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Efficacy of pipelle endometrial sampling in diagnosing endometrial pathologies in postmenopausal women with asymptomatic thick endometrium in comparison to fractional curettage

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***Abstract*---**Objective: To evaluate the efficacy of pipelle endometrial sampling (PES) in diagnosing endometrial pathologies in patients with asymptomatic thick endometrium compared to fractional curettage (FC). Methods: A prospective, comparative, observational study was conducted, involving 100 postmenopausal women with asymptomatic thickened endometrium. Demographic characteristics, clinical features, and transvaginal ultrasound measurements were recorded. PES was performed as an outpatient procedure, followed by confirmatory FC under general anesthesia. Histopathological examination was conducted for both PES and FC samples. Diagnostic accuracy, pain scores, and association with endometrial hyperplasia and carcinoma were assessed. Results: The mean age of the participants was 56.7±2.8 years, with a mean body mass index of 29.6±3.6 kg/m2. The mean endometrial thickness was 14.3±2.9 mm. PES yielded 73 (73%) adequate samples, while FC yielded 87 (87%) adequate samples. Pain scores were significantly lower for PES compared to FC (3.23±1.23 vs. 6.48±1.54, respectively, $p < 0.001$). PES demonstrated a sensitivity rate of 81.25% and a specificity rate of 100% for endometrial hyperplasia, and a sensitivity rate of 60% and specificity rate of 100% for endometrial carcinoma. Conclusions: Pipelle endometrial sampling is an effective and well-tolerated method for diagnosing endometrial pathologies in postmenopausal women

with asymptomatic thickened endometrium. It demonstrates high sensitivity and specificity rates for endometrial hyperplasia and carcinoma. The procedure offers advantages over fractional curettage in terms of pain scores and patient comfort.

***Keywords*---**pipelle endometrial sampling, fractional curettage, postmenopausal women, endometrial hyperplasia, endometrial carcinoma.

Introduction

Postmenopausal women with asymptomatic thick endometrium pose a diagnostic challenge in clinical practice due to the potential presence of endometrial pathologies, including endometrial hyperplasia and cancer [1]. Accurate and timely diagnosis is crucial to guide appropriate management decisions and ensure optimal patient outcomes. Among the diagnostic methods available, pipelle endometrial sampling and fractional curettage have emerged as two commonly employed techniques for evaluating the endometrium in this specific population [2]. Pipelle endometrial sampling has gained popularity in recent years as a minimally invasive outpatient procedure with several advantages. This technique utilizes a flexible suction curette that can be easily navigated through the cervical canal to obtain endometrial tissue samples. The procedure is well-tolerated by patients, requires minimal anesthesia or sedation, and can be performed in an office setting. The collected tissue samples are subsequently subjected to histopathological examination, allowing for the detection of various endometrial pathologies [3].

In contrast, fractional curettage has been a traditional diagnostic method utilized for endometrial evaluation. This technique involves the removal of multiple tissue fragments from the uterine cavity using a sharp curette [4]. The obtained tissue samples are then sent for histopathological analysis. Fractional curettage is generally performed under anesthesia in an operating room, and its utilization has been established in the diagnostic workup of endometrial disorders [5].

Despite the widespread use of both pipelle endometrial sampling and fractional curettage, a comprehensive comparison of their efficacy in diagnosing endometrial pathologies in postmenopausal women with asymptomatic thick endometrium is still limited. Existing studies have reported varying diagnostic accuracy rates, with some favoring one method over the other [6]. Therefore, there is a need for further investigation to provide clarity and evidence-based recommendations for clinical practice. The primary aim of this study is to evaluate and compare the efficacy of pipelle endometrial sampling and fractional curettage in diagnosing endometrial pathologies in postmenopausal women with asymptomatic thick endometrium.

Patients and Methods

This prospective, comparative, observational clinical study was conducted at the gynecology clinic of Benha University Hospital. The study protocol was approved

by the Human Research Ethics Committee of Banha Faculty of Medicine, and written informed consent was obtained from all individual patients prior to their participation. The study was done over a period of one year, from January 2020 to January 2021. The study included a total of 100 postmenopausal women who presented to the gynecology clinic with asymptomatic thickened endometrium exceeding 5 mm on transvaginal ultrasound. Patients meeting the selection criteria were consecutively enrolled in the study.

Pipelle biopsy was done as an outpatient initial step then confirmatory fractional curettage under general anaesthesia was done one month later. All subjects fitting the selection criteria were enrolled. The sample size calculated is 100. Inclusion criteria were asymptomatic postmenopausal women with accidentally discovered thick endometrium more than 5 mm on transvaginal Ultrasound. Exclusion criteria included pre and perimenopausal women, cases with postmenopausal bleeding, patients with history of past or current malignancy and patients with abnormal endometrial pattern like irregular endometrial linning, free fluid in endometrial cavity, focal lesions or hypervascularity.

Patients were subjected to demographic characteristics [Age, parity, and body mass index (BMI)]. Clinical presentation [Duration of menopause, presence of comorbidities, and use of hormone replacement therapy (HRT)]. Transvaginal ultrasound measurements [Endometrial thickness, presence of any abnormal endometrial patterns, and any additional findings]. Procedure details [Date of Pipelle biopsy and fractional curettage, anesthesia type used for fractional curettage, and any complications encountered during the procedures]. Histopathological results [The final histopathological diagnosis obtained from both Pipelle biopsy and fractional curettage specimens].

Procedures

All eligible patients underwent an initial outpatient Pipelle endometrial sampling procedure. The Pipelle biopsy was performed using a sterile disposable Pipelle device. Local anesthesia (lidocaine 2%) was administered to the cervix before the procedure. The endometrial sample was obtained by inserting the Pipelle device through the cervical os and gently aspirating the endometrial tissue. The collected sample was immediately fixed in formalin for histopathological examination. Confirmatory fractional curettage was performed under general anesthesia approximately one month after the Pipelle biopsy. The procedure was carried out in the operating room using a sharp curette. The uterine cervix was dilated, and the endometrial tissue was sampled using a sharp curette. The obtained tissue samples were also fixed in formalin for histopathological analysis.

Histopathological Examination

The formalin-fixed tissue samples obtained from both Pipelle biopsy and fractional curettage were processed and analyzed by experienced pathologists who were blinded to the patients' clinical information. The specimens were embedded in paraffin, sectioned, and stained with hematoxylin and eosin. The histopathological examination aimed to identify and classify endometrial pathologies, including endometrial hyperplasia and endometrial cancer.

Outcome Measures

The primary outcome measure was the diagnostic accuracy of Pipelle endometrial sampling compared to fractional curettage in detecting endometrial pathologies, including endometrial hyperplasia and endometrial cancer. Secondary outcome measures included procedure-related complications, patient tolerability and the need for repeat sampling or subsequent interventions based on the initial results.

Statistical analysis

The statistical analysis was performed using SPSS v25 (IBM©, Armonk, NY, USA). For quantitative parametric data, the mean and standard deviation (SD) were used to present the results. Quantitative non-parametric data were presented as the median and interquartile range (IQR), which represents the middle 50% of the data. Qualitative variables were described using frequency and percentage (%), and the Chi-square test was utilized for their analysis. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated to compare the diagnostic efficacy of Pipelle endometrial sampling and fractional curettage. A two-tailed P value of less than 0.05 was considered statistically significant, indicating a significant difference or association between variables.

Results

The main clinical features of study group are shown in the following tables and Graph. Table 1 shows that mean age of participating women was 56.7±2.8 years and ranged from 48.3 to 63.7 years. Mean body mass index (BMI) was 29.6±3.6 kg/m^2 and ranged from 22.6 to 35.5. mean endometrial thickness was 14.3 ±2.9 mm, ranging from 11.3 to 23.3 mm. Menopausal Duration had a mean value of 7.2 ± 3.4. 32 (32%) had Previous Hormone Replacement Therapy and 48 (48%) had comorbidities. 73 (73%) samples out of the 100 were adequate and 27 (27%) were inadequate using pipelle. However, by fractional curettage, 87 (87%) were adequate samples and 13 (13%) were inadequate. Table 1

Table 1: Basic characters of the studied sample

Participant Characteristics (n=100)	Mean ±SD	Range
Age (years)	56.7±2.8	48.3-63.7
BMI (kg/m^2)	29.6±3.6	22.6-35.5
Endometrial Thickness (mm)	14.3±2.9	11.3-23.3
Menopausal Duration (years)	7.2 ± 3.4	3 - 15
Previous Hormone Replacement Therapy	32 (32%)	
Comorbidities	48 (48%)	

BMI: body mass index.

Table 2 and Figure 1 shows the endometrial histopathology results of the inadequate pipelle samples, the highest being proliferative endometrium at

40.7%. Endometrial hyperplasia came in 22.2 %, no cases were diagnosed as endometrial carcinoma among these samples.

Table 2: Histopathology results of cases with inadequate samples by Pipelle

Endometrial lesion	Number (n = 27)	Test	p
Proliferative endometrium	11 (40.7%)	X^2=3.963	0.265
Secretory endometrium	6 (22.2%)		
Simple endometrial hyperplasia	6 (22.2%)		
Complex endometrial hyperplasia	0 (0%)		
Atrophic endometrium	4 (14.8%)		

X2= Chi-square test

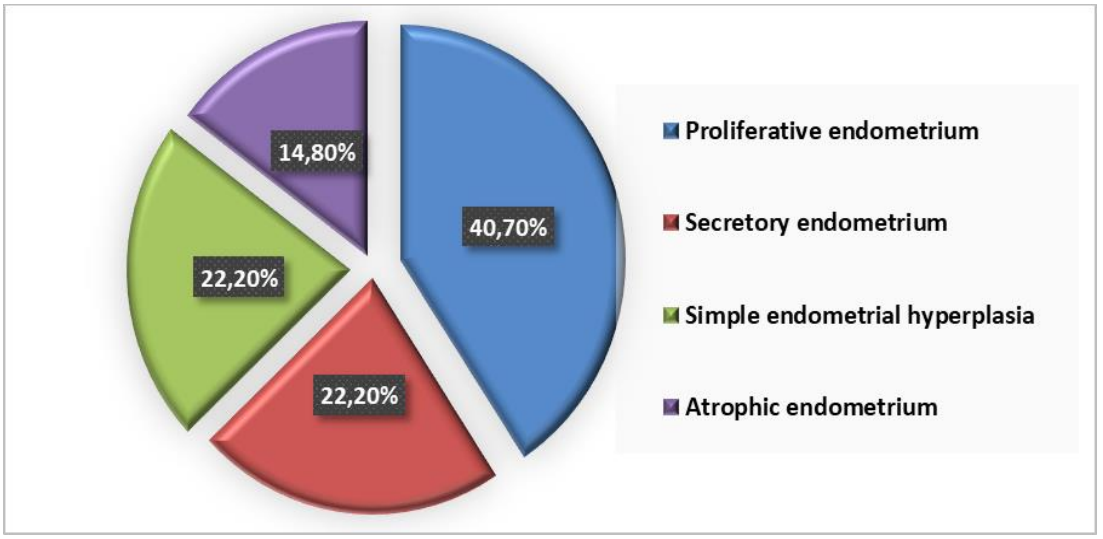

Figure 1. Histopathology distribution in cases with inadequate samples by pipelle

Table 3 and Figure 2 show all results Pipelle biopsy sampler and fractional curettage, 36 % of patients were diagnosed as proliferative endometrium by Pipelle compared to 40 % by fractional curettage. 15 % of patients were diagnosed as endometrial hyperplasia by Pipelle while comparedto 16 % by fractional curettage. Atypical endometrial hyperplasia was found in 2 % in Pipelle samples and not confirmed by fractional curettage. Adenocarcinoma found in 1 % of Pipelle samples while in 2 % in fractional curettage samples. Histopathological diagnosis was insignificantly different between both studied group (P-value = 0.369).

Table 3: Histopathological diagnosis by Pipelle biopsy and Fractional curettage

Diagnosis	Pipelle biopsy		Fractional curettage		Test	p
	Number (100) %		Number (100) %			
Proliferative endometrium	36	36	40	40	X^2=7.605	0.369
Secretory endometrium	18	18	22	22		
Simple hyperplasia	15	15	16	16		
Complex hyperplasia	0	0	2	2		
Complex hyperplasia with atypia	2	2	3	3		
Adenocarcinoma	1	1	2	2		
Atrophic endometrium	1	1	0	0		
Insufficient sample	27	27	15	15		

X2= Chi-square test

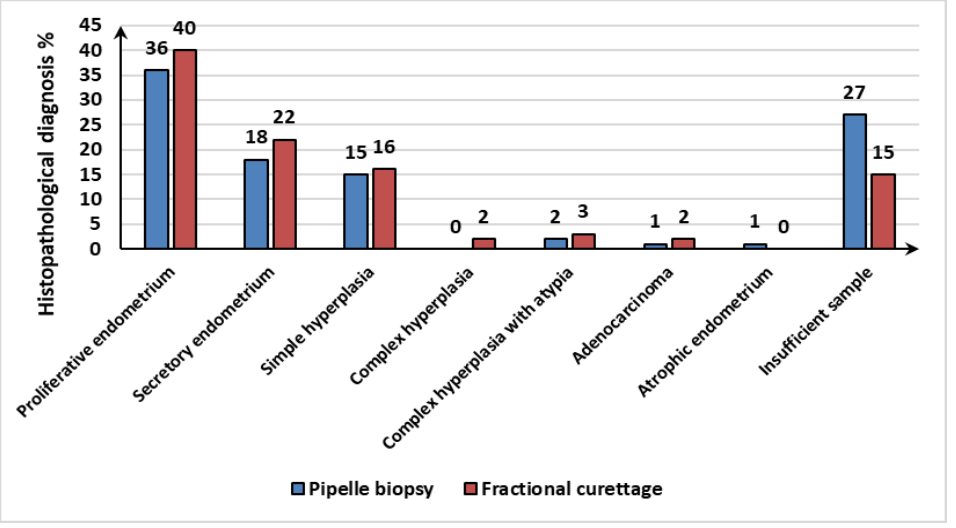

Figure 2: Histopathological distribution in the studied groups

Pain score was significantly lower in Pipelle biopsy in comparison to fractional curettage (3.23 ± 1.23 vs. 6.48 ± 1.54, respectively, P-value < 0.001). Table 4 and Figure 3

Table 4: Comparison between Pipelle and Fractional curettage regarding post-procedure pain

	Mean Pain score ± SD	Range
Pipelle biopsy	3.23 ± 1.23	2-6
Fractional curettage	6.48 ± 1.54	6-10
p	t=6.547, p<0.001*	

t=T student test, * =p<0.05

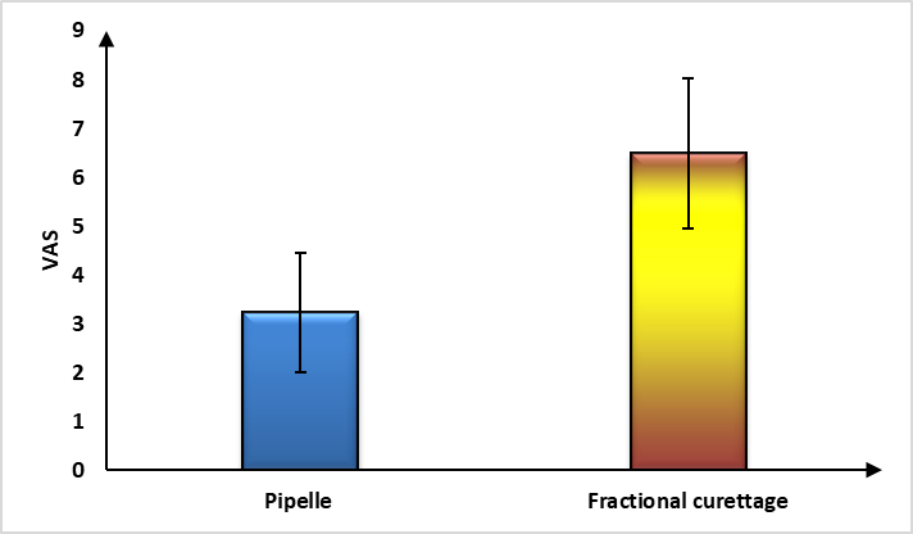

Figure 3: Pain comparison between pipelle endometrial sampling and fractional curettage

The sensitivity rate of PES for endometrial hyperplasia is reported to be 81.25%, the specificity rate is 100%, and the overall accuracy rate of 85% with 100% PPV and 57.14% NPV. There was a highly significant association between PES and the diagnosis of endometrial hyperplasia (P-value < 0.001). In the case of endometrial carcinoma, PES demonstrates a sensitivity rate of 60%, specificity rate of 100% and accuracy rate of 98%. Moreover, the PPV was 100% and the NPV was 97.94%. There was a significant association between PES and the diagnosis of endometrial carcinoma (P-value = 0.029). Table 5 and Figure 4

Table 5: Validity of Pipelle endometrial sampling for endometrial hyperplasia and endometrial carcinoma

Validity of PES	Endometrial hyperplasia (%)	Endometrial carcinoma (%)
Sensitivity rate	81.25	60
Specificity rate	100	100
Accuracy rate	85	98
PPV	100	100
NPV	57.14	97.94
AUC	0.908	0.800
p-value	<0.001*	0.029*

PPV: positive predictive value, NPV: negative predictive value, AUC: area under the curve, *: significant as p-value < 0.05.

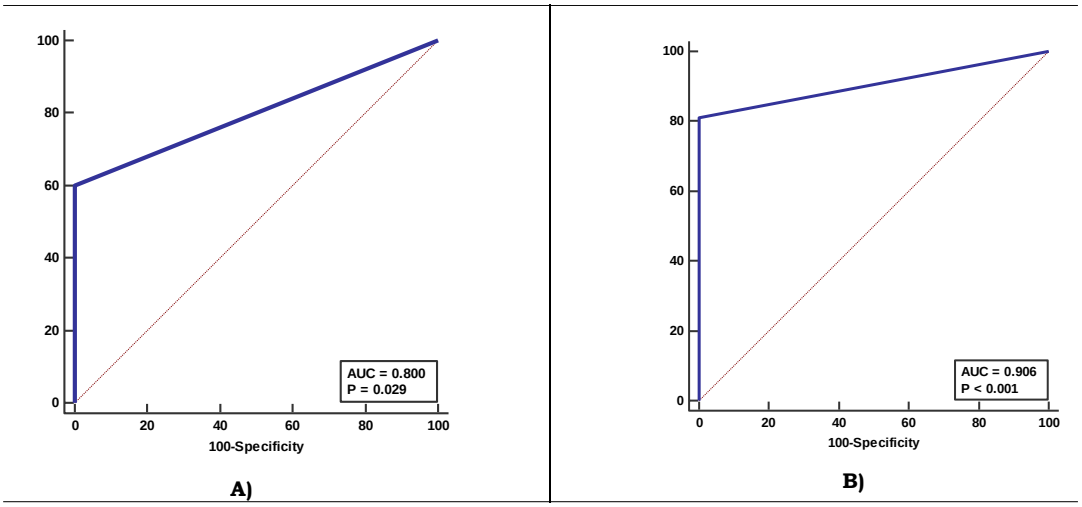

Figure 4: A) Validity of Pipelle endometrial sampling for prediction of endometrial hyperplasia and B) for prediction of endometrial carcinoma

Discussion

Pipelle biopsy is a safe, simple, cost-effective, and less painful alternative to D&C. It can be done on an outpatient epartment basis and does not require general anesthesia [3]. In this study, the primary objective was to assess the adequacy of the sample in order to make a definitive diagnosis. The adequacy rate using pipelle aspirator was 73% compared with D&C, which was 87%. This shows a 14% difference in outcome of adequacy between the two, which is not a significant difference. Thus, pipelle holds good with regard to sample adequacy. Our study draws parallel to a study done by Giannecopoulos et al. wherein the adequacy rate was 76.4% and the inadequacy rate was 21% [7].

The objective was to draw comparisons between the histopathological findings of pipelle endometrial biopsy and fractional curettage. There were 23 cases (23%) with discordant reports between pipelle and D&C. The sample that was diagnosed as complex hyperplasia with atypia by pipelle was reported as simple hyperplasia without atypia on D&C. One proliferative endometrium was diagnosed as atrophic by pipelle and one squamous cell carcinoma (SCC) by pipelle gave no opinion by D&C. Pipelle biopsy was comparable with D&C in 53% of the cases.

The sensitivity of Pipelle device in detecting endometrial hyperplasia was 59.1%, specificity was 92.4%, concordance was 85.8%, PPV was 58.9%, and NPV was 91.8%. From the above findings, we can decipher that the pipelle device would be more useful in ruling out endometrial hyperplasia and carcinoma than in diagnosing them, as the specificity and NPV are in the higher range with 92.4% each and sensitivity and PPV derived in our study were in the lower range (58.9%). Thus, the test should be limited to patients who have low risk for hyperplasia and endometrial carcinoma for confirming normalcy rather than for detecting hyperplasia itself.

Our study is comparable to a study by Fuat Demirkiran et al. wherein sensitivity of pipelle biopsy in detection of hyperplasia was 67% and NPV of pipelle biopsy was 99% for malignancy. It showed that neither pipelle nor D&C is an adequate method for focal endometrial pathologies. Both biopsy methods are not perfect, but pipelle biopsy is a cheaper and easier technique compared with D&C, and ultrasonographic findings of endometrium should be considered prior to endometrial biopsy [8].

In our study for detection of endometrial carcinoma, out of the two adenocarcinomas diagnosed by D&C, using pipelle, one gave the same diagnosis as D&C, but the second one showed hypersecretory changes. Although using pipelle one SCC was identified, the same sample came back inadequate using D&C. Similarly, in a study by Ferry et al. poor results were obtained in well-differentiated, low volume, and minimally invasive tumors, i.e., most early tumors, precluding its use as a screening tool. A positive biopsy can save patients the time, cost, and inconvenience of a D&C. However, in light of these findings, a nonspecific finding should be interpreted with caution [9].

Our study is comparable to a study by Bunyavejchevin et al. wherein the sensitivity and specificity of pipelle in endometrial tissue samplings compared with fractional curettage were 87.5% and 100%, respectively. In their study, 1 out of 3 cases of endometrial adenocarci- noma could not be diagnosed by pipelle. They concluded that the use of pipelle to replace fractional curettage in the management of postmenopausal bleeding should be done with caution. False negative results could occur in focal disease of malignancy of the endometrium [10]. Contrary to our study, a study by Yasmin et al. has shown 100% sensitivity and 94% specificity for diagnosing endometrial hyperplasia using pipelle and 75% sensitivity and 100% specificity for endometrial carcinoma [11].

Interestingly, Ilavarasi et al. in their study analyzed the efficacy of pipelle biopsy by adequacy of the sample obtained and also to establish the reliability by comparing the histopathology report obtained by pipelle biopsy with that of the hysterectomy specimen. They proved that pipelle had 75% sensitivity, 100% specificity, 100% PPV and 97.9% NPV, and 98% accuracy in diagnosing endometrial carcinoma [12]. In addition, a study by Abdelazim et al. showed 100% sensitivity, 100% specificity, and 100% accuracy for diagnosing endometrial hyperplasia as well as carcinoma. In this study also, 97.9% of the sample collected by pipelle was adequate for HPE [13].

In our study, the sensitivity was 51.3%, PPV was 51%, specificity was 98.9%, NPV was 99%, and concordance rate was 98.3% for diagnosing endometrial carcinomas. The low rate of sensitivity may be because the number of cases of carcinoma was limited to two. Thus, the values obtained may not adequately demonstrate the accuracy of pipelle in diagnosing endometrial cancer. To obtain more fruitful results with respect to endometrial carcinoma, a larger sample size inclusive of more postmenopausal women who are predisposed to endometrial carcinoma should be included in such a study.

Many studies compared the validity and accuracy of Pipelle biopsy with D&C in the detection of various endometrial abnormalities. A comprehensive meta-

analysis assessed the diagnostic value of Pipelle biopsy for atypical hyperplasia and endometrial cancer (EC). The analysis demonstrated a sensitivity ranging from 81% to 99% and a specificity of 98% for Pipelle biopsy. Higher accuracy was observed in symptomatic bleeding and postmenopausal women, particularly for the diagnosis of EC compared to atypical endometrial hyperplasia. The detection rate of EC was higher in postmenopausal women (99.6%) compared to premenopausal women (91%) when using the Pipelle device. However, limited evidence exists regarding the detection of atypical hyperplasia in postmenopausal women, with only one study available that did not allow for subgroup analysis. According to the cited study, Pipelle biopsy demonstrated a sensitivity of 81% and a specificity exceeding 98%. Overall, this research suggests that Pipelle biopsy outperforms other endometrial sampling techniques in detecting both EC and atypical hyperplasia, with higher accuracy observed in postmenopausal women compared to premenopausal women [14]

Several studies have compared the validity and adequacy of Pipelle endometrial sampling with D&C (dilation and curettage) and hysterectomy specimens. Regarding the detection of endometrial polyps, Pipelle biopsy demonstrated a sensitivity of 12.5%, specificity of 100%, PPV of 100%, and NPV of 88.7%. In comparison, D&C showed higher sensitivity (87.5%) and NPV (98%), but lower specificity (94.8%) and PPV (70%) for identifying endometrial polyps. For hyperplasia without atypia, Pipelle biopsy exhibited a sensitivity of 23.5%, specificity of 100%, PPV of 100%, and NPV of 78%. In contrast, D&C demonstrated a sensitivity of 55.6%, specificity of 95.8%, PPV of 83.3%, and NPV of 85.2% for identifying hyperplasia without atypia. Comparing Pipelle biopsy and hysterectomy histological results for hyperplasia with atypia, the sensitivity of Pipelle was 50%, specificity was 100%, and both PPV and NPV were 100%, respectively. In the same study, D&C exhibited a sensitivity of 83.3%, specificity of 98.3%, and NPV of 98.3% for the identification of hyperplasia with atypia [15].

Some investigations have reported a concordance rate of histologic results between Pipelle biopsy and hysterectomy of 62%, and between D&C and hysterectomy of 67%. In the same study, the sensitivity of Pipelle biopsy and D&C for detecting simple hyperplasia was 41.7% and 45%, respectively. For detecting atypia, both techniques exhibited a sensitivity of 71.4%. Notably, the sensitivity of D&C in detecting atrophic endometrial tissue was significantly higher at 80% compared to 37.5% for Pipelle biopsy (P=0.030). However, all other parameters were similar between the two groups. The authors concluded that Pipelle biopsy and D&C were equally effective as diagnostic approaches for endometrial pathologies. However, neither method was found to be adequate for detecting focal endometrial pathologies and endometrial hyperplasia. On the other hand, both Pipelle biopsy and D&C provided samples suitable for the reliable diagnosis of atypia [16].

Finally, as pipelle is an inexpensive, painless, easy method, the benefits outweigh the risks, and it would be more cost-effective for patients to undergo pipelle to confirm normalcy and rule out hyperplasia rather than undergoing D&C at the very beginning. This study had some limitations: This single-center study conducted on postmenopausal women with asymptomatic thickened endometrium has limitations that should be considered. The findings may not be

generalizable due to the specific clinic setting, potentially introducing selection bias. Long-term follow-up data and assessment of interval cancers were not captured, limiting the understanding of the diagnostic methods over time. The presence of inadequate samples obtained by both Pipelle biopsy and fractional curettage may impact overall diagnostic accuracy. The delay between procedures and potential changes in the endometrium during this period could affect the results. Furthermore, the study did not specify whether pathologists were blinded to the alternative sampling method, which may introduce performance bias in result interpretation.

Conclusions

Pipelle endometrial sampling is an effective and well-tolerated method for diagnosing endometrial pathologies in postmenopausal women with asymptomatic thickened endometrium. It demonstrates high sensitivity and specificity rates for endometrial hyperplasia and carcinoma. The procedure offers advantages over fractional curettage in terms of pain scores and patient comfort. PES can be considered a reliable initial step in the diagnostic workup of these patients, with FC reserved for confirmatory purposes.

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