Int. J Med. Pharm. Res.
P-ISSN: 2958-3675 | E-ISSN: 2958-3683
Available on: https://ijmpr.in/

International Journal
of Medical and Pharmaceutical Research

ORIGINAL ARTICLE OPEN ACCESS

Validity of ACR TI-RADS Size- Based Biopsy Recommendations in Diagnosing Thyroid Malignancy

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OPEN ACCESS

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Received: 02-07-2025
Accepted: 11-08-2025
Available Online: 21-08-2025

ABSTRACT

Background: The American College of Radiology (ACR) TI-RADS 2017 guidelines recommend size-based thresholds for biopsy of thyroid nodules, aiming to improve diagnostic accuracy while minimizing unnecessary procedures. However, the validity of these criteria in real-world clinical settings, particularly in India where the incidence of differentiated thyroid cancer (DTC) is rising, remains underexplored.
Objective: To evaluate the diagnostic performance of ACR TI-RADS 2017 size-based biopsy recommendations in identifying thyroid malignancy.
Methods: A prospective study was conducted at Government Medical College, Thiruvananthapuram, including 240 thyroid nodules from 162 patients over a period of 1.5 years. All nodules >1 cm or TIRADS 4/5 nodules >5 mm underwent ultrasound-guided FNAC. Nodules with Bethesda categories 4–6 underwent surgery; Bethesda 3 nodules were either followed up or surgically excised based on patient preference. Final outcomes were based on cytology (Bethesda 2) or histopathology.
Results: Of the 226 nodules with definitive outcomes, the malignancy rate was 11.5%. The ACR TI-RADS size criteria demonstrated a sensitivity of 92.85% and specificity of 63.07% in detecting malignancy. Among biopsies performed as per ACR size recommendations, 15.29% were malignant. Only 1 out of 124 nodules not meeting biopsy criteria was malignant (0.8%).
Conclusion: The ACR TI-RADS 2017 size-based biopsy thresholds exhibit high sensitivity and moderate specificity, effectively minimizing missed malignancies while avoiding a large number of unnecessary FNACs. However, a small risk of missing cancers persists, raising the need to re-evaluate the size criteria, especially for nodules with high-risk sonographic features. Larger multicenter studies are essential to optimize these thresholds for enhanced diagnostic precision.

Key Words: *Thyroid nodule, ACR TIRADS, Fine needle aspiration cytology, Bethesda cytology thyroid, Papillary carcinoma thyroid, Follicular carcinoma thyroid.*

INTRODUCTION

In India, incidence of differentiated thyroid cancer (DTC) has increased over the past decade by 55%[1]. To stratify the risk for malignancy and for selection of thyroid nodules for fine-needle aspiration cytology (FNAC), ultrasound-based risk-stratification systems have been developed by many national and international thyroid societies and by the American College of Radiologists (ACR)[2]. The various ultrasound stratification systems also recommend size cut off criteria above which biopsy is indicated. Among the various US risk stratification systems, revised ACR TIRADS which came in 2017 is considered to be more objective with lesser interobserver variability[3]. According to ACR TIRADS, FNAC is suggested for thyroid nodule with TIRADS 3 $\geq$2.5cm, TIRADS 4 $\geq$ 1.5cm, and TIRADS 5 $\geq$1cm, maximum diameter.

Most clinicians usually order for FNAC for suspicious nodules even at a smaller size itself. This study has assessed the performance of size cut off criteria of ACR TIRADS in selecting nodules for FNAC; in diagnosing malignancy in thyroid nodule.

METHODS

The study was approved by the institutional research committee and the Human ethics committee of the Government Medical College Thiruvananthapuram vide HEC.No.06/04/2019/MCT dated 10.05.2019 for a period of one and half years from the date of ethics committee approval. All patients, 12 years of age or above, with thyroid nodule on palpation or by ultrasonography, attending the Endocrinology Outpatient department, Medical college, Thiruvananthapuram during the study period were consecutively included in the study after getting written informed consent. Hormonal parameters evaluated include serum total thyroxine (T4), Thyroid stimulating hormone (TSH) and Anti TPO antibody (ATPO) levels. The hormonal evaluation was done using Eclysys 2000 Electro-chemiluminescence system with commercially available kits (Roche, Germany). All nodules of size >1cm in maximum diameter and those with TIRADS score of 4 or 5 with maximum diameter >5mm underwent ultrasound-guided FNAC. All Bethesda 4, 5 and 6 nodules underwent thyroidectomy. Patients with Bethesda 3 nodules were given option of close follow up or surgery. Those who preferred surgery underwent thyroidectomy. Histopathological report of all nodules that underwent surgery were collected.

RESULTS

Two-hundred-and-forty nodules from 162 patients were included for analysis. The cytology wise distribution of the nodules and their status according to ACR TIRADS size cut off criteria are given in Table (1). The gold standard for analysis was considered as a final outcome variable. Final outcome variable was defined as FNAC report of Bethesda 2(benign) or all other nodules which had undergone surgery and HPR is available as benign or malignant. Sixteen nodules with a Bethesda 3 report did not undergo surgery. Excluding those nodules, a total of 226 nodules were available for analysis with a final outcome variable. Analysis was done on comparison of proportion of malignancy in nodules that satisfied and didn't satisfy the size criteria of ACR TIRADS(Table 2).

Prevalence of differentiated thyroid cancer in the study population was 11.5% (26 out of 226 nodules). The sensitivity and specificity of size cut off criteria of 2017 ACR TIRADS were 84%, 62.6% respectively. The positive predictive value and negative predictive value were 21.8% and 96%. Chance of missing malignancy in un-indicated biopsies was one in 32 nodules (3.07%).

Table 1: Frequency of indicated and un-indicated biopsies in each Bethesda category

	Nodules not satisfying size criteria (n=136)	**Nodules satisfying size criteria (n=104)**
Bethesda 2	123	72
Bethesda 3	10	13
Bethesda 4	1	3
Bethesda 5	1	3
Bethesda 6	1	13

Table 2 : Predictive accuracy of size cut off criteria of ACR TIRADS

N= 226	**Malignant**	**Benign**
Satisfied size cut off (n= 96)	21	75
Didn't satisfy cut off (n=130)	4	126

DISCUSSION

The performance of various risk stratification systems in reducing "unnecessary" biopsies were of clinical concern and assessed in various studies. In the present study the size cut off criteria of ACR TIRADS had higher sensitivity thus higher chance for selecting malignant nodules for FNAC.

In a study of comparison of seven US risk stratification systems on 2000 nodules Ha et al [4] have found that the unnecessary FNAC rate was lowest in the ACR guidelines (25.3%), where it was 51.7% for ATA guidelines.

Ting Xu et al have also demonstrated lowest rate of unnecessary FNAC with the 2017ACR system (17.3%) on comparison with two other systems [5].

Castellana et al[6] showed higher relative diagnostic Odds ratio for ACR-TIRADS versus ATA (p=0.002) or K-TIRADS (p=0.002), due to a higher relative likelihood ratio for positive results.

In a study by Middleton et al [7], the needle cytology yield of malignancy for ACR TIRADS was 14.2%, which was significantly higher than that of the ATA guidelines (p <0.0001). The percentage of benign nodules that were biopsied was 47.1% for the ACR TI-RADS as compared to 78.1% for the ATA guidelines, which was significantly lower for ACR TIRADS (p < 0.001).

Grani et al [8] assessed the performances of 5 internationally endorsed sonographic classification systems in reducing the number of unnecessary thyroid biopsies while improving diagnostic accuracy and found that the ACR TIRADS outperformed the others, classifying over half the biopsies as unnecessary with a false negative rate of 2.2%.

Sakajiri et al have studied whether the size of thyroid nodules in ACR-TIRADS ultrasound categories 3 and 4 is correlated with the Bethesda cytopathology classification and found that there were no significant differences between nodule size and fine needle aspiration biopsy classification in any of the ACR-TIRADS categories [9].

Overall, from various studies ACR TIRADS system had better test performance characteristics predicting malignancy and avoiding unnecessary biopsies. The present study is also in agreement with it.

The main reason of the better performance of ACR TIRADS considered could be the objectivity of the assessment based on points. More combinations of ultrasound characteristics could be classified. For example, the nodules with regular shape and margins, mild hypo-echogenicity and mixed composition will be classified as ACR-TIRADS 3, while being categorized as EU-TIRADS 4 and class 2 (intermediate risk) of the AACE/ACE/AME. They cannot be classified by the ATA system, which is characterized by a significant number of not-classifiable lesions.

Conclusion

The study demonstrates that the current size cutoff criteria recommended by the ACR TI-RADS system offer moderate diagnostic accuracy in predicting thyroid malignancy. While the criteria help reduce unnecessary biopsies, a significant proportion of malignant nodules may fall below the recommended thresholds, potentially delaying diagnosis. On the contrary, the relevance of early detection on difference in outcome and overdiagnosis of thyroid malignancy are also a matter of concern in thyroid nodules. These findings suggest a need to reconsider size-based biopsy recommendations, especially in nodules with high-risk sonographic features. Further large-scale, multicenter studies are warranted to refine the size thresholds to enhance both sensitivity and specificity in malignancy detection.

Acknowledgement:

I thank my patients who have participated in the study. I extend my sincere thanks to Dr. Ramesh Gomez, Dr. C.Jayakumari for their valuable comments in editing the manuscript. I extend my appreciation and thanks to Dr. Anish T, for the valuable guidance in statistical analysis of the work. I extend my sincere thanks to my colleagues, Dr. Geena, Dr. Nandini, Dr. Ajeesh, Dr. Karthik, Dr. Shameer, Dr Sandra and Dr Rameez for their help. I thank Dr Arun Kumar A for his valuable comments and advice.

Author contribution statement:

Author 1: did conception of the research idea, designed the work, did Ultrasound guided FNAC on all the study subjects, collected data and did analysis and interpretation (ICMJE Criteria 1). Author 2: acquisition of data for the study by doing ultrasound thyroid for all study subjects and ACR TIRADS scoring(ICMJE Criteria 1). Author 3: critical revision for important intellectual content(ICMJE Criteria 2) Author 4: did critical revision and final approval of the version to be published (ICMJE Criteria 3). Author 5: did critical reviosion.

Author disclosure statement: No conflicts of interests.

Funding statement: No funding information to share.

Data availability: Authors declare that the data related to the study will be made available upon request

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