

## ADVANCES IN THYROID-NODULE DIAGNOSIS: THE IMPACT OF SONOELASTOGRAPHY ON CLINICAL PRACTICE

Jagadesh Krishnamoorthy <sup>1</sup>, Yuvabalakumaran Govindarajar <sup>2</sup>,  
Vinoth Kumar Sundaram <sup>3</sup>, Balameenakshi Bagavathsingh <sup>4</sup>,  
Divya karuppusamy <sup>5</sup> and Sanjay Kanth Balachandar <sup>6\*</sup>

<sup>1,4,5</sup> Junior Resident, Department of Radiodiagnosis, Vinayaka Missions Kirupananda Variyar Medical College and Hospitals, Sankari Main Road (NH-47), Seeragapadi, Salem.

<sup>2</sup> Professor and Head, Department of Radiodiagnosis, Vinayaka Missions Kirupananda Variyar Medical College and Hospitals, Sankari Main Road (NH-47), Seeragapadi, Salem.

<sup>3</sup> Professor, Department of Radiodiagnosis, Vinayaka Missions Kirupananda Variyar Medical College and Hospitals, Sankari Main Road (NH-47), Seeragapadi, Salem.

<sup>6</sup> Junior Resident, Department of Radiodiagnosis, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (Simats) Deemed University, Saveetha Nagar, Thandalam, Chennai.

\*Corresponding Author Email: [sanjaykanth.b@gmail.com](mailto:sanjaykanth.b@gmail.com)

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### Abstract

**Introduction:** The increasing detection of thyroid nodules through advanced imaging techniques highlights the need for non-invasive diagnostic methods. Sonoelastography, a novel ultrasound technique measuring tissue elasticity, appears promising for assessing thyroid nodules. This study aims to evaluate the diagnostic accuracy of sonoelastography in distinguishing benign from malignant thyroid nodules, focusing on its sensitivity, specificity, and correlation with histopathological findings. **Materials and Methods:** The study involved 40 individuals with identifiable thyroid nodules, who underwent high-frequency B-mode ultrasound and sonoelastography, followed by fine needle aspiration cytology (FNAC) for cytological analysis. **Results:** In this investigation, a cohort of 40 participants with clinically identifiable thyroid nodules underwent a diagnostic regimen comprising high-frequency B-mode ultrasound followed by sonoelastography. Each case was further evaluated using fine needle aspiration cytology (FNAC) for cytological analysis. The study found that the concurrent application of sonoelastography and B-mode ultrasound accurately classified thyroid nodules as benign or malignant in 87.5% of instances. Specifically, sonoelastography demonstrated a high sensitivity of 94.1%, indicating its efficacy in correctly identifying malignant nodules. Its specificity was recorded at 81%, reflecting its ability to recognize benign nodules. The positive predictive value, an indicator of the likelihood that patients with a positive screening test truly have the disease, was notably high at 98.2%. Conversely, the negative predictive value, which assesses the probability that patients with a negative screening test are disease-free, was 87%. **Conclusion:** The findings confirm the value of sonoelastography as a reliable and non-invasive method for evaluating thyroid nodules. Its high sensitivity and specificity demonstrate its potential to enhance diagnostic accuracy as an adjunct to B-mode ultrasound, potentially decreasing the need for invasive FNAC and thus reducing patient discomfort and healthcare costs. The successful use of sonoelastography in this study supports its integration with traditional ultrasound techniques to improve diagnostic outcomes. Future research with larger and more varied populations is essential to further validate these results and advance the adoption of sonoelastography in routine clinical practice, potentially transforming the management of thyroid nodule cases.

**Keywords:** Thyroid-nodules, Sonoelastography, Ultrasound imaging, FNAC, Diagnostic Accuracy, Benign Thyroid Lesions

### 1.0 INTRODUCTION

The identification of thyroid-nodules has grown more frequent, primarily due to the extensive adoption of high-resolution imaging methods. Epidemiological research indicates that while 3-8% of the general population exhibit palpable thyroid-nodules, ultrasonography reveals the presence of nodules in a remarkable 19-67% of

individuals [1, 2]. Although the majority of nodules are benign, the possibility of malignancy highlights the necessity for accurate diagnostic techniques to guide clinical decision-making. Traditionally, FNAC has been considered the gold standard for assessing thyroid-nodules, demonstrating a sensitivity range of 65-98% and a specificity range of 72-100% [3]. However, FNAC's invasiveness, coupled with limitations like non-diagnostic samples and indeterminate results, has prompted the search for alternative diagnostic tools. Sonoelastography, a novel non-invasive technique that gauges tissue stiffness, has emerged as a valuable adjunct to conventional ultrasonography. The fundamental idea is that malignant nodules are generally firmer than benign ones, attributable to factors such as heightened cellular density and fibrosis [4]. Recent innovations have improved sonoelastography, augmenting its capacity to discern between benign and malignant thyroid nodules, and potentially diminishing the necessity for invasive interventions [5, 6]. This study seeks to evaluate the diagnostic precision of sonoelastography in categorizing thyroid nodules and its association with histopathological outcomes. By integrating recent findings and technological advancements in the field, we seek to evaluate the potential of sonoelastography to improve patient management and minimize unnecessary interventions.

## **2.0 MATERIALS AND METHODS**

### **2.1 Study Design and Context:**

This cross-sectional research was undertaken at Vinayaka Mission Medical College and Hospital, Salem, Tamil Nadu, spanning from February 2020 to April 2021. The study enlisted a total of 40 patients presenting with clinically palpable thyroid-nodules.

#### **2.1.1 Participants:**

The inclusion criteria encompassed individuals presenting with palpable neck swellings, located either centrally or laterally, and those exhibiting symptoms of hypo- or hyperthyroidism. Exclusion criteria ruled out patients with diffuse thyroid gland enlargement lacking a focal palpable nodule, those with multiple nodular thyroid glands, individuals with a prior history of thyroid disorders and treatments, pregnant women, and those unwilling to partake in the study. Ethical approval was secured from the IEC (Ref: VMKVMC&H/ IEC/20/55), and all participants provided informed consent.

#### **2.2 Imaging Techniques:**

High-resolution B-mode ultrasound and sonoelastography were conducted utilizing a GE LOGIQ F8 equipped with a high-frequency linear transducer. The ultrasound evaluations examined multiple characteristics of the thyroid nodules, such as dimension, contour, position, composition, echogenicity, border definition, presence of a halo, calcifications, and vascular distribution. The "Thyroid Imaging Reporting and Data System (TI-RADS)" was employed for classification based on ultrasound attributes.

#### **2.3 Sonoelastography Technique:**

Sonoelastography was performed promptly following the B-mode ultrasound, with patients positioned supine and their necks extended. The transducer was positioned perpendicular to the thyroid gland's surface, ensuring the nodule was centered in the image. The region of interest (ROI) covered no more than 25% of the lesion, with at

least 5mm of normal surrounding tissue included for comparison. The elastography score was assigned based on the Asteria et al. (2008) scoring system, ranging from 1 to 4 [7].

#### 2.4 Ultrasound-Guided FNAC:

All patients underwent ultrasound-guided FNAC under aseptic conditions using a 22-gauge needle. The procedure was performed at least twice to ensure adequate sampling, and the aspirated material was smeared onto glass slides, fixed in 95% alcohol, and sent for cytological examination.

#### 2.5 Statistical Statement:

Data analysis was conducted utilizing SPSS, version 28. Descriptive statistics were employed to encapsulate the demographic and clinical attributes of the participants. The diagnostic precision of sonoelastography was appraised by computing sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), with FNAC serving as the benchmark standard. A p-value of less than 0.05 was deemed to be statistically significant.

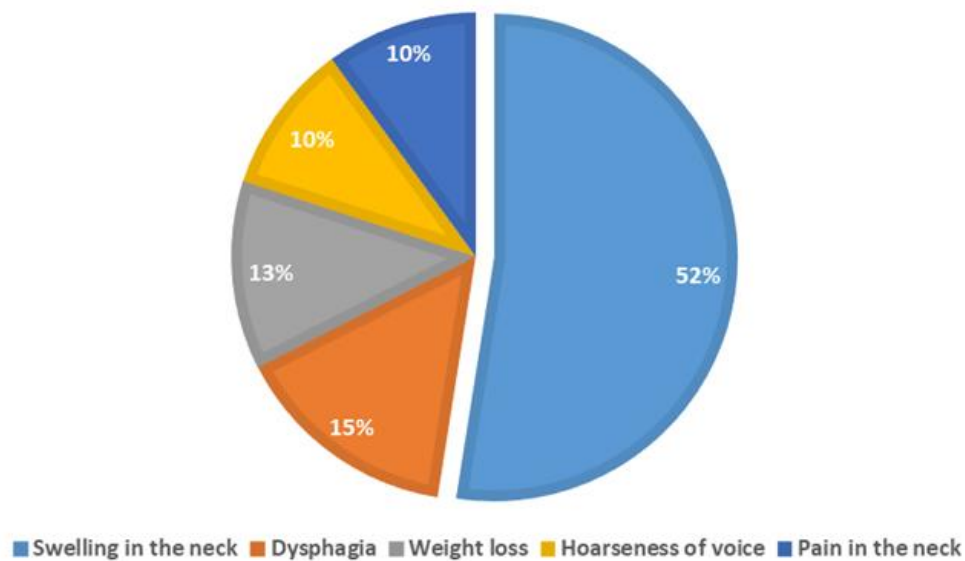
### 3.0 RESULTS

#### 3.1 Demographic and Clinical Characteristics:

The study encompassed 40 patients, with an average age of 48.5 years (ranging from 23 to 71 years). The predominant gender among the participants was female (n=35, 87.5%), with a smaller representation of males (n=5, 12.5%). The most frequent clinical symptom was neck swelling (n=21, 52.5%), succeeded by difficulty swallowing (n=6, 15%), weight reduction (n=5, 12.5%), voice hoarseness (n=4, 10%), and neck pain (n=4, 10%) (Table 1 & Figure 1).

**Table 1: Overview of Participant Demographics, Clinical Presentation, and Diagnostic Findings**

Demographic/Clinical Characteristic	Details
Total Participants	40
Mean Age	48.5 years (range: 23-71 years)
Gender Distribution	Female: 35 (87.5%), Male: 5 (12.5%)
Clinical Presentation	Swelling in the neck: 21 (52.5%)
	Dysphagia: 6 (15%)
	Weight loss: 5 (12.5%)
	Hoarseness of voice: 4 (10%)
	Pain in the neck: 4 (10%)
Ultrasound & Sonoelastography	Right lobe nodules: 22 (55%)
	Left lobe nodules: 18 (45%)
Findings	TI-RADS 2 (benign): 18 (45%)
	TI-RADS 3: 9 (22.5%)
	TI-RADS 4: 8 (20%)
	TI-RADS 5 (malignant): 5 (12.5%)
	Elastography scores: Type-II (soft): 20 (50%)
	Type-III (moderately hard): 13 (32.5%)
	Type-IV (hard): 7 (17.5%)
FNAC Correlation	Type-II: 1 malignant, 19 benign
	Type-III: 2 malignant, 11 benign
	Type-IV: 7 malignant, 0 benign
Diagnostic Accuracy of Sonoelastography	Sensitivity: 94.1%
	Specificity: 81%
	PPV: 98.2%
	NPV: 87%



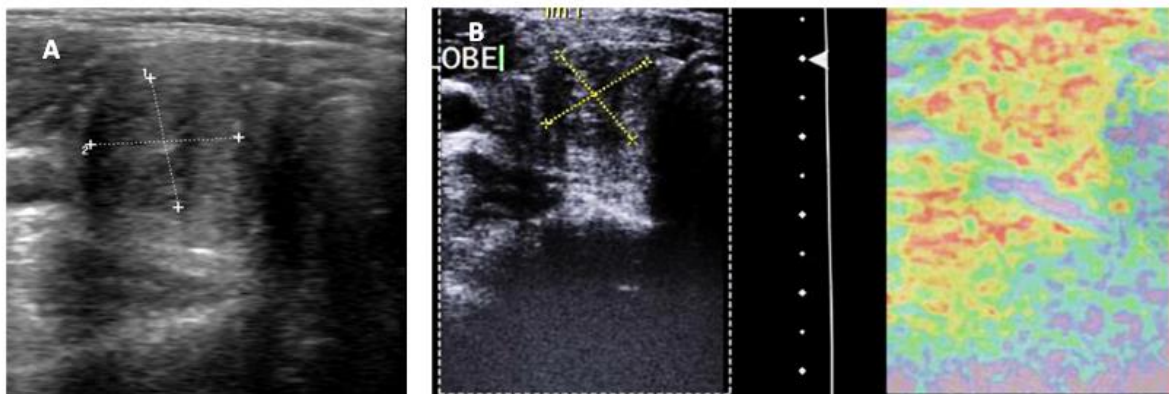
**Figure 1: Clinical presentations of the study participants with the largest share, 52%, experiencing swelling in the neck, followed by 15% with dysphagia, 13% with weight loss, 10% with hoarseness of voice, and another 10% with pain in the neck**

### 3.2 Ultrasound and Sonoelastography Findings:

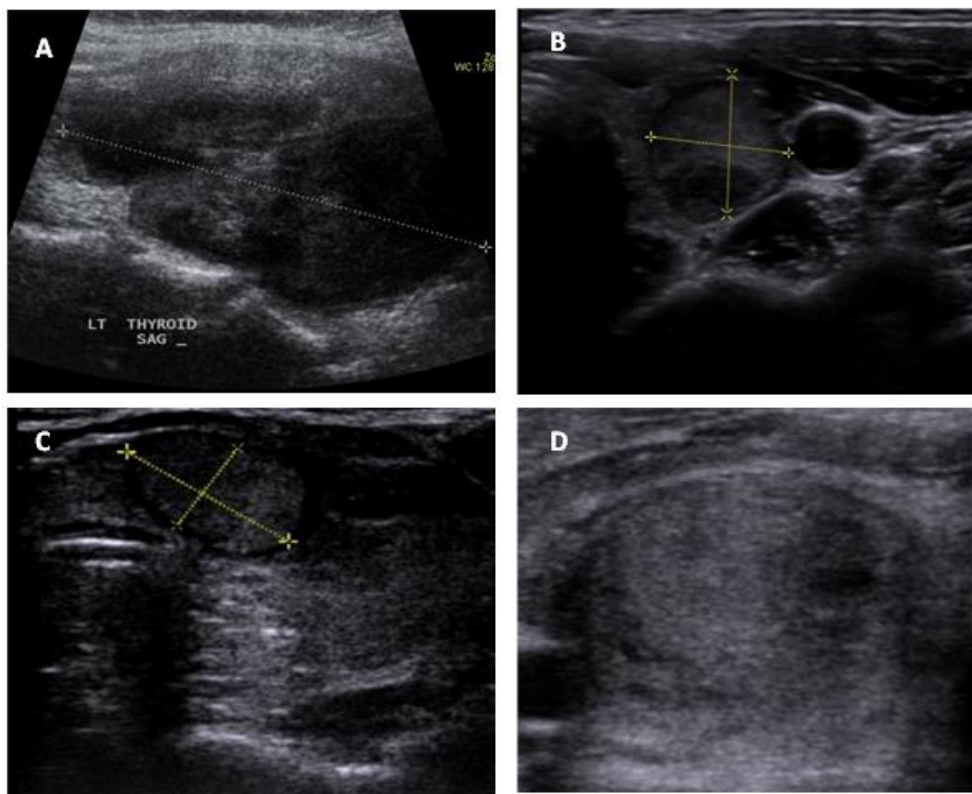
The evaluation of thyroid-nodules through B-mode ultrasound and sonoelastography provided insightful details regarding their anatomical distribution and characteristics. A significant portion of the nodules, constituting 55% (n=22), were identified in the right lobe of the thyroid gland, whereas the left lobe harbored the remaining 45% (n=18) of the nodules. This distribution underscores the importance of thorough examination of both lobes during diagnostic procedures.

The application of the “TI-RADS” scoring system further refined the diagnostic process. A total of 18 nodules, accounting for 45% of the cases, were assigned a “TI-RADS” score of 2, signifying the presence of benign features. This classification aids in reducing unnecessary interventions for nodules with a low likelihood of malignancy. On the other hand, the study identified 9 nodules (22.5%) with a TI-RADS score of 3, 8 nodules (20%) with a score of 4, and 5 nodules (12.5%) with a score of 5. The increasing “TI-RADS” scores correlate with a higher suspicion of malignancy, necessitating further investigation or intervention.

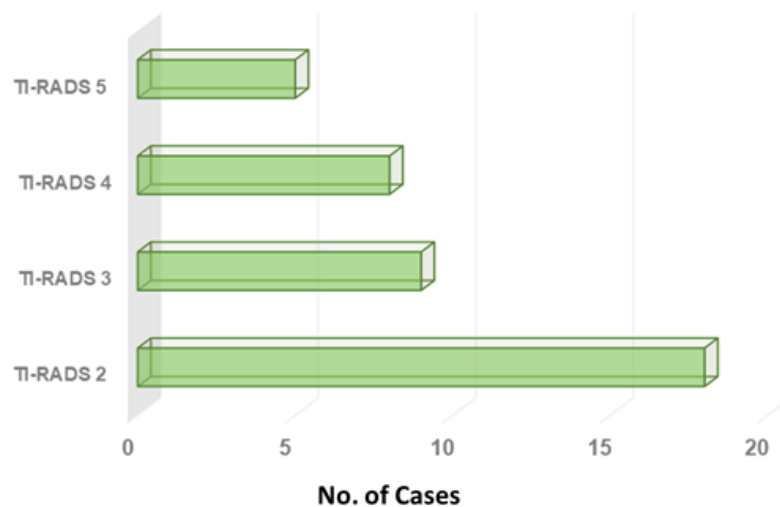
Elastography, a technique assessing the stiffness of the nodules, yielded scores ranging from Type-II (soft) to Type-IV (hard). Half of the nodules (n=20, 50%) were categorized as Type-II, indicating softer consistency, which is often associated with benignity. In contrast, 13 nodules (32.5%) were classified as Type-III (moderately hard), and 7 nodules (17.5%) were deemed Type-IV (hard), suggesting a higher likelihood of malignancy. These elastography scores provide valuable information for risk stratification and aid in the decision-making process for further management of the nodules (Table 1, Figure 2-4).



**Figure 2: (A) The USG image depicts a heterogeneous lesion in the right lobe of the thyroid, characterized by scattered specks of calcification, classified as TI-RADS 4. (B) The color-coded elastogram image portrays the lesion as firm, with an elastography score of 4**



**Figure 3: (A)USG image displays a lobulated heterogeneous hypoechoic lesion featuring septations, categorized as TI-RADS 5. (B) The USG image presents a well-delineated nodule with a cystic component, assigned a TI-RADS 2 classification. (C) The USG image illustrates a well-defined isoechoic nodule encircled by a hypoechoic rim, identified as TI-RADS 3. (D) The USG image depicts a well-delineated solid lesion containing a few cystic components within, designated as TI-RADS 4**



**Figure 4: Distribution of Cases based on TI-RADS scoring system**

### 3.3 Correlation with Histopathology:

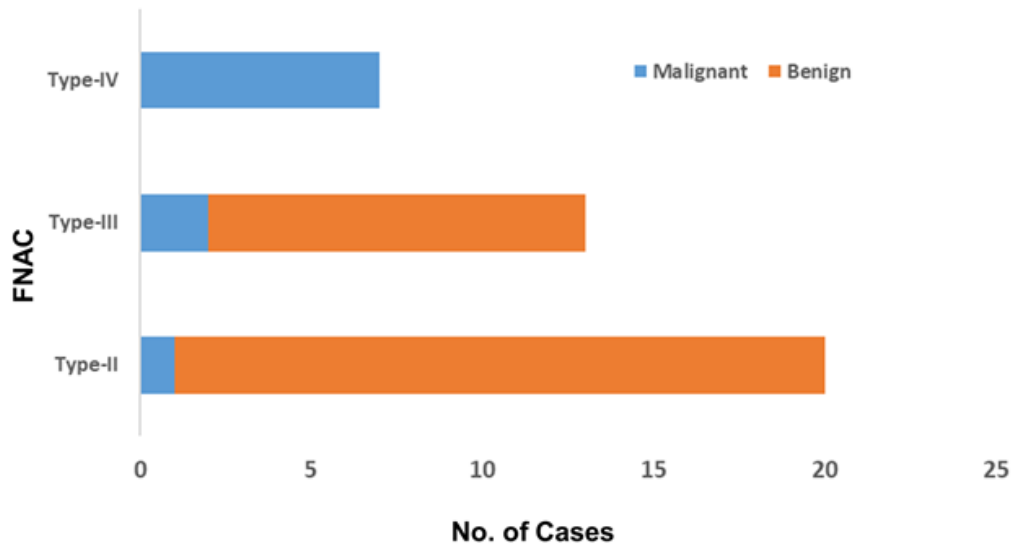
FNAC was performed on all patients to validate the findings obtained from elastography. The correlation between elastography scores and FNAC results provided a deeper understanding of the diagnostic accuracy of sonoelastography. In the group of nodules categorized as Type-II on elastography, which signifies a softer consistency, only one nodule was found to be malignant upon FNAC analysis, while the remaining nodules in this category were confirmed to be benign. This indicates a high level of accuracy in identifying benign nodules using elastography.

For nodules scored as Type-III on elastography, indicative of a moderately hard consistency, a slightly higher rate of malignancy was observed. Out of this group, two nodules were identified as malignant, while eleven were found to be benign. This suggests that while Type-III nodules have a higher likelihood of being malignant compared to Type-II nodules, a significant proportion still remains benign.

In the case of nodules scored as Type-IV on elastography, representing a hard consistency, all seven nodules were confirmed to be malignant through FNAC. This underscores the strong association between a hard consistency on elastography and malignancy, making it a critical marker for identifying potentially malignant thyroid nodules.

The overall sensitivity of sonoelastography, which measures its ability to correctly identify malignant nodules, was found to be 94.1%. This high sensitivity indicates that sonoelastography is highly effective in detecting malignant thyroid nodules. The specificity of the technique, which measures its ability to correctly identify benign nodules, was 81%. This suggests that while sonoelastography is quite accurate, there is still room for improvement in distinguishing benign nodules. The PPV of 98.2% indicates that when sonoelastography suggests a nodule is malignant, it is very likely to be correct. The negative predictive value (NPV) of 87% suggests that when sonoelastography indicates a nodule is benign, it is correct most of the time, but not as reliably as when predicting malignancy.

Overall, these results highlight the potential of sonoelastography as a non-invasive diagnostic tool for differentiating between benign and malignant thyroid nodules, with a strong ability to detect malignancy but a slightly lower accuracy in confirming benignity (Table 1 & Figure 5).



**Figure 5: Distribution of Malignant and Benign cases based on FNAC types**

#### 4.0 DISCUSSION

The increasing identification of thyroid nodules in clinical settings demands the advancement of diagnostic techniques to precisely distinguish between benign and malignant lesions. Our study contributes to this evolving landscape by evaluating the diagnostic utility of sonoelastography, a technique that has gained prominence for its non-invasive nature and ability to provide valuable insights into tissue stiffness.

Recent progress in elastography technology has facilitated more accurate evaluations of nodule stiffness, a key element in differentiating benign from malignant thyroid lesions. Our findings demonstrate a high sensitivity (94.1%) and specificity (81%) of sonoelastography in conjunction with B-mode ultrasound, aligning with contemporary studies that underscore the potential of elastography in enhancing the diagnostic accuracy of conventional ultrasound [5, 6]. The integration of elastography into the diagnostic workflow has shown promise in reducing unnecessary invasive procedures, thereby streamlining patient management [8, 9].

A novel aspect of our study is the application of TI-RADS in conjunction with elastography scores. This approach has facilitated a more structured and standardized assessment of thyroid nodules, thereby improving diagnostic consistency. Our results indicate that nodules classified as Type-IV on elastography exhibited a strong correlation with malignancy, reinforcing findings from recent studies that advocate for the predictive value of higher elastography scores in indicating malignancy [10, 11].

The utility of sonoelastography in the context of TI-RADS categorization represents a significant advancement in the field. By offering an extra dimension of diagnostic data, sonoelastography holds the promise to enhance the risk stratification of thyroid nodules, assisting clinicians in making more informed choices concerning the necessity for FNAC or surgical intervention.

While our study underscores the potential of sonoelastography, it is imperative to acknowledge the limitations inherent to the technique, such as operator dependency and challenges in assessing nodules with complex characteristics. Future studies should aim at overcoming these constraints and investigate the incorporation of artificial intelligence and machine learning algorithms to improve the precision and consistency of elastography measurements [12, 13].

In succinct, our research contributes to the expanding pool of evidence that endorses the utility of sonoelastography as an important complement to B-mode ultrasound in assessing thyroid nodules. The integration of elastography with TI-RADS categorization constitutes a pioneering strategy that shows potential in enhancing the diagnostic precision and clinical management of thyroid-nodules.

## 5.0 CONCLUSION

Our research underscores the potential of sonoelastography as a valuable adjunct to B-mode ultrasound in the comprehensive evaluation of thyroid nodules. By providing additional insights into tissue stiffness, sonoelastography enhances the diagnostic accuracy in distinguishing between benign and malignant nodules. The integration of elastography scores with the “TI-RADS” classification further refines the risk stratification of thyroid nodules, aiding clinicians in making informed decisions regarding the necessity for further diagnostic procedures. Future studies should aim to address the limitations of sonoelastography and explore the integration of advanced technologies, such as artificial intelligence and machine learning algorithms, to further enhance its diagnostic utility in the management of thyroid-nodules.

### Conflict of Interest:

The authors declare that they have no conflict of interest related to the content of this study.

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