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THE OUTCOME OF MISOPROSTOL FOR THE TREATMENT OF INCOMPLETE ABORTION

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ABSTRACT

Objective: *In this study our main aim is to evaluate the outcome of misoprostol 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, on day 15 follow up no patient was significantly anemic in any group. But more patients in Misoprostol group (63.3% versus32.25%) complained of mild bleeding or spotting in comparison to MVA group. Also, there was no significant difference in mean Hemoglobin concentration between case and control measured at the end of treatment.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.* ***Conclusion:*** *We conclude that, Misoprostol was safer, and more acceptable than MVA to most of the women enrolled in the study.*

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

INTRODUCTION

Miscarriage, also known in medical terms as a spontaneous abortion and pregnancy loss, is the natural death of an embryo or fetus before it is able to survive independently.[1-2] Some use the cutoff of 20 weeks of gestation, after which fetal death is known as a stillbirth.[3] The most common symptom of a miscarriage is vaginal bleeding with or without pain.[1] Sadness, anxiety and guilt may occur afterwards.[3][14] Tissue and clot-like material may leave the uterus and pass through and out of the vagina.[15] When a woman keeps having miscarriages, infertility is present.[5]

For the treatment of incomplete abortion surgical procedure like Manual Vacuum Aspiration (MVA) is associated with risks of hemorrhage, infection, cervical trauma, uterine perforation, other long-term morbidities like intrauterine adhesions, secondary infertility, ectopic pregnancy, chronic pelvic pain and others. Moreover, this procedure needs skilled individuals, special equipment's and organized set up which are not always possible in low resource settings. Medical management with Misoprostol, a synthetic Prostaglandin E, analogue ripens the cervix and causes expulsion of retained product of conception by uterine contraction. Thereby avoids complications associated with surgical methods. Misoprostol is chief, widely available, and stable at room temperature. For administration of Misoprostol neither special equipment's nor trained individual is required, even it can be administered by the patient herself. So, use of Misoprostol in the treatment of incomplete abortion may be safe and effective and can reduce maternal mortality and morbidities significantly.[6] In this study our main aim is to evaluate the outcome of misoprostol for the treatment of incomplete abortion.

OBJECTIVE

- To assess the outcome of misoprostol for the treatment of incomplete abortion.

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 case (n=60) and control (n=62) were distributed into five groups in frequency ranges < 20, (21-25), (26- 30), (31-35) and > 35yrs. In case group 60 women were divided into 12 (20%), 28 (46.7%), 14 (23.3%), 04 (6.7%), 02 (3.3%) and in control group total 62 women were divided into 04(6.5%), 10(16.1%), 26 (41.9%), 14 (22.6%), 08 (12.9%) in five groups. The following table is given below in detail.

Table 1: Distribution of age among study group.

Age in groups			Study groups	
		Case	Control	
	n	%	n	%
< 20 Years	12	20.00	04	6.50
21 to 25 Years	28	46.70	10	16.10
26 to 30 Years	14	23.30	26	41.90
31 to 35 Years	04	6.70	14	22.60
> 35 Years	02	3.30	08	12.90
Total	60	100.00	62	100.00

In table-2 shows clinical characteristics of patients**.** 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 patients (Distribution of gestational age, uterine size, parity and others).

Gestational age weeks	**Misoprostol**	**MVA**
	9.47(SD ± 2.03)	**10.39 (SD ± 1.39)**
(Mean)		
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 distribution of the patients according to follow-up after 15 days where on day 15 follow up no patient was significantly anemic in any group. But more patients in Misoprostol group (63.3% versus32.25%) complained of mild bleeding or spotting in comparison to MVA group. The following table is given below in detail.

Table 3: Follow up at day 15 Study groups.

ANAEMIA	**Case**		**Control**		
	n	**%**	**n**	**%**	
Mild	**46**	**76.66**	**51**	**82.25**	
Moderate	14	23.30	11	17.75	P>0.05 NS
Total	60	100.00	62	100.00	
PV BLEEDING					
Nil	18	30.00	41	66.13	
Mild	38	63.00	20	32.25	P>0.05 NS
Moderate	04	6.70	01	1.62	
Total	60	100.00	62	100.00	
SIZE OF UTERUS					
Normal	38	63.40	39	62.93	
Reduced	20	33.30	21	33.87	
As Before	02	3.30	02	3.20	P< 0.01 HS
Total	60	100.00	62	100.00	

In table-4 shows distribution of Hemoglobin concentration (gm/ dl) among study group. There was no significant difference in mean Hemoglobin concentration between case and control measured at the end of treatment. The following table is given below in detail.

Table 4: Distribution of Hemoglobin concentration (gm/ dl) among study group.

HEMOGLOBIN¯

CONCENTRATION N		**MEAN**	**±SD**	**MEDIAN**	**RANGE**	**SIGN**
On admission						
Case	60	10.73	0.61	10.50	10-12.5	
Control	62	10.91	0.68	11.00	10-12.5	p>0.05
Total	122	10.82	0.65	11.00	10-12.5	
On day 15						
Case	60	10.08	0.57	10.00	9.5-11.5	
Control	62	10.14	0.59	10.00	9.5-11.5	p>0.05
Total	122	10.11	0.57	10.00	9.5-11.5	

In table-5 shows distribution of worst features and tolerability among study groups, on return visit all women were inquired about the worst features they experienced during their treatment.The following table is given below in detail.

Table 5: Distribution of worst features and tolerability among study groups.

Study groups	Case		Control		
	n	%	n	%	
WORST FEATURES					
Pain	36	60.00	26	41.93	
Bleeding	24	40.00	36	58.07	p <o.cl; S
Total	60	100.00	62	100.00	
TOLERABILITY					
Tolerable	08	13.30	38	61.29	
Moderately tolerable	16	26.70	08	12.90	P<0.00i IS
Easily Tolerable	36	60.00	16	25.81	
Total	60	100.00	62	100.00	

In figure-1 shows distribution of complications among study groups. 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 figure is given below in detail.

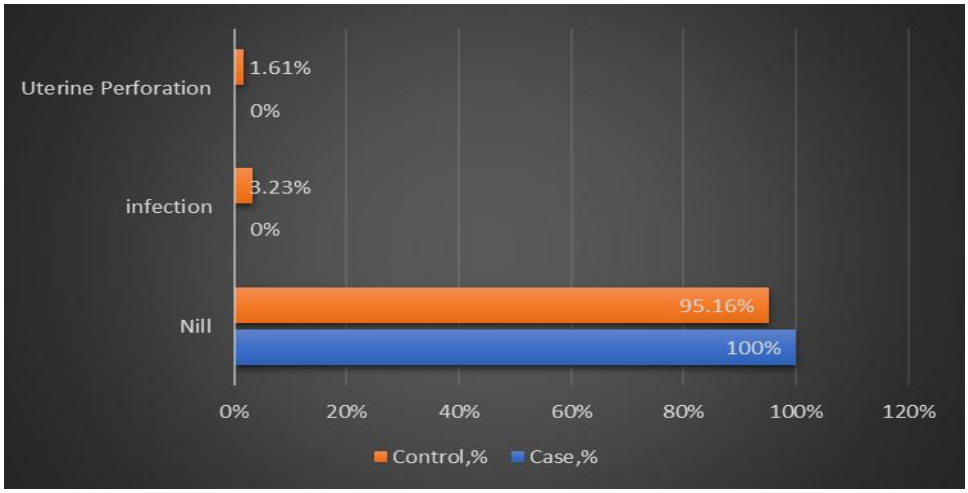

Figure 1: Distribution of complications among study groups.

In figure-2 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. The following figure is given below in detail.

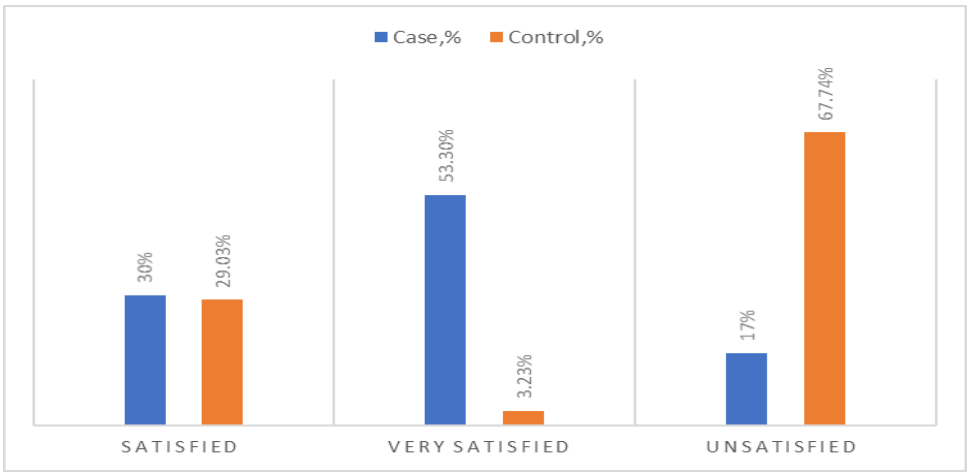

Figure 2: Distribution of satisfaction of patients among study groups.

DISCUSSION

Spontaneous abortion is one of the most common complications of pregnancy. It is estimated that as many as 12%-15% of clinically recognized pregnancies and as many as 17%- 22% of all pregnancies result in spontaneous abortion. [7]The accepted and standard treatment of spontaneous abortion is till now surgical procedure either by sharp curettage or manual vacuum aspiration, depending on local practice standards.[8]

One study assessed the bleeding pattern in woman when treated with Misoprostol. In this randomized trial they observed that prolong bleeding at least 2 weeks is common in medical treatment with Misoprostol. Heavy bleeding occurred only few days after treatment and but no significant changes in hemoglobin concentration found between two groups[9]. In current study we also observed that bleeding continued for long time even up to 15 days in women who were treated with Misoprostol but there was no significant difference in mean haemoglobin concentration in two groups measured at the end of treatment.

Most women receiving Misoprostol reported bleeding for prolong duration which was mainly mild and moderate type. Heavy bleeding occurred only few days following treatment. They also complain of pain and abdominal cramps.

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.

CONCLUSION

We conclude that, Misoprostol was safer, and more acceptable than MVA to most of the women enrolled in the study.

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