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Evaluation of focal breast lesions using ultrasound elastography with FNAC and/or histopathology correlation among patients visiting breast ultrasound and mammography units at Tikur Anbessa Specialized Teaching Hospital, Ethiopia, August, 2025

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Abstract

Background: Breast cancer continues to be a major cause of illness and death worldwide, including in Ethiopia. Traditionally, diagnosis in Ethiopia has relied on clinical palpation, mammography, and B-mode ultrasonography (US). Histopathological examination continues to be the gold standard for definitive diagnosis. Recently, elastography has emerged as a promising adjunct to B-mode ultrasonography, enhancing specificity and aiding in the early detection of breast cancer.
Methodology: A prospective analytical cross-sectional study was carried out at Tikur Anbessa Specialized Hospital (TASH) between December 1, 2024 and April 30, 2025.
Result: The study involved 100 patients, 72% had malignant breast lesions, 26% benign, and 2% atypical, with invasive carcinoma and fibroadenoma being the most common. BI-RADS alone showed high sensitivity (98.6%) but low specificity (7.7%). Adding elasticity scoring and strain ratio improved diagnostic accuracy. Elasticity scoring achieved 96% sensitivity and 69% specificity, while strain ratio had 98.6% sensitivity and 54% specificity. Serial testing method provided a more balanced approach with 93% sensitivity, 86.9% specificity, and 93.5% accuracy, reducing false positives while maintaining diagnostic strength.
Conclusion: This study highlights the clinical value of integrating BI-RADS, elasticity scoring, and strain ratio in the ultrasound assessment of breast lesions.

Keywords: BIRADS 3, BIRADS 4, breast lesion, cytology, elasticity scoring, elastography, histopathology, sensitivity and specificity, strain ratio, ultrasound

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Introduction

Breast cancer is the most common malignancy among women worldwide, with approximately 2.3 million new cases and 670,000 deaths reported in 2022(1). In Ethiopia, breast cancer is the leading cancer among women, accounting for about one-third of female cancers and one-fifth of all cancers overall. Despite this high burden, early and accurate diagnosis remains a major challenge (2).

Traditionally, breast cancer diagnosis in Ethiopia has relied on clinical examination, mammography, and conventional B-mode ultrasonography, with histopathology as the diagnostic gold standard (3). Although ultrasound is widely used because of its availability, non-invasiveness, and real-time imaging capability, its relatively low specificity limits its ability to reliably distinguish benign from malignant lesions. This limitation is particularly evident in BI-RADS category 3 and 4A lesions, where malignancy risk is low but not negligible. As a result, many patients undergo frequent follow-up or unnecessary biopsies, which increase cost, patient anxiety, and healthcare burden. Poor patient adherence to imaging follow-up, largely due to financial limitations and inadequate awareness, often compels clinicians to opt for biopsy even in cases with a low likelihood of malignancy (4, 5).

Ultrasound elastography, introduced as a technique to assess tissue stiffness, provides additional functional information that complements conventional ultrasound (6, 7). Both strain elastography and shear wave elastography have demonstrated improved specificity in differentiating benign from malignant breast lesions, particularly in equivocal cases (8, 9). Several international studies have shown that elastography, especially quantitative parameters such as strain ratio, can safely downgrade a significant proportion of BI-RADS 4A lesions, thereby reducing unnecessary biopsies without compromising cancer detection. Consequently, elastography has been incorporated into the ACR BI-RADS lexicon as an adjunct imaging tool (11, 12, 13).

While extensive evidence from Asia, the Middle East, South America, and other regions supports the diagnostic value of elastography, data from sub-Saharan Africa, including Ethiopia, are scarce. Differences in patient demographics, breast cancer biology, healthcare access, and imaging practice patterns limit the direct applicability of foreign data to the Ethiopian population (14 -28).

Therefore, there is a critical need to evaluate the role of ultrasound elastography in the characterization of breast lesions in Ethiopia. Generating local evidence on its diagnostic performance, particularly for BI-RADS 3 and 4A lesions, may help optimize patient management, reduce unnecessary biopsies, and improve cost-effective breast cancer care in resource-limited setting.

Objective

General Objective: To evaluate focal breast and post-mastectomy chest wall lesions using ultrasound elastography and correlate findings with FNAC/CNB results at TASH.

Specific Objective: To determine the diagnostic performance (sensitivity, specificity, PPV, NPV, and accuracy) of ultrasound elastography in differentiating benign from malignant lesions.

Materials and Methods

The study was conducted at Tikur Anbessa Specialized Hospital (TASH) in Addis Ababa, the main teaching hospital of the School of Medicine at Addis Ababa University, which provides a wide range of clinical services. This single-center prospective analytical cross-sectional study was carried out from December 1, 2024 to April 30, 2025, to evaluate focal breast and post-mastectomy chest wall lesions using ultrasound elastography with correlation to FNAC/CNB findings. The source population included all patients attending the Breast and Mammography Unit of the Radiology Department, while the study population consisted of eligible patients who met the predefined inclusion and exclusion criteria.

The study included females aged 16 to 80 years who had sonographically visible solid breast lesions smaller than 3 cm and categorized as BI-RADS 3, 4, or 5 on conventional ultrasound. For BIRADS 3 lesions, only those that had undergone fine needle aspiration cytology (FNAC) or biopsy were considered. Exclusion criteria were cystic lesions, solid lesions classified as BIRADS 2, lesions larger than 3 cm, lesions situated close to the skin surface or chest wall, and lesions without cytological or histopathological confirmation.

The sample size was calculated to be 138 based on a proportion estimate of p=0.9. After accounting for a 5% non-response rate, the final adjusted sample size was 145. A biopsy enriched convenience sampling technique was employed. A pre-prepared data collection checklist adapted from ACR BIRADS guideline was used as the primary tool for data collection.

The imaging equipment we used was the Mindray DC-60 Exp system, using the L14-6NE high-frequency linear array transducer.

Data collection tool and procedure

Lesions were initially evaluated using conventional B-mode ultrasonography, following a radial scanning pattern with patients in the supine position. Each lesion was classified into an appropriate BIRADS category based on conventional ultrasound features.

Elastography Technique and Parameters

Strain elastography data were obtained by positioning the field-of-view box to encompass the area from the subcutaneous fat layer down to the pectoralis muscle, while carefully avoiding the rib cage. Proper compression was verified by the appearance of two to three green blocks on the vertical column display on the left side of the ultrasound monitor; one or no block indicated insufficient compression, while four to five blocks signaled excessive pressure.

Elasticity scores (ES) were assigned according to the 5-point Tsukuba classification system introduced by Itoh et al (31).

Lesions scoring 1 to 3 were classified as benign, while scores of 4 or 5 were considered suspicious for malignancy.

The strain ratio (SR) was calculated by positioning the first region of interest (ROI) within the lesion and the second ROI in adjacent subcutaneous fat at a similar size and depth. This measurement was repeated three times, and the average value was used to provide a quantitative evaluation of tissue stiffness.

Histopathology

The lesions underwent fine-needle aspiration cytology (FNAC), ultrasound-guided core biopsy, or surgical excision, with histopathological findings serving as the reference standard for evaluating the results of conventional ultrasound and elastography.

Data Quality Control and Statistical Analysis

Radiological image acquisition and evaluation were performed by a single radiologist trained in breast strain elastography. To ensure quality control, the operator received prior training in strain elastography techniques and adhered strictly to the standardized data collection procedures described above. The primary investigator checked the data for accuracy and consistency to ensure its completeness and quality, and then entered it into IBM SPSS version 25.0 for analysis.

Nominal variables were summarized using frequencies and percentages. The associations between BI-RADS score, elasticity score, and strain ratio with biopsy results were analyzed, and a p-value of <0.05 was considered statistically significant. Receiver operating characteristic (ROC) curves were generated to evaluate the diagnostic performance of the methods by calculating the area under the curve (AUC). Comparisons between AUC values were performed descriptively, and no formal statistical test for differences between AUCs was applied. Correlations among the different diagnostic modalities were also assessed. The results were presented using tables and charts.

Operational Definitions

BIRADS score (BS)- Negative or Benign lesions:1 to 3, positive or Suspicious lesions: 4 and 5 (ACR BI-RADS Atlas, 5th Edition, Breast Imaging Reporting and Data System)

Elasticity Score (ES)- Negative or Benign lesions: ES 1 to 3, Positive or Suspicious lesions: ES 4 and 5 (Itoh A et al. Breast disease: clinical application of US elastography)

Strain Ratio (SR) - Negative or Benign lesions: SR < 3.1, Positive or Suspicious lesions: SR ≥ 3.1 (Zhi et al ultrasonic in breast cancer diagnosis)

Parallel testing method:
A lesion is classified as positive or suspicious if any one of the following parameters is positive or suspicious: BI-RADS score, elasticity score, or strain ratio.

Serial testing method:
A lesion is classified as positive or suspicious only when all three parameters: BI-RADS score, elasticity score, and strain ratio are positive or suspicious.

Ethical clearance was obtained from the Research and Ethics Committee of the Radiology Department at Addis Ababa University. Informed consent was obtained from all patients. All patient information was kept confidential and anonymous; direct identifiers such as names or specific addresses were not used. Participation in the study was strictly voluntary.

Results

Between December 1, 2024 and April 30, 2025 a total of 112 eligible patients with breast and post-mastectomy chest wall lesions were recruited. However, 12 cases were excluded due to loss to follow-up. In these patients, BI-RADS classification and strain elastography assessment were performed, but histopathological confirmation was unavailable either because the biopsy results were non-diagnostic or the patients did not undergo biopsy.

Consequently, 100 participants were included in the final analysis and subsequent follow-up phase. The final sample size was smaller than the initially calculated sample size due to time constraints and loss to follow-up. This reduction in sample size may have decreased the statistical power of the study and could limit the generalizability of the findings.

The largest proportion of participants 36% were aged 31–40 years, followed by 33% in the 41–50 age group. Fourteen participants 14% were aged 21–30 years, and 6% were 60–70 years old. The mean age of the participants was 42.6 years, with a standard deviation of 11 years (Table 1).

Most participants underwent examination for breast lump followed by routine screening (figure 1).

Histopathological evaluation of FNAC and core needle biopsy (CNB) specimens revealed that, among the 100 patients included in the study, 72 had malignant lesions, 26 had benign lesions, and 2 had atypical lesions. The most common malignant diagnosis was invasive carcinoma while fibroadenoma was the most frequently identified benign lesion (Figure 2).

The high proportion of malignant cases is consistent with the nature of our institution as a tertiary referral center, where most referred patients present with clinically and radiologically suspicious lesions. Additionally, the study population consisted primarily of lesions selected for biopsy, which inherently included cases with higher suspicion for malignancy, while clearly benign-appearing lesions were less likely to undergo tissue sampling due to feasibility and clinical practice considerations.

The majority of the examined breast tissues exhibited a homogeneous distribution of fibro glandular element and located in the right breast. The upper outer quadrant was the most common site of breast lesions.

When evaluating all lesions, nearly half (48%) were classified as BI-RADS category 5, followed by 38% in category 4A. Categories 4B and 3 accounted for 10% and 4% of cases, respectively. Only a small number of lesions (4%) were categorized as benign (BI-RADS 3), while the majorities (96%) were considered suspicious (BI-RADS 4 or 5). Benign lesions typically featured oval shapes, parallel orientation, circumscribed margins, and hypoechoic echogenicity without posterior features, calcifications, or associated findings. In contrast, suspicious lesions were usually irregular, non-parallel, and non-circumscribed, with hypoechoic echotexture and internal vascularity.

Analysis of BI-RADS categorization showed that most benign lesions were classified as categories 3 and 4A, whereas the majority of malignant lesions were assigned to categories 4 and 5. The two atypical lesions were categorized as BI-RADS 3 and 4A.

Although lesions categorized as BI-RADS 4–5 showed higher odds of malignancy on FNAC/CNB, the association between BI-RADS category and FNAC/CNB result was not statistically significant ($p = 0.35$). This is likely due to the small number of cases in the BI-RADS 1–3 categories, resulting in class imbalance and reduced statistical power to detect a true association. The limited sample size in the lower BI-RADS groups may also have produced wide confidence intervals and unstable estimates, reducing the precision of the findings. Therefore, the lack of statistical significance should not be interpreted as contradicting the established diagnostic value of BI-RADS, but rather as a reflection of study-specific limitations, including the skewed case distribution and the relatively small number of benign lesions. (Table 2).

Using a BI-RADS cutoff of ≥4 to indicate malignancy, the diagnostic performance metrics demonstrated a sensitivity of 98.6% (95% CI: 96–100%) and a specificity of 7.7% (95% CI: 0–18%). The positive predictive value (PPV) was 74.7% (95% CI: 66–83%), while the negative predictive value (NPV) was 66.7% (95% CI: 13–100%), with an overall diagnostic accuracy of 74.5% (95% CI: 66–83%). Receiver operating characteristic (ROC) curve analysis showed an area under the curve (AUC) of 0.89 (95% CI: 0.83–0.95), indicating good overall discriminative ability of the BI-RADS scoring system. However, despite its high sensitivity, the low specificity resulted in the misclassification of 24 benign lesions as false positives (Figure 3).

Elastography assessment demonstrated that most benign lesions had elasticity scores of 2 or 3, whereas the majority of malignant lesions were assigned scores of 4 and 5. The two atypical lesions received elasticity scores of 3 and 4.

Statistical analysis revealed a highly significant association between elasticity score and FNAC/CNB results ($p < 0.001$). Lesions with elasticity scores of 4–5 had approximately 52 times higher odds of malignancy compared to those with scores of 1–3, indicating strong predictive value of higher elasticity scores for malignancy (Table 3).

Using an elasticity score cutoff of ≥4 to indicate malignancy, the diagnostic performance analysis demonstrated a sensitivity of 95.8% (95% CI: 91–100%) and a specificity of 69.2% (95% CI: 56–87%). The positive predictive value (PPV) was 89.6% (95% CI: 83–96%), while the negative predictive value (NPV) was 85.7% (95% CI: 71–100%), with an overall diagnostic accuracy of 88.8% (95% CI: 83–95%). Receiver operating characteristic (ROC) curve analysis showed an area under the curve (AUC) of 0.92 (95% CI: 0.88–0.98), indicating excellent discriminative ability of the elasticity scoring system. Despite this strong performance, 8 benign lesions were misclassified as false positives (figure 4).

Strain ratio analysis showed that 14 benign lesions had values below the cutoff of 3.1, whereas the majority of malignant lesions (71 cases) demonstrated strain ratios ≥3.1. Both atypical lesions had strain ratios below 3.1. Statistical analysis demonstrated a highly significant association between strain ratio and FNAC/CNB results ($P < 0.001$). Lesions with a strain ratio ≥3.1 had approximately 83-fold higher odds of malignancy compared to those with strain ratios <3.1. (Table 4)

Using a strain ratio cutoff value of 3.1 to indicate malignancy, the diagnostic performance analysis demonstrated a sensitivity of 98.6% (95% CI: 96–100%) and a specificity of 53.8% (95% CI: 35–73%). The positive predictive value (PPV) was 85.5% (95% CI: 78–93.1%), while the negative predictive value (NPV) was 93.3% (95% CI: 81–100%), with an overall diagnostic accuracy of 86.7% (95% CI: 80–93%). Receiver operating characteristic (ROC) curve analysis showed an area under the curve (AUC) of 0.85 (95% CI: 0.74–0.95), indicating good discriminative ability of the strain ratio method. Despite its effectiveness, the system misclassified 12 benign lesions as false positives (Figure 5).

A total of 13 patients were evaluated for suspected post-mastectomy chest wall recurrence. Histopathology confirmed 11 (84.6%) malignant lesions (all invasive carcinoma) and 2 (15.4%) benign lesions (one fat necrosis and one with no evidence of malignancy).

On BI-RADS assessment, lesions were distributed across probably benign to highly suspicious categories. Elastography demonstrated predominantly high elasticity scores, and most lesions had a strain ratio >3.1.

Diagnostic performance analysis for post mastectomy chest wall lesion showed:

BI-RADS: Sensitivity 91%, Specificity 50%, PPV 91%, NPV 50%, Accuracy 84.6%.

Elasticity Score: Sensitivity 91%, Specificity 100%, PPV 100%, NPV 66.7%, Accuracy 92.3%.

Strain Ratio: Sensitivity 100%, Specificity 50%, PPV 92%, NPV 100%, Accuracy 92.3%.

In the post-mastectomy chest wall lesion subgroup, elastography parameters demonstrated higher diagnostic accuracy compared to BI-RADS alone. However, this subgroup analysis is descriptive in nature and explicitly limited by the small sample size, which reduces statistical power and restricts the generalizability of the findings.

Diagnostic Performance of Combined Methods

When BI-RADS and elasticity scores were combined using a serial testing approach, the method achieved a sensitivity of 94.4%, specificity of 71.6%, PPV of 96.8%, NPV of 59.8%, and an overall diagnostic accuracy of 92.3%. A Spearman correlation coefficient of 0.873 demonstrated a strong correlation between the two scoring systems. Under this approach, the combined method yielded 7 false-positive cases.

When BI-RADS and strain ratio were combined using a serial testing approach, the method achieved a sensitivity of 97.2%, specificity of 57.4%, PPV of 92.9%, NPV of 78.2%, and an overall accuracy of 91.3%. The Spearman correlation coefficient was 0.594, indicating a moderate correlation between the two methods. Under this approach, the combined strategy resulted in 11 false-positive cases.

For the combination of elasticity score and strain ratio, serial testing yielded a sensitivity of 94.4%, specificity of 85.8%, PPV of 97.5%, NPV of 69.2%, and accuracy of 93.9%. The Spearman correlation coefficient of 0.703 indicated a strong correlation between these modalities. With this approach, the combined method produced 4 false-positive cases.

When all three methods, BI-RADS, elasticity score, and strain ratio, were combined using a serial testing approach, the results showed a sensitivity of 93%, specificity of 86.9%, PPV of 97.6%, NPV of 63.9%, and an overall accuracy of 93.5%. This combined approach resulted in 3 false-positive cases (Figure 6). The diagnostic performance of individual and combined methods using a serial testing approach is summarized in Table 5.

Discussion

In this study, the majority of participants presented with a palpable breast lump (63%), followed by individuals undergoing routine screening (19%). These findings are comparable to reports from Bangladesh, where breast lumps and breast pain were identified as the most common reasons for seeking breast evaluation [23, 24].

The analysis of 100 patients evaluated using FNAC and CNB revealed that 72% of lesions were malignant, while 26% were benign. Invasive carcinoma constituted the majority of malignant cases (93.1%), whereas fibroadenoma was the most frequently identified benign lesion. These findings differ from reports from studies conducted in India, where a higher proportion of benign breast lesions have been described. Despite this variation in the overall distribution of benign and malignant lesions, the histopathological pattern remains consistent across studies, with fibroadenoma representing the most common benign lesion and invasive ductal carcinoma being the most prevalent malignant tumor [16–18].

Regarding ultrasound characteristics, benign lesions in the present study predominantly demonstrated an oval shape (75%), parallel orientation (75%), circumscribed margins (100%), and a hypoechoic echotexture (100%). In contrast, malignant lesions were more frequently associated with irregular shape (63.5%), non-parallel orientation (72.5%), non-circumscribed margins (64.5%), hypoechoic echotexture (80.2%), and increased vascularity (74%). These findings are consistent with previously published studies, including those conducted at Enam Medical College and Hospital in India, which reported similar ultrasound characteristics distinguishing benign from malignant breast lesions [23].

Receiver operating characteristic (ROC) analysis of the BI-RADS scoring system in the current study demonstrated a high sensitivity of 98.6% but relatively low specificity of 7.7% using BI-RADS ≥4 as the threshold for malignancy. The area under the curve (AUC) was 0.89, indicating strong overall diagnostic performance. These findings are comparable to results reported in a study conducted at Aster CMI Hospital in India [18]. This comparison highlights the value of BI-RADS as a highly sensitive screening tool; however, its relatively low specificity emphasizes the need for complementary diagnostic modalities to improve overall diagnostic accuracy and specificity.

Similarly, ROC analysis of the elasticity scoring (ES) system demonstrated a sensitivity of 96% and specificity of 69% when elasticity scores ≥4 were considered indicative of malignancy with an AUC of 0.92. These findings are in agreement with results reported from Aster CMI Hospital, where elasticity scoring achieved a sensitivity of 92.3%, specificity of 94.6%, and an AUC of 0.98 [18]. The high sensitivity observed in both studies supports the clinical utility of elasticity scoring as a non-invasive technique for differentiating benign from malignant breast lesions.

Furthermore, ROC analysis of the strain ratio in the present study demonstrated a sensitivity of 98.6% and specificity of 53.8% at a cutoff value of 3.1, with an AUC of 0.85. The strain ratio yielded a positive predictive value (PPV) of 85.5%, a negative predictive value (NPV) of 93.3%, and an overall diagnostic accuracy of 86.7%. These findings are comparable to those reported in a study conducted at Aster CMI Hospital [18]. Although the specificity observed in our study was relatively lower, the high sensitivity and comparable diagnostic accuracy suggest that strain ratio measurement can serve as a useful adjunct in the evaluation of suspicious breast lesions, particularly in high-sensitivity screening settings.

In the present study, the combined use of BI-RADS and elasticity scores using a serial testing approach resulted in a sensitivity of 94.7%, specificity of 71.4%, PPV of 96.8%, NPV of 59.8%, and an overall diagnostic accuracy of 92.3%. These findings are consistent with previous research conducted in Brazil, where the integration of elastography with conventional ultrasound improved diagnostic performance by increasing sensitivity, specificity, and overall accuracy [29]. This supports the additional value of elastography when used alongside conventional ultrasound in the evaluation of breast lesions.

Finally, the relatively high prevalence of malignancy in the study population (72%) likely influenced the predictive values observed. Higher disease prevalence tends to increase the positive predictive value while reducing the negative predictive value. Although sensitivity and specificity are theoretically independent of disease prevalence, the relatively small proportion of benign cases may affect the precision of specificity estimates. Additionally, diagnostic accuracy may appear higher in populations with a high proportion of malignant lesions.

Strengths and Limitations of the Study

This study provides a comprehensive evaluation of multiple diagnostic modalities with robust statistical analyses, including contingency table and ROC curve assessments, offering clinically relevant insights into diagnostic performance. However, several limitations should be acknowledged. The relatively high prevalence of malignant cases and the single-center referral setting may introduce referral and selection bias, thereby limiting the generalizability of the findings. The results may also have been influenced by operator dependence, particularly in image acquisition and interpretation. In addition, interobserver variability was not assessed, making it difficult to determine how consistently the imaging features and diagnostic thresholds could be reproduced across different radiologists or institutions. This lack of reproducibility assessment may limit the applicability of the findings in routine clinical practice, where variability in reader experience and technique can influence diagnostic performance. Furthermore, the actual sample size was smaller than initially planned, and no external validation of the diagnostic cutoffs was performed. These factors should be considered when interpreting the findings and extrapolating them to broader patient populations.

Conclusions

The findings of this study suggest that integrating BI-RADS with ultrasound elastography, including elasticity scoring and strain ratio, may enhance the evaluation of breast lesions by improving specificity and potentially reducing false-positive classifications compared to conventional ultrasound alone. Multiparametric ultrasound, combining B-mode imaging and elastography, could be considered as a complementary approach in clinical assessment. However, these results are based on a study population with a relatively high prevalence of malignancy and a single-center design; therefore, they should be interpreted cautiously and may not be directly generalizable to screening populations or settings with lower disease prevalence.

Conflict of Interest:

The authors declare no conflicts of interest.

Financial Declaration / Funding:

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Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Addis Ababa University, College of Health Sciences, Department of Radiology Ethical Review Committee (ERC) issued approval Ref. DRPC/009/2017.

Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue. Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work.

Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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Tables & Figures

Table 1: Age distribution of patients with breast and post-mastectomy chest wall lesions visiting the breast and mammography unit, radiology department, TASH (December 1, 2024 to April 30, 2025)

Age category	Frequency	Percent
21-30	14	14
31-40	36	36
41-50	33	33
51-60	10	10
61-70	6	6
71-80	1	1
Total	100	100

Table 2: Contingency table showing the association between BI-RADS scores and FNAC/CNB results among patients at the breast and mammography unit, radiology department, TASH (December 1, 2024 to April 30, 2025)

BIRADS score*FNAC/		FNAC/CNB		Chi-square=0.875
		Benign	Malignant	P-value=0.35
BIRADS score	BIRADS 1 to 3	2	1	Odds ratio=6
	BIRADS 4 and 5	24	71	

Table 3: Contingency table showing the association between elasticity scores and FNAC/CNB result among patients at the breast and mammography unit, radiology department, TASH (December 1, 2024 to April 30, 2025)

* FNAC/CNB		FNAC/CNB		Chi-
		Benign	Malignant	P-value<001
Elasticity	score 1 to 3	18	3	Odds ratio=52
	score 4 and 5	8	69	

Table 4: Contingency table showing the association between strain ratio and FNAC/CNB results among patients at the breast and mammography unit, radiology department, TASH (December 1, 2024 to April 30, 2025)

Strain ratio * FNAC/CNB		FNAC/CNB		Chi-square=40.3
		Benign	Malignant	P-value<0.001
Strain ratio	<3.1	14	1	Odds ratio=83
	>=3.1	12	71	

Table 5: Diagnostic performance of individual and combined methods using a serial testing approach among patients at the breast and mammography unit, radiology department, TASH (December 1, 2024 – April 30, 2025).

Diagnostic performance of single and combined methods using serial approach	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy	Area under curve (AUC)
BIRADS score	98.6%	7.70%	74.7%	66.7%	74.5%	0.89
Elasticity score	95.8%	69.2%	89.6%	85.7%	88.8%	0.92
Strain Ratio	98.6%	53.8%	85.5%	93.3%	86.7%	0.85
BIRADS score and Elasticity score	94.4%	71.6%	96.8%	59.8%	92.3%	
BIRADS score and Strain ratio	97.2%	57.4%	92.9%	78.2%	91.3%	
Elasticity score and Strain ratio	94.4%	85.8%	97.5%	69.2%	93.9%	
BIRADS score, Elasticity score and Strain ratio	93.0%	86.9%	97.6%	63.9%	93.5%	

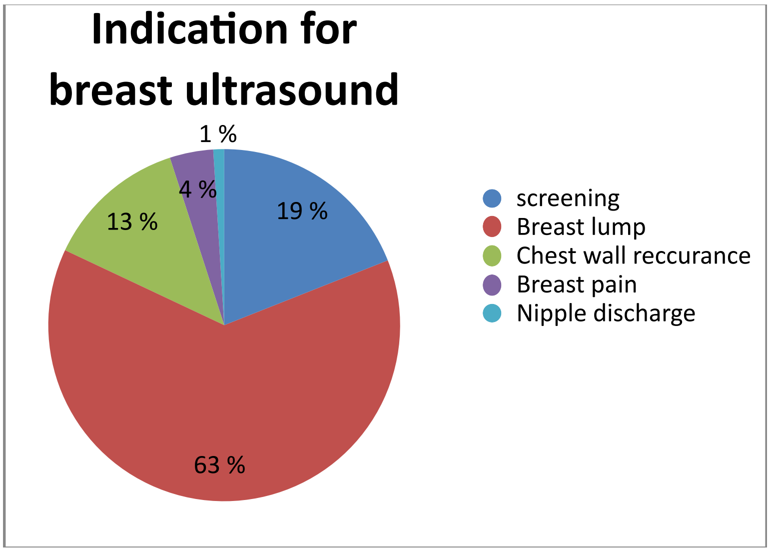

Figure 1: Pie chart illustrating indications for breast ultrasound among patients visiting the breast and mammography unit, radiology department, TASH (December 1, 2024 to April 30, 2025)

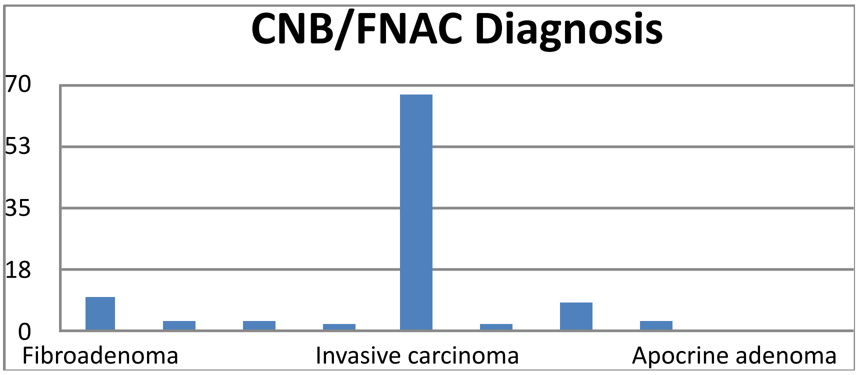

Figure 2: Bar chart showing CNB/FNAC diagnosis of breast and post-mastectomy lesions among patients attending the breast and mammography unit, radiology department, TASH (December 1, 2024 to April 30, 2025)

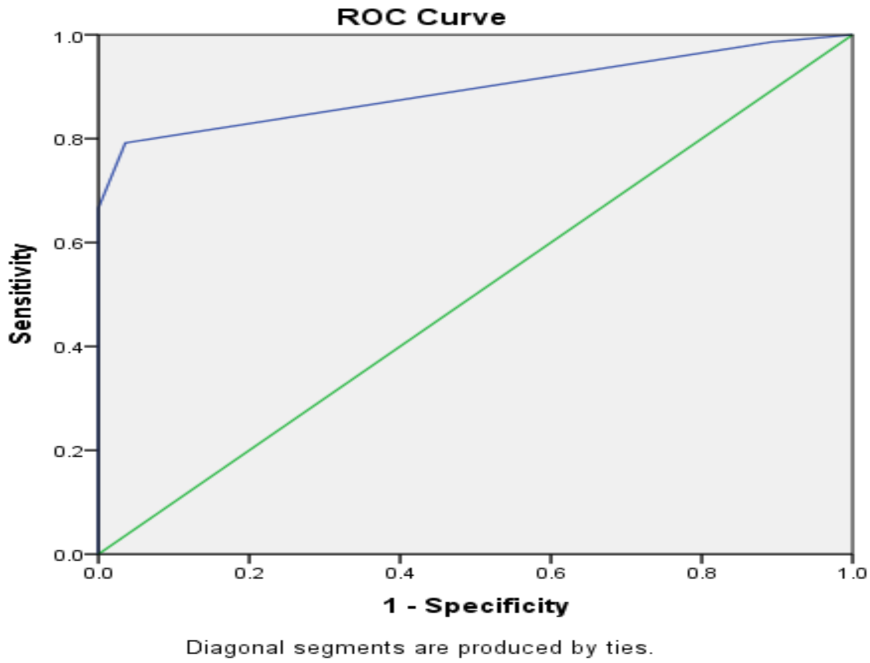

Figure 3**:** ROC curve analysis of the BI-RADS scoring system for breast and post-mastectomy lesions evaluated at the breast and mammography unit, radiology department, TASH (December 1, 2024–April 30, 2025) demonstrated an AUC of 0.89 (95% CI: 0.83–0.95).

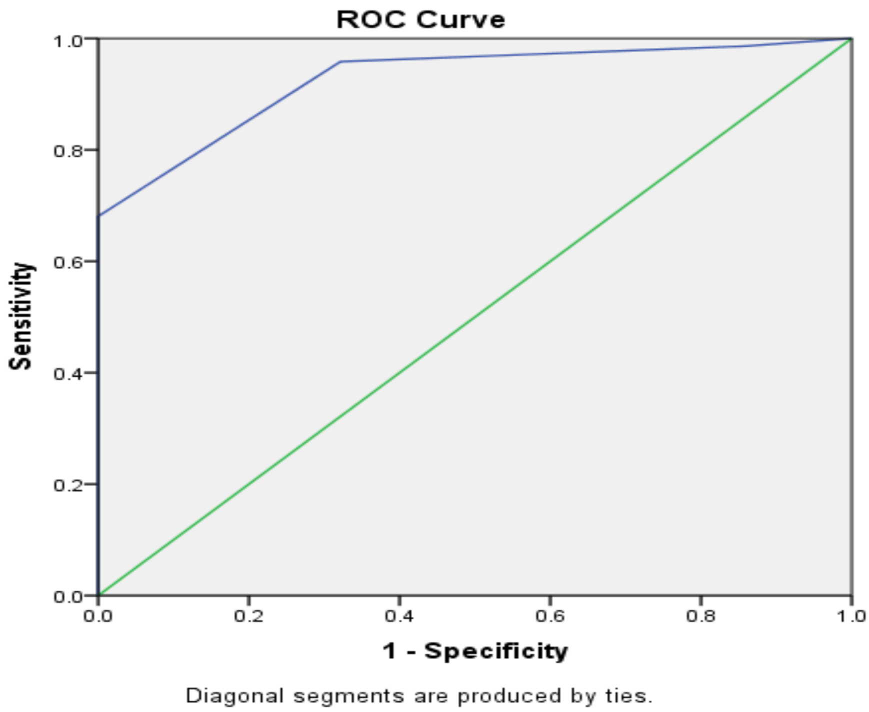

Figure 4**:** ROC curve analysis of the elasticity scoring system for breast and post-mastectomy lesions assessed at the breast and mammography unit, radiology department, TASH (December 1, 2024–April 30, 2025) showed an AUC of 0.92 (95% CI: 0.88–0.98).

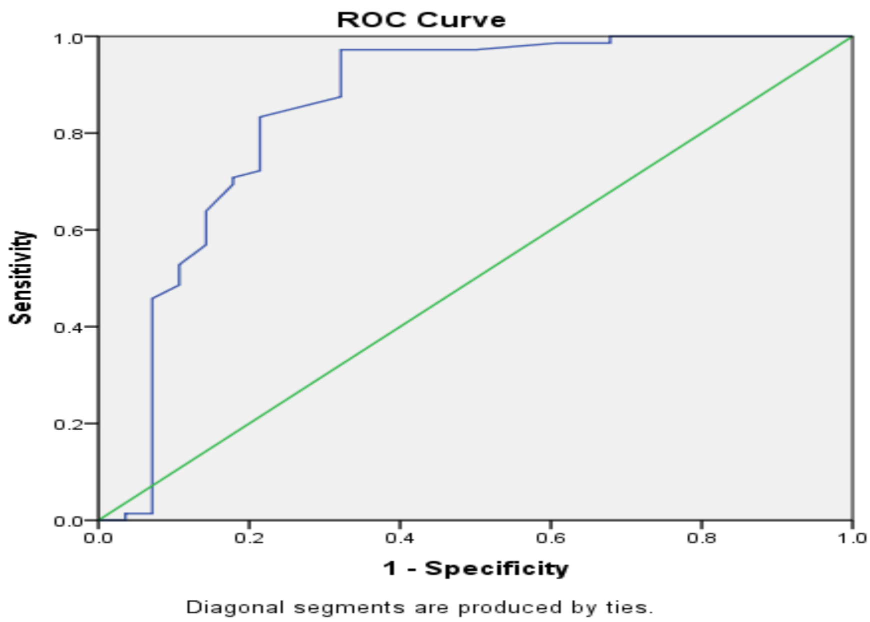

Figure 5**:** ROC curve analysis of the strain ratio for breast and post-mastectomy lesions evaluated at the breast and mammography unit, radiology department, TASH (December 1, 2024–April 30, 2025) demonstrated an AUC of 0.85 (95% CI: 0.74–0.95).

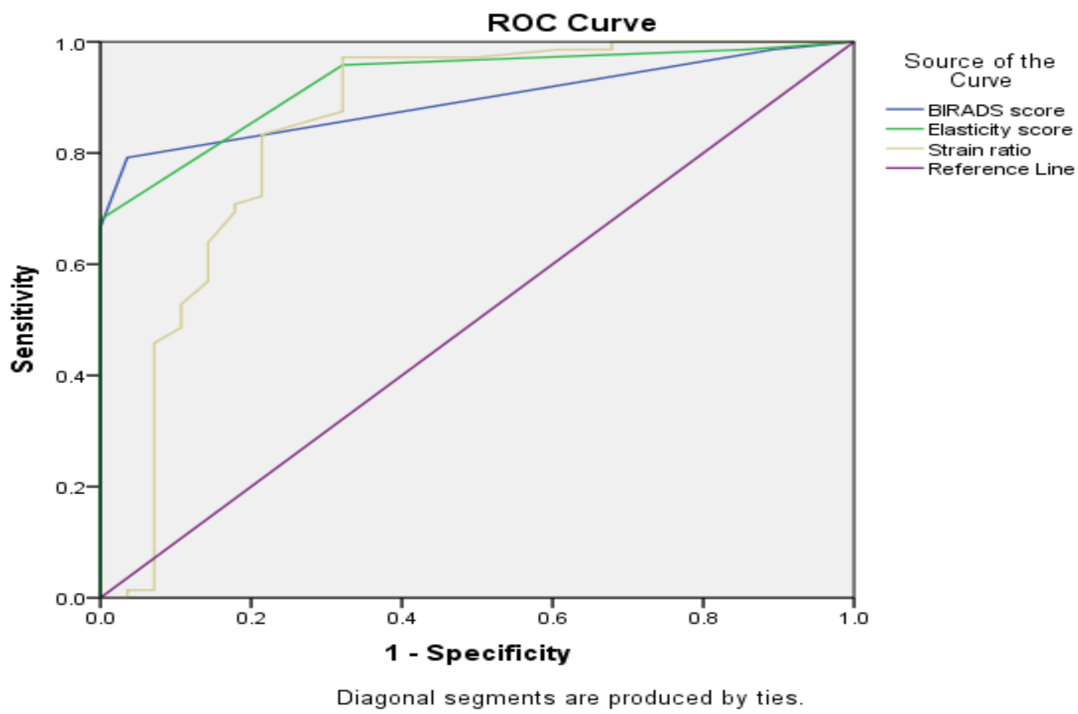

Figure 6**:** Combined ROC curve for the BI-RADS score, elasticity score, and strain ratio, illustrating their respective areas under the curve (AUC): BI-RADS score 0.89, elasticity score 0.92, and strain ratio 0.85, based on data from breast and post-mastectomy lesions in patients evaluated at the breast and mammography unit, radiology department, TASH, between December 1, 2024, and April 30, 2025.

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Declarations

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