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Diagnostic Accuracy of Shear Wave Elastography to Differentiate Between Benign and Malignant Thyroid Nodules Taking Histopathology of FNAC Specimen as Gold Standard

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ABSTRACT

Objective: To determine diagnostic accuracy of shear wave elastography to differentiate amongst benign and malignant thyroid nodules taking histopathology of FNAC specimen as gold standard.
Study Design: Cross sectional study.
Place and Duration of Study: Combined Military Hospital, Multan Pakistan, from Aug 2024 to Jan 2025.
Methodology: In this study two hundred and eighty patients underwent ultrasonic shear wave elastography examination for assessment of the thyroid nodules, elasticity index was measured for each patient and a cutoff value of >66Kpa was taken as suspicion for malignancy. All the patients later went through fine needle aspiration biopsy and status of malignancy confirmed by pathologist (taken as gold standard).
Results: All the patients successfully underwent the study. The mean age of the patients turned out 48.90±12.97 years whereas male to female ratio was 1.28:1 and average nodule size was 1.04 cm with a range of 0.18 to 2.50 cm. The result Shear wave elastography is 78.18% sensitive, 76.52% specific and 77.68% accurate in distinguishing malignant thyroid nodules with a PPV of 82.69% and NPV of 70.97%.
Conclusion: Shear wave elastography is good non-invasive modality in diagnosing the thyroid malignancy with a reasonable percentage of sensitivity and specificity. However, the variable range of its accuracy may advocate more comprehensive studies on the subject.

Keywords: Thyroid Malignancy, Shear Wave Elastography, SWE, Thyroid Histopathology, Diagnostic Accuracy.

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INTRODUCTION

Thyroid nodules can be benign or malignant with a reported global burden of 586,202 cases in one calendar year.[1] In Pakistan, thyroid carcinoma constitutes almost 1.2% of all malignancies.[2] The majority of nodules are benign and do not require immediate intervention but nodules with suspicious features may necessitate close monitoring and additional diagnostic tests to determine presence of malignancy.[3] For this purpose, histopathology of fine needle aspiration biopsy (FNAC) specimen provides definitive management, but due to its invasive nature, non-invasive and cheaper investigatory tools are preferred.[4] One such non-invasive method is shear wave elastography. The diagnostic accuracy of shear wave elastography to differentiate malignant from benign nodules has shown quite variable results.

A systemic review found the pooled sensitivity and specificity of shear wave elastography at 79.2% and 84.5% respectively.[5] Another study on 1098 enlarged thyroid patients (84.4% females and 17.6% males) found that 33.8% (n=371) were malignant and 66.2% (n=727) were benign, confirmed by histopathology.[6] In another study that included 157 patients (109 females and 48 males) having a mean age of 37.64±9.44 years, it was found that at an elasticity index cut-off limit of 66kPa, sensitivity, specificity, PPV, NPV and accuracy of shear wave elastography to differentiate malignant thyroid masses from benign ones was 81.5%, 92.3%, 68.8%, 96% and 90.5%, respectively.[7] The traditional ultrasound methods currently lack the necessary precision for accurately predicting thyroid malignancy, which is why fine-needle aspiration (FNAC) remains a crucial, minimally invasive diagnostic approach for assessing the risk of thyroid malignancy. While FNAC significant drawbacks, including a high rate of non-diagnostic outcomes complicate subsequent clinical management.[8,9]

Since all thyroid nodules are not malignant, it means that invasive tests should not be performed in all the patients. However, in reality, practice is

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otherwise. This may be due to lack of availability of cheaper and reliable modality of investigation. One of the investigation, in this regard, has gained recent popularity owing to its low cost and easy accessibility is shear wave elastography. For this purpose, we conducted this study to determine diagnostic accuracy of shear wave elastography to discern amongst benign and malignant thyroid nodules keeping histo-pathology as gold standard. The findings of this trial will address the discrepancy in the existing literature.

METHODOLOGY

This cross sectional trial was held in the Department of Radiology, Combined Military Hospital Multan, Pakistan having a duration period of six months from Aug 2024 to Jan 2025 after due endorsement from the Hospital Ethical Committee vide reference number 95/2024 dated 25 July 2024. The sample size was measured using MedCalc sample size calculator by using sensitivity and specificity measures and keeping the confidence level at 95%, absolute precision at 10%, sensitivity 79.2%[5] and specificity at 84.5%.[5] Calculated sample size was 188 but we increased it to 280 to cater for potential dropouts if any.

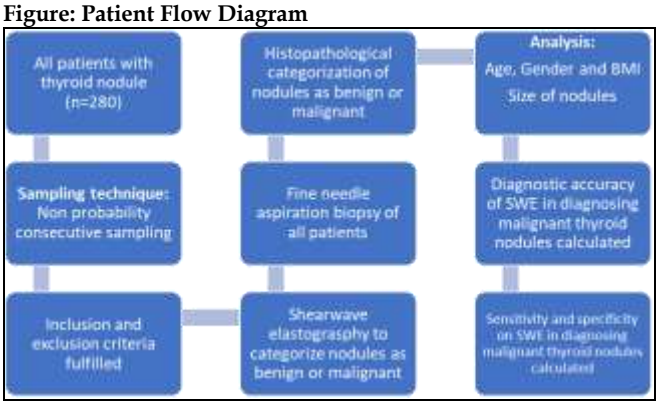
Inclusion Criteria: Patients of either gender aging between 18 and 75 years with solitary suspicious thyroid nodule for ≥3 months from the time of initial presentation were included.

Exclusion Criteria: Patients with mental illness who could not give consent due to in capacitance, patients with known malignancy confirmed by previous medical records, patients with already diagnosed thyroid disease and patients on amiodarone or lithium assessed by previous medical records were excluded from the study.

Patients who were referred to department of radiology for ultrasonic screening of thyroid nodule were selected by non-probability consecutive sampling and written informed consent was taken from all the participants. After this they were carefully screened by carefully assessing their medical record for any positive history leading to their exclusion from the study as per exclusion criteria. Basic characteristics counting age, gender, body mass index (kg/m2) and thyroid nodule size (in centimeter, cm) were documented on the performa. Thyroid nodule was labelled as malignant at a cut-off mean elasticity index (Emean) value of >66kPa while Emean value of ≤66kPa was considered benign, this measurement was done by a consultant radiologist having a minimum 5 years' experience post fellowship. All the Patients were subjected to fine needle aspiration biopsy and specimen were obtained by a consultant surgeon under radiological guidance, these samples were sent to in-hospital histopathology lab where consultant pathologist made a conclusion of benign or malignant thyroid nodule depending upon histology findings (Gold standard). All data was recorded on a well-designed performa.

The data was evaluated by using statistical software package for social sciences (SPSS) version 25. Quantitative variables like age, BMI and thyroid nodule size are expressed as Mean±SD. The categorical variables like gender, thyroid nodule status, sensitivity, specificity, NPV (Negative predicted value), PPV (Positive predicted value), TN (True Negative), TP (True positive), FP (False Positive) and FN (False Negative) were represented as frequency and percentages. Diagnostic accuracy was assessed based on sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). A 2×2 table was drawn to determine sensitivity, specificity, negative predictive value, positive predictive value and accuracy. Patient flow diagram is shown in Figure.

Figure: Patient Flow Diagram



RESULTS

Two hundred and eighty patients were included in final analysis of our study. Patients had a mean age of 48.90±12.97 years. There were 157(56.1%) male patients and 123(43.9%) female patients with male to female ratio was 1.28:1. Mean BMI was calculated as 25.7±2.89 kg/m2. Emean measured by Shear wave elastography was >66Kpa and labelled as malignant in 156(55.7%) of the patients whereas as benign nodules were detected in 124(44.3%) of the patients. The average nodule size was 1.04±0.48 cm. Details of these basic parameters are given in Table-I.

Table-I: Summary of Patient Demographics (n=280)

Variables	Mean±SD
Age in years	48.90±12.97
Body Mass Index in kg/m2	25.70±2.89
Size of the Nodule (in cm)	1.04±0.48

A 2 by 2 contingency table was developed to evaluate the shear wave elastography's diagnostic precision. The estimated diagnostic accuracy was 77.68%, with sensitivity of 78.18%, specificity of 76.52%, PPV of 82.69% and NPV of 70.97% was estimated of shear wave elastography in diagnosing malignant thyroid nodule (Table-II).

Table-II: Assessing Diagnostic Accuracy of shear Wave Elastography (n=280)

	Histopathology	
Shear Wave Elastography	**Malignant (n=165)**	**Benign (n=115)**
Positive (n=156)	129(46.07%)	27(9.64%)
Negative (n=124)	36(12.85%)	88(31.42%)

Diagnostic Accuracy =77.68%
Sensitivity = 78.18%
Specificity = 76.52%
PPV = 82.69%
NPV =70.97%

DISCUSSION

This study found out that Shear wave elastography is 78.18% sensitive and 76.52% specific and 77.68% accurate in diagnosing malignant thyroid nodules. Thyroid nodules are in fact common, making it significant to discriminate between the malignant and benign natures. Due to the constraints of clinical tests in this regard, ultrasonography serves as primary modality to identifying nodules that require further histological assessment.[10] Shear wave elastography (SWE) is distinguished from other elastography techniques by its outstanding accuracy in assessing thyroid nodules. Its excellent sensitivity and specificity help to reduce the number of patients who go through avoidable aggressive treatments.[11]

The SWE has already been stated as a valuable tool to discriminate amongst the malignant and benign thyroid nodules status. This research highlights a significant percentage of the patients later confirmed as malignant thyroid nodules had SWE Emax value >66Kpa which is consistent with previous studies.[12,13] A similar cross sectional study conducted by Awan *et al.*,[14] having a sample size of 180 subjects found SWE is 83.9% accurate in diagnosing malignant status of thyroid nodules later confirmed by fine needle aspiration biopsy (gold standard), this result is consistent with our study showing accuracy of SWE at 77.68%, the positive and negative predicted values of the former and later studies are 65%, 86.3% and 82.69%, 70.97% respectively. However, its pertinent to mention that sample size of our study is greater. A systemic review by Qiu *et al.,* on similar yet different subject (as they determined the sensitivity and specificity of SWE in diagnosing thyroid malignancy in those patients who underwent fine needle aspiration biopsy with undetermined result prior to SWE testing), they found out that SWE is 79.2% sensitive and 84.5% specific, both with 95% confidence interval (CI),[15] these results are consistent with our study.

Another systemic review comprising of 72 researches and 13505 patients by Cantisani *et al.*,[16] by using SWE found out malignancy rate at 33% whereas the overall sensitivity and specificity for qualitative SWE were found to be 84% and 81% respectively, these results are similar to our study. They also tested the quantitative use of SWE for the same purpose and it yielded lesser sensitivity and specificity. Mahmoud *et al.*,[17] conducted a similar study but the used strain elastography and even this modality was able to differentiate malignancy with an accuracy of 84%. The results of Iftikhar *et al.,* are also consistent with our study declaring SWE 84.78% sensitive in differencing the thyroid malignancy.[18]

Filho *et al.*,[19] conducted a systemic review and meta-analysis of 26 researches, they established the sensitivity and specificity of SWE for diagnosing a malignant thyroid nodules are 77% and 76% respectively but their accuracy varied amongst the studies, ranging from 53% to 95%. To minimize the varied level of accuracy a trial conducted by Soloman *et al.,* advocated integration of elastography with contrast-enhanced ultrasound (CEUS) to enhance the sensitivity and accuracy of identifying malignant thyroid nodules, surpassing the effectiveness of using either CEUS or elastography independently. This method may provide a non-invasive, dependable, and effective strategy for diagnosing and managing malignant thyroid nodules.[20]

CONCLUSION

Shear wave elastography is good non-invasive modality in diagnosing the thyroid malignancy with a reasonable percentage of sensitivity and specificity. However, the variable range of its accuracy may advocate more comprehensive studies on the subject.

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Authors' Contribution

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

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

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

HRI & NS: 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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