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RISK STRATIFICATION OF THYROID NODULES - COMPARITIVE STUDYBETWEEN TI-RADS, CYTOLOGY, AND HISTOPATHOLOGY.

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ABSTRACT

Background: thyroid nodule is defined as a lesion that is distinct and may be differentiatedfrom the surrounding thyroid parenchyma by clinical examination, Ultrasound or othersensitive imaging modalities. [1] It may be solitary or multiple nodular goitres. A nodulecan be solid, or cystic and may or may not be functional. The prevalence rates are highly dependent on the method of identification. The purpose of the current research is to evaluate the reliability of TIRADS in determining the malignancy in the thyroid nodule so that invasive cytology and surgery can be avoided in the low-risk group.

Material and Methods: This study was done to evaluate and compare the thyroid nodules by sonography with FNAC and biopsy in various disorders of the thyroid gland.This study was conducted in Department of General Surgery, sree mookambika institute of medical sciences , Kanyakumari. Study conducted from November 2022 to September 2023

Result: According to these findings, TI-RADS have a sensitivity of about 95.83%, Specificity of approximately 88.67%, the positive predictive value of approximately 79.31 %, the negative predictive value of approximately 97.92 % compared with FNAC(cytology). Fisher's Exact Test was performed and results shown as 0.000, which is significant. P-Value of this comparison is < 0.001 (p-value = <0.001), which issignificant, and there is a strong association between TI-RADS and FNAC.

Conclusion: In conclusion, from the study, it was made out that the PPV for malignancy washigh for TIRADS category 5 and 4 nodules. TIRADS is a straightforward and practicalmethod of assessing thyroid nodules and can be used in practice as the overall agreement between observers for assigning TIRADS category was substantial.

Keywords: Thyroid imaging reporting and data system

INTRODUCTION:

A thyroid nodule is defined as a lesion that is distinct and may be differentiatedfrom the surrounding thyroid parenchyma by clinical examination, Ultrasound or othersensitive imaging modalities. [1] It may be solitary or multiple nodular goitres. A nodulecan be solid, or cystic and may or may not be functional. The prevalence rates are highly dependent on the method of identification. The prevalence varies from 4 to 7%by just palpation, [2,3]

Almost 12% of adult Asian Indians have been shown to have a palpable nodulein a recent population-based study, [4]whereas by using the imaging modalities such asthe high-resolution US; it ranges between 20 to 76% in the adult population.

When patients were assessed by ultrasound, the prevalence of a thyroid nodulewas 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 imaging 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]

Multinodular goitre is primarily a degenerative disease, endemic in areas wherethe soil is deficient in Iodine. It is the commonest swelling of the thyroid gland for whichthe patients seek medical attention.

The malignancies of thyroid also present as goitre but are the uncommon cause of thyroid enlargement. When faced a patient who presents with the thyroid swelling, the surgeon has to differentiate between more common benign goitres from malignantones in order to prevent unnecessary surgeries for benign diseases of thyroids and atthe same time, avoid missing of malignancy with disastrous effects. History and clinical examination alone cannot adequately differentiate betweenthe benign causes of thyroid enlargement and the malignant causes, especially the differentiated thyroid malignancies.

The importance of the evaluation of thyroid nodules is the possibility of malignancy. The incidence of thyroid cancer is low (1-1.8 per 100,000).[9] There are vast differences in the reported percentage of malignancy among the clinically or thyroid nodules detected by radiologically.The average prevalence of malignancy rates across the world in thyroidnodules, from 4.0 to 6.5% on evaluation by an invasive procedure.[10,11] There are well-established ultrasound findings that differentiate benign and malignant thyroid nodules.[12,13,14] There are several classification systems which categorise thyroidnodules according to the risk of cancer.[15,16,17]

The ultrasonographic characteristics of a thyroid nodule associated with a higher incidence of malignancy include hypoechogenicity, increased intra-nodular vascularity, irregular margins, microcalcifications, absent halo, and a taller than-wide shape measured in the transverse dimension.[18]

Several benign and malignant ultrasound grayscale and Doppler features haveemerged in the last decade that may be used in various ways to assign probabilities, along with another method based on the Breast Imaging Reporting and Data System(BIRADS), Thyroid Imaging Reporting and Data Systems (TIRADS) of thyroid nodules have been proposed for risk stratification.[5]

TIRADS score is given based on USG features and sent for Fine Needle Aspiration (FNA) Cytology or follow-up, according to the variable risk of malignancy.

Horvath et al. first used the terminology of TIRADS. [16] The initial purpose of TIRADS is to improve patient management and cost-effectiveness by avoiding unnecessary FNA Biopsies in patients with thyroid nodules.

Neck ultrasound has long been used to evaluate the size, character, and location of thyroid nodules, monitor nodule growth and identify loco-regional lymphadenopathy. FNAC is recommended for palpable nodules, but the indication forthis procedure in non-palpable nodules is a matter of controversy.

Some clinicians recommend ultrasound-guided FNAC while others consider that a clinical follow up is sufficient in the absence of a history of familial thyroid canceror head/neck irradiation. Fine-needle aspiration (FNA) is considered a cost-effective method and accurate for evaluating thyroid nodules, for the differential diagnosis of these thyroid nodules, with high diagnostic sensitivity and specificity.[19,20,21]

The purpose of the current research is to evaluate the reliability of TIRADS in determining the malignancy in the thyroid nodule so that invasive cytology and surgerycan be avoided in the low-risk group.

MATERIALS AND METHODS

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This study was done to evaluate and compare the thyroid nodules by sonography with FNAC and biopsy in various disorders of the thyroid gland.This study was conducted in Department of General Surgery, sree mookambika institute of medical sciences , Kanyakumari. Study conducted from November 2022 to September 2023.77 cases admitted in General Surgery Ward with nodular thyroid enlargement and underwent thyroidectomy.

INCLUSION CRITERIA:

- Patients of both sexes and between 13 – 75 years
- Patients with thyroid nodules in the euthyroid state

EXCLUSION CRITERIA

- Diagnosed cases of benign or carcinoma thyroid on follow up for residual diseaseor recurrence.
- Cases not willing to undergo treatment.

Patients attending the surgical outpatient department with nodular thyroid enlargement and underwent thyroidectomy subsequently included in the study with their consent and after verifying the inclusion and exclusion criteria. Demographic data and risk factors for thyroid malignancy, along with the historyof the patient were recorded in the proforma. All selected cases subjected to Ultrasonography, and ACR-TIRADS score obtained. FNAC was done and reported according to the Bethesda system of Cytopathology reporting. Patients posted for thyroidectomy, and Histopathological report of the specimen collected.

In the end, TIRADS score compared with the FNAC, and HPE reports in assessing or

predicting the malignancy in a thyroid nodule.

RESULTS:

From the study done for evaluating the thyroid nodules by sonography with FNAC and biopsy in various disorders of the thyroid gland, the following observationsmade.

Table No 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
Total	77	100

In the study, thyroid nodules were frequent in 31-50 years age groupindividuals.

Graph No 1: Age distribution in the study population

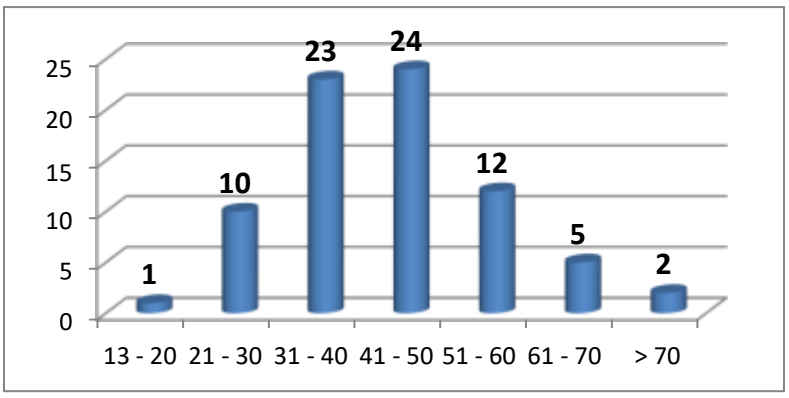
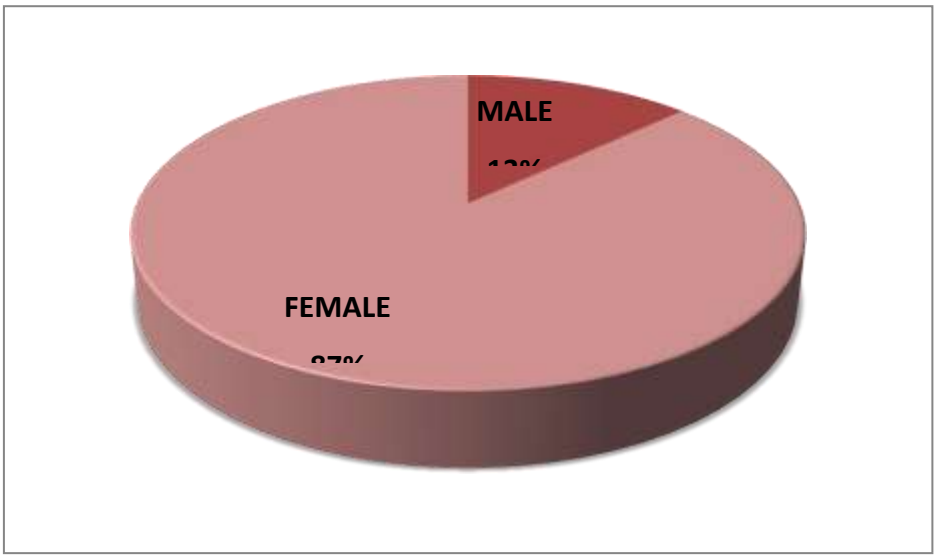


Table No 2: Sex distribution in the study population

Sex	No of cases	Percentage
Male	10	13
Female	67	87
Total	77	100

Graph No 2: Sex distribution in the study population



In the study, females were 87%, and males were 13%.

Table No 6: 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

Graph No 3: Histopathology Report of Thyroidectomy specimen

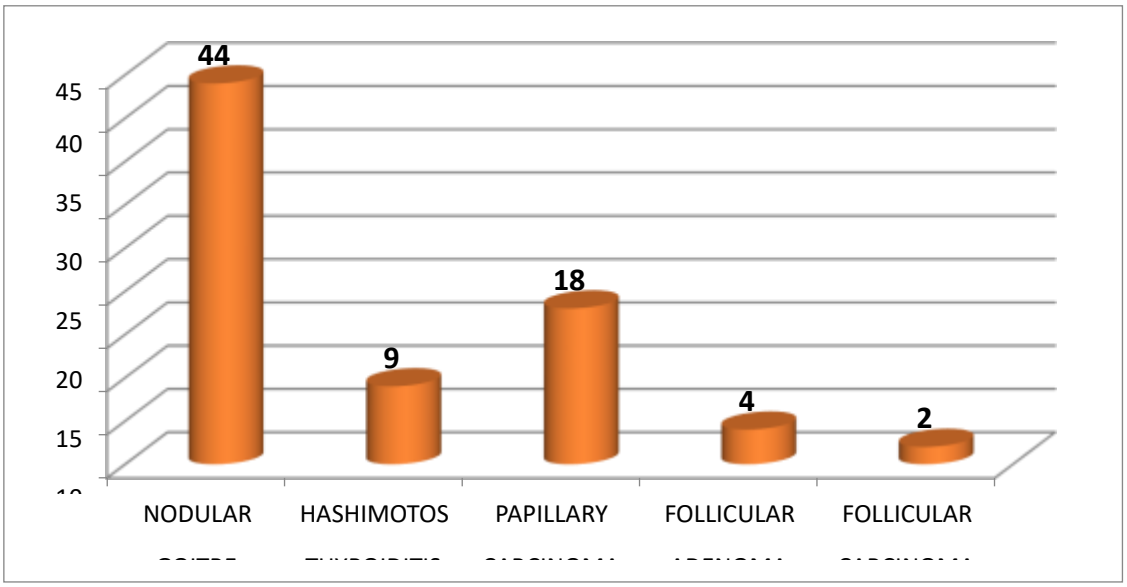


Table No 3: Comparison of TIRADS, FNAC and Histopathology Reports

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

In the study, there were no cases resulted in TR 1. Among the 32 cases in TR2FNAC and histopathology was proved to be benign in all the 100% cases. Sixteen cases were in TR3 among them FNAC and histopathology showed benign aetiology in 15 and malignant features in 1 case subsequently. In 12 cases with TR4, five werebenign, two were malignant, and 5 showed follicular lesions on FNAC, and onhistopathology nine turned out to be benign lesions, and three were of malignancy. Among the 17 cases in TR5 16 were malignant and one was benign on FNAC and histopathology.

Table No 4: 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

Among 77 cases, of a total 48 cases which labelled as benign (mostly TR 2, TR3), 47 cases are also proven to be benign, and only one case turned out as malignanton FNAC. Of a total of 29 cases which labelled as malignant (TR 4, TR 5) on TR- RADS, 23 are proven to be malignant on FNAC, and only six turned out as benign onFNAC.

According to these findings, TI-RADS have a sensitivity of about 95.83%, Specificity of approximately 88.67%, the positive predictive value of approximately 79.31 %, the negative predictive value of approximately 97.92 % compared with FNAC (cytology).

Fisher's Exact Test was performed and results shown as 0.000, which is significant. P-Value of this comparison is < 0.001 (p-value = <0.001), which issignificant, and there is a strong association between TI-RADS and FNAC.

Table No 5: 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

Among 77 cases, of a total 48 cases which labelled as benign (mostly TR 2, TR3), 47 cases are also proven to be benign, and only one case turned out as malignanton HPE. Of a total of 29 cases which 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 a sensitivity of about 82.45%, Specificity of about 95%, positive predictive value (PPV) of approximately 97.92%, negative predictive value (NPV) of approximately 65.52 % compared with HPE.

On performing the Pearson Chi-square test shown the result as 89.304, which is significant. PValueof this comparison is < 0.001 (p-value =<0.001), which is significant, so there is a strong association between TI-RADS and HPE.On analysing above two tables, shows a significant statistical association between TI-RADS, FNAC and HPE

DISCUSSION:

The accessibility of TI-RADS and validation of this USG classification system by the ACR permit a precise both clinical and pathological correlation. As noted from the previous

studies, a robust clinical and pathological correlation will guide in definingthe risk of malignancy and proper direct management of thyroid lesions.[22]

In many countries; surgeons, endocrinologists, and radiologists become awareof using the TI-RADS for analysis of thyroid lesions and regularly use it in their clinical performance.[23]FNAC is useful and less expensive for detecting malignancy of thyroid, but it isa minimally invasive procedure. Performing FNAC in all thyroid nodules is neither advisable nor cost-effective, so it is crucial to select the cases according to their risk of malignancy. In an attempt to help this selection, several classifications based on sonographic features have proposed it recently.

USG of the thyroid performed in the initial evaluation of the nodule along with the gland. As the prevalence of thyroid nodule is very high, patients for whom FNAC recommended is still under debate.However, a general agreement not yet mentioned gives the difficulty in reproducing different classification systems or even the low correlation between the USG reports and FNAC.[24]

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 know 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 setupwhere 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 is in use for many years and is familiar to many radiologists. Therefore, we assessed thyroid nodules based on ACR-TIRADS.[25] In this study, the peak incidence noted in the age group of 41 -50 years. The youngest patient was 18yrs, and the 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.

Abdelkader et al. [26] studied 100 patients; 22 males and 78 females with meanage 43.7 ± 11.5; range: 22-60 years.

When comparing our results with the results of a study done by **Singaporewalla et al.** [29] the US of thyroid nodules in our study had a comparable sensitivity in predicting malignancy (82.45% versus 71.5%) and specificity (95% versus 84%). We also had a better NPV of TI-RADS score predicting malignancy (65.5% versus 91.5%) and PPV 97.92%.

Among 77 cases, of a total 48 cases which labelled as benign (mostly TR 2, TR3), 47 cases are also proven to be benign, and only one case turned out as malignanton FNAC. Of a total of 29 cases which labelled as malignant (TR 4, TR 5) on TR- RADS, 23 are proven to be malignant on FNAC, and only six turned out as benign onFNAC.

According to these findings, TI-RADS have a sensitivity of about 95.83%, Specificity of approximately 88.67%, the positive predictive value of approximately 79.31 %, the negative predictive value of approximately 97.92 % compared with FNAC (cytology).

Among 77 cases, of a total 48 cases which labelled as benign (mostly TR 2, TR3), 47 cases are

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

In **Chandramohan, *et al*.[26]** study of ultrasound TIRADS category and surgicalhistopathology for patients who underwent surgery (*n*=168), The PPV for malignancyof TIRADS 2, 3, 4a, 4b, 4c, and 5 categories was 6.6%, 32%, 36%, 64%, 59%, and 91%, respectively. In conclusion, the PPV for malignancy was high for TIRADS category five and 4c nodules. Reassigning TIRADS category 4a nodules as TIRADS 3 will improve the PPV and specificity of TIRADS.

According to **Periakaruppan, *et al.*[27]**, *study* out of the 184 nodules, 117 categorised under TIRADS 2, none turned out to be under Bethesda IV or higher, which means none of the nodules turned out to be malignant. Thirteen classified underTIRADS 4, and 9 as TIRADS 5 category.
The nodules classified Bethesda I and II were benign, and those nodules classified as Bethesda IV-VI was deemed to be malignant.Among the 45 nodules labelled as TIRADS 3, 42 nodules are Bethesda II and one nodule each in Bethesda I, III, and IV, on FNAC respectively.Few nodules which appeared suspicious on USG are classified as TIRADS 4 and TIRADS 5 but turned out to be benign in FNAC according to Bethesda classification. Considering all nodules, the proportion of nodules being malignant classified as TIRADS 2 were 0.0, TIRADS 3 were 7.7, TIRADS 4 was 38.4, andTIRADS 5 was 53.9%.

In this study, sensitivity is 92.3%, specificity is 94.15%, and PPV is 54.54%, and NPVis 99.38%. A significant association is noted between TIRADS and Bethesda system of classification ($P < 0.001$).
In a study by **Stephanie A. Fish[31]**, a total of 832 nodules evaluated with ultrasound before FNA cytology. Seventy-nine nodules measured lower than 1 cm andremoved from the study. Another 251 nodules excluded due to indeterminate cytologyresults. The final study included 502 nodules in 477 patients.

Thirty-six (7.2%) nodules determined to be malignant. In general, strictly following the recommendations from the risk-stratification systems decreased the number of FNAs to between 17.1% and 53.4%. The most effective method was ACRTIRADS, which would have reduced the biopsy number by greater than half (53.4%) with 2.2% false-negative rate. The false-negative rate was due to nodules with a final
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diagnosis of malignancy, but no biopsy recommendation based on the risk- stratification system. Many more biopsies recommended as most of the systems hadsimilar discriminatory capacities to identify malignancy. K-TIRADS was the poor performer, as it reduced the number of biopsies by only 17.1%. Eleven nodules diagnosed as malignant would have misclassified as not requiring FNA by at least oneof the TIRADS systems. All five systems missed three cancers; which were either isoechoic or hyperechoic and had no other suspicious features. The best performanceis by ACR TIRADS by classifying more than half of

FNA cytology as unnecessary withonly 2.2% false-negative rate.

CONCLUSION:

In conclusion, from the study, it was made out that the PPV for malignancy washigh for TIRADS category 5 and 4 nodules. TIRADS is a straightforward and practicalmethod of assessing thyroid nodules and can be used in practice as the overall agreement between observers for assigning TIRADS category was substantial.

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