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## The role of shear wave elastography in assessment of solid breast masses classified as BIRADs III & BIRADs IV by ultrasonography

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### Abstract

**Background:** Breast cancer remains a significant global healthcare challenge, with approximately 570,000 breast cancer-related deaths reported in 2015. Historically, the evaluation of breast masses relied heavily on physical palpation by physicians. However, recent advancements have introduced elastography into imaging systems, which assesses the elasticity or softness of breast lesions using ultrasound. This study aims to evaluate the efficacy of shear wave elastography in downgrading solid breast masses, reducing the false positive predictive value of the BI-RADS system, and minimizing unnecessary benign biopsies.

**Method:** cross-sectional analytic study involved 51 female patients attending the Breast Clinic at Al-Yarmouk Teaching Hospital in Baghdad for routine check-ups or follow-up of previously diagnosed breast pathology. Each patient underwent breast ultrasound, followed by a true cut biopsy. The breast lumps were classified into BI-RADS III and IV, with tissue elasticity measured by shear wave elastography. These findings were then compared with histopathology results. Results: the study found a strong correlation between breast lump shape and malignancy ( $P = 0.007$ ), with the majority of malignant tumors (94.1%) exhibiting irregular shapes. Masses with shear wave values exceeding 64 Kpa were predominantly malignant (88.9%,  $p < 0.001$ ). Malignancy was significantly higher among BI-RADS IV masses (82.1%,  $p < 0.001$ ). Hypochoic and heterogeneous patterns were also more common in malignant lumps ( $p < 0.001$ ).

**Conclusion:** shear wave elastography demonstrated high sensitivity and specificity, significantly reducing the false positive rate of malignancy in BI-RADS IV classified breast masses.

**Keywords:** Solid breast masses, shear wave electrography, BIRAD system, ultrasound

### Introduction

Breast cancer is a major global health issue, with approximately 570,000 deaths attributed to the disease in 2015 alone [1]. In Iraq, breast cancer is the most prevalent cancer among women, accounting for nearly one-third of all cancers diagnosed in Iraqi females [2, 3]. This malignancy typically originates in the mammary gland, with most cases arising from the cells lining the lactiferous ducts and ductules, known as ductal carcinoma, or from the cells in the mammary lobules, referred to as lobular carcinoma [4]. While these are the most common sites, breast cancer can occasionally develop in other parts of the mammary gland [4]. The anatomy of the mammary gland is crucial for understanding breast cancer's pathogenesis and for accurate diagnosis through imaging. Ultrasonography is a key tool for visualizing the various components of the breast, including the skin, areola, nipple, subcutaneous fatty layer, fibro-glandular portion, and retro-glandular layer [5]. The skin appears as two parallel echogenic lines with a hypochoic dermal layer between them, while the nipple and areola, being hypochoic, often attenuate the ultrasound beam, which can obscure adjacent pathology [6]. The mammary ductules, seen as tubular structures on ultrasound, vary in echogenicity based on their contents and decrease in size as they branch toward the periphery [7]. The subcutaneous fatty layer, composed of hypochoic adipose tissue, varies in thickness according to the patient's body habitus and is interspersed with Cooper's ligaments, which appear as hyperechoic lines [8]. The fibro-glandular portion, located between the subcutaneous fatty layer and the retro-glandular layer, is cone-shaped and more echogenic if it contains more fibro-glandular tissue, as opposed to fat [9].

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The echogenicity of the breast tissue can vary due to factors like age, lactation status, and menstrual cycle [10]. Posterior to the fibro-glandular portion, the retro-glandular layer contains hypoechoic fatty tissue and is bordered by the pectoralis muscle, which is more echogenic than fat tissue [6, 8]. Ultrasonography also effectively visualizes lymph nodes, which normally appear kidney-shaped with a hyperechoic hilum [11]. Malignant lymph nodes tend to lose this fatty hilum and become more round, with decreased echogenicity in the cortex, often appearing cystic, making Doppler imaging useful for differentiation [12]. Despite its utility, ultrasonography has limitations, particularly in detecting microcalcifications, a task better suited to mammography [13]. Nonetheless, advanced techniques like shear wave elastography have improved the ability to assess tissue hardness, offering greater precision in breast cancer diagnosis and reducing the need for invasive biopsies [14]. The aim of study is to assess the value of incorporating shear wave elastography in the grading of solid breast masses classified as BI-RADS III and IV. And to evaluate the effectiveness of shear wave elastography in reducing the false positive predictive value of the BI-RADS system by downgrading solid breast masses.

## Methods

This cross-sectional, analytic study involved 51 female patients from middle and older age groups who attended the Breast Clinic at Al-Yarmouk Teaching Hospital in Baghdad for routine check-ups or follow-up of previously diagnosed breast pathology. All patients had breast lesions classified as BI-RADS III or IV. The study was conducted over two years, with data collected weekly from January 2020 to January 2022. Clinical data, including age, presenting symptoms, history of previous breast surgery, history of breast cancer, and prior imaging studies, were recorded. Each patient underwent breast examination using B-mode ultrasound and shear wave elastography (SWE). Subsequently, a true cut biopsy (TCB) was performed on each lesion, with histopathological results obtained later for correlation. Ultrasound examinations were conducted using a General Electric LOGIC P7 machine equipped with a 3-12 MHz linear probe. Patients were positioned supine with their arms raised above their heads to ensure full exposure of the breast tissue and axillary tail. Targeted sonography was performed on the mass, followed by measurement of mass hardness or shear wave elasticity values. These values were compared with the normal adjacent tissue, with images and measurements documented for analysis. TCB was performed by a specialist radiologist using a BARD MAX-CORE disposable core biopsy instrument with a 14-16 gauge needle and a length of 10-20 cm. Under aseptic conditions, local anesthesia with 2% lignocaine was administered, and the skin was incised. Four biopsy samples were taken from each mass at different angles. The samples were preserved in formalin and sent for histopathological examination, where lesions were classified as benign or malignant. Ultrasound images were analyzed by a consultant radiologist, focusing on the morphological features of each lesion. Out of the initial 84 patients, 33 were excluded due to non-conforming features, leaving 51 patients in the study. Data were processed using Microsoft Excel and analyzed with SPSS (version 24). Sensitivity, specificity, predictive values, and accuracy rates were calculated using MedCalc

statistical software for ROC curve analysis.

## Results

This study conducted on 51 female patients with breast masses. The highest distribution of patients 62.7% (32) were > 45 years. The commonest histopathological type was invasive ductal carcinoma 56.8% (29), followed by 21.6% (11) with fibroadenoma. The majority of breast masses were diagnosed by histopathology to have malignancy 33 (64.7%). As clarified in table (1).

**Table 1:** Age groups and histopathological features of breast lump (n=51)

Variable	N.	%	
Age groups in year)	≤ 45	19	37.3
	> 45	32	62.7
Histopathological type	Fibroadenoma	11	21.6
	Papilloma	5	9.8
	Stromal fibrosis	2	3.9
	Mucinous carcinoma	1	2.0
	Invasive lobular carcinoma	3	5.8
	Invasive ductal carcinoma	29	56.8
Type of tumor	Benign	18	35.3
	Malignancy	33	64.7

The majority of breast masses (39) 76.5% were classified as BI-RAD IV. The spiculated margin was the commonest feature by ultrasound in 17 (33.3). Breast masses with hypoechoic feature in ultrasound was seen in 28 (54.9%). Irregularity in shape were the commonest in 34 (66.7%) of the breast masses. As clarified in table (2).

**Table 2:** Ultrasound characteristics features of breast lump (n=51)

Variables	N.	%	
BI-RADS	III	12	23.5
	IV	39	76.5
Shape	Irregular	34	66.7
	Oval	13	25.5
	Rounded	4	7.8
Margin	Spiculated	17	33.3
	Circumscribed	12	23.5
	Micro lobulated	8	15.7
	Indistinct	6	11.8
	Angular	8	15.7
Orientation	Oblique	15	29.4
	Horizontal	9	17.6
	Taller than wider	27	52.9
Echo pattern	Hypoechoic	28	54.9
	Isoechoic	13	25.5
	Heterogeneous	10	19.6
Vascularity	Absent	7	13.7
	Central	21	41.2
	Central and peripheral	21	41.2
	Peripheral	2	3.9

We compare the result of shear wave measurements by ultrasound with the gold standard diagnostic histopathology as a reference. It showed that cut off value of > 64 with AUC (92.1%), accuracy 79.80%, and 95% confidence interval (81.1%-97.8%) was with the highest sensitivity (90.91%), highest specificity (88.89%), positive predictive value (93.7%), and negative predictive value (84.2%). As illustrated in detail in table (3).

**Table 3:** ROC curve results for SWE using histopathological diagnosis as reference, Validity of screening tests for SWE using histopathological diagnosis as reference

Cut off value	AUC %	95% C.I.	P - value
> 64	92.1%	81.1% - 97.8%	< 0.001
<b>AUC = Area Under Curve, 95% C.I. = 95% confidence interval</b>			
Sensitivity%	Specificity %	PPV%	NPV%
90.91%	88.89%	93.7%	84.2%
Accuracy %			
79.80%			

PPV% = positive predictive value%, NPV% = negative predictive value%, AUC = Area Under Curve, 95% C.I. = 95% confidence interval

Malignant breast lump was significantly distributed with the highest proportion among women elder than 45 years 81.3% (26) (P = 0.002). Masses with shear wave > 64 Kpa were mostly malignant 88.9% (32) (P = < 0.001). Malignancy was significantly higher among lumps with BI-RAD IV 82.1% (32) (P = <0.001). Masses with spiculated, indistinct, and angular margin were significantly higher (P = < 0.001) in malignant lump [17 (100%), 6 (100%), and 6 (75%) respectively], while circumscribed and micro lobulated were mostly in benign breast lump [11 (91.7%), and 5 (62.5%)

respectively]. Hypochoic and heterogeneous pattern were significantly higher among malignant breast lump [12 (92.3%), and 10 (100%) respectively (P = < 0.001)], while isoechoic was mostly distribution among benign cases 12 (92.3%). A strong association between the shape of breast lump and malignancy (P = 0.007), where the majority of malignant breast tumor 32 (94.1%) were with irregular shape, and the majority of benign breast lump were with rounded and oval shape [4 (100%) and 12 (92.3%) respectively. As showed in table (4).

**Table 4:** Distribution of the type of tumor according to age and other ultrasound features (n=51)

Variables	Total	Type of tumor				P-value	
		Benign		Malignant			
		N.	%	N.	%		
Age groups (In year)	≤ 45	19	12	63.2	7	36.8	0.002
	> 45	32	6	18.8	26	81.3	
Shear Wave Elasticity	≤ 64	15	14	93.3	1	6.7	<0.001
	> 64	36	4	11.1	32	88.9	
BI-RADS	III	12	11	91.7	1	8.3	<0.001
	IV	39	7	17.9	32	82.1	
Margin	Speculated	17	0	0.0	17	100.0	<0.001
	Circumscribed	12	11	91.7	1	8.3	
	Micro lobulated	8	5	62.5	3	37.5	
	Indistinct	6	0	0.0	6	100.0	
	Angular	8	2	25.0	6	75.0	
Orientation	Oblique	15	10	66.7	5	33.3	<0.001
	Horizontal	9	8	88.9	1	11.1	
	Taller than wider	27	0	0.0	27	100.0	
Echo pattern	Hypochoic	28	6	21.4	22	78.6	<0.001
	Isoechoic	13	12	92.3	1	7.7	
	Heterogeneous	10	0	0.0	10	100.0	
Shape	Irregular	34	2	5.9	32	94.1	0.007
	Oval	13	12	92.3	1	7.7	
	Rounded	4	4	100.0	0	0.0	

Chi-square is significant at p< 0.05.

Fibroadenoma was with the highest level of shear wave elasticity among benign breast lump (57 ± 14), and invasive ductal carcinoma was with the highest level of shear wave

elasticity among malignant breast lump (183±41), and this difference was found to be significant (P = 0.001). As illustrated in table (5).

**Table 5:** Distribution of shear wave elasticity according to breast lump histopathological type (n=51)

Histopathological type	Shear wave (Kpa) (Mean ± SD)	P-value	F	
Histopathological type	Fibroadenoma	(57±14)	0.001	41.188
	Papilloma	(42±30)		
	Stromal fibrosis	(50±5)		
	Mucinous carcinoma	(90±4)		
	Invasive lobular carcinoma	(136±27)		
	Invasive ductal carcinoma	(183±41)		

One way ANOVA test is significant at p< 0.05.

Cases with malignant breast lump were with mean age of (55.67 ± 10.954), while patients with benign breast lump were within age of (43.89 ± 8.622) and this difference found to be significant P = <0.001. Also, cases with malignant

breast lump were with mean SWE of (48.61±18.706), while patients with benign breast lump were within SWE of (140.97±40.019) and this difference found to be significant P = <0.001. As showed in table (6).

**Table 6:** Mean of age and SWE distribution among benign and malignant breast cancer

Variable	Benign (n=18) (Mean ± SD)	Malignant (n=33) (Mean ± SD)	P- value
Age (In years)	(43.89±8.622)	(55.67±10.954)	< 0.001
SWE (kPa)	(48.61±18.706)	(140.97±40.019)	<0.001

t-test is significant at  $P < 0.05$

In table (7), breast mass with BI-RADS III were found to be statistically with no significant association with both SWE of  $\leq 64$  Kpa and benign diagnosis ( $P = 0.142$ ), while BIRADS IV were found a statistical association with both

SWE and histopathological diagnosis, where Benign lump associated with  $SWE \leq 64$  Kpa and benign type 6 (85.7%), also BIRADS IV were associated with  $SWE > 64$  Kpa and malignant type 31 (96.9%).

**Table 7:** Correlation between BI-RADS and SWE with histopathological diagnosis

Variable				Type of tumor				P- value
				Benign		Malignant		
				N.	%	N.	%	
BI-RADS	III	Shear Wave Elasticity	$\leq 64$	8	100.0	0	0.0	0.142
			$> 64$	3	75.0	1	25.0	
	IV	Shear Wave Elasticity	$\leq 64$	6	85.7	1	14.3	< 0.001
			$> 64$	1	3.1	31	96.9	

Chi-square is significant at  $p < 0.05$

### Discussion

Breast masses are a common concern in outpatient clinics, significantly straining healthcare resources and causing considerable anxiety among patients due to the fear of malignancy. Reducing unnecessary surgeries or invasive treatments for benign lesions is crucial, especially with evolving techniques like Shear Wave Elastography (SWE), which can help in distinguishing between benign and malignant breast masses without missing potentially malignant lesions [15]. SWE is an advanced ultrasound technology that provides quantitative data, offering a reproducible method for differentiating solid breast masses. Unlike conventional elastography, SWE measures tissue stiffness within a region of interest (ROI) and compares it with surrounding fatty breast tissue, which varies mildly with location, hormonal status, age, and pathology [16]. The malignancy probability for BI-RADS III and IV lesions can reach up to 94%, leading to a high rate of unnecessary biopsies. Therefore, it is essential to enhance the accuracy of differential diagnosis using SWE to reduce the false positive rate associated with the BI-RADS system [16]. Our study revealed that the most common benign lesion was fibroadenoma, while invasive ductal carcinoma was the most common malignant mass. The shape and margin of the breast lump were significant indicators of malignancy; irregular shapes and indistinct, speculated, or angular margins were strongly associated with malignant lumps, while oval and rounded shapes with circumscribed or microlobulated margins were more common in benign lesions ( $p < 0.001$ ). These findings are consistent with those reported [17, 18]. The echo patterns observed during ultrasound also provided critical insights. A heterogeneous echo pattern was exclusively found in malignant lesions, while an isoechoic pattern was predominantly associated with benign lumps, aligning with the study by S. Hari and SB Poul *et al.* [19]. Furthermore, the mean shear wave elasticity measured in kilopascals (kPa) was significantly higher in malignant breast lesions compared to benign ones, which can be attributed to the high cellularity and desmoplastic reactions within malignant tissues. For instance, invasive ductal carcinoma showed a mean elasticity of  $183 \pm 41$  kPa, while benign lesions like fibroadenomas exhibited much lower values ( $57 \pm 14$  kPa)

[20]. The cutoff value for SWE in our study was  $>64$  kPa, which demonstrated high sensitivity (90.91%) and specificity (88.89%) in detecting malignant breast lumps. This cutoff is comparable to other studies, such as Evans *et al.*, who reported a cutoff of 50 kPa, and Chang *et al.*, who suggested a higher cutoff of 80 kPa. Variability in cutoff values across studies could be due to differences in the patient population, the proportion of malignant masses, and other technical factors [20]. One of the key findings of our study was that incorporating SWE into the diagnostic process allowed for the downgrading of about 17.9% of lesions initially classified as BI-RADS IV by B-mode ultrasound to BI-RADS III. These downgraded lesions, which exhibited benign SWE features and benign histopathology, could be managed with clinical and radiological follow-up instead of biopsy, thus reducing unnecessary invasive procedures and alleviating patient anxiety [15, 21]. However, there were pitfalls in SWE interpretation, as about 25% of benign masses (classified under BI-RADS III) showed false positive SWE results (greater than 64 kPa). Such discrepancies might be due to technical factors like uneven probe application, intrinsic mass characteristics, or the lesion's depth and proximity to highly attenuating structures like the nipple. This phenomenon has been observed in other studies, including those by Ji Hyun Youk *et al.* [22]. Despite these challenges, SWE proves to be a valuable tool in enhancing diagnostic accuracy and reducing the burden on healthcare systems by minimizing unnecessary biopsies.

### Conclusion

Our study concluded that combining shear wave elastography (SWE) with B-mode ultrasound imaging significantly enhances the diagnostic accuracy for distinguishing between benign and malignant breast masses, potentially increasing the positive predictive value (PPV). Malignant breast diseases were strongly associated with higher SWE values compared to benign lesions. Through ROC curve analysis, a cutoff value of  $>64$  KPa was identified as having the highest sensitivity and specificity for detecting malignant breast lumps. Additionally, irregular shape, speculated or angular margins, indistinct borders, and a heterogeneous echo pattern were all significantly linked to

malignant breast masses, highlighting the importance of these features in diagnostic evaluation.

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