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Research Paper

Value of 2D Shear Wave Elastography in Suspicious Thyroid Nodules

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ABSTRACT:

BACKGROUND:

Thyroid nodules are found in one every two people, who checked under ultrasonography examination. Though only 4-7% are clinically noticeable, there is increased in cancer incidence. Shear wave elastography (SWE) is simple noninvasive method to differentiate between benign and malignant nodules.

OBJECTIVE:

To assess the differences in shear wave elastography indices between benign and malignant thyroid nodules by generating a cutoff value with best sensitivity and specificity.

PATIENTS AND METHODS:

A total of 55 patients with solid thyroid nodules were evaluated by conventional ultrasonography and shear wave elastography were mean shear wave elasticity indices measured followed by ultrasound guided fine needle aspiration cytology ,were histopathology was available for 7 patients.

RESULTS:

The results shows that the mean shear wave elastography parameter were higher in malignant thyroid nodules compared with benign ones. Nodules with irregular margins and micro-calcifications had significantly higher Mean elasticity and elasticity ratio ($P<0.05$) to those with macro-calcifications or no calcifications. Receiver operating characteristic curve analysis was constructed for shear wave elastography parameters as predictors of malignant thyroid nodules. The best predictors were Elasticity–mean (E-mean) of >47.2 with 94.1% sensitive, 97.4% specific, and 96.4% accurate in diagnosis of malignancy. When combining signs of high suspicion of malignancy (thyroid imaging reporting and data system 4-5 and cut point > 47.2 kilopascal of Elasticity- mean), the sensitivity was 82.4%, specificity was 97.4%, and accuracy was 92.7% in differentiation between benign and malignant thyroid nodules, with positive predictive value and negative predictive value of 93.3% and of 92.5%, respectively.

CONCLUSION:

Shear wave elastography indices were all significantly higher in malignant thyroid nodules compared to benign ones. The cut-off value of Elasticity mean (E-mean) (47.2 kilopascal) had a sensitivity of 94.1, specificity 97.4, positive predictive value 94.1%, negative predictive value 97.4%, and an accuracy 96.4%.

KEYWORDS: Shear wave elastography, thyroid imaging reporting and data system.

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INTRODUCTION:

Thyroid nodule disease is common problem in the community especially in women occurring up to 50% in general population, however only 7-15% can carry risk of cancer(1,2). Most thyroid nodules are benign and the commonest cause is nodular hyperplasia(1).

Although cancerous thyroid nodules account for 7% ,it is important to identified it correctly and accurately(2). They can be identified during routine physical examination or by conventional ultrasound, computed tomography, magnetic resonance imaging and 18 FDG-PET scanning(2). High resolution ultrasound is simple, easy, inexpensive and noninvasive method that can be used as first line modality for evaluating thyroid nodules(3). Ultrasound provide information about the presence, site, size of nodules and also give details about composition and other nodules features that may related to their histopathology(2).

Ultrasound used as a guide for fine needle aspiration cytology (FNAC) for nodules that are suspicious[4]. There are many features in thyroid nodules than can be evaluated by conventional ultrasound and its existence increase suspicion of that nodule being malignant[5]. American college of radiology- Thyroid imaging and reporting data system (ACR-TIRADS) scoring system is a new system that published in 2017 which provide risk stratification system in order to classify thyroid nodules according to their appearance on ultrasound[3]. According to ACR-TIRADS thyroid nodules features by ultrasound classified into 5 categories including echogenicity, composition, margin, shape and echogenic foci in which each feature is assigned from 0-3 points [3]. The total score for the nodule determine its risk level which is ranged from TIRADS 1(benign) to TIRADS 5 (highly suspicious)[6]. Finally when measuring maximum diameter of the nodule and its TIRADS score level, these determine whether the nodule will be followed up by ultrasound examination or recommends FNA biopsy[6]. Ultrasound criteria for malignant nodules include shape (taller than wider), echogenicity (markedly hypo echoic), margins(spiculated) and the presence of calcification (micro-macro calcification)[7]. Elastography is a new and noninvasive imaging technique that has been used in addition to ultrasound to measure tissue stiffness[8]. SWE was firstly proposed in diagnosing thyroid nodules in 2010 by Sebag et al [8]. Tissue stiffness is determined by structural properties of its matrix [9]. When there is pathological changes ,such as tumor or inflammation, this will alter tissue composition and structure and also increased lesion stiffness[9]. In SWE, the elastic pulses from the probe stimulate a target tissue providing shear wave (SW) passing perpendicular to conventional ultrasound wave[10]. Shear waves are the transverse component of particle that rapidly attenuated by the tissue (1-10m/s), this transverse component measured as numerical value corresponding to shear wave speed[11]. The speed is related to Young modulus formula in which elasticity assessed from shear wave propagation speed[11,9]. Two methods used for clinical evaluation of thyroid nodules, point shear wave and 2Dshear wave elstography[12]. In 2D SWE, a color coded map of shear wave speed displayed in the field of view (FOV) when activated so one or more measurement region of interest (ROI) can be put in the FOV[10]. The stiffness of particular ROI include mean stiffness (E mean), maximal stiffness(E-max) and minimal stiffness(E=min) expressed as shear wave speed (m/s)or elasticity (Kpa)[13].

AIM OF THE STUDY:

To assess differences in SWE indices between benign and malignant thyroid nodules by generating a cutoff value with best sensitivity and specificity in combination with TIRADS system.

PATIENTS AND METHODS:

Study design: This prospective study was conducted in the Radiology Department, Oncology teaching hospital, medical city complex/ Baghdad/ Iraq, during the period from April, 2021 to December, 2021.

The ethical approval was taken from scientific committee of the Iraqi board of diagnostic radiology. An oral informed consent was taken from all patients.

Inclusion criteria:

Adult patients aged ≥18 years, Suspicious TIRADS III, IV and V nodules, when a patient had numerous thyroid nodules the one that seemed the most suspicious was chosen, no therapy or biopsy before US examination, thyroid nodule diameter between 8mm and 40mm), patients with solid or mostly solid thyroid nodules (cystic part<50%). **Exclusion criteria :** Diffuse thyroid disease, nodules that had undergone FNA, previous history of radiation therapy of head and neck region, previous diagnosis of thyroid cancer, insufficient FNAB sample for pathological diagnosis (Bethesda I) or samples with results of atypia of undetermined significance (Bethesda III).

Ultrasonographic examination:

conventional US and SWE scans were performed using a real-time US device (Philips epic elite) equipped with eL18-4MHz linear array transducer. All SWE parameters were adjusted to allow for distinct and complete imaging of the nodules.

When patients lied on the bed in a supine position with slight extension of the head, the suspicious areas, including the target nodules and adjacent surrounding tissues were thoroughly scanned. The suspicious nodules with the higher TIRADS score [3,4,5] was chosen. For patients with more than 1 nodule, if the nodules were in the same TI-RADS category, the largest lesion was selected. For nodule with TIRADS 3 score, nodule size > 2.5cm was selected.

In a free hand technique, SWE imaging was acquired on longitudinal sections. The probe was placed gently on the patient's neck without excessive external compression. The real-time

SWE were displayed in dual mode alongside the grey-scale US images for evaluating the anatomical location. The region of interest (ROI) (Q-box) of the system was placed in the thyroid nodule with surrounding normal parenchyma, which showed translucent colored area of tissue hardness overlaid B-mode image with a range from blue to red. The lowest hardness was presented blue and the highest hardness was presented red (0-200 kPa).

Fixed 2×2-mm ROIs were located over the stiffed part of the lesion, avoiding visible calcifications, cystic component and artifacts with optimal image showing color homogeneity on the screen. A second same sized ROI was located in the normal thyroid parenchyma. The SWE system analyzed elasticity parameters of E-average (mean) (mean value of the ROI located in the stiffed region), E-max (maximum value of the ROI located in the stiffed region), and E-min (minimum value of the ROI located in the stiffed region), was calculated automatically. Elasticity ratio (ER) is the ratio of mean stiffness of lesion to normal surrounding parenchyma. We acquired three or more SWE cine loops that lasted for >10 seconds (s) from each lesion for analysis. During examinations, patients were asked to refrain from movements and hold their breath for at least 3s. After SWE, nodules underwent US-guided FNAC.

Statistical analysis : The data analyzed using Statistical Package for Social Sciences (SPSS) version 26. The data presented as mean, standard deviation and ranges. Categorical data presented by frequencies and percentages. Independent t-test and Analysis of Variance (ANOVA) (two tailed) was used to compare the continuous variables accordingly. Chi-square test was used to compare the US findings with benign and malignant thyroid nodules. The diagnostic ability of SWE parameters to differentiate malignant from benign thyroid nodules was evaluated using Receiver operating characteristic (ROC). A level of P – value less than 0.05 was considered significant.

RESULTS:

A total of 55 patients with solitary (n=25) and multiple (n=30) thyroid nodules were included in this study. In patient with multiple nodules (multi-nodular thyroid), the most suspicious nodule was selected. Thyroid nodules with ACR-TIRADS III, IV and V included in this study based on US findings.

According to the histopathological examination, the final status of the enrolled thyroid nodules was benign in 38 patients (69.1%) and malignant in 17 (30.9%). (Figure 1).

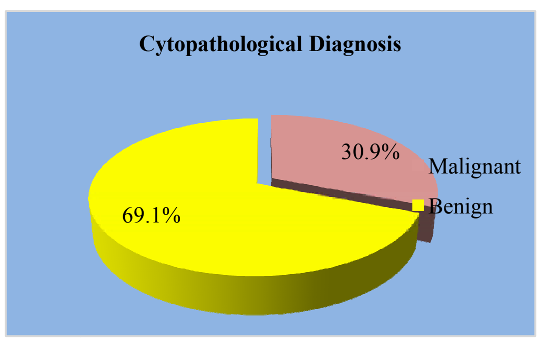

Figure 1: Distribution of the study patients by results of histopathology.

In the present study, US features that significantly associated with an increased risk of malignancy were solitary nodule (44%, P=0.043), irregular margins (68.8%, P= 0.001), micro-calcifications (80%, P= 0.036), and TIRADS 5 (87.5%, P= 0.001). (Table 1).

Table 1: Distribution of study patients by histopathological diagnosis and US findings.

US Findings	Histopathological Diagnosis		Total (%) n= 55	P-Value
	Malignant Lesion (%) n= 17	Benign Lesion (%) n= 38		
Multiplicity				
Solitary Nodule	11 (44.0)	14 (56.0)	25 (45.5)	**0.043**
Multiple Nodules	6 (20.0)	24 (80.0)	30 (54.5)	
Margins				
Well Defined	6 (15.4)	33 (84.6)	39 (70.9)	**0.001**
Irregular	11 (68.8)	5 (31.3)	16 (29.1)	
Taller than Wide	1 (50.0)	1 (50.0)	2 (3.6)	
Calcifications				
No	7 (22.6)	24 (77.4)	31 (56.4)	**0.036**
Macro-calcifications	6 (31.6)	13 (68.4)	19 (34.5)	
Micro-calcifications	4 (80.0)	1 (20.0)	5 (9.1)	
TIRADS				
III	2 (25.0)	6 (75.0)	8 (14.5)	**0.001**
IV	8 (20.5)	31 (79.5)	39 (70.9)	
V	7 (87.5)	1 (12.5)	8 (14.5)	

Generally, the mean SWE parameters were significantly higher in malignant nodules as compared with the benign ones as shown in (Table 2).

Table 2: Comparison between thyroid lesions according to the SWE parameters.

SWE Parameters	Histopathological Diagnosis		P - Value
	Malignant Lesions Mean ± SD	Benign Lesions Mean ± SD	
E-max (kPa)	76.9 ± 22.01	37.9 ± 11.96	**0.001**
E-mean (kPa)	64.3 ± 17.3	31.1 ± 10.3	**0.001**
E-min (kPa)	52.1 ± 12.1	25.5 ± 8.11	**0.001**
ER	3.78 ± 1.49	2.30 ± 1.03	**0.001**

ER =Elasticity ratio (mean stiffness of lesion to normal parenchyma)

The best cut point of E-max was 50.9 kPa. The sensitivity (SN), specificity (SP), and accuracy (Acc) of E-max in diagnosis of malignant thyroid lesions were 94.1%, 94.7%, and 94.5%, respectively, with 88.9% PPV and 97.3% NPV. The cut point of E-mean was 47.2 kPa, and it was 94.1% sensitive, 97.4% specific, and 96.4% accurate in diagnosis of malignancy and (Table 3).

Table 3: Diagnostic accuracy of SWE parameters in predictions of malignant thyroid nodules.

SWE Parameters	Cut-off value	SN	SP	PPV	NPV	Accuracy
E-max (kPa)	50.9	94.1%	94.7%	88.9%	97.3%	94.5%
E-mean (kPa)	47.2	94.1	97.4	94.1%	97.4%	96.4%
E-min (kPa)	34.1	94.1%	94.7%	88.9%	97.3%	94.5%
ER	2.26	94.1%	63.2%	53.3%	96%	72.7%

The sensitivity, specificity, accuracy, PPV and NPV in differentiating benign from malignant thyroid nodules were 94.1%, 18.4%, 41.8%, 34% and 87.5% respectively for TIRADS by conventional US (Table 4).

Table 4: Sensitivity, specificity, and accuracy of TIRADS in diagnosis of thyroid lesions.

TIRADS	Histopathological Diagnosis		Total
	Malignant	Benign	
(Suspicious) IV and V	16	31	47
(Probably benign) III	1	7	8
Total	17	38	55

When combining signs of high suspicion of malignancy (TIRADS 4-5 and cut point >47.2 kPa of E- mean), the SN was 82.4%, SP was 97.4%, and accuracy was 92.7% in differentiation between benign and malignant thyroid nodules, with PPV and NPV of 93.3% and of 92.5%, respectively (Table 5).

Table 5: Sensitivity, specificity, and accuracy of US TIRADS 4-5 and SWE- mean in diagnosis of thyroid lesions.

Combined TIRADS + SWE-mean (kPa)	Histopathological Diagnosis		Total
	Malignant	Benign	
Malignant	14	1	15
Benign	3	37	40
Total	17	38	55

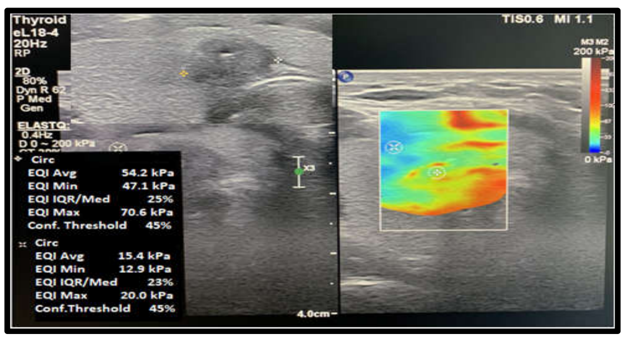

Figure 2: A 33 years old female with multiple nodules. B mode US shows solid hypoechoic nodule with macrocalcification (TIRADS4). (SWE) displayed relatively heterogenous color elasticity signal. Measured elasticity parameters of E -Avg of 54.2 kPa, E-max of 70.6kPa and E-min of 47.1 kPa were obtained suggesting malignant nodule. FNAC revealed (Bethesda 4 suspicious for follicular neoplasia), patient underwent total thyroidectomy and final histopathological diagnosis was papillary carcinoma.

DISCUSSION:

To our knowledge, this is the first study in Iraq that investigate the new generation of elasticity imaging modalities using shear wave elastography (SWE) rather than the established and widely used strain elastography method in evaluating thyroid nodules. Furthermore, we assessed the diagnostic performance of a combination of SWE and ACR TI-RADS categories in comparison to the performance of TI-RADS alone.

According to the multiplicity of thyroid nodules, our study found that 11/17 (64.7%) of malignant lesions were single nodules as opposed to 35.3% of malignant lesions which were part of multi-nodular goiter. Similarly, a larger study conducted by Al-Hakami et al (14) included 987 patients where 420 (42.6%) with a solitary thyroid nodule and 567 (57.4%) with multi-nodular goiter (MNG). The occurrence of malignancy was statistically significant between solitary nodules and MNG (p<0.001). Of the 567 patients with multiple nodular disease, there were 458 patients with benign nodules and 109 patients with malignant nodules. Out of 420 patients with solitary thyroid nodules, there were 192 patients with malignant nodules and 228 with benign nodules. As a result, they claim that solitary thyroid nodules are a predictor of cancer, which is agreed with the current study.

TI-RADS assessment of a nodule entails a thorough examination of its composition, echogenicity, shape, margin, and echogenic foci. The points assigned to these characteristics are cumulative and given a higher weight than in other systems. Our results showed that the rate of malignancy was significantly higher in TI-RADS 5 as compared with others TI-RADS 3 and 4 consistent with many other studies[15]. Malignant nodules, in our cohort, associated significantly with irregular margin and the presence of echogenic foci consistent with many other studies[16,17].

Shear wave elastography is a relatively newer technique that is more reliable and reproducible than older variants of elastography [18]. The role of SWE in thyroid nodule evaluation has not been investigated in Iraq thus far. The current study demonstrated that the quantitative parameters of elasticity indices of SWE (E-max, E-mean, E-min and E ratio) were significantly higher in malignant thyroid nodules in comparison to benign nodules. This observed correlation between SWE indices and the likelihood of thyroid malignancy is consistent with other recent international studies [19,20,21]. Out of the four indices, E-mean and E-max are the most frequently utilized[22].

According to SWE parameters values in prediction of malignant thyroid nodules, in our study, in which 30.9% of the nodules were malignant, the optimal cutoff value of E-mean was 47.2 kPa and E-max was 50.9 kPa, these results were close to the value reported by other studies which ranged between 30.5 -85.2 kPa for E-mean and 26.6-54.5 kPa for E-max as detailed in summary Table 1. The SWE index with the highest diagnostic efficiency in our study was E-mean with a sensitivity and specificity of 94.1% and 97.4% respectively which is higher than what has reported previously Table below.

Summary of studies which reported the SWE cutoff values in the last ten years.

Author	Year	Study groups	SWE Indices	Cutoff value	Sensitivity	Specificity
Huang *et al*(23)	2020	Ca =48 BN =23	E-max E-mean E-ratio	54.5 kPa 39.9 kPa 2.2	68% 60.42% 72.92%	91.30% 91.30% 78.26%
Wang *et al.*[24]	2017	Ca =106 B=216	E-max E-mean	47.0 kPa 23.0 kPa	59.4% 60.4%	90.0% 91.2%
Duan *et al.*(25)	2016	Ca =91 BN =76	E-mean E-max	34.5 kPa 53.2kPa	83.7% 82.1%	77.4% 62.3%

Before 2017, SWE and B-mode characteristics have been combined by Dobruch-Sobczak et al.(26) to improve cancer detection rate, however, no substantial improvement in the distinguishing of malignant from benign thyroid nodules was seen. After the release of ACR-TIRDS, several studies have examined the benefit of combining the TIRADS with SWE to improve its limited specificity, Hang et al.[27] showed that AUC of the SWE+ TIRADS score was 0.917 as compared to the TIRADS-alone score of 0.896, however, statistically, their results were not significant. Later, Tuan et al(28). Depicted that the sensitivity of gray scale US alone was significantly greater than the sensitivity of gray scale US combined with SWE (P<0.0001). In contrast, the specificity of the combination of gray scale US and SWE was significantly greater than that of gray scale US alone (p = 0.007). Recently, Baz et al.[21] reported in a cohort of 99 patients that combined TI-RADS and SWE (E-mean) had better sensitivity for detection of malignancy (84.8% vs. 90.%) but further reduce the specificity (83.3% vs. 68.1%). We have shown that combining SWE (E-mean) with TI-RADS substantially improves the specificity (97.4% vs. 18.4%) and test accuracy (92.7% vs. 41.8%), however, it slightly reduces the sensitivity (82.4%, vs. 94.1%). In practice refining the number of false-positive cases from 31 to 1 reduces the need for an unnecessary sampling of the nodule and assures the patient, however, follow up with size monitoring will help to reduce the possibility for missing false-negative cases.

CONCLUSION:

TI-RADS is highly sensitive but with low specificity in differentiation benign from malignant thyroid nodules. Shear wave elastography indices were all significantly higher in malignant thyroid nodules compared to benign ones. The best cut-off value of E-mean (47.2 kPa) had a sensitivity of 94.1%, specificity 97.4%, PPV 94.1%, NPV 97.4%, and an accuracy 96.4%.Combining E-mean with TI-RADS significantly improves TIRADS specificity and reduces the high false-positive results.

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