

**Role of TIRADS in Detecting Malignancy in a Thyroid Nodule****Shadik Basha Shaik<sup>1</sup>, P. Venkareddy<sup>2</sup>, K. Bhargavi<sup>3</sup>, Arumulla Mithilesh<sup>4</sup>**<sup>1</sup>Assistant Professor, Department of Surgery, Guntur Medical College, Guntur<sup>2</sup>Assistant Professor, Department of Surgical Oncology, Guntur Medical College, Guntur<sup>3</sup>Post Graduate, Department of General Surgery, GMC, Kadapa<sup>4</sup>Assistant Professor, Department of Radiology, AIIMS, Mangalagiri

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Conflict of interest: Nil

**Abstract:**

**Background:** The main concern for the evaluation of thyroid nodules is the possibility of malignancy. The incidence of thyroid cancer is low. There are wide variations in the reported proportions. The terminology of TIRADS was first used by Horvath to improve patient management and cost-effectiveness by avoiding unnecessary FNA Biopsies in patients with thyroid nodules.

**Aim:** The aim of the study is to evaluate the reliability of TIRADS in determining the malignancy in the thyroid nodule so that the invasive cytology and surgery can be avoided in low risk group.

**Methodology:** This was a Prospective observational study, done in 77 with nodular thyroid enlargement and underwent thyroidectomy the Department of General surgery, Tertiary Care Centre, for a period of 2 years.

**Results:** Thyroid nodules were common in 31-50 years age group. In the study females were 87% and males were 13%. On TIRADS score no cases were in TR1, 42% of cases were TR2, 21% cases were TR3, 15% of cases were TR4 and 22% of cases fall in TR5 categories. FNAC showed benign lesions in 68% nodules, 2% cases were FLUS, 6% were of suspicious of follicular neoplasm, 9% cases were suspicious formalgnancy and 15% cases showed malignant features on cytology. Histopathological examination of thyroidectomy specimen showed nodular goitre in 57% of cases, hashimotos thyroiditis in 12% cases, papillary carcinoma in 23% cases, follicular adenoma in 5% of cases, follicular carcinoma was seen in 3% of cases. Among the 32 cases in TR2 FNAC and histopathology was proved to be benign in all the 100% cases. 16 cases were in TR3 among them FNAC and histopathology showed benign cytology in 15 and malignant features in 1 case subsequently. In 12 cases with TR4 5 were benign, 2 were malignant and 5 showed follicular lesions on FNAC, and on histopathology 9 turned out to be benign lesions and 3 were of malignancy. Among the 17 cases in TR5 16 were malignant and 1 was benign on FNAC and histopathology.

**Conclusion:** The PPV for malignancy was high for TIRADS category 5 and 4 nodules. Overall agreement between observers for assigning TIRADS category was substantial. Thus, TIRADS is a simple and practical method of assessing thyroid nodules and can be used in practice.

**Keywords:** TIRADS, Thyroid Nodule, Malignancy.

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**Introduction**

Thyroid nodule can be solid, or cystic, and may or not be functional. Prevalence rates are largely dependent on the identification method. By just palpation, the prevalence rate range from 4 to 7%. [1,2,3]

Almost 12% of adult Asian Indians have been shown to have a palpable nodule in a recent population-based study, whereas by using the imaging modalities such as the high-resolution Ultrasonogram, it ranges from 20 to 76% in the adult population. [4] When patients were assessed by ultrasound, the prevalence of a thyroid nodule was as high as 80% among the iodine-deficient parts of India. [5] This is much higher than diagnosed on clinical

examination. The nodules discovered with radiographic studies are called Thyroid Incidentalomas. [6,7] The correlation between imaging methods and the prevalence reported at surgery and autopsy ranges between 50 and 65%. [8]

In a Multi nodular goiter history and clinical examination alone cannot adequately differentiate between the benign causes of thyroid enlargement and the malignant causes especially the differentiated thyroid malignancies. The main concern for the evaluation of thyroid nodules is the possibility of malignancy. The incidence of thyroid cancer is low (1-1.8 per 1, 00,000). There are wide variations in the reported proportions of

malignancy among the clinically or radiologically detected thyroid nodules. The average prevalence of malignancy rates across the world in thyroid nodules, as evaluated by invasive procedure ranges from 4.0 to 6.5%. [9,10,11] There are well established ultrasound findings that differentiate benign and malignant thyroid nodules. [12,13,14]

There are several classification systems which categorize thyroid nodules according to the risk of cancer. [15,16,17] The sonographic characteristics of a thyroid nodule associated with a higher likelihood of malignancy include Hypo echogenicity, increased intranodular vascularity, irregular margins, microcalcification, absent halo, and a taller than-wide shape measured in the transverse dimension. [18] Several benign and malignant ultrasound gray scale and Doppler features have emerged over the last ten years that may be used in different ways to assign probabilities, together with a method based on the Breast Imaging Reporting and Data System (BIRADS),

Thyroid Imaging Reporting and Data Systems (TIRADS) have been proposed for risk stratification of thyroid nodules. The nodules are usually divided into different categories based on TIRADS and are then referred for Fine Needle Aspiration (FNA) Biopsy or follow-up, according to the variable risk of malignancy. The terminology of TIRADS was first used by Horvath et al. [16]

Some clinicians recommend ultrasound guided FNAC while others consider that a clinical follow up is sufficient in absence of history of familial thyroid cancer or head/neck irradiation. For the differential diagnosis of these thyroid nodules, fine-needle aspiration (FNA) is considered an accurate and cost-effective method for evaluating thyroid nodules, with a high diagnostic sensitivity and specificity. [19,20,21] The purpose of present study is to evaluate the reliability of TIRADS in determining the malignancy in the

thyroid nodule so that the invasive cytology and surgery can be avoided in low risk group.

### Aim

Aim of the study is to define a risk stratification system for thyroid nodules and to determine the reliability of TIRADS classification in predicting thyroid malignancy in thyroid nodules in comparison with cytology.

### Methodology

This was a Prospective observational study done to evaluate and compare the thyroid swelling by sonography with FNAC and biopsy in various disorders of thyroid gland, in the Department of General surgery, Tertiary Care Centre over a period of 2 years in 77 patients admitted in General Surgery Ward with nodular thyroid enlargement and underwent thyroidectomy.

Demographic data and risk factors for thyroid malignancy along with the history of the patient were recorded in the proforma. All selected cases were subjected to Ultrasonographic and ACR-TIRADS score was obtained. FNAC was done and reported according to Bethesda system of Cytopathology reporting. Patients were posted for thyroidectomy and Histopathological report of specimen was sent. At the end TIRADS score was compared with the FNAC and HPE reports in assessing or predicting the malignancy in a thyroid nodule.

**Statistics:** Data collected was entered in Microsoft excel and analyzed using SPSS -22.0 version. Percentages, proportions and chi square tests were done for qualitative data and Mean and standard deviation was calculated for continuous data. Sensitivity, specificity, positive and negative predictive values were calculated for TIRADS vs FNAC and HPE. A p value of 0.05 was taken as significant.

### Results

**Table 1: Age distribution in the study population**

Age in years	No of Cases	Percentage
13 - 20	1	2
21 - 30	10	13
31 - 40	23	28
41 - 50	24	31
51 - 60	12	16
61 - 70	5	7
> 70	2	3
<b>Total</b>	<b>77</b>	<b>100</b>

**Table 2: Sex distribution in the study population**

Sex	No of cases	Percentage
Male	10	13
Female	67	87
<b>Total</b>	<b>77</b>	<b>100</b>

**Table 3: Composition of the Thyroid Nodules**

Composition	Score	No of cases	Percentage
Cystic / spongiform	0	0	0
Mixed cystic & solid	1	58	75
Completely solid	2	19	25

**Table 4: Echogenicity of the Thyroid Nodules**

Echogenicity	Score	No of cases	Percentage
Anechoic	0	8	10
Hyper or isoechoic	1	47	61
Hypoechoic	2	22	29
Very hypoechoic	3	0	0

**Table 5: Shape of the Thyroid Nodules**

Shape	Score	No of cases	Percentage
Wider than tall	0	67	87
Taller than wide	3	10	13

**Table 6: Margin of the Thyroid Nodules**

Margin	Score	No of cases	Percentage
Smooth/ ill-defined	0	71	92
Lobular / irregular	2	6	8
Extra thyroidal extension	3	0	0

**Table 7: Echogenic foci in the Thyroid Nodules**

Echogenic foci	Score	No of cases	Percentage
None or comet tail artefact	0	44	57
Macro calcifications	1	8	10
Peripheral rim calcification	2	1	2
Punctate echogenic foci	3	24	31

**Table 8: TIRADS score for the Thyroid Nodules**

TIRADS	Grade	No of cases	Percentage
Benign	TR1	0	0
Not suspicious	TR2	32	42
Mild suspicious	TR3	16	21
Moderately suspicious	TR4	12	15
Highly suspicious	TR5	17	22

**Table 9: FNAC of the Thyroid Nodules**

FNAC	Bethesda class	No of cases	Percentage
Non-diagnostic	I	0	0
Benign	II	52	68
AUS/FLUS	III	1	2
Suspicious of follicular neoplasm	IV	5	6
Suspicious for malignancy	V	7	9
Malignant	VI	12	15

**Table 10: Histopathology Report of Thyroidectomy specimen**

Histopathology Report	No of cases	Percentage
Nodular Goitre	44	57
Hashimotos Thyroiditis	9	12
Papillary Carcinoma	18	23
Follicular Adenoma	4	5
Follicular Carcinoma	2	3

**Table 11: Comparison of TIRADS, FNAC and Histopathology Reports**

TIRADS Grade	FNAC			HPE	
	Benign	Malignant	Follicular lesion	Benign	Malignant
TR1	0				
TR2	32(41.5%)			32(100%)	
TR3	16(21%)	1(6.3%)		15(93.7%)	1(6.3%)

TR4	12(15.5%)	5(41.7%)	2(16.6%)	5(41.7%)	9(75%)	3(25%)
TR5	17(22%)	1(5.8%)	16(94.2%)		1(5.8%)	16(94.2%)

**Table 12: Comparison of TI-RADS with FNAC**

	FNAC Malignant(Positive)	FNAC Benign(Negative)	Total
TR 4, TR 5(Positive)	23	6	29
TR 2, TR 3(Negative)	1	47	48
Total	24	53	77

**Table 13: Comparison of TIRADS with histopathology**

	HPE benign	HPE malignant	Total
TR 2, TR 3(Negative)	47	1	48
TR 4, TR 5(Positive)	10	19	29
Total	57	20	77

## Discussion

Evaluation of a thyroid nodule disease based on a process of four-step (Quadruple assessment) including; Detailed history, plus clinical examination, Laboratory exams involving thyroid function tests, Thyroid US, and US-guided FNAC based on TI-RADS features. [22] It resembles the triple assessment of the breast lumps. However, TI-RADSUS features are still not routinely used in several teaching institutes. [23] The accessibility of TI-RADS and recent validation of this US classification system by the ACR permits a precise clinical and pathological correlation. As noted from the preceding studies, a strong clinicopathological correlation will guide us in defining the risk of malignancy and hence direct our proper management of thyroid lesions. [24]

In many countries around the world; surgeons, radiologists, and endocrinologists become aware of using the US classification system (TI-RADS) for evaluation of thyroid lesions and use it regularly in their clinical performance. [25]

Ultrasound of thyroid should be performed in the initial assessment of the gland and the nodule. Since the prevalence of thyroid nodule is very high, patients for whom FNAC should be recommended is still controversial. FNAC is a useful and inexpensive tool for detecting malignancy of thyroid, but it is a minimally invasive procedure. Performing such test in all thyroid nodules is neither cost effective nor advisable, thus it is important to select the cases according to their malignancy risk. Several classifications based on sonographic features have been proposed in the recent past, in an attempt to help this selection. However, a general agreement has not been established, given the difficulty of reproducibility of different classifications proposed or even due to the low correlation between the ultrasound reports and FNAC results. [26]

Many previous studies have proven the usefulness of ultrasound evaluation of thyroid nodules and its ability to differentiate benign from malignant

nodules. Several classification systems have been proposed to stratify the risk of malignancy in thyroid nodules. Most of them are complex using several ultrasound features and formulae which are not easy to use in daily practice, especially in a tertiary care teaching setup where examiners of varying experience perform ultrasound scans. Of all the systems, the classification proposed by ACR-TIRADS is simple and similar to BIRADS system which has been in use for many years and is familiar to most radiologists. Therefore, we assessed thyroid nodules based on ACR-TIRADS. [27,28,29,30]

**Age and sex distribution:** In this study, peak incidence was noted in the age group of 41 -50 years. The youngest patient was 18yrs and eldest was 72yrs. In this study 67 were female and 10 were males. A female to male's ratio in the study was 6.7: 1.

In Abdelkader et al [31] which included 100 patients; 22 males and 78 females with mean age  $43.7 \pm 11.5$ ; range: 22-60 years. In Periakaruppan, et al., [32] A total of 184 patients were included in this study, out of which 156 were females. These thyroid nodules are predominantly found in and around 30-60 yrs. of life. The patients in this age group amount to 137 patients, approximately 75% of our study population. In Chandramohan, et al. [33] Out of 272 nodules, 154 benign nodules (119 were females, 35 were males) and among 118 malignant nodules (75 were females, 43 were males). Malignancy was more common among male patients presenting with a thyroid nodule ( $P = 0.01$ ). When comparing our results with the outcomes of a study that was done by Singaporewalla et al [34] the US impression of thyroid nodules in our study had a comparable sensitivity in predicting malignancy (71.5 % versus 70.6%) but lower specificity (85% versus 90.4%). We also had a comparable NPV of TI-RADS score predicting malignancy (91.5% versus 93.8%).

There is no doubt that, using the TI-RADS system for US reporting permits clinicians to improve their US skills and track their results in comparison with

the FNAC findings. In our study there were no cases with TR 1. Among the 32 cases in TR2 FNAC and histopathology was proved to be benign in all the 100% cases.

16 cases were in TR3 among them FNAC and histopathology showed benign etiology in 15 and malignant features in 1 case subsequently. In 12 cases with TR4 5 were benign, 2 were malignant and 5 showed follicular lesions on FNAC, and on histopathology 9 turned out to be benign lesions and 3 were of malignancy.

Among the 17 cases in TR5 16 were malignant and 1 was benign on FNAC and histopathology. Among 77 cases, of a total 48 cases which are labelled as benign (mostly TR 2, TR 3), 47 cases are also proven to be benign and only one case turned out as malignant on FNAC.

Of a total of 29 cases which are labelled as malignant (TR 4, TR 5) on TR-RADS, 23 are proven to be malignant on FNAC and only 6 turned out as benign on FNAC. According to these findings TI-RADS have sensitivity of about 95.83%, Specificity of about 88.67%, positive predictive value of about 79.31 %, negative predictive value of about 97.92 % compared with FNAC (cytology).

Among 77 cases, of a total 48 cases which are labelled as benign (mostly TR 2, TR 3), 47 cases are also proven to be benign and only one case turned out as malignant on HPE. Of a total of 29 cases which are labelled as malignant (TR 4, TR 5) on TR-RADS, 19 are proven to be malignant and 19 turned out as benign on HPE.

According to these findings TI-RADS have sensitivity of about 82.45%, Specificity of about 95%, positive predictive value (PPV) of about 97.92%, negative predictive value (NPV) of about 65.52 % compared with HPE. In Singaporewalla et al study, they had 20 patients that were classified as TI-RADS 5 (malignant on the US), only 12 were confirmed as malignant with FNAC biopsy and the remaining were benign. This gives them a 60% accuracy of US in predicting malignancy. Similarly, in our study, we found that among the 14 cases that were categorized as TIRADS 5, 10/14 cases had a FNAC biopsy established as cancer (71.4% accuracy).

Ultrasound impression of thyroid nodules had a lower sensitivity in predicting malignancy (70.6% compared to 88%) but higher specificity (90.4% compared to 49%). We also had a higher positive and negative predictive value of TIRADS score predicting malignancy as well (60% compared to 49%, and 93.8% compare to 88%, respectively). Overall, we had an accuracy of 83%. In our study, the risk of malignancy for the different TIRADS categories was 0% (TIRADS 2), 9.5% (TIRADS

3), 33.3% (TIRADS 4) and 60% (TIRADS 5).

In Abdelkader et al [31] study in 55 patients with thyroid nodules of probably benign (TI-RADS 3) nature, and FNA cytology established this result in 45/55 patients revealing an 82% concordance rate between US and FNAC. Among the 31 cases that were categorized as TI-RADS 4 (indeterminate), 8/31 cases were benign on FNAC (Bethesda II), 1/31 cases had a FNAC biopsy established as cancer. Remaining 22/31 patients were fallen in Bethesda III, IV, and V giving a 70.9% concordance rate between the US and FNAC. Among the 14 cases that were categorized as TI-RADS 5 (malignant on the US), 2/14 patients were benign on FNAC biopsy (false-positive impression of the US), 5/14 cases were suspicious on FNAC (Bethesda IV), and 7/14 cases had a FNAC biopsy established as cancer giving a 50% concordance between the US and FNAC. From the previous results, the overall concordance rate between US TI-RADS and Bethesda is 67.6%

The overall concordance rate of US TI-RADS with the final PO Histological results for predicting malignancy for predicting malignancy was 75.4% with a sensitivity of 76.9% and specificity 91.3%, PPV 71.4%, and NPV 76.4%. On the other hand, the overall concordance rate of FNAC with the final PO Histological findings for predicting malignancy was 95% with a sensitivity of 81.8% and specificity 98%, PPV 90%, and NPV 96%.

In Chandramohan, et al. [33] study of ultrasound TIRADS category and surgical histopathology for patients who underwent surgery (n=168), The PPV for malignancy was 6.6%, 32%, 36%, 64%, 59%, and 91% for TIRADS 2, 3, 4a, 4b, 4c, and 5 categories, respectively. In conclusion, the PPV for malignancy was high for TIRADS category 5 and 4c nodules. Reassigning TIRADS category 4a nodules as TIRADS 3 will improve the PPV and specificity of TIRADS. In Kwak et al.[35] describes 0%, 1.7%, 3.3%, 9.2%, 44.4–72.4%, and 87.5% risk of malignancy for TIRADS 2, 3, 4a, 4b, 4c, and 5 categories, respectively. However, in a subsequent retrospective validation study, the authors found a 7.3% and 8.3–96.6% risk of malignancy in TIRADS 3 and TIRADS 4-5 categories of thyroid nodules. According to Periakaruppan, et al [32], study out of the 184 nodules, 117 were categorized under TIRADS 2, 45 were classified under TIRADS 3, 13 were classified under TIRADS 4, and 9 were classified under TIRADS 5. The nodules classified as Bethesda I and II were considered benign, and those nodules classified as Bethesda IV–VI were considered malignant. Out of the 117 TIRADS 2 nodules, none turned out to be under Bethesda IV or higher, which means none of these nodules turned out to be malignant.

Among the 45 nodules labeled as TIRADS 3, 42 nodules were in Bethesda II and 1 nodule each in Bethesda I, III, and IV, respectively. There were few nodules which appeared suspicious on ultrasound to be classified under TIRADS 4 and TIRADS 5 but turned out to be benign in Bethesda classification. Considering all nodules, the proportion of malignant nodules classified as TIRADS 2, TIRADS 3, TIRADS 4, and TIRADS 5 were 0.0, 7.7, 38.4, and 53.9%, respectively. This resulted in 92.3% sensitivity, 94.15% specificity, and 54.54% PPV, and 99.38% NPV for our study. Significant association was noticed between TIRADS and Bethesda system of classification ( $P < 0.001$ ).

In a study by Stephanie A. Fish [36] A total of 832 nodules were evaluated with ultrasound prior to FNA. 79 nodules measured less than 1 cm and were excluded from the study. Another 251 nodules were excluded owing to indeterminate cytology results. The final cohort included 502 nodules in 477 patients. Thirty-six (7.2%) nodules were determined to be malignant. In general, strictly adhering to the recommendations from the risk-stratification systems reduced the number of FNAs to between 17.1% and 53.4%.

The most effective system was the ACR TIRADS, which would have reduced the number of biopsies by more than half (53.4%) with a false negative rate of 2.2%. The false negative rate was due to nodules with a final diagnosis of malignancy, but no biopsy recommendation based on the risk-stratification system. Most of the systems had similar discriminatory capacities to identify malignancy, but they recommended completing many more biopsies. K-TIRADS was the weakest performer, as it reduced the number of biopsies by only 17.1%.

Eleven nodules diagnosed as malignant would have been misclassified as not requiring FNA by at least one of the TIRADS systems. Three cancers were missed by all five systems; these were either isoechoic or hyperechoic and had no other features considered suspicious. The ACR TIRADS performed best by classifying more than half of FNAs as unnecessary with a false negative rate of only 2.2%.

### Conclusion

In conclusion, from the study it was made out that the PPV for malignancy was high for TIRADS category 5 and 4 nodules. Overall agreement between observers for assigning TIRADS category was substantial. Thus, TIRADS is a simple and practical method of assessing thyroid nodules and can be used in practice.

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