

Research Article

Role of Ultrasound Elastography in Differentiating Benign and Malignant Breast Lesions

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A B S T R A C T

Background: Breast cancer is the most common malignancy among women worldwide. Accurate differentiation between benign and malignant breast lesions is essential for appropriate management. Conventional B-mode ultrasonography (US) is highly sensitive but limited in specificity. Ultrasound elastography (USE), by assessing tissue stiffness, offers a promising adjunctive diagnostic tool.

Objectives: To evaluate the role of ultrasound elastography in differentiating benign and malignant breast lesions and to compare its diagnostic performance with B-mode ultrasonography and histopathology as the reference standard.

Materials and Methods: This prospective observational study included 80 female patients with 100 breast lesions. Each lesion was evaluated using B-mode US and strain elastography, followed by histopathological correlation. Elastography parameters included Tsukuba elasticity score and strain ratio (SR). Statistical analysis was performed using the t-test, Chi-square test, Mann-Whitney U test, ROC analysis, and McNemar test, with $p < 0.05$ considered significant.

Results: The mean age of patients was 44.26 ± 12.38 years. Histopathology revealed 63 benign and 37 malignant lesions. Mean elasticity scores were 2.11 ± 0.73 (benign) and 4.21 ± 0.61 (malignant), and mean SR values were 1.68 ± 0.57 and 4.82 ± 1.19 , respectively ($p < 0.001$). An SR cutoff of 2.8 yielded AUC = 0.94, sensitivity = 91.9%, specificity = 88.9%, and accuracy = 90%. Combined B-mode + elastography improved diagnostic accuracy to 92.5%.

Conclusion: Ultrasound elastography significantly improves the diagnostic accuracy of B-mode ultrasonography in differentiating benign from malignant breast lesions. It is a reliable, non-invasive, and quantitative imaging tool that enhances specificity and reduces unnecessary biopsies in routine breast imaging.

Keywords: Breast Lesions, Ultrasound Elastography, Strain Ratio, Tsukuba Elasticity Score, Diagnostic Accuracy

Introduction

Breast cancer is the most common malignancy affecting women worldwide and remains a leading cause of cancer-related morbidity and mortality. The global incidence of breast cancer has been rising steadily in both developed and developing nations, with lifestyle changes, urbanization, and delayed diagnosis contributing significantly to this trend.¹ In low- and middle-income countries, limited access to screening programs and diagnostic infrastructure further compounds late-stage presentations and poor outcomes. Early and accurate detection of breast cancer is therefore crucial for improving patient prognosis and survival rates. Imaging plays a pivotal role in breast cancer screening, diagnosis, and management. The commonly used imaging modalities include mammography, ultrasonography (US), and magnetic resonance imaging (MRI). Mammography, though considered the current gold standard for population-based screening, demonstrates reduced sensitivity in younger women, those with dense breasts, or small non-calcified lesions.² Conventional B-mode ultrasonography, owing to its real-time visualization, cost-effectiveness, and safety, has become a preferred modality for characterizing palpable and non-palpable breast lesions. However, its diagnostic specificity remains limited, as benign and malignant lesions can exhibit overlapping sonographic features.³ This limitation often leads to unnecessary biopsies and patient anxiety. MRI provides superior soft-tissue contrast and functional information but is limited by high cost, longer scan times, and restricted availability, particularly in resource-limited settings.

To overcome these challenges, ultrasound elastography (USE) has emerged as a promising adjunctive imaging technique. USE evaluates tissue stiffness by measuring the degree of deformation (strain) or the propagation speed of shear waves when external or internal stress is applied. Since malignant tissues tend to be harder and less elastic than benign ones, assessment of tissue stiffness provides valuable diagnostic information beyond conventional gray-scale imaging.⁴ Elastography enhances the functional assessment of breast lesions by quantifying tissue elasticity, thereby improving differentiation between benign and malignant pathologies.

Two primary techniques of elastography are currently in use: strain elastography (SE) and shear-wave elastography (SWE). SE estimates tissue deformation caused by manual compression, providing semi-quantitative information through color-coded maps and strain ratios, whereas SWE quantitatively measures the velocity of shear waves generated within tissue, offering operator-independent and reproducible results.⁵⁻⁸ Several studies have demonstrated that integrating elastographic parameters such as elasticity score, strain ratio, and shear-wave velocity can significantly

increase the specificity of ultrasonography, thereby reducing unnecessary biopsies while maintaining high sensitivity for malignancy detection. Moreover, incorporating elastographic findings with the Breast Imaging Reporting and Data System (BI-RADS) has been shown to improve diagnostic confidence and inter-observer agreement.⁹ Although numerous international studies have highlighted the potential of ultrasound elastography in breast lesion evaluation, data from Indian populations remain relatively limited. Given the high prevalence of benign breast diseases in the Indian context and the socio-economic burden associated with invasive diagnostic procedures, establishing the clinical utility of elastography is particularly relevant.

Therefore, the present study was designed to evaluate the role of ultrasound elastography in differentiating benign and malignant breast lesions, to compare its findings with conventional B-mode ultrasonography and histopathology, and to determine its diagnostic performance.

Materials and Methods

Study Design And Setting

This study was a hospital-based prospective observational study conducted in the Department of Radiodiagnosis. All 104 patients referred for breast ultrasonography with palpable or mammographically detected breast lesions were included after obtaining written informed consent.

Study Population

Female patients presenting with breast lumps or clinically suspected breast lesions were enrolled in the study. Patients of all age groups who underwent both conventional B-mode ultrasonography and ultrasound elastography, followed by histopathological confirmation, were included.

Inclusion Criteria

- Patients with palpable or radiologically detected breast lesions.
- Lesions that could be adequately visualized on both B-mode ultrasound and elastography.
- Patients who underwent histopathological examination (core needle biopsy or excision biopsy).

Exclusion Criteria

- Patients with purely cystic lesions.
- Lesions not accessible for adequate compression or elastographic evaluation.
- Patients with prior breast surgery, radiotherapy, or chemotherapy in the same breast.
- Patients who refused or were unfit for biopsy.

Ultrasound Examination

All ultrasound and elastography examinations were performed using a high-frequency linear array transducer (7–12 MHz) on a [mention ultrasound system model, e.g.,

GE Logiq E9/Samsung RS80A]. Patients were positioned supine or slightly oblique with the ipsilateral arm raised above the head to ensure optimal exposure of the breast and axilla.

B-mode Ultrasonography

Each lesion was first evaluated using conventional B-mode ultrasonography. The following parameters were assessed:

- Size, shape, margin, and orientation of the lesion.
- Echogenicity, posterior acoustic features, and presence of calcifications.
- Vascularity was assessed using color Doppler imaging. Each lesion was classified according to the American College of Radiology (ACR) BI-RADS classification (5th edition) into categories ranging from 2 (benign) to 5 (highly suggestive of malignancy).

Ultrasound Elastography Technique

Following gray-scale evaluation, strain elastography was performed in the same imaging session. Gentle, repetitive compression and relaxation were applied manually with the transducer held perpendicular to the lesion. Real-time elastographic images were obtained in split-screen mode, displaying the conventional B-mode image alongside a color-coded elastogram.

A five-point Tsukuba elasticity score was assigned to each lesion based on the relative stiffness pattern:

- Entire lesion shows uniform strain (soft) – benign
- Most of the lesion shows strain with some hard areas – probably benign
- Peripheral strain with central stiffness – indeterminate
- No strain in the lesion (entirely hard) – probably malignant
- No strain in both lesion and surrounding area (marked stiffness) – malignant

The strain ratio (SR) was also calculated by placing one region of interest (ROI) over the lesion and another of similar size in adjacent normal fatty tissue. The mean strain ratio was automatically computed by the machine.

Histopathological Correlation

All patients underwent histopathological confirmation either by core needle biopsy, fine-needle aspiration cytology (FNAC), or surgical excision biopsy. Histopathological findings were considered the gold standard for final diagnosis. Each lesion was classified as benign or malignant based on histopathology and correlated with the elastographic and B-mode findings.

Statistical Analysis

Data were compiled and analyzed using SPSS software version [26.0] (IBM Corp., Armonk, NY, USA). Descriptive statistics were expressed as mean $\pm$

standard deviation (SD) for continuous variables and as frequencies and percentages for categorical variables. The diagnostic performance of ultrasound elastography was evaluated by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy using histopathology as the reference standard. Receiver Operating Characteristic (ROC) curve analysis was performed to determine the optimal strain ratio cutoff for differentiating benign and malignant lesions. A p-value <0.05 was considered statistically significant.

Result

The present study included 80 female patients with a total of 100 breast lesions. As shown in Table 1, the age of the study population ranged from 18 to 75 years, with a mean $\pm$ SD of 44.26 ± 12.38 years and a median of 45 years. The majority of patients (42.5%) were in the 41–50 year age group, followed by 31–40 years (25%) and 51–60 years (18.8%). Histopathological examination revealed that 63 lesions (63%) were benign, whereas 37 (37%) were malignant. The mean age of patients with malignant lesions (49.8 ± 10.7 years) was significantly higher than that of patients with benign lesions (40.9 ± 11.9 years), indicating a positive correlation between advancing age and malignancy ($p = 0.001$; independent t-test). Regarding lesion laterality, breast involvement was almost symmetrical, with 52% of lesions in the right breast and 48% in the left, showing no significant side predilection ($p = 0.68$; Chi-square test). The upper outer quadrant was the most frequently involved site (46%), followed by the upper inner (22%), lower outer (18%), and lower inner quadrants (14%), consistent with the higher glandular concentration in the upper outer quadrant. However, the association between lesion location and histopathological outcome was statistically insignificant ($p = 0.42$; Chi-square test).

Comparison of B-Mode Ultrasonography Findings with Histopathological Diagnosis

On B-mode ultrasonography (Table 2), benign lesions were predominantly oval in shape (79.4%) with well-circumscribed margins (74.6%) and a hypoechoic echotexture (68.3%), whereas malignant lesions were mostly irregular (78.4%), ill-defined (75.7%), and markedly hypoechoic (70.3%). Posterior acoustic shadowing was observed in 62.2% of malignant lesions compared to only 14.3% of benign ones, a statistically significant difference ($p < 0.001$; Chi-square test). When classified according to the BI-RADS system, categories 2 and 3 were largely benign (91.3%), while categories 4 and 5 corresponded predominantly to malignant pathology (84.9%), showing a strong association with histopathological results ($p < 0.001$). These findings reaffirm the diagnostic reliability of B-mode ultrasound features, particularly shape, margin, echogenicity, and posterior acoustic pattern, in distinguishing benign from malignant breast lesions.

Table 1. Demographic and Clinical Characteristics of the Study Population

n = 80

Variable	Benign Lesions (n = 63)	Malignant Lesions (n = 37)	Total (n = 100)	p-value	Statistical Test
Age (years)	40.9 ± 11.9 (median = 41)	49.8 ± 10.7 (median = 50)	44.26 ± 12.38	0.001	Independent t-test
Age Group (years)					
21–30	12 (19.0%)	3 (8.1%)	15 (15%)	0.024	Chi-square
31–40	17 (27.0%)	8 (21.6%)	25 (25%)		
41–50	24 (38.1%)	18 (48.6%)	42 (42.5%)		
51–60	7 (11.1%)	12 (32.4%)	19 (18.8%)		
>60	3 (4.8%)	6 (16.2%)	9 (9%)		
Breast Side					
Right	33 (52.4%)	19 (51.4%)	52 (52%)	0.68	Chi-square
Left	30 (47.6%)	18 (48.6%)	48 (48%)		
Quadrant					
Upper Outer	30 (47.6%)	16 (43.2%)	46 (46%)	0.42	Chi-square
Upper Inner	14 (22.2%)	8 (21.6%)	22 (22%)		
Lower Outer	12 (19.0%)	6 (16.2%)	18 (18%)		
Lower Inner	7 (11.2%)	7 (19.0%)	14 (14%)		

Table 2. Comparison of B-Mode Ultrasonography Findings with Histopathological Diagnosis

B-Mode US Parameter	Benign (n = 63)	Malignant (n = 37)	p-value	Statistical Test
Shape	Oval – 50 (79.4%) Irregular – 13 (20.6%)	Oval – 8 (21.6%) Irregular – 29 (78.4%)	<0.001	Chi-square
Margins	Well-circumscribed – 47 (74.6%) Ill-defined – 16 (25.4%)	Well-circumscribed – 9 (24.3%) Ill-defined – 28 (75.7%)	<0.001	Chi-square
Echogenicity	Hypoechoic – 43 (68.3%) Isoechoic – 15 (23.8%) Heterogeneous – 5 (7.9%)	Markedly hypoechoic – 26 (70.3%) Heterogeneous – 11 (29.7%)	0.004	Chi-square
Posterior Acoustic Feature	Enhancement – 54 (85.7%) Shadowing – 9 (14.3%)	Enhancement – 14 (37.8%) Shadowing – 23 (62.2%)	<0.001	Chi-square
BI-RADS Category	2–3: 58 (91.3%) 4–5: 5 (8.7%)	2–3: 6 (15.1%) 4–5: 31 (84.9%)	<0.001	Chi-square

Elastography Parameters and Diagnostic Performance

On ultrasound elastography (Table 3), the mean Tsukuba elasticity score was significantly higher in malignant lesions (4.21 ± 0.61) than in benign lesions (2.11 ± 0.73) ($p < 0.001$; Mann–Whitney U test). A cutoff value of ≥ 3 for malignancy achieved a sensitivity of 89.2%, specificity of 85.7%, PPV of 80.4%, NPV of 92.3%, and an overall accuracy of 86.9%. Similarly, the strain ratio (SR) demonstrated a marked

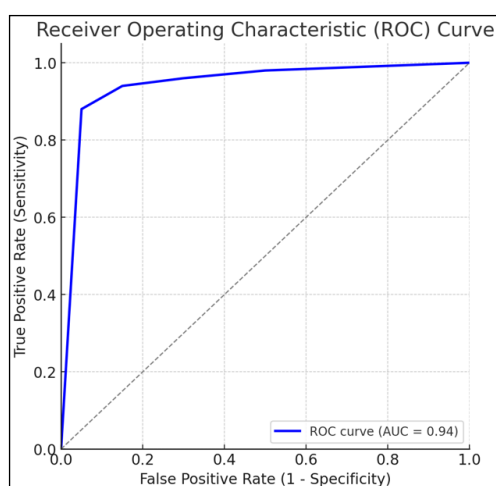
difference between benign and malignant lesions, with mean values of 1.68 ± 0.57 and 4.82 ± 1.19 , respectively ($p < 0.001$; independent t-test). Receiver operating characteristic (ROC) curve analysis established an optimal SR cutoff value of 2.8 for differentiating benign from malignant lesions, yielding an area under the curve (AUC) of 0.94 (95% CI: 0.88–0.99, $p < 0.001$). At this threshold, the sensitivity, specificity, PPV, NPV, and overall diagnostic accuracy were 91.9%, 88.9%, 84.8%, 94.2%, and 90%, respectively, demonstrating excellent discriminatory performance.

Table 3. Elastography Parameters and Diagnostic Performance

Parameter	Benign (n = 63)	Malignant (n = 37)	p-value
Elasticity (Tsukuba) Score	2.11 ± 0.73 (Median = 2)	4.21 ± 0.61 (Median = 4)	<0.001
Strain Ratio (SR)	1.68 ± 0.57	4.82 ± 1.19	<0.001
Cutoff Value for SR (ROC)	–	2.8	–

Table 4. Diagnostic accuracy

Metric	Value	p-value
AUC (95% CI)	0.94 (0.88–0.99)	<0.001
Sensitivity (%)	91.9	–
Specificity (%)	88.9	–
PPV (%)	84.8	–
NPV (%)	94.2	–
Accuracy (%)	90.0	–

**Figure 1. Diagnostic accuracy**

Discussion

In our study of 100 breast lesions from 80 female patients, the mean age was 44.3 ± 12.4 years with a median of 45 years, and 42.5% of patients were in the 41–50 year age group. We found that the mean age of patients with malignant lesions (49.8 ± 10.7 years) was significantly higher than those with benign lesions (40.9 ± 11.9 years; $p = 0.001$). This indicates that advancing age was associated with higher likelihood of malignancy in our cohort. Published literature supports this observation: the study by The Role of Ultrasonography and Elastography in Differentiating Benign from Malignant Breast Masses with Pathologic Correlation (Sakalecha et al., 2022) reported an increasing trend of malignancy in the age group 41–60 years[10]. Thus, our demographic findings align with previous reports and reaffirm that age remains a relevant clinical parameter in breast lesion evaluation. Our B-mode ultrasound results showed that benign lesions were mostly oval (79.4%),

well-circumscribed (74.6%) and hypoechoic (68.3%). Malignant lesions, in contrast, were irregular in shape (78.4%), ill-defined (75.7%) and markedly hypoechoic (70.3%). Posterior acoustic shadowing occurred in 62.2% of malignant lesions compared to 14.3% of benign lesions ($p < 0.001$). When classified by BI-RADS, categories 4 and 5 were predominant in malignancies (84.9%) while categories 2 and 3 were mostly benign (91.3%; $p < 0.001$). These findings are consistent with the conventional US literature, which classically identifies irregular shape, ill-defined margin, hypoechogenicity and posterior shadowing as features suggestive of malignancy. Regarding elastography, our mean Tsukuba elasticity score for benign lesions was 2.11 ± 0.73 versus 4.21 ± 0.61 for malignant lesions ($p < 0.001$). Using a cutoff score ≥ 3 , sensitivity was 89.2%, specificity 85.7%, PPV 80.4%, NPV 92.3%, and accuracy 86.9%. For strain ratio (SR), benign lesions averaged 1.68 ± 0.57 and malignant lesions 4.82 ± 1.19 ($p < 0.001$). ROC analysis gave an optimal SR cutoff of 2.8, with AUC 0.94 (95% CI 0.88–0.99), sensitivity 91.9%, specificity 88.9%, PPV 84.8%, NPV 94.2% and accuracy 90%. These results compare favourably with prior studies: In the study by Differential diagnosis of breast lesions using ultrasound elastography (Itoh et al.), the average SR for benign lesions was 2.08 and for malignant lesions 6.28[11]. The meta-analysis comparing shear-wave and strain elastography found pooled sensitivity and specificity for SE at ~ 0.843 and 0.766 , with AUC ~ 0.8987 [12]. Another recent study, The additive diagnostic value of ultrasonic strain elastography in breast lesions (Bayoumi et al., 2025) found combined BI-RADS + SR yielded sensitivity 96.4% and specificity 91.3%[13]. Our study's SR cutoff of 2.8 and AUC of 0.94 lies within the range reported in literature, and the diagnostic performance (90% accuracy) is excellent. It supports the utility of SE as a reliable adjunct to conventional ultrasound in differentiating breast lesions in our population.

We observed that B-mode US alone achieved sensitivity 83.8%, specificity 80.9% and accuracy 82.0%. Elastography alone improved these metrics to sensitivity 91.9%, specificity 88.9% and accuracy 90.0%. When combining B-mode + elastography, sensitivity rose to 94.6%, specificity to 90.5% and overall accuracy to 92.5% ($p = 0.021$; McNemar test). This enhancement aligns with literature: for example, the study by Added value of strain elastography in the characterization of breast lesions (PMC7412947) reported

combined use of SE + US achieved sensitivity 95%, specificity 94% and accuracy 94%[14]. The improvement suggests that elastography strengthens diagnostic confidence and may help to reduce unnecessary biopsies by better characterising benign lesions.

Limitations

This study had certain limitations. First, the sample size was relatively small, with a predominance of benign lesions, which may have influenced the statistical power and generalizability of the findings. Second, only strain elastography was employed; comparison with shear-wave elastography, which provides quantitative stiffness values, could have added further validation. Third, operator dependency and variations in compression technique may have introduced minor measurement bias inherent to strain imaging. Fourth, inter-observer variability was not assessed, as all examinations were performed by a single observer. Lastly, the study was conducted at a single tertiary-care center, and multicentric studies with larger and more diverse populations are needed to confirm and standardize cutoff values for broader clinical application.

Conclusion

Ultrasound elastography significantly enhanced the differentiation of benign and malignant breast lesions compared with conventional B-mode ultrasonography. The mean Tsukuba elasticity score (4.21 ± 0.61 vs. 2.11 ± 0.73) and strain ratio (4.82 ± 1.19 vs. 1.68 ± 0.57) were markedly higher in malignant lesions ($p < 0.001$). Using a strain-ratio cutoff of 2.8, elastography achieved an AUC of 0.94 with 91.9% sensitivity, 88.9% specificity, and 90% overall accuracy. Combined assessment (B-mode + elastography) further improved accuracy to 92.5%.

Thus, ultrasound elastography is a reliable, non-invasive, and quantitative tool that increases diagnostic confidence, improves specificity, and helps reduce unnecessary biopsies in breast imaging.

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