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Original article:

Comparative study of ultrasonography by tirads classification and histopathology in solitary thyroid nodule

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Abstract:

Aim: To compare findings of USG of thyroid by TIRADS classification and histopathological examination in STN and to assess the effectiveness by TIRADS classification in management.

Methodology: 56 euthyroid patient with clinically palpable STN more than 1cm were selected and subjected to detailed ENT including indirect laryngoscopy, systemic Examination and USG by TIRADS classification. They were subjected to definitive surgical procedure i.e Hemithyroidectomy or Total Thyroidectomy. Post-operative specimen was sent for histopathology. Data obtained was analysed using appropriate statistical test and inference draw.

Result: We found that Sensitivity, specificity of USG by TIRADS classification for differentiating benign and malignant thyroid nodule were 85.7% and 96.36% respectively. Accuracy being 95.16%. PPV and NPV was 75% and 98.14%.

Conclusion: TIRADS classification is simple practical method of accessing thyroid nodule with high PPV for malignancy and justified on routine basis for management of STN.

Keywords: Solitary thyroid nodule , TIRADS ultrasonography

Introduction:

Solitary nodules are one of the commonest presentations of thyroid disorder[1].In India the prevalence of a palpable thyroid nodule in the community is about 12.2%[2]. A solitary nodule has a higher risk of malignancy than a multinodular goitre[3].The incidence of malignancy in STN is 10- 30%[4, 5]. Solitary thyroid nodule is more common in woman with female to male ratio being 6:1[6]. When thyroid nodule is present in men, the risk of malignancy is twice that of female[7]. The incidence of unsuspected carcinoma is quite high in solitary thyroid nodule in euthyroid patient to justify exploration in all cases in which patient is fit for surgery[8].

The initial evaluation of thyroid nodules should always focus on exclusion of malignancy. Ultrasonography is the initial investigation and histopathology is considered gold standard. The terminology of TIRADS was first used by Horvath et al[9]. Thyroid Imaging Reporting and Data System (TIRADS) was further

modified and described by Kwak *et al*[10]. It is a relatively simple system which can be easily adopted, just like Breast Imaging-Reporting and Data System (BIRADS) which has been successfully used for several years to assess breast lesions[11]and for its management. On the basis of TIRADS classification, patients are classified into six categories ranging from normal thyroid to a malignant nodule[12].

Methodology / materials and methods:

Study design: Descriptive study

Period of study: 2 year study from August 2016 to September 2018.

Sampling method: Every consecutive patient of either sex attending E.N.T OPD and Surgery OPD, of a Tertiary Health Care Centre, fulfilling inclusion criteria was included in the study. Prior Institutional Ethical Committee clearance was obtained.

Written informed consent taken. The study comprised of 62 patients.

Inclusion criteria:

- Patients of solitary Thyroid Nodule of either sex of age 18 and above.
- All euthyroid patients with clinically palpable solitary nodule of more than 1 cm.

Exclusion criteria:

- Multinodular goitre on ultrasonography.
- Previously operated cases.

The selected patients were subjected to detailed history and complete ENT examination. A detailed history of thyroid swelling was inquired. Detailed clinical, systemic examination and local examination of neck was done. Indirect laryngoscopy using 70 degree endoscope was done to evaluate vocal cord mobility. Thyroid function test (T3, T4, and TSH) was done to confirm euthyroid status.

Ultrasonography technique and TIRADS classification of STN:

It was done on OPD basis by a senior radiologist using Esote My lab 50 X vision machine with higher resolution equipped with Linear probe of 7.5 MHz to 12MHz. With the help of clinical information, they evaluated the sonographic features such as the internal composition, echogenicity, margins, presence and type of calcifications, and the shape of all solitary thyroid lesions.

Solid component, hypoechogenicity, microcalcification, taller than wider shape and irregular margins were considered high risk features.The radiologists then reviewed the ultrasound findings and determined the category of a particular lesion according to the TIRADS classification suggested by Kwak et al[10], wherein, normal thyroid gland was classified under TIRADS 1 (negative), benign nodule under TIRADS 2, probably benign nodule (no suspicious ultrasound features) under TIRADS 3, a nodule with low suspicion under TIRADS 4A, a nodule with intermediate suspicion for malignancy (two suspicious ultrasound features with or without lymphadenopathy) under TIRADS 4B and a nodule highly suggestive of malignancy (four or five suspicious ultrasound features with or without lymphadenopathy) under TIRADS 5.

Cervical lymph nodes were evaluated for their size, loss of the central, acrogenic hilum, presence of irregular and indistinct margin, micro calcification, and necrotic changes.

CLASSIFICATION[13]

TIRADS 1 - Normal thyroid gland

TIRADS 2 - Benign gland

TIRADS 3 - Probably benign

TIRADS 4A - Suspicious lesion

TIRADS 4B- Probably malignant

TIRADS 5 - Proven malignant

Fine Needle Aspiration Cytology Technique:

FNAC and if required ultrasonography guided FNAC was done on OPD basis using aseptic precaution.The results obtained were classified according to Bethesda classification.

CT scan was planned in those patients who were diagnosed to have malignancy on FNAC to know the extent and to stage the disease. Routine blood investigations,chest x-ray (PA view), neck x-ray lateral view was done.

Patients were subjected to definitive surgical procedures according to standard guidelines i.e. Hemithyroidectomy or Total thyroidectomy, with preservation of parathyroid gland depending upon USG and FNAC report and also after considering any high risk features for malignancy.Histopathology reporting was done and those patients who had benign lesion on histopathology were discharged and routine follow up of patients was done and those with malignancy were managed according to standard guidelines for head and neck malignancy.

Statiscal analysis:

SPSS version 16.0 was used to calculate all the statistical parameters.

Sensitivity, Specificity, positive and negative predictive value of each TIRADS group was calculated compared with the gold standard histopathology using appropriate formula.Fischer's exact test or Chi square test was used to analyze the significance of difference between frequency distribution of the data.In analyses, $P\ value < 0.05$ was taken to indicate statistical significance and the accuracy of TIRADS was determined.

Observation and results:

1) The mean age was 37.48 ± 10.60 years.
2) Ratio of Male: female in my study was 1: 5.8
3) In my study all patient came with complaint of neck swelling which was the primary concern. Sudden increase in size was observed in 8 (12.9%) patients. Change in voice was observed in 7 (11.29%) patients. 5 (8.04%) patients showed symptom of dysphagia. Only one subject had difficulty in breathing. 1 patient came with symptom of pain.
4) 47 (75.8%) patients came early to the hospital with complaint of neck swelling for </=12 months, followed by 8 (12.9%) patients who had goitre of 13-24 months duration. While, only 1 (1.6%) patient had neck swelling for 37-48 months. Four patients had neck swelling for more than 48 months.

Table 1: Showing distribution of patient according to Bethesda system and TIRADS Classification (N=62)

Classification System		**No. of patients**	**Percentage (%)**
Bethesda System	Category 1	7	11.29
	Category 2	41	22.58
	Category 3	6	9.68
	Category 4	4	6.45
	Category 5	1	1.61
	Category 6	3	4.84
Total		62	100
TIRADS Classification	TIRADS 2	40	64.52
	TIRADS 3	14	22.58
	TIRADS 4a	3	4.84
	TIRADS 4b	3	4.84
	TIRADS 5	2	3.23
Total		62	100

5) In my study, on FNAC it was observed that 7(11.29%) patients belonged to category 1 having inconclusive or bloody aspirate. We found that majority of patients, that is 41 (22.58%) belonged to category 2 having colloid/ cystic/ follicular cells/ adenoma. This was followed by 6 (9.68%) patients in category 3 having atypic cells with lymphocytes. Category 4 of Bethesda showing suspicious lesion for follicular neoplasm was observed in 4 (6.45%) patients and category 5 Bethesda having suspicion for malignancy was found in only 1 (1.61%) patient and 3 (4.84%) patients had category 6 on Bethesda indicating malignancy.
6) TIRADS 1 is considered normal thyroid gland. According to TIRADS classification, majority of the patients that is 40 (64.5%) were classified under TIRADS 2 having benign lesion. 14 (22.6%) patients were under TIRADS 3 having probably benign lesion. 3 patients (4.84%) were in TIRADS 4a having low suspicious lesion. TIRADS 4b who had high suspicious lesion were found in 3 (4.84%) patients and TIRADS 5, comprising 2 (3.23%) patients was found to have malignant lesion.
7) For the convenience of statistical analysis, to calculate the ability of TIRADS classification to detect malignancy, patient were interpreted into 2 groups.
   Benign group - TIRADS 2, TIRADS 3
   Malignant group - TIRADS 4a, TIRASDS 4b, TIRADS 5.

Table 2: Distribution of patients according to Surgery performed (N=62).

Surgery performed	**No of patients**	**Percentage (%)**
Hemithyroidectomy	55	88.71
Total thyroidectomy with central compartment node clearance.	4	6.45
Hemithyroidectomy followed by Completion thyroidectomy and central compartment node clearance.	3	4.84
Total	62	100.0

8) Hemithyroidectomy was performed in 55 (88.7%) patient. 4 (6.5%) patients who had malignancy on FNAC underwent CT scan. All four patients were found to have stage 2 thyroid malignancy, hence underwent total thyroidectomy with central compartment neck node clearance. 3 patient who were diagnosed to have benign lesion on FNAC but their histopathology report showed malignancy, had to undergo repeat surgery and completion thyroidectomy with central compartment neck clearance was performed in each of them after appropriate Staging and considering high risk feature as per standard guidelines.

Table 3: Distribution of subjects according to Histopathology findings in patients (N=62).

Histopathology	**No of patients**	**Percentage (%)**
Colloid cyst/ goiter/ cystic nodule	32	51.61
Hasimotos thyroiditis	1	1.61
Follicular adenoma	22	35.48
Follicular Carcinoma	2	3.23
Follicular variant of papillary carcinoma	2	3.23
Papillary carcinoma	3	4.84
Total	62	100.0

9) In my study it was found that majority of the patients that is 32 (51.61%) patients had colloid goitre / cystic nodule as diagnosis followed by 22 (35.48%) patients who follicular adenoma. 1 (1.61%) patient had showed hashimotos thyroiditis. Thus it was observed that benign lesion comprised of 55 (88.71%) of the total study patients. Carcinoma was diagnosed in total 7 patients. Papillary carcinoma was observed in 3 (4.84%) patients. While, 2 (3.23%) patients showed follicular carcinoma and 2 (3.23%) patients showed follicular variant of papillary carcinoma.
10) Transient hypoparathyroidism was most common complication and was found in 5 (8.06%) patient, among which three patient underwent total thyroidectomy and two patient underwent completion thyroidectomy. 1(1.61%) patient had transient nerve paresis and that patient had hashimotos thyroiditis on histopathology and had undergone hemithyroidectomy. One patient each of hemithyroidectomy presented with complication of wound infection and seroma formation. One patient diagnosed to have malignant nodule had permanent hypoparathyroidism and also right side recurrent nerve palsy after undergoing completion thyroidectomy.

Table 4: Diagnostic utility of TI-RADS interpretation and histopathology interpretation in study subjects.

		Histopathology interpretation		
		Benign	Malignant	Total
TI-RADS interpretation	Benign(2,3)	53	1	54
	Malignant(4a,4b,5)	2	6	8
Total		55	7	62

	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Accuracy	p Value
USG TIRADS	85.7%	96.36%	75%	98.14%	95.16%	<0.0001

It was observed that USG by TIRADS classification, have a sensitivity of 85.7%, specificity of 96.36%, PPV of 75% and NPV of 98.14%. Its accuracy to diagnose malignancy is 95.16%.
The P value observed is <0.0001 which is statically significant.

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Discussion

In India the prevalence of a palpable thyroid nodule in the community is about 12.2%. However, thyroid cancer is quite rare with incidence of 8.7 per 100000 people per year[14, 15].Malignancy occur in about 5% of all thyroid nodules independent of their size[16]. Solitary thyroid nodules (STN) occur in 4 - 7% of the adult population with 10- 20% incidence of malignancy[17].So, people should be educated to take early intervention. The main goal is to identify those STN with malignant potential as they are amendable to medical or surgical management. Hence it is become mandatory to develop a tool which can differentiate benign from malignant thyroid nodule. Thus, STN should be characterized properly for optimum management[16].

The terminology "Thyroid Imaging Reporting and Data System" (TIRADS) was first used by Horvath et al. They described 10 USG patterns of thyroid nodules and related the rate of malignancy according to the pattern. However, these USG patterns were not applicable to all thyroid nodules and seemed difficult to use in routine clinical practice. To further achieve a practical tool in the hands of sonographers in analysing thyroid nodules and to improve communication between radiologists and clinicians, Russ et al. Recommended another TIRADS classification[18].

According to TIRADS classification, majority 40 (64.5%) of the patients were classified under TIRADS 2 having benign lesion. 14 (22.6%) patients were under TIRADS 3 having probably benign lesion. 3 patients (4.84%) were in class 4a having low suspicious lesion. TIRADS 4b with high suspicious lesion were found in 3 (4.84%) patients and 2 (3.23%) patients were having TIRADS 5, malignant lesion. For the convenience of statistical analysis, to calculate the ability of TIRADS classification to detect malignancy, patient were interpreted into 2 groups. Benign group includes TIRADS 2, 3 and malignant group includes TIRADS 4a, 4b, 5.Out of 62 subjects in total, 54 (87.09%) subjects were diagnosed with benign tumour (TIRADS 2 and 3) while, 8 (12.90%) subjects were diagnosed with malignant tumour (TIRADS 4a, 4b and 5).It was observed that all patients in benign category of TIRADS were found to have benign nodule on histopathology except one case who belonged to TIRADS 3, but was found to have papillary carcinoma. Out of three patients of class 4a, one patient had malignancy and other two had benign lesion on histopathology. All the three patients of class 4b and all the two patients of class 5 were found to have carcinoma on histopathology.

According to Bhatnagar et al[19]2017, out of sixty patients with STN, distribution of cases according to TIRADS classification system was, 10 patients, 29 patients, 12 patints,5 patients and 4 patients in TIRADS class 2, 3, 4a, 4b and class 5 respectively. All patients in benign category of TIRADS were found to have benign nodule on histopathology except one case who belonged to TIRADS 3, but was found to malignant on histopathology. Out of 17 patients in class 4a and 4 b, four patients were found to have malignancy. All the four patients from class 5 were malignant on histopathology. Chandramohan et al[20]2016reported that out of 346 patients, 66 and 122 patients were in TIRADS class 2 and 3 respectively out of which 3 and 30 patients were found to have malignancy respectively. Patients in Class 4a, 4b, 4c and 5 were 49, 27, 35 and 47 respectively out of which 14,

14, 16 and 41 patients were malignant.Also, according to Bersenaset al[21]2017, most frequent category in TIRADS classification of STN was benign (69.23%) and malignant category account for about 17.64%. According to study by Rahal Junior et al[22]2016, the proportion of malignancies among TIRADS 2 was 0.8%, and TIRADS 3 was 1.7%. Among those classified as TI-RADS 4A, proportion of malignancies was 16.0%, 43.2% in 4B, 72.7% in 4C and 91.3% among TI-RADS 5 ($p<0.001$), showing clear association between TI-RADS and biopsy results.Friedrich-Rust et al[23]2013 reported that 100% of patients with thyroid nodules scored as TIRADS-2 had benign nodules while 87% of nodules scored TIRADS-5 were malignant which can be correlated with the present study. In contrast, Wang et al[24]2017 reported that the malignancy risk was 2.6% among class 3 nodules which was beyond the recommended malignancy rate (<2.0%). The malignancy risk was 16.4% among class 4a nodules.

Surgical management was done using standard guidelines. In this study, Hemithyroidectomy was performed in 55 (88.7%) patients with STN with benign diagnosis. Total thyroidectomy with central compartment neck dissection was performed in 7 patients. In our study, we had 3 cases of Papillary carcinoma, these were diagnosed preoperatively on FNAC..All these cases underwent total thyroidectomy with central compartment node clearance.

In our study, we had 2 patients of Follicular variant of papillary carcinoma. Both these cases were having pre-operative FNAC report suggestive of benign lesion, so we underwent hemithyroidectomy but after histopathology reported iagnosed it as malignant, we did completion thyroidectomy in these 2 patients. Both these patients were under malignant group of TIRADS. This can be correlated with study by Jena et al[25]2015 in which hemithyroidectomy was performed in benign nodules by FNAC report. In those cases where postoperative HPE was reported as malignant, completion thyroidectomy of the remaining lobe was done. Total thyroidectomy was done in those cases where FNAC was reported as malignant. Study by Deepthi et al[26]2017reported that small benign solitary nodules regress with medical therapy alone. In large solitary nodules, and in those nodules not regressing with medical therapy, hemithyroidectomy was adequate. In multinodular goiter and malignant nodules, total thyroidectomy was advocated.
In their study, hemithyroidectomy was done in benign STN patients (39 patients out of 67) and total thyroidectomy was done in malignant nodule .

In our study, distribution of patients was done according to histopathology findings. It was found that majority of the patients that is 32 (51.61%) patients had colloid goitre / cystic nodule as diagnosis followed by 22 (35.48%) patients who had follicular adenoma. 1 (1.61%) patient had hashimoto's thyroiditis. Thus it was observed that, benign lesions were present in 55 (88.71%) of the total study patients. Papillary carcinoma was observed in 3 (4.84%) patients. While, 2(3.23%) patients each had follicular carcinoma and follicular variant of papillary carcinoma. These findings were in accordance with the study by Kehet al[27]2015, in which majority 37.7% of patients of STN had follicular adenoma followed by colloid nodule in 19.7% patients. 16.4% and 14.8% patients had papillary carcinoma and follicular carcinoma respectively. Only 3.3% patients had

hashimoto's thyroiditis. Also, according to study by Md. Abul Hossain et al[28]2015,histopahtological examination of STN revealed nodular colloidal goitre 52%, follicular adenoma 34%, papillary carcinoma 12%, follicular carcinoma 4%, anaplastic carcinoma 2% and auto immune thyroiditis 6% which correlates our study.

In this study, it was observed that USG by TIRADS classification, have a sensitivity of 85.7%, specificity of 96.36%, Positive predictive value (PPV) of 75% and Negative predictive value (NPV) of 98.14%. Its accuracy to diagnose malignancy is 95.16%. The P value observed was (<0.0001) which is statically significant. Similarly, according to Macedoet al[29] 2018, the sensitivity, specificity, NPV and accuracy of the TI-RADS were 100, 61.6, 100, and 63% respectively. Also Chandramohanetal[20]2016 concluded that the diagnostic performance of TIRADS considering categories 4a, 4b, 4c, and 5 as malignant and categories 2 and 3 as benign was- Sensitivity = 72%, specificity = 68.8%, PPV = 63.9%, negative predictive value (NPV) = 76.2%, and accuracy = 70.2%.Bhatnagar et al[19]2017 also revealed that the sensitivity and specificity for Irregular contours were 44.4% and 94.12%, for taller than wide were 22.22% and 100%, for microcalcification were 33.3% and 94.12%, for marked hypoechogenicity were 78% and 70.89% and for solid consistency were 89 and70.5% respectively. The risk of malignancy was found to increase from TIRADS 3 to TIRADS5.Also, In a study by According to study by Zhang et al[30]2015, the sensitivity, specificity, PPV, NPV and accuracy of TIRADS were 97%, 90%, 40%, 99%, and 91%, respectively similar to this study. In accordance with our study, Wei et al[31] in 2016 reported that pooled sensitivity and specificity were 0.79 and 0.71 respectively. In a study by Srinivas et al[32] 2016. The risk of malignancy in TIRADS categories 1 and 2 was found to be 0%, 0.64% in category 3, 4.76% in category 4A, 66.67% in category 4B, 83.33% in category 4C, and 100% in category 5. A study by Delfim et al[33]2017 sensitivity was (82.0%) and specificity was (87.6%),

Limitations of study:

1. The number of malignant cases studied during this limited period was not sufficient enough to make concrete conclusions, and needs a larger data to come to a final conclusion and justifyits use in surgical management in day to day management of Solitary Thyroid Nodule.
2. The experience of the Radiologist is an important factor affecting the outcome of the study.

Conclusion:

In our study It was observed that in three cases in which malignancy was missed on FNAC, all these 3 cases were under malignant group of TIRADS classification. Thus if TIRADS classification was considered for management, second surgery in those patient could have been avoided.

It was observed that USG by TIRADS classification have good sensitivity, specificity, positive and negative predictive value being 85.7%, 96.36%, 75% and 98.14 % respectively. In our study USG TIRADS have a good accuracy rate to diagnose malignancy.

USG is a non-invasive, cheap, easily accessible and accurate modality to diagnose malignant thyroid lesion and TIRADS classification have good ability to differentiate between benign and malignant nodules ,thus can help

the clinician in management of STN on routine basis thus avoiding second thyroid surgery which carries high mortality and morbidity.

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