



The American College of Radiology «White Paper» on risk classification of thyroid nodules (TI-RADS): does it simplify or complicate current classification systems?

Editors
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The American College of Radiology (ACR) has recently issued a «white paper» on cancer risk stratification of thyroid nodules (1), which complements the 2015 document on thyroid ultrasound reporting lexicon (2).

This new initiative stems from:

- The high prevalence of thyroid nodules in clinical practice, which may reach 70% with the use of high-resolution (13 MHz) ultrasound probes
- The benign nature of the large majority of these nodules
- The lenient clinical course and low mortality of most cases of thyroid cancer, particularly if inferior to 1 cm
- The risk of overdiagnosis, i.e. the diagnosis of tumors that would not, if left alone, result in symptoms or death.

According to the ACR, the existing documents on cancer risk stratification of thyroid nodules are complex, occasionally contradictory, and not always supported by available evidence, which may explain their lack of widespread adoption in clinical practice.

The ACR believes that the «White Paper» may be innovative because:

- It uses a common lexicon for the ultrasound characteristics of the nodule
- It is simple to apply in clinical practice
- It can risk-stratify all the nodules
- It is almost completely EBM-based.

The paper is the result of an intense effort by the ACR TI-RADS Committee, based on conference calls, e-mails and online surveys.

ACR TI-RADS

In the document, a thyroid nodule is categorized according to 5 basic ultrasound characteristics: composition, echogenicity, shape, margin, and echogenic foci. The variation within each of these basic characteristics is awarded a score. The sum of the different scores allows the stratification of the nodule into one of 5 levels, each associated with a specific clinical recommendation.

Characteristic	Results	Score
Composition	Spongiform, cystic or almost completely cystic	0 points
	Mixed cystic and solid	1 point
	Solid or almost completely solid	2 points
Echogenicity	Anechoic	0 points
	Hyperechoic or isoechoic	1 point
	Hypoechoic	2 points
	Very hypoechoic	3 points
Shape	Wider-than-taller	0 points
	Taller-than-wider	3 points
Margin	Smooth	0 points
	Lobulated or irregular	2 points
	Extra-thyroidal extension	3 points
Echogenic foci	None or large comet-tail artifacts	0 points
	Macrocalcifications	1 point
	Peripheral (rim) calcifications	2 points
	Punctate echogenic foci	3 points

Summing up the different scores it is possible to derive the following TI-RADS levels:

Final Score	TI-RADS level	Risk of Cancer	Clinical Recommendation	
0 points	TR 1	Benign	No FNA	
Up to 2 points	TR 2	Not Suspicious	No FNA	
3 points	TR 3	Mildly Suspicious	≥1.5 cm	Follow Up
			≥2.5 cm	FNA
4-6 points	TR 4	Moderately Suspicious	≥1 cm	Follow Up
			≥1.5 cm	FNA
≥ 7 points	TR 5	Highly Suspicious	≥0.5 cm	Follow Up (between 5 and 9 mm only in particular situations)
			≥1 cm	FNA

Validation of ACR TI-RADS

The proposed system has been validated through a purposely-established database of more than 3000 nodules (3). Analysis of these data has shown cancer risk levels of no more than 2% for TR1 and TR2 nodules, 5% for TR3 nodules, 5% to 20% for TR4 nodules, and at least 20% for TR5 nodules.

Ultrasound Reporting

The ACR recommends that the report include:

- Measurement of the three axes of the nodule
- Reproducibility of the measures during follow-up
- Location of the nodule if this has the potential to make surgery more complex
- Description of 4 nodules at most
- Nodular growth if increase of the maximum diameter superior to 20% or 50% of the volume
- Timing of future evaluations (ultrasound evaluations to be halted past 5 years if nodule stable)
- Indication for FNA (2 nodules at most).

COMMENTS

Strong points of the «white paper»

The attribution of a score to the main ultrasound characteristics of a thyroid nodule (composition, echogenicity, shape, margin, and echogenic foci) allows a rapid definition of the level of risk, which guides management. The TI-RADS document is already validated at the time of publishing (3).

Controversial Points

TI-RADS, like other systems, does not include the vascularization of the nodule, although its potential use is mentioned in the presence of a mixed nodule or a cystic nodule with a solid component.

The size of the nodule weighs heavily on the decision to proceed to FNA for the levels TR3-TR5. This may lead to the situation where a 1.3 cm solid nodule, hypoechoic and with irregular margin (score of 6, TR 4) is not submitted to FNA because its size is less than 1.5 cm. In clinical practice, a patient informed that this kind of lesion may entail a risk of cancer between 5% and 20%, may find difficult to accept this advice.

Another point of debate seems to be the advice to discontinue ultrasound surveillance in the presence of a nodule stable at 5-year follow-up.

Comparison with the clinical practice guidelines of the American Thyroid Association (ATA) and the Korean Thyroid Association (KTA)

In TI-RADS there are frequent references to these two documents. The ATA proposes 5 levels, like the ACR, but the two systems differ in their FNA recommendations for the three intermediate levels, with the ACR favoring a less invasive approach. In the TR2 level, for example, the ACR does not suggest FNA, while the ATA recommends FNA for nodules more than 2 cm. In the TR3 and TR4 levels the size threshold for FNA proposed by the ATA is lower than for the ACR (1.5 vs. 2.5 cm and 1.0 vs. 1.5 cm, respectively).

The ACR document appears particularly conservative when confronted with the guidelines of the KTA (K-RADS). The K-RADS includes *de facto* 4 levels, because level 1 corresponds to absence of nodules. Differently from the ACR and the ATA, K-RADS proposes FNA for benign nodules (TR 2) if their size is more than 2 cm. In analogy to the suggestions of the ATA, the threshold for FNA for lesions in the intermediate levels is expanded to nodules smaller than that suggested by the ACR.

CONCLUSIONS

In the presence of nodules clearly benign or, conversely, highly suspicious, the management recommendations of the ACR overlap with those of the ATA and the KTA. Between these extremes, however, the three systems of stratification differ in the number and characteristics of individual levels, with consequent variation in clinical management.

Contrary to the stated goal of the ACR, the number of levels of stratification proposed may have added to complexity, making it more difficult to allocate a lesion to a specific level.

An attempt at simplification is the classification proposed by the American Association of Clinical Endocrinology-Associazione Medici Endocrinologi (AACE-AME) (6), which defines only 3 levels. While the definitions of benign and highly suspicious nodules do not differ from the levels proposed by the ACR, the ATA, and the KTA, the presence of a single intermediate class in the AACE-AME classification seems to make it more suitable for use in clinical practice. The trend towards reduced complexity is shared by other scientific societies, from the original 6 levels of Howarth, one of which divided into 2 subgroups, to the 5 levels of the ATA (2015) (4) and of the ACR (2017) (1), to the 4 of the KTA (2016) (5), to the 3 of the AACE-AME (2016) (6).

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