

Comparison of sampling adequacy between OPD based pipelle biopsy and in-patient conventional D&C, presented with abnormal uterine bleeding

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Author's Contribution

^{1,2} Conception of study

¹ Experimentation/Study conduction

^{1,2,3,4,5,6}

Analysis/Interpretation/Discussion

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Abstract

Objective: To determine agreement on the adequacy of a sample by pipelle biopsy and conventional dilatation and curettage in patients with abnormal uterine bleeding.

Study design: Cross-sectional study

Setting and Duration of Study: Department of Obstetrics and Gynecology, Islamic International Medical College Trust, Railway Hospital Rawalpindi. The study was carried out over a period of six months (11-07-2012 to 14-01-2013).

Patients and Methods: 84 patients presented with abnormal uterine bleeding age 45 years and older, attended Gynecology department of Railway Hospital Rawalpindi. Who qualified the inclusion criteria were enrolled in this study by non-probability consecutive sampling technique. The diagnostic intervention for endometrial sampling was by pipelle device and by conventional D&C (Dilatation & Curettage). Both procedures were performed in the OT at the same time. First, the pipelle sample was taken and was labeled as "A" then conventional D&C was performed and was labeled as "B". Both samples were sent to the pathologist, who was blinded as to the method of sample collection for histopathology assessment. Adequacy of the sample was assessed as per the operational definition. A database was made in SPSS version 17. Kappa statistics were applied to assess the agreement.

Results: Out of 84 patients, 80 (98.8%) of the patients had an adequate sample with Pipelle Biopsy as compared to conventional curettage and dilatation (D&C). We, therefore, recommend the use of pipelle biopsy as a first-line tool for endometrial assessment for our setups instead of D&C.

Conclusion: Our study concluded that the Pipelle biopsy is a useful and convenient method for the patients and physicians as compared to D&C performed in the operating theatre. It is useful in obese and high-risk patients with minimum chances of perforation of the uterus due to its soft flexible tip.

Keywords: Pipelle, Dysfunctional Uterine Bleeding, Dilatation and curettage, Abnormal uterine bleeding.

Introduction

Abnormal uterine bleeding (HMB and AUB) is the most common symptom in the women of reproductive age and it accounts for almost 33% of outpatient referrals.^{1,2} In addition to this, postmenopausal women presenting with bleeding also constitute a big proportion of patients presenting in outpatient clinics. Endometrial sampling for histopathology is often required for evaluation of heavy menstrual bleeding and post-menopausal bleeding to rule out premalignant lesions that are endometria hyperplasia and malignancy of endometrium.^{3,4,5,6,7}

Hysteroscopic guided endometrial sampling is the gold standard^{8,9}, but because of its invasiveness and inconvenience, traditionally in our setups, Dilatation, and Curettage (D&C) is performed without hysteroscopic guidance requiring hospitalization, complete laboratory workup, in operation theatre (OT) facilities, risks of general anesthesia, risk of infection and perforation of uterus. Recently, endometrial sampling is possible as an outpatient procedure due to the development of this equipment. These modern equipment enable this procedure to be carried out with much less risk as compared to conventional procedures that are diagnostic D & C. Pipelle is an instrument used for endometrial biopsy in OPD and it has revolutionized the management of abnormal uterine bleeding.^{8,10,11} Various devices are available including the pipelle curette (endocurette, Midvale, Utah, USA).² Pipelle endometrial biopsy is a useful office procedure for the assessment of patients with abnormal uterine bleeding. Now in a single visit, the patient can be evaluated to rule out pre-malignant/malignant lesions of the endometrium as pipelle does not need in-patient admission and anesthesia. Moreover, the procedure-related risk of diagnostic D&C is remote. Regarding the accuracy of pipelle in ruling out malignancy, it is equally accurate than diagnostic D&C.^{12,13}

Thus endometrial sampling by pipelle in outpatient is a cost-effective procedure as it is convenient, safe, cheap, accurate and acceptable.^{14,15,16} Around 10% of the sampling done by pipelle is inadequate so that no

tissue for the biopsy is available however in post-menopausal women this percentage is increased to 68%.^{17,18}

Patients and Methods

This Cross-sectional study was conducted in the Department of Obstetrics and Gynecology, Islamic International Medical College Trust, Railway Hospital Rawalpindi from July 2012 to January 2013.

84 patients, 45 years of age and older who presented with abnormal uterine bleeding were enrolled in this study after obtaining informed consent for participation and with approval from the hospital ethical committee.

Patients with lower genital tract infections, polyp, the central endometrial thickness of less than 4 mm, bleeding disorders (deranged platelet count, PT/APTT, bleeding and clotting time), systemic disorders (thyroid and liver dysfunctions) and taking anticoagulants, were excluded from this study. Non-probability consecutive sampling technique was used for the eligible woman after clinical assessment of the patient with complete history, examination, baseline investigations including pelvic ultrasound.

The diagnostic intervention for endometrial sampling was done by pipelle device and by conventional D&C. Both procedures were performed in OT at the same time. First, the pipelle sample was taken and was labeled as "A" then conventional D&C was performed, and the sample was labeled as "B". Both samples were sent to the pathologist for histopathology assessment. The pathologist was blinded to the method of sample collection. Adequacy of the sample was ensured according to the operational definition.

A database was made in SPSS version 17. Quantitative variables like age and parity were presented as mean and standard deviation. Qualitative variables like agreement of histopathologists on the adequacy of the two procedures were presented as frequency and percentage. Kappa statistics were applied to assess the agreement.

Result

Descriptive statistics were calculated for the age of patients (years) in terms of mean standard deviation as 45.95±3.03, in which the minimum number of patients were of 40 years and the maximum number of patients was 57 years. 37 (44%) patients fall in 35 – 45 years and 47 (56%) of patients fall in 46 – 55 years.

Table:1 Comparison of age with parity

Age	Parity	Frequency	Percent	Valid %	Cumulative %
40-45	1-3	6	17.1	17.1	17.1
	4-6	27	77.1	77.1	94.3
	>7	2	5.7	5.7	100.0
Total		35	100.0	100.0	
46-50	1-3	8	17.8	17.8	17.8
	4-6	36	80.0	80.0	97.8
	>7	1	2.2	2.2	100.0
Total		45	100.0	100.0	
>50	4-6	4	100.0	100.0	100.0

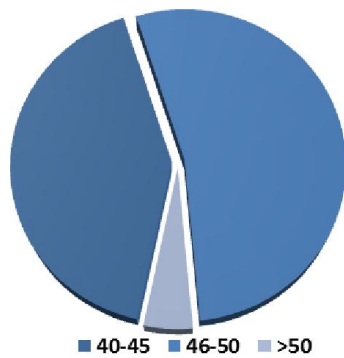


Figure-I: Age distribution of study participants

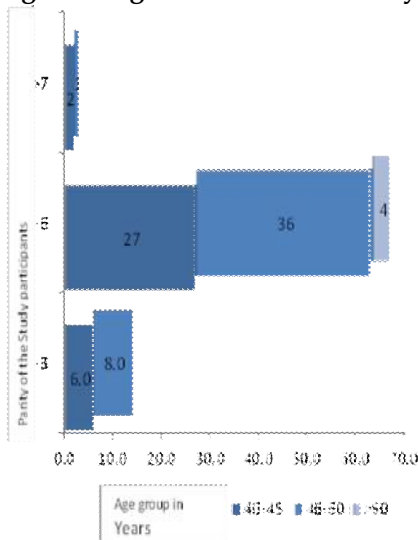


Figure-II: Parity distribution according to the Age group

Mean standard deviations of parity of 84 patients were 4.71±1.51, whereas the frequency and percentages of multipara were 50(60%) and grand multi 33(39%), and only 1(1%) was of nulliparity.

Table2: Comparison of Diagnosis with age and parity

Diagnosis	Age Years			To tal	Parity(n)			To tal
	40-45	46-50	>50		1--3	4--6	>7	
Continuous Vaginal Bleeding	2	1	0	3	3	0	0	3
Heavy Menstrual Bleeding	2	1	0	3	2	1	0	3
Intermenstrual Bleeding	0	2	0	2	0	2	0	2
Irregular Menstruation	0	1	0	1	0	1	0	1
Menorrhagia	19	25	3	47	10	39	1	50
Menorrhagia secondary to vaginal discharge	1	1	0	2	0	2	0	2
Menorrhagia with Rt. Adnexal mass	1	0	0	1	0	0	1	1
Oligomenorrhagia	2	2	0	4	1	3	0	4
Polymenorrhagia	6	9	1	16	2	13	1	16
Post-Menopausal Bleeding	2	3	0	5	1	4	0	5
Total	35	45	4	84	14	67	3	84

Patients came with different kinds of diagnoses with abnormal uterine bleeding, in which the maximum number of patients came with menorrhagia i.e. with 47(56%), whereas 16(19%) came with inter-menstrual bleeding and only one patient come with irregular menstruation.

Table. No. 3: Agreement on the adequacy of a sample by Pipelle Biopsy and D&C

		Agreement on the adequacy of a sample by D&C		Total
		Yes	No	
Agreement on the adequacy of a sample by Pipelle Biopsy	Yes	80	0	80
	No	1	3	4
		98.80%	0.00%	95.20%
		1.20%	100.00%	4.80%
Total		81	3	84
		100.00%	100.00%	100.00%

Adequacy of sample performed according to inclusion criteria of the study, in which kappa statistics were applied between the pipelle biopsy and conventional dilatation and curettage (D & C) in patients with abnormal uterine bleeding. Among 84 patients, 80 (98.8%) of the patients, came with agreement on the adequacy of the sample, between both the procedures as shown in Table No.3.

Table:4 k-Value showing the Measurement of agreement of adequacy for Pipelle Biopsy and D&C

	Value	Approx. Sig.
Measure of Agreement of Kapa	0.851	0
Total Number of Patients (n)	84	

The kappa statistics ($k = 0.851$) were calculated which was statistically significant ($p\text{-value} = 0.000$), which means that there is almost a perfect agreement on the adequacy of pipelle biopsy compared to conventional curettage and dilatation (D & C) as shown in the Table No. 4.

Discussion

Irregular vaginal bleeding accounts for 70% of referrals to gynecologists in the pre-menopausal age group. There is a need for endometrial assessment in these patients and different methods for evaluation are being developed which ranges from traditional diagnostic D&C, hysteroscopic guided biopsies and outpatient endometrial sampling by different instruments like pipelle biopsy forceps. These procedures are further compared to their adequacy, accuracy, reliability, and acceptability. Diagnostic D&C is replaced by outpatient pipelle biopsy in the

developed world but it is still practiced in our hospitals for endometrial assessment.

The current study shows, the age of patients (years) in terms of mean standard deviation as

45.95 ± 3.03 , in which the minimum age of the patient was 40 years and the maximum was 57 years and patients in the age group of 51 and above are only 3%.

The mean standard deviation of parity of 84 patients were 4.71 ± 1.51 , whereas the frequency and percentages of multipara were 50(59.5%) and grand multi 33(39.3%), and only one patient was of nulliparous. In contrast, with our study, the study of Bano et.al. Revealed that grand multiparas were 58% (36) and para 3 and less were 42% (26)¹⁹ & none of the patients was nulliparous. On the contrary, the results of the study of Yasmin et.al. showed the percentages of Nulliparous, multiparous and grand multiparous as 2%, 45%, and 53% respectively.¹⁹

In the current study, patients came with various kinds of diagnoses with abnormal uterine bleeding, in which the maximum number of patients came with menorrhagia i.e. with 47(56%), whereas 16(19%) came with intermenstrual bleeding and only one patient came with irregular menstruation. Similarly, in the study by Yasmin et.al. the percentages of menorrhagia are 38%, irregular menstrual bleeding is 48%, postmenopausal bleeding is 14% which are almost similar to the current study.¹⁹

In our study, adequacy of sample performed according to inclusion criteria of the study, in which kappa statistics was applied between the pipelle biopsy and conventional dilatation and curettage (D & C) in patients with abnormal uterine bleeding. Out of 84 patients, 80 (98.8%) of the patients were with agreement on the adequacy of the sample between both the procedures. The kappa statistics ($k = 0.851$) were calculated which was statistically significant ($p\text{-value} = 0.000$), which means that there is almost a perfect agreement on the adequacy of pipelle biopsy compared to conventional dilatation and curettage (D & C). Likewise, in the study of Williams A, Brechin S, Porter A, Warner P, Critchley H shows that in 200 high-risk women, adequate samples were significantly more likely to be obtained by Tao Brush than Pipelle ($P < 0.001$).¹⁷ The adequacy of a specimen by pipelle biopsy was 92%. Similarly, the study of Bano I, Anwar A, Tahir N, Shaheen T shows pipelle biopsy forceps is reliable as compared to D&C.²⁰ On the contrary, in the study of Yasmin F, Farrukh R, Kamad F, it is determined that Pipelle biopsy has reduced the number of D&Cs performed in operation theatres due to its cost-effectiveness, adequacy, and acceptability.

Now the patients are assessed during their first visit by pipelle biopsy and for confirmation of premalignant or malignant nature of the disease at an earlier stage for better management of the patient [19]. Likewise, in a study conducted by Behmanfar F, Khanchchian T, Mazoochi MS, Fahiminead T at Kashan compared the efficiency of pipelle on 200 patients and concluded that pipelle is 94% efficient as compared to D&C which is 93%.²¹

So, our study results were evident that pipelle endometrial biopsy is better as compared to D&C and pipelle is an instrument of choice for endometrial assessment in peri menopausal and post-menopausal women and we advise pipelle biopsy forceps as a tool for endometrial assessment instead of D&C.

Conclusion

The conclusion of the study was that the Pipelle biopsy is a useful method. It is convenient for the patient and doctor as well and noninvasive as compared to D&C and can be performed in OPD. It can replace the D&C having added risks of anesthesia, infections, and requirement of operation theatre facilities. Pipelle has a soft flexible tip so there are very fewer chances of perforation and it can be done on the first visit so that the time for diagnosing the nature of the disease is minimized.

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