomplicated spontaneous incomplete abortion was included in this study. Among them 64 patients were randomized in group 'A' as case who were treated with Misoprostol and 64 patients were in group 'B' as control who were treated with Manual Vacuum Aspiration. ***Results:*** During the study, where the mean gestational size of uterus was 9.52 weeks at the time of initial examination. The mean size of uterus in misoprostol group was 9.07(SD ±1.93) and that of MVA group was 9.87 (SD± 1.35). More women in case group had no child of viable age on the other hand increased number of women in control group had at least one viable birth. 36 (60%) out of 60 women in misoprostol group 26 (41.93%) out of 62 reported pain and 36 (58.07%) out of 62 women in MVA and 24 (40%) patients in misoprostol arm said bleeding as the worst feature. Thirty six percent women in misoprostol group and 16% women in MVA group reported that the adverse effects were easily tolerable. Thirty percent women in Misoprostol arm and 29.03 % women in MVA arm were satisfied with their respective treatment. But only 3.23% patients in MVA arm while 53.30% women in Misoprostol arm were very satisfied with their allocated treatment. Fifty (83.3%) patients out of 60 in Misoprostol arm and 18 (29.03) out of 62 women in control group said that they would choose the method again if they face such a problem in future. When they were asked whether they would recommend it to their friends 93.3% patients in Misoprostol group and only 12.5% in MVA group said that they would do it. ***Conclusion:*** We conclude that, Misoprostol was not more effective than MVA (83.33% versus 87.10%, the difference was not statistically significant) but Misoprostol was safer and more acceptable to patients than MVA in treating incomplete abortion.

Keywords: Manual Vacuum Aspiration (MVA), Misoprostol, incomplete abortion.

INTRODUCTION

Early pregnancy failure is a major public health problem throughout the world. It is estimated that-approximately 10-15% of all pregnancies end in spontaneous miscarriage. Abortion may be defined as expulsion or extraction of the placenta or membrane, without an identifiable foetus or with a fetus (alive or dead) weighing less than 500 gm. Incomplete abortion is the expulsion of some, but not all, of the product of conception and needs immediate care. Limited access to safe post abortion care also contributes significantly to maternal mortality and morbidity in developing world [1-3].

In most of the developing countries Dilatation, Evacuation and Curettage (D, E&C) is the standard approach for the treatment of incomplete abortion. However, in the developed countries, Manual Vacuum Aspiration (MVA) is the standard method for evacuation

of retained product of conception because of fear of hemorrhage and sepsis [4]. D&C was replaced by MVA which was found to be just as effective as D&C but cheaper and with fewer side effects. This technique requires a syringe and cannula made of plastic material are used to produce negative pressure to create vacuum inside the syringe for aspiration of uterine contents. But unfortunately, both these procedures (MVA and D&C) are not always possible in low resource settings as they require special equipment and trained individuals [3,5].

Misoprostol could be an effective alternative to MVA for the treatment of incomplete abortion allowing women to avoid surgical interventions and associated risks. Misoprostol is cheap, widely available and stable at room temperature and can be administered by patient herself [1,2,6]. Misoprostol can be administered by oral, sub lingual, vaginal and rectal route. On the other hand, side effects of Misoprostol like nausea, vomiting, and abdominal cramps are minimum and tolerable. In this our main aim is to assess the efficiency of misoprostol versus manual vacuum aspiration for the treatment of incomplete abortion.

OBJECTIVE

General objective:

To evaluate the efficiency of misoprostol versus manual vacuum aspiration for the treatment of incomplete abortion.

Specific objective:

- To identify clinical characteristic of the patients.
- To detect outcome of treatment of the patients.

METHODOLOGY

Study type: this was a Hospital Based Randomized Controlled Trial study.

Study place and period:

This study was conducted in in-patient patient Department of Obstetrics and Gynaecology, Chittagong Medical College and Hospital from October 2007 to September 2008.

Study population: A total of 128 women between the age of 15 to 40 years with diagnosis of first trimester uncomplicated spontaneous incomplete abortion was included in this study. Among them 64 patients were randomized in group 'A' as case who were treated with Misoprostol and 64 patients were in group 'B' as control who were treated with Manual Vacuum Aspiration.

Inclusion criteria

- Incomplete abortion -diagnosed clinically and Sonographically.
- Gestational age < 12 weeks.
- Haemodynamically stable patients.
- Women willing to return for follow up.

Data collection procedure:

After enrollment patients in Misoprostol group were asked to take 600 pgm Misoprostol orally. All the possible adverse effects like nausea, vomiting, abdominal pain, shivering, fever another was mentioned to the patients and advised to call on duty doctor even the investigator if any problem arises.

Patients allocated for the MVA group were transferred to gynae operation theatre and MVA was done by the investigator herself. Along with proper counseling Diclofenac Sodium suppository was given per-rectally for control of pain. Injection Ergometrine (2 amp) intramuscularly was given as per hospital protocol. Ciprofloxacin (Tab 500 mg B. D) and Metronidazole (Tab 400mg t.d.s) were given to both group of patients because of high rate of infection. Women were discharged on next day irrespective of their abortion status. In addition, women were provided with name and contact information of the investigator to speak with in the event of complications or any other reason. The importance of follow up visits was stressed with all women.

A follow up schedule was fixed on day seven and day fifteen. At each follow up all women were examined clinically to assess the general condition as anemia, blood pressure and abortion status was assessed. Bimanual examination was done to ensure that the uterus had involuted properly.

The women who were found that abortion was completed clinically no Ultrasonography (USG) was done at day seven follow up. If any complain like excessive vaginal bleeding or uterus was not involuted adequately, USG was done on day seven follow up. If sonography suggested that significant amount of retained product of conception present within the uterus, were regarded as incomplete evacuation and woman were given options to wait for another one week for spontaneous expulsion or immediate surgical evacuation. Women, who disagreed to wait, underwent MVA.

All women who refused to wait for spontaneous expulsion or failed to expel within 15 days in Misoprostol group or women who were diagnosed as incomplete evacuation in surgical group, all were counted as treatment failure and managed by MVA. Ultrasonography and blood for Hb% were done to all women on day fifteen.

Statistical Analysis:

The test statistics used to analyze the data were descriptive statistics. Chi- square (x^2) and unpaired ^{4}f test. Means were compared by unpaired'f test and Chi-Square (x^2) were used for proportion. For all analytical tests, the level of significance was set at <0.05 and P

<0.05 was considered significant. The summarized data were presented in the form of tables and charts.

RESULTS

In table-1 shows age distribution of the patients where the mean age group in Misoprostol group was 24.83 (SD±4.53) years and in MVA group 29.13(SD± 5.13) years. The mean age group in Misoprostol group was lower than that of MVA group. The following table is given below in detail:

Table-1: Age distribution of the patients

Age (Years)	n	Mean	± sd	Median	Range	Sign.
CASE	60	24.83	4.53	25.00	19-37	
CONTROL	62	29.13	5.13	28.00	20-40	P < 0.001 S
TOTAL	122	27.12	5.18	26.00	19-40	

In table-2 shows clinical characteristics of the patients where the mean gestational size of uterus was 9.52 weeks at the time of initial examination. The mean size of uterus in misoprostol group was 9.07(SD ±1.93) and that of MVA group was 9.87 (SD± 1.35). More women in case group had no child of viable age on the other hand increased number of women in control group had at least one viable birth. The following table is given below in detail:

Table-2: Clinical characteristics of the patients

Variable	Misoprostol, (Mean)	MVA, (Mean)
Gestational age weeks	**9.47(SD ± 2.03)**	**10.39 (SD ± 1.39)**
Size of uterus	**9.07(SD ± 1.93)**	**9.87(SD± 1.35)**
Parity		
0	**16**	**6**
>1	**44**	**58**
Previous miscarriage	**14**	**18**
Previous TOP	**14**	**14**

In table-3 shows Almost all women returned for follow up except two women in control group lost from follow up after seven days. Hundred percent (60 out of 60) women in case group and 96.90% (62 out of 64) women in control group returned for follow up. The following table is given below in detail:

Table - 3: Follow up of patients on day seven (Day 7)

Follow up at day 7	Study groups				Sig
	Case n %		Control n %		
ANAEMIA					
Mild	**44**	**73.30**	**56**	**90.32**	**P<0.05 S**
Moderate	**16**	**26.70**	**06**	**9.68**	
Total	**60**	**100.00**	**62**	**100.00**	
PV BLEEDING					
Nil	**02**	**3.34**	**14**	**22.58**	**P<0.001 FIS**
Mild	**40**	**66.60**	**42**	**67.74**	
Moderate	**18**	**30.06**	**06**	**9.68**	
Total	**60**	**100.00**	**62**	**100.00**	
SIZE OF UTERUS					
Normal	**08**	**13.30**	**00**	**0.00**	**P<0.01 HS**
Reduced	**44**	**73.40**	**60**	**96.78**	
As Before	**08**	**13.30**	**02**	**3.22**	
Total	**60**	**100.00**	**62**	**100.00**	

In table-4 shows distribution of outcome of treatment among study groups. When the women who returned for follow up at 2 weeks interval were analyzed, 83.33% (50out of 60) patients assigned to Misoprostol and 87.10% (54 out of 62) women assigned to MVA had complete abortion following having of their allocated treatment. The following table is given below in detail:

Table-4: Distribution of outcome of treatment among study groups.

Outcome of treatment	Study groups			
	Case		Control	
	n	%	n	%
Complete Expulsion	**50**	**83.33**	**54**	**87.10**
(Success) Incomplete Expulsion (Failure)	**10**	**16.67**	**08**	**12.90**
Total	**60**	**100.00**	**62**	**100.00**

Chi-square ($\%^2$) value = 0.433, df= 1 P >0.05 NS

In table-5 shows management of treatment failure. All patients who refused to wait tor spontaneous expulsion or failed to expel within 15 days in Misoprostol group or women who were diagnosed as incomplete evacuation after surgical procedure all were counted as treatment failure. A total 10 patients in Misoprostol group and 8 women in MVA group were declared as treatment failure and were managed either by MVA or repeat MVA. The following table is given below in detail:

Table -5: Management of treatment failure

Management of Failure	Study groups			
	Case		Control	
	n	%	n	%
By MVA	**10**	**100.00**	**00**	**0.00**
By Repeat MVA	**00**	**0.00**	**08**	**100.00**
Total	**10**	**100.00**	**08**	**100.00**
2 Chi-square (/) value =	18.000, df= 1,		p< 0.001	HS

In table-6 shows distribution of the patients according to complications. Complications like cervical trauma, blood transfusion and others were not reported by any patient. Two patients in Misoprostol group presented as having pelvic infection who were treated with additional antibiotics. Only one patient in MVA group was suspected as a case of iatrogenic uterine perforation identified during the procedure and kept under close observation for 48 hours and necessary investigations were done. As patient's condition improved, she was discharged after three days. The following table is given below in detail:

Table -6: Distribution of complications among study groups

Complications	Study groups			
	Case		Control	
	n	%	n	%
Nil	**60**	**100.0**	**59**	**95.16**
Infection	**00**	**00**	**02**	**3.23**
Suspected Uterine Perforation «•	**00**	**0.0**	**01**	**1.61**
Total	**60**	**100.0**	**62**	**100.00**

Relative Risk (RR) of Infection in Misoprostol Group = 0 RR of Infection in MVA group = 2 (Cl 1.67-2.39)
RR of Uterine perforation in Misoprostol Group = 0
RR of Uterine perforation in MVA group = 1.98 (Cl 1.66- 2.36)

In table-7 shows women's report of overall satisfaction with given treatment. Thirty percent women in Misoprostol arm and 29.03 % women in MVA arm were satisfied with their respective treatment. But only 3.23% patients in MVA arm while 53.30% women in Misoprostol arm were very satisfied with their allocated treatment. Fifty (83.3%) patients out of 60 in Misoprostol arm and 18 (29.03) out of 62 women in control group said that they would choose the method again if they face such a problem in future. When they were asked whether they would recommend it to their friends 93.3% patients in Misoprostol group and only 12.5% in MVA group said that they would do it. The following table is given below in detail:

Table-7: Distribution of satisfaction of patients among study groups

Study groups					Sig.
	Case		Control		
	n	%	n	%	
SATISFACTION PATIENT'S					
Satisfied	18	30.00	18	29.03	P<0.001 HS
Very Satisfied	32	53.30	02	3.23	
• Unsatisfied	10	16.70	42	67.74	
Total	60	100.00	62	100.00	
Choose the method again					
Yes	50	83.30	18	29.03	P< 0.001 HS
No	10	16.70	44	70.97	
Total	60	100.00	62	100.00	
Recommend method to friend					
Yes	56	93.30	08	12.50	P< 0.001 HS
No	04	6.70	54	87.50	
Total	60	100.00	62	100.00	

DISCUSSION

This randomized prospective study determined that both 600 pgm oral Misoprostol and manual vacuum aspiration were highly effective (83.30% versus 87.10%) in the treatment of incomplete abortion but safety and acceptability were higher in Misoprostol group.

In a previous randomized trial conducted by one study where they observed that success was very high in both arms. Complete expulsion was 96.3% and 91.5% in Misoprostol and MVA group respectively [2]. In current study the success rate was in 83.33% in Misoprostol and 87.10% in MVA arm respectively. The difference was not statistically significant ($p > 0.05$). It is similar to the other study where it was observed that success rate was 94.5% with Misoprostol and 99.1% with MVA [7]. It is evaluated that efficacy is not the only important factor for selection of a treatment option for the treatment of incomplete abortion [20]. The efficacy of Misoprostol treatment for early pregnancy failure has varied greatly ranging from 13 to 100 percent shown in retrospective and prospective studies. This variation may be attributable to small sample sizes, the type of pregnancy failure (anembryonic gestations and embryonic or fetal death versus- incomplete abortion), the dose and route of administration of Misoprostol and the criteria used to define success [7].

In a study done in 1999 to determine whether medical treatment of early pregnancy failure represents a reasonable alternative to surgical treatment. In the medical arm of study, 800 pgm Misoprostol was applied in posterior fornix of vagina. Misoprostol was re-administered only if ultrasound images revealed evidence of persistent of pregnancy tissue. Fifteen out of 25 women in medical arm (60%; 95% Cl, 0.41-0.79) had successful pregnancy termination and did not require curettage.

There was no significant difference between the medical and surgical treatment with respect to either post treatment [8].

In a randomized clinical trial study, compared the quality of life (QOL) and acceptability between medical and surgical treatment group. They observed that there was no difference in QOL except bodily pain. Medical treatment was associated with higher level of bodily pain [9].

In another randomized trial conducted one study using 400 pgm oral misoprostol four hourly up to a total of 1200 pgm demonstrated that there was significant lower incidence of immediate and short-term complications in the group treated with Misoprostol in comparison to surgically treated patient [10].

In present study rates of complications were higher in MVA group. Two women in MVA group came with fever and vaginal discharge on day seven follow up and diagnosed as having pelvic infection. They were treated with additional antibiotics for pelvic infection. The total infection rate was minimum in this study which probably due to the routine use of antibiotics in both group of patients. Only one woman in MVA group was suspected as a case of uterine perforation during the procedure and kept under close observation for 72 hours. Patient condition improved and she was discharge after 3 days. Irrespective of methods used, patients of both sides were satisfied with the procedure they allocated. But significantly more women in misoprostol group were highly satisfied with the procedure they received and would choose the method again if they face such a problem in future and recommend to their friends if needed. Women who treated with Misoprostol praised the method because of its simplicity and less intense pain while women receiving MVA praised the good counseling and care.

CONCLUSION

We conclude that, Misoprostol was not more effective than MVA (83.33% versus 87.10%, the difference was not statistically significant) but Misoprostol was safer and more acceptable to patients than MVA in treating incomplete abortion.

REFERENCE

1. Curtis, C. (2007). Meeting health care needs of women experiencing complications of miscarriage and unsafe abortion: USAID's postabortion care program. *Journal of midwifery & women's health*, *52*(4), 368-375.
2. Weeks, A., Alia, G., Blum, J., Winikoff, B., Ekwaru, P., Durocher, J., & Mirembe, F. (2005). A randomized trial of misoprostol compared with manual vacuum aspiration for incomplete abortion. *Obstetrics & Gynecology*, *106*(3), 540-547.
3. Maternal and Neonatal Program Effort Index (MNPI). Source: Population Reference Bureau - 2002 Women of our world ; 2001 World Population Data Sheet; The world Youth, 2000; and 1999 Breastfeeding Patterns in the Developing World.
4. Griebel, C. P., Halvorsen, J., Golemon, T. B., & Day, A. A. (2005). Management of spontaneous abortion. *American family physician*, *72*(7), 1243-1250.
5. Gemzell-Danielsson, K., Fiala, C., & Weeks, A. (2007). Misoprostol: first-line therapy for incomplete miscarriage in the developing world. *BJOG*, *114*(11), 1337-9.
6. Shwekerela, B., Kalumuna, R., Kipingili, R., Mashaka, N., Westheimer, E., Clark, W., & Winikoff, B. (2007). Misoprostol for treatment of incomplete abortion at the regional hospital level: results from Tanzania. *BJOG: An International Journal of Obstetrics & Gynaecology*, *114*(11), 1363-1367.
7. Dao, B., Blum, J., Thieba, B., Raghavan, S., Ouedraego, M., Lankoande, J., & Winikoff, B. (2007). Is misoprostol a safe, effective and acceptable alternative to manual vacuum aspiration for postabortion care? Results from a randomised trial in Burkina Faso, West Africa. *BJOG: An International Journal of Obstetrics & Gynaecology*, *114*(11), 1368-1375.
8. Muffley, P. E., Stitely, M. L., & Gherman, R. B. (2002). Early intrauterine pregnancy failure: a randomized trial of medical versus surgical treatment. *American journal of obstetrics and gynecology*, *187*(2), 321-326.
9. Harwood, B., Nalsen, T (2008). Quality of life and acceptability of medical versus surgical management of early pregnancy failure. *BJOG*; *115*, 501- 508.
10. Chung, T. K. H., Lee, D. T. S., Cheung, L. P., Haines, C. J., & Chang, A. M. Z. (1999). Spontaneous abortion: a randomized, controlled trial comparing surgical evacuation with conservative management using misoprostol. *Fertility and sterility*, *71*(6), 1054-1059.