

Correlation of Thyroid Imaging Reporting and Data System (TIRADS) and histopathology. A single-center Observational Study

Wizra Faiz, Sarfraz Latif, Zia us Salam Qazi, Maham Malik, Shehryar Haider, Humna Usman

ABSTRACT:

Objective: To correlate TIRADS with the final histopathology in patients undergoing thyroid surgery.

Study design & settings: prospective observational study at Department of ENT, Shaikh Zayed Hospital, Lahore.

Methodology: We included 142 patients with thyroid nodules who underwent ACR TI-RADS-reported neck ultrasonography at our center followed by thyroid surgery. Histopathology was the reference standard. For diagnostic testing, TI-RADS 1-3 were prespecified as test negative and TI-RADS 4-5 as test positive. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), diagnostic accuracy, and receiver operating characteristic (ROC) analysis were calculated.

Results: The largest age group was 30-39 years (42/142; 29.6%). There were 120 females and 22 males (female:male ratio approximately 5.5:1). TI-RADS distribution was TR1 3, TR2 23, TR3 62, TR4 48, and TR5 6. Histopathology showed 88 benign (62.0%) and 54 malignant (38.0%) nodules. Using TI-RADS 1-3 as test negative and TI-RADS 4-5 as test positive, sensitivity was 64.8%, specificity 78.4%, PPV 64.8%, NPV 78.4%, and diagnostic accuracy 73.2%. ROC analysis showed AUC 0.726 (95% CI 0.637-0.816; $p < 0.01$), indicating approximately 72.6% discriminatory ability.

Conclusion: ACR TI-RADS showed a significant association with histopathology in this surgically selected tertiary-care cohort. Diagnostic performance was moderate, and the observed malignancy frequencies were not strictly monotonic across all categories. These findings should not be generalized to unselected thyroid-nodule populations without qualification.

Keywords: Thyroid Nodule; Ultrasonography; Thyroid Neoplasms; Risk Assessment; Diagnostic Imaging.

How to cite this Article:

Faiz W, Latif S, Qazi ZUS, Malik M, Haider S, Usman H. Correlation of Thyroid Imaging Reporting and Data System (TIRADS) and histopathology. A single-center Observational Study. J Bahria Uni Med Dental Coll. 2026;16(4):1044-50 DOI: <https://doi.org/10.51985/JBUMDC20261105>

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Received: 15-07-2026

Accepted: 29-09-2026

1st Revision: 02-08-2026

2nd Revision: 15-09-2026

INTRODUCTION:

Thyroid and thyroid-related malignancies are common in our healthcare setting. Thyroid nodules account for about 8.5% of our population, with women being more susceptible to them than males.¹ Clinical examination alone cannot efficiently differentiate nodules of benign and malignant potential.² Thyroid nodules can be evaluated using several imaging modalities including plain radiograph, radionuclide imaging, ultrasonography, CT and MRI.³ The key job in analysis of a thyroid nodule is the probability of cancer. Effective and accurate diagnosis of benign nodule versus malignant has been an ongoing challenge on clinical grounds. The extensive employment of high-resolution ultrasound has enhanced the chance for the diagnosis of thyroid nodules. The use of ultrasound is harmless, readily available, cost-effective, and uses no ionized radiation. The widespread use of high-quality ultrasonography in the identification of nodules in the thyroid has considerably increased the likelihood of diagnosis, with an estimated incidence of up to 67% in the general public. In the year 2015, a unique ultrasonography risk stratification system for identifying nodular thyroids, the Thyroid Imaging Reporting and Data System (TIRADS), was suggested by the American College

of Radiology (ACR) to instruct for FNAC.⁴ The TIRADS is a systematized scoring system that applies many thyroid ultrasonographic criteria, including composition, echogenicity, shape, margin, and echogenic foci, in response to additional recommendations from various societies.⁵ A cumulative score was computed for observed characteristics in each category of ACR TIRADS, namely: 1- normal thyroid gland, 2- benign lesions, 3- probably benign lesions, 4- suspicious lesions, 5- malignant lesions.² Nodule of Ultrasonographic interest, defined as the collective score of all the variables calculated by the radiologists using TIRADS scoring system for each nodule in a thyroid gland was considered in case of multiple thyroid nodules. The nodule with the most suspicious sonographic features (and highest TIRADS score) was taken as the nodule of interest.⁶⁻⁸

Ultrasound has several limitations, such as variations in resolution across different equipment, discrepancies between observers, and limited specificity caused by the overlap in sonographic features between benign nodules and thyroid cancer. The TIRADS classification system aims to reduce the impact of these constraints. Thus, the definitive method to distinguish between thyroid nodules is through the surgical excision of the nodule and subsequent analysis of its histopathological report.^{9,10} Standardized imaging-based risk stratification systems have gained popularity in recent years due to their ability to reduce needless invasive operations while facilitating collaboration among radiologists, surgeons, endocrinologists, and pathologists. In clinical practice, the treatment of thyroid nodules relies not only on the predicted risk of malignancy but also on striking a balance between the necessity for prompt identification and the avoidance of excessive fine needle aspiration cytology (FNAC) and surgical intervention in patients with benign tumors. A standardized approach to classifying thyroid nodules based on sonographic features is provided by a structured reporting system like ACR TI-RADS, which enables clinicians to triage patients who need additional testing or surgery. However, local disease incidence, referral system, operator expertise, and differences in ultrasound interpretation (interobserver variation) all affect these systems' diagnostic performance. Therefore, before TI-RADS is widely used in normal clinical decision-making, it is crucial to validate its performance in individual institutions. This also helps identify the applicability of TI-RADS in various medical settings.

The ACR developed the TI-RADS to standardize ultrasound reporting and improve the accuracy of differentiating benign from malignant thyroid nodules. However, its diagnostic performance may vary across populations due to differences in demographics, disease patterns, and imaging practices. Since most validation studies have been conducted in Western settings, there is a need to assess its reliability in our local population. The concordance of rationality and reliability of TIRADS in the assessment of thyroid nodules are evaluated in a couple of studies; however, mostly they are retrospective,

not representing data for TIRADS scoring system in our setup and they were deficient in rigorous reference standard.

The study seeks to assess the practical use of TIRADS in the assessment of thyroid nodules and to compare it with the gold standard histological results in our specific clinical setup.

METHODOLOGY

After approval from Ethical Review Committee of Shaikh Zayed Hospital (TERC/SC/INT/2025/367), data was prospectively collected from the Otolaryngology (ENT) department's computerized database and files reviewed over a period of one year. Patients of age 16- 65 years of both gender presenting to ENT clinic for evaluation of thyroid nodules with ultrasound neck done from our center with the TIRADS reported and undergoing thyroid surgery were included whereas patients who received management for thyroid related conditions previous thyroid surgery / radioactive iodine ablation/ tyrosine kinase inhibitor, patients who underwent radiation therapy for head and neck cancers and those who did not consent to participate were excluded. This study was approved by the Institutional ethical review committee.

The TIRADS, a systemized scoring system, calculated by radiologists, for each nodule in a thyroid gland was considered in case of multiple thyroid nodules. The nodule of interest was determined to be the one with the highest TIRADS score and the most suspicious sonographic features. Following that, patients underwent surgery in accordance with clinical and ultrasound findings. Pathologists performed histological analyses on the surgically obtained specimens after they had been preserved in 10% formalin for the next 24 hours. Findings of Papillary carcinoma, Follicular carcinoma, Medullary carcinoma, Anaplastic carcinoma and poorly differentiated carcinoma were treated as malignant lesions whereas adenomatoid nodules, colloid goiter, follicular adenoma, nodular goiter and lymphocytic thyroiditis were taken as benign on histopathology. The final histological analysis and the ACR-TIRADS ultrasonography report score were compared. Consultant radiologists with expertise in head and neck imaging analyzed all ultrasound reports using the American College of Radiology TI-RADS scoring. The standardized grading method based on composition, echogenicity, shape, margin characteristics, and echogenic foci was used to evaluate each thyroid nodule. The final TI-RADS category was created by adding the individual feature scores. To adhere to ACR guidelines, only the dominant nodule with the highest TI-RADS score and the most alarming sonographic appearance was chosen for statistical analysis in patients with multiple thyroid nodules.

Because eligibility required thyroid surgery, this cohort represents a surgically selected referral population rather than an unselected population of patients with thyroid nodules. Diagnostic indices, especially predictive values

Table 1: Study participant's age and gender distribution (n=142)

Age Ranges (years)	Gender Females	Gender Male	Total
16-19	1	3	4(2.8%)
20-29	29	5	34(24%)
30-39	40	2	42(29.6%)
40-49	22	10	32(22.5%)
50-59	18	1	19(13.4%)
>60	10	1	11 (7.7%)

Table 2: Thyroid nodule distribution per TIRADS scoring (n=142)

TIRADS Score	Frequency	Percentage (%)
TIRADS 1	3	2.1
TIRADS 2	23	16.2
TIRADS 3	62	43.7
TIRADS 4	48	33.8
TIRADS 5	6	4.2
Total	142	100

Table 3: Presenting according to histopathological assessment and TIRADS among study participants

Histopathological Diagnosis										
	Adenomatoid nodule	Colloid goiter	Follicular adenoma	Nodular goiter	Lymphocytic thyroiditis	Follicular CA	Papillary CA	Poorly differentiated CA	Medullary CA	Total
TIRADS 1	2	0	1	0	0	0	0	0	0	3(2.1%)
TIRADS 2	1	0	14	2	0	0	6	0	0	23(16.2%)
TIRADS 3	9	1	30	0	9	4	7	0	2	62(43.7%)
TIRADS 4	9	0	6	0	4	6	18	2	3	48(33.8%)
TIRADS 5	0	0	0	0	0	0	5	0	1	6(4.2%)
Total	21(14.8%)	1(0.7%)	51(35.9%)	2(1.4%)	13(9.2%)	10(7%)	36(25.4%)	2(1.4%)	6(4.2%)	142(100%)

Table 4: Correlation of TI-RADS category with final histopathology (n=142)

TI-RADS category	Benign, n (%)	Malignant, n (%)	Total nodules	Risk of malignancy
TI-RADS 1	3 (100.0%)	0 (0.0%)	3	0.0%
TI-RADS 2	17 (73.9%)	6 (26.1%)	23	26.1%
TI-RADS 3	49 (79.0%)	13 (21.0%)	62	21.0%
TI-RADS 4	19 (39.6%)	29 (60.4%)	48	60.4%
TI-RADS 5	0 (0.0%)	6 (100.0%)	6	100.0%
Total	88 (62.0%)	54 (38.0%)	142	38.0% overall

Figure 1: The occurrence of TIRADS subcategory amongst histopathologically (gold standard) determined benign and malignant nodules

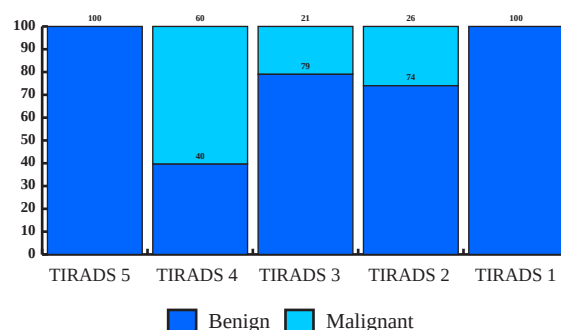


Table 5: 2x2 diagnostic contingency table using TI-RADS 1-3 as test negative and TI-RADS 4-5 as test positive (n=142)

Diagnostic classification	Histopathology malignant	Histopathology benign
TI-RADS 4-5 (test positive)	35 (TP)	19 (FP)
TI-RADS 1-3 (test negative)	19 (FN)	69 (TN)

Figure 3: Area Under the Curve (AUC) for TIRADS score and histopathology of thyroid nodules

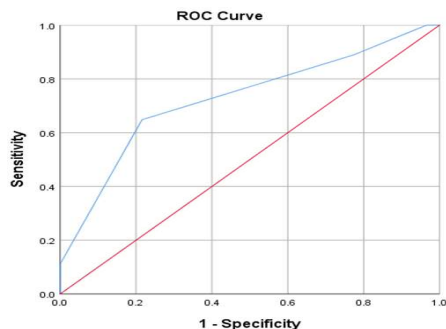
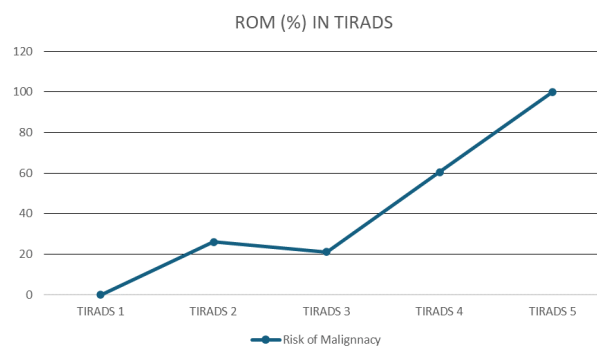


Figure 2: ROM (Risk of Malignancy) in each TIRADS score



and the observed prevalence of malignancy, may therefore be affected by referral/selection (spectrum) bias and should be interpreted within this clinical context. A computerized database was used to maintain the data collected, and statistical analysis was performed using the available study dataset. Continuous variables were summarized using mean and standard deviation where appropriate, while categorical variables were summarized as frequencies and percentages. Histopathological diagnosis was the reference standard. For the prespecified diagnostic threshold, TI-RADS 1-3 were classified as test negative and TI-RADS 4-5 as test positive. The resulting 2×2 table was used to calculate sensitivity, specificity, PPV, NPV, and diagnostic accuracy. ROC analysis was used to summarize discrimination across the ordinal TI-RADS score, and the AUC was reported with its 95% confidence interval. A p-value <0.05 was considered statistically significant.

RESULTS:

There were 142 patients in the study. The largest age group was 30-39 years (42/142; 29.6%), followed by 20-29 years (34/142; 23.9%). The cohort comprised 120 females (84.5%) and 22 males (15.5%), giving a female:male ratio of approximately 5.5:1. The Table 2 shows the thyroid nodule distribution per TIRADS category in our study. Out of 142 nodules, 2.1% was labelled as TIRADS 1, 16.2% were grouped into TIRADS 2, 43.7% nodules segregated to TIRADS 3, 33.8% in TIRADS 4 and 4.2% were identified as TIRADS 5. Out of total 142 nodules, 88 (62%) of the nodules were benign and 54 (38%) malignant. Among the benign nodules on final histopathology, 21/88 (14.8%) were adenomatoid nodules, 1/88 (0.7%) were colloid goiter, 51/88 (35.9%) were follicular adenoma, 2/88 (1.4%) were nodular goiter and 13/88 (9.2%) cases were lymphocytic thyroiditis. In our study of 142 nodules, 54 (38%) were malignant. 36/54 (25.4%) were described as papillary carcinoma, 10/54 (7%) expressed as follicular carcinoma, 2/54 (1.4%) as poorly differentiated carcinoma and 6/54 (4.2%) medullary cancer. 3(2.1%) nodule was noted as TIRADS 1 which were benign on final histopathology. Each of the 23(16.2%) nodules grouped into TIRADS 2, 17/23 (74%) were benign and 6/23 (26%) were malignant on histopathology. For TIRADS 3, 49/62 (79%) nodules were benign and 13/62 (21%) malignant. Among TIRADS 4, 19/48 (39.6%) were benign and 29/48 (60.4%) were malignant. In TIRADS 5, 6/6 (100%) nodules were histopathologically malignant. The occurrence of TIRADS subcategory amongst histopathologically determined benign and malignant nodules is illustrated in Figure 1.

Diagnostic performance was calculated using the explicit threshold TI-RADS 1-3 = test negative and TI-RADS 4-5 = test positive. This classification yielded 35 true positives, 19 false positives, 19 false negatives, and 69 true negatives (Table 5). Using this threshold, sensitivity was 64.8% (35/54),

specificity 78.4% (69/88), PPV 64.8% (35/54), NPV 78.4% (69/88), and diagnostic accuracy 73.2% (104/142). The NPV value of 74.8% reported previously was a numerical error and has been corrected consistently to 78.4%. ROC analysis yielded an AUC of 0.726 (standard error 0.046; 95% CI 0.637-0.816; p<0.01), corresponding to approximately 72.6% discriminatory ability for distinguishing malignant from benign nodules. The AUC should not be interpreted as meaning that TI-RADS distinguishes malignancy '72.6 times.'

DISCUSSION:

The use of ultrasound thyroid for screening purposes has resulted in an exponential rise in reporting of nodules in thyroid gland among the general population. With an incidence of 2–6% when palpated, 19–35% when observed on ultrasonography, and 8–65% when recorded in autopsy data, thyroid nodules are widespread and mostly benign.⁷ According to a study of examination of a thyroid nodule that is incidentally discovered or clinically noticeable includes a fourfold evaluation comprising of a complete history and physical examination, thyroid function tests (TFTs), ultrasound imaging of thyroid, and USG-guided aspiration cytology or decompression depending on ultrasonographic features.⁸ Credible and consistent USG criteria are implied for the best use of resources and decreasing the stress as well as financial burden of patients during subsequent studies.⁹ USG and FNAC (fine needle aspiration cytology), both play a vital role in the diagnosis of TNs (thyroid nodules). The “American Thyroid Association's” (ATA) recommendations now include the Bethesda system of thyroid cytology; however, they do not yet include the TIRADS scoring for ultrasound reporting of TNs.¹⁰

The affirmation of the “Thyroid Imaging Reporting and Data System” (TIRADS) by the “American College of Radiologists” (ACR) in 2017, is a chance to correlate thyroid nodule sonographic images with clinical information.¹¹ Horvath et al.¹² was the first one who suggested to summarize the various thyroid nodule ultrasonography features into several TIRADS classifications according to their risk for malignancy. TIRADS is a risk evaluating system for identifying thyroid nodules on ultrasound imaging, and it uses the “Breast Imaging Reporting and Data System” (BIRADS) classification as a template, which is a component of the triple evaluation of breast lumps. It provides a reliable measure of the clinico-radiological correlation between thyroid nodules and cancer for medical practitioners treating TNs.¹³ All over the globe, in majority of countries, radiologists, endocrinologists and surgeons have opted using TIRADS scoring in their clinical practice religiously thereby shortening of the learning curve. TIRADS comes with an advantage of it being designed to simplicity and help provide ease in assessing the risk of malignancy (ROM) as well as reducing the total of FNAC tests performed on patients who have TNs with lesser malignancy potential.²

Several studies have compared TIRADS with Bethesda scoring system to study the correlation between the sonographic findings and cytology of nodules of interest. Our study evaluated the TIRADS score with histopathology, keeping histopathology as gold standard reference. In our study, 62% of thyroid nodules came as benign and 38% were malignant on histopathology. According to the study of Ahmed et al.¹⁴ 48.6% nodules were reported as malignant and 51.4% were benign. Whereas García-Moncó Fernández et al.¹⁵ in their study were able to include 28.5% of malignant TNs and 71.5% benign ones. The observed malignancy frequencies were 0.0% in TR1, 26.1% in TR2, 21.0% in TR3, 60.4% in TR4, and 100.0% in TR5. Importantly, the pattern was not strictly monotonic across adjacent categories because TR2 had a slightly higher malignancy frequency than TR3 (26.1% vs 21.0%). The clinically important separation in this surgically selected cohort occurred mainly at TR4 and TR5.

The anticipated malignancy risk in the initial 2017 study¹⁶ was derived from a partial analysis of 3,433 nodules with cytological findings. The results¹⁷ stated the published malignancy rates for each point given by “ACR TI-RADS”, with each verified category were 0.3%, 1.5%, 4.8%, 9.1% and 35% for TIRADS 1,2,3,4, and 5 respectively. In comparison to a study done in Chennai² the ROM(risk of malignancy) were documented as 4.2% , 13.3% , 57.9% and 100% in TIRADS 2, 3, 4 and 5 respectively, marking a higher malignant potential in TIRADS 2, 3& 4 of our study. However, in our study, the ROM in TIRADS 5 are comparable with the results of the study mentioned above. R. M. Singaporewalla⁸ reported in their study the ROMs in TIRADS 2,3,4 & 5 as 0%, 9.5%, 33.3% & 60% respectively. Kwak et al.¹⁸ documented the ROM in “TIRADS” 2, 3, 4a, 4b, 4c, and 5 as 0%, 11.7% 3.3% 9.2%, 44.4-72.4% and 87.5% respectively. In a few studies, the results of ROM in TIRADS 5 were 77.8%¹⁹ 86.5%¹⁴ and 97.14%²⁰ which were lesser than our results. Horvath et al.²¹ reported that 98.85% of TIRADS 5 nodules had thyroid malignancy, however in the present study, histopathology revealed that 100% of TIRADS 5 TNs were malignant. The clinical accuracy of TIRADS was noted in the study done by Anuradha et al.²² in India, which claimed the clinical accuracy of “TIRADS” and stated the predictive value for malignant potential for TIRADS 2, 3, 4a, 4b, 4c, and 5 categories was 6.6%, 32%, 36%, 64%, 59%, and 91% respectively. Park et al.²³ reported ROMs of TIRADS 2-5 as 9.6% ,31.1%, 76.8% and 100%. Srinivas et al.²⁴ had observed the ROM for TIRADS 4 & 5 nodules as of 83.3% and 100% respectively. Another French paper²⁵ showed that the malignancy rates were 0%,2.2%, 57.9% and 100 % for respective score of TIRADS 2, 3, 4 & 5.

The results support the usefulness of TI-RADS as a standardized imaging framework, but they do not demonstrate a uniform stepwise increase in malignancy across every

category. The substantial rise in malignancy frequency in TR4 and TR5 is more informative than the small non-monotonic difference between TR2 and TR3. Histopathology remained the reference standard in this study. The relatively high malignant proportion in this cohort, including the unexpectedly high malignancy frequencies in lower/intermediate categories, should be interpreted in light of spectrum and referral/selection bias. All participants underwent thyroid surgery at a tertiary-care center, so patients with more concerning clinical or imaging features were more likely to enter the study than patients managed conservatively. Consequently, the 38.0% malignancy prevalence and predictive values observed here should not be generalized to community-based or otherwise unselected thyroid-nodule populations. We should also take note of the moderate sensitivity found in the study we conducted. The final TI-RADS category may be affected by minute variations in the evaluation of margins, echogenic foci, or nodule form. Ultrasound assessment is still operator-dependent. Additionally, while some benign lesions show worrisome ultrasound characteristics, certain malignant thyroid tumors may show very benign sonographic appearances. The significance of combining clinical examination, biochemical tests, cytology, and radiological assessment rather than depending solely on any one diagnostic modality is highlighted by these overlapping imaging findings, which unavoidably lower diagnostic accuracy.

With the prespecified TI-RADS 1-3 versus 4-5 threshold, specificity and NPV were both 78.4%, sensitivity was 64.8%, PPV was 64.8%, and overall accuracy was 73.2%. These values indicate moderate diagnostic performance in this selected surgical cohort. Predictive values are prevalence-dependent and therefore should be interpreted cautiously in settings with a different spectrum of disease. The tertiary-care referral setting and restriction to surgically treated patients likely enriched the sample for malignancy and may explain why the observed category-specific malignancy frequencies differ from those reported in unselected populations. Although TIRADS 1 & 2 categories were considered benign, most of the patients in these cases underwent surgery for cosmetic reasons as well as the relief of the compressive symptoms because of the presence of huge goiter. These reasons are comparable to a study done in India². Using TI-RADS 1-3 as test negative and TI-RADS 4-5 as test positive, sensitivity, specificity, PPV, NPV, and diagnostic accuracy were 64.8%, 78.4%, 64.8%, 78.4%, and 73.2%, respectively. Reported by George N.A et al.²⁰ in his study the “sensitivity, specificity, PPV and NPV of TIRADS risk of malignancy” were narrated as 72.3%, 66.7%, 97.1% and low respectively. This study had a high PPV as compared to our study as well as study done by Horvath et al.¹², while the specificity was lesser than ours (78.4% vs 66.7%). In an another Indian study²², the clinical efficacy of TIRADS keeping malignancy potential among class 4a, 4b, 4c, and

5 and benign scores as 2 and 3; the following values were noted as specificity, sensitivity, NPV and PPV are noted as 68.8%, 72%, 76.2%, and 63.9% respectively. Comparing this one to our study, higher specificity & NPV, lower sensitivity and yet comparable PPV (64.8% compared to 63.9%) was seen. Data was analyzed by Chi-Square test for correlation of ROM in thyroid nodules in histopathology with “TIRADS” scoring. TIRADS was tallied as significant ($p < 0.01$) in determining the malignant potential in histopathology. This outcome corresponds with one of the Tamil Nadu studies² where the p value of TIRADS 2,4 and 5 was statistically significant on Chi-square test ($p = 0.000$). To find ways to improve these data outcomes, we want to review our findings in the upcoming years. Finding the thyroid nodule's malignancy risk and avoiding needless FNAC of benign-looking nodules are the objectives of the TIRADS scoring system.

Limitations: This was a single-center study restricted to patients who underwent thyroid surgery, creating referral/selection (spectrum) bias and an enriched malignancy prevalence of 38.0%. Therefore, the observed prevalence, PPV, NPV, and category-specific malignancy frequencies should not be generalized to unselected thyroid-nodule populations. The relationship between histopathology and TR4 subgroups was not evaluated, and the small number of TR1 nodules limited category-specific inference. Additional limitations include possible interobserver variation because ultrasound examinations were reported by multiple radiologists and incomplete documentation of all individual sonographic features in some reports. Future multicenter prospective studies should use standardized image acquisition, blinded or consensus TI-RADS assessment, complete source-data verification, and inclusion of both surgically and non-surgically managed nodules where an appropriate reference standard is available.

CONCLUSION:

In this surgically selected single-center cohort, ACR TI-RADS category was significantly associated with final histopathology, with a marked increase in malignancy frequency in TR4 and TR5. However, malignancy frequencies were not strictly monotonic across all categories, and diagnostic performance at the TI-RADS 1-3 versus 4-5 threshold was moderate (sensitivity 64.8%, specificity 78.4%, NPV 78.4%, accuracy 73.2%). These findings support TI-RADS as an adjunct to clinical assessment but do not justify recommending routine adoption or relying on TI-RADS alone for surgical selection.

Conflict of Interest: None

Fundings: No funding source

Use of Artificial Intelligence (AI) Disclosure: There is no AI tool used.

Authors Contribution:

Wizra Faiz: Principal investigator, study conception and design, data collection, statistical analysis, manuscript drafting and corresponding.

Sarfraz Latif: Supervision, critical review of study design, manuscript editing, approval of final draft

Zia us Salam Qazi: Assisted in data collection, literature review, contributed to manuscript writing.

Maham Malik: Assisted in data collection, literature review, contributed to manuscript writing

Shehryar Haider: Supervision, critical review of study design, manuscript editing, approval of final draft

Humna Usman: Assisted in data collection, literature review, contributed to manuscript writing

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