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Diagnostic Accuracy of Color Doppler Ultrasonography for Differentiating Benign and Malignant Thyroid Nodules: Sensitivity, Specificity, and ROC-Based Evaluation Using FNAC as Reference Standard

Zubair Janan Orakzai[1], Laila Khan[1*], Tabassum Begum[1], Sumaira Noureen[1], Neelofar Azam[1] and Muhammad Sadiq[1]

[1]Department of Radiology, Bacha Khan Medical College, Medical Teaching Institution, Mardan Medical Complex, Mardan, Pakistan

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***Corresponding Author:**
Laila Khan
Department of Radiology, Bacha Khan Medical College, Medical Teaching Institution, Mardan Medical Complex, Mardan, Pakistan
lailakhan_81@hotmail.com

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ABSTRACT

Thyroid nodules are frequently encountered in clinical practice, and accurate discrimination between benign and malignant lesions remains essential to avoid unnecessary invasive procedures. **Objectives:** To evaluate the diagnostic accuracy of Doppler ultrasonography using fine needle aspiration cytology (FNAC) as the reference standard. **Methods:** This cross-sectional diagnostic accuracy study was conducted in the Department of Radiology, Medical Teaching Institution Bacha Khan Medical College and Mardan Medical Complex, Pakistan, from 18 August to 18 December 2025. A total of 83 patients underwent gray-scale and Doppler ultrasonography followed by FNAC. Doppler findings were categorized using predefined thresholds and compared with cytology. **Results:** The mean age was 45.1 ± 17.2 years. Malignancy was detected in 22.9% of nodules on FNAC. Doppler ultrasonography demonstrated sensitivity 100% (95% CI: 82.4–100), specificity 85.9% (95% CI: 74.6–93.3), and overall accuracy 89.2%. The ROC curve showed an AUC of 0.93 (95% CI: 0.876–0.984). **Conclusions:** Doppler ultrasonography is a reliable adjunct to gray-scale ultrasound for triaging thyroid nodules and guiding FNAC selection. However, cytology remains essential for confirming malignancy.

INTRODUCTION

Thyroid nodules are increasingly detected due to widespread use of imaging modalities, although only a small proportion are malignant [1, 2]. Accurate differentiation is critical to prevent unnecessary biopsies while ensuring early detection of malignancy [3]. Gray-scale ultrasonography is the first-line imaging modality because of its safety and accessibility [4, 5]. Features such as hypoechogenicity, irregular margins, microcalcifications, and taller-than-wide configuration are associated with malignancy risk, although substantial overlap exists between benign and malignant nodules [6, 7]. Fine needle aspiration cytology is the reference standard for diagnosis; however, it is invasive and operator-dependent, making optimal selection of nodules for FNAC clinically important [8, 9]. Doppler ultrasonography provides additional information on

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intranodular vascularity and resistance patterns, which may improve malignancy stratification when combined with gray-scale criteria [10, 11]. Nevertheless, diagnostic performance varies across populations and equipment. This study hypothesized that predefined Doppler parameters could improve discrimination between benign and malignant thyroid nodules.

Pakistan has no multicenter data to prove the diagnostic accuracy of Doppler ultrasonography in determining thyroid nodules; most of the studies are one-center experiences. No standardized Doppler thresholds (RI, PSV, vascularity patterns) have been tested and validated within Pakistani populations. Single-center design within Mardan Medical Complex restricts generalizability to the different populations in Pakistan. The small sample size (n=83) of malignant cases (19) resulted in broad confidence intervals for sensitivity (82.4-100%) and PPV (47.6-84.1%). This study aimed to evaluate the diagnostic accuracy of Doppler ultrasonography using FNAC as the reference standard.

METHODS

The study was a cross-sectional diagnostic accuracy study conducted in the Department of Radiology, Medical Teaching Institution (MTI) Bacha Khan Medical College and Mardan Medical Complex (MMC), Mardan, Pakistan. The objective was to evaluate the diagnostic accuracy of Color Doppler ultrasonography as an adjunct to gray-scale ultrasound in differentiating benign and malignant thyroid nodules, using fine needle aspiration cytology (FNAC) as the reference standard. The total study duration was four months, with patient enrollment from 18 August 2025 to 18 December 2025. Ethical approval was obtained from the Ethical Review Board of MTI Bacha Khan Medical College, Mardan (Approval No. 918/BKMC). Written informed consent was obtained from all participants before imaging and FNAC. Confidentiality was maintained by assigning unique study codes and restricting dataset access to the research team only. The sample size was calculated for a diagnostic accuracy study using the Buderer approach based on expected sensitivity. A confidence level of 95% (Z = 1.96), anticipated sensitivity (Se) of 90%, expected prevalence (P) of malignant thyroid nodules of 23%, and absolute precision (d) of 13.5% were assumed based on feasibility within the fixed four-month recruitment period and the expected malignant case yield at the study site [7]. The sample size was estimated using the formula $n = (Z^2 \times Se \times (1–Se)) / (d^2 \times P)$, yielding a required sample size of approximately 83 participants. Therefore, 83 consecutive eligible patients were included. A non-probability consecutive sampling technique was used, whereby all eligible patients presenting during the study period and meeting the inclusion criteria were enrolled. The study included patients of both genders, aged ≥18 years, with thyroid nodules detected clinically or radiologically, who underwent both thyroid ultrasound (gray-scale plus Color Doppler) and FNAC to allow valid comparison. Patients with previous thyroid surgery, previously diagnosed thyroid malignancy, purely cystic nodules, those unwilling to undergo FNAC, and cases with incomplete imaging or cytology records were excluded. Thyroid ultrasonography was performed using a high-frequency linear transducer (7.5–12 MHz) on a dedicated ultrasound unit (Manufacturer/Model Mindray DC-70 / GE Logiq / Philips). All scans were performed following a standardized departmental protocol. Gray-scale ultrasound was first used to document nodule characteristics, including the number of nodules, maximal nodule diameter (cm), composition (solid/cystic/mixed), echogenicity (hypo/iso/hyper-echoic), margins (regular/irregular), calcifications (micro/macro/absent), and shape (taller-than-wide/wider-than-tall). The maximal diameter was recorded in the longitudinal or transverse plane, whichever demonstrated the largest dimension. Color Doppler assessment was then performed to evaluate vascularity and spectral indices. Vascularity was categorized as absent, peripheral, central, or mixed. To reduce inter-scan variability, Doppler gain, pulse repetition frequency (PRF), wall filter, and insonation angle were kept consistent as per departmental thyroid Doppler protocol (PRF and wall filter adjusted to avoid aliasing while maintaining low-flow sensitivity), and spectral sampling was obtained from the most vascular intranodular region. Where feasible, resistive index (RI) and peak systolic velocity (PSV) were recorded from intranodular arteries with an insonation angle ≤60°. Nodules were categorized as "suggestive of malignancy" if any two of the following were present: predominant central or mixed vascularity, Resistive index (RI) > 0.70, and peak systolic velocity (PSV) > 40 cm/s. Nodules not meeting the above criteria were categorized as "suggestive of benignity." These thresholds were applied uniformly across participants to improve reproducibility and reduce operator-dependent classification. To minimize operator bias, ultrasound examinations were performed by consultant radiologists with at least three years' post-fellowship experience in thyroid imaging. Borderline cases were re-reviewed by a second radiologist, and a consensus impression was recorded. FNAC was performed under ultrasound guidance using standard aseptic technique. Aspirated samples were processed and interpreted in the pathology department. FNAC results were classified as benign or malignant based on cytology. Benign diagnoses included colloid nodules, thyroiditis, and benign cysts, whereas malignant diagnoses included papillary carcinoma, follicular neoplasm/suspicious lesions, and other malignancies. FNAC served as the

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reference standard for diagnostic accuracy calculations in this study (histopathology was not available for all cases). Clinical and imaging data were documented on a structured proforma developed before data collection. The proforma included demographics, presenting symptoms, gray-scale ultrasound variables, Doppler vascularity pattern, RI, PSV, Doppler impression (benign vs malignant), and FNAC outcome. Operational definitions were prespecified to ensure consistency across measurements and recording. Data were entered and analyzed using SPSS version 26.0. Continuous variables (age, nodule size, RI, PSV) were summarized as mean ± standard deviation. Normality was assessed using the Shapiro–Wilk test before reporting parametric summaries. Categorical variables were presented as frequencies and percentages. The association between Doppler impression and FNAC diagnosis was assessed using the Pearson Chi-square test, and the strength of association was quantified using Cramer's V. Diagnostic accuracy indices (sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy) were calculated using a 2×2 contingency table. Exact binomial 95% confidence intervals were computed for sensitivity, specificity, PPV, and NPV. Receiver operating characteristic (ROC) curve analysis was performed to evaluate overall discriminatory performance, and the area under the curve (AUC) was reported with 95% confidence intervals. Statistical significance was set at $p \leq 0.05$.

RESULTS

The mean age of participants was 45.1 ± 17.2 years, with the largest proportion aged >50 years (39.8%). Females constituted 51.8% of the study population. Neck swelling was the predominant presenting symptom (69.9%), while hoarseness was the least frequent (Table 1).

Table 1: Baseline Demographic and Presenting Clinical Features

Variables	Category	n (%), Mean ± SD
Age (Years)	Mean ± SD	45.12 ± 17.24
	Range	19–75
Age Category	≤30 Years	22 (26.5%)
	31–40 Years	20 (24.1%)
	41–50 Years	8 (9.6%)
	>50 Years	33 (39.8%)
Gender	Male	40 (48.2%)
	Female	43 (51.8%)
Presenting Symptom	Neck Swelling	58 (69.9%)
	Pain	12 (14.5%)
	Dysphagia	10 (12.0%)
	Hoarseness	3 (3.6%)
Duration of Swelling (Months)	Mean ± SD	18.67 ± 10.19
	Range	2–35

Slightly more than half of the participants had solitary nodules (50.6%). The mean nodule size was 2.34 ± 1.05 cm, with 59.0% measuring >2 cm. Solid composition was the most common structural pattern, and hypoechogenicity, irregular margins, calcifications, and taller-than-wide configuration were frequently observed as suspicious gray-scale features. Gray-scale ultrasonography characteristics are detailed (Table 2).

Table 2: Gray-Scale Ultrasonography Features of Thyroid Nodules (n=83)

Ultrasound Features	Category	n (%)
Number of Nodules	Solitary	42 (50.6%)
	Multiple	41 (49.4%)
Nodule Size (cm)	Mean ± SD	2.34 ± 1.05
	Range	0.65–4.18
	≤1.0 cm	7 (8.4%)
	1.1–2.0 cm	27 (32.5%)
	>2.0 cm	49 (59.0%)
Composition	Solid	29 (34.9%)
	Cystic	28 (33.7%)
	Mixed	26 (31.3%)
Echogenicity	Hypoechoic	32 (38.6%)
	Isoechoic	28 (33.7%)
	Hyperechoic	23 (27.7%)
Margins	Regular	44 (53.0%)
	Irregular	39 (47.0%)
Calcification	Absent	29 (34.9%)
	Macrocalcification	30 (36.1%)
	Microcalcification	24 (28.9%)
Shape	Taller-Than-Wide	44 (53.0%)
	Wider-Than-Tall	39 (47.0%)

Central and mixed vascularity were the predominant Doppler patterns (55.4% combined). The mean resistive index (RI) was 0.72 ± 0.14, with 57.8% demonstrating RI > 0.70. Based on predefined Doppler criteria, 28 nodules (33.7%) were categorized as suggestive of malignancy. FNAC identified 19 malignant nodules (22.9%), with papillary carcinoma being the most frequent malignant subtype (Table 3).

Table 3: Color Doppler Ultrasonography Findings and Fine Needle Aspiration Cytology (FNAC) Findings of Thyroid Nodules (n=83)

Variables	Category / Summary	n (%) or Mean ± SD
Doppler		
Vascularity Pattern	Absent	19 (22.9%)
	Peripheral	18 (21.7%)
	Central	21 (25.3%)
	Mixed	25 (30.1%)
Resistive Index (RI)	Mean ± SD	0.72 ± 0.14
	Range	0.45–0.94
RI Category	≤ 0.70	35 (42.2%)
	> 0.70	48 (57.8%)

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PSV (cm/s)	Mean ± SD	39.51 ± 14.59
	Range	15.20–64.30
Color Doppler Impression	Suggestive of Benign	55 (66.3%)
	Suggestive of Malignant	28 (33.7%)
Fine Needle Aspiration Cytology (FNAC)		
Final FNAC Diagnosis	Benign	64 (77.1%)
	Malignant	19 (22.9%)
Benign Subtypes	Colloid Nodule	25 (30.1%)
	Thyroiditis	24 (28.9%)
	Benign Cyst	15 (18.1%)
Malignant Subtypes	Papillary Carcinoma	8 (9.6%)
	Follicular Neoplasm / Suspicious	4 (4.8%)
	Others	7 (8.4%)

RI = Resistive Index; PSV = Peak Systolic Velocity

A statistically significant association was observed between Doppler impression and FNAC diagnosis (χ^2 = 48.401, p<0.001; Cramer's V = 0.764). The cross-tabulation of Doppler impression and FNAC findings is shown (Table 4).

Table 4: Association of Color Doppler Impression with FNAC Findings (n=83)

Color Doppler Impression	FNAC Benign, n (%)	FNAC Malignant, n (%)	Total	χ^2 (df)	p-value	Cramer's V
Suggestive of Benign	55 (100.0%)	0 (0.0%)	55	48.401 (1)	<0.001	0.764
Suggestive of Malignant	9 (32.1%)	19 (67.9%)	28			
Total	64 (77.1%)	19 (22.9%)	83			

The Pearson Chi-square test was applied as all expected cell counts were ≥5. A p-value ≤0.05 was considered statistically significant

Color Doppler ultrasonography demonstrated an overall diagnostic accuracy of 89.2%, with sensitivity 100% (95% CI: 82.4–100) and specificity 85.9% (95% CI: 74.6–93.3). The area under the ROC curve was 0.93 (95% CI: 0.876–0.984), indicating excellent discriminatory performance (Table 5).

Table 5: Diagnostic Accuracy of Color Doppler Ultrasonography Using FNAC as Gold Standard (n=83)

Diagnostic Measures	Value (%)	95% Confidence Interval
Sensitivity	100.0	82.4 – 100.0
Specificity	85.9	74.6 – 93.3
Positive Predictive Value (PPV)	67.9	47.6 – 84.1
Negative Predictive Value (NPV)	100.0	93.5 – 100.0
Overall Diagnostic Accuracy	89.2	–
Area Under ROC Curve (AUC)	0.93	0.876 – 0.984

CI = Confidence Interval; PPV = Positive Predictive Value; NPV = Negative Predictive Value

DISCUSSION

In this diagnostic accuracy study (n=83), Doppler ultrasonography demonstrated high diagnostic performance with an accuracy of 89.2%, sensitivity of 100%, specificity of 85.9%, and an AUC of 0.93. These findings confirm excellent discriminatory ability and support its role as an adjunct to gray-scale imaging in thyroid nodule evaluation. The very high sensitivity and negative predictive value indicate that Doppler imaging is particularly useful for ruling out malignancy when features favor benignity. Similar diagnostic performance has been reported in recent international cohorts, where Doppler parameters enhanced malignancy stratification when combined with suspicious gray-scale features such as hypoechogenicity, irregular margins, microcalcifications, and taller-than-wide configuration [12, 13]. Malignant nodules in the present study more frequently demonstrated central or mixed vascularity and elevated RI values (>0.70), consistent with published evidence indicating altered intranodular perfusion and vascular resistance in malignancy [14, 15]. However, Doppler thresholds remain susceptible to operator technique and equipment settings, which may explain variability in sensitivity and specificity across populations [16, 17]. The moderate positive predictive value observed reflects the influence of disease prevalence and overlapping vascular patterns between benign and malignant nodules, a limitation also described in previous studies, reinforcing the necessity of FNAC confirmation in suspicious lesions [18, 19]. The 100% sensitivity and NPV in this study should be interpreted cautiously due to the limited number of malignant cases (n=19), which resulted in wide confidence intervals [20]. Multicenter studies integrating standardized Doppler thresholds with established ultrasound risk-stratification systems are recommended to improve generalizability [21, 22].

The design was cross-sectional, which does not allow the determination of the prognostic value of Doppler in nodule progression or recurrence. There was no comparison with newer methods of ultrasound (elastography, contrast-enhanced ultrasound). There was no formal inter-observer test in spite of the consensus review of borderline cases. Pakistan studies. Multicenter prospective studies in multiple Pakistani cities are required to establish the Doppler thresholds in different populations. Proper and bigger samples with malignant cases would give specific confidence intervals. Prolonged follow-up with correlations of Doppler results, histopathology, and clinical results is to be carried out.

CONCLUSIONS

Color Doppler ultrasonography demonstrates excellent diagnostic accuracy and very high sensitivity for differentiating benign from malignant thyroid nodules when used as an adjunct to gray-scale ultrasound, fulfilling the primary study objective. The high AUC confirms strong discriminatory capability, supporting Doppler imaging as a

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reliable triage tool to guide FNAC prioritization. Nevertheless, cytology remains essential for definitive diagnosis in nodules with suspicious imaging characteristics.

Authors' Contribution

Conceptualization: ZJO
Methodology: ZJO, LK, SN
Formal analysis: TB
Writing and Drafting: ZJO, LK, TB, SN, NA, MS
Review and Editing: ZJO, LK, TB, SN, NA, MS

All authors approved the final manuscript and take responsibility for the integrity of the work.

Conflicts of Interest

All the authors declare no conflict of interest.

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