Section: Obstetrics and Gynaecology

Original Research Article

A STUDY TO COMPARE THE PIPELLE ENDOMETRIAL SAMPLING VS. DILATATION AND CURETTAGE IN WOMEN WITH ABNORMAL UTERINE BLEEDING: A HOSPITAL BASED PROSPECTIVE STUDY

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Received : 03/03/2025
Received in revised form : 26/04/2025
Accepted : 14/05/2025

Keywords:
Endometrium, uterus, bleeding, menopause.

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DOI: 10.47009/jamp.2025.7.4.16

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (4); 76-80

ABSTRACT

Background: To investigate causes of AUB, histopathology may be required. For this biopsy can be taken using dilatation and curettage or pipelle technique can be used. D&C needs general anesthesia, and associated with risk of perforation, infections, costly, pain and discomfort. To overcome these limitations one method is Pipelle method. Compared to D&C it is associated with less pain and is more safe, simple and free from complications. **Objective:** To compare Pipelle endometrial sampling vs. dilatation and curettage in women with abnormal uterine bleeding. **Materials and Methods:** Hospital based cross sectional study was carried out among 100 patients with complaints of abnormal uterine bleeding. Endometrial sampling was performed by the Pipelle device in 50 patients and conventional dilatation and curettage in 50 patients. Time required for the procedure, acceptability and pain during procedure and post-operative pain was noted by numerical rating pain scale. **Result:** Patients in both groups were comparable for age, endometrial thickness, per vaginal findings, per abdomen findings, comorbidities, parity and menopause status. Sample adequacy was similar by both methods. Pipelle method was more acceptable (98% vs. 68%), less painful, and less time consuming compared to the D&C method. Differences in terms of acceptability, pain and time taken were significant for pipelle group. ($p<0.05$). **Conclusion:** Endometrial biopsy with pipelle as an outpatient procedure is safe, minimally invasive with less chances of perforation and infection. It has lower pain scores and requires fewer instruments. It is efficient method for evaluating AUB with good patient compliance, acceptancy, sample adequacy and less time taking.

INTRODUCTION

Excessive, more frequent, irregular and prolonged bleeding from the corpus of the uterus is known as abnormal uterine bleeding (AUB).[1] It is estimated that in women of age group 15-45 years, the prevalence of AUB is around 3-30%. In India, the prevalence of AUB is around 17.9%.[2]

AUB can take two common forms i.e. acute or chronic. Acute is one which presents with a very blood loss suddenly in a very short span of time which must be treated vigorously. While, the chronic AUB is one which may be present for a prolonged period of time, but may not warrant attention. However, it may be disturbing but may not be like that of acute one. Whenever the blood loss during a typical menses is more than 80 ml, it is termed as heavy. Whenever the menstrual period extends beyond eight days, it is called prolonged. Heavy and prolonged is the term used when both above mentioned things happen together. If the menses do not occur for more than 90 days, it is called as amenorrhea. Irregular menses are those when it is more than 10 days for variation in cycle length from one cycle to second cycle. When the bleeding occurs after vaginal intercourse, it is called as post coital bleeding. Any bleeding that occurs after giving the hormone, it is called as breakthrough bleeding and unscheduled bleeding. Whenever there is decrease in the level of progesterone due to any reason and the bleeding occurs, it is called as withdrawal bleeding. Any bleeding that happens after one year from the menopause, it is called as postmenopausal bleeding.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

A wide variety of causes are responsible for AUB.[3] "The international federation of gynaecology and obstetrics (FIGO) has approved a new classification system (polyps, adenomyosis, malignancy, coagulopathy, ovulatory disorders, endometrial causes, iatrogenic, not otherwise classified [PALM-COEIN]) for causes of AUB in non-gravid women.[3]

To investigate the causes of AUB, it is necessary to take a good history and carry out a thorough clinical examination. Certain investigations like ultrasound and complete blood picture etc. should be carried out to arrive or confirm the diagnosis. If a woman was having anovulation of chronic nature, then histopathology may be required. For this biopsy can be taken using the hysteroscopic technique. It is considered as gold standard. For histopathology, we should take the endometrial samples. For taking these samples, either dilatation and curettage (D & C) or pipelle technique can be used.[4]

In these two, Dilatation and Curettage is most commonly used method. In Dilatation and Curettage method, patient needs general anesthesia. Moreover, there is a risk of perforation of the uterus. The patient may be exposed to infections. It is costly for the patients. It is associated with pain. It is also associated with a lot of discomfort.

To overcome these limitations associated with Dilatation and Curettage method, other techniques have been evolved. One such method is Pipelle method.[5] It is a well-known method used to take the biopsy from the endometrium. It is a plastic tube which is not completely rigid. It opens on single side. For its insertion in the uterus, cervical dilatation is not a requirement. It is associated with a very low degree of pain while taking the sample. It can cover 5-15% of area to take the sample. Failure to take sample can occur in 10% of the cases. Compared to Dilatation and Curettage method, this method is associated with less pain and more safety for the patients. It is simple and free from the complications.[5]

Hence, it is necessary to carry out studies that can compare these two methods. With this background, present study was carried out to evaluate differences in the procedure of pipelle endometrial biopsy and dilatation and curettage based on time taken for procedure, perception of pain, acceptability of procedure and safety of procedure and to determine and compare the adequacy of the endometrium sample obtained from both the procedures for Histopathology.

MATERIALS AND METHODS

Study Design: Hospital based cross sectional study

Sample size calculation:

Considering prevalence of AUB as 17% based on a previous study, with 95% confidence level, and 8% allowable error, the sample size came out to be 85. We were able to include 100 cases in the present study.

Study subjects: Patients attending department of obstetrics and gynaecology of Malla Reddy Hospital with complaints of abnormal uterine bleeding were selected to study after taking informed consent from the participant.

Study period: January 2020 to June 2021

Study tool: Case sheet proforma

Instruments: 1. Sim's speculum 2. Vulsellum 3. Uterine sound 4. Pipelle curette 5. Hegar's dilators 6. Endometrial biopsy curette 7. Sponge holding forceps 8. Betadine 9. 10%formalin

Inclusion Criteria

1. Age 35 – 60years.
2. Patients with or without medical disorders with abnormal uterine bleeding.
3. Patients who have given consent for the study.

Exclusion Criteria

1. Pregnancy
2. Acute Pelvic inflammatory disease
3. Carcinoma cervix

Methodology

After obtaining clearance from Head of department, Scientific Committee, Institutional Ethic Committee 100 patients were selected for the study from Gynecology OPD of Malla Reddy hospital. After taking an informed consent, detailed clinical assessment of the patient including clinical history, general physical examination, pelvic examination of the patient and basic investigations and ultrasound of abdomen and pelvis was done. Endometrial sampling was performed by the Pipelle device in 50 patients and conventional dilatation and curettage in 50 patients. The patient's bladder was emptied before the procedure. The patient was made to lie in dorsal position. A speculum examination was done followed by bimanual pelvic examination to assess the size and position of the uterus.

Time required for the procedure, acceptability and pain during procedure and post operative pain was noted by numerical rating pain scale. Under aseptic conditions parts were painted and draped. cervix was then visualized using a sims speculum. Anterior lip of the cervix was held with vulsellum to provide gentle traction whilst a sound was inserted through the cervical os. After assessing the position and size of the uterine cavity, in 50 patients Pipelle endometrial device was introduced without cervical dilatation. After creating negative pressure and with a rotatory movement it was withdrawn and sample was collected into a solution of formalin and labelled. In another 50 patients, injection tramadol was given and dilatation with Hegar's dilators was done if required. A small sharp endometrial biopsy curette was introduced, thorough and gentle sampling of all parts of the uterine cavity was done and the sample obtained was collected into formalin solution and labelled. Sample was labelled and sent to a pathologist, who was blinded to the methods of sampling for histopathology assessment.

Statistical Analysis

The data was entered in the Microsoft Excel worksheet and analysed using proportions and mean

ISSN (O): 2687-5365; ISSN (P): 2753-6556

values. For comparison of proportions in two groups, chi square test was used. For comparison of mean values in two groups, independent samples t test was used. A p value of less than 0.05 was considered as statistically significant.

RESULTS

Table 1: Comparison of clinical features in two groups

Clinical Features	Dilatation and curettage group		Pipelle group	
	No.	%	No.	%
Continuous Bleeding	1	2	3	6
Frequent bleeding	6	12	3	6
Heavy menstrual bleeding	27	54	20	40
Irregular cycles	10	20	13	26
Post menopausal bleeding	6	12	11	22

There was one case of continuous bleeding in Dilatation and Curettage group and three in pipelle group. Frequent bleeding cases were double in Dilatation and Curettage group compared to the pipelle group. Heavy menstrual bleeding cases were 27 in Dilatation and Curettage group compared to 20 cases in pipelle group. (Table 1)

Table 2: Comparison of baseline characteristics in two groups

Characteristics		Dilatation and curettage group		Pipelle group		p
		No.	%	No.	%	
Menopause status	Post menopause	6	12	10	20	0.2752
	Pre menopause	44	88	40	80	
Parity	Nullipara	0	0	1	2	0.1017
	Para 1	2	4	1	2	
	Para 2	29	58	23	46	
	Para 3	16	32	13	26	
	4 & above	3	6	12	24	
Comorbidities	Present	19	38	18	36	0.8359
	NONE	31	62	32	64	
Per abdomen findings	Soft	41	82	47	94	0.0648
	Mass	9	18	3	6	
Per vaginal findings	Abnormal (atrophic/bulky)	36	72	29	58	0.1422
	Normal	14	28	21	42	
Endometrial thickness	Increased (> normal)	48	96	45	90	0.2396
	Normal	2	4	5	10	
Mean age		44.52±7.81 years		45.52±8.25 years		0.5325

Patients in both the groups were comparable for age, endometrial thickness, per vaginal findings, per abdomen findings, comorbidities, parity and menopause status. These differences in the proportions/mean values were not found to be statistically significant. (Table 2)

Table 3: Comparison of method performance in two groups

Performance of method		Dilatation and curettage group		Pipelle group		p
		No.	%	No.	Percentage	
Sample adequacy	Adequate	49	98	46	92	0.1524
	Not adequate	1	2	4	8	
Acceptance of procedure	Acceptable	34	68	49	98	< 0.001
	Not acceptable	16	32	1	2	
Mean pain score		5.88±1.49		2.5±1.07		< 0.001
Mean time taken for procedure in min		11.28±2.86		3.92±1.08		< 0.001

In terms of sample adequacy, the Dilatation and Curettage method gave adequate sample in 98% of the cases while it was slightly lower pipelle method where it gave adequate sample in 92% of the cases. But the difference was not found to be statistically significant ($p>0.05$). 98% of women who underwent the pipelle procedure said it was acceptable compared to only 68% of women who underwent the Dilatation and Curettage method. Hence, in the terms of acceptance, pipelle procedure was more acceptable by women and the difference was found to be statistically significant ($p<0.05$). The mean pain score was also significantly lesser in the pipelle group compared to the Dilatation and Curettage group ($p<0.05$). At the same time the average time taken for completion of the procedure was almost four times lesser in the pipelle group compared to the Dilatation and Curettage group ($p<0.05$). (Table 3)

ISSN (O): 2687-5365; ISSN (P): 2753-6556

DISCUSSION

In the present study, abnormal uterine bleeding was commonly seen in 36-39 years. Overall, 30% of women belonged to 36-39 years, 29% belonged to 40-44 years, 26% belonged to 45-49 years. Mean age was 44.52±7.81 years. Among the 50 women in Pipelle group, 32% of the women belonged to the age group of 36-39 years. Mean age was 43.38±5.97 years. In a study done by Noor N et al,[6] 68% of patients were in the age group of 40-50 years. 25% belonged to 51-60 years and 7% belong to 61-70 years of age group. In another study done by Kaur H et al,[7] age group 35 – 40 contributed to 8%, 41 – 45 years contributed to 34.5%. 40% belonged to age group of 46– 50 years and 17% belonged to age group >50 year. In a study done by Patankar AM et al,[8] the majority of the patients 40.8% belonged to the age group of 40-45 years, 32% belonged to 46-50 years. The mean age of patients was 48.68 ± 6.62 years. In a study done by Abdelazim IA et al,[9] the median age of the studied population was 44.5 years. In a study done by Alliratnam AS et al,[10] the mean age of the study population was 42.2 years. In a study by Shivangi et al,[11] majority of the patients 43.8% of abnormal uterine bleeding were found in the age group of 40 to 49 years followed by 32.5% patients in the age group of 30 to 39 followed by 21.2% patients in the age group of 50 to 59 years of age. Only 2.5% patients were found in the age group of 60 to 69 years. Mean age of the patients was found to be 43.89 years and standard deviation was found to be 7.38 years. In a study by Moradan Sanam et al,[12] the mean age of the study group was 46.19 ± 6.45 years ranging from 37 to 57. In a study by Kaiyrlykyzy A et al,[13] included 158 patients with a median age of 42 (34 48.3) years old.

Among the dilatation and curettage group, 2% had continuous bleeding, 12% had frequent bleeding, 54% had heavy menstrual bleeding, 20% have irregular cycles and 12% had post-menopausal bleeding. Among the Pipelle group, 6% had continuous and frequent bleeding each, 40% had heavy menstrual bleeding, 23% had irregular cycles and 22% had post-menopausal bleeding. In the study done by Noor N et al,[6] 27% had Postmenopausal bleeding, 38% of patients with heavy menstrual bleeding. 26% had intermenstrual bleeding. 09% presented with post-coital bleeding in another study done by Patankar AM et al,[8] 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%)]. In another study done by Abdelazim IA et al 9, the presenting symptoms of the studied cases were; menorrhagia (n=53), polymenorrhagia (n=37), metrorrhagia or irregular bleeding (n=26) and postmenopausal bleeding (n=24). In another study done by Alliratnam AS et al,[10] menorrhagia and polymenorrhea was the chief complaints. In a study done by Jain M et al,[14] Menorrhagia 42.16% Metrorrhagia 3.35% Menometrorrhagia 1.86% Oligomenorrhea 13.80% Polymenorrhea 5.22% Polymenorrhagia 5.59% Continuous bleeding per vaginum 27.61% post-menopausal 0.37%

In the present study, among the dilatation and curettage group, 88% were of pre-menopausal group and 12% were of post-menopausal group. Among the Pipelle group, 80% were of pre-menopausal group and 20% were of post-menopausal group. In a study done by Kaur H et al,[7] 88.5% of the were belonging to peri menopausal age group. 11.5% belong to menopausal age group. In a study by Kaiyrlykyzy A et al,[13] with 18.99% postmenopausal women.

In the present study, among the dilatation and curettage group, 58% were para II, 32% were para III, 6% were para IV and 4% were para-I. Among the Pipelle group, 46% were para II, 13% were para III, 12% were para IV and 2% were para I and 2% were nulliparas. In a study done by Noor N et al,[6] 83% of patients had parity of P1-P4. 12% were nulli para while 05% had parity of 5 or more In another study done by Kaur H et al,[7] nulliparous were 2%, 14% were para I, 36.5% were para II, 28.9% were para III, 19% were para IV. In another study done by Patankar AM et al,[8] 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. In a study done by Abdelazim IA et al,[9] the median parity among the study population was 3.5. In a study done by Alliratnam AS et al,[10] the average parity among the women with dysfunctional uterine bleeding (DUB) was 2.7 In a study by Moradan Sanam et al 12, the mean parity was 2.9 ± 0.89 ranging from one to five times.

In the present study, among dilatation and curettage group, 62% did not have any comorbidities, 20% had hypothyroidism, diabetes and hypertension were present in 16% each, 2% had epilepsy. Among Pipelle group, 64% did not have any comorbidities, 4% had hypothyroidism and asthma, diabetes and hypertension were present in 10% and 12% respectively.

In the present study, mean pain score of dilatation and curettage group was 5.88±1.49, whereas for pipelle was 2.5±1.07. The difference in the means of pain was statistically significant. In the present study, the mean time required for dilatation and curettage was 11.28±2.86 min, whereas for pipelle was 5.88±1.49 min. The difference in the means of time was statistically significant. In the present study, among the dilatation and curettage, acceptance of the procedure was expressed by 68%. Among the pipelle group, acceptance of the procedure was expressed by 98%. The difference between the two was statistically significant. In a study by Critchley et al,[15] Pipelle biopsy provided an acceptable endometrial sample for 79% of moderate-risk women, but only 43% of high-risk women.

In the present study, among the dilatation and curettage group, sample was adequate in 98%. Among pipelle group, sample was adequate in 92%. The difference between the two is not statistically

ISSN (O): 2687-5365; ISSN (P): 2753-6556

significant with p value of 0.1. In a study done by Kaur H et al,[7] among the dilatation and curettage group, sample was adequate in 97%. Among pipelle group, sample was adequate in 88%. The difference between the two was statistically significant. In a study by Moradan Sanam et al 12, one hundred and ten subjects (84.6%) of the samples obtained by Pipelle and 117 subjects (90%) of those obtained by D& C were sufficient. The samples were sufficient in both methods in 109 subjects (83.8%) and were insufficient in both methods in 12 subjects (9.2%). In one subject (0.8%) the pipelle sample had adequacy but in D&C sample was insufficient. Eight subjects (6.2%) had adequate sample by D&C and were insufficient by pipelle. In a study by Kaiyrlykyzy A et al,[13] which included 158 patients, Inadequate biopsy samples were obtained in 25 out of 158 patients (18.8%). In a study by Mathew et al 16, sample adequacy was 96% in pipelle. In a study by Chaudhary A et al,[17] sample adequacy was 95% in pipelle. In a study by Szymon Piatek et al,[18] had adequate sample in 259 out of 312 women 83.01% in whom pipelle biopsy was performed. In a study by Piatek et al,[19] 895 endometrial sampling procedures were performed. Three hundred and thirty-nine patients underwent Pipelle biopsy, while 556 had D&C. Adequate sample was obtained in 37.9% of pipelle and 62.1% of D&C. Insufficient samples were found in 60 (17.3%) and 88 (15.8%) patients, respectively.

CONCLUSION

Endometrial biopsy with pipelle as an outpatient procedure is a safe, minimally invasive with less chances of perforation and infection. It has lower pain scores and requires fewer instruments. It is efficient method for evaluating AUB with good patient compliance, acceptancy, sample adequacy and less time taking. Hence it can be used as a first line method for endometrial sampling Limitation of the study is focal lesions missed by pipelle.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556