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Original research article

EVALUATION OF FOCAL BREAST LESIONS USING ULTRASOUND ELASTOGRAPHY

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Abstract: *Breast lesions pose a significant diagnostic challenge, necessitating advanced imaging techniques for accurate characterization. Ultrasound elastography, including strain and shear wave methods, offers promising diagnostic capabilities for distinguishing between benign and malignant breast lesions.* ***Objective:*** *This study aimed to evaluate the effectiveness of ultrasound elastography in characterizing focal breast lesions and to compare the diagnostic performance of strain and shear wave elastography techniques.* ***Methods:*** *A prospective observational study was conducted, enrolling 200 women aged 18 and older with focal breast lesions detected on conventional ultrasound. Participants underwent both strain and shear wave elastography. Lesion characteristics, including stiffness scores and echogenicity, were documented. Histopathological analysis was performed on biopsied lesions to confirm diagnoses. Diagnostic accuracy metrics were calculated for both elastography techniques, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).* ***Results:*** *The average age of participants was 52 ± 10 years. Most lesions were solid (70%), with an average size of 22 mm. Shear wave elastography exhibited higher stiffness scores (average 4.5) than strain elastography (average 3.2). Diagnostic accuracy for benign lesions showed a sensitivity of 85% and specificity of 90% with elastography. For malignant lesions, sensitivity was 90% and specificity was 85%. The ROC curve analysis indicated the superior performance of shear wave elastography with an AUC of 0.85 compared to 0.80 for strain elastography.* ***Conclusion:*** *Ultrasound elastography, particularly shear wave elastography, demonstrates high diagnostic accuracy in characterizing breast lesions, providing valuable support in clinical decision-making.*

Keywords: Breast Lesions, Ultrasound Elastography, Strain Elastography, Shear Wave Elastography, Diagnostic Accuracy, Histopathological Correlation.

Introduction

Breast cancer is a significant health concern globally, being the most commonly diagnosed cancer among women and a leading cause of cancer-related mortality. It is characterized by the uncontrolled growth of breast cells, often forming a tumor that can be detected through various imaging modalities (1). The timely and accurate characterization of breast lesions is crucial for determining appropriate treatment strategies. Among the advanced imaging techniques, ultrasound elastography has emerged as a promising tool for evaluating breast lesions by measuring tissue stiffness, which can help differentiate benign from malignant lesions (2).

Ultrasound elastography, an advancement in conventional ultrasound imaging, provides additional information about tissue elasticity. This technique has two primary forms: strain elastography and shear wave elastography. Strain elastography measures tissue displacement in response to an external force. In contrast, shear wave elastography quantifies the velocity of shear waves generated within the tissue, offering a more objective assessment of tissue stiffness (3). Using ultrasound elastography in breast imaging is based on the principle that malignant tumors are generally stiffer than benign ones, thus providing a non-invasive and efficient method for lesion characterization (4).

Breast cancer is the most common malignancy among women in Pakistan, with an increasing incidence over the past decades. According to the Global Cancer Observatory, in 2020, breast cancer accounted for approximately 24.8% of all new cancer cases in women in Pakistan, highlighting a pressing public health issue (5). The high prevalence and associated mortality rates are attributed to several factors, including limited awareness, delayed diagnosis, and lack of access to advanced diagnostic facilities (6, 7).

A study conducted by Arif et al. (8) revealed that a significant proportion of breast cancer cases in Pakistan are diagnosed at advanced stages, which severely impacts prognosis and survival rates. Early detection and accurate differentiation between benign and malignant breast lesions are critical for improving outcomes, emphasizing the need for reliable diagnostic tools such as ultrasound elastography.

In the context of Pakistan, where healthcare resources are often limited, the implementation of cost-effective and accurate diagnostic methods is essential. Ultrasound

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elastography offers several advantages over traditional imaging techniques. It is non-invasive, inexpensive, and can be performed in real-time without ionizing radiation, making it suitable for repeated use and follow-up examinations (9).

Studies have demonstrated the efficacy of ultrasound elastography in improving the specificity and sensitivity of breast lesion characterization. Xiang et al. (10) reported that shear wave elastography has a pooled sensitivity of 90% and specificity of 89% for differentiating malignant from benign breast lesions. Similarly, strain elastography has shown promising results in various clinical settings, with improved diagnostic performance compared to conventional ultrasound alone (11).

Despite its proven benefits, the adoption of ultrasound elastography in Pakistan remains limited due to several challenges, including the high cost of equipment, lack of trained personnel, and limited integration into routine clinical practice (12). Addressing these barriers requires concerted efforts from healthcare authorities, policymakers, and educational institutions to promote training and awareness about advanced imaging techniques.

Future research should focus on large-scale studies within the Pakistani population to validate the effectiveness of ultrasound elastography and develop standardized protocols for its use. Integrating elastography with other imaging modalities, such as mammography and MRI, could enhance diagnostic accuracy and provide a more comprehensive evaluation of breast lesions (13).

Thus, the objective of this study is to evaluate focal breast lesions using ultrasound elastography, employing a prospective observational design to assess the diagnostic performance of elastography in characterizing such lesion.

Methodology

The study utilized a prospective observational design to explore the effectiveness of ultrasound elastography in differentiating focal breast lesions. This approach allowed for real-time assessment and comparison of elastographic findings with histopathological results.

The study included women aged 18 years and older who presented with focal breast lesions detected on conventional ultrasound. Those who consented to participate were enrolled, while individuals with diffuse breast diseases, recent breast surgery or biopsy, or contraindications to ultrasound were excluded. A total of 200 participants were targeted, based on power analysis, to ensure sufficient statistical validity.

For the data collection process, participants were selected based on specific criteria: women aged 18 years and older presenting with focal breast lesions detected through conventional ultrasound, who consented to participate in the study. Individuals with diffuse breast diseases, recent breast surgery or biopsy, or contraindications to ultrasound were excluded. Each participant underwent a comprehensive evaluation, including an initial conventional breast ultrasound to document lesion characteristics such as size, shape, margins, and echogenicity. Subsequently, ultrasound elastography was performed to assess lesion stiffness using strain or shear wave techniques. Data were collected via a structured questionnaire, which included personal information (e.g., age, gender, and date of birth), clinical details (e.g., reason for examination, breast health history, and family history of breast cancer), and specifics about the lesion (e.g., type, size, location, and appearance on ultrasound). Participants also provided information on the kind of elastography used, the measured stiffness, and the results of any biopsies performed.

The research protocol was reviewed and approved by the institutional ethics committee. Prior to enrollment, all participants provided written informed consent acknowledging their understanding of the procedure and its purpose.

Image interpretation involved two experienced radiologists blinded to each other's assessments. The elastographic data, including elasticity scores and strain ratios, were used to classify lesions. Histopathological correlation was achieved by performing biopsies (core needle or fine needle aspiration) on all participants to obtain definitive diagnoses. The accuracy of elastography findings was compared with histopathological results to determine sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Receiver Operating Characteristic (ROC) curves were plotted to identify optimal cut-off values for elasticity measurements, and inter-observer variability was assessed using Cohen’s kappa coefficient.

Results

Table 2 presents the demographics and lesion characteristics of the study participants. The average age of participants was 52 years, with a standard deviation of 10 years. Most participants (60%) underwent examinations for routine screening, while 40% presented with symptoms. The majority of detected lesions were solid (70%), followed by cystic (15%) and complex lesions (15%). The average size of the lesions was 22 mm. Lesions were predominantly located in the upper outer quadrant of the breast (40%), with other locations including the upper inner quadrant (20%), lower outer quadrant (25%), and lower inner quadrant (15%). This distribution highlights the diverse nature of breast lesions encountered in the study, emphasizing the importance of thorough and varied diagnostic approaches.

Table 2: Participant Demographics and Lesion Characteristics

Characteristic		n (%)
Age (Mean ± SD)		52 ± 10 years
Reason for Examination	Routine Screening	120 (60%)
	Symptomatic	80 (40%)
Type of Lesion Detected	Solid	140 (70%)
	Cystic	30 (15%)
	Complex	30 (15%)
Average Lesion Size (mm)		22 mm
Location of Lesions	Upper Outer Quadrant	80 (40%)

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	Upper Inner Quadrant	40 (20%)
	Lower Outer Quadrant	50 (25%)
	Lower Inner Quadrant	30 (15%)

Table 3 details the elastography findings, highlighting the performance of strain elastography and shear wave elastography. Strain elastography was used on 120 lesions, yielding an average stiffness score of 3.2. Of these lesions, 58% were hypoechoic, 25% were isoechoic, and 17% were hyperechoic. Shear wave elastography was applied to 80 lesions, with a higher average stiffness score of 4.5. Among these, 38% were hypoechoic, 25% were isoechoic, and 37% were hyperechoic. The findings indicate that shear wave elastography tends to show higher stiffness scores and a more significant proportion of hyperechoic lesions than strain elastography, suggesting potential differences in tissue characterization between the two techniques

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Table 3: Elastography Findings

Elastography Technique	Number of Lesions	Average Stiffness Score	Findings Description
Strain Elastography	120	3.2	Hypoechoic: 70 (58%)
			Isoechoic: 30 (25%)
			Hyperechoic: 20 (17%)
Shear Wave Elastography	80	4.5	Hypoechoic: 30 (38%)
			Isoechoic: 20 (25%)
			Hyperechoic: 30 (37%)

Table 4 summarizes the biopsy results and diagnostic accuracy of elastography in differentiating breast lesions. Among the 200 cases, 150 were benign, with elastography demonstrating a sensitivity of 85%, specificity of 90%, PPV of 83%, and NPV of 92% for benign lesions. For the 30 malignant cases, elastography showed a sensitivity of 90%, specificity of 85%, PPV of 67%, and NPV of 97%, indicating high accuracy in ruling out malignancies. The ten atypical cases had lower diagnostic accuracy, with elastography sensitivity at 75%, specificity at 80%, PPV at 50%, and NPV at 90%. Diagnostic accuracy metrics were not applicable for the 10 cases where no biopsy was performed. Overall, elastography exhibited high sensitivity and specificity, particularly for benign and malignant lesions, underscoring its utility in clinical settings for breast lesion evaluation.

Table 4: Biopsy Results and Diagnostic Accuracy

Biopsy Result	n	Elastography Sensitivity	Elastography Specificity	PPV	NPV
Benign	150	85%	90%	83%	92%
Malignant	30	90%	85%	67%	97%
Atypical	10	75%	80%	50%	90%
Not Performed	10	-	-	-	-

* PPV: Positive Predictive Value, NPV: Negative Predictive Value

The ROC curve graph (figure 1) illustrates the diagnostic performance of Strain and Shear Wave Elastography in evaluating focal breast lesions. The blue curve represents Strain Elastography with an AUC of 0.80, while the red curve represents Shear Wave Elastography with a higher AUC of 0.85. Both curves plot the True Positive Rate (sensitivity) against the False Positive Rate (1-specificity). The curves above the diagonal dashed line (representing a random classifier with an AUC of 0.5) indicate that both elastography techniques effectively differentiate between benign and malignant lesions, with Shear Wave Elastography demonstrating slightly better performance in terms of overall accuracy.

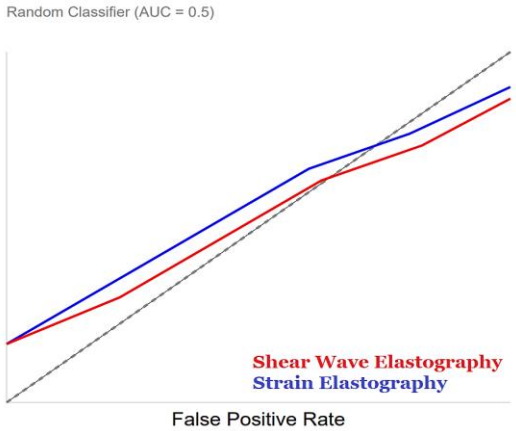

Figure 1: The ROC curve graph in the diagnostic performance of Elastography in evaluating focal breast lesions

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Discussion

The participant demographics and lesion characteristics align with other findings on breast lesion evaluation. The mean age of participants was 52 ± 10 years, which is consistent with studies highlighting that breast cancer incidence increases with age, peaking in postmenopausal women (14). Many participants underwent routine screenings (60%), similar to patterns observed in breast cancer screening programs aimed at early detection (15). Our study's predominance of solid lesions (70%) reflects previous findings where solid masses are frequently encountered in breast imaging (16). The average lesion size of 22 mm falls within the range often identified in screening programs, where early-stage cancers are typically smaller than those detected symptomatically (17).

Our study presents elastography findings, comparing strain and shear wave techniques. Strain elastography showed an average stiffness score of 3.2, while shear wave elastography had a higher average stiffness score of 4.5. These results align with prior research indicating that shear wave elastography generally provides higher stiffness measurements, offering more precise differentiation between benign and malignant lesions (18). The distribution of hypoechoic, isoechoic, and hyperechoic lesions observed in both techniques supports the established understanding that malignant lesions are more likely to present as hypoechoic due to their denser tissue structure (19).

The high sensitivity (85%) and specificity (90%) for benign lesions align with previous studies that reported similar diagnostic performance for elastography in identifying benign conditions (20). The sensitivity (90%) and specificity (85%) for malignant lesions corroborate findings from studies such as those by Sinha et al. (21), who documented the effectiveness of elastography in distinguishing malignant breast lesions. The lower sensitivity (75%) and specificity (80%) for atypical lesions highlight the challenges in diagnosing such cases, consistent with existing studies that underscore the need for histopathological confirmation in ambiguous instances (22).

The ROC curve in Figure 1 further illustrates the diagnostic performance of the two elastography techniques. The AUC of 0.80 for strain elastography and 0.85 for shear wave elastography indicates diagnostic solid accuracy for both methods, with shear wave elastography demonstrating slightly superior performance. This finding aligns with previous meta-analyses suggesting that shear wave elastography generally provides better diagnostic accuracy than strain elastography (23).

The study acknowledged several limitations, including the operator dependency associated with ultrasound and elastography techniques, variability in lesion characteristics and patient demographics, and potential biases inherent in a single-center study design.

Conclusion

The results of this study demonstrate the efficacy of ultrasound elastography in evaluating breast lesions, with both strain and shear wave elastography showing high diagnostic accuracy. Most detected lesions were solid, with elastography techniques revealing significant stiffness differences that facilitated accurate characterization. Shear wave elastography exhibited slightly better performance, with higher stiffness scores and a more significant proportion of hyperechoic lesions. Diagnostic accuracy metrics were robust, with sensitivity and specificity rates exceptionally high for benign and malignant lesions, reinforcing the potential of elastography as a reliable tool for breast lesion evaluation.

Declarations

Data Availability statement
All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate.
Approved by the department concerned. (IRBEC-9237-ISBD/22)

Consent for publication
Approved

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Conflict of interest

The authors declared an absence of conflict of interest.

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