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Ultrasound Based Thyroid Imaging Reporting and Data System (ACR-TIRADS) in Risk Stratification of Malignancy in Thyroid Nodules

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ABSTRACT

Purpose: To evaluate thyroid nodules using gray scale sonography and color Doppler and categorise them as per American college of radiology (ACR) (2017) Thyroid imaging reporting and data system (TIRADS)[1,2] classification. To assess diagnostic performance of TIRADS in detecting the risk of malignancy by comparing with cyto/pathological findings.

Materials and methods: We examined thyroid gland of 102 adult patients who presented clinically or incidentally with 201 thyroid nodules using ultrasound, after obtaining consent and relevant clinical history.

High resolution gray scale ultrasonography: The number and size of the nodules were recorded. Each nodule was evaluated for five sonological features: composition, echogenicity, shape, margin, presence and type of echogenic foci in the lesion. Each feature was assigned a point and a total score was calculated for each nodule and was assigned a specific TIRADS category (TR1 to TR5).

Color Doppler: All the thyroid nodule/s were examined and their vascularity pattern was categorised into one of the following types: absent, peripheral, intranodular or mixed (peripheral and intranodular).

The diagnostic performance of ACR proposed TIRADS classification system was evaluated with FNAC (cytopathology) correlation in all patients.

Results and conclusions: The ACR proposed TIRADS is a reliable, highly specific and accurate classification system for stratifying thyroid nodules according to their risk of malignancy based on their sonographic features. This can be a useful tool towards standardizing a protocol for reporting and management of thyroid nodules. Furthermore, by following the ACR TIRADS recommendations FNACs can be avoided in a significant number of benign thyroid nodules.

Keywords: TIRADS, ACR TIRADS, TIRADS 2017, Thyroid ultrasound, Thyroid nodule, Thyroid cancer, Thyroid

INTRODUCTION

A thyroid nodule is a discrete lesion within the thyroid gland that is radiologically distinct from surrounding thyroid parenchyma.[1] Over the past decade, with the advent of recent advances in ultrasound (USG) technology along with its easy accessibility and availability, there has been a tremendous increase in detection rate of thyroid nodules.

In India, the prevalence of thyroid nodules is 12.2%, seen more commonly among females.[2] Most of these nodules are benign, malignancy being rare, seen in just 5% of the clinically detected nodules.[2] The prime challenge of a clinician is to distinguish a benign nodule from a malignant one.

The imaging modality of choice for assessment of the thyroid nodule is USG. Sonographic characteristics show a considerable overlap in appearance of benign and malignant thyroid lesions.[3] Assessment of color flow pattern in thyroid nodule is also used as an adjunct to gray scale sonographic signs.[4]As of now, Fine

Needle Aspiration Cytology (FNAC) continues to be the best triage for preoperative evaluation of thyroid nodules. In view of the ubiquity of thyroid nodules, it is not feasible to do FNAC of every thyroid nodule.

It is imperative to follow a standardized lexicon and risk stratification system for thyroid nodules. For this purpose, in 2009 Hovarth et al[5] coined the term TIRADS (Thyroid imaging reporting and data system). Thereafter, multiple versions of TIRADS have been published using various criteria. The American College of Radiology (ACR) proposed the TIRADS classification in 2015[6] which was further modified in 2017[7]. It uses a system based on allocating points for different sonographic features of nodules in five morphologic categories (composition, echogenicity, shape, margin and echogenic foci).

The primary objective of our study was to evaluate the ultrasound based ACR TIRADS as a risk stratification tool for thyroid malignancy and henceforth, determine its diagnostic accuracy.

MATERIALS AND METHODS

The cross sectional study was conducted for a duration of 1.5 years. Adult patients detected incidentally or clinically with nodular thyroid disease, referred to the Department of Radiodiagnosis, Maulana Azad Medical College and Lok Nayak Hospital, New Delhi, were taken up for the study. Overall, 102 adultpatients of either sex with 201 thyroid nodules were selected and examined by grayscale ultrasonography and color Doppler.

The institutional review board and local ethics committee at the university approved this study. After explaining the study process in detail to the patients, written informed consent was obtained from all participants.

1. **High resolution grayscale ultrasonography:** The Patients underwent USG examination of the thyroid gland on Siemens ACUSON S2000 using high frequency linear probe (4-9 MHz). The number and size of the nodules were recorded. Each nodule was evaluated for sonological features under five categories: composition, echogenicity, shape, margin and echogenic foci. Subsequently, each feature was assigned a specific point and a total score was calculated for each nodule. Further, based on the total score, each nodule was assigned a specific ACR TIRADS risk level(Table 1). In case a patient presented with multiple thyroid nodules, a maximum of four nodules with highest total score were reported.

COMPOSITION (CHOOSE 1)	POINTS
Cystic or almost completely cystic	0
Spongiform	0
Mixed cystic and solid	1
Solid or completely solid	2
Cannot be determined due to calcifications	2
ECHOTEXTURE (CHOOSE 1)	POINTS
Anechoic	0
Hyperechoic or Isoechoic	1
Hypoechoic	2
Very Hypoechoic	3
Cannot be determined	1
SHAPE (CHOOSE 1)	POINTS
Wider than tall	0
Taller than wide	3
MARGIN (CHOOSE 1)	POINTS
Smooth	0
Ill defined	0
Lobulated or Irregular	2
Extra thyroidal extension	3
Cannot be determined	0
ECHOGENIC FOCI (CHOOSE ALL THAT APPLY)	POINTS
None or large comet tail artifacts (>1mm)	0
Macrocalcifications	1
Peripheral (rim) calcifications	2
Punctate echogenic foci (<1 mm)	3

TOTAL SCORE	ACR TIRADS LEVEL
0	TIRADS 1 (TR1) -BENIGN
2	TIRADS 2 (TR2) -NOT SUSPICIOUS
3	TIRADS 3 (TR3) -MILDLY SUSPICIOUS
4-6	TIRADS 4 (TR4) -MODERATELY SUSPICIOUS
≥ 7	TIRADS 5 (TR5) -HIGHLY SUSPICIOUS

CATEGORY 1- Composition:

- *Cystic:* Entirely fluid filled.
- *Spongiform*: Composed predominantly (> 50%) of tiny cystic spaces. No points to be entered for other categories.
- *Mixed cystic and solid*: Composed of both soft tissue and cystic components.

- *Solid*: Composed entirely/nearly entirely of soft tissue, with few tiny cystic spaces.

CATEGORY 2 - Echogenicity:

- *Anechoic:* Absence of echogenicity in a cystic nodule.
- *Isoechoic*: Similar echogenicity relative to adjacent thyroid tissue.
- *Hyperechoic*: Increased echogenicity relative to adjacent thyroid tissue.
- *Hypoechoic*: Decreased echogenicity relative to adjacent thyroid tissue.
- *Very hypoechoic*: Decreased echogenicity relative to adjacent strap muscles.

CATEGORY 3 – Shape:

- *Taller-than-wide*: AP diameter is more than the transverse diameter when measured in the transverse plane
- *Wider than tall*: Transverse diameter is more than AP diameter. This category also includes round nodules where AP diameter is equal to transverse diameter.

CATEGORY 4 - Margin:

- *Smooth*: Uninterrupted, well-defined, curvilinear edge.
- *Ill-defined*: Border of the nodule is difficult to distinguish from thyroid parenchyma.
- *Irregular margin*: The outer border of nodule is spiculated, jagged, or with sharp angles.
- *Lobulated*: Border has focal round soft tissue protrusions into the adjacent parenchyma.
- *Extrathyroidal extension*: Nodule extends through the thyroid border. This category involves frank invasion into adjacent structure and minimal extra thyroidal extension (presence of border abutment, contour bulging or loss of overlying echogenic thyroid border).

CATEGORY 5 - Echogenic foci:

- *Large comet-tail artifact*: Echogenic foci with V-shaped echoes >1 mm deep Figure 1.
- *Macrocalcifications*: Coarse echogenic foci with posterior acoustic shadow.
- *Peripheral calcifications*: Calcifications occupying majority of the margin of nodule.
- *Punctate echogenic foci*: "Dot-like" foci with no posterior acoustic shadow or artifacts.

2. **Color Doppler:** Vascularity of thyroid nodules was evaluated on Doppler. Vascularity pattern of the nodules was categorised into one of the following types: absent, peripheral, intranodular or mixed (peripheral and intranodular). *Vascularity of the nodule is not a part of ACR proposed TIRADS.*

Reference Standard-Cyto/histopathological findings were considered gold standard in all cases.

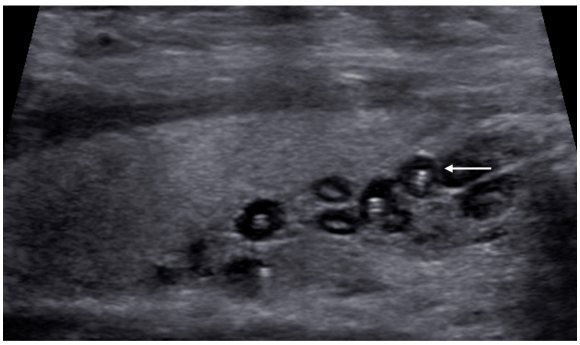

Figure 1 : High resolution gray scale ultrasound of right lobe of thyroid (LS) reveals multiple small (avg size ~8x9 mm) round anechoic cystic nodules with smooth margins. Note made of an echogenic focus showing reverberation artifact suggestive of a large comet tail artifact (arrow) present within each nodule.

Statistical Analysis- The qualitative variables were summarized using frequencies/percentages and compared using Chi-square test. Sensitivity, specificity, PPV and NPV of ACR TIRADS in comparison with Cyto/histopathology (gold standard) was calculated. A *P*-value < 0.05 was assumed statistically significant. Statistical Package for Social Sciences (SPSS) version 17.0 was used for analysis.

RESULTS

A total of 102 adult patients with nodular thyroid disease were included in the study. In 40% of these patients, thyroid

nodules were detected incidentally on other imaging modalities (CT neck/chest and carotid Doppler). A female predilection was found in our study (Females- 78.3%, Males- 21.6%; M:F ratio- 3.6:1). 73 patients had a solitary thyroid nodule, whereas 29 patients were detected with multiple thyroid nodules, making a total of 201 nodules. Majority of the patients (45 %) were less than 30 years (range: 18-78 years). Four patients were excluded from the study because FNAC revealed non diagnostic findings and a definitive diagnosis could not be made.

Of the total 201 thyroid nodules, 188 (93.53%) were benign and 13 (6.46 %) were malignant as described in Table 2.

Table 2: Distribution of thyroid nodules based on pathological diagnosis (n=201)

Cytopathological	Diagnosis	Number of nodules	Percentage (%)
Benign			
	Adenomatoid nodule	28	13.93
	Colloid Nodule	158	78.60
	Follicular adenoma	2	0.99
Total		188	93.53
Malignancy			
	Papillary carcinoma	7	3.48
	Follicular carcinoma		
	Medullary carcinoma	2	0.99
	Thyroid lymphoma	1	0.49
Total		13	6.46

Table 3 enumerates the grayscale sonographic features of the nodules as per ACR TIRADS lexicon with associated malignancy risk for each feature. As the point level for each feature increased, their risk of malignancy increased. A statistically significant relationship existed between risk of malignancy and the ACR TIRADS categories (composition, echotexture, shape, margin and echogenic foci).

In our study, the major sonographic features that showed significant association with malignancy were further analysed. Sensitivity, specificity, positive predictive value and negative predictive values were calculated for each major feature is shown in Table 4.

Vascularity of the thyroid nodules was also assessed as - absent, peripheral, intranodular or mixed, however vascularity pattern of the nodule is not included in ACR TIRADS. Vascularity pattern of the nodule was compared with pathological report. As per our study, no statistically significant correlation was found between vascularity pattern and thyroid malignancy ($p>0.05$).

Table 3 : Correlation of sonographic features with pathological findings and associated risk estimated for each feature (n = 201)

Major TIRADS Features		Cytology		Total nodules	Risk of Malignancy
		Benign	Malignant		
Composition	Solid	55	13	68	19.1 %
	Cystic	62	0	62	0.0 %
	Mixed cystic and solid	66	0	66	0.0 %
	Spongiform	5	0	5	%
Echotexture	Isoechoic	84	2	86	2.3 %
	Anechoic	67	0	67	0.0 %
	Hyperechoic	30	0	30	0.0 %
	Hypoechoic	5	8	13	61.5 %
	Very hypoechoic	0	3	3	100 %
	Cannot be determined	2	0	2	0.0 %
Shape	Wider than tall	187	10	197	5.07 %
	Taller than wide	1	3	4	75 %
Margin	Smooth	177	6	183	3.2 %
	Ill defined	9	0	9	0.0 %
	Lobulated/Irregular	2	5	7	71.4 %
	Extrathyroid extension	0	2	2	100 %
Echogenic foci	None	109	7	116	6 %
	Comet tail artefact	58	0	58	0.0 %
	Macrocalcifications	20	1	21	4.7 %
	Peripheral rim calcifications	3	0	3	0.0 %
	Punctate echogenic foci	1	5	6	83.3%

The thyroid nodule was allocated points for different sonographic features as per the five ACR TIRADS categories and classified into five TIRADS risk levels (TR1-TR5). Figure 2 shows a representative case from our study classified as ACR TIRADS level 1 (TR1) and was proven on cytopathology as benign. Another representative case is shown in Figure 3 which was categorised as ACR TIRADS level 5 (TR5). It underwent USG guided FNAC and was proven to be malignant.

Table 4: Summary of the statistical performance of major USG feature

Sonographic feature	Sensitivity(%)	Specificity(%)	PPV (%)	NPV (%)
Solid composition	100.0	70.7	19.1	100.0
Hypoechoic/very hypoechoic echotexture	84.6	97.3	68.7	98.9
Lobulated/irregular margin	45.4	98.9	71.4	96.9
Taller than wide shape	23.1	99.5	75	94.5
Extra thyroidal extension	25.0	100.0	100.0	96.9
Punctate echogenic foci	38.5	99.5	83.3	95.9

Figure 4 shows distribution of nodule into TIRADS level. In our study, TR1 level was dominant, accounting for 32.8 % thyroid nodules.

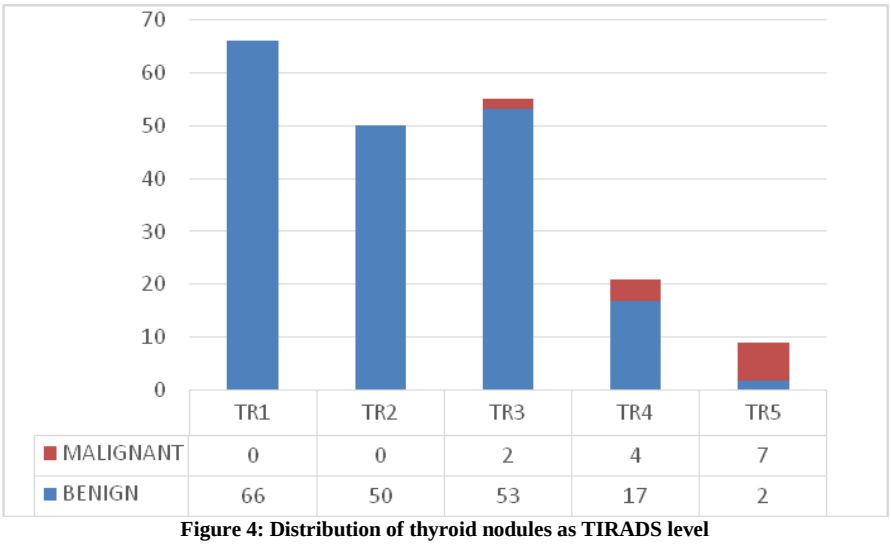

Figure 4: Distribution of thyroid nodules as TIRADS level

The different TIRADS levels were confronted with results of FNAC/histopathology and the risk of malignancy was calculated. The risk of malignancy for TR1 and TR2 was 0.0%, TR3-3.6 %, TR4-19% and TR5 -77.7%. According to our study, the risks of malignancy significantly rise as TIRADS level increased from TR1 to TR5.

According to ACR proposed TIRADS classification, TR4 and TR5 nodules are classified as moderately and highly suspicious with their risk of malignancy being 5-20 % and more than 20 % respectively. The risk of malignancy of TR1, TR2 and TR3 nodules is less than 5 %.[13] Henceforth, for the purpose of this analysis TR4 and TR5 are considered malignant and TR1, TR2 and TR3 are considered benign. The sensitivity, specificity, positive predictive value and negative predictive value of ACR TIRADS was found to be 84.6 %, 89.9 %, 36.7 % and 98.8% respectively. The overall diagnostic accuracy of the ACR TIRADS classification in detecting risk of thyroid malignancy was found to be 89.5%.

FIGURE 2 : ACR TIRADS 1 (BENIGN)

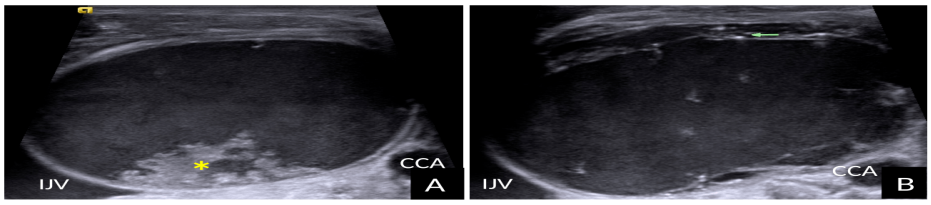

Fig 2 (A-B): USG of right lobe of thyroid reveals a 5.5 cm (max. diameter), oval, smoothly marginated, anechoic cystic nodule. Few moving and dependent echogenic debris (*) are seen within (A). Few echogenic foci (arrow) with comet tail artifact are seen in the anterior wall of the cyst (B). The nodule is seen insinuating between the right internal juglar vein (IJV) and right common carotid artery and displacing the IJV laterally.

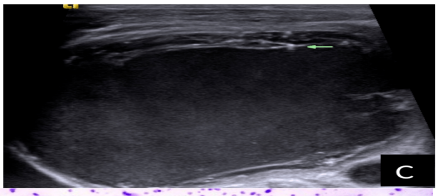

Fig 2 (C) : ACR TIRADS ASSESSMENT
1.Composition : Cystic [point 0]
2.Echogenicity : Anechoic [point 0]
3.Shape : Wider than tall [point 0]
4.Margin : Smooth [point 0]
5.Echogenic foci : Large comet tail artifact (arrow) [point 0]
TOTAL SCORE = 0
ACR TIRADS LEVEL : TR1

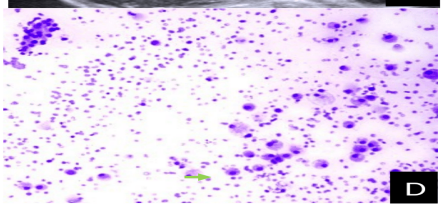

Fig 2 (D) : Cytological evaluation of the nodule reveals benign follicular epithelial cells with foamy macrophages (arrow) in a background of abundant colloid suggestive of **colloid nodule**.

Figure 3: ACR TIRADS 5 (HIGHLY SUSPICIOUS)

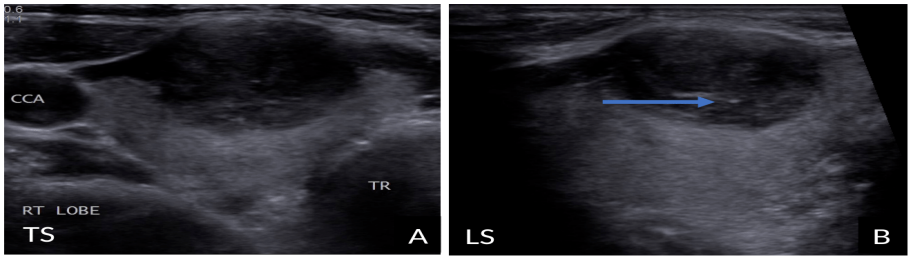

Fig 3 (A-B): USG right lobe of thyroid reveals a 1.7 cm (max. diameter) oval, solid nodule appearing hypoechoic to surrounding thyroid parenchyma and adjacent strap muscles. Few punctate echogenic foci are noted within (arrow). The nodule is bulging through anterior thyroid border suggestive of extra

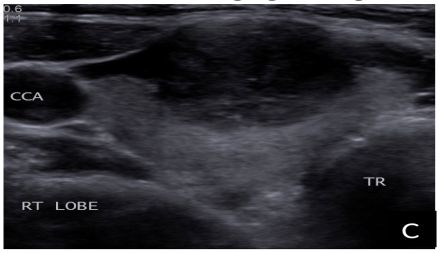

Fig 3 (C) : ACR TIRADS ASSESSMENT
1.Composition : Solid [point 2]
2.Echogenicity : Very hypoechoic [point 3]
3.Shape : Wider than tall [point 0]
4.Margin : Extra thyroid extension [point 3]
5.Echogenic foci : Punctate echogenic foci [point 3]
TOTAL SCORE = 11
ACR TIRADS LEVEL : TR5

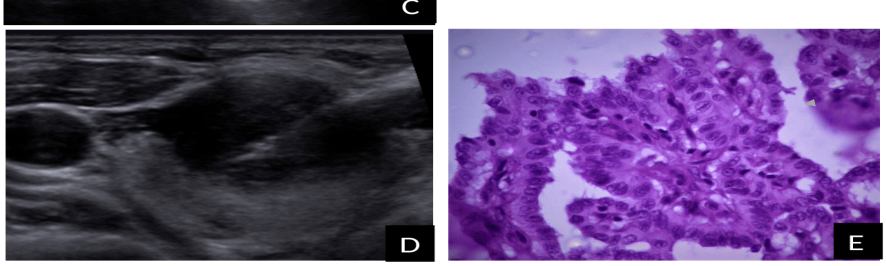

Fig 3 (D-E) : USG guided FNAC : Echogenic needle is seen entering the nodule obliquely (D). Histopathological evaluation of the nodule reveals papillae lined by cuboidal cells with nuclear crowding. There is optical clearing of nuclei with nuclear groove (arrow) and pseudoinclusions suggestive of **papillary carcinoma of thyroid.**

DISCUSSION

In 2015, the American College of Radiology developed a set of standard lexicon for USG reporting of thyroid nodules and proposed TIRADS classification on the basis of the lexicon. TIRADS is a risk stratification system to stratify nodules into five risk levels (TR1-TR5) based on their sonographic features. The main aim is to develop a standardised a diagnostic approach and provide guidance for FNAC/biopsy of selected thyroid nodules.

As per TIRADS thyroid nodules were evaluated under five categories: composition, echogenicity, shape, margin and echogenic foci. Each USG feature is assigned a point in each category and total score is calculated to determine a specific TIRADS level to predict risk of thyroid malignancy. Our study revealed, increasing risk of malignancy among higher scored sonographic feature.

Solid nodules were most common component comprising of 33.8% of nodules, followed by mixed solid cystic comprising of 32.8 %. All the malignant nodules were solid and the risk of malignancy for solid nodule was highest, 19.1%. None of the other nodules were malignant and hence had 0% risk of malignancy. Kwak et al also reported higher rates of malignancy in solid nodule.

Most of the nodules were isoechoic (42.7%), followed by anechoic (33.3%) and hyperechoic (14.9%). Hypoechoic and very hypoechoic nodules comprised of 6.4 % and 1.5 % of nodules, respectively. Most of the malignant nodules were hypoechoic or very hypoechoic, their risk of malignancy was 61.5% and 100% respectively. Two nodules appeared isoechoic in echotexture were diagnosed as papillary carcinoma of thyroid. Non of the hyperechoic or anechoic or spongiform nodule were malignant. Middleton et al also reported higher risk of malignancy in hypoechoic and very hypoechoic nodules. The risk of malignancy for anechoic, and hyperechoic nodules was 0%. Popli et al, emphasised that all the nodules with hyperechoic and anechoic echotexture are benign.

Majority of the thyroid nodules in our study were wider than tall comprising 93.7 % and only 7% were taller than wide. The risk of malignancy was high for taller than wide nodules as 75%. Popli et al and Hong et al also mentioned that taller than wider shape has higher prevalence of malignancy.

Majority of the nodules in our study had smooth margin (91.0%), followed by ill defined margin (4.5%), lobulated/irregular margin (3.4%) and extra thyroidal extension (1%). Risk of malignancy for smoothly marginated nodules was 3.2 %. Irregular/ lobulated margins or extra thyroidal extension is considered to represent aggressive growth pattern. Nodules with lobulated/irregular margins had 71.4 % risk of malignancy. All the nodules with extra thyroidal extension were malignant and their risk of malignancy was 100%.Our findings are in concordance with Mohanty et al who reported extra thyroidal extension to have 100% risk of malignancy while lobulated/irregular margins had 38% risk of malignancy.

Out of the 201 thyroid nodules 57.7% had no echogenic foci within. Risk of malignancy in nodules with no echogenic foci was 6%. The most common echogenic foci was comet tail artifact seen in 28.8 %, followed by macrocalcifications in 10.4%, peripheral rim calcification in 1.5% and punctate echogenic foci in 2.9%. The bright echogenic foci with comet tail artifacts are likely caused by microcrystals or aggregates of colloid substance, none of these nodules were malignant suggesting 0% risk of malignancy. The risk of malignancy was highest for nodules with punctate echogenic foci, associated with 83.3% risk of malignancy. Middleton et al also reported that risk of malignancy in nodules without echogenic foci was 9.7% and in nodules with punctate echogenic foci was 35%.

In our study, sonographic features that show statistically significant correlation with malignancy include solid composition,

hypoechogeneicity, very hypoechogenicity, irregularly/lobulated margins, taller than wide shape, extra thyroid extension and punctate echogenic foci.

None of the nodules belonging to TR1 orTR2 were found to be malignant, hence, in our study the risk of malignancy for these nodules was 0%. Only 2 out of 55 nodules were malignant in TR3 giving risk of malignancy as 3.6 %. The numbers of the higher scored suspicious features were found more in TR4 and TR5 nodules. The risk of malignancy for TR4 was 19 % and TR5 was 77.7 %. Our data substantiated the findings of Middleton et al that concluded that the aggregate risk levels for TR1, TR2, TR3, TR4 and TR5 nodules were 0.3%, 1.5%, 4.8%, 9.1% and 35% respectively.

The sensitivity, specificity, positive predictive value and negative predictive value of TIRADS in predicting malignancy in our study was 84.6 % , 89.9 % , 36.7 % and 98.8% respectively. The diagnostic accuracy of TIRADS was 89.5 %. Our findings were concordant with Ahmadi et al who reported that the sensitivity, specificity, positive predictive value and negative predictive value were 78.4 % (69.8-87.0 %), 73.2 % (67.5-78.9 %), 52.3% (43.7-60.8 %) and 90.1 % (85.8-94.3 %).

CONCLUSION

In conclusion, the ACR proposed TIRADS is a reliable and accurate system for stratifying thyroid nodules according to risk of malignancy based on their sonographic features. Point based system is reproducible and easy to use which enables the examiner to focus attention on each important sonographic category. This can be a useful tool towards standardising reporting and management of thyroid nodules. Furthermore, by following the ACR TIRADS recommendations unnecessary FNACs can be avoided in significant number of benign thyroid nodules.

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