

Original Article

Diagnostic Accuracy of Elastography in Diagnosing Breast Cancer, taking Histopathology as Gold Standard

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Abstract

Objective: To determine the diagnostic accuracy of breast ultrasound elastography for detecting breast cancer, using histopathology as the gold standard.

Methodology: This cross-sectional diagnostic accuracy study was conducted from February to August 2022 in the Department of Radiology at LUMHS, Hyderabad. Women aged 18–60 years presenting with mastalgia or a palpable breast lump suspicious for malignancy were included. All participants underwent breast ultrasound elastography, and the findings were classified as benign or malignant using the five-point Tsukuba scoring system. Histopathological examination of specimens obtained through ultrasound-guided core needle biopsy or surgical excision served as the gold standard. Diagnostic accuracy was assessed by calculating sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Data were analyzed using SPSS version 25.

Results: A total of 206 women were included, with a mean age of 47.66 ± 8.98 years. Of these, 52 (25.20%) were menstruating, while 154 (74.80%) were menopausal. Using histopathology as the gold standard, elastography demonstrated a sensitivity of 83.01%, specificity of 75.47%, PPV of 90.71%, NPV of 60.61%, and overall diagnostic accuracy of 81.07%.

Conclusion: Breast ultrasound elastography demonstrated promising diagnostic performance in evaluating women with breast lesions suspicious for malignancy. Its relatively high sensitivity and PPV suggest that it may be a useful adjunct to conventional breast imaging; however, histopathological examination remains essential for definitive diagnosis.

Keywords: Breast cancer, elastography, sensitivity, specificity, diagnostic accuracy.

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Introduction

Breast cancer represents a most frequently reported malignancy among female population around the world, with up to 11.6% newly diagnosed annual cases.¹ It is the second most prevalent cause of cancer-associated mortality, representing a significant public health concern due to rising incidence and substantial healthcare burden.^{1,2} Its development is influenced by multiple demographic, hormonal, genetic, reproductive, and environmental factors, such as age, family history, inherited genetic mutations, prolonged hormonal exposure, obesity, and lifestyle-related factors.³⁻⁶ The substantial global burden of breast cancer, characterized by a high number of cases occurring each year, with over 2.3 million newly diagnosed cases each

year, and considerable disease-associated morbidity and mortality, necessitates early and accurate detection to facilitate timely and appropriate treatment and improve clinical outcomes.^{6,7}

Breast cancer may present with a wide range of clinical manifestations, while a palpable breast lump remains a most frequent presenting complaint, with nipple retraction and skin changes further raising the suspicion of malignancy. Similarly, mastalgia is also a common complaint among women attending breast clinics.^{8,9}

Although many breast lumps are benign, benign and malignant breast lesions may exhibit overlapping clinical characteristics, which makes it challenging to accurately differentiate between benign and malignant lesions,

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potentially leading to misdiagnosis and sequentially inappropriate patient management.¹⁰

The conventional diagnostic evaluation of suspected breast cancer is commonly based on the clinical examination, imaging, and pathological evaluation. Mammography and ultrasonography serve as the principal imaging modalities in breast lesions assessment. Mammography is valuable in detecting suspicious masses and microcalcifications.

Ultrasonography, on the other hand, is widely used to characterize palpable and non-palpable breast lesions and to evaluate dense/fibroglandular tissue because of its ability to differentiate between cystic lesions and solid lesions.^{11,12} Ultrasound elastography is a non-invasive imaging technique that identifies the stiffness of tissues, providing additional information to conventional ultrasound. According to the recent evidences, the elastography possess a diagnostic potential of in differentiating benign and malignant breast lesions, like a systematic review showed high sensitivity and specificity of 86% and 87%, respectively, for mean shear-wave speed measurements.¹³ Another recent meta-analysis also demonstrated a sensitivity of 90% and specificity of 78% for ultrasound elastography, reflecting promising diagnostic performing, whereas the findings varied according to the uses of technique.¹⁴

Breast cancers are characteristically harder than surrounding tissue and benign lesions because they cause scarring (desmoplasia) and change the normal structure of the surrounding tissue. Though, the elastography should be interpreted alongside conventional imaging and should not replace histopathological confirmation when biopsy is indicated.

Although biopsy followed by histopathological examination provides a definitive diagnosis, while it is invasive, costly and stress-inducing, and a significant proportion of biopsies performed for suspicious lesions turn out to be benign, reflecting the need for non-invasive imaging techniques that can better characterize suspicious breast lesions and decrease the unnecessary biopsies.

However present study was aimed to evaluate the diagnostic accuracy of ultrasound elastography in the differentiation benign from malignant breast lesions, taking histopathology as the reference diagnostic method, by calculating sensitivity, specificity, PPV, NPV and overall diagnostic accuracy.

Methodology

This cross-sectional, diagnostic accuracy study was conducted at the Department of Radiology of Liaquat University of Medical and Health Sciences, Hyderabad. Study was conducted during a period of six months from February 2022 to August 2022. Women patients aged 18 to 60 years presenting with complaints including mastalgia, nipple discharge, cystic lesions and more commonly a lump in the breast, and clinical/physical breast examination indicative of breast cancer, undergoing breast ultrasound elastography for characterization of the breast lesion and who were willing and scheduled for histopathological examination through core needle biopsy or the surgical excision were included. However, all the women who were previously diagnosed for breast cancer who have received chemotherapy, radiotherapy, or other treatment before elastography, women with recurrent breast cancer or previously treated for breast lesions, patients with technically inadequate elastography findings and those who refused to take part in the study or unwilling to undergo histopathological examination, in addition to lactating women and those who were planning to become pregnant were excluded. Non-Probability, consecutive sampling technique was used. Informed consent was obtained from each participant after explaining the purpose of study. The entire demographic and clinical characteristics were assessed, including age, duration of the disease, and relevant clinical history, by using a structured proforma. Subsequently, all the participants underwent conventional breast ultrasonography followed by ultrasound elastography, performed by a qualified radiologist using standardized procedures having minimum experience of 5 years. The ultrasound elastography findings were categorized according to the predefined scoring system (Tsukuba five-point strain elastography scoring system), where score 1–3 was suggestive of benign lesions, while score 4–5 was considered as malignancy. Furthermore, histopathological examination of tissue obtained through ultrasound-guided core needle biopsy or the surgical excision and served as the reference standard. The radiologist was kept unaware of the histopathological and elastography findings, to avoid the bias in study.

Correspondingly, the breast ultrasound elastography findings were compared with histopathological findings to assess the sensitivity, specificity, PPV, NPV and overall diagnostic accuracy. All the relevant data were analyzed using SPSS version 25. Categorical variables were expressed as frequency and percentage, while

numerical data were expressed as mean and standard deviation ($\bar{X} \pm \text{SD}$). The sensitivity, specificity, PPV, NPV and accuracy were calculated by a 2 x 2 table.

Results

Overall 206 women were enrolled, with mean age of 47.66 ± 8.98 years. Majority were postmenopausal (154, 74.76%) and the rest (52, 25.24%) were premenopausal. Out of all participants, a higher proportion of women (142, 68.93%) had a palpable lump, followed by mastalgia among (64, 31.07%) of the women. A breast cancer history was reported by 44 patients (21.36%) and previous irradiation by 32 (15.53%), while overall mean elasticity score was 3.36 ± 0.89 , as presented in table I.

Table I: Demographic and clinical characteristics of study population. (n=206)

Variables	Mean +SD, n(5%)	
Mean age of the patients	47.66 ± 8.98 years	
Mean elasticity score	3.36 ± 0.89	
Menstrual status		
Menstrual	52	25.24%
Menopausal	154	74.76%
Presenting complaint		
Mastalgia	64	31.07%
Palpable lump	142	68.93%
History of breast cancer		
Yes	44	21.36%
No	162	78.64%
History of irradiation		
Yes	32	15.53%
No	174	84.47%

Out of all 140 lesions, 140 (67.96%) were identified as malignant and 66 (32.04%) were identified as benign, while histopathologically 153 lesions (74.27%) were diagnosed as malignant and 53 (25.73%) lesions were identified as benign, as shown in table II.

Table II: Distribution of elastography and histopathology findings. (n=206)

Variables	N	%
Elastography findings		
Yes	140	67.96%
No	66	32.04%
Histopathology findings		
Yes	153	74.27%
No	53	25.73%

On the comparison with histopathology, elastography correctly identified 127 malignant lesions (true positives) and 40 benign lesions (true negatives), with 13 false positive and 26 false negative. The calculated sensitivity was 83.01%, specificity was 75.47%, PPV was 90.71%

and NPV was 60.61%, while overall diagnostic accuracy was 81.07%, as shown in table III.

Table III: Diagnostic accuracy of elastography taking histopathology as gold standard (n=206)

Elastography	Histopathology		
	Positive	Negative	Total
Positive	127	13	140
Negative	26	40	66
Total	153	53	206
Sensitivity = 83.01%, Specificity = 75.47%, PPV = 90.71%, NPV = 60.61%, Diagnostic accuracy = 81.07%			

Based on stratification, elastography performed consistently across age and menopausal groups, the sensitivity stayed at around 83% and diagnostic accuracy at approximately 81% in all the groups, followed by slightly higher specificity and NPV among advanced age women (76.74% and 63.46% respectively) and in postmenopausal women (76.19% and 62.75% respectively) compared to those aged under 40 and premenopausal women (70–73% and 50–53% respectively), reflecting that the accuracy of elastography was not affected by age or menopausal status, as presented in table IV.

Discussion

Breast cancer remains a major global health concern, highlighting the importance of accurately distinguishing benign from malignant breast lesions to guide appropriate clinical management. In this regard, elastography provides complementary information about tissue stiffness alongside conventional ultrasonography, potentially improving the differentiation of benign and malignant lesions.^{14,15} In the present study, the diagnostic performance of breast elastography was evaluated against histopathology as the reference standard in 206 patients. The mean age was 47.66 ± 8.98 years, and most participants were menopausal (74.8%). These demographic findings were comparable to those reported by Umar S et al.,¹⁶ who observed a mean age of 45.47 ± 8.73 years, slightly lower than that of the present study population. In contrast, Jesrani A et al.¹⁷ evaluated strain elastography against histopathology in patients presenting with palpable breast lumps and pathological nipple discharge and reported a younger study population, with a mean age of 37.40 ± 11.54 years. These differences in the mean age of participants may be attributable to variations in study populations and patient selection criteria.

In this study, 21.4% of patients had a previous history of breast cancer, while 15.5% had a previous history of

Table IV: Diagnostic accuracy of Elastography according to age and menopause status taking histopathology as gold standard. (n=206)

Elastography	Histopathology		
	Positive	Negative	Total
	Age ≤40		
Positive	35	3	38
Negative	7	7	14
Total	42	10	52
Sensitivity = 83.33%, Specificity = 70.00%, PPV =92.11%, NPV =50.0% , Diagnostic accuracy =80.77%			
	Age >40		
Positive	92	10	102
Negative	19	33	52
Total	111	43	154
Sensitivity =82.88%, Specificity = 76.74%, PPV =90.20%, NPV =63.46%, Diagnostic accuracy =81.17%			
Pre- Menopause status			
Positive	34	3	37
Negative	7	8	15
Total	41	11	52
Sensitivity = 82.93%, Specificity = 72.73%, PPV = 91.89%, NPV = 53.33%			
Diagnostic accuracy = 80.77%			
Menopause status			
Positive	93	10	103
Negative	19	32	51
Total	112	42	154
Sensitivity = 83.04%, Specificity =76.19%, PPV= 90.29%, NPV = 62.75%, Diagnostic accuracy =81.17%			

irradiation, suggesting presence of increased clinical risk profile in a considerable proportion of the study population. Contrary to our findings, in the study of Lin X et al.¹⁸ previous breast cancer history was reported in only 1.4% of patients. The substantially higher proportion observed in our study subjects may reflect differences in patient selection and a greater representation of those in a higher-risk clinical setting. Similarly, in previous studies conducted by Joshi R et al.¹⁹ and Jung W L et al.²⁰ patients with a prior history of breast cancer were specifically excluded from the analysis. Since previous malignancy and its treatment may complicate the interpretation of imaging findings and potentially influence elastographic measurements,²¹ the differences in eligibility criteria may explain the higher-risk profile of our study population. Therefore, the inclusion of patients with a previous history of breast cancer in our study is more representative of patients encountered in routine diagnostic practice.

In this study cohort, mean elasticity score was 3.36 ± 0.89 , with elasticity score ≤ 3 noted in 35.9% of lesions, whereas 64.1% had elasticity score >3 , suggesting relatively increased stiffness in majority of case and were more suspicious of malignancy. These finding were consistent with the study by Kanagaraju V et al.²² who accessed 50 palpable breast masses using strain elastography with histopathology as the reference

standard. They found 47 patients with elasticity scores >3 (94%) and reported significant association between higher elasticity scores and malignant histopathology ($P < 0.001$). In contrast, Gu Y et al.²³ reported the elasticity scores from 1 to 5 in the sequence of 5.5%, 23.2%, 36.1%, 22.1%, and 13.1% of lesions respectively, demonstrating that scores ≤ 3 accounted for 64.8%, whereas scores >3 accounted for 35.2% of lesions. They included a broad spectrum of BI-RADS 2–5 solid lesions, with 2,811 benign and 1,560 malignant lesions. Therefore, the higher frequency of elasticity scores >3 in our study may be explained by differences in patient selection criteria, prevalence of malignancy, and lesion characteristics.

In this series, 153 (74.3%) patients were histopathology identified with malignancy, while elastography classified 140 (68.0%) patients as positive for malignancy. In comparison to this study Umar S et al.¹⁶ reported that the shear wave elastography identified 57 (33.5%) patients as malignant, while histopathology confirmed malignancy among 60 (35.3%) of the patients. On the other, in the study by Farooq F et al.²⁴ histopathologically confirmed malignant lesion were 115(74.2%) and 40(25.8%) were benign, while elastography identified 110 (71.0%) lesions as malignant and 45 (29.0%) as benign, the findings were comparable to this study.

According to the current study, elastography showed a sensitivity of 83.01%, specificity of 75.47%, positive predictive value (PPV) of 90.71%, negative predictive value (NPV) of 60.61%, and overall diagnostic accuracy of elastography was 81.07%, reflecting good diagnostic performance for detecting breast malignancy and that elastography was more effective in predicting malignancy than ruling it out. However, the occurrence of false-positive and false-negative results indicates that elastography should be considered an adjunct to, rather than a replacement for, definitive diagnostic methods. The findings of the present study were broadly consistent with those reported by Umar S et al.,¹⁶ who documented a sensitivity of 84.21%, specificity of 89.38%, PPV of 80.0%, NPV of 91.82%, and overall diagnostic accuracy of 87.65%. Compared with their findings, the present study demonstrated slightly lower sensitivity, specificity, NPV, and overall diagnostic accuracy, but a higher PPV. These differences may reflect variations in patient characteristics, disease prevalence, and study populations. These differences may be attributable to variations in patient selection, prevalence of malignancy and lesion characteristics. Notably, considerably lower prevalence of malignancy (35.5%) than prevalence observed in our cohort (74.3% histopathologically confirmed cases), which may partly explain the substantially higher PPV observed in our study. Consistently, the Jesrani A et al¹⁷ reported 88.57% sensitivity, 90.20% specificity, 75.61% PPV, 95.83% NPV, and 89.78% overall diagnostic accuracy.

The lower NPV in our study is particularly important because it indicates that a negative elastography result cannot reliably exclude malignancy. Consistent with the findings of our study, Rehan A et al²⁵ reported that the diagnostic accuracy of strain ultrasound elastography showed 91.02% sensitivity, 83.33% specificity, 88.75% PPV, 86.54% NPV and 87.88% diagnostic accuracy in the differentiation of breast lesions, taking histopathology as the gold standard.

Overall, elastography observed to be a valuable and reliable modality for characterizing breast lesions by most of the studies. A slight difference in the diagnostic accuracy across the studies evaluating ultrasound elastography for breast lesions may be due to the variations in elastography techniques, difference in diagnostic cutoff values, difference in selection of patients, characteristics of the lesion and the operator experience. Though, the elastography cannot replace histopathology, so it should be used together with

ultrasound, and all suspicious lesions should still be biopsied for a definitive diagnosis.

Conclusion

Elastography was observed to be a non-invasive, non-stressing, reliable and useful tool for distinguishing malignant from benign breast lesions, with consistent performance across the age groups and menopausal status. It is specifically good at confirming malignancy, while a negative finding cannot safely rule out the malignancy. It should therefore be used alongside conventional ultrasound to improve lesion assessment and guide decisions on biopsy, whereas histopathology remains essential for a definitive diagnosis.

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