

**Research Article****Comparison of Efficacy between Balloon Inflation and Utero Vaginal  
Packing in Term of Control of Primary Post-Partum  
Hemorrhage after Vaginal Delivery**<sup>1</sup>Ayesha Iqbal, <sup>2</sup>Hafiz Mahmood Ahmedand <sup>3</sup>Zahid Sharif<sup>1</sup>Ex. House Officer

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**ABSTRACT**

**Objective:** To compare the efficacy of manual vacuum aspiration (MVA) and medical treatment in the management of first trimester missed miscarriage.

**Material and methods:** This randomized controlled was conducted at Department of Obstetrics and Gynaecology, Mayo hospital Lahore from January 2017 to June 2017.

**Results:** Efficacy was noted in 48 (92.3%) patients and 40 (76.9%) patients respectively in group A & B. Efficacy rate in group A was significantly ( $P = 0.05$ ) higher as compared to group B. Mean age of the patients was  $29.63 \pm 6.68$  years, mean age of the patients of study group A was  $30.23 \pm 6.72$  years and mean age of patients of group B was  $29.02 \pm 6.65$  years.

**Conclusion:** Results of this study revealed that MVA is better treatment modality as compared to medical management (misoprostol intravaginally). Efficacy rate was significantly higher in MVA group as compared to medical treatment group. In older age group MVA group was found with significantly higher rate of efficacy as compared to medical management group.

**Keywords:** Manual vacuum aspiration, dilatation and evacuation, incomplete abortion.

**INTRODUCTION**

Missed abortion is a relatively common event, occurring in up to 10-20% of recognized pregnancies<sup>1</sup>. Missed abortion is in utero death of the embryo or fetus before the 20th week of gestation with retained products of conception. Missed abortions also may be referred to as blighted ovum, anembryonic pregnancy, or fetal demise<sup>2</sup>.

For the past 50 years, surgical evacuation by dilatation and curettage (D&C) has been the primary treatment of missed abortion.<sup>3</sup> This procedure is generally considered safe, but complications such as infection, bleeding, uterine

perforation and decreased fertility occur in up to 10 percent of women<sup>3</sup>. Recent studies have questioned the need for routine D&C, suggesting that expectant or medical management might be more appropriate.<sup>3</sup>

A medical abortion is one that is brought about by taking medications that will end a pregnancy.<sup>4</sup> Many drugs are used for medical abortion these are misoprostol, mifepristone and methotrexate. Misoprostol and mifepristone are commonly used drugs for medical abortion.<sup>5</sup> Vaginal misoprostol is a safe, effective

and acceptable method of inducing abortion with a reported effectiveness of 88–94%.<sup>6</sup>

In one study by Shuaib AA et al<sup>7</sup> 52 women were allocated to receive intravaginal misoprostol, 80.7% achieved a successful complete expulsion of the products of conception. Shankar M et al<sup>8</sup> also concluded that 77.3% women achieved successful complete medical evacuation by receiving misoprostol. Shah N et al<sup>9</sup> also found 48% success rate with intravaginal misoprostol for the complete evacuation of first trimester missed abortion.

Another way to treat first trimester missed miscarriage is by means of manual vacuum aspiration. It is the most common method in our setup believe to be safe and cost effective in experienced hands. But even with advancement in medical science, unsafe abortion related complications contribute to 10 to 13% in developing countries.<sup>10</sup> In one study by Tasnim N et al,<sup>11</sup> complete evacuation was achieved in 89.6% with manual vacuum aspiration. In a study by Hemlin J et al<sup>12</sup> success rate with manual vacuum aspiration was 95.2%. Edwards S<sup>13</sup> also reported success rate with manual vacuum aspiration as 98%. Ansari R et al<sup>14</sup> found success rate with manual vacuum aspiration as 97.7%.

We would conduct study in the department of obstetrics and gynaecology, Mayo hospital Lahore, for our population that mostly belongs to lower socio-economic class. We will compare the efficacy of both methods of uterine evacuation with misoprostol or with manual vacuum aspiration. It will provide a new guideline for the management of miscarriage in first trimester in our population.

### OPERATIONAL DEFINITION

**Efficacy:** Efficacy was measured in term of complete abortion:

**Complete Abortion:** When the uterine cavity is empty on pelvic USG.

#### **Manual Vacuum Aspiration (MVA):**

MVA was performed using a flexible "Ipas Easy Grip" cannula attached to a 60 ml syringe

(aspirator), with a double locking valve mechanism (IPAS Chapel Hill NC 27514 USA).

**Medical Management:** 800µg misoprostol was given intravaginally.

#### **First Trimester Missed Abortion:**

Diagnosis was made by the presence of all of them:

1. Regression of pregnancy symptom like nausea, vomiting, morning sickness.
2. Smaller size of uterus in relation duration of pregnancy on bimanual pelvic examination.
3. Absent cardiac activity on ultrasound.

### MATERIAL AND METHODS

This randomized controlled was conducted at Department of Obstetrics and Gynaecology, Mayo hospital Lahore from January 2017 to June 2017.

#### **Inclusion Criteria:**

- Patients with first trimester missed miscarriage of less than 12 weeks gestation diagnosed by ultrasound showing gestational sac of less than 25 mm in diameter with no fetal cardiac activity.
- Age 18 to 40 years.
- Primary para, multi para and grandmultipara.

#### **Exclusion Criteria:**

- Patients with known hypersensitivity to misoprostol.
- Gestation >12 weeks.
- Patients having ectopic pregnancy or molar pregnancy.
- Patients with septic abortion.
- Patients with previous c-section.

### DATA COLLECTION PROCEDURE

Total 104 patients with first trimester missed abortion were included in this study after scrutinized by inclusion criteria and after taking written consent from Institutional Review Board. Written consent was taken from every patient. All included patients were offered to pick up a slip from total mixed up slips (half-slips was contain letter "A" and other half-slips contain letter "B") and she was placed in that group (Group-A or

Group-B according to slip). In this way two groups were made. In group A Manual Vacuum Aspiration was done and in Group B Misoprostol was given intra virginally.

In Group A, prophylactic antibiotic (Doxycycline 100 mg) was given 1 hour before the procedure and oral analgesic (tab valium and tab brufen) was also given. Local analgesia in the form of paracervical block was given. Uterine cavity was evacuated with manual vacuum aspiration. Effectiveness was measured in terms of complete evacuation, which was confirmed peroperatively when pink or red foam without RPOC's passed through the cannula. Incomplete evacuation was diagnosed when products of conception was passing continuously inspite of inserting cannula more than 4 times and another procedure was required to evacuate the uterus.

Second group consisted of patients receiving misoprostol intra vaginally. Each case received misoprostol 800µg per vagina with 2.5ml hydroxyethyl gel. The misoprostol was obtained as white powder made by crushing tablets of Cytotec (Searle, Skokie, Illinois, USA). The white powder was mixed with repacked sterile 2.5ml hydroxyethyl gel (SmithKline, Glaxo, Karachi, Pakistan) and the mixture was drawn into a sterile 5ml disposable syringe without a needle. This was then squirted into posterior vaginal fornix and the time was noted. Pelvic USG was performed, if found the RPOCs then 400µg misoprostol was repeated at six hourly intervals for maximum two doses. Final outcome was assessed after 18 hours (on completion of 3 doses).

Efficacy of both groups was noted in pre-designed proforma. Demographic data of all the patients was also be entered in performa.

#### **DATA ANALYSIS PROCEDURE:**

All the data was entered in SPSS V17 for statistical analysis. Quantitative variable like age, gestational age was presented as mean  $\pm$  SD, while qualitative variable like efficacy and parity was presented in frequency and percentages. Chi-square test was applied to compare the efficacy in both groups. Stratification was done for age,

gestational age and parity. Post stratification. Chi-square test was applied to see the level of significance. P-values  $\leq$  0.05 was considered statistically significant.

#### **RESULTS**

Total 104 patients with first trimester missed miscarriage of less than 12 weeks gestation were included in this study. Mean age of the patients was  $29.63 \pm 6.68$  years, mean age of the patients of study group A was  $30.23 \pm 6.72$  years and mean age of patients of group B was  $29.02 \pm 6.65$  years. (Table 1)

Total 25 (48.08%) patients of group A belonged to age group 20-30 years and 27 (51.92%) patients belonged to age group 31-40 years. In group B, 32 (61.54%) patients belonged to age group 20-30 years and 20 (38.46%) patients belonged to age group 31-40 years. (Fig. 1)

In group A, 29 (55.77%) patients belonged to 1-6 weeks gestational age group and 23 (44.23%) patients belonged to 7-12 weeks gestational age group. In group B, 33 (63.46%) patients belonged to 1-6 weeks gestational age group and 19 (36.54%) patients belonged to 7-12 weeks gestational age group. (Fig. 2)

Patients of study group A were managed by MVA and patients of study group B were managed by Medical treatment. Efficacy was noted in 48 (92.3%) patients and 40 (76.9%) patients respectively in group A & B. Efficacy rate in group A was significantly ( $P = 0.05$ ) higher as compared to group B. (Table 2)

Patients were divided into two age groups i.e. age group 20-30 years and age groups 31-40 years. Total 25 patients of group A 32 patients of group B belonged to age group 20-30 years and efficacy was noted in 22 (88%) patients of group A and 27 (84.4%) patients of group B. But insignificant ( $P = 1.00$ ) difference of efficacy was noted. (Table 3) Total 27 patients of group A and 20 patients of group B belonged to age group 31-40 years. Efficacy was noted in 26 (96.3%) patients and 13 (65%) patients of group A and B. Difference of efficacy rate between the both groups was

statistically significant with p value 0.007. (Table 4)

Patients were divided into two groups according to their gestational age i.e. 1-6 weeks gestation and 7-12 weeks gestation. In 1-6 weeks gestation group, there were 29 patients in group A and 33 patients in group B. Efficacy was noted in 25 (86.2%) patients of group A and 25 (75.8%) patients of group B but the difference of efficacy rate was statistically insignificant (P = 0.350) between the both groups. (Table 5)

In gestation group 7-12 weeks, there were 23 patients in group A and 19 patients in group B. Efficacy was noted 23 (100%) patients of group A and 15 (78.9%) patients of group B and the difference was statistically significant (P = 0.034) between the both groups for efficacy. (Table 6)

In study group A and B, total 9 patients and 17 patients respectively were primary paras and efficacy was noted in 9 (100%) patients and 13 (76.5%) patients of group A and B. Difference for efficacy rate was statistically insignificant (P = 0.263). (Table 7)

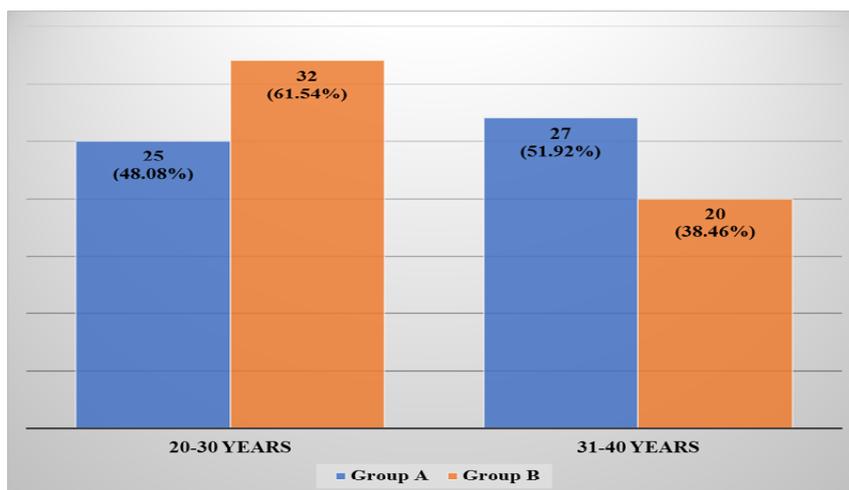
In study group A, 22 patients were multiparas and in group B, 19 patients were multiparas. Efficacy was noted in 19 (86.4%) patients and 16 (84.2%) patients of group A and B respectively. But the difference of efficacy between both groups was statistically in insignificant (P = 1.00). (Table 8)

Total 21 patients and 16 patients of group A and B were grand multiparas. Efficacy was noted in 20 (95.2%) patients and 11 (68.8%) patients of group A and B. Difference of efficacy between the both groups was statistically insignificant (P = 0.066). (Table 9)

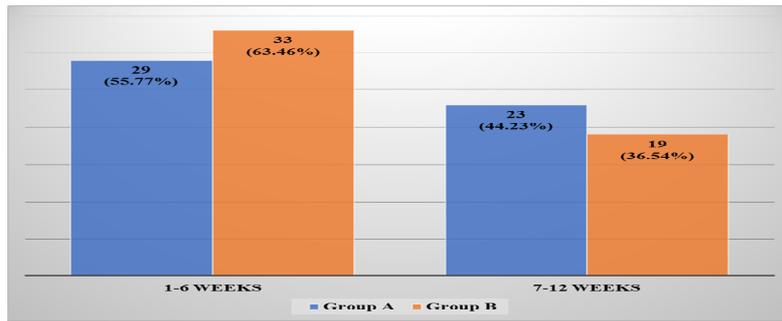
**Table 1** Mean and SD for age and gestational age

Study Group	Age		Gestational Age (Weeks)	
	Mean	SD	Mean	SD
A	30.23	6.720	6.15	3.670
B	29.02	6.649	5.65	3.514
Total	29.63	6.680	5.90	3.584

**Fig. 1** Age distribution of patients



**Fig. 2** Gestational age distribution



**Table 2** Comparison of efficacy for both groups

Group	Efficacy		Total	P value
	Yes	No		
A	48 92.3%	4 7.7%	52	0.05
B	40 76.9%	12 23.1%	52	

**Table 3** Comparison of efficacy for age groups 20-30 year

Group	Efficacy (P value = 1.00)		Total
	Yes	No	
A	22 88.0%	3 12.0%	25
B	27 84.4%	5 15.6%	32

**Table 4** Comparison of efficacy for age groups 31-40 years

Group	Efficacy (P value = 0.007)		Total
	Yes	No	
A	26 96.3%	1 3.7%	27
B	13 65.0%	7 35.0%	20

**Table 5** Comparison of efficacy for different gestational age group 1-6 weeks

Group	Efficacy (P value = 0.350)		Total
	Yes	No	
A	25 86.2%	4 13.8%	29
B	25 75.8%	8 24.2%	33

**Table 6** Comparison of efficacy for different gestational age group 7-12 weeks

Group	Efficacy (P value = 0.034)		Total
	Yes	No	
A	23 100.0%	0	23
B	15 78.9%	4 21.1%	19

**Table 7** Comparison of efficacy for primary para

Group	Efficacy (P value = 0.263)		Total
	Yes	No	
A	9 100.0%	0	9
B	13 76.5%	4 23.5%	17

**Table 8** Comparison of efficacy for multipara

Group	Efficacy (P value = 1.00)		Total
	Yes	No	
A	19 86.4%	3 13.6%	22
B	16 84.2%	3 15.8%	19

**Table 9** Comparison of efficacy for grand multipara

Group	Efficacy (P value = 0.066)		Total
	Yes	No	
A	20 95.2%	1 4.8%	21
B	11 68.8%	5 31.2%	16

**DISCUSSION:**

It is highly important to prioritize the options for management of early pregnancy losses because high prevalence of miscarriage and related complications has substantial health and economic cost. Manual vacuum aspiration (MVA) is an alternative to the standard surgical curettage, performed under local anesthesia. Manual vacuum aspiration can be performed without the need for a fully equipped operation theatre as it does not need electricity and can be carried out under Paracervical block. In countries with a small number of physicians, manual vacuum aspiration can be safely and effectively used by mid-level health care providers such as mid-wives. World health organization (WHO) recommends as the manual vacuum, aspiration preferred methods for the first trimester abortion.<sup>15</sup>

In present study, patients of study group A were managed by MVA and patients of study group B were managed by Medical treatment. Efficacy was noted in 92.3% patients and 76.9% patients respectively in group A & B. Efficacy rate in group A was significantly (P = 0.05) higher as compared to group B.

Biqueet al<sup>16</sup> have compared the efficacy of MVA with that of the misoprostol for treatment of incomplete abortion. Follow-up at seven days' post-treatment reported success rate of 100% for MVA and 91% for misoprostol (100% vs. 91%; p 0.002). The results of the study favor manual vacuum aspiration as the preferred method for uterine evacuation during first trimester of pregnancy. This method is faster and more

efficacious than medical termination with misoprostol especially at 9-12 weeks of gestation.<sup>17</sup>

In one study by Tasnim N et al,<sup>18</sup> complete evacuation was achieved in 89.6% with manual vacuum aspiration. In a study by Hemlin J et al<sup>19</sup> success rate with manual vacuum aspiration was 95.2%. Edwards S et al<sup>20</sup> also reported success rate with manual vacuum aspiration as 98%. Ansari R et al<sup>21</sup> found success rate with manual vacuum aspiration as 97.7%. All these studies are in agreement with our findings.

The success rates of medical evacuation vary from 25% up to 97% for oral, sublingual or vaginal misoprostol in different studies. These variations between studies probably reflect the different misoprostol regimens used, routes of administration, and the definitions of success rate.<sup>22</sup>

In one study by Shuaib AA et al<sup>22</sup> 52 women were allocated to receive intravaginal misoprostol, 80.7% achieved a successful complete expulsion of the products of conception. Shankar M et al<sup>23</sup> also concluded that 77.3% women achieved successful complete medical evacuation by receiving misoprostol. Shah N et al<sup>24</sup> also found 48% success rate with intravaginal misoprostol for the complete evacuation of first trimester missed abortion. Results of all these studies are also in agreement with our study. In our study mean age of the patients was 29.63 ± 6.68 years, mean age of the patients of study group A was 30.23 ± 6.72 years and mean age of patients of group B was 29.02 ± 6.65 years. The mean age of the study

population and the mean gestational age in our study are also comparable with that of Gazvani et al 2004.<sup>25</sup>

#### CONCLUSION:

Results of this study revealed that MVA is better treatment modality as compared to medical management (misoprostol intravaginally). Efficacy rate was significantly higher in MVA group as compared to medical treatment group. In older age group MVA group was found with significantly higher rate of efficacy as compared to medical management group.

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