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ORIGINAL RESEARCH ARTICLE

Diagnostic accuracy of Trans-vaginal sonography in detection of Endometrial Carcinoma in women having post-menopausal bleeding

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Abstract

Background: Bleeding Per vagina following established menopause is called post menopausal bleeding. The significance of postmenopausal bleeding, whatever slight it may be, should not be underestimated. As many as one-third of the cases are due to malignancy. The same importance is also given to those eases where normal menstruation continues even beyond the age or 55 years. In recent years, health aspects of postmenopausal women have gained immense importance as it owes significance importance in gaining life expectancy in these women. **Aim and Objectives :** The aim of this study was to determine the sensitivity and specificity of transvaginal sonography in detection of endometrial carcinoma. **Material and** M**ethods:** This study hospital based prospective observational study, has been carried out from May 2020 to April 2021 in the department of Obstetrics and Gynaecology of BMC & H. A total of 96

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postmenopausal women who attended outpatient department at the Obstetrics and Gynaecology department of BMCH with the complaint of vaginal bleeding will be included after application of exclusion criteria. Template was generated in MS excel sheet and analysis was done on SPSS. **Results:** In the present study 1 (53.1%) patients were 51-60 years of age, Mean age (mean ± SD) of patients was 53.6771±6.3965. In our study, 89 (92.7%) patients had endometrial halo. We have found that 49% postmenopausal women have atrophic and senile cystic atmhy, 6.3% patients have carcinoma endometrium. mean years of menopause (mean ± SD) of patients was 7.1406 ± 5.4967. Mean endometrial thickness (mean ±SD) of Patients was 6.7604± 4.3067. In the present study, there is more chance of carcinoma in women with >50 years of age. There is more chance (19.4%) of carcinoma in women having BMI >25. There is 50% chance of endometrial carcinoma in women with other CA and 75% chance of endometrial carcinoma in women with HT N & DM. **Conclusion:** Transvaginal sonography is safe, simple, non invasive and cost effective in the diagnosis of endometrial carcinoma.

Keywords: Bleeding, Endometrial Carcinoma, post-menopausal, Trans-vaginal sonography

Introduction

According to WHO, the disability adjusted life expectancy (DALE) exceeds 70 years in about 24 countries, with women living longer than men by an average of 7 to 8 years.[1] The average age at menopause ranges from 45 years in the Indian woman to 51 years in the Western population depending on the hereditary, life style and nutritional factors.[2,3,4] In whole world, 40% of cancers in women are comprises of due to gynaecological cause (breast, ovary, endometrium., cervix). However, there are huge differences depending upon incidence and geographical distribution. The incidence of endornetrial cancer is 3.7% to 17.9% in postmenopausal women with abnormal uterine bleeding.[5,6] The incidence of endometrial cancer in asymptomatic women was 0.13% and at is was seen in 0.63%.[7]

If diagnosed early, it can be cured with very less morbidity and mortality. Localized disease (stage l and II) has a 5-year survival of 87% and 76% respectively, but much poorer for stage III with 5 year survival rate of <60%.[8] Endometria1 polyps often have hyperplastic changes and the risk of premalignant to malignant polyp increases with age, menopausal status and hypertension.[9] There is no mass screening programme in early detection of endometrial carcinoma in contrast to cervical carcinoma.

Traditionally dilation and curettage has been used for endometrial sampling. Dilation and curettage are invasive, and is associated with a 1-2% complication clue, thus less invasive endometrial biopsy techniques are increasingly favoured for evaluating these women.[10] Although many safe techniques are now available for detecting and diagnosing neoplastic lesions of the endometrium, these methods are invasive.[11,12]

So, we should use sonic non-invasive method like transvaginal ultrasonography as a screening method for early detection of endometrial carcinoma. We can semen patients as per the Findings of ultrasound so that we can decide which patients should undergo endometrial biopsy for

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confirmation of endometrial carcinoma.

Besides endometrial carcinoma. transvaginal sonography can detect other endometrial pathologies also. Transvaginal sonography yields even more detailed images of the uterus.[13,14] It provides detailed picture of endometrium. Endometrial morphology and thickness can be measured accurately by which decisions can be taken for endometrial biopsy. The thickness and internal echo texture of the endometrium in the various phases of menstrual cycle as seen in transvaginal sonogram correlates well with endometrial histology, It provides a good patient acceptance also.

Transvaginal sonography measurement of endometrial thickness and morphology has been demonstrated to have high accuracy in excluding endometrial polyps, hyperplasia and cancer in women with postmenopausal bleeding.[15] It is minimally invasive and has high cancer detection rates.[16,17]

In with 31% or less combined prevalence of endometrial carcinoma or atypical adenomatous hyperplasia, algorithms utilizing transvaginal sonography as the initial test are most cost effective when compared to biopsy-based algorithms in evaluating perimempausal and Postmenopausal women with abnormal vaginal bleeding.[18]

The study purpose is to determine the diagnostic accuracy of transvaginal sonography by detecting the endometrial thickness and echogenicity which is later confirmed by histopathological findings.

Materials and Methods

A hospital based prospective observational study has been carried out from MaY 2020 to April 2021 in the department of Obstetrics and Gynaecology of 111VIC8d1. A total of 96 postmenopausal women who attended outpatient department at the Obstetrics and Gynaecology department of BMCH with the complaint of vaginal bleeding will be included after application of exclusion criteria.

Study Design : Prospective observational study.

Place of Study: The Obstetrics and Gynaecology department of Burdwan Medical College and Hospital, Burdwan, West Bengal, India.

Study Period: From May, 2020 to October, 2021. For data collection, 12 months have been allocated, for data analysis, 3 months and for result and conclusion, 3 months have been allocated.

Sample Size: Considering the prevalence of Endometrial Carcinoma in women having Postmenopausal bleeding to be 4% 1471, data applied in the formula- $4PQ /L^2$ [Where P= Prevalence, Q= 1-P, maximum allowable error up to 10% of Prevalence], total number of samples comes out to be 96.

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Inclusion Criteria : Last menstrual cycle at least one year back (Menopausal women), all patients with complaints of postmenopausal bleeding, Age 40 years and above, not on any hormonal treatment and absence of other pelvic diseases and coagulation disorder.

Exclusion Criteria : Patients with any structural uterine pathology, such as fibroid, adenomyosis, endometriosis and patients who are not giving a valid consent for TES.

Study variables : Variables like age, height, weight, Moil, blood pressure, clinical presentation of the patient, blood samples for investigations- CBC, Blood Glucose, Urea, Creatinine, Lipid Profile, BT/CT, FT4, TSH, PT/INR, APTT, Transvaginal Ultrasonographic evaluation of Uterus and Adnexa, Endometrial Thickness by TVS and Endometrial Biopsy by Dilatation and Curettage were collected.

Outcome parameters : Sensitivity, Specificity, Positive Predictive Value, Negative Predictive value of TVS in diagnosis of Endometrial Carcinoma.

Statistical technique:

After getting Institutional Research Ethics Committee clearance all the relevant collected data were compiled on a master chart first. Then organized by using scientific calculator and standard statistical formulas. Percentages were calculated to find-out the proportion of the findings. Further statistical analyses of the results were done by computer software device as statistical packages for social scientist (SPSS). The results were presented in tables, figures, diagrams etc. For the validity. of the study outcome, sensitivity, specificity, accuracy, positive and negative predictive values of the TVS findings in the diagnosis of endometrial pathology were calculated after confirmation of the diagnosis by histopathology and were calculated by standard formula.

For significance of differences Fisher's exact test, Chi test were done where applicable. A "p" value <0.05 was considered as significant.

The subject is asked to empty the bladder before the examination. A small amount of gel is applied over the transducer tip and the probe is covered by a condom. A small amount of lubricant gel is applied over the probe to allow easy insertion. Transvaginal transducer of 5.5 to 8-5 MHz was used.

Histopathological diagnosis of the endometrium was obtained from specimens obtained by dilatation arid curettage or operative hysteroscopy guided biopsy or by hysterectomy.. The histopathology of the endometrium was considered gold standard.

Statistical Analysis:

Statistical analysis was done using Microsoft Excel and SPSS software. $P<0.05\%$ was considered significance level for the study.

Results

In this prospective observational study, 96 postmenopausal women were involved in the study and outcome analysed using various parameters. All the relevant collected data were compiled on a master chart first. Then organized by using scientific calculator and standard statistical

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formulas. Percentages were calculated to find-out the proportion of the findings. Further statistical analyses of the results were done by computer software device as statistical Packages for social scientist (SPSS). The results were presented in tables, figures, diagrams etc. For the validity of the study outcome, sensitivity, specificity, accuracy, positive and negative predictive values of the 'TVS findings in the diagnosis of endometrial pathology were calculated after confirmation of the diagnosis by histopathology and were calculated by standard formula.

For significance of differences Fisher's exact test, Chi test were done where applicable. A "p" value <0.05 was considered as significant.

Sample size: 96

TVS performed in 96

Histopathological diagnosis obtained in 96

Table 1: Distribution of study population according to age, distribution of other diseases, BMI and appearance. (n=96)

Age in group	**Frequency**	**Percentage (%)**
41-50	31	36.5
51-60	51	53.1
61-70	10	10.4
Total	**96**	**100.0**
Distribution of other diseases		
Breast CA	1	1..0
CA caecum	1	1.0
DM	9	9.4
DM and Anemia	1	1.0
Hypertension	12	12.5
Hypertension and DM	4	4.2
Nil	68	70.8
BMI		
< 25	60	62.5
> 25	36	37.5
Appearance		
Heterogeneous	8	8.3
Homogenous	88	91.7

In the present study 35 (36.5%) patients were 41-50 years of age, 51 (53.1%) patients were 51-60 years of age and 10 (10.4%) patients were 61-70 years of age. Majority of the women belong to the age group 51-60 years (53.1%). Mean age (mean ± SD) of patients was 53.6771±6.3965. In our study, 1 (1.0%) patient had Breast CA, 1 (1.0%) patient had CA caecum, 9 (9.4%) patients had DM, 1

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(1.0%) patient had DM & anemia, 12 (12.5%) patients had HTN and 4 (4.2%) patients had HTN & DM. In our study. 60 (62.5%) patients had <25 BM1 and 36 (37.5%) patients had >25 BMI. In the study 8 (8.3%) had heterogeneous appearance and 88 (91.7%) had homogenous appearance (Table 1)

Figure 1: Distribution of study population according to characteristics.

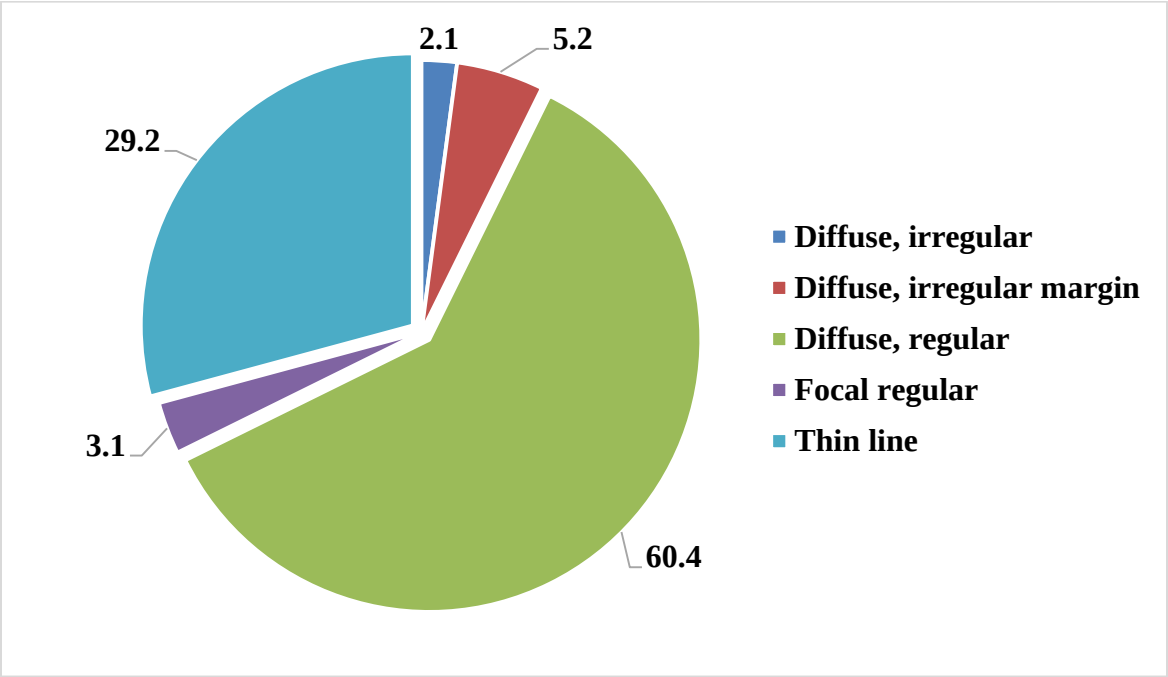

Figure1 shows that 2 (2.1%) patients were diffuse, irregular, 5 (5.2%) patients were diffuse, irregular margin, 58 (60.4%) patients were diffuse, regular, 3 (3.1%) patients were focal, regular and 28 (29+2%) patients were thin line. (Figure 1)

Table 2 : Distribution of study population according to endometrial halo, distribution of HPE. (n=96)

Endometrial halo	**Frequency**	**Percentage (%)**
No	7	7.3
Yes	89	92.7
Distribution of HPE		
Atrtophic & senile cystic atrophy	47	49.0
Carcinoma	6	6.3
Complex hyperplasia atypia	5	5.2
Polyp	3	3.1
Proliferative	30	31.3
Simple hyperplasia	5	5.2

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In our study, 89 (92.7%) patients had endometrial halo. In our study, we have histopathological examination (I-IPE) as gold standard. We have found that 49% postmenopausal women have atrophic and senile cystic atmhy, 6.3% patients have carcinoma endometrium, 5.2% patients have complex hyperplasia atypia, 3.1% patients have polyp, 31.3% patients have proliferative endometrium, and 5.2% patients have simple hyperplasia. We are considering carcinoma and complex hyperplasia atypia as abnormal endometrium in this study, as complex hyperplasia atypia has a serious potential to be converted into carcinoma. (Table 2)

Table 3 : Distribution of study population according to mean years of menopause and endometrial thickness. (n=96)

	Number	Mean	SD	Minimum	Maximum	Median
Years of Menopause	96	7.1406	5.4967	1.0000	25.0000	6.0000
Endometrial thickness	96	6.7604	4.3067	1.0000	28.0000	6.0000

In above table showed that the mean years of menopause (mean ± SD) of patients was 7.1406 ± 5.4967. Mean endometrial thickness (mean ±SD) of Patients was 6.7604± 4.3067. (Table 3)

Table 4 : Comparison of age with HPE, BMI with HPE, endometrial halo With HPE, endometrial appearance with FPE and characteristics of endometrium obtained from TVS with HPE (n=96)

	≤ 50	**> 50**
Age with HPE	(3/35) 8.6%	(8/61) 13%
	< 25	**> 25**
BMI with HPE	(4/60) 6.7%	(7/36) 19.4%
	Present	**Absent**
Endometrial VA and complex hyperplasia atypia	(5/89) 5.6%	(6/7) 85.7%
	Homogenous	**Heterogenous**
Endometrial carcinoma & complex hyperplasia atypia	(4/88) 4.5%	(7/8) 87.5%
	Normal	**Abnormal**
Characteristics of Endometrial carcinoma and complex hyperplasia aypia	(3/86) 3.4%	(8/10) 80%

In the present study, there is more chance of carcinoma in women with >50 years of age. There

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is more chance (19.4%) of carcinoma in women having BMI >25. There is more chance (5.6%) of endometrial carcinoma in Women with absence of endometrial halo in TVS. There is more chance (87.5%) of having endometrial carcinoma if there is heterogenous appearance of the endometrium in TVS. There is more chance (80%) of carcinoma in having an abnormal characteristic in TVS of endometrium. (Table 4)

Table 5 : Comparison of other diseases with HPE (n=96)

Other diseases	Other CA	DM	HTN	HTN & DM	Nil
Endometrial CA and complex hyperplasia atypia	50% (1/2)	10% (1/10)	8.3% (1/12)	75% (3/4)	7.3% (5/68)

In this study, there is 50% chance of endometrial carcinoma in women with other CA and 75% chance of endometrial carcinoma in women with HT N & DM. (Table 5)

Table 6 : Comparison of endometrial thickness with histopathology (n=96)

In this study, we are considering a cut of value for endometrial thickness. Considering >5mm as a cut of value, we will assess the diagnostic accuracy of TVS in diagnosis of endometrial carcinoma.

Considering >5mm - Positive TVS
≤ 5mm- Negative TVS

	Positive TVS (>5mm)	Negative TVS (≤ 5mm)	P Value
Endometrial carcinoma and complex hyperplasia atypia	(10/51) 19%	(1/45) 2%	0.0189 (<0.05) Statistically Significant

There is statistical significance between endometrial thickness and endometrial carcinoma and complex hyperplasia atypia (which has very serious potential to develop into carcinoma) in women with postmenopausal bleeding. (Table 6)

Discussion

This study is a prospective observational study. Most of the patients were of age 51-60 years with a percentage of 53.1%. Women with all parity were represented in this study. In this study, women have attained menopause in various times. The distribution range was between 2 to 12 years of age. In this study, 20.9% of patients had associated comorbid diseases. In this study, 62.5% patients were with BI I <25 and 37.5% patients with BM1 >25. The study by Gull B et al.

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(2001) reported that several risk factors including. hypertension and diabetes was associated with increased endometrial thickness and abnormality.[18] In our study, there is 50% chance of having carcinoma in patients with other carcinoma & 75% chance of having carcinoma in patients with both HTN & DM.

Transvaginal sonography parameters take into consideration were appearance of the endometrial stripe (homogenous/ heterogenous), characteristic feature (diffuse/focal), endometrial halo (present/absent). In our study, this is found that there is 85.7% chance of endometrial carcinoma in patients with absence of endometrial halo. There is 87.5% chance of endometrial carcinoma in patients with heterogenous appearance of endometrium in TVS. There is 80% chance of having endometrial carcinoma in patients with presence of abnormal characteristics of endometrium as found in TVS.

A study by Bakaur SH et al. (1999) it is shown that for detection of endometrial hyperplasia/carcinoma, endometrial thickness >4.0 mm had a sensitivity of 92.9% (95% CI 64.2-99_6), specificity of 50% (95% CI 38.8 - 61.2), a positive predictive value or 24.1% (95% CI 13.9 - 37.9), and a negative predictive value of 97.6% (95% CI – 85.9 - 99.9).[19] In our study, considering cut off value of endometrial thickness as >5 mm, Sensitivity is 90.9%, Specificity is 51.]%,, Positive Predictive Value is 19.6%, Negative predictive Value is 97.7%. So, there can he reduction of the need for invasive procedure of patients with postmenopausal bleeding with endometrial thickness of ≤5mm.

This shows that a cut off of 5 mm of the Endometrial. Thickness obtained from TVS is highly accurate in excluding endometrial carcinoma in women with postmenopausal bleeding. As per the Compendium of Selected Publications by AGOG it recommends that if the endometriurn is thin by TVS, most commonly defined s a thickness of ≤5mm, the risk of cancer is sufficiently low that a biopsy may be deferred.[20]

In a cross-sectional study done by M S Showkat et al. (2013) with 40 patients who are clinically suspected having thickened endometrium The sensitivity, specificity, PIN, NPV of TVS in detection of endometrial carcinoma was found to be 67%, 100%, 100% and 97%.[21] In our study, sensitivity-, specificity, PP V, NPV of TVS in detecting endometrial carcinoma considering cut of value of endometrial thickness as >5nim found to be 90.9%, 51.7%, 19.6%, 97.7% respectively. So, taking a value as cut off, the need for invasive procedure can be reduced in those patients.

In a stud by F Olaya et al. (n04) the sensitivity of TVS in detecting deep invasion, i.e., more than 50% of the myometrial thickness was 94.1%, while the specificity was 84.8% and the overall accuracy was. 88%.[22] So, in Patients with a cut off of >5mm, TVS can he performed for detection of endometrial carcinoma as well as for detection of myomettial invasion in patients with endometrial carcinoma from which prognosis of carcinoma can de deferred.

In a study by M N Nasri et al. has shown that a normal ultrasound appearance of the endometrium in postmenopausal Women reliably excludes significant endometrial pathology. Also., changes in the thickness and texture of the endometrium detected by ultrasound correlated

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with subsequent pathological findings.[23] In. our study, there is 87.5% chance of carcinoma in patients with heterogenous appearance of endometrium deferred from TVS. So invasive procedure can be lessened if there is abnormal appearance of endometrium. If there will be correlation of abnormal appearance and endometrial thickness is greater than the cut off value, then there will be more chance of carcinoma. In these cases, we can avoid the invasive procedure like HPE in these women.

In a study by B Karlssen et al. (1995) that the risk of finding pathologic enclatnebium at curettage when the endometrium is ≤4mm as measured by transvaginal ultrasonography is 5.5%. Thus, in women with postmenopausal bleeding and an endometrium <4 nun it would seem justified to refrain from curettage.[24] In our study, we have taken the cut off value as 5mtn. In those women with endometrial thickness ≤5mm, we can easily refrain them from any invasive procedure like HPE.

In a study by M Niknejadi et al. (2012) was designed to assess the diagnostic accuracy of transvaginal ultrasonography (TVS) in uterine -pathologies or infertile patients using hysteroscopy as the gold standard. The result of this study was that the overall sensitivity, specificity, positive and negative predictive values for TVS in the diagnosis of uterine abnormality was 79%, 82%, 84% and 71%, respectively.[25] So, there is much accuracy in detection of endometrial carcinoma by TVS mainly from refraining these postmenopausal bleeding women patients from invasive procedures like HPE.

This study shows if the cut off value for endometrial thickness is taken as 5mm, sensitivity, specificity, PPV, NPV is 90.9%, 51.7%, 19.6% and 97.7% respectively. B. Randelzhofer et al. in a study analyzed various sonomorphological criteria prospectively in 321 women. Using the cut-off point of 0.1 for the probability of endometrial malignancy, the sensitivity and specificity were 96.8% and 61.9%, respectively, with an accuracy of 72.3%. In contrast, the differentiation by endometrial thickness as the sole criterion (cut-off point 5 mm) achieved a sensitivity of 97.9% and a specificity of 33.2%, with an accuracy of 52.3%. The combination of thickness with morphological features can be used in the diagnosis of benign and malignant endometrial disease with considerable accuracy in women with postmenopausal bleeding.[26]

Limitation of the study

Present study was conducted in a tertiary care centre, most of people belonged to poor socioeconomic status where concern for women's health was less and there were irregular checkups.

Conclusion

Transvaginal sonography is safe, simple, non invasive and cost effective in the diagnosis of endometrial carcinoma. It should be used as a first line investigation in women with postmenopausal bleeding. If endometrial thickness comes out to be >5mm in 'TVS, then we should consider for D/C biopsy of that woman. Due to time limitation, study was conducted in

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few number of patients. Further study may be conducted with large number of patients. As our study is small, we can't comment on decrease in the need for invasive procedures. We can suggest that those women with endometrial thickness >5mm obtained from INS should undergo D/C endometrial biopsy.

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