Section: Medicine

Original Research Article

COMPARATIVE STUDY OF TRANSVAGINAL SONOGRAPHY AND PIPELLE ENDOMETRIAL SAMPLING IN ABNORMAL UTERINE BLEEDING

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ABSTRACT

Background: Abnormal Uterine bleeding (AUB) is bleeding from the uterus that is longer than usual or occurs at an irregular time. Transvaginal Sonography (TVS) is the initial diagnostic modality in assessment of patients presenting with AUB. It is inexpensive, non-invasive investigation to visualize the endometrium and endometrial cavity. Pipelle Endometrial Sampling (PES) is the outpatient based procedure which is simpler, cost effective procedure for endometrial tissue sampling. Very few studies have been done in India comparing TVS and PES in patients with AUB. The aim & objective of the study in to compare diagnostic accuracy of TVS and Pipelle Endometrial Sampling in patients presenting with AUB by correlating with hysterectomy. To assess the adequacy of Pipelle Endometrial Sampling in collected specimens. **Materials and Methods:** This prospective, comparative study is done over period of 2 years (2021 -2022). A total of 39 women above the age of 30 years presenting with complaints of abnormal bleeding uterine were included in the study. Any vaginal or cervical cause of bleeding, blood dyscrasias, pregnancy related causes of bleeding, patient with history of drug intake like anticoagulants and hormone replacement therapy were excluded. These women underwent clinical examination, investigations and TVS, followed by PES and hysterectomy. Only patients undergoing both PES and hystetectomy were included in the study. **Result:** 39 patients presented with HMB or menorrhagia / PMB as clinical symptom were enrolled for the study. 10 patients had inadequate samples, as patients were mostly post menopausal and the endometrium was thin and atrophic. 29 cases with findings of PES and HPE were included in the study. TVS diagnosed endometrium as normal in 22 (75.8%) cases with Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 94.44%, 90.90%, and 94.44%, 90.9% and 93.1% respectively (p value <0.001). TVS diagnosed endometrium as abnormal in 7(24.13%) cases in the form of carcinoma in 2 cases, polyp in 2 cases and hyperplasia in 3 cases with overall Sensitivity, Specificity, PPV, NPV and Diagnostic Accuracy of. 85.71%, 86.36%, 66.66% 95% and 86.20% respectively.(P value <0.001) PES showed histologic features of normal endometrium in 21 (72.41%) cases with Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 88.23%, 91.6%, and 93.75%, 84.6% and 89.65% respectively.(p value <0.001) and as abnormal in 8(27.59%) cases in the form of carcinoma in 2 cases, polyp in 2case and hyperplasia in 4 cases with overall Sensitivity, Specificity, PPV, NPV and Diagnostic Accuracy of. 57.14%, 81.8%, 50% 85.71% and 75.86% respectively. (p<0.068). Combined TVS and PES has Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 88.88%, 90.90%, and 94.11%, 83.33% and 89.65% respectively for normal endometrium (p< 0.001) and has Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 71.4%, 81.81%, and 55.55%, 90% and 79.31% respectively for abnormal endometrium.(p< 0.008). The additional advantage of TVS is that it can also detect other abnormalties in the uterus like fibroids and adenomyosis, any adnexal masses and polycystic ovaries as other causes of AUB, however PES provides tissue diagnosis. The main limitation for Pipelle Endometrial Sampling is of inadequate samples in postmenopausal patients with thin endometrium accounting for 25.64%. **Conclusion:** Transvaginal Sonography should be used as initial diagnostic modality in assessment of

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patients presenting with AUB followed by Pipelle Endometrial Sampling, which is simpler, semi-invasive, outpatient based procedure to evaluate endometirial tissue. A combined TVS and PES is more accurate in arriving at the diagnosis of AUB, thereby obviating the need for more invasive procedures like Dilatation & Curettage and hyseroscopic biopsy.

INTRODUCTION

AUB is one of the most common complaints presenting in gynec OPD and accounts for 17.9% of Indian population.[1] Pelvic ultrasound is the initial diagnostic imaging modality in evaluation of endometrium in women presenting with abnormal uterine bleeding. It will determine the etiology of the bleeding such as fibroid uterus, increased endometrial thickness or a focal mass. Thickened endometrium will indicate an underlying pathology or hormonal imbalance or malignancy.[2] TVS is an inexpensive, non- invasive modality to visualize the endometrial cavity.TVS identifies myometrial abnormalities, such as fibroids and adenomyosis, thickened endometrium, due to hyperplasia or endometrial cancer that may warrant a histopathological diagnosis.[3] TVS can reliably assess endometrial thickness and uterine cavity morphology.[4]

Dilatation and curettage, hysteroscopic biopsy and endometrial samplings are used for tissue diagnosis of AUB,[5] and Diagnostic Curettage is the method of choice for evaluating endometrial abnormalities,[6] but it is an invasive procedure, and requires admission and anesthesia and hence the need for simpler, cheaper, semi-invasive procedures with less complications like PES.[7] Hence the study is done to compare Diagnostic Accuracy of TVS and PES in patients presenting with AUB by correlating with hysterectomy as gold standard.

Review of literature

Pipelle, developed by cornier was first employed for endometrial sampling in fertility studies,[8] and its use extended to detect pathological lesions. Nowadays, the Pipelle biopsy is performed as an endometrial biopsy method extensively. It is safe, cheap and non-invasive as well as its complication is too rare, it doesn't need operation room and anesthesia.[9,10]

The major concern of Pipelle is the less material.[11] Several studies have shown that the validity and adequacy of PES in comparison with D&C and hysterectomy specimens.[12]

With respect to reliability of PES in the determination of endometrial polyps, the procedure was confirmed to have less sensitivity of 12.5%, specificity 100%, Positive Predictive Value (PPV) of 100% and Negative Predictive Value (NPV) of 88.7%.

Several studies have reported the validity and adequacy of PES in comparison with D&C and hysterectomy specimens.[12] Özdemir et al, Evaluated endometrial thickness with TVS and Histopathology in premenopausal women with abnormal vaginal bleeding, out of 144 women, 113 (78.4%) had normal and 31(21.6%) had an abnormal endometrium.[13]

MATERIALS AND METHODS

The study is prospective and observational with Descriptive and Analytical statistics analysis and study design is for 2 years. The cases were studied for a period of 2 years (24months) in East Point College of Medical Sciences and Research Centre, Bangalore. Patients referred to Dept of Radiodiagnosis for pelvic ultrasonography with history of AUB, over period of 2yrs from 1st January 2021 – 31st December 2022 were included in the study. A total of 39 patients enrolled for the study. 29 Patients with all 3 procedures (TVS, PES and Hysterectomy) were included.

Inclusion Criteria

Patients more than 30 years with history of AUB were included.

Exclusion Criteria

Patients presenting with vaginal or cervical cause of bleeding, blood dyscarias, Pregnancy related causes of bleeding, patient with h/o drug intake (Anticoagulant and hormone replacement therapy).

Methodology

All data are recorded including age, parity, onset, duration of complaints, interval and amount of bleeding, obstetrical, medical and surgical interventions and any previous treatment history. All patients were clinically evaluated for general, systemic, and gynecological examination. Informed written consent was obtained for USG and special consent was taken for TVS. Ethical clearance was obtained from ethical committee.

Initially USG is done by transabdominal route with transabdominal probe with full urinary bladder to measure the uterus and adnexa followed by TVS after emptying the bladder; Transvaginal ultrasound examination was done using GE VOLUSON E6 equipment with 7.5 MHZ vaginal transducer. The thickest part of endometrium was measured perpendicular to its longitudinal plane in anteroposterior diameter, between echogenic borders and looked for any intraluminal pathologies.

Patient underwent PES after taking consent. The Pipelle device, a flexible, thin instrument with inbuilt suction, was used for endometrial sampling. After inserting the device, the inner piston was withdrawn to create suction, allowing for the collection of a sample by rotating the cannula. A strip of endometrium was peeled off and sucked into the syringe for histopathological analysis and specimen was sent for HPE. Then the patient underwent hysterectomy within a week, which is the gold standard. The endometrial findings on TVS and histopathology of PES were compared with

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hysterectomy specimens. All data was entered in MS Excel sheet and analyzed by descriptive statistics for proportion and mean, inferential statistics by chi square test for significant difference between proportions. Sensitivity analysis, positive predictive and negative predictive value was calculated. Correlation between the variable will be analyzed using Spearmen's correlation test. P value < 0.05 was considered for statistical significance.

RESULTS

A total of 39 patients were included in the study. In our study, AUB was found more commonly in 41-50 years same as found in 19 (48.7%) cases in premenopausal women. [Figure 1]

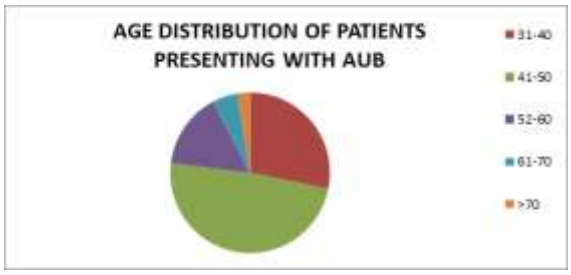

Figure 1: Shows distribution of age of patients presenting with AUB.

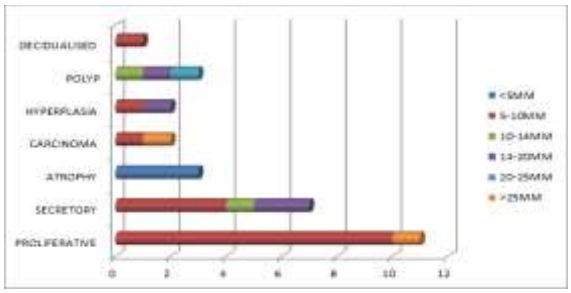

Figure 2: Showing endometrial thickness on TVS and HPE correlation.

Endometrial thickness was most commonly seen between 5-10 mm in 10 cases (34.48 %) and seen having proliferative endometrium., followed by secretory endometrium in 4 (13.79%) cases. Figure 2. Among normal endometrium on histopathology was seen in 12 (54.54%) cases and 7 (24.2%) cases of abnormal endometrium. [Figure 2]

Out of 29 cases studied on PES, 21 (72.48%) cases were found to have normal endometrium and 8(27.5%) cases were found to be abnormal. [Figure 3]

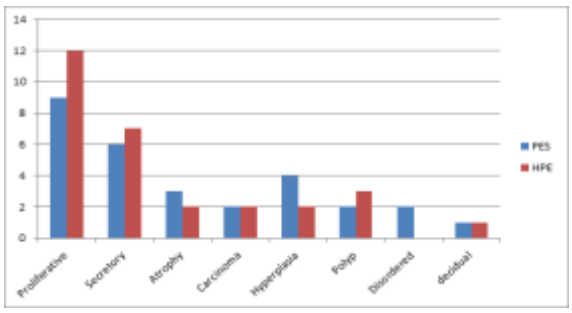

Figure 3: Comparison of PES with HPE

PES on comparison with histopathology showed Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 83%, 95.6%, and 83.2%, 95.6% and 93.1% respectively for proliferative endometrium. 80%, 95.8%, and 80%, 95.8% and 93.1% respectively for secretory endometrium, 33%, 92.8%, and 83.3%, 92.8% and 93.1% respectively for atrophic endometrium, Sensitivity, Specificity, PPV, NPV and 100% for carcinoma, 89.2%,89.2%and 86.2% respectively for polyp, 50%, 92.5%, and 33%, 96.1% and 89.6% respectively for endometrial hyperplasia and diagnostic accuracy of 89.6% for others. [Figure 4]

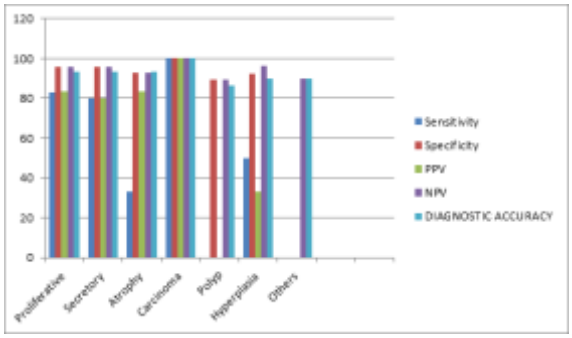

Figure 4: Comparison of PES and HPE in detection of type of endometrium

With cut off of 14mm in premenopausal and 5mm in post menopausal,[15] and specific intraluminal abnormalties, TVS diagnosed endometrium as normal in 22 (75.86) cases with Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 94.44%, 90.90%, and 94.44%, 90.9% and 93.1% respectively. TVS diagnosed endometrium as abnormal in 7 (24.13%) cases with overall Sensitivity, Specificity, PPV, NPV and Diagnostic Accuracy of. 85.71%, 86.36%, 66.66% 95% and 86.20% respectively. [Figure 5]

PES showed normal endometrium in 21 (72.14%%) cases with Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 88.23%, 91.6%, and 93.75%, 84.6% and 89.65% respectively. PES featured endometrium as abnormal in 8(20.51%) cases with overall Sensitivity, Specificity, PPV, NPV and Diagnostic Accuracy of. 57.14%, 81.8%, 50% 85.71% and 75.86% respectively.

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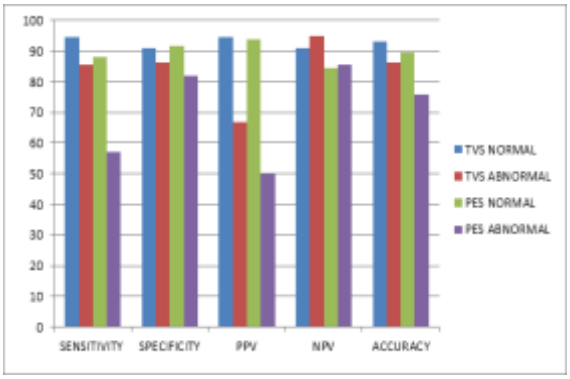

Figure 5: Comparison of TVS and PES in differentiation of normal and abnormal endometrium

DISCUSSION

39 patients enrolled for the study.10 patients had scanty specimen leading to inadequate or non-opinion reports on PES. AUB was found commonly in premenopausal women between in 41-50 years in 19 (48.7%) cases, similar to study by Mamatha S et al.[14] [Figure 1]

Endometrial thickness was most commonly seen between 5-10 mm in 10 cases (34.48 %) and seen having proliferative endometrium, similar to study by Mamatha s et al,[14] have also found most of endometrium were seen between 5-8mm in 34.6% of cases and secretory endometrium in 4 (13.79%) cases. [Figure 2].

Out of 29 hysterectomy specimens studied, 22 (75.8%) cases were found to have normal endometrium and 7(31.8%) cases had abnormal endometrium on HPE. Among normal endometrium on histopathology, 12 (54.54%) cases had proliferative endometrium, 7 (24.13%) cases had secretory endometrium, and 2 (6.89%) cases had atrophic endometrium, 1 (3.44%) decidual endometrium. Among 7 (24.2%) cases of abnormal endometrium 2(6.89%) cases were carcinoma, 2 (6.89%) cases were hyperplasia 3 (10.3%) cases were polyps. [Figure 3]

Out of 29 cases studied on PES, 21 (72.41%) cases were found to have normal endometrium and 8 (27.58 %) cases were found to be abnormal. 21 (72.41%) cases had normal endometrium in the form of proliferative endometrium in 9(31.03%) cases, 6 (20.6%) cases had secretory endometrium, 3(10.3%) cases had atrophic endometrium, 2(6.89%) disordered endometrium, 1(3.44%) had decidual endometium. Abnormal endometrium on PES was seen in 8 (24.13%) cases; 2(6.89) cases were diagnosed as carcinoma, 4(13.79%) cases as hyperplasia and 2(6.89%) cases as polyp. [Figure 3]

With cut off of 14mm in premenopausal and 5mm in post menopausal,[15] and specific intraluminal abnormalties, TVS diagnosed endometrium as normal in 22 (75.86%) cases with Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 94.44%, 90.90%, and 94.44%, 90.9% and 93.1% respectively. TVS diagnosed endometrium as abnormal in 7 (24.13%) cases in the form of carcinoma in 2 cases, polyp in 3 cases and hyperplasia in 2 cases with overall Sensitivity, Specificity, PPV, NPV and Diagnostic Accuracy of. 85.71%, 86.36%, 66.66% 95% and 86.20% respectively. [Figure 5] Polyp was diagnosed by TVS in 2 cases with sensitivity, Specificity, PPV, NPV and Diagnostic Accuracy of. 79.1, 93.2%, 79.1% 93.2% and 89.7% respectively. PES did not detect any polyp and falsely detected polyp when it was not there (specificity of 89.2% and diagnostic accuracy of 86.2%. A study by Kazandi M et al, have opined lower detection rate of polyps in respect to Pipelle with sensitivity of 12.5%, specificity of 100%, positive predictive value (PPV) 100% and negative predictive value (NPV) 88.7%.[12]

Carcinoma was detected by both PES and TVS 100% sensitivity and specificity. Hyperplasia was detected by TVS in 3cases with Sensitivity Specificity, PPV, NPV and Diagnostic Accuracy of. 79.1, 93.2%, 79.1% 93.2% and 89.7% respectively and PES detection of hyperplasia in 4 cases with Sensitivity Specificity, PPV, NPV and Diagnostic Accuracy of. 79.1, 93.2%, 79.1% 93.2% and 89.7% respectively, similar to the most recent study done by Ilavarasi CR et al, to compare the histopathology report obtained by Pipelle biopsy with the hysterectomy specimen.[16] PES showed normal endometrium in 21(72.41%) cases with Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 88.23%, 91.6%, and 93.75%, 84.6% and 89.65% respectively. PES featured endometrium as abnormal in 8(27.58%) cases in the form of carcinoma in 2 cases, polyp in 1 cases and hyperplasia in 4 cases with overall Sensitivity, Specificity, PPV, NPV and Diagnostic Accuracy of. 57.14%, 81.8%, 50% 85.71% and 75.86% respectively.

Figure 1: Showing adequacy of pes samples by various studies and their percentage

	Total	Percentage
Our study	39	74.0
Shazia fakhar et al,(10) 2008	100	98.0
Bakour SH, (17)2000	248	70.2
Kazandi et al, (12)2012	82	93.0
Sanam and majid ,(6) 2015	130	88.0
Epstein E et al, (18)2001	133	84.0
Mamatha S et al, (14)2019	81	93.0
Ibrahim SA et al, (19)2019	480	98.2

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PES on comparison with histopathology showed Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 83%, 95.6%, and 83.2%, 95.6% and 93.1% respectively for proliferative endometrium. 80%, 95.8%, and 80%, 95.8% and 93.1% respectively for secretory endometrium, 33%, 92.8%, and 83.3%, 92.8% and 93.1% respectively for atrophic endometrium, Sensitivity, Specificity, PPV, NPV and 100% for carcinoma, 89.2%,89.2%and 86.2% respectively for polyp, 50%, 92.5%, and 33%, 96.1% and 89.6% respectively for endometrial hyperplasia and diagnostic accuracy of 89.6% for others. Figure 4 The findings are in consensus with study done by Mamata S et al,[14] which also shows sensitivity of 71.4%, 100 %, 80% for and 57.1% for proliferative endometrium, carcinoma, simple hyperplasia and polyp respectively.[14] [Figure 4]

Combined TVS and PES has Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 88.88%, 90.90%, and 94.11%, 83.33% and 89.65% respectively for normal endometrium and has Sensitivity, Specificity, PPV, NPV and diagnostic accuracy of 71.4%, 81.81%, and 55.55%, 90% and 79.31% respectively for abnormal endometrium.

Sample adequacy: Among 39 patients undergoing PES in our institution, 10(25.64%) cases were excluded from the study due to inadequate sampling/ non opinion samples.

Several studies have shown the sample adequacy when doing PES; Shazia fakhar et al in 2008 studied a totol of 100 patients with adequate samples of 74%, Bakour SH et al, 2000 , studied a total of 248 patients with sample size of 70.2%, Kazandi et al, 2012, studied a total of 82 patients with sam ple size of 93%, San am and Majid et al, 2015 studied 130 patients with sample size of 88%, Epstein E et al, 2001 studied 133 patients with sample size adequacy of 84%. [Table 1]

The inadequacy of sample size is seen in post menopausal women with thin endometrium., similar reason quoted by recent studies done by Mamatha S et al, 2019 and Ibrahim SA et al, 2019, who have studied 81 and 480 patients with sample size adequacy of 93% and 98.2% respectively. [Table 1]

Limitation of the study is small sample size the study has to be done in higher population in Indian set up.

CONCLUSION

This study shows that combined use of Transvaginal Sonography (TVS) with its information of myometrium, adnexa and intraluminal pathologies and PES which provides tissue biopsy will yield more accurate diagnosis of AUB and will obviate the need for invasive procedures like Dilatation and Curettage and Hysteroscopic Biopsy.

The insufficient samples in PES are more likely due to thin endometrim in post-menopausal women.

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