Original Research Article

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A clinical study comparing the accuracy of the clinical examination, ultrasonography, fine needle aspiration cytology with that of histopathology

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ABSTRACT

Background: Fine needle aspiration cytology (FNAC) is considered the gold standard diagnostic test for the diagnosis of thyroid nodules. FNAC is a cost-effective procedure that provides specific diagnosis rapidly with minimal complications. Aims was to compare efficacy of Clinical diagnosis, ultrasonography (USG), FNAC with one another and with that of histopathological examination (HPE) diagnosis.

Methods: It is a prospective comparative study in 60 patients admitted with thyroid swellings in the department of General Surgery were taken for study purpose. The clinical diagnosis, ultrasonogram report, FNAC and HPE were included in the study.

Results: Thyroid disease is 4.54 times more common in females. Thyroid disease is more common in the reproductive age group with the mean average age of 37.91±11.02 years. The male:female sex ratio for carcinoma is 1:2.33. Benign thyroid disorders constitute 83.3% of the total thyroid disorders. The overall efficacy of FNAC (88.33%) is far higher than USG (76.66%) and clinical diagnosis (56.66%). Sensitivity for diagnosis of thyroiditis clinically is very poor (45.45%) as compared to diffuse goiter (71.43%). FNAC can reasonably differentiate benign from malignant lesion most of the time with sensitivity of about 90%.

Conclusions: Ultrasonogram alone cannot correctly diagnose different types of benign lesions with accuracy. However, it can most of the time differentiate benign from a malignant lesion. It has an overall efficacy of 76.7%. The efficacy of FNAC is nearly 90% making it an essential diagnostic tool for diagnosing thyroid disease.

Keywords: Histopathology, FNAC, Ultrasound

INTRODUCTION

Thyroid gland is unique among endocrine glands in that it is the first endocrine gland to appear in the fetus. It is the largest of all endocrine glands (weighing about 25-30 gm) and is the only one which is amenable to direct physical examination. Thyroid is one of the most common clinical entities seen by the well experienced surgeons, fresh surgeon, post graduate/an under graduate.

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. What is the incidence of each of the different thyroid diseases, its sex ratio, etc. We need to analyze this. Moreover, we have an array of tests to diagnosis the disease of thyroid ranging from skillful clinical examination, different imaging modalities, cytology, histopathology to the most sophisticated PET

scan. In a country like India where the main constraint is affordability, we cannot put the patient through a lot of expensive investigations.¹

We need to know what investigations are to be done and when to be done. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of these investigations have to be analyzed. Does the particular investigation we do add any additional information to help in treating the patient one should be aware of the strengths and limitations of these methods? This study, in comparing the accuracy of the clinical examination, ultrasonography, FNAC with that of histopathology, would help us to achieve these objectives.

METHODS

It is a prospective and comparative study in 60 patients admitted with thyroid swellings in the department of general surgery were taken for study purpose. Study done from May 2019 to April 2021 for a period of two year. Patients were clinical diagnosed with ultrasonogram report, FNAC and HPE were included in the study. Patients were selected randomly with random allocation software is created in Microsoft visual basic 6. Patient randomization were done after enrollment in the study by us and random sequence will be generated and opened by the default viewer for the output file with total sample size 60.

Histopathology report was taken as the gold standard, clinical diagnosis, USG and FNAC were compared with that of HPE. Informed written consent was obtained from all the patients participating in the study.

Inclusion criteria

Patients with palpable thyroid swellings admitted during the study period were included in the study.

Exclusion criteria

Patients for whom either FNAC or USG report was not available, admitted for completion thyroidectomy, whom the final HPE report was thyroglossal cyst, with toxic goiters and whom the FNAC was non-diagnostic/unsatisfactory, diagnosis was not made because of inadequate cellular material.

Patients who satisfied the inclusion criteria were taken for study purpose. The information collected regarding all the selected cases was recorded in a Master Chart. Data analysis was done with the help of computer using epidemiological information package (EIP 2002). Using, this software range, frequency, percentage, mean and standard deviation were calculated. Sensitivity, specificity, accuracy, positive predictive value and negative predictive value were calculated

RESULTS

All the patients admitted with thyroid lesions and satisfying the inclusion criteria were included in the study population. There were totally 60 cases. After excluding cases of: Completion thyroidectomies (3 cases), thyroglossal cyst (3 cases), USG and/or FNAC done elsewhere (13 cases) and without USG or FNAC report (3 cases).

We had in total of 60 cases for the study purpose over the past two years.

The histopathology report was taken as the gold standard and other parameters where compared with that of HPE.

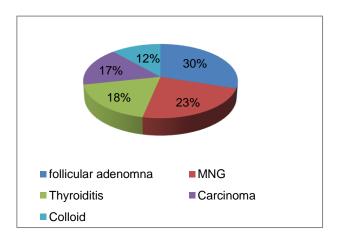


Figure 1: Percentage of cases asper HPE diagnosis.

Benign thyroid disorders constituted 83.3% (50 0f 60) of the total thyroid disorders. Follicular adenoma alone constituted around 30% of the total thyroid disorders inflammatory thyroid disease (Thyroiditis) constituted about 18.3% out of which Hashimoto's thyroiditis alone constituted nearly 95%. Thyroid carcinoma constituted another 1/6th of the total thyroid disorder (16.7%) out of which papillary carcinoma alone constituted 80% (8 0f 10) and 20% cases were found to be follicular carcinoma.

Table 1: Demographic distribution of cases in study.

Variables	Cases						
	N	%					
Age group (years)							
<20	3	5.00					
20-29	11	20.00					
30-39	19	35.00					
40-49	20	31.67					
50-59	4	3.33					
>60	3	5.00					
Gender							
Female	49	81.67					
Male	11	18.33					

The 66.7% of the study population was in the age group between 30 to 49 years. Only 10% of the patients were

less than 20 or more than 60. Thyroid disease is more common in the reproductive age group with the mean average age of 37.91±11.02 years. Thyroid disease is 4.54 times more common in females.

The mean age was maximum for carcinoma 49.3 ± 8.73 ranging from 38 to 63 and minimum for colloid goiter 29.85 ± 9.75 ranging from 16 to 43. The mean age of follicular adenoma, MNG and thyroiditis were found to be 32.5 ± 8.59 , 37.07 ± 9.07 and 42.63 ± 10.27 respectively.

In all thyroid disease female predominance was seen, being maximum in MNG and colloid goiter (1:6) and minimum- in carcinoma (2.33 times). The male: female ratio of follicular adenoma and thyroiditis were 1:5 and 1:4.5 respectively.

Benign thyroid disorder constituted 83.3% of the total thyroid disorders. Carcinoma thyroid had a higher mean age while the benign disorders occurred at mean lowerage. The male:female sex ratio for carcinoma is 1:2.33.

The overall efficacy of FNAC (88.33%) is far higher than USG (76.66%) and clinical diagnosis (56.66%).

Table 2: General efficacy of different investigations.

Investigation	Cases confirmed positive in this investigation and HPE		
	N	%	
Clinical diagnosis	34	56.66	
USG	46	76.66	
FNAC	53	88.33	

Sensitivity for diagnosis of thyroiditis clinically is very poor (45.45%) as compared to diffuse goiter (71.43%). The sensitivity of diagnosing thyroiditis very poor (43%).

Many patients (nearly 40%) who were diagnosed as solitary nodule clinically, had a second nodule on ultrasound, making USG a sensitive tool to diagnose MNG (Adenomatous goiter). Sensitivity and specificity to diagnose a carcinoma is 70% and 96% respectively.

FNAC can reliably differentiate benign from malignant lesion most of the time with sensitivity of 80%. Sensitivity for thyroiditis was nearly 91%, a disease where clinical diagnosis and USG are unable to establish the diagnosis most of the time.

Table 3: Efficacy of clinical diagnosis.

Disease	Sensitivity	Specificity	Accuracy	PPV	NPV
STN	66.67	88.10	81.67	70.59	86.05
MNG	57.14	89.13	81.67	61.54	87.23
Thyroiditis	45.45	89.80	81.67	50.00	88.00
Carcinoma	50.00	86.00	80.00	41.67	89.58
Diffuse goiter	71.43	94.34	91.67	62.50	96.15

Table 4: Efficacy of USG in diagnosing thyroid disorders.

Disease	Sensitivity	Specificity	Accuracy	PPV	NPV	
STN	77.78	95.24	90.00	87.50	90.91	
MNG	85.71	89.13	88.33	70.59	95.35	
Thyroiditis	63.64	91.84	86.67	63.64	91.84	
Carcinoma	70.00	96.00	91.67	77.78	94.12	
Diffuse goiter	71.43	98.11	95.00	83.33	96.30	

Table 5: Efficacy of FNAC in diagnosing thyroid disorders.

Disease	Sensitivity	Specificity	Accuracy	PPV	NPV
STN	94.44	97.61	96.66	94.44	97.61
MNG	93.33	91.11	91.67	77.78	97.62
Thyroiditis	90.91	97.96	96.67	90.91	97.96
Carcinoma	80.00	100.00	96.67	100.00	96.15
Diffuse goiter	85.71	98.11	96.67	85.71	98.11

DISCUSSION

In this study of thyroid swellings comprising of 60 cases, 66.7% of the study population was in the age group between 30 to 49 years with a mean age of 37.91 years. This result is comparable to the results obtained by Kapur and coauthors who found 54% of the patients in the 20-40

years.² of age group, while Ghoshal et al found 30-50 years as the common age group.³ The mean age was maximum for carcinoma 49.3±8.73 ranging from 38 to 63 and minimum for colloid goiter 29.85±9.75 ranging from 16 to 43. The mean ages of Follicular adenoma, MNG and thyroiditis were found to be 32.5±8.59, 37.07±9.07 and 42.63±10.27 respectively. These results are

comparable to the results given by Rajan et al in a clinical, ultrasonographical and pathological study of 654 cases of goiters in Madurai Tamil Nadu.⁴ Mean age of 49.3 suggests increased incidence compared to other benign disorders as is widely quoted in literature.

There was a clear preponderance of females to males almost 4.5:1ratio, (81.67% females) affected with thyroid pathologies. This finding is consistent with almost all studies of thyroid diseases. In all thyroid diseases female predominance was seen, being maximum in MNG and colloid goiter (1:6) and minimum in carcinoma (2.33 times) this denotes the increased incidence of carcinoma in male population which is consistent with that in the literature. The male: female ratio of Follicular adenoma and Thyroiditis were 1:5 and 1:4.5 respectively.

Jarlov in 2000 has studied the observer variation in diagnosis of thyroid gland.⁵ He stated that clinically estimating the thyroid gland (size and morphology) was subject to considerable observer variation, and the observer variation was greatest concerning the palpation of a solitary thyroid nodule where even experienced doctors had difficulties in reproducing their own evaluations. The reproducibility was not improved when the doctors had additional access to patient history and clinical examination as well as the scintigram. Jarlov et al earlier in his article had concluded that palpation of the thyroid should not be used when an accurate size evaluation is considered of importance.⁶ There was an average error of 39% among doctors in evaluating the gland. Lisboa et al stated in his article that clinical examination of the thyroid is unreliable in establishing the presence of goiter in schoolchildren because it tends to overestimate thyroid size. Nevertheless, it can be used as a screening test. Palpation of thyroid size is neither accurate nor reproducible if an exact volume is aimed at. A rough division into small, medium and large goiters is reproducible and rather accurate and may therefore be applied. Studies have given an accuracy value ranging from as low as 30% to as high as 80% in various thyroid disorders. STN was the most common clinical diagnosis (17) followed by MNG (13), carcinoma (12), diffuse goiter and thyroiditis (9) each.

In our study, 34 cases out of the 60 were found to be correctly diagnosed by clinical examination with overall efficacy of 56.6%. Of the 26 which were wrongly diagnosed (5) of the clinically diagnosed carcinomas turned out to be thyroiditis finally, (2) turned out to be follicular adenomas (2) STNs turned out to be follicular carcinomas, (3) STN s turned out to be MNGs. (3) Diffuse goiters turned out to be multinodular goiters. (2) Thyroiditis turned out to be Carcinomas and (2) to be Follicular adenomas (2). MNG s turned out to be follicular adenomas on histopathology (1) diffuse goiter and (1) MNG finally turned out to be thyroiditis, (1) thyroiditis and (1) MNG turned out to colloid goiter on histopathology.

Ultrasound is increasingly being regarded as the "true" diagnosis in the morphological description of the thyroid gland. It has been demonstrated that thyroid imaging is subject to considerable observer variation. Roles of USG in the assessment of thyroid swellings are detection of thyroid and other cervical masses before and after thyroidectomy. Differentiation of benign from malignant masses on the basis of their sonographic appearance. Provides the size and multicentricity of the lesion, Invasion into adjacent structures. Guidance for FNAC. To detect cervical lymphadenopathy and sub clinical nodularity.

Features suggestive of malignancy on USG are (almost always), hypoechoic pattern incomplete peripheral halo, irregular margins, internal microcalcification, presence of cervical lymphadenopathy and peripheral degeneration in mixed nodules. Features suggestive of benign diseases on USG are-halo sign (transonic uniform rim surrounding the mass), variable echogenicity, multilocularity, large cystic lesion, diffusely nodular nonhomogeneous gland and peripheral calcification. Moon et al has studied the ultrasonogram in 857 patients and showed an acceptable malignancypredicting value of USG in thyroid nodules supporting the potential role of USG for predicting malignancy in selected patients with thyroid nodules.8 However, the high rate of indeterminate results precludes it from being a standard independent diagnostic method at the present time.

USG correctly diagnosed malignancy in (1) patient in whom FNAC failed to achieve the correct diagnosis. On the other hand, FNAC revealed malignancy in (1) patient in whom USG indicated a benign lesion. In our study, (7) malignancies recognized by USG were confirmed on HPE later. In (3) patients, in which USG gave a false negative diagnosis of benign disease, HPE revealed in follicular carcinoma in (2) and papillary carcinoma in (1). In (2) of these patients USG gave diagnosis of follicular adenoma and in (1) as multinodular goiter. In (1) patient false positive diagnosis of malignancy turned out to be thyroiditis. Thus, sometimes it is not possible to differentiate between benign lesions and malignancy. Katz et al 1984 also found that USG was unable to differentiate between thyroiditis and malignant lesions. 9

In our study, we found the sensitivity and specificity of USG to be 77.78% and 95.24% in solitary thyroid nodules. In consistency with our study, Watters et al found that the sensitivity and specificity of USG were 74% and 83% respectively. They emphasized that the USG has an added advantage of allowing the whole gland to be examined rather than the dominant nodule; but was limited by the fact that no features were pathognomonic for malignancy. So, it should be regarded as a complementary rather than an alternative investigation to FNAC in the management of solitary thyroid nodules. Jones et al found the sensitivity and specificity of USG to be 75% and 61% respectively. 11

Table 6: Comparison between different studies on ultrasonography.

Study	Year	N	Sensitivity (%)	Specificity (%)			
Comparison between different studies on USG							
Watters et al ¹⁰	1992	100	74	83			
Jones et al ¹¹	1990	120	75	75			
Gurumani et al ¹²	2013	50	71.4	77.7			
Present	2021	60	77.78	95.24			
Comparison between similar studies on FNAC							
Al-Sayer et al ¹³	1985	70	86	93			
Cusick et al ¹⁴	1990	283	76	58			
Manoj et al ¹⁵	2006	75	80	86.6			
Present	2021	60	94.44	92.86			

The 46 out of 60 cases were correctly diagnosed by USG. Of the (14) false diagnosis (3) MNGs and (1) carcinoma on USG turned out to be thyroiditis on HPE. (1) MNG and (2) STNs on USG turned out to be carcinoma on HPE. (3) Thyroiditis and (1) carcinoma on USG turned out to be follicular adenoma on HPE. (1) Thyroiditis and (1) colloid turned out to MNG on HPE, and (1) MNG on USG turned out to be colloid goiter on HPE.

The sensitivity and PPV were maximum for MNG (85.71) and minimum for thyroiditis (63.64) whereas the accuracy, NPV and specificity were maximum for colloid goiter. PPV and accuracy were minimum for thyroiditis indicating that USG is not a very useful diagnostic tool in it's diagnosis which was started by Katz et al.⁹

FNAC is found to be the most useful first line of investigation than other investigations like USG, thyroid scan and serologic studies. FNAC leads to early diagnosis and aids in the treatment of thyroid lesions. FNAC has good amount of accuracy up-to 97% in the preoperative diagnosis of various thyroid lesions. This has been claimed by Handa et al while others believe, correct preoperative diagnosis can be made only in 25%, hence there is marked discrepancy regarding this subject. ¹⁶ The sensitivity was minimum for carcinoma (80%) and maximum for STN (94.44%), specificity was 91.11 for MNG and 100% for carcinoma. The PPV for MNG was 77.78% and 100% for carcinoma. Similar findings have been corroborated by numerous authors like Suen et al and Gupta et al. ^{15,17}

FNAC correctly gave the diagnosis in 53 out of 60 patients with an overall efficacy of 88.33. Out of the (7) cases falsely diagnosed on FNAC (2) MNGs and (1) follicular neoplasm finally turned out to be carcinoma on HPE. (1) MNG turned out to be Follicular adenoma (1) thyroiditis turned out to be colloid and vice versa.

The false negative and false positive FNAC diagnosis for malignancy in various series ranged from 5-10% [18-20, 38]. In our study it ranged from 5-20% in various

disorders. In our study 11.7% (n=7) cases were diagnosed as malignant on FNAC, out of which all were papillary carcinomas and no medullary carcinoma. Handa et al diagnosed 2.53% cases as papillary carcinoma and 0.69% cases as medullary carcinoma. Gupta et al found 12% papillary carcinoma and 0% medullary carcinoma. Tabaqchali et al found 14% papillary and 0.7% medullary carcinoma. Medullary carcinoma. Support of the suppor

Ultrasonogram and FNAC when assessed together had higher sensitivity and specificity in general compared to when used alone. with over all combined sensitivity of about 95.2% and specificity of about 94.8% possibly covering the short comings when used alone, making them integral parts of triple assessment.

The results, we found, in our study are comparable to other studies on FNAC. The false negatives especially in follicular carcinoma prevent it from being taken as the gold standard for diagnosing thyroid diseases. The final diagnosis as well as any further treatment were subsequently changed depending on the final histopathology diagnosis. Hence histopathology is taken as the gold standard investigation in diagnosing thyroid disorders.

Limitations

Our study was conducted in a resource limited setting with no external funding. One of the limitations of our study was a small sample size. A prospective clinical study is required to strengthen the present study findings.

CONCLUSION

Thyroid disorders are common disorders in the community occurring frequently in the reproductive age group. They predominantly affect females. Malignant disease has a lesser female predominance than benign disease. Malignant thyroid disorders constitute 1/6th of the total thyroid disorders, papillary thyroid carcinoma is the most common type of malignancy encountered.

Clinical diagnosis is not an accurate method to diagnose thyroid disorders because about 44% of diseases were not correctly diagnosed by clinical examination. It should always be followed by ultrasonogram and FNAC. Ultrasonogram alone cannot correctly diagnose different types of benign lesions (MNG, STN, thyroiditis) with accuracy. However, it can most of the time differentiate benign from a malignant lesion. It has an overall efficacy of 76.7%.

The efficacy of FNAC is nearly 90% making it an essential diagnostic tool for diagnosing thyroid disease. All thyroid disorder patients should be subjected to FNAC before surgery. When combined together ultrasonogram and FNAC have higher sensitivity and specificity. The final diagnosis as well as any further treatment were subsequently changed depending on the

final histopathology diagnosis. Hence Histopathology is taken as the gold standard investigation in diagnosing thyroid disorders.

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Institutional Ethics Committee

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