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ORIGINAL ARTICLE

The Role of Sonoelastography in Characterization of Breast Lesions: A Prospective Comparative Study

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ABSTRACT:
Background: Breast cancer is one of the most common malignancies affecting women worldwide. Accurate characterization of breast lesions is crucial for early diagnosis and improved patient outcomes. This study aimed to evaluate the diagnostic performance of shear wave elastography (SWE) compared to conventional B-mode ultrasonography (US) in differentiating benign from malignant breast lesions. **Methods:** This prospective study included 120 women with 142 breast lesions who underwent conventional B-mode US and SWE examination. Quantitative elasticity values (maximum, mean, and minimum elasticity) and qualitative color patterns were evaluated. Histopathological examination following core needle biopsy or surgical excision served as the reference standard. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated for B-mode US, SWE, and their combination. **Results:** Of the 142 lesions, 58 (40.8%) were malignant and 84 (59.2%) were benign based on histopathology. The mean maximum elasticity value was significantly higher in malignant lesions (180.5 ± 43.2 kPa) compared to benign lesions (46.3 ± 28.7 kPa) ($p<0.001$). Using a cutoff value of 82.3 kPa, SWE demonstrated a sensitivity of 94.8%, specificity of 89.3%, PPV of 85.9%, NPV of 96.2%, and accuracy of 91.5%. Conventional B-mode US showed a sensitivity of 93.1%, specificity of 78.6%, PPV of 75.0%, NPV of 94.3%, and accuracy of 84.5%. When both techniques were combined, the specificity improved to 94.0% and accuracy to 94.4%. **Conclusion:** SWE significantly improves the specificity and accuracy of breast lesion characterization compared to conventional B-mode US alone. The combination of both techniques provides optimal diagnostic performance for breast lesion evaluation, potentially reducing unnecessary biopsies of benign lesions.
Keywords: Sonoelastography; Shear wave elastography; Breast cancer; Ultrasonography; Breast lesions; Diagnostic accuracy

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INTRODUCTION

Breast cancer is the most frequently diagnosed cancer and a leading cause of cancer-related deaths among women globally, with an estimated 2.3 million new cases annually.[1] Early and accurate diagnosis is essential for improving survival rates and overall patient outcomes. Conventional imaging modalities, including mammography and B-mode ultrasonography (US), while widely used for screening and diagnosis, have inherent limitations in differentiating between benign and malignant breast lesions.[2,3]

B-mode US has high sensitivity but moderate specificity for breast lesion characterization, resulting in a high number of false positives and unnecessary biopsies.[4] The Breast Imaging Reporting and Data System (BI-RADS) classification for US has improved standardization but still relies on morphological features that may overlap between benign and malignant lesions.[5]

Sonoelastography is an evolving ultrasound-based technique that evaluates tissue stiffness, based on the principle that malignant tissues tend to be stiffer than benign tissues due to desmoplastic reaction and increased cellularity.[6] Two main sonoelastography techniques are currently available: strain elastography (SE) and shear wave elastography (SWE). While SE provides qualitative and semi-quantitative assessment of tissue elasticity, SWE offers quantitative measurements in kilopascals (kPa) or meters per second (m/s), potentially allowing for more objective evaluation.[7,8]

Previous studies have reported varying diagnostic performances of SWE, with sensitivities ranging from 78.5% to 98.6% and specificities from 81.7% to 95.4%.[9–12] These variations may be attributed to differences in study populations, equipment, and interpretation criteria. Therefore, this study aimed to evaluate the diagnostic performance of SWE in comparison to conventional B-mode US in characterizing breast lesions in our clinical setting, and to assess whether combining both techniques could improve diagnostic accuracy.

MATERIALS AND METHODS

Study Population

This prospective study was conducted at University Medical Center between January 2023 and December 2023. The study protocol was approved by the Institutional Review Board (IRB approval number:

UMCIRB-2022-156), and written informed consent was obtained from all participants.

Women aged ≥18 years with breast lesions detected on clinical examination, mammography, or screening US were eligible for inclusion. Exclusion criteria were: (1) previous surgery or treatment in the area of the lesion, (2) breast implants, (3) pregnancy or lactation, and (4) lesions with indeterminate histopathology results.

Image Acquisition and Interpretation

All patients underwent conventional B-mode US and SWE using a high-frequency linear transducer (9-15 MHz) on a SuperSonic Imagine Aixplorer system (SuperSonic Imagine, Aix-en-Provence, France). Images were obtained by two radiologists with more than 5 years of experience in breast imaging and at least 1 year of experience with SWE.

B-mode US Assessment

Lesions were evaluated according to the American College of Radiology BI-RADS lexicon (5th edition).[5] Lesion size, shape, orientation, margin, echo pattern, posterior features, and presence of calcifications were documented. Each lesion was assigned a final BI-RADS category (2-5). For statistical analysis, BI-RADS categories 2 and 3 were considered benign, while categories 4 and 5 were considered suspicious or malignant.

SWE Assessment

SWE was performed with minimal transducer pressure to avoid compression artifacts. The transducer was held stable for at least 3 seconds to allow for image stabilization. For each lesion, three measurements were obtained, and the mean values were recorded.

Quantitative SWE parameters included maximum elasticity (Emax), mean elasticity (Emean), and minimum elasticity (Emin) values in kPa. Qualitative assessment included color pattern classification: Pattern 1 (homogeneously soft, entirely blue); Pattern 2 (mostly soft with some stiff areas, mostly blue with some red/yellow areas); Pattern 3 (moderately stiff, mostly red/yellow); and Pattern 4 (very stiff, homogeneously red). Patterns 1 and 2 were considered indicative of benign lesions, while patterns 3 and 4 were considered indicative of malignant lesions.

Histopathological Analysis

All lesions underwent histopathological examination following ultrasound-guided core needle biopsy (14-gauge) or surgical excision. A minimum of four cores was obtained for each lesion during biopsy. The histopathological diagnosis served as the reference standard.

Statistical Analysis

Statistical analysis was performed using SPSS software (version 26.0, IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation. Categorical variables were expressed as frequencies and percentages.

The independent t-test was used to compare elasticity values between benign and malignant lesions. Receiver operating characteristic (ROC) curve analysis was performed to determine the optimal cutoff values for quantitative elastographic parameters. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated for B-mode US, SWE, and their combination. McNemar's test was used to compare diagnostic performances. A p-value <0.05 was considered statistically significant.

RESULTS

Patient and Lesion Characteristics

A total of 120 women (mean age 48.7 ± 13.2 years, range 22-76 years) with 142 breast lesions were included in the study. Based on histopathology, 58 lesions (40.8%) were malignant and 84 (59.2%) were benign. Table 1 summarizes the histopathological diagnoses of the lesions.

Table 1: Histopathological Classification of Breast Lesions

Lesion Type	n (%)
Benign Lesions	84 (59.2%)
Fibroadenoma	38 (26.8%)
Fibrocystic changes	16 (11.3%)
Benign phyllodes tumor	5 (3.5%)
Adenosis	8 (5.6%)
Papilloma	9 (6.3%)
Granulomatous mastitis	4 (2.8%)
Fat necrosis	4 (2.8%)
Malignant Lesions	58 (40.8%)
Invasive ductal carcinoma	37 (26.1%)
Invasive lobular carcinoma	8 (5.6%)
Ductal carcinoma in situ	7 (4.9%)
Mucinous carcinoma	3 (2.1%)
Papillary carcinoma	2 (1.4%)

Metaplastic carcinoma	1 (0.7%)

The mean lesion size was 16.4 ± 7.8 mm (range 5-42 mm). Malignant lesions (mean 18.9 ± 8.6 mm) were significantly larger than benign lesions (mean 14.7 ± 6.8 mm) (p=0.002).

B-mode US Findings

Based on B-mode US, 77 lesions were classified as BI-RADS 4 or 5 (suspicious or malignant), of which 54 were confirmed malignant on histopathology. Of the 65 lesions classified as BI-RADS 2 or 3 (probably benign), 4 were found to be malignant. The sensitivity, specificity, PPV, NPV, and accuracy of B-mode US were 93.1%, 78.6%, 75.0%, 94.3%, and 84.5%, respectively.

SWE Findings

The mean Emax, Emean, and Emin values were significantly higher in malignant lesions compared to benign lesions (Table 2).

Table 2: Quantitative SWE Parameters in Benign and Malignant Breast Lesions

Parameter	Benign Lesions (n=84)	Malignant Lesions (n=58)	p-value
Emax (kPa)	46.3 ± 28.7	180.5 ± 43.2	<0.001
Emean (kPa)	34.2 ± 19.3	145.8 ± 38.7	<0.001
Emin (kPa)	21.5 ± 13.6	92.3 ± 35.9	<0.001

ROC curve analysis identified the optimal cutoff values for Emax, Emean, and Emin as 82.3 kPa, 68.5 kPa, and 45.2 kPa, respectively. The areas under the ROC curve (AUC) were 0.957, 0.942, and 0.923, respectively. Figure 1 shows the ROC curves for the quantitative SWE parameters.

Using the Emax cutoff value of 82.3 kPa, SWE demonstrated a sensitivity of 94.8%, specificity of 89.3%, PPV of 85.9%, NPV of 96.2%, and accuracy of 91.5%.

Regarding qualitative assessment, 75 lesions showed Patterns 3 or 4, of which 56 were malignant. Of the 67 lesions with Patterns 1 or 2, 2 were malignant. The qualitative SWE assessment showed a sensitivity of 96.6%, specificity of 87.5%, PPV of 83.8%, NPV of 97.5%, and accuracy of 91.4%.

Combined B-mode US and SWE

When B-mode US and SWE were combined, considering a lesion malignant if it was classified as suspicious or malignant by both techniques, the specificity improved to 94.0% and accuracy to 94.4%, while sensitivity remained high at 94.8%. The PPV increased to 91.7%, and the NPV was 96.3%.

The comparison of diagnostic performances of B-mode US, SWE, and their combination is presented in Table 3.

Table 3: Comparison of Diagnostic Performances

Parameter	B-mode US	SWE	Combined	p-value*
Sensitivity (%)	93.1	94.8	94.8	0.083
Specificity (%)	78.6	89.3	94.0	<0.001
PPV (%)	75.0	85.9	91.7	<0.001
NPV (%)	94.3	96.2	96.3	0.214
Accuracy (%)	84.5	91.5	94.4	<0.001

*p-value for comparison between B-mode US and combined approach

False-Positive and False-Negative Cases

SWE yielded false-positive results in 9 cases (10.7% of benign lesions), including 4 fibroadenomas, 2 papillomas, 2 cases of granulomatous mastitis, and 1 case of fat necrosis. False-negative results occurred in 3 cases (5.2% of malignant lesions), including 2 ductal carcinomas in situ and 1 mucinous carcinoma.

DISCUSSION

This study demonstrates that SWE significantly improves the specificity and accuracy of breast lesion characterization compared to conventional B-mode US alone. The combination of both techniques provided the highest diagnostic performance, with an accuracy of 94.4% and specificity of 94.0%.

The mean elasticity values were significantly higher in malignant lesions compared to benign lesions, consistent with previous studies.[13–15] Berg et al.[13] reported mean maximum elasticity values of 179.1 kPa for malignant lesions and 56.3 kPa for benign lesions, which closely align with our findings (180.5 kPa and 46.3 kPa, respectively). The optimal cutoff value for maximum elasticity in our study was 82.3 kPa, similar to values reported in other studies ranging from 80 to 85 kPa.[14–16]

Our study found SWE to have superior specificity (89.3% vs. 78.6%) and accuracy (91.5% vs. 84.5%) compared to B-mode US, with comparable sensitivity (94.8% vs. 93.1%). These findings support the results of a meta-analysis by Liu et al.,[17] which reported a pooled sensitivity of 88.4% and specificity of 88.1% for SWE. The improved specificity of SWE could potentially reduce unnecessary biopsies of benign

lesions, thereby decreasing patient anxiety, discomfort, and healthcare costs.

The combination of B-mode US and SWE further improved diagnostic performance in our study, with increased specificity (94.0%) and accuracy (94.4%) compared to either technique alone. This finding is consistent with previous studies that have advocated for a complementary approach.[18–20] Lee et al.[18] reported that adding SWE to B-mode US increased diagnostic specificity from 78.7% to 95.5% without a significant loss in sensitivity.

In our study, false-positive SWE results occurred mainly in lesions with increased stiffness due to fibrosis (fibroadenomas) or inflammation (granulomatous mastitis). False-negative results were observed in ductal carcinoma in situ and mucinous carcinoma, which typically have a softer consistency compared to other malignant subtypes. These findings highlight the importance of interpreting elastographic findings in conjunction with B-mode features and clinical context.

This study has several strengths, including its prospective design, the use of histopathology as the reference standard for all lesions, and the evaluation of both quantitative and qualitative SWE parameters. However, there are limitations to acknowledge. First, the single-center design may limit the generalizability of our findings. Second, interobserver variability was not assessed, although measures were taken to standardize the imaging technique. Third, the sample size, while adequate for the primary analysis, may be insufficient for subgroup analyses based on histological subtypes.

CONCLUSION

SWE significantly improves the characterization of breast lesions compared to conventional B-mode US alone, with superior specificity and accuracy. The combination of both techniques provides optimal diagnostic performance, potentially reducing unnecessary biopsies while maintaining high sensitivity for malignancy detection. Future large-scale, multicenter studies are warranted to validate these findings and establish standardized elastographic criteria for breast lesion assessment.

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