



ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE
DEPARTMENT OF OTORHINOLARYNGOLOGY-HEAD
AND NECK SURGERY

Concordance Between Fine-Needle Aspiration Cytology and
Histopathological Findings Among Thyroidectomy Patients at St.
Paul's Hospital Millennium Medical College, Addis Ababa,
Ethiopia

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March, 2026

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Abstract

Background: Fine-needle aspiration cytology (FNAC) serves as the primary preoperative diagnostic tool for thyroid nodules, but its performance varies across settings due to differences in operator expertise, Bethesda classification implementation, and local disease patterns. In Ethiopia, where goiter remains endemic, institution-specific FNAC accuracy data against histopathology are limited.

Objective: To evaluate the concordance between Fine-Needle Aspiration Cytology and postoperative histopathological findings among patients undergoing thyroidectomy at St. Paul's Hospital Millennium Medical College.

Methods: This retrospective diagnostic accuracy study included 400 consecutive patients who underwent thyroidectomy with available preoperative Fine-Needle Aspiration Cytology and postoperative histopathology results at St. Paul's Hospital Millennium Medical College from January 2022 to December 2025. Data on demographics, clinical characteristics, ultrasound findings, and cytology and histopathology results were collected using structured checklists from electronic medical records. Statistical analyses were performed using IBM SPSS Statistics version 27. Diagnostic performance metrics including sensitivity, specificity, positive predictive value, and negative predictive value were computed. Cohen's kappa coefficient was used to measure agreement between Fine-Needle Aspiration Cytology and histopathology. A p-value less than 0.05 was considered statistically significant.

Results: A total of 400 patients undergoing thyroidectomy were analyzed (median age 39 years, IQR: 30–50; 90.3% female). FNAC diagnoses predominantly comprised Bethesda Category II (benign; 68.0%), Category IV (follicular neoplasm; 11.3%), and Category VI (malignant; 11.0%). After excluding non-diagnostic Category I (3.8%) and indeterminate Categories III/IV (13.1%) cases, diagnostic accuracy analysis of 331 patients revealed FNAC sensitivity of 73.6%, specificity of 96.9%, positive predictive value of 87.0%, and negative predictive value of 93.0%. Substantial agreement was observed between FNAC and histopathology for malignancy detection (Cohen's kappa = 0.764).

Conclusion: FNAC shows good diagnostic accuracy in this Ethiopian cohort, particularly high specificity for ruling out malignancy, supporting its role as an effective triage tool.

Keywords: Diagnostic accuracy; Fine-needle aspiration cytology; Postoperative biopsy; Thyroid nodules; Bethesda system; Ethiopia

Abbreviations and Acronyms

ENT	Ear Nose Throat
FNAC	Fine-Needle Aspiration Cytology
IQR	Interquartile Range
ORL-HNS	Otorhinolaryngology-Head and Neck Surgery
SPHMMC	St. Paul's Hospital Millennium Medical College
SPSS	Statistical Package for Social Sciences

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1. Introduction

1.1 Background

The thyroid gland is a vital endocrine organ situated in the lower part of the neck. It has a characteristic butterfly shape, consisting of two lobes connected by a narrow tissue bridge called the isthmus. The gland is affected by various disorders, which encompass a broad spectrum of conditions resulting from either excessive or insufficient hormone production, structural abnormalities, or neoplastic transformation (1).

Thyroid nodules are among the most common endocrine abnormalities worldwide, and accurate diagnosis is essential for appropriate clinical management (2,3). Fine-needle aspiration cytology (FNAC) is widely used as the first-line, minimally invasive diagnostic technique for evaluating thyroid nodules due to its simplicity, safety, and cost-effectiveness. FNAC plays a key role in differentiating benign from malignant lesions, thereby guiding decisions on surgical intervention (4,5).

To enhance diagnostic consistency and communication between cytopathologists and clinicians, the Bethesda System for Reporting Thyroid Cytopathology provides a standardized framework for FNAC reporting. This system reduces inter-observer variability and minimizes diagnostic errors in cytological interpretation (6,7).

Despite its advantages, FNAC has certain limitations, such as issues of sample adequacy, operator dependency, and interpretive variability, which can affect its diagnostic accuracy (8). In contrast, histopathological examination of postoperative thyroidectomy specimens remains the gold standard for definitive diagnosis, allowing detailed characterization of lesions, confirmation of malignancy, and assessment of prognosis (9).

In Ethiopia, thyroid diseases continue to pose a significant public health burden, particularly in areas with endemic goiter (9). However, limited local evidence exists on the diagnostic performance of FNAC compared with postoperative histopathology. Evaluating the accuracy and reliability of FNAC in this context is critical to improving diagnostic efficiency, avoiding unnecessary surgeries, and optimizing healthcare resource utilization.

Therefore, this study aims to compare the diagnostic accuracy of fine-needle aspiration cytology with postoperative histopathology among patients undergoing thyroidectomy at St. Paul's Hospital Millennium Medical College (SPHMMC), Addis Ababa. The findings are

expected to provide evidence-based insights to strengthen diagnostic practices and guide management of thyroid nodules in the Ethiopian healthcare setting.

1.2 Statement of the problem

Thyroid nodules represent a major health concern due to their potential risk of malignancy. Globally, the incidence of thyroid cancer has been steadily increasing, with an estimated 249,538 new cases and 44,799 deaths reported in 2021, contributing significantly to cancer-related disability-adjusted life years (DALYs)(10). In Sub-Saharan Africa, the burden of thyroid malignancy is further exacerbated by limited diagnostic capacity, late presentation, and a high prevalence of endemic goiter, which complicates early detection and management (11).

Ethiopia faces similar challenges, with thyroid disorders being common, particularly in regions affected by iodine deficiency (12). However, the true prevalence and pattern of thyroid malignancy remain underreported, mainly due to inadequate diagnostic facilities and weak surveillance systems. Misdiagnosis or delayed diagnosis of thyroid lesions can lead to unnecessary surgical interventions for benign conditions or missed opportunities for early treatment of malignant cases, thereby increasing patient morbidity, mortality, and healthcare costs (13). In Ethiopia, the burden of delayed diagnosis can be compounded by endemic goiter and limited healthcare services, making the effective evaluation of thyroid nodules critically important.

Although FNAC is widely used as an initial diagnostic tool for evaluating thyroid nodules, its diagnostic accuracy can be affected by factors such as sample adequacy, operator expertise, and interpretive variability (14). Postoperative histopathology, while being the gold standard, is invasive and only available after surgical excision, underscoring the need for a reliable preoperative diagnostic method (15).

Despite the introduction of the Bethesda System for Reporting Thyroid Cytopathology to improve diagnostic standardization, there is limited evidence in Ethiopia regarding the accuracy and concordance of FNAC with postoperative histopathology. This gap hampers evidence-based decision-making and efficient resource utilization.

Therefore, this study aims to compare the diagnostic accuracy of FNAC with postoperative biopsy results among patients undergoing thyroidectomy at St. Paul's Hospital Millennium Medical College, Addis Ababa. The findings are deemed to help determine FNAC's reliability

in the Ethiopian healthcare context and support improved diagnostic and management strategies for thyroid nodules.

1.3 Significance of the study

This study aims to fill a critical gap in the literature on the diagnostic accuracy of FNAC compared to postoperative biopsy for thyroid lesions, especially in the Ethiopian healthcare setting where data are limited. It will provide local practitioners—including pathologists, endocrine surgeons, and ORL-HNS specialists—with practical guidance on FNAC’s diagnostic performance and its agreement with histopathology. This information is vital for improving preoperative diagnosis, refining surgical decisions, and reducing unnecessary surgeries or missed malignancies, thereby improving patient outcomes and optimizing resource use. Additionally, the findings will help healthcare policymakers and institutional leaders update clinical protocols and training programs, strengthening capacity among professionals managing thyroid diseases. For future researchers, this study offers a foundation for exploring factors that affect FNAC accuracy and fostering studies to validate findings and develop evidence-based guidelines suitable for resource-limited settings.

2. Literature review

2.1 Overview of FNAC and Its Diagnostic Challenges

Fine-needle aspiration cytology (FNAC) involves using a thin needle (typically 22-25 gauge) to extract cells from thyroid nodules for microscopic examination, serving as a minimally invasive diagnostic procedure (16). This technique is widely applied in thyroid diagnosis to differentiate benign from malignant lesions, guiding decisions on surgery while avoiding unnecessary interventions due to its simplicity, safety, cost-effectiveness, and rapid results (17). Globally, FNAC enjoys high acceptance, bolstered by the Bethesda System for Reporting Thyroid Cytopathology, which standardizes categories from non-diagnostic to malignant, achieving sensitivities of 80-95%, specificities up to 98%, and accuracies around 90-97% in various studies (7,18).

Despite these strengths, FNAC faces key limitations that impact its reliability. A primary challenge is its inability to distinguish follicular adenoma from follicular carcinoma, as both exhibit similar cytological features like microfollicular architecture, lacking evidence of capsular or vascular invasion visible only on histopathology after surgical resection (19). Other issues include operator dependency, sample inadequacy (affecting 4-12% of cases), interpretive variability in indeterminate categories (e.g., atypia of undetermined significance or follicular lesions), and lower sensitivity for small tumors (<1 cm) or certain malignancies like follicular variants (20). These limitations signpost towards FNAC's role as a triage modality rather than a definitive diagnostic method, with histopathology remaining the gold standard.

2.2 Empirical review

A comprehensive nationwide cohort study from Sweden examined 2,519 patients who underwent surgery for thyroid cancer between 2004 and 2013 was conducted. Among these cases, 2,332 (92.6%) had histologically confirmed thyroid cancer and were included in the analysis. For the 1,965 cases where FNAC was utilized, the overall diagnostic sensitivity reached 81.6%. This sensitivity varied substantially with lesion size: for tumors larger than 1 cm, FNAC sensitivity increased to 86.5%, while lesions smaller than 1 cm demonstrated a notably lower sensitivity of 61.5%. Furthermore, when ultrasound guidance was employed during FNAC in lesions over 1 cm (n = 1,504), the sensitivity improved to 86.9%, compared to 76.9% for FNAC performed without ultrasound guidance (n = 118) (20).

In Poland, a retrospective study analyzed 344 patients aged between 18 and 86 years. A statistically significant correlation was found between FNAC and histopathology results. Despite this, 86 patients (25%) were misdiagnosed based on FNAC findings. The sensitivity of FNAC was calculated at 92.31%, demonstrating its strong ability to detect malignancies. However, its specificity was somewhat lower, at 82.08%. The study also reported positive and negative predictive values of 68.57% and 96.08%, respectively (21).

In an Indian study, Fatima and colleagues assessed FNAC results from 100 patients presenting with both palpable and non-palpable thyroid swellings. They classified findings using the Bethesda system, revealing 84% benign cases, 2% as Atypia of Undetermined Significance or Follicular Lesion of Undetermined Significance (AUS/FLUS), 5% follicular neoplasms, 4% suspicious for malignancy, and 5% malignant lesions. The FNAC demonstrated a sensitivity of 81.8%, specificity of 88.3%, a positive predictive value of 64%, a negative predictive value of 95%, and an overall accuracy of 87%. Another Indian study reported FNAC sensitivity and specificity of 82.6% and 95.2%, respectively (22).

Meanwhile, a tertiary hospital in Nagpur, Maharashtra, conducted a two-year study encompassing 295 thyroid lesion cases. This study confirmed a sensitivity of 80% and an exceptionally high specificity of 98.44%. The positive predictive value was 94.11%, with overall diagnostic accuracy at 94.05%, and false positive and negative rates were low at 1.19% and 4.76% (23). In a similar Indian study, the overall accuracy of FNAC was 94.7% (24).

Another Indian prospective and observational study included seventy patients, correlating FNAC diagnoses with histopathology. The analysis revealed FNAC sensitivity of 83.3%, perfect specificity of 100%, a positive predictive value of 100%, and a negative predictive value of 96.7%. Despite these impressive metrics, the overall diagnostic accuracy was calculated at 95.71% (25).

Recently in India, a study evaluated 104 patients with thyroid lesions over an 18-month period using FNAC. The results were categorized following the Bethesda system, revealing a diverse distribution across categories. Six cases fell into Bethesda Category I (Unsatisfactory samples), while the vast majority (85 cases or 81.7%) were classified as Bethesda Category II (Benign). A smaller number of patients represented Bethesda Category III (Atypia of Undetermined Significance) with one case, Category IV (Follicular Neoplasm) with four cases, Category V (Suspicious for Malignancy) just one case, and Category VI (Malignant) with seven cases (26).

Between January 2018 and December 2020, a cross-sectional study was conducted at the Departments of Otolaryngology-Head & Neck Surgery and Pathology at Chittagong Medical College, Chattogram, Bangladesh. The study involved 80 patients presenting with thyroid swellings. On FNAC examination, 64 cases (80%) were identified as non-neoplastic, while 16 cases (20%) were neoplastic. Within the non-neoplastic group, nodular goiter was the predominant diagnosis, accounting for 62 cases (77.5%), with lymphocytic thyroiditis observed in 2 cases (2.5%). Among the neoplastic swellings, 2 cases (2.5%) were follicular lesions, 12 cases (15%) diagnosed as papillary carcinoma, 1 case (1.25%) as follicular carcinoma, and another case (1.25%) was suspicious for malignancy (27).

Histopathological analysis of the same cohort revealed 60 cases (75%) were non-neoplastic and 20 cases (25%) neoplastic. Of the non-neoplastic lesions, 59 (73.75%) were nodular goiter and 1 (1.25%) was lymphocytic thyroiditis. The neoplastic lesions included 3 cases (3.75%) of follicular adenoma, 13 (16.25%) of papillary carcinoma, 3 (3.75%) follicular variant of papillary carcinoma, and 1 (1.25%) follicular carcinoma (27).

From December 2021 to May 2023, a cross-sectional observational study was performed at the Department of ENT and Head and Neck Surgery, Dhaka Medical College Hospital, Bangladesh. Among 61 patients studied, Bethesda Class II (Benign) constituted the majority at 62.2% (38 cases). Follicular Neoplasm or Suspicious for Follicular Neoplasm (Class III) accounted for 8.19% (5 cases), while Atypia of Undetermined Significance or Follicular Lesion of Undetermined Significance (Class IV) represented 13.1% (8 cases). Suspicious for Malignancy (Class V) comprised 11.4% (7 cases), and Malignant (Class VI) was reported in 4.91% (3 cases). Histopathological examination confirmed 42 benign lesions (68.9%) and 19 malignant cases (31.1%). While comparing FNAC with histopathology, there were six false positives and two false negatives. Additionally, 17 cases were true positives, and 36 were true negatives (28).

A study conducted in the Al-Baha region, Saudi Arabia between 2022 and 2023 included 52 patients. Of these patients, 30 (58%) had benign lesions confirmed on histology: 22 cases of nodular goiter and 8 cases of follicular adenoma. The remaining 22 patients (42%) were diagnosed with malignant lesions, including 12 cases of papillary carcinoma (distributed as 10 preoperative Bethesda Category 5, one Category 3, and one Category 6), eight noninvasive follicular thyroid neoplasms with papillary-like nuclear features (NIFTP) (five Category 4, one Category 2, and two Category 3), and two cases of follicular carcinoma (one Category 2 and

one Category 3). The overall diagnostic accuracy of FNAC in this cohort was 90%. The interrater reliability between clinical FNAC results and histopathological diagnosis, assessed via Cohen's kappa coefficient, showed a moderate agreement level at 61.3% (4).

In Kuwait, a prospective evaluation of 160 thyroid lesion cases categorized cytologic diagnoses ranging from colloid goiter (32.5%) to inflammatory conditions and malignancies like papillary carcinoma. FNAC showed outstanding diagnostic performance with sensitivity at 90.2%, specificity at 98.2%, and accuracy of 97.1% (29).

At Salmaniya Medical Complex, a tertiary care center in the Kingdom of Bahrain, a retrospective single-center observational study was conducted to assess FNAC accuracy. Postoperative histology results revealed that 62% of patients had benign lesions, while 38% were diagnosed with malignancies. Bethesda II was the most common category in the sample, with 14.3% having a final histopathological diagnosis of malignancy (false negative results). Malignancy was found in 84% and 96.8% of Bethesda V and VI, respectively. In this study, FNAC data achieved an 80.95% sensitivity, specificity of 93.51% specificity, and an overall accuracy of 87.86%. The positive predictive value was 91.07%, and an 85.71% negative predictive value (30).

Similarly, in Egypt, a retrospective study at Qena Oncology Center examined histopathology from thyroid surgeries between January 2021 and June 2022. Benign lesions accounted for 74.5% of cases, while malignancies made up 25.6%, predominantly papillary carcinoma variants. FNAC sensitivity for malignancy was 68%, though specificity reached 100%, with no false positives. Overall FNAC accuracy stood at 91.8%, indicating its strong preoperative diagnostic value, despite some sensitivity limitations (31).

A retrospective study conducted in Libya analyzed 62 patients with thyroid lesions who underwent preoperative FNAC followed by surgical resection. Data collection spanned from January 2017 to December 2022. The results demonstrated that FNAC achieved a sensitivity of 94%, indicating a high rate of correctly identifying malignant lesions. Specificity was slightly lower at 91%, reflecting its performance in correctly classifying benign cases. The positive predictive value was 80%, while the negative predictive value was notably high at 97%. Overall, the diagnostic accuracy of FNAC in this cohort was determined to be 92% (5).

At Mulago National Referral Hospital, Uganda, 99 patients who underwent clinical and laboratory evaluation and thyroidectomy were analyzed. The proportion of patients with malignancy was 13.3%, with papillary thyroid carcinoma being the most predominant type and

colloid goiter was the most predominant benign thyroid disease. The sensitivity was 61.5% and specificity 89.5% (32).

Over five years in Somalia, researchers studied 231 patients undergoing preoperative FNAC and histopathology. The results demonstrated remarkable correspondence: sensitivity reached 91.1%, specificity 96.6%, and accuracy 94.9%. According to Bethesda categories, 61% of cases were benign (Bethesda II), with 95.7% confirmed benign on final histology. Bethesda III and IV showed lower frequencies and benign outcomes in neoplasm-suspicious cases. Bethesda V cases showed 88.6% malignancy on follow-up, while Bethesda VI (9.1%) confirmed papillary thyroid carcinoma universally (33).

A retrospective cross-sectional descriptive study was conducted at Black Lion Hospital in Ethiopia, involving 687 patients who underwent cytopathologic evaluation for thyroid lesions between January 2015 and August 2019. The distribution of cytopathologic diagnoses was as follows: 33 cases (4.8%) were non-diagnostic (inconclusive), 504 cases (73.4%) were benign or non-neoplastic lesions, 51 cases (7.4%) were follicular neoplasms, 11 cases (1.6%) were Hurthle cell neoplasms, 3 cases (0.4%) were suspicious for malignancy, and 85 cases (12.4%) were malignant. Among the benign group, colloid goiter was predominant, accounting for 458 (90.9%) of cases. Papillary carcinoma was the most common malignant type, comprising 43 (48.9%) of the malignant lesions, followed by anaplastic (undifferentiated) carcinoma at 20 cases (23.6%). Furthermore, eleven cases had benign cytopathologic diagnoses confirmed by FNAC, although two were found malignant upon histologic examination. Conversely, six cases had malignant FNAC diagnoses, but two were reclassified as adenomas based on histopathology (34).

2.3 Relevance to the Ethiopian setting

Ethiopia requires additional data on FNAC performance given the high prevalence of endemic goiter attributable to historical iodine deficiency, constrained diagnostic infrastructure, and underreporting of thyroid malignancies amid increasing global thyroid cancer incidence. Local evidence gaps persist, as evidenced by Weyessa et al., who reported 4.8% non-diagnostic rates and diagnostic discrepancies, such as two cases initially deemed benign by FNAC but confirmed malignant on histopathology, underscoring the need for updated, institution-specific validation (34).

This study is hoped to address these gaps through evaluation of FNAC-histopathology concordance among thyroidectomy patients at SPHMMC, utilizing contemporary local data. It

contributes to broader diagnostic enhancement by refining Bethesda System implementation, minimizing unnecessary surgeries (e.g., through improved management of indeterminate categories), optimizing resource allocation in resource-constrained public hospitals, and informing national guidelines amid challenges like delayed presentations and inadequate surveillance.

Global literature affirms FNAC's utility in thyroid diagnosis, yet critical gaps persist: absence of recent Ethiopian data beyond the 2015-2019 Black Lion Hospital study; inconsistent sensitivity and specificity metrics influenced by operator expertise, ultrasound guidance, and lesion characteristics, requiring validation against current local protocols; unexamined facility-specific performance variations at high-volume centers like SPHMMC despite superior international outcomes; and challenges in Bethesda classification application in low-resource settings due to sample inadequacy, interpretive variability, and resource limitations, with no prior local studies employing Cohen's kappa for concordance assessment.

Hence, this study is designed to bridge these deficiencies by delivering SPHMMC-specific FNAC-histopathology concordance data, diagnostic accuracy measures, and Bethesda System performance metrics to underpin refined local guidelines.

2.4 Conceptual framework

This is a conceptual framework developed specifically for this study by the principal investigator through reviewing related studies (25,28,30,31,35) in which this study is intended to revolve.

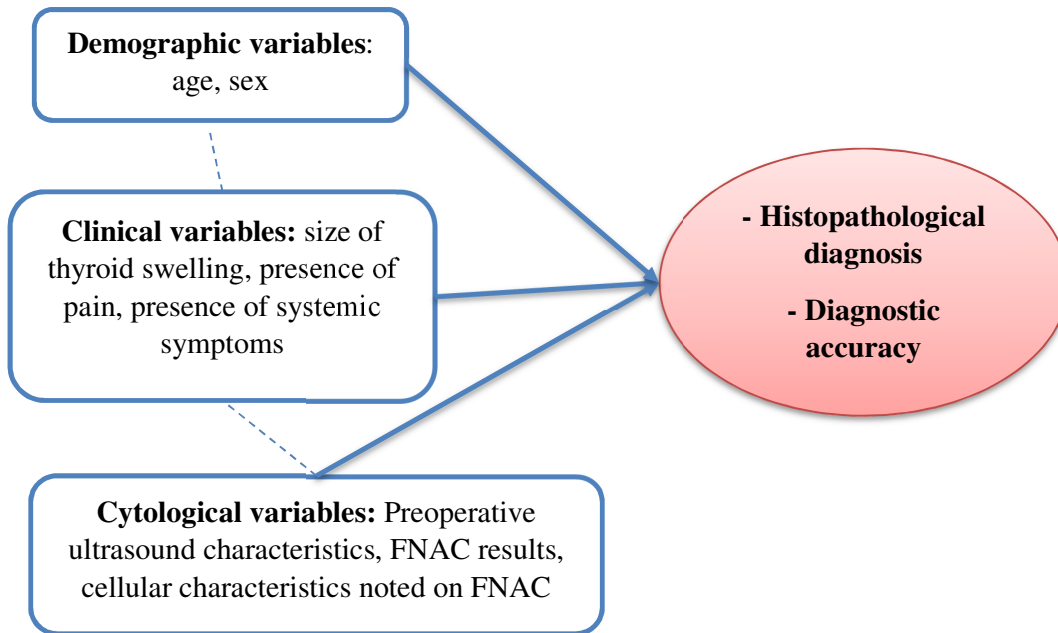


Figure 1. Conceptual framework for *factors associated with histopathological diagnosis and diagnostic accuracy* (Source: (25,28,30,31,35))

3. Objective of study

3.1 General objective

- To evaluate the concordance between FNAC and postoperative histopathological findings among patients undergoing thyroidectomy at St. Paul's Hospital Millennium Medical College.

3.2 Specific objectives

- To assess the distribution of different thyroid lesion types diagnosed by FNAC and confirmed by histopathology.
- To determine the diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy) of FNAC using histopathology as the gold standard.
- To assess the degree of concordance between FNAC and histopathological diagnoses in thyroidectomy patients

4. Methods and Materials

4.1 Study area

The study took place at SPHMMC, a leading government hospital situated in Addis Ababa, Ethiopia's capital. SPHMMC employs over 2,800 staff members across clinical, academic, administrative, and support roles, delivering specialized medical care to patients referred nationwide. Established in 1969, the hospital manages care for about 200,000 patients each year and serves a catchment area of more than 5 million people. As a major referral institution, it also provides education for undergraduate and postgraduate students in health sciences. The facility includes over 700 inpatient beds.

The ORL-HNS department within the hospital is organized into distinct units for emergency care, otology, head and neck, and general ENT. It is equipped with eighteen ward beds and two operating room tables. The department is staffed by eight specialists, residents, and specialized nursing personnel.

4.2 Study period

The study period spanned from January 1, 2022, to December 31, 2025, with the proposed data collection scheduled from December 15, 2025, to February 31, 2026.

4.3 Study design

This study employed a retrospective cross-sectional diagnostic accuracy study with paired samples.

4.4 Population

4.4.1 Source population

All patients undergoing thyroidectomy surgery at SPHMMC, Addis Ababa, Ethiopia.

4.4.1 Study population

Eligible patients undergoing thyroidectomy at SPHMMC, Addis Ababa, Ethiopia during the study period.

4.5 Eligibility criteria

4.5.1 Inclusion criteria

- Patients who underwent thyroidectomy at SPHMMC.
- Patients who had preoperative FNAC performed on their thyroid nodules.
- Patients with available postoperative histopathological biopsy results.

- Adult patients aged 14 years and above.

4.5.2 Exclusion criteria

- Patients without both FNAC and postoperative biopsy results.
- Patients who underwent thyroid surgery for reasons other than neoplastic or nodular thyroid disease (e.g., trauma).
- Pediatric patients under 14 years of age.
- Patients who had prior thyroid surgery or intervention before the current thyroidectomy.

4.6 Sample size determination

The sample size for this study was calculated using the single population proportion formula. In line with the primary objective, the expected sensitivity of FNAC to detect malignancy was taken as 61.5%, based on a previous study (32).

$$n = \frac{z^2 p(1 - p)}{e^2}$$

n = the required sample size

p = the expected sensitivity of FNAC (61.5% or 0.615).

$Z_{\alpha/2}$ = the z-score for the desired confidence level at 95% confidence level = 1.96

e = the desired margin of error (precision) = 5% (0.05)

Accordingly,

$$n = \frac{(1.96)^2 * 0.615(1 - 0.615)}{0.05^2}$$

$$n = \frac{(1.96)^2 * 0.615(0.385)}{0.05^2}$$

$$n = 363$$

Hence, by adding 10% for contingency to the calculated sample size (that is, 363), the total sample size required for this study becomes 399 patients.

4.7 Sampling technique

From January 1, 2022, to December 31, 2025, approximately 412 patients with thyroid pathologies are estimated to undergo thyroidectomy at SPHHMC. Since the required sample size for the study is 399 and the anticipated number of eligible patients during the study period

is 412, the investigator has determined that including all patients who meet the criteria—representing 100% of the estimated cohort—is appropriate for analysis.

4.8 Data collection tools and procedures

Data were collected using a structured, pre-tested checklist adapted from previously published literature (25,28,30,31,35). The checklist consists of three sections: demographic information, clinical details, and histopathological parameters. Data were obtained from patient registry logbooks, archives, and the EMR database. Medical records of patients who underwent thyroidectomy during the study period were identified and reviewed. Two data collectors were recruited and provided with one day of training on standardized data collection procedures.

4.9 Study variables

4.9.1 Dependent variable

- Histopathological diagnosis (benign or malignant)
- Accuracy measures of FNAC (sensitivity, specificity, positive predictive value, negative predictive value)

4.9.2 Independent variables

- **Demographic variables:** age, sex of the patient
- **Clinical variables:** size of thyroid nodule, presence of pain or tenderness, presence of systemic symptoms
- **Cytological variables:** Preoperative ultrasound characteristics, FNAC results, cellular characteristics noted on FNAC

4.10 Operational definitions

- **FNAC:** A minimally invasive diagnostic procedure in which a thin, hollow needle is used to extract cells from a thyroid nodule for microscopic examination to determine the presence or absence of malignancy (36).
- **Postoperative Biopsy:** Histopathological examination of the thyroid tissue obtained after surgical thyroidectomy, considered the gold standard for confirming the diagnosis of benign or malignant thyroid lesions (37).
- **Sensitivity of FNAC:** The proportion of patients with malignant thyroid lesions correctly identified as positive by FNAC compared to the postoperative biopsy results (20).
- **Specificity of FNAC:** The proportion of patients with benign thyroid lesions correctly identified as negative by FNAC compared to the postoperative biopsy results (20).

- **Thyroidectomy:** A surgical procedure involving partial or total removal of the thyroid gland, performed in patients with thyroid nodules or pathology requiring definitive diagnosis or treatment (38).

4.11 Data quality management

To ensure the reliability and integrity of the data collected for this study, a comprehensive data quality management strategy was implemented. An English version checklist, developed after an extensive literature review, served as the primary tool for data collection.

Prior to the commencement of data collection, a brief training session focusing on the data collection process was conducted for the two experienced residents designated as data collectors. Close supervision was maintained throughout the data collection phase to monitor adherence to protocols.

To enhance data quality, filled checklists underwent a rigorous verification process. The data collectors and the principal investigator double-checked the completed checklists daily for consistency and completeness.

4.12 Data processing and analysis

Data entry was performed using Kobo Toolbox, and statistical analysis was conducted using IBM SPSS Statistics version 27. Sorting, frequencies, and cross-tabulations were used to identify missing values and assess variables. Normally distributed data were presented as mean $\pm$ standard deviation, while non-normally distributed data were presented as median with interquartile range (IQR). Percentages and frequencies were computed for categorical variables. The diagnostic validity of FNAC relative to biopsy was evaluated using sensitivity, specificity, and positive and negative predictive values. Agreement between FNAC and biopsy was assessed using Cohen's kappa coefficient, with a p-value <0.05 and 95% confidence interval considered statistically significant. Finally, the study findings were presented using diagrams, tables.

4.13 Ethical consideration

Ethical approval was obtained from the Institutional Review Board (IRB) of SPHMMC. Prior to retrieving and reviewing patient records, a permission letter was submitted to the Office of Chief Clinical Director. Following this, trained data collectors were introduced to each team unit and familiarized with the study procedures. Anonymity and confidentiality of the data collection checklist were maintained. To ensure participant confidentiality, all collected

information were anonymized and encrypted. Identifiers were de-identified, and the dataset was securely stored with a user-protected password.

4.14 Dissemination of the study findings

The results of this study will be submitted to the Department of Otorhinolaryngology-Head and Neck Surgery at SPHMMC as partial fulfillment of the requirements for the Specialty Degree in Otorhinolaryngology-Head and Neck Surgery. The findings will also be shared with key clinical stakeholders, including the pathology, endocrinology and surgery units, to inform and enhance clinical practice. In addition, we plan to present the study outcomes at annual Ethiopian conferences that focus on related thematic areas. Following the thesis defense, the manuscript will be submitted to a peer-reviewed scientific journal for potential publication.

5. Results

5.1 Demographic data of the study sample

This retrospective study evaluated 400 patients who underwent thyroidectomy. Age distribution exhibited positive skewness (skewness = 0.499; SE = 0.122), with median age 39 years (IQR: 30–50). Participants aged ≤ 30 years comprised 25.8% (n=103), while those aged 31–40 years accounted for 31.0% (n=124). Females predominated (90.3%, n=361), yielding a male-to-female ratio of 1:9 (Table 1).

Table 1. Demographic characteristics of patients who underwent thyroidectomy at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, from January 1, 2022 to December 31, 2025

Variable	Frequency	Percent (%)
Age group		
≤ 30 years	103	25.8
31–40 years	124	31.0
41–50 years	84	21.0
51–60 years	58	14.5
>60 years	31	7.8
Sex		
Male	39	9.8
Female	361	90.3

5.2 Clinical and related characteristics of the study sample

Among the studied thyroidectomy patients, FNAC was performed with equal frequency using ultrasound guidance (50.5%) and palpation guidance (49.5%). Most nodules exceeded 2 cm in size (71.0%), with smaller lesions (≤ 2 cm) comprising 29.0%. Multiple nodules predominated (81.2%) over solitary nodules (18.8%). Ultrasonographically, isoechoic nodules were most common (67.0%), followed by hypoechoic (28.7%) and hyperechoic (4.3%) patterns. Smooth margins characterized 85.0% of lesions, while irregular margins occurred in 15.0%, and calcifications were present in 23.5% (Table 2).

Table 2. Clinical and paraclinical characteristics of patients who underwent thyroidectomy at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, from January 1, 2022 to December 31, 2025

Variable	Frequency	Percent (%)
Aspiration performed under		
Palpation-guided	198	49.5
Ultrasound-guided	202	50.5
Size		
≤2 cm	116	29.0
>2 cm	284	71.0
Number of nodules		
Solitary	75	18.8
Multiple	325	81.2
Echogenicity		
Hypoechoic	115	28.7
Isoechoic	268	67.0
Hyperechoic	17	4.3
Margins		
Smooth	340	85.0
Irregular	60	15.0
Calcifications		
Absent	306	76.5
Present	94	23.5

5.3 Cytological details of the study sample

Among all the studied thyroidectomy patients, FNAC diagnoses followed Bethesda categorization, with benign Category II predominating (68.0%), followed by follicular neoplasm (Category IV, 11.3%), malignant Category VI (11.0%), suspicious for malignancy Category V (4.3%), atypical/FLUS Category III (1.8%), and non-diagnostic Category I (3.8%). Vascularity was normal in 78.5% and increased in 21.5%. Surgery comprised lobectomy (74.5%), total thyroidectomy (18.3%), and subtotal thyroidectomy (7.2%). Histopathology confirmed benign lesions in 74.0%, papillary carcinoma in 20.5%, follicular adenoma in 3.0%, follicular/medullary carcinoma in 1.0% each, and other malignancies in 0.5%. Capsular invasion occurred in 20 (17.9%), lymph node involvement in 10.6% (n=11), and extrathyroidal extension in 4.9% (n=5) (Table 3).

Table 3. Cytological details of patients who underwent thyroidectomy at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, from January 1, 2022 to December 31, 2025

Variable	Frequency	Percent (%)
FNAC diagnosis		
Category I	15	3.8
Category II	272	68.0
Category III	7	1.8
Category IV	45	11.3
Category V	17	4.3
Category VI	44	11.0
Vascularity		
Normal	314	78.5
Increased	86	21.5
Type of surgery		
Lobectomy	298	74.5
Subtotal thyroidectomy	29	7.2
Total thyroidectomy	73	18.3
Histopathological diagnosis		
Benign	296	74.0
Follicular adenoma	12	3.0
Papillary carcinoma	82	20.5
Follicular carcinoma	4	1.0
Medullary carcinoma	4	1.0
Other malignancy	2	0.5
Capsular invasion (n=112)		
Absent	92	82.1
Present	20	17.9
Lymph node involvement (n=104)		
Absent	93	89.4
Present	11	10.6
Extrathyroidal extension (103)		
Absent	98	95.1
Present	5	4.9

5.4 Diagnostic performance metrics

After excluding non-diagnostic (Bethesda category I) and indeterminate (categories III/IV) cases, we compared FNAC diagnostic results with histopathology (the reference standard) for detecting thyroid malignancy in 331 patients undergoing thyroidectomy. FNAC identified 53 true positives and 251 true negatives. The sensitivity of FNAC was 73.6% (95% CI: 64.5–81.2%), indicating that it correctly detected most malignant cases identified by histopathology. Its specificity was 96.9% (95% CI: 93.8–98.6%), showing a high ability to correctly identify patients without histopathology-confirmed thyroid malignancy. The PPV was 87.0% (95% CI: 77.6–93.1%), reflecting a high probability that patients with neoplastic features in FNAC results truly had malignancy confirmed by histopathology. The NPV was 93.0% (95% CI:

89.6–95.6%), indicating a strong likelihood that negative FNAC results corresponded to absence of malignancy on histopathology (Table 4).

Table 4. Concordance Between Preoperative FNAC Diagnoses (Bethesda Classification) and Postoperative Histopathological Findings, with Diagnostic Performance Metrics Using Histopathology as the Reference Standard

		Histopathology		Total	Sensitivity	Specificity	PPV	NPV
		Malignant	Benign					
FNAC	Malignant	53	8	61	73.6%	96.9%	87.0%	93.0%
	Benign	19	251	270				
	Total	72	259	331				
Kappa index				0.746			P<0.001	
Observed agreement				91.8%				

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

5.4 Intermodality concordance

The agreement between the two methods was substantial, with a Cohen's kappa statistic of 0.746 ($p < 0.001$), with a percentage of observed agreement of 91.8% (Table 4).

6. Discussion

The present study aimed to evaluate the concordance between FNAC and histopathological findings among thyroidectomy patients at SPHMMC, Addis Ababa, Ethiopia. After excluding non-diagnostic (Bethesda category I) and indeterminate (categories III/IV) cases, FNAC showed a sensitivity of 73.6%, specificity of 96.9%, PPV of 87.0%, and NPV of 93.0% for detecting thyroid malignancy using histopathology as the reference standard (n=331). Furthermore, there was substantial intermodality agreement, with Cohen's kappa of 0.746 ($p < 0.001$) and 91.8% observed agreement. These findings indicate reliable FNAC performance in this Ethiopian setting, particularly its high specificity in ruling out malignancy.

In this study, the sensitivity of FNAC at 73.6% (95% CI: 64.5–81.2%) indicates its capacity to correctly identify most thyroid malignancy cases confirmed by histopathology. This value is lower than the overall diagnostic sensitivity reported in India (80%), Swedish (81.6%), Somali (91.1%) and Libyan cohorts (94%) (5,20,23,33). Conversely, it exceeds the 61.5% sensitivity from a Ugandan study using similar methods (histopathology gold standard) (32). The observed discrepancy likely reflects exclusion of indeterminate cases here, which reduces false negatives but narrows the denominator, as well as differences in operator expertise and the differences in the collection and processing of thyroid cytological specimens.

FNAC in this study demonstrated a specificity of 96.9%, indicating excellent ability to correctly identify benign cases confirmed by histopathology. This specificity closely aligns with values reported in prior Somali (96.6%) and Indian (98.44%) studies (23,33). Conversely, it exceeds the 89.5% and 91% specificities from Ugandan and Libyan studies (5,32).

In this study, FNAC demonstrated a PPV of 87.0% (95% CI: 77.6–93.1%), indicating a high likelihood that positive results truly represented thyroid malignancy confirmed by histopathology. This value is slightly lower than the 94.11% reported in an Indian study, but substantially exceeds the 47.1% and 80% PPVs from the Ugandan and Libyan studies (5,23,32).

The NPV was 93.0% (95% CI: 89.6–95.6%), showing strong reliability in ruling out malignancy when FNAC was negative. This figure aligns closely with Ugandan cohorts (93.9%) and compares favorably to Polish (96.1%) and Libyan (97%) studies (5,21,32).

Overall diagnostic accuracy reached 91.8%, reflecting high observed agreement between FNAC and histopathology. This surpasses the 85.8% accuracy from Uganda (32). The value compares favorably to Saudi Arabia (90%), Libyan (92%) and Indian (94%) surgical cohorts, validating robust FNAC performance in this Ethiopian tertiary center (4,5,23). In the present study setting, the majority of misdiagnosis cases can be attributed to processing technique

errors; our laboratory staff used only conventional techniques instead of cytologically new technique such as liquid-based cytology. Additionally, while in Sweden, 85% of the aspirations were done via ultrasound guided, in this study, only half were done under US guidance (20). Furthermore, substantial agreement was observed between FNAC and histopathology ($\kappa = 0.764$), indicating strong beyond-chance concordance for malignancy detection. This value exceeds the moderate agreement ($\kappa = 0.613$) reported by Alzahrani et al. in Saudi cohorts (4). Exclusion of indeterminate cases artificially inflates κ (91.8% observed agreement), while full-spectrum studies may decrease the coefficient.

In general, variations in diagnostic performance metrics across studies may arise from differences in patient populations (age, nodule size), operator experience with FNAC, lesion characteristics (size, Bethesda category), and reference standards (histopathology protocols). Prior studies consistently demonstrate that FNAC accuracy improves with ultrasound guidance, experienced operators, and standardized Bethesda reporting, though performance may be lower in resource-limited settings due to these factors.

7. Strength and Limitations

7.1 Strength

- The study was conducted at one of Ethiopia's largest referral hospitals, where diverse clinico-demographic characteristics are well-represented.

7.2 Limitations

- The study analyzed only surgical cases, potentially inflating specificity by excluding non-operated benign nodules.
- Exclusion of non-diagnostic (Bethesda I) and indeterminate (III/IV) cases limits generalizability to real-world FNAC performance, where these comprise 10-25% of results.
- Lack of details regarding operator experience, or inter-observer variability assessment may confound accuracy estimates and restrict deeper insights.

8. Conclusion and Recommendation

8.1 Conclusion

FNAC demonstrated good diagnostic accuracy for thyroid malignancy in this Ethiopian cohort, with a sensitivity of 73.6% and a specificity of 96.9%. The positive and negative predictive values were 87.0% and 93.0%, respectively. Substantial agreement was observed between FNAC and histopathology (Cohen's kappa 0.746). Moreover, overall, the findings reinforce that FNAC is a practical, minimally invasive preoperative modality with strong exclusion capability for thyroid neoplasms in resource-limited Ethiopian hospitals.

8.2 Recommendation

Based on the findings obtained in this study, the following recommendations can be forwarded.

For Clinicians:

- FNAC should be considered a reliable triage tool for thyroid nodules due to its high specificity (96.9%) and good diagnostic accuracy in ruling out malignancy, particularly so for preoperative evaluation in high-volume referral hospitals like ours.
- Given its capacity to identify most malignancies with substantial histopathology agreement, FNAC can complement clinical assessment and ultrasound, potentially reducing unnecessary thyroidectomies—especially in resource-limited Ethiopian settings.

For Researchers:

- Further research with larger, multicenter Ethiopian studies is warranted to validate FNAC accuracy across full Bethesda spectra, including indeterminate cases.
- Research is needed to develop standardized training and assess interobserver variability for consistent FNAC quality in low-resource contexts.

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St. Paul's Hospital Millennium Medical College
Department of Otorhinolaryngology-Head and Neck Surgery

Annex

Annex I: Information sheet

This note will be read for medical director of the hospital before collecting any information from the registries.

Greetings. My name is Dr. Mohamed Jamal, and I am a postgraduate student in Department of Otorhinolaryngology-Head and Neck Surgery at SPHMMC.

This department of the hospital was selected to conduct the proposed study entitled **“Concordance Between Fine-Needle Aspiration Cytology and Histopathological Findings Among Thyroidectomy Patients at St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia”** as it is among the leading centers where the highest number of individuals undergoing thyroidectomy can be recruited, and it represents patients from various clinico-demographic characteristics.

I am humbly requesting your esteemed office to give me permission to conduct the stated study in this hospital. Please read the following information for further understanding:

Study procedure: to achieve the planned objective of this study, socio-demographic data, clinical data, imaging and histopathological details of patients will be extracted from patients’ medical records using structured checklist. If your esteemed institution allows the undertaking of this study, the data collectors will be using a checklist to collect necessary data from the medical records of patients. I would very much appreciate your cooperation in this study.

Risks and benefits: The result of the study is believed to help responsible body to advance care for such specific group of patients and help to optimize clinical care among the target population.

Confidentiality: All the collected information will be kept confidential and used only for the study purpose. No one except the members of the research team will have access to the information collected. The name and/or other personal information of patients will not be notified in any report. All computer records of the study will be kept in a secured place with password protection.

Contact Address of the Principal Investigator

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Annex II: Data collection format

001. Data collector: code ____/____/____ Name _____

002. Date of data collection ____/____/____ Time _____

003. Checked by supervisor: Signature _____ day _____ month _____ year _____

1. Demographic details			
SN	Question	Response	Skip
Section 1: Demographic details			
101	Age in years		
102	Sex	1. Male 2. Female	
Section 2: Clinical variables			
201	Clinical presentation (multiple responses are possible)	1: Thyroid swelling/nodule 2: Neck discomfort/pain 3: Symptoms of hyperthyroidism 4: Symptoms of hypothyroidism 5: Others (specify): _____	
202	Thyroid function status (based on lab results)	1. Euthyroid 2. Hyperthyroid 3. Hypothyroid 4. Unknown	
Section 3: Preoperative Evaluation			
301	FNAC performed under:	1. Palpation-guided 2. Ultrasound-guided	
302	Sampling adequacy	1. Adequate 2. Inadequate (Unsatisfactory)	
303	FNAC diagnosis (report according to Bethesda System):	1. Category I - Non-diagnostic/unsatisfactory 2. Category II - Benign 3. Category III - Atypia of Undetermined Significance/Follicular Lesion of Undetermined Significance 4. Category IV - Follicular Neoplasm or Suspicious for Follicular Neoplasm 5. Category V - Suspicious for Malignancy 6. Category VI - Malignant	
Section 4: Imaging details			
401	Ultrasound features of thyroid nodule(s):	Size (cm): _____	
		Number of nodules: _____	

402	Echogenicity:	1. Hypoechoic 2. Isoechoic 3. Hyperechoic Level: _____	
403	Margins:	1. Smooth 2. Irregular	
404	Calcifications:	1. Present 2. Absent	
405	Vascularity:	1. Increased 2. Normal 3. Decreased	
5: Surgical details			
5.1	Type of surgery:	1: Total thyroidectomy 2: Lobectomy 3: Subtotal thyroidectomy	
Section 6: Postoperative Histopathology			
601	Final histopathological diagnosis:	1: Benign (Non-neoplastic lesions, specify): _____ 2: Follicular adenoma 3: Papillary carcinoma (specify variant if known): _____ 4: Follicular carcinoma 5: Anaplastic carcinoma 6: Medullary carcinoma 7: Other malignancies (specify): _____	
602	Tumor capsular or vascular invasion:	1: Present 2: Absent	
603	Lymph node involvement:	1: Present 2: Absent	
604	Extrathyroidal extension:	1: Present 2: Absent	