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# Assessment of Thyroid Nodules using TIRADS Classification: Interobserver Agreement and Correlation with Histopathology

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## Abstract

Classification of thyroid nodules (TNs) based on TIRADS (Thyroid Imaging Reporting and Data System) category is important for predicting malignancy, avoiding unnecessary biopsy and aiding in the management of patients. A prospective nonintervention study was carried out in the period from February 2020 to February 2021 in King Fahad Specialist Hospital in Dammam (Saudi Arabia). The study included 222 patients with suspected TNs (TIRADS 3-5). The thyroid ultrasound scanning was performed with a high frequency linear array probe (9 MHz and 15 MHz). The thyroid gland and adjacent neck tissues were scanned. The diagnostic performance of the TIRADS classifications was evaluated against final histology. Three highly experienced sonographers independently rated the US features of each nodule. Each sonographer assigned points to each TN for the five separate categories (composition, echogenicity, shape, margin, and echogenic foci), according to the TIRADS protocols produced by ACR. Cohen's kappa scale was used to measure the interobserver agreement in categorizing TNs, and then the performance of ACR TIRADS categories for predicting malignancy was assessed using fine needle aspiration (FNA) as reference standard. For estimation of the diagnostic performance of ACR TIRADS to predict malignancy, the category for each TN was assigned by the principal investigator (Observer 1). This study included only TIRADS 3-5 (mildly to highly suspicious nodules: TR3-TR5), according to ACR TIRADS classification. The agreement for all sonographic features of TN among three observers (principal Observer 1 and two sub-investigators [Observer 2 and Observer 3]) was perfect, being 0.91-1.00 (Cohen's kappa). Out of 222 patients with TNs, the percentage of malignancy in 68 TIRADS-5 nodules was 91.2%, while in 154 TIRADS 3-4 nodules the percentage of malignancy was 29.9%. The study concluded that interobserver agreement in TIRADS classification and characterization of suspicious thyroid nodule was perfect.(**International Journal of Biomedicine. 2022;12(3):385-390.**)

**Keywords:** ACR TIRADS • thyroid nodule • histopathology • interobserver agreement

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## Abbreviations

**ACR**, American College of Radiology; **ATA**, American Thyroid Association; **ETE**, extrathyroidal extension; **EF**, echogenic foci; **FNA**, fine needle aspiration; **FNAB**, FNA biopsy; **Ob**, observer; **TIRADS**, Thyroid Imaging Reporting and Data System; **BI-RADS**, Breast Imaging Reporting and Data System; **TN**, thyroid nodule.

# Introduction

Thyroid nodules (TNs) are a common clinical problem with a prevalence of 19% to 68%,[1,2] and 7% to 15% of TNs are malignant, accounting for 96% of all endocrine cancers in 2014.[3,4] Currently, grayscale thyroid ultrasonography is widely used in the screening and differential diagnosis of TNs.

To standardize the reporting of results of thyroid ultrasound and stratify the risk of malignancy,[5] Horvath et al.[6] in 2009 developed the Thyroid Imaging Reporting and Data System (TIRADS), taking the Breast Imaging Reporting and Data System (BI-RADS)[7] as a model, and then TIRADS was modified by the American College of Radiology (ACR).[8]

BI-RADS classification was defined as follows[9]:

•BI-RADS 3 (probably benign): ≤ 2% malignancy risk
•BI-RADS 4A (low suspicion): >2% to ≤10% malignancy risk
•BI-RADS 4B (moderate suspicion):>10% to ≤50% malignancy risk
•BI-RADS 4C (high suspicion): >50% to <95% malignancy risk
•BI-RADS 5 (probably malignant): ≥ 95% malignancy risk

At the time of its release, there were already a variety of other ultrasound-based TN classification systems in existence.[8] One of the more popular classifications remains the 2015 ATA guidelines.[10] A key difference between the 2017 ACR TIRADS criteria[8] and the 2015 ATA criteria [10] is that the TIRADS criteria use morphologic features rather than a pattern-based, whole-nodule approach. This strategy is based on data showing that the 2015 ATA criteria can fail to classify a small proportion of nodules that have a high likelihood of being malignant.[11]

The initial purpose of TIRADS was to improve patient management and avoid unnecessary FNAB in patients with TNs; however, its clinical use is still limited, and its application in clinical practice is being questioned.[12]

The TNs that require US-guided FNAB were classified by ultrasound according to the internal component, echogenicity, margins, presence of calcifications, and shape at the time of FNAB. The internal component of the nodules was classified as solid or mixed. Echogenicity was classified as hyperechoic, isoechoic, hypoechoic, or marked hypoechoic. Margins were classified as well-circumscribed, micro-lobulated, or irregular. Calcifications, when present, were categorized as microcalcifications or macrocalcifications and shape either taller than wider or wider than taller.[13]

The validity and reliability of different TIRADS classifications systems in the assessment of TNs are evaluated in many studies; however, most of them are retrospective, and lacked a rigorous reference standard.

# Methodology

A prospective nonintervention study was carried out in the period from February 2020 to February 2021 in King Fahad Specialist Hospital in Dammam (Saudi Arabia). The study included 222 patients with suspected TNs (TIRADS 3-5). The diagnostic performance of the TIRADS classifications was evaluated against final histology. Three highly experienced sonographers independently rated the US features of each nodule. Cohen's kappa scale was used to measure the interobserver agreement

In our study, GE LOGIQ E10, GE LOGIQ E9, and GE LOGIQ S8 &TOSHIBA 1700 ultrasound machines with high frequency probe were used for data collection.

The final diagnosis of TNs was based on FNA results as a standard for assessing the diagnostic performance of TIRADS for the classification of TNs and predicting malignancy.

This study was approved by the Ethics Committee of the Research Centre (King Khalid Medical City-RC-KKMC) at King Fahad Specialist Hospital in Dammam (Saudi Arabia). A verbal consent from all patients was taken after describing the purpose and nature of the study.

# Technique

The thyroid ultrasound scanning was performed with a high frequency linear array probe (9 MHz and 15 MHz). The thyroid gland and adjacent neck tissues were scanned with patients lying supine, neck extended, each lobe of the thyroid gland scanned in transverse and longitudinal planes. Three highly experienced sonographers independently rated the following US features of each nodule: nodule position (left lobe, right lobe, or isthmus); the maximum diameter; composition (solid, cystic, mixed); echogenicity (hyperechoic, isoechoic, hypoechoic—all with respect to the surrounding thyroid parenchyma—or markedly hypoechoic, i.e., less echoic than the adjacent strap muscle), shape (taller than wider or wider than taller), margins (well-defined, ill-defined, microlobulated or irregular, infiltrative, peripheral halo, lobulated or smooth), presence or absence of other echogenic foci and suspicious neck lymph nodes. Each sonographer assigned points to each TN for the five separate categories (composition, echogenicity, shape, margin, and echogenic foci), according to the TIRADS protocols produced by ACR. For estimation of the diagnostic performance of ACR TIRADS to predict malignancy, the category for each TN was assigned by the principal investigator (Ob1). This study included only TIRADS 3-5 (mildly to highly suspicious nodules: TR3-TR5), according to ACR TIRADS classification. Each TN was characterized by three sonographers with high experience in performing ultrasound (Ob1 and two sub-investigators [Ob2 and Ob3]).

Statistical analysis was performed using statistical software package SPSS version 25.0 (Armonk, NY: IBM Corp.).

# Results

The study revealed that females were affected by TNs more frequently than males (76.6% and 23.4%). Concerning TN echogenicity, Ob1 stated that 55.4% of TNs were hypoechoic, 37.4% - isoechoic, 5% - hyperechoic, and only 2.3% of TNs were markedly hypoechoic. Ob2/Ob3 stated that 54.5%/55% of TNs were hypoechoic, 38.3%/37.8% - isoechoic, 5%/5% - hyperechoic, and only 2.3%/2.3% of TNs - markedly hypoechoic (Table 1).

***Table 1.***

***Characterization of TNs based on echogenicity, composition, shape, margin, and echogenic foci by three investigators, according to the TIRADS protocols produced by ACR and interobserver agreement for each category using kappa scale***

| Categories of thyroid nodules | | | |
|---|---|---|---|
| **Echogenicity** | Observer 1 | Observer 2 | Observer 3 |
| Hypoechoic | 123 (55.4%) | 121 (54.5%) | 122 (55%) |
| Hyperechoic | 11 (5%) | 11 (5%) | 11 (5%) |
| Isoechoic | 83 (37.4%) | 85 (38.3%) | 84 (37.8%) |
| Markedly hypoechoic | 5 (2.3%) | 5 (2.3%) | 5 (2.3%) |
| Total | 222 | 222 | 222 |
| Measure of agreement (kappa) | 0.967 Ob1/Ob2 | 0.992 Ob1/Ob3 | 0.976 Ob2/Ob3 |
| **Composition** | Observer 1 | Observer 2 | Observer 3 |
| Mixed | 17 (7.7%) | 17 (7.7%) | 17 (7.7%) |
| Solid | 205 (92.3%) | 205 (92.3%) | 205 (92.3%) |
| Total | 222 | 222 | 222 |
| Measure of agreement (kappa) | 1.00 Ob1/Ob2 | 1.00 Ob1/Ob3 | 1.00 Ob2/Ob3 |
| **Shape** | Observer 1 | Observer 2 | Observer 3 |
| Taller than wider | 11 (5%) | 11 (5%) | 11 (5%) |
| Wider than taller | 211 (95%) | 211 (95%) | 211 (95%) |
| Total | 222 | 222 | 222 |
| Measure of agreement (kappa) | 1.00 Ob1/Ob2 | 1.00 Ob1/Ob3 | 1.00 Ob2/Ob3 |
| **Margin** | Observer 1 | Observer 2 | Observer 3 |
| ETE | 1 (0.5%) | 1 (0.5%) | 1 (0.5%) |
| Lobulated | 12 (5.4%) | 11 (5%) | 12 (5.4%) |
| Smooth | 209 (94.1) | 210 (94.5%) | 209 (94.1) |
| Total | 222 | 222 | 222 |
| Measure of agreement (kappa) | 0.958 Ob1/Ob2 | 0.919 Ob1/Ob3 | 0.958 Ob2/Ob3 |
| **Echogenic foci** | Observer 1 | Observer 2 | Observer 3 |
| Macrocalcification | 21 (9.5%) | 22 (9.9%) | 21 (9.5%) |
| Microcalcification | 77 (34.7%) | 75 (33.8%) | 76 (34.2%) |
| None | 114 (51.4%) | 115 (51.8%) | 115 (51.8%) |
| Peripheral calcification | 10 (4.5%) | 10 (4.5%) | 10 (4.5%) |
| Total | 222 | 222 | 222 |
| Measure of agreement (kappa) | 0.985 Ob1/Ob2 | 0.993 Ob1/Ob3 | 0.978 Ob2/Ob3 |

A strong agreement was found between the three observers in TN echogenicity as kappa values for interobserver variability were 0.967 for Ob1-Ob2, 0.992 for Ob1-Ob3, and 0.976 for Ob2-Ob3.

For nodule composition, the three observers had the same results as all of them stated that about 92.3% of TNs were solid and only 7.7% were mixed. The kappa value for the measure of agreement was 1.00.

For the TN shape, the three observers had the same results, as all of them stated that about 95% of TNs were wider than taller and only 5% were taller than wider; the kappa value for the measure of agreement was 1.00.

When evaluating the nodule margin, Ob1 stated that 94.1% were smooth, 5.4% - lobulated, and only 0.5% had ETE. Ob2/Ob3 stated that 94.5%/94.1% of TNs were smooth, 5%/5.4% - lobulated, and only 0.5%/0.5% of TNs had ETE. Thus, a strong increment of the agreement was found among the three observers: the kappa values for interobserver variability were 0.958 for Ob1-Ob2, 0.919 for Ob1-Ob3, and 0.958 for Ob2-Ob3.

For the presence of EF within the nodules, Ob1 stated that EF was not found in 51.4% of cases, microcalcification - 34.7%, macrocalcification - 9.5%, and peripheral calcification - 4.5%. Ob2/Ob3 stated that EF was not found in 51.8%/51.8% of cases, microcalcification - 33.8%/34.2%, macrocalcification - 9.9%/9.5%, and peripheral calcification - 4.5%/4.5%. Thus, a strong increment of the agreement was found between the three observers: the kappa values for interobserver variability were 0.985 for Ob1-Ob2, 0.933 for Ob1-Ob3, and 0.978 for Ob2-Ob3.

The TIRADS category was specified for each nodule by the sum of points for the five categories (Table 2). Ob1 determined that about 41% of TNs were moderately suspicious (TIRADS-4), 30.6% were highly suspicious (TIRADS-5), and 28.4% were mildly suspicious nodules (TIRADS-3). Ob2/Ob3 concluded that about 43.2%/42.3% of TNs were TIRADS-4, 28.8%/29.7% were TIRADS-5, and 27.9%/27.9% were TIRADS-3.

***Table 2.***

***Frequency distribution of classification of TN based on TIRADS by three observers***

| TIRADs level | Observer 1 | Observer 2 | Observer 3 |
|---|---|---|---|
| Mildly Suspicious Nodule | 63 (28.4%) | 62 (27.9%) | 62 (27.9%) |
| Moderately Suspicious Nodule | 91 (41%) | 96 (43.2%) | 94 (42.3%) |
| Highly Suspicious Nodule | 68 (30.6%) | 64 (28.8) | 66 (29.7%) |
| Total | 222 | 222 | 222 |
| Measure of agreement (kappa) | 0.966 Ob1/Ob2 | 0.979 Ob1/Ob3 | 0.959 Ob2/Ob3 |

Thus, a strong agreement in ACR TIRADS categories was found between the three observers as kappa values for interobserver variability were 0.966 for Ob1-Ob2, 0.979 for Ob1-Ob3, and 0.959 for Ob2-Ob3 (Table 2, Fig.1).

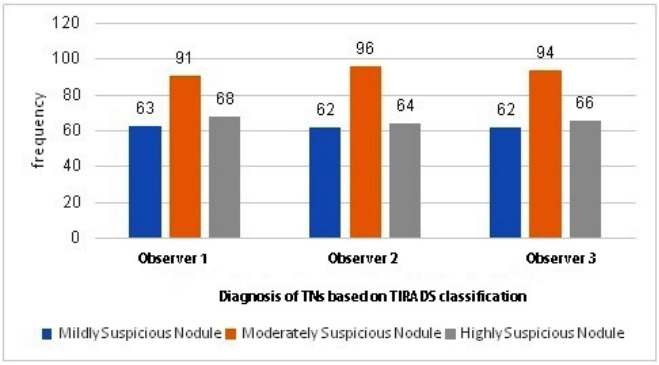



***Fig. 1.*** *Frequency distribution of diagnosed TN based on TIRADS by three observers.*

The performance of ACR TIRADS in classifying TN and assessing the malignancy risk was determined by Ob1, according to the FNA results. Out of 222 patients with TNs, the percentage of malignancy in 68 TIRADS-5 (high suspicion) nodules was 91.2%, while in 154 TIRADS 3-4 (low to moderate suspicion) nodules, the percentage of malignancy was 29.9% (Table 3).

***Table 3.***

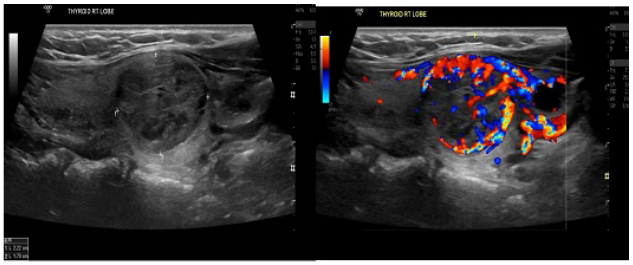
***The performance of ACR TIRADS in classifying TN and assessing the malignancy risk by Ob1, according to the FNA results***

| | | | FNA result | | Total |
|---|---|---|---|---|---|
| | | | Benign | Malig-nant | |
| TIRADS level | Mildly to Moderately Suspicious Nodule | Count | 108 | 46 | 154 |
| | | Within TIRADS level,% | 70.1 | 29.9 | 100.0 |
| | | Within FNA results,% | 94.7 | 42.6 | 69.4 |
| | | Total,% | 48.6 | 20.7 | 69.4 |
| | High Suspicious Nodule | Count | 6 | 62 | 68 |
| | | Within TIRADS level,% | 8.8 | 91.2 | 100.0 |
| | | Within FNA results,% | 5.3 | 57.4 | 30.6 |
| | | Total,% | 2.7 | 27.9 | 30.6 |
| Total | | Count | 114 | 108 | 222 |
| | | Within TIRADS level,% | 51.4 | 48.6 | 100.0 |
| | | Within FNA results,% | 100.0 | 100.0 | 100.0 |
| | | Total,% | 51.4 | 48.6 | 100.0 |

Figures 2-5 present the features of the diagnosed TNs based on ACR TIRADS and FNA results.

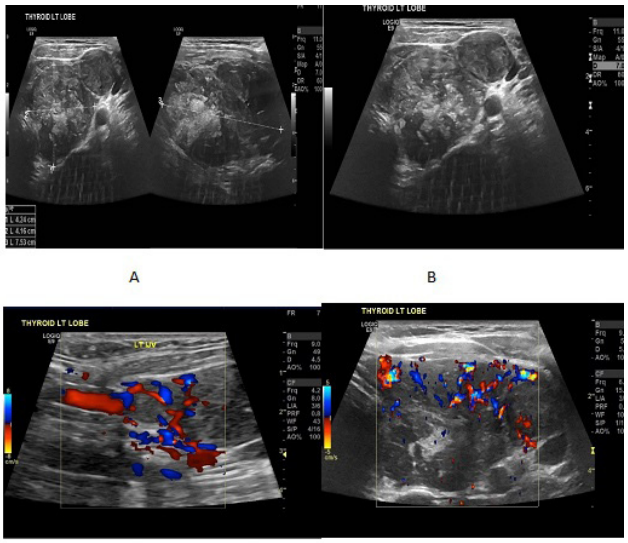
## Discussion

Our study clarified that about 48.6% of TNs were malignant on histopathology results, and 51.4% were benign. According to García-Moncó Fernández et al.,[14] 28.5% of TNs were malignant and 71.5% were benign.



A B

***Fig. 2.*** *(A and B). TN: solid, hypoechoic, wider than taller, smooth margin, no calcification, TIRADS-4, FNA – benign.*

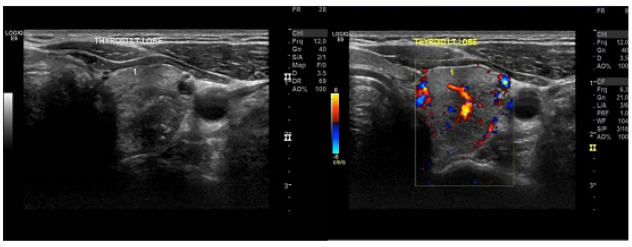



A B

C D

***Fig. 3.*** *(A, B, C, D) Gray scale and Doppler. Solid, hypoechoic, smooth margin, taller than wider, IJV invasion with tumor thrombus, TIRADS-5, FNA – malignancy.*


A



B C

***Fig. 4.*** *(A, B, C). TN: solid, hypoechoic, wider than taller with microcalcification, Doppler score- 4, TIRADS-5, FNA-malignancy.*

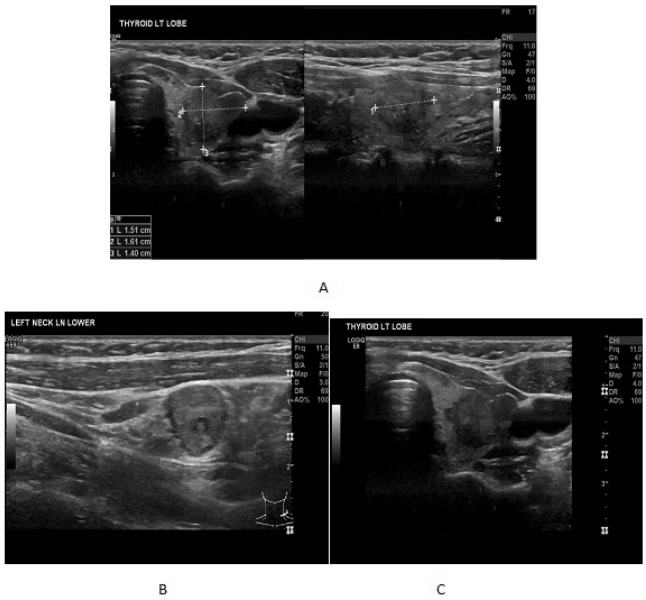



***Fig. 5.*** *(A,C) TN: solid, hypoechoic, wider than taller, microcalcification; B – an associated LN, TIRADS 5, FNA – malignancy.*

The TIRADS classification used in this study was primarily defined and evaluated by E. Horvath et al.,[6] who prospectively correlated the FNAB results of 500 nodules with the defined US patterns and generated a TIRADS group classification (TIRADS 1–6 for general thyroid pathology and TIRADS 2–6 for nodules).

Our study included 222 patients with suspicious nodules, TIRADS 3-5. In a study by E. Horvath,[6] TIRADS 2-5 were based on different B-mode and Duplex US criteria. In this study with 1097 nodules, 100% of patients with TNs scored as TIRADS 2 had benign nodules, while 86.5% of nodules scored TIRADS 5 were malignant. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were 88, 49, 49, 88, and 94%, respectively.

In our study, with the use of five ACR TIRADS categories, strong agreements between the three observers were found. Our results differed from those of A. Chandramohan et al.,[15] who also evaluated interobserver agreement for reproducibility of ultrasound features of TNs. Thus, in a general agreement between observers 1 and 2 who prospectively assessed the thyroid nodules was better than between observers 3 and 1 and observers 3 and 2. Agreement was good between observers for assessment of calcification (k=0.577); fair for composition (k=0.425), shape (k=0.436) and margins (k=0.412) of the thyroid nodules. The agreement was poor for echogenicity (k=0.299) of thyroid nodules. Overall agreement was good between observers (k=0.569) for assigning the TIRADS category to the thyroid nodules. However, inter-observer agreement for each category of TIRADS was variable with good agreement for combined TIRADS category 4c and 5 (k=0.685, $P$<0.001); poor for TIRADS category 4a (k=0.201, $P$<0.001) and 4b (k=0.164, $P$<0.001) categories and fair for the rest.

The differences in the agreements may be explained by the fact that the study by A. Chandramohan et al.[15] included all TIRADS categories and even TIRAD 4 classified to a-b and c.

In our study, out of 222 patients with TNs, in 68 TIRADS-5 nodules, the percentage of malignancy in FNA results was 91.2%, while in 154 TIRADS 3-4 nodules the percentage of benign lesions was 70.1%. These results are consistent with Horvath et al.,[6] who found the following percentages of malignancy: TIRADS 2 (0% malignancy), TIRADS 3 (<5% malignancy), TIRADS 4 (5%–80% malignancy), and TIRADS 5 (>80% malignancy). In contrast, in a study by Friedrich-Rust et al.,[12] only 28%–42% of TIRADS-5 were diagnosed as malignant.

Our results on the TIRADS-5 category with 91.2% of malignancy were also similar to A. Chandramohan et al.[15] (91%) and Kwak et al.[13] (87.5%). The other two studies compared histology and FNAB result and the TIRADS category and found that in TIRADS ≥4 the percentage of malignancy was 86% and 77%, respectively.[14,16]

## Conclusion

We found that there was a perfect interobserver agreement for assigning ultrasound features of thyroid nodules and for determining TIRADS category for each thyroid nodule. The percentages of malignancy were as follows: TIRADS-5 (91.2% malignancy) and TIRADS 3-4 (29.9% malignancy).

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## Competing Interests

The authors declare that they have no competing interests.

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