Original Article

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Efficacy of Ultrasound Intrinsic Compression Strain Elastography in Prediction of Malignancy in Thyroid Nodules with Fine Needle Aspiration Cytology Correlation

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Abstract

Background: Different diagnostic modalities are used to evaluate and diagnose efficiently thyroid nodules. These include Clinical Examinations, Thyroid Function Test (TFT), Scintiscan, Ultrasonography (USG), Fine Needle Aspiration Cytology (FNAC), and Histopathological examination. However, clinical assessment, TFT and USG have been poor parameters for assessing thyroid nodules. The objective is to this study was aimed to evaluate the efficacy of Ultrasound Elastography for the prediction of malignancy in thyroid nodule. **Subjects and Methods:**After obtaining written informed consent, demographic data such as age, sex and clinical features like, swelling, mode of onset, difficulty in swallowing, difficulty in breathing, hoarseness of voice obtained through an interview and recorded on predesigned and pretested proforma (Annexure II). Further these patients were subjected Grayscale Ultrasound, Ultrasound Elastography and FNAC. **Results:** Malignant lesions were noted in 19 patients on FNAC. Among them, 16 (84.21%) patients had malignant lesions while 3 (15.79%) patients had benign lesions based on combined USE and ECI criteria. This difference was statistically significant ($p<0.001$). The sensitivity of combined USE and ECI criteria in the diagnosis of malignant lesions was 84.21% with Specificity of 81.69%, PPV 55.17% and NPV 95.08%. **Conclusion:** Based on the findings of this study it may be concluded that, USE as determined by the Ragos criteria, TI RADS score are highly associated with malignant thyroid lesions and useful in differentiating the malignant thyroid lesions from benign ones.

Keywords: Thyroid Function Test (TFT), Scintiscan, Ultrasonography (USG), Fine Needle Aspiration Cytology (FNAC)

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Introduction

Thyroid gland is unique among endocrine organs as it is the largest endocrine gland in the body and the first to develop in fetal life. Even after 100 years, thyroid gland has been the subject of intense research and considerable attention due to the vast array of developmental, inflammatory, hyperplastic and neoplastic disorders which are exceedingly common in clinical practice. [1]

Thyroid disease is of common occurrence, especially in iodine deficient areas. Thyroid nodule is an abnormal growth of thyroid cells into a lump within thyroid. These nodules have a reported prevalence of four to seven percent of adult population. [2] The incidence of clinically apparent thyroid nodules in general population is four to five percent. [3]

Thyroid nodules represent a difficult diagnostic problem. Benign nodules can be caused by adenomas, colloid nodules, cysts, infectious nodules, lymphocytic or granulomatous nodules, hyperplastic nodules, thyroiditis, and congenital anomalies. Malignant nodules are classified as differentiated (Papillary adenocarcinoma, follicular adenocarcinoma), medullary carcinoma, undifferentiated (Small cell, giant cell and carcinosarcoma) and miscellaneous (Lymphoma, sarcoma, squamous cell carcinoma, fibrosarcoma, mucoepithelial carcinoma and metastatic tumors). However, the cancer rate is low. [4] The incidence of malignancy in patients who undergo Fine Needle Aspiration Cytology (FNAC) is in the range of 9-14%, independent of the number of nodules present. 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. [4]

The usual presentation of thyroid disease is being swelling, pressure symptoms or signs of toxicity. [5] Importance of dis-

crete thyroid nodule lies in the risk of neoplasia as compared to other thyroid swellings. Different diagnostic modalities are used to evaluate and diagnose efficiently thyroid nodules. These include Clinical Examinations, Thyroid Function Test (TFT), Scintiscan, Ultrasonography (USG), Fine Needle Aspiration Cytology (FNAC), and Histopathological examination. However, clinical assessment, TFT and USG have been poor parameters for assessing thyroid nodules. [6]

On physical examination, a hard or firm nature is associated with thyroid malignancy. However, palpation is very subjective and limited in patients with multinodular goiter or small deep-seated nodules. [7]

Conventional USG has been widely used to determine which nodules should be biopsied. There are several suspicious USG features that predict thyroid cancer, such as hypoechogenicity, marked hypoechogenicity, a microlobulated or spiculated margin, micro- or macro-calcifications, and a taller-than-wide shape. [8] Although conventional US can provide meaningful information in thyroid nodule diagnosis, there has been considerable variation in diagnostic performances. [9]

Ultrasonographic studies have suggested that USG alone is not sufficiently reliable to differentiate benign from malignant nodules. Final diagnosis requires morphological examination of lesions and for this FNAC or histological examination becomes mandatory. [10–15] FNAC is widely accepted and has become cornerstone in evaluation of thyroid nodules because it is a simple and accurate screening test with high sensitivity and specificity in the preoperative evaluation of thyroid lesions. The routine use of FNAC in the assessment of thyroid nodules has reduced the number of patients subjected to thyroidectomy for benign diseases of the thyroid. [9] Due to its simplicity, low cost and absence of major complications, this procedure is being performed on an increasing number of patients, which has led to the detection of thyroid cancers at earlier stages, resulting in better outcome of patients. Overall diagnostic efficacy of FNAC is 94.2%.

Ultrasound elastography is a non-invasive tool, which was introduced by Ophir et al. [11] in 1991, and it has shown a promising application for evaluating the stiffness of tissue. US-based elastography can provide an objective evaluation of tissue stiffness. [12] There are two kinds of elastography (strain and shear wave elastography) that are currently used in radiological settings. [13] Most malignant nodules are characterized by the composition of their abnormally firm stroma due to the presence of collagen and myofibroblasts, which make it possible to identify thyroid cancers using elastography imaging. Real-time elastography is only a qualitative ultrasound technique. [14] Ultrasound elastography (USE) the most important addition to the armamentarium of sonographic techniques and it has been the main focus of thyroid USG imaging Research in the last decade. Hence, the final decision or radiological diagnosis is usually based on a combination of conventional US and elastography. However, the data on using various approaches for the evaluation of stiffness with USE is limited and yielded conflicting results. Although many reports have compared conventional US with elastography, these studies, however, are limited in sample size and have reported a wide range of sensitivities and specificities. [15] This prompted us to evaluate the efficacy of USE for the prediction of malignancy in thyroid nodule with FNAC as a standard reference which may help to prevent unnecessary invasive diagnostic procedures in a substantial proportion of patients with completely soft benign nodules.

Subjects and Methods

Study design: The study design was a hospital based crossectional study.

Study period: The present study was conducted from June 2017 to May 2018.

Place: This study was carried out in the Department of Radiodiagnosis at Yashoda superspeciality hospital, Somajiguda, Hyderabad.

Source of Data : Patients referred to the radiology department with thyroid swelling and clinically suspected thyroid lesions.

Sample Size : A total of 100 patients with thyroid swelling and clinically suspected thyroid lesions were studied.

Inclusion criteria:

Patients with thyroid swelling and clinically suspected thyroid lesions referred for ultrasonography of thyroid.

Exclusion criteria :

- Previous surgery or radioiodine therapy
- Patients with predominantly cystic (anechoic nodules without solid components).
- Nodules in Isthmus.
- On ultrasound, thyroid nodules with peripheral calcification are excluded because posterior shadowing calcification produces artifacts (assessed on elastography examination).
- Patient with Hypertension and arrhythmias to avoid variability in intrinsic compression due to carotid pulsations.

After obtaining written informed consent, demographic data such as age, sex and clinical features like, swelling, mode of onset, difficulty in swallowing, difficulty in breathing, hoarseness of voice obtained through an interview and recorded on predesigned and pretested proforma (Annexure II). Further these patients were subjected Grayscale Ultrasound, Ultrasound Elastography and FNAC.

Results

Table 1: Distribution of the patients according to the Age group, Gender, Clinical features, Clinical Diagnosis and power doppler imaging findings

Gender	**Distribution (n=100)**	
	Number	**Percentage**
Male	23	23.00
Female	77	77.00
Total	100	100.00
Age Group		
20 or less	6	6.00
21 to 30	15	15.00
31 to 40	16	16.00
41 to 50	26	26.00
51 to 60	30	30.00
61 to 70	5	5.00
71 to 80	2	2.00
Clinical features		
Swelling	93	93.00
Difficulty in swallowing	22	22.00
Difficulty in breathing	11	11.00
Hoarseness of voice	11	11.00
Clinical diagnosis		
Benign	78	78.00
Malignant	22	22.00
Findings		
Absent blood flow (I)	11	11.00
Peripheral blood flow(II)	51	51.00
Central blood flow (IIIA)	22	22.00
Central and peripheral blood flow (IIIB)	16	16.00
Absent blood flow (I)	11	11.00

Discussion

Thyroid nodules are relatively common and carry a low, but noticeable risk of malignancy. The most important challenge is differentiating benign from malignant nodules, and precise diagnosis and management of malignant nodules in the early stages. [16] A total of 100 patients who presented with thyroid swelling and were clinically suspected to have thyroid lesions were enrolled. These patients were subjected to imaging studies that is, grayscale ultrasound imaging, ultrasound elastography and these findings were correlated with FNAC diagnosis in order to evaluate the accuracy of ultrasound elastography and combined grayscale ultrasound imaging along with ultrasound elastography. The various radiological approaches for thyroid nodules range from conventional ultrasound till MRI updates (including Diffusion weighted imaging [DWI]) including radionuclide studies as isotope scanning and Fluorodeoxyglucose Positron Emission Tomography (FDG-PET). Conventional US considered the initial tool for detection and characterization of thyroid nodules. The present study was aimed to evaluate the efficacy of Ultrasound Elastography for the prediction of malignancy in thyroid nodule.

Epidemiological data suggests that, Thyroid nodules are less frequent in men than in women, [17] accordingly in the present

Table 2: Distribution of the patients according to the Grayscale Ultrasound Imaging findings

Grayscale Ultrasound	Findings	Distribution (n=100)	
		Number	Percentage
Composition (Score)	Spongiform (0)	69	69.00
	Solid or almost completely solid (2)	25	25.00
	Mixed cystic and solid (1)	6	6.00
	Total	100	100.00
Echogenicity (Score)	Hyperechoic or isoechoic (1)	57	57.00
	Hypoechoic (2)	31	31.00
	Very hypoechoic (3)	12	12.00
	Anechoic (0)	0	0.00
	Total	100	100.00
Shape (Score)	Wider than tall (0)	78	78.00
	Taller than wide (3)	22	22.00
	Total	100	100.00
Margins (Score)	Smooth (0)	75	75.00
	Lobulated or irregular (2)	17	17.00
	Extra thyroidal extension (3)	8	8.00
	Total	100	100.00
Echogenic foci (Score)	None or large comet tail artifacts (0)	100	100.00
	Macrocalcifications (1)	0	0.00
	Peripheral (rim) calcifications (2)	0	0.00
	Punctate echogenic foci (3)	0	0.00
	Total	100	100.00

study females outnumbered males as 77% of the patients were females and 33% of the patients were males with the male to female ratio of 1:3.34. Most of the patients were aged between 51 to 60 years (30%) followed by 41 to 50 years (26%). The means age was 44.37±14.02 years. The mode of onset was gradual in all the patients and welling was the common clinical presentation noted in 93% of the patients. Based on clinical assessment, majority of the lesions were diagnosed as benign (78%) lesions and 22% as malignant lesions.

Grayscale ultrasound imaging revealed spongiform composition in 69% of the patients. 57% of the patients had hyperechoic or isoechoic lesions. Majority of the patients (78%) had wider than tall lesions. Smooth margins were noted in majority of the patients (75%).

None of the patient had lesions suggestive of comet tail artifacts, macrocalcifications, peripheral (rim) calcifications, punctuate echogenic foci and calcifications.

61% of the patients had ECI of ≤3.1 and 39% of the patients had ECI of > 3.1. The mean ECI was 2.30±1.67.

Power Doppler imaging revealed most of the patients with peripheral blood flow (51%) while, central blood flow was noted in 22% and central and peripheral blood flow in 16% and absent blood flow in 11% of the patients.

Based on TI RADS score, most of the patients has score suggestive of benign lesions (50%) while high suspicious lesions were noted in 21% of the patients, moderately suspicious in 8%, mildly suspicious in 2% and not suspicious in 19% of the patients. In this study based on Ragos criteria, 34% and 25% of the patients had score of 1 and 2 respectively suggestive of benign lesions. Score of 3 suggestive of intermediate lesions was noted in 10% of the patients and score of 4 and 5 suggestive of malignant lesions was noted in 23% and 8% of the patients respectively. In the present study, radiological diagnosis by combining USE with ECI revealed

Table 3: Distribution of the patients according to the TI RADS score, elasticity contractility index, RAGOS criteria (score), radiological diagnosis based on combined USE and ECI

TI RADS score	Distribution (n=100)	
	Number	Percentage
Benign (TR1)	50	50.00
Not suspicious (TR2)	19	19.00
Mildly suspicious (TR3)	2	2.00
Moderately suspicious (TR4)	8	8.00
Highly suspicious (TR5)	21	21.00
Elasticity contractility index		
≤3.1	61	61.00
> 3.1	39	39.00
RAGOS criteria (score)		
Benign (1)	25	25.00
Benign (2)	34	34.00
Intermediate (3)	10	10.00
Malignant (4)	23	23.00
Malignant (5)	8	8.00
Radiological diagnosis		
Benign	61	61.00
Malignant	29	29.00
Intermediate	10	10.00

Table 4: Distribution of the patients according to the FNAC diagnosis, lesions based on FNAC Diagnosis

FNAC Diagnosis (BETHESDA System)	Distribution (n=100)	
	Number	Percentage
Colloid goitre	32	32.00
Carcinoma	23	23.00
Benign follicular nodule	22	22.00
Hashimoto's thyroiditis	7	7.00
Lymphocytic thyroiditis	5	5.00
Hyperplastic nodule	3	3.00
Adenomatous nodule	3	3.00
Follicular nodule	2	2.00
Hurthle cell neoplasm	1	1.00
Colloid nodule	1	1.00
Benign thyroid nodule	1	1.00
Total	100	100.00
Lesions		
Benign	77	77.00
Malignant	23	23.00

benign lesions in 61% of the patient's malignant lesions in 29% of the patients and intermediate lesions in 10% of the patients. Colloid goitre was the common diagnosis on FNAC noted in 32% of the patients. Based on Bethesda system for reporting

Table 5: Co-relation between RAGOS criterion and FNAC diagnosis

RAGOS Criteria	FNAC Diagnosis				Total (n=100)	
	Benign (n=77)		Malignant (n=23)			
	No.	%	No.	%	No.	%
Benign (1)	25	100.00	0	0.00	25	25.00
Benign (2)	30	88.24	4	11.76	34	34.00
Intermediate (3)	6	60.00	4	40.00	10	10.00
Malignant (4)	15	65.22	8	34.78	23	23.00
Malignant (5)	1	12.50	7	87.50	8	8.00
Total	77	77.00	23	23.00	100	100.00

Table 6: Correlation between TI RADS score and FNAC diagnosis

TI RADS score	FNAC Diagnosis				Total (n=100)	
	Benign (n=77)		Malignant (n=23)			
	No.	%	No.	%	No.	%
Benign	50	100.00	0	0.00	50	50.00
Not suspicious	19	100.00	0	0.00	19	19.00
Mildly suspicious	2	100.00	0	0.00	2	2.00
Moderately suspicious	3	37.50	5	62.50	8	8.00
Highly suspicious	3	14.29	18	85.71	21	21.00
Total	77	77.00	23	23.00	100	100.00

Table 7: Accuracy of ECI alone in the diagnosis of malignant lesion considering FNAC as standard of reference

ECI findings	FNAC Diagnosis				Total (n=100)	
	Malignant		Benign			
	No	%	No	%	No	%
> 3.1	18	78.26	21	27.27	39	43.33
≤3.1	5	21.74	56	72.73	61	67.78
Total	23	23.00	77	77.00	100	100.00

Table 8: Accuracy of combined USE with ECI in the diagnosis of malignant lesion considering FNAC as standard of reference

Radiological	FNAC Diagnosis				Total (n=100)	
	Malignant		Benign			
	No.	%	No.	%	No.	%
Malignant	16	84.21	13	18.31	29	32.22
Benign	3	15.79	58	81.69	61	67.78
Total	19	21.11	71	78.89	90	100.00

thyroid cytopathology, 77% of the patients had benign lesions and 23% of the patients had malignant lesions. Out of 23 patients with malignant lesions, papillary carcinoma was the common malignant lesion noted in 14 patients (60.87%) followed by anaplastic carcinoma in five patients (21.74%) and follicular carcinoma in four patients (17.39%). Out of 77 patients with benign lesions, colloid goitre was the common benign lesion noted in 32 patients (41.56%) followed by benign follicular nodule in 22 patients (28.57%).

Score of four and five suggestive of malignancy was noted in 23 and eight patients respectively. Of them, 34.78% and 87.5% had malignant lesions and 65.22% and 12.5% of the patients had benign lesions on FNAC. This difference was statistically

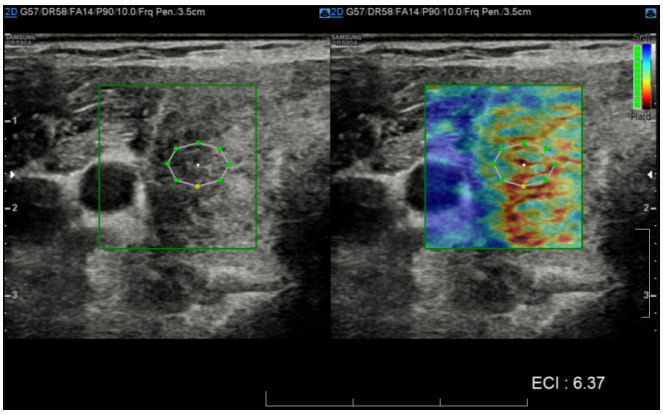

Figure 1: A 52 year old male patient whose ultrasound had hypoechic nodule, ill defined margins, TI-RADS 4, Ragos criteria 4, ECI 6.3, on FNAC, it is a papillary carcinoma and bethesda category VI on FNAC

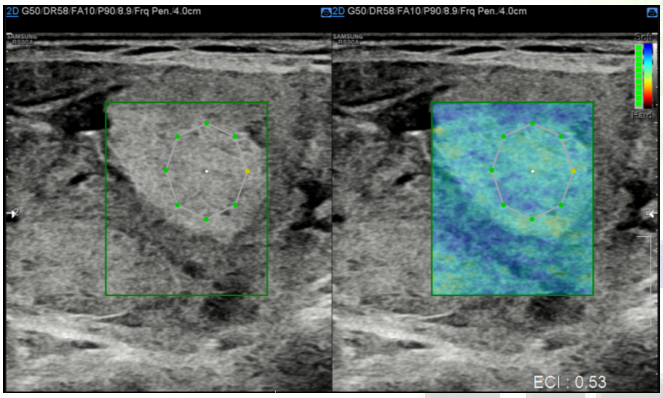

Figure 2: A 45 year old female patient whose ultrasound had spongiform hyperechoic nodule with regular margins, Ragos criteria 2, ECI 0.5, on FNAC, it is Bethesda category 2 and FNAC, it is a colloid goitre

significant (p<0.001).

TI RADS score suggestive of highly suspicious lesions was noted in 21 patients of them, 78.26% of the patients had malignant lesions and 3.06% of the patients had benign lesion on FNAC. This difference was statistically significant (p<0.001). in the diagnosis of malignant lesions was 27.27% with Specificity of 21.74%, PPV 58.85% and NPV 8.20%.

Malignant lesions were noted in 19 patients on FNAC. Among them, 16 (84.21%) patients had malignant lesions while 3 (15.79%) patients had benign lesions based on combined USE and ECI criteria. This difference was statistically significant (p<0.001). The sensitivity of combined USE and ECI criteria in the diagnosis of malignant lesions was 84.21% with

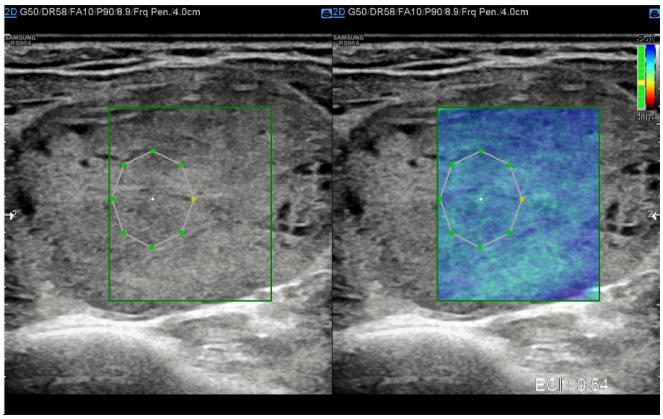

Figure 3: A 32 year old female patient, whose ultrasound had spongiform isoechoic nodule, well defined margins, ragos criteria 2, ECI 0.5, on FNAC, it is BETHESDA category II and diagnosis is benign follicular nodule

Specificity of 81.69%, PPV 55.17% and NPV 95.08%. [18]

Malignant lesions were noted in 23 patients on FNAC. Among them, 5 (21.74%) patients had ECI ≤3.1 and 18 (78.26%) patients had ECI > 3.1. This difference was statistically significant (p<0.001). The sensitivity of ECI.

PPV, positive predictive value; NPV, negative predictive value; USE, combination of conventional ultrasonography and elastography; SE, strain elastography; SWE ,shear wave elastography; ND, not determined.

From the above table it is evident that the diagnostic accuracy of USE and ECI is high and in agreement with the studies by Ragazzoni et al. and Unluturk et al. but low compared to Sweel et al. However it was high compared to Kim et al. Russ et al. Moon et al. Cappeli et al. and Trimboli et al. [18–26]

Overall, USE as determined by the Ragos criteria and TI RADS score are highly associated with malignant thyroid lesions and useful in differentiating the malignant thyroid lesions from benign ones. Furthermore, radiological diagnosis by combining USE (Ragos criteria with score of four or five) along with ECI (cut of value of ≥3.1) is highly sensitive and accurate in differentiating malignant thyroid lesions patients with completely soft benign nodules.

Conclusion

Based on the findings of this study it may be concluded that, USE as determined by the Ragos criteria, TI RADS score are highly associated with malignant thyroid lesions and useful in differentiating the malignant thyroid lesions from benign ones. Furthermore, radiological diagnosis by combining USE (Ragos criteria with score of four or five)

Table 9: PPV, positive predictive value; NPV, negative predictive value; USE, combination of conventional ultrasonography and elastography; SE, strain elastography; SWE ,shear wave elastography; ND, not determined.

Study	Year	No. of cases	Type	Sensitivity (%)	Specificity (%)	Accuracy (%)	PPV (%)	NPV (%)
Trimboli et al.[18]	2012	198	SE	97.0	34.0	50.0	33.0	97.0
Ragazzoni et al.[19]	2012	132	SE	85.0	83.7	84.1	69.4	92.8
Cappelli et al.[20]	2012	159	SE	ND	70.8	73.6	26.3	100
Moon et al.[21]	2012	703	SE	92.2	65.0	73.4	54.1	94.9
Unluturk et al.[22]	2012	237	SE	41.0	93.0	81.0	67.0	83.0
Veyrieres et al.[23]	2012	297	SWE	97.1	55.3	ND	22.5	99.3
Shweel et al.[24]	2013	66	SE	95.4	94.8	95.2	82.3	98.8
Russ et al.[25]	2013	4,550	SE	98.5	44.7	48.3	ND	99.8
Kim et al.[26]	2013	99	SWE	50.0	80.0	78.6	ND	ND
Present study	2017	100	SWE	84.21	84.69	82.22	55.17	95.08

along with ECI (cut of value of ≥3.1) is highly sensitive and accurate in differentiating malignant thyroid lesions patients with completely soft benign nodules. Hence patients presenting with thyroid nodules may be investigated for Gray Scale Ultrasound imaging and Ultrasound Elastography which may be helpful in preventing invasive diagnostic procedures in a substantial proportion of patients with completely soft benign nodules.

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