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A Comparative Study of Pipelle Aspiration Biopsy and Dilatation & Curettage in Diagnosing Endometrial Hyperplasia With Hysterectomy as the Gold Standard

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Abstract

Objectives: Abnormal uterine bleeding (AUB) is a common gynecological complaint requiring accurate endometrial assessment. This study aimed to compare the diagnostic accuracy of Pipelle aspiration biopsy and dilatation & curettage (D&C) with histological findings from hysterectomy specimens in patients with AUB.

Materials and Methods: In this retrospective cross-sectional study, medical records of 124 women diagnosed with endometrial hyperplasia who underwent subsequent hysterectomy between 2018 and 2023 at Kamali hospital, Karaj, were reviewed. Preoperative endometrial sampling was performed via Pipelle (n=65) or D&C (n=59). Histopathological results from both methods were compared with the final hysterectomy findings. Diagnostic accuracy, sensitivity, specificity, and concordance rates were calculated.

Results: The overall diagnostic concordance with hysterectomy findings was 72.88% for D&C and 70.76% for Pipelle. For the detection of atypia, D&C showed a sensitivity of 76% (95% CI: 52%–92%), specificity of 86% (95% CI: 72%–96%), and accuracy of 83% (95% CI: 71%–91%), while Pipelle demonstrated a sensitivity of 73% (95% CI: 54%–87%), specificity of 80% (95% CI: 63%–91%), and accuracy of 77% (95% CI: 65%–86%). The confidence intervals for these metrics overlapped substantially. No statistically significant differences were found between the two methods in direct comparisons (P>0.05). D&C was associated with a lower rate of pathological upgrading than Pipelle (13.16% vs. 22.22% for missed atypia). However, this difference was not statistically significant (P=0.31).

Conclusions: Both Pipelle and D&C demonstrate comparable diagnostic performance, with high and statistically similar concordance rates with final hysterectomy pathology. D&C shows a non-significant trend towards higher accuracy and a lower rate of missed atypia. Clinicians should be aware of the potential for underdiagnosis of atypia with both methods, particularly with Pipelle, when planning management strategies for endometrial hyperplasia.

Keywords: Abnormal uterine bleeding, Endometrial hyperplasia, Pipelle, Dilatation and curettage, Hysterectomy, Diagnostic accuracy

Introduction

Abnormal uterine bleeding (AUB) represents one of the most prevalent gynecological complaints, accounting for approximately 5% of all visits to gynecologists and significantly impacting women's quality of life and healthcare resources (1,2). It is a broad term encompassing any deviation from the normal menstrual cycle in terms of regularity, frequency, duration, or volume of flow outside of pregnancy (3). The clinical significance of AUB is particularly pronounced in perimenopausal and postmenopausal women, as it often serves as the primary presenting symptom for underlying endometrial pathology, ranging from benign polyps and hyperplasia to endometrial carcinoma (4). Consequently, the accurate and timely evaluation of the endometrium in these patients is not merely a diagnostic exercise but a critical intervention for the early detection of premalignant and malignant conditions, ultimately influencing patient survival and treatment outcomes (5).

The endometrial lining, which is the source of bleeding, requires direct sampling for a definitive histological diagnosis. For decades, dilatation and curettage (D&C) have been regarded as the historical "gold standard" for obtaining endometrial tissue (6). This procedure involves mechanical dilation of the cervical canal followed by systematic scraping of the endometrial cavity, typically performed under general or regional anesthesia in an operating room setting. While D&C allows for more extensive sampling of the endometrium than office-based techniques, it is not without significant drawbacks. It is an invasive procedure associated with potential complications such as uterine perforation, cervical injury, intrauterine adhesions (Asherman's syndrome), hemorrhage, and infection (7,8). Furthermore, it requires hospital

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admission, operating room time, and anesthesia services, making it a costly, resource-intensive intervention with inherent risks.

Driven by the need for safer, more cost-effective, and patient-friendly alternatives, the late 20th century saw the development and adoption of various office-based endometrial sampling devices. Among these, the Pipelle de Cornier® (Pipelle) has emerged as the most widely used and studied device globally (9). This flexible, disposable plastic cannula, with an outer diameter of approximately 3.1 mm, is designed to be introduced through the cervix without prior dilation. The creation of negative pressure by withdrawing an internal piston enables aspiration of endometrial tissue. Its advantages are manifold: it can be performed swiftly in an outpatient setting without anesthesia, is well-tolerated by most patients, significantly reduces costs, and minimizes the risk of serious complications (8,10). Its high accuracy in detecting diffuse endometrial carcinoma, with reported sensitivity rates often exceeding 99%, has cemented its role in clinical practice (11).

However, a persistent and significant concern regarding Pipelle biopsy is its efficacy in accurately diagnosing focal intrauterine lesions and specific endometrial hyperplasias, particularly those with atypia. The device samples only a small portion (4%-15%) of the total endometrial surface area, potentially missing focal abnormalities such as polyps, submucosal fibroids, or geographically irregular hyperplastic or cancerous lesions (12,13). This limitation is clinically critical because the presence of cytological atypia within endometrial hyperplasia is the single most important prognostic factor, escalating the risk of progression to endometrial cancer from less than 5% in hyperplasia without atypia to up to 30% in its atypical counterpart (14). An inaccurate diagnosis can therefore lead to either overtreatment of benign conditions or, more dangerously, undertreatment of premalignant lesions.

The existing body of literature presents a complex picture. While numerous studies have compared the diagnostic agreement between Pipelle and D&C, often showing comparable results for global diagnoses, their relative accuracy against the definitive benchmark—the hysterectomy specimen—remains a subject of debate, especially concerning the critical detection of atypia (15,16). Many studies use D&C itself as the reference standard, which is a methodological limitation given that D&C is also a sampling technique and not a true gold standard like complete hysterectomy, which allows for a full histological examination of the entire endometrium.

Therefore, this study aims to address this evidence gap by directly comparing histopathological diagnoses from preoperative Pipelle aspiration biopsies and D&C procedures with final pathological findings from subsequent hysterectomy specimens in a cohort of women presenting with AUB. By using hysterectomy as the unequivocal diagnostic benchmark, this research aims to provide a more robust, clinically relevant comparison of the diagnostic accuracy, sensitivity, and specificity of these two common sampling techniques, with a particular focus on their performance in identifying endometrial atypia. The findings will provide clinicians with valuable guidance on selecting the most appropriate diagnostic pathway for women with AUB, balancing accuracy, safety, cost, and patient comfort.

Materials and Methods

Study Design and Setting

A retrospective cross-sectional study was conducted by reviewing the medical records of patients who presented with AUB at the Kamali Teaching Medical Center in Karaj, Iran, between March 2018 and March 2023. The study period was selected to ensure an adequate sample size and to reflect contemporary clinical practice before the widespread adoption of the newer WHO/EIN classification system at our institution.

Study Population and Sampling

The study population consisted of women with a preoperative diagnosis of endometrial hyperplasia who subsequently underwent a hysterectomy. Patient records were identified through the hospital's medical archive system using relevant diagnostic and procedure codes. The choice between Pipelle and D&C was based on clinician preference, patient tolerance, and resource availability, reflecting real-world practice.

A convenience sequential sampling method was employed. Using findings from a prior study (15) and assuming an effect size (difference in accuracy) of 15% with a confidence level of 95% and a power of 80%, a minimum sample size of 124 patients was calculated using the standard formula for comparing two proportions. Ultimately, 124 patients met the inclusion criteria: 65 had undergone an initial Pipelle biopsy and 59 had undergone D&C.

Inclusion criteria

- Women aged 18 years or older presenting with AUB.
- A preoperative endometrial tissue diagnosis of hyperplasia was obtained via either Pipelle aspiration biopsy or Dilatation & Curettage (D&C).
- Performance of a hysterectomy (total or subtotal) within six months of the initial biopsy.
- Availability of complete histopathological reports for both the initial biopsy and the hysterectomy specimen.

Exclusion criteria

- Incomplete medical records or missing pathology reports.
- A prior history of endometrial cancer or other pelvic malignancies.
- Receipt of hormonal therapy for endometrial

hyperplasia between the initial biopsy and the hysterectomy.

Data Collection and Variables

A structured data collection sheet was designed to extract the following information from each patient's medical record:

- Demographic data: Age at the time of procedure.
- Procedure data: Type of initial endometrial sampling method (Pipelle or D&C). Data on sample adequacy (e.g., "insufficient for diagnosis") were also collected where available; no cases were excluded for this reason, as all included biopsies provided a definitive diagnosis of hyperplasia.
- Pathological data: The histopathological diagnosis from the initial biopsy and the final diagnosis from the hysterectomy specimen.

Endometrial pathology was classified according to the World Health Organization (WHO) 1994 classification system into the following categories: This system was used for consistency with the existing pathology reports generated during the study period at our institution.

- Simple hyperplasia without atypia
- Simple atypical hyperplasia
- Complex hyperplasia without atypia
- Complex atypical hyperplasia
- Endometrial carcinoma

Description of Procedures

Pipelle endometrial biopsy: This procedure was performed in an outpatient setting without anesthesia. Following a bimanual examination and insertion of a speculum, the flexible Pipelle catheter (Laboratoire CCD, France) was introduced through the cervix into the uterine cavity. The inner piston was withdrawn to create suction, and the device was rotated and moved gently to aspirate endometrial tissue.

D&C: This procedure was performed in an operating room under general or regional anesthesia. The cervix was dilated, and the endometrial cavity was systematically curetted using a sharp curette.

Hysterectomy: The hysterectomy specimens (total or subtotal) were considered the gold standard for definitive diagnosis. The specimens were fixed in formalin, carefully examined, and fully processed for histopathological analysis. All pathological evaluations were performed by at least two experienced gynecological pathologists, with a minimum of 5 years' experience in the field.

All pathological specimens were evaluated by experienced gynecological pathologists who were blinded to the results of the other sampling method. They were not blinded to the clinical context (e.g., AUB) as this information is typically provided on pathology requisition forms. Inter-observer variability was not formally assessed, as consensus diagnoses were used for clinical reporting.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 22.0 (Armonk, NY: IBM Corp). Continuous variables (age) were presented as mean ± standard deviation (SD). Categorical variables were expressed as frequencies and percentages. The chi-square test (or Fisher's exact test, where appropriate) was used to assess the association between the preoperative biopsy results and the final hysterectomy diagnosis. Diagnostic performance measures, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy, were calculated for both Pipelle and D&C in detecting endometrial atypia (considering hysterectomy as the gold standard). The 95% confidence intervals (CIs) for these measures were also reported. McNemar's test was used to compare the sensitivity and specificity of the two methods. The chi-square test was used to compare upgrade rates and concordance. A P value of less than 0.05 was considered statistically significant for all tests.

Results

A total of 124 women who met the inclusion criteria were included in the final analysis. The study population was divided into two groups based on the initial endometrial sampling method: the Pipelle group (n=65, 52.4%) and the D&C group (n=59, 47.6%).

Baseline Characteristics

The mean age of the participants was 44.15 ± 4.38 years. The mean age in the Pipelle group was 45.58 ± 4.25 years (range: 37-56), and in the D&C group, it was 42.59 ± 4.27 years (range: 34-58). The difference in mean age between the two groups was not statistically significant (P=0.12). Data on other potential confounders, like body mass index (BMI) and menopausal status, were not consistently available in the medical records for analysis.

Distribution of Pathological Findings

The distribution of the initial pathological diagnoses from the Pipelle and D&C samples, as well as the final diagnoses from the hysterectomy specimens, is summarized in Table 1.

Concordance Between Preoperative Biopsy and Hysterectomy

The overall diagnostic concordance between preoperative biopsy and final hysterectomy pathology was 70.76% (46/65) in the Pipelle group and 72.88% (43/59) in the D&C group. The detailed concordance rates for each diagnostic category are presented in Table 2.

Diagnostic Performance for Detecting Atypia

The sensitivity, specificity, and accuracy of both methods for the critical detection of endometrial atypia (defined as SAH, CAH, or carcinoma) were calculated. The results are shown in Table 3 and Figure 1. Direct comparison

Table 1. Distribution of Pathological Findings in Preoperative Biopsies and Hysterectomy Specimens

Pathology Result	Pipelle Biopsy (n=65)	D&C Biopsy (n=59)	Hysterectomy (n=124)
Simple hyperplasia	19 (29.23%)	24 (40.68%)	37 (29.84%)
Simple atypical hyperplasia	0 (0%)	0 (0%)	1 (0.81%)
Complex hyperplasia	17 (26.15%)	14 (23.73%)	36 (29.03%)
Complex atypical hyperplasia	29 (44.62%)	21 (35.59%)	49 (39.52%)
Endometrial carcinoma	0 (0%)	0 (0%)	1 (0.81%)

Table 2. Concordance Between Preoperative Biopsy and Hysterectomy Diagnosis

Preoperative Diagnosis (Pipelle)	n	Concordant Hysterectomy Diagnoses (n, %)	Preoperative Diagnosis (D&C)	n	Concordant Hysterectomy Diagnoses (n, %)
Simple hyperplasia without atypia	19	13 (68.42%)	Simple hyperplasia without atypia	24	19 (79.17%)
Complex hyperplasia without atypia	17	11 (64.71%)	Complex hyperplasia without atypia	14	9 (64.29%)
Complex atypical hyperplasia	29	22 (75.86%)	Complex atypical hyperplasia	21	15 (71.43%)
Total	65	46 (70.76%)	**Total**	59	43 (72.88%)

using McNemar's test showed no statistically significant difference in sensitivity (P=0.80) or specificity (P=0.45) between the two methods.

Pathological Upgrade

A key finding was the rate of "pathological upgrade," where a preoperative diagnosis of hyperplasia without atypia was changed to a diagnosis with atypia (or carcinoma) upon hysterectomy. This occurred in 8 of 36 cases (22.22%) initially diagnosed as non-atypical by Pipelle, compared to 5 of 38 cases (13.16%) initially diagnosed as non-atypical by D&C. This difference was not statistically significant (P=0.31, Chi-square test), highlighting the potential for underdiagnosis of atypia with both methods. However, it was more pronounced with Pipelle (Figure 2).

In summary, while both Pipelle and D&C showed good overall concordance with final hysterectomy pathology, D&C demonstrated marginally higher overall accuracy and a superior ability to rule out atypia, as evidenced by its higher specificity and negative predictive value. However, these differences were not statistically significant. The higher upgrade rate from Pipelle biopsies indicates a greater risk of missing significant atypical lesions preoperatively, but this finding also did not reach statistical significance.

Discussion

This retrospective study aimed to evaluate and compare the diagnostic accuracy of Pipelle endometrial biopsy and D&C against the gold standard of hysterectomy pathology in women presenting with AUB and a preoperative diagnosis of endometrial hyperplasia. Our key findings indicate that while both methods demonstrate substantial diagnostic concordance, D&C exhibits a trend towards superior performance, particularly in the critical task of identifying endometrial atypia. However, the differences were not statistically significant.

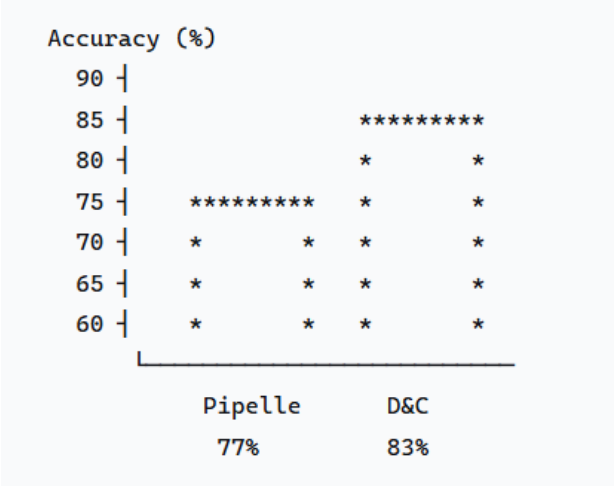

Figure 1. Bar Chart Comparing the Diagnostic Accuracy of Pipelle and D&C. The chart includes error bars representing the 95% confidence intervals, illustrating the overlap between the two methods.

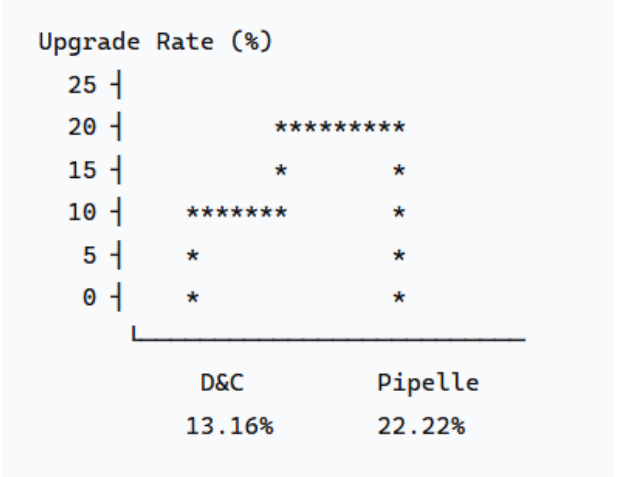

Figure 2. Rate of Pathological Upgrade to Atypia from Non-Atypical Biopsies. The figure clearly labels the absolute numbers and percentages, and includes a note on the p-value for the comparison.

The overall concordance rates with the final hysterectomy diagnosis were 72.88% for D&C and 70.76% for Pipelle. This marginal difference, though not drastic, is clinically significant. It underscores the fundamental limitation of any blind sampling technique: the risk of missing focal lesions. The Pipelle device samples only an estimated 4%-15% of the endometrial surface area (17), making it inherently susceptible to sampling error, especially in cases of focal atypia or early carcinoma. While D&C is also a sampling procedure, it allows for a more extensive, albeit still not complete, evaluation of the endometrial cavity, which likely accounts for its higher accuracy in our study and others (18,19).

The most critical finding of our analysis lies in the detection of atypia. The presence of cytological atypia is the single most important prognostic factor in endometrial hyperplasia, escalating the risk of progression to endometrial cancer from <5% in hyperplasia without atypia to up to 30% in its atypical counterpart (20). In our cohort, D&C demonstrated higher sensitivity (76% vs. 73%), specificity (86% vs. 80%), and overall accuracy (83% vs. 77%) for detecting atypia compared to Pipelle. However, as the confidence intervals overlapped substantially and direct statistical tests showed no significant difference, these findings should be interpreted as indicating a trend rather than definitive superiority. Consequently, the NPV of D&C was higher (86% vs. 80%), indicating that a D&C diagnosis of "no atypia" is more reliable for ruling out a precancerous lesion than the same diagnosis from a Pipelle biopsy.

The pathological upgrade rate starkly illustrates this performance gap. We found that 22.22% of cases diagnosed as non-atypical hyperplasia by Pipelle were upgraded to atypia (or worse) upon hysterectomy, compared to 13.16% of cases diagnosed by D&C. This higher upgrade rate associated with Pipelle is a major concern. Even if not statistically significant in our cohort, it implies that a not-insignificant number of women with a premalignant condition may be initially misclassified and potentially managed conservatively (e.g., with progestin therapy alone), risking disease progression due to under-treatment. This finding aligns with a recent study by Woo Yeon Hwang et al, which also reported a significantly higher upgrade rate to carcinoma following aspiration biopsy (27.3%) compared to D&C (15.0%) (21).

Our results contribute to a complex body of literature. While many studies and a well-cited meta-analysis report excellent sensitivity (>99%) for Pipelle in detecting frank endometrial carcinoma, its performance in accurately classifying hyperplasias, particularly concerning atypia, is less robust (21,22). This discrepancy is logical; advanced carcinoma often presents as a diffuse endometrial lesion easily captured by a blind biopsy, whereas atypia can be highly focal and patchy. Our study reinforces that the high cancer sensitivity should not be extrapolated to imply equal proficiency in diagnosing precursor lesions. Our study cohort was relatively young (mean age ~44 years) compared to the typical perimenopausal peak for endometrial hyperplasia. This may limit the generalizability of our findings to older populations, where the prevalence of atrophy and cancer is higher. The lack of data on confounders like BMI and menopausal status is another limitation, as these factors influence endometrial pathology risk. Based on our findings, we propose a nuanced approach to endometrial sampling:

- Pipelle biopsy remains a valuable first-line tool in the diagnostic workup of AUB due to its excellent patient acceptability, low cost, and low complication rate. A positive result for carcinoma or atypia is highly reliable for initiating definitive treatment. Future cost-effectiveness analyses incorporating patient preference data would strengthen this recommendation.
- However, a Pipelle result showing hyperplasia without atypia should be interpreted with caution, especially in high-risk patients (e.g., those with persistent bleeding, obesity, or PCOS). In such cases, the significant risk of an underlying atypical lesion (22% in our study) must be acknowledged.
- D&C should be strongly considered in cases where the Pipelle sample is insufficient, discordant with clinical or sonographic findings, or shows non-atypical hyperplasia in a patient for whom the risk of missing a focal atypia is deemed unacceptable. D&C provides a more comprehensive sample and greater diagnostic confidence for ruling out atypia.

Limitations of the Study

Several limitations of our study must be acknowledged. Its retrospective design introduces the potential for selection and information bias. The lack of randomization in the choice of sampling method is a key limitation, as clinician preference could introduce confounding. The use of the WHO 1994 classification system, while common in the existing literature, is outdated; the modern endometrial intraepithelial neoplasia system provides better reproducibility and risk stratification (14). We did not evaluate the impact of endometrial thickness or the specific sonographic characteristics of the endometrium, which could influence diagnostic yield. Furthermore, the procedures and pathological analyses were performed by multiple clinicians and pathologists, introducing potential variability, though this also reflects real-world practice. Inter-observer variability among pathologists was not assessed, which is a known challenge in diagnosing hyperplasia.

Conclusions

In conclusion, our study demonstrates that both Pipelle aspiration and D&C are effective diagnostic tools for evaluating endometrial hyperplasia, showing comparable overall accuracy. D&C shows a non-significant trend

towards greater accuracy, with higher concordance with final hysterectomy pathology and a superior ability to detect or rule out endometrial atypia. The numerically higher rate of pathological upgrade from Pipelle biopsies for non-atypical results underscore a critical limitation, even though it was not statistically significant in this study. Clinicians must be aware of this diagnostic pitfall. A Pipelle biopsy result of hyperplasia without atypia, particularly in the context of persistent symptoms or high-risk factors, may warrant further diagnostic evaluation with D&C to ensure that a precancerous lesion is not missed, thereby optimizing patient management and outcomes.

Authors' Contribution

Conceptualization: Shima Mohammadian, Ramesh Baradaran Bagheri
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Writing–original draft: Shima Mohammadian, Ramesh Baradaran Bagheri, Roya Gharedaghi
Writing–review & editing: Shima Mohammadian, Ramesh Baradaran Bagheri, Roya Gharedaghi.

Conflict of Interests

Authors have no conflict of interest.

Data Availability Statement

Data supporting the findings of this study are available upon reasonable request from the corresponding author.

Declaration of AI-assisted Tools in the Writing Process

The authors used DeepSeek (V3) AI tool for editing in order to enhance the quality of this manuscript. All content was checked by the authors, who accept full responsibility for its accuracy.

Ethical Issues

The study protocol was approved by the Ethics Committee of Alborz University of Medical Sciences (Approval Code: IR.ABZUMS.REC.1402.313). Due to the study's retrospective nature, the ethics committee waived the requirement for informed consent; however, patient confidentiality was strictly maintained throughout the research.

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