RESEARCH PAPER

Evaluation of ACR-TIRADS Classification System in Risk Stratification of Thyroid Nodules: A Prospective Observational Study

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Received: 16th Dec, 2025; Revised: 8th Feb 2026; Accepted: 12th Feb, 2026; Available Online: 28th Feb, 2026

Abstract
Aim: To determine the sensitivity and specificity of ACR-TIRADS with final histopathology report, evaluate the diagnostic accuracy of USG-guided FNAC with final histopathology report, and determine the concordance between ACR-TIRADS score and Bethesda classification of FNAC.
Material and Methods: This prospective observational study was conducted in the Department of General Surgery, Kasturba Medical College, Manipal, from March 2019 to August 2020. Forty-eight patients admitted for thyroid surgeries with available ACR-TIRADS and Bethesda FNAC reports were included. Clinical data, imaging findings, and cytology reports were collected and correlated with final histopathological findings. Statistical analysis was performed to determine sensitivity, specificity, and diagnostic accuracy.
Results: Among 48 patients, 87.5% were females with mean age 31-60 years. According to ACR-TIRADS classification, 37.5% were TR4 (moderately suspicious), 35% were TR3 (mildly suspicious), 22% were TR2 (not suspicious), and 4% were TR5 (highly suspicious). FNAC revealed 52% benign (Bethesda II), 14% suspicious for malignancy (Bethesda V), and 4% malignant (Bethesda VI) lesions. Final histopathology confirmed malignancy in 33% cases. ACR-TIRADS demonstrated high sensitivity (81.25%) and specificity (78.12%) with overall diagnostic accuracy of 79.17%. FNAC demonstrated sensitivity of 75% and specificity of 78.57%. Moderate agreement was noted between ACR-TIRADS and Bethesda classification (kappa = 0.45).
Conclusion: The American College of Radiology TI-RADS demonstrates excellent discriminatory capability for thyroid malignancy risk assessment using sonographic characteristics. Initial screening with USG and ACR-TIRADS scoring helps identify benign lesions and reduces unnecessary biopsies while appropriately triaging suspicious lesions for FNAC.
Key Words: ACR-TIRADS, Thyroid nodules, Fine needle aspiration cytology, Bethesda classification, Risk stratification
How to cite this article: Bathala BT, Bhat PM, Prasad SS, Hegde KS. Evaluation of ACR-TIRADS Classification System in Risk Stratification of Thyroid Nodules: A Prospective Observational Study. Int J Drug Deliv Technol. 2026;16(2): 630-636. DOI: 10.25258/ijddt.16.2.67

Introduction

Thyroid gland disorders encompass a spectrum ranging from simple thyroid nodules to malignancy. Patients commonly present with palpable nodules in the anterior neck or as incidental findings during imaging studies. Thyroid nodules are characterized as focal abnormalities that appear ultrasonographically different from normal thyroid tissue, as established by American Thyroid Association.

Women disproportionately experience thyroid nodular disease, with population studies indicating 5-8.5% prevalence[1]. Clinical presentations span from isolated lesions to multifocal disease, with varying echogenic patterns and internal architecture. In the Indian population, thyroid nodules have a prevalence of 12.2%[2]. While most thyroid nodules follow an indolent course, accurate differentiation between benign and malignant lesions is crucial. Thyroid malignancy represents the most common endocrine malignancy encountered by general surgeons, with nodules larger than 4cm raising particular concern for malignancy. The annual incidence of thyroid malignancy is 8.7 per 100,000 people[3].

Ultrasonography serves as the primary imaging modality for thyroid nodule detection and assessment. Thyroid ultrasound can identify nodules in up to 67% of the population[4]. However, ultrasound-detected nodules, particularly those smaller than 1cm, demonstrate highly diverse patterns that complicate differentiation between benign and malignant lesions. Recent meta-analysis has shown that "combined sensitivity and specificity of ultrasound" for thyroid nodule diagnosis were 0.88 and 0.86 respectively[5]. Fortunately, less than 10% of thyroid nodules are malignant[6].

The need for accurate risk stratification has led to development of several classification systems, including TIRADS (2009), modified TIRADS (2011), British U-system (2014), and ATA guidelines (2015)[7]. The American College of Radiology TIRADS (ACR-TIRADS) classification system, introduced in 2017, has gained widespread acceptance[8],[9]. Recent network meta-analysis demonstrates that "ACR TIRADS" achieved optimal performance with TR5 as the most accurate risk threshold[10].

Cytological evaluation through fine-needle aspiration continues to serve as the gold standard for thyroid cancer risk determination[11]. The recently updated 2023 Bethesda System has refined the six diagnostic categories with "single name for each" category and updated risk of malignancy percentages[12]. Contemporary research shows that "Bethesda III and IV" nodules require careful evaluation with malignancy rates varying significantly[13]. However, histopathological examination following surgery provides the ultimate diagnosis.

Recent comparative studies indicate that "diagnostic efficacy" varies among different TIRADS systems, with ACR-TIRADS demonstrating competitive performance in pediatric populations as well[14]. This study evaluates the ACR-TIRADS classification system's effectiveness as a non-invasive method for differentiating benign from malignant thyroid nodules and determining the need for FNAC.

Material and Methods

Study Design: Prospective observational study

Study Setting: Department of General Surgery, Kasturba Medical College, Manipal,Karnataka, India

Study Duration: March 2019 to August 2020

Study Population: All patients admitted for thyroid surgery during the study period

Inclusion Criteria:

- Patients admitted and planned for thyroid surgery
- Available ACR-TIRADS scoring
- Available Bethesda classification FNAC reports
- Age 18-90 years

Exclusion Criteria:

- FNAC or TIRADS reports from external facilities
- Previous history of thyroid surgery
- Thyroid echography not reported according to ACR-TIRADS
- FNAC cytology not reported according to Bethesda classification
- Age below 18 years or above 90 years

Sample Size: Sample size was calculated based on expected sensitivity of 80% with 95% confidence interval and 10% precision, requiring minimum of 45 patients. We included 48 consecutive patients meeting inclusion criteria during the study period.

Methodology:

We enrolled consecutive individuals meeting study parameters. Our protocol encompassed complete thyroid function assessment, FNAC analysis, and definitive surgical management. Clinical data, imaging findings, and cytology reports were systematically collected using standardized proformas. All data were correlated with final histopathological reports.

For statistical analysis, ACR-TIRADS TR2-3 were classified as benign predictions, while TR4-5 were considered malignant predictions. Similarly, Bethesda classifications II-III were considered benign, while IV-V were classified as malignant, following established protocols[13].

To minimize bias, all ultrasound examinations were performed by experienced radiologists blinded to the surgeon's notes on clinical findings. FNAC was performed by cytopathologists, and histopathological examination was conducted by pathologists blinded to imaging results. All data were correlated with final histopathological reports.

Age, gender, thyroid function status, and nodule size were identified as potential confounders that could influence diagnostic accuracy. The predominantly female study population (87.5%) and high prevalence of euthyroid patients (89%) were considered in result interpretation.

Informed Consent: Obtained from all study participants

Ethical Clearance: Obtained from institutional ethics committee

Statistical Analysis: Sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were calculated. Cohen's kappa coefficient was used to assess agreement between ACR-TIRADS and Bethesda classifications. Statistical significance was set at $p<0.05$.

Results

The study included 48 patients who underwent thyroid surgery (Fig.1- Participant Flow Diagram). The demographic profile revealed female predominance (87.5%) with male patients comprising 12.5%. The mean age group was 31-60 years. Thyroid function assessment revealed 89% euthyroid patients, 4% hyperthyroid, and 6% hypothyroid patients.

ACR-TIRADS classification distribution showed TR4 (moderately suspicious) in 37.5% of cases, followed by TR3 (mildly suspicious) in 35%, TR2 (not suspicious) in 22%, and TR5 (highly suspicious) in 4% of cases.

FNAC results according to Bethesda classification revealed 52% benign lesions (Category II), 14% suspicious for malignancy (Category V), and 4% malignant lesions (Category VI). When categorized as benign (Bethesda II-III) versus malignant (Bethesda IV-V), benign lesions comprised 54% and malignant lesions 37% of cases.
Final histopathological examination confirmed malignancy in 33% of cases and benign pathology in 66% of cases.

ACR-TIRADS Performance:
The distribution of benign versus malignant thyroid nodules (Chart 1) across ACR-TIRADS categories (TR2-TR5) indicated a clear increasing trend in malignancy rates from TR2 (9.1% malignant) to TR5 (100% malignant), demonstrating the effectiveness of ACR-TIRADS risk stratification.
Among 28 lesions classified as mostly benign (TR2-3) by ACR-TIRADS (Table 1), 3 were malignant on final histopathology. Of 20 lesions classified as mostly malignant (TR4-5), 13 were confirmed malignant on histopathology ($p<0.001$).

ACR-TIRADS demonstrated:

- Sensitivity: 81.25% (95% CI: 61.5-93.0%)
- Specificity: 78.12% (95% CI: 63.2-88.5%)
- Overall diagnostic accuracy: 79.17% (95% CI: 66.6-88.1%)

FNAC Performance:
Among 26 lesions classified as benign by FNAC, 4 were malignant on final histopathology. Of 18 lesions classified as malignant by FNAC, 12 were confirmed malignant on histopathology. (Table 2)
FNAC demonstrated:

- Sensitivity: 75% (95% CI 47.62% to 92.73%)
- Specificity: 78.57% (95% CI 59.05% to 91.70%)
- Positive predictive value 66.67% (95% CI 48.24% to 81.10%),
- Negative predictive value 84.62% (95% CI 69.73% to 92.92%)

Concordance Analysis:
(Table 3) Moderate agreement was observed between ACR-TIRADS scores and Bethesda classification (kappa value = 0.45).

Discussion
Sonographic assessment combined with percutaneous needle sampling constitutes the cornerstone of contemporary thyroid lesion evaluation. Establishing accurate non-invasive cancer risk stratification is essential to prevent unnecessary invasive interventions. The ACR-TIRADS scoring system, based on ultrasonographic features, provides standardized assessment for thyroid nodule evaluation.
We observed a progressive escalation in cancer probability correlating with ascending TI-RADS categories, validating the system's risk stratification capability in our institutional cohort. However, our TR2 malignancy rate of 9.1% was higher than that reported by Mohanty et al. (<2%)[15] and Periakaruppan G et al. (0%)[16]. A large retrospective study by Middleton et al. involving 3,422 thyroid nodules revealed a malignancy rate of 1.5% for TR2[17].
The TR5 malignancy rate in our study was 100%, considerably higher than the ACR-TIRADS white paper recommendation (>20%), and studies by Mohanty et al. (56%)[15], Periakaruppan G et al. (77.8%)[16], and Middleton et al. (35%)[17].
Our study demonstrated high sensitivity, specificity, and negative predictive value for ACR-TIRADS when correlated with histopathology. The sensitivity findings align with studies by Zhang et al. (73.1%)[18], Chandramohan et al. (72%)[19], and Chakravarthy et al. (83.6%)[20]. Some studies reported higher sensitivity, including Periakaruppan G et al. (92.3%)[16] and Nam et al. (100%)[21].
Recent network meta-analysis by Yang et al. confirms that ACR-TIRADS achieves competitive diagnostic performance among various TIRADS systems, with TR5 representing the optimal cut-off threshold[10]. This supports our findings of excellent specificity for higher-risk categories. The updated 2023 Bethesda System has enhanced standardization with simplified nomenclature, which improves consistency in cytopathological reporting[12].
Contemporary research by Li et al. demonstrates that ACR TI-RADS maintains effectiveness across different populations, including paediatric patients, though with varying sensitivity and specificity profiles[14]. This suggests broader applicability of our findings beyond adult populations.
The moderate agreement between ACR-TIRADS and Bethesda classification (kappa = 0.45) suggests complementary rather than redundant roles for these diagnostic modalities. This finding supports the sequential use of ultrasound-based risk stratification followed by cytological assessment for suspicious lesions. Recent

prospective studies confirm that Bethesda III and IV categories require individualized management approaches, as demonstrated by varying malignancy rates[13].

The demographic composition of our study population may have influenced diagnostic accuracy results. The marked female predominance (87.5%) reflects the typical epidemiological pattern of thyroid disease but may limit applicability to male populations where nodule characteristics and malignancy patterns can differ. The predominance of euthyroid patients (89%) suggests our findings are most applicable to patients with normal thyroid function, as hyperthyroid or hypothyroid states can alter glandular echotexture and potentially affect ultrasound-based risk stratification accuracy.

Recent meta-analysis data showing combined ultrasound sensitivity and specificity of 0.88 and 0.86 respectively[5] closely align with our ACR-TIRADS performance metrics, validating our methodology and results within the broader literature context.

Findings may be generalizable to similar tertiary care settings with experienced radiologists. However, performance may vary in primary care settings or with less experienced operators.

Limitations: The study's limitations include a relatively small sample size and single-center design. There may also be an observer variability in Ultrasound interpretation. Larger multicenter studies would provide more robust validation of these findings. The marked female predominance (87.5%) reflects the typical epidemiological pattern of thyroid disease but may limit applicability to male populations where nodule characteristics and malignancy patterns can differ. The predominance of euthyroid patients (89%) suggests our findings are most applicable to patients with normal thyroid function, as hyperthyroid or hypothyroid states can alter glandular echotexture and potentially affect ultrasound-based risk stratification accuracy.

Conclusion

ACR-TIRADS classification system demonstrates high specificity and accuracy for thyroid nodule risk stratification based on ultrasound features. Initial screening with ultrasonography and ACR-TIRADS scoring effectively identifies benign lesions, reducing unnecessary biopsies while appropriately directing suspicious lesions for FNAC evaluation. This approach optimizes patient management by decreasing costs and risks associated with unnecessary procedures in patients with benign nodules or indolent cancers.

The combination of ACR-TIRADS and FNAC provides comprehensive evaluation for thyroid nodules, supporting evidence-based clinical decision-making in thyroid surgery.

Acknowledgment

The authors acknowledge the support of the Department of General Surgery and Pathology, Kasturba Medical College, Manipal, for facilitating this research study.

Conflicts of Interest

The authors declare no conflicts of interest related to this study.

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Figures, Charts & Tables:

Fig.1- Participant Flow Diagram

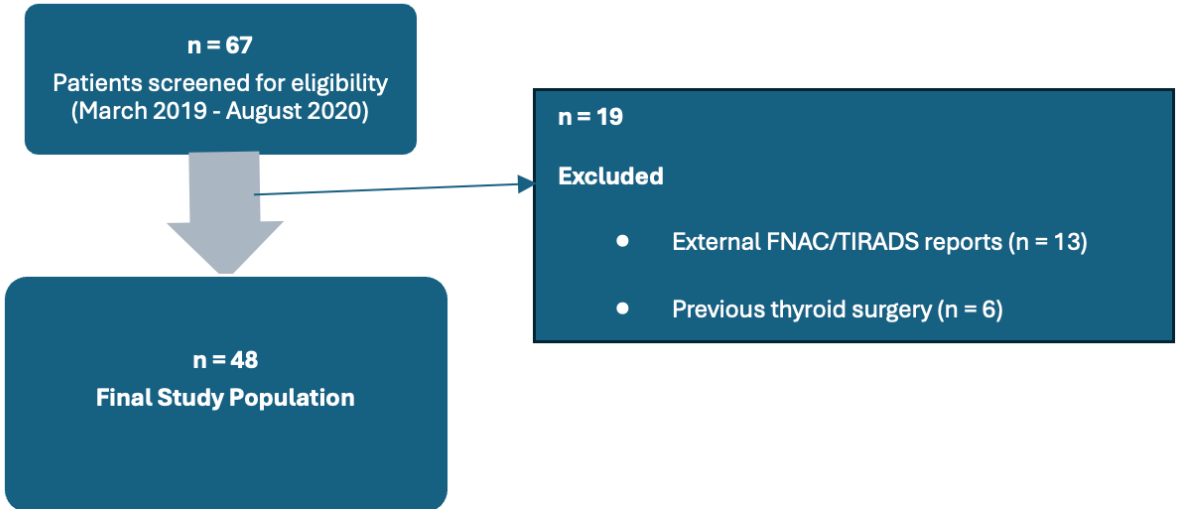
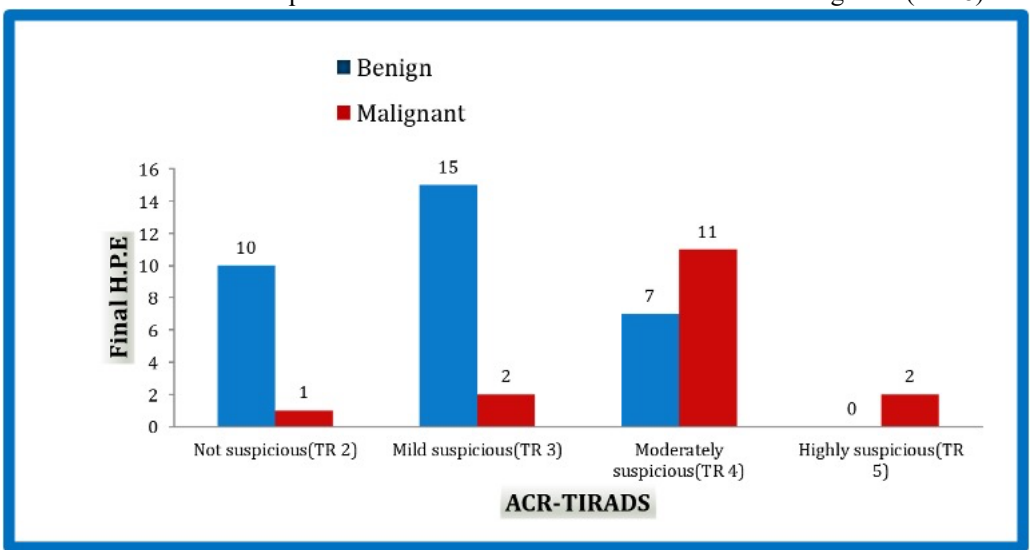


Chart 1 :Clustered bar chart of comparison of ACR-TIRADS score with final HPE diagnosis (N=48)



	N	Final H.P.E	
FNAC(Bethesda classification)		**Benign**	**Malignant**
Benign(II and III)	26	22(84.6%)	4(15.4%)
Malignant(IV, V and VI)	18	6(33.3%)	12(66.7%)
Total	44	28	16
Chi-square value = 12.09; P = 0.001:: Kappa Value = 0.52; P = 0.001			

Table 1: Comparison of ACR-TIRADS score(benign and malignant) with Final H.P.E (N=48)

	N	Final H.P.E	
ACR-TIRADS SCORE		Benign	Malignant
Mostly Benign(TR 2,3)	28	25(89.2%)	3(10.8%)
Mostly Malignant(TR 4,5)	20	7(35.0%)	13(65.0%)
Total	40	32	16
Chi-square value = 15.47; P < 0.001:: Kappa Value = 0.56; P < 0.001			

Table 2: Comparison of Bethesda classification of FNAC(benign and malignant) with Final H.P.E (N=48)

USG	FNAC	
	Malignant (IV,V and VI)	Benign (II and III)
	Count(%)	Count(%)
Mostly Malignant (TR 4 and 5)	13(65%)	7(35%)
Mostly Benign (TR 2 and 3)	5(20.8%)	19(79.2%)
Total	18	26
Chi-square value = 8.80; P = 0.003:: Kappa Value = 0.45; P = 0.003		

Table 3: Correlation of ACR-TIRADS and FNAC