ORIGINAL ARTICLE OUTPATIENT ENDOMETRIAL BIOPSY WITH PIPELLE Vs DIAGNOSTIC DILATATION AND CURETTAGE

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Background: Pipelle is a silastic curette which does not require a tenaculum or straightening of the cervical fundus axis because of its flexibility and does not require general anaesthesia, whereas Dilatation and curettage (D&C) requires hospitalization and general anaesthesia along with the problem of postoperative pain. The objective of the study was to assess the effectiveness of Pipelle sampling in terms of adequate specimen collection and patients' knowledge and perception about Pipelle and compare it D&C. Methods: In this randomized control trial, 203 women presenting with abnormal uterine bleeding were enrolled. The patients were randomly assigned to one of the two procedures. In group A 102 patients were subjected to Pipelle endometrial sampling and in group B 101 patients were enrolled for D&C. Frequencies of adequacy of histopathology reports and cost effectiveness of both groups were compared. Patient's knowledge, perception, pain and acceptability of the procedure of both groups were also assessed and compared. Results: The mean age of the patients was 46.3±4.45 years. Tissue obtained for histopathology was 100% adequate when the procedure was D&C while it was 98% in Pipelle group. In group-A 92% patients experienced no discomfort, with only 2% experiencing severe pain and 6% mild pain. On the other hand in group-B, 45% patients experienced moderate and 5% experienced severe pain up to 9 on visual analogue scale (VAS) postoperatively and requiring post-operative analgesia. The acceptability for the Pipelle suction curette was 98% and for the D&C group was 34%. Regarding previous knowledge of procedure none of patients (100%) knew about Pipelle procedure but 98% patients were aware of D&C procedure. Pipelle was eight times more cost effective as compared to D&C. Conclusions: The results of obtained by endometrial sample by Pipelle and D&C are compareable. Pipelle significantly produced less pain than D&C.

Keywords: Pipelle, suction curette, dilatation and curettage, pre-menopause, visual analogue scale J Ayub Med Coll Abbottabad 2014;26(2):145–8

INTRODUCTION

Abnormal uterine bleeding accounts for more than 70% of all gynecological consultations in the peri and postmenopausal years.1 Main aim of investigations for abnormal uterine bleeding is to exclude intrauterine pathology, particularly endometrial cancer. More than 90% of patients with endometrial carcinoma present with irregular or post-menopausal bleeding. However only 20% of patients with postmenopausal bleeding will not have any significant pathology as a cause of their bleeding.² Endometrial carcinoma is the most common malignancy of the female genital tract in U.K. Developing countries and Japan has the incidence rate four to five times lower than western industrialized nations with the lowest being in India and South Asia. Any factor that increases exposure to unopposed oestrogen increases the risk of this cancer. Screening for endometrial carcinoma or its precursors (hyperplasia) is justified for certain high risk women.^{3,4} Dilatation and Curettage (D&C)is the most commonly employed method for endometrial sampling as in 60% of cases less than half of uterine cavity is curetted, there is a risk of general

anaesthesia, infection and perforation. This has led to the advent of new and simpler methods for endometrial sampling.^{5,6} As the safety and acceptability of these devices have been established. these methods are commonly used in tertiary gynaecological care and more recently have been successfully introduced in primary care.⁶ A large number of various outpatient endometrial sampling procedures are available currently such as Accurette, Gynoscann, Nowak curette, Pipelle, Vabra aspiration, Z-sampler. But our focus is on endometrial sampling by Pipelle. The Pipelle is a thin plastic tube, 3 mm in diameter and is the most convenient, best tolerated and least expensive outpatient endometrial sampling procedure. Pipelle samples only 4% of endometrial surface and has a sensitivity of 67-97%. Office endometrial biopsy can often expedite appropriate evaluation and therapy and in most cases can be performed instead of D&C. Novak curette (5mm in diameter) can induce some discomfort at the time of its passage but newer silastic curette, have smaller diameter (3 mm), flexible and better can be tolerated by patients. Pipelle is devoid of serrated teeth and because of its flexibility, usually does not require a tenaculum or straightening of the cervical fundus axis.⁷ Pipelle does not require a syringe or pump nor require general anaesthesia or cervical dilatation and permits almost painless endometrial sampling.^{8,9} The study was conducted to assess the effectiveness of pipelle sampling in terms of our patients prior knowledge about pipelle, sample adequacy, degree of acceptability, discomfort and pain during and after procedure and cost effectiveness and compare it with conventional method of inpatient sampling i.e., D&C.

MATERIAL AND METHODS

It was a randomized controlled trial in which 203 women presenting with abnormal uterine bleeding were enrolled from gynaecological outpatient department of Railway Hospital Rawalpindi from February 2010 to May 2012. All women whether peri/post-menopausal with abnormal vaginal bleeding were included in the study. Patients with lower genital tract infection, known case of cervical stenosis, premature menopause and pregnant women were excluded from the trial. After informed consent, women were divided into two groups randomly by lottery method. Patients in group-A underwent outpatient endometrial sampling while those in group-B for in patient diagnostic D&C. Both groups were matched epidemiologically. A detail clinical assessment of patients performed in the out patients department including history, examination, base line investigations and pelvic ultrasonography.

Experience regarding procedure was asked from patients and was categorized as poor, satisfactory, good, and excellent. Acceptability of the procedure mainly referred to whether the patient would recommend this procedure to others or not and it was asked simply as yes or no. Pain and discomfort during procedure was asked from patient on Simple Visual Analogue Scale graded from 0–10. The device was introduced through the cervical canal into the uterine cavity and drawn outside with rotatory movement to get sample. The endometrial tissue thus obtained was sent for histopathology. After the procedure patients were asked about the degree of discomfort and whether they would be willing to undergo the same procedure again if necessary. In group B patients were admitted and procedure was performed under general anaesthesia and after D&C, samples were sent for histopathology. Pathologists were blind regarding the method of sample collection. All information collected was recorded in a pre-designed pro forma. Data was analysed using SPSS-18. Frequencies of adequacy of histopathology specimen of both groups was calculated. Patients knowledge, perception, pain and acceptability of procedure by both groups was assessed.

RESULTS

The mean age of the patients was 46.3 ± 4.45 years. The mode of parity was 5. Tissue obtained for histopathology was 100% adequate when the procedure was D&C and whiles it was 98% in Pipelle group. The types of endometrial lesions according to pathology reports consisted of secretory and proliferative endometrium, cystic, adenomatous and atypical hyperplasia and molar pregnancy. Incidence of histopathological patterns was shown in table-1. Proliferative endometrium was most common finding on histopathology 40.5% indicating anovulation as the leading cause of abnormal uterine bleeding. One case of molar pregnancy was diagnosed on Pipelle biopsy. Data obtained regarding patients acceptability is shown in figure-2. The acceptability for the Pipelle suction curette was 98% and for the D&C group was 34%. Regarding patients prior knowledge of pipelle, no patient in group A knew about pipelle but in Group-B 98% patients had knowledge about D&C as shown in graph. Vast majority of patients, 92% experienced no discomfort, with only 2% experiencing severe pain and 6% mild pain in group-A. In group-B 45% patients' experienced postoperative moderate and 5 % experienced severe pain up to 9 on visual pain analogue scale and required post-operative analgesia. Pipelle is eight times more cost effective as compared to conventional method of endometrial sampling (D&C).

Histopathology reports	Group-A n=102	Group-B n=101
Proliferative Endometrium	52 (53%)	33 (32.6%)
Secretory Endometrium	22 (21.5%)	44 (43.5%)
Cystic hyperplasia	16 (15.6%)	10 (9.9%)
Adenomatous hyperplasia	10 (9.8%)	13 (12.8%)
Atypical hyperplasia	2 (1.96%)	1 (0.99%)
Molar pregnancy	1 (0.98%)	0

 Table-1: Incidence of histo-pathological patterns

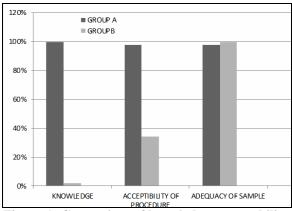


Figure-1: Comparison of knowledge, acceptability of procedure and adequacy of sample

DISCUSSION

The main reason for performing endometrial biopsy in women with abnormal uterine bleeding is to confirm the benign nature of the problem, by ruling out endometrial carcinoma, so that medical treatment or conservative surgery can be offered and unnecessary radical surgery can be avoided. Endometrial sampling by means of Pipelle biopsy is a minimally invasive alternative for commonly performed procedure dilatation and curettage or gold standard hysteroscopy and curettage. Currently, the Pipelle endometrial sampling device is the most popular 324method for sampling the endometrial lining.¹⁰ The study was conducted to evaluate the efficacy of Pipelle as a tool for endometrial biopsy. As the Pipelle does not usually require cervical dilatation due to it diameter and flexibility the procedure was well tolerated and was acceptable to the patients.

Our study demonstrates pipelle's acceptability was (98%) more than D&C group (34%). The acceptability of pipelle in our study is much more than the study of Abeera *et al.* in 2005 where it was quoted to be 11–42% in different age groups.¹¹

The result of our study showed outpatient endometrial biopsy to be a successful procedure and when adequate specimens are obtained. It has been argued that a positive test result is highly accurate but a negative test result is of limited accuracy and only moderately useful.¹² According to Abeera *et al.*¹¹ 95.5% patients had an adequate sample, 4% had inadequate sample with 1.4% ending as failed sample. In that study majority of failed samples were in postmenopausal women, heavy vaginal bleeding and cervical stenosis. While in our study only two patients had inadequate sample .One patient was nulliparous, had cervical stenosis and due to pain inadequate sample was received, other patient was postmenopausal and adequate sample could not be obtained due to atrophic endometrium. Another study conducted in 2007 showed 98% of cases the sample was adequate.⁵ Our study showed the detection rate of endometrial hyperplasia ,secretory, proliferative and molar pregnancy were 100% by pipelle. Other studies shown that pipelle and D&C produced the same detection rate of endometrial pathology.^{11,13} The Pipelle has been declared the best device compared to other endometrial sampling techniques for detection of endometrial carcinoma and atypical hyperplasia.¹⁴ However accuracy is high when an adequate sample is obtained, as a cases of endometrial carcinoma were subsequently detected on inadequate specimen of pipelle.¹⁵ Thus, further evaluation of cases is required where symptoms persist despite a negative biopsy or when other risk factors for endometrial carcinoma are present. Mechado *et al* found 16.9% accuracy for detection of endometrial carcinoma and atypical hyperplasia.¹⁶ This lead to the conclusion that pipelle is good device for diagnosis of malignant disease and hyperplasia ,both with and without atypia, as compared to benign diseases, which was also reported in a study by Clark and Colleagues.¹⁷

We had no procedure failure or operative complication (pre/postoperative) except pain. Vast majority of patients, 92% experienced no discomfort, with only 2% experienced severe pain and 6% experienced mild pain. In group-B, 45% patient's experienced postoperative moderate and 5% experienced severe pain up to 9 on visual pain analogue scale and required post-operative analgesia. While according to Abeera *et al*¹¹ 5% of patients had slight discomfort and 94% experienced no discomfort.

The cost per case was 8000 PKR for D&C group as compared to 1000 PKR for pipelle. The cost included the procedure, anaesthesia, surgery and in patients charges, which was also supported in other studies.⁵

The most important aspect of our study is that Knowledge and perception regarding pipelle and D&C was analysed for first time in our population .Unfortunately, none of our patients were aware of Pipelle in group-A. However, 98% patients did know about the role of D&C for screening of endometrial carcinoma.

CONCLUSION

Pipelle is an outpatient procedure, avoiding general anaesthesia along with its associated complications, does not require operation theatre space or staff is less painful, more cost effective and last but not the least obtains an adequate sample with reliable histopathology results when compared with D&C. It is suggested that this device should be replaced by the traditional method of endometrial sampling by D&C. There is need to bring about awareness regarding the procedure in our community.

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