Research Article

Combined Thyroid Imaging Report and Data System Ti-Rads and Ultrasound Guided Fine Needle Aspiration Biopsy in Solid Thyroid Nodules

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Abstract

The aim of this study is to evaluate the utility of UGFNA (ultrasound guided fine needle aspiration biopsy) after evaluating solid thyroid nodules with the risk stratification diagnostic tool, the Thyroid Imaging Reporting and Data System (TI-RADS) classification system. Real time elastography results will be used as one of the six criteria as suspicion for malignancy. The study group comprised 108 cases evaluated by means of ultrasound (Hitachi Preirus Machine, linear multi frequency probe). A pathology report was completed in all cases and considered a diagnostic gold standard. Ultrasound results: TI-RADS 3 (cancer risk < 5%) 3 cases; TI-RADS 4A: 31 cases (cancer risk < 10%), TI-RADS 4B: 50 cases (high risk of malignancy up to 60%); TI-RADS 5: 6 cases (cancer risk > 90%). UGFNA results: 4 cases BETHESDA BI (3.6%) I, 46 cases BII (27.77%), 30 cases BIII (27.77%), 4 cases Bethesda IV (3.70%) and 24 cases BV and VI (22.22%). The pathology certified thyroid cancer in 30 cases: 27 PTC and 3 FTC. Ultrasound evaluation was unclear in TI-RADS 4A and 4B cases (81/108 cases). TI-RADS 2,3 and 5 cases were correctly evaluated by means of TI-RADS. Borderline ultrasound characteristics required further evaluation. TI-RADS 4B cases should be biopsied in order to have a correct approach. The results were that the combination of the two procedures would increase the diagnostic quality, reduce the number of unnecessary UGFNA and would focus on the important lesions to be clarified. However, the TI-RADS model cannot substitute UGFNA.

ABBREVIATIONS

ATA: American Thyroid Association; FTC: Follicular Thyroid Cancer; NPV: Negative Predictive Value; PPV: Positive Predictive Value; PTC: Papillary Thyroid Cancer; SD: Standard Deviation; SE: Strain Elastography; SPSS: Statistical Package for Social Sciences; TI-RADS: Thyroid Imaging Report and Data System; UGFNA: Ultrasound Guided Fine Needle Biopsy

INTRODUCTION

The current management guidelines of thyroid nodules [1-3] recommend ultrasound guided fine needle aspiration (UGFNA) in cases of suspect thyroid nodules. The American Thyroid Association (ATA) [1] has stated that FNAB is the procedure of choice for the evaluation of thyroid nodules. The current indications are controversial: any solid isoechoic nodules larger than 1.5 cm in diameter, or hypo echoic nodules larger than1

cm in diameter [1]; any solid nodule larger than 1 cm with the exception of risk factors; when the lesion is larger than 5 mm in diameter or regardless of the diameter, any nodule with suspicious characteristics [3] are recommended for fine needle biopsy (FNAB) [2]. There are some differences between these 3 major Guidelines, especially in respect to the size and the category of the nodular lesion that should be referred for biopsy [4]. Because the most common cause of inadequate cytological diagnosis is sampling error, current guidelines recommend ultrasound guided biopsy procedure [2].

As known [2], in specialized centers, the diagnostic capacity of FNAB is good, with a pooled sensitivity of 83% (range 65-98%), specificity of 92% (72-100%), with low rates of false results: false positive 5% (range 1-11%) and false negative 5% (range of 0-7%) [5]. In less specialized centers, the diagnostic values are not so good [6]. Also the limited application rate of up to 66% is still a challenge in the FNAB diagnostic approach [7].

The TI-RADS system stratifies the risk of malignancy, similar to the BI-RADS system [8,9] which was created for a better evaluation of cases recommended for UGFNA. The described sensitivity is high, 88%-92.5% [8,9] with a low specificity of 49%-42% [7], but however, with excellent PPV = 88% and NPV = 94%.

Real time elastography is a newly developed ultrasound method, which evaluates the stiffness of a nodule, using the Young elasticity module [10]. The principle of the method is based on higher stiffness in cases with malignancy. The results from recent literature reviews are excellent, the method having good sensibility and specificity [11,12], 90% respectively 81%. Russ [13] integrated the information from elastography as criteria in the TI-RADS system in order to increase the cost effectiveness of the diagnosis, and also to focus e attention on the correct nodules for biopsy. Using the TI-RADS system, the number of recommended biopsies was reduced by 35 to 42% [13-15] when TI-RADS 2, TI-RADS 3, were considered as a clear diagnosis for benign lesions [16]. However, borderline results, 4A and 4B cases are still recommended to biopsy for clarification, and TI-RADS 4C and 5 for confirmation.

The aim of our study is to verify where TI-RADS can be securely used for detecting thyroid nodules without UGFNA evaluation.]

MATERIALS AND METHODS

Algorithm

All patients were evaluated by means of thyroid ultrasound, UGFNA and a pathology report was considered as the gold standard for thyroid cancer diagnosis. Only solid thyroid nodules were evaluated in the current study. The patients were informed regarding the purpose and procedure of UGFNA. Informed consent was signed before any procedure and the study protocol was approved by the Ethics Committee of the Endocrine Unit.

Ultrasound evaluation

The same high - resolution linear probe was used for ultrasound assessment. Conventional and strain elastography was performed with a Hitachi Preirus, multi frequency linear probe, 6-13 MHz, Hitachi Medical Corporation, Tokyo, Japan. Prospective evaluation of the real time images was made according to the modified TI-RADS classification proposed by Russ, with elastography criteria strain ratio higher than 4 [13] (Table 1). The risk stratification was the following: TI-RADS 1 = no risk; TI-RADS 2 = no risk; TI-RADS 3 = risk of malignancy less than 5%; TI-RADS = 4 risk for malignancy less than 10%; TI-RADS = 4 B malignancy risk up to 60% and TI-RADS 5 = malignancy risk higher than 85% [15].

Real time elastography

Strain elastography was performed, after the conventional ultrasound evaluation, as recommended, with mild external pressure. It was always checked on the preset pressure scale, using only the 3-4 grade. For each nodule, the observers recorded not only the conventional color map elastography, red, green and blue, but also the quantitative evaluation. Strain ration higher than 4 was considered a positive criterion in the TI-RADS system (Table 1).

UGFNA

The same doctor, DS, a specialized endocrinologist in thyroid pathology, performed the UGFNA. All procedures were made with the patient in supine position, with the head in hyperextension, under ultrasound surveillance, with the same ultrasound device. The maneuver employed 25 and 27 gauge sterile needles attached to 10cc syringes. The needle was inserted parallel to the transducer, with direct visualization and confirmation that the needle had reached the lesion. The needle performed "coring" movements through which the material was collected. Each nodule was approached at least 3 times from different regions.

The sampled cellular material was placed on glass slides for conventional smears. The majority of the slides were quickly fixed in 95% ethyl alcohol for the Papanicolaou stain and Hematoxilin - Eosin stain (H&E stain), and some slides were air - dried. Specimen adequacy was not evaluated on site.

Cytological examination

The slides were assessed, reviewed and reported by pathology specialists, MD and MC, with a special interest in thyroid cytology and pathology. The reporting was done using the Bethesda System for Reporting Thyroid Cytopathology [17]. The pathologists were blinded to the ultrasound report.

Pathological report

A pathology report was made in all cases and it was considered the gold standard for the current study. The pathologists in our team, MD and MC, performed the pathology evaluation on formalin fixed and paraffin embedded tissue. The surgical specimens were allowed a 24 hour period of fixation in

Table 1: TI-RADS Classification (adapted from Russ et al. [13].)].

TI-RADS	Interpretation	Ultrasonographic findings
1	Normal thyroid findings	Normal thyroid tissue without any nodular aspect
2	Constantly benign aspect	• simple cyst, spongiform nodules • "white knight" • isolated macrocalficication, nodular hyperplasia
3	Very probably benign	Nosignsof high suspicion, isoechoic or hyperechoic, partial incapsulated
4A	Undetermined	Nosignsof high suspicion, mildlyhypoechoic, encapsulatednodule
4B	Suspicious	• irregularshape • tallerthanwide, irregularborders, microcalcifications, markedlyhypoechoic, high stiffnesswith elastography 1 or 2 signsandnolymphnodemetastasis
5	Highly suspicious	• irregularshape/ tallerthanwide, irregularborders • microcalcifications • markedlyhypoechoic • high stiffness with elastography: strain ratio > 4 3 to 5 signsand/orlymphnodemetastasis

Abbreviations: TI-RADS: Thyroid Imaging Reporting Data System

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10% formalin followed by grossing according to international protocols [18]. Immunohistochemical evaluations with HBME and CK-19 reactions were performed on paraffin embedded tissue. We used the immunohistochemical expression of CK19 (RK108 clone) and HBME1 (HMME1clone) to establish their accuracy in differentiating benign (non-neoplastic and neoplastic) from malignant follicular lesions, especially follicular adenoma from the follicular variant of papillary thyroid carcinoma. The pathologists were blinded to the ultrasound and cytology report

Statistical analysis

Data were collected and analyzed using SPSS v.17 statistical software package (SPSS Inc., Chicago, IL, USA). Clinical and laboratory characteristics of the patients were expressed as mean, standard deviation (SD), median, and range. Prior analysis, variables were tested for normality using the Shapiro - Wilk test respectively for homogeneity of variances with Levene's test. Sensitivity, specificity, positive and negative predictive values, and likelihood ration were calculated using TI-RADS 2,3 for benign lesions, 4A for both benign and malignant lesions, respectively for score 4B and 5 for malignant lesions.

RESULTS

The pathology report considered as the diagnostic gold standard in the 108 evaluated cases, certified the diagnosis of thyroid cancer in 30 cases (27.77%): 27 PTC (25.00%) and 3 FTC (2.77%) cases. The 78 benign cases were adenomatoid goiter (19; 17.59%), colloid goiter (15; 13.88%), follicular adenomas (16; 14.81%), Hurthle cell lesions (9; 8.33%), (follicular neoplasia (2; 1.85%)), autoimmune thyroid disease (15; 13.88%), granulomatous thyroiditis (2; 1.85%). The benign tumors (follicular adenomas and Hurthle cell adenomas) showed weak, patchy staining for CK19 and HMBE1. The vast majority of malignant tumors were intensely positive for CK19 and HMBE1, with 92.59% of the PTC positive and 66.66% of the FTC positive for at least one of the markers. Both markers were considered efficient in the diagnosis of malignant tumors and in differentiating them from follicular adenomas.

The results of the cytology reports in the UGFNA in the 108 cases were: 4 cases (3.6%) BETHESDA I, 46 cases (42.59%) BETHESDA II, with benign characteristics, none of them being cancer at the pathological evaluation, 30 cases (27.77 %) with intermediate results: BETHESDA III, 4 cases BETHESDA IV (3.70%) and 24 cases BETHESDA V and VI (22.22%). The 4 BETHESDA I cases classified as non - diagnostic were rejected for quantitative reasons, less than 6 groups of benign follicular

cells with at least 10 cells/group. The vast majority of Bethesda II cases presented as colloid predominant smear with benign appearing follicular cells with macro follicular arrangement. The Bethesda III cases were deemed inconclusive due to cytological or architectural equivocal atypia in smears with little colloid. The Bethesda IV category comprised cases with cytology suggestive or suspicious for follicular neoplasm - smears with scant colloid, with numerous follicular cells with complete or incomplete micro follicular arrangement, some with Hurthle cell morphology. The cases from the BETHESDA V (Suspicious for malignancy) and BETHESDA VI (Malignant) were grouped together. All 24 of them showed architectural and cytological features of papillary carcinoma - papillae composed of cells with nuclear enlargement with powdery fine chromatin, with nuclear grooves and pseudo inclusion, nuclear overlapping. Some cells evidencing squamoid cytoplasm and psammoma bodies were identified on a few slides.

As seen in Table (2), the cytology results showed excellent sensitivity (92.30%) and specificity (97.43%) in the diagnosis of solid thyroid nodules. It is worth mentioning that only 2 out of 108 cases (1.8%) were negative in the UGFNA evaluation due to puncture outside the nodule.

The conventional ultrasound results are presented in Table (3). Suspect ultrasound criteria for malignancy were recorded. The observed ultrasound anomalies were correlated with the cytology results and always compared with the pathology report. The evaluated nodules presented 1- 3 or 4 different ultrasound findings: none of the nodules had all the suspect ultrasound findings. As seen in Table (3), the accuracy of isolated ultrasound criteria is relatively low. Compared with the UGFNA results, the sensitivity and specificity of isolated ultrasound criteria are low. T It is worth mentioning the specificity of 100% of extra capsular invasion and lymph node metastasis, but these characteristics are rare and the sensitivity is extremely low so it cannot be universally used (Table 3).

The results by applying the modified TI-RADS system, were the following: 2 cases (1.85%) were classified as TI-RADS 2 category, 9 cases (8.33%) were classified as TI-RADS 3; all were benign in the cytology and pathology report; 31 cases (28.70%) were classified as TI-RADS 4A, 29 of them being benign, but 2 cases were malignant, both in the cytology and pathology report; 50 cases (46.29%) were comprised in TI-RADS 4B category, 38 of them being benign, 12 being malignant. From the 16 TI-RADS, 5 cases were confirmed by the pathology reports as thyroid cancer. Figure (1a,1b) represent such a case of PTC, identified by UGFNA, with an increased risk stratification on ultrasound,

Table 2: Ultrasound evaluation, cytology and pathology results in 108 evaluated.

Cytology report BETHESDA	No of cases	T 2	I 3	R 4A	A 4B	DS 5	Pathology report Benign	Pathology report Malignant
I	4	0	3	1	0	0	3	1
II	44	1	6	22	15	0	44	0
III	32	1	0	6	22	3	29	3
IV	4	0	0	0	4	0	2	2
V&VI	24	0	0	2	9	12	0	24
Total	108	2	9	31	50	16	78	30

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Table 3: Conventional ultrasound criteria and cytology report in 108 evaluated cases, 78 benign cases and 30 cancer cases (according to the final pathology report).

	Pathology					Cytology				
	BN 78	CA 30	Sensitivity %	Specificity %	Accuracy %	I 4	II 46	III 30	IV 4	V/VI 24
Tall shape	20	22	78.57	25.64	40.74	2	15	3	3	19
Irregular margins	12	25	83.33	15.38	15.74	0	3	11	3	20
Absent hallo	27	23	76.66	34.61	31.48	1	19	7	2	21
Hypo Ecogeneity	42	22	73.33	53.80	46.29	3	24	15	2	20
In homogeneity	55	17	56.66	34.61	31.48	2	20	23	3	14
Calcifications	5	4	20.00	5.45	8.33	0	1	3	0	5
Invasion	0	4	15.38	100.00	3.70	0	0	0	1	3
Lymph nodes	0	3	10.00	100.00		0	0	0	0	3
BN = benign thyroid nodule CA= thyroid cancer										

confirmed in the pathology report. Figure (2a,2b) evidence an intermediate risk nodule with clear UGFNA results, suggestive for papillary carcinoma, the follicular variant. In our study, cancer was confirmed by the pathology report in 3 out of these 30 cases and with BETHESDA III by the cytology report. All 3 cancer cases were classified as moderate and high risk nodules: TI-RADS 4B (1 case) and TI-RADS 5 (2 cases). The number of cases is too low to conclude that Bethesda III + moderate or high - risk TI-RADS should be considered highly predictive for malignancy, but a combined analysis of the two techniques should be considered. Figure (3a,3b) demonstrate the ultrasound and cytological results of such a case, where there was a high risk in ultrasound and an unclear UGFNA result. In the cases with a Bethesda IV result, elastography should be considered besides the UGFNA result, in order to prepare for the surgical removal of the thyroid. Figure (4a,4b) evidence such a case, where TI-RADS 4C raises a high suspicion of cancer in a follicular neoplasia case.

The diagnostic value of the TI-RADS model was better than in any considered classic ultrasound criteria offering a sensitivity of 55.38%, and specificity of 93.33%, with a better accuracy of 62.96% when compared with conventional ultrasound criteria, ranging from 8.33% to 46.29.

DISCUSSION

UGFNA is still recommended as the diagnostic procedure which indicates the therapeutic approach in the diagnosis of thyroid nodular disease [3,4]. However, the compliance of patients remains a challenge of the procedure [20]. A number of papers suggest that elastography can change the attitude towards UGFNA: providing additional information; the association of grey scale US and elastography facilitates the evaluation of nodules with intermediate cytology [21]; no need for procedure: in cases of soft nodules, without any gray scale suspicious characteristics, UGFNA can be postponed [22,23] or can be recommended, regardless of the appearance in conventional US [22].

In our study, the modified TI-RADS evaluation was without any doubt in all TI-RADS 2, TIRADS 3 and the majority (90.32%) of TI-RADS 4A cases and in all TI-RADS 5 cases. The 50 TI-RADS 4B cases were unclear after ultrasound and elastography evaluation,
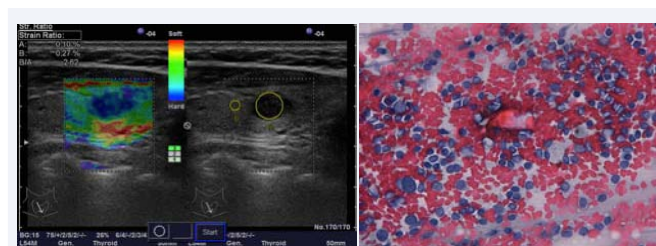

Figure 1 (A) [TI-RADS 5 Nodule: solid, ill defined margins, marked hypo echoic, in homogenous, and increased strain color map 4 (B): [UGFNA of malignant nodule with abundant atypical follicular cells, with nuclear chromatin clearing, molding, grooves and pseudo inclusions. (PAP stain 200x)].
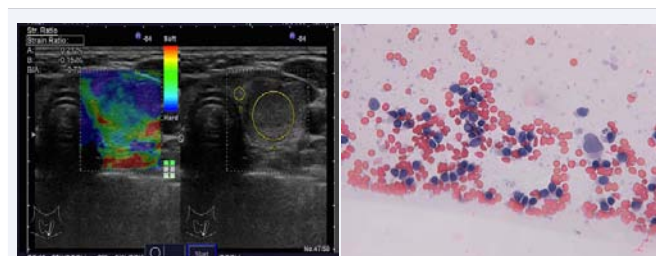

Figure 2 (A) TI-RADS 4B nodule: solid, oval, normal shape, good margins, hypoechoic, no calcification, and homogenous, increased strain, color map 3 (B) UGFNA of malignant nodule showing nuclear features suggestive of PTC and incomplete micro follicular and trabecular architecture, Bethesda IV/V (PAP stain 200x)

being associated with a theoretical risk of malignancy of over 60%, with a real prevalence of cancer of 22%. In these cases, UGFNA was imperative in order to make a clear recommendation for the patient: follow-up, unilateral or total thyroidectomy.

In the 31 4A category cases, 22 had a benign cytology report, all confirmed at pathology evaluation, 6 cases had BETHESDA III cytology mainly with micro follicular appearance not consistent for diagnostic of follicular neoplasia and 2 cases had typical papillary carcinoma cytology, classified as BETHESDA V and confirmed in the pathological report. There was one non
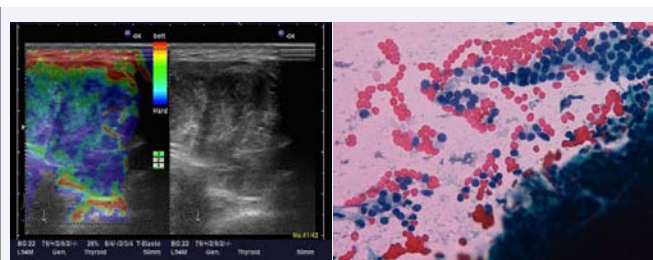
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Figure 3 (A) TI-RADS 5 nodule: irregular shape, irregular margins, in homogeneous, disruption of the thyroid capsule, increased strain, color map 4
(B) UGFNA - suspicious of a follicular neoplasm showing a cellular aspirate composed of crowded 3dimensional clusters of follicular cells with complete and incomplete micro follicles. BETHESDA III (Pap stain 200x)
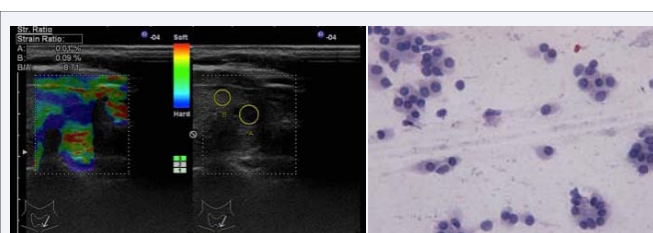

Figure 4 (A) [TI-RADS 4C lesion: small oval shape, intense hypoechoic, in homogenous, irregular margins, no calcification, and increased strain, color map 5
(B) UGFNA showing a cellular aspirate composed predominately of complete and incomplete micro follicles with slightly atypical nuclei and partial Hurthlle cell morphology. The smear was reported Bethesda IV but proved to be FTC on the pathological exam.

diagnostic cytology report, and it was confirmed as cancer in the pathology report. The prevalence of 9.67% of cancer in this category is correct, but it must be discussed whether such a value is acceptable for a diagnostic error for a diagnostic technique. Other studies found the same results [8-10], TI-RADS 4B cases being unclear after ultrasound evaluation. Considering these results, UGFNA was necessary only in 50 out of the 108 cases, respectively in all TI-RADS 4B cases. By not performing UGFNA 11 cases of thyroid cancer would have been missed and also 50 patients classified with moderate risk (up to 75) of thyroid cancer could have been misled.

The calculated risk for thyroid malignancy is similar to the previous published results [14,16,17]: 9.67% in TI-RADS 4A cases (3/31 = 9.67%), 22% in TI-RADS 4B cases (11/50 = 22%) respectively 100 % in TI-RADS 5 cases (16/16 = 100%). Despite this good risk stratification for thyroid malignancy, without UGFNA, cases with thyroid cancer could have been missed, if TI-RADS 4A and 4B cases would not have been biopsied. TI-RADS seems to be a good model for stratifying the risk of thyroid malignancy, which helps focus the attention on cases where UGFNA is imperative [24,25] but cannot be used universally. TI-RADS can be used only in risk stratification and for the identification of cases that should be referred to puncture biopsy, but a diagnosis based only on ultrasound cannot be sustained. A combined approach is still required [26,27]. TI-RADS evaluation is described to decrease the number of unnecessary FNAB procedures [27,28]. Some studies recommend puncture only in cases with an increased cancer risk,

4B and 5 [16], although others prefer to have biopsy results in all cases with a risk of malignancy: TI-RADS 4A, 4B and 5 [13].

Another aspect of thyroid nodular disease is follicular neoplasia. 2 out of 4 BETHESDA IV cases were confirmed by the pathology report, and the 3rd FTC was overlooked in the cytology report (BETHESDA III) but identified in the pathology report. Regarding the TI-RADS risk category, all 3 cancers were classified as TI-RADS 5, due to hypo ecogeneity, intra nodular in homogeneity and increased strain.

In cases identified with follicular adenoma, Bethesda II and III cases, ultrasound showed mixed results, predominantly TI-RADS 3 and 4 A and some 4B nodules. These results suggest that the current recommendation of referral to surgery for intermediate UGFNA cases with an intermediate malignancy risk identified by TI-RADS, is the proper approach [25].

Despite these exceptions, in the majority of cases, ultrasound high - risk nodules are suggested by cytology results and confirmed by pathology reports while very low and low risk nodules are indicated by cytology results and confirmed by pathology results.

The study limitations are: there were many nodules with a benign cytology, with no collateral indication for surgery (compression, high dimensions, functional autonomy or cosmetic reason) were not sent to surgery and were, according to the study design, not included in the analysis. Conversely the number of TI-RADS 3 and 4 A nodules appear lower than in the real prevalence in the thyroid nodular disease population. Due to ethical reasons, not all evaluated nodules were sent to surgery. We analyzed only a percentage of the cases that indicated UGFNA, because of the low compliance of patients for this procedure.

CONCLUSION

The TI-RADS system for the diagnosis of a nodular thyroid is a useful tool in stratifying the risk for malignancy. Benign thyroid findings (TI-RADS 2 and 3 cases) cannot undergo UGFNA evaluation. Highly suspect findings, classified as TI-RADS 5 cases, also cannot undergo UGFNA evaluation, but a clearer indication in current guidelines is required. The intermediate risk category, TI-RADS 4B cases cannot be judged without the UGFNA procedure. The combination of the two procedures increases the diagnostic quality, reduces the number of unnecessary UGFNA and focuses on the suspicious lesions which are required to be clarified by UGFNA.

Combined evaluation with TI-RADS risk stratification and UGFNA ensure correct clinical decisions: follow - up, unilateral lobectomy or total thyroidectomy.

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AUTHOR CONTRIBUTIONS

DS. performed the thyroid evaluation, thyroid ultrasound and UFGNA. M.D. and M.C performed the cytological evaluation. MC

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and CD conceived and designed the experiments; FB. analyzed the data and contributed reagents/materials/analysis tools; DS and FB wrote the paper. MD and MC realized all the images for the materials used in this research; some of the images were used in this manuscript.

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