Original Article

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Radiology Section

Diagnostic Accuracy of Thyroid Imaging, Reporting and Data System Combined with Strain Elastography in the Evaluation of Thyroid Nodules

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ABSTRACT

Introduction: It is estimated that the prevalence of thyroid nodules is about 3-8% and there are always chances of malignancy in thyroid nodule which should not be underestimated. Fine Needle Aspiration Cytology (FNAC) is an efficient tool for diagnosing thyroid malignancies. Strain elastography measures the stiffness of nodules using ultrasound and serves as an additional diagnostic tool in differentiating benign and malignant thyroid nodules depending on their hardness.

Aim: To characterise thyroid nodules based on Thyroid Imaging Reporting And Data System (TIRADS) combined with strain elastography in differentiating benign from malignant thyroid nodules and correlating them with FNAC/Histopathological Examination (HPE).

Materials and Methods: A prospective cross-sectional study was conducted in which total of 135 patients were included who were diagnosed to have thyroid nodules by B-mode ultrasound or by palpation. For the evaluation of the strain ratio, the average strain value was obtained from 4 continuous frames of strain images and ratio of less than 2.50 was benign and more than 2.50 was considered malignant. Combined TIRADS and strain elastography scores were obtained and the results were correlated with histological findings by performing an FNAC/Biopsy. All statistical analysis were performed using Statistical Package for Social Science (SPSS, version 17) for Microsoft windows. The data were expressed as Mean and Standard Deviation (SD). Chi-square test were used for qualitative data.

Results: Among the 135 thyroid nodules, Ultrasonography (USG) TIRADS scoring system differentiated benign and malignant nodules with sensitivity of 83%, while the specificity was 96.4%, Positive Predictive Value (PPV)=83.3%, Negative Predictive Value (NPV)=96.4% and accuracy of 94.1%. Strain elastography differentiated benign from malignant nodules with of sensitivity was 91.7%, while the specificity was 99.0%, PPV=95.7%, NPV=95.7% and accuracy of 98% while the combined TIRADS and strain elastography score differentiated benign from malignant nodules with sensitivity of 95.83%, while the specificity was 100%, PPV=100%, NPV=99.1% and accuracy of 99.3%.

Conclusion: Grey scale ultrasound is an efficient tool for diagnosis of thyroid nodules. Elastography can further help in characterising thyroid nodules and can help in identifying sites for FNAC. Combination of both B-mode Ultrasound findings and strain elastography yield a better diagnosis.

Keywords: Fine needle aspiration cytology, Grey scale ultrasound, Thyroid malignancies

INTRODUCTION

Thyroid nodule is defined as a discrete lesion that can be differentiated radiologically from thyroid parenchyma which is surrounding it [1]. Prevalence is said to be approximately 4% to 7% in the general population. The advent of high resolution ultrasound has resulted in increased detection of incidental asymptomatic thyroid nodules. Zamora EA et al., showed that incidental thyroid nodules in adults was as much as 27% to 67% [2]. Various studies have shown prevalence of malignancy in these incidental nodules to vary from 2% to 12% [3]. Imaging modalities like Doppler ultrasound, Computed Tomography (CT), nuclear scans and Positron Emission Tomography (PET) have been used to differentiate benign and thyroid nodules. TIRADS based on five ultrasound features was created with the primary aim of providing guidelines in management of these nodules [4]. Ultrasound guided FNAC is preferred for evaluation of any suspicious nodule. It is an invasive procedure and when multiple nodules are encountered, only the most suspicious nodule is selected for aspiration [5].

Elastography is a recent non-invasive dynamic imaging method which assesses the elasticity or hardness of lesions to make the diagnosis. The Elastographic image is acquired through compressing continuously and then the transducer decompression. After compression the deformation in the tissue due to stress is measured and malignant lesions are harder than benign nodules. In comparison to the conventional Ultrasound alone, higher accuracy is showed by the strain elastography score combined with conventional US [6-9]. There are numerous studies published on this topic [5-9], but very few are there in which strain elastography is combined with TIRADS.

In this present study, authors seek to establish the diagnostic efficacy of strain elastography in combination with TIRADS to distinguish malignant and benign thyroid nodules by correlating with FNAC or Histopathological Examination (HPE).

MATERIALS AND METHODS

This prospective cross-sectional study was conducted after getting approval from our Institutional ethics committee (1323/IEC/2017) and consent was obtained from all patients. A total of 135 patients with thyroid nodules who came to Department of Radiology, SRM Medical College hospital and Research Centre during the period from January 2018 to July 2019 were included in the study. According to a study on management of thyroid nodules in adults [10], considering the prevalence of thyroid malignancy in patients with thyroid nodules as 15% with a precision of 6% and 95% confidence interval, the sample size was calculated as 135.

Inclusion criteria: The patients found to have solid and solid cystic thyroid nodules detected by ultrasound, palpation or incidentally.

Exclusion criteria: The patients found to have diffuse thyroid enlargement with no focal nodule, purely calcified and purely cystic nodule and patients not willing for FNAC.

All the patients underwent sonography, elastography and pathological analysis. The findings of B-mode and elastography were correlated with FNAC or postsurgical histopathological examination. B mode Ultrasound of the thyroid gland was performed with a PHILIPS AFFINITY 30 using high frequency probe (7.5 to 12 MHz) with patients in supine position and extension of the neck. The lesions were categorised using TIRADS scoring system [4].

Ultrasound Elastography was performed with PHILIPS AFFINITY 30 at the same time as the B-mode examination. Ultrasound strain elastography colour coding was done and strain ratio was calculated from the strain elastography colour coded images. While performing ultrasound elastography, an electronic box was used; this included selected nodule and a sufficient amount of surrounding parenchyma. Within this box, 2 regions of interests were identified, the first one corresponding to the nodule and the second one corresponding to the softest area of normal parenchyma, identified by its blue color on an elastosonogram. Elasticity score was obtained by doing strain elastography. Score 1 and 2 indicated a benign lesion, score 3 was considered as indeterminate and score 4 was considered as malignant [11]. The strain ratio was calculated as the ratio of thyroid nodule strain over the strain of the softest area of parenchyma. The strain ratio of more than 2.50 is considered malignant in most of the recently published articles; hence cut-off value of 2.5 was taken [12,13].

In present study authors have combined TIRADS 1, 2, 3 and 4a, strain elasto-score 1,2,3 and strain ratio of <2.5 as benign nodules. TIRADS 4b, 4c, strain elastography score 4 and strain ratio >2.5 as malignant nodules [14-16].

Ultrasound guided FNAC was performed using 22-gauge needle and it lesion was aspirated using freehand technique. Samples were spread on the slides, dried and were kept in 95% alcohol for Papanicolaou staining. Few of the patients who underwent surgery for thyroid nodules were followed-up by HPE.

STATISTICAL ANALYSIS

All statistical analysis was performed using Statistical Package for Social Science (SPSS, version 17) software for Microsoft Windows. Descriptive statistics were presented as numbers and percentages. The data were expressed as Mean and SD. Chi-square test were used for qualitative data. ROC curve were used for screening test. A two sided p-value < 0.05 was considered statistically significant.

RESULTS

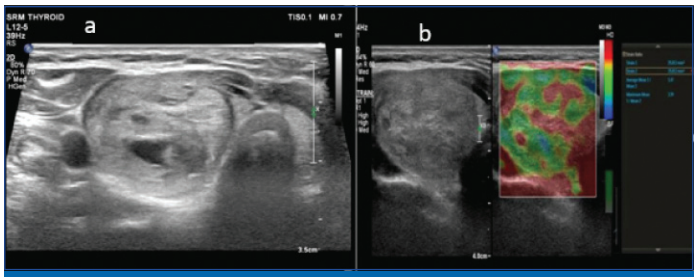
A total of 135 patients with thyroid nodules were included in the study. Age and sex distribution of the patients is given in [Table/Fig-1]. The most common presenting complaint was mass in the neck seen in 47 (35%) of patients followed by dysphagia in 32 (24%) and hoarseness of voice in 29 (21%) of cases. In rest of the patients the nodules were incidentally detected and the patients were asymptomatic. Thyroid nodules were observed in both the lobes in 52 patients (39%), left lobe alone in 42 patients (31%) and right lobe alone in 41 patients (30%).

A total of 111 patients had a TIRADS score of three or lower. Eleven patients were categorised as TIRADS 4. A total of 13 patients had a TIRADS score of 5. Elastography strain ratio was more than or equal to 2.50 in 22 patients (16.3%) and less than 2.50 in 113 patients (83.7%).

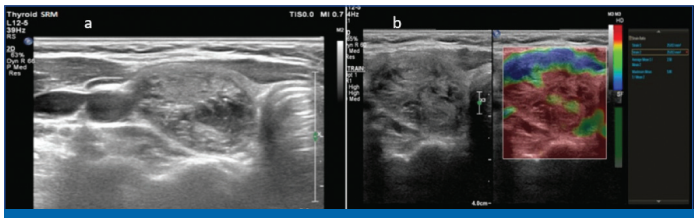
Amongst 135 patients, conclusive diagnosis was obtained by means of FNAC in 125 patients and histopathological examination in rest of the 10 patients. A total of 109 patients (80.7%) had benign nodules [Table/Fig-2a,b]. A total of 15 patients had papillary carcinoma [Table/Fig-3a,b] and one patient had medullary carcinoma by FNAC. Ten patients with inconclusive results or having follicular feature underwent surgery. Histopathological examination of the specimen showed two follicular adenomas, seven follicular carcinoma and one hurthle cell carcinoma [Table/Fig-4].

Age group	Male	Female	Total
<20	3	2	5 (4%)
20-39	20	44	64 (47%)
40-59	21	27	48 (36%)
>60	8	10	18 (13%)
Total	52 (39%)	83 (61%)	135 (100%)

[Table/Fig-1]: Age and sex distribution of patients.



[Table/Fig-2a & 2b]: a) B Mode Ultrasound of follicular adenoma showing a well defined hyperechoic lesion with few anechoic areas and hypoechoic halo in right lobe of thyroid-TIRADS 2; b) On elastography the lesion appeared soft in most parts which was categorised as Grade 2.Strain ratio was less than 2.5.



[Table/Fig-3a & 3b]: a) A heteroechoic lesion with microcalcifications in right lobe of thyroid-TIRADS 5; b) On elastography most of the lesion was hard which was categorised as Grade 4. Strain ratio was more than 2.5.

FNAC/HPE	Frequency	Percentage
Colloid goitre	60	44
Adenomatoid nodule	33	24
Multinodular goiter	16	12
Follicular adenoma	2	2
Papillary carcinoma	15	11
Follicular carcinoma	7	5
Medullary carcinoma	1	1
Hurthle cell carcinoma	1	1

[Table/Fig-4]: Different types of benign and malignant lesions observed in FNAC/HPE findings (N=135).

The final diagnosis was compared to the TIRADS score. Out of 135 nodules, 24 nodules were found malignant by TIRADS score. All patients with Score 4b, 4c and 5 were found to be malignant but four patients with score 4a were found to be benign. Rest 111 cases were found benign by TIRADS out of which 107 were benign in FNAC and rest 4 turned out to be malignant [Table/Fig-5].

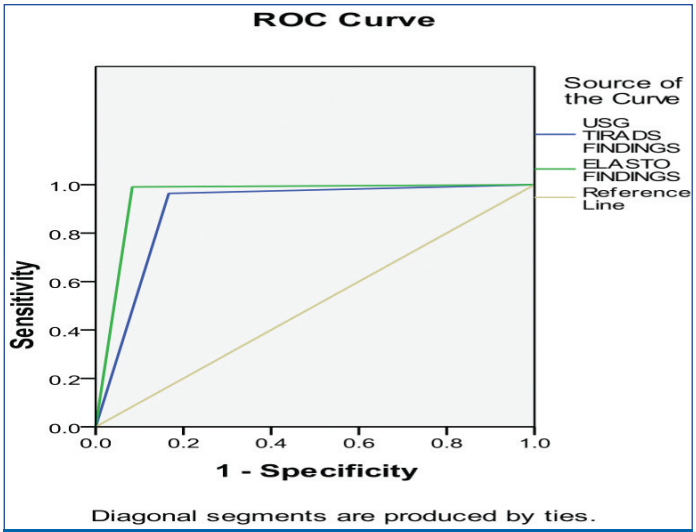
USG TIRADS Findings	FNAC Findings		Total	Chi-square test value	p-value
	Malignant	Benign			
Malignant	20 (83.3%)	4 (16.7%)	24 (100.0%)	85.857	<0.001
Benign	4 (3.6%)	107 (96.4%)	111 (100.0%)		
Total	24 (17.8%)	111 (82.2%)	135 (100.0%)		

[Table/Fig-5]: Diagnostic accuracy of USG TIRADS finding with FNAC findings. p-value <0.05 was considered statistically significant

Out of 135 nodules, 23 nodules were found malignant by strain elastography score and strain ratio. In that 22 nodules were proven malignant by FNAC and the remaining 1 turned out to be benign. Rest 112 cases were found benign by strain elastography score and strain ratio, out of which 110 were benign in FNAC and rest 2 turned out to be malignant. The association between USG Elastography and cytology was found to be statistically significant (p-value-<0.001) [Table/Fig-6]. Using ROC analysis, differentiation of benign and malignant nodules by USG TIRADS scoring system with Area Under the Curve (AUC) was=0.87 (0.8-0.95). Differentiating benign and malignant nodules by USG Elastography grading system with AUC was= 0.87 (0.8-0.95) [Table/Fig-7].

USG elastography findings	FNAC Findings		Total	Chi-square test value	p-value
	Malignant	Benign			
Malignant	22 (95.7%)	1 (4.3%)	23 (100.0%)	115.018	<0.001
Benign	2 (1.8%)	110 (98.2%)	112 (100.0%)		
Total	24 (17.8%)	111 (82.2%)	135 (100.0%)		

[Table/Fig-6]: Diagnostic accuracy of USG Strain Elastography score and Strain ratio findings with FNAC findings.
Data are expressed as mean percentage values. p values less than 0.05 were considered to be significant.



[Table/Fig-7]: ROC Curve of TIRADS, elastography and combined scoring.

Out of 135 nodules in our study, 24 nodules were found malignant by combined TIRADS and strain elastography. In that 23 nodules were proven malignant by FNAC and the remaining 1 turned out to be benign. Rest 111 cases were found benign by combined TIRADS and strain elastography, Out of which 110 were benign in FNAC and rest 1 turned out to be malignant. So out of 135 nodules, 133 nodules diagnosed by combined TIRADS and strain elastography had similar results to that of FNAC.

USG TIRADS scoring system differentiated benign and malignant nodules with sensitivity of 83%, while the specificity was 96.4%, and diagnostic accuracy was 94.1%.

While the combined TIRADS and strain elastography score differentiated benign from malignant nodules with sensitivity of 95.83%, while the specificity was 100%. The diagnostic accuracy of the combined scoring was 99.3% [Table/Fig-8].

Categories	TIRADS	Elasto	Combined
Sensitivity	83%	91.7%	95.83%
Specificity	96.4%	99%	100%
Accuracy	94.1%	98%	99.3%
PPV	83.3%	95.7%	100%
NPV	96.4%	95.7%	99.1%

[Table/Fig-8]: Sensitivity and specificity of TIRADS, elasto and combined scoring.

DISCUSSION

In this study, among 135 cases, most of the patients were between 20-60 years (83%) years of age. Mean age of study population for malignancy was 42 years and benign lesions were 30 years. This is similar to the study done by Du L et al., in which the highest proportion of the thyroid cancer cases was in the 40-59 age groups [17].

Majority of the patients were females, accounting for 6% and the incidence of thyroid malignancy was higher in males. This correlated well with other studies by Nachiappan AC et al., and Ding X et al., which have shown female predominance in the occurrence of thyroid nodules [18,19]. However, the incidence of thyroid malignancy was higher in males than in females (15 out of 60 nodules in males were malignant vs 9 out of 75 nodules in females). This finding contradicts GLOBOCAN study showing that thyroid cancer accounted for 2.1% of the total cancer incidence in 2012, with a worldwide age-standardised incidence rate of 4.0 (1.9 in males, 6.1 in females) per 100,000 person-years [20]. This can be explained by the limited number of males in the study sample and the overall sample size which confidently affected the result of the study in this respect.

In our study, TIRADS had a sensitivity, specificity and diagnostic accuracy of 83%, 96.4% and 94.1%, respectively. Studies evaluating TIRADS score to predict malignancy showed sensitivity varying from as low as 75% to as high as 97%. Specificity was usually more than 95% [21]. This illustrates that TIRADS score is reliable in diagnosing malignancies but not so good in ruling them out.

Unlütürk U et al., showed a low sensitivity of 41% and acceptable sensitivity of 81% while Russ G demonstrated a specificity of 98.5% but specificity was only 44.7% [22,23]. Zhao CK et al., showed sensitivity varying from 15.7 to 89% and specificity from 58.9 to 95.3% [8]. The variability can be attributed to the absence of fixed guidelines and different strain ratios for different studies to determine whether a nodule is malignant or not. Elastography has also been shown to have inter-observer variations. Nodule depth is another factor in assessing the presence of malignancy. The deeper the nodule, the less pressure it will receive and thus less tissue distortion will be observed on compression. Multiple studies confirmed that among all the US strain elastography analysis, the strain ratio was considered to be the strongest independent predictor of thyroid gland malignancy [8,9]. In the present study, the strain ratio was <2.50 in 112 (83.7%) cases which were benign and ≥2.50 was in 23 (16.3%) cases which was malignant. In this study we assessed the combined diagnostic performance of SE with TIRADS score framework and accomplished sensitivity of 95.8%, specificity of 100%, negative predictive value of 99.1% and accuracy of 99.3%. This was superior to either modality on their own.

Only very few studies are available which have combined TIRADS and ultrasound elastography, to calculate overall diagnostic accuracy. Diagnostic accuracy was more than 90% in all these studies [Table/Fig-9] [16,24-29].

Studies	Sample size	Sensitivity	Specificity	Reference standard
Trimboli P et al., 2012 [24]	498	97	100	FNAC or HPE
Gaur S 2019 [25]	50	90	97	FNAC or HPE
Pei S et al., 2020 [16]	1525	94.3	95.6	FNAC or HPE
Sui X et al., 2016 [26]	97	95.45	95.35	HPE
Du YR et al., 2018 [27]	142	94.44	87.14	FNAC or HPE
Lin ZM et al., 2019 [28]	226	83.9	89.1	HPE
Sachdev N et al., 2018 [29]	78	81.8	90.9	FNAC or HPE

[Table/Fig-9]: Correlation with previous studies [16,24-29].
Data shown as percentage values

Limitation(s)

The present study is limited by the number of patients included. Large prospective studies are needed to confirm these results and establish the accuracy of the new technique. Larger sample size will

also help in determination of strain ratio cut off values. Elastographic results can be affected by the characteristics of the nodule which include calcifications, cystic components, and carotid artery pulsation. Shear wave elastography was not done in present study.

CONCLUSION(S)

The combination of Strain elastography with gray scale has to be used in the daily practice to enhance the specificity as well as sensitivity especially in the borderline and equivocal cases to minimise the demand for much more invasive procedures like surgery or FNAC.

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