## **ORIGINAL ARTICLE**

# Misoprostol Versus Outpatient Manual Vacuum Aspiration (MVA) for Termination of Pregnancy: A Quasi Experimental Study

Safia Khalil, Nighat Shaheen

#### ABSTRACT

**Objective:** To compare the safety and efficacy of Misoprostol versus Outpatient manual vacuum aspiration (MVA) for termination of pregnancy.

Study Design: Quasi experimental study

Place and Duration of Study: Conducted in Cantonment General Hospital from 1/1/2015-31/1/2015

**Materials and Methods:** Women eligible for both MVA and Misoprostol were included in this study. Women were allocated to either group according to the option chosen by them. Misoprostol was administered at a dose of 400 microgram sublingual, 4 doses four hours apart. Manual vacuum aspiration was performed according to practice guidelines provided by IPAS Certified Professionals.<sup>1</sup> Primary outcome measure was achievement of complete evacuation within 24 hours.

**Results:** Out of 101 women, 68 (62.3%) were in MVA group and 33 (32.6%) in Misoprostol group. Complete evacuation was achieved in 28 (82.1%) women in the Misoprostol group and 68 (100 %) in the MVA group within 24 hours (P value 0.003). Five women had failed medical termination. None of the women required hospital admission. There was no statistical difference between the two groups (p value 0.079) in terms of total number of visits or requirement of analgesia.

**Conclusion:** Both Manual Vacuum Aspiration (MVA) and Misoprostol are safe and effective alternatives for termination of pregnancy but the former is more likely to achieve complete evacuation within 24 hours.

Key Words: Efficacy, Manual Vacuum Aspiration (MVA), Misoprostol, Outpatient, Safety, Suction Curettag.

### Introduction

About 15 % of all pregnancies result in miscarriage. The world wide abortion rate is 28 per 1000 women aged 15-44 years.<sup>2</sup> The bulk of these miscarriages occur in underdeveloped countries. In low resource settings, there is a high incidence of unwanted pregnancies. Most of these pregnancies succumb due to poor antenatal care, malnutrition or induced miscarriages. Lack of post abortion care is one of the leading causes of maternal mortality, accounting for about 7.9% of maternal deaths. Part of maternal mortality due to sepsis is also contributed by it.<sup>3</sup> In Pakistan, abortions (both spontaneous and induced) are responsible for 5.6 % - 11% of maternal mortality.<sup>4</sup> This is mainly due to overburdened public

Department of Gynaecology Cantonment General Hospital, Rawalpindi Correspondence: Dr. Nighat Shaheen Department of Gynaecology Cantonment General Hospital, Rawalpindi E-mail: nighats82@gmail.com

Funding Source: NIL; Conflict of Interest: NIL Received: May 10, 2018; Revised: January 31, 2019 Accepted: February 27, 2019 health sector, high total fertility rate (3.8%), low contraceptive prevalence (35%), lack of resources, inability to access to safe abortion care and poor understanding of legislation by health care professionals and patients.<sup>5</sup> In the last 30 years, there has been effort at the international as well as regional level to improve service provision for miscarriages and to evaluate its effectiveness by measuring quantifiable objectives. This included legislation, introduction of misoprostol, evolution and provision of manual vacuum aspiration and monitoring of these efforts.<sup>4</sup> Most of the studies done in this context are based on In patient category. Both MVA and Misoprostol have been shown to be effective methods of termination of pregnancy in admitted patients. Outpatient or community use of MVA has not been studied so far. Few good quality studies from South Asia and Africa (Pakistan, India, Nepal & Bangladesh) have shown that Misoprostol use is safe in community.<sup>6</sup> Outpatient provision of termination facilities has several advantages including cost and convenience. It is extremely useful in far flung areas where access to established medical facilities is not available.

Our study is designed to bridge this gap. Our study intends to address the provision of safe and effective methods of termination of pregnancy in an Outpatient setting which is likely to have a larger effect in low resource settings. We compared Manual Vacuum Aspiration with medical termination (Misprostol) in cases where both options were suitable for the woman. Apart from assessing the safety & efficacy, it will also give us an insight into the patient preference in our culture. The Objective of our study was to compare Misoprostol Versus Outpatient Manual Vacuum Aspiration (MVA) for Termination of Pregnancy.

#### **Materials and Methods**

This Quasi experimental study was conducted in Cantonment General Hospital Rawalpindi from 1/1/2015 -31/1/2015. Approval from institutional ethical committee was obtained. 107 women consented to participate in the study. Nonprobability convenience sampling technique was used to collect sample. All women with an indication for termination of pregnancy with

- A crown rump length of 7-40 mm without cardiac activity (missed miscarriage)or
- Mean gestational sac diameter between 25 and 45 mm without fetal pole (anembryonic pregnancy) or
- Passage of products of conception with the residual anterior-posterior endometrial lining ≥30 mm [retained products of conception (RPOCs)] or
- Uterine size <13 weeks Were included in the study.

Hemodynamically unstable women, septic abortion, suspected ectopic pregnancy, known bleeding disorders, uterine anomalies and those taking anticoagulant therapy were excluded from the study. Women were educated about various options for termination of pregnancy. Those not willing /suitable for expectant management were allocated to either group according to the option chosen by the woman. Group one received misoprostol while group two underwent manual vacuum aspiration in the Outpatient department. Misoprostol was administered at a dose of 400 microgram sublingual, 4 doses four hours apart ( total 8 tablets of 200 micrograms). Manual vacuum aspiration was performed according to practice guidelines provided by IPAS by Certified Professionals. A pelvic ultrasound was performed after 24 hours to confirm completion of evacuation. Estimation of blood loss was subjective. Women who had incomplete evacuation were administered 600 microgram misoprostol in line with FIGO recommendation and required follow up visits at 01 week post procedure. Those who had persistant RPOCs despite following this protocol were declared failed medical treatment. These women had to undergo MVA to remove RPOCs. Contraceptive advice was provided afterwards and the woman was advised follow-up after one week. All data was entered on a preformed Performa. Systematic review done by Linet T et al was used as a guideline for protocol development of medical & surgical methods of termination of pregnancy.<sup>7</sup> Primary outcome measure was achievement of complete evacuation within 24 hours. Other outcome measures included duration of hospital stay, no. of hospital visits, procedure related blood loss, requirement of post procedure analgesia, need for repeat / alternate procedure, adverse effects and complications.

Data was analyzed on SPSS 22. Descriptive statistics included means & frequencies. Means were calculated and compared for age, gravidity, parity, gestational age, duration of hospital stay and number of hospital visits. T test was applied to calculate the difference. Frequencies and percentages were calculated for type of selected procedure, indication of termination, achievement of complete evacuation within 24 hours. Chi square test was applied to calculate the p values. Other variables include procedure related blood loss (mild ,moderate, severe), requirement of analgesia (yes, no), need for repeat procedure (yes, no), adverse effects (fever shivering, gastrointestinal side effects) and complications (hemorrhage , infection , perforation). Frequencies and percentages were calculated for these as well and chi square was applied.

#### Results

Total 107 women were enrolled in the study, out of which 68 (62.3%) were in MVA group and 33 (32.6%) in Misoprostol group. Six women (5.6%) opted for dilatation and curettage (D & C) and were excluded

#### from the study.

Mean age of women undergoing MVA was  $28.55 \pm 5.228$  and in Misoprostol group was  $27.95 \pm 2.681$ . Mean gestational age in MVA group was  $10.59 \pm 3.053$  and in Misoprostol group was  $12.31 \pm 3.248$ . Mean gravidity was  $3.35 \pm 1.483$  in MVA group and  $2.78 \pm 1.281$  in Misoprostol group. Mean parity was  $1.84 \pm 1.417$  versus  $1.52 \pm 1.051$ . The two groups were comparable in these respects.

Regarding indications for termination of pregnancy, 31(29%) women had missed miscarriage, 77 (65.4%) had incomplete miscarriage and 6 (5.2%) had termination of pregnancy for other reasons [anencephalic fetus (n=4,3.7%), blighted ovum (n=2, 1.9%)]. One woman (0.9%) had a previous scar of lower segment cesarean section. The two groups did not differ in the indication of termination of pregnancy (p value = 0.07).

Complete evacuation was achieved in 28 (82.1%) women in the Misoprostol group and 68 (100 %) in the MVA group within 24 hours. Five women had failed medical termination. This difference was statistically significant (p value 0.003).

Mean no. of visits required in the Misoprostol group was  $2.8 \pm 0.837$ . None of the women had retained products of conception following MVA and the mean no. of required visits in this group was 1. This difference was statistically significant (p value 0.01). Most of the women did not return for follow up visit (n=89, 83.2%). Twelve women (17.6%) in the MVA group returned for follow up and five (17.8%) in the Misoprostol group. There was no statistical difference between the two groups in terms of return to follow up (p value = 0.497). When the total number of visits were considered (procedure related plus follow-up visit), there was no statistical difference between the two groups (p value 0.079).

Only six women (5.6 %) required analgesia and the requirement for analgesia did not differ with the type of procedure undertaken (p value =0.529). None of the women required hospital admission. No complications or adverse effects were reported. There was no report of moderate or severe blood loss during the study in either group. Contraceptive counseling was provided to 79 (73.9%) women.

#### Discussion

Zaidi S et al has conducted two of the largest studies

regarding abortion care in Pakistan and Bangladesh in 2014.<sup>4,5</sup> They explain the prevailing situation of abortion care in detail. It is an alarming situation. There is a large unmet need for abortion care in our country (estimated at around 20% in 2012).<sup>8</sup> It is one of the major target areas that need improvement if we aim to achieve Sustained Development Goals.

Regarding the choice of method NP Khawaja et al report that women are aware of the modern methods which are safe and effective.<sup>9</sup> Similarly in our study most of the women opt for new methods of abortion care. This is because of increased awareness probably because of lesser cultural inhibition and positive role of media. On the other hand complications in underdeveloped countries are common due to widespread illegal abortion. Shahab et al report that a significant percentage of women (5%) have a fear of the pain and complications<sup>10</sup>. These women prefer dilatation and curettage under anesthesia instead of modern methods. In our study a small number of women opt for D& C probably for similar reasons.

At the moment abortion for unwanted pregnancies is restricted in Pakistan to save the life of the mother.<sup>11</sup> Other indications for termination are similar in both groups and were not related to the choice of procedure.

Our study shows that both methods are safe, effective and tolerable to the women with little analgesia requirement. There is no significant blood loss, hospital admission, complication or side effects. Several other studies show similar results. Speedie J et al have developed a one stop evaluation unit for Manual Vacuum Aspiration.<sup>12</sup> They find it safe and acceptable with significant reduction in cost. However they do not compare it with other modalities. Ansari A et al has confirmed its safety in high risk cardiac patients.<sup>13</sup> In our study, only those women who have a failed medical termination are not satisfied with the chosen method. They have two options. One is to take higher doses of Misoprostol with or without Mifepristone as reported by Meena SR et al and Li YT et al respectively.<sup>14,15</sup> The other option is to undergo MVA as suggested by Heller et al.<sup>16</sup> All of the women in our study chose the second option. In our study, all procedures are done by certified doctors. However, in a systematic review Ngo TD et al has shown that Manual Vacuum aspiration is safe in the hands of mid level care providers as well.<sup>17</sup>

Speedie J et al has found that Manual Vacuum Aspiration is a good opportunity to offer long acting reversible contraception.<sup>10</sup> Eighty percent women in

their study opt for long acting reversible contraceptive methods. Korjamo R and Laursen L also find that women are more receptive to contraceptive advice during this period.<sup>18,19</sup> This is in contrast to our study. Although contraceptive counseling is provided to a significant proportion of women, majority (66%) opt for barrier methods or no method at all. This indicates a need for research into the local problems associated with contraception. Counseling methods need to be improved and designed to address the local concerns. Current situation of contraceptive use in Pakistan is unlikely to change until and unless there is a mechanism of continuous positive feedback by women who are successfully using reliable contraceptive methods. Also, backstreet abortion is cheap and readily available. Most women feel it an easy way out instead of regularly using contraception.

Increasing role of community workers for provision of abortion care in the outreach is being explored. Early reports by Constant D et al and Gupta P et al are encouraging.<sup>20,21</sup> They have shown that misoprostol administration by community workers at home is safe and efficacious.

One of the limitations of our study is small sample size. This is mainly because majority of women as well as care providers feel more comfortable with in patient management. The reasons for such preference need to be explored. Another limitation is poor follow-up.This is mainly due to a lack of integrated services. Most of the women who report for follow up are those who are concerned about retained products of conception. Apart from hospital visit, other means for follow-up can be explored e.g. telephonic contact etc. Aiken ARA et al has evaluated newer techniques like telemedicine to facilitate followup.<sup>22</sup> Another limitation is that the reasons for preference of a particular method were not interviewed further.

Termination of pregnancy is a wide area of research. Barriers to implementation of safe and effective abortion care need future research.<sup>6</sup>

#### Conclusion

Both Manual Vacuum Aspiration (MVA) and Misoprostol are safe and effective alternatives for termination but the former is more likely to achieve complete evacuation within 24 hours, larger prospective studies are needed to confirm these findings.

Table I: Demographic Features of Women in Treatment Groups

	Misoprostol ( group 1)	Manual Vacuum Aspiration ( group 2)	Failed medical treatment	D& C
Age	27.95 + 2.681 _	28.55 + <u>5</u> .228	33.00 + 6.8 <u>3</u> 1	23.31 + 4. <u>7</u> 32
Gestational Age	12.31 + 3.284 _	10.59 + 3.053	11.00 + 2.646	11.33 + 1.633
Gravidity	2.78 + 1. <u>2</u> 81	3.35 + 1.483	4.06 + 4.336	2.33 + 1.506
Parity	1.52 + 1. <u>0</u> 51	1.84 + <u>1</u> .417	2.40 + 2. <u>3</u> 02	0.67 + 0. <u>8</u> 16

Table II: Indication for Termination in Misoprostol &MVA Groups

	Misoprostol ( group 1)	Manual Aspiration (group 2)	Vaccum
Missed miscarriage	13(12.8%)	11(10.8%)	
Incomplete miscarriage	51(50.4%)	15(14.8%)	
Therapeutic (anencephalic, blighted )	4(3.7%)	2(1.9%)	

Table III: Outcome Measures in Misoprostol vs. MVA

	Misoprostol	Manual Vaccum	P value
	( group 1)	Aspiration	
		(group 2)	
Complete evacuation within 24			
Hours	23 (82.1%)	68 (100 %)	0.003
Moderate /severe blood loss			
	0	0	0
Need for hospital admission			
	0	0	0
Mean procedure no. of related			
Visits	2. <u>8</u> + 0.837	1	0.001
No. of follow up visits			
	5 (17.8% )	12 (17.6% )	0.497
Analgesia requirement			
	3 (10.7%)	3 ( 4.4%)	0.529
Complications/ side			
effects	0	0	0

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