Original Article

Manual vacuum aspiration: a safe and cost-effective substitute of Electric vacuum aspiration for the surgical management of early pregnancy loss

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Abstract

Objective: To compare the efficacy, safety and cost-effectiveness of Manual vacuum aspiration (MVA) with Electrical vacuum aspiration (EVA) in the management of first trimester pregnancy loss.

Methods: A single-centre randomized controlled trial (RCT) was conducted at Maternal and Child Health Centre (MCHC), Unit-I, Pakistan Institute of Medical Sciences (PIMS), Islamabad from April 2007- Dec 2008. A total of 176 cases with early pregnancy loss at < 12 weeks gestation, with a diagnosis of anembryonic pregnancy, incomplete, missed or septic induced abortion and molar pregnancy were randomly allocated to either MVA or EVA in the operation theatre.

Results: A total of 176 women were included out of which 70 underwent EVA and 106 had MVA. Baseline characteristics were similar in the two groups except significantly higher gestational age and gestational sac diameter in MVA group. Majority of EVA were performed under general anaesthesia (95.7%) while majority of MVA were performed under paracervical block (60.3%). Complete evacuation was achieved in 89.6% with MVA vs 91.4% with EVA (p=0.691). MVA was superior in terms of significantly less blood loss (62.08 ± 32.19 vs 75.71 ± 35.53; p=0.008), shorter hospital stay (12.26hours ± 6.97 vs 19.54hours ± 7.95; p=0.000) and less hospital cost (Rs 1419.5 ± 1337.620 vs Rs. 3222.5 ± 1816.02; p=0.000). Post-operative pain assessment by visual analogue score (VAS) at 0 and 6 hours showed no significant difference (p=0.845 and p=0.157 respectively). The only complication was uterine perforation in 2(2.4%) cases both belonging to EVA.

Conclusion: MVA is a safe and effective alternative of conventional EVA. It is superior to EVA in terms of reduced cost and need for general anaesthesia and is thus useful at low resource setting with scarcity of electricity and general anaesthesia.

Keywords: Manual vacuum aspiration, Electrical vacuum aspiration, Early pregnancy loss (JPMA 61:149; 2011).

Introduction

Early pregnancy loss also known as miscarriage or abortion is a common experience for women and is responsible for the maximum number of pregnancy losses.[1] Approximately one in four women will experience such a loss in her life time.[2] Local data shows an annual abortion rate of 29 per 1000 in women aged 15-49 years.[3] Incomplete and missed miscarriage being the commonest, occurs in approximately 15 % of clinically recognized pregnancies and in 890,000 women per year.[4]

Despite advancement in the medical technology, unsafe abortion related complications contribute to 10-13 % of maternal deaths in the developing countries.[5] Thus a search for safe and cost effective uterine evacuation method continues. Currently available methods include vacuum aspiration, sharp curettage, medical evacuation with misoprostol and expectant management. Vacuum aspiration has come up as the most widely used method due to its safety and being less painful than evacuation and curettage (E&C) and medical methods.[2] A high efficacy of vacuum aspiration with success rate between 95-100% has been reported in various trials.[2,4] Of the two modalities of vacuum aspiration, electrical vacuum aspiration (EVA) employs an electric vacuum pump while in Manual vacuum aspiration (MVA) the vacuum is created using a hand activated plastic syringe. MVA is superior to EVA in that it is light weight, inexpensive, can be performed under local anaesthesia and does not require electricity. It is specially valuable in low resource settings where electricity and surgical suites are not widely available.[4,6,7]

The technique of MVA has been in use since 1973 for management of incomplete abortion and elective termination of early pregnancy with varying reports on its safety and efficacy.[7-9] Its use has been extended for the management of missed miscarriage and molar pregnancy.[10] Although the technique of MVA has been used widely in USA, African, Asian and European countries, its use in Pakistan, despite being a low resource country, is low. No local data is available to prove its feasibility, safety and efficacy over EVA in our setup.

Hence we conducted this study with the aim of comparing the safety and efficacy of MVA over EVA in first trimester pregnancy losses.

Patients and Methods

A randomized trial was done from April 2007- Dec 2008 at Maternal and Child Health (MCH) centre, Pakistan Institute of Medical Sciences (PIMS). All patients with gestational age of less than 12 weeks admitted in gynaecological ward with the diagnosis of anembryonic pregnancy, incomplete miscarriage, missed miscarriage, molar pregnancy and septic induced abortion were recruited in the study. Diagnosis was established using an amalgam of history, physical examination and ultrasonographic (US) scanning. Urinary pregnancy test and serum β HCG were done when ultrasound was suggestive of retained products of conception while the history and examination were inconclusive of pregnancy. Patients with uterine anomalies, abnormal coagulation profile, extreme anxiety, known or expected ectopic pregnancy and medically and haemodynamically unstable patients were excluded from the study.

For the purpose of study foetal demise was defined as lack of cardiac activity at crown-rump length (CRL) of ≥ 5mm.[11] In addition, criteria for an anembryonic pregnancy included gestational sac with a mean diameter of ≥ 16mm without an embryo.[12] An incomplete miscarriage was defined as passage of products of conception with the residual anterior-posterior endometrial lining of ≥ 30mm and uterine size less than 13 weeks.[13]

All cases presenting in the odd dated days of the week underwent MVA while the patients presenting in the even dated days underwent EVA. Both the procedures were performed in operation theatre dedicated for minor surgeries. An informed consent for the procedure of vacuum aspiration and general anaesthesia, if needed, was taken. All EVA procedures were performed under total intravenous anaesthesia (TIVA). While majority of MVA's were performed under paracervical block with 10-20 ml of 1% lignocaine using Glick technique[14] alone, or in combination with systemic analgesia (Nalbin, Pethidine). Need for TIVA in the latter group was determined by patients intolerability to pain. EVA was performed in a conventional way using an Atom vacuum extractor UP-40 aspirator system while 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). Completeness of procedure was assessed through sharp curettage and ultrasound, if required. Products of conception were sent for histopathology for confirmation of intrauterine pregnancy. Patients were kept in recovery room for 30 min and later transferred to their respective wards.

The primary outcome measures assessed were the success rate of the procedure, defined as complete uterine evacuation (confirmed through sharp curettage) and procedure related complications including uterine perforation, bleeding, infection and vagal shock. Secondary outcome measures included mean hospital stay, operating time, cost of procedure and post-operative time using visual analogue score at 1 and 6 hours.

Data was analyzed through SPSS version 15. Chi square and student t-test were used for categorical and continuous variables respectively. Adjustments for significant differences in baseline characteristics including age, parity, gestational age, co-existing risk factors, indications for procedure, gestational sac size, CRL was made using linear model for continuous response variables and multivariate logistic regression models for categorical response variables. Odd ratios were presented with 95% CI.

Results

A total of 176 women with first trimester pregnancy loss underwent either an EVA (n=70) or an MVA (n=106). Characteristics of the study population at enrollment was similar in two groups except gestational age and gestational sac diameter which was significantly higher in MVA group

Table-1: Baseline characteristics of the study population.

	MVA n=106	EVA n=70	p-value*
Age(yrs)			
mean±SD	27.34±5.352	26.34±5.042	0.218
Gestational age(wks)			
mean±SD	9.7±1.440	9.04±1.748	0.008
Parity,n(%)			
- Primigravida	40(37.73)	30(42.85)	
- Multigravida	61(57.54)	39(55.71)	0.44
- Grandmultigravida	5(4.71)	1(1.42)	
Indication for procedure,n(%)			
- Incomplete miscarriage	45(42.45)	33(47.14)	
- Missed miscarriage	38(35.84)	19(27.14)	
- Anembryonic pregnancy	16(15.09)	10(14.28)	0.54
- Molar pregnancy	5(4.71)	4(5.71)	
- Septic induced abortion	2(1.88)	4(5.71)	
Co-existing risk factors,n(%)			
Low risk patients	94(88.68)	64(91.43)	
High risk patients	12(11.32)	6(8.57)	
- Previous 1 LSCS$	2	2	
- Previous II LSCS	4	1	0.46
- Previous III LSCS	1	0	
- Hypertension	1	2	
- Diabetes mellitus	1	1	
- Previous gynaecological surgeries	3	0	
Ultrasonographic parameters mean±SD			
- Crown-rump length (CRL),mm	44.98±11.79	43.42±13.23	0.642
- Gestational sac diameter ,mm	58.39±6.558	46.91±11.937	0.004
- RPOCs#, mm	29.6±8.78	30.09±11.93	0.862

*pvalue <0.005 is considered significant. Chi-square test and students t-test were used for categorical and continuous variables respectively.
$ Lower segment caesarean section.
# Retained products of conception.

Table-2: Adverse events of MVA vs EVA.

	MVA n=106	EVA n=70	p-value*	95% CI Upper	lower
Blood loss mean±SD	62.08±32.190	75.71±35.532	0.008	-23.664	-3.614
Post operative VAS#					
- 0 hours	3.91	3.96	0.845	-0.57	0.467
- 6 hrs	1.11	1.33	0.157	-0.514	0.083
Uterine perforation, n(%)	2(2.4)	0(0)	0.248		

*pvalue <0.005 is considered significant. Chi-square test and students t-test were used for categorical and continuous variables respectively.
VAS- Visual Analogue Score.

Table-3: Secondary outcome measures.

	MVA n=106	EVA n=70	p-value*	95% CI Upper	lower
Hospital stay(hrs) mean±SD	12.26±6.971	19.54±7.95	0	-9.521	-5.036
Operating time (min) mean±SD	10.71±2.770	9.59±2.880	0.01	0.276	1.968
Hospital cost, (Rs)	1419±1337.62	3222.5±1816.02	0	-2272.65	-1333.28
($)	17.23	39.1			

*pvalue <0.005 is considered significant. Chi-square test and students t-test were used for categorical and continuous variables respectively.
Rs- Rupees.
$- US Dollars.

(Table-1). Of the total EVA procedures 95.7% were performed under general anaesthesia. On the other hand majority of MVA procedures were performed under paracervical block alone (60.3%) or in combination with systemic analgesia (34.9%). In 4.7% of the MVA cases, elective general anaesthesia was given on patient's request, where as 10(9.4%) required additional administration of general anaesthesia due to intolerability of pain despite paracervical and systemic analgesia in MVA patients.

The complete evacuation rate (success rate) for both treatment modalities was similar, 89% for MVA and 91.4% for EVA (p=0.69). The remaining cases required sharp curettage to complete the process in both the groups.

With regards to the safety and adverse events of the two treatment modalities no differences were observed between groups in terms of blood loss and post-operative pain severity score. Mean blood loss was 62 ± 32.19 ml in MVA vs. 75.7±35.5 ml in EVA group. There was no case of major haemorrhage requiring blood transfusion. Procedure related uterine perforation occurred in 2 (2.4%) patients both belonging to EVA group (Table-2).

The mean hospital stay was significantly shorter in MVA group 12.26 ±6.97 hrs vs 19.54±7.59 hrs in EVA group. Operating time was higher in MVA than EVA, (p=0.010). Similarly mean treatment cost was significantly lower in MVA than EVA group Rs1419.5±1337.62 vs Rs 3222.5±1816.02 (Table-3).

Discussion

MVA has been used worldwide for more than 30 years and has been a safe and effective procedure for the management of early pregnancy loss.[15,16] Despite being simple, inexpensive and easy to handle tool, its use in most of the hospitals is restricted due to unfamiliarity of the clinicians with its use. The technique was introduced in our institution only recently and was new for the residents as well other faculty members who were more versed with EVA. A high success rate with no major complications with MVA provides evidence that the technique is safe and easy to learn.

Complete evacuation rate with single intended modality was 89.7% for MVA vs 91.4% for EVA. Other studies comparing MVA with EVA have shown similar success rates, 95.2% vs. 97.6% and 98% vs. 95% respectively.[9,17] A meta analysis based on the results of 10 studies involving 1660 women have shown no significant difference between the two methodologies in terms of complete abortion rate (RR 1.00;95% CI 0.99-1.02).[18] However, no local data is available regarding a comparison between these two modalities. The only available study in this regard has compared MVA with misoprostol and has shown 100% success rate with MVA vs. 92 % for misoprostol.[19]

The operating time for MVA was significantly longer than EVA. The most likely explanation for this difference was significantly higher gestational age and gestational sac diameter in MVA group in our study. Similar observations were made in the meta analysis of 10 studies with a gestational age of less than 50 days.[18] Time consumed in repeated emptying of MVA syringe due to its limited capacity of 60 ml may be a contributing factor in such cases.

With regards to the safety and adverse effects of two treatment modalities, MVA was found safer than EVA. No uterine perforation occurred in MVA group versus two perforations in EVA group. This may be attributable to flexible, soft and easy to handle cannula used in MVA versus metallic hard and non flexible cannula in EVA. Review of literature in this regard shows a uterine perforation rate of 0.06% for MVA.[8] Minor complications though not seen in our study, have been reported in 0.7%-2% cases.[4,8,10,20] Infection being the commonest among these.

With reference to cost effectiveness of procedure, the mean hospital cost was significantly less for MVA than EVA. The difference in cost was due to reduction in hospitalization time and less frequent use of general anaesthesia in MVA group. Similar trend was observed in studies from Kenya, from Mexico and Magotti where hospital stay was 49%-45% and 40.5% less for MVA respectively compared with conventional procedure[20,21] and duration of hospital stay was 10.6 hours compared to 17.96 hrs for conventional procedures.[21] It is important to highlight that hospital related charges were only partially paid by the patient .Its equation with the hospital cost conveys the cost of procedure to the health care system if all the charges were actually paid as bills.

The study does not allow any determination of whether the procedure of EVA is more painful than MVA because almost all (95.7%) cases of EVA were performed under TIVA as per departmental policy, while majority of MVA (95.2%) were performed under para cervical block alone or in combination with systemic analgesia. However need for additional anaesthesia in only 9.6% cases provides evidence that the procedure can be used in low resource settings where general anaesthesia is not available. Safety advantages of analgesia over anaesthesia cannot be over emphasized and should be taken into consideration while conducting these comparative studies.

Post procedure pain assessment using visual analogue score showed no difference between the two groups. The findings are contrary to those of Edwards[17] who found significantly higher pain severity score in MVA (3.7±2.3) vs EVA (2.8±2.4). The probable reason for this difference could be the variable individual threshold for pain. The issue needs further evaluation through larger randomized trials.

This study provides a valuable contribution to the literature. Majority of the studies published so far have used MVA for elective termination of pregnancy and incomplete miscarriage.[20,22] There is scarcity of data with regards to the use of MVA in molar pregnancy and septic induced abortion.[23] The successful use of MVA in 5 cases of molar pregnancy and two cases of septic induced abortion in our study provides an evidence to extend the use of this inexpensive and easy to handle tool in these conditions. The major concern in evacuation of molar pregnancy with MVA is excessive blood loss which is expected to worsen due to time consumed in emptying of the syringe. The risk can be minimized by following strict recruitment criteria of less than 12 weeks uterine size and by using more than one MVA aspirator.

To date this is the first ever study conducted in Pakistan to compare MVA with EVA in a local scenario. We believe that our study will help raise interest of clinicians in this method and increase its acceptance in terms of managing first trimester pregnancy loss. Incorporation of this technique in primary health facilities will help to decentralize the post abortion care in settings where there is scarcity of electricity and operation theatre facilities.

Conclusion

Manual vacuum aspiration is a safe and effective alternative to traditional electric vacuum aspiration. It is superior to EVA in terms of cost, reduced need for general anaesthesia and no need for electricity. While some training is required to familiarize the clinicians with proper use of aspirator and flexible cannula, the training cost is not greater in terms of benefits achieved through this low cost technology in settings with meager health resources.

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