Validation of TIRADS ACR Risk Assessment of Thyroid Nodules in Comparison to the ATA Guidelines

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INTRODUCTION

Thyroid nodules are a very common clinical problem with prevalence of up to 68% in adults on high-resolution ultrasound (US).¹ US-guided fine-needle aspiration biopsy (FNAB) is known to be the test of choice used to determine the nature of the nodules. That being said, only 4–15% of all thyroid nodules are found to be malignant.²,³ Furthermore, most nodules that are proven malignant by cytology, especially when smaller than 1 cm, are usually not clinically significant, and show non-aggressive behavior.⁴–⁶

Reducing the number of US-guided FNAB performed on benign nodules while identifying clinically significant malignant nodules is imperative. Outcome of such reduction in number of FNABs will reduce costs, unnecessary patient anxiety and discomfort, bleeding risks...
caused directly from the procedure, as well as risks from withdrawal from anticoagulant treatment. According to the Society of Interventional Radiology, thyroid FNA demands certain withdrawal from anticoagulation, although not all societies recommend withdrawal, given very low risk of bleeding.[2]

Several guidelines were suggested for risk stratification of thyroid nodules by US. Most commonly used are the American Thyroid Association (ATA) guidelines published in 2015 and the American College of Radiology (ACR) Thyroid Imaging Reporting and Data System (TIRADS) guidelines published in 2017.

The aim of our study was to prospectively validate and compare TIRADS ACR 2017 and ATA 2015 risk stratification for thyroid carcinoma, in our patient population, specifically pertaining to reduction of unnecessary biopsies.

MATERIAL AND METHODS

This prospective study cohort comprised 281 nodules in 245 patients who underwent FNAB between May 2018 and June 2019 at our institution. Patients were referred for biopsy after undergoing an initial US examination in other various outpatient clinics with various levels of accuracy of TIRADS grading. The study received an Institutional Review Board approval of our hospital; Helsinki committee, Rambam health-care center. Informed consent was signed before the procedure by all patients.

All patients over 18 years old who were referred for thyroid nodule FNAB from outpatient and inpatient clinics were included in the study.

The US examinations were performed using a linear 5–12 MHz transducer (Epiq 7, Philips Medical Systems). Images of the biopsied nodule were obtained.

The nodule biopsied was chosen according to TIRADS ACR and/or the ATA risk criteria. If there was a disagreement between the methods whether to perform a FNAB, the FNAB was performed. The US examinations were performed by a single senior radiologist (NB) with 15 years of experience.

Data collected included patient age, gender, reason for FNAB referral, and nodule characteristics with corresponding TIRADS and ATA grading and cytological results using Bethesda scoring for each nodule.

Cytology was analyzed by a single cytologist (LM) with 20 years of experience.

Pathology results were collected for those patients included in the statistical analysis that underwent surgery in our institution.

RESULTS

Two hundred and thirty-five nodules were included in the statistical analysis. Statistical analysis was performed only on those nodules that according to the TIRADS ACR and/or ATA guidelines were eligible for FNAB. Nodules that underwent FNA due to treating physician request or patient request due to anxiety but were not eligible for FNAB were excluded from the study.

The study included one hundred ninety-six female and 39 male patients. The average age was 57 years (SD ± 13.5). Sonographic grading of all included nodules according to TIRADS and ATA is shown in Table 1.

Thirteen of 235 nodules underwent surgery in our institution. Fourteen of 235 nodules had a cytology result of Bethesda 6. Two of them had a result of medullary carcinoma on pathology and eight had a result of papillary carcinoma. Four patients (nodules) with Bethesda 6 did not return to our center and their pathology results were not available. Two nodules had a cytology result of Bethesda 4, one of them had a result of follicular carcinoma on pathology and one had a result of Hurthle cell carcinoma. One nodule had a cytology result of Bethesda 3 with a pathology result of benign follicular oncocytic nodule. Two hundred and eighteen nodules had a cytology result of Bethesda 2. Of the 14 nodules graded Bethesda 6, 12 were graded sonographically according to TIRADS criteria as TIRADS 5, one nodule was graded as TIRADS 3, and one as TIRADS 4, whereas according to ATA criteria, 12 of them were graded as high suspicion, one was graded as low suspicion, and one as intermediate suspicion [Table 2].

We found an agreement between the two criteria methods in 58.2% (137/235) of the cases. In 35.3% (83/235) of the cases, ATA recommended FNAB while TIRADS did not. In 6.4% (15/235) of cases, TIRADS recommended FNAB while ATA did not. The calculated specificity for ATA criteria was 7% (15/221) and for TIRADS was 37% (81/221). The calculated sensitivity was 100% (14/14) for ATA and 86% (12/14) for TIRADS.

Correlation between TIRADS and ATA grading systems and Bethesda cytology scoring shows a difference with a high statistical significance (P < 0.001) between the two distributions of risk grades (Bethesda 2 vs. Bethesda 3–6) for both grading systems [Table 3], thus validating them as a tool in differentiating malignant from benign nodules.

Fifteen nodules could not be graded according to ATA, due to the fact that they showed both malignant and benign features, such as solid or partially cystic nodules with hyperechogenicity, isoechogenicity, irregular margins, microcalcifications, or taller-than-wide shape...
Table 1: Sonographic scoring of all included nodules according to TIRADS and ATA.

|                | ATA                     | TIRADS                  |
|----------------|-------------------------|-------------------------|
|                | Total No. | High | Intermediate | Low | Very low | No grade | Total No. | TIRADS5 | TIRADS4 | TIRADS3 | TIRADS2 | TIRADS1 |
|                | %          | %    | %            | %   | %       | %        | %          | %       | %       | %       | %       | %       |
| TOTAL          | 235        | 100  | 51           | 100 | 78      | 100      | 83         | 100     | 8        | 100     | 15       | 100     |
| Microcalcifications |           |      |              |     |         |          |            |         |          |         |          |        |
| No             | 186        | 79   | 13           | 25  | 77      | 99       | 81         | 98      | 8        | 100     | 7        | 47      |
| Yes            | 49         | 21   | 38           | 75  | 1       | 1        | 2          | 2       | 0        | 8       | 53       | 3       |
| Peripheral rim calcifications |           |      |              |     |         |          |            |         |          |         |          |        |
| No             | 225        | 96   | 47           | 92  | 73      | 94       | 82         | 99      | 8        | 100     | 15       | 100     |
| Yes            | 10         | 4    | 4            | 8   | 5       | 6        | 1          | 1       | 0        | 0       | 0        | 4       |
| Macrocalfication |            |      |              |     |         |          |            |         |          |         |          |        |
| No             | 191        | 81   | 37           | 73  | 65      | 83       | 71         | 86      | 6        | 75       | 12       | 80      |
| Yes            | 44         | 19   | 14           | 27  | 13      | 17       | 12         | 14      | 2        | 25       | 3        | 20      |
| Comet tail artifact |            |      |              |     |         |          |            |         |          |         |          |        |
| No             | 223        | 95   | 47           | 92  | 76      | 97       | 80         | 96      | 7        | 88       | 13       | 87      |
| Yes            | 12         | 5    | 4            | 8   | 2       | 3        | 3          | 4       | 1        | 13       | 2        | 13      |
| No echogenic foci |            |      |              |     |         |          |            |         |          |         |          |        |
| No             | 109        | 46   | 46           | 90  | 25      | 32       | 22         | 27      | 5        | 63       | 11       | 73      |
| Yes            | 126        | 54   | 5            | 10  | 53      | 68       | 61         | 73      | 3        | 38       | 4        | 27      |
| Extra thyroidal extension |         |      |              |     |         |          |            |         |          |         |          |        |
| No             | 234        | 100  | 50           | 98  | 78      | 100      | 83         | 100     | 8        | 100     | 15       | 100     |
| Yes            | 1          | 0    | 1            | 2   | 0       | 0        | 0          | 0       | 0        | 0       | 0        | 0       |
| Irregular borders |            |      |              |     |         |          |            |         |          |         |          |        |
| No             | 226        | 96   | 42           | 82  | 78      | 100      | 83         | 100     | 8        | 100     | 15       | 100     |
| Yes            | 9          | 4    | 9            | 18  | 0       | 0        | 0          | 0       | 0        | 0       | 0        | 0       |
| Ill-defined borders |          |      |              |     |         |          |            |         |          |         |          |        |
| No             | 231        | 98   | 48           | 94  | 78      | 100      | 82         | 99      | 8        | 100     | 15       | 100     |
| Yes            | 4          | 2    | 3            | 6   | 0       | 0        | 1          | 1       | 0        | 0       | 0        | 0       |
| Smooth borders |            |      |              |     |         |          |            |         |          |         |          |        |
| No             | 13         | 6    | 12           | 24  | 0       | 0        | 1          | 1       | 0        | 0       | 0        | 0       |
| Yes            | 222        | 94   | 39           | 76  | 78      | 100      | 82         | 99      | 8        | 100     | 15       | 100     |
| Taller than wide |           |      |              |     |         |          |            |         |          |         |          |        |
| No             | 217        | 92   | 40           | 78  | 78      | 100      | 81         | 98      | 8        | 100     | 10       | 67      |
| Yes            | 18         | 8    | 11           | 22  | 0       | 0        | 2          | 2       | 0        | 0       | 5        | 33      |
| Wider than tall |            |      |              |     |         |          |            |         |          |         |          |        |
| No             | 37         | 16   | 16           | 31  | 5       | 6        | 8          | 10      | 2        | 25       | 6        | 40      |
| Yes            | 198        | 84   | 35           | 69  | 73      | 94       | 75         | 90      | 6        | 75       | 9        | 60      |
| Very hypoechoic nodule |        |      |              |     |         |          |            |         |          |         |          |        |
| No             | 228        | 97   | 48           | 94  | 74      | 95       | 83         | 100     | 8        | 100     | 15       | 100     |

(Contd...)
Table 1: (Continued).

|                         | ATA                           | TIRADS                       |
|-------------------------|-------------------------------|------------------------------|
|                         | Total                         | TIRADS5                     |
|                         | No.  %                        | No. %                       |
| Yes                     | 7  3                          | 4  7                        |
| Hypoechoic nodule       |                               |                             |
| No                      | 111  47                       | 9  17                       |
| Yes                     | 124  53                       | 45  83                      |
|                         | Intermediate suspicion        | TIRADS4                     |
|                         | No.  %                        | No. %                       |
| Yes                     | 236  53                       | 73  85                      |
| Hyper or Isoechoic nodule |                             |                             |
| No                      | 139  59                       | 49  91                      |
| Yes                     | 96  41                        | 5  9                        |
|                         | Low suspicion                 | TIRADS3                     |
|                         | No.  %                        | No. %                       |
| Yes                     | 227  97                       | 54  100                     |
| Anechoic nodule         |                               |                             |
| No                      | 8  3                          | 0  0                        |
|                         | Very low suspicion            | TIRADS2                     |
|                         | No.  %                        | No. %                       |
| Yes                     | 194  83                       | 54  100                     |
| Solid nodule            |                               |                             |
| No                      | 41  17                        | 0  0                        |
| Yes                     | 194  83                       | 54  100                     |
|                         | High suspicion                | TIRADS1                     |
|                         | No.  %                        | No. %                       |
| Yes                     | 232  99                       | 54  100                     |
| Cystic and solid nodule |                               |                             |
| No                      | 3  1                          | 0  0                        |
|                         | Cystic nodule                 |                             |
| No                      | 234  100                      | 54  100                     |
|                         | No.  %                        | No. %                       |
| Yes                     | 1  0                          | 0  0                        |

TIRADS: Thyroid Imaging Reporting and Data System, ATA: American Thyroid Association
Table 2: Outcome of nodules with a cytology result of Bethesda 3–6.

| S. No. | Size (cm) | TIRADS | ATA      | Cytology       | Pathology |
|--------|-----------|---------|----------|----------------|-----------|
| 1.     | 1         | 5       | High suspicion | Bethesda 6      | PTC\(^a\) |
| 2.     | 1         | 5       | High suspicion | Bethesda 6      | PTC\(^a\) |
| 3.     | 1         | 5       | High suspicion | Bethesda 6      | PTC\(^a\) |
| 4.     | 3.8       | 5       | High suspicion | Bethesda 6      | PTC\(^a\) |
| 5.     | 2         | 5       | High suspicion | Bethesda 6      | PTC\(^a\) |
| 6.     | 1.4       | 5       | High suspicion | Bethesda 6      | PTC\(^a\) |
| 7.     | 2         | 5       | High suspicion | Bethesda 6      | PTC\(^a\) |
| 8.     | 1.2       | 4       | Intermediate suspicion | Bethesda 6 | PTC\(^a\) |
| 9.     | 1.5       | 5       | High suspicion | Bethesda 6      | Not available |
| 10.    | 2.1       | 5       | High suspicion | Bethesda 6      | Not available |
| 11.    | 2         | 5       | High suspicion | Bethesda 6      | Not available |
| 12.    | 1.5       | 3       | Low suspicion | Bethesda 6      | Not available |
| 13.    | 1.5       | 5       | High suspicion | Bethesda 6      | MC\(^b\) |
| 14.    | 1.5       | 5       | High suspicion | Bethesda 6      | MC\(^b\) |
| 15.    | 3.8       | 4       | Intermediate suspicion | Bethesda 4 | Follicular carcinoma |
| 16.    | 6         | 3       | Low suspicion | Bethesda 4      | Hurtle cell carcinoma |
| 17.    | 1         | 4       | Intermediate suspicion | Bethesda 3 | Benign follicular oncocytic nodule |

\(^a\)PTC: Papillary thyroid carcinoma, \(^b\)MC: Medullary carcinoma

Table 3: Correlation between TIRADS and ATA grading systems and Bethesda cytology scoring.

| Bethesda scoring | Total | 2  | 3–6 |
|------------------|-------|----|-----|
|                  | No.   | %  | No. | %  |
| Total            | 235   | 100| 219 | 100|
| ATA              | 51    | 22 | 39  | 18 |
| High suspicion   | 51    | 22 | 39  | 18 |
| Intermediate      | 78    | 33 | 76  | 35 |
| Low suspicion     | 83    | 35 | 81  | 37 |
| Very low         | 8     | 3  | 8   | 4  |
| TIRADS            | 15    | 6  | 15  | 7  |
| TIRADS 5          | 54    | 23 | 42  | 19 |
| TIRADS 4          | 98    | 42 | 96  | 44 |
| TIRADS 3          | 68    | 29 | 66  | 30 |
| TIRADS 2          | 13    | 6  | 13  | 6  |
| TIRADS 1          | 2     | 1  | 2   | 1  |

Chi-square \(P\)-value
- Total: 0.001*
- High suspicion: 0.001*
- Intermediate suspicion: 0.001*
- Low suspicion: 0.001*
- Very low suspicion: 0.001*

TIRADS: Thyroid Imaging Reporting and Data System, ATA: American Thyroid Association

DISCUSSION

Thyroid nodules are seen in up to 68% in adults on high-resolution US.\(^1\) US-guided FNAB is known to be the test of choice to determine the nature of the nodules, but only 4–15% of all nodules are malignant.\(^2,3\)

Furthermore, even those nodules that were proven malignant by cytology, especially when smaller than 1 cm, are usually not clinically significant, and show non-aggressive behavior.\(^4,6\)

The ATA guidelines which characterize the nodule by its size, shape, echogenicity, margins, presence of calcification, and evidence of extra thyroidal extension (ETE) are widely used for evaluation and management of thyroid nodules and

[Figures 1 and 2]. None of these nodules had a positive cytology (Bethesda 5–6) [Table 3].

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for the recommendation of FNAB. Suspicious characteristics for malignancy include hypoechoic solid component, irregular margins, taller-than-wide shape, presence of rim or microcalcification, and evidence of ETE. These nodule characteristics classify the risk of malignancy into five categories, which include benign pattern, very low suspicion pattern, low suspicion pattern, intermediate suspicious pattern, and high suspicion pattern. However, nodules that are echogenic or isoechoic and possess malignant features cannot be classified. The recommendation for FNAB is determined by the specific category in combination with the nodule size. For nodules with high or intermediate suspicion, FNAB is recommended when the nodule is 1 cm or larger, for nodules with low suspicion, FNAB is recommended when the nodule is 1.5 cm or larger and for nodules with very low suspicion, FNAB is recommended when the nodule is 2 cm or larger.

The recent ACR TIRADS is an US reporting system for thyroid nodules proposed by the ACR, published in April 2017. The ACR TIRADS uses a slightly different scoring system for the recommendation of FNAB of thyroid nodules. The ACR TIRADS categorizes the nodule according to composition, echogenicity, shape, margin, and echogenic foci. Suspicious characteristics for malignancy include hypoechoic solid component, but also very hypoechoic solid component (more hypoechoic than the strap muscles) which is considered as a higher risk for malignancy than simply hypoechoic, lobulated or irregular margins, evidence of ETE, taller-than-wide shape, and presence of microcalcification. Rim calcifications and also macrocalcification have a risk of malignancy according to the ACR TIRADS but these kinds of calcifications carry a lower risk than microcalcifications. Each malignant feature is given an assigned number of points that add up to a sum of points for each nodule, thus categorizing each nodule into five categories: TIRADS 1 – benign, TIRADS 2 – not suspicious, TIRADS 3 – mildly suspicious, TIRADS 4 – moderately suspicious, and TIRADS 5 – highly suspicious. For nodules with TIRADS 5, FNAB is recommended when the nodule is 1 cm or larger, for TIRADS 4, FNAB is recommended when the nodule is 1.5 cm or larger and for TIRADS 3, FNAB is recommended when the nodule is 2.5 cm or larger. Specific recommendations are given for follow-up US examinations for each category according to the nodule size.

We examined the two cases that had a cytology result of Bethesda 5–6 that ATA recommended to perform FNAB but TIRADS did not. In the first case, the nodule measured 1.5 cm and was graded as TIRADS 3 by TIRADS ACR and as low suspicion by ATA. Due to the nodule's size that was <2.5 cm but equal or larger than 1.5 cm, FNAB was not recommended by TIRADS, but was recommended by ATA. TIRADS recommended follow-up in this case [Figure 3].

In the second case, the nodule measured 1.2 cm and was graded as TIRADS 4 by TIRADS ACR and as intermediate suspicion by ATA. Due to the nodule's size that was <1.5 cm, FNAB was not recommended by TIRADS, but was recommended by ATA. TIRADS recommended follow-up in this case as well [Figure 4].

Cytology reports are given according to the Bethesda system, summarized in Table 4. Several studies compared the ATA guidelines to the ACR TIRADS guidelines. Pandya et al. recently published a
In a retrospective study, Gao et al. compared three classification systems: ACR TIRADS, KWAK-TIRADS, and 2015 ATA guidelines. The authors found that ACR TIRADS had a higher specificity, whereas the ATA guideline yielded a higher sensitivity.

Middleton et al. concluded in a retrospective study that the TIRADS ACR compares favorably with the ATA 2015 guidelines. Furthermore, the TIRADS ACR has a higher biopsy yield of malignancy, primarily due to reduced number of biopsies of benign nodules.

In a retrospective study, Wu et al. found that the ACR TIRADS guidelines were superior to the ATA guidelines in terms of reducing the number of unnecessary FNA biopsies. In addition, they found that 6% of nodules could not be evaluated by ATA guidelines since the stratification in the ATA guidelines does not include the evaluation of hyperechoic or isoechoic nodules with malignant features such as taller than wide and microcalcifications. They found that 16.7% of these nodules were malignant.

Hoang et al., in a retrospective study, found that ACR TIRADS criteria offer a meaningful reduction in the number of thyroid nodules recommended for biopsy and significantly improve the accuracy of recommendation for nodule management. High suspicion nodules that did not meet the criteria for biopsy with ACR TIRADS guidelines are recommended for follow-up US.

In contrast to these studies that were retrospective, our study is a prospective study. During the study, nodules were accurately graded at the time of performance of the US-guided FNAB and not evaluated retrospectively on the images. Our cohort included patients that already underwent an US examination and were referred to us for the biopsy.

Our study is compatible with other studies, confirming ATA guidelines have a lower specificity in comparison to the ACR TIRADS guidelines. This can be explained by the fact that the ACR guidelines increase the threshold for FNA biopsies in moderately suspicious nodules from 1 cm (as in the ATA guidelines) to 1.5 cm and from 1.5 cm to 2.5 cm in low suspicious nodules.

ACR TIRADS recommends follow-up guidelines for nodules based on a lower size threshold than the one being used for biopsy. Given the indolent behavior of small thyroid cancers, Oda et al. and Hoang et al. concluded that observation of small suspicious nodules is a safe strategy. In our study, we observed two cases of confirmed papillary carcinoma, in which the ATA guidelines recommended to perform FNAB while TIRADS ACR did not recommend FNAB but did recommend follow-up.

Active surveillance of papillary microcarcinomas is considered a valid option in certain cases. The first publications regarding

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**Table 4:** The Bethesda system for reporting thyroid cytopathology: Recommended diagnostic categories.

1. Non-diagnostic or unsatisfactory.
2. Benign.
3. Atypia of undetermined significance or follicular lesion of undetermined significance.
4. Follicular neoplasm or suspicious for follicular neoplasm.
5. Suspicious for malignancy.
6. Malignant.
active surveillance of papillary thyroid carcinoma came from Japan.[16] Ito et al. concluded in a review that active surveillance is the optimal first-line management for all adult patients with low-risk papillary microcarcinomas. They described high-risk features as clinical nodal metastasis, distant metastasis, or significant extrathyroidal extension such as the trachea and recurrent laryngeal nerve.[17] Active surveillance has also been approved in the 2015 ATA guidelines as a management option in the United States,[3] aiming to reduce over treatment as well as morbidity and costs related to surgical treatment of patients with low-risk thyroid malignancies.[18,19]

The goal of our study was to reduce unnecessary biopsies, thus, we need to evaluate the specific group of 83 patients, (83/235) representing 35.3% of the study population, in which ATA recommended FNAB while TIRADS did not. In this group, there were 35 patients with TIRADS 4, 33 patients with TIRADS 3, and 15 patients with TIRADS 2. The reason for not recommending biopsy according to TIRADS in this group was strictly due to size threshold. Our study has several limitations; first, the small number of thyroid carcinoma cases in our study does not allow an evaluation with a statistical significance for the group of patients. Fourteen of 235 nodules had a cytology result of Bethesda 6, giving 6% (14/235) prevalence of thyroid cancer in our study compared to 4–15% in the literature. This relatively lower prevalence does not affect the sensitivity or the specificity. Second, a single radiologist performed all US examinations and graded the nodules on site before performing the FNAB. Furthermore, most of the patients were referred for FNAB from outpatient clinics. These clinics are various and patient information from these clinics are not available to us. Therefore, follow-up US examinations and pathology results from surgeries not performed in our institution are lacking.

CONCLUSION

Our prospective study showed that application of ACR TIRADS criteria can significantly reduce the number of US-guided FNA performed on benign nodule compared to ATA criteria.

Using ACR TIRADS, we showed a reduction of 35% in unnecessary biopsies with a cost of only two missed carcinomas that remained on further follow-up.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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