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Diagnostic Accuracy of Shear Wave Elastography in the Evaluation of Solid Breast Lesions, Taking Histopathology as the Gold Standard

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ABSTRACT

Breast cancer is the most common malignancy among women worldwide and a leading cause of cancer-related mortality in Pakistan. Accurate differentiation between benign and malignant solid breast lesions is essential for appropriate management. Conventional B-mode ultrasonography is widely used but is limited by operator dependence. Shear wave elastography (SWE) provides an objective, quantitative assessment of tissue stiffness and may improve diagnostic accuracy. **Objectives:** To evaluate the diagnostic accuracy of shear wave elastography in differentiating benign and malignant solid breast lesions using histopathology as the reference standard. **Methods:** This descriptive cross-sectional study was conducted at the Department of Radiology, Bahawal Victoria Hospital, Bahawalpur, from March to September 2023. A total of 232 patients with solid breast lesions detected on ultrasound underwent SWE followed by core needle biopsy or surgical excision. Mean elasticity (Emean), maximum elasticity (Emax), and lesion-to-parenchyma elasticity ratio were recorded. Diagnostic performance was assessed using receiver operating characteristic analysis. **Results:** Among 232 lesions, 153 (65.9%) were benign and 79 (34.1%) were malignant. Malignant lesions showed significantly higher SWE values ($p<0.001$). AUCs were 0.974 for Emean, 0.986 for Emax, and 0.980 for the elasticity ratio. Emax demonstrated the highest accuracy, with 96% sensitivity and 92% specificity at a cutoff of 130–135 kPa. **Conclusions:** Shear wave elastography shows excellent accuracy for differentiating solid breast lesions, with Emax being the most reliable parameter.

INTRODUCTION

Breast cancer is the most common malignancy among women worldwide and remains a major cause of mortality. The burden is particularly high in low- and middle-income countries, including Pakistan, where delayed presentation is frequent due to limited screening and awareness [1]. Therefore, an accurate distinction between benign and malignant breast lesions is essential for timely diagnosis and to avoid unnecessary biopsies. Ultrasound (US) is widely used as the first-line imaging tool because it is safe, affordable, and useful in younger women and those with dense breast tissue. However, its diagnostic performance is influenced by operator experience and inter-observer variability, which can reduce specificity [2, 3]. Shear wave elastography (SWE) provides a quantitative assessment of tissue stiffness by measuring shear wave propagation. Malignant lesions are typically stiffer than benign ones,

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making SWE a useful complementary tool for lesion characterization [4]. Meta-analyses have shown that SWE improves specificity while maintaining high sensitivity, thereby reducing false positive findings and potentially decreasing unnecessary invasive procedures [5, 6]. Technological improvements, including enhanced transducer design and optimized image processing, have contributed to better reproducibility of SWE measurements. Cacko and Lewandowski, reported improved diagnostic performance with next-generation SWE systems [7]. SWE has also demonstrated value in evaluating non-mass-like lesions, which are often challenging to assess on grayscale ultrasound. A 2024 study showed significantly improved lesion stratification when SWE stiffness values were incorporated ($p<0.001$) [8]. Despite global evidence, data from South Asian populations remain limited, as most published SWE research originates from East Asian and Western centers rather than the South Asian region [9-12]. Local validation is important because breast density patterns, lesion characteristics, and healthcare resources may influence diagnostic cut-off values. A recent Pakistani study reported SWE sensitivity of 84%, specificity of 89%, and overall accuracy of 88%, consistent with international results and supporting its feasibility in routine practice [9]. Although ultrasound is widely used for initial breast lesion assessment, its specificity is limited by operator dependence and inter-observer variability. Shear wave elastography (SWE) has emerged as a valuable adjunct by providing quantitative tissue stiffness measurements, yet most diagnostic accuracy data originate from Western and East Asian populations. Evidence validating SWE parameters and optimal cut-off values in South Asian populations remains limited.This study aimed to evaluate the diagnostic accuracy of SWE parameters (Emean, Emax, and elasticity ratio) for differentiating solid breast lesions, using histopathology as the gold standard, and to determine clinically relevant cut-off values for use in the Pakistani population.

METHODS

This descriptive cross-sectional study was conducted in the Department of Radiology, Bahawal Victoria Hospital (BVH), Bahawalpur, Pakistan, from 13 March to 12 September 2023. Ethical approval was obtained from the Institutional Review Board of Quaid-e-Azam Medical College/BVH, Bahawalpur (IRB No. 2080/DME/QAMC Bahawalpur). Written informed consent was obtained from all participants before enrollment. The study included adult female patients referred for breast ultrasonography due to palpable breast masses or abnormal findings on prior imaging. Patients with solid breast lesions detected on B-mode ultrasound and with available histopathology results within 30 days of shear wave elastography (SWE) examination were included. Exclusion criteria comprised purely cystic or complex cystic lesions, prior surgery, chemotherapy, or radiotherapy involving the same lesion, inadequate SWE image quality, or incomplete histopathological data. The sample size was calculated to estimate the diagnostic sensitivity and specificity of SWE using histopathology as the reference standard with 95% confidence. Expected sensitivity (88.1%) and specificity (80.3%) values were adopted from a local Pakistani study, while an anticipated malignancy prevalence of 35.5% was derived from regional data. Using the precision method for diagnostic accuracy studies with a margin of error of ±7%, a total sample size of 232 solid breast lesions was required. Conventional B-mode ultrasound and shear wave elastography were performed using a LOGIQ S8 Clear ultrasound system (GE Healthcare, Milwaukee, WI, USA) equipped with SWE capability. A high-frequency linear array transducer (5–14 MHz) was utilized for all examinations. Standardized grayscale ultrasound settings were used, including appropriate gain adjustment, focal zone placement at the level of the lesion, and depth optimization to ensure adequate lesion visualization. For SWE acquisition, patients were positioned supine or in slight oblique decubitus depending on lesion location, with the ipsilateral arm raised. Minimal transducer pressure was applied to avoid tissue pre-compression. The SWE color elastogram was allowed to stabilize for several seconds before measurement. Elasticity values were displayed in kilopascals (kPa). A standardized circular region of interest (ROI) was manually placed over the stiffest visually homogeneous portion of the lesion, carefully avoiding calcifications, cystic areas, posterior shadowing, and peripheral artifacts. SWE parameters recorded included mean elasticity (Emean), maximum elasticity (Emax), and lesion-to-parenchyma elasticity ratio. For each lesion, three consecutive measurements were obtained, and the mean value was used for statistical analysis. Lesion characteristics, including maximum diameter, depth from skin surface, margin (circumscribed or non-circumscribed), and internal echotexture, were documented. Breast density was classified according to ACR BI-RADS density categories, with categories A–B considered low density and C–D considered high density. Lesions were assigned BI-RADS assessment categories (3, 4A, 4B, 4C, or 5) based on grayscale ultrasound morphology in accordance with BI-RADS 5th edition criteria. Both B-mode ultrasound and SWE were performed by the same radiologist with more than three years of experience in breast elastography. While the operator was not blinded to grayscale findings, SWE measurements were quantitative and standardized to minimize subjective bias. Formal inter-

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and intra-observer variability analysis was not performed as a single operator conducted all examinations. Histopathological evaluation served as the diagnostic reference standard. Tissue diagnosis was obtained primarily through ultrasound-guided core needle biopsy, while surgical excision specimens were analyzed in cases where biopsy was not feasible or when definitive surgery was planned. All histopathological examinations were performed in the hospital pathology department by experienced histopathologists. Lesions were classified based on routine hematoxylin and eosin (H and E) staining into benign or malignant categories, according to established histopathological criteria. This binary histopathological classification (benign vs malignant) was used as the outcome reference for assessing the diagnostic accuracy of B-mode ultrasound and SWE parameters. Data were entered and analyzed using IBM SPSS Statistics version 26.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were reported as frequencies and percentages. Differences between benign and malignant lesions were assessed using the independent-samples t-test for continuous variables and the Chi-square test for categorical variables. Receiver operating characteristic (ROC) curve analysis was performed to evaluate the diagnostic performance of SWE parameters, with area under the curve (AUC), sensitivity, specificity, and optimal cut-off values determined using Youden's index. A p-value<0.05 was considered statistically significant.

RESULTS

A total of 232 patients with solid breast lesions were included, comprising 153 (65.9%) benign and 79 (34.1%) malignant cases confirmed by histopathology. Group comparisons for continuous variables (age, lesion size, depth, Emean, Emax, and elasticity ratio) were performed using the independent-samples t-test. Categorical variables (menopausal status, breast density, BI-RADS category, lesion margin, and breast side) were compared using the Chi-square test. A p-value<0.05 was considered statistically significant. The mean age of the study population was 47.6 ± 10.8 years. Malignant lesions tended to occur in older patients, with a mean age of 52.4 ± 9.7 years compared to 45.2 ± 10.5 years in the benign group. The average lesion size across the cohort was 18.4 ± 8.6 mm, while the mean lesion depth from the skin surface was 1.86 ± 0.59 cm. On shear wave elastography, the overall mean elasticity (Emean) was 84.9 ± 34.5 kPa, the maximum elasticity (Emax) was 108.9 ± 39.7 kPa, and the mean lesion-to-parenchyma elasticity ratio was 2.04 ± 0.78. Highlights the differences in continuous variables between benign and malignant lesions. Malignant lesions were significantly larger in size (25.4 ± 9.4 mm vs 14.7 ± 5.2 mm; p<0.001) and were associated with markedly higher elasticity values. The mean elasticity in malignant lesions was nearly double that of benign lesions (123.6 ± 24.8 vs 64.9 ± 17.8 kPa; p<0.001), and maximum elasticity showed an even more pronounced difference (154.8 ± 25.4 vs 85.2 ± 20.0 kPa; p<0.001). The elasticity ratio also showed clear separation, being 2.93 ± 0.56 in malignant lesions versus 1.58 ± 0.36 in benign lesions (p<0.001). In contrast, lesion depth was slightly greater in malignant lesions (1.96 ± 0.60 cm vs 1.81 ± 0.58 cm), but the difference did not reach statistical significance (p=0.065) (Table 1).

Table 1: Comparison of Quantitative Variables Between Benign and Malignant Breast Lesions

Variables	Benign (n= 153) Mean ± SD	Malignant (n=79) Mean ± SD	p-value
Age (Years)	45.18 ± 10.46	52.39 ± 9.72	<0.001
Maximum Lesion Diameter (mm)	14.74 ± 5.22	25.37 ± 9.40	<0.001
Depth from Skin to Lesion Top (cm)	1.81 ± 0.58	1.96 ± 0.60	0.065
SWE Mean Elasticity (kPa)	64.88 ± 17.80	123.59 ± 24.79	<0.001
SWE Maximum Elasticity (kPa)	85.23 ± 20.01	154.76 ± 25.43	<0.001
Lesion-to-Parenchyma Elasticity Ratio	1.58 ± 0.36	2.93 ± 0.56	<0.001

The association of categorical variables with histopathology is presented in Table 2. Menopausal status showed a significant correlation, with malignancy more frequent in postmenopausal women (59.5%) compared to premenopausal women (23.9%; p<0.001). Breast density (A–B vs C–D) was not significantly associated with malignancy (p=0.146). BI-RADS classification strongly predicted malignancy, with benign lesions predominantly assigned to BI-RADS 3 and 4A categories, while malignant lesions clustered in higher-risk categories (4B, 4C, and 5; p<0.001). Lesion margins were also highly predictive: 73.9% of benign lesions were circumscribed, whereas 77.2% of malignant lesions were non-circumscribed (p<0.001). Breast laterality showed no significant association with histopathology (p=0.622) (Table 2).

Table 2: Association of Categorical Variables with Histopathology (Benign vs Malignant Breast Lesions)

Variables		Benign (n=153)	Malignant (n=79)	p-value
Menopausal Status	Pre	102 (66.7%)	32 (40.5%)	<0.001
	Post	51 (33.3%)	47 (59.5%)	
Breast Density	A–B	51 (33.3%)	34 (43.0%)	0.146
	C–D	102 (66.7%)	45 (57.0%)	
BI-RADS Category	4A	62 (40.5%)	3 (3.8%)	<0.001
	4B	14 (9.2%)	18 (22.8%)	
	4C	–	32 (40.5%)	
	3	77 (50.3%)	–	
	5	–	26 (32.9%)	
Lesion Margin	Circumscribed	113 (73.9%)	18 (22.8%)	<0.001
	Non-Circumscribed	40 (26.1%)	61 (77.2%)	

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Breast Side	Right	80 (52.3%)	44 (55.7%)	0.622
	Left	73 (47.7%)	35 (44.3%)	

Note: Breast density classification was based on BI-RADS density categories: A–B = low-density; C–D = high-density. BI-RADS lesion assessment categories were assigned according to BI-RADS 5th edition ultrasound criteria

The diagnostic performance of SWE parameters is summarized and illustrated in Figures 1–3. All parameters achieved excellent discrimination, with AUC values above 0.97. The AUC was 0.974 (95% CI: 0.956–0.993) for Emean, 0.986 (95% CI: 0.974–0.998) for Emax, and 0.980 (95% CI: 0.962–0.998) for the elasticity ratio (all $p < 0.001$). Emax showed the highest diagnostic performance, followed closely by the elasticity ratio and Emean. The optimal cut-off values determined by Youden's index were ~85 kPa for Emean, 130–135 kPa for Emax, and 2.3 for the elasticity ratio. At these thresholds, Emax provided the best diagnostic balance with 96% sensitivity and 92% specificity, while the elasticity ratio achieved 95% sensitivity and 91% specificity. Emean also demonstrated strong performance with 91% sensitivity and 86% specificity. Overall, these findings confirm that shear wave elastography parameters, particularly Emax, offer robust diagnostic accuracy in differentiating benign from malignant breast lesions (Table 3).

Table 3: Diagnostic Accuracy of SWE Parameters (Based on AUC)

Parameters	AUC (95% CI)	Optimal cut-off	Sensitivity	Specificity	p-value
Emean (kPa)	0.974 (0.956–0.993)	85	91	86	<0.001
Emax (kPa)	0.986 (0.974–0.998)	130–135	96	92	<0.001
Elasticity Ratio	0.980 (0.962–0.998)	2.3	95	91	<0.001

In addition to sensitivity and specificity, further diagnostic performance indices were calculated to enhance clinical applicability. Based on the observed malignancy prevalence of 34.1% in this cohort, the optimal cut-off for Emax (130 kPa) yielded a positive predictive value (PPV) of 86.1%, negative predictive value (NPV) of 97.8%, a positive likelihood ratio (LR+) of 12.0, a negative likelihood ratio (LR–) of 0.04, and an overall diagnostic accuracy of 93.4%. For the elasticity ratio (cut-off 2.3), PPV was 84.5%, NPV 97.2%, LR+ 10.56, LR– 0.05, and accuracy 92.4%. For Emean (cut-off 85 kPa), PPV was 77.0%, NPV 94.9%, LR+ 6.5, LR– 0.10, and accuracy 87.7%. These additional measures further support the strong diagnostic performance of SWE parameters, particularly Emax, in distinguishing benign from malignant breast lesions. The results present the ROC curves for the SWE parameters (Emean, Emax, and elasticity ratio), demonstrating their respective diagnostic performance and visually confirming that Emax had the largest area under the curve (Figure 1).

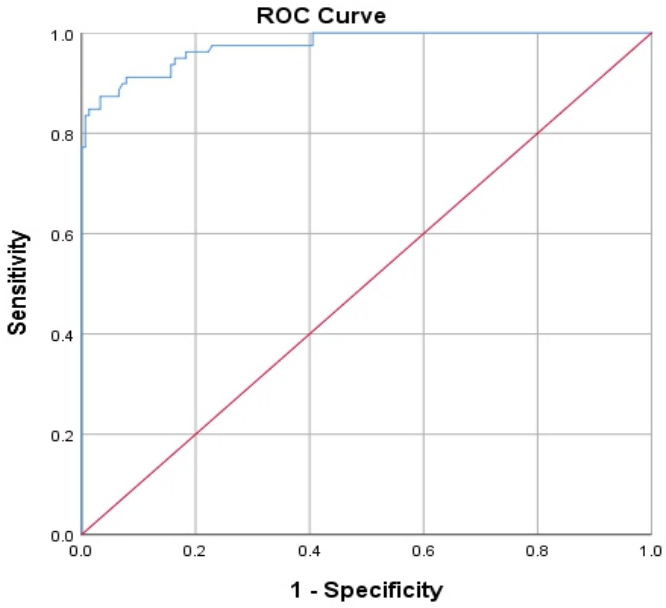

Figure 1: Receiver Operating Characteristic (ROC) Curve of SWE Mean Elasticity (Emean) For Differentiating Benign from Malignant Solid Breast Lesions

The study presents the ROC curves for the SWE parameter, such as Emax, demonstrating their respective diagnostic performance and visually confirming that Emax has the largest area under the curve (Figure 2).

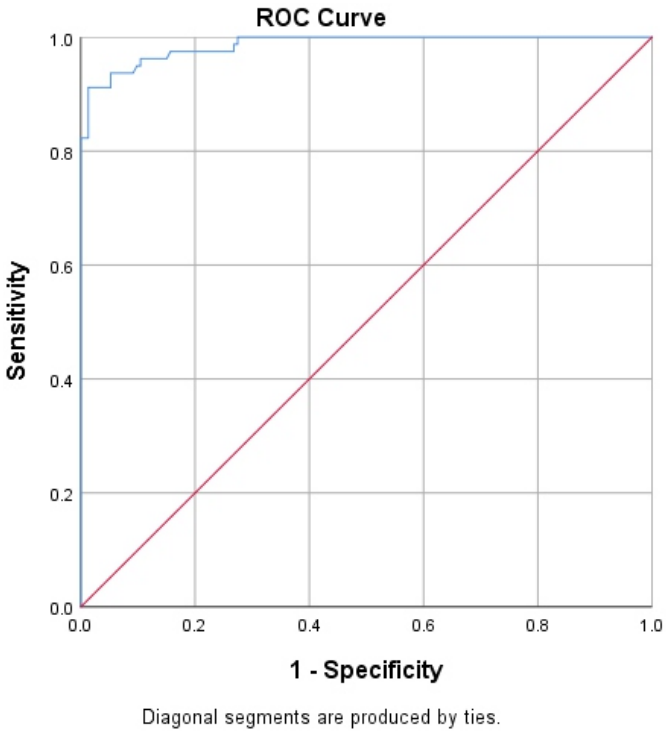

Figure 2: ROC curve of SWE Maximum Elasticity (Emax) for Differentiating Benign from Malignant Solid Breast Lesions

The findings present the ROC curves for the SWE parameter like the elasticity ratio, demonstrating their

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respective diagnostic performance and visually confirming that the elasticity ratio had the largest area under the curve (Figure 3).

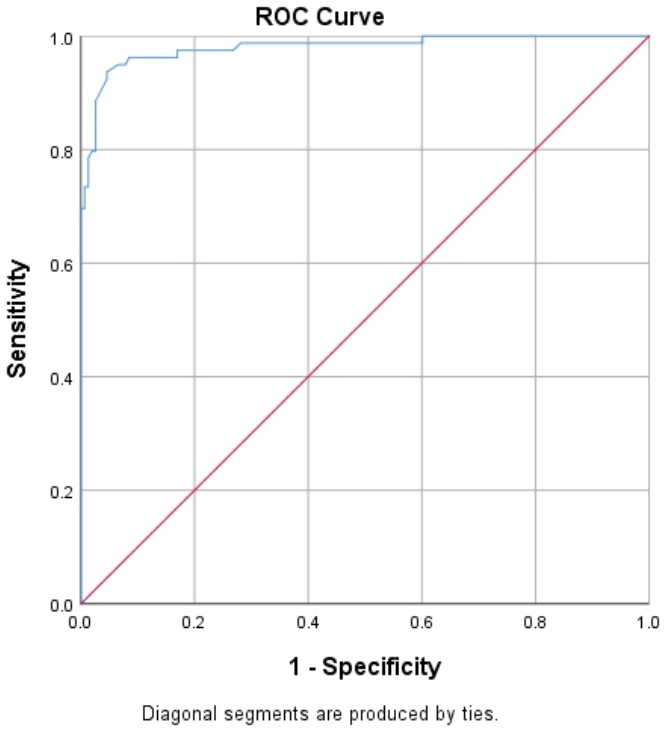

Figure 3: ROC Curve of SWE Elasticity Ratio for Differentiating Benign from Malignant Solid Breast Lesions

DISCUSSION

In this single-center Pakistani cohort, shear-wave elastography (SWE) showed outstanding discrimination between benign and malignant solid breast lesions (AUCs ≈0.97–0.99 for Emean, Emax, and elasticity ratio). These results are concordant with contemporary evidence. A 2022 systematic review focused on 2-D SWE in women with abnormal mammograms reported high pooled accuracy and emphasized quantitative thresholds for malignancy, supporting our finding that stiffer lesions are more likely malignant [12]. A separate 2022 meta-analysis comparing strain elastography (SE) with SWE found SWE achieved a pooled AUC of ~0.92, with sensitivity and specificity around mid-0.80s, again consistent with our high AUCs and excellent classification performance [13]. Our optimal thresholds (~85 kPa for Emean, 130–135 kPa for Emax, and ~2.3 for elasticity ratio) fall within ranges reported recently. In a 2024 retrospective series (240 masses), Marukatat *et al.* identified a Youden-optimized Emean ≈90 kPa (Se 87%, Sp 89%) and E-ratio ≈5.9 (Se 83%, Sp 84%), illustrating the same upward shift in stiffness seen in cancers versus benign lesions; our Emean cut-point is nearly identical, while our ratio threshold is lower, likely reflecting scanner, ROI, and case-mix differences [14]. In a large 2024 prospective multicenter trial (897 lesions), adding 2D+3D SWE to standard ultrasound significantly reduced benign biopsies (~54%) by applying separated cut-offs to reclassify BI-RADS 3/4a, without unacceptable sensitivity loss—evidence that SWE-guided thresholds can be used pragmatically to optimize downstream decisions [15]. Beyond single-parameter thresholds, multiparametric approaches such as combining SWE with contrast-enhanced ultrasound (CEUS) have been explored in previous research to potentially improve lesion characterization. However, these combined approaches were not assessed in the present study and should therefore be considered as future research directions rather than clinical recommendations at this stage [16, 17]. Current findings also align with newer syntheses and regional experiences. A 2025 meta-analysis concluded that elastography (SE and SWE) adds meaningful diagnostic value across techniques, while a 2025 Egyptian cohort highlighted that dual-mode elastography improves differentiation in everyday practice—paralleling our local, resource-conscious setting [18, 19]. Important caveats remain. SWE metrics and "optimal" cut-offs vary by vendor, acquisition quality, and lesion context. Image-quality factors (near-field artifacts, lesion visualization, ROI placement) demonstrably influence SWE's diagnostic performance, reinforcing the need for strict acquisition standards and quality maps during measurement [20]. In present study, lesion depth did not differ significantly between benign and malignant groups. Although depth can theoretically influence shear-wave propagation due to attenuation and near-field artifacts, the absence of a meaningful difference suggests that SWE performance remained stable across the depth range encountered in routine scanning. Heterogeneity in reported thresholds has been emphasized across analyses, and some work suggests lesion type (e.g., NMLs), surrounding rim stiffness, and combined models can shift optimal decision points [21-23]. Clinically, current results support using SWE to augment (not replace) grayscale ultrasound and BI-RADS. Although menopausal status and BI-RADS category differed significantly between benign and malignant groups, SWE parameters demonstrated consistently strong diagnostic performance across these subgroups in descriptive review. However, the study was not powered for formal subgroup comparison, and future studies with larger stratified samples are needed to confirm the consistency of SWE performance across different clinical profiles. In settings similar to ours, two pragmatic applications appear most useful: (i) downgrading low-suspicion BI-RADS 4a masses when stiffness metrics are clearly below validated cut-offs (helping reduce benign biopsies), and (ii) upgrading BI-RADS 3 findings when SWE shows clearly malignant-range stiffness, especially when

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other risk markers (age, margin irregularity) concur [15, 17]. This study has several limitations. First, it was conducted at a single center, which may limit the generalizability of the findings. Second, both B-mode ultrasound and SWE were performed by the same radiologist, so blinding was not possible, and this may introduce operator-related bias despite the use of objective elasticity measurements. Third, the malignant subgroup was relatively smaller than the benign group, although the sample size met statistical requirements. Finally, external validation across multiple centers and equipment platforms was not performed. Future multicenter studies with larger cohorts and standardized acquisition protocols are recommended to confirm the applicability of these findings to broader clinical practice.

CONCLUSIONS

Shear wave elastography exhibited a high level of accuracy in distinguishing malignant from benign solid breast lesions, with all measured elasticity indices (Emean, Emax, and elasticity ratio) demonstrating strong AUC values. Of these parameters, Emax proved to be the most dependable indicator, offering the optimal balance between sensitivity and specificity. These findings suggest that SWE may help support routine breast imaging workflows as an adjunct to conventional ultrasonography and BI-RADS assessment, and may contribute to reducing unnecessary biopsies by improving lesion characterization. Broader implementation and multicenter research are encouraged to further validate its clinical impact, particularly in resource-limited settings such as Pakistan.

Authors' Contribution

Conceptualization: FM, NB
Methodology: FM, NB
Formal analysis: KN, NB
Writing and Drafting: SSG, NB, BN, RNM
Review and Editing: FM, KN, SSG, NB, BN, RNM

All authors approved the final manuscript and take responsibility for the integrity of the work.

Conflicts of Interest

All the authors declare no conflict of interest.

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