Research Article

Comparison of Adequacy of Endometrial Sampling by Manual Vacuum Aspiration and Conventional Dilatation and Curettage for Histopathology in Abnormal Uterine Bleeding.

Amna Z. Eusaph[1], Tehreem Babar[2], Rabia Wajid[3], Shamila Ijaz Munir[4], Fatima Waheed[5]

[1-3,5]Department of Obstetrics & Gynaecology, KEMU/ Lady Willingdon Hospital, Lahore; [4]Department of Obstetrics & Gynaecology, FJMU/ Sir Ganga Ram Hospital, Lahore

Abstract

Background: Abnormal uterine bleeding is a common problem experienced by women of reproductive age. Dilatation and curettage (D&C) is one of the most popular method for diagnosing the pathology. But with the advent of method like Manual Vacuum Aspiration (MVA) having multiple advantages, its use should also be promoted in low resource settings like ours.

Objective: To compare the adequacy of endometrial sampling with dilatation and curettage for endometrial sampling in women with abnormal uterine bleeding.

Methods: This randomized control study was done at Lady Willingdon Hospital Lahore over a period of 6 months from July 2015 to January 2016. A total of 140 patients (70 in each group) were taken using simple random sampling. The sample group was divided in two groups i.e. Group A & Group B. In Group A endometrial tissue was sampled by conventional D&C and in Group B by MVA. For Group A, D&C patients came to operation theatre NPO along with baseline investigations. Anesthesia was administered. In Group B patients, no preoperative preparation was done. Analgesia was given. Data was analyzed by SPSS version 20.

Results: The mean age in D & C group was 42.96 4.315 years and 43.01 5.645 years in the MVA group. In D & C group 69 (98.36%) cases needed analgesia while in MVA group only 6(8.6%) required analgesia which was significantly lower than D & C group, p-value < 0.0001. D & C and MVA groups, sample was adequate in 63 (90%) of the females with statistically same value in both group with p-value > 0.05.Post-operative vaginal bleeding occurred in 16(22.9%) and 2(2.9%) cases in D & C and MVA group respectively with significantly lesser rate in MVA group, p-value < .0001. The mean cost in D & C was Rs.1000 17.025 and in MVA group, it was Rs. 397.86 13.285. The mean cost in MVA group was significantly lower than D & C group, p-value < 0.0001.

Conclusion: MVA is a procedure which yields same adequacy of endometrial sampling as conventional dilatation and curettage. MVA, at the same time is easy to perform with lesser complications, needs minimum analgesia and is a cost-effective method for low resource settings like ours.

Corresponding Author | **Dr. Rabia Wajid,** Department of Obstetrics & Gynaecology, KEMU/ Lady Willingdon Hospital, Lahore **Email:** dr.rabia.adnan@gmail.com

Key Words: Abnormal uterine bleeding, endometrial sampling, efficacy, safety, cost effectiveness, MVA, D&C

Introduction

Abnormal uterine bleeding is defined as the change in menstrual duration, regularity, frequency and volume of flow outside pregnancy .[1] Abnormal uterine bleeding and its subgroup, Heavy Menstrual bleeding (HMB) is a problem, accounting for a major chunk of burden on the gynecological outpatient

department .About one third of them belong to peril and post-menopausal age group. It has been estimated that 15-25% of women will be diagnosed with endometrial carcinoma before menopause.[2]

According to the FIGO Seminal 2011 publication, which presented both the systems –terminology and definitions: (FIGO-AUB System 1) and classification of causes of AUB in the reproductive years, PALMCOEIN system (FIGO-AUB System 2). The PALM group stands for Polyps, Adenomyosis, Leiomyomas and Malignancy. COEIN stands for Coagulopathies, Ovulatory disorders, Primary Endometrial disorders, Iatrogenic and not otherwise classified. [3]

A number of investigations are available for women presenting with abnormal uterine bleeding. The usual first line investigation is pelvic ultrasound, followed by endometrial sampling. Sampling of endometrium is usually the first interventional diagnostic step, in all women with more than 35 years of age presenting with abnormal uterine bleeding. Accuracy of dilation and curettage for detecting endometrial hyperplasia and carcinoma is 92.1 % and has a complication rate of 1-2 % .[4, 5, 6, 7]

Common complications of dilatation and curettage include uterine perforation, false passage, and severe hemorrhage, vaginal and cervical lacerations. Dilation and curettage is also associated with HCV seropositivity in Pakistan. Other disadvantages are the use of anesthesia, hospital admission and cost. [8,9,10]

Previously MVA was used only for incomplete miscarriage but now it is also being considered in missed miscarriages, termination of pregnancy and endometrial sampling. Manual vacuum aspiration has many advantages over the sharp curettage. Manual vacuum aspiration can be used as an easy method of endometrial sampling in the office settings. Its small cannula reduces the need for cervical dilatetion. Cannula is disposable but vacuum aspirator is reusable, so the cost is reduced. There is no need of operation theatre and general anesthesia. [11, 12]

Accuracy of manual vacuum aspiration in taking endometrial sampling is almost as good as compared to that of dilatation and curettage. This has been proved by a study done by Sirimai and colleagues.[10] The difference is minimal, so advantages of manual vacuum aspiration are more than that of dilatation and curettage. [12]

One out patient MVA endometrial sampling costs Rs. 500/- as compared to D&C which costs Rs. 3,200/- requiring hospital stay. So MVA can be of substantial financial benefit in countries like Pakistan.[5]

A large number of conventional Dilatation and curettage procedures are performed in public sector hospitals on daily basis. This entails a lot of burden on hospital resources and logistics. The advantages of MVA are that it is a quick, cheap, an outdoor procedure, with no special preparation and no anesthesia requirement. And no lengthy hospital stay is needed. The rationale for carrying out this study is that if manual vacuum aspiration proves itself as effective as dilatation and curettage in terms of adequacy of endometrial sampling, it may become a practical and cost effective tool for endometrial sampling and a very useful option for low resource setting like ours.

Objective:

To compare manual vacuum aspiration and dilatation and curettage for endometrial sampling in women presenting with abnormal uterine bleeding in terms of:

- Adequate sample for histopathology (pathologist finds endometrial epithelium, gland and stroma).
- Analgesia requirement.
- Cost effectiveness.

OPERATIONAL DEFINITIONS:

Adequate Endometrial Sample **:** Adequate sample means one or more pieces of endometrium, large enough to determine gland to stroma ratio and endometrial morphological features.

Inadequate Endometrial Sample: A sample consisting of only of blood, cervical mucus, endocervical epithelium, or blood with fragments of endometrial glands or insufficient stroma for histopathological assessment or diagnosis.

Histopathology: It is the diagnosis and study of diseases of tissues and involves examination of tissues and/or cells under the microscope

Methods:

It was a randomized controlled trial, conducted at Lady Willingdon Hospital, Lahore over a period of 6

months after approval of synopsis and ethical approval of Institutional Review Board of KEMU. Sample size of 140 patients (70 patients in each group) is estimated by using 95% confidence level, 10% absolute precision with expected percentage manual vacuum aspiration as 88.9% and dilatation and curettage as 91.1%.

$$= \frac{Z^2_{1-\alpha/2}\,[P_1\,(1-P_1)\;+\;P_2\,(1-P_2)]}{d^2}$$

$Z\frac{2}{1}-\propto/2$ = Confidence Level 95% = 1.96

P_1 = Population proportion 1 = 88.9%

P_2 = Population proportion 2 = 91.1%

d = Absolute precession 10%

Simple random sampling was done.

Women who were more than 35 years old, with abnormal uterine bleeding (change in menstrual duration, regularity, frequency and volume of flow outside pregnancy).[1], having endometrial thickness more than 10-12 millimeters on Transvaginal scan and willing to participate in research were included in the study. Pregnant women, those with blood clotting problems, allergic to anesthesia drugs, with known cervical stenosis, uterine anomalies and those unwilling to participate were excluded from the study.

The study group comprised of women at greater than 35 years of age presenting to Gynecology outdoor department at Lady Willingdon Hospital. When detailed menstrual history, symptoms and investigations (Baseline investigations especially CBC and pelvic scan) indicated that endometrial sampling was mandated, women were selected for this study. The patient was counseled and procedure was explained to her. Patient was advised to come on any day in last week of regular cycle for endometrial sampling. It could be done on any random day in patients with irregular cycle. The sample group was divided randomly into two groups. They were labeled as Group A & Group B. Group A was sampled by conventional D & C and Group B by MVA. For Group A, D&C patients came to operation theatre, NPO along with Laboratory reports of Hemoglobin and Hepatitis B&C screening. IV line was maintained. Injection Propofol was given. Hegar's dilator was used for cervical dilatation. Metal uterine curette was used to collect endometrial sample. The tip of the tool was oval shaped and slightly bent. Here we used curette with looped width of five millimeters. It was inserted into uterus and endometrial samples were collected from all the walls of uterus and fundus.

In Group B patients, no preoperative preparation was required. IV line was maintained and a pain killer given. MVA consists of 3 cm diameter plastic cylinder with 60 ml volume; a valve at the top of cylinder is present to resist air entry when closed. Core axis of cylinder has two wings. Core axis of tool is pulled to close the valves and vacuum is generated inside the cylinder by the expansion of wings that resist air to get inside the cylinder. A cannula is inserted to the channel at the top of cylinder. In this study plastic disposable cannula of 3 mm with 24 cm length was used with marking outside showing uterine cavity size. The cannula was inserted inside cervix until it reached the uterine fundus and endometrial samples were taken by pulling cannula in and out of uterus and rotated, until it reached all the walls and fundus of uterus. Dilatation of cervix was not required in most of the cases except those having undergone Cesarean Section previously and those with pin point cervix.

The samples of Group A & B were collected in formalin bottles and sent to histopathology lab without mentioning the sampling technique. In both groups same criteria were used for histopathological examination.

The data was entered and analyzed by using SPSS-20. Quantitative variable such as age was shown as mean $\pm$ S.D. Qualitative variable like gender was presented as frequency and percentages. Comparison of two groups' parameters was done by applying Chi-square test. P-value ≤ 0.05 was considered significant.

Results:

The mean age of Patients in this study was 42.99 $\pm$ 5.006 years while in D & C group the mean age was 42.96 $\pm$ 4.315 years and in MVA group the mean age was 43.01 $\pm$ 5.645 years (Table 1)

The overall age distribution can be seen in (Figure 1)

The age ranged from 35 to 55 years in D&C group and 35 to 60 years in MVA group.

The parity distribution can be seen in Figure (2)

The mean parity in the D&C group was 4.90±2.746 and 4.01±1.378 in the MVA group.

In D & C group 69 (98.6%) cases needed analgesia while in MVA group only 6 (8.6%) required analgesia. Analgesia requirement in MVA group was significantly lower than D & C, p-value < 0.0001(Table 2)

In D & C group 20 (28.57%) cases presented with Polymenorrhagia, 31 (44.29%) presented with Menorrhagia, 8 (11.43%) cases presented with Metrorrhagia and 11 (15.71%) presented with Menometrorrhagia. In MVA group 29 (41.43%) cases presented with Polymenorrhagia, 22 (31.43%) presented with Menorrhagia, 4 (5.71%) cases presented with Metrorrhagia and 15 (21.43%) presented with Menometrorrhagia.

The mean cost in D & C group was 1000 ± 17.025 Rupees and it was was 397.86 ± 13.285 Rupees in the MVA group. The mean cost in MVA group was significantly lower than D & C group, p-value < 0.0001. (Table 3)

Post-operative vaginal bleeding occurred in 16 (22.9%) cases and 2 (2.9%) cases in D & C and MVA group respectively with significantly less rate in MVA, p-value < 0.0001. (Table 4)

In D & C and MVA groups, sample was adequate in 63 (90%) and 64 (91.4%) of the females respectively with statistically the same rate of sample adequacy in both groups, p-value > 0.05. (Table 5)

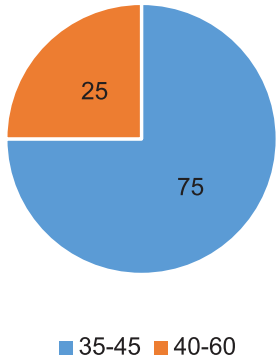

Figure 1: *Age distribution of cases in both groups*

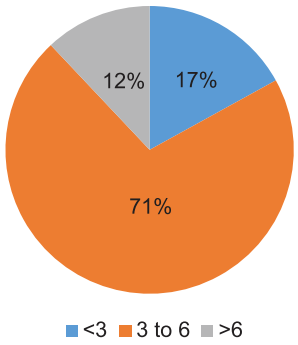

Figure 2: *Parity Distribution of cases in both groups*

Table 1: *Descriptive statistics of age (years)*

	Mean	S.D	Minimum	Maximum
D & C	42.96	4.315	35	55
MVA	43.01	5.645	35	60
Total	42.99	5.006	35	60

Table 2: *Comparison of analgesia requirement in both study groups*

		Study groups		
				Total
		D & C	MVA	
Analgesia requirement	Yes	69	6	75
		98.6%	8.6%	53.6%
	No	1	64	65
		1.4%	91.4%	46.4%
	Total	70	70	140
		100.0%	100.0%	100.0%

Chi-square = 113.98
P-value < 0.0001

Table 3: *Comparison of sample adequacy in both study groups*

		Study groups		
				Total
		D & C	MVA	
Adequacy of sample	Yes	63	64	127
		90%	91.4%	90.7%
	No	7	6	13
		10%	8.6%	9.3%
	Total	70	70	140
		100.0%	100.0%	100.0%

Table 4: *Comparison of post-operative vaginal bleeding in both study groups*

		Study groups		
				Total
Post Op per vaginal bleeding	Yes	16	2	18
		22.9%	2.9%	12.9%
	No	54	68	122
		77.1%	97.1%	87.1%
	Total	70	70	140
		100.0%	100.0%	100.0%

Chi-square = 12.49
P-value < 0.0001

Table 5: *Comparison of cost in both study groups*

	Mean	S.D	Minimum	Maximum
D & C	1000.00	17.025	900	1100
MVA	397.86	13.285	300	400
Total	698.93	302.535	300	1100

Independent sample t-test = 233.287
P-value < 0.0001

Discussion:

Abnormal uterine bleeding (AUB) is not a disease, but a symptom. Most of the females present in the gynecological clinics due to AUB. It occurs in various forms such as menorrhagia, polymenorrhea, polymenorrhagia, metrorrhagia and menometrorrhagia. FIGO, in 2010, accepted a new classification system to define the causes of AUB in the reproductive years which was modified later on as explained earlier. The system is based on the terminology PALM-COIEN apart from issues addressing duration, regularity, frequency and volume of flow.[3] Heavy menstrual bleeding a part of the spectrum accounts for 12 percent of all the referrals. Dilatation and curettage is considered a standard method for

acquiring adequate endometrial tissue for the microscopic diagnosis. The use of manual vacuum aspiration is an option as well. [13]

In a study done by Sirimai and colleagues at Siriraj Hospital, Thailand, the reported mean age of the patients undergoing endometrial biopsy by either method was 49.3 ± 8.5 years old which is higher than our study.[10]

In our study most of the cases presented with Menorrhagia (37.9%) followed by, Polymenorrhagia (35.0%), Menometrorrhagia (18.6%) and Metrorrhagia (8.6%). A study done on more than thousand patients with Abnormal Uterine Bleeding, the largest number of patients (33%) presented with menorrhagia and 11.89% with hypomenorrhoea. These results are comparable to that of our study.[14, 15]

In the study done by Boonyarangkul et al, the median visual analog score noted while performing MVA-procedure was markedly lower than the median visual analog score during the sharp curettage .[16] We didn't compare mean pain but in D & C group 69 (98.6%) cases needed analgesia while in MVA group only 6 (8.6%) required analgesia. Analgesia requirement in MVA group was significantly lower than D & C, p-value < 0.0001.

In a randomized controlled trial performed in 2015, a comparison of the adequacy of endometrial sample and the post-procedural pain between the MVA and metal curettage method was done.[12] The study result showed the tissue obtained was adequate in both the groups. The same result was obtained in our study as well.

Similarly, Buranawarodomkul reported that endometrial tissue obtained from MVA was adequate for pathological diagnosis in 88.9% in the D&C group, compared to 91.1% obtained from the MVA method.[12] These findings are also consistent with our findings and similar results were obtained by Kitiyodom. [17]

MVA is an attractive option because it is convenient, safe and cost effective. According to a local study, the cost of procedure was very low in MVA group (PKR 1410 ± 243.4) as compared to PKR 3460 ± 908.24 in D&C group.[18] Similarly, in another local study, the mean cost of MVA was reported as Rs. 4820 ± 270.76 versus Rs. 14,280 ± 927.38 for D&C. 19 In our study, the mean cost in MVA group was significantly lower than D & C group, p-value < 0.0001 as one device can be reused after sterilizing

Recently a study was done in 2016, to evaluate the correlation of endometrial pathology, from the sample derived from manual vacuum aspiration (MVA) and sharp metal curettage.[14] Like our study they included females more than 35 years of age with abnormal uterine bleeding. Pathological correspondence between tissue obtained from MVA and the most severe pathology was 92.7% and the Kappa agreement was 0.86 (K = 0.86, p-value < 0.05). They concluded that MVA could diagnose all cases including that of endometrial hyperplasia and malignancy and serve as an alternative diagnostic procedure in women with abnormal uterine bleeding [14].

Conclusion:

Through the findings of this study we found MVA as an effective alternative diagnostic method to conventional D & C as it provides statistically equal rate of adequacy of endometrial tissue sampling for diagnosing cases of endometrial pathology including malignancy. MVA, never used in our set up before, is easy to perform with less intra and post-operative complications, with lesser need for analgesia. It is a cost-effective method for sampling as the equipment can be used again after sterilization.

Future recommendation: In future by adopting an easier option like MVA and its newer version , we can obtain adequate endometrial tissue sample for histopathological findings as that from dilatation and curettage which can help us go a long way forward in reducing procedure related hospital burden.

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Conflict of Interest: The authors declare no conflict of interest
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