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Original paper

Diagnostic reliability of the Thyroid Imaging Reporting and Data System (TI-RADS) in routine practice

Allen San Shell Jabar[A,B,C,D,E,F], Prakashini Koteshwara[A,B,C,D,E,F], Jasbon Andrade[A,B,C,D,E,F]

Department of Radiodiagnosis and Imaging, Kasturba Medical College, Manipal Academy of Higher Education (MAHE), Manipal, India

Abstract

Purpose: To evaluate the diagnostic reliability of Thyroid Imaging Reporting and Data System (TI-RADS) classifications described by American College of Radiology (ACR) and Kwak *et al.* by calculating the risk of malignancy, to assess the role of TI-RADS in reducing fine-needle aspiration cytology (FNAC) of benign lesions.

Material and methods: This was a prospective study during the period from December 2017 to August 2018. Thyroid nodules were classified using ACR TI-RADS and TI-RADS proposed by Kwak *et al*. The TI-RADS categorisations were compared to the final diagnosis obtained by cytopathological/histopathological analysis. The risk of malignancy for each category was calculated. Sensitivity, specificity, and positive and negative predictive values for individual suspicious ultrasound features were also assessed.

Results: We evaluated a total of 127 thyroid nodules. The risk of malignancy was 0% in ACR TR1, 0% in ACR TR2, 6.9% in ACR TR3, 29.2% in ACR TR4, and 80% in ACR TR5 categories. The risk of malignancy for TI-RADS according to Kwak *et al*. were 0%, 0%, 21.5%, 32.4%, 100% for TI-RADS 2, 3, 4A, 4B, and 4C categories, respectively. Kwak TI-RADS 2 and 3 had higher sensitivity in predicting benignity compared to ACR TR1 and 2 (35.4% vs. 25.9%).

Conclusions: We found TI-RADS classification to be a reliable, non-invasive, and practical method for assessing thyroid nodules in routine practice. TI-RADS can safely avert avoidable FNACs in a significant proportion of benign thyroid lesions.

Key words: thyroid imaging reporting and data system, thyroid ultrasound, ACR-TI-RADS, Kwak TI-RADS, thyroid nodule, fine-needle aspiration cytology.

Introduction

High-resolution sonography is a safe, valuable, nonionising, cost-effective, readily available imaging tool for identification of clinically suspected thyroid nodules. Various studies mentioned a prevalence of 2-6% of thyroid lesions on palpation, 19-35% on sonography, and 8-65% in autopsy data [1]. Fine-needle aspiration cytology (FNAC) remains pivotal for the assessment of thyroid nodules, but it is mildly distressing, leads to additional healthcare costs, and contains rare a low risk of infection and scarring [2]. There is a growing need to craft and utilise a dependable ultrasound categorisation for evaluating thyroid nodules and discriminating benign and malignant lesions with a reasonable level of certainty, through which we could also cut short a number of unnecessary invasive FNACs. Numerous studies have proposed a thyroid imaging reporting and data system (TI-RADS). These studies also brought to light a significant number of parameters for quantitative analysis of sonographic features [3,4]. However, the implication of these parameters differed in each study. We investigated the TIRADS classifications proposed in 2011 by Kwak *et al*. and the 2017 ACR-TI-RADS [5,6]. The Kwak TI-RADS is simple and similar to BI-RADS system, which has been in use for several years and is familiar to most radiologists. In ACR-TI-RADS points are given

Correspondence address:
Dr. Prakashini Koteshwara, Department of Radiodiagnosis and Imaging, Kasturba Medical College, Manipal Academy of Higher Education (MAHE), Manipal, India, e-mail: docprakashinik@yahoo.co.in

for various ultrasound features in a thyroid nodule, with more suspicious features being awarded additional points. When assessing a nodule, its point total determines the nodule's ACR TI-RADS stage, which varies from TR1 (benign lesion) to TR5 (high suspicion of malignancy) [6,7]. This study was performed to prospectively investigate the diagnostic reliability of the aforementioned TI-RADS classification system in differentiating benign and malignant lesions by stratifying the risk of malignancy separately for individual TI-RADS categories and for various ultrasound features. We also wanted to estimate the decrease in the number of unnecessary FNACs.

Material and methods

This was a hospital-based, time-bound, prospective study conducted between December 2017 and August 2018 (a period of nine months) in the Department of Radiodiagnosis and Imaging. Institutional Ethics Committee approval was obtained prior to this prospective study. The study group comprised of 127 patients referred to the Department of Radiodiagnosis with clinically suspected thyroid nodules. These patients underwent conventional high-resolution sonography, and depending on the presence or absence of various sonographic features the thyroid nodules were categorised according to TI-RADS classification. The study required an invasive investigation (FNAC) to be conducted on patients. Informed consent was obtained from every patient. All patients who did not give consent for FNAC and those with bleeding diathesis were excluded from the study. Cases with nondiagnostic or indeterminate cytology results were also excluded from our study. In cases where thyroid biopsy/surgery were performed, both the sonographic and cytopathology results were followed up with the final histopathology report.

Sonography technique

Ultrasound evaluation was performed on a Philips Epiq 5G ultrasound machine using a high-frequency linear L18-5 probe.

With the patient supine and neck hyper-extended, the entire gland was examined. Hyperextension of the neck was obtained by placing a pad under the shoulders. The neck was scanned in sagittal, transverse, and oblique sections to optimally visualise both lobes of the thyroid and isthmus. Imaging of the lower poles of thyroid was done by making the patient swallow, because this tends to raise the thyroid gland in the neck.

Specific attention was prospectively directed to nodule characteristics (like composition, shape, echogenicity, margins, and echogenic foci) as those used in the ACR lexicon to describe thyroid nodules [7]. Points were assigned to each nodule for the separate categories according to ACR-TI-RADS guidelines [6]. The sum of the points in each category determined the TI-RADS level

assigned to each nodule, with TR1 indicating 0 points; TR2 – 2 points; TR3 – 3 points; TR4 – 4-6 points; and TR5 – 7 or more points. The data obtained from the ACR point table were used to assess the Kwak TI-RADS category because the five suspicious features mentioned by Kwak *et al.* were a subset of the nodule characteristics described in the ACR lexicon. These suspicious features included: solid composition, marked hypoechogenicity, microcalcification, taller than wide shape, and irregular margins. Our analysis differed slightly from the lexicon of the Kwak TI-RADS committee with respect to margin shape. In studies conducted by Srinivas *et al.* and Chandramohan *et al.*, who assessed Kwak TI-RADS, ill-defined margins were included under irregular margin characteristics, and they found statistically significant correlation with malignancy [8,9]. In the ACR point table both ill-defined and irregular margins are categorised separately under margin characteristics, with the former lacking points and the latter contributing 2 points. According to the guidelines of the ACR TI-RADS committee, if composition, echogenicity, or margins could not be determined for any reason like dense posterior acoustic shadowing from macrocalcification, they were allocated 2, 1, or 0 points, respectively.

Ultrasound-guided fine-needle aspiration cytology technique

Ultrasound-guided FNAC of dominant or suspicious nodule was performed. The majority of FNACs were performed on an outpatient basis. FNAC was performed using a 23-gauge needle attached to a 10-ml syringe. Two to three aspirations were performed on each nodule and cytology smears prepared for analysis. FNAC cases that were non-diagnostic were included in the final analysis only if surgical histopathology was available.

Statistical analysis

Collected data was entered into a Microsoft Excel data sheet and were analysed using the SPSS 25 version software. Specificity, sensitivity, and positive and negative predictive value (with 95% confidence interval [95% CI]) were calculated and used to evaluate the reliability of TI-RADS in differentiation between benign and malignant features. The odds ratio was determined to quantify how strongly the presence or absence of a particular suspicious ultrasound feature was associated with malignancy in the study population. The p values were measured using Student's t-test. In all analyses, $p < 0.05$ was taken to indicate statistical significance.

Results

Of a total of 127 nodules included in this study, 110 nodules were from females (86.6%) and 17 from males (13.4%), with a male-to-female ratio of 1 : 6.4. We observed a slightly

higher female-to-male ratio in our study, but our study only represented the values obtained from a single hospital and was not a multicentric study. Out of 127 nodules studied 104 nodules were benign (94 nodules in females, 10 nodules in males) and 23 nodules were malignant (16 nodules in females, seven nodules in males). Malignancy was more common among male patients who presented with a thyroid nodule (not statistically significant, $p = 0.084$). There was no significant difference in the mean age of patients with benign (mean age was 46.6 ±13.3 years) and malignant thyroid nodules (mean age was 47.3 ±12.6 years) ($p = 0.818$).

ACR-TI-RADS

We found that the risk of malignancy increased as the ACR-TI-RADS category increased. The risk of malignan-

cy in ACR TI-RADS category 1 and 2 were found to be 0%, 6.9% in category 3, 30.9% in category 4, and 77.7% in category 5.

Kwak TIRADS

None of the nodules assessed in our study could be categorised into Kwak TI-RADS 5. Similarly, TI-RADS 1 refers to normal thyroid according to Kwak TI-RADS. Barring these two categories, we found in our study that the risk of malignancy significantly rose as the TI-RADS category increased. The risk of malignancy in TI-RADS categories 2 and 3 was found to be 0%, 21.5% in category 4A, 32.4% in category 4B, and 100.0% in category 4C (Tables 1 and 2).

In our study sonological features that showed a significant association with malignancy were solid composition,

Table 1. Cross tabulation depicting nodule distribution in Kwak and ACR TI-RADS

		ACR TI-RADS					Total
		TR1	TR2	TR3	TR4	TR5	
Kwak TI-RADS	TI-RADS 2 Benign	6	0	0	0	0	6
	TI-RADS 3 Probably benign	0	26	10	3	0	39
	TI-RADS 4A Low suspicion of malignancy	0	1	27	22	1	51
	TI-RADS 4B Intermediate suspicion of malignancy	0	0	6	16	6	28
	TI-RADS 4C Moderate suspicion of malignancy	0	0	0	0	3	3
	Total	6	27	43	41	10	127

Table 2. Frequency of ultrasound features of thyroid nodules according to ACR-TI-RADS descriptors

Ultrasound feature		Benign	Malignant	Total	Risk of malignancy (%)
Composition	Cystic or predominantly cystic	2	0	2	0
	Spongiform	4	0	4	0
	Mixed solid-cystic	44	0	44	0
	Solid or predominantly solid	54	23	77	29.8
Echogenicity	Anechoic	3	0	3	0
	Hyperechoic or isoechoic	89	6	95	6.3
	Hypoechoic	8	16	24	66.6
	Very hypoechoic	0	1	1	100
Shape	Wider than tall or round	98	20	118	16.9
	Taller than wide	2	3	5	60.0
Margin	Smooth	79	16	95	16.8
	Ill-defined	16	4	20	20.0
	Lobulated or irregular	4	3	7	42.8
	Extra-thyroidal extension	1	0	1	0
Echogenic foci	None/large comet tail artefact	66	10	76	13.1
	Macrocalcifications	21	6	27	22.2
	Peripheral rim calcification	11	3	14	21.4
	Punctate echogenic foci	2	4	6	66.6

Table 3. Statistical results of suspicious ultrasound features

Feature	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	PLR	NLR	OR	P
Solid composition	100	48	29.8	100	1.9	0.0	43.5	0.008*
Irregular + ill-defined margin *	30.4	80.7	25.9	84.0	1.5	0.8	1.8	0.239
Irregular margin*	13.0	96.1	42.8	83.3	3.3	0.9	3.7	0.09
Ill-defined margin*	17.3	84.6	20.0	82.2	1.1	0.9	1.1	0.8
Taller than wide	8.7	98.0	50.0	82.9	4.5	0.9	4.85	0.12
Micro-calcification	17.4	98.0	66.6	84.3	9.0	0.8	10.7	0.008*
Calcification	56.5	66.9	27.6	87.3	1.7	0.6	2.63	0.039*
Macro-calcification	26.0	79.8	22.2	83.0	1.29	0.9	1.39	0.53
Peripheral rim calcification	8.7	89.4	15.3	81.5	0.8	1.0	0.8	0.26
Hypoechoic	69.5	92.0	66.7	92.9	8.7	0.3	26.2	< 0.0001*

*In our study, while categorising lesions based on Kwak TI-RADS, we considered the margin characteristic 'ill-defined' along with irregular margins, similarly to studies by Srinivas *et al*. and Chandramohan *et al*., who also evaluated Kwak TI-RADS. Kwak *et al*. and ACR-TI-RADS do not mention ill-defined margin as suspicious feature.

hypoechogenicity, and calcification including microcalcification. Out of the suspicious sonological features hypoechogenicity and microcalcification showed the highest positive predictive value (PPV) (66.7%) for malignancy (Table 3).

Estimation of decrease in unnecessary fine-needle aspiration cytologies using TIRADS

Using Kwak TI-RADS all nodules characterised under category 2 and 3 were benign on cyto/histopathology. Therefore, the specificity of TI-RADS categories 2 (4.7%) and 3 (30.7%) in labelling a nodule as benign was found to be 100%. The estimated decrease in unnecessary FNACs in our study was found to be 35.43%.

Specificity of ACR TI-RADS category TR1 and TR2 in labelling a nodule as benign was also found to be 100%. By avoiding these nodules the estimated decrease in unnecessary FNACs in our study would have been 25.98%.

Discussion

In 2005 the Society of Radiologists in Ultrasound (SRU) published their guidelines to help in deciding which thyroid nodules needed FNA and which that did not [10].

Table 4. Comparison of malignancy risk according to various studies that employed Kwak TI-RADS

TI-RADS	Risk of malignancy [%]				
	Kwak *et al.*	Kwak *et al.*	Chandramohan *et al.*	Srinivas *et al.*	Our study
1	0		0	0	
2	0		6.6	0	0
3	1.7	7.3	32	0.64	0
4A	3.3	8.3-96.6	36	4.76	21.5
4B	9.2		64	66.67	32.4
4C	44.4-72.4		59	83.33	100
5	87.5		91	100	

Subsequently, many other studies have proven the usefulness of ultrasound evaluation of thyroid nodules and its ability to differentiate benign from malignant nodules [3-5,11-17]. Also, professional societies brought forth their guidelines, which either focused on or included suggestions for use of ultrasonographic findings in determining whether a nodule required FNA [18-22]. All these guidelines were chiefly built upon sonographic appearance and nodule size. The ultrasonographic appearance is important because it lends information pertaining to risk of malignancy. To predict with complete certainty if a nodule is malignant or benign is not attainable, even if strong trends exist based on ultrasonographic features. Some nodules that appear malignant will turn out to be benign, and some that appear benign will end up being malignant. To diagnose all thyroid malignancies, we will have to preform biopsy on all thyroid nodules, which is impractical and invasive. Recognising the fact that some thyroid malignancies might be missed, our goal should be in increasing the detection of significant cancers while reducing the FNA of benign nodules. Nodule size is significant because it is inversely related to prognosis [23]. Therefore, most guidelines suggest FNA from large nodules even if the risk of malignancy is low.

Most of the guidelines are complex, employing several sonography features and formulae that are not easy to use in daily practice. We investigated the TI-RADS classification proposed by Kwak *et al*., which is simple and similar to the BI-RADS system that has been in use for many years and is familiar to most radiologists. Kwak *et al*. found various independent ultrasonographic features that were significantly associated with malignancy. These included hypoechogenicity, marked hypoechogenicity, taller than wide shape, micro calcifications, microlobulated or irregular margins, and solid composition. We also compared our results with those obtained by Srinivas *et al*. [8] and Chandramohan *et al*. [9], who also evaluated the efficacy of Kwak TI-RADS in differentiating benign and malignant nodules (see Table 4). Our results

suggest that the following independent sonological features are significantly associated with malignant cytology: solid composition, hypoechogenicity, and the presence of calcifications (including microcalcifications).

Many authors have stratified the risk of each TIRADS category separately. Though, there were differences in these values, they all followed a common pattern, with the risk of malignancy increasing from TIRADS 2 through TIRADS 5 category.

Kwak *et al.* had observed that irregular margins had the highest odds ratio for malignancy followed by taller than wide shape, marked hypoechogenicity, micro calcification, and solid composition of a thyroid nodule. We observed that solid composition had highest odds ratio, followed by hypoechogenicity and micro calcifications. Hypoechogenicity was considered one of the features of malignancy by Horvath *et al.* [3] and Kwak *et al.* [5] though the latter included only marked hypoechogenicity for TIRADS categorization. In our study we found hypoechogenicity to be a strong independent predictor of malignancy. Studies by Kwak *et al.* and Chandramohan *et al.* also found statistically significant association of hypoechogenicity with malignancy. On the other hand, Srinivas *et al.* found no relation between hypoechogenicity and malignancy (Table 5).

Also, we analysed 28 4B nodules that were present in our study, of which nine were malignant. The presence of hypoechogenicity appears to be a strong predictor of malignancy in Kwak TI-RADS-4B. Six out of the nine malignant nodules in TI-RADS 4B had hypoechogenicity, whereas only three out of 19 benign nodules had hypoechogenicity. Sensitivity of hypoechogenicity for identifying 4B malignant nodules was 66.67%, specificity 84.2%, positive likelihood ratio 4.2, PPV 66.67%, and NPV 84.2%. Our sample size was only 127. Also, the percentage of nodules that were malignant (18.1%) in our study was quiet high, probably due to our institution being a tertiary care referral centre. Hence, the discrepancies arising due to the disparity in frequency of malignant nodules may also have contributed to hypoechogenicity being a relevant finding in our study.

Even though microcalcification is a strong predictor of malignancy, we found the presence of calcification alone (either macrocalcification/peripheral rim calcification/microcalcification) to be an independent strong predictor of malignancy (Table 6). Vinayak and Sande in their study found that all 14 of the studied thyroid lesions with macrocalcifications were benign [24]. A point to be noted here is that macrocalcification casts a dense posterior acoustic shadow and might impair proper evaluation of the nodule; hence, we cannot say with certainty that other echogenic foci, especially microcalcifications, were absent.

Bonavita *et al.* in their study observed that the presence of hyperechogenicity or the – white knight appearance was 100% sensitive for a nodule to be benign [25].

Table 5. Comparison of statistical results analysing the significance of hypoechogenicity between various studies

Suspicious ultrasound feature			Malignant nodule		Total
			Present	Absent	
Hypoechogenicity	Present	Kwak *et al.*	169	508	677
		Chandra-mohan *et al.*	41	24	65
		Srinivas *et al.*	5	88	93
		Our study	16	8	24
	Absent	Kwak *et al.*	106	875	981
		Chandra-mohan *et al.*	77	130	207
		Srinivas *et al.*	20	252	272
		Our study	7	96	103
Hypoechogenicity		Kwak *et al.*	Chandra-mohan *et al.*	Srinivas *et al.*	Our study
	Sensitivity (%)	61.4	34.7	20.0	69.5
	Specificity (%)	63.2	84.4	74.1	92.0
	PPV (%)	24.9	63.0	5.3	66.7
	OR	2.7	2.8	0.7	26.2
	P	< 0.0001*	0.0003*	0.51	< 0.0001*

We found that the odds ratio for a lesion that is either isoechoic or hyperechoic being benign was 16.81 (95% CI: 5.71-49.48) ($p < 0.0001$).

Hoang *et al.* noted that although a cystic component occurs in 13-26% of all thyroid malignancies, a predominantly cystic appearance is uncommon [26]. Popli *et al.* in their study observed that all of the four cystic nodular lesions and seven lesions that showed hyperechogenicity in their study were found to be benign on FNAC [27]. Horvath *et al.* in their study found that anechoic, non-vascularised lesions with hyperechoic spots classified as a colloid type 1 lesion were found to have 0% risk of malignancy. In our study all the 50 nodules that had mixed solid-cystic component or predominantly cystic component presented benign cytopathology. Malignancy was seen only among solid nodules. Hence, our study is concordant with the fact that malignancy is uncommon in predominantly cystic lesions.

We also evaluated the risk stratification system proposed by the American College of Radiology Thyroid Imaging Reporting and Data System (ACR-TI-RADS) [6]. The ACR-TI-RADS committee classified thyroid nodules into five risk levels according to their ultrasonographic features. The ACR-TI-RADS uses a system based on allocating points for different ultrasonographic features of nodules in five morphologic categories (composition, echogenicity, margins, echogenic foci, and shape). The point system may seem cumbersome compared with an approach based on pattern recognition, but the advantage of point systems is that they are relatively easy to use and

Table 6. Frequency and statistical analysis of calcification in thyroid nodules

Ultrasound feature		Benign	Malignant	Total	Risk of malignancy (%)
Echogenic foci	None/large comet tail artefact	66	10	76	13.1
	Macrocalcifications	21	6	27	22.2
	Peripheral rim calcification	11	3	14	21.4
	Punctate echogenic foci	2	4	6	66.6
Ultrasound feature		Malignant nodule		Total	Risk of malignancy (%)
		Present	Absent		
Micro-calcification	Present	4	2	6	66.7
	Absent	19	102	121	
Calcification	Present	13	34	47	27.6
	Absent	10	69	79	

can be integrated into practices with varying volumes of patients with thyroid nodules and practices with varying levels of professional expertise. At least this approach forces the person who is obtaining and interpreting the thyroid images to focus his or her attention on each of the five important morphologic categories. Another benefit is that if future data ascribe previously unrecognised significance to sonographic findings, those findings can be easily incorporated into the ACR TI-RADS. A limitation of the point-based system is that certain findings have different implications, depending on other associated findings.

The TR1 and TR2 nodules have a risk of malignancy lower than 2%, and FNA was not recommended for these nodules. The TR3, TR4, and TR5 nodules were predicted to have a risk of malignancy of less than 5%, 5.1-20%, and greater than 20%, respectively, with FNA recommended for those nodules with threshold sizes of 2.5, 1.5, and 1.0 cm, respectively.

We did not follow ACR guidelines (neither category nor size criterion) while advising FNA correlation to retrospectively assess the impact in reducing unwarranted FNACs that are routinely being performed (Table 7).

Kwak vs. ACR-TI-RADS

Kwak TI-RADS 2 and 3 had higher sensitivity in predicting benignity compared to ACR TR1 and 2 (43.2% vs. 31.7%), thus being slightly better in predicting unnecessary FNAC.

Table 7. Comparison of risk of malignancy predicted in ACR TI-RADS

ACR TI-RADS	Risk of malignancy [%]		
	ACR predicted (%)	Middleton *et al*. [21]	Our study
TR1	< 2	0.3	0
TR2		1.5	0
TR3	5	4.8	6.9
TR4	5.1-20	9.1	29.2
TR5	> 20	35.0	80

PPV of Kwak TI-RADS 4 (including 4A + 4B + 4C) in assessing malignancy was 28.05%, with a sensitivity of 100% and specificity of 43.27%. PPV of TR4 and TR5 in assessing malignancy was 23.8%, with a sensitivity of 86.9% and specificity of 53.2%.

Conclusions

We found TI-RADS classification (both ACR and Kwak TI-RADS) to be a reliable, noninvasive, and practical method for assessing thyroid nodules in routine practice. Both TI-RADS classifications can safely avert avoidable FNACs in a significant proportion of benign thyroid lesions. Being a point-based system and also being amenable to future modifications, we prefer the use of ACR-TI-RADS.

Limitations

The sample size was limited due to the time-bound nature of the study.

The lengths of experience of the observers were not uniform. Analysis of interobserver variability was not conducted.

False negative and false positive cytology may have had an impact on the results obtained.

Conflict of interest

The authors report no conflict of interest.

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