Original Article

Diagnostic accuracy of TI-RADS in the diagnosis of Thyroid Nodules, keeping Ultrasound-Guided FNAC as the Gold Standard

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ABSTRACT

Background: To determine the diagnostic accuracy of Thyroid Imaging Reporting and Data System (TI-RADS) in predicting thyroid malignancy using ultrasound-guided fine needle aspiration cytology (FNAC) as the gold standard.

Methodology: This retrospective cross-sectional study was conducted from August 2019 to April 2025 at the Interventional Radiology Department of Rehman Medical Institute. The study included 424 patients with thyroid nodules who underwent ultrasound evaluation using TI-RADS classification followed by ultrasound-guided FNAC. Statistical analysis was performed to calculate sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy.

Results: The overall sensitivity and specificity of TI-RADS were 54.55% and 75.79%, respectively, with PPV of 20.69% and NPV of 93.51%. The risk of malignancy for TI-RADS categories 3, 4, and 5 were 22.7%, 29.16%, and 86.66%, respectively. TI-RADS 2 demonstrated high specificity (98.2%), while TI-RADS 5 showed perfect sensitivity (100%). A significant association was found between TI-RADS scores and Bethesda classification ($P < 0.001$), with an area under the curve of 0.932.

Conclusion: TI-RADS is a useful tool for thyroid nodule evaluation, particularly in high-risk categories. However, the moderate overall accuracy highlights the need for larger multicenter studies to improve generalizability and reduce interobserver variability.

KEY WORDS: Thyroid nodules, TIRADS, ultrasound-guided FNAC, Bethesda classification, diagnostic accuracy.

INTRODUCTION

Thyroid nodules are a common clinical observation, found in up to 50% of individuals on ultrasonography. While most are benign, a small percentage can be malignant, necessitating accurate diagnostic tools for appropriate management. The prevalence increases with age and is higher in women compared to men.[1]

Ultrasound (US) is the primary imaging modality for evaluating thyroid nodules, providing detailed information about their characteristics.[2] However, US alone cannot reliably differentiate between benign and malignant nodules.[1,2] To standardize reporting and risk stratification, the Thyroid Imaging Reporting and Data System (TIRADS) was developed, categorizing nodules

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into five risk levels based on specific ultrasound features.

There are various variations of TIRADS such as the American College of Radiology (ACR) TIRADS, the European TIRADS (EU TIRADS) and the Korean TIRADS (K TIRADS) with differing scoring criteria.[3,4] ACR TIRADS awards points for features such as composition, echogenicity, shape, margin, and echogenic foci, and places nodules at five risk levels. EU-TIRADS uses a simpler five-category system based on suspicious features. K-TIRADS uses a five-point system, focusing on nodule composition and echogenicity.

Fine Needle Aspiration Cytology (FNAC), particularly when ultrasound-guided, remains the gold standard for definitive diagnosis.(4). Several studies have evaluated the diagnostic accuracy of TIRADS using FNAC as the reference standard, with varying results.

The aim of this study was to determine the diagnostic accuracy of TI-RADS in predicting thyroid malignancy using ultrasound-guided FNAC as the gold standard.

MATERIALS AND METHODS

This retrospective cross-sectional study was conducted from August 2019 to April 2025 in the Interventional Radiology Department of Rehman Medical Institute. The study included patients with palpable thyroid nodules or clinical suspicion of thyroid disease referred for ultrasound-guided FNAC. Patients with previous thyroid nodule operations or carcinoma, those undergoing or previously undergoing radiation therapy, and patients without a tissue diagnosis according to FNAC were excluded.

Ethical approval was obtained from the Rehman Medical Institute Ethical Review Board (approval number: RMI-IRB/2025/04-15).

Ultrasound Technique: Ultrasound examinations were performed using high-resolution linear probes (7.5MHz). Patients were positioned supine with dorsiflexed heads to maximize neck exposure. B-mode sonography and Doppler evaluation assessed thyroid nodule characteristics including size, composition, echogenicity, margins, and calcifications. The ACR TI-RADS criteria were employed to characterize nodules into five categories (TI-RADS 1-5) based on malignancy risk.

The TIRADS classification system used in this study categorizes thyroid nodules based on specific ultrasound features:

- TIRADS 1: Benign (no FNA required)
- TIRADS 2: Not suspicious (no FNA required)
- TIRADS 3: Mildly suspicious (FNA if ≥2.5 cm, follow-up if ≥1.5 cm)
- TIRADS 4: Moderately suspicious (FNA if ≥1.5 cm, follow-up if ≥1 cm)
- TIRADS 5: Highly suspicious (FNA if ≥1 cm, follow-up if ≥0.5 cm)

FNAC Procedure:

Informed written consent was obtained from all patients prior to FNAC. The procedure was performed using a 22/23-gauge hypodermic needle with a non-aspiration capillary action technique. Samples were processed and analyzed using the Bethesda classification system (Bethesda 1-6) by a single experienced pathologist to maintain consistency.

The samples were then processed and analyzed using the Bethesda classification system:

- Bethesda 1: Non-diagnostic
- Bethesda 2: Benign
- Bethesda 3: Atypia of undetermined significance (AUS)/Follicular lesion of undetermined significance (FLUS)
- Bethesda 4: Follicular neoplasm
- Bethesda 5: Suspicious for malignancy
- Bethesda 6: Malignant

Statistical Analysis: Data were analyzed using SPSS software version 25. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positivity likelihood ratio, negativity likelihood ratio, and accuracy were calculated. Student's t-test was utilized to measure significance. Quantitative variables were described numerically and in percentages. The chi-squared test was used to analyze associations between variables, with P-values < 0.05 considered

Table-I: Distribution of TI-RADS categories among study participants.

TI-RADS Category	*No. of Nodules*	*Benign*	*Uncertain*	*Suspicious*	*Malignant*
TI-RADS 1	2	0	0	2	0
TI-RADS 2	112	100	8	2	0
TI-RADS 3	194	150	26	16	2
TI-RADS 4	102	62	20	6	12
TI-RADS 5	14	6	2	2	4

Table-II: Diagnostic performance of TI-RADS categories

TI-RADS Category	*Sensitivity (%)*	*Specificity (%)*	*PPV (%)*	*NPV (%)*
TI-RADS 2	-	98.2	-	-
TI-RADS 3	50.0	90.7	-	-
TI-RADS 4	85.7	78.6	-	-
TI-RADS 5	100.0	60.0	-	-

significant. Odds ratio and relative risk were calculated to compare US results with FNAC findings.

RESULTS

Our study included 424 individuals with thyroid nodules evaluated using both TI-RADS and FNAC. The cohort comprised 82 males (19.3%) and 342 females (80.7%), with a mean age of 43.01 years (range: 11-87 years). FNAC was conducted using a 23G needle for 400 patients and a 22G needle for 24 patients. The incidence of malignancy was higher in females (68% of malignant cases).

Table-I shows the distribution of TI-RADS scores among the study participants. The overall diagnostic performance of TI-RADS was as follows: sensitivity 54.55% (95% CI: 38.85% to 69.61%), specificity 75.79% (95% CI: 71.16% to 80.01%), PPV 20.69% (95% CI: 15.88% to 26.49%), and NPV 93.51% (95% CI: 91.20% to 95.24%). The accuracy of ultrasound in detecting malignancy was 61%.

Table-II presents the diagnostic performance across different TI-RADS categories. TI-RADS 2 demonstrated high specificity (98.2%), while TI-RADS 5 showed perfect sensitivity (100%). The risk of malignancy for TI-RADS 3, 4, and 5 were 22.7%, 29.16%, and 86.66%, respectively.

Table-III: Distribution of FNAC results according to Bethesda classification

Bethesda Category	*No. of Patients*	*Percentage*
Bethesda 1	4	0.9%
Bethesda 2	318	75.0%
Bethesda 3	58	13.7%
Bethesda 4	26	6.1%
Bethesda 5	6	1.4%
Bethesda 6	12	2.8%

Table-III shows the distribution of FNAC results according to the Bethesda classification. A significant association was found between TI-RADS scores and Bethesda classification ($P < 0.001$), with an area under the curve of 0.932, indicating high diagnostic accuracy.

Among the nodules classified as TI-RADS 3, a subset had indeterminate or suspicious cytology (Bethesda III and IV). Of these: One patient declined further FNAC but was followed with ultrasound and showed stable disease. Three patients underwent surgery, which revealed benign pathology in all cases (one with a background of Grave's disease, one with benign cystic nodular goitre, and one with a hyperplastic colloid nodule). One patient with a FNAC showing oncocytic neoplasm (Bethesda IV) had a benign pathology on final histology.

DISCUSSION

Our study evaluated the diagnostic accuracy of TI-RADS in 424 patients with thyroid nodules, using ultrasound-guided FNAC as the gold standard. The overall sensitivity (54.55%) and specificity (75.79%) of TI-RADS in our study were moderate compared to literature reports, which generally indicate higher diagnostic accuracies.

The excellent performance of TI-RADS in extreme categories (high specificity for TI-RADS 2 at 98.2% and perfect sensitivity for TI-RADS 5 at 100%) aligns with previous studies, confirming its utility in confidently identifying low-risk and high-risk nodules. However, the moderate overall accuracy highlights challenges in intermediate-risk categories.[3-5]

Literature reports generally indicate higher diagnostic accuracies for TIRADS. Salman et al.[4] reported ultrasound sensitivity of 73.9% and specificity of 72.6%, while Deniz et alfound sensitivity and specificity values of 74.5% and 68.1%, respectively.[5] Chandra et al.[6] documented even higher values with sensitivity at 82.35% and specificity at 92.30%. Several factors may contribute to the lower diagnostic accuracy observed in our study, including sample characteristics, ultrasound equipment, operator expertise, and interpretation criteria.

Dong et al.[7] noted that different TIRADS systems (ACR-TIRADS vs. Chinese-TIRADS) have varying diagnostic performances, suggesting that the choice of system affects outcomes. Gao et al. reported the highest diagnostic accuracy when combining TIRADS with shear wave elastography (SWE), underscoring the benefits of multimodal approaches.

The significant association between TI-RADS scores and Bethesda classification ($P < 0.001$) with an AUC of 0.932 demonstrates that TI-RADS is a valuable tool for risk stratification. This is consistent with findings from Salman et al.[4] and Nie et al.,[8] who reported strong diagnostic performance of TIRADS in various settings.

When comparing the diagnostic accuracy of each TIRADS category to the literature, our findings include:

- TIRADS 2: Our study reported a specificity of 98.2%, consistent with Liang et al., who found high specificity and minimal false positives.[9]
- TIRADS 3: Our study indicated a sensitivity of 50% and specificity of 90.7%, whereas Deniz et al. reported 74.5% sensitivity and 68.1% specificity.[5]
- TIRADS 4: Our study showed sensitivity and specificity of 85.7% and 78.6%, compatible with Gao et al.'s findings.[10]
- TIRADS 5: Our study reported 100% sensitivity and 60% specificity. Ahmed et al. found a sensitivity of 96.6%, highlighting its efficacy in detecting malignant nodules.[11]
- TIRADS 1 and 2 categories showed high specificity without true positives or false negatives, indicating appropriate avoidance of FNAC in these low-risk categories. TIRADS 3, including nodules with low suspicion, had more frequent FNAC procedures. Our findings of moderate sensitivity and high specificity for TIRADS 3 align with Deniz et al.'s results, where FNAC often confirmed benign results in low-risk nodules.[5]

Khan et al.and Jamal et al reported similar distributions, with Bethesda 2 (Benign) being the most common category, comprising approximately 60-70% of cases. Our study shows a slightly higher proportion (75%) in Bethesda 2, indicating a high rate of benign cytological findings.[12,13]

Future research should address larger, multicenter studies to verify these results, lessen inter-observer variability, and evaluate the application of advanced imaging techniques such as shear wave elastography and contrast-enhanced ultrasound to improve diagnostic precision.

CONCLUSION

TI-RADS demonstrates moderate diagnostic accuracy in evaluating thyroid nodules, with excellent performance in low and high-risk categories. The significant association with Bethesda classification and high AUC value supports its clinical utility. However, the moderate overall accuracy and variable sensitivity for intermediate categories highlight the need for further refinement and multicenter validation. Combining TI-RADS with advanced imaging techniques may enhance diagnostic precision and patient management.

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U.S.U.: Data collection and analysis; Critical revision of the manuscript.
A.N.K.: Concept and design; Supervision and critical revision.
M.K.: Data collection; Data visualization.
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