

COMPARATIVE STUDY OF ENDOMETRIAL SAMPLING USING PIPELLE WITH HYSTEROSCOPIC-GUIDED BIOPSY

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ABSTRACT

BACKGROUND

Hysteroscopic-guided biopsy is the gold standard for endometrial sampling, but it carries risk of general anaesthesia, infection and perforation, whereas Pipelle does not require anaesthesia or cervical dilatation and it allows outpatient and painless endometrial sampling.

The aim of the study is to determine the reliability and accuracy of Pipelle aspiration in acquiring an adequate and representative endometrial sample and to compare its histopathology with hysteroscopic-directed biopsy.

MATERIALS AND METHODS

A prospective observational comparative study evaluating the role of Pipelle aspiration as an outpatient procedure in endometrial sampling of perimenopausal women with AUB. 150 perimenopausal women with clinical diagnosis of abnormal uterine bleeding were selected from the Gynaecology OPD of IOG, Chennai, between October 2014 and September 2015. They were subjected to endometrial sampling by Pipelle followed by hysteroscopic-directed biopsy. The efficacy of Pipelle was determined by correlating the histopathological results obtained from it and the hysteroscopic-directed biopsy.

RESULTS

The histopathology of the endometrium obtained using Pipelle's curette showed a sensitivity of 93%, specificity of 90% in the detection of abnormal findings with PPV of 88% and NPV of 94%. However, accuracy of Pipelle is found to be less in the diagnosis of polyps and submucous fibroids with accuracy of nearing 100% when using hysteroscopy.

CONCLUSION

Pipelle endometrial sampling is convenient, easy, painless and safe in obtaining an adequate sample for histopathology with high sensitivity and specificity for endometrial pathologies and endometrial carcinoma.

KEYWORDS

Pipelle Endometrial Sampling, Hysteroscopy, Endometrial Pathology, Biopsy.

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BACKGROUND

Abnormal uterine bleeding (AUB) is a common reason for woman of all ages to consult their gynaecologists. One-third of patients attending the Gynaecology OPD present with complaints of AUB.¹ This proportion rises to 70% in the perimenopausal and postmenopausal age group.² Setzler and colleagues demonstrated that 18% of perimenopausal women had menorrhagia and/or metrorrhagia and one fifth of them were due to premalignant/malignant disease. Abnormal uterine bleeding can occur due to structural and nonstructural causes.³ The main aim of investigation for AUB

is to rule out intrauterine pathology, particularly endometrial cancer.⁴ Endometrial sampling becomes mandatory when a woman is found to have high-risk factors for endometrial pathology such as perimenopausal bleeding, postmenopausal bleeding or history of chronic anovulation. The irregularity in menstrual cycle during perimenopausal period can be due to anovulation or due to irregular maturation of follicles.⁵ Endometrial biopsy or curettage could be safe, effective and most commonly used diagnostic step in evaluation of AUB after ruling out medical causes. About a quarter of gynaecologic surgeries involve AUB.⁶

Hysteroscopic-directed biopsy is considered as gold standard for sampling the endometrium, but it carries risk of complications of general anaesthesia, infection and perforation. This led to the advent of simpler methods for endometrial sampling. One such method is the use of Pipelle. It is a disposable polypropylene sheath with an inner plunger. It is comfortable for patient. It does not require general anaesthesia. It can be used by anyone trained in the

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use of an uterine sound and is simpler than the insertion of an IUCD.

Pipelle sampling enables quick sampling of endometrium (5-15 seconds) and the entire procedure can be completed within 10-15 minutes. It is safe, acceptable and cost effective when compared with hysteroscopy. Concerns regarding use of Pipelle are adequacy of sample obtained,⁷ non-sampling of focal intrauterine lesions⁸ and the accuracy of histopathology report of tissue sampled.

Aims and Objectives

The objective of the study is to compare Pipelle aspiration with hysteroscopic-directed biopsy in obtaining adequate and representative endometrial sample and to compare the histopathology report of both the procedures.

MATERIALS AND METHODS

It is a prospective, observational, comparative study evaluating the role of Pipelle aspiration as an outpatient procedure in endometrial sampling of perimenopausal women with AUB. After getting clearance from institutional ethical committee, 150 perimenopausal women with clinical diagnosis of abnormal uterine bleeding were selected from the Gynaecology OPD of IOG, Chennai, between October 2014 and September 2015.

A complete history was taken and recorded from all the patients thus selected. These patients were subjected to a general and bimanual pelvic examination. Baseline investigations were performed. Anaesthetic assessment was obtained. Endometrial sampling by Pipelle device without anaesthesia followed by endometrial sampling by hysteroscopy under anaesthesia was then done. Both procedures were performed at the same time for the purpose of maintaining synchronicity in the timing of sample. Both the samples were sent to pathologist and histopathological report of both the procedures were compared.

Inclusion Criteria

1. Women of perimenopausal age group with symptoms suggestive of AUB.
2. Women who are clinically stable and anaesthetically fit for hysteroscopy.
3. Not on hormonal drugs for treatment.
4. Women not on thyroid drugs.
5. Not known to have bleeding diathesis.

Exclusion Criteria

1. Nulliparous women.
2. Patient on hormonal management for AUB.
3. Previous 2 or more LSCS scars.
4. Women on anticoagulant therapy.
5. Patients who are clinically unstable.

RESULTS

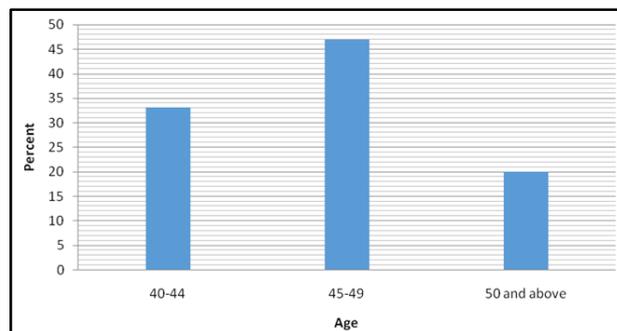


Figure 1. Age Group

Of the 150 patients, the maximum number of patients (46%) were noted in the age group of 45-49 years, followed by 34% in the age group 40-44 years. 20% of the study subjects were in the age group of 50 years and above.

Duration of AUB/(in months)	Number of Patients (n=150)	Percent
1-6 months	72	48
6-12 months	48	32
More than 12 months	30	20
Total	150	100

Table 1. Duration of AUB (in Months)

Majority of the patients (48%) presented within 6 months of onset of symptoms. 32% presented between 6-12 months and 20% presented after 12 months of onset of symptoms.

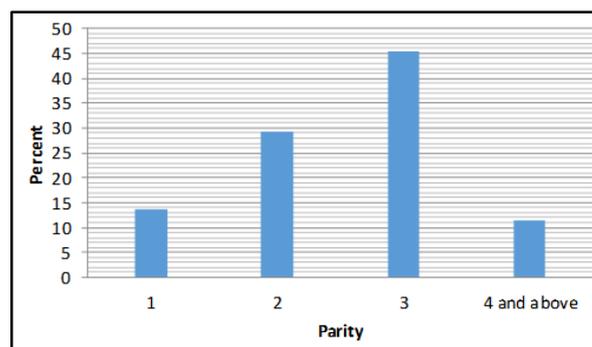


Figure 2. Parity

Multiparous women especially 3 and above were most commonly affected. Nulliparous women were not included in the study.

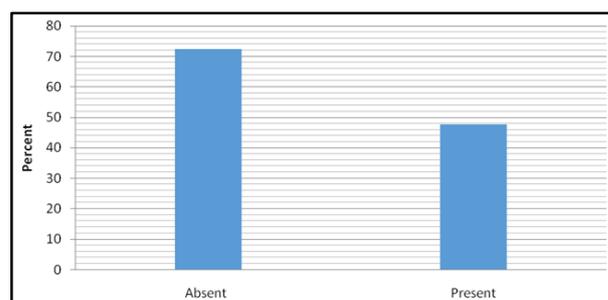


Figure 3. Family History

There were no family history of any significant medical illness in 74% of the cases, whereas 26% of patients had family history of some medical illness. Hypertension and diabetes mellitus was most commonly noted in this group. Fibroid uterus (2%), carcinoma colon (1%) and carcinoma lung (1%) was also noted in a first-degree family relative in this group. Of the patient with family history of carcinoma colon (postmenopausal, ET=4) and carcinoma lung (premenopausal, ET=15), the HPE report was atrophic endometrium and simple hyperplasia without atypia, respectively.

Findings	No. of Patients (n=150)	Percent
Normal	30	20
Bulky uterus	54	36
8-10 weeks	31	20.67
10-12 weeks	18	12
More than 12 weeks	17	11.33
Total	150	100

Table 2. Bimanual Examination

Of the 150 patients, 20% patients had normal size uterus, 36% had bulky uterus, 20.67% had 8-10 weeks size uterus, 12% had 10-12 weeks size uterus and 11.33% had more than 12 weeks size uterus.

	No. of Patients (n=150)	Percent
Sampling Procedure		
Pipelle		
• Easy	142	94.7
• Not easy	8	5.3
Hysteroscope		
• Easy	124	82.7
• Not easy	26	17.3

Table 3. Ease of Sampling Procedure

The percentage of patients in which Pipelle was termed not easy was 5.3% when compared to 17.3% in hysteroscopy. Applying the Fischer's exact test for value of ease of procedure of Pipelle endometrial sampling vs. hysteroscope the calculated P value is 0.125, which is statistically not significant. Thus, comparing the ease of Pipelle procedure with hysteroscope, though 26 cases of hysteroscope were termed not easy compared to 8 by Pipelle that was not statistically significant.

Tissue Adequacy	No. of Patients (n=150)	Percent
Pipelle		
• Adequate	139	92.7
• Scanty	11	7.3
Hysteroscope		
• Adequate	142	94.7
• Scanty	8	5.3

Table 4. Tissue Adequacy

Of the 150 subjects, scanty tissue was reported by the pathologist in 5.3% of the cases in hysteroscope group. 7.3% of Pipelle sample was scanty. Of 150 cases, in 4.6%,

there was no histopathology reported due to scanty endometrium. Though the procedure was perceived as easy, sufficient sample was not obtained in 6 Pipelle sample.

	Pipelle	Hysteroscope
Normal	84	76
Hyperplasia	57	66
Polyp	1	5
Scanty endometrium	7	1
Submucous fibroid	0	1
Adenocarcinoma	1	1
Total	150	150

Table 5. Comparison of the Pathological Diagnosis of Endometrium Sampled by Pipelle Aspiration and Hysteroscopic-Directed Biopsy

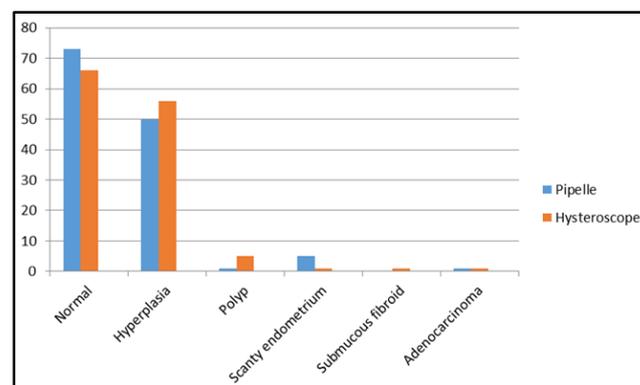


Figure 4. Comparison of the Histopathological Diagnosis

Pipelle was able to diagnose all the normal histopathologic findings (76 patients), but it underdiagnosed 7 patients having hyperplasia and polyp as normal. Out of the 66 cases of hyperplasia, 57 cases were diagnosed correctly by Pipelle. Remaining 9 were diagnosed as normal or scanty endometrium, as Pipelle failed to obtain representative sample of the underlying pathology. Of the 5 polyps, only 1 was diagnosed correctly, but 4 were labelled as normal. But, Pipelle missed the submucous fibroid that was diagnosed by hysteroscopy. Pipelle was able to diagnose one patient with adenocarcinoma in our study.

The results were analysed using Chi-square test where histopathology of Pipelle's and hysteroscopy-guided biopsy were compared. There was statistically significant with p value of 0.000.

DISCUSSION

This comparative study evaluated the role of Pipelle aspiration versus hysteroscopic-guided biopsy among 150 perimenopausal individuals presenting with features of Abnormal Uterine Bleeding (AUB) in diagnosing endometrial pathology.

The results of this study are discussed below- Sampling with Pipelle was easy in 94.7% of the subjects while it was easy in only 82.7% of the subjects with hysteroscope. Tissue was adequate in 92.7% of the patients sampled using Pipelle while hysteroscope gave an adequate tissue in 94.7% of the individuals.

In the present study, abnormal findings like hyperplasia, polyp and malignancy were noted in 57 patients (43.8%) while the remaining 56.2% of the patients had a normal endometrium either proliferative or secretory. Pipelle succeeded in diagnosing the one case of adenocarcinoma as hysteroscopy. In a study by Alliratnam et al, it was concluded that Pipelle had 97% sensitivity, 100% specificity and 100% predictive value in obtaining the endometrial sampling.⁹

While Pipelle biopsies and D and C have a nearly equal level of success in widespread endometrial lesions, Pipelle biopsies provide limited diagnostic accuracy in cases with focal pathologies.¹⁰

Critchley HO et al¹¹ in UK also proved that Pipelle biopsy could obtain adequate endometrial sample in low-risk women of perimenopausal age (79%) compared to high-risk postmenopausal women (43%) Guido et al did Pipelle biopsies in 65 patients and found that adequate tissue for analysis was obtained in 97%. Ben Baruch et al in Israel at the same time proved that sufficient endometrial sample was obtained in 90.6% of women and the discomfort caused was only very slight.

Guido and associates concluded that Pipelle is excellent for detecting global processes of the endometrium than focal lesions. The results were same in our study where Pipelle missed focal lesions, i.e. 4 of 5 polyps detected by hysteroscopy and a case of submucous fibroid that was missed by Pipelle was diagnosed by hysteroscopy.

49% of the patients were found to have some abnormality in hysteroscope such as polyp, hyperplasia and submucous fibroid. 51% of the patient had normal findings.

In this study, hysteroscopy was able to detect uterine cavity abnormalities with a correct diagnosis in 98% of the cases. There was statistically significant correlation between Pipelle and hysteroscopy with a p value of 0.000, respectively, whereas the results in this study is 72% and 100%. Many authors have concluded that Pipelle is an accurate and acceptable method.^{8,12,13}

SUMMARY

The study group were 40 years and above with 46% of them belonging to the 45-49 age group. Majority of patients (48%) had presented within 6 months of onset of symptoms.

Both Pipelle's curette and hysteroscopic biopsy produced statistically significant results while investigating perimenopausal bleeding (p=0.000). Endometrial aspiration is preferably performed in premenstrual phase. It can be combined with Pap smear and endocervical curettage to rule out cervical lesions. When histopathology of endometrium was obtained using Pipelle's curette, correct diagnosis could be obtained in 93% of the cases. Similarly, when hysteroscopy was performed, the correct diagnosis was 98%. Pipelle showed a sensitivity of 93%, specificity of 90% in the detection of abnormal findings with PPV of 88% and NPV of 94%. However, accuracy of Pipelle is found to be less in the diagnosis of focal lesions like polyps and submucous fibroids as it is a blind procedure. Hence, hysteroscopy can be planned for individuals who have thick endometrium on imaging and in individuals whose HPE by Pipelle is

inadequate or atrophic and when there is dys-synchronicity between symptoms and histopathology.

CONCLUSION

Endometrial sampling using Pipelle is an easy, effective and safe method for obtaining endometrial tissue for diagnosis in patients with abnormal uterine bleeding. It can be done as an outpatient procedure. Moreover, it is cost effective, is minimally-invasive procedure and has better patient compliance in addition to the added advantage of no use of anaesthesia or other procedure complications like perforation compared to hysteroscopy.

It can be considered as the first line investigation for obtaining an adequate endometrial sample for histology in patients with AUB with high sensitivity and specificity even for the detection of hyperplasia and malignancy. Thus, Pipelle has a central role for Endometrial Sampling as an Outpatient (ESOP) procedure for abnormal uterine bleeding in perimenopausal women according to the new guidelines for the management of dysfunctional uterine bleeding, before considering any other diagnostic modalities. Therefore, it is essential to broaden its use and include it in the routine diagnostic modalities.

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