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DIAGNOSTIC ACCURACY OF ULTRASOUND IN CHARACTERIZATION OF THYROID NODULES ON THE BASIS OF TIRADS CLASSIFICATION KEEPING FNAC AS GOLD STANDARD

Original Research

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ABSTRACT

Background: Thyroid nodules are increasingly common and pose a diagnostic challenge, particularly in distinguishing benign from malignant lesions. In low-resource settings like Pakistan, effective and accessible diagnostic tools are essential to guide appropriate clinical management and avoid unnecessary invasive procedures. The Thyroid Imaging Reporting and Data System (TIRADS) offers a standardized ultrasonographic approach for risk stratification of thyroid nodules. However, its validation in local populations remains limited.

Objective: To assess the diagnostic performance of TIRADS in differentiating benign and malignant thyroid nodules in a Pakistani population, using fine-needle aspiration cytology (FNAC) as the reference standard.

Methods: A cross-sectional validation study was conducted at Jinnah Postgraduate Medical Centre, Karachi, from April to September 2024. A total of 100 patients with thyroid nodules were enrolled. Ultrasound examinations were performed by an experienced radiologist using a 7–15 MHz transducer. Nodules were categorized according to TIRADS, and all participants underwent FNAC for histological confirmation. Diagnostic metrics—sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy—were calculated. Stratified analysis was conducted based on gender, age, location, and thyroid function status.

Results: The mean age of participants was 46.91 ± 18.25 years, with a slight female predominance (56%). Malignancy was identified in 64% of cases on ultrasound and 78% on FNAC. TIRADS demonstrated 80.8% sensitivity, 95.5% specificity, 98.4% PPV, 58.3% NPV, and 84.0% overall accuracy. TIRADS 5 was the most frequent category (24%). Higher sensitivity was noted among rural residents (85.7%) and females (84.1%), while specificity declined in patients over 60 years (80%).

Conclusion: TIRADS offers high diagnostic accuracy in confirming thyroid malignancy and is a valuable triage tool in resource-limited settings. However, its limited NPV warrants cautious interpretation of low-risk classifications. Local validation and radiologist training are essential for optimized use.

Keywords: Cytology, Diagnosis, Malignancy, Sensitivity and Specificity, Thyroid Nodule, Ultrasonography, TIRADS.

INTRODUCTION

The incidence of thyroid nodules has seen a steady rise in the Pakistani population, with reported prevalence rates ranging between 11% and 14.35% (1,2). Among these cases, thyroid cancer (TC) presents a significant concern due to its disproportionately higher incidence in females, with a female-to-male ratio of 2.6:1. In Pakistan, TC accounts for approximately 2.1% of all malignancies—an alarming figure that surpasses the prevalence seen in countries such as the United States (3–5). These trends underscore the critical need for early and accurate differentiation between benign and malignant thyroid nodules to guide appropriate clinical management and avoid the potential consequences of missed or delayed diagnoses. Ultrasonography (US) remains the first-line imaging modality for evaluating thyroid nodules due to its non-invasive nature, affordability, and broad accessibility in clinical settings (6–8). Despite its widespread use, the reliability of US can be compromised by its operator-dependent nature, which may affect diagnostic accuracy. In contrast, fine-needle aspiration cytology (FNAC) is widely regarded as the gold standard for definitive diagnosis of thyroid nodules, allowing direct cytological assessment (9,10). However, FNAC is not without limitations; it is an invasive, time-consuming, and relatively costlier procedure, which may not always be necessary for nodules that are ultimately proven to be benign.

To address this challenge, professional bodies such as the Society of Radiologists in Ultrasound (SRU) have issued guidelines recommending selective use of FNAC, focusing on nodule characteristics such as size, calcifications, and growth patterns to triage patients appropriately (11). Yet, the global medical community has witnessed an increasing shift toward ultrasound-guided FNAC to minimize the risk of overlooking malignancies, even in nodules that may appear benign on imaging (11,12). This has prompted a broader discussion on the potential of standardized ultrasonographic criteria—particularly systems like TIRADS (Thyroid Imaging Reporting and Data System)—to more accurately stratify thyroid nodules and determine the need for biopsy. Although several international studies have explored the diagnostic utility of US in comparison to FNAC, their findings have often been inconclusive, largely due to limited sample sizes and heterogeneous methodologies (13,14). Importantly, no large-scale study from Pakistan has yet evaluated the diagnostic accuracy of US using the TIRADS classification system in distinguishing between benign, suspicious, and malignant thyroid nodules. This represents a significant gap in local literature, especially considering the high prevalence of thyroid malignancies in the country and the need for resource-sensitive diagnostic strategies. The objective of this study is to assess the diagnostic accuracy of ultrasound in classifying thyroid nodules based on the TIRADS system in comparison with FNAC findings. This research aims to determine whether ultrasonography can serve as a reliable, less invasive, and more accessible alternative to FNAC in the Pakistani clinical context.

METHODS

This cross-sectional validation study was carried out at the Department of Radiology, Jinnah Postgraduate Medical Centre, Karachi, over a six-month period from April 2024 to September 2024. The study aimed to evaluate the diagnostic accuracy of ultrasonographic features in distinguishing between benign and malignant thyroid nodules, using fine-needle aspiration cytology (FNAC) as the reference standard. A total of 100 patients were enrolled through non-probability sequential sampling. The sample size was calculated using the Lin Naing Sample Size calculator, referencing the study by Youssef A et al., which reported a sensitivity of 100%, specificity of 94.12%, and a prevalence of 14.35%, with a 5% margin of error applied to both sensitivity and specificity estimates (1). Eligible participants included adults aged 18 years or older, of either gender, who presented with clinically or radiologically detectable solid or partially solid thyroid nodules. Exclusion criteria included patients with purely cystic nodules lacking complex sonographic features, a prior diagnosis of thyroid carcinoma, history of thyroid surgery or radiation therapy, non-diagnostic FNAC results, pregnancy, or any contraindication to undergoing ultrasound or FNAC procedures (15). Only those participants who completed both ultrasound and FNAC, with complete diagnostic data available, were included in the analysis. Written informed consent was obtained from all participants prior to data collection. Ethical approval for the study was obtained from the Institutional Review Board of Jinnah Postgraduate Medical Centre. Patient data were recorded using a structured proforma, including demographic information, presenting complaints, sonographic characteristics, TIRADS classification, and FNAC results.

Ultrasound examinations were conducted by a senior radiologist with over five years of experience, using a high-resolution ultrasound system equipped with a 7–15 MHz linear array transducer. Patients were positioned supine with the neck slightly extended, and gel was applied to ensure optimal acoustic coupling. Both transverse and longitudinal planes of the thyroid lobes and isthmus were imaged. Each thyroid nodule was evaluated for size (longitudinal, transverse, and anteroposterior dimensions), echogenicity (hypoechoic, isoechoic, hyperechoic, or complex), composition (solid, cystic, or mixed), presence of calcifications, margin definition (regular or irregular), shape (parallel or non-parallel), and vascularity using color Doppler (peripheral, central, or mixed flow). FNAC procedures were performed under ultrasound guidance in the institutional pathology department, and cytological assessments were conducted by a senior histopathologist who was blinded to the ultrasound findings to prevent observer bias. All personal and diagnostic information was treated with confidentiality, and counselling was provided where necessary to ensure participants' understanding and comfort with the procedures. Statistical analysis was conducted using IBM SPSS version 25.0 and Microsoft Excel 365. Continuous variables such as age and nodule dimensions were summarized using means and standard deviations, while categorical variables—including gender, ultrasound features, TIRADS categories, and cytological diagnoses—were reported as frequencies and percentages. A 2×2 contingency table was used to calculate diagnostic parameters including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy of ultrasonographic features in identifying malignant nodules. The chi-square test was applied to determine associations between selected categorical variables, with a p-value <0.05 considered statistically significant.

RESULTS

The study included a total of 100 participants with a mean age of 46.91 ± 18.25 years, ranging from 18 to 75 years, reflecting a wide age distribution among patients presenting with thyroid nodules. On average, participants had 2.03 ± 0.78 nodules per individual, with nodule sizes ranging from 0.54 cm to 4.99 cm. Ultrasound-based measurements yielded a mean nodule size of 2.87 ± 1.41 cm, closely corresponding to actual dimensions and supporting the reliability of ultrasonographic assessment. A slight female predominance was observed in the study cohort, with 56% females and 44% males. Regarding geographic distribution, rural residents slightly outnumbered their urban counterparts (52% vs. 48%). Thyroid function profiles revealed that 36% of the participants were hypothyroid, 35% euthyroid, and 29% hyperthyroid. The most common presenting symptoms included asymptomatic nodules (30%), neck swelling (26%), pain (26%), and hoarseness (18%). Evaluation of sonographic characteristics showed hyperechoic nodules in 63% of cases, followed by isoechoic (55%), hypoechoic (52%), and complex echogenicity patterns in 53%. A nearly even distribution was noted in composition, with cystic components present in 52% and solid in 49%. Features associated with malignancy such as irregular margins (54%) and non-parallel orientation (51%) were frequently encountered. Vascularity assessment using color Doppler revealed an even distribution between peripheral and central vascularity patterns.

Regarding the TIRADS classification, the most common category was TIRADS 5, accounting for 24% of the cases, highlighting a considerable proportion of nodules with high suspicion for malignancy. Ultrasound-based characterization classified 64% of nodules as malignant and 36% as benign. In contrast, FNAC identified 78% of the nodules as malignant and 22% as benign, reinforcing its role as the reference standard. When evaluated against FNAC, ultrasonography using the TIRADS system demonstrated a sensitivity of 80.8%, specificity of 95.5%, and an overall diagnostic accuracy of 84.0%. The positive predictive value (PPV) stood at 98.4%, while the negative predictive value (NPV) was 58.3%. The false positive rate was calculated at 4.5%, and the false negative rate at 19.2%. Stratified analysis by gender revealed that males had a higher sensitivity (84.1%) compared to females (76.5%), whereas females exhibited perfect specificity (100%) relative to males (91.7%). In terms of age groups, patients aged 31–60 years had the highest sensitivity and specificity, both at 100%, while those above 60 years showed reduced specificity (80%) and accuracy (80%). Rural patients demonstrated superior diagnostic performance, with a sensitivity and specificity of 85.7% and 100%, respectively, compared to their urban counterparts with 75% sensitivity and 91.7% specificity. When analyzed by thyroid function, euthyroid and hypothyroid individuals showed moderate sensitivity (85.2% and 79.3%) and high specificity (87.5% and 100%), while hyperthyroid individuals showed slightly reduced sensitivity (77.3%) but retained 100% specificity.

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Table 1: Profile of the quantitative variables of the study Population

Variable	Mean	Std. Deviation	Range
Age (years)	46.91	18.25	18-75
Number of Nodules	2.03	0.78	1-3
Nodule Size (cm)	2.87	1.41	0.54-4.99
Longitudinal Dimension	2.63	1.34	0.57-5.00
Transverse Dimension	2.67	1.34	0.52-4.99
AP Dimension	2.47	1.25	0.51-4.80

Table 2: Profile of the qualitative variables of the study Population

Characteristic	Category	Frequency	Percentage
Gender	Female	56	56.0
	Male	44	44.0
Location	Rural	52	52.0
	Urban	48	48.0
Thyroid Function	Euthyroid	35	35.0
	Hyperthyroid	29	29.0
	Hypothyroid	36	36.0
Presenting Symptom	Asymptomatic	30	30.0
	Neck swelling	26	26.0
	Pain	26	26.0
	Hoarseness	18	18.0

Table 3: Sonographic characteristics and echogenicity parameters in study population

Sonographic Characteristic and Echogenicity Parameters	Category	Frequency	Percentage
Echogenicity Parameters	Hypoechoic	48.0	52.0
	Isoechoic	45.0	55.0
	Hyperechoic	63.0	37.0
	Complex Echogenicity	53.0	47.0
Composition	Cystic Component	52.0	48.0
	Solid Component	49.0	51.0
Calcification		50.0	50.0
Margins	Regular Margins	50.0	50.0
	Irregular Margins	54.0	46.0
	Poorly Defined Margins	45.0	55.0
Shape	Parallel Orientation	41.0	59.0
	Non-Parallel Orientation	51.0	49.0
Vascularity	Peripheral Vascularity	49.0	51.0
	Central Vascularity	49.0	51.0

Table 4: Overall results of ultrasonography and FNAC findings for the characterization of thyroid nodules

Thyroid Nodule	Ultrasound Findings	FNAC Findings
Benign	36 (36%)	22 (22%)
Malignant	64 (64%)	78 (78%)
Total	100 (100%)	100 (100%)

Table 5: Diagnostic accuracy of ultrasonography for characterization of thyroid nodules keeping FNAC findings as gold standard

Thyroid Nodule Characterization on Ultrasound Findings (TIRADS Classification based)	FNAC Findings				
	Benign		Malignant		Total
Benign	21 (True Positives)		15 (False Positives)		36
Malignant	01 (False Negatives)		63 (True Negatives)		64
Total	22		78		100
Sensitivity (%)	Specificity (%)	Accuracy (%)	PPV (%)	NPV (%)	
80.8	95.5	84.0	98.4	58.3	

PPV: Positive Predictive Value, NPV: Negative Predictive Value

Table 6: Diagnostic accuracy of ultrasonography for characterization of thyroid nodules keeping FNAC findings as gold standard (stratification analysis for study confounders)

Study Confounders	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Gender					
Female	84.1%	91.7%	97.4%	61.1%	85.7%
Male	76.5%	100.0%	100.0%	55.6%	81.8%
Age Groups					
Upto 30 Years	78.9%	100.0%	100.0%	60.0%	84.0%
31-60 Years	82.4%	100.0%	100.0%	64.7%	86.7%
>60 Years	80.0%	80.0%	95.2%	44.4%	80.0%
Catchment Area					
Rural	85.7%	100.0%	100.0%	62.5%	88.5%
Urban	75.0%	91.7%	96.4%	55.0%	80.0%
Thyroid Status					
Euthyroid	85.2%	87.5%	95.8%	63.6%	83.3%
Hyperthyroid	77.3%	100.0%	100.0%	58.3%	80.0%
Hypothyroid	79.3%	100.0%	100.0%	53.8%	81.8%

PPV: Positive Predictive Value, NPV: Negative Predictive Value

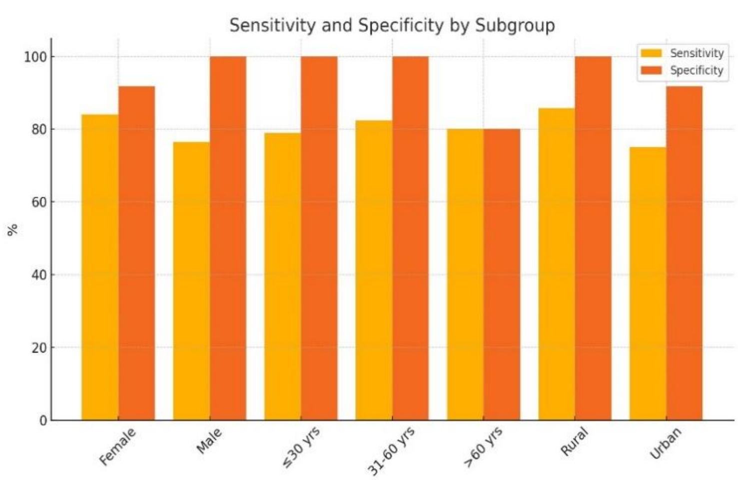

Figure 1 Sensitivity and Specificity by Subgroup

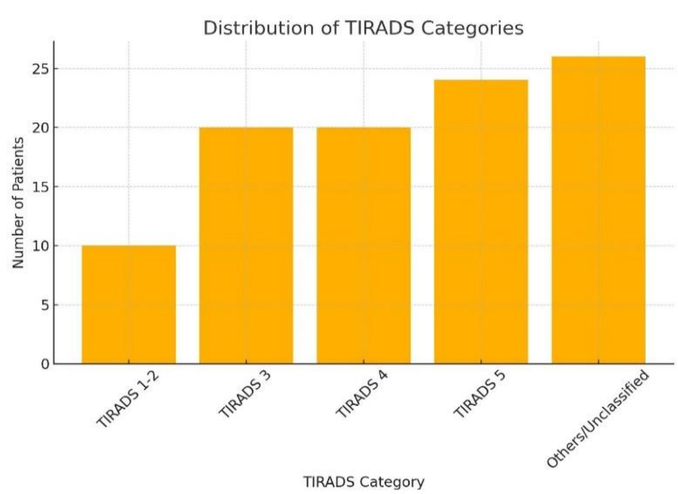

Figure 2 Distribution of TIRADS Categories

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DISCUSSION

The diagnostic evaluation of thyroid nodules continues to pose a considerable challenge in clinical settings, particularly within resource-constrained healthcare systems such as those in Pakistan. This study provided valuable insights into the applicability of the TIRADS classification system in a Pakistani population, highlighting its strengths in identifying malignancies while revealing critical limitations that require cautious clinical application. The findings showed that ultrasonography based on TIRADS achieved high specificity (95.5%) and positive predictive value (98.4%), indicating strong performance in confirming malignancy when high-risk features are present. However, the modest negative predictive value (58.3%) suggests a potential risk of underdiagnosis in nodules classified as benign, necessitating vigilant follow-up strategies. In comparison with prior regional data, the diagnostic parameters observed in this study differed in meaningful ways (16,17). While one local study reported higher sensitivity and lower specificity, the more balanced profile in the present findings may reflect distinctions in methodology, age demographics, or the diagnostic reference standard used (18). Their use of histopathology instead of FNAC and a younger patient cohort (mean age 34 years) contrasts with the older age group (mean age 46.9 years) and FNAC-based confirmation used here. Such differences highlight the influence of both patient population and diagnostic protocols on the interpretation of imaging-based systems like TIRADS. The nearly perfect positive predictive value aligns with earlier South Asian research, reinforcing the system's capacity for ruling in malignancy, particularly for TIRADS 4 and 5 nodules. However, the observed 41.7% false-negative rate in nodules categorized as benign or low risk raises important concerns (19,20). This discrepancy, when compared to previous findings showing much higher negative predictive values, may be attributed to higher malignancy prevalence in the current population (38% vs. 27.4%) or inconsistencies in ultrasound interpretation across different clinical settings. These observations suggest that clinicians in Pakistan must apply greater caution in dismissing nodules with low TIRADS scores, as their malignant potential may be underestimated.

Demographic variations further underscored the necessity for localized validation of TIRADS criteria. The specificity observed in rural populations (100%) contrasted with slightly lower values in urban patients (91.7%), while gender-based differences showed higher sensitivity in females (84.1%) and perfect specificity in males (100%). This finding diverged from previous data showing higher specificity in male cohorts, suggesting that the influence of demographic factors may differ depending on regional context, operator experience, and population characteristics (21). Similarly, age-stratified analysis revealed reduced specificity (80%) and negative predictive value (44.4%) in older patients, mirroring trends observed in Mediterranean populations and reinforcing the need for age-adjusted diagnostic thresholds. The significant correlation observed between sonographic features such as irregular margins, microcalcifications, and malignancy supports the clinical relevance of these markers, even in operator-dependent settings. These results are consistent with previous studies that identified these features as critical malignancy predictors ($p<0.001$) (22,23). Despite concerns surrounding the variability in image acquisition and interpretation, the reproducibility of these associations reinforces their diagnostic utility, particularly when supported by standardized training. This study's methodology presents several strengths, including its prospective design, rigorous inclusion criteria, and comprehensive evaluation of TIRADS performance in comparison to FNAC. The stratified subgroup analysis provided further depth, offering insights into how diagnostic accuracy may vary across gender, age, location, and thyroid status. Nonetheless, limitations must be acknowledged. The single-center setting may limit external generalizability, and the selective use of FNAC based on TIRADS scores introduces verification bias, potentially overestimating diagnostic performance. The overall sample size, while adequate for the primary objective, became constrained in subgroup analyses, limiting the statistical power for stratified comparisons.

For clinical practice in Pakistan and similar healthcare systems, the findings suggest three key implications. First, TIRADS categories 4 and 5 should be regarded as definitive indicators for FNAC, particularly in populations with a high baseline prevalence of thyroid malignancy. Second, nodules in TIRADS category 3, although classified as low risk, should be subjected to regular ultrasonographic monitoring due to the high false-negative rate. Third, efforts must focus on standardized sonographer training to improve consistency in nodule characterization, as previous studies have demonstrated significant improvements in diagnostic accuracy through structured education programs. In the broader context of thyroid cancer management in resource-limited environments, TIRADS remains an indispensable triage tool. However, its diagnostic value hinges on consistent image acquisition, skilled interpretation, and access to reliable cytopathological services. To strengthen the system's effectiveness, national quality assurance protocols should be established, and future multicenter studies involving larger and more diverse populations are recommended. Such initiatives would enhance the robustness of diagnostic criteria, promote early and accurate detection, and optimize the use of limited healthcare resources in high-burden regions.

CONCLUSION

This study highlights the clinical value of the TIRADS classification system as a practical and efficient tool for identifying malignant thyroid nodules, particularly in resource-constrained settings like Pakistan. While its strong predictive capacity supports its use in guiding decisions for fine-needle aspiration in high-risk cases, the limitations observed in ruling out malignancy emphasize the importance of cautious interpretation. The findings reinforce the need to complement ultrasound assessment with clinical judgment and regular follow-up, especially in vulnerable patient groups. Moving forward, broader multicenter studies and structured radiologist training are essential to refine and standardize TIRADS application within South Asian populations, ultimately contributing to earlier detection and improved management of thyroid cancer.

AUTHOR CONTRIBUTION

Author	Contribution
Fatima Safina*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Sumera Tabasum	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Mariam Naeem	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published

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