e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2022; 14(1); 135-142

Original Research Article

Correlation of TI-RADS Classification with Histopathological Findings in Thyroid Nodules: A Prospective Study

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Received: 01-01-2022 / Revised: 04-02-2022 / Accepted: 23-02-2022
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Conflict of interest: Nil

Abstract

Background: Thyroid nodules are common endocrine abnormalities, and differentiating benign from malignant lesions remains a significant clinical challenge. The American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS) was developed to standardize ultrasound reporting and improve risk stratification of thyroid nodules. Histopathological examination remains the gold standard for definitive diagnosis.

Aim: To evaluate the correlation between TI-RADS classification and histopathological findings in thyroid nodules and to determine the diagnostic accuracy of TI-RADS in predicting thyroid malignancy.

Materials and Methods: This prospective observational study was conducted on 110 patients with thyroid nodules who underwent ultrasonographic evaluation and subsequent histopathological examination. Thyroid nodules were categorized according to the ACR TI-RADS classification system (TR1–TR5). Histopathological diagnosis was considered the gold standard. The association between TI-RADS categories and histopathological findings was assessed using the Chi-square test. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated using standard 2 × 2 contingency tables. Statistical analysis was performed using IBM SPSS Statistics version 27.0, and a p-value <0.05 was considered statistically significant.

Results: The mean age of the study participants was 42.8 ± 12.6 years, and females constituted 80.0% of the study population. The most common TI-RADS category was TR4 (34.5%), followed by TR3 (29.1%). Histopathological examination revealed that colloid nodules were the most frequent lesion (38.2%), followed by nodular goiter (21.8%) and follicular adenoma (14.5%). Among malignant lesions, papillary thyroid carcinoma was the predominant subtype (14.5%), followed by follicular carcinoma (3.7%). A statistically significant association was observed between TI-RADS classification and histopathological diagnosis ($p < 0.001$). All TR1 and TR2 nodules were benign, while malignancy rates increased progressively across higher TI-RADS categories, reaching 85.7% in TR5 nodules. When TR4 and TR5 categories were considered positive for malignancy, TI-RADS correctly identified 26 of 28 malignant lesions and 68 of 82 benign lesions. The sensitivity, specificity, PPV, NPV, and overall diagnostic accuracy of TI-RADS were 92.9%, 82.9%, 65.0%, 97.1%, and 85.5%, respectively.

Conclusion: A significant correlation exists between TI-RADS classification and histopathological findings in thyroid nodules. The risk of malignancy increases progressively with higher TI-RADS categories. TI-RADS demonstrated excellent sensitivity, high negative predictive value, and good overall diagnostic accuracy, making it a reliable, non-invasive risk stratification tool for the evaluation of thyroid nodules and for guiding decisions regarding biopsy, surgery, and clinical follow-up.

Keywords: Thyroid nodule; TI-RADS; ACR TI-RADS; Histopathology; Thyroid carcinoma; Ultrasonography; Diagnostic accuracy.

Introduction

Thyroid nodules are among the most common endocrine disorders encountered in clinical practice. With the widespread use of high-resolution ultrasonography, the detection of thyroid nodules has increased substantially over the last two decades. Epidemiological studies have reported that thyroid nodules can be detected by palpation in approximately 4–7% of adults, whereas

ultrasonography may identify nodules in up to 50–60% of the general population. Despite their high prevalence, only a small proportion of thyroid nodules are malignant, making accurate risk stratification essential to avoid unnecessary invasive procedures and surgeries [1].

Ultrasonography is the imaging modality of choice for the initial evaluation of thyroid nodules because of its accessibility, cost-effectiveness, and ability to characterize suspicious morphological features. Several sonographic characteristics, including solid composition, marked hypoechogenicity, irregular margins, taller-than-wide shape, and microcalcifications, have been shown to be associated with an increased risk of malignancy [2]. However, the interpretation of individual ultrasound features may be subjective and may vary among observers, necessitating the development of standardized reporting systems.

To improve consistency in reporting and management recommendations, various Thyroid Imaging Reporting and Data System (TI-RADS) classifications have been proposed. Among these, the American College of Radiology (ACR) TI-RADS introduced by Tessler et al. in 2017 has gained widespread acceptance because of its structured scoring system based on five sonographic characteristics: composition, echogenicity, shape, margin, and echogenic foci [3]. The cumulative score categorizes thyroid nodules into five risk groups ranging from TR1 (benign) to TR5 (highly suspicious), thereby facilitating standardized clinical decision-making and reducing unnecessary fine-needle aspiration biopsies.

Several studies have evaluated the diagnostic performance of TI-RADS in predicting thyroid malignancy. Middleton et al. (2018) demonstrated that ACR TI-RADS possesses high sensitivity and acceptable specificity for differentiating benign from malignant thyroid nodules, while also reducing the number of unnecessary biopsies compared with other risk stratification systems [4]. Similarly, Grani et al. (2018) reported a progressive increase in malignancy risk across higher TI-RADS categories, supporting the clinical utility of ultrasound-based risk stratification systems in routine practice [5].

Subsequent investigations further validated the usefulness of TI-RADS in various clinical settings. Ha et al. (2019) observed that the combination of suspicious echogenic foci with TI-RADS classification significantly improved diagnostic performance for predicting thyroid cancer [6]. Furthermore, several systematic reviews and comparative studies published up to 2021 confirmed that TI-RADS provides reliable risk stratification and demonstrates good diagnostic accuracy in differentiating benign from malignant thyroid nodules, thereby assisting clinicians in selecting patients for biopsy and surgical management [7,8].

Aim & Objectives

Aim: To evaluate the correlation between Thyroid Imaging Reporting and Data System (TI-RADS) classification and histopathological findings in patients presenting with thyroid nodules and to determine the diagnostic accuracy of TI-RADS in predicting thyroid malignancy.

Objectives

Primary Objective: To assess the association between TI-RADS categories and histopathological diagnosis of thyroid nodules.

Secondary Objectives

- To determine the distribution of thyroid nodules according to TI-RADS classification.
- To analyze the histopathological spectrum of thyroid nodules.
- To evaluate the prevalence of benign and malignant thyroid lesions among the study population.
- To determine the sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy of TI-RADS in predicting malignancy.
- To assess the trend of increasing malignancy risk across successive TI-RADS categories.

Materials & Methods

Study Design: This prospective observational study was conducted to evaluate the correlation between Thyroid Imaging Reporting and Data System (TI-RADS) classification and histopathological findings in thyroid nodules and to determine the diagnostic accuracy of TI-RADS in predicting thyroid malignancy.

Study Place: The study was conducted in the Department of Radiodiagnosis in collaboration with the Departments of Pathology at R.D.J.M Medical College & Hospital, Turki, Muzaffarpur, Bihar, India**,** where patients with clinically or radiologically detected thyroid nodules were evaluated and managed according to institutional protocols.

Study Period: The study was carried out over a period of 10 months from March 2021 to December 2021. During this period, eligible patients presenting with thyroid nodules were consecutively recruited and prospectively followed until histopathological diagnosis was obtained.

Study Population: The study population comprised adult patients presenting with thyroid nodules who underwent ultrasonographic

evaluation using the TI-RADS classification system and subsequently underwent surgical excision or biopsy with histopathological examination.

A total of 110 patients fulfilling the eligibility criteria were included in the study.

Ethical Considerations: The study protocol was approved by the Institutional Ethics Committee before commencement of the study. Written informed consent was obtained from all participants prior to enrollment. Confidentiality and anonymity of patient information were maintained throughout the study. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki, and participation was entirely voluntary.

Inclusion Criteria: Patients aged 18 years and above with clinically palpable or ultrasonographically detected thyroid nodules who underwent TI-RADS evaluation and subsequent histopathological examination and provided written informed consent were included in the study.

Exclusion Criteria: Patients below 18 years of age, those with diffuse thyroid disease without discrete nodules, previously diagnosed thyroid malignancy, prior thyroid surgery, incomplete clinical, radiological, or histopathological records, unwillingness to participate, or absence of histopathological confirmation were excluded from the study.

Methodology

After obtaining informed consent, detailed demographic and clinical information including age, gender, presenting symptoms, duration of illness, and relevant medical history were recorded using a predesigned proforma.

All patients underwent detailed thyroid ultrasonography performed by experienced radiologists using a high-frequency linear transducer (7.5–15 MHz).

The ultrasonographic characteristics evaluated included nodule composition (cystic, mixed, or solid), echogenicity, shape, margins, presence of echogenic foci or calcifications, vascularity, and cervical lymph node status.

Each nodule was assigned a TI-RADS score according to the American College of Radiology (ACR) TI-RADS guidelines. Based on the cumulative score, nodules were categorized as:

- TR1: Benign
- TR2: Not suspicious
- TR3: Mildly suspicious
- TR4: Moderately suspicious
- TR5: Highly suspicious

The radiological findings were documented and correlated with subsequent histopathological findings.

Surgical Procedure: The decision regarding surgical intervention was made by the treating surgical team based on clinical examination, imaging findings, and institutional management protocols.

The surgical procedures performed included:

- Hemithyroidectomy (lobectomy)
- Near-total thyroidectomy
- Total thyroidectomy
- Thyroidectomy with lymph node dissection, when indicated

Excised specimens were immediately sent to the Department of Pathology in 10% neutral buffered formalin for histopathological examination.

Histopathological Investigation: Gross examination of thyroid specimens was performed according to standard pathological protocols.

Representative tissue sections were processed, embedded in paraffin, sectioned at 3–5 µm thickness, and stained with Hematoxylin and Eosin (H&E).

Histopathological diagnoses were categorized as:

Benign Lesions

- Colloid nodule
- Nodular goiter
- Follicular adenoma
- Hashimoto thyroiditis

Malignant Lesions

- Papillary thyroid carcinoma
- Follicular carcinoma

Histopathological diagnosis served as the gold standard for final confirmation.

Outcome Measures

Primary Outcome Measure: Correlation between TI-RADS classification and histopathological diagnosis of thyroid nodules.

Secondary Outcome Measures

- Distribution of thyroid nodules according to TI-RADS categories.
- Histopathological spectrum of thyroid nodules.
- Prevalence of benign and malignant lesions.
- Diagnostic performance of TI-RADS in predicting thyroid malignancy.
- Trend of increasing malignancy risk across TI-RADS categories.

Statistical Analysis: Data were entered into Microsoft Excel 2021 (Microsoft Corporation, Redmond, WA, USA) and subsequently analyzed

using IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, NY, USA). Continuous variables such as age were expressed as mean ± standard deviation (SD), whereas categorical variables were summarized as frequencies and percentages. Descriptive statistics were used to present demographic characteristics, TI-RADS categories, and histopathological diagnoses.

The association between TI-RADS classification and histopathological findings was evaluated using the Chi-square (χ^2) test or Fisher's exact test whenever appropriate.

A p-value of less than 0.05 was considered statistically significant.

For diagnostic accuracy analysis, histopathological diagnosis was considered the gold standard. TI-RADS categories TR4 and TR5 were regarded as positive for malignancy, whereas TR1–TR3 were considered negative. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated using standard 2 × 2 contingency tables. Ninety-five percent confidence intervals (95% CI) were determined for all diagnostic parameters.

Results

A total of 110 patients with thyroid nodules were included in the study. The mean age of the participants was 42.8 ± 12.6 years. Females constituted 80.0% of the study population.

Table 1: Demographic Characteristics of Study Participants (n = 110)

Characteristics	Variable	Frequency (n)	Percentage (%)
Age Group (years)	<30	18	16.4
	30–39	28	25.5
	40–49	34	30.9
	50–59	20	18.2
	≥60	10	9.1
Gender	Male	22	20.0
	Female	88	80.0

Mean age: 42.8 ± 12.6 years

Table 1 show that the majority of patients belonged to the 40–49 years age group (30.9%), followed by the 30–39 years age group (25.5%). Patients aged less than 30 years constituted 16.4% of the study population, while 18.2% and 9.1% were in the 50–59 years and ≥60 years age groups, respectively. Females predominated in the study, accounting for 88 (80.0%) cases, whereas males constituted 22 (20.0%) cases, yielding a female-to-male ratio of 4:1.

Table 2: Distribution of Thyroid Nodules According to TI-RADS Classification (n = 110)

TI-RADS Category	Frequency (n)	Percentage (%)
TR1 (Benign)	8	7.3
TR2 (Not Suspicious)	18	16.4
TR3 (Mildly Suspicious)	32	29.1
TR4 (Moderately Suspicious)	38	34.5
TR5 (Highly Suspicious)	14	12.7
Total	110	100.0

Table 2 show that the largest proportion of thyroid nodules was categorized as TR4 (moderately suspicious), comprising 38 (34.5%) cases. TR3 (mildly suspicious) nodules accounted for 32 (29.1%) cases, while TR2 (not suspicious) and TR5 (highly suspicious) categories represented 18 (16.4%) and 14 (12.7%) cases, respectively. Only 8 (7.3%) nodules were classified as TR1 (benign).

Table 3: Histopathological Diagnosis of Thyroid Nodules (n = 110)

Histopathological Diagnosis	Frequency (n)	Percentage (%)
Colloid Nodule	42	38.2
Nodular Goiter	24	21.8
Follicular Adenoma	16	14.5
Hashimoto Thyroiditis	8	7.3
Papillary Thyroid Carcinoma	16	14.5
Follicular Carcinoma	4	3.7
Total	110	100.0

Table 3 present, colloid nodules were the most frequent diagnosis, observed in 42 (38.2%) patients, followed by nodular goiter in 24 (21.8%) patients and follicular adenoma in 16 (14.5%) patients. Among malignant lesions, papillary thyroid carcinoma was the predominant histological subtype, accounting for 16 (14.5%) cases, while follicular carcinoma was diagnosed in 4 (3.7%) cases. Hashimoto thyroiditis was identified in 8 (7.3%) patients.

Overall, benign lesions constituted the majority of thyroid nodules, with colloid nodules and nodular goiter being the most frequent histopathological findings, whereas papillary thyroid carcinoma was the most common malignant diagnosis.

Table 4: Correlation Between TI-RADS Classification and Histopathological Findings (n = 110)

TI-RADS Category	Benign n (%)	Malignant n (%)	p value
TR1	8 (100.0)	0 (0.0)	< 0.001
TR2	18 (100.0)	0 (0.0)	
TR3	30 (93.8)	2 (6.2)	
TR4	24 (63.2)	14 (36.8)	
TR5	2 (14.3)	12 (85.7)	
Total	82 (74.5)	28 (25.5)	

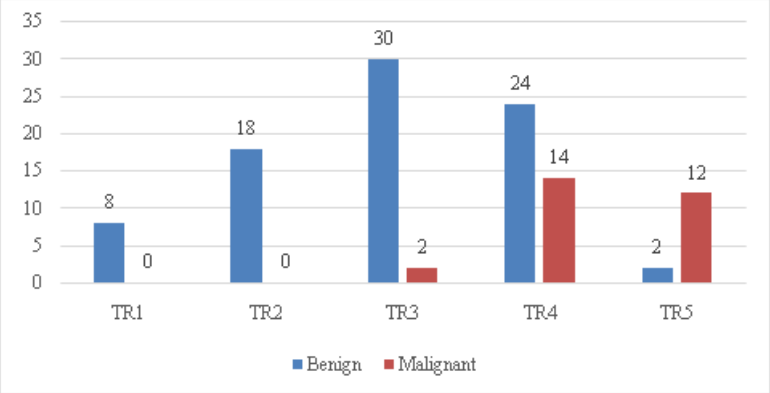

Figure 1: Correlation Between TI-RADS Classification and Histopathological Findings

Table 4 and figure I, show that a significant association was observed between TI-RADS classification and histopathological diagnosis ($p < 0.001$). All nodules classified as TR1 and TR2 were benign on histopathological examination. Among TR3 nodules, only 2 (6.2%) were malignant, whereas 30 (93.8%) were benign. The proportion of malignant lesions increased substantially with higher TI-RADS categories. In the TR4 category, 14 (36.8%) nodules were malignant, while in the TR5 category, 12 (85.7%) nodules were confirmed as malignant on histopathology. Overall, 82 (74.5%) nodules were benign and 28 (25.5%) were malignant. These findings indicate a progressive increase in the likelihood of malignancy with increasing TI-RADS category.

Table 5: Diagnostic Performance of TI-RADS (TR4–TR5 Considered Positive for Malignancy) (n=110)

Histopathology	TI-RADS Positive	TI-RADS Negative	Total
Malignant	26	2	28
Benign	14	68	82
Total	40	70	110

Table 5 show that out of the 28 histopathologically confirmed malignant lesions, 26 were correctly identified by TI-RADS, whereas 2 cases were missed. Among the 82 benign lesions, 68 were correctly categorized as negative, while 14 were falsely classified as positive. Thus, TI-RADS identified 40 nodules as positive and 70 as negative for malignancy.

Table 6: Diagnostic Accuracy of TI-RADS in Predicting Malignancy

Parameter	Value (%)	95% Confidence Interval
Sensitivity	92.9	76.5–99.1
Specificity	82.9	73.0–90.3
Positive Predictive Value	65.0	49.5–78.5
Negative Predictive Value	97.1	89.9–99.6
Accuracy	85.5	77.5–91.4

Table 6 show the diagnostic accuracy analysis demonstrated that TI-RADS had a sensitivity of 92.9% and a specificity of 82.9% for predicting malignant thyroid nodules. The positive predictive value and negative predictive value were 65.0% and 97.1%, respectively. The overall diagnostic accuracy was 85.5%. These findings indicate that TI-RADS is a highly sensitive and reliable imaging-based risk stratification tool, particularly useful for ruling out malignancy in thyroid nodules due to its excellent negative predictive value.

Discussion

In the present study, the mean age of the participants was 42.8 ± 12.6 years, with the highest proportion of patients belonging to the 40–49 years age group (30.9%). Females constituted 80.0% of the study population, resulting in a female-to-male ratio of 4:1. The predominance of middle-aged individuals observed in our study is consistent with the established epidemiological pattern of thyroid nodules. Thyroid nodules are most frequently encountered during the fourth and fifth decades of life, likely due to cumulative hormonal, environmental, and metabolic influences. Similar observations were reported by Magri et al. (2020), who found that most patients undergoing evaluation for thyroid nodules belonged to the middle-aged population, with a marked female predominance [9]. Likewise, El-Halaby et al. (2021) reported a mean age of approximately 46 years among patients with thyroid nodules, which closely resembles the mean age observed in the present study [10].

The marked female predominance observed in our study is also in agreement with previous literature. Thyroid disorders are known to occur more frequently in women due to hormonal influences, autoimmune susceptibility, and estrogen receptor expression within thyroid tissue. Modi et al. (2020) similarly reported a significantly higher prevalence of thyroid nodules among females compared with males [11]. Therefore, the demographic profile observed in the present study is consistent with global epidemiological trends.

The present study demonstrated that TR4 nodules constituted the largest proportion (34.5%), followed by TR3 nodules (29.1%). TR5 nodules accounted for 12.7% of all nodules. The predominance of intermediate-risk categories observed in our study is comparable to findings reported by Xiao et al. (2020), who demonstrated that the majority of thyroid nodules were categorized within the intermediate and moderately suspicious TI-RADS groups [12]. Similarly, Soylemez and Gunduz (2021) observed that TR3 and TR4 nodules represented the largest proportion of evaluated nodules across different risk stratification systems [13]. These findings suggest that most thyroid nodules encountered in routine clinical practice fall into categories requiring either close surveillance or further diagnostic evaluation.

The relatively lower proportion of TR5 nodules in the present study may reflect the comparatively lower prevalence of malignant lesions within the study population. This observation further supports the usefulness of TI-RADS as a risk stratification tool capable of categorizing nodules into clinically meaningful groups.

Histopathological examination revealed that colloid nodules were the most common lesion (38.2%), followed by nodular goiter (21.8%) and follicular adenoma (14.5%). Among malignant lesions, papillary thyroid carcinoma represented the most common malignancy (14.5%), while follicular carcinoma accounted for 3.7%. These findings are in agreement with the established histopathological spectrum of thyroid nodules. Benign lesions generally constitute the majority of thyroid nodules encountered in clinical practice. El-Halaby et al. (2021) similarly reported colloid nodules and nodular hyperplasia as the predominant benign lesions on histopathology [10]. Furthermore, papillary thyroid carcinoma was identified as the most common malignant lesion, which corresponds with global thyroid cancer statistics indicating that papillary carcinoma accounts for approximately 80–85% of all thyroid malignancies.

Modi et al. (2020) also reported papillary thyroid carcinoma as the predominant malignant histological subtype among nodules categorized as suspicious by TI-RADS [11]. Therefore, the histopathological distribution observed in the present study is consistent with previously published literature.

One of the most important findings of the present study was the statistically significant association between TI-RADS classification and histopathological diagnosis ($p < 0.001$). All TR1 and TR2 nodules were benign, whereas the proportion of malignant lesions increased progressively from TR3 to TR5 categories. Notably, 85.7% of TR5 nodules were malignant. These findings strongly support the validity of TI-RADS as a malignancy risk stratification system. Modi et al. (2020) demonstrated a direct correlation between increasing ACR TI-RADS scores and malignancy risk, with higher TI-RADS categories showing significantly greater rates of malignant cytology and histopathology [11]. Similarly, Magri et al. (2020) reported that malignancy rates increased consistently with ascending TI-RADS categories, confirming the predictive value of the classification system [9].

The high malignancy rate observed among TR5 nodules in the present study is also supported by Xiao et al. (2020), who reported that high-risk TI-

RADS categories demonstrated the strongest association with thyroid cancer diagnosis [12]. Therefore, our findings reinforce the concept that increasing TI-RADS scores correspond to increasing histopathological evidence of malignancy.

When TR4 and TR5 categories were considered positive for malignancy, TI-RADS correctly identified 26 of 28 malignant lesions and correctly excluded malignancy in 68 of 82 benign lesions. These findings indicate excellent screening performance. The small number of false-negative cases demonstrates the ability of TI-RADS to detect most malignant nodules. Similar observations were reported by Magri et al. (2020), who found that TI-RADS effectively identified malignant nodules while maintaining acceptable specificity [9]. Likewise, El-Halaby et al. (2021) demonstrated that TI-RADS achieved high diagnostic performance when correlated with histopathological findings [10].

The presence of false-positive cases observed in the present study may be attributed to overlap in ultrasonographic features between benign hyperplastic nodules and malignant lesions. Nevertheless, the low false-negative rate emphasizes the usefulness of TI-RADS as a screening and triage tool for selecting nodules requiring biopsy.

The present study demonstrated a sensitivity of 92.9%, specificity of 82.9%, positive predictive value of 65.0%, negative predictive value of 97.1%, and overall diagnostic accuracy of 85.5%.

These findings compare favorably with previously published studies. Magri et al. (2020) reported high sensitivity and diagnostic performance for ACR TI-RADS when histopathology was used as the reference standard [9]. Similarly, Modi et al. (2020) found that higher TI-RADS categories were strongly predictive of malignancy and that the system exhibited excellent sensitivity for identifying malignant thyroid nodules [11]. El-Halaby et al. (2021) also demonstrated that TI-RADS achieved high sensitivity and negative predictive value, supporting its role as a reliable non-invasive diagnostic tool [10].

The exceptionally high negative predictive value (97.1%) observed in the present study is clinically important because it indicates that nodules classified as low risk are highly unlikely to be malignant. Consequently, TI-RADS may help reduce unnecessary biopsies and surgical interventions while maintaining patient safety.

Limitations of the study

- The study was conducted at a single tertiary care centre, which may limit the generalizability of the findings to other populations and healthcare settings.
- The sample size of 110 patients, although adequate for statistical analysis, may not fully represent the entire spectrum of thyroid nodules encountered in clinical practice.
- Histopathological confirmation was available only for patients who underwent surgical excision or biopsy, which may introduce selection bias.
- Inter-observer variability in ultrasound interpretation and TI-RADS categorization was not evaluated.
- The study did not assess the role of fine-needle aspiration cytology (FNAC) as an intermediate diagnostic modality between imaging and histopathology.
- Long-term follow-up of patients was not performed; therefore, the prognostic significance of various TI-RADS categories could not be evaluated.
- Advanced imaging techniques and radiomic analysis were not included, which may further improve diagnostic performance.

Conclusion

The present study demonstrated a strong and statistically significant correlation between TI-RADS classification and histopathological findings in thyroid nodules ($p < 0.001$). The likelihood of malignancy increased progressively with higher TI-RADS categories, with all TR1 and TR2 nodules proving benign on histopathology, whereas the majority of TR5 nodules were malignant.

Histopathological examination revealed that benign lesions predominated, accounting for 74.5% of cases, while malignant lesions constituted 25.5%. Papillary thyroid carcinoma was the most common malignant lesion identified.

TI-RADS exhibited excellent diagnostic performance, with a sensitivity of 92.9%, specificity of 82.9%, negative predictive value of 97.1%, and overall diagnostic accuracy of 85.5%. The high negative predictive value suggests that TI-RADS is particularly effective in excluding malignancy in thyroid nodules and may help reduce unnecessary invasive procedures.

Therefore, TI-RADS serves as a reliable, non-invasive, and clinically useful risk stratification system for the evaluation of thyroid nodules and can effectively guide decision-making regarding biopsy, surgical intervention, and patient follow-up.

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