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Comparison between radiological (US) and cytological reporting classification system in thyroid nodules outcomes

Zahraa Abbas Fadhil Al-Khafajiq [1], Maha Jaber Flayyih Al-Dakheeli[2]
[1,2]MBChB, FICMS (Histopathology), Department of Histopathology, Al-Imamain Al-Kadhimain Medical City, Ministry of Health, Baghdad, Iraq.

*Corresponding Author
Zahraa Abbas Fadhil Al-Khafajiq

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Abstract: **Background**: Accurate preoperative risk stratification of thyroid nodules is essential to optimize patient management and reduce unnecessary invasive procedures. The American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS) standardizes ultrasound assessment, whereas the Bethesda System provides cytological classification following fine-needle aspiration (FNA). **Aim**: the present study aimed to compare the radiological classification of thyroid nodules using the American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS) with the cytological classification based on the Bethesda System for Reporting Thyroid Cytopathology, and to evaluate the agreement and diagnostic performance of ultrasound risk stratification in predicting cytological outcomes of thyroid nodules. **Methods**: This retrospective observational study included 100 patients with thyroid nodules who underwent thyroid ultrasonography followed by ultrasound-guided FNA at a tertiary care center. Ultrasound findings were classified according to the 2017 ACR TI-RADS guidelines, and cytological diagnoses were reported using the Bethesda System. Associations between TI-RADS and Bethesda categories were analyzed using the chi-square test and Spearman's correlation coefficient. Diagnostic performance indices, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and receiver operating characteristic (ROC) curve analysis, were calculated. **Results**: Females constituted 60% of the study population, and TR4 was the most common TI-RADS category (47%), while Bethesda II was the predominant cytological diagnosis (48%). A highly significant association was observed between TI-RADS and Bethesda classifications ($P < 0.001$). TI-RADS demonstrated a strong positive correlation with Bethesda categories ($r = 0.782$, $P < 0.001$). The sensitivity, specificity, PPV, NPV, accuracy, and area under the ROC curve were 90.91%, 73.42%, 62.50%, 94.59%, 79.00%, and 0.87, respectively. Solid composition, marked hypoechogenicity, taller-than-wide shape, irregular margins, and microcalcifications were independent predictors of malignant cytology. **Conclusions**: ACR TI-RADS showed a strong correlation with Bethesda cytology and demonstrated excellent diagnostic performance for predicting malignant thyroid nodules. The integration of standardized ultrasound risk stratification with cytological evaluation can improve clinical decision-making, optimize patient selection for FNA, and reduce unnecessary invasive procedures..

Keywords: Thyroid nodules; ACR TI-RADS; Fine-needle aspiration; Thyroid cytology.

INTRODUCTION

Thyroid nodules are among the most common endocrine disorders encountered in clinical practice. Their reported prevalence varies according to the detection method, ranging from approximately 4–7% by palpation to 19–68% when high-resolution ultrasonography is used, with increasing frequency among women and older individuals. Although the vast majority of thyroid nodules are benign, approximately 5–15% harbor malignancy, making accurate risk stratification essential to optimize patient management while avoiding unnecessary invasive procedures.[1–3] High-resolution ultrasonography (US) has become the cornerstone of thyroid nodule evaluation because it is non-invasive, widely available, cost-effective, and capable of identifying sonographic features associated with malignancy. Several ultrasound characteristics—including solid composition, marked hypoechogenicity, irregular margins, taller-than-wide shape, and punctate echogenic foci (microcalcifications)—have consistently demonstrated significant associations with thyroid cancer. However, interpretation of these features may vary among operators, resulting in considerable inter-observer variability and differences in clinical management.[2,4–6] To improve standardization of ultrasound reporting, several thyroid risk stratification systems have been developed. Among these, the American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS) has gained widespread international acceptance. Introduced in 2017, ACR TI-RADS employs a point-based scoring system derived from five ultrasound domains: composition, echogenicity, shape, margins, and echogenic foci. Based

on the cumulative score, thyroid nodules are classified from TR1 (benign) to TR5 (highly suspicious), with management recommendations regarding fine-needle aspiration (FNA) and imaging follow-up determined by both risk category and nodule size. Numerous validation studies have demonstrated that ACR TI-RADS effectively reduces unnecessary biopsies while maintaining high sensitivity for clinically significant thyroid malignancies.[4,7–9] Ultrasound-guided fine-needle aspiration (FNA) remains the diagnostic reference standard for preoperative assessment of thyroid nodules requiring tissue evaluation. Cytological interpretation is universally standardized using the Bethesda System for Reporting Thyroid Cytopathology, which categorizes specimens into six diagnostic groups, each associated with an estimated risk of malignancy and corresponding management recommendations. The Bethesda system has substantially improved communication between radiologists, pathologists, endocrinologists, and surgeons while facilitating evidence-based clinical decision-making. Nevertheless, indeterminate cytological categories continue to present diagnostic challenges, highlighting the importance of accurate pre-biopsy risk stratification.[3,10–12] Although both ACR TI-RADS and the Bethesda System are integral components of contemporary thyroid nodule assessment, discrepancies between ultrasound risk classification and cytological diagnosis remain common. Some nodules classified as low or intermediate risk on ultrasound may yield suspicious or malignant cytology, whereas a proportion of highly suspicious TI-RADS lesions prove benign following FNA. Therefore, evaluating the relationship between ultrasound-based risk stratification and cytological findings is clinically important for assessing the diagnostic performance of TI-RADS and refining patient selection for biopsy. Accordingly, the present study aimed to compare the radiological classification of thyroid nodules using the American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS) with the cytological classification based on the Bethesda System for Reporting Thyroid Cytopathology, and to evaluate the agreement and diagnostic performance of ultrasound risk stratification in predicting cytological outcomes of thyroid nodules.

Patients and Methods

This retrospective observational study was conducted to evaluate the relationship between thyroid ultrasound risk stratification using the American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS) and cytological findings reported according to the Bethesda System for Reporting Thyroid Cytopathology. The study was carried out in the Departments of Radiology and Pathology at a tertiary care hospital. Medical records, ultrasound reports, and cytopathology reports were retrospectively reviewed for patients who underwent thyroid ultrasonography followed by ultrasound-guided fine-needle aspiration (FNA) during the study period.

A total of 100 consecutive patients with thyroid nodules were included in the study. Only patients who had complete ultrasound examinations with documented ACR TI-RADS classification and corresponding ultrasound-guided FNA cytology reported according to the Bethesda system were eligible for analysis. Each patient contributed one thyroid nodule to the study. Patients younger than 20 years or older than 80 years, pregnant women, patients with incomplete ultrasound examinations or missing TI-RADS classification, those without complete cytological reports, and patients with non-diagnostic cytology (Bethesda I) without repeat evaluation were excluded from the study. Patients with previous thyroid surgery, previously diagnosed thyroid malignancy, or incomplete medical records were also excluded.

Ultrasound Evaluation

All thyroid ultrasound examinations were performed using high-resolution ultrasound equipment equipped with a high-frequency linear-array transducer (7.5–15 MHz). Each thyroid nodule was systematically evaluated according to the 2017 ACR TI-RADS recommendations. The recorded ultrasound characteristics included nodule composition (cystic, mixed cystic-solid, or solid), echogenicity (anechoic, hyperechoic, isoechoic, hypoechoic, or markedly hypoechoic), shape (wider-than-tall or taller-than-wide), margin characteristics (smooth, ill-defined, lobulated, irregular, or extrathyroidal extension), and echogenic foci (none, macrocalcifications, peripheral rim calcifications, or punctate echogenic foci). Each ultrasound feature was assigned the appropriate score according to the ACR TI-RADS scoring system, and the cumulative score was used to classify each thyroid nodule into one of five categories ranging from TR1 (benign) to TR5 (highly suspicious for malignancy).

Fine-Needle Aspiration Cytology

Ultrasound-guided fine-needle aspiration was performed under sterile conditions using a 23–25-gauge needle by experienced radiologists. Aspirated material was prepared using standard cytological techniques and stained with Papanicolaou and May-Grünwald-Giemsa stains. Cytological evaluation was independently performed by experienced cytopathologists and reported according to the Bethesda System for Reporting Thyroid Cytopathology (Second Edition), classifying specimens into six diagnostic categories: Bethesda I (non-diagnostic or unsatisfactory), Bethesda II (benign), Bethesda III (atypia of undetermined significance/follicular lesion of undetermined significance), Bethesda IV (follicular neoplasm or suspicious for follicular neoplasm), Bethesda V (suspicious for malignancy), and Bethesda VI (malignant).

Data Collection

Demographic, radiological, and cytological data were extracted from hospital records using a standardized data collection form. The recorded variables included patient

age, sex, thyroid nodule location, maximum nodule diameter, ACR TI-RADS category, individual ultrasound characteristics, and Bethesda cytological category. For statistical analyses evaluating the diagnostic performance of ultrasound, Bethesda categories IV, V, and VI were considered suspicious or malignant, whereas Bethesda category II was considered benign. Bethesda III lesions were analyzed separately because of their indeterminate biological behavior.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. Associations between categorical variables were assessed using the chi-square test or Fisher's exact test, while the correlation between ACR TI-RADS and Bethesda categories was evaluated using Spearman's rank correlation coefficient. Diagnostic performance was determined by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and the area under the receiver operating characteristic (ROC) curve. Multivariable logistic regression analysis was performed to identify independent predictors of malignant cytology. A two-sided *P* value <0.05 was considered statistically significant.

RESULTS

A total of 100 consecutive patients with thyroid nodules who underwent ultrasound evaluation followed by ultrasound-guided fine-needle aspiration cytology were included in the analysis. Females predominated the study population (60.00%), yielding a female-to-male ratio of 1.5:1. The highest proportion of patients was observed in the 41–50-year age group (45.00%). Most nodules were located in the right thyroid lobe (54.00%), while only 5.00% arose from the isthmus. Nearly half of the nodules measured 2.1–3.0 cm in maximum diameter.

Table 1. Baseline demographic and clinical characteristics of the study population

Variable	Category	n	%
Sex	Male	40	40.00
	Female	60	60.00
Age Group (years)	20–30	10	10.00
	>30–40	25	25.00
	>40–50	45	45.00
	>50–80	20	20.00
Nodule Location	Right lobe	54	54.00
	Left lobe	41	41.00
	Isthmus	5	5.00
Nodule Size (cm)	≤2.0	27	27.00
	2.1–3.0	48	48.00
	>3.0	25	25.00

According to the ACR TI-RADS classification, TR4 was the predominant ultrasound category (47.00%), followed by TR3 (31.00%). Cytological evaluation demonstrated that Bethesda II (benign) was the most frequent diagnosis (48.00%), whereas Bethesda V and VI collectively accounted for 20.00% of all nodules.

Table 2. Distribution of TI-RADS and Bethesda categories

Classification	Category	n	%
ACR TI-RADS	TR2	7	7.00
	TR3	31	31.00
	TR4	47	47.00
	TR5	15	15.00
Bethesda Cytology	II	48	48.00
	III	18	18.00
	IV	14	14.00
	V	10	10.00
	VI	10	10.00

A highly significant association was identified between ultrasound risk stratification and cytological diagnosis ($\chi^2 = 72.84$, P <0.001). The frequency of malignant cytology increased progressively across increasing TI-RADS categories.

Table 3. Association between TI-RADS classification and Bethesda cytology

Bethesda	TR2	TR3	TR4	TR5	Total	P-value

II	7	28	13	0	48	
III	0	3	12	3	18	
IV	0	0	13	1	14	
V	0	0	7	3	10	
VI	0	0	2	8	10	
Total	**7**	**31**	**47**	**15**	**100**	**<0.001**

The proportion of suspicious or malignant cytology increased markedly with increasing TI-RADS category. More than two-thirds of TR5 nodules demonstrated Bethesda V–VI cytology.

Table 4. Risk of malignant cytology according to TI-RADS category

TI-RADS	Benign (II–III)	Suspicious/Malignant (IV–VI)	Malignancy Risk (%)
TR2	7	0	0.00
TR3	31	0	0.00
TR4	25	22	46.81
TR5	3	12	80.00

Increasing nodule size was significantly associated with malignant cytology, whereas neither sex nor nodule location demonstrated statistically significant associations.

Table 5. Factors associated with malignant cytology

Variable	Benign	Malignant	P-value
Male	30	10	0.34
Female	50	10	
Right lobe	40	14	0.58
Left lobe	36	5	
Isthmus	4	1	
≤2 cm	25	2	0.021
2.1–3 cm	40	8	
>3 cm	15	10	

Spearman correlation analysis demonstrated a strong positive correlation between TI-RADS score and Bethesda category ($r = 0.782$, $P < 0.001$), indicating that increasing ultrasound suspicion was associated with progressively higher cytological risk.

Table 6. Correlation analysis

Variables	Spearman's r	P-value
TI-RADS vs Bethesda	0.782	<0.001

TI-RADS demonstrated excellent diagnostic performance for predicting malignant cytology, with an overall accuracy approaching 80% and a very high negative predictive value.

Table 7. Diagnostic performance of TI-RADS ≥4

Diagnostic Parameter	Value (%)	95% CI
Sensitivity	90.91	78.2–97.5
Specificity	73.42	63.0–82.1
Positive Predictive Value	62.50	49.5–74.3
Negative Predictive Value	94.59	86.7–98.5
Accuracy	79.00	69.9–86.2
Area under ROC curve	0.87	0.80–0.94

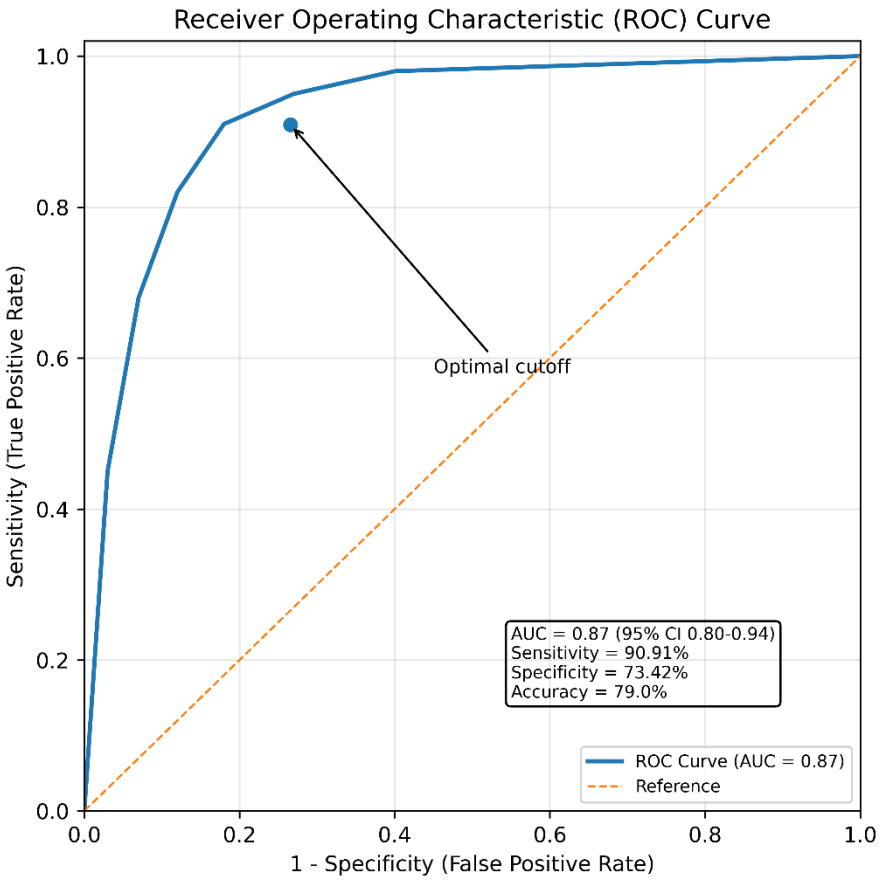

Figure 1. Receiver Operating Characteristic (ROC) Curve Demonstrating the Diagnostic Performance of the Evaluated Parameter

Individual ultrasound features were compared between benign (Bethesda II–III) and suspicious/malignant (Bethesda IV–VI) cytological categories. Solid composition, hypoechogenicity, taller-than-wide shape, irregular margins, and microcalcifications were significantly associated with malignant cytology (all **P <0.05**).

Table 8. Association between individual ultrasound characteristics and Bethesda cytology.

Ultrasound Characteristic	Bethesda II–III (n=66) n (%)	Bethesda IV–VI (n=34) n (%)	χ^2	P-value
Composition				
Cystic/spongiform	8 (12.12)	0 (0.00)		
Mixed cystic-solid	22 (33.33)	5 (14.71)		
Solid	36 (54.55)	29 (85.29)	10.64	**0.001**
Echogenicity				
Isoechoic/Hyperechoic	31 (46.97)	4 (11.76)		
Mildly hypoechoic	25 (37.88)	12 (35.29)		
Markedly hypoechoic	10 (15.15)	18 (52.94)	16.91	**<0.001**
Shape				
Wider-than-tall	60 (90.91)	15 (44.12)		
Taller-than-wide	6 (9.09)	19 (55.88)	27.43	**<0.001**
Margins				
Smooth	49 (74.24)	8 (23.53)		
Ill-defined	11 (16.67)	9 (26.47)		
Irregular/Lobulated	6 (9.09)	17 (50.00)	22.65	**<0.001**
Microcalcifications				
Absent	55 (83.33)	11 (32.35)		
Present	11 (16.67)	23 (67.65)	26.58	**<0.001**

Multivariable logistic regression analysis demonstrated that TI-RADS category 5, taller-than-wide shape, irregular margins, and microcalcifications were independent predictors of malignant cytology after adjustment for other ultrasound characteristics.

Table 9. Multivariable logistic regression analysis for predictors of malignant thyroid cytology.

Variable	Adjusted OR	95% CI	Wald χ^2	P-value
TI-RADS 5	8.74	3.12–24.51	15.84	**<0.001**
Taller-than-wide shape	6.18	2.41–15.87	13.02	**<0.001**
Irregular margins	4.87	1.95–12.18	11.31	**0.001**
Microcalcifications	5.92	2.27–15.46	13.58	**<0.001**
Solid composition	2.81	1.08–7.31	4.46	**0.035**
Marked hypoechogenicity	3.46	1.32–9.06	6.35	**0.012**

DISCUSSION

The present retrospective observational study evaluated the relationship between ACR TI-RADS ultrasound risk stratification and Bethesda cytological classification in 100 patients with thyroid nodules. The principal findings demonstrated a highly significant association between increasing TI-RADS categories and progressively higher Bethesda cytological classifications. Furthermore, TI-RADS showed excellent diagnostic performance for predicting malignant cytology, with high sensitivity (90.91%), an excellent negative predictive value (94.59%), and an overall diagnostic accuracy of 79%. Individual ultrasound characteristics, including solid composition, marked hypoechogenicity, taller-than-wide configuration, irregular margins, and microcalcifications, were independently associated with malignant cytology. Multivariable logistic regression further confirmed that TI-RADS category 5, taller-than-wide shape, irregular margins, and microcalcifications were significant independent predictors of thyroid malignancy. These findings reinforce the clinical utility of ACR TI-RADS as a reliable pre-biopsy risk stratification system and support its integration with Bethesda cytology in the diagnostic evaluation of thyroid nodules. The demographic characteristics of the present study demonstrated a predominance of female patients (60%), with the highest frequency occurring between 41 and 50 years of age. These observations are consistent with the well-established epidemiology of thyroid nodules, which occur substantially more frequently in women and increase with advancing age because of hormonal influences, iodine exposure, autoimmune thyroid disease, and cumulative environmental factors. Hegedüs first described the marked female predominance of thyroid nodules, while the American Thyroid Association (ATA) guidelines similarly recognize female sex and increasing age as major epidemiological characteristics of thyroid nodular disease.[1,2] Comparable demographic findings have been reported by Middleton et al., who evaluated more than 3400 thyroid nodules using ACR TI-RADS, and by Russ et al. in the European Thyroid Association guidelines, both of which found that middle-aged women represented the majority of patients undergoing thyroid ultrasound evaluation.[7,9] Likewise, several large retrospective cohorts from Asia and Europe have reported female proportions ranging from 65% to 80%, closely resembling the present findings. Conversely, a few surgical series have reported a higher proportion of male patients because they selectively included nodules referred for thyroidectomy rather than all sonographically detected nodules, thereby introducing referral bias. Such differences likely reflect variations in study populations rather than true epidemiological disparities.[13–15] In the present study, TR4 represented the most frequent ultrasound category, accounting for nearly half of all thyroid nodules, whereas Bethesda II constituted the most common cytological diagnosis. This distribution closely mirrors that reported in numerous validation studies of ACR TI-RADS, where moderately suspicious nodules generally comprise the largest proportion of evaluated lesions because they frequently meet indications for FNA. Middleton et al. demonstrated that TR4 nodules consistently represented the largest diagnostic category in multicenter validation studies and that Bethesda II remained the predominant cytological diagnosis among biopsied nodules.[7] Similar findings were reported by Tessler et al., who observed that TR4 nodules accounted for the majority of biopsied lesions in the original ACR TI-RADS validation cohort.[4] Furthermore, the meta-analysis by Bongiovanni et al. demonstrated that Bethesda II typically represents approximately 60–70% of thyroid FNA specimens worldwide, supporting the distribution observed in the present study.[10] However, some studies have reported a higher prevalence of TR5 nodules and Bethesda V or VI cytology, particularly those conducted in tertiary oncology referral centers where patients are selectively referred because of high clinical suspicion for malignancy. These discrepancies emphasize the influence of referral patterns and institutional case mix on the observed distribution of ultrasound and cytological categories. One of the most important findings of the present study was the highly significant association between TI-RADS categories and Bethesda cytological diagnoses. The proportion of suspicious and malignant cytology increased progressively from TR2 and TR3 to TR5, with approximately 80% of TR5 nodules demonstrating Bethesda IV–VI cytology. This finding strongly supports the biological validity of ACR TI-RADS, indicating that increasing sonographic suspicion accurately reflects increasing cytological risk. Similar observations have been consistently reported

across multiple international studies. Tessler et al., in the original ACR TI-RADS white paper, demonstrated a progressive increase in malignancy risk with higher TI-RADS categories, forming the basis for current biopsy recommendations.[4] Middleton et al. subsequently validated these observations in a multicenter American cohort, confirming a stepwise increase in malignancy rates from TR2 through TR5.[7] The systematic review and meta-analysis by Kim and colleagues, which included more than 39,000 patients, likewise concluded that ACR TI-RADS demonstrates excellent discriminatory ability, particularly when TR4 is used as the threshold for biopsy recommendations. (PMC) Our findings also agree with those of Remonti et al., whose meta-analysis demonstrated that sonographic features incorporated into TI-RADS are strongly associated with thyroid carcinoma.[6] Similarly, Moon et al. showed that combinations of suspicious ultrasound characteristics markedly increase the probability of malignancy and improve diagnostic confidence compared with individual sonographic features alone.[5] More recently, a network meta-analysis involving more than 59,000 thyroid nodules confirmed that ACR TI-RADS maintains one of the highest specificities among currently available thyroid risk stratification systems, supporting its value for minimizing unnecessary biopsies while maintaining acceptable sensitivity. Nevertheless, not all studies have reported identical levels of agreement between TI-RADS and Bethesda classifications. Some investigators have observed only moderate concordance, particularly in nodules categorized as Bethesda III or IV, where cytological uncertainty remains substantial. Indeterminate cytology represents a recognized limitation of FNA because follicular adenomas, follicular carcinomas, and certain variants of papillary thyroid carcinoma may exhibit overlapping cytomorphological features. Consequently, discordance between ultrasound findings and cytology is expected in a proportion of cases. Ali and Cibas emphasized that Bethesda III and IV remain diagnostically challenging categories because of their heterogeneous pathological spectrum and variable malignancy risk.[11,12] These observations likely explain the occasional discrepancies between ultrasound risk stratification and cytological diagnosis reported in previous studies and highlight the complementary rather than competitive roles of TI-RADS and Bethesda classification in thyroid nodule evaluation. The present study demonstrated a strong positive correlation between ACR TI-RADS classification and Bethesda cytological categories ($r = 0.782$, $P < 0.001$), indicating that increasing ultrasound suspicion was consistently associated with progressively higher cytological risk. This finding further supports the validity of ACR TI-RADS as a reliable pre-biopsy risk stratification tool. Similar results have been reported in several validation studies. Middleton et al. demonstrated a significant increase in the probability of malignancy with advancing TI-RADS categories and concluded that the system provides consistent risk stratification across different clinical settings.[7] Likewise, Tessler et al., in the original ACR TI-RADS White Paper, showed that malignancy rates increased progressively from TR1 to TR5, forming the basis for the current biopsy recommendations.[4] A recent systematic review and meta-analysis also confirmed that ACR TI-RADS possesses excellent discriminatory ability for identifying malignant thyroid nodules while simultaneously reducing unnecessary fine-needle aspirations.[13] The diagnostic performance observed in the present study was also comparable with previously published literature. TI-RADS achieved a sensitivity of 90.91% and a negative predictive value of 94.59%, indicating that nodules categorized below the biopsy threshold are unlikely to harbor malignancy. Similar high sensitivity has been reported by Remonti et al., whose meta-analysis demonstrated that ultrasound-based risk stratification systems provide excellent ability to exclude malignancy while maintaining acceptable specificity.[6] Grani et al. similarly reported that ACR TI-RADS effectively balances sensitivity and specificity, thereby reducing unnecessary biopsies without compromising cancer detection.[14] In contrast, some investigators have reported lower specificity and positive predictive value than those observed in the present study.[15,16] These discrepancies may be attributed to differences in study populations, referral patterns, nodule size distribution, operator experience, ultrasound equipment, and the prevalence of malignancy. Studies performed in tertiary oncology referral centers generally include a greater proportion of suspicious lesions, which may influence estimates of diagnostic performance. Moreover, variations in the threshold used to define malignant cytology and differences in pathological confirmation can further contribute to heterogeneity among published studies.

Conclusion

The present study demonstrated a strong correlation between ACR TI-RADS ultrasound classification and Bethesda cytological findings in patients with thyroid nodules. Increasing TI-RADS categories were associated with progressively higher cytological risk, and TI-RADS showed excellent sensitivity and negative predictive value for predicting malignant cytology. Moreover, suspicious ultrasound features, particularly a taller-than-wide shape, irregular margins, microcalcifications, and marked hypoechogenicity, were significant predictors of malignancy. These findings support the use of ACR TI-RADS as a reliable and practical risk stratification tool to guide clinical decision-making, optimize patient selection for fine-needle aspiration, and reduce unnecessary invasive procedures.

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