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THE SIGNIFICANCE OF THE COMBINED USE OF THE TI-RADS SYSTEM, ELASTOGRAPHY AND FINE NEEDLE ASPIRATION BIOPSY IN THE DIAGNOSIS AND TREATMENT TACTICS IN THYROID NODULES

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The results of examination and treatment of 399 patients aged 12 to 83 years with thyroid nodules of various morphological structures were analyzed. All patients were ranked into 2 groups. Group 1 included 127 (37.6 %) patients who underwent a fine needle aspiration biopsy of thyroid nodules. The 2nd group included 212 (62.4 %) patients who underwent ultrasound examination using the TI-RADS system, sonoelastography in combination with fine needle aspiration biopsy. Surgical treatment was performed in 50 (group 1) (39.3 %) of 127 patients, benign tumors were diagnosed in 40 (80 %), malignant tumors in 10 (20 %). Surgical treatment in group 2 was performed in 52 (24.5 %) of 212 patients, benign tumors were detected in 33 (63.5 %) patients, malignant in 19 (36.5 %). The combined use of the TI-RADS system, sonoelastography and fine needle aspiration biopsy contributed to a significant increase in the frequency of detection of thyroid nodules of malignant structure, which amounted to 36.5 % in patients of the main group (versus 20 % in patients of the control group) and a decrease in the frequency of surgical interventions by more than 1.5 times in patients of the second group.

Key words: thyroid gland, nodular formations, ultrasound examination, fine needle aspiration biopsy, sonoelastography, stratification systems.

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ЗНАЧЕННЯ КОМБІНОВАНОГО ВИКОРИСТАННЯ СИСТЕМИ TI-RADS, ЕЛАСТОГРАФІЇ ТА ТОНКОГОЛКОВОЇ АСПІРАЦІЙНОЇ БІОПСІЇ У ДІАГНОСТИЦІ ТА ЛІКУВАННІ ВУЗЛОВИХ УТВОРЕНЬ ЩИТОВИДНОЇ ЗАЛОЗИ

Було проаналізовано результати обстеження та лікування 399 пацієнтів віком від 12 до 83 років з вузловими утвореннями щитовидної залози різних морфологічних структур. Усі пацієнти класифікувались на 2 групи. Перша група включала 127 (37,6 %) пацієнтів, яким виконували тонкоголкову аспіраційну біопсію вузлових утворень щитовидної залози. Друга група включала 212 (62,4 %) пацієнтів, яким проводили ультразвукове обстеження за допомогою системи TI-RADS, та соноеластографію в поєднанні з тонкоголковою аспіраційною біопсією. Хірургічне лікування проводили у 50 (1 група) (39,3 %) зі 127 пацієнтів, доброякісні пухлини діагностували у 40 (80 %), злоякісні – у 10 (20 %). Хірургічне лікування у 2-й групі проводили у 52 (24,5 %) з 212 пацієнтів, доброякісні пухлини були виявлені у 33 (63,5 %) пацієнтів, злоякісні – у 19 (36,5 %). Комбіноване використання системи TI-RADS, соноеластографія та тонкоголкова аспіраційна біопсія сприяли надійному збільшенню частоти виявлення вузлових утворень щитовидної залози злоякісної структури, що становило 36 % основної групи (проти 20 % у пацієнтів контрольної групи) і зменшенню частоти хірургічних втручань більш ніж 1,5 рази у пацієнтів другої групи..

Ключові слова: щитовидна залоза, вузлові утворення, ультразвукове обстеження, тонкоголкова аспіраційна біопсія, соноеластографія, системи стратифікації.

Clinical and epidemiological studies of recent decades indicate a steady trend towards an increase in nodular formations (NF) of the thyroid gland (TG). In the general population, the proportion of palpable NF TG is 4–7 %, and their detection by ultrasound increases to 30–67 %. At the same time, TG cancer accounts for 5–15 % of all NF of the organ [7, 14].

The issues of diagnostic and therapeutic-tactical strategy for TG NF have been the subject of lively discussion for many years. The diagnostic informativeness of ultrasound for the verification of TG NF varies from 19 to 67 % [5, 14].

The introduction of fine needle aspiration biopsy (FNAB) in the preoperative diagnosis of NF allowed to reduce the number of unjustified surgical interventions performed for diagnostic purposes for non-tumor diseases and benign TG tumors by more than 2 times. [5, 6, 9]

From the standpoint of modern approaches, indications for FNAB in patients with NF TG should be justified taking into account the total assessment of echographic criteria according to the TI-RADS system (Thyroid Imaging Reporting and (integral) Data System) – a model of unified assessment and standardization of ultrasound criteria (images) of NF depending on the risk of their malignancy, since the dynamics and rate of NF growth is determined not only by the morphological structures of nodes [5, 8]. The undoubted advantage of the integrated model of NF images according to the TI-RADS system, based on the qualitative characteristics of nodes, is a good correlation with the international cytological classification of TG pathologies adopted in 2010 – The Bethesda System for Reporting Thyroid Cytopathology (TBSRTC) [4, 6, 8]. Y.K.Alexandrov et al believe that the TI-RADS system regulates the interpretation of echographic signs of NF TG, and thereby levels the probability of error in the formulation of the diagnosis. And the combined use of TI-RADS – TBSRT allows you to individualize the therapeutic and tactical algorithm.

In recent years, the role and significance of a type of ultrasound of TG - ultrasound compression elastography (carried out in real time) in the differential diagnosis of NF TG have been actively discussed. As an additional technology to traditional ultrasound, sonoelastography (SEG) is based on studying the mechanical properties of tissues, measuring the level and amplitude of their deformation when performing metered local compression of the examined area by a sensor (Єultrasonic palpation") [1]. As an additional technology to traditional ultrasound, sonoelastography (SEG) is based on studying the mechanical properties of tissues, measuring the level and amplitude of their deformation when performing metered local compression of the examined area by a sensor ("ultrasonic palpation") [1].

At the same time, with the help of a color Doppler, the doctor receives information about the degree of deformation and density (elasticity) of the thyroid tissue under study, highlighting tougher areas in a certain color as an "index" of malignancy corresponding to the density characteristics of malignant growth.

The results of the meta-analysis [1, 5, 10] and the clinical recommendations of the European Federation of Societies for Ultrasound Technology in Medicine and Biology (EFSU MB) [10, 11] suggest that SEG has slightly greater diagnostic accuracy in the risk stratification of thyroid cancer than FNAB. On the other hand, SEG increases the accuracy of FNAB.

Thus, the issues of differential diagnosis and morphological verification of NF TG nodes are still far from a final solution. There are no universally recognized unified prognostic models that allow to determine the malignancy of NF TG in accordance with the requirements of evidence-based medicine.

The purpose of the study was to assess the effectiveness of the combined use of the TI-RADS system, sonoelastography and fine needle aspiration biopsy in the diagnosis and therapeutic tactics for thyroid nodules.

Material and methods. The results of examination and treatment of 399 patients aged 12 to 83 years with nodular (average size 23.33±16.7 mm) TG formations of various morphological structures, located in the Educational and Surgical Clinic of the Azerbaijan Medical University in the period from 2015 to 2021, were analyzed. There were 351 women (88.8 %). There were 48 men (11.2 %). The age of the patients ranged from 12 to 83 years. The average age was (45.1±26.9) years.

Methodologically, the conduct of this study corresponded to the standards of the Helsinki Declaration adopted in June 1964 (Helsinki, Finland) and revised in October 2000 (Edinburgh, Scotland).

The diagnostic algorithm included routine general clinical examinations (collection of complaints and anamnesis, examination of the anterior surface of the neck and areas of regional lymph flow, palpation of the anterior surface of the neck), laboratory examination of hormonal status, ultrasound with evaluation of echographic criteria according to the TI-RADS system, supplemented by SEG, FNAB, followed by cytological examination in accordance with the international classification system Bethesda.

In accordance with the features of the applied diagnostic and therapeutic-tactical algorithm, all patients were divided into two groups. The 1st (control) group included 127 (37.6 %) patients who were FNAB with NF TG according to generally accepted indices [6, 7, 14]. Treatment tactics in these patients were determined depending on the results of FNAB. The second (main) group consisted of 212 (62.4 %) patients in whom the diagnostic and therapeutic-tactical algorithm was based on a comprehensive

assessment of the ultrasound criteria of the NF according to the TI-RADS system, the results of the SEG and cytological examination according to the Bethesda system.

Patients of group 1 underwent ultrasound of the TG according to the standard protocol on the Aplio XG ultrasound machine (Toshiba, Japan) using a linear sensor with a frequency of 8–12 MHz. Patients of the 2nd (main) group underwent SEG in a modification of compression elastography on a color digital portable ultrasound scanner "Sonoscape S9" using a linear sensor with a frequency of 8–12 MHz. For a structured (point-based) evaluation of the obtained sonoelastograms, the Ueno scale of standard elastographic images used for the TG was used Rago, et al. The systematization of SEG data characterizing tissue elasticity based on the analysis of color images reflecting the affected area was evaluated on a 5–point scale T.Rago,et al. [2].

The scale A – 1 point, indicating the elasticity of the entire NF together with the perinodular tissue of the TG, is depicted in green.

The scale is B – 2 points, the elasticity of the node was determined for the most part, encoded in blue and green images.

The scale of C – 3 points, the node elastic only on the periphery, was depicted in green on the periphery and blue in the center.

The D – scale is 4 points, the knot is not elastic, it was encoded in a blue image. There was no hypoechoic rim "hallo" around the node.

The scale is E – 5 points, neither the node nor the surrounding tissues of the TG are elastic, the image is blue. A fuzzy hypoechoic rim "hallo" was visualized around the node.

The qualitative characterization of the NF TG was carried out according to the TI-RADE system, which regulates the interpretation of echographic criteria, as well as the result of FNAB and SEG. An updated version (2018) of the Bethesda terminology classification was used to unify the evaluation of the results of cytological study.

Statistical processing of the results of the study was carried out using the software packages Stat Soft Statistica 12.0 and Microsoft Office Excel – 2010. The statistical reliability of the data was assessed using the coefficient of difference of average values according to the t-Student criterion. The coefficient of difference was considered statically significant at $p<0.05$. When analyzing the SEG data, quantitative and nonparametric indicators (Pearson's criterion χ^2) and indices of the ROC curve were evaluated.

Results of the study and their discussion. The evaluation of the obtained results was carried out taking into account the echographic criteria of the NF according to the TI-RADS system of comparison of SEG images and data from cytological and pathomorphological studies of the NF TG.

In group 1, the cytological characteristics of the NF corresponded to the classification according to the system Bethesda 1 in 8 (6.3 %) patients, Bethesda 2 – in 77 (60.6 %), Bethesda 3 – in 19 (15 %), Bethesda 4 – in 9 (7.1 %), Bethesda 5 – in 10 (7.9 %) and Bethesda 6 – in 4 (3.11 %) (table 1).

Table 1

The structure of clinical groups depending on the cytological characteristics of the thyroid gland according to the Bethesda system

Clinical Groups	Bethesda Classification System						
	Bethesda 1	Bethesda 2	Bethesda 3	Bethesda 4	Bethesda 5	Bethesda 6	Total
1st	8	77	19	9	10	4	127
2nd	4	140	37	16	11	4	212
Total	12	217	56	25	21	8	339

Surgical treatment was performed in accordance with the recommendations of the Association of Endocrine Surgeons.

In the 1st (control) group, 50 (39.3 %) of 127 patients underwent surgical intervention. At the same time, thyroidectomy was performed in 38 (76 %) patients, hemithyroidectomy – in 12 (24 %). During the pathomorphological examination of surgical materials, a benign tumor was verified in 40 (80.0 %), malignant – in 10 (20.0 %). Papillary cancer prevailed in the structure of malignant tumors of the TG, which was diagnosed in 8 (80%) patients. Hurthle cell carcinoma (in 1) 10 %)) and follicular variant of papillary cancer (in 1)10.0 %)) were less frequently observed.

In group 2, the cytological characteristics of the NF corresponded to the classification system "Bethesda 1" in 4 (1.9 %) patients, "Bethesda 2" – in 140 (66 %), "Bethesda 3" – in 37 (17.5 %), "Bethesda 4" – in 16 (7.5 %), "Bethesda 5" – 11(5.2 %) and "Bethesda 6" – 4 (1.9 %). In this group, ultrasound NF criteria according to the TI-RADS 2 system were detected in 6 (2.8 %) patients, TI-RADS 3 – in 115

(54.2 %), TI-RADS 4 – in 76 (35.8 %), TI-RADS 5 – in 15 (7.1 %). A comparison of the results of ultrasound stratification of the risk of malignant TG nodules according to the TI-RADS classification with the results of histological examination and cytological examination according to the Bethesda system is presented in table 2.

Table 2

Comparison of Bethesda categories with TI-RADS

	Bethesda 1n	Bethesda 2n	Bethesda 3n	Bethesda 4n	Bethesda 5n	Bethesda 6n
TR2	0(0)	4(2.7)	2(5.4)	0(0)	0(0)	0(0)
TR3	3 (75.0)	104(74.3)	6(16.2)	2(12.5)	0(0)	0(0)
TR4	0(0)	31(22.1)	28(75.7)	12(75.0)	2(45.5)	3(75.0)
TR5	1 (25.0)	1(0.9)	1(2.7)	2(12.5)	9(54.5)	1(25.0)
Total	4(100)	140(100)	37(100)	16(100)	11(100)	4(100)

Note: In parentheses – percentages; $\chi 2=47.72$; $P < 0.001$.

When ranking SEG images on the scale T.Rago in group 2, 4 (1.9 %) nodes of the TG were assigned to a scale of 2, 123 (58.0 %) nodes - to a scale of 3, 83 (39.2 %) nodes – to a scale of 4, 2 (0.9 %) nodes – to a scale of 5. Comparison of the results of cytological examination and sonoelastography of the NF TG shown in fig. 1.

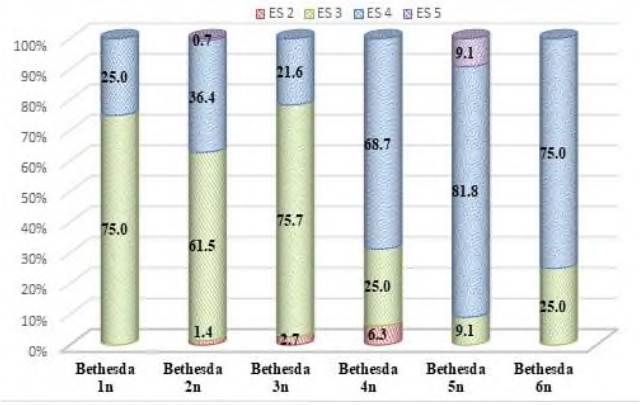
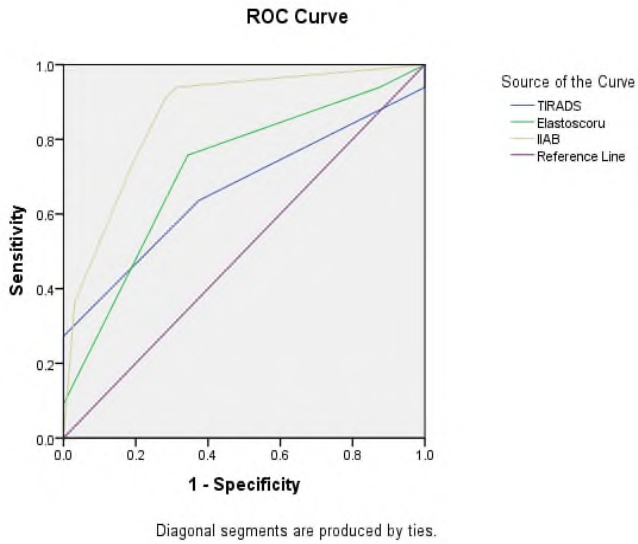


Fig. 1. Comparison of Bethesda categories with Tsukuba elasticity index ($\chi 2=49.77$; $P < 0.001$).

In the 2nd (main) group, surgical treatment was performed in 52 (24.5 %) of 212 patients, which is more than 1.5 times less than in patients of the 1st (control) group. We explain this by improving preoperative diagnostics, thanks to the combined use of the TI-RADS system, SEG and FNAB techniques. 41 (78.8 %) of 52 patients underwent thyroidectomy, 11 (21.2 %) had hemithyroidectomy. In the main group, during the pathomorphological examination of surgical preparations, benign tumors were detected in 33 (63.5 %) patients, malignant – in 19 (36.5 %). Malignant tumors were represented by papillary cancer in 15 (78.9 %) patients, Hurthle cell cancer – in 3 (15.8 %), follicular variant of papillary cancer – in 1 (5.3 %) patient.



As can be seen from the data presented, in group 2, the sensitivity of TI-RADS was 79.3 %, specificity – 95.2 %, positive predictive value – 95.8 %, negative predictive value – 76.9 %. The sensitivity of the SEG was 68.3 %, specificity – 66.7 %, positive predictive value – 80.0 %, negative predictive value – 51.9 %. These indices when performing FNAB were 93.5 %; 86.7 %; 93.6 % and 86.8 %, respectively (Fig.2). Consequently, the differences between the presented data are statistically significant ($p<0.05$).

As can be seen from the analysis, the area of the ROC curve for TI-RADS was: S=0.663±0.069; 95 % CI (0.528–0.797); p=0.024, that is, it is a statistically significant marker in the diagnosis of NF.

Indices (test)	Square	Statistical error	Statistical significance – p	95 % confidence interval	
				Lower bound	Upper bound
TI-RADS	0.663	0.069	0.024	0.528	0.797
SEG	0.718	0.064	0.003	0.592	0.844
FNAB	0.863	0.047	< 0.001	0.772	0.954

Fig. 2. ROC curve reflecting the predictive capabilities of the integrated use of TI-RADS, SEG, FNAB, 95 % confidence interval

The integral assessment of the sensitivity and specificity of the SEG method is an equally significant diagnostic criterion in the diagnosis of NF. S=0.718±0.064; 95 % CI (0.592–0.844); p=0.003.

The most significant marker in the diagnosis of NF was the FNAB test: S=0.863±0.047; 95 % CI (0.772–0.954); p< 0.001.

The effectiveness of differential diagnosis of NF TG depends directly on the degree of introduction into clinical practice of modern stratification systems that allow to verify the morphological structure of nodes with high reliability, to neutralize the probability of errors in the formulation of the diagnosis and the choice of therapeutic tactics [5, 6, 9, 14].

When assessing the diagnostic informativeness of FNAB in patients of the 1st (control) group, the sensitivity of the method was 10%, specificity – 74.4 %, positive predictive value – 9.1 %, negative predictive value – 76.3 %.

In the 2nd (main) group, these indices were 93.5 %; 86.7 %; 93.6 % and 86.8 %, respectively. As can be seen from the presented data, there are statistically significant differences between the SEG images and the results of cytological examination (p<0.05). The results obtained by us are consistent with the literature data [4, 10, 11]. The effectiveness of SEG, as one of the new ultrasound technologies characterized by high resolution, was tested by us in 212 patients with NF TG of various morphological structures. The results of our study show that the density characteristics of the NF TG, determined by the color pattern allocated during the SEG, are comparable with the literature data [4, 11]. Thus, according to our data, tougher areas of NF, as an "indicator" of malignancy, graded by IV–V points, characterize SEG as a method that increases the accuracy of FNAB, which is consistent with the data of other authors [3, 10, 11]. The results of our study give reason to believe that FNAB, carried out under the control of SAG, allows the procedure to be carried out in a targeted manner, thereby reducing the frequency of FNAB used in routine practice. On the other hand, we fully agree with the opinion of E.L.Bederin ,et al [2] that the SEG method cannot become an alternative to morphological research, but its use increases the effectiveness of preoperative diagnosis of NF TG.

The results obtained by us show that the use of SEG contributed to a decrease in the number of thyroidectomies from 39.3 % in patients of the control group to 24.5 % in patients of the main group. Similar data are given by E.L.Bederina, et al. [2], according to which, the frequency of thyroidectomy using the SEG technique was 22.6 %. According to our data, the sensitivity of the SEG was 68.3 %, specificity – 66.7 %, positive predictive value – 80.0 %, negative predictive value – 51.9 %.

According to L.A.Timofeeva [3], the sensitivity of the SEG for the detection of malignant NF was 91.6 %, the specificity was 88.8 %. Similar results were obtained by E.L.Bederina et al. [2], according to which these indices were 95.3 and 98.2 %, respectively. According to P.H.M.Moreas et al. [10], the sensitivity of the SEG was 82 %, specificity – 88 %, positive predictive value – 75 %, negative predictive value – 91 %.

The TI-RADS system has high sensitivity and negative prognostic value in the diagnosis of TG cancer. According to G. Russ et al. [13], SEG images of NF (density, hypoechogenicity, contour irregularity, vertical spatial orientation, the presence of microcalcinates characterize the malignancy of the tissue structure of nodes and are qualified as TI-RADS – 4 and TI-RADS – 5. According to the results of our study, in 51 (63 %) of 81 patients, NF stratified by the TI-RADS – 4 and TI-RADS – 5 system were assigned to the Bethesda cytological classification 4 and 6. According to our data, the sensitivity of the TI-RADS system was 79.3 %, specificity – 95.2 %, positive predictive value-95.8 %, negative predictive value – 76.9 %. These indicators correspond to the data of other authors [15].

Conclusions

1. The diagnostic and therapeutic-tactical algorithm for NF TG should be based on a cumulative assessment of ultrasound criteria according to the TI-RADS system, the results of SEG and cytological examination according to the Bethesda classification.

2. The use of FNAB under the control of SEG made it possible to individualize treatment tactics and reduce the frequency of surgical interventions by more than 1.5 times – from 39.3 % in patients of the control group to 24.5 % in patients of the main group. We explain the decrease in the frequency of thyroidectomy in patients of the main group by improving preoperative diagnosis due to the combined use of TI-RADS, SEG and FNAB.

3. The combined use of SEG and FNAB made it possible to perform targeted biopsy of NF TG and contributed to a significant increase in the frequency of detection of NF of a malignant nature. So, if in the control group, during the pathomorphological examination of postoperative drugs, a malignant tumor was verified in 20 % of patients, then in the main group this indicator was 36.5 % (p<0.05).

4. According to our data, with FNAB performed under the control of SEG and TI-RADS, the sensitivity of the method was 93.5 %, specificity – 86.7 %, positive predictive value – 93.6 %, negative predictive value – 86.8 %.

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