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Original article

Accuracy of ACR-TIRADS in assessment and diagnosis of thyroid nodules in patients underwent thyroid surgery in Taksin Hospital

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Background: Ultrasound is generally considered most suitable to evaluate thyroid nodule sonographic morphology. The ultrasound-based risk stratification systems have been used to assess the probability of cancer in thyroid nodules.

Objective: To determine the efficacy of ultrasound-based American College of Radiology Thyroid Imaging Reporting and Data System (ACR-TIRADS) in estimating the risk of malignancy in thyroid nodules in Thailand.

Methods: A descriptive retrospective cross-sectional study was conducted at Taksin Hospital. In total, 324 patients with thyroid nodules underwent sonography and surgery; their pathological diagnoses were available, from January 2008 to April 2022. The ACR-TIRADS and ultrasound features were used to determine the risk of malignancy of thyroid nodules by using surgical histologic pathology from the tissue as the gold standard.

Results: Of the 324 cases, 276 females (85.2%) and 48 males (14.8%) were eligible for inclusion. The risk of malignancy in thyroid nodules according to ACR-TIRADS had a sensitivity of 94.8%, specificity of 79.3%, positive predictive value (PPV) of 50.0%, negative predictive value (NPV) of 98.6%, and accuracy of 82.1%. The ultrasound findings with high malignancy risks were extra-thyroidal extension, lobulated or irregular margin, taller-than-wide shape, very hypoechoic, punctate echogenic foci and enlarged cervical lymph nodes.

Conclusion: The ultrasound scoring-based ACR-TIRADS is a good indicator for evaluating cancer risk of thyroid nodules, determining further management, and reducing unnecessary thyroid biopsies.

Keywords: Thyroid imaging reporting and data system (TIRADS), thyroid nodule, ultrasound.

Thyroid nodules can be commonly found in clinical practice, with 4.0 - 7.0% having palpable nodules [1] and 33.0 - 68.0% having nodules detectable on ultrasound. [2, 3] The prevalence of thyroid cancer in patients with thyroid nodules ranges from 5.0 - 15.0%. [4] According to the report from the National Cancer Institute (Thailand) during 2016 - 2018 [5], the estimated incidence rate of thyroid cancer in Thai males and females were 1.6 and 6.9 per 100,000 population, respectively. Moreover, thyroid cancer is the sixth most common cancer in Thai women.

The evaluation of thyroid nodules should include the clinical symptoms, thyroid function tests, and ultrasonographic findings. The high-resolution ultrasound is generally considered to be the first choice for the evaluation of thyroid morphology.[3] It characterizes and helps predict the risk of cancer as well as determine a need for further diagnostic procedures such as fine-needle cytology.

Several ultrasound-based risk stratification systems for evaluating thyroid nodules have been developed by different societies. [6 - 11] The American College of Radiology Thyroid Imaging Reporting and Data System (ACR-TIRADS)[9, 10], plays an analogous role to the Breast Imaging Reporting and Data System (BIRADS), which is one of the practical methods that implies the potential risk of malignancy and provides effective communication among radiologists and clinicians. Koc AM, *et al.* [12] has compared the thyroid malignancy risk assessment systems and found that ACR-TIRADS showed better specificity and accuracy than the European Thyroid Association Thyroid Imaging Reporting and Data System (EU-TIRADS) and American thyroid

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association (ATA). The ACR-TIRADS is designed to identify the probability of malignancies [13] resulting in reducing the number of unnecessary thyroid biopsies.[14 - 17]

The aim of the study was to determine the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of ACR-TIRADS in estimating the malignancy risk of thyroid nodules by comparing it with the pathological results from thyroid surgery at a hospital in Thailand.

Materials and methods

A descriptive retrospective cross-sectional study was conducted at Taksin Hospital between January 2008 to April 2022. This study has been approved by the Ethics Committee of the Bangkok Metropolitan Administration, Bangkok, Thailand (no. S014h/65_EXP). In total 324 cases with thyroid nodules that underwent thyroid ultrasound before thyroid surgery and having available pathological reports were included in this study. The exclusion criteria were: the patients who underwent thyroid surgery without available pathological report or ultrasound images on picture archiving and communication system (PACS). Ultrasound images on PACS were retrospectively reviewed by a radiologist who was blinded to the patient clinical data and their pathological results. The accuracy of radiologic interpretation was confirmed by calculating intra-observer reliability of a radiologist reviewing ultrasonographic images before the study, which was performed on 20 cases with thyroid nodules (kappa value of 0.9). Thyroid nodules were characterized by the following ultrasound features: composition, echogenicity, shape, margin, echogenic foci, then adding points from all categories to determine ACR-TIRADS level. The scoring-based ACR-TIRADS is classified into five levels, namely: TR1 (benign) to TR5 (highly suspicious of malignancy) (Table 1). Ultrasonographic features of the identified enlarged cervical lymph nodes with suspicious nodal metastasis (round shape and loss of fatty hilum) [4, 18] were also recorded.

Statistical analysis

Data were analyzed using SPSS statistics software (version 26.0). Demographic data of patients (gender, age, and pathological report) were expressed as number, percent and mean ± standard deviation (SD). Continuous variables were determined for normal distribution (Kolmogorov - Smirnov test) before using parametric statistics. The difference between variables were determined by unpaired *t* - test for normal distribution. Categorical variables were evaluated with Fisher's exact test or Chi- square test as appropriate. $P < 0.05$ was considered to be statistically significant. ACR-TIRADS and ultrasound features for sensitivity (Se), specificity (Sp), positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated.

Table 1. Five categories of ultrasound features of the ACR-TIRADS and scoring system.

ACR-TIRADS									
Composition (Choose 1)		**Echogenicity (Choose 1)**		**Shape (Choose 1)**		**Margin (Choose 1)**		**Echogenic foci (Choose all that apply)**	
Cystic or almost completely cystic	0 points	Anechoic	0 points	Wider-than-tall	0 points	Smooth	0 points	None or large comet-tail artifacts	0 points
Spongiform	0 points	Hyperechoic or Isoechoic	1 point	Taller-than-wide	3 points	Ill-defined	0 points	Macrocalcifications	1 point
Mixed cystic and solid	1 point	Hypoechoic	2 points			Lobulated or irregular	2 points	Peripheral (rim Calcifications)	2 points
Solid or almost completely solid	2 points	Very hypoechoic	3 points			Extra-thyroidal extension	3 points	Punctate echogenic foci	3 points

Add points from all categories to determine ACR-TIRADS level				
0 points Benign	**2 points Not suspicious**	**3 points Mildly suspicious**	**4 to 6 points Moderately suspicious**	**7 points or more Highly suspicious**
No FNA	No FNA	FNA if ≥ 2.5 cm Follow if ≥ 1.5 cm	FNA if ≥ 1.5 cm Follow if ≥ 1.0 cm	FNA if ≥ 1.0 cm Follow if ≥ 0.5 cm

Sample size was based on the formula [19] as follows:

$$n_{se} = \frac{Z^2_{1-\alpha/2} \times Se \times (1-Se)}{d^2 \times P}$$

$$n_{sp} = \frac{Z^2_{1-\alpha/2} \times Sp \times (1-Sp)}{d^2 \times (1-P)}$$

This study considered $Z_{1-\alpha/2} = 1.96$, d = 0.6 and P (prevalence of thyroid carcinoma in thyroid nodule) = 26.56 percent by Wongwattana P, *et al.* [20] On the other hand, sensitivity and specificity were 0.93 and 0.72, were calculated by Harmontree S. [21] We obtained n = 328 which was the highest sample size adding 10.0% to compensate unreachable data for this study.

Results

Of the 324 cases, 276 (85.2%) were female; 48 (14.8%) were male, with their age ranged 12 - 83 years (mean 46.9 ± 13.9 years). The majority of the patients (266 cases, 82.1%) had benign thyroid nodules. Malignant thyroid lesions were diagnosed in 58 cases (17.9%). There was no significant correlation between malignant thyroid nodules and demographic variables (gender and age with $P = 0.566$ and 0.077, respectively).

The association between the ultrasonographic features and malignancy risk are demonstrated in Table 2 and Figure 1.

In terms of nodule composition, solid or almost completely solid had moderate risk of malignancy (34.5%), which showed a statistically significant difference ($P < 0.001$) compared to mixed cystic and solid (5.7%) and cystic or almost completely cystic or spongiform (0.0%). Regarding, echogenicity, very hypoechoic nodules had a very high risk of malignancy (85.7%), which also showed a statistically significant difference ($P < 0.001$) compared to hypoechoic (35.3%), hyperechoic or isoechoic (6.1%) and anechoic nodules (0.0%).

About the shape, taller-than-wide shape had a very high risk of malignancy (90.0%), whereas wider-than-tall shape had a low risk of malignancy (15.6%) with statistically significant difference ($P < 0.001$).

As for nodular margin study, there were very high malignancy risk in extra-thyroidal extension (100.0%) and lobulated or irregular margin (89.7%), without significant difference in either group. Nevertheless, both extra-thyroidal extension and lobulated or irregular margin had higher malignancy risk compared with smooth or ill-defined margin (9.6%) with statistically significant difference ($P < 0.001$).

Regarding echogenic foci, punctate foci had a higher malignancy risk (71.4%) with statistically significant difference ($P < 0.001$), compared with peripheral (rim) calcifications (20.0%), macrocalcifications (5.3%) and none or large comet-tail artifacts (6.3%). Concerning enlarged cervical lymph node with suspicious malignant features, it showed very high risk of malignancy (92.3%) with statistical significance ($P < 0.001$) compared those with no enlarged lymph nodes (11.4%).

The malignant nodules were diagnosed as papillary cancer (n = 47), follicular cancer (n = 9) and lymphoma (n = 2). Most of non - malignant nodules were nodular goiter (n = 206), followed by benign follicular nodules/adenoma (n = 24), adenomatous goiter (n = 11), thyroiditis (n = 9), hyperplastic nodule (n = 9) and others (n = 7), respectively.

In this study, there were no risk of malignancy of thyroid nodules (0.0%) in ACR-TIRADS 1 or 2. The malignancy risk in ACR-TIRADS 3, 4, and 5 were 3.3%, 23.1%, and 88.9%, respectively.

Considering ACR-TIRADS 1 - 3 as benign, and ACR-TIRADS 4, 5 as positive for malignancy (Table 3), ACR-TIRADS can estimate the malignancy risk of thyroid nodules with a sensitivity of 94.8%, specificity of 79.3%, PPV of 50.0%, NPV of 98.6%, and accuracy of 82.1%. (Table 4). The Kappa of 0.549 indicated fair to good agreement beyond chart (0.40 - 0.75). [22]

The sensitivity, specificity, PPV, NPV, and accuracy of ultrasonographic findings with high malignancy risk (extra-thyroidal extension, lobulated or irregular margin, enlarged cervical lymph nodes, taller-than-wide shape, very hypoechoic, and punctate echogenic foci) are also shown in Table 4. All mentioned findings showed high specificity (94.0 - 100.0), high accuracy (83.3 - 89.5), high PPV (71.4 - 100.0), high NPV (83.1 - 93.2) but low sensitivity (6.9 - 69.0).

Table 2. Ultrasonographic features of thyroid nodules and malignancy risk.

	Malignant (n = 58) n (%)	Benign (n = 266) n (% of all)	Risk	*P*-value
Composition				
Group 1 Cystic or almost completely cystic or spongiform	0 (0.0)	39 (22.8)[b]	0.0	
Mixed cystic and solid	8 (100.0)	132 (77.2)	5.7	0.203[ns]
Group 2 Cystic or almost completely cystic or spongiform	0 (0.0)	39 (29.1)[b]	0.0	
Solid or almost completely solid	50 (100.0)	95 (70.9)	34.5	< 0.001[*]
Group 3 Mixed cystic and solid	8 (13.8)	132 (58.1)[a]	5.7	
Solid or almost completely solid	50 (86.2)	95 (41.9)	34.5	< 0.001[*]
Echogenicity				
Group 1 Anechoic	0 (0.0)	44 (22.2)[b]	0.0	
Hyperechoic or isoechoic	10 (100.0)	154 (77.8)	6.1	0.125[ns]
Group 2 Anechoic	0 (0.0)	44 (40.0)[b]	0.0	
Hypoechoic	36 (100.0)	66 (60.0)	35.3	< 0.001[*]
Group 3 Anechoic	0 (0.0)	44 (95.7)[b]	0.0	
Very hypoechoic	12 (100.0)	2 (4.3)	85.7	< 0.001[*]
Group 4 Hyperechoic or isoechoic	10 (21.7)	154 (70.0)[a]	6.1	
Hypoechoic	36 (78.3)	66 (30.0)	35.3	< 0.001[*]
Group 5 Hyperechoic or isoechoic	10 (45.5)	154 (98.7)[b]	6.1	
Very hypoechoic	12 (54.5)	2 (1.3)	85.7	< 0.001[*]
Group 6 Hypoechoic	36 (75.0)	66 (97.1)[b]	35.3	
Very hypoechoic	12 (25.0)	2 (2.9)	85.7	< 0.001[*]
Shape				
Wider than tall	49 (84.5)	265 (99.6)[b]	15.6	
Taller than wider	9 (15.5)	1(0.4)	90.0	< 0.001[*]
Margin				
Group 1 Smooth or ill defined	28 (51.9)	263 (98.9)[b]	9.6	
Lobulated or irregular	26 (48.1)	3 (1.1)	89.7	< 0.001[*]
Group 2 Smooth or ill defined	28 (87.5)	263 (100.0)[b]	9.6	
Extra-thyroidal extension	4 (12.5)	0 (0.0)	100.0	< 0.001[*]
Group 3 Lobulated or irregular	26 (86.7)	3 (100.0)[b]	89.7	
Extra-thyroidal extension	4 (13.3)	0 (0.0)	100.0	1.000[ns]
Echogenic foci				
None or large comet-tail artifacts	15 (25.9)	224 (84.2)[a]	6.3	
Presence of calcifications	43 (74.1)	42 (15.8)	50.6	< 0.001[*]
Group 1 None or large comet-tail artifacts	15 (93.8)	224 (92.6)[b]	6.3	
Macrocalcifications	1 (6.3)	18 (7.4)	5.3	1.000[ns]
Group 2 None or large comet-tail artifacts	15 (88.2)	224 (96.6)[b]	6.3	
Peripheral (rim) calcifications	2 (11.8)	8 (3.4)	20.0	0.143[ns]
Group 3 None or large comet-tail artifacts	15 (27.3)	224 (93.3)[a]	6.3	
Punctate echogenic foci	40 (72.7)	16 (6.7)	71.4	< 0.001[*]
Group 4 Macrocalcifications	1 (33.3)	18 (69.2)[b]	5.3	
Peripheral (rim) calcifications	2 (66.7)	8 (30.8)	20.0	0.267[ns]
Group 5 Macrocalcifications	1 (2.4)	18 (52.9)[b]	5.3	
Punctate echogenic foci	40 (97.6)	16 (47.1)	71.4	< 0.001[*]
Group 6 Peripheral (rim) calcifications	2 (4.8)	8 (33.3)[b]	20.0	
Punctate echogenic foci	40 (95.2)	16 (66.7)	71.4	0.003[*]
Enlarged lymph node				
No enlarged lymph node	34 (58.6)	264 (99.2)[b]	11.4	
Enlarged lymph node	24 (41.4)	2 (0.8)	92.3	< 0.001[*]

a = Chi-square test, *b* = Fisher's exact test
ns = no significant difference * = highly significant difference

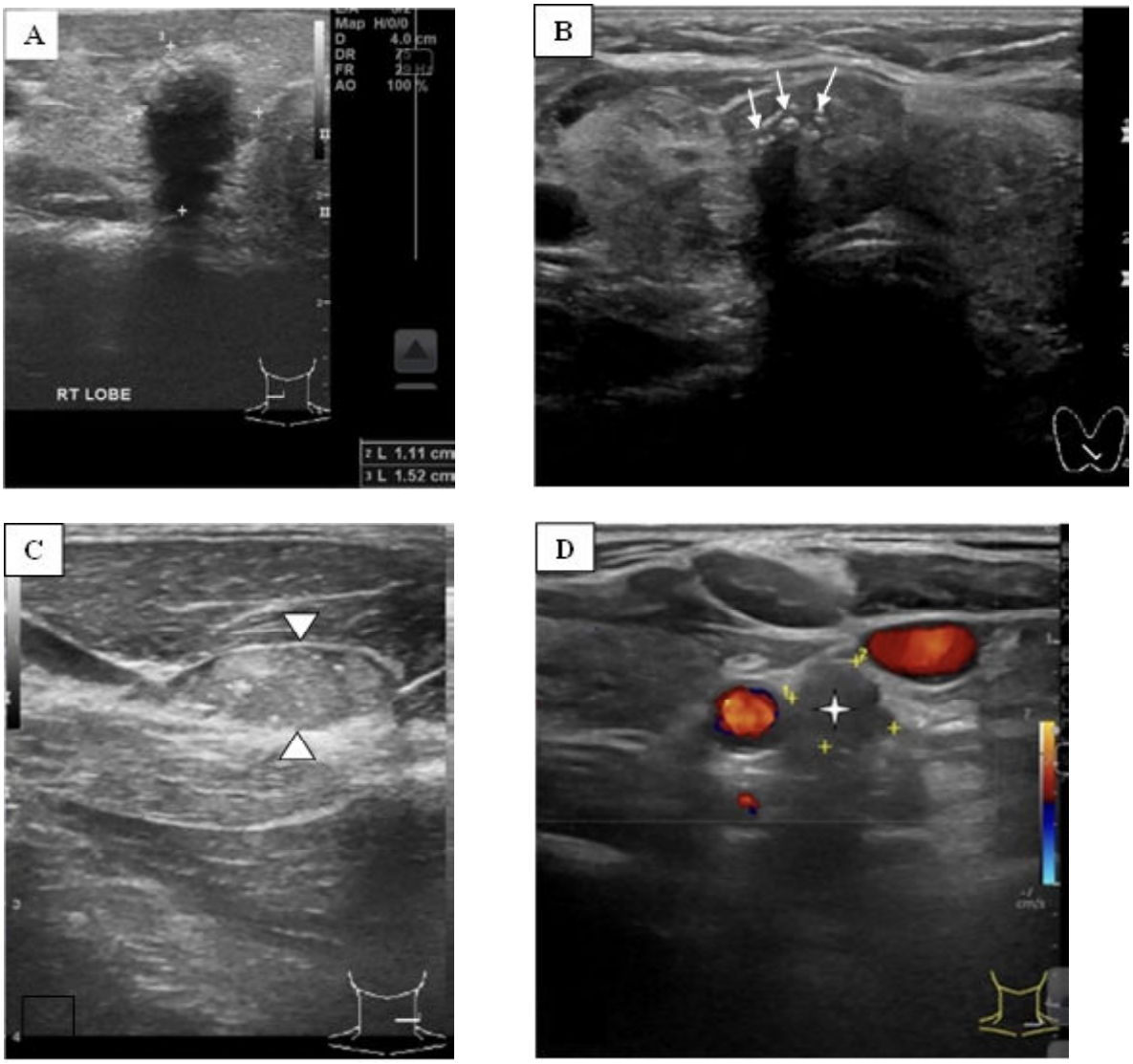

Figure 1. The sonographic findings with high malignancy risk: **(A)** Solid, very hypoechoic, taller- than-wide shape, and irregular margin (white block arrows); **(B)** Hypoechoic nodule with punctate echogenic foci (white line arrows); **(C)** Enlarged lymph node with loss of fatty hilum and internal microcalcifications (white arrow heads); and **(D)** Enlarged lymph node with round shape with irregular border and loss of fatty hilum (white star).

Table 3. Relation of ACR-TIRADS level and malignancy confirmed by surgical pathology.

ACR-TIRADS	Surgical pathology		Total	*P*- value	*K*- value
	Malignant (n = 58)	Benign (n = 266)			
ACR-TIRADS 4, 5	55	55	110		
ACR-TIRADS 1, 2, 3	3	211	214		
Total	58	266	324	< 0.001*	0.549

* = highly significant difference

Table 4. Accuracy of ultrasonographic features with high malignancy risk and ACR-TIRADS.

Ultrasonographic features and ACR-TIRADS	Sensitivity	Specificity	Accuracy	PPV	NPV
Extra-thyroidal extension	6.9	100.0	83.3	100.0	83.1
Lobulated or irregular margin	44.8	98.9	89.2	89.7	89.2
Enlarged cervical lymph nodes	41.4	99.3	88.9	92.3	88.6
Taller-than-wide shape	15.5	99.6	84.6	90.0	84.4
Very hypoechoic	20.7	99.3	85.2	85.7	85.2
Punctate echogenic foci	69.0	94.0	89.5	71.4	93.2
ACR-TIRADS	94.8	79.3	82.1	50.0	98.6

Table 5. ACR-TIRADS in assessment the malignancy risk of thyroid nodule.

Study	Year	Gold standard	Sensitivity	Specificity	Accuracy	PPV	NPV
Wang Y, *et al.*[24]	2017	Pathology	97	73.2	83.1	72	97.2
Zheng Y, *et al.*[25]	2018	FNA/Pathology	99	43.4	60	42.7	99.1
Ruan JL, *et al.*[26]	2019	FNA	96.7	77.3	84.9	73.3	97.3
Gao L, *et al.*[27]	2019	Pathology	81.6	79.7	80.9	88.7	68.9
Harmontree S.[21]	2021	FNA	92.9	72.3	73.9	22	99.2
Wongwattana P, *et al.*[20]	2021	Pathology	100	63.8	73.8	50	100
Chen F, *et al.*[28]	2022	Pathology	78	90	84	90	78
This study	2022	Pathology	94.8	79.3	82.1	50	98.6
Li W, *et al.*[14]*	2021	FNA/Pathology	89	70			

Discussion

Ultrasonography is generally used to evaluate thyroid morphology for prediction the risk of cancer. There are several ultrasound-based risk stratification systems of thyroid nodules in different societies. [6-11] Koc AM, *et al.* [12] compared thyroid malignancy risk assessment system of ATA, ACR-TIRADS and EU-TIRADS. The sensitivity and specificity were as follows; ATA (82.2, 53.5), ACR-TIRADS (48.9, 60.6) and EU-TIRADS (86.7, 49.0). ACR-TIRADS showed higher specificity and accuracy than ATA and EU-TIRADS.

In Thailand, Siriraj Thyroid Imaging Reporting and Data System (Siriraj-TIRADS) [11] has been conducted since 2017, which was comparable to TIRADS classification (by Horvath E, *et al.*[6] The Siriraj-TIRADS had high sensitivity (95.0 %) and moderate specificity (64.8%) for cancer prediction. Nevertheless, Phuttharak W, *et al.* [23] investigated interobserver agreement between two radiologists among ACR-TIRADS, Siriraj-TIRADS and EU-TIRADS for diagnosis of highly suspicious thyroid nodules, and ACR-TIRADS showed higher inter-observer agreement.

Therefore, this study aims to assess the efficacy of ultrasound-based ACR-TIRADS in estimating the risk of malignancy in thyroid nodules by comparing it with the pathological results from surgery. The results showed high sensitivity (94.8%) and moderate specificity (79.3%), which was similar to a meta-analysis study by Li W, *et al.* [14] which have shown pooled sensitivity and specificity of 89.0% and 70.0%, respectively. Harmontree S.[21] also assessed this efficacy and reported high sensitivity (92.9%) and moderate specificity (72.3%). However, both previous studies used ACR-TIRADS for stratification of thyroid nodules and determined sensitivity and specificity by using cytologic results from fine-needle aspiration. This study has strengths in two aspects. First, it included a large number of patients with pathology-confirmed diagnosis. Second, it determined malignancy risk by using postoperative pathological results. There were several studies reporting ultrasound-based ACR-TIRADS, compared to the pathological results of thyroid surgery, which was concordant with this study and more precise than comparing with FNA (Table 5).

The risk of malignancy of thyroid nodules according to ACR-TIRADS in this study showed the similar trend as other studies [20, 21, 24, 25, 27] that was no malignancy in both TIRADS level 1 and 2 nodules; therefore, FNA should not be recommended in nodules with both levels. The risk of malignancy in TIRADS 3 level in this study was 3.3%, that was comparable to other studies (0.0 - 14.1%). The guideline recommends to perform FNA in ACR-TIRADS 3 nodules if the size ≥ 2.5 cm. [10] For TIRADS 4 and 5 nodules, there was an increased trend of malignancy risk in most studies. [6, 13, 20, 21, 25, 27, 28] The PPV in TIRADS 4 and 5 in this study was 50.0%, which was variable in other studies (22.0 - 90.0%).[20, 21, 24 - 28] Fifty-five false positive lesions in this study were 42 nodular goiters, 3 hyperplastic nodules, 9 benign follicular nodules/adenomas and 1 thyroiditis. Some lesions had calcified portions either microcalcifications or coarse calcifications that lead to added points to determine ACR-TIRADS level. The coarse calcifications are more frequently seen in benign nodular goiters than malignant nodules. The presence of microcalcifications is highly suggestive of malignancy detected in papillary thyroid carcinoma that corresponds to clusters of psammoma bodies at histopathology. [29] Microcalcifications may be seen in other benign thyroid nodules such as nodular goiter, adenoma, and lymphocytic thyroiditis. [29, 30] However, the presence of microcalcifications in thyroid nodules increases the malignancy risk three-fold, while the nodule with coarse calcifications increases cancer risk two-fold. [31] The ACR guideline recommends performing FNA in ACR-TIRADS 4 and 5 nodules if the size ≥ 1.5 cm and ≥ 1.0 cm, respectively. [10]

The ultrasonographic findings with high malignant risks were extra-thyroidal extension, lobulated or irregular margin, taller-than-wide shape, very hypoechoic, punctate echogenic foci and enlarged cervical lymph nodes, which showed high sensitivity, high accuracy, high PPV, high NPV, but low sensitivity. In addition, the prevalence of thyroid cancer in this study was 17.9%, which was slightly higher than previous reports (5.0 - 15.0%).[4] This may be caused by the present study using pathology-confirmed diagnosis as the gold standard, which could detect more malignancy cases than using FNA cytology.

The present study had some limitations, however. This was a retrospective study, which may have selection bias to benign thyroid nodules that did not need surgery. The other limitation was that there was only one radiologist reviewing ultrasound images, even the intra-observer reliability with *K* - value was 0.9.

Conclusion

The ultrasound scoring-based ACR-TIRADS is suitable for evaluating thyroid nodule, which helps estimate the malignant probability of thyroid cancer, determines further management, and reduces unnecessary thyroid biopsies. Future prospective studies with larger sample size or a systematic review with meta-analysis, should be considered.

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Conflict of interest statement

Each of the authors has completed an ICMJE disclosure form. None of the authors declare any potential or actual relationship, activity, or interest related to the content of this article.

Data sharing statement

The present review is based on the reference cited. Further details, opinions, and interpretation are available from the corresponding authors on reasonable request.

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