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Original Research Article

# A Prospective Study to Evaluate Diagnostic Efficacy of Ultrasound and Colour Doppler in Predicting Malignancy in Nodular Thyroid Disease with Pathological Correlation

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**Conflict of interest: Nil**

**Abstract**

**Background:** Nodular thyroid disease presents with one or more nodular lesions in thyroid gland which may be clinically occult. Thyroid nodules occur frequently in general population and are estimated to show a prevalence of 4-7% by palpation alone and 20-76% by ultrasound (USG) in adults. The prevalence reported by USG correlates with the surgery and autopsy prevalence in the range of 50-65%[5]. Majority of these lesions are readily detected by high resolution ultrasonography (USG).

**Objective:** To evaluate the diagnostic efficacy of ultrasound in predicting malignancy in nodular thyroid disease with pathological correlation.

**Methods:** A prospective study was carried out from Jan 2013 to Oct 2014 in 130 patients of both sexes in a tertiary care hospital reporting for neck swelling. The USG results were reported as benign, malignant and suspicious for malignancy.

**Results:** The majority of the patients were females in age group of 21-50 years. Anterior or lateral neck swelling was the presenting complaint in all cases. Among 130 patients, 150 thyroid nodules were evaluated 32 nodules were interpreted as malignant in USG. Overall, after pathological correlation, 42 nodules confirmed to be malignant. The strong sonological predictors for malignancy in thyroid nodules were markedly hypoechoic echotexture, poor ill-defined margins, taller than wide shape, lack of perinodular halo, central color flow in doppler and presence of cervical lymphadenopathy. The overall diagnostic accuracy of ultrasound in predicting malignancy in nodular thyroid disease was about 77.4%.

**Conclusion:** Ultrasonography is safe, reliable and radiation free diagnostic tool for delineating malignancy in thyroid nodules. It has fairly acceptable sensitivity and specificity.

**Keywords:** USG (ultrasonography), FNAC (fine needle aspiration cytology), thyroid nodule, HPE (histopathological examination).



## Introduction

Any abnormal growth that forms a lump in thyroid gland is referred as thyroid nodule. Thyroid disorders show a fairly high prevalence in general population and are observed to be one of the commonest head and neck disorder. They may present with

clinically palpable or occult solitary or multiple thyroid nodules. Previous studies estimated a 4% to 7% prevalence of palpable thyroid nodules in adults in United States with females affected more than males. It has been observed that the prevalence of these nodules increases with age. Most of these thyroid nodules encountered in general population are asymptomatic and benign in nature. The overall risk of thyroid malignancy is very low and contributes to less than 1% of all malignancies. Identification of these malignant nodules assumes clinical importance since these patients are candidates for early surgical intervention. Management guidelines from American Thyroid Association clearly states that a diagnostic USG should be done in all patients with thyroid nodules and fine needle aspiration (FNAC) in nodules suspicious for malignant nodules[7]. The gray scale features evaluated were shape, margins, composition, echogenecity, presence of intralesional calcifications, presence of absence of perinodular halo and presence of cervical lymphadenopathy. Vascular signal (presence/absence) and pattern (peripheral, central or mixed) was determined by color doppler.

## Aims and Objectives

The study was designed to evaluate the gray scale and color doppler features of benign and malignant thyroid nodules and to assess the diagnostic efficacy of ultrasonography and color Doppler in predicting malignancy in thyroid nodules with pathological correlation.

## Material and Methods

A tertiary care hospital based prospective study was carried out from Jan 2013 to Oct 2014 in 130 patients in the department of Radiodiagnosis and Imaging.

### Inclusion Criteria:

- Patients with palpable nodular swelling of thyroid glands of both sexes in all age group were included.

### Exclusion Criteria:

- Patients with ulcerating or fungating lesions.
- Post-op patients operated for neck swelling.
- Unwilling patients

### Technical Considerations:

Patients underwent a neck sonography on LOGIC P-5 (WIPRO GE HEALTH CARE) using 12MHz linear array transducer. Doppler settings were standardized to compare the vascularity of thyroid pathologies among different patients. Patients were examined in supine position after slightly hyper-extending the neck. The thyroid gland was scanned in transverse and longitudinal planes with 12MHz linear array transducer. The sonological parameters assessed in thyroid nodules to differentiate these lesions into benign and malignant variety were shape, margins, presence of peripheral halo, internal contents, echogenecity of nodules as compared to normal thyroid glandular parenchyma, presence of calcification and nature (micro or macrocalcification), presence of cervical lymphadenopathy and vascular signal and pattern. A USG guided FNAC was conducted after sonological interpretation after taking a written consent.

### Sonological Evaluation

The echogenecity (figure 1: A, B & C) was determined as hyperechoic, hypoechoic, markedly hypoechoic, isoechoic and anechoic as compared to normal glandular parenchyma. The internal composition (figure 2 A, B & C) was assessed as solid including predominantly solid, mixed solid-cystic and cystic that also included predominantly cystic composition. Margins (Figure 3 A, B) were described as well or completely defined and ill or poorly defined. The next criteria for

assessment was presence or absence of peripheral halo (figure 4 A, B). The shape was classified as taller than wide and not taller than wide (figure 5 A, B). The nodules were assessed for presence of intralesional calcifications (figure 6 A, B) and an attempt was made to subclassify them into microcalcifications or macrocalcifications. The neck was scanned for presence of significant cervical lymphadenopathy. Vascular signal (presence/absence) and pattern (peripheral or perinodular, central or intranodular and mixed or peripheral-central) was determined by color doppler (figure 7 A, B). In patient with multiple nodules, each nodule was classified separately.

The sonological predictors of a malignant lesion were with taller than wide shape, poorly defined margins, absence of perilesional halo, markedly hypoechoic appearance, presence of calcification-typically microcalcification (<2mm), presence of cervical lymphadenopathy and intranodular or central color flow in doppler.

**Statistical Analysis**

Statistical analysis was conducted with the statistical package for the social science system version (SPSS) 17.0. Continuous variables are presented as mean ± SD, and categorical variables are presented as absolute numbers and percentage. Nominal categorical data between the groups were compared using Chi-square test or Fisher's exact test as appropriate. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated to analyze the diagnostic accuracy of ultrasound and correlating with FNAC as the gold standard. For all statistical tests, p value of $< 0.05$ was taken to indicate a significant difference.

**Results**

Overall, 150 nodules from 130 patients were assessed by USG. Of the included age group (11-80 years), the youngest patient was 18 year old female whereas the oldest patient was a male aged 70 (chart 1). The highest number of cases were seen in the age group of 31-40 years, 35 out of 130 cases (i.e 26.9%). Less than 20 years age group contributed to the least number of patients i.e 2 (1.53%).

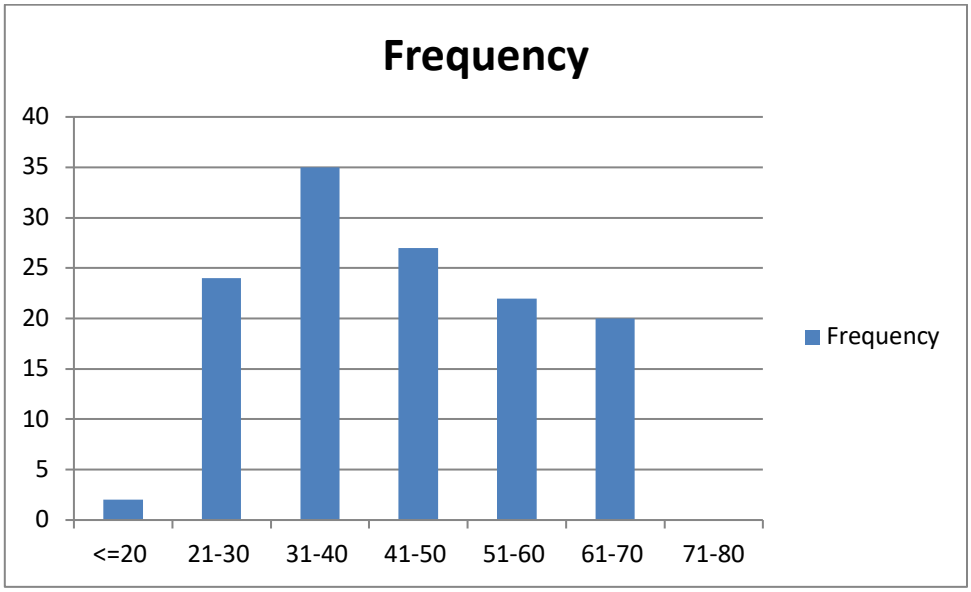


**Chart 1: Age wise distribution (n=130)**

Of all patients included, 92 (70.7%) were female (chart 2).

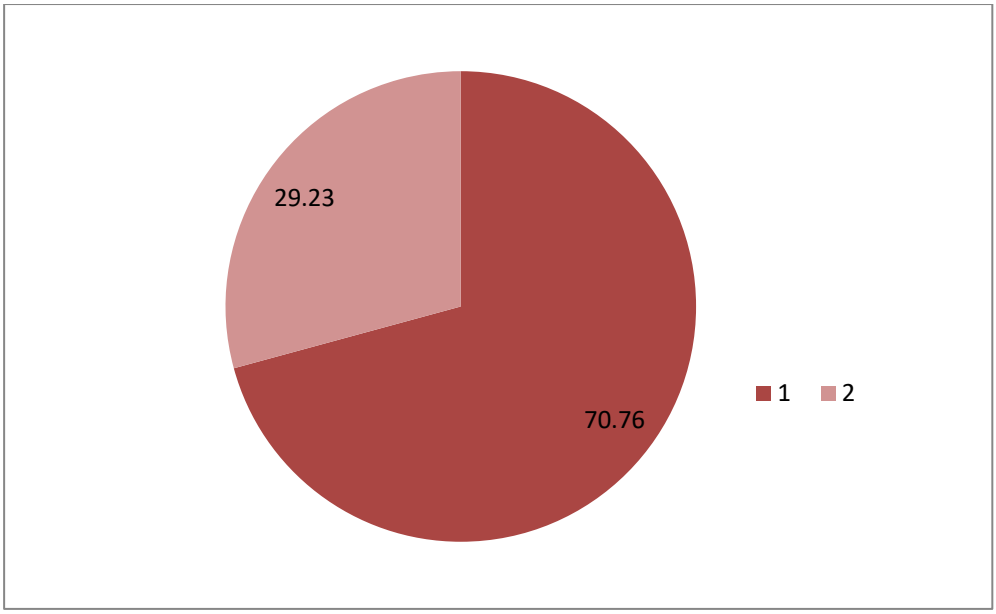


**Chart 2: Sex wise distribution (n=130)**

**1: Female, 2: Male**

In gray scale ultrasound with color Doppler, 118 (78.67%) out of 150 nodules were reported as benign and 32 (29.23%) were reported as malignant (chart 3).

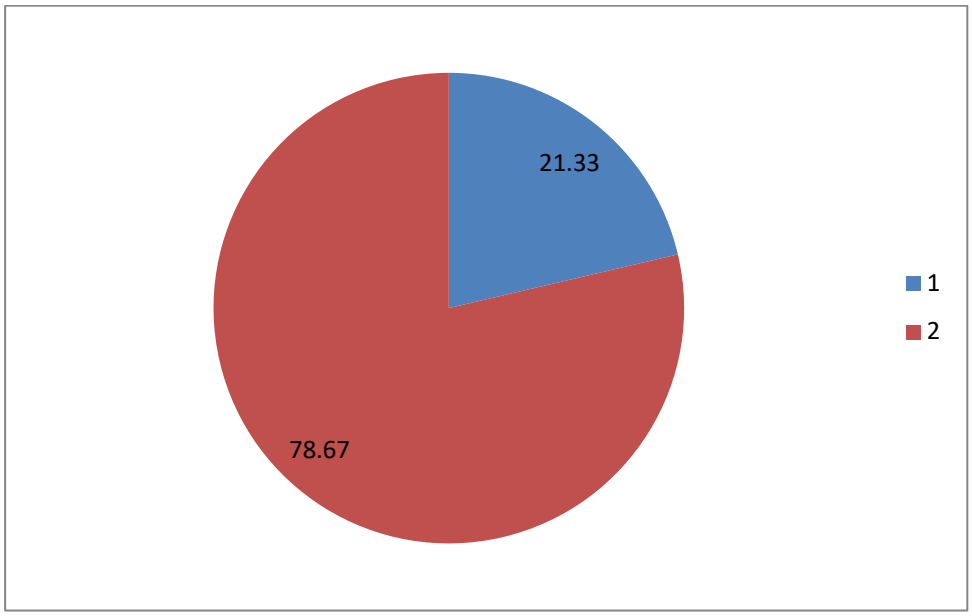


**Chart 3: Distribution of nature of thyroid nodules on USG (n=150)**

**1: Malignant, 2: Benign**

When these results were compared with pathological impression, it was found that 108 nodules out of 150 (72%) finally proved to be benign and 10 sonologically benign nodule came out to be malignant in FNAC/HPE (in selective cases) examination (chart 4).

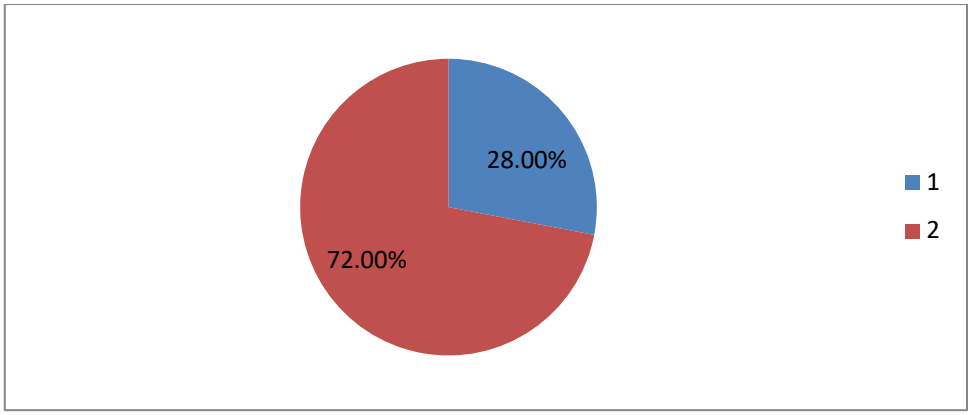


**Chart 4: Distribution of nature of thyroid nodules on FNAC/HPE**

**1: Malignant, 2: Benign**

Of all the Malignant types, Papillary variety was seen in 29 (69%) of all malignant nodules. The medullary, anaplastic and follicular subtypes were confirmed in 7, 3 and 2 nodules respectively by pathological analysis. One malignant nodule showed features of lymphoma in FNAC.

**Images of gray scale ultrasound and color doppler**

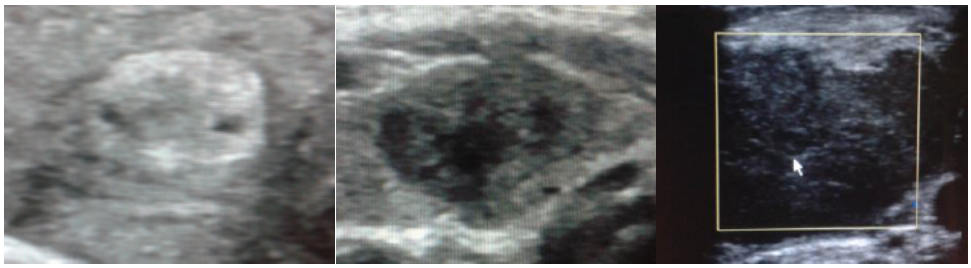

**Figure 1 (A, B and C): Echogenecity in gray scale USG– Longitudinal sections of thyroid lesions showing hyperechoic (A), hypoechoic (B) and markedly hypoechoic appearance of these lesions**

**Figure 2(A, B): Internal composition of thyroid nodules in USG – Solid composition (A) and mixed solid-cystic (B) and cystic (C) composition of thyroid lesions in longitudinal B mode US images**

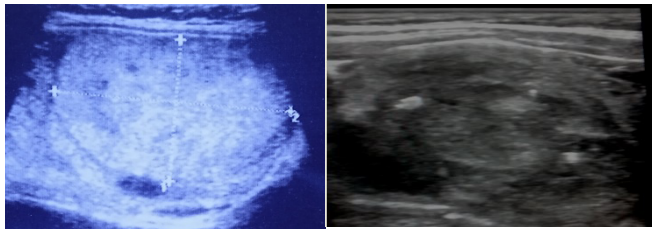

**Figure 3(A, B): Margins – Figure A shows smooth well-defined margins whereas margins are poorly delineated in image B in longitudinal B mode images of the lesions**

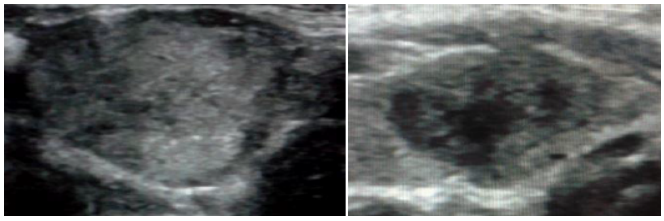

**Figure 4(A, B): Presence or absence of peripheral halo – A well-defined perilesional halo is appreciated in figure A. Figure B shows lack of a peripheral halo surrounding the thyroid nodule**

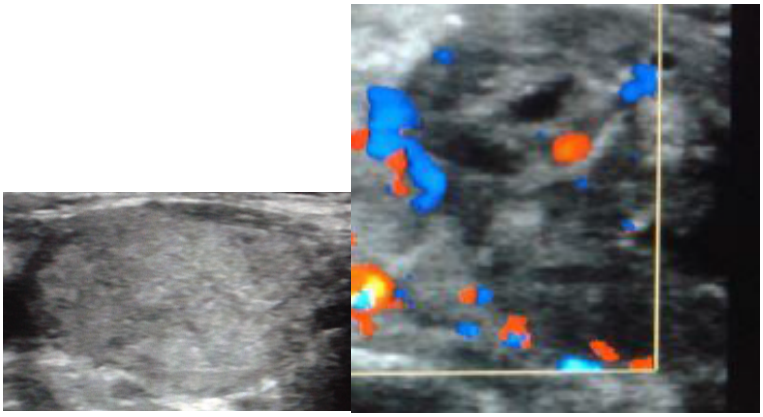

**Figure 5(A, B): Shape – Not taller than wide shape of a thyroid nodule (A) which came out to be benign after FNAC. A classic markedly hypoechoic solid nodule (B) later proved to be malignant shows taller than wide shape**

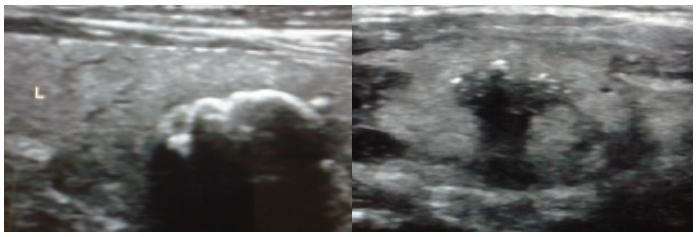

**Figure 6 (A, B): Calcifications – Macrocalcification with eggshell pattern (A) and microcalcifications in a solid throid nodule in figure B**

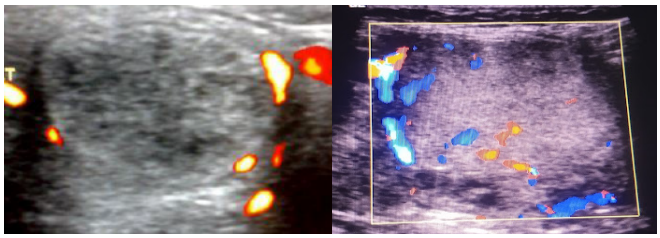

**Figure 7(A, B) Color flow pattern in color doppler ultrasound – Figure A shows peripheral or a perinodular pattern of color flow in a pathologically proven follicular adenoma. Mixed central and peripheral color flow in an another benign colloid nodule (B)**

## Discussion

Nodular thyroid disease is common and majority of the patients have benign lesions. Clinically a thyroid nodule is a discrete lesion within the thyroid gland that is distinguishable from the normal thyroid tissue[5]. An accurate differentiation of thyroid nodules into

benign and malignant subtypes is needed to prevent unnecessary surgical interventions in patients with benign nodules and to ensure timely detection of malignant nodules at the same time. The goal of conducting this study was to avoid invasive and costly investigations in most patients with benign thyroid disease without missing the minority of patients who have thyroid malignancy. The aim of this study was to assess apply various gray scale ultrasound criteria's like shape, margins, presence of peripheral halo, internal composition, echogenecity of nodules as compared to normal thyroid glandular parenchyma, presence of calcification and nature (micro or macrocalcification) and presence of cervical lymphadenopathy and vascular signal and pattern in differentiating these nodules in benign and malignant varieties.

**Table 1**: **Various USG features of benign and malignant thyroid nodules**

| USG Variables | | FNAC | | Total | P value |
|---|---|---|---|---|---|
| | | Malignant | Benign | | |
| Echogenicity | Hyperechoic | 00(00%) | 04(3.7%) | 04(2.7%) | <0.0001(S) |
| | Hypoechoic | 12(28.6%) | 78(72.2%) | 90(60%) | |
| | Markedly Hypoechoic | 27(64.3%) | 09(8.3%) | 36(24%) | |
| | Isoechoic | 03(7.1%) | 11(10.2%) | 14(9.3%) | |
| | Anechoic | 00(00%) | 06(5.6%) | 06(4%) | 0.083(NS) |
| Internal Contents | Solid | 26(61.9%) | 74(68.5%) | 100(66.7%) | |
| | Cystic | 05(11.9%) | 21(19.5%) | 26(17.3%) | |
| | Mixed | 11(26.2%) | 13(12.0%) | 24(16%) | |
| Margins | Well/Smooth | 08(19.0%) | 97(89.8%) | 105(70%) | <0.0001(S) |
| | Ill/Poorly defined | 34(81.0%) | 11(10.2%) | 45(30%) | |
| Peripheral Halo | Present | 07(16.7%) | 91(84.3%) | 98(65.3%) | <0.0001(S) |
| | Absent | 35(83.3%) | 17(15.7%) | 52(34.7%) | |
| Shape | Taller Than Wide | 35(83.3%) | 04(3.7%) | 39(26%) | <0.0001(S) |
| | Not Taller Than Wide | 07(16.7%) | 104(96.3%) | 111(74%) | |
| Calcifications | Present | 18(42.9%) | 37(34.3%) | 55(36.7%) | 0.326(NS) |
| | Absent | 24(57.1%) | 71(65.7%) | 95(63.3%) | |
| Cervical Adenopathy | Present | 14(33.3%) | 00(00%) | 14(9.3%) | <0.0001(S) |
| | Absent | 28(66.7%) | 108(100%) | 136(90.7%) | |
| Doppler Colour Flow | Peripheral | 03(7.7%) | 61(59.8%) | 64(45.4%) | <0.0001(S) |
| | Central | 32(82.0%) | 11(10.8%) | 43(30.5%) | |
| | Mixed | 04(10.3%) | 30(29.4%) | 34(24.1%) | |

**Table 2: Diagnostic accuracy of USG features of malignant nodules**

| USG Characteristics | Sensitivity(%) | Specificity(%) | PPV(%) | NPV(%) | Diagnostic(%) Accuracy |
|---|---|---|---|---|---|
| Poorly Defined Margins | 80.95 | 89.81 | 75.56 | 92.38 | 87.33 |
| Presence of Calcification | 42.86 | 65.74 | 32.73 | 74.74 | 59.33 |
| Solid Composition | 61.9 | 31.48 | 26 | 68 | 40 |
| Absent or | 83.33 | 84.26 | 67.31 | 92.86 | 84 |

| | | | | | |
|---|---|---|---|---|---|
| Irregular Halo | | | | | |
| Markedly Hypoechoic | 64.29 | 91.67 | 75 | 86.84 | 84 |
| Shape Taller than Wide | 83.33 | 96.3 | 89.74 | 93.69 | 92.67 |
| Presence of Cervical Adenopathy | 33.33 | 100 | 100 | 79.41 | 81.33 |
| Central Colour Flow in Doppler | 82.05 | 89.22 | 74.42 | 92.86 | 87.23 |

**PPV: Positive predictive value, NPV: Negative predictive value**

**Table 3: Comparison of ultrasound with Fine needle aspiration/ histopathology**

| USG Characteristic | FNAC Characteristic | | |
|---|---|---|---|
| | **Malignant** | **Benign** | **Total** |
| **Malignant** | 20 (47.6%) | 12(11.1%) | 32(21.3%) |
| **Benign** | 22 (52.4%) | 96(88.9%) | 118(78.7%) |
| **Total** | 42 (100%) | 108(100%) | 150 (100%) |

It is requested to take into consideration table 1, 2 and 3 while interpreting the findings in the discussion part of this study. The study included the patients from the age range of 11-80 years. The maximum number of patients were seen in the middle age group of 31-50 years (49%). There were only two patients in < 20 years age group. Out of 130 patients, 92 were females. 42 nodules were declared malignant on pathological confirmation of which 22 were present in females thus signifying that malignant thyroid disease is also more common in females. These findings were agreed in other literatures. A similar female preponderance of thyroid nodules was observed by Dr Rojeski MT and Dr Gharib H[8] in their study conducted in 1985. The middle age group prevalence was observed by Dr Abid Ali and Dr Mohammed Nasir[9] in their study on 80 subjects from 2011-2013. In our study, the benign spectrum of thyroid nodules comprised majorly of colloid goitre and follicular adenoma. The most common benign pathology encountered was colloid nodule. The malignant spectrum comprised of papillary, follicular, medullary, anaplastic carcinomas and lymphomas. The most common malignancy was papillary carcinoma which contributed to 29 (69%) of all malignant nodules. The medullary, anaplastic and follicular subtypes were confirmed in 7, 3 and 2 nodules respectively by pathological analysis. One malignant nodule came out as lymphoma in FNAC. These findings were comparable to the findings of the study done by Dr Abid Ali and Dr Mohammed Nasir[9] in their study on 80 subjects from 2011-2013 in which colloid nodule was the most common benign disease (59%). Among the malignant pathologies, papillary carcinomas were most common (68%).

In this study, 4 nodules appeared hyperechoic in USG and sonologically diagnosed as benign none of which came out to be malignant on histopathology. 90 nodules were characterised as hypoechoic of which 12 were proved to be malignant after pathological confirmation. In USG, 36 nodules were categorised as markedly hypoechoic and 27 of them confirmed to be malignant after pathological evaluation. 3 of total 14 isoechoic nodules were reported as malignant after lab confirmation. 6 nodules were anechoic and all of them proved to be benign. In our study we found that the ultrasound had a specificity of 92%, positive predictive

value of 75%, negative predictive value of 86% and a diagnostic accuracy of 84% for predicting malignancy for markedly reduced echotexture of thyroid nodules. Previous studies also showed similar findings. Won Jing Moon[10] et al conducted a study in 2003 which showed a high sensitivity (91%) of ultrasound parameters of hypoechogenecity as a marker of malignancy. K.T Wong[11] et al in 2005 reported that incidence of malignancy for hyperechoic nodule is only 4% and thus a hyperechoic nodule is most likely to be benign. In another study conducted by H Y. Yen et al. it was concluded that most of the hypoechoic nodules were benign since benign nodules are overall more common. The incidence of malignancy in an isoechoic nodule was found to be 26% whereas malignancy was seen in 63% of hypoechoic nodules.

Of 150 nodular lesions, 100 nodules were solid, of them 26 were confirmed to be malignant. 26 nodules were purely or predominantly cystic of them and majority of them came benign after pathological confirmation. Of 24 mixed solid-cystic, 11 proved to be to be malignant. Out of proven 42 malignant cases, 26 (61.9%) were solid or predominantly solid and rest were either predominantly cystic and mixed (solid-cystic) however none of the malignant nodule was purely cystic. In our study we ascertained that the sonological sensitivity and specificity was 62% and 31% respectively with a low diagnostic accuracy of 40% for predicting malignancy based on this sonological feature. Thus it is not considered as an ideal criteria for predicting malignancy in thyroid nodules through ultrasonography. A study by Frates MC[12] et al in 2005 proposed that a predominantly solid component is regarded as being suggestive of a malignant nature rather than a benign nodule with high sensitivity (70-75%) but with low positive predictive value (16-27%). In a study by Weinke et al in 2003 and Lannuccilli JD et al in 2004, findings suggested that about 60%–83% of benign nodules were predominantly solid. In our study, most of the benign nodules, as well as the malignant nodules, were predominantly solid or solid-cystic with predominant solid component. Thus a predominantly solid component alone cannot be a useful criterion for the differentiation of malignant from benign nodules.

If the nodular margins couldn't be delineated in half or more than half of its circumference then it was considered ill-defined in our study. Out of proven 42 nodules, 34 showed ill-defined or poorly defined margins and at the same time, well-defined margins were appreciated in 97 proven benign nodules. Thus the ultrasound sensitivity and specificity for ill defined margins for detecting malignancy in our study was 81% and 90% respectively with a high negative predictive value of 92% and high diagnostic accuracy of 87%. In a studies by Solbiati L[13] et al in 2001 and Papini[14] et al in 2002, findings suggested that blurred or ill-defined nodular margins favour a diagnosis of malignancy.

In our study, partial or complete halo surrounding a thyroid nodule was present in 91 out of 108 (84.2%) benign nodules. 31 (73.8%) of overall malignant nodules show complete absence of peripheral halo. The sensitivity, specificity and PPV for absent halo in malignant nodules was 13%, 72% and 12.5% respectively, thus making it an insignificant marker of malignancy in a thyroid nodule. The studies by Propper RA[15] et al in 1980 and by Solbiati L[16] et al in 1985, suggested that the peripheral sonolucent halo that completely or incompletely surrounds a thyroid nodule may be present in 60% to 80% of benign nodules and 15% of thyroid cancers. Chan BK [17] et al in 2003 reported that 10-25% of papillary thyroid carcinomas have either a complete or an incomplete halo. Our study ascertained the ultrasound sensitivity

and specificity of 83% and 84% respectively for this feature. The negative predictive value (92.86%) was recorded to be very high for this feature.

In our study, the taller than wide shape on transverse scan was seen in 04 out of 108 proven benign (3.7%) and 35 of 42 proven malignant nodules (83.4%). This shows that it is a good predictor of malignancy in a thyroid nodule. Previous studies by Kim EK[18] et al in 2002 and Moon WJ[19] et al in 2008 suggested that taller than wide shape is specific for differentiating malignant from benign nodules because malignant neoplasm tend to grow across normal tissue planes, whereas benign nodules grow parallel to normal tissue planes. We recorded the sonological specificity of 96.3% for this feature. The overall diagnostic accuracy (92.67%) for this criteria was highest amongst all sonological features studied. The negative predictive value was recorded to be 93.69%.

In our study, presence of calcifications within nodules was taken as one of the parameters to differentiate malignant from benign nodules. Out of 108 benign nodules, 37 (34.2%) showed intralesional calcifications. In rest of the 71 benign nodules, calcification was absent. 18 (42.8%) of 42 malignant nodules showed presence of calcifications within the nodules. In results of a previous study conducted by Frates[12] Et al in 2005, the presence of a microcalcifications in a predominantly solid nodule increased the risk of cancer by three times as compared with predominantly solid nodules without any calcifications. Our study revealed a negative predictive value of 74.74% for this feature in predicting malignancy. The sensitivity (42.86%) and specificity (65.74) was low.

In our study, cervical lymphadenopathy nodes was seen with 14 of 42 malignant (33.34) malignant nodules. None of the benign nodule showed cervical lymphadenopathy. 11 were found in patients with papillary carcinoma and 3 in patients with medullary carcinoma. In sonography, the enlarged metastatic lymph nodes were round and hypoechoic with loss of central fatty echogenic hilum. Microcalcifications were seen in the enlarged lymph nodes of one patient of papillary carcinoma. Previous study by Yuen and Ahuja AT[11] suggested that the cervical lymph node metastasis occurs most commonly with papillary carcinoma at presentation in 30-40% of patients. Frates MC [12] Et al concluded from their studies that USG feature of lymph node appearing rounded, enlarged, ill-defined, poorly marginated, heterogeneously hypoechoic appearance with loss of fatty hilum with presence of calcifications and central vascularity suggested possibly a metastatic etiology. This features showed a specificity and positive predictive value of 100% in our study with a diagnostic accuracy of 81.33%.

Color doppler provides a display of the blood flow in relation to the thyroid nodules. The presence and absence of color flow and various patterns of color flow like peripheral or perinodular, central or intranodular and mixed or peripheral-central were evaluated. 32 (76.1) of 42 malignant nodules showed intense intranodular or central color flow. However only 9 (8.3%) benign nodules showed central color flow. Whereas peripheral or perinodular color flow was seen in only 3 malignant nodules as compared to 61 benign nodules. Thus we found that most of the benign nodules showed perinodular color flow and intense central or intranodular color flow was seen in majority of malignant thyroid nodules. In this study, the sensitivity and specificity for this feature was 82.05% and 89.22% with a high negative predictive value (92.86%) for central color flow in malignant thyroid nodular disease. The diagnostic accuracy (87.23%) was also determined to be very high for this feature.

Past studies by Pappini E[14] Et all in 2002 and Chammas MC[20] et all in 2005, demonstrated that 80% to 95% of hyperplastic goitres and adenomatous nodules display peripheral vascularity, whereas 70% to 90% of thyroid malignancies display internal or central vascularity, with or without a peripheral component.

The overall sonological specificity for predicting the malignancy in nodular thyroid disease was reported to be 88.89%, however the sensitivity was relatively less (47.26%). The overall diagnostic accuracy by ultrasound was recorded to be 77.33% which was fairly acceptable.

## Conclusion

Although there is some overlap between the USG appearance of benign and malignant nodules, features like markedly reduced echogenecity, taller than wide shape, irregular-poorly defined margins, microcalcifications, presence of cervical lymphadenopathy and intranodular vascularity were more suggestive of a malignant etiology. The high sensitivity and specificity of US in detecting benign and malignant nodules coupled with USG assisted FNAC has lead to a profound change in the management of thyroid nodules, avoiding unwarranted surgeries in patients with benign diseases. It helps in avoiding invasive and costly investigations in most patients with benign disease without missing the minority of patients who have thyroid malignancy.

## Declarations

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**Ethics statement:** Ethical approval was taken from institutional ethics committee before conducting this study.

**Patient consent:** Consent was taken from the patients to use medical data for research and publication purpose.

**Author contributions:** All authors were actively involved in managing this patient and have substantially contributed in designing, drafting and editing the manuscript.

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