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ORIGINAL ARTICLE

The Added Value of Breast Elastography in Improving the Diagnostic Accuracy of BI-RADS Categorization of Mammographically Indeterminate Breast Lesions

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ABSTRACT

Background: Breast cancer is the most frequent cancer among women. Early detection of breast cancer is critical for improving prognosis. The current study aims to establish the added value of ultrasound (US) elastography to the BI-RADS classification system in the categorization of ambiguous breast lesions following mammography as a first step. **Methods:** This cross-sectional study was performed at the Radiology Department of Zagazig University. Cases were referred from the outpatient clinic of the general surgery department with suspected breast lesions. All study population subjected to full history taking (clinical presentation, age, family and past history), clinical examination, histopathological and imaging examination (Conventional B-mode breast US and breast elastography). **Results:** Elasticity and velocity detected by shear wave elastography were significantly elevated among cancerous lesions compared to benign lesions (P =0.02, 0.01, respectively). There was a significant variance between the qualitative measurements between malignant and benign lesions (P =0.02). Combining conventional imaging with shear wave elastography (SWE) reported a sensitivity of 83.3% and specificity of 91.7% with an AUC of 0.94. **Conclusion:** SWE is a simple method with great diagnostic accuracy that can be easily combined with a B-mode US examination in the same session, increasing its specificity. It demonstrated usefulness in reducing the frequency of needless biopsies.

Keywords: breast elastography, BI-RADS, mammography, breast lesions.

INTRODUCTION

Breast cancer (BC) is the most common malignancy among women globally, providing a huge public health problem owing to its high prevalence and fatality rates [1]. Early and accurate diagnosis is crucial for effective treatment and improving patient outcomes [2]. Mammography is still the principal imaging technique for BC monitoring and diagnosis, offering valuable insights into the structural and morphological characteristics of breast lesions. However, mammography has inherent limitations, particularly in dense breast tissues, which can obscure lesions and lead to indeterminate findings [3]. This often necessitates additional imaging modalities to enhance diagnostic accuracy and guide clinical [2].

The classification of Breast Imaging Reporting and Data System (BI-RADS) was created to unify documentation and increase interaction among radiologists and physicians. While BI-RADS provides a structured framework for assessing and managing breast lesions, challenges remain in accurately categorizing indeterminate lesions (BI-RADS category 3 and 4) which often necessitate further diagnostic intervention to distinguish benign from malignant pathology [4].

Elastography is an emerging ultrasound-based imaging technique that evaluates the tissues mechanical features, particularly their stiffness and elasticity. Breast elastography offers a non-invasive means to detect malignant and benign and differentiate between them regarding that compared to benign tissues, malignant tissues are often stiffer. Shear-wave elastography (SWE) and strain elastography (SE) are the main elastography teschniques. SWE assesses the speed at which mechanically produced SW propagates through tissue, whereas SE assesses the distortion of tissue in reaction to an external force, providing a more objective and quantitative assessment of tissue stiffness [5].

Recent investigations found that the integration of elastography with conventional ultrasound (US) and mammography can remarkably enhance the accuracy of diagnosis of breast lesion characterization. Elastography has shown promise in decreasing the number of unnecessary biopsies for benign tumors and in enhancing the specificity of breast cancer diagnosis without compromising sensitivity. This added value is particularly relevant for BI-RADS 3 and 4 lesions, where distinguishing benign from malignant findings is critical yet challenging [6,7]. The potential of elastography to complement BI-RADS categorization is supported by numerous clinical investigations, which concluded that elastography significantly improves the overall diagnostic accuracy of breast imaging when combined with BI-RADS classification [5,8].

The integration of elastography into routine breast imaging practice holds the promise of enhancing the diagnostic workflow, providing a more reliable differentiation of indeterminate breast lesions, and potentially improving patient outcomes through earlier and more accurate diagnosis. As technology keeps on developing, more investigations and defined practices will be required to fully realize its benefits and incorporate it effectively into clinical practice [4]. The current study aims to establish the added value of US elastography to the BI-RADS classification system in the categorization of ambiguous breast tumors following mammography as a first step.

METHODS

This cross-sectional study was performed on 30 cases at the radiology department of Zagazig University. Cases were referred from the outpatient clinic of the general surgery department with suspected breast lesions during the period from March 2023 to September 2023. Verbal and written informed consent were obtained from all participants after an explanation of the procedure and medical research.

The research was conducted under the Helsinki Declaration for human research. This study was performed after the approval of the Institutional Review Board (IRB#10340).

Cases with the following criteria were included; cases with indeterminant breast lesions on mammography (BI-RAD 3 or 4). Patients with positive findings on 2D ultrasound. Patients signed the informed consent. Cases with the following characteristics were excluded; Patients unwilling to complete the study. Patients with a history of chemotherapy.

All study population subjected to full history taking (clinical presentation, age, family and past history), clinical examination, and imaging examination (Conventional B-mode breast US and breast elastography).

Imaging procedure:

The study was performed on an ultrasound scanner (TOSHIBA APLIO 500) with a real-time tissue elastography unit. The ultrasound probe was a 7.5 MHz linear array electronic probe. After palpating both breasts for any noticeable abnormalities, the case requested to lie supine and turn slightly to the contralateral side with the ipsilateral arm lifted over her head.

Techniques

Conventional ultrasound

Breast lesions were first examined using standard B-mode US. Radial scanning of the whole breast and axillary tail on both sides was carried out. Images of breast lesions were taken both longitudinally and transversely.

Images were categorized into one of five groups according to the BI-RADS criteria for US:

Category 1 is a normal result. 2 includes benign findings. 3: likely benign findings. 4: suspicious findings of malignancy. 5: findings highly suspicious for malignancy.

Elastography

A free-hand, real-time assessment of US elastography was carried out in the same session. In the first step, SW is produced by applying focused acoustic radiation force from a linear ultrasonic array, which induces localized tissue deformation and tension. After that, the generated SW moves much more slowly into the surrounding tissues in the transverse plane, perpendicular to the main wave that produces the acoustic radiation force, causing shear changes in the tissue.

Step 2 uses fast plane wave excitation to track the propagation of SW velocities and tissue movement. A speckle-tracking approach is used to quantify the shifting of tissue.

Step 3 involves using the deformation of tissue maps to calculate the SW velocity, which is commonly expressed in m/sec. The shear modulus, which is determined by applying a straightforward mathematical formula that expresses tissue stiffness and elasticity in pressure units, usually kilopascals (K.Pa), is directly proportional to the distribution of SW velocities at each pixel. An estimate of a density equivalent to water (1 g/cm3) is shown by a color bar connecting shear velocity and shear modulus. The type of soft tissue will affect the actual density estimates, which can also be derived from numbers that have been reported in the previous reports.

In color elastograms, red is typically used to convey hard consistency, blue to denote soft consistency, and green and yellow to express moderate stiffness. comprehending and interpreting color elastograms and SW velocities necessitates a thorough understanding of SWE's underlying US physics.

Histopathological examination (reference standard):

Lesions were biopsied by US-guided fine needle aspiration cytology (FNAC) and surgical biopsy. Pathologic analysis of breast lesion samples was performed in the Pathology Department of Zagazig University by a group of experienced pathologists. Histopathologic diagnoses from surgical or biopsy specimens were acquired and utilized as reference standards.

Revising imaging and pathological results:

Findings from ultrasound, elasticity grading and strain ratios have been compared to histological diagnosis.

STATISTICAL ANALYSIS

The data were analyzed using IBM SPSS 23.0 for Windows (SPSS Inc., Chicago, IL, USA) and the Jamovi project (2022) (Version 2.3). Quantitative data was presented employing mean and standard deviation, whilst categorical data was reported using count and percentages. To compare categorical data, the Chi-square (x2) and Fisher's exact test (f) were utilized. For the relationship between quantitative variables in two groups: Independent t-test (parametric test) and Mann-Whitney U test (non-parametric test). The ROC Curve (receiver operating characteristic) is a valuable tool for determining the sensitivity and specificity of quantitative diagnostic tests that assign cases to one of two groups. Binary logistic regression was used to determine the diagnostic value of the investigated diagnostic procedures. P-values < 0.05 considered significant.

RESULTS

The mean age of cases was 45.9 ± 11.2. Ten patients (33.3%) were less than 40 years old, and 6 patients (20%) were older than 60 years. Regarding family history, 12 patients (40%) had positive family history. As regards the site of lesion, 12 patients (40%) had left breast lesions while 18 patients (60%) had right breast lesions. Regarding breast composition, 17 patients (56.7%) were ACR B, while 13 patients (43.3%) were ACR C. As regards mass shape, 9 patients (30%) had irregular mass, while 12 patients (40%) had oval masses, 2 patients (6.7%) had rounded masses and 7 patients (23.3%) had ill-defined masses. Regarding mass density, 7 patients (23.3%) had isodense masses, while 23 patients (76.7%) had hyper-dense masses. The other mass characteristics among studied patients were listed in Table (1).

Concerning mass characteristics detected by ultrasound among studied patients, As regards mass shape 17 patients (56.7%) had irregular masses, while 10 patients (33.3%) had oval masses, and only 3 patients (10%) had rounded masses. Regarding mass margin, 12 patients (40%) had speculated masses, 10 patients (33.3%) had well-circumscribed masses, 4 (13.3%) had micro-lobulated masses, 2 patients (6.7%) had well-defined masses, 1 patient (3.3%) had angular mass, 1 patient (3.3%) had macro-lobulated mass. The other mass characteristics data were listed in Table (2).

The elasticity detected by SWE had a mean of 79.47 ± 44.34. As regards velocity, it had a mean of 4.95 ± 1.8. As regards qualitative measurements, the most frequent color detected was yellow and red in 10 (33.3%) patients, followed by blue with spots like green in 7 (23.3%) patients, then blue in 5 (16.7%) patients, blue to green in 4 (13.3%) patients, multicolored with red and orange in 2 (6.7%) patients, patchy green and multicolored with red, orange and blue in 1 (3.3%) patient. Regarding color pattern, 5 (16.7%) patients showed color 1, 11 (36.7%) patients showed color 2, 11 (36.7%) patients showed color 3 and 3 (10%) patients showed color 4. SWE detected the BI-RADS 3 category in 14 (46.7%) patients and the BI-RADS 4 category in 16 (53.3%) patients. histopathology diagnosed 14 benign masses, specifically 13 cases (43.3%) of fibroadenoma and 1 case (3.3%) of atypical fibroadenoma. Additionally, 16 malignant masses were identified, including 7 cases (23.3%) of medullary carcinoma, 4 cases (13.3%) of infiltrating ductal carcinoma, 3 cases (10%) of atypical ductal hyperplasia, and 2 cases (6.7%) of ductal carcinoma in situ (Table 3).

Elasticity and velocity detected by shear wave elastography were significantly elevated among cancerous lesions in comparison to benign lesions (P =0.02 and 0.01, respectively). There was also a significant difference between the qualitative measurements between benign and malignant lesions (P =0.02) (Table 4).

From the total 14 benign lesions, mammography classified 12 lesions (85.7%) as BI-RADS 3 and only 2 lesions (14.3%) were BI-RADS 4, while

(68.8%) of the malignant lesions were BI-RADS4 and (31.3%) were BI-RADS 3. As regards ultrasound; from the total 14 benign lesions, ultrasound classified 12 lesions (85.7%) as BI-RADS 3 and 2 lesions (14.3%) were classified as BI-RADS 4, while (81.3%) of the malignant lesions were BI-RADS 4 and 3 lesions (18.8%) were BI-RADS 3. SWE classified 12 lesions (85.7%) from the total 14 benign lesions as BI-RADS 3 and classified 2 lesions (14.3%) as BI-RADS 4, while (87.5%) of the malignant lesions were BI-RADS 4 and (12.5%) were BI-RADS 3 (Table 4).

On conducting ROC curve analysis for discriminating between benign and malignant lesions by elasticity values detected by SWE, at a cut-off point of 80.2, it shows sensitivity of 68.75%, specificity of 85.71%. Mammography showed a sensitivity of 68.8% and specificity of 85.7, while ultrasound showed a sensitivity of 81.3%, and specificity of 85.7%. Combining conventional imaging with SWE reported a sensitivity of 83.3% and specificity of 91.7% (Table 5).

Table (1): Demographic data, clinical and mass characteristics detected by mammography among studied patients.

Variable	All patients (n=30)
Age (years)	
• Mean ± SD	45.9 ± 11.2
• (range)	(31 – 67)
Age groups (N. %)	
• <40	10 (33.3%)
• 40-50	11 (36.7%)
• 50-60	3 (10%)
• ≥ 60	6 (20%)
Family history (N. %)	
• No	18 (60%)
• Yes	12 (40%)
Site of lesion (N. %)	
• Left	12 (40%)
• Right	18 (60%)
Breast composition	
• ACR B	17 (56.7%)
• ACR C	13 (43.3%)
Mass shape	
• Irregular	9 (30%)
• Oval	12 (40%)
• Rounded	2 (6.7%)
• Ill defined	7 (23.3%)
Mass density	
• Iso-dense	7 (23.3%)
• Hyper-dense	23 (76.7%)
Mass margin	
• Well-circumscribed	14 (46.7%)
• Speculated	16 (53.3%)
Asymmetry	
• No	25 (83.3%)
• Yes	5 (16.7%)
Calcification	
• No	12 (40%)
• Micro, amorphous, scattered	13 (43.3%)
• Micro, pleomorphic, scattered	4 (13.3%)
• Macro-calcification	1 (3.3%)

Table (2): Mass characteristics detected by ultrasound among studied patients.

Variables (N. %)		**All patients (n=30)**
Mass shape	Irregular Oval Rounded	17 (56.7%) 10 (33.3%) 3 (10%)
Mass margin	Angular Macro-lobulated Micro-lobulated Speculated Well-circumscribed Well-defined	1 (3.3%) 1 (3.3%) 4 (13.3%) 12 (40%) 10 (33.3%) 2 (6.7%)
Mass echo-pattern	Hypoechoic Heterogeneous Hypoechoic heterogeneous Hypoechoic heterogeneous with area of cystic changes Hypoechoic with fluid level and internal echoes	9 (30%) 9 (30%) 10 (33.3%) 1 (3.3%) 1 (3.3%)
Calcification	No Punctate Scattered	13 (43.3%) 13 (43.3%) 4 (13.3%)
Posterior features	No Acoustic enhancement Acoustic shadowing	25 (83.3%) 2 (6.7%) 3 (10%)
Orientation of lesion	Non-parallel, taller than wider Parallel, wider than taller	16 (53.3%) 14 (46.7%)

Table (3): Shear wave elastography and histopathological findings among studied patients.

Variable	**All patients (n=30)**
Elasticity (Kpa) • Mean ± SD • Range	79.47 ± 44.34 (17.2 – 184.4)
Velocity (m/s) • Mean ± SD • Range	4.95 ± 1.8 (2.16 – 9.10)
Qualitative measurements (N. %) • Blue • Blue with spots like green • Yellow and red • Patchy green • Blue to green • Multicolored with red and orange • Multicolored with red, orange and blue	5 (16.7%) 7 (23.3%) 10 (33.3%) 1 (3.3%) 4 (13.3%) 2 (6.7%) 1 (3.3%)
Color pattern (N. %) • 1 • 2 • 3 • 4	5 (16.7%) 11 (36.7%) 11 (36.7%) 3 (10%)

Variable	All patients (n=30)
BI-RADS (N. %) • BI-RADS 3 • BI-RADS 4	 14 (46.7%) 16 (53.3%)
Benign • Fibroadenoma • Atypical fibroadenoma	 13 (43.3%) 1 (3.3%)
Malignant • Atypical ductal hyperplasia • Ductal carcinoma in situ • Infiltrating ductal carcinoma • Medullary carcinoma	 3 (10%) 2 (6.7%) 4 (13.3%) 7 (23.3%)

BI-RADS: Breast-Imaging Reporting and Data System

Table (4): Shear wave elasticity findings and BI-RADS system classification by different modalities among studied groups.

Variable		Benign lesions (n=14)	Malignant lesions (n=16)	P value
Elasticity (Kpa) • Mean ± SD • Range		 59.5 ± 27.8 (31.5 – 122)	 96.9 ± 49.4 (17.2 – 184)	**0.02**
Velocity (m/s) • Mean ± SD • Range		 4.09 ± 1.07 (2.28 -9.1)	 5.7 ± 2 (2.28 – 9.10)	**0.01**
Qualitative measurements (N. %) • Blue • Blue with spots like green • Yellow and red • Patchy green • Blue to green • Multicolored with red and orange • Multicolored with red, orange and blue		 4 (28.6%) 3 (21.4%) 2 (14.3%) 1 (7.1%) 4 (28.6%) 0 (0%) 0 (0%)	 1 (6.3%) 4 (25%) 8 (50%) 0 (0%) 0 (0%) 2 (12.5%) 1 (6.3%)	**0.02**
Color pattern (N. %) • 1 • 2 • 3 • 4		 4 (28.6%) 7 (50%) 3 (21.4%) 0 (0%)	 1 (6.3%) 4 (25%) 8 (50%) 3 (18.8%)	0.07
Mammography	BI-RADS 3 BI-RADS 4	12 (85.7%) 2 (14.3%)	5 (31.3%) 11 (68.8%)	**0.004**
Ultrasound	BI-RADS 3 BI-RADS 4	12 (85.7%) 2 (14.3%)	3 (18.8%) 13 (81.3%)	**<0.001**
SWE	BI-RADS 3 BI-RADS 4	12 (85.7%) 2 (14.3%)	2 (12.5%) 14 (87.5%)	**0.01**

*Mann-Whitney test, Chi-square test.
SWE: Shear wave elasticity, BI-RADS: Breast-Imaging Reporting and Data System.

Table (5): ROC curve analysis of elasticity value in differentiating benign from malignant lesions and comparison of the diagnostic accuracy of imaging techniques.

ROC curve analysis of elasticity value						
Variable	**Cutoff-point**	**Sensitivity (%)**	**Specificity (%)**	**PPV (%)**	**NPV (%)**	**AUC**
Elasticity value	80.2	68.75%	85.71%	84.62%	70.59%	0.748
Comparison of the diagnostic imaging techniques						
Variable	**Sensitivity (%)**		**Specificity (%)**		**Accuracy (%)**	**AUC**
Mammography	68.8%		85.7%		76.7%	0.772
Ultrasound	81.3%		85.7%		83.3%	0.835
Mammo + U/S + SWE	83.3%		91.7%		86.7%	0.942

ROC: Receiver Operating Characteristic Curve.

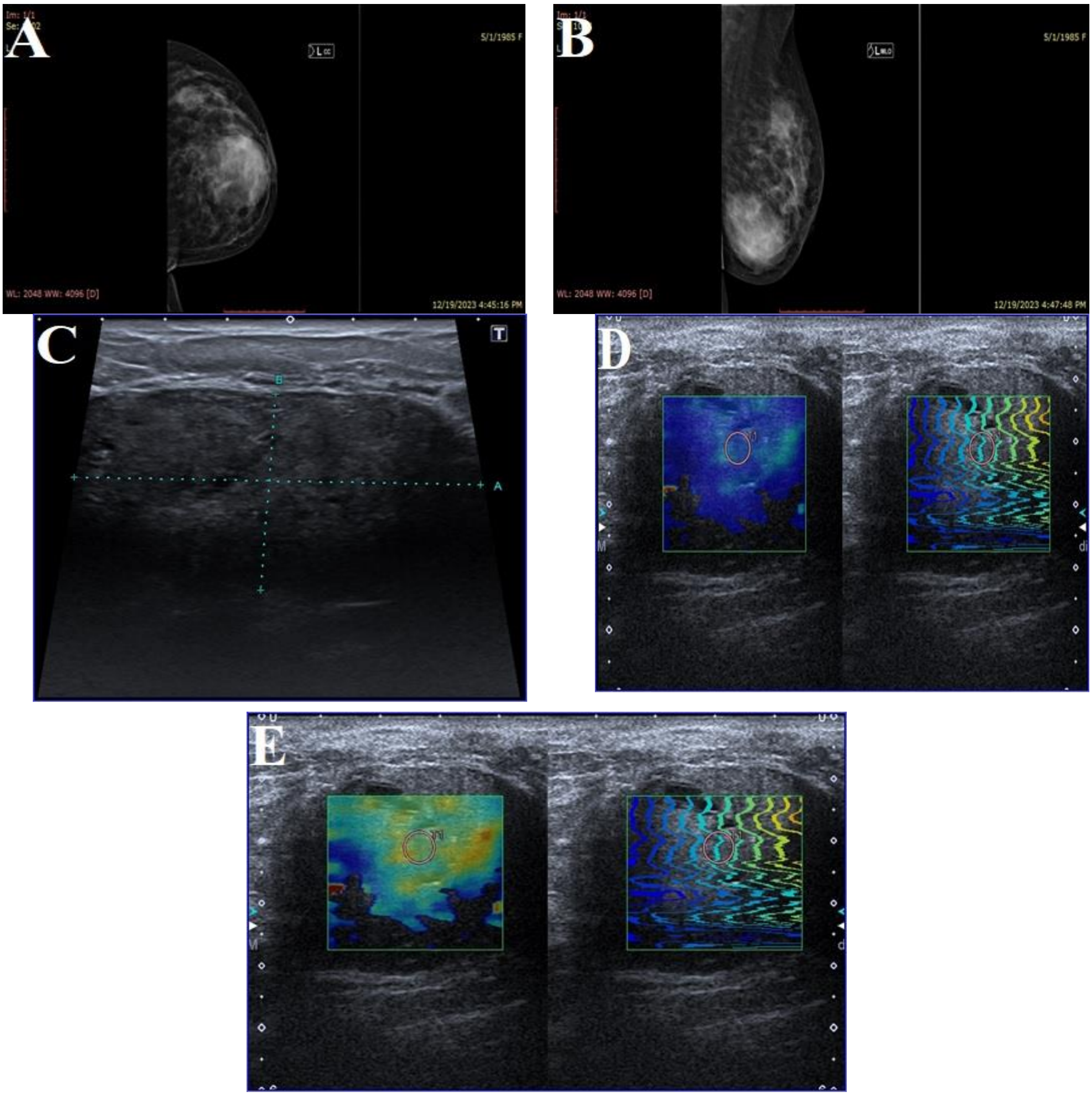

Figure 1: A 34-year-old female patient presented with left breast UOQ freely mobile palpable lump. (A, B) Digital Mammography show ACR C heterogeneous dense breast, Left UOQ well-circumscribed, rounded-shaped, hyperdense mass, **The mass was categorized as BI-RADS III.**
(C) Conventional ultrasound shows a well-circumscribed parallel hypoechoic solid mass measuring (64x31mm.) **The mass was categorized as BI-RADS III.** (D, E) Shearwave elastography: showing ;(D) elasticity mode (E mean = 40.0kPa; color mode, pattern 1) (E); speed mode (3.64 m/s). (benign lesion). Histopathology using FNAC: fibroadenoma

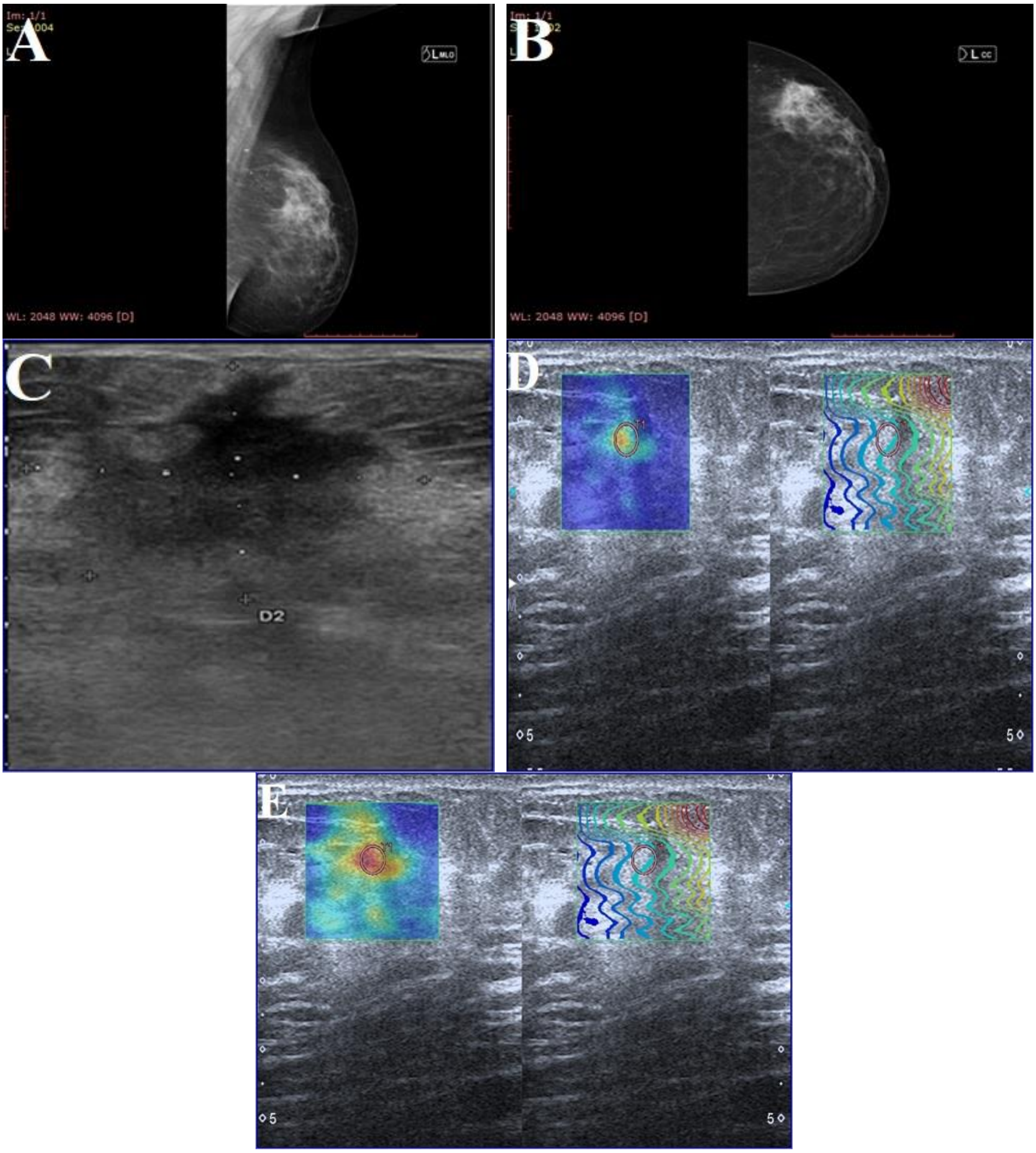

Figure 2: 37 years old female patient presented with left palpable breast mass and +ve family history. (A, B) Digital Mammography shows ACR B Scattered fibro-glandular parenchyma, Left UOQ irregular-shaped, spiculated hyperdense mass with microcalcifications. **The mass was categorized as BI-RADS IV.** (C) B-mode ultrasound shows an ill-defined, spiculated hypoechoic mass measuring (30x25 mm) **The mass was categorized as BI-RADS IV.** (D, E) shear-wave elastography: elasticity mode showing (D); elasticity mode (E mean =90.9 kPa; color mode: pattern 4) (E); speed mode (5.46 m/s) (malignant lesion). Histopathology using FNAC: infiltrating ductal carcinoma

DISCUSSION

BC is the most prevalent malignant tumor in women, with a frequency of up to 30% [9]. As a result, early detection and exact assessment of breast lesions are extremely important for improving patients' prognosis. US can detect breast nodules in both fatty and dense glandular tissues. Furthermore, it is the appropriate imaging tool to guide the following operations, increasing its efficacy in BC diagnosis [10]. SE creates an image depending on the tissue's relative deformation from an external (manual compression of the transducer) or case source. Measuring the amount of force or stress while compression is difficult, and absolute elasticity cannot be determined [11], whereas, BI-RADS can efficiently discriminate between benign and malignant tumors by classifying breast pictures [12].

The present cross-section study conducted in Zagazig University Hospitals on thirty patients with suspected breast lesions were subjected to mammography, US and SWE to determine the ability of US elastography in distinguishing between malignant and benign breast lesions and assess its added value to BI-RADS categorization using histologic examination as the reference standard.

Our studied sample presented with a mean age of 45.9 ± 11.2 years, 10 cases (33.3%) were less than 40 years old, and 6 patients (20%) were older than 60 years. Regarding family history, 12 patients (40%) had positive family history. As regards the site of lesion, 12 patients (40%) had left breast lesions while 18 patients (60%) had right breast lesions. While Chang *et al*., [11] conducted a prospective study in Seoul National University Hospitals on 150 females with a mean age of 47.8 years, who had breast lesions to evaluate the diagnostic efficacy of both SWE and SE in differentiating between benign and cancerous tumors.

Our results showed mass characteristics on mammography assessment, as regards mass shape, 9 masses (30%) had irregular shapes, while 12 masses (40%) had oval shapes, 2 masses (6.7%) were rounded and 7 masses (23.3%) were ill-defined. Regarding mass density 7 masses (23.3%) were isodense, while 23 masses (76.7%) were hyperdense, 14 masses were well-circumscribed and 16 masses were speculated, only five masses (16.7%) were asymmetric density. As regard calcification, only one mass (3.3%) had micro-calcifications, while 13 masses (43.3%) had micro-calcifications amorphous and scattered. While 4 masses (13.3%) had micro-calcifications pleomorphic and scattered. The most frequent location of lesions was at the right upper outer quadrant in 13 lesions (43.3%), followed by 8 (26.7%) lesions at the left upper outer quadrant, and the least frequent location of lesions was at the right lower outer quadrant in 2 patients (6.7%).

Our results showed mass characteristics on ultrasound, 56.7% were irregular in shape, while 10 masses (33.3%) were oval and only 3 masses (10%) were rounded, 40% had speculated margin, 33.3% were well-circumscribed, 13.3% were micro-lobulated, 6.7% were well defined and 3.3% were macro-lobulated. 33.3% were hypoechoic heterogeneous, while 30% were hypoechoic, 30% were heterogeneous, 3.3% were hypoechoic heterogeneous with area of cystic changes and 3.3% were hypoechoic with fluid level and internal echoes. The most frequent calcification was punctuated (43.3%), and scattered calcification (13.3%), while 43.3% of masses showed no calcification.

The current study revealed shear wave elastography findings among studied cases, the mean elasticity and velocity detected were 79.47 ± 44.34, and 4.95 ± 1.8 respectively, and the most frequent color detected was yellow and red (33.3%), followed by blue with spots like green in 23.3%, then blue in 16.7%, blue to green in 4 (13.3%), multicolored with red and orange in 2 (6.7%), patchy green and multicolored with red, orange and blue in 1 (3.3%). In contrast to our results, a study done by Lee *et al*., [4] to assess the additional value of SWE in the assessment of breast masses identified by screening US imaging, found that the stiffness color was red for nine masses (5.7%), green to orange for 25 masses (15.7%), light blue for 47 masses (29.6%), and the maximum was dark blue for 78 masses (49.0%).

Regarding Elasticity and velocity detected by SWE, they were significantly elevated among cancerous lesions compared to benign lesions (P =0.02, and 0.01, respectively). There was a substantial variance between the qualitative measurements between benign and cancerous masses (P =0.02). Consistent with our results Lee *et al*., [4] stated that benign masses had lower quantitative elasticity values (41.4 ± 6 32.1 kPa) than malignant masses (maximum elasticity, 119.0 ± 6 52.2 kPa) (P <0.001). Another study carried out by Chang *et al*., [11] showed that on B-mode US, the mean size of benign lesions was 1.1 ± 0.8 cm, while of cancerous masses was 2.3 ± 1.3 cm. SWE revealed that benign lesions had a mean elasticity of 47.3 ± 44.3 kPa, while malignant lesions had a mean elasticity value of 150.0 ± 52.3 kPa (p <

0.0001). Regarding the ultrasound-detected cancer characteristics, the results found by Berg *et al*., [13] investigation found that red color of 160 kPa or above was utilized to upgrade BI-RADS 3 masses diagnosed by employing diagnostic US. Because BI-RADS category 3 lesions have a very low malignancy incidence in the screening scenario, there may be debates over whether or not to upgrade these lesions to 4a category based on elevated values of elasticity on SWE for screening US-observed lesions [14].

The current findings proved that using elasticity values of SWE at a cut-off point of 80.2, it had a sensitivity of 68.75%, specificity of 85.71% and AUC of 0.748, while that of the velocity used at a cut-off point of 5.1, had a sensitivity of 68.75%, specificity of 85.71%, AUC of 0.772, and PPV of 84.6% for both. This was agreed with Chang *et al*., [11] who evaluated both SWE and SE in the differentiation of breast lesions and showed similar overall diagnostic performance (AUC, 0.928 vs 0.943). The sensitivity of SWE was greater than that of SE (95.8% vs. 81.7%; p = 0.002), and the specificity of SE was greater than that of SWE (93.7% vs. 84.8%; p = 0.016) when the optimal cutoff points 80 kPa in SWE and an elasticity score between 3 and 4 in SE were employed. Nevertheless, the ability to differentiate between cancerous and benign tumors was enhanced by the combination of B-mode US and elastography (SE or SWE). Also, in accordance with our results, many studies showed the same cutoff points, and the mean elasticity scores and SWE values [11,15]. It has been proposed that elastography can assist in differentiating between benign tumors and suspicious solid masses, hence minimizing false-positive results [16]. In numerous earlier studies, the addition of elastography improved diagnostic efficiency by increasing specificity in differentiating tumors from cancers [17,18].

From the total 14 benign lesions, mammography classified 12 lesions (85.7%) as BI-RADS 3 and only 2 lesions (14.3%) were BI-RADS 4, while 68.8% of the malignant lesions were BI-RADS 4 and 31.3% were BI-RADS 3. As regards ultrasound, from the total 14 benign lesions, ultrasound classified 12 lesions (85.7%) as BI-RADS 3 and 2 lesions (14.3%) were BI-RADS 4, while (81.3%) of the malignant lesions were BI-RADS 4 and 3 lesions (18.8%) were BI-RADS 3. SWE classified 12 lesions (85.7%) from the total 14 benign lesions as BI-RADS 3 and classified 2 lesions (14.3%) as BI-RADS 4, while 87.5% of the malignant lesions were classified as BI-RADS 4 and 12.5% were classified as BI-RADS 3.

There may be debates concerning promoting BI-RADS 3 lesions to 4a based on great values of elasticity on SWE for screening US-detected lesions, even if the malignancy incidence of these lesions is by definition extremely low in the screening scenario [14,19]. Similar to our findings, other papers have utilized SWE in conjunction with B-mode US imaging to detect invasive breast tumors that appear benign [11,13].

Mammography showed a sensitivity of 68.8% and specificity of 85.7%, while ultrasound showed a sensitivity of 81.3%, and specificity of 85.7%. Combining conventional clinical imaging with SWE results reported sensitivity (83.3%), and specificity (91.7%). This was in consistent to previous investigations by Kim *et al*., [20] and Berg *et al*., [11], who revealed that the added SWE characteristics to the B-mode US-based BI-RADS analysis also demonstrated a rise in specificity, and can appropriately diagnose 100% of malignancies for biopsy by utilizing a mix of imaging techniques. Sravani *et al*., [21] determined that combining B-mode US and SWE for imaging produced the best results in terms of sensitivity and NPV, which was 100%. Sensitivity increased significantly in this trial, going from 90.6% to 100%. However, with combined imaging, the specificity dropped dramatically from 90% by B-mode US to 72.2%. With a cut-off value of 3.43 m/s (90%), B-mode US and SWV had the maximum specificity. At 90.7%, the SWV displayed the highest PPV.

Limitations:
There are certain limitations in our study. Firstly, the sample size of 30 participants may be relatively small, which could impact the statistical power and precision of the results. A larger sample size might have provided more robust conclusions and allowed subgroup analyses to establish the added value of ultrasound (US) elastography to the BI-RADS classification system in the categorization of ambiguous breast lesions following mammography as a first step. Secondly, the study was conducted at a single center, which may limit the generalizability of the findings to other populations or healthcare settings. Variations in patient disease severity, or healthcare practices in different settings could affect the performance of breast US and breast elastography. Further studies are needed to confirm our findings.

Declaration of interest:
The authors report no conflicts of interest.
Funding information:

This study was not supported by any source of finding.

CONCLUSION

SWE is a simple method with great diagnostic accuracy that can be easily combined with a B-mode US examination in the same session, increasing its specificity. It demonstrated usefulness in reducing the frequency of unnecessary biopsies.

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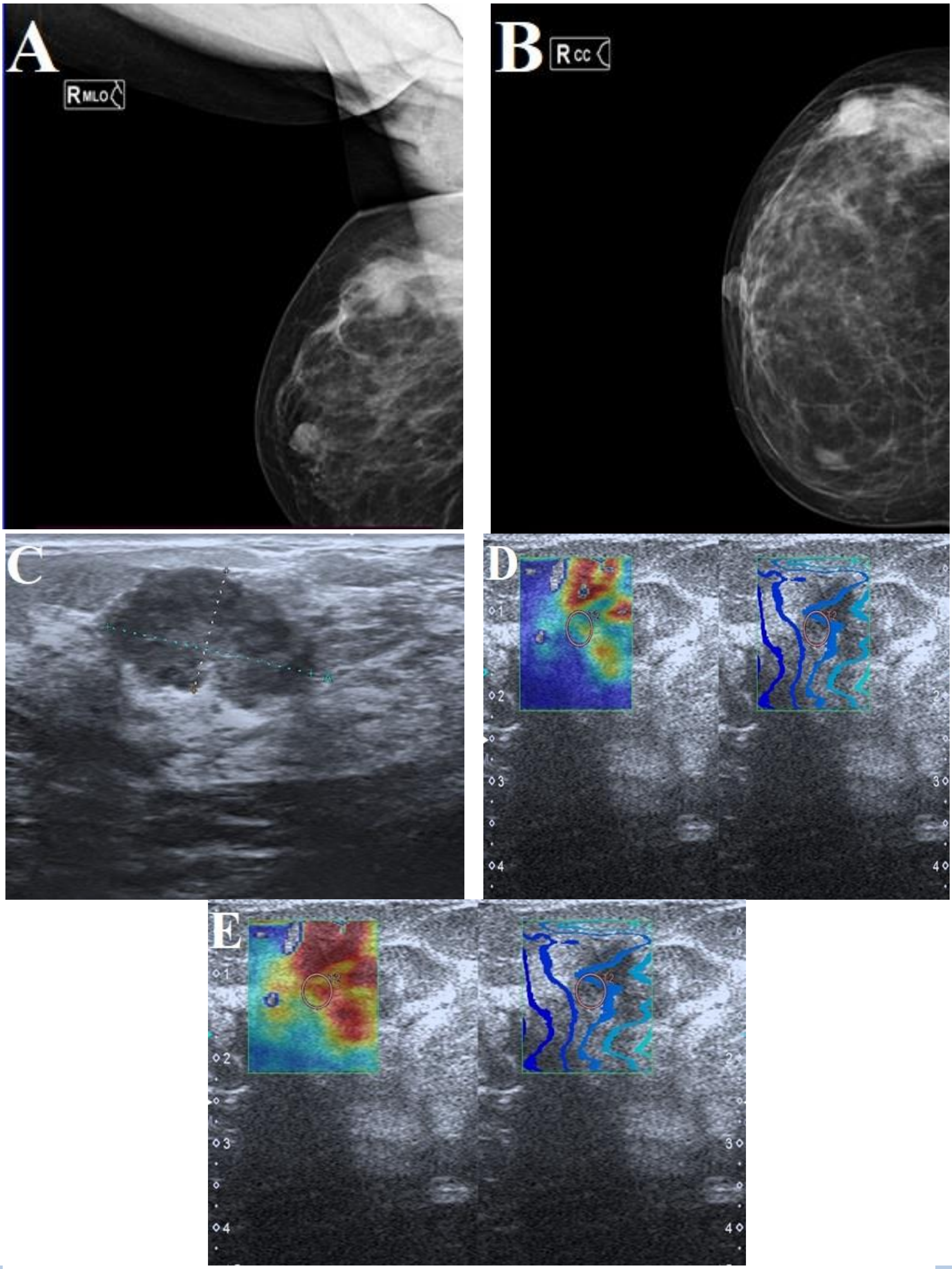

Supplementary Figure (1): 31 years old female patient presented with right breast mass. (A, B) Digital Mammography shows. ACR C heterogeneous dense breast, Right UIQ ill-defined, hyperdense mass with obscured margin, **the mass was categorized as BI-RADS IV.** (C) B-mode ultrasound shows an irregular shaped spiculated hypoechoic heterogenous mass with posterior acoustic enhancement measuring (25x 15 mm) **The mass was categorized as BI-RADS IV.** (D, E) shear-wave elastography: propagation mode showing (D); elasticity mode (E mean =73.3 kPa; color mode: pattern 3) (E); speed mode (4.89 m/s) (malignant lesion), Histopathology using FNAC: infiltrating lobular carcinoma.

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