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Original Research Article

Histopathological correlation of transvaginal sonography and hysteroscopy in women with postmenopausal bleeding

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ABSTRACT

Background: Postmenopausal bleeding is defined as vaginal bleeding occurring after 12 months of amenorrhea. It is a symptom which may have benign or malignant etiology and hence prompt examination is necessary to make a correct diagnosis. This is a prospective interventional study conducted to correlate findings of transvaginal sonography (TVS), hysteroscopy/ versascopy and the final histopathological diagnosis.
Methods: Prospective study was conducted in 100 patients with post-menopausal bleeding. All patients underwent TVS followed by hysteroscopy and guided biopsy, results of which were compared with the gold standard i.e., histopathology.
Results: For diagnosing abnormal histopathology, the overall sensitivity and specificity for TVS was 85.96% and 34.88% respectively whereas it was 70% and 72% respectively for hysteroscopy. For diagnosing malignancy, the sensitivity and specificity of TVS was 91.6% and 25% respectively and was 91.6% and 100% respectively for hysteroscopy. On combining both modalities the sensitivity and specificity increased to 83% and 100% respectively.
Conclusions: TVS can be used as screening modality with cut off endometrial thickness (ET) of 4 mm with good sensitivity. However, specificity is low, hence hysteroscopy followed by endometrial biopsy is recommended as the diagnostic modality in evaluation of postmenopausal bleeding.

Keywords: Postmenopausal bleeding, TVS, Hysteroscopy

INTRODUCTION

Postmenopausal bleeding is defined as vaginal bleeding occurring after 12 months of amenorrhea.[1] 5% of women attending gynaecology OPD come with presenting symptoms of postmenopausal bleeding.[2] It is a symptom which may have benign or malignant etiology and hence prompt and thorough examination is necessary to make a correct diagnosis. Early detection is the primary aim to improve overall survival in endometrial carcinoma.

The ideal diagnostic method should be safe, less invasive, less expensive and with rapid reproducible results. Examination under anaesthesia and dilatation and curettage have been considered the gold standard since decades. However recent studies suggest that less than 10% of women with postmenopausal bleeding have endometrial carcinoma, while majority of them have no significant pathology.[3] So over 90% of women presenting with postmenopausal bleeding are subjected to an unnecessary invasive procedure making the need for a less invasive procedure for screening such as TVS.

TVS is a simple, well tolerated, non-invasive out-patient procedure. A study by Diaa et al concluded that the sensitivity and specificity for identifying endometrial pathology were 73.8% and 73.7% respectively. It is a useful screening test to determine which patients need further investigations and to follow up high risk patients. An ET cut off of 5mm for detection of endometrial pathology had an overall efficacy of 81%.[4] However a meta-analysis[5] of 85 studies showed that an ET >4 mm identified 96% of endometrial cancer which is now the guideline as per ACOG 2018.[6] Study by Diaa et al showed

that although less sensitive than hysteroscopy/versascopy in direct diagnosis of endometrial pathology, TVS can reach higher sensitivity if in addition to endometrial features, presence of myometrial invasion, detection of other concomitant pelvic pathology like adnexal mass and fibroids are taken into account.

Looking at the sensitivity and specificity of TVS, it can tell us when hysteroscopy/versascopy should be used for evaluation of uterine causes in women with postmenopausal bleeding. Since TVS is relatively cheap, non-invasive, easy and doesn't need anaesthesia, it could be used as a first screening test for postmenopausal bleeding followed by hysteroscopy and guided biopsy for final diagnosis.

Hysteroscopy / versascopy is a procedure that allows direct visualisation of the cavity of uterus and endocervix.[7] The cervix is dilated and the scope is introduced into the uterus to visualise all the walls, the uterine cavity, endometrial lining, bilateral tubal ostia and endocervix.[8] Versascopy is done in cases of cervical stenosis when hysteroscopy fails. It is done with a micro-hysteroscope of 1.8 mm thickness. It is small enough to be introduced through most cervices without dilatation and is designed to minimise trauma and discomfort.[9] Hysteroscopy shows great efficiency in diagnosis of focal abnormalities of endometrium which can be missed on ultrasonography.[4] It is of great value in delineating and simultaneously taking adequate therapeutic steps to manage intra-cavitatory lesions. Tissue biopsy performed under direct visualisation offers further diagnostic advantage in detecting endometrial pathologies as compared to random sampling of endometrium.[10] The specificity and sensitivity were 84.2% and 78.3% respectively.

Endometrial curettage / biopsy is a must for diagnosing the underlying pathology in women with postmenopausal bleeding. Curettage is mandatory for asymptomatic postmenopausal women with an ET>12 mm and symptomatic postmenopausal women with an ET> 4 mm as both have equal risk of carcinoma.[11]

This study aimed to find out the efficacy of TVS and hysteroscopy/ versascopy in evaluation of women with postmenopausal women and correlate the findings with histopathology of the endometrium taken as gold standard.

METHODS

This observational and prospective study was conducted at the department of obstetrics and gynaecology at Sir Gangaram hospital, New Delhi from July 2006 to November 2008. Hundred and six women of postmenopausal bleeding were selected from gynaecology OPD. After detailed history and thorough clinical examination, patients were subjected to TVS followed by hysteroscopy versascopy. Hysteroscopy was performed in 59 patients, versascopy in 35 patients and versascopy followed by hysteroscopy in 6 patients. The guided biopsies or endometrial curetting were sent for histopathological evaluation. Six patients were excluded from the study as they were diagnosed to have pyometra on TVS; hence hysteroscopy/ versascopy was not performed. Pyometra was drained in these patients. Hence hundred patients were recruited for the study.

After complete history taking, general and systemic examination, pre operative investigations, all patients underwent TVS followed by hysteroscopy/versascopy with D and C and endometrial sample was sent for histopathological examination.

Following parameters were noted in all patients on TVS, which included ET and morphological features.

ET

It was measured as an average of endometrium thickness on both longitudinal and transverse scans of uterus, as in postmenopausal women it is not possible to note the longitudinal sections as a continuous line. The cut off value was taken as 4mm for differentiating between abnormal and normal endometrium.

The various TVS reports were: Normal, polyp, hyperplasia, atrophy and carcinoma.

All patients were them subjected to hysteroscopy/ versascopy using the Karl Stoz rigid hysteroscope followed by directed biopsies under short GA. Endometrial lining was classified into-Benign conditions including atrophic/polyp/fibroid/ simple hyperplasia. Suspicious looking including carcinoma/atypical hyperplasia.

Following hysteroscopy, endometrial biopsy was performed from most suspicious areas as well as curettage of the whole cavity was done.

Histologic diagnosis was given by pathologists who were blinded to hysteroscopy and sonographic findings. A spectrum of histopathological findings was documented on biopsy including atrophy, polyp, proliferative, cancer endometrium, inadequate, hyperplasia without atypia, cystic glandular hyperplasia, hyperplasia with atypia and squamous cell cancer of cervix. The data was analysed using standard statistical methods i.e., cross tabulation of data to form contingency tables, chi square test, ANNOVA test and p value was calculated with significance level at <0.05. Standard formulae for calculation of sensitivity, specificity, positive and negative predictive values of TVS and hysteroscopy/versascopy in diagnosing abnormal histopathology and CA endometrium were used, with histopathology reports taken as gold standard.

RESULTS

The spectrum of histopathological findings documented on biopsy in the decreasing order of their frequency were

hyperplasia without atypia-25%, atrophy-21%, polyp-17%, proliferative-13%, cancer endometrium-12%, inadequate-8%, hyperplasia with atypia-2%, squamous cell cancer of cervix-1% and actionomycosis-1%.

The incidence of benign causes leading to postmenopausal bleeding was 87%.

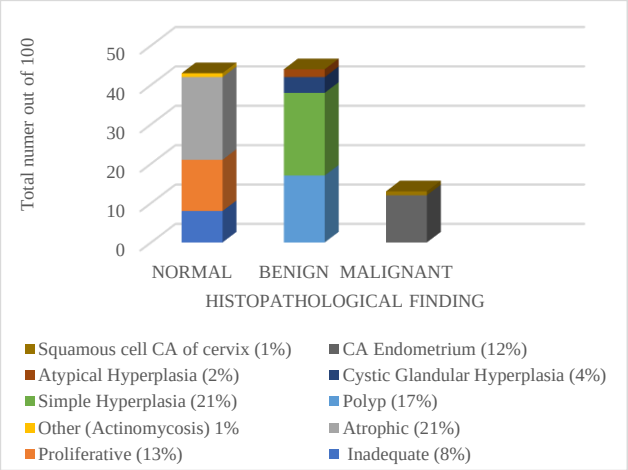

Figure 1: HPE findings among the study population, (n=100).

Malignancy was found in 13% of cases of which endometrial cancer consisted of 12% and squamous cell carcinoma consisted of 1%.

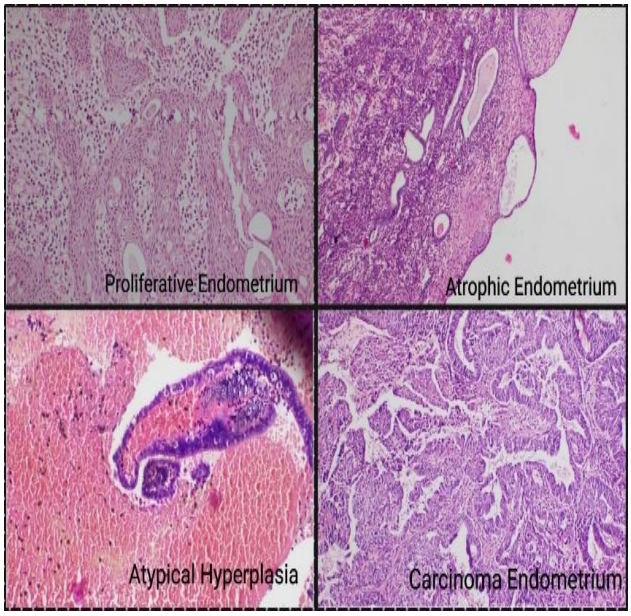

Figure 2: Histopathology slides of endometrium.

Table 1: Demography.

HPE	Age (years)				BMI (kg/m^2)			Parity		Duration since menopause (Years)			
	41-50	51-60	61-70	>71	<26	26-30	>30	P_0	$P_{\geq 1}$	<2	2-5	5-10	>10
Normal	12	21	7	3	13	22	8	1	42	15	9	9	10
Benign	12	22	7	3	13	19	12	1	43	13	9	10	12
Malignant	1	6	2	4	2	4	7	1	12	1	3	3	6
Total	25	49	16	10	28	45	27	3	97	29	21	22	28

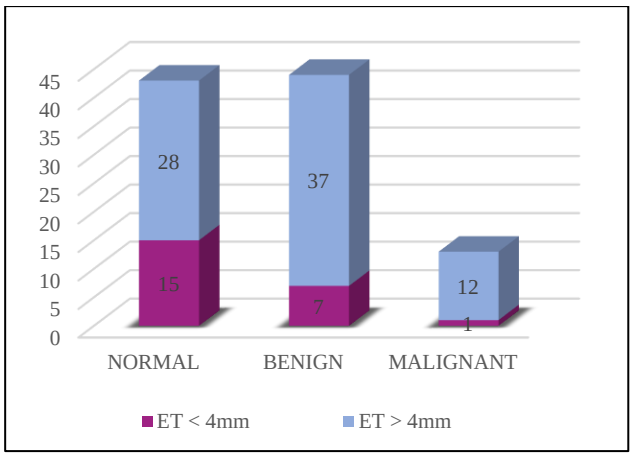

Figure 3: Findings of TVS correlation with HPE, (n=100).

Out of seventy-seven patients with ET more than more than 4 mm, forty-nine had abnormal histopathology. Out of twenty-three patients with ET less than 4 mm only eight patients had abnormal HPE findings. Out of the twelve patients with cancer endometrium, eleven (91%) had ET more than 4 mm. Hence the p value was significant (0.022) suggesting positive correlation of ET more than 4 mm and histopathology report.

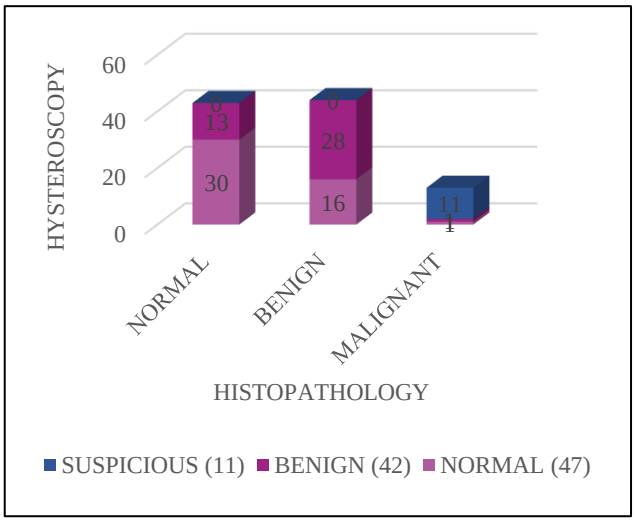

Figure 4: Findings of hysteroscopy/versascopy correlation with HPE.

Out of 47 patients with normal findings on hysteroscopy/versascopy thirty cases had normal histopathology and seventeen had abnormal histopathology. Out of 42 patients who had benign findings on hysteroscopy/versascopy, 19 had abnormal histopathology. Out of twelve patients with carcinoma endometrium, one case was under diagnosed on hysteroscopy as endometrial polyp which was found to be malignant on HPE.

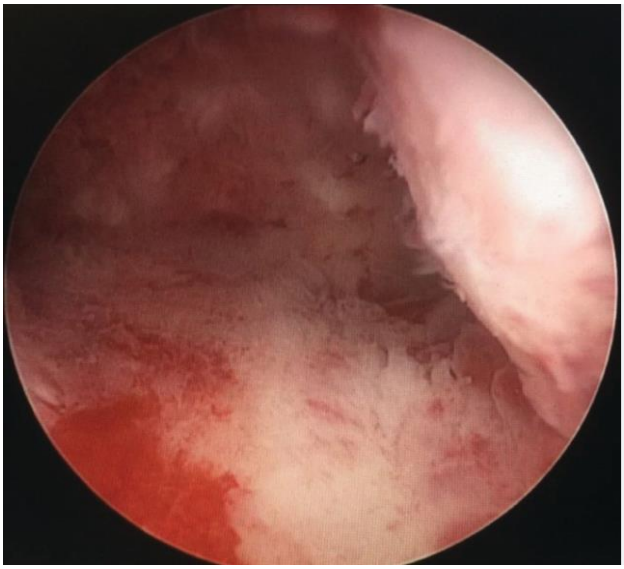

Figure 5: Endometrial hyperplasia on the hysteroscopy.

Table 2: ET, hysteroscopy findings and combination of both correlation with abnormal histopathology.

TVS	Abnormal histopathology including polyp, hyperplasia and cancer		
	Abnormal	**Normal**	**Total**
ET			
ET > 4 mm	49	28	77
ET < 4 mm	8	15	23
Total	57	43	100
Hysteroscopy/ versascopy			
Suspicious	40	12	52
Benign	17	31	48
Total	57	43	100
Et on TVS + hysteroscopy/ versascopy			
ET > 4 mm + suspicious hysteroscopy	10	0	10
ET <4 mm + benign hysteroscopy	47	43	90
Total	57	43	100

The sensitivity, specificity, positive and negative predictive value of ET on TVS, hysteroscopy findings and a combination of both in diagnosing abnormal histopathology were calculated using standard the statistical formulae using the above findings (Table 2) and tabulated.

Table 3: Comparative table between TVS, hysteroscopy/ versascopy and combination of TVS and hysteroscopy/ versascopy with the abnormal histopathology (polyp, hyperplasia and cancer).

Test	TVS (%)	Hysteroscopy / versascopy (%)	Combination of TVS and hysteroscopy (%)
Sensitivity	85.96	70.17	17.54
Specificity	34.88	72.09	100
Positive predictive value	63.63	76.92	100
Negative predictive value	65.21	64.58	47.77
False negative	14.03	29.82	82.45
False positive	65.12	27.9	00

The combination of TVS and hysteroscopy/ versascopy reached higher specificity up to 100% in diagnosing abnormal histopathology.

Table 4: Correlation of ET, hysteroscopy findings and combination of both with benign and malignant (endometrial cancer) HPE.

TVS	Histopathology		
	Malignant	**Benign**	**Total**
ET			
ET > 4 mm	11	66	77
ET <4 mm	01	22	23
Total	12	88	100
Hysteroscopy			
Suspicious	11	00	11
Benign	01	88	89
Total	12	88	100
ET on TVS + hysteroscopy			
Et >4 mm +suspicious hysteroscopy	10	0	10
Et <4 mm + benign hysteroscopy	2	88	90
Total	12	88	100

The sensitivity, specificity, positive as well as the negative predictive value of endometrium thickness on the transvaginal sonography, hysteroscopy findings and a combination of both in the diagnosing malignancy or carcinoma endometrium were calculated using the standard statistical formulae using the above findings as well as tabulated in the Table 4.

Table 5: Comparative table between TVS, hysteroscopy/ versascopy and combination of TVS and hysteroscopy/ versascopy with benign and malignant histopathology, (n=100).

Test	TVS (%)	Hysteroscopy/ versascopy (%)	Combination of TVS and hysteroscopy (%)
Sensitivity	91.66	91.66	83.3
Specificity	25	100	100
Positive predictive value	14.28	100	100
Negative predictive value	95.65	98.86	97.7
False negative	8.3	83	16.66
False positive	75	0	0

Both TVS and hysteroscopy had a good sensitivity individually in diagnosing CA endometrium. Although specificity of TVS was low but it showed a high negative predictive value (95.65%), combining both modalities lead to a specificity of 100%

DISCUSSION

Postmenopausal bleeding might be the first indication of malignancy of genital tract; hence it is imperative to investigate the women. Therefore, prompt and thorough examination and investigation is mandatory in order to a make correct diagnosis.[12]

Benign conditions represent the most frequent cause of postmenopausal bleeding and can cause considerable distress. The primary aim of the initial investigation is to evaluate endometrial carcinoma and its precursors.[12] However histopathological examination gives the final diagnosis. The present study included hundred women of postmenopausal bleeding who were subjected to TVS followed by hysteroscopy/versascopy and guided biopsy or endometrial curettage.

In the present study a spectrum of histopathological findings was documented on biopsy (Figure 1). In decreasing order of the frequency, they were hyperplasia without atypia-25%, atrophy-21% (Figure 2), polyp-17%, proliferative-13% (Figure 2), cancer endometrium- 12% (Figure 2), inadequate-8%, hyperplasia with atypia-2% (Figure 2), squamous cell cancer of cervix-1% and actinomycosis-1%.

The incidence of carcinoma endometrium was 12% in our study and was found similar in most recent studies such as Tandulwadkar et al (13.3%), Junnare et al (14%) and Mansingh et al (10%).[13,15,16]
Various risk factors associated with postmenopausal bleeding and endometrial cancer were evaluated in the present study which included age, body mass index and parity. In the present study, majority of women presented between the age group of 51-60 years (Table 1). The mean age of presentation was 59.6 years. The risk of endometrial cancer in women with postmenopausal bleeding rises with age from approximately 1% at less than 50 years of age to 25% at the age of more than 70 years.[17]

In the present study, with the advancing age there was an increased incidence of endometrial carcinoma from 12% to 30%. Thirty percent of the patient were in the age group of more than 70 years which is comparable with Gredmark et al whereas Tandulwadkar et al found 33% of cases above the age of 55.[13,17] The dictum of age as an independent risk factor for development of cancer was found to be true in our study.

The risk of carcinoma endometrium is associated with obesity. As seen in Table: 1, among the 12 patients with carcinoma endometrium 50% were obese (body mass index more than 30), 33% were overweight (body mass index-26-30) and 16% had normal body mass index (20-25). However, 2 patients with normal body mass index had endometrial cancer. Out of these two, one had family history of endometrial cancer and second had past history of breast cancer. In present study we found an association of obesity with cancer endometrium in 50 % of the cases which is comparable to Tandulwadkar et al with 62.5% cases being obese.[13]

The incidence of malignancy as an underlying cause of postmenopausal bleeding increased as the duration since menopause increased. Among the twelve patients (Table 1) diagnosed with endometrial carcinoma, five patients (41.66%) developed cancer when the duration was more than ten years. When the duration of menopause was less than 2 years, benign conditions were more frequent. In present study the risk of endometrial cancer was 91% if duration since menopause was more than 2 years which is comparable to the study by Veena et al which reported the incidence as 80%.[18]

For decades examination under anesthesia and dilatation and curettage have been considered as the “gold standard” investigative procedures for patients with postmenopausal bleeding. However about 60% of the endometrium is not biopsied in patients as it is a blind procedure resulting in failure in prediction and management.[19] Now we have more scientific and accurate diagnostic modalities available to TVS, hysteroscopy/versascopy and us. We primarily evaluated the postmenopausal bleeding women with TVS which included ET with cut off 4 mm which is now the standard as per 2018 ACOG guidelines and morphological variations of endometrium for predicting abnormal histopathology.[6]

Out of 77 patients with ET more than more than 4 mm, 49 had abnormal histopathology. Out of 23 patients with ET less than 4 mm only eight patients had abnormal HPE findings which included four polyps, three simple hyperplasia and one endometrial cancer. Hence the p value

was significant (0.022) suggesting positive correlation of ET more than 4mm and histopathology report.

Sensitivity and specificity of TVS to diagnose abnormal histopathology was calculated by standard statistical formulae. The sensitivity of ET for diagnosing abnormal HPE was found to be 85.96%. This was comparable to results by Tinelli et al (89%), Timmermans et al (97%), Babacan et al (96%) and Pushpa et al (87%) and Junnare et al (93%).[15,20-23] The specificity of ET on TVS to diagnose abnormal histopathology was 34.88% which was comparable to Babacan et al (13.8%) and Timmermans et al (56%).

Out of the twelve patients with cancer endometrium, eleven (91%) had ET more than 4 mm. Only one patient had ET less than 4mm, but was diagnosed on hysteroscopy as focal elevated hyper vascular lesion at the cornua which was reported as malignancy on HPE.

The sensitivity of TVS for diagnosing cancer endometrium or Malignancy was found to be 91.66%. Similar findings were noted by Tandulwadkar et al (50%), Krishnamoorthy et al (100%) and Kadakola et al (100%) in 2015.[13,14,24] Though the specificity in our study was only 25%, the negative predictive value was 95.65%.

Hysteroscopy/ versascopy was done for further evaluation of women with postmenopausal bleeding. Both the modalities provide direct pictures of endometrium and great efficacy in diagnosing focal lesions of endometrium, which could hardly be seen on TVS.

When hysteroscopy and versascopy directed histopathology was compared (Figure 4), out of 47 patients with normal findings on hysteroscopy/versascopy thirty cases had normal histopathology and seventeen had abnormal histopathology. Out of 42 patients who had benign findings on hysteroscopy/versascopy (Figure 5), nineteen had abnormal histopathology. Out of these nineteen patients, only one had cancer endometrium that was reported as benign polyp.

In our study, the overall efficacy of hysteroscopy for detecting abnormal histopathology was found to be with a sensitivity of 70% and specificity of 72% respectively (Table 5) which were compared to Tinelli et al[20](2008), Tandulwadkar et al and Junnare et al and all three reported a sensitivity and specificity of more than 90%, Babacan et al reported a lower specificity of 41.4% but this could be attributed to observer bias.[13,15,20,22]

On the other hand, in our study the sensitivity of hysteroscopy in predicting endometrial cancer or malignancy was 91.66% and specificity was 100% (Table 5) which was compared to other studies such as Tandulwadkar et al, Krishnamoorthy et al and Mansingh et al and all their sensitivity and specificity values were similar to our study.[13,14,16]

When TVS and hysteroscopy/ versascopy were considered together histopathological diagnosis was more accurate. In our study all the patients with ET more than 4 mm and suspicious hysteroscopy had abnormal histopathology including polyp, hyperplasia or cancer. Thus, on combining the two tests, specificity of 100% was obtained to detect abnormal histopathology and endometrial carcinoma.

The present study was conducted in the department of obstetrics and gynaecology at Sir Gangaram hospital over a period of 2 years. Hundred patients of postmenopausal age with chief complaint of abnormal bleeding per vaginum were included in the study. The mean age of presentation of postmenopausal bleeding in the study group was 59.6 years. The peak age of presentation of postmenopausal bleeding and endometrial cancer in the study group was 51-60 years. In our study, on histopathological analysis hyperplasia without atypia was present in 25%, hyperplasia with atypia-2%, atrophy-21%, polyp-17%, proliferative endometrium-13%, cancer endometrium-12%, inadequate tissue-8%, squamous cell cancer of cervix-1% and actinomycosis-1%. We found that the risk of endometrial carcinoma increased with the duration of menopause. The risk was 91% when the duration of menopause was more than 2 years. The risk of endometrial cancer increased from 12% in age group of 51-60 years to 30% in age group of more than 71 years. Our study showed obesity as risk factor to be present in 50% of the patients with endometrial carcinoma. The overall sensitivity and specificity of TVS in predicting abnormal histopathology was 85.96% and 34.88% respectively but for endometrial carcinoma was 91.66% and 25% respectively. In the present study, overall sensitivity and specificity of hysteroscopy/ versascopy was 70% and 72% for diagnosing abnormal histopathology, but for endometrial cancer was 91.66% and 100% respectively, hence hysteroscopy/versascopy was more specific for diagnosing endometrial cancer. Our study showed that combining TVS and hysteroscopy/ versascopy resulted in sensitivity of 83% and specificity of 100% for diagnosing carcinoma endometrium, hence specificity was improved using both modalities i.e., TVS and hysteroscopy /versascopy. Comparison with various recent studies show that the results are still similar even after so many years yet again confirming our inference.

Limitations

Both TVS and hysteroscopy findings are observer based and may vary with skill or experience of the observer and that may be a limitation to our findings in the study.

CONCLUSION

Trans vaginal sonography when used as a screening modality for postmenopausal bleeding, with cut off value for ET as 4 mm, resulted in good sensitivity in predicting abnormal histopathology. However, specificity is low, hence versascopy/ hysteroscopy followed by endometrial biopsy is recommended as the diagnostic modality in evaluation of postmenopausal bleeding women.

Postmenopausal bleeding is a symptom with underlying etiology being benign or malignant. Therefore, prompt and thorough examination is necessary in order to make a correct diagnosis.

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