

Value of Shear Wave Elastography in Discriminating Category IV Breast Lesions According to Breast Imaging-Reporting and Data System

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ABSTRACT

Background: Breast cancer is the second cause of cancer death in women. Shear wave elastography (SWE) is an ultrasound (US) procedure that can improve the sensitivity and the specificity in the diagnosis of breast lesions.

Objectives: To evaluate the value of SWE to discriminate benign from malignant Breast Imaging-Reporting and Data System (BI-RADS) IV breast lesions.

Materials and methods: A cross sectional analytic study was done in the Radiology Department, Oncology Teaching Hospital, Baghdad Medical City, Baghdad, Iraq. The study period was one year (February 2020 to January 2021). The study included 42 female patients with suspicious breast lesions in the group BI-RAD 4 by mammography and US. Shear wave elastography was done for all patients. The final diagnosis of all breast lesions were done by fine needle aspiration cytology or true cut biopsy or excisional biopsy.

Results: The final histological diagnosis showed that 23 (54.8%) of study patients were with benign breast lesions. There was a statistically significant association between the quality of SWE and histopathological diagnosis as the proportion of malignant breast lesions was significantly higher among the patients with score 5 (homogenous dark blue) images (85.7%, $P = 0.004$). Subjects with malignant lesions had a significantly higher mean of E-mean SWV than those with benign lesions (133.8 versus 75.47 kPa, $P = 0.001$). The best cut point of E-mean SWV was 83 kPa (E-mean SWV > 83 kPa is predictive for malignant lesion of breast) with 89.5% sensitivity, 60.9% specificity, and 73.8% accuracy.

Conclusion: SWE have a significant diagnostic value in differentiation of BI-RADS IV breast lesions into benign and malignant in both qualitative and quantitative patterns. The best cut off value in SWE is 83 KPa for E-mean.

Keywords: Shear Wave Elastography; BI-RADS IV; Breast lesions.

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INTRODUCTION

Carcinoma of the breast is a global problem, 1.7 million new cases are diagnosed annually. About sixty percent of mortality as a result of the breast cancer occurs in developing countries [1]. Breast cancer is the 2nd leading cause of cancer death in women, went beyond just by lung cancer according to the American Cancer Society in the United States [2]. Within the Eastern Mediterranean Region (EMR), carcinoma of breast is the 4th cause of

mortality, after cardiovascular accidents, diseases of infection, and injuries [3]. International Agency for Research on Cancer (IARC) reported that more than 290 thousand cases of cancer were newly diagnosed among female in EMR during 2012, 99 thousand cases were detected as breast cancer in that area [4].

Breast cancer consequences depend on the diagnosis degrees: cancers are detected early, cancers can be diagnosed correctly, and proper multimodality management can be delivered in a timely fashion, programs to encourage breast self-monitoring and clinical examination of breast and mammographic screening are important early detection steps [5]. Recently, a great deal of research has been focused on the combined use of different imaging modalities in order to in-

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crease diagnostic accuracy of radiological imaging techniques [6]. Many of papers have proven the ACR BI-RADS lexicon for ultrasound (US) to be an effective method in the differential diagnosis of many types of breast lesion and the detection of malignancy. However, the US features used in Breast Imaging-Reporting and Data System (BI-RADS) contain some similarity between benign and malignant breast lesions, especially in BI-RADS 4 lesions, as this group includes a wide spectrum of breast masses with a broad range of risk for malignancy (2%-95%). According to the risk of malignancy, BI-RADS 4 breast lesions further divided into 3 groups; A low risk (2-9%), B moderate risk (10-49%), and C high risk of malignancy (50-95%) [7].

More recent, US techniques have led to improve breast mass characterization [8]. Shear wave elastography (SWE) is a ultrasound technique that can estimate tissue stiffness (elasticity) and many recent papers conclude that SWE improves the detection accuracy and the specificity of conventional US alone in the assessment of breast lesions [9, 10]. It was recommended that SWE could be used as an additional criterion to decrease false positives results of breast US characterization, and therefore improve diagnostic accuracy [11].

We aimed to evaluate the value of SWE in discrimination between benign and malignant BI-RADS 4 breast lesions.

MATERIALS AND METHODS

A cross-sectional analytic research was carried out in the Radiology Department, Oncology Teaching Hospital, Baghdad Medical City, Baghdad, Iraq. The current study covered a period from February 2020 to January 2021. Forty-two female patients with suspicious breast lesions grouped as the BI-RADS 4 by mammography and US were included in this study. The study was approved by the scientific committee of the Iraqi Board of Diagnostic Radiology. Informed consent was taken from all participants after explanation of the study.

Patients with first time presentation of breast lesions, age above 18 years, and BI-RADS 4 breast lesions according to the BI-RADS criteria for mammography and the US were included in the study. While, patients with previous breast surgery, previous history of radiotherapy and/or chemotherapy for breast cancer, recent breast trauma within 6 months, who didn't wish to participate in the study, and those who lost to follow-up were excluded. Patients data were collected from each participant and include full clinical history regarding the presenting symptoms, previous breast diseases, family history of breast cancer or other cancers as well as menstrual history. Then SWE were done for all patients.

Shear wave elastography

The examination were done in the supine position after complete uncover the breast and axilla, the examination was done using LOGIQ S8 (GE medical system, USA) using a 9L broad-spectrum linear probe (frequency 2-9 MHz). First the patient were examined by conventional B-mode US imaging of the target lesions, then SWE was performed after activation of elastography function, a rectangle shaped field of view (FOV) was set for SWE acquisition, and stiffness was displayed as a color map in that FOV as a real-time in which the lesion as well as the tissue around it was included, the color scale graded from red (lower KPa) to dark blue (higher KPa). SWE measurements were acquired while minimizing the pre-compression as well as asking our patients to stop respiration

during the data acquisition. A corresponding B-mode image was also displayed for better delineation of the margins of each lesion, 2 mm circular region of interest (ROI) were selected from stiffest part of the lesion. The stiffness of the surrounding normal tissue was also measured using ROI with similar diameter. The maximum shear wave Elasticity (E max), mean shear wave Elasticity (E mean), minimum shear wave Elasticity (E min), and shear wave Elasticity standard deviation (ESD) were automatically calculated by the ultrasound system. All SWE and conventional US images were securely stored on the ultrasound system's internal hard disk.

Shear wave finding interpretation include qualitative and quantitative assessment of elasticity: distribution of E. color was from red to blue and recognized in following patterns; score 1 (red) and score 2 (heterogeneous red or orange), score 3 (heterogeneous green), score 4 (heterogeneous light blue), and score 5 (homogenous dark blue). In addition to quantitative parameters, E max, E mean, and E min in KPa; the higher elasticity score as well as higher KPa guided toward malignancy.

The Final diagnosis of all breast lesions were reached by fine needle aspiration cytology (FNAC) or true cut biopsy or excisional biopsy.

Statistical analysis

the analysis of the data using Statistical Package for Social Sciences (SPSS) version 25. The data were presented as mean, standard deviation, and ranges. Categorical data presented by frequencies and percentages. Independent t-test (two tailed) was used to compare the continuous variables accordingly. Chi-square test was used to assess the association between histological detection and qualitative SWE. Receiver operating characteristic (ROC) curve analysis was used for prediction of SWE as diagnostic of BI-RAD 4 breast lesions. Pvalue of < 0.05 was considered significant.

RESULTS

The total of 42 females were enrolled in this study. All subjects presented with BI-RAD 4 breast lesions, based on mammography and US findings. Patients age ranged from 26 to 69 years with a mean of 47.35 years \pm 10.20 years. The highest proportion of the patients (n = 19, 45.2%) were found in the age group of 41-50 years. The majority of the patients (n = 33, 78.6%) were without a family history of breast cancer. The distribution of the studied patients according to the final histological diagnosis showed that 23 (54.8%) of study patients were with benign breast lesions, while the remaining 19 (45.2%) had a malignant lesion Table 1.

The distribution of the SWV values in the studied patients is shown in Table 2. The E-max SWV ranged from 25 to 256 kPa with a mean of 127.6 \pm 69.18 kPa. The E-mean SWV ranged from 21 to 256 kPa with a mean of 101.8 \pm 58.38 kPa. E- mini SWV ranged from 12 to 221 kPa with a mean of 75.78 \pm 46.42 kPa.

Qualitative SWE

The highest E. color score was 4 (heterogeneous light blue) in 15 lesions (35.7%), and the lowest was the score 3 (heterogeneous without blue or green color) in 4 (9.5%), as shown in Figure 1.

In the current study, there was a statistically significant association between the quality of SWE and histopathological diagnosis. The proportion of malignant breast lesions

Table 1. Intraoperative and postoperative complications in the patients of both groups.

Variable	Number	Percentage
Age groups per years		
> 30	3	7.2
30-40	5	11.9
41-50	19	45.2
> 50	15	35.7
Total	42	100
Family history of breast cancer		
Yes	9	21.4
No	33	78.6
Total	42	100
Histological type		
Benign	23	54.8
Malignant	19	45.2
Total	42	100

Table 2. Distribution of the SWV values in 42 patients.

SWV	Mean ± SD	Range
E- Max (kPa)	127.6 ± 69.18	25 – 256
E-Mean (kPa)	101.8 ± 58.38	21 – 256
E-Mini (kPa)	75.78 ± 46.42	12 – 221

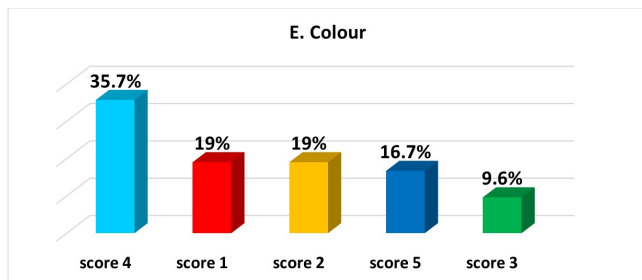


Figure 1. Distribution of the study patients by qualitative SWE.

was significantly higher among the patients with score 5 (homogenous dark blue) images (85.7%) (P = 0.004) as shown in Table 3.

There was a statistically significant difference between benign and malignant lesions in regards to the E-mean SWV (P = 0.001) Table 4.

Receiver operating characteristic (ROC) curve analysis was constructed for SWE as a predictor for BI-RAD 4 breast lesions. As shown in Table 5 and Figure 2, the cut point of E-mean SWV was 83 kPa, E-mean SWV > 83 kPa is predictive for malignant lesion of breast, as a large significant area under the curve (AUC= 78.8%) indicating significant association between higher level of E-mean SWV and diagnosis of malignant lesions. The E-mean SWV was 89.5% sensitive, 60.9% specific, and 73.8% accurate in diagnosis of BI-RAD 4 breast lesions. Figures 3 and 4 are examples of some images of included patients in the study.

DISCUSSION

Studies approved the ACR BI-RADS lexicon for US to be an effective system in the differentiation between benign and malignant breast lesions. However, the ultrasound characteristics used in BI-RADS contain a similarity between benign and malignant breast masses, particularly in group 4 lesions, as this group includes 3 subgroups; A with low (2-9%), B moderate (10-49%), and C with high risk of malignancy (50-95%) [7]. Therefore, there will be unavoidable unnecessary puncture biopsies on many benign cases if it is operated on all grade 4 lesions [12, 13]. In the last two decades, many non-invasive imaging techniques are developed and equipped to examine the soft tissue stiffness (elasticity) [14].

In this study, histopathological evaluation showed that 23 (54.8%) of study patients were with benign breast lesions, while the remaining 19 (45.2%) had a malignant lesion. El-moneam et al. study [15] in 2016 found that histopathological evaluation of 63 BI-RAD 4 lesions revealed 37 lesions (58.7%) as malignant and 26 lesions (41.3%) as benign. The difference between the two studies might be attributed to the difference in the proportion of different BI-RADS 4 breast lesions according to the risk of malignancy and geographical variation.

Regarding the qualitative method of SWE there was a significant association between the quality of SWE and histopathological diagnosis. The proportion of malignant breast lesions was significantly higher among the patients with score 5 (homogenous dark blue) images (85.7%, P-value = 0.004). Sixteen of the malignant lesions (84%) display solid criteria as score 4 and 5 and three malignant lesions (16%) display score 1 and 2 while only 6 of benign lesions (26%) display same solid criteria. These results were in agreement with the results of Ren et al. [16] where 266 breast lesions investigated, 71 lesions were malignant. Qualitative assessment with SWE of these malignant lesions showing 61 lesions (85%) display score 4 and 5 while only 32 (16%) of benign lesions display score 4 and 5.

Shear wave elastography can be detected quantitatively measure the lesion stiffness. The stiffness of the malignant lesions is generally increased, and that of benign lesions is less [15]. Our study revealed a statistically significant difference between benign and malignant lesions in regards to the E-mean SWV. Patients with malignant lesions had a significantly higher mean of E-mean SWV than those with benign lesions (133.8 versus 75.47 kPa, P= 0.001). By comparison to Farghadani et al. study [16], a different results observed, as noticed that E-mean for benign and malignant masses was 34.04 ± 19.51 kPa and 161.92 ± 58.14 kPa, respectively. Lee et al study [17] observed that, E-mean of malignant lesions (184.3 kPa) was significantly more than that of the benign lesion (complex cystic lesions, 45.5 kPa) (P-value < 0.001). Awad et al. study [18] showed that the lesions classified as BIRADS 4 had their elasticity values in the borderline range. The elasticity values for the malignant lesions ranged from 100102 kPa. The value for the benign lesion was 99 kPa and referred this because, in malignant lesions lower values were often found in their centers. This difference can be explained not only the difference in sample size but also the depth of the mass (deep masses > 2 cm from the skin surface), presence of calcification within lesions, and uneven pressure may reflect recruitment bias [19]. Besides, the short distance from nipple is a significant factor associated with false positive SWE result [20].

Table 3. Distribution of histopathological diagnosis by qualitative SWE*.

E. Color	Histopathological Diagnosis		Total (%) n=42
	Malignant Total number = 19 Number (%)	Benign Total number =23 Number (%)	Number (%)
Score 4 (heterogeneous Light Blue)	10 (66.7)	5 (33.3)	15 (35.7)
Score 1 (Red)	1 (12.5)	7 (87.5)	8 (19.0)
Score 2 (heterogeneous red or Orange)	2 (25.0)	6 (75.0)	8 (19.0)
Score 5 (homogenous Dark Blue)	6 (85.7)	1 (14.3)	7 (16.7)
Score 3 Green	0 (0)	4 (100.0)	4 (9.6)

* P-Value=0.004

Table 4. Comparison between breast lesions by E-mean SWV value.

Variable	Histopathological Diagnosis		P Value
	Malignant Lesions Mean ± SD	Benign Lesions Mean ± SD	
E-Mean (kPa)	133.8 ± 53.80	75.47 ± 48.72	0.001

Table 5. Diagnostic accuracy for prediction of Breast lesions with BI-RAD 4.

E-mean SW (kPa)	Cut-off value	Sensitivity	Specificity	PPV	NPV	Accuracy
		83	89.5%	60.9%	65.4%	87.5%

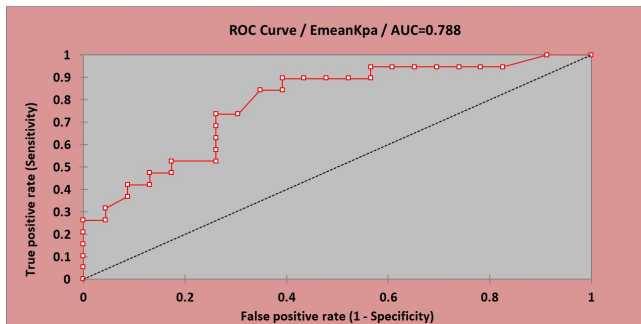


Figure 2. ROC curve for E-mean SWV in diagnosis of BI-RAD IV breast lesions.

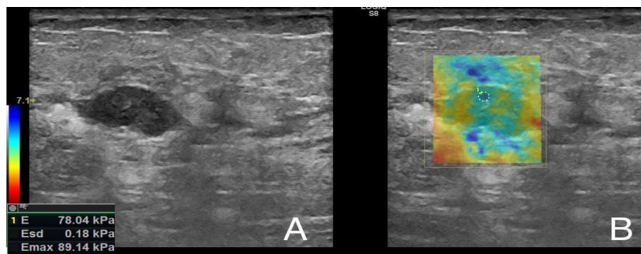


Figure 3. A 27-years-old patient with palpable breast mass, (A) B mode ultrasound shows well circumscribed oval hypoechoic mass with angular margin inferiorly, (B) SWE shows the soft nature of mass (E mean=78 KPa). The final diagnosis was fibroadenoma by histopathology.

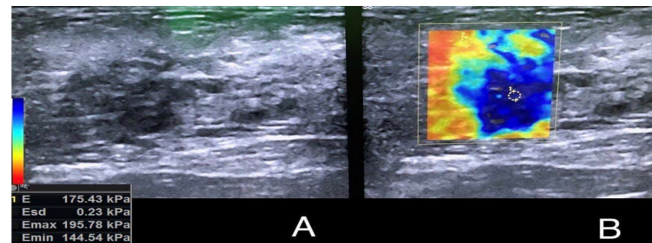


Figure 4. A 60-years-old lady with a family history of breast cancer. (A) B mode ultrasound (B) SWE. US shows ill-defined hypoechoic area which appear hard on SWE (E mean=175 KPa). The final diagnosis was ductal carcinoma in situ (DCIS) by histopathology.

The ranges of cutoff values between benign and malignant breast lesions for each parameter with 2-mm ROIs have been reported to be as follows: 33.3-80 kPa for Emean; 46.7-93.8 kPa for E-max, E-mean appears to be widely used in the diagnosis of breast lesions [21].

In this study, we reported that the ROC curve analysis was constructed for SWE as a predictor for BI- RADS IV lesions, the cut point of E-mean SWV was 83 kPa, E-mean SWV > 83 kPa is predictive for the malignant lesion of the breast. The E-mean SWV was 89.5% sensitive, 60.9% specific, and 73.8% accurate in diagnosis of BI- RADS IV lesions. Both Park et al.[20] and Choi et al. [22] consider E-mean 85.1 KPa as a cut point to discriminate benign from malignant lesions in their studies, however their diagnostic parameters results are different in comparison to our study. The first study gave 68.4% sensitivity, 93.2% specificity, and 80% accuracy, while,

the second one gave 78.4% sensitivity, 95.2% specificity and 84.5% accuracy. Farghadani et al. study [16] showed that the sensitivity was 94.59%, while the specificity and accuracy were 93.02% and 93.75% respectively. The study concluded that SWE has better diagnostic value in determining breast masses and can increase the diagnostic function. Ren et al. [23] using maximum SWS value as main parameter achieved the highest diagnostic performance (AUROC-max = 0.805) with an optimal cut-off value setting at 6.02 m/s, sensitivity of 63.4%, specificity of 87.7%, accuracy of 81.2%, positive predictive value (PPV) of 65.2%, and negative predictive value (NPV) of 86.8%. Many factors can lead to this difference among studies such as, sample size and factors related to the disease including duration, grading and lesion size as very large lesions may have extended size beyond maximum 5-cm SWE overlay or sometimes beyond the field of view. Therefore, that the examiner might not catch the stiffest portion of the mass, which would result in erroneous SW elastographic stiffness assessment. Other factors related to the device in-

clude; the operator experience, degree of probe compression and placement of the region of interest away from stiffest portion of the lesion or surrounding tissue [24].

The current study didn't take the grading system according to the risk of malignancy of the BI-RADS 4 breast lesion and this is one of limitation of the study. Another limitation was the small sample size.

CONCLUSION

Shear wave elastography have a significant diagnostic value in determining the nature of BI-RADS IV breast lesions and it's differentiation into benign and malignant in both qualitative and quantitative patterns. The best cut-off value in SWE was 83 KPa for E-mean.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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