Diagnostic Performance of the American College of Radiology Thyroid Imaging Reporting and Data System

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Abstract

Aim: A study was conducted in our hospital to find the diagnostic performance of the American College of Radiology (ACR) Thyroid Imaging Reporting and Data System (TI-RADS) in distinguishing benign and malignant thyroid swellings.

Materials and methods: A total of 50 subjects were enrolled in this prospective observational study after obtaining consent. Ultrasonography was done in all patients and thyroid swellings were classified by the ACR TI-RADS system. The final diagnosis was made based on histopathological examination. The results were analyzed and the diagnostic indicators of ACR TI-RADS and its individual components were derived.

Results: The mean age of the study sample was 44.18 years with a standard deviation of 14.29 years. The most common clinical presentation was multinodular goiter (76%). Benign lesions (80%) were more common than malignant lesions (20%) as diagnosed by histopathological examination. Of these, the most common malignancy was papillary carcinoma (60%). The risk of malignancy of TR1 was 0%, TR2 was 5.6%, TR3 was 10%, TR4 was 54.5%, and TR5 was 100%. The ACR TI-RADS classification system had good sensitivity (80%) and specificity (87.5%) with a diagnostic accuracy of 86%.

Conclusion: The study has shown that lower TI-RADS classes were commonly associated with benign lesions and higher TI-RADS classes were frequently associated with malignant lesions. The diagnostic indicators showed that the ACR TI-RADS is a dependable system to detect malignancy in thyroid swellings.

Clinical significance: Enlargement of the thyroid gland is a frequent complaint among patients presenting in a hospital. Evaluation of these swellings is required to detect malignancy. Several studies have been done describing the accuracy of Thyroid Imaging Reporting and Data System (TI-RADS), which was proposed by the ACR utilizing ultrasonography in the foreign population. The utility of this system in our population was scarcely studied. This warrants a study to assess the diagnostic performance of this classification and its utility in the Indian population.

Keywords: American College of Radiology Thyroid Imaging Reporting and Data System Classification, Prospective observational study, Thyroid swellings, Ultrasonography.

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Introduction

Thyroid disorders are widely prevalent worldwide. They cause a significant disease burden in the Indian population. Swelling of the thyroid gland also known as goiter (from the Latin word guttār) is an important thyroid disorder presenting to the surgical outpatient department. Recent population studies have proved that approximately 12% of adults have a palpable goiter.1 Thyroid enlargement may be benign or malignant. Early detection of malignancy is essential to plan the management accordingly. Even though we largely rely on invasive techniques like fine needle aspiration cytology (FNAC) to make a diagnosis, the utility of noninvasive methods like ultrasonography is increasing in the past decade. Ultrasound helps in evaluating the characteristics of thyroid nodules and draining lymph nodes. Of the nodules identified in ultrasound, only 10% are malignant.2 The Thyroid Imaging Reporting and Data System (TI-RADS) was proposed to identify the possibility of malignancy in thyroid swellings based on certain ultrasound features.3 The system was later modified by the American College of Radiology (ACR). Thyroid Imaging Reporting and Data System criteria can be used in our clinical setting to distinguish between benign and malignant thyroid swellings. This can decrease the number of invasive investigations done and also provide a proper management plan for the patient. Even though several studies have been done abroad, very few published studies are available studying the utility of ACR TI-RADS in the Indian population. Therefore, a study was conducted to find the diagnostic accuracy of ACR TI-RADS (2017) classification and its individual components in differentiating benign and malignant thyroid swellings.
**Materials and Methods**

This is a prospective observational study conducted in Dr DY Patil Medical College, Hospital and Research Centre, Pune, India between August 2018 and September 2020. All patients above 12 years of age who were admitted with thyroid swelling in the Department of Surgery were included. Patients who did not give consent and those who were not willing for investigative procedures were excluded. Their history including age, sex, the onset of swelling, associated symptoms, treatment, and family history of endocrine disorders was noted. Physical examination of the thyroid gland was done to assess the size of swelling, number of swellings, and presence of nodules. A clinical diagnosis was made based on the history and physical examination. A baseline thyroid function test was done and the thyroid status of the patient was noted. An ultrasound of the thyroid gland was done with a 7.5-MHz high-frequency linear array transducer by a senior radiologist. All ultrasound features were noted and the swelling was graded as per ACR TI-RADS classification. Fine needle aspiration was performed by a pathologist and a cytological diagnosis was made. Surgical excision of the thyroid gland either partly or in total was done and the specimen was examined microscopically and the diagnosis was made. The findings in FNAC and histopathology were noted. All collected data were tabulated in Microsoft Excel and analyzed using the social science statistics software web version.

**Ethics**

Institute ethical committee approval was taken before the study. Consent of patient taken only after giving full information about the study. The patient was assured his/her reports were kept confidential.

**Results**

A total of 50 subjects were enrolled in the study. The study sample had a mean age of 44.18 years with a standard deviation of 14.29 years, the oldest enrolled was 78 years and the youngest was 18 years old. There were 35 (70%) females and 15 (30%) males in the study sample.

Clinically, 11 (22%) subjects presented with solitary nodules, 38 (76%) presented with multiple nodules, and only 1 (2%) had no nodules on examination. Multinodular goiter was the most common clinical presentation.

**Fine Needle Aspiration Cytology**

Fine needle aspiration cytology of the thyroid swellings was done and showed that 37 (76%) subjects had benign lesions, 5 (10%) had malignant lesions, and the FNAC of 8 (16%) subjects were inconclusive. Fine needle aspiration cytology has a good specificity (100%) but low sensitivity (50%) (Table 1).

**Histopathological Examination**

Thyroidectomy was done for all patients and all samples were examined by a pathologist. The final diagnosis was made based on the histopathological findings. Benign thyroid nodules (80%) were more common than malignant nodules (20%). Among the malignant nodules, the most common was papillary carcinoma (60%) followed by follicular carcinoma (20%), medullary (10%), and anaplastic carcinoma (10%) (Fig. 1).

**ACR TI-RADS**

Among the 50 study subjects, ultrasonography done showed that 9 (18%) subjects fall under TR1, 18 (36%) subjects under TR2, 10 (20%) subjects under TR3, 11 (22%) subjects under TR4, and 2 (4%) subjects under TR5. Among the 9 subjects in TR class 1, all had benign swellings. Among the 18 subjects in class TR2, 17 (94.4%) had benign lesions and only 1 (5.6%) had malignancy. Of the 10 subjects in class TR3, 9 (90%) had benign swellings and only 1 (10%) was malignant. However, in class TR4, 6 (54.5%) out 10 subjects had benign lesions and 5 (45.5%) had malignant lesions and in TR5, all subjects had malignancy (100%). The risk of malignancy of TR1 was 0%, TR2 was 5.6%, TR3 was 10%, TR4 was 54.5%, and TR5 was 100%. Thus, benign swellings were strongly associated with lower TI-RADS classes and malignant swellings were associated with higher TI-RADS classes (Fig. 2). The sensitivity of ACR TI-RADS is 80% and the specificity is 87.5% (Table 2).

**Components of ACR TI-RADS**

The components of ACR TI-RADS are composition, shape, echogenicity, margins, and echogenic foci. Among the 50 subjects, 13 (26%) subjects had cystic thyroid swelling, 34 (68%) subjects had swellings with mixed composition, i.e., cystic and solid components, 3 (6%) had solid thyroid swellings. Also, 12 (24%) subjects had anechoic swellings, 32 (64%) subjects had hyperechoic/isoechoic swellings and 6 (12%) had hypoechoic swellings. As for shape, 6 (12%) subjects had swellings that were wider than taller and 44 (88%) subjects had thyroid swellings that were taller than wider. Of the 50 patients, 5 (10%) had lobulated/irregular margins and 45 (90%) had smooth margins. Furthermore, 27 (54%) had macrocalcifications and the rest had no echogenic foci. The diagnostic performance of the different components is listed below (Table 3). The mean nodular size on ultrasonography was 2.2 cm with a standard deviation of 1.1

![Fig. 1: Diagnosis of thyroid swellings](image_url)

**Table 1: Diagnostic performance of FNAC**

| Diagnostic indicator       | Percentage |
|----------------------------|------------|
| Sensitivity                | 50         |
| Specificity                | 100        |
| Positive predictive value  | 100        |
| Negative predictive value  | 88.9       |

![Table 1](image_url)
The smallest nodule measured 1 cm and the largest measured 5.7 cm with a range of 4.7 cm.

**Discussion**

The prospective observational study showed that multinodular goiter (76%) was the most common clinical presentation among patients presenting with thyroid swellings. Similar to our study results, a study done by Varma, showed that multinodular disease outnumbers single nodules by about 4 to 1.1

**ACR TI-RADS**

Thyroid Imaging Reporting and Data System was devised by the ACR to diagnose lesions suggestive of malignancy based on ultrasound features of the thyroid swellings. While TR1 and TR2 were not suggestive of malignancy TR3 to TR5 were lesions suspicious for malignancy. In our study, the risk of malignancy in TR1 = 0%, TR2 = 5.6%, TR3 = 10%, TR4 = 54.5%, and TR5 = 100%. Similar to our results, a study conducted by Jameel 5 showed that the risk of malignancy in TR4 = 57.9% and TR5 = 100%. Tappouni et al.6 have stated that the risk of malignancy was estimated to be ≤ 2% for TR1 and TR2, 2.1–5% for TR3, 5.1–20% for TR4, and >20% for TR5. As per our study, benign swellings were commonly associated with lower TI-RADS classes and malignant swellings were associated with higher TI-RADS classes.

According to our study, the diagnostic performance of ACR TI-RADS classification was as follows: sensitivity = 80%, specificity = 87.5%, positive predictive value = 61.5%, negative predictive value = 94.6%, accuracy = 86%. This shows that ACR TI-RADS has good sensitivity (i.e., rules out the possibility of malignancy) and specificity (i.e., detects the possibility of malignancy). According to a study conducted in India,7 the diagnostic performance of ACR TI-RADS was: sensitivity = 72%, specificity = 68.8%, positive predictive value = 63.9%, negative predictive value = 76.2%, and accuracy = 70.2%. A study by Tan et al.8 demonstrated that ACR TI-RADS had a sensitivity of 85.7% similar to our study but had a specificity of 51.1% which was very low compared to our study. This proves that ultrasonography utilizing ACR TI-RADS is a good non-invasive tool to differentiate between benign and malignant swellings. However, the sample size is inadequate to validate the classification system. The following features are components of ACR TI-RADS:

**Composition of Thyroid Swelling**

Thyroid swellings in our study were predominantly mixed type-solid and cystic (68%) followed by cystic/spongiform type (26%) and solid type (6%). A solid nodule was more commonly indicative of malignancy and had a specificity of 100%. However, it had a low sensitivity. Malignant nodules were said to appear solid when compared to normal thyroid parenchyma.9

**Echogenicity**

Of the total 50 patients, 12 (24%) patients had anechoic lesions, 32 (64%) were hyperechoic or isoechoic, and 6 (12%) were hypoechoic. Anechoic echogenicity was predominantly associated with benign lesions. Hypoechoic lesions were equally associated with benign and malignant lesions in our study. According to a study by Hoang et al., hypoechoicnecity had good sensitivity in detecting malignancy but lower specificity.9 However, our study showed that hypoechoicnecity had good specificity (92.5%) in detecting malignancy. Papini et al. stated that hypoechoicnecity was present in 55% of benign nodules10 similar to our study.

**Shape of Thyroid Swellings**

In our study, only 6 (12%) were taller than wider while 44 (88%) were wider than taller. Swellings that were taller than wider were highly specific to malignancy (97.4%). A study by Kim et al. showed that a thyroid nodule that is taller than it is wider had 93% specificity for detecting malignancy.11

**Margins**

In our study, the swellings predominantly had smooth margins (90%) and only 10% had lobulated or irregular margins. Irregular margin indicates infiltration of surrounding thyroid parenchyma.

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**Table 2: Diagnostic performance of ACR TI-RADS**

| Diagnostic indicator          | Percentage |
|------------------------------|------------|
| Sensitivity                  | 80         |
| Specificity                  | 87.5       |
| Positive predictive value    | 61.5       |
| Negative predictive value    | 94.6       |
| Accuracy                     | 86         |

**Table 3: Diagnostic performance of individual components of ACR TI-RADS**

| Diagnostic indicator | Composition (%) | Echogenicity (%) | Shape (%) | Margins (%) | Echogenic foci (%) |
|----------------------|-----------------|-----------------|-----------|-------------|------------------|
| Sensitivity          | 30              | 80              | 50        | 30          | 80               |
| Specificity          | 100             | 52.5            | 97.4      | 95          | 52.5             |
| Positive predictive value | 100           | 29.6            | 83        | 60          | 29.6             |
| Negative predictive value | 85.1          | 91.3            | 88.6      | 84.4        | 91.3             |
| Accuracy             | 86              | 58              | 88        | 82          | 58               |
Our study had shown that irregular margins have a good specificity (95%) but low sensitivity (30%). The sensitivity of irregular margins varies widely from 7 to 97% in different studies.12-14

**Echogenic Foci**
Echogenic foci such as calcifications occur in both benign and malignant lesions. Our study showed that 54% of the total patients had thyroid swellings with macrocalcifications. This feature had a sensitivity of 80% and a specificity of 52.5%. Macrocalcifications were commonly present in medullary and papillary carcinoma.9,15

**Size of Nodule**
Even though the size of the nodule is not a part of the diagnostic criteria of ACR TI-RADS, the system has made recommendations regarding biopsy and follow-up care based on the size of the nodules. In our study, the mean size was 2.2 cm with a standard deviation of 1.1 cm. However, the recommendations given by ACR TI-RADS were not practiced in our hospital setting. According to Hoang et al.,9 size of the nodule does not help predict or rule out malignancy.

Further studies may be required to explore the follow-up recommendations of ACR TI-RADS classification.

**ACR TI-RADS and FNAC**
On comparing ultrasound and FNAC, ACR TI-RADS had a better sensitivity, i.e., it can be used as a screening tool for all thyroid swellings to detect features of malignancy. However, specificity and positive predictive value for malignancy were less in ACR TI-RADS as compared to FNAC showing that on suspicion of malignancy in ultrasonography, further work-up should be done. The negative predictive value of ACR TI-RADS is also higher. Thus, ACR TI-RADS is a superior diagnostic tool in the evaluation of thyroid swellings. A study conducted by Tan et al. has also shown that ACR TI-RADS is a better diagnostic indicator and that, it may help to reduce unnecessary invasive procedures like FNAC.8

**Conclusion**
With our study, we have concluded that ACR TI-RADS adopted by ultrasonography is a reliable method to detect features of malignancy in thyroid swellings. Furthermore, ultrasound is a safe and quick procedure costing less than other invasive investigative procedures and could be incorporated into our clinical practice.

**Clinical Significance**
Early detection of thyroid malignancy is essential to prevent morbidity. Invasive investigations like FNAC and biopsy are routinely used to find the nature of thyroid swellings. However, they cause significant distress to the patient. On the other hand, ultrasonography is a simpler non-invasive technique that is being increasingly used for the same. American College of Radiology TI-RADS classification utilizing ultrasound has been shown to detect malignant thyroid swellings with good precision. Its applicability in the evaluation of thyroid swellings in the Indian population should be studied. Hence, we conducted a study to find the diagnostic accuracy of ACR TI-RADS classification.

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