Eur J Transl Myol 32 (4): 10635, 2022 doi: 10.4081/ejtm.2022.10635

Comparing shear wave elastography and fine needle aspiration in the diagnosis of solid thyroid nodules

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Abstract

This descriptive study was performed on individuals who were referred to Imam Reza Hospital for fine needle aspiration biopsy (FNAB) based on the results of gray scale ultrasound and the decision of the referring physician. In addition to determining the gray scale characteristics of the nodules, shear wave elastography (SWE) was also performed and the results were recorded. These were also taken from the patients FNAB results. Finally, the findings of SWE and FNAB methods were compared and analyzed using SPSS software version 16. Based on the results presented herein, a significant relationship was observed between the results of SWE and FNA in the diagnosis of malignancy in solid thyroid nodules. This agreement was found to be higher in men (K = 0.866) than women (K = 0.849). Taken together, our data suggest that shear wave elastography can replace FNA in the diagnosis of malignancy in solid thyroid nodules.

Key Words: Fine-needle aspiration (FNA); shear wave elastography (SWE); thyroid nodule.

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Thyroid nodules are palpable or non-palpable, detected by imaging masses in the thyroid gland that cause Thyroid Nodule Disease (TND).[1] This complication may be due to a multitude of thyroid disorders and is one of the most common endocrine disorders, the prevalence of which has gradually increased in recent years. While most are benign, about 5% of all palpable nodules are malignant.[1-3] Methods used to assess thyroid nodules include: measurement of serum levels of thyroid hormones, radioisotope scanning, ultrsonography and fine needle aspiration biopsy.[4] Fine-needle aspiration biopsy *(*FNAB*)* is currently the standard method for distinguishing between benign and malignant thyroid nodules.[5] In fact, the routine method is nodule examination, gray scale ultrasound properties and Doppler characteristics of the lesion.[6] If necessary, based sonographic findings, patients are referred for *FNAB* and the treatment method is decided based on the pathology result.[7] In recent years, elastography has been used to diagnose pathologies of organs, including the thyroid. In this method, the amount of tissue stiffness is measured. Elastography is performed by two methods including Shear Wave Elastography (SWE) and Strain Elastography (SE).[8] In the SE method, the tissue is repeatedly pressed with an ultrasound probe, and the device shows a qualitative estimate in the form of color codes of tissue stiffness by calculating the displacement of tissue points due to pressure. In SE method, the result depends on how the probe is pressed by the performer, which is not precisely controllable and the result of the study is qualitative.[9,10] In a newer method, i.e., SWE, the results are quantitative because the method is based on the degree of the stiffness of the tissue, by calculating the shear wave velocity in that tissue, and the amount of the stiffness of the tissue is not only displayed in color

Table 1. *The normality of the studied quantitative variables.*

Variables	Min	Max	Middle	Average	p-value
Age (years)	24	57	39	39.91±7.37	0.309
Weight (kg)	54	87	68	69 ±8	0.335
Height (cm)	154	183	163	165.46 ±7.38	<0.001
Body mass index (2kg / m)	20.45	30.06	25.18	25.19 ±2.35	0.798
Nodule size (mm)	3	62	16	19.27 ±10.6111	0.007

codes, but also measured quantitatively with a number in kilopascals (KP) or meters per second units.[11]
Given that studies show that FNAB, in addition to being aggressive, has high rate of false negative results in nodules larger than 4 cm,[12] in this study SWE and FNAB results were compared in patients referred to our hospital to evaluate the value of SWE vs FNAB in the diagnosis of solid thyroid nodules.

Materials and Methods

Study Design

This descriptive study was performed on individuals, who were referred to Imam Reza Hospital in Kermanshah-Iran for FNAB based on the results of gray scale ultrasound and the decision of a treating physician. The project was carried out after approval by the Research Council of the Medical School (Code 990769). The purpose of the study was described to all enrolled patients and written consent was obtained from them. All patients' information was kept confidential. In all stages of research, all ethic recommendations of the declaration of Helsinki and of the ethic research committees of the University of Medical Sciences were followed. Sampling method in this study was convenience sampling and only patients with the followung inclusion criteria were enrolled: Existence of solid or mostly-solid thyroid nodules in previous grayscale ultrasound; no previous treatment for thyroid nodules; no history of radiotherapy in the head and neck area; consent to participate in the study.

Sample size

The minimum required sample size of 144 people was calculated with the assumption of 0.84 specificity and 95% confidence and estimation accuracy of 0.06.[4]

$$N=(Z_{1-\alpha/2})^2.\ \rho\ (1-\rho)\ /d^2$$

Procedure

At first, the project assistant explained the conditions of the project to the patients so that they could enter the project by completing the informed consent form. Then, in addition to gray scale ultrasonography, elastography with SWE waves (elastography device of supersonic) was taken from the eligible patients included in the study and the findings were recorded. Then FNAB was taken if indicated according to the TI-RAD guidelines. FNAB results, elastographic findings and demographic information (age, gender, height, weight) of each person were entered in a questionnaire adjusted by the facilitator based on the main objectives and important variables of the study. Finally, the findings of SWE and FNAB methods were compared and analyzed with the below software. The specifications of the ultrasound device are as follows: Supersonic^{R} Aixplorer MACH^{TM} 30 ultrosound system. Transducer used: Super Linear^{TM}

Table 2. *Evaluation of the variables of the subjects with positive and negative elastography results.*

Variable		Elastography	Frequency	Average rating	p -value
Height		Positive	67	70.77	0.552
		Negative	78	74.92	
Nodule size		Positive	67	90.16	<0.001
		Negative	78	58.26	
Age		Positive	67	37.21±6.34	<0.001
		Negative	78	42.23±7.44	
Weight		Positive	67	67.09±8.07	0.007
		Negative	78	70.64±7.55	
BMI		Positive	67	24.78±2.36	0.051
		Negative	78	25.55±2.3	

Table 3. *Evaluation of the variables of the subjects with positive and negative FNAB results.*

Variable	FNAB	Frequency	Average rating	p -value
Height	Positive	61	70.98	0.62
	Negative	84	74.47	
Nodule size	Positive	61	100.23	<0.001
	Negative	84	53.23	
Age	Positive	61	37.33±6.56	<0.001
	Negative	84	41.79±7.4	
Weight	Positive	61	67.2±7.63	0.02
	Negative	84	70.31±7.99	
BMI	Positive	61	24.9±2.4	0.197
	Negative	84	25.41±2.29	

SL 18-15 with 5-18 MHZ band width. According to previous studies,[13,14] cut-off point for positive and negative elastography result were 66 KPa.

Statistical analysis

The collected information was finally entered into SPSS statistical software version 16. Quantitative and age data analysis was performed with tables, graphs, data frequency, mean, median, variance, and standard deviation. Kolmogorov-Smirnov test was used to evaluate the normality of quantitative variables. Independent t-test was used to evaluate quantitative data in groups and Mann-Whitney test was used for quantitative data with non-normal distributions. Cohen's kappa coefficient was used to evaluate the agreement between the two methods. A significance level of p-value 0.05 was considered for all tests.

Results

In this study, a total of 145 patients were included in the study, of which 106 were women (73.1%) and 39 were men (26.9%). The variables of age, weight, height, body mass index and nodule size were studied in terms of normality. According to the results of Kolomogorov-Smirnov test, the variables of age, weight and body mass index followed the normal distribution, while the variables of height and nodule size did not (Table 1).
The variables of the subjects with positive and negative elastography results are listed in Table 2. The results of Mann-Whitney test showed that height and BMI were not significantly associated with the positive and negative results of elastography (P> 0.05) but the variables of nodule size, weight and age were significantly associated with the positive and negative results of elastography (P <0.05). The variables of the subjects with positive and negative FNAB results are shown in Table 3. The results showed that the variables of height, weight and BMI were not linked to the positive and negative FNAB result (P> 0.05), but the variables of nodule size and age were significantly related to positive and negative FNAB result (P <0.05).
The agreement between FNAB and elastography in the diagnosis of solid nodules in the studied patients showed that out of 145 subjects, elastography results were positive in 67 (46.2%; Figure 1). In addition, 59 (40.7%) of the 67 patients who tested positive for elastography were also FNAB positive. Eight (5.5%) of those in whom the elastography result was positive, the FNAB result was negative. Elastography results of 78 patients (53.8%) were negative, which in 76 cases (52.4%) agreed with the results of FNAB. Furthermore, 2 cases (1.4%) of the cases that were reported negative by elastography were positive in the study with FNAB. Based on the Chi-Square results, there was a significant agreement (K = 0.86) between the results of the two methods (P <0.001). Figure 2 shows the agreement between FNAB and elastography in the diagnosis of solid nodules in women. The results revealed that out of 145 people studied, 106 were women. Elastography results were positive in 56 patients (52.8%). Moreover,

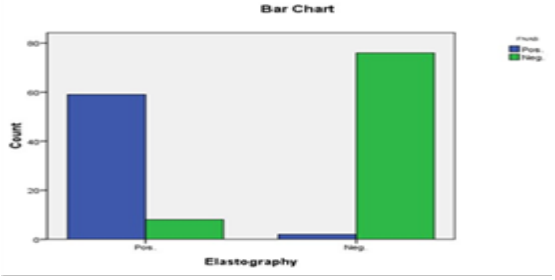

Fig 1. *Evaluation of the agreement btween FNAB and elastography in the diagnosis of solid nodules.*

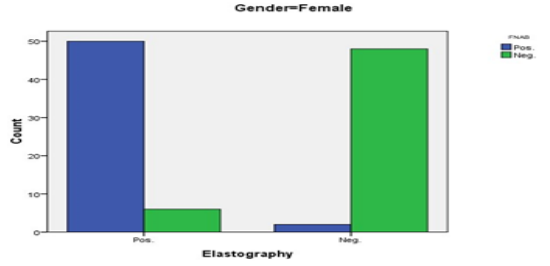

Fig 2. *Evaluation of the agreement between FNAB and elastography in the diagnosis of solid nodules in women.*

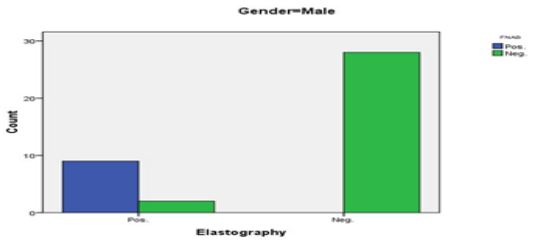

Fig 3. *Evaluation of the agreement between FNAB and elastography in the diagnosis of solid nodules of men.*

50 (47.2%) of the 56 patients who tested positive for elastography were also FNAB positive. Six (5.7%) of those with positive elastography exhibited a negative FNAB result. The elastography results of 50 patients (47.2%) were negative, of which 48 (45.3%) agreed with the FNAB results. In addition, 2 cases (1.9%) with negative elastography were positive in the study with FNAB. Based on Chi-Square results, a significant agreement (K = 0.849) was found between the results of the two methods in the diagnosis of malignancy in solid nodules in women (P <0.001). The agreement between FNAB and elastography in the diagnosis of solid nodules in men is shown in Figure 3. Of the 145 people studied, 39 were men. Elastography results were positive in 11 patients (28.2%). Nine (23.1%) of the 56 patients who tested positive for elastography were also FNAB positive. Furthermore, 2 (5.1%) of the subjects with positive elastography showed negative results for FNAB. Elastography results of 28 patients (71.8%) were negative, which were consistent with FNAB results in all cases. Based on the Chi-Square results, a significant agreement was observed (K = 0.866) between the results of the two methods in the diagnosis of malignancy in solid nodules of the studied men (P <0.001).

Discussion

FNAB can diagnose thyroid malignancies with high sensitivity and specificity. Thyroid resection has significantly reduced the number of thyroidectomy surgeries when less than 20% of thyroid nodules are operated on.[15-17] Therefore, the aim of this study was to evaluate the degree of agreement between SWE results and thin FNAB in the diagnosis of solid thyroid nodules. The results of age, BMI and nodule size in terms of FNAB result showed that nodule size in people with FNAB positive result was significantly higher than people with negative FNAB result. The mean age of FNAB-negative subjects was significantly higher than that of FNAB-positive subjects. The mean BMI in FNAB-negative subjects was higher than FNAB-positive subjects, but this difference was not statistically significant (P> 0.05). Based on the most important results of the present study, elastography results were positive for 46.2% of all subjects. In addition, 40.7% of people with positive elastography results were positive for FNAB, and 5.5% of people with positive elastography results were negative for FNAB. Elastography results were also reported to be negative for 53.8% of individuals; which in 52.4% were consistent with the results of FNAB. Furthermore, 1.4% of cases with negative results of elastography was found to be positive by FNAB. Elastography results were positive in 52.8% of women. 47.2% of women with positive elastography had FNAB positive. Furthermore, 5.7% of women with positive elastography results showed FNAB negative. Also, elastography results were negative in 47.2% of women studied, which in 45.3% agreed with the results of FNAB. In addition, 1.9% of cases with negative elastography were positive in the study with FNAB. Elastography results were positive in 28.2% of men. Also, 23.15 of the men with positive elastography were also FNAB positive. In addition, 5.1% of men with positive elastography were negative for FNAB. Elastography results were negative for 71.8% of the men, who found to be in agreement with the FNAB results in all cases. The results of a retrospective study by Park et al. (2014)[18] on the validation of SWE in predicting thyroid malignancy showed that all elastography indices of malignant thyroid nodules were significantly higher than benign nodules and the combined use of findings of Gray-scale ultrasonography and elastography ultrasound scales showed higher sensitivity in diagnosis compared to using only Gray-scale ultrasonography. In addition, the results of this study showed that quantitative SWE parameters are independent predictors of thyroid malignancy and together with Gray-scale ultrasonography are helpful in predicting thyroid malignancy.[18] The results of a case report study by Ma et al. (2014)[19] on a 49-year-old woman with a thyroid nodule showed that SWE was a useful adjunct to conventional B-mode ultrasound in guiding FNAB from the thyroid nodule.[19] According to the results of Azizi et al.'s study in 2015,[20] the sensitivity and specificity were 79.27% and 71.52% for predicting thyroid cancer by a single cut-off of 3.54 m/s as the maximum shear wave velocity (SWV). Positive and negative predictive values (PPV; NPV) were 26.75% and 96.34%, respectively. SWV ≥3.54 m/s was found to be associated with a higher sensitivity, specificity, PPV and NPV, when compared with B-mode US properties for predicting thyroid cancer. Thyroid nodule stiffness measured by SWE is also an independent predictor of thyroid cancer.[20] A cross-sectional study by Farghadani et al. (2019),[4] compared sensitivity and specificity of the two dimensional-shear wave elastography (2D-SWE) method in comparison with FNA in determining the malignant thyroid nodules, where SWE gave the highest surface area under the curve and the highest sensitivity and specificity with 0.94, 100% and 84%, respectively, and a cut-off point of 1.7 in the determination of malignant thyroid nodule. Both methods have been

reported to be good references for decision making about thyroid nodules.[4] Li et al. in 2019,[21] in a retrospective study examined the diagnostic value of FNA and ultrasound in the diagnosis of cancer. They observed that FNA combined with ultrasound could significantly improve the sensitivity and accuracy in detecting thyroid nodules ≤1 mm, but did not significantly improve the diagnosis of thyroid nodules larger than one mm.[21] Based on the results of the present study, a significant relationship was observed between the results of SWE and FNA in the diagnosis of malignancy in solid thyroid nodules. This agreement was found to be higher in men (K = 0.866) than women (K = 0.849). According to various studies,[13,14] the best cut-off point is at 65 and 66 KPa and in this study, 66 KPa has been selected. Based on the findings of the study, the mean age was not significantly different between men and women (P> 0.05). Thyroid solid nodules were in the range of 3 to 62 mm. No significant difference was found in the size of thyroid nodules in men and women (P> 0.05). In the study of age, BMI and nodule size according to the elastography result, it was observed that the nodule size in individuals was not significantly associated with the positive and negative elastography results (P> 0.05). The mean age of negative elastography subjects was significantly higher than positive elastography subjects. Mean BMI was higher in negative elastography subjects than in positive elastography subjects; however, this difference was not statistically significant (P> 0.05).

In conclusion, given the significant agreement between the two methods, SWE can replace FNA in the diagnosis of malignancy in solid thyroid nodules.

List of acronyms

BMI – body mass index
FNA - fine-needle aspiration
FNAB - fine-needle aspiration biopsy
KP – kilopascals
NPV – Negative predictive value
PPV – Positive predictive value
SE - Strain Elastography
SWE - shear wave elastography
TND - thyroid nodule disease

Contributions of Authors

FN, AP, RN, ZK, MHRS, PBK, NB participated in conception and design of the study, acquisition, analysis and interpretation of data, wrote the manuscript, performed literature review, article drafting and revision, reviewed and edited the manuscript critically, all authors readed and approved the final version.

Acknowledgments None

Funding None

Conflict of Interest

The authors declare no conflict of interests.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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Submission: May 23, 2022
Revision received: May 31, 2022
Accepted for publication: May 31, 2022