**ORIGINAL ARTICLE**

# Comparison of Efficacy and Morbidity of Pipelle Vs Conventional Endometrial Sampling

NADIA KHURSHID[1], FARHAN SADIQ[2], SAMEERA AKHTAR[3]

## ABSTRACT

**Objective:** To compare the efficacy and morbidity of Pipelle endometrial sampling and conventional D&C sampling in patients with abnormal uterine bleeding and post menopausal bleeding.
**Study design**: Quasi experimental study.
**Setting**: Department of Obstetrics and Gynaecology, Jinnah Hospital, Lahore.
**Duration**: The study was conducted over a period of six months from 07.01.2008 to 06.07.2008
**Methods:** The study comprised of 100 patients meeting inclusion criteria who were divided into two groups. In group-A, the endometrial sampling was done by Pipelle suction cannula. In group-B, the endometrial sampling was done by conventional dilatation and curettage (D&C).
**Results**: The mean age (±SD) of the study group was 45.4±7.2 years. The most common presenting complaint was menorrhagia (n=45). An adequate sample was obtained in 96% of cases by Pipelle and in 100% of cases by D&C. Both samples labeled as inadequate with pipelle method were polyps.. The procedure related morbidity was negligible in Pipelle sampled group as compared to D&C group.
**Conclusion:** We found that the pipelle is a user and patient friendly device. It is safe and cost effective technique for getting an adequate endometrial sample for histology, with high sensitivity and specificity for detection of hyperplasia and malignancy.
**Key words**: Pipelle, abnormal uterine bleeding, endometrial carcinoma

## INTRODUCTION

Endometrial sampling for histopathology is important in the assessment of abnormal uterine bleeding, which is a major problem accounting for 33% of outpatient gynaecological referrals, including 69% of referrals in peri and post menopausal women. Ten percent are found to have endometrial carcinoma on histopathology[1].

Previously the gold standard method for sampling the endometrium was dilatation and curettage (D&C) under general anaesthesia. However it is now recognized that the D&C is really just another blind sampling technique, which often samples less than half of the endometrium. The method also requires laboratory investigations, hospitalization and carries the added risk of infection, perforation and general anaesthesia[2]. Currently outpatient endometrial biopsy by Pipelle has replaced D&C as the first line diagnostic test in the evaluation of abnormal uterine bleeding as both have been shown to have similar accuracy but with the former promising more safety and cost effectiveness[3].

Hysteroscopic directed endometrial biopsy is another modality which is being increasingly used in the West in postmenopausal and rapid access clinics[4]. Hysteroscopy is being used in our setup too though as yet sparingly. However, this modality has the limitation of expertise, expense and availability.

We decided to compare the adequacy and reliability of Pipelle to the conventional D&C. The safety and acceptability of this device has been reported in various studies and after successful use in tertiary care practice, it has been introduced in primary care. However, there are still concerns regarding the adequacy of the sample obtained, non sampling of focal intrauterine lesions and the accuracy of the histopathology reports of the tissues sampled. Therefore in our setup D&C is still more commonly used for endometrial sampling, even at the tertiary care level.

This study was conducted to establish the validity of Pipelle and adequacy of the endometrium sampled by Pipelle for histolpathology so that the number of traditional D&C done under general anaesthesia could be reduced to minimum.

## PATIENTS AND METHODS

This quasi experimental study was conducted in the Department of Obstetrics and Gynaecology, Jinnah Hospital, Lahore for a period of six months from 07.01.2008 to 06.07.2008. The study comprised of 100 patients meeting the inclusion criteria. They were divided into two groups. In group-A, endometrial

[1]*Consultant Gynecologist & Obstetrician, Rashid Latif Medical College Lahore.*
[2]*Consultant Surgeon, Rashid Latif Medical College Lahore.*
[3]*Sr. Registrar Gyne & Obs, Continental Med College, Lhr.*
*Correspondence to Dr. Nadia Khurshid, Consultant Gynaecologist*

sampling was done by Pipelle suction cannula. In group-B, endometrial sampling was done by conventional dilatation and curettage under general anaesthesia. Sampling technique was non-probability purposive. Women more than 40 years of age with abnormal uterine bleeding were included in the study. Patients with lower genital tract infection, pregnancy related bleeding, known cervical stenosis, central endometrial thickness <4mm and those who had had D&C or endometrial biopsy within 04 weeks were excluded from the study.

The selection of patients was done from gynaecology outpatient department. The study was conducted after ethical clearance from the hospital administration. The Informed consent was taken from patients. The demographic features including age, parity and method of contraception were noted. The detailed history and complete physical examination was done and findings were recorded. The ultrasound examination was done to record endometrial thickness and to rule out any other pelvic pathology.

The patients were allocated to either Pipelle sampling or conventional D&C groups using random numbers. All biopsy specimens were placed in 10% formaldehyde and were sent for tissue processing and staining. The sample adequacy was defined as sample of more than 2mm in size. The interpretation of all samples was carried out by the histopathologist. Data were collected by filling the attached proforma. After the procedures, patients were followed for upto 7 days. The histopathology reports were categorized as proliferative, secretory, hyperplasia (simple, cystic), hyperplasia with atypia or complex hyperplasia, endometritis and carcinoma.

The primary outcome measure was the validity of the Pipelle technique for determining the histopathology of the endometrium in women with abnormal uterine bleeding especially for ruling out the endometrial carcinoma. The secondary outcome measure was the adequacy of tissue for histopathology, associated complications of the procedure and its success rate. The sample was labeled as inadequate by histopathologist when no endometrial tissue was present in the specimen sent. The database was made in SPSS version 10.

## RESULTS

During the study period from Jan 1, 2008 to July 6, 2008, total 100 patients with menstrual abnormalities were selected from out patient department of Jinnah Hospital, Lahore. Out of 100 patients, 50 underwent Pipelle sampling (Group A) and 50 patients had endometrial biopsy by D&C (Group B). The mean age (±SD) of the study group was 45.4±7.2 years, while the mean age of menarche was 13.3±1.1 years. The mode of parity was 6. Mean central endometrial thickness was 10.3±4.9mm. The most common presenting complaint was menorrhagia (n=45) followed by polymenorrhagia (n=30), irregular bleeding (n=14) and post menopausal bleeding (n=11). The tissue obtained for histopathology was 100% adequate when the procedure was D&C, while it was adequate in 96% of cases by Pipelle. The two cases were reported as inadequate for histopathological reporting and both were found to be polyps on D&C report. The histopathology results obtained by D&C and Pipelle are shown in Table I.

Table I: Cases distribution according to endometrial histopathology report

| Endometrial histopathological report | Group-A | Group-B |
|---|---|---|
| Secretory | 7 | 7 |
| Proliferative | 21 | 21 |
| Hyperplasia | 9 | 9 |
| Hyperplasia with atypia | 6 | 4 |
| Endometritis | 4 | 4 |
| Carcinoma | 1 | 1 |
| Polyp | - | 4 |
| Inadequate | 2 | - |

Table II is representing the statistical figures analyzing the reliability of Pipelle sampling. The analysis is based on the histopathology reports.

Regarding morbidity of both procedures (Table III), the severity of pain was taken as a key indicator which was assessed using visual analogue scale. The pain was found to be mild in 46 patients (92%) in group A and in 20 patients (40%) in group B. While no patient in group A had moderate pain as assessed on visual analogue scale, 30 patients (60%) in D&C group had it. Analgesia was required in 17 patients (34%) in group A and in 40 patients (80%) in group B.

Table II: Statistical reliability data according to H/P results in pipelle sampled group

| Endometrial Histopathology | Sensitivity | Specificity | +ve predictive value | -ve predictive value |
|---|---|---|---|---|
| Carcinoma | 100 | 100 | 100 | 100 |
| Endometrial Hyperplasia | 100 | 100 | 100 | 100 |
| Secretory endometrium | 100 | 100 | 100 | 100 |
| Hyperplasia with atypia | 100 | 98 | 80 | 100 |
| Proliferative endometrium | 94 | 93 | 94 | 93 |
| Endometritis | 57 | 97 | 57 | 97 |

Table III: Distribution of cases by morbidity.

| Morbidity merits | Group A | Group B |
|---|---|---|
| Mild pain | 46(92%) | 20(40%) |
| Moderate pain | 0 | 30(60%) |
| Analgesia need | 17(34%) | 40(80%) |
| Hospitalization | 0 | 2(4%) |
| Adequate sample size | 48(96%) | 49(98%) |
| Inadequate sample size | 2(4%) | 0 |

The complications which included infection and anesthesia related problems like difficult intubation developed in only 2 patients (4.0%) of group –B. We had no procedure failure. The time for mobilization was 5.84±1.58 hours and the mean hospital stay was 8.90±1.81 hours for group-B. On the other hand, hospitalization or anaesthesia was not involved in Pipelle sampling group which was a definite advantage. In terms of morbidity the results were significant in favor of group A ($p<0.001$).

## DISCUSSION

The main reason for performing the endometrial biopsy in women with abnormal uterine bleeding is to confirm the benign nature of the problem by ruling out endometrial carcinoma, so that the medical treatment or conservative surgery can be offered and unnecessary radical surgery can be avoided.

Various methods of endometrial sampling are in practice, including invasive or non invasive and either on an inpatient or outpatient basis. The D&C is an invasive inpatient procedure performed under general anesthesia while Pipelle is an outpatient procedure that is performed without anaesthesia, analgesia or any premedication in conjunction with the pelvic examination. Concern has been expressed that the Pipelle samples only 4% of the endometrial cavity[5] and may miss the focal malignant lesion. However, provided, the samples are successfully obtained, this technique has reported sensitivity of 44.6 to 84%[6]. The sensitivity of this technique has been shown to improve for all types of endometrial diseases if Pipelle sampling is complemented with ultrasound[7]. The main disadvantage of the use of Pipelle, however, remains the relatively high proportion of inadequate samples**.**

In our study, we set a cut off limit for a central endometrial thickness of >4mm as indicative of adequate sampling with Pipelle method. This is for the reason that probability of getting an adequate sample drops down to 27% when central endometrial thickness is <5mm[10]. In 96% of cases the sample was adequate in our study while inadequacy was reported in 11% of cases in other studies[4]. Choudry *et al* 2005, in their study showed Pipelle endometrial sample adequacy of 98%[8]. These results were consistent with our study (96.0%).

In a study by Bunyavejchevin *et al* 2001, showed that by not performing dilatation & curettage under general anaesthesia prior to surgery resulted in significant savings, in terms of hospitalization, costs and bed occupancy. They concluded that whenever endometrial sampling by means of the Cornier Pipelle yielded the diagnosis of carcinoma, it could be confidently relied upon[9]. Therefore the Pipelle sampling method was proved as best compared to other endometrial sampling techniques for detection of endometrial carcinoma and atypical hyperplasia[11].

The accuracy is high when an adequate endometrial sample is obtained. As the cases of endometrial carcinoma were subsequently detected on inadequate specimen of Pipelle.[12] Thus further evaluation of cases is required where symptoms persist despite a negative biopsy or when other risk factors for endometrial carcinoma are present[13 14]. In our study both the inadequate samples on pipelle were benign polyps & no case of endometrial carcinoma was missed.

Our study has shown low sensitivity (57%) but high specificity (97%) for Pipelle in diagnosing endometritis (Table II). Similarly the diagnosis of proliferative endometrium by pipelle has 94% sensitivity & 93% specificity. However, atypical hyperplasia has a sensitivity & specificity of 100% and 98% respectively. This lead to the conclusion that the Pipelle was superior for diagnosing malignant disease and hyperplasia as compared to benign diseases- a finding which was also reported in a study by Clark *et al*, 2002[12.].

Regarding the comparison of morbidity, we had no procedure failure or operative complication except difficult endotracheal intubation in two cases of group B. The cost per case was more for D&C group as compared to pipelle group.

## CONCLUSION

Pipelle is an important diagnostic tool in the investigation of abnormal uterine bleeding with the diagnostic accuracy though being comparable to D&C yet having the advantages of being safer, quicker, reliable and cost effective. It is recommended that D&C should be replaced by Pipelle as first line investigation for abnormal uterine bleeding in gynecological care.

## REFERENCES

1. Symonds IM, Establishing outpatient hysteroscopy service. Current Obstet Gynecol 1999;9 :158-62.
2. Lawrence P, O' Connell, Fries MH , Zeringue E, Brehm W. Triage of abnormal post menopausal bleeding. Comparison of endometrial biopsy and transvaginal sonohysterography versus fractional curettage with

hysteroscopy. Am J Obstet Gynecol 1998;178 :956-61.
3. Seamark CJ. Endometrial sampling in general practice. Br J Gen Pract 1998 ;48: 1597-1598.
4. Polena V , Mergul JI , Zerat L, Sananes S . The role of pipelle (R) Mark II sampling in endometrial disease diagnosis. Eur J Obstet Gynecol Repord Biol 2006 Oct 6 ; [ Epub ahead of print ].
5. Rodriguez GC, Yaqub N, King ME. A comparison of the pipelle device and the vabra aspirator as measured by endometrial denudation in hysterectomy specimens: The pipelle device samples significantly less of the endometrial surface than the vabra aspirator. Am J Obstet Gynecol 1993 ; 168: 1-55.
6. Van Den Bosch T, Vandendael A, Van Schoubroeck D, Wranz PA, Lombard CJ. Combining vaginal ultrasonography and office endometrial sampling in the diagnosis of endometrial disease in postmenopausal women. Obstet and Gynecol 1995; 85:349-52.
7. Stovall TG, Ling FW, Morgan PL. A prospective randomized comparison of the pipelle endometrial sampling device with the Novak curette. Am J Obstet Gynecol 1991; 165: 1287-90.
8. Choudry A, Javaid M. Clinical usefulness of Pipelle endometrial sampling. Pak Armed Forces Med J 2005;5: 122-5
9. Bunyavejchevin S, Triratanachat S, Kankeow K, Limpaphayom KK.Pipelle versus fractional curettage for the endometrial sampling in postmenopausal women. J Med Assoc Thai 2001;84: S326-30.
10. Elsandabesee D, Greenwood P.The performance of pipelle endometrial sampling in a dedicated postmenopausal bleeding clinic. J Obstet Gynecol 2005;25 (1): 32-34.
11. Dijkuijen FP, Mole BW,Brolmann HA, Heintz AP. The accuracy of endometrial sampling in the diagnosis of patients with endometrial carcinoma and hyperplasia: a meta analysis. Cancer 2000;89:1765-72.
12. Clark TJ, Mann CH, Shah N, Khan KS, Song F, Gupta JK. Accuracy of outpatient endometrial biopsy in the diagnosis of endometrial cancer : a systemic quantitative review. BJOG 2002;109:313-321.
13. Ferry J, Farneworth A, Webster M, Wren B. The efficacy of Pipelle endometrial biopsy in detecting endometrial carcinoma. Aust NZ Obstet Gynecol1993;33:76-8.
14. Penny G, Vale L,Souter V, Templeton A. Endometrial assessment procedure: an audit of current practice in Scotland. Hum Repord1997;12:2041-5.