

Role of Ultrasound Elastography in the Evaluation of Thyroid Nodules With Cytological Correlation

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Abstract

Background and purpose

Thyroid nodules are among the most commonly encountered endocrine findings in clinical practice, with a significant proportion identified incidentally on high-resolution ultrasonography. Although the overwhelming majority are benign, approximately 5–15% harbour malignancy, making reliable preoperative characterisation indispensable. Conventional ultrasonography with Thyroid Imaging Reporting and Data System (TIRADS) classification provides validated risk stratification; however, its specificity remains limited owing to overlapping sonographic features between benign and malignant lesions. Ultrasound elastography—a technique that quantifies tissue stiffness as a surrogate for pathological change—has emerged as a promising adjunct in this diagnostic context. To evaluate the diagnostic performance of ultrasound elastography in differentiating benign from malignant thyroid nodules and to compare its efficacy with conventional ultrasonography, using fine-needle aspiration cytology (FNAC) as the reference standard.

Methods

This prospective observational study was conducted at the Department of Radiodiagnosis, Era's Lucknow Medical College and Hospital, Lucknow, over 24 months. Sixty-eight consecutive patients with focal thyroid nodules detected on ultrasonography were enrolled. All participants underwent conventional B-mode ultrasonography with ACR-TIRADS categorisation, qualitative strain elastography using Rago's scoring system, quantitative strain ratio analysis, and ultrasound-guided FNAC. Diagnostic performance metrics—sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy—were calculated for each modality. Receiver operating characteristic (ROC) curve analysis determined the optimal strain ratio cut-off.

Results

Of 68 patients (mean age 35.66 ± 11.72 years; 76.5% female), FNAC confirmed 49 (72.1%) benign and 19 (27.9%) malignant nodules. Malignancy rates increased significantly across rising TIRADS categories ($p < 0.001$). Conventional ultrasonography (TIRADS ≥ 4) achieved sensitivity 73.7%, specificity 63.3%, and accuracy 66.2%. Qualitative colour-mapping elastography demonstrated sensitivity 73.7%, specificity 81.6%, and accuracy 79.4%. Quantitative strain ratio analysis at a threshold of >2.8 yielded sensitivity 84.2%, specificity 79.6%, and accuracy 80.9%. Combined elastographic assessment achieved the highest specificity (98.0%) and overall diagnostic accuracy (86.8%). ROC analysis identified an optimal strain ratio cut-off of >2.45 (AUC = 0.887).

Conclusion

Ultrasound elastography significantly augments the diagnostic evaluation of thyroid nodules beyond conventional ultrasonography. Quantitative strain ratio analysis demonstrated the

highest individual sensitivity, whereas combined qualitative and quantitative elastography achieved superior specificity and accuracy. Elastography serves as a reliable, non-invasive adjunct to TIRADS assessment and holds potential for reducing unnecessary FNAC procedures.

Keywords: Thyroid nodule · Elastography · Strain ratio · Colour mapping · ACR-TIRADS · Fine needle aspiration cytology · Thyroid carcinoma · Ultrasound

Background

Thyroid nodules represent one of the most prevalent endocrine disorders in clinical practice. The widespread adoption of high-resolution ultrasonography has markedly increased their detection rate, with autopsy series reporting prevalence exceeding 50% in the general population. The clinical challenge lies not in detection but in characterisation: while the vast majority of nodules are benign, approximately 5–15% harbour malignancy, necessitating a reliable and cost-effective strategy for preoperative risk stratification.

High-resolution B-mode ultrasonography remains the primary imaging modality for thyroid nodule evaluation owing to its accessibility, real-time capability, and established diagnostic criteria. The American College of Radiology Thyroid Imaging Reporting and Data System (ACR-TIRADS) provides a standardised, reproducible framework for assigning malignancy risk based on sonographic characteristics, including nodule composition, echogenicity, shape, margin, and the presence of calcifications. Despite its widespread adoption, conventional ultrasonography is constrained by a relatively modest specificity, reflecting substantial overlap in sonographic appearance between benign and malignant lesions.

Ultrasound elastography is a relatively recent functional imaging technique that assesses tissue mechanical stiffness—a parameter intrinsically linked to the underlying pathological process. Malignant thyroid nodules typically exhibit increased rigidity secondary to elevated cellularity, desmoplastic stromal reaction, and fibrosis, in contrast to the compliance characteristic of benign colloid nodules. Elastography may be performed qualitatively through colour-mapping (strain elastography) or quantitatively through strain ratio measurements, the latter affording objective, observer-independent assessment.

Fine needle aspiration cytology (FNAC) remains the definitive pre-surgical diagnostic tool for thyroid nodules, offering high sensitivity and specificity. As an invasive procedure, it is associated with patient discomfort, rare haemorrhagic and infectious complications, and a non-diagnostic yield of up to 20% in some series. The development of robust non-invasive imaging biomarkers capable of reducing the burden of unnecessary FNAC is therefore of considerable clinical value.

The present study was undertaken to evaluate the diagnostic performance of strain elastography—both qualitative and quantitative—in differentiating benign from malignant thyroid nodules at a tertiary care centre in northern India, using FNAC as the reference standard, and to determine its incremental value over conventional TIRADS-based ultrasonography.

Methods

Study design and ethical considerations

This was a prospective observational study conducted in the Department of Radiodiagnosis in collaboration with the Department of Otorhinolaryngology, Era's Lucknow Medical College and Hospital, Lucknow, Uttar Pradesh, India, over a period of 24 months. Ethical approval was obtained from the Institutional Ethics Committee, and written informed consent was obtained

from all participants prior to enrolment. The study was conducted in accordance with the Declaration of Helsinki.

Study population

Consecutive patients referred from the Department of Otorhinolaryngology with focal thyroid nodules detected on ultrasonography were enrolled. Inclusion criteria were: (1) adults aged 18 years or older with one or more focal thyroid nodules on B-mode ultrasonography; and (2) willingness to undergo FNAC. Patients were excluded if they had (1) purely cystic thyroid lesions ($\geq 90\%$ cystic component); (2) diffuse thyroid enlargement without a discrete focal nodule; or (3) refused FNAC. A total of 68 patients met the eligibility criteria and were included in the final analysis. Sample size was estimated based on published sensitivity of strain elastography for malignant thyroid nodules (approximately 80%), at 90% study power and 5% significance level.

Ultrasonographic evaluation and ACR-TIRADS classification

All examinations were performed on a LOGIQ Fortis ultrasound system (GE Healthcare) equipped with a high-frequency linear transducer (9–15 MHz). Patients were examined in the supine position with the neck gently hyperextended. Each nodule was assessed for maximum diameter, composition (solid, predominantly solid, mixed cystic-solid, predominantly cystic), echogenicity relative to adjacent thyroid parenchyma (hyperechoic, isoechoic, hypoechoic, markedly hypoechoic), shape (wider-than-tall versus taller-than-wide), margins (smooth, irregular/lobulated), and echogenic foci (macrocalcification, peripheral rim calcification, punctate echogenic foci). Vascularity was assessed using colour Doppler. Each nodule was assigned an ACR-TIRADS category (1–5) by a consultant radiologist with more than five years of thyroid imaging experience, who was blinded to the clinical history.

Elastography protocol

Strain elastography was performed immediately following B-mode examination, with the patient maintaining the same position. A region of interest (ROI) was positioned to include the nodule and an equal or greater area of adjacent normal thyroid parenchyma. The operator applied gentle, repetitive manual compression in the axial plane, maintaining a compression ratio between 2 and 4 as indicated by the real-time quality bar. A minimum of three acceptable elastographic frames were acquired per nodule.

Qualitative assessment employed Rago's five-point elastography scoring system: score 1, entirely soft (homogeneous green throughout); score 2, predominantly soft with small hard areas (predominantly green with small blue areas); score 3, mixed stiffness (green and blue equally distributed); score 4, predominantly hard (predominantly blue with small green areas); score 5, entirely hard (homogeneous blue throughout). Scores 4 and 5 were classified as suggestive of malignancy.

For quantitative assessment, the mean strain ratio was calculated by placing a circular ROI within the thyroid nodule and an equal-sized ROI in the adjacent normal thyroid parenchyma. Three measurements were obtained and averaged. A strain ratio exceeding 2.8 was used as the threshold for malignancy, based on published literature.

Fine needle aspiration cytology

Ultrasound-guided FNAC was performed on all nodules by an experienced interventional radiologist using a 22-gauge needle under strict aseptic precautions, without local anaesthesia. A minimum of two passes were made per nodule. Aspirated material was smeared onto glass slides, fixed in 95% ethanol, and stained with haematoxylin and eosin and Papanicolaou stains. Cytological analysis was performed by a consultant histopathologist blinded to the imaging findings. Results were classified using the Bethesda System for Reporting Thyroid Cytopathology.

Statistical analysis

Data were entered and analysed using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation (SD); categorical variables as frequencies and percentages. The chi-square test was used to assess associations between categorical variables, and the independent samples t-test for continuous data. Diagnostic performance parameters—sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy—were calculated for conventional TIRADS, colour-mapping elastography, strain ratio elastography, and combined elastographic assessment using FNAC as the gold standard. ROC curve analysis was performed to determine the optimal strain ratio cut-off value and calculate the area under the curve (AUC). A p-value of <0.05 was considered statistically significant.

Results

A total of 68 patients were enrolled. Age ranged from 16 to 65 years (mean 35.66 ± 11.72 years). Females constituted 76.5% of the cohort, yielding a female-to-male ratio of 3.25:1. The majority of patients (91.2%) were euthyroid at presentation; hypothyroidism and hyperthyroidism were present in 7.4% and 1.5% of cases, respectively.

On B-mode ultrasonography, mixed cystic-solid nodules were the most common sonographic pattern (44.1%), followed by solid nodules (30.9%), predominantly solid (16.2%), and predominantly cystic nodules (8.8%). Taller-than-wide orientation was identified in 10.3% of nodules. Irregular or lobulated margins were observed in 17.6% of cases. Punctate echogenic foci were noted in 13.2% of nodules.

ACR-TIRADS categorisation revealed: TIRADS 2 in 25.0% of cases; TIRADS 3 in 27.9%; TIRADS 4 in 36.8%; and TIRADS 5 in 10.3%. The frequency of malignancy increased progressively with rising TIRADS category, from 0% in TIRADS 2 to 85.7% in TIRADS 5 nodules ($p < 0.001$).

Qualitative elastography revealed score 2 as the most frequent finding (30.9%), followed by score 4 (25.0%), score 3 (22.1%), score 1 (13.2%), and score 5 (8.8%). Quantitative strain ratio values ranged from 1.35 to 4.32 (mean 2.49 ± 0.70). Twenty-six nodules (38.2%) demonstrated strain ratios exceeding the 2.8 threshold.

FNAC identified 49 benign lesions (72.1%) and 19 malignant lesions (27.9%). Among benign lesions, colloid goitre was the most frequent diagnosis, followed by thyroiditis and follicular adenoma. Among malignant lesions, papillary thyroid carcinoma predominated, followed by follicular carcinoma and one case of medullary thyroid carcinoma.

ROC curve analysis for quantitative strain ratio yielded an AUC of 0.887 (95% CI: 0.805–0.969; $p < 0.001$). The statistically optimal cut-off by Youden's index was >2.45 ; however, the predefined threshold of >2.8 provided superior specificity and clinical applicability in practice.

Moderate to good agreement was observed between elastographic findings and FNAC diagnosis on Cohen's kappa analysis.

Table 1 Comparative diagnostic performance of conventional ultrasonography (ACR-TIRADS), colour-mapping elastography, quantitative strain ratio, and combined elastography for thyroid nodule characterisation (reference: FNAC)

Modality	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Conventional USG (TIRADS ≥ 4)	73.7	63.3	45.2	85.7	66.2
Colour-mapping elastography	73.7	81.6	63.6	87.0	79.4
Strain ratio (>2.8)	84.2	79.6	61.5	92.9	80.9
Combined elastography	57.9	98.0	91.7	87.5	86.8

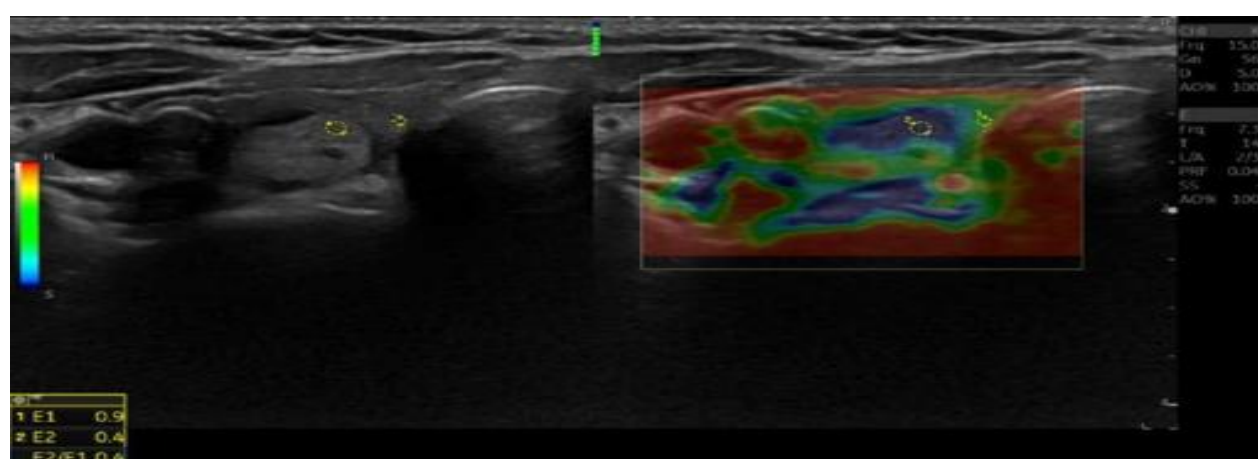


Fig. 3 On B-mode ultrasound, there is well defined hyperechoic lesion in right thyroid lobe. The lesion is soft with strain ratio 0.4 (FNAC confirmed the diagnosis of colloid module).



Fig. (A): On B-mode ultrasound, left thyroid lobe is diffusely enlarged show coarse and heterogenous echotexture with multiple ill defined hypoechoic areas and vascularity noted within, categorized as TI-RADS 2.



Fig. 2 (B): On strain elastography, the lesion is soft with a strain ratio of 0.6 which is less than malignant cutoff. (FNAC confirmed the diagnosis of thyroiditis) .

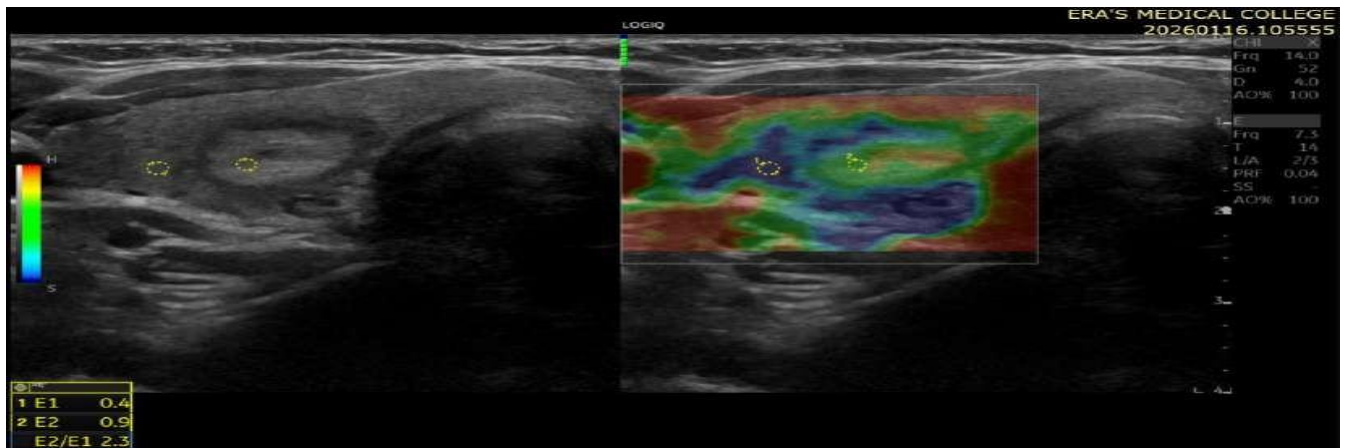


Fig. 3: On B-mode ultrasound, there is solitary, oval , isoechoic thyroid nodule with smooth margins ,wider than taller lesion with thin ,complete peripheral halo noted in right thyroid lobe categorized as TI-RADS 2. on strain elastography, the lesion is soft with a strain ratio of 2.3 which is less than malignant cutoff.(FNAC confirmed the diagnosis of Follicular thyroid adenoma.



Fig. 4(A): On B-mode ultrasound, there is hypoechoic solid thyroid module with irregular margins and coarse internal calcification with increased internal vascularity

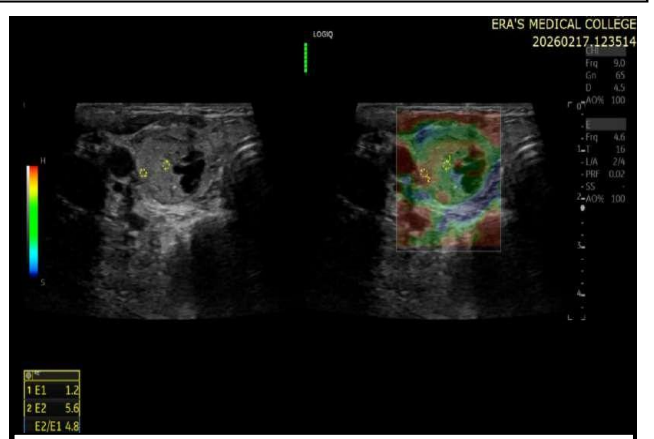


Fig. 4(B): On strain elastography, the lesion is hard with a strain ratio of 4.8 which is more than malignant cutoff.(FNAC confirmed the diagnosis of medullary thyroid



Fig. 5: On B-mode ultrasound, there is solid, hypoechoic, wider than taller lesion with few specks of calcification within noted in right thyroid lobe categorized as TI-RADS 4. on strain elastography, the lesion is hard with a strain ratio of 4.3 which is more than malignant cutoff.(FNAC confirmed the diagnosis of papillary thyroid carcinoma)

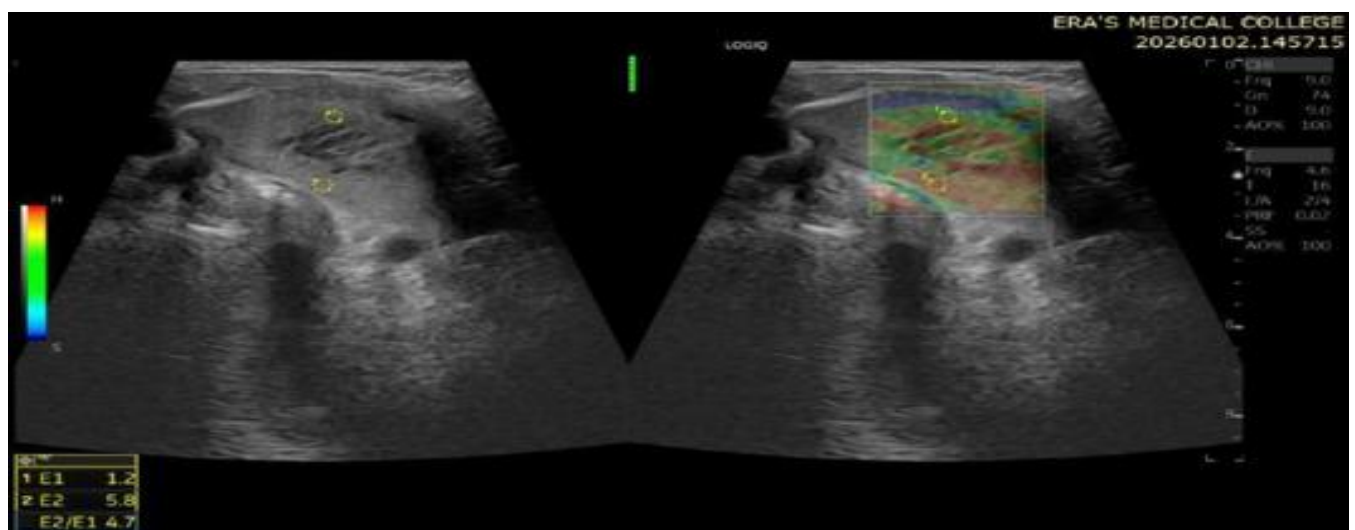
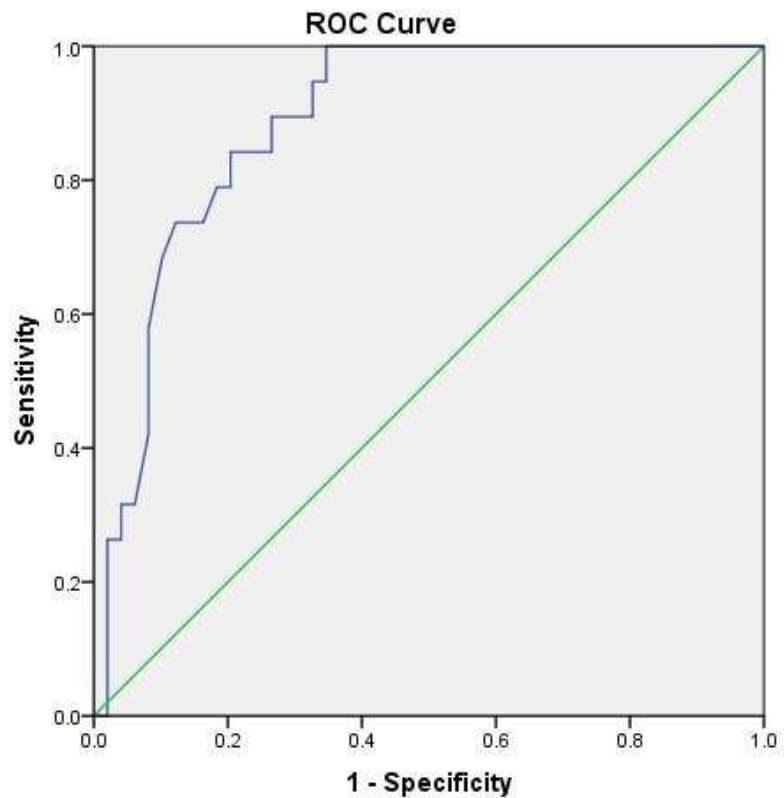
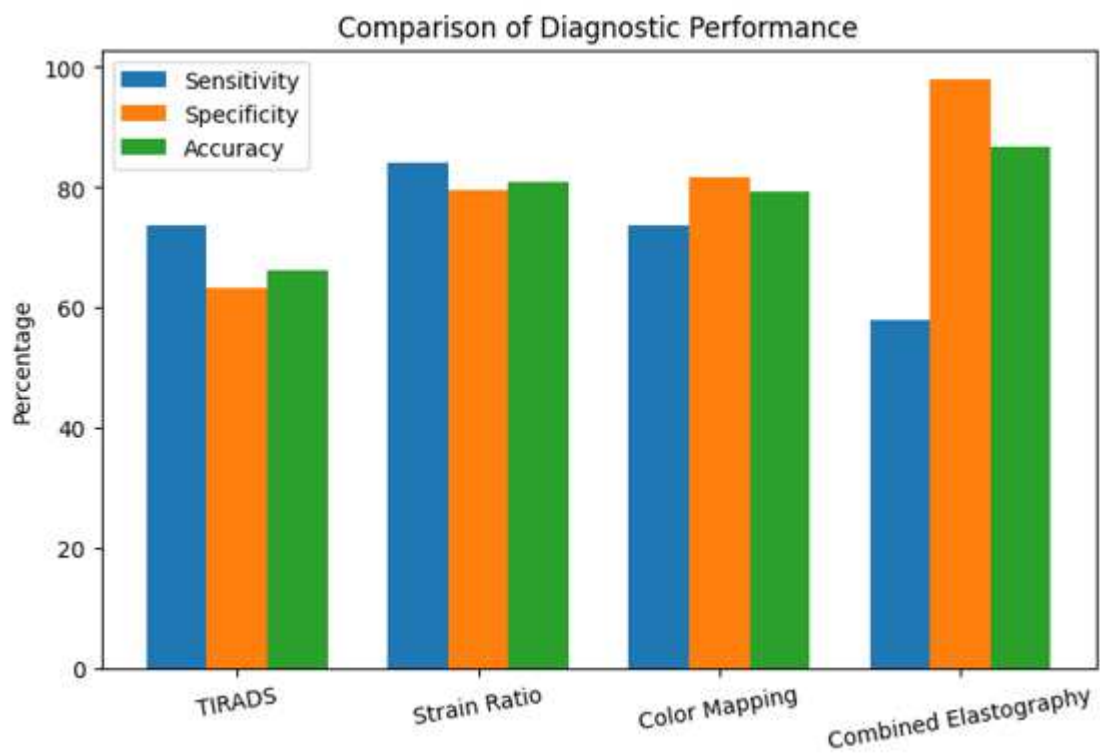


Fig. 6: B-mode ultrasound, there is predominantly solid, isoechoic to mildly hypoechoic thyroid nodule with irregular margins, wider than taller lesion with increased internal vascularity within noted in right thyroid lobe categorized as TI-RADS 4. on strain elastography, the lesion is hard with a strain ratio of 4.7 which is more than malignant cutoff. (FNAC confirmed the diagnosis of Follicular thyroid carcinoma).



Diagonal segments are produced by ties.

ROC curve analysis yielded an optimal strain ratio cut-off of >2.45 with an area under the curve (AUC) of 0.887. However, the predefined threshold of >2.8 provided better overall diagnostic performance and clinical applicability.



Discussion

The present study demonstrates that ultrasound elastography provides clinically meaningful incremental diagnostic value in the characterisation of thyroid nodules when used as an adjunct to conventional B-mode ultrasonography and TIRADS assessment. The observed demographic profile—female predominance and mean age in the fourth decade—is consistent with the established epidemiology of thyroid nodular disease.

The strong positive correlation between rising ACR-TIRADS category and malignancy rate ($p < 0.001$) affirms the validity of TIRADS as a risk-stratification tool in this cohort. However, conventional ultrasonography at a TIRADS ≥ 4 threshold achieved only modest specificity (63.3%), reflecting the well-recognised problem of overlapping sonographic features between hyperplastic nodules and early-stage differentiated thyroid carcinomas. This limitation underscores the need for supplementary modalities.

Qualitative colour-mapping elastography demonstrated a meaningful improvement in specificity (81.6%) compared with conventional ultrasonography alone. This finding aligns with the biological rationale: malignant thyroid nodules consistently exhibit greater mechanical stiffness owing to desmoplastic fibrosis and increased nuclear-to-cytoplasmic ratio, rendering them visually harder on elastographic colour maps. Our results are concordant with those of Saleem et al. (2022) and Thomas et al. (2022), who similarly reported improved specificity with strain elastography over conventional sonography.

Quantitative strain ratio analysis at the >2.8 threshold achieved the highest sensitivity (84.2%) among individual modalities tested, with an accuracy of 80.9%. The AUC of 0.887 for strain ratio compares favourably with previously published values, which range from 0.80 to 0.94. Although Youden's index identified an optimal cut-off of >2.45 , the clinical performance at >2.8 was superior in terms of specificity, and we concur with Mena et al. (2023) and Okasha et al. (2021) that a higher threshold reduces false-positive rates in populations with a relatively high prevalence of benign nodular disease.

The most striking finding was achieved with combined qualitative and quantitative elastographic assessment, which yielded a specificity of 98.0% and overall accuracy of 86.8%. This near-perfect specificity suggests that when both colour-mapping and strain ratio are concordantly negative for malignancy, the probability of harbouring malignancy is extremely low, and observation rather than FNAC may be considered in appropriately selected patients. This approach could potentially reduce the procedural burden on patients and healthcare systems, particularly in settings with limited pathology resources.

The sensitivity of combined assessment (57.9%) was, however, lower than strain ratio alone, attributable to the strict requirement for both modalities to yield positive findings. Clinicians must therefore be cautious in using combined assessment as a sole screening tool; rather, it is best employed to triage TIRADS 4 nodules in which FNAC may otherwise be reflexively performed.

Certain limitations of this study merit acknowledgement. The study was conducted at a single tertiary care centre with a relatively modest sample size, which may limit generalisability. The absence of histopathological correlation (surgical resection) for all nodules—relying instead on FNAC as the gold standard—introduces the possibility of sampling error, particularly for follicular lesions where FNAC cannot reliably distinguish adenoma from carcinoma. Furthermore, strain elastography is operator-dependent, and the learning curve associated with optimal compression technique may affect reproducibility in different hands. Shear wave elastography, which is operator-independent and provides absolute stiffness measurements in kilopascals, was not available during the study period and represents an important avenue for future investigation.

Taken together, the findings of this study support the integration of strain elastography into the routine evaluation protocol for thyroid nodules, particularly for nodules categorised as TIRADS 3 and 4, where the clinical decision to perform FNAC is most uncertain.

Conclusion

Ultrasound elastography—both qualitative colour-mapping and quantitative strain ratio analysis—significantly improves the diagnostic evaluation of thyroid nodules beyond conventional B-mode ultrasonography and TIRADS classification. Strain ratio analysis at a threshold of >2.8 demonstrated the highest individual sensitivity, while combined elastographic assessment achieved near-perfect specificity (98.0%) and the highest overall accuracy (86.8%). Elastography is a safe, non-invasive, and readily available adjunct to conventional ultrasonography that enhances preoperative nodule characterisation and holds promise for reducing unnecessary FNAC procedures in appropriately selected patients. Future multicentre studies with histopathological correlation and incorporation of shear wave elastography are warranted.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Institutional Ethics Committee of Era's Lucknow Medical College and Hospital. Written informed consent was obtained from all study participants.

Consent for publication

Written consent for publication was obtained from all participants.

Availability of data and materials

The datasets generated and analysed during this study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

No funding was received for this study.

Authors' contributions

[Author initials]: study concept and design, data collection, imaging interpretation, manuscript preparation. [Author initials]: otorhinolaryngological evaluation and FNAC supervision. All authors read and approved the final manuscript.

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