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Comparison the accuracy of thyroid sono-elastography vs. ultrasound-guided fine needle aspiration cytology with thyroid malignancy diagnosis histopathology

Sarah Abd Elmageed Mahmoud [1], Mohamed Elsayed Enaba [1], Mohamed Moustafa Shareef [2], Yasser Moustafa Hafez [2], Ibrahim Abbas [3]

[1]Internal Medicine Department, Tanta University Hospital, Faculty of Medicine, University of Tanta, Tanta, AL Gharbia, Egypt; [2]Pathology Department, Tanta University Hospital, Faculty of Medicine, University of Tanta, Tanta, AL Gharbia, Egypt; [3]Diagnostic Radiology Department, Faculty of Medicine, University of Tanta, Tanta, AL Gharbia, Egypt
E-mail: sara.abdelmegeed@med.tanta.edu.eg

Objective. The intend of the present study was to assess the diagnostic performance of strain elastography in investigating the thyroid nodule malignancy taking the surgical biopsy as a gold standard reference test.

Methods. The study included 120 patients with 123 thyroid nodules, of which 67 had total thyroidectomy. The American College of Radiology Thyroid Imaging Reporting and Data Systems (ACR-TIRADS) were evaluated for all nodules. All suspicious nodules were referred for a fine needle aspiration cytology (FNAC) if they fulfilled the required size. Strain elastography was performed for each suspicious nodule. Ultrasound-guided FNAC was performed for all suspicious nodules. Total thyroidectomy was performed in those whom the suspicious nodules were proven by FNAC.

Results. Strain ratio had a sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of 84%, 81%, 95%, 85%, and 84%, respectively, with a cut point 1.96. Elasticity score had a sensitivity, specificity, PPV, NPV, and diagnostic accuracy of 100%, 80%, 95%, 85% and 87%, respectively, with a cut point 0.96. The elasticity score had a statistically significantly odds ratio for detecting the benignity 3.9 C. I (1.6–9.3).

Conclusion. Strain elastography has a high diagnostic performance in detecting the malignant as well as benign nodules, thus it can limit the rate of unneeded FNAC or surgery especially among B3 and B4 groups with indeterminate cytology.

Key words: elastography, malignancy, nodules, thyroid

The thyroid nodule is a focal well-defined area with an altered echogenicity radiologically distinct from the adjacent thyroid tissue (Popoveniuc and Jonklaas 2012). The prevalence of thyroid nodule among populations is estimated to be 19–67% (Vargas-Uricoechea et al. 2017). A nodule within the thyroid gland can be palpable in the neck or detected only by ultrasonography.

The potential for a thyroid nodule to be malignant is worrisome. It needs early thorough investigations and proper decision by the management. The majority of thyroid nodules are benign, however, malignancy has been found in about 5–15% of cases (Alexander et al. 2004). Risk factors for malignancy include age, gender (more in females), family history, and previous radiation exposure. Two thirds of all

Corresponding author: Sarah Abd Elmageed Mahmoud, Assistant Lecturer at the Internal Medicine Department, Tanta University Hospital, Faculty of Medicine, University of Tanta, Tanta, AL Gharbia, Egypt; phone: +201032753954; e-mail: sara.abdelmegeed@med.tanta.edu.eg.

cases of thyroid cancer occur between 20–55 years, anaplastic thyroid cancer mostly after age of 60, and medullary thyroid cancer in infants and adolescents carrying the RET (rearranged during transfection) proto-oncogene mutation (Papini et al. 2002).

High resolution ultrasound with risk stratification scores has been very useful in predicting the thyroid nodule malignancy. Similar to BIRADS (Breast Imaging Recording and Data System) for scoring of breast lesions, there is TIRADS (Thyroid Imaging Recording and Data System), a risk stratification system for the classification of thyroid nodules (Moifo et al. 2013).

In the ACR-TIRADS (American College of Radiology Thyroid Imaging Reporting and Data System) score, the thyroid nodules have been classified into five categories according to the composition, echogenicity, shape, margin, and echogenic foci/calcification. TIRADS scores 1 and 2 lesions has been referred as benign, while TIRADS scores 3, 4, and 5 will need further evaluation by fine needle aspiration cytology (Horvath et al. 2017). Sonographic features suggestive for malignancy include solid nodules, hypoechogenecity, microcalcification, irregular margin, and a shape that is taller than wider (Brito et al. 2014).

Ultrasound sono-elastography technique is used to assess the tissue elasticity for the degree of stiffness. In strain elastography, operators use manual thyroid nodule compression to generate color-coded elastograms and stiffness ratios between nodule and the adjacent normal thyroid. This gives a score of 1–5 (Rago score) or 1–4 (Asteria score) with score 4 in Asteria and score 5 in Rago referring to the no elasticity and score 1 referring to the elasticity in the whole nodule (Rago et al. 2007). This added ultrasonographic feature can help in predicting the malignancy, especially in cytologically indeterminate thyroid nodules that may cause confusion in the decision of the surgery. This technique, when added to conventional ultrasound, can be very helpful in reducing the need for the fine needle aspiration cytology and complications of surgery.

Shear wave elastography (SWE) is a new quantitative elastography, which uses acoustic radiation force created by a focused ultrasound beam. The displacement induced at the focus produces a shear wave, which conveys information about the local elastic properties of the tissue, thus providing a quantitative approach to elasticity values (Yeon et al. 2020). This new technique is more reproducible, quantitative, and less dependable on the individual operator. The Bethesda System for Reporting Thyroid Cytopathology (TBSRTC) is used to classify the thyroid lesion into six categories from I being non-diagnostic to VI being malignant and recommended for the total thyroidectomy (Cibas and Ali 2009).

Discrepancies between high resolution ultrasound reports and ultrasound-guided (US-guided) fine needle aspiration cytology (FNAC) reports; however, are not uncommon and may cause confusion in the decision of the operation increasing the rates of unneeded surgeries.

In this study, we assessed the accuracy of highly suspicious ultrasonographic features in addition to elasticity parameters comparing them with US-guided FNAC in diagnosing the thyroid nodule malignancy. The surgical biopsy was used as the gold standard reference test. In our study, different states of thyroid function were considered, unlike most studies working only on euthyroid nodules.

Material and Methods

Subjects. Our study is a prospective observational cohort study that was carried out on 120 patients with suspicious 123 thyroid nodules. They were recruited from the Endocrinology Outpatient Clinic in the period from May 2021 to June 2023 at the Tanta University Hospital, Egypt.

The permission to conduct this study and to use the facilities in the hospital was obtained from the Research Ethics Committee as a part of Quality Assurance Unit in Faculty of Medicine at Tanta University. The informed oral and written consents were obtained from all patients after full explanation of the whole observational process. The privacy of all patients' data was granted by a special code number for every patient file that included all the investigations.

Inclusion and exclusion criteria. We included all the adult patients above 18 years of age with suspicious solid or partially solid thyroid nodule on high resolution ultrasound imaging. We excluded: 1) patients with completely benign features (purely cystic nodule by ultrasound), which will not need surgical excision or biopsy; 2) pregnant women deferring the intervention for their thyroid nodules; 3) patients not consenting to participating in the study; 4) patients with suspicious thyroid nodules, but not willing to do the surgical removal either due to multiple co morbidities or fearing from the consequences of the operation (those were removed from the analysis); and 5) patients, which were dropped out from the follow up process after the initial ultrasonographic findings.

Monitored parameters. All patients were subjected to thorough history taking complete physical examination and complete thyroid function tests: thyroid-stimulating hormone (TSH), free triiodothyronine (FT3), free thyroxine (FT4). Thyroid autoantibodies were done when required (anti-thyroid peroxidase, anti-thyroglobulin in subclinical hypothyroidism, and anti-TSH receptor antibodies in cases of a thyroid nodule on top of suspected Graves' disease). Thyroid scintigraphy scan with radioactive iodine was performed in cases suspected to have a toxic nodule or toxic multinodular goiter. A high-resolution ultrasound imaging by TOSHIBA Aplio 500 (using a high frequency linear transducer 10–18 MHz) with comment on nodule consistency, echogenicity, shape, margin, calcification, and vascularity was used. Strain elastography technique with ultrasound was applied to the nodules assessing for its stiffness in relation to the surrounding tissues giving a score of 1–4 with score 1 – referring to the elasticity or score 4 – referring to the no elasticity in the whole nodule. Strain ratio was measured by repetitive compression of the nodule using the same ultrasound probe longitudinally. Two areas were chosen, ROI (region of interest) and a normal reference area of adjacent thyroid tissue or muscle. The ratio was calculated automatically by dividing the elasticity in the reference area with the area of the interest. FNAC was done by highly experienced well-trained personnel under ultrasound guidance when indicated.

Only the nodules undergoing surgical excisions were statistically analyzed taking the surgical biopsy as the reference gold standard test. The primary outcomes were estimating the sensitivity, specificity, positive and negative predictive values for highly suspicious sonographic findings (echogenicity, shape, margin, vascularity, and pattern of calcifications in the nodules) and comparing them with the diagnostic performance of the same features when elasticity score was added. The secondary outcome compared the risk of malignancy in the different states of thyroid function (hyperthyroidism, hypothyroidism, and euthyroid patients).

Statistical analysis. Data were analyzed using the IBM® SPSS statistical software, version 21. We used the one-sample Kolmogorov-Smirnov test to check the normality of data. Numerical data were presented as a mean ± standard deviation (SD). The categorical data were presented as a number and percentage. Chi-squared test was used for comparing the qualitative data. The level of significance was adopted at $p<0.05$.

Results

Our study included 120 patients with 123 suspicious thyroid nodules (ACR-TIRADS III–V) that were prospectively followed up for subsequent US-guided FNAC and thyroidectomy histopathological results. Their age ranged from 20–55 years with a female predominance (71.5% vs. 28.5%). Prevalence of ultrasonographic characters for the whole group of suspicious nodules are shown in Table 1.

Surgical biopsy was performed in 67 cases, while 56 nodules were not operated. Only 67 patients with 67 suspicious nodules were subjected to total thyroidectomy. The operated nodules were classified as follow: one Bethesda II (BII) nodule, 29 BIII, 29 BIV, 7 BV, and one BVI nodule. The malignancy was proved by the surgical biopsy in only 12 nodules: nine of them were classic papillary carcinomas and three were follicular ones. Fifty-five removed nodules were confirmed to be benign.

In the operated cases, there were 35 euthyroid patients (6 of them were malignant), 24 hypothyroid patients (4 of them were malignant), and 8 hyperthyroid patients (2 of them were malignant). The percentage of malignancy in each thyroid state of function was as follows: 17.1%, 16.6%, 25% for euthyroid, hypothyroid, and hyperthyroid patients, respectively. The individual ultrasonographic highly suspicious criteria were assessed for the sensitivity, specificity, positive predictive value (PPV), positive predictive value (NPV), and odds ratio for malignancy. It was shown that microcalcifications and irregular margin have the highest diagnostic accuracy for malignancy. The irregular margin has the highest odds ratio for malignancy, which was significantly higher than the rest of the suspicious criteria.

Table 1
Prevalence of ultrasonographic characters among studied nodules

Thyroid characteristics		Cases (n=123)	
		No.	(%)
Composition	Mixed solid and cystic	56	45.5
	Solid	67	54.5
Echogenicity	Hypoecoic	98	79.7
	Isoechoic	25	20.3
Echogenic foci	No calcification	102	82.9
	Macro calcification	13	10.6
	Micro calcification	7	5.7
	peripheral calcification	1	0.8
Margin	Regular	116	94.3
	Irregular	7	5.7

Table 2
Diagnostic performance of individual ultrasound suspicious criteria, ultrasound parameters integration and ultrasound elasticity score in detecting benign lesions

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)	p-value	OR (95% CI)
Solid consistency	83.3	47.2	74.3	92.8	53.7	0.150	2.1 (0.8–5.2)
Hypochogenicity	91.6	23.6	79.2	92.8	35.8	0.250	1.2 (0.5–3.0)
Microcalcification	41.6	94.5	37.5	88.1	85.0	0.620	3.5 (1.2–6.2)
Irregular margin	23.1	96.0	50.0	84.1	82.0	0.030*	4.2 (1.8–10.3)
One parameter	18.0	32.0	5.1	66.6	30.0	0.010*	2.1 (0.8–5.2)
Two parameters	81.8	67.0	67.0	94.8	70.0	0.030*	6.9 (1.8–15.3)
Elasticity score	85.5	91.6	97.9	57.9	85.0	0.001*	3.9 (1.6–9.3)

Abbreviations: NPV – negative predictive value; PPV – positive predictive value. *p<0.05.

Table 3
Prevalence of malignancy in thyroid nodule according to elastography score

Electrography score	Malignant cases (n=12)	
	No.	(%)
Score 1 (n=36)	0	0.0
Score 2 (n=52)	1	1.9
Score 3 (n=25)	2	8.0
Score 4 (n=10)	9	90.0

Table 4
Relationship between elasticity score of thyroid nodule and surgical biopsy results

Elasticity score	Benign (n=55)		Malignant cases (n=12)		X^2 p-value
	No.	(%)	No.	(%)	
Score 1	21	100.0	0	0.0	
Score 2	26	96.3	1	3.7	43.2
Score 3	7	77.7	2	22.3	0.001*
Score 4	1	10.0	9	90.0	

*p<0.05

Using a combination of two ultrasonographic parameters had significantly higher risk for malignancy than using one parameter (OR 6.9 vs. 2.1, respectively). Assessing the accuracy of the elasticity score in detecting benign nodules is showed in Table 2. The prevalence of malignancy in each elastography score, score 4 had the highest prevalence of malignancy (90%), is shown in Table 3.

The percentage of benign nodules in each elasticity score was compared to the percentage of malignancy in each score and proved to be statistically significant (Table 4). It showed a significantly high PPV (97.9%) and diagnostic accuracy (85%) for benign nodules. Regarding the FNAC results, its diagnostic accuracy in detecting thyroid malignancy, specificity, NPV, and PPV were significantly higher in B5 and B6 groups. Regarding the strain ratio, it proved to have significantly high diagnostic accuracy, PPV, NPV, sensitivity, and specificity for differentiating thyroid lesions (either benign or malignant) in the whole Bethesda group. The cutoff point was 1.96, above which the malignancy was predicted by a percentage of 95% (Table 5, Figure 1).

Diagnostic accuracy of ACR-TIRADS score for diagnosing thyroid nodule malignancy showed a fair area under the curve (0.77) with 83% sensitivity, 60% specificity, and 85% diagnostic accuracy. Combination of the two techniques, ACR-TIRADS with elastography, showed a significantly higher sensitivity, specificity, PPV, NPV, and diagnostic accuracy (Table 6, Figure 2).

Discussion

Conventional grey scale ultrasound using ACR-TIRADS is considered to be the most widely used grading system for the suspicious thyroid nodules. However, the percentage of the false positive results from that technique cannot be neglected. Its low specificity, as confirmed by many studies (Huh et al. 2021; Eidt et al. 2023), is considered to be a strong underlying factor behind the large number of FNAC procedures. Subsequently, the number of unnecessary thyroidectomy operations (especially for indeterminate nodules) is increasing with its different hazards such as permanent hypoparathyroidism and recurrent laryngeal nerve damage.

From the TIRADS components, we have found that the presence of microcalcification and irregular

Table 5
Diagnostic accuracy of FNAC Bethesda, strain ratio for diagnosis of thyroid malignancy

Group	AUC	p-value	COP	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Whole group	0.73	0.160	2.50	90	57	85	65	73
B3–B4	0.55	0.630	3.43	60	40	55	60	55
B5–B6	0.70	0.001*	5.50	80	95	90	100	70
Whole group	0.94	0.009*	1.96	84	81	95	85	84
B3–B4	0.99	0.010*	2.50	66	80	65	65	90
B5–B6	1.00	0.001*	2.70	80	100	85	95	95

Abbreviations: AUC – area under curve; COP – cut of point; FNAC – fine needle aspiration cytology; NPV – negative predictive value; PPV – positive predictive value. *p<0.05.

Table 6
Diagnostic accuracy of elasticity scoring, TIRADS score and (combined TIRADS score and elasticity score) for diagnosis of thyroid malignancy

Group	AUC	COP	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Whole group	0.98	0.96	100.0	80	95	85	87
B3–B4	0.86	3.50	66.0	100	70	90	91
B5–B6	0.85	3.00	100.0	70	95	80	89
Whole group	0.77	3.50	83.0	60	85	70	85
B3–B4	0.76	3.50	71.2	70	68	67	90
B5–B6	0.57	4.00	40.0	75	55	68	78
Whole group	0.93	4.50	100.0	77	85	70	95
B3–B4	0.91	4.50	91.2	75	78	87	90
B5–B6	1.00	4.00	100.0	100	95	95	100

Abbreviations: AUC – area under curve; COP – cut of point; NPV – negative predictive value; PPV – positive predictive value, TI-RADS – Thyroid Imaging Reporting and Data Systems.

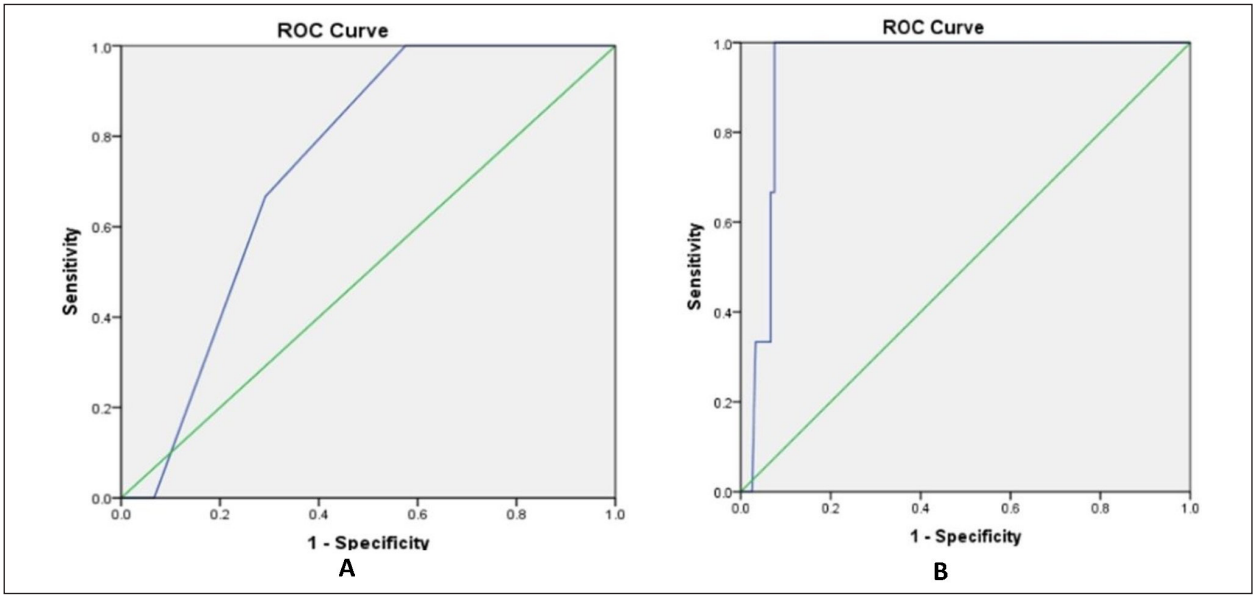

Figure 1. The receiver operating characteristic curve (ROC) of the whole FNAC (fine needle aspiration cytology) group **(A)** and strain ratio for whole cases in FNAC **(B)** to distinguish the benign from malignant nodule (surgical biopsy is the gold standard).

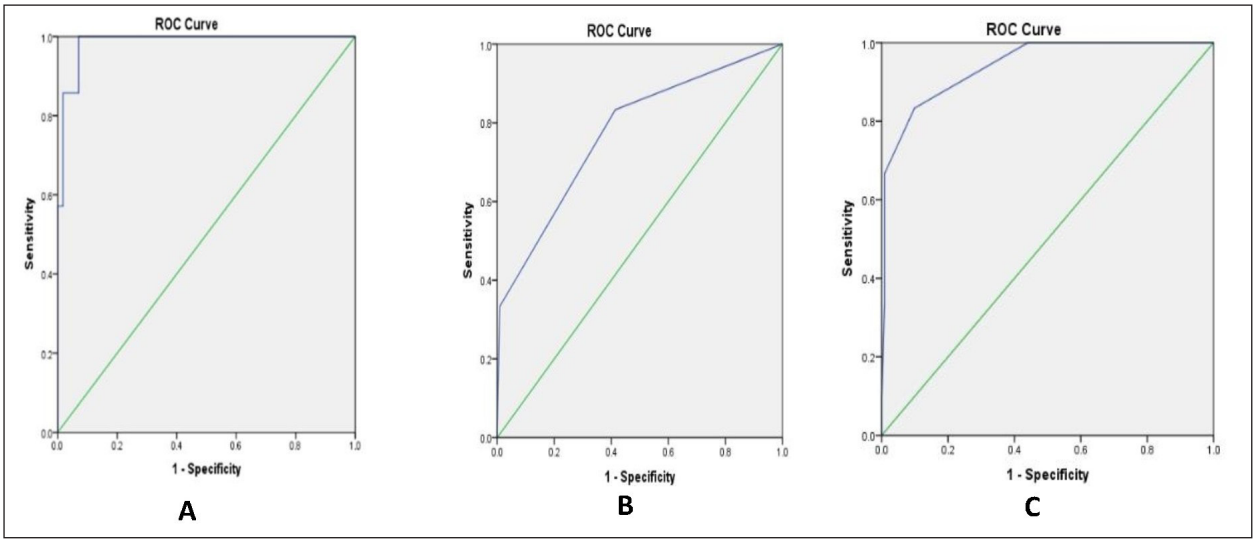

Figure 2. The receiver operating characteristic curve (ROC) of the elasticity score for whole group **(A)**, TIRADS (Thyroid Imaging Recording and Data System) for whole cases in FNAC (fine needle aspiration cytology) **(B)**, and combined TIRADS score and elasticity score for whole cases in FNAC **(C)** to distinguish the benign from malignant nodule.

margin had the highest diagnostic accuracy (85 and 82, respectively) and the highest specificity (94.5 and 96, respectively). However, the sensitivity of each of them was very low (41.6, 23.1). On the contrary, solid composition and hypoechogenecity had the highest sensitivity (83.3 and 91.6, respectively) and the lowest specificity (47.27 and 23.64, respectively), and diagnostic accuracy (53.73 and 35.82, respectively). The presence of irregular margin followed by microcalcifications had the highest odds ratios for malignancy (4.2 and 3.5, respectively).

In a study by Garino et al. (2015) on histologically indeterminate thyroid nodules, they have demonstrated that the presence of an irregular margin had an odds ratio of 5.1 (1.4–21.6) and a diagnostic accuracy of 73%, which were statistically significant. We also assessed the diagnostic performance of the combination of two ultrasonographic suspicious parameters. In accordance with previous studies (Garino et al. 2015; Yoon et al. 2018), we found that using more ultrasonographic parameters was better than using one parameter. By using the combination of two parameters, the specificity was higher (88 vs. 32).

Applying the whole TIRADS score yielded a sensitivity of 83%, specificity 60%, PPV 85%, NPV 70%, and the diagnostic accuracy 85%. These results are close to those demonstrated by Hao et al. (2023). They have reported an AUC (area under group), sensitivity, specificity, and accuracy of conventional ACR TI-RADS as 0.828, 83.9%, 66.0%, and 75.9%, respectively.

The assessment of tissue elasticity by different ultrasonographic techniques has been investigated in the diagnosis of solid organ malignancy by many authors. Saleem et al. (2022) have assessed the diagnostic performance of strain elastography in suspicious thyroid nodules taking the FNAC as the gold standard test. They have reported a sensitivity, specificity, PPV, NPV, and diagnostic accuracy of 93.46%, 91.0%, 91.74%, 92,86%, and 92.2%, respectively.

Similarly, Lalwani et al. (2023) have assessed the diagnostic performance of elastography strain ratio for the diagnosis of malignant thyroid nodules taking FNAC as the gold standard at a tertiary care hospital in Pakistan. They have concluded that elastography and strain ratio are highly valuable in discriminating benign from malignant thyroid nodules. However, the technique of elastography application is still not widely used by most radiologists and even not very recognized among endocrinologists throughout the developing world including Egypt.

In our study, we investigated the diagnostic performance of strain elastography while taking the surgical biopsy as the gold standard. The strain ratio had a specificity of 81% at a cut point 1.96, which means a low percent of false positive results that may proceed to unnecessary thyroidectomy. Similarly, the elasticity score had a specificity of 80% at a cut-off

point 0.96 for the whole group and reaches 100% in BIII and BIV groups at a cut-off point 3.5.

As regard to sensitivity, PPV, NPV, and diagnostic accuracy, our study demonstrated that strain ratio had 84% sensitivity, 95% PPV, 85% NPV, and 84% of accuracy for the whole group with an AUC of 0.94. The diagnostic accuracy was especially higher (90%) in BIII and BIV groups that were classified as having indeterminate cytology. Hence, the nodules with low elasticity scores can only be followed up before considering FNAC.

In a meta-analysis conducted by Cantisani et al. (2022), the pooled sensitivity, specificity, and AUC were 84%, 81%, and 0.89, respectively for qualitative ultrasound strain elastography (USE) and 83%, 80%, and 0.93 for semi-quantitative USE. Above mentioned results are close to those ones obtained in our study.

In a recent meta-analysis, Zhang et al. (2023) have demonstrated that the existing evidence showed that elastosonography cannot completely replace the conventional ultrasound in the diagnosis of malignant thyroid nodules and that the combination of elastosonography and conventional ultrasound gives a better diagnostic precision.

As regard to FNAC results, considering BIII–BVI as positive cytology, we obtained a good sensitivity for malignancy of about 90%, low specificity 57%, PPV 85%, NPV65%, and a good accuracy of 73%. The results reported by Muratli et al. (2014) were close to our results. The sensitivity was 87.1% and specificity 64.6%. The PPV, NPV and accuracy rates were 76.1%, 79.5%, and 77.3%, respectively.

Although FNAC had a significant role in limiting the need for thyroid surgeries by proving a fair sensitivity, specificity, PPV, NPV, and diagnostic accuracy (Sinna and Ezzat 2012; Sharma 2015; Iqbal et al. 2016; Alhassan et al. 2022), the findings of BIII and BIV (indeterminate cytology) has a greater possibility of being benign than malignant (malignancy risk not exceeding 40%). However, surgery even total thyroidectomy may still be required for confirmation of malignancy (Bongiovanni et al. 2019).

Hajmanoochehri and Rabiee (2015) have concluded that despite FNAC having a good sensitivity and an acceptable specificity in the diagnosis of thyroid nodule malignancy, most of the false positive results were among cases of indeterminate cytology (follicular neoplasm/suspicious of follicular neoplasm).

In our study, we had only 7 malignant BIII and BIV thyroid nodules out of 58 indeterminate nodules as confirmed by surgical biopsies, which correlated to only 12%. Hence, the need for an additional more specific tool, which can help in the thyroid surgeries number reduction is emerged. Similar to investigation of the diagnostic performance of strain elastography in detecting malignant nodules, we investigated the efficacy of the same tool in the diagnosis of benign thyroid nodules. Elasticity score revealed a very good diagnostic accuracy and predictive values in that setting too. Elasticity score results were classified as benign (in score 1 and 2) or malignant (score 3 and 4). The prevalence of thyroid malignancy versus benignity was compared for each score and was found to be statistically significant ($p<0.001$). These results mean that elasticity score could detect 11 malignant nodules out of 12 (91.6%) and detected 47 benign nodules out of 55 (85.45%).

The sensitivity, specificity, PPV, NPV, and diagnostic accuracy of elasticity score in detecting benign thyroid lesions were as follow: 85.5%, 91.6%, 97.9%, 57.9%, and 85%. The odds ratio was 3.9 with $p<0.001$. Thus, using elasticity score especially for indeterminate thyroid nodules can limit the need for thyroidectomy and those lesions can be followed up by sono-elastography instead.

A recent systematic review by Klarich and White (2023) have concluded that USE is more accurate at identifying benign nodules than ultrasound. Thus, nodules with a size less than 10 mm appearing benign on USE could be excluded from the serial ultrasound follow-up. They have found no significant difference between USE and ultrasound at identifying the malignant nodules.

Finally, by examining the prevalence of malignancy in each thyroid state of function, the prevalence was 17.1% (6/35) in euthyroidism, 16.6% (4/24) hypothyroidism, and 25% (2/8) hyperthyroidism. The percentage is unexpectedly high in the cases of hyperthyroidism. The two hyperthyroid malignant cases had toxic solitary nodules. Aksoy et al. (2020) have reported an increasing number of thyroid carcinomas among hyperthyroid patients. They have retrospectively included a total of 591 patients who had surgical excision of the thyroid due to the hyperthyroidism. Thyroid cancer was confirmed in 131 patients, i.e. 9 of 22.6%. Therefore, the necessity to assess the suspicious nodule in hyperthyroid patients before radioactive iodine is increasing (Aksoy et al. 2020).

Our study has the advantage of being prospective and that it assessed the diagnostic performance of strain elastography in diagnosing both malignant and benign thyroid nodules.

Conflict of interest: *The authors reported no conflict of interest.*

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