Zagazig University Medical Journal
www.zumj.journals.ekb.eg

https://doi.org/10.21608/zumj.2022.155829.2619 Volume 30, Issue 4, July 2024

Manuscript ID ZUMJ-2208-2619 (R6)
DOI 10.21608/ZUMJ.2022.155829.2619

ORIGINAL ARTICLE

Validity of Russ modified TIRADS Classification in Detection of Thyroid Nodules Malignancy Risk

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Submit Date 11-08-2022
Revise Date 14-11-2022
Accept Date 2022-11-21

ABSTRACT

Background: The use of ultrasound aids in the identification of thyroid nodules, but it is still crucial to determine whether or not they are problematic using non-invasive methods. **Aim of work:** To evaluate validity of TIRADS in diagnosis of nature of thyroid nodules. **Patients and methods:** A cross sectional study was conducted on 95 nodules derived from thirty patients in radio diagnosis department in Zagazig University hospital from February 2018 to June 2019. All patients underwent complete history taking, full clinical examination, ultrasonographic evaluation of thyroid gland and Fine needle aspiration cytology (FNAC) for solitary nodule or the most suspicious nodules in patients with multinodular goiter and then smears were pathologically assessed. **Results:** About 73% of patients were females with mean age 46 years. Out of the ninety-five nodules, fifty were assesses using US-guided FNAB. Ten nodules were malignant. Papillary carcinoma was the most common accounting for seven nodules. Thyroid Imaging Reporting and Data System (TIRADS) 3 was the most commonly encountered category accounting (42%) while The different TIRADS categories were confronted with the results of pathology and the risk of malignancy were Compared with benign nodules, significantly higher percentages of malignant nodules wee solid, hypoechoic, with irregular margins, taller-than-wide morphology, with microcalcifications, markedly hypoechoic or associated abnormal cervical lymphadenopathy. Tab and T5 predict malignant nature of nodule with sensitivity 90%, specificity 95%, and 95% accuracy. **Conclusions:** Russ' modified TIRADS classification is reliable in both stratifying nodular thyroid disease based on the risk of malignancy and predicting thyroid malignancy.

Keywords: TIRADS, Thyroid, Malignancy, Nodules.

INTRODUCTION

A lot of people utilize ultrasound (US) to evaluate their thyroid glands [1]. In normal community, thyroid nodules are quite common (20% to 76%), and their frequency rises with age. [2]. Nodules might be cancerous or benign. Less than 10% of thyroid nodules are cancerous, according to some studies [3].

The more thyroid nodules that have been found, the more thyroid fine needle aspiration cytology (FNAC) tests that have been performed, and as a result, the more thyroid cancer diagnoses that have been made. Although numerous recommendations and research contend that suspicious US characteristics should be taken into account when determining which thyroid nodules should undergo biopsy, Better recommendations for facilitating US reports are still required in order to connect with and clear up confusion among doctors and patients difficulties that are comparable to those that led to the creation of BI-RADS categorizations [3-4].

The most reliable and economical approach for evaluating thyroid nodules for diagnosis is FNA. Fine-needle aspiration cytology will be required for questionable nodules (FNAC). For doctors and radiologists, choosing nodules for FNAC remains challenging since the classification of the same thyroid nodule might vary depending on the ultrasound classification system that is being utilized [5].

To categorize thyroid gland nodules and address the issue of nodule selection for FNAC, a useful thyroid imaging reporting and data system (TIRADS) has recently been advocated [5]. The terminology "Thyroid Imaging Reporting and Data System" (TIRADS) was first used by Horvath et al. in 2009 [6], it is an adaptation of the "Breast Imaging Reporting and Data system (BIRADS) of the American College of Radiology [7]. This categorization was created to standardize thyroid ultrasound data reporting that physicians could understand and to categorize a lesion's risk of malignancy based on its US characteristics [8].

Aim of the study: To evaluate validity of TIRADS in diagnosis of nature of thyroid nodules of Zagazig University Hospital.

METHODS

This cross-sectional study was conducted in Radiodiagnosis Department, Zagazig university hospitals from February 2018 to June 2019. Thirty adult patients of both sexes known or clinically suspected to have solitary thyroid nodule or multiple nodules were involved in the study. We included patients' preliminary diagnosed by ultrasound and known or clinically suspected to have solitary thyroid nodule or multiple nodules and fit for US-guided FNA. Patients with bleeding disorders or those on anticoagulant therapy, thyrotoxic and patients who unfit for examination were excluded from the study.

All patients had thorough history collection, thorough clinical examinations, ultrasonography, and analysis of the color doppler. Patients were scanned while lying flat on their backs with an "oatmeal" cushion slightly hyperextending their neck. To best see the internal jugular veins, carotid arteries, isthmus, and both thyroid lobes, the neck was scanned in sagittal, transverse, and oblique sections. Hyperechogenicity, isoechogenicity, hypoechogenicity, and significant hypoechogenicity were the four categories for echogenicity. Echogenicity like to that of the adjacent healthy thyroid gland is referred to as "isoechogenicity. If the echogenicity of a nodule was lower than that of the superficial surrounding neck muscles, it was categorized as having "marked hypoechogenicity." When calcification was detected, it was divided into macrocalcifications (more than 1 mm with acoustic shadowing) and microcalcifications (less than 1 mm). The nodule's form was classified as wider-than-tall and taller-than-wide (larger in its antero-posterior dimension than in its transverse dimension). Vascularity was categorized using color Doppler ultrasonography (absent, peripheral, or central). The size, absence of the central echogenic hilum, presence of an uneven border, microcalcification, and necrotic alterations of cervical lymph nodes were all assessed. Each nodule is classified into a TIRADS category, ranging from 1 to 5. A typical gland is represented by TI-RADS 1. Simple cyst, spongiform cyst, isolated macrocalcification, and typical subacute thyroiditis are present in the thyroid gland of TIRADS 2 (benign nodule). TIRADS 3 (likely benign) iso- or hyperechogenic nodule without any very worrisome US characteristics. TIRADS 4A (low suspicious) is modestly hypoechogenic and lacks any US traits that would raise suspicion. There are one or two high-suspect US characteristics on TIRADS 4B (high suspicious), but no adenopathy. Adenopathy and/or three very suspicious US characteristics are seen in TIRADS 5 (high suspicious) [9].

The patient was positioned in a supine posture with the neck slightly extended and the skin was cleaned with betadine solution for the ultrasound guided fine needle aspiration (FNA) procedure. Directly over the lesion, the transducer was positioned. The transverse plane was scanned to locate the lesion prior to aspiration, and color Doppler imaging was then used to show any significant blood arteries in and around the nodule so that vascular harm could be prevented throughout the procedure. The needle was inserted into the syringe with the connected needle perpendicular to or parallel to the transducer depending on where it was positioned underneath or next to the transducer, and the needle tip was carefully observed throughout the procedure. The biopsy was carried out after the needle had reached the desired area. All needle motions were continually monitored in real time throughout the process. The gathered material is spread out on glass slides, fixed in 95% ethyl alcohol, and then dried. To get any leftover substance for cell blocking, the syringe was washed with regular saline solution. The smears were evaluated by an experienced pathologist.

Administrative considerations: The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. A written informed consent was handled from the patient to contribute to the study. Approval for execution the research was gotten from Radiodiagnosis and Pathology Departments, Zagazig University Hospitals after receiving Institutional Review Board (IRB) approval. IRB#:4353/7-2-2018

STATISTICAL ANALYSIS

Data were analyzed by Statistical Package of Social Science (SPSS), software version 24.0 (SPSS Inc., 2016). Continuous data were presented as the Mean ± SD if normally distributed or Median (Range) if not normally distributed. Normality was checked by Shapiro test. Categorical data were presented by the count and percentage. Chi-squared test is used to discover if there is a relationship between two categorical variables. Independent-samples t-test is used to determine if a difference exists between the means of two independent groups on a continuous dependent variable. Mann-Whitney u test (nonparametric alternative to independent-samples t-test).Fisher's Exact Test: for (2X2) (RXC) table. It is an alternative to chi-squared test when the expected cell count is less than five. Pearson's and Spearman correlation coefficients were used to estimate is the strength of linear relationship between two continuous variables; at least one of the two variables must follow a normal and not normal distribution, respectively. P-value <0.05 indicates significant difference and P-value >0.05 indicates non-significant difference.

RESULTS

The current study included ninety-five nodules out of thirty patients who fulfilled the inclusion criteria were selected for the study. There were ten patients with solitary thyroid nodule and twenty patients with multiple nodules (10 patients had five nodules, five patients had four nodules and five patients had 3 nodules. Fifty nodules out of ninety-five nodules underwent FNAC. FNAC was done for all the solitary nodules (10), and from the most two suspicious nodules of the patients with multiple nodules (40 nodules firm eighty-five nodules). Females constituted (73.3%) of the studied patients. Their ages ranged from 20 to 73 years with a mean of 46 years (Table 1).

All patients were subjected to US-guided FNAC, from whom fifty nodules were biopsied. The results of FNAC were confirmed by surgery for ten patients. Ten nodules of total fifty were malignant, and papillary carcinoma was the most common accounting for seven nodules. Two nodules were diagnosed as medullary carcinoma and another one was follicular carcinoma (Table 2). The ultrasound features of each thyroid nodule were characterized and classified into TIRADS categories according to modified Russ TIRADS as showing in figure 1. TIRADS 3 was the most commonly encountered category accounting for twenty-one nodules (42%) while TIRADS 5 was least common accounting for four nodules (8%). Compared with benign nodules, significantly higher percentages of malignant nodules wee solid (100% vs. 67.5%; p =0.046) or hypoechoic (70% vs. 20%; p 0.002), had irregular margins (50% vs. 0%; p < 0.001), taller-than-wide morphology (30% vs. 2.5%; p = 0.022), microcalcifications (50% vs. 5%; p0.002), markedly hypoechoic (20% vs. 0%; p =0.037) or associated abnormal cervical lymphadenopathy (20% vs. 0%; p = 0.037) (Table 3). The different TIRADS categories were confronted with the results of pathology and the risk of malignancy was calculated for each TIRADS category as shown in table 2 (0 for both TIRADS T2 and T3, ten in TIRADS 4A, 83.3 in TIRADS 4B in and one hundred in TIRADS 5). (Figure 4)

There was statistically significant relation between TIRADS categories and nature of nodules. TIRADS 4B and 5 significantly increased risk of malignancy (COR=171 (95% Confidence interval 13.9-2100.1) (Table 4). Regarding individual ultrasonographic features, sensitivity of being taller than wide, microcalcification within nodule, being solid, Halo sign, suspicious lymph node, irregular margin, hypoechoic, markedly hypoechoic, and intravascular vascularity were 30%, 50%, 27%, 20% , 50%, 72.7%, 20% and 80% respectively. All these signs apart from halo sign had excellent specificities ranging from 82.5% to 100%. All the studied criteria had accuracy ranged from 52 to 90% (lowest accuracy prevailed in solid criteria and halo sign 52 and 54 respectively (Table 5). TIRADS 4b and T5 predict malignant nature of nodule with sensitivity 90%, specificity 95%, positive predictive value 81.8%, negative predictive value 97.4% and 95% accuracy (good positive test) (Table 6).

Table (1): Distribution of the studied patients according to demographic characteristics

	N=30	%
Gender:		
▪ Male ▪ Female	8 22	26.7 73.3
Age (years):		
▪ Mean ± SD ▪ Range	46.94 ± 12.63 20 - 73	

Qualitative data was represented as number and percentage.

Table (2): Distribution of the studied patients according to nodule pathology

Variables	**N=50**	**%**
Pathology:		
▪ Malignant ▪ Benign	10 40	20 80
Type:		
▪ Papillary cell carcinoma ▪ Medullary carcinoma ▪ Follicular carcinoma ▪ Hashimoto thyroiditis ▪ Colloid goiter-nodular hyperplasia ▪ Follicular adenoma	7 2 1 3 33 4	14 4 2 6 66 8

Qualitative data was represented as number and percentage.

Table (3): Comparison between ultrasonographic findings among the studied paints and nodule pathology

Ultrasonographic findings	Pathological type			Test		OR (95% CI)
	Total N=50(%)	Malignant N=10(%)	Benign N=40 (%)	X^2	p	
Taller than wider:						
▪ Present ▪ Absent	4 (8) 46(92)	3 (30) 7 (70)	1 (2.5) 39 (97.5)	Fisher	0.022*	16.17 (1.5 – 184.6)
Markedly hypoechoic:						
▪ Present ▪ Absent	2 (4) 48 (96)	2 (20) 8 (80)	0 (0) 40(100)	Fisher	0.037*	23.8 (1.05-542)
Microcalcification:						
▪ Present ▪ Absent	7 (14) 43 (86)	5 (50) 5 (50)	2 (5) 38 (95)	Fisher	0.002*	19 (2.9-125.32)
Solid nodule:						
▪ Present ▪ Absent	37 (74) 13 (26)	10 (100) 0 (0)	27 (67.5) 13 (32.5)	Fisher	0.046*	10.3 (0.56-189.4)
Halo sign:						
▪ Absent ▪ Present	38 (76) 12 (24)	10 (100) 0 (0)	28(70) 12 (30)	Fisher	0.046*	9.2 (0.5-169.7)
Suspicious LN:						
▪ Absent ▪ Present	48 (96) 2 (4)	8 (80) 2 (20)	40 (100) 0 (0)	Fisher	0.037*	23.8 (1 -542.3)
Irregular and lobulated margin:						
▪ Present ▪ Absent	5 (10) 45 (90)	5 (50) 5 (50)	0 (0) 40 (100)	Fisher	<0.001**	81 (3.9-1674)
Intranodular vascularity:						
▪ Absent ▪ Present	35 (70) 15 (30)	2 (20) 8 (80)	33 (82.5) 7 (17.5)	Fisher	0.001**	18.9 (3.3-108.6)
Hypoechoic:						
▪ Absent ▪ Present	35 (70) 15 (30)	3 (30) 7 (70)	32 (80) 8 (20)	Fisher	0.002*	9.3 (1.96-44.4)

*p<0.05 is statistically significant **p≤0.001 is statistically highly significant COR Crude odds ratio CI Confidence interval
χ^2 Chi square test

Table (4): Performance of ultrasonographic findings among the studied patients in diagnosis of pathological type of nodule

Ultrasonographic findings	Sensitivity	Specificity	PPV*	NPV**	Accuracy
▪ Taller than wider:	30	97.5	75	84.8	84
▪ Microcalcification	50	95	71.4	88.4	88
▪ Solid nodule	27	100	100	32.5	52
▪ Halo sign	0	69.2	0	71.1	54
▪ Suspicious LN	20	100	100	83.3	84
▪ Irregular margin	50	100	100	88.9	90
▪ Markedly Hypoechoic	20	100	100	83.3	84
▪ Intranodal vascularity	80	82.5	53.3	94.3	82
▪ Hypoechoic	72.7	79.5	50	91.2	87

* Positive predictive value ** Negative predictive value

Table (5): Comparison between TIRDAS among the studied paints and nodule pathology

	Pathological type		Test		COR (95% CI)
	Malignant N=10(%)	Benign N=40 (%)	χ^2	p	
▪ T4b, T5 ▪ T 2, 3, 4a	9 (90) 1 (10)	1 (2.5) 39 (97.5)	Fisher	<0.001**	171 (13.9-2100.1)
	N=10 (%)	N=40 (%)	χ^2	p	Risk for malignancy
▪ TIRADS 2 ▪ TIRADS 3 ▪ TIRADS 4A ▪ TIRADS 4B ▪ TIRADS 5	0 (0) 0 (0) 1 (10) 5 (50) 4 (40)	9 (22.5) 21 (52.5) 1 (2.5) 5 (12.5) 4 (10)	15.59	<0.001**	0 0 10 83.3 100

**$p\leq0.001$ is statistically highly significant χ^2 Chi square test

Table (6): Performance of ultrasonographic findings among the studied patients in diagnosis of pathological type of nodule

TIRDAS	Sensitivity	Specificity	PPV	NPV	Accuracy
▪ T4b, T5	90	95	81.8	97.4	95

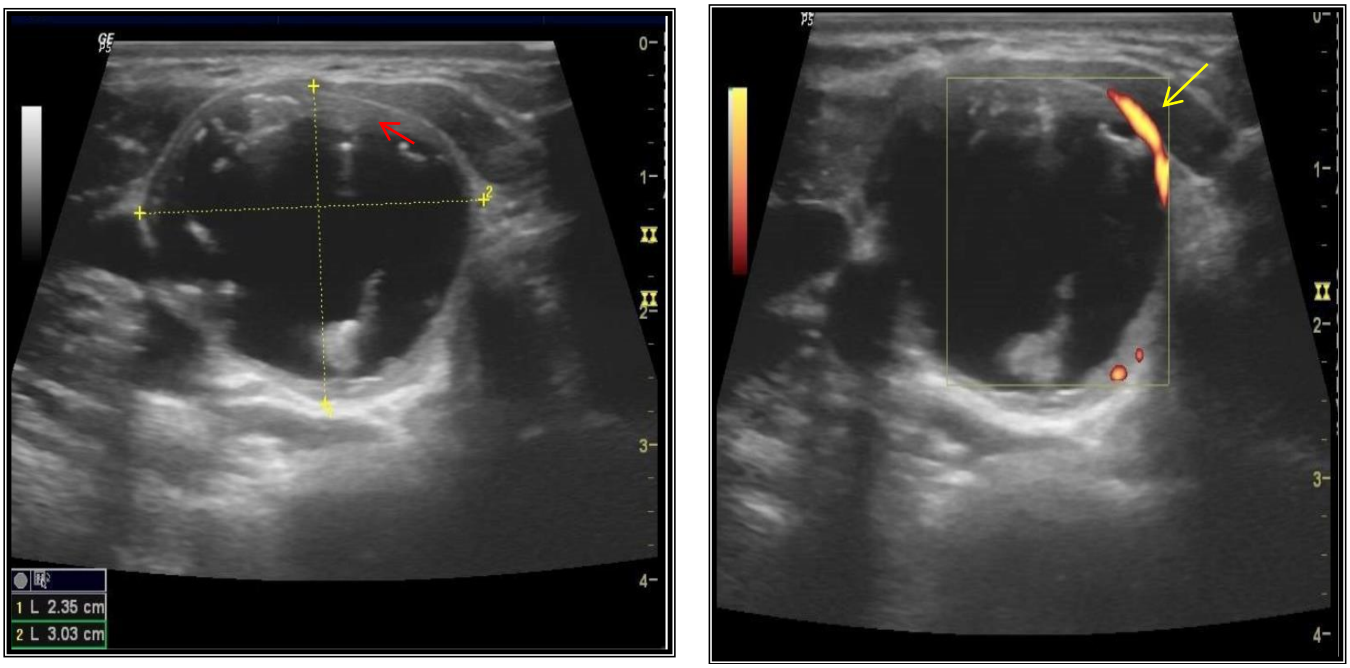


Figure (1); Ultrasound image of the right lobe of the thyroid gland in a transverse plane shows:
(a) Cystic nodule showed calcification with comet tail artifact (red arrow)
(b) Peripheral vascularity (yellow arrow)

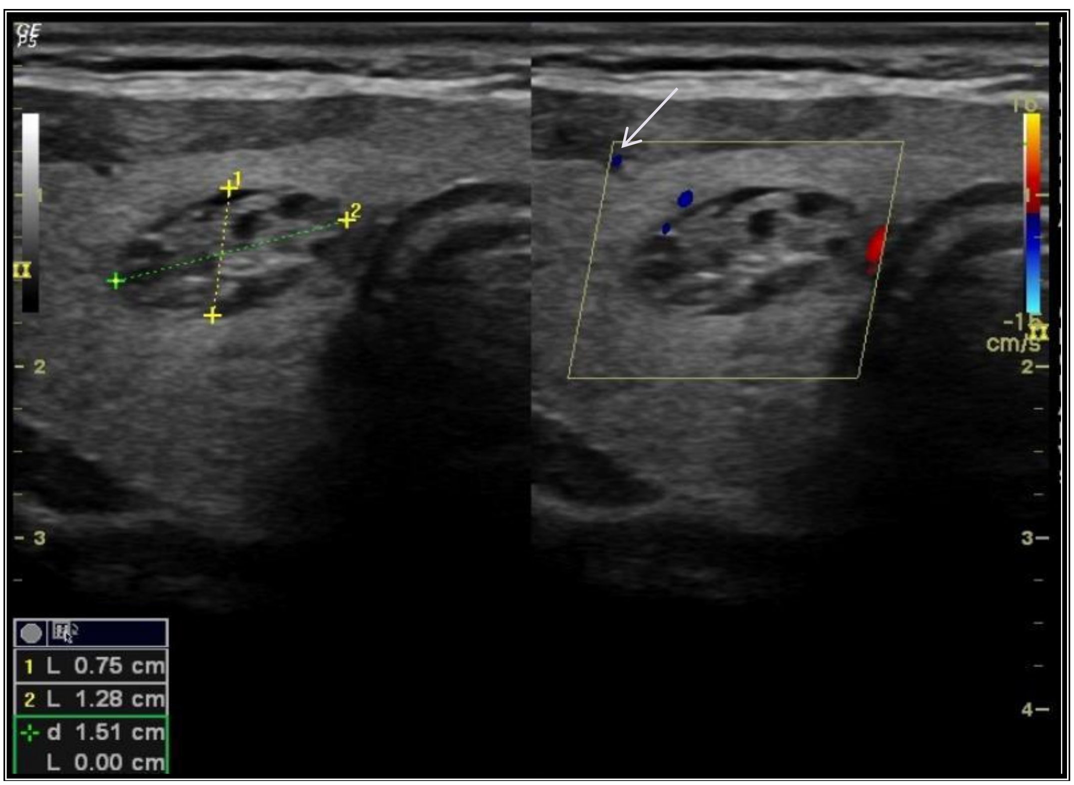


Figure (2); Ultrasound image of the right lobe of thyroid gland in a transverse plane shows: Spongiform nodule, color Doppler image showed peripheral vascularity (white arrow

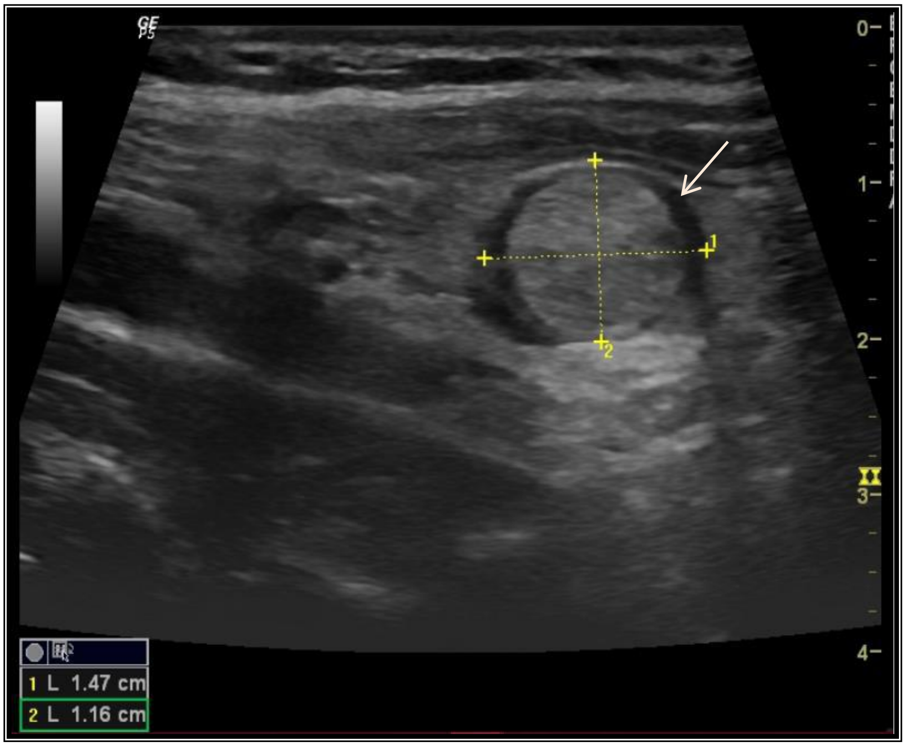
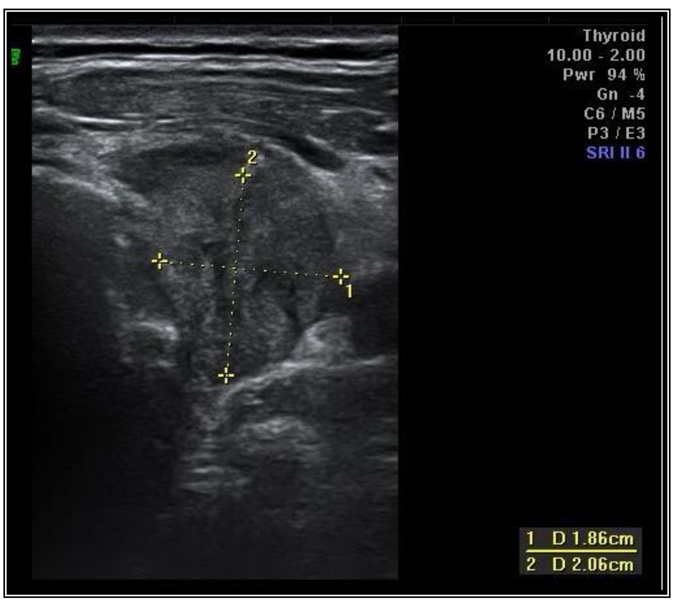
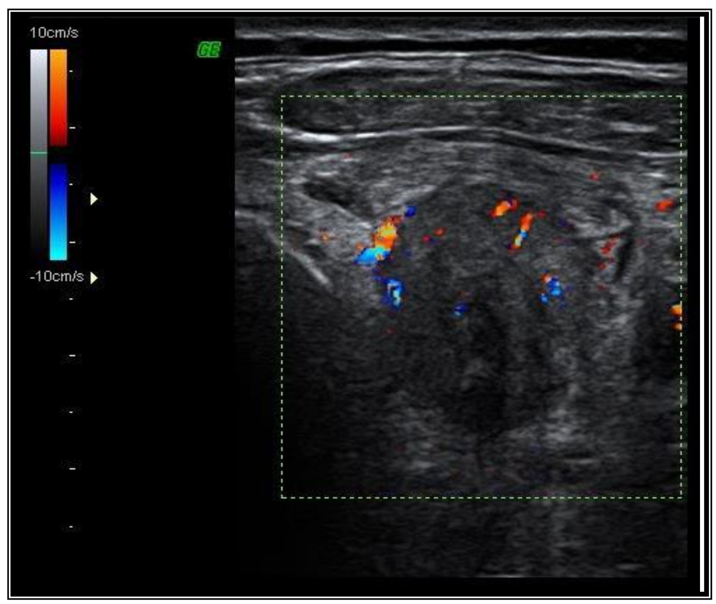


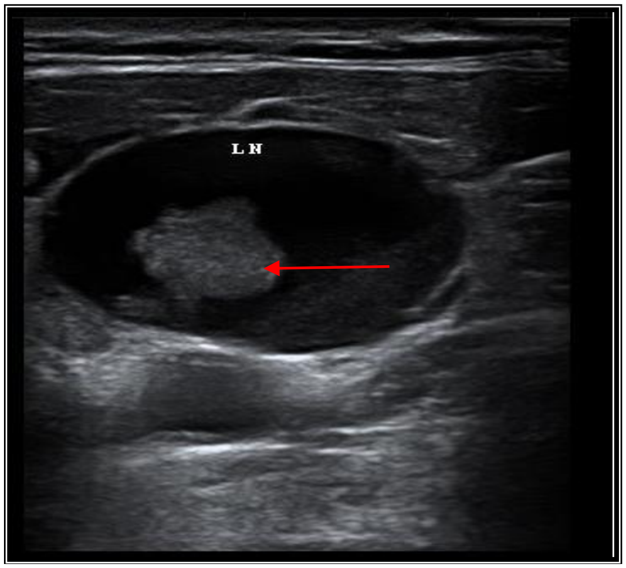
Figure (3); Ultrasound image of the right lobe of the thyroid gland in a transverse plane shows rounded shape, hyperechoic, well defined margin solid nodule with halo sign (white arrow).



(a)



(b)



(c)

Figure (4) ; Ultrasound image of the left lobe of the thyroid gland in a transverse plane shows taller than wide shape nodule, irregular margin, hypoechoic solid nodule (a). .color Doppler showed internal vascularity (b) suspicious lymph node is detected showed necrotic changes (c) red arrow.

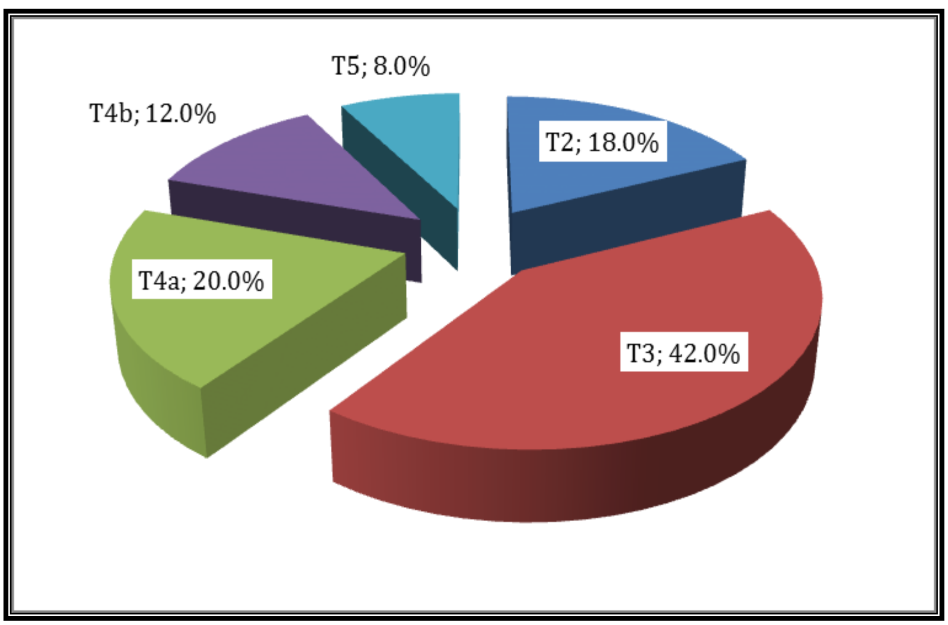


Figure (5): Pie chart showing distribution of the studied patients according to TIRADS classification

DISCUSSION

The reported prevalence of thyroid nodules (TNs) ranges from 2% to 6% on palpation, from 19% to 35% on ultrasound (US), and from 8% to 65% at autopsy [10]. Incidental TNs are being found more frequently as a result of clinical practice's broad use of sensitive imaging. For the initial identification and assessment of TNs, US is the most precise and economical procedure [11].

Kwak et al. [12] added a subtype (4c) to TIRADS system proposed before [6]. They came to the conclusion that there are five key ultrasonic characteristics that are strongly related with cancer: solid component, pronounced hypoechogenicity, microlobulated or irregular borders, microcalcifications, and taller than wide form. The use of TIRADS was enabled by these risk stratifications for thyroid cancer. [10].

TIRADS was created with the intention of improving patient care and lowering costs by reducing the amount of needless tiny needle aspirations for cytology (FNAC). Basic parameters were offered for FNAC nodule selection to maximize advantages and minimize expenditures. The greatest tool for managing thyroid nodules and determining if a thyroid nodule has to be operated on or monitored further is FNAC. TIRADS is thought to be the sole process used to identify high-risk nodules for biopsy, and it is thought to be complimentary to FNAC [6].

However, not all the ultrasound features of nodules proposed by Horvath et al can be applied with certainty in daily practice, and as regards Kwak et al. [10], they did not use suspicious cervical lymph nodes within their classification. Thus, for further simplification, Russ et al. in 2013 proposed a classification system that is easy to use in clinical practice and easy to remember [9]. The acronym TIRADS seems to have come to stay. It harmonizes the reporting of thyroid US findings in a very simply way that facilitates comprehension across different specialties. For any such classification system to be useful for routine clinical practice, it should be simple to use, reproducible and very reliable. Women are more prone to thyroid problems than men [13]. The current study included thirty patients; 73.3% were females while 26.7% were males. The estimated prevalence of thyroid cancer less than 10% [14]. .The proportion of malignant thyroid nodules obtained in our study was exceeding that value (20%), however it was less than that obtained in a previous study (30.8%) [13].

From the current results, the risk of malignancy significantly increased from TIRADS 3 to 5. This was zero for TIRADS 2 so it is considered ultrasonographically as a typically benign lesion. Horvath also suggested a malignant risk of less than 5% for TIRADS 3 [6]. The current findings (0%) are within this range suggested by Horvath and similar to that obtained by a previous study (0.25%) [6, 9]. Russ and colleagues [9] reported a malignant risk of about 6% for TIRADS 4A and in the present study it was 10 %. For TIRADS 4B, risk of malignancy ranged from 10 to 80% according to former studied [6, 9, 14] in a slight proximity to the current study where risk was 83.3 %. This may be attributed to small number of nodules in ours. Finally, all TNs in TIRADS 5 category proved to be malignant (100%), similar to that of Russ et al. [9], and Moifo et al. [14], Horvath et al. [6], and Kwak et al. [12] report for this category a probability of malignancy of 85-99%. In a previous study by Shin and coworkers, suspicious sonographic features were defined as irregular or microlobulated margin, marked hypoechogenicity, microcalcifications and a shape that was taller than wide . In the presence of even one of these sonographic findings the sensitivity, specificity and accuracy were 93.8%, 66% and 74.8%, respectively [15].

In the current study, these ultrasound features (Talller than wide, markedly hypoechoic, lobulated-irregular margin, microcalcification hypoechogenisity, presence of suspicious cervical lymph nodes) were found to be highly suspicious for malignancy as can be seen from the sensitivities, specificities, PPV and NPV. These values were similar to that obtained by Moifo et al. [14] in his study. A previous study conveyed that the three sonographic features that are meaningful findings in the diagnosis of thyroid malignancy were the presence of microcalcifications, marked hypoechogenecity and a taller-than-wide shape [16].

Ahn et al. compared the different sets of guidelines including AACE (American

Association of Clinical Endocrinologists) criteria for discriminating benign and malignant thyroid nodules. AACE recommendations state that FNAC should be done on any hypoechoic nodules that have at least one of the additional ultrasonography characteristics listed below: more than broad or with intranodular vascular patches or microcalcifications with uneven edges [17]. In the study of Moifo et al., 21% of malignant nodules did not have suspicious malignant features on US and were classified as TIRADS 3. However, in the present study, all the nodules with no suspicious US features were classified as TIRADS 2 and 3 and were benign [14].

In the current study, it was found that ultrasound features (spongiform and cystic pattern, hyperechogenisity, absent vascularity and halo sign) were significantly & exclusively associated with benignity. The sensitivity and specificity of halo sign was 0% and 69.2% respectively. Brito et al. found that two nodule features, spongiform and cystic, were significantly associated with an increased likelihood of nodule benignity. Yet the confidence that nodules with these features are not malignant is higher for cystic nodules than for spongiform nodules [18]. Because it is simple for individuals who do US to tally the number of questionable US characteristics, TIRADS can be used in the clinical setting. This will considerably enhance the flow of information between radiologists and physicians. Additionally, this will be more beneficial in environments where FNAB is not easily accessible. Due to the probable risk of malignancy implied by the TIRADS classification and US findings of the lesions, judgments will thus largely be focused on these [14].

In our study, we found a 0% risk of malignancy in TIRADS 2and TIRADS 3 lesions. So, it can be affirmed confidently that all TIRADS category 2 and 3 lesions can be left alone and regular periodic follow up for the change in the ultrasonographic features of the lesion help in reducing unnecessary FNACs by around 58%.

The strength of the current study is that both ultrasonographic features were correlated with pathological diagnosis to better evaluate performance of TIRADS. The study had some limitations. The number of the participants was not large and being applied in one center. So, large scale multicenteric studied should be applied to verify role of TIRADS in evaluation pathologic nature of nodules.

CONCLUSIONS

We concluded that Russ' modified TIRADS classification is reliable in both stratifying nodular thyroid disease based on the risk of malignancy and predicting thyroid malignancy. It could lead to a significant decrease of the number of unnecessary FNABs. We therefore advocate for implementation of TIRADS categorization in the daily work of the radiologist and raising awareness of the system.

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To Cite:

Abdo, D., Abd-Alatef, A., Tantawy, H. Validity of Russ modified TIRADS Classification in Detection of Thyroid Nodules Malignancy Risk. ***Zagazig University Medical Journal*****, 2024; (1133-1144): -. doi: 10.21608/zumj.2022.155829.2619**