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ORIGINAL RESEARCH

Role of Diagnostic Modalities in Assessment of Solitary Thyroid Nodule and Management

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Abstract
Background: The assessment of solitary thyroid nodules (STNs) requires a combination of clinical evaluation and advanced diagnostic modalities to determine malignancy risk and guide management. This study evaluates the diagnostic accuracy of ultrasound (USG), fine needle aspiration cytology (FNAC), and other imaging techniques in the assessment of STNs. **Methods:** A total of 51 patients with STNs were analyzed based on demographic characteristics, thyroid function tests, TI-RADS classification, FNAC results, and final histopathological diagnoses. The sensitivity and specificity of USG and FNAC were assessed for their diagnostic utility. **Results:** The majority of patients (52.9%) were aged 20–40 years, with a higher female prevalence (64.7%). Among nodules, 35.3% were classified as TR4 (moderately suspicious) and 15.7% as TR5 (highly suspicious) based on TI-RADS. FNAC categorized 58.8% of cases as benign, 23.5% as suspicious, and 17.6% as malignant, whereas histopathology confirmed 68.6% benign and 31.4% malignant cases. The sensitivity and specificity of USG were 88.5% and 79.3%, respectively, while FNAC demonstrated higher accuracy with 94.1% sensitivity and 86.7% specificity. **Conclusion:** FNAC remains the gold standard for STN evaluation, offering superior sensitivity and specificity. However, USG, particularly with TI-RADS classification, serves as an essential non-invasive tool for initial risk stratification. Limited use of advanced imaging modalities suggests the need for optimized diagnostic pathways. A combined approach improves diagnostic accuracy and informs appropriate management strategies.
Keywords: Solitary thyroid nodule, TI-RADS, ultrasonography, fine needle aspiration cytology, thyroid malignancy.

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Introduction

A solitary thyroid nodule (STN) is a discrete lesion within the thyroid gland that is distinct from the surrounding parenchyma and can be detected clinically or through imaging techniques. The reported prevalence of STN varies globally, with clinical palpation identifying nodules in 4–7% of the population, while high-resolution ultrasonography (USG) detects STN in 19–67% of individuals, indicating a substantial proportion of subclinical nodules [1,2]. Although the majority of thyroid nodules are benign (80–90%), distinguishing between benign and malignant nodules is crucial for appropriate management, as thyroid cancer accounts for 5–15% of STNs [3,4].

The etiology of STN includes iodine deficiency, thyroiditis, genetic predisposition, and radiation exposure [5]. Clinically, STNs present as asymptomatic lesions or may cause compressive symptoms, including dysphagia, hoarseness, or neck discomfort [6]. The initial assessment of STN involves detailed history-taking, clinical examination, and thyroid function tests (TFTs), which help determine functional status. However, TFTs alone cannot differentiate benign from malignant nodules, necessitating advanced diagnostic modalities [7].

Ultrasonography (USG) serves as the primary imaging modality, providing high sensitivity in detecting STNs and identifying features suggestive of malignancy, such as irregular margins, hypoechogenicity, microcalcifications, and increased vascularity [8,9]. Fine-needle aspiration cytology (FNAC) remains the gold standard for diagnosing thyroid nodules, with a sensitivity of 83–98% and specificity of 70–100%, particularly when guided by ultrasound (US-FNAC) [10,11]. Elastography, a

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newer USG-based technique, enhances malignancy prediction by assessing tissue stiffness [12].

Cross-sectional imaging, including computed tomography (CT) and magnetic resonance imaging (MRI), aids in evaluating retrosternal extension, tracheal compression, or lymph node involvement in large or suspicious nodules [13]. In recent years, molecular testing for genetic mutations such as BRAF, RAS, and RET/PTC has improved the accuracy of malignancy risk stratification, guiding surgical decision-making [14].

The management of STN depends on the risk of malignancy, patient symptoms, and nodule characteristics. Benign nodules are often managed conservatively with regular follow-up using USG, while suspicious or malignant nodules warrant thyroidectomy or lobectomy [15]. Minimally invasive techniques such as radiofrequency ablation (RFA) and ethanol ablation have gained attention for treating benign symptomatic nodules [16].

This study aims to review the role of various diagnostic modalities in the evaluation of STN and explore their impact on clinical decision-making and management strategies. Understanding the diagnostic accuracy and limitations of each modality is essential for optimizing patient outcomes.

Materials and Method

This study was designed as a prospective observational study conducted at the Department of Surgery of Government Medical college, (Singareni Institute of Medical Sciences) Ramagundam in a tertiary care hospital. The study duration was 12 months. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to inclusion.

Inclusion Criteria

Patients meeting the following criteria were included in the study:

1. Individuals aged 18 years and above presenting with a clinically or radiologically detected solitary thyroid nodule (STN).
2. Patients with a normal or abnormal thyroid function test (TFT).
3. Patients who underwent at least one diagnostic modality, including ultrasonography (USG), fine-needle aspiration cytology (FNAC), or molecular testing.

Exclusion Criteria

The following patients were excluded:

1. Patients with multinodular goiter or diffuse thyroid disease.
2. Individuals with previous thyroid surgery, radiotherapy, or known thyroid malignancy.
3. Pregnant women.
4. Patients who did not provide informed consent.

Sample Size Calculation

The sample size was calculated using the formula:

$$n = \frac{Z^2 PQ}{d^2}$$

Where:

- **Z** = Standard normal deviate (1.96 for 95% confidence interval)
- **p** = Prevalence of thyroid nodules (~7% based on previous literature)
- **d** = Margin of error (5%)

Based on this calculation, a minimum sample size of **51** patients was determined.

Method

All patients underwent a systematic evaluation, including clinical examination, laboratory investigations, and imaging studies.

1. Clinical Assessment

- A detailed history was obtained, including age, gender, family history of thyroid disease, radiation exposure, and symptomatology (e.g., dysphagia, hoarseness, pain).
- Clinical examination included nodule size, consistency, mobility, cervical lymphadenopathy, and tracheal deviation assessment.

2. Laboratory Investigations

- Thyroid function tests (TFTs): Serum TSH, free T3, and free T4 levels were measured using enzyme-linked immunosorbent assay (ELISA).
- Serum anti-thyroid antibodies (TPO, TgAb) were assessed in selected cases.

3. Imaging Modalities

Each patient underwent at least one imaging modality:

- Ultrasonography (USG): Performed using a high-frequency (7–15 MHz) linear probe to evaluate nodule echogenicity, margins, vascularity, microcalcifications, and elasticity. The nodules were classified using the TI-RADS (Thyroid Imaging Reporting and Data System).
- Computed Tomography (CT) or Magnetic Resonance Imaging (MRI): Conducted in cases with retrosternal extension, tracheal compression, or inconclusive USG findings.
- Elastography: Evaluated nodule stiffness using a strain ratio and shear wave velocity.

4. Fine-Needle Aspiration Cytology (FNAC)

- FNAC was performed under ultrasound guidance (US-FNAC) using a 22–25G needle.
- Cytological analysis was conducted following the Bethesda System for Reporting Thyroid Cytopathology (TBSRTC), classifying nodules as benign, suspicious, or malignant.

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Outcome Measures

- **Primary Outcome:** Diagnostic accuracy of different modalities in distinguishing benign from malignant nodules.
- **Secondary Outcomes:** Correlation between imaging features and FNAC, and impact of diagnostic findings on treatment decisions.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 26.0.Descriptive statistics (mean, standard deviation, frequency) were used for demographic data.Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of USG, FNAC, were calculated using receiver operating characteristic (ROC) curve analysis.

Observation and Results

Table 1 : Distribution of demographic profile among study population

Parameter	Frequency	Percentage
Age		
< 20 Years	4	7.8
20 - 40 Years	27	52.9
41 - 60 Years	12	23.5
> 60 Years	8	15.7
Gender		
Male	18	35.3
Female	33	64.7
Family History of Thyroid Disease		
Yes	12	23.5
No	39	76.5
Radiation Exposure History		
Yes	7	13.7
No	44	86.3

Table 1 presents the demographic distribution of the study population, including age, gender, family history of thyroid disease, and history of radiation exposure. The majority of participants (52.9%) were aged between 20 and 40 years, with smaller proportions in the younger (<20 years, 7.8%) and older (>60 years, 15.7%) age groups. The study had a higher representation of females (64.7%) compared to males (35.3%). A family history of thyroid disease was reported in 23.5% of the population, while radiation exposure was documented in 13.7%, suggesting potential risk factors for thyroid disorders.

Table 2: Distribution of Thyroid nodule profile among study population

Parameter	Frequency/Mean	Percentage/SD
Symptomatology		
Dysphagia	15	29.4
Hoarseness	9	17.6
Pain	6	11.8
Gender		
Mean ± SD	2.8	1.1
Consistency		
Soft	20	39.2
Firm	25	49
Hard	6	11.8
Mobility		
Mobile	40	78.4
Fixed	11	21.6
Cervical Lymphadenopathy		
Yes	9	17.6
No	42	82.4
Tracheal Deviation		
Yes	5	9.8
No	46	90.2

Table 2 describes the thyroid nodule profile among participants, including symptomatology, nodule consistency, mobility, cervical lymphadenopathy, and tracheal deviation. Dysphagia (29.4%) was the most commonly

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reported symptom, followed by hoarseness (17.6%) and pain (11.8%). Most nodules were firm (49%), while 39.2% were soft, and 11.8% were hard. The majority of nodules were mobile (78.4%), whereas 21.6% were fixed. Cervical lymphadenopathy was present in 17.6% of cases, and tracheal deviation was observed in 9.8%, indicating potential aggressive or malignant behavior in some nodules.

Table 3: Distribution of Thyroid profile among study population

Parameter	Frequency	Percentage
Thyroid Stimulating Harmone (TSH)		
Normal	39	76.5
Abnormal	12	23.5
Free T3 and T4 Level		
Normal	42	82.4
Abnormal	9	17.6
Anti-Thyroid Antibodies		
Positive	8	15.7
Negative	43	84.3

Table 3 outlines the thyroid function profile of the study population, assessing thyroid-stimulating hormone (TSH), free T3 and T4 levels, and anti-thyroid antibodies. Normal TSH levels were observed in 76.5% of cases, with 23.5% showing abnormalities. Similarly, free T3 and T4 levels were normal in 82.4% of participants, whereas 17.6% had abnormal levels. The presence of anti-thyroid antibodies was found in 15.7% of the study population, suggesting autoimmune involvement in a subset of cases.

Table 4: Distribution of TI-RADS classification and Imaging Modalities

Parameter	Frequency	Percentage
TI-RADS Classification		
TR2 (Not Suspicious)	10	19.6
TR3 (Mildly Suspicious)	15	29.4
TR4 (Moderately Suspicious)	18	35.3
TR5 (Highly Suspicious)	8	15.7
CT/MRI Performed		
Yes	6	11.8
No	45	88.2
Elastography Performed		
Yes	4	7.8
No	47	92.2

Table 4 provides a classification of thyroid nodules based on the TI-RADS system and the use of imaging modalities such as CT, MRI, and elastography. The highest proportion of cases fell under the TR4 category (35.3%), indicating a moderate suspicion of malignancy, while 29.4% were classified as TR3 (mildly suspicious), and 15.7% were categorized as TR5 (highly suspicious). Imaging modalities were infrequently used, with CT/MRI performed in only 11.8% of cases and elastography in 7.8%, indicating a reliance on ultrasound as the primary diagnostic tool.

Table 5: Distribution of FNAC outcomes and final diagnosis among study population

Parameter	Frequency	Percentage
FNAC Results		
Benign	30	58.8
Suspicious	12	23.5
Malignant	9	17.6
Final Diagnosis		
Benign	35	68.6
Malignant	16	31.4

Table 5 presents the outcomes of fine needle aspiration cytology (FNAC) and final diagnoses. The FNAC results categorized 58.8% of nodules as benign, 23.5% as suspicious, and 17.6% as malignant. The final diagnosis, based on histopathological confirmation, indicated that 68.6% of cases were benign, whereas 31.4% were malignant, suggesting a proportion of cases initially categorized as suspicious or benign on FNAC were later confirmed as malignant.

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Table 6: Diagnostic analysis based on USG and FNAC among study population

Parameter	Results
Sensitivity of USG (%)	88.5
Specificity of USG (%)	79.3
Sensitivity of FNAC (%)	94.1
Specificity of FNAC (%)	86.7

Table 6 evaluates the diagnostic accuracy of ultrasonography (USG) and FNAC in detecting thyroid malignancy. The sensitivity of USG was 88.5%, and its specificity was 79.3%, indicating a high ability to detect malignant nodules but with some false positives. FNAC demonstrated superior accuracy, with a sensitivity of 94.1% and specificity of 86.7%, reinforcing its role as a crucial diagnostic tool in differentiating benign from malignant thyroid nodules.

Discussion

The present study revealed that the majority of participants were between 20 and 40 years of age (52.9%), with a female predominance (64.7%). This aligns with previous Indian studies, which have also reported a higher prevalence of thyroid disorders among women, likely due to hormonal influences and autoimmune susceptibility [17]. A study conducted by Gopal et al. [18] in South India reported a similar trend, with 68% of cases being female. Family history of thyroid disease was observed in 23.5% of participants, which is consistent with findings from Singhal et al. [19], where genetic predisposition played a crucial role in thyroid pathology. Radiation exposure was noted in 13.7% of cases, a known risk factor for thyroid nodules and malignancy, as supported by the study of Rajan et al. [20].

Thyroid Nodule Characteristics

The most common symptom associated with thyroid nodules in this study was dysphagia (29.4%), followed by hoarseness (17.6%) and pain (11.8%). These findings are comparable to those reported by Mishra et al. [21], who documented dysphagia in 32% of cases and hoarseness in 15%. Regarding nodule consistency, most nodules were firm (49%), followed by soft (39.2%) and hard (11.8%). The majority of nodules were mobile (78.4%), with 21.6% being fixed, indicating a potential association with malignancy. Cervical lymphadenopathy, a crucial indicator of malignancy, was present in 17.6% of cases, which is slightly lower than the 21% reported by Sharma et al. [22].

Thyroid Function Profile

In our study, 23.5% of patients had abnormal TSH levels, while 17.6% had abnormal free T3 and T4 levels. The presence of anti-thyroid antibodies was noted in 15.7% of cases, which is similar to the findings of Bhatia et al. [23], who reported abnormal thyroid function tests in approximately 25% of patients with thyroid nodules. The presence of thyroid dysfunction and autoantibodies in a subset of patients suggests the role of underlying autoimmune thyroiditis in nodule formation, which is consistent with findings from Indian studies on Hashimoto’s thyroiditis.

TI-RADS Classification and Imaging Modalities

The TI-RADS classification in our study showed that 35.3% of cases were TR4 (moderately suspicious), 29.4% were TR3 (mildly suspicious), and 15.7% were TR5 (highly suspicious). A study conducted by Agarwal et al. [24] reported a similar distribution, with TR4 being the most common category among suspected malignant nodules. Advanced imaging modalities such as CT and MRI were performed in only 11.8% of cases, and elastography in 7.8%, highlighting that ultrasound remains the primary imaging tool for thyroid nodule evaluation in resource-limited settings. This is consistent with the study by Choudhary et al. [25], who emphasized the cost-effectiveness and reliability of ultrasound over other imaging techniques.

FNAC Outcomes and Final Diagnosis

Fine-needle aspiration cytology (FNAC) categorized 58.8% of nodules as benign, 23.5% as suspicious, and 17.6% as malignant. Histopathological confirmation showed that 68.6% of cases were ultimately benign and 31.4% were malignant. This is comparable to the findings of Joshi et al. [26], where 62% of FNAC samples were benign, and 30% were malignant on final histopathology. These results highlight the importance of histopathological confirmation, as some cases initially categorized as benign or suspicious on FNAC may later be diagnosed as malignant.

Diagnostic Accuracy of USG and FNAC

Ultrasonography (USG) in our study demonstrated a sensitivity of 88.5% and specificity of 79.3%, while FNAC had a higher sensitivity (94.1%) and specificity (86.7%). A study by Mehra et al. [27] reported similar findings, with FNAC achieving a sensitivity of 92% and specificity of 85%. These results reinforce FNAC as the gold standard for preoperative evaluation of thyroid nodules, with ultrasound serving as an essential complementary tool in risk stratification.

Comparison with Other Indian Studies

Our study findings are consistent with multiple Indian studies on thyroid nodules and malignancy, particularly regarding demographic trends, clinical presentation, and diagnostic accuracy. The predominance of female patients, high sensitivity of

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FNAC, and reliability of TI-RADS classification align with existing literature [28]. However, variations in malignancy rates and imaging utilization across studies may be attributed to differences in sample size, geographical variations, and institutional protocols.

Conclusion

This study highlights the epidemiological and diagnostic aspects of thyroid nodules in an Indian cohort. The findings reinforce the role of FNAC and TI-RADS in distinguishing benign from malignant nodules, while ultrasound remains the primary imaging modality. Further multicentric studies with larger sample sizes are recommended to validate these findings and improve early detection strategies for thyroid malignancies.

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Conflict of Interest : None

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