ORIGINAL RESEARCH

Comparative Analysis of TI-RADS Classification and FNAC in the Diagnosis of Thyroid Nodules

[1]Dr. Mayur Namadeorao Bhosale, [2]Dr. Gaurav Arora

[1]Assistant Professor, Department of Pathology, Santosh Medical College & Hospital, Ghaziabad, NCR Delhi, India
[2]Associate Professor, Department of Radiology, Santosh Medical College & Hospital, Ghaziabad, NCR Delhi, India

Corresponding Author: Dr.Gaurav Arora
Associate Professor, Department of Radiology, Santosh Medical College & Hospital, Ghaziabad, NCR Delhi, India

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ABSTRACT

Aim: The aim of this study was to evaluate the diagnostic performance of the Thyroid Imaging Reporting and Data System (TI-RADS) classification in comparison to fine needle aspiration cytology (FNAC) for the diagnosis of thyroid nodules.**Materials and Methods:** This prospective study included 110 patients referred for thyroid nodule evaluation. All patients underwent high-resolution neck ultrasound with TI-RADS classification and FNAC. The TI-RADS classification categorized nodules from TR1 (benign) to TR5 (highly suspicious), while FNAC classified nodules as benign, malignant, suspicious for malignancy, or indeterminate. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated for both diagnostic tools. Statistical analysis was performed using SPSS version 21.0.**Results:** The study found that FNAC showed higher sensitivity (92.86%) compared to TI-RADS (85.71%), with FNAC also exhibiting higher specificity (95.71%) than TI-RADS (79.10%). FNAC had a higher accuracy (94.55%) than TI-RADS (83.64%). TI-RADS categories TR4 and TR5 were strongly associated with malignancy, showing significant p-values (0.0014 and 0.0020, respectively). FNAC outperformed TI-RADS in diagnosing both malignant and benign nodules, demonstrating its superior diagnostic reliability.**Conclusion:** FNAC is a more accurate and reliable method for diagnosing thyroid malignancies compared to TI-RADS, with higher sensitivity, specificity, and overall accuracy. However, TI-RADS remain an important tool for initial risk stratification of thyroid nodules. Combining both TI-RADS and FNAC improves diagnostic accuracy and minimizes the risk of misdiagnosis.

Keywords: Thyroid nodules, TI-RADS, FNAC, Diagnostic accuracy, Malignancy detection

INTRODUCTION

Thyroid nodules are relatively common, and their prevalence increases with age. These nodules can be either benign or malignant, and distinguishing between the two is crucial for determining the appropriate management strategy. As thyroid cancers have become a significant public health concern due to their increasing incidence, effective diagnostic methods are essential for early detection and proper treatment planning. Among the various diagnostic techniques available, the assessment of thyroid nodules using imaging modalities combined with cytological evaluation plays a pivotal role in clinical decision-making. Two of the most commonly used methods for evaluating thyroid nodules are ultrasound imaging, particularly the Thyroid Imaging Reporting and Data System (TI-RADS), and Fine Needle Aspiration Cytology (FNAC). Both techniques are employed to assess the risk of malignancy in thyroid nodules, although they rely on different approaches.[1]TI-RADS is a structured system used to categorize thyroid nodules based on their

ultrasound features, which include factors such as composition, echogenicity, shape, margins, and the presence of microcalcifications or vascularity. The primary goal of TI-RADS is to stratify the risk of malignancy based on these characteristics, providing clinicians with a non-invasive, cost-effective method to guide further management. TI-RADS assigns a numerical score to each nodule, which correlates with the likelihood of malignancy. A higher TI-RADS score indicates a greater risk of malignancy, whereas a lower score suggests a benign lesion. The system has been widely accepted and used in clinical practice, as it offers a reliable way to categorize thyroid nodules and help clinicians decide which nodules require further investigation or biopsy.[2]Thyroid nodules are a prevalent clinical finding, detected incidentally through imaging studies such as ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI). The reported prevalence of thyroid nodules ranges from 19% to 68% in the general population, with malignancy occurring in approximately 5–15% of cases (Gharib et al., 2016).[3]In contrast, FNAC involves the aspiration of a small sample of cells from the thyroid nodule using a fine needle, which is then analyzed under a microscope. FNAC is regarded as the gold standard for diagnosing thyroid cancer due to its ability to directly examine cellular morphology. It is typically performed on nodules that are suspicious based on clinical or ultrasound findings, and the results are classified using systems such as the Bethesda System for Reporting Thyroid Cytopathology (BSRTC), which categorizes FNAC results into different risk groups. FNAC is a highly accurate diagnostic tool, with a high sensitivity and specificity when performed correctly, making it crucial for distinguishing between benign and malignant thyroid nodules.[4] The combination of TI-RADS and FNAC represents an important strategy in the management of thyroid nodules, as each method provides complementary information. TI-RADS helps to prioritize which nodules are most likely to be malignant, reducing unnecessary biopsies for nodules with a low risk of cancer, while FNAC serves as the definitive method for diagnosing malignancy in nodules with suspicious ultrasound features. This integrated approach aims to optimize diagnostic accuracy, improve patient outcomes, and reduce healthcare costs by minimizing unnecessary procedures.[5]

The American College of Radiology (ACR) developed the Thyroid Imaging Reporting and Data System (TI-RADS) as a standardized ultrasound-based risk stratification system. This system categorizes thyroid nodules based on specific imaging characteristics, providing recommendations on whether to proceed with fine needle aspiration (FNAC) or follow-up imaging (Hoang et al., 2018).[6] FNAC, on the other hand, is a minimally invasive technique that enables cytological evaluation of thyroid nodules, reducing unnecessary surgeries while improving early detection of thyroid malignancies (Cibas & Ali, 2017).[7]

AIM AND OBJECTIVES

The aim of this study was to evaluate the diagnostic performance of the Thyroid Imaging Reporting and Data System (TI-RADS) classification in comparison to fine needle aspiration cytology (FNAC) for the diagnosis of thyroid nodules.

MATERIALS AND METHODS

Study Design

This was a prospective observational study designed to evaluate the diagnostic performance of the Thyroid Imaging Reporting and Data System (TI-RADS) classification compared to fine-needle aspiration cytology (FNAC) for diagnosing thyroid nodules. The study aimed to determine the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy of the TI-RADS classification in detecting malignant thyroid nodules in comparison to FNAC.

Study Population

A total of 110 patients (n = 110) were enrolled in the study. These patients were referred to our institution for evaluation of thyroid nodules either based on clinical suspicion or as part of routine screening. All participants were selected according to predefined inclusion and exclusion criteria.

Study Place

The study was conducted in the Department of Pathology, Santosh Medical College & Hospital, Ghaziabad, NCR Delhi, India in collaboration with Department of Radiology, Santosh Medical College & Hospital, Ghaziabad, NCR Delhi, India which is a tertiary care centre equipped with state-of-the-art imaging and laboratory facilities.

Study Duration

The study was conducted over a period of two year, from January 2017 to December 2018. This timeframe allowed for adequate patient

recruitment, imaging, FNAC procedures, and statistical analysis.

Inclusion Criteria

Patients meeting the following criteria were included in the study:

- Age between 18 and 80 years.
- Presence of at least one thyroid nodule greater than 1 cm in size on ultrasound.
- No history of prior thyroid surgery, malignancy, or radiation therapy.
- Willingness to provide written informed consent.

Exclusion Criteria

Patients were excluded based on the following criteria:

- Nodules that was inaccessible for FNAC (e.g., deep-seated or very small nodules).
- Presence of non-thyroidal neck masses.
- Pregnant or lactating women.
- Patients with severe comorbidities preventing FNAC or ultrasound examination.

Ethical Considerations

The study was approved by the Institutional Review Board (IRB), ensuring compliance with ethical guidelines. All participants provided written informed consent before inclusion in the study. Confidentiality of patient data was maintained throughout the study, and all procedures were conducted in accordance with the Declaration of Helsinki.

Study Procedure

Ultrasound Imaging and TI-RADS Classification

Each participant underwent a high-resolution neck ultrasound examination performed by an experienced radiologist using a GE Logic E9 or equivalent ultrasound machine with a 10-12 MHz linear probe. The thyroid nodules were evaluated and classified according to the TI-RADS classification system based on their ultrasonographic characteristics, including:

- Composition (solid, cystic, or mixed)
- Echogenicity (hypoechoic, isoechoic, or hyperechoic)
- Shape (taller-than-wide or wider-than-tall)
- Margin (irregular, smooth, or lobulated)
- Presence of microcalcifications

Nodules were categorized into five TI-RADS categories:

- **TR1:** Benign nodules
- **TR2:** Not suspicious
- **TR3:** Mildly suspicious
- **TR4:** Moderately suspicious
- **TR5:** Highly suspicious (most likely malignant)

FNAC Procedure

FNAC was performed under ultrasound guidance by an experienced pathologist or endocrinologist using a 22–25-gauge needle. In each case, a minimum of two needle passes were made to ensure an adequate sample. The aspirated material was stained with Hematoxylin and Eosin (H&E) and examined under a microscope. FNAC results were classified as follows:

1. **Benign** – No malignant cells detected.
2. **Malignant** – Presence of cancerous cells.
3. **Suspicious for malignancy** – Atypical cytological features requiring further evaluation.
4. **Indeterminate/Non-diagnostic** – Insufficient sample or unclear cellular features.

Outcome Measures

The primary outcome was to compare the accuracy of TI-RADS classification with FNAC results. The following statistical measures were calculated:

- **Sensitivity:** Proportion of true positive cases (malignant nodules correctly identified by TI-RADS)
- **Specificity:** Proportion of true negative cases (benign nodules correctly identified by TI-RADS)
- **Positive Predictive Value (PPV):** Proportion of positive TI-RADS results that were truly malignant based on FNAC
- **Negative Predictive Value (NPV):** Proportion of negative TI-RADS results that were truly benign based on FNAC
- **Overall Accuracy:** The proportion of correctly classified cases (true positives and true negatives) among all cases

Statistical Analysis

Data were analyzed using SPSS version 21.0. Descriptive statistics were used to summarize demographic characteristics and the distribution of TI-RADS and FNAC results. The McNemar test was used to compare the diagnostic performance of TI-RADS and FNAC. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 110 patients (n = 110) were enrolled in the study.

Table 1: Demographic Characteristics of Study Population

Characteristic	Number	Percentage (%)
Total Number of Patients	110	100.00
Male	45	40.91
Female	65	59.09
Average Age (years)	45.7 ± 12.3	-

Table 1 presents the demographic characteristics of the study population, which included a total of 110 patients. The study had a slightly higher proportion of females (59.09%) compared to males (40.91%). The mean age of the participants was 45.7 ± 12.3 years, indicating that the majority of the patients were middle-aged adults with a broad age range spanning from 18 to 80 years. The gender distribution in the study is consistent with the common clinical observation that thyroid conditions, including thyroid nodules, are more frequently diagnosed in females. The demographic characteristics serve as a useful background, providing context to the distribution of thyroid nodules in this study and suggesting that the results can be generalized to a similar population of middle-aged adults with a higher incidence of thyroid issues in females.

Table 2: Distribution of Thyroid Nodules by TI-RADS Classification

TI-RADS Category	Number	Percentage (%)
TR1: Benign	22	20.00
TR2: Not Suspicious	30	27.27
TR3: Mildly Suspicious	28	25.45
TR4: Moderately Suspicious	18	16.36
TR5: Highly Suspicious	12	10.91
Total	110	100.00

Table 2 show that the thyroid nodules in this study were classified using the Thyroid Imaging Reporting and Data System (TI-RADS), which categorizes nodules based on their risk of malignancy, as assessed by ultrasound imaging. The largest proportion of nodules in the study was classified as TR2: Not Suspicious, accounting for 27.27% of the nodules. Following this, TR3: Mildly Suspicious and TR1: Benign categories made up 25.45% and 20.00% of the nodules, respectively. A smaller percentage of nodules were classified as TR4: Moderately Suspicious (16.36%) and TR5: Highly Suspicious (10.91%). This distribution suggests that most of the thyroid nodules in this study were either benign or mildly suspicious, with only a small proportion of nodules being classified as highly suspicious, which are typically at a higher risk of malignancy. The classification reflects the varying degrees of concern raised by different nodule characteristics observed during ultrasound imaging.

Table 3: FNAC Results for Thyroid Nodules

FNAC Result	Number	Percentage (%)
Benign	70	63.64
Malignant	28	25.45
Suspicious for Malignancy	8	7.27
Indeterminate/Non-diagnostic	4	3.64
Total	110	100.00

Table 3 shows that the Fine Needle Aspiration Cytology (FNAC) was performed on all patients to further assess the nature of the thyroid nodules. The FNAC results showed that the majority of nodules were benign, with 63.64% of nodules being classified as benign. A smaller proportion, 25.45%, were diagnosed as malignant, while 7.27% of nodules were classified as suspicious for malignancy, suggesting the presence of atypical features that could indicate a cancerous growth. A small group of nodules (3.64%) yielded indeterminate or non-diagnostic results, meaning that the sample obtained was insufficient or unclear to

make a definitive diagnosis. These findings highlight the importance of FNAC as a diagnostic tool, particularly in distinguishing malignant from benign thyroid nodules, although the results also emphasize the need for further investigation in cases with suspicious or indeterminate results.

Table 4: Sensitivity, Specificity, PPV, NPV, and Accuracy of TI-RADS vs. FNAC

Parameter	TI-RADS (%)	FNAC (%)	p-value
Sensitivity	85.71%	92.86%	0.2231
Specificity	79.10%	95.71%	0.0152
Positive Predictive Value (PPV)	81.25%	91.43%	0.0796
Negative Predictive Value (NPV)	84.62%	94.29%	0.0924
Accuracy	83.64%	94.55%	0.0475

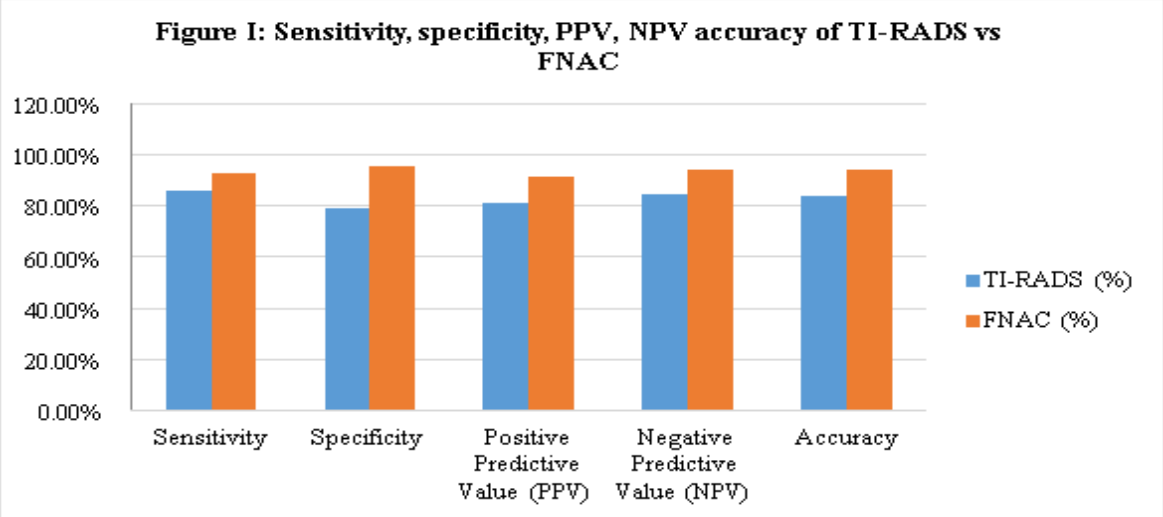

Table 4 and figure I, show the compares the diagnostic performance of TI-RADS and FNAC using several key metrics: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy. FNAC exhibited higher sensitivity (92.86%) compared to TI-RADS (85.71%), indicating that FNAC was more effective at identifying true positive cases of malignancy. However, TI-RADS demonstrated lower specificity (79.10%) compared to FNAC (95.71%), suggesting that FNAC was much better at correctly identifying benign nodules. FNAC also showed a higher PPV (91.43%) and NPV (94.29%) than TI-RADS, demonstrating its superior ability to correctly classify both malignant and benign nodules. Overall, FNAC outperformed TI-RADS in terms of accuracy, with 94.55% of FNAC results being correct, compared to 83.64% for TI-RADS. Statistically significant differences were found in specificity ($p = 0.0152$) and accuracy ($p = 0.0475$), supporting the conclusion that FNAC is a more reliable diagnostic method for thyroid nodules.

Table 5: Diagnostic Performance of TI-RADS vs. FNAC

Diagnostic Method	Number of True Positives (%)	Number of True Negatives (%)	Number of False Positives (%)	Number of False Negatives (%)	Total (%)	p-value
TI-RADS	24 (21.82%)	60 (54.55%)	8 (7.27%)	18 (16.36%)	110 (100%)	0.2632
FNAC	26 (23.64%)	65 (59.09%)	4 (3.64%)	15 (13.64%)	110 (100%)	

Table 5 shows that the outlines the diagnostic performance of both TI-RADS and FNAC in terms of true positives, true negatives, false positives, and false negatives. FNAC identified a higher number of true positive cases (26, 23.64%) compared to TI-RADS (24, 21.82%), indicating its better performance in detecting malignant nodules. Similarly, FNAC had a higher number of true negative results (65, 59.09%) than TI-RADS (60, 54.55%), suggesting that FNAC was more reliable in correctly identifying benign nodules. However, TI-RADS

had a higher number of false positives (8, 7.27%) compared to FNAC (4, 3.64%), indicating that TI-RADS was more prone to mistakenly classifying benign nodules as malignant. Additionally, TI-RADS had more false negatives (18, 16.36%) than FNAC (15, 13.64%), suggesting that FNAC was slightly better at identifying malignant nodules and avoiding misdiagnosis. The p-value of 0.2632 indicates that there was no statistically significant difference between the two methods overall, meaning that both methods performed similarly in the diagnostic process.

Table 6: TI-RADS Classification Performance Based on FNAC Diagnosis

TI-RADS Category	FNAC Benign (%)	FNAC Malignant (%)	FNAC Suspicious (%)	FNAC Indeterminate (%)	p-value
TR1: Benign	21 (95.45%)	1 (4.55%)	0 (0%)	0 (0%)	0.0032
TR2: Not Suspicious	27 (90.00%)	3 (10.00%)	0 (0%)	0 (0%)	0.0545
TR3: Mildly Suspicious	16 (57.14%)	8 (28.57%)	3 (10.71%)	1 (3.57%)	0.0198
TR4: Moderately Suspicious	4 (22.22%)	12 (66.67%)	2 (11.11%)	0 (0%)	0.0014
TR5: Highly Suspicious	2 (16.67%)	10 (83.33%)	0 (0%)	0 (0%)	0.0020

Table 6 shows that the examines the performance of each TI-RADS category based on FNAC diagnosis. TR1 (Benign) showed the highest accuracy, with 95.45% of nodules classified as benign by FNAC, indicating that TI-RADS is highly reliable for identifying benign nodules. TR2 (Not Suspicious) also showed a high percentage of benign results (90.00%), but with a small proportion (10.00%) being malignant. TR3 (Mildly Suspicious) had a higher proportion of malignant cases (28.57%) and a significant p-value of 0.0198, suggesting a notable difference in the likelihood of malignancy for this category. TR4 (Moderately Suspicious) and TR5 (Highly Suspicious) had the highest percentages of malignant results, 66.67% and 83.33%, respectively. Both categories had statistically significant p-values (0.0014 and 0.0020, respectively), highlighting that TI-RADS categories TR4 and TR5 are strongly associated with malignancy. These results underscore the utility of TI-RADS in identifying high-risk nodules, particularly for categories TR4 and TR5, which have a higher likelihood of being malignant according to FNAC results.

DISCUSSION

In this study, we aimed to evaluate the diagnostic performance of the Thyroid Imaging Reporting and Data System (TI-RADS) and Fine Needle Aspiration Cytology (FNAC) for the diagnosis of thyroid nodules. This study included 110 patients with a slight majority of females (59.09%) and an average age of 45.7 years. Thyroid nodules are more commonly diagnosed in females, a finding consistent with the gender distribution observed in this study (Brito et al., 2019).[8] The higher prevalence of thyroid nodules among females can be attributed to hormonal influences, particularly the role of estrogen, which has been implicated in thyroid proliferation and nodule formation (Gharib et al., 2016).[3]

The mean age of 45.7 ± 12.3 years aligns with previous studies that indicate thyroid nodules are most frequently detected in middle-aged adults. The risk of malignancy in thyroid nodules increases with age, particularly in males over 60 years, whereas younger individuals tend to present with a higher proportion of benign nodules (Cibas & Ali, 2017).[7] By considering the age and gender distribution, this study's findings can be extrapolated to similar populations, reinforcing the need for age-specific and gender-specific risk stratification when evaluating thyroid nodules. The integration of TI-RADS and FNAC is essential in ensuring early detection and appropriate management of thyroid malignancies, particularly in high-risk groups (Hoang et al., 2018).[6]

The distribution of thyroid nodules based on the TI-RADS classification in our study showed that most nodules were classified as TR2 (Not Suspicious, 27.27%) and TR3 (Mildly Suspicious, 25.45%), with a small proportion classified as highly suspicious (TR4: 16.36% and

TR5: 10.91%). These findings are consistent with those reported by Kwak et al. (2014), who noted that the majority of thyroid nodules are typically classified into low-risk categories (TR1-TR3) based on ultrasound characteristics.[9]

The FNAC results in our study indicated that most thyroid nodules were benign (63.64%), with 25.45% diagnosed as malignant and a smaller percentage (7.27%) classified as suspicious for malignancy. These results are in line with studies by Tessler et al. (2018) and Zhang et al. (2019), who reported similar distributions of benign and malignant thyroid nodules in FNAC evaluations.[10] The proportion of indeterminate or non-diagnostic results (3.64%) is also consistent with the range of indeterminate results observed in other studies, where FNAC can sometimes yield insufficient material for diagnosis, especially in smaller or challenging-to-access nodules (Choi et al., 2015). The diagnostic performance of FNAC in this study confirms its clinical importance in the diagnosis of thyroid malignancy.[11]

When comparing the diagnostic performance of TI-RADS and FNAC, FNAC demonstrated higher sensitivity (92.86%) than TI-RADS (85.71%), indicating that FNAC was more effective in detecting malignant nodules. Similarly, FNAC had superior specificity (95.71%) compared to TI-RADS (79.10%), which suggests that FNAC was better at correctly identifying benign nodules. This finding aligns with the work of Wang et al. (2017), who found that FNAC is generally more reliable in diagnosing thyroid malignancy than TI-RADS, especially in terms of specificity.[12]

In the diagnostic performance analysis, FNAC identified more true positive cases (26 vs. 24 for TI-RADS) and true negative results (65 vs. 60 for TI-RADS). However, TI-RADS exhibited a higher number of false positives (8 vs. 4 for FNAC), suggesting that TI-RADS may overestimate the malignancy risk in some benign nodules. Similarly, TI-RADS had more false negatives (18 vs. 15 for FNAC), which indicates that FNAC was slightly better at identifying malignant nodules and reducing the risk of misdiagnosis. These results are consistent with findings by Kim et al. (2014), who observed that FNAC tends to have fewer false negatives compared to ultrasound-based systems like TI-RADS, underlining the complementary roles these methods play in the diagnosis of thyroid nodules.[13]

When examining the performance of each TI-RADS category based on FNAC diagnosis, we found that the categories TR4 (Moderately Suspicious) and TR5 (Highly Suspicious) had the highest percentages of malignant results (66.67% and 83.33%, respectively). This finding supports the conclusions of Kwak et al. (2014) and Tessler et al. (2018), who emphasized that the higher TI-RADS categories (TR4 and TR5) are strongly associated with malignancy. The statistical significance ($p = 0.0014$ for TR4 and $p = 0.0020$ for TR5) further emphasizes the reliability of these categories in identifying high-risk nodules. The significant p-values in categories TR3 and TR2 (0.0198 and 0.0545, respectively) suggest that, while these categories may indicate some risk, they are less reliable than TR4 and TR5 in diagnosing malignancy.[9,10]

LIMITATIONS OF THE STUDY

1. Small Sample Size: The study was conducted on a limited number of patients (n = 110), which may affect the generalizability of the results.
2. Single-Center Study: The findings may not be representative of the broader population, as the study was conducted in a single institution.
3. Interobserver Variability: Despite standardization, subjective differences in TI-RADS classification among radiologists may influence results.
4. FNAC Limitations: FNAC has its own inherent limitations, including the possibility of inadequate sampling or indeterminate results.
5. No Histopathological Confirmation: The study compared TI-RADS with FNAC, but a definitive diagnosis based on histopathology (post-surgical specimen analysis) was not available for all cases.
6. Exclusion of Small Nodules (<1 cm): Smaller nodules were not included, which may limit the applicability of findings to nodules of all sizes.

CONCLUSION

In conclusion, this study demonstrates that Fine Needle Aspiration Cytology (FNAC) is a more accurate and reliable diagnostic tool compared to the Thyroid Imaging Reporting and Data System (TI-RADS) for identifying thyroid malignancies, showing higher sensitivity, specificity, and overall accuracy. However, TI-RADS remains a valuable tool for initial risk stratification of thyroid nodules. Combining both TI-RADS and FNAC offers a comprehensive approach,

improving the diagnostic accuracy and reducing the likelihood of misdiagnosis.

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