

Original Article

Diagnostic Accuracy of Strain Elastography in Thyroid Nodule Assessment Using Histopathology as Reference Standard

Nosheen Siddique,¹ Saman Chaudhry,² Amna Rehan,³ Abdul Rauf,⁴ Ayesha Muneer⁵

^{1,3,4,5}Department of Radiology, Faisalabad Medical University, Faisalabad; ²Department of Radiology, Fatima Jinnah Medical University, Lahore

Abstract

Background: Ultrasound elastography functions on the property of soft tissues that deform readily than harder ones under compression. This technique is beneficial in differentiating malignant and benign lesions in different organs i.e. breast, lymph nodes, prostate and pancreas. Recent years have seen significant research in differential diagnosis using this method.

Objectives: The study aims to find diagnostic accuracy of ultrasound elastography (USE) in thyroid nodule assessment using histopathology results as reference standard.

Methods: This study employed a prospective observational design to find diagnostic accuracy of USE in identification of thyroid nodules to be benign or malignant. A comprehensive review of existing literature on USE and thyroid nodule characterization was conducted. The study included 175 patients aged between 18 and 80 years, presenting with one or more solid nodules in the thyroid lobe. Patients aged 18-80 years with solid nodules in the thyroid lobe identified by conventional ultrasound were included. Ultrasound elastography was performed, and strain ratios were calculated from the strain elastography color-coded images. These strain ratios were compared with histopathology reports to determine diagnostic accuracy and find correlation between ultrasound elastography findings and histopathology results. Institutional Review Board approval was obtained to ensure adherence to ethical guidelines and hence, written agreement was made with all participants of study.

Results: The results obtained through this comparative study of using strain elastography and histopathology to differentiate benign and malignant thyroid nodules were very convincing and consistent to previous studies. Statistical analysis results came out to be as sensitivity 94.38%, specificity 90.70%, PPV 91.30%, NPV 93.98% and diagnostic accuracy 92.57%.

Conclusion: The research findings indicate that strain ultrasound elastography is key imaging technique in detection of malignant thyroid nodules. Non-invasiveness and high diagnostic accuracy compels to use the method for identifying malignant thyroid nodules.

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Corresponding Author | Dr. Nosheen Siddique, Associate Professor of Radiology, Faisalabad Medical University, Faisalabad ; **Email:** drnosheenahmad@hotmail.com

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Introduction

Thyroid nodular disease is common in iodine deficient areas. Patients are directed to an endocrinologist when a thyroid nodule is suspected. Typically, an ultrasound is conducted to verify the nodule's pre-

sence and evaluation of the entire gland's condition. Ultrasonography can identify thyroid nodules in 27%-67% of the adult population, while palpation can detect them in 4%-7% of cases.¹ Cantisani et al.² conducted a systematic review and meta-analysis in order to evaluate the diagnostic performance of ultrasound elastography (USE) to assess the risk of malignancy aiming to compare qualitative, semi-qualitative and quantitative elastography methods. The conclusion was, presence of thyroid stimulating hormones and anti-thyroid antibodies points towards existence of functional thyroid disease. Other tests prior to treatment of nodular disease are Calcitonin level and fine needle aspiration cytology (FNAB).² Although Ultrasonography gives valuable information about potential malignancy but its capacity to differentiate benign and malignant lesions is not up to the mark. The study of sohil S et al.³ concluded that mean elasticity index obtained through quantitative shear wave elastography (SWE) is reliable parameter in prediction of malignancy in small, solid suspicious nodules. Hence, FNAB having 90% diagnostic sensitivity for thyroid malignant is used.⁴ However, major drawback of FNAB is its invasiveness.

Ultrasound elastography is an old technique used for real-time information about soft tissue lesions using the tissues elasticity.⁵ There are various studies in differential diagnosis. A study of 56 patients with thyroid nodules (out of which 64.29% were benign while 35.71% were malignant) in the study and concluded that sensitivity, specificity and accuracy of elastography is 80%, 88.9% and 85.7% respectively.⁶ The strain ratio demonstrated more convincing results i.e. sensitivity, specificity and accuracy came out to be 80%, 94.4%, and 89.3% respectively. Another study reported sensitivity of strain ultrasound elastography as 94.0%, specificity 90.20%, PPV 90.38%, NPV 93.88% and diagnostic accuracy 92.08% to distinguish benign thyroid nodules and malignant ones using histopathology as the gold standard.⁷ Kalaiarasan P et al.⁸ found statistical analysis results of strain elastography score more convincing i.e. sensitivity, specificity, PPV, NPV and accuracy as 95.83%, 100%, 100%, 99.1% and 99.3% respectively in distinguishing benign and malignant nodules.

Referred investigations concluded with inconsistent results of statistical matrix regarding the reliability of strain ultrasound elastography technique used to differentiate benign and malignant thyroid nodules. This study aims to compare diagnostic accuracy of strain ultrasound elastography in assessment of thyroid nodules considering histopathology results as reference standard. The study project aims to make an addition in finding a

non-invasive, economical, and readily accessible imaging technique for our community to detect malignant thyroid nodules and subsequent treatment.

Methods

175 patients were of the age 18~80 of both genders were included in the study who were detected with solid thyroid nodule (one or more) by ultrasound and referred to the Radiology department of Allied Hospital, Faisalabad. Patients having thyroid nodules in the isthmus, near major blood vessels, or those occupying more than 75% of the thyroid lobe were excluded due to potential intrusion with elastography measurements. Additionally, nodules with more than 15% cystic content or those showing specific calcification patterns, such as peripheral egg-shell calcification or extensive coarse calcifications, were excluded as these could affect the accuracy of the technique.

The study was designed aiming for a 95% confidence level, and targeting a precision of 10% sensitivity and 5.56% specificity. The anticipated presence of malignant thyroid nodules was 35.71%, while strain elastography exhibited 80.0% sensitivity and 94.44% specificity in effectively distinguishing between thyroid nodules.

Data collection procedure includes following informed permission, elastography and pathological investigation performed on each patient. Histopathological analysis and elastography results were correlated. Data analysis was done using SPSS 25.0 software. Mean and standard deviation for age, disease duration and nodule size were taken. Gender and thyroid nodules classification (benign or malignant) on the basis of strain ultrasound and histopathology, were presented as frequencies and percentages. A 2x2 contingency table was used to calculate key diagnostic properties. Age, gender, length of illness, and nodule size were stratified. The accuracy of post-stratification diagnosis was computed.

Table 1: Diagnostic matrix for calculation of statistics

Strain USG elastography	Histopathology Findings	
	Malignant	Benign
Malignant	True Negative TP	False Negative FP
Benign	False Negative FN	True Negative TN

- Sensitivity: $TP / (TP+FN) \times 100$
- Specificity: $TN / (FP+TN) \times 100$
- Positive predictive value: $TP / (TP+FP) \times 100$
- Negative predictive value: $TN / (FN+TN) \times 100$
- Diagnostic accuracy: $(TP+TN) / (TP+FP+FN+TN) \times 100$

Results

Patients included for the study were of the age 18~80 years with a mean age of 46.77 ± 12.46 years. 131 patients were between the ages of 18 and 50 years. Number of male and female patients were almost equal i.e. 89 and 86 respectively. The mean sickness duration was 10.01 ± 3.30 months. The nodule's mean size was 4.69 ± 1.49 cm. Ultrasound elastography results confirmed that malignant thyroid nodules exist in 92 patients. 84 cases came out to be true positive i.e. histopathology verified the malignant thyroid nodules, whereas 8 cases were false positive when compared with histopathology results i.e. identified malignant thyroid is actually benign lesion. Out of USG negative patients, true negative were 78 while false negative were 5. Statistical analysis of strain elastography for identification of benign thyroid nodules malignant ones separately taking histopathology results as reference standard gave convincing results i.e. sensitivity 94.38%, specificity 90.70%, PPV 91.30%, NPV 93.98%, and overall diagnostic accuracy of 92.57%.

The findings of the study are consistent to the previous studies. Table 2 presents the statistical analysis of patients distributed on the basis of age, gender, duration of disease and nodule size. The subsequent phase of this research will involve conducting a larger, multicenter study to validate the findings of this investigation.

Discussion:

Detection of thyroid nodules is done by various techniques i.e. palpation, ultrasound, ultrasound elastography and autopsy. Prevalence rates differ with respect to the technique used. Prevalence of thyroid nodules is gradually increasing. The risk factors for thyroid nodules include

female gender, age, iodine deficiency and previous head and neck radiation. Ultrasonography is cost effective and readily available. Fine needle aspiration biopsy helps to differentiate benign and malignant thyroid nodules. In case of unclear Cytology results, ultrasound and elastography become valuable diagnostic modalities. Strain elastography calculates strain ratio after colors assessment in surrounding and within nodules on 4-5 scale scoring system. An elevated strain ratio suggests malignancy. Ultrasonic probe generates an acoustic pulse carrying a quantitative elastic value in shear wave elastography. The real time elastography is produced based on this acoustic pulse which is evaluated to identify thyroid nodules.

The study has been carried out to ascertain how accurately strain elastography can identify that thyroid nodule is benign or malignant. In order to conduct statistical analysis, histopathology results are considered as reference standard. Statistical results of the study revealed that strain elastography technique is highly accurate and endorsed its frequent use. Overall sensitivity, specificity, PPV, NPV, and diagnostic accuracy were 94.38%, 90.70%, 91.30%, 93.98%, and 92.57%, respectively.

Latif et al.⁶ conducted a study on 56 individuals with thyroid nodules (64.29% benign and 35.71% malignant). The elastography score had an accuracy of 85.7%, specificity of 88.9%, and sensitivity of 80%. Strain ratio methodology produced 89.3% accuracy, 94.4% specificity, and 80% sensitivity.

A study demonstrated the sensitivity, specificity, PPV, NPV, and diagnostic accuracy of strain ultrasound elastography to classify benign and malignant thyroid nodules as 94.0%, 90.20 percent, 90.38 percent, and

Table 2: Diagnostic accuracy of Ultrasound Elastography against different stratifications

Distribution of Patients w.r.t.		Sensitivity (Sn)	Specificity (Sp)	Positive Predictive Value (PPV)	Negative Predictive Value (NPV)	Diagnostic Accuracy
		%	%	%	%	%
Age	18-50 (n=131)	92.96	88.33	90.41	91.38	90.84
Years	51-80 (n=40)	100	96.15	94.74	100	97.73
Gender	Male (n=89)	97.67	95.65	95.45	97.78	96.63
	Female (n=86)	91.30	85	87.50	89.47	88.37
Duration of Disease Months	≤12 (n=138)	94.12	90	90.14	94.03	92.03
	>12 (n=37)	95.24	93.75	95.24	93.75	94.59
Size of nodule mm	≤ 5cm(n=121)	91.07	89.23	87.93	92.06	90.08
	> 5 (n=54)	100	95.24	97.06	100	98.15
	Left (n=50)	96.67	85.00	90.63	94.44	92.00
Total	n=175	94.38	90.70	91.30	93.98	92.57

92.0 percent, respectively.⁷

Kalaiarasan et al.⁸ reported exceptionally high diagnostic metrics when combining TIRADS with strain elastography, achieving a sensitivity of 95.83%, specificity and PPV of 100%, NPV of 99.1%, and overall diagnostic accuracy of 99.3%, establishing the synergy of modalities. Similarly, Lalwani et al.⁹ assessed strain ratio (SR) with a cut-off of >2.32 and obtained sensitivity of 92.31%, specificity of 87.5%, and diagnostic accuracy of 87.5% in 150 patients, underscoring its applicability in resource-limited settings.

Baz et al.¹⁰ demonstrated that integrating shear wave elastography (SWE), TI-RADS, and color Doppler imaging yielded high diagnostic accuracy, with malignant nodules showing significantly high elasticity indices and vascularity ($p < 0.05$). Elshafey et al.¹¹ reinforced these findings through a prospective cohort study, confirming improved malignancy detection when combining SWE and TI-RADS. The multimode approach enhances the detection rate of malignant nodules.

Kim et al.¹² highlighted enhanced reproducibility and histopathological concordance using total-nodule tracing in SWE, reporting intrarater coefficient of variation (CV) of 1.4%–1.7% versus 13.4%–16.9% for focal ROI ($p < 0.001$), and significant association with fibrosis markers ($p < 0.001$).

Hassan et al.¹³ evaluated 80 patients and showed strain USE achieved 95% sensitivity, 90.5% specificity, and 93% diagnostic accuracy, consistent with its reliability in real-world clinical use. Another study by the same group reported similar metrics with an AUC of 0.933 and optimal strain ratio cut-off of 2.57. The study concluded that ultrasound elastography is a valuable diagnostic tool in detection of thyroid nodules due to its high sensitivity and specificity.¹⁴

A prospective study by Naji et al.¹⁵ focusing on Bethesda category III (atypia of undetermined significance or follicular lesion of undetermined significance) found strain elastography helpful in surgical decision-making, achieving sensitivity of 82.35%, specificity of 80.77%, and diagnostic accuracy of 81.4% with SR cut-off value as 3.59.¹⁵ A similar study was by Stoian et al. in which diagnostic performance of USE in thyroid nodules with Bethesda III cytology. Investigation showed that combining strain USE with TI-RADS improved sensitivity to 89.5% in Bethesda III nodules, highlighting its additive value.¹⁶

Although fine-needle aspiration cytology (FNAC) is definitive diagnostic tool but strain USE showed comparable diagnostic ability compared to FNAC, with

sensitivity of 93.46%, specificity of 91%, and accuracy of 92.27%, suggesting its use as a reliable non-invasive alternative. Hence, ultrasound elastography aids in initial assessment and reduce unnecessary biopsies.¹⁷

However, the ElaTION study by Mehanna et al.¹⁸ concluded that ultrasound elastography (USE) and fine-needle aspiration test (FNAC) are comparable techniques from results point of view. FNAC in conjunction with ultrasound elastography does not provide additional benefit. Cancer detection rates were as 14% with USE vs. 16% with FNAC ($p = 0.39$). The number of unclear results was also close (19% vs. 16%, $p = 0.11$) i.e. no extra benefit of USE in some cases.

Two recent investigations further support our findings. Liu et al.¹⁹ established that combining elastography with Thyroid Imaging Reporting and Data System (TIRADS) with elastography significantly improved diagnostic efficacy in indeterminate nodules with the area under the curve as 0.955. Similarly, Han et al.²⁰ calculated diagnostic accuracy of ultrasound elastography as 92% in detection of malignant thyroid nodules i.e. supporting the outcome of this study.

Mahmoud et al.²¹ evaluated the diagnostic precision of strain ultrasound elastography (USE) in comparison to fine-needle aspiration cytology (FNAC) for thyroid lesions. The sensitivity, specificity, positive predictive value, and negative predictive value of strain USE were recorded at 84%, 81.0%, 95%, and 85%, respectively. The study concluded that strain USE is a non-invasive method of choice with high diagnostic accuracy, supporting preoperative diagnosis and decision-making.

Collectively, these studies reinforce the importance of strain elastography in thyroid nodule characterization and optimizing clinical decision-making, either used independently or in conjunction with conventional ultrasound modalities.

Conclusion

Strain ultrasound elastography is the preferred non-invasive technique for identifying malignant thyroid nodules. It has significantly increased our capacity to identify malignant thyroid nodules prior to surgery and aids surgeons in making the best decisions. Therefore, in order to accurately diagnose malignant thyroid nodules prior to surgery and choose the best surgical strategy, strain ultrasound elastography may be performed on a regular basis in all thyroid lesions. Future research may focus on exploring the role of artificial intelligence in interpretation and validation of findings across diverse populations.

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Authors' Contribution:

NS: Acquisition of data, Conception & design, critical revision for important intellectual content, final approval of the version to be published

SC: Analysis & interpretation of data, drafting of article

AR: Analysis & interpretation of data, drafting of article

AR: Analysis & interpretation of data

AM: NS: Acquisition of data, Conception & design, drafting of article

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