

Original Research

To compare the diagnostic accuracy of endometrial aspiration biopsy using Pipelle device in comparison with dilatation and curettage

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ABSTRACT

Aim: To compare the diagnostic accuracy of endometrial aspiration biopsy using Pipelle device in comparison with dilatation and curettage.

Materials and Methods: This interventional comparative study was conducted in the Department of Obstetrics and Gynecology between September 2023 and August 2024. The study included a total of 70 patients diagnosed with abnormal uterine bleeding (AUB), all of whom provided written informed consent. Ethical committee approval was obtained prior to the initiation of the study. Endometrial sampling was performed using two different techniques: 45 patients underwent sampling using a Pipelle device, while the other 45 patients were subjected to a dilatation and curettage (D&C) procedure. Both samples (Pipelle and D&C) were sent to a histopathologist, who was blinded to the method of sample collection. The histopathological findings from both procedures were then compared.

Results: The sensitivity rating for Pipelle biopsy in detecting simple hyperplasia without atypia came to 80.0% while the specificity rating was 86.9% and the accuracy rating reached 83.9%. The significant P value and strong correlation suggests that the Pipelle biopsy produces results comparable to D&C biopsy when determining simple hyperplasia without atypia. The sensitivity score for Pipelle biopsy tests reached 100% and the specificity score reached 97.4% when evaluating patients with proliferative endometrium and led to a P value of <0.001 which indicates flawless agreement with D&C biopsy results for this condition. The sensitivity and specificity of 100% marked both Pipelle and D&C biopsies in endometrial carcinoma diagnosis since their accuracy reached 100% with a virtually sure P value (<0.001).

Conclusion: Endometrial sampling with pipelle device is safe and easy method for diagnosis which can be done as an outpatient procedure. Pipelle is cost effective and better patient compliance with advantage of no anesthesia or other complications like perforation compared to D&C.

Keywords: Endometrial aspiration biopsy, Pipelle, Dilatation, curettage

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Introduction

Abnormal Uterine Bleeding (AUB) is one of the common disorders in gynecology and accounts for more than 70% of gynecological consultations among perimenopausal and postmenopausal women.¹⁻

³Endometrial assessment is indicated at the age of 40 years to exclude endometrial hyperplasia or

carcinoma as less than 1% endometrial carcinoma occur under 35 years and 6% in those with less than 45 years. Endometrial assessment in AUB includes the various diagnostic modalities mainly USG, endometrial curettage and office based methods including biopsy by hysteroscopy or endometrial sampling such as Pipelle.⁴⁻⁶ D&C gold standard for

endometrial sampling but in 60% of cases less than half of uterine cavity is curetted, with added risk of complications of general anesthesia, infections, perforation.^{7,8} Pipelle does not require a general anesthesia and pump or cervical dilation and permits almost painless endometrial sampling. Pipelle can be used on outpatient basis and it is cost effective as compared with D&C.⁹⁻¹¹ This study is being conducted to assess and compare the diagnostic accuracy of Pipelle & D & C in patient with AUB.

Materials and Methods

This interventional comparative study was conducted in the Department of Obstetrics and Gynecology between September 2023 and August 2024. The study included a total of 70 patients diagnosed with abnormal uterine bleeding (AUB), all of whom provided written informed consent. Ethical committee approval was obtained prior to the initiation of the study.

A detailed clinical assessment was performed for each patient in the outpatient department. This assessment included a thorough history, physical examination, and baseline investigations. A transvaginal sonography (TVS) was conducted for all patients before performing the endometrial biopsy. The uterus was scanned in both sagittal and longitudinal projections using a 5.0- to 7.5-MHz vaginal transducer. The thickest anteroposterior diameter of the endometrial stripe was measured in the sagittal plane with digital calipers, and the endometrial thickness was recorded.

Endometrial sampling was performed using two different techniques: 45 patients underwent sampling using a Pipelle device, while the other 45 patients were subjected to a dilatation and curettage (D&C) procedure. The Pipelle device, a flexible, thin instrument with inbuilt suction, was used for endometrial sampling. After inserting the device, the inner piston was withdrawn to create suction, allowing for the collection of a sample by rotating the cannula. A strip of endometrium was peeled off and sucked into the syringe for histopathological analysis.

In cases where the Pipelle procedure was performed in the outpatient department, the patients were transferred to the operating theater for the D&C procedure, where general anesthesia was administered. The procedure involved dilatation of the cervix using Hegar's dilators, followed by the introduction of a small sharp curette for gentle sampling of all parts of the uterine cavity.

Both samples (Pipelle and D&C) were sent to a histopathologist, who was blinded to the method of sample collection. The histopathological findings from both procedures were then compared.

Statistical analysis was performed using SPSS software, with appropriate tests applied to assess the significance of the findings.

Inclusion Criteria

- Reproductive women
- Peri-menopausal women
- Post-menopausal women presenting with AUB

Exclusion Criteria

- Pregnancy
- Patients with lower genital tract infections
- Pelvic inflammatory disease
- Clotting disorders or coagulopathy
- Carcinoma of the cervix
- Hormonal Replacement Therapy
- Adnexal masses or lesions

RESULTS

According to Table 1 the samples gathered by Pipelle from 45 patients demonstrated appropriate adequacy levels. Histopathological assessment of the samples proved suitable for 42 patients among the total subject group of 45, representing 93.3% of the group while 4.4% had inadequate specimens. The clinical procedure resulted in one insufficient sample that prevented adequate analysis for a total of 45 patients. The data shows that the Pipelle device successfully obtains dependable endometrial tissue suitable for analysis because most obtained samples were sufficient.

The adequacy assessment of endometrial tissue from D&C procedures appeared in Table 2 among 45 medical patients undergoing this procedure. Out of 45 patients undergoing medical procedures, 43 patients (95.5%) received adequate sample collection while no participants recorded scanty specimens. The samples collected by Pipelle revealed inadequate results in 2 patients among the 45 treated individuals (4.4%). The majority of endometrial samples collected by D&C methods met standards for histopathological examination although the samples proved slightly more adequate than those obtained with Pipelle.

Data pertaining to the histopathological results from both Pipelle and D&C biopsy procedures are presented in Table 3. Both survey methods found "simple hyperplasia without atypia" as the most common result which occurred in 53% of the patients using Pipelle and in 57% of patients undergoing D&C testing. Ten patients (22.2%) among those undergoing Pipelle sampling underwent diagnosis of "disordered proliferative endometrium" while eight patients (17.7%) received this result from D&C testing. The medical examination of "Proliferative endometrium" revealed 5 cases (11.1%) when using Pipelle samples and then a diagnosis of 6 cases (13.3%) with D&C samples. Endometrial polyp existed in 2 patients (4.4%) who underwent both Pipelle aspiration and D&C procedures. Patients belonging to both groups presented an equal case (2.2%) of "endometrial carcinoma." Both Pipelle samples and D&C samples exhibited hormonal effects on two patients (4.4% in Pipelle and 2.22% D&C). The "others" category included no reported findings in the analysis of the

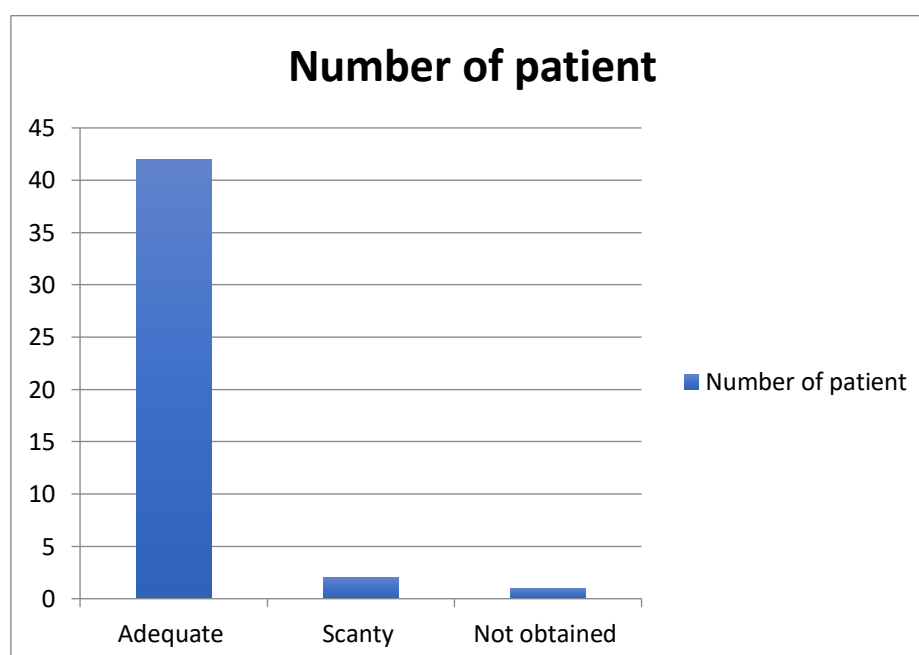
two groups. The histopathological data collected by using Pipelle and D&C techniques were equivalent while showing slight differences in result frequencies. The research presents Table 4 to analyze key performance indicators between Pipelle and D&C biopsy tests including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy together with P values when assessing various histopathological findings. The sensitivity rating for Pipelle biopsy in detecting simple hyperplasia without atypia came to 80.0% while the specificity rating was 86.9% and the accuracy rating reached 83.9%. The significant P value and strong correlation suggests that the Pipelle biopsy produces results comparable to D&C biopsy when determining simple hyperplasia without atypia. Disordered proliferative endometrium yielded limited success with Pipelle biopsy because its sensitivity stood at 57.1% but it achieved successful specificity at 86.6% which corresponded to a PPV of 47.1% alongside an NPV of 90.6%. The statistical

significance of the P value at 0.002 indicates strong evidence of relationship between both testing methods but Pipelle shows inferior detection outcomes compared to other results.

The sensitivity score for Pipelle biopsy tests reached 100% and the specificity score reached 97.4% when evaluating patients with proliferative endometrium and led to a P value of <0.001 which indicates flawless agreement with D&C biopsy results for this condition. The sensitivity rate of Pipelle biopsies stood at 42.9% when detecting endometrial polyps but their specificity rate reached 94.6%. The probability values showed PPV at 42.9% alongside NPV at 95.6% with P value of 0.007. The detection of endometrial polyps through Pipelle procedure shows moderate outcomes that demonstrate stronger specificity but less sensitive performance. The sensitivity and specificity of 100% marked both Pipelle and D&C biopsies in endometrial carcinoma diagnosis since their accuracy reached 100% with a virtually sure P value (<0.001).

Table 1. Adequacy in pipelle

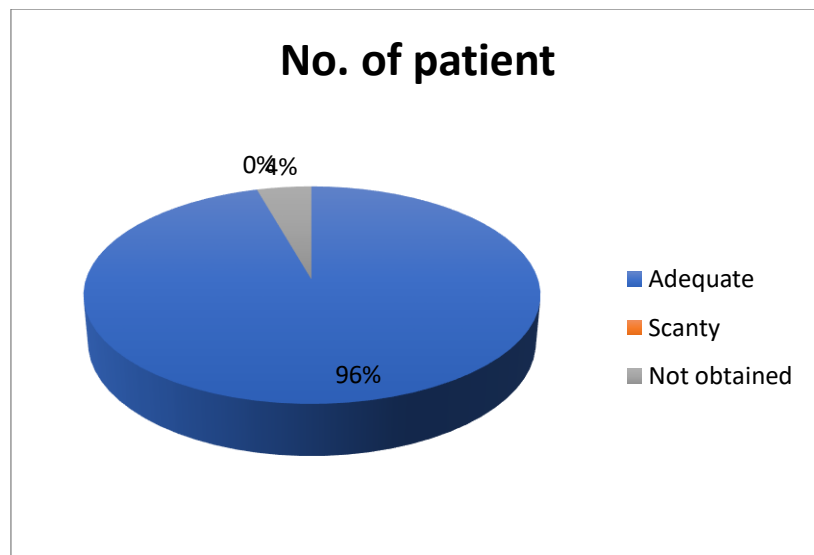
Adequacy in pipelle	Number of patient	%
Adequate	42	93.3
Scanty	2	4.4
Not obtained	1	2.2
Total	45	100



Graph 1. Adequacy in pipelle

Table 2. Adequacy in D&C

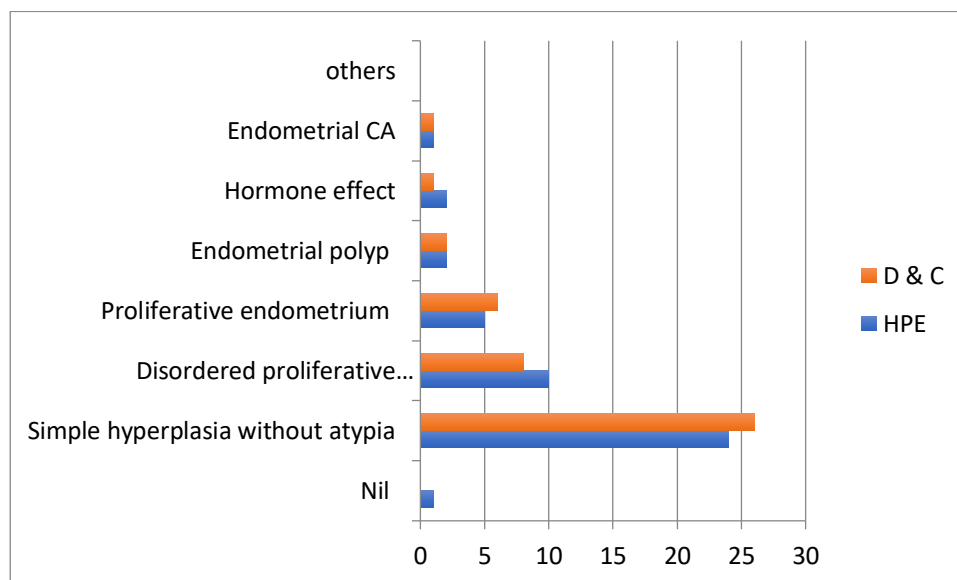
Adequacy in D & C	No. of patient	%
Adequate	43	95.5
Scanty	0	0
Not obtained	2	4.4
Total	45	100



Graph 2. Adequacy in D&C

Table 3. Comparison of pipelle HPE and D & C

Finding	Number	Percentage	Number	Percentage
Nil	1	2.2	0	0
Simple hyperplasia without atypia	24	53	26	57
Disordered proliferative endometrium	10	22.2	8	17.7
Proliferative endometrium	5	11.1	6	13.3
Endometrial polyp	2	4.44	2	4.4
Hormone effect	2	4.44	1	2.22
Endometrial CA	1	2.2	1	2.22
others	0	0	0	0



Graph 3. Comparison of pipelle HPE and D & C

Table 4. Correlation of pipelles HPE in comparison with D&C HPE

Findings	Sensitivity	Specificity	PPV	NPV	Accuracy	P value
Simple hyperplasia without atypia	80.0	86.9	82.3	85.1	83.9	<0.001
Disordered proliferative endometrium	57.1	86.6	47.1	90.6	81.5	0.002
Proliferative Endometrium	100.0	97.4	71.4	100.0	97.5	<0.001

Endometrial polyp	42.9	94.6	42.9	95.6	90.1	0.007
Endometrial CA	100	100	100	100	100	<0.001

Discussion

Many authors concluded that the Pipelle is an accurate and acceptable outpatient sampling technique when compared with D&C. In this study, the Pipelle device had 97% sensitivity, 100% specificity and 100% predictive values in obtaining the endometrial sample, also it was 100% accurate for diagnosing proliferative and secretory endometrium and also endometrial carcinoma. Mechado and colleagues reviewed 1535 reports of endometrial biopsies taken from outpatients using the Cornier Pipelle, in pre- and postmenopausal patients with abnormal vaginal bleeding, to establish the accuracy of endometrial biopsy with the Cornier Pipelle in the diagnosis of endometrial cancer and atypical endometrial hyperplasia.¹² The Cornier Pipelle was 84.2% sensitive, 99.1% specific, 96.9% accurate, with 94.1% PPV and 93.7% NPV for detection of endometrial carcinoma and atypical hyperplasia and they concluded that endometrial biopsy taken with the Cornier Pipelle is an accurate method for diagnosis of endometrial cancer and its precursor atypical hyperplasia. A meta-analysis to assess the accuracy of endometrial sampling devices in detection of endometrial carcinoma and atypical hyperplasia was done by Dijkhuijzen et al.¹³ They concluded that the endometrial biopsy with the pipelle is superior to other endometrial techniques in detection of endometrial carcinoma and atypical hyperplasia in pre- and postmenopausal women. In the study by Abdelazim et al.¹⁴, The pipelle and D & C were compared and the authors reported 100% sufficient sample in conventional D & C and 97.7% for pipelle that is higher by both methods in comparison to our study. It may be due to different techniques and instruments and also pathologist's experience. In a study by Naderi and colleagues¹⁵ the sufficiency rates were 91.6% and 98.3% by pipelle and D & C respectively. These are higher sufficient rates than our study. The study by Mousavifar et al.¹⁶ reported 94% sufficiency rate for pipelle samples that is more than results of this study. The other studies (Behnarnfiar et al, 2004; Fakhar et al, 2008; Bano et al, 2011)¹⁷⁻¹⁹ were also reported better rates for both pipelle and D & C in comparison with our study. A significant number of cases showed disordered proliferative pattern in this study. Disordered proliferative pattern lies at one end of the spectrum of proliferative lesions of the endometrium that includes carcinoma at the other end with intervening stages of hyperplasias. The term "disordered proliferative endometrium" has been used in a number of ways and is somewhat difficult to define. It denotes an endometrial appearance that is hyperplastic but without an increase in endometrial volume.²⁰ It also refers to a proliferative phase endometrium that does not seem appropriate for any one time in the menstrual cycle, but is not abnormal enough to be considered hyperplastic. Disordered

proliferative pattern resembles a simple hyperplasia, but the process is focal rather than diffuse.

In the present study incidence of carcinoma endometrium was more common in the 51-60 years age group. The result of this study was almost similar to data mentioned by Yusuf et al. and Escoffery et al. in their study.^{21,22}

Conclusion

Endometrial sampling with pipelle device is safe and easy method for diagnosis which can be done as an outpatient procedure. Pipelle is cost effective and better patient compliance with advantage of no anesthesia or other complications like perforation compared to D&C. The accuracy for histopathological diagnosis is good if sample is adequate, hence it can be used as a first line method for endometrial sampling. Additional diagnostic methods need to be applied if sample obtained is inadequate for histological examination.

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