ORIGINAL RESEARCH PAPER

Radio-Diagnosis

SONOELASTOGRAPHY AS AN ADJUNCT IN THE CHARACTERIZATION OF SOLID BREAST LESIONS: A PROSPECTIVE COMPARATIVE STUDY WITH CONVENTIONAL ULTRASONOGRAPHY AND MAMMOGRAPHY

KEY WORDS: sonoelastography, strain ratio, Tsukuba elasticity score, breast lesion characterization, BI-RADS, breast ultrasonography

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ABSTRACT

Background: Breast cancer is among the most prevalent malignancies in women globally, with early and accurate lesion characterization being critical to improving clinical outcomes. Conventional breast imaging modalities, including mammography and B-mode ultrasonography, demonstrate limited specificity owing to overlapping morphological features between benign and malignant solid lesions. Sonoelastography, which provides an objective assessment of tissue stiffness, has emerged as a promising adjunct to conventional imaging. **Objectives:** To evaluate the diagnostic performance of sonoelastography in differentiating benign from malignant solid breast lesions and to compare it with conventional B-mode ultrasonography and mammography using histopathology as the reference standard. **Methods:** This prospective observational cross-sectional study enrolled 100 consecutive female patients (aged 20–70 years) with focal breast lesions confirmed on sonography at a tertiary care centre over 18 months. Each participant underwent B-mode ultrasonography followed by real-time strain sonoelastography in the same session. Lesions were characterized using the five-point Tsukuba elasticity scoring system and quantitative strain ratio measurements. Mammography was also performed where clinically indicated. Histopathological diagnosis served as the gold standard. Statistical analysis included chi-square tests, Mann–Whitney U test, Cohen's kappa, and receiver operating characteristic (ROC) curve analysis. **Results:** Of 100 lesions evaluated, 66 (66%) were benign and 34 (34%) were malignant on histopathology. The mean age was significantly higher in malignant lesions (53.91 ± 10.54 years) compared to benign lesions (43.14 ± 11.79 years; $p < 0.001$). Strain ratio was significantly elevated in malignant lesions (mean 4.05 ± 1.37) versus benign lesions (mean 2.13 ± 1.00; $p < 0.001$). At a cutoff of ≥2.7, strain ratio achieved the highest diagnostic agreement with histopathology (= 0.724). ROC analysis demonstrated the highest area under the curve (AUC) for strain ratio (0.905; 95% CI: 0.838–0.971), followed by Tsukuba score (AUC = 0.902), ultrasound BI-RADS numeric (AUC = 0.899), and mammography BI-RADS (AUC = 0.846; all $p < 0.001$). **Conclusion:** Sonoelastography significantly enhances the characterization of solid breast lesions by providing quantitative biomechanical information beyond morphological imaging. Integration of strain ratio measurement and Tsukuba scoring into routine breast ultrasound protocols may improve diagnostic specificity, reduce unnecessary benign biopsies, and support more precise clinical decision-making.

INTRODUCTION

Breast cancer represents one of the leading malignancies affecting women worldwide and constitutes a major public health burden due to its high incidence and associated morbidity and mortality [1]. Accurate differentiation of benign from malignant solid breast lesions is central to effective clinical management, reducing both missed cancers and unnecessary biopsies.

Mammography remains the cornerstone of breast cancer screening; however, its sensitivity is significantly reduced in dense breasts, in younger women, and in the postoperative setting. Overlapping glandular tissue may obscure lesions or create false-positive findings, often necessitating additional investigation [2]. B-mode ultrasonography serves as a valuable adjunct, particularly in evaluating palpable masses and mammographically dense breasts, and allows real-time morphological assessment standardized by the Breast Imaging Reporting and Data System (BI-RADS). Despite these advantages, considerable morphological overlap between benign and malignant solid lesions limits its specificity and leads to a high rate of benign biopsies [3].

Sonoelastography is an ultrasound-based technique that objectively assesses tissue stiffness by measuring deformation in response to an applied mechanical force. Since malignant lesions typically exhibit increased rigidity due to desmoplastic stromal reaction, increased cellularity, and extracellular matrix remodeling, elastography provides biologically grounded functional information that complements conventional morphological assessment [4,5]. Two principal techniques exist: strain elastography, which measures relative tissue deformation, and shear-wave elastography, which quantitatively maps absolute stiffness. Qualitative assessment employs color-coded stiffness maps evaluated using standardized scoring systems such as the five-point Tsukuba elasticity scoring system, while quantitative methods derive numerical strain ratios to improve reproducibility and interobserver agreement [6].

Multiple studies have reported that incorporation of elastography into breast imaging protocols improves specificity without significantly compromising sensitivity, particularly in lesions categorized as BI-RADS 3 and 4a, where conventional imaging alone is often insufficient to guide biopsy decisions [7,8]. By reducing false-positive rates, elastography has the potential to minimize unnecessary invasive procedures, decrease patient anxiety, and optimize healthcare resource utilization [9,10].

Despite promising evidence, variability in reported diagnostic performance across studies highlights the need for context-specific evaluation. The present study was designed to systematically evaluate the role of sonoelastography in characterizing solid breast lesions at a tertiary care centre in northern India, and to compare its diagnostic performance with conventional B-mode ultrasonography and mammography using histopathology as the reference standard.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective observational cross-sectional study conducted in the Department of Radiodiagnosis, Dr. KNS Memorial Institute of Medical Sciences, Barabanki, Uttar Pradesh, India, a tertiary care teaching hospital serving both urban and rural populations. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrollment. The study adhered to the principles of the Declaration of Helsinki.

Participants

One hundred consecutive female patients aged 20–70 years presenting with focal solid breast lesions confirmed on sonography between January 2024 and June 2025 were enrolled. Patients with breast implants, superficial lesions less than 5 mm in depth, or pure cystic lesions were excluded. Sample size was calculated based on published prevalence data using the formula $n = (4 \times P \times q) / L^2$, yielding a minimum of 91 participants; accounting for a 20% non-response rate, the final sample size was fixed at 100.

Imaging Protocol

All patients initially underwent conventional B-mode ultrasonography using a GE LOGIQ P9 ultrasound system with a 5–10 MHz linear array transducer. Patients were examined in the supine or supine oblique position with the ipsilateral arm raised. Each lesion was evaluated for size, shape, orientation, margin characteristics, echogenicity, internal architecture, posterior acoustic features, and axillary lymph node status. Lesions were classified according to the standard ultrasound BI-RADS categories.

Following B-mode assessment, real-time free-hand strain sonoelastography was performed in the same session without repositioning the patient. Minimal and uniform manual compression was applied through the transducer. Qualitative elastographic evaluation used the five-point Tsukuba elasticity scoring system (score 1: entirely soft; score 5: predominantly stiff encompassing the entire mass and surrounding tissue), with scores ≥4 classified as positive for malignancy [6]. For quantitative assessment, strain ratio was calculated by placing a region of interest (ROI) over the lesion and a corresponding ROI over adjacent normal breast adipose tissue at the same imaging depth. The strain ratio was automatically computed by the system.

Mammography was performed on patients where clinically indicated or as part of routine screening. Mammographic findings were classified using the standard BI-RADS lexicon, with BI-RADS 4 or 5 considered positive.

Reference Standard

Histopathological diagnosis was obtained for all lesions through fine-needle aspiration cytology (FNAC), core needle biopsy, surgical excision, or radical surgery, as determined by the treating clinician. Histopathological findings served as the reference standard for all comparative analyses.

Statistical Analysis

Data were entered and analyzed using SPSS version 20 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation; categorical variables were expressed as frequencies and percentages. Association between imaging parameters and histopathological diagnosis was assessed using the chi-square test. Normality of continuous variables was tested using the Shapiro–Wilk test; the Mann–Whitney U test was applied where normality was violated. Cohen's kappa coefficient quantified agreement between each imaging modality and histopathology. ROC curve analysis was performed to determine the area under the curve (AUC), 95% confidence intervals, and optimal cutoff values. A p-value less than 0.05 was considered statistically significant.

RESULTS

Demographic and Clinical Characteristics

A total of 100 female patients were enrolled. The majority were in the 40–49 age group (28%), followed by 50–59 years (24%), 30–39 years (22%), ≥60 years (16%), and 20–29 years (10%). The mean age of patients with malignant lesions (53.91 ± 10.54 years) was significantly higher than those with benign lesions (43.14 ± 11.79 years; $p < 0.001$). A statistically significant association was observed between menopausal status and malignancy ($\chi^2 = 15.661$, $p < 0.001$); post-menopausal women had the highest malignancy proportion (55.0%), compared to 33.3% in the peri-menopausal and 12.8% in the pre-menopausal group. A positive family history of breast cancer was numerically more frequent in malignant cases (48.1% vs. 28.8%) but did not reach statistical significance ($p = 0.069$). On histopathological analysis, 66 lesions (66%) were benign and 34 (34%) were malignant.

The palpable lump was the most common presenting symptom (70%), followed by incidental detection (11%), breast pain with lump (10%), and nipple discharge (9%). Lesion distribution was nearly equal between the right (52%) and left (48%) breasts. The upper outer quadrant was the most frequently involved site (40%). Mean maximum lesion dimension was 22.31 ± 11.69 mm (range: 6–53 mm); lesion size category showed no statistically significant association with malignancy ($p = 0.686$).

Conventional Ultrasonography

Lesions were distributed across BI-RADS categories as follows: BI-RADS 3 (18%), 4A (26%), 4B (22%), 4C (18%), and 5 (16%). Defining positivity as BI-RADS ≥4A, 82% of lesions were classified as positive, capturing all 34 malignant lesions (sensitivity 100%); however, diagnostic agreement with histopathology was only fair ($k = 0.203$, $p = 0.001$), indicating a high false-positive rate. Margin characteristics demonstrated a highly significant association with malignancy ($\chi^2 = 40.954$, $p < 0.001$): spiculated margins were exclusively malignant (100%), circumscribed margins were exclusively benign (100%), and angular margins showed 70% malignancy. Non-parallel (taller-than-wide) orientation correlated significantly with malignancy (62% malignant vs. 6% for parallel orientation; $\chi^2 = 34.938$, $p < 0.001$). Suspicious axillary lymph nodes were present in 20 cases, all of which were malignant (100%; $\chi^2 = 48.529$, $p < 0.001$).

Mammography

Mammographic BI-RADS distribution was: BI-RADS 1–2 (20%), 3 (35%), 4 (25%), and 5 (20%). Using BI-RADS 4 or 5 as positive, mammography identified 85.3% of malignant lesions as positive and 75.8% of benign lesions as negative ($\chi^2 = 33.794$, $p < 0.001$), with moderate agreement ($k = 0.566$). ROC analysis demonstrated an AUC of 0.846 (95% CI: 0.765–0.928; $p < 0.001$).

Qualitative Sonoelastography (Tsukuba Score)

Tsukuba score ≥4 was observed in 36 lesions, of which 28 (77.8%) were malignant. Among the 64 elastography-negative lesions, only 6 (9.4%) were malignant. This association was highly significant ($\chi^2 = 48.040$, $p < 0.001$), with substantial agreement with histopathology ($k = 0.692$). ROC analysis yielded an AUC of 0.902 (95% CI: 0.841–0.963; $p < 0.001$).

Quantitative Sonoelastography (Strain Ratio)

The mean strain ratio was significantly higher in malignant lesions (4.05 ± 1.37; range 1.30–6.57) compared to benign lesions (2.13 ± 1.00; range 0.82–6.39). Given non-normal distribution confirmed by the Shapiro–Wilk test ($p < 0.001$ for benign; $p = 0.044$ for malignant), the Mann–Whitney U test demonstrated a highly significant difference ($U = 214.0$, $Z = <6.607$, $p < 0.001$).

Using a strain ratio cutoff of ≥2.7, 41 lesions were classified as positive, of which 31 (75.6%) were malignant; among 59 strain ratio-negative lesions, only 3 (5.1%) were malignant. This yielded the highest agreement with histopathology among all modalities evaluated $k = 0.724$; $\chi^2 = 53.617$, $p < 0.001$). ROC analysis demonstrated the highest AUC for strain ratio (0.905; 95% CI: 0.838–0.971; $p < 0.001$).

Table 1 summarizes the ROC performance of all evaluated parameters. Table 2 summarizes the sensitivity, specificity, positive and negative predictive values, and diagnostic agreement (k) of each modality with histopathology.

Table 1. ROC (AUC) Analysis of Imaging and Elastographic Parameters for Prediction of Malignancy (N = 100)

Parameter	AUC	Std. Error	95% CI	p-value
Strain ratio	0.905	0.034	0.838–0.971	< 0.001
Tsukuba elastography score	0.902	0.031	0.841–0.963	< 0.001
US BI-RADS (numeric)	0.899	0.031	0.839–0.959	< 0.001
Mammography BI-RADS (numeric)	0.846	0.042	0.765–0.928	< 0.001

AUC = area under the curve; CI = confidence interval; US = ultrasonography.

Table 2. Diagnostic Agreement (Kappa) of Imaging Modalities with Histopathology (N = 100)

Modality	Positivity Criterion	Sensi-tivity (%)	Speci-ficity (%)	PPV (%)	NPV (%)	Kappa (k)	p-value
B-mode US	BI-RADS ≥4A	100	27.3	41.5	100	0.203	0.001
Mammo-graphy	BI-RADS 4/5	85.3	75.8	64.4	90.9	0.566	< 0.001
Tsukuba-score	≥4	82.4	87.9	77.8	90.6	0.692	< 0.001
Strain ratio	≥2.7	91.2	84.8	75.6	94.9	0.724	< 0.001

US = ultrasonography; PPV = positive predictive value; NPV = negative predictive value.

Combined Imaging Assessment

When a combined rule designating a lesion as positive if any modality returned a positive result was applied, 91% of lesions were classified as positive, capturing all malignant cases (100% sensitivity). However, agreement with histopathology was poor (k = 0.097, p = 0.024), reflecting substantially reduced specificity and an increased false-positive rate compared to individual modality analysis.

DISCUSSION

The present study evaluated the diagnostic utility of sonoelastography in characterizing solid breast lesions among 100 patients at a tertiary care centre in northern India. The primary finding is that quantitative strain ratio measurement achieved the highest diagnostic accuracy (AUC = 0.905) and the greatest agreement with histopathology (k = 0.724) among all modalities evaluated, including B-mode ultrasonography and mammography. These results support the integration of elastographic assessment into routine breast imaging protocols.

Demographic findings in the present study are consistent with established epidemiological patterns. Malignant lesions occurred at a significantly older mean age (53.91 ± 10.54 years) compared to benign lesions (43.14 ± 11.79 years; p < 0.001), corroborating the known age-related increase in breast cancer risk. Post-menopausal women accounted for the highest proportion of malignant cases (55.0%), reflecting the role of hormonal factors in carcinogenesis. Comparable findings have been reported by Balçık et al. [11] and Wahib et al. [12], who documented increasing malignancy prevalence with advancing age in elastography studies.

Conventional B-mode ultrasonography demonstrated 100% sensitivity for malignancy detection at the BI-RADS ≥4A threshold; however, diagnostic agreement with histopatho-logy was only fair (k = 0.203), reflecting a high false-positive rate. Morphological features retained strong predictive value: spiculated and angular margins were almost exclusively malignant, circumscribed margins were entirely benign, and non-parallel orientation was associated with 62% malig-nancy. These findings align with Ricci et al. [13], who reported B-mode sensitivity of 90% with specificity of only 60%, underscoring the intrinsic trade-off between sensitivity and specificity in morphological imaging. The AUC for US BI-RADS numeric (0.899) demonstrates the high discriminatory potential of structured ultrasound scoring but emphasizes that morphology alone produces unacceptably high false-positive rates.

Mammography achieved moderate agreement (k = 0.566) and an AUC of 0.846, consistent with reported pooled sensitivities of 82–90% in similar study populations [12]. Mammographic sensitivity remained lower than that of sonoelastographic parameters in this cohort, a finding particularly relevant given the younger age distribution and denser breast tissue common in South Asian populations.

Qualitative elastography using Tsukuba score ≥4 demonstrated substantial agreement with histopathology (k = 0.692) and an excellent AUC of 0.902, consistent with Balçık et al. [11] who reported 80% of malignant lesions scoring ≥4 on the Tsukuba scale with sensitivity of 85.5% and specificity of 84.8%. The qualitative approach is operationally straightforward and integrates seamlessly into routine ultrasound workflow; however, it is subject to operator variability, particularly in lesions with heterogeneous stiffness patterns.

Quantitative strain ratio measurement was the strongest independent predictor of malignancy in the present study. The mean strain ratio in malignant lesions (4.05 ± 1.37) was approximately twice that in benign lesions (2.13 ± 1.00; p < 0.001), consistent with findings by Yıldız et al. [14] and Thomas et al. [15]. At a cutoff of ≥2.7, strain ratio produced the highest k (0.724) and highest AUC (0.905), demonstrating a superior balance of sensitivity and specificity. The optimal cutoff identified here (≥2.7) is somewhat lower than thresholds reported in some comparable studies (3.0–4.52) [11,15], potentially reflecting differences in equipment, patient population, and breast composition. Given the comparatively younger age distribution and denser fibroglandular breast tissue documented in South Asian women relative to Western cohorts, regional variation in baseline stromal stiffness and subcutaneous adipose thickness may plausibly shift the optimal strain ratio cutoff downward, underscoring the importance of locally validated, population-specific thresholds rather than direct adoption of Western reference values.

The improvement from AUC 0.899 (B-mode alone) to AUC 0.905 (strain ratio) may appear incremental numerically, but the increase in k from 0.203 to 0.724 is clinically substantial, representing a shift from fair to substantial agreement and corresponding to a marked reduction in false-positive diagnoses. This finding parallels Kim et al. [16], who reported AUC improvement from 0.795 with B-mode alone to 0.916 when elastography was added. Wahib et al. [12] further reported that elastography addition improves specificity by up to 25% and reduces benign biopsy rates by approximately 20–30%.

The combined "any positive" rule achieved 100% sensitivity but yielded the poorest agreement (k = 0.097), markedly increasing the false-positive burden. This demonstrates that indiscriminate multimodal combination does not improve and may worsen diagnostic utility; a structured, algorithmic integration of elastographic parameters—particularly for BI-RADS 3 and 4A lesions—offers a more clinically rational approach.

Suspicious axillary lymph nodes were associated with malignancy in 100% of cases ($\chi^2 = 48.529, p < 0.001$), confirming the importance of comprehensive axillary assessment as a complementary marker during breast ultrasound evaluation.

Several limitations should be acknowledged. The study was conducted at a single centre, which may limit generalizability. The sample size of 100 lesions, while adequate for the statistical objectives, restricts subgroup analyses. Operator dependency inherent to strain elastography may influence reproducibility, particularly in deep or adipose-rich lesions. The study evaluated strain elastography exclusively; comparative performance with shear-wave elastography, which provides absolute stiffness values, warrants further investigation. Formal interobserver variability analysis was not performed. Future multicentric studies with larger sample sizes, including shear-wave elastography and artificial intelligence–assisted analysis, are warranted to establish standardized thresholds and validate clinical integration protocols.

CONCLUSION

Sonoelastography significantly improves the characterization of solid breast lesions beyond what is achievable with conventional B-mode ultrasonography and mammography alone. Quantitative strain ratio measurement at a threshold of ≥2.7 demonstrated the highest diagnostic agreement with histopathology (k = 0.724) and the greatest discriminatory performance (AUC = 0.905) in this cohort. Integration of both qualitative Tsukuba scoring and quantitative strain ratio analysis into routine breast ultrasound workflows may enhance diagnostic confidence, reduce unnecessary benign biopsies, and support more precise risk stratification in patients presenting with solid breast lesions.

Author Contributions

Dr. Shefali: study design, data acquisition, imaging analysis, manuscript preparation. Dr. Ruchika Singh: study conception, supervision, critical revision. Both authors reviewed and approved the final manuscript.

Conflict of Interest: The authors declare no conflicts of interest.

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Ethics Approval

Ethical approval was granted by the Institutional Ethics Committee, Dr. KNS Memorial Institute of Medical Sciences, Barabanki, UP. All participants provided written informed consent.

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