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A comparative study between pipelle endometrial sampling and dilatation curettage in abnormal uterine bleeding

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Abstract
Objective: To compare the diagnostic accuracy of endometrial aspiration biopsy (EAB) using Pipelle device with dilatation and curettage(D&C) histopathology.
Methods: A comparative study of 81 patients with abnormal uterine bleeding carried out in the Department of Obstetrics and Gynecology between November 2018 and October 2019. Endometrial sampling with Pipelle was performed in 81 patients followed by formal D&C under anesthesia after ruling out other causes of AUB. Samples were labeled as A and B and sent to a histopathologist who was blinded as to the method of sampling. The histopathology reports of both samples were compared.
Results: Total number of patients enrolled in this study was 81 patients with abnormal uterine bleeding. In present study it was observed that increased endometrial thickness was not always associated with adequate tissue diagnosis. Endometrial thickness of less than 5mm was found in 14.8%, 5-8mm was found in 34.6%, 9-10mm noted in 28.4%, 12-16mm noted in 13.6% & more than 16mm was seen in 8.6% of study subjects. Mean ± SD: 9.87±8.01 mm. If upper limit of normal ET 16mm is taken as cutoff, adequacy rate in Pipelle and D&C were 92.1% and 90.5% respectively and if ET >16mm, adequacy rate in Pipelle and D&C were 72.2% and 77.8% respectively. In present study, it was observed that increased ET was not always associated with adequate sample. Among 14 patients of PMB 11 patients had abnormal ET (61.1%). In 81 cases of Pipelle 11.1% Pipelle sample was scanty and in 1 subject no sample was obtained. Major portion of Pipelle sample (87.7%) was adequate. Of the 81 subjects of D&C, scanty tissue was reported in 8.6% and sample was adequate in 87.7%. No sample was obtained in 3.7%. The Sensitivity of Pipelle in obtaining a adequate tissue comparing it with D&C by applying Fisher exact test is calculated to be 95.71%, Specificity =71.43% Positive predictive value=97.10% and Negative predictive value =62.50%. The accuracy is 93.51%. The calculated p value is <0.001which is statistically very highly significant. In this study, comparing Pipelle with D&C, the Pipelle device had 100% sensitivity, 97.4 specificity, PPV 71.4%, NPV 100%, 97.5% accurate for proliferative endometrium. The sensitivity, specificity, PPV, NPV, Accuracy rate were 100% in endometrial CA and hormone progesterone effect. The sensitivity is 80% in simple hyperplasia without atypia and 57.1% in disordered proliferative endometrium and in endometrial polyp the sensitivity was 42.9%. The calculated P value is <0.001 which is statistically significant. No adverse effects were noted in both Pipelle and D&C procedures.
Conclusion: Endometrial sampling using Pipelle device is an easy and safe method of getting tissue diagnosis, which can be done as an outpatient procedure. Pipelle is cost effective and has better patient compliance in addition to the added advantage of no anesthesia or other procedure complications like perforation compared to D&C.

Keywords: Abnormal uterine bleeding, Pipelle device, Dilatation and Curettage.

Introduction
Abnormal Uterine Bleeding (AUB) is one of the common disorders in gynecology and accounts for more than 70% of gynecological consultations among perimenopausal and postmenopausal women. The bleeding could be a sign of underlying localized condition of uterus including infection, benign and malignancy. Endometrial assessment in AUB includes the various diagnostic modalities mainly ultrasonography, endometrial curettage and office based methods including biopsy by hysteroscopy or endometrial samplers such as Pipelle [1, 2]. Endometrial assessment is indicated at the age of 40 years to exclude endometrial hyperplasia or carcinoma as less than 1% endometrial carcinoma occur under 35 years of age and 6% in those 45 years or less [3]. When a woman is found to have high risk factors for endometrial pathology, such as perimenopausal abnormal uterine bleeding, postmenopausal uterine bleeding or history of

chronic anovulation sampling of endometrium becomes mandatory [4]. Hysteroscopic biopsy & D&C is considered as the standard for endometrial sampling without its place in gynecology being challenged. But in 60% of D&C, less than half of uterine cavity is curetted, with added risk of complications of general anesthesia, infection, perforation, consuming operative room, invasive and large proportion of hospital bed usage. This has led to the advent of simple methods for endometrial sampling. Pipelle does not require a general anaesthesia or analgesia and can be performed in the outpatient or general practice setting. EAB done using a special device called Pipelle and D&C were equally successful for diagnosing endometrial pathologies. Though many studies have been reported about the effectiveness of Pipelle type device in outpatient endometrial sampling, very few studies are available from India. This study is being conducted to establish the validity of Pipelle & adequacy of endometrium sampled by Pipelle for histopathology. The present study is taken up to compare the diagnostic accuracy of endometrial aspiration biopsy using Pipelle device with D&C in AUB patients.

Methodology

An interventional comparative study of 81 patients, 30 years of age & older who presented with abnormal uterine bleeding in the Department of Obstetrics and Gynecology was undertaken to study the diagnostic value of Pipelle Endometrial sampling with Dilatation & Curettage after providing informed consent. The study period was one year from November 2018 to October 2019. Ethical committee approval was obtained. Reproductive women, Peri menopausal and Post-menopausal women who presents with abnormal uterine bleeding were included in the study. Pregnancy, Patients with lower genital tract infections, Pelvic inflammatory disease, clotting disorders or coagulopathy, Carcinoma cervix, Hormonal Replacement Therapy, Adnexal Mass/lesions were excluded from the study. A detailed clinical assessment of patient was performed in the outpatient department including history, physical examination and base line investigations. A transvaginal sonography was performed before endometrial biopsy. The uterus was scanned in the sagittal and longitudinal projections with the use of 5.0-to-7.5 MHz vaginal transducers. The thickest anteroposterior diameter of the endometrial stripe was then measured in the sagittal plane with digital calipers on the display. The endometrial thickness was then recorded. Diagnostic intervention endometrial sampling by Pipelle device without anesthesia, and endometrial sampling by D&C under anesthesia was then done.

The Pipelle device used for sampling is a flexible thin device with inbuilt suction. The inner piston of the device is then withdrawn to create suction and the endometrial sample is obtained by rotating the cannula and a strip of endometrium is peeled off and sucked into the syringe. Following Pipelle procedure in OPD patient shifted to OT, anesthesia was given and D&C procedure was done. After dilatation with Hegars dilators, a small sharp curette was introduced; systematic, thorough and gentle sampling of all parts of the uterine cavity was done. Both samples were sent to a histopathologist who was blinded as to the method of sample collection for histopathology assessment. The reports from Pipelle biopsy and diagnostic D&C standard are compared. Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. The following assumptions on data is made, Assumptions: 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random, Cases of the samples should be independent. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small. Sensitivity, Specificity, PPV, NPV, Accuracy are computed to find the diagnostic properties of Pipelle against HPE. The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Results

Of the 81 patients studied 49 (60.5%) were perimenopausal. Of the study group 1-6 months duration of AUB was seen in 70.4% of the subjects, 6-12 months in 12.3%, more than 12 months of AUB in 17.3% of subjects. Premenopausal women included in the study had heavy menstrual bleeding (HMB) as their main complaint. Polymenorrhea was the second most common complaint in this group. Prolonged bleeding following a period of amenorrhoea was the third most common complaint in this group. Past history of medical illness noted in 46.9% of the subjects. Hypothyroidism was the commonest of medical illness noted in 16% of patients, followed by hypertension in 8.6%, diabetes in 2.5% of the subjects. Combination of HTN+DM in 7.4% who were in some form of treatment at the time of admission. Anaemia was present in 3.7% of AUB patients. DM + HTN + Hypothyroidism was noted in 1.2%, 2.5% were the case of Breast-CA. 2 patients had epilepsy, 1 patient had CKD and 1 patient had Rheumatoid arthritis.

33.3% of subjects had normal sized uterus, whereas 66.6% had abnormal. Among them uterus 8-12 weeks size were in 19.7%, 12-16 weeks size uterus were in 7.4%, Bulky uterus were in 34.6% & uterus size not made out in 4.9%. Endometrial thickness of less than 5mm was found in 14.8%, 5-8mm was found in 34.6%, 9-10mm noted in 28.4%, 12-16mm noted in 13.6% & more than 16mm was seen in 8.6% of study subjects. Mean ± SD: 9.87±8.01mm.

Table 1: Adequacy in Pipelle

Adequacy in Pipelle	No. of patients	%
Adequate	71	87.7
Scanty	9	11.1
Not obtained	1	1.2
Total	81	100.0

Table 2: Adequacy in D & C

Adequacy in D & C	No. of patients	%
Adequate	71	87.7
Scanty	7	8.6
Not obtained	3	3.7
Total	81	100.0

Table 3: Comparison of Pipelle HPE and D&C HPE

Findings	Pipelle HPE (n=81)		D&C HPE (n=81)	
	No. of patients	%	No. of patients	%
Nil	7	8.6	7	8.6
simple hyperplasia without atypia	34	41.9	35	43.2
disordered proliferative endometrium	17	20.9	14	17.3
proliferative endometrium	7	8.6	5	6.2
endometrial polyp	7	8.6	7	8.6
hormone effect	5	6.2	5	6.2
endometrial CA	2	2.5	2	2.5
others	2	2.5	6	2.5

Table 4: Adequacy in Pipelle/ D&C distribution in relation to endometrial thickness (ET)

	TVS ET		Total (n=81)	P value
	Normal (n=63)	Abnormal (n=18)		
Adequacy in Pippelle				
▪ Adequate	58(92.1%)	13(72.2%)	71(87.7%)	0.039*
▪ Scanty	5(7.9%)	4(22.2%)	9(11.1%)	
▪ Not obtained	0(0%)	1(5.6%)	1(1.2%)	
Adequacy in D & C				
▪ Adequate	57(90.5%)	14(77.8%)	71(87.7%)	0.214
▪ Scanty	4(6.3%)	3(16.7%)	7(8.6%)	
▪ Not obtained	2(3.2%)	1(5.6%)	3(3.7%)	

The Sensitivity of Pipelle in obtaining a adequate tissue comparing it with D&C by applying Fisher exact test is calculated to be 95.71%, Specificity =71.43% Positive predictive value=97.10% and Negative predictive value =62.50%. The accuracy is 93.51%. The calculated p value is <0.001which is statistically very highly significant. Thus it is informed that Pipelle is as good as D&C in obtaining an adequate endometrial tissue sample.

Table 5: Correlation of Pipelle HPE in comparison with D&C HPE

Findings	Observation					Correlation					
	TP	FP	FN	TN	Total	Se	Sp	PPV	NPV	Accuracy	P value
simple hyperplasia without atypia	28	6	7	40	81	80.0	86.9	82.3	85.1	83.9	<0.001**
disordered proliferative endometrium	8	9	6	58	81	57.1	86.6	47.1	90.6	81.5	0.002**
proliferative endometrium	5	2	0	74	81	100.0	97.4	71.4	100.0	97.5	<0.001**
endometrial polyp	3	4	4	70	81	42.9	94.6	42.9	95.6	90.1	0.007**
hormone effect	5	0	0	76	81	100.0	100.0	100.0	100.0	100.0	<0.001**
endometrial CA	2	0	0	79	81	100.0	100.0	100.0	100.0	100.0	<0.001**
others	1	1	5	72	81	16.7	96.6	50.0	93.5	92.4	0.021*

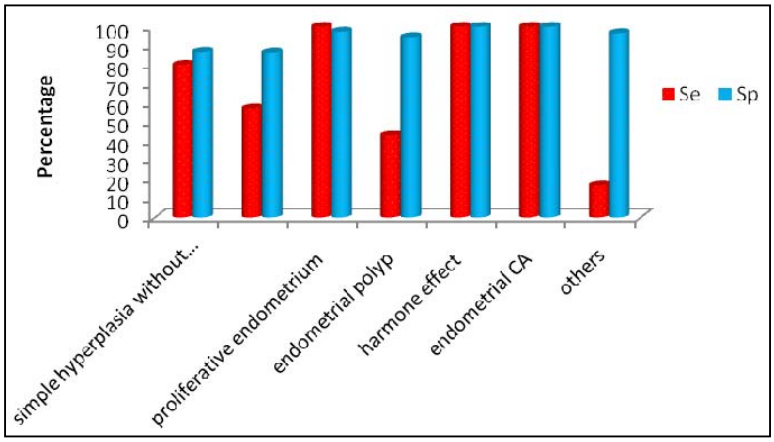

Fig 1: Show the percentage of Se and Sp

In this study, the Pipelle device had 100% sensitivity, 97.4 specificity, PPV 71.4%, NPV 100%, 97.5% accurate for proliferative endometrium. The sensitivity, specificity, PPV, NPV, Accuracy rate were 100% in endometrial CA and hormone progesterone effect. The sensitivity 80% in simple hyperplasia without atypia and 57.1% in disordered proliferative endometrium and in endometrial polyp the sensitivity was 42.9%. The calculated P value is <0.001 which is statistically significant.

The observation shows that Pipelle endometrial sampling is in

par with D&C in obtaining a tissue diagnosis.

Discussion

The evaluation of abnormal uterine bleeding begins with a history, physical examination, and pelvic examination which includes a cervical cytology of the ectocervix and the endocervical canal. Although medical history is not specific enough to make a firm diagnosis for AUB, some questions assist in further narrowing the diagnostic possibilities, questions placing the bleeding in context of a woman's other health considerations (age, weight, previous menstrual patterns, medical problems, are most valuable in diagnosis. Furthermore, consistent questioning about of the broad categories of AUB (pregnancy complications, bleeding diathesis, anovulation, and structural lesions) helps to avoid omitting important history. When the source of the bleeding is determined to be the uterine cavity, sampling of the endometrium for pathology examination is usually considered to be mandatory. D&C was traditionally the method of choice for investigating patients with postmenopausal bleeding. However, in approximately 60% of the D&C procedures less than half of the uterine cavity is curetted. Most focal lesions (polyps and fibroids) are missed by D&C in postmenopausal women with AUB [5]. Another drawback of D&C is that this procedure is performed under anesthesia. D&C is now considered to be outdated practice and is replaced by less invasive outpatient evaluation using endometrial biopsy devices and outpatient hysteroscopy guided biopsies [6]. For the diagnosis of diffuse lesions (endometrial hyperplasia or carcinoma), the accuracy of outpatient endometrial biopsy has proven to be similar to the more invasive and costly D&C. Many instruments have been devised for the sampling of endometrial tissue and evaluation of the endometrial cavity. In 1882, Moriche obtained the first endometrial sample using a catheter and endometrial biopsy has been performed in an outpatient setting since 1935. The 1970's saw the introduction of Vabra curette followed by the Pipelle sampler in the 1980's. The Vabra aspirator has been used extensively over the past 20 years. This disposable device requires an external vacuum source, usually an electric pump, which can be quite noisy and startling to the patient. The cannula is commonly plastic, with a 4- mm diameter, although 2and 3mm stainless steel curettes are also available. A circumferential in-and-out motion is used to obtain a sample, and patient discomfort may necessitate intravenous analgesia. Moreover, if the cervix is stenotic, larger cannulas may be difficult to introduce and cervical dilation may be necessary before sampling can be done. Vabra aspiration produces a sample comparable to that obtained with dilatation and curettage. The Pipelle has become one of the most popular new devices, because it requires little expertise and can be used by anyone experienced in sounding the uterus [7, 8]. Developed by Cornier, it was originally employed for endometrial sampling in fertility studies but its usefulness in the diagnosis of pathological lesions was soon realized. The Pipelle curette offers two advantages: it can traverse most cervical canals without prior dilation or use of a vulsellum and it is generally well tolerated without analgesia.. In his first series Cornier found four cases of endometrial cancer in 75 women with unexplained vaginal bleeding. Studies in women with known endometrial cancer have shown the Pipelle to be sensitive, although small localized lesions may be missed. When compared with conventional D&C the Pipelle has proved good [9]. Some investigators were concerned that the Pipelle might sample less of the endometrium, although this was not reflected in lower diagnostic accuracy [10]. A review of the studies containing information regarding the accuracy of endometrial sampling using 18 different devices from 1966 to 1999, was done by Dijkhuizen *et al*, identified 39 informative studies involving 7914 women [11]. The studies included combinations of menopausal and or perimenopausal women. Either subsequent formal D&C or hysterectomy was used as a reference compared with office endometrial biopsy. Diagnostic accuracy was better in menopausal women. Yet overall, accuracy was good in all women, especially with the use of the Pipelle brand of curette, where sensitivity for endometrial carcinoma was 99.6% and specificity was 91%. Sensitivity for atypical hyperplasia was 81% with a specificity exceeding 98%. A similar systematic review by Clark *et al* [12] involving 1013 patients from 11 primary studies using 6 different commercial clinic biopsy instruments identifies good accuracy for a biopsy to identify endometrial cancer if the specimen was adequate for evaluation. The combined failure rate for obtaining an adequate specimen was 7%, and biopsy failure was more common in menopausal women. Endometrial biopsy results were also compared with the reference standards D&C or hysterectomy. When a biopsy was positive for cancer, the post biopsy probability of endometrial cancer was 81.7% (95% confidence interval (CI) 59.7-92.9). The pooled probability that a negative biopsy missed an endometrial cancer was 0.95 (95% CI;0.4-2.4). Endometrial sampling is associated with a greater percentage of false-negative results if the pathology is local, such as endometrial polyps. Guido and associates (1995) reported false negative results in 11 of 65 patients-17%-undergoing Pipelle endometrial sampling for abnormal bleeding [13]. Five of these 11 had malignant tissue present only in endometrial polyps, and another 3 patients had disease localized to less than 5% of the endometrial surface. Overall a positive result was accurate in the diagnosis of endometrial cancer whereas a negative result was not. Therefore if an endometrial biopsy is negative in a situation where AUB continues, or if a biopsy cannot be obtained, then further more aggressive diagnostic efforts are warranted. Several studies comparing the adequacy of sampling using Pipelle device with D&C have shown a comparable ability to detect abnormalities [14]. In a meta-analysis comparing endometrial sampling techniques, the Pipelle was found to be most accurate. Among postmenopausal women, the sensitivity for detection of atypical endometrial hyperplasia was 81% and for detection of endometrial cancer as 99.6%. The sensitivity of the device for the detection of endometrial cancer among premenopausal women was 99.6%. The specificity of the Pipelle device for diagnosing endometrial hyperplasia or malignancy was 98%. Silver *et al* made a randomized study comparing Novak and Pipelle endometrial biopsy instruments with respect to quality of the biopsy obtained and pain related to the procedure. The instruments yielded biopsies of similar quality (p =.856). Pain scores were lower for the Pipelle (p=.001). Williams *et al* reported that women over 54 years had more inadequate samples with Pipelle [15]. D&C and Pipelle had comparable results as per our observations. In our study, age group of 30-40 years 16 patients had adequate sample in D&C,15 out of 16 had adequate sample in Pipelle. Out of 49 pateints between the age group of 41-50 years 45 patients had adequate sample in both procedure. Scanty was obtained in 4 subjects in pipelle,3 subjects in D&C and in 1 subject sample was not obtained. Between 51-60years,8 subjects had adequate sample in D&C,2 were missed in D&C.7 subjects had adequate sample, 2 had scanty sample & in 1 subject sample not obtained. Thus no association between age or menopausal status and adequacy of the sample is formulated.

Table 6: Sample adequacy compared with other studies

Study	Year	No of patients	Sample adequacy (%)
Present study	2019	81	92
Shazia Fakhar [8]	2008	100	98
Fouzia Yasmin [1]	2007	100	100
Abera Choudary [3]	2005	350	98
Epstein [16]	2001	133	84
Bakour [17]	2000	248	70.20

In our study histopathology report was available in 71 of the 81 Pipelle samples and 71 of 81 D&C samples. Comparing Pipelle with D&C, Sensitivity of Pipelle in obtaining a adequate tissue by applying the Fisher exact test is calculated to be 95.71%, Specificity =71.43%, Positive predictive value=97.10% and Negative predictive value =62.50%, Accuracy=93.51%.

Table 7: Pipelle biopsy for diagnosis of endometrial lesions

Year	References	Cases	Curettage or hysterectomy	Pipelle	Specimen satisfaction (%)	Pathological accuracy (%)
2019	Present study	81	81	81	87.7%	70.4%
2015	Sanam and Majid [2]	130	130	130	88.0	94.0
2013	Leng *et al*.	200	200	200	93.0	85.0
2012	Kazandi *et al* [18].	82	82	82	93.0	66.0
2008	Fakhar *et al* [8].	100	100	100	98.0	94.0
2003	Machado *et al* [19].	1535	168	1535	73.9	96.9
1995	Guido *et al* [20]	65	65	65	97.0	83.0

Mild discomfort in 10% of women of Pipelle sampling. Pain scores were lower for the Pipelle (21). In present study, no adverse effects were reported. Pipelle is cost effective. The average cost of a Pipelle sampling is Rs.250 compared to Rs.2000 of D&C which includes procedure, anesthesia, surgery and inpatient charges.

Conclusion

Endometrial sampling using Pipelle device is an easy and safe method of getting tissue diagnosis which can be done as an outpatient procedure. Pipelle is cost effective and has better patient compliance in addition to the added advantage of no anesthesia or other procedure complications like perforation compared to D & C. Thus it can be considered as the first line investigation for getting an adequate endometrial sample for histology in patients with AUB with high sensitivity and specificity even for the detection of hyperplasia and malignancy.

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