Section: Obstetrics and Gynecology

Original Research Article

STUDY OF PIPELLE ENDOMETRIAL ASPIRATION CYTOLOGY VERSUS HYSTEROCOPIC GUIDED BIOPSY IN POST MENOPAUSAL WOMEN AT A TERTIARY CARE CENTRE

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ABSTRACT

Background: Aims: To study and compare pipelle's endometrial sampling findings with hysteroscopic guided biopsy findings in post-menopausal women **Materials and Methods:** The Prospective Observational study was conducted in 18 months in 60 Women with post-menopausal uterine bleeding with ultrasound findings of endometrial thickness greater than or equal to 4mm, with white discharge, with lower abdominal pain. **Result:** Pipelle biopsy showed high specificity (97.92% to 100%) and high sensitivity, especially for secretory endometrium, hyperplasia without atypia, and hyperplasia with atypia (100%). Positive predictive values (PPV) were perfect (100%) for most conditions, except for endometrial polyp and adenocarcinoma endometrium (PPV of 50% and 66.67%, respectively). Negative predictive values (NPV) were uniformly high. Overall accuracy ranged from 98% to 100%, indicating high reliability of Pipelle biopsy in diagnosing endometrial pathologies. **Conclusion:** Pipelle biopsy as a reliable and efficient method for diagnosing endometrial pathologies. Its high diagnostic accuracy, coupled with its outpatient feasibility and cost-effectiveness, positions it as an invaluable tool in contemporary gynaecological practice.

INTRODUCTION

Abnormal uterine bleeding (AUB) is a prevalent gynecological issue affecting women of various age groups, particularly those in the perimenopausal and postmenopausal stages. AUB accounts for a significant proportion of gynecological consultations, contributing to approximately 33% of outpatient presentations, and this number rises to nearly 70% among perimenopausal and postmenopausal women. One of the critical concerns with AUB, especially in postmenopausal women, is the potential underlying malignancy, such as endometrial cancer, which necessitates prompt and accurate diagnostic evaluation.[1,2]

Endometrial cancer is notably the most common gynecologic malignancy in developed countries, and it ranks as the sixth most prevalent cancer among women globally with over 400,000 new cases per year. According to World cancer Research Fund International 2022 (WCRF) mortality rate from endometrial cancer in world is 1.7 Age Standardised Rate(ASR) while in India it is 0.96 and ranks 3rd .The investigation of postmenopausal bleeding (PMB) is thus crucial, as it can be the initial symptom of endometrial carcinoma, which has a higher incidence in women aged 75-79 years.[3] Given the substantial risk of malignancy associated with PMB, any new-onset bleeding during this phase should be assumed to be cancerous until proven otherwise. Therefore, an effective and reliable method of endometrial sampling is essential for the timely diagnosis and treatment of endometrial pathologies.

Traditionally, the gold standard for endometrial sampling has been hysteroscopy and is commonly considered for the evaluation of endometrial pathologies, allowing a direct view of the uterine cavity to perform the biopsy. It may not be readily available in all healthcare settings, particularly in low-resource environment and cost may be high. Due to these limitations, simpler and less invasive methods for endometrial sampling have been developed. Among these, the Pipelle endometrial sampler has gained popularity due to its ease of use,

cost-effectiveness, and the ability to perform the procedure on an outpatient basis without the need for anesthesia.[4] The Pipelle device is a flexible polypropylene sheath with an inner plunger, designed to create negative pressure and aspirate endometrial tissue quickly and with minimal discomfort to the patients.

This study aims to compare the diagnostic accuracy of Pipelle endometrial aspiration cytology with hysteroscopic-guided biopsy in postmenopausal women by evaluating the histopathological findings from both methods, to determine the effectiveness of the Pipelle sampler in identifying endometrial pathologies, including malignancies, in a minimally invasive and outpatient setting. This comparison is particularly relevant given the increasing need for cost-effective and accessible diagnostic tools in gynaecological practice, especially for populations with limited access to specialized care. The Pipelle endometrial sampler offers a promising alternative to hysteroscopic guided biopsy that could simplify the diagnostic process and increase accessibility. This study will provide valuable insights into the comparative effectiveness of these methods, potentially in forming clinical practice and guidelines for the management of AUB in postmenopausal women.

MATERIALS AND METHODS

The Prospective Observational study was conducted in the Department of Obstetrics and Gynaecology, Gandhi Medical College and Hospital, Secunderabad, Telangana, India in 18 months (July 2022 to December 2023) in 60 post-menopausal women who attended Obstetrics and Gynaecology Gandhi Medical College and Hospital, Secunderabad, Telangana, India.

Inclusion Criteria: Women with post-menopausal uterine bleeding with ultrasound findings of endometrial thickness greater than or equal to 4mm, with white discharge, with lower abdominal pain

Exclusion Criteria: Post-menopausal bleeding due to cervical and vaginal causes. Asymptomatic post-menopausal women with endometrial thickness less than 4mm, with bleeding disorders and dyscrasias, anticoagulant therapy ,attained premature menopause naturally or due to surgery, irradiation or chemotherapy ,on HRT, Injuries to genital tract .

Ethical clearance was obtained from institutional review board of Gandhi Medical College and Hospital, Secunderabad, Telangana, India. Before start of the study the purpose of the study was explained to the study participants and written informed consent was obtained.

Measured variables/parameters studied:

Demographics: Name and age of the study participants were recorded.

Detailed history: Detailed history of complaints, her past menstrual history, obstetric history, past medical history, family history and drug history were recorded along with baseline investigations and ultrasonography

Endometrial sampling and biopsy: Endometrial sampling was done with pipelle and biopsy was done by hysteroscopy.

Endometrial sampling was performed using a Pipelle device. The Pipelle, a thin, flexible plastic tube with a suction mechanism, was inserted through the cervix into the uterine cavity. The inner piston of the Pipelle was withdrawn to create suction, allowing endometrial tissue to be collected into the device. This process typically involved a gentle rotating motion to ensure an adequate and representative sample of the endometrial lining.

Subsequently, a biopsy was conducted via hysteroscopy. The patient was placed in the lithotomy position, and local or general anaesthesia was administered as required. The hysteroscope, a thin, lighted tube with a camera, was carefully inserted through the cervix into the uterine cavity. Sterile saline solution was used to distend the uterine cavity, providing a clear view of the interior.

Under direct visualization, areas of interest were identified, and biopsy forceps were used to obtain tissue samples. The hysteroscopy allowed precise targeting and removal of abnormal or suspicious tissue. After the biopsy, the instruments were withdrawn, and the samples were sent to the pathology lab for analysis. The procedure was performed with meticulous attention to aseptic technique to minimize the risk of infection.

Laboratory Processing

The collected samples from both the Pipelle and hysteroscopy biopsy were immediately placed in labelled containers with formalin or another suitable fixative to preserve the tissue. The samples were then transported to the pathology lab, ensuring proper handling to avoid any degradation. In the lab, the tissue samples

were processed using standard histological techniques. The samples were dehydrated through a series of alcohol solutions and then embedded in paraffin wax blocks to create a solid medium for thin sectioning. Thin sections, typically 4-5 micrometres, were cut from the paraffin blocks using a microtome. The sections were mounted on glass slides and stained with haematoxylin and eosin (H&E) to differentiate the cellular components and structures for microscopic examination. A pathologist examined the stained slides under a microscope, assessing the tissue morphology and identifying any abnormalities or pathological changes. A detailed pathology report was then prepared, documenting the findings, and communicated to the referring physician for further clinical correlation and management.

After obtaining informed consent from 60 postmenopausal women, the objectives of the study were explained, ensuring confidentiality and anonymity. The demographics, including the names and ages of the participants, were documented. A comprehensive history was taken, covering current

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complaints, past menstrual history, obstetric history, past medical history, family history, and drug history. Baseline investigations and ultrasonography were also performed. Endometrial sampling was conducted using a Pipelle device, followed by a biopsy performed via hysteroscopy. The collected data was entered into Excel for subsequent statistical analysis.

Statistical Analysis

The statistical analysis was carried out using IBM SPSS (Statistical Package for Social Sciences) statistical version 27. The analysis includes frequency table, bar, pie chart, all quantitative variables were estimated using measures of central location (mean and median) and measures of dispersion (standard deviation). Chi-square was employed to find association between categorical variables. The quality of the microscopic analysis with Pipelle collection and hysteroscopy biopsy was evaluated by estimating sensitivity, specificity, probability of false positives and false negatives, accuracy, and positive and negative predictive values. P≤0.05 was set as significant value.

RESULTS

Table 1: Distribution of study participants

Age	**Frequency**	**Percentage**
<50	5	8.3
50-60	27	45
>60	28	46.7
Mean±SD	59.85±8.188	
Parity		
Nulli	5	8.3
Multi	55	91.7
Endometrial Thickness		
4-6	8	13.3
6.1-8	13	21.7
8.1-10	20	33.3
10.1-12	4	8.3
12.1-14	8	13.3
>14	7	11.7

The participants, 5 individuals (8.3%) were under the age of 50, 27 individuals (45%) were between the ages of 50 and 60, and 28 individuals (46.7%) were over the age of 60. The mean age of the participants was 59.85±8.188 years.

Among the participants, 5 individuals (8.3%) were nulliparous (had no previous pregnancies), while 55 individuals (91.7%) were multiparous (had one or more previous pregnancies).

Participants with an endometrial thickness of 4-6 mm accounted for 8 individuals (13.3%), while those with a thickness of 6.1-8 mm included 13 individuals (21.8%). A thickness of 8.1-10 mm was observed in 18 participants (30%).

Table 2: Tissue adequacy for pipelle and hysteroscopic biopsy

Adequacy	**Pipelle Biopsy**		**Hysteroscopic Biopsy**	
	N	**%**	**N**	**%**
Adequate	53	88.3	57	95
Inadequate	7	11.7	3	5

The adequacy of tissue samples obtained by Pipelle biopsy and hysterectomy is presented in Table 4 and Graph 4. Pipelle biopsy yielded adequate tissue in 53 cases (88.3%) and inadequate tissue in 7 cases (11.7%). In comparison, hysterectomy provided adequate tissue in 57 cases (95%) and inadequate tissue in 3 cases (5%).

Table 3: HPE report of pipelle biopsy

Pipelle Biopsy	**Frequency (N=53)**	**Percentage**
Atropic endometrium	2	3.8
Proliferative endometrium	25	47.2
Secretory endometrium	14	26.4
Hyperplasia without atypia	4	7.5
Hyperplasia with atypia	3	5.7
Endometrial polyp	3	5.7
Adenocarcinoma endometrium	2	3.8
HPE Report		
Atropic endometrium	3	5.3
Proliferative endometrium	28	49.1
Secretory endometrium	14	24.6
Hyperplasia without atypia	4	7
Hyperplasia with atypia	2	3.5

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Endometrial polyp	2	3.5
Adenocarcinoma endometrium	4	7

Histopathological examination (HPE) findings from Pipelle biopsies among 53 participants are presented. Proliferative endometrium was the most common finding, observed in 25 cases (47.2%). Secretory endometrium was identified in 14 cases (26.4%). Atrophic endometrium was present in 2 cases (3.8%).

Histopathological examination (HPE) findings from ultrasound-guided hysteroscopic biopsies among 57 participants. The most frequent findings were proliferative endometrium, observed in 28 cases (49.1%), followed by secretory.

Table 4: Correlation of pipelle's aspiration with hysteroscopic guided biopsy

HPE Report	Pipelle Biopsy		Hysteroscopic Biopsy		P-VALUE
	N	%	N	%	
Atropic endometrium	2	3.8	3	5.3	0.500
Proliferative endometrium	25	47.2	28	49.1	0.726
Secretory endometrium	14	26.4	14	24.6	0.500
Hyperplasia without atypia	4	7.5	4	7	0.641
Hyperplasia with atypia	4	7.5	2	3.5	0.500
Endometrial polyp	2	3.8	2	3.5	0.500
Adenocarcinom a endometrium	2	3.8	4	7	0.518

Chi-square P≤0.05 is statistically significant

Two biopsy methods for diagnosing various endometrial conditions confirms no statistically significant differences between the two methods for these diagnoses ($p \leq 0.05$).

Table 5: Association of endometrial thickness with histopathological findings

HPE Report	≤10		>10		P-value
	N	%	N	%	
Atropic endometrium	3	7.5	0	0	0.431
Proliferative endometrium	19	52.5	9	45	0.500
Secretory endometrium	7	17.5	7	35	0.160
Hyperplasia without atypia	3	7.5	1	5	0.736
Hyperplasia with atypia	3	7.5	0	0	0.660
Endometrial polyp	3	7.5	0	0	0.431
Adenocarcinom a endometrium	0	0	2	10	0.264

Chi-square P≤0.05 is statistically significant

Endometrial thickness with histopathological findings although not statistically significant, highlight the distribution of various endometrial conditions relative to endometrial thickness.

Table 6: Association between endometrial thickness with pipelle's aspiration

HPE REPORT	≤10		>10		P-VALUE
	N	%	N	%	
Atropic endometrium	2	3.03	0	0	0.660
Proliferative endometrium	16	48.5	9	47.1	0.581
Secretory endometrium	7	18.2	7	35.3	0.160
Hyperplasia without atypia	3	6.1	1	5.9	0.736
Hyperplasia with atypia	4	3.03	0	0	0.660
Endometrial polyp	2	3.03	0	0	0.660
Adenocarcinom a endometrium	0	0	2	11.8	0.110

Chi-square P≤0.05 is statistically significant

Association between endometrial thickness and histopathological findings from Pipelle's aspiration confirms no statistically significant.

Table 7: Efficacy of pipelle biopsy results in comparison to hysteroscopic-guided biopsy

Findings	Specificity	Sensitivity	PPV	NPV	Accuracy
Atropic endometrium	100%	50%	100%	98%	98%
Proliferative endometrium	100%	96%	100%	6.2%	98%
Secretory endometrium	100%	100%	100%	100%	100%
Hyperplasia without atypia	100%	100%	100%	100%	100%
Hyperplasia with atypia	100%	100%	100%	100%	100%
Endometrial polyp	100%	97.96%	50%	100%	98%
Adenocarcinoma endometrium	97.92%	100%	66.67%	100%	98%

The results indicate high specificity for all conditions, ranging from 97.92% to 100%, demonstrating the ability to correctly identify absence of the respective conditions. Sensitivity levels are uniformly high, particularly notable for conditions such as secretory endometrium,

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hyperplasia without atypia, and hyperplasia with atypia, all achieving 100%. Positive predictive values (PPV) are perfect (100%) for most conditions, except for endometrial polyp and adenocarcinoma endometrium where PPV is 50% and 66.67%, respectively. Negative predictive values (NPV) are uniformly high, reflecting the ability to correctly identify absence of conditions. Overall accuracy across all conditions is strong, with values ranging from 98% to 100%.

DISCUSSION

Postmenopausal bleeding (PMB) is a significant clinical concern that requires prompt evaluation due to its association with various underlying pathologies, including endometrial cancer, which is one of the most common gynaecological malignancies. Menopause, defined as the cessation of menstrual periods for at least 12 consecutive months, marks a natural transition in a woman's reproductive life. PMB, characterized by vaginal bleeding occurring after this period, represents approximately 5% of all gynaecological outpatient visits and necessitates thorough investigation to rule out malignancy.[4,5]

Traditionally, Dilatation and Curettage (D&C) was the standard method for evaluating PMB. However, its invasiveness, requirement for general anaesthesia, and inability to adequately sample the entire uterine cavity in a significant proportion of cases have led to the adoption of less invasive alternatives. Hysteroscopic-guided biopsy emerged as a superior method for its ability to provide direct visualization of the uterine cavity and targeted biopsy of suspicious lesions. Nevertheless, its cost and the need for specialized equipment limit its widespread use, especially in resource- constrained settings.[6]

Pipelle endometrial aspiration cytology has gained popularity as a less invasive, cost-effective outpatient procedure for evaluating endometrial pathology in women presenting with AUB or PMB. This method involves using a thin, flexible catheter to obtain endometrial tissue samples, which are then analyzed for abnormalities. Studies have demonstrated Pipelle's efficacy in diagnosing endometrial cancer when sufficient tissue is collected, highlighting its role in early outpatient evaluation and timely management.[4]

In the context of healthcare disparities, particularly in countries with varying healthcare access, the adoption of Pipelle offers significant advantages in terms of accessibility and cost- effectiveness compared to traditional methods like D&C and hysteroscopy. In Brazil, for example, where long waiting times and limited resources impact healthcare delivery, Pipelle has become a practical tool for expediting diagnosis and improving patient outcomes.[5]

As medical societies and guidelines advocate for early outpatient endometrial evaluation in women with AUB and PMB. Thereby in the current study pipelle endometrial aspiration cytology versus hysteroscopy guided biopsy in post- menopausal women was utilized to find the efficacy of pipelle endometrial aspiration cytology. While hysteroscopy remains the gold standard for comprehensive endometrial assessment, Pipelle's utility in detecting endometrial cancer underscores its potential as a primary diagnostic tool in routine clinical practice.

In the current study, the majority of participants experiencing postmenopausal bleeding were aged over 60 years, constituting 46.7% of the study population. This demographic trend is consistent with findings from other research studies: Lavanya S et al,[7] reported 45% of their participants were over 50 years old, Vasudev V et al,[8] noted 66.3% were above 50 years, and Vasudeva S et al,[8] included exclusively participants aged above 50 years. The mean age of participants in current study was 59.85±8.188 years, which aligns closely with the age demographics observed in similar investigations: Nagalakshmi M et al,[9] reported a mean age of 54.76±8.02 years, while Trojano G et al,[10] documented an average age of 59.5 years.

In the current study the age ranged from 42-76 years, whereas in the Vasudev V et al,[8] study age range was from 41-80 yrs. while the study done by M et al was 42-84 yrs. respectively. These findings collectively underscore the predominance of older age groups among women experiencing postmenopausal bleeding, highlighting the importance of age as a significant demographic factor in such studies.

In the current study, 91.7% of participants have experienced multiple pregnancies. This proportion is consistent with findings from similar studies: Nagalakshmi M et al,[9] reported 96%, Lavanya S et al,[7] found 89%, and Vasudeva S et al. observed 97.6% of participants were multiparous. These results underscore the high prevalence of multiparity among women included in studies focusing on this demographic, highlighting its relevance as a characteristic of the study population across various research contexts.

Risk factors such as early marriage, multiparity, and multiple sexual partners contribute to the development of cervical cancer. Advanced age, obesity, early menarche, late menopause, diabetes, hypertension, and polycystic ovaries increase the predisposition to endometrial cancer. Obtaining a detailed medical history is crucial as it forms the initial and most important step in diagnosing these conditions. Thorough clinical evaluation then guides the diagnostic process effectively, which are in line with current study.

In current study, 71.7% of participants had an endometrial thickness exceeding 8.1 mm. This finding contrasts with Nagalakshmi et al,[9] where 36% of participants had similar thickness. The significance of endometrial thickness lies in its association with heightened risk factors for endometrial pathology, particularly in cases of

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abnormal uterine bleeding (AUB) during perimenopause or post menopause, or a history of chronic anovulation. Elevated thickness often signals potential malignancy or benign conditions such as hyperplasia, myoma, or polyps. Current guidelines recommend that asymptomatic postmenopausal women with an endometrial thickness exceeding 5 mm, as detected by ultrasound, should undergo hysteroscopy and endometrial biopsy, despite discrepancies in defining what constitutes a thickened endometrium. While recent trends advocate for investigating lesions only in cases of postmenopausal bleeding when thickness exceeds 4 mm, systematic biopsy collection remains crucial for symptomatic patients due to reported instances of cancer even in those with ultrasound-measured endometrial thicknesses below 5 mm. Thereby in the current with participants with >4mm were included being the strength of the study. In the current study there was no significant difference in the pathology and endometrial thickness in both Pipelle biopsy and ultrasound-guided hysteroscopic biopsy.

In Pipelle biopsy, endometrial thickness was deemed sufficient in 88.3% of participants, whereas hysteroscopic biopsy showed adequate thickness in 95% of cases. In studies by Nagalakshmi et al,[9] and Mamatha S, Lakshmikantha G,[15] the adequacy rates of Pipelle biopsy were reported as 94%, and 87.7%, respectively. This comparison highlights the slightly higher adequacy rate of endometrial thickness assessment achieved through hysteroscopic biopsy compared to Pipelle biopsy. Achieving adequate endometrial tissue sampling is crucial for accurate diagnosis and management of endometrial pathologies, ensuring comprehensive evaluation and appropriate clinical decision- making.

Atrophic endometrium was observed in 2 participants (3.8%) via Pipelle and in 3 participants (5.3%) via hysteroscopy (p = 0.500). Proliferative endometrium was identified in 25 participants (47.2%) with Pipelle and 28 participants (49.1%) with hysteroscopy (p = 0.726). Secretory endometrium was present in 14 participants (26.4%) for Pipelle and 14 participants (24.6%) for hysteroscopy (p = 0.500). Hyperplasia without atypia was noted in 4 participants (7.5%) with Pipelle and 4 participants (7.0%) with hysteroscopy (p = 0.641). Hyperplasia with atypia was found in 2 participants (3.8%) for Pipelle and 2 participants (3.5%) for hysteroscopy (p = 0.500). Endometrial polyps were reported in 2 participants (3.8%) for Pipelle and 2 participants (3.5%) for hysteroscopy (p = 0.500). Finally, adenocarcinoma endometrium was detected in 4 participants (7.5%) via Pipelle and 4 participants (7.0%) via hysteroscopy (p = 0.518). Statistical analysis indicated no significant difference between the two biopsy methods in terms of detecting these various endometrial pathologies.

Lavanya S et al,[7] reported a distribution of various endometrial pathologies in women presenting with postmenopausal bleeding, including proliferative type (22%), atrophic type (13%), cystoglandular hyperplasia (10%), endometrial hyperplasia (9%), endometritis (7%), fibroids (5%), and endometrial polyp (4%). Malignant findings included well-differentiated endometrioid carcinoma (12%) and cervical carcinoma (18%). Within the subgroup of endometrial carcinoma, 7% were well-differentiated endometrioid type, 3% moderately differentiated, 1% villoglandular type, and 1% poorly differentiated. Cervical cancer consisted of well-differentiated squamous cell carcinoma in 16% and moderately differentiated in 2% of cases.

In the current study, the findings reveal robust diagnostic performance metrics for Pipelle biopsy across various endometrial pathologies. Specificity levels are consistently high, ranging from 97.92% to 100%, indicating the biopsy's ability to accurately identify the absence of specific conditions. Sensitivity rates are notably strong, particularly achieving 100% for conditions such as secretory endometrium, hyperplasia without atypia, and hyperplasia with atypia. This underscores the biopsy's effectiveness in correctly detecting the presence of these pathologies. Positive predictive values (PPV) are excellent (100%) for most conditions, except for endometrial polyps and adenocarcinoma endometrium, where PPV is slightly lower at 50% and 66.67%, respectively. Negative predictive values (NPV) are uniformly high, indicating the biopsy's ability to reliably identify the absence of these conditions. Overall accuracy across all conditions is robust, ranging from 98% to 100%, reinforcing the reliability of Pipelle biopsy in diagnosing a spectrum of endometrial pathologies.

Comparative insights from Guner et al,[13] align with the current study, demonstrating a similar distribution of negative and positive biopsy results, highlighting consistency in diagnostic outcomes. Additionally, Nagalakshmi N et al,[9] reported strong sensitivity (66.67%), specificity (100%), PPV (100%), NPV (97.72%), and accuracy (97.72%) specifically for diagnosing endometrial carcinoma using Pipelle biopsy, reflecting its efficacy in oncological diagnostics. Factors such as the presence of malignancy confined to polyps or prior dilatation and curettage procedures impacting tissue availability. These observations underscore the importance of biopsy technique and patient history in achieving accurate diagnostic outcomes in clinical practice.

In summary, while Pipelle biopsy demonstrates high overall diagnostic accuracy and reliability across a range of endometrial conditions, variations in positive predictive values may arise depending on specific pathologies. Understanding these nuances aids in optimizing biopsy strategies and enhancing diagnostic efficacy in the management of endometrial health concerns.

CONCLUSION

In conclusion, this study underscores Pipelle biopsy as a reliable and efficient method for diagnosing

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endometrial pathologies. Its high diagnostic accuracy, coupled with its outpatient feasibility and cost-effectiveness, positions it as an invaluable tool in contemporary gynaecological practice. By leveraging its strengths and addressing potential limitations, clinicians can confidently integrate Pipelle biopsy into their diagnostic algorithms, ultimately improving diagnostic precision and patient care outcomes in the management of endometrial abnormalities.

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