"ROLE OF THYROID IMAGING, REPORTING AND DATA SYSTEM IN DIFFERENTIATION OF BENIGN AND MALIGNANT THYROID LESIONS AND CYTOPATHOLOGICAL CORRELATION AT TERTIARY CARE CENTRE, BELAGAVI - A ONE YEAR HOSPITAL BASED STUDY"

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LIST OF ABBREVIATIONS USED

FNAC	–	Fine Needle Aspiration Cytology
BIRADS	–	Breast Imaging Reporting Ana Data System
TIRADS	–	Thyroid Imaging Reporting And Data System
ACR	–	American college of Radiology
HPE	–	Histopathological examination
AP	–	Antero-posterior
CT	–	Computed tomography
MRI	–	Magnetic Resonance Imaging
TSI	–	Thyroid stimulating immunoglobulin
TSH	–	Thyroid stimulation hormone
MEN	–	Multiple Endocrine Neoplasia
USG	–	Ultrasonography
TTW	–	Taller-Than-Wider Shape
ATA	–	American Thyroid Association
EXTN	–	Extension

ABSTRACT

INTRODUCTION

Thyroid gland is the largest and the most superficially located endocrine gland because of which it is evaluated excellently by Ultrasonography.

In India the prevalence of a palpable thyroid nodule in the community is about 12.2%, according to a recent study. However, thyroid cancer is quite rare, and the incidence is 8.7 per 100000.

Thyroid Imaging, Reporting, And Data System (ACR- TIRADS) gives the guidelines to differentiate the thyroid nodules into benign or malignant and is an excellent tool to rule out thyroid malignancy and hence reduce the need of invasive procedures like fine needle aspiration(FNA) or biopsy.

Therefore, the main aim of our study is to differentiate palpable thyroid nodule into benign or malignant based on ACR- TIRADS guidelines and compare sonographic findings with cytopathology.

OBJECTIVES:

1. To study the role of Thyroid Imaging, Reporting, and Data System (ACR-TIRADS) in differentiation of benign and malignant thyroid lesions
2. To correlate the Ultrasonographic findings with cytopathological reports over a period of one year at KLEs Dr. Prabhakar Kore charitable hospital.

MATERIAL AND METHODS:

The current study was a prospective observational study, conducted in the Dr.Prabhakar Kore hospital and MRC, KLE University, Belgaum between January 2019 and December 2019 for a period of 1 year in 40 patients having palpable thyroid

nodules. All the study participants were evaluated with a thorough clinical history and physical examination.

40 patients were included in the study. They were evaluated with grey-scale Ultrasonography of thyroid nodules, and were assigned TI-RADS category based on evaluation of echogenicity, composition, margins, shape and echogenic foci. Then the reports were correlated with cytology or pathological reports to know the sensitivity and specificity of the ACR TI-RADS system.

RESULTS

Our study included evaluation of 40 nodules in 40 patients which included: 32 females and 8 males with mean age of 49.5 years. 36 nodules (90%) nodules were benign and 4 nodules (10%) were malignant.

Features like shape, margins, echogenicity and echogenic foci were statistically significant in differentiating benign and malignant lesions. However composition was not statistically significant in prediciting the malignancy according to the present study. Overall the ACR TI-RADS system has a sensitivity and specificity of 78.3% and 100% respectively.

INTERPRETATIONS AND CONCLUSIONS

The study is based on ACR TI-RADS scoring system to stratify the nodules into TR1 to TR5 categories based on various features which could predict the benignity or malignancy and to correlate the findings with histopathological reports. The method is simple and easily applicable in evaluation of the thyroid nodules in daily practice. This system has proven to have high predictability to detect a malignant nodule in the present study with best cut-off point being TR4 category.

USG features like irregular margins, taller than wide shape, increased hypoechogenicity and punctuate calcifications are associated with malignancy and features like smooth margins, hyper or anechogenicity, wider than tall shape are associated with benign nodules.

KEYWORDS

Ultrasound (US), Thyroid Imaging Reporting and Data System (TI-RADS, TR), Thyroid nodules

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INTRODUCTION

The thyroid gland is the largest and superficially located gland and helpful in is maintaining the normal growth and activity of humans. The secretionsfrom the gland are regulated by its own auto-regulatorymechanism. Any discrepancy in the auto-regulatory function due to external or internal factors resultsin thyroid function disorders.[1]

The diseases involving the thyroid may include simple nodular goitre to malignant conditions like medullary / papillary thyroid carcinoma. Hence it is very essential to evaluate the thyroid gland for early detection and treatment of the thyroid disorders. Imaging is a very essential tool which helps for the evaluation if the thyroid gland.According to a recent study, in India the prevalence of a palpable thyroid nodule in the community is about 12.2%. These nodules can be either benign or malignant. However, thyroid cancer is quite rare, and the incidence is 8.7 per 100000.[2]

Ultrasonography (USG) is an excellent modality for the evaluation of the thyroid gland as the gland is located superficially and is the largest endocrine gland. The availability of high resolution grey-scale imaging, colour doppler study and elastography in the evaluation of thyroid has made sonography the best modality for its imaging. [3]

Sonography is an excellent tool which helps in the detection of early malignancy. Few of the features which suggest benignity of the nodule include halo around nodule, cystic nodule, avascularity, enlarged thyroid with multiple nodules. Features suggesting malignancy include microcalcifications, extension beyond thyroid margin, cervical lymph nodal metastasis, Taller than wide in transverse

plane,markedly hypoechoic; less specific features inculde no halo around nodule, Ill-defined or irregular margin, solid, Increased central vascularity.[4] But the imaging findings has to be ultimately confirmed by fine needle aspiration cytology (FNAC) or biopsy. These procedures are invasive and are associated with complications like hemorrhage and infections. Hence committee of American college of radiology(ACR) published a white paper on Thyroid Imaging, Reporting, And Data System (TIRADS) compiles all the features and gives the guidelines to differentiate the thyroid nodules in to benign or malignant nodules. The committee also gave recommendations for fine needle aspiration (FNA) based on TIRADS category and size of the nodule, hence reduce the need for invasive procedures like FNA or biopsy.

ACR TI-RADS uses five feature categories—Composition, echogenicity, shape, Margin and Echogenic foci to determine risk level of malignancy which ranges from TR1 (benign) to TR5 (highly suspicious).[5]

Therefore, the main aim of our study is to differentiate palpable thyroid noduleinto benign or malignant based on ACR- TIRADS guidelines and compare the results with cytopathology reports.

OBJECTIVES

1. To study the role of Thyroid Imaging, Reporting, and Data System (ACR TI-RADS)in differentiation of benign and malignant thyroid lesions
2. To correlate the ultrasonographic findings with cytopathological reports over a period of one year at KLE'S Dr. Prabhakar kore charitable hospital.

REVIEW OF LITERATURE

BRIEF REVIEW OF DEVELOPMENT OF THYROID GLAND:

Thyroid gland originates from the endodermal cells dorsal to the tuberculum impar. These cells evaginate through the tongue substance in the midline and form the thyroglosssal duct which is ventral to the hyoid bone. The thyroglossal duct at the level of trachea forms a bilobed structure which later forms the lobes and isthmus of the thyroid gland. The thyroglossal duct later disappears, but sometimes the distal end persists as the pyramidal lobe and the proximal end of the duct is seen at foramen caecum of the tongue. [6]

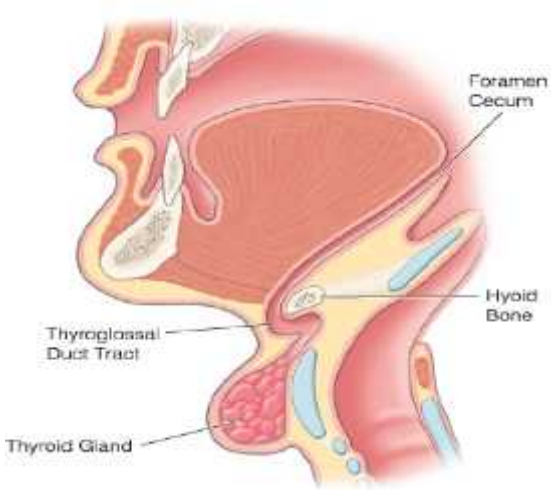


Fig 1. Development of thyroid gland showing tract of thyroglossal duct

ANATOMY OF THYROID GLAND:

The thyroid is a bilobed structure which is located over the anterior aspect of the lower neck over the cricoid cartilage and trachea. It has two lobes(the right and the left lobe) which is connected by the isthmus. 10 – 40 % of the individuals have a pyramidal lobe. There are carotid vessels along the lateral aspect of the thyroid gland and strap muscles located anterior to the gland. The gland is covered by a true and a false capsule which is a derivative of the pretracheal fascia. The ligament of Berry

which is the thickened part of the false capsule connects the lateral lobe of the gland to the cricoid cartilage because of which the thyroid gland moves up and down with deglutition. [7]

Each lobe measures about 5 cm, 3 cm, 2 cm in length, breadth and thickness respectively and the isthmus measures 4 to 6 mm. [7, 8]

The antero-posterior diameter is considered to be most precise dimension because it is relatively independent of asymmetry between the two lobes. A measurement of AP diameter more than

2 cm indicates that the gland is enlarged. [7]

The volume of thyroid is more in the iodine deficiency state and in patients with acute hepatitis or chronic renal failure. The thyroid volume is decreased in patients with chronic hepatitis or in patients treated with thyroxine or radioactive iodine. [8]

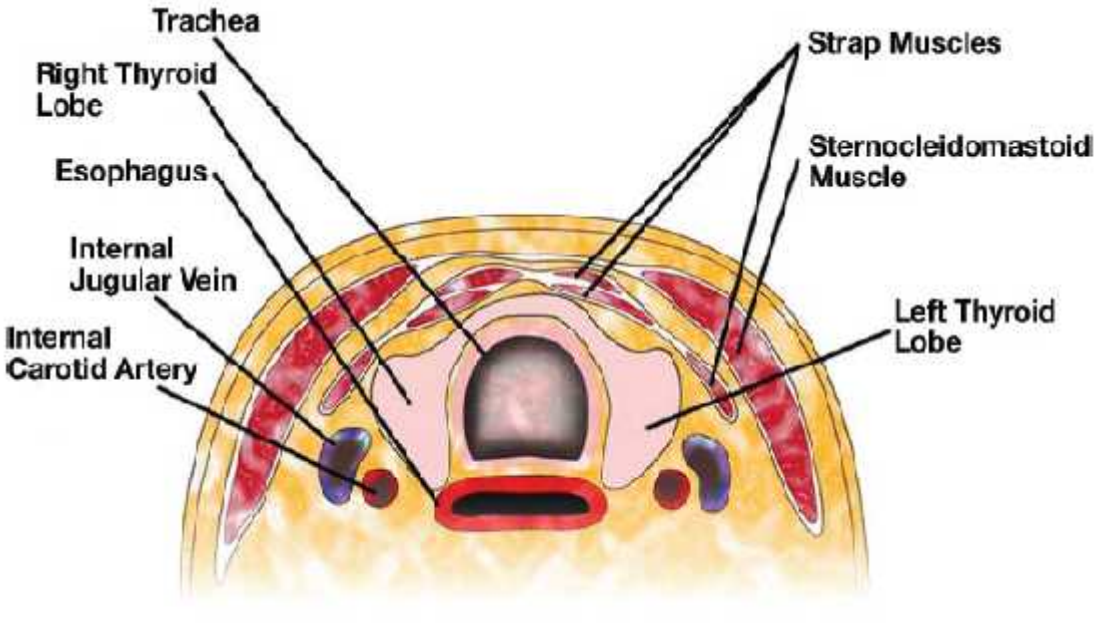


Fig 2. Diagrammatic illustration of cross-sectional anatomy of the thyroid and adjacent soft-tissue structures

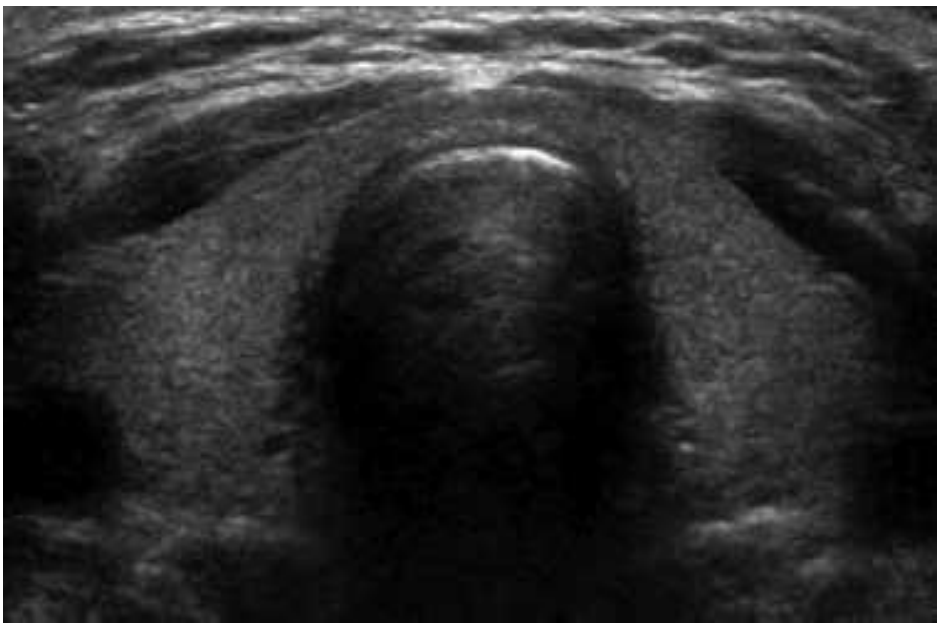
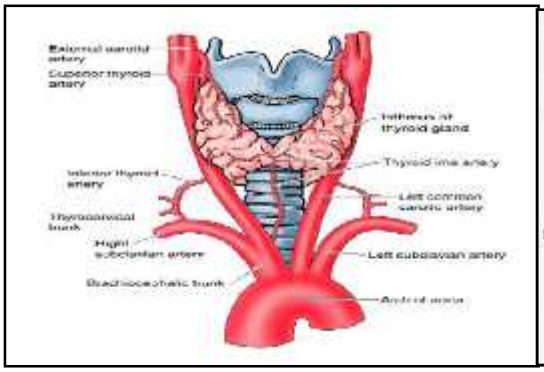


Fig 3. Transverse Ultrasound image showing the homogeneous echogenicity of the normal thyroid tissue

BLOOD SUPPLY:

ARTERIES: Thyroid gland is mainly supplied by the superior and inferior thyroid arterieswhich are branches from the external carotid artery and the thyrocervical trunk respectively. [9, 10]

VEINS: The thyroid gland is drained by the superior and middle thyroid veins which drain into the internal jugular vein and by the inferior thyroid vein which drains into the leftbrachiocephalic vein. [9, 10]



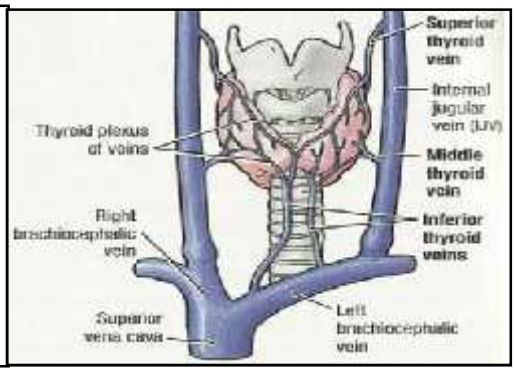


Fig 4. Arterial supply to thyroid gland **Fig 5. Venous drainage of thyroid gland**

IMAGING APPEARANCE OF THYROID

Ultrasonography (USG): Normal thyroid tissue is homogenous and uniform in echotexture. Capsule is seen as a thin hyperechoic line surrounding the thyroid gland. It is an excellent modality for the visualization and evaluation of the thyroid gland.[11,15]

On sonography the superior thyroid artery and vein are located at the upper pole of each lobe. The inferior thyroid artery is located posterior to the lower third of each lobe, whereas the inferior thyroid vein is located at the lower pole. The peak systolic velocity in the major thyroid arteries varies between 20 – 40 cm /sec and in the intraparenchymal arteries it is about 15 – 30 cm / sec. [11, 15]

Computed tomography(CT): On non-contrast CT, the gland is seen as a homogenous hyperdense structure (HU +80 to +100) as compared to the neck musculature. The hyperdensity is due to presence of iodine within the gland. On post contrast study, the gland shows homogenous enhancement. [12]

On magnetic resonance imaging (MRI): The thyroid is mildly hyperintense (compared to neck musculature) on T1-weighted MR images and iso- to mildly hyper-intense on T2-weighted images. The gland shows intense homogeneous enhancement on post contrast (gadolinium) study. MR and CT imaging is essential to know the precise anatomic information regarding the position of the thyroid relative to its adjacent structures. Thyroid nodules are detected incidentally at 9% of neck CT and MR imaging studies. [13]

Of the three, Ultrasound remains the best modality for the evaluation of nodules within the superficially located thyroid, as it is widely available and cost effective. Hence incidentally detected thyroid nodules at CT or MR imaging are to be further evaluated with Ultrasound. [11]

Scincitigraphy: It is the procedure to assess the functional activity of the thyroid gland. Based on the functional activity, the nodules can be hot or cold nodule. Hot nodules are the normal functional nodules and are less likely malignant. The cold nodules are non-functional. Of these 77% are benign and 23% are malignant. [7]

BRIEF REVIEW OF HISTOLOGY OF THYROID GLAND:

The gland is divided into lobules by the fibrous septae arising from the capsule. The lobules are made of follicles which are filled with colloid substance. Each follicle has a basement membrane over which follicular cells are lined. Thin connective tissue fills the space between the follicles. Parafollicular cells are present in between the basement membrane and follicular cells. [15]

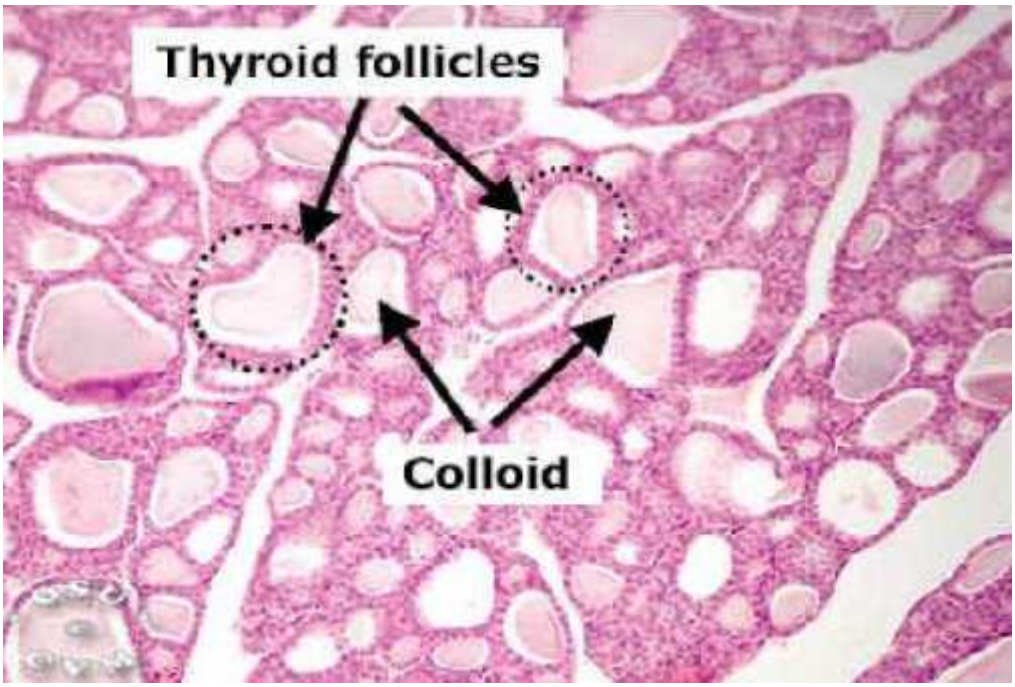


Fig 6. Microscopic anatomy of thyroid gland

REVIEW ON FUNCTION OF THYROID HORMONES: [16, 17]

Thyroid hormones play an important role in growth & maturation. T3 & T4 play an important role even in fetal life for maturation of growth centres.

a. Effect on growth: Thyroid hormones are also important in stimulation of the process of bone remodelling and normal functioning of skeletal muscles. [16]
b. Effect on central nervous system: T3 & T4 are essential for proper growth of cerebrum, cerebellum, proliferation and branching of nerve fibers, along with myelination. Their deficiency leads to cretinism while the hyperthyroid state induce anxiety, nervousness and paranoia. [17]
c. Effect on metabolism :
    i. Stimulate fat metabolism [17]
    ii. Stimulate carbohydrate metabolism – induce glycolysis, gluconeogenesis and increased insulin secretion. These effects are due to overall increase in the cellular metabolic enzymes. [17]
    iii. Increases basal metabolic rate [16,18]
d. Effect on Cardiovascular system - Increases blood flow and cardiac output, heart rate, heart strength and normal arterial pressure [18]
e. Effect on sympathetic system: Thyroid hormones facilitate the actions of catecholamines i.e, glycogenolysis, adipose tissue lipolysis and gluconeogenesis. Thyroid hormones increase the beta-1 adrenergic receptors of heart, hence induce increased catecholamine response to heart (eg:tachycardia, palpitation) in thyrotoxicosis. [16,17]
f. Increases gastrointestinal tract motility. [17]
g. Effect on menstrual and reproductive function: Decreased thyroid hormone results in menorrhagia, polymenorrhoea, irregular menses and amenorrhoea. It is

also required for proper maintenance of pregnancy, its deficiency results in infertility.

h. The parafollicular cells secrete calcitonin hormone which regulates the circulating calcium levels. [8]

REVIEW OF DISEASES ASSOCIATED WITH THYROID:

Hyperthyroidism: Excessive release of the thyroid hormones is called as hyperthyroidism. It manifests as nervousness, weight loss with good appetite, palpitation, muscle weakness, rapid pulse, heat intolerance, fatigability, fine tremors of the hand, excessive perspiration and variable enlargement of thyroid gland. Causes of hyperthyroidism include diffuse hyperplasia of thyroid gland associated with Graves' disease (major cause), hyperfunctional multinodular goiter, exogenous thyroid hormone administration, thyroiditis and hyperfunctional adenomas.

Hypothyroidism: Decreased synthesis of thyroid hormone is called as hypothyroidism. It manifests as cretinism (in infancy and early childhood) and myxedema (in older children or adult). It is seen as severe mental retardation, short stature, coarse facial features and protruding tongue. Myxedema is seen as slowing of mental and physical activity.

The causes of hypothyroidism include decrease in the hormone synthesis due to iodine deficiency, drugs, hashimoto thyroiditis; insufficient thyroid parenchyma due to developmental,radiation injury, surgical ablation; pituitary lesions leading to reduced TSH secretion and hypothalamic lesions.

Pathological conditions associated with thyroid gland are:

CONGENITAL ANOMALIES: [9]

- Aplasia / Hypoplasia of thyroid gland
- Lateral aberrant thyroid.
- Ectopic thyroid tissue
- Thyroglossal duct anomalies.

BENIGN LESIONS [7]

Inflammatory conditions:

- Acute suppurative thyroiditis
- Subacute thyroiditis
- Riedel's thyroiditis
- Autoimmune thyroiditis (Hashimoto's thyroiditis)
- Chronic thyroiditis including chronic granulomatous thyroiditis,

Benign nodules :

- Benign follicular nodule
- Adenomatoid nodule
- Colloid nodule

Adenomas

- Follicular
- Hurthle cell adenoma

MALIGNANT LESIONS [7]

- Papillary carcinoma
- Follicular carcinoma
- Hurthle cell carcinoma

- Poorly differentiated carcinoma
- Anaplastic/undifferentiated carcinoma
- Medullary carcinoma
- Lymphoma
- Metastasis

THYROIDITIS:[10]

Thyroiditis is the inflammation of the thyroid gland. It includes infectious thyroiditis, subacutegranulomatous thyroiditis, subacute lymphocytic thyroiditis (painless thyroiditis) and fibrous thyroiditis (Riedel'sthyroiditis).

Acute suppurative thyroiditis: It is caused due to bacterial infection and it most commonly affects children. Sonography shows abscess with enlarged lymph nodes.

Subacute granulomatous thyroiditis: It is caused by viral infection.

Sonography shows diffuse enlarged thyroid gland with hypoechoic foci within it.

Hashimoto's thyroiditis: It is the autoimmune thyroiditis caused by autoantibodies against thyroglobulin and thyroid peroxidase. Sonography shows diffuse enlarged gland with coarse echotexture, pseudonodulations and thin fibrous septations. On colour Doppler, it shows decreased vascularity.

Riedel's thyroiditis: This condition is associated with mediastinal and retroperitonealfibrosis. On sonography, the thyroid gland is enlarged and demonstrates inhomogenous echotexture.

Graves' disease: It is an autoimmune disorder due to production of autoantibodies against thyroid stimulation hormone(TSH) receptors, thyroid stimulating immunoglobulin(TSI), thyroid growth stimulating immunoglobulins and TSH binding inhibitor immunoglobulins.

BENIGN NODULES: [19, 49]

The causes of thyroid nodular diseases are caused by hormonal imbalance, iodine deficiency and medications that lead to poor utilization of iodine. Goiter is the overall increase in the size of the thyroid glanddue to hyperplasia. These nodules are called as hyperplastic, adenomatous or colloid nodules.

When the nodules undergo liquefactive degeneration, they become colloid nodules.On sonography these nodules are isoechoic to the adjacent normal thyroid parenchyma while few of them are hyperechoic. The nodules show a peripheral hypoechoic halo due to compression of normal tissue, vascularity and edema. The ancehoic nodules contain serous or colloid material within it.

Hemorrhage within it is seen as a hyperechoic foci. The aggregates of the colloid material give echogenic foci with comet tail artifacts. These nodules may show a thin peripheral rim of calcifications or coarse calcifications. [19]

ADENOMAS:

The adenomas usually do not alter the thyroid function, however, 10% of the nodules cause hyperthyroidism. Pathologically they are differenciated into fetal adenoma, hurthle cell adenoma and embryonal adenoma. On sonography, these adenomas appear as solid hyper/ iso / hypoechoic lesions. A smooth peripheral hypoechoic halo can also be seen due to capsule and vascularity. [20]

CARCINOMAS:

The most common type of thyroid carcinoma is the papillary thyroid carcinoma. It accounts for around 85% of all the thyroid carcinomas. About 5 - 15% of carcinomas are follicular carcinomas, 5 % of cases are medullary thyroid carcinomas and less than 5% thyroid carcinomas are anaplasticcarcinomas.

Solitary nodules in young males are mostly neoplastic. Hot nodules are usually benign and approximately 23% of cold nodules are malignant. [19]

PAPILLARY THYROID CARCINOMA:

It is the most common thyroid carcinoma and is seen in the age group of 25 – 50 years. It is associated withthe history of ionizing radiation. OrphanAnnie eye nuclei on microscopy are typical of the carcinoma and it contains branching papillae with a fibrovascular stalk. Psammoma bodies are also seen which represent concentrically calcifiedstructures. [21]

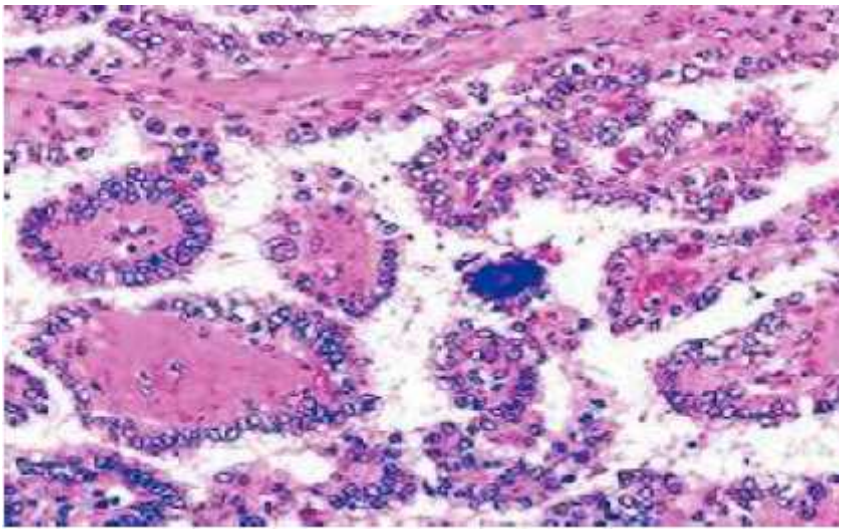


Fig 7. Microscopic picture of papillary thyroid carcinoma showing Orphan Annie eye nuclei with Psammoma bodies.

Follicular variant of the papillary carcinoma shows characteristic nuclei of papillary thyroid carcinoma but has a follicular architecture. Other variants include tall cell variant and diffuse sclerosing variant. Papillary microcarcinoma is a variant where there arefeaturesof papillary thyroid carcinomaand are less than 1 cm in size.On sonography, they appear as hypoechoic lesions with microcalcifications. Many a times these conditions are asymptomatic and present as a cervical lymph nodal mass. Most lesions show increased vascularity. [21, 22]

Papillary microcarcinomasappear as a small,hyperechoic patch under the capsule with thickening of capsule with its retraction or it is seen as a minute hypoechoic nodule with blurred irregular outline. [21, 22]

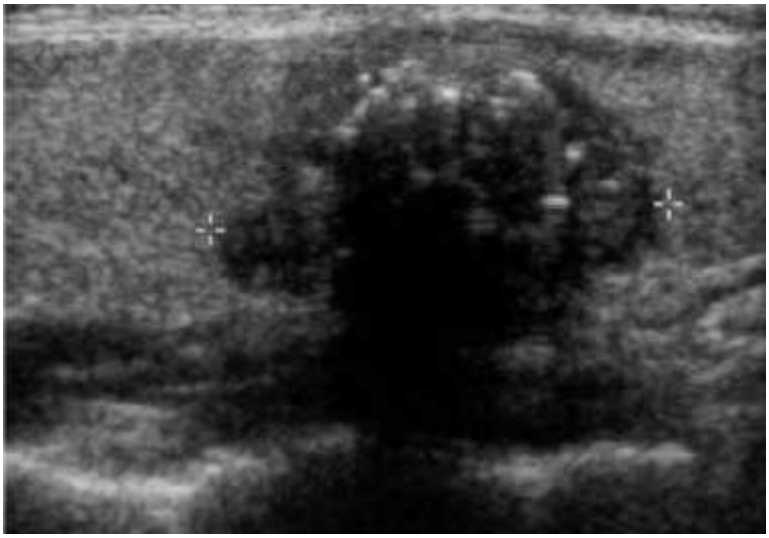


Fig 8. Sonographic image of papillary thyroid carcinoma showing multiplemicrocalcifications

FOLLICULAR THYROID CARCINOMA:

Peak age of incidence is 40-50 years and is seen in females. It is associated with dietary iodine deficiency. Microscopically they are composed of fairly uniform cells forming smallfollicular cells which contain colloid. [23, 24]

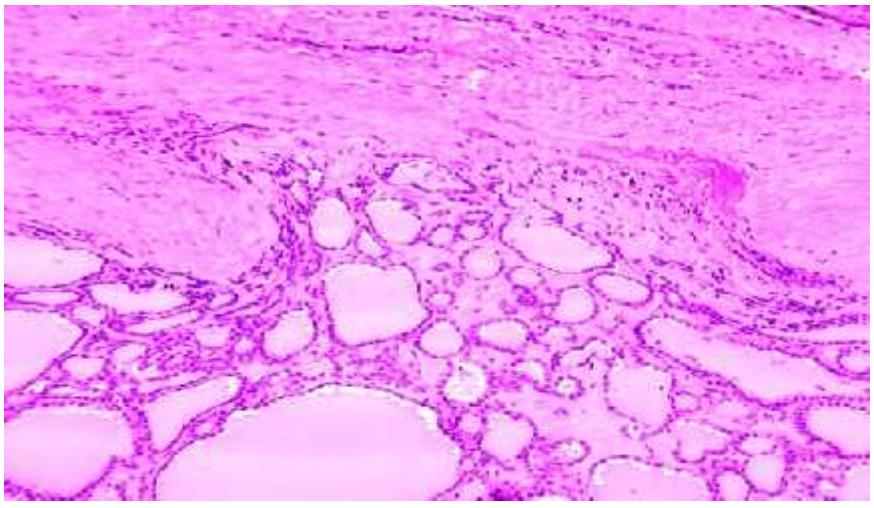


Fig 9. Follicular thyroid carcinoma showing capillary invasion

Sonographically, it cannot be differentiated from the follicular adenoma. However, features like irregulartumor margins, thick irregular halo and a tortuous arrangement of internalblood vessels suggest carcinoma rather than adenoma. [23, 24]

They present as a painless swelling and haematogenous spread to bones, lungs and liver is reported. [23, 24]

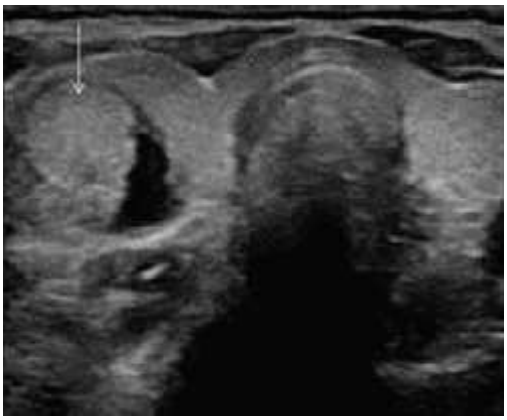
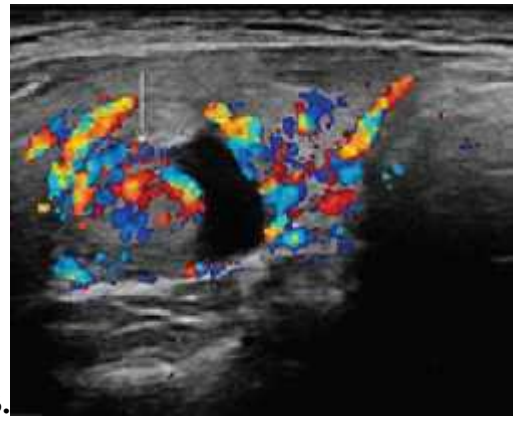
A.  **B.** 

Fig 10. Sonographic image of Follicular thyroid carcinoma

ANAPLASTIC CARCINOMA:

Anaplastic carcinoma is called as undifferentiated carcinoma. It is composed of highly anaplastic cells with variable morphology. Mean age of occurance is 65 years. It presents as a enlarged neck mass with invasion into adjacent vital structures. It is fatal and has 100% mortality. [27]

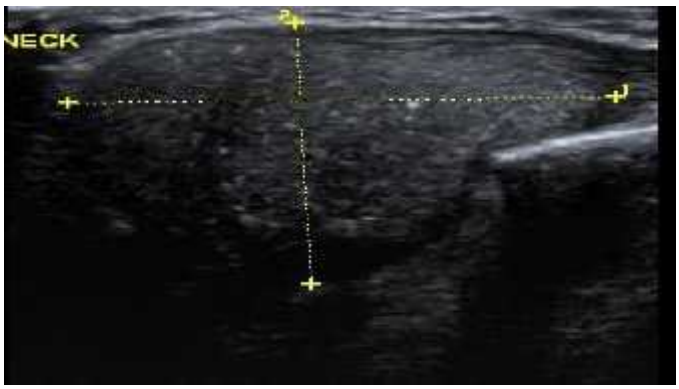


Fig 11. Sonographic image of anaplastic carcinoma of thyroid gland

MEDULLARY THYROID CARCINOMA:

These carcinomas present as a solitary nodule. C cells or clear cells which secrete calcitonin are the neuroendocrine neoplasms derived from parafollicular cells. On microscopy, they show polygonal to spindleshaped cells which may form nests, trabeculae and even follicles with amyloid deposits in the adjacent stroma.On sonography the lesions appear hypoechoic. Coarse calcifications are seen. 80 % of these carcinomas are sporadic, and rest are associated with multiple endocrine neoplasm (MEN) syndromes. [25]

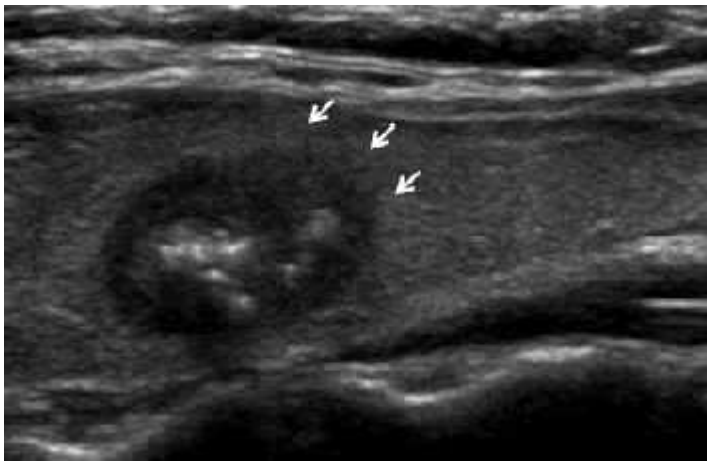


Fig 12. Sonographic image of Medullary thyroid carcinoma

Lymphoma of thyroid gland is mostly non-Hodgkin's lymphoma. It consists of 4% of all the thyroid malignancies. On sonography it is seen as an extremelyhypoechoic and lobulated mass.[26]

Melanoma (39%), breast (21%)and renal cell carcinoma (10%) are the leading causes of metastasis to thyroid gland. On sonography metastasis of thyroid gland appearsas a solid, homogenously hypoechoic masses without calcifications.[27]

HISTORICAL REVIEW OF THYROID ULTRASONOGRAPHY:

Solbiati L et al suggested that the ultrasound evaluation of the gland helps to differentiate the gland into benign and malignant. They concluded that hyperechoic nodules are mostly benign. They also said the pattern of calcification and peripheral halo are criteria for differentiating benign from malignant disease.[28]

Yokozawa T et al concluded that a conventional FNAC is less efficient than sonography. They studied a group of 678 patients sequentially as having bided FNAC in detecting the pathology. They conducted a study on 678 patients who were diagnosed as benign nodules using conventional FNAC. Of them, 571 patients (84.2%) showed the same diagnosis in USG guided FNAC. Remaining 107 patients (15.8%) showed malignancy after USG guided FNAC was performed. Post-surgery, histopathology showed thyroid cancer in 99 of the 107 patients. [29]

Hong et al conducted a study on 90 patients who presented with thyroid nodules and around 145 nodules in these patients were examined using ultrasonography. They stated that the predictivity of ultrasound was not dependent on size of thyroid nodule and concluded that sonography is anefficient imaging technique to diagnose thyroid cancer.[30]

Aparna et al in 2012 conducted a study which stated that texture, size, margin, echogenicity and vascularity are important in discriminating benign from malignant nodule andmalignancy was not dependent on hypoechogenicity, vascularity of any type, ill-defined margin and microcalcification. The characteristics independently were not sensitive and specific.[47]

DIFFERENCIATING BENIGN AND MALIGNANT NODDULE ON SONOGRAPHY

A number of features have been described to differentiate benign and malignant lesions. Following are the features to be evaluated for the characterization of the nodules. [31, 32]

i. Echogenicity : benign nodules are usually hyper or iso echoic whereas malignant nodules are hypoechoic solid masses.[34]

ii. Content: cystic or spongiform appearance is more suggestive of benign nature. Malignant nodules are generally solid hypoechoic lesions.[34]

iii. Shape: the malignant nodules have the tendency to grow and invade into normal tissues. Hence a shape of taller than wide is more indicative of malignancy

iv. Margins: a well defined lesion with a hypoechoic peripheral halo is a feature of benign nodule whereas a malignant nodule has an irregular poorly differentiated margin with absence of the halo. [34]

v. Calcifications: large coarse calcification is a feature of benignity. Peripheral calcifications are also seen in benign nodules. Fine microcalcifications are seen in malignant nodules. [33]

vi. Vascularity: Peripheral vascularity is a feature of benign adenomatous noudule while increased internal and central vascularity is a feature of malignancy. [35]

vii. Malignant cervical lymph nodes: presence of hypoechoic, rounded, necrotic cervical lymph nodes indicate they are metastatic. Presence of hypoechoic solid thyroid nodule with a necrotic lymph node is strongly suggestive of malignancy.

viii. Sonoelastography: it is based on the principle that pathology alters the physical characteristics. There are four elastographic patterns that are described as follows: [36]

Pattern 1: elasticity in the whole nodule.

Pattern 2: large part of the nodule show elasticity with inconstant appearance of anelastic areas

Pattern 3: constant presence of large anelastic areas at periphery.

Pattern 4: uniformly anelastic.

78 – 100 % of benign nodules show pattern 1 to 2, whereas 88 – 96 % ofmalignant nodules show pattern 3 to 4.

THE CONCEPT OF TI-RADS:

Though, various features have been described for the differentiation of benign and malignant nodules, there is no single criteria which can decide the nature of the nodule. Hence there is a need for an integrated approach for the evaluation of nodules and which allows the classification of nodules and thereby rule out benign nodules and avoid unnecessary invasive procedures. TI-RADS is a standardized approach for evaluation and management of the thyroid nodules.Various committees have proposed TI-RADS system of categorization of thyroid nodules based on various features into benign and malignant lesions.

An evaluation system for thyroid nodules called TI-RADS (Thyroid Imaging Reporting and Data System)was proposed by Horvath et al, similar to the Breast Imaging Reporting and Data System (BIRADS). In 2011, this study was complimented by Kwak et al, by adding one more subtype. This system used the following 7 characteristics to score the thyroid nodules –

hypoechogenicity,microcalcifications, partially cystic nodule with eccentric location of the fluid, portion and lobulation of the solid component, irregular margins, perinodular thyroid parenchyma invasion, taller-than-wide shape and intranodular vascularity.[37]

KOREAN TI-RADS (K TI-RADS)

IN 2016, Korean Society of Thyroid Radiology suggested the K-TI-RADS for the ultrasound assessment of thyroid nodules and stratification of the requirement for FNA and malignancy. They also included the stratification of indications for lymph node sampling.

This method has a five-stage system of assessment which uses descriptive, pattern recognition findings on ultrasound and size measurement. This system classified the nodules into 5 groups from TR1 to TR5 ranging from no nodule to high suspicious nodule.

Features such as purely cystic/anechoic, comet tail artefact, spongiform were included in the benign K TI-RADS 2 group.

The categorization is determined by assessment of echogenicity, shape/contour and three specific suspicious ultrasound features (microcalcifications, nonparallel orientation and spiculated / microlobulated margins).

Solid hypoechoic nodules are considered to have higher risk than partially cystic or iso / hyperechoic nodules.[37]

EUROPEAN TI-RADS (EU TI-RADS)

This system was proposed by the European Thyroid Association which gave guidelines for ultrasound assessment of thyroid nodules and stratification of requirement for FNA and malignancy. This system classified the nodules into 5 groups from TR1 to TR5 ranging from no nodule to high suspicious nodule. The

study stated that the risk of malignancy for TI-RADS 1 and 2 is 0 %, TI-RADS 3 is 2 – 4%, TI-RADS 4 is 6 – 17% & TI-RADS 5 is 26 – 87 %. [38]

ACR TI-RADS

In 2015, a committee convened by American college of Radiology published a white paper on approach to incidental thyroid nodules and proposed a standard terminology (lexicon) for ultrasound reporting.

The committee published a white paper that presented a new risk stratification system for classifying thyroid nodules on the basis of their appearance on ultrasound. The committee published the final corrected article in April 2018. [39, 40]

The committee also published an article to offer practical guidance on how to implement and apply ACR TI-RADS based on the author's experience with the system. The committee proposed the categorization of thyroid nodules based on the following 5 characteristics - composition, echogenicity, margins, echogenic foci and size of the nodules. Scores were given based on the above characteristics and the nodule was graded in to 5 grades (TR1 –TR5) i.e. from benign to highly suspicious of malignancy. [5]

The TI-RADS criteria proposed by the ACR committee are as follows:

Based on ultrasound features, thyroid nodules are evaluated under the following five categories- Composition, Echogenicity, Shape, Margin and Echogenic foci

Each feature is assigned 0-3 points

The nodule's point total determines its risk level, which ranges from TR1 (benign) to TR5 (highly suspicious).

The scoring for each feature is as follows: [5]

a. Composition:

Cystic or completely cystic: 0 points

Spongiform: 0 points

Mixed cystic and solid: 1 point

Solid or almost completely solid: 2 points

b. Echogenicity:

Anechoic: 0 points

Hyper- or Isoechoic: 1 point

Hypoechoic: 2 points

Very hypoechoic: 3 points

c. Shape: (assessed on the transverse plane)

Wider than tall (WTT): 0 points

Taller than wide (TTW): 3 points

d. Margin:

Smooth: 0 points

Ill-defined: 0 points

Lobulated/irregular: 2 points

Extra-thyroidal extension: 3 points

e. Echogenic foci:

None: 0 points

Large comet-tail artifact: 0 points

Macrocalcifications: 1 point

Peripheral/rim calcifications: 2 points

Punctate echogenic foci: 3 points

If there are multiple nodules, only the four highest-scoring nodules (need not be the largest) should be scored, reported, and followed up.[5]

Spongiform or predominantly cystic nodules are benign inherently. So here no further points are to be added (automatically TR1). [5]

Scoring and classification[5]

TR1: 0 points - benign

TR2: 2 points - not suspicious

TR3: 3 points - mildly suspicious

TR4: 4-6 points - moderately suspicious

TR5: ≥7 points - highly suspicious

REPORTING CONSIDERATIONS[5]

Reports of thyroid ultrasonography should include the following elements:

1. Tri-dimensional measurements of the right and left lobes and the antero-posterior dimension of the isthmus
2. An overall description of the thyroid parenchyma
3. Formal description of up to the four most suspicious nodules
4. Recommendations for management

Every report that includes one or more formally reported nodules must also provide recommendations for management, whether FNA, follow-up USG, or no further action.

Risk of malignancy and ACR-TI-RADS: [5]

Risk of malignancy analysed on the basis of study conducted on 3433 nodules with cytological results showed rates of >20% for TR5, 5-20% for TR4, 5% for

TR3and <2% for TR1/TR2 nodules. The final analysis of the study showedthe malignancy rates to be:

TR1: 0.3%

TR2: 1.5%

TR3: 4.8%

TR4: 9.1%

TR5: 35%

Comparison with other classification systems

The ACR system was published in 2017, preceded by K TI-RADS (2017) and followed by EU TI-RADS (2017). The studies showed that the ACR system has specificity of 53-67% and sensitivity of 75-97% which is either the lowest specificity and highest sensitivity amongst other compared systems. With the other two studies, the ACR system had the overall greatest performance, resulting in lower rates of unnecessary fine needle aspiration (false positive rates).Good inter-observer agreement regarding decision to biopsy has also been shown (Cohen- kappa 0.61).[41]

STUDY BASED ON ACR TI-RADS

A study was conducted in by Azab et al 2019, based on ACR TI-RADS for the stratification of benign and malignant nodules and which was further followed-up by histological correlation. The study was done on 40 thyroid nodules, out of which 31 nodules (77.5%) were benign and 9 nodules (22.5%) were malignant; there was a significant risk of increasing malignancy from TI-RADS TR1 to TR5 (p value < 0.001).They concluded that ACR TI-RADS scoring system is a simple and easy method to be applied in daily ultrasound practice and it has an excellent diagnostic accuracy for the diagnosis of malignant thyroid nodules and in the present study, as therisk of malignancy increases as the TI-RADS level increases from TR1 to

TR5.Also there was increasein the incidence of solid thyroid nodules, veryhypoechoic thyroid nodules, taller than wider nodules,nodules having lobulated or irregular margins, noduleshaving extrathyroidal extension and thyroid noduleswith punctate echogenic foci in the malignant groupthan in the benign group. And there was an increase in the incidence of cystic, mixed cysticand solid thyroid nodules, nodules having smoothmargin, nodules having ill-defined margin, nodules withno calcifications, and thyroid nodules with large comettail artifacts in the benign group than in the malignant group with p values of 0.018, 0.018, 0.005, 0.036, 0.02, and0.049 respectively

Another study was conducted based on ACR TI-RADS for the stratification of benign and malignant nodules and inter-observer variation in assigning the groups. They observed that the risk of malignancy for very low suspicion, low suspicion, intermediate suspicion and highsuspicion patterns were 2%, 12.7%, 26.3% and 29.8% respectively. Inter-observer agreement for final categoryassignment was moderate (κ - 0.518).The study concluded that estimated risk of malignancy in the high suspicion pattern of the 2015 American Thyroid Association (ATA) thyroid biopsyguidelines appears to be less than stated. However, this needs further validation in a larger cohort study.[43]

Barbosa et al in 2019, conducted a study in 2019 on 140 indeterminate thyroid nodules and concluded that ultrasound classifications i.e., ACR TI-RADS and ATA guidelines, are helpful to manage indeterminate thyroid nodules and suggest a conservative approach to low-risk nodules andBethesda III, whereas molecular testing and surgery is needed for high-risk US suspicion nodules andBethesda IV or V.[48]

FNAC OF THYROID:

Materials required for collecting the specimen[44]

1) Consent

2) Gauze pads

3) Container with ethanol

4) Glass slides

5) 10-mL plastic syringes,

6) Disposable 23- or 27-gauge needles, 1.5 inches long

7) Gloves

8) Laboratory slips with the patient's name, OP number, biopsy sites, andother relevant information to be transferred to the cytology laboratory

9) Local anaesthetic Lidocaine (if needed)

Collection of Specimen: [44,45]

Patient position: supine position with neck extended.

Skin is painted with povidone iodine and it is draped. The patient is instructed not to move or swallow. Then the lesion is focused on a high frequency linear Ultrasound probe. Povidone iodine acts as coupling agent, hence gel is not used. Local anaesthetic can be used if needed.

A 23 to 27 gauge needle is used which is attached to a 10ml syringe. The transducer is placed over the thyroid gland and the lesion is localized and its relation to adjacent vessel is identified. The needle is advanced parallel or perpendicular to the probe and into the lesion and then aspirated.

Materials obtained from aspiration biopsy is smeared on a glass slide and immediately placed in 95% ethanol for Papanicolaou staining. Then the specimen is sent to pathology for reporting. [46]

MATERIALS AND METHODS

This study has been undertaken on the patients referred to the Department of Radio-Diagnosis, KLEs Dr. Prabhakar Kore hospital during the study period (January 2019 to December 2019).

Material and methods:

Source of data:

A one year Hospital based prospective observationalstudy was conducted in the department of Radio-diagnosis, on the patients who met the inclusion criteria and did not get excluded, from January 2019 to December 2019 at KLEs Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

Method of collection of data:

Study design: Hospital based prospective observational study

Sample size: 40

$$\text{Sample size} = \frac{Z^2 pq}{d^2}$$

where: z^2- standard normal variate at a 95% degree of confidence = 1.96

p - Expected proportion from population prevalence of palpable thyroid nodules. Prevalence of palpable thyroid nodules in Indian population is 12.2% .[2]

q = 100-p

d - margin of error = 10%

Sampling method:all the eligible subjects were recruited into the study by convenient sampling till the sample size was reached.

Duration: One year: Between 1st January 2019 to 31st December 2019

Inclusion criteria:

Patients with palpable thyroid swelling

Exclusion criteria:

- Patient not willing to undergo ultrasound examination or further cytopathological / histopathological evaluation of thyroid masses after ultrasound examination.
- Patient with history of bleeding disorders.
- Known cases of thyroid malignancy and who have undergone treatment
- Cases with indeterminate cytopathological/ histopathological results

Statistical data analysis:

Data collected was entered in a MS Excel Sheet and then the p value, sensitivity and specificity was calculated using the SPSS22 software.

PROCEDURE:

An informed consent was obtained from all the subjects.

The above mentioned study population who met the inclusion criteria were subjected to ultrasonography of thyroid on GE VOLUSON 7 or GE VOLUSON 8 machine equipped with a 7.5–12 MHz high frequency linear array transducer. The patients were examined on real-time, two-dimensional, gray-scale and the images were saved on a portable drive. The nodules were graded into 5 groups i.e., from TR1

to TR5 based on the sonography findings. In case a thyroid has more than one nodule, that one nodule which had high malignant features was included in the study.

Then FNAC/biopsy was performed and the sonological findings were compared with cytopathological / histopathological(HPE) reports. In cases of multiple nodules, the nodules which had the most suspicious sonographic findings for malignancy or the dominant thyroid nodule were selected for fine needle aspiration.

RESULTS

The present study has been conducted on 40 patients who presented with primarythyroid swelling. The thyroid gland of these patients were evaluated by Ultrasonography and FNAC / HPE examination.Ultrasonographically the thyroid nodules were evaluated as per guidelines given by American college of Radiology for shape, content of the nodules, echogenic foci and margins following which the TIRADS score and category was assigned. The results are as follows.

Table 1: Age wise distribution of patients

Age groups	No of patients	% of patients
<=40yrs	11	27.50
41-50yrs	9	22.50
51-60yrs	11	27.50
>=61yrs	9	22.50
Total	40	100.00
Mean age	49.58	

In our study, 11 patients belonged to age group of 40 or less years, 9 patients were of 41 – 50 years, 11 patients in the age group of 51 – 60 years and 9 patients of more than or equal to 60 years. Mean age of the patients was 49.58 years.

Figure 1: Age wise distribution of patients

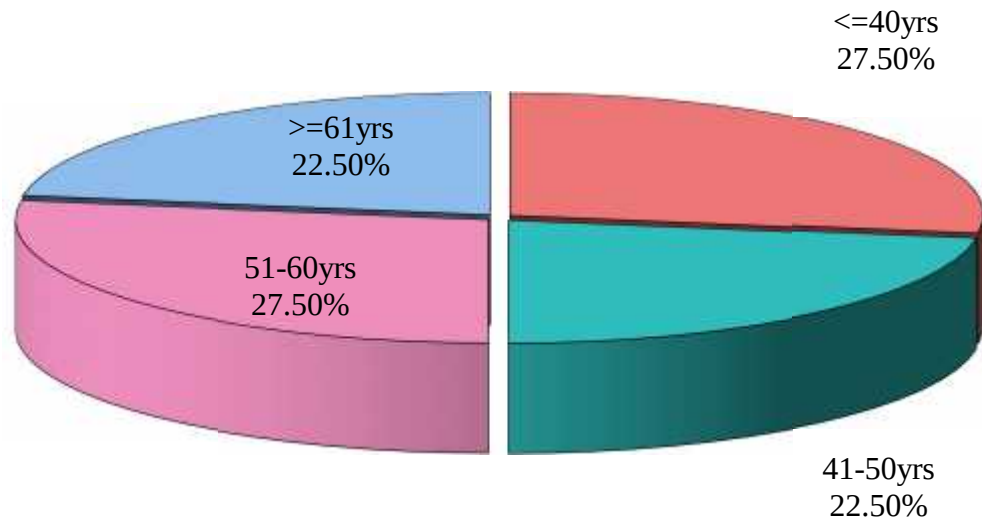


Table 2: Gender wise distribution of patients

Gender	No of patients	% of patients
Male	8	20.00
Female	32	80.00
Total	40	100.00

Most patients in our study group were females (80%) and the rest 20% were males.

Figure 2: Gender wise distribution of patients

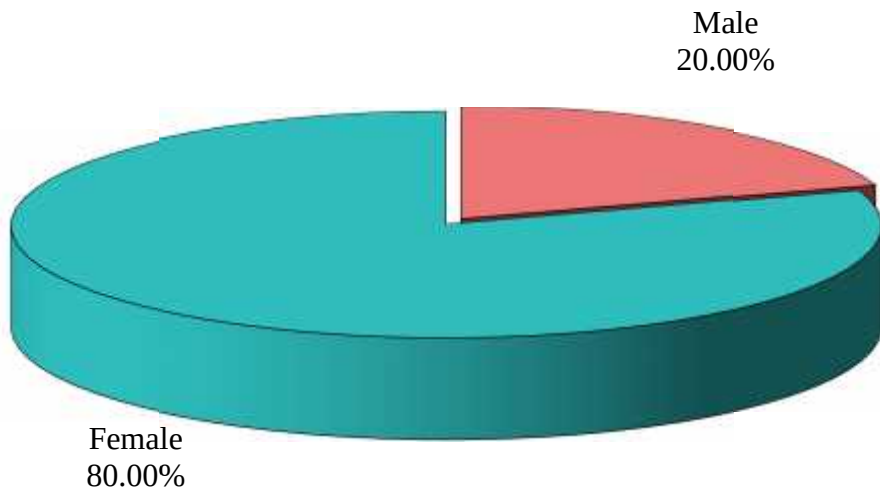


Table 3: Thyroid lesions according to number of nodules

Number of nodules	Benign	%	Malignant	%	Total	%
Single	16	94.12	1	5.88	17	42.50
Multiple	20	86.96	3	13.04	23	57.50
Total	36	90.00	4	10.00	40	100.00

Of 40 patients, 17 patients had solitary nodules and 23 patients had multiple nodules.

Figure 3:Thyroid lesions according to number of nodules

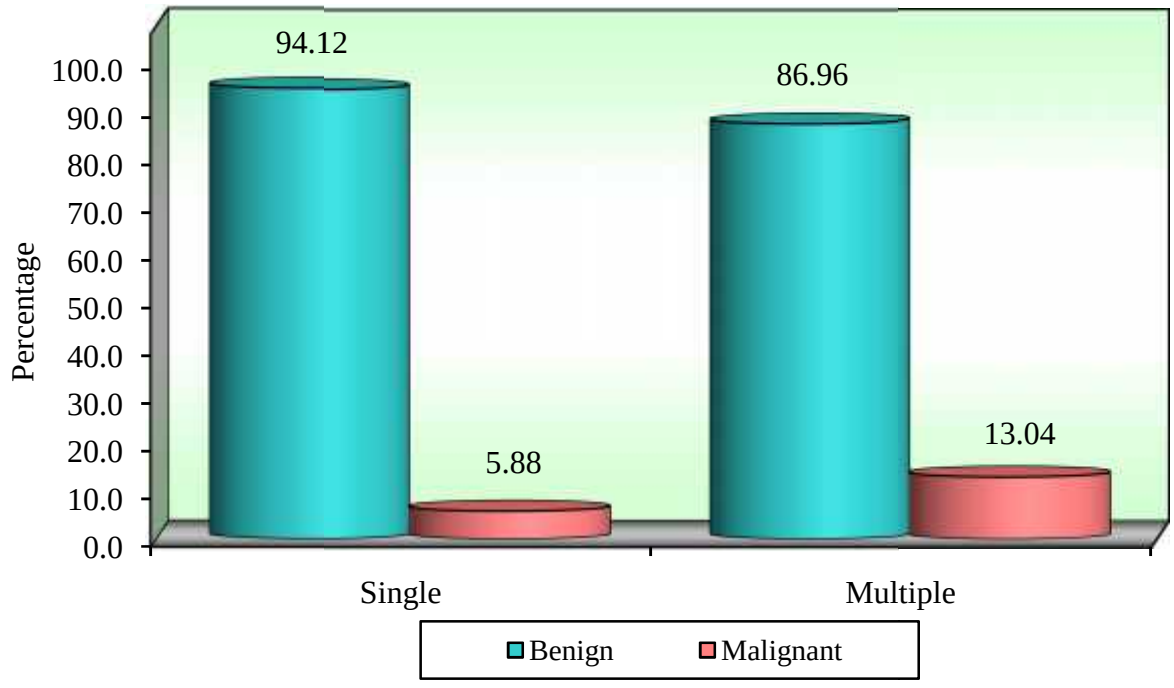


Table 4: Thyroid lesions according to composition

Composition	Benign	%	Malignant	%	Total	%
Cystic	4	100.00	0	0.00	4	10.00
Mixed	16	100.00	0	0.00	16	40.00
Solid	16	80.00	4	20.00	20	50.00
Total	36	90.00	4	10.00	40	100.00

4 out of 40 nodules were of cystic composition and all of them were benign. 16 nodules were of mixed composition of which all of them were benign. The rest 16 nodules were of solid composition and 80 %(16 nodules) of them were benign and the remaining 20% (4 nodules) turned out to be malignant.

Figure 4: Thyroid lesions according to composition

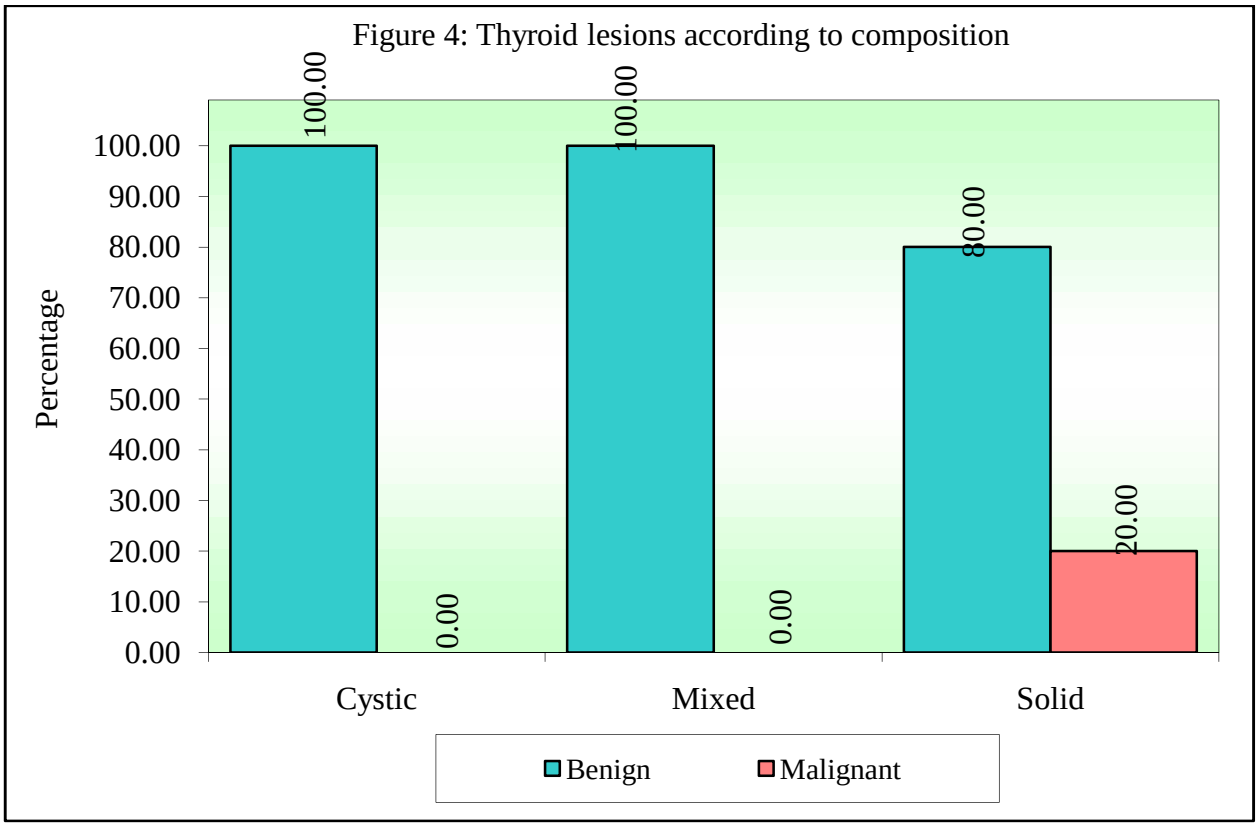


Table 5: Thyroid lesions according to Echogenicity

Echogenicity	Benign	%	Malignant	%	Total	%
Anechoic	4	100.00	0	0.00	4	10.00
Hyperechoic	15	100.00	0	0.00	15	37.50
Isoechoic	13	86.67	2	13.33	15	37.50
Hypoechoic	4	80.00	1	20.00	5	12.50
Marked hypoechoic	0	0.00	1	100.00	1	2.50
Total	36	90.00	4	10.00	40	100.00

4 out of 40 nodules were anechoic cystic nodules and all of them were benign lesions. 15 nodules of the total were hyperechoic and 100% of them were benign on pathological examination. A total of 15 nodules were isoechoic, of them 13 (86.6 %) were benign and 2 nodules (13.3%) were malignant. 5 of the 40 lesions showed hypoechogenicity. Of the 5 nodules, 4 (80%) were benign and 1 (20%) was malignant. One nodule showed marked hypoechogenicity which was malignant.

Figure 5: Thyroid lesions according to Echogenicity

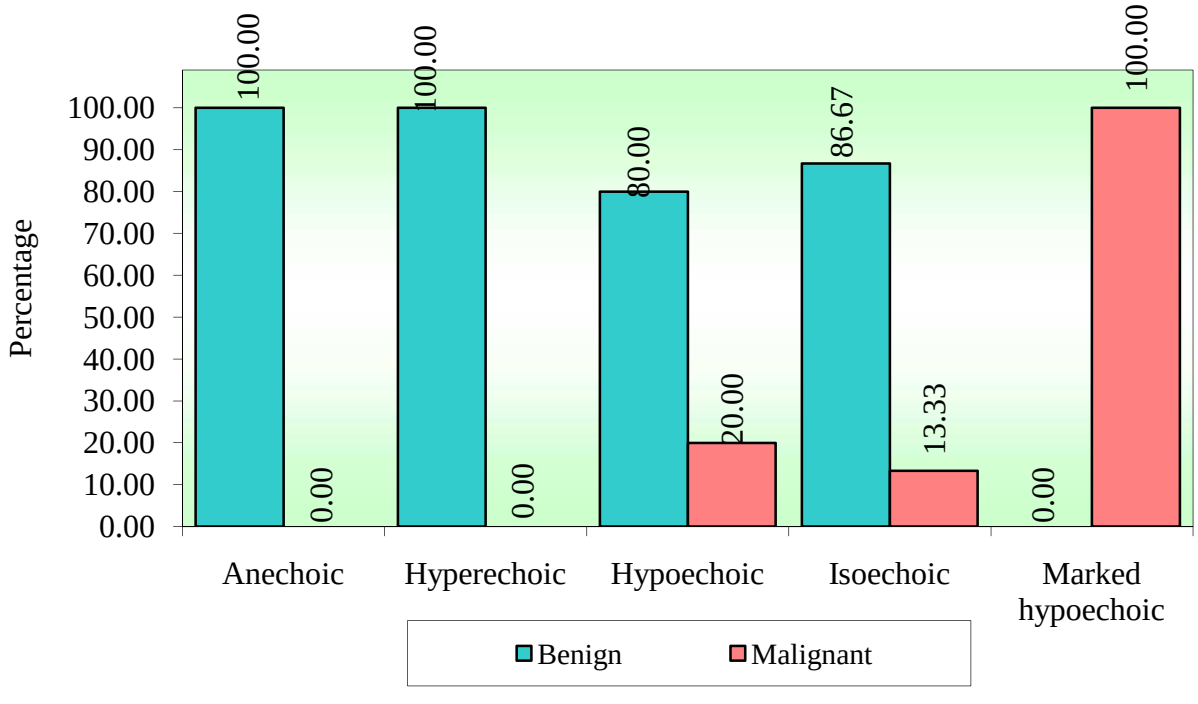


Table 6: Thyroid lesions according to shape

Shape	Benign	%	Malignant	%	Total	%
WTT	35	94.59	2	5.41	37	92.50
TTW	1	33.33	2	66.67	3	7.50
Total	36	90.00	4	10.00	40	100.00

92.5 % (37 of 40) nodules were wider than tall in shape and 94.5% (35 nodules) of them were benign nodules. 3 nodules were taller than wide in shape of which 2 nodules (66.6%) turned out to be malignant and only one was benign.

Figure 6:Thyroid lesions according to shape

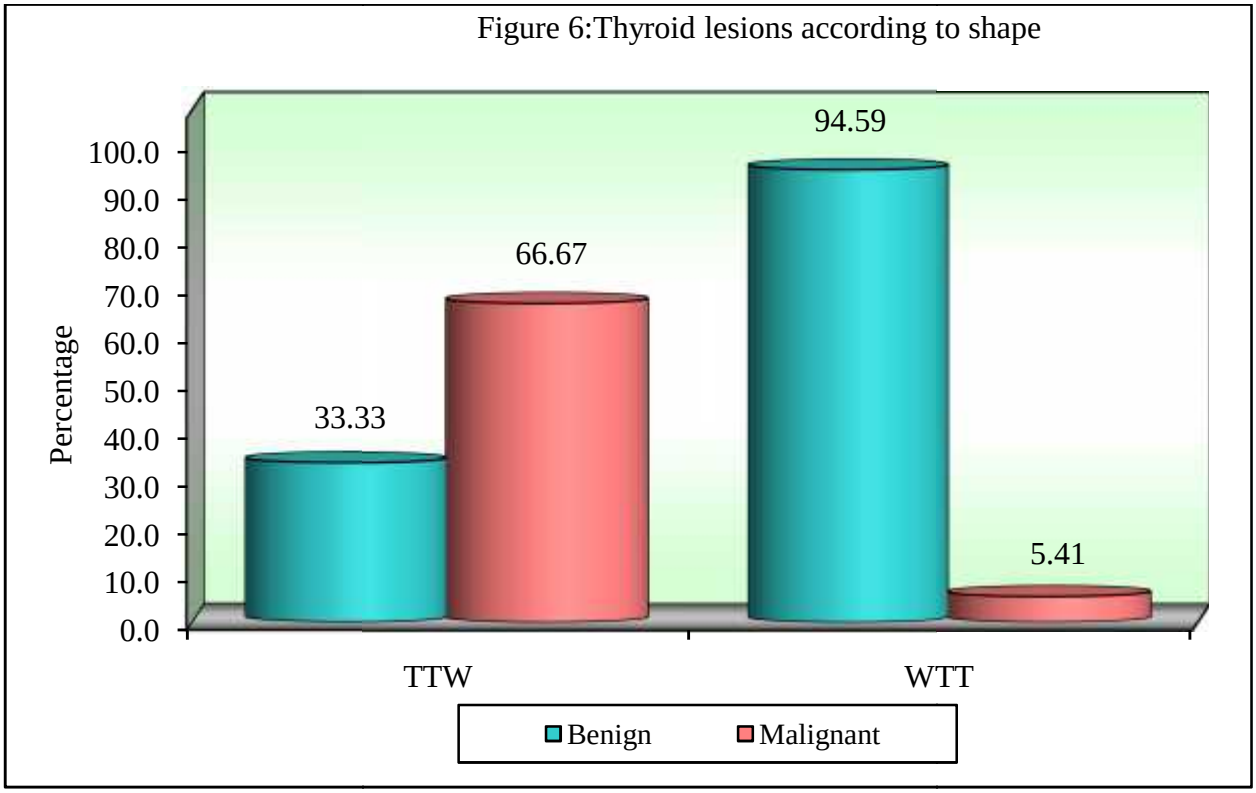


Table 7: Thyroid lesions according to margin

Margin	Benign	%	Malignant	%	Total	%
Extra-thyroidal extension	0	0.00	1	100.00	1	2.50
Irregular	1	33.33	2	66.67	3	7.50
Smooth	35	97.22	1	2.78	36	90.00
Total	36	90.00	4	10.00	40	100.00

A total of 36 nodules had smooth margins of which 97.2% (35 nodules) were benign and only 1 nodule was malignant. 3 nodules had irregular margins and 66.6 % (2 nodules) turned out to be malignant. One nodule had extra-thyroidal extension which was later proven to be malignant.

Figure 7: Thyroid lesions according to margin

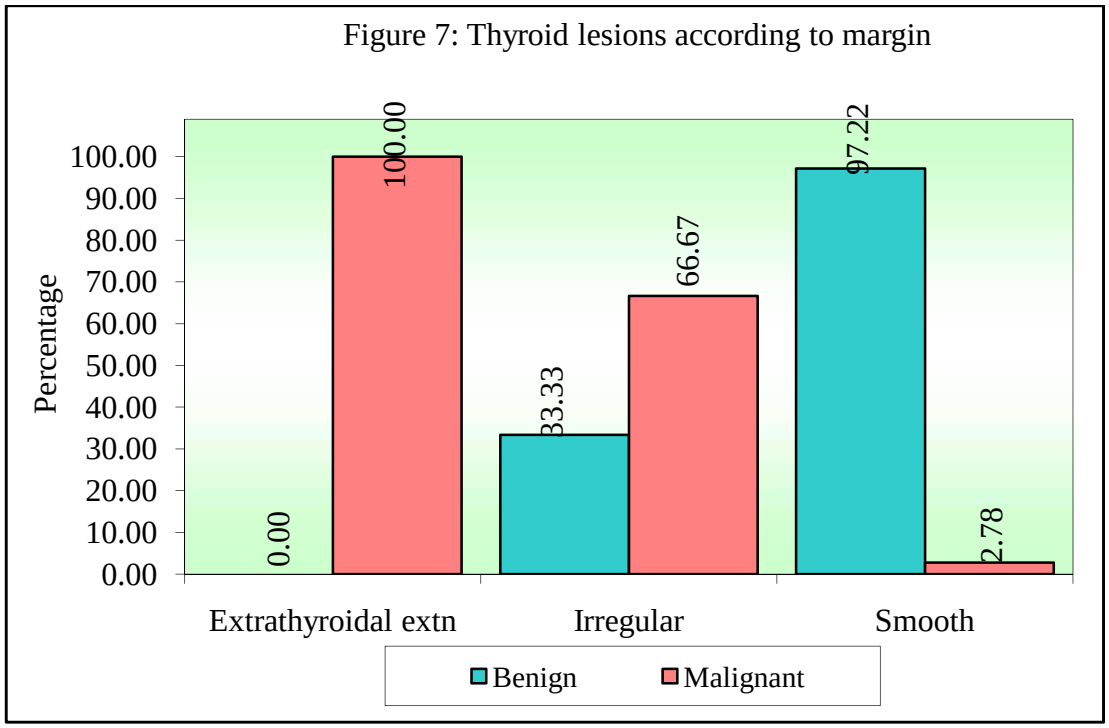


Table 8: Thyroid lesions according to Echogenic Foci

Echogenic Foci	Benign	%	Malignant	%	Total	%
Comet tail	3	100.00	0	0.00	3	7.50
Macrocalcification	3	100.00	0	0.00	3	7.50
Punctate calcification	1	25.00	3	75.00	4	10.00
Rim calcifications	0	0.00	0	0.00	0	0.00
Nil	29	96.67	1	3.33	30	75.00
Total	36	90.00	4	10.00	40	100.00

3 out of the 40 nodules showed comet tail artifacts, and all of them were benign. 4 nodules showed punctate calcifications and 75 %(3 nodules) of them turned out to be malignant. Also 3 nodules showed macrocalcifications and all were benign lesions.

Figure 8: Thyroid lesions according to Echogenic Foci

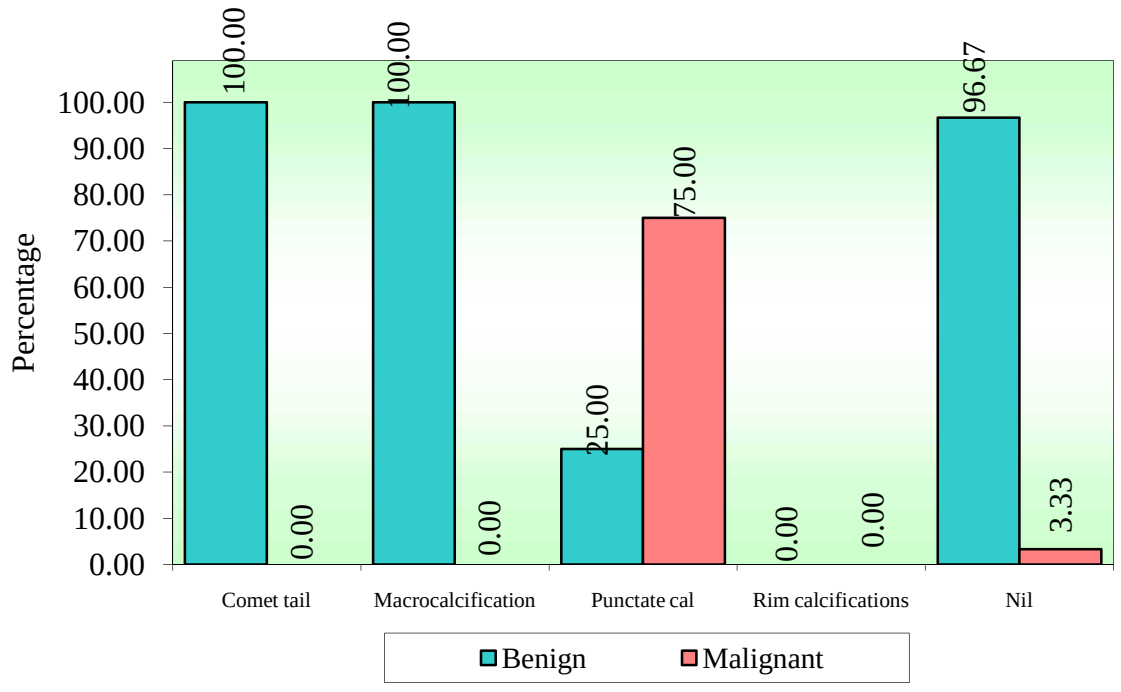
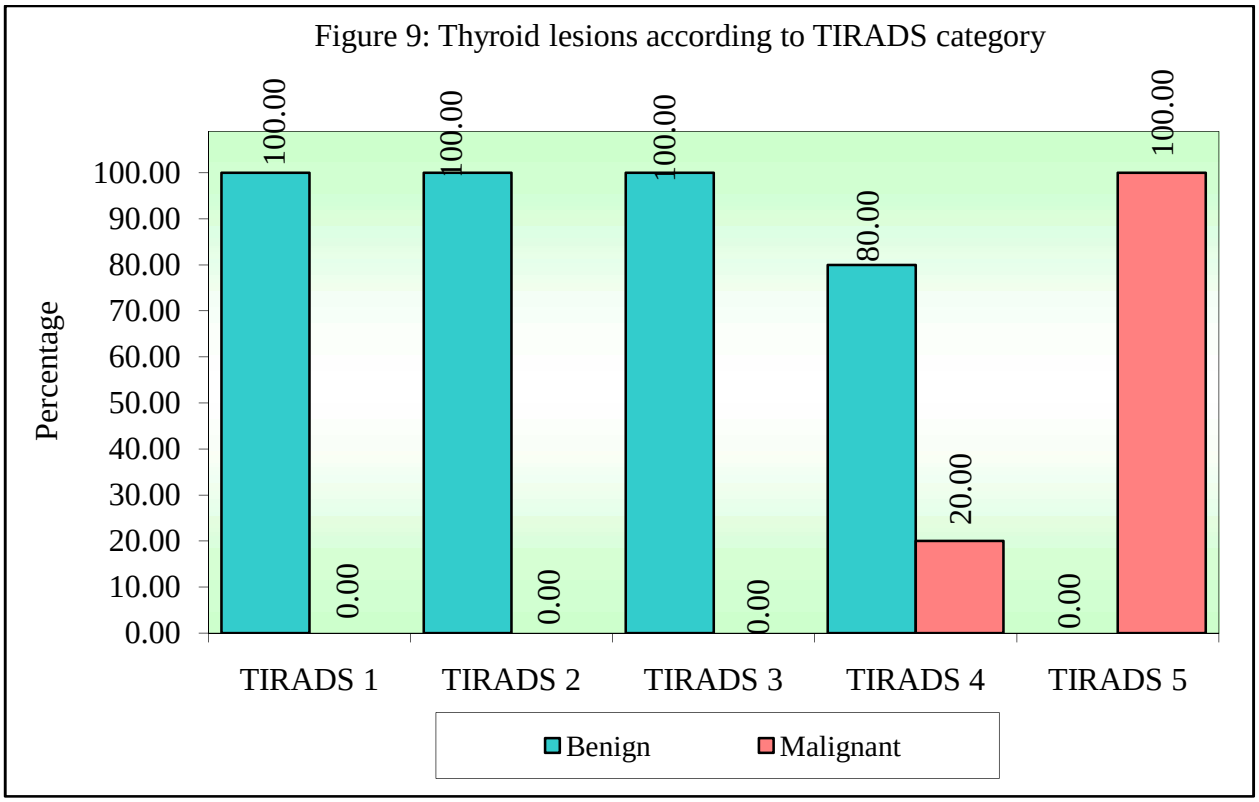


Table 9: Thyroid lesions according to TIRADS category

TIRADS category	Benign	%	Malignant	%	Total	%
TIRADS 1	4	100.00	0	0.00	4	10.00
TIRADS 2	12	100.00	0	0.00	12	30.00
TIRADS 3	16	100.00	0	0.00	16	40.00
TIRADS 4	4	80.00	1	20.00	5	12.50
TIRADS 5	0	0.00	3	100.00	3	7.50
Total	36	90.00	4	10.00	40	100.00

Out of 40 nodules, 4 nodules were categorized in TIRADS-1, 12 in TIRADS-2 and 16 in TIRADS-3 category and all of the nodules turned out to be benign. 5 nodules were grouped in TIRADS-4 category of which 4 nodules (80%) turned out to be benign and1 nodule(20%) was proven to be malignant. 3 nodules were categorized into TIRADS-5 category and all of them were malignant.

Figure 9: Thyroid lesions according to TIRADS category



DISCUSSION

Ultrasonography is the most common modality used for the evaluation of thyroid nodules. The guidelines for systematic evaluation of thyroid nodules was provided by committee by American College of Radiology, by which the nodules are be stratified into 5 categories(TIRADS 1 to TIRADS 5) depending on the possibility of risk for malignancy and also recommend the criteria for biopsy. The nodules were evaluated based on 5 characteristics(composition, echogenicity, shape, margin, and presence of echogenic foci) and TIRADS score is assigned depending on probability of malignancy.

Our study included 40 patients, of which 32(80%) were females and the rest 8(20%) were males and the mean age of the patients being 49.5 years. Our study was conducted on 40 thyroid nodules, and sonographic assessment was done based on ACR-TIRADS template to determine the score and assign the nodule into benign or malignant category. The findings were then correlated with the histological report following FNA or surgical excision.

Out of 40 nodules, 90% (36 nodules) of them were benign and 10% (4 nodules) were malignant. All the 4 malignant nodules had solid composition and all the nodules with cystic composition were benign. Similar results were found with the study conducted by Azab et al. [42]which showed all the cystic nodules to be benign and a high incidence of malignancy in solid nodules.

In our study, 100 % of the nodules with anechogenecity or hyperechogenecitywere benign and one nodule which was very hypoechoic was malignant. However, there was no significant difference in the benignity or

malignancy in the nodules with iso or hypoechogenicity. These results corresponds to the previous study conducted by Azab et al. [42]

Middleton et al.[43] stated that 12.9% of nodules which had smooth margins and 44.7% of nodules which had lobulated orirregular marginswere malignant. Thyroid nodules with irregular and lobulatedmargins are more associated with malignancy. Our study is comparable to the previous study and in our study, 66.7% of the malignant group nodules showed irregular margins. Extrathyroidal extension is also an important indicator of malignancy. In our study, one nodule had extrathyroidal extension and was found to be malignant.

Regarding shape of the nodule, the nodules with taller than wide shape are more suspicious of malignancy. In our study, we found that 66.7 %(two out of three) nodules which had taller than wide shape were malignant. This study was in agreement with the previous study conducted by Azab et al. [42] which stated that that there was a high significant statistical increase in the incidence of taller than wider nodules in the malignancy group as compared to the benign group.

Study by Middleton et al[43] and Azab et al[42] found that punctate echogenic foci in solid nodules have a 35% and 66.7% risk of malignancy respectively. Our study was comparable to the previous studies where 75% nodules with punctuate calcifications had malignancy. Also in our study, all the nodules with comet tail and macrocalcifications were benign.

A significant statistical relationship was observed between risk of malignancy and echogenicity, shape, margins and echogenic foci with p values

of 0.018, 0.016, 0.0001 and 0.0001 respectively. As the score in each category increased, there was an increase in the chance of malignancy. These findings were corresponding to the study conducted by Middleton et al[43]. However, there was no significant statistical association between composition of the nodules with malignancy.

Middleton et al.[43] found that the risk of malignancy for TR3, TR4 & TR5 to be 4.8%, 9.1%, and 35% respectively. Azab et al. [42] stated that there was asignificant statistical trend of an increased risk of malignancy as the TIRADS level increased from TR1 to TR5with p value of < 0.001. In the current study, all the nodules with TIRADS grade TR1, TR2 & TR3 were benign, 80 %(32) nodules in TR4 category were benign & rest 20% (8) nodules were malignant. 100 %(3) nodules in the TR5 category were malignant. There was a statistically significant increase in the chance of malignancy from TR1 to TR 5 category with p value of 0.0001.

Overall, according to the present study, the best cut-off point to differentiate benign and malignant nodules according to the ACR-TIRADS system is TR4, and the ACR TI-RADS system has a sensitivity and specificity of 78.3% and 100% respectively in differentiating benign and malignant nodules. This is in correspondence with study by Azabet al.[42]

CONCLUSION

The study is based on ACR TI-RADS scoring system to stratify the nodules into TR1 to TR5 categories based on various features which could predict the benignity or malignancy and to correlate the findings with histopathological reports. The method is simple and easily applicable in evaluation of the thyroid nodules in daily practice. This system has proven to have sensitivity and specificity of 78.3% and 100% respectively in differentiating benign and malignant nodules according to the present study. According to the present study, there was an increased risk of malignancy from TR1 to TR5 category.

USG features like irregular margins, taller than wide shape, very hypoechogenicity and punctuate calcifications are associated with malignancy and features like smooth margins, hyper or anechogenicity, wider than tall shape are associated with benign nodules.

The TIRADS system also gives further guidelines to the physician / surgeon regarding follow-up / biopsy depending on the TIRADS grade. Also the method helps in avoiding unwanted FNAC procedures.

The main limitation of the present study was the small study group, and the study needs to be conducted on a larger group for more accuracy.

SUMMARY

In our study 40 patients who had palpable thyroid mass were evaluated with Ultrasonography with ACR-TIRADS system. Overall, 36 patients(90%) had benign nodules and 4 patients (10%) had malignant nodules.

4 nodules were categorized in TR-1 group, 12 in TR-2 group and 16 in TR-3 group, and all the nodules in TR-1 to TR-3 group were benign. 5 nodules were categorized in TR-4 group of which 1 nodule (20%) was malignant. 3 patients were categorized in TR-5 group and 100% of them were malignant.

Features like shape, margins, echogenicity and echogenic foci were statistically significant in differentiating benign and malignant lesions. However composition was not statistically significant in predicting the malignancy according to the present study.

USG features like irregular margins, taller than wide shape, very hypoechogenicity and punctuate calcifications are associated malignancy and features like smooth margins, hyper or anechogenicity, wider than tall shape are seen with benign nodules.

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ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed-to-be-University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' By MHRD (...)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone (+ 91-0)831 Office 2472550
Principal 2471701
Fax No +91 (0)831 - 2470759

Ref: MDC/DOME/ 73 **Date: 24/11/2018**

To,

REGISTRATION NO. BS0118006
PG student in Radio-Diagnosis,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ROLE OF THYROID IMAGING REPORTING AND DATA SYSTEM IN DIFFERENTIATION OF BENIGN AND MALIGNANT THYROID LESIONS AND CYTOPATHOLOGICAL CORRELATION AT TERTIARY CARE CENTRE, BELAGAVI – A ONE YEAR HOSPITAL BASED STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE I

INFORMED CONSENT

TITLE: "ROLE OF THYROID IMAGING, REPORTING, AND DATA SYSTEM IN DIFFERENTIATION OF BENIGN AND MALIGNANT THYROID LESIONS AND CYTOPATHOLOGICAL CORRELATION AT TERTIARY CARE CENTRE, BELAGAVI - A ONE YEAR HOSPITAL BASED STUDY"

PRINCIPAL INVESTIGATOR: REGISTRATION NO. BS0118006

INTRODUCTION AND PURPOSE:

Thyroid nodules are most commonly benign. Classification of the nodules based on the TIRADS criteria helps to avoid subjecting patients to invasive procedures.

PROCEDURE:

I request you to kindly participate in the study titled **"ROLE OF THYROID IMAGING, REPORTING, AND DATA SYSTEM IN DIFFERENTIATION OF BENIGN AND MALIGNANT THYROID LESIONS AND CYTOPATHOLOGICAL CORRELATION AT TERTIARY CARE CENTRE, BELAGAVI - A ONE YEAR HOSPITAL BASED STUDY"** which is being conducted by **REGISTRATION NO. BS0118006**,post-graduate in Department of Radio- diagnosis at J. N. Medical College Belagavi, Karnataka, under the guidance of Dr. _____, Professor, Department of Radio diagnosis, J. N. Medical College, Belagavi.

We request you to participate in this study as you are eligible to be included. During the study you will be asked questions regarding your present and past medical history and you will be required to answer to the best of your knowledge. You will also be clinically examined as per the protocol drawn.

If you agree to participate in the study, please furnish the details pertaining to the study.

BENEFITS:

- Ultrasonography is a noninvasive modality

COMPLICATIONS:

- No risk to the patient has been documented from Ultrasound imaging of the thyroid conducted earlier.
- FNAC / biopsy is an invasive procedure and is associated with complications such as hemorrhage, infection etc.

ALTERNATIVES:

If the patient is not willing to take part in the study, his / her treatment or any other further investigations the patient wants to undergo in future in KLE will not be affected by his / her decision.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part I can later change my mind and withdraw from the study. My decision will not change the present or future healthcare services or other

services that I receive. The study doctor or the sponsor may stop my participation in this study. I will inform the doctor incase of any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study I will receive the standard treatment for patients with my condition.

COSTS:

NIL (The study is to be conducted on the participants who are advised Ultrasonography as an investigation for thyroid swelling by the referring consultant and the participants will bear the charges for it.)

Payment for Participation: No incentive will be paid to you for participating in this study.

COMPENSATION:

In the event that I become injured as a result of taking part in this study, treatment whatever available at KLE charitable hospital, Belagavi, will be offered to me. No reimbursement, compensation or free medical care is given.

CONFIDENTIALITY:

All information collected about me during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify me in this research record. Information from this study may be published but my identity will be confidential in any publication.

QUESTION:

If any enquiries in the future or incase of research related injury illness, you may contact the following people:

Dr. REGISTRATION NO. BS0118006
Post-Graduate, Department of
Radio-Diagnosis.
J.N.Medical College, Belagavi

Dr _____
Guide,
Professor, Department of Radio-Diagnosis
J.N.Medical College,
Belagavi

Dr. Roopa M Bellad
Professor and Unit
Head of Pediatrics
Chairman,
J.N. Medical College Institutional Ethical
Committee for Human Subjects Research

CONSENT TO PARTICIPATE IN RESEARCH STUDY:

1. I understand that I am participating in the study, which includes Ultrasonographic evaluation of the thyroid, FNAC / biopsy of the thyroid lesion.

2. I confirm that I have read and understood the information in the patient information sheet. Procedure is explained to me in detail along with information about the advantages and disadvantages of taking part in the study. I have been given the opportunity to discuss all aspects of the trial, to ask questions and hereby consent to participate in the trial outlined above.

3. I understand that the decision to take part in this study is completely voluntary and I am aware that I can choose to withdraw from the study at any point of time.

4. I consent to the photographing or recording of the procedure to be performed including appropriate portions of my body, for medical, scientific or educational purposes provided my identity is not revealed in the pictures or by the descriptive texts accompanying them.

5. I understand that there is no significant risk involved in the test that would be done in this study.

6. No guarantee or assurance has given by anyone as to the results that may be obtained.

7. My signature on this form signifies that I have willingly decided to participate after understanding the above information.

Participant's Name/ legally authorized _____

representative

Signature _____

Name and signature of witness _____

Name and signature of interviewer _____

Date:

Place:

1. My signature on this form signifies that I have willingly decided to participate after understanding the above information.

Participant's / Legally authorized representative's name_____

Signature _____

Name and signature of witness _____

Investigators name and Signature : …….

Date:

Place: Belagavi

ANNEXURE III

PROFORMA

Name: **OP/IP No.:**

Age/Sex: **HPE No.**

Marital Status: **FNAC Number:**

Address:

Chief Complaints:

Clinical and Family History:

Clinical Examination:

Ultrasound findings:

The right lobe of thyroid measures- cm.

The isthmus is normal and measures- mm.

The left lobe of thyroid measures – cm.

Description of the parenchyma:

Number of nodules:

Description of Nodule:

Composition: cystic/ spongiform/ mixed cystic and solid/ solid

Echogenicity: anechoic/ iso or hyperechoic / hypoechoic / very hypoechoic

Shape: wider than tall / taller than wide

Margins: well defined / ill defined / irregular or lobulated / extra thyroidal extension

Echogenicfoci: no or large comet tail artifact / macrocalcification/ peripheral calcification / punctate calcification

Total score:

TI-RADS grade:

Fine needle Aspiration Cytology report:

Laboratory Investigations:

Histopathological diagnosis:

Diagnosis:

ANNEXURE IV: FIGURES

1. **A 31 year old female came with history of thyroid swelling. USG revealed a solitary nodule. The nodule had following features -** Wider than taller shape, Iso Echogenicity, Solid Content, No echogenic foci, Smooth Margin. TIRADS grade of 3 was given. FNAC showed it to be colloid goiter.

Fig 13.Ultrasound image of colloid goiter

2. **A 47 year old female came with history of thyroid swelling. USG revealed a solitary nodule. The nodule had following features -** Wider than taller shape, Iso Echogenicity, mixed solid-cystic Content, No echogenic foci, Smooth Margin. TIRADS score of 2 was given. FNAC showed it to be colloid goiter with cystic degeneration.

Fig 14.Ultrasound image of colloid goiter with cystic degeneration –

3. **A 75 year old female came with history of swelling in the neck. USG revealed a multiple nodules. The nodule had following features -** Wider than taller shape, anechogenicity, cystic Content with comet tail artifacts, Smooth Margin. TIRADS score of 0 was given. FNAC showed it to be colloid goiter.

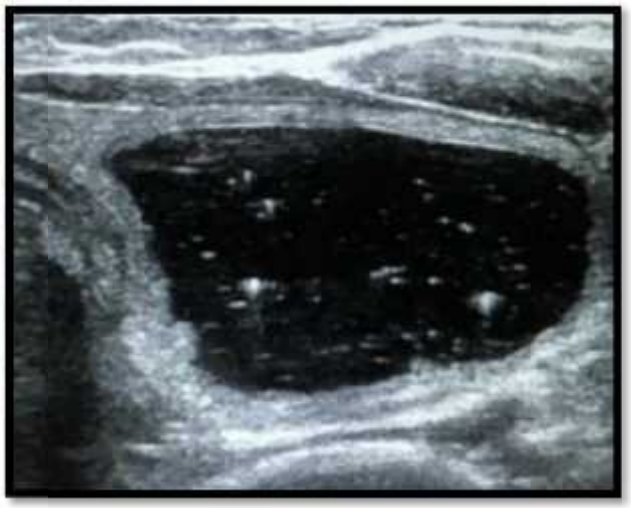


Fig 15. Ultrasound image of colloid goiter

4. **A 24 year old female came with history of palpable thyroid swelling. USG revealed a solitary nodule. The nodule had following features -** Wider than taller shape, Isoechogenicity, solid Content, No echogenic foci, Smooth Margin. TIRADS score of 4 was given. FNAC showed it to be adenomatous hyperplasia.

Fig 16. Ultrasound image of Adenomatous Hyperplasia

5. **A 58 year old female came with history of thyroid swelling. USG revealed a solitary nodule. The nodule had following features -** Wider than taller shape, marked hypochogenicity, solid Content with No echogenic foci. TIRADS score of 4 was given. FNAC showed it to be follicular neoplasm. Further excision biopsy was done which showed it to be **follicular carcinoma**.

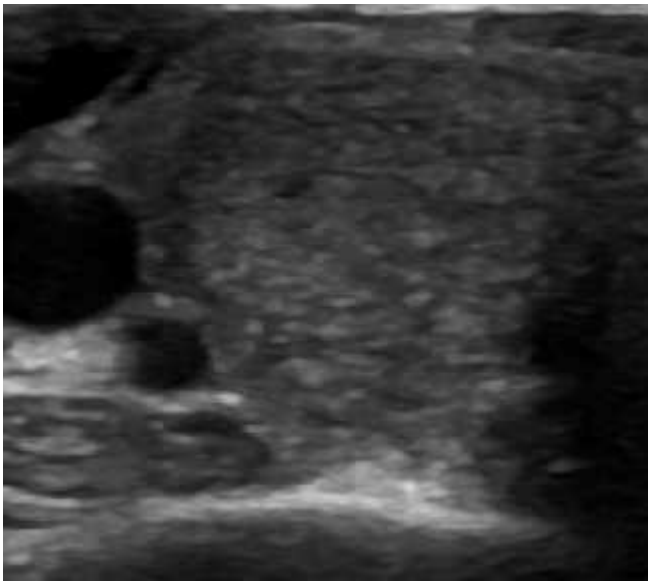


Fig 17. Ultrasound image of follicular carcinoma

6. **A 60 year old female came with history of thyroid swelling. USG revealed a multiple nodules. The nodule had following features –**isoechogenicity, solid Content with microcaclifications and had extrathyroidal extension. TIRADS grade of 5 was given. FNAC showed it to befollicular neoplasm. Further excision biopsy was done which showed it to be **follicular carcinoma**.

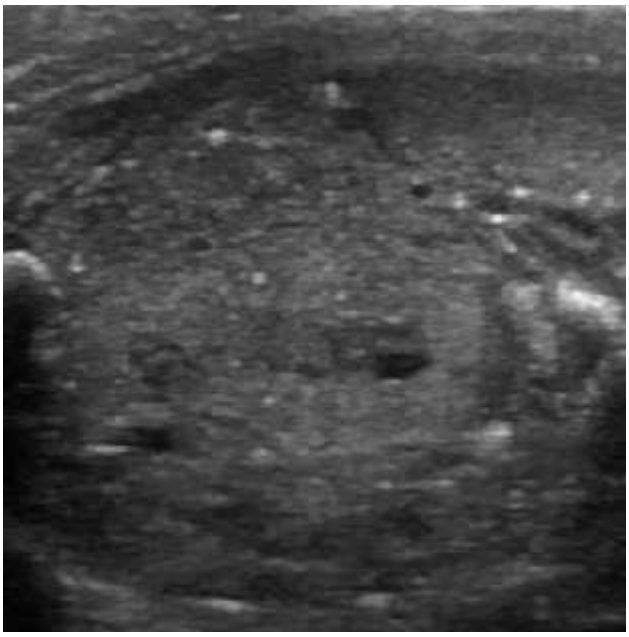
7. 

Fig 18. Ultrasound image of follicular carcinoma

ANNEXURE V: KEY TO MASTERCHART

Cal	:	calcification
Ext	:	Extension
F	:	Female
M	:	Male
TTW	:	Taller than wide
WTT	:	Wider than tall

SL NO.	IP / OP NO.	AGE	SEX	TFT	SIZE OF THYROID GLAND	NO. OF NODULES	DESCRIPTION OF THE NODULE							FNAC/ BIOPSY REPORT
							COMPOSITION	ECHOGENICITY	SHAPE	MARGINS	ECHOGENIC FOCI	TIRADS SCORE	TIRADS GRADE	
1	3043471	31	F	NORMAL	ENLARGED	1	SOLID	ISOECHOIC	WTT	SMOOTH	NIL	3	TR3	COLLOID GOITRE
2	4540329	47	F	NORMAL	NORMAL	1	MIXED	ISOECHOIC	WTT	SMOOTH	COMET TAIL	2	TR 2	COLLOID GOITRE WITH CYSTIC DEGENERATION
3	4842420	41	F	NORMAL	NORMAL	3	MIXED	ISOECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE WITH CYSTIC DEGENERATION
4	5132240	54	F	NORMAL	ENLARGED	2	CYSTIC	ANECHOIC	WTT	SMOOTH	NIL	0	TR1	COLLOID GOITRE WITH CYSTIC DEGENERATION
5	927745	67	F	NORMAL	ENLARGED	3	SOLID	HYPOECHOIC	WTT	IRREGULAR	PUNCTATE CAL	9	TR5	PAPILLARY CARCINOMA
6	5149303	27	M	NORMAL	NORMAL	1	SOLID	ISOECHOIC	WTT	SMOOTH	NIL	3	TR3	ADENOMATOUS HYPERPLASIA
7	5120956	75	F	NORMAL	NORMAL	2	CYSTIC	ANECHOIC	WTT	SMOOTH	COMET TAIL	0	TR1	COLLOID GOITRE
8	1351735	73	M	NORMAL	NORMAL	1	CYSTIC	ANECHOIC	WTT	SMOOTH	COMET TAIL	0	TR1	COLLOID GOITRE WITH CYSTIC DEGENERATION
9	5163089	31	M	NORMAL	NORMAL	1	SOLID	ISOECHOIC	WTT	SMOOTH	NIL	3	T3	FOLLICULAR ADENOMA
10	5296472	53	F	HYPOTHYROIDISM	ENLARGED	3	SOLID	HYPERECHOIC	WTT	SMOOTH	NIL	3	TR3	COLLOID GOITRE
11	5206089	60	M	HYPOTHYROIDISM	ENLARGED	4	SOLID	HYPERECHOIC	WTT	SMOOTH	NIL	3	TR3	MULTINODULAR GOITRE
12	5259248	48	F	NORMAL	NORMAL	1	SOLID	HYPERECHOIC	WTT	SMOOTH	NIL	5	T4	COLLOID GOITRE
13	5130556	45	F	NORMAL	ENLARGED	4	MIXED	HYPERECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE
14	4232204	72	F	NORMAL	NORMAL	3	MIXED	HYPERECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE WITH CYSTIC DEGENERATION
15	5419125	60	F	NORMAL	NORMAL	1	CYSTIC	ANECHOIC	WTT	SMOOTH	NIL	0	TR1	COLLOID GOITRE
16	5159483	27	F	NORMAL	NORMAL	1	SOLID	ISOECHOIC	WTT	SMOOTH	PUNCTATE CAL	6	TR4	HURTLE CELL ADENOMA
17	5474722	35	F	NORMAL	ENLARGED	3	SOLID	ISOECHOIC	TTW	IRREGULAR	PUNCTATE CAL	11	TR5	PAPILLARY CARCINOMA
18	5474564	63	M	NORMAL	ENLARGED	3	MIXED	ISOECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE
19	4981966	24	F	NORMAL	NORMAL	1	SOLID	HYPERECHOIC	WTT	SMOOTH	MACROCALCIFICATION	4	TR4	ADENOMATOUS HYPERPLASIA
20	5263523	39	M	NORMAL	NORMAL	2	MIXED	HYPERECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE
21	4108248	51	F	NORMAL	NORMAL	2	SOLID	HYPERECHOIC	WTT	SMOOTH	NIL	3	TR3	COLLOID GOITRE
22	5564345	60	F	-	ENLARGED	3	MIXED	HYPOECHOIC	WTT	SMOOTH	NIL	3	TR3	COLLOID GOITRE
23	3383762	54	F	NORMAL	NORMAL	1	SOLID	ISOECHOIC	WTT	SMOOTH	NIL	3	T3	HURTLE CELL ADENOMA
24	979175	60	F	HYPOTHYROIDISM	ENLARGED	4	MIXED	ISOECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE
25	5656970	61	F	HYPOTHYROIDISM	ENLARGED	4	SOLID	ISOECHOIC	WTT	SMOOTH	NIL	3	T3	COLLOID GOITRE
26	517889	46	F	NORMAL	NORMAL	1	SOLID	HYPOECHOIC	TTW	IRREGULAR	NIL	6	TR4	HURTLE CELL ADENOMA
27	4904252	60	F	NORMAL	ENLARGED	4	SOLID	ISOECHOIC	TTW	TRATHYROIDAL E	PUNCTATE CAL	11	TR5	FOLLICULAR CARCINOMA
28	5089453	68	F	HYPOTHYROIDISM	ENLARGED	4	MIXED	ISOECHOIC	WTT	SMOOTH	NIL	2	TR2	MULTINODULAR GOITRE
29	5128333	45	F	NORMAL	NORMAL	1	SOLID	HYPERECHOIC	WTT	SMOOTH	NIL	3	TR3	COLLOID GOITRE
30	5114934	32	F	-	NORMAL	2	MIXED	ISOECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE WITH CYSTIC DEGENERATION
31	5132942	51	F	-	NORMAL	1	SOLID	HYPERECHOIC	WTT	SMOOTH	NIL	3	TR3	ADENOMATOUS HYPERPLASIA
32	5145951	43	M	NORMAL	NORMAL	2	MIXED	HYPOECHOIC	WTT	SMOOTH	MACROCALCIFICATION	3	TR3	COLLOID GOITRE WITH CYSTIC DEGENERATION
33	5170503	18	F	NORMAL	NORMAL	1	MIXED	HYPERECHOIC	WTT	SMOOTH	MACROCALCIFICATION	3	TR3	HYPERPLASTIC NODULE WITH CYSTIC DEGENERATION
34	5177972	42	F	HYPERTHYROIDISM	NORMAL	2	MIXED	HYPERECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE
35	5196069	29	F	NORMAL	ENLARGED	3	MIXED	HYPERECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE
36	5167526	72	F	NORMAL	ENLARGED	4	SOLID	HYPERECHOIC	WTT	SMOOTH	NIL	3	TR3	COLLOID GOITRE
37	5211784	40	M	NORMAL	NORMAL	1	MIXED	ISOECHOIC	WTT	SMOOTH	NIL	2	TR2	COLLOID GOITRE WITH CYSTIC DEGENERATION
38	942042	43	F	NORMAL	NORMAL	1	SOLID	HYPERECHOIC	WTT	SMOOTH	NIL	3	TR3	COLLOID GOITRE
39	957170	78	F	NORMAL	ENLARGED	3	MIXED	HYPOECHOIC	WTT	SMOOTH	NIL	3	TR3	COLLOID GOITRE
40	4552148	58	F	NORMAL	NORMAL	1	SOLID	MARKED HYPOECHOIC	WTT	SMOOTH	NIL	5	TR4	FOLLICULAR CARCINOMA