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Role of Transvaginal Shear Wave Elastography in Diagnosis of benign and malignant endometrial lesions

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Abstract: Background: Endometrial lesions are a common cause of abnormal uterine bleeding. Ultrasound is a reliable diagnostic tool for those lesions, but not all patients exhibit definite changes in ultrasound, making additional techniques necessary. Elastography, such as shear wave elastography, can assess the mechanical properties of the endometrial lesions and provides a quantitative measure of tissue stiffness and so aids in differentiating different pathologies. Our study aimed to determine the role of shear wave elastography (SWE) in diagnosis of different benign and malignant lesions. Methods: Thirty female patients presented by abnormal uterine bleeding with pathologically proven benign and malignant endometrial pathologies were included in this prospective study and assessed with transvaginal SWE. The mean elasticity values (in Kilopascals), and the ratio of the mean elasticity of the lesion to the mean myometrial elasticity (E/M ratio) were calculated in variable lesions. Results: There was a statistically significant difference in the mean elasticity value (E mean) (P >0.001) as well as the E/M ratio of different benign and malignant lesions (P >0.0001). E mean value in endometrial carcinoma is 39.79 ± 3.65, endometrial hyperplasia is 24.24 ± 1.52, and endometrial polyp 15.74 ± 2.71., the E/M ratio of uterine polyp (0.36 ± 0.07) was statistically significantly lower than other subgroups (P >0. 1). Conclusions: Shear wave elastography is an effective additional method in differentiating between benign and malignant endometrial lesions when combined with conventional ultrasonography

Keywords: *Shear wave elastography, Endometrial lesions, E mean, E/M ratio*

Introduction

Endometrial cancer (EC) and endometrial hyperplasia and polyps are the most common malignant and benign uterine endometrial cavity lesions, respectively (1).

Endometrial polyps are localized hyperplastic overgrowths of endometrial glands and stroma that form a sessile or pedunculated projection from the surface of the endometrium. They are a common condition in gynecology and their prevalence can be up to 40%. Endometrial polyps can be benign, premalignant (atypical endometrial hyperplasia) or malignant (endometrial carcinoma) (2)

Endometrial cancer (EC) was the 6th leading cause of cancer-related deaths in 2020. It is a malignancy that originates in the endometrial gland. the incidence of EC has been on the rise in the past decade, seriously threatening the life and health of women. EC has occupied the first place in the incidence of malignancies of female reproductive system in developed countries. (3)

Atypical endometrial hyperplasia (AEH) is the precancerous lesion for EC, and its clinical symptoms is equivalent to that of highly differentiated EC. The co-incidence rate for AEH and EC were 15–55%, and they are similar in terms of surgical techniques and clinical therapies. Hence, it is important to raise the rate of detection of EC and AEH [4].

Elastography is a new non-invasive ultrasound method that evaluates tissue's mechanical stiffness based on Hooke's law. This technique may be able to provide an extra pattern for endometrial pathologies' characterization. and widen the scope of conventional sonological investigations defined in the IETA statement [5].

Recent studies have shown that SWE is more accurate than conventional transvaginal ultrasound in detection of endometrial lesions. Yet, each diagnostic imaging procedure has its own advantages along with disadvantages, and no imaging examination is enough to accurately diagnose the disease. As a result, SWE should not replace conventional transvaginal ultrasound but should be an addition to it [6].

METHODS

1. Study type and population:

A prospective study that was conducted at a tertiary hospital and included all the consecutive female patients with abnormal bleeding from the uterus that may be related to a focal or diffuse endometrial irregularity on primary transabdominal or TVS referred to the department of radio-diagnosis for transvaginal SWE and were subjected after that to histopathological correlation of the excised lesion or the biopsy. During the period from September 2013 to March 2024, In addition to the transvaginal SWE data, the variables collected included the patients' demographics, medical history, and clinical characteristics. The exclusion criteria included patients receiving estrogen replacement therapy /chemotherapy or radiotherapy (n=9), patients who had a curettage, patients with an IUD for endometrial pathology (n=2) , as well as virgin female (n=3) and cases where pathological reports were not accessible (n=7).Finally, 30 patients were enrolled in the study, their age ranged from 20 to 75 years with a mean age of42.81 ± 11.45 years. The study has been carried out in accordance with the code of ethics of the World Medical Association (Declaration of Helsinki) — Ethical Principles for Medical Research Involving Human Subjects. Approval was obtained from the Zagazig University institutional review board (IRB) (Zu-IRB #10742/30-4-2023) and the patient's informed consent was waived. All patients were subjected to transvaginal SWE in addition to histopathological examinations of the excised mass or the biopsy.

All patients are subjected to the following: Complete history taking including Personal history, including the age, residency, gravidity and parity, menstrual history: Date of last menstrual period, duration, regularity, History of abnormal uterine bleeding and family history of endometrial carcinoma or lesions. Also, Physical examination by Gynecologist.

2-Transvaginal ultrasound and SWE:

The imaging study for the research consisted of Ultrasonography and Shear Wave Elastography (SWE), which were performed using Toshiba Canon Aplio 500 ultrasound machine (made in Japan) with a multifrequency 3.5-8.8 MHz transvaginal probe. The patients were lying in patient lies supine in lithotomy position and a protective condom was covering the transvaginal probe.

Gray scale ultrasound (B-Mode) examination was performed in sagittal and axial planes to evaluate the uterine endometrium and myometrium was with paying special attention to each. Observation whether that the endometrium had a focal mass or widespread thickening.

After that, Color Doppler imaging was done to evaluate the mass's vascularity.

After ensuring the endometrial pathology of interest was perfectly prepared the pathological lesion of endometrium or sub-endometrium was examined with SWE.

3-SWE examination:

In Shear wave elastography, the transducer was kept stationary with light pressure and a generous amount of coupling gel during acquisition of each SWE sonogram, using B-mode to ensure the endometrial or sub-endometrial pathology of interest. After freezing the elastography image, a circular ROI of various diameters is placed within the elastography window. Color-saturated images were used to perform calculations. In the present study, tissue elasticity was measured in kilopascals (kPa) of the spectrum scale, which guided the placement of the ROI cursor. Each pixel in the SWE image represented the tissue stiffness as a semi-transparent color map with a range of dark blue to red (0–180 kPa), signifying a low to high shear modulus (stiffness). This color map's level of homogeneity was observed for different endometrial or sub-endometrial pathologies. Next, The standard regions of interest were utilized to produce the quantitative evaluation of tissue stiffness of diseases. (Q-box).

Images with speckling or an empty Q-box were not included. Within the ROI, the system yielded the mean (Emean) and maximum (Emax), elasticity values for each measurement. Mean elasticity value of normal myometrium was also calculated to obtain E/M ratio. Overall, the imaging study was conducted with meticulous attention to detail to ensure results obtained accuracy.

Histopathology Analysis

Every patient had additional histopathology assessment, either hysterectomy, endometrial biopsy, or hysteroscopic biopsy. The definitive histological diagnosis was regarded as the most reliable.

Statistical analysis

Statistical analysis was done by SPSS version 28 (IBM Co., Armonk, NY, USA).

Quantitative data were presented as mean and standard deviation (SD), analysed by one-way ANOVA (F) test with post hoc test (Tukey). Categorical data were presented as frequency and percentage.

ROC curve analysis was used to estimate the diagnostic performance of every SWE cutoff value to select the best one based on Youden index.

A two tailed P value < 0.05 was considered statistically significant.

RESULTS

This study consisted of 30 patients suspected to have endometrial abnormalities that were included in this study, with a mean age of 42.81 ± 11.45 years (range between 20 and 75 years). More than two thirds of patients (69.4%) were premenopausal.**,**

As shown in **Table 1**, Endometrial lesions were classified by transvaginal SWE as endometrial carcinoma 14 (46.6 %), polyp 10 (33.3%), hyperplasia 6 (20%).

There was a statistically significant difference among SWE mean values of the studied lesions (P<0.001), value of carcinoma was significantly higher than that of hyperplasia and both were significantly higher than that of polyp. Also, there was a significant difference among the studied lesions regarding endometrial/myometrial ratio (P<0.001) as ratios of carcinoma and hyperplasia were significantly higher than that of polyp **(Table 2).**

Shear wave elastography mean values (of lesion and normal myometrium) and Endometrial/Myometrial ratio had a significant diagnostic ability for assessment of malignant endometrial lesions as:

Mean value of lesion cut off (>34.2 kPa) showed sensitivity of 90%, specificity of 94.12%, PPV of 90% and NPV of 94.1% (AUC=0.941, P<0.001).

Endometrial/Myometrial ratio cut off (>0.6) showed sensitivity of 100%, specificity of 82.94%, PPV of 85.6% and NPV of 100% (AUC=0.809, P<0.001).

A Sixty -one year old Female patient presented by post-menopausal bleeding for few months and increased the last 2 weeks (Figure 1).

Table 1: Transvaginal SWE diagnosis of the studied patients (n=30)

	N	%
Carcinoma	14	46.6
Polyp	10	33.3
Hyperplasia	6	20

Table 2: Shear wave elastography values of the studied lesions

	Carcinoma (n=11)	Polyp (n=9)	Hyperplasia (n=7)	P value
Mean value (of lesion)	37.79 ± 4.65 [a]	15.74 ± 2.71 [b]	24.24 ± 2.52 [c]	**<0.001***
	34.2 - 46.2	10.1 - 19.1	21.5 – 29.5	

Data are presented as mean ± SD and range, *: Statistically significant as P value<0.05, Different lower-case letters indicate significant difference in pairwise comparison.

Table 3: Diagnostic performance of shear wave elastography values for differentiation between benign and malignant endometrial lesions

	Cut-off	Sensitivity	Specificity	PPV	NPV	AUC	P value
Mean value (of lesion)	>34.2	90	94.12	90	94.1	0.941	**<0.001***
Endometrial/ Myometrial ratio	>0.6	100	82.94	85.6	100	0.809	**<0.001***

*: Statistically significant as P value<0.05, PPV: Positive predictive value, NPV: Negative predictive value, AUC: Area under the curve

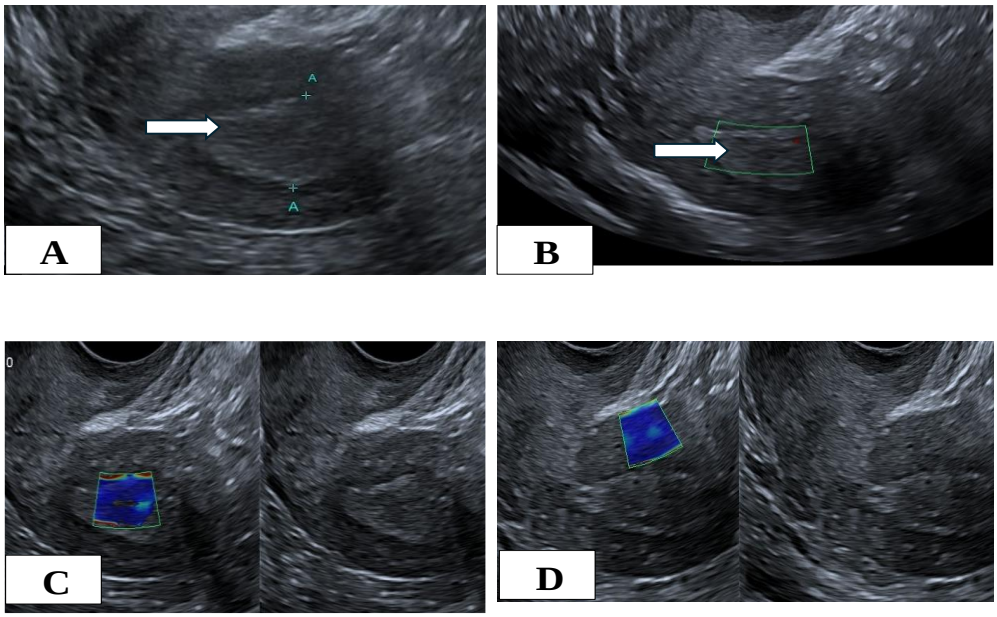

Figure 1: Endometrial hyperplasia in a Fifty -three years old Female patient presented by post-menopausal bleeding for few months and increased the last 2 weeks. (A) B-mode TVS (sagittal plane): homogenously thickened Endometrium, measures about 19 mm, intact endo-myometrial junction. (B) SWE: homogenous

color map with the E mean of the lesion = 22.9 Kpa. (C) SWE: The E mean of normal myometrium =54.3 Kpa., E/M ratio=0.57

DISSCUSSION

Because of their non-specific clinical manifestation and features on primary imaging assessment, endometrial diseases typically present a diagnostic difficulty to radiologists and gynecologists. The primary examination of choice is transvaginal ultrasonography (TVS), but the results are non-specific and can include widespread thickening, a localized lesion, or endometrial heterogeneity.[7].

Our study aimed to determine the added value of transvaginal shear wave elastography (SWE) in diagnosis of different benign and malignant endometrial lesions patients with abnormal uterine bleeding, that would improve the presurgical personalized medical care.

In our study, 69.4% of patients were premenopausal while the rest (30.6%) were postmenopausal. This agrees with ***Wozniak et al***, (8) and ***Latif et al, (9)*** studies in which 75% & 74% of patients were premenopausal and 25% & 24% were postmenopausal. But this is in contrast with ***Ma et al. (6),*** who found that 59% were postmenopausal and 41% were premenopausal state.

In our study, the most common lesion was endometrial carcinoma for 14 patients (46.6%), and the least common lesion was hyperplasia (20%). Our results were in agreement with ***Vora et al (10).,*** who stated that the most common lesion examined was of malignant nature (38.3%).

Upon qualitative analysis of the elastography using color maps, we discovered that endometrial cancer displayed varying degrees of homogeneity, with 45.4% of cases exhibiting heterogeneous maps and 85.7% of patients exhibiting homogeneous maps. and 100% of endometrial polyps showed homogenous colour map. This in line with ***Vora et al. (10),*** who discovered that while 100% of patients with endometrial hyperplasia displayed a homogenous map, 35.7% of cases of endometrial cancer showed heterogeneous color maps. The pleomorphism and necrotic alterations that may be present in carcinoma might be used to illustrate this shift in color map.

With the development of ultrasound technology, improving the accuracy of the early diagnosis of EC has become a research hotspot. Studies have shown that the hardness of endometrial lesions is closely related to their biological characteristics, and elastography can directly analyze the hardness of tissues, which provides a new idea for the differential diagnosis of benign and malignant endometrial lesions.

Our study stated that values of endometrial carcinoma were higher than that of endometrial hyperplasia and both were statistically significantly higher than that of endometrial polyp indicating that shear wave elastography mean values of malignant endometrial lesions are higher than that of benign endometrial lesions.

The E mean of endometrial carcinoma (EC) appears to be in the range of 34.2 Kpa to 46.2 Kpa, while the shear wave mean values in individuals with benign lesions were in the range of 10.1-19.1 in endometrial polyps and 21.5 to 29.5 Kpa in endometrial hyperplasia. So, these results agreed with ***Ma et al. (6),*** that stated that the range mean value of shear wave elasticity in EC and AEH (21.36 -55.56KPa) were significantly higher than the benign group (9.94 – 25.98KPa).

Also, our results were in line with ***Du et al. (11),*** using shear wave elastography, showed E mean values to be significantly lower in benign tissue with a range of 15.68–21.20 Kpa compared to a range of 38.46 Kpa–49.36 Kpa.

Guler et al. (12), The mean value (E mean) was statistically significantly higher in group III (malignant endometrial lesions) when compared to group I (normal endometrium) and group II (benign endometrial lesions). Also, Using strain elastography, ***Latif et al. (9)***, discovered a statistically significant difference between the mean strain ratio (SR) of endometrial hyperplasia (2.7) and endometrial cancer (11.4).

This was similar to ***Che et al. (13),*** results who found that like other cancerous tissues that are usually harder than the healthy tissue, endometrial cancer demonstrated higher SR than other benign pathologies.

We found some overlap may occur between atypical endometrial hyperplasia and endometrial carcinoma. The pleomorphism and necrotic alterations that may be observed in cancer provide an explanation for this. The

elasticity characteristics of these two groups did not differ statistically significantly based on a quantitative analysis. And this was similar to ***Vora et al. (10),*** results.

Thus, it may be suggested that endometrial cancer pathologically experiences a range of increasing cellular pleomorphism, with an early stage increase in nuclear atypia and a later stage increase in a solid component. As a result, elastography may not show an apparent variance between the elasticity values of hyperplastic endometrium and cancer in its early stages. The elasticity of both groups was less than that of the myometrium.

Marshall et al (14), stated that all studies performed on women with increased endometrial thickness or endometrial lesions found statistically significant differences between the stiffness of endometrial carcinoma and benign endometrial lesions when using elastography.

Our study used endometrial/myometrial ratio that appears to be statistically significantly higher in malignant endometrial carcinoma (0.78+\- 0.1) than that of benign endometrial lesions (E\M ratio of polyp & endometrial hyperplasia is 0.36+\-0.07 and 0.69+\- 0.07 respectively).

Our study found that both Shear wave elasticity and E/M ratio can effectively assess benign and malignant endometrial lesions, with AUC values of 0.941 and 0.809 respectively, and P values of <0.001.

We found that E mean cut off value of Shear wave elasticity **>** 34.2 to differentiate malignant from benign endometrial lesions showed 90% sensitivity, 94.12 % specificity, 90% PPV, and 94.1% NPV.

E/M ratio cut off value > 0.6 to differentiate malignant from benign endometrial lesions showed sensitivity of 100%, specificity 82.9%, PPV 85.6% and NPV 100%.

Our results revealed that Sensitivity and specificity of SWE for diagnosis of endometrial polyps were 90% & 100 %, This agreed to some extent with ***Wozniak (8) who*** stated that the sensitivity, specificity in cases of endometrial polyps – 85.7% and 77.7%, respectively.

The sensitivity and specificity of SWE for diagnosis of EC in our study were 90% & 92.31% that agreed with ***Bian et al. (15),*** who revealed that he pooled Sensitivity, and Specificity of SWE for the diagnosis of EC were 91%, 90% respectively.

These results were consistent with the potentially high diagnostic accuracy of SWE for EC, suggesting that SWE may be a good tool for the differential diagnosis of benign and malignant endometrial tumours and could predict the prognosis of patients with EC.

According to ***Ragab et al. (16),*** SWE is an accurate tool for identifying this gynaecological problem. The sensitivity is 93%, the specificity is 91%, the positive likelihood ratio is 10.6, and the negative likelihood ratio is 0.08. Our findings are consistent with those of ***Acar et al. (17)***, who discovered that uterine adenomyosis was identified with sensitivity, specificity, positive predictive value, and negative predictive value of 89.7 percent, 92.9 percent, 97.2 percent, and 76.5 percent, respectively,

Conclusions

Trans vaginal Shear wave elastography is an effective additional method in differentiating between benign and malignant endometrial lesions when combined with conventional ultrasonography. This technique can not only obtain quantitative indicators, but also provide new information about the elastic hardness of tissue and so, improve the diagnostic accuracy of different endometrial lesions but also has the potential to reduce the use of endometrial biopsies by determining the nature of tissue.

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