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Assessing the Specificity and Sensitivity of Fine Needle Aspiration (FNA) for Patients with Thyroid Imaging Reporting and Data System (TIRADS)-3 Thyroid Nodules-Single Center Study

Othman Alshehre, Fahad Aldowsari, Mojahed Alamri, Tahani Alshehri, Ahmed Altwaim, Halah Alqahatani, Alanoud Aljoudi, Amer Alzahrani, Haitham Aljedani, Bushra Albazi

Interventional Radiology Department, Prince Sultan Military Medical City, Riyadh, Saudi Arabia
Email: tee.alshehri@gmail.com

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Abstract

Introduction: Thyroid nodules are commonly discovered as palpable neck masses or incidentally via imaging. They are localized lesions that may be solid, cystic, or mixed. FNA is the best way to distinguish between benign and malignant nodules. **Aim:** The study aimed to assess the Sensitivity and Specificity of Fine Needle Aspiration (FNA) in diagnosing malignancy within the TIRADS 3 nodules. **Methods:** 523 patients with 617 thyroid nodules were classified using ultrasound (TIRADS) followed by FNA. Cytological results were reported using the Bethesda system. **Results:** The majority of nodules were classified as TIRADS 3 (44.7%), FNA revealed 78.1% benign and 21.9% malignant nodules in all TIRADS, while 19.6% of TIRADS 3 nodules were malignant. Diagnostic performance of FNA was excellent, with a sensitivity 99.3% specificity 100%. **Conclusion:** The integration of TIRADS imaging, FNA cytology, and Bethesda classification provides a reliable and cost-effective diagnostic pathway for thyroid nodules. This approach minimizes unnecessary surgeries and ensures timely detection of malignancy.

Subject Areas

Radiology & Medical Imaging

Keywords

Thyroid, TIRADS, FNA, Nodules

1. Introduction

Thyroid nodules are commonly seen as palpable neck masses or incidentally discovered on imaging done for other reasons. They are localized lesions within the thyroid gland, and may be solid, cystic or mixed [1] [2].

The high prevalence of thyroid nodules affects approximately 50% of the adult population by age 60, according to the American Thyroid Association [3].

The prevalence is particularly significant in Saudi Arabia, where thyroid cancer has emerged as the second most common malignancy among females [4] [5].

Although most nodules are benign and asymptomatic, and only 5% - 15% of them are malignant, a precise and accurate evaluation tool is essential to exclude malignancy and to help with management for those nodules [1] [2].

While ultrasonography (US) serves as the primary diagnostic tool, its limited specificity and the subjective nature of inter-observer interpretation often lead to diagnostic uncertainty [3].

To resolve this variability and lack of standardized US reports, the Thyroid Imaging Reporting and Data System (TIRADS) was established by the American College of Radiology (ACR) to provide a universal language, improve ultrasound accuracy, and minimize reliance on subjective interpretation [6] [7].

The ACR TIRADS is globally used, and it is unique among other systems, because it uses a cumulative scoring points system for each US feature to determine malignancy (Composition, Echogenicity, Shape, Margin, Echogenic Foci (calcification)).

The summation of these points scores divides the nodules into 5 groups, where TIRADS 1 is benign and TIRADS 5 is malignant [6].

The key point of ACR TIRADS is to avoid unnecessary management by keeping a conservative approach. Unlike other systems, it sets higher thresholds for sizes before recommending FNAs; this threshold-based approach significantly reduces the number of FNAs performed on benign nodules without missing a clinically significant number of malignancies [8].

However, a significant "grey zone" exists regarding the management of TI-RADS 3 low-suspicion nodules, as international guidelines from the ACR, American Thyroid Association (ATA), and Korean Thyroid Association (K-TIRADS) offer differing recommendations for intervention [3] [7] [9].

These differences make a "grey zone" where the decisions of doing FNAs depend on the clinician's judgment or patients' concerns rather than solid, standardized evidence. Some clinicians prefer to do early intervention even though the malignancy risk is below 5%; this approach is driven by concerns to avoid any treatment delay. Patients' "cancer anxiety" also plays a significant role, as many patients prefer to do the FNAs, for certain results, over the long-term monitoring stress. Clinicians are also concerned about the individual risk factors that are not reflected by TIRADS [2] [3] [7].

This discrepancy highlights the need for more focused TIRADS 3 studies, since

there is not enough research focusing on TIRADS 3 nodules specifically to prove the need for FNAs, especially in the Saudi population.

Consequently, this study at Prince Sultan Military Medical City (PSMMC) aims to fill this literature gap by evaluating the sensitivity, specificity, and false-negative rates of fine-needle aspiration (FNA) in TIRADS 3 nodules to determine the reliability of conservative management versus the necessity for earlier invasive intervention.

2. Literature Review

After the success story of BIRADS in breast imaging and its efficacy, researchers were motivated to apply a similar framework for thyroid US reports to replace ambiguous terminology like "probably benign" [6] [7].

In 2009, Horvath *et al.* [6] proposed the first TIRADS version inspired by BI-RADS to bridge the gap between US imaging and cytopathological results.

Following that, the American College of Radiology refined the point-based TI-RADS system in 2017, which has since demonstrated a 30% - 40% reduction in unnecessary biopsies while significantly increasing clinician diagnostic confidence according to a study done by Joo *et al.* (2023) [7] [10].

While TIRADS provides sonographic risk assessment, definitive clinical management is provided by the Bethesda System for Reporting Thyroid Cytopathology (BSRTC), which classifies the FNAs results into six groups. Each group is linked to specific risks of malignancy (ROM) and management pathways [11].

The diagnostic performance of TIRADS is validated through its correlation with BSRTC. Several studies have measured this association; one of the largest studies was done involving 3400 nodules by Middleton *et al.* in 2018 confirm that as TI-RADS scores increase, cytopathological malignancy risk rises proportionally, with current thresholds preventing approximately 22% of unnecessary fine-needle aspirations (FNAs) [8].

In regional studies, Basha *et al.* (2019) [12]. observed a 95% sensitivity for the system, and significant concordance with benign cytopathological outcomes and TIRADS 3 nodules. These findings agreed with Ali & Cibas (2021) [13] and Grani *et al.* (2019) [14]. These results strengthen the case for conservative management for low-suspicion nodules.

Further analytic studies, by Foroughi *et al.* (2022) [15], revealed that use of TI-RADS could significantly decrease numbers of performed FNAs. Reporting a sensitivity of 76.19% and a specificity of 47.54%.

An important link between TIRADS and BSRTC appears when a nodule is at low-risk in TIRADS, such as TIRADS 3, but indeterminate in BSRTC, the actual ROM is lower than the same Bethesda results in TIRADS 4 or 5. This "double-validation" approach is essential; it supports a more conservative approach rather than proceeding directly to diagnostic surgery (lobectomy) [16] [17].

Furthermore, a debate persists regarding overdiagnosis, with some researchers such as Durante, C *et al.* suggesting that identifying slow-growing tumors in low-

risk categories may not offer clinical benefit [18] [19].

Most previous studies and literature had studied the TIRADS as a whole system (from TIRADS 1 - 5) rather than evaluating the subcategories individually (TIRADS 3), as this group represents a mildly suspicious grey zone; its behavior may be limited when mixed with data of high-risk (TIRADS 4 - 5).

Therefore, additional focused studies on TIRADS 3 are needed to help understand the management of TIRADS 3 nodules. This study aims to address the gap in the literature. The results of this study may assist in decision-making for low-risk nodules.

3. Methodology

3.1. Overview and Design

- **Design**: Retrospective cohort study.
- **Setting**: interventional radiology unit, Medical Imaging Department, PSMMC, Riyadh, Saudi Arabia.
- **Period**: Jan. 2022 - Oct. 2023.
- **Ethics**: IRB approved from PSMMC (E-2296); patient confidentiality maintained.

3.2. Selection Criteria

- **Inclusion**: All patients with thyroid nodules undergoing ultrasound-guided FNA.
- **Exclusion**: FNA of lymph nodes; incomplete medical records/missing data.

3.3. Data Extracted (Cerner PowerChart)

- **Ultrasound report**: Size, location (lobe/isthmus), count, and TIRADS category.
- **FNAs details**: Number of needle passes, complications, and radiologist details.
- **Cytopathology results**: Results categorized by the Bethesda System (BSRTC).

3.4. Statistical Analysis

- **Software**: SPSS version 26.
- **Methods**: Chi-squared for qualitative data; Mean ± SD for quantitative data ($p < 0.05$ significance).
- **Metrics**: Sensitivity, Specificity, PPV, NPV, and Accuracy.

4. Results

This section shows the results of a retrospective analysis of Fine-Needle Aspiration (FNA) performance in thyroid nodules. A total of 523 patients with 617 nodules were included, with one case presented with multiple nodules. Demographic characteristics, nodule features, and Bethesda category distributions are presented in relation to final FNA results to evaluate the reliability of FNA and TIRADS in clinical practice.

4.1. Demographic Data for All TIRADS Nodules (523 pts\617 Nodules)

Table 1 included 523 cases with a mean age of 48.0 ± 13.6 years (range: 12 - 90). Most patients were above 50 years (227 - 43.4%), followed by those aged 41 - 50 years (144 - 27.5%).

Table 1. Distrubtion of the studied cases according to demographic data (n = 523).

Demographic Data	No.	%
Age (years)		
12 - 20	10	1.9
21 - 30	43	8.2
31 - 40	99	18.9
41 - 50	144	27.5
>50	227	43.4
Min.-Max.	12.0 - 90.0	
Mean ± SD.	48.03 ± 13.57	
Median (IQR)	48.0 (39.0 - 57.0)	
Gender		
Male	86	16.4
Female	437	83.6

4.2. TIRADS Distribution

Table 2 and Figure 1 showed that the largest proportion was classified as TIRADS 3 (276 - 44.7%), followed by TIRADS 4 (232 - 37.6%). TIRADS 5 nodules represented (60 - 9.7%), while TIRADS 2 and TIRADS 1 accounted for (37 - 6.0%) and (8 - 1.3%), respectively. Mixed categories (TIRADS 3/4 and 4/5) were rare, observed in only (3 - 0.5%) and (1 - 0.2%) of nodules.

Table 2. Distrubtion of TIRADS/nodules (n = 617).

TIRADS/nodule	No.	%
TIRADS 1	8	1.3
TIRADS 2	37	6.0
TIRADS 3	276	44.7
TIRADS 4	232	37.6
TIRADS 5	60	9.7
TIRADS 3/4	3	0.5
TIRADS 4/5	1	0.2

Figure 1. Distribution of TIRADS/nodule (n = 617).

4.3. Demographic Data for TIRADS 3 Nodules (227 Patients\276 Nodules)

Table 3 included 227 cases with a mean age of 47.69 ± 13.36 years (range: 16 - 81). Most patients were above 50 years (94 - 41.4%), followed by those aged 41 - 50 years (63 - 27.8%), Females predominated (189 - 83.3%) compared to males (38 - 16.7%).

Table 3. Distribution of TIRADS 3 cases according to demographic data (n = 227).

Demographic Data	No.	%
Age (years)		
12 - 20	5	2.2
21 - 30	18	7.9
31 - 40	47	20.7
41 - 50	63	27.8
>50	94	41.4
Min. - Max.	16.0 - 81.0	
Mean ± SD.	47.69 ± 13.36	
Median (IQR)	47.0 (39.0 - 56.0)	
Gender		
Male	38	16.7
Female	189	83.3

4.4. FNA Results for TIRADS 3 Nodules

Table 4 and **Figure 2** showed that most nodules were benign (222 - 80.4%), while malignant lesions accounted for a smaller proportion (54 - 19.6%).

Table 4. Distribution of TIRADS 3 cases according to FNA result (n = 276).

FNA result	No.	%
Benign	222	80.4
Malignant	54	19.6

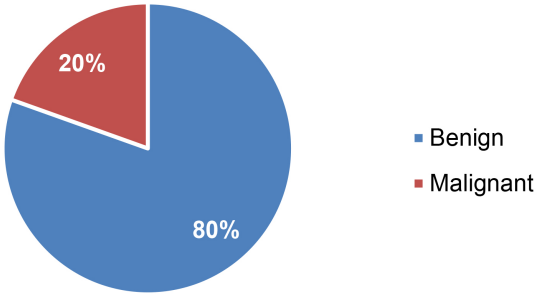

Figure 2. Distribution of TIRADS 3 cases according to FNA result (n = 276#).

4.5. Bethesda Classification for TIRADS 3 Nodules

Table 5 showed that most nodules were classified as Diagnostic Category 2 (211 - 76.4%), followed by Category 3 (41 - 14.9%). Smaller proportions were reported in Category 1 (11 - 4.0%) and Category 4 (10 - 3.6%), while only negligible percentages were observed in Category 5 (2 - 0.7%) and Category 6 (1 - 0.4%).

Table 5. Distribution of TIRADS 3 cases according to Bethesda (n = 276).

Bethesda	No.	%
Diagnostic Category 1	11	4.0
Diagnostic Category 2	211	76.4
Diagnostic Category 3	41	14.9
Diagnostic Category 4	10	3.6
Diagnostic Category 5	2	0.7
Diagnostic Category 6	1	0.4

4.6. Diagnostic Performance of FNA Results in TIRADS 3 Nodules

Table 6 showed excellent diagnostic performance with sensitivity (100.0%), specificity (100.0%), PPV (100.0%), NPV (100.0%), and accuracy (100.0%). The false negative rate (FNR) was (0.0%), indicating no risk of missing malignant nodules.

4.7. Association between FNA Results and Bethesda Categories

There is a highly significant association between FNA results and Bethesda categories. All nodules classified as Bethesda 1 & 2 were benign (100.0%), while all

nodules classified as Bethesda 3 to 6 were malignant (100.0%). The chi-square test revealed a statistically significant difference $p < 0.001^*$ as shown in Table 7.

Table 6. Performance metrics (sensitivity, specificity, and accuracy) of FNA results in TIRADS 3 nodules.

	Malignant	Benign	Sensitivity	Specificity	PPV	NPV	Accuracy	FNR
FNA (+ve)	TP 54 (100.0)	FP 0 (0.0)	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
FNA (−ve)	FN 0 (0.0)	TN 222 (100.0)						

Table 7. Relation between FNA results and bethesda categories in TIRADS 3 nodules (n = 276).

Bethesda nodule	FNA result				χ^2	^{FE}p
	Benign (n = 222)		Malignant (n = 54)			
	No.	%	No.	%		
1	11	5.0	0	0.0	258.468*	<0.001*
2	211	95.0	0	0.0		
3	0	0.0	41	75.9		
4	0	0.0	10	18.5		
5	0	0.0	2	3.7		
6	0	0.0	1	1.9		

*: Statistically significant at $p \leq 0.05$.

5. Discussion

According to demographic characteristics (Table 1) The study included 523 patients with thyroid nodules, with a mean age of 48.0 ± 13.6 years (range: 12 - 90). Most patients were above 50 years (43.4%, Table 1). This age distribution reflects the well-established trend that thyroid nodules increase with age due to cumulative hormonal and environmental exposures. The female predominance (83.6%) is consistent with global literature, which attributes this disparity to estrogen influence and autoimmune thyroid diseases. These results agree with Streinu *et al.* (2024) [20], who reported a higher prevalence in older women, confirming the demographic pattern observed in this study.

For TIRADS distribution (Table 2, Figure 1), most nodules were classified as TIRADS 3 (44.7%). This distribution reflects the common occurrence of indeterminate nodules in clinical practice, which often require further cytological evaluation. These results agree with Basha *et al.* (2019) [12] who observed that TIRADS 3 nodules had the highest concordance with benign cytology, this agree with my

results where TIRADS-3 was the largest group and mostly benign.

Regarding sub-analysis of TIRADS 3 nodules (**Tables 3-7**), in the subgroup of 276 TIRADS 3 nodules, most were benign (222 nodules, 80.4%), while 54 nodules (19.6%) were malignant. Bethesda outcomes (**Table 5**) showed predominance of category 2 (211 nodules, 76.4%) followed by category 3 (41 nodules, 14.9%). Diagnostic performance was perfect (**Table 6**), with sensitivity, specificity, PPV, NPV and accuracy all at 100% and no false negatives. The association between FNA and Bethesda categories was highly significant ($p < 0.001$), as shown in **Table 7**, where all nodules in Bethesda 172 were benign, and all nodules in Bethesda 3 - 6 were malignant. These findings highlight the reliability of FNA in indeterminate nodules, even in TIRADS 3, and suggest a higher malignancy risk compared to international reports. These results are closer to Barbosa *et al.* (2019) [16], who reported a much higher rate (23.3%) in TIRADS 3. But disagree with Torres-Cuenca *et al.* (2025) [21] reported that lower malignancy rates in TIRADS 3 nodules (<5%) compared to the 19.6% malignant rate observed in my study. Yoon *et al.* (2014) [22] reported only 1.9% malignancy in TIRADS 3.

6. Conclusions

This study confirms the diagnostic value of integrating TIRADS, FNA and Bethesda systems in thyroid nodules evaluation. Most nodules were TIRDAS 3 (44.7%) and TIRADS 4 (37.6%) with a notable finding that 19.6% of TIRADS 3 nodules were malignant. This rate is significantly higher than the malignancy risk reported in international studies, where TIRADS 3 nodules generally show <5% malignancy.

FNA demonstrated excellent diagnostic performance (sensitivity 99.3%, specificity 100%, accuracy 99.8%) while the Bethesda system refined risk stratification with category 2 strongly associated with the benign outcomes (71.8%) and higher categories consistently linked to malignancy. The strong statistical association ($p < 0.001$) between FNA and Bethesda categories validates their predicative accuracy.

In conclusion, the combined use of TIRADS imaging, FNA cytology and Bethesda classification provides a reliable and cost-effective diagnostic pathway, minimizing unnecessary surgeries and ensuring timely detection of malignancy. The higher malignancy rate observed in TIRADS 3 nodules in my population emphasizes the importance of FNA in indeterminate nodules.

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Conflicts of Interest

The authors declare no conflicts of interest.

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