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A Comparative Study of Improvised Manual Vacuum Aspiration Versus Pipeline Sampling for Endometrial Sampling

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ABSTRACT

Objective: To compare the safety and efficacy of Improvised S2Q manual vacuum aspiration and Pipelle sampling as a diagnostic procedure for the evaluation of women presenting with abnormal uterine bleeding.

Study Design: Quasi-experimental study.

Place and Duration of Study: Department of Obstetrics and Gynecology, Combined Military Hospital, Lahore Pakistan, from Oct 2021 to Aug 2022.

Methodology: A total of 148 females over 35 years of age with abnormal uterine bleeding, who needed endometrial sampling, were divided into two groups of 74 participants each. Group-A underwent endometrial sampling by Improvised S2Q manual vacuum aspiration, while Group-B underwent endometrial sampling by Pipelle sampler.

Results: Mean age of patients was 47.36±8.34 years in Group-A and 48.20±8.96 years in Group-B, while the mean BMI was 30.59±4.67 kg/m2 and 27.39±2.50 kg/m2 in Groups A and B, respectively. The volume of specimen obtained was found to be higher in the Improvised S2Q manual vacuum aspiration-Group as compared to the pipeline sampling-Group. The operating time in the Improvised S2Q manual vacuum aspiration-Group was 3.37±0.49 minutes, while in the pipeline sampling-Group, it was 3.20±0.55 minutes. No difference was found in the two procedures for side effects (tachycardia, pain/cramps) and complications (significant blood loss, perforation, infection), added analgesia or histopathology report.

Conclusion: Improvised S2Q manual vacuum aspiration can be used as an alternative low-cost procedure for endometrial sampling in women with abnormal uterine bleeding.

Keywords: Biopsy, Curettage, Endometrium, Manual vacuum aspiration, Pipeline sampling.

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INTRODUCTION

Abnormal uterine bleeding (AUB) is a common pathology and is defined in literature as any amount of bleeding which is irregular or regular but heavy and troublesome for the patient, affecting the quality of life. It includes heavy menstrual, intermenstrual, postcoital, and postmenopausal bleeding.[1] All cases of abnormal uterine bleeding which are refractory to treatment warrant further investigations, especially an endometrial biopsy to exclude underlying premalignant or malignant disorder as a cause.[2] Traditionally, endometrial biopsy was done under general anaesthesia; an outdoor procedure was introduced, i.e., Pipelle sampling.[3] While outdoor techniques are blind, overall specificity, sensitivity, and cost-effectiveness are quite acceptable compared to the gold standard hysteroscopy-guided sampling techniques since the latter is costly and not widely available.[4-6] These single-use samplers are commercially sold in the markets for nearly PKR 1200/ piece. The conventional IPAS MVA is also available for endometrial evaluation at a high price of 12,500 per device.[7]

The relatively low cost of improvised MVA may help reduce healthcare costs in our hospitals without compromising patient care. On the contrary, Improvised S2Q MVA is very economical, with the total set-up instrument cost being just PKR 250. The same instrument set-up was previously assessed for incomplete miscarriages and was an effective alternative to IPAS MVA.[7] In the current study, it has been tested for endometrial biopsy in non-gravid patients. The study aims to compare the safety and efficacy of S2Q Improvised Manual vacuum aspiration and pipeline sampling as a diagnostic procedure for evaluation in women presenting with abnormal uterine bleeding.

METHODOLOGY

The study was carried out at the Department of Obstetrics and Gynecology, CMH Lahore Pakistan, from October 2021 to August 2022, after the approval of the Ethical Review Committee (ERC No 630/ERC/CMH/LMC). The sample size was calculated using the

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Cochrane formula, taking adequacy of MVA of 98.8% and dilation and curettage as 98%.[8]

Inclusion Criteria: Women aged more than 35 years with abnormal uterine bleeding coming to the Outpatient Department who needed endometrial sampling were enrolled for the study.

Exclusion Criteria: Women with an abnormal pap smear, current hormonal use and patients with stenotic cervical ostium or a history of surgery on the cervix were excluded from the study.

Non-probability consecutive sampling technique was followed. The participants were divided into 2 Groups of 74 participants each; Group-A underwent endometrial sampling by Improvised S2Q MVA, while Group-B underwent endometrial sampling by pipeline sampler. They were counselled regarding the study, and written informed consent was taken. Anonymity was ensured. The patients were informed that the study results would be published for educational purposes. Detailed clinical history and examination were done for each patient. The patient's age, BMI, parity, educational status and menstrual history were recorded. Preoperatively, after informed consent, patients were asked to empty their bladders. A standardized sterile technique was adopted, and patients were draped. A bimanual examination was performed. Both procedures were done without analgesia in the outpatient department. The endometrial curetting was sent for histopathology in a 10% buffered formalin solution.

A Pipelle sampler is a 23.5 cm long flexible polypropylene device with a 2.4mm perforation near its endocrine end. The inner piston was withdrawn immediately after insertion to create negative pressure and suck endometrial tissues into the device. If the sample seemed inadequate on visual assessment, the procedure was repeated. The Improvised S2Q MVA equipment consisted of the big nozzle, 60 cc syringe, a relation catheter (size varying from 8F to 14F according to the cervical opening), a plunger of a 20 cc syringe to holding plunger of a big nozzle syringe in a state of negative pressure. Training of procedure was given to the medics and paramedics including the house officers and nursing staff. Nelaton catheter with size as per bimanual assessment findings was introduced into uttering cavity till it touched the fundus, creating negative pressure by withdrawing the piston of big nozzle syringe and holding it in its place with a 20 cc plunger. Then back and forth movement was given to the tube with gentle rotation to cure all the walls. The net pressure generated was 600 mm Hg in Improvised S2Q MVA, the same as standard IPAS MVA, an FDA-approved device.

The primary outcome measured was specimen adequacy, defined as the volume of tissue obtained during the procedure for the pathologist to make a diagnosis. An inadequate sample was defined as consisting of only blood or cervical mucus with fragments of endocervical tissues or a large amount of blood with only small fragments of endometrial glands and stroma. The physiological change included inactive endometrium, proliferative endometrium, secretory endometrium and atrophic endometrium. Benign pathology included endometritis and endometrial polyps, while malignant pathology included endometrial hyperplasia with or without atypia and endometrial cancer. The operating time for endometrial sampling by MVA and pipeline sampling was also assessed. The operation time was measured as follows: Time Start from the moment the speculum was inserted into the vagina; Time Finished-time when endometrial tissues are aspirated. The safety of the two procedures was assessed based on the following criteria: side effects (tachycardia, pain/cramps) and complications (significant blood loss, perforation, infection, and need for additional analgesic). Tachycardia was defined to occur if the heart rate increased to >100/min.[9]

The presence of pain was noted if the patient expressed onset of pain during the procedure or if she was already experiencing pain; the severity increased than what she experienced during the procedure. Significant blood loss was labelled if there was blood loss of more than 150ml as average blood loss in either procedure is usually less than 15ml, and a blood loss more than ten times can indicate a potential perforation.[10]

Patients were detained for complete observation for 2 hours following the procedure. They were discharged on prophylactic antibiotic erythromycin. On discharge, they were given 24/7 access to the hospital and provided a phone number for emergency contact. On the day of follow-up after two weeks, patients were interviewed about any vaginal discharge, duration of pelvic pain after the procedure, and analgesia dependence. Their histopathology report was reviewed. Further management of the patient depended on the pathological result.

Data was entered into Statistical Package for Social Sciences (SPSS) version 26:00. Descriptive statistics

(mean, standard deviation and percentages) were used to summarize the demographic variables. The chi-square test and Independent samples t-test were used to compare the outcome of the two Groups. The *p*-value of 0.05 or less was taken as significant.

RESULTS

A total of 148 patients fulfilling inclusion criteria were recruited in the study. The mean BMI was 30.59±4.67 kg/m² and 27.39±2.50 kg/m² in Groups A and B, respectively. Most patients were multiparous 119(80.4%) and premenopausal 98(66.2%). There was a preponderance of overweight patients 67(45.3%) with less than a secondary level of education 100(67.6%) (Table-I). The most frequently used size of relation catheter in an Improvised S2Q MVA device was 8F.

Table-I: Demographic Characteristics of Participants (n=148)

Characteristics	n(%)
Age	
35-40 years	52(35.2)
41-50 years	48(32.4)
ears	36(24.3)
>60 years	12(8.1)
Parity	
Nulliparous	29(19.6)
Multiparous	119(80.4)
Education	
<Secondary	100(67.6)
>Secondary	48(32.4)
Menopausal Status	
Pre menopausal	98(66.2)
Post menopausal	50(33.8)
Body Mass Index	
Normal weight (18-24.9)	19(12.8)
Overweight (25-29.9)	67(45.3)
Obese (>30)	62(41.9)

An adequate sample was obtained in 95.9% of procedures by Improvised S2Q MVA and 93.2% of procedures by Pipelle. The volume of specimen obtained was higher in the Improvised S2Q MVA Group than the Pipelle Group, with a *p*-value of <0.001. None of the pipeline Groups had a specimen volume of >30ml. The operating time in the Improvised S2Q MVA -Group was 3.37±0.49 minutes, while in the Pipelle-Group, it was 3.20±0.55 minutes. There was no case of uterine perforation. No difference was found in the two procedures for side effects, complications, added analgesia or histopathology report. The most common endometrial pattern on histopathology was a physiological change in both the procedures (43,58.2% and 40,54% in Improvised S2Q MVA and pipeline, respectively), followed by benign changes (24,32.3% and 20,29.7% in Improvised S2Q MVA and pipeline respectively) (Table-II).

Table-II: Comparison of Improvised MVA and Pipelle Groups (n=148)

Variables	Group A Improvised MVA n=74	Group B Pipelle n=74	*p*-value
Operating Time (minutes)			
Mean±SD	3.37±0.49	3.20±0.55	0.052a
Age	**n(%)**	**n(%)**	
35-40 years	26(35.1)	26(35.1)	0.424b
41-50 years	28(37.8)	20(27.1)	
Ears	12(16.3)	24(32.4)	
>60 years	8(10.8)	4(5.4)	
Tachycardia			
Yes	10(13.5)	11(14.9)	0.814b
No	64(86.5)	63(85.1)	
Pain/Cramps			
Yes	4(5.4)	4(5.4)	0.411b
No	7(9.5)	2(2.7)	
Mild discomfort only	63(85.1)	68(91.9)	
Significant Blood Loss			
Yes	1(1.35)	2(2.7)	0.563b
No	73(98.6)	72(97.3)	
Perforation			
Yes	0	0	NA
No	74(100)	74(100)	
Infection			
Yes	5(6.8)	3(4.1)	0.469b
No	69(93.2)	71(95.9)	
Added Analgesia Needed			
Yes	5(6.8)	2(2.7)	0.247b
No	69(93.2)	72(97.3)	
Histopathology			
Inadequate	3(4.1)	5(6.8)	0.385
Physiological change	43(58.2)	40(54)	
Benign pathology	24(32.3)	22(29.7)	
Malignant pathology	4(5.4)	7(9.5)	
Volume of Specimen Obtained			
1-10	0	24(32.4)	<0.001 b*
11-20	2(2.7)	33(44.6)	
21-30	18(24.3)	17(23)	
31-40	40(54.1)	0	
41-50	11(14.8)	0	
>50	3(4.1)	0	

A: Independent samples t test b: Chi-square test: statistically significant*

DISCUSSION

Endometrial sampling should be considered in the evaluation of AUB if the age of the patient is over forty-five, treatment failure, or other risk factors are present for endometrial pathology.[11] The mean age in our study was 47.78±8.64 years. The majority of the patients in our study were multiparous 119(80.4), which is comparable with other contemporary studies.[12,13]

In our study, operating time in Improvised S2Q MVA was found to be 3.37±0.49 minutes, while in Pipelle Group, it was 3.20±0.55 minutes. The result is comparable to a recent study, where the procedure time was found to be 3.1±0.62 min and 3.01±0.77 min for MVA and Pipelle, respectively.[14]

The primary outcome measure in the study was specimen adequacy, defined as the volume of tissue obtained during the procedure for the pathologist to make a diagnosis. An inadequate sample was defined as consisting of only blood or cervical mucus with fragments of endocervical tissues or a large amount of blood with only small fragments of endometrial glands and stroma. Our study obtained an adequate sample in 95.9% of procedures by Improvised S2Q MVA and 93.2% by pipeline sampling. The volume of the specimen obtained was significantly higher (*p*-value <0.001) in the Improvised S2Q MVA Group compared to the Pipelle Group. None of the pipeline Groups had a specimen volume of >30ml. No significant complications were found in the current study in both procedures. Findings are similar to multiple studies.[15-17] Most patients remained free of infection, probably because of the high level of disinfection and prophylactic antibiotics. 94.6% of patients in MVA and those undergoing pipeline sampling reported no pain or mild discomfort. Tomar *et al*.[9] have reported similar findings with fewer complications. A recent study has also revealed that MVA is associated with comparatively fewer complications and does not require added analgesia.[18]

The current study is the first in Pakistan to compare the endometrial sampling by Improvised S2Q MVA with Pipelle. Moreover, the exciting aspect is the improvisation done with MVA converting it into a low-cost device for a low-resource country like Pakistan. The device is user-friendly, used once only and hence avoids the procedure of high-level disinfection for conventional MVA. However, it has been carried out in one centre with a limited sample size, with a comparison done with Pipelle. Further, large-scale multi-centre studies comparing Improvised S2Q MVA with conventional IPAS MVA will corroborate the evidence.

CONCLUSION

Improvised S2Q MVA can be used as an alternative to Pipelle endometrial sampler for evaluating women with Abnormal Uterine Bleeding as an outpatient procedure. The volume of specimens obtained for histopathology by Improvised S2Q MVA is much higher in less time with no significant complications.

Conflict of Interest: None.

Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

SB & QN: Data analysis, drafting the manuscript, critical review, approval of the final version to be published.

ST & HT: Data acquisition conception, study design, approval of the final version to be published.

SN & SN: Data interpretation, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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