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Orignal Article

DIAGNOSTIC RELIABILITY OF THYROID IMAGING REPORTING AND DATA SYSTEM (TIRADS), A NON INVASIVE CLASSIFICATION IN DIFFERENTIATION BETWEEN BENIGN AND MALIGNANT THYROID LESIONS

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Abstract: ***Prevalence of thyroid nodules is increasing all over the world. An ultrasound based thyroid imaging reporting and data system classification has been developed . To classify thyroid nodules and address the issue of nodule selection for FNAC, a useful thyroid imaging reporting and data system (TIRADS) has been developed. This study aims at evaluating the reliability of the daily use of ACR-TIRADS classification in differentiating between benign and malignant thyroid lesions and hence avoiding invasive FNAC procedure in benign lesions. 60 patients , patients with clinically suspected or ultrasound diagnosed thyroid nodules were subjected to undergo conventional high resolution sonography of the thyroid gland and then categorized according to ACR-TIRADS Classification. Ultrasound guided fine needle aspiration cytology (FNAC) of suspicious or dominant nodule were evaluated according to BETHESDA system of Classification for reporting thyroid cytopathology. The relation between TIRADS and BETHESDA was evaluated using the histopathological report , which was used as the standard final diagnosis for Comparison. In this study on comparing the TIRADS scoring system on initial assessment to predict the efficacy in differentiating benign and malignant lesions versus the final biopsy report it is found that TIRADS is effective in predicting malignancy in a suspicious thyroid nodule with significant p value of 0.05 and with sensitivity of 77.36 % specificity of 57.14% positive predictive value (PPV) of 93.18% and negative predictive value of (NPV) 25% at 95% confident interval. Aims and***

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Dedication: *During his tenure as Adjunct Professor Dr. P.D. Gupta brought laurels to Manipal University, by conducting summer course, published books and guiding research in Pharmaceutics and Mechanical engineering. We are happy to dedicate this research work to him on his 85th Birthday.*

objectives of this study is to find the effectiveness of the TIRADS scoring system is a statistically significant scoring system in differentiating benign and malignant lesions of the thyroid gland on initial assessment and hence help preclude FNAC in benign lesions.

Keywords: Thyroid nodule, Tirads, Bethesda

INTRODUCTION

The population frequently experiences thyroid nodules. Nodules on the thyroid are becoming more common. Palpation can identify them in 2%–6% of the population, Ultrasound can identify them in 19%–35%, and autopsy data can identify them in 8%– 65% of the population. The most reliable and economical imaging technique for diagnosing thyroid nodules is ultrasound. Numerous academic articles have investigated the use of ultrasound criteria to distinguish between benign and malignant thyroid nodules. Hypoechogenicity, microcalcification, taller-than-wide shape, uneven or microlobulated borders, and enhanced intranodular vascularity are suspicious characteristics of nodules that indicate cancer. Fine needle aspiration cytology (FNAC) is mandatory in the preoperative diagnosis of thyroid nodules to distinguish benign from malignant nodules. It is still unclear how thyroid nodules should be chosen for FNAC. To classify thyroid nodules and address the issue of nodule selection for FNAC, a useful thyroid imaging reporting and data system (TIRADS) has been developed. Thus, in this study, we will attempt to demonstrate the effectiveness of TIRADS scoring in identifying malignancy in a thyroid nodule that has been clinically or radiologically diagnosed. Aims and objectives of this study is to find the effectiveness of the TIRADS scoring system in predicting thyroid malignancy in a patient presenting with a thyroid nodule which is either palpable on clinical examination or is detected on radiological investigations

MATERIAL AND METHODS

Source of data: The study was conducted on patients admitted at admitted in department of general surgery, SDM College of Medical Sciences and Hospital, Dharwad with clinical or on ultrasound suspected with thyroid nodules who were undergoing total thyroidectomy . A prospective study was planned. The study was undertaken on patients admitted from January 1st 2021- December 30th 2022. The study was approved by ethics committee of the hospital and informed written consent was obtained from all the patients.

Inclusion criteria: All patients with age equal to or above 18 years who are Clinically or on ultrasound suspected to have thyroid nodules. Further all patients who underwent total thyroidectomy in the study period.

Exclusion criteria :
Patients of age group less than 18 years
Patients who underwent partial thyroidectomy were excluded
Patients with clinically suspected thyroid nodules will undergo conventional high resolution sonography of the thyroid gland, and depending on the presence or absence of various sonographic features the thyroid nodules will be categorized according to ACR-TIRADS classification which includes composition, echogenicity, shape, margin, echogenic foci as variables. Ultrasound guided Fine needle aspiration cytology (FNAC) of suspicious or dominant nodule under aseptic precautions after taking consent will becarried out using 23gauge needle attached to 10ml syringe, 2-3 aspirations will be done and cytology smear will be prepared and will be evaluated according to Bethesda system of classification for reporting thyroid cytopathology. The relation between TIRADS and Bethesda will be evaluated .The Histopathological report will be used as the standard final diagnosis for comparison

Statistical analysis: Data is analysed using SPSS software version 21 and Excel. Categorical variables are given in the form of frequency table. Continuous variables are given in Mean ± SD/ Median (Min, Max) form. Categorical variables are analysed by Chi square test.

RESULTS

1. Distribution according to age: Data contains measurements on 60 subjects whose age ranges from 18-81 with mean age 45.27 ± 14.57years. The following tables gives the summary of data. See table 1).

2. **Distribution of subjects according to Gender**. See table 2
3. **Distribution according to symptoms:** Out of 60 subjects, all 60 (100%) had swelling in neck See table 3.
4. **Distribution of subjects according to pressure and toxic symptoms:** Out of 60 subjects, 51 (85%) of subjects experienced pressure symptoms and 9 (15%) did not. 54 (90%) of subjects had toxic symptoms and 6 (10%) did not. See table 4.
5. **Distribution of subjects according to clinical examination:** Out of 60 subjects, 17 (26.7%) of subjects had solitary nodule and 44 (73.3%) had multinodular goitre. See table 5.
6. **Distribution of subjects according to TIRADS Score.** Out of 60 subjects, 18 (30%) of them had TIRADS score of 1, 15 (25%) had score of 2, 11 (18.3%) had score of 3, 11 (18.3%) had score of 4 and 5 (8.3%) of subjects had score of 5. See table 6.
7. **Distribution of subjects according to BETHESDA Score:** Out of 60 subjects, 44 (73.3%) had BETHESDA score of 2, 7 (11.7%) had score of 4, 4 (6.7%) had score of 3. See table 7.
8. **Distribution of subjects according to outcome of FNAC report.** Out of total 60 patients, 47(78.3%) patients were reported under benign category on final FNAC report and 13 (21.7%) were reported as malignant. See table 8.
9. **Distribution according to final histopathological report.** Out of total 60 patients, 53(88.3%) patients were reported under benign category on final biopsy report and 7 (11.7%) were reported as malignant. See table 9.
10. **Agreement between FNAC and Biopsy by Kappa statistics.** There is 83.33% agreement between FNAC and BIOPSY reports with a significant p value of < 0.001. See table 10.
11. **Association between TIRADS** report and biopsy report by Chi square test. This test proves the significant association between TIRADS and biopsy reports with significant p value of 0.05. See table 11
12. **Sensitivity , Specificity , PPV and NPV** of the study is depicted in table 12. Sensitivity of TIRADS scoring system according to the present study is found to be 77.36% and Specificity is 57.14%. Positive Predictive Value (PPV) and Negative Predictive Value (NPV) respectively are 93.18 % and 25 %.

DISCUSSION

A thyroid nodule is a clinical entity which is radiologically different from the rest of the thyroid parenchyma [1]. Significant concerns have been raised about the increased incidence of thyroid cancer in the thyroid nodule [2]. However at the other end of the spectrum studies are emerging reporting a decreased incidence of malignancy in thyroid nodule and raising concerns about overtreatment [3]. Typically, ultrasound is the first modality used to diagnose intra-thyroid lesions [4]. It is an useful investigation to differentiate between benign and malignant lesions however this distinction cannot be easily made [5].

The ultrasound based Thyroid Imaging Reporting And Data System (TIRADS) is gradually emerging as a valuable evaluation tool in decision making regarding thyroid nodules especially in those whom malignancies are suspected [6]. Our study's objective was to evaluate how well the TIRADS grading system distinguished between benign and malignant thyroid nodules [7].

The standard ultrasonic parameters have been researched pretty thoroughly. Although taken separately, they do not show a good predictive value for the probability of malignancy, the various proposed algorithms that make up their relationship produce superior results. Although the ideal formula in this regard has not yet been discovered, considerable clinical research is being done to enhance the ones that already exist. This has resulted in uneven, widely varied examination and classification of thyroid lesions rather than the development of a systematic, universal evaluation of thyroid nodules [8].

There is currently no ultrasound classification method that can accurately predict the malignancy of thyroid nodules. There is nearly always some degree of overlap between the appearances of benign and malignant nodules, as well as a compromise between sensitivity and specificity. A perfect system will enable the identification of physiologically significant disease while preventing the over investigation of benign disease and the overdiagnosis of subclinical malignancies. Even in asymptomatic patients, thyroid ultrasonography boosted thyroid nodule diagnosis in the general population.

Table 1: Distribution of subjects according to age

Variables	Subcategory	Number of Subjects (%)
Age (years)	=20	2 (3.3%)
	21 - 40	23 (38.3%)
	41 - 60	23 (38.3%)
	61-80	11 (18.3%)
	>80	1 (1.7%)
	Mean ± SD Median (Min, Max)	45.27 ± 14.57 46 (18, 81)

Table 2: Distribution of subjects according to Gender. Out of 60 subjects, 56 (93.3%) were female and 4 (6.7%) were male.

Variable	Subcategory	Number of subjects
Gender	Female	56 (93.3%)
	Male	4 (6.7%)

Table 3: Distribution of subjects according to swelling in neck..

Variable	Subcategory	Number of subjects
Swelling in neck	Yes	60 (100%)
	No	0

Table 4: Distribution of subjects according to pressure and toxic symptoms.

Variable	Subcategory	Number of subjects
Pressure symptoms	Yes	51 (85%)
	No	9 (15%)
Toxic symptoms	Yes	54 (90%)
	No	6 (10%)

Table 5: Distribution of subjects according to solitary nodule.

Variable	Subcategory	Number of subjects
Solitary nodule	Yes	16 (26.7%)
	No	44 (73.3%)
Multinodular	Yes	44 (73.3%)
	No	16 (26.7%)

Table 6: Distribution of subjects according to TIRADS Score.

Variable	Subcategory	Number of subjects
TIRADS Score	1	18 (30%)
	2	15 (25%)
	3	11 (18.3%)
	4	11 (18.3%)
	5	5 (8.3%)

Table 7: Distribution of subjects according to BETHESDA Score.

Variable	Subcategory	Number of subjects
BETHESDA Score	1	1 (1.7%)
	2	44 (73.3%)
	3	4 (6.7%)
	4	7 (11.7%)
	5	2 (3.3%)
	6	2 (3.3%)

Table 8: Distribution of subjects according to outcome of FNAC report.

Variable	Subcategory	Number of subjects
FNAC Report	Benign	47 (78.3%)
	Malignant	13 (21.7%)

Table 9 : Distribution of subjects according to outcome of Biopsy

Variable	Subcategory	Number of subjects
Biopsy	Benign	53 (88.3%)
	Malignant	7 (11.7%)

Table 10: Agreement between outcome of FNAC and Biopsy.

Variable		Biopsy outcome		Total
		Benign	Malignant	
FNAC outcome	Benign	45 (84.9%)	2 (28.6%)	47 (78.33%)
	Malignant	8 (15.1%)	5 (71.4%)	13 (21.66%)

Below table gives the association between Biopsy and TIRADS Score.

Agreement	Expected Agreement	Kappa	Std. Err	p-value
83.33%	71.72%	0.6293	0.148	<0.001*

Table 11::gives the association between Biopsy and TIRADS Score.

		Biopsy			Value
		Malignant	Benign	Total	
TIRADS Score	1	1 (14.3%)	17 (32.1%)	18 (23.2%)	P value = 0.05[C] Chi square value =3.764
	2	1 (14.3%)	14 (26.4%)	15 (20.35%)	
	3	1 (14.3%)	10 (18.9%)	11 (16.6%)	
	4	2 (28.6%)	9 (17%)	11 (22.8%)	
	5	2 (28.6%)	3 (5.7%)	5 (17.15%)	

Table 12:. Association between Biopsy and TIRADS Score

	Value	95% CI
Sensitivity	77.36	0.6447 to 0.8655
Specificity	57.14	0.2505 to 0.8418
Positive Predictive Value (PPV)	93.18	0.8177 to 0.9765
Negative Predictive Value (NPV)	25.00	0.1018 to 0.4950

The American Thyroid Association's (ATA's) current recommendations for adult patients with thyroid nodules and differentiated thyroid carcinoma include the following: (1) thyroid nodules measuring 1 cm and up with a moderate to high sonographic pattern; (2) thyroid nodules measuring 1.5 cm and up with a low suspicious pattern; and (3) thyroid nodules measuring 2 cm and up with a very low suspicious ultrasound pattern. (4) Ultrasound characteristics play a key role in determining the likelihood of cancer. According to the American Thyroid Association (ATA), a high suspicion ultrasonographic pattern is defined as a solid hypoechoic nodule or solid

hypoechoic component of a partially cystic nodule with one or more of the following characteristics: irregular margins, microcalcifications, a shape that is taller than wide, rim calcifications with a small extrusive soft tissue component, and evidence of extrathyroidal extension. Thyroid nodules having hypoechoic characteristics, smooth edges without microcalcification, extrathyroidal expansion, or a taller than wide form are all considered to be intermediately worrisome sonographic patterns. Low suspicion sonographic patterns are defined as isoechoic or hyperechoic solid nodules, partially cystic nodules, eccentric solid areas devoid of microcalcification, irregular margins, extrathyroidal extension, or shapes that are taller than wide, while very low suspicion sonographic patterns are defined as spongiform or partially cystic nodules devoid of any of the sonographic features described in low, intermediate, or high suspicion patterns. The ATA recommends malignancy risks of more than 70 to 90 percent for high suspicion patterns, 10 to 20 percent for intermediate suspicion patterns, 5 to 10 percent for low suspicion patterns, less than 3 percent for very low suspicion patterns, and less than 1 percent for benign patterns [9].

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 only process used to select high-risk nodules for biopsy, and it is thought to be complimentary to FNAC [8].

The effectiveness of the TIRADS grading system in identifying cancer in thyroid nodules that are worrisome and avoiding FNAC in benign nodules has thus been the subject of numerous research. In their study, Gilles et al. (2021) came to the conclusion that knowing the advantages and disadvantages of the various TIRADS scoring systems will help to enhance each one and may serve as the foundation for a final universal standardization. With the ultimate goal of minimizing needless thyroid biopsies without endangering the detection of clinically relevant cancers, efforts should be made to integrate the many methods used around the world [10].

According to Azin Shayganfar et al. (2020), thyroid nodules with TIRADS 4 and 5 with a diameter of less than 12 mm are highly suggestive of cancer and should be taken into consideration as criteria for fine needle aspiration biopsy [11].

In their investigation, Shan Jiang et al. [13] came to the conclusion that utilizing ultrasound features, thyroid nodule malignancy is difficult to predict. The nodule size also limits using ultrasound characteristics to evaluate PTC [12].

Joanna Grace Dy et al. [14], demonstrated that the appearance of solid thyroid nodules is a reliable indicator of thyroid cancer. The risk of thyroid cancer increases with higher TIRADS categorization.13 TIRADS is a \sensitive categorization for identifying thyroid cancer patients and can be used to help determine whether a fine needle aspiration biopsy is necessary. Although multivariate analysis did not approach statistical significance, ultrasound characteristics including significantly hypoechoic nodules and nodules with irregular boundaries were linked to an increased chance of malignancy [9]. In their investigation, Boniface Moifo et al. [15] came to the conclusion that Russ' modified TIRADS classification is accurate at identifying thyroid cancer. However, further proof is required before widespread adoption and utilization [15].

Using ultrasound, a non-invasive method, a TIRADS scoring system was employed in the current investigation to distinguish between benign and malignant thyroid nodules. The patient was included to the study and scored after meeting the exclusion and inclusion criteria.

The incidence of thyroid nodules among 60 participants in the study was found to be more common among females than in males and the age distribution ranged from 18 - 81 years, mean being 45.27 ± 14.57 years. All patients presented with neck swelling , the majority of them had clinical presentation as multinodular goitre i.e,44 (73.3%) multinodular and 17 (26.7%) patients had solitary nodule at the time of presentation. On TIRADS classification majority were reported under TIRADS 1 i.e., 18 patients (30%), followed by 15 (or 25%) under TIRADS 2, 11 (18.3%) patients under TIRADS 3 and TIRADS 4 each, and 5 (8.3%) patients under TIRADS 5.

FNAC done among 60 patients in this study reported majority under BETHESDA Score 1 i.e., 44 (73.3%) patients out of 60, followed by 7 (11.7%) patients under BETHESDA 4 , and 4 (6.7%), 2 (3.3%), 2 (3.3%), 1 (1.7%) patients under BETHESDA 3,5,6,1 category respectively. Therefore, 53 (88.3%) of them as reported on the FNAC were benign, while 7 (11,7%) were malignant.

When the relationship between the TIRADS score and the biopsy report was examined, the results were P value = 0.05, Chi square value =3.764 Hence the results of the Chi square test show that there is significant relationship between the TIRADS Score and the biopsy results.

Sensitivity of TIRADS scoring system according to the present study is found to be 77.36% and Specificity is 57.14%. Positive Predictive Value (PPV) and Negative Predictive Value (NPV) respectively are 93.18 % and 25 %. According to the Chi-square test, there is a substantial correlation between the histological report and TIRADS score with a p value of 0.05.

CONCLUSION

The TIRADS scoring system is a statistically significant scoring system in differentiating benign and malignant lesions of the thyroid gland on initial assessment . Hence helps preclude FNAC in patients with benign lesions.

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