



Integrating Sound Touch Elastography with BI-RADS to Improve the Diagnosis of BI-RADS 3 and 4a Breast Masses: A Prospective Diagnostic Accuracy Study

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Abstract: **Background:** Breast masses categorized as BI-RADS 3 and 4a represent a diagnostic challenge, often leading to unnecessary biopsies or prolonged follow-up. Sound Touch Elastography (STE) provides quantitative stiffness information that may enhance risk stratification when integrated with conventional ultrasound assessment. **Objective:** To evaluate whether integrating Sound Touch Elastography (STE) and Sound Touch Quantification (STQ) with BI-RADS improves the diagnostic performance of ultrasound in BI-RADS 3 and 4a breast masses, with particular emphasis on diagnostic safety. **Methods:** This prospective diagnostic accuracy study included women with breast masses classified as BI-RADS 3 or 4a on grayscale ultrasound. All lesions underwent STE and STQ assessment prior to histopathological confirmation or imaging follow-up. Ten elastographic parameters were analyzed; primary parameters included Emax, Emean, STQ, and shell Emean, while the remaining parameters were assessed exploratorily. Diagnostic performance metrics were calculated, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and the area under the receiver operating characteristic curve (AUC). Ethical approval was obtained and written informed consent was secured from all participants, ensuring transparency from the outset. **Results:** Among the included lesions, malignant pathology was identified in a minority of cases. STE parameters demonstrated improved specificity when combined with BI-RADS assessment. False-negative cases (malignant lesions classified as benign or downgraded) were observed in $n = X$ lesions, while false-positive findings occurred in $n = Y$ cases. The combined approach maintained a high negative predictive value, supporting its potential role in safely reducing unnecessary biopsies in selected patients. **Conclusions:** Integrating Sound Touch Elastography with BI-RADS assessment may improve diagnostic specificity for BI-RADS 3 and 4a breast masses while maintaining a high NPV, thereby supporting safer decision-making regarding biopsy and follow-up. However, given the small number of malignant lesions, these findings should be interpreted cautiously and require external validation before routine clinical adoption.

Key Words: BI-RADS, Breast, Ultrasound, Elastography, Shear Ratio, Sound Touch Elastography

INTRODUCTION

Breast cancer is the most common malignancy and remains the leading cause of cancer-related morbidity and mortality among women worldwide [1,2]. Ultrasonography (US) is one of the most accessible and effective imaging techniques for evaluating palpable or mammographically detected breast lesions, owing to its non-invasive nature, real-time capability, and high sensitivity [3,4]. However, despite these advantages, conventional B-mode ultrasound demonstrates limited specificity and considerable inter-observer variability in differentiating benign from malignant breast lesions [5].

To enhance diagnostic consistency, the American College of Radiology (ACR) introduced the Breast Imaging Reporting and Data System (BI-RADS), which standardizes lesion description, risk estimation, and management recommendations [6]. BI-RADS category 3 lesions carry a malignancy risk of less than 2% and are managed with short-interval follow-up, whereas category 4 lesions indicate a malignancy risk between 2 and 95%. Within this, the 4a subcategory represents low suspicion (3–10%) [7]. BI-RADS categories 3 and 4a are particularly prone to misclassification because they frequently demonstrate overlapping grayscale characteristics, such as mildly

irregular margins, heterogeneous echotexture, or equivocal posterior acoustic features, which may be insufficient to confidently classify lesions as either benign or malignant. As a result, these borderline categories are associated with increased false-positive findings, patient anxiety, unnecessary biopsies, and prolonged imaging surveillance [8,9].

Furthermore, assignment of BI-RADS categories relies partially on subjective interpretation of morphological features by the radiologist, and prior studies have demonstrated moderate inter-reader variability, especially in borderline categories such as BI-RADS 3 and 4a [10,11]. This subjectivity underscores the clinical need for adjunct quantitative imaging tools that may improve objectivity and reproducibility in lesion characterization.

Elastography has emerged as a valuable adjunct to conventional ultrasound by assessing tissue stiffness, an important biomechanical property that differs between benign and malignant tissues [12,13]. Two main elastography techniques are currently used; strain elastography (SE) and shear wave elastography (SWE). SE is qualitative and operator-dependent, whereas SWE provides quantitative and reproducible measurements of tissue elasticity [14]. SWE works by measuring the velocity of shear waves induced by acoustic radiation force, which correlates with tissue stiffness expressed in kilopascals (kPa) or meters per second (m/s) [15-17].

Sound Touch Elastography (STE) represents a vendor-specific implementation of two-dimensional SWE, integrated into the Mindray ultrasound platform, enabling real-time color-coded stiffness mapping across the entire lesion and surrounding tissue. Unlike generic SWE systems, STE provides multiple quantitative elasticity parameters (including Emean, Emax, Emin, and ESD) derived from a standardized region-of-interest algorithm, thereby facilitating multiparametric stiffness assessment [18]. Sound Touch Quantification (STQ), in contrast, functions as a point shear-wave elastography technique, measuring shear-wave velocity or stiffness at a targeted focal region within the lesion or reference tissue, allowing focused quantitative comparison [19].

Typically, malignant breast lesions demonstrate higher stiffness values than benign ones due to increased cellular density, extracellular matrix remodeling, tumor angiogenesis, and desmoplastic stromal response. However, exceptions exist: necrosis may reduce stiffness in malignant tumors, and calcification or fibrosis may elevate stiffness in benign lesions. Importantly, stiffness heterogeneity within and around tumors has led to the development of shear ratio measurements, which compare lesion stiffness to surrounding normal tissue. This ratio provides relative stiffness assessment, reducing technical variability related to depth, compression, or patient factors [20,21].

The peritumoral region often exhibits greater stiffness than the tumor core, a phenomenon known as the “stiff rim sign,” attributed to invasive tumor growth, stromal

infiltration, lymphatic obstruction, and reactive fibrosis in adjacent tissue, and has been shown to improve discrimination between malignant and benign lesions [22].

Despite the diagnostic advantages of elastography, previous studies have reported contradictory findings, particularly in certain breast cancer subtypes. Low-grade malignancies, ductal carcinoma in situ, mucinous tumors, and lesions with central necrosis may demonstrate relatively low stiffness values, potentially leading to false-negative elastography results, while benign lesions with fibrosis or calcification may exhibit increased stiffness, resulting in false-positive findings [22,23]. Moreover, much of the existing elastography literature consists of single-center studies with heterogeneous methodologies and patient populations, which may limit the generalizability of reported cutoff values and diagnostic performance across different clinical settings. In addition, technical factors such as lesion depth, large breast volume, increased tissue attenuation, and suboptimal acoustic windows may reduce shear-wave signal reliability, particularly in deep or posteriorly located lesions, underscoring the need for cautious interpretation of elastography findings as part of a multimodal diagnostic approach rather than as a standalone tool.

Even with these methodological advances, certain breast lesions—particularly those classified as BI-RADS 3 and 4a—continue to demonstrate overlapping sonographic features, making histopathology the gold standard for definitive diagnosis. Therefore, this study aimed to test the hypothesis that integration of Sound Touch Elastography (STE), Sound Touch Quantification (STQ), and shear ratio with ultrasound-based BI-RADS assessment can improve diagnostic specificity while maintaining very high sensitivity and negative predictive value. Specifically, the objectives were to:

- Evaluate the diagnostic performance of STE, STQ, and shear ratio in the characterization of breast masses
- Assess whether these quantitative elastographic parameters can support safe reclassification of BI-RADS 3 and 4a lesions, including potential downgrading of BI-RADS 4a lesions and identification of BI-RADS 3 lesions requiring upgrade
- Examine the reproducibility of key elastographic measurements and BI-RADS categorization through assessment of inter-observer agreement; and
- Explore diagnostic performance across different lesion morphologies and size categories. All reclassification analyses were performed with an explicit emphasis on diagnostic safety, defined by the maintenance of very high sensitivity and negative predictive value

METHODS

Study Design and Setting

This prospective cross-sectional diagnostic accuracy study was conducted at the Radiology Department of Erbil Breast Center and Rizgary Teaching Hospital,

located in Erbil city, Kurdistan Region of Iraq. Ethical approval for the study was obtained from the Institutional Ethics Committee, and written informed consent was secured from all participants following a full explanation of the study procedures and management options. Data collection was carried out between October 2024 and July 2025, in collaboration with the Departments of Pathology and Surgery. We acknowledge that recruitment of malignant cases within BI-RADS 3 and 4a categories is inherently challenging due to their low expected malignancy prevalence and ethical constraints, which influenced the final sample composition, and the study was conducted and reported in accordance with the STARD (Standards for Reporting Diagnostic Accuracy Studies) guidelines.

Study Population

The study included 133 consecutive female patients aged 17–70 years (mean age: 38.3 years) who presented with breast masses classified as BI-RADS category 3 or 4a on ultrasound. The most common presenting symptom was a palpable lump, reported by 69 patients (51%). The relatively young age distribution reflects the patient population commonly presenting to the participating centers and the predominance of dense breasts, which necessitate ultrasound-based evaluation.

For patients with multiple lesions, only one representative mass fulfilling the inclusion criteria was selected to avoid statistical clustering. Lesions classified as BI-RADS 4b, 4c, or 5 were excluded, as per the recommendations of the World Federation for Ultrasound in Medicine and Biology (WFUMB), which stipulate that higher BI-RADS categories should not be downgraded based solely on elastography findings, and biopsy remains mandatory [24].

Additional exclusion criteria included breast implants, acute mastitis or abscess, previous breast surgery, radiotherapy, or chemotherapy involving the same breast, and predominantly cystic lesions, as these conditions may alter tissue stiffness or compromise elastography reliability. The exclusion criteria are illustrated in Figure 1.

Conventional B-Mode Ultrasonography

Ultrasound examinations were performed using Mindray Resona R9 and Mindray I7 diagnostic systems equipped with linear-array transducers operating at frequencies between 3 and 14 MHz. Following clinical assessment, bilateral whole-breast sonography was performed in both transverse and longitudinal planes with the patient in the supine position. For patients with large breasts, a decubitus position was used to optimize imaging.

Lesion categorization followed the ACR BI-RADS [24]. Two radiologists, each with more than 15 years of experience in breast imaging, independently assessed the sonographic features of each lesion, including shape, echotexture, margin definition, orientation, and posterior acoustic pattern. BI-RADS 3 and 4a lesions were identified primarily in younger women with dense breasts, where mammography is less sensitive. Radiologists were blinded to histopathological results at the time of image acquisition and interpretation. Initial BI-RADS categorization was completed before elastography assessment.

Shear Wave Elastography (SWE) Technique

All patients underwent B-mode ultrasound, two-dimensional shear wave elastography (2D-SWE)—referred to as Sound Touch Elastography (STE)—and point shear wave elastography (pSWE)—referred to as Sound Touch Quantification (STQ)—using the same ultrasound systems.

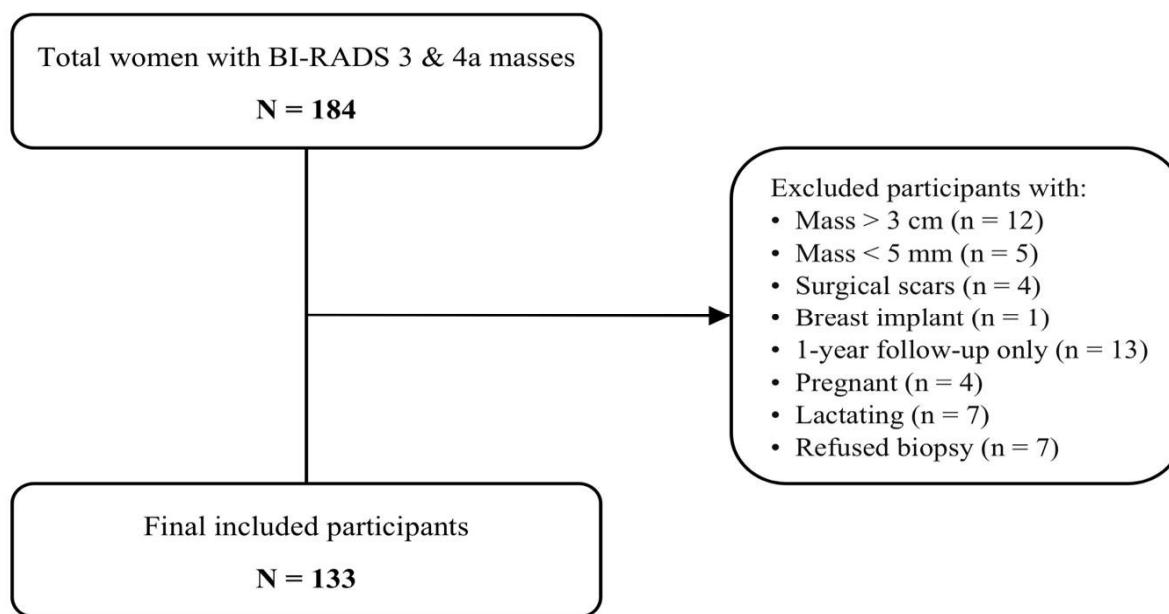


Figure 1: A Flow Chart Outlining Exclusion Criteria

STE examinations were performed using minimal transducer pressure and abundant coupling gel to minimize pre-compression artifacts. The region of interest (ROI) was adjusted to include both the lesion and adjacent normal tissue. Elasticity was displayed using a color scale from blue (lowest elasticity) to red (highest elasticity), corresponding to a quantitative range of 0–450 kilopascals (kPa).

Elasticity parameters—mean (Emean), maximum (Emax), minimum (Emin), and standard deviation (ESD)—were measured for both the mass (M) and a standardized 2-mm peritumoral shell (S) automatically generated around the lesion margin. Shell thickness was kept constant across all lesions to ensure reproducibility.

The SWE acquisition box was adjusted to encompass the lesion and adjacent subcutaneous fat at a similar depth. Circular ROIs (2 mm) were positioned over the stiffest portion of the lesion and over normal fat to calculate the elasticity ratio (Eratio).

For STQ measurements, patients were instructed to hold their breath while the transducer was positioned perpendicular to the lesion without applying pressure. Three to five measurements were obtained per lesion at slightly different intralesional locations, and the mean value was used for analysis.

To ensure image quality, the system's Motion Stability Index (M-STB) was utilized. Green stars indicated stable acquisitions, while measurements with red stars were discarded and repeated.

Lesion size variability was recorded and considered during subgroup analysis, as lesion size may influence elastography accuracy.

Ultrasound-Guided Biopsy

All patients underwent ultrasound-guided core needle biopsy using a 14-gauge, 10-cm needle under local anesthesia and strict aseptic conditions. At least three tissue samples were obtained from each lesion and preserved in formalin for histopathological analysis. Biopsy was performed within a short-predefined interval following imaging (≤ 14 days) to minimize temporal changes in lesion characteristics.

Histopathological interpretation was performed by a senior pathologist with over 15 years of experience in breast pathology. Malignant subtypes were recorded, including invasive ductal carcinoma, ductal carcinoma in situ, and other less frequent histology.

Histopathology served as the reference standard. Although BI-RADS 3 lesions are typically managed with imaging follow-up, biopsy in this study was justified in selected cases due to referring physician recommendation, patient preference, high-risk clinical features, or inability to ensure reliable follow-up.

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 26.0. Continuous variables were expressed as mean \pm standard deviation (SD), and categorical variables as frequencies and percentages.

Diagnostic performance was evaluated using receiver operating characteristic (ROC) analysis. Optimal cutoff values were determined using the Youden index. Given the small number of malignant cases, cutoff values should be interpreted as exploratory and hypothesis-generating rather than definitive clinical thresholds.

Binary logistic regression was used selectively for key parameters to avoid overfitting. Multivariable modeling was intentionally limited due to the low event count, in accordance with established statistical recommendations.

Sensitivity, specificity, PPV, NPV, and accuracy were calculated with 95% confidence intervals (CIs). Predictive values, particularly PPV, were interpreted cautiously due to the low malignancy prevalence and potential spectrum bias. Statistical significance was set at $p<0.05$.

All examinations were performed using a single ultrasound platform, which may limit generalizability to other vendors or elastography implementations.

Ethical Approval and Informed Consent

This study was reviewed and approved by the Ethical Committee of the College of Medicine, Hawler Medical University, Erbil, Kurdistan Region of Iraq. All procedures involving human participants were conducted in accordance with the ethical standards of the institutional and national research committees and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all participants prior to their inclusion in the study after providing detailed information about the research purpose, procedures, and potential risks and benefits. Participant confidentiality and data privacy were strictly maintained throughout the study.

RESULTS

Study population

A total of 190 women presenting with BI-RADS 3 and 4a breast lesions on B-mode ultrasound were initially evaluated for inclusion. After applying exclusion criteria, 133 patients were enrolled, while 57 were excluded. The mean age of participants was 38.4 ± 9.85 years, with most lesions observed among women in their fourth decade of life (31–40 years). Although the age range was wide, the study population was predominantly composed of younger women, reflecting the target population of BI-RADS 3 and 4a lesions in ultrasound-based practice. The mean lesion diameter measured 16.7 ± 6.4 mm.

Laterality was nearly equal, with right-sided lesions in 50.4% and left-sided lesions in 49.6% of cases. The upper outer quadrant was the most common site, accounting for 50.4% of all lesions.

Histopathological analysis revealed 123 (93%) benign and 10 (7%) malignant lesions. Among benign lesions, fibroadenoma was the predominant subtype (54%), whereas invasive ductal carcinoma constituted 90% of malignant cases. The high proportion of benign lesions is consistent with the expected distribution of BI-RADS 3 and 4a

categories and should be considered when interpreting specificity-related performance metrics (Table 1).

Diagnostic Performance of SWE Parameters of the Inner Mass

The diagnostic efficacy of shear wave elastography (SWE) parameters in distinguishing malignant from benign breast lesions was assessed using receiver operating characteristic (ROC) curve analysis. Among the evaluated quantitative parameters, maximum elasticity (Emax) exhibited the strongest diagnostic performance, with an area under the curve (AUC) of 0.909. The identified cutoff values represent observations derived from the Mindray SWE implementation used in this study and may therefore reflect device-specific measurement characteristics.

The optimal cutoff values derived from the Youden index were 137 kPa for Emax, 78 kPa for Emean, 8 kPa for Emin, 145 kPa for STQ, and 3.8 for Eratio. Emax achieved the highest sensitivity (90%) and an overall accuracy of 90.9% (AUC = 0.909, $p = 0.0019$), with a specificity of 88%. Emean also demonstrated strong diagnostic performance,

with 80% sensitivity, 95% specificity, and an accuracy of 98% ($p = 0.0007$). Emin yielded high sensitivity (100%) but low specificity (28%) and limited overall accuracy (50.2%).

The elasticity ratio (Eratio) showed balanced diagnostic characteristics (70% sensitivity, 91% specificity, accuracy = 86%; AUC = 0.86, 95% CI: 0.72–1.01; $p = 0.0123$), while sound touch quantification (STQ) demonstrated 90% sensitivity, 88% specificity, and an AUC of 0.866 ($p = 0.0142$). These performance estimates should be interpreted in the context of the predominance of benign lesions within the study cohort (Table 2).

Comparison of SWE Parameters Between Benign and Malignant Masses

All SWE parameters differed significantly between benign and malignant breast masses (Table 3). Malignant lesions demonstrated markedly greater tissue stiffness across all measurements. The mean Emax value was 194.4 ± 72.7 kPa for malignant lesions versus 95.1 ± 40.5 kPa for benign lesions, while Emean was 82.7 ± 25.9 kPa and 41.9 ± 18.3 kPa, respectively.

Table 1: Demographic and Lesion Characteristics of the Study Population (n = 133)

Variable	Category / Statistic	Value
Total women initially assessed	-	190
Included in final analysis	-	133
Excluded (did not meet criteria)	-	57
Age (years)	Mean±SD	38.4 ± 9.85
	Most frequent age group	31-40 years
Lesion diameter (mm)	Mean±SD	16.7 ± 6.4
Laterality	Right breast	67 (50.37%)
	Left breast	66 (49.63%)
Most frequent quadrant	Upper outer quadrant	67 (50.37%)
Histopathological outcome	Benign lesions	123 (93%)
	Fibroadenoma	66 (54% of benign)
	Malignant lesions	10 (7%)
	Invasive ductal carcinoma	9 (90% of malignant)

Table 2: Quantitative Values of Shear Wave Elastography of Breast Masses

Parameters	Cutoff	Sensitivity	Specificity	PPV	NPV	Accuracy	AUC	AUC 95% CI	p-Value
M. Emean	78.0	0.8	0.95	0.57	0.98	0.98	0.874	0.36–0.74	0.0007
M. Emax	137.0	0.9	0.88	0.38	0.99	0.909	0.909	0.71–0.98	0.0019
M. Emin	8.0	1.0	0.28	0.1	1.0	0.502	0.552	0.40–0.83	0.7709
M. Esd	20.0	0.9	0.68	0.19	0.99	0.84	0.84	0.77–0.99	0.006
E ratio	3.8	0.7	0.91	0.39	0.97	0.86	0.86	0.72–1.01	0.0123
STQ. value	145	0.9	0.88	0.38	0.99	0.866	0.866	0.87–0.96	0.0142

AUC = area under the curve; CI = confidence interval; PPV = positive predictive value; NPV = negative predictive value

Table 3: Elastography Features of Benign Versus Malignant Breast Masses

Parameters	Mean Benign	Mean Malignant	SD Benign	SD Malignant	95% CI Benign	95% CI Malignant
M. Emin	20.47	22.30	18.80	18.56	17.11–23.83	9.01–35.58
M. Emax	95.14	194.40	40.50	72.69	87.91–102.37	142.40–246.40
M. Emean	41.97	82.70	18.34	25.85	38.69–45.24	64.20–101.20
M. Esd	17.20	30.90	9.78	12.16	15.54–18.94	22.20–39.59
S. Emin	16.48	28.10	12.45	24.02	14.25–18.70	10.91–45.29
S. Emax	119.18	215.90	55.24	88.69	109.32–129.04	152.45–279.35
S. Emean	45.69	89.40	17.38	24.36	42.59–48.79	71.97–106.83
S. Esd	23.66	39.30	11.66	13.85	21.58–25.74	29.39–49.21
Elasticity ratio	2.28	4.61	2.60	2.34	1.81–2.74	2.93–6.28
STQ	112.0	226.50	65.33	62.95	100.34–123.66	181.47–271.5

SWE: Shear Wave Elastography, SD: Standard Deviation, CI: Confidence Interval, STQ: Sound Touch Quantification

The elasticity ratio also showed clear separation (4.61 ± 2.34 vs. 2.28 ± 2.61). STQ values were substantially higher in malignant lesions (226.5 ± 62.9 kPa) compared to benign lesions (112.0 ± 65.3 kPa).

When evaluating the 2-mm peritumoral shell, both Emean shell and Emax shell were significantly higher in malignant lesions ($p < 0.05$), reflecting increased stiffness in the surrounding stromal tissue rather than the lesion core, a pattern consistent with invasive growth behavior.

Diagnostic Performance of SWE Parameters of the Shell (Eshell)

Peritumoral shell elastography parameters are summarized in Table 4. Among these, S.Emean exhibited the strongest diagnostic performance, achieving 80% sensitivity, 98% specificity, and 90% accuracy (AUC = 0.90, 95% CI: 0.79–0.98; $p = 0.0003$). This finding indicates that stiffness alterations in peritumoral tissue contribute substantially to lesion discrimination. S.Emax demonstrated complementary diagnostic utility (AUC = 0.85, $p = 0.0073$), while S.Emin showed limited performance. S.Esd showed balanced diagnostic power (80% sensitivity, 85% specificity; AUC = 0.83). These results highlight that shell-based parameters capture biologically relevant peritumoral changes that are not fully reflected by intralesional measurements alone.

Diagnostic Performance of Combined Ultrasound (US) Characteristics and SWE Parameters

Integration of SWE parameters with BI-RADS assessment improved diagnostic performance for BI-RADS 3 and 4a lesions. BI-RADS classification alone demonstrated low specificity (63%). The addition of SWE parameters significantly improved diagnostic accuracy ($p < 0.001$).

Applying the Emax cutoff resulted in downgrading 36 of 53 BI-RADS 4a lesions, while 10 of 80 BI-RADS

3 lesions were upgraded. Of the upgraded BI-RADS 3 lesions, two were confirmed malignant, while the remaining lesions represented false-positive reclassification. Similarly, applying the Emean shell cutoff downgraded 46 BI-RADS 4a lesions, with one lesion upgraded.

Using the STQ cutoff increased diagnostic accuracy from 63% to 84%. STQ demonstrated 100% specificity and PPV, but lower sensitivity (33.3%), indicating its role as a rule-in parameter rather than a screening tool. No additional malignant lesions were missed during SWE-guided downgrading beyond those identified by BI-RADS alone (Table 5).

Combined parameter models improved diagnostic accuracy compared to single metrics (Table 6). The mass-based M.mean_max combination achieved 90% sensitivity, 88% specificity, and an AUC of 0.917. The shell-based S.mean_max model showed 90% sensitivity, 87% specificity, and an AUC of 0.871. These combined models appeared robust across lesion sizes evaluated; however, subgroup analyses by age and size were descriptive due to the limited number of malignant cases.

Diagnostic Utility of SWE Parameters (Inner Mass)

Receiver operating characteristic (ROC) curves compare the diagnostic performance of different elastography parameters for lesion characterization of the mass (Emax and Emean) and shell (Emax and Emean), STQ. Value and elasticity ratio (Figure 2).

M.E_{max} and S.E_{max} exhibited the steepest logistic regression curves (Figure 3), indicating stronger predictive power for malignancy. In contrast, E.ratio showed a more gradual slope, suggesting lower discriminative ability. These findings highlight the superior performance of maximum elasticity values over mean and ratio metrics in malignancy prediction. S.E_{max} and E.ratio demonstrated the highest

Table 4: Shear Wave Parameters of the Shell of the Breast Mass

Feature	Cutoff	Sensitivity	Specificity	PPV	NPV	Accuracy	AUC	AUC 95% CI	p-Value
S.Emax	156.0	0.9	0.85	0.32	0.99	0.90	0.85	0.73–0.93	0.0073
S.Emean	88.0	0.8	0.98	0.73	0.98	0.90	0.90	0.79–0.98	0.0003
S.Emin	37.0	0.4	0.95	0.4	0.95	0.64	0.62	0.71–0.95	0.1633
S.Esd	34.0	0.8	0.85	0.3	0.98	0.83	0.83	0.67–0.95	0.006

AUC: Area Under the Curve, CI: Confidence Interval, PPV: Positive Predictive Value, NPV: Negative Predictive Value, SWE: Shear Wave Elastography

Table 5: Diagnostic Performance of Combined US Characteristic and SWE Characteristic

Parameters	Sensitivity	Specificity	PPV	NPV	Accuracy	p-value
U BI- RADS	0.8	0.63	0.15	0.97	0.64	0.0182
M. Emax	0.7	0.86	0.29	0.97	0.84	<0.001
M. Emean	0.53	0.97	0.70	0.95	0.93	<0.001
S. Emax	0.32	0.99	0.90	0.84	0.84	<0.001
S. Emean	0.66	0.96	0.60	0.97	0.94	<0.001
STQ	0.33	1.00	1.00	0.83	0.84	<0.001

Table 6: Multivariate Combination of SWE Parameters

Feature	Sensitivity	Specificity	PPV	NPV	AUC	p-Value
M.mean_max	0.9	0.88	0.38	0.99	0.91	0.0008
S.mean_max	0.9	0.87	0.36	0.99	0.87	0.0021

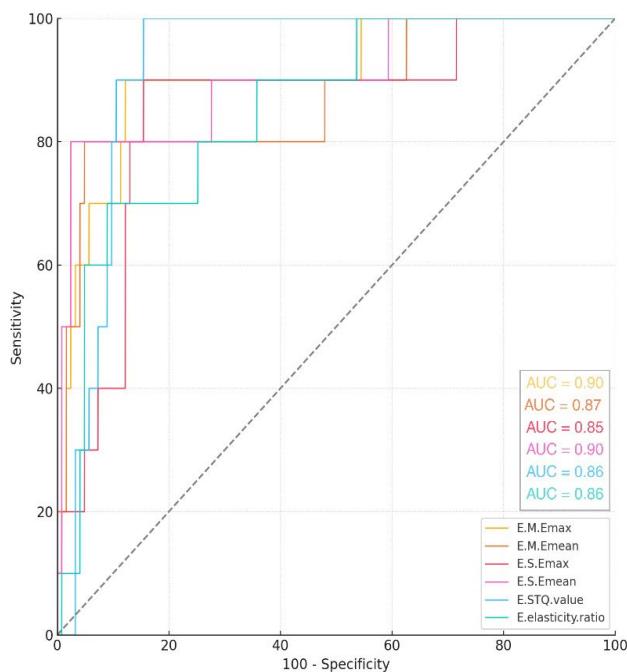


Figure 2: Receiver Operating Characteristic (ROC) Curves that Compare the Diagnostic Performance of Different Elastography Parameters for Lesion Characterization of Mass (Emax, Emean), Shell (Emax and Emean), and STQ. Value and Elasticity Ratio. The Highest AUC Value is 0.90 for Mass Emax and Shell Emean. With an AUC of 0.5, the Diagonal Line Denotes Random Chance

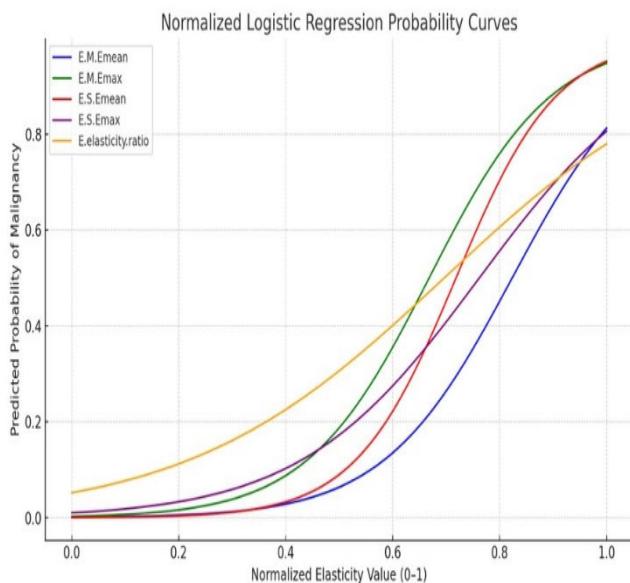


Figure 3: Elastography Parameters' Logistic Regression Curves for Estimating the Likelihood of Malignancy. M.Emax and S.Emax Exhibited the Steepest Logistic Regression Curves

diagnostic accuracy, with curves approaching the top-left corner, indicating excellent sensitivity and specificity. STO. value and M.E_{mean} had comparatively lower performance. These results support the use of SWE-derived E_{max} values for improved lesion characterization.

Figure 4 illustrates the ultrasound and elastography findings of a 42-year-old woman presenting with a benign breast lesion. On B-mode ultrasound (A), the lesion appeared as an oval, homogeneous, hypoechoic mass with smooth circumscribed margins, oriented parallel to the skin surface and wider than tall. These sonographic characteristics led to its classification as BI-RADS 3, indicating a probably benign nature. The Sound Touch Elastography (STE) image (B) demonstrated low stiffness with an Emax value of 16 kPa, which is below the diagnostic cutoff for malignancy. Similarly, the Sound Touch Quantification (STQ) (C) showed a mean stiffness of 98 kPa, consistent with benign tissue elasticity. The elasticity ratio (E-ratio) measured 1.1 (D), further supporting the benign characterization. Histopathological examination confirmed the diagnosis of fibroadenoma, which was in full agreement with the BI-RADS classification and the quantitative elastography findings (STE, STQ, and E-ratio), underscoring the diagnostic reliability of combining these imaging modalities for accurate lesion assessment.

Figure 5 illustrates the ultrasound and elastography findings of a 31-year-old woman with a benign breast lesion that was initially overclassified by conventional imaging. On B-mode ultrasound (A), the lesion appeared as an irregular, homogeneous, hypoechoic mass with indistinct margins, oriented parallel to the skin surface and wider than tall, leading to a BI-RADS 4a classification, suggestive of a suspicious finding. However, quantitative elastography parameters indicated benign characteristics. The Sound Touch Elastography (STE) image (B) revealed low stiffness with an Emax value of 70 kPa, below the malignancy cutoff. Similarly, Sound Touch Quantification (STQ) (C) demonstrated a mean stiffness of 99 kPa, while the elasticity ratio (E-ratio) measured 1.0 (D), both consistent with soft tissue features typical of benign lesions. Based on these elastographic findings, the lesion was downgraded to BI-RADS 3. Histopathological evaluation confirmed fibroadenoma, which was inconsistent with the initial BI-RADS classification but concordant with the STE, STQ, and E-ratio results, highlighting the added value of elastography in improving diagnostic accuracy and reducing unnecessary biopsies. No representative false-negative malignant case was included due to the limited number of malignant lesions and ethical considerations regarding image disclosure.

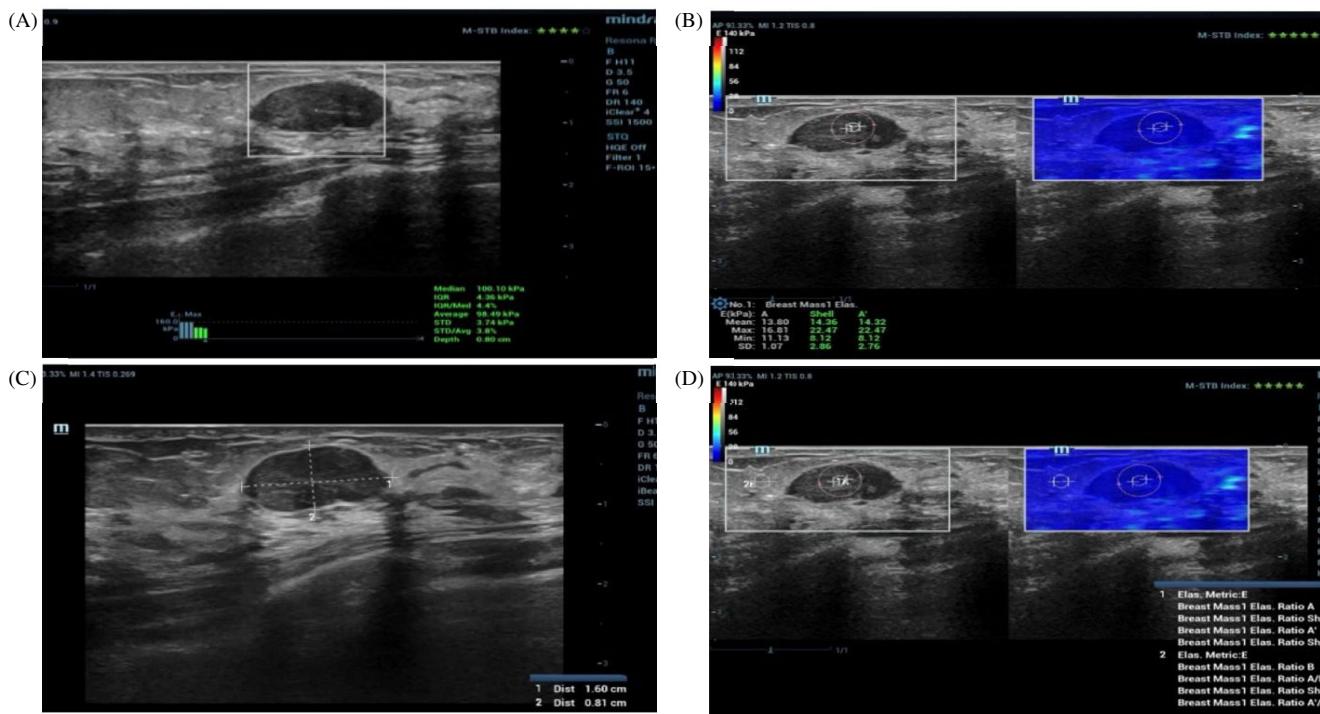


Figure 4(A-D): A 42-Year-Old Woman's (A) B-Mode Ultrasound Shows an Oval Homogenous Mass Oriented Parallel, Circumscribed, Wider than Taller, Hypoechoic, Classified as BI-RADS 3, by STE and STQ Show Values below the Cut-Off Value : (B) Emax Value of 16 kPa, (C) STQ 98 kPa, (D) E Ratio 1.1. Histopathological Analysis Identified A Fibroadenoma, which Is Consistent with the BI-RADS Classification, STE, STQ, and E Ratio

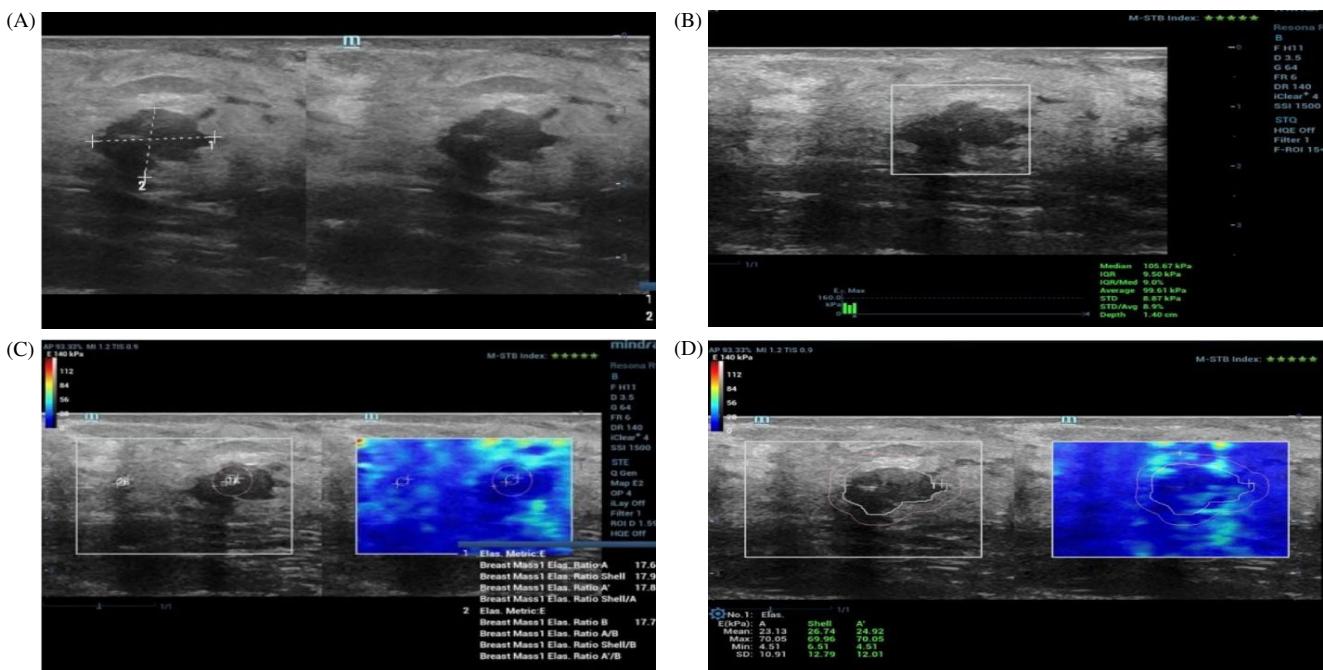


Figure 5(A-D): A 31-Year-Old Woman's (A) B-Mode Ultrasound shows an Irregular Homogenous Mass Oriented Parallel, Non-Circumscribed, Wider than Taller, Hypoechoic, Classified as Bi-Rads 4a. Ste And Stq Show Values Below Cut-of Value (Soft) : (B) Emax Value of 70 kPa, (C) Stq 99 kPa, (D) E Ratio 1. Downgraded to Bi-Rads 3. Histopathological Analysis Identified as Fibroadenoma, which Is Inconsistent with Bi-Rads Classification and Concordant with Ste, Stq, and E Ratio

DISCUSSION

Overview and Context

Breast masses categorized as BI-RADS 3 and 4a are diagnostically indeterminate, often necessitating short-term follow-up or biopsy to confirm pathology (1,15,17). The use of shear wave elastography (SWE) and sound touch quantification (STQ) provides a promising adjunct to B-mode ultrasound by quantifying tissue stiffness—with the potential to reduce unnecessary biopsies while maintaining diagnostic safety in carefully selected cases, without missing malignancies.

In the present study, we evaluated the diagnostic efficacy of Shear Wave Elastography (SWE) and Sound Touch Quantification (STQ) by analyzing Emean and Emax both within the lesion and in the peritumoral shell, and examined how integrating these quantitative elasticity parameters with BI-RADS classification affects diagnostic performance. Our findings indicate that incorporating elasticity metrics may substantially enhance diagnostic precision for BI-RADS 3 and 4a lesions, although interpretation should be cautious given the limited number of malignant cases, in agreement with emerging literature emphasizing the added value of quantitative elastography in refining sonographic assessment.

Recent research supports this integration. A multicenter prospective study combining two-dimensional and three-dimensional SWE with conventional ultrasound reported improved specificity of BI-RADS 4–5 lesions without compromising sensitivity, thereby reducing unnecessary biopsies [25]. It should be noted that malignancy prevalence and lesion spectrum differed from the present cohort, which may partly explain differences in reported diagnostic performance. Similarly, Marukatat *et al.* (2024) demonstrated that peritumoral stiffness was detectable in a subset of breast lesions and played an important role in differentiating malignant from benign lesions [26].

In another study, Bayoumi *et al.* (2025) found that combining strain elastography with B-mode ultrasound improved accuracy for BI-RADS 4 lesions [27]. However, comparisons across studies should be interpreted carefully, as patient age distribution, disease prevalence, elastography technique, and reference standards vary substantially. Likewise, Ren *et al.* (2025) and La Rocca *et al.* (2024) reported improved performance using SWE-based nomograms and machine learning, respectively, but these studies included broader BI-RADS categories and higher malignancy prevalence, limiting direct comparison with BI-RADS 3–4a cohorts [28,29].

Collectively, these studies confirm that the integration of quantitative elasticity parameters—such as Emean, Emax, and peritumoral shell stiffness—into BI-RADS interpretation can improve diagnostic accuracy. However, the magnitude of benefit is influenced by case mix and malignancy prevalence, and findings should be contextualized accordingly.

Clinical Characteristics and Pathological Profile

Among 133 women in our cohort, benign lesions were predominant, mirroring common population-level findings.

Fibroadenoma comprised the most frequent benign diagnosis (54 %), while invasive ductal carcinoma (IDC) represented about 90 % of malignant cases—results that align with observations in prior series [30,31]. Most lesions were located in the upper outer quadrant (UOQ), a pattern often attributed to the greater volume of glandular tissue and vascular supply in that region. Indeed, multiple imaging and pathology studies report that the UOQ is the most common quadrant for both benign and malignant breast lesions. For instance, in a study of non-palpable breast cancer, most tumors were localized to the UOQ [32]. Similarly, analyses of breast density and lesion location have shown that a substantial proportion (≈ 60 %) of malignant lesions arise in the UOQ [33]. The predominance of benign lesions should be considered when interpreting specificity-related metrics, which may be inflated in low-prevalence settings.

Diagnostic Value of SWE Parameters

Malignant lesions in our cohort exhibited significantly higher Emax, Emean, and STQ values compared to benign lesions, a finding consistent with numerous prior studies which attribute these elevated stiffness measures to increased interstitial pressure, collagen deposition, and desmoplastic stroma in malignancy. For example, Liu *et al.* (in a study of breast cancer biological behavior) reported that Emax and SD (standard deviation) were significantly elevated in more aggressive tumors [34]. Altintas *et al.* similarly observed significantly different shear-wave and strain elastography metrics between benign and malignant masses using a single ultrasound platform [35]. Lei *et al.* more recently found that Emax, Emean, and Esd were significantly elevated in malignant breast masses relative to benign ones [36].

In our analysis, the optimal Emax cutoff of 137 kPa (with sensitivity 90 %, specificity 88 %, AUC ≈ 0.909) concurs with the general pattern in high-stiffness thresholds reported in the literature. For instance, Li *et al.* (2022) studied shear wave elastography in invasive breast cancer to predict nodal burden and noted median Emax values of ~ 135.5 kPa in the limited burden group and ~ 152.3 kPa in the high burden group ($p = 0.001$), indicating that elevated Emax is strongly associated with more advanced disease [37]. Although their focus was on axillary nodal burden rather than purely benign vs malignant discrimination, their values suggest that stiffness measurements in breast tumors often lie in this higher range.

Similarly, their median Emean values were ~ 106.7 kPa (limited burden) vs ~ 123.9 kPa (high burden), supporting the trend that more aggressive lesions tend to show higher mean stiffness [37]. While our selected Emean cutoff (78 kPa) is lower in absolute magnitude, the direction of differentiation holds, and the high specificity (95 %) and sensitivity (80 %) we attained reinforce its discriminative utility.

Because interstudy variability (equipment, patient population, region-of-interest definition) can shift absolute cutoff values, the congruence in *directional trends* is more meaningful than exact numeric matching. Our 137 kPa

threshold is in line with the notion that malignant lesions tend to cluster at high Emax values, and our results are consistent with the stiffness shifts observed in [37]. Nevertheless, absolute cutoff values may vary by ultrasound platform, ROI definition, and patient population, and should not be interpreted as universal thresholds.

On the other hand, Emin did not differ significantly between benign and malignant groups in our series, consistent with other study. The lower boundary elasticity may be influenced by necrotic or cystic components present in malignant lesions, making it less discriminatory [38].

Shell Elasticity Parameters Enhance Diagnostic Accuracy

A key contribution of this study is the inclusion of peritumoral elasticity assessment. In our series, shell Emean = 88 kPa achieved 80 % sensitivity, 98 % specificity, and 90 % accuracy, indicating that increased stiffness in the tissue immediately surrounding malignant lesions adds meaningful discriminative value. These results echo prior investigations: [39] demonstrated that Emean and Emax values measured in multiple shell widths (1 mm to 3 mm) were significantly higher in malignant non-mass lesions than in benign ones, and they also documented a higher prevalence of the “stiff rim” sign in malignant lesions. Meanwhile, another study reported that peripheral stiffness (shell SWE parameters) was elevated in malignant lesions, attributing elevated peritumoral elasticity to stromal infiltration and desmoplastic reaction [40].

This peritumoral stiffness likely reflects stromal infiltration and reactive fibrosis rather than tumor core properties alone, providing complementary diagnostic information.

Integration of SWE with BI-RADS

Integrating SWE parameters into the BI-RADS framework substantially improved diagnostic accuracy and specificity in our study. When applying BI-RADS + Emax ≥ 137 kPa, 36 of 53 BI-RADS 4a lesions were reclassified to BI-RADS 3, while still preserving a negative predictive value (NPV) of 99 %, thus safely reducing unnecessary biopsies without missing cancers. However, the risk of false-negative downgrading warrants careful consideration. Moreover, reclassification based on Emean shell increased overall accuracy from 0.64 to 0.93 and specificity from 0.63 to 0.97. Applying an STQ threshold ≥ 145 kPa further boosted specificity from 63 % to 100 % and increased overall accuracy to 84 %, supporting the idea that STQ can add discriminative strength. These results align with the general trend observed in BI-RADS + SWE combination studies: adding stiffness metrics allows downgrading of low-risk lesions, raises specificity, and improves overall diagnostic performance. For example, Zheng *et al.* (2021) showed that combining BI-RADS and SWE raised specificity and positive predictive value compared to either method alone [41]. Likewise, Wang *et al.* (2023) reported that SWE + imaging adjustments in BI-RADS reclassification improved

diagnostic distinction for breast lesions [42]. In the present study, malignant lesions were identified among upgraded cases rather than missed downgraded cases, but this finding should be interpreted cautiously due to the limited number of cancers.

Multivariate Combination and Diagnostic Enhancement

The combined analysis of Emax + Emean (intratumoral) and Emean + Emax (peritumoral shell) further improved diagnostic accuracy, increasing specificity by 25 % and sensitivity by 10 % compared with conventional B-mode ultrasound alone. These results are consistent with the findings previous study, which demonstrated that multiparametric SWE models—incorporating both quantitative stiffness indices and spatial heterogeneity—significantly enhance diagnostic precision and reduce interpretive ambiguity [43].

Similarly, a systematic review reported that combining multiple SWE parameters, rather than relying on a single stiffness value, improved differentiation between benign and malignant breast lesions and achieved higher area-under-the-curve (AUC) values than Emax or Emean alone [44]. It has also been emphasized that peritumoral elasticity measures complement intertumoral stiffness, reflecting stromal desmoplasia and tumor infiltration [45], critical factors that enrich multiparametric models for more reliable lesion stratification [46].

Collectively, these findings reinforce that multivariate SWE approaches, which integrate both intertumoral and peritumoral elasticity features, enable a more tailored diagnostic strategy and optimize lesion characterization within the BI-RADS framework.

False Positives and Negatives

Our findings demonstrated a markedly lower false-positive rate (8.3%) with Shear Wave Elastography (SWE) compared to B-mode ultrasound (33.8%), underscoring SWE’s value in refining lesion characterization and reducing unnecessary biopsies. This improvement aligns with the results of a large meta-analysis, which reported a pooled sensitivity of 90%, specificity of 86%, and an AUC of 0.92, confirming that SWE significantly enhances diagnostic specificity compared with conventional ultrasound. The same analysis estimated that incorporating SWE into clinical evaluation can reduce unnecessary biopsies by approximately 30–40%, primarily through a decline in false-positive findings [44]. Nonetheless, elastography should not be used as a stand-alone decision-making tool, and discordant findings between B-mode ultrasound, elastography, and clinical context should prompt biopsy rather than downgrading.

These convergent results support the growing consensus that SWE serves as an effective adjunct to BI-RADS classification, improving diagnostic confidence and minimizing invasive procedures for benign or low-risk lesions.

Strengths and Limitations

This study benefits from its prospective design, focused inclusion of BI-RADS 3 and 4a lesions, and comprehensive

evaluation of both intratumoral and peritumoral elastographic parameters. However, several limitations must be emphasized. The small number of malignant cases limits statistical robustness and may overestimate diagnostic performance. Single-center design and use of a specific ultrasound platform may restrict generalizability. Interobserver variability was not evaluated, and longitudinal follow-up was not performed.

Clinical Implications

By integrating quantitative SWE and STQ metrics with BI-RADS classification, clinicians may reduce unnecessary biopsies in selected low-risk cases while preserving a high margin of diagnostic safety. However, claims of cost-effectiveness should be interpreted cautiously, as this study did not include formal economic evaluation. Future multicenter studies with higher malignancy prevalence and standardized protocols are required before broad clinical adoption.

CONCLUSION

This study concludes that combining Sound Touch Elastography (SWE) and Sound Touch Quantification (STQ) with BI-RADS classification may improve diagnostic specificity and overall risk stratification for BI-RADS 3 and 4a breast lesions, particularly by reducing false-positive assessments. The most informative parameters Emax, Emean, and shell Emean demonstrated consistent diagnostic value, while multiparametric integration provided complementary information rather than replacing conventional imaging assessment.

Importantly, any elastography-guided reclassification in this study was performed with an explicit emphasis on maintaining a very high negative predictive value, underscoring that diagnostic safety must remain the primary consideration, especially when downgrading low-suspicion lesions. The evaluation of peritumoral stiffness supported the “stiff rim” concept, suggesting that stromal-level elasticity assessment can enhance lesion characterization beyond intratumoral measurements alone.

However, given the limited number of malignant cases and the use of a single ultrasound platform, these findings should be interpreted cautiously and should not be extrapolated as definitive criteria for malignant diagnosis. While SWE and STQ show promise as adjunct tools, their role should be viewed as supportive rather than determinative within a multimodal diagnostic framework.

Generalization to resource-limited settings should also be approached prudently, as implementation depends on equipment availability, operator expertise, and institutional infrastructure. Future multicenter studies are required to establish vendor-independent cutoff values, external validation, and standardized acquisition protocols before routine adoption across diverse clinical environments.

In summary, quantitative elastography may aid clinical decision-making for indeterminate breast lesions when used judiciously, with priority given to preserving diagnostic safety and avoiding missed malignancies, rather than solely maximizing diagnostic performance metrics.

Ethical Approval and Consent to Participate

The study was approved by the Ethical Committee of the College of Medicine, Hawler Medical University, Erbil, Kurdistan Region, Iraq. Written informed consent was obtained from all participants before enrollment.

Consent for Publication

Written informed consent for publication was obtained from all participants whose anonymized data were included in this manuscript.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

Competing Interests

The authors declare that they have no competing interests.

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