



Added Value of Qualitative Shear Wave Elastography (SWE) to US-BIRADS in the Diagnosis Of Breast Cancer

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Abstract

Background: Shear wave elastography (SWE) is useful for the benign / malignant differentiation of solid breast lesions and was included in the 5th edition of the Breast Imaging-Reporting and Data System (BI-RADS).

Aim: to investigate the performance of qualitative Shear Wave Elastography (SWE) combined with the conventional US-BI-RADS for detection of malignancy in breast lesions.

Methods: This prospective study included 275 female patients with 347 breast lesions. The Conventional US characteristics and SWE colour overlay patterns of each breast lesion were separately recorded and analyzed in accordance with the American College of Radiology (ACR) Ultrasound Lexicon and then classified in accordance with the ACR BI-RADS assessment categories.

Results: For differentiation of benign and malignant breast lesions, conventional US-BIRADS had shown sensitivity: 98.08%, specificity: 63.87%, positive predictive value : 68.92%, negative predictive value : 97.60% and accuracy : 79.25%. The statistical indices for the combined analysis of both conventional US-BIRADS and qualitative SWE (colour overlay patterns) for differentiation of benign and malignant breast lesions are: sensitivity: 98.08%, specificity : 81.15%, positive predictive value : 80.95%, negative predictive value : 98.10% and accuracy : 88.76%.

Conclusion: Adding qualitative SWE (Colour overlay pattern) to conventional U/S-BIRADS, improves the specificity and overall diagnostic accuracy for detection of malignancy in breast masses.

Keywords: Shear wave elastography (SWE), US-BIRADS, breast cancer

Introduction

The incidence of breast cancer has increased substantially in recent years (1).

Some breast masses do not show definite malignant features on ultrasound, but they also do not fulfill the criteria for benign lesions, categorized as BI-RADS category 4a. The recommended management of such masses is biopsy, although the positive predictive value (PPV) of BI-RADS category 4a masses is only 6% (2).

Shear wave elastography (SWE) has been shown to improve the specificity for solid masses in the breast, as tissue stiffness or elasticity of breast cancers is known to be harder than that of benign masses (3).

SWE is useful for the benign / malignant differentiation of solid breast lesions and was included in the 5th edition of the Breast Imaging-Reporting and Data System (BI-RADS) (4).

Complex cystic and solid breast lesions are suspicious for malignancy and classified as BI-RADS category 4. Therefore, these lesions require a biopsy and/or surgical excision for diagnostic purposes. Recent studies have reported that SWE is useful in differentiating benign from malignant complex breast masses and a combination of SWE and US potentially reduce unnecessary biopsies (5).

Circumscribed oval malignant masses, which would otherwise be assessed at US as probably benign and followed up, can be recognized as suspicious with SW elastography, and biopsy can be performed. On the other hand, masses with low suspicion for malignancy, BI-RADS category 4a, which appears as benign at SW elastographic imaging may be downgraded to BI-RADS category 3 and safely followed up(6).

In a systematic scoring review performed by *Mao YJ, et al., (7)*, it was found that SWE has high diagnostic accuracy in distinguishing malignant from benign breast lesions. In addition, the combination of SWE and conventional US has the highest discriminating power for the detection of a malignancy and so SWE is showing promise for integration into routine imaging protocols.

The purpose of this study was to investigate the performance of qualitative Shear Wave Elastography (SWE) combined with the conventional US-BI-RADS for detection of malignancy in breast lesions.

SUBJECTS& METHODS

This study is a prospective analysis that included 275 female patients with 347 breast lesions, who were referred to the radio-diagnosis departments at Baheya Institute and National Cancer Institute in the durations between May to December 2020 and January to June 2021.

Inclusion criteria

1. Palpable breast / axillary tail lesions at physical examination.
2. Breast mass and non-mass lesions detected by conventional US or mammograms.
3. Solid or complex solid / cystic breast lesions.

Exclusion criteria

1. Breast lesions with poor shear wave quality features e.g.:
 - Deeply located lesions: Maximum depth of generating sufficient SWs= 4.5 cm.
 - Lesions for which the region of interest (ROI) could not be placed appropriately (contaminated internally from calcifications or externally from the skin or chest wall).
 - Images recording artefactual stiffness e.g. exerting excess pressure with the probe while performing SWE or inability to hold the probe still for few seconds.
2. Pure simple cystic breast lesions.
3. Patients with incomplete data.
4. Patients without pathological examination results and those who lost follow up.

The patients were examined as the following:

1. Conventional B-Mode US and SWE examinations were performed with the same US scanner using 6-15L and 9L probes respectively, while the patient is in the supine position.
2. The transverse and longitudinal conventional US images for each breast lesion were obtained using the 6-15L linear array transducer.
3. Two-dimensional SWE was performed using the 9L linear transducer in a plane showing the longest diameter of the breast mass, keeping the transducer very lightly applied (to prevent artefactual stiffness) with generous amounts of contact jelly for a few seconds, allowing the SWE image to stabilize.
4. A colour-coded map of tissue elasticity representing young's modulus in kilopascals (kPa) was obtained and superimposed on the real-time greyscale ultrasound image with a default colour scale ranging from 0 (dark blue; soft) to 180 kPa (red; hard).

Image Interpretation and analysis:

❖ Interpretation of Conventional US images:

- The characteristics of conventional US images of breast lesions were analyzed in accordance with the American College of Radiology (ACR) Ultrasound Lexicon (**Table 3**) and classified in accordance with the ACR BI-RADS assessment categories (**Table 4**).

Table 1: Summary of the Ultrasound Lexicon (8)

Ultrasound Lexicon		
Breast composition	a. homogeneous - fat b. homogeneous - fibroglandular c. heterogeneous	
Mass	shape	oval - round - irregular
	margin	Circumscribed or Not-circumscribed: indistinct, angular, microlobulated, spiculated
	orientation	parallel - not parallel
	echo pattern	anechoic - hyperechoic - complex cystic/solid hypoechoic - isoechoic - heterogeneous
	posterior features	no features - enhancement - shadowing - combined pattern
Calcifications	in mass - outside mass - intraductal	
Associated features	architectural distortion - duct changes - skin thickening - skin retraction - edema - vascularity (absent, internal, rim) - elasticity	
Special cases <i>(cases with a unique diagnosis)</i>	simple cyst - clustered microcysts - complicated cyst - mass in or on skin - foreign body (including implants) - intramammary lymph node - AVM - Mondor disease - postsurgical fluid collection - fat necrosis	

Table 2: US-BIRADS Assessment Categories (8)

Final Assessment Categories			
	Category	Management	Likelihood of cancer
0	Need additional imaging or prior examinations	Recall for additional imaging and/or await prior examinations	n/a
1	Negative	Routine screening	Essentially 0%
2	Benign	Routine screening	Essentially 0%
3	Probably Benign	Short interval-follow-up (6 month) or continued	>0 % but ≤ 2%
4	Suspicious	Tissue diagnosis	4a. low suspicion for malignancy (>2% to ≤ 10%) 4b. moderate suspicion for malignancy (>10% to ≤ 50%) 4c. high suspicion for malignancy (>50% to <95%)
5	Highly suggestive of malignancy	Tissue diagnosis	≥95%
6	Known biopsy-proven	Surgical excision when clinical appropriate	n/a

- In this study, BI-RADS 2 & 3 categories were considered to be benign while BI-RADS 4, 5 & 6 categories were considered to be malignant.

❖ **Interpretation of Qualitative SWE images:**

- The region of interest (ROI) of the SWE colour map was adjusted to sufficiently include the mass and surrounding breast tissue, but not to include the skin and chest wall.
- SWE colour overlay patterns was assessed in this study using the four-colour overlay pattern proposed by Tozaki et al.(9) as follows:
 - Pattern 1: There is no difference from the colour around the lesion and the margin of the lesion or in its interior (Coded blue homogeneously).
 - Pattern 2: There is a difference from the colour around the lesion and the margin of the lesion or in its interior, but extending beyond the lesion and continued vertically in cords on the cutaneous side or in the thoracic wall side (Artefact unique to SWE).
 - Pattern 3: A localized colored area is present at the margin of the lesion.
 - Pattern 4: Colored areas are present in the interior of the lesion heterogeneously.
- We considered lesions with SWE colour overlay patterns 1 and 2 are likely those presenting benign behavior while lesions with SWE colour overlay patterns 3 and 4 are those having malignant behavior.
- We investigated the added diagnostic value of qualitative SWE (colour overlay patterns) to conventional US-BIRADS, in distinguishing malignant from benign breast masses in all patients. In our analysis, positive result from either was counted as malignant.

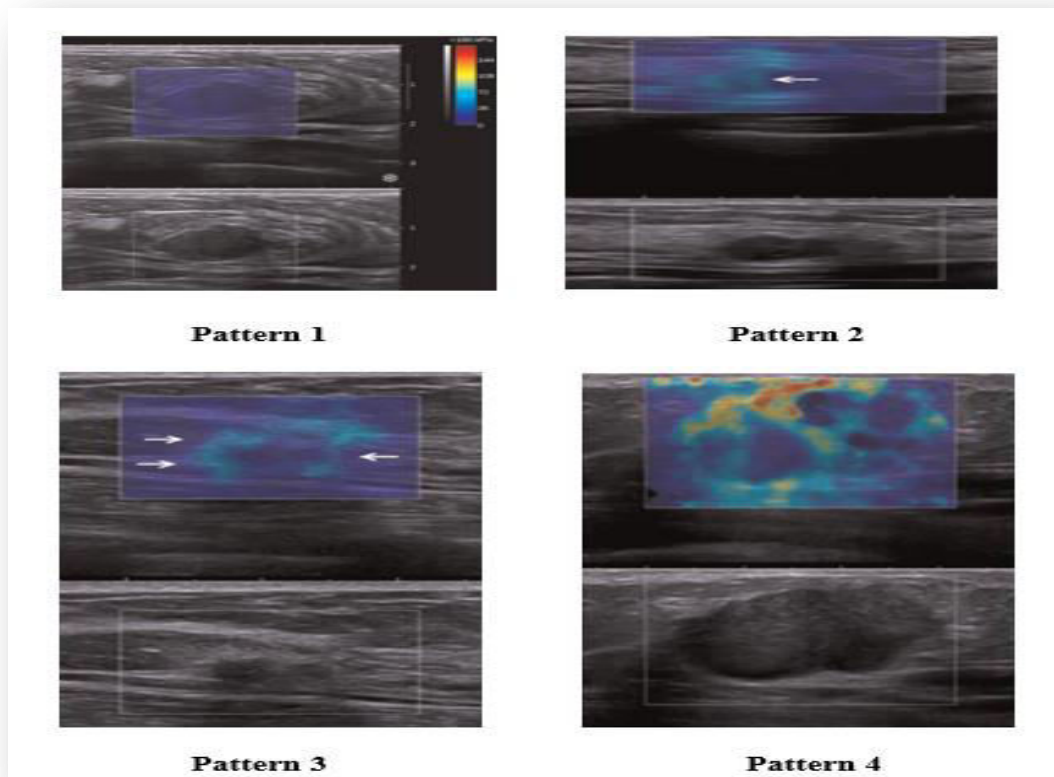


Fig.1: Shear wave elastography colour overlay patterns(9).

Histopathological correlation:

- Histo-pathological results obtained from ultrasound-guided core-needle biopsy, ultrasound-guided vacuum-assisted excision and surgical excision served as the standard of reference for suspicious breast lesions, and stability on follow up served as the standard of reference for benign ones.

Statistical analysis:

- Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) version 28 (IBM Corp., Armonk, NY, USA). Standard diagnostic indices including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic efficacy were calculated. Logistic regression was done to detect malignancy by different combinations . P value less than 0.05 was considered as statistically significant.

RESULTS

- This prospective study evaluated 347 breast lesions, 191 breast lesions (55.0%) proved to be benign, and 156 masses (45.0%) proved to be malignant (**Table 5**).
- The benign breast lesions consisted of fibroadenoma (n= 96), benign phylloides (n= 7), fibroadenosis (n= 11), fibrocystic changes (n= 4), PASH (n= 3), fat necrosis (n= 8), papilloma (n= 7), hamartoma (n= 13), reactive lymphoid hyperplasia in axillary tail LN & IMLN (n= 9), AVM (n= 1), sebaceous cyst (n= 1), lipoma (n= 1), epidermoid cyst (n= 2), duct ectasia (n= 1), galactocele (n= 1) (**Table 3**).

Table 3: Distribution of benign pathologies among studied patients.

	Count	%
Fibroadenoma:	96	50.3%
Benign phylloides	7	3.6%
Fibroadenosis	11	5.8%
Fibrocystic changes	4	2%
PASH	3	1.6%
Fat necrosis	8	4.2%
Papilloma	7	3.6%
Hamartoma	13	6.8%
Periductal mastitis	3	1.6%
Reactive lymphoid hyperplasia (Axillary tail LN& IMLN)	9	4.7%
AVM	1	0.5%
Sebaceous cyst	1	0.5%
Lipoma	1	0.5%
Epidermoid cyst	2	1.0%
Duct ectasia	1	0.5%
Galactocele	1	0.5%

- The malignant breast lesions consisted of Classic IDC (n= 92), Invasive Tubular / Cribriform Carcinoma (n= 7), Mucinous Carcinoma (n= 8), Papillary Carcinoma (n= 7), Medullary Carcinoma (n= 2), Paget's disease of the nipple (n= 3), ILC (Invasive Lobular carcinoma) (n= 20), DCIS (Ductal Carcinoma in Situ) (n= 8), Malignant Phylloides (n= 6), Epithelial Myoepithelial Carcinoma (n= 1), Metastatic IMLN (n= 2) (**Table 4**).

Table 4 Distribution of malignant pathologies among studied patients.

	Count	%
IDC (Invasive Ductal Carcinoma):	92	58.9%
Paget's disease of the nipple	3	1.9%
ILC (Invasive Lobular carcinoma)	20	12.8%
DCIS (Ductal Carcinoma in Situ)	8	5.1%
Malignant Phylloides	6	3.8%
Epithelial Myoepithelial Carcinoma	1	0.6%
Metastatic IMLN	2	1.2%

- The most common benign pathology was fibroadenoma, while the most common breast malignancy was invasive ductal carcinoma.

Conventional Ultrasound Findings

- The ultrasound characteristics of each breast lesion were separately recorded. Regarding the breast changes associated with malignant mass lesions, 33.5% were associated with architectural distortion (n= 107), 2.3% were associated with nipple inversion (n= 7), 10.0% were associated with ductal extensions (n= 32) and 1.6 % were associated with pectoral muscle invasion (n= 5) (*Table 5*).

Table 5: Distribution of breast changes associated with mass lesions among studied patients.

		Count	%
Arch. Distortion	No	213	66.5%
	Yes	107	33.5%
Nipple changes	Non	313	97.7%
	Nipple inversion	7	2.3%
Duct extension	No	288	90.0%
	Yes	32	10.0%
Skin changes	No	302	94.5%
	Skin thickening	15	4.5%
	Skin retraction	2	0.6%
	Skin nodule	1	0.3%
Pectoral Muscle Invasion	No	315	98.4%
	Yes	5	1.6%
Edema	No	309	96.5%
	Yes	11	3.5%
Vascularity	Absent	150	46.8%
	Internal Vascularity	132	41.3%
	Rim vascularity	38	11.9%

- Regarding the conventionalUS-BIRADS of the studied breast lesions, 7.2% were classified as BIRADS II (n= 25), 28.8% were BIRADS III (n= 100), 19 % were BIRADS IVa (n= 66), 8.9% were BIRADS IVb (n= 31), 17.6% were BIRADS IVc (n= 61), 17.9% were BIRADS V (n= 62) and 0.6% were BIRADS VI (n= 2) (*Table 6*).

Table 6: Distribution of conventional US-BIRADS and US-BIRADS assessment among studied patients.

		Count	%
Conventional US-BIRADS	BIRADS II	25	7.2%
	BIRADS III	100	28.8%
	BIRADS IVA	66	19.0%
	BIRADS IVB	31	8.9%
	BIRADS IVC	61	17.6%
	BIRADS V	62	17.9%
US-BIRADS Assessment	BIRADS VI	2	0.6%
	Benign	125	36.0%
	Malignant	222	64.0%

- Based on the conventional US-BIRADS, 36.0% of the studied breast lesions were judged to be benign (n= 125) and 64% were judged to be malignant (n= 222) (**Table 7**).
- For differentiation of benign and malignant breast lesions, conventional US-BIRADS had shown sensitivity : 98.08%, specificity : 63.87%, positive predictive value : 68.92%, negative predictive value : 97.60% and accuracy : 79.25%. (**Table 5**).

Table 7: Conventional US-BIRADS statistical analysis in differentiation of benign and malignant breast lesions.

Statistic	Value
Sensitivity	98.08%
Specificity	63.87%
Positive Predictive Value	68.92%
Negative Predictive Value	97.60%
Accuracy	79.25%

Qualitative Ultrasound Shear Wave Elastography (SWE) Findings

- SWE colour overlay patterns were assessed in this study using the four-colour overlay pattern proposed by Tozaki et al. (9) as follows:
 - Pattern 1: There is no difference from the colour around the lesion and the margin of the lesion or in its interior (Coded blue homogeneously).
 - Pattern 2: There is a difference from the colour around the lesion and the margin of the lesion or in its interior, but extending beyond the lesion and continued vertically in cords on the cutaneous side or in the thoracic wall side (Artefact unique to SWE).
 - Pattern 3: A localized colored area is present at the margin of the lesion.
 - Pattern 4: Colored areas are present in the interior of the lesion heterogeneously.
- In this study, the distribution of Shear-wave Elastography colour overlay patterns among studied patients was 32.9% Pattern 1, 5.2% Pattern 2, 23.6% Pattern 3 and 38.3% Pattern 4 (**Table 8**).

Table 8: Distribution of Shear-wave Elastography colour overlay patterns among patients.

		Count	%
Shear-wave Elastography (Color Pattern)	Pattern 1	114	32.9%
	Pattern 2	18	5.2%
	Pattern 3	82	23.6%
	Pattern 4	133	38.3%

We considered lesions with SWE colour overlay patterns 1 and 2 are likely those presenting benign behavior while lesions with SWE colour overlay patterns 3 and 4 are those having malignant behavior. Based on the SWE colour overlay patterns, 38.0% of the studied breast lesions were judged to be benign (n= 132) and 62% were judged to be malignant (n= 215). In correlation to the final histopathology, combined analysis of both conventional US-BIRADS and SWE colour overlay patterns has revealed 98.1% true malignant lesions (n= 153 / 156) and 81.2% true benign ones (n= 155 / 191).

Table 9: Correlation between conventional US-BIRADS + SWE colour overlay patterns and final histopathology.

		Final Histopathology			
		Malignant		Benign	
		Count	%	Count	%
US-BIRADS + Qualitative SWE	Malignant	153	98.1%	36	18.8%
	Benign	3	1.9%	155	81.2%

The statistical indices for the combined analysis of both conventional US-BIRADS and qualitative SWE (colour overlay patterns) for differentiation of benign and malignant breast lesions are: sensitivity : 98.08%, specificity : 81.15%, positive predictive value : 80.95%, negative predictive value : 98.10% and accuracy : 88.76%. (Table 10).

Table 10: Statistical indices for the combined analysis of both conventional US-BIRADS and Qualitative SWE in differentiation of benign and malignant breast lesions.

Statistic	Value
Sensitivity	98.08%
Specificity	81.15%
Positive Predictive Value	80.95%
Negative Predictive Value	98.10%
Accuracy	88.76%

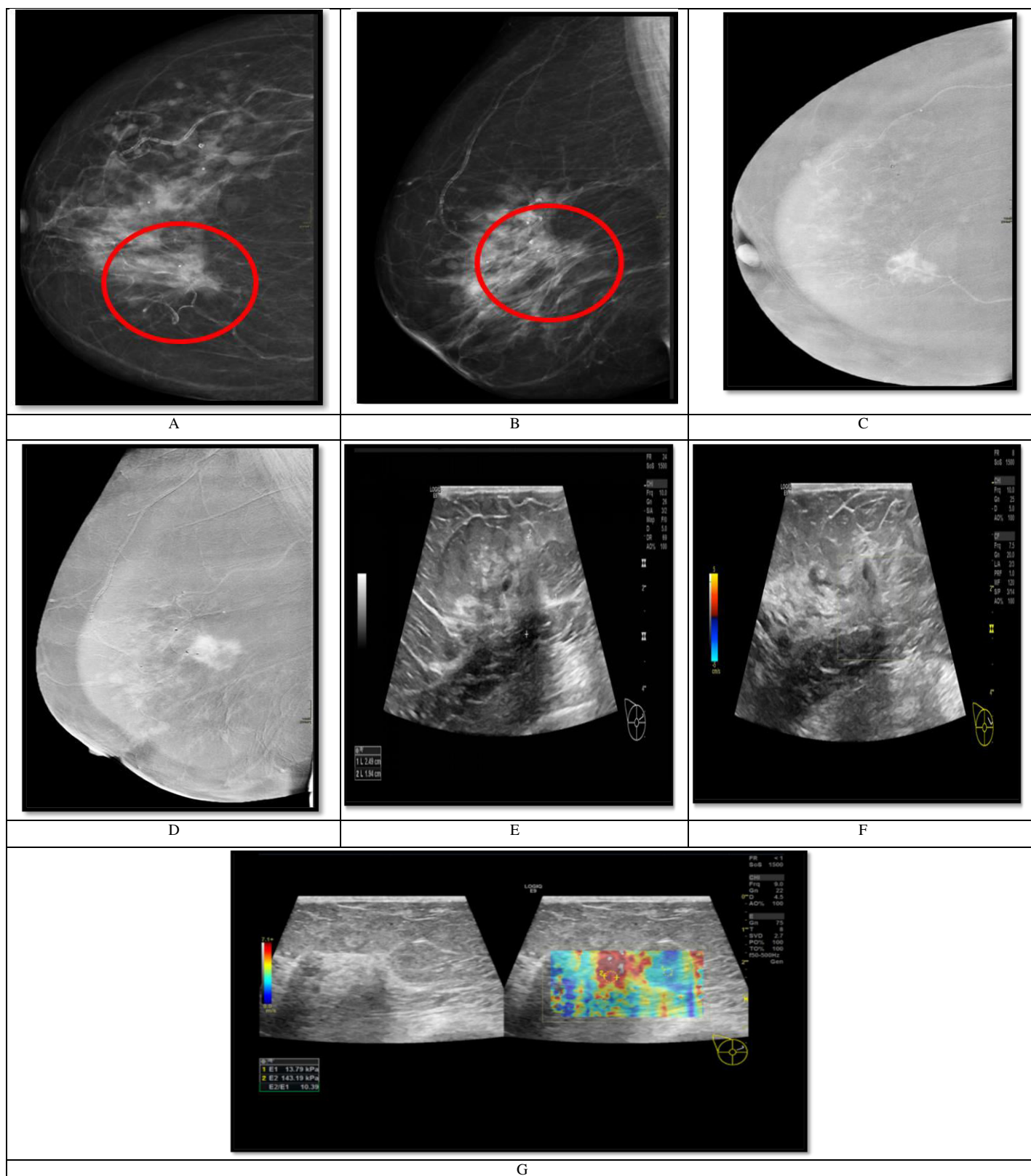


Fig 2: A 71 -years-old female patient, presented for screening purpose. a & b: Right CC & MLO mammographic views showing UIQ focal asymmetry with related parenchymal distortion (Red circle). c & d: Right CC & MLO CESM subtraction images showing pathological avid heterogeneous enhancement of the UIQ focal asymmetry and related parenchymal distortion.e & f: Greyscale and color Doppler ultrasound images of the right breast revealing correlate ill-defined area of altered hypoechoic parenchyma with related distortion at 2-3 o'clock location, measuring about 2.5 x 2 cm. No prominent internal vascularity could be depicted on color Doppler application. The lesion was classified as BIRADS 4c. g: Shear wave elastography and greyscale ultrasound image of the right breast UIQ lesion showing: SWE colour overlay pattern 4:

Colored areas are present in the interior of the lesion heterogeneously. The maximal stiffness of the lesion = 143 kPa. Stiffness ratio = 10.3. Final diagnosis: Invasive duct carcinoma, grade I, with minimal lobular differentiation.

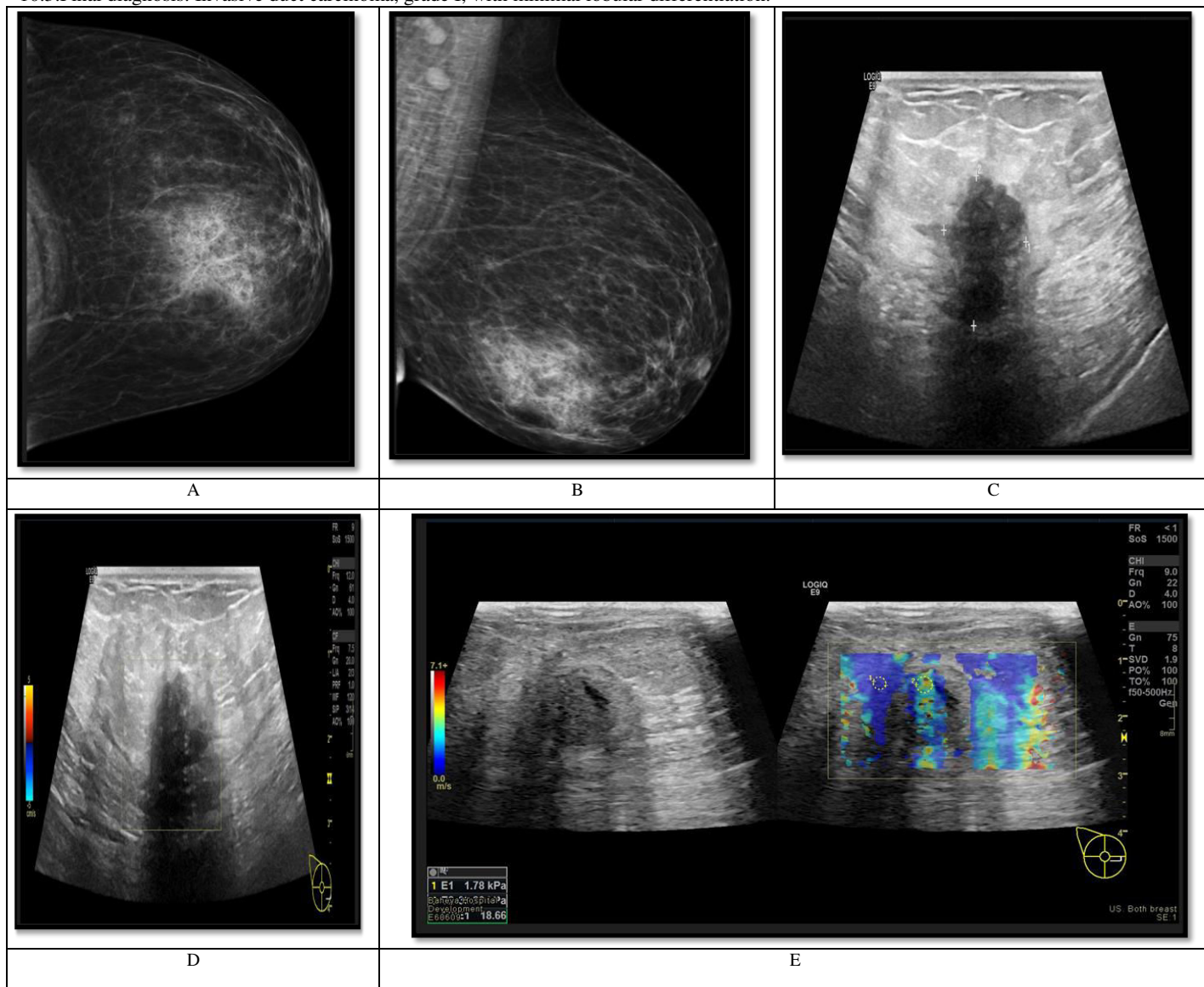


Fig 3: A 53 -years-old female patient, presented with left breast lump.a & b: Greyscale and color Doppler ultrasound images of the left breast revealing round well circumscribed solid hypoechoic mass lesion at 9-10 o'clock location, measuring about 20 x 19 mm. No internal vascularity was depicted on color Doppler application. The lesion was classified as BIRADS 4a.c: Shear wave elastography and greyscale ultrasound image of the left breast UIQ mass lesion showing:SWE colour overlay pattern 2: There is a difference from the colour around the lesion and the interior of the lesion, but extending beyond the lesion and continued vertically in cords on the cutaneous side or in the thoracic wall side (Artefact unique to SWE).The maximal stiffness of the lesion = 4.7 kPa. Stiffness ratio = 0.9. Final diagnosis: Fibroepithelial neoplasm, consistent with sclerosed intra-canalicular fibroadenoma.

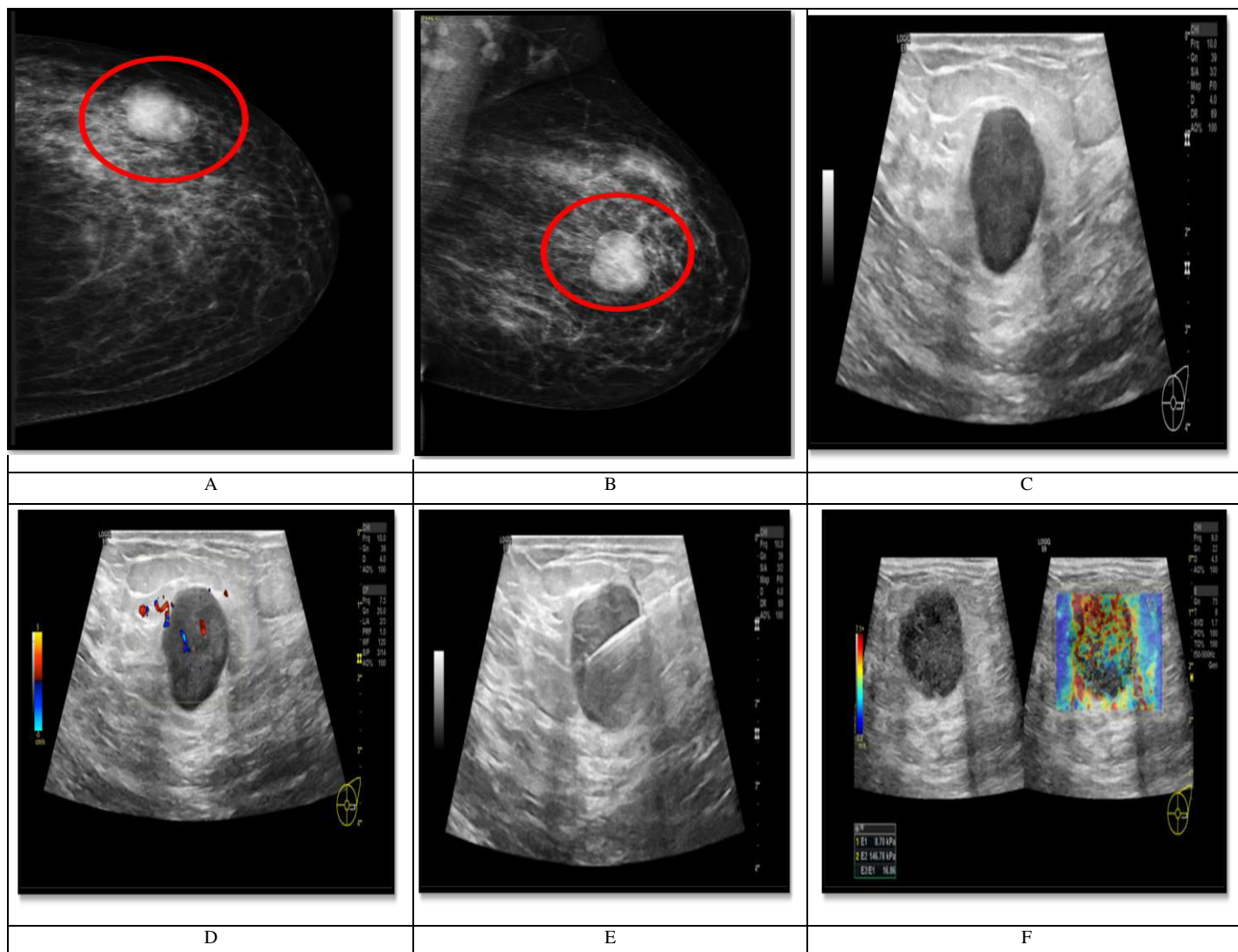


Fig 4: A 49 -years-old female patient, presented with left breast lump. a & b: Left CC & MLO mammographic views showing LOQ well circumscribed high-density oval mass lesion (Red Circle).c & d: Greyscale and colour Doppler ultrasound images of the left breast revealing correlate well circumscribed oval hypoechoic solid mass lesion at (4 o'clock) location, showing avid internal vascularity on colour Doppler. The lesion was classified as BIRADS 4a.e : Shear wave elastography and greyscale ultrasound image of the left breast (4 o'clock) mass lesion, showing:SWE colour overlay pattern 4: Colored areas are present in the interior of the lesion heterogeneously.The maximal stiffness of the lesion = 146.78 kPa. Stiffness ratio = 16.86.f: Greyscale ultrasound image of the tru-cut needle biopsy of the left breast (4 o'clock) mass lesion. Final diagnosis: Invasive duct carcinoma, grade III.

DISCUSSION

In recent years, there has been a marked rise in the incidence of breast cancer. (10).US elastography seeks to identify tissue stiffness to distinguish malignant from benign breast tumours (11).

Shear wave elastography (SWE) has been shown to improve the specificity for solid masses in the breast, as tissue stiffness or elasticity of breast cancers is known to be harder than that of benign masses (12).

Recent studies have reported that SWE is useful in differentiating benign from malignant complex breast masses and a combination of SWE and US potentially reduce unnecessary biopsies (12).

The chance of malignancy has a wide range for BI-RADS 4 lesions, according to the recently issued BI-RADS category, and increases with BI-RADS category from 4a to 4c. It has been reported, nonetheless, that using a single cut-off value on SWE for B-mode US would result in rates of false negatives (FNR) that vary from 0% to 36% and false positives (FPR) that range from 0% to 40.6%. (13).

The breast tissue elasticity measured by SWE varies depending on the inherent tissue characteristics of the breast structures. For example, Emean measured in vivo by SWE ranges from 5 to 10 kPa in fatty tissue and

from 30 to 50 kPa in breast parenchyma. Pathologic conditions change breast tissue elasticity; in general, benign lesions tend to be harder than normal breast tissue but softer than malignant lesions (13).

In this study, we evaluated the effectiveness of qualitative SWE in conjunction with conventional US BI-RADS categorization for differentiating between benign and malignant breast lesions.

In the current work, 191 breast lesions (55.0%) proved to be benign, and 156 lesions (45.0%) proved to be malignant.

Zheng et al., (10), reported that among the 120 solid breast masses, 75 benign and 45 malignant masses were pathologically confirmed. Among the benign masses, there were 40 cases of breast fibroadenoma, 15 cases lobular adenomatoid hyperplasia, 5 cases of papilloma, 4 cases of lipoma, and 11 cases of inflammatory mass. Among the malignant masses, there were 25 cases of invasive ductal carcinoma, 7 cases of invasive lobular carcinoma, and 13 cases of other masses.

In our evaluation we first analyzed the characteristics of conventional US images of the included breast lesions, in accordance with the American College of Radiology (ACR) Ultrasound Lexicon and classified in accordance with the ACR BI-RADS assessment categories.

For differentiation of benign and malignant breast lesions, conventional US-BIRADS had shown sensitivity : 98.08%, specificity : 63.87%, positive predictive value : 68.92%, negative predictive value : 97.60% and accuracy : 79.25% .

Lee, Su Hyun, et al., (12), studied the diagnostic performances of B-mode ultrasound with BI-RADS assessment in differentiating benign from malignant breast lesions. Considering BI-RADS category 4a or higher as testing positive for malignancy, they reported sensitivity of 100 %, specificity of 29.9 % , PPV of 55.4 % and the NPV of 100 %.

Similar results were also encountered in work of **Zheng et al., (10)**, who showed that the size, shape, margin, internal echo, microcalcification, lateral acoustic shadow and posterior acoustic enhancement of benign and malignant masses were significantly different.

For the qualitative assessment of breast lesions on SWE, a 4-color pattern classification based on color stiffness and heterogeneity was proposed by **Tozaki and Fukuma in (9)**: in **Pattern 1**, no difference from the color around the lesion is observed at the margin of the lesion or in its interior (coded blue homogeneously); in **Pattern 2**, a color that differs from the color around the lesion is observed at the margin or in the interior of the lesion, but it extends beyond the lesion and continues vertically in cords on the cutaneous side or the thoracic wall side (vertical stripe pattern artifacts); in **Pattern 3**, a localized colored area is present at the margin of the lesion; and in **Pattern 4**, colored areas are present in the interior of the lesion heterogeneously.

Pattern 2 is a unique artifact frequently observed during SWE examinations, with reported ranges from 7% to 24%. Patterns 3 and 4 are characterized by peripheral increased stiffness (the “stiff rim sign”) and heterogeneous color map features, suggestive of malignancy (15).

The stiff rim sign may be caused by (1) a desmoplastic reaction or the infiltration of cancer cells into the interstitial tissues or the intraductal component; or (2) internal low shear wave amplitude and/or noise as well as peripheral high-speed shear wave in the lesion caused by attenuation of the energy of the shear wave in the periphery of the lesion. Elastic heterogeneity is regarded to represent histologic heterogeneity of malignant lesions that are in part more cellular due to lymphocytic infiltration and/or in part more necrotic (16)

We considered lesions with SWE colour overlay patterns 1 and 2 are likely those presenting benign behavior while lesions with SWE colour overlay patterns 3 and 4 are those having malignant behavior.

In our study, combined analysis of both conventional US-BIRADS and SWE colour overlay patterns has revealed sensitivity of 98.08%, specificity of 81.15%, positive predictive value of 80.95%, negative predictive value of 98.10% and accuracy of 88.76%, for differentiation of benign and malignant breast lesions.

Our results were concordant with **Gweon, Hye Mi, et al., (17)**, who reported that for the four-colour overlay pattern, the area under the ROC curve (Az) was 0.947; with a cutoff point between pattern 2 and 3, sensitivity and specificity were 94.4 % and 81.4 % . According to the homogeneity of the elasticity, the Az

was 0.887; with a cutoff point between reasonably homogeneous and heterogeneous, sensitivity and specificity were 86.1 % and 82.5 %.

Berg et al., (6), proposed qualitative E values, Ecol (a 6-point color score of maximum elasticity: red, orange, green, light blue, dark blue, or black), Ehom (homogeneity of elasticity: very homogeneous, reasonably homogeneous, or heterogeneous), and Esha (lesion shape: oval, round, or irregular). In the fifth edition of the Breast Imaging Reporting and Data System (BI-RADS), descriptors for qualitative elasticity assessment were added: soft, intermediate, and hard. It is emphasized that a soft elastogram must not supersede morphologic analysis. Stiffness as a feature of malignant masses may be considered along with their much more important morphologic characteristics.

Youk et al., (16), stated that from a color-coded elasticity map displayed in real time on SWE, the elasticity of breast lesions can be qualitatively evaluated for their diagnosis. In general, color map features can be visually assessed on the spot before measuring elasticity quantitatively, making the qualitative method more instantaneous. The color displayed for each pixel represents the elasticity information of the corresponding tissue, and once the color map features of the lesion are screened, an ROI can be placed over the stiffest part of the lesion to measure the elasticity quantitatively.

Through our study, we recommend the following regarding application of ultrasound SWE in the assessment of breast lesions;

1. Elastography is a complimentary technique to B-mode imaging. SWE should be performed and interpreted along with standard B-mode imaging.
2. SWE should be routinely added to standard B-mode imaging in the assessment of solid and complex breast mass or non-mass lesions.
3. Downgrading B3 or B4A using SWE criteria is reasonable, but downgrading a B4b, B4c, or B5 is not recommended. If B-mode or another imaging technique is diagnostic of a B2 (e.g., fat necrosis), elastography should not be used to upgrade a lesion.
4. SWE should not be used when a lesion is very superficial (< 3 mm) from the skin surface or if the lesion is very deep (> 4 cm) from the skin surface. SE should not be used if the lesion is larger than the FOV box.

In our study, we found that the application of ultrasound SWE in the assessment and monitoring of cancerous disease can be limited by several factors;

First, we did not evaluate the inter-observer or intra-observer variability. Several previous studies have reported that the reproducibility of SWE was high.

A **second** limitation is that although the diagnostic performance of combined B-mode ultrasound and qualitative SWE was evaluated, these results are limited to our study. The specific guideline for the combination of the BI-RADS score and SWE values was not provided.

A **third** limitation is that the SWE was performed after B-mode ultrasound by the same radiologist. This set up may have influenced our results.

CONCLUSION

Adding qualitative SWE increased the diagnostic performance of conventional B-mode ultrasound for detection of malignancy in breast lesions.

Declarations

Consent for publication: I attest that all authors have agreed to submit the work.

Availability of data and material: Available

Competing interests: None

Funding: No fund

Conflicts of interest: no conflicts of interest.

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