

ULTRASOUND STRAIN ELASTOGRAPHY IN THE DIAGNOSIS OF BREAST LESIONS

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How to cite this article

Begum T, Noureen S, Orakzai ZJ, Khan L, Baig H, Azam N. Ultrasound Strain Elastography in the Diagnosis of Breast Lesions. J Gandhara Med Dent Sci. 2026;13(4):63-67. <http://doi.org/10.37762/jgm.13-4.961>

Date of Submission: 23-06-2026

Date Revised: 07-09-2026

Date Acceptance: 10-09-2026

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ABSTRACT**OBJECTIVES**

To determine the diagnostic performance of ultrasound strain elastography for differentiating benign and malignant breast lesions, using histopathology as the reference standard.

METHODOLOGY

This prospective diagnostic-accuracy study was conducted in the Department of Radiology, Bacha Khan Medical College and Mardan Medical Complex, Mardan, from January to March 2026. Ninety-seven patients with suspected breast lesions were enrolled by non-probability consecutive sampling. Conventional ultrasonography followed by strain elastography was performed in all patients. BI-RADS category, elasticity score, and strain ratio (cut-off 3.5) were compared with histopathology. Data were analyzed using IBM SPSS Statistics version 25.

RESULTS

Strain elastography showed a sensitivity of 94.9%, specificity of 86.2%, positive predictive value of 82.2%, negative predictive value of 96.2%, and overall accuracy of 89.7%. Elastography findings were strongly associated with histopathological diagnosis ($p < 0.001$). BI-RADS category, elasticity score, and strain ratio also showed strong to very strong correlations with histopathology.

CONCLUSION

Ultrasound strain elastography demonstrated high diagnostic performance in differentiating benign from malignant breast lesions. Used as an adjunct to conventional ultrasonography and BI-RADS assessment, it may improve diagnostic confidence and help reduce unnecessary biopsy.

KEYWORDS: Breast Neoplasms, Breast Ultrasonography, Elasticity Imaging Techniques, Histopathology, Predictive Value of Tests, Sensitivity and Specificity, Strain Elastography

INTRODUCTION

Breast lesions are common clinical and radiological findings, and accurate characterization is essential for timely diagnosis and appropriate management.¹ Although most breast lesions are benign, distinguishing benign from malignant disease remains a key diagnostic challenge.² Early and accurate diagnosis of breast cancer is important for improving clinical outcomes.³ Ultrasonography is a widely used first-line imaging modality for breast assessment, particularly in younger women and those with dense breast tissue. It provides information on lesion morphology, margins, echotexture, and vascularity.⁴ The Breast Imaging Reporting and Data System (BI-RADS) standardizes reporting and guides clinical decision-making; however, conventional ultrasonography has limited specificity and may therefore contribute to unnecessary biopsy of benign lesions.⁵ Ultrasound elastography has emerged as an adjunct imaging technique based on the principle that malignant tissue is generally stiffer than benign tissue. Strain elastography assesses tissue deformation under applied pressure and provides

qualitative and quantitative estimates of tissue stiffness, including elasticity score and strain ratio.⁶ These parameters may improve lesion characterization when conventional sonographic morphology is indeterminate. Recent studies suggest that adding elastography to conventional ultrasonography can improve diagnostic discrimination and refine BI-RADS stratification, particularly for borderline or indeterminate lesions.^{7,8} The present study therefore evaluated the diagnostic performance of ultrasound strain elastography in differentiating benign and malignant breast lesions and assessed the association of elastography parameters with histopathological findings.

METHODOLOGY

This prospective diagnostic-accuracy study was conducted in the Department of Radiology, Bacha Khan Medical College and Mardan Medical Complex (MTI), Mardan, from January to March 2026. Ethical approval was obtained from the institutional ethical review board (Reference No. 936/BKMC; 14 January 2026), and the study was conducted in accordance with institutional

requirements and the principles of the Declaration of Helsinki. Patients with clinically or radiologically suspicious breast lesions who met the eligibility criteria were enrolled using a non-probability consecutive sampling technique. A total of 97 patients were included. The sample size was calculated using a diagnostic-accuracy approach based on an expected sensitivity of approximately 85%, a 95% confidence level ($Z = 1.96$), and a 7% margin of error; the calculated sample size was increased to 97 to allow for potential data loss.⁹ Adult patients with a breast lump or suspicious breast lesion who underwent ultrasonography and had histopathological verification were eligible. Patients with previous breast surgery, ongoing treatment for breast malignancy, recurrent lesions, or incomplete imaging or histopathological data were excluded. On conventional ultrasonography, BI-RADS categories 2-3 were considered benign/likely benign, and categories 4-5 were considered suspicious/malignant for the study analysis. Elastography was assessed qualitatively by elasticity score (scores 1-3, soft; scores 4-5, hard) and quantitatively by strain ratio. A strain-ratio cut-off of 3.5 was used to classify lesions as benign or malignant. Histopathological diagnosis was the reference standard. Data were recorded on a structured proforma. All patients underwent B-mode ultrasonography followed by strain elastography using standardized imaging procedures. Recorded variables included age, lesion size, clinical symptoms, sonographic shape, margins, echogenicity, posterior acoustic shadowing, BI-RADS category, elasticity score, and strain ratio. Histopathological findings from biopsy or surgical excision were subsequently recorded. Imaging was interpreted by qualified radiologists using consistent diagnostic criteria. Ultrasound equipment was calibrated before data collection, and data entry was cross-checked to minimize transcription errors. Data were analyzed using IBM SPSS Statistics version 25. Continuous variables are presented as mean $\pm$ standard deviation and categorical variables as frequency and percentage. Associations between imaging findings and histopathological diagnosis were assessed with the chi-square test, with Cramer's V used as an effect-size measure. Sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios, and overall diagnostic accuracy were calculated with 95% confidence intervals. Spearman's rho was used to assess correlations between imaging parameters and histopathology. A p-value < 0.05 was considered statistically significant.

RESULTS

The mean age of the 97 participants was 46.0 ± 13.2 years. More than half were older than 45 years (54.6%),

32.0% were aged 30-45 years, and 13.4% were younger than 30 years. A family history of breast cancer was present in 18.6%. Mean lesion size was 2.85 ± 0.82 cm, pain was reported by 41.2%, and 54.6% of lesions were in the left breast.

Table 1: Demographic and Clinical Characteristics (n = 97)

Variable	Value	
Age (years)	46.0 $\pm$ 13.2	Age (years)
< 30 years	13 (13.4%)	< 30 years
30-45 years	31 (32.0%)	30-45 years
> 45 years	53 (54.6%)	> 45 years
Family history of breast cancer	No	79 (81.4%)
	Yes	18 (18.6%)
	Lesion size (cm)	2.85 $\pm$ 0.82
Pain	No	57 (58.8%)
	Yes	40 (41.2%)
Side of breast	Left	53 (54.6%)
	Right	44 (45.4%)

Ultrasound features were significantly associated with histopathological diagnosis. Irregular shape ($\chi^2 = 25.63$, $p < 0.001$; Cramer's V = 0.51) and ill-defined margins ($\chi^2 = 33.35$, $p < 0.001$; V = 0.59) showed large associations with malignancy. Posterior acoustic shadowing ($\chi^2 = 16.67$, $p < 0.001$; V = 0.42) and a hypoechoic pattern ($\chi^2 = 9.14$, $p = 0.003$; V = 0.31) showed moderate associations. BI-RADS category was very strongly associated with histopathology ($\chi^2 = 71.72$, $p < 0.001$; V = 0.86).

Table 2: Association of Ultrasound Findings with Histopathology (n = 97)

Variable	Benign (n=58)	Malignant (n=39)	χ^2	P-value	Cramer's V
Irregular Shape			25.63	<0.001	0.51 (Large)
Regular	45 (81.8%)	10 (18.2%)			
Irregular	13 (31.0%)	29 (69.0%)			
Ill-defined Margins			33.35	<0.001	0.59 (Large)
Well-defined	45 (86.5%)	07 (13.5%)			
Ill-defined	13 (28.9%)	32 (71.1%)			
Posterior Shadowing			16.67	<0.001	0.42 (Moderate)
Absent	46 (75.4%)	15 (24.6%)			
Present	12 (33.3%)	24 (66.7%)			
Hypoechoic Pattern			9.14	0.003	0.31 (Moderate)
No	36 (75.0%)	12 (25.0%)			
Yes	22 (44.9%)	27 (55.1%)			
BI-RADS Category			71.72	<0.001	0.86 (Very Large)
2	31 (100%)	0 (0%)			
3	22 (88.0%)	03 (12.0%)			
4	5(31.3%)	11 (68.8%)			
5	0 (0%)	25 (100%)			
BI-RADS ≥ 4			66.93	<0.001	0.83 (Very Large)
2-3	53 (94.6%)	03 (5.4%)			
4-5	05 (12.2%)	36 (87.8%)			

Elastography findings were also strongly associated with histopathological diagnosis. An elasticity score of 4-5 was associated with malignancy ($\chi^2 = 63.06$, $p < 0.001$; Cramer's $V = 0.81$), as was a strain ratio > 3.5 ($\chi^2 = 61.64$, $p < 0.001$; $V = 0.80$). The odds of malignancy were markedly higher for hard lesions (OR = 100.8, 95% CI 23.6-430.5) and for lesions with a strain ratio > 3.5 (OR = 115.6, 95% CI 23.2-576.6).

Table 3: Association of Elastography Findings with Histopathology (n = 97)

Elastography Parameter	Benign (n=58)	Malignant (n=39)	χ^2	p-value	Cramer's V	Odds Ratio (95% CI)
Elasticity Score						
Score 1-3 (Soft)	55 (90.2%)	06 (9.8%)				
Score 4-5 (Hard)	3 (8.3%)	33 (91.7%)	63.06	<0.001	0.81 (Very Large)	100.8 (23.6-430.5)
Strain Ratio (Cut-off = 3.5)						
≤ 3.5 (Benign)	50 (96.2%)	02 (3.8%)				
> 3.5 (Malignant)	8 (17.8%)	37 (82.2%)	61.64	<0.001	0.80 (Very Large)	115.6 (23.2-576.6)

Using a strain-ratio cut-off of 3.5, strain elastography achieved a sensitivity of 94.9%, specificity of 86.2%, positive predictive value of 82.2%, negative predictive value of 96.2%, and overall diagnostic accuracy of 89.7%. The positive likelihood ratio was 6.87, and the negative likelihood ratio was 0.06, supporting useful rule-in and strong rule-out performance, respectively.

Table 4: Diagnostic Accuracy of Strain Elastography (cut-off = 3.5; n = 97)

Parameter	Value (%)	95% Confidence Interval
Sensitivity	94.9%	82.7% – 99.4%
Specificity	86.2%	74.6% – 93.9%
Positive Predictive Value (PPV)	82.2%	67.9% – 92.0%
Negative Predictive Value (NPV)	96.2%	86.8% – 99.5%
Accuracy	89.7%	81.7% – 94.9%
LR+	6.87	3.84 – 12.29
LR–	0.06	0.02 – 0.23

BI-RADS category correlated very strongly with histopathology (Spearman $r = 0.822$, $p < 0.001$). Elasticity score ($r = 0.784$, $p < 0.001$) and strain ratio ($r = 0.817$, $p < 0.001$) also showed very strong positive correlations with histopathological diagnosis. Correlations among BI-RADS category, elasticity score, and strain ratio were strong to very strong.

Table 5: Correlation analysis (Spearman's rho; n=97)

Variable Pair	R-Value	p-value	Interpretation
BI-RADS vs Histopathology	0.822	<0.001	Very strong
Elasticity Score vs Histopathology	0.784	<0.001	Very strong
Strain Ratio vs Histopathology	0.817	<0.001	Very strong
Elasticity Score vs BI-RADS	0.724	<0.001	Very strong
Strain Ratio vs BI-RADS	0.624	<0.001	Strong
Strain Ratio vs Elasticity Score	0.698	<0.001	Strong

DISCUSSION

This study demonstrated strong diagnostic utility of ultrasound strain elastography for differentiating benign from malignant breast lesions. Both the qualitative elasticity score and quantitative strain ratio were closely associated with histopathology, while the strain-ratio model showed high sensitivity, specificity, and overall accuracy. These findings are consistent with evidence that adding strain or shear-wave elastography to conventional ultrasonography can improve lesion stratification and refine BI-RADS-based decision-making, particularly for indeterminate lesions. Tang et al., Gu et al., and Mumtaz et al. similarly reported improved diagnostic characterization when elastography was incorporated into breast ultrasonography.^{10,11,12} Conventional ultrasound features, including irregular shape, ill-defined margins, posterior acoustic shadowing, and hypoechogenicity, were significantly associated with malignancy, and BI-RADS showed a particularly strong relationship with histopathology. This supports the role of grayscale ultrasonography as the basis of breast lesion assessment while highlighting the additional value of elastography when morphology alone is insufficient. Studies by Zhi et al. and Yang et al. have shown improved discrimination when elastography is incorporated into BI-RADS-based assessment, while Bayoumi et al. reported added diagnostic value of strain elastography in BI-RADS 4 lesions.^{13,14,15} The very large effect sizes

and high odds ratios observed for elasticity score and strain ratio indicate that lesion stiffness was strongly associated with malignant pathology. Shahzad et al. similarly found that elastography-derived measures improved differentiation between benign and malignant breast lesions, particularly when interpreted alongside BI-RADS.¹⁶ These findings support the use of elastography as an adjunct rather than a replacement for conventional ultrasonography. The high negative predictive value (96.2%) and low negative likelihood ratio (0.06) are clinically important because they indicate good rule-out performance. This may be particularly useful for reducing unnecessary invasive procedures in sonographically suspicious but elastographically soft lesions. Other studies have likewise reported that elastography can improve specificity and refine management of low- to intermediate-suspicion breast lesions.^{12,13,15,17} The correlation analysis further demonstrated consistency between BI-RADS, elasticity score, strain ratio, and histopathological diagnosis. Similar relationships between elastographic stiffness and pathological characteristics have been reported by Frimpong et al.¹⁸ In addition, studies addressing automated three-dimensional elastography and interobserver reliability suggest increasing technical maturity and reproducibility of elastography-based breast assessment.^{9,19} Emerging quantitative and machine-learning approaches may further improve standardization and prediction.^{14,20,21}

LIMITATIONS

The study was conducted within a single institutional setting and included a relatively small sample, which may limit external generalizability. Strain elastography is also operator-dependent. Larger multicenter studies using standardized acquisition and interpretation protocols are required to validate the diagnostic thresholds and performance estimates reported here.

CONCLUSION

Ultrasound strain elastography showed high diagnostic performance for differentiating benign and malignant breast lesions. Both elasticity score and strain ratio were closely associated with

histopathology, and the strain-ratio model demonstrated high sensitivity, specificity, and negative predictive value. As an adjunct to conventional ultrasonography and BI-RADS assessment, strain elastography may improve diagnostic confidence and help reduce unnecessary biopsy.

CONFLICT OF INTEREST: None

FUNDING SOURCES: None

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AUTHORS CONTRIBUTION

Tabassum Begum - Concept & Design; Data Acquisition; Data Analysis/Interpretation; Drafting Manuscript; Critical Revision; Supervision; Final Approval

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The authors accept responsibility for all aspects of the work and will ensure that any concerns regarding the accuracy or integrity of any part are properly investigated and resolved.



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