








American Thyroid Association and Thyroid Imaging Reporting and Data System developed by the American College of Radiology: which one is better at predicting malignancy risk?

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SUMMARY

OBJECTIVE: The aim of this study was to compare the capacity of American Thyroid Association and Thyroid Imaging Reporting and Data System developed by the American College of Radiology in predicting malignancy risk of thyroid nodules and to verify which one is better at avoiding unnecessary fine needle aspiration.

METHODS: This was a cross-sectional study with 565 thyroid nodules, followed at a tertiary care hospital, in an iodine-replete area. Those were classified as American Thyroid Association and Thyroid Imaging Reporting and Data System developed by the American College of Radiology systems and stratified according to the Bethesda classification of fine needle aspiration. The values of sensibility, specificity, positive predictive value, and negative predictive value accuracy were calculated. Also, the percentage of unnecessary biopsies was presented.

RESULTS: The mean age of the individuals was 58.2±13.5 [26–90] years for benign nodules and 41.7±15.6 [23–66] years for malignant nodules ($p=0.002$). Regarding gender, 92.6% ($n=150$) of the individuals with benign nodules and 85.7% ($n=06$) with malignant nodules were females ($p=0.601$). For American Thyroid Association, 90.9% of sensibility, 51.4% of specificity, 52.6% of accuracy, 10.2% of positive predictive value, and 98.9% of negative predictive value were found. For Thyroid Imaging Reporting and Data System developed by the American College of Radiology, 90.9% of sensibility, 49.7% of specificity, 52.1% of accuracy, 9.9% of positive predictive value, and 98.9% of negative predictive value were found. Notably, 12.3% of unnecessary fine needle aspiration were found in American Thyroid Association and 44.4% were found in Thyroid Imaging Reporting and Data System developed by the American College of Radiology.

CONCLUSION: Both Thyroid Imaging Reporting and Data System developed by the American College of Radiology and American Thyroid Association are able to predict the malignancy risk of thyroid nodules. Thyroid Imaging Reporting and Data System developed by the American College of Radiology was better at avoiding unnecessary fine needle aspiration.

KEYWORDS: Thyroid nodule. Fine-needle aspiration. Cross-sectional study.

INTRODUCTION

Thyroid nodules are a common clinical diagnosis. Its prevalence among randomly selected individuals varies from 19 to 68%^{1,2}. Most of these nodules do not cause significant symptoms; therefore, the main challenge in the treatment is to discard malignancy^{3,4}.

The gold standard test for thyroid nodules evaluation is ultrasound^{5,6}, which identifies the suspicious ones that should be biopsied through fine needle aspiration (FNA). When FNA is well indicated, it reduces the number of individuals submitted to surgery due to benign diseases and allows the diagnosis of those with cancer^{3,7}. However, unnecessary FNA leads to more investigative thyroid procedures and higher costs for the Brazilian public health system⁸.

The mainly used risk stratification systems are obtained from the American Thyroid Association (ATA)⁹ last actualized in 2015 and the Thyroid Imaging Reporting and Data System developed by the American College of Radiology (ACR-TIRADS)¹⁰ from 2017, since they provide an effective malignancy risk stratification^{11,12}. Worldwide, the studies comparing these systems concluded that ACR-TIRADS leads to fewer unnecessary biopsies^{13,14}.

Only two Brazilian studies on this subject were found^{15,16}. Neither of them finds relevant differences between ATA and ACR-TIRADS. Furthermore, Macedo¹⁵ did not consider the most recent ACR-TIRADS classification and Rosario¹⁶ only evaluated nodules with indeterminate cytology. Besides, they

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Conflicts of interest: the authors declare there is no conflicts of interest. Funding: none.

Received on June 24, 2023. Accepted on July 23, 2023.

did not analyze which system is better at avoiding unnecessary FNA. Based on this context, this study aims to compare the capacities of ATA and ACR-TIRADS in malignancy-risk prediction¹ and verify which one is better at avoiding unnecessary FNA², especially in the Brazilian population, evaluated in the public health care system.

METHODS

Study design and participants

This is a cross-sectional study, developed at Santa Casa de Misericórdia de Belo Horizonte, a tertiary care hospital in an iodine-replete area, from January 2018 to October 2020. It follows the 196/96 National Health Board resolution and has obtained ethical approval from the Ethics and Research Committee (CAAE: 19375119.7.0000.5138). Informed consent was obtained from participants.

Data collection

Data were collected from the charts of individuals with thyroid nodules submitted to FNA following GE LOGIQ™ P9 ultrasonography. The criteria for FNA were based on the expertise of the attending physician and it was not evaluated in our study (patients were recruited after FNA). To reduce bias, all nodules were evaluated by the same pathologist. Location, size, composition, echogenicity, shape, margin, and vascularization were used to classify each nodule according to ATA and ACR-TIRADS.

ACR-TIRADS stratification ranges from 1 (benign – 0 points), 2 (not suspicious – 2 points), 3 (mildly suspicious – 3 points), 4 (moderately suspicious – 4–6 points) to 5 (highly suspicious – 7 or more points). Nodules are scored according to their composition, echogenicity, shape, margin, and echogenic foci¹⁰. ATA stratification also ranges from ATA 1 (benign), 2 (very low suspicion), 3 (low suspicion), 4 (intermediate suspicion) to ATA 5 (highly suspicious). The following patterns were considered suspicious: irregular margins, microcalcifications, taller than wide shape, disrupted rim calcifications with small extrusive hypoechoic soft tissue components, and evidence of extrathyroidal extension⁹.

To compare these systems, ATA and ACR-TIRADS were separated into four groups according to the prediction of the risk of malignancy of the classification systems. Nodules that were classified as ACR-TIRADS 1, 2, and 3 and ATA 1 (benign), 2 (very low suspicion), and 3 (low suspicion) were considered to have low suspicion for malignancy. Nodules that were classified as ACR-TIRADS 4 and 5, and ATA 4 (intermediate suspicion), 5 (high suspicion), and 6 (indeterminate) have high suspicion of malignancy. It is crucial to point out that ATA does

not classify isoechoic or hyperechoic nodules with malignant features (microcalcification, irregular margin or extrathyroidal extension, or taller than wide shape). These nodules could be malignant in almost 20% of the cases, hence classifying them to have high suspicion of malignancy^{10,11,12,14,15}, which was done based on the previous rate of malignancy predicted by the classification systems^{9,10}.

Following the classification, the nodules went through FNA and the cytological results were classified into the Bethesda system. Bethesda II nodules were considered benign while Bethesda V and VI were considered malignant¹⁶. Nodules with incomplete description or not classified by the Bethesda system were excluded.

Unnecessary fine needle aspiration

Unnecessary FNA nodules were considered with benign cytology (Bethesda II) punctured without indication from ACR-TIRADS and ATA or with indication from only one of the systems, resulting in benign cytology (Bethesda II).

Evaluated outcomes

Our primary outcome was to verify the capacity of ATA and ACR-TIRADS in malignancy assessment, by calculating sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV).

The second outcome was to verify the capacity of ATA and ACR-TIRADS guidelines in avoiding unnecessary FNA. Hence, only the nodules classified as Bethesda II, V, and VI were selected and evaluated retrospectively how they were stratified by ATA and ACR-TIRADS. Bethesda I, III and IV nodules were not included in the analysis due to the impossibility of assigning its behavior. These nodules are still being followed and a new analysis will be performed properly.

Data analysis

Quantitative data were summarized using exploratory analysis. Categorical data were presented in absolute frequency and percentage. Quantitative data were presented in mean ± standard deviation. The age of participants was analyzed by the Kolmogorov-Smirnov test with normal distribution and compared by the t-test. Chi-square test was used to compare categorical variables and outcomes. When necessary, Fisher's exact test and Monte Carlo simulation were used. The analysis was made by the SPSS 20 software.

RESULTS

A total of 565 consecutive nodules submitted to FNA were analyzed, of which 35 were excluded due to a lack of ultrasound

data or nodule stratification. In sum, 169 nodules were included: 30.5% (n=162) benign (Bethesda II) and 1.3% (n=07) malignant (Bethesda V or VI). The remaining 364 nodules, divided into Bethesda I (n=273), Bethesda III (n=68), and Bethesda IV (n=23), were not included due to the lack of anatomopathological confirmation. About 7.1% (12/169) of nodules could not be classified by ATA, all being Bethesda II. This happened because ATA does not classify isoechoic or hyperechoic nodules with microcalcifications, irregular margins, extrathyroidal extension, or diameter taller than wide. However, they were included in our study because they can be classified by ACR-TIRADS.

From the individuals comprehended, the mean age was 58.2 ± 13.5 [26–90] years for benign nodules and 41.7 ± 15.6 [23–66] years for malignant nodules, with $p=0.002$. Concerning

the gender, 92.6% (n=150) of the individuals with benign nodules and 85.7% (n=06) with malignant nodules were females ($p=0.435$). There was no significant difference between gender and final diagnosis.

The nodule's locations, characteristics, and the presence or absence of suspicious lymph nodes are described in Table 1. The factors related with a greater risk of malignancy were <1 cm size, hypoechogenicity, extra thyroid extension, irregular margins, and presence of calcifications.

According to Table 2, the majority of the nodules were classified as ACR-TIRADS 1–3 and ATA 1–3 (benign), and the classifications were able to discriminate into malignant and benign nodules as seen by p-value. The nodules classified as ATA 6 (non-classified) were included in the ATA 4 and ATA

Table 1. Analysis of the ultrasonographic characteristics of nodules.

| Variables | Final diagnosis | | Total | Risk of malignancy (%) | p-value |
|--------------------------|-----------------|-----------|-------------|------------------------|------------------|
| | Benign | Malignant | | | |
| Composition | | | | | |
| Pred. cistic | 6 (3.3%) | 0 (0.0%) | 6 (3.1%) | 0.0% | 0.606 |
| Pred. solid | 63 (34.8%) | 2 (18.6%) | 65 (33.9%) | 3.2% | |
| Mixed | 25 (13.8%) | 0 (0.0%) | 25 (13.0%) | 0.0% | |
| Spongiform | 4 (2.2%) | 0 (0.0%) | 4 (2.1%) | 0.0% | |
| Solid | 83 (45.9%) | 9 (81.8%) | 92 (47.9%) | 10.8% | |
| Echogenicity | | | | | |
| Anechoic | 7 (3.9%) | 0 (0.0%) | 7 (3.6%) | 0.0% | 0.039* |
| Hyperechoic or isoechoic | 98 (54.1%) | 2 (18.2%) | 100 (52.1%) | 2.0% | |
| Hypoechoic | 71 (39.2%) | 9 (81.8%) | 80 (41.7%) | 12.7% | |
| Very hypoechoic | 5 (2.8%) | 0 (0.0%) | 5 (2.6%) | 0.0% | |
| Shape | | | | | |
| Taller-than-wider | 8 (4.4%) | 0 (0.0%) | 8 (4.2%) | 0.0% | 0.476* |
| Wider-than-taller | 173 (95.6%) | 11 (100%) | 184 (95.8%) | 6.4% | |
| Margin | | | | | |
| Smooth or ill-defined | 161 (89.0%) | 5 (45.5%) | 166 (86.5%) | 3.1% | 0.003 |
| Lobulated or irregular | 13 (7.2%) | 4 (36.4%) | 17 (8.9%) | 30.8% | |
| Extrathyroidal extension | 7 (3.9%) | 2 (18.2%) | 9 (4.7%) | 28.6% | |
| Echogenic Foci | | | | | |
| None calcifications | 161 (89.0%) | 5 (45.5%) | 166 (68.5%) | 2.1% | <0.001 |
| Macrocalcifications | 13 (7.2%) | 4 (36.4%) | 17 (8.9%) | 30.8% | |
| Microcalcifications | 7 (3.9%) | 2 (18.2%) | 9 (4.7%) | 28.6% | |
| Suspicious lymph nodes | | | | | |
| Yes | 6 (3.3%) | 2 (18.2%) | 8 (2.4%) | 33.3% | 0.069 |
| No | 175 (96.7%) | 9 (81.9%) | 184 (95.8%) | 5.1% | |

Pred.: predominantly. Source: elaborated by the author. *Fisher test; *Chi-squared test.

Table 2. Risk of malignancy for American Thyroid Association and Thyroid Imaging Reporting and Data System developed by the American College of Radiology classifications.

| Classification | Final diagnosis | | Total | Risk of malignancy (%) | p-value |
|----------------|-----------------|------------|-------------|------------------------|---------|
| | Benign | Malignant | | | |
| TIRADS 1–3 | 90 (49.7%) | 1 (9.1%) | 91 (47.4%) | 1.1% | 0.009 |
| TIRADS 4–5 | 91 (50.3%) | 10 (90.9%) | 101 (52.6%) | 11% | |
| ATA 1–3 | 93 (51.4%) | 1 (9.1%) | 94 (49%) | 1.1% | 0.010 |
| ATA 4–6 | 88 (48.6%) | 10 (90.9%) | 98 (51%) | 11.4% | |

ATA 1: benign nodule; ATA 2: very little suspicion; ATA 3: little suspicion; ATA 4: intermediary suspicion; ATA 5: high suspicion; ATA 6: non-classified. Source: elaborated by the author.

Table 3. Sensibility, specificity, accuracy, positive predictive value, and negative predictive value of American Thyroid Association and Thyroid Imaging Reporting and Data System developed by the American College of Radiology.

| Parameters | ATA | ACR-TIRADS |
|-------------|-------|------------|
| Sensibility | 90.9% | 90.9% |
| Specificity | 51.4% | 49.7% |
| Accuracy | 52.6% | 52.1% |
| PPV | 10.2% | 9.9% |
| NPV | 98.9% | 98.9% |

PPV: positive predictive value; NPV: negative predictive value. Source: elaborated by the author.

5 categories because their risk of malignancy are more close to these ATA categories in previous studies^{11-13,16-18}.

As seen in Table 3, sensibility and NPV were similar in both classifications. Furthermore, specificity, accuracy, and PPV from both systems were similar, but slightly higher in ATA.

Concerning the FNA's, ACR-TIRADS pointed to 44.4% (72/162) of punctions as unnecessary, in comparison to ATA, with 12.3% (20/162), $p < 0.001$, which means that less nodules would be involved in a procedure if only ACR-TIRADS were used.

DISCUSSION

In this study, the capacity of ACR-TIRADS and ATA systems at predicting malignancy risk in thyroid nodules was compared. In addition, the capacity of these systems at avoiding unnecessary biopsies was investigated. According to the ATA and ACR-TIRADS classifications^{10,11}, nodules with <1 cm with ultrasound malignant characteristics could be submitted to FNA according to clinical judgment. The nodules with this condition in this study with FNA indicated were classified as high or intermediary ultrasound suspicion, showing that the clinical judgment of the physician was important. In our study,

we had 15 nodules with <1 cm, and all of them had high or intermediary ultrasound suspicion. This demonstrates that the physician's clinical judgment was important to indicate the FNA.

Nonetheless, other two studies^{19,20} found opposite results, with ATA's sensitivity being higher than ACR-TIRADS' (80–82 vs 48.9–76%) and ACR-TIRADS' specificity being higher than ATA's (60.6–97.5 vs 53.5–96.3%). However the values are quite close, concluding that both systems can effectively predict malignancy risk.

In this study, the mean age of individuals with malignant nodules was lower than the benign ones, which is supported by the findings in other studies that evaluate predictive features for malignancy^{21,22}. In accordance with our results, other studies also did not find differences in gender²¹.

The values of sensitivity and NPV were similar in both classifications and comparable to those obtained in another Brazilian study¹⁵. Specificity, accuracy, and PPV were similar but slightly higher in ATA, as the results shown by Cheng et al.⁷, in which ATA presented a higher specificity and NPV. In agreement, a study¹² showed that the ATA guidelines yielded a significantly higher specificity (79.6 vs. 71.5%), while ACR-TIRADS had a higher sensitivity (83.2 vs. 77.3%). Thus, both systems could be used for nodule evaluation, without any significant difference in diagnosis.

On the contrary, our study found that ACR-TIRADS is better at avoiding unnecessary FNA, which could be used as selection criteria. This result is in accordance with Grani et al.¹³, in which ACR-TIRADS allowed the higher reduction of biopsied nodules (268/502; 53.4%), which was significantly higher than ATA (220/502; 43.8%). The number of benign nodules biopsied using ACR-TIRADS (31.9–47.1%) was also smaller compared to ATA (69.3–78.1%) in two studies^{14,20}. Hence, ATA tends to indicate FNA in smaller nodules than ACR-TIRADS, leading to more procedures.

It is relevant to mention that studies about this topic are scarce in Brazil and only two studies were found^{15,16}. Considering that

Brazil is an enormous country with a high population diversity, results obtained from international studies such as those in Singapore⁵, Italy¹², and Turkey^{18,19} cannot be fully validated, reinforcing the necessity of new research. Our study has shown that both systems are effective at helping health professionals to indicate who should undergo biopsies procedures. Hence, the choice of use should be considered with other factors such as examiner skills and resources' availability. In this matter, ACR-TIRADS is found to be better at avoiding unnecessary biopsies, a strong advantage when considering that Brazil's ground health system is public, and supplies are often deficient⁹.

Nevertheless, this study has potential limitations. In previous studies^{10-12,14,15}, the malignancy risk in ATA in non-classified nodules was around 20%. In this study, this could not be possible due to the small number of malignant nodules found (n=7) and because Bethesda I, III, and IV were excluded from the final analysis. Additionally, a higher number of Bethesda I nodules were included in this sample, when compared to that presented in most studies, roughly 15% of Bethesda I nodules¹⁵, explained by the difficulty in maintaining the individuals' follow-up throughout COVID-19 pandemic and due to the high number of nodules with <1 cm submitted to FNA. Furthermore, Bethesda III and IV nodules, considered of indeterminate cytology, were excluded. Due to the pandemic, the second FNA biopsy of these nodules and the surgery were delayed, when indicated and the findings could not be included here. Hence, data will be updated after these procedures and published soon in another article. Another limitation is that the final diagnoses in our study were based on the cytopathology, which can cause false negatives and false positives when compared with the surgical histology. The probability of a false diagnosis in Bethesda II and Bethesda V is very low, varying from <3 and <1%, respectively, when compared with histopathology²⁰. Also, the low number of malignant nodules could be due to the exclusion

of Bethesda III and IV. Moreover, our study tended to suffer from a selection bias because all FNAs were indicated by multiple professionals following different criteria that are not specified in the individual's charts.

CONCLUSION

We found that ACR-TIRADS and ATA are equally capable of predicting malignancy risk at the same level, presenting similar results in every evaluated aspect (sensitivity, specificity, PPV, NPV, and accuracy). Despite that, our study found that ACR-TIRADS was better at avoiding unnecessary FNAs, making it a better choice for our public health system. Future studies in the Brazilian population with a higher number of nodules may be conducted, including those with indeterminate cytology.

ACKNOWLEDGMENTS

The authors would like to thank Dr. Janaine Cunha Polese, who assisted in writing.

AUTHORS' CONTRIBUTIONS

MNA: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. **JRC:** Conceptualization, Writing – original draft, Writing – review & editing. **LMS:** Conceptualization, Writing – original draft, Writing – review & editing. **LFGGM:** Conceptualization, Writing – original draft, Writing – review & editing. **RFO:** Formal Analysis, Investigation, Writing – original draft, Writing – review & editing. **MCBÁ:** Formal Analysis, Investigation, Methodology. **FCPM:** Conceptualization, Data curation, Formal Analysis, Project Administration, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing.

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