Effect of ultrasound-elastography in diagnosing malignant thyroid nodules: a single-center experience

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Background

Thyroid disease has a common occurrence, especially in iodine-deficient areas. Thyroid nodules have been reported in as many as 50% of the population, on autopsy. They may be discovered in up to 41% of the patients on ultrasonography (US).

Aim

The aim of this study is to introduce the value of US-elastography in the diagnosis of thyroid nodules for reducing the number of unnecessary thyroidectomies, which add burden to the patient and community, and consequently, the complications of this surgery will be reduced.

Patients and methods

This prospective cohort study was conducted at El Demerdash, Ain Shams University Hospital, on 50 patients with the diagnosis of multinodular goiter, who were treated by total thyroidectomy between November 2016 and November 2018, with minimum follow-up of 1 month postoperatively. All patients who accepted to participate in our study were consented for participation after ethical committee approval.

Results

Using the US-elastography, we noted that the scores 3–4 were seen in eight (16%) of 50 patients, where six (12%) of them were malignant and two (4%) were benign. However, the scores 1 and 2 were detected in 42 (100%) patients, and all were benign. The two false-positive patients with scores 3–4 diagnosed with the elastography scoring system could be owing to calcifications and fibrotic changes, rendering the nodules harder. On the contrary, no false-negative results were found as score 1 and 2 by the elastography scoring system. **Conclusion**

Conclusively, in the future, fine-needle aspiration cytology may not be used for the diagnosis of malignancy in patients presented with multinodular goiters who were diagnosed as being suspicious of malignancy by sono-elastography.

Keywords:

diagnosis, thyroid nodules, ultrasound-elastography

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Introduction

Thyroid disease has a common occurrence, especially in iodine-deficient areas. Thyroid nodules have been found in as many as half of the population, on autopsy. They may be discovered in up to 41% of the patients on ultrasonography (US) [1].

The thyroid nodule incidence has increased owing to several factors such as radiation, exposure, iodine intake, early detection, obesity, insulin resistance, genetics, and inorganic phosphates. The annual thyroid cancer rate has increased by 300% [2].

The malignant risk in the patients who undergo fineneedle aspiration cytology (FNAC) is in the range of 9–14%. In multinodular thyroids, the cancer risk per nodule is decreasing, approximately proportional to the increase of the number of nodules; therefore, the cancer rate per patient remains the same as in single nodular thyroids [1].

US is widely used to diagnose and characterize thyroid nodules and to assess diffuse thyroid disease. The main US features indicative of nodular malignancy are solid consistence, hypoechogenicity, 'taller-thanwide' shape, irregular margins or no halo, microcalcifications, and intranodular vascularization at Doppler. However, none of these signs display sensibility and/or specificity at a level that would

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allow either positive diagnosis or exclusion of carcinoma with a high degree of confidence [3].

FNAC is the next accepted diagnostic step. The results may be nondiagnostic, nonneoplastic, atypia/follicular lesion, suspicious of malignancy, and malignant [4].

FNA biopsy allows a definitive benign or malignant diagnosis in 60–80% of all nodules. However, 10–25% of the cases are reported as indeterminate cytologic diagnoses [5].

The most common complications after FNAC are minimal pain or small hematoma. However, in a few patients, a large serious hematoma compressing the upper airway occurred with stridor [6]; in addition, it is important to discuss with the patients that there are false-negative and false-positive results [7].

It is not accepted to biopsy every thyroid nodule diagnosed by US. Different reasons for limiting thyroid biopsy include the small percentage of expected malignant nodules, the small number of cases of thyroid cancer, the economic costs, and the patient anxiety for the possibility of having cancer thyroid. So, reliable guidelines for selecting nodules that need and that do not need biopsy have become essential [8].

Elastography is a general term for the dynamic use of US to provide an estimation of tissue stiffness by measuring to what degree a mass deforms under compressive stress with an estimate of the elasticity degree of a nodule [9].

Ultrasound-elastography has become, in the last decade, the most important addition to the sonographic techniques. With its various approaches to analyzing stiffness and with more than 100 papers published, many of them reporting conflicting results, US-elastography has been the main focus of thyroid US imaging research [10].

In 2008, Asteria *et al.* [11] defined a score of 1 as elasticity that is the nodule is entirely soft, 2 as most of the nodule is soft, 3 as most of the nodule is hard, and 4 as the nodule is entirely hard. In their study, nodules with Asteria scores of 3 and 4 were regarded as suspicious malignant elastographic features [11].

The elastography increases the specificity of gray-scale US in the identification of malignant nodules and in the identification of nodules that require fine-needle aspiration biopsy (FNAB). It must be regarded as an important complement and not a substitute for gray-scale US [12].

The nodules' appearance by elastography can change the need for subsequent FNAB. In the cases of soft nodules, without any gray-scale US suspicious characteristics, the FNAB can be delayed; however, if elastogram showed a hard nodule, then FNAB was indicated, regardless of the aspect in gray-scale US [13].

Most of the recent studies agree that the important role of US-elastography is to indicate which nodules can be followed up without a need for FNAB or surgery. The body of knowledge about thyroid elastography has grown dramatically, even in the short time span from the publication of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) guidelines [14].

Aim The aim of this study is to introduce the value of US-elastography in the diagnosis of thyroid nodules for reducing the number of unnecessary thyroidectomies, which add burden to the patient and community, and consequently, the complications of this surgery will be reduced.

Moreover, the study highlights the value of the multidisciplinary team in the diagnosis and management, as the radiologists and pathologists will have an important role in the preoperative diagnosis and consequently the management regarding the comparison of the results of the elastography, FNAC, and the postoperative histopathological examination of the examined nodules.

Patients and methods

Patients This prospective cohort study took place at El Demerdash, Ain Shams University Hospital, on 50 patients diagnosed with multinodular goiter, who were treated by total thyroidectomy done by the same surgical team between November 2016 and November 2018 with minimum postoperative follow-up of 1 month.

All patients who accepted to participate in our study were consented for participation after ethical committee approval.

Inclusion criteria

The following were the inclusion criteria:

(1) Patients with symptomatic thyroid nodules, for example, compression symptoms.

- (2) Patients with incidental discovery of thyroid nodules during US or computed tomography neck examination.
- (3) Patients with thyroid nodules showing solid or predominantly solid nature by the US.

Exclusion criteria

The following were the exclusion criteria:

- (1) Patients with purely cystic nodules.
- (2) Patients with toxic goiter.
- (3) Patients diagnosed as having thyroiditis.

Method

All patients were subjected to the following.

Preoperative assessment

- (1) Full clinical history including past medical history.
- (2) Full clinical examination including head and neck, chest, abdomen, and vital signs.
- (3) Routine preoperative investigations, for example, blood tests and serum calcium.
- (4) Recent thyroid profile, for example, free T3, free T4, and TSH.

Neck ultrasonography

Real-time conventional US examination was performed for all patients. Positioning of the patients was done in the supine position on their back with slight extension of the neck over a pillow under shoulders with avoiding any over stretching of the neck muscles. Then placing the probe with the US gel on the patient's neck to obtain both transverse and longitudinal images for each thyroid nodule. Specific evaluation and comment on the diameter, cystic nature, and calcification was documented as important excluding points. The nodules were described as solid or predominantly solid if the cystic component was less than 75%.

Marked hypoechogenicity, irregular margin (no halo sign), microcalcifications, and taller than oval shape were considered as suspicious malignant features by the gray-scale US. Presence of one or more of these features renders the nodule 'suspicious nodule,' whereas 'probably benign nodule' was described in their absence.

Ultrasound-elastography

After US, sono-elastography technique (strain elastography) was performed with the same probe using split-screen technology while activating the elastography function.

Gentle sustained manual compression using free hand was applied on the neck. According to the manufacturer, the stiffest structures and the most deformed soft tissues were displayed in different colors, so the stiffest structures with the lowest elastic strain or no strain were displayed in blue or red, whereas the soft tissues with the greatest elastic strain were displayed in green or blue.

Sono-elastography scoring system was performed based on Asteria *et al.* [11] which is the widely used evaluation system for the assessment of thyroid nodules depending on the predominant pattern of color of the nodule.

- (1) Score 1: elasticity is shown in the whole nodule.
- (2) Score 2: large part of the examined nodule showed elasticity.
- (3) Score 3: stiffness is present in a large area of the nodule.
- (4) Score 4: no elasticity in the nodule.

With the scale of 1–4, the score of 3 and 4 indicated a nodule with high suspicion of malignancy.

Fine-needle aspiration for the examined nodules

FNAC with histopathological examination was done for the dominant accessible thyroid nodules as well as the adjacent thyroid parenchyma.

(1) Vocal cord function evaluation and documentation before surgery.

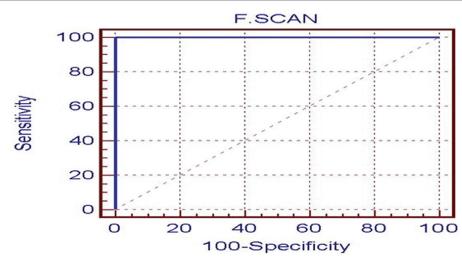
Preoperative comorbid conditions such as hypertension and diabetes were optimized whenever possible before surgery.

Operative technique

After general anesthesia, the patient was placed in supine position with slight neck extension using a pillow or sand bag under the shoulders. Overextension was avoided, especially in the elderly patients. Upward tilting of the operating table was done to reduce venous congestion.

A curved collar incision was done \sim 4 cm above the suprasternal notch extending to the sternomastoid muscle laterally. After division of the skin, subcutaneous tissue, and the platysma, upper and lower skin flaps were raised by a combination of both sharp and blunt dissection in the plane anterior to the anterior jugular vessels.

The upper flap was dissected to the level of the thyroid notch, whereas the lower flap to the suprasternal notch. The skin flaps were held apart with silk sutures (Fig. 1).



Fixation of dissected skin flaps.

Midline incision was made through the fascia over the thyroid, then separation of the strap muscles with its dissection from the thyroid gland was done to be retracted laterally. We did not divide the strap muscles routinely except in large or vascular goiter where greater exposure with safe access was needed.

The thyroid lobe was delivered forward using the index finger between the thyroid lobe and the strap muscles, after which the middle thyroid vein was ligated and divided if present. Further sharp and blunt dissection was done to divide any adhesions lateral to the thyroid with more medial retraction to the thyroid lobe using a gauze swab.

The thyroid lobe was then fully mobilized by ligating and dividing the superior thyroid vessels at the upper pole, with absorbable 2/0 Vicryl suture close to the thyroid gland to protect the external branch of the superior laryngeal nerve from any damage.

The recurrent laryngeal nerve was identified before further dissection of the thyroid lobe took place, so gentle dissection of the overlying fascial layers was done to expose the nerve which usually lies deep to the inferior thyroid artery. Precise identification of the nerve and the artery should be done before ligating any structure. Then the small branches of the inferior thyroid vessels were tied and divided close to the gland staying on its capsule.

To protect the nerve at its most danger point where it enters the larynx passing through Berry's ligament, the suspensory fascia must be divided carefully while staying close to the gland and dissecting it layer by layer being certain that only fascia and small arterial branches were divided (Fig. 2).

Careful identification of the parathyroid glands should be done. During dissection of the thyroid gland, we preserved the inferior thyroid artery branches that supply the parathyroid glands with teasing the parathyroid glands away from the thyroid gland with their intact blood supply, leaving them free but viable.

Further dissection of the thyroid gland was done close to its capsule using the bipolar diathermy while dissecting the gland more medially from its attachment with the larynx and trachea to avoid any heat conduction that could injure the recurrent laryngeal nerve or the blood supply of the parathyroid glands.

After the thyroid lobe was fully mobilized, we started dissection of the isthmus and the pyramidal lobe then the other lobe was dissected by the same manner described above with safe identification of the recurrent laryngeal nerve and parathyroid glands of the other site as mentioned before. The total thyroid specimen was excised and sent for histopathology (Fig. 3).

Re-examination of the operative bed for any bleeding was done. Single-limbed suction drain was placed deep to the strap muscles and brought laterally.

The midline was sutured by 3/0 Vicryl interrupted sutures, then the platysma was closed separately by 3/0 Vicryl sutures, and then the subcutaneous layer followed by continuous subcuticular closure of the skin by 3/0 Prolene suture or 3/0 PDS suture.

Figure 2



Identification of the recurrent laryngeal nerve (RLN).

Postoperative follow-up

Early postoperative follow-up during hospital stay included the following:

- (1) Vital signs: blood pressure, pulse, temperature, and respiratory rate.
- (2) Voice and swallowing.
- (3) Manifestation of hypocalcaemia and calcium levels for iatrogenic hypoparathyroidism.

Follow-up was done in the outpatient clinic at 1, 2, and 4 weeks and following the operation to follow-up the progression of patient as well as to detect possible postoperative complications.

Outcome measures

The outcome measures were concluding the elastography sensitivity and specificity in the diagnosis of thyroid nodules by correlation of the histopathological results of the specimens with the preoperative conventional neck US, US-elastography, and FNAC examination results.

Statistical analysis

Data were collected, revised, coded, and entered to the Statistical Package for Social Science (IBM SPSS), version 23 (Armonk, NY: IBM Corp.). The

Figure 3



Excised thyroid gland sent for histopathology.

quantitative data were presented as mean, SDs, and ranges when their distribution was found to be parametric. Moreover, qualitative variables were presented as number and percentages.

So, the *P* value was considered significant as follows:

- (1) P value more than 0.05: nonsignificant
- (2) P value less than 0.05: significant
- (3) P value less than 0.01: highly significant.

Results

The duration of the goiter ranged from 6 months to 3 years at presentation to the hospital. All goiters were multinodular. Slow-growing goiters were 41 (82%), (growing over 2–3 years) and rapid-growing goiters were nine (18%), (growing over 6–9 months) (Fig. 4). All the 50 participants were euthyroid, as shown in Table 1.

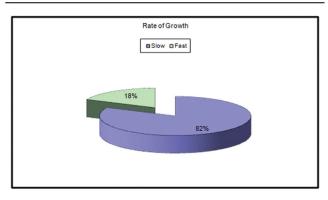
The relation between the conventional US findings and their corresponding postoperative histopathology results for all the patients is showed in Table 2, with statistical significance regarding the nodule margins, echogenicity, and presence of halo (Fig. 5).

The sonographic findings suspecting malignancy whether positive or negative were related to the histopathological examination, as shown in Tables 3 and 4.

Table 4 shows a 2×2 table used to calculate US's sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) (Fig. 6).

Table 5 shows a 2×2 table used to calculate FNAC's sensitivity, specificity, PPV, and NPV.

Figure 4



Rate of goiter growth in all patients.

The relation between the elastosonography findings and their corresponding postoperative histopathology results for all the patient showed that all the 42 patients with elasticity score favoring benign nature of the nodule (score 1-2) were confirmed benign by histopathology, whereas of the eight patients with elasticity score favoring malignancy (score 3-4), only six were confirmed malignant by the histopathology, as shown in Tables 6 and 7.

Table 7 shows a 2×2 table used to calculate elastosonography's sensitivity, specificity, PPV, and NPV (Fig. 7).

Discussion

Thyroid nodules represent a major challenge in its diagnosis and safe management for clinicians, radiologists, and pathologists. Extending the use of cross-sectional imaging has increased the incidental discovery of thyroid nodules in patients undergoing non-thyroid investigations, which subsequently need further investigations, whereas increased risk of thyroid malignancy may be predicted by the clinical factors [15].

Physical examination and symptoms only were poor to identify malignant thyroid lesions; therefore, clinical assessments together with radiological and pathological evaluation were important to discriminate the relatively rare thyroid malignancy from common benign thyroid nodules. A pragmatic approach to thyroid nodules should be applied to avoid unnecessary investigations and surgical interventions for those lesions with low risk for malignancy [16].

Several studies investigated US and its value in evaluating the thyroid nodules. The American Thyroid Association released its latest guidelines recommending US as the next step in the workup of

Table 1 Clinical characteristics of the patients	Table 1	racteristics of the patients
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<i>N</i> =50	n (%)
Type of thyroid enlargement	
Nodular	50 (100)
Type of nodularity	
Multinodular	50 (100)
Functional state	
Euthyroid	50 (100.0)
Rate of growth	
Slow	41 (82)
Fast	9 (18)

palpably detected thyroid nodules, if thyroid function test results were normal [17].

It must be noted that US is operator and instrument dependent. Specific criteria by US have been described to differentiate between malignant and benign lesions. However, US is not accepted in any reference as the only method to make a final approach decision for thyroid nodules [18].

Multiple suspicious malignant criteria by US were reported in other similar studies. In our study, we took four criteria suspecting malignancy: irregularity of the margins, hypoechogenicity of the nodules, absence of halo, and calcifications, as reported in Moon *et al.* [18]. Beside the previous four criteria, we added the assessment of the vascularity (peripheral or central). Perithyroid tissue invasion was excluded for being a sign of advanced malignancy. It was considered not reliable in case we found the suspicious sonographic features each alone.

Suspicious criteria such as hypoechogenicity, microcalcifications, margin irregularity, and hypervascular patterns were all found separately in benign nodules proved by histopathology, whereas all these criteria were found in US report of seven (14%) patients in our study and four (8%) of them were malignant in the postoperative histopathology results.

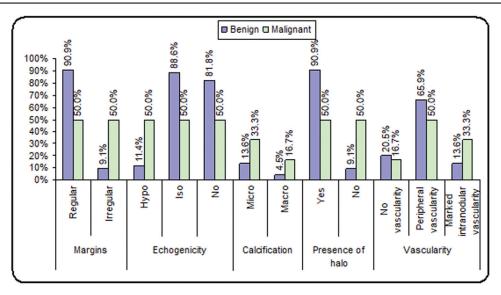
In our study, conventional sonography has 66.66% sensitivity and 93.2% specificity as it suspected malignancy (positive suspecting findings) in seven patients; four of them were confirmed malignant and three of them were confirmed benign by histopathological examination of the specimens accounting for low PPV (57.14%) and it suspected benignity (negative suspecting findings) in 43 patients; 41 of them were perfectly correlated with the histopathology, accounting for high NPV (95.34%). These results showed nearly the same values of the

Table 2 Conventional	ultrasonographic	findings and their	corresponding	postoperative	histopathology results

US	Findings	Ν	Patholo	Pathology[n (%)]	
			Benign	Malignant	
Margins	Regular	43	40 (90.9)	3 (50)	0.007
	Irregular	7	4 (9.1)	3 (50)	
Echogenicity	Нуро	8	5 (11.4)	3 (50.0)	0.015
	Iso	42	39 (88.6)	3 (50.0)	
	No	39	36 (81.8)	3 (50.0)	0.196
Calcification	Micro	8	6 (13.6)	2 (33.3)	
	Macro	3	2 (4.5)	1 (16.7)	
Presence of halo	Yes	43	40 (90.9)	3 (50.0)	0.007
	No	7	4 (9.1)	3 (50.0)	
	No vascularity	10	9 ((20.5)	1 (16.7)	
Vascularity	Peripheral vascularity	32	29 (65.9)	3 (50)	0.466
	Marked intranodular vascularity	8	6 (13.6)	2 (33.3)	

US, ultrasonography.^a χ^2 test *P* value more than 0.05: nonsignificant; *P* value less than 0.05: significant; *P* value less than 0.01: highly significant.

Figure 5



Conventional US findings and their corresponding postoperative histopathology results. US, ultrasonography.

 Table 3 Patients with positive or negative suspicious

 ultrasonography findings of their examined nodules

Sonographic findings suspecting malignancy	Ν	Histopathology
Positive		Malignant 4
Irregular		
Hypoechogenicity	7	
No hale		
Micro/macro calcify		
Central vascularity		Benign 3
Negative		Malignant 2
Regular		
Iso/hyper echogenicity		
Presence of halo	43	
No calcification		
No/peripheral vascularity		Benign 41

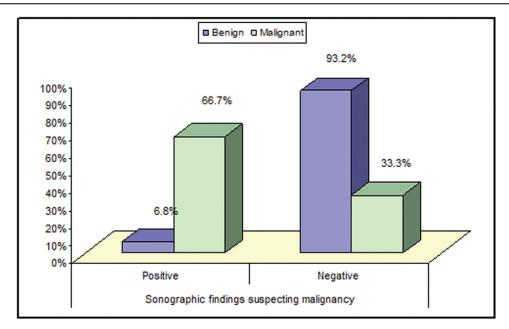
Table 4 2x2 table (sonographic findings of the examined nodules)

Sonographic findings suspecting malignancy	Histopatho	Histopathology [n (%)]	
	Benign	Malignancy	
Positive	3 (6.8)	4 (66.7)	
Negative	41 (93.2)	2 (33.3)	

conventional sonography in the previous studies done regarding this concern.

The relatively high percentage of the false-positive results found by the gray-scale US is considered its main drawback, which may lead to a large number of unnecessary biopsies.





US sensitivity, specificity, positive predictive value and negative predictive value. US, ultrasonography.

Table 5 2×2 table (fine-needle aspiration cytology findings th	е
examined nodules)	

Cytopathology	Histopathology [n (%)]	
	Malignancy	No malignancy
Positive	4 (80.0)	3 (6.67)
Negative	1 (20.0)	42 (93.33)

Although the American Thyroid Association recommended using the FNAC as the procedure of choice to evaluate thyroid nodules [17], the differentiation between malignant and benign lesions by FNAC could be sometimes hard and difficult. FNAC is specifically inadequate to differentiate between follicular adenoma and carcinoma, which are more common than other lesions [19].

FNAC may be inadequate and not completely accurate for diagnosis in multinodular goiter, as the sensitivity, specificity, and the PPV of FNAC in thyroid malignancies were documented as 65–82%, 52-68%, and 63-89% respectively [20]. Moreover, FNAC was reported nondiagnostic in 12–20% of the cases in these studies [21].

In this study, FNAC showed a sensitivity of 80% by detecting patients with cancer thyroid and a specificity of 93.3% by distinguishing healthy individuals. The NPV was 97.7%, whereas the PPV was 57.14%. So our study results were near to the study findings of Kizilkaya *et al.* [22] regarding FNAC specificity and its PPV, which were 84.5 and 52.6%, respectively, although Kizilkaya

Table 6 Comparison of elastosonography and postop	erative
histopathology results	

Elastosonography score	n (%)		ology (%)]			
		Benign	Malignant			
Favouring benign (scores 1–2)	42 (84)	42 (95.5)	0			
Favouring malignancy (scores 3–4)	8 (16)	2 (4.5)	6 (100.0)			

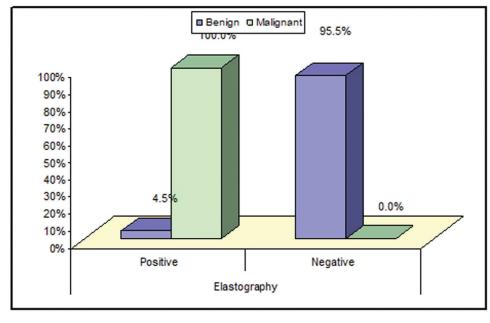
Table 7	2×2	table	(elastography	findings	of the e	examined
nodules)					

Elastography	Histopatho	Histopathology [n (%)]		
	Benign	Malignancy		
Positive	2 (4.5)	6 (100.0)		
Negative	42 (95.5)	0		

et al. [22] showed lower sensitivity (35.7%) and lower NPV (73.1%) than our results.

In our study, the FNAC sensitivity and specificity in cancer detection was near to the literature, but the PPV was lower when compared with the literature; this could be owing to different factors such as radiology, pathology, the materials used in FNAC, and the presence of multiple nodules. Moreover, the invasive nature of the FNAC is considered another disadvantage. Because of all these disadvantages, we searched in our study for a noninvasive method with fewer variables that could be used in the diagnosis and management of patients with multinodular goiter.





Elastosonography's sensitivity, specificity, positive predictive value and negative predictive value.

Hence, introducing the elastographic assessment beside the conventional gray-scale US had a great advantage in improving the sensitivity, specificity, and the PPV. The scoring system of the elastography depends upon the analysis of color distribution after being superimposed on the B-mode image plus it can minimize or even eliminate the role of FNAC in diagnosing patients with multinodular goiter preoperatively. In our study, we investigated the elastography and its supplementary role in the diagnosis of thyroid nodules, as our elastographic findings were able to discriminate malignant nodules from the benign ones. Rago et al. [23] reported the great potential of elastography in diagnosing thyroid cancer, specifically in nodules with indeterminate cytology. They documented that the specificity, sensitivity, PPV, NPV, and accuracy of the elastography in the diagnosis of malignant thyroid nodules were 100, 97, 100, 98, and 96%, respectively. Asteria et al. [11] have reported in their elastographic evaluation of 86 nodules in 67 patients a specificity of 81% and sensitivity of 94%. In 2012, Hong et al. [24] concluded that specificity, sensitivity, PPV, NPV, and accuracy were 90, 88, 81, 93, and 87%, respectively, using a six-scale elasticity scoring system.

Later on, the existing body of knowledge allowed the elaboration of several meta-analyses which offer a more comprehensive view on the usefulness of the elastographic techniques.

In our study, we used the same elasticity scoring system of Asteria *et al.* [11]. Our study showed comparable

results with their study regarding the PPV and NPV of the scan but with higher sensitivity and specificity as their study reported a sensitivity, specificity, PPV, and NPV of 94, 81, 71.5, and 92.5%, respectively, whereas in our study, it was 100, 95.45, 75, and 100%, respectively.

Using the US-elastography, we noted that the scores 3–4 were seen in eight (16%) of 50 patients, and six (12%) of them were malignant and two (4%) were benign, However, the scores 1 and 2 were detected in 42 patients, and all were benign (100%). The two false-positive patients with scores 3–4 diagnosed with the elastography scoring system could be owing to calcifications and fibrotic changes rendering the nodules harder. On the contrary, no false-negative results were found as score 1 and score 2 by the elastography scoring system.

So, the combination of the conventional US and the elastographic parameters with a sensitivity of 100% and specificity of 95.45% allows us to determine a group of patients with benign lesions with a high degree of certainty.

In our study, all patients were enrolled without any previous selection, unlike some past studies where bias in sample selection was noticed, for example, selecting patients who were referred for surgery.

Based on this study results, elastography may assist in the diagnosis of all patients with thyroid nodules, especially if done in selected cases, such as indeterminate or suspicious FNAC, as it would yield more applicable results most probably.

Some limitations were found in our present study, such as the insignificant predictive value of the elastography in differentiating benign thyroid nodules from the malignant ones, which may be owing to the small sample size, electing participants from the entire referred population without any preliminary selection, and as a result, the low number of malignant nodules.

Conclusion

In the future, FNAC may not be used for the diagnosis of malignancy in patients presented with multinodular goiters who were diagnosed as suspicious of malignancy by sono-elastography.

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Conflicts of interest

There are no conflicts of interest.

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