

Concordance Between TI-RADS and Bethesda System for Reporting Thyroid Cytopathology and Their Correlation with Histopathology

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Abstract

Background: Thyroid nodules are increasingly detected with high-resolution ultrasonography (HRUS). Although most are benign, accurate malignancy risk stratification is essential to avoid unnecessary procedures. Assessing alignment between ultrasound and cytology-based classification systems may improve overall decision-making.

Objective: To assess concordance between ACR TI-RADS and revised 2017 Bethesda System (TBSRTC), compare their diagnostic performance against histopathology, and evaluate the value of combined interpretation.

Methods: This prospective observational study included 200 patients with thyroid nodules at Nizam's Institute of Medical Sciences, India. Nodules were assigned paired ACR TI-RADS categories (TR2–TR5) on HRUS and FNAC Bethesda categories II–VI. Bethesda I and incomplete paired data were excluded. Histopathology, supplemented by immunohistochemistry when indicated, served as the reference standard. Concordance and diagnostic indices (sensitivity, specificity, PPV, NPV, and accuracy) were calculated.

Results: Mean age was 45.4±8 years and 79% were female. TR4 (42.5%) and Bethesda II (55.5%) were most common. Malignancy rates increased with category (Bethesda II 18.5%, III 35.2%, IV 50.0%, V 71.4%, VI 93.3%; TI-RADS 2 12.5% to TI-RADS 5 87.5%). Concordant high-risk TR5 with Bethesda VI was 100% malignant (10/10). Papillary thyroid carcinoma and variants predominated. Bethesda outperformed TI-RADS in specificity (87.2% vs 53.9%) and accuracy (77.3% vs 65.3%), while TI-RADS showed higher sensitivity (77.8% vs 66.7%); both had acceptable NPV (~73–74%) and 0.71 (TI-RADS).

Conclusion: TI-RADS and Bethesda show limited concordance but demonstrate increasing malignancy risk with higher categories. Bethesda provides higher specificity as well as overall accuracy, while both systems maintain acceptable negative predictive value in the operated subset.

Keywords: Fine-needle aspiration, thyroid nodule, thyroid neoplasms, ti-rads, ultrasonography

Introduction

Thyroid nodules constitute one of the most common endocrine presentations encountered in routine clinical practice and are being detected with increasing frequency because of the expanding use and improving resolution of neck imaging.¹ High-frequency ultrasonography can identify thyroid nodules

in a substantial proportion of otherwise asymptomatic individuals, with prevalence estimates approaching two-thirds of screened populations in some series, and detection rates rising with age and in iodine-deficient settings. Women are affected more commonly than men, and although most nodules are benign, a clinically meaningful minority harbor malignancy requiring accurate risk

stratification.²

High-resolution ultrasound (HRUS) is the first-line modality for thyroid nodule assessment because it is widely available, non-invasive, and capable of characterizing features associated with malignancy risk including composition, echogenicity, shape, margins, and presence of calcifications. However, interpretation of sonographic features can be subjective, and individual ultrasound signs show imperfect diagnostic performance when used in isolation, contributing to heterogeneity in biopsy recommendations and further management. To address these problems, structured ultrasound risk-stratification systems have been developed.³ Among these, the American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS) is most commonly used.⁴ Fine-needle aspiration cytology (FNAC) remains central to thyroid nodule evaluation because it is minimally invasive, relatively inexpensive, and provides direct cellular-level assessment that complements imaging morphology. Cytological reporting has been standardized through The Bethesda System for Reporting Thyroid Cytopathology (TBSRTC), which defines six diagnostic categories linked to implied risks of malignancy and evidence-based clinical management recommendations.⁵ In contemporary practice, TI-RADS and TBSRTC are frequently used in parallel—TI-RADS guiding the indication for FNAC and Bethesda results guiding the need for repeat aspiration, molecular testing where available, or surgery.⁶ Conceptually, this combined approach should improve precision by leveraging complementary information such as macroscopic structural risk from ultrasound and microscopic cellular risk from cytology. However, discordance between imaging suspicion and cytological category is not uncommon, particularly in intermediate-risk nodules, and the extent to which the two systems align (or fail to align) varies across studies and populations.⁷

Despite the widespread adoption of ACR TI-RADS and the revised 2017 Bethesda system, important knowledge gaps remain regarding the degree of concordance between these two classification frameworks when applied contemporaneously to the same nodules. The present prospective study was therefore designed to quantify agreement between TI-RADS and Bethesda categories, to assess and compare their diagnostic performance against histopathology as the gold standard, and to determine whether integrating both systems

improve malignancy risk stratification for thyroid nodules in routine clinical workflow.

Methods

This prospective, observational study was conducted in the Department of Pathology, Nizam's Institute of Medical Sciences (NIMS), Hyderabad, India. The duration of study was 18-months extending from August 2023 to February 2025. The study was conducted after obtaining approval from the Institutional Ethics Committee. Patients were explained in detail about the purpose of the study and a written informed consent was obtained from all participants prior to enrolment.

Patients presenting with thyroid swelling/thyroid nodule during the study period who underwent HRUS with documented ACR TI-RADS categorization (TR2–TR5) and FNAC reported as per the revised 2017 Bethesda System (Bethesda II–VI), and who provided written informed consent with complete paired TI-RADS and Bethesda data available, were included in the study. Those with no discrete nodule HRUS (TI-RADS 1), non-diagnostic or inadequate FNAC smears (Bethesda I), incomplete paired data (missing TI-RADS or Bethesda category), or those who declined informed consent were excluded. A total of 200 patients constituted the final study cohort after application of these criteria. In patients with multiple nodules, the index nodule subjected to FNAC (typically the most suspicious on ultrasound and/or clinically dominant nodule) was considered for analysis to ensure paired comparison between TI-RADS and Bethesda categories.

HRUS was performed using the Esaote MyLab 7™ system. Each nodule was evaluated using the ACR TI-RADS (2017) lexicon across five sonographic domains: composition, echogenicity, shape (wider-than-tall vs taller-than-wide), margins, and echogenic foci. Points were assigned for each domain, summed to obtain the total TI-RADS score and nodules were categorized into TR1–TR5 as per ACR recommendations. TI-RADS categorization recorded at the time of clinical reporting was used for subsequent concordance and diagnostic performance analyses.

FNAC was performed under aseptic precautions using standard aspiration technique with a 21-gauge needle, after appropriate patient positioning and localization of the nodule. Aspirated material was expressed onto labelled glass slides, smears were prepared, and slides were

stained with Papanicolaou (PAP) and May-Grünwald-Giemsa (MGG) stains. Cytological interpretation was rendered by pathologists according to the revised 2017 Bethesda System for Reporting Thyroid Cytopathology (TBSRTC), assigning each case to one of the six Bethesda categories (I–VI). Cases reported as Bethesda I (non-diagnostic/unsatisfactory) were excluded as per study criteria.

Histopathological examination was done in all operated cases. Specimens were fixed in 10% neutral buffered formalin, followed by routine paraffin processing and hematoxylin and eosin (H&E) staining. Where required for definitive characterization (e.g., challenging follicular-patterned lesions or confirmation of carcinoma subtype), immunohistochemistry (IHC) was performed using the Ventana BenchMark Ultra platform in accordance with institutional protocols. Histopathological diagnosis was considered the gold standard for correlation and for calculating diagnostic performance parameters in surgically resected cases.

Demographic and clinical details were recorded in a structured proforma. TI-RADS categories and Bethesda categories were tabulated and assessed for concordance. For correlation with histopathology, diagnostic performance indices—sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy—were calculated using histopathology as the reference standard in operated cases. Statistical analysis was performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA), and a two-tailed p value <0.05 was considered statistically significant.

Results

A total of 200 patients were included. The mean age was 45.4 years (range: 15–82; SD: 8 years), with peak incidence in the 31–40-year age group (54 cases, 27%). Females predominated with a male-to-female ratio of 1:3.76 (158 females, 79% vs 42 males, 21%). The right lobe was the most common nodule site (58%, n=116), followed by the left lobe (38%, n=76) and isthmus (4%, n=8) (Table 1).

TI-RADS 4 was the most frequent ultrasound category (42.5%, n=85), followed by TI-RADS 3 (35.5%, n=71) and TI-RADS 5 (13.5%, n=27). Among Bethesda categories, the majority were Bethesda II (55.5%, n=111), followed by Bethesda III (21.0%, n=42). On cross-tabulation, TI-RADS 2 and 3 cases were predominantly Bethesda II (52.9% and 76.1% respectively), while TI-RADS 5 showed the strongest association with higher-risk cytology categories—Bethesda V (29.6%) and VI (40.7%) (Table 2).

Histopathological confirmation was available for 75/200 cases (37.5%), of which 39 (52.0%) were benign and 36 (48.0%) were malignant. Malignancy rates increased progressively with higher Bethesda categories: 18.5% in Bethesda II, 35.2% in III, 50% in IV, 71.4% in V, and 93.3% in VI. For TIRADS, malignancy rose from 12.5% (TIRADS 2) to 33.3% (TIRADS 3), 46.7% (TIRADS 4), and 87.5% (TIRADS 5). On combined analysis, concordant high-risk pairings carried the highest malignancy: TR5 + Bethesda VI was 100% malignant (10/10), TR4 + Bethesda V showed 75.0% malignancy (6/8), while concordant low-risk TR2 + Bethesda II was

Table 1 Demographic and Clinical Profile of Patients with Thyroid Nodules (n = 200)

Parameter	Value	Parameter	Value
Mean Age	45.4 years	Median	43.5 years
Age Range	15–82 years	SD	8 years
Peak Age Group		31–40 years (54 cases)	
Sex	n	%	M:F Ratio
Male	42	21	1:3.76
Female	158	79	
Location	n	%	
Right Lobe	116	58	
Left Lobe	76	38	
Isthmus	8	4	

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Table 2 Cross-tabulation of ACR TI-RADS Categories (TR2–TR5) with Bethesda System Categories (n=200)

TI-RADS	Beth II	Beth III	Beth IV	Beth V	Beth VI	Total (%)
2	9 (52.9%)	7 (41.2%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	17 (8.5)
3	54 (76.1%)	11 (15.5%)	1 (1.4%)	3 (4.2%)	2 (2.8%)	71 (35.5)
4	43 (50.6%)	22 (25.9%)	2 (2.4%)	11 (12.9%)	7 (8.2%)	85 (42.5)
5	5 (18.5%)	2 (7.4%)	1 (3.7%)	8 (29.6%)	11 (40.7%)	27 (13.5)
Total	111 (55.5%)	42 (21.0%)	5 (2.5%)	22 (11.0%)	20 (10.0%)	200 (100)

Table 3 Histopathological Correlation of Bethesda and TI-RADS Categories and Combined TI-RADS–Bethesda Concordance (n=75)

Bethesda	n=75	Benign n (%)	Malignant n (%)	Key Malignant Diagnoses	
II	27	22 (81)	5 (18.5)	PTC-4, FVPTC-1	
III	17	11 (64.7)	6 (35.2)	FVPTC-4, PTC-2	
IV	2	1 (50)	1 (50)	Follicular Ca-1	
V	14	4 (28.5)	10 (71.4)	PTC-8, FVPTC-1, EFVPTC-1	
VI	15	1 (6.6)	14 (93.3)	PTC-9, FVPTC-3, FC-1, Met-1	
Total	75	39 (52)	36 (48)		
TIRADS	n	Benign n (%)	Malignant n (%)	Key Malignant Diagnoses	
2	8	7 (87.5)	1 (12.5)	Follicular Ca-1	
3	21	14 (66.7)	7 (33.3)	FVPTC-5, PTC-1, Met-1	
4	30	16 (53.3)	14 (46.7)	PTC-11, FVPTC-3	
5	16	2 (12.5)	14 (87.5)	PTC-10, FVPTC-3, FC-1	
Total	75	39 (52)	36 (48)		
TIRADS	Bethesda	Total	Benign n (%)	Malignant n (%)	Interpretation
2	II	5	4 (80)	1 (20)	Low risk
2	III	2	2 (100)	0 (0)	Low risk
2	IV	1	1 (100)	0 (0)	Discordant
3	II	12	9 (75)	3 (25)	Low risk
3	III	7	5 (71.4)	2 (28.6)	Intermediate risk
3	IV	1	0 (0)	1 (100)	Discordant
3	V	1	0 (0)	1 (100)	High risk
4	II	10	9 (90)	1 (10)	Discordant
4	III	7	4 (57.1)	3 (42.9)	Intermediate–high risk
4	V	8	2 (25)	6 (75)	High risk
4	VI	5	1 (20)	4 (80)	Very high risk
5	III	1	0 (0)	1 (100)	Discordant
5	V	5	2 (40)	3 (60)	High risk
5	VI	10	0 (0)	10 (100)	Very high risk
Total		75	39 (52)	36 (48)	

Table 4 Comparative Diagnostic Performance, Risk of Malignancy, Agreement, and ROC Analysis of ACR TI-RADS and the Bethesda System Against Histopathology (n=75)

Measure	Bethesda	ACR TI-RADS	Interpretation
Diagnostic Performance			
Sensitivity (%)	66.67	77.78	
Specificity (%)	87.18	53.85	
PPV (%)	82.76	60.87	
NPV (%)	73.91	72.41	
Accuracy (%)	77.33	65.33	
Risk of Malignancy by Category (%)			
Category II / TI-RADS 2	18.52	12.50	
Category III / TI-RADS 3	35.29	33.33	
Category IV / TI-RADS 4	50.00	46.67	
Category V / TI-RADS 5	71.43	87.50	
Category VI	93.33	—	
Inter-System Agreement			
Linear kappa	0.111	—	Slight agreement
Quadratic kappa	0.196	—	Slight agreement
Z-value	1.045	—	Not significant ($p = 0.296$)
ROC Analysis			
AUC	0.81	0.71	Bethesda: good; TI-RADS: fair diagnostic accuracy

Note: ACR TI-RADS = American College of Radiology Thyroid Imaging Reporting and Data System; PPV = positive predictive value; NPV = negative predictive value; AUC = area under the receiver operating characteristic curve; ROC = receiver operating characteristic.

80% benign (4/5). Discordant combinations such as TR4 + Bethesda II (10% malignancy) highlight cases where imaging and cytology diverge. PTC was the most common malignancy overall (Table 3).

On the histopathology-confirmed subset (n=75), TI-RADS had higher sensitivity (77.78% vs 66.67%) while Bethesda had higher specificity (87.18% vs 53.85%) and overall accuracy (77.33% vs 65.33%). Bethesda also showed a higher PPV (82.76% vs 60.87%), while NPV was comparable (73.91% vs 72.41%). ROM increased progressively for both systems, reaching 93.33% for Bethesda VI and 87.50% for TIRADS 5. Weighted Kappa showed only slight inter-system agreement ($\kappa=0.111$, $p=0.296$), indicating the two systems categorize nodules differently in many cases. ROC analysis yielded AUC of 0.81 for Bethesda (good) and 0.71 for TI-RADS (fair) (Table 4).

Discussion

The present prospective study evaluated how

well ultrasound risk stratification using ACR TI-RADS aligns with cytologic risk stratification using the 2017 Bethesda System and how both perform against histopathology. The rationale for pairing these systems is strongly grounded in their original design goals: the ACR TI-RADS framework introduced by Tessler *et al*⁸ emphasizes standardized ultrasound feature scoring to rationalize biopsy thresholds and reduce unnecessary FNACs, whereas the revised cytology nomenclature and implied malignancy risks described by Cibas ES⁹ aim to improve reproducibility and align cytology categories with management pathways. In this cohort, TI-RADS 4 and Bethesda II were the dominant categories which reflects the common real-world scenario of many nodules falling into intermediate sonographic suspicion while remaining cytologically benign.

Agreement was slight and not statistically significant (linear-weighted $\kappa=0.111$; quadratic-weighted $\kappa=0.196$; $p=0.296$) indicating that the two systems often classify the same nodule into different risk strata.

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Clinically, this low concordance implies that TI-RADS and Bethesda should not be interpreted as interchangeable systems, as each captures different aspects of malignancy risk. This contrasts with the stronger concordance reported in several tertiary-care series. For example, Periakaruppan *et al.*¹⁰ demonstrated an orderly stepwise rise in malignancy risk across ultrasound categories and emphasized that there is a remarkable correlation between imaging and cytology in their workflow. Similarly, Dhar *et al.*¹¹ reported substantial agreement between ACR TI-RADS and TBSRTC ($\kappa \approx 0.69$) in a large dataset and found that both systems correlate significantly with histopathology with very high specificities reported for both modalities. The comparatively low agreement in this cohort may reflect differences in case-mix (a high concentration of TR3–TR4 nodules and Bethesda II cytology) and inherent variability in ultrasound interpretation across operators. Additionally, cytology sampling error and follicular-patterned lesions can yield benign or indeterminate FNAC despite suspicious ultrasound morphology, which can further attenuate categorical concordance.

When benchmarked against histopathology both systems demonstrated the expected gradient of malignancy across increasing categories, with very high malignancy at the extremes (TR5 and Bethesda VI). However, researcher found that Bethesda classification outperformed TI-RADS in specificity (87.18% vs 53.85%) and overall accuracy (77.33% vs 65.33%), while “both systems retained acceptable negative predictive value for excluding malignancy in the operated subset”. In a large cohort analysis, Huang *et al.*¹² showed that TR3 nodules yielded the highest negative predictive value when compared with both Bethesda scoring and histopathology, whereas TR4–TR5 categories demonstrated more variable positive predictive value. At a broader evidence-synthesis level, the meta-analysis by Li *et al.*¹³ found that ACR TI-RADS generally provides favorable sensitivity and moderate specificity across diverse settings. low TI-RADS specificity in this is likely influenced by the heavy representation of TR4 nodules thereby generating more false positives when histopathology is used as the reference.

An important finding from this data is the divergence between implied risks of malignancy and observed malignancy rates within the operated subset. The malignancy rate for Bethesda II in resected cases was higher than the classic implied risk for benign

cytology, suggesting selection effects: nodules proceeding to surgery despite benign FNAC are often enriched for worrisome ultrasound features or patient preference, all of which increase the pretest probability of malignancy and can inflate the apparent false-negative rate of FNAC. This interpretive caution is consistent with the broader cytology literature. Grimmichova T¹⁴ demonstrated that FNA molecular testing is having potential for detection of thyroid malignancy and its optimal use can lead to improvements in diagnosis of these cases. Likewise, Azzam EZ *et al.*¹⁵ highlighted that TIRADS scores 4 and 5 confer an increased risk of malignancy in cases if Bethesda III and IV thyroid nodules. In this study limited number of Bethesda IV cases precludes firm conclusions for follicular neoplasm/suspicious for follicular neoplasm, but the presence of malignancy in this small subset aligns with the known difficulty of diagnosing follicular carcinoma cytologically and the need for histologic capsular/vascular invasion assessment.

Finally, combined-category analysis suggests that the integrated use of TI-RADS and Bethesda is most valuable at concordant extremes: On combined analysis, concordant high-risk pairings carried the highest malignancy: TR5 + Bethesda VI was 100% malignant (10/10) and TR4 + Bethesda V showed 75.0% malignancy (6/8). Concordant low-risk pairing TR2 + Bethesda II was predominantly benign (80%, 4/5). Discordant combinations such as TR4 + Bethesda II (10% malignancy) highlight cases where imaging and cytology diverge.

The limitations of this study include the availability of histopathology only in the surgically treated subset, which may introduce verification and selection bias because nodules taken for surgery often have higher pretest suspicion and can inflate malignancy estimates in lower TI-RADS or Bethesda categories. The single-center design may limit external generalizability. Ultrasound assessment is inherently operator dependent and interobserver variability was not formally measured.

In conclusion, TI-RADS and the Bethesda System demonstrated limited concordance in categorical assignment, yet both showed a progressive rise in malignancy risk across increasing categories on histopathology correlation. Bethesda categorization provided higher specificity and overall accuracy than TI-RADS alone, while both systems retained acceptable negative predictive value for

excluding malignancy in the operated subset. Concordant findings at the low- and high-risk extremes were most clinically decisive,

supporting routine integrated use of TI-RADS and Bethesda to strengthen rule-out and rule-in decisions in thyroid nodule evaluation.

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