



Role of Strain Ratio Elastography in Suspected Malignant Breast Mass and Correlation with Histopathology Subtypes

Deena Sherdil Saleem^{1*} and Salwa Ahmed Al-Najjar²

¹Department of Radiology, College of Medicine, Hawler Medical University, Erbil, Kurdistan Region, Iraq

*Corresponding author: Deena Sherdil Saleem (e-mail: deena_saleem@yahoo.com).

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Abstract Background and Objectives: Strain Ratio (SR) elastography is an emerging adjunct to conventional ultrasound in breast imaging, providing a semi-quantitative assessment of tissue stiffness. However, its diagnostic performance and correlation with histopathological subtypes remain insufficiently studied in Middle Eastern populations. **Objective:** To evaluate the diagnostic accuracy of SR elastography in differentiating benign from malignant breast lesions and to assess its association with histopathological subtypes and BI-RADS classification. **Methods:** This prospective diagnostic accuracy study included 179 breast masses examined at a tertiary center in the Kurdistan Region between June 2024 and July 2025. All participants underwent B-mode ultrasound, mammography and SR elastography. Histopathology served as the reference standard. Diagnostic performance was evaluated using receiver Operating Characteristic (ROC) analysis. The Kruskal-Wallis test and Pearson correlation analysis were applied where appropriate. **Results:** SR elastography demonstrated excellent discriminatory ability, with an Area Under the Curve (AUC) of 0.90 (95% CI: 0.844–0.957, $p < 0.001$). An SR cutoff value of 3.45 for predicting malignancy yielded a sensitivity of 86.3% and specificity of 85.5%. Malignant lesions had significantly higher SR values than benign lesions (4.98 ± 2.15 Vs 2.34 ± 1.34 , $p < 0.001$). SR values differed significantly across histopathological subtypes ($p < 0.001$), with invasive ductal carcinoma demonstrating the highest stiffness. Moderate positive correlations were observed between SR and ultrasound BI-RADS ($r = 0.423$) and mammographic BI-RADS ($r = 0.438$). **Conclusion:** SR elastography shows high diagnostic accuracy for distinguishing benign from malignant breast lesions and demonstrates significant associations with histopathological subtypes and BI-RADS classification. Incorporating SR into routine breast ultrasound protocols may improve diagnostic precision and reduce unnecessary biopsies. Larger multicenter studies are required to validate cutoff values and standardize clinical implementation.

Key Words Strain Ratio, Elastography, Breast Cancer, BI-RADS, Histopathology, Ultrasound Imaging

INTRODUCTION

Breast cancer is the most frequently diagnosed cancer and a leading cause of cancer-related mortality among women worldwide, with more than 2.3 million new cases reported annually [1-3]. In Iraq, it remains the most common malignancy among women and a major contributor to cancer-related deaths [2]. Despite advances in screening, accurate characterization of breast masses remains a diagnostic challenge, particularly in younger women and those with dense breast tissue. While mammography is the cornerstone of screening, its performance is limited in these populations. Breast ultrasonography is therefore widely used as a complementary or primary imaging modality [4,5].

Ultrasound elastography has emerged as an important adjunct, enabling noninvasive assessment of tissue

stiffness, a feature closely associated with malignancy [6]. Strain Ratio (SR) elastography integrates qualitative and semi-quantitative parameters and has been shown to improve lesion characterization and positive predictive value within the Breast Imaging Reporting and Data System (BI-RADS) framework [7-9]. However, its clinical implementation remains heterogeneous. Reported SR cutoff values vary considerably across studies, as emphasized by the World Federation for Ultrasound in Medicine and Biology (WFUMB), limiting reproducibility and standardization [10]. In addition, limited data are available regarding the association between SR measurements and specific histopathological subtypes of breast cancer, particularly in Middle Eastern populations [11,12].

Given these inconsistencies and regional data gaps, there is a need to clarify the diagnostic performance and pathological correlations of SR elastography in routine clinical practice.

The present study aims to evaluate the diagnostic accuracy of Strain Ratio (SR) elastography in differentiating benign from malignant breast masses and to examine its correlation with histopathological subtypes and BI-RADS categorization. The study further seeks to determine an optimal SR cutoff value applicable to a Middle Eastern population to improve diagnostic precision and clinical decision-making.

MATERIALS AND METHODS

Study Design and Setting

This prospective diagnostic accuracy study included 179 breast lesions from 163 female patients and was conducted between June 2024 and July 2025 at the Department of Radiology and Imaging, Diagnostic Breast Center, Rizgary Teaching Hospital, Hawler Medical University, Erbil, Kurdistan Region, Iraq.

Participants

A total of 163 female patients presenting with 179 breast masses were included. Participants' ages ranged from 13 to 100 years.

Inclusion Criteria

Female patients with clinically suspected malignant breast masses classified as BI-RADS 3–5.

Exclusion Criteria

- BI-RADS category 2 lesions
- Breast infection or inflammatory disease
- Prior breast surgery, chemotherapy, or radiotherapy
- Breast implants

All criteria were applied consistently prior to imaging analysis.

Sample Size

Sample size was calculated to ensure adequate precision for diagnostic accuracy estimates (Ahmed, 2024). Assuming a sensitivity of 0.90 and specificity of 0.85 at a 95% confidence level ($Z = 1.96$) with 7% precision ($d = 0.07$), the minimum required sample was 115 lesions. To compensate for potential exclusions and incomplete data, at least 132 lesions were targeted. The final dataset included 179 lesions, exceeding the calculated requirement.

Ultrasound Examination

All patients underwent bilateral whole-breast B-mode ultrasonography using a General Electric (GE) Versana Premier system with a 3–12 MHz linear probe. Two radiologists with nine years of dedicated breast imaging experience performed all examinations. Patients were positioned supine with the ipsilateral arm elevated. Lesions were evaluated and categorized according to the Breast Imaging Reporting and Data System (BI-RADS) into categories 3–5 [13].

Strain Elastography

Real-time strain elastography was performed immediately following B-mode ultrasound. The elastography field included tissue from the subcutaneous fat layer to the pectoral muscle, centered on the lesion. Mild repetitive compressions were applied under visual quality control.

Elastograms were displayed as a color-coded stiffness map:

- Green/yellow/red: Soft
- Mixed (green and blue): Intermediate
- Blue: Hard

For strain ratio calculation, two standardized Regions of Interest (ROIs) were placed:

- E1 (lesion ROI)
- E2 (adjacent subcutaneous fat ROI at similar depth)

The Strain Ratio (SR) was calculated as fat-to-lesion ratio ($E2/E1$) [14].

(Terminology was standardized across all measurements.)

Statistical Analysis

All analyses were performed using SPSS version 27 (IBM Corp., Armonk, NY, USA). Descriptive statistics summarized demographic characteristics and lesion features. Diagnostic performance of SR was evaluated using Receiver Operating Characteristic (ROC) curve analysis, with Area Under the Curve (AUC) and 95% confidence intervals reported. Sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), overall accuracy and likelihood ratios were calculated at both predefined and optimal cutoff values determined using Youden's Index.

Comparisons of SR values across histopathological subtypes were performed using the Kruskal-Wallis test with post-hoc analysis where appropriate. Correlations between SR values and ultrasound and mammographic BI-RADS categories were assessed using Pearson's correlation coefficient.

Subgroup analyses were performed according to age, menopausal status and lesion size.

Inter-observer reliability was assessed in a randomly selected 20% subset of cases independently reviewed by both radiologists. Agreement was quantified using the Intraclass Correlation Coefficient (ICC). A p-value <0.05 was considered statistically significant.

RESULTS

Among the 179 lesions, most participants were married (89.4%) and housewives (89.9%). Nearly half were unable to read or write (48.0%). The majority reported a sufficient socioeconomic level (59.2%) and most were multiparous or grand multiparous (82.1%). Detailed demographic characteristics are presented in Table 1.

Personal history of breast cancer was uncommon (2.8%), whereas 19.0% reported a family history. Breastfeeding was frequent (77.1%), while hormonal therapy use was reported in 15.1% of cases. Most patients presented with a unilateral palpable lump, predominantly located in the upper outer quadrant. Comprehensive clinical characteristics are summarized in Table 2.

Ultrasound and mammography demonstrated significantly different BI-RADS category distributions (χ^2 , $p<0.001$). Mammography classified a higher proportion of lesions as BI-RADS 5, whereas ultrasound distributed more cases across BI-RADS 4 subcategories (Figure 1).

ROC analysis demonstrated excellent diagnostic performance of SR elastography (AUC = 0.90, 95% CI: 0.844–0.957, $p<0.001$). At the optimal cutoff value of 3.45, sensitivity was 86.3% and specificity was 85.5% (Table 3, Figure 2).

Malignant lesions demonstrated significantly higher SR values than benign lesions (4.98 ± 2.15 Vs 2.34 ± 1.34 ; $p<0.001$), with a large effect size (Cohen's $d = 1.91$) (Table 4).

SR values differed significantly across histopathological subtypes (Kruskal–Wallis $H = 92.544$, $p<0.001$) (Table 5).

Malignant subtypes, particularly invasive ductal carcinoma, showed higher SR values, whereas benign lesions such as fibroadenoma and mastitis demonstrated lower values. Median-based analysis confirmed this variability ($p<0.001$).

Moderate positive correlations were observed between SR and ultrasound BI-RADS ($r = 0.423$, $p<0.001$) and

mammography BI-RADS ($r = 0.438$, $p<0.001$). A stronger correlation was identified between ultrasound and mammography BI-RADS classifications ($r = 0.639$, $p<0.001$) (Figure 3).

Table 1: Sociodemographic Characteristics of Participants (n = 179)

Variable	Frequency	Percent
Education		
Can't read and write	86	48.0
Can read and write	23	12.8
Elementary	34	19.0
Secondary	17	9.5
Bachelor	19	10.6
Occupation		
Housewife	161	89.9
Full-time	1	0.6
Part-time	15	8.4
Student	2	1.1
Marital State		
Married	160	89.4
Single	8	4.5
Separated	1	0.6
Widow	10	5.6
Standard of Living		
More than sufficient	21	11.7
Sufficient	106	59.2
Insufficient	52	29.1
Parity		
Nulliparous	23	12.8
Primiparous	9	5.0
Multiparous	89	49.7
Grand multiparous	58	32.4

Table 2: Risk Factors and Clinical Features of Participants (n = 179)

Variable	Category	Frequency	Percent
History of Breast Cancer	Yes	5	2.8
	No	174	97.2
History of Hormonal Use	Yes	27	15.1
	No	152	84.9
Family History of Breast Cancer	Yes	34	19.0
	No	145	81.0
Breastfeeding	Yes	138	77.1
	No	41	22.9
Early Menarche	Yes	32	17.9
	No	147	82.1
Late Pregnancy	Yes	18	10.1
	No	161	89.9
Breast Screening History	Yes	38	21.2
	No	141	78.8
First Symptom	Lump	171	95.5
	Pain	6	3.4
	Redness	1	0.6
	Nipple discharge	1	0.6
Laterality	Unilateral	176	98.3
	Bilateral	3	1.7
Side Affected	Right	103	57.5
	Left	76	42.5
Location of Mass	Upper Outer Quadrant (UOQ)	104	58.1
	Upper Inner Quadrant (UIQ)	34	19.0
	Lower Outer Quadrant (LOQ)	17	9.5
	Lower Inner Quadrant (LIQ)	15	8.4
	Subareolar	2	1.1
	Retroareolar	6	3.4
	Axillary tail	1	0.6
Skin Changes	Yes	31	17.3
	No	148	82.7
Nipple Discharge	Yes	3	1.7
	No	176	98.3

Table 3: Diagnostic accuracy of Strain Ratio (SR) Elastography for Differentiating Benign from Malignant Breast Lesions

Cutoff (SR)	Sensitivity (%)	Specificity (%)	AUC (95% CI)	p-value
3.45	86.3	85.5	0.900 (0.844–0.957)	<0.001

Cutoff chosen based on Youden’s index; values are from SPSS ROC analysis

Table 4: Comparison of Strain Ratio between Benign and Malignant Breast Lesions

Variable	Biopsy Result	N	Mean±SD	t (df)	p-value	Mean Difference (95% CI)	Effect Size (Cohen’s d [95% CI])
Strain Ratio	Benign	62	2.34±1.34	-8.80 (177) ¹	<0.001	-2.64 (-3.23, -2.05)	1.91 (1.04, 1.72)
	Malignant	117	4.98±2.15				

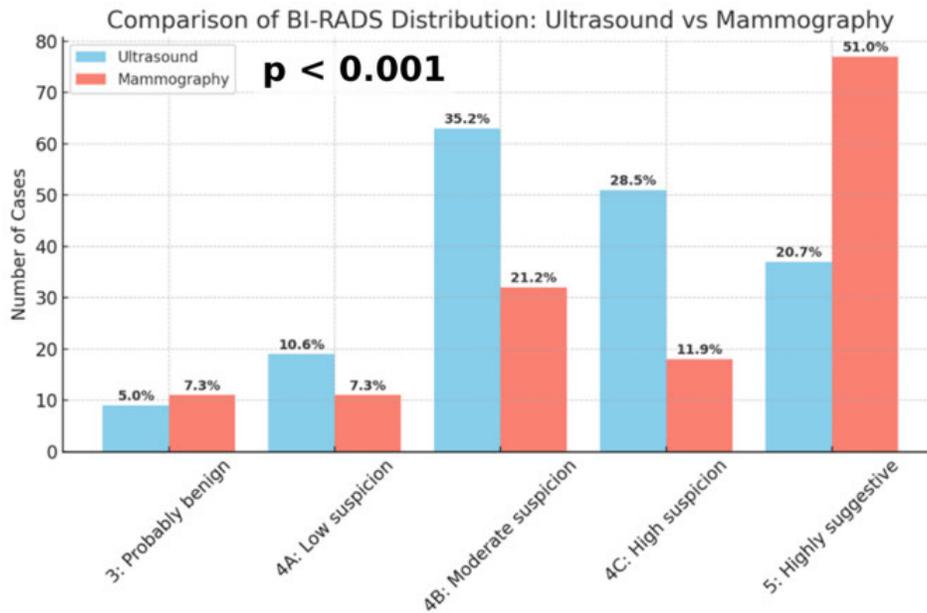


Figure 1: Comparison of BI-RADS Distribution: Ultrasound Vs Mammography

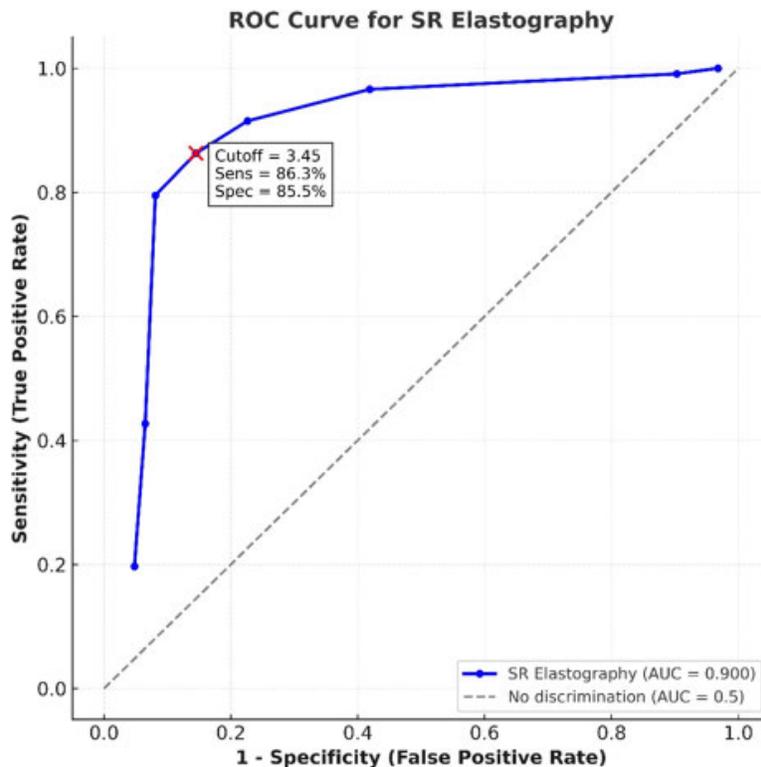


Figure 2: Roc Curve for SR Elastography

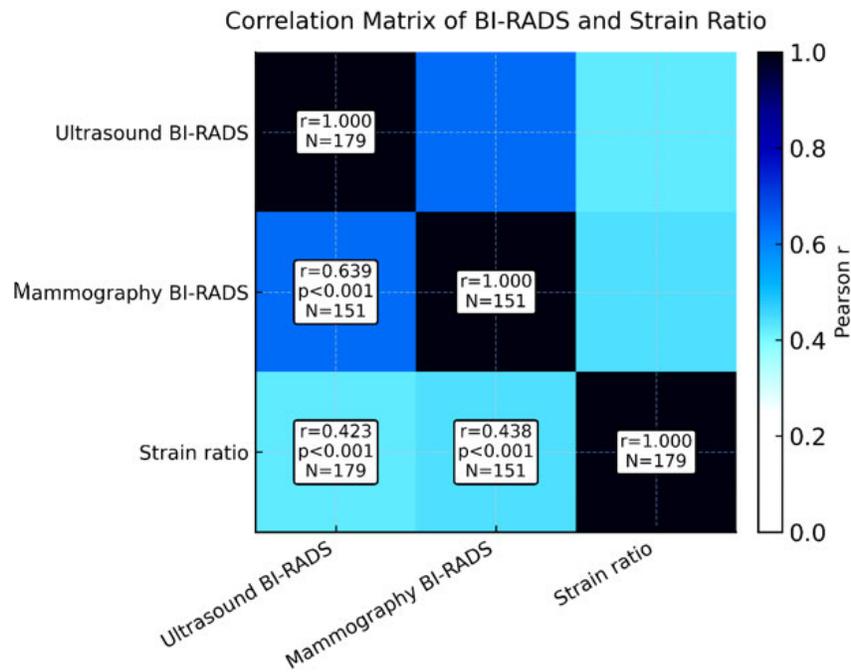


Figure 3: Correlation between BI-RADS and Strain Ratio

Table 5: Distribution of Strain Ratio Relative to Median (3.9) Across Subtypes

Histopathological Subtype	>Median (n)	≤Median (n)	
Fibroadenoma	3	30	
Papilloma	0	5	
Mastitis	0	8	
Granulomatous Mastitis	0	4	
Fibrosis	0	1	
Fibroadenosis	0	1	
Focal Hyperplasia	0	1	
Fat Necrosis	0	6	
Phylloid Tumor	2	0	
Fibrocytic	0	1	
Invasive Ductal Carcinoma	72	26	
IDC and DCIS	3	0	
Invasive Lobular Carcinoma	6	6	
DCIS	1	2	
IDC and LC	1	0	
Test	Statistic	df	p-value
Kruskal–Wallis H	92.544	14	<0.001
Median-based Chi ²	76.987	14	<0.001

DISCUSSION

Main Findings

The present study demonstrates that Strain Ratio (SR) elastography provides strong discriminatory ability for differentiating benign from malignant breast lesions. Rather than reiterating numerical metrics, the key finding is the consistent separation in stiffness values between malignant and benign masses, supporting the clinical applicability of SR as an adjunct to conventional ultrasound in breast imaging [15].

The diagnostic performance observed in this cohort is comparable to prior studies reporting high accuracy across diverse populations [16–18]. Importantly, the identified cutoff value aligns with ranges commonly reported in the literature, reinforcing the potential reproducibility of SR thresholds. However, variability in proposed cutoffs persists internationally, as some studies have suggested lower thresholds [19]. Such

heterogeneity likely reflects differences in breast density distribution, equipment calibration, ROI selection technique and patient demographics, underscoring the ongoing challenge of standardization.

Malignant lesions demonstrated substantially higher stiffness than benign lesions, which is biologically plausible given tumor-associated desmoplasia, increased cellularity and stromal fibrosis [20,21]. While overlap in SR values between certain benign and malignant entities has been documented, our findings reinforce the overall robustness of stiffness-based differentiation. The observed variability in rare benign conditions highlights the importance of integrating SR findings with morphological ultrasound features rather than relying on stiffness alone [5,22].

Moderate correlations between SR and BI-RADS classifications support the complementary role of elastography within structured imaging assessment systems [23]. These associations suggest that SR may enhance stratification of indeterminate lesions, particularly within the BI-RADS 4 spectrum, where management decisions are often challenging [24,25]. The stronger correlation between ultrasound and mammography classifications confirms their established complementary roles. Notably, differences in category distribution suggest that ultrasound combined with SR elastography may provide greater diagnostic granularity in dense breast tissue, a population in which mammography sensitivity is reduced.

Evaluation across histopathological subtypes further demonstrated distinct stiffness patterns, with invasive ductal carcinoma exhibiting higher SR values compared to several other entities [26,27]. These findings support the biological premise that tumor composition influences elastographic behavior. However, conclusions for rare subtypes remain limited due to small sample sizes.

A major strength of this study is its prospective design and its focus on histopathological subtype correlation within a Middle Eastern population, a region where elastography data remain limited. Nevertheless, several limitations warrant consideration. The study was conducted within a single metropolitan area, potentially limiting external generalizability. Although interobserver agreement was high, elastography remains operator-dependent and reproducibility across different platforms and institutions may vary. Additionally, limited numbers in rare subgroups restricted detailed comparative analysis.

From a clinical standpoint, SR elastography offers a cost-effective adjunct capable of improving diagnostic confidence and potentially reducing unnecessary biopsies. However, broader implementation requires standardized acquisition protocols, consensus regarding optimal cutoff thresholds and structured operator training. Future multicenter investigations with larger cohorts are needed to establish population-adjusted cutoff values and integrate elastography into unified diagnostic algorithms.

CONCLUSION

This study demonstrates that Strain Ratio (SR) elastography provides strong diagnostic discrimination between benign and malignant breast lesions. Rather than reiterating numerical performance metrics, the findings highlight the consistent stiffness differences observed in malignant tumors, particularly invasive ductal carcinoma and support the incremental value of SR within structured BI-RADS assessment.

Importantly, SR elastography may be particularly useful in refining management decisions for indeterminate BI-RADS 4 lesions, where biopsy decisions are often clinically challenging. By improving lesion stratification, SR has the potential to reduce unnecessary biopsies and associated healthcare costs, especially in resource-limited settings where advanced imaging modalities such as MRI are not widely accessible. Integration of SR into routine ultrasound evaluation may enhance diagnostic confidence and optimize patient triage.

Future multicenter studies with larger and more diverse cohorts are warranted to validate standardized cutoff thresholds and develop population-specific reference values. Establishing consensus acquisition protocols and structured operator training will be essential to minimize variability and facilitate broader clinical implementation.

Funding

This research received no external funding.

Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (Research Ethics Committee) of the College of Medicine, Hawler Medical University.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

The data presented in this study are available on request from the corresponding author.

Consent to Participate

Written informed consent was obtained from all individual participants included in the study. For participants under 18 years of age, consent was obtained from a parent or legal guardian.

Consent to Publish

The authors hereby give their full consent for the publication of this manuscript, including all associated data, figures and supplementary materials, in the designated journal.

Acknowledgement

Many thanks for all the participants who participated in the current study.

Ethical Statement

The study protocol was approved by the Research Ethics Committee of Hawler Medical University. All procedures were conducted in accordance with institutional standards and the Declaration of Helsinki and its later amendments. Written informed consent was obtained from all participants prior to enrollment. For patients under 18 years of age, parental consent was obtained.

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