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Indian Journal of Obstetrics and Gynecology Research

Journal homepage: www.ijogr.org

Original Research Article

A diagnostic value of Pipelle endometrial sampling in comparison with dilatation and curettage among patients with abnormal uterine bleeding

Maheshwari Vaijinath[1], Rashmi S Desai[2]*, Nachiketha S Vishwaradhya[2], Venkatesh Kariganur Vasudevamurthy[2]

[1]*Dept. of Obstetrics and Gynecology, Bidar Institute of Medical Sciences, Bidar, Karnataka, India*
[2]*Dept. of Obstetrics and Gynecology, Karnataka Medical College and Research Institute, Hubballi, Karnataka, India*

ARTICLE INFO

Article history:
Received 16-05-2024
Accepted 18-07-2024
Available online 04-11-2024

Keywords:
Abnormal uterine bleeding
Pipelle
Endometrial sampling
Endometrial thickness

ABSTRACT

Background: Pipelle aspirator and Dilatation and Curettage (D&C) commonly used to obtain the endometrial sample in patients of abnormal uterine bleed (AUB). This study was conducted to determine the reliability of pipelle device in acquiring an adequate representative endometrial sample when compared to D&C.

Materials and Methods: This prospective comparative study was conducted in a tertiary care hospital in India. One hundred cases of AUB attending the outpatient clinic due to endometrial causes (thick endometrium≥ 12mm in the reproductive and ≥ 4mm in postmenopausal age) were included for the study. Exclusion criteria: AUB due to proven endometrial polyp, coagulopathy. The endometrial sample was taken by the Pipelle device and D&C on the same day. A pathologist, who was blinded to the methods of sample collection, reported the same. The histopathology reports of the Pipelle were compared with that of the D&C sample and the D&C report was considered the gold standard.

A 2×2 table of true positive (TP) true negative (TN), False positive (FP) and False negative (FN) was prepared and used for calculating sensitivity, specificity of the pipelle method when compared to D&C.

Results: The pathologists classified 96% of the pipelle and 100% of D&C samples as adequate. Higher age, postmenopausal status and thinner endometrium were associated with inadequate sample in pipelle. Pipelle sample had 100% sensitivity and specificity for detecting endometrial carcinoma, hyperplasia, with or without atypia. Pipelle method could not identify any of the polyp, diagnosed with D&C. Pipelle had good correlation for detecting proliferative, secretory endometrium and endometritis.

Conclusion: Pipelle device provides adequate sample for histopatholgical examination 96% of the patients. Pipelle sample is 100% sensitive and specific for diagnosing endometrial carcinoma, endometrial hyperplasia with or without atypia. Pipelle method is ineffective for diagnosing polyp.

1. Introduction

Endometrial sampling is an essential investigation for women having abnormal uterine bleeding (AUB). Even though hysteroscopic guided endometrial biopsy is considered as the gold standard for endometrial sampling, it is not widely practised for lack of resources.[1] Dilatation and Curettage (D&C) is the most widely used method traditionally for obtaining the endometrial sample, since it ensures adequate tissue sample for diagnosis and tissue diagnosis correlates well with histo-patholgical examination, performed after hysterectomy.[2,3] It also offers therapeutic advantage in many cases of AUB and helps in control of acute bleeding. Main disadvantages of D&C being need for general anaesthesia, operating room time and

* *Corresponding author*.
E-mail address: drrashmidesaiobg@gmail.com (R. S. Desai).

https://doi.org/10.18231/j.ijogr.2024.105

subsequent need for large proportion of hospital resources. It is invasive which carries risk of uterine perforation, infection and significant post-operative pain.

Due to these shortfalls, a simpler method for endometrial sampling using a device called as Pipelle aspirator has come in to practice. Pipelle does not require general anesthesia or analgesia and procedure can be performed in the outpatient department or general practice setting, and is cost-effective.[4] It is shown to be associated with higher patients satisfaction than D&C method. There are few studies showing good result in diagnosis of endometrial pathologies using Pipelle device.[5,6] This study was conducted to determine the reliability of pipelle device in acquiring an adequate representative endometrial sample compared to D&C and to compare the results of histopathological diagnosis of pipelle sampling with D&C method.

2. Materials and Methods

The study was approved by the ethical committee of the hospital. Informed written consent was obtained from all the women participating in the study. This prospective comparative study was conducted in a tertiary care hospital in India, from March 2021 to September 2022. One hundred women attending the outpatient department of the hospital who satisfied inclusion criteria were included in this study.

Women suffering from AUB due to endometrial causes were considered for the study. Inclusion criteria were women with AUB due to endometrial etiology, as indicated by thick endometrium of more than 12mm in the reproductive, premenopausal age group and more than 4mm in postmenopausal women in the trans-vaginal sonography (TVS). Exclusion criteria were women having AUB due to proven focal endometrial polyp (where hysteroscopy was preferred), women having coagulopathy, thrombocytopenia, or those who are on anticoagulants, women having pregnancy related bleeding, genital infections and pelvic inflammatory diseases or women with endocrinal disorders like hypothyroidism or those who were on hormonal replacement therapy. A detailed clinical assessment of the patient was performed in the outpatient department including history, physical examination, and baseline investigations like complete blood counts, renal functions test, prothrombin time and INR, TSH levels. TVS was performed on the outpatient basis to confirm that AUB was due to the endometrial pathology. Written informed consent was obtained from women after ascertaining that they are willing to undergo endometrial sample by both Pipelle method as well as D&C method. The endometrial sampling was taken in the premenstrual phase of their menstrual cycle by the Pipelle device in the ward on day of surgery (D&C). The Pipelle was introduced without performing cervical dilatation and withdrawn slowly outside the uterus with a rotatory movement to get the sample. If the sample was insufficient, the procedure is repeated once more. The sample was collected in a container and labeled as sample A. The patients underwent D&C under general anaesthesia in the operation theater on the same day. During the surgery, cervical dilatation was performed, endometrial sample was curetted and it was labeled as sample B. Both samples were sent to a pathologist, who was blinded to the methods of sampling. The histopathology reports of the Pipelle sample were compared with that of the D&C sample and the D&C report was considered the gold standard. Endometrial samples were reported as proliferative endometrium, secretory endometrium, hyperplasia without atypia, hyperplasia with atypia, carcinoma, polyp and endometritis.

The sample size was calculated based on below mentioned formula: $n = 4PQ / l^2$, where P= prevalence; Q= 100-P; l=Allowable error. Considering the prevalence of AUB in the outpatient to be 50% and allowable error of 20% of prevalence (10), sample size necessary was calculated to be 100 samples.

Data was entered and analysed using Statistical Package for the Social Sciences software version 20 for Windows (International Business Machines Corp, Chicago IL, USA). Descriptive statistics of the explanatory and outcome variables were calculated by mean, standard deviation for quantitative variables, frequency and proportions for qualitative variables. An independent sample t test was used to compare continuous variable between two groups. A 2×2 table of true positive (TP) true negative (TN), False positive (FP) and False negative (FN) was prepared and used for calculating sensitivity, specificity, positive predictive value and negative predictive value of the pipelle method when compared to D&C (taken as the gold standard).The level of significance was set at 5%.

3. Results

Total of 220 women were screened for the study, of which many women were excluded from the study for the following reasons: women having uterine/cervical polyp (17), hypothyroidism (28), pelvic inflammatory disease (14), patient on anticoagulants (9), pregnancy related bleed (7), not willing to participate in the study (45). So 100 women were included in the study and all the 100 women completed the study protocol and were considered for the statistical analysis.

Most of women were in the age group of 46-50 years (Table 1). Majority of study participant belonged to low socioeconomic status (55%) socioeconomic status. Majority of the patients included in this study (78%) were either in the reproductive age or peri-menopausal phase and 22% of the women were in the postmenopausal phase. Most of the women had complaints for a period of 2 to 6 months (42%), 9% having symptoms between 6 to 12 months, 31% having symptoms more than 12 months and 18% of cases have

complaints for a period of less than one month. Most of the women had parity 1-2 (42%), 41% women were with parity 3-4. Ten percent of the women were nulliparous, and 7% women had parity >4. In our study majority of the cases had endometrial thickness between 15-20 mm (45%), followed by 9-14 mm (38%) and 4-8 mm (17%).

The pathologists who were blinded to the technique of sample collection, classified 96% of the pipelle samples as adequate and all the 100% of D&C collected samples as adequate. Demographic parameters were compared between patients who had inadequate sample in the pipelle method to those who had adequate sample for reporting (Table 2). Higher age group, postmenopausal status and thinner endometrium on the TVS were found to be significantly more in patients where inadequate sample in pipelle was seen.

Histopathology reports from Pipelle and D&C are shown in Table 3. Sensitivity, specificity, positive predictive value and negative predictive value for pipelle was calculated for all diagnoses of the histopathology results, after excluding the four inadequate samples, since there was no match available against the D&C report (Table **??**).

Pipelle sampling had 100% sensitivity and specificity for detecting carcinoma, endometrial hyperplasia without atypia and with atypia. Pipelle method failed to detect both cases of polyp.

4. Discussion

In the present study, 96% samples collected by pipelle and 100% samples collected from D&C method were classified as adequate by the pathologists for the HPR reporting. Previous studies have noted that adequate sample can be collected by Pipelle method in 98% and 92% of cases.[6–8] Gupta M et al noted Pipelle device was inadequate in 6.55% patients (29/ 443).[9] These results are similar to our study. But few other studies have noted Pipelle as adequate in only about 80.56%, 84.6% samples, which is significantly lower than our study.[10,11]

We found that higher age group, postmenopausal bleeding, and thin endometrium on the TVS were significant predictors of failure of adequate sample in pipelle ($p < 0.001$), while socioeconomic status, comorbidities, parity did not affect the success rate of the pipelle endometrial sampling. Our findings of high failure rates in elderly postmenopausal women with abnormal bleeding having thin endometrium on the TVS are also noted in the other previous studies.[12–14] The reason for the high failure rate in the these categories of patients may be due to postmenopausal atrophy of the endometrial tissue and endometrial cavity obliteration, thereby making little endometrial tissue available for sampling. But in more than 80% of the postmenopausal bleed patients, adequate pipelle sample was obtained. Hence even in these patients, Pipelle endometrial sampling should be the first line of management, since once adequate sample is available, reporting accuracy is good even in these subset of patients. If the adequate sample is not available, despite repeated sampling attempts in pipelle method, then only D&C should be considered.

In the present study, sample was adequate in all 100 patients of D&C method, which is similar to most of the other studies. But very few studies have noted that sample collected from D&C also may be insufficient. Sanam et al noted inadequate sample in D&C method to be about 10%,[10] while other studies have noted 4% to 8.9% of D&C samples to be inadequate.[5,11]

Pipelle method was 100% sensitive and 100% specific for diagnosis of endometrial carcinoma. Similar results were noted in previous other studies,all of which have noted that pipelle is 100% sensitive and specific for diagnosis of carcinoma.[5,8,9,11,15]

Present study also noted pipelle technique to be 100% sensitive and specific for detection of hyperplasia with or without atypia. Similarly Abdelazim et al also noted 100% sensitivity and specificity for hyperplasia with or without atypia.[15] Whereas few studies have noted sensitivity for endometrial hyperplasia to be about 90% and specificity to be 100%.[5,9] Few other studies have noted even lower sensitivity of around 73-80% and specificity to be around 86%-97%.[8,11]

There were 2 cases of polyp in our study, both of which were picked up only by D&C, whereas the pipelle sampling failed to do so in all. Other studies also have noted that pipelle was able to pick up only 16%, 22% 42% and 60% of the polyp cases.[5,8,11,15] These studies noted that pipelle was 94-100% specific in detecting the polyp.[5,8,11] Other studies also conclude that endometrial sampling is associated with a higher percentage of false-negative results if the pathology is focal, such as endometrial polyps. Thus pipelle method may not be reliable to detect a focal endometrial pathology like, polyp.

There was a case of endometritis in the D&C specimen of the study, with additional false positive result in pipelle method. Thus specificity of endometritis in pipelle method is good.

Most of the samples in the present study were proliferative endometrium. We noted that sensitivity for detecting proliferative endometrium to be 97.2%. Whereas, most of the other studies have noted 100% sensitivity for detecting proliferative endometrium by pipelle method.[5,8,9] Specificity for proliferative endometrium was 100% in our study, whereas the same was 85, 92, 96, 97% in other studies.[5,8,9,11]

Secretory endometrium was 2^{nd} most common finding in our study and pipelle technique was 94.4% sensitive and 96.5% specific for detecting the same. Few other studies also have noted similar results.[5,8,15] Few other studies have noted 100% sensitivity for secretory endometrium, but

Table 1: Demographic parameters

	Mean	SD
Age (in years)	49.28	6.62
Parity	2.51	1.36
Age of menarche (in years)	13.4	0.99
Socioeconomic status: low/middle/ high	55/44/1	
AUB in reproductive age / Postmenopausal bleed	78/22	
Endometrial thickness on TVS (in mm)	13.64	4.19
Anemia: Yes/ No	40/60	
Comorbidity: none/ HTN/ DM2/ HTN+DM2	54/13/16/17	

Numbers presented are mean and Standard deviations or absolute numbers

Table 2: Risk factors for inadequate sample in Pipelle method

	Inadequate sample in Pipelle (n=4)	Adequate sample in Pipelle (n=96)	P
Age in years	55.05 ± 1.5	49.01 ± 6.6	0.046*
Parity	1.50±1.73	2.55±1.34	0.132
Age of menarche	13.50±1.29	13.39±0.98	0.83
AUB of reproductive age/ Postmenopausal bleed	1/3	77/19	0.03*
Comorbidities: None/HTN/DM/HTN+DM	2/0/1/1	52/13/15/16	0.82
Anemia: Yes/ No	0/4	40/56	0.09
Socioeconomic status: Low/Middle/ Upper class	3/1/0	52/43/1	0.709
Endometrial thickness on TVS (in mm)	5.25±1.89	13.98±3.89	0.001*

Numbers presented are mean and Standard deviations or absolute numbers
*Statistically significant

Table 3: Histopathology report of endometrial sample in D&C and Pipelle methods

	Pipelle (n=100)	D and C (n=100)
Proliferative endometrium	35	37
Secretory endometrium	19	20
Hyperplasia without atypia	19	19
Hyperplasia with atypia	9	9
Carcinoma	12	12
Polyp	0	2
Endometritis	2	1
Inadequate Sample	4	0
Total	**100**	**100**

Numbers presented are absolute numbers

Table 4: Diagnostic reliability of Pipelle endometrial sample when compared with D&C sample

TP	FP	FN	TN	Sensitivity TP X 100 / (TP+FN)	Specificity TN X 100 / (TN+FP)	PPV TP X100 /(TP+FP)	NPV TN X 100 /(TN+FN)	Accuracy (TP+TN) X 100 / (TP+TN+FP+FN)	
Proliferative	35	0	1	64	97.22%	100%	100%	98.46%	99.00%
Secretory	17	3	1	83	94.44%	96.51%	85%	98.8%	96.15%
Hyperplasia without atypia	19	0	0	81	100%	100%	100%	100%	100%
Hyperplasia with atypia	9	0	0	9	100%	100%	100%	100%	100%
Carcinoma	12	0	0	12	100%	100%	100%	100%	100%
Polyp	2	0	2	98	0%	100%	0	98%	98%
Endometritis	1	1	0	98	100%	99%	50%	100%	99%

specificity of around 97-99%.

Main limitation of the present study is that, we have taken D&C sample as gold standard, rather than hysteroscopy guided endometrial biopsy. Secondly, study correlating histopathology reports with biopsy report in women who underwent hysterectomy subsequently will be more useful. Thirdly, we have not compared these two procedures in terms of cost, which could be a main factor in developing country like India, where a large proportion of patients belong to lower socioeconomic class. The previous experience of the doctor in performing the procedure was not taken in to account as it might be related to the sample inadequacy rate for Pipelle method.

5. Conclusion

Endometrial sampling using a Pipelle device is a simple and convenient way to obtain a tissue for diagnosis, which provides adequate sample for histopatholgical examination in most of the patients. Thin endometrium on TVS, postmenopausal bleed and higher age were risk factors for sample inadequacy in pipelle method, which was seen in 4% of patients. Pipelle sample is 100% sensitive and specific for diagnosing endometrial carcinoma, endometrial hyperplasia with or without atypia. Pipelle method is ineffective for diagnosing local endometrial pathology like polyp. Pipelle samples correlate well for proliferative, secretory endometrium and endometritis when compared to D&C samples.

6. Source of Funding

None.

7. Conflict of Interest

None declared.

Acknowledgments

None declared. ‘No external funding and no competing interests declared’.

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Author’s biography

Maheshwari Vaijinath, Senior Resident

Rashmi S Desai, Assistant Professor https://orcid.org/0000-0002-2605-3288

Nachiketha S Vishwaradhya, Professor

Venkatesh Kariganur Vasudevamurthy, Assistant Professor

Cite this article: Vaijinath M, Desai RS, Vishwaradhya NS, Vasudevamurthy VK. A diagnostic value of Pipelle endometrial sampling in comparison with dilatation and curettage among patients with abnormal uterine bleeding. *Indian J Obstet Gynecol Res* 2024;11(4):586-590.