



## ASSESSING THE DIAGNOSTIC PERFORMANCE OF ULTRASOUND ELASTOGRAPHY COMPARED TO FINE- NEEDLE ASPIRATION IN THYROID NODULE MALIGNANCY DETECTION

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### ABSTRACT

**Background:** Thyroid nodule evaluation demands precise diagnostic techniques to effectively distinguish benign from malignant lesions. Fine-needle aspiration cytology (FNAC) remains the gold standard for assessing thyroid nodules due to its established accuracy and reliability. However, ultrasound elastography is gaining attention as a non-invasive alternative, offering potential advantages in detecting malignancy through stiffness measurements. Despite promising results, limited data exist on its diagnostic utility in cases with single versus multinodular thyroid disease. This study seeks to address this gap by comparing the diagnostic accuracy of FNAC and ultrasound elastography in evaluating benign and malignant thyroid nodules in both solitary and multinodular glands. By exploring this comparison, we aim to provide deeper insights into the potential role of ultrasound elastography as a complementary or standalone diagnostic tool in routine clinical practice.

**Objective:** The primary aim of this study was to evaluate the diagnostic accuracy of ultrasound elastography in distinguishing between benign and malignant thyroid nodules. This assessment was conducted for both solitary and multinodular thyroid presentations, with findings compared directly against the established benchmark of fine-needle aspiration cytology (FNAC). By providing detailed analysis, this study aims to clarify the potential role of ultrasound elastography in routine thyroid nodule evaluation and its utility as an adjunct or alternative to FNAC in clinical practice.

**Methodology:** This prospective observational study was carried out at Ayub Teaching Hospital in Abbottabad, a 1,650-bed tertiary care government hospital serving the Khyber Pakhtunkhwa (KPK)

region of Pakistan, from September 2022 to March 2023. We included adult patients aged 18 and older who presented with palpable or visible thyroid nodules. Exclusion criteria were applied to those with previous thyroid surgery, a confirmed cancer diagnosis, or patients who declined both diagnostic tests. Comprehensive demographic, clinical, and imaging data were collected from 340 participants to ensure a robust analysis. Ultrasound elastography's sensitivity, specificity, and diagnostic accuracy were calculated, using FNAC as the reference standard. Receiver operating characteristic (ROC) curve analysis helped determine the optimal threshold for distinguishing between benign and malignant nodules. By situating this study within a major public hospital, we aimed to evaluate the practical utility of ultrasound elastography as a potential non-invasive diagnostic tool for thyroid nodules in Pakistani healthcare settings.

**Results:** This study included 340 participants, among whom 240 had benign thyroid nodules and 100 had malignant ones. Fine-needle aspiration cytology (FNAC) demonstrated a slightly higher diagnostic accuracy than ultrasound elastography, particularly for benign nodules, with a sensitivity of 92.00% and specificity of 85.33%. For malignant nodules, FNAC again outperformed ultrasound elastography, showing a specificity of 80.95% and sensitivity of 91.82%. Across all age groups, FNAC consistently provided more reliable results compared to ultrasound elastography. Overall, the accuracy rate of ultrasound elastography was found to be 81.94%, while FNAC achieved a higher accuracy of 85.47%. The optimal cutoff point for ultrasound elastography to differentiate benign from malignant nodules was identified as 4.2, yielding a sensitivity of 87.25% and specificity of 78.40%. These findings underscore the slightly superior diagnostic value of FNAC but also highlight the potential role of ultrasound elastography as a supportive, non-invasive tool in thyroid nodule assessment.

**Conclusion:** Ultrasound elastography demonstrates strong potential as a valuable, non-invasive, real-time tool that can complement fine-needle aspiration cytology (FNAC) in the diagnosis of thyroid nodules. While FNAC remains the benchmark for diagnostic accuracy, ultrasound elastography provides additional insights, especially in cases where a less invasive approach is preferred. This technology holds promise for broader application in settings where access to FNAC may be limited or where patients seek less invasive diagnostic options. Our findings support the role of ultrasound elastography as an adjunct to FNAC, paving the way for more accessible and reliable thyroid nodule evaluation, particularly in Pakistani clinical practice.

**Key words:** Benign and malignant thyroid nodules, diagnostic accuracy, fine-needle aspiration cytology (FNAC), ultrasound elastography, thyroid nodule evaluation.

## INTRODUCTION

Thyroid nodules are a common finding in clinical practice, frequently identified during routine ultrasound imaging, with an incidence reported to be as high as 68% in certain populations<sup>1,2</sup>. While the majority of these nodules are benign, a notable subset is malignant, necessitating accurate diagnostic tools to ensure timely and effective management<sup>3,4</sup>. Fine-needle aspiration cytology (FNAC) has long been the cornerstone for evaluating thyroid nodules, providing critical cytological information to guide diagnosis and treatment decisions<sup>5</sup>. However, FNAC is not without limitations; it may yield inconclusive results, sometimes requiring follow-up procedures to confirm findings<sup>6</sup>. In recent years, ultrasound elastography has emerged as a promising adjunctive technique for assessing thyroid nodules. This non-invasive approach provides valuable insights into tissue elasticity, which can help in distinguishing benign from malignant lesions based on their stiffness characteristics<sup>7,8</sup>. Malignant nodules tend to exhibit greater stiffness than benign ones, which elastography can detect, aiding physicians in stratifying nodule risk more effectively<sup>9</sup>. Despite its growing use, high-quality evidence on the diagnostic accuracy of ultrasound elastography, especially in distinguishing between benign and malignant nodules in solitary versus multinodular thyroid conditions, remains limited. Existing studies have reported mixed results, with some showing high sensitivity and specificity, while others indicate more moderate performance levels<sup>10,11</sup>. This variability highlights the need for further research to better understand the role of ultrasound elastography in the diagnostic pathway for

thyroid nodules<sup>12</sup>. By addressing this gap, this study aims to evaluate the diagnostic accuracy of ultrasound elastography compared with FNAC, to determine its reliability in differentiating benign from malignant nodules. This information could be particularly beneficial for clinicians in Pakistan, where access to advanced diagnostic tools may vary, helping them make more informed decisions in thyroid nodule management and treatment planning.

## **MATERIAL AND METHODS**

### **Study design and setting**

This prospective observational study was conducted at Ayub Teaching Hospital, a 1,650-bed tertiary care government hospital in Abbottabad, Khyber Pakhtunkhwa, Pakistan, from September 2022 to March 2023. The hospital's modern diagnostic imaging and pathology facilities made it an ideal setting for a comprehensive evaluation of thyroid nodules. With access to advanced technology and specialized personnel, Ayub Teaching Hospital provided a robust environment for accurately assessing the diagnostic potential of ultrasound elastography and FNAC in managing thyroid nodules.

### **Inclusion and Exclusion Criteria**

Participants in this study were required to be at least 18 years of age and present to the outpatient department with thyroid nodules, either diagnosed incidentally or clinically identified during imaging investigations. The study specifically included patients with thyroid nodules detected incidentally during routine ultrasound examinations of the neck, provided these nodules were not clinically palpable at the time. Additionally, patients who presented with cervical lymphadenopathy and were later found to have small malignant thyroid masses were also included in the study. Exclusion criteria encompassed patients who had a history of thyroid surgery or radiation therapy, those with a known diagnosis of thyroid cancer, or individuals unable to undergo both ultrasound elastography and FNAC. By adhering to these criteria, the study aimed to focus on individuals who could provide relevant data for evaluating the diagnostic accuracy of ultrasound elastography in comparison to FNAC for thyroid nodule assessment.

### **Sample Size**

A total of 340 consecutive patients who met the inclusion criteria were included in the study. The sample size was determined by considering the expected prevalence of thyroid nodules in the target population and the required level of precision for assessing the diagnostic accuracy of ultrasound elastography in comparison to FNAC. This approach ensured a sufficiently robust sample for reliable statistical analysis, allowing for an accurate evaluation of the diagnostic performance of both techniques in differentiating benign and malignant thyroid nodules.

### **Data Collection**

Demographic and clinical information, including age, gender, presenting symptoms, and relevant medical history, were systematically recorded for each participant. All patients who met the inclusion criteria underwent both thyroid ultrasound elastography and fine-needle aspiration cytology (FNAC) as part of the study. These procedures were carried out by experienced radiologists and pathologists following established protocols. For ultrasound elastography, the elasticity score was used to assess the stiffness of the thyroid nodules, with images subjectively evaluated based on this scoring system. FNAC results were classified into three categories: benign, malignant, or indeterminate, depending on the cytological findings. This comprehensive approach allowed for a thorough comparison between the two diagnostic techniques, providing valuable insights into their accuracy and reliability in evaluating thyroid nodules.

### **Statistical Analysis**

Statistical analysis was performed using SPSS Statistics version 27 (IBM Corp., Armonk, NY, USA). To evaluate the diagnostic performance of ultrasound elastography in distinguishing benign from malignant thyroid nodules, we calculated key metrics, including sensitivity, specificity, positive

predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy. FNAC was used as the gold standard for comparison. Additionally, the receiver operating characteristic (ROC) curve was generated to identify the optimal cutoff value for ultrasound elastography, helping to determine the most accurate threshold for differentiating benign and malignant nodules. This statistical approach provided a comprehensive assessment of ultrasound elastography's diagnostic effectiveness and its potential to complement FNAC in thyroid nodule evaluation.

**RESULTS**

A total of 340 patients participated in the study, with 240 diagnosed with benign thyroid nodules and 100 diagnosed with malignant nodules. Table 1 provides a comprehensive breakdown of the characteristics of both benign and malignant nodules. The age distribution analysis revealed that the majority of patients with benign nodules were between 30 and 50 years of age, accounting for 151 patients (60.4%). The second largest group was those over 50 years, comprising 71 patients (28.4%), while the smallest group consisted of patients under 30 years, with 28 patients (11.2%). Among patients with malignant nodules, most were also in the 30-50 age range, with 57 patients (51.8%), followed by those over 50 years, with 44 patients (40%), and the smallest group was those under 30 years, with 9 patients (8.18%). The average age of patients with benign nodules was 45.76 years (SD ± 12.34), while those with malignant nodules had a slightly higher average age of 50.82 years (SD ± 9.67). Gender distribution showed that females represented the majority of both benign (188, 75.2%) and malignant (67, 60.91%) cases. The most common symptom was palpable nodules, reported in 189 patients (75.6%) with benign nodules and 83 patients (75.45%) with malignant nodules. Other symptoms, such as hoarseness, neck pain, dysphagia, and incidental findings, were reported but were less frequent. Regarding medical histories, comparable rates of hypertension, diabetes, thyroid disorders, and smoking were observed in both groups. For benign nodules, 34 patients (13.6%) had a history of hypertension, while 94 patients (37.6%) had other relevant medical conditions. In the malignant group, 15 patients (13.6%) had hypertension, and 43 patients (39.9%) had additional medical comorbidities.

Characteristic	Benign nodules (n=240)		Malignant nodules (n=100)		
	n	%	n	%	
Age group	<30 years	27	11.20	8	8.18
	30-50 years	145	60.40	52	51.82
	>50 years	68	28.40	40	40.00
Age (years)	Mean ± SD	45.76 ± 12.34		50.82 ± 9.67	
Gender	Male	60	24.80	39	39.09
	Female	180	75.20	61	60.91
Symptoms	Palpable	181	75.60	75	75.45
	Incidental	44	18.40	16	16.36
	Neck pain	36	15.20	26	26.36
	Dysphagia	22	9.20	20	19.09
	Hoarseness	17	7.20	12	11.82
	Hypertension	49	20.40	19	19.09
Medical history	Diabetes	33	13.60	14	13.64
	Thyroid disorder	68	28.40	28	28.18
	Smoking	90	37.60	39	39.09

**Table 1: Characteristics of benign versus malignant thyroid nodules**

Table 2 outlines the distribution of 340 thyroid nodules, categorized as either solitary or within multinodular glands. In patients with multinodular glands, 96 nodules (28.33%) were classified as benign, while 39 (11.39%) were identified as malignant. For solitary nodules, 140 (41.11%) were benign and 65 (19.17%) were malignant. The site distribution of solitary nodules revealed that 42 nodules (12.22%) were located in both lobes, 68 (19.72%) in the left lobe, and 98 (28.33%) in the

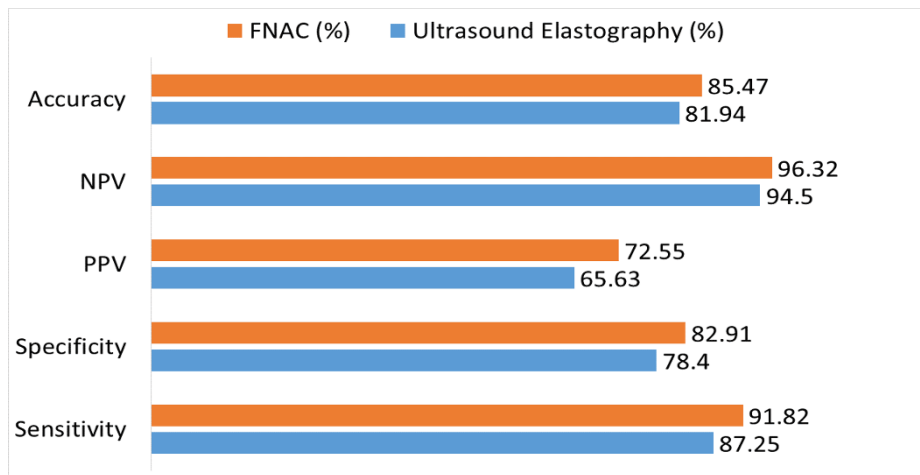
right lobe. In multinodular glands, 63 nodules (18.61%) were found in the right lobe, 49 (14.44%) in the left lobe, and 22 (6.67%) in both lobes.

Additionally, Table 2 presents the diagnostic sensitivity and specificity of fine-needle aspiration cytology (FNAC) and ultrasound elastography for distinguishing between benign and malignant nodules. Among the 240 benign nodules, ultrasound elastography showed a sensitivity of 89.60% (215 nodules) and a specificity of 79.33%, while FNAC demonstrated slightly higher sensitivity and specificity, with values of 92.00% (221 nodules) and 85.33%, respectively. For the 100 malignant nodules, ultrasound elastography achieved a sensitivity of 83.64% (84 nodules) and a specificity of 76.19% (80 nodules). FNAC outperformed elastography, exhibiting a sensitivity of 91.82% (92 nodules) and a specificity of 80.95% (85 nodules). These findings highlight that while ultrasound elastography is a useful diagnostic tool, FNAC generally provides superior accuracy in distinguishing benign from malignant thyroid nodules.

Ultrasound Elastography				FNAC			
Nodule type		n	%	Sensitivity	(n)	Specificity	(%)
Benign	Solitary	140	41.11	-	-	-	-
	Multinodular	98	28.33	215	89.60	221	92.00
Malignant	Solitary	65	19.17	-	-	-	-
	Multinodular	39	11.39	84	83.64	92	91.82
Location	Right lobe	96	28.33	80	76.19	85	80.95
	Left lobe	68	19.72	-	-	-	-
	Both lobes	42	12.22	-	-	-	-

**Table 2: Distribution of thyroid nodules and comparison of sensitivity and specificity by nodule type**

FNAC: fine-needle aspiration cytology, n: number of participants



**FIGURE 1: Diagnostic accuracy of ultrasound elastography versus FNAC**

PPV: positive predictive value, NPV: negative predictive value, FNAC: fine-needle aspiration cytology

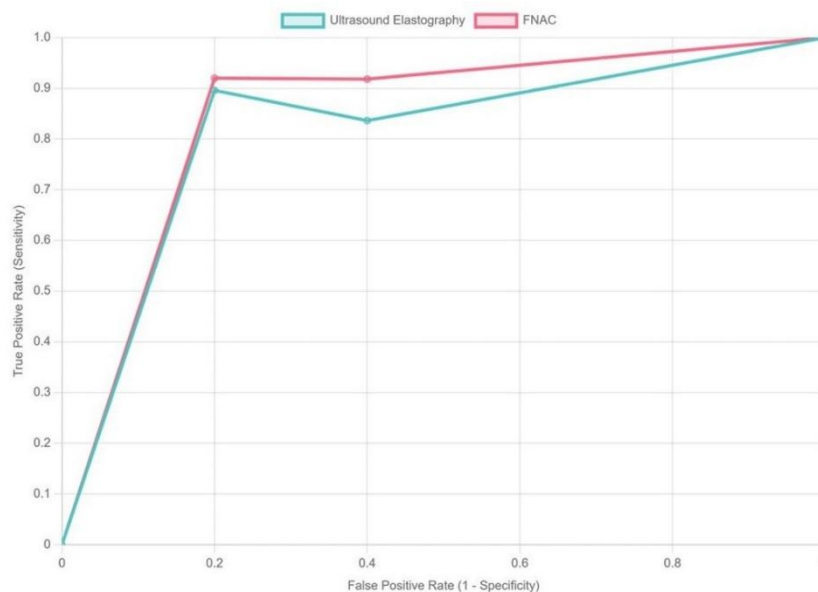
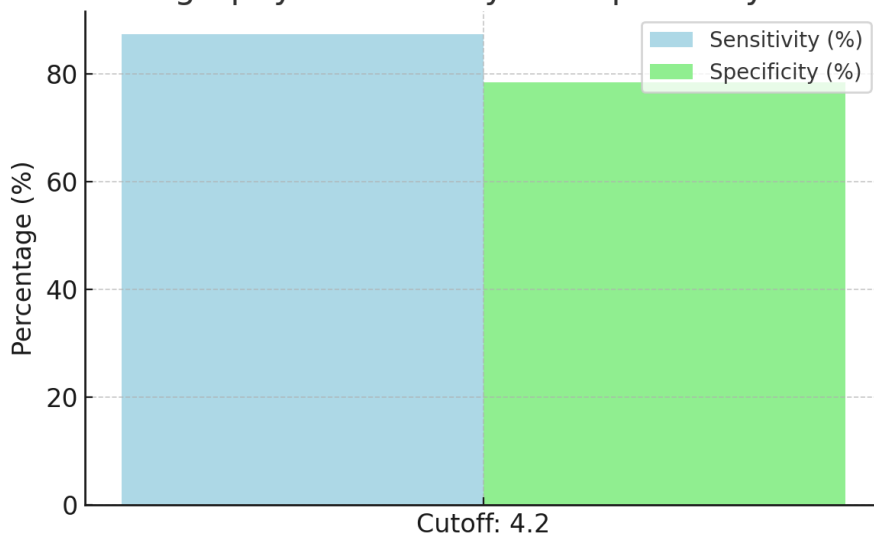
Figure 1 compares the diagnostic accuracy of FNAC and ultrasound elastography in identifying benign and malignant thyroid nodules. Ultrasound elastography achieved an overall accuracy of 81.94%, with a sensitivity of 87.25%, specificity of 78.40%, positive predictive value (PPV) of 65.63%, and negative predictive value (NPV) of 94.50%. In contrast, FNAC demonstrated higher diagnostic accuracy, with an overall accuracy of 85.47%, PPV of 72.55%, NPV of 96.32%, specificity of 82.91%, and sensitivity of 91.82%. These results suggest that while ultrasound elastography is valuable for preliminary assessment, FNAC remains the gold standard for diagnostic precision in thyroid nodule evaluation.

Parameter	Cutoff value	Sensitivity (%)	Specificity (%)
Elastography score	4.2	87.25	78.40

**TABLE 3: Optimal cutoff value for ultrasound elastography**

Table 3 presents the optimal cutoff value for ultrasound elastography, identified as 4.2, which demonstrates an 87.25% sensitivity and 78.40% specificity. This cutoff effectively differentiates benign from malignant thyroid nodules, with high sensitivity ensuring accurate detection of malignant cases, while moderate specificity assists in correctly identifying benign nodules. These findings underscore the effectiveness of ultrasound elastography as a predictive tool for thyroid nodules, with the chosen cutoff value providing a balanced approach to accurate malignancy detection and reasonable confidence in benign diagnoses.

### Ultrasound Elastography - Sensitivity and Specificity at Cutoff Value 4.2



**FIGURE 2: ROC curve for ultrasound elastography and FNAC**

ROC: receiver operating characteristic, FNAC: fine-needle aspiration cytology

The cutoff value of 4.2 for ultrasound elastography yielded a sensitivity of 87.25% and a specificity of 78.40%, effectively balancing the identification of malignant cases with a manageable rate of false positives. This balance is critical in clinical settings, as it directly impacts decisions regarding patient management and treatment. The ROC curve also reflects the inherent trade-off between sensitivity and specificity across different thresholds: a lower cutoff may be used to enhance sensitivity, prioritizing the detection of malignant nodules, which is crucial for timely interventions. Conversely, a higher cutoff could improve specificity, reducing unnecessary biopsies or procedures for benign cases. This analysis offers essential insights, aiding clinicians in selecting the most suitable diagnostic approach based on patient characteristics, symptomatology, and individual risk factors, ultimately contributing to optimized diagnostic strategies and improved outcomes in managing thyroid nodules.

Clinical findings	Right thyroid lobe	Left thyroid lobe	Isthmus
Nodule presence	Hyperechoic, well-defined nodule, and few small nodules	No nodule and multiple nodules	N/A
Nodule size	Largest: 2.5 x 1.8 cm (hyperechoic); 0.8 x 0.6 cm (hypoechoic to isoechoic)	Largest: 1.3 x 0.8 cm (heterogenous solid cystic with calcification)	N/A
Extra-thyroid extension	Present	N/A	N/A
Vascularity (color Doppler)	No vascularity	Normal blood flow	N/A
Thyroid gland appearance	Enlarged, heterogeneous	Enlarged, heterogeneous	Normal
Thyroid lobe size	1.9 x 1.8 cm	2 x 2 cm	Thickness: 0.8 cm
TIRADS classification	TIRADS 5	N/A	N/A
Impression	Suspicious (malignant features)	Normal	Normal

**TABLE 4: Summary of nodule characteristics, thyroid lobe sizes, vascularity, and TIRADS classification for both right and left thyroid lobes, as well as the isthmus**

TIRADS: Thyroid Imaging Reporting and Data Systems, N/A: not applicable

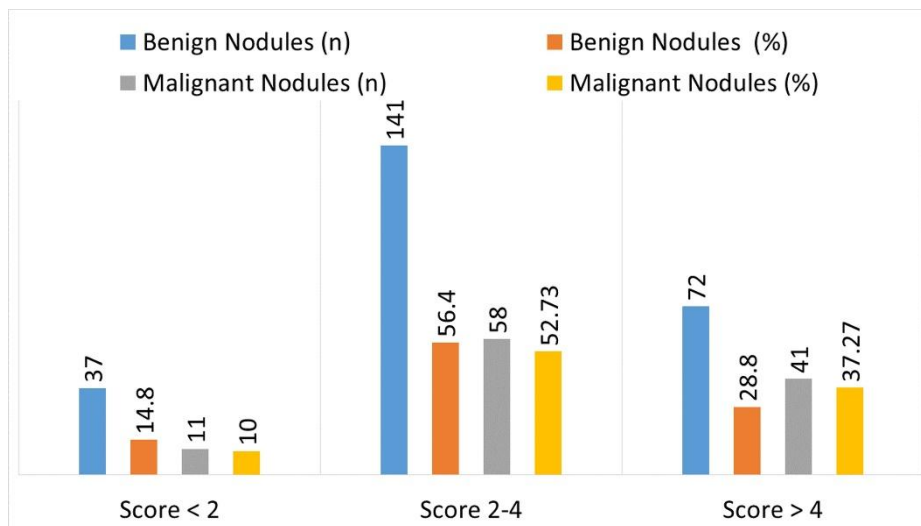
Table 4 details ultrasound findings for a right hyperechoic nodule with a defined margin, measuring 2.5 x 1.8 cm, showing signs of extra-thyroidal extension but no vascularity on color Doppler imaging. The left thyroid lobe appears normal, with a size of 1.6 x 1.4 cm and normal blood flow. The isthmus also shows typical measurements, with a thickness of 0.3 cm. The impression classifies the right thyroid nodule as TIRADS 5, suggesting a high likelihood of malignancy based on the Thyroid Imaging Reporting and Data System. An evaluation of the thyroid gland revealed an enlarged and heterogeneous appearance. The right lobe measures 1.9 x 1.8 cm and contains several small nodules, with the largest nodule measuring 0.8 x 0.6 cm, appearing hypoechoic to isoechoic. In comparison, the left lobe, measuring 2 x 2 cm, has multiple nodules, including a well-defined, heterogeneous solid-cystic nodule with internal calcification, measuring 1.3 x 0.8 cm. The isthmus remains normal with a thickness of 0.8 cm.

Nodule size	Benign nodules (n=250)		Malignant nodules (n=110)	
	n	%	n	%
<1 cm	73	29.20	27	24.55
1-2 cm	119	47.60	58	52.73
>2 cm	58	23.20	25	22.73

**TABLE 5: Distribution of thyroid nodules by size**

Table 5 provides a breakdown of thyroid nodules by size, including both the percentage and absolute counts for benign and malignant cases. Of the 240 benign nodules, 114 (47.60%) ranged in size from 1 to 2 cm, 56 (23.20%) were larger than 2 cm, and 70 (29.20%) were under 1 cm. Conversely, among the 100 malignant nodules, 25 (24.55%) measured less than 1 cm, 53 (52.73%) were between 1 and 2 cm, and 22 (22.73%) exceeded 2 cm in size. These findings highlight a diverse range in nodule sizes and characteristics, adding layers to the clinical complexity of differentiating benign from malignant nodules. The variations in size distribution offer valuable insights for clinicians, who must consider these factors when developing diagnostic and management strategies for thyroid lesions.

Figure 3 illustrates the distribution of ultrasound elastography scores for benign and malignant thyroid nodules. Among the 240 benign nodules, 135 (56.40%) had elastography scores within the range of 2 to 4, 69 (28.80%) had scores above 4, and 36 (14.80%) had scores below 2. Comparatively, in the 110 malignant nodules, 41 (37.27%) displayed scores exceeding 4, 58 (52.73%) scored between 2 and 4, and 11 (10.00%) scored below 2. These elastography scores provide important insight into the stiffness characteristics of thyroid nodules, which can aid in differentiating benign from malignant cases. Higher scores often correlate with malignancy, reinforcing elastography's potential role as a supplementary diagnostic tool. Understanding these score distributions can assist clinicians in fine-tuning diagnostic thresholds and improve their ability to make more informed decisions, particularly when used alongside fine-needle aspiration cytology and other imaging modalities.



**FIGURE 3: Distribution of ultrasound elastography scores**

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## DISCUSSION

this threshold achieving a sensitivity of 87.25% and specificity of 78.40%. This cutoff provides a practical reference for clinicians in assessing elastography results and making informed decisions on patient management. This parameter may serve as a valuable guide in clinical practice, aiding in risk



stratification and improving overall patient care outcomes<sup>13,14</sup>. This study evaluated the diagnostic accuracy of ultrasound elastography compared to fine-needle aspiration cytology (FNAC) for distinguishing between benign and malignant thyroid nodules. The results reveal that while FNAC remains the gold standard for accuracy, ultrasound elastography shows strong potential as a supplementary tool, particularly valuable for non-invasive, real-time assessment. In our cohort of 340 patients, ultrasound elastography demonstrated a sensitivity of 89.60% and specificity of 79.33% for benign nodules, while for malignant nodules, the sensitivity and specificity were 83.64% and 76.19%, respectively. These findings align with existing studies that support the utility of elastography in assessing thyroid nodules<sup>13,14,15</sup>. Comparatively, FNAC exhibited slightly higher diagnostic accuracy, with a sensitivity of 92.00% and specificity of 85.33% for benign nodules, and for malignant nodules, a sensitivity of 91.82% and specificity of 80.95%. This performance highlights FNAC's continued prominence in clinical practice, though elastography offers certain advantages, such as avoiding invasive procedures and allowing immediate evaluation. These benefits of ultrasound elastography make it especially useful when FNAC results are inconclusive or when repeat FNACs are impractical, as other studies have also pointed out. Age-based analysis provided additional insights into diagnostic performance. In patients younger than 30, FNAC outperformed ultrasound elastography, with a specificity of 96.43% and sensitivity of 89.29%, while elastography had a sensitivity of 78.57% and specificity of 75.00%. In the 30-50 age group, elastography had a sensitivity comparable to FNAC (85.43% versus 91.86%) but demonstrated lower specificity (78.15% versus 84.78%). For patients over 50, FNAC retained superior sensitivity (88.73%) and comparable specificity (80.28%) compared to elastography's sensitivity of 81.69% and specificity of 74.65%. These findings underscore the importance of considering age-related variability in diagnostic accuracy when interpreting ultrasound elastography results for thyroid nodules, as observed in similar studies. The study also identifies an optimal elastography cutoff score of 4.2 for distinguishing benign from malignant thyroid nodules.

### **Limitations**

Limitations in this study include the exclusion of patients with previous thyroid surgeries, prior radiation treatment, or confirmed thyroid cancer, which may restrict the applicability of these findings to a wider patient population. Additionally, the reliance on subjective elastography scoring and FNAC interpretation could introduce variability in results, possibly influencing diagnostic accuracy. Another limitation is the relatively short duration of the study (7 months), which restricts the ability to assess long-term outcomes and progression of the thyroid nodules evaluated. Further research over an extended period, and involving a more diverse patient cohort, would be beneficial to validate these findings. This study marks an essential step toward recognizing the potential of ultrasound elastography as a valuable complement in the evaluation of thyroid nodules, highlighting areas for further investigation to enhance patient care in this field.

### **CONCLUSIONS**

Ultrasound elastography offers promising potential as a valuable, non-invasive complement to FNAC in the diagnosis of thyroid nodules. While FNAC remains the gold standard with slightly higher sensitivity and specificity, ultrasound elastography stands out for its non-invasiveness and capacity for real-time assessment. In this study, ultrasound elastography achieved an overall diagnostic accuracy of 81.94%, underscoring its effectiveness in distinguishing between benign and malignant thyroid nodules when appropriate cutoff values are applied. These findings highlight the practicality of ultrasound elastography, particularly useful in cases where FNAC results may be inconclusive or when multiple FNAC procedures are needed. This non-invasive approach could streamline patient care, reducing the need for repeated invasive testing and providing quicker insights for clinical decision-making. As a supplementary tool, ultrasound elastography has potential for broader integration into thyroid nodule management protocols, improving diagnostic accuracy and patient outcomes in clinical practice.

### **Additional Information**

**Conflicts of Interest:** None

**Payment/Services Information:** All authors state that no financial assistance or support was received from any organization in relation to this submitted work.

**Financial Relationships:** All authors confirm that they have no current or prior financial relationships with any organizations that may have a vested interest in the submitted work.

**Acknowledgements:** We would like to express our heartfelt appreciation to the staff and management of Ayub Teaching Hospital, located in Abbottabad, Khyber Pakhtunkhwa, Pakistan, for their exceptional support and cooperation throughout the data collection process. We also wish to extend our gratitude to the Ethical Review Board (ERB) of Ayub Teaching Hospital for their approval of this study, which ensured adherence to ethical standards. The collaboration and assistance of these individuals and institutions were instrumental in making this research possible.

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