

Original Article

Assessing the Efficacy of Pipelle Sampling as Outpatient Diagnostic Test in a Tertiary Care Hospital-Rawalpindi, 2020

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¹ Conception of study

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Abstract

Objective: To assess the effectiveness and enlist clinical factors, which may affect the effectiveness of Pipelle sampling in diagnosing endometrial pathology in patients with abnormal uterine bleeding and Post-menopausal Bleeding.

Study Design: 'Analytical Cross-Sectional' study.

Place and Duration: Gynaecology Department at Combined Military Hospital Rawalpindi, in collaboration with Histo-Pathology Department, of six months duration i.e. from 1st December 2019 to 31st May 2020.

Material and Methods: 100 female patients of the outpatient department with presenting complaints of either abnormal or post-menopausal bleeding were included in the study in the specified time frame. After informed written consent, Pipelle endometrial sampling was done on an outpatient basis, and by consecutive sampling technique using the lottery method, the sample was sent for histopathological evaluation. Evaluated factors studied were: indications for the procedure, age, parity, age of menarche.

Results: Of the total patients evaluated, 91% (n=100) were non-malignant, while 4% (n=100) were malignant. Inadequate tissue was obtained in 5% of samples. The most common histopathological findings among the reproductive age group were Proliferative and Secretory phase endometrium 64% (n=100). While in the Post-menopausal age group 4% (n=100) were Endometrial carcinoma on histopathology. Inadequate tissue samples 5% (n=100) were noted among the Post-menopausal group. 6% of samples showed endometrial hyperplasia. Pipelle Endometrial Sampling had sensitivity and specificity, in diagnosing the endometrial pathologies is summarized in Table 3.

Conclusion: Pipelle Endometrial Sampling is an effective, safe, simple, and acceptable procedure for diagnosing endometrial pathology. It is cost-effective requiring no anesthesia with high sensitivity and specificity for detecting endometrial pathology.

Keywords: Abnormal uterine bleeding, Pipelle endometrial sampling, Post-menopausal bleeding.

Introduction

Abnormal uterine bleeding which was previously known as Dysfunctional uterine bleeding is irregular uterine bleeding with no recognized underlying uterine pathology.¹ This disruption in the bleeding pattern is usually a result of hormonal imbalance. The bleeding pattern is unpredictable, it may be heavy or scanty inflow and it may be frequent, prolonged, or random in duration.² One third of women attending gynecological outpatient clinics are with complaint of Abnormal uterine bleeding and the frequency of this problem increases in pre-menopausal and post-menopausal years.³ Endometrial Sampling is recommended at forty years of age as the risk of Endometrial cancer is less than 1% under the age of 35 years and 6% prevalence is in women who are 45 years or less.⁴ Evaluation of Abnormal uterine bleeding in pre-menopausal women should be based on symptomatic and clinical presentation.^{5,6} Endometrial Sampling is indicated even if the hysteroscopic findings are normal.⁷

Endometrial Sampling is the gold standard for investigating patients with abnormal uterine bleeding. Pipelle endometrial sampling is now commonly performed in outpatient clinics, as it is safe, cheap, easy to perform requiring no indoor admission and anesthesia and it has no known major complications.⁸ The main reason for performing Pipelle endometrial sampling is to differentiate between malignant and non-malignant pathology so that appropriate treatment can be started.⁹

Materials and Methods

This analytical cross-sectional study was conducted in Combined Military Hospital Rawalpindi, from 1st December 2019 to 31st May 2020. Permission of the hospital ethical committee was taken before conducting this study. A hundred women were included after taking the informed consent. A detailed history and examination were done in an outpatient gynecology clinic. Baseline investigations along with Pelvic ultrasound were advised. Pipelle Endometrial Sampling was performed by introducing Cusco's speculum to visualize the cervix and pipelle was gently inserted in the uterine cavity, the inner sheath was withdrawn and it was rotated up and down. The endometrial tissue obtained was placed in a sample bottle containing 10% Formalin. The sample was then sent to the histopathology department of a hospital

with proper labelling of the sample as well as brief clinical notes including patient age, history, and duration, and type of bleed was endorsed by the sampling physician. Report of Histopathology was collected from the histopathology department after specified days through the specific ID of all patients. All women above 40 years of age, with complaints of abnormal uterine bleeding and post-menopausal bleeding, were included in the study. The exclusion criteria were women with age less than 40 years, pregnancy, bleeding disorders, cervical stenosis, lower genital tract infections, hormonal intake, hormonal contraceptive history, and those taking anticoagulants. Eligible women were tested through a consecutive sampling method. All the relevant information was recorded on self-administered proformas. All data obtained were entered in MS Excel Sheet version 2019 and statistical data was analyzed by using SPSS Software version 25. Descriptive analysis of both qualitative /quantitative variables was carried out, and frequencies were calculated. Risk factors were identified. Sensitivity, specificity, positive, and negative predictive values were calculated. Data was organized and presented in form of tables. The analysis was significant at a 95% confidence interval and Chi-Square was used as a test of significance.

Results

During 06 months study period, about 100 patients underwent Pipelle Sampling for different menstrual cycle irregularity complaints. 68% of patients were in the age group of 40-50 years. 25% in 51-60 years and 7% in 61-70 years of age group. 83% of patients had parity of P1-P4. 12% were nulli-para while 05% had parity of 5 or more. The age of menarche was 11-13 years in 87% of patients and 13% fell in the 14-16 years of age group. All these statistics are shown in the table of demographic characteristics. The patients who underwent pipelle sampling. 27% had Post-menopausal bleeding, 38% of patients with heavy menstrual bleeding. 26% had intermenstrual bleeding. 09% presented with Post-cortical bleeding (shown in the tabulated form), 91% of histopathology samples were non-neoplastic, while 04% of samples were neoplastic. 05% of samples had scanty tissue which was not enough for diagnosis and they were in the Post-menopausal age group. Incidences of histopathological patterns are shown in Table 2. Proliferative endometrium 33% was the most common histopathological finding, indicating anovulation as the cause of abnormal uterine bleeding. Sensitivity,

specificity, positive, and negative predictive value for Pipelle was calculated for all histopathological samples, after excluding 05 inadequate samples. The Pipelle device was found to have 52% sensitivity, 100% specificity, 100% positive, and 94% negative predictive value for endometrial carcinoma. There were no

complications noted with the said procedure except for a mild degree of discomfort.

In this study, the Pipelle device was % accurate for diagnosing Proliferative, secretory phase, endometrial carcinoma, endometrial hyperplasia, and chronic endometritis.

Table 1: Demographic Information of Patients

Demographic Information	NUMBER OF CASES n=100	PERCENTAGE %
Age Groups		
40-50 years	68	68%
51-60 years	25	25%
61-70 years	07	07%
Parity		
Nullipara	12	12%
P ₁ -P ₅	83	83%
≥P ₅	05	05%
Age of menarche		
11-13 years	87	87%
14-16 years	13	13%
PRESENTING COMPLAINTS		
Post-menopausal bleeding	27	27%
Intermenstrual bleeding	26	26%
Heavy menstrual bleeding	38	38%
Post-coital bleeding	09	09%

Table 2: Histopathological results of Pipelle sampling (n=100)

HISTOPATHOLOGICAL DIAGNOSIS	NUMBER OF CASES n=100	PERCENTAGE%
Proliferative endometrium	33	33%
Secretory endometrium	31	31%
Chronic endometritis	13	13%
Endometrial polyp	06	06%
Senile atrophic endometrium	02	02%
Scanty tissue	05	05%
Endometrial hyperplasia without atypia	03	03%
Endometrial hyperplasia with atypia	03	03%
Endometrial carcinoma	04	04%

Table 3: Effect modifier like Age stratification with the comparison of Efficacy of among both groups

ENDOMETRIAL HISTOPATHOLOGY	SENSITIVITY	SPECIFICITY	POSITIVE PREDICTIVE VALUE	NEGATIVE PREDICTIVE VALUE
Proliferative endometrium	92%	100%	100%	97%
Secretory endometrium	97%	99%	97%	99%
Chronic endometritis	87%	100%	100%	98%
Endometrial polyp	62%	100%	100%	89%
Endometrial hyperplasia without atypia	50%	96%	51%	96%

Endometrial hyperplasia	78%	89%	50%	97%
with atypia				
Endometrial carcinoma	52%	100%	100%	94%

Discussion

33% of the clientele attending the gynaecology clinic has the main complaint of Abnormal uterine bleeding.¹⁰ In females who are in the age bracket of 40 years or more, it certainly is important to investigate this complaint to rule out any malignant entity and to confirm the benign nature of the disease and treat it accordingly.¹¹ Previously Diagnostic Dilatation and curettage was the gold standard for investigating patients with Abnormal uterine bleeding, but the need for hospital admission, general anesthesia, and the cost has made it a less favorable option.¹² Regarding outpatient diagnostic gynecological procedures, ultrasonography is one of the minimally invasive modalities which can avoid 40% of histological assessment of endometrium, although the cut-off limit for endometrial thickness is still not clear¹³, a thin regular endometrium is reliable in excluding endometrial carcinoma.¹⁴ The outpatient-based procedures are gaining popularity for quite some time because of their safety, cost-effectiveness, easy accessibility, and better patient acceptability e.g. Pipelle Sampling device, Vabra, and Z samples. Pipelle is a flexible, polypropylene device, which was introduced in the 1980s. It is a thin, plastic suction tube about 3mm in diameter with graduated markings designed on it.¹⁵ The most common presenting complaint in our study was heavy menstrual bleeding (38%) followed by post-menopausal bleeding (27%) which is in comparison to a study performed by Mathew et al¹⁶ and Samal et al¹⁷, where heavy menstrual bleeding was the leading complaint in the perimenopausal age group. This is also supported by a similar study done by Muzaffar et al.¹⁸ The incidence of the non-neoplastic lesion in our study was 91% and 4% were neoplastic lesions. This is similar to studies conducted by Mathew et al¹⁶, and Abdelazim IA et al²⁰, and Chaudhary A et al¹⁹ where sample adequacy was 96%, 97.9%, and 95% respectively and in our study, the sample adequacy was 95%. There were 05 cases of inadequate samples which is in comparison to a study conducted by Fakhar S et al⁹, where there were 02 inadequate samples and a similar study by Mathew et al¹⁶ had 05 inadequate samples. In our study, these inadequate samples were in a post-menopausal age group. Proliferative endometrium was the commonest histopathological finding of 33% followed by secretory

endometrium 31%. Endometrial hyperplasia with and without atypia 03% each. 13% were chronic endometritis and 06% were endometrial polyps on histopathology. These findings are in comparison to a study conducted by Samal K et al¹⁷, where similar findings were observed. 13% of chronic endometritis cases were observed in the reproductive age group. In this study, Pipelle was seen to have 100% specificity and positive predictive value, 52% sensitivity, and 94% negative predictive value for endometrial carcinoma and these findings are similar to a study done by Mathew et al¹⁶ where Pipelle showed 50% sensitivity and 100% specificity for detecting endometrial carcinoma. Our study showed 78% sensitivity, 89% specificity for endometrial hyperplasia with atypia with 50% positive, and 97% negative predictive value. This is similar to a study by Mathew et al¹⁶ and Sanam M et al.²² 05 inadequate samples in our study were in the post-menopausal age group, they went on to have diagnostic dilation and curettage which showed atrophic endometrium on histopathology. This is comparable to a study done by Asif et al²¹ where inadequate samples were 04%. Pipelle Sampling is an effective tool in diagnosing endometrial pathology when combined with proper history, examination, and ultrasound.

Conclusion

We conclude that Pipelle is a safe, cost-effective, and reliable device for diagnosing Endometrial pathologies especially endometrial carcinoma and hyperplasia. Its performance is better in diagnosing global endometrial pathology rather than focal pathology. In high-risk women, this procedure along with ultra-sound can achieve a reliable diagnosis. The time has come to base our diagnosis of different diseases through outpatient, safe, reliable patient-friendly procedures.

Limitation

It is a single-center study, done on a small sample size so it cannot be generalized. Taking this study as a reference point, future multi-centered research with a larger sample size is recommended.

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