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Comparison Between Pipelle Endometrial Sampling and Dilatation and Curettage Among Women with Abnormal Uterine Bleeding

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Abstract

Background and objectives: Abnormal uterine bleeding is one of the most widespread gynecological complaints that necessitate endometrial biopsy. Obtaining a sufficient specimen allowing a histopathological diagnosis is as important as patients' safety. The purpose of the study was to compare the efficiency of pipelle device to dilatation and curettage in obtaining high-quality endometrial tissue for histopathological analysis.

Methods: A prospective cohort study of 57 patients presented with Abnormal uterine bleeding from June 1st, 2022 to June 1st, 2023. The endometrial sampling was ~~a~~ccomplished using the pipelle gadget without first performing cervical dilatation. The same patient then underwent conventional Dilatation and Curettage to obtain a second sample. The Dilatation and curettage report was used as a reference when comparing the Pipelle sample's histopathology reports to those of the Dilatation and curettage sample.

Results: The pipelle's sensitivity was 81.3%, specificity was 100%, with a 100% positive predictive value which makes the accuracy 94.7% in diagnosing secretory endometrium. Furthermore, for proliferative endometrium, it showed a sensitivity, specificity, PPV, and NPV of 100%,98.1%, 75%, and 100% respectively making the accuracy 96.5%. while for hyperplasia without atypia and disordered endometrium, the accuracy was 98.2%. The analysis showed that the histopathology results of the pipelle were in concordance with the results obtained by Dilatation and Curettage, with a p-value of less than 0.001.

Conclusion: The results obtained by pipelle are almost as accurate as Dilatation and curettage, so it can be used in the first-line diagnosis of endometrial biopsy.

Keywords: Dilatation and curettage, Endometrial tissue, Histopathology, Pipelle.

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Introduction

Abnormal uterine bleeding (AUB) stands out as a prevalent concern in gynecology, impacting approximately 70% of women throughout their lifetime from menarche until after menopause.[1] It is identified by bleeding patterns that deviate from the norms observed in a regular menstrual cycle, including variations in frequency, duration, and volume. Or any bleeding after menopause.[2] Nearly 30% of outpatient clinic attendance in the reproductive age group is attributable to AUB.[3] It is crucial to assess AUB in women over 35 or during menopause to confirm whether the condition is benign and rule out intrauterine pathology, especially endometrial cancer. [4] The precursor lesions of endometrial carcinoma can be correctly diagnosed through endometrial biopsy and histopathological evaluation.[5] For women with AUB or postmenopausal hemorrhage who exhibit risk factors for endometrial cancer, the American College of Obstetricians and Gynecologists (ACOG) advises employing ultrasound and endometrial sampling. [6] Dilatation and curettage (D&C) has been the gold standard for sampling of the endometrium for many decades, but in 60% of the cases, the sample taken by curetting was even less than 50% of the uterine cavity. Despite this, the patient must go through hospital admission and general anesthesia in the operation theatre, which has made the procedure costly and less desirable. [7] There is also an added risk of infection, cervical laceration, and perforation of the uterine cavity.[8, 9] As a result, new and simpler methods have emerged for taking samples from the endometrium. Many devices are now available, including the pipelle device.[10] The pipelle device is a flexible polypropylene tube that has a suction mechanism, there is no need for dilatation, the tube is pushed directly into the endometrial cavity through the cervix, which makes it suitable for outpatient settings.[11] For the past twenty years, the pipelle (aspiration) for sampling of the endometrium has been utilized for the assessment of AUB. Its importance is that there is not any form of anesthesia or hospital stay and it can be done in an outpatient clinic setting. [3,5] The office procedures are more convenient, cheaper, and with fewer side effects in comparison to D&C.[7] However, the pipelle biopsy has not been well-studied in Sulaimania maternity hospital and it is not commonly used, because most endometrial tissue evaluations are performed using D&C. Concerns persist about the adequacy of the obtained sample, specifically the inability to capture lesions that are focal and uncertainties surrounding the precision of the histopathology report for the sampled tissue. Therefore, this study aimed to investigate the histopathology results obtained by the pipelle biopsy in comparison to the histopathology results confirmed by the D&C to evaluate the efficacy, sensitivity, and specificity of the pipelle endometrial biopsy.

Patients and Methods

A prospective cohort study was carried out from June 1st, 2022 to June 1st, 2023 on 57 patients who had an abnormal uterine hemorrhage and were admitted to Sulaimani Maternity Teaching Hospital. After the approval of the study proposal by the ethical committee of the Kurdistan Higher Council of Medical Specialties (KHCMS) (No.1391 on August 14, 2022). The participants gave verbal and written informed consent for participation in the study. They were also given the right to refuse participation for any reason. The inclusion criteria were patients 35 years of age and above presented with AUB or less than 35 years that have risk factors of endometrial cancer and postmenopausal bleeding of any quantity. While patients with any pregnancy-associated bleeding, local infection, bleeding disorders and use of anticoagulants, and ultrasound findings of endometrial thickness

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less than 4 and suspicion of polyp were set as the exclusion criteria for this study. Patients were assessed thoroughly including taking a detailed history to record the demographic features including age, body mass index residency, menarche, parity, history of PCOS, infertility, use of hormonal treatment, any associated medical disease, and family history of malignancy mainly endometrial, ovarian and cervical cancer. Examination, and investigations, including a pelvic ultrasound. At first, the pipelle device was inserted without dilatation of the cervix and taken out from the uterine cavity in a rotating manner to obtain the required amount of endometrium for sampling and then followed by obtaining another sample from the same patient by the standard D&C. The samples were assigned different labels and submitted to a pathologist, who didn't know about the way the samples were taken to provide a true histopathological evaluation. The histopathology reports of the Pipelle samples were then put in comparison to those of the D&C samples, with the reports from the D&C serving as the reference standard. Prior to data entry and analysis, the study's questions were coded after data collection. An Excel spreadsheet was used for data entry, and the IBM SPSS Statistical Package for the Social Sciences, version 24.0 software was used for statistical analysis. The data presented in tabular forms shows the frequency and relative frequency distribution of different variables among both groups. Chi-square tests were used to compare the categorical data between the two ways of diagnosis (Curettage and pipelle. Cross tabulation was done between the two forms of diagnosis to calculate the sensitivity, specificity, and accuracy of pipelle in respect to gold standard method (Curettage).
The threshold for statistical test significance was set at p-values of 0.05.

Results

Based on demographic data shown in Table (1), the mean age of the studied patients was 45± 12 years. Almost half of the patients were between 35-45 and the other half were between 46-57. While the mean of their BMI was 28±2.9, 61.4% of them were in the overweight category, 31.6% were obese and only 7% of them were in the normal weight category. Two-thirds of the patients were from urban residences. Regarding parity, 61.4% of the cases were P_2 to P_4. There weren't any nulliparous patients included in our study.

Table (1): Demographic Characteristics of the Studied Patients.

Variables	mean± SD	(n)	(%)
Age (years)	45.28 ± 12.8		
35 - 45		28	49.1%
46 - 57		29	50.9%
BMI (kg/m^2)	28.75 ± 2.90		
20 - 24.99 (normal)		4	7.0%
25 - 29.99 (overweight)		35	61.4%
30 and more (Obese)		18	31.6%
Residency			
Rural		19	33.3%
Urban		38	66.7%
Parity			
P1		2	3.5%
P2 – P4		35	61.4%
P5 and more		20	35.1%

n (%): number and percentage of the patients.

Table (2) describes the past medical of the patients. The mean age of menarche was 12.94±0.23, menarche of 63.2% of the participants were 11-12 years. 36.8% of them were 13-15 years. 84.2% of them didn't have history of PCOS, and only 9 patients had history of PCOS. Most of the patients didn't have history of infertility 93%. Regarding the

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use of hormonal treatment, 64.9% of them were not using any hormonal treatment. 21.1% had a history of using combined oral contraceptive pills, 7% of them were on progesterone mostly for control of menorrhagia, and 4 patients had history of using treatment for infertility. Patients were asked about associated medical diseases. 6 patients had diabetes mellitus, 11 were hypertensive and 1 patient had hypothyroidism.

Table (2): This Table Describes the Past Medical History of the Patients.

Variables	N	%
Age of menarche (years)		
Mean ± SD	12.94± 0.23	
11 - 12	36	63.2%
13 - 15	21	36.8%
History of PCOS		
Positive	9	15.8%
Negative	48	84.2%
History of infertility		
Positive	4	7.0%
Negative	53	93.0%
History of hormonal treatment		
Nil	37	64.9%
Combined Contraceptive Pills	12	21.1%
Progesterone	4	7.0%
Ovulation induction drugs	4	7.0%
Medical diseases		
None	39	68.4%
Diabetes Mellitus	6	10.5%
Hypertension	11	19.3%
Hypothyroidism	1	1.8%
Total	57	100.0%

n (%): number and percentage of the patients.

All the patients underwent pelvic ultrasound and their endometrial thickness was measure. As shown in Table (3), the mean was 11.04± 3.89. 47.4% of them had an endometrial thickness between 5-10 mm, 38.6% of the ET was between 11-14 mm, and 14% of them was between 15-29mm.

Table (3): Endometrial Thickness by US.

	Frequency	Percentage
Endometrial thickness by US (mm)		
Mean ± SD	11.04 ± 3.89	
5 - 10	27	47.4%
11 – 14	22	38.6%
15 - 29	8	14.0%
Total	57	100%

Table (4) presents a comparison of the HPE data obtained by D&C and pipelle sampling. Proliferative endometrium was the most common finding in both pipelle sample and D&C, followed by secretory and disorganized proliferative endometrium. Only D&C was able to identify the polyp; pipelle sampling was unable to do so. In pipelle sampling, the percentage of patients unable to collect a sample was 10.5%, while in D&C, it was 1.8%.

Table (4): The Comparison of the HPE Results Obtained by Pipelle Sampling and D&C

Result of HPE	By D&C (n)	By pipelle (n)	By D&C (%)	By pipelle (%)
Atrophic	2	2	3.5%	3.5%
Proliferative endometrium	25	23	43.9%	40.4%
Secretory endometrium	16	13	28.1%	22.8%
Disordered proliferative	7	8	12.3%	14%
Polyp	1	0	1.8%	0%
Hyperplasia with atypia	2	1	3.5%	1.8%
Hyperplasia without atypia	3	4	5.3%	7.0%
Inconclusive	1	6	1.8%	10.5%
Total	57	57	100%	100%

n (%): number and percentage of the patients.

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In this study, the pipelle has 81.3% sensitivity, 100% specificity, and a 100% positive predictive value which makes the accuracy 94.7% in diagnosing secretory endometrium. Furthermore, for proliferative endometrium, it showed a sensitivity, specificity, PPV, and NPV of 100%,98.1%, 75%, and 100% respectively making the accuracy 96.5%. while for hyperplasia without atypia and disordered endometrium, the accuracy was 98.2% as shown in table (5). The analysis showed that the histopathology results of the pipelle were in concordance with the results obtained by D&C, with a p-value of less than 0.001 which is statistically significant as shown in Table (6). Both cases of atrophic endometrium, all three cases of hyperplasia without atypia, and the cases of disordered endometrium were diagnosed by both the pipelle and D&C. Furthermore, the pipelle was able to diagnose 23 cases of proliferative out of 25 diagnosed by D&C. Regarding the secretory endometrium 13 out of 16 was detected. The D&C detected two cases of hyperplasia with atypia while the pipelle detected one of them.

Table (5): Sensitivity, Specificity, PPV, and NPV of The HPE Report Obtained Through Pipelle Sampling were Evaluated in Comparison with D&C.

	Sensitivity	Specificity	PPV	NPV	Accuracy
Secretory	81.3 %	100.0 %	100.0 %	93.2 %	94.7 %
Proliferative	92.0 %	100.0 %	100.0 %	94.1 %	96.5 %
Hyperplasia without atypia	100.0 %	98.1 %	75.0 %	100.0%	98.2 %
Disordered proliferative	100.0 %	98.0 %	87.5 %	100.0%	98.2 %

Discussion

AUB stands out as a prevalent gynecological concern in women presenting to health facilities. In order to rule out endometrial pathology, especially endometrial carcinoma and confirming the benign nature of the condition, endometrial biopsy needs to be performed. D&C has been primarily the Gold standard for diagnosis.[9,12,13] The significant benefits of pipelle over D&C are the absence of the need for general anesthesia, reduction in the number and frequency of complications, cost-effectiveness, and decreased time of the procedure.[14] Therefore, in this study pipelle sampling results were compared to the gold standard, D&C. During a standard pelvic examination, pipelle sampling can be performed without the need for general anesthesia or analgesics. Liu et al., Sanam et al., and Abdelazim et al. all concluded that pipelle is a reliable and accurate outpatient sampling procedure when compared to D&C.[14-16] In this study; the pipelle device had around 93% sensitivity, 100% specificity, and 96.9% accuracy in obtaining the endometrial samples. Nevertheless, various sensitivity, specificity, and accuracy results were observed in similar studies including 80.4% sensitivity, 96.5% specificity, and 96.4% accuracy, 81% sensitivity, 96.5% specificity, and 96% accuracy, and 85% sensitivity, 100% specificity, and 98.5% accuracy. [17, 18,19]

The histopathological diagnosis of this study showed that the results of the pipelle were significantly consistent with the results obtained by D&C. The diagnostic results were similar for atrophic endometrium, hyperplasia without atypia, and the cases of disordered endometrium. However, out of 25 cases that D&C identified as proliferative endometrium, the pipelle was able to identify 23 of them. For the 16 secretory endometrium cases, the pipelle diagnosed 13 cases. One of the two cases of hyperplasia with atypia were detected by the pipelle. However, in both pipelle and D&C procedures, the quality of the diagnostic data is notably influenced by indications, age, and menopausal status.

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Table (6): Accuracy of the Pipelle in Diagnosis in Comparison to D&C

		Diagnosis by Curettage								Total of Pipelle	P value
		Atrophic	Proliferative endometrium	Secretory endometrium	Polyp	Hyperplasia with atypia	Hyperplasia without atypia	Inconclusive	Disordered proliferative		
Diagnosis by Pipelle	Atrophic	2	0	0	0	0	0	0	0	2	< 0.001*
	Proliferative endometrium	0	23	0	0	0	0	0	0	23	
	Secretory endometrium	0	0	13	0	0	0	0	0	13	
	Polyp	0	0	0	0	0	0	0	0	0	
	Hyperplasia with atypia	0	0	0	0	1	0	0	0	1	
	Hyperplasia without atypia	0	0	1	0	0	3	0	0	4	
	Inconclusive	0	1	2	1	1	0	1	0	6	
	Disordered proliferative	0	1	0	0	0	0	0	7	8	
Total of D and C		2	25	16	1	2	3	1	7	57	

Important variables influencing a diagnostic pipelle biopsy include BMI, number of vaginal births, and endometrial thickness.[20] The endometrial thickness was measured with a mean ± SD of 11.04mm ± 3.89. The endometrial thickness was the main factor influencing the ability to take a satisfactory endometrial sample.[21] A study conducted by Aue-Aungkul et al. showed that in a group of women having an endometrial thickness of less than 8 mm, there is a 28.8% chance of obtaining insufficient endometrial sample.[22] In this study, the pipelle had an accuracy of 94.7% for diagnosing secretory

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endometrium, with 81.3% sensitivity, 100% specificity, and 100% PPV. Additionally, for proliferative endometrium it demonstrated sensitivity, specificity, PPV, and NPV of 100%, 98.1%, 75%, and 100%, respectively, making the accuracy 96.5%. The accuracy was 98.2% for hyperplasia without atypia and disordered endometrium. Therefore, the finding of this study show that the pipelle could be used as an alternative of D&C. This observation aligns with findings from previous studies by Sanam et al. performed in Iran and Kaur et al performed in India.[15,19] A meta-analysis by Dijkhuizen et al. included 39 trials and 7914 women, it was conducted to assess the effectiveness of endometrial sampling devices in identifying atypical hyperplasia and endometrial cancer. They concluded that the pipelle-assisted endometrial biopsy is more effective than other endometrial methods at identifying endometrial carcinoma and atypical hyperplasia in pre-and postmenopausal women.[23] Also in a three-year prospective study, performed by Rezk et al. 2016 in Egypt included 538 patients with AUB, it was concluded that pipelle endometrial sampling is equally accurate and concordant with hysterectomy as D&C biopsy.[24] The limitation of the study includes the small sample size of 57 patients with AUB. There were not any cases of endometrial cancer because most of the cases where there is a suspicion of malignancy are listed for hysteroscopy and not D&C. Another limitation was that some of the samples were obtained by registrars not well experienced with using the pipelle device.

Conclusion

This study concluded that pipelle can be performed as an outpatient procedure because it is easier to use, affordable, and patient-friendly. Therefore, it can be used as the first line of diagnosis in patients presenting with AUB to make an early diagnosis of a variety of premalignant and malignant endometrial conditions. In addition, pipelle is known to inflict less harm to cervical tissue than D&C, which is known to improve obstetric outcomes in subsequent pregnancies. Pipelle has a positive predictive value and diagnostic value that are nearly as definitive as D&C.

Conflicts of interest:

The authors declare no conflict of interest.

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