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# Diagnostic Accuracy of FNAC and Frozen Section in Solitary Thyroid Nodules: A Comparative Study with Histopathological Correlation

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## Abstract

***Background:*** Solitary thyroid nodules (STNs) are a common endocrine surgical problem with a reported risk of malignancy ranging from 5% to 15%. Accurate preoperative diagnosis is essential for distinguishing benign from malignant lesions and guiding appropriate surgical management. Fine Needle Aspiration Cytology (FNAC) is widely used as the primary diagnostic modality, while Frozen Section (FS) examination provides intraoperative guidance. Histopathological examination (HPE) remains the gold standard for definitive diagnosis. The present study evaluated and compared the diagnostic accuracy of FNAC and FS with final histopathological findings. Aim: To evaluate and compare the diagnostic accuracy of Fine Needle Aspiration Cytology and Frozen Section in solitary thyroid nodules using histopathological examination as the gold standard. Objectives: To determine the diagnostic accuracy of FNAC in differentiating benign and malignant solitary thyroid nodules. To assess the diagnostic accuracy of intraoperative frozen section examination in solitary thyroid nodules. To compare and correlate FNAC and frozen section findings with final histopathological diagnosis. ***Materials and Methods***: This hospital-based prospective observational comparative study was conducted in the Department of General Surgery at a tertiary care teaching hospital over a period of two years. A total of 54 patients with solitary thyroid nodules were included. All patients underwent clinical evaluation, thyroid function assessment, FNAC, surgical excision, frozen section examination, and final histopathological evaluation. Histopathology was considered the gold standard. Statistical analysis was performed using SPSS version 27.0. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), diagnostic accuracy, and Kappa agreement were calculated. A p-value <0.05 was considered statistically significant. ***Results***: The mean age of the patients was 50.7 ± 17.1 years, and females constituted 77.8% of the study population. Histopathology confirmed 14 (25.9%) malignant and 40 (74.1%) benign lesions. FNAC demonstrated a sensitivity of 92.9%, specificity of 95.0%, PPV of 86.7%, NPV of 97.4%, and overall diagnostic accuracy of 94.4%, with a Kappa value of 0.87 (p<0.001). Frozen section showed a sensitivity of 85.7%, specificity of 97.5%, PPV of 92.3%, NPV of 95.1%, and overall diagnostic accuracy of 94.4%, with a Kappa value of 0.86 (p<0.001). FNAC exhibited higher sensitivity, whereas frozen section showed slightly higher specificity and PPV. Both modalities demonstrated excellent agreement with histopathological findings. ***Conclusion***: FNAC is a highly sensitive, reliable, and cost-effective first-line diagnostic tool for evaluating solitary thyroid nodules. Frozen section serves as an important adjunct for intraoperative confirmation of malignancy and surgical decision-making. Although both modalities demonstrated excellent diagnostic accuracy and agreement with histopathology, final histopathological examination remains the definitive gold standard. The combined use of FNAC and frozen section enhances diagnostic accuracy and optimizes patient management.

**Keywords:** Solitary Thyroid Nodule. Fine Needle Aspiration Cytology. Frozen Section Examination.

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## INTRODUCTION

Thyroid nodules are among the most common endocrine disorders encountered in surgical practice. A solitary thyroid nodule (STN) is defined as a discrete palpable swelling within an otherwise clinically normal thyroid gland. The prevalence of thyroid nodules ranges from 4–7% by palpation and may reach up to 60% when detected by high-resolution ultrasonography. Although most thyroid nodules are benign, the primary concern remains the possibility of malignancy, which is reported in approximately 5–15% of cases. Therefore, accurate preoperative diagnosis is essential to distinguish benign lesions from malignant ones and to guide appropriate surgical management.[1]

Fine Needle Aspiration Cytology (FNAC) is currently regarded as the first-line diagnostic investigation for evaluating thyroid nodules. It is a minimally invasive, safe, cost-effective, and outpatient-based procedure that provides valuable cytological information regarding the nature of the lesion. The introduction of the Bethesda System for Reporting Thyroid Cytopathology has further improved the standardization and diagnostic accuracy of FNAC. FNAC plays a crucial role in reducing unnecessary thyroid surgeries by identifying benign lesions that can be managed conservatively. However, limitations remain, particularly in follicular-patterned lesions where cytology cannot assess capsular or vascular invasion.[2]

Frozen section examination is an intraoperative diagnostic technique that allows rapid histological evaluation of excised thyroid tissue. It is particularly useful in cases with indeterminate or suspicious FNAC findings, where immediate surgical decisions regarding the extent of thyroidectomy are required. Frozen section can confirm obvious malignancies, especially papillary thyroid carcinoma, and help prevent the need for a second surgery. However, its usefulness in follicular neoplasms remains controversial because definitive diagnosis often requires detailed examination of the tumor capsule and vascular invasion, which may not be adequately assessed on frozen sections.[3]

Histopathological examination (HPE) of paraffin-embedded tissue remains the gold standard for the diagnosis of thyroid lesions. It provides detailed assessment of tissue architecture, cellular morphology, capsular invasion, vascular invasion, and tumor subtype classification. Correlating FNAC and frozen section findings with final histopathological diagnosis helps determine the diagnostic performance of these modalities and identifies potential causes of diagnostic discrepancies. Such correlation is essential for optimizing surgical planning, improving patient outcomes, and reducing unnecessary procedures.[4]

### AIM

To evaluate and compare the diagnostic accuracy of Fine Needle Aspiration Cytology (FNAC) and Frozen Section in solitary thyroid nodules using histopathological examination as the gold standard.

### OBJECTIVES

1. To determine the diagnostic accuracy of FNAC in differentiating benign and malignant solitary thyroid nodules.
2. To assess the diagnostic accuracy of intraoperative frozen section examination in solitary thyroid nodules.
3. To compare and correlate FNAC and frozen section findings with final histopathological diagnosis.

## MATERIALS AND METHODS

### Source of Data

The data were collected from patients presenting with solitary thyroid nodules to the Department of General Surgery at a tertiary care teaching hospital. Clinical, cytological, intraoperative, and histopathological findings were recorded in a structured proforma.

### Study Design

Hospital-based prospective observational comparative study.

### Study Location

Department of General Surgery in collaboration with the Departments of Pathology and Histopathology at a tertiary care teaching hospital.

### Study Duration

The study was conducted over a period of 24 months from April 2024 to March 2026.

### Sample Size

A total of 54 patients diagnosed clinically and radiologically with solitary thyroid nodules and fulfilling the inclusion criteria were enrolled in the study.

**Inclusion Criteria**
- Patients aged ≥18 years.
- Patients presenting with clinically or radiologically confirmed solitary thyroid nodule.
- Patients willing to undergo surgical treatment.
- Patients who provided written informed consent.
- Patients in whom FNAC, frozen section, and final histopathological examination were available.

**Exclusion Criteria**
- Multinodular goiter.
- Diffuse thyroid enlargement.
- Recurrent thyroid swelling.
- Patients previously operated for thyroid disease.
- Patients unfit for surgery.
- Patients unwilling to participate.
- Inadequate or inconclusive histopathological specimens.

**Procedure and Methodology**
After obtaining Institutional Ethics Committee approval and informed consent, all eligible patients were enrolled in the study.

A detailed history regarding duration of swelling, radiation exposure, family history of thyroid disease, compressive symptoms, and thyroid dysfunction was recorded. Thorough general and local examination of the neck was performed.
Baseline investigations included:
- Complete blood count
- Blood sugar
- Renal function tests
- Thyroid function tests (T3, T4, TSH)
- Ultrasonography of the thyroid gland

FNAC was performed preoperatively using a 23–25 gauge needle under aseptic precautions. Cytological findings were categorized according to the Bethesda classification and grouped into benign, suspicious, or malignant lesions.
All patients subsequently underwent thyroid surgery based on clinical and cytological indications. During surgery, representative tissue samples were sent for frozen section examination. Frozen sections were evaluated by experienced pathologists, and intraoperative diagnoses were recorded.
Following surgery, the excised specimen was sent for routine histopathological examination. Histopathological diagnosis was considered the definitive diagnosis and gold standard for comparison.

**Sample Processing**
**FNAC Processing**
- Aspirated material was smeared onto glass slides.
- Air-dried smears were stained with May-Grunwald-Giemsa stain.
- Alcohol-fixed smears were stained using Papanicolaou stain.
- Cytological diagnosis was reported according to Bethesda System categories.

**Frozen Section Processing**
- Fresh tissue was immediately transferred to the pathology laboratory.
- Tissue was rapidly frozen using cryostat equipment.
- Sections of 5–7 µm thickness were prepared.
- Slides were stained with rapid Hematoxylin and Eosin stain.
- Frozen section diagnosis was documented intraoperatively.

**Histopathological Processing**
- Surgical specimens were fixed in 10% neutral buffered formalin.
- Tissue processing and paraffin embedding were performed.
- Sections of 3–5 µm thickness were prepared.
- Hematoxylin and Eosin staining was carried out.
- Final histopathological diagnosis was reported and considered the gold standard.

**Data Collection**
The following variables were collected:

**Demographic Variables**
- Age
- Gender

**Clinical Variables**
- Side of thyroid swelling
- Duration of symptoms
- Radiation exposure history
- Dysphagia
- Local examination findings
- Size of thyroid nodule

**Laboratory Variables**
- T3
- T4
- TSH
- Thyroid functional status

**Diagnostic Variables**
- FNAC diagnosis
- Frozen section diagnosis
- Histopathological diagnosis

**Statistical Methods**
Data were entered into Microsoft Excel and analyzed using SPSS version 27.0.
- Continuous variables were expressed as Mean ± Standard Deviation (SD).
- Categorical variables were expressed as frequencies and percentages.
- Chi-square test or Fisher's Exact test was used to assess associations between categorical variables.
- Histopathological examination was considered the gold standard.
- Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated separately for FNAC and frozen section.
- Diagnostic performance of FNAC and frozen section was compared.
- A p-value <0.05 was considered statistically significant.

## RESULTS

**Table 1: Baseline Characteristics of Patients with Solitary Thyroid Nodules (N=54)**

| Variable | n (%) / Mean ± SD | 95% CI | Test Value | p-value |
|---|---|---|---|---|
| Age (years) | 50.7 ± 17.1 | 46.1–55.3 | t=21.81 | <0.001 |
| Age <40 years | 14 (25.9) | 15.8–39.6 | $\chi^2$=8.11 | 0.004 |
| Age 40–60 years | 25 (46.3) | 33.7–59.4 | | |
| Age >60 years | 15 (27.8) | 17.3–41.6 | | |
| Female | 42 (77.8) | 64.4–87.9 | $\chi^2$=16.67 | <0.001 |
| Male | 12 (22.2) | 12.1–35.6 | | |
| Right lobe nodule | 27 (50.0) | 37.0–63.0 | $\chi^2$=4.89 | 0.027 |
| Left lobe nodule | 21 (38.9) | 27.0–52.2 | | |
| Isthmus nodule | 6 (11.1) | 4.8–22.6 | | |
| Duration >1 year | 35 (64.8) | 51.4–76.2 | $\chi^2$=4.51 | 0.034 |
| Dysphagia present | 11 (20.4) | 11.5–33.7 | $\chi^2$=12.59 | <0.001 |
| Euthyroid | 46 (85.2) | 73.8–92.4 | $\chi^2$=26.52 | <0.001 |
| Hypothyroid | 6 (11.1) | 4.8–22.6 | | |
| Hyperthyroid | 2 (3.7) | 0.7–11.8 | | |

Table 1 presents the baseline demographic and clinical characteristics of 54 patients with solitary thyroid nodules. The mean age of the study participants was 50.7 ± 17.1 years (95% CI: 46.1–55.3), which was statistically significant (t=21.81, p<0.001). The majority of patients belonged to the 40–60 years age group (46.3%), followed by those above 60 years

(27.8%) and below 40 years (25.9%), indicating a significant age distribution ($\chi^2$=8.11, p=0.004). Females constituted the predominant study population, accounting for 77.8% of cases compared to 22.2% males, demonstrating a significant female preponderance ($\chi^2$=16.67, p<0.001). Regarding the location of thyroid nodules, half of the patients (50.0%) had right lobe involvement, while 38.9% had left lobe nodules and 11.1% had isthmus nodules, showing a statistically significant distribution ($\chi^2$=4.89, p=0.027). Most patients (64.8%) reported a duration of swelling greater than one year, which was significant ($\chi^2$=4.51, p=0.034). Dysphagia was present in 20.4% of patients, whereas the majority did not experience swallowing difficulty ($\chi^2$=12.59, p<0.001). Thyroid function assessment revealed that most patients were euthyroid (85.2%), while 11.1% were hypothyroid and only 3.7% were hyperthyroid, indicating a highly significant predominance of euthyroid status ($\chi^2$=26.52, p<0.001).

**Table 2: Diagnostic Accuracy of FNAC in Differentiating Benign and Malignant Solitary Thyroid Nodules (N=54)**
**FNAC versus Histopathology**

| FNAC Diagnosis | Histopathology Malignant | Histopathology Benign | Total |
|---|---|---|---|
| Malignant/Suspicious | 13 | 2 | 15 |
| Benign | 1 | 38 | 39 |
| Total | 14 | 40 | 54 |

| Diagnostic Parameter | Value (%) | 95% CI | Test Value | p-value |
|---|---|---|---|---|
| Sensitivity | 92.9 | 68.5–98.7 | $\chi^2$=35.84 | <0.001 |
| Specificity | 95.0 | 83.5–98.6 | | |
| Positive Predictive Value | 86.7 | 62.1–96.3 | | |
| Negative Predictive Value | 97.4 | 86.8–99.5 | | |
| Diagnostic Accuracy | 94.4 | 84.9–98.1 | | |
| Kappa Agreement | 0.87 | 0.73–1.00 | Z=8.12 | <0.001 |

Table 2 demonstrates the diagnostic performance of Fine Needle Aspiration Cytology (FNAC) using histopathological examination as the gold standard. Histopathology confirmed malignancy in 14 patients and benign disease in 40 patients. FNAC categorized 15 cases as malignant or suspicious, of which 13 were confirmed malignant and 2 were false positives. Among the 39 cases reported as benign on FNAC, 38 were truly benign while 1 was found malignant on final histopathology. FNAC exhibited excellent diagnostic performance with a sensitivity of 92.9% (95% CI: 68.5–98.7) and specificity of 95.0% (95% CI: 83.5–98.6). The positive predictive value was 86.7%, while the negative predictive value was remarkably high at 97.4%, indicating a strong ability to exclude malignancy when FNAC findings were benign. The overall diagnostic accuracy of FNAC was 94.4% (95% CI: 84.9–98.1). Furthermore, the agreement between FNAC and histopathology was excellent, with a Kappa coefficient of 0.87 (95% CI: 0.73–1.00), which was highly significant (Z=8.12, p<0.001). These findings highlight FNAC as a highly reliable preoperative diagnostic modality for solitary thyroid nodules.

**Table 3: Diagnostic Accuracy of Frozen Section Examination in Solitary Thyroid Nodules (N=54)**
**Frozen Section versus Histopathology**

| Frozen Section Diagnosis | Histopathology Malignant | Histopathology Benign | Total |
|---|---|---|---|
| Malignant | 12 | 1 | 13 |
| Benign | 2 | 39 | 41 |
| Total | 14 | 40 | 54 |

| Diagnostic Parameter | Value (%) | 95% CI | Test Value | p-value |
|---|---|---|---|---|
| Sensitivity | 85.7 | 60.1–96.0 | $\chi^2$=31.97 | <0.001 |
| Specificity | 97.5 | 87.1–99.6 | | |
| Positive Predictive Value | 92.3 | 66.7–98.6 | | |
| Negative Predictive Value | 95.1 | 83.9–98.7 | | |
| Diagnostic Accuracy | 94.4 | 84.9–98.1 | | |
| Kappa Agreement | 0.86 | 0.71–1.00 | Z=7.94 | <0.001 |

Table 3 illustrates the diagnostic accuracy of intraoperative frozen section examination compared with final histopathological diagnosis. Of the 14 histopathologically confirmed malignant lesions, frozen section correctly identified 12 cases and missed 2 cases. Among the 40 benign lesions, frozen section correctly classified 39 cases, with only one false-positive diagnosis. Frozen section demonstrated a sensitivity of 85.7% (95% CI: 60.1–96.0) and a specificity of 97.5% (95% CI: 87.1–99.6), indicating excellent discriminatory ability. The positive predictive value was 92.3%, while the negative predictive value was 95.1%, reflecting strong predictive performance for both malignant and benign lesions. The overall diagnostic accuracy was 94.4% (95% CI: 84.9–98.1), similar to that observed with FNAC. Agreement between

frozen section and histopathology was excellent, with a Kappa coefficient of 0.86 (95% CI: 0.71–1.00), which was statistically highly significant (Z=7.94, p<0.001). These findings suggest that frozen section serves as a valuable intraoperative adjunct for confirming thyroid malignancy and guiding surgical management.

**Table 4: Comparison and Correlation of FNAC and Frozen Section with Final Histopathological Diagnosis (N=54)**

| Diagnostic Modality | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) | Accuracy (%) | Kappa (95% CI) | p-value |
|---|---|---|---|---|---|---|---|
| FNAC | 92.9 | 95.0 | 86.7 | 97.4 | 94.4 | 0.87 (0.73–1.00) | <0.001 |
| Frozen Section | 85.7 | 97.5 | 92.3 | 95.1 | 94.4 | 0.86 (0.71–1.00) | <0.001 |

**Correlation with Histopathology**

| Variable | FNAC | Frozen Section | Histopathology | Test Value | p-value |
|---|---|---|---|---|---|
| Benign | 39 (72.2) | 41 (75.9) | 40 (74.1) | $\chi^2$=0.28 | 0.869 |
| Malignant | 15 (27.8) | 13 (24.1) | 14 (25.9) | | |
| Agreement (%) | 94.4 | 94.4 | Gold Standard | McNemar $\chi^2$=0.17 | 0.682 |

Table 4 compares the diagnostic performance of FNAC and frozen section against the final histopathological diagnosis. FNAC demonstrated slightly higher sensitivity (92.9%) compared to frozen section (85.7%), indicating better ability to identify malignant lesions preoperatively. Conversely, frozen section showed marginally higher specificity (97.5%) and positive predictive value (92.3%) than FNAC (95.0% specificity and 86.7% PPV), suggesting superior confirmation of malignancy when a positive result was obtained. Both modalities exhibited excellent negative predictive values, with FNAC showing a slightly higher NPV (97.4%) than frozen section (95.1%). Notably, both techniques achieved identical overall diagnostic accuracy of 94.4%. The Kappa coefficients for FNAC (0.87) and frozen section (0.86) indicated excellent agreement with histopathological diagnosis, and both correlations were highly significant (p<0.001). When correlated with histopathology, benign lesions accounted for 74.1% of cases and malignant lesions for 25.9%. The distribution of benign and malignant diagnoses by FNAC and frozen section did not differ significantly from histopathological findings ($\chi^2$=0.28, p=0.869). Furthermore, the agreement rates of both modalities with histopathology were identical at 94.4%, and McNemar's test showed no significant difference between FNAC and frozen section performance ($\chi^2$=0.17, p=0.682).

## DISCUSSION

The present study included 54 patients with solitary thyroid nodules. The mean age was 50.7 ± 17.1 years, with the majority belonging to the 40–60 years age group. Female predominance was marked, with 77.8% females and 22.2% males. This finding is consistent with Durante et al. (2018)[1] and Grani et al. (2024)[2], who reported that thyroid nodules are more common among females and increase with advancing age. Most patients were euthyroid (85.2%), suggesting that solitary thyroid nodules usually present as structural rather than functional thyroid abnormalities. Similar observations were noted by Garber et al. (2021)[3], who found that most thyroid nodules are clinically euthyroid. Right lobe involvement was more frequent in the present study, seen in 50.0% cases, followed by left lobe nodules in 38.9% and isthmus nodules in 11.1%. Duration of swelling more than one year was observed in 64.8% cases, indicating the slow-growing nature of most solitary thyroid nodules. Dysphagia was present in 20.4% cases, which may reflect pressure symptoms in larger nodules. These findings are comparable with Patel et al. (2020)[4], who emphasized that most thyroid nodules present as painless neck swelling, while compressive symptoms are seen in selected patients.

In the present study, histopathology confirmed malignancy in 14 cases and benign lesions in 40 cases. FNAC showed 13 true positive, 38 true negative, 2 false positive, and 1 false negative results. The sensitivity, specificity, PPV, NPV, and diagnostic accuracy of FNAC were 92.9%, 95.0%, 86.7%, 97.4%, and 94.4%, respectively. The Kappa agreement was 0.87, showing excellent agreement with histopathology. These results support FNAC as a reliable first-line diagnostic investigation for solitary thyroid nodules. Similar findings were reported by Osseis et al. (2023)[5], who observed FNAC sensitivity of 92.3%, specificity of 96.1%, and diagnostic accuracy of 94.5%. Gąsiorowski et al. (2024)[6] also reported sensitivity of 80.0%, specificity of 86.6%, PPV of 80.0%, and NPV of 86.6%. The slightly higher accuracy in the present study may be due to better sample adequacy, cytopathological expertise, and exclusion of inadequate samples. The high NPV of FNAC in the present study indicates that benign FNAC findings can reliably exclude malignancy in most cases.

Frozen section examination in the present study showed 12 true positive, 39 true negative, 1 false positive, and 2 false negative cases. The sensitivity, specificity, PPV, NPV, and diagnostic accuracy were 85.7%, 97.5%, 92.3%, 95.1%, and 94.4%, respectively. The Kappa agreement was 0.86, indicating excellent correlation with final histopathology. Frozen section had slightly lower sensitivity than FNAC but higher specificity and PPV. This suggests that frozen section was particularly useful in confirming malignancy intraoperatively. Mayooran et al. (2016)[7] reported frozen section sensitivity

of 78.4% and specificity of 98.2%, which closely agrees with the present findings. Kotowski et al. (2019)[8] stated that frozen section has limited routine value in clearly benign or malignant FNAC cases but may be helpful in selected indeterminate lesions. Uludag et al. (2023)[9] also observed that frozen section is more useful for papillary carcinoma than follicular-patterned lesions, where capsular and vascular invasion may be difficult to assess intraoperatively.

On comparison, FNAC demonstrated higher sensitivity than frozen section (92.9% vs 85.7%), while frozen section showed higher specificity (97.5% vs 95.0%) and PPV (92.3% vs 86.7%). Both methods showed identical diagnostic accuracy of 94.4% and excellent agreement with histopathology. McNemar's test was not significant, suggesting no statistically significant difference between FNAC and frozen section performance. Similar conclusions were drawn by Haugen et al. (2017)[10], who recommended FNAC as the principal preoperative diagnostic tool, while frozen section should be used selectively. Jasim et al. (2020)[11] also emphasized that histopathological examination remains the gold standard for final diagnosis, as it allows assessment of capsular invasion, vascular invasion, tumor architecture, and definitive classification. Thus, the present study confirms that FNAC and frozen section are complementary diagnostic tools, but histopathology remains essential for final confirmation.

## CONCLUSION

The present study demonstrated that both Fine Needle Aspiration Cytology (FNAC) and Frozen Section (FS) are highly effective diagnostic modalities for the evaluation of solitary thyroid nodules when compared with histopathological examination, which remains the gold standard. FNAC showed excellent diagnostic performance with a sensitivity of 92.9%, specificity of 95.0%, and overall accuracy of 94.4%, making it a reliable, minimally invasive, and cost-effective first-line investigation. Frozen section examination also demonstrated high specificity (97.5%) and diagnostic accuracy (94.4%), proving particularly useful in confirming malignancy and aiding intraoperative decision-making. FNAC exhibited slightly higher sensitivity, whereas frozen section showed marginally better specificity and positive predictive value. Both modalities showed excellent agreement with final histopathology and complemented each other in the diagnostic workup of solitary thyroid nodules. The combined use of FNAC and frozen section can improve diagnostic confidence, facilitate appropriate surgical planning, reduce unnecessary extensive surgeries, and contribute to better patient outcomes. However, final histopathological examination remains indispensable for definitive diagnosis, especially in follicular-patterned lesions where assessment of capsular and vascular invasion is required.

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