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Histo-pathological study of endometrium by Pipelle sampling device versus Hysteroscopy guided biopsy in women with Abnormal Uterine Bleeding

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Abstract
Background: Hysteroscopy and guided biopsy has been considered as gold standard for assessing the endometrium and detecting or ruling out endometrial cancer in current gynaecology practice but it carries risk of anaesthesia, perforation whereas, Pipelle sampling is safe, efficient, without use of anesthesia, and cost effective.
The objective of the study was to compare the histopathological findings with Pipelle endometrial sampling device, its reliability and predictive value, with histopathology on hysteroscopy guided biopsy.
Materials and Methods: A prospective cohort study evaluating the role of Pipelle aspiration as an outpatient procedure in endometrial sampling of women >18years with AUB. 50 women with clinical diagnosis of abnormal uterine bleeding were selected from the Gynaecology OPD of Kasturba hospital, Delhi. They were subjected to endometrial sampling by Pipelle followed by hysteroscopic-directed biopsy in premenstrual phase. 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 has high **specificity** (100%) and positive predictive value (100%) for diagnosing endometrial pathology while sensitivity 25% and negative predictive value 76.32%.
Conclusion: Office endometrial biopsy by Pipelle sampling device should be the initial diagnostic procedure of choice due to its convenience, accuracy, availability, safety and low cost. Hysteroscopy should be reserved for triage of cases where a focal lesion, irregular or thick endometrium is suspected on sonography or symptoms persist despite treatment according to histopathology on endometrial aspiration biopsy.

Keywords: Endometrial aspiration biopsy, abnormal uterine bleeding, hysteroscopy, Pipelle's curette

Introduction
Menstrual problems are responsible for much of the morbidity, significantly impacting quality of life and imposing financial burdens. It affects one in every five women during their life span. They are responsible for 30% of attendance of gynecology outpatient department amongst women in reproductive age group and 50% in Peri-menopausal women [1]
These complaints may significantly affect quality of life, result in time off work, lead to surgical intervention including hysterectomy, and ultimately have a significant impact on the health care system. The choice of which modality to use for investigation is influenced by: risk of endometrial disease, menopausal status, availability of investigative methods and whether exogenous hormones are being taken. The Pipelle endometrial sampling device is a safe, efficient and cost effective means of evaluating the uterine endometrium. The procedure is easily accomplished in the out patients setting. There is evidence that endometrial sampling alone may miss lesions in between 10 to 33% of cases [2].
Hysteroscopy has been generally accepted as the gold standard for the evaluation of the uterine cavity because entire endometrial cavity is directly visualized to identify the pathological changes which maybe the cause of bleeding and perform the biopsy of the suspected lesion under direct visual inspection [3]. Use of hysteroscopy in abnormal uterine bleeding is almost replacing blind curettage, as it "sees", "decides" and sometimes treat the cause. This is because the uterine cavity can be observed and the area in question can be biopsied. The major problem with a regular hysteroscopy is the need for general anaesthesia, non-availability and higher cost of procedure. The need of the hour is to find an outpatient, simple, Efficiant, accurate and cost

effective diagnostic modality to rule out endometrial carcinomas and its precursors which can be easily applied to masses. The objective of the study was to compare the histopathological findings with Pipelle endometrial sampling device and histopathology on hysteroscopy guided biopsy.

Methods

The study was carried out in the department of Obstetrics and Gynecology at Kasturba hospital, Delhi, India, after ethical clearance from institutional ethical committee. 50 patients of age >18 years were included, who were admitted with the history of abnormal uterine bleeding; excluding any demonstrable pelvic pathology like cancer of cervix, vagina or endometrium on clinical examination and active pelvic infection. Detailed history, examination and investigations were done. Endometrial aspiration with pipelle cannula was done in premenstrual phase. Hysteroscopic examination was done in all patients pre-menstrually. Biopsy was taken from suspected area and subjected to histopathological examination. The findings of histopathology of hysteroscopy guided biopsy and histopathology of endometrial biopsy were correlated. Data were recorded on a predesigned proforma. Statistical analysis was done of data obtained in terms of sensitivity, specificity, positive predictive value and negative predictive value.

Results

The mean age of the patients was 42.48 ± 10.17. 48% belonged to reproductive age group, 34% belonged to perimenopausal age group and 18% belonged to post-menopausal age.

Commonest presenting complaint was menorrhagia, found in 58%, followed by post-menopausal bleeding in 18%. Other symptoms were polymenorrhagia 12% whereas 10% had metropathia haemorrhagica. Only 1 patient had metrorrhagia. 83% of the patients in the premenopausal age presented after 4 months of onset of disease while in post-menopausal age nearly 89% of the patients presented within 1-4 months of onset of disease.

Endometrial Aspiration Biopsy was found to be adequate in 94%. Only 3 cases out of 50 had inadequate sample. In 84% cases, procedure was completed within 10-15minutes while only in 1 case (2%) more than 20 minutes was taken for the whole procedure.

On histopathology of endometrial aspiration biopsy, normal endometrium was found in 88% patients. Out of these, 39 had proliferative endometrium. Preinvasive lesions like Atypical and Complex hyperplasia were seen in 2 cases (4%). One case was diagnosed to have Polyp.

Hysteroscopy guided biopsy was taken in 48 out of 50 cases but it could not be taken in 2 cases due to cervical stenosis due to which operative hysteroscope could not be introduced.

On histopathology of hysteroscopic guided biopsy, majority of the cases 29 cases (58%) revealed proliferative endometrium, while 2 cases (4%) had secretory endometrium. Hence, a total of normal endometrium was diagnosed on histopathology in 31 cases (62%).

The most common abnormal finding was polyp in 8 cases (16%) on histopathogy. Hyperplasia in 2 cases (4%), one each of simple hyperplasia and atypical hyperplasia, Chronic endometritis in 2 cases (4%). While one case (2%) thought to be a fibroid polyp with infection on hysteroscopy was diagnosed to be endometrial carcinoma on histopathology.

Biopsy reports were inadequate in 4 cases (8%). 2 patients (4%) had cervical stenosis due to which operative hysteroscope could not be introduced, so biopsy could not be taken.

Table 1: Comparison of Histopathology of Endometrial Aspiration Biopsy and Histopathology of Hysteroscopy Biopsy

Findings	HPE EA	HPE HYS Biopsy	P value
Normal	44(88.00%)	31(64.58%)	<0.0001
Polyp	1(2.00%)	8(16.67%)	
Atypical hyperplasia	1(2.00%)	1(2.08%)	
Simple hyperplasia	0(0.00%)	1(2.08%)	
Complex hyperplasia	1(2.00%)	0(0.00%)	
Endometrial carcinoma	0(0.00%)	1(2.08%)	
Chronic Endometritis	0(0.00%)	2(4.17%)	
Inadequate	3(6.00%)	4(8.33%)	
Total	50(100.00%)	48(100.00%)	

Total of 48 cases were used for comparison and correlation, as in 2 cases biopsy were not taken on hysteroscopy guided biopsy due to stenosed os. (Table 1 and 2)

88% were reported normal on histopathology of endometrial aspiration while 64.58% were normal on hysteroscopy guided biopsy. Out of 42 cases that were reported normal on histopathology of endometrial aspiration biopsy, 29 cases were also normal on hysteroscopy biopsy while 9 cases were found to have abnormal findings on hysteroscopy guided biopsy and 4 cases were inadequate for reporting on histopathology of hysteroscopy guided biopsy.

Polyps were the most common pathology confirmed on hysteroscopy guided biopsy. All the polyps were also removed surgically using resectoscope. Out of 8 polyps (16.67%) confirmed on hysteroscopy biopsy, only 1 polyp (2%) was correctly reported on endometrial aspiration biopsy, while rest 6 cases were reported normal and 1 sample was found inadequate by endometrial aspiration biopsy.

Preinvasive lesions like Atypical hyperplasia and Complex hyperplasia were correctly diagnosed on EA. One case of atypical hyperplasia on Hysteroscopy biopsy was also correctly diagnosed by endometrial aspiration biopsy while 1 case of complex hyperplasia on endometrial aspiration biopsy was diagnosed endometrial carcinoma on hysteroscopy guided biopsy.

Chronic endometritis was another finding which was missed by endometrial aspiration which was confirmed in 2 cases only on hysteroscopy biopsy.

Overall statistical significant correlation of p value <0.0001 (<0.05) was calculated for the diagnosis of abnormal findings on histopathalogy of hysteroscopy guided biopsy over endometrial aspiration biopsy indicating hysteroscopy guided biopsy is better diagnostic modality (Table 1).

Endometrial aspiration biopsy has high specificity (100%) and positive predictive value (100%) for diagnosing endometrial pathology while sensitivity 25% and negative predictive value 76.32% taking histopathology of hysteroscopy guided biopsy as gold standard.

Table 2: Correlation of Histopathology of Endometrial Aspiration Biopsy and Histopathology of Hysteoscopy Biopsy

Histopathology of Endometrial aspiration	Histopathology of Hysteroscopy Biopsy							Total
	Normal	Polyp	Simple hyperplasia	Atypical hyperplasia	Endometrial Ca	Chronic Endometritis	Inadequate	
Normal	29(93.55%)	6(75.00%)	1(100.00%)	0(0.00%)	0(0.00%)	2(100.00%)	4(100.00%)	42(87.50%)
Endometrial polyp	0(0.00%)	1(12.50%)	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)	1(2.08%)
Atypical hyperplasia	0(0.00%)	0(0.00%)	0(0.00%)	1(100.00%)	0(0.00%)	0(0.00%)	0(0.00%)	1(2.08%)
Complex hyperplasia	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)	1(100.00%)	0(0.00%)	0(0.00%)	1(2.08%)
Inadequate	2 (6.45%)	1 (12.50%)	0 (0.00%)	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)	3(6.25%)
Total	31 (100.00%)	8 (100.00%)	1 (100.00%)	1(100.00%)	1(100.00%)	2(100.00%)	4(100.00%)	48(100.00%)

Discussion

Abnormal uterine bleeding is one of the most common condition for which patients seek advice in the gynecology out-patient department. The use of blind endometrial sampling alone to evaluate the uterine cavity, by itself, is not a very accurate technique for diagnosing pathologic conditions commonly associated with menorrhagia, such as endometrial polyps, submucous myoma, focal endometrial abnormalities including adenocarcinoma and its precursors.

Intrauterine visualization by hysteroscopy for the evaluation of patients with abnormal uterine bleeding (AUB) represents the "gold standard" today. The entire endometrial cavity is directly visualized to identify the pathological changes which maybe the cause of bleeding and perform the biopsy of the suspected lesion under direct visual inspection. This also has the added advantage of treating the lesion also, in case of focal pathology like polyp. However, hysteroscopy is expensive in comparison and requires considerable operator skill.

The non-availability of a suitable test for a uterine cause of AUB could prevent months of delay in making the correct diagnosis and planning a treatment. Hence the need for a diagnostic modality which safe, accurate, cost effective and easily available is essential. The major issues of concern regarding use of Pipelle, are adequacy and accuracy of sample obtained, and non-sampling of focal intrauterine lesions. Although, role of hysteroscopy and its diagnostic performance in terms of specificity and sensitivity has been appraised in various studies, its comparative diagnostic value against endometrial aspiration has not been explored.

On comparing the results of histopathology of endometrial aspiration biopsy with histopathology of hysteroscopy guided biopsy, the adequacy of sampling with endometrial aspiration biopsy was 93.75% while with hysteroscopic guided biopsy was 91.66% in our study which is comparable to the study conducted by Nalina *et al*. (2017) [4] found tissue was adequate in 92.7% of the patients sampled using Pipelle while hysteroscope gave an adequate tissue in 94.7% of the individuals.

88% were reported normal on histopathology of endometrial aspiration while 64.58% were normal on hysteroscopy guided biopsy.

Out of 42 cases that were reported normal on histopathology of endometrial aspiration biopsy, 29 cases were also normal on hysteroscopy biopsy while 9 cases were found to have abnormal findings on hysteroscopy guided biopsy and 4 cases were inadequate for reporting on histopathology of hysteroscopy guided biopsy.

Polyps were the most common pathology that was missed by endometrial aspiration as they recoil from the passing Pipelle cannula. The true incidence of endometrial polyp is difficult to determine as most of them are detached piecemeal during curettage and are not recognised both on gross examination and on microscopy, but are better diagnosed by hysteroscopic examination.

However none of the cases with premalignant or malignant lesions were missed on histopathology by endometrial aspiration biopsy.

The present study proves that hysteroscopy guided biopsy is better diagnostic modality for endometrial pathology on correlating it with EA. (P value 0.0001)

Endometrial aspiration biopsy has high specificity (100%) and positive predictive value (100%) for diagnosing endometrial pathology.

This very high specificity and positive predictive value indicates that it is able to correctly diagnose an abnormal finding if detected. While it has low sensitivity 25% is mainly because focal intrauterine pathologies like intrauterine polyps and fibroids were missed.

The good negative predictive value 76.32% indicates that it can correctly rules out all those who don't have abnormal pathology.

Dijkhuizen MD, *et al*. conducted a meta analysis to find the accuracy of endometrial sampling in the diagnosis of patients with endometrial carcinoma and hyperplasia and concluded that pipelle was the most sensitive technique with a sensitivity of 81% and the specificity of all devices was >98% [5].

In our study, Histopathology of hysteroscopy guided biopsy was considered as gold standard and histopathology of endometrial aspiration biopsy findings were compared.

Hence, by comparing the diagnostic value of endometrial aspiration considering hysteroscopy guided biopsy as the gold standard, there seems to be 100% specificity and positive predictive value compare to the study conducted by Nalina *et al*. (2017) [4] but a low sensitivity of 25% is detected in our study and the most commonly missed diagnosis was benign intracavitary polyp and fibroid as it is a blind procedure.

Conclusion

Endometrial aspiration biopsy is simple, cost effective, OPD procedure with 100% specificity and 100% positive predictive value for diagnosing endometrial pathology. However, it lacks specificity for focal intrauterine pathologies like polyps and fibroids. But it is very helpful diagnostic modality to rule out the most ominous and sinister conditions like atypical hyperplasia and precursors of malignancy.

Hysteroscopy and guided biopsy has, without doubt, been reiterated as gold standard for assessing the endometrium and detecting or ruling out not only endometrial cancer, but also benign lesions like polyps and fibroids, in current gynaecology practice. It is a safe, acceptable and well-tolerated procedure that provides useful information about the uterine cavity. Guided biopsy improves the diagnostic accuracy of hysteroscopy in detecting endometrial pathology.

Office endometrial biopsy by Pipelle sampling device should be the initial diagnostic procedure of choice due to its convenience, accuracy, availability, safety and low cost. Hysteroscopy should be reserved for triage of cases where a focal lesion, irregular or thick endometrium is suspected on sonography or symptoms

persist despite treatment according to histopathology on endometrial aspiration biopsy.

Fig 1: Hyperplastic Endometrium on Hysteroscopy

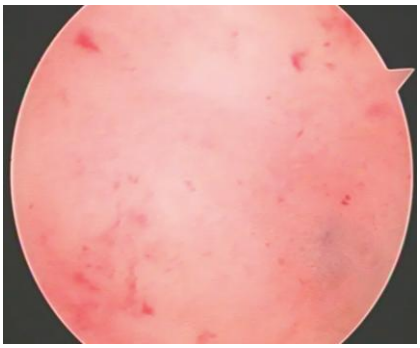

Fig 2: Atrophic Endometrium on Hysteroscopy

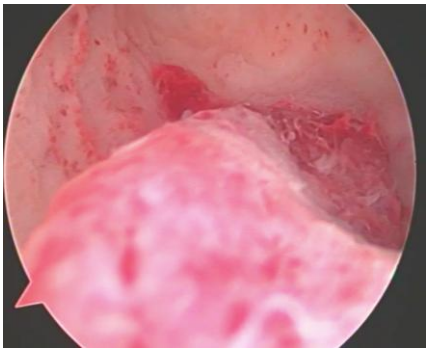

Fig 3: Polyp on Hysteroscopy

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