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ORIGINAL

Correlation between TI-RADS classification, fine needle aspiration biopsy and kerosene biopsy in the diagnosis of nodular thyroid disease

Correlación entre la clasificación TI-RADS, biopsia por aspiración por aguja fina y biopsia por parafina en el diagnóstico de la enfermedad nodular tiroidea

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ABSTRACT

Introduction: nodular thyroid disease requires invasive and non-invasive diagnostic means for its diagnosis, the former being the gold standard.
Objective: to determine the existence of correlation between the results of TI-RADS, Bethesda classifications and kerosene biopsy in patients with nodular thyroid disease treated at the General Teaching Hospital "Abel Santamaría Cuadrado" between 2019 and 2022.
Methodological design: an observational, analytical and cross-sectional study was carried out. The universe consisted of 202 patients according to inclusion criteria. To test the effectiveness of the procedures, sensitivity and specificity were evaluated. Cohen's Kappa was used to determine the agreement between variables.
Results: 63 patients were studied, with a mean age of 50.11 ± 15.71 years and a predominance of female sex (82.5 %). A benign nodular disease was identified by biopsy in 73 % of the patients. Inter-instrument agreement was Kappa=0.733 (good agreement) between TI-RADS and biopsy, Kappa=0.374 (poor agreement) between Bethesda and biopsy and Kappa=0.445 (moderate agreement) between TI-RADS and Bethesda. The sensitivity of TI-RADS was 88.2 % and specificity 89.1 % and of Bethesda the sensitivity was 94.1 % and specificity 55.6 %.
Conclusions: there was good concordance between TI-RADS and kerosene biopsy, poor concordance between fine needle aspiration biopsy and kerosene biopsy and moderate concordance between TI-RADS classification and fine needle aspiration biopsy.
Keywords: Thyroid Nodular Disease; Fine Needle Biopsy; Biopsy; Ultrasonography; Cancer.

RESUMEN

Introducción: la enfermedad nodular tiroidea requiere de medios diagnósticos invasivos y no invasivos para su diagnóstico, siendo los primeros el patrón de oro.
Objetivo: determinar la existencia de correlación entre los resultados de las clasificaciones TI-RADS, Bethesda y la biopsia por parafina en pacientes con enfermedad nodular tiroidea atendidos en el Hospital General Docente "Abel Santamaría Cuadrado" entre 2019 y 2022.
Diseño metodológico: se realizó un estudio observacional, analítico y transversal. El universo estuvo constituido por los 202 pacientes según criterios de inclusión. Para comprobar la efectividad de los procedimientos se evaluaron la sensibilidad y especificidad. Para determinar el acuerdo entre variables se estudió la Kappa de Cohen.
Resultados: Se estudiaron 63 pacientes, con una edad media de 50,11 ± 15,71 años y predominio del sexo femenino (82,5 %). En el 73 % de los pacientes se identificó mediante biopsia una enfermedad nodular benigna. El acuerdo entre instrumentos fue de Kappa=0,733 (buena concordancia) entre TI-RADS y biopsia, Kappa=0,374 (escasa concordancia) entre Bethesda y biopsia y de Kappa=0,445 (moderada concordancia) entre TI-RADS y Bethesda. La sensibilidad del TI-RADS fue del 88,2 % y la especificidad del 89,1 % y de Bethesda la sensibilidad del 94,1 % y especificidad del 55,6 %.
Conclusiones: existió buena concordancia entre TI-RADS y biopsia en parafina, una escasa concordancia entre la biopsia por aspiración por aguja fina y la biopsia en parafina y una moderada concordancia entre la clasificación TI-RADS y la biopsia por aspiración por aguja fina.

Palabras clave: Enfermedad Nodular Tiroidea; Biopsia por Aguija Fina; Biopsia; Ultrasonografía; Cáncer.

INTRODUCTION

In Latin America and the Caribbean, in 2019, malignant tumors were responsible for 1.4 million deaths, with a standardized mortality rate of 115.7 deaths per 100,000 population. The five main types of cancer-causing mortality were cancer of the trachea, bronchus, lung, breast cancer, cancer of the colon and rectum, leukemia, and multiple lymphomas and myelomas. Cuba is the sixth country in the region in terms of cancer mortality and years of life potentially lost.1

In Cuba, about the 10 leading causes of death, death from malignant tumors ranks second with a rate of 232.6 deaths per 100,000 inhabitants, preceded by heart disease (rate of 267.3 per 100,000 inhabitants). Both causes account for 49.8% of all deaths in 2020.2

Nodular thyroid disease (NCD) is defined by the presence of solid, liquid, or mixed thyroid nodules, whether palpable or not. It can present as a solitary thyroid nodule or diffuse and multinodular goiters. It represents a monoclonal lesion with a multifactorial pathophysiological background where multiple mitogenic pathways converge, characteristic of the follicular cell stimulating system, some of them with inhibited activity under physiological conditions and stimulated to a greater or lesser extent in the context of a nodular lesion.3-5

The incidence in different contexts and the burden of surgical interventions for this entity are variable and multifactorial, including factors such as existing protocols, specialized personnel, and availability of resources.

Acosta Guerrero et al.6 investigated with the aim of clinically and epidemiologically characterizing patients undergoing surgical treatment for thyroid cancer. Forty-five patients with thyroid cancer were

operated on from January 2015 to December 2018, which represented 0.4% of the total number of operations performed in that period.

In Pinar del Río, Breña Pérez et al.7 conducted a study to describe the clinical and cytological characteristics of patients with nodular thyroid disease who underwent fine needle aspiration biopsy in 2016 at the "Abel Santamaría Cuadrado" General Teaching Hospital. The study revealed that 13 458 surgeries were performed during the period, of which 106 were thyroid surgeries (0.8 %). The percentage of thyroid-related surgeries exceeds that reported by other studies,6 representing a health problem for the institution and the province.

At present, nodular thyroid diseases are frequent entities with a significant incidence and a threat to the patient's life. It is an entity that is among the first causes of morbidity within thyroid diseases, and our country is not exempt from this.

The use of less invasive and more accurate methods is a necessity in the diagnosis of the patient, as well as for the optimization of the health system's resources. Despite large international volumes of information on the subject, there is still disagreement.

In the province of Pinar del Río, and specifically in the General Teaching Hospital "Abel Santamaría Cuadrado," epidemiological studies on thyroid nodular disease are collected; however, there are no studies that correlate the results between TI-RADS classifications, fine needle aspiration biopsy, and kerosene biopsy.

The present study was carried out to determine the existence of a correlation between the results of TI-RADS, Bethesda classifications of fine needle aspiration biopsy, and kerosene biopsy in patients with nodular thyroid disease.

METHODS

An observational, analytical, and cross-sectional study was conducted in patients with nodular thyroid disease attended by the General Surgery service of the General Teaching Hospital "Abel Santamaría Cuadrado" between 2019 and 2022.

The study population consisted of 202 patients with nodular thyroid disease attended by the General Surgery service of the General Teaching Hospital "Abel Santamaría Cuadrado" between 2019 and 2022. The sample consisted of 63 patients who underwent fine needle aspiration biopsy, imaging study according to TI-RADS, and kerosene biopsy.

Patients over 18 years of age, regardless of sex, with a diagnosis of nodular thyroid disease who underwent fine needle aspiration biopsy, TI-RADS imaging study, and kerosene biopsy and who agreed to participate in the study were included.

Patients with a history of previous hematologic diseases, initially diagnosed in other institutions, or with incomplete data in the medical history were excluded.

The medical records of the patients seen during the study period and the thyroid consultation record book were reviewed to obtain some data. A data collection form will be used to capture the case information.

FNA procedure

Fine needle aspiration was performed with the patient in the supine or sitting position with the neck hyperextended. The patient was instructed to swallow saliva -which facilitates the localization of the nodule while holding it with one hand- in the palpable ones; those guided by ultrasound are located with the transducer, and the puncture site is marked at skin level, then the needle is introduced, and its position in the nodule is rectified with the ultrasound equipment. The small 24 or 27 G needle was inserted into the periphery of the nodule, and with an up-and-down motion, the sample was taken; the needle was rotated and then withdrawn as soon as blood appeared at its posterior end. The patient should not

swallow saliva during the procedure. Using a very fine needle is not painful (no anesthesia is needed) and reduces bleeding, thus avoiding contamination of the specimen with blood and increasing its quality.

A cytopathologist was present to see if the sample was adequate when it was taken or guided by ultrasound. When a cyst was aspirated, a sample was taken from the residual area; only if the nodule appears calcified or fibrous should a following aspiration with a Franzen gun (syringe holder) or only cytopuncture be performed, always without aspiration, to avoid excessive contamination of the sample with blood.

Preparation of the slides

The cells were ejected and spread on a slide. The needle was rinsed and placed in a container as an adjunct to the spreads. The smears were fixed with 95% alcohol and stained with Papanicolaou, Hematoxylin, and eosin, air-dried for Romanowsky-type staining. Nuclear features are best appreciated with Papanicolaou's stain, while Romanowsky's stain is useful for evaluating cytoplasmic details and extracellular material, such as colloid.

Histopathological diagnoses were regrouped into benign and malignant pathology. For the comparative purposes of methods, definitions were leveled: TI-RADS 2,3 and 4a with Bethesda II-III: Low suspicion of malignancy, T-RADS 4b, 4c and 5 with Bethesda IV-V-VI: High suspicion of malignancy.

Statistical processing

With the data obtained from information collection, a database was created in SPSS 25.0.

At the statistical level, descriptive statistics were used to calculate the qualitative variables' absolute and relative percentage frequencies. The quantitative variables' medical, standard deviation, minimum, and maximum were calculated.

To check the effectiveness of the FNA and TI-RADS procedure, the results were evaluated in terms of sensitivity (Se) and specificity (Sp) compared to the surgical specimen kerosene biopsy.

Sensitivity is the ability to correctly classify a diseased individual, i.e., the probability that the test will achieve a positive result for a diseased subject. Sensitivity is, therefore, the ability of the test to detect disease. The ideal test should be 100% sensitive, i.e., no false negative results.

Specificity is the ability to correctly classify a healthy individual, i.e., the probability that the test will achieve a negative result for a healthy subject. Specificity is, therefore, the ability of the test not to make a mistake in detecting a disease. The ideal test should be 100% specific, i.e., no false-positive results.

A false positive is a test result that indicates that a person has a particular disease or condition when, in fact, he or she does not.

A false negative is a test result that indicates that a person does not have a particular disease or condition when, in fact, he or she does. False-negative results are related to the specificity of the test.

They were calculated as follows:

- Se = true positive / (true positives + false negatives);
- Sp = true negative / (true negatives + false positives);

To determine the agreement between variables, Cohen's kappa was studied where:

- 0.00 - 0.20 (Low agreement)
- 0.20 - 0.40 (Strong agreement)
- 0.40 - 0.60 (Moderate agreement)
- 0.60 - 0.80 (Good agreement)
- 0.80 - 1.00 (Very good agreement)

Ethical aspects

The study will be carried out in accordance with the ethical principles for medical research in humans, established in the Declaration of Helsinki as amended by the 59th General Assembly, Seoul, Korea, October 2008, and in accordance with the provisions of the Cuban National Health System, foreseen in

Law No. 41 of Public Health. Its execution will have the approval of the Scientific Council and the Ethics Committee of the institution. Fundamental aspects such as the reliability of the information, adequate processing and standardization of the data for its tabulation, analysis and interpretation will be taken into consideration. Informed consent will be requested from the patients or their relatives in case they are not in full use of their faculties.

RESULTS

A total of 63 patients were studied, with a mean age of 50.11 ± 15.71 years (minimum: 22 years, maximum: 93). There was a predominance of patients between 30 and 60 years of age (65.1 %) and of female patients (82.5 %) (Table 1).

Table 1. Distribution according to age and sex of patients diagnosed with nodular thyroid disease, Hospital General Docente "Abel Santamaría Cuadrado" January 2019 - July 2022.

Age	Sex Male		Sex female		Total	
(in years)	No.	%	No.	%	No.	%
< 30	4	36,4	2	3,8	6	9,5
30 - 60	6	54,5	35	67,3	41	65,1
> 60	1	9,1	15	28,9	16	25,4
Total	11	17,5	52	82,5	63	100

Source: own elaboration.

No patients with TI-RADS 1 and 6 were reported. 30.2 % of the patients were found in the TI-RADS 4a group. 31.8 % of the patients presented a TI-RADS value higher than 4th. It was identified that 47.6 % of the patients were in the Bethesda IV category; 42.8 % of the patients were classified as Bethesda III or lower (Table 2).

Table 2. Distribution according to TI-RADS and cytological diagnosis by FNAB of patients with nodular thyroid disease, Hospital General Docente "Abel Santamaría Cuadrado" January 2019 - July 2022.

Study	Category	No.	%
TI-RADS	TI-RADS 2	15	23,8
	TI-RADS 3	9	14,3
	TI-RADS 4a	19	30,2
	TI-RADS 4b	10	15,9
	TI-RADS 4c	7	11,1
	TI-RADS 5	3	4,8
Bethesda	**II**	22	34,9
	III	5	7,9

IV	30	47,6
V	3	4,8
VI	3	4,8

Source: own elaboration.

A benign nodular disease was identified by biopsy in 73 % of the patients. Follicular adenoma was the most common benign histological variant in 25.4% of patients, while the most common malignant variant was papillary carcinoma (19% of patients) (Table 3).

Table 3. Distribution according to histological diagnosis by FNA of patients diagnosed with nodular thyroid disease, Hospital General Docente "Abel Santamaría Cuadrado" January 2019 - July 2022.

Histopathological diagnosis	Histological diagnosis	No.	%
Benigne (n=46)	Follicular adenoma	16	25,4
	Nodular colloid goiter	9	14,3
	Multinodular goiter	15	23,8
	Nodular hyperplasia	2	3,2
	Hashimoto's thyroiditis	4	6,3
Malign (n=17)	Hurthle cell carcinoma	3	4,8
	Follicular carcinoma	1	1,6
	Medullary thyroid carcinoma	1	1,6
	Papillary carcinoma	12	19
	Total	63	100

Source: own elaboration.

Analysis of the TI-RADS classification with ENT histopathology showed that in TI-RADS categories 2 and 3 there were no malignant cases, while in 4c and 5 100% of the cases were malignant (table 4).

Table 4. Correlation TI-RADS-histopathology in patients diagnosed with nodular thyroid disease, Hospital General Docente "Abel Santamaría Cuadrado" January 2019 - July 2022.

Category according to TI-RADS	Histopathological diagnosis			
	Malign		Benigne	
	No.	%	No.	%
TI-RADS 2	0	0	15	32,6
TI-RADS 3	0	0	9	19,6

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TI-RADS 4a	2	11,8	17	37,0
TI-RADS 4b	5	29,4	5	10,9
TI-RADS 4c	7	41,2	0	0
TI-RADS 5	3	17,6	0	0
Total	17	100	46	100

Source: own elaboration.

Analysis of the Bethesda classification with NCD histopathology showed that in Bethesda categories II and III the proportion of malignant cases was lower than in categories V and VI where 100 % of the cases were malignant (Table 5).

Table 5. Cyto-histopathological correlation in patients diagnosed with nodular thyroid disease, Hospital General Docente "Abel Santamaría Cuadrado" January 2019 - July 2022.

Category according to Bethesda system	Histopathological diagnosis			
	Malign		Benigne	
	No.	%	No.	%
II	1	5,9	21	45,7
III	1	5,9	4	8,6
IV	9	52,9	21	45,7
V	3	17,6	0	0
VI	3	17,6	0	0
Total	17	100	46	100

Source: own elaboration.

Cohen's Kappa index of inter-instrument agreement was 0.733 (good agreement) for TI-RADS, with a p<0.001. The sensitivity of TI-RADS was 88.2 % and specificity 89.1 % in the diagnosis of malignancy of nodular thyroid disease (Table 6).

Table 6. Diagnostic validity of TI-RADS in patients diagnosed with nodular thyroid disease, Hospital General Docente "Abel Santamaría Cuadrado" January 2019 - July 2022.

Diagnosis according to TI-RADS	Histopathological diagnosis				Total	p
	Malign		Benigne			
	No.	%	No.	%		
Malign	(VP) 15	88,2	(FP) 5	10,9	20	
Benigne	(FN) 2	11,8	(VN) 41	89,1	43	<0,001
Total	17	100	46	100	63	

Source: own elaboration. VP: True positive, VN: True negative, FP: False positive, FN: False negative *Value calculated by Chi-square test.

Cohen's Kappa index of inter-instrument agreement was 0.374 (poor agreement) for FNA, with a p<0.001. The sensitivity of FNAB was 94.1% and specificity 55.6% in the diagnosis of malignancy of nodular thyroid disease (Table 7).

Table 7. Diagnostic validity of FNA in patients diagnosed with nodular thyroid disease, Hospital General Docente "Abel Santamaría Cuadrado" January 2019 - July 2022.

Diagnosis according to BAAF	Histopathological diagnosis				Total	p
	Malign		Benigne			
	No.	%	No.	%		
Malign	(VP) 16	94,1	(FP) 20	43,5	36	
Benigne	(FN) 1	5,9	(VN) 26	55,6	27	<0,001
Total	17	100	46	100	63	

Source: own elaboration. VP: True positive, VN: True negative, FP: False positive, FN: False negative *Value calculated by Chi-square test.

CONCLUSIONS

A higher incidence was identified in females between the third and sixth decades. Benign lesions were predominant according to TI-RADS and kerosene biopsy and were highly suspected of malignancy according to Bethesda criteria. Among benign lesions, follicular adenoma was the most common, and papillary carcinoma was among malignant lesions. TI-RADS and fine needle aspiration biopsy showed adequate sensitivity for diagnosing malignant nodular thyroid disease. There was good agreement between TI-RADS and kerosene biopsy, poor agreement between fine needle aspiration biopsy and kerosene biopsy, and moderate agreement between TI-RADS classification and fine needle aspiration biopsy.

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None.

CONFLICT OF INTEREST
None.