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
2 Experimentation/Study conduct
4 Analysis/Interpretation/Discussion
1 Manuscript Writing
5 Critical Review
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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. 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. 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. 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. Evaluation of Abnormal uterine bleeding in pre-menopausal women should be based on symptomatic and clinical presentation. Endometrial Sampling is indicated even if the hysteroscopic findings are normal.

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. The main reason for performing Pipelle endometrial sampling is to differentiate between malignant and non-malignant pathology so that appropriate treatment can be started.

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 | PERCENTAGE |
|------------------------------------------|-----------------|------------|
| **Age Groups**                           | n=100           |            |
| 40-50 years                              | 68              | 68%        |
| 51-60 years                              | 25              | 25%        |
| 61-70 years                              | 07              | 07%        |
| **Parity**                               |                 |            |
| Nullipara                                | 12              | 12%        |
| P1-5                                    | 83              | 83%        |
| ≥P5                                     | 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 | 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%                       |
### Discussion

33% of the clientele attending the gynaecology clinic has the main complaint of Abnormal uterine bleeding. 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. Previsously 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. 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 clear. A thin regular endometrium is reliable in excluding endometrial carcinoma. 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. 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 al and Samal et al, where heavy menstrual bleeding was the leading complaint in the per-menopausal age group. This is also supported by a similar study done by Muzaffar et al. 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 al, Abdelazim IA et al, and Chaudhary A et al 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 al, where there were 02 inadequate samples and a similar study by Mathew et al 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 al, 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 al 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 al and Sanam M et al. 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 al 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 ultrasound 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.
References

1. Khrouf M, Terras K. Diagnosis and management of formerly called dysfunctional uterine bleeding according to PALMCOEIN FIGO classification and the new guidelines. J Obstet Gynecol India. 2014 Dec; 64 (6): 388-93 [Medline] DOI: 10.1007/S13224-014-0641-1
2. Davis E, Sparzak PB. Abnormal uterine bleeding (Dysfunctional Uterine Bleeding). Stat Pearls [Internet] 2018 Jan. [Medline] [Full text] (http://creativecommons.org/licenses/by/4.0)
3. Aston B. Discussion of best practice guidelines for asymptomatic post-menopausal endometrial thickening. Aust NZ J Obstet Gynecol. 2015;55 (1):100-1 DOI: 10.1111/aof.12301
4. Saadia A, Mubarak A, Zubair A, Jamal S, Zafar A. Diagnostic accuracy of endometrial curettage in endometrial pathology. J Ayub Med Coll Abbottabad. 2011;23 (1):129-31 http://www.ayubmed.edu.pk/JAMC/23-1/Aiza.pdf
5. American College of obstetricians and gynecologists ACOG practice bulletin No.149: Endometrial cancer. Obstet Gynecol. 2015; 125:1006-26, [PubMed] [Google Scholar] DOI: 10.1097/01.AOG.0000462977.61229.de
6. American College of obstetricians and gynecologists, ACOG committee opinion no 557: Management of Abnormal uterine bleeding is non-pregnant reproductive-aged women. Obstet Gynecol. 2013; 121:891-6 [PubMed] [Google Scholar] DOI: 10.1097/01.aog.0000428646.67925.9a
7. Beebejaui Y, Varma R. Heavy menstrual flow: current and future trends in management. Rev Obstet Gynecol 2013; 6(3-4): 155-64. PMID: 24826205
8. Piatek S, Panek G, Wielgos M. Assessment of the usefulness of Pipelle biopsy in gynecological diagnostics. Ginekol Pol. 2016; 87(8): 559-64 DOI: 10.5603/JP.2016.0044
9. Fakhar S, Saeed G, Khan AH, Alam AY. Validity of Pipelle endometrial sampling in patients with Abnormal uterine bleeding. Ann Saudi Med. 2008; 28(3): 188-191 DOI: 10.5144/0256-4947.2008.188
10. Khan S, Hameed S, Umber A. Histopathological pattern of endometrium on Diagnost D+C in patients with Abnormal uterine bleeding. Ann King Edward Med Univ. 2011; 17:166. [Google Scholar] http://doi.org/10.21649/akemu.v17i2.285
11. Goldstein SR. Modern evaluation of endometrium. Obstet Gynecol. 2010; 116: 168-76 doi: 10.1099/aog.0.31811dd5d577
12. Shams G. Comparison of Pipelle de cornier with conventional dilatation and curettage in terms of patients’ acceptability. J Postgrad Med Inst (Peshawar-Pakistan) 2012; 26: 418-21 [Google Scholar] http://www.jpjni.org.pk/index.php/jpjni/article/view/1377
13. Opmeer BC, Van Doorn HC, Heintz AP, Burger CW, Bossuyt PM, Mol BW. Improving the existing diagnostic strategy by accounting for characteristics of the women in the diagnostic workup for postmenopausal bleeding BJOG. 2007 Jan; 114(1):51-8 DOI: 10.1111/j.1471-0528.2006.01168.x.
14. Van Den Bosch T. Van Schoubroeck D, Domali E, Vergote I, Mertens P, Amant F, Timmerman D. A thin and regular endometrium on ultrasound is very unlikely in patients with endometrial malignancy, ultrasound Obstet Gynecol 2007; 29(6): 674-9 http://doi.org/10.1002/aog.4031
15. Illavarase CR, Jeythi GS, Alva NK. Study of the efficacy of Pipelle Biopsy Technique to diagnose endometrial disease in abnormal uterine bleeding. J Mid-life Health. 2019; 10: 75-80 DOI: 10.4103/jmh.JMH_109_18
16. Mathew SM, Thomas PA. Prospective Study on the efficacy of Pipelle biopsy to diagnose endometrial pathology in patients with abnormal uterine bleeding Int J Reprod Contracept Obstet Gynecol 2019; 8: 4238-43 DOI: 10.18203/2320-1770.ijrcog20194608
17. Samal R, Vaithly AS, Habeebullah S. Clinicopathological analysis of abnormal uterine bleeding in reproductive and Post-menopausal women in a tertiary care center of South eastern part of India. Indian J Obstet Gynecol Res 2020; 7(1): 66-70 DOI: 10.18231/j-ioggv.2020.014
18. Muzaffar M, Akhter KA, Yasmeen S, Rehman MU, Iqbal W, et al. Menstrual irregularities with excessive blood loss: a clinic pathological correlation. J Pak Med Assoc. 2005; 55(11): 486-489 PMID: 16304868
19. Chaudry A, Javaid M. Clinical usefulness of Pipelle endometrial sampling. Pak Armed Forces Med J 2005; 55; 122-125 https://Pafmj.org/index.php/PAFMJ/article/view/1223
20. Abdelazim IA, Aboelezz A, Abdul Kareem AF. Pipelle Endometrial sampling versus conventional Dilatation and curettage in patients with Abnormal uterine bleeding, J Turk Ger Gynecol Assoc. 2013; 14(1): 1-5 https://doi.org/10.1016/S2305-0500(13)60115-3
21. Asif AZ. An acceptable outpatient technique for endometrial biopsy. J College Physician Surg Pak. 1999; 9(1): 14-16 DOI: http://dx.doi.org/10.18203/2320-1770.ijrcog20160600
22. Sanam M, Majid MMK. Comparison of the diagnostic value of dilatation and curettage versus endometrial biopsy by Pipelle, a clinical trial. Asian Pacific J Cancer Prevent. 2015;16(12):4971-5 https://doi.org/10.7314/APJCP.2015.16.12.4971