

## **Evaluation of Diagnostic Accuracy of TIRADS by Ultrasonography in Thyroid Lesions with Cytological and Histopathological Correlation**

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**Conflicts of Interest:** Nil

### **Abstract**

**Objective:** To assess the correlation between ultrasound-based TIRADS and the Bethesda system on FNAC for evaluating thyroid nodules and to determine the diagnostic accuracy of TIRADS in malignancy risk stratification.

**Materials and Methods:** A prospective cross-sectional study was conducted on patients presenting with thyroid nodules at a tertiary care hospital. Each nodule was evaluated using ultrasound according to TIRADS criteria, and FNAC was performed and categorized per the Bethesda system. The sensitivity, specificity, and predictive values of TIRADS were calculated against cytological diagnosis.

**Results:** Among the nodules evaluated, a significant correlation was found between high TIRADS categories (4 and 5) and Bethesda IV–VI categories, with TIRADS 5 showing a high malignancy risk. The sensitivity and

specificity of TIRADS in identifying malignant nodules were found to be 100% & 92.2% respectively.

**Conclusion:** TIRADS is a valuable risk stratification tool that correlates well with cytological outcomes and can reduce unnecessary FNACs in patients with low-risk nodules.

**Keywords:** TIRADS, Bethesda system, FNAC, thyroid nodules, ultrasound, thyroid cancer

### **Introduction**

Thyroid incidentalomas are the most common endocrine incidentalomas, with prevalence ranging from 2% to 67% depending on diagnostic modality used <sup>1</sup>. In India, palpable thyroid nodules are detected in 8.5% of the population, affecting over 42 million people <sup>1</sup>. High-resolution ultrasound and ultrasound-guided FNAC are key tools in evaluation. The ACR-TIRADS, introduced in 2017, standardizes malignancy risk stratification and reduces unnecessary biopsies <sup>2</sup>. FNAC, interpreted using

the Bethesda System, remains a gold standard with sensitivity between 55–98% <sup>4</sup>. This study aims to assess TIRADS accuracy in identifying malignant nodules to improve patient care and avoid unnecessary interventions.

## Materials and Methods

**Study Design and Duration:** This prospective cross-sectional study was conducted at Gandhi Medical College, Bhopal, over a period of 18 months (May 2023 to November 2024), following approval from the Institutional Ethics Committee.

**Inclusion Criteria:** Patients with clinically palpable thyroid nodules.

## Exclusion Criteria

- Patients with normal thyroid gland or TIRADS 1 nodules
- Pregnant patients
- Those not consenting to ultrasound or FNAC

**Ultrasound Evaluation:** Thyroid ultrasound was performed using a high-resolution linear array transducer (5–12 MHz). Patients were positioned supine with neck extension for optimal visualization. Grayscale imaging assessed nodule location, size, shape, margins, composition, echogenicity, and echogenic foci. Color Doppler was used to evaluate vascularity (peripheral, internal, or absent). Nodules were categorized per TIRADS criteria.

**Reference Standard:** TIRADS classifications were compared with cytological and histopathological findings for diagnostic validation.

**Sample Size:** Based on an expected sensitivity of 95%, specificity of 70%, disease prevalence of 20%, and 95% confidence level, the minimum required sample size was 101. The study included 102 cases.

**Data Management and Statistical Analysis:** Data were entered in Microsoft Excel and analyzed using SPSS v22.

Descriptive statistics were applied. Diagnostic performance of TIRADS was assessed using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy.

**Ethical Considerations:** Ethical clearance was obtained. Written informed consent was secured from all participants prior to enrolment.

## Results

### Demographics:

- Mean age:  $43.09 \pm 15.83$  years
- Gender distribution: Predominantly female population (78.4%)
- Most patients were aged 31–40 years (27.7%)

### Ultrasound Characteristics:

1. Shape
  - Wider-than-tall configuration was the most frequently observed shape, seen in 97 nodules (87 benign, 10 malignant).
  - Taller-than-wide configuration was less common, seen in 5 nodules, of which 2 were malignant (40%).
2. Margins
  - Smooth margins were present in 88 nodules (86 benign, 2 malignant).
  - Lobulated margins were seen in both benign (4) and malignant (5) cases.
  - Ill-defined margins and extrathyroidal extension were seen exclusively in malignant lesions (1 and 4 cases, respectively).
3. Composition
  - Solid composition was found in 41 nodules (34 benign, 7 malignant).
  - Predominantly solid nodules (4 cases) showed a high malignancy rate (75%).
  - Solid-cystic nodules were mostly benign (52 benign, 2 malignant).

- Cystic and anechoic nodules (3 cases) were exclusively benign.
4. Echogenicity
- Hypoechoic nodules had a significant association with malignancy (5 malignant, 1benign).
  - Heterogeneous echogenicity was also notable among malignancies (5 malignant, 2benign).
  - Hyperechoic and anechoic nodules were exclusively benign.
  - Isoechoic nodules were mostly benign, but 2 malignancies were identified.
5. Calcifications
- Punctate echogenic foci (microcalcifications) were observed only in malignant lesions (2 cases).
  - Macro calcifications were seen in both benign (6) and malignant (1) nodules.
  - Peripheral (rim) calcifications and comet tail artifacts were exclusive to benign nodules.
6. Vascularity
- Internal vascularity was found predominantly in malignant lesions (11 malignant vs. 4benign).
  - Peripheral vascularity was only seen in benign nodules (9 cases).
  - Absent vascularity was highly associated with benign lesions (77 benign vs. 1malignant).

#### **Distribution according to TIRADS:**

- TIRADS 2 (benign): 47.1%
- TIRADS 3 (low suspicion): 34.3%
- TIRADS 4 (moderate suspicion): 13.7%
- TIRADS 5 (high suspicion): 4.9%

Most nodules were TIRADS 2 or 3, indicating a lower suspicion of malignancy, while higher TIRADS scores (4 and 5) showed a stronger association with malignancy.

Distribution according to Bethesda:

- Bethesda II (benign): 77.4%

- Bethesda I (non-diagnostic): 9.8%
- Bethesda IV (suspicious for malignancy): 5.88%
- Bethesda VI (malignant): 5.88%
- Bethesda III: 0.98%
- Bethesda V: 0%

Bethesda II dominated the cytology results, while Bethesda VI nodules strongly correlated with TIRADS 5 and confirmed malignancy.

#### **Distribution of Bethesda IV & VI Categories**

- TIRADS 4 Nodules (Moderate Suspicion): Total cases: 14
  - Out of 14, 6 were categorised as Bethesda IV (5 follicular neoplasms, 1 Hürthle cell neoplasm) and one case of Hürthle cell carcinoma (Bethesda VI).
  - Require surgical histopathology due to cytological ambiguity.
- TIRADS 5 Nodules (High Suspicion): Total cases: 5
  - All classified as Bethesda VI (malignant).
  - Histopathology confirmed 100% malignancy:
    - 1 follicular variant of papillary carcinoma.
    - 3 medullary carcinomas.
    - 1 anaplastic carcinoma

Correlation between TIRADS, Bethesda, and Final Diagnosis:

- All TIRADS 2 & 3 nodules were benign on final histology/cytology
- All malignant & suspicious cases (total cases 12) were seen in TIRADS 4 & 5 categories
- Strong correlation observed between higher TIRADS scores and higher Bethesda categories (IV/VI)

#### **Diagnostic Accuracy of TIRADS**

- Sensitivity: 100%
- Specificity: 92.22%
- Accuracy: 93.14%
- Positive Predictive Value (PPV): 63.16%

- Negative Predictive Value (NPV): 100%

### Statistical Analysis

- Chi-square test (TIRADS vs Bethesda):  $\chi^2 = 53.48$ ,  $p\text{-value} < 0.01$  (highly significant)
- Spearman's correlation (TIRADS vs Bethesda):  $\rho = 0.763$ ,  $p < 0.001$  (significant positive correlation)
- 95% CI for accuracy (Wilson method): 86.5%–96.6%

### Discussion

This study assessed thyroid nodules using ultrasound in a predominantly female group (78.4%) with an average age of  $43.09 \pm 15.83$  years. Most patients were aged 31–40 (27.7%).

### Ultrasound Findings

A wide shape (wider-than-tall) was the most common (95.1% of nodules), mostly benign. The less common taller-than-wide shape appeared in just 4.9% (5 nodules), but 40% of those (2 cases) were cancerous—suggesting it's a high-risk feature despite its rarity. Smooth margins were seen in 88 nodules—only 2 of them were malignant (2.3%). Lobulated or illdefined margins and extrathyroidal extension were much more frequent in cancers. Solid or predominantly solid nodules (total 45 nodules) had a malignancy rate of 22.2%, where ascystic or mixed nodules were almost always benign. All 3 purely cystic/anechoic nodules were non-cancerous. Hypoechoic nodules had an 83.3% malignancy rate (5 out of 6), and heterogeneous ones had a 71.4% malignancy rate (5 out of 7). Hyperechoic and anechoic nodules were 100% benign. Microcalcifications (punctate echogenic foci) were only seen in malignant cases. Internal vascularity was seen in 15 nodules, and 73.3% of these (11) were cancerous. In contrast, 89.5% of nodules with no vascularity were benign. TIRADS Classification: Most thyroid nodules were classified as TIRADS 2 (47.1%) or TIRADS 3 (34.3%), both considered low risk,

and all of these turned out to be benign. The cancer cases were found only in the higher-risk categories—TIRADS 4 (13.7%) and TIRADS 5 (4.9%)—showing a clear link between higher TIRADS scores and malignancy.

**Bethesda Cytology:** When looking at cytology results from the Bethesda system, the majority of nodules were Bethesda II (77.4%), confirming they were benign. A smaller number fell into Bethesda IV (5.88%), which are suspicious and often require surgery, and Bethesda VI (5.88%), which are clearly malignant. Notably, all Bethesda VI nodules matched TIRADS 5 and were confirmed as cancer, including aggressive types like medullary and anaplastic carcinoma. Overall, TIRADS performed extremely well. It correctly identified all cancerous nodules, giving it 100% sensitivity, and was also highly reliable at confirming benign nodules, with 92.22% specificity. Its total accuracy was 93.14%. When TIRADS said a nodule was benign, it was always right (100% negative predictive value). There was a strong, statistically significant correlation between TIRADS scores and Bethesda results, reinforcing TIRADS as a dependable, non-invasive tool for risk assessment.

### Limitations

1. The study's single-centre setting and limited, uneven sample size—with most nodules in low-risk categories—may limit the generalizability and affect diagnostic accuracy metrics.
2. Differences in ultrasound interpretation and TIRADS scoring, particularly among less experienced radiologists, could introduce variability in results.
3. Including only cases with cytology or histology may have led to selection bias, while the absence of advanced imaging techniques and follow-up data limits deeper diagnostic evaluation.

## Recommendations

1. TIRADS-based ultrasonography is an effective, non-invasive first-line tool for thyroid nodule assessment, optimizing biopsy decisions and reducing unnecessary interventions.
2. Enhanced diagnostic accuracy requires standardized training, consistent TIRADS application, and integration with clinical and laboratory data, supported by further large-scale validation.

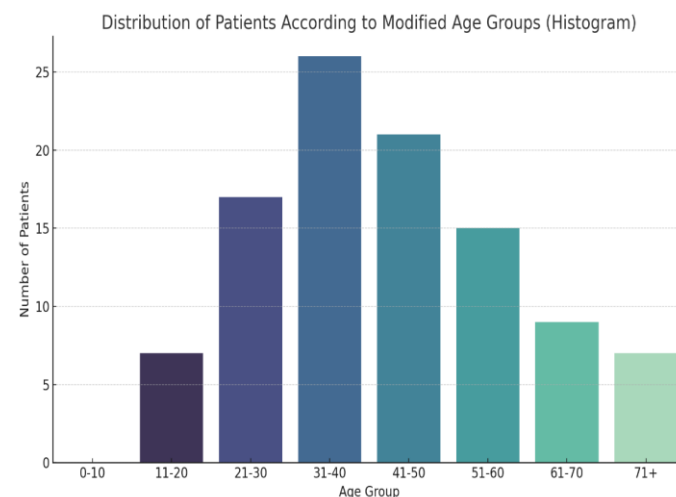
## Conclusion

Ultrasound is a safe, accessible, and reliable way to check thyroid nodules, offering detailed views that help tell harmless from suspicious ones. The TIRADS system adds value by sorting nodules into risk categories based on their features, reducing the need for unnecessary biopsies. When needed, FNAC—guided by ultrasound—is a quick and accurate method to confirm if a nodule is cancerous. This study found that higher TIRADS scores closely matched malignant results, showing strong agreement with FNAC findings. Overall, TIRADS proves to be a helpful tool in guiding biopsy decisions and improving how thyroid nodules are managed in everyday care.

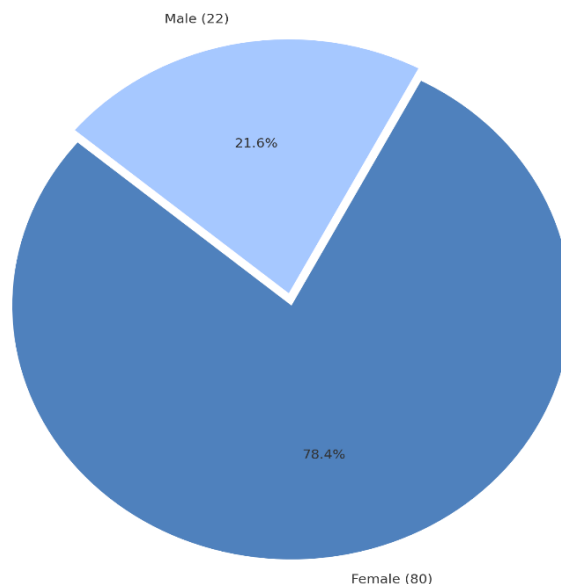
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## Legend Tables and Graphs



Graph 1: The histogram shows the distribution according to age



Graph 2: The pie chart shows the distribution according to sex

Table 1: Distribution according to TIRADS of thyroid nodule

TIRADS	Number of Patients	Percentage (%)
2	48	47.1%
3	35	34.3%
4	14	13.7%
5	5	4.9%
Total	102	100%

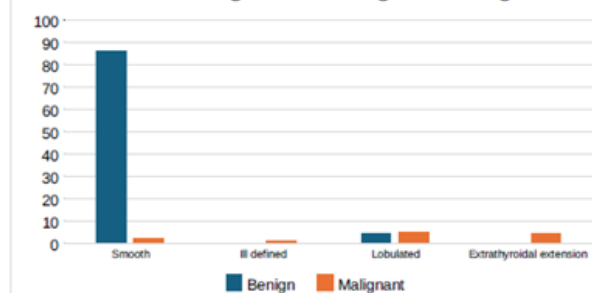
Table 2: Distribution according to Bethesda category of thyroid nodule

Bethesda	Number of Patients	Percentage (%)
I	10	9.8%
II	79	77.4%
III	1	0.98%
IV	6	5.88%
V	0	0.0%
VI	6	5.88%
Total	102	100%

Table 3: Association between Bethesda grade & TIRADS

Bethesda Grade	TIRADS 2	TIRADS 3	TIRADS 4	TIRADS 5
I	4	4	2	0
II	44	31	4	0
III	0	0	1	0
IV	0	0	6	0
V	0	0	0	0
VI	0	0	1	6

Graph 3: Distribution of margins in benign & malignant lesions



Graph 3: The histogram shows the distribution of margins in benign & malignant lesions

Table 4: Distribution of composition in benign & malignant lesions

Composition	Benign	Malignant
Solid	34	7
Predominantly solid	1	3
Cystic	3	0
Solid-cystic	52	2

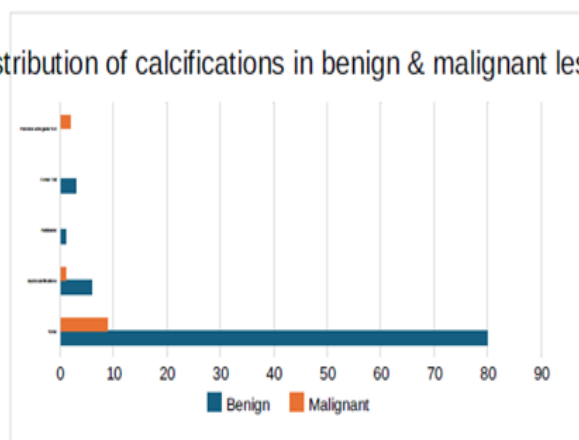
Table 5: Distribution of echogenicity in benign & malignant lesions

Echogenicity	Benign	Malignant
Hypoechoic	1	5
Heterogenous	2	5
Hyperechoic	47	0
Isoechoic	37	2
Anechoic	3	0

Table 6: Distribution of calcifications in benign & malignant lesions

Calcifications	Benign	Malignant
None	80	9
Macrocalcifications	6	1
Peripheral	1	0
Comet Tail	3	0
Punctate echogenic foci	0	2

Graph 4: Distribution of calcifications in benign & malignant lesions



Graph 4: The histogram shows the distribution of calcifications in benign & malignant Lesions



Table 7: Distribution of vascularity in benign & malignant lesions

Vascularity	Benign	Malignant
Absent	77	1
Internal	4	11
Peripheral	9	0

Table 8: Distribution of Bethesda IV & VI cases

TIRADS	Bethesda IV & VI	Number of cases	Percentage
4	Follicular neoplasm	5	41.6%
4	Hürthle cell neoplasm	1	8.30%
5	Follicular variant of papillary carcinoma	1	8.30%
4	Hürthle cell carcinoma	1	8.30%
5	Medullary Carcinoma	3	25%
5	Anaplastic carcinoma	1	8.30%

Table 9: Predicted diagnosis and Final diagnosis

		Based on TIRADS Scoring(Predicted diagnosis)	
		Benign(TI-RADS 2 & 3)	Malignant(TI-RADS 4 & 5)
Final diagnosis based on cytology & histology	Benign	83	7
	Follicular neoplasm & Malignant(Bethesda IV & V)	0	12

Table 10: Diagnostic Accuracy Metrics

Accuracy	93.14%
Sensitivity	100%
Specificity	92.22%
Positive Predictive Value (PPV)	63.16%
Negative Predictive Value(NPV)	100%

Case 1 – 61-year-old male patient came with chief complaints of painful neck swelling for 45 days.

Figure 1:



Size: 28.8x29.3mm

Location: Left lobe

Composition: Solid

Echotexture: Isoechoic

Shape: Wider than taller

Margins: Smooth

Calcifications: None

Vascularity: Absent

TIRADS: 3

Cytology: Follicular adenoma

Bethesda grade: II

Case 2 - 52-year-old male patient came with chief complaints of neck swelling for 3 months.

Figure 2:



Size: 17.5x18.8mm

Location: Right lobe

Composition: Solid

Echotexture: Isoechoic with peripheral halo

Shape: Wider than taller

Margins: Smooth

Calcifications: None

Vascularity: Peripheral

TIRADS: 3

Cytology: Colloid Goitre

Bethesda grade: II

Case 3 - 96-year-old female patient came with chief complaints of swelling in the neck with dysphagia for 6 months

Figure 3:



Size: 6.5x7.5cm

Location: Left lobe

Composition: Solid

Echotexture: Heterogenous hypoechoic nodule

Shape: Wider than taller

Margins: Extrathyroidal extension

Calcifications: Punctate echogenic foci

Vascularity: Internal

TIRADS: 5

Cytology: Medullary carcinoma of thyroid

Bethesda grade: VI

Case 4 - 65-year-old female patient came with chief complaints of swelling in the neck for 5 months

Figure 4:



Size: 32x44mm

Location: Left lobe

Composition: Solid

Echotexture: Isoechoic

Shape: Wider than taller

Margins: Smooth

Calcifications: None

Vascularity: Internal

TIRADS: 4

Cytology: Hurthle cell neoplasm

Bethesda grade: IV

Case 5- 29-year-old female patient came with chief complaints of swelling in the neck for 4 months

Figure 5:



Size: 38.5x39.6mm

Location: Right lobe

Composition: Solid-cystic

Echotexture: Isoechoic

Shape: Wider than taller



Margins: Smooth

Calcifications: None

Vascularity: Absent

TIRADS: 4

Cytology: Hyperplastic nodular goitre

Bethesda grade: II

Case 6- 22-year-old female patient came with chief complaints of swelling in the neck for 2 months

Figure 6:



Size: 20x35.9mm

Location: Left lobe

Composition: Solid

Echotexture: Hypoechoic

Shape: Wider than taller

Margins: Smooth

Calcifications: None

Vascularity: Absent

TIRADS: 4

Cytology: Nodular hyperplasia

Bethesda grade: II