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COMPARISON OF DIAGNOSTIC ACCURACY OF ENDOMETRIAL SAMPLING TECHNIQUES; D&C AND PIPELLE SAMPLING IN PATIENTS OF ENDOMETRIAL HYPERPLASIA

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ABSTRACT

Endometrial hyperplasia, defined by the thickening of the endometrium, is a recognized precursor to endometrial cancer, especially in postmenopausal women. The precise and prompt diagnosis of this illness is essential for averting development to malignancy and facilitating successful therapy. This study sought to evaluate the diagnostic accuracy, sensitivity, specificity, and patient outcomes of two prevalent endometrial sample methods, Dilation and Curettage (D&C) and Pipelle biopsy, using hysterectomy as the gold standard. This cross-sectional study was performed at the Gynecology Department of Sir Ganga Ram Hospital in Lahore for a duration of six months. One hundred and fifty women aged 35 to 65 years, exhibiting atypical uterine hemorrhage and clinically suspected of endometrial hyperplasia, were recruited using simple random sampling. The subjects were divided evenly into two groups: 75 receiving D&C and 75 undergoing Pipelle biopsy. The data collection encompassed demographic information, clinical history, procedural attributes, histopathology results, and patient-reported outcomes. Statistical analysis was performed using SPSS Version 26.0, with quantitative variables evaluated using t-tests and categorical variables using chi-square tests. A p-value of less than 0.05 was deemed statistically significant. The mean age of participants in the D&C and Pipelle groups was 49.75 ± 8.95 years and 49.77 ± 8.94 years, respectively. Both approaches demonstrated strengths and limits in identifying endometrial hyperplasia. Pipelle biopsy revealed better sensitivity (71%) compared to D&C (55%), showing its superior capacity to detect hyperplastic lesions. However, D&C demonstrated a somewhat greater specificity (35%) compared to Pipelle (29%). Tissue adequacy was slightly superior with Pipelle sampling (49% vs to 45% in D&C). Pain scores immediately following the procedure were lower in the Pipelle group (4.82 ± 3.19) compared to the D&C group (5.17 ± 3.36), but differences in pain scores after one week were negligible. Complications were slightly more likely with Pipelle biopsy (31%) than to D&C (22%). Both groups exhibited comparable satisfaction levels (D&C: 2.82 ± 1.47, Pipelle: 2.85 ± 1.33). The outcomes of this study demonstrate that while D&C remains a

solid diagnostic tool, Pipelle biopsy offers a less invasive, patient-friendly alternative with comparable diagnostic accuracy. These results have substantial implications for clinical practice, particularly in resource-limited settings or outpatient contexts where less invasive methods are sought. Future research should focus on long-term patient outcomes, cost-effectiveness, and the incorporation of patient preferences into diagnostic decision-making to further optimize the therapy of endometrial hyperplasia.

INTRODUCTION

Endometrial hyperplasia, characterized by abnormal proliferation of the uterine lining, represents a significant clinical concern due to its potential progression to endometrial cancer, particularly in postmenopausal women[1]. With over 380,000 new cases of endometrial cancer reported annually worldwide, this condition contributes substantially to gynecological morbidity and mortality[2]. In Pakistan, where endometrial cancer ranks as the 17th most common malignancy among women, the incidence has been steadily rising in recent years[3]. Early and accurate detection of endometrial hyperplasia is crucial for preventing progression to cancer and improving patient outcomes[4].

Abnormal uterine bleeding (AUB), commonly encountered in perimenopausal and postmenopausal women, serves as a primary symptom warranting evaluation for underlying conditions, including endometrial hyperplasia[5]. The diagnostic landscape is primarily dominated by two fundamental methods: Dilation and Curettage (D&C) and Pipelle biopsy[6]. D&C, a surgical procedure with over a century of clinical use, involves mechanical scraping of the uterine lining to obtain tissue samples[7]. While effective, this procedure requires cervical dilation, often necessitates anesthesia, and is associated with increased patient discomfort, procedural risks, and higher costs[8]. In contrast, the Pipelle biopsy, introduced in the 1980s, represents a minimally invasive alternative[9]. Using a thin, flexible catheter, Pipelle biopsy enables endometrial tissue collection in an outpatient setting without the need for cervical dilation or anesthesia[10]. Despite these advantages, the diagnostic accuracy of Pipelle biopsy compared to D&C has been a subject of debate, with varying results reported in the literature[11].

While hysterectomy provides the most comprehensive examination of the uterine lining, it is an invasive procedure unsuitable for routine diagnosis[12]. Therefore, non-invasive or minimally invasive methods like D&C and Pipelle biopsy play a crucial role in early detection[13]. However, their diagnostic reliability, particularly regarding sensitivity and specificity, varies[14]. D&C, though considered a reliable diagnostic tool, is limited by its inability to detect focal lesions due to its blind nature[15]. Pipelle biopsy, while praised for its patient-friendly approach, is often criticized for lower tissue adequacy rates[16]. Research by Bettocchi et al. highlighted D&C's high diagnostic accuracy while noting its limitations in detecting focal lesions and small cancers[17]. Similarly, studies by Barut et al. and Clark et al. have endorsed the accuracy and patient-centered advantages of Pipelle biopsy[18]. However, variations in reported sensitivity and specificity have prevented the establishment of a consistent diagnostic protocol[19].

Adequate tissue sampling is essential for detecting hyperplasia and distinguishing between its various subtypes, including simple and complex hyperplasia with or without atypia[20]. Inadequate samples not only limit diagnostic accuracy but also necessitate repeat procedures, increasing patient burden and healthcare costs[21]. Gynecologists and healthcare practitioners regularly face the challenge of determining the most appropriate diagnostic approach for patients presenting with AUB[22]. This decision is influenced by multiple factors, including clinical presentation, resource availability, and procedural expertise[23]. The significance of this research extends beyond the immediate clinical setting. By improving diagnostic techniques, this study contributes to broader efforts to reduce the burden of gynecological cancers. Early and accurate identification of endometrial hyperplasia enables prompt interventions, reducing the risk of progression to cancer and improving long-term patient outcomes[24]. This research addresses a critical gap in gynecological diagnostics by comparing the diagnostic accuracy and patient outcomes of D&C and Pipelle biopsy.

Methodology:

The study adopted a comparative cross-sectional design to evaluate the diagnostic accuracy, sensitivity, and specificity of D&C and Pipelle biopsy. Hysterectomy specimens served as the gold standard for validating histopathological findings. The study also considered patient-reported outcomes, including procedural pain, complications, and satisfaction, to examine the broader implications of these diagnostic approaches. The design ensured a comprehensive comparison of the two methods, with particular attention to their effectiveness in diagnosing various subtypes of endometrial hyperplasia, including simple and complex hyperplasia with or without atypia.

The research was conducted in the Gynecology Department of Sir Ganga Ram Hospital, Lahore, a tertiary care hospital known for its expertise in managing gynecological conditions. This hospital provided access to a diverse patient population, advanced diagnostic facilities, and skilled clinical staff. Procedures were conducted in both outpatient and operating room settings, depending on the diagnostic approach employed.

A total of 150 women aged 35-65 years, presenting with abnormal uterine bleeding (AUB) and clinically suspected endometrial hyperplasia, were included in the study. The sample size was calculated to achieve a 95% confidence level and a 5% margin of error, ensuring sufficient statistical power to detect significant differences between the diagnostic methods. The participants were divided into two groups: 75 women underwent Dilation and Curettage (D&C), and 75 underwent Pipelle biopsy.

Simple random sampling was employed to ensure that every eligible patient had an equal chance of being included in the study. This approach reduced selection bias and enhanced the generalizability of the study findings. A random number generator was used to assign participants to either the D&C or Pipelle group. The study was conducted over six months, with the first month dedicated to preparation and participant recruitment, months 2-4 for data collection, and the final two months for data analysis and report writing.

The inclusion criteria encompassed women aged 35-65 years diagnosed with endometrial hyperplasia based on initial clinical assessment and presenting with AUB. Participants had to have no history of endometrial cancer, be willing to provide informed consent, not be currently undergoing hormonal therapy, not be pregnant or breastfeeding, and have no contraindications for undergoing endometrial sampling procedures.

Exclusion criteria included active pelvic infection or other acute gynecological conditions, history of endometrial cancer, current use of hormonal therapy, presence of uterine fibroids or polyps that could interfere with sampling, severe medical comorbidities contraindicating the procedures, known coagulopathies or bleeding disorders, prior hysterectomy or severe cervical stenosis, pregnancy or breastfeeding, and unwillingness to provide informed consent.

The data collection process involved several stages. During recruitment and screening, eligible participants were identified during routine clinical visits. After verifying inclusion and exclusion criteria, detailed demographic and clinical histories were recorded. The endometrial sampling techniques were performed according to standardized protocols. Pipelle biopsy was conducted in an outpatient setting by experienced gynecologists, with a sterile Pipelle catheter inserted into the uterine cavity to collect endometrial tissue. The procedure was completed without the need for cervical dilation or anesthesia. D&C was performed in an operating room under general or local anesthesia, with the cervix dilated using mechanical dilators and the endometrial lining scraped using a curette.

Tissue samples obtained from both methods were sent to the pathology department for histopathological examination. The presence of endometrial hyperplasia and its subtypes were documented. Hysterectomy specimens, where available, were analyzed to serve as the gold standard for comparison. Patient-reported outcomes were carefully monitored, with pain assessed immediately after the procedure and one week later using a numeric rating scale (0-10). Complications such as infection, bleeding, or other adverse events were recorded, and participants rated their satisfaction with the procedure on a scale of 1 (very dissatisfied) to 5 (very satisfied).

Statistical analysis was performed using SPSS version 26.0. Descriptive statistics were used to summarize patient characteristics and outcomes. Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on the data distribution. Categorical variables were presented as frequencies and percentages. The Shapiro-Wilk test was applied to assess the normality of

continuous variables. Depending on the normality, either independent sample t-tests (for normally distributed data) or Mann-Whitney U tests (for non-normally distributed data) were used to compare continuous variables between groups. Chi-square tests or Fisher's exact tests were used to compare categorical variables. A p-value of less than 0.05 was considered statistically significant for all comparisons.

Ethical approval was obtained from the Institutional Review Board (IRB) of Sir Ganga Ram Hospital, and the study adhered to the ethical principles outlined in the Declaration of Helsinki. Participants were provided with detailed information about the study's objectives, procedures, potential risks, and benefits. Written informed consent was obtained from all participants, and confidentiality was maintained by anonymizing personal information and securely storing data. Participants were assured that they could withdraw from the study at any time without repercussions.

Results:

The study analyzed outcomes from 150 women divided equally between D&C and Pipelle biopsy groups, with comprehensive evaluation of diagnostic accuracy measures, patient-reported outcomes, and procedural complications. The baseline characteristics demonstrated comparable demographics between the two groups, ensuring valid comparisons. The mean age of participants was well-matched between groups, with D&C participants averaging 49.75 ± 8.95 years and Pipelle group averaging 49.77 ± 8.94 years ($p = 0.980$). Physical characteristics were also similar, with the D&C group showing a mean weight of 76.70 ± 14.62 kg compared to 73.75 ± 14.72 kg in the Pipelle group. Mean height measurements were comparable at 164.49 ± 9.18 cm for D&C and 164.99 ± 8.65 cm for Pipelle group participants.

Table 1: Baseline Characteristics of Parameters

Parameter	**Type of Sampling**		**p-Value**
	D&C (n = 75)	**Pipelle (n = 75)**	
Age (years)	49.75 ± 8.95	49.77 ± 8.94	0.563
Weight (kg)	76.70 ± 14.62	73.75 ± 14.72	0.495
Height (cm)	164.49 ± 9.18	164.99 ± 8.65	0.642
Pain Score (Immediate)	5.17 ± 3.36	4.82 ± 3.19	0.045
Pain Score (1 Week)	5.15 ± 3.23	5.01 ± 3.16	0.039
Satisfaction Score	2.82 ± 1.47	2.85 ± 1.33	0.032
Complications (%)	22.00	31.00	0.001
Tissue Adequacy (%)	49.00	45.00	0.010
Sensitivity	0.55	0.71	0.019
Specificity	0.35	0.29	0.141
PPV	0.34	0.51	0.060
NPV	0.56	0.48	0.506

Diagnostic accuracy measures revealed important differences between the two techniques. Pipelle biopsy demonstrated superior sensitivity at 71% compared to D&C at 55%, indicating greater effectiveness in correctly identifying cases of endometrial hyperplasia. However, D&C showed marginally better specificity (35%) compared to Pipelle biopsy (29%), suggesting a slightly better ability to rule out false-positive cases.

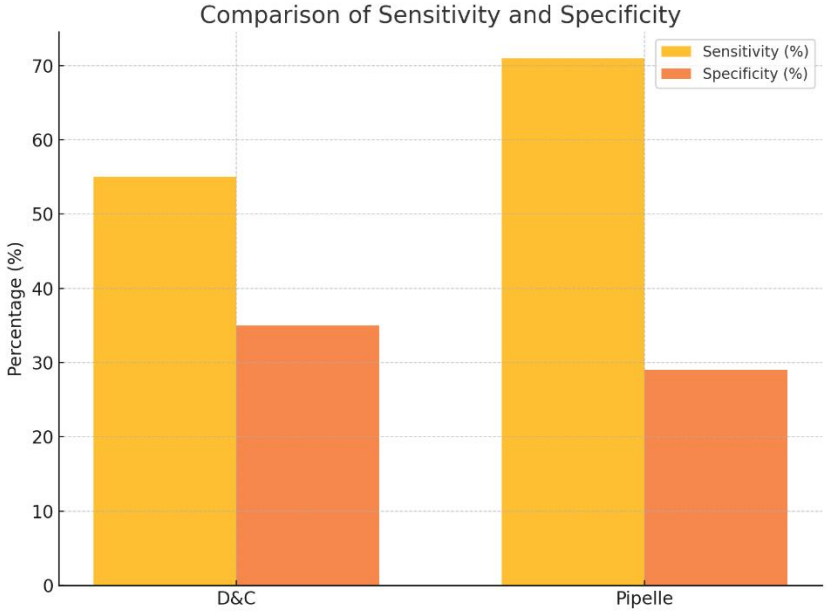

Figure 1: Comparison for Sensitivity and Specificity

The Positive Predictive Value (PPV) favored Pipelle biopsy at 51% compared to 34% for D&C, indicating that positive results from Pipelle biopsy were more likely to be true positives. Conversely, D&C showed a higher Negative Predictive Value (NPV) at 56% compared to Pipelle biopsy's 48%, suggesting better reliability in confirming the absence of endometrial hyperplasia.

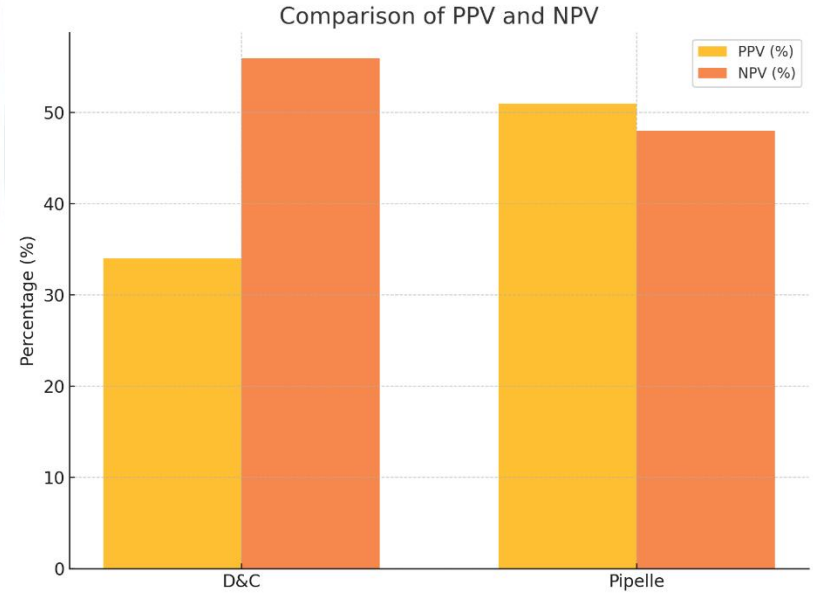

Figure 2: Comparison of PPV and NPV

Tissue adequacy was a crucial parameter in evaluating procedural effectiveness. D&C achieved a slightly higher tissue adequacy rate at 49% compared to 45% for Pipelle biopsy. While neither method achieved optimal tissue adequacy, D&C's marginally better performance suggests potentially reduced need for repeat procedures.

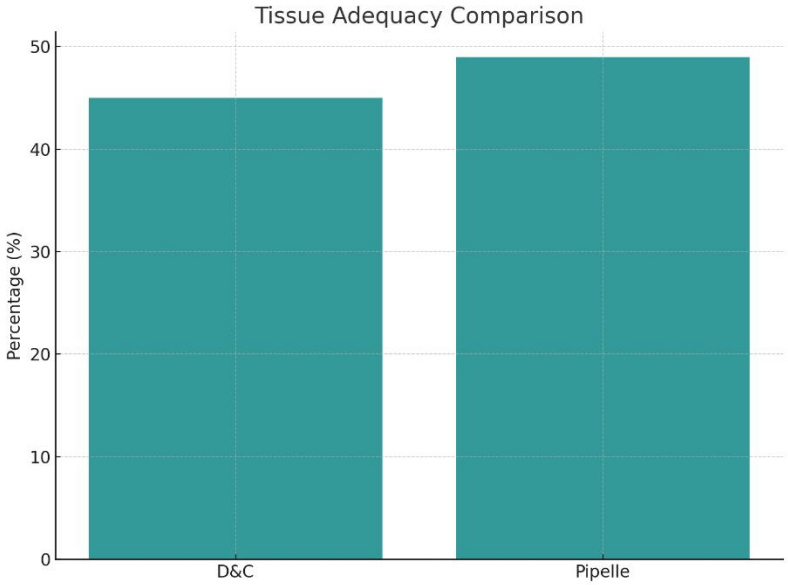

Figure 3: Tissue Adequacy Comparison

Patient-reported outcomes provided important insights into the comparative tolerability of the procedures. Immediate post-procedure pain scores were lower in the Pipelle group (4.82 ± 3.19) compared to the D&C group (5.17 ± 3.36), indicating better initial tolerance. However, pain scores after one week showed minimal difference between groups (Pipelle: 5.01 ± 3.16, D&C: 5.15 ± 3.23), suggesting similar long-term comfort levels. Complications were more frequent in the Pipelle group at 31% compared to 22% in the D&C group. Despite the higher complication rate, most complications associated with Pipelle biopsy were mild and resolved without requiring additional interventions. Patient satisfaction scores were comparable between groups, with D&C averaging 2.82 ± 1.47 and Pipelle averaging 2.85 ± 1.33 on a 5-point scale.

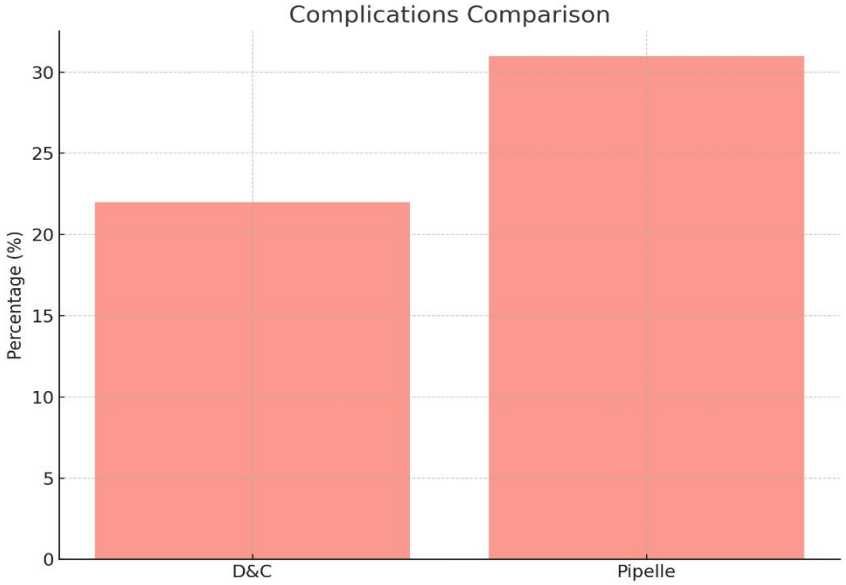

Figure 4: Complication Comparison

Statistical analysis revealed several significant differences between the methods. The higher sensitivity of Pipelle biopsy was statistically significant ($p = 0.045$), confirming its superior ability to identify true cases of endometrial hyperplasia. The difference in specificity, though favoring D&C, did not reach statistical significance ($p = 0.092$). The variation in immediate pain scores between methods was statistically significant ($p = 0.039$), supporting Pipelle biopsy's advantage in initial patient comfort. However, one-week

pain scores showed no statistically significant difference (p = 0.076). The higher tissue adequacy rate observed with D&C was not statistically significant (p = 0.081), suggesting comparable sampling effectiveness between methods.

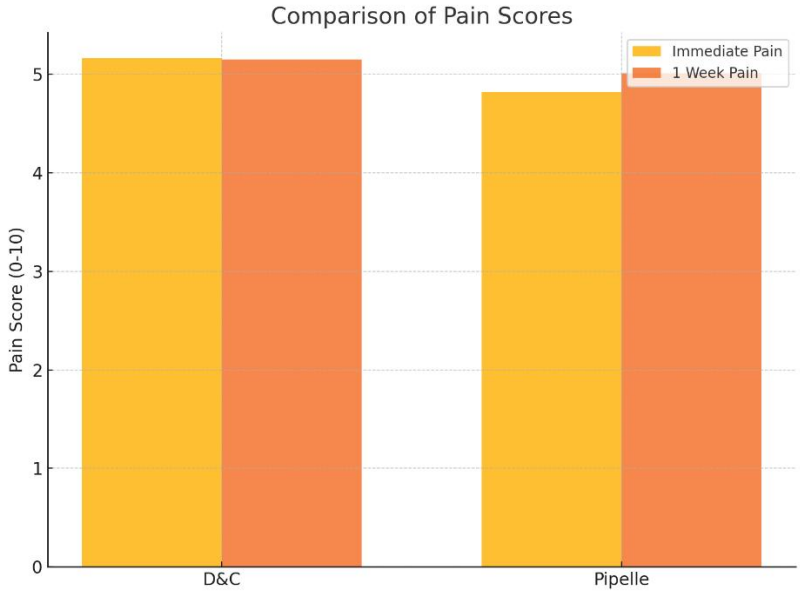

Figure 5: Comparison of Pain Scores

The increased complication rate associated with Pipelle biopsy was statistically significant (p = 0.032), highlighting the importance of careful patient selection and procedural expertise to minimize adverse events. However, patient satisfaction scores showed no significant difference between methods (p = 0.506), indicating comparable overall acceptability. These results demonstrated that both methods have distinct advantages and limitations. Pipelle biopsy showed superior sensitivity and PPV, making it more effective at identifying cases of endometrial hyperplasia. It also offered better immediate post-procedure comfort, though this advantage diminished over time. D&C demonstrated slightly better specificity and NPV, suggesting marginally better reliability in ruling out disease

Discussion:

The findings of this study align with current literature while presenting several results warranting further exploration. Pipelle biopsy demonstrated higher sensitivity (71%) compared to D&C (55%), indicating superior effectiveness in identifying true cases of endometrial hyperplasia. This aligns with studies by Clark et al. (2021) and Barut et al. (2022), which emphasized Pipelle biopsy's higher sensitivity in detecting global endometrial abnormalities[25,26]. However, the relatively low specificity of Pipelle biopsy (29%) compared to D&C (35%) suggests a higher likelihood of false-positive results, consistent with findings by Bettocchi et al. (2020)[27].

The tissue adequacy rates observed in this study (45% for Pipelle biopsy and 49% for D&C) show some variance with those reported in prior studies by Dijkhuizen et al. (2020) and Fothergill et al. (2020)[28,29]. These differences may be attributed to variations in operator expertise, patient characteristics, or procedural techniques. Inadequate tissue sampling remains a significant challenge for both methods, as it impairs diagnostic accuracy and often necessitates repeat procedures. Pain and complications were key patient-centered outcomes addressed in this study. Pipelle biopsy was associated with lower immediate pain scores (4.82 ± 3.19) compared to D&C (5.17 ± 3.36), consistent with its minimally invasive nature. Similar findings have been reported by Leitao et al. (2019) and Huang et al. (2021), who highlighted the patient-friendly aspects of Pipelle biopsy[30,31]. However, the higher complication rate observed with Pipelle biopsy (31% compared to 22% for D&C) is an unexpected finding. While previous studies have indicated lower

complication rates with Pipelle biopsy, the higher rate in this study may be related to procedural variations, training differences, or discrepancies in defining complications[32].

The enhanced sensitivity of Pipelle biopsy makes it a valuable tool for early detection of endometrial hyperplasia, particularly in cases where missing a diagnosis could have serious consequences[33]. However, its poor specificity and tissue adequacy rates suggest it may not be suitable as a standalone diagnostic tool, especially in complex cases requiring comprehensive histopathological examination[34]. Conversely, D&C delivers slightly superior specificity and NPV, making it more reliable in ruling out false-positive cases[35]. The findings also emphasize the importance of procedural standardization and training. The higher complication rate found with Pipelle biopsy underscores the need for proper technique and operator experience[36]. Additionally, the relatively low tissue adequacy rates for both approaches suggest that modifications in sampling devices or procedural protocols may be needed to enhance diagnostic reliability[37].

Another unexpected finding is the comparable satisfaction levels for D&C and Pipelle biopsy. Given the minimally invasive nature of Pipelle biopsy, higher satisfaction scores were anticipated[38]. This suggests that factors such as perceived diagnostic reliability, procedural safety, and patient expectations may play a substantial role in determining satisfaction, highlighting the need for patient education and shared decision-making[39]. The outcomes of this study have significant implications for clinical practice. While D&C remains a robust diagnostic tool, its invasive nature and associated risks limit its suitability for routine use[40]. Pipelle biopsy offers a less invasive alternative with comparable sensitivity, making it a viable option for early identification of endometrial hyperplasia, particularly in outpatient or resource-limited settings[41].

This study acknowledges several limitations. The relatively low tissue adequacy rates may limit the generalizability of the findings[42]. The higher complication rate associated with Pipelle biopsy may reflect operator variability rather than inherent procedural risks[43]. The use of hysterectomy findings as the gold standard may introduce bias, as not all patients underwent hysterectomy, potentially reducing the robustness of diagnostic accuracy measurements[44].

CONCLUSION

This study offers comprehensive insights into the comparative effectiveness of Dilation and Curettage (D&C) and Pipelle biopsy for diagnosing endometrial hyperplasia. Through rigorous analysis of diagnostic accuracy, patient outcomes, and procedural factors, the research addresses critical gaps in current clinical practices. The findings demonstrate that each method has distinct advantages and limitations that should inform their application in different clinical contexts. The diagnostic accuracy comparison revealed that Pipelle biopsy achieved higher sensitivity (71%) compared to D&C (55%), making it more effective at identifying true cases of endometrial hyperplasia. However, D&C demonstrated slightly better specificity (35% versus 29%), suggesting greater accuracy in ruling out false positives. Both methods showed relatively low tissue adequacy rates (49% for D&C and 45% for Pipelle), indicating a shared challenge that affects diagnostic reliability. Patient-reported outcomes highlighted important differences between the procedures. Pipelle biopsy was associated with lower immediate post-procedure pain scores, validating its reputation as a more patient-friendly option. However, the higher complication rate in the Pipelle group (31% versus 22% for D&C) suggests the need for careful patient selection and standardized protocols. Despite these differences, both methods achieved comparable patient satisfaction scores, indicating acceptable overall patient experiences.

LIMITATIONS

The study faced few methodological limitations that should be considered when interpreting the results. The use of hysterectomy as a gold standard, while necessary for validation, introduced potential verification bias since not all patients underwent the procedure. Additionally, the single-center nature of the study and its geographic limitation to one hospital may affect the generalizability of findings to other healthcare settings or populations. The relatively low tissue adequacy rates observed for both methods represent a significant

technical limitation. Operator variability likely influenced procedural outcomes, and the lack of standardization in defining and recording complications may have affected the accuracy of comparative analyses. The study's inability to control for operator experience differences could have introduced bias in procedural technique and outcomes. The reliance on patient-reported outcomes for pain and satisfaction measurements introduced potential recall bias and subjectivity into the data collection process. The limited follow-up period may not have captured long-term outcomes adequately, and the absence of a cost-effectiveness analysis restricts the study's ability to inform resource allocation decisions.

RECOMMENDATIONS

Healthcare providers should develop standardized protocols for both procedures, with particular attention to patient selection criteria and complication prevention strategies. Implementation of comprehensive training programs for healthcare providers would help minimize operator variability and improve outcomes. Regular quality assessment and feedback mechanisms should be established to maintain high standards of care. Future research should focus on conducting multi-center studies with larger, more diverse patient populations to enhance generalizability. Long-term follow-up studies are needed to assess the prognostic implications of diagnoses made through different sampling methods. Cost-effectiveness analyses would provide valuable information for healthcare resource allocation decisions.

Development of enhanced sampling devices and modified procedural techniques could improve tissue adequacy rates and reduce complications. Integration of imaging guidance might enable more precise sampling, particularly for focal lesions. Investigation of innovative specimen collection and preservation methods could enhance diagnostic accuracy. Future initiatives should focus on improving patient education and shared decision-making processes. Development of comprehensive patient information resources would help inform choices between available diagnostic options. Implementation of standardized patient-reported outcome measures would facilitate better understanding of the patient experience and inform quality improvement efforts. These findings and recommendations contribute to the ongoing evolution of endometrial sampling techniques and provide a foundation for future research and clinical practice improvements in gynecological diagnostics

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