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Original Research Article

Role of pipelle versus dilatation and curettage in tissue diagnosis abnormal uterine bleeding

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ABSTRACT

Background: Menstrual irregularities and abnormal heavy menstruation account for up to 26-35% of women attending Gynecological outpatient Department. Abnormal Uterine Bleeding (AUB), it is more common at extremes of age endometrial hyperplasia occurs in 5-10% of patients with post-menopausal bleeding out of which atypical hyperplasia has 26-32 % risk of having malignancy in future. Therefore, endometrial sampling for histopathology is important in the assessment of abnormal uterine bleeding is mandatory. Our study was conductive to know the effectiveness of pipelle type devices, versus Dilatation and curettage in obtaining quality endometrial tissue for histopathological examination.
Methods: The study was undertaken in Department of obstetrics and gynaecology along with department of Pathology at Rajarshi Chhatrapati Shahu Maharaj, government medical college, Kolhapur after getting approval from the Hospital Committee on Clinical Research and Ethical Committee of the institution, during the period from October 2016 to March 2017 (six months). Total number of subjects included in study is Hundred after taking into consideration of inclusion and exclusion criteria.
Results: The ease of doing procedure was much easier as compared to D&C and the Tissue sample obtained for histopathological examination were as par D&C. It was concluded that histopathology report was available in 92 of the 100 pipelle samples and 93 of 100 D&C samples. It was also, observed that increased endometrial thickness was not always associated with adequate tissue diagnosis.
Conclusions: Pipelle is simple, affordable, patient friendly can be easily performed with minimal training, which can be performed in Outpatient Gynaecological Department. The diagnostic value and positive predictive value of Pipelle is at par with conventional D&C. So, pipelle can be recommended for all perimenopausal patients with AUB to rule out various, premalignant and malignant conditions of the endometrium.

Keywords: Endometrial quality tissue, Histopathology, Pipelle, Transabdominal Ultrasound

INTRODUCTION

Menstrual irregularities and abnormal heavy menstruation account for up to 26-35% of women attending Gynaecological outpatient Department. Although women of any age group can be affected by Abnormal Uterine Bleeding (AUB), it is more common in the age group of 35-45 years of age.[1] About 10 -25% of women experience episodes of AUB at some point of time during their lifetime.

Setzler & colleagues found that 18% of peri-menopausal women had menorrhagia or metrorrhagia and one fifth of these were due to premalignant or malignant disease.[2] Endometrial hyperplasia occurs in 5-10% of patients with post-menopausal bleeding out of which atypical hyperplasia has 26-32% risk of having malignancy in future. About 10% of patients with post-menopausal bleeding have endometrial cancer. Therefore, endometrial sampling for histopathology is important in the assessment of abnormal uterine bleeding is mandatory.

To date, hysteroscopic biopsy and D&C is considered as the standard for endometrial sampling without its place in gynaecology being challenged. There are various other methods which are less traumatic can be performed at ease and without anaesthesia to obtain quality samples for HPR examination.

Of the several office endometrial sampling methods, the Pipelle is a disposable polypropylene sheath with an inner plunger has been found to be very comfortable, patient friendly, can be done without anaesthesia and gave comparable histological findings from tissue obtained by D&C, hysterectomy or stiff metal curette.[3] This device can be used by anyone trained in the use of a uterine sound and is simpler than the insertion of an IUCD.[4] Pipelle enables quick sampling of endometrium (5-15 sec of operating time) and the entire procedure can be accomplished within 10-15 minutes. The safety and acceptability of this device has been reported in various studies & after successful use in tertiary care practice, it has been introduced into primary care. But there is still concern regarding obtaining the quality tissue endometrial sample by pipelle as compared to D&C. Though many studies have been reported about the effectiveness of pipelle type devices, very few studies are available from India. This study is being conducted to establish the validity and reliability in obtaining quality endometrial tissue for histopathological examination by pipelle. This study seeks to place D&C in its historical perspective and to chart the development of pipelle for sampling the endometrial lining of the uterus.

METHODS

The study was undertaken in Department of Obstetrics and Gynecology along with Department of Pathology at Rajarshi Chhatrapati Shahu Maharaj, Government Medical College, Kolhapur after getting approval from the Hospital Committee on Clinical Research and Ethical Committee of the institution, during the period from October 2016 to March 2017 (six months).

All women's of age group 35 and above attending gynaecology clinic with abnormal uterine bleeding in the Department of Obstetrics and Gynaecology during the study period.

Total number of cases of abnormal uterine bleeding attending gynaecology clinic during the study period were 356. Total number of abnormal uterine bleeding cases during the prescribed period in age group 35 and above were 212. The number of cases meeting the inclusion criterion were 122 out of which 22 cases refused to be the part of study. Hence, the sample size for the study was 100.

Inclusion criteria

Inclusion criteria of this study were perimenopausal women who presented with abnormal uterine bleeding, postmenopausal bleeding

Exclusion criteria

Patients were coming with pregnancy, patients with lower genital tract infections, pelvic inflammatory disease, clotting disorders or coagulopathy, carcinoma cervix, fibroid uterus, congenital anomalies of uterus, patients on hormonal therapy, excluded from the study.

The study was an observational correlation study. After assessment of inclusion and exclusion criteria, 100 cases of abnormal uterine bleeding patients were selected for the study. Thorough clinical assessment of the patient was performed in the outpatient department which included history, physical examination and baseline investigations. Transabdominal sonography was performed before taking an endometrial biopsy to avoid invasive procedures like transvaginal sonography. Routine Pap smear was performed in all cases.

Both the procedures were performed in Operation Theatre first pipelle curettage without anaesthesia followed by Dilatation and curettage under Anaesthesia. Both the procedures were performed in the same setting to maintain the synchronicity in the timing of samples and to prevent inconvenience to the patient. The two different samples after labelling were sent to the Histopathologist who was blinded regarding the method of sample collection for histopathology assessment.

The pipelle device used for sampling was by Gynetics medical products, Belgium.

RESULTS

This observational clinical correlation diagnostic study was designed to compare the efficiency of Pipelle endometrial sampling with dilatation and curettage in obtaining a sufficient quality endometrial sample for histopathological diagnosis.

The ease of the procedure (subjective assessment by the doctor who performed the procedure, taking into consideration the time taken to negotiate the cervix and sampling procedure as whole) and sample adequacy was then compared.

Pipelle sampling was termed not easy only in one case compared to 12 D&C cases, though the association was statistically not significant. There was no association between ease of pipelle sampling or sample adequacy with age or menopausal status.

In our study group, the maximum number of patients (37%) were noted in the age group of 41-45 years, followed by 29% in the age group 46-50 years. 24% of the study subjects were in the age group of 35-40 years and 10% of the subjects were more than 50 years.

In our study group 1-6 months duration of AUB was seen in 60% of the subjects, 6-12 months in 20%, more than 12 months of AUB in 9% of subjects and postmenopausal bleeding was seen in 11%.

In our study group, 8 patients were nulliparous and 92 patients were parous women. Of the parous women, 33% patients were Para 2, 29% patients were Para 3 and 26% of the patients were Para 5 and above.

Table 1: Parity index, past history, family history, contraception history, pap smear status, per-vaginal findings' and the presentation with or without bleeding in the study group.

Parity Index	Number of patients (n=100)	Percentage
Nulliparous	8	8.0
Parous	92	92.0
Past history		
Absent	58	58.0
Present	42	42.0
Family history		
Absent	82	82.0
Present	18	18.0
Contraception		
Not sterilized	27	27.0
Sterilized	73	73.0
Pap smear		
NAD	45	45
Abnormal	55	55
Per vaginal		
Normal	43	43.0
Bulky uterus	57	57.0
Per speculum		
Bleeding	17	17.0
No bleeding	83	83.0

Of the 100 patients there was a past history of some medical illnesses noted in 42% of the subjects. Hypertension was the commonest of the medical illnesses noted, accounting to 22%, followed by Diabetes mellitus in 17% who were in some form of treatment at the time of admission. In our study group, 27% of patients were not sterilized and 73% were sterilized. None of the patients were using additional contraceptive methods other than barrier methods at the time of admission.

Table 2: Correlation between endometrial thickness and sufficient sample in the subjects studied.

Endometrial thickness (mm)	Adequate		Scanty		%
	D&C	Pipelle	D&C	Pipelle	
4.0	4	4	1	1	5.0
5-8	28	28	2	2	30.0
9-12	23	23	3	3	26.0
13-16	30	29	1	2	31.0
>16	8	8	0	0	8.0

Bimanual per vaginal examination was done out of which 43% of subjects had normal sized uterus, whereas 57% had bulky uterus at the time of admission in our study group. In our study group, 45% had no abnormality detected in Pap smear, whereas some abnormality was detected in 55%, of which inflammatory Pap smears accounted for 51%, ASCUS-2% and LSIL-2%. Cervical biopsy was done in indicated cases and no malignancies were found. Of the 100 subjects, scanty tissue was reported by the pathologist in 7% of the cases in the D&C group and 8% of the Pipelle sample was scanty. Of 100 cases, in 6% there was no histopathology reported due to scanty endometrium. An easy procedure doesn't always result in obtaining an adequate sample.

Table 3: Sampling procedure in the subjects studied- ease of procedure.

Sampling Procedure		Number of patients (n=100)	Percentage
D&C	Not Easy	12	12.0
	Easy	88	88.0
PIPELLE	Not Easy	1	1.0
	Easy	99	99.0

The Sensitivity of pipelle in obtaining adequate tissue comparing it with D&C by applying the chi square test is calculated to be 96.8%, Specificity =85.7% Positive predictive value =98.9% and negative predictive value =66.7%. Thus, it is inferred that pipelle is as good as D&C in obtaining an adequate endometrial tissue sample endometrial thickness of 4.0mm was found in 5% of subjects, 12-16 mm was noted in 31%, 5-8 mm noted in 30% of subjects, 9-12 mm noted in 26%, and >16 mm in 8% of subjects. The Mean±SD in the study group was 10.96±3.9.

In this study, it was observed that increased endometrial thickness was not always associated with adequate tissue diagnosis. Applying the Fischer's exact test, the ease of procedure of pipelle versus D&C was calculated and following results obtained sensitivity =100% Specificity =8.3%, Positive predictive value =88.9% Negative predictive value =100%. The calculated p value is 0.125 which is statistically not significant.

Table 4: Compares the different endometrial pattern with thickness.

Histopathological pattern	TAS ET(mm)					Total (n=100)
	<4.0 (n=5)	5-8 (n=30)	9-12 (n=26)	13-16 (n=31)	>16 (n=8)	
Proliferative endometrium	2(40%)	14(46.7%)	12(46.2%)	14(45.2%)	2(25%)	44(44%)
Secretory endometrium	1(20%)	11(36.7%)	7(26.9%)	8(25.8%)	4(50%)	31(31%)
Simple hyperplasia	0(0%)	0(0%)	1(3.8%)	6(19.4%)	2(25%)	9(9%)
Scanty endometrium	1(20%)	1(3.3%)	3(11.5%)	1(3.2%)	0(0%)	6(6%)
Complex hyperplasia	0(0%)	1(3.3%)	0(0%)	1(3.2%)	0(0%)	2(2%)
irregular shedding	0(0%)	2(6.7%)	1(3.8%)	0(0%)	0(0%)	3(3%)
Adeno Ca endometrium	0(0%)	0(0%)	1(3.8%)	0(0%)	0(0%)	1(1%)
Complex atypical endometrium	0(0%)	0(0%)	1(3.8%)	0(0%)	0(0%)	1(1%)
Disordered proliferative	0(0%)	1(3.3%)	0(0%)	0(0%)	0(0%)	1(1%)
Hyperplastic endometrial polyp	0(0%)	0(0%)	0(0%)	1(3.2%)	0(0%)	1(1%)
Atrophic endometrium	1(20%)	0(0%)	0(0%)	0(0%)	0(0%)	1(1%)

The sample was sufficient in 93% of patients in D&C sampling and 92% of patients in pipelle sampling. The most common endometrial pattern identified was proliferative phase endometrium (44%). Secretory phase endometrium was second most common (31%) followed by simple hyperplasia (9%), irregular shedding (3%), complex hyperplasia (3%), atypical complex hyperplasia (1%) disordered proliferative (1%), polyp (1%), atrophic endometrium (1%) and endometrial carcinoma (1%). The correlations might not be accurate as there was no standardized time interval between the TVS examination and tissue sampling. Moreover, some patients had bleeding at the time of admission, that might have accounted to the scanty sample despite thickened endometrium.

DISCUSSION

The most common presenting complaint in the premenopausal age group was menorrhagia, followed by polymenorrhagia, and prolonged bleeding following a period of amenorrhoea. Postmenopausal bleeding was noted in 11 subjects of the study group

Ben Baruch et al reported that there was no significant correlation noted between age and success of sampling in relation to tissue obtained on histopathological examination with pipelle.

Out of the total 11 cases of Post-menopause in our study the total number of patients who had difficult D&C procedures were 4 out of 11, while no one had difficulty while performing the pipelle procedure.

Williams et al reported that nulliparity was significantly associated with insertion failure for Pipelle.[6] Insertion of pipelle was unsuccessful in 22% of attempts in nulliparous women compared with 8% parous women. Tissue available was inadequate more in nulliparous women (25% inadequate rate) compared with parous women (5% inadequate rate). They found the effect of parity on adequacy of specimen is independent of device insertion failure, but no certain explanation was given.

Bakour et al reported that there was no association between adequate sample and parity using multivariate regression analysis model.[7]

In our study, though it was expected that the procedure would be difficult in patients who were nulliparous but it was easy procedure in all nulliparous patients in our study.

Bakour et al found that increasing the age of the patient was associated with insufficient pipelle samples on unadjusted analysis, but when other variables were combined in a multivariate regression analysis to control for confounding, it became insignificant.

D&C and pipelle had comparable results as per our observations. In our study, 23 out of 24 subjects between age group 35-40 had an adequate D&C sample compared to 1 scanty sample.

Ben Baruch et al reported that sufficient sample was available only in 74 of 88 Pipelle procedures (84.1%) in postmenopausal group compared to 80 of 84 procedures (95.2%) in premenopausal age group.[8] Correlating premenopausal women with postmenopausal women (in the premenopausal age group, adequate sample was obtained in 85 out of 89 patients and in 83 out of 89 patients in D&C and pipelle respectively. Studies have reported the success of pipelle in obtaining an adequate sample ranging from 67% to 98%.

In a study comparing pipelle with D&C, Shazia Fakhar et al reports that an adequate sample was obtained in 98% of cases by pipelle and in 100% of cases by D&C.[9] pipelle had a sensitivity, specificity, positive predictive value and negative predictive value of 100% for

diagnosing endometrial carcinoma, hyperplasia and secretory endometrium.

Dijkhuizen et al in their meta-analysis reported that the sample size weighted sensitivity of nine studies that used the pipelle device in the detection of atypical hyperplasia was 82.3%. The specificity was 100% in those studies.

McCluggage reported about the artefacts in endometrial biopsy specimens, especially in outpatient sampling. Some of these may be misinterpreted as endometrial hyperplasia or even as carcinoma if not appreciated to be artefactual. Telescoping refers to glands within glands and is commonly seen.

Dijkhuizen et al, found that detection rate for endometrial carcinoma was higher in postmenopausal women compared with premenopausal women. In both postmenopausal and premenopausal women, the pipelle was the best device, the detection rates of 99.6% and 91% respectively.

In our study, there were 9 patients with simple hyperplasia, 2 patients with complex hyperplasia without atypia and 1 patient with complex hyperplasia with atypia. All samples of simple hyperplasia, complex hyperplasia without atypia and atypia were picked up by both pipelle and D&C patients. Also, we had one case of endometrial cancer which was accurately picked up by pipelle sampling technique which was confirmed by definitive surgery.

In another comparative study by Gloria et al undertaken to evaluate the ability of preoperative endometrial sampling to accurately diagnose high grade endometrial tumours, sensitivity of pipelle and curettage was 93.8% and 97% in patients with low grade cancer and 99.2% and 100% in patients with high grade cancer. Good agreement was observed between the preoperative and the hysterectomy histologic diagnosis (kappa=0.69), and between the preoperative and hysterectomy tumour grade.[10]

In a study by Behnamer et al, the sample sufficiency of the two methods were comparable: 157 (94%) in pipelle vs. 156 (93%) in D&C.[11]

In ipelle study by Choudary et al, the study revealed sample adequacy of 98%.[12] The only inadequate samples were from postmenopausal ladies with atrophic endometrium.

Bakour et al followed up 74 patients of 248 women who had insufficient tissue at pipelle endometrial sampling. None of them had endometrial cancer or hyperplasia.[7]

Contrary to that Farrell and collegues demonstrated that, in postmenopausal women in whom the result of pipelle sampling was insufficient, 20% had uterine pathology after a second investigation. In 3% of cases this was malignant disease.[13]

El sandabesee et al examined the factors that would affect the adequacy of endometrial samples in terms of their suitability for histopathological examination. He found that the ability to obtain an adequate endometrial sample was primarily affected by the endometrial thickness. There is only a 27% probability of getting an adequate endometrial sample in the group of women with an endometrial thickness of <5 mm.

In our study, it was observed that increased endometrial thickness was not always associated with adequate tissue diagnosis. Of the 5 patients with endometrial thickness of 4 mm, adequate tissue for histopathological diagnosis was available in 4cases in pipelle and D&C as well. Scanty tissue was noted in 1 among 5 patients in both D&C and pipelle group. woman).

Gordon et al reported that endometrial polyps or submucous fibroids were found in half of the cases with an inadequate pipelle sample, where definitive histology was available.[14] Van den Bosch et al also reported that pipelle failed to detect endometrial polyps and submucous myoma.[15]

In our study, it was noted that 1 out of 8 patients who yielded scanty endometrium on pipelle sampling, in D&C, diagnosis came as endometrial polyp.

So, doing a Son hysterography, which identifies polyps better than transvaginal ultrasound may help in diagnosing lesions when pipelle sampling fails to give a diagnosis despite thickened endometrium.

TAS can be a valuable aid in evaluating women presenting with a complaint of abnormal vaginal bleeding by demonstrating anatomic findings frequently not discernible on pelvic examination, such as small cysts and leiomyomas and even endometrial carcinoma, and in evaluating the endometrium thickness

In our study there are no pathognomonic sonographic characteristics that correlate completely with histology, so comprehensive tissue diagnosis remains the gold standard. Measurements of ET have been shown to be highly reproducible to both intra and interobserver measurement.[21]

In our study histopathology report was available in 92 of the 100 pipelle samples and 93 of 100 D&C samples. Comparing pipelle with D&C, Sensitivity of pipelle in obtaining adequate tissue by applying the chi square test is calculated to be 96.8%, Specificity =85.7%, Positive predictive value =98.9% and Negative predictive value =66.7%.

In our study, no adverse effects during Pipelle curettage were reported but very few patients mentioned mild pain which was well tolerated.

Studies by Fakhar et al have proved pipelle to be affordable and patient friendly.[9] The average cost of a pipelle sampling is Rs.250 compared to Rs.2000 of D&C which includes procedure, anaesthesia, surgery and inpatient charges.

Therefore, pipelle is certainly more Affordable and reach of general population than D&C as majority of our patients are not Insured.

Tissue obtained for histopathology was 93% adequate when the procedure was D&C while it was adequate in 92% of cases by pipelle. Thus, pipelle had comparable tissue adequacy with D&C.

The sensitivity of pipelle in obtaining an adequate tissue comparing it with D&C by applying the chi square test is calculated to be 96.8%, Specificity =85.7%, Positive predictive value =98.9% and Negative predictive value =66.7%. The calculated p value is <0.001 which is statistically very highly significant.

The pipelle device picked up all cases of endometrial hyperplasia and 1 case of endometrial carcinoma. Thus, the predictive value of pipelle for diagnosing endometrial carcinoma and endometrial hyperplasia is percent compared to D&C in our study. No complications were noted in both D&C and pipelle sampling.

CONCLUSION

The following conclusion was derived from the study on diagnostic value of pipelle endometrial sampling versus Dilatation and Curettage in patients with abnormal uterine bleeding:

Pipelle is simple, affordable, patient friendly which can be done in Outpatient Gynaecological Department. Thus, it can be considered as the gold standard for getting a sufficient quality endometrial tissue for Histopathological examination in AUB patients for early diagnosis of various premalignant and malignant conditions of the endometrium. Pipelle is also known to cause less cervical tissue damage compared to D&C, which is known to have better Obstetric outcome in future Pregnancy. The diagnostic value and positive predictive value of pipelle is at par with conventional D & C, so pipelle can be recommended for all perimenopausal patients with AUB. Pipelle requires less skill and requires less time as compared to D and C and therefore it can be done by any trained paramedical or junior staff in shorter duration

And lastly, sterile operation theatre environment is not needed for pipelle endometrial sampling. Therefore, it can be used in combination with Pap smear for large scale screening camp procedures.

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