Section: General Surgery

Original Research Article

DIAGNOSTIC ACCURACY OF TRIPLE ASSESSMENT IN COMPARISON WITH HISTOPATHOLOGICAL EXAMINATION IN PATIENTS WITH THYROID NODULES

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ABSTRACT

Background: Thyroid diseases are common. Very small nodules and subclinical pathologies may easily be missed and prevalence of nodules in autopsy series is much higher and approaches 50%. Clinical signs and symptoms are inadequate to diagnose thyroid disorder. USG gives complete evaluation of thyroid. FNAC gives cytological details. Triple assessment prevents unnecessary and avoidable surgery in commonly seen multinodular goitres & other benign lesions. **Objective:** To investigate effectiveness of triple assessment in diagnosis of malignancy. **Materials and Methods:** Diagnostic accuracy study was carried out among 50 inpatients admitted for evaluation of thyroid nodules and underwent clinical examination, ultrasound, ultrasound guided FNAC for evaluation of thyroid nodules during the study period. Detailed history, clinical examination, ultrasonography, fine needle aspiration cytology was carried out. Patients were subjected to surgical treatment wherever indicated. Sensitivity, specificity, positive predictive value and negative predictive value of all the three components of triple assessment were compared. Wherever surgical intervention was undertaken the same was compared with HPE findings. **Result:** Most commonly affected age group was 20-40 years. Females were commonly more affected than males. Most of the patients had swelling from 1-2 years. Dysphagia was seen 8% of the cases. 88% of the cases had firm swelling. Lymph node involvement was seen in 12% and carotid pulse was seen in all cases. Most common clinical diagnosis was solitary thyroid nodule in 80% of the cases. Only 20% were having multinodular goitre. Sensitivity of triple test and histopathology for benign and malignant lesions: 100% Specificity of triple test and histopathology for benign lesions: 100% PPV: 100% NPV:100% Accuracy: 100%. **Conclusion:** The triple assessment in our study was accurate predictor of malignancy, the diagnostic accuracy of triple test and histopathology for malignant lesions, specificity, sensitivity, PPV, NPV was 100%, that proved it as a best initial test for diagnosis of malignancy preoperatively.

INTRODUCTION

Thyroid gland is the largest endocrine organ in the body. Thyroid disorders can be broadly classified as disorders of functions, disorders of structure and miscellaneous. Disorder of structure, due to various etiological factors, will give rise to thyroid swelling in neck region. Thyroid swellings can vary right from simple diffuse physiological goitre to a high-grade malignancy. Thyroid diseases are common worldwide and in India too there is a significant burden of thyroid disease. It has been estimated that thyroid disease has a reported prevalence of 4% to 7% in the general population on neck palpation.[1] However, very small nodules and subclinical pathologies may easily be missed and the prevalence of nodules in autopsy series is much higher and approaches 50%. Some authors have suggested that

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in absolute numbers, about 42 million people in India suffer from thyroid diseases.[2] Clinical signs and symptoms are inadequate to diagnose the thyroid disorder as some similar presentations are seen in various thyroid swellings. For example, thyroglossal cyst and isthmic cyst can both present with a midline neck swelling with cystic consistency, which must be differentiated based on clinical examination. Management of thyroid swelling begins with taking a complete history of the patient, thorough clinical examination, lab investigations (mainly thyroid function tests - free T3, free T4 and ultra-thyroid stimulating hormone i.e., TSH levels in serum) to know the functional state of thyroid gland; FNAC and radiological investigations (USG).[3]

USG gives complete evaluation of thyroid with respect to its size, echotexture, multicentricity, its shape, presence of nodules and their details, vascularity, the involvement of lobes and isthmus, presence of calcification, infiltration in surrounding structure, localise lesion for FNAC, assess cervical lymphadenopathy, etc. FNAC gives cytological details to reach the final diagnosis, required for management planning. It is advised to do USG prior to FNAC. Triple assessment consisting of physical examination including risk stratification, imaging (USG) followed by image guided FNAC will clinch the benign and malignant nature of thyroid lesion effectively. Triple assessment prevents unnecessary and avoidable surgery in commonly seen multinodular goitres & other benign lesions.[4]

This study aims to investigate effectiveness of triple assessment in clinching the diagnosis of malignancy and to guide the management in patients presenting with thyroid nodules.

MATERIALS AND METHODS

Diagnostic accuracy study was carried out in Department of General Surgery, Malla Reddy Institute of Medical Sciences, Suraram, Medchal from JANUARY 2020 TO JUNE 2021 among 50 in patients who were admitted for evaluation of thyroid nodules and underwent clinical examination, ultrasound, ultrasound guided FNAC for evaluation of thyroid nodules during the study period

Patients with thyroid nodules, aged 18-70 years of either gender, who have given written consent on the informed consent form were included. Patients not willing for ultrasonography, image guided FNAC, to undergo surgery were excluded.

After taking approval from scientific committee and ethics committee, informed consent was taken from the patient. Detailed history regarding thyroid dysfunction, family history of thyroid disease and risk of thyroid malignancy was obtained. All patients were physically examined with special attention to any clinical features of malignancy like involvement of surrounding structures and presence of lymph nodes etc. All patients were subjected to ultrasonography (USG) with special reference to size of lesion, number of lesions and any features of malignancy. Further, all patients were subjected to image guided FNAC (fine needle aspiration cytology). Patients were subjected to surgical treatment wherever indicated. Sensitivity, specificity, positive predictive value and negative predictive value of all the three components of triple assessment were compared. Wherever surgical intervention was undertaken the same was compared with HPE findings.

Statistical Analysis: All data was collected in approved proforma, and entered in MS excel 2019, and was subjected to statistical analysis. Descriptive data was analysed using proportions.

RESULTS

Table 1: Distribution of participants as per different characteristics

Characteristics		Number	%
Age (years)	20-30	19	38
	31-40	18	36
	41-50	7	14
	51 and above	6	12
Sex	Male	13	26
	Female	37	74
Duration of swelling (years)	1-2	19	38
	3-5	18	36
	6-8	7	14
Clinical presentation	Pain	3	6
	Dysphagia	4	8
	Dyspnoea	0	0
Consistency of swelling	Firm	44	88
	Hard	6	12
Lymph node	Yes	6	12
Carotid pulse	Yes	50	100

Most commonly affected age group was 20-40 years. Females were commonly more affected than males. Most of the patients had swelling from 1-2 years. Dysphagia was seen 8% of the cases. 88% of the

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cases had firm swelling. Lymph node involvement was seen in 12% and carotid pulse was seen in all cases. (Table 1)

Table 2: Clinical diagnosis of the swelling

Clinical diagnosis	Number	%
Solitary thyroid nodule	40	80
Multinodular goitre	10	20

Most common clinical diagnosis was solitary thyroid nodule in 80% of the cases. Only 20% were having multinodular goitre. (Table 2)

Table 3: Diagnostic accuracy of triple test and Histopathology for benign lesions

		Result of histopathology		Total
		Yes	No	
Results of triple test	Yes	41	0	41
	No	0	9	9
Total		41	9	50

Sensitivity of triple test and histopathology for benign lesions: 100% Specificity of triple test and histopathology for benign lesions: 100% PPV: 100% NPV:100% Accuracy: 100%. (Table 3)

Table 4: Diagnostic accuracy of triple test and Histopathology for malignant lesions

		Result of histopathology		Total
		Yes	No	
Results of triple test	Yes	9	0	9
	No	0	41	41
Total		9	41	50

Sensitivity of triple test and histopathology for malignant lesions: 100% Specificity of triple test and histopathology for benign lesions: 100% PPV: 100% NPV:100% Accuracy: 100%. (Table 4)

DISCUSSION

Thyromegaly or nodular lesions in the thyroid are commonly seen in surgical OPD. In overwhelming majority of these lesions are benign in nature and are usually due to degenerative diseases like multinodular goitre. However, the malignancy of thyroid though rare, also presents as nodular lesion of thyroid. Thyroid swelling is probably the most common endocrine problem in the world today. Normal thyroid gland is impalpable. Enlargement of the thyroid gland is the most common manifestation of the thyroid disease. The enlargement may be either generalized or localized, which again may be toxic or nontoxic. The nontoxic goitre is further divided on etiological basis as endemic goitre and sporadic goitre. The endemic goitre is defined as one where more than 10% of population shows thyroid swelling. A thyroid nodule is a discrete lesion within the thyroid gland that is palpably and/or sonographically distinct from the surrounding thyroid parenchyma. A solitary thyroid nodule exists within a thyroid gland of normal dimensions and morphology, whereas a dominant thyroid nodule exists within a diffuse or multinodular goitre. Thyroid nodules come to clinical attention when noted by the patient or as an incidental finding during routine physical examination or during a radiologic procedure, such as carotid ultrasonography (USG) or neck computed tomography (CT). Several disorders may be the cause of a thyroid nodule. The majority of thyroid nodules are asymptomatic. Their clinical importance is primarily related to the need to exclude a thyroid malignancy.[5]

Thyroid nodules are very common, with an estimated prevalence of approximately 4% by palpation (5% in women and 1% in men living in iodine sufficient regions). A thyroid nodule larger than 1 cm in diameter is usually palpable. However, the detection of a nodule by palpation also depends on its location within the thyroid, on the structure of the patient's neck and on the experience of the examiner. In the Framingham Study, clinically apparent thyroid nodules were present in 6.4% of the women and 1.6% of the men who participated, with an estimated annual incidence, by palpation, of 0.001.[5] The lifetime risk of developing a thyroid nodule is reported to be 15%. Nevertheless, only 5% of the clinically apparent thyroid nodules are malignant. Thyroid carcinoma annual incidence is 1-2 per 100,000 population, which accounts for 90% of the malignancies of the entire endocrine system, 1% of total human malignancies and 0.5% of total deaths from malignancies,[51] Although thyroid malignant tumors are not usually aggressive, thyroid malignancies are responsible for more deaths than all other malignancies of the endocrine system Due to the wide use of USG, the prevalence of thyroid nodules has increased to within a range of 20% to 67% in randomly selected populations, with a higher frequency in women and the elderly. This means that a thyroid nodule found incidentally in an asymptomatic patient (thyroid incidentaloma) is not rare.[6]

Moreover, in patients with a clinically palpable nodule the USG may identify additional nodules in 20-48% of subjects. Thus, the use of USG alters the primary evaluation of thyroid nodularity based on

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palpation. In addition, the prevalence of thyroid nodules in patients with no history of thyroid disease was 37-57% in surveys based on autopsy.[7] Thyroid nodules constitute a diagnostic challenge mainly because of the need to exclude thyroid malignancy. It is also necessary to exclude nodular hyperfunction (autonomous adenoma or toxic multinodular goitre). Physical examination of the thyroid is a safe, non-invasive and rapidly performed procedure that is commonly used to assess the thyroid for size, shape, consistency, tenderness and the presence of nodularity. While ultrasonography represents a more sensitive diagnostic tool, patients are unlikely to receive such testing unless clinical suspicion exists thus thyroid palpation represents a key method of reaching such suspicion. Ultrasonography is the recommended next step in the evaluation of thyromegaly detected on physical examination.

Thyroid nodules are found in approximate 5% of the general population and 95% of these nodules are benign in nature. Although certain sonographic features of thyroid nodules have been associated with an increased risk of malignancy (i.e. predominantly solid nodule, hypo echogenicity, microcalcification, macrocalcification, ill-defined margins, intranodular vascularity, and taller-than-wide shape), no one feature is sensitive or specific enough to either exclude or diagnose malignancy. High-resolution ultrasonography has the capability to detect small, nonpalpable thyroid nodules, termed "incidentalomas" in the literature.[8]

Although most "incidentalomas" are benign, monitoring is required as the risk for malignancy in asymptomatic nodules found in non-irradiated glands ranges from 0.45% to 13%. Of note, a recent study suggests that the presence of benign appearing enlarged cervical lymph nodes on ultrasound evaluation increases the predictive value in diagnosing thyroid cancer. Biopsy via ultrasound guided fine needle aspiration is the gold standard to diagnosis thyroid cancer. Thyroid ultrasonography also helps to identify other potential thyroid disease. Diffuse thyroid echogenicity on sonography has been shown to predict patients with diffuse lymphocytic thyroiditis who are prone to develop hypothyroidism

The patients were between 20 to 65 years of age with a mean age of 35 years. These findings correlate with studies conducted by Chowdury et al,[9] who suggested occurrence of multinodular goitre in 2nd and 3rd decade of life. Risk factors that increase the probability of malignancy of a thyroid nodule are age under 30 or over 60 years male sex (8% versus 4% in female), history of head and neck irradiation in childhood and family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia (MEN) type 2.

In the present study, 74% were Female and 26% were male. Sex distribution was similar when compared to Afroze et al,[10] and Mans Akerman,[11] where there was strong evidence of female preponderance. The commonest clinical presentation is swelling in front of the neck and majority presented between 6 months to 3 years Thyroid nodules are more frequent in women, in iodine deficient regions, in older ages and in patients with a history of head or neck irradiation. The mean duration of swelling in years was 2.56 ± 1.70. 38% with duration Clinical presentation: In the present study based on clinical presentation, 6% had pain, 8% had dysphagia. Based on consistency, in 88% the swelling was Firm and in 12% it was Hard. Lymph node swelling in 12% and carotid pulse felt in all the patients.

FNAC: Based on FNAC findings, benign lesions were nodular goitre (20%), hyperplastic thyroid nodule (4%), colloid nodule (28%), benign cystic lesion (16%). Suspicious malignant lesions were follicular neoplasia (22%) and malignant lesions identified were papillary carcinoma (10%).

The overall sensitivity in present study was 82.92%, 100%, while the specificity was 82.92%, 100% for both benign and malignant lesions. FNAC has certain limitations because of suspicious diagnosis.

In Altavilla et al study,[12] the overall sensitivity was 71.43% and in Gharib et al study,[13] over all sensitivity was 98%. These supports the present study which show the overall sensitivity was 75.31% & 52.63% for benign and malignant lesions respectively. In Altavilla et al,[12] the overall specificity was 100% and in Gharib et al,[13] over all specificity was 99%. These supports the present study which show the overall sensitivity was 100%, for benign and malignant lesions respectively.

On FNAC 34 nodules were identified as benign and 16 were malignant. Out of the benign nodules on FNAC, 8 were benign cystic lesions, 2 were hyperplastic thyroid nodule, 14 were colloid nodules, 10 were nodular goitre.

Out of the 16 suspicious malignancy and malignant lesions, 11 were follicular neoplasia and 5 were papillary carcinoma. On Histopathology, the 8 benign cystic lesions were diagnosed as 1 benign cystic lesion, 3 benign follicular adenoma, 1 as colloid nodule, 2 as multinodular goitre, 1 as nodular goitre. Hyperplastic thyroid nodules were diagnosed as benign follicular adenoma on HPE. Out of the 14 colloid nodules, 3 were diagnosed as benign follicular adenoma and 11 as colloid nodule. Out of the 10 nodular goitre, 2 were diagnosed as benign follicular adenoma, 6 as multinodular goitre, 2 as nodular goitre. Out of the 11 suspicious malignant lesions, 6 were diagnosed a benign follicular adenoma, 1 as colloid nodule, 4 as papillary carcinoma of thyroid. All the 5 papillary carcinomas diagnosed on FNAC were confirmed as the same of Histopathology. In the present study none of the patients were posted for repeat FNAC due to inadequate sample. All the samples were adequate. The adequacy of the smear was 100% in our study, supported with studies of Cap et al 14 where it was 92.5%. Management guidelines for patients with thyroid nodules and differentiated thyroid cancer recommend FNAC as the procedure choice in the evaluation of thyroid nodules.

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Ultrasonography: High frequency (7-15 MHz) linear-array transducer is used. Since thyroid is located superficial sonography is the best imaging modality for evaluation of thyroid. Scanning is done both in transverse and longitudinal planes. Real time imaging of thyroid gland is done; it is performed using both gray-scale and color Doppler techniques.

The thyroid nodules on USG were subdivided in to 3 groups-benign, suspicious and malignant on the basis of various sonographic features. Features suggestive of malignancy on USG are-hypoechoic pattern, incomplete peripheral halo, irregular margins, internal micro calcification, increased vascularity, 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 in homogenous gland and peripheral calcification.

In our study, out of 24 cases diagnosed to be malignant on USG, 12 cases were confirmed on histopathology and remaining 12 cases were differed to be benign. In 5 cases in whom USG gave false negative diagnosis of benign disease, histopathology revealed papillary carcinoma. The overall sensitivity in our series was 81.7%, 63.16%, while the specificity was 77.78%, 85.19% for both benign and malignant lesions on USG.

In Watters et al,[15] the overall sensitivity was 74%. These supports the present study which show the overall sensitivity was 80.48% & 22.2% for benign and malignant lesions respectively. In Watters et al,[15] the overall specificity was 83%. These supports the present study which show the overall specificity was 77.78% & 85.19% for benign and malignant lesions respectively.

Watter et al,[15] interpreted an USG report as suggestive of malignancy if the nodule was solid or of a mixed solid-cystic variety and a hypoechoic and no haloed lesion. They emphasized that the USG has 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 pathognomic for malignancy, so that it should be regarded as complementary rather than an alternative investigation to FNAC in the management of solitary thyroid nodule. It has been a consistent observation according to published literature, that the risk of thyroid cancer is less with multiple nodules than with the solitary nodules. High resolution real-time USG is far better than clinical examination in detecting thyroid nodularity.

Histopathology: Based on histopathological findings, Benign cystic lesions (2%), Benign follicular adenoma (32%), Colloid nodule (26%), Multinodular goitre (16%), Nodular goitre (6%), Papillary carcinoma (18%) Manderkar et al 16 in 1995 found that from 1557 smears reported 89.58% were benign and 1.73% were malignant lesion. Silverman et al,[17] in 1986 reported out of 273 cases, 13 (04.76%) with thyroiditis. In our study we had no single patient with thyroiditis. Taking into consideration Histopathology as a gold standard, correlation of FNAC finding with histopathology finding was done. Out of 19 reported malignant conditions which include 19 (17.14%) papillary carcinoma, from which all correlated as papillary carcinoma on FNAC, so the sensitivity and specificity of FNAC with histopathology are 75.31% and 100% for benign lesions and 52.63% and 100% for malignant lesions respectively the present study findings are similar to the findings of Goellner et al,[13] Altavilla et al,[12] and Manderkar et al.[16]

Ultrasonography with Histopathology: In the present study, On USG, 40 cases were diagnosed as benign and 10 as malignant. Based on ultrasound findings, Cystic lesions (12%), Hyperechoic nodule (44%), Multi nodular goitre (14%) Suspicious multinodular goitre in 6% and malignant mixed echogenic nodule in 6%. Out of 6 cystic lesions on USG, 5 were diagnosed as colloid nodule and 1 as nodular goitre. Out of 22 hyperechoic nodules on USG, 13 were diagnosed as benign follicular adenoma, 7 as colloid nodule, 1 as multinodular goitre, and 1 as papillary carcinoma Out of 12 multinodular goitre cases on USG, 6 were diagnosed as papillary carcinoma of thyroid, 2 as nodular goitre, 2 as multinodular goitre, 1 as colloid nodule and 1 as benign follicular adenoma. Out of 7 suspicious malignancies, 1 was diagnosed a benign cystic lesion, 2 as benign follicular adenoma, 3 as multi nodular goitre, 1 as papillary carcinoma of thyroid. Out of 3 malignant lesions on USG, 1 is confirmed as papillary carcinoma thyroid and 2 as multinodular goitre.

Limitations of The Study

1. Smaller malignant lesions can be mistaken as benign lesion on ultrasound (e.g. Small papillary carcinoma can be mistaken as colloid goiter).
2. There can be inter observer variation on ultrasound evaluation.
3. Follicular adenoma and follicular neoplasm are difficult to differentiate on ultrasound.

CONCLUSION

Thyromegaly or nodular lesions of thyroid are common and majority of these are benign in nature, malignancy though rare also presents as nodular lesion of thyroid. It is impossible to diagnose differentiated malignancies of thyroid from benign conditions based on history and physical examination alone. The triple assessment in our study was accurate predictor of malignancy, the diagnostic accuracy of triple test and histopathology for malignant lesions, specificity, sensitivity, PPV, NPV was 100%, that proved it as a best initial test for diagnosis of malignancy preoperatively. Similarly, the diagnostic accuracy of triple test and histopathology for benign lesions, specificity, sensitivity, PPV, NPV was 100%. Thus, Triple assessment prevents unnecessary and avoidable

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surgery in commonly seen multinodular goitres & other benign lesions.

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