

Ultrasonography-Based Classification and Reporting System for the Malignant Risk of Thyroid Nodules

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Objective: The aim of this study was to test the predictive value of a Thyroid Imaging Reporting and Data System (TI-RADS) for malignant thyroid nodules.

Methods: Ultrasonographic data was examined for 910 thyroid nodules with histopathologically confirmed diagnoses. Nodules were placed into incomplete (category 0) or complete final categories (1, 2, 3a, 3b, 3c, 4, or 5) based on the presence and number of ultrasonographic features of malignancy, and the predictive value for the malignancy of nodules in categories 2–4 was assessed.

Results: The overall rate of malignancy among thyroid nodules included in the study was 59.34%. The rate of malignancy gradually increased according to TI-RADS categories as follows: category 2, 5.4%; category 3 (a–c), 36% to 92%; and category 4, 99.0%. When nodules of category 2 were counted as benign, the reliability of the TI-RADS classification for determining the risk of malignancy was as follows; sensitivity, 98.15%; specificity, 47.84%; positive predictive value, 73.31%; negative predictive value, 94.65%; and odds ratio, 48.61.

Conclusions: The TI-RADS classification used in this study is relatively simple and provides a reliable measure of the risk of malignancy of thyroid nodules. (*J Nippon Med Sch* 2017; 84: 118–124)

Key words: thyroid nodules, ultrasonography, Thyroid Imaging Reporting and Data System

Introduction

Thyroid nodules have become increasing common. To evaluate these nodules, the optimal technique is believed to be high-resolution ultrasonography^{1–3}, and research has focused on identifying reliable ultrasonographic features to predict malignant potential and guide further clinical decision-making. The Thyroid Imaging Reporting and Data System (TI-RADS) was proposed in 2009^{4,5}, and many clinical studies have examined its various methods of classification^{1,6–8}. However, these classification methods are complex and difficult to master and have been slowly accepted. Individual ultrasonographic signs that have been associated with malignant thyroid nodules include a height-to-width ratio >1, marked hypoechogenicity, microcalcifications, and irregular borders^{9–11}. With these signs we formulated a simple TI-RADS classification scheme for determining the risk of malignancy in thyroid

nodules. To test the feasibility of the TI-RADS classification method we compared the results with surgical pathology reports.

Methods

Patients

Enrolled as subjects for this study were patients who had undergone thyroidectomy at the Affiliated Union Hospital of Fujian Medical University from January 2013 through October 2014. Inclusion criteria were preoperative thyroid ultrasonographic data that was stored in the Picture Archiving and Communication Systems (PACS) and could be classified according to the TI-RADS criteria; confirmed postoperative histopathological diagnoses in pathologists' reports that included clear descriptions of the locations and sizes of the nodules corresponding to the preoperative ultrasonographic findings; and ultra-

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sonographic examinations performed within 8 weeks before surgery. The final subjects were 812 patients, 203 male and 609 female, aged 12 to 77 years (mean age, 46.42 years) with 910 thyroid nodules. Written informed consent was obtained from all subjects or their guardians. This study was approved by the Ethics Committee of Fujian Medical University and was performed in accordance with the Declaration of Helsinki.

Ultrasonography protocol

Multislice scanning of the bilateral thyroid lobes and isthmus was performed with a color Doppler ultrasonography system (GE LOGIQ E9, GE Medical Systems, Milwaukee, WI, USA, or Toshiba Aplio 500, Toshiba Medical Systems Co., Tochigi, Japan) with 10- to 14-MHz linear array high-frequency probes. The examinations were performed in the preset thyroid mode, and the gain, depth, and focusing sites were adjusted according to patient-specific circumstances to ensure that the images would be displayed clearly. Examinations were performed with the patient in a supine position and the patient's head leaning back to fully expose the anterior part of the neck. Each nodule was described in detail according to location, size, relationship with the capsule, shape, height-to-width ratio, edges, borders, structural components, echogenicity, and calcifications. The cervical lymph nodes were sequentially scanned, and ultrasonographic features of the lymph nodes were recorded. All images were stored in a PACS workstation.

Ultrasonographic criteria for the TI-RADS

Based on ultrasonographic findings of malignant thyroid nodule that well accepted in the correlative literature⁹⁻¹², the following ultrasonographic signs were chosen to assess the possible malignancy of the nodule: (1) ratio of the anteroposterior to transverse diameter on the maximal longitudinal plane (height-to-width ratio) >1 ; (2) irregular boundary, including miniscule sublobules or angulation in partial or complete nodule borders; (3) marked hypoechogenicity in comparison to the echogenicity of the muscles of the anterior part of the neck; (4) internal microcalcifications (diameter of hyperechoic spots <1 mm); (5) breach in the thyroid capsule; and (6) signs of metastasis to the cervical lymph nodes, including microcalcifications, liquefied zones, and diffuse or focal hyperechoic areas (Fig. 1).

TI-RADS classification

According to the ultrasonographic features, nodules were classified with the TI-RADS into a total of 6 categories: an incomplete category (category 0) and 5 complete final categories (categories 1–5).

Category 0: the thyroid gland showed heterogeneous echoes, without nodule

Category 1: benign nodules; i.e., colloidal nodules and cysts

Category 2: possible benign nodules; i.e., the nodules did not exhibit any of the ultrasonographic signs of malignancy

Category 3: malignant nodule or possible malignancy could not be ruled out; i.e., the nodule was found to have 1 or more of the ultrasonographic features of malignancy

Category 3a: the nodule has 1 sign of malignancy

Category 3b: the nodule has 2 signs of malignancy

Category 3c: the nodule has 3 signs of malignancy

Category 4: strong possibility of malignancy; i.e., the nodule has ≥ 4 signs of malignancy

Category 5: malignancy confirmed with fine needle aspiration (FNA) cytology

Nodules that exhibited at least 1 of the ultrasonographic features of malignancy accompanied by a breach in the thyroid capsule or signs of malignancy in the lymph nodes of the adjacent basin were classified as category 4. Multiple nodules were evaluated individually.

All ultrasonographers who performed the prospective assessment were experienced and familiar with this classification method, and each nodule was evaluated by at least 2 ultrasonographers. The image classification and assessment of the thyroid nodules in the PACS workstation were performed before surgery.

Statistical analysis

The SPSS software package (SPSS for Windows, version 16.0; SPSS Inc., Chicago, IL, USA) was used to analyze the relevant data. The *t*-test was used to compare the differences in age and nodule size between patients with benign or malignant nodules, and the χ^2 test or Fisher's exact comparison was performed to compare differences of sex and features of malignancy between benign and malignant nodules and the risk of malignancy among TI-RADS categories (categories 2–4). All hypothesis tests were 2-sided, with $P<0.05$ indicating statistical significance. The sensitivity, specificity, positive predictive value, negative predictive value, and odds ratio were analyzed, with nodules in TI-RADS category 2 considered benign and those in categories 3 and 4 considered malignant.

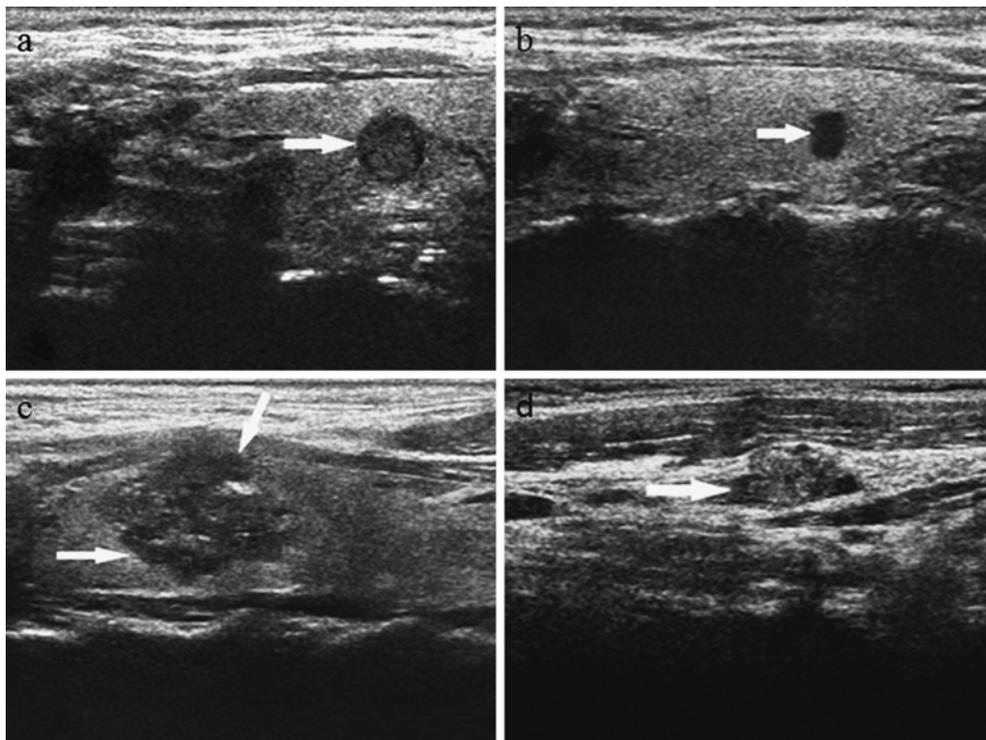


Fig. 1 Ultrasonographic signs of malignancy in thyroid nodules
a: Left thyroid nodule. Nodule (**arrow**) exhibited hypoechogenicity, with height-to-width>1. **b:** Left thyroid nodule. Nodule (**arrow**) exhibited markedly hypoechogenicity, with height-to-width>1. **c:** Right thyroid nodule. Nodules (**arrows**) showed irregular borders, broke through the capsule, and showed hyperechoic spots inside the nodules. **d:** Metastasis of thyroid cancer in right neck lymph node. The lymph node (**arrow**) showed focal hyperechoic regions and microcalcifications inside.

Table 1 Relationship between TI-RADS category and pathological types of thyroid nodules [n (% of pathologic type)]

	Pathological type	Category 2	Category 3a	Category 3b	Category 3c	Category 4	Nodules
Benign	Adenomatous hyperplastic nodule	117 (44.82)	83 (31.80)	54 (20.70)	7 (2.68)	0 (0.00)	261
	Adenoma	56 (58.95)	26 (27.37)	9 (9.47)	3 (3.16)	1 (1.05)	95
	Atypical adenoma	4 (33.33)	4 (33.33)	1 (8.33)	3 (25.00)	0 (0.00)	12
	Other benign nodule	0 (0.00)	1 (50.00)	0 (0.00)	1 (50.00)	0 (0.00)	2
Malignant	Papillary carcinoma	8 (1.53)	57 (10.92)	171 (32.76)	161 (30.84)	125 (23.95)	522
	Follicular carcinoma	2 (28.57)	2 (28.57)	3 (42.86)	0 (0.00)	0 (0.00)	7
	Medullary carcinoma	0 (0.00)	3 (37.50)	1 (12.50)	0 (0.00)	4 (50.00)	8
	Other malignant nodule	0 (0.00)	2 (66.67)	0 (0.00)	0 (0.00)	1 (33.33)	3
Total		187	178	239	175	131	910

Results

Relationship between histopathological diagnoses and TI-RADS category

Included in the study were 910 thyroid nodules, of which 370 were benign and 540 (59.34%) were malignant, from 812 patients. The relationship between histopathological diagnoses and TI-RADS category is shown in **Table 1**.

Factors associated with malignancy

Patients with malignant nodules had a mean age (44.61 ± 12.01 years) statistically lower than that of patients with benign nodules (48.72 ± 12.69 years, $t=4.509$, $P<0.001$). Furthermore, malignant nodules (1.31 ± 1.10 cm) were significantly smaller than benign nodules (2.77 ± 1.55 cm, $t=15.616$, $P<0.001$). Both benign nodules and malignant nodules were more common in female patients than in male patients; however, the male/female ratios of benign

Table 2 Comparison the 6 sonographic features between benign and malignant nodules

Factor	Malignant	Benign	Total	Sensitivity	Specificity
Height-to-width ratio	179 (92.75)	14 (7.25)	193	33.15%	96.22%
Microcalcification	259 (81.70)	58 (18.30)	317	47.96%	84.32%
Markedly hypoechogenicity	88 (95.65)	4 (4.35)	92	16.30%	98.92%
Irregular edge	410 (82.16)	89 (17.84)	499	75.93%	75.95%
Capsule-breaking	60 (96.77)	2 (3.23)	62	11.11%	99.46%
Lymph node metastasis	95 (95.96)	4 (4.04)	99	17.59%	98.92%

Note: The comparison of 6 sonographic features between the benign and malignant groups appear to be statistically significant ($P=0.000$, using the chi-square test). Number in parenthesis is percent of nodules with this factor to be this type of nodule.

Table 3 Malignant risk comparison of different TI-RADS classified nodules (%)

	Category 2	Category 3a	Category 3b	Category 3c	Category 4	All categories
Malignant	10 (5.35%)	64 (35.96%)	175 (73.22%)	161 (92.00%)	130 (99.24%)	540 (59.34%)
Benign	177 (94.65%)	114 (64.04%)	64 (26.78%)	14 (8.00%)	1 (0.76%)	370 (40.66%)
All nodules	187	178	239	175	131	910

Note: For each category, the number of malignant nodules and benign nodules differed significantly, $P=0.000$.

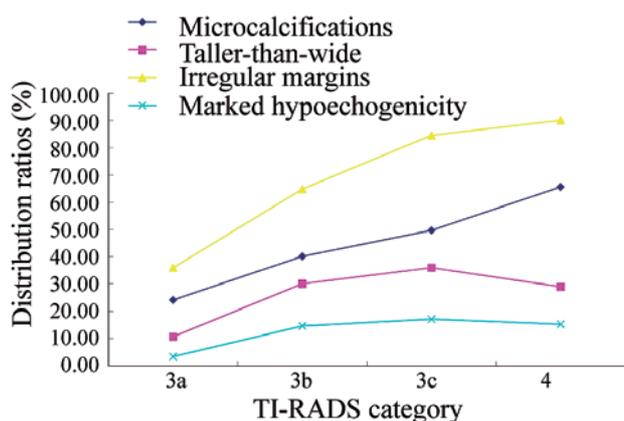


Fig. 2 Distribution ratios of 4 ultrasonographic signs of malignancy in each TI-RADS category.

nodules (0.332) and malignant nodules (0.330) did not differ significantly ($\chi^2=0.001$, $P=0.976$).

The following ultrasonographic features of malignancy were significantly more common (χ^2 test, $P=0.000$) among malignant nodules than among benign nodules: height-to-width ratio>1, microcalcifications, marked hypoechogenicity, irregular borders, breach of the thyroid capsule, and lymph node metastases. The sensitivities and specificities, respectively, of the 6 malignant ultrasonic signs in diagnosing malignant thyroid nodules were as follows: height-to-width ratio>1, 33% and 96%; microcalcification, 48% and 84%; irregular margin, 76% and 76%; extremely low echo, 16% and 99%; nodule-breakthrough thyroid

capsule, 11% and 99%; and lymph node metastasis, 18% and 99% (Table 2).

Relationship between TI-RADS category and ultrasonographic features of malignancy

The number of nodules of each category was as follows (Table 3): category 2, 187 nodules (20.5%); category 3a, 178 nodules (19.6%); category 3b, 239 nodules (26.3%); category 3c, 175 nodules (19.2%); and category 4, 131 nodules (14.4%). Of 4 ultrasonographic features of malignancy (Fig. 2), marked hypoechogenicity was rare in category 3a, height-to-width ratio>1 was common in categories 3b and 3c, and the occurrence microcalcifications and irregular borders increased with increasing TI-RADS category.

The proportion of malignant nodules in each TI-RADS category was gradually increased. The χ^2 test showed a significant difference in distribution of benign and malignant nodules among TI-RADS categories 2, 3a, 3b, and 3c ($P=0.000$) (Table 3). The area under the receiver-operating curve for TI-RADS classification diagnosis was 0.894 (95% confidence interval, 0.874–0.915) (Fig. 3). When nodules in TI-RADS category 2 were considered benign and those in categories 3 and 4 were considered malignant, the following values of the TI-RADS classification scheme were obtained: sensitivity, 98.15%; specificity, 47.84%; positive predictive value, 73.31%; negative predictive value, 94.65%; and odds ratio, 48.61 (95% confidence interval, 25.172–93.858).

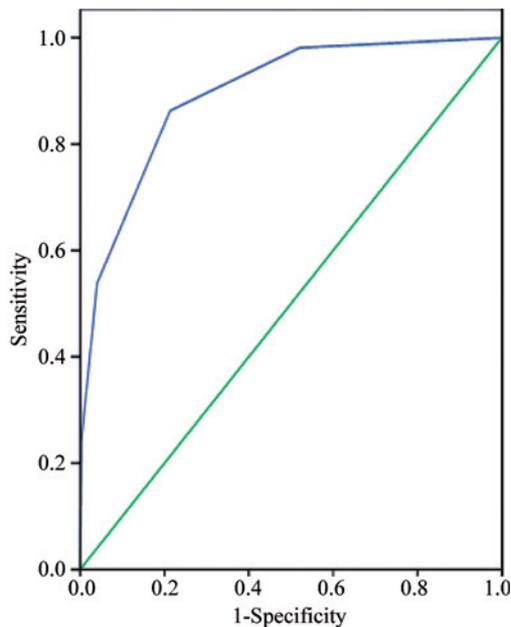


Fig. 3 Receiver operating characteristic (ROC) curve of TI-RADS classification method in diagnosing benign and malignant thyroid nodules.

Discussion

The Breast Imaging Reporting and Data System (BI-RADS) was published in 1992 by the American College of Radiology to guide the assessment of breast lesions¹³ and is now in its fifth edition. In 2009, the BI-RADS was referred to in the first proposal of the concept of a TI-RADS to systematically diagnose and assess the risk of malignancy of thyroid nodules on the basis of ultrasonographic features^{4,5}. Several TI-RADS have been investigated, and all are based on the presence or absence of nodules and the presence of ultrasonographic features that have been associated with the risk of malignancy. Systems have either 6 categories (categories 1–6)^{5,6,12,14} or 7 categories (categories 0–6)¹⁵. Nodules are classified into the following categories: absent, category 0 or 1; without ultrasonographic signs of malignancy (benign), category 1 or 2; probably benign, category 2 or 3; possibly malignant, category 4 (with subcategories a and b or a-c, depending on the number of findings suggestive of malignancy), highly suspicious for malignancy, category 5; and confirmed malignant with FNA, category 6.

In contrast, the BI-RADS classification of breast masses includes an incomplete category, category 0, that indicates that the examination is indeterminate and must be supplemented with additional imaging, and complete final categories. The BI-RADS category 1 includes examinations that show no signs of malignancy or masses but

have findings consistent with fibrocystic disease or dysplasia¹³. Because breast diseases and thyroid diseases differ in natural history and prognosis, the BI-RADS classification scheme cannot be automatically applied to the TI-RADS.

One purpose for using the TI-RADS is to confirm the presence of thyroid nodules. When thyroid nodules are not detected with ultrasonography, no other imaging is required, because ultrasonography is the most reliable method of detection. Categories 0 and 1 of the BI-RADS could be merged as the incomplete category (category 0) in the TI-RADS, and normal thyroids do not need to be included in the TI-RADS classification. Therefore, when the echogenicity of the thyroid parenchyma is inhomogeneous despite nodules being neither confirmed nor ruled out, the result should be placed in category 0 (incomplete). If a nodule is found, the result can be placed in a complete category (1–5), depending on the risk of malignancy.

We evaluated a TI-RADS comprised of the following categories.

Category 0 (incomplete). The echogenicity of the thyroid substance was inhomogeneous, but no nodule was confirmed or excluded. For example, the ambiguous nodules of Graves' disease and Hashimoto's thyroiditis, which would need further follow-up and observation, would be in Category 0.

Category 1: benign

Category 2: might be benign

Category 3: suspicion of malignancy. Category 3 is further subdivided into categories 3a, 3b, and 3c, according to the risk of malignancy.

Category 4: highly suspicious of malignancy

Category 5: malignancy confirmed by cytology

Based on the various ultrasonographic features of malignancy, diffuse thyroid malignancies such as diffuse sclerosing papillary carcinoma and diffuse lymphoma can be classified as category 3a, 3b, 3c or 4.

Although the classification of thyroid nodules as benign or malignant according to ultrasonographic findings has been reported by several authors^{4,5,12,16}, these methods are too complex for routine clinical use and cannot be easily standardized. In the present study, we aimed to develop a convenient and reliable TI-RADS¹⁷. Proposals^{6,14} have been made to include 4 signs—height-to-width ratio >1, microcalcification, marked hypoechogenicity, and irregular borders—in TI-RADS classifications that are easily mastered and can be uniformly applied. In addition to these 4 signs, a breach in the thyroid capsule and cer-

vical lymph node metastasis are considered signs of malignancy; thus, the TI-RADS classification proposed in the present study includes 6 key ultrasonic features that are used to evaluate the risk of malignancy in thyroid nodules. When histopathologic diagnoses were examined, these ultrasonographic features were more commonly observed for malignant nodules than for benign nodules, and the differences were statistically significant.

This study further analyzed the distribution of the ultrasonographic features of malignancy signs among all nodules classified with the TI-RADS. The present results showed that the prevalence of microcalcifications and irregular borders increased with the malignant risk of TI-RADS category, indicating that when these 2 signs are present, the possibility of malignancy is increased. Marked hypoechogenicity is a ultrasonographic feature that is specific to malignant thyroid nodules and is closely associated with papillary carcinoma^{9,18}. In the present study marked hypoechogenicity was rare among nodules in category 3a, indicating that this sign has an extremely low probability of appearing in thyroid nodules if other signs of malignancy are absent. Because cystic papillary thyroid cancer is extremely rare¹⁹ and solid benign thyroid nodules are extremely common, a solid nodule cannot become a sign to assess benign and malignant nodules. Because color Doppler ultrasonography has no clear indicator for discriminating benign and malignant nodules²⁰⁻²² and because ultrasound elastography technology is immature^{23,24}, these 2 modes were not used to examine the thyroid nodules included in the present study.

Standards of care dictate that when the risk of disease is low, such as <1% for acute coronary heart disease or 0.5% for breast cancer, further clinical evaluation is not needed. When the risk of thyroid cancer is being considered on the basis of ultrasonographic imaging, when can FNA cytology be avoided?²⁵ Rates of malignancy have varied from 1.7% to 29.8% among nodules classified with a TI-RADS as benign, from 3.3% to 80% among nodules classified as suspicious for malignancy, and from 64.8% to 100% among nodules classified as highly suspicious for malignancy^{4-6,12,14}. In the present study, the rates of histopathologically confirmed malignancy were 5.4% in nodules of TI-RADS category 2, 36% to 92% in nodules of category 3a to 3c, and 99.0% in nodules of category 4. If nodules of category 2 were regarded as benign while those of categories 3 and 4 were regarded as malignant, the chance of misdiagnosis of malignancy was low (sensitivity=98% and negative predictive value=95%), but the

false-positive rate was higher (specificity=48% and positive predictive value=73%). These results were probably due to the rate of malignancy among nodules classified as TI-RADS category 3a being as low as 36%. These results suggest that nodules in TI-RADS category 2, i.e., those without the predefined ultrasonographic features of malignancy, do not require FNA biopsy. The need for FNA among nodules in TI-RADS category 3a may vary, whereas immediate FNA should be recommended for nodules of TI-RADS category 3b or higher.

The advantages of ultrasonographic imaging of the thyroid gland can be further refined according to the occurrence and development of thyroid diseases and their prognostic characteristics, thereby further improving TI-RADS classification methods to optimize diagnosis and follow-up for patients with thyroid nodules and minimizing unnecessary surgery. The TI-RADS classification method presented here is convenient and reliably predicts the risk of malignancy for thyroid nodules and, thus, has the potential to guide the appropriate treatment and improve its clinical value.

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