

EFFICACY OF MANUAL VACUUM ASPIRATION VS CONVENTIONAL EVACUATION AND CURETTAGE

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ABSTRACT

OBJECTIVES

To evaluate the safety and efficacy of Manual Vacuum Aspiration (MVA) compared to Conventional Evacuation and Curettage (E & C) in managing first trimester miscarriage.

METHODOLOGY

A total of 160 patients were enrolled in this comparative study. Patients were categorized into two groups (Group A undergoing MVA) and (Group B undergoing E&C). Each group had 80 cases randomly selected. Stable patients with miscarriages < 12 wks of gestation and no comorbid were included in the study. Data was recorded on pre-designed proforma, and analysis was done by SPSS Software.

RESULTS

Efficacy of MVA was 97.5% and 92.5% in E&C, with a 7.5% vs 30% complication rate in MVA and E&C Group, respectively. The mean duration of the procedure was 9 minutes in the MVA group versus 18.8 minutes in the E&C group. The hospital stay was 14.2 hours vs 20.3 hours in MVA and E&C Group. 16.25% vs 46.25% of women in MVA vs E&C Group reported post-op pain. 93.75% of women were satisfied with MVA, whereas only 50% of women were satisfied with E&C. 81.25% 91.25% required Anesthesia/Analgesia in MVA and E&C Group, respectively.

CONCLUSION

MVA is a more effective and rapidly performing outpatient procedure with a lower complication rate. In this study efficacy of MVA is 97.5% compared to the E&C group, i.e., 92%. Its safety, cost-effectiveness and efficacy advocate its extended use as an alternative to the conventional surgical method of miscarriage.

KEYWORDS: Manual Vacuum Aspiration(MVA), Evacuation and Curettage(E&C), Miscarriage. Surgical Methods of Miscarriage(SMM), Para Cervical Block(PCB)

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INTRODUCTION

Miscarriage is an event in a women's life that is beyond her control, and it needs special attention to manage. It is imperative to consider that pregnancy is a dynamic process, and even if the viability of a pregnancy is confirmed, it does not necessarily imply that pregnancy will continue. However, if fetal heart pulsation is detected at 6 weeks, there is a 90% chance of pregnancy

continuation beyond the 1st Trimester.¹ Loss of pregnancy during the first 24 weeks of gestation is termed miscarriage; nevertheless, WHO defines miscarriage as a loss of pregnancy before 20 weeks or loss of fetus weighing 500gm or less.² An estimated 23 million miscarriages occur every year worldwide. It is the most common complication of early pregnancy, affecting 15% of clinically recognized pregnancies. This substantially impacts couple's physical and psychological well-being, with some experiencing post-traumatic stress disorder.³ Multiple pregnancy losses can have a significant psychological toll on the affected couples. Recurrent miscarriage accounts for 2-5% of all miscarriage.⁴ The risk of miscarriage is multivariate, and 80% of early pregnancy loss occurs in the 1st trimester, beyond which the risk of miscarriages decrease.⁵ A miscarriage could be managed conservatively according to a woman's clinical presentation and desires; it includes expectant management, where 85% resolve within 3 weeks or medical management, with only 10% fail, requesting other methods. According to indication and patient choices, the surgical method could be exercised according to indication and patient choices.⁶ As per a more recent Cochrane review, the surgical approach had higher rates of miscarriage resolution than medical and expectant management. The relative success rate was 58% with expectant management, 81% with medical management and 96% with surgical management.⁷ The NICE recommends expectant management for 7-14 days like the 1st line management strategy for miscarriage and considers other options where women are at increased risk of hemorrhage.⁸ According to WHO, MVA is the preferred method of uterine evacuation for post-abortion care/treatment (WHO, 2000). Although WHO recommends that sharp curettage be used only if Manual Vacuum Aspirator is not available. Surgical management of miscarriage (SMM) is used instead of Evacuation of Retained Products of Conception. It is usually safe, but patient counselling about associated risks is important, which includes the risk of anesthesia, infection, retained products of conception (3-5%), uterine perforation (0.5) and Asherman's syndrome (rarely) as a result of over-vigorous curettage.⁹ MVA is rising up in developing settings for surgical management of miscarriage and replacing the conventional dilatation and evacuation universally. The exact pioneers of MVA are not known surely; however, this technique is attributed to Harvey Karman, a U.S psychologist, who in the

1970s introduced it as office management for termination of pregnancy. MVA is an addition to the Management options for women who wish to have surgical management as an outpatient procedure; it helps reduce the cost and enhances patient satisfaction. It is a safe and effective alternative to conventional surgical methods in the theater.¹⁰ According to a survey, approximately 2.2 million abortions occur in Pakistan, with an annual abortion rate of 50/1000 pregnancies, which puts a substantial burden on the health sector¹¹. In regions of the world with limited resources, this technique is highly accepted as an office procedure due to its reliability, safety, and cost-effectiveness for managing the first trimester miscarriages.¹² NICE guidelines on the management of miscarriage recommend that clinically appropriate patients should also be offered the option of MVA under local anesthesia in an outpatient department or clinical settings.¹³ RCOG evidence-based guidelines recommend MVA as an effective and acceptable surgical method of termination of pregnancy.¹⁴ The WHO also recommends MVA as a preferred method for uterine evacuation in early pregnancy.¹⁵ Despite current international guidelines, recommendations on MVA and plenty of research studies on safety and efficacy, it is not correlating with the practical use of this technique by regional health facilities. So, this study could be an operational review on its use and an addition to the already done work and a motivation to accept the alternate techniques in a low resource setting to improve the maternal health care system.

METHODOLOGY

This comparative study was conducted at the Gynaecology department of civil hospital Mattani from January 2017 to August 2019. A total of 160 women were enrolled. Patients were categorized into group A undergoing MVA and group B undergoing E & E&C. Each group had 80 cases randomly selected. Stable patients with >10gm/dl hemoglobin diagnosed with a missed miscarriage, incomplete miscarriage, blighted ovum, Anembryonic pregnancy and RPOCs were included in this study. On the other hand, patients with gestational age >12 weeks, uterine malformation, focal uterine lesions, e.g., fibroid, suspected molar pregnancy, Heterotopic pregnancy, history of previous surgery on uterus including C/Section, women with a history of prior handling, septic abortion, PID and other pelvic pathology were excluded. However, gestational age of < 12 weeks was the limit for both groups.

Informed consent was obtained, and the type of anesthesia/Analgesia was discussed with the woman, including Laryngeal Mask Anesthesia (LMA) and Para Cervical Block (1% lignocaine) intramuscular injection of Nalbin with antiemetic. Antibiotics (Amoxicillin & metronidazole) were offered an hour before the procedure with a sip of water. Cervical priming was considered where there was a history of closed Cervical to reduce the resistance of the cervix and pressure applied for entering the uterus and hence the risk of cervical trauma. Baseline routine investigations were done to assess hemoglobin level and blood groups with Rh factor to identify the woman requiring anti D prophylaxis and transfusion of blood & blood products. The evacuated tissue was inspected clinically as well as sent for histopathological examination. Efficacy of the procedure was measured by complete evacuation, not requiring repeat medical or surgical method of miscarriage and minimal to no complications. The complete evacuation was ensured clinically, supplemented by Ultrasound examination with no evidence of RPOCs. Overall, patients were assessed for

completeness of evacuation, duration of the procedure, blood loss, duration of hospital stay and satisfaction. Patients were discharged according to clinical conditions varying from 6hrs to 48hrs antibiotics and analgesics with the advice of follow up after 1 week. Data were recorded on the pre-designed form. Statistical analysis was accomplished through SPSS version 20. Quantitative data were analyzed for the mean, whereas percentages were calculated for categorical variables. Patients undergoing MVA or E&C were compared, and categorical variables between the two groups were compared using a Chi-square test. A P-value of < 0.05 was considered statistically significant.

RESULTS

A total of 160 women with 1st-trimester miscarriages were enrolled; 50% underwent either MVA or E&C. Primary outcome measures were efficacy, safety and complete evacuation. On the other hand, secondary outcomes included the need for Anesthesia/Analgesia, hospital stay, operating time, post-op pain and patient satisfaction.

Table 1: Socioeconomic & Clinical Characteristics Distribution

Age	MVA n=80		E&C n=80	
	Frequency	Percentage	Frequency	Percentage
15-25	25	31.25%	20	25.00%
26-35	40	50.00%	22	27.50%
36-45	15	18.75%	38	47.50%
Mean age	33.3 years		37.34 years	
Occupation				
None	15	18.75%	37	46.25%
Housewife	50	62.50%	39	48.75%
Employee	15	18.75%	4	5%
Education				
Illiterate	21	26.25%	15	18.75%
Primary	16	20.00%	30	37.50%
Secondary	14	17.50%	8	10.00%
Intermediate	16	20.00%	10	12.50%
Graduation	13	16.25%	17	21.25%
Gravidity				
PG	22	27.50%	15	18.75%
Multigravida	18	22.50%	9	11.25%
Grand Multigravida	30	37.50%	24	30.00%
Period of Gestation				
< 6 weeks	33	41.25%	17	21.25%
< 12 weeks	47	58.75%	63	78.75%
Mean Gestational Age	7.02 weeks		7.04 weeks	
Indications				
Blighted Ovum	25	31.25%	13	16.25%
Missed Miscarriage	21	26.25%	29	36.25%
Incomplete Miscarriage	34	42.50%	38	47.50%
Risk Factors:				
Low risk	55	68.75%	68	85.00%
High risk	25	31.25%	12	15.00%
Hypertension	18	22.50%	5	6.25%
Diabetes Mellitus	7	8.75%	4	5.00%
Cardiac disease	0	0.00%	2	2.50%
Chronic Kidney Disease	0	0.00%	1	1.25%

Table 2: Comparison of Procedure Outcome

	MVA n=80		E&C n=80		P-Value
	Frequency	Percentage	Frequency	Percentage	
Need for Anesthesia / Analgesia	65	81.25%	73	91.25%	0.0001
Para Cervical Block	35	43.75%	8	10.00%	
Laryngeal Mask Anesthesia	5	6.25%	37	46.25%	
Intramuscular sedation	25	31.25%	28	35.00%	
No anesthesia / no analgesia required	15	18.75%	7	8.75%	
Duration of Procedure					
<10 min	48	60.00%	26	32.50%	0.0001
>10 min	28	35.00%	38	47.50%	
>20 min	4	5.00%	16	20.00%	
Mean duration	9 min		18.8 min		
Hospital Stay					
<12 hrs.	63	78.75%	18	22.50%	0.0001
<24 hrs.	14	17.50%	48	60.00%	
>24 hrs.	3	3.75%	14	17.50%	
Mean stay in hours	14.2 hrs.		20.3 hrs.		
Post-op Pain					
Yes	13	16.25%	37	46.25%	0.0001
No	67	83.75%	43	53.75%	
Satisfaction					
Yes	75	93.75%	40	50.00%	0.0001
No	5	6.25%	40	50.00%	
Complications					
Yes	6	7.50%	24	30.00%	0.0001
No	74	92.50%	56	70.00%	

Table 3: A Complication of Procedure Outcome

	MVA n=80		E & C n=80		P-Value
	Frequency	Percentage	Frequency	Percentage	
A. Early					
Anesthesia	0	0.00%	0	0.00%	0.0001
Bloos loss (>100 ml)	3	3.75%	10	12.50%	
ervical Trauma	1	1.25%	5	6.25%	
Uterine perforation	0	0%	1	1.25%	
B. Late					
Incomplete Evacuation	2	2.50%	6	7.50%	
Infection	0	0.00%	2	2.50%	
C. Total	6	7.50%	24	30.00%	

Table 4: Comparison of Success/Failure

	MVA n=80	ENC n=80	P-Value
Complete Evacuation			
Achieved	78 (97.5%)	74 (92.5%)	0.15
Not Achieved	02 (2.5%)	06 (7.5%)	

DISCUSSION

The International Federation of Gynae & OBS and the world health organization have recommended medical management or Aspiration techniques for miscarriages. Since the last decade, medical management and MVA have been emphasized; medical management has shown applaudable outcomes. Still, MVA has not gained much acceptance in Pakistan for various reasons, including social, financial, skills and awareness related issues, although it is a cheaper and safer technique than the conventional/traditional surgical method of evacuation. Morbidity associated with

MVA is nil to minimal. It could be managed by a prudent strategy like cervical priming before the procedure to reduce trauma to the genital tract, including perforation, use of antibiotics to reduce the risk of infection and procedure performance by most experienced hands. This procedure mostly does not require anesthesia or Operation Theater. In the present study, we compared the outcomes of MVA with E&C in cases of 1st - trimester pregnancy failure. Our study procedure was successful in 97.5% of patients in the MVA group vs 92.5% in the E&C group. However, the difference is insignificant statistically (P-value = 0.15). The efficacy of MVA is consistent with the

result of prior studies. The efficacy of both procedures in our study was comparable to the study of Tayyab¹⁶ where the efficacy of MVA vs E&C was (95.6 vs 91.1%), Salem¹⁷ et al. (98.6Vs 88.5%), Qamar¹⁸ et al. (98% vs 95%), Shaheen¹⁹ et al. (92.3% Vs 76.9%). K Kaneez²⁰ et al. (95.6 Vs 85.8) and Jayashree V²¹ et al. reported 97.5% efficacy of MVA. Jehan Ara²² et al. and ElieNKWabong²³ are comparable to our study in terms of efficacy, operating time and hospital stay. In the present study mean age of the patient was 33.3years and 28.6years in MVA and E&C groups, respectively. In contrast to our study, Jayashree V²¹ et al. reported that the mean age of the E&C group was 24.8 years VS 24.39 years in the MVA group, whereas the mean age of patients undergoing SMM in other studies was comparable to our study. Different studies had different reproductive age groups; mostly between 20-30 years like Tayyab¹⁶ et al. study showed (30.47 years), Islam²⁴ et al. (25 years), Sunil²⁵ et al. (20-29 years). In our study, the mean gestational age at the time of miscarriage was 7.04 weeks Vs 7.02 weeks in MVA and E&C groups, respectively, with a minimum of 4 weeks Period of Gestation and a maximum of 12 weeks Period of Gestation. Tayyab¹⁶ et al. reported a mean gestational age of 8.65 weeks with 6-11 weeks. A study by Islam²⁴ et al. showed a mean age of 9.4 weeks with 9-11 weeks. Our study shows the highest number of great grand multipara (37) in the E&C group with the diagnosis of miscarriage and grand multi-para (30) in the MVA group. In Sunil²⁵ et al. study, Multiparous women constituted the maximum number of patients in both study groups. In most of the woman were housewives, i.e., 62.5% Vs 48.25% in MVA & E&C groups, respectively, whereas in Elie NKWabong²⁶ study majority of the woman were either students or housewives, especially in the latter MVA group. In our study, most cases underwent SMM to indicate incomplete miscarriage in both groups 42.5% and 47.5% in the MVA vs E&C group respectively while most of the cases were low risk in both groups, which is low risk compared to other research studies. More complications were observed in the E&C group (30%) than in MVA (6%), but these were minor complications and successfully managed in time with no mortality or life-threatening complications reported. No anesthesia complications were found in both groups. Our study results were statistically significant for complications (P = 0.0001). Islam²⁴ et al. study had comparable results to our study regarding complications. Our study showed more Blood loss (62.5%) in the E&C group than in the

MVA group (25%), and Jayashree V²¹ reported higher blood loss (21.3%) in the E&C group with no excess blood loss in the MVA group and Sunil k²⁵ research also showed similar results. In contrast to our study, K kaneez²⁰ showed slightly higher blood loss in the MVA group than in E&C (45.6% vs 40.2%). As far as Cervical trauma is concerned, in our study, it was found in 1.25% of cases in the E&C group, but no such complication was reported in the MVA group. Jayashree V²¹ did not report any Cervical trauma or uterine perforation in their studies. In our study, the incomplete evacuation was 7.5% in the E&C group and 2.5% in the MVA group, whereas Jayashree V²¹ reported a repeat procedure for 10% Vs 2.5% for the E&C Vs MVA group, respectively. In contrast to our study, K kaneez²⁰ et al. reported 65.2% of patients had complete evacuation in the E&C group and 63% in the MVA group, which is lesser than that achieved with E&C. Our study showed a 93.75% satisfaction rate in the MVA group and 50% in the E&C group showing a statistically significant difference between the study groups. In our study, the mean hospital stay was 14.2hrs VS 20.3 hrs. in MVA vs E&C groups, respectively which is significant statistically (P-value = 0.0001). Research by K Kaneez²⁰ et al. showed shorter hospital stay in the MVA group, which correlates well with the findings of our study. Our study showed a shorter time required for MVA than E&C (9m vs 18.8m) regarding time consumption. The difference is significant statistically (P = 0.0001). Our study results for time consumption are comparable with a research study done by Islam R.²⁴ Similarly, Jayashree V²¹ et al. study reported a statistically significant difference in both groups, i.e., 7.89min for E&C and 5.93min for MVA. In contrast to our study, K Kaneez²⁰ reported a shorter procedure time in the E&C group (8.7min) than in the MVA group (9.1 min). MVA is an effective modality and a reasonable option for managing early pregnancy failure in developing countries with economic turmoil. In the face of inadequate budget allocation towards the healthcare system and local financial instability, it is advisable to manage the early pregnancy loss with MVA as a Surgical Method of Miscarriage.

LIMITATIONS

The small sample size during a limited time frame in a single health centre all were limitations of this study. Thus, generalization of the result could not be recommended. Multicentric studies with a larger sample size are required to evaluate the safety and

efficacy of various treatment modalities to develop guidelines regarding maternal health.

CONCLUSION

The judicious use of MVA is found promising for women with early pregnancy failure in terms of safety, cost-effectiveness, and efficacy. In this study efficacy of MVA is 97.5% compared to the E&C group, i.e., 92%. A highly motivated, experienced clinician, careful case selection, patient feedback, regular audits, and a proper periodic hands-on training system would help establish MVA as a safe and effective choice for women requiring a surgical method of miscarriage (SMM).

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