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Integrating imaging and cytology: Correlation of TIRADS scores with the Bethesda classifications in thyroid nodules

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Abstract:
Thyroid nodules are common and require accurate imaging and cytological assessment for malignancy risk stratification. Therefore, it is of interest to evaluate the correlation between ACR TIRADS and TBSRTC in 136 thyroid nodules, with histopathological correlation in 47 cases. TIRADS and TBSRTC showed 87.5% concordance (κ=0.554), with biopsy agreement of 85.1% and 95.7%, respectively. TIRADS showed higher sensitivity (87.5%) and NPV (97.1%), whereas TBSRTC showed higher specificity (100%), accuracy (95.7%) and AUC (0.875). Thus, data shows that complementary use of TIRADS and TBSRTC may improve diagnostic precision by combining the imaging-based risk assessment with cytological confirmation.

Keywords: Bethesda system, diagnostic accuracy, fine-needle aspiration cytology (FNAC), histopathology, malignancy risk stratification, thyroid cancer, thyroid nodule, the Bethesda system for reporting thyroid cytopathology (TBSRTC), American College of Radiology (ACR TIRADS)

Background:
Thyroid nodules are frequently detected incidentally during physical exams or imaging, with varying prevalence by detection method: 4-7% by palpation and 19-68% by high-resolution ultrasound **[1]**. In India, 12.2% of individuals have palpable thyroid nodules **[2]** and thyroid cancer incidence, particularly among women, is rising and with an estimated 38,574 new cases projected by 2025 **[3].** The age-standardized incidence rate (ASIR) of thyroid cancer in India is relatively low, ranging from approximately 1 to 3.5 per 100,000 population, with higher rates reported among women and in select high-incidence regions such as Kerala and the Northeast **[4].** The growing incidence of thyroid cancer underscores the importance of diagnostic methods for early cancer detection. Two widely used systems are in place to standardize the evaluation and reporting of thyroid nodules: the Thyroid Imaging Reporting and Data System (TIRADS) by ACR (American College of Radiology) and The Bethesda System for Reporting Thyroid Cytopathology (TBSRTC). TIRADS is primarily used for risk stratification, while TBSRTC aids in cytological confirmation **[1]**. Both systems are valuable in clinical practice, but it's essential to understand how TIRADS scores relate to TBSRTC classifications to enhance diagnostic accuracy and improve patient care **[5].** Therefore, it is of interest to assess the rate of concordance between the two systems, evaluate their diagnostic accuracy, identify any discrepancies between TIRADS and Bethesda classifications and analyze potential reasons for their discrepancies.

Materials and Methods:
This is a retrospective cross-sectional analytical study conducted in the Department of Pathology in a tertiary care hospital in patients with single or multiple thyroid nodules from January 2022 to March 2024. Patients detected with a thyroid nodule in B-mode ultrasound and either direct FNAC or Ultrasound-guided FNAC was done were included in the study. Known cases of thyroid malignancy, patients without TIRADS scores and/or TBSRTC classification, TBSRTC category I (Non – diagnostic) and postoperative thyroid scan cases are excluded. Institutional ethics committee approval was also obtained vide No. IEC-328/2024.

Thyroid ultrasound:
The thyroid ultrasound examination was done using a linear array 9L transducer in B mode with a frequency of 4-11 MHz, using transverse and longitudinal scanning of the thyroid gland for all cases. ACR TIRADS (American College of Radiology) scoring system was used to analyze the nodules of the thyroid using an ultrasound. The ultrasound examination considers the following parameters - composition, echogenicity, shape, margin and echogenic foci.

FNAC of thyroid nodules:
FNAC was performed under aseptic conditions using a 21-gauge needle, either by direct palpation for accessible nodules or ultrasound guidance for small or deep-seated nodules. For cystic lesions, fluid was aspirated using a syringe, centrifuged and smears were prepared from the sediment. Two passes were made per nodule to ensure adequate sampling. Smears were fixed in 70% ethyl alcohol, stained with hematoxylin & eosin and Leishman stains and then evaluated for adequacy per TBSRTC criteria.

Statistical analysis:
Fine-needle aspiration cytology (FNAC) results were reported according to the Bethesda System for Reporting Thyroid Cytopathology (TBSRTC). Category I (non-diagnostic) cases were excluded. For statistical analysis, categories II–IV were grouped as non-malignant and categories V–VI as malignant to facilitate binary analysis. Bethesda categories III and IV were included in the non-malignant group based on institutional management protocols. As these categories are considered

indeterminate in standard practice, this approach may introduce misclassification bias and should be considered when interpreting the diagnostic performance measures. Descriptive statistics were presented using frequencies and percentages. To evaluate how well TIRADS and TBSRTC could detect malignancy, ROC (Receiver Operating Characteristic) curve analysis was done and the Area under the Curve (AUC) was calculated for both methods against biopsy results. Diagnostic performance and ROC analysis were performed only in cases with available histopathological correlation (n=47), which may introduce verification bias. Depending on how the data was distributed, suitable statistical tests were used. We calculated sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and overall diagnostic accuracy for TIRADS and TBSRTC. The level of agreement between TIRADS, TBSRTC and biopsy findings was assessed using Cohen's Kappa statistic.

Results:

There were 145 cases of thyroid swelling during the study period. One hundred thirty-six cases were included in the study following selection criteria. The majority were females (n-125, 91.9%) with a mean age of 41.5 years. The age range was from 10 to 73 years. There were 61 cases of nodular swelling (44.8%) and 75 cases of diffuse swelling (55.1%). FNAC results were categorized according to the Bethesda system (TBSRTC). TIRADS scores of 1-3 were considered benign, while TIRADS 4 and 5 were considered malignant. TBSRTC categories were also descriptively stratified as benign (Category II), indeterminate (Categories III and IV) and malignant/high-risk (Categories V and VI). For statistical analysis, categories II–IV were grouped as non-malignant and categories V–VI as malignant. Biopsy reports were available for 47 cases and diagnostic performance metrics were calculated based on this subset, which may limit generalizability. Out of 47 cases, eight were malignant and 39 were benign. The most common malignancy was papillary thyroid carcinoma (PTC, 6 cases, 12.7%). Category I of TBSRTC was excluded from this study for being non-diagnostic or having no significant findings. Category II of TBSRTC had the maximum number of cases (116, 85.29%), while category IV had 2 cases (1.47%). Bethesda III & IV nodules were distributed across multiple TIRADS categories, with a greater proportion seen in intermediate and higher TIRADS scores. One hundred seven cases (78.6%) had a TIRADS score of 1-3 suggesting benign pathology. TIRADS scores of 4 and 5 were given in 29 cases (21.3%). One hundred twenty-four cases (91.1%) were classified as non-malignant (including benign & indeterminate categories) under TBSRTC by FNAC, while 12 cases were malignant (8.8%). Among the 29 nodules with TIRADS scores of 4–5, 17 were classified as benign by TBSRTC, suggesting a higher false-positive rate for TIRADS. Within the biopsy-correlated subset, none of the nodules categorized as benign (TIRADS 1–3) were found to be malignant on histopathology **(Table 1).** However, one case classified as malignant on cytology (Bethesda V/VI) but without histopathological correlation had been assigned a benign TIRADS score (1–3). This discrepancy reflects the difference between the biopsy-correlated subset and the complete study cohort. Among Bethesda III & IV nodules, 37.5% (3 out of 8 nodules) were categorized as TIRADS 4-5. Of the eight biopsy-confirmed malignant cases, TIRADS correctly identified 7 of 8 cases as malignant (87.5%), while TBSRTC correctly identified 6 of 8 cases (75%). The remaining two malignant cases were misclassified as benign, representing false-negative results. TIRADS showed a concordance of 85.11% with final biopsy results, while TBSRTC showed a higher concordance of 95.74%, with most cases falling into the benign category. Overall concordance between TIRADS, TBSRTC and biopsy in this study is approximately 82.98%. A concordance of 87.5% is found between TIRADS and TBSRTC (**Table 2, 3).** Among the 47 cases with histopathological correlation, TIRADS showed a sensitivity of 87.5% (95% CI: 47.3–99.7%), specificity of 84.6% (95% CI: 69.5–94.1%), positive predictive value of 53.8% (95% CI: 25.1–80.8%), negative predictive value of 97.05% (95% CI: 84.7–99.9%) and an overall diagnostic accuracy of 85.11% (95% CI: 71.7–93.8%). TBSRTC showed a sensitivity of 75% (95% CI: 34.9–96.8%), specificity of 100% (95% CI: 91.0–100%), positive predictive value of 100% (95% CI: 54.1–100%), negative predictive value of 95.12% (95% CI: 83.5–99.4%) and an overall diagnostic accuracy of 95.74% (95% CI: 85.5–99.5%). These findings should be interpreted with caution due to the limited number of biopsy-confirmed malignant cases. TBSRTC showed excellent specificity and PPV, although two malignant cases were misclassified as benign. In comparison, TIRADS showed higher sensitivity and NPV. The agreement between the TBSRTC and TIRADS score and the final histopathology diagnosis was determined for both malignant and benign cases **(Table 2).** The Kappa value between TIRADS and biopsy results is 0.578, indicating moderate agreement in this cohort. The Kappa value between TBSRTC and biopsy results is 0.833, reflecting almost perfect agreement, although 2 cases were falsely classified as benign by TBSRTC even though the biopsy showed malignancy. Concordance represents overall agreement between systems, whereas sensitivity and specificity were calculated separately for diagnostic performance against histopathology. Twelve cases (8.8%) were classified as malignant by both TIRADS and TBSRTC, while 107 cases (78.6%) were classified as non-malignant by FNAC/TBSRTC and TIRADS. The number of malignant cases identified by TBSRTC reflects cytological classification across the full cohort, whereas histopathological confirmation of malignancy was available only in a subset of cases (n=47), which accounts for the difference in absolute numbers. However, 17 cases (12.5%) were classified as malignant by TIRADS but benign by TBSRTC, suggesting TIRADS had a higher false-positive rate **(Table 4).** When TBSRTC was compared against TIRADS classification, sensitivity was 100%, specificity 86.29%, PPV 41.38%, NPV 100% and accuracy 87.5%. The Kappa value between TIRADS and TBSRTC was 0.554, indicating moderate agreement. This comparison reflects classification agreement and not diagnostic validation against histopathology, which may artificially increase sensitivity due to methodological bias. The moderate kappa value despite the high percentage agreement is likely influenced by the predominance

of benign nodules in the study population, as kappa adjusts for agreement expected by chance and is affected by disease prevalence. A ROC curve was calculated for TBSRTC and TIRADS compared to histopathological diagnosis wherever available. ROC analysis showed good discriminatory performance for both diagnostic systems. The AUC was 0.875 for TBSRTC and 0.861 for TIRADS, indicating good ability to distinguish benign from malignant nodules within the biopsy-confirmed subset.

Table 1: Distribution of TIRADS Categories across Different TBSRTC Categories (n=136)

TBSRTC	TIRADS 1	TIRADS 2	TIRADS 3	TIRADS 4	TIRADS 5	Total
Category II	28	49	25	13	1	116
Category III	0	2	3	1	0	6
Category IV	0	0	0	1	1	2
Category V	0	0	0	3	4	7
Category VI	0	0	0	3	2	5
Total	28	51	28	21	8	136

Table 2: Concordance between TIRADS, TBSRTC and Biopsy (n=47)

Comparison	Total cases	Concordant cases	Concordance %
TIRADS vs TBSRTC	136	119	87.50%
TIRADS vs Biopsy	47	40	85.11%
TBSRTC vs Biopsy	47	45	95.74%
TIRADS vs TBSRTC vs Biopsy (all 3)	47	39	82.98%

Table 3: Biopsy correlation with TIRADS and TBSRTC Categories (n=47) (Percentages calculated row-wise)

Parameter	Category	Biopsy				Total	
		Malignant		Benign			
		No. of cases	%	No. of cases	%	No. of cases	%
TIRADS	Malignant	7	53.80%	6	46.20%	13	27.70%
	Benign	1	2.90%	33	97.10%	34	72.30%
TBSRTC	Malignant	6	100.00%	0	0.00%	6	12.80%
	Benign	2	4.90%	39	95.10%	41	87.20%
Total		8	17.00%	39	83.00%	47	100.00%

Table 4: Concordance between TIRADS and stratified TBSRTC categories (n=136)

	TBSRTC		
	Malignant	Non-malignant	Total
TIRADS	No.of cases (%)	No.of cases (%)	No.of cases (%)
Malignant	12 (41.4%)	17 (58.6%)	29 (21.3%)
Benign	0 (0%)	107 (100%)	107 (78.7%)
Total	12 (8.8%)	124 (91.2%)	136 (100%)

Table 5: Comparison of TBSRTC performance metrics with various studies

Sensitivity	Specificity	PPV	NPV	Accuracy	References
75%	100%	100%	92%	93.50%	**[14]**
70%	100%	100%	93%	-	**[15]**
78.70%	100%	100%	23.08%	80%	**[16]**
100%	60%	94%	100%	94.70%	**[17]**
75%	100%	100%	95%	95.70%	Present study

Table 6: Comparison of TIRADS performance metrics with various studies

Sensitivity	Specificity	PPV	NPV	References
63.63%	84.94%	50%	90.80%	**[18]**
77.80%	75.50%	53.80%	90.20%	**[19]**
73.70%	57.60%	26.40%	91.40%	**[20]**
94.40%	96.50%	77.30%	99.30%	**[21]**
87.50%	84.60%	53.80%	97.05%	Present study

Table 7: Percentage of agreement of TIRADS and TBSRTC with Biopsy in various studies

	Abdelkader *et al.* [22]	George *et al.* [16]	Biswas *et al.* [18]	Present study
TIRADS with Biopsy	75.40%	75%	80.86%	85.11%
TBSRTC with Biopsy	81.80%	83.30%	84.34%	95.74%

Table 8: AUC values in various studies

AUC values	References
0.91 (TBSRTC), 0.7 (TIRADS)	**[16]**
0.932	**[26]**
0.913 (TIRADS)	**[27]**
0.972 (TIRADS with TBSRTC as gold standard)	**[28]**
0.156 (TBSRTC), 0.178 (TIRADS)	**[29]**

Discussion:

The mean age of 41.5 years observed in our study is similar to the results found in other studies **[6-8]**. In our study, 91.9% of participants were women, indicating a higher occurrence of thyroid nodules in women akin to other studies **[8, 9].** TIRADS and TBSRTC are crucial tools for assessing thyroid nodules, with distinct advantages for either. While TIRADS provides a non-invasive imaging-based risk stratification, TBSRTC via FNAC remains the reference standard for cytological evaluation. Studies consistently indicate that combining these two methods enhances diagnostic accuracy **[10-13, 30].** Diagnostic performance of TIRADS and TBSRTC: the two systems agreed in 119 cases (87.5%), where 12 cases (8.8%) were classified as malignant by both and 107 cases (78.6%) as benign by both. However, 17 cases (12.5%) were classified as malignant by TIRADS but benign by TBSRTC. TIRADS may overestimate malignancy risk due to overlapping ultrasound features between benign and malignant nodules. These results indicate that TIRADS had higher sensitivity and NPV, while TBSRTC shows superior specificity and overall accuracy for confirming malignancy. The higher false positive rate (12.5%) observed with TIRADS can be attributed to several factors including inter-observer variability, ultrasound features of some nodules that overlap between benign and malignant and some benign conditions like colloid nodules or Hashimoto's

thyroiditis can exhibit features that mimic malignancy. The performance metrics of TIRADS and TBSRTC reported in various studies are outlined below **(Table 5, 6).** Conversely, TBSRTC misclassified two biopsy-confirmed malignant cases as benign, highlighting its susceptibility to false negatives. In this study, TIRADS correctly identified 7 out of 8 biopsy-confirmed malignant cases (87.5%) and showed higher sensitivity than TBSRTC, which correctly identified 6 out of 8 (75%). One malignant case was falsely classified as benign by TIRADS. The lower sensitivity of TBSRTC can be attributed to sampling errors inherent in FNAC, which is a blind procedure that may fail to capture representative cells from heterogeneous nodules. This contributed to possible false negative results. Additionally, follicular carcinoma, encapsulated follicular variant of papillary thyroid carcinoma (EFVPTC) (both were labelled benign by TBSRTC in our study) and Noninvasive Follicular thyroid neoplasm with papillary like nuclear features (NIFTP) cannot be diagnosed on FNAC and need a biopsy for confirmation as capsular breach and vascular invasion are best studied only on biopsy. They often resemble benign lesions cytologically and may lack all the prominent nuclear features of papillary thyroid carcinoma, which FNAC can thus miss. In contrast, TIRADS, based on ultrasound characteristics, helps detect suspicious nodules early. Interestingly, none of the nodules labeled as benign (TIRADS 1–3) were found to be malignant upon biopsy, highlighting the NPV and the reliability of TIRADS in ruling out malignancy. Agreement between TIRADS and biopsy and comparison with previous studies: We found that the agreement between TIRADS and biopsy results was moderate (kappa = 0.578), reflecting the inherent variability in interpreting imaging findings, indicating that TIRADS still misclassifies some cases. Many studies in the literature reported moderate agreement between TIRADS and histopathological diagnoses **(Table 7).** However, our study had a relatively lower agreement of TIRADS with biopsy since TIRADS is primarily an imaging-based classification; several factors, such as operator skill, patient characteristics and lesion size, influence the interpretation of imaging findings. In contrast, the agreement between TBSRTC and biopsy was significantly higher (kappa = 0.833), showing the reliability of TBSRTC in predicting malignancy. The overall concordance of TIRADS, TBSRTC and biopsy was 82.98%, higher than that of George *et al.* (69.8%) and Biswas *et al.* (73.04%) **[16, 18]**. The moderate kappa value (0.554) between TIRADS and TBSRTC reflects their differences in classification criteria. TIRADS showed a higher false-positive rate, whereas TBSRTC showed greater specificity in confirming malignancy. A similar kappa value of 0.493 was reported between TBSRTC and TIRADS by Biswas *et al.* **[18].** A fair agreement was found between the TIRADS classifications and the Bethesda categories in young adults (κ = 0.238) by Zloczower *et al.* **[23].** Regmi *et al.* observed 77.77% agreement in diagnosis between TIRADS and TBSRTC **[24]**. Singaporewalla *et al.* reported an agreement of 83% between these two systems **[25]**. In our study, the concordance between TIRADS and TBSRTC was 87.5%, yet the kappa value was only 0.554, indicating moderate agreement. Similarly, TIRADS and biopsy had 85.11% agreement but a moderate kappa value of 0.578. These differences occur because percent agreement only measures how often two methods give the same result, while kappa accounts for the agreement that might happen by chance. The predominance of benign nodules may have inflated raw agreement percentages. Kappa adjusts for this and provides a more realistic measure of true consistency. On the other hand, TBSRTC showed a very high concordance with biopsy (95.74%) and a substantial kappa value of 0.833, suggesting almost perfect agreement. These values likely reflect the higher diagnostic specificity of FNAC, as the cytology diagnosis is more consistent with the final histopathological findings. However, these findings should be interpreted cautiously due to the limited number of biopsy-confirmed malignant cases. Clinical implications: TIRADS showed high sensitivity and negative predictive value but comparatively lower specificity, resulting in a higher false-positive rate. This is likely because ultrasonographic features such as hypoechogenicity, irregular margins, microcalcifications and taller-than-wide shape may also be present in benign conditions including Hashimoto thyroiditis, hyperplastic nodules and colloid nodules **[26]**. Conversely, TBSRTC showed excellent specificity and positive predictive value but comparatively lower sensitivity, reflecting the potential for sampling errors and false-negative cytological results. These findings indicate that the two systems have complementary strengths. TIRADS is well suited for initial imaging-based risk stratification and exclusion of malignancy, whereas TBSRTC is more useful for confirming malignancy following cytological evaluation. Therefore, the combined use of TIRADS for selecting nodules requiring FNAC and TBSRTC for cytological confirmation may improve diagnostic accuracy and optimize clinical management while reducing unnecessary invasive procedures. ROC analysis showed good overall discriminatory ability for both systems, with TBSRTC showing a slightly higher AUC (0.875) than TIRADS (0.861). However, these findings should be interpreted cautiously because ROC analysis was performed in only 47 biopsy-confirmed cases, resulting in relatively wide confidence intervals and limited precision. AUC values observed in other studies are listed in **Table 8.** In the subset with histopathological correlation, TBSRTC showed higher specificity and overall diagnostic accuracy; however, it missed two malignant cases, highlighting the limitation of FNAC due to sampling errors. The study's results highlight how TIRADS can be integrated with TBSRTC in assessing thyroid nodules. TIRADS showed good diagnostic performance as an imaging-based risk stratification tool in this cohort and may be particularly useful for excluding malignancy because of its high negative predictive value. However, the significant number of false positives in TIRADS categories 4 and 5 means that confirmatory FNAC testing is essential for determining the best management strategies. Thus, TBSRTC offers greater accuracy and specificity since it relies on direct microscopic evaluation of thyroid cytology. By combining TIRADS and TBSRTC, the diagnostic errors in high-risk cases can be reduced.

Limitations of the study:
The limitations of this study include a small sample size and the chance of reporting errors arising from the TIRADS and TBSRTC, which can vary between observers. The grouping of Bethesda III and IV under the non-malignant category may have introduced misclassification bias, as these are cytologically indeterminate and include lesions with variable malignant potential. Histopathological correlation was available only in a subset of cases (47/136) as biopsy was performed primarily in nodules with higher clinical or radiological suspicion of malignancy. This results in partial verification bias and selection bias, as benign (low-risk) nodules were less likely to undergo histopathological confirmation. As a result, diagnostic performance measures such as sensitivity, specificity and predictive values may be overestimated. The relatively small number of malignant cases may affect the stability of sensitivity and predictive value estimates and reduce the generalizability of the findings.

Conclusion:
TIRADS and TBSRTC provide complementary information in thyroid nodule evaluation. TIRADS aids in initial risk stratification, while TBSRTC improves malignancy confirmation. Their combined use may enhance diagnostic accuracy and optimize patient management.

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