

# VALIDITY OF A NEW ULTRASOUND (USG) CLASSIFICATION SYSTEM FOR DIFFERENTIATING BETWEEN BENIGN AND MALIGNANT SOLID THYROID NODULES

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## ABSTRACT

**OBJECTIVE:** Evaluate the validity of a new ultrasound classification system in differentiating malignant from benign solid thyroid nodules, keeping FNAB (H/P) as gold standard. **MATERIAL AND METHODS:** This was a cross sectional validation study conducted in the Department of Radiology, Military Hospital Rawalpindi. Histopathology (FNAB) was carried out at Armed Forces institute of Pathology (AFIP), Rawalpindi by histopathologist. The duration of study was 08 months (November 2012 till June 2013). **RESULTS:** A total of 210 patients were included in this study. Majority of the patients i.e. 27.14% (n=57) were between 41-50 years, mean and sd was calculated as  $42.34 \pm 4.78$  years, 56.19% (n=118) were male and 43.81% (n=92) females, frequency of thyroid nodules (on FNAB as gold standard) reveals as 19.52% (n=41) malignant and 80.48% (n=169) benign, validity of a new ultrasound classification system in differentiating malignant from benign solid thyroid nodules, keeping FNAB (H/P) as gold standard was calculated in Table No. 4, where 17.62% (n=37) true positive, 4.29% (n=9) false positive, 1.90% (n=4) false negative, 76.19% (n=160) true negative, while sensitivity, specificity, positive predictive value, negative predictive value and validity/diagnostic accuracy was recorded as 90.24%, 94.67%, 80.43%, 97.56% and 93.81% respectively. **CONCLUSION:** We concluded that the validity of a new ultrasound classification system in differentiating malignant from benign solid thyroid nodules, keeping FNAB (H/P) as gold standard is significantly higher and recommended for diagnosis of malignant solid thyroid nodules in future. **Key words:** Thyroid nodules, new ultrasound classification system, malignant, diagnostic accuracy

## Introduction

Thyroid nodules are a common clinical condition. Increasing with patient age, thyroid nodules are found in up to 20% of adults by palpation and in up to 70% on sonography and autopsy studies.<sup>1</sup>

Thyroid ultrasound (US) is the major diagnostic modality for evaluating thyroid nodules. Classic US characteristics of a benign nodule include an ovoid or flat shape isoechogenicity, a smooth margin, and peripheral vascularity.<sup>2</sup> US features predictive of malignant nodules include the presence of micro

calcifications, marked hypoechogenicity, irregular margins, absence of a halo, predominantly solid composition, taller-than-wide shape and intranodular vascularity. Some investigators suggest that a combination of these US findings provides better diagnostic accuracy than only one of these findings.<sup>2,4</sup> On the basis of a new Ultrasound classification system of Young Hun Lee, ultrasound features of solid thyroid nodules are prospectively classified into one of five categories:

1. Benign
2. Probably benign

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3. Borderline
4. Possibly malignant
5. Malignant

This classification differs from the previous one in that it only includes solid thyroid nodules and has 5 categories while old one included both solid and cystic nodules and had 2 categories.<sup>2,3</sup>

US may be helpful in planning the extent of surgery in patients with a reading of suspicious for malignancy on FNAB. Thyroid malignancy occurs in approximately 26% of patients with suspicious for malignancy, with sensitivity, specificity of 83.3%, 94.9% respectively for new US classification. The sensitivity, specificity for old classification was 96.4%, 74.5% respectively.<sup>5,6</sup>

The aim of this study is to explore the accuracy of US diagnosis for benign and malignant solid thyroid nodules using Lee et al' real-time US performance and classification system with 5 categories.<sup>2</sup>

## Methodology

After acquiring permission from Hospital ethical committee, indoor cases fulfilling the inclusion / exclusion criteria were included in the study after obtaining written informed consent.

Ultrasonography was performed using a 7.5 MHz probe of Aloka SSD 5500 in dimly lit room with comfortable temperature (22 - 24C) in supine position. All cases undergoing ultrasound also underwent after fine needle aspiration biopsy for cytology by histopathologist. The data was recorded on the Performa.

## Results

A total of 210 cases fulfilling the inclusion/exclusion criteria were included in the study to evaluate the validity of a new ultrasound classification system in differentiating malignant from benign solid thyroid nodules, keeping FNAB (H/P) as gold standard.

Age distribution of the patients was done which shows that majority of the patients i.e. 27.14% (n=57) were between 41-50 years, followed by 24.29%

(n=51) between 31-40 years, 20.48%(n=43) between 20-30 years, 17.62% (n=37) between 51-60 years and 10.47% (n=22) between 61-70 years, mean and SD was calculated as  $42.34 \pm 4.78$  years (Tab. 1).

Age (in years)	No. of Patients	%
20-30	43	20.48
31-40	51	24.29
41-50	57	27.14
51-60	37	17.62
61-70	22	10.47
<b>Total</b>	<b>210</b>	<b>100</b>
<b>Mean and sd</b>	<b>42.34 ± 4.78</b>	

**Table 1:** Age distribution of the patients (n = 210)

Gender distribution of the patients was done where 56.19% (n=118) were male and 43.81% (n=92) females (Tabl. 2).

Frequency of thyroid nodules (on FNAB as gold standard) reveals as 19.52% (n=41) malignant and 80.48% (n=169) benign (Tab. 3)

Validity of a new ultrasound classification system in differentiating malignant from benign solid thyroid nodules, keeping FNAB (H/P) as gold standard was calculated (Tab. 4) where 17.62% (n=37) true positive, 4.29% (n=9) false positive, 1.90% (n=4) false negative, 76.19% (n=160) true negative, while sensitivity, specificity, positive predictive value, negative pre-dictive value and validity/diagnostic accuracy was recorded as 90.24%, 94.67%, 80.43%, 97.56% and 93.81% respectively.

Gender	No. of Patients	%
Male	118	56.19
Female	92	43.81
<b>Total</b>	<b>210</b>	<b>100</b>

**Table 2:** Gender Distribution of the patients (n = 210)

Thyroid nodules	No. of Patients	%
Malignant	41	19.52
Benign	169	80.48
<b>Total</b>	<b>210</b>	<b>100</b>

**Table 3:** Frequency of thyroid nodules (on FNAB as gold standard) (n = 210)

USG	FNAB		Total
	Positive	Negative	
Positive	True positive(a) 37 (17.62%)	False positive (b) 9 (4.29%)	a + b 46(21.90%)
Negative	False negative(c) 4 (1.90%)	True negative (d) 160 (76.19%)	c + d 164(78.10%)
<b>Total</b>	<b>a + c</b> <b>41 (19.52%)</b>	<b>b + d</b> <b>169(80.48%)</b>	<b>210(100%)</b>

Sensitivity =  $a / (a + c) \times 100 = 90.24\%$   
 Specificity =  $d / (d + b) \times 100 = 94.67\%$   
 Positive predictive value =  $a / (a + b) \times 100 = 80.43\%$   
 Negative predictive value =  $d / (d + c) \times 100 = 97.56\%$   
 Validity/Accuracy rate =  $(a + d) / (a + d + b + c) \times 100 = 93.81\%$

**Table 4:** Validity of a new ultrasound classification system in differentiating malignant from benign solid thyroid nodules, keeping FNAB (H/P) as gold standard (n=210)

## Discussion

Thyroid nodules are a common clinical problem. Epidemiologic studies have shown the prevalence of palpable thyroid nodules to be approximately 5% in women and 1% in men living in iodine-sufficient parts of the world.<sup>8,9</sup> In contrast, high-resolution ultrasound (US) can detect thyroid nodules in 19–67% of randomly selected individuals with higher frequencies in women and the elderly.<sup>10</sup> The clinical importance of thyroid nodules rests with the need to exclude thyroid cancer which occurs in 5–15% depending on age, sex, radiation exposure history, family history, and other factors.<sup>11,12</sup>

At present, real time ultrasonography remains the best modality to screen thyroid nodules and to determine which nodules should be studied by FNAB suspicion for malignancy.<sup>13,14</sup> Conventionally, sonographic signs that correlate with malignant lesions include the following:

- Hypoechoogenicity
- Blurred or irregular margins
- Microcalcifications, an
- Anteroposterior / transverse diameter of  $\geq 1$  cm
- Intranodular predominantly central vascularity<sup>15-16</sup>

However the sensitivity, specificity, NPV, and PPV are considerably variable from study to study.<sup>17-18</sup>

We planned this study to explore the accuracy of US diagnosis for benign and malignant solid thyroid nodules using Lee et. al' real-time US performance

and classification system with 5 categories.

Our findings revealed frequency of thyroid nodules (with FNAB as gold standard) as 19.52% (n=41) malignant and 80.48% (n=169) benign. The validity of Young Hun Lee ultrasound classification system in differentiating malignant from benign solid thyroid nodules, keeping FNAB (H/P) as gold standard was calculated as 17.62% (n=37) true positive, 4.29% (n=9) false positive, 1.90% (n=4) false negative, 76.19% (n=160) true negative, while sensitivity, specificity, positive predictive value, negative predictive value and validity/diagnostic accuracy was recorded as 90.24%, 94.67%, 80.43%, 97.56% and 93.81% respectively.

The findings of the study are in agreement with a previous USG study by Kwak et al, where thyroid malignancy occurs in approximately 26% of patients with suspicious for malignancy, with sensitivity, specificity of 83.3%, 94.9% respectively. The sensitivity and specificity for the previous diagnostic criteria were 96.4% and 74.5% respectively.<sup>5,6</sup> Our new Ultrasonography classification system can more reliably differentiate between benign and malignant thyroid nodules (as confirmed on FNAB) and is significantly helpful to the physicians for accurate diagnosis.

Kim and colleagues<sup>7</sup> prospectively analyzed 155 incidentally discovered, non-palpable, solid thyroid nodules and found a mean number of 2.6 suspicious findings per malignant nodule and an overall sensitivity and specificity of 94% and 66% respectively.

Ultrasound is also superior to computed tomography scanning in evaluating the presence of abnormal cervical lymph nodes. Cervical lymph nodes can be involved in 20% - 50% of patients with differentiated thyroid cancer; more specifically, in those individuals with papillary thyroid cancer.<sup>19-20</sup> Preoperative ultrasound can identify suspicious cervical lymphadenopathy in 20%–31% of cases of thyroid cancer, thereby potentially altering the extent of and overall surgical approach in these patients.<sup>21-22</sup> This imaging modality allows for the early detection of non-palpable cervical lymph node metastasis prior to thyroidectomy in patients with FNA-proven or suspected thyroid cancer that otherwise might have been missed intraoperatively, thereby minimizing the risk for persistent disease.<sup>88-90</sup>

The determined accuracy of US diagnosis for benign and malignant solid thyroid nodules using real-time US using the 5 category classification system for solid nodules is better than the previous one and is recommended for standard usage of evaluation of solid thyroid nodules.

## Conclusion

We concluded that the validity of Lee et al ultrasound classification system in differentiating malignant from benign solid thyroid nodules, keeping FNAB (H/P) as gold standard is significantly higher and recommended for evaluation of solid thyroid nodules.

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