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A study of Correlation of Pre-operative US Elastography with Post-operative Histopathology in Patients with Thyroid Nodule

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ABSTRACT

Background: As the incidence of thyroid lesions continues to rise, accurate differentiation between benign and malignant thyroid nodules becomes essential to guide appropriate treatment decisions. Unnecessary invasive procedures should be minimized to optimize patient care. Ultrasound Elastography, a non-invasive imaging technique assessing tissue stiffness, has shown promising potential in this context.

Aim of the work: This study aimed to validate the utility of ultrasonography with elastography in diagnosing benign versus malignant conditions of the thyroid gland by correlating the results with histopathology reports.

Patients and Methods: Twenty patients with thyroid swellings or nodules were included in the study. Demographic information, clinical features, and ultrasound findings were collected and analyzed. Elastography results were compared with histopathological findings to evaluate the diagnostic accuracy of the technique.

Results: By comparing the results of elastography with the results of the biopsy, the 10 benign nodules by elastography were confirmed by biopsy. However, from the 10 malignant nodules, 6 of them were confirmed by biopsy and 4 of them were diagnosed by biopsy to be benign nodules. Based on that the accuracy of elastography to differentiate the benign from the malignant nodules was 80% with a sensitivity of 96.6%, specificity of 71.4%, PPV of 60%, and NPV of 100%.

Conclusion: Ultrasound elastography proves to be an effective and non-invasive tool for diagnosing thyroid nodules, with a significant potential to reduce unnecessary interventions and improve patient care. Its role as a complementary diagnostic technique highlights its importance in guiding treatment decisions and evaluating prognosis for patients with thyroid pathologies.

Keywords: Ultrasound; Elastography; Thyroid Nodule; Benign; Malignant

INTRODUCTION

The thyroid gland is the largest and the first endocrine gland to form during embryonic development. Thyroid nodules with detectable clinical symptoms occur in about 4-5% of the population. Only about 1 in 10 thyroid nodules are malignant, therefore the vast majority [90%] are completely safe [1].

Due to its excellent sensitivity for detecting tiny nodules, ultrasound is often the method of choice for assessing thyroid morphology. Ultrasound is a beneficial imaging modality since it may detect cystic lesions while being non-invasive and relatively inexpensive. Color Doppler imaging not only illustrates the morphology but also aids in determining the blood flow [2].

Malignancy can be predicted using ultrasound elastography characteristics such as hypoechogenicity, microcalcifications, a taller-than-wide form, uneven or microlobulated borders, and enhanced intranodular vascularity [3].

US elastography is a potential new way to evaluate thyroid nodules. It enables "virtual palpation" of the nodule, which may not be physically perceptible. Using ultrasound, elastography may measure tissue stiffness without causing damage to the patient [4]. Ultrasound strain elastography [USE] has emerged into a common US assessment technique during the past several years and has been advocated for distinguishing malignant from benign thyroid nodules based on their flexibility [5].

The elasticity score [ES] is a qualitative result of USE, while the strain ratio [SR] is a semiquantitative result expressed in terms of relative strain and calculated by dividing the mean strain within the lesion by the mean strain of the surrounding normal tissue. Softer components of the body deform more easily than harder parts when tissues are compressed, which is the basis for USE [5].

USE has been found to accurately distinguish between malignant and normal thyroid nodules [6]. USE has been shown to have poorer sensitivity and specificity than the traditional US in a number of studies, contradicting previous findings [7, 8].

As a result, further research is required to validate USE's efficacy, and the debate about its usefulness continues. Preparation of the patient, hospitalization, anesthetic, and surgery are all necessary for histopathological examination [HPE] of the removed thyroid enlargement, which is the most accurate technique to determine the pathology. So that proper surgery and patient counseling can be planned before a definitive pre-operative diagnosis of malignancy is made. It is a challenge in clinical practice to consistently identify the few malignant tumors from the many harmless benign nodules [9].

The study's goal is to compare post-operative histopathological findings in patients with thyroid nodules to those found on pre-operative US Elastography.

PATIENTS AND METHODS

This prospective study was conducted at Al-Azhar University Hospital on 20 cases of thyroid swelling or nodules. The diagnosis and surgical decision were made according to US Elastography. We followed the Helsinki declaration principals. Ethical approval was obtained from the Institutional review board of Al-Azhar University. Written informed consent was obtained from every patient before recruitment. We included the patients according to the following criteria:

The Inclusion criteria were: Patients of either sex or age between 18 to 60 years old diagnosed with thyroid swelling or nodule.

The Exclusion criteria were: Patients refusing to participate in the study, patients unfit for the surgery, patients with hypo or hyperthyroidism and patients with previous thyroid operation.

All patients were subjected to personal and past history taking, general examination, local abdominal examinations, and routine laboratory investigations three days before the surgery.

American Thyroid Association [ATA] guidelines were followed in the management of thyroid nodules and biopsies were performed by radiologists under ultrasound guidance.

Ultrasound examination

A neck ultrasound was performed using a portable scanner equipped with a high frequency linear 7.5-10 MHz transducer. The patient was positioned in a supine posture, and the ultrasound probe was applied to the fully extended neck to conduct a standard ultrasonographic examination. Subsequently, the identified nodule was gently compressed with consistent and light pressure. The operator then delineated a box encompassing the nodule of interest, along with an adequate amount of surrounding thyroid tissue, for further evaluation. Elastography, a technique based on the assessment of tissue displacement through the analysis of ultrasound images before and after compression, was employed to track the propagation of the imaging beam, strict measures were implemented to ensure the maintenance of a consistent level of pressure throughout the examination. Specialized software was employed, which facilitated precise measurement of tissue distortion. This elasticity software incorporated a pressure monitoring scale to accurately monitor the applied force. To enhance lesion identification, B mode images and elasticity images were simultaneously displayed side by side on a single screen. During the examination of each lesion, numerous frames of elasticity images were captured by continuously moving the probe during compression and relaxation. These frames were then stored in the cine buffer memory of the scanner. Subsequently, the most suitable B mode ultrasound elastogram image pairs were selected for further examination.

The elasticity image was meticulously matched with an elasticity color scale, color images were systematically generated using consistent image processing parameters for the duration of the study. In order to assess the elasticity images, we examined the color pattern within the nodule and analyzed the color scales that emerged from the signals acquired pre- and post-compression. The evaluation was conducted using the Tsukuba scoring system [10], which categorizes the color scales into five distinct scores. The nodules were assessed and categorized based on their firmness. Nodules with a score of 1 and 2 were observed to exhibit softness, indicating a benign nature. Nodules with a score of 3 displayed a moderate level of hardness, typically associated with benign characteristics. Conversely, nodules with scores of 4 and 5 demonstrated a notable firmness, suggesting a malignant nature.

Postoperative histopathological analysis

Postoperative histopathology diagnosis was for each nodule to confirm the diagnosis.

Statistical analysis

The collected data were coded, processed, and analysed using the SPSS [Statistical Package for Social Sciences] version 26 for Windows® [IBM SPSS Inc, Chicago, IL, USA]. Quantitative data were expressed as mean ± SD [Standard deviation]. Qualitative data was expressed as numbers and percentages.

RESULTS

A total of 20 patients were included in this study. Table 1 described the demographics, clinical, and laboratory findings of the patients. The mean age of the studied patients was 46.24 ± 4.88 years. Most of the patients were in the age category of 30 – 50 years old. As regards their gender distribution, 60% of the patients were female and 40% were male. The mean weight of the studied patients was 88.11 ± 11.97 Kg, the mean height was 1.71 ± 0.04 meters, and the mean BMI was 30.37 ± 4.40 kg/m^2. In terms of the disease duration, it was 2.31 ± 2.24 years with a range of 0.5 – 3.6 years. As regards the patient's diagnosis, 35% of the patients were Multinodular goiter, 50% were suspicious thyroid malignancy, and 15 % were Nodular goiter.

As regards the nodule characteristics, the mean nodular size was 23.5±10.1 mm, 45% of the nodules were right, 70% were with nodular borders, 60% were with solid components, 60% were without calcification, and 70 % were vascular. As regards the elastography results, 50% of the nodules were benign and 50% were malignant. However, the pathology results showed that 70% of the nodules were benign and 30% were malignant.

Correlation analysis between the malignant nodules and different study variables revealed a statistically significant correlation between it the nodule size, border, Hypoechoic, microcalcifications, and family history [P value < 0.05 for all] [Table 4]. By comparing the results of elastography with the results of the biopsy, the 10 benign nodules by elastography were confirmed by biopsy. However, from the 10 malignant nodules, 6 of them were confirmed by biopsy and 4 of them were diagnosed by biopsy to be benign nodules [Table 5].

Based on that the accuracy of elastography to differentiate the benign from the malignant nodules was 80% with a sensitivity of 96.6%, specificity of 71.4%, PPV of 60%, and NPV of 100% [Table 6].

Table [1]: Demographics and clinical data of the studied patients.

Variables	Mean ± SD or N [%]
Gender	
Male	12 [60%]
Female	8 [40%]
Age [years]	46.24 ± 4.88
Weight [Kg]	88.11 ± 11.97
Height [meter]	1.71 ± 0.04
BMI [kg/m^2]]	30.37 ± 4.40
Disease duration [years]	2.31 ± 2.24
Positive family history	7 [35%]
History of any other disease	9 [45%]
Smoking	12 [60%]
Laboratory findings	
Hb [gm/dl]	11.63 ± 1.04
Platelets [10^3/UL]	254.60 ± 18.51
WBCs [10^3/UL]	7.24 ± 2.83
TSH	4.76 ± 7.76
FT3	3.15 ± 0.52
FT4	1.06 ± 0.35
Diagnosis	
Multinodular goiter	7 [35%]
Suspicious thyroid malignancy	10 [50%]
Nodular goiter	3 [15%]

Table [2]: US feature of the studied patients

U/S features		N [%]
Nodule location	Right	9 [45%]
	Left	5 [25%]
	Bilateral	6 [30%]
Nodule border	Regular	14 [70%]]
	Irregular	6 [30%]
Component	Solid	12 [60%]
	Solid+cystic	8 [40%]
Echogenity	Isoechoic	6 [30%]
	Hyperechoic	8 [40%]
	Hypoechoic	6 [30%]
Calcification	None	12 [60%]
	Micro+	4 [20%]
	Macro+	4 [20%]
Presence of halo	Present	15 [75%]
	Absent	5 [25%]
Vascularity	Present	14 [70%]
	Absent	6 [30%]

Table [3]: Nodule characteristics according to elastography and specimen pathology results

Nodule size [mm]. Mean ±SD		23.5±10.1
Elastography [n, %]	Benign	10 [50%]
	Malignant	10 [50%]
Pathology result. [n, %]	Benign	14 [70%]
	Malignant	6 [30%]

Table [4]: Correlation of malignant nodules with Laboratory, Anthropometric, and Clinical Parameters

	Malignant nodules	
	r	P-value
Age [years]	0.352	0.083
Female sex	0.333	0.072
Disease duration	-0.311	0.094
Nodule size	0.386	0.015*
Irregular borders	0.242	0.018*
Solid content	0.274	0.175
Hypoechoic	0.405	0.021*
microcalcification	0.695	0.019*
Presence of halo	0.134	0.515
Vascularity	0.035	0.875
Family history	0.834	0.039*

Table [5]: Correlation of Elastography, with Biopsy Examination

Elastography	Biopsy		Total
	Benign	**Malignant**	
Benign	10 [50%]	0 [0%]	10 [50%]
Malignant	4 [20%]	6 [30%]	10 [50%]
Total	14 [70%]	6 [30%]	20 [100%]

Table [6]: Sensitivity, specificity, and accuracy of Elastography of the studied group

	Accuracy	sensitivity	specificity	PPV	NPV
Elastography	80.00	96.6%	71.4%	60.00%	100%

PPV: Positive predictive value. NPV: Negative predictive value

DISCUSSION

Thyroid nodule detection rates are high, and the incidence of thyroid cancer is rising, both of which raise questions about the best way to treat these growths. However, incidental thyroid nodules are detected at rates of 17%-67% with US [11], 16%-17% with neck CT or MRI scans [12], 1%-2% with 18F-fluorodeoxyglucose [FDG]-positron emission tomography [PET]/CT scans [13], and 60% in autopsy specimens [14]. The prevalence of palpable thyroid nodules is low [3%-4%].

Identifying whether nodules are benign and decreasing the number of unnecessary thyroid surgery are the primary goals of preoperative screening of thyroid nodules [14]. Shear wave elastography [SWE] is a unique ultrasonic technology that enables quantitative measurements of tissue elasticity by following the propagation of shear waves through the body. This method requires less skill from the operator and yields consistent results [15].

The goal of this study was to show that ultrasonography with elastography is a valid tool that can be used to tell if a state of the thyroid gland is benign or cancerous by comparing it to the histopathology report. This goal was clarified by examining 20 cases of thyroid enlargement or nodule. Similar to the results of **Garg *et al.*** [14], who observed that 85.4% [n = 100] of the research population was female, we discovered a female predominance in the current investigation, with 8 males [40%] and 12 females [60%] participating. The literature reports a preponderance of females. It appears that predisposing factors include pregnancy, iodine deficiency, cervical irradiation, and menstruation [16].

Patients' ages ranged from 18 to 60 years old in this study, with a mean age of 46.24 ± 4.88 years; this is similar to the findings of a study by **N'gouan *et al.*** [16], who found a mean age of 43.77 14. The ages of the oldest and youngest patients were, respectively, 19 and 71. According to **Brandenstein *et al.*** [17], the participants' ages ranged from 24 to 84 years old, with a mean age of 56 14 years. Two studies [18, 19] found this young adult age. A median age of 40 has also been found by other African authors; three studies [20-22] reported that the average age of people with thyroid functioning abnormalities is 75.50 years in Europe.

Correspondingly, **Abdelshafy *et al.*** [23] reported that the length of the goiter ranged from 6 months to 3 years at presentation to the hospital, so the mean disease duration was 2.31 2.24 years [range, 5 months to 3.6 years].

Thirty percent were hypoechoic in terms of echogenicity, whereas only 18.6 percent were in the study by **Garg *et al.*** [14]. **Baig *et al.*** [24] found that 33.3 percent of their cases were hypoechoic.

Twenty percent of the cases in this investigation exhibited microcalcifications, which is similar to the percentage identified by **Garg *et al.*** [14], who examined the same population of patients. However, 7.1% of participants in **Baig *et al.*** [24]'s study exhibited microcalcifications. In his research, **Zahiri *et al.*** [25] observed that 12.5% of people with thyroid ultrasounds had calcifications, but there was no sign of cancer.

Six [30%] of the patients in our study exhibited irregular nodule borders; 30% were hypoechoic; 20% of the cases had microcalcifications; 25% had no halo; and 30% had no vascularity. Nodule hypoechogenicity [markedly hypoechoic nodules have even greater association with malignancy]; the absence of a peripheral hypoechoic halo; the presence of microcalcifications; an anteroposterior diameter greater than the transverse diameter; irregular contours; and poorly defined margins are all criteria for malignancy risk on ultrasound imaging. Doppler flow studies show that nodules with higher resistance indices in the arteries supplying the nodule are more likely to be malignant, as are nodules with more vascularity in the center than the periphery.

Despite the fact that 25% of thyroid nodules lacked a halo, the capsule or pseudocapsule of the surrounding capsular arteries, fibrous connective tissue, compressed thyroid parenchyma, and persistent inflammatory infiltrates all contribute to the hypoechoic halo seen around most nodules [27]. Most benign nodules have a hypoechoic halo around them. There is a correlation between having no halo and a higher risk of cancer [28].

In investigations using elastography, 50% of the cases were malignant; however, the percentage of malignant thyroid nodules varies widely, from 9.4% in a study by **Azizi *et al.*** [29] to 31.0% in a study by **Moon *et al.*** [7].

Consistent with the findings of **Garg *et al.*** [14], who determined that histopathological diagnosis was benign in 84 nodules and malignant in 33 lesions, this investigation indicated that 70% of the nodules under examination were benign and the other 30% were malignant.

Ten of the twenty Elastography instances in this study were malignant, while the other ten were benign. Of the biopsied cases, six [30%] were malignant, while the other fourteen [70%] were benign. The importance of USE in ruling out malignancy was demonstrated in a series of 142 nodules with indeterminate cytological results by **Rago *et al.*** [30], where only one of 103 nodules classified as negative on elastography had malignancy on histopathological correlation.

The median size of the thyroid nodules analyzed by USG, USE, and FNA in our patients was 14 [9-24] cm^2, according to the study by **Garg *et al.*** [14]. The mean nodule size in the patients studied was 23.510.1 [5 - 40]. Thyroid cancer has been found to have a bimodal distribution [a higher risk in both younger and older age groups], according to some studies [31]. Both the investigations and the meta-analysis by **Campanella *et al.*** [28]

found no statistically significant association between age and malignant nodules.

Similarly, **Campanella *et al.*** [28] found that the highest risk of malignancy for US characteristics was seen for nodule height greater than width, absence of halo sign, microcalcifications, and irregular margins, and the lowest risk was seen for nodule size R4 cm and single nodule, we found a significant relationship in the present study between malignant nodules and nodule size, irregular borders, Hypoechoic, and micro-calcification.

Our findings revealed a substantial connection between malignant nodules and atypical margins. However, uneven margins are a strong indicator of malignancy [PPV: 32.1%-86.7%] [32-35]. Sensitivity: 29.0%-71.4%; Specificity: 87.1%-98.6%. The US pattern of composition or echogenicity is less important in determining the malignancy risk of nodules with irregular edges [32–34]. Compared to partly cystic nodules that are isoechoic or hyperechoic [47.8% - 88.9%] [32, 34, 35], the malignancy risk for irregular edges in solid hypoechoic nodules is similar to or higher. Malignant nodules and micro-calcification were found to have a strong correlation in the current investigation. Total calcification of nodules [1 cm] increases the risk of cancer to between 18.4% and 23.3%. PTCs accounted for 100% of reported malignant tumors with 100% calcified nodules, and the vast majority of PTCs were very aggressive [36]. Microcalcifications have been linked to elevated risk of cancer in a number of prior investigations [33, 37, 38]. It is unclear, however, whether or not this correlation constitutes an additional risk of malignancy [35, 34].

Malignant nodules were significantly associated with larger nodule sizes. **Angell *et al.*** [38], authors of a recent study, found that 14% of benign nodules and 25% of malignant nodules experienced considerable nodule growth according to the ATA criteria. There is still debate about whether or not the pace of nodule growth can be used as an indicator of malignancy risk [38, 39]. Due to the fact that many malignant nodules may not develop into something serious, some benign nodules grow slowly whereas others expand fast, as reported by **Angell *et al.*** [38]. However, high-grade malignancies such anaplastic thyroid carcinoma and lymphoma can cause solid nodules to form quickly.

Contrary to expectations, the present findings show no significant association between malignant nodules and solid content. The solid content of a nodule is an independent predictor of malignancy, as indicated by many authors [32-35, 43].

Consistent with a meta-analysis by **Campanella *et al.*** [28], who found that a family history of thyroid carcinoma is the clinical feature that was associated with a higher risk of thyroid carcinoma, we found a positive correlation between family history and malignant nodules in the present study.

Our results agree with two studies [44, 45], who suggested that a malignancy risk can be elevated in a hypoechoic nodule with a spongiform appearance, we found a positive correlation between hypoechoic and malignant nodules in the present investigation.

Similar to the other reports finding not consistent relationships between vascularity patterns and malignancy risk, we found no statistically significant link between malignant nodules and the vascularity of the nodules. According to **Chung *et al.*** [46], all thyroid nodules, intranodular vascularity has been shown to be no better than gray-scale US alone in predicting malignancy risk [34, 47]. According to a systematic review conducted by **Khadra *et al.*** [48], it is possible that color Doppler US cannot be used to assess the likelihood that thyroid nodules are cancerous.

Our study found that elastography had a sensitivity of 96.6% for distinguishing between benign and malignant thyroid nodules, a specificity of 71.4%, and an accuracy of 80%, numbers that are very close to those found in a study by **Garg *et al.*** [14], who found a sensitivity of 87.88%, a specificity of 88%, and an accuracy of 82.05%. Elastography has been shown to have considerable promise in the diagnosis of thyroid cancer, particularly in nodules with unclear cytology, as described by **Rago *et al.*** [49]. Elastography was shown to have a 100% specificity, 97% sensitivity, 100% positive predictive value [PPV], and 98% negative predictive value [NPV] in the detection of malignant thyroid nodules.

Elastographic assessment of 86 nodules in 67 patients by **Asteria *et al.*** [50] showed 81% specificity and 94% sensitivity. Using a six-scale elasticity scoring system, **Hong *et al.*** [51] in 2012 reached the following conclusions: specificity 90%; sensitivity 88%; positive predictive value 93%; negative predictive value 87%; accuracy 87%. Ultrasound scan was determined to be a specific [67%] and sensitive [83%], according to research by **N'gouan *et al.*** [16].

To date, the largest meta-analysis of pSWE studies has been conducted by **Zhan *et al.*** [52], who looked at information from 2436 thyroid nodules. With an average sensitivity of 80% and specificity of 85%, the authors discovered that pSWE was effective in determining whether nodules were benign or malignant. The pooled sensitivity of pSWE was 86.3% and the pooled specificity was 89.5%, according to a meta-analysis of studies that included a total of 1617 thyroid nodules [53]. Shear wave elastography [SWE] is a unique ultrasonic technology that enables quantitative measurements of tissue elasticity by following the propagation of shear waves through the body. This method requires less skill from the operator and yields consistent results [15].

This discrepancy may be attributable to the 4, 5, or 6-point rating of USE thyroid tissue stiffness and the manner of case section [49, 51, 54].

Although other studies have indicated diagnostic accuracies of 90-95% for elastography [55-57], we found it to be only 80% effective in our own. A poorer diagnostic accuracy of USE was reported for diagnosis of follicular thyroid cancer [58], which is consistent with our own findings. **Zhang *et al.*** [59] and **Dong *et al.*** [53] found that the overall rate of correct diagnoses was 87%. When compared to ultrasound-guided [USG] thyroid assessment, thyroid elastography requires less skill from the operator. Therefore, the repeatability of elastography surpasses that of ultrasound [61]. Similar to our findings, **Baig *et al.*** [24] reported that elastography had an overall diagnostic accuracy of 70.3%.

Four out of nine follicular carcinomas were missed on USE in a meta-analysis published by **Bojunga *et al.*** [55], leading to suggestions that USE is unsuitable for the identification of follicular carcinoma. Thyroid elastography is expected to successfully detect most kinds of thyroid cancer due to the increased stiffness seen in all thyroid tumors [61]. However, elastography has a lower success rate in detecting follicular thyroid carcinoma due to the disease's association with altered elastic properties [61]. Malignant nodules could be ruled out by elastography, as shown by **Zhao *et al.*** [56], who evaluated 103 patients with elastography and found a statistically significant correlation between elasticity score and cytological results.

Conclusion: Ultrasound elastography proves to be an effective and non-invasive tool for diagnosing thyroid nodules, with a significant potential to reduce unnecessary interventions and improve patient care. Its role as a complementary diagnostic technique highlights its importance in guiding treatment decisions and evaluating prognosis for patients with thyroid pathologies.

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