



## A prospective study on the accuracy of Pipelle in diagnosing endometrial pathology in Abnormal Uterine Bleeding

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### ABSTRACT

#### Background

Abnormal uterine bleeding (AUB) is responsible for more than 70 percent of all gynaecological consultations among women in the peri-menopausal and post-menopausal stage. The index study was undertaken to assess the adequacy of the sample, diagnostic accuracy and pattern of the endometrial biopsy obtained through Pipelle technique in AUB.

#### Methods

A prospective cohort study was undertaken among 76 women who are >35 years including post-menopausal women, visiting the Obstetrics and Gynaecology OPD with abnormal uterine bleeding and underwent Pipelle aspiration followed by hysterectomy. A detailed history, clinical examination and ultrasound scan are done. The histopathology finding of the Pipelle was assessed and compared with the hysterectomy histopathology finding in whom hysterectomy was done; to evaluate the diagnostic accuracy of the Pipelle. Also, the adequacy of the sample collected using Pipelle for histopathology was also assessed.

#### Results

The mean (SD) age of the study participants was 53.08 years. Among the samples obtained by Pipelle, 94.7% were of adequate sample for examination. In the pipelle based HPE of AUB, majority of the patients had hyperplasia without atypia (27.6%), followed by carcinoma endometrium (22.4%). Pipelle biopsy showed highest sensitivity for hyperplasia without atypia (87.5%), highest specificity for secretory (100%) and atrophic endometrium (100%) and highest accuracy for atrophic endometrium (98.6%) followed by carcinoma endometrium (95.8%).

#### Conclusion

Diagnostic accuracy of all major pathologies of AUB, such as disordered proliferative endometrium, hyperplasia with atypia, Atrophic endometrium and carcinoma endometrium, were above 90%.

**Keywords:** endometrial sampling, abnormal uterine bleeding, Pipelle, dilatation and curettage, diagnostic accuracy

### I. INTRODUCTION

Abnormal uterine bleeding (AUB) is one of the most frequent diseases in the field of gynaecology and is responsible for more than 70 percent of all gynaecological consultations among women in the peri-menopausal and post-menopausal stage. It is possible that the bleeding is an indication of an underlying localised illness of the uterus, such as an infection, a benign ailment, or even cancer.[1] It is believed that the prevalence of abnormal uterine bleeding among women of reproductive age worldwide ranges from 3 percent to 30 percent, with a greater incidence occurring around the time of menarche and perimenopause.[2] Acute AUB may happen on its own or on top of chronic AUB, which is a term that describes abnormalities in menstrual flow that have been present for the majority of the preceding six months.[3]

Evaluation of abnormal uterine bleeding in women under the age of 40 or in post-menopausal women is of the utmost significance to establish that the condition in question is of a benign nature and to rule out the possibility of endometrial cancer. This is done in order to facilitate the provision of medicinal or conservative therapy and the avoidance of needless drastic surgery.[4] Hysteroscopic biopsy and , dilatation and curettage (D&C) are regarded to be the gold standard for endometrial sampling, and their position in the field of gynaecology has not been called into question. However, in sixty percent of dilation and curettage procedures, less than half of the uterine cavity is curetted. This presents an increased risk of consequences related to general anaesthesia, including infection, perforation, consumption of operation room time, degree of invasiveness, and high percentage of hospital bed utilisation. Because of this, more simple approaches to endometrial sampling have become available. Pipelle is a



minimally invasive procedure that may be carried out in an outpatient or general practise environment without the need for general anaesthesia or analgesics.[1] Pipelle endometrial biopsy is one of the most common diagnostic procedures for women who are experiencing abnormal uterine bleeding or bleeding after menopause.[5] A comprehensive meta-analysis demonstrated that its sensitivity ranges from 81 to 99 percent, and its specificity reaches 98 percent.[6]

The Pipelle device, which was designed in 1984 by Cornier E. in Paris, France, is now the vacuum aspiration tool that is used most often in office sample procedures.[7] Its use does not call for the administration of general anaesthesia nor does it necessitate hospitalisation; rather, it may be carried out as an outpatient or office treatment.[8,9] Even though a great number of research have been conducted and reported on the efficacy of devices of the Pipelle type in outpatient endometrial sampling,[10–15] there are relatively few studies in Indian settings,[1,16,17] and none could be found in current settings. Hence the index study was undertaken to assess the adequacy of the sample, diagnostic accuracy and pattern of the endometrial biopsy obtained through Pipelle' technique in AUB.

## II. MATERIALS AND METHODS

### Study Settings

The current study was undertaken following a prospective cohort design out in the Department of Obstetrics and Gynaecology at MOSC Medical College of Kerala, India. The study was conducted over a period of 1 year 6 months

### Study Population

Women of age >35 years and post-menopausal women visiting the Obstetrics and Gynaecology OPD, MOSC Kolenchery, with abnormal uterine bleeding and underwent pipelle aspiration over a period of 1 year 6 months, was requested to give an informed consent to be enrolled in the study and followed up for further management . Women who underwent subsequent hysterectomy are considered for study. The study excluded pregnant women, those experiencing bleeding caused by cervical or vaginal pathology, individuals with abnormal uterine bleeding due to coagulation disorders, drugs or endocrine factors, as well as women who had genital tract infections or pelvic inflammatory disease (PID).

### Sample size and sampling technique

The study's minimum required sample size was determined to be 72, with reference to the study done by Mathew SM et al.[17]. Convenient sampling till the sample size was achieved was undertaken.

### Data collection

Woman of age >35 years with abnormal uterine bleeding (including post-menopausal bleeding) visiting Obstetrics and Gynaecology outpatient department of MOSC Medical College were taken. A detailed history, clinical examination and ultrasound scan were done. An informed consent was taken before enrolling them into the study. Endometrial sampling was performed using a Pipelle biopsy technique, and anesthesia was not administered during the procedure. Histopathology reports were subsequently gathered, and both sample adequacy and endometrial patterns were examined and analyzed. They were then followed up for further management. Those who underwent hysterectomy are analyzed for endometrial pathology, which is the gold standard and compared with Pipelle endometrial biopsy finding for calculating diagnostic accuracy.

### Data Analysis

The data was input into Microsoft Excel, and the analysis was carried out using SPSS version 26.0. Categorical variables were expressed in frequencies and proportions. Mean and standard deviation (SD) was calculated for continuous variables. Association between Endometrial thickness and carcinoma was assessed by independent t test. Association between body mass index (BMI) and Carcinoma endometrium was determined by chi-square test. A significance level of less than 0.05 was deemed significant. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were evaluated for the pipelle biopsy concerning each of the outcomes assessed in cases of abnormal uterine bleeding (AUB).

## III. RESULTS

In the study, 76 patients were included with a response rate of 95%. The mean (SD) age of the study participants was 53.08 (8.56) years. Majority of the study participants belonged to the age group of 45-49 years (34.2%). The mean (SD) BMI of the patients was 29.34 (5) Kg/m<sup>2</sup>. Other demographic and clinical characteristics of the study population are enumerated in Table 1.



Table 1: Demographic and clinical profile of the women in the study (N=76)

Variable	Frequency	Percentage
Age		
35-39 years	1	1.3
40-44 years	7	9.2
45-49 years	26	34.2
50-54 years	16	21.1
55-59 years	11	14.5
>59 years	15	19.7
Body Mass Index		
Normal	9	11.8
Overweight	34	44.7
Class I obesity	25	32.9
Class II Obesity	6	7.9
Class III Obesity	2	2.6
Comorbidities		
Diabetes	38	50.0
<b>Hypertension</b>	24	31.6
Hypothyroidism	10	13.2

Table 2: Parity and Menstrual history of the women in the study (N=76)

	Frequency	Percentage
<b>Parity &amp; Living Children</b>		
Nulliparous	1	1.3
P1L1	4	5.3
P2L2	44	57.9
P3L3	22	28.9
P4L4	4	5.3
P8L8	1	1.3
Type of Delivery in past		
Normal Delivery	53	69.7
LSCS	19	25.0
Normal + LSCS	3	3.9
Nulliparous	1	1.3
Menstrual cycles regularity		
Regular	23	30.3
Irregular	24	31.6
Menopause	29	38.2
Type of Abnormal bleeding		
Heavy menstrual bleeding	29	38.2
Prolonged bleeding >8 days per menstrual period	11	14.5
Frequent bleeding, menses with <24 days intervening	7	9.2
Post menopausal bleeding	29	38.2

In the present study, 5.3% of the patients were using contraception. All were using copper T or condoms. No hormonal contraceptives were used.

Among the samples obtained by Pipelle, 94.7% were of adequate sample for examination. Majority of them had mild pain (55.3%), while 44.7% reported moderate pain following the Pipelle procedure. Oral analgesics

was required by 10.52% of the patients. All patients were given only oral analgesics. None of them required sedation.

In the pipelle based HPE of AUB, majority of the patients had hyperplasia without atypia (27.6%), followed by carcinoma endometrium (22.4%) and proliferative endometrium (21.1%). (Table 3)



Table 3: Pipelle HPE findings

	Frequency	Percentage
Proliferative endometrium	16	21.1
Secretory endometrium	4	5.3
Hormonally modified endometrium	0	0
Disordered proliferative endometrium	3	3.9
Hyperplasia without atypia	21	27.6
Hyperplasia with atypia	8	10.5
Atrophic endometrium	3	3.9
Carcinoma endometrium	17	22.4

The diagnostic validity of the Pipelle biopsy for the AUB patients for various outcomes are enumerated in Table 4. Pipelle biopsy showed highest sensitivity for hyperplasia without atypia

(87.5%), highest specificity for secretory (100%) and atrophic endometrium (100%) and highest accuracy for atrophic endometrium (98.6%). (Table 4)

Table 4: Diagnostic validity of the Pipelle biopsy for the AUB patients

Diagnosis	Sensitivity	Specificity	PPV	NPV	Accuracy
Normal (proliferative + secretory)	75	95.8	90	88.5	88.9
Proliferative endometrium	82.3	96.3	87.5	94.6	93.1
Secretory endometrium	57.1	100	100	95.6	95.8
Disordered proliferative endometrium	50	97.1	66.7	67	95.8
Hyperplasia without atypia	87.5	87.5	66.7	96.1	87.5
Hyperplasia with atypia	83.3	95.5	62.5	98.4	94.4
Atrophic endometrium	75	100	100	98.6	98.6
Carcinoma endometrium	88.9	98.1	94.1	96.4	95.8

Among the ones with additional findings (33), 60.6% reported fibroid uterus, followed by adenomyosis. The Mean (SD) endometrial thickness measured by ultrasound was 12.87 mm (SD. 5.47). Among the women with post-menopausal bleeding, endometrial thickness was significantly higher among the carcinoma endometrium patients (p=0.013). No significant association between BMI and carcinoma endometrium was found. (p=0.162) There was no significant association between the endometrial thickness and the hyperplasia with atypia status (p=0.216).

#### IV. DISCUSSION

Abnormal uterine bleeding (AUB), with a reported occurrence ranging from 14% to 25% among women of reproductive age, stands out as one of the most common issues encountered in gynaecology clinics. This condition has a significant negative effect on women's quality of life and may be quite debilitating.[18] More straightforward approaches to endometrial sampling for AUB evaluation have become available.[1,17] Pipelle biopsy for exploring the pathology of the abnormal uterine bleeding is one such methods. The mean age of our study participants was 53.08 years, which was slightly

older than the patients included in the previous studies.[12,13,16] In the present study, the majority of the patients had either heavy menstrual bleeding (HMB) (38.2%) and post-menopausal bleeding (PMB) (38.2%). While Mathew et al also reported HMB as the most common pattern, the proportion was much higher than our study (66%), while PMB was only among 19%.[17] Ilavarasi et al reported a still higher prevalence of HMB (83.6%), while PMB was reported among 16.3% of women only.[16] Mamatha et al reported HMB as the most common pattern among premenopausal women.[1] No significant association between BMI and Carcinoma endometrium was found among the patients in the present study. BMI has shown to affect the accuracy of the diagnostic procedures for AUB.[7]

In the index study, among the samples obtained by pipelle, the adequacy rate was 94.7%. Mathew et al reported a similar adequacy rate of 96%.[17] Abdelazim et al reported an adequacy rate of 97.9%.[13] Ilavarasi et al reported a much lower adequacy rate of 77.9% in their study.[16] Mamatha et al and Piatek et al also reported lower adequacy rate than our study (87.7% & 83.01%).[1,7] Tanko et al reported a success rate of 80.56% in pipelle biopsy, which varied across the age groups.[8] It is suggested for the examination of AUB to do a transvaginal scan since it may



identify localised lesions.[17] Among the patients of the current study, mean endometrial thickness measured by ultrasound was 12.87 mm, which was slightly higher than the median endometrial thickness of 11 mm in Abdelazim et al study.[13]

Most patients in the present study reported HPE finding of hyperplasia without atypia (27.6%), followed by carcinoma endometrium (22.4%). Mamatha et al study found that 41.9% of the patients had hyperplasia without atypia and 20.9% had disordered proliferative endometrium, which was higher than our study.[1] This is not in line with the findings of Mathew et al, who reported proliferative endometrium and secretory endometrium as the most common HPE pattern in pipelle (31.6% & 20.8%) i.e more than 50% were normal studies.[17] Ilavarasi et al also reported a similar finding to that of Mathew et al, wherein 49.1% of the patients had either proliferative or secretory endometrium, followed by simple hyperplasia(13.5%).[16] Atrophic endometrium, adenocarcinoma was reported by 4.7% and 5.7% in Ilavarasi et al.[16] The differential pattern might be due to the incidence of the pathology in the respective populations studied since they are from different regions of the state and country.

The sensitivity for the proliferative endometrium and secretory endometrium was 82.3% and 57.1%, respectively in our study. Mathew et al reported mixed findings of lower sensitivity for proliferative endometrium (66.6%) and higher sensitivity for secretory endometrium (81.3%) than our study.[17] In our study, The specificity for the proliferative endometrium and secretory endometrium was 96.3% and 100% respectively. Accuracy was 93.1% and 95.8%, respectively. Mathew et al reported a mixed findings of higher specificity for proliferative endometrium (93.9%) and lower specificity for secretory endometrium (88.2%) than our study. Also, lower accuracy was reported by Mathew et al for both secretory and proliferative endometrium (86.6%).[17]

In the current study, pipelle biopsy showed a sensitivity, specificity and accuracy of 50%, 97.1% and 95.8% for the Disordered proliferative endometrium. Mamatha et al reported a lower sensitivity and accuracy of 57.1% and 81.5%. [1] Pipelle biopsy in the present study showed a sensitivity, specificity and accuracy of 87.5%, 87.5% and 87.5% for the hyperplasia without atypia, while Mamatha et al reported a lower accuracy of 83.9%. [1] Tanko et al reported higher diagnostic accuracy of 93.75%. [8]

While pipelle diagnosis of hyperplasia with atypia showed a sensitivity, specificity and

accuracy of 83.3%, 95.5% and 94.4% in our study, Mathew et al reported a higher sensitivity (100%), but lower specificity (91.9%) as well as accuracy (92.5%) than our study.[17] In contrast, Tanko et al reported lower sensitivity of 50% and higher specificity and accuracy of 100% and 99.31%, respectively.[8] Pipelle biopsy in the present study showed a sensitivity, specificity, and accuracy of 75%, 100% and 98.6% for the Atrophic endometrium, while Ilavarasi et al reported a lower sensitivity (50%) and accuracy (94.9%) than our study.[16]

In the present study, pipelle biopsy showed a sensitivity, specificity and accuracy of 88.9%, 98.1% and 95.8% for the Carcinoma endometrium. In contrast, Mathew et al study had a lower sensitivity of 50%, lower accuracy 94%, and higher specificity of 100% for adenocarcinoma.[17] Ilavarasi et al reported a lower sensitivity (75%) but higher specificity (100%) and accuracy (98%) than our findings.[16] Mamatha et al, Aimagambetova et al and Tanko et al reported 100% diagnostic accuracy for adenocarcinoma.[1,8,12] Abdelazim et al reported 100% diagnostic accuracy for endometrial hyperplasia, endometrial carcinoma, proliferative and secretory endometrium.[13]

## V. CONCLUSION

Overall, the adequacy of sampling for HPE by pipelle biopsy was 94.7% in the present settings. This leaves scope for improving the technique and expertise for sampling through pipelle. Diagnostic accuracy of all major pathologies of AUB, such as disordered proliferative endometrium, hyperplasia with atypia, Atrophic endometrium and carcinoma endometrium, were above 90%. This indicates the potential role of the pipelle, a relatively simpler procedure, in diagnosing AUB among the perimenopausal women in the present settings. Further multi-centric studies must be conducted to improve the validity of findings. Future studies should also include the patient satisfaction component to understand and quantify the patient perspective towards this relatively cheaper and equally effective technique in diagnosing AUB.

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