

Thyroid Imaging Reporting and Data System (TIRADS) in Stratifying Risk of Thyroid Malignancy in a Tertiary Care Hospital

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ABSTRACT

Background: The American College of Radiology Thyroid Imaging Reporting and Data System (ACR-TIRADS) is utilized to stratify malignancy risk in thyroid nodules and reduce unnecessary biopsies.

Objective: To determine the diagnostic accuracy of the ACR-TIRADS system for stratifying thyroid malignancy risk in patients undergoing thyroidectomy, using histopathology as the gold standard.

Methods: A cross-sectional study was conducted with 187 patients undergoing thyroidectomy. The study spanned April 24 to October 24 for data collection, with an additional 3 months for data analysis and manuscript completion. Preoperative ultrasound findings were classified using ACR-TIRADS. Diagnostic accuracy measures sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated against final histopathological results.

Results: The sample was predominantly female (95.2%) with a mean age of 42.5 ± 10.9 years. Final histopathology confirmed malignancy in 29.4% nodules (29.4%). The ACR-TIRADS system demonstrated high specificity (97%) but low sensitivity (3.6%). The positive predictive value was 33%, the negative predictive value was 70%, and the overall diagnostic accuracy was 69%.

Conclusion: The ACR-TIRADS system exhibits high specificity but poor sensitivity for detecting thyroid malignancy, indicating high reliability in ruling out benign disease but a significant risk of missing malignant nodules. Its use should be supplemented with clinical judgment and other diagnostic modalities to minimize false negatives.

Keywords: *Thyroid nodule, thyroid cancer, TIRADS, diagnostic accuracy, ultrasonography.*

INTRODUCTION

Thyroid nodules are an exceedingly prevalent clinical finding, with a prevalence as high as 67% in random ultrasound screening of adult populations [1]. The central diagnostic challenge lies in identifying the small minority of malignant nodules, which account for approximately 4-10% of all cases [2]. Despite this low probability, thyroid cancer stands as the most common endocrine malignancy worldwide. It is notably the second most common cancer diagnosed in young women, underscoring the importance of accurate detection [3].

High-resolution ultrasonography (USG) is the primary and most sensitive imaging modality for the initial evaluation and characterization of thyroid nodules. To standardize reporting, reduce inter-observer variability, and guide clinical decision-making regarding fine-needle aspiration cytology (FNAC), several evidence-based risk stratification systems have been developed. These include the American College of Radiology's Thyroid Imaging Reporting and Data System (ACR-TIRADS), the European Thyroid Association (EU-TIRADS), and the Korean Society of Thyroid Radiology (K-TIRADS)

guidelines [4, 5]. Among these, ACR-TIRADS has gained widespread international adoption due to its structured, point-based scoring system that categorizes nodules based on composition, echogenicity, shape, margin, and echogenic foci [6].

The primary strength of ACR-TIRADS, as highlighted in validation studies, is its high specificity, which is instrumental in reducing unnecessary invasive procedures for benign nodules [7, 8]. However, its reported sensitivity is highly variable across different populations and clinical settings [9]. Some studies report sensitivities above 80%, while others document significant rates of missed malignancies, particularly in nodules with atypical or benign-appearing features such as cystic papillary carcinomas or follicular variants [7, 10, 11]. This variability suggests that diagnostic performance may be influenced by factors such as operator expertise, ultrasound machine quality, and underlying population demographics [12, 13].

Accordingly, local validation of internationally developed ultrasound risk stratification systems, such as ACR-TIRADS, remains crucial to confirm their diagnostic reliability and reduce unnecessary interventions in specific clinical populations [14]. This study aims to determine the diagnostic accuracy of the ACR-TIRADS

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system for stratifying thyroid malignancy risk in patients undergoing thyroidectomy at a tertiary care center in Karachi, Pakistan, using definitive histopathological analysis as the gold standard.

METHODS

A cross-sectional study was conducted in the Department of General Surgery and ENT at The Indus Hospital, Karachi. The study spanned April 24 to October 24 for data collection, with an additional 3 months for data analysis and manuscript completion. The study was approved by the institutional ethics review board (IHHN_IRB_2024_02_013).

The study included adult patients (18-80 years) of both genders with a clinically and sonographically confirmed thyroid nodule who were scheduled for total thyroidectomy, subtotal thyroidectomy, or lobectomy. Patients with indeterminate FNAC results who did not undergo surgery, those with a prior diagnosis of thyroid malignancy, and postoperative follow-up patients were excluded.

The sample size was calculated using OpenEpi version 3. With a sensitivity of 83.3%, a specificity of 92.9%, and a malignancy prevalence of 29%, at a 95% confidence interval and a 10% margin of error, a sample size of 187 was required [7, 15]. Participants were selected via non-probability consecutive sampling.

Data were collected using a structured questionnaire after obtaining informed consent. Data was collected from history, examination findings, investigations, and operative notes. Variables included demographic details (age, gender), presenting complaints, clinical findings, ACR-TIRADS classification based on preoperative ultrasound, type of surgery performed, and the final histopathological diagnosis (benign vs. malignant).

Data were analyzed using SPSS version 26. Quantitative variables, such as age, were reported as mean \pm standard deviation. Qualitative variables, such as gender, TIRADS classification, and histopathology results, were reported as frequencies and percentages. A cross-table was constructed to calculate sensitivity, specificity, PPV, NPV, and overall accuracy of the ACR-TIRADS system against the histopathological gold standard.

RESULTS

Our study included 187 patients, of whom n=9 (4.8%) were male, and n=178 (95.2%) were female, with a mean age of 42.5 ± 10.9 years (range, 18-72 years). Among the total patients, the most common presenting complaint was thyroid swelling, reported by 185 patients (98.5%). Shortness of breath was the second most frequent complaint, seen in 145 patients (77.5%), while

hypo-/hyperthyroidism was diagnosed in 57 (30.4%) individuals, followed by voice change, reported by 13 (6.8%) patients. Ultrasound evaluation using the TIRADS system showed that of 187 thyroid nodules, 181 (96.8%) were classified as benign, while just 6 (3.2%) were malignant. The final histopathological analysis revealed that of 187 thyroid nodules, 132 (70.6%) were benign and 55 (29.4%) were malignant (**Table 1**). According to operative procedures total thyroidectomy was 100(53.3%) followed by lobectomy 75(40.1%) while subtotal thyroidectomy was 12(6.4%).

Table 1: Socio-demographic features of patients.

Variables	Frequency (%)
Gender	
Male	9(4.8)
Female	178(95.2)
Presenting Complaints	
Thyroid swelling	185(98.5)
Weight loss	9(4.8)
Voice changes	13(6.8)
Shortness of breath	145(77.5)
Hypo-/hyperthyroidism	57(30.4)
Ultrasound Findings (TIRADS)	
Benign	181(96.8)
Malignancy	6(3.2)
Final Histopathological Diagnosis	
Benign	132(70.6)
Malignant	55(29.4)

3 (33.3%) males reported shortness of breath, whereas only 39 (21.9%) were female, with a p value of 0.423. Among males 6(66.7%) reported hypo/hyperthyroidism whereas females were 39(21.9%) with p value 0.849.

Among 187 assessed patients, TIRADS classified 181 benign and six as malignant. Whereas 128 were confirmed benign and 53 were histopathologically malignant. Among those classified as malignant by TIRADS, four were benign, and only two were truly malignant. This gives the TIRADS system a sensitivity of 3.6%, specificity of 97%, PPV of 33%, and NPV of 70%, with an overall accuracy of 69% (**Table 2**).

Table 2: Accuracy of TIRADS in detecting malignant thyroid nodule.

TIRADS Findings	Histopathological Findings		Diagnostic Accuracy Parameters				
	Benign n(%)	Malignant n(%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Overall Accuracy (%)
Benign	128 (70.7%)	53 (29.3%)	3.6	97	33	70	69
Malignant	4 (66.7%)	2 (33.3%)					

PPV: Positive predictive value, NPV: Negative predictive value

DISCUSSION

The present study evaluated the diagnostic performance of the ACR-TIRADS system in a surgical cohort of 187

patients. Our findings revealed a remarkably high specificity of 96.9% but a notably low sensitivity of 3.6%, resulting in an overall accuracy of 69%. This profile indicates that while ACR-TIRADS is exceptionally reliable for correctly identifying benign nodules (*i.e.*, ruling out disease), it missed a substantial proportion (63.6%) of histologically proven malignant lesions in our population.

This pattern of high specificity but unexpectedly low sensitivity is both consistent and divergent with the existing literature. Our specificity aligns perfectly with the core design intention of ACR-TIRADS: reducing unnecessary biopsies. Studies by Özdemir *et al.* reported specificities of 95.4% and 87%, respectively, confirming its strength in this area [16]. However, our observed sensitivity of 3.6% is considerably lower than those reported in other meta-analyses, which often report sensitivities ranging from 75% to 91% for detecting malignant nodules [9]. This significant discrepancy warrants careful interpretation.

Several factors may explain this stark finding. Firstly, selection bias is a critical consideration. Our study cohort consisted exclusively of patients who underwent surgery, which inherently selects for a population with higher clinical suspicion, larger nodules, or symptomatic disease (*e.g.*, 77.5% had shortness of breath) [17]. This is not the general screening population for which TIRADS was primarily designed. Malignancies in our cohort may have had more "benign-looking" or indeterminate sonographic features that prompted surgery based on clinical factors (*e.g.*, compression symptoms, rapid growth) rather than TIRADS score alone, thus skewing the results towards a population where ACR-TIRADS would perform poorly. Secondly, inter-observer variability in ultrasound interpretation, a known limitation of all TIRADS systems, could play a significant role [13, 18]. Subtle malignant features might have been under-scored by the reporting radiologists. Finally, the specific histopathological distribution of cancer types in our population (*e.g.*, a higher proportion of follicular or aggressive variants) might also contribute to these findings, as these can present with less suspicious ultrasound features [19].

Compared with other guidelines, our results reinforce the known trade-off inherent in ACR-TIRADS's conservative design. A recent meta-analysis by Piticchio *et al.* showed that ACR-TIRADS consistently assigns fewer nodules to biopsy categories compared to EU-TIRADS or K-TIRADS, prioritizing specificity at the potential expense of sensitivity [20]. This is further supported by Kim *et al.*'s systematic review, which found that ACR-TIRADS has one of the highest specificities among major systems, making it a valuable tool for reducing unnecessary

procedures despite potential sensitivity limitations in specific settings [21].

The clinical implication of our finding is profound. A sensitivity of 3.6% implies that relying solely on ACR-TIRADS to decide against biopsy would miss nearly two-thirds of cancers in a high-risk surgical population. Therefore, rigid adherence to ACR-TIRADS without integrating clinical context is fraught with risk. Factors such as patient age, family history of thyroid cancer, history of radiation exposure, rapid nodule growth, firm consistency on palpation, and the presence of suspicious lymphadenopathy must be integral parts of the decision-making process [4, 5, 19].

This study has limitations. Its single-center, cross-sectional design with a selected surgical cohort limits the generalizability of the sensitivity and NPV to the general population with thyroid nodules. The high proportion of female patients, while reflective of the epidemiology of thyroid disease, limits gender-based analysis. The potential for inter-observer variability in USG reporting was not assessed.

When evaluating thyroid nodules, FNAC and ultrasound complement each other. FNAC provides cytologic diagnosis and guides final treatment. In contrast, ultrasound (using structured reporting systems like ACR-TIRADS or K-TIRADS) provides risk stratification and targets the most suspicious region for sampling. Experience from other countries shows that structured US reporting maintains high sensitivity for malignancy while reducing needless FNAs. There is obvious potential for a locally calibrated P-TIRADS that retains the core US lexicon but modifies size thresholds, weights clinical modifiers, and incorporates cost-sensitive pathways due to variations in prevalence, resource availability, and practice patterns in Pakistan, and the fact that demographic and iodine-deficiency may result in alteration of sonographic patterns [22]. By minimizing unnecessary biopsies and procedures, a P-TIRADS validated against local FNAC and histopathology data would likely improve diagnostic accuracy and save money, a crucial factor in our healthcare system.

CONCLUSION

In conclusion, the ACR-TIRADS system demonstrated exceptionally high specificity but alarmingly low sensitivity in our surgical population. It serves as an excellent rule-out test for benignity, but must not be used in isolation to rule out malignancy. A comprehensive, patient-tailored diagnostic approach that integrates strong clinical suspicion and risk factors remains paramount. Future research should validate these findings in a general endocrine clinic cohort and explore integrating adjunctive modalities, such as elastography or artificial intelligence, to enhance sensitivity while

preserving the high specificity that makes ACR-TIRADS a valuable tool.

ETHICS APPROVAL

It has been approved by the institutional ethics review board (IHHN_IRB_2024_02_013). All procedures performed in studies involving human participants were conducted in accordance with the ethical standards of the institutional and/or national research committee and the Helsinki Declaration.

CONSENT FOR PUBLICATION

Data were collected using a structured questionnaire after obtaining written informed consent from patients.

AVAILABILITY OF DATA

Data may be provided upon request.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Declared none.

AUTHORS' CONTRIBUTION

Mahtab Washdil is the corresponding author. Mahtab Washdil and Kiran Shahzadi have decided on the topic and have written a synopsis under the supervision of Nazia Lodhi. Aiman Aamir, Rabika Fatima, Mahnoor Washdil, and Kiran Shahzadi have collected and analysed the data. The final manuscript has been compiled by Mahtab Washdil and Kiran Shahzadi and proofread by Nazia Lodhi and Ghina Shamsi.

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