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Correlation Between TIRADS Score by Ultrasonography and Thyroid Function Tests, Fine Needle Aspiration Cytology and Histopathology Findings of Thyroid Nodules

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Abstract

Background: Thyroid nodules are a common presentation in otolaryngology-head and neck clinics. The detection of thyroid nodules has increased significantly with the advancements in radiological technology such as computed tomography and ultrasound. The present study aims to improve the clinical practice and management of thyroid disorders by establishing correlations between ultrasound and cytological findings in the diagnosis of thyroid nodules. The present study was conducted to study the ultrasound characteristics of thyroid nodule using TIRADS score and to correlate ultrasonography findings with Thyroid function test, fine needle aspiration cytology and HPE reports. **Subjects and Methods:** We have included age group of 20-60 years, patients willing to give informed consent, clinically diagnosed thyroid nodule. Thyroid ultrasound was performed with a Samsung UGEO H60 equipped with a 7-12 MHz linear-array transducer with color and power doppler capability. The ultrasound characteristics of the thyroid nodule was studied and categorized using TIRADS classification. Continuous variables are given in Mean ± SD/ Median (Min, Max) form. Applicability of TIRADS and FNAC to predict malignancy are obtained by simultaneously maximizing the sensitivity and specificity to obtain Cutoff value. P-value less than or equal to 0.05 indicates statistical significance. **Results:** The average age of our study population was 50.08 ± 12.82 with majority of them between 41 to 50 years. Female predominance was observed, who accounted for about 88.6% of the study population. There was no association of nodules with thyroid profile. 16 (45.7%) had TIRADS of III, 13 (37.1%) had II. 4 (11.5%) subjects TIRADS was IV, 1 (2.8%) subject had I and 1 (2.8%) had V. 15 (42.9%) had BETHESDA III, 13 (37.1%) had II, 3(8.7%) subjects had IV, 2 (5.7%) had I. Cutoff of TIRADS II, 100 % sensitivity and 46.88% specificity and p=0.083, it is not predicting Malignancy. Cut off III had 25% sensitivity, which was almost same for BETHESDA II and III. Incidence of identifying malignancy by TIRADS III was 18.75% (2/16 TIRADS), for IV 25% (1/4 of TIRADS IV). Hence, TIRADS III and IV has better predictability of malignancy. **Conclusion:** There is no significant association in the distribution of affected lobes and their TIRADS score. Also, the distribution of TIRADS and BETHESDA had similar pattern with no significant difference. Mean values of Thyroid profile were in normal limits with no much deviation even among the malignant cases.

Keywords: TIRADS, BETHESDA, FNAC, HPE reports.

INTRODUCTION

Thyroid disorders, particularly hypothyroidism, have been frequently managed in clinical practice. The incidence of these conditions has significantly increased in recent years. Thyroid nodules are common, with prevalence rates varying depending on the detection method used. Clinical examination alone has a reported detection rate of 4 to 7%. However, imaging modalities, such as ultrasonography (US), reveal a higher prevalence. High- resolution ultrasonography alone can detect thyroid nodules in 20 to 76% of the adult population.[1,2] On examination, a hard or firm texture of a thyroid nodule is often associated with malignancy. However, palpation is subjective and may be insufficient for detecting malignancy in cases of multinodular goiter or small, deeply situated nodules.

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Consequently, a significant number of patients undergo unnecessary thyroid surgery. Therefore, there is a need to advance and refine non-invasive techniques for malignancy assessment.

Ultrasound elastography (USE) has recently been introduced for the clinical evaluation of thyroid nodules.[3] USE is an ultrasound-based procedure that evaluates the biomechanical properties of tissue. It provides an objective measurement of tissue stiffness.[4] In clinical practice, though many reports have matched conventional US with elastography, final decision or diagnosis is based on a combination of conventional US and elastography. Imaging modalities for thyroid gland comprise ultrasonography (US), computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET) and nuclear scintigraphy.[3] Ultrasound has a significant role in diagnosis and management of benign and malignant thyroid nodules. CT and MRI imaging offer additional information about extension of thyroid disease into adjacent structures like, trachea, larynx, esophagus, and great vessels.[3] Fine Needle Aspiration Cytology (FNAC) is an effective method for diagnosing malignancy in thyroid nodules. FNAC provides direct and valuable information, surpassing other diagnostic techniques in accuracy. It is a cost-effective, safe procedure

that enhances the selection of patients for surgical intervention.[2] The present study was conducted to study the ultrasound characteristics of thyroid nodule using TIRADS score and to correlate ultrasonography findings with Thyroid function test, fine needle aspiration cytology and HPE reports.

METHODS

The present study was conducted in department of Radio Diagnosis Akash medical college and research institute. We have included age group of 20-60 years, patients willing to give informed consent, clinically diagnosed thyroid nodule. Thyroid ultrasound was performed with a Samsung UGEO H60 equipped with a 7-12 MHz linear-array transducer with color and power doppler capability. The ultrasound characteristics of the thyroid nodule was studied and categorized using TIRADS.

TIRADS Classification.[5]

- TIRADS 1: normal thyroid gland
- TIRADS 2: benign lesions
- TIRADS 3: probably benign lesions
- TIRADS 4: suspicious lesions
- TIRADS 5: probably malignant lesions (more than 80% risk of malignancy) A quantitative analysis of serum levels of T3, T4 and TSH were assessed.

Ultrasound guided FNAC was performed with a 22-gauge needle attached to a 10-ml disposable plastic syringe. The target of FNAC had been the solid portion of the sponge-like nodule. Samples obtained from the aspiration biopsy was expelled on glass slides and smeared. For each sample, four to five slides fixed in 95% ethanol was sent to the Department of Pathology for Papanicolaou staining. Cytopathologists had interpreted the FNAC slides. Malignant nodules were confirmed surgically, while nodules diagnosed as benign during the first FNAC were confirmed as benign nodules by means of surgery or repeat FNAC.

The Bethesda System for Reporting Thyroid Cytopathology.[5]

1. Non-diagnostic
2. Benign
3. Atypia of Undetermined Significance or Follicular Lesion of Undetermined Significanc
4. Follicular Neoplasm or Suspicious for a Follicular Neoplas
5. Suspicious for Malignanc
6. Malignant

Data was analyzed using SPSS software. Categorical variables are given in the form of frequency table. Continuous variables are given in Mean ± SD/ Median (Min, Max) form. Applicability of TIRADS and FNAC to predict malignancy are obtained by simultaneously maximizing the sensitivity and specificity to obtain Cutoff value. P-value less than or equal to 0.05 indicates statistical significance.

RESULTS

Data contains measurements of 35 subjects with thyroid nodule, whose age ranges from 29– 83 years. The correlation analysis is not possible as there are 35 cases only and of which only 4 cases have been diagnosed with malignancy. Also, the TIRADS and BETHESDA subdivisions has very less population distribution as well as there are not continuous variables either to derive ROC curve or to obtain correlation analysis with thyroid profile parameters such as T3, T4 and TSH. Hence, we have assessed for the sensitivity parameters for various cut offs of BETHESDA and TIRADS.

Table 1: Thyroid profile - Frequency distribution of patients studied

Variables	No. of Patients	%
T3		
• <0.9	16	45.7%
• 0.9-2.8	19	54.3%
• >2.8	0	0.0
• T4		
• <5.0	4	11.4%
• 5.0-12.0	31	88.6%
• >12.0	0	0.0
• TSH		
• <0.5	2	5.7%
• 0.5-5.0	28	80.0%
• >5.0	5	14.3%
Mean T3	0.886 ± 0.285	
T4	6.956 ± 2.308	
TSH	4.075 ± 9.484	

From the table above, we can analyze that the majority of patients have thyroid parameters within normal limits, with mean values for T3, T4, and TSH being normal. Although 5 patients have elevated TSH levels, including one with a TSH level as high as 56 mcg/dl, the increased TSH or any changes in T3 and T4 are not consistent with the malignancy observed on HPE.

Table 2: Distribution of patients based on affected side of the lobe

Laterality of affected lobe	N	%	TIRADS 1	2	3	4	5
Right lobe	13	37.1%	1	4	8	0	0
Left lobe	11	31.4%	1	3	6	1	0
Bilateral	8	22.9%	0	2	2	3	1
Bilateral lobe + isthmus	2	5.7%	0	2	0	0	0
Isthmus	1	2.9%	0	2	0	0	0

The right lobe is more commonly affected, but it has a sim ilar incidence to the left lobe, with no significant difference. Additionally, there is minimal variation in the distribution of USG grading among these affected lobes.

Table 3: Distribution of subjects according to TIRADS

Variable	Subcategory	Number of subjects (%)
TIRADS	I	1 (2.8%)
	II	13 (37.1%)
	III	16 (45.7%)
	IV	4 (11.5%)
	V	1 (2.8%)
Total		**35 (100%)**

Out of 35 (100%) subjects, 16 (45.7%) are TIRADS III, 13 (37.1%) are TIRADS II. 4, (11.5%) TIRADS are IV, 1 (2.8%) are TIRADS I and 1 (2.8%) are TIRADS V.

Table 4: Distribution of subjects based on BETHESDA grading

FNAC (BETHESDA)	N (%)
I	2 (5.7%)
II	13 (37.1%)
III	15 (42.9%)
IV	3 (8.7%)
V	1 (2.8%)
VI	1 (2.8%)

Out of 35 (100%) subjects, 15 (42.9%) are FNAC III, 13 (37.1%) are II, 3(8.7%) subjects are IV, 2 (5.7%) are I, 1 (2.8%) subject are V and 1 (2.8%) subject are VI.

Table 5: Distribution of subjects according to TIRADS over FNAC (BETHESDA)

Variable	Subcategory	TIRADS					Total
		I	II	III	IV	V	
		Number of subjects (%)					
FNAC (BETHESDA)	I	0	1 (7.7%)	1 (6.3%)	0	0	2 (5.7%)
	II	1 (100%)	7 (53.8%)	5 (31.2%)	0	0	13 (37.1%)
	III	0	5 (38.5%)	9 (56.2%)	1 (25%)	0	15 (42.9%)
	IV	0	0	0	2 (50%)	1 (100%)	3 (8.6%)
	V	0	0	1 (6.3%)	0	0	1 (2.8%)
	VI	0	0	0	1 (25%)	0	1 (2.8%)
Total		1 (100%)	13 (100%)	16 (100%)	4 (100%)	1 (100%)	**35 (100%)**

P=0.191, Not Significant, Fisher Exact Test

There was no significant association between TIRADS and BETHESDA grading of the thyroid nodules.

Table 6: Diagnostic analysis of TIRADS at cutoff II

	Value (95% CI)
Cut off	II
Sensitivity (95% CI)	100 % (39.76%, 100%)
Specificity (95% CI)	46.88% (29.09%, 65.26%)
PPV (95% CI)	65.31% (57.62%, 72.27%)
NPV (95% CI)	100% (78.20%, 100%)
p-value	0.083

(TIRADS III, IV, V are considered positive, Malignant in HPE is considered positive)

With cutoff of TIRADS II, 100 % sensitivity and 46.88% specificity and p=0.083, it is not predicting Malignancy.

Table 7: Diagnostic analysis of TIRADS at cutoff III.

	Value (95% CI)
Cut off	III
Sensitivity (95% CI)	25 % (0.63%, 80.59%)
Specificity (95% CI)	87.10% (70.17%, 96.37%)
PPV (95% CI)	65.96% (21.98%, 93.02%)
NPV (95% CI)	53.73% (39.36%, 67.51%)
p-value	0.515

(TIRADS IV, V are considered positive; Malignant in HPE is considered positive)

With cutoff of TIRADS III, 25 % sensitivity and 87.10% specificity and p=0.515, it is not predicting Malignancy.

Table 8: Diagnostic analysis of TIRADS at cutoff IV

	Value (95% CI)
Cut off	IV
Sensitivity (95% CI)	0 % (0%, 60.24%)
Specificity (95% CI)	96.77% (83.30%, 99.92%)
PPV (95% CI)	0
NPV (95% CI)	49.18% (47.58%, 50.79%)
p-value	0.716

(TIRADS V considered positive, Malignant in HPE is considered positive)

With cutoff of TIRADS I, 0 % sensitivity and 96.77% specificity and p=0.716, it is not predicting Malignancy.

Table 9: Diagnostic analysis of FNAC at cutoff II

	Value (95% CI)
Cut off	II
Sensitivity (95% CI)	100% (39.76%, 100%
Specificity (95% CI)	48.39% (30.15%, 66.94%)
PPV (95% CI)	65.96% (57.95%, 73.15%)
NPV (95% CI)	100% (78.20%, 100%)
p-value	0.066

(FNAC III, IV, V, VI are considered positive, Malignant in HPE is considered positive)

With cutoff of FNAC II, 100% sensitivity and 48.39% specificity and p=0.066, it is not predicting Malignancy.

Table 10: Diagnostic analysis of FNAC at cutoff III

	Value (95% CI)
Cut off	III
Sensitivity (95% CI)	50% (6.76%, 93.24%)
Specificity (95% CI)	90.32% (74.25%, 97.96%)
PPV (95% CI)	83.78% (54.67%, 95.68%)
NPV (95% CI)	64.37% (40.24%, 82.89%)
p-value	**0.030**

(FNAC IV, V, VI are considered positive, Malignant in HPE is considered positive)

With cutoff of FNAC III, 100% sensitivity and 48.39% specificity and p=0.030, it is predicting Malignancy.

Table 11: Diagnostic analysis of FNAC at cutoff IV

	Value (95% CI)
Cut off	IV
Sensitivity (95% CI)	40% (5.27%, 85.34%)
Specificity (95% CI)	100% (88.78%, 100%)
PPV (95% CI)	100% (15.81%, 100%)
NPV (95% CI)	62.50% (44.90%, 77.32%)
p-value	**0.001**

(FNAC V, VI are considered positive, Malignant in HPE is considered positive)

With cutoff of FNAC III, 100% sensitivity and 6.45% specificity and p=0.001, it is predicting Malignancy.

Table 12: Comparison of TIRADS vs BETHESDA grades

BETHESDA Grade	Number subjects (%)	TIRADS Score	Number subjects (%)	TIRADS inference
I	2	II	1 (2.85%)	Benign
		III	1 (2.85%)	Benign
II	13	I	1 (2.85%)	Benign
		II	7 (20%)	Benign
		III	5 (14.3%)	Benign

		II	5 (14.3%)	Benign
			7 (20%)	Benign
		III	2 (5.7%)	Malignant
III	15	IV	1 (2.85%)	Benign
IV	3	IV	2 (5.7%)	Benign
		V	1 (2.85%)	Benign
V	1	III	1 (2.85%)	Malignant
VI	1	IV	1 (2.85%)	Malignant
Total			**35 (100%)**	

Out of 35 (100%), 15 subjects with Bethesda grade III, 7 (20%) had TI-RADS 3 score. Out of 13 subjects with Bethesda Grade II, 7 (20%) subject had TI-RADS II grade.

Table 13: Distribution of subjects based on TIRADS over Benign/Malignant HPE

Variable	Subcategory	HPE	
		Benign N (%)	**Malignant N (%)**
TIRADS	I	1 (3.20%)	0.00%
	II	13 (42.00%)	0.00%
	III	13 (42.00%)	3 (75.00%)
	IV	3 (9.60%)	1 (25.00%)
	V	1 (3.20%)	0.00%

Out of 31 (100%) subjects, who had benign lesions, 13 (42.00%) had TIRADS II, 13 (42.00%) had TIRADS III. Out of 4 (100%) subjects with Malignant lesions 3 (75.00%) had TIRADS III and 1 (25.0).

DISCUSSION

In the present study, we had included 35 patients clinically diagnosed with thyroid nodules, required USG thyroid followed by FNAC based on the USG and underwent thyroidectomy. The mean age of the study population was 50.08 ± 12.82 years. Of the 35 cases, majority of them: 15 (42.9%) were aged between 41 to 50 years. In the present study, we observed female predominance, who were accounted for 88.6% (31/35) years. Periakaruppan G et al,[6] had observed that patients in their 30s and 60s were commonly affected which was like our observation, with 8 out of 35 patients aged >60 years. Also, like the present study, females' predominance was observed, accounting for 84.7% of the total population. Even in Muthanna BA et al,[7] the patients aged between 31 to 40 years were more with female predominance (74.25%).

We did not observe much deviation in either the mean values or the population distribution with respect to T3, T4 and TSH from the normal range. Though five patients had higher TSH, four of them had <7mcg/dl only one patient has 56.83mcg/dl, it had not association with incidence of malignancy. Hence, we could analyse that the thyroid profile is not suitable marker for diagnosing either benign or malignant outcome of thyroid nodules. Miao S et al,[7] have observed minimal association of malignancy with thyroid profile, this could be probably since thyroid nodules affecting hypothalamic-pituitary axis is comparatively lesser. Haymart MR et al,[8] in their study have described that thyroid cancer raised serum TSH might be associated with thyroid cancer but few cases even with normal TSH ranges also had diagnosed with malignancy. So, we can analyse that thyroid profile is not the reliable factor for diagnosing thyroid cancers.

We did not find much difference in the affected laterality of the thyroid lobes as well as the distribution of TIRADS grading among these affected lobes. Upon analyzing the severity based on ultrasound findings, 16 subjects (45.7%) are classified as TIRADS III, 13 (37.1%) as TIRADS II, 4 (11.5%) as TIRADS IV, 1 (2.8%) as TIRADS I, and 1 (2.8%) as TIRADS V. Similarly, FNAC results showed that 15 subjects (42.9%) are classified as Bethesda III, 13 (37.1%) as Bethesda II, 3 (8.7%) as Bethesda IV, and 2 (5.7%) as Bethesda I, reflecting a distribution similar to that observed with TIRADS. Periakaruppan G et al,[6] 92% of the patients with nodules had fallen under TIRADS grade II and III. On further analysis, Bethesda I and II was the commonest. They had not included TIRADS IV, considering them as proven cases of malignancy. On comparing the distribution of populations between TIRADS and Bethesda, we observed that out of the 2 patients with Bethesda I, 1 was classified as TIRADS I and 1 as TIRADS II. Of the 13 cases with Bethesda II, 7 were classified as TIRADS II, 5 as TIRADS III, and 1 as TIRADS I. Of the 15 cases with Bethesda III on FNAC, 9 were also classified as TIRADS III, 5 as TIRADS II, and 1 as TIRADS IV. Among the 3 patients with Bethesda IV, 2 were classified as TIRADS IV and 1 as TIRADS V. 1 patient with Bethesda V was diagnosed as TIRADS III, and 1 patient with Bethesda VI was classified as TIRADS IV. On analyzing the sensitivity markers for TIRADS with cut off of II to diagnose malignant cases, we found that it was 100% sensitivity with 100% negative predictive value (NPV), which is one of the better observations. The specificity and positive predictive values (PPV) were 46.88% and 65.31%, this was moderately significant with p value of 0.083. Similarly, for cut off of III, the sensitivity obtained was 25% only, with specificity of 87.10%, PPV and NPV of 65.96% and 53.73% respectively. The significance of TIRADS III in identifying the malignancy among our study population was not significant (p = 0.515). Whereas for BETHESDA cut off of II, the sensitivity and negative predictive values were 100%, the PPV and NPV assessed were 48.39% and 65.96% which is similar to TIRADS II. Unlike TIRADS III, BETHESDA III was significant in diagnosing malignant nodules, with the sensitivity, specificity, PPV and NPV of 50%, 90.32%, 83.78% and 64.37%, with p value of 0.03. On histopathological view, 4/35 (11.43%) of the patients were diagnosed to be with malignant nodule and the rest 31(88.56%) were benign. Chandramohan A et al,[9] had found that the PPV for malignancy was 6.6%, 32%, 36%, 64%, 59%, and 91% for TIRADS 2, 3, 4A, 4B, 4C, and 5 categories.

In Periakaruppan G et al,[6] out of 184 cases, 13 (7.1%) were observed to be malignant. In Kwak JY et al,[10] the incidence of malignancy was 7.3%. In the present study, none of the cases with BETHESDA I, II and IV were diagnosed to be having malignant nodules on HPE. Out of 15 cases of BETHESDA III, two had malignant changes and the rest were benign. These two patients on USG had TIRADS grade III. One each patient with BETHESDA V and VI were diagnosed with malignancy, of these one each belonged to TIRADS

grade III and IV respectively. Hence, the incidence of identifying malignancy by TIRADS III was 18.75% (2/16 TIRADS), for IV 25% (1/4 of TIRADS IV) respectively. In Muthanna BA et al,[11] 28 (13.5%) were found to be malignant. The percentage of malignant thyroid nodules was higher in nodules with TIRADS scores 4 and 5. Unlike the present study, Periakaruppan G et al,[6] had reported 0% malignancy risk for TIRADS 1 and TIRADS 2. The risk of malignancy in our study for TIRADS 3, TIRADS 4, and TIRADS 5 were 2.2%, 38.5% and 77.8%, respectively. In Horvath et al., risk of malignancy detection was 0% in TIRADS 2, 3.4% in TIRADS 3, 10 to 80% in TIRADS 4 and 87% in TIRADS 5 which was deviated from our study. Kwak et al,[10] had reported 0% is expected for TIRADS 2, 1.7% for TIRADS 3, a risk of 3.3 to 72.4% for TIRADS 4 and of 87.5% for TIRADS 5, which could explain our outcome. As per Moifo et al,[13] it was TIRADS categories were 0% for TIRADS2, 2.2% for TIRADS3, 5.9–57.9% for TIRADS4, and 100% for TIRADS5. In Srinivas et al,[14] it was reported that the malignancy identified by TIRADS categories 1, 2, 3, 4A, 4B, 4C, and 5 was 0, 0, 0.64, 4.76, 66.67, 83.33, and100%, respectively. In Muthanna BA et al,[11] the percentage of malignant thyroid nodules was 1% and 2%, respectively, for TIRADS 2 and 3 categories. There was a significant correlation between the USG findings and FNNAC findings in TIRADS scoring system. They had included 202 cases whereas our study had just 35 cases among which only four of them were diagnosed to be malignant, hence analysing this correlation was not possible.

CONCLUSION

According to our observations, thyroid nodules are common among elderly age group. The incidence of malignancy was 4/35 (11.42%). There is no significant association in the distribution of affected lobes and their TIRADS score. Also, the distribution of TIRADS and BETHESDA had similar pattern with no significant difference. Mean values of Thyroid profile were in normal limits with no much deviation even among the malignant cases. Incidence of identifying malignancy by TIRADS III was 18.75% and for TIRADS IV 25%. On analysing the sensitivity parameters, cut off of II gave 100% sensitivity indicating, more II of TIRADS is effective in diagnosing malignancy.

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