

A Study to Evaluate the Reliability of Thyroid Imaging Reporting and Data System in Risk Stratification of Thyroid Swelling

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Received: 01-08-2025 / Revised: 15-09-2025 / Accepted: 21-10-2025

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Conflict of interest: Nil

Abstract

Background: Thyroid swellings are among the most common endocrine disorders, with a significant female predominance and variable malignancy potential. Accurate preoperative differentiation between benign and malignant nodules is essential to prevent unnecessary surgeries. Ultrasonography, when standardized through the Thyroid Imaging Reporting and Data System (TIRADS), offers a non-invasive, cost-effective, and reproducible method for risk stratification, particularly in resource-limited settings.

Aim: To assess the reliability of the Thyroid Imaging Reporting and Data System (TIRADS) in stratifying the malignancy risk of thyroid swellings and correlating ultrasonographic findings with histopathological outcomes.

Methodology: A prospective study was conducted on 50 patients admitted for thyroid surgery at the Department of General Surgery, Narayana Medical College Hospital, from January 2023 to June 2024. All patients underwent detailed clinical examination, thyroid function tests, and ultrasonography. Nodules were classified using TIRADS, and postoperative histopathological examination (HPE) served as the gold standard for comparison. Diagnostic parameters including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for various sonographic features.

Results: Among 50 cases, females constituted 92% and the majority were aged 30–59 years. Most patients were euthyroid (76%). Histopathologically, colloid goitre (66%) was most common, followed by papillary carcinoma (10%). Malignancy correlated strongly with higher TIRADS categories—100% in TIRADS 5 and 22.2% in TIRADS 4c. Sonological features showing high diagnostic accuracy included a taller-than-wide shape (specificity 95.23%, NPV 97.5%) and irregular margins (specificity 90.47%, NPV 92.68%).

Conclusion: TIRADS is a reliable, affordable, and reproducible tool for differentiating benign from malignant thyroid nodules. It effectively guides FNAC and surgical decisions, reducing unnecessary interventions. Its integration into routine thyroid evaluation can enhance diagnostic precision in Indian healthcare settings.

Keywords: Thyroid Nodule, TIRADS, Ultrasonography, Histopathological Correlation.

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Introduction

Thyroid swelling is a common condition encountered in surgical departments. Most cases are benign, with goitre being the most prevalent, though some are malignant. In Southeast Asia, approximately 172 million people are affected by goitre, while iodine deficiency impacts around 600 million individuals.

In India alone, about 42 million people suffer from thyroid diseases. The prevalence of thyroid swellings in adults ranges between 4% and 7%, with discrete thyroid swellings reported in 8.5% of the Indian population. Women are four times more likely to develop thyroid swellings than men. [1,2,3] Thyroid swellings can appear as isolated or

dominant nodules. The true incidence of thyroid nodules may be underestimated in clinical evaluations, as small, impalpable nodules are often detected during surgery. Common symptoms include swelling, pressure effects, or signs of thyroid dysfunction. Solitary thyroid nodules (STN) carry a higher risk of malignancy than other thyroid nodules, with about 15% of STNs being cancerous.

However, clinical symptoms alone cannot reliably distinguish between benign and malignant nodules. [4] Surgical complications may include recurrent laryngeal nerve (RLN) injury, hypoparathyroidism, and the need for lifelong thyroid hormone

replacement. Various diagnostic tools, such as thyroid function tests, thyroid antibody levels, isotope scans, ultrasonography, and fine-needle aspiration cytology (FNAC), help assess thyroid nodules. Among these, cytological and histopathological examinations remain the gold standard. [5,6,7,8]

Ultrasonography plays a crucial role in thyroid nodule evaluation due to its affordability, portability, non-invasiveness, and lack of ionising radiation. When combined with clinical suspicion, ultrasound findings help categorise patients as high-risk or low risk. In resource-limited healthcare settings like India, cost-effective diagnostic tools are essential. The Thyroid Imaging Reporting and Data System (TIRADS) standardises ultrasound findings by classifying thyroid nodules into five categories based on specific sonographic features, aiding in distinguishing benign from malignant nodules. [9,10]

Despite its benefits, ultrasonography has limitations, including variability in equipment resolution, observer-dependent interpretation, and overlapping imaging features. The TIRADS classification system helps address these limitations by providing a structured approach to thyroid nodule assessment.

Aim of the study: To assess the reliability of Thyroid Imaging Reporting and Data System in the risk stratification of thyroid swellings.

Objectives: To determine the role of ultrasound in the diagnosis and management of thyroid disorders. To evaluate the accuracy of TIRADS classification

in diagnosis of thyroid disorders. To distinguish between the malignant and benign solitary nodular lesions, thereby reducing the cost of unnecessary surgery for a benign lesion. To confirm the clinically obvious malignancy of thyroid thereby determining the type of surgery

Methodology

This was a Prospective study done in 50 cases admitted for thyroid surgery in the wards of Department of General Surgery, Narayana Medical College Hospital during the period from January 2023 to June 2024.

Patients with goitre will be evaluated clinically. Relevant aspects of patient's history including age, sex, rapidity of growth, recent onset of hoarseness, dysphagia, dyspnoea, symptoms of hypo or hyperthyroidism, history of head and neck irradiation, family history of endocrine diseases will be included. Physical examination to determine whether the gland was diffusely enlarged, solitary, nodular or multinodular with symmetric or asymmetric enlargement will be done. In nodular swelling, the size, shape, consistency, location and mobility will be assessed. A thyroid function test and an ultrasound will be performed. Post operatively histopathological examination of the specimen will be carried out in the Department of Pathology, Narayana Medical College Hospital. The ultrasound findings will be classified into various classes of TIRADS and the reliability of the same will be assessed by comparing with HPE diagnosis.

Results

Table 1: Age & Sex Distribution

Age category	Frequency	Percentage
20-29	2	2.41
30-39	17	25.63
40-49	10	18.55
50-59	12	27.21
60-70	9	18
Gender	Frequency	Percentage
Female	46	92
Male	4	8

Table 2: Biochemical Status

Biochemical status	Frequency	Percentage
Euthyroid	38	76
Hyperthyroid	5	10
Hypothyroid	5	10
Subclinical Hyperthyroid	1	2
Subclinical Hypothyroid	1	2
Total	50	100

Table 3: Differential Diagnosis of Thyroid Swellings

HPE	Frequency	Percentage
Adenoma	2	4
Anaplastic Carcinoma	1	2
Colloid Goitre	33	66
Follicular Carcinoma	2	4
Hashimotos Thyroiditis	4	8
Hurthle Cell Neoplasm	1	2
Lymphocytic Thyroiditis	1	2
Normal	1	2
Papillary Carcinoma	5	10
Total	50	100

Table 4: Distribution Based On Tirads Classification

TIRADS	Frequency	Normal	Benign	Malignancy
1	1	1		
2	4		4	
3	6		6	
4a	10		10	
4b	15		14	1
4c	9		7	2
5	5			5
Total	50	1	41	8

Table 5: Table Showing Significance of Sonological Features

Nodularity	Malignancy		Total
	Yes	No	
Yes	8	37	45
No	0	4	4
Solid Components			
Yes	8	27	35
No	0	14	14
Hypogenecity			
Yes	8	28	36
No	0	14	14
Microcalcification			
Yes	7	4	11
No	5	34	39
Taller than wider			
Yes	7	2	9
No	1	40	41
Irregular margins			
Yes	5	4	9
No	3	38	41

Table 6: Table Showing Statistics Significance of Sonological Features

Parameter	Sensitivity	Specificity	PPV	NPV	Accuracy
Nodularity	100	9.75	17.78	100	24.49
Solid Components	100	34.14	22.85	100	44.9
Hypoechogenecity	100	50	22.22	100	44
Microcalcification	58.33	89.47	63.63	87.11	82
Taller Than Wide	87.5	95.23	77.78	97.5	94
Irregular Margins	62.5	90.47	55.56	92.68	86

Discussion

Thyroid swellings continue to be among the most frequently encountered clinical presentations in

endocrine surgery. These swellings encompass a wide pathological spectrum, ranging from benign conditions such as colloid goitres and hyperplastic nodules to more sinister pathologies like papillary,

follicular, medullary, and anaplastic thyroid carcinomas.

Despite the predominance of benign lesions, the risk of malignancy within thyroid nodules remains a critical concern, with global literature estimating the incidence of cancer in thyroid nodules to be between 5–15%. This underlying malignancy potential mandates meticulous evaluation and risk stratification, as early and accurate diagnosis significantly influences treatment planning and prognosis.

Historically, the diagnostic approach to thyroid nodules has relied on a combination of clinical palpation, thyroid function tests, radionuclide scans, and fine-needle aspiration cytology (FNAC). While FNAC remains a cornerstone in the evaluation of thyroid nodules, especially for cytological categorization (Bethesda system), it has limitations in cases with indeterminate cytology (Bethesda III and IV) and is also subject to sampling errors and interpretive subjectivity. Similarly, clinical examination alone is inadequate in distinguishing benign from malignant nodules, particularly for small or deep-seated lesions.

In recent years, high-resolution ultrasonography has emerged as a vital tool for the initial assessment of thyroid nodules. However, the traditional use of ultrasound was limited by lack of standardization and high inter-observer variability, leading to inconsistent diagnostic outcomes. To overcome these challenges, structured sonographic classification systems such as the Thyroid Imaging Reporting and Data System (TIRADS) were developed.

Demographic Profile and Epidemiological Relevance: Thyroid disorders exhibit a clear demographic pattern, influenced by age, gender, and geographical factors. In the current study, a significant female predominance was observed, with 92% of participants being women, reflecting the global epidemiological trend that thyroid diseases—particularly nodular and autoimmune conditions—are more common in females. This gender disparity is widely attributed to the modulatory role of oestrogen on thyroid epithelial proliferation and immune responses, which may predispose women to both benign and malignant thyroid pathologies.

Furthermore, the age distribution in this cohort showed that most patients were between 30 and 59 years, which corresponds to the fourth to sixth decades of life—a well-recognized peak period for thyroid nodule presentation. This age range represents the most clinically active phase of adult life, where individuals are more likely to seek medical attention for neck swellings due to cosmetic or symptomatic concerns. It also aligns

with hormonal fluctuations and increasing cumulative exposure to environmental and dietary risk factors (such as iodine deficiency, radiation exposure, or endocrine disruptors). This pattern mirrors findings from numerous studies. For instance, Gupta et al [11] in a comprehensive survey across multiple Indian centers, noted that over 70% of thyroidectomy cases occurred in women aged 35–60 years, reinforcing the age-gender vulnerability profile observed in the present study. Additionally, international data from the World Health Organization (WHO) and American Thyroid Association (ATA) have long acknowledged this demographic skew.

Biochemically, the study observed that 76% of the patients were euthyroid, indicating that thyroid functional status does not always correlate with the presence of structural abnormalities. Many nodular lesions—including several malignancies—may exist without significant alterations in TSH, T3, or T4 levels, thereby reinforcing the need for structural assessment through imaging rather than relying solely on biochemical evaluation. This finding is in line with existing literature, which reports that a large percentage of thyroid cancers are discovered incidentally in euthyroid individuals.

Ultrasound and TIRADS as Frontline Diagnostic Tools: Ultrasonography (USG) stands as the cornerstone in the initial evaluation of thyroid nodules, offering a non-invasive, accessible, and cost-effective modality capable of delineating structural and vascular characteristics of the gland. It provides real-time visualisation of nodule composition (solid vs cystic), echogenicity, margins, calcifications, vascular flow, and extrathyroidal extension—all of which are vital in malignancy risk assessment.

However, traditional ultrasound interpretation has historically been plagued by subjectivity and inter-observer variability, especially when evaluating borderline features such as ill-defined margins or subtle calcifications. To address this limitation, the Thyroid Imaging Reporting and Data System (TIRADS) was developed—modelled after the BI-RADS system used in breast imaging—to standardize sonographic reporting and guide clinical management.

The first iteration of TIRADS was introduced by Horvath et al [12] in 2009, which was subsequently refined by Kwak et al. and later formalized by the American College of Radiology (ACR) into the widely adopted ACR-TIRADS system. Each TIRADS variant assigns a risk category based on the cumulative presence of specific ultrasound features.

These include: Composition (solid, cystic, spongiform), Echogenicity (hyperechoic, isoechoic, and hypoechoic), Margins (smooth, irregular, lobulated), Shape (wider-than-tall vs taller-than-wide), Echogenic foci (microcalcification, comet tail, macrocalcifications). Based on the total score, nodules are classified into TIRADS 1 (normal) to TIRADS 5 (highly suspicious), with increasing risk of malignancy along the spectrum. This scoring system provides objective criteria that clinicians and radiologists can use to: Determine the need for FNAC, Plan surveillance intervals, and decide on surgical intervention for high-risk nodules.

In the present study, this framework was applied prospectively to classify thyroid nodules in 50 patients, with findings subsequently correlated with histopathological diagnosis post-thyroidectomy. This real-time application validates TIRADS as a frontline decision-making tool, especially in resource-limited settings where advanced molecular testing may not be readily available.

Notably, the application of TIRADS significantly reduces unnecessary FNACs and surgeries by identifying nodules with low malignant potential. For example, TIRADS 2 and 3 lesions, which have very low risk (<5%), may be safely monitored, thereby avoiding overtreatment. Conversely, TIRADS 4 and 5 lesions, which demonstrate progressively higher malignancy risk, can be triaged appropriately for FNAC or direct surgical excision.

Distribution of TIRADS Categories and Histopathological Correlation: The TIRADS categories in this study spanned from 1 to 5. Most lesions were classified as TIRADS 4a (20%), 4b (30%) and 4c (18%), indicating a high proportion of suspicious nodules. The highest incidence of malignancy was observed in TIRADS 5 (100%), followed by TIRADS 4c (22.2%) and 4b (6.7%). This aligns with Kwak et al.'s study (2011), which demonstrated a malignancy rate of 87.5% in TIRADS 5 nodules and 43.2% in TIRADS 4c nodules. Similarly, studies by Russ et al. and Park et al. support a direct correlation between higher TIRADS categories and increasing malignancy risk. Thus, the current findings reaffirm the clinical utility of TIRADS in differentiating malignant from benign thyroid nodules pre-operatively.

Diagnostic Performance of TIRADS Sonographic Features: An important objective of this study was to assess how effectively specific sonographic features within the TIRADS framework correlate with malignancy. Each suspicious feature—nodularity, solid composition, hypoechogenicity, microcalcifications, taller-than-wide shape, and irregular margins—was examined independently for its diagnostic performance using sensitivity, specificity, positive predictive value (PPV), and

negative predictive value (NPV). These findings were then compared to previously published literature.

Nodularity: In this study, nodularity was present in all malignant cases, giving it a sensitivity of 100%. However, its specificity was only 9.75%, with a PPV of 17.78%. These findings suggest that while nodularity is ubiquitous in thyroid malignancy, it is not discriminatory since it is also present in many benign conditions such as colloid goitres. This mirrors the findings of Bonavita et al., who suggested that nodularity alone should not be relied upon for risk stratification due to its high prevalence in both benign and malignant nodules. The high NPV (100%) does, however, support the exclusion of malignancy in non-nodular cases.

Solid Composition: Solid components within nodules are another hallmark of potential malignancy. In the current study, solid composition demonstrated a sensitivity of 100% and specificity of 34.14%, with a PPV of 22.85% and NPV of 100%. These results align with those reported by Moon et al., who found solid nodules to be significantly associated with malignancy, though not exclusively malignant. The moderately low specificity again emphasizes that solid nodules, although concerning, need corroborative features for malignancy prediction.

Hypoechogenicity: Hypoechogenicity, a common feature in papillary carcinoma, yielded a sensitivity of 100% and specificity of 50%. Its PPV (22.22%) was low, but NPV was 100%. The study by Kim et al. corroborated this pattern, identifying hypoechogenicity as a sensitive indicator but emphasizing its limited specificity. The high NPV affirms that absence of hypoechogenicity makes malignancy unlikely, though its presence alone cannot confirm it.

Microcalcifications: Among all features, microcalcifications offered a balanced profile: sensitivity of 58.33%, specificity of 89.47%, PPV of 63.63%, and NPV of 87.18%. Microcalcifications are widely considered highly specific for papillary thyroid carcinoma, often reflecting psammoma bodies on histopathology. These results are consistent with the study by Rago et al., which cited microcalcifications as the most specific ultrasonographic marker for malignancy. The relatively lower sensitivity could be due to under-detection or presence of alternative calcific patterns in other types of thyroid cancer.

Taller-Than-Wide Shape: This feature showed one of the highest diagnostic values in the study: 87.5% sensitivity, 95.23% specificity, 77.78% PPV, and 97.56% NPV. The taller-than-wide configuration represents vertical growth through tissue planes, which is uncharacteristic of benign

growths and thus a strong predictor of malignancy. Kwak et al. emphasized the utility of this feature in distinguishing suspicious nodules, and the present findings strongly support its role. The near-perfect NPV and high specificity make this a reliable indicator when planning surgery.

Irregular Margins: Irregular margins, suggesting infiltrative growth, were present in 62.5% of malignancies with a specificity of 90.47%, PPV of 55.56%, and NPV of 92.68%. Irregular margins have also been highlighted by Moon et al. and Alexander et al. as indicative of malignant behaviour, particularly in papillary thyroid carcinoma. While their presence raises suspicion, their absence does not reliably exclude malignancy.

Kwak et al. (2011): Pioneering Validation of TIRADS: Kwak and colleagues were among the first to validate a structured TIRADS model in a large retrospective analysis of 1,524 thyroid nodules. They reported malignancy rates of: 87.5% in TIRADS 5, 43.2% in TIRADS 4c, and 4.8% in TIRADS 3, which are comparable to the rates observed in the present study (e.g., 100% in TIRADS 5, 22.2% in 4c, and 6.7% in 4b). Park et al. (2016): Integration with FNAC: Park et al. emphasized the enhanced diagnostic performance of TIRADS when used in conjunction with fine-needle aspiration cytology (FNAC), especially in nodules with indeterminate cytology (Bethesda III and IV). Their prospective multicenter study demonstrated that TIRADS scoring helped reduce unnecessary FNACs, particularly for nodules in TIRADS 3 and below, while ensuring high detection in TIRADS 4 and 5 lesions.

Russ et al. (2013): European Consensus and High NPV: Russ et al. developed a European TIRADS (EU-TIRADS) model and conducted one of the most comprehensive prospective studies on ultrasound-based thyroid risk stratification. They emphasized the high negative predictive value (NPV) of lower TIRADS categories, demonstrating that TIRADS 2 and 3 nodules have an NPV exceeding 95%, similar to the findings of current study where nodules with lower scores (TIRADS 1–3) were predominantly benign. Moon et al. (2008) Significance of Individual Sonographic Features: Moon et al. contributed significantly to the understanding of specific sonographic features predictive of malignancy.

Their analysis of features such as microcalcifications, hypoechogenicity, irregular margins, and taller-than-wide shape matches this study's conclusion that these features, particularly taller-than-wide shape (97.56% NPV) and microcalcifications (89.47% specificity), are highly predictive of thyroid cancer.

Current study highlights how the Thyroid Imaging Reporting and Data System (TIRADS) serves as a valuable tool in this context, offering a reliable, non-invasive, and reproducible framework for the risk stratification of thyroid swellings. In a country where advanced diagnostics like molecular testing, elastography, or routine CT/MRI scans are often unavailable or unaffordable, TIRADS represents a pragmatic alternative that leverages widely available ultrasound technology. According to data from the Indian Council of Medical Research (ICMR) and various regional studies, thyroid disorders affect approximately 42 million people in India, with an increasing incidence of nodular thyroid disease and thyroid cancer, particularly papillary carcinoma. However, a significant portion of the population—especially in low-resource settings—lacks access to regular screening and early diagnostic interventions. Many nodules are detected incidentally or present late due to sociocultural factors, poor health literacy, and limited specialist availability.

In such settings, the TIRADS classification bridges the gap between clinical suspicion and confirmatory diagnosis. Its implementation can: Enhance early detection of suspicious nodules, Reduce reliance on unnecessary fine-needle aspirations or surgeries for benign lesions, Prioritize high-risk patients for surgical intervention or cytological confirmation, and standardize reporting across radiologists with varied experience levels.

Influence on Surgical Decision-Making: In current study, patients in higher TIRADS categories (especially 4c and 5) demonstrated a high correlation with malignancy. This supports the current surgical trend of tailoring intervention based on sonological risk: TIRADS 1–3: Typically observed unless symptoms or growth warrant further action. TIRADS 4a–4c: Indicate a need for further investigation, preferably with FNAC. TIRADS 5: Strong candidate for surgical intervention even without FNAC, especially if corroborated by clinical suspicion. This risk-adapted strategy has been endorsed by the ATA and other expert consensus guidelines. The study findings support the surgical community's shift from “operate all nodules” to “operate smartly,” reducing unnecessary surgeries and improving outcomes.

Conclusion

TIRADS, a structured ultrasound-based classification system, was effective in stratifying nodules from benign to highly suspicious. Most patients fell into TIRADS categories 4a to 5, with malignancy rates increasing significantly across higher categories reaching 100% in TIRADS 5. Key sonographic features such as

microcalcifications, taller-than-wide shape, and irregular margins were shown to be highly predictive of malignancy, with strong specificity and negative predictive value. The findings support TIRADS as a practical tool, especially in resource-limited Indian settings, to guide fine-needle aspiration cytology (FNAC) and surgical decisions. The present study validates the Thyroid Imaging Reporting and Data System (TIRADS) as a reliable, cost-effective, and non-invasive tool for stratifying the malignancy risk of thyroid swellings. When interpreted systematically, TIRADS correlates strongly with histopathological outcomes and enhances pre-operative decision-making. Features such as microcalcifications, taller-than-wide shape, and irregular margins showed high specificity and predictive value.

The system's high negative predictive value also supports the safe observation of low-risk nodules, thereby minimizing unnecessary interventions. In an Indian healthcare context—where accessibility, affordability, and patient burden are key concerns—TIRADS offers a pragmatic solution for effective thyroid cancer risk management.

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