

# DIAGNOSTIC ACCURACY OF TIRADS (THYROID IMAGING REPORTING AND DATA SYSTEM) IN IDENTIFYING THYROID NODULES ON ULTRASOUND, USING BETHESDA CYTOLOGICAL CATEGORIES FROM FINE NEEDLE ASPIRATION CYTOLOGY AS THE GOLD STANDARD

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## ABSTRACT

**Background & Objectives:** To determine the diagnostic accuracy of TIRADS (Thyroid Imaging Reporting and Data System) in identifying thyroid nodules on ultrasound, using Bethesda Cytological categories from Fine Needle Aspiration Cytology as the gold standard.

**Methods:** 130 patients, diagnosed with both; solitary nodules and multi-nodular goiters were included. TIRADS scoring by using ultrasound was done. Fine needle aspiration cytology (FNAC) was done and the Bethesda category was recorded. All the data was analyzed in SPSS v.25.

**Results:** The mean age of patients was  $38.6 \pm 15.6$  years. There were 51.5% males and 48.5% females. The average nodule size was  $2.52 \pm 1.10$  cm, with 52.3% having solitary nodules and 47.7% multi-nodularity. FNAC Bethesda showed high sensitivity (85.7%–100%) and diagnostic accuracy (86.6%–98.4%), with better performance in larger nodules, females, and nodules present for over eight months. Positive TIRADS and Bethesda scores were found in 35.4% and 38.5% of patients, respectively.

**Conclusion:** FNAC Bethesda and TIRADS demonstrated high diagnostic sensitivity and accuracy, especially in larger nodules, solitary nodularity, females, and prolonged swelling.

**Key Words:** Thyroid nodules, Ultrasonography, Diagnostic accuracy, Cytology

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Thyroid disorders are prevalent globally, with a significant number of adults experiencing palpable nodules.<sup>1</sup> In India alone, an estimate of about 42 million people suffer from thyroid disorders.<sup>2</sup> Since there is lack of data regarding the prevalence of thyroid disorders in Pakistan however studies suggest that hypothyroidism in Pakistani adults is about 4.1% and in children it is about 5.4%.<sup>3</sup>

The incidence of thyroid cancer is increasing, although most nodules are benign. Physical examination detects nodules in about 5% of cases, while incidental findings on ultrasonography indicate a prevalence ranging from 20% to 76%.<sup>4</sup> One of the most prevalent cancers of the head and neck area is thyroid carcinoma. In the majority of nations, mortality rates for both sexes were less than one per 100,000.<sup>5,6</sup>

Even though the majority of goiters are benign, it's crucial to identify those that may be cancerous. The main imaging technique used to assess goiters is ultrasound. On ultrasound, some characteristics of thyroid nodules are linked to cancer. To detect malignant traits in thyroid nodules, various TIRADS have been created over time. To give each nodule a TIRADS score, these algorithms take into account elements including composition, echogenicity, form, borders, and echogenic foci. Malignant hypoechoic solid nodules are more likely to be taller

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than wide, have irregular or poorly defined borders, have microcalcifications, or exhibit extrathyroidal expansion. Clinicians use the TIRADS score to help them decide if FNAC is necessary for a nodule. By enabling targeted sampling of worrisome nodules, ultrasound-guided FNAC lessen the need for needle procedures on benign thyroid nodules. There are currently several TIRADS systems in use, all of which seek to detect cancerous characteristics in thyroid nodules by ultrasonography.<sup>7,8</sup>

According to one study, involving 210 patients with a total of 233 thyroid nodules, the sensitivity of TIRADS was 83%, specificity was 96.4%, and diagnostic accuracy was 94.1%. The researchers concluded that TIRADS is a valuable diagnostic classification system for predicting malignancy, and its use in conjunction with FNAC utilizing the Bethesda classification can help avoid unnecessary surgical procedures.<sup>9</sup>

The rationale for this study stems from the need to enhance the diagnostic accuracy and decision-making process in evaluating thyroid nodules. While there have been numerous studies comparing TIRADS scoring with histopathological diagnosis, there is limited number of studies investigating the correlation between TIRADS scoring and FNAC. Thus, this study aimed to fill this research gap by determining the diagnostic accuracy of TIRADS in thyroid nodules on ultrasound, using Bethesda cytological categories as the gold standard. By comparing TIRADS scoring with FNAC results, we can provide valuable insights into the efficacy of TIRADS as a predictive tool for malignancy in thyroid nodules. The findings would contribute to refining the risk stratification and management strategies for patients with thyroid nodules, potentially reducing unnecessary surgical procedures and guiding appropriate clinical decision-making. The study's outcomes would serve as a valuable resource for healthcare professionals, enabling them to make informed and evidence-based decisions in the assessment and treatment of thyroid nodules.

## METHODS

After obtaining approval from the Ethical Review Board (SMDC/SMRC/236-22, 17-04-2024), this Cross-sectional study was carried out at the Department of Radiology, Sharif Medical city Hospital, Lahore, from April to October 2024. Sample size of 130 was calculated with confidence level 95% and expected prevalence of benign as 87.8%, sensitivity of TIRADS as 80%, 13%

malignancy of error and specificity of 92.7% with 5% margin of error.<sup>10</sup> All the patients who fulfilled the following section criteria were enrolled by applying Non-Probability consecutive sampling technique.

**Study Design:** “Cross sectional study”

**Study venue & period:** Radiology department, Sharif Medical City Hospital, Lahore from April to October 2024.

**Inclusion:** Both males and females of age above 12 years, with both solitary thyroid nodules and multinodular goiters were enrolled.

**Exclusion:** Pregnant / Lactating Women, Bethesda Category I (Non-diagnostic) and III (Indeterminate) on FNAC. Patients with history of toxic solitary nodular and or multinodular goiters (toxic solitary nodular and multinodular goiters are characterized by abnormal thyroid function, which can significantly affect the ultrasound characteristics and interpretation of nodules) or those with thyroiditis (thyroiditis is an inflammatory condition that can alter the ultrasound appearance of the thyroid gland and nodules) were excluded.

Upon receiving approval from the hospital's ethical committee, informed consent was obtained from the patients. The following basic data was collected: patient's name, age, gender, size, site (level/right/bilateral), nodularity (solitary/multinodular), and duration of swelling. A consultant radiologist with more than 5 years of experience performed the TIRADS scoring on ultrasound for all patients. Subsequently, a follow-up was conducted, during which a consultant histopathologist with more than 5 years of experience will perform fine needle aspiration cytology, and the Bethesda category will be recorded. All collected data were documented using a predefined proforma.

**ACR-TIRADS Scoring:** It was carried out only by a consultant radiologist with minimum of five

Years of experience. The assigned scores as follows.

TR1: 0 points, indicating a benign condition

TR2: 2 points, suggesting a lack of suspicion.

TR3: 3 points, indicating mild suspicion.

TR4: 4-6 points, pointing to moderate suspicious

TR5: > 7 points, indicating a high level of suspicion

Tr1 and TR2 were taken as benign and TR3, TR4 & TR5 were taken as malignant.

The Bethesda system for reporting Thyroid Cytopathology: It was carried out by a consultant histopathologist with a minimum of five years of experience. The assigned categories are as follows:

- Category I: Non-Diagnostic
- Category II: Benign
- Category III: Indeterminate (Atypia of undetermined significance / follicular lesion of undertermined significance.
- Category IV: Suspicious for follicular Neoplasm
- Category V: Suspicious for Malignancy
- Category VI: Malignant

Category II was taken as Benign and category IV-VI was taken as Malignant.

The collected data was entered in Statistical Package for Social Sciences v.27.0 and later on was analyzed through it. To evaluate the diagnostic performance of ultrasound TIRADS, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated by using 2x2 contingency table.

**RESULTS**

The mean age of the patients was  $38.60 \pm 15.6$  years. There were 67 (51.5%) males and 63 (48.5%) females. The mean size of the nodule was  $2.52 \pm 1.10$  cm. Left side of nodule in 61 (46.9%) patients, right side of nodule in 56 (43.1%) patients and bilateral in 13 (10%) patients. Solitary nodularity was present in 68 (52.3%) patients and multi-nodularity in 62 (47.7%) patients. The mean duration of swelling was  $7.36 \pm 2.85$  months. Table-I

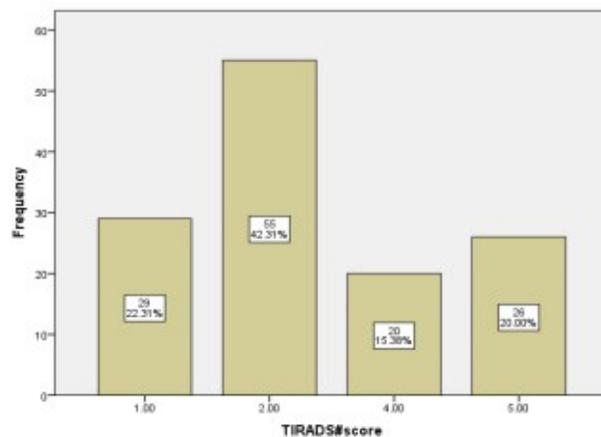
There were one TRIADS score in 29 (22.31%) patients, two TRIADS score in 55 (42.31%), four TRIADS score in 20 (15.38%) and 26 (20.0%) TRIADS score in 26 (20.0%) patients. Figure-I

Comparison between FNAC Bethesda and TIRADS classifications for 130 patients. Sensitivity was 93.4%, specificity 91.67%, PPV was 86.0%, NPV 96.2% and diagnostic accuracy was 92.3%. Table-II

The diagnostic accuracy of TIRADS is also given in table-III when patients were divided in different groups.

**Table 1:** Bassline features of patients enrolled in the study

Parameters	Statistics
<b>n</b>	130
<b>Age (years)</b>	$38.6 \pm 15.6$
<b>Gender</b>	
<b>Males</b>	67 (51.5%)
<b>Females</b>	63 (48.5%)
<b>Size of nodules (cm)</b>	$2.52 \pm 1.10$
<b>Site of nodule</b>	
<b>Left</b>	61 (46.9%)
<b>Right</b>	56 (43.1%)
<b>Bilateral</b>	13 (10.0%)
<b>Nodularity</b>	
<b>Solitary</b>	68 (52.3%)
<b>Multinodular</b>	62 (47.7%)
<b>Duration of swelling</b>	$7.36 \pm 2.85$



**Figure-1:** TIRADS Score

**Table 2:** Accuracy of TIRADS against FNAC Bethesda

FNAC Bethesda	TIRADS		Total
	Positive	Negative	
<b>Positive</b>	43	7	50
<b>Negative</b>	3	77	80
<b>Total</b>	46	84	130
<b>Sensitivity</b>			93.40%
<b>Specificity</b>			91.67%
<b>PPV</b>			86.00%
<b>NPV</b>			96.20%
<b>Diagnostic Accuracy</b>			92.30%

**Table 3:** Accuracy of TIRADS against FNAC when controlled for effect modifiers

	Sensitivity	Specificity	PPV	NPV	Accuracy
Age 15-45 years	96.20%	90.90%	82.80%	98.00%	92.60%
Age >45 years	89.40%	93.10%	89.40%	93.10%	91.60%
Male	90.40%	91.30%	82.60%	95.40%	91.00%
Female	96.00%	92.10%	88.80%	97.20%	93.60%
Size of nodule 1-2 cm	85.70%	86.70%	75%	92.80%	86.60%
Size of nodule 3-4 cm	100%	97.40%	96.10%	100%	98.40%
Solitary nodule	100%	90.20%	87.00%	100%	94.10%
Multi-nodular	84.20%	93.00%	84.20%	93.02%	90.30%

### Discussion

In this study, 130 patients with a mean age of  $38.6 \pm 15.6$  years were included, with 51.5% male and 48.5% female participants. The average nodule size was  $2.52 \pm 1.10$  cm, with nodules located on the left in 46.9% of cases, on the right in 43.1%, and bilaterally in 10%. Solitary nodularity was observed in 52.3% of patients, while 47.7% had multi-nodularity. Positive TIRADS scores were seen in 35.4% of patients, and 38.5% had positive Bethesda scores. The sensitivity of the FNAC Bethesda classification ranged from 85.7% to 100% across various parameters, with diagnostic accuracy between 86.6% and 98.4%. Nodularity and nodule size significantly influenced diagnostic outcomes, with sensitivity and accuracy higher in solitary nodules and larger nodules (3–4 cm). Gender-based analysis showed higher sensitivity in females (96%) compared to males (90.4%). Diagnostic performance improved with longer nodule durations, achieving 96.2% accuracy for nodules persisting beyond eight months. The most common endocrine condition is thyroid nodules, which affect 10–70% of people and have a 3–9% risk of becoming cancer.<sup>11</sup> Even yet, FNA is the most precise method of diagnosing thyroid nodules that are physically visible.<sup>12</sup> Greyscale and colour observations Doppler ultrasonography is only a very good indicator of cancer when multiple symptoms show up in a nodule at the same time. In a group of patients with microcalcifications, an intramodular low echogenicity pattern, and the lack of the halo sign, a high degree of specificity was achieved for the interpretation of thyroid carcinomas.<sup>15</sup>

According to one study, involving 210 patients with a total of 233 thyroid nodules, the distribution of malignancy within the TIRADS categories was as follows: TIRADS2 (0%), TIRADS3 (2.2%), TIRADS 4A (5.9%), TIRADS4B (57.9%), and

TIRADS5 (100%). The study reported the diagnostic performance of TIRADS, with a sensitivity of 83%, specificity of 96.4%, and an overall diagnostic accuracy of 94.1%. The researchers concluded that TIRADS is a valuable diagnostic classification system for predicting malignancy, and its use in conjunction with FNAC utilizing the Bethesda classification can help avoid unnecessary surgical procedures.<sup>9</sup>

In a study conducted by Anwar et al., TIRADS scoring was compared with the histopathological diagnosis for thyroid nodules. Out of the total nodules assessed, 171 (83.41%) were classified as benign and 34 (16.58%) as malignant based on TIRADS scoring. But, about 180 (87.80%) of the nodules were benign on biopsy, whereas the remaining lesions were malignant. According to calculations, TIRADS's sensitivity, specificity, and diagnostic accuracy were 80%, 92.77%, and 91.21%, respectively. The Ultrasonographic ACR-TIRADS grading and risk stratification approach showed significant sensitivity in identifying thyroid nodule malignancy, the researchers concluded. It was judged to be a trustworthy method for the preliminary evaluation of thyroid nodules, and judgements could be made with confidence in light of its findings.<sup>7,16</sup>

De et al., conducted another observational study on 137 consecutive participants with a single euthyroid nodule. All subjects received USG according to TIRADS and FNAC if relevant. The gold standard was a surgical biopsy report. TIRADS had 80%, 47.2%, 61%, 51.3%, and 77.3% sensitivity, specificity, accuracy, PPV, and NPV, while FNAC had 80%, 90%, 85%, 86%, and 86.6% of these metrics. Compared to TIRADS, FNAC categorisation was more specific and similarly sensitive. Micro-calcification was the most sensitive (80%) and specific (86%), among the individual

USG measures. The specificities for irregular margin and taller-than-wider form were 89% and 92%, respectively. The final HPE revealed cancer in three patients (14.28%) receiving surgery who had benign cytology and worrisome USG findings (particularly TIRADS 4 & 5).<sup>17</sup>

Al Shoaibi and associates evaluated the outcomes of FNAC and ultrasonography in the treatment of thyroid nodules. FNA cytology revealed that 1.2% of the 124 patients with thyroid lesions that were benign on ultrasonography were malignant, while 98.38% of them were benign. Out of 9 cases with malignant thyroid lesions, 44.4% were found to be benign and 55.6% were proven to be malignant by FNAC. They came to the conclusion that ultrasonography was a useful technology that could distinguish between benign and malignant nodules with high diagnostic accuracy.<sup>18</sup>

In addition to enabling risk classification, the TIRADS scoring system helps clinicians decide whether to "be observed" or do fine needle aspiration cytology on thyroid nodules. The risk stratification method that is most frequently utilised in our situations is ACR-TIRADS. The relative accuracy of several TIRAD systems is being investigated. ACR-TIRADS has been the basis for the development of "artificial intelligence" (AI-TIRADS) in recent years. The use of artificial intelligence, according to Tobriner and colleagues, marginally increases specificity while preserving sensitivity.<sup>19</sup>

ACR-TIRADS had the maximum sensitivity (94.5%), according to Soylemiz and colleagues' study evaluating the relative accuracy of TIRAD on 939 nodules. The most sensitive risk categorisation method for thyroid nodules, they concluded, was ACR-TIRADS. They added that it is more sensitive than the Bethesda system.<sup>20</sup> Magri and Colleagus have out a prospective investigation on 255 participants in a related study. They contrasted the outcomes of the corresponding biopsy specimens with those of the ACR- and EU-TIRADS. Comparable to our results, the sensitivity of ACR-TIRADS and EU-TIRADS for malignancy identification was determined to be 77.08% and 88%, respectively. They came to the conclusion that, when biopsy is used as a reference point, both of these risk stratification algorithms perform well in identifying thyroid cancer.<sup>21</sup>

Image-based risk stratification algorithms advise whether a particular thyroid nodule should be watched, have FNAC, or undergo a semi-invasive procedure. Numerous studies that compare the

outcomes of these two with differing degrees of accuracy may be found in the literature. In a research on TIRADS accuracy, Naushaba Malik and colleagues compared the results with FNAC and discovered a strong agreement between the two. While TIRADS V exhibited a strong correlation with malignancy on cytology, they discovered that thyroid nodules with TIRADS II, III, and IVa displayed benign cytological results. They came to the conclusion that TIRADS classification was a valid method for evaluating thyroid nodules and could be applied on its own to identify the kind of thyroid lesion. In a related study conducted in Multan, Pakistan, Nighat and associates contrasted the TIRADS scores with FNAC. They discovered that the TIRADS sensitivity was 77.8%, the specificity was 75.5%, the PPV was 53.8%, and the NPV was 90.2% while evaluating thyroid nodules in 201 individuals. Thyroid nodule malignancy was predicted with an overall diagnosis accuracy of 76.1%. They came to the conclusion that thyroid nodule cancer can be detected with high diagnostic accuracy using the TIRADS score.<sup>22,23</sup>

## CONCLUSION

The study concludes that FNAC Bethesda and TIRADS classifications are effective diagnostic tools, with high sensitivity and accuracy, particularly in larger nodules, solitary nodularity, females, and prolonged swelling duration. Thus in future, TIRADS can be used as first line dignostic tool for diagnosis of thyroid nodules. These findings will contribute to refining the risk stratification and management strategies for patients with thyroid nodules, potentially reducing unnecessary surgical procedures and guiding appropriate clinical decision-making. It will now serve as a valuable resource for healthcare professionals, enabling them to make informed and evidence-based decisions in the assessment and management of thyroid nodules.

## AUTHORS CONTRIBUTION

**Rafia Irum:** Conceptulaization of Study Design, Litterature Reseach, Data Interpretaion, Proof Reading

**Hira Bushra:** Litterature Reseach, Data interpretaion,

**Riffat Kamal:** Statistical Analysis

**Maryam Rehman:** Critical analysis and revision of manuscript.

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