Thyroid nodules: diagnostic performance of ATA and ACR tirads on risk for malignancy

Nódulos de tireoide: desempenho diagnóstico de ATA e tirads ACR para risco de malignidade

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ABSTRACT
Aim: we aimed to compare the American Thyroid Association (ATA) and The American College of Radiology Thyroid Imaging Reporting and Data System (ACR TIRADS) guidelines that stratify the risk of nodule malignancy and compare with cytological classification. Then, the diagnostic performance of the ATA and ACR TIRADS categories for predicting malignancy were performed. Methods: a total of 190 thyroid nodules image obtained from 120 individuals were classified in accordance with ACR TIRADS and ATA guidelines. After classified, all nodules
were categorized by using cytological classification (2017 Bethesda System).

Results: comparing diagnostic accuracy of each ultrasound classification, both of them revealed the same sensitivity and negative predictive value but ACR TIRADS reached higher positive predictive value. A high positive correlation between the two methods were found (r=0.860, p <0.0001). The ATA and ACR TIRADS classifications were correlated with the cytological analysis, but the correlation was weak. Conclusions: Both guidelines have similar accuracy in the ultrasound evaluation of thyroid nodules but have shown an overestimation of the presence of malignant thyroid neoplasms.

Keywords: thyroid, malignancy risk, ata, tirads, bethesda system, diagnostic accuracy.

RESUMO

Objetivo: o nosso objectivo era comparar as directrizes da American Thyroid Association (ATA) e do The American College of Radiology Thyroid Imaging Reporting and Data System (ACR TIRADS) que estratificam o risco de malignidade dos nódulos e comparam com a classificação citológica. Em seguida, foi realizado o desempenho diagnóstico das categorias ATA e ACR TIRADS para prever a malignidade. Métodos: um total de 190 imagens de nódulos da tiroíde obtidas de 120 indivíduos foram classificadas de acordo com as directrizes ACR TIRADS e ATA. Depois de classificados, todos os nódulos foram categorizados utilizando a classificação citológica (Sistema Bethesda 2017).Resultados: comparando a precisão diagnóstica de cada classificação ultra-sônica, ambos revelaram a mesma sensibilidade e valor preditivo negativo, mas o ACR TIRADS atingiu um valor preditivo positivo mais elevado. Foi encontrada uma correlação positiva elevada entre os dois métodos (r=0,860, p <0,0001). As classificações ATA e ACR TIRADS foram correlacionadas com a análise citológica, mas a correlação foi fraca.Conclusões: Ambas as directrizes têm uma precisão semelhante na avaliação ultra-sónica dos nódulos da tiroíde, mas mostraram uma sobrestimação da presença de neoplasias malignas da tiroíde.

Palavras-chave: tiroíde, risco de malignidade, ata, tirads, bethesda system, precisão diagnóstica.

1 INTRODUCTION

Thyroid nodules are a common neck condition, with a prevalence in ultrasound (US) exams ranging from 19% to 68% of the population \(^1\). US is the preferred screening method and enables determining whether these nodules are associated with malignancy \(^2\). However, US imaging and diagnosis depend on the expertise of the operator and are prone to substantial interobserver variation. Thyroid nodule grading systems have been developed to minimize the influence of the background and experience of the professionals who perform US thyroid scans. Such guidelines help determine whether a nodule needs to be scheduled
for fine needle aspiration (FNA) biopsy \(^3, 4\). The American Thyroid Association (ATA) developed guidelines to stratify risk from a very low to high suspicion of malignancy; the most current version of these guidelines was issued in 2015 \(^5\). The American College of Radiology (ACR) recently published the latest version of its Thyroid Imaging Reporting and Data System (TIRADS), which suggests that nodules be stratified according to ultrasonographic features and the risk of malignancy \(^6, 7\). The ACR committee decided against the pattern-based approach used by the ATA because the ATA guidelines were unable to classify 3.4% of 1,293 nodules, among which 18.2% were malignant \(^8\).

Studies have compared different guidelines for evaluating thyroid nodules, but comparisons of the ACR TIRADS and ATA guidelines are scarce. Gao et al. (2019) reports that the ACR TIRADS and ATA guidelines perform better at differentiating nodules >1 cm. The ATA guidelines provide better diagnostic efficiency than ACR TIRADS. Therefore, the ATA guidelines yield higher sensitivity, whereas ACR TIRADS has higher specificity \(^9\). Although the ATA guidelines are more popular, the TIRADS is more often adopted for clinical practice due to the fact that it is a simple, practical method with a good level of inter-observer agreement \(^10\). Considering this context, the aim of the present study was to compare the performance of these two US classification systems (ATA and ACR TIRADS) to the results of the cytological examination.

**2 MATERIAL AND METHODS**

A sample of 190 consecutive thyroid nodule images from 120 individuals were retrieved from the files of the Radiology Service of the authors’ Institutions between February 2017 and December 2018. All samples fulfilled the criteria of presence of thyroid nodules that required US with FNA biopsy to elucidate the diagnosis. The study was approved by the Ethics Committee of the authors’ Institutions, written informed consent was obtained from all patients.

The images were classified in accordance with ACR TIRADS and ATA guidelines by two blinded experienced radiologists. Based on the US classification proposed by the ATA guidelines, the thyroid nodules were categorized into the following degrees of suspicion: high suspicion, intermediate suspicion, low suspicion, very low suspicion and benign \(^5\). About ACR TIRADS guidelines, the nodules were classified as the recommendation based on the risk-stratification
system of suspicious or benign/not suspicious nodules. It is based on five categories of US findings (composition, echogenicity, shape, margin and echogenic foci), with a higher cumulative score indicative of a greater likelihood of malignancy. Thus, the nodules were classified as ACR TIRADS 1 (0 points, benign), ACR TIRADS 2 (2 points, not suspicious), ACR TIRADS 3 (3 points, mildly suspicious), ACR TIRADS 4 (4-6 points, moderately suspicious) and ACR TIRADS 5 (≥7 points, highly suspicious) (7). In cases of a disagreement regarding the ATA or ACR TIRADS classification, the analysis proceeded until consensus was reached.

The cytological classification was based on the findings of the microscopic examination after FNA biopsy which the material was analyzed by an experienced pathologist that is blinded about imaging and clinical features. Each nodule was categorized using the 2017 Bethesda System for Reporting Thyroid Cytopathology (11). The nodules were qualified as (1) nondiagnostic or unsatisfactory, (2) benign, (3) atypia of undetermined significance or follicular lesion of undetermined significance, (4) follicular neoplasm or suspicious for a follicular neoplasm, (5) suspicious for malignancy, and (6) malignant (11). Depending on the Bethesda category which suggests different clinical management, cases with Bethesda IV, V and VI were confirmed by histopathological analyses after excision.

2.1 STATISTICAL ANALYSIS

We assembled a database using the Statistical Package for Social Sciences (SPSS) version 21.0. Kappa coefficients were calculated to measure inter-observer agreement regarding the ATA and ACR TIRADS classifications. Descriptive statistical analysis was applied to the variables to calculate proportions, measures of central tendency and variability for the sociodemographic and clinical characteristics as well as the ATA and ACR TIRADS variables. The Kolmogorov-Smirnov test was used to evaluate the normality of the data. The chi-square test, Kruskal-Wallis test and Mann-Whitney U-Test were used to compare the sociodemographic and clinical characteristics of the individuals, when appropriate, with the statistical significance level set at 5% (p < 0.05). The diagnostic performance of the ATA and ACR TIRADS categories for predicting malignancy was dichotomized as positive and negative for malignant nodules. Sensitivity, specificity, positive predictive value (PPV)/malignancy rate and
negative predictive value (NPV) were calculated. The statistical models for the evaluation of the diagnostic performance were performed as described by Collins and Huynh (2014) (12). Spearman’s correlation coefficients were calculated for the variables of the scales.

3 RESULTS

Most individuals evaluated were female (86.8%) with the mean age 53.07 ± 1.95 years. The nodules affected predominantly the left lobe of the thyroid (49.5%), presenting as multiple nodules (57.0%). Mean diameter was 17.87 ± 0.80 mm. The clinical characteristics of the nodules are available in Table 1. When evaluating cytopathological exams 6.7% were classified with Bethesda categories 1, 84.8% Bethesda 2, 6.3% Bethesda category 3 and 2.2% Bethesda category 6. No patient was classified as Bethesda category 4 or 5. The most frequent ATA and ACR TIRADS were ACR TIRADS 4 (44.3%), the ATA low suspicion category (37.1%) (Table 2). All malignant nodules were classified as ACR TIRADS 5 and ATA high suspicion, with a malignancy rate of 16.0% for ACR TIRADS 5 and 6.6% for ATA high suspicion (Tables 3 and 4). All malignant lesions were classified as papillary thyroid carcinoma. The US exams illustrated a representative image of each ATA and ACR TIRADS category (Figure 1 and Figure 2, respectively).

Comparing diagnostic accuracy, the two image classification systems had the same sensitivity and negative predictive value (NPV), but ACR TIRADS achieved higher specificity and positive predictive value (PPV) than the ATA system (Table 3). A strong positive correlation was found between the ATA and TIRADS classification systems (r = 0.860, p <0.0001, Spearman’s correlation test). The ATA and ACR TIRADS classifications were statistically correlated with the cytopathological analysis, but the correlation was weak (ACR TIRADS: r = 0.179, p = 0.023; ATA: r = 0.170, p = 0.031).

Inter-observer agreement was strong for the both image categories (Kappa = 0.839 for ACR TIRADS and 0.807 for ATA).

4 DISCUSSION

Many previous studies have compared different thyroid classification guidelines. This is the first study to compare US image classification systems (ATA and ACR TIRADS) to the cytological examination (Bethesda System).
Both image classification systems (ATA and ACR TIRADS) had the same sensibility and NPV, but the ACR TIRADS had higher sensibility and PPV than the ATA system. These results agree with data reported by Gao et al. (2019), who found that ACR TIRADS had a higher specificity but contradictory findings compared to the ATA guidelines, which yielded higher sensitivity (9). The present study showed a lack of statistically significant differences in the diagnostic performance of the two guidelines. However, a recent study found that the ACR TIRADS classification system had a larger area under the receiver operating characteristic curve for the identification of cytologically high-risk nodules, whereas the ATA classification leaves nodules at relatively high risk of malignancy ‘unclassified’ (13).

Test validity regards the extent to which it is useful in quantitative or qualitative terms for diagnosing (concurrent or concurrent validity) or predicting (predictive validity) an event. An ideal diagnostic test should always provide the proper answer, that is a positive result in individuals with disease and a negative result in individuals without disease (12). In the present study, both guidelines exhibited the same capacity for diagnostic performance. In agreement with this finding, a previous study showed that the ATA system and previous version of TIRADS achieved the same sensitivity for the diagnosis of malignant thyroid lesions (14). However, it has been demonstrated that the ACR TIRADS system classifies a greater percentage of malignant nodules than the ATA system (7).

During the analyses, some US images were classified as ATA high suspicion and ACR TIRADS 5, but only four cases obtained a cytological confirmation of malignant nodules. This reveals that the both classification systems overestimate the presence of malignant lesions. This could explain the weak correlations between the two classification systems and the Bethesda categories. The rate of malignancy found in another study for nodules >1 cm with indeterminate cytology was higher than that expected originally by the Bethesda System (15). However, this cytology classification system was able to diagnose all malignant lesions. This study not found suspicious specimens (Bethesda IV or V category). Therefore, considering the rarity of these specimens, these could occur (16).

Thyroid nodules are common, and the reported prevalence of nodular thyroid disease depends largely on the identification method. Therefore, the
increasing use of sensitive imaging techniques leads to an increased detection of thyroid nodules \(^{(17)}\). These nodules are more frequent in women, as reported in our study, and the frequency increases with age \(^{(18)}\). Age, nodule size and clinical presentation are not related to malignancy. There is a tendency toward statistical significance with regards to the anatomical site, but this tendency has no clinical significance. It is important to note that in our service, the malignancy rates of thyroid nodules based on cytological patterns associated with ATA and ACR TIRADS were lower than expected \(^{(19)}\). Even at lower malignancy rates, it should be considered the fact of US and cytological examination were performed by an experienced radiologists and pathologists and inter-observer agreement is strong for ATA risk stratification and TIRADS criteria.

Although no statistically significant difference was found between the two US classification systems, each system uses different parameters for classifying nodules. Each of the five ATA risk classes is defined by a specific set of features, which include the presence and intranodular location of a solid component, echogenicity, margins, calcifications, shape and extra-thyroidal extension \(^{(5)}\). ACR TIRADS assesses the presence of five equally-weighted nodule features (solid component, hypoechogenicity or marked hypoechogenicity, microlobulated or irregular margins, microcalcifications or mixed calcifications and taller-than-wide shape) and assigns the nodule to one of five categories based on the number of suspicious features it displays \(^{(6, 7)}\). However, if these two classifications are associated with other parameters, as pattern of vascularity, the occurrence of false positives may be reduced.

This study has the advantages and limitations associated with the cross-sectional design. Some limitations should be considered when interpreting the results, such as the fact that it is a retrospective study and included some images and characteristics that were not possible classify in accordance with the ATA or ACR TIRADS guidelines. The number of individuals participating in the study may be a limiting factor. However, the analysis of the accuracy of the two ultrasound diagnostic methods associated with cytopathological data provides important data for the clinical approach of patients with thyroid lesions. In summary, the ACR TIRADS and ATA guidelines had similar accuracy in the US evaluation of thyroid nodules but overestimated the occurrence of malignant thyroid neoplasms in the present study. In the clinical practice, therefore, the choice of the thyroid
classification method should be based on the ability of each professional in evaluating parameters for the classification of nodules.

CONFLICT OF INTEREST
We declare that we have no conflict of interest.

ETHICAL APPROVAL
The study had been approved by the local ethical committee and follows local and international laws and guidelines.

INFORMED CONSENT
Informed consent is obtained from all individual participants included in the study.
REFERENCES


5. Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: the American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid 2016;26:1-133.


Fig. 1 Representative images of ATA categories. (a) Example of high suspicion: solid nodule in superior third of right lobe, markedly hypoechoic exhibiting irregular outlines with macrocalcifications. (b) Example of intermediate suspicion: hypoechogenic solid nodule in superior third of right lobe exhibiting regular outlines without calcifications. (c) Example of low suspicion category: mixed echoic nodule in middle third of right lobe, predominantly solid exhibiting isoechochogenicity in relation to cystic component (less than 50%) with regular outlines without calcifications. (d) Example of very low suspicion category: mixed nodule in middle third of right lobe, predominantly anechoic with solid component less than 50% exhibiting regular outlines without calcifications. (e) Example of benign category: colloid nodule in inferior third of right lobe, anechoic with a little echoic focus exhibiting regular outlines without calcifications.

Fig. 2 Representative images of ACR TIRADS categories. (a) Example of ACR TIRADS 1: cystic anechoic nodule with fine echogenic septa in peripheral area exhibiting regular outlines without calcifications. (b) Example of ACR TIRADS 2: solid nodule with predominantly isoechochogenicity in relation to the parenchyma, with hypoechoic halo, exhibiting regular outlines without calcifications. (c) Example of ACR TIRADS 3: solid nodule, hyperechogenic regular outlines without calcifications. (d) Example of ACR TIRADS 4: solid nodule, hyperechogenic, with exophytic aspect exhibiting regular outlines without calcifications. (e) Example of ACR TIRADS 5: solid hypoechoic nodule exhibiting irregular outlines with calcifications in peripheral area.
### Table 1. Clinical characteristics of 190 samples.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Benign No. of samples=175 (%)</th>
<th>Malignant No. of samples=4 (%)</th>
<th>Undetermined*** No. of samples=11 (%)</th>
<th>Total No. of samples=190 (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>24 (13.7%)</td>
<td>0 (0.0%)</td>
<td>1 (9.1%)</td>
<td>25 (13.2%)</td>
<td>0.36</td>
</tr>
<tr>
<td>Female</td>
<td>151 (86.3%)</td>
<td>4 (100.0%)</td>
<td>10 (90.9%)</td>
<td>165 (86.8%)</td>
<td></td>
</tr>
<tr>
<td>Age (y.o.)</td>
<td>54.55±0.45</td>
<td>46.00±7.50</td>
<td>50.5±22.33</td>
<td>53.07±1.95</td>
<td>0.59</td>
</tr>
<tr>
<td>Nodule size (mm)</td>
<td>16.67±9.31</td>
<td>28.75±8.14</td>
<td>25.86±14.2</td>
<td>17.87±0.80</td>
<td>0.07</td>
</tr>
<tr>
<td>Clinical presentation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solitary nodule</td>
<td>76 (43.4%)</td>
<td>1 (25.0%)</td>
<td>3 (27.3%)</td>
<td>80 (43.0%)</td>
<td>0.68</td>
</tr>
<tr>
<td>Multiple nodules</td>
<td>99 (56.6%)</td>
<td>3 (75.0%)</td>
<td>8 (72.7%)</td>
<td>110 (57.0%)</td>
<td></td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left lobe</td>
<td>90 (51.4%)</td>
<td>0 (0.0%)</td>
<td>4 (36.4%)</td>
<td>94 (49.5%)</td>
<td></td>
</tr>
<tr>
<td>Right lobe</td>
<td>68 (38.8%)</td>
<td>4 (100.0%)</td>
<td>7 (63.6%)</td>
<td>79 (41.6%)</td>
<td></td>
</tr>
<tr>
<td>Isthmus</td>
<td>17 (9.8%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>17 (8.9%)</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-square test (benign x malignant x undetermined), ** Kruskal-Wallis test (benign x malignant x undetermined), *** Bethesda category 3.

### Table 2. Distribution of thyroid nodules in accordance with Bethesda categories.

<table>
<thead>
<tr>
<th>Bethesda Category</th>
<th>No. of samples=178 (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bethesda 1</td>
<td>12 (6.7%)</td>
<td></td>
</tr>
<tr>
<td>Bethesda 2</td>
<td>151 (84.8%)</td>
<td></td>
</tr>
<tr>
<td>Bethesda 3</td>
<td>11 (6.3%)</td>
<td></td>
</tr>
<tr>
<td>Bethesda 4</td>
<td>0 (0.0%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Bethesda 5</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Bethesda 6</td>
<td>4 (2.2%)</td>
<td></td>
</tr>
</tbody>
</table>

*Chi-square test.

### Table 3. Distribution of benign and malignant nodules in accordance with TIRADS categories.

<table>
<thead>
<tr>
<th>ACR TIRADS Category</th>
<th>No. of samples=176 (%)</th>
<th>Benign No. of samples=162 (%)</th>
<th>Malignant No. of samples=4 (%)</th>
<th>Undetermined No. of samples=10 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR TIRADS 1</td>
<td>4 (2.3%)</td>
<td>4 (2.5%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>ACR TIRADS 2</td>
<td>15 (8.5%)</td>
<td>15 (9.3%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>ACR TIRADS 3</td>
<td>54 (30.7%)</td>
<td>49 (30.2%)</td>
<td>0 (0.0%)</td>
<td>5 (50.0%)</td>
</tr>
<tr>
<td>ACR TIRADS 4</td>
<td>78 (44.3%)</td>
<td>76 (46.9%)</td>
<td>0 (0.0%)</td>
<td>2 (20.0%)</td>
</tr>
<tr>
<td>ACR TIRADS 5</td>
<td>25 (14.2%)</td>
<td>18 (11.1%)</td>
<td>4 (100.0%)</td>
<td>3 (30.0%)</td>
</tr>
</tbody>
</table>

### Table 4. Distribution of benign and malignant nodules in accordance with ATA categories.

<table>
<thead>
<tr>
<th>ATA Category</th>
<th>No. of samples=178 (%)</th>
<th>Benign No. of samples=165 (%)</th>
<th>Malignant No. of samples=4 (%)</th>
<th>Undetermined No. of samples=9 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High suspicion</td>
<td>61 (34.3%)</td>
<td>57 (34.6%)</td>
<td>4 (100.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Intermediate suspicion</td>
<td>43 (24.2%)</td>
<td>39 (23.6%)</td>
<td>0 (0.0%)</td>
<td>4 (44.5%)</td>
</tr>
<tr>
<td>Low suspicion</td>
<td>66 (37.1%)</td>
<td>63 (38.2%)</td>
<td>0 (0.0%)</td>
<td>3 (33.3%)</td>
</tr>
<tr>
<td>Very low suspicion</td>
<td>5 (2.8%)</td>
<td>3 (1.8%)</td>
<td>0 (0.0%)</td>
<td>2 (22.2%)</td>
</tr>
<tr>
<td>Benign</td>
<td>3 (1.7%)</td>
<td>3 (1.8%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>
Table 5. Comparison of the diagnostic precision of ATA and TIRADS.

<table>
<thead>
<tr>
<th>Imaging method</th>
<th>Cytological analyzes</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>Accuracy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Malignant No. of samples</td>
<td></td>
<td>Benign No. of samples</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACR TIRADS (5 category)</td>
<td>+ 4</td>
<td>100.0%</td>
<td>88.8%</td>
<td>18.2%</td>
<td>100.0%</td>
<td>89.1%</td>
</tr>
<tr>
<td>ACR TIRADS (1 to 4 categories)</td>
<td>- 0</td>
<td>100.0%</td>
<td>66.3%</td>
<td>6.5%</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td>ATA (High suspicion category)</td>
<td>+ 4</td>
<td>100.0%</td>
<td>65.5%</td>
<td>6.5%</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td>ATA (Intermediate suspicion to benign categories)</td>
<td>- 0</td>
<td>100.0%</td>
<td>66.3%</td>
<td>6.5%</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>

* Mann–Whitney U-test. P=0.69