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ORIGINAL ARTICLE

Diagnostic accuracy of thyroid imaging reporting and data system (Ti-Rads) in distinguishing benign from malignant nodules, keeping histopathology as gold standard in a tertiary care hospital

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ABSTRACT

Background: thyroid nodules are common particularly in iodine-deficient regions such as Pakistan and most are benign. Accurate, non-invasive risk stratification is therefore essential to avoid missed cancers and unnecessary procedures. The American college of radiology thyroid imaging reporting and data system (ti-rads) offers a standardized ultrasound framework. This study evaluated the diagnostic accuracy of ti-rads against histopathology and compared performance with fine-needle aspiration cytology (fnac).

Methods: In a single-center cross-sectional study over 10 months, 150 adults (20–60 years) with a single thyroid nodule underwent high-resolution ultrasound with ti-rads scoring and ultrasound-guided fnac. A surgical/biopsy subset had histopathology as the reference standard. Data were analyzed in spss v25; continuous variables were summarized as mean±SD or median. Diagnostic metrics (sensitivity, specificity, positive predictive value (ppv), negative predictive value (npv), accuracy) were calculated from 2×2 contingency tables versus histopathology

Results: women comprised 85.3% (128/150); mean age 42.4±14.2 years; right-lobe nodules were common (69.3%). ti-rads distribution favoured lower risk (tr3 62.0%, tr4 22.0%). in 32 cases with histopathology, ti-rads showed sensitivity of 70.0%, specificity 77.3%, ppv 58.3%, npv 85.0%, and accuracy 75.0% with 95%CI range (67.2% – 81.0%)**.** FNAC performed better having sensitivity of 90.9%, specificity 81.0%, ppv 71.4%, npv 94.4%, and accuracy 84.4%. histopathology-based risk of malignancy rose stepwise with ti-rads category. tr2 33.3% (4/12), tr3 50.0% (4/8), tr4 70.0% (7/10), tr5 100% (2/2). **Conclusion**: Ti-rads showed moderate diagnostic performance with a graded increase in malignancy risk, suggesting its potential usefulness as a triage or screening framework. FNAC appeared to offer higher sensitivity and npv, highlighting its value in confirming or excluding malignancy.

Keywords: Diagnostic Accuracy, FNAC, Histopathology, Thyroid Nodules, Ultrasound

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Introduction

Thyroid nodules are a significant and increasing health problem worldwide. They are defined as discrete lesions of the thyroid gland, typically found incidentally during imaging performed for another issue (1). Although most nodules are benign, small

proportions are malignant, necessitating accurate evaluation to avoid both overtreatment and missed cancers (2). Studies show that thyroid nodules are present in a small percentage of the population by physical examination, in a larger percentage via ultrasound, and in many more cases by autopsy studies (3, 4).

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The differences in detected rates reflect both variability in diagnostic methodology and the increasing use of high-definition imaging, which can detect small and asymptomatic nodules. In areas like Pakistan, the impact of thyroid disease is much greater, mainly due to iodine deficiency, which continues to be a public health issue. (5) The prevalence of thyroid nodules is also much higher in women, with a female-to-male ratio of approximately 4:1 (6).

Ultrasound remains the most widely used imaging modality to assess thyroid nodules. It is non-invasive, relatively cheap, and safe (does not use ionizing radiation), and is widely available in almost all healthcare facilities (7, 8). High-resolution ultrasound allows for visualization of the thyroid in greater detail and also helps to provide information about nodules beyond just the size, such as morphology and internal features (9). However, ultrasound does have some limitations, such as being unable to distinguish between benign and malignant nodules. For example, if two nodules look similar sonographically, the clinician might not be able to draw a distinction. This can result in both over diagnosis and under treatment of disease (4).

When evaluating thyroid nodules, physicians routinely initiate the process with a high resolution ultrasound scan (10) however, it is not entirely definitive. The problem of distinguishing between benign and malignant nodules is particularly difficult since they all show the same morphology. Thus, a more definitive type of testing has evolved. Fine needle aspiration cytology (FNAC) is widely used for making proper diagnosis.

In FNAC, cells are extracted from nodules, by a thin needle and viewed under a microscope. The FNAC has certain advantages but also has disadvantages. FNAC can be uncomfortable and/or painful, which causes bruising or infections and increases treatment costs (11, 12). Furthermore the FNAC is an inconclusive result 55 to 75% of the time requiring a second test to be performed, while 3% to 7% of FNAC results are confirmed malignancy (13,14,15) Therefore; there is an increasing need for a reproducible and consistent way with ultrasound to know the risk of malignancy to decrease unnecessary biopsies.

In 2017, the American College of Radiology (ACR) developed the Thyroid Imaging Reporting and Data System (TI-RADS) .TI-RADS method was derived from a similar approach for breast imaging, BI-RADS. TI-RADS standardizes ultrasound evaluation based on five key features—nodule composition, echogenicity, shape, margins, and echogenic foci—and assigns risk categories from TR1 to TR5 (16; 8,17).

Characteristics like denser nodules, prominence of deep colour, irregular borders, micro calcifications, and a taller-than-wide shape can predispose the nodule to being classified, elevating risk of carcinoma (5). This scoring system reduces unnecessary

biopsies, improves diagnostic accuracy, and minimizes interobserver variability (18).

Methods

This cross-sectional study was conducted in the Dow Institute of Radiology (DIR) in collaboration with the Department of Histopathology, at Dow International Medical College, Dow University of Health Sciences, Karachi, over a period of 10 months following ethical approval (Letter no IRB-2613/DUHS/Approval/2022/06). A total of 150 patients presented with neck pain and lump aged 20 -60 years referred to ultrasound neck and FNAC in our department having single thyroid nodule were recruited. The patients were excluded if they were previously diagnosed with thyroid cancer, had a thyroidectomy, were pregnant or did not undergo FNAC or biopsy in our center. Written informed consent was obtained from all participants after explaining the procedure and its potential complications. Demographic data including age, gender, contact information, serum T3, serum T4, and duration of symptoms were recorded on preformed proforma. Ultrasound examinations were performed by two dedicated radiologists/experienced sonologists using either a Philips IU22 or Supersonic ultrasound machine with a 5–12 MHz linear array probe. Both transverse and longitudinal images of the thyroid nodules were acquired and imaging findings were reported according to TI-RADS and documented on a structured data collection form. All patients subsequently underwent ultrasound-guided FNAC at the Vascular Interventional Radiology (VIR) Department, DIR DUHS. FNAC was performed by a single interventional radiologist with 10–15 years of experience, using a 23-gauge needle attached to a 20 cc syringe under continuous negative pressure until blood appeared in the syringe hub. The aspirate was sent to the pathology department for slide preparation and staining. Rapid on-site evaluation (ROSE) by a cytotechnologist ensured adequacy of samples, defined as at least six groups of well-preserved thyroid follicles with a minimum of 10 cells per group. In cases of inadequate yield, FNAC was repeated. For each patient, at least four slides and a cell block were prepared and reported according to the Bethesda System for Reporting Thyroid Cytopathology (TBSRTC).

Patients were subsequently followed through the treatment process and final histopathology reports were traced on Hospital Management Information System (HMIS) for comparison. Statistical Package for Social Sciences (SPSS) version 25 was used for data management and analysis. Quantitative variables like age, serum TSH, serum T3, serum T4 and size of the thyroid nodule were reported as mean and standard deviation if distribution was normal otherwise median with Inter Quartile Range was reported. Qualitative variables like gender, clinical indication, symptoms, location of the thyroid nodule, Benign and malignant nodules on ultrasound, FNAC and on histopathology were reported in frequency/ percentages. To determine sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of ultrasound TIRADS and FNAC against the gold standard i.e. histopathology, a 2x2 contingency table was used.

Result

In this cohort of 150 thyroid nodules, women predominated (128/150, 85.3%). Presenting complaints were nearly balanced, with neck pain in 80 (53.3%) and neck swelling in 70

(46.7%). Lesions more frequently involved the right lobe (104, 69.3%) than the left (46, 30.7%) (Table 1 (A)). The mean age was 42.4 ± 14.2 years. Thyroid function showed T3 [2.20 ± 0.72 nmol/L (median 2.04)], T4 7.92 ± 6.68 µg/dL (median 7.15)], and TSH [1.11 ± 0.97 µIU/mL (median 0.89)]. The longest nodule diameter averaged 3.32 ± 1.53 cm with a median 3.00 cm (IQR 2.12–4.55) (Table 1 (B)). Overall, the sample is female-predominant with right-sided nodules slightly more common and laboratory values within expected ranges

Table 1. Demographic characteristics

A) Categorical variables

Characteristic (N=150)	Category	N (%)
Gender	Female	128 (85.3%)
	Male	22 (14.7%)
Clinical indication	Neck pain	80 (53.3%)
	Neck swelling	70 (46.7%)
Location of nodule	Right lobe	104 (69.3%)
	Left lobe	46 (30.7%)

B) Continuous variables

Variable	Mean ± SD	Median (IQR)	Min–Max
Age (years)	42.44 ± 14.16	43.00 (31.25–51.00)	12.00–80.00
Serum T3 (nmol/L)	2.20 ± 0.72	2.04 (1.70–2.45)	1.42–5.88
Serum T4 (µg/dL)	7.92 ± 6.68	7.15 (5.80–8.75)	1.11–76.70
TSH (µIU/mL)	1.11 ± 0.97	0.89 (0.28–1.56)	0.00–5.67
Nodule longest diameter (cm)	3.32 ± 1.53	3.00 (2.12–4.55)	0.40–6.40

Table 2 shows most nodules in this cohort were low-to-intermediate suspicion on TIRADS and the cytology mirrored it.

Table 2: Distribution of TI-RADS, Bethesda, and Histopathology results.

Variable (N)	Category	Count	Percent
U/S TI-RADS Score (N=150)	TR3	93	62.0%
	TR4	33	22.0%
	TR2	22	14.7%
	TR5	2	1.3%
Bethesda Score (N=150)	II	94	62.7%
	I	20	13.3%
	IV	19	12.7%
	III	14	9.3%
	V	3	2.0%
Histopathology Result (N=32)	Benign nodular hyperplasia	15	46.9%
	Papillary carcinoma	8	25.0%
	Follicular neoplasm	7	21.9%
	Medullary carcinoma, low grade	1	3.1%
	Anaplastic thyroid carcinoma	1	3.1%

In our study comparison of TI-RADS with histopathology in 32 patients' demonstrated moderate diagnostic performance. TI-RADS correctly identified 7 malignant and 17

benign cases, with 5 false positives and 3 false negatives. The calculated sensitivity was 70%, showing its ability to detect malignancy, while specificity was 77.3%, indicating good performance in ruling out benign cases. The positive predictive value (PPV) was 58.3%, reflecting a modest probability that a TI-RADS malignant result truly indicates malignancy. In contrast, the negative predictive value (NPV) was 85%, showing stronger reliability in excluding malignancy. Overall diagnostic accuracy was 75%, supporting TI-RADS as a useful screening tool (table 3 A& 4)

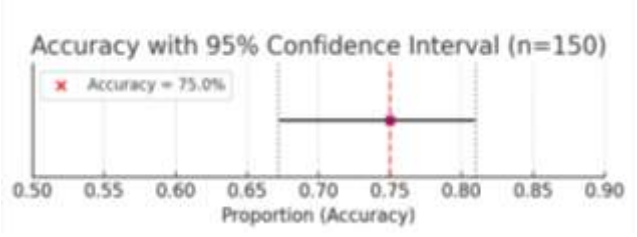
FNAC called 14 cases malignant; 10 were truly malignant and 4 were benign .It called 18 cases benign; 17 were truly benign and 1 malignant was missed Overall, FNAC was correct in 27/32 (84.4%).having Sensitivity 90.9%, Specificity 81.0%, PPV 71.4%, NPV 94.4%(table 3B & 4)

Table 3 :(A) Cross-Tabulation of TI-RADS Classification & FNAC with Histopathology

3A: TI-RADS Classification and Histopathology Results			
	Histopathology Malignant	**Histopathology Benign**	**Total**
TI-RADS Malignant	7 (TP)	5 (FP)	12
TI-RADS Benign	3 (FN)	17 (TN)	20
Total	10	22	32
3B: Cross-Tabulation of FNAC and Histopathology Results			
	Histopathology Malignant	**Histopathology Benign**	**Total**
FNAC Malignant	10 (TP)	4 (FP)	14
FNAC Benign	1 (FN)	17 (TN)	18
Total	11	21	32

Table 4: Diagnostic Performance Metrics of TI-RADS Compared to Histopathology

Measures	**TIRADS**	**FNAC**
Sensitivity	70%	90.5%
Specificity	77.3%	81.0%
Positive Predictive Value	58.3%	71.6%
Negative Predictive Value	85%	94.4%
Accuracy	75%	84.8%



The cross shows observed **accuracy** of **75%** while the **horizontal black bar** shows the **95% CI range (67.2% – 81.0%)**.

As TI-RADS category increases, the likelihood of Risk of malignancy (ROM) rises. In the histopathology subset, TR2 had a low ROM (33.3 4/12), TR3 showed a substantial moderate ROM (50%, 4/8), TR4 had a substantial high ROM (70%, 7/10), and TR5 was uniformly malignant in this dataset (100%, 2/2). This stepwise pattern supports TI-RADS validity. However these percentages reflect only patients who underwent surgery/histopathology and carries risk of selection bias and small data especially TR5 (n=2) challenges its precision.

Table 5: Risk of Malignancy (Rom) TI-RADS

TI-RADS Category	**n**	**Malignant (n)**	**ROM (%)**

TR2	12	4	33.3
TR3	8	4	50
TR4	10	7	70.0
TR5	2	2	100.0

As per our study, TI-RADS serves well as a triage/screening tool, however, FNAC outperforms TI-RADS overall—particularly for sensitivity and NPV—supporting its strength for confirming and excluding malignancy and saved 10% in our case .The PPVs of both tests are modest and broadly comparable (≈59–71%, suggesting that for TI-RADS suspicious nodules, FNAC may not markedly increase the post-test probability on its own and can be skipped in resource constrained settings as definitive diagnosis relies on histopathology. However and decisions should follow guideline-based pathways and clinical context rather than a single test result.

Discussion

This study evaluated the diagnostic value of thyroid imaging reporting and data system (TI-RADS) in differentiating between benign and malignant thyroid nodules using histopathology as the gold standard according to which it was possible to conclude on the accuracy of this system. According to the results, TI-RADS can be a beneficial non-invasive tool of preliminary risk stratification of nodules in the sphere of thyroid care, especially in low-income/developing and transitional countries like Pakistan (8, 10).

In general, TI-RADS had the sensitivity and specificity of 70 and 77.3% respectively. These outcomes imply a moderate performance to predict real malignant lesions but the capacity to exclude nodules that appear to be malignant was fairly good. High negative predictive value (NPV) 85% was most notable as well because it indicated that the nodules that are interpreted as low risk (TR1 to TR3) are least likely to be malignant. Although this observation supports the use of TI-RADS in eliminating the necessity of using invasive testing like fine-needle aspiration cytology (FNAC) or surgery on nodules that are at low risk of development (1,12,18). But in our study performing FNAC for TI-RADS 2–3 nodules can help avoid missing roughly 10% of malignancy.

The positive predictive value of 58.3% does not reflect the high-level mark, which means that the prediction of the malignancy by ultrasound imaging does not align closely with the final histopathological judgment. The present finding is aligned with the previously reported literature demonstrating a significant overlap in the set of characteristics between the benign and malignant nodules in ultrasound. (5, 19) Thus, high TI-RADS are to be viewed as an evidence of an increase in the level of suspicion rather than the actual indicator of malignancy. This is also favoured by our study that as TI-RADS category rises, the likelihood of Risk of malignancy (ROM) rises .This stepwise rise in ROM across higher TI-RADS categories, although consistent with international findings, may therefore partly reflect this bias. Consequently, the predictive value of TI-RADS observed here may not fully represent its performance in the broader thyroid nodule population.

The diagnostic accuracy of all TI-RADS in the current research was found to be 75%. Such finding supports the clinical efficacy of TI-RADS as a triage based system, but would not justify its replacement of histopathological validation. However, TI-RADS may also help organize an effective diagnostic procedure as it helps sort out the order of priorities based on the need of the

patients to undergo fine-needle aspiration cytology or biopsy /surgery (20, 21).

False positives in this study could have occurred due to benign nodules exhibiting ultrasound features that are typical of malignancy such as irregular margins and/or heterogeneous texture similarly, false negatives may be attributable to malignancies that do not conform to the typical sonographic features. This highlights the need for clinicians to consider their TI-RADS score in light of patient care, history and additional work-up if warranted (16,22).

Several studies have reported higher TI-RADS sensitivity than ours. Patil et al. (19) found 85.3% sensitivity; Ishtiaq et al. (22) from Peshawar reported 80% sensitivity and 92.8% specificity against histopathology; and Khan et al. (23) observed 87.5% sensitivity and 91.4% NPV, albeit with lower specificity (31.6%), underscoring how performance varies with population and thresholds. Zahoor et al. (12) in Southern Punjab (n=360) reported accuracy 76.2% (sensitivity 78.4%, specificity 74.5%), broadly consistent with our findings. Jamal et al. (20) further showed TI-RADS can reduce unnecessary biopsies. Differences across studies likely reflect variation in demographics and iodine status, radiologist expertise and inter-observer agreement, and differing diagnostic thresholds. Inclusion of indeterminate/borderline nodules may also reduce sensitivity; as such lesions often lack classic malignant sonographic features and can be under-classified by TI-RADS.

Our study has a limitation as inter-observer agreement was not assessed, which limits the confidence in its reproducibility in routine practice. A key challenge in using TI-RADS is its subjective interpretation, as radiologists may differ in assessing features like echogenicity, margins, or microcalcifications, making the scoring experience-dependent. While more experienced radiologists tend to be consistent, less experienced ones may over- or under-classify nodules, which reduces reproducibility and can lead to inconsistent recommendations for FNAC or follow-up. Prior studies (10, 20) have shown such inter-observer differences can impact diagnostic accuracy.

Study limitations

A key limitation is that TI-RADS involves subjective interpretation and is operator dependent; image acquisition and scoring may vary with radiologist experience. This was a single-centre study with a relatively small sample, which limits the generalizability of the findings. In addition, we did not assess inter-observer agreement, so the reproducibility of TI-RADS scoring in our setting remains uncertain.

Conclusion

TI-RADS showed moderate diagnostic performance with a graded increase in malignancy risk, suggesting its potential usefulness as a triage or screening framework. FNAC appeared to offer higher sensitivity and NPV, highlighting its value in confirming or excluding malignancy. In resource-limited settings, proceeding directly to biopsy in higher-risk categories (e.g., TR4–TR5) could be considered, though such an approach should be applied cautiously and requires further validation before replacing FNAC. These findings should also be viewed in light of the small surgical subset and possible selection bias, which may limit the precision of PPV estimates and overall generalizability.

Future recommendations

Larger, multicenter studies with balanced gender representation are needed to enhance generalizability and probe possible gender-related differences, particularly in iodine deficient settings such as Pakistan. Incorporating advanced imaging (e.g., shear-wave elastography, contrast-enhanced ultrasound) may curb false positives. Cost effectiveness evaluations tailored to resource-limited systems are essential to gauge economic impact. Finally, combining TI-RADS with molecular testing—especially for indeterminate nodules—could improve diagnostic precision and reduce unnecessary procedures. Collectively, these steps would refine TI-RADS as a reliable, non-invasive framework for thyroid nodule risk stratification.

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All the authors agree to take responsibility for every facet of the work, making sure that any concerns about its integrity or veracity are thoroughly examined and addressed.