Comparison of Diagnostic Efficacy of Pipelle Endometrial Biopsy with Dilatation and Curettage in Patients with Abnormal Uterine Bleeding

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ABSTRACT

BACKGROUND

Abnormal Uterine Bleeding (AUB) is a common presenting complaint in peri- and post-menopausal women. In these cases, dilatation and curettage (D&C) is the gold standard for assessing Endometrial abnormalities. However, D&C is Gold Standard, requires anaesthesia and hospitalization, and is frequently associated with complications. Thus, a non-invasive, outpatient procedure such as Pipelle biopsy is preferred. We wanted to compare histopathological findings of Pipelle endometrial biopsy with that of D&C, in cases of AUB.

METHODS

This was a prospective, observational, and comparative study performed over a period of 18 months. This study involved 125 cases of AUB and transabdominal ultrasonography was performed. Endometrial samples were obtained in each patient, initially by OPD based Pipelle biopsy followed by operation theatre-based D&C method. Each sample was then subjected to histopathological examination (HPE) for thorough and independent microscopic examination for comparative analysis. Finally, sample adequacy, sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of both the methods were estimated and compared.

RESULTS

The mean age of the patients was 48.68 ± 6.62 years. Majority of the women were multiparous (98.4%), had heavy uterine bleeding (65.6%) as the presenting complaint, and had ultrasonographically normal uterus (47.2%). The sample adequacy rate was 96.8% from Pipelle biopsy and 96% with D&C method. The most common findings on HPE were proliferative and secretory endometrium, and simple hyperplasia with / without atypia. The sensitivity, specificity, NPV, PPV, and accuracy of Pipelle biopsy to diagnose endometrial adenocarcinoma was 100%.

CONCLUSIONS

Endometrial biopsy with Pipelle is easy, safe, painless, and OPD based procedure for obtaining adequate sample for HPE. It has high sensitivity and specificity for diagnosing endometrial pathologies and endometrial carcinoma.

KEYWORDS

Abnormal Uterine Bleeding, Endometrial Biopsy, Hyperplasia, PALM-COIEN, Perimenopause, Pipelle Endometrial Biopsy

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BACKGROUND

Abnormal Uterine Bleeding (AUB) is a ubiquitous finding, mostly in perimenopausal and postmenopausal age group, with a rising proportion of 69%. In India, the prevalence of AUB is 17.9%.[1]. AUB may be defined as a menstrual pattern that varies in frequency, regularity, duration, and volume from a pattern observed during a normal menstrual cycle or after menopause.[2] The presentation pattern consists of heavy and/or prolonged periods and any form of irregular bleeding per vagina.[3] AUB may be due to benign (polyp, fibroids, endometriosis, etc.) or malignant abnormalities of reproductive tract, infections (bacterial, viral, fungal, etc.), pregnancy-related complications, iatrogenic factors, or systemic diseases.[4] However, in majority of cases, there are no underlying organic abnormalities and such condition is termed as dysfunctional uterine bleeding (DUB).[5]

In India, the risk of endometrial cancer in postmenopausal women with bleeding is 4%.[6] Hence, every case of postmenopausal bleeding should be thoroughly investigated to rule out endometrial hyperplasia and cancer. Various methods of evaluating the AUB are ultrasound, saline infusion sonography, hysteroscopy, and endometrial biopsy (EB).[7] Moreover, in many cases, dilatation and curettage (D&C) is considered as a method of choice. But, due to its associated surgical- and anaesthesia-related risks, expense, and postoperative pain, other suitable methods have been tried.[5] Hence, less invasive methods like Pipelle, Tao brush, Vabra, and jet irrigation have been introduced to increase the availability, reduce the number and incidence of complications, as well as lower the cost of endometrial pathology diagnostics.[8] Due to high sensitivity and simplicity, Pipelle has become a popular tool in diagnosis of endometrial cancer.[9]

We wanted to compare the histopathological findings of endometrial aspiration biopsy, by Pipelle with that of endometrial biopsy, obtained by D&C.

METHODS

This was a prospective, observational, and comparative study conducted from June 2017 to November 2018 in the Department of Obstetrics and Gynaecology, Indira Gandhi Government Medical College and Hospital, Nagpur, Maharashtra. The study commenced after obtaining approval of Institutional Ethics Committee and written informed consent of the patients.

Women aged 40 years or more, presenting with AUB, not receiving hormonal therapy, with no past history of any haematological disorders, and no contraindication for D&C were included in the study. While, women receiving oral contraceptive pills, with premalignant and malignant lesions of the cervix, and pregnancy and related causes of per vaginal bleeding were excluded from the study. A total of 125 women attending the Gynaecology Out-Patient Department (OPD) with complaints of AUB and fulfilling the inclusion criteria were enrolled. A thorough history was obtained and complete physical and gynaecological examination (i.e., per speculum, per vaginal) were performed. Basic laboratory investigations such as complete blood count (CBC), blood grouping, transvaginal sonography (TVS), liver function test (LFT), kidney function test (KFT), and thyroid profile were performed. After signing the informed written consent, enrolled patients underwent endometrial biopsy by both Pipelle (performed OPD) and D&C methods (performed in operation theatre). Following this, histopathology reports of samples obtained by Pipelle and D&C methods were compared.

Statistical Analysis

The data was collected, and graphics were designed with the help of Microsoft Excel 2016. Data was presented as frequencies and percentages. The sample size was calculated based on prevalence obtained from previous similar studies (53% in Pipelle biopsy, 32.6% in D & C), power of study was 90% and alpha error was 5%. Considering 10% loss to follow up patients, the estimated sample size was found to be 125. Finally, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated.

RESULTS

The majority of the patients belonged to the age group of 40-45 years [51 (40.8%)], followed by 46-50 years [40 (32%)] (Table 1). The mean age of patients was 48.68 ± 6.62 years. It was observed that parity 3 (N = 54, 43.2%) followed by parity 4 (N = 37, 29.4%) was the most common presentation amongst the patients.

The majority of the patients had the chief complaint of heavy menstrual bleeding [82 (65.6%)] followed by irregular bleeding [19 (15.2%)] and postmenopausal bleeding [15 (12%)] (Table 2). While on USG, the most common finding was normal uterus [59 (47.2%)] followed by bulky uterus [30 (24%)] and uterus with fibroid [11 (8.8%)]. The sample adequacy rate with D&C and Pipelle device/EB were 96% and 96.8%, respectively. On histopathological examination (HPE), amongst 125 cases, by both the methods, we observed an equal number of patients with proliferative endometrium i.e., 67 (53.6%) and one patient (0.8%) had irregular shredding of endometrium. On Pipelle aspiration biopsy, 1 patient, on HPE, had few spindles with no evidence of atypia and in these patients, it was difficult to introduce curette, in traditional D&C, because of stenosed cervix. HPE of samples from Pipelle aspiration biopsy revealed 1 patient each with complex hyperplasia without atypia, xanthomatous endometritis, and tissue showing small fragments of inflammatory exudates, while these finding were missed in samples obtained from D&C method.

According to the PALM-COEIN classification, majority of the patients had ovulatory dysfunction [N = 68, 48%] followed by patients with endometrial involvement [N=19, 15.2%] and least common cause was not yet identified

[N=1, 0.8%]. Moreover, none of the patients had coagulopathy and iatrogenic cause of AUB.

The sensitivity, specificity, positive predictive value, negative predictive value, accuracy of Pipelle biopsy in diagnosing endometrial histological abnormality is depicted in Table 6.

Characteristics	Number of Patients (N = 125)	Percent (%)
Age Groups (Years)		
40 - 45	51	40.8
46 - 50	40	32.0
51 - 55	11	8.8
56 - 60	15	12.0
61 - 65	08	6.4
Parity		
0	01	0.8
1	01	0.8
2	26	20.8
3	54	43.2
4	37	29.6
5	05	4.0
6	01	0.8

Table 1. Distribution of Patients According to Age and Parity

Chief Complaints	Number of Patients (N = 125)	Percent (%)
Chief Complaints		
Heavy menstrual bleeding	82	65.6
Irregular bleeding	19	15.2
Abdominal pain	1	0.8
Dysmenorrhoea	2	1.6
Amenorrhoea	2	1.6
Postmenopausal bleeding	15	12.0
Inter-menstrual bleeding	04	3.2
USG findings		
Uterus normal	59	47.2
Uterus bulky	30	24.0
Uterus with fibroid	11	8.8
Small size uterus	10	8.0
Polyp	06	4.8
Adenomyotic uterus	04	3.2
Ovarian cyst	02	1.6
Hypertrophied changes of cervix	01	0.8
Simple Nabothian Cyst	01	0.8
Carcinoma endometrium	01	0.8

Table 2. Distribution of Patients According to the Chief Complaints and USG Findings

Sample	EB Report [N (%)]	D&C Report [N (%)]
Adequate	121 (96.8)	120 (96)
Inadequate	4 (3.2)	5 (4)
Total	**125 (100)**	**125 (100)**

Table 3. Distribution of Patients According to Adequacy of Sample

Sr. No.	Sample	EB		D&C	
		N	%	N	%
1	Proliferative	67	53.6	67	53.6
2	Secretory	19	15.2	21	16.8
3	Simple hyperplasia	14	11.2	15	12.0
4	Mixed pattern	03	2.4	05	4.0
5	Sample inadequate	04	3.2	05	4.0
6	Hormonal imbalance	03	2.4	02	1.6
7	Cystic hyperplasia	06	4.8	05	4.0
8	Complex hyperplasia without atypia	01	0.8	00	00
9	Xanthomatous endometritis	01	0.8	00	00
10	Tissue shows small fragments of inflammatory exudate	01	0.8	00	00
11	Irregular shedding of endometrium	01	0.8	01	0.8
12	Adenocarcinoma	04	3.2	04	3.2
13	Few spindle cell with no evidence of atypia	01	0.8	00	00

Table 4. Findings of Histopathological Examination of Pipelle Aspiration Biopsy versus D&C Group (N = 125)

	Number of Participants	Percent (%)
Polyp	06	4.8
Adenomyosis	04	3.2
Leiomyoma	11	8.8
Malignancy and Hyperplasia	16	12.8
Coagulopathy	00	00
Ovulatory dysfunction	68	54.4
Endometrial	19	15.2
Iatrogenic	00	00
Not yet identified	01	0.8
Total	125	100

Table 5. Distribution of Patients According to PALM-COEIN Classification

Sr. No.	Diagnosis	Sensitivity	Specificity	PPV	NPV	Accuracy
1	Proliferative	91.04	89.65	91.04	89.65	90.4
2	Secretory	76.19	97.11	84.21	95.28	93.6
3	Simple hyperplasia	73.33	97.27	78.57	96.39	94.4
4	Mixed pattern	40.0	99.16	66.67	97.54	96.8
5	Sample inadequate	0.0	0.0	0.0	0.0	0.0
6	Hormonal imbalance	0.0	0.0	0.0	0.0	0.0
7	Cystic hyperplasia	80.0	98.33	66.67	99.15	98.3
8	Complex hyperplasia without atypia	0.0	0.0	0.0	0.0	0.0
9	Xanthomatous endometritis	100	100	100	100	100
10	Tissue shows small fragments of inflammatory exudate	0.0	0.0	0.0	0.0	0.0
11	Irregular shedding of endometrium	0.0	0.0	0.0	0.0	0.0
12	Adenocarcinoma	100	100	100	100	100
13	Few spindle cells with no evidence of atypia	0.0	0.0	0.0	0.0	0.0

Table 6. Sensitivity, Specificity, Predictive Values, and Accuracy of the Pipelle Device for Diagnosing Endometrial Histology in Patients with Abnormal Uterine Bleeding

DISCUSSION

In the present study, the total number of patients attending the OPD over a period of one year, was 1059, out of which 546 were of menstrual irregularities, thus, amounting to 51.55%. However, according to an estimate, AUB accounts to 33% of patients attending the Gynaecology OPD and about two-third cases require hysterectomy.[10] The structural and functional aetiologies of AUB are clubbed under PALM-COEIN acronym: polyps, adenomyosis, leiomyoma, malignancy, coagulopathy, ovulatory disorders, endometrial, iatrogenic, and not otherwise classified. [11,12] Thus, the main purpose of endometrial sampling is to accurately detect the aetiology of AUB, so that they can be managed promptly.

In the present study, the incidence of AUB was maximum in the age group of 40-45 years followed by 46-50 years. Similar finding was observed by Moradan et al.[13] Chandrakumari et al.[14] and Kumari et al.[15] Thus, highlighting that AUB is common during perimenopausal period. It was observed from the present study, that as compared to nulliparous, AUB is frequently observed in multiparous women. Amongst 125 patients, 123 (98.4%) were multiparous, 1 (0.8%) was primipara, and 1 (0.8%) was nullipara. Similar finding was observed by Kumar S, who reported that 98% cases of AUB were multiparous and 44% cases in para 1-3.[16] Similarly, Singh et al. observed that 92% patients of AUB were multiparous and 8% were nulliparous.[17]

The commonest complaint, in the present study, was heavy menstrual bleeding (65.6%) which was consistent with findings of Abdelazim et al. (37.85%),[18] and Alliratnam et al. (50%).[19] Moreover, other studies performed by Bhavani et al.[20] and Avantika et al.[21] had similar findings. Ultrasonographically, in the present study, majority of the patients had normal uterus (47.2%), followed by bulky uterus (24%), uterus with fibroid (8.8%), and small size uterus (8%). Similarly, Ilavarasi et al. reported that out of the 114 USG reports, the most common uterine pathology was fibroid (27.2%) followed by thickened endometrium in (21.05%), adenomyosis (14.9%), and endometrial polyp (7.89%).[10] However, Talukdar et al. observed that amongst 103 patients of AUB, majority of the cases had fibroid uterus (45.63%), followed by bulky uterus (29.12%), adenomyosis (10.69%), and thickened endometrium (11.65%).[22] It was found that in 10-25% of cases D&C alone might overlook the finding of an existing endometrial pathology. Complications such as uterine perforation (0.6-1.3%), infection (0.3-0.5%), unexpected haemorrhage (0.4%), and also those arising from use of general anaesthesia are commonly noted thus prolonging the hospital stay.[21]

Hence, office biopsy procedures like Pipelle biopsy device which is simple, quick, inexpensive, and safe with good patient acceptability are preferred over D&C.[9] Pipelle biopsy yields sufficient sample which is requisite for the interpretation by a pathologist. However, inadequate sample was found in three cases of hormonal imbalance (2.4%) and six cases of cystic hyperplasia (4.8%). In the present study, the adequacy of sample obtained from Pipelle and D&C method were 96.8% and 96%, respectively. This was comparable with findings of Patil et al., who reported sample adequacy by Pipelle and D&C method of 96% and 96%, respectively. [23] However, Chandrakumari et al. reported 95.24% and 100% adequacy with Pipelle and D&C method, respectively.[14] Similarly, Abdelazim et al. reported 97.9% adequacy rate with Pipelle and 100% adequacy rate with D&C method.[18] Thus, Pipelle biopsy is an effective method of acquiring adequate samples without the use of anaesthesia.

On HPE, in the present study, proliferative type of endometrium was observed in 53.6% of the patients, which is more than that reported by Gerald et al. (42.4%),[24] endometrial hyperplasia was observed in 19.2% of the patients which is less than that reported by Supriya et al. (38%),[25] and endometrial carcinoma was noted in 3.2% which is similar to that reported by Avantika et al. (3%).[21] On comparing the findings of HPE of Pipelle biopsy with D&C, there were 11.2% and 12% of simple hyperplasia without atypia cases, respectively.

However, higher incidence was observed by Rachamallu et al. and they reported simple hyperplasia without atypia in 57.1% and 61% cases by Pipelle and D&C method, respectively.[3] In the present study, there was low sensitivity in detecting proliferative (91.04%) and secretory (76.19%) type of endometrium, Pipelle biopsy had a high NPV (96.39%) and high accuracy rate (94.4%) in diagnosing simple hyperplasia of endometrium. However, in study by Nalina et al., the sensitivity, specificity, PPV, and NPV of Pipelle biopsy in histologically detecting Endometrial abnormalities was 93%, 90%, 88%, and 94%, respectively.[26] Good accuracy of Pipelle biopsy, in the present study, was observed in detecting simple hyperplasia (94.4%), cystic hyperplasia (98.3%), xanthomatous endometritis (100%), and adenocarcinoma (100%). Similar findings were demonstrated by various studies.[14,18,27-29]

For diagnosing endometrial carcinoma, in the present study, Pipelle aspiration biopsy had sensitivity, specificity, positive predictive, and negative predictive value of 100% which is consistent with the study performed by Rachamallu et al.[3] and Nadia et al. (both 100%).[30] The accuracy of D&C and Pipelle biopsy in cases of malignancy with AUB is almost similar.[31] However, Pirog et al. stated that the accuracy of curettage and Pipelle biopsy in differentiating between benign from malignant condition is uncertain.[32] The present study has limitations in the form of small sample size obtained from a single center, thus, its findings cannot be generalised. Further multicentric studies recruiting higher number of patients and focussing on benign and malignant lesions of uterus needs to be performed.

CONCLUSIONS

Endometrial biopsy with Pipelle is an OPD procedure and results in 96.8% adequate samples. Also, due to its high sensitivity, specificity, positive and negative predictive values, it is being performed frequently in patients with AUB with hyperplasia and malignancy. Moreover, this OPD procedure has the advantages of diagnosing endometrial pathologies in a large population, cut down the hospital stay, is cost-effective, and results in high patient compliance. Thus, to obtain adequate endometrial sample for HPE, in peri- and post-menopausal women with AUB, Pipelle biopsy should be considered as primary investigation.

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