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Comparison of the Diagnostic Accuracy of Pipelle Endometrial Sampling with Dilatation and Curettage in Cases of Abnormal Uterine Bleeding in Perimenopausal and Post Menopausal Women

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Abstract: ***Background: Endometrial sampling for histopathology is important in the assessment of abnormal uterine bleeding. Aim of the study is mainly to compare the diagnostic accuracy of the pipelle device in acquiring an adequate and representative sample from the endometrium in perimenopausal and postmenopausal women. Method: An observational clinical correlation diagnostic study of 100 patients in perimenopausal and postmenopausal age group women with abnormal uterine bleeding carried out in the Department of Obstetrics and Gynecology, Endometrial sampling with Pipelle curette was performed in 100 patients before giving anaesthesia followed by Dilatation & curettage. The histopathology reports of both samples were compared. Results: 96% of the samples obtained by conventional D&C, while 93% of the samples obtained by the pipelle device were adequate for histopathological examination. In this study the pipelle device had 100% sensitivity, 100% specificity and 100% accuracy for diagnosing endometrial hyperplasia and endometrial carcinoma. Both pipelle and D&C failed to detect polyps. The adequacy and diagnostic accuracy of Pipelle in comparison with D&C is with sensitivity of 96.88%, specificity of 100%, PPV of 100% and NPV of 57.14%. Conclusion: The Pipelle sampling can be considered as a first line investigation for getting an adequate endometrial sample and high sensitivity and specificity for the detection of hyperplasia and malignancy. Thus Pipelle has an added advantage of no anesthesia or other procedural complications compared to D&C.***

Keywords: Abnormal uterine bleeding, Pipelle, Dilatation and Curettage, Histopathological examination, perimenopausal, post menopausal

1. Introduction

Endometrial sampling for histopathological analysis is very much important in the diagnosis of abnormal uterine bleeding, which is a major problem accounting for nearly 33% of outpatient gynaecological referrals[1]. This proportion rises to 70% in the perimenopausal and postmenopausal years[2]. Setzler & colleagues (1990) found that 18% of perimenopausal women had menorrhagia or metrorrhagia & one fifth of these were due to premalignant or malignant disease. Endometrial hyperplasia occurs in nearly 5-10% of patients with postmenopausal bleeding. If abnormal uterine bleeding is persistent or recurrent in a patient or if obesity or chronic anovulation is present then the diagnosis of endometrial cancer should be considered in premenopausal women. When a woman is found to have risk factors for endometrial pathology, such as perimenopausal abnormal uterine bleeding, postmenopausal uterine bleeding or history of chronic anovulation, sampling of endometrium becomes mandatory[3].

To date, D&C and Hysteroscopic study is mainly considered as the standard for sampling of endometrium. But in 60% of D&C, with added risk of complications of anaesthesia , infection,perforation & nearly less than half of endometrium is curetted[4]. This has led to the advent of simple methods for outpatient endometrial sampling. Of the several office endometrial sampling methods, the Pipelle which is a disposable polypropylene sheath with an inner plunger has been found to be very comfortable and gave comparable histological findings from tissue obtained by D&C, hysterectomy or stiff metal curette[5]. It does not require anaesthesia. It is simpler than the insertion of IUCD[6].

Pipelle enables quick sampling of endometrium. The entire procedure can be completed within 10-15 minutes. The safety & acceptability of pipelle has been reported in various studies. After successful use in tertiary care, it has been introduced into primary care. The pipelle is highly acceptable and it is cost effective when compared with curettage. Yet, there are still concerns regarding the adequacy, nonsampling of intrauterine lesions & accuracy of histopathology report of tissue sampled. D&C is commonly used even at tertiary care level[6]. Though many studies have reported about the effectiveness of pipelle type device in outpatient endometrial sampling, very few studies are available from India. This study is conducted to establish the diagnostic accuracy of pipelle and adequacy of endometrium sampled by pipelle for histopathology.

2. Aims and Objectives

Aim of the study is mainly to compare the diagnostic accuracy of the pipelle device in acquiring an adequate sample from the endometrium.

The primary outcome measurement will be the accuracy of pipelle in determining the histopathology of endometrium in perimenopausal women with abnormal uterine bleeding and postmenopausal women with bleeding.

The secondary outcome measurement will be the adequacy of specimen for histopathology and associated complications of procedure.

3. Materials and Methods

Inclusion criteria include perimenopausal women with abnormal uterine bleeding and postmenopausal bleeding.

Exclusion criteria excludes women with blood dyscrasias, suspected pregnancy related bleeding, endometrial thickness ≤ 4 mm, failed pipelle endometrial sampling, carcinoma cervix and fibroid uterus.

Both sagittal and coronal view scanned with emphasis on endometrium. Endometrial echotexture, margins and thickness were noted. The thickness of the endometrium was measured in the sagittal plane. Patient is posted for endometrial sampling electively after getting assessment in the premenstrual period among the perimenopausal group whereas in postmenopausal women it is done soon after getting assessment. Consent obtained and without anaesthesia diagnostic intervention Pipelle endometrial sampling followed by diagnostic reference standard D&C Endometrial sampling was done with anesthesia. For the purpose of synchronicity both the procedures were done at the same time. Endometrium stripe is obtained by moving the pipelle up and down inside the uterine cavity. The cannula is rotated during removal and a strip of endometrium is peeled off. The tissue is sucked into the syringe. Following this procedure, anaesthesia given and D&C proceeded. Routinely D&C requires cervical dilatation of more than 8 mm. The pathologist is blinded to the method of sample collection. The histopathology report contains whether the sample is from endometrium, tissue is adequate or inadequate for diagnosis and the type of endometrial abnormality. The reports from pipelle and D&C are compared.

All the patients were followed up and treated medically or surgically. Patients with inadequate sample from both Pipelle and D&C were further investigated with saline infusion sonography and intervention done.

4. Results

Out of 100 patients 47% were in the age group of 41-45 years and 20% of the subjects were>50 years. Mean ±SD of the age group was 45.27±4.404 years.(Table 1).In the study group 18% women were with postmenopausal bleeding. The perimenopausal age group women with AUB were 82%.

Table 1: Age Distribution

Age in Years	Number of Patients	Percentage
41–45	47	47%
46–50	33	33%
>50	20	20%
Total	100	100%

In the study group, among the perimenopausal age group women 60.98% of the subjects had AUB for a period of 1 – 6 months, 24.39% of them had AUB for a period 6 – 12 months and 14.63% of them had AUB for a period of more than 12 months. (Table 2) The main complaint of the patients included in the study was menorrhagia.

Table 2: Duration of Aub in Perimenopausal Women

Duration in Months	Number of Patients	Percentage
0 – 6 Months	50	60.98%
6 - 12 Months	20	24.39%
>12 Months	12	14.63%
Total	82	100%

Of the 100 women 10% were nulliparous and 90% were multiparous women. (Table 3). History of comorbid medical illness were noted in 42 % and 58% patients did not have risk factors. The commonest being the hypertension accounting for 18%. (Table 4). ET was 5 - 8 mm in 33 %, 12 - 16 mm in 32%, 9 – 12 mm in 23% &>16mm in 12 %. The mean Endometrial Thickness mean ± SD was 10.54±2.973. (Table 5).

Table 3: Parity Index

Parity Index	Number of Patients (N=100)	Percentage (100%)
Nulliparous	10	10%
Para1	13	13%
Para2	23	23%
Para3	27	27%
Para 4 & Above	27	27%

Table 4: Presence of Risk Factors

Particulars	Number of Patients (N=100)	Percentage (100%)
Anemia	5	5.0%
HT/DM	11	11.0%
HT	18	18.0%
Epilepsy	1	1.0%
H/O – PTB	1	1.0%
DM	6	6.0%
Obesity	40	40.0%

Table 5: TVS ET (mm) in the subjects studied:

TVS ET (mm)	Number of Patients	Percentage
5 – 8	33	33%
9–12	23	23%
13–16	32	32%
>16	12	12%
Total	100	100%

Of the 100 subjects, the endometrial sample was reported as inadequate in 4% of the cases in D&C group and in 7% of Pipelle group. Though the procedure was perceived easy, sufficient sample was not obtained in 7% in the pipelle group. (Table 6).Statistical inference: $X^2 = 6.799$, df = 1, p = 0.009 p< 0.05, significant. The Sensitivity of pipelle in obtaining an adequate tissue in comparison with D&C by applying the Fisher's Exact test, the sensitivity 96.88%, specificity 100%, PPV 100% and NPV 57.14%. P value is <0.009, statistically highly significant. Thus it is inferred that Pipelle is as good as D&C in obtaining an adequate endometrial tissue sample.(Table 7).

Table 6: Adequacy of Sample with Pipelle and D&C:

Tissue Adequacy	Number of Patients(N=100)	Percentage (100%)
D&C		
Adequate	96	96%
Inadequate	4	4%
PIPELLE		
Adequate	93	93%
Inadequate	7	7%

Table 7: Correlation between Adequacy of Sample with Pipelle and D&C

			D&C – Adequacy		Total
			Adequate	Inadequate	
Pipelle–Adequacy	Adequate	Count	91	2	93
		% within D&C– Adequacy	94.79%	50%	93.00%
	Inadequate	Count	5	2	7
		% within D&C – Adequacy	5.21%	50%	7.00%
	Total	Count	96	4	100
		% within D&C– Adequacy	100.00%	100.00%	100.00%

In the perimenopausal age group, adequate sample was obtained in 80 out of 82 patients in D&C group and 77 out of 82 patients in Pipelle group. Inadequate sample was noted in 2 patients in D&C and 5patients in Pipelle sampling in this age group. In postmenopausal age group, adequate sample was noted in 16 out of 18 patients in D&C group and inadequate in 2 patients and similar results were obtained in pipelle sampling in this age group.(Table 8). Hence no correlation was observed between menopausal status and sample adequacy.

Table 8: Correlation between Menopausal Status and Adequacy

	D&C		PIPELLE	
	Adequate	Inadequate	Adequate	Inadequate
Perimenopausal	80	2	77	5
Postmenopausal	16	2	16	2
Total	96	4	93	7
	X^2 =1.017		X^2 =1.017	1.017
Statistical Inference	df = 1		df = 1	
	p = 0.313		p = 0.313	
	p> 0.05		p> 0.05	
	not significant		not significant	

In our study, it was observed that increased endometrial thickness was not always associated with adequate tissue sampling. Of the scanty samples by Pipelle and D&C, 2 patients had bleeding at the time of sampling which might have accounted to the scanty endometrium on HPE.(Table 9). Hence no correlation was observed between endometrial thickness and sample adequacy.

Table 9: Correlation Between Endometrial Sample Thickness And Sufficient Sample

ET mm	D&C		PIPELLE	
	Adequate	Inadequate	Adequate	Inadequate
5 – 8	31	2	28	5
9–12	22	1	22	1
13–16	31	1	31	1
>16	12	0	12	0
Total	96	4	93	7
Statistical Inference	X^2 = 5.297		X^2 = 5.258	
	df = 3		df = 3	
	p = 0.151		p = 0.154	
	p> 0.05		p> 0.05	
	not significant		not significant	

The inadequate samples common to both pipelle endometrial sampling and D&C reported as scanty endometrium but with suspicious TVS finding were further investigated with sonohysterogram and found to have 2 endometrial polyps. The types of endometrium according to histopathology report consisted of secretory endometrium, proliferative endometrium, atrophic endometrium, endometrial polyp, endometrial hyperplasia (simple, complex with/without atypia, cystoglandular hyperplasia) and carcinoma (adenocarcinoma).

The endometrial sample was sufficient in 96% of patients with D&C sampling and 93% of patients with Pipelle sampling. The most common endometrial pattern identified was proliferative endometrium (40%). Secretory endometrium was the second most common (25%) followed by simple hyperplasia (9%), complex hyperplasia(9%), endometritis (3%), cystoglandular hyperplasia (2%), atrophic endometrium (5%) , scanty endometrium (4%) and endometrial carcinoma (3%).(Table 10).

Table 10: HPE of Endometrial Sampling in the Study Population

HPE	Number of Patients (n=100)	Percentage (100%)
Proliferative Endometrium	40	40%
Secretory Endometrium	25	25%
Simple Hyperplasia	9	9%
Complex Hyperplasia with Atypia	2	2%
Complex Hyperplasia without Atypia Cystoglandular	7	7%
Hyperplasia without Atypia	2	2%
Endometritis	3	3%
Atrophic Endometrium	5	5%
Scanty Endometrium	4	4%
Adenocarcinoma	3	3%

Endometrial sample, applying Chisquare test, X^2 = 33.761 and the calculated p value is 0.001 (p< 0.05) which is statistically significant. Comparing D&C sample adequacy with histopathology of endometrial sample, applying Chisquare test, X^2 = 61.744 and the calculated p value is 0.000 (p< 0.05) which is statistically significant. (Table 11).

Table 11: Correlation between Adequacy of Sampling Technique and Histopathology of Endometrial Sampling:

HPE	D&C		PIPELLE	
	Adequate	Inadequate	Adequate	Inadequate
Secretory Endometrium	25	0	25	0
Proliferative Endometrium	40	0	40	0
Simple Hyperplasia Complex	9	0	9	0
Hyperplasia With Atypia	2	0	2	0
Complex Hyperplasia without Atypia	7	0	7	0
Cystoglandular Hyperplasia without Atypia	2	0	2	0
Endometritis	3	0	2	1
Atrophic Endometrium	5	0	3	2
Scanty Endometrium	0	4	0	4
Adenocarcinoma	3	0	3	0
Statistical Inference	X^2 = 61.744, df = 13,		X^2 = 33.761, df = 13,	
	p = 0.000		p = 0.001	
	p< 0.05, significant		p< 0.05, significant	

The diagnostic accuracy of Pipelle in comparison with D&C is with sensitivity of 96.88%, specificity of 100%, PPV of 100% and NPV of 57.14%. Comparing histopathological report of Pipelle endometrial sampling with D&C sampling, the sensitivity, specificity, PPV and NPV for Endometrial carcinoma and endometrial hyperplasia is 100%. The statistical inference was X^2 = 295.000, df = 90 and p = 0.000 (p <0.05), statistically significant. (Table 12).

Table 12: The Validity of Pipelle Device in Comparison with D&C in Diagnosing Endometrial Pathology in Patients with Abnormal Uterine Bleeding

HPE	Sensitivity	Specificity	PPV	NPV
Proliferative Endometrium	100%	100%	100%	100%
Secretory Endometrium	100%	100%	100%	100%
Endometrial Hyperplasia	100%	100%	100%	100%
Endometritis	75%	100%	100%	98.94%
Atrophic Endometrium	71.43%	100%	100%	97.85%
Endometrial Carcinoma	100%	100%	100%	100%

The observation shows that Pipelle endometrial sampling is in par with D&C in obtaining an accurate tissue diagnosis. Both Pipelle and D&C failed to detect polyps. Of the 100 patients who were followed up in our study 76 subjects of perimenopausal age group who were at no risk or low risk for malignancy responded to medical management. Totally 23subjects for varying indications like failed medical management, endometrial carcinoma , with risk of endometrial malignancyand one postmenopausal women with inadequate sampling by both Pipelle and D&C found to have polyp by saline infusion sonography underwent hysterectomy. One (perimenopausal women) subject with inadequate endometrial sampling by both Pipelle and D&C underwent Hysteroscopy.

Among them 13 were postmenopausal women and the remaining were from perimenopausal age group. The postmenopausal women with endometrial sampling reported as adenocarcinoma (1), complex hyperplasia with atypia (1), complex hyperplasia without atypia (2), simple hyperplasia (2) and the remaining subjects (7) of perimenopausal women were those who did not respond to medical management. The 4 inadequate samples common to both Pipelle and D&C subjected to Sonohysterogram detected polyps in 2 cases (one from postmenopausal age group and the other from perimenopausal age group). Both were advised hysteroscopic removal of polyps. The postmenopausal patient did not give consent for hysteroscopy and hence proceeded with hysterectomy and the perimenopausal women underwent hysteroscopic polypectomy. The HPE reports were Hyperplastic polyps in both. (Table 13).

Table 13: Posthysterectomy HPE in the Study Population

HPE	Number of Patients (n=23)	Perimenopausal	Postmenopausal
Proliferative Endometrium	4		
Simple Hyperplasia	5	2	3
Complex Hyperplasia with Atypia	2	1	1
Complex Hyperplasia without Atypia	5	3	2
Cystoglandular Hyperplasia without Atypia	2	2	0
Hyperplastic Polyp	1	0	1
Endometritis	1	0	1
Adenocarcinoma	3	1	2

In patients who underwent hysterectomy, the inadequate reporting was present in one person in common to both Pipelle and D&C. Comparing the Pipelle adequacy taking histopathological report from hysterectomy as gold standard, applying Chisquare test, X^2 = 28.620, df = 10 and p = 0.001 (p < 0.05) which is statistically significant.(Table 14).

Table 14: Correlation of Pipelle and D&C Adequacy with Posthysterectomy HPE

HPE	Number of Patients (n=23)	PIPELLE / D&C	
		Adequate	Inadequate
Proliferative Endometrium	4	4	0
Simple Hyperplasia	5	5	0
Complex Hyperplasia With Atypia Complex Hyperplasia	2	2	0
Without Atypia	5	5	0
Cystoglandular Hyperplasia Without Atypia	2	2	0
Hyperplastic Polyp	1	0	1
Endometritis	1	1	0
Adenocarcinoma	3	3	0
Total	23	22	1

Comparing histopathological report of endometrial sampling by Pipelle with posthysterectomy HPE, the sensitivity, specificity, NPV and PPV for endometrial hyperplasia and endometrial carcinoma is 100% and it was similar to D&C. (Table 15).

Table 15: The Accuracy of Sampling Procedures in Diagnosing Endometrial Pathology in Patients with Abnormal Uterine Bleeding who Underwent Hysterectomy

HPE	SENSITIVITY		SPECIFICITY		PPV		NPV	
	PIP	D&C	PIP	D&C	PIP	D&C	PIP	D&C
Proliferative Endometrium	**100%**	**100%**	100%	100%	**100%**	**100%**	100%	100%
Simple Hyperplasia	**100%**	**100%**	100%	100%	**100%**	**100%**	100%	100%
Complex Hyperplasia wth Atypia	**100%**	**100%**	100%	100%	**100%**	**100%**	100%	100%
Complex Hyperplasia without Atypia	**100%**	**100%**	100%	100%	**100%**	**100%**	100%	100%
Cystoglandular Hyperplasia without Atypia	**100%**	**100%**	100%	100%	**100%**	**100%**	100%	100%
Hyperplastic Polyp	**50%**	**50%**	100%	100%	**100%**	**100%**	95.65%	95.65%
Endometritis	**100%**	**100%**	100%	100%	**100%**	**100%**	100%	100%
Adenocarcinoma	**100%**	**100%**	100%	100%	**100%**	**100%**	100%	100%

The diagnostic accuracy of Pipelle in comparison with posthysterectomy HPE, the sensitivity of Pipelle is 95.83%, specificity is 100%, PPV is 100% and NPV is 98.72%.

5. Discussion

In our study adequacy of sample was obtained in 97.56% using pipelle in perimenopausal age group and 88.9% in postmenopausal women. In the study by Ben Baruch et al[7] who reported that 92.4 %of premenopausal patients and 84.09% in postmenopausal women had sufficient sample by pipelle. It is also comparable to the study done by Abdelazim et al8 who reported 97.9% adequacy with pipelle and Shazia fakhar et al9 who reported 98% adequacy with pipelle.

In our study the diagnostic accuracy of the sample was present in 93% with pipelle and 96% with D&C patients. Sensitivity of pipelle in comparison with D&C is 96.88% and specificity is 100% with positive predictive value of 100% and negative predictive value of 57.14%.

Pipelle was 100% sensitive in diagnosing endometrial carcinoma and hyperplasia but was less sensitive for endometritis and atrophic endometrium. Both pipelle and D&C failed to detect polyps. It is comparable with Van den Bosch et al[10] who reported that Pipelle failed to find submucous myoma and polyps and Epstein et al[11] who also reorted Pipelle missed all polyps. The results in our study are comparable to the study by Abdelazim et al[8] with respect of endometrial carcinoma and hyperplasia but defers from his study in diagnosing polyps (100% detection using pipelle). Our study also is comparable with Shazia et al[9] and Fouzia et al[1].

In our study it was observed that endometrial thickness was not associated with adequacy of sample because ET less than 4mm was excluded from the study. 4 inadequate samples with pipelle and D&C were subjected to sonohysterogram and all 4 had polyps. This is comparable with Elsandabesee et al[12]. Comprehensive tissue diagnosis remains the gold standard. Measurement of endometrial thickness have been found to be highly reproducible to inter and intraobserver measurement. An ET measurement in premenopausal women does not predict the presence of endometrial disease as they do in peri and postmenopausal women[13].

In a study by Naderi et al[14], comparing the accuracy of Pipelle and D&C pipelle was suggested as first diagnostic procedure in comparison with D&C and hysterectomy as it necessitates anaesthesia. Machado et al[15] concluded that pipelle sampling is an accurate method for diagnosis of endometrial cancer and its precursor atypical hyperplasia.

6. Conclusion

No particular patterns were observed between ET and endometrium by HPE in peri and postmenopausal patients. Some patients had bleeding at the time of admission and the timing between ET measurement and endometrial sampling varied, which would have been a cause for this discrepancy. The endometrial sample was sufficient in 96% of patients with D&C sampling and 93% of patients with Pipelle sampling.

Pipelle biopsy and D&C showed almost equal success rate in the diagnosis of endometrial pathologies. Neither pipelle nor D&C is adequate method for focal endometrial pathologies. Pipelle biopsy is a cheaper and easy technique compared with D&C, and ultrasonographic findings of endometrium should be considered prior to endometrial biopsy. In detecting uterine polyps, the best sensitive investigation is hysteroscopy and sonohysterography.

The adequacy and diagnostic accuracy of Pipelle in comparison with D&C is with sensitivity of 96.88%, specificity of 100%, PPV of 100% and NPV of 57.14%. Comparing the diagnostic accuracy and adequacy of Pipelle with D&C, the calculated p value is <.005 which is statistically very significant. The posthysterectomy HPE reports were correlated with Pipelle endomertrial sampling and the validity of Pipelle was found. The sensitivity, specificity, PPV and NPV for endometrial hyperplasia and endometrial carcinoma were 100%.

The diagnostic accuracy of Pipelle in comparison with posthysterectomy HPE, the sensitivity of Pipelle is 95.83%, specificity is 100%, PPV is 100% and NPV is 98.72%.

Comparing the Pipelle adequacy taking histopathological report from hysterectomy as gold standard, the calculated p value is $p = 0.001$ ($p < 0.05$) which is statistically significant.

The diagnostic accuracy of the Pipelle device is comparable with Dilatation and curettage in acquiring an adequate sample from the endometrium. The patients' acceptability of Pipelle device in diagnosis of abnormal uterine bleeding in perimenopausal and postmenopausal women is good. The

efficacy of Pipelle in determining the histopathology of endometrium in perimenopausal women with abnormal uterine bleeding and postmenopausal women with bleeding is high.

The adequacy of specimen for histopathology from Pipelle is representative of endometrial pathology and with no complications of procedure. Pipelle biopsy and D&C showed almost equal success rate in the diagnosis of endometrial pathologies. Neither pipelle nor D&C is adequate method for focal endometrial pathologies. Yet pipelle biopsy is a cheaper and easy technique compared with D&C, and ultrasonographic findings of endometrium should be considered prior to endometrial biopsy. The Pipelle sampling can be considered as the first line investigation for getting an adequate representative endometrial sample for histology in patients with AUB.

Pipelle has very high sensitivity and specificity for the detection of endometrial hyperplasia and malignancy. Pipelle has better patient compliance and hence can be used as an outpatient procedure. Thus Pipelle has an added advantage of no anesthesia or other procedural complications.

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