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DIAGNOSTIC ACCURACY OF TIRADS ON ULTRASONOGRAPHY IN EVALUATING THYROID NODULES KEEPS HISTOPATHOLOGY AS A GOLD STANDARD

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ABSTRACT

Introduction: Thyroid nodules are commonly encountered in clinical practice. Differentiating between benign and malignant lesions is crucial for proper treatment. Ultrasonography with TIRADS classification helps stratify the risk. This study aims to assess TIRADS' accuracy in distinguishing between benign and malignant thyroid nodules by validating it against histopathological findings.

Methodology: A cross-sectional study was conducted at CMH Muzaffarabad from September 19, 2023, to March 18, 2024, involving 153 patients with thyroid nodules. Ultrasonography with ACR-TIRADS scoring by a radiologist classified nodules as benign or

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malignant. Histopathological analysis of thyroidectomy specimens served as the reference standard for evaluating TIRADS diagnostic performance. Parameters assessed included sensitivity, specificity, PPV, NPV, and accuracy.

Results: In a study with 153 patients, 56.2% were male and 43.8% were female, with a mean age of 53.3 ± 10.75 years. The mean nodule size was 2.5 ± 1.3 cm. Histopathology confirmed 69.9% malignant and 30.1% benign lesions. Ultrasonography detected 62.1% malignant and 37.9% benign nodules. Ultrasonography showed a sensitivity of 85.9%, specificity of 93.4%, PPV of 96.8%, NPV of 74.1%, and overall accuracy of 88.2% in distinguishing between benign and malignant lesions.

Conclusion: The ACR-TIRADS scoring system in ultrasound is highly sensitive and specific in distinguishing between benign and malignant thyroid nodules. This non-invasive tool reliably guides clinical decisions, minimizing unnecessary invasive procedures. However, for conclusive diagnosis in suspicious cases, histopathological confirmation is still necessary.

Keywords: Thyroid Nodules, Ultrasonography, TIRADS, Histopathology, Diagnostic Accuracy, Thyroid Malignancy.

INTRODUCTION

Thyroid nodules are common clinical findings, with a prevalence of 19–68% in the general population, as detected by ultrasonography (USG). While the majority of these nodules are benign, a small proportion can be malignant, necessitating an accurate and reliable diagnostic approach to distinguish between the two.[1-2] Ultrasonography plays a pivotal role in the initial assessment of thyroid nodules due to its non-invasive nature, affordability, and high sensitivity. However, variability in radiologists' interpretation and the overlap of sonographic features between benign and malignant nodules pose challenges in accurate diagnosis.[3-4]

To standardize the evaluation of thyroid nodules on USG, the Thyroid Imaging Reporting and Data System (TIRADS) was introduced. Several TIRADS classifications have been developed, including those by the American College of Radiology (ACR-TIRADS), Kwak-TIRADS, and EU-TIRADS, which categorize nodules based on suspicious ultrasound features such as echogenicity, margins, shape, and calcifications.[5-6] These systems aim to stratify the risk of malignancy and guide the decision-making process for fine-needle aspiration cytology (FNAC).[7]

Despite its widespread adoption, the diagnostic accuracy of TIRADS scoring in differentiating benign from malignant thyroid nodules remains an area of ongoing research.

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Histopathology, obtained through FNAC or surgical excision, serves as the gold standard for definitive diagnosis.[8] Therefore, evaluating the sensitivity, specificity, and overall accuracy of TIRADS in comparison to histopathological findings is crucial for validating its clinical utility. This study aimed to assess the diagnostic accuracy of TIRADS scoring in ultrasonography, using histopathology as the reference standard.

METHODOLOGY

This cross-sectional validation study was conducted at the Radiology Department of Combined Military Hospital (CMH), Muzaffarabad, from September 19, 2023, to March 18, 2024. A total of 153 patients fulfilling the inclusion criteria were enrolled. The sample size was calculated considering a 95% confidence level, a 10% desired precision for sensitivity, and a 5.4% desired precision for specificity and estimated prevalence of malignant thyroid nodules as 40.65%,[9] with the sensitivity and specificity of TIRADS scoring on ultrasonography as 80.0% and 92.7%,[10] respectively, for differentiating benign from malignant thyroid nodules. The sampling technique employed was convenient sampling.

Patients included in the study were aged between 30 and 70 years, presented with a palpable thyroid nodule of any size on clinical examination, and had a disease duration of more than three months. Exclusion criteria comprised patients with a previous history of thyroid surgery, those with a histopathologically confirmed thyroid malignancy based on medical records, patients diagnosed with toxic solitary nodular or multinodular goiters, and individuals with thyroiditis.

Ethical approval for the study was obtained from the institutional ethics committee, and informed consent was obtained from all patients or their legal representatives. Certificate from ethical committee was obtained - Ref No. Ethical committee / DME 818. Patients with goiters at ENT Outpatient Department were considered. Clinical history included onset, progression, duration of thyroid enlargement, and symptoms like pain, hoarseness, swallowing difficulties, heat intolerance, weight changes, back pain, and more. Physical examination focused on site, size, shape, nodules' number, vocal cord mobility, lymphadenopathy, and signs of thyroid disorders. Laboratory tests were done for diagnosis and surgery suitability.

All patients received thyroid and neck ultrasonography with ACR-TIRADS scoring done by a radiologist. TIRADS categories included TR1 (benign), TR2 (not suspicious), TR3 (mildly suspicious), TR4 (moderately suspicious), and TR5 (highly suspicious). Patients were

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managed based on ACR-TIRADS guidelines. Thyroidectomy specimens underwent histopathological evaluation by qualified pathologists. A simplified analysis grouped TR1 and TR2 as "Benign" and TR3, TR4, and TR5 as "Malignant," which was compared with biopsy results categorized as "Benign" or "Malignant."

Data in SPSS 25.0 was analyzed for age, disease duration, and lesion size. Gender, lesion types on ultrasound and histopathology were presented in terms of frequency and percentage. Sensitivity, specificity, and other diagnostic values were calculated using 2x2 contingency tables to differentiate benign and malignant thyroid lesions on ultrasound compared to histopathology. Age, gender, disease duration, and lesion size were considered as effect modifiers and controlled through stratification. Diagnostic accuracy post-stratification was determined.

RESULTS

A total of 153 patients with palpable thyroid nodules were included in this study. Among these, 86 (56.2%) were male, and 67 (43.8%) were female. The age range of patients was between 30 and 70 years, with a mean age of 53.3 ± 10.75 years. Stratification of age groups revealed that 49 (32.0%) patients were between 30 and 50 years of age, while 104 (68.0%) were in the 51–70-year age group.

The mean size of the thyroid nodules was 2.5 ± 1.3 cm. The majority of patients, 103 (67.3%), had nodules measuring ≤2 cm in diameter, while 50 (32.7%) had nodules larger than 2 cm. The mean duration of nodule presence was 5.65 ± 1.6 months. Most patients, 84 (54.9%), had nodules present for ≤3 months, whereas 69 (45.1%) had nodules persisting for more than 3 months. Histopathological analysis classified 107 (69.9%) lesions as malignant and 46 (30.1%) as benign. Ultrasonographic evaluation using the ACR-TIRADS scoring system identified 95 (62.1%) lesions as malignant and 58 (37.9%) as benign (Table 1).

The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy of ultrasonography in differentiating benign and malignant thyroid lesions were calculated. The sensitivity was 85.9%, specificity 93.4%, PPV 96.8%, NPV 74.1%, and accuracy 88.2% (Table 2).

Further stratification of histopathological and ultrasonographic findings was performed based on gender, age, nodule size, and duration (Tables 3–6). The results demonstrated consistently high sensitivity and specificity across all stratified subgroups, reinforcing the reliability of ultrasonography in distinguishing between benign and malignant thyroid nodules.

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Table-1: Frequency distribution of different variables (n=153)

Variables		Frequency	Percent
Gender	Male	86	56.2%
	Female	67	43.8%
Age groups	30-50 years	49	32.0%
	51-70 years	104	68.0%
	Mean age	53.3±10.75 years	
Nodule size	≤2 cm	103	67.3%
	>2 cm	50	32.7%
	Mean size	2.5±1.3 cm	
Duration of nodule	≤5 months	84	54.9%
	>5 months	69	45.1%
	Mean duration	5.65±1.6 months	
Histopathology	Malignant	107	69.9%
	Benign	46	30.1%
Ultrasonography	Malignant	95	62.1%
	Benign	58	37.9%

Table-2: Findings of lesions on histopathology and Ultrasonography

Lesions on Ultrasonography	**Lesions on Histopathology**		**Total**	
	Malignant	Benign		
Malignant	92	3	95	Sn=85.9% Sp=93.4% PPV=96.8% NPV=74.1% Accuracy=88.2%
Benign	15	43	58	
Total	107	46	153	

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Table-3: Stratification of findings of lesions on histopathology and Ultrasonography with respect to gender

Gender	**Lesions on Ultrasonography**	**Lesions on Histopathology**		**Total**	
		Malignant	Benign		
Male	Malignant	51	1	52	Sn=89.4%, Sp=96.5%, PPV=98.1%, NPV=82.3 %, DA=91.8%
	Benign	6	28	34	
	Total	57	29	86	
Female	Malignant	41	2	43	Sn=82.0%, Sp=88.2%, PPV=95.3%, NPV=62.5%, DA=83.5%
	Benign	9	15	24	
	Total	50	17	67	

Table-4: Stratification of findings of lesions on histopathology and Ultrasonography with respect to age groups

Age groups	**Lesions on Ultrasonography**	**Lesions on Histopathology**		**Total**	
		Malignant	Benign		
30-50 years	Malignant	32	0	32	Sn=82.0%, Sp=100.0%, PPV=100.0%, NPV=58.8%, DA=85.7%
	Benign	7	10	17	
	Total	39	10	49	
51-70	Malignant	60	3	63	Sn=88.2%,

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years	Benign	8	33	41	Sp=91.6%, PPV=95.2%, NPV=80.4%, DA=89.4%
	Total	68	36	104	

Table-5: Stratification of findings of lesions on histopathology and Ultrasonography with respect to size of nodule

Size of nodule	**Lesions on Ultrasonography**	**Lesions on Histopathology**		**Total**	
		Malignant	Benign		
≤2 cm	Malignant	57	3	60	Sn=85.1%, Sp=91.6%, PPV=95.0%, NPV=76.7%, DA=87.3%
	Benign	10	33	43	
	Total	67	36	103	
>2 cm	Malignant	35	0	35	Sn=87.5%, Sp=100.0%, PPV=100.0%, NPV=66.7%, DA=90.0%
	Benign	5	10	15	
	Total	40	10	50	

Table-6: Stratification of findings of lesions on histopathology and Ultrasonography with respect to duration of nodule

Duration of nodule	**Lesions on Ultrasonography**	**Lesions on Histopathology**		**Total**	
		Malignant	Benign		
≤5	Malignant	53	1	54	Sn=86.8%,

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months	Benign	8	22	30	Sp=95.6%, PPV=98.1%, NPV=73.3%, DA=89.2%
	Total	61	23	84	
>5 months	Malignant	39	2	41	Sn=84.7%, Sp=91.3%, PPV=95.1%, NPV=75.0%, DA=86.9%
	Benign	7	21	28	
	Total	46	23	69	

DISCUSSION

Nodules in the thyroid gland may raise concerns about cancer for patients and clinicians. Despite past norms of cytological evaluations for thyroid nodules, efforts are now focused on initial risk stratification to potentially avoid unnecessary cytological evaluations. Advanced medical imaging has increased clinicians' confidence in managing nodules more accurately. Recent progress has been made in this field, aiming to rely more on imaging for risk assessment. However, until enough evidence supports image-based risk stratification alone, histopathological diagnoses may still be necessary.[11]

Pre-operative ultrasonography helps the surgeon locate and aspirate suspicious thyroid nodules. While ultrasound results are promising, adjunct histopathological evaluation is necessary to fully assess the disease.[12-13] Our study demonstrates that ultrasonography effectively differentiates between benign and malignant thyroid nodules. Ultrasonography's diagnostic performance includes 85.9% sensitivity, 93.4% specificity, 96.8% PPV, 74.1% NPV, and 88.2% overall accuracy. While limited studies directly compare TIRADS scores with biopsies, most examine sonographic scores against FNAC results, aiming to clarify the underlying pathology.

Al shoaibi and colleagues found that ultrasonography was highly accurate in distinguishing between benign and malignant thyroid nodules. Among patients with lesions initially considered benign on ultrasonography, the overwhelming majority (98.38%) were indeed benign according to FNA cytology, while a small percentage (1.2%) were malignant. For patients with lesions identified as malignant on ultrasonography, over half (55.6%) were

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confirmed as malignant by FNA cytology. In conclusion, the study highlighted the value of ultrasonography for accurately diagnosing thyroid nodules.[14]

Rahimi M and colleagues compared pre-operative sonography and FNA cytology results with biopsy findings in 144 patients with thyroid nodules. Among 14 cases initially suspected malignant, 13 were confirmed so on biopsy of resected specimens.[15]

The TIRADS scoring system aids in risk assessment for thyroid nodules, guiding clinical decisions on whether to perform fine needle aspiration cytology or simply observe the nodule. ACR-TIRADS is commonly utilized for risk stratification. Ongoing research compares different TIRAD systems for accuracy, with recent development of AI-TIRADS. Tobriner BW et al. noted that artificial intelligence, based on ACR-TIRADS, enhances specificity while maintaining sensitivity.[16]

Soylemiz et al. analyzed 939 nodules to compare the TIRAD Systems, finding ACR-TIRADS most sensitive (94.5%). They deemed ACR-TIRADS the best for nodule risk assessment, with greater sensitivity than the Bethesda system against histopathological findings.[17]

In a study similar to ours, Flavia Magri and colleagues compared ACR-TIRADS and EU-TIRADS in 255 patients. They found that EU-TIRADS had a higher sensitivity for detecting malignancy (88%) than ACR-TIRADS (77.08%), similar to our results. They concluded that both systems perform well in detecting thyroid malignancy when compared to biopsy results.[18]

Image-based risk systems aid in deciding whether a thyroid nodule needs invasive testing or observation. Studies compare their accuracy, like Naushaba Malik and team's research that found strong agreement between TIRADS and FNAC results. TIRADS II, III, and IVa nodules showed benign features, while TIRADS V correlated with malignancy. Their study supports using TIRADS as a reliable tool to assess thyroid nodules and determine their nature.[19]

In a study conducted in Multan, Pakistan, Nighat and colleagues compared TIRADS scores with FNAC while studying 201 thyroid nodule cases. They reported TIRADS sensitivity of 77.8%, specificity of 75.5%, PPV of 53.8%, and NPV of 90.2%. The overall diagnostic accuracy for thyroid nodule malignancy prediction was 76.1%. Their conclusion highlighted the TIRADS score as highly accurate in detecting thyroid nodule malignancy.[20]

In a 2020 meta-analysis by Wei Li and colleagues involving 16 studies with 18,614 patients and 21,882 nodules, ACR-TIRADS showed 89% sensitivity and 86% specificity, with a

diagnostic odds ratio of 18.46 when compared with FNAC, biopsy, or both. Despite a slight decrease in sensitivity, ACR-TIRADS was found to significantly reduce unnecessary biopsies.[21]

Zeeshan Jamal and team conducted a multicenter study comparing FNAC, sonography, and biopsy results, finding that FNAC and ultrasonography had similar sensitivity, but FNAC was more specific than sonography.[22]

The study objectively assesses thyroid nodules using ultrasonography, comparing results directly with biopsy, the gold standard. This can aid clinicians in making safer decisions confidently. We propose that histopathological examination of all thyroid nodules, despite TIRADS scores, is unnecessary, saving time and money without compromising patient safety. This would reduce unnecessary surgeries and lab burden, while contributing our experience to existing literature.

Given the small sample size and the operator dependency in ultrasonography of thyroid nodules, this study compares TIRADS scores with biopsy results instead of FNAC, making direct comparisons challenging. Further multicenter studies and meta-analyses are needed to evaluate the effectiveness of using TIRADS scores in ultrasonography for assessing thyroid nodules in our settings.

CONCLUSION

The ACR-TIRADS scoring on ultrasonography is highly sensitive, specific, and accurate in distinguishing between benign and malignant thyroid nodules. It is a reliable, non-invasive tool that can inform clinical decisions and minimize unnecessary invasive procedures. However, histopathological confirmation is crucial for definitively diagnosing suspected cases.

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