Original Article

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Diagnostic Accuracy of Shear Wave Elastography in Diagnosing Malignant Breast Lesions Taking Histopathology as Gold Standard

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ABSTRACT

Objective: To assess the diagnostic accuracy of shear wave elastography (SWE) in detecting malignant breast lesions, using histopathology as the gold standard.
Methodology: This cross-sectional validation study was conducted in the Department of Diagnostic Radiology, Combined Military Hospital, Lahore, from January to October 2024. A total of 170 female patients aged 20–60 years, regardless of marital status, with suspected breast lesions persisting for more than one month and measuring >1 cm on conventional ultrasonography, were included. All patients underwent conventional B-mode ultrasonography followed by SWE. The findings of SWE were then compared with histopathology results to determine its diagnostic accuracy.
Results: The mean age of the participants was 45.47 ± 8.73 years. The mean lesion size was 3.24 ± 1.36 cm, while the mean disease duration was 12.92 ± 5.81 weeks. SWE identified malignant lesions in 57 patients (33.5%), whereas histopathology confirmed malignancy in 60 patients (35.3%). The sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy of SWE, using histopathology as the gold standard, were 84.21%, 89.38%, 80.0%, 91.82%, and 87.65%, respectively. The incidence of breast cancer in the study population was 35.5%.
Conclusion: Shear wave elastography is a simple, cost-effective, and non-invasive imaging modality with high diagnostic accuracy for detecting malignant breast lesions.
Keywords: Breast cancer; Breast lesions; Diagnostic accuracy; Histopathology; Shear wave elastography.

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Introduction

Breast cancer is one of the most frequently diagnosed cancer globally, with approximately 2.3 million new cases each year.[1] In 2023, it accounts for 30% of all newly diagnosed cancer cases in united states.[2] The disease burden has shown rising trend over the years with an annual rate of 4 to 6%.[1] The epidemiological burden is relatively higher in Asian countries due to changes in human development indices and epidemiological transitions. As per Asia-global cancer observatory, there were 1.1 million newly diagnosed breast cancer cases in Asia.[3] According to National Cancer Registry of Pakistan: First Comprehensive Report of Cancer Statistics 2015-2019, breast cancer was the most commonly diagnosed malignancy among female with almost half of the total cancer cases in Pakistan.[4]

The breast cancer has become a significant public health concern. Early diagnosis and classification are the vital component of an effective management. A spectrum of diagnostic algorithms based on imaging and molecular biotechnology have been developed. Conventional B-mode ultrasonography (US) along with mammography has been employed as initial screening tools for evaluation of suspected breast lesion. The Breast Imaging Reporting and Data System (BI-RADS®) developed to standardized breast lesion characterization helps in better risk assessment. [5] Despite this, some breast lesion exhibit indeterminate or overlapping features warranting further histopathological correlation to exclude malignancy. It has been observed that BI-RADS® 3 and 4 lesions have low specificity, leading to unnecessary biopsies.[6] To avoid this and to improve diagnostic characterization of the lesion, US elastography as an alternative, non-invasive imaging approach has been introduced.

US elastography offers critical insight into tissue elasticity, essential for understanding the texture and density of tissue, thus facilitating the diagnosis of various entities like fibrosis and malignancy. Standard US elastography evaluates tissue compression mechanics together with transducer to evaluate tissue elasticity and stiffness. The tissue response to mechanical deformation or vibration is analyzed and generated as a quantifiable color-coded map.[7] Two distinct forms of elastography are currently in practice; strain elastography (SE) and shear wave elastography (SWE). SE is more operator dependent and lack the quantification of elasticity modulus, while SWE offers more quantitative data (usually measured in kilopascals).[8]

A number of studies has evaluated the efficacy of SWE in characterizing breast lesions and to distinguish benign from malignant ones, as malignant lesions generally demonstrate higher stiffness as compared to benign.[6, 8] Evidence suggests that SWE, when used as an adjunct to conventional US, resulted in better specificity of breast US without effecting sensitivity, thereby decreasing the number of benign biopsies for BI-RADS® 4 and 5 lesions.[9] The reported diagnostic accuracy (sensitivity and specificity) of SWE in differentiating benign and malignant breast lesions is very high.[10] While SWE has shown promising diagnostic accuracy, most studies focus on Western populations, with limited data from our region. Given the high burden of breast cancer locally, this study aims to evaluate the diagnostic accuracy of SWE in distinguishing benign from malignant breast lesions in our local population. The findings may support its role in reducing unnecessary biopsies and optimizing breast cancer diagnostics in resource-limited settings.

Methodology

This cross-sectional validation study was conducted in the Department of Diagnostic Radiology, Combined Military Hospital, Lahore, from January to October 2024, over a period of one year. Approval was obtained from the hospital's Research Review Board prior to the commencement of the study (Research Review Board Number: 583/2024). Informed written consent was obtained from all participants.

A total of 170 patients meeting the inclusion and exclusion criteria were enrolled. The sample size was calculated using a sensitivity and specificity calculator, based on a 95% confidence level, 10% desired precision, a prevalence of malignant breast lesions of 64.1%[8], and reported sensitivity and specificity of SWE in diagnosing malignant breast lesions of 88.1% and 80.3%, respectively[11]. Patients were selected using a non-probability consecutive sampling technique.

Female patients aged 20–60 years, irrespective of marital status, presenting with a breast lesion persisting for more than one month and measuring >1 cm on conventional ultrasonography were included. Lesions exhibiting features such as spiculations, punctate calcifications, duct extension, and non-compressibility were eligible for the study.

Patients were excluded if they had exclusively cystic lesions on conventional ultrasonography, breast implants, lesions located less than 5 mm from the skin surface (superficial lesions), biopsy-confirmed breast cancer, or if they were undergoing treatment (chemotherapy or hormonal therapy).

Relevant clinical data were recorded for all patients. A trained radiologist with expertise in breast imaging performed conventional ultrasonography followed by SWE using a GE Logiq P7 ultrasound system. SWE images were obtained without applying transducer pressure to avoid altering stiffness measurements. Regions of interest (ROIs) were placed on the lesion and surrounding tissue to obtain quantitative stiffness measurements in kilopascals (kPa). Elasticity values were displayed on a color scale ranging from dark blue (lowest stiffness) to red (highest stiffness), with a range of 0 to 180 kPa. Multiple measurements were taken, and mean elasticity values were automatically calculated. A mean elasticity value of 45.3 kPa was used as the cutoff for differentiating benign from malignant breast lesions[12]. All patients subsequently underwent histopathological evaluation for comparison with SWE findings.

All collected data, including age, lesion size, lesion duration, SWE findings, and histopathology results, were analyzed using SPSS Version 26.0. Mean SD were calculated for continuous variables (age, lesion size, and lesion duration), while categorical variables (SWE and histopathology findings) were summarized as frequencies and percentages. A 2×2 contingency table was used to calculate the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy of SWE, using histopathology as the gold standard. Stratification was performed for age, lesion duration, and lesion size. Statistical significance was determined using the Chi-square test, with a p-value <0.05 considered statistically significant.

Results

The mean age of the patients was 45.47 ± 8.73 years (range: 22-60 years). The mean size of the breast lesion was 3.24 ± 1.36 cm (range: 1.50-6.50 cm) while mean duration of the disease was 12.92 ± 5.81, ranging from 4 to 24 weeks (Table I).

Table I: Age of patients and characteristics of breast lesions presented as mean ± SD. (n=170)

Variable	**Values, (Mean ± SD)**
Age (years)	45.47 ± 8.73
Size of lesion (cm)	3.24 ± 1.36
Duration of lesion (weeks)	12.92 ± 5.81

SWE diagnosed 57 (33.5%) patients as having malignant lesions, whereas histopathology confirmed malignant breast lesions in 60 (35.3%). Of age, size and duration of lesion, only size of the lesion has shown to be statistically significant associated with SWE findings with p-value of <0.001 (Table II). The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of SWE was calculated using 2x2 table, taking histopathology as gold standard, which came out to be 84.21%, 89.38%, 80.0%, 91.82% and 87.65% respectively (Table III). The overall incidence of breast cancer in our studied population was determined to be 35.5%.

Table II: Stratification of age, size and duration of lesion with incidence of malignancy on SWE (n=170)

Variable	**Shear Wave Elastography Findings, n (%)**		**p-value**
	Benign n=113 (66.5%)	**Malignant n=57 33.5%)**	
Age (years)			0.743
20 – 30	3 (60.0%)	2 (40.0%)	
31 – 40	37 (72.54%)	14 (27.45%)	
41 – 50	41 (64.06%)	23 (35.93%)	
51 – 60	32 (64.0%)	18 (36.0%)	
Size of lesion			<0.001
(cm)	31 (75.06%)	10 (24.39%)	
0.5 – 2	54 (72.0%)	21 (28.0%)	
2.1 – 3.5	21 (50.0%)	21 (50.0%)	
3.6 – 5.0	7 (33.33%)	14 (66.66%)	
5.1 – 6.5			
Duration of			0.701
lesion (weeks)	37 (64.91%)	20 (35.08%)	
0 – 8	45 (70.03%)	19 (29.68%)	
9 – 16	31 (63.26%)	18 (36.73%)	
17 – 24			

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51 – 60	32 (64.0%)	18 (36.0%)	
Size of lesion			<0.001
(cm)		10 (2	
0.5 – 2	31 (75.06%)	4.39%)	
2.1 – 3.5	54 (72.0%)	21 (28.0%)	
3.6 – 5.0	21 (50.0%)	21 (50.0%)	
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lesion (weeks)			
0 – 8	37 (64.91%)	20 (35.08%)	
9 – 16	45 (70.03%)	19 (29.68%)	
17 – 24	31 (63.26%)	18 (36.73%)	
Sensitivity = 84.21%,		Specificity = 89.38%	
Positive predictive value = 80.0%			
Negative predictive value = 91.82%			
Diagnostic accuracy = 87.65%			

Discussion

Our study assessed the diagnostic efficacy of SWE in distinguishing benign and malignant breast lesions, with histopathology as gold standard, and has shown promising results, yielding a sensitivity of 84.21%, specificity of 89.38%, positive predictive value of 80.0%, negative predictive value of 91.82%, and an overall diagnostic accuracy of 87.65%. The observed high specificity and negative predictive value highlights its significance in ruling out malignancies, ultimately lessening the need for unnecessary biopsies. The relatively low positive predictive value represents the challenges in diagnosing benign lesions exhibiting features overlapping with malignancy, a finding already reported and published in the literature and discussed in subsequent sections.

Our study has shown consistent and comparable results reported by different authors. Aiman Ashraf et al. has conducted similar study evaluating the role of SWE in suspicious breast lesions. They reported a specificity of 80.3%, sensitivity of 88.1%, positive predictive value of 88.8%, negative predictive value of 79.03% and diagnostic accuracy of 85.29 %, closely reflecting our findings.[11] Hina Rehman et al. studied the diagnostic role of elastography for malignant breast lesions.[13] They found that age and size of lesions are strongly associated with chances of malignancy on elastography. While in our study, only the size of lesion has shown significant association with incidence of malignancy. Rafia Shahzad et al. has stated comparable diagnostic accuracy, with sensitivity of 95.8% with a specificity of 85.7%.[12] The slight variation can be due to lesion size, inter-observer variability or population heterogeneity.

Pillai A et al. performed a systemic review and meta-analysis evaluating the diagnostic value of SWE in breast lesion characterization.[14] The found a summarized sensitivity and specificity of 85% and 87%, respectively. Elaggan AM et al. addressed a relatively higher diagnostic accuracy of 90% for SWE in BI-RADS® 3 and 4 lesions.[15] This can be attributed to size of the lesion, operator expertise or population selection criteria. Our study went through comparison with diagnostic study done by Chamming's F et al. who reported a sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of 89%, 69%, 100%, 80%, 100% and 86% respectively.[16] Pesce et al. studied the diagnostic accuracy of SWE using QelaXtoTM software with cut-off value of 50 kPa. The reported a sensitivity of 87% with false positive rate of 17.65%.[17] Similarly, a meta-analysis by Chen L et al. stated a pooled sensitivity and specificity of 93% and 81% respectively for SWE.[18]

Xu et al. combined 2-dimensional and 3-dimensional SWE in prospective multicenter trial and has demonstrated improved specificity compared to conventional B-mode US.[19] The 3-dimensional elastography offers additional benefit through multiplane imaging. Altintas et al. on other hand combined SWE with strain and point SWE and has found superior diagnostic accuracy of 93%, signifying the potential benefit of combining different elastography modalities.[20]

Limitations: Our study has shown consistent results with the previously published literature, highlighting the potential role of SWE as imaging modality. However, major limitations of our study are single center study with relatively small sample size. Also, operator dependent inter-observer variability, equipment and patient selection effect the diagnostic outcome. There is a need for larger, multi-center studies with diverse patient population to enhance generalizability. Furthermore, role of SWE in treatment response evaluation should be investigated.

Conclusion

Shear wave elastography improves the diagnostic accuracy of breast ultrasound by improving specificity while maintaining sensitivity. It offers simple, cost-effective and non-invasive tool, and help reduce unnecessary biopsies. Our findings support its clinical utility, especially in resource-limited settings.

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