Original Article

Diagnostic yield of combined ACR TI-RADS and Sonoelastography in solid thyroid nodules in tertiary care center: an analytical study

Saubhagya Dhakal,[1] Shailendra Katwal,[2] Sharma Paudel,[3] Birendra Kumar Yadav[4]

[1]Department of Radiology, National Academy of Medical Sciences, Kathmandu, Nepal

[2] Department of Radiology, Dadeldhura Subregional Hospital, Dadeldhura, Nepal

[3]Department of Radiology, Maharajgunj Medical Campus, Kathmandu, Nepal

[4]Department of Medicine, National Academy of Medical Science, Kathmandu, Nepal

Corresponding Authors: Dr. Sharma Paudel,

Email: sharmapaudel@gmail.com ORCID; https://orcid.org/0000-0001-7973-2711

Academic Editor: Dr. Kapil Amgain

ABSTRACT

Background: Thyroid nodules are prevalent, and accurate differentiation between benign and malignant nodules is crucial for management. We aim to evaluate the effectiveness of combining Thyroid Imaging Reporting and Data System (TIRADS) scoring with strain elastography, specifically the Elasticity Contrast Index (ECI), to differentiate between benign and malignant thyroid nodules.

Methods: This analytical cross-sectional study involved 77 patients with solid thyroid nodules identified through B-mode ultrasonography. ACR TI-RADS scores, ECI values, and combined scores were compared with Fine needle aspiration Cytology (FNAC) results. Statistical analysis was performed using SPSS, and Pearson correlation tests were conducted to assess the correlation with FNAC findings.

Result: The TI-RADS scoring system has a sensitivity of 83.3%, a specificity of 66.1%, and a positive predictive value of 42.9% for distinguishing benign and malignant nodules. Strain elastography with ECI values has a sensitivity of 94.4%, specificity of 98.3%, PPV of 94.4%, and NPV of 98.3%. Combining ACR TI-RADS and strain elastography achieves a sensitivity of 100%, specificity of 66.1%, NPV of 100%, and PPV of 47.4%.

Conclusion: The study emphasizes the benefits of integrating noninvasive methods like ultrasound elastography and ACR TI-RADS for improved diagnostic precision, minimizing invasion and patient discomfort. This strategy is particularly advantageous for TI-RADS 3 nodules and reduces unnecessary procedures. However, FNAC should be reasonable and validated for higher classifications.

Keywords: Diagnostic Imaging; Elastography; Fine-Needle Aspiration; Thyroid Nodule; Ultrasonography

Article Information

Received: 6 July 2024 Accepted: 30 August 2024 Published online: 31 August 2024

INTRODUCTION

Thyroid nodules – abnormal growths in the thyroid gland with distinct radiological features – can be benign or malignant. Clinical guidelines recommend diagnostic ultrasonography (USG) for all patients with thyroid nodules, followed by Fine Needle Aspiration Cytology (FNAC) for potentially malignant nodules [1].

The prevalence of detectable thyroid nodules is around 5% in women and 1% in men in areas with sufficient iodine intake [2]. Ultrasound is a crucial non-invasive imaging modality endorsed by the American Thyroid Association (ATA) and the British Thyroid Association (BTA) [3]. Despite ultrasound's increased identification of nodules (approximately 60%), the malignancy rate remains relatively low, ranging from 5% to 15% [4]. Ultrasound's widespread availability and cost-effectiveness ultrasound, utilizing high-frequency transducers and brightness-mode US, faces challenges in accurately differentiating between benign and malignant nodules [5].

The introduction of the TI-RADS classification, adapted from the Breast Imaging Reporting and Data System (BIRADS), aims to standardize malignancy risk assessment in thyroid nodules. This system categorizes nodules on a 0 to 5 scale, analyzing factors such as nodule composition, echogenicity, shape, margins, and echogenic foci emphasizing the importance of cross-referencing with FNAC outcomes for accurate diagnosis [6,7].

The Elasticity Contrast Index (ECI), rooted in strain elastography, quantitatively assesses nodule hardness. Ultrasound elastography, a non-invasive diagnostic tool, presents potential advantages over invasive procedures [8].

Numerous studies have delved into the utility of ECI, ACR TI-RADS, and the synergistic utilization of ECI and ACR TI-RADS in diagnosing solid thyroid nodules. Studies have shown ECI sensitivity (60% to 99%) and specificity (54% to 99%) surpassing those of TI-RADS. The combined use of sonoelastography and ACR TI-RADS demonstrates sensitivity (81% to 97%) and specificity (50% to 100%) [9].

While FNAC is preferred by the American Thyroid Association [5], exploring the combined use of TI-RADS and ECI in distinguishing benign from malignant thyroid nodules, particularly in the context of Nepal, this study seeks to fill this gap. The rationale for this study lies in the need to validate and establish a non-invasive diagnostic protocol that minimizes unnecessary FNAC procedures, particularly for nodules that fall into the indeterminate category (TI-RADS 3 and 4).

METHODS

The study was an analytical cross-sectional study conducted at the Department of Radiology and Imaging, Maharajgunj Medical Campus, from September 2019 to September 2020. Ultrasonography and strain elastography were performed in the USG unit, and pathological reports were obtained from the Department of Pathology or patients.

Ethical clearance were obtained before data collection from Institutional Review Committee, Institute of Medicine with reference number 27/076/077. Patient consent was obtained after explaining the details and implications. Patients who failed to provide consent were excluded from the study. This study followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) 2019 guidelines for the Observational study [10].

The sample size was calculated using the similar study. Zhang et all showed a sensitivity of 84 percent by sonoelastography in the differentiation of benign and malignant thyroid nodules [11], which leads to a sample size of 73. Lin ZM et al showed the sensitivity of combined sonoelastography and TI-RADS in the diagnosis of solid thyroid nodules to be 83.9 % [12], leading to a sample size of 74. We used 95% level of confidence with error of estimate to be 10%, thus making sample size of 77 patients.

Patients diagnosed with solid thyroid nodules in the Ultrasound unit in the radiology department were included. Exclusion criteria included patients not giving consent, children under 18, and cystic thyroid lesions detected in USG. Repeat imaging was done for the patients with indeterminate test results.

The study involved a single examiner using a MEDISON ACCUVIX A30 USG machine with a high frequency (7-12 MHz) linear probe. The patients were examined in a supine position with a pillow placed on the back. The thyroid nodules were classified into TI-RADS categories, with suspicious nodules TI-RADS 3 and 4, and malignant nodules being TI-RADS 5. The elastography was calculated using the Region of Interest (ROI) into the solid nodules, with ROI selected across at least two-thirds of the lesion. Nodules with an ECI value greater than 3.5 were considered malignant, while those less than 3.5 were considered benign [Figure 1].

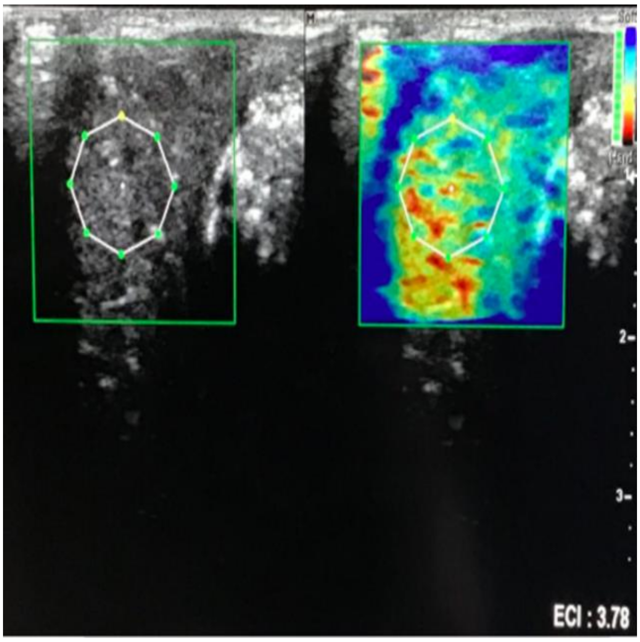

Figure 1: Ultrasound elastography showing Elasticity Contrast Index (ECI) value.

The patient was informed about the procedure of FNAC and its complications, and written consent was obtained. Using ultrasound guidance, 5 ml of 1% local anesthetic was infiltrated into the skin and underlying fat. A 22-gauge needle was passed into the lesion to obtain a cellular sample. The sample was smeared into slides, air-dried, wet-fixed in Papanicolaou solution, and sent to a pathology laboratory for cytological analysis. A follow-up of the FNAC report was done and was considered the gold standard due to its widespread acceptance, high diagnostic accuracy, and noninvasive nature (5).

The study involved two experienced observers. Indeterminate cases underwent review with repeated cytology and follow-up scans for conclusive results. Expert consultation from senior radiologists and pathologists provided valuable insights. Proactive patient follow-up ensured study validity, data completeness, and clinical outcome verification.

Data analysis utilized SPSS version 25, and Microsoft Excel aided in the presentation. Cases with missing data were excluded. The independent t-test compared normally distributed variables in binary groups, while the Mann-Whitney U test handled non-normally distributed variables. A student t-test compared qualitative data. The Pearson correlation test assessed correlations between TI-RADS, ECI, and combined ECI/TI-RADS in differentiating benign and malignant thyroid nodules, with statistical significance set at $P < 0.05$

The kappa test was used to statistically evaluate the inter-rater reliability between ultrasound imaging and histopathological final diagnoses. According to Cohen's guidelines, the interpretation of Kappa values is as follows: ≤ 0 signifies no agreement, 0.01–0.20 indicates none to slight agreement, 0.21–0.40 suggests fair agreement, 0.41–0.60 denotes moderate agreement, 0.61–0.80 reflects substantial agreement, and 0.81–1.00 indicates almost perfect agreement [13].

RESULTS

The study included 77 patients with a wide age range (19 to 84 years). Females were more compared to males with a male-to-female ratio of 4:9. The distribution of solid thyroid nodules showed a higher prevalence in the left lobe (54.5%), followed by the right lobe (42.9%) and the isthmus (2.6%).

The study observed that most of the nodules fell into the TI-RADS 3 category (n=42, 54.55%), followed by TI-RADS 4 (n=25, 32.47%) and TI-RADS 5 (n =10, 12.99%).

Lesions with ECI values over 3.5 were considered malignant, with 59 (76.6%) benign and 18 (23.4%) malignant. Among all ECI values, the lowest obtained value was 0.66 and the highest value was 5.6.

In FNAC, 59 (77.6%) nodules were benign and 18 (23.4%) were malignant. The malignant nodule in our study was more in the left lobe followed by the right lobe and the isthmus. The imaging-histological agreement value for detecting benign and malignant thyroid nodules was 85%. Applied inter-rater reliability Cohen's Kappa showed a substantial agreement of coefficient 0.8.

The specificity (98.3%) and PPV (98.3%) of sonoelastography (ECI) were the highest among all the study parameters, while sensitivity (100%) and NPV (100%) were highest for combined ECI and TI-RADS, followed by ECI alone.

The area under the ROC curve is largest with ECI (0.998) followed by combined TI-RADS and ECI (0.954) and then by TI-RADS (0.825) with P value <0.001, suggesting the accuracy of ECI was highest among all the other parameters in the diagnosis of malignant thyroid nodules.

The area under the curve for ECI was 0.998 with a cutoff of 3.5 and the sensitivity and specificity were 94.4 and 98.3% [Figure 2].

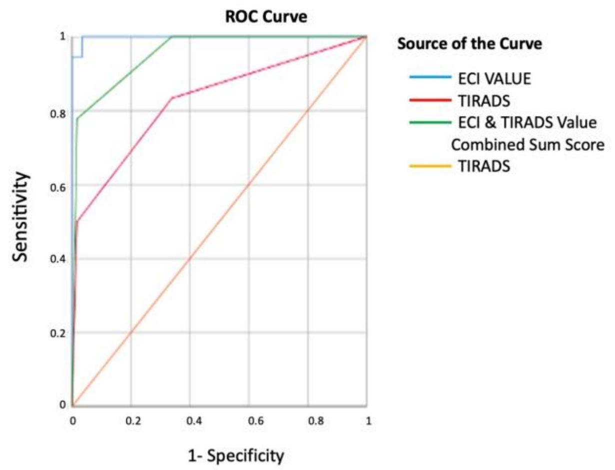

Figure 2: Receiver operating characteristic curve (ROC) showing sensitivity and specificity of ECI, TIRADS, and Combined ECI and TIRADS compared to Fine needle aspiration cytology (FNAC).

There was a strong significant correlation between ECI findings and FNAC compared to the rest of the study variables with a strong correlation between ECI and FNAC with r= 0.832 which is statistically significant (p-value <0.001). The ECI and TI-RADS had the least correlation (r=0.568, p<0.001).

DISCUSSION

This article explores the application of ultrasound and elastography for assessing thyroid nodules, aiming to offer noninvasive and precise diagnostic methodologies. Ultrasonography, endorsed as a primary approach by medical associations like the American Thyroid Association and the British Thyroid Association, supersedes fine-needle aspiration cytology (FNAC), acknowledged for its limitations and patient burden [14].

Patient demographics ranged from 19 to 84 years, with a mean age of 47.62 years. Predominantly, individuals within the 30-45 age group were observed, aligning with findings by Kumar et al [15]. A notable gender-based disparity was noted, with 83.15% of thyroid nodules occurring in females, consistent with a study by Di Z et al. in 2019 [16], attributing this trend to the influence of estrogen and estrogen hormone receptors on thyroid cells [17].

Divergent criteria for categorizing Thyroid Imaging Reporting and Data System (TI-RADS) and elastography exist across studies. In this investigation, TI-RADS 3 and 4 nodules were deemed suspicious, while TI-RADS 5 were considered malignant. The study evaluated TI-RADS and Elastography Classification Index (ECI) performance in diagnosing solid thyroid nodules. TI-RADS exhibited moderate sensitivity and specificity, similar to previous studies by Kim et al. [18], whereas ECI demonstrated high sensitivity and specificity, consistent with Cho et al.'s findings [19]. Combining TI-RADS and ECI yielded perfect sensitivity but reduced specificity, paralleling Gaur et al.'s results [20].

Table 1: Comparison of sensitivity, specificity, PPV, and NPV of ECI, TIRADS, and combined ECI and TIRADS with FNAC of various studies. NA= Not available

Studies	Sample size	Year		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
P Kalaiyarashan et al [23]	135	2020	ECI	91.7	99	95.7	95.7
			TIRADS	83	96.4	83.3	96.4
			COMBINED	95.83	100	100	99.1
Gaur S et al [20]	50	2019	ECI	90.9	97.4	90.9	97.4
			TIRADS	90	95	81.8	97.4
			Combined	90.9	97.4	90.9	97.4
Trimboli P et al [21]	498	2012	Combined	97	100	NA	NA
Du YR et al [22]	142	2018	Combined	94.4	87.14	NA	NA
Present Study	77	2020	ECI	94.4	98.3	94.4	98.3
			TIRADS	83.3	66.1	42.9	92.9
			Combined	100	66.1	47.4	100

Higher specificity was demonstrated by Trimboli et al. [21] attributing it to limited parameters in ACR TI-RADS compared to this study, while lower specificity was reported by Du et al. [22] due to the exclusion of nodules larger than one centimeter. These findings highlight the potential of combining imaging techniques for enhanced diagnostic accuracy in thyroid nodule evaluation. Comparisons of sensitivity and specificity of various studies are shown [Table 1].

However, interobserver variability and the need for further research and standardization should be addressed. These techniques can potentially improve patient outcomes and reduce unnecessary invasive procedures, warranting continued investigation and refinement.

Comparing TI-RADS, ECI, and FNAC results revealed moderate correlation between TI-RADS and FNAC, a strong correlation between ECI value and FNAC, and a moderate correlation between TI-RADS and ECI value. These findings highlight elastography's, particularly ECI's, potential as a valuable tool in thyroid nodule diagnosis.

This study highlights the potential of combining TI-RADS and Elasticity Contrast Index (ECI) for more accurate, non-invasive diagnosis of thyroid nodules, reducing reliance on fine-needle aspiration cytology (FNAC). This approach could minimize patient discomfort and unnecessary invasive procedures while standardizing nodule evaluation in clinical practice. Future research should validate these findings across diverse populations, explore integration with other diagnostic tools, and assess the long-term accuracy and economic benefits. Advancing ultrasound and elastography technology could further enhance the diagnostic precision of TI-RADS and ECI, offering a more efficient and patient-friendly approach to thyroid nodule management.

These noninvasive modalities enhance diagnostic precision while mitigating invasiveness and patient discomfort. However, successful integration into clinical protocols necessitates meticulous research and validation. The selection between FNAC and noninvasive approaches is contingent upon various factors, including equipment accessibility, medical expertise, patient preferences, and the specific clinical context. The study's constrained sample size underscores the imperative for larger, prospective investigations to substantiate the efficacy and accuracy of these innovative techniques.

CONCLUSION

This study highlights the value of combining ultrasound elastography and TI-RADS in diagnosing thyroid nodules. The results show that this integration achieves high diagnostic accuracy, particularly for TI-RADS 3 nodules, reducing the need for invasive procedures like FNAC. The strong correlation between ECI values and FNAC results underscores the potential of these noninvasive methods to enhance patient care by improving diagnostic precision and minimizing unnecessary interventions. Further validation and integration into clinical practice are merited.

Conflicts of Interest: The authors declare that there is no conflict of interest regarding the publication of this article.

Funding: The authors declare that writing and publishing this manuscript was not funded by any organization.

Acknowledgment: Appreciating biostatisticians for their invaluable support in article submission, their expertise in statistical analysis and interpretation significantly improved research quality.

Disclosure: This project was part of MD thesis.

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