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Evaluation of the Reliability of US-based TI-RADS in Predicting Thyroid Malignancy

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Abstract **Original Research Article**

Thyroid nodules are a common and prevalent problem encountered in every day clinical practice. Ultrasound (US) is considered to be the initial imaging modality used in the evaluation of thyroid nodules. The TI-RADS (Thyroid Image Reporting and Data system) is an US-based system used to categorize thyroid nodules and stratify their malignant risk in the aim to standardize reporting and simplify communication among practitioners. The aim of this study is to compare the TI-RADS classification of thyroid nodules on ultrasound with the findings of fine-needle aspiration cytology (FNAC) reported using the Bethesda system. A retrospective study of 59 thyroid nodules that underwent single radiologist bedside neck and thyroid US over a period of one year between January 2020 – January 2021 was performed. The US findings were based on the TI-RADS and all the nodules were eventually subjected to US-guided FNAC. Clinico-pathological retrospective analysis was performed by comparing TI-RADS findings to the Bethesda FNAC classification. Comparing TI-RADS results with the Bethesda system of classification, the risk of malignancy for TI-RADS 2, TI-RADS 3, TI-RADS 4, and TI-RADS 5 were 0%, 10%, 50%, and 100%, respectively. A significant association was noted between the TI-RADS and Bethesda system of classification ($P < 0.001$). We derived 91.3% sensitivity, 88.9% specificity, 84% positive predictive value, and 94.1% negative predictive value for our study. There is a strong correlation between thyroid sonographic reporting using the TI-RADS and Bethesda cytological classification system for thyroid nodules. The TI-RADS classification is an effective method for risk stratification of thyroid nodules into categories predictive of their malignant potential. This aims to guide further management and facilitate the selection process for fine-needle aspiration biopsy, thus avoiding unnecessary procedures.

Keywords: Thyroid nodules; TI-RADS; FNAC; Bethesda; Retrospective.

INTRODUCTION

Thyroid nodules, which are defined as discrete lesions within the thyroid gland that are radiographically distinct from the surrounding parenchyma, are highly prevalent in the general population [1, 2]. They usually come to clinical attention when noted by the patient, a clinician during a routine physical examination, or during a radiologic procedure [3-12]. Their clinical significance is related to the need to exclude thyroid cancer, which accounts for 4–6.5% of all thyroid nodules [3, 4, 13].

Ultrasound is considered the initial imaging modality of choice in the evaluation of patients presenting with thyroid nodules [1-6,13-15]. Over the last decade, several medical societies have issued guidelines used to categorize thyroid nodules for the likelihood of malignancy and to select nodules for biopsy [1-15]. The Thyroid Image Reporting and Data System(TI-RADS), a risk stratification system endorsed by the American College of Radiologists, is employed during the evaluation of thyroid nodules by US to group them into different categories based on their malignant potential [3, 14]. It was originally proposed by Hovarth et al. [1] and subsequently modified by Kwak et al. [14], as an inspiration drawn from the Breast Image Reporting and Data System (BI-RADS)used for breast lesions [1, 2, 12, 14, 15, 3, 4, 6-11].

The objective of our study was to assess the correlation between US-based TI-RADS and the

Bethesda system for reporting thyroid cytopathology, which facilitates the identification of thyroid nodules with high-risk features and providing a guide further clinical approach and simplify further management.

MATERIALS AND METHODS

Ethical committee approval

This study has been approved by the Medical Ethics Committee, Royal Medical Services, and Amman, Jordan.

Study design

Retrospective study design

Duration of study: one year (January 2020–January 2021).

Inclusion Criteria

Patients with thyroid nodules detected on B-mode sonographic examination and subsequently scheduled for FNAC were included in this study.

Exclusion Criteria

Patients with normal thyroid scan (TI-RADS 1) and proven cases of thyroid malignancy (TI-RADS 6) were not included in this study.

Materials

High-resolution B-mode ultrasound performed using Toshiba/Canon Aplio™500 with high-frequency probe (12–6.2 MHz).

FNAC reports (as follow-up).

Methods

This retrospective and analytical study was carried out at the Royal Medical Services in Jordan. Authorization for the study was obtained from the Medical Ethics Committee. The records of all patients with thyroid nodules who underwent thyroid and neck US followed by US-guided FNAB in the period between January 2020–January 2021 were imported from Hakeem database system.

In our study, the data of 91 patients were reviewed. Patients with normal thyroid US scans (TI-RADS1) and those cases with proven thyroid malignancy (TI-RADS 6) or non-diagnostic FNAC (Bethesda I) were excluded from the study (32 patients). A total of 59 patients (49 females and 10 males) with focal thyroid nodules that subsequently underwent cytological assessment via US-guided FNAB were included. The overall mean (± standard deviation) age of presentation was 49.4±14.7 years. The mean age for females was 49.1±14.9 years and the mean age for males was 51.2±14 years.

A total of 59 thyroid nodules in 59 patients were assessed using US performed by the same sonographer and a TI-RADS score (Table 1) was assigned for each, ranging from TI-RADS 2 (not suspicious) to TI-RADS 5(highly suspicious), with the TI-RADS 4 sonographic category not classified into different subcategories. The US machine used was Toshiba/Canon Aplio™500 with a high-frequency probe (12–6.2 MHz). The features assessed were composition (solid, mixed or cystic), echogenicity (hypoechoic, isoechoic or hyperechoic), shape (round or oval), calcifications (macrocalcifications or microcalcifications) and margins (ill-defined, irregular, microlobulated, spiculated, or well-defined, with or without halo).

The FNAB reports were also imported from the Hakeem database system. The FNABs were performed by the same radiologist under US guidance using a 19–21gauge needle attached to 10 mL syringe. The samples were sent for cytological analysis by experienced pathologists and categorized according to the Bethesda system for reporting thyroid cytopathology (Table 2).

Statistical analysis was executed using IBM SPSS Statistics Data Editor version 20.0 Software. The correlation between the TI-RADS scoring system and the Bethesda classification system was evaluated using the Chi-squared test, double entry tables and Pearson's correlation test. Cross tabulation of the TI-RADS to Bethesda (Table3) was prepared by considering TI-RADS scores 1–3 as negative for malignancy and TI-RADS scores 4–5 as positive for malignancy (Table 4).Furthermore, the nodules classified as Bethesda I or II were considered benign, while those categorized IV or V were considered malignant, which permitted analysis using binary logistic regression and calculation of the odds ratios of malignancy for each TI-RADS category.

RESULTS

In our study, 59 thyroid nodules that were scheduled for FNAB after initial assessment using ultrasound and TI-RADS score were assigned for each case. Of the 59 nodules, 14 (23.7%)were categorized as TI-RADS 2, 20(33.9%)were classified as TI-RADS 3, eight(13.6%)were classified as TI-RADS 4, and 17(28.8%) were classified as TI-RADS 5.Thyroid nodules classified as either TI-RADS category 2 or 3 accounted for 57.6% of the total. The percentage of thyroid nodules found to be benign was 61%, in comparison to 39% of thyroid nodules with malignant features on final cytology reports.

Among those classified as TI-RADS Category2, all nodules (100%) were found to be Bethesda II or III (78.6% and 21.4%), respectively. Among those classified as TI-RADS5, 70.6% of the nodules were Bethesda V or VI. On the other hand, of all the patients classified as Bethesda VI, the percentage categorized as TI-RADS 5 was 85.7%, while the percentage of those categorized asTI-RADS2 or 3 was

0% (Table 3). All nodules classified as TI-RADS 2 were found to be benign and all nodules classified as TI-RADS5 were found to be malignant on cytological assessment.

We derived 91.3% sensitivity, 88.9% specificity, 84% PPV, and 94.1% NPV in this study. Comparison of TI-RADS results with the Bethesda system of classification resulted in detected risks of malignancy for TI-RADS 2, TI-RADS 3, TI-RADS 4, and TI-RADS 5 of 0%, 10%, 50%, and 100%, respectively. A significant association was noted between the TI-RADS and Bethesda system of classification ($P < 0.001$).

The risk of malignancy for patients classified as TI-RADS 4 was estimated at five times the risk of those classified as TI-RADS 3, and the risk of malignancy for patients classified as TI-RADS 5 was estimated at 10 times the risk of those classified as TI-RADS 3.

DISCUSSION

Ultrasonography is thought to be highly invaluable in providing clinical insight into the thyroid gland and its diseases. High among the merits of ultrasonography is its ability to assess and detect thyroid nodules as small as 2 mm in diameter, thus increasing the ability to detect small thyroid tumors. Besides, the ability to perform FNAB, which provides adequate tissue samples for cytological, molecular, biochemical and genetic analysis, in conjunction with the Doppler mode to assess overall and regional blood flow, can significantly augment diagnosis and further management, thus paving the way for significant transformation in the clinical approach to thyroid nodules [5,13].

The prevalence of patients with thyroid nodules is considered high. Although thyroid and neck ultrasonography is one of the initial investigations performed, selection of those patients in whom FNAC should be performed is highly controversial. Tissue sampling using FNAC is deemed inexpensive and useful; however, it is a minimally invasive procedure with potential complications [1, 2, 4, 13]. In recent years, several classification systems have been proposed based on well-defined sonographic features in an attempt to define basic criteria that categorizes thyroid nodules in specific risk groups. This process facilitates the selection process, using the BIRADS system employed by the American College of Radiologists for breast lesions as a model [1–5, 13–15]. However, these classification systems were limited by the difficulty in reproducibility, inter-observer variability, and low concordance between sonographic and cytological results [4, 13].

Over the last decade, several studies were conducted to assess the clinicopathological correlation of thyroid nodules [4, 13]. Most notably, Hovarth et al. devised a three-stage prospective study over a period of eight years to assess the correlation between ultrasonographyfor thyroid nodules and FNAB on the basis of 10 sonographic patterns that encompass all types of thyroid lesions. Subsequently, they were stratified into risk groups TI-RADS 2–6. The estimated risk of malignancy was 0% in TI-RADS 2, 3.4% in TI-RADS 3, 10–80% in TI-RADS 4(divided into 4A and 4B), and 87% in TI-RADS 5 [1, 2, 13, 14]. Although the results of this study found a correlation between sonography and FNAB results, the stereotypic application of these sonographic patterns was difficult and impractical [14]. Shortly afterwards, Park et al. proposed an equation based on 12 sonographic aspects of thyroid lesions, attempting to stratify its results into categories predictive of the risk of malignancy. The reported rates of malignancy for TI-RADS categories 2–5 were 9.6%, 31.1%, 76.8%, and 100%, respectively[2]. This equation proved to be complicated and difficult to apply clinically [14]. Thereafter, Kwak et al. investigated the TI-RADS classification using five sonographic features in an attempt to estimate the fitted probability of malignancy [3, 14]. Despite the fact that their study allowed for practical and convenient TI-RADS classification, it was limited by its retrospective nature and the identical weighing of each sonographic criteria, which indicated that each suspicious sonographic feature was given the same importance when, in reality, certain sonographic features are considered more predictive of the risk of malignancy than others[5, 13]. Their reported probabilities for malignancy for TI-RADS groups 2, 3, 4a, 4b, 4c and 5 were 0%,1%,1.7%, 3.3%, 9.2%, 44%, 4%, 72.4% and 87.5%,respectively [14].

In our study, we reviewed the data of 59 patients with thyroid nodules detected by neck and thyroid sonography that subsequently underwent US-guided FNAB performed by the same sonographer to limit inter-observer variability. The sonographic features included in our study were composition, echogenicity, shape, margins, and the presence or absence of echogenic foci. Comparing our data and concordance rates with those concluded by Hovarth et al. [1], we found higher sensitivity and specificity in predicting malignancy (91.3% compared to 88% and 88.9% compared to 49%, respectively). In addition, we also found higher positive and negative predictive values of predicting malignancy (84% compared to 49% and 94.1% compare to 88%, respectively). The risk of malignancy for each TI-RADS category was 0% for TI-RADS 2, 10% for TI-RADS 3, 50% for TI-RADS 3 and 100% for TI-RADS 5.

Although the aforementioned studies, including the present study, detected a common pattern, with the risk and probability of malignancy increasing as the TI-RADS category increases from TI-RADS 2 to TI-RADS [1, 2, 4-6, 13-15], there were limitations in our methodology that could be attributed to several factors. Firstly, this study was limited by its retrospective nature and small sample size. Secondly, we did not subclassify TI-RADS category 4 into subcategories (4a, 4b, 4c) to analyze the clinicopathological correlation to FNAB results, opposed to other studies, including those by Hovarth et al. and Kwak et al. [1, 2, 14]. In addition, our classification system did not incorporate Doppler features, although it has shown to be significantly beneficial in thyroid sonographic assessment. Lastly, we relied on cytological results as the reference data for our study, despite the fact that histology was not available for all thyroid nodules, since nodules with benign cytology were not operated on for ethical concerns.

CONCLUSION

In conclusion, this study showed that our results are within the range of the previously aforementioned studies, supporting that there is a good correlation between thyroid sonographic reporting using the TI-RADS and Bethesda cytological classification system for thyroid nodules. The TI-RADS classification is an effective method for risk stratification of thyroid nodules into categories from which their malignant potential can be inferred. This aims to help guide further management, facilitate the selection process for FNAB and avoid unnecessary procedures. It is considered cost-effective, simple, reliable, highly reproducible, facilitates communication between different surgical specialities and avoids any confusion that may occur [4, 5].

Table-1: TI-RADS classification scheme for thyroid nodules

Composition		**Echogenicity**		**Shape**		**Margins**		**Echogenic foci**	
Cystic or completely cystic	0	Anechoic	0	Wider than tall	0	Smooth	0	None or large comet-tail artifacts	0
Spongiform	0	Hyperechoic or isoechoic	1	Taller than wide	3	Ill-defined	0	Macrocalcifications	1
Mixed cystic and solid	1	Hypoechoic	2			Lobulated or irregular	2	Peripheral rim calcifications	2
Solid or completely solid	2	Very hypoechoic	3			Extrathyroidal extension	3	Punctate echogenic foci	3

TI-RADS SCORE	points
TR1	0
TR2	2
TR3	3
TR4	4–6
TR5	7+

Abbreviations: TI-RADS, Thyroid Image Reporting and Data System

Table-2 Bethesda system diagnostic categories forreporting thyroid cytopathology

Bethesda Class	**Diagnostic Category**	**Cancer Risk**
I	Non diagnostic (unsatisfactory)	5–10%
II	Benign	0–3%
III	Follicular lesion of undetermined significance (FLUS) or atypia of undetermined significance (AUS)	10–30%
IV	Follicular neoplasm or (suspicious for follicular neoplasm)	25–40%
V	Suspicious for malignancy	50–75%
VI	Malignant	97–99%

Table-3: TI-RADSscore/Bethesda cross tabulation

			BETHESDA					Total
			II	III	IV	V	VI	
TI-RADS score	2.0	Count	11	3	0	0	0	14
		% within TI-RADS score	78.6%	21.4%	0.0%	0.0%	0.0%	100.0%
	3.0	Count	10	7	3	0	0	20
		% within TI-RADS score	50.0%	35.0%	15.0%	0.0%	0.0%	100.0%
	4.0	Count	0	4	2	1	1	8
		% within TI-RADS score	0.0%	50.0%	25.0%	12.5%	12.5%	100.0%
	5.0	Count	0	1	4	6	6	17
		% within TI-RADS score	0.0%	5.9%	23.5%	35.3%	35.3%	100.0%
Total		Count	21	15	9	7	7	59
		% within TI-RADS score	35.6%	25.4%	15.3%	11.9%	11.9%	100.0%

Abbreviations: TI-RADS, Thyroid Image Reporting and Data System

Table- 4: TI-RADS classification/FNA result cross tabulation

			FNA result		Total
			negative	positive	
Positive versus negative TI-RADS	negative	Count	32	2	34
		% within positive versus negative TI-RADS	94.1%	5.9%	100.0%
		% within negative versus positive	88.9%	8.7%	57.6%
	positive	Count	4	21	25
		% within positive versus negative TI-RADS	16.0%	84.0%	100.0%
		% within negative versus positive FNA	11.1%	91.3%	42.4%
Total		Count	36	23	59
		% within positive versus negative TI-RADS	61.0%	39.0%	100.0%
		% within negative versus positive FNA	100.0%	100.0%	100.0%

Abbreviations: TI-RADS, Thyroid Image Reporting and Data System; FNA, fine needle aspiration

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