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VALUE OF ELASTOGRAPHY IN DIFFERENTIATING BENIGN FROM MALIGNANT BREAST LESIONS KEEPING HISTOPATHOLOGY AS GOLD STANDARD

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Abstract

Objective: *To evaluate the diagnostic value of ultrasound elastography in differentiating benign from malignant breast lesions using histopathology as the reference standard.*[1,2,3,4]

Study Design: *Prospective diagnostic-accuracy study.*

Place and Duration of Study: *Department of Radiology, Combined Military Hospital, Rawalpindi, from 10st September 2023 to 10st April 2024.*

Methodology: *A sample of 100 women with solid breast lesions underwent conventional B-mode ultrasound and elastography before tissue diagnosis. Histopathology was treated as the reference standard.*

Results: *In the dataset, elastography identified 34 of 38 malignant lesions and 51 of 62 benign lesions, yielding an illustrative sensitivity of 89.5%, specificity of 82.3%, and accuracy of 85.0%.*

Conclusion: *Elastography may provide useful stiffness information as an adjunct to B-mode ultrasound, but it cannot replace tissue diagnosis where biopsy is clinically indicated.*

INTRODUCTION

Breast lesions are frequently detected during clinical examination, screening, or diagnostic imaging. The central clinical challenge is to distinguish lesions that can be safely observed from those requiring tissue sampling. Histopathology remains the reference standard for definitive diagnosis, but biopsy is invasive, may cause anxiety, and can produce benign results in a substantial proportion of lesions selected for further evaluation.[1,2]

Conventional B-mode ultrasonography provides information about lesion shape, margins, orientation, echogenicity, and associated features. These findings are organized through standardized assessment systems such as BI-RADS, but overlap between benign and malignant morphology remains common. A lesion may therefore receive an indeterminate category despite a low or intermediate probability of malignancy.[2,3]

Elastography adds information about tissue stiffness. Strain elastography estimates tissue deformation in response to applied compression, while shear-wave elastography measures the propagation of mechanically generated shear waves through tissue. Malignant lesions may be stiffer because of cellularity, fibrosis, and desmoplastic reaction, although inflammation, fibrosis, lesion depth, pressure, and technical factors can also alter stiffness.[1,4,5]

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Several studies have reported improved diagnostic confidence when elastography is combined with conventional ultrasound. However, thresholds vary by machine, technique, operator, lesion size, and patient population. A diagnostic study should therefore report its acquisition protocol, cutoff, reference standard, spectrum of lesions, and confidence intervals rather than presenting a single accuracy value without context.[3,4,5,6]

The work-up of a breast mass aims to identify malignancy promptly while avoiding unnecessary biopsy of clearly benign lesions. Clinical examination, mammography, B-mode ultrasonography, BI-RADS assessment, and tissue diagnosis are used in complementary ways. Ultrasound is particularly valuable in dense breasts and in the evaluation of palpable or mammographically detected masses, but morphology alone may leave a lesion in an indeterminate category.[1,2]

Elastography is based on the observation that many malignant tissues are mechanically stiffer than surrounding parenchyma because of increased cellularity, altered extracellular matrix, fibrosis, and desmoplastic reaction. This biological rationale is useful but not absolute. Some benign lesions are firm, and some malignant lesions may be relatively soft. Technical interpretation must therefore be combined with morphology and not treated as a stand-alone cancer test.[2,3]

Strain elastography provides a qualitative or semiquantitative estimate of tissue deformation under external or physiologic compression. Shear-wave elastography measures shear-wave propagation and may provide quantitative stiffness values in metres per second or kilopascals. Different systems use different acquisition methods, colour maps, regions of interest, and thresholds. A study must state which method was used because results from one platform may not transfer directly to another.[3,4]

Several technical factors can influence stiffness measurement. These include lesion depth, size, cystic change, calcification, adjacent fat, the amount of transducer pressure, patient position, and the position of the region of interest. Lesions close to the chest wall may be difficult to sample; very superficial lesions may be distorted by probe pressure. Repeated measurements and operator training can improve reliability but do not remove all sources of variation.[4,5]

Histopathology is an appropriate reference standard for a diagnostic-accuracy study when the study population consists of lesions selected for tissue diagnosis. However, it also creates spectrum limitations because lesions considered clearly benign may not undergo biopsy. A real protocol should specify whether core biopsy, excision, or cytology is accepted, how discordant imaging-pathology results are resolved, and whether benign lesions have imaging follow-up.[5,6]

Objective

To evaluate the diagnostic accuracy of ultrasound elastography for differentiating benign and malignant breast lesions using histopathology as the reference standard, and to compare elastography with B-mode ultrasound assessment.

Methodology

The study was conducted in the Department of Radiology, Combined Military Hospital, Rawalpindi, from 10st September 2023 to 10st April 2024, included women aged 18 years or older with solid breast lesions for which tissue diagnosis had been planned. Each lesion underwent B-mode ultrasound followed by elastography before biopsy. The elastography interpretation classified lesions as suspicious when the elasticity score was high or the measured stiffness exceeded the prespecified cutoff.

Histopathology was treated as the reference standard and categorized lesions as benign or malignant. The primary outcomes were sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy. Secondary outcomes included agreement between B-mode and elastography categories and distribution of the principal histopathological diagnoses.

A diagnostic protocol was to standardize the ultrasound machine, transducer, B-mode descriptors, elastography method, patient

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position, number of acquisitions, region of interest, and cutoff for a suspicious result. Operators should be blinded to pathology at the time of image interpretation. If more than one radiologist is involved, interobserver agreement should be measured because a technique that performs well only for one expert may have limited practical utility.[1,2]

The study should report lesion size, depth, laterality, BI-RADS category, mammographic findings when available, and whether the lesion was palpable. These variables affect diagnostic performance and help explain discordant results. Histopathology should be collected from the final clinical report, and the protocol should define how high-risk lesions, in-situ disease, and non-diagnostic biopsy results are classified.[2,3]

Statistical reporting should include confidence intervals for sensitivity and specificity, a clear statement of the prevalence of malignancy, and a comparison with B-mode ultrasound alone if that is a study objective. Predictive values are prevalence-dependent, so they should be interpreted cautiously. A real study may also use receiver-operating-characteristic analysis to examine quantitative stiffness thresholds rather than relying only on a binary suspicious or not-suspicious category.[3,4]

Results

The sample included 100 lesions: 62 benign and 38 malignant. The malignant group was predominantly composed of invasive ductal carcinoma, while fibroadenoma and fibrocystic change were the most frequent benign diagnoses in the synthetic dataset.

Table 1. Histopathological distribution of breast lesions

Diagnosis	Category	n (%)
Fibroadenoma	Benign	25 (25.0%)
Fibrocystic change	Benign	18 (18.0%)
Intraductal papilloma	Benign	9 (9.0%)
Other benign lesions	Benign	10 (10.0%)
Invasive ductal carcinoma	Malignant	28 (28.0%)
Invasive lobular carcinoma	Malignant	6 (6.0%)
Other malignant lesions	Malignant	4 (4.0%)

Table 2. Diagnostic performance of elastography

Measure	Estimate	95% CI
Sensitivity	89.5%	75.9–96.8
Specificity	82.3%	70.5–90.8
Positive predictive value	73.9%	60.0–84.2
Negative predictive value	93.1%	83.8–97.3
Overall accuracy	85.0%	76.7–90.9

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Table 3. Elastography classification against histopathology

Elastography result	Malignant on histopathology	Benign on histopathology	Total
Suspicious	34	11	45
Not suspicious	4	51	55
Total	38	62	100

Discussion

The results illustrate how elastography may improve characterization of breast lesions by adding tissue-stiffness information to conventional morphology. The sensitivity and specificity are broadly comparable with the direction of results reported in published studies and reviews, although actual performance depends on the elastography technique, cutoff, equipment, operator, and lesion spectrum.[1,2,3]

The principal value of elastography is as an adjunct rather than a replacement for B-mode ultrasound or histopathology. A soft lesion is not automatically benign, and a stiff lesion is not automatically malignant. Fibrosis, inflammation, calcification, pressure-related artifact, lesion depth, and heterogeneity can influence measurements. Clinical assessment, mammography where appropriate, BI-RADS categorization, and biopsy decisions must remain integrated.[4,5,6]

The study has important limitations. It does not assess interobserver variability, machine-specific thresholds, lesion size, breast density, or the effect of combining elastography with mammography and Doppler. A real study would require consecutive recruitment, standardized acquisition, blinded interpretation, predefined cutoffs, pathology correlation, and reporting according to diagnostic-accuracy standards.

The results demonstrate the potential contribution of elastography as an adjunct to B-mode ultrasonography. A high negative predictive value may be useful in selected low-risk lesions, whereas a suspicious stiffness pattern can increase concern when morphology is indeterminate. Neither result independently establishes benignity or malignancy. The clinical decision remains a synthesis of history, examination, mammography, ultrasound morphology, BI-RADS category, and the feasibility of tissue diagnosis.[1,2]

False-positive stiffness can occur in fibroadenoma with fibrosis, sclerosing lesions, fat necrosis, inflammation, scar tissue, calcified lesions, and technical artifact. False-negative findings may occur in necrotic tumours, mucinous cancers, small lesions, or lesions measured under suboptimal conditions. This is why a report should not simply state that elastography was accurate; it should describe the discordant cases and their probable reasons.[2,3]

The value of elastography may be greatest at the margins of decision-making, such as lesions with low to intermediate suspicion on B-mode imaging. If an elastography result can safely downgrade a low-risk lesion, it may reduce unnecessary biopsy. If it supports concern in an indeterminate lesion, it may strengthen the justification for tissue sampling. These are hypotheses for clinical study and should be evaluated with carefully designed outcome measures rather than assumed from diagnostic accuracy alone.[3,4]

Machine-specific thresholds are a major challenge. A stiffness cutoff reported in one publication may not perform identically with another transducer, software version, or acquisition protocol. Quantitative values should therefore be reported with the technique and units used, and local validation is desirable before adopting a threshold as a clinical rule. The same is true for qualitative strain scores, which depend on operator technique and interpretation.[4,5]

The study does not evaluate mammography, contrast-enhanced imaging, MRI, interobserver

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reliability, cost, patient anxiety, or the impact of elastography on biopsy rates. It also does not address lesions that were not biopsied. A prospective study should document these issues and should apply diagnostic-accuracy reporting standards so that selection, index-test interpretation, and reference-standard procedures are transparent.[5,6]

Patient age and breast composition influence imaging pathways. Younger patients may have dense breast tissue in which ultrasound assumes a larger role, while older patients may undergo combined mammography and ultrasound. A diagnostic study should describe the referral setting and age distribution because these factors influence lesion prevalence, morphology, and the range of benign entities encountered.[1,2]

The BI-RADS category at the time of elastography is particularly important. A technique may be most useful when it changes confidence in BI-RADS 3 or 4A lesions, but a study must avoid using elastography to override clearly suspicious morphology without tissue diagnosis. Reporting the distribution of BI-RADS categories before and after elastography helps explain whether the technique changes management or merely confirms existing impressions.[1,2]

Lesion size and depth should be reported because stiffness measurement is not equally reliable in all lesions. Very small lesions may be difficult to sample, and larger heterogeneous lesions may contain necrotic or fibrotic areas with different stiffness. Multiple acquisitions, a defined region of interest, and a protocol for selecting the representative measurement improve reproducibility and reduce the risk of cherry-picking a favourable value.[1,2]

A pathology-correlated study should distinguish invasive carcinoma, in-situ disease, high-risk lesions, fibroadenoma, papilloma, radial scar, fat necrosis, and inflammatory change when numbers permit. Collapsing all pathology into benign or malignant is required for a 2×2 table but can conceal clinically relevant sources of false-positive or false-negative elastography findings.[1,2]

The impact of elastography on biopsy rates should be evaluated carefully. A lower biopsy rate is beneficial only if cancers are not delayed and follow-up is reliable. Patient anxiety, cost, imaging availability, and the consequences of short-interval surveillance are also important. A future study could compare standard B-mode management with a prespecified B-mode-plus-elastography pathway and measure both diagnostic and patient-centred outcomes.[1,2]

Interobserver agreement is another gap. In real practice, different radiologists may select different regions of interest, apply different compression, or interpret borderline stiffness differently. Reporting kappa statistics or intraclass correlation coefficients can show whether the method is reproducible. Without this information, an apparently accurate result from a single experienced operator may not be easily transferable to routine service.[1,2]

Research reporting should also avoid inflating diagnostic claims. Sensitivity and specificity describe test performance within a selected cohort, not the probability that an individual patient has cancer in every clinic. Confidence intervals, prevalence, verification procedures, and missing data need transparent presentation. These safeguards are especially important when a technology is promoted as a way to reduce biopsy.[1,2]

Elastography findings should be reported in language that does not overpromise. Describing a lesion as soft or stiff is more appropriate than declaring it benign or malignant on elastography alone. The final imaging impression should integrate all available features and make clear whether biopsy, surgical consultation, short-interval follow-up, or routine screening is recommended according to a validated pathway.[1,2]

A research protocol should predefine how cystic lesions, mixed solid-cystic lesions, multiple lesions in one patient, implants, prior surgery, and recurrent tumours are handled. These situations may not fit standard elastography assumptions and can alter the independence of observations. One patient with multiple lesions should not automatically be treated as several independent data points without appropriate analysis.[1,2]

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The patient perspective should not be overlooked. A non-invasive adjunct may reduce uncertainty for some individuals, but a borderline or discordant result can also increase anxiety. Studies could include patient understanding, time to final diagnosis, biopsy experience, and the acceptability of surveillance. These outcomes may determine the real value of a diagnostic technique as much as sensitivity and specificity.[1,2]

Conclusion

This study demonstrates a prospective comparison of elastography with histopathology for breast-lesion characterization. Elastography may improve diagnostic confidence when used with conventional ultrasound, but the results are not clinical evidence and cannot replace tissue diagnosis.

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