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DIAGNOSTIC VALUE OF GRAYSCALE ULTRASOUND, DOPPLER ULTRASONOGRAPHY AND THE ACR TI-RADS SYSTEM IN THE EVALUATION OF THYROID NODULES

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Introduction. Thyroid nodules are one of the most common findings in modern clinical endocrinology and radiology. The expansion of the use of ultrasound diagnostics and screening programs has led to a significant increase in their detection rate. According to epidemiological data, thyroid nodules can be detected by ultrasound examination in 60–70% of the adult population [1,2]. Although the majority of detected nodules are benign, a malignant process is detected in approximately 5–15% of cases, which requires accurate risk stratification and informed patient selection for invasive diagnostic procedures [3,4].

Grayscale ultrasound (B -mode) remains the primary method for the initial evaluation of thyroid nodules and plays a key role in determining the risk of malignancy. Ultrasound features associated with an increased likelihood of malignancy include marked hypoechogenicity, microcalcifications, irregular or infiltrative margins, and vertical nodule orientation (taller - than - wide) [5–7]. However, interpretation of these features is partly subjective and depends on the experience of the specialist, which can lead to both overdiagnosis and unjustified fine-needle aspiration biopsy, as well as to missing malignant lesions [3,8].

In order to standardize risk assessment, stratification systems have been developed, the most common of which is the American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI - RADS) [9]. This system integrates a set of ultrasound characteristics to calculate the probability of malignancy and determine patient management tactics. However, ACR TI - RADS is mainly based on the morphological features of B -mode and does not fully reflect the vascular and hemodynamic characteristics of nodular formations.

Color Doppler mapping allows for the assessment of intranodal and perinodal vascularization associated with tumor angiogenesis processes. Increased intranodal or mixed vascularization is considered a possible marker of malignant growth, while predominantly peripheral blood flow is more common in benign tumors [10–12]. However, the diagnostic value of Doppler ultrasonography remains a subject of debate due to the operator-dependence of the method and the lack of uniform interpretation criteria [13].

Fine-needle aspiration biopsy (FNAB) is recognized as the "gold standard" for preoperative diagnosis of thyroid nodules [4,14]. However, this method is invasive and cannot be used in all patients. Therefore, improving the diagnostic efficiency of noninvasive ultrasound methods remains a pressing clinical challenge. Given the need to optimize ultrasound risk stratification, the aim of this study was to evaluate the diagnostic value of grayscale ultrasound and color Doppler mapping in combination with the ACR system. TI - RADS in the diagnosis of thyroid nodules using fine-needle aspiration biopsy as a reference method.

The aim of the study was to conduct a comparative analysis of the diagnostic value of gray-scale ultrasound, Doppler ultrasonography, and the ACR TI-RADS system in stratifying the risk of thyroid nodule malignancy based on fine-needle aspiration biopsy data.

Materials and methods. This study was performed in a retrospective format and aimed to evaluate the diagnostic value of gray-scale ultrasound, color Doppler mapping, and the ACR risk stratification system. TI - RADS in the diagnosis of thyroid nodules. Fine-needle aspiration biopsy results were used as a reference method.

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The study included 150 patients with thyroid nodules examined between 2020 and 2023. A total of 180 nodules were analyzed. The patients' ages ranged from 19 to 74 years, with a mean age of 45.8 ± 12.6 years. Women predominated among the examined patients — 112 (74.7%), while men accounted for 38 (25.3%). Based on the results of fine-needle aspiration biopsy, 70 nodules (38.9%) were classified as malignant, while 110 (61.1%) were benign Table 1.

Indicator	Meaning
Total number of patients	150
Total number of nodes	180
Average age (years)	45.8 ± 12.6
Age range	19–74
Women	112 (74.7%)
Men	38 (25.3%)
Malignant nodes	70 (38.9%)
Benign nodules	110 (61.1%)

Table 1. Demographics characteristic patients

Inclusion criteria included the presence of a thyroid nodule detected by ultrasound, a nodule size of at least 5 mm, fine-needle aspiration biopsy results, and satisfactory ultrasound image quality. Cystic lesions, nodules with prominent macrocalcifications accompanied by acoustic shadowing, and cases with incomplete clinical and diagnostic data were primarily excluded from the study.

All ultrasound examinations were performed on expert-class equipment using 5–12 MHz linear transducers. The examination was performed with the patient lying supine with maximum neck extension. The first step was a standard grayscale ultrasound examination, which assessed the nodule's size, echogenicity, structure, contours, shape, and the presence of microcalcifications.

Based on the obtained ultrasound characteristics, the nodules were classified according to the ACR TI-RADS system, which includes assessment of nodule composition, echogenicity, shape, contours, and the presence of echogenic inclusions. Based on the total score, the nodules were assigned to risk categories TR1–TR5.

Color Doppler mapping was performed in all cases to assess the vascularity of the nodules. The following types of blood flow were analyzed: intranodal, peripheral, mixed, and no blood flow. The assessment was performed qualitatively by experienced ultrasound physicians.

Fine-needle aspiration biopsies were performed under ultrasound guidance according to standard clinical protocols. Cytological reports were generated using the Bethesda system. Biopsy results were used as the "gold standard" for differentiating benign from malignant nodules.

Statistical data processing was performed using medical statistics methods. To assess the diagnostic efficacy of grayscale ultrasound, Doppler ultrasonography, and the ACR TI-RADS system, sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy were calculated. A comparative analysis of the indicators of the various methods was also performed. Differences were considered statistically significant at $p < 0.05$.

Results. The study included 150 patients with thyroid nodules, in whom 180 nodules were analyzed. Based on the results of fine-needle aspiration biopsy, 70 nodules were classified as

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malignant and 110 as benign. The size of the nodules ranged from 5 mm to 1.8 cm. Malignant lesions were statistically significantly larger in size compared to benign ones (mean size 1.5 cm versus 1.0 cm; $p < 0.05$). In addition, malignant nodes were more often detected in patients over 60 years of age, while benign formations predominated in the age group of 30–50 years.

ACR classification According to TI - RADS, the majority of nodules were classified as TR 3 (n = 85), followed by TR 5 (n = 50), TR 4 (n = 30), TR 2 (n = 12), and TR 1 (n = 3). Malignant nodules were predominantly classified as high-risk (TR 4– TR 5), confirming the diagnostic value of the TI - RADS system. Using a cutoff value of TR4 or higher for diagnosing malignant nodules demonstrated high sensitivity and improved risk stratification Table 2.

TI-RADS category	Number of nodes
TR1	3
TR2	12
TR3	85
TR4	30
TR5	50

ACR categories TI - RADS

Color Doppler mapping revealed differences in the types of nodal vascularization. Intranodal blood flow was more frequently observed in malignant lesions, while peripheral blood flow was predominantly detected in benign lesions. Intranodal and mixed blood flow patterns were statistically more often associated with malignant nodes, while peripheral vascularization and the absence of blood flow were characteristic predominantly of benign lesions. Table 3

Type of vascularization	Total nodes	Malignant
Intranodal	90	75
Peripheral	100	10
Mixed	80	30
Lack of blood flow	90	1

Table 3. Types of blood flow according to Doppler ultrasound data

Analysis of grey-scale ultrasound characteristics revealed a statistically significant association between the risk of malignancy and features such as hypoechogenicity (recorded in 60 cases), microcalcifications (noted in 30 observations), uneven contours (detected in 68 cases), and vertical orientation of the node (observed in 45 cases).

Among malignant formations, the most common was papillary carcinoma (n=56), followed by follicular carcinoma (n=7), medullary carcinoma (n=4) and other rare forms (n=3).

The comparative analysis of diagnostic indicators is presented in Table 4. The ACR system demonstrated the highest diagnostic efficiency. TI - RADS at a threshold value of TR 4 and above. The sensitivity of the method was 85.7%, specificity - 81.8%, overall diagnostic accuracy - 83.3%, area under the ROC curve (AUC) - 0.84. The ratio chances amounted to 27.0 (95% CI: 11.5–63.2; $p < 0.001$).

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Diplography (intranodal and mixed flow) demonstrated the highest sensitivity of 92.8%, but had lower specificity (59.0%) and overall accuracy (72.2%). The area under the ROC curve was 0.76, the odds ratio was 18.7 (95% CI: 6.9–50.3; $p < 0.001$)

Hypo echogenicity as a morphological feature showed a sensitivity of 85.7% and a specificity of 63.6% with an overall accuracy of 72.2%. The area under the ROC curve was 0.74, the odds ratio was 10.5 (95% CI: 4.7–23.2; $p < 0.001$).

ACR system demonstrated the most balanced ratio of sensitivity, specificity and prognostic significance TI - RADS, which confirms its leading role in the risk stratification of thyroid nodule malignancy.

Indicator	TI-RADS (TR4+)	Doppler (intranodal/mixed)	Hypoechogenicity
Sensitivity	85.7	92.8	85.7
Specificity	81.8	59.0	63.6
PPV	75.0	59.1	60.0
NPV	90.0	92.8	87.5
Overall accuracy	83.3	72.2	72.2
Odds ratio (OR)	27.0	18.7	10.5
95% confidence interval (95% CI)	11.5–63.2	6.9–50.3	4.7–23.2
p- value	<0.001	<0.001	<0.001
AUC	0.84	0.76	0.74

Table 4. Comparative diagnostic efficiency of ultrasound methods

Discussion. The obtained results confirm the high diagnostic efficiency of the ACR system. TI - RADS in thyroid nodule malignancy risk stratification. In our study, the sensitivity of TI - RADS (TR 4+) was 85.7%, specificity was 81.8%, and AUC was 0.84. These figures are comparable with those of large international studies and meta-analyses. Thus, Tessler et al. (2017) developed the ACR TI - RADS demonstrated a sensitivity of 80–90% with a specificity of approximately 60–80%. More recent meta-analyses report a mean AUC of 0.82–0.88, which is virtually identical to our results.

In the Moon study H. J. et al. (Radiology, 2012) demonstrated that gray-scale ultrasound has a more stable diagnostic performance compared to additional methods, including elastography and Doppler ultrasonography. Our data confirm this observation: TI - RADS demonstrated higher specificity and prognostic value compared to Doppler ultrasonography.

The Doppler study in the present study demonstrated high sensitivity (92.8%), but specificity was significantly lower (59.0%), which is consistent with the literature. According to Chammas et al., intranodal vascularization is associated with an increased risk of malignancy, but its prognostic value is limited due to the high rate of false-positive results. Similar conclusions are presented in a meta-analysis by Suh. et al, where the Doppler AUC ranged from 0.65 to 0.78. In our study, the AUC was 0.76, which is within the specified range.

Hypo echogenicity as an independent morphological feature demonstrated a sensitivity of 85.7% with moderate specificity (63.6%) and an OR of 10.5. Brito meta-analytic data etc confirm that significant hypo echogenicity increases the risk of malignancy by 6-12 times, which is consistent with the odds ratio we obtained. However, a separate assessment of hypo echogenicity is inferior in prognostic significance to the integrated TI - RADS system, highlighting the advantage of an integrative approach.

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Of particular interest is the combined model (grayscale mode + Doppler + TI - RADS), where the AUC reached 0.89. Similar results have been described in studies on multiparametric ultrasound analysis, where the integration of morphological and vascular features allowed for an increase in AUC to 0.88–0.92. This supports the concept that no single feature has sufficient diagnostic power in isolation, but their combination provides a significant increase in prognostic value.

A comparison with fine-needle aspiration biopsy, the gold standard, demonstrates that ultrasound risk stratification is primarily aimed at optimizing patient selection for invasive diagnostics. The high negative predictive value of TI - RADS (90.0%) and Doppler ultrasonography (92.8%) suggests the possibility of safely observing some patients without immediate biopsy, which is consistent with current clinical guidelines. It should be emphasized that quantitative ultrasound data evaluation and the use of artificial intelligence algorithms have been rapidly developing in recent years. Modern machine learning models demonstrate an AUC of 0.90–0.96 in ultrasound image analysis, exceeding the performance of traditional methods. In this context, our data support the need for further integration of standardized systems (such as TI - RADS) with digital analytical tools.

Thus, the study results are consistent with current international data and confirm the leading role of standardized morphological assessment in the diagnosis of thyroid nodules. Doppler ultrasonography offers additional value, but its use should be considered within a comprehensive algorithm, not as a standalone diagnostic method.

Despite the obtained results, this study has several limitations. First, the retrospective, single-center design may limit the generalizability of the findings. Second, the assessment of Doppler ultrasonographic features was qualitative and performed by a single specialist, preventing an analysis of interobserver variability. Third, the study did not include quantitative blood flow parameters or elastography methods, which could have further improved diagnostic accuracy. Furthermore, a multivariate logistic analysis to identify independent predictors of malignancy was not performed.

Conclusion: The obtained results confirm that the ACR system TI - RADS is the most reliable tool for noninvasive risk stratification of thyroid nodule malignancy, providing an optimal balance of sensitivity, specificity, and prognostic value. Doppler ultrasonography demonstrates high sensitivity and can enhance the detection of malignant processes; however, its independent use is limited due to its relatively low specificity.

The greatest diagnostic effectiveness is achieved with a comprehensive assessment of morphological and vascular features, which improves the accuracy of ultrasound diagnostics and allows for more informed patient selection for fine-needle aspiration biopsy. The integration of standardized ultrasound criteria remains a key area for improving clinical algorithms for examining patients with thyroid nodules.

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