MANUAL VACUUM ASPIRATION (MVA): A SAFE AND EFFECTIVE ALTERNATIVE FOR THE SURGICAL MANAGEMENT OF EARLY PREGNANCY LOSS

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ABSTRACT

Objective: To assess and document safety, efficacy and patient acceptability of Manual vacuum aspiration (MVA) in the management of early pregnancy loss (EPL), performed in the treatment room setting.

Study Design: Quasi-experimental, (clinical trial),

Place and Duration of Study: Treatment Room, OBGYN department, PNS Shifa from Nov 2010 to 31st Mar 2013.

Material and Methods: Single centre prospective study conducted at Obstetric & Gynecology department, PNS Shifa from Nov 2010 to Mar 2013. A total of 414 women with EPL consented for MVA in the treatment room under local anesthesia, out of which 400 women underwent MVA.

Results: Overall MVA was 94.5% effective in treating pregnancies through 13 weeks of gestation. There were no major complications. Minor complications: retained products of conception and endometeritis were treated easily.

Conclusion: MVA is safe, effective and economical alternative to conventional dilatation and curettage for the treatment of EPL. Treatment in the outpatient setting allows better post-procedure physical and emotional quality of life; avoids general anesthesia, has immense potential in primary health care setting.

Keywords: Early pregnancy loss, Manual Vacuum Aspiration.

INTRODUCTION

Early pregnancy loss (EPL) is common. spontaneous and missed miscarriages occur in approximately 15% of clinically recognized pregnancies; contribute considerably to OBGYN workload[1]. In Pakistan approximately 890,000 women present with EPL annually[2]. Annual miscarriage rate is 29 per thousand women aged 15-49 years[2]; 197,000 women treated for post abortion complications in public health sector annually[3]. Unsafe abortions contribute 13% of maternal mortality[3]. Quest for safe and effective management method for EPL continues. Current options include surgical evacuation (suction curettage, D&C under GA), medical abortion with misoprostol, or expectant treatment[4-6]. Expectant management carries higher risk of incomplete miscarriage[7-9]. Medical abortion entails frequent visits to the gynecologist, often need after working hours intervention, success decreases with increasing gestation6. About 88% of women opt for definitive surgical management[7]. MVA is in use since 1973. WHO recommends MVA as the treatment of choice for women with EPL[8]. Several studies report success with MVA for EPL management[7-9]. Despite global success , MVA usage is not common in Pakistan. D&C remains in vogue despite the disadvantages. EVA under GA is practiced partially. Theatre availability remains a problem entailing long waits both for patient and gynecologist. Therefore a need was felt to assess safety, effectiveness and patient acceptability of MVA for EPL management in a treatment room setting for integration into routine gynecological practice.

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MATERIAL AND METHODS

Study population: 414 consecutive women with diagnosis of EPL up to 13 weeks, reporting to the gynae outpatient department from 1st Nov 2010 to 31st Mar 2013;. Period of gestation was calculated by LMP and transvaginal

ultrasound(TVU). Patients with missed miscarriage (fetal demise, an-embryonic gestation), incomplete abortion, and failed medical abortion were offered MVA. For purpose of study: on TVU fetal demise was defined as lack of cardiac activity at crown-rump length (CRL) between 7 and 40 mm; An-embryonic pregnancy as mean gestational sac diameter between 25 and 45 mm with no fetal pole; and incomplete abortion as passage of products of conception with the residual anterior-posterior endometrial lining ≥30 mm

Table-1: Showing characteristics of the study population (n=414).

Mean age(years)	**28 ± 4**
Parity	
Primigravida	126 (31.5%)
Multigravida	244 (61%)
Grandmultigravida	30 (7.5%)
Gestational age	
< 63 days	118 (29.5%)
64 – 91 days	270 (67.5%)
>91 days(incomplete abortion)	12 (3%)
Marital status: married	400 (100 %)
Indications	
Early fetal demise	234 (58.5%)
Incomplete abort	134 (28.5%)
Failed medical abortion	54 (13.5%)
Incomplete early mid-trimester	12 (3%)
Previous miscarriage	154 (38.5%)
Previous termination of pregnancy	66 (19%)
Cervical priming done	114 (53.5%)
Mean time interval b/w misoprostol and MVA	160 min

Table-2: Showing study results (n=400).

Over all efficacy	
Successful MVA	378 (94.5%)
Failed MVA	22 (5.5%)
Requiring surgical evacuation	14(3.5 %)
Vaginal Bleeding < 50ml	374 (93.5%)
50-75 ml	26 (6.5%)
Endometritis	08 (2%)
Procedure Time	
<15 mins	158 (39.5%)
15–30 mins	216 (54%)
30–45 mins	22 (5.5 %)
>45 mins	4 (1%)
Hospital Stay 2 hours	336 (84%)
2-12 hours	44 (11%)
12-24 hours	20 (5%)
Em MVA	08 (2%)
Geographical	08 (2%)
workload	04 (1%)
Patient acceptability	N: 40
Subsequent MVA Yes	180 (45%)
No	100 (25%)
IDK*	120 (30%)
Recommend MVA Yes	140 (35%)
No	120 (30%)
IDK*	140 (35%)

*IDK- I don't know

and uterine size <13 weeks gestation[10]. Approval for the study was taken from hospital ethical committee.

All consenting women at gestation <13 weeks (91 days) with missed miscarriage, incomplete miscarriage, failed medical abortion with willingness to comply with the study protocol and follow-up visit schedule were included in the study . Women who were hemodynamically unstable, septic abortion, suspected ectopic pregnancy, known bleeding disorders, uterine anomalies, taking anticoagulant, and extreme anxiety were excluded.

At enrollment written informed consent was obtained, baseline interview was conducted; detailed obstetric history, baseline demographic measurements(age, parity, marital status, and education) were recorded. After clerking, clinical, pelvic, TVS assessment of the patient was done. Blood group-Rh status, hemoglobin levels were assessed. All patients were given Tab Ibuprofen(Brufen) 400mg and Cap Doxycycline (Vibramycin)100mg half hour before MVA. Cervical priming with misoprostol (Cytotec)400mcg sublingually was done in women with missed miscarriage with unripe cervix 2 hours before the procedure. MVA was performed by one trained doctor assisted by one trained midwife using hand held 60 ml syringe (Ipas MVA Plus) attached to Ipas easy-grip uterine cannula, in treatment room under para-cervical block (with 10 ml of 1% Lignocaine solution using Glick technique). Products of conception were sent for histopath. Injection Anti D was given if patient was Rh negative. Women were observed and monitored for complications for 2 hours post procedure. Post procedure pain was assessed using visual analogue score immediately and 02 hours post procedure[11]. After 02 hours women were allowed to go home if clinically well, complication free and hemodynamically stable. At follow up visit one week post procedure; patients were assessed clinically and by TVU for completeness of the procedure and complications. Histopath report was reviewed. Patient acceptability for MVA was assessed by asking whether they will choose MVA in case of subsequent EPL and recommend MVA to other women with EPL.

The data was analyzed by SPSS version 20 means & standard deviation & frequency were calculated.

RESULTS

Four hundred and fourteen women with EPL were enrolled for MVA. Fourteen women were excluded from the study; in 10 women procedure was abandoned for fear of creating a false channel in cervix; 04 women did not allow cuscos speculum and had the procedure under GA. Characteristics of the study population (table-1) show mean age as 28 years. Majority (61%), were multigravida. Period of gestation was between 9 weeks to 13 weeks in the majority. Commonest indication for MVA was early fetal demise (58.5%). 38.5% of the women had history of previous miscarriage. Cervical priming was required in 53.5% of cases (all had missed miscarriage). Mean time interval between misoprostol administration and MVA was 160 minutes. Mostly MVA was performed by consultant (42.5%) but as experience with procedure grew, the junior team members got trained; senior registrars, fellowship and membership residents also performed MVA. Only 1% patients complained of severe pain immediately after MVA. Minimal pain (55.5%) to uncomfortable (35%) reported by majority patients immediately after MVA. Two hours post procedure either the patient had minimal (33.5%) or no pain (38%) (fig-1). MVA was successful in 94.5% of cases table-2. MVA failed to evacuate the uterus in 22 (5.5%); out of which 08 patients had spontaneous expulsion and 14 women underwent EVA under GA. There were only 08 cases of endometritis which were treated with no long term sequelae. In most cases the blood loss was <50 ml. No patient required transfusion. No patient had uterine perforation. Time taken to perform MVA was 15 to 30 minutes in majority (54%), with only 4 patients requiring more than 45 mins to complete the procedure. 84% of the MVA cases were discharged from hospital within two hours of procedure. Patient response to MVA was mixed with 45 % women opting for

subsequent MVA and 35 % women agreed to recommend MVA to others.

DISCUSSION

The primary purpose of the study was to assess and document safety of MVA for management of EPL. MVA for management of EPL is in use since 1973, its safety documented by a number of studies[7-9]. Despite being safe, inexpensive, requiring less capital investment[13], MVA is not offered routinely by many hospitals and many health care professionals are not familiar with the MVA equipment and usage. MVA facility was recently incorporated in our department. Before offering MVA routinely, 4 day workshop in collaboration with NCMNH (National committee on maternal and neonatal health) for the faculty, residents, nursing and paramedic staff was organized. Only certified health care professionals later conducted MVA. This ensured patient and equipment safety and help standardize MVA.

The study demonstrated that MVA was safe and effective in 94.9% of cases with EPL up to 13 weeks (91 days); this compares well with other studies showing efficacy of MVA[7-14]. Period of gestation in majority (67.5%) of the cases was between 9 and 13 weeks. Gestational age in the study population is significantly higher than that in the published studies[13,14]. In 3% of the cases MVA was performed on gestation >13 week. No patient had uterine perforation or excessive blood loss requiring blood transfusion. 94% of the cases remained complication free; being at par with international and local studies. MVA failed in 5.5% of women and 3.5% required surgical evacuation. The 22 cases of failed MVA were probably due to initial inexperience with MVA and MVA performed by junior doctors. With cervical priming nearly all cases of fetal demise were successfully managed. Average hospital stay was 2 hours in 84% of the patients; 11% women stayed in hospital > 2 hours because of pain. 5% women had longer hospital stay for other reasons: emergency MVA done late in the evening, MVA delayed because of prioritized resident workload, and patients coming from distant areas. MVA was cost effective, less resource intensive, requiring no GA, with shorter hospital stay compared to a conventional curettage under GA. This compares favorably with other studies.

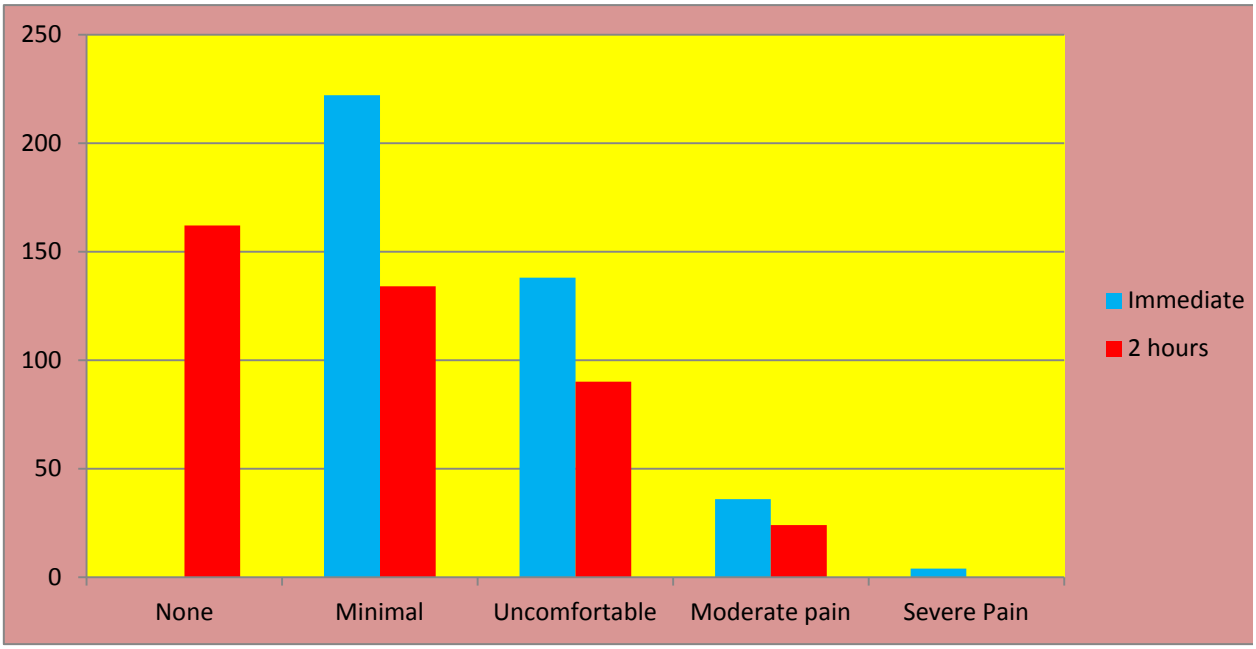

Figure 1. Pain severity: Immediate and 2 hours post procedure.

Average time taken for MVA was 15- 30 minutes in 54% of cases. Longer time was due to limited 60 ml. capacity of the MVA syringe, time taken to empty and recharge the Ipas MVA syringe specially for higher gestations. Post procedure pain was assessed by visual analogue scale. Majority of the patients experienced minimal pain.

Completion of the procedure was assessed clinically and TVS, avoiding curettage altogether which is in line with WHO guidelines, as opposed to a local study where completion was ascertained by sharp curettage[14]. The response to MVA was mixed; probably because the technique was new and women were not used to the wakeup procedure. Pre-procedure counseling was of utmost importance in guiding patient response. Our study is probably the first local study to assess patient acceptability, along with safety and efficacy.

Strength of the study was that MVA was done by trained Health care professionals exclusively in an outpatient treatment room setting and not in operation theatres, thereby leaving theatres for more complex procedures and emergencies. Limitation of the study could be the small sample size. While the results of the initial study are being reported a larger study is planned. Major issues identified for a successful MVA service were: training of obstetricians and support staff; building confidence of midwifery staff; and pre-procedure counseling of patients. With regular usage all these issues can be addressed.

CONCLUSION

MVA is safe, effective, simple and cost effective alternate to conventional D&C for EPL. MVA avoids the need for general anesthesia, theatres and electricity; has minimal complications, and better post procedure physical and emotional quality of life, hence has advantages both for the patient and the healthcare system. With effective training it can be easily integrated in the primary health care system.

CONFLICT OF INTEREST

This study has no conflict of interest to declare. Abstract and results of this study were accepted and presented in an oral presentationat the International conference on Medical Education, organised by Association for Excellence in Medical Education(AEME) and held on 07th-09th March 2014 at University of Health Sciences(UHS) Lahore, Pakistan. No funding was received from any agency or institution.

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