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Diagnostic value of strain elastography and shear wave elastography in differentiating benign and malignant breast lesions

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BACKGROUND: Conventional B-mode breast ultrasonography, though the primary modality to determine benign or malignant nature of a solid breast lesion, sometimes encounters overlapping sonographic morphological features in a single lesion. Elastography leads to improvement by evaluating the structural aspects and characterization of the lesion as benign or malignant on the basis of multi-parametric assessment.

OBJECTIVE: Determine the role of strain elastography (SE) and shear wave elastography (SWE) in differentiating benign and malignant breast lesions.

DESIGN: Cross sectional

SETTING: Radiology department of hospital

PATIENTS AND METHODS: Patients meeting inclusion criteria referred to our hospital for ultrasonography followed by biopsy or surgical excisions were examined with B-mode ultrasonography and by both strain and shear wave elastography.

MAIN OUTCOME MEASURES: Mean values of SE and SWE in benign and malignant breast lesions, determination of cutoff using AUC curves and sensitivity and specificity of both techniques.

SAMPLE SIZE: One hundred breast lesions from 95 consecutive patients.

RESULTS: The mean (SD) strain elastography ratio in the overall patient population was 4.1 (2.0). Cutoff for benign vs. malignant lesions was 2.86 on the ROC curve. The AUC was 0.911 (95%CI; 0.835-0.988: SE, 0.039) with a sensitivity of 95.8% and a specificity of 89.3%. For the SWE kPa values, the ROC curve showed the AUC was 0.929 (95% CI, 0.870-0.988; SE: 0.030, *P*<.001). Assigning 45.3 as a cut off value provided a sensitivity of 95.8% with a specificity of 85.7%; the positive predictive value was 94.5% and the negative predictive value was 89.6%. The Breast Imaging Reporting and Data System (BI-RADS) category alone was able to differentiate between benign and malignant lesions with a sensitivity of 91.7% and a specificity 100% keeping the cut off value between 4a and 4b. The area under the ROC curve was 0.979. Combining the three (BI-RADS + SE + SWE) distinguished benign vs. malignant lesions with a sensitivity up to 100% and specificity up to 96.3%.

CONCLUSION: Combining SE and SWE as a complementary tool with conventional B-mode ultrasonography has a significant potential for better characterization of solid breast lesions and decreasing unnecessary biopsies of BI-RADS IVa lesions.

LIMITATIONS: Single institution study.

CONFLICT OF INTEREST: None.

Conventional B-mode ultrasonography (USG), in conjunction with mammography, has been the initial method for assessing benign and malignant breast lesions. The Breast Imaging Reporting and Data System (BI-RADS) sonographic criteria and further sonographic advances have led to better characterization of breast lesions. Still, some lesions show overlapping sonographic features of both malignant and benign lesions and histopathological correlation becomes the ultimate test for final diagnosis. Here elastography comes to the rescue by assessing the stiffness of breast lesions, thus providing structural evaluation in addition to morphological sonographic assessment.[1]

The mechanical properties of tissues are measured by determining the response of tissue to acoustic energy, as stiffness is a biomarker of tissue pathology.[2] Elastography is a promising and complementary sonographic tool for characterizing solid breast masses on the basis of tissue stiffness. Stiffness increases as the malignant nature of the tissue increases. Diagnostic performance is increased when conventional B-mode USG is combined with elastography.[3]

Two types of elastographic techniques are used; strain elastography (SE) and shear wave elastography (SWE). In SE, gentle repetitive compression is applied to the breast tissue with a USG probe resulting in tissue displacement (strain) which is then measured. Malignant lesions are stiffer than benign ones and have lower strain values. The technique allows for qualitative as well as semi-quantitative assessments of a lesion. Qualitative assessment is based on a color scale using a five-point visual scoring system devised by Tsukubas. A color closer to either the red or blue end of the color spectrum, depending upon imaging system used, shows the stiffest tissue and hence increased probability of malignancy. Semi-quantitative assessment is done by calculating the strain elastography ratio which is higher for malignant lesions. SWE implies the propagation of shear waves through the lesion of interest. Propagation is faster through solid hard lesions than through softer ones. Qualitative assessment is again done by using a color-scaled image. Quantitative assessment is made by calculating a maximum elasticity value (kPa). Malignant lesions being harder than benign lesions tend to have higher kPa values.[4]

The role of elastographic techniques to supplement the diagnostic efficiency of USG in breast lesions has been studied extensively. Fairly high sensitivity and specificity is reported in literature for the SE ratio,[5-8] and for SWE.[9] The sensitivity of SWE for Asian and European populations is reported as 84% and 92% while specificity is between 87% and 89% for both populations, respectively. The area under the curve (AUC) was calculated as 0.92 for an Asian population and 0.95 for a European population in a recent meta-analysis.[10] The rationale of the present study was to determine the role of SE ratio and SWE in differentiating benign and malignant breast lesions in our local population as the incidence of breast cancer in Pakistan is among the highest in Asia. Moreover, patients usually present at a younger age as compared to global data.[11]

PATIENTS AND METHODS

This prospective study was conducted at the Radiology Department of Inmol Hospital, Lahore, Pakistan with the approval of our Institutional Review Board. Informed consent was taken from all the patients. During January to June 2021, 100 solid breast lesions from consecutive patients referred to our hospital for ultrasonography followed by biopsy or surgical excisions were included in the study. Simple cysts were excluded. A Toshiba Aplio 500 Ultrasound Machine was used to obtain images in all the patients. For patients with more than one lesion, multiple lesions were selected. All the lesions were examined first with conventional B-mode USG by a radiologist having more than ten years' experience of breast imaging. BI-RADS category was assigned to all the lesions based on B-mode imaging. The same radiologist then performed elastography of all the lesions. Strain elastography images were generated by applying gentle repetitive compression by transducer. Color scale strain images were recorded and the SE ratio was calculated. SWE was then performed without manual compression on all the lesions. Color scale shear wave images were recorded and kPa values were determined for all the lesions. To obtain elastography images, the same depth, focus position and gain settings were used as during conventional B-mode imaging (**Figures 1 and 2**). All the patients were then followed and histopathology results were recorded. Complete agreement was observed between radiologists on interpreting the findings of the study.

Statistical analysis was performed using IBM SPSS version 20.0. Mean with standard deviation was used for age and median and interquartile range for lesion size. The *t* test was used to evaluate the difference in lesion size. Receiver operating characteristic (ROC) curve analysis was performed to determine cutoff. The optimal cutoff values were determined by using the Youden index (maximum of sensitivity + specificity - 1).[12] Combined ROC curves were obtained by using binary logistic regression and finding the probability followed by ROC curves analysis. Sensitivity, specificity, positive

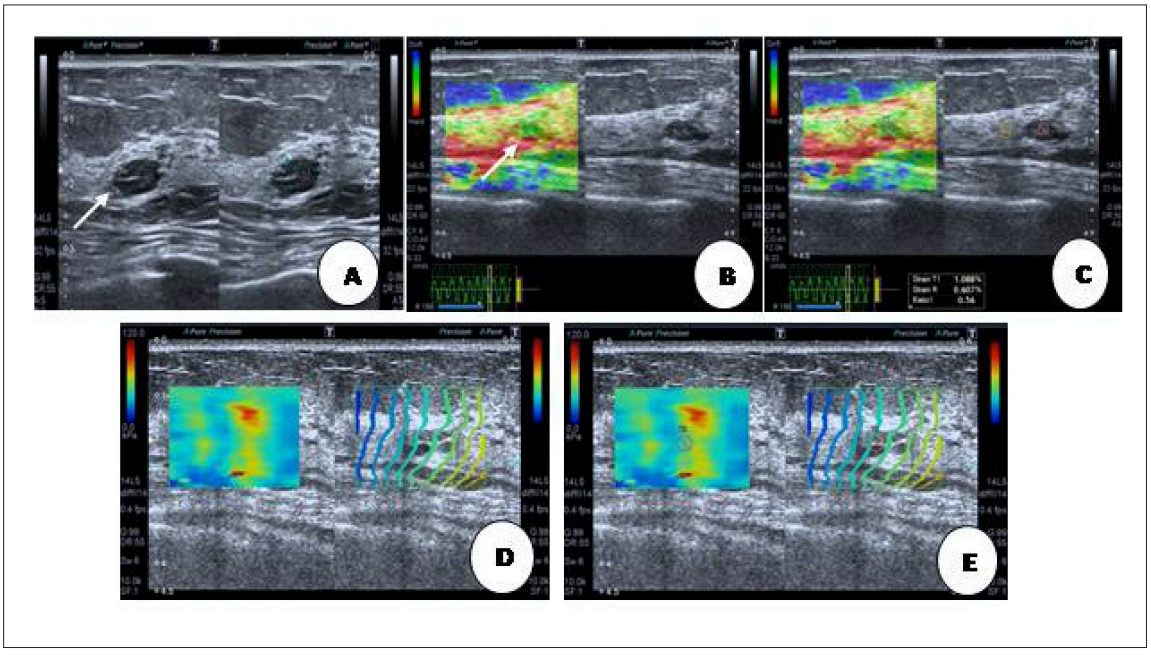

Figure 1. Screening mammography detected left breast abnormality in a 45-year-old woman. (A) Grayscale ultrasound showed a well-defined oval shaped hypoechoic lesion (arrow) at 2 o'clock position in the left breast having partially indistinct margins. It was categorized as a BI-RADS category IVa with low suspicion of malignancy. (B) By strain elastography, the mass was graded with a visual score of 2 according to the Tsukuba system (arrow). (C) Strain ratio was 0.6. (D) By shear wave elastography, the mass was graded with a visual score of 2. (E) KPa value was 43. Ultrasound guided core biopsy confirmed the lesion to be a fibroadenoma.

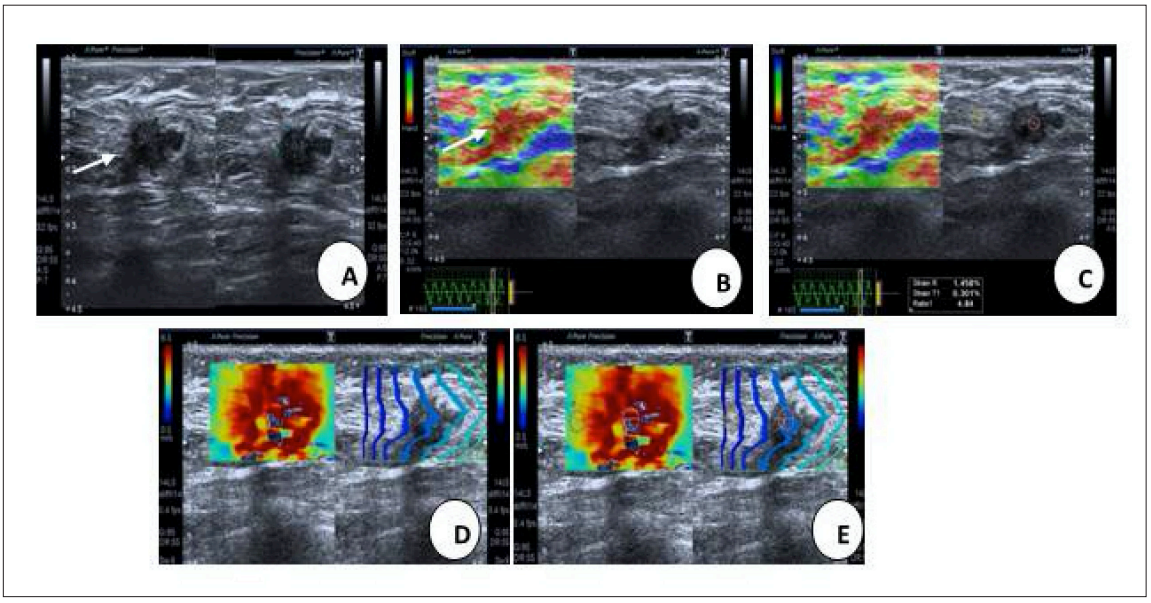

Figure 2. Screening mammography detected right breast abnormality in a 50-year-old woman. (A) Grayscale ultrasound showed an irregular hypoechoic mass (arrow) at 9 0' clock position in the right breast which was categorized as BI-RADS category 4c with high suspicion of malignancy. (B) By strain elastography, the mass was graded with a visual score of 4 according to the Tsukuba system (arrow). (C) Strain ratio was 4.8. (D) By shear wave elastography, the mass was graded with a visual score of 5. (E) kPa value was 68. Ultrasound guided core biopsy confirmed the lesion to be invasive ductal carcinoma.

predictive value (PPV) and negative predictive values (NPV) were determined using a 2×2 table. *P* values <.05 were considered significant.

RESULTS

The mean (SD) age of the 95 patients was 43.2 (13.3) years (range; 15-70). The median (IQR) size was 19.0 (16.0) mm for benign lesions (n=28) and 22.5 (17.8) for malignant lesions (n=72) (**Figure 3**). Lesion size in benign vs. malignant lesions was not significantly different (*P*=.1465).

Among benign lesions, fibroadenoma was the commonest histology found in 18 patients followed by ductal hyperplasia and benign phyllodes in 3 patients each, fibrosis in 2 patients and fibrocollagenous lesions and inflammation were found in 1 patient each (**Table 1**). Among malignant lesions, invasive ductal carcinoma (IDC) was the commonest histology observed in 63 patients followed by ductal carcinoma in situ in 5 patients. Invasive lobular carcinoma and malignant phyllodes were observed in 2 patients each .

Mean lesion size was largest in malignant phyllodes (91.5 mm); in benign phyllodes mean lesion size was 60.0 mm. In the rest of the histopathologies including IDC, mean lesion size did not exceed 30 mm. Mean (SD) SE ratio in the overall patient population was 4.1 (2.0) (**Table 1**). Overall mean (SD) shear wave kPa values were 61.7 (25.0) kPa [range; 14.1-126.7]. In benign lesions mean shear wave values were 36.6 (13.2) kPa ranging from 14.1-68.1; in malignant lesions the values were significantly high (*P*<.001). In benign lesions (n=28), the value was 1.7 (0.5) and in malignant lesions (n=72) it remained 5.1(1.5) (*P*<.001). Cutoff for benign vs. malignant lesions was 2.86 on the ROC curve. The AUC was 0.911 (95% CI; 0.8-0.99: SE, 0.04) with a sensitivity of 95.8% and 89.3% specificity (**Figure 4A**). Positive predictive value (PPV) was 97.2% and negative predictive value (NPV) was 96.3%.

Table 2 shows BI-RADS classification of the lesions. In BI-RADS category 2 and 3, no patient had malignant histopathology. In 4a, 14 (70.0%) were benign and 6 (30.0%) were malignant. In category 4b-5, all patients were malignant and no benign lesion was identified histopathologically. In category IVb, IVc, and V mean elasticity ratios were above the cutoff value (2.86) for differentiating benign vs. malignant lesions. In category IVa, the mean value was slightly below the cutoff for the SWE kPa values. THe ROC curve showed the AUC was 0.929 (95% CI, 0.87-0.98; SE: 0.030, *P*<.001). Assigning 45.3 as cut off value provided a sensitivity of 95.8%

Table 1. Mean strain elastography ratio and shear wave KPa values for different histopathologies.

Lesion character	Strain elastography ratio	KPa value
Overall (n=100)	4.1 (2.0)	61.7 (2.5)
Benign (n=28)	1.7 (0.5)	36.6 (13.2)
Malignant (n=72)	5.1 (1.5)	71.6 (21.4)
Fibroadenoma (n=18)	1.6 (0.5)	34.8 (1.1)
Ductal hyperplasia (n=3)	1.9 (0.1)	25.2 (1.1)
Fibrosis (n=2)	1.7 (0.2)	53.5 (2.1)
Benign Phyllodes (n=3)	1.9 (0.2)	35.6 (1.3)
Fibrocollageneous (n=1)	2.49	64.5
Inflammation (n=1)	2.47	42.1
Malignant phyllodes (n=2)	6.5 (4.6)	55.2 (6.8)
Invasive ductal carcinoma (n=63)	5.0 (1.5)	71.4 (2.1)
Invasive lobular carcinoma ((n=2)	4.7 (0.0)	70.6 (0.00)
Ductal carcinoma in situ (n=5)	5.8 (1.1)	54.3 (9.9)

Data are mean (standard deviation).

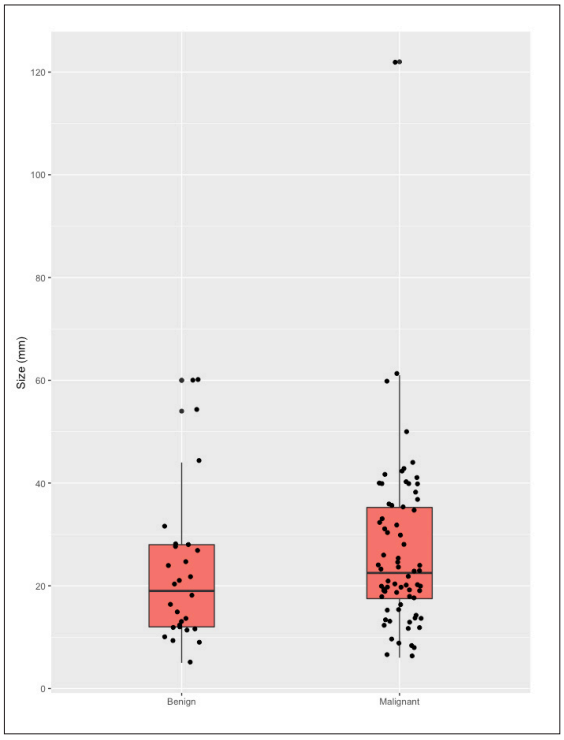

Figure 3. Comparison of lesion size in benign and malignant lesions.

Table 2. BI-RADS versus strain elastography ratio and shear wave KPa values.

BI-RADS category	II (n=12)	III (n=2)	IVa (n=20)	IVb (n=8)	IVc (n=32)	V (n=26)
Strain elastography ratio	1.57 (0.5)	2.59 (0.2)	2.85 (2.1)	4.77 (2.4)	4.99 (1.4)	5.22 (1.4)
Shear wave KPa	35.0 (7.0)	43.6 (2.1)	42.1 (17.0)	63.9 (9.5)	75.4 (24.6)	73.6 (19.8)

Data are mean (standard deviation)

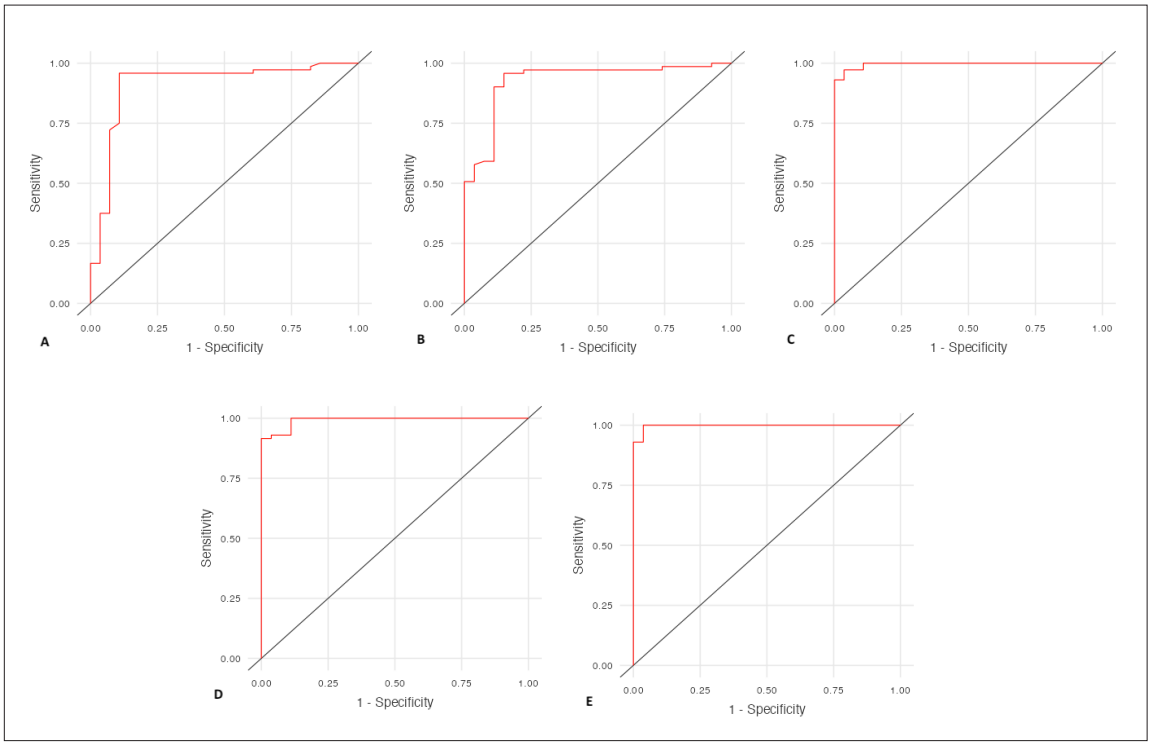

Figure 4. ROC curves for strain elastography ratio (A), shear wave elastography (B) and combination of strainelastography ratio and BI-RADS [C], shear wave elastography and BI-RADS (D), and all three together (E).

with specificity of 85.7%; PPV was 94.5% and NPV was 89.6% (**Figure 4B**).

BI-RADS Category alone was able to differentiate between benign and malignant lesions with the sensitivity of 91.7% and specificity of 100% keeping the cut off value between IVa and IVb. Area under the ROC curve was 0.979. Combining SE with BI-RADS classification sensitivity increased to 97.2% and specificity became 92.9%. On the other hand SWE when combined with BI-RADS classification increased the sensitivity from 91.7% to 100% but specificity was compromised and became 88.9%. Combining three (BI-RADS + SE + SWE) increased the sensitivity to 100% and specificity up to 96.3% (**Figure 4E**).

Out of 14 benign lesions in BI-RADS category IVa, 11 were classified as benign according to SWE. So adding SWE features in conventional BI-RADS features could down grade 78.6% patients (11 out of 14) and an invasive procedure could be avoided. One false negative result in category IVa was obtained by SWE where histopathology showed IDC while SWE demonstrated a benign finding (kPa value was 41.6 which is below the cut off for malignant lesions). However, these lesions were diagnosed accurately with SE. Similarly, the addition of SE in conventional BI-RADS classification downgraded 12 out of 14 benign lesions to 85.7%. One malignant lesion in IVa was misdiagnosed as benign by SE which was diagnosed accurately as malignant by SWE (**Table 3**).

In our understanding, adding strain and shear wave elastographic features to conventional BI-RADS classification can downgrade 78.6-85.7% lesions to

category 3 and invasive procedures (biopsy) can be avoided. One benign lesion of category II had high SW features and one each in category IVc and V had low values (**Table 3**).

DISCUSSION

SE and SWE are two commonly employed elastographic techniques in USG for differentiating benign from malignant breast lesions. After the introduction of elasticity assessment in the BI-RADS Atlas Fifth edition by the American College of Radiology, its use has increased in the evaluation of breast lesions.[13] The rate of benign findings in biopsy ranges from 70%-90% and only 10%-30% of biopsies are malignant.[14] Development of reliable noninvasive techniques is necessary to increase consistent results and increase patient comfort.

A recent multicenter trial evaluating the potential of SE ratio and SWE in reducing unnecessary biopsies among breast cancer patients had encouraging results.[15] The authors reported that the addition of both SE ratio and SWE in conventional USG could reduce the rate of unnecessary biopsies in category 4a patients up to 35% while keeping the rate of undetected malignancies lower than 2%. In the present study we evaluated the added advantage of breast elastography as an adjunct to conventional breast USG for more accurate characterization of benign and malignant breast lesions. In addition, this study determined the optimal cut-off points of elasticity and strain ratios for differentiating breast lesions.

Both SE ratio and SWE values were significantly different in our study for benign and malignant lesions. Similarly. both augmented the diagnostic efficiency of conventional USG and BI-RADS classification. The sensitivity of SE ratio was 95.8% and specificity was 89.3% with AUC of 0.911 in our study. Diagnostic efficiency was increased when BI-RADs and SE ratio was combined and attained a sensitivity of 97.2% and specificity of 92.9% with the combination of BI-RADS+SE ratio+SWE making sensitivity as high as 100% and specificity of 96.3%.

In a study by Seo et al regarding differentiation of benign and malignant breast lesions, patients were assessed using ultrasound and BI-RADS-ACR assessment categories and their elasticity ratio and mean elasticity value for SWE and SE ratio were calculated. AUCs obtained to compare the diagnostic efficiencies of two elastographic techniques showed no significant difference (elasticity ratio, 0.868; mean elasticity, 0.898; strain ratio, 0.929; and $P>.05$). However, significantly higher accuracy was achieved when the two elastographic modalities were used in combination.[16] In another study conducted by Tay et al comparing SE and SWE showed higher AUC for SE (.878) than SWE (.697).[17] The sensitivity and specificity for SWE were 73.7 % and 82.5 %, respectively. On the other hand, sensitivity and specificity for SE were 94.7% and 81%, respectively. These results are consistent with our study showing AUC of SE ratio as 0.911 with a sensitivity of 95.8% and specificity was 89.3%.

Another study conducted by Cantisani et al also stated that using SE and SWE as an adjunct to conventional breast USG would improve BI-RADS category assessment and characterization/differentiation of benign and malignant breast lesions. Their study explained the higher accuracy of SE over SWE.[18] We have observed comparable sensitivity in

Table 3. Discrepant results between strain and shear wave elastography.

Accurately diagnosis	BI-RADS	Histopathology	SER	KPa
Strain elastography	2	Fibroadenoma	1.50	48.30
Strain elastography	4a	Fibrocollageneous	2.49	64.50
Strain elastography	4a	Fibroadenoma	1.07	65.0
Strain elastography	4a	Fibrosis	1.82	68.10
Strain elastography	5	Invasive ductal carcinoma	4.97	18.60
Strain elastography	4c	Invasive ductal carcinoma	6.02	29.20
Strain elastography	4a	Invasive ductal carcinoma	6.36	41.6
Shear wave elastography	4a	Benign	3.01	36.6
Shear wave elastography	4a	Benign	3.25	34.7
Shear wave elastography	4a	Malignant	1.8	52.3

both SE ratio and SWE; however, the specificity of SE ratio is slightly superior to SWE (89.3% vs. 85.7%). Similar observations have been reported in a recent meta-analysis showing slightly better results for SE ratio as compared to SWE.[19]

In another meta-analysis conducted by Luo et al of 14 studies encompassing 1951 patients and 2060 breast lesions concluded that SWE led to improvement in differential diagnosis of breast lesions.[20] When SWE is used combined with SE for differentiation of breast lesions, the diagnostic value of this combination exceeded the diagnostic value of SWE or SE alone. Multivariate logistic regression analysis showed diagnostic advantages in terms of standard deviation for combined SWE and SE as compared to SWE alone.[21] Quantitative parameters of SWE and SE were comparable. The highest sensitivity and specificity for SE ratio, and SWE mean were achieved at cut-off values of 3.91 and 113 kPa, respectively.[22] In our observation, combing BI-RADS with SE and SWE also enhanced the sensitivity up to 100% and specificity up to 96.3%.

SWE can be used to compare stiffness of central tumor tissue, tissue at the tumor border and peritumoral stroma and can thus differentiate benign from malignant breast lesions. This is based on the fact that stiffness determined by SWE at the tumor border and peritumoral stroma were markedly different for benign and malignant lesions. Moreover, the higher the stiffness values for malignant masses, the higher the histopathologic grade and aggressive subtypes. Thus tissue stiffness measured by SWE can also help in prediction of cancer prognosis.[23] It also provides a quantitative value for Young's elastic modulus for tissues using supersonic shear wave propagation. This justifies its highly reproducible aspect.[24] Studies have shown good reproducibility of both SWE and SE by the different operators using the same ultrasound machine and same probe.[25,26]

We have studied 100 breast lesions with 20 breast lesions classified as category IVa. Out of these 20 lesions, 14 were benign and 6 were malignant lesions. It was our area of interest, as all Category II and III lesions were benign and all IVb and IVc were malignant on histopathology. We came across two false positive and one false negative SE ratio finding in category IVa lesions during our study. However these lesions were correctly diagnosed using SWE. The cut-off value was 45.3 kPa for SWE with AUC 0.929 and sensitivity of 95.8% and specificity of 85.7% using Youden index. Cut-off values reported in literature for SWE are between 36.1-87.5 kPa. A higher cut-off potentially decreases the unnecessary biopsies by increasing sensitivity in IVa lesions but reports have shown that some malignancies were missed in studies where high optimal cut-off values were selected for SWE (87.5kpa and 56 kPa).[4,27] One such lesion was identified in our study, which was categorized as IVa; the histopathology was IDC, but the SWE value was below our cut–off of 41.6 kPa. However, the lesion was correctly diagnosed by the SE ratio value which was 6.36, above the cut-off value of 2.86.

In conclusion, both SE ratio and SWE values augmented the diagnostic efficiency of conventional USG and BI-RADS classification. Diagnostic efficiency was increased when BI-RADs, SWE and SE ratio were combined and attained a sensitivity as high as 100% and specificity of 96.3%. These results are in agreement with other reports.[28] In our findings, combining strain and shear wave elastography as a complementary tool to conventional B-mode ultrasonography has a significant potential in better characterization of solid breast lesions. It can also significantly decrease unnecessary biopsies of BI-RADS IVa lesions.

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