Original Article

# Performance of European Thyroid Imaging Reporting and Data System in Stratifying Malignancy Risk of Thyroid Nodules: A Prospective Study

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## Abstract

**Background:** There is a limited number of studies reporting the performance of European Thyroid Imaging Reporting and Data System (EU-TIRADS) guideline in identifying thyroid nodule malignancy. We aimed to evaluate diagnostic accuracy of EU-TIRADS regardless of thyroid nodule size. **Methods:** During August 2019-November 2021, subjects with thyroid nodules were prospectively included. Sonographic characteristics were recorded and scored as per EU-TIRADS guideline. Finally, fine-needle aspiration (FNA) was performed, and cytological findings were reported. **Results:** Totally, 1266 thyroid nodules from 984 subjects were assessed, of which 295 nodules were smaller than 10 mm and 971 nodules were 10 mm or larger. Among nodules <10 mm, prevalence rates of malignancy for EU-TIRADS classes 2–5 were 0.0%, 3.7%, 20.6%, and 40.9%, respectively; these rates among nodules ≥10 mm were 2.3%, 4.0%, 19.3%, and 43.2%, respectively. The accuracy values of EU-TIRADS class 5 and EU-TIRADS class 4 or 5 in diagnosis of malignancy for nodules <10 mm were 86.4% and 79.7%, respectively; these rates for nodules ≥10 mm were 83.8% and 76.3%, respectively. Hypoechogenicity, microcalcification, ill-defined and irregular margins were predictors for malignancy regardless of thyroid nodule size. **Conclusion:** EU-TIRADS could provide an acceptable malignancy risk stratification that is helpful for better distinguishing benignity from malignancy, as well as preventing unnecessary FNA biopsies, in thyroid nodules irrespective of their size.

**Keywords:** Malignancy, Thyroid Imaging Reporting and Data System, thyroid nodules, ultrasonography

## Introduction

Thyroid nodules are commonly diagnosed among adult population in clinical practice and/or with ultrasonography. They are usually asymptomatic; however, up to a sixth of them can be malignant.[1] Therefore, distinguishing between benign and malignant thyroid nodules is important. For this aim, ultrasound-guided fine needle aspiration (FNA) biopsy with cytology is principally recommended; however, FNA overuse can be associated with rising healthcare costs and stress for the cases.[2,3] For selective FNA biopsies, an ultrasound-based risk stratification system for thyroid nodule malignancy was developed in 2009 by Horvath *et al*.[4] named Thyroid Imaging Reporting and Data System (TIRADS). Since that time, various versions of this system have been proposed, such as American College of Radiology TIRADS, Korean TIRADS, and European TIRADS (EU-TIRADS).[5,6]

EU-TIRADS was developed by European Thyroid Association in 2017.[7] A limited number of studies have reported the performance of this guideline in identifying thyroid nodule malignancy with variable accuracy values. A recent meta-analysis on four studies reported that the pooled sensitivity and specificity for nodule malignancy were 85% and 61%, respectively;[8] however, more studies are needed to reach a more comprehensive consensus on the accuracy of EU-TIRADS in detecting malignant thyroid nodules.

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Thyroid nodules are common diseases of thyroid gland in Iran due to dietary iodine deficiency. Also, previous data have shown that there has been an increasing trend towards incidence of thyroid cancer (mostly papillary thyroid cancer) in this country over the past decade.[9,10] Therefore, it is important to distinguish between malignant and benign nodules using an accurate diagnostic approach.

Most of the studies assessing the diagnostic performance of TIRADS guidelines were conducted on thyroid nodules larger than 10 mm, while a considerable percentage of thyroid malignancies pertains to nodules smaller than 10 mm (microcarcinomas).[11] In the present study, we aimed to evaluate the performance of EU-TIRADS in discriminating benignity from malignancy regardless of thyroid nodule size.

## Materials and Methods

From August 2019 to November 2021, subjects with thyroid nodules were prospectively included in this study. The cases were referred by an endocrinologist from clinics of Shahid Beheshti Teaching Hospital or private offices in Babol, northern Iran to the radiologists for sonography and FNA biopsy. The patients were excluded if they met the following criteria: (1) nodules with purely cystic component; (2) nodules with atypical diagnosis in cytology; (3) subjects not willing to participate in the survey. A written informed consent was obtained from all of the participants. The study protocol was approved by the ethics committee of Babol University of Medical Sciences (code: IR.MUBABOL.REC.1400.155). The patients' information was kept confidential.

Thyroid ultrasonography was conducted by two senior radiologists using a Samsung H60 ultrasound machine with a 3–14 MHz linear probe. The following sonographic characteristics were recorded for each nodule: size, calcification (microcalcification, coarse calcification, rim calcification), margins (regular, ill-defined, irregular), echogenicity (hyperechogenicity, isoechogenicity, hypoechogenicity), composition (solid-cystic, solid), and shape (taller-than-wide, wider-than-tall). The nodules findings were then evaluated as per the EU-TIRADS guideline. According to EU-TIRADS, irregular shape (nonoval or round), irregular margins, microcalcifications, and a marked hypoechogenicity, are defined as ultrasound features of high suspicion for malignancy.[7] This system is categorized as follows: EU-TIRADS 2 (benign, malignancy risk of 0%), EU-TIRADS 3 (low risk, malignancy risk of 2%–4%), EU-TIRADS 4 (intermediate risk, malignancy risk of 6%–17%), EU-TIRADS 5 (high risk, malignancy risk of 26%–87%). The radiologists reviewed the thyroid nodules independently and any disagreements were resolved by consensus. The interobserver agreement between the radiologists was assessed with Kappa statistics.

The FNA biopsy was performed under the guidance of ultrasound by an expert radiologist using a 5 ml plastic syringe attached to a 23-gauge needle with the free hand-biopsy technique. The specimens were then smeared on microscope glass slides, dried in the air, and fixed with 95% alcohol. Most of the thyroid nodules underwent FNA once by the radiologist. There were a few nodules underwent FNA twice. The cytological assessment was conducted by two expert pathologists who were blinded to the ultrasonographic diagnosis of the thyroid nodules. The final decision (suspicious for benignity or malignancy) was made with consensus. We excluded FNA aspirates with scant cellularity.

The collected data initially underwent descriptive analysis using SPSS software (IBM, Armonk, NY, USA); then, performance of the EU-TIRADS guideline in the diagnosis of malignant thyroid nodules was calculated, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy. To estimate the ability of the EU-TIRADS for predicting the malignancy, we used a receiver operator characteristics (ROC) analysis, as estimated by the area under the curve (AUC). These analyses were conducted for cut-off values of 4 and 5 for the EU-TIRADS, separately. Logistic regression analysis was used to investigate the association between different ultrasonographic characteristics and malignancy risk; the results were presented as odds ratio (OR) along with 95% confidence interval (CI). A $P < 0.05$ was considered as significant.

## Results

A total of 984 subjects (112 men and 872 women, with a mean age of 45.4 ± 13.1 years old) with 1266 thyroid nodules were finally included in this study, of which 295 nodules were smaller than 10 mm and 971 nodules were 10 mm or larger. In total, 163 nodules (12.9%) were suspected to be malign, of which 138 malignant nodules were consistent with papillary thyroid carcinoma and others were follicular neoplasm according to cytology. A good interobserver agreement was seen between the two radiologists (Kappa = 0.75).

Table 1 shows the distribution of benign and malignant thyroid nodules for different categories of EU-TIRADS. Among nodules <10 mm, prevalence rates of malignancy for

**Table 1: Rates of malignancy in European Thyroid Imaging Reporting and Data System categories according to the thyroid nodule size**

| Risk category | Benign nodules, *n* (%) | Malignant nodules, *n* (%) | Prevalence of malignancy (%) |
|---|---|---|---|
| <10 mm | | | |
| EU-TIRADS 2 | 28 (10.6) | 0 | 0.0 |
| EU-TIRADS 3 | 182 (69.2) | 7 (21.9) | 3.7 |
| EU-TIRADS 4 | 27 (10.3) | 7 (21.9) | 20.6 |
| EU-TIRADS 5 | 26 (9.9) | 18 (56.3) | 40.9 |
| ≥10 mm | | | |
| EU-TIRADS 2 | 85 (10.1) | 2 (1.5) | 2.3 |
| EU-TIRADS 3 | 550 (65.5) | 23 (17.6) | 4.0 |
| EU-TIRADS 4 | 96 (11.4) | 23 (17.6) | 19.3 |
| EU-TIRADS 5 | 109 (13.0) | 83 (63.4) | 43.2 |

EU-TIRADS: European Thyroid Imaging Reporting and Data System

EU-TIRADS classes 2–5 were 0.0%, 3.7%, 20.6%, and 40.9%, respectively. These rates among nodules ≥10 mm were 2.3%, 4.0%, 19.3%, and 43.2%, respectively.

The performance of EU-TIRADS in diagnosis of malignant nodules according to the nodule size was presented in Table 2. The accuracy values of EU-TIRADS class 5 and EU-TIRADS class 4 or 5 in nodules <10 mm were 86.4% and 79.7%, respectively. These rates in nodules ≥10 mm were 83.8% and 76.3%, respectively. Comparing these values showed no significant differences between nodules smaller and larger than 10 mm in diagnostic performance of EU-TIRADS [Table 2].

The results of ROC curve analysis for the ability of EU-TIRADS categories in differentiating malignant from benign nodules have been demonstrated in Figures 1 and 2. In nodules <10 mm, the predictive ability of EU-TIRADS with a cut-off set at 4 was a bit higher than that of EU-TIRADS 5 (AUC = 0.790 vs. AUC = 0.732). Similarly, in nodules ≥10 mm, a slightly higher predictive ability was observed for EU-TIRADS 4 or 5 compared with EU-TIRADS 5 (AUC = 0.783 vs. AUC = 0.752). Figures 3-6 demonstrate the ultrasound-guided FNA of thyroid nodules with their cytological findings.

In Tables 3 and 4, the potential association between the sonographic features and risk of malignancy in nodules <10 mm and ≥10 mm has been represented, respectively. In nodules smaller than 10 mm, hypoechogenicity (OR = 5.91), microcalcification (OR = 4.30), ill-defined margin (OR = 4.15), and irregular margin (OR = 9.17) were found as predictors for malignancy. In nodules ≥10 mm, hypoechogenicity (OR = 3.81), microcalcification (OR = 5.38), solid component (OR = 4.40), ill-defined margin (OR = 2.94), and irregular margin (OR = 4.45) were associated with risk of malignancy.

## Discussion

In this study, we assessed the diagnostic performance of EU-TIRADS guideline in 295 nodules smaller than 10 mm and 971 nodules larger than 10 mm. The malignancy rates in each EU-TIRADS category were almost comparable between the two size groups of the nodules, and were in the range cited in

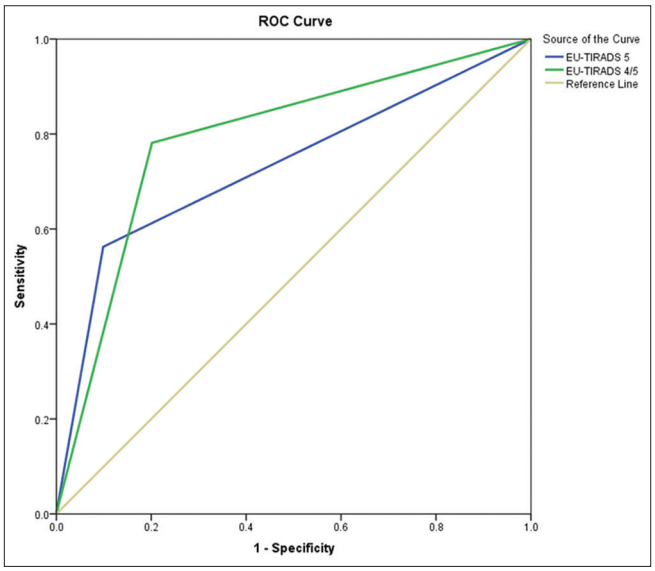


**Figure 1:** ROC curve of EU-TIRADS (category 5; category 4 or 5) for predicting malignancy of thyroid nodules smaller than 10 mm. ROC: Receiver operating characteristic, EU-TIRADS: European Thyroid Imaging Reporting and Data System

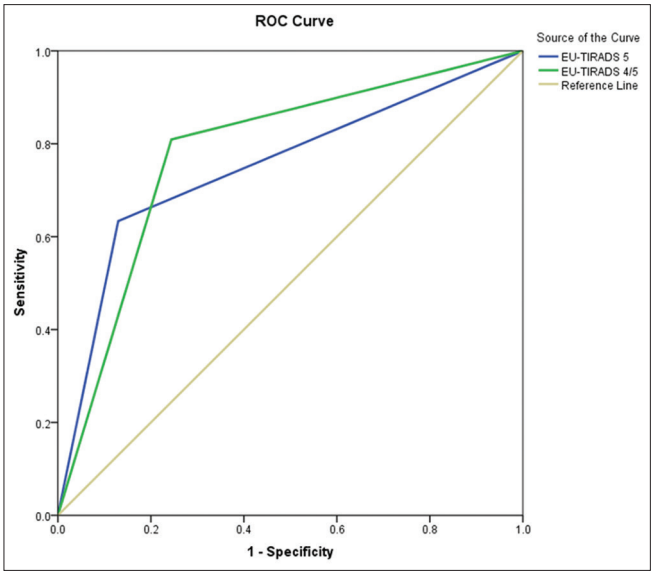


**Figure 2:** ROC curve of EU-TIRADS (category 5; category 4 or 5) for predicting malignancy of thyroid nodules larger than 10 mm. ROC: Receiver operating characteristic, EU-TIRADS: European Thyroid Imaging Reporting and Data System

**Table 2: Performance of European Thyroid Imaging Reporting and Data System for diagnosis of malignancy according to the thyroid nodule size**

| Risk category | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) | Accuracy (%) |
|---|---|---|---|---|---|
| EU-TIRADS 5 | | | | | |
| <10 mm | 56.3 | 90.1 | 40.9 | 94.4 | 86.4 |
| ≥10 mm | 63.4 | 87.0 | 43.2 | 93.8 | 83.8 |
| *P* | 0.589 | 0.220 | 0.911 | 0.853 | 0.322 |
| EU-TIRADS 4 or 5 | | | | | |
| <10 mm | 78.1 | 79.6 | 32.1 | 96.8 | 79.7 |
| ≥10 mm | 80.9 | 75.6 | 34.0 | 96.2 | 76.3 |
| *P* | 0.914 | 0.181 | 0.837 | 0.861 | 0.263 |

PPV: Positive predictive value, NPV: Negative predictive value, EU-TIRADS: European Thyroid Imaging Reporting and Data System

**Table 3: Association of different sonographic characteristics with cytology findings in thyroid nodules smaller than 10 mm**

| Sonographic features | Benign nodules, *n* (%) | Malignant nodules, *n* (%) | OR (95% CI) | *P* |
|---|---|---|---|---|
| Echogenicity | | | | |
| Hyperechogenicity | 173 (96.1) | 7 (3.9) | 1 | |
| Isoechogenicity | 51 (92.7) | 4 (7.3) | 0.89 (0.21-3.87) | 0.880 |
| Hypoechogenicity | 39 (65.0) | 21 (35.0) | 5.91 (2.02-17.30) | 0.001 |
| Calcification | | | | |
| Negative | 207 (94.5) | 12 (5.5) | 1 | |
| Rim calcification | 9 (81.8) | 2 (18.2) | 3.87 (0.62-24.10) | 0.147 |
| Microcalcification | 23 (60.5) | 15 (39.5) | 4.30 (1.39-13.25) | 0.011 |
| Coarse calcification | 18 (90.0) | 2 (10.0) | 1.22 (0.21-7.27) | 0.824 |
| Microcalcification + coarse calcification | 6 (85.7) | 1 (14.3) | 2.39 (0.15-37.61) | 0.534 |
| Composition | | | | |
| Solid-cyst | 60 (98.4) | 1 (1.6) | 1 | |
| Solid | 203 (86.8) | 31 (13.2) | 4.83 (0.60-38.83) | 0.138 |
| Nodule size (mm) | | | | |
| <5 | 67 (94.4) | 4 (5.6) | 1 | |
| ≥5 | 196 (87.5) | 28 (12.5) | 2.85 (0.79-10.25) | 0.108 |
| Taller-than-wide shape | | | | |
| Negative | 257 (91.5) | 24 (8.5) | 1 | |
| Positive | 6 (42.9) | 8 (57.1) | 0.67 (0.14-3.20) | 0.619 |
| Margin of nodule | | | | |
| Regular | 220 (94.0) | 14 (6.0) | 1 | |
| Ill-defined | 40 (72.7) | 15 (27.3) | 4.15 (1.59-10.83) | 0.004 |
| Irregular | 3 (50.0) | 3 (50.0) | 9.17 (1.06-78.82) | 0.043 |

OR: Odds ratio, CI: Confidence interval

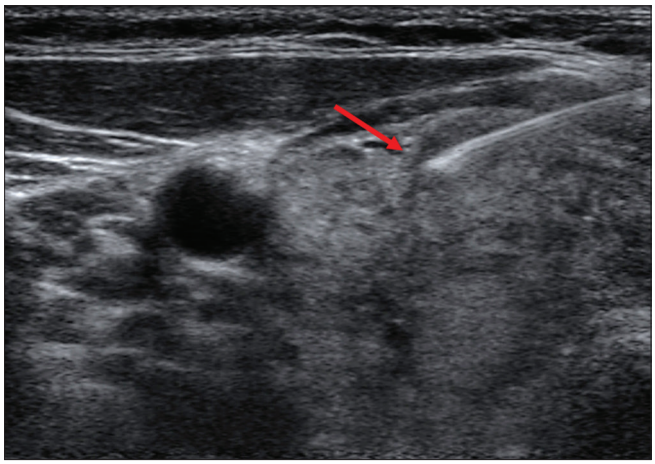

**Figure 3:** The ultrasound-guided fine-needle aspiration from an isoechoic solid nodule with a rim calcification and a diameter of 4.9 mm (EU-TIRADS 3), which was proved by cytology to be a nodular goiter. EU-TIRADS: European Thyroid Imaging Reporting and Data System. Red arrow shows the nodule

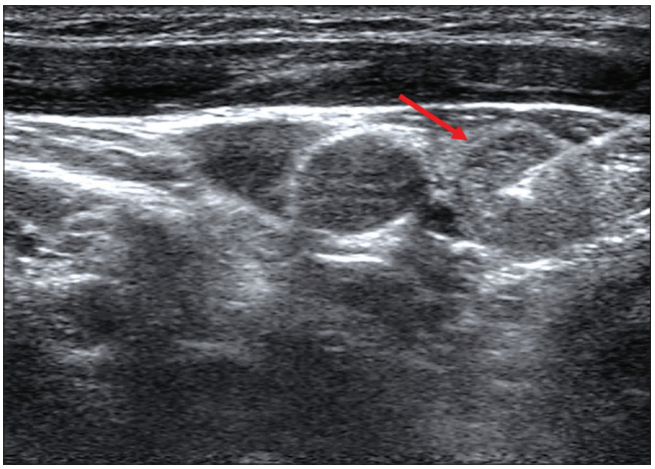

**Figure 4:** The ultrasound-guided fine-needle aspiration from a mildly hypoechoic solid nodule with a regular margin and a diameter of 9.5 mm (EU-TIRADS 4), which was proved by cytology to be a colloid nodule. EU-TIRADS: European Thyroid Imaging Reporting and Data System. Red arrow shows the nodule

the guidelines;[5,12] however, it is noteworthy that none of the nodules <10 mm was malignant in EU-TIRADS class 2, while 2.3% of the nodules ≥10 mm were malignant in the same class. In the study by Kovatcheva *et al*.[13] assessing the diagnostic performance of EU-TIRADS irrespective of nodule size, the malignancy rates in EU-TIRADS classes 2–5 were 0.0%, 0.0%, 3.8%, and 30.6%, respectively, which were somewhat lower than those found in our study; on the other hand, some other studies reported higher malignancy rates compared with our study.[12,14] A recent meta-analysis by Castellana *et al*.[15] reported that the prevalence of malignancy in the EU-TIRADS classes 2–5 is 0.5%, 5.9%, 21.4%, and 76.1%, respectively.

Our findings also showed an acceptable accuracy for EU-TIRADS in diagnosis of malignant thyroid nodules. In both size groups of the nodules, the specificity and NPV were

**Table 4: Association of different sonographic characteristics with cytology findings in thyroid nodules larger than 10 mm**

| Sonographic features | Benign nodules, *n* (%) | Malignant nodules, *n* (%) | OR (95% CI) | *P* |
|---|---|---|---|---|
| Echogenicity | | | | |
| Hyperechogenicity | 533 (93.8) | 35 (6.2) | 1 | |
| Isoechogenicity | 163 (88.6) | 21 (11.4) | 1.08 (0.56-2.09) | 0.801 |
| Hypoechogenicity | 144 (65.8) | 75 (34.2) | 3.81 (2.30-6.33) | <0.001 |
| Calcification | | | | |
| Negative | 634 (92.7) | 50 (7.3) | 1 | |
| Rim calcification | 48 (82.8) | 10 (17.2) | 2.14 (0.95-4.83) | 0.064 |
| Microcalcification | 88 (57.1) | 66 (42.9) | 5.38 (3.27-8.84) | <0.001 |
| Coarse calcification | 57 (95.0) | 3 (5.0) | 0.54 (0.15-1.93) | 0.351 |
| Microcalcification + coarse calcification | 13 (86.7) | 2 (13.3) | 0.97 (0.18-5.23) | 0.979 |
| Composition | | | | |
| Solid-cyst | 113 (98.3) | 2 (1.7) | 1 | |
| Solid | 727 (84.9) | 129 (15.1) | 4.40 (1.03-18.72) | 0.045 |
| Nodule size (mm) | | | | |
| <20 | 500 (83.8) | 97 (16.2) | 1 | |
| ≥20 | 340 (87.9) | 47 (12.1) | 0.84 (0.53-1.33) | 0.466 |
| Taller-than-wide shape | | | | |
| Negative | 816 (88.3) | 108 (11.7) | 1 | |
| Positive | 24 (51.1) | 23 (48.9) | 1.00 (0.46-2.15) | 0.999 |
| Margin of nodule | | | | |
| Regular | 739 (90.8) | 75 (9.2) | 1 | |
| Ill-defined | 89 (65.9) | 46 (34.1) | 2.94 (1.78-4.86) | <0.001 |
| Irregular | 12 (54.5) | 10 (45.5) | 4.45 (1.54-12.81) | 0.006 |

OR: Odds ratio, CI: Confidence interval

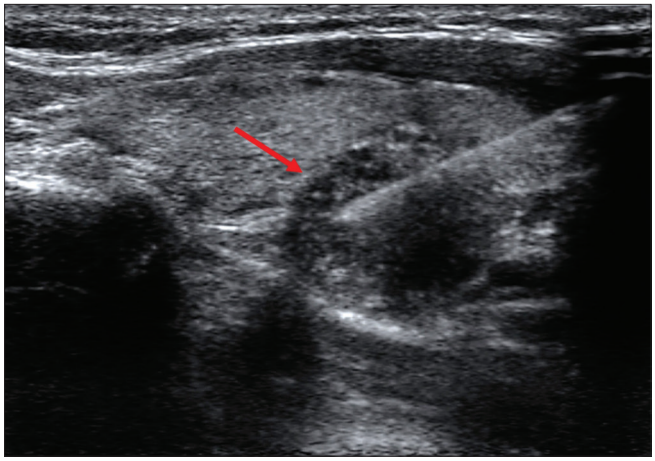

**Figure 5:** The ultrasound-guided fine-needle aspiration from a hypoechoic solid nodule with punctate echogenic foci and a diameter of 15 mm (EU-TIRADS 5), which was proved by cytology to be a papillary carcinoma. EU-TIRADS: European Thyroid Imaging Reporting and Data System. Red arrow shows the nodule

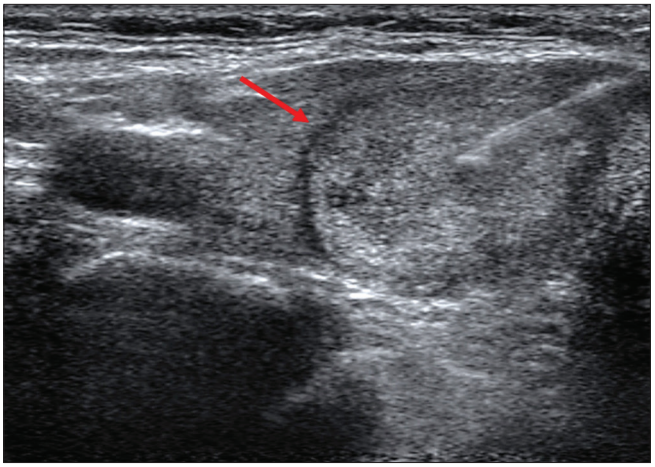

**Figure 6:** The ultrasound-guided fine-needle aspiration from a hyperechoic solid nodule with a regular margin and a diameter of 17 mm (EU-TIRADS 3), which was proved by cytology to be a nodular goiter. EU-TIRADS: European Thyroid Imaging Reporting and Data System. Red arrow shows the nodule.

higher than sensitivity and PPV, respectively, for category 5. When the analyses were done for EU-TIRADS with a cut-off set at 4, sensitivities and NPVs partially increased compared with the category 5; conversely, specificities, PPVs, and accuracies decreased. In a recent meta-analysis by Kim *et al*.,[16] they reported that sensitivity and specificity of EU-TIRADS 5 were 78% (similar to our findings) and 89% (higher than our findings), respectively; these values for EU-TIRADS 4 or 5 were 96% (higher than our findings) and 48% (lower than our findings), respectively. Overall, the differences in the values of diagnostic parameters of EU-TIRADS could partly result from differences in the skills of radiologists or pathologists, as well as quality of the imaging devices, tests per case percentages, etc.

According to the present study, diagnostic parameters of EU-TIRADS for nodules <10 mm and ≥10 mm did not differ significantly; in other words, nodule size did not affect the diagnostic performance of EU-TIRADS guideline. These

findings were in agreement with the study by Trimboli *et al*.,[17] but in contrast to Kovatcheva *et al*.'s study.[13] Overall, as per the EU-TIRADS guideline, FNA biopsy is recommended for the following conditions:[7] (1) category 5: nodules larger than 10 mm, or nodules <10 mm when suspicious lymph nodes are found; (2) category 4: nodules larger than 15 mm; and (3) category 3: nodules larger than 20 mm. Considering the results found in our survey, it is recommended to use EU-TIRADS guideline in assessment of nodules with any sizes for better distinguishing benignity from malignancy, as well as preventing unnecessary FNA biopsies; however, more surveys need to be done to extend our knowledge toward the diagnostic performance of EU-TIRADS guideline comparing with other guidelines.

In the present study, it was observed that hypoechogenicity, microcalcification, ill-defined, and irregular margins were predictors for malignancy in thyroid nodules <10 mm and ≥10 mm. Of course, solid composition was associated with risk of malignancy in nodules ≥10 mm as well. These results were consistent with previously published data.[18,19] On the other hand, nodule size and taller-than-wide shape did not have a significant association with nodule malignancy. It is noteworthy that the number of nodules with a taller-than-wide shape was low; so, these results should be interpreted with caution.

The strength points of this study were mainly its prospective design and a large number of nodules assessed. On the other hand, lack of the histological results of the malignant nodules was a limitation of the present survey. Another limitation was lack of evaluation of atypia and Bethesda classification. Furthermore, it would be more valuable to design new studies comparing the diagnostic accuracy of EU-TIRADS with Artificial Intelligence TIRADS. Moreover, it is proposed to carry out multicenter studies with larger sample sizes of different thyroid cancer types (such as papillary carcinoma, follicular neoplasm, etc.) in the future, in order to better identify the diagnostic performance of EU-TIRADS for these cancers separately.

## Conclusion

The results of the present study demonstrated that EU-TIRADS can provide an acceptable malignancy risk stratification that is helpful for better distinguishing benignity from malignancy, as well as preventing unnecessary FNA biopsies, in thyroid nodules irrespective of their size.

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### Conflicts of interest

There are no conflicts of interest.

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