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Original Research Article

Evaluation of endometrial pathology with transvaginal sonography (TVS) and pipelle sampling device in women with post-menopausal bleeding per vagina

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Abstract

Background: Bleeding per vagina following established menopause is called Post-Menopausal bleeding; even without amenorrhea or irregularity menstruation continuing after age of 55 years should be investigated. The objective of this study was to study the correlation of findings in TVS and Pipelle sampling biopsy in diagnosis of endometrial pathology. **Methods :** The present Prospective Observational study was conducted in the Department of Obstetrics and Gynaecology, Department of Pathology, and Department of Radiology , Calcutta National Medical College and Hospital, Kolkata, West Bengal, India between March 2022 to February 2023. Outdoor patients in postmenopausal age group presenting with Post-menopausal bleeding per vagina during same period after fulfilling the inclusion criteria were included in the study. Statistical data were analysed by using Microsoft Excel and SPSS V.20 software. **Results :** We found that, out of 50 patients, 26(52%) patients were <50 years of age, 22(44.0%) patients were 51-60 years of age, 2(4.0%) patients were >61 years of age .The mean age of patients was 51.7600 years. We observed 32(64.0%) patients had 1-3 months duration of post-menopausal bleeding and 18(36.0%) patients had 4-6 months duration of PMB. We found that, 46(92.0%) patients had Successful entry of Pipelle's into endometrial cavity which was statistically significant. Our study showed that,

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09(100.0%) patients were with detected endometrial carcinoma and atypical endometrial hyperplasia in TVS and was statistically significant. About 07(87.78%) patients were detected with endometrial carcinoma and atypical complex endometrial hyperplasia in Pipelle's biopsy which was statistically significant. **Conclusion :** The clinical approach to post-menopausal bleeding requires prompt and efficient evaluation to exclude or diagnose endometrial carcinoma and endometrial hyperplasia.

Keywords : Endometrial pathology, menopause, pipelle sampling, transvaginal sonography

Introduction :

Menopause is defined as permanent cessation of menstruation at the end of reproductive life due to loss of ovarian follicular activity.[1] In clinical diagnosis, stoppage of menstruation (amenorrhea) for twelve consecutive months. The age of menopause seems to be genetically determined and is unaffected by race, socioeconomic status, age at menarche or number of prior ovulations.[2]

Early studies reported risk of endometrial cancer associated with post-menopausal bleeding as 53-58%.[3]

However more recent reports suggest the incidence to be 1.5-2.8% with an average of 11%. This may reflect increasing awareness of post-menopausal bleeding with all women referred for investigation rather than just those at high risk.

Persistent stimulation of endometrium by unopposed oestrogen is the single most important factor for development of endometrial cancer.

Post-menopausal bleeding is also associated with other non-endometrial cancer most common because being Carcinoma Cervix with incidence of 0.8-1.3%.[4]

A case of postmenopausal bleeding is considered to be endometrial cancer unless proved otherwise.

The primary goal in diagnostic evaluation of post-menopausal women with bleeding per vagina is to exclude malignancy.

Endometrial cancer is the most common gynecologic malignancy. The worldwide incidence of endometrial cancer has risen over the last 20 years.[5] Increases in the rates of obesity and decreases in the rates of fertility suggest that the incidence of endometrial cancer will continue to increase in postmenopausal women, becoming a substantial public health problem worldwide.[6,7] This rise in its incidence has implications for both primary prevention and screening.

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Although vaginal bleeding is the most common symptom in patients with endometrial cancer, up to 20% of patients who are diagnosed with endometrial cancer are asymptomatic at the time of diagnosis.[8] Moreover, it is often difficult to define abnormal uterine bleeding in perimenopausal women, who usually experience irregular menstruation as their ovarian function declines; in addition, clinicians have differing assessments regarding the exact mechanism constituting the perimenopausal state.

Many studies have validated the use of transvaginal ultrasonography (TVS) as the initial screening method for endometrial cancer. Although an endometrial thickness (ET) of ≥5 mm is regarded as the cut-off value for postmenopausal women who present with vaginal bleeding, it warrants further investigation.[9] Furthermore, there is no established consensus on the ET threshold that distinguishes normal from malignant pathology in postmenopausal women without bleeding. Because the factors associated with a thickened endometrium in these women remain undetermined, the clinical management of women with an incidentally detected thickened endometrium has not been standardized or established. TVS is usually requested by general practitioners as a part of the general investigation of women complaining of various symptoms involving the abdomino-pelvic region, and the cut-off value for ET is unclear under various clinical conditions. Therefore, women with vaginal bleeding or spotting may undergo repeated TVS and unnecessary invasive diagnostic tests.

Materials and Methods

Present hospital based Prospective Observational study was conducted in the Department of Obstetrics and Gynaecology and Department of Pathology, Calcutta National Medical College and Hospital in collaboration with Department of Pathology and Department of Radiology, Calcutta National Medical College and Hospital, Kolkata, West Bengal, India between March 2022 to February 2023.

50 patients approximately. (From past observations it has been seen that there are 1-2 patients per OPD who comes with this problem. We will be attending around 50-52 OPD which gives us a population around 50 after applying all the exclusion criteria. Hence we will be doing complete enumeration that is work with all the patients instead of a sample).

Inclusion Criteria: The study included outdoor patients in postmenopausal age group presenting with Post-menopausal bleeding per vagina.

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Exclusion Criteria: Patients with

1) Local gynaecological cause (including obvious cervical growth, vaginal/vulval causes of bleeding, pelvic inflammatory disease, acute vaginal infections etc.)
2) Coagulation disorder (normal activated partial thromboplastin time (APTT) and normal platelet count)
3) Drug intake that can lead to vaginal bleeding (anticoagulants, hormone replacement therapy, hormonal contraceptives)
4) Abnormal thyroid function tests
5) Abnormal liver function test

Parameters to be studied:

a) Presenting symptoms- Postmenopausal bleeding.
b) Total number of patients under the study: Women in post-menopausal age group
c) Histopathological report findings of Pipelle's endometrial biopsy
   Proliferative endometrium, Secretory endometrium, Simple hyperplasia, Complex hyperplasia, Complex hyperplasia with atypia, Adenocarcinoma, Atrophic endometrium, Adenomatous polyp, Leiomyomatous polyp, Stromal sarcoma, Scanty tissue etc
d) Radiological report of Transvaginal sonography

Method of sample collection :

Pipelle's endometrial biopsy in OPD: With the patient in dorsal position, the cervix is held with vulsellum/allis tissue forceps during insertion of the pipelle sampler into the cervix without anaesthesia. On reaching the uterine fundus, the piston is withdrawn to create negative pressure. Endometrial tissue is aspirated from all the uterine Walls, and the sample is sent in a container with ten percent formalin for Histopathological examination (HPE) to the Department of Pathology in same Institution.

For endometrial thickness patient will be send to Radiology department for Transvaginal sonography.

Method of data collection :

Data collection was done in Pre-designed format after taking written consent. History taking and proper clinical examination in O.P.D. will identify patients who will be undergoing Pipelle's biopsy and transvaginal sonography for further follow up and management. After biopsy and

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sonography data from pathology report and radiology report will be collected from the patient in their subsequent visits to the O.P.D.

Method of Data Analysis Plan :

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 20.0. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. p-value ≤ 0.05 was considered for statistically significant

Ethical considerations- Study was initiated after obtaining the informed consents from the participants and ethical clearance from the institutional ethical committee.

Results

Table 1: Distribution of age, parity, Post-Menopausal bleeding in group

Age in group	Frequency	Percent
≤50	26	52.0%
51-60	22	44.0%
≥61	2	4.0%
Total	50	100.0%
Parity		
0	1	2.0
1	3	6.0
2	8	16.0
3	17	34.0
4	11	22.0
5	6	12.0
6	3	6.0
7	1	2.0
Duration of post-menopausal bleeding (months)		
1-3	32	64.0
4-6	18	36.0

In our study, 26 (52.0%) patients were ≤50 years of age, 22 (44.0%) patients were 51-60 years of age and 2 (4.0%) patients were ≥61 years of age. In the study, 1(2.0%) patient had parity 0, 3(6.0%) patients had parity 1, 8(16.0%) patients had parity 2, 17(34%) patients had parity 3, 11(22.0%) patients had parity 4, 6(12.0%) patients had parity 5, 3(6.0%) patients had parity 6,

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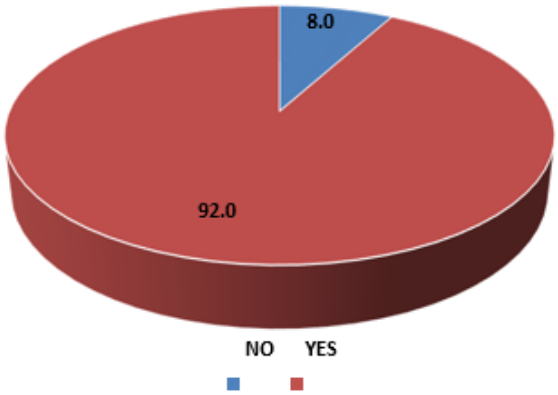
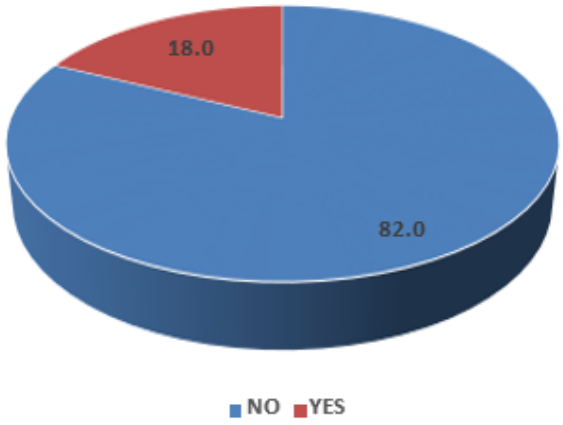
1(2.0%) patient had parity 7. In our study, 32(64.0%) patients had 1-3 months duration of post-menopausal bleeding, 18(36.0%) patients had 4-6 months duration of post-menopausal bleeding. (Table 1)

Figure 1 : Distribution of Successful entry of Pipelles into endometrial cavity



In our study, 46 (92.0%) patients had Successful entry of Pipelles into endometrial cavity. The value of z is 7.8446. The value of p is <0.00001. The result is significant at p < .05. (Figure 1)

Figure 2 : Distribution of Whether Endometrial pathology detected in TVS



In our study, 09 (18.0%) patients had endometrial carcinoma and atypical hyperplasia detected in TVS. The value of z is 5.099. The value of p is < .00001. The result is significant at p < .05. (Figure 2)

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Table 2: Distribution of TVS Findings

TVS Findings	Frequency	Percent
Endometrial hyperplasia, bulky uterus	6	12.0
Uterus normal size, adnexae normal	5	10.0
Small atrophied uterus	9	18.0
Uterus just bulky with normal adnexae	5	10.0
Uterus normal size, rest NAD	9	18.0
Uterus normal size,? micropolyp	1	2.0
Irregular endometrial outline, enlarged uterus	2	4.0
Enlarged uterus with nodular hyprechoic lesion in post wall	1	2.0
Bulky uterus with thick and irregular endometrial lining	2	4.0
Fluid in endometrial cavity, uterus slightly enlarged, irregular endometrial outline	2	4.0
Elongated uterus with adnexae normal	2	4.0
Hyperechoic lesion with regular contour	2	4.0
Endomyometrial junction poorly formed	1	2.0
Increased vascularity in endometrial Cavity with low resistance	1	2.0
Hyperechoic endometrium ,uterus normal size	2	4.0
Total	**50**	**100.0**

Findings in TVS suggestive of endometrial carcinoma was bulky uterus with thick and irregular endometrial lining, enlarged uterus with fluid in endometrial cavity and irregular outline, increased vascularity in endometrial cavity with low resistance, poorly formed endo-myometrial junction. Features suggestive of Atypical complex endometrial hyperplasia was thickened irregular outline of endometrium with enlarged uterus, enlarged uterus with nodular hyperechoic lesion in posterior wall. The result is not significant at $p < .05$. (Table 2)

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Table 3: Distribution of HPE Report of Pipelle endometrial biopsy

HPE Report of Pipelle Endometrial Biopsy	Frequency	Percent
Atrophic endometrium	14	28.0
Atypical complex endometrial hyperplasia	3	6.0
Chronic endometritis	6	12.0
Disordered proliferative phase	2	4.0
Endometrial carcinoma endometriod type	1	2.0
Endometrial polyp	2	4.0
Features of endometrial carcinoma,endometroid type	1	2.0
High grade endometrial carcinoma	2	4.0
Hyperplasia without atypia	6	12.0
Material inadequate for histological analysis	2	4.0
Materials inadequate for histological analysis	2	4.0
Proliferative endometrium	7	14.0
Secretory endometrium	2	4.0
Total	**50**	**100.0**

In our study, 14(28.0%) patients had atrophic endometrium, 7(14.0%) patients with proliferative endometrium,6(12.0%) patients with chronic endometritis, 2(4.0%) patients with disordered proliferative phase,6(12.0%) patients hyperplasia without atypia,4(8.0%) patients with material inadequate for histological analysis,2(4.0%) patients with secretory endometrium, 2(4.0%) patients with endometrial carcinoma endometriod type, 3(6.0%) patients with atypical complex endometrial hyperplasia, 2(4.0%) patients with High grade endometrial carcinoma,2(4.0%) patients with endometrial polyp. The value of z is 2.8696. The value of p is .0041. The result is significant at $p < .05$. (Table 3)

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Table 4: Distribution of different parameters

Whether Endometrial pathology detected in Pipelle)	Frequency	Percent	Pvalue
No	43	86.0%	< .00001
Yes	07	14.0%	
Whether endometrial pathology detected in DC Biopsy			
No	41	82.0%	< .00001
Yes	09	18.0%	
Distribution of was followed by hysterectomy			
No	23	46.0%	0.05
Yes	27	54.0%	

In our study, 07 (14.0%) patients had Endometrial pathology (endometrial carcinoma and atypical complex hyperplasia) detected in Pipelle's biopsy. The result is significant at $p < .05$. In our study, 09 (18.0%) patients had endometrial pathology (endometrial carcinoma and atypical complex hyperplasia) detected in DC Biopsy. The value of p is $< .00001$. The result is significant at $p < .05$. In our study, 27 (54.0%) patients had was followed by hysterectomy. Indication for hysterectomy was hyperplasia without atypia (22.2%), proliferative endometrium (11.1%), endometrial adeno carcinoma (14.81%), mucinous carcinoma (3.7%), serous carcinoma (3.7%), atypical complex endometrial hyperplasia (11.1%). The result is not significant at $p < .05$. (Table 4)

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Table 5: Distribution of HPE report of DC Biopsy

HPE Report of DC Biopsy	Frequency	Percent
Atrophic endometrium	14	28.0
Atypical complex endometrial hyperplasia	3	6.0
Chronic endometritis	6	12.0
Disordered proliferative phase	2	4.0
Endometrial adeno carcinoma, endometroid type	4	8.0
Endometrial polyp	2	4.0
Hyperplasia without atypia	6	12.0
Mucinous carcinoma	1	2.0
Proliferative endometrium	7	14.0
Secretory endometrium	2	4.0
Serous carcinoma	1	2.0
Weak proliferative with endometrial polyp	2	4.0
Total	**50**	**100.0**

In our study, 14(28.0%) patients had atrophic endometrium,6(12.0%) patients had chronic endometritis,7(14.0%) patients with proliferative endometrium,6(12.0%) patients had hyperplasia without atypia, 2(4.0%) patients with disordered proliferative phase,2(4.0%) patients with endometrial polyp, 2(4.0%) patients had weak proliferative with endometrial polyp,2(4.0%) patients had secretory endometrium, 4(8.0%) patients with endometrial adeno carcinoma endometriod type, 1(2.0%) patient with mucinous carcinoma and 1(2.0%) patient with serous carcinoma. The value of p is .0041. The result is significant at $p < .05$. (Table 5)

Table 6: Distribution of mean Age, mean Parity

	Number	Mean	SD	Minimum	Maximum	Median
Age	50	51.7600	4.7748	45.0000	65.0000	50.0000
Parity	50	3.3800	1.4270	0.0000	7.0000	3.0000

In above table showed that the mean Age (mean ± s.d.) of patients was 51.7600±4.7748. Mean Parity (mean±s.d.) of patients was 3.3800±1.4270. (Table 6)

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Table 7: Distribution of mean duration of post-menopausal bleeding (months) and mean Endometrial thickness (in mm)

	Number	Mean	SD	Minimum	Maximum	Median
Duration of post-menopausal Bleeding (months)	50	3.0200	1.2696	1.0000	6.0000	3.0000
Endometrial thickness (in mm)	50	9.01	8.15	1.50	28.00	6.05

In above table showed that the mean duration of post-menopausal bleeding (months) (mean±s.d.) of patients was 3.0200 ± 1.2696. Mean duration of Endometrial thickness (in mm) (mean±s.d.) of patients was 9.01 ± 8.15. (Table 7)

Table 8: Association between Endometrial pathology detected in Pipelle (Yes/No) and Endometrial pathology detected in DC BIOPSY.

		Whether Endometrial pathology detected in Pipelle		Total		
		NO	YES		p Value	Significance
Whether endometrial pathology detected in DC Biopsy	**NO**	41(95.35)	0(0)	41(82)	<0.001	Significant
	YES	2(4.65)	7(100)	9(18)		
Total		43(100)	7(100)	50(100)		

In our study, 07(87.78%) patients were detected with endometrial carcinoma and atypical complex hyperplasia in Pipelle's biopsy out of 09 (100%) detected in DC Biopsy. (Table 8)

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Table 9: Association between Endometrial Ca detected in TVS (Yes/No) and Endometrial carcinoma detected in DC Biopsy.

		Whether Endometrial Ca detected in TVS		Total		
		NO	YES		p Value	Significance
Whether endometrial carcinoma detected in DC Biopsy	NO	41(100)	0(0)	41(82)	<0.001	Significant
	YES	0(0)	9(100)	9(18)		
Total		41(100)	9(100)	50(100)		

In our study 09(100.0%) patients were detected with endometrial carcinoma and atypical endometrial hyperplasia in TVS out of 09(100%) detected by DC biopsy. (Table 9)

Table 10: Diagnostic accuracy of Pipelle's biopsy and TVS

System	TP	TN	FP	FN	Sensitivity	Specificity	PPV	NPV	Diagnostic accuracy
TVS	09	41	0	0	100	100.00	100.00	100.00	100.00
Pipelle	07	41	0	02	87.78	100.00	100.00	95.35	96.00

In our study, sensitivity of TVS was 100% and that of Pipelles was 87.78% in detecting endometrial pathology (endometrial carcinoma and atypical complex endometrial hyperplasia), predictive value of both was 100%. Diagnostic accuracy in detecting endometrial pathology of TVS was 100% and that of Pipelle's was 96%. (Table 10)

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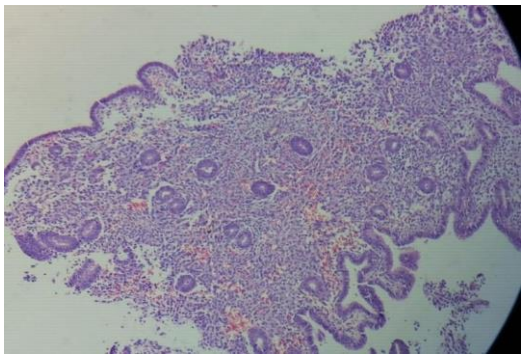

Image 1: Proliferative Endometrium

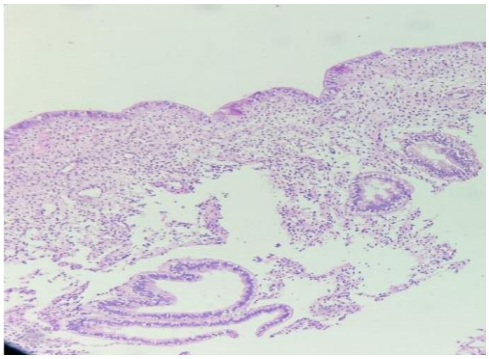

Image 2: Secretory Endometrium

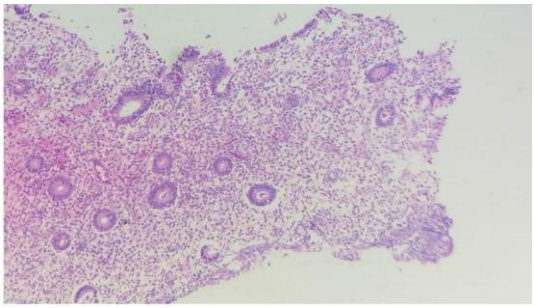

Image 3: Atrophic Endometrium

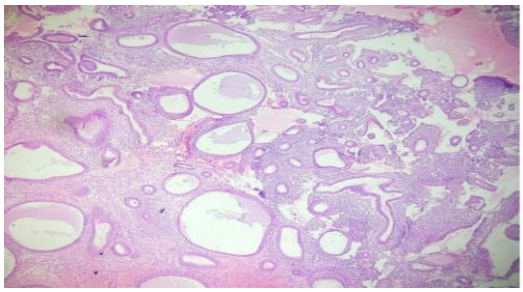

Image 4: Hyperplasia without atypia (cystic glandular)

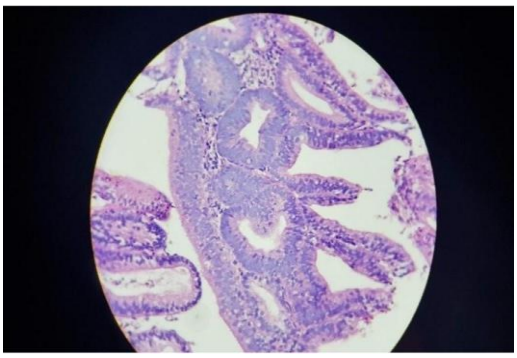

Image 5: Atypical Hyperplasia

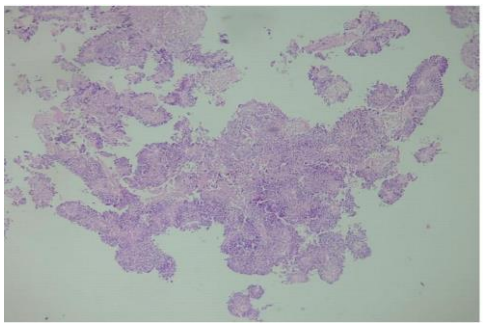

Image 6: Endometrial adenocarcinoma

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Discussion :

The present study was a Prospective Observational study. This study was conducted from One year at Department of Obstetrics and Gynaecology and Department of Pathology, Calcutta National Medical College and Hospital in collaboration with Department of Pathology and Department of Radiology, Calcutta National Medical College and Hospital, Kolkata.50 patients were included in this study.

Sharma J et al[10] found that all women with postmenopausal uterine bleeding mandate examination for endometrial diseases especially endometrial carcinoma. In current scenario, hysteroscopy has replaced traditional Dilatation and Curettage as diagnostic procedure of choice. The sample was sent for Histopathological Examination (HPE), the accuracy of vaginal ultrasound and Pipelle was measured. In 21% patients, endometrial carcinoma was found, endometrial hyperplasia in 26%, atrophic endometrium in 18%, endometrial polyp in 10% and no specific pathology in 20%. Endometrial thickness measured by Transvaginal ultrasound ranged from 1mm to 28mm with mean of 10.16mm and median of 11.5mm.

Our study showed that in DC Biopsy 6(12.0%) patients had endometrial carcinoma, endometrial hyperplasia with atypia in 3 (6.0%), endometrial hyperplasia without atypia in 6 (12.0%), atrophic endometrium in 14 (28.0%), endometrial polyp in 2 (4.0%), chronic endometritis in 6 (12.0%). Endometrial thickness measured by TVS ranged from 1.50mm to 28mm with mean of 9.01mm.

Jain U et al[11] observed that abnormal bleeding from uterus is a commonly encountered complaint in gynaecological practice. Rural cases were 78.41% of the total cases. The presenting symptoms majority were menometorrhagia (49.33%). Histopathology reports were negative for malignancy (60.79%), Hyperplasia without atypia (12.33%), suspicious for malignant tumor (0.44%), atrophic endometrium (4.40%), endometritis (9.69%). Pipelle biopsy procedure is a simple, easy, patient friendly technique to obtain endometrial biopsy on the outpatient basis without need of patient admission and anaesthesia.

Park YR et al[12] showed that to assess the clinical usefulness and diagnostic accuracy of ultrasonographic measurement of endometrial thickness (ET) in women with endometrial hyperplasia or cancer (EH+). This retrospective cohort study included 29,995 consecutive women who underwent transvaginal ultrasonography (TVS) for an incidental finding of a thickened endometrium at the health screening and promotion centre at Asian Medical Centre between 2006 and 2010. Endometrial histology was the reference standard for calculating accuracy. Of the 92

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patients, 78 (84.8%) had normal pathology, while 14 (15.2%) had endometrial pathology (EH+), including 5 patients (35.7%) with simple hyperplasia without atypia, 3 (21.4%) with complex hyperplasia, and 6 (42.9%) with endometrial carcinoma, all stage Ia.

It was found in our study that in Pipelle's biopsy 2(4.0%) patients had endometrial carcinoma endometriod type, 2 (4.0%) patients had high grade carcinoma, 6 (12.0%) patients had atypical complex endometrial hyperplasia, 6 (12.0%) patients had hyperplasia without atypia, 2 (4.0%) patients had endometrial polyp, 4 (8.0%) patients had materials inadequate for histological analysis. p value <0.0001 and was statistically significant.

In TVS, 6 (12.0%) patients had endometrial carcinoma, 3 (6.0%) patients with atypical endometrial hyperplasia, 6 (12.0%) patients had hyperplasia without atypia, endometrial polyp in 2 (4.0%) patients. p value <0.0001 and was statistically significant.

Gupta M et al[13] showed that we aimed to assess the patient knowledge/choice for subsequent procedure, sampling adequacy, and diagnostic accuracy of Pipelle endometrial sampling and conventional D&C in patients with abnormal uterine bleeding (AUB). This study included total 443 women >40 years of age, with AUB requiring endometrial evaluation. Pipelle biopsy was done without cervical dilation followed by D&C. The histopathology of both the procedures was compared, considering histopathology of the D&C sample as gold standard. Outcomes were compared among the two procedures.

We showed that, the mean Age of patients was [51.7600±4.7748.], Parity of patients was [3.3800±1.4270] and Duration of post-menopausal bleeding (months) of patients was [3.0200±1.2696].

In our study, 07 (77.78%) patients had Endometrial Ca and Atypical endometrial hyperplasia detected in Pipelle and 09 (100%) patients had Endometrial Ca and atypical endometrial hyperplasia detected in TVS compared to 09 (100.0%) detected by DC biopsy.

Ibrahim Anwar Abdelazim[14] compared the diagnostic accuracy of Pipelle endometrial sampling with conventional dilatation and curettage in patients with abnormal uterine bleeding. 140 patients were included in this study. 100% of samples obtained by DC biopsy while 97.9% obtained by Pipelle device. In this study Pipelle device had 100% sensitivity 100% specificity and 100% predictive value in diagnosing endometrial hyperplasia, endometrial carcinoma, proliferative and secretory endometrium.

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Sudha Menon[15] conducted a prospective study in 100 patients to correlate Endometrial thickness by TVS and compared with gold standard of histopathological examination (HPE) of the endometrium by fractional curettage (FC) and concluded that TVS can be easily performed and is less expensive and a useful diagnostic tool in evaluation of PMB with a cut off value of 10.8mm EMT gives a high sensitivity (92.3%) and moderate specificity (62.7%).

In our study 100% sample was collected by DC Biopsy and 92.0% sample collected by Pipelle's endometrial sampler.

Our study showed predictive value of Pipelle and TVS to be 100%, sensitivity of Pipelle's biopsy was of 87.78% and that of TVS was 100%. Specificity of both was 100%. Diagnostic accuracy in detecting endometrial pathology of TVS was 100% and that of Pipelle's was 96%.

Conclusions

In our study 09 (100.0%) patients were detected with endometrial carcinoma and atypical endometrial hyperplasia by DC Biopsy and the results were statistically significant. We observed that 27(54.0%) patients underwent hysterectomy but the results were not significant. In our study the sensitivity of TVS and Pipelle device in diagnosing endometrial carcinoma and atypical endometrial hyperplasia was100% and 87.78% respectively, specificity of 100%, 100% predictive value and diagnostic accuracy of 96% for Pipelle's and 100% for TVS. Hence, Transvaginal ultrasonography and Pipelle's endometrial biopsy combined can be appropriate for an initial evaluation of post-menopausal bleeding per vagina to detect any endometrial pathology.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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