

DIAGNOSTIC ACCURACY OF ULTRASOUND ELASTOGRAPHY IN FOCAL BREAST LESIONS KEEPING HISTOPATHOLOGY AS GOLD STANDARD: A CROSS-SECTIONAL STUDY

Original Research

Naila Rehman^{1*}, Syed Muhammad Shahnawaz Hyder², Muhammad Nafees³, Sameena Kausar⁴.

¹MBBS, FCPS-Resident (Diagnostic Radiology), Department of Radiology, Indus Hospital & Health Network, Karachi, Pakistan.

²MBBS, FCPS, Fellowship Body Imaging, Consultant Radiologist, Department of Radiology, Indus Hospital & Health Network, Karachi, Pakistan.

³MBBS, FCPS, OJT-MRI, PAF Hospital, Islamabad, Pakistan.

⁴Assistant Professor of Dermatology, Combined Military Hospital Malir, Karachi, Pakistan.

Corresponding Author: Naila Rehman, MBBS, FCPS-Resident (Diagnostic Radiology), Department of Radiology, Indus Hospital & Health Network, Karachi, Pakistan, malik_aqib@hotmail.com

Acknowledgement: The authors acknowledge the support of the Department of Radiology for facilitating this research.

Conflict of Interest: None

Grant Support & Financial Support: None

ABSTRACT

Background: Breast cancer frequently presents as a focal breast lesion, and accurate non-invasive characterization remains essential to guide clinical decision-making and avoid unnecessary biopsies. Conventional B-mode ultrasonography, although sensitive, has limited specificity, particularly in women with dense breast tissue. Ultrasound elastography evaluates tissue stiffness and has emerged as a promising adjunct technique to improve lesion characterization. Shear wave elastography provides quantitative elasticity measurements, potentially enhancing diagnostic confidence, especially in resource-limited settings where reducing invasive procedures is clinically and economically important.

Objective: To determine the diagnostic accuracy of shear wave elastography in differentiating benign and malignant focal breast lesions using histopathology as the reference standard.

Methods: A cross-sectional diagnostic accuracy study was conducted on 100 consecutive women presenting with focal breast lesions confirmed on B-mode ultrasound. All participants underwent shear wave elastography prior to tissue diagnosis. Quantitative stiffness measurements were recorded, and lesions were classified as benign or malignant based on predefined elasticity thresholds. Histopathology or fine-needle aspiration cytology served as the gold standard. Diagnostic performance parameters, including sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy, were calculated. Stratified analyses were performed to assess the influence of age, body mass index, and marital status.

Results: Histopathological examination identified malignant lesions in 31% and benign lesions in 69% of cases. Shear wave elastography categorized 30% of lesions as malignant and 70% as benign. Compared with histopathology, elastography demonstrated a sensitivity of 74.2%, specificity of 89.9%, positive predictive value of 76.7%, negative predictive value of 88.6%, and an overall diagnostic accuracy of 85.0%. The highest accuracy was observed in women aged 25–40 years (89.7%), followed by those older than 40 years (84.8%) and younger than 25 years (80.0%). Diagnostic accuracy was slightly higher in participants with body mass index ≤ 25 kg/m² compared with those above this threshold. High specificity was consistently maintained across all subgroups.

Conclusion: Shear wave elastography demonstrated good diagnostic accuracy and high specificity in distinguishing benign from malignant focal breast lesions. Its integration with conventional ultrasonography can enhance diagnostic confidence and support reduction of unnecessary biopsies, particularly in settings with limited resources.

Keywords: Accuracy, Breast Neoplasms, Diagnostic Imaging, Elasticity Imaging Techniques, Sensitivity and Specificity, Ultrasonography.

INTRODUCTION

Breast cancer remains one of the most frequently diagnosed malignancies among women worldwide and commonly presents as a palpable breast lump, making early recognition a critical determinant of outcome (1). Globally, the incidence of breast cancer is estimated at approximately 54 cases per 100,000 individuals, reflecting a substantial and persistent public health burden (2). Although breast lumps can arise from both benign and malignant conditions across all age groups, benign lesions are considerably more prevalent in younger women. Evidence from Pakistan indicates that up to 83% of breast lesions in teenagers and young women are benign, while 17% are malignant, underscoring the diagnostic challenge of accurately characterizing breast masses in this population (3). Given that prognosis and survival are strongly linked to early and accurate detection, timely differentiation between benign and malignant breast lesions is essential for appropriate management and outcome prediction (4). Conventional imaging modalities such as ultrasonography and mammography are widely used for the initial assessment of breast lesions; however, both techniques have recognized limitations. Mammography may yield false-negative results in women with dense breast tissue, while ultrasonography, despite its sensitivity, often demonstrates limited specificity, leading to a high rate of unnecessary biopsies (5,6). These invasive procedures not only impose psychological distress and physical discomfort but also contribute to increased healthcare costs, a concern that is particularly relevant in low- and middle-income countries. Therefore, there is a growing need for adjunctive, non-invasive imaging techniques that can improve diagnostic confidence and reduce avoidable interventions.

Malignant breast tumors are biologically characterized by increased tissue stiffness compared with benign lesions and normal parenchyma. Sonoelastography exploits this property by evaluating tissue elasticity in response to externally applied stress, measuring displacement changes that reflect tissue rigidity. Lower elasticity values correspond to stiffer, and often malignant, tissues, whereas higher elasticity is typically seen in benign lesions (7,8). Shear wave elastography, in particular, provides quantitative and qualitative information on tissue stiffness through visualization of shear wave propagation, allowing relative comparison of lesion rigidity with surrounding tissue (9). Over recent years, ultrasonic elastography has demonstrated promising specificity and diagnostic performance as a non-invasive method for breast lesion characterization, complementing conventional ultrasound findings (10,11). The rapid evolution of imaging technologies such as real-time elastography has enhanced the ability to distinguish benign from malignant breast lesions with greater accuracy. Its advantages—including non-invasiveness, improved specificity, shorter examination time, and lower cost—make it an attractive alternative or adjunct to biopsy, especially in resource-constrained settings like Pakistan. Despite growing international evidence, local data evaluating the diagnostic accuracy of shear wave elastography in the assessment of indeterminate breast lesions remain limited. Therefore, the objective of the present study is to determine the diagnostic accuracy of shear wave elastography in differentiating benign and malignant breast lesions detected on ultrasonography, with the rationale that improved early diagnostic precision may facilitate timely clinical decision-making, reduce unnecessary biopsies, and ultimately lower disease-related morbidity, mortality, and economic burden.

METHODS

This cross-sectional validation study was conducted in the Department of Radiology at Fazaia Postgraduate Medical Institute, PAF Hospital, Islamabad, over a six-month period from September 2023 to March 2024, following approval from the institutional research ethics committee. The study was designed to evaluate the diagnostic performance of shear wave elastography in differentiating benign from malignant breast lesions, using histopathology or fine-needle aspiration cytology (FNAC) as the reference gold standard. Written informed consent was obtained from all participants prior to enrollment, and the study procedures adhered to established ethical principles for human research. The sample size was calculated using a sensitivity and specificity calculator, based on an anticipated sensitivity of 92.2%, specificity of 96.2%, an expected disease prevalence of 29.7%, a 95% confidence level, and a 10% margin of precision (12). A total of 100 female participants were recruited using a non-probability consecutive sampling technique. Women aged between 15 and 65 years presenting with palpable breast lumps that were confirmed on B-mode ultrasonography were included. Patients with recurrent breast lesions, a prior history of breast surgery, or those in whom tissue sampling was not clinically indicated were excluded to minimize confounding and ensure diagnostic clarity. Each participant underwent a detailed clinical assessment and physical examination prior to imaging. Conventional B-mode ultrasonography was initially performed to assess lesion morphology, size, and

location. Lesions deemed suspicious on grayscale imaging were subsequently evaluated using shear wave elastography. Elastographic examinations were performed by a consultant radiologist who was blinded to the cytological and histopathological findings to reduce observer bias. During elastography, the ultrasound probe was positioned centrally over the lesion, with the field of view extending from the skin surface to the pectoralis muscle in the anteroposterior plane, ensuring inclusion of a 5-mm margin of surrounding normal tissue. For each lesion, multiple measurements were obtained, and the highest value from at least three valid readings was recorded.

Breast lesions were classified as malignant on shear wave elastography if the maximum shear wave velocity (V_{max}) was ≥ 4.5 m/s, corresponding to a Young’s modulus of ≥ 85 kPa, or if the mean stiffness value was ≥ 3.8 m/s (60 kPa). Lesions with values below these thresholds were categorized as benign. Following elastographic assessment, ultrasound-guided tissue sampling was performed using FNAC or Tru-cut biopsy, depending on lesion characteristics and clinical indication. All specimens were examined by a consultant pathologist with a minimum of three years of professional experience, who was blinded to the elastography results. The presence of malignant cells on microscopic examination confirmed malignancy, whereas their absence indicated a benign lesion. Data were entered and analyzed using SPSS version 25. Quantitative variables, including age and body mass index (BMI), were summarized as mean values with standard deviations, while qualitative variables were expressed as frequencies and percentages. Diagnostic accuracy parameters for shear wave elastography, including sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy, were calculated using a 2×2 contingency table with histopathology or FNAC as the reference standard. Stratification was performed to control potential effect modifiers such as age, BMI, and marital status, and post-stratification comparisons were assessed using the Chi-square test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 100 female patients presenting with focal breast lesions were included in the analysis. The mean age of the study population was 39.27 ± 11.28 years, with an age range of 18 to 62 years. Nearly half of the participants (46%) were older than 40 years, reflecting a predominance of lesions in the relatively older age group. The mean body mass index was 24.56 ± 4.03 kg/m², ranging from 17.10 to 37.00 kg/m², and the majority of patients (70%) had a BMI of ≤ 25 kg/m². With regard to marital status, most participants were married (79%), while single and divorced or widowed women constituted smaller proportions of the cohort. On shear wave elastography assessment, 30% of the breast lesions were categorized as malignant and 70% as benign. Histopathological evaluation using biopsy or FNAC identified malignancy in 31% of cases and benign pathology in 69%, demonstrating close agreement between elastographic findings and the reference standard. When elastography results were compared against histopathology, true-positive findings were observed in 23 cases and true-negative findings in 62 cases, while false-positive and false-negative results occurred in 7 and 8 cases, respectively. Based on these findings, shear wave elastography demonstrated a sensitivity of 74.2% and a specificity of 89.9%. The positive predictive value was 76.7%, while the negative predictive value reached 88.6%. Overall diagnostic accuracy was calculated at 85.0%, indicating strong performance of elastography in differentiating malignant from benign focal breast lesions. Subgroup analysis revealed variation in diagnostic performance across demographic and anthropometric strata. Diagnostic accuracy was highest among patients aged 25–40 years (89.7%), followed by those older than 40 years (84.8%), whereas comparatively lower accuracy was observed in patients younger than 25 years (80.0%). In terms of body mass index, patients with BMI ≤ 25 kg/m² demonstrated slightly higher diagnostic accuracy (86.9%) compared with those with BMI > 25 kg/m² (82.1%). Sensitivity was notably higher in the higher BMI group, while specificity was superior among patients with lower BMI. Analysis by marital status showed the highest diagnostic accuracy in married women (88.6%), whereas lower accuracy was observed among single (75.0%) and divorced or widowed participants (66.7%), likely reflecting smaller subgroup sizes. Across all strata, specificity consistently remained high, supporting the reliability of shear wave elastography in ruling out benign lesions.

Table 1: Frequency of positive and negative findings for ultrasound elastography and histopathology in total study population

Test	Positive	Negative	Total
Histopathology	31 (31.0%)	69 (70.0%)	100 (100.0%)
Elastography	30 (30.0%)	70 (70.0%)	100 (100.0%)

Table 2: Overall diagnostic accuracy of ultrasound elastography for diagnosing focal breast lesions keeping histopathology as gold standard

Ultrasound Elastography Findings	Histopathology Positive	Histopathology Negative	Total
Positive (Test +)	TP = 23	FP = 7	30
Negative (Test -)	FN = 8	TN = 62	70
Total	31	69	100
Diagnostic Accuracy Parameters			
Sensitivity	74.2%		
Specificity	89.9%		
Positive Predictive Value (PPV)	76.7%		
Negative Predictive Value (NPV)	88.6%		
Diagnostic Accuracy	85.0%		

Table 3: Diagnostic accuracy of ultrasound elastography for diagnosing focal breast lesions keeping histopathology as gold standard

Stratification Variable	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
Age <25 years	60.0	90.0	75.0	81.8	80.0
Age 25–40 years	77.8	90.0	70.0	93.1	89.7
Age >40 years	76.5	89.7	81.3	86.7	84.8
BMI ≤25	63.2	97.6	92.3	85.4	86.9
BMI >25	91.7	77.8	64.7	95.5	82.1
Single	50.0	80.0	33.3	88.9	75.0
Married	80.0	92.6	83.3	90.9	88.6
Divorced/Widow	50.0	80.0	66.7	66.7	66.7

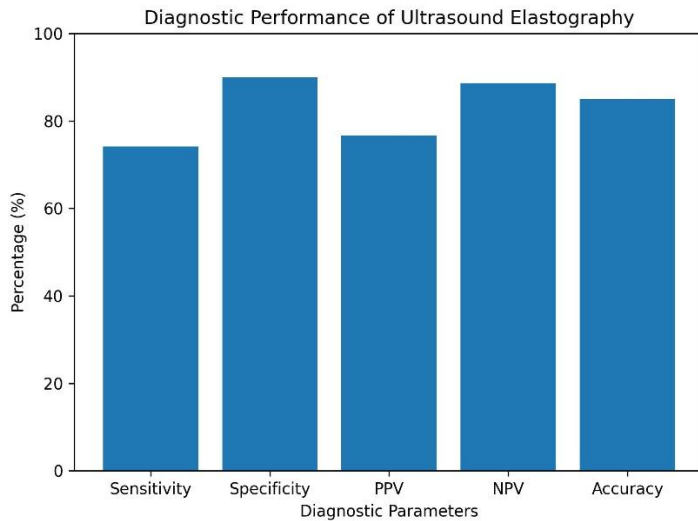


Figure 2 Diagnostic Performance of Ultrasound Elastography

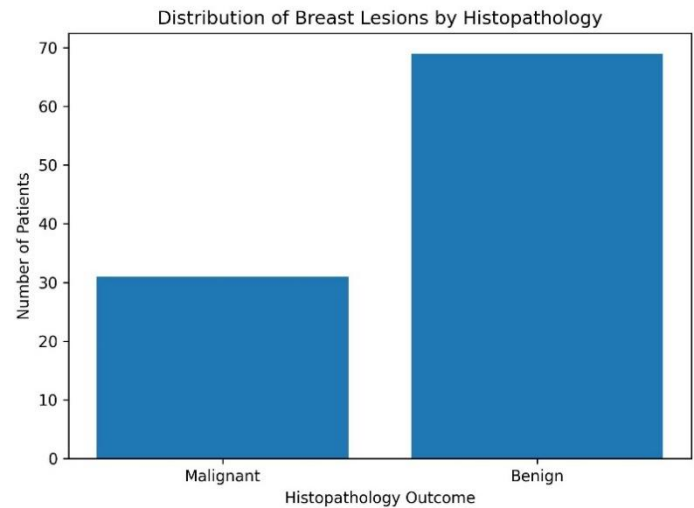


Figure 2 Distribution of Breast Lesions by Histopathology

DISCUSSION

The findings of the present study reinforce the growing role of breast sonoelastography as a valuable adjunct to conventional ultrasound in differentiating benign from malignant breast lesions. By assessing tissue stiffness relative to surrounding parenchyma, elastography provides an objective, quantifiable extension of clinical palpation, thereby enhancing lesion characterization beyond morphological assessment alone (13). Among the two clinically available elastographic techniques, shear wave elastography was employed in this study because of its ability to generate reproducible quantitative measurements of tissue elasticity expressed as shear wave velocity or Young's modulus, both of which increase in stiffer, malignant tissues and decrease in softer, benign lesions (14,15). This quantitative capability allows for more standardized interpretation and supports its integration into routine breast imaging workflows (13–15). The diagnostic performance observed in this study aligns well with the broader body of published evidence evaluating elastography for breast lesion assessment. The overall diagnostic accuracy of 85%, coupled with high specificity and negative predictive value, is comparable to ranges reported in multiple clinical studies and large pooled analyses, which consistently demonstrate strong discriminative ability of shear wave elastography across different elasticity parameters (16,17). The high specificity observed supports the utility of elastography as a reliable rule-out tool, particularly valuable in reducing false-positive findings and limiting unnecessary biopsies. This characteristic is clinically relevant, as one of the primary shortcomings of conventional ultrasound is its limited specificity, which often leads to invasive procedures for lesions that ultimately prove benign (5,6). The subgroup analysis provided further insight into factors influencing elastographic performance. Higher diagnostic accuracy was observed among women aged 25–40 years and those with a body mass index of 25 kg/m² or less. These findings may reflect more favorable breast tissue composition and acoustic conditions in these groups, rather than a true decline in test performance among other subgroups. Variations in glandular density, breast thickness, and adipose tissue distribution are known to affect shear wave propagation and image quality, potentially influencing stiffness measurements and diagnostic accuracy (18). Despite these variations, elastography maintained consistently high specificity across all age, BMI, and marital status categories, underscoring its robustness and reliability across diverse patient profiles.

When considered alongside conventional B-mode ultrasound, the addition of elastography appeared to enhance diagnostic specificity without a marked compromise in sensitivity. This complementary effect has been repeatedly emphasized in the literature, where elastography-based stiffness assessment refines lesion characterization and supports more confident exclusion of malignancy in low- to intermediate-suspicion cases (19–21). The present results further support the practical value of elastography in assisting BI-RADS categorization, particularly by reducing benign biopsies in lesions that are morphologically indeterminate but elastographically soft. Such an approach is especially pertinent in resource-limited settings, where minimizing invasive procedures and optimizing cost-effective diagnostics are critical. The strengths of this study include the use of histopathology or FNAC as a reference standard, blinding of both radiologist and pathologist to reduce observer bias, and stratified analysis to explore the influence of demographic and

anthropometric variables on diagnostic performance. The quantitative thresholds applied for shear wave elastography were based on established values reported in prior studies, enhancing comparability with existing literature. However, several limitations must be acknowledged. The relatively small sample size and single-center design may limit generalizability. The exclusive use of shear wave elastography restricts direct comparison with strain elastography, and the absence of interobserver variability assessment may have influenced measurement consistency. In addition, shear wave elastography is known to be less reliable in deeply located lesions and in individuals with higher BMI due to signal attenuation, which may partly explain subgroup variability. The lack of universally standardized, manufacturer-independent cutoff values also remains a challenge for widespread reproducibility. Future research would benefit from larger, multicenter studies incorporating standardized acquisition protocols, interobserver reliability analysis, and direct comparison of different elastographic techniques. Integration of lesion size, depth, and BI-RADS categories into diagnostic modeling may further refine risk stratification. Despite these limitations, the present study adds meaningful evidence supporting the clinical value of shear wave elastography as a non-invasive, accurate, and practical tool that enhances breast lesion evaluation, reduces unnecessary biopsies, and strengthens diagnostic confidence when used alongside conventional ultrasound, particularly in settings with constrained healthcare resources.

CONCLUSION

Shear wave ultrasound elastography proved to be a reliable adjunct to conventional B-mode ultrasound for the evaluation of focal breast lesions, demonstrating strong diagnostic performance when compared with histopathological findings. Its ability to effectively exclude malignancy supports a more conservative and informed approach to the management of lesions with benign imaging features, thereby helping to reduce unnecessary biopsies and associated patient burden. The stable performance observed across different patient subgroups suggests that elastography can be applied consistently in routine clinical practice, with only minor influence from patient-related factors such as tissue composition. Overall, the findings of this study support the integration of shear wave elastography into standard breast imaging protocols, where it can enhance lesion characterization, refine BI-RADS assessment, and contribute to more accurate and confident clinical decision-making.

AUTHOR CONTRIBUTIONS

Author	Contribution
Naila Rehman*	Substantial Contribution to study design, analysis, acquisition of Data
	Manuscript Writing
	Has given Final Approval of the version to be published
Syed Muhammad Shahnawaz Hyder	Substantial Contribution to study design, acquisition and interpretation of Data
	Critical Review and Manuscript Writing
	Has given Final Approval of the version to be published
Muhammad Nafees	Substantial Contribution to acquisition and interpretation of Data
	Has given Final Approval of the version to be published
Sameena Kausar	Contributed to Data Collection and Analysis
	Has given Final Approval of the version to be published

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