นิพนธ์ต้นฉบับ **Original Articles**

เปรียบเทียบความแม่นยำของระบบการรายงานผลอัลตราซาวด์ ACR-TIRADS และ S-detect เพื่อวินิจฉัยก้อนไทรอยด์ที่มีความเสี่ยงเป็นมะเร็งไทรอยด์

Comparison of ACR-TIRADS and S-detect to evaluation of thyroid nodule

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บทคัดย่อ

หลักการและเหตุผล : ปัจจุบันอัลตราซาวด์ถูกนำมาใช้กันอย่างแพร่หลายในการตรวจหาและช่วยในการวินิจฉัยของก้อนไทรอยด์ในเวชปฏิบัติ ในขณะเดียวกันปัญญาประดิษฐ์ (AI) ถูกพัฒนาและนำมาใช้กันอย่างแพร่หลาย เพื่อช่วยเพิ่มความแม่นยำและลดภาระงานของรังสีแพทย์ในการแยกความแตกต่างระหว่างก้อนไทรอยด์ที่เป็นเนื้องอกธรรมดาและมะเร็งไทรอยด์

วัตถุประสงค์ : การศึกษานี้มีจุดมุ่งหมายเพื่อศึกษาการรายงานผลอัลตราซาวด์ไทรอยด์ตาม ACR-TIRADS ในการพยากรณ์โรคมะเร็งไทรอยด์ของผู้ป่วยในโรงพยาบาลบุรีรัมย์ เปรียบเทียบกับปัญญาประดิษฐ์ S-detect

วิธีการศึกษา : ระหว่างเดือนพฤษภาคม พ.ศ. 2567-ตุลาคม พ.ศ. 2567 เก็บข้อมูลผู้ป่วย 52 รายที่มีก้อนต่อมไทรอยด์ 138 ก้อน ผู้ป่วยทุกรายก่อนการผ่าตัดหรือก่อนใช้เข็มเจาะดูดเซลล์ไปตรวจ (Fine needle aspiration) ในโรงพยาบาลบุรีรัมย์ จะได้รับการตรวจอัลตราซาวด์และประเมินความเสี่ยงของการเป็นมะเร็งไทรอยด์ตาม ACR-TIRADS (TR1-TR5) ซึ่งทุกรายจะมีการใช้ปัญญาประดิษฐ์ S-detect ในการวินิจฉัยก้อนไทรอยด์ในคราวเดียวกัน และนำไปเปรียบเทียบกับผลตรวจทางพยาธิวิทยา หรือ cytopathology เป็น gold standard

ผลการศึกษา : การศึกษานี้มีกลุ่มตัวอย่างผู้ป่วยทั้งหมด 52 ราย แบ่งเป็น ผู้ป่วยชาย 5 ราย ผู้ป่วยหญิง 47 ราย ก้อนไทรอยด์ 138 ก้อน แบ่งเป็นก้อนเนื้องอกธรรมดา 114 ก้อน และก้อนมะเร็ง 24 ก้อน ลักษณะจากการตรวจอัลตราซาวด์ของก้อนไทรอยด์ซึ่งมีความสัมพันธ์อย่างมีนัยสำคัญทางสถิติของมะเร็งไทรอยด์ ได้แก่ ก้อนที่มีลักษณะเสียงสะท้อน very hypoechoic รูปร่าง taller than wide ขอบเขตของก้อนแบบ irregular หรือขนาดของก้อนขยายออกไปนอกต่อมไทรอยด์ มีหินปูนขนาดเล็กภายในก้อน และพบต่อมน้ำเหลืองโตบริเวณคอ ความไวของการรายงานผลก้อนไทรอยด์ตาม ACR-TIRADS มีความไวสูงกว่า S-detect (ร้อยละ 87.5 เทียบกับ ร้อยละ 33.3) แต่ในขณะเดียวกัน S-detect มีความจำเพาะสูงกว่า (ร้อยละ 64.9 เทียบกับค่าทำนายผลบวกที่สูงกว่า (ร้อยละ 22.1 เทียบกับ ร้อยละ 61.5) และ ค่าทำนายผลลบที่สูงกว่า ACR-TIRADS (ร้อยละ 7.0 เทียบกับ ร้อยละ 87.2) รวมถึงความแม่นยำที่สูงกว่าด้วย (ร้อยละ 44.2 เทียบกับ ร้อยละ 84.8)

สรุป : การอัลตราซาวด์โดยรายงานผลตาม ACR-TIRADS เป็นเครื่องมือที่ดีในการประเมินความเสี่ยงของมะเร็งต่อมไทรอยด์ ในขณะที่ S-detect ก็มีความจำเพาะและความแม่นยำค่อนข้างสูงในการช่วยวินิจฉัยก้อนไทรอยด์ แต่ก็ยังไม่สามารถทดแทนการตรวจอัลตราซาวด์ของรังสีแพทย์ได้

คำสำคัญ : ระบบการรายงานผลอัลตราซาวด์ของต่อมไทรอยด์ (TIRADS) ก้อนไทรอยด์ มะเร็งไทรอยด์ อัลตราซาวด์ S-detect ปัญญาประดิษฐ์ (AI)

ABSTRACT

Background : Ultrasound is widely used for detecting and characterizing thyroid nodules in clinical practice. Artificial intelligence (AI) is also widely used in many fields, especially for differentiating between benign and malignant thyroid nodules.

Objective : This prospective study aims to evaluate the diagnostic accuracy of the American College of Radiology Thyroid Imaging Reporting and Data System (ACR-TIRADS) and S-detect (Samsung, Medison Co.).

Methods : Between May 2024 and October 2024, 52 patients with 138 thyroid nodules were enrolled at Buri Ram Hospital. All nodules, regardless of size, underwent pre-operative ultrasound evaluation using ACR-TIRADS categories (TR) and S-detect. Surgical pathology or cytopathology served as the gold standard for determining malignancy risk.

Results : A total of 52 patients (M=5, F=47) with 138 thyroid nodules (114 benign and 24 malignant) were included in this study. Ultrasound features that showed a highly statistically significant association with malignancy included very hypoechoic nodules, a taller-than-wide shape, lobulated or irregular borders, extra-thyroidal extension, punctate echogenic foci, and enlarged cervical lymph nodes. ACR-TIRADS demonstrated higher sensitivity than S-detect for diagnosing thyroid nodules (87.5% vs. 33.3%) but lower specificity (64.9% vs. 95.6%), positive predictive value (22.1% vs. 61.5%), negative predictive value (7.0% vs. 87.2%), and overall accuracy (44.2% vs. 84.8%).

Conclusion : ACR-TIRADS demonstrated higher sensitivity, while S-detect showed greater specificity and accuracy in determining the malignancy risk of thyroid nodules; however, manual ultrasound remains essential for comprehensive evaluation.

Keywords : Thyroid imaging reporting and data system (TIRADS), Thyroid nodule, S-detect, Artificial Intelligent (AI), Ultrasound.

Introduction

Thyroid nodules are a common finding in clinical practice. Their incidence increases with age, is more frequent in women, and is higher in individuals with iodine deficiency or those exposed to radiation. The prevalence of thyroid nodules is 2-6% by palpation, 19-35% by ultrasound, and 8-65% in autopsy studies(1). However, only approximately 5% of thyroid nodules are malignant(2,3), and most patients remain asymptomatic. These characteristics can lead to the disease being overlooked by patients, resulting in delayed treatment or, conversely, overtreatment.

High-resolution ultrasound is generally considered the first-line modality for evaluating thyroid morphology(4). Sonographic features of malignant thyroid nodules include a solid component, very hypoechoic patterns, taller-than-wide dimensions, irregular or lobulated borders, and microcalcifications. However, the sensitivity and specificity of these features vary, and no single feature reliably determines the nature of thyroid nodules(5).

The Thyroid Imaging Reporting and Data System (TIRADS)(6), introduced by the American College of Radiology (ACR) in 2017, is widely used for thyroid nodule assessment. ACR-TIRADS scores nodules based on five categories: composition, echogenicity, shape, margin and echogenic foci.

Thyroid nodules are stratified into five ACR-TIRADS categories (TR1 to TR5) based on their total score, with malignancy risks ranging from benign (TR1), no suspicion (TR2) to highly suspicious (TR5). The malignancy risks for TR3, TR4, and TR5 are 5%, 5-20%, and no less than 20%, respectively.(7,8)

S-detect (Samsung Medison Co., Seoul, South Korea) is an AI-based computer-aided diagnostic system for ultrasonography that uses deep learning algorithms.(9,10) According to Choi et al.(9), in a study involving 89 patients, the sensitivity of S-detect was similar to that of experienced sonographers (90.7% vs. 88.4%, $p > 0.99$). S-detect was deemed acceptable for the characterization of thyroid nodules, and its classifications of ultrasound characteristics—including composition, orientation, echogenicity, and spongiform—showed substantial agreement (kappa = 0.659, 0.740, 0.733, and 0.658, respectively).

This prospective study aims to evaluate the diagnostic efficacy of ACR-TIRADS and S-detect in assessing thyroid nodules.

Materials and methods

The descriptive prospective study was conducted at Buri Ram Hospital from May 1st, 2024, to October 31st, 2024. This study was approved by the Ethics Committee of Buri Ram Hospital, Thailand (BR. 0033.102.1/24). According to the pre-experiment results, the sensitivity of ACR-TIRADS was 0.91(11). The sample size was calculated using the formula, where Z(0.975) was 1.96, the proportion (p) was 0.91, the margin of error (d) was 0.05, and the level of significance (α) was 0.05.

$$n = \frac{z^2_{1-\frac{a}{2}} p(1-p)}{d^2}$$

The estimated sample size was 139.

Patients

The inclusion criteria included thyroid nodules of any size with a complete preoperative ultrasonographic and pathological report from thyroidectomy or a cytopathologic result from fine needle aspiration (FNA) based on the 2023 Bethesda System for Reporting Thyroid Cytopathology.[12]

The exclusion criteria were: (I) any pathological or cytopathologic report with uninterpretable results; (II) patients who refused surgery or FNA; (III) cytopathologic reports classified as Bethesda I or Bethesda III.

If a patient had more than one nodule, each nodule was reviewed by a pathologist to ensure complete information.

Ultrasound examination and analysis

Ultrasonography was performed prior to FNA or thyroidectomy. Patients were positioned in the supine position, and a Samsung Ultrasound RS85 Prestige (version 2.05.1a.3001) equipped with a 2–14 MHz linear transducer probe was used by a radiologist with 11 years of experience in ultrasound.

The ACR-TIRADS scores were reported in accordance with the 2017 ACR-TIRADS guidelines. The size of each thyroid nodule (on the transverse plane) and evidence of abnormal cervical lymph nodes were documented.

S-detect (Samsung Medison Co.) was subsequently utilized to automatically delineate the nodule contour. Manual adjustments were made when the software-generated boundary of the nodule was inaccurate. Finally, S-detect provided a judgment of either "possibly benign" or "possibly malignant" regarding the nature of the thyroid nodules.

The ultrasonographic features of malignant thyroid nodules (TR5) and benign thyroid nodules (TR2), as well as S-detect, are shown in Figure 1.

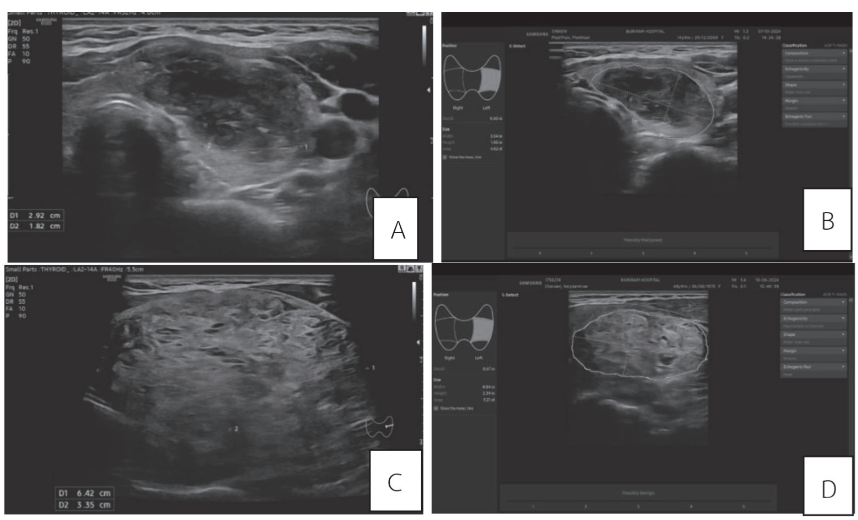

Figure 1 The gray scale ultrasound images and S-detect of malignant thyroid nodules (A, B) and benign thyroid nodules (C, D). The S-detect automatically calculated the nodule margin and displayed nodule characteristics on the right of the screen with diagnostic results shown as the bottom (B, D).

Statistician analysis

The data in this study were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Demographic data of the patients (gender, age, and pathological reports) were expressed as numbers, percentages, and means ± standard deviations (SD), as appropriate. Differences between variables were determined using an unpaired t-test for normally distributed data. Categorical variables were evaluated using Fisher's exact test, which appropriated for small sample size. A p-value of <0.05 was considered statistically significant. Sensitivity (Se), specificity (Sp), positive predictive value (PPV), negative predictive value (NPV), and accuracy for ACR-TIRADS and S-detect were calculated.

Results

Of the 71 patients, 19 were excluded due to unclear pathological and cytopathological findings. Ultimately, 52 patients (5 men (9.6%) and 47 women (90.4%), mean age 52.4 years; age range 14–86 years), comprising 138 nodules (1–6 nodules per patient), were included in the study. Among these, 114 nodules (82.6%) were benign, and 24 nodules (17.4%) were malignant.

The diameters of the nodules ranged from 2 to 102 mm, with an average of 23.4 ± 19.9 mm. There was no significant correlation between malignant thyroid nodules and demographic variable (gender and age with p = 0.578 and 0.130, respectively).

All malignant nodules were pathologically confirmed as follows: 16 papillary carcinomas, 3 lymphomas, 3 anaplastic carcinomas, and 2 follicular carcinomas. The 114 benign nodules included 74 nodular goiters, 10 oncocytic adenomas, 8 follicular adenomas, 7 colloid cysts, 4 cases of thyroiditis, 2 adenomatous goiters, 3 Bethesda II nodules, and 6 other types.

The characteristics of malignant and benign thyroid nodules are shown in Table 1.

There was no statistically significant association between nodule composition and malignant thyroid nodules (p = 0.181). However, ultrasound features that showed highly statistically significant associations with malignancy (p < 0.001) included very hypoechoic nodules (100%), taller-than-wide shape (100%), lobulated or irregular borders (100%), extra-thyroidal extension (100%), punctate echogenic foci (75%), and enlarged cervical lymph nodes (100%).

The prevalence or risk of malignancy in relation to ACR-TIRADS was 0%, 0%, 5.9%, 18.4%, and 100% in TR1, TR2, TR3, TR4, and TR5, respectively. Considering that ACR-TIRADS 1–3 are classified as low risk for malignancy and ACR-TIRADS 4–5 as high risk for malignancy (Table 2), ACR-TIRADS was able to estimate the malignancy risk of thyroid nodules with the following performance: sensitivity of 87.5%, specificity of 64.9%, positive predictive value (PPV) of 22.1%, negative predictive value (NPV) of 7.0%, and accuracy of 44.2%.

As shown in Table 3, when compared to ACR-TIRADS, the S-detect system had significantly lower sensitivity but higher specificity, PPV, NPV, and overall accuracy. S-detect estimated the malignancy risk of thyroid nodules with a sensitivity of 33.3%, specificity of 95.6%, PPV of 61.5%, NPV of 87.2%, and accuracy of 84.8%.

Table 1. Ultrasonographic features of malignant and benign thyroid nodules

Ultrasonographic features	Malignant (n=24) n (%)	Benign (n = 114) n (%)	p-value
Composition			0.181*
cystic or completely cystic	0 (0.0%)	6 (100.0%)	
Spongiform	0 (0.0%)	8 (100.0%)	
Mixed cystic and solid	3 (10.0%)	27 (90.0%)	
Solid or almost completely solid	21 (22.3%)	73 (77.7%)	
Echogenicity			<0.001*
Anechoic	0 (0.0%)	1 (100.0%)	
Hyperechoic or isoechoic	3 (4.8%)	60 (95.2%)	
Hypoechoic	53 (75.7%)	17 (24.3%)	
Very hypoechoic	4 (100.0%)	0 (0.0%)	
Shape			<0.001*
Wider than tall	19 (14.3%)	114 (85.7%)	
Taller than wide	5 (100.0%)	0 (0.0%)	
Margin			<0.001*
Smooth or ill defined	15 (11.6%)	114 (88.4%)	
Lobulated or irregular	8 (100.0%)	0 (0.0%)	
Extra-thyroidal extension	1 (100.0%)	0 (0.0%)	
Echogenic foci			<0.001*
None or large comet-tail artifacts	12 (10.3%)	105 (89.7%)	
Macrocalcifications	5 (45.5%)	6 (54.5%)	
Peripheral (rim) calcifications	1 (50.0%)	1 (50.0%)	
Punctate echogenic foci	6 (75.0%)	2 (25.0%)	
Enlarged lymph node			<0.001*
No enlarged lymph node	18 (13.6%)	114 (86.4%)	
Enlarged lymph node	6 (100.0%)	0 (0.0%)	
ACR-TIRADS			<0.001*
TR1	0 (0.0%)	1 (100.0%)	
TR2	0 (0.0%)	25 (100.0%)	
TR3	3 (5.9%)	48 (94.1%)	
TR4	9 (18.4%)	40 (84.6%)	
TR5	12 (100.0%)	0 (0.0%)	
S detect			<0.001*
Possibly benign	16 (12.8%)	109 (87.2%)	
Possibly malignancy	8 (61.5%)	5 (38.5%)	

*Fisher's exact test

Table 2. Relation of ACR-TIRADS level and malignant confirmed by pathology

ACR-TIRADS Level	Malignant (n = 24) n (%)	Benign (n = 114) n (%)	p-value
ACR-TIRADS 1-3	3 (12.5%)	74 (64.9%)	
ACR-TIRADS 4 and 5	21 (87.5%)	40 (35.1%)	
Total	24 (100.0%)	114 (100.0%)	0.008*

*Fisher's exact test

The numbers in the n (%) columns represent the count (n) and percentage (%) of cases within the malignant or benign group at each ACR-TIRADS level.

The p-value of 0.008 indicates a statistically significant difference ($p < 0.05$) between the distribution of malignant and benign cases across the ACR-TIRADS levels.

Table 3. Diagnostic performance of ACR-TIRADS and S-detect for differentiating benign and malignant thyroid nodules.

Diagnostic parameters	ACR-TIRADS n (%)	S-detect n (%)
Sensitivity	21 (87.5%)	8 (33.3%)
Specificity	74 (64.9%)	104 (95.6%
Positive Predictive Value (PPV)	21 (22.1%)	8 (61.5%)
Negative Predictive Value (NPV)	3 (7.0%)	109 (87.2%)
Accuracy	61 (44.2%)	117 (84.8%)

Discussion

The ACR-TIRADS classification guideline has become one of the most widely used sonographic risk stratification systems[13-14], aimed at reducing unnecessary fine needle aspiration (FNA) and surgery.

The results of this study demonstrate statistically significant ultrasonographic features associated with malignant thyroid nodules, including very hypoechoic nodules, a taller-than-wide shape, lobulated or irregular borders, extra-thyroidal extension, punctate echogenic foci, and enlarged cervical lymph nodes. These findings are consistent with the previous study by Hamontree S[15], which showed that ultrasonographic features associated with a high malignancy risk included very hypoechoic texture, a taller-than-wide shape, irregular margins, and calcifications, with high specificity (99.4%, 99.4%, 83.7%, and 88.6%, respectively). Similarly, Chainamnan W[16] reported that ultrasound findings associated with a high malignancy risk included extra-thyroidal extension, lobulated or irregular margins, a taller-than-wide shape, very hypoechoic texture, punctate echogenic foci, and enlarged cervical lymph nodes (specificities were 100%, 98.9%, 99.6%, 99.3%, 94.0%, and 99.3%, respectively). These results are also consistent with the recommendations in the White Paper of ACR-TIRADS (2017)[7].

The risk of malignancy for thyroid nodules classified by ACR-TIRADS in this study aligns with trends observed in other studies [13, 14, 16]. For example, according to Chainamnan W[16], the study showed no risk of malignancy (0.0%) in ACR-TIRADS 1 or 2. The malignancy risk in ACR-TIRADS 3, 4, and 5 was 3.3%, 23.1%, and 88.9%, respectively.

No malignancies were found in TIRADS level 1 or 2 nodules in this study, confirming that FNA is not recommended for nodules at these levels. The malignancy risk for TIRADS 3 nodules in this study was 5.9%, which is consistent with previous studies reporting risks between 0.0% and 22.6%[13, 14, 15, 16]. Guidelines recommend FNA for TIRADS 3 nodules if the size is ≥ 2.5 cm[7].

For TIRADS 4 and 5 nodules, the malignancy risk increased in this study (18.4% and 100%, respectively), consistent with findings from other studies[7, 13, 14, 15, 16]. The ACR guideline recommends FNA for TIRADS 4 and 5 nodules if the size is ≥ 1.5 cm and ≥ 1.0 cm, respectively[7].

Most studies included in Table 4 were retrospective and evaluated only one nodule per case. In contrast, this study included thyroid nodules subjected to FNA or surgery (1-6 nodules per case), which may have introuced selection bias. Nevertheless, all studies in Table 4 demonstrate the high sensitivity of ACR-TIRADS in assessing the malignancy risk of thyroid nodules, reaffirming the utility of the 2017 ACR-TIRADS guideline[7] in reducing unnecessary FNAs and optimizing thyroid nodule management. This approach also helps minimize psychological stress and financial burdens for patients with thyroid nodules.

Table 4. Diagnostic performance of ACR-TIRADS in assessing malignancy risk of thyroid nodules

Study	Year	n (nodules)	Gold standard	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Peng C, et al[8]	2024	94	Pathology/ FNA	84.6%	40.4%	63.8%	68.0%	64.9%
This study	2024	138	Pathology/ FNA	87.5%	64.9%	22.1%	7.0%	44.2%
Wongwattana P, et al[13]	2021	128	Pathology	100.0%	63.8%	50.0%	100.0%	73.8%
Hamontree S[15]	2021	180	FNA	92.9%	72.3%	22.0%	99.2%	73.9%
Tribumrungsuk P, et al[14]	2023	201	Pathology/ FNA	70.5%	73.6%	58.2%	82.7%	71.6%
Chainamnan W[16]	2023	324	Pathology	94.8%	79.3%	50.0%	98.6%	82.1%

On the other hand, the results of this study showed that S-detect had significantly lower sensitivity than ACR-TIRADS but higher specificity (95.6% vs. 64.9%), PPV (61.5% vs. 22.1%), accuracy (84.8% vs. 44.2%), and NPV (87.2% vs. 7.0%).

From this study, we can conclude that in clinical practice, ACR-TIRADS is more effective at detecting malignant nodules (87.5%) compared to S-detect (33.3%). On the other hand, S-detect performs better in ruling out benign nodules (95.6%) than ACR-TIRADS (64.9%).

ACR-TIRADS is suitable for initial screening due to its higher sensitivity, while S-detect is better for confirming benign cases due to its high specificity and accuracy.

Compared with the study by Peng C, et al.[8], which conducted a retrospective analysis on 94 suspicious thyroid nodules to examine the diagnostic efficacy of ACR-TIRADS, S-Detect, and ECI, this study found a lower sensitivity for S-detect (33.3% vs. 98.1%), higher specificity (95.6% vs. 45.2%), a similarly moderate PPV (61.5% vs. 65.2%), higher accuracy (84.8% vs. 66.0%), and a higher NPV (87.2% vs. 67.9%). This discrepancy may be due to the inclusion of all thyroid nodules in this study, whereas Peng C, et al. selected only suspicious thyroid nodules (TIRADS 3-5).

In recent years, many AI technologies have been developed in the field of thyroid ultrasound, with S-detect being one of the most widely used systems[17, 18].

Barczyñski M, et al[19]. reported that the sensitivity and NPV of S-detect for identifying the nature of thyroid nodules were comparable to those of surgeons with specialized ultrasound skills (sensitivity: 90% vs. 90%; NPV: 96.9% vs. 97.4%). Wei Q, et al.[20] demonstrated that the accuracy, sensitivity, specificity, PPV, and NPV of S-detect were 77.0%, 91.3%, 65.2%, 68.3%, and 90.1%, respectively. Compared to less experienced radiologists, S-detect showed improved diagnostic accuracy, specificity, and AUC ($p < 0.05$). However, for more experienced radiologists, there was no significant improvement.

Similarly to Li Y, et al[21], The sensitivity, accuracy and Acc of the AI system were 0.95, 0.84 and 0.753, respectively. These were not statistically different from those of experienced radiologist but were significant superior to those of residents (all p, 0.01).

Limitations

The estimated sample size was 139 nodules, but this study included only 138, as 19 nodules were excluded due to a cytopathology report classified as Bethesda I. However, this exclusion did not significantly affect the overall statistical results.

Conclusion

For diagnosing the malignancy risk of thyroid nodules, ACR-TIRADS demonstrates high sensitivity, while S-detect shows high specificity, NPV and accuracy. S-detect is a valuable tool for enhancing the diagnostic accuracy of benign thyroid nodules for non-radiologists and less experienced radiologists performing thyroid ultrasounds, helping to reduce unnecessary FNA.

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