

Study of Usefulness of Endometrial Pipelle Biopsy Procedure in an Endometrial Sampling of Abnormal Uterine Bleeding

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ABSTRACT

Introduction: Abnormal bleeding from uterus is a commonly encountered complaint in gynecological practice. As per the National Health Portal report of India (2017) prevalence of AUB is 17.9%. A Gynae Endocrine Society of India (GESI) initiative in collaboration with Endocrine Committee of Association of Obstetrics and Gynecologists of India recommended that endometrial aspiration is preferred procedure for taking endometrial sample for histopathology examination in place of Dilatation and curettage. D&C should not be the procedure of choice for endometrial assessment.

Methodology: A retrospective analysis was done of the abnormal uterine bleeding (AUB) cases who underwent endometrial biopsy using pipelle procedure. The duration of study was from January 2016 to December 2017 at the Private Hospital Clinic of Shivpuri, Madhya Pradesh. Those women who had complaints of AUB were included and as per the recommended protocol for AUB management by GESI required endometrial sampling. Case records of patients those who had undergone endometrial biopsy by pipelle procedure were analyzed. The procedure was “successful” if the cervical os was negotiated successfully and even if after three attempts failed to negotiate cervix it was a “failure.”

Result: Of the total 230 cases attempted for pipelle procedure, 227 cases (98.69%) were successful. The 98% cases the sample obtained was satisfactory. 41.40% of cases were in the age group of 30-40 years. Maximum cases (44.49%) were para 3. Rural cases were 78.41% of the total cases. The presenting symptoms majority were menometorrhagia (49.33%). Histopathology reports were negative for malignancy (60.79%). Hyperplasia without atypical (12.33%) positive suspicious for malignant tumor (0.44%) atrophic endometrium (4.40%) endometriosis (9.69%).

Conclusion: Pipelle biopsy procedure is a simple, easy, patient friendly technique to obtain endometrial biopsy on the outpatient basis without need of patient admission and anesthesia

Keywords: Abnormal uterine bleeding, Endometrial biopsy, Pipelle procedure.

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INTRODUCTION

Abnormal uterine bleeding (AUB) is a commonly encountered complaint in gynecological practice. From reports of western studies. Heavy menstrual bleeding affects 7 to 25% of women in the reproductive age group.^{1,2} The prevalence varies in each country. As per the National Health Portal report of India in 2017 that in India the prevalence of AUB is around 17.9%.³

Benign and malignant pathologies may cause abnormal uterine bleeding in women in the uterus. Previously the nomenclature for AUB was nonuniform and inconsistent.

In 2011, Malcom et al.⁴ gave a classification called PALM-COIEN to facilitate the clinicians, investigators, researchers, and patients. This classification system for AUB was approved by International Federation of Gynecology and Obstetrics executive board as FIGO classification system. There are nine main categories, which are arranged according to acronym PALM-COIEN—polyp, adenomyosis, leiomyoma, malignancy, hyperplasia, coagulopathy, ovulatory dysfunction, endometrial, iatrogenic and not yet classified. In general, the components of PALM group are structural which can be visualized by imaging techniques or histopathology whereas COIEN group is nonstructural abnormalities and cannot be visualized by imaging or histopathology.

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As per the guidelines⁵ on five evidence-based clinical practice recommendations for Indian women, A GESI initiative in collaboration with Endocrine Committee of Association of Obstetrics and Gynecologists of India recommended endometrial histopathology is in AUB In women >40 years (grade A; level 2). In women <40 years who have high risk factors for carcinoma endometrium such as irregular bleeding, obesity associated with hypertension, PCOS, diabetes, endometrial thickness >12 mm, family history of malignancy of ovary/breast/endometrium/colon, use of tamoxifen for HRT or breast cancer, late menopause, hereditary nonpolyposis colorectal cancer, AIB unresponsive to medical treatment (grade A; level 2).² Endometrial aspiration should be the preferred procedure for obtaining an endometrial sample for histopathology. If endometrium is thick on imaging, but where HPE is inadequate or atrophic, hysteroscopy should be performed to rule out polyps (grade A; level 2).³ Dilatation and curettage should not be the procedure of choice for endometrial assessment.

Reporting System for Endometrial Cytology⁶

Specimen adequacy

Satisfactory for evaluation

Less than optimal

Unsatisfactory for evaluation

Interpretation/result

Negative proliferative or secretory phase, atrophic endometrium

Atypical endometrial cells of undetermined significance (AEC-US) suspicious for benign endometrial disease (bleeding due to ovarian dysfunction, iatrogenic changes, infection), or simple endometrial hyperplasia (biopsy not recommended)

Atypical endometrial cells encompassing the spectrum of precursors to endometrial malignant tumor (AEC-PEMT) suspicious for complex endometrial hyperplasia, simple or complex atypical endometrial hyperplasia, adenocarcinoma in situ (biopsy recommended)

Positive suspicious for a malignant tumor

The AUB needs evaluation by multiple diagnostic methods such as dilatation and curettage (D and C) endometrial biopsy, transvaginal Sonography (TVS). Saline infusion sonography (SIS) hysteroscopic guided biopsy and MRI occasionally. For endometrial evaluation D and C is a painful and costly method which requires dilatation and anesthesia in O/T, that is why D and C is a less practical tool and usually performed in the hospital setting. In accordance with the recommended guidelines of GESI where endometrial aspiration was preferred over D and C, the present study was done where pipelle procedure was used to obtain endometrial samples without the need for cervical dilatation.

METHODOLOGY

A retrospective analysis was done of the AUB cases who underwent endometrial biopsy using pipelle procedure. The duration of the study was from January 2016 to December 2017 at the private clinic of Shivpuri.

The inclusion criteria for the study were those women reporting with complaints of AUB, and as per the recommended protocol for AUB management by GESI required endometrial sampling.

The exclusion criteria were (a) positive pregnancy tests, (b) endometrium <4 mm on USG, (c) women on hormone therapy during the last 6 months, (d) history/evidence suggestive of active pelvic infection, (e) medical disorders.

Case records of patients those who had undergone endometrial biopsy by pipelle procedure during the study period were obtained. All the case records were meticulously for detailed information.

As an outpatient procedure, the endometrial samples were obtained by pipelle procedure (Fig. 1) as on the OPD examination table without the need for cervical dilatation and anesthesia. All cases had received Inj Atropine as premedication.

The procedure was labeled as successful if the cervical os was negotiated successfully without any dilatation and anesthesia and an endometrial sample was obtained. Failure to negotiate the os without any dilatation and anesthesia in three attempts and subsequent failure to obtain endometrial biopsy was labeled as a failure of the procedure. These women underwent endometrial sampling by pipelle and specimen was sent for the histopathological exam (HPE). Adequacy of a sample obtained was reported by histopathologist based on an assessment of specimen adequacy using the new reporting system for endometrial cytology as unsatisfactory, less than optimal, satisfactory (3) based on the amount of sample obtained.



Fig. 1: Pipelle canula

Pipelle a single-use, sterile, disposable, suction curette for obtaining a histological biopsy of the uterine mucosal lining or sample extraction of uterine menstrual content for microscopic examination or culturing.

We have also analyzed these women by age, parity, menstrual symptoms and associated symptoms on clinical evaluation. These women were further managed either conservatively or surgically depending upon the histopathological reports. Timely follow-up was done in conservatively managed patients.

RESULT

The retrospective analysis was done of the AUB cases who underwent endometrial biopsy using pipelle outpatient procedure. The duration of the study was from January 2016 to December 2017 at the Private Hospital Clinic of Shivpuri. The number of women enrolled in the study were 230 cases. Of these 230 cases, 3 cases were labeled as a failure where the pipelle procedure could not be done be negotiated through cervical OS, and the endometrial sample could not be obtained by pipelle procedure.

The remaining 227 cases were labeled successful, and samples were obtained for histopathological reporting.

Graph 1 shows that in 98.69% cases of AUB, the procedure was done successfully. Graph 2 shows 97.90% case sample was satisfactory for Histopathological testing and only in 2.10% cases it less than optimum. On analyzing the age maximum women (41.40%) were in the age group of 30–40 years (Table 1). Parity distribution analysis showed

maximum cases (44.49%) were para 3 (Table 2). Rural cases were 78.41% of the total cases (Table 3).

Adequacy of Histopathological Samples

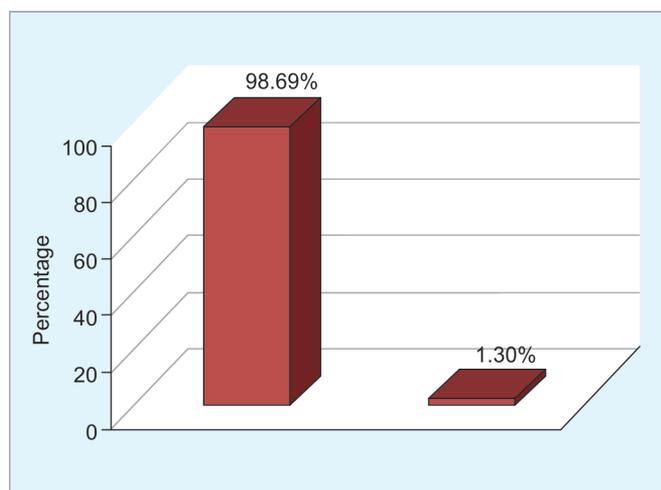
The 222 samples (98%) were satisfactory, five cases (2%) were less than optimal, and no case was reported as unsatisfactory based on the assessment of specimen adequacy using the new reporting system for endometrial cytology.

Clinical Presentation of AUB Cases

Graph 3 shows that the presenting symptoms of the majority of the studied cases were menometrorrhagia (49.33%), menorrhagia (21.58%), postmenopausal bleeding (7.9%), polymenorrhea (06.60%), metrorrhagia or irregular bleeding (04.40%) and postmenopausal bleeding (18) menometrorrhagia with acute emergent abnormal bleeding (04.80%).

Histopathological Reporting (Table 4)

Majority of cases were negative (proliferative, secretory and disordered proliferative) (60.79%). About 12.33% of cases had Hyperplasia without atypical atypical endometrial cells of undetermined significance (AEC-US). Atypical endometrial cells encompassing the spectrum of precursors to endometrial malignant tumor (AEC-

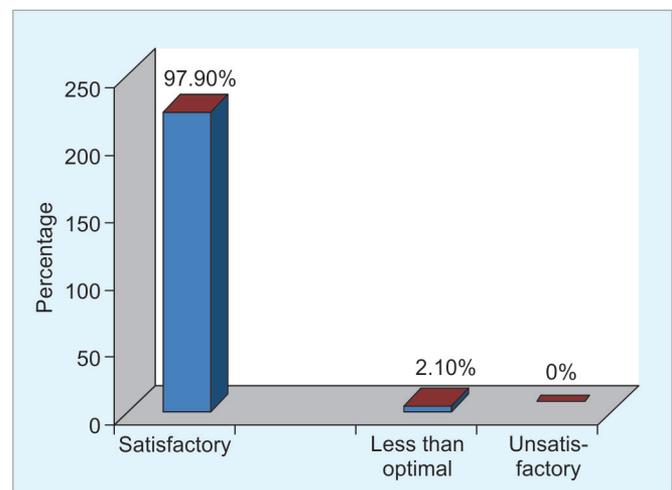


Graph 1: Successful introduction of pipelle through cervix

Table 1: Analysis of age wise distribution of AUB cases

Age group	Number of cases	% of cases
30–40	116	51%
41–50	94	41.40%
51 and above	17	7.48%

Maximum number of cases were in the age group of 30–40 years (41.40%)



Graph 2: Specimen adequacy

Table 2: Analysis of parity wise distribution of cases

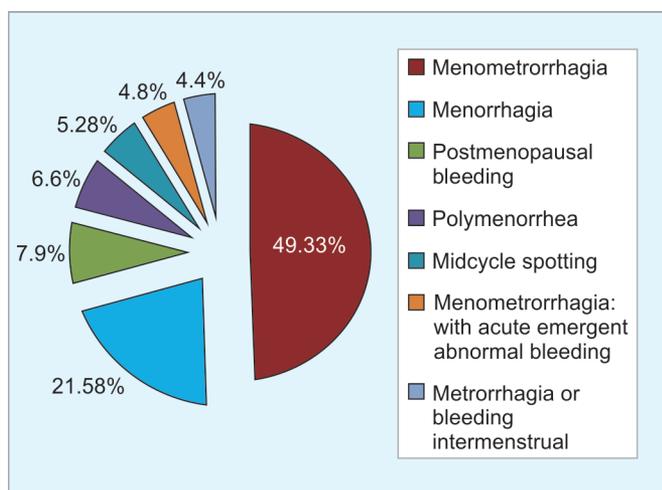
Parity	Number of cases	% of cases
Primipara	45	19.82%
Parity 2	59	26%
Parity 3	101	44.49%
GRAND MULTI G5+	22	9.69%

Maximum cases (44.49%) were para 3

Table 3: Analysis on the basis of the residential status of cases

Residential status	Number of cases	% of cases
Urban	49	21.58%
Rural	178	78.41%

Rural cases were 78.41% of the total cases



Graph 3: Distribution cases on basis of clinical presentation

PEMT) was reported in 1.76% cases. Positive suspicious for malignant tumor was in 0.44%. Atrophic endometrium was found in 4.40%. Other pathologies reported were endometritis (9.69%), adenomatous polyp (7.92%) and placental site reaction (2.64%).

DISCUSSION

AUB needs evaluation by multiple diagnostic methods such as trans vaginal sonography (TVS), saline infusion sonography (SIS), hysteroscopic guided biopsy, endometrial biopsy by dilatation and curettage (D&C) and MRI for evaluation.

D&C is a painful and costly method which requires dilatation and anesthesia in O/T, that is why D&C is a less practical tool and usually performed in an OT setting.

Pipelle procedure for endometrial aspiration avoids general anesthesia, as it does not requires cervical dilatation. Endometrial aspiration can be the preferred procedure for obtaining an endometrial sample for histopathology.

Fakhar et al.⁷ reported in their study that they obtained an adequate sample in 98% of cases by pipelle and in 100% of cases by D&C for diagnosing endometrial carcinoma, hyperplasia, and secretory endometrium. In their study, they compared it with D&C which however we could not do due to limited resources. They In their study report pipelle had high diagnostic sensitivity, specificity and negative predictive value (100%, 98%, 100%, respectively) for hyperplasia with atypia and low sensitivity (57%) and positive predictive value (57%) but high specificity (97%) and negative predictive value (97%) for endometritis. Similarly, for proliferative endometrium pipelle technique had values of 94% and 93% for sensitivity and specificity respectively.

In another study by Abdelazim⁸ reported 100% of the samples obtained by conventional D and C, while 97.9% of the samples obtained by the pipelle device were adequate for histopathological examination. The histopathological analysis of 140 samples obtained by conventional D&C

Table 4: Results based on cytoarchitectural criteria

Disease	No. of cases	Percentage
Negative	16	60.79
proliferative or Secretary	24	138
Disordered proliferative phase	98	
Hyperplasia without atypical atypical endometrial cells of undetermined significance (AEC-US) suspicious for benign endometrial disease	28	12.33
Atypical endometrial cells encompassing the spectrum of precursors to endometrial malignant tumor (AEC-PEMT) suspicious for complex endometrial hyperplasia, simple or complex atypical endometrial hyperplasia	4	1.76
Positive suspicious for malignant tumor	1	0.44
Atrophic endometrium	10	4.40
Endometritis	22	9.69
Adeomyomatous polyp	18	7.92
Placental site reaction	6	2.64
Total	227	100

revealed proliferative endometrium in 37 specimens, secretory endometrium in 33 specimens, endometrial hyperplasia in 49 specimens (45 without atypia and 4 with atypia), endometritis in eight specimens, endometrial polyps in three specimens and malignant endometrium in 10 specimens. In this study; the Pipelle device had 100% sensitivity, 100% specificity and 100% accuracy for diagnosing endometrial hyperplasia, endometrial carcinoma, proliferative and secretory endometrium. Also, it had 88.9% sensitivity, and 99.2% negative predictive value (NPV) and 99.3% accuracy for diagnosing endometritis and it had 60% sensitivity, 89.6% NPV and 98.6% accuracy for diagnosing endometrial polyps.

Rezk⁹ and Choudry¹⁰ in their studies also have reported the effectiveness and acceptability of pipelle endometrial sampling in comparison to dilatation and curettage (D&C).

Alliratnam et al.¹¹ in their study reported that for obtaining the endometrial sample the sensitivity of pipelle sampling was 97% and the specificity was 100% when compared with D&C sampling. The diagnosis made by the HPE report by the sample obtained from pipelle sample had shown a very high sensitivity, specificity, positive predictive value, and negative predictive value, except for the diagnosis of endometrial polyp which the pipelle sample was not able to detect.

Hung et al.¹² in their study reported sensitivity of pipelle and curettage was 93.8% and 97% in patients with low-grade cancer and 99.2% and 100% in patients

with high-grade cancer. Good agreement was observed between the preoperative and the hysterectomy histologic diagnoses (Kappa = 0.69), and between the preoperative and hysterectomy tumor grade (Kappa = 0.78).

Machado et al.¹³ reviewed 1535 reports of endometrial biopsies taken from outpatient using the cornier pipelle, in pre- and postmenopausal patients with abnormal vaginal bleeding to establish the accuracy of endometrial biopsy with the cornier pipelle in the diagnosis of endometrial cancer and atypical endometrial hyperplasia. The cornier pipelle was 84.2% sensitive, 99.1% specific, 96.9% accurate, with 94.1% PPV, and 93.7% NPV for detection of endometrial carcinoma and atypical hyperplasia and they concluded that endometrial cancer and its precursor atypical hyperplasia.

A meta-analysis to assess the accuracy of endometrial sampling devices in the detection of endometrial carcinoma and atypical hyperplasia was done by Dijkhuijen et al.¹⁴ They concluded that the endometrial biopsy with the pipelle is superior to other endometrial techniques in detection of endometrial carcinoma and atypical hyperplasia in pre- and postmenopausal women. In this study; the pipelle had 88.9% sensitivity, 99.2% NPV and it was 99.3% accurate for diagnosing endometrial polyps.

CONCLUSION

Our study concludes that endometrial sampling using Pipelle can replace the conventional D&C method of endometrial sampling as it does not require anesthesia and cervical dilatation.

In our study in 98.69% cases of AUB, the procedure was done successfully, and in 97.09% cases, the adequate tissue sample was obtained to establish the histopathological diagnosis correctly. Maximum cases (51%) were in the age group of 30 to 40 years. Maximum cases (44.49%) were para 3. Rural cases were 78.41% of the total cases.

RECOMMENDATIONS

The present study suggests pipelle biopsy procedure is a simple, easy, patient-friendly technique to obtain endometrial biopsy on the outpatient basis without the need for patient admission and anesthesia. Further randomized trials can be done to establish its efficacy

LIMITATION OF STUDY

In our study due to fewer resources the dilatation and curettage could not be done simultaneously to establish sensitivity, specificity, positive predictive value, the negative predictive value of the procedure.

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