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ORIGINAL RESEARCH

Comparison of diagnostic efficacy of pipelle endometrial biopsy with dilatation and curettage in patients with abnormal uterine bleeding

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ABSTRACT

Aim: The study was designed to evaluate the diagnostic efficacy of pipelle endometrial biopsy in patients with abnormal uterine haemorrhage in comparison to dilatation and curettage. **Materials and methods:** The prospective, observational, and comparative study that was conducted in the Obstetrics and Gynaecology Department. A total of 100 women who met the inclusion criteria and were attending the Gynaecology Out-Patient Department (OPD) with complaints of AUB were enrolled. The outpatient department conducted a comprehensive clinical evaluation of the patient, which encompassed a history, physical examination, and baseline investigations. Pipelle device endometrial sampling was performed without anaesthesia for diagnostic intervention, followed by D&C endometrial sampling under anaesthesia. The significance of study parameters on a categorical scale between two or more groups has been determined using Fisher/Chisquare exact test. **Results:** The age category of 40-45 years comprised the majority of the patients (40%). 48.2 ± 6.21 years was the average age of the patients. Parity 3 (44%) and parity 4 (29%) were the most prevalent presentations among the patients. The chief complaint of the majority of the patients was excessive menstrual bleeding (65%), followed by irregular bleeding (15%) and postmenopausal bleeding (12%). The most prevalent observation during USG was a normal uterus (47%), followed by a bulky uterus (24%), and a uterus with a fibroid (9%). The sample adequacy rate with D&C and Pipelle device/EB was 95% and 96%, respectively. In both methodologies, we observed an equal number of patients with proliferative endometrium (53%), and one patient (1%) had irregular shredding of endometrium during histopathological examination (HPE) of 100 cases. One patient underwent a Pipelle aspiration biopsy and exhibited a low number of spindles on HPE, with no indication of atypia. **Conclusion:** Endometrial biopsy with Pipelle is an outpatient procedure that generates 96.8% satisfactory samples. Additionally, it is being implemented frequently in patients with AUB who have hyperplasia and malignancy as a result of its exceptional sensitivity, specificity, and positive and negative predictive values.

Keywords: Pipelle endometrial biopsy, Dilatation and Curettage, Abnormal uterine bleeding

INTRODUCTION

Abnormal uterine bleeding (AUB) is a prevalent condition in the field of gynaecology, accounting for over 70% of gynaecological consultations among perimenopausal and postmenopausal women.[1]AUB is prevalent in India at a rate of 17.9%.[2]AUB can be defined as a menstrual pattern that differs in frequency, regularity, duration, and volume from a pattern observed during a typical menstrual cycle or after menopause.[3]

Heavy and/or prolonged periods, as well as any form of irregular vaginal haemorrhage, comprise the presentation pattern. AUB may be the result of benign (polyps, fibroids, endometriosis, etc.) or malignant abnormalities of the reproductive tract, infections (bacterial, viral, fungal, etc.), pregnancy-related complications, iatrogenic factors, or systemic diseases.[4]Nevertheless, in the majority of cases, there are no underlying organic abnormalities, and this condition is referred to as dysfunctional uterine bleeding (DUB).[5]

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Endometrial assessment in AUB encompasses a variety of diagnostic modalities, including ultrasonography, endometrial curettage, and office-based methods, such as hysteroscopy-assisted biopsy or endometrial samplers like Pipelle.[6]Endometrial examination is recommended at the age of 40 to rule out endometrial hyperplasia or carcinoma, as less than 1% of endometrial carcinoma cases occur in individuals under the age of 35 and 6% in those aged 45 years or younger.[7] Sampling of the endometrium is mandatory when a woman is identified as having high risk factors for endometrial pathology, such as perimenopausal abnormal uterine bleeding, postmenopausal uterine haemorrhage, or a history of chronic anovulation..[8]

The standard for endometrial sampling is hysteroscopic biopsy and D&C, and its position in gynaecology is not in question. However, in 60% of D&C procedures, less than half of the uterine cavity is cured, which increases the risk of complications such as infection, perforation, invasiveness, and the need for a significant amount of hospital bed time. This has resulted in the development of straightforward endometrial sampling techniques. Pipelle is performed in the ambulatory or general practice setting and does not necessitate general anaesthesia or analgesia. The diagnosis of endometrial pathologies was equally successful with EAB performed using a specialised device called Pipelle and D&C. Despite the numerous studies that have been conducted on the efficacy of Pipelle type devices in outpatient endometrial sampling, there are a limited number of studies available from India.

The objective of the current investigation was to evaluate the diagnostic efficacy of pipelle endometrial biopsy in patients with abnormal uterine haemorrhage in comparison to dilatation and curettage.

MATERIALS AND METHODS

After obtaining clearance from ethical committee, the prospective, observational and comparative study conducted in the Department of Obstetrics and Gynaecology.A total of 100 women who met the inclusion criteria and were attending the Gynaecology Out-Patient Department (OPD) with complaints of AUB were enrolled.

Inclusion criteria

- Women who were at least 40 years old and diagnosed with AUB.
- Hormonal therapy was not being administered.
- No prior history of haematological disorders.
- There was no contraindication to D&C.

Exclusion criteria

- Women who are taking oral contraceptives.
- Premalignant and malignant lesions of the cervix.
- Pregnancy and related causes of per vaginal haemorrhage.

Methodology

The outpatient department conducted a comprehensive clinical evaluation of the patient, which encompassed a history, physical examination, and baseline investigations. A transvaginal sonography was conducted prior to the endometrial biopsy. 5.0-to-7.5 MHz vaginal transducers were employed to scan the uterus in the sagittal and longitudinal projections. The digital callipers on the display were used to measure the thickest anteroposterior diameter of the endometrial stripe in the sagittal plane. The endometrial thickness was subsequently measured. Pipelle device endometrial sampling was performed without anaesthesia for diagnostic intervention, followed by D&C endometrial sampling under anaesthesia.

The Pipelle device, which is a thin and flexible device with an integrated vacuum system, is employed for sampling. The inner piston of the device is subsequently retracted to generate suction. The endometrial sample is obtained by rotating the cannula, and a strip of endometrium is peeled off and sucked into the syringe. After the Pipelle procedure in the OPD, the patient was transferred to the OT, where anaesthesia was administered and the D&C procedure was performed. A small, sharp curette was introduced after dilatation with Hegars dilators, and a systematic, thorough, and gentle sampling of all portions of the uterine cavity was performed. The histopathologist, who was unaware of the sample collection method, was sent both samples for histopathological evaluation. The diagnostic D&C standard and Pipelle biopsy reports are compared.

STATISTICAL ANALYSIS

The results of continuous measurements were presented as Mean ± SD, while the results of categorical measurements were presented as Number (%). The 5% level of significance was used to evaluate the significance. The significance of study parameters on a categorical scale between two or more groups was determined using the Fisher/Chisquare exact test in a non-parametric setting for qualitative data analysis. When cell samples were exceedingly small, a Fisherman exact assay was implemented. The data was analysed using SPSS 18.0 and the R environment ver.3.2.2.

RESULTS

The age group of 40-45 years comprised the plurality of patients (40%), with 46-50 years comprising the second largest proportion (35%). 48.2 ± 6.21 years was the average age of the patients. Parity 3 (44%) and parity 4 (29%) were the most prevalent presentations among the patients.(Table 1)

Heavy menstrual bleeding was the primary complaint of the majority of patients (65%), with irregular bleeding (15%) and postmenopausal bleeding (12%) following in that order. Normal uterus was the most frequently observed finding during USG (47%), with

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bulky uterus (24%), and uterus with fibroid (9%) following in that order. (Table 2). Sample adequacy rates were 95% and 96% for the Pipelle device/EB and D&C, respectively. (Table 3)

In both methodologies, we observed an equal number of patients with proliferative endometrium (53%), and one patient (1%) had irregular shredding of endometrium during histopathological examination (HPE) of 100 cases. In one patient who underwent Pipelle aspiration biopsy, there were only a few spindles on HPE, and there was no evidence of atypia. In these patients, the stenosed cervix made it difficult to introduce a curette during traditional D&C. The HPE of samples from Pipelle aspiration biopsy revealed that one patient each had complex hyperplasia without atypia, xanthomatousendometritis, and tissue showcasing small fragments of inflammatory exudates. These findings were not observed in samples obtained from the D&C method. (Table 4)

Table 1: Distribution of Patients According to Age and Parity

		Number	Percent (%)
Age (years)	40-45	40	40%
	46-50	35	35%
	51-55	8	8%
	56-60	11	11%
	61-65	6	6%
Parity	0	1	1
	1	1	1%
	2	20	20%
	3	44	44%
	4	29	29%
	5	4	4%
	6	1	1%

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

		Number	Percent (%)
Chief complaints	Heavy menstrual bleeding	65	65%
	Irregular bleeding	15	15%
	Abdominal pain	1	1%
	Dysmenorrhoea	2	2%
	Amenorrhoea	2	2%
	Postmenopausal bleeding	12	12%
	Inter-menstrual bleeding	3	3%
USG findings	Uterus normal	47	47%
	Uterus bulky	24	24%
	Uterus with fibroid	9	9%
	Small size uterus	8	8%
	Polyp	4	4%
	Adenomyotic uterus	3	3%
	Ovarian cyst	2	2%
	Hypertrophied changes of cervix	1	1%
	Simple Nabothian Cyst	1	1%
	Carcinoma endometrium	1	1%

Table 3: Distribution of Patients According toAdequacy of Sample

		Pipelle Aspiration Biopsy	D&C Report
Sample	Adequate	96(96%)	95(95%)
	Inadequate	4(4%)	5 (5%)
Total		100	100

Table 4: Findings of Histopathological Examination of Pipelle Aspiration Biopsy versus D&C Group

		Pipelle Aspiration Biopsy		D&C	
		N	%	N	%
	Proliferative	53	53%	53	53%
	Secretory	15	15%	17	17%
	Simple hyperplasia	11	11%	12	12%

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Sample	Mixed pattern	2	2%	4	4%
	Sample inadequate	4	4%	4	4%
	Hormonal imbalance	2	2%	3	3%
	Cystic hyperplasia	5	5%	3	3%
	Complex hyperplasia without atypia	1	1%	0	0
	Xanthomatous endometritis	1	1%	0	0
	Tissue shows small fragments of inflammatory exudate	1	1%	0	0
	Irregular shedding of endometrium	1	1%	1	1%
	Adenocarcinoma	3	3%	3	3%
	Few spindle cell with no evidence of atypia	1	1%	0	0

DISCUSSION

The assessment of abnormal uterine haemorrhage commences with a history, physical examination and pelvic examination, which includes a cervical cytology of the ectocervix and the endocervical canal. Despite the fact that the medical history is insufficiently detailed to allow for a definitive diagnosis of AUB, certain enquiries can help to further restrict the diagnostic possibilities. These enquiries place the bleeding in the context of a woman's other health concerns.

In the current investigation, the age group of 40-45 years exhibited the highest incidence of AUB, followed by 46-50 years. Moradan S et al[9], Chandrakumari AS et al[10], and Kumari A et al[11] observed comparable results. Consequently, emphasising that AUB is prevalent during the perimenopausal period. The present study revealed that AUB is more frequently observed in multiparous women than in nulliparous women. Of the 100 patients, 98 (98%) were multiparous, 1 (1%) was primipara, and 1 (1%) was nullipara. Kumar S et al[12] reported that 98% of AUB cases were multiparous, while 44% of cases in para 1-3 were multiparous. A similar observation was made. In the same vein, Singh A et al[13] found that 92% of AUB patients were multiparous and 8% were nulliparous.

The most prevalent complaint in the current study was excessive menstrual bleeding (65%), which was in agreement with the findings of Abdelazim IA et al[14] (37.55%) and Alliratnam AS et al[15] (50%). Additionally, Bhavani N et al[16] and Avantika G et al[17] conducted additional research that yielded comparable results. The majority of patients in the current study had a normal uterus (47%), followed by an obese uterus (24%), a uterus with a fibroid (9%), and a small uterus (8%) in terms of ultrasonography. Similar to Ilavarasi CR et al[18], the most prevalent uterine pathology in the 114 USG reports was fibroid (27.2%), followed by distended endometrium (21.05%), adenomyosis (14.9%), and endometrial polyp (7.89%). Nevertheless, Talukdar B et al[19] found that the majority of the 103 patients with AUB had a fibroid uterus (45.63%), followed by a bulky uterus (29.12%), adenomyosis (10.69%), and a distended endometrium (11.65%).

Therefore, office biopsy procedures, such as the Pipelle biopsy device, are preferred over D&C due to their simplicity, rapidity, affordability, and safety, as well as their high level of patient acceptance. The pipelle biopsy produces an adequate sample for pathological interpretation. The sample adequacy derived from the Pipelle and D&C methods was 96% and 95%, respectively, in the current investigation. Patil P et al[20] reported sample adequacy of 96% and 96%, respectively, using the Pipelle and D&C methods. This was comparable to their findings. Nevertheless, Chandrakumari AS et al[10] reported 95.24% and 100% adequacy with the Pipelle and D&C methods, respectively. In the same vein, Abdelazim IA et al[14] reported a 97.9% adequacy rate with Pipelle and a 100% adequacy rate with the D&C method. Consequently, pipelle biopsy is a viable approach to obtaining sufficient samples without the necessity of anaesthesia.

The proliferative type of endometrium was observed in 53% of the patients in the present research, which is higher than the 42.4 percent reported by Gerald DF et al[21]. Upon comparing the results of HPE of Pipelle biopsy with D&C, 11% and 12% of the cases were straightforward hyperplasia without atypia, respectively.

The present study demonstrated a low sensitivity in the detection of proliferative (91.04%) and secretory (74.21%) endometrium. However, Pipelle biopsy had a high NPV (95.32%) and an exceptionally high accuracy rate (95.2%) in the diagnosis of uncomplicated hyperplasia of the endometrium. Nevertheless, the sensitivity, specificity, PPV, and NPV of Pipelle biopsy in the histological detection of endometrial abnormalities were 93%, 90%, 88%, and 94%, respectively, in a study conducted by Nalina S et al[22].

The sensitivity, specificity, positive predictive value, and negative predictive value of Pipelle aspiration biopsy were all 100% in the present study for the diagnosis of endometrial carcinoma. This is in agreement with the findings of Rachamallu L et al[23] and Nadia K et al[24], who also achieved a 100% sensitivity and specificity. In cases of malignancy with AUB, the accuracy of D&C and Pipelle biopsy is nearly identical. The findings of the present investigation are not generalisable due to the small

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sample size obtained from a single centre. Additional multicentric studies that recruit a greater number of patients and concentrate on benign and malignant uterine lesions are required.

CONCLUSION

Endometrial biopsy with Pipelle is an outpatient procedure that generates 96.8% satisfactory samples. Additionally, it is being implemented frequently in patients with AUB who have hyperplasia and malignancy as a result of its exceptional sensitivity, specificity, and positive and negative predictive values. In addition, this outpatient procedure has the potential to diagnose endometrial pathologies in a large population, reduce the length of hospital stay, be cost-effective, and produce high patient compliance. Pipelle biopsy should be regarded the primary investigation in peri- and post-menopausal women with AUB in order to obtain an adequate endometrial sample for HPE.

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