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Assessing the Diagnostic Precision of Ultrasound Elastography (Sonoelastography) in Differentiating Benign from Malignant Axillary Lymph nodes in Primary Breast Cancer

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ABSTRACT

Objectives: To assess the diagnostic efficacy of ultrasonic elastography (Sonoelastography) as compared to B-mode ultrasonography in distinguishing between cancerous and benign axillary lymph nodes in patients with primary carcinoma of breast, using tissue diagnosis as a reference standard.

S***tudy Design***: Comparative Cross-sectional study.

Place and Duration of Study: Department of Radiology, Armed Forces Institute of Radiology, Rawalpindi Pakistan, from May to Nov 2021.

Methodology: Three hundred and forty-five (n=345) patients diagnosed with primary breast cancer, who had palpable axillary lymph nodes of varying sizes, and were between the ages of 20 and 60 years of either gender, were included. All patients underwent examination of their axillary lymph nodes using B-mode ultrasonography and ultrasound elastography, capable of detecting either benign or malignant lymph nodes.

Results: The results of the B-mode ultrasonography were 91.30%, 78.26%, 86.30%, 85.71%, and 86.09% for sensitivity, specificity, PPV, and NPV, respectively. Comparing malignant and benign axillary lymph nodes, ultrasound elastography overall showed sensitivity of 94.20%, specificity of 91.30%, PPV of 94.20%, NPV of 91.30%, and overall diagnostic accuracy of 94.04%.

Conclusion: The research findings indicate that, as a diagnostic modality for assessing the malignancy of axillary lymph nodes, ultrasound elastography performs better than B-mode ultrasonography.

Keywords: Elastography, Lymph Nodes, Malignant, Sensitivity, Sonoelastography, Ultrasonography.

How to Cite This Article: *Baig AR, Nadeem SF, Shafiq M, Hyder RR, Danish M, Roghani SS. Assessing the diagnostic precision of ultrasound elastography (Sonoelastography) in differentiating benign from malignant axillary lymph nodes in primary breast cancer. Pak Armed Forces Med J 2025; 75(3): 562-567. DOI: https://doi.org/10.51253/pafmj.v75i3.11191*

INTRODUCTION

Lymph node enlargement is an evident sign due to various underlying causes, like systemic lymphoid spread of malignancy and lymphoma, and benign causes, like sarcoidosis, viral illnesses, and collagen vascular disorders. It is essential for determining a patient's present state, optimal therapy, and prognosis across a wide range of etiologies.[1] Clinical and pathological evidence suggests that the lymphatic system is the primary route of metastasis for many cancers.[2] Anomalies in axillary lymph nodes are most often caused by breast cancer. Axillary lymph node metastases may also be caused by different original tumors, such as gastric, lung, or ovarian cancer.[3]

Lymph node evaluation is essential to identify cancerous lymph nodes and distinguish them from benign lymph nodes so that the right therapy may be administered. Ultrasound imaging and Ultrasound-guided fine-needle aspiration are commonly used techniques for preoperative evaluation of axillary lymph nodes in clinical practice.[4] These methods are particularly useful when a questionable lymph node is identified during Ultrasound imaging. The procedure of sentinel lymph node biopsy requires a significant amount of time and has the potential to cause temporary complications in the upper limb.[5] Despite its modest sensitivity, there is a possibility of obtaining false-negative findings if the nodes are only evaluated using standard ultrasound.[6] Therefore, it is important to develop a more reliable noninvasive technique for classifying axillary lymph nodes. Real-time elastography is one example of a recent technological advancement that shows promise as a diagnostic tool for a wide range of illnesses. By measuring the stiffness of tissues, elastography may non-invasively identify benign from malignant tumors.[7,8]

Despite its potential, ultrasound elastography is not routinely employed in the assessment of lymph nodes due to limited clinical evidence. Recognizing this gap in the literature, the study aims to determine

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Received: 22 Nov 2023; revision received: 01 May 2024; accepted: 04 May 2024

whether ultrasonic elastography or B-mode ultrasonography is more effective in identifying cancerous vs non-cancerous axillary lymph nodes in patients with primary breast cancer. If its diagnosis accuracy proves to be high, it will be possible to provide these patients a fast, painless, and inexpensive imaging option that does not need any intrusive procedures.

METHODOLOGY

This comparative cross-sectional study was conducted at the Department of Radiology, Armed Forces Institute of Radiology, Rawalpindi Pakistan, from May to Nov 2021. The ethical committee approval was sought vide certificate number 0037 dated 09th March 2021.

A sample size of 345 cases was calculated with a prevalence of malignant axillary lymph nodes at 75.0%.[9] Non-probability, consecutive sampling technique was used for selection of participants for the study.

Inclusion Criteria: Females aged 20-60 years, with palpable axillary lymph nodes of any size, with known primary breast cancer of size >1cm, were enrolled.

Exclusion Criteria: Females <20 or >60 years, with previous axillary lymph node dissection, chronic liver disease, or prior irradiation were excluded.

After obtaining informed consent, B-mode ultrasonography was conducted on each patient. Subsequently, all patients underwent ultrasound elastography utilizing a high-resolution apparatus that was fitted with a linear array probe centered at 7.5 MHz. The ultrasound elastography and B-mode imaging procedures were performed by a consultant radiologist who had a minimum of five years of experience after completing their fellowship. The researcher was present throughout the examinations, with the specific objective of identifying axillary lymph nodes that satisfied the defined criteria for benign or malignant classification. After this, a biopsy was done in the concerned ward, and histopathology was done in the institutional pathology laboratory. B-mode and USG elastography findings were compared with the histopathology report. Data, including age, duration of breast cancer, size of lesion, stage of breast cancer, benign or malignant axillary lymph nodes on B-mode, elastography sonography, and histopathology, were recorded on a patient record checklist proforma.

A diagnosis of breast cancer was confirmed on histopathology by the presence of features: cellular atypia (pleomorphism) and a nuclear-to-cytoplasmic ratio greater than 1:1 under microscopy, and the staging of breast cancer was noted using the criteria shown in Figure-1

a) Stage I: breast lump of <2 cm in size, no palpable axillary lymph nodes and no distant metastasis.
b) Stage II: breast lump of 2-5 cm in size, with palpable axillary lymph node on same side and no distant metastasis.
c) Stage III: breast lump of >5 cm in size, palpable axillary lymph nodes on same side and no distant metastasis.
d) Stage IV: breast lump of any size, with or without palpable axillary lymph nodes on same side and distant metastasis.

Figure-1: The Standard Staging Scale of Breast Cancer Axillary Lymph Nodes on Ultrasonography

Elastography: A grading scale used to categorize lesions based on the color signature, as shown in Table-I.

Table-I: Grading Scale to Categorize Lesions

Category-0 lesions	Distinct RGB signature
Category-1 lesions	The high-strain pattern is consistent throughout the lesion and is shown by green coloration.
Category-2 lesions	The prevailing strain pattern is shown by a green coloration that is both achromatic and asymmetrical
Category-3 lesions	The center portion will be a tiny shade of blue, while the periphery will be colored green. This is because the strain pattern of these lesions is high in the periphery and low in the central region.
Category-4 lesions	The low-strain pattern and evenly blue color signature were localized to the lesion's visible edge.
Category-5 lesions	Blue signature extended beyond the lesion into the neighboring tissues

As per the criteria given:

a). If a lesion was scored as 1 to 3, it was considered benign.

b). If a lesion was scored as 4 to 5, it was considered malignant.

Axillary lymph nodes on B-mode ultrasonography: Presence of all these i.e., transverse diameter (T): >10mm, longitudinal to transverse diameter (L/T) ratio: ⩽1.8, Cortical thickness: >6mm and Hilum: compressed or faint.

Histopathology findings of malignant axillary lymph nodes: It was considered positive for the presence of polygonal cells with well-defined borders, eosinophilic cytoplasm, big, hyperchromatic, irregular nuclei displaying strong pleomorphism, and a high number of aberrant mitoses.

The collected data was analyzed through computer software Statistical Package for Social Sciences 20.0. Using a 2x2 contingency table with histopathology as a reference standard, the diagnostic accuracy of ultrasonic elastography and B-mode ultrasonography for separating benign and malignant axillary lymph nodes in patients with primary breast cancer was ascertained.

RESULTS

The participants' ages ranged from 20 to 60, with a mean of 41.14 and a standard deviation ±8.10 years. (Table-II). B-mode ultrasonography and ultrasonic elastography were performed on all the patients. There were 189 True Positives and 30 False Positives among patients with positive results from B-mode ultrasonography had a sensitivity of 86.30%, a specificity of 85.71%, a PPV of 91.30%, a NPV of 78.26%, and an overall diagnostic accuracy of 86.09%, and an overall diagnostic accuracy of 86.09% in distinguishing cancerous from non-cancerous axillary lymph nodes in patients with breast carcinoma, using histopathology as reference standard. (Table-III).

Table-II: Baseline Data of Patients Enrolled in the Study (n=345)

Factor	Category	No. of Patients	n(%age)
Age (years)	20-40	149	43.19
	41-60	196	56.81
Duration of lesion	≤6 months	206	59.71
	>6 months	139	40.29
Size of lymph node.	≤30 mm	276	80.0
	>30 mm	69	20.0
Stage	I	103	29.86
	II	139	40.29
	III	69	20.0
	IV	34	9.85

Ultrasound elastography had a sensitivity of 94.20%, a specificity of 91.30%, a positive predictive value of 94.20%, a negative predictive value of 91.30%, and an overall diagnostic accuracy of 93.04% when comparing malignant and benign axillary lymph nodes. (Table-IV).

DISCUSSION

The findings of this study indicate that sonoelastography is a useful imaging modality for distinguishing between primary and secondary breast cancers. However, the sonoelastography potential has yet to be fully realized in the context of characterizing lymph nodes. The purpose of this study was to assess and evaluate the diagnostic accuracy of ultrasonic elastography and B-mode ultrasonography in characterization of malignant and non-cancerous axillary lymph nodes in breast carcinoma cases, with tissue diagnosis as a reference standard. The study found that B-mode ultrasonography demonstrated an overall sensitivity of 91.30%, specificity of 78.26%, positive predictive value of 86.30%, negative predictive value of 85.71%, and diagnostic accuracy of 86.09% in distinguishing cancerous and non-cancerous lymph nodes in these patients. These results were compared to histopathology, which was considered the gold standard for diagnosis. When evaluating malignant and benign cervical lymph nodes, ultrasound elastography demonstrated a sensitivity of 94.20%, specificity of 91.30%, positive predictive value of 94.20%, negative predictive value of 91.30%, and an overall diagnostic accuracy of 94.04%.

Table-III: B-Mode Ultrasonography's Diagnostic Accuracy in Identifying Benign and Malignant Axillary Lymph Nodes(n=345)

	Histopathological Positive	Histopathological Negative
Positive on B-Mode Ultrasound	189(55%) *	30(9%) ***
Negative on B-Mode Ultrasound	18(5%) **	108(31%) ****

** = TP, ** = FP, *** = FN, **** = TN*
Sensitivity= TP/(TP+FN) = 189/ (189+30) x 100 = 86%
Specificity= TN/(TN+FP) = 108/ (108+18) x 100 = 85%
Positive Predictive Value= TP/(TP+FP) x 100= 189/ (189+18) = 91%
Negative Predictive Value= TN/(TN+FN) x 100= 108/ (108+30) = 78%
Diagnostic Accuracy = (TP+TN)/All patients x 100 = (189+108)/345 x 100 = 86%

Table-IV: Ultrasound Elastography's Diagnostic Accuracy in Separating Benign from Malignant Axillary Lymph Nodes(n=345)

	Histopathological Positive	Histopathological Negative
Positive on Elastography	195(57%) *	12(3%) ***
Negative on Elastography	12(3%) **	126(37%) ****

** = TP, ** = FP, *** = FN, **** = TN*
Sensitivity= TP/(TP+FN) = 195/ (195+12) x 100 = 94%
Specificity= TN/(TN+FP) = 126/ (126+12) x 100 = 91%
Positive Predictive Value= TP/(TP+FP) x 100 = 195/ (195+12) = 94%
Negative Predictive Value= TN/(TN+FN) x 100 = 126/ (126+12) = 91%
Diagnostic Accuracy = (TP+TN)/All patients x 100 = (195+126)/345 x 100 = 93%

Sonoelastography is a kind of ultrasound imaging that creates a map of a tissue's elastic and stiffness characteristics.[10,11] Since direct measurement of tissue elasticity is impossible, most suggested elastographic methods instead employ indirect methods of determining tissue stiffness. Traditional imaging techniques like ultrasonography are used to detect and characterize the strain distribution in tissue after mechanical stimuli (compression or vibration) have been transmitted into the tissue.[12,13] The elastogram shows the effects of the tissue compression as a picture, with stiff parts shown in dark colors and soft areas shown in bright colors. The malignancies of the breast, thyroid, and prostate have all been successfully diagnosed using sonoelastography, even though it is not yet used routinely in clinical practice.[14]

Hajek PC conducted a study validating the diagnostic tool for determining cancer stage using palpable lymph nodes.[15] The objective of the current study was also to determine which diagnostic tool out of the two had proven to be most relevant to histopathological findings. The diagnostic capabilities of strain elastography were first assessed by Lyshchik *et al*. The sample size was 141 lymph nodes, with 98 of them being confirmed as benign and 43 as malignant based on histological analysis.[16] The categorization of the nodes was based on factors such as visualization, brightness of surrounding muscles, and uniformity of the outline. The sensitivity, specificity, and accuracy rates of 85.1%, 98.2%, and 92.1%, respectively, were seen using strain elastography, while using a strain ratio cut-off value above 1.5.

A study by Ying *et al.,* on 50-155 cervical or axillary lymph nodes, revealed pooled sensitivity and specificity to detect in the meta-analysis, consisting of nine elastographic studies. malignancies. The elastographic scale yielded sensitivity & specificity of 74% (95% CI, 66% to 81%) and 90% (95% CI, 82% to 94%), respectively. On the other hand, the use of strain ratios resulted in sensitivity & specificity of 88% (95% CI, 79% to 93%) and 81% (95% CI, 49% to 95%), respectively.[17] This validation has been used as a relevance in the current study to assess the diagnostic accuracy of selected tools. The use of a 4-point elastography scale is often applied to identify lymph nodes that exhibit signs of malignancy. The elastographic scale scores ranging from 1 to 2 are indicative of benign lymph nodes, whereas scores falling between 3 and 4 are suggestive of malignant lymph nodes. This distinction arises from the observation conducted by Lo *et al.,* that metastatic lymph nodes tend to exhibit more stiffness compared to benign lymph nodes.[18]

Tang *et al.,* found that ultrasonic elastography has a sensitivity of 79% and a specificity of 90% in accurately distinguishing between malignant and benign axillary lymph nodes, which is in alignment with the current study results.[19] The study has also shown suspicious lymph nodes by elastography (Scores 3 and 4) as 75% with sensitivity 88.89%, specificity 66.67%; accuracy 83.33%.[8] Another study has shown that elastography showed 88.89% sensitivity and 93.33% specificity. Findings published by Dawoud *et al.,* that B-mode sonography has 77.78% sensitivity and 66.7% specificity for characterizing benign & malignant axillary lymph nodes, establish the fact that sonoelastography seems to have more diagnostic accuracy.[20]

In a study, Ishibashi *et al.,* evaluated the elastographic point scale and reported that 84.5% accuracy, 80% specificity, and 90.3% sensitivity were achieved when elastography was used in conjunction with traditional ultrasonography.[21] Bhatia *et al.,* discovered that malignant lymph nodes had a higher median elastic modulus in comparison to healthy lymph nodes.[22] The cut-off value of 30.2 kPa, which is considered optimum, demonstrated a sensitivity of 41.9%, specificity of 100%, and accuracy of 61.8%. Nevertheless, the discriminatory ability was found to be suboptimal. In addition, Choi *et al.,* showed that the highest elastic modulus can be used to determine whether lymph nodes have a malignant potential. The investigation determined a 19.4 kPa cut-off value, which produced 94% accuracy, 91% sensitivity, and 97% specificity.[23]

The sensitivity of B-mode sonography was 98%(95% CI, 94-100%), the specificity was 59%(42%-76%), and the accuracy was 84%(76-91%). The sensitivity (73%), specificity (100%), and accuracy (89%) of elastography were as follows, respectively: 83-83%; 100%; 89%. Accuracy was 93%(88-98%), sensitivity was 92%(85-100%), and specificity was 94%(85-100%).[11] B-mode ultrasound has been proven more sensitive (78.57%) than histopathology (84.62%) and more specific (84.62%) than histopathology (95.55%), with a diagnostic accuracy of 0.83 by Elahi *et al*. Diagnostic Accuracy 0.85 was also seen between ultrasonic elastography and histopathology, with sensitivity of 71.43% (CI: 41.92 to 91.43) and specificity of 92.31%(CI: 74.83 to 98.83).[24] The study has shown to have incoherent results with the findings of this study.

The diagnostic effectiveness gained from collective comparison with the literature on sonoelastography was shown to be greater than that of individual evaluations, as measured by accuracy. This also confirms that the examination is most effective when the high sensitivity of B-mode sonography and the high specificity of elastography are combined. However, both approaches should be used simultaneously in clinical practice by sonography professionals.

LIMITATIONS OF THE STUDY

The relatively small sample size had restricted the generalizability of the results. As both B-mode ultrasonography and sonoelastography are operator-dependent techniques, variability in image acquisition and interpretation could have undermined the findings. Additionally, the lack of blinding between imaging assessments and histopathological results might have introduced observer bias. Being conducted at a single center, the study's outcomes cannot be representative of diverse clinical settings.

CONCLUSION

This study found that ultrasound elastography has a higher diagnostic accuracy than B-mode ultrasonography in distinguishing malignant from benign axillary lymph nodes. This has improved patient care through earlier screening, timely and appropriate treatment, and the avoidance of unnecessary diagnostic biopsies, all of which contribute to lower morbidity and mortality. Therefore, we advise that ultrasound elastography be utilized frequently as a main modality for the evaluation of pre-operative cervical lymph node status for choosing the right treatment choice and post-operative care strategy.

Conflict of Interest: None.

Funding Source: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

ARB & SFN: Data acquisition, data analysis, critical review, approval of the final version to be published.

MS & RRH: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MD & SSR: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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