Nodules—a type of abnormality detected by ultrasound—are extremely common in the thyroid gland. Up to two-thirds of adults have nodules in this gland, and most are benign or only cause a slow-growing cancer that
is no threat to life.

A minority are aggressive cancer that requires treatment, leaving physicians and patients with a problem—which nodules need to be biopsied for malignancy tests, which nodules show a small risk and merit observation without a biopsy, and which need no follow-up at all?

"If you have a cancer that is not going to harm you, and you are not aware of it, is it useful to do a fine-needle aspiration?" said Franklin Tessler, M.D., C.M, a professor in the University of Alabama at Birmingham Department of Radiology. "People are asking, what are we doing? Are we using scarce resources wisely?"

Thyroid cancers are greatly over-diagnosed in the United States. About three-quarters of thyroid cancers in women and nearly one-half in men would not—if the nodules had been left alone and not biopsied with a needle—resulted in symptoms or death.

Tessler and a national committee of experts have now published American College of Radiology guidelines for an ultrasound-based risk stratification system to identify nodules that warrant biopsy or sonographic follow-up. The guidelines, they write, are "designed to identify most clinically significant malignancies while reducing the number of biopsies performed on benign nodules."

"This potentially will have a big public health effect," said Tessler, who is also the Radiology executive vice chair and medical director, vice chair for Radiology Informatics, and division director of Diagnostic Radiology. The 15 co-authors on the blue-ribbon committee with Tessler are at Washington University School of Medicine; Keck School of Medicine, University of Southern California; Duke University School of Medicine; the University of Alabama at Birmingham; Brown University; Stanford University Medical Center; Brigham and Women's Hospital;
Hammers Healthcare Imaging, New Haven, Connecticut; Yale School of Medicine; Johns Hopkins University, School of Medicine; the University of Pennsylvania; Mayo Clinic College of Medicine; and the University of Texas Health Sciences Center.

Their Thyroid Imaging, Reporting and Data System, or TI-RADS, is modeled after the American College of Radiology's BI-RADS, a widely accepted risk stratification system for breast lesions.

The experts sought guidelines that are 1) founded on ultrasound features defined in their previously published lexicon; 2) easy to apply across a wide gamut of ultrasound practices; 3) able to classify all thyroid nodules; and 4) evidence-based, to the greatest extent possible, with the aid of underlying data on 3,800 nodules and more than 100,000 cancers.

Their new guidelines follow many attempts over the past 15 years to create guidelines for whether to do a fine-needle aspiration biopsy. Most are based on details of the appearance and size of nodules that are visualized with high-resolution ultrasound.

But "the plethora, complexity and lack of congruence of these systems has limited their adoption by the ultrasound community and inspired our effort to publish a classification system under the auspices of the American College of Radiology," Tessler and colleagues write.

The American College of Radiology TI-RADS has five different categories for nodule appearance—composition, echogenicity, shape, margin and echogenic foci. The shape category has two choices—wider-than-tall vs. taller-than-wide. The other four categories have four choices each, such as "hypoechoic" under the category echogenicity or "lobulated or irregular" under margin. Each choice as a point value, ranging from 0 to 3 points. "Wider-than-tall," for example, is 0 points, and "taller-than-wide" is 3 points.
As the authors explain, "Points are given for all the ultrasound features in a nodule, with more suspicious features being awarded additional points. ... When assessing a nodule, the reader selects one feature from each of the first four categories and all the features that apply from the final category and sums the points. The point total determines the nodule's ACR TI-RADS level, which ranges from TR1, benign, to TR5, high suspicion of malignancy."

If the sum is 0 points, the nodule is TR1 and the guidelines recommend no fine-needle aspiration or follow-up. If the sum is 2 points, the nodule is TR2, or "not suspicious," and the guidelines recommend no fine-needle aspiration or follow-up.

A sum of 3 points is TR3, or "mildly suspicious." For these nodules, the guidelines recommend fine-needle aspiration if the nodule is 2.5 centimeters or greater, or about 1 inch or more, and they recommend follow-ups with subsequent ultrasounds if it is 1.5 centimeters or greater.

TR4 nodules, or "moderately suspicious," are 4 to 6 points, and TR5 nodules, or "highly suspicious," are 7 points or more. For TR4 nodules, the guidelines recommend fine-needle aspiration if the nodule is 1.5 centimeters or greater and follow-ups if it is 1 centimeter or greater. For TR5 nodules, the guidelines recommend fine-needle aspiration if the nodule is 1 centimeter or greater and follow-ups if it is 0.5 centimeters or greater.

The guidelines recommend limiting fine-needle aspiration to two nodules per patient because biopsy of three or more nodules is poorly tolerated by patients, and the third biopsy increases cost with little added benefit and some additional risk. The guidelines also suggest appropriate timing for follow-up sonograms.
"The ACR TI-RADS is designed to balance the benefit of identifying clinically important cancers against the risk and cost of subjecting patients with benign nodules or indolent cancers to biopsy and treatment," the authors write. "Our recommendations for follow-up ultrasound substantially mitigate the possibility that significant malignancies will remain undetected over time and are concordant with the increasing trend toward active surveillance, or 'watchful waiting,' for low-risk thyroid cancer."

Their white paper, "ACR thyroid imaging, reporting and data system (TI-RADS): White paper of the ACR TI-RADS committee," was published in the *Journal of the American College of Radiology*.


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