RESEARCH PAPER

Clinical, Laboratory, and Ultrasonographic Characteristics of Thyroid Nodules and Their Association with Histopathological Examination: A Descriptive Study

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Abstract

Background: Thyroid nodules are highly prevalent, yet differentiating benign from malignant lesions remains challenging. This study aimed to describe the demographic, laboratory, and ultrasonographic profiles of thyroid nodule patients and evaluate their association with histopathological malignancy.

Methods: This prospective cross-sectional study included 44 patients (aged 18–60 years) presenting with thyroid nodules at Minia University Hospital (April 2024–April 2025). All patients underwent clinical examination, routine laboratory investigations, high-resolution thyroid ultrasonography with ACR TI-RADS classification, and ultrasound-guided FNAC with Bethesda reporting. Patients with Bethesda III–VI cytology underwent surgery, with histopathology serving as the reference standard.

Results: Females predominated (93.2%). Histopathology revealed 63.6% benign and 29.5% malignant lesions. Age and sex showed no significant association with malignancy ($P = 0.204$, 0.232). TI-RADS classification ($P = 0.007$) and Bethesda category ($P = 0.005$) were significantly associated with histopathological outcome. Taller-than-wide shape, irregular margins, calcification, suspicious cervical lymph nodes, and extrathyroidal extension were all significantly associated with malignancy ($P < 0.001$). Baseline laboratory parameters were within normal limits.

Conclusion: ACR TI-RADS and specific suspicious ultrasound features significantly discriminate malignant from benign thyroid nodules. These conventional tools remain essential but may benefit from complementary biomarkers for indeterminate cases.

Keywords: Thyroid nodules, ACR TI-RADS, Bethesda classification, ultrasonography, histopathology, FNAC.

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Introduction

Recently, thyroid nodules have become a globally prevalent endocrine disease. With the continuous development of diagnostic techniques such as ultrasound (US) and fine-needle aspiration (FNA), the proportion of malignant thyroid nodules has been increasing annually (1).

The incidence of thyroid nodules is high, with a reported prevalence of 19 to 67% in the general population (2).

US has well-known utility for evaluating thyroid nodules and is recommended as a first-line imaging approach to determine the need for further cytological examination (3).

US-guided fine-needle aspiration cytology (FNAC) is a minimally invasive procedure that can provide valuable clinical and pathological information through evaluation of thyroid nodule aspirates using the Bethesda classification system (4).

For most patients, the combination of US and FNAC is the optimal diagnostic approach. However, the reported proportion of specimens determined to be cytologically indeterminate using FNAC ranges from 15 to 30% (5).

Our study aimed to describe the demographic, baseline laboratory, and ultrasonographic profiles of patients presenting with thyroid nodules, and to evaluate the association between these conventional clinical and sonographic features (including ACR TI-RADS categories and specific suspicious ultrasound signs) and final histopathological diagnosis.

Patients and methods

This prospective cross-sectional study was conducted at the Endocrinology Outpatient Clinic, Department of Internal Medicine, Minia University Hospital, in collaboration with the Departments of Radiology, Clinical Pathology, and Pathology, Faculty of Medicine, Minia University. Patients were recruited from April 2024 to April 2025. The study included 44 consecutive eligible patients of both sexes, aged 18–60 years, who attended the Endocrinology Outpatient Clinic for evaluation of one or more clinically detected or incidentally discovered thyroid nodules.

Inclusion Criteria

Patients were eligible if they: Were aged 18–60 years, had at least one clinically or incidentally detected thyroid nodule, had adequate clinical and laboratory data and were willing to participate and provided written informed consent.

Exclusion Criteria

Patients were excluded if they had: Toxic nodular goiter or levothyroxine-treated hypothyroidism, previous thyroid surgery or thyroid/neck radiotherapy, severe acute infection or active inflammatory disease, serious cardiovascular, cerebrovascular, or other significant chronic systemic disease affecting the studied biomarkers, current or previous non-thyroid malignancy and inadequate clinical, laboratory, cytological, or sampling data.

Methods

All patients were subjected to the following:

A comprehensive medical history was taken, focusing on the mode of nodule discovery, compressive symptoms, family history of thyroid disease, and relevant comorbidities. A thorough clinical examination was performed to assess thyroid size, nodule characteristics (consistency, mobility, tenderness), and the presence of cervical lymphadenopathy.

Routine Laboratory Investigations

Baseline laboratory parameters were assessed to evaluate the general health and systemic status of the patients. Complete blood counts (CBC) were performed using an automated hematology analyzer. Coagulation profiles (PT, PC, INR), renal function tests (urea, creatinine), and liver function tests (ALT, AST) were measured using an automated clinical chemistry analyzer. Additionally, serum thyroid-stimulating hormone (TSH), free triiodothyronine (FT3), and free thyroxine (FT4) were measured using competitive ELISA kits.

Ultrasonographic Evaluation

High-resolution thyroid ultrasonography was performed by an experienced radiologist using a 7–15 MHz linear-array transducer. For each targeted nodule, the following sonographic features were recorded:

Location and Number: Lobe distribution and solitary vs. multiple nodules. **Composition:** Solid vs. mixed (cystic and solid). **Echogenicity:** Hypoechoic vs. isoechoic/hyperechoic. **Shape:** Wider-than-tall vs. taller-than-wide. **Margins:** Smooth/well-defined vs. ill-defined vs. lobulated/irregular. **Echogenic Foci:** Presence or absence of calcifications. **Aggressive Features:** Presence of suspicious cervical lymph nodes and extrathyroidal extension. Nodules were also scored and categorized according to the ACR TI-RADS system (TR1 to TR5).

Cytological and Histopathological Evaluation

Ultrasound-guided FNAC was performed for nodules meeting the biopsy criteria (ACR TI-RADS 3–5). Cytology was reported using the Bethesda System. Patients with Bethesda III–VI nodules underwent thyroid surgery, and the postoperative histopathological examination served as the gold standard for final diagnosis (benign vs. malignant). Bethesda II nodules were classified as benign based on cytology.

Ethical Considerations

The study protocol was approved by the Research Ethics Committee, Faculty of Medicine, Minia University (approval No. 1119; March 15, 2024). All participants received an explanation of the study procedures and provided written informed consent. Confidentiality was maintained using unique study codes, and the study was conducted in accordance with the Declaration of Helsinki.

Statistical Analysis

Data were analyzed using SPSS version 25. Descriptive statistics were used to summarize the demographic, clinical, and laboratory profiles of the study population, with continuous variables presented as medians and interquartile ranges (IQR), and categorical variables as frequencies and percentages. To identify predictors of malignancy, the baseline characteristics, routine laboratory investigations, and ultrasonographic features were compared between the benign and malignant groups. Categorical variables were compared using the Chi-square test or Fisher's exact test, while continuous variables were compared using the Mann-Whitney U test. A p-value < 0.05 was considered statistically significant.

Results

Table (1): Baseline Characteristics of the Study Population

Variable	Studied population (n = 44)
Age	
Youth (19-44)	16 (36.4%)
Middle age (45-59)	22 (50%)
Elderly	6 (13.6%)
Sex	
Male	3 (6.8%)
Female	41 (93.2%)
US Imaging	
TI-RADS 3	23 (52.3%)
TI-RADS 4	15 (34.1%)
TI-RADS 5	6 (13.6%)
FNAC	
Bethesda 2	3 (6.8%)
Bethesda 3	21 (47.7%)
Bethesda 4	15 (34.1%
Bethesda 5	2 (4.5%)
Bethesda 6	3 (6.8%)
Histopathology	
No histopathological diagnosis	3 (6.8%)
Benign	28 (63.6%)
Malignant	13 (29.5%)

Categorical variables are presented as frequency (n) and percentage (%).

The study population comprised 44 patients. Middle-aged individuals (45–59 years) represented the largest age group (50%), followed by younger adults aged 19–44 years (36.4%). Females constituted the vast majority of participants (93.2%), reflecting the known higher prevalence of thyroid nodules among women. Regarding ultrasound findings, the majority of nodules were classified as TIRADS 3 (52.3%) and TIRADS 4 (34.1%), indicating that most cases fell within the intermediate suspicion categories. Cytological evaluation using FNAC revealed that Bethesda III (47.7%) and IV (34.1%) were the most frequent categories, indicating that most nodules belonged to indeterminate cytological categories. Histopathological examination revealed benign lesions in 63.6% of cases and malignant lesions in 29.5%, whereas Histopathological diagnosis was unavailable in 6.8% of patients because they were managed conservatively without surgical intervention. (Table 1)

Table (2): Baseline characteristics in relation to histopathological diagnosis of the study population

Variable	Benign	Malignant	P value
Age			
Youth (19-44)	12 (42.9%)	4 (30.8%)	0.204
Middle age (45-59)	14 (50%)	5 (35.8%)	
Elderly	2 (7.1%)	4 (30.8%)	
Sex			
Male	1 (3.6 %)	2 (15.4%)	0.232
Female	27 (96.4%)	11 (84.6%)	
US Imaging			
TI-RADS 3	17 (60.7%)	3 (23.1%)	0.007*
TI-RADS 4	10 (35.7%)	5 (38.5%)	
TI-RADS 5	1 (3.6%)	5 (38.5%)	
FNAC			
Bethesda 3	17 (60.7%)	4 (30.8%)	0.005*
Bethesda 4	11 (39.3%	4 (30.8%	
Bethesda 5	0 (0%)	2 (15.4%)	
Bethesda 6	0 (0%)	3 (23.1%)	

- Chi square /Fisher exact test used to compare qualitative data between groups.

**** Statistically significant at P < 0.05***

There was no statistically significant association between histopathological outcome and either age (P = 0.204) or sex (P = 0.232). Although benign lesions were more frequently observed among middle-aged patients (50.0%), malignant lesions showed relatively higher proportions among middle-aged (38.5%) and elderly (30.8%) patients. Females constituted the majority of cases in both benign (96.4%) and malignant (84.6%) groups. In contrast, ultrasound TI-RADS classification showed a statistically significant association with histopathological diagnosis (P = 0.007). Benign lesions were predominantly classified as TI-RADS 3 (60.7%), whereas malignant lesions were more commonly classified as TI-RADS 4 and TI-RADS 5 (38.5% each). Similarly, FNAC Bethesda classification was significantly associated with histopathological findings (P = 0.005). Benign lesions were mainly categorized as Bethesda III (60.7%) and Bethesda IV (39.3%), while malignant lesions were distributed across higher Bethesda categories, with Bethesda V (15.4%) and Bethesda VI (23.1%) observed exclusively in malignant cases. (Table 2)

Table (3): Baseline laboratory investigations of the study population

Variable	Studied groups n=44
Hb (g/dL) Median (IQR)	11.2 (10.8 – 11.9)
TLC (×10³/µL) Median (IQR)	8 (5.7 – 9.8)
Platelet (×10³/µL) Median (IQR)	279 (251 – 302)
INR Median (IQR)	1.06 (1.02 – 1.2)
PT (seconds) Median (IQR)	12 (11.5 – 12.47)
PC (percent) Median (IQR)	88.5 (86.2 – 90)
Creatinine (mg/dl) Median (IQR)	1 (0.8 – 1.2)
Urea (mg/dl) Median (IQR)	37.5 (33 – 44)
ALT (U/L) Median (IQR)	18.5 (16.2 – 23.7)
AST (U/L) Median (IQR)	19.5 (17 – 28.75)

-Quantitative data are presented as median (interquartile range, IQR).

Overall, the baseline laboratory parameters were within the normal reference ranges, indicating that the study population had no major hematological, renal, hepatic, or coagulation abnormalities. The median hemoglobin level was 11.2 gm/dL (IQR: 10.8–11.9), while the median total leukocyte count was 8 ×10³/µL (IQR: 5.7–9.8) and platelet count was 279 ×10³/µL (IQR: 251–302). Coagulation parameters were within expected ranges, with median INR, PT, and prothrombin concentration of 1.06, 12.0 seconds, and 88.5%, respectively. Renal function was preserved, as reflected by median creatinine and urea levels of 1.0 mg/dL and 37.5 mg/dL, respectively. Liver enzymes also remained within acceptable limits, with median ALT and AST values of 18.5 U/L and 19.5 U/L. (Table 3)

Table (4): Association between ultrasonographic (US) characteristics and histopathological diagnosis of thyroid nodules

Variable	Benign	Malignant	P value
Site			
Bilateral	6 (21.4%)	0 (0%)	
Left lobe	9 (32.1%)	6 (46.2%)	0.186
Right lobe	13 (46.4%)	7 (53.8%)	
Number			
Single	20 (71.4%)	12 (92.3%)	0.133
Multiple	8 (28.6%)	1 (7.7%)	
Composition			
Solid	15 (53.6%)	11 (84.6%)	0.055
Mixed	13 (43.4%)	2 (15.4%)	
Echogenicity			
Hypoechoic	15 (53.6%)	10 (76.9%)	0.154
Isoechoic	13 (46.4%)	3 (23.1%)	
Shape			
Round	1 (3.6%)	0 (0%)	<0.001*
Taller than wider	1 (3.6%)	10 (76.9%)	
Wider than taller	26 (92.9%)	3 (23.1%)	
Margin			
Ill defined	3 (10.7%)	3 (23.1%)	<0.001*
Well defined	25 (89.3%)	3 (23.1%)	
Lobulated/irregular	0 (0%)	7 (53.8%)	
Calcification			
No	24 (85.7%)	0 (0%)	<0.001*
Yes	4 (14.3%)	13 (100%)	

Cervical lymph node No Yes	28 (100%) 0 (0%)	4 (30.8%) 9 (69.2%)	<0.001 *
Extra thyroid extension No Yes	28 (100%) 0 (0%)	6 (46.2%) 7 (53.8%)	<0.001 *

- Chi square /Fisher exact test used to compare qualitative data between groups.

**** Statistically significant at P < 0.05.***

Table 4 summarizes the analysis of the relationship between ultrasonographic characteristics and histopathological diagnosis demonstrated that several sonographic features were significantly associated with thyroid malignancy. Nodule shape showed a highly significant association with malignant disease ($p < 0.001$), with malignant nodules more frequently exhibiting a taller-than-wide configuration, whereas benign nodules predominantly demonstrated a wider-than-tall appearance. Margin characteristics also differed significantly between the two groups ($p < 0.001$). Irregular or lobulated margins were predominantly observed in malignant nodules, whereas smooth, well-defined margins were more common in benign nodules. Calcification showed one of the strongest associations with malignancy ($p < 0.001$), as calcifications were identified in all malignant cases but were uncommon among benign nodules. Similarly, cervical lymph node involvement and extrathyroidal extension were observed almost exclusively in malignant nodules, demonstrating highly significant differences between benign and malignant groups (both $p < 0.001$). These findings are consistent with the ACR TI-RADS classification, which stratifies the risk of thyroid malignancy based on ultrasonographic features.

Discussion

The present study included 44 patients with thyroid nodules, with a marked female predominance of 93.2%. Half of the participants were aged 45–59 years. **George et al., (6)** similarly reported female predominance in a clinical thyroid nodule cohort.

The marked female predominance in the present study most likely reflects the higher prevalence of thyroid nodules among women rather than a higher intrinsic risk of thyroid malignancy.

ACR TI-RADS 3 was the most frequent ultrasonographic category, followed by TI-RADS 4 and 5. Bethesda III and IV constituted most cytological diagnoses. This distribution reflects the study's selection criteria because only TI-RADS 3–5 nodules meeting FNAC recommendations were included, while patients with Bethesda III–VI cytology generally underwent surgery. Therefore, the high proportion of indeterminate nodules should not be considered representative of all thyroid nodules in the general population.

Histopathological examination identified 28 benign and 13 malignant nodules, while three Bethesda II cases were managed without surgery. Malignancy therefore represented 29.5% of the total population and 31.7% of patients with an available histopathological diagnosis. This relatively high prevalence of malignancy was expected because the study population consisted of selected thyroid nodules referred for FNAC and/or surgery according to suspicious ultrasonographic and cytological findings rather than an unselected thyroid nodule population.

Neither age nor sex was significantly associated with malignancy. This agrees with **Castro et al., (7)**, who found no significant predictive value for these variables in patients with suspicious thyroid nodules. However, other studies have reported associations between malignancy and male sex or older age **(8,9)**. The absence of significance in the present study may be related to the limited sample size, particularly the small number of male participants and malignant cases.

In contrast, both ACR TI-RADS and Bethesda classifications were significantly associated with histopathological diagnosis. Benign nodules were predominantly classified as TI-RADS 3, whereas malignant lesions were more frequently categorized as TI-RADS 4 or 5. Similarly, Bethesda V and VI occurred exclusively among malignant cases. These findings agree with **Eissa et al., (10)** , who demonstrated increasing malignancy risk with higher TI-RADS and Bethesda categories. Nevertheless, both systems remain risk-stratification tools rather than substitutes for histopathological diagnosis.

Therefore, complementary biomarkers such as Midkine-derived ratios may further improve diagnostic confidence, particularly in nodules with indeterminate cytological findings.

Routine laboratory investigations demonstrated generally preserved renal, hepatic, and coagulation parameters, indicating the absence of major systemic abnormalities that could potentially confound the study findings. These results support the interpretation that the observed differences were more likely related to the underlying thyroid pathology rather than to significant systemic dysfunction.

A taller-than-wide configuration was significantly associated with malignancy, occurring in 76.9% of malignant nodules compared with 3.6% of benign nodules. This finding agrees with previous meta-analyses identifying nonparallel orientation as a highly specific sonographic sign of thyroid malignancy **(11)**.

Nevertheless, its diagnostic value should be interpreted alongside other suspicious features because its independent predictive contribution may vary after adjustment for coexisting sonographic characteristics **(12)**.

Lobulated or irregular margins were also strongly associated with malignancy, whereas most benign nodules had smooth, well-defined margins. Irregular margins may reflect infiltrative tumor growth and disruption of the normal interface between the nodule and surrounding thyroid tissue. However, ill-defined margins should not be considered equivalent to irregular or infiltrative margins because poor demarcation may also occur in benign lesions **(13)**.

Calcification was present in all malignant nodules but in only 14.3% of benign nodules, indicating a strong association with malignancy in the present cohort. This finding is consistent with the meta-analysis by **Remonti et al., (14)** which included 52 observational studies comprising 12,786 thyroid nodules. They reported that microcalcifications had a pooled specificity of 87.8% and a positive likelihood ratio of 3.26 for thyroid carcinoma, although sensitivity was only 39.5%.

Although calcifications were strongly associated with malignancy in the present study, they should always be interpreted in conjunction with other suspicious ultrasound features rather than as an isolated diagnostic sign.

Suspicious cervical lymph nodes and extrathyroidal extension were also predominantly observed in malignant nodules. These findings are clinically important because suspicious lymph nodes may indicate regional metastatic spread, whereas extrathyroidal extension suggests invasion beyond the thyroid capsule. Suspicious lymph nodes are assessed separately from the numerical ACR TI-RADS score, while extrathyroidal extension contributes directly to the margin score **(15)**.

In contrast, nodule site, number, composition, and echogenicity were not significantly associated with malignancy. Although solid composition and hypoechogenicity were more frequent among malignant lesions, their lack of statistical significance may be related to the limited sample size and the restricted categorization of echogenicity. These features also generally have lower specificity than taller-than-wide orientation, irregular margins, and suspicious echogenic foci.

Thus, the significant association between higher ACR TI-RADS categories and malignant histopathology was supported by the accumulation of suspicious sonographic characteristics among malignant nodules. Taller-than-wide orientation, irregular margins, calcification, suspicious cervical lymph nodes, and extrathyroidal extension provided the clearest discrimination. Nevertheless, no individual ultrasound feature is diagnostic in isolation, and ultrasonography should remain a risk-stratification tool interpreted together with cytology, clinical assessment, and relevant biomarkers **(13)**.

Conclusion

Neither age nor sex was significantly associated with histopathological malignancy. In contrast, both ACR TI-RADS and Bethesda classifications showed significant associations with final diagnosis. Among ultrasonographic features, taller-than-wide orientation, irregular margins, calcification, suspicious cervical lymph nodes, and extrathyroidal extension were strongly associated with malignancy (all $P < 0.001$), while nodule site, number, composition, and echogenicity were not. These findings confirm that conventional risk-stratification tools remain essential but insufficient alone, supporting the need for complementary biomarkers such as Midkine-derived ratios to improve diagnostic confidence in indeterminate nodules.

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