

Accuracy of American College of Radiology Thyroid Imaging Reporting and Data System in Characterisation of Thyroid Nodules: A Tertiary Hospital Study in India

Ifsheen Fatima¹, Rajul Rastogi¹, Probal Chatterjee², Ashutosh Kumar³

Departments of ¹Radiodiagnosis, ²Otolaryngology and Head and Neck Surgery and ³Pathology, Teerthanker Mahaveer Medical College and Research Center, Teerthanker Mahaveer University, Moradabad, Uttar Pradesh, India

Abstract

Background: Thyroid nodules (TNs) are commonly and frequently encountered in the day-to-day clinical practice. Clinical suspicion of malignancy as well as patient anxiety is the frequent reasons for fine-needle aspiration cytology or biopsy (FNAC/B) of TN. American College of Radiology has developed a Thyroid Imaging Reporting and Data System (ACR TI-RADS) based on TN ultrasound features to suggest malignancy to minimise the number of TN subjected to FNAC/B. Aim to assess the diagnostic accuracy of ACR TI-RADS in our Tertiary Hospital Health Facility. **Patients, Materials and Methods:** Sixty-nine patients with TN included in our study following institutional ethics committee approval and written informed consent underwent high-resolution ultrasonography followed by FNAC using a high-frequency linear transducer on Siemen Acuson S3000 ultrasound scanner. The data were recorded in the predesigned proforma followed by statistical analysis to assess the diagnostic accuracy of ACR TI-RADS. **Results:** Our study had female predominance (50/69) with the left side more commonly affected (37/69). The mean age of the participants was 42.2 ± 15.6 years with significantly higher age at presentation in those with malignant TN. Mixed nodules were predominant (46/69) with nearly half of the malignant nodules being solid and only 8/61 benign nodules being solid. Although the majority of the nodules were hyperechoic (50/69 including 2 malignant), a significant number of the hypoechoic/very hypoechoic nodules (6/14) were malignant with only 8/61 benign nodules being hypoechoic. Half of the malignant nodules (4/8) had lobulated or ill-defined margins, whereas only 2/61 benign nodules had similar margins. The majority (5/8) of the malignant TN had internal punctate echogenic foci with only 1/61 benign TN showing similar appearance. Half of the malignant TN (4/8) had lymphadenopathy, whereas it was noted in only 2/61 cases of benign TN. **Conclusions:** TNs though have a high prevalence, but malignant TNs are uncommon with majority being solid, taller than wider, hypoechoic with microcalcifications. The presence of adenopathy is usually a feature of malignant thyroid nodule rarely seen with benign nodules. Thus, to summarise all TNs should be thoroughly evaluated as per ACR TI-RADS for stratification of risk of malignancy.

Keywords: American College of Radiology Thyroid Imaging Reporting and Data System, characterisation, thyroid nodule

INTRODUCTION

The American Thyroid Association defines the thyroid nodule as a “discrete lesion within the thyroid gland” and appears radiologically different radiological from the adjacent surrounding parenchyma of the thyroid gland.^[1] The prevalence is 5% to 7% of the adult population by physical examination of clinically significant thyroid nodules (TNs).^[1,2] Nodules may be solitary, multiple, cystic, or solid.

Existing medical literature has shown increased prevalence of nodular thyroid pathology with advancing age along with female dominance with majority (approximately 90%) of

detected nodules being benign and hence insignificant lesions leaving a small percentage (approximately 4.0%–6.5%) malignant lesions being the major cause of concern.^[2,3] Over

Address for correspondence: Prof. Rajul Rastogi,
Department of Radiodiagnosis, Teerthanker Mahaveer Medical College and
Research Center, Teerthanker Mahaveer University, Moradabad - 244 001,
Uttar Pradesh, India.
E-mail: eesharastogi@gmail.com

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the past few years, the prevalence has shown a significant rise probably related to increased imaging and awareness.

Ultrasonography (USG) plays a pivotal role in diagnosis, confirmation, localization, and characterisation of TNs along with the differentiation of benign and malignant nodules. As no single USG finding has been described as a high predictor of malignancy till date, hence several attempts of devising imaging scores utilising multiple parameters have been made for the assessment of the risk of malignancy in a thyroid nodule. Thyroid Imaging Reporting and Data System (TI-RADS) refers to such uniform standardised USG-based classification developed considering the prevalence, guidelines, and published research focused on risk assessment and is nowadays used internationally by clinicians.^[3,4]

Although the vascularity as determined by color Doppler imaging (CDI) of the thyroid nodule is considered important determinant factor in tumor expansion, invasion, and metastatic spread, its major limitation is scanner dependence. Several studies have proved that real-time CDI improves the risk stratification of any thyroid nodule scoring system.^[4,5]

Although USG-guided, fine-needle aspiration cytology (FNAC) is considered a best and most accurate tool to characterise a thyroid nodule for planning surgery, USG screening characterisation of thyroid nodule for distinct benignity or suspicious malignancy can help in decreasing the number of FNACs, an invasive investigation on benign nodules which form major proportion of the TNs.

American College of Radiology (ACR) TI-RADS has been shown to be one of the best performers in selecting TN for FNAC.^[6] Hence, our study aimed at evaluating ACR TI-RADS with cytology in determining its optimal utility in day-to-day clinical radiology as a robust tool for predicting the risk of malignancy.

Aim and objective

The aim of the study was to evaluate and assess the diagnostic accuracy of ACR TI-RADS scoring in clinically suspected TNs with pathological correlation.

PATIENTS, MATERIALS AND METHODS

Study design

The study was observational and cross-sectional.

Source of data

The data were acquired from patients visiting our hospital.

Period of study

The study period was 18 months. This observational, cross-sectional, hospital-based study was conducted on 69 patients referred to the department of radiodiagnosis of our institution following approval from the institutional ethics committee and written, informed consent from participants using the following strict criteria:

Inclusion criteria

- All patients with TN >10 mm on high-resolution USG.^[1,7]

Exclusion criteria

- Patients that did not have tissue diagnosis based on FNAC.

All patients included in the study underwent B-mode USG using a high-frequency, linear transducer (9–11 MHz) on Siemens Acuson S3000 ultrasound scanner in supine position with dorsiflexed head exposing the neck maximally using a pillow under the shoulder. The ultrasound gel was applied on the transducer to reduce interference of air with skin and probe during USG.^[8]

The detected TNs were characterised into benign or malignant nodule using B-mode USG in both transverse and longitudinal planes using the ACR TI-RADS as detailed in Annexure 1. The nodule with malignant features or the largest nodule was included in our study results in case of multiple TNs.

All the TNs evaluated by HRUS underwent FNAC for final diagnosis as benign or malignant nodule.

The data were recorded in the predesigned pro forma following by statistical analysis using appropriate tools and methods to assess the diagnostic accuracy of ACR TI-RADS.

All the quantitative variables were described in number or expressed as percentage. The differences within groups were analysed using *P* value which was considered statistically significant when <0.05.

OBSERVATIONS, RESULTS AND ANALYSIS

Out of 69 study subjects, 19 were male and 50 were female. Out of 69 study subjects, in 37 cases, left side was involved, whereas in 23 cases, the right side was involved and 9 cases had bilateral involvement [Table 1].

Out of 69 study subjects, 46 cases had mixed composition, whereas 12 cases were solid, and 11 cases had cystic/spongiform composition (*P* < 0.05). Based on echogenicity, 50 cases were hyperechoic, 12 were hypoechoic, 5 were anechoic,

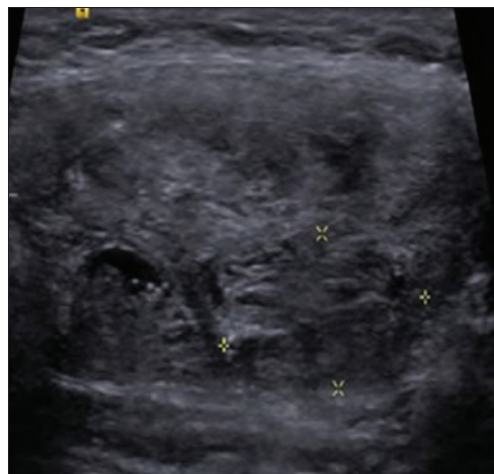


Figure 1: American College of Radiology Thyroid Imaging Reporting and Data System 2 thyroid nodule

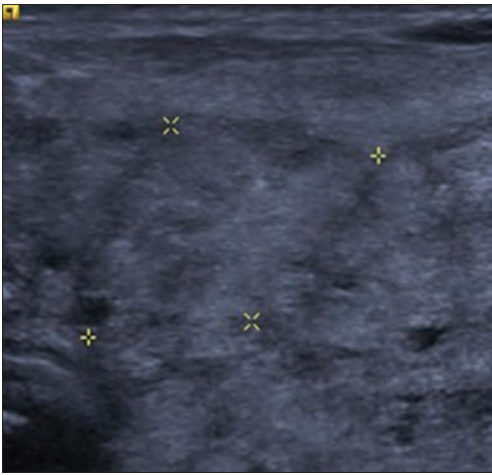


Figure 2: American College of Radiology Thyroid Imaging Reporting and Data System 3 thyroid nodule



Figure 3: American College of Radiology Thyroid Imaging Reporting and Data System 4 thyroid nodule

and 2 were very hypoechoic ($P < 0.05$). According to shape of thyroid nodule, 66 cases were wider, whereas only three cases were taller ($P < 0.05$) [Table 2].

Out of 69 study subjects, 63 cases had smooth/ill-defined margins, whereas only six cases had lobulated or irregular margins. There was a statistically significant difference between echogenicity of benign and malignant nodules ($P < 0.05$). There was a statistically significant difference between lymph node enlargement of benign and malignant nodules ($P < 0.05$) [Table 2].

Table 3 shows the distribution of study participants according to ACR TI-RADS and histopathology. Out of 62 cases diagnosed as benign by ACR TI-RADS, 59 cases were confirmed as benign by histopathology [Figures 1-3]. Whereas out of seven cases diagnosed as malignant by ACR TI-RADS, five cases were confirmed as malignant by histopathology.

Table 4 shows that the sensitivity and specificity of ACR TI-RADS was 96.7% and 62.5%, respectively.

DISCUSSION

Our, observational, hospital-based study on 69 patients included 61 benign and 8 malignant TNs. The nodules were characterised as benign or malignant using ACR TI-RADS followed by comparison with FNAC.

In our study, we found that ACR TI-RADS had a high accuracy of 92.8%. This finding was in contrast to a study by Borlea *et al.*^[5] on 133 TNs with poor performance of ACR TI-RADS. These differences may be due to demography or quality of histology.

Sex distribution in our study is similar to a study by Sachdev *et al.*^[9] on 100 patients but latter had a higher occurrence of malignant nodules, i.e, 11.5% versus 22% (ours vs. Sachdev).

In our study on nodules with unknown cytology, the accuracy of differentiating malignant from benign nodules with B-mode USG using ACR TI-RADS was much high than Stoian *et al.*^[10]

Table 1: Distribution of the study participants according to the demographic characteristics

Characteristics	Benign (n=61)	Malignant (n=8)	Total (n=69)	P
Gender				
Female	44	6	50	0.616
Male	17	2	19	
Side involved				
Right	22	1	23	0.069
Left	33	4	37	
Bilateral	6	3	9	

being 92.8% versus 74.9%. These differences may be due to the high-generation ultrasound scanners used in our study.

In our study, we achieved an accuracy of 92.8% in differentiating benign from malignant nodules using ACR TI-RADS. Our results were similar to the study by Jabar *et al.*,^[11] who in their study concluded that both US RSSs can be safely applied to a large proportion of benign appearing TN for avoiding FNAC.

The sensitivity, specificity, and accuracy reported in our study using ACR TI-RADS were 96.7%, 62.5%, and 92.8%, respectively, which was significantly higher than that reported by Hoang *et al.*^[12] in their study on 100 cytologically and/or pathologically proven TN including 15 malignant nodules being 87%, 51%, and 56%, respectively. This higher accuracy in our study may be due to the improved generation of ultrasound scanners.

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) reported in our study using ACR TI-RADS were 96.7%, 62.5%, 95.2%, and 71.4%, respectively, which was similar to that reported by Horvath *et al.*,^[13] who in their study achieved an overall sensitivity/specificity of 99.6%/74.35% with PPV/NPV of 82.1%/99.4% for TI-RADS 4 and 5.

Table 2: Distribution of study participants according to the thyroid nodule characteristics on ultrasonography

Characteristics	Benign (n=61)	Malignant (n=8)	Total (n=69)	P
Composition				
Cystic/Spongiform	11	0	11	0.025
Mixed (cystic and solid)	42	4	46	
Solid	8	4	12	
Echogenicity				
Anechoic	5	0	5	<0.001
Hyperechoic	48	2	50	
Hypoechoic	8	4	12	
Very hypoechoic	0	2	2	
Shape				
Wider > taller	60	6	66	0.034
Taller > wider	1	2	3	
Margin				
Smooth/ill defined	59	4	63	0.001
Lobulated or irregular	2	4	6	
Extra-thyroidal extension	0	0	0	
Echogenic foci				
None/large comet tail artifacts	42	1	43	<0.001
Macrocalcifications	14	2	16	
Peripheral (rim) calcifications	4	0	4	
Punctate echogenic foci	1	5	6	
Lymph nodes				
Subcentimetric	59	4	63	0.001
Enlarged	2	4	6	

Table 3: Distribution of study participants according to American College of Radiology has developed a Thyroid Imaging Reporting and Data System and histopathology

ACR TI-RADS	Histopathology		Total (n=69)	P
	Benign (n=61)	Malignant (n=8)		
Benign	59	3	62	<0.001
Malignant	2	5	7	

ACR TI-RADS: American College of Radiology has developed a Thyroid Imaging Reporting and Data System

Table 4: Statistical Parameter of American College of Radiology has developed a Thyroid Imaging Reporting and Data System versus fine needle aspiration cytology

Characteristics	ACR TI-RADS
Sensitivity	96.7
Specificity	62.5
PPV	95.2
NPV	71.4
Accuracy	92.8

ACR TI-RADS: American College of Radiology has developed a Thyroid Imaging Reporting and Data System, PPV: Positive predictive value, NPV: Negative predictive value

The sensitivity, specificity, PPV, NPV, and accuracy reported in our study using ACR TI-RADS were 96.7%, 62.5%, 95.2%, 71.4%, and 92.8%, respectively. Our results were superior to the results of Dawoud and Dawoud^[14] who in their study

observed a sensitivity/specificity of 94.12%/76.74% for 81.67% accuracy when TIRAD 4/5 features were combined with elastography (Asteria score 3/4).

In our study, we achieved the sensitivity, specificity, PPV, and NPV of 96.7%, 75%, 96.6%, and 71.4% with an overall accuracy of 92.8% using ACR TI-RADS 4/5 as malignant. However, Stoian *et al.*^[15] in their study on 174 TNs including 29 malignant nodules using B-mode USG and USE evaluating the performance of TI-RADS for the differentiation of benign from malignant nodules reported the sensitivity/specificity of 97.93/86.20% and PPV/NPV of 97.26%/89.28% with an accuracy of 95.97% when TI-RADS-4B and 5 were considered malignant. Thus, our study had a lower specificity and NPV without major difference in sensitivity, PPV, and accuracy. This difference may be due to age and gender along with demographic and criteria differences in two studies.

Our study had a sensitivity similar to Russ *et al.*^[16] (95.7% vs. 96.7% our study), but NPV was much lower (70.4% vs. 99.7%) with higher accuracy in our study (92.8% vs. 62%).

Hong *et al.*^[17] in their study had a predominance of females (214 vs. 29) similar to our study (F: M = 50:19). These authors concluded that predictive values of internal microcalcifications, type of margins, A/T ratio, and significant intranodular vascularity for detecting malignancy depend significantly on size of thyroid nodule, but the predictive value of echogenicity and USE is independent of size. These findings support high accuracy of ACR TI-RADS in our study.

In our study, we achieved the sensitivity, specificity, PPV, and NPV of 96.7%, 75%, 96.6%, and 71.4%, with an overall accuracy of 92.8% using ACR TI-RADS 4/5 as malignant. Our results were superior to the study by Horvath *et al.*,^[18] who in their prospective study on 1097 TNs reported the sensitivity/specificity of 88%/49% and PPV/NPV of 49%/88% with an accuracy of 94% using TI-RADS category which when correlated with final diagnosis achieved on fine-needle aspiration biopsy (FNAB). The authors finally concluded that TI-RADS categorisation not only helps in improving patient management but also made it cost-effective and FNAB needless.

Limitations of the study

Our study was a hospital-based study with small sample volume and poor representation of malignant TN. Although FNAC was included in our study, FNAB or postsurgical histology was not a part of our study.

CONCLUSIONS

- Age of presentation of malignant TN is more than a decade higher than benign nodules. TNs whether benign or malignant are more common in females and are usually unilateral. The majority of benign TNs are solid, whereas malignant nodules may be solid or complex. The majority of the benign TNs are iso to hyperechoic with few slightly hypoechoic to adjacent thyroid parenchyma. In contrast, majority of the malignant TNs are slight to intensely hypoechoic. TNs with ill-defined margins are usually malignant. Echogenic foci representing microcalcifications are seen mainly in the malignant TN and are usually not a feature of benign nodule. Lymphadenopathy is usually associated with malignant TN representing nodal metastases with occasional reactive adenopathy accompanying benign TN. ACR TI-RADS has higher sensitivity, NPV, and accuracy than specificity and PPV. Hence, ACR TI-RADS should be used for the routine evaluation of TN for their risk stratification of risk for malignancy.

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Conflicts of interest

There are no conflicts of interest.

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ANNEXURE**Annexure 1: ACR TI-RADS^[5]**

Category	USG findings	ACR TI-RADS
1	No nodules	Score=0
2	Cyst/spongiform	Score=2
3	Oval, smooth margins, iso-/hyperechoic, no suspicious feature	Score=3
4	Oval, smooth margins, mild hypoechoic, no suspicious feature	Score=4–6
5	Suspicious features (min 1) Irregular shape Irregular margins Microcalcifications Marked hypoechoic	Score \geq 7

USG: Ultrasonography, ACR TI-RADS: American College of Radiology has developed a Thyroid Imaging Reporting and Data System