ORIGINAL ARTICLE

Manual Vacuum Aspirator: A Safe and Effective Tool for Decentralization of Post Miscarriage Care

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ABSTRACT

Objective: To compare the efficacy and safety of Manual Vacuum Aspiration (MVA) performed as outpatient versus inpatient procedure in terms of success rate, blood loss, hospital stay and procedure related complications.

Study Design: A quasi-experimental study.

Place and Duration of Study: Maternal and Child Health Centre (MCHC), Unit-I, Pakistan Institute of Medical Sciences (PIMS), Islamabad, from December 2009 to December 2010.

Methodology: Cases with early pregnancy failure (incomplete, missed and an embryonic) at gestational age less than 12 weeks were allocated to MVA as outpatient or elective procedure performed in the operation theatre. Studied variables were noted as above.

Results: A total of 177 women were eligible for study, out of whom 78 underwent MVA as outpatient procedure and 99 as indoor procedure. The baseline characteristics were comparable in both groups except significantly high multipara in the indoor group. Complete evacuation was achieved in 96.1% in outpatient vs. 79.7% in indoor cases (p=0.001). Outpatient group had a shorter hospital stay (median 3 hours, IQR-1 vs. 10 hours, IQR-4; p < 0.001), though the median hospital cost was less but statistically insignificant (Rs. 800, IQR-25 vs. 735, IQR-1265; p=0.728). Blood loss was comparable in both groups (median 60 ml, IQR-20 vs. 60 ml-IQR-30; p=0.350). There were two uterine perforations noted in the inpatient group (2.02%) vs. none in outpatient setting.

Conclusion: Outpatient based manual vacuum aspiration is a safe and effective tool for management of early pregnancy loss. A decentralized approach proved useful in reducing hospital stay.

Key Words: *Manual Vacuum Aspiration (MVA). Outpatient. Evacuation. Abortion. Early pregnancy loss.*

INTRODUCTION

Early pregnancy loss is a common experience in a women's life and accounts for 14 - 19% of recognized pregnancies.[1,2] Approximately one in four women experience such a loss in her lifetime and local data shows an annual miscarriage rate of 29 per 1000 in women aged 15 - 49 years.[3-5] Therapeutic options range from expectant management, medical completion and surgical evacuation. The choices amongst surgical methods include evacuation and curettage and vacuum aspiration. The Manual Vacuum Aspiration (MVA) technique has developed which is now a favorable choice over Electrical Vacuum Aspiration (EVA). It is based on the same law of suction as EVA. It utilizes hand held aspirator with attached silastic cannula which carries not only less chance of blood loss, pain and injuries but also the great advantage of being operated manually and thus can be performed in an area where there is less or no electricity. It is a simple procedure hence, can be operated by primary health care providers. Thus, MVA is superior to EVA in that it is light weight, inexpensive, can be performed under local anaesthesia. It is especially valuable in low resource settings where electricity and surgical suites are not widely available.[6]

Like many other procedures, management of early pregnancy failure has moved from operating room to ambulatory setting, however, the experience is limited and concerns are enormous. Data from South Africa, Europe and Canada shows that majority of cases of early pregnancy failure are still being managed in operation theatre usually under general anaesthesia.[7-9] With advancement in technology, today, women are diagnosed quite early with first trimester pregnancy loss and can be safely managed by MVA in office based setting rather than the operating theatre. Office based management reduces cost for both the patient and the health department and makes it possible for the woman to avoid operating room which in turn decreases waiting time, admissions and sooner return to home with early mobilization.[10] Many studies have been conducted worldwide and locally where they have compared MVA with conventional EVA.[6,11,15] There is only limited data available internationally on use of MVA as office setting procedure for surgical management of early pregnancy loss and no local data is available with regard to its use in office setting.

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The study was conducted with an objective to assess safety and efficacy of outpatient based MVA in comparison with inpatient based elective procedure.

METHODOLOGY

It was a quasi-experimental study conducted from December 2009 to December 2010. All married women presenting to Maternal and Child Health Centre, Pakistan Institute of Medical Sciences, Islamabad, with first trimester pregnancy loss were identified for possible enrollment. Diagnosis of early pregnancy loss was established by using a triad of history, physical examination and ultrasonographic scanning. Serum β-HCG was done when ultrasound was suggestive of retained products of conception while the history and examination were inconclusive of pregnancy. Exclusion criteria were bleeding disorders, hemodynamic instability, haemoglobin less than 8.0 g/dl, cardio-pulmonary disease, uncontrolled diabetes mellitus epilepsy, severe anxiety or inability to tolerate pelvic exams, molar pregnancy, septic induced abortions and untreated cervicitis. Gestational age was estimated by using fetal pole and mean gestational sac diameter.

All cases presenting in the odd dated days of the week underwent MVA in the operation theatre designated for minor surgeries and women presenting in the even dated days underwent MVA as a day care procedure. An informed consent for the procedure and anaesthesia, if needed, were taken. MVAs as day care procedure were performed under paracervical block with 10 - 20 ml of 1% lignocaine alone using Glick technique,[12] in combination with intramuscular diclofenac sodium or oral ibuprofen. A majority of MVAs in the operation theatre were performed under paracervical block or in combination with systemic analgesia (nalbin, pethidine). Need for Total Intravenous Anaesthesia (TIVA) in this group was assessed by patients' intolerability to pain. Patients were rushed to operation theatre if there was intolerability to pain, excessive haemorrhage or difficulty in performing the procedure. MVA was performed in both the groups 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). Complete uterine evacuation was confirmed by sharp curettage and ultrasound. Products of conception were sent for histopathology for confirmation of intrauterine pregnancy. Patients undergoing MVA as day care procedure were retained in the recovery room for a few hours. Once the patient is hemodynamically stable, with minimal pervaginal bleeding, fully mobilized without assistance and has received necessary precautions, warning signs (abdominal pain, heavy pervaginal bleeding and foul smelling discharge) and follow-up advice, she may be discharged. Indoor admission was offered to those patients who had persistent pain or heavy vaginal bleeding. MVA's performed in the operation theatre were discharged at least 12 hours after the procedure as a standard hospital protocol. Clinical stability, mobilization and necessary follow-up advice was ensured before the women were discharged.

The outcome measures assessed were the success rate of the procedure defined as the complete uterine evacuation (confirmed through sharp curette and ultrasound, if needed),[13] median blood loss (blood loss was calculated from the volume of the blood in the MVA syringe),[14] median hospital stay, and procedure related complications (uterine perforation, haemorrhage, infection and vagal shock).

Sample size calculation was done by using WHO sample size calculator, taking confidence level of 95%, population proportion of 88% (MVA efficacy),[15] absolute precision of 5% and it turned out to a minimum sample of 163 patients and 177 patients were included.

Data was analyzed through Statistical Package for Social Sciences (SPSS) version 15. Chi-square and student's t-test were used for categorical and numerical variables respectively. The normality of the continuous variables was checked by using Kolmogorov Smirnov test and Mann-Whitney U-test was employed to compare the medians of both groups for variables who did not follow normality and Interquartile Range (IQR) was calculated as the difference between the third and the first quartile in the data sheet. P-value < 0.05 was considered significant for all significance tests.

RESULTS

A total of 177 patients with early pregnancy failure were randomly allocated to Manual Vacuum Aspiration 78 (44%) performed as day care procedure and 99 (56%) indoor procedure. Referring to Table I, the baseline characteristics were comparable except significantly higher number of multigravidas in the indoor group. Ultrasound based fetal parameters were similar in the two groups. The major indications for MVA were incomplete abortion followed by missed and blighted ovum. The two groups were comparable in terms of indications except a higher number of missed abortions in the indoor group. However, the difference was not statistically significant. A majority of procedures were performed under paracervical block and systemic analgesia in both the groups.

Referring Table II, complete evacuation was achieved using MVA as a single modality in 75 (96.1%) of day care group vs. 79 (79.7%) in indoor group. Similarly, the median hospital stay was significantly shorter in day care group as compared to indoor group 3.0 hours (Interquartile range (IQR)=1) vs. 10.0 hours (IQR=4, $p < 0.001$). Although the median treatment cost was statistically insignificant for both the groups (Rs. 800, (IQR=25) vs. Rs. 735 (IQR=1265; p=0.728), the mean hospital cost was noted significantly low for the outdoor

group as compared to the indoor group (Rs. 779.49 ± 49.30 vs. Rs. 1238.13 ± 870.008; p < 0.001).

There was no major complication in either group except uterine perforation noted in two cases (2.02%) performed in operation theatre both with missed miscarriage. Further no daycare procedure was moved to operating room or converted to general anaesthesia for patient discomfort. Median blood loss was comparable in both the groups (60.0 ml, IQR=20 vs. 60.0 ml, IQR=30 p=0.350). None of the patients from office setting required transfer to operating room or converted to general anaesthesia for patient discomfort.

Table I: Baseline characteristics of the study population.

	Day care group n=78	Indoor group n=99	p-value*
Age (years) mean±SD	27.15 ± 4.7	27.2 ± 5.20	0.949
Gestational age (weeks) mean±SD	9.927 ± 1.258	9.727 ± 1.458	0.338
Parity, n (%)			
Primigravida	25 (32.0)	32 (32.3)	0.043
Multigravida	38 (48.7)	60 (60.6)	
Grandmultigravida	15 (19.2)	7 (7.07)	
Indication for procedure, n (%)			
Incomplete miscarriage	37 (47.4)	45 (45.5)	0.944
Missed miscarriage	28 (35.8)	38 (38.3)	
Anembryonic pregnancy	13 (16.6)	16 (16.2)	
Co-existing risk factors, n (%)			
Low risk patients	76 (97.4)	88 (88.8)	0.401
High risk patients			
Previous I LSCS@	1 (1.28)	2 (2.02)	
Previous II LSCS	0	4 (4.04)	
Previous III LSCS	1 (1.28)	1 (1.01)	
Diabetes mellitus	0	1 (1.01)	
Previous pelvis surgery	0	3 (3.03)	
Ultrasound parameters mean±SD			
Crown-rump length (CRL), mm	51.21 ± 9.50	46.27 ± 10.85	0.069
Gestational sac diameter, mm	52.94 ± 9.19	58.39 ± 6.55	0.060
RPOCs#, mm	26.36 ± 6.74	29.49 ± 8.94	0.088
Type of anaesthesia used, n (%)			
Paracervical block with intravenous analgesia	78 (100%)	95 (95.9)	0.1313
TIVA^	0	4 (4.04)	

** p-value < 0.005 is considered significant. Chi-square & Fisher's exact test and Student's t-test were used for qualitative and quantitative variables respectively.*
@ Lower segment caesarean section.
 # Retained products of conception.
^ Total intravenous anaesthesia.

Table II: Safety and effectiveness of MVA as outdoor and indoor procedure.

	Day care group n=78	Indoor group n=99	p-value*
Uterine perforation, n (%)	0 (0)	2 (2.02)	0.207
Blood loss (ml) Median (IQR)#	60.0 (20)	60.0 (30)	0.350
Complete evacuation rate, n (%)	75 (96.1)	79 (79.7)	0.001
Total cost (Rs) Median (IQR)	800 (25)	735 (1265)	0.728
Hospital stay (hours) Median (IQR)	3 (1)	10 (4)	< 0.001

** p-value < 0.005 was considered significant. Chi-square test/ Fisher's exact test for qualitative data and Mann Whitney U-test for comparison of medians was used.*
 # IRQ: Interquartile range.

DISCUSSION

With increasing burden of patients in tertiary care hospitals with limited health and financial resources many procedures have moved from operating room to ambulatory setting. The same is true for the management of early pregnancy failure. With an incidence of 14 - 19% of early pregnancy failure the intervention is likely to significantly reduce the cost incurred by inpatient treatment of such cases.

The office setting was found equally safe as inpatient setting. The estimated blood loss was same in both the groups. Some studies have even shown less blood loss in office setting MVA compared to inpatient procedures (70 ml vs. 311 ml) and lower overall complication rate (8% vs. 40%).[16] In this study, no perforation was found in the outpatient setting. The two cases of perforation in the study group were due to missed miscarriage. The contribution of general anaesthesia in these cases leading to uterine relaxation might have played an additional role. The reported incidence of uterine perforation is 0.05%,[17] compared to 2.02% in this study. The occurrence of perforation in these two cases signifies the importance of individualization before offering MVA as outpatient procedure.

The effectiveness of procedure was assessed through completeness of evacuation with single modality of MVA using sharp curettage as a gold standard. The tool of sharp curettage was used for this purpose because of the experience of our residents in using this instrument where completeness of procedure is confirmed by grating sensation. The other tools used for this purpose are persistent vaginal bleeding, need for re-evacuation on follow-up visits or ultrasound based assessment of Retained Products of Conception (RPOCs). The applicability of this tool is limited by the fact that patients in our setup usually belong to low socio-economic status and have logistic problems and thus poor follow-up is expected. It has been seen that even in the best settings with incorporation of agreement to return to follow-up, the majority of women (65%) do not return.[16] The importance of follow-up, however, cannot be over-emphasized keeping in mind that low follow-up rate are common in surgical abortion and may be considered as proxy indicators of safety and low rate of complications.

Decentralization of post-abortion care from inpatient to outpatient has shown an almost 1000 dollars saving in direct and indirect cost per case.[18] The saving of cost is partly attributable to manual vacuum aspiration *per se*, the major factor contributing to this saving is shift from operating room to an outpatient setting, saving not only the cost of anaesthesia but also admission cost. Other authors have also reported substantial savings offered

Annex 1: Consent form.

Manual Vacuum Aspiration

Maternal and Child Health Centre, Pakistan Institute of Medical Sciences, Islamabad, Pakistan.

- I have been informed that:
- A procedure will be performed to empty my uterus by using aspiration canula as a treatment for my first trimester pregnancy loss.
- Prior to the procedure I will undergo certain blood tests to check anemia and Rh type. If I am Rh negative, Anti-D will be administered.
- Two medications will be offered to me prior to the procedure: oral Ibuprofen or intramuscular diclofenac sodium and paracervical block by lidocaine to lessen the cramping and pain. To the best of my knowledge I am not allergic to these drugs.
- Certain complications may arise like incomplete evacuation of uterus, excessive bleeding, allergic reaction and perforation for which I may be shifted to operation theatre and managed accordingly.
- In the event of an unexpected complication during MVA, I request and authorize the physician to do whatever is needed to protect my health.

I have been informed about the procedure and have had time to think about it. I have had all my questions answered.

I hereby consent that _____ do the procedure "Manual Vacuum Aspiration" for me.

Signature of patient:_____ Date:_____

Hospital No:_____

Witness:_____ Date:_____

Signature of doctor:_____ Date:_____

by MVA in ambulatory setting.[19-21] A recent cost-effective model examining different case settings have shown that using MVA could save 799 million $ per year over the traditional EVA performed in inpatient.[17]

In the present study, the median cost was less though it was statistically non-significant but the mean hospital cost was noted comparatively very high in indoor group (Rs. 1238) in contrast to OPD group (Rs. 779.49). A shift to performing MVA outside the hospital or operating room setting helps conserve resources that can be directed to provide other essential healthcare services for women and families and additional savings are realized when abortion services are moved out of the operating room reducing expenditure for anaesthesia, hospital infrastructure and sterile supplies and patient recovery care thus reducing the overall cost of the procedure indirectly.

In this study, the number of subjects were higher in inpatient group as compared to office setting. This was due to the fact that patients were evaluated in detail after recruitment. Cases with missed miscarriage, previous pelvic surgeries were preferably done in inpatient setting as shown in Table I. The idea of outpatient based management of early pregnancy loss through MVA is far from new. However, it was a new experience for authors, thus, a more cautious approach was utilized.

The major contribution of this study is not only saving the cost *per se* but also giving us the confidence in generalizing the results at primary settings where anaesthesia services are not available. It has been established by WHO safe abortion guidance that services for the management of miscarriage should be provided at the lowest appropriate level of health care system and that MVA can be provided at primary care level upto 12 completed weeks of pregnancy.[22,23] The mid-level workers can be trained in this regard to provide early and safe services without making the patient suffer due to long distances.

This study is limited by the fact that the choice and satisfaction of patients was not examined. However, there are multiple studies that have examined and analyzed patients' preference and satisfaction with office based procedure for early pregnancy loss and has found equal satisfaction in both the groups.[15]

CONCLUSION

MVA in office setting is safe, cost-effective and reduces hospital stay as compared to inpatient based management. The intervention provides an excellent opportunity for decentralization of post-abortion care. Incorporation of evaluation of patients' satisfaction and choice would further strengthen the model.

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