e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2022; 14(6); 378-386

Original Research Article

Safety and Efficacy of Manual Vacuum Aspiration and Uterine Curettage for Treatment of First Trimester Incomplete Abortion: A Prospective Observational Study

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Received: 15-04-2022 / Revised: 23-05-2022 / Accepted: 08-06-2022
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Conflict of interest: Nil

Abstract

Background: Uteine evacuation is the removal of products of conception. There are many ways of performing this in the first trimester such as vacuum aspiration, surgical methods and pharmacological methods. Within these categories there are several different methods that can be employed. These depend upon the experience and training of the staff available, and the equipment and materials provided at the time

Objectives: To assess the safety and efficacy of MVA with EVA in pregnancy termination upto 10 weeks with regards to procedure time, blood loss, pain complications and duration of hospital stay.

Methods: A prospective randomized comparative study of 200 patients with a history of less than or equal to 10 weeks gestation seeking MTP, attending Obstet and Gynae OPD of Dr Ram Manohar Lohia Combined Hospital, Lucknow.

Statistical analysis consists of (chi)2 test, student 't' test and z – test.

Result: The time taken, blood loss, pain, complications and duration of hospital stay was significantly less in MVA group as compared to EVA group ($p < 0.05$).

Conclusion: MVA is safe & effective with less complications, less bleeding, and needing less resources.

Keywords: Manual Vacuum Aspiration, Electric Vacuum Aspiration, Abortion, Complications.

Introduction

Abortion is the termination of pregnancy by expulsion of an embryo from the uterus prior to viability. Some studies suggested that 20% of all pregnancies worldwide end in abortion. Nearly half of these abortions are unsafe and often illegal. We can classify abortion clinically into different types as follows: Incomplete abortion, if bleeding has begun and the cervix is dilated but the tissue from pregnancy still

in the uterus[1]. Inevitable abortion, a condition of pregnancy in which spontaneous termination is imminent and cannot be prevented; it is characterized by bleeding, uterine cramping, dilatation of the cervix and presentation of the conceptus in the cervical os. Missed abortion, is a common complication of early pregnancy occurring in up to 15% of all clinically recognized pregnancies[2]. Additionally, incomplete abortions can lead to more serious complications such as haemorrhage, sepsis, and in the worst-case scenario, death. Incomplete abortions are generally treated with surgical or medical uterine evacuation[3].

Uterine evacuation is the removal of products of conception. There are many ways of performing this in the first trimester such as vacuum aspiration, surgical methods and pharmacological methods. Within these categories there are several different methods that can be employed. These depend upon the experience and training of the staff available, and the equipment and materials provided at the time. A patient's individual clinical status, uterine size, pregnancy length and patient's choice are important considerations in deciding which method is best suited[4].

The treatment options for early pregnancy failure include expectant management, medical termination with misoprostol and surgical evacuation. Traditionally, first-line surgical management has been dilatation and curettage (D&C) which requires trained personnel, operating room, presence of an anaesthetist and sometimes blood transfusion. Despite careful and skilled intervention, even in best hands complications like haemorrhage, incomplete evacuation, perforation and infection can occur[5].

The first report of uterine evacuation using vacuum was published in China in 1958 before the technique was later adopted, refined and popularised in the other parts of the world. In 1972, Harvey Karman introduced a surgical evacuation technique using syringe and vacuum known as manual vacuum aspiration (MVA) and has been used for management of miscarriages and elective termination of pregnancy since then. The usage was later extended to include missed miscarriage and second trimester miscarriage/ termination with low reported complication rates[6].

Overall effectiveness and patient satisfaction for MVA are much higher, and complication rates much lower than DNC. This method of evacuation is safe and can easily be performed in any setting, including an office, emergency room, or the operating room and may be performed by a wide range of trained medical personnel including midwives and nurses. When conducted in the outpatient setting rather than operating room, vacuum uterine aspiration can result in substantial cost savings 4,8 and significant reduction in procedure time (3.7 minutes for MVA vs 10.2 minutes for DNC)[7].

Very little data is available to prove its feasibility, safety and efficacy over D&C in this area. Hence, we conducted this study with the aim of comparing the safety and efficacy of MVA over D&C in first trimester Incomplete abortion.

Aim and Objectives

1. Compare effectiveness in term of complete evacuation of product of MVA and uterine curettage in first trimester incomplete abortion.
2. Compare safety in term of post procedure complication, infection, bleeding and duration of hospital stay in MVA and uterine curettage in first trimester incomplete abortion.

Methodology

Study Area: Study will be carried out at Dr Ram Manohar Lohia Combined Hospital, Lucknow.

Study Duration: May 2018 to April 2019

Type of Study: Prospective observational method

Sampling Method: Convenience sampling method

Sample size: Assuming that the Duration of procedure can be one of the comparison criteria between MVA group and Uterine curettage group. As per the previous study the mean duration of procedure in MVA group was 5.93±1.11 minute, whereas for D&C group it was 7.89±2.08 minutes. (based on study by Jayshree V et al[8], at 2-sided test with 95% confidence level (α=5%) and 80% power, expected sample size in both group is 12 each, i.e total 24, but the minimum sample size should be 30, so 30 sample size should be taken for each group i.e total 60 sample size. (30 with MVA and 30 D&C). will take 200 sample size (100 with MVA and 100 D&C)

Statistical Methods: Statistical analysis will be carried out with the help of Microsoft Excel and Epi info 7.1 software. The description of the data will be done in form of arithmetic mean +/- SD (or median) for quantitative data while in the form of frequencies (%) for qualitative (categorical) data. P-values of < 0.05 will be considered significant. For comparison of categorical variables (i.e. to examine the associations between qualitative/quantitative variables), chi-square test will be used if the number of elements in each cell are 5 or higher and Fisher's exact test, otherwise.

Methodology

This is a Prospective observational study undertaken in 200 patients with incomplete abortion, in the reproductive age group with a history of less than or equal to 12 weeks gestation, attending Obst and Gynae OPD of Dr Ram Manohar Lohia Combined Hospital, Lucknow.

Inclusion Criteria:

1. Women in the reproductive age group with history of < 12 weeks gestation, irrespective of any parity.
2. Incomplete abortions.

Exclusion Criteria:

1. Ectopic pregnancy
2. Molar pregnancy
3. Uterine anomalies
4. Pelvic infection
5. Bleeding disorders

Patients presenting with incomplete abortion will undergo MVA or D & C during study period will be enrolled in study after inclusion and exclusion criteria. In all selected cases, a detailed history will be taken of menstrual, contraceptive, obstetric, medical & surgical conditions. Clinical examination including general physical & systemic examination will be done by consultant. Bimanual Pelvic examination will be done to know the position, size & mobility of uterus, the presence of infection, any forniceal tenderness (PID) & ectopic pregnancy.

The patients are then subjected to investigations which include:

a) Percentage
b) Blood group and Rh – typing
c) Urine examination for microscopy, albumin & sugar and, if required,
d) Ultrasonography,

After explaining the procedure, its advantages and complications to the patient, an informed written consent will be taken. The patients will them subjected to either MVA or D & C. In all 200 cases, the time taken for the procedure, total blood loss, post – operative pain & bleeding, other complications, and duration of hospital stay will be studied.

Time: Time taken for the procedure will be measured in minutes, from the insertion of the cannula into the uterus till the signs of complete evacuation of the uterus.

Blood loss: Blood loss during the procedure measured in milliliter by noting the collection in the MVA syringe and the suction jar in MVA & D&C respectively:

Measurement of blood loss will include the products of conception, decidual tissue and blood.

Pain: In both groups, the pain appreciated by the patient will be graded as: Grade 1: Nil, Woman is comfortable. No facial expressions of pain. Not complaining of cramping in lower abdomen.

Grade 2: Minimal, Woman complaining of mild cramping pain in lower abdominal. No facial expressions of pain.

Grade 3: Moderate. No analgesis needed

Woman complaining of moderate cramping lower abdominal pain Facial expressions of pain noted. Pain is tolerable

Grade 4: Severe. Needing analgesics

Woman complaining of severe pain in lower abdomen. Facial expressions indicating severe pain. May or may not be associated with nausea, vomiting.

In the post-operative period, the amount of bleeding will be assessed by checking the soakage of the diapers. In both groups, bleeding will be graded as:

Grade 1: Less than normal i.e., spotting only or no bleeding

Grade 2: Normal i.e., soakage of one pad.

Grade 3: More than Normal i.e., soakage of 2 or more pads.

The woman will be monitored for anesthesia complications like headache, nausea, vomiting & allergic drug reactions.

In cases Rh – Ve women, Anti – Rh –D immunoglobulin will be given. Depending on the severity of pain, amount of bleeding & any other complication, patient will be discharged accordingly with appropriate contraceptive method. On discharge, woman will be advised to watch for signs & symptoms requiring immediate attention:

- Prolonged bleeding (more than 2 week)
- Prolonged cramping (more than a few days)
- Excessive bleeding
- Fever, chills, or malaise
- Fainting

Result

We had selected 200 women in the study, 100 women had undergone MVA and 100 women D& C as per the selection criteria

Table 1: Distribution of study subjects as per age

Age (yrs)	MVA (n=100)	D& C (n=100)
≤20	8	10
21 – 25	46	51
26 – 30	35	30
31 – 35	7	6
> 35	4	3
Total	100	100

Table 1 shows distribution of study subjects as per age. In both procedures, maximum number of cases were in the age group of 21-25 years (46), followed by that of 26-30 years (35), least number of cases were in the age group > 35 years. This holds good for D&C group also. In MVA, maximum number of cases were in the age group of 21 – 25 years. In MVA group mean age group 25.52±4.11, whereas in D&C group mean age was 24.86±3.94, on applying t test we found p value 0.24.

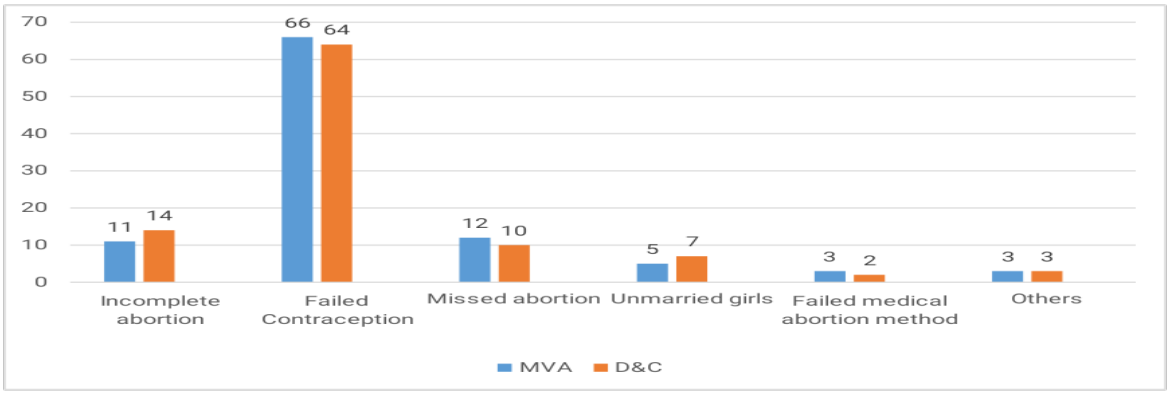

Fig 1: Distribution of study subjects as per Reason for MTP

Fig 1 shows distribution of study subjects as per Reason for MTP. In both the group i.e MVA group or D&C group highest number of study subjects i.e 66% and 64% having failed contraception as reason for MTP, missed abortion in 12% in MVA and 10% in D&C group whereas failed medical abortion method was the reason in 3% (MVA) and 2% (D&C).

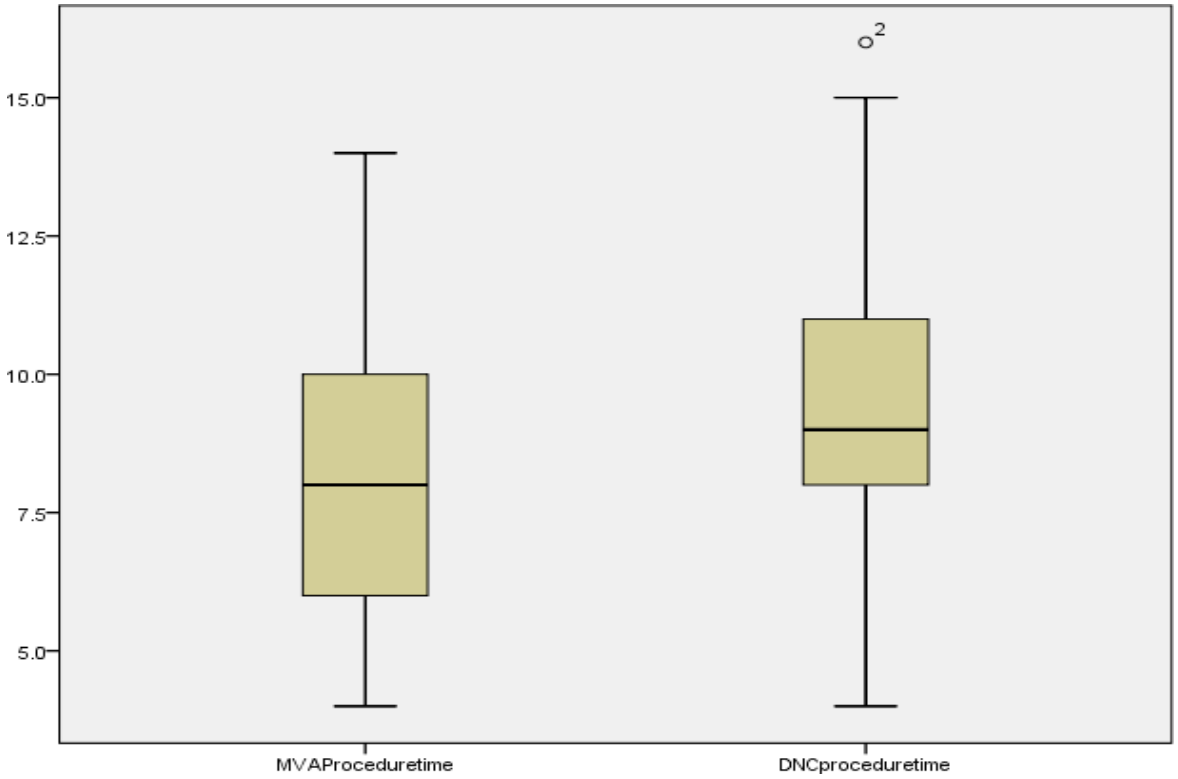

Figure 2: Procedure Time (Minutes) in both the study group

Fig 2 shows Procedure Time (Minutes) in both the study group. In MVA group the mean procedure time was 8.17±2.49 min, whereas 9.58±2.35. On applying t test we found very significant difference between two group with p value <0.001.

Table 2: Hospital stay in both the procedure

	MVA mean ±S.D	D&C Mean ± S.D	't' – value	p – value
Hospital stay duration (hours)	8.70±2.05	15.81±4.41	- 14.62	<0.001

Table 2 shows Hospital stay in both the procedure. There is a highly significant difference in the Hospital stay duration in MVA as compared to D&C (p <0.001). In MVA, hospital stay duration during the procedure is less.

Table 3: Type of Anesthesia given in both the procedure

Type of Anesthesia	MVA (n = 100)	D&C (n = 100)	Total
IV	7	23	30
Cervical block	84	61	145
IV + Cervical block	4	8	12
Spinal	5	8	13
Total	100	100	200

Table 3 shows type of Anesthesia given in both the procedure. Cervical block was used in 84% cases of MVA & 61% of EVA cases. IV was used in 23% of D&C cases. So, in majority of MVA and D&C cases cervical block was preferred.

Table 4: Number of Cases according to pain VAS Score

Pain score VASScore	MVA	D&C	Total	
1-3	37	9	46	Chi-square- 22.13, P value- <0.001
4-6	48	61	109	
7-10	15	30	45	
Total	100	100	200	

Table 4 shows Number of Cases according to pain VAS Score. In the MVA group, 37% of cases had pain VAS score 1-3, 48% had VAS score 4-6 whereas 15% had VAS score 7-10. & In the D&C group, 61% cases had VAS Score 4-6, 30% had VAS Score 7-10 whereas 9% had VAS Score 1-3. So, the pain appreciated by patients in MVA procedure is less as compared to D&C. This is statistically highly significant (p<0.001).

Table 5: Complications in both procedures

Complications	MVA (n = 100)	D&C (n = 100)	Total
Cervical laceration	3	12	15
Repeat procedure	8	3	11
Retained product	18	12	30
Blood transfusion	4	12	16
Total	33	39	72

Table 5 shows Complications in both procedures. 12 cases of cervical laceration in D&C group occurred during the

insertion of rigid cannulae whereas 3 cases of cervical laceration in MVA group. Repeat procedure is needed in 8 cases in MVA group whereas in 3 cases in D&C group. 18 subjects had retained product in MVA group whereas 12 had retained product in D&C group. Blood transfusion is needed in 12 cases in D&C group whereas 4 subjects in MVA group.

Discussion

Age:

In this study In MVA group mean age group 25.52±4.11, whereas in D&C group mean age was 24.86±3.94. In other similar study conducted on this topic such as study by Anozie, O.B. et al[9] in their study found that Six hundred and twenty-five women were treated with MVA with their age ranging from 15 to 48 years with a mean age of 28.5 ± 5.3 years, which is almost similar to our study. In the study by Bhardwaj M et al[2] patients who sought MTP were from 22 to 42 yrs. of age. Incidence was maximum in 26-30 yrs of age group (60%). This is the group of women in their active reproductive career in this environment. Incidence declined sharply after 35 yrs. In 35-40 yrs age group it was minimum as fertility also to fall after the age of 35 yrs.

In present study in both the group i.e MVA group or D&C group highest number of study subjects i.e 66% and 64% having failed contraception as reason for MTP, missed abortion in 12% in MVA and 10% in D&C Procedure Time taken (minutes).

In the present study, there was a significantly less time consumed for MVA procedure as compared to Uterine curettage procedure ($p < 0.001$). This was comparable with Islam R et al and Toshiyuki Kakinuma. So, MVA helped save the time of both the patient & the clinician.

Duration of Hospital stay (Hours)

The duration of hospital stay was significantly less in MVA group ($p < 0.05$). This was comparable with BUTT TA et al[13], Islam R et al[11]. Farooq F et al[12], compared MVA with sharp curettage & interpreted that MVA had shorter hospital stay i.e 3.3±0.91 hrs as compared with 6.14±2.48 hrs in sharp curettage. Study by Jayshree et al[8] shows Only one patient (1.2%) had two days of hospital stay when compared to 8 patients (10%) in D&C group. but the Chi-square difference is statistically insignificant.

Type of anaesthesia

In the present study paracervical block was used in 84% cases of MVA & 61% of D&C cases. General anaesthesia was used in 23% of D&C cases. So, in majority of MVA and D&C cases paracervical block was preferred. Study by Jayshree et al(8) shows that MVA was done entirely under para- cervical block. But D&C group, 80% cases required short general anaesthesia/ TIVA (total Intravenous analgesia). Only 20% cases were done under para-cervical block.

Pain

In the present study, MVA group appreciated less pain and required less analgesia as compared to D&C group, which is statistically highly significant ($p<0.001$). In the study Azman A et al[6] shows The mean pain score was 4.5 (±1.6 SD) with the lowest reported score was 1 while two respondents gave the score of 8. More than ninety percent of the women reported the score of 6 or less which is translated into mild to moderate pain. All five women who reported severe pain (score 7 and 8/10) were multigravida and 4 of them received parenteral Pethidine as analgesia. Analysis showed that there was no significant difference in mean pain score in related to parity, occupations or education levels.

Complications:

In the present study 12 cases of cervical laceration in D & C group occurred during the insertion of rigid cannulas whereas 3

cases of cervical laceration in MVA group. Repeat procedure is needed in 8 cases in MVA group whereas in 3 cases in D&C group. 18 subjects had retained product in MVA group whereas 12 had retained product in D & C group. Blood transfusion is needed in 12 cases in D & C group whereas 4 subjects in MVA group. Several studies have compared MVA and D & C. Verkuyl et al. conducted a randomized study including 357 patients with incomplete miscarriage prior to 18 weeks of gestation and showed that MVA was associated with significantly less bleeding and pain and a shorter duration of surgery than D & C. However, there was no significant difference in the incidences of uterine perforation and septicaemia. In the study by Jayshree et al[8] they found The presence of retained products and the need for repeat procedure was observed in 2.5% of MVA cases versus 10% in D & C group, which is comparable to our study. Uterine perforation and cervical laceration were not found in both groups which may be due to better experienced surgeon or other factor related to study subjects. Study by Islam R et al[11] shows that manual vacuum aspiration was associated with a low rate of complication and also there was no maternal death. Two factors may be associated with its low complication rate. Prior cervical dilatation with small cervical dilator decreases the chance of cervical injury or uterine perforation. Secondly the surgeon in this study was quite experienced in MVA and very comfortable with intrauterine procedure. K. Mahomed[14] compared MVA V/s Sharp curettage in incomplete abortion 12 weeks gestation and concluded MVA as more effective than sharp curettage with 0% incomplete evacuations in MVA V/s 0.7% in EVA ($p<0.0.05$).

Conclusion:

By this study, it is concluded that, both MVA and D&C are effective for first trimester incomplete abortion. The clinician has to make decision as to which method to use for individual patients with different characteristics. MVA has become safer and more feasible in low resource settings. MVA can be preferred for first trimester incomplete abortion. This preference is based on the results which show similar efficacy, shorter procedure duration, less blood loss and less need for anaesthesia and pain relief with MVA.

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