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St. Paul's Hospital Millennium Medical College**

St. Paul's Hospital Millennium Medical College

Department of radiology and medical radiology technology

Graduate study program

**Concordance between radiologic and pathologic findings of patients with image
guided transthoracic biopsy or fine needle aspiration done among patients who
visited interventional radiology unit at SPHMMC**

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Addis Ababa, Ethiopia

August 2024



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A retrospective chart review study.**

By Fikeremaryam Alehegn (MD, Radiology resident)

Advisors:

- 1. Mr. Kasim Muhammed (Associate Professor in Biostatistics)**
- 2. Etenesh Tewolde MD; MSK, body and interventional radiology sub-specialist**

A Research thesis to be submitted to St. Paul Hospital Millennium Medical College, Department of Radiology and Medical Radiology Technology in Partial fulfillment of the Requirements for the speciality certificate in radiology.

Addis Ababa, Ethiopia, August 2024

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Acronyms and Abbreviations

NSCLC: Non small cell lung cancer

SCLC: Small cell lung cancer

TB: Tuberculosis

NHL: non-Hodgkin lymphoma

HL: Hodgkin lymphoma

MRI: Magnetic resonance imaging

CT: Computed tomography

PET: Positron emission tomography

FNAC: Fine needle aspiration cytology

CNB: Core needle biopsy

IR: interventional radiology

GLOBOCAN: Global cancer observatory

BIRADS: Breast imaging reporting and data system

PIRADS: Prostate imaging reporting and data system

MRT: Medical Radiology Technology

PPV: Positive predictive value.

NPV: Negative predictive value.

SPHMMC: Saint Paul's Hospital Millennium Medical College.

BLH: Black Lion Hospital

FMOH: Federal Ministry of Health

SPSS 27: Statistical Package for the Social Science

Abstract

Background- Thoracic lesions include variety of benign and malignant conditions of the lung, pleura, mediastinum and vertebra. Diagnosis of these lesions requires clinical data, laboratory investigations and radiologic imagings including x-ray, ultrasound, chest CT, MRI and PET Scan. If required, the next step is pathologic diagnosis; image guided percutaneous biopsy being one of the common minimally invasive modern procedures for obtaining tissue samples. This study examines the concordance between radiologic reports and histopathologic findings and evaluates the contribution of image-guided sampling to our clinical practice.

Objectives: To assess the concordance between radiologic and pathologic findings of patients with image guided transthoracic biopsy/FNAC done at SPHMMC interventional radiology (IR) unit from November 2019 -April 2024.

Methods: A retrospective chart review was conducted from May to June 2024 at Saint Paul's Hospital Millennium Medical College (SPHMMC) in Addis Ababa. All patients who had image-guided transthoracic biopsies after detection of a mass/nodule on chest CT during the study period were included. Data were collected by the principal investigator and a trained radiology resident. Radiologic reports were categorized by three readers as benign, malignant (not otherwise specified); primary lung (pleural, mediastinal) malignancy or metastatic lesion. Inter-reader radiologic and radiopathologic concordance was assessed using kappa statistics (Fleiss' and Cohen's Kappa).

Result and conclusion: The radiopathologic agreement among patients undergoing image-guided transthoracic biopsy/FNAC at our hospital's IR unit was borderline moderate (Cohen's kappa value of 0.406). We observed an 80.2% concordance rate, with notable discordance seen in pleural metastatic adenocarcinomas and common inflammatory lesions like TB. Our study found that image-guided transthoracic CNB/FNAC is safe and effective with diagnostic yield of 86.3%, and procedural complication of minimal pneumothorax in 6.9% of cases. Lesions smaller than 2cm, and post-procedural pneumothorax were significant factors affecting diagnostic yield.

Keywords- Transthoracic, Biopsy, Image guided, concordance, Radiologic, Pathologic, Lung cancer, Saint Paul's Hospital Millennium Medical College, Interventional radiology, Retrospective Chart Review

1. Introduction

1.1. Background

Thoracic lesions include variety of benign and malignant conditions of the lung, pleura, mediastinum and vertebra. These lesions are common in both the developing and developed world, including Ethiopia contributing significantly to the global disease burden.

Malignant conditions of the lung mainly imply lung cancer and metastasis. Primary lung cancer is a malignant tumor that originates in the tissues of the lung. Based on the type of the malignant cells primary lung cancer can be broadly classified into two as non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). NSCLC includes several subtypes including adenocarcinoma, squamous cell carcinoma and large cell carcinoma. It is also known that there are other uncommon forms of primary lung cancer, such as carcinoid tumor, pleuropulmonary blastoma, adenosquamous carcinoma, salivary gland type carcinoma, and others(1). From these histologic types about 15% of lung cancers are SCLC and the remaining 85% represent NSCLC(2).

Among the multiple risk factors associated with lung cancer, smoking stands out as the leading preventable risk factor(2). A meta-analysis examining the risk of smoking, involving over 7 million individuals and more than 50,000 incident lung cancer cases, revealed a pooled multiple-adjusted lung cancer relative risk of 6.99 in women and 7.33 in men(3). However, findings from a study on clinical characteristics and molecular profiles of lung cancer in Ethiopia suggest a different pattern, as lung cancer cases in Ethiopia often occur without significant personal tobacco use and at a younger age, presenting at later stages(4). This study proposed that exposure to biomass fuel could be a more significant risk factor(4). Additional risk factors include second hand smoking, radon exposure, asbestos, other environmental exposures and family history(2).

Benign conditions of the lung and pleura are also common and include masses and inflammatory diseases including bacterial, fungal, parasitic and viral infections which sometimes mimic malignant on radiologic imaging. Bacterial pneumonia, which is one of the frequent causes of hospitalization, is an acute pulmonary infection caused by different groups of bacterial species. Another prevalent infectious disease of the lungs is tuberculosis (TB), which is a contagious bacterial infection caused by *Mycobacterium tuberculosis*. Even though it primarily affects the lungs, TB may also involve other extrapulmonary sites such as the pleura, lymph nodes, bones,

abdomen, central nervous system, meninges and the genitourinary system. Lung infections can also be caused by fungi, particularly in endemic regions and in immunocompromised individuals. These include *Pneumocystis pneumonia*, aspergillosis, histoplasmosis, coccidioidomycosis and cryptococcosis. Additional inflammatory lung lesions presenting as lung masses include infected congenital cysts, organizing pneumonia, and post-infectious or autoimmune linked granulomas such as those associated with sarcoidosis and granulomatous polyangiitis.

Similarly, the mediastinum can also be affected by a range of benign lesions and malignant primary and metastatic tumors, the majority of which present in the form of mediastinal masses. The mediastinum is the central part of the thoracic cavity which is bordered anteriorly by the sternum, posteriorly by the vertebral cavity and laterally by the pleural cavity enclosing the lungs on either side. It contains vital tissues and organs including the heart and major vessels, esophagus, the trachea, thymus, lymph nodes, nerves and other structures. It is divided radiologically as anterior, middle and posterior mediastinum. The most frequent etiologies of anterior mediastinal masses are thymic malignancies and lymphoma, with approximate incidences of 35% and 25% respectively(5). Infections like TB can also involve the mediastinal structures including the lymph nodes, skeletal tissues, and cardiac structures.

Diagnosis of intrathoracic lesions requires clinical data and laboratory investigations. Nevertheless, overlapping symptoms, such as fever and weight loss, are frequently associated with both infectious and malignant illnesses, leading to uncertain clinical diagnosis. Radiologic imaging is the next investigative modality for intrathoracic lesions which includes chest x-ray, ultrasound, chest CT, MRI and PET Scan. However, neoplastic and infectious pathologies could still demonstrate similar nonspecific imaging features. In such circumstances and if specific pathologic diagnosis to initiate specific treatment is mandated, the next step would be taking biopsy or FNAC. Intrathoracic tissue biopsy includes image guided percutaneous biopsy, bronchoscopy and transbronchial biopsy, endobronchial ultrasound guided biopsy, video assisted thoracoscopic surgery and open surgical biopsy.

Image guided percutaneous biopsy/FNAC is one of common medical procedures done for diagnosis of intrathoracic lesions. These well-established minimally invasive technique for the diagnosis of thoracic malignancies is done by trained radiologists mostly interventional radiologists or chest imaging subspecialists under guidance of CT-scan, real time ultrasound or

fluoroscopy. Tissue sample are then taken either by core needle biopsy or fine needle aspiration. CT guided lung biopsy has a sensitivity of 90% and a specificity of 97%, with a false-positive rate of 1–2% (6). The sampled tissue is then examined by the pathologist to give a specific cytohistologic diagnosis.

1.2. Statement of the problem

According to the most recent 2022 GLOBOCAN estimate, primary lung cancer is the most common carcinoma in the world with an estimate of 2.48million new cases(7). It is also the leading cancer in mortality with an estimate of 1.8million deaths in 2022(7). Across Africa, lung cancer ranks as the 7th most common cancer, representing 4.2% of new cancer cases and 6% of cancer-related mortality(8). In East Africa, however, lung cancer is relatively less prevalent, ranking as the 12th most common cancer and contributing to 2.2% of new cancer cases and 2.9% of cancer-related deaths(9). Nonetheless, in Ethiopia, lung cancer maintains a higher rank than the regional East African status, standing as the 9th most common cancer, with a prevalence of 2.4 cases per 100,000 population over five years, and accounting for 3.1% of new cancer cases and 4.4% of cancer-related deaths(10).

Despite being preventable and treatable, infectious diseases like tuberculosis (TB) continue to pose a significant threat worldwide. It is estimated that a quarter of the global population is infected with TB, resulting in approximately 10.6 million new cases and 1.3 million deaths each year(11). The burden of such infectious chest pathologies is particularly severe in low-income countries, with Africa having the highest annual incidence rate of 208 cases per 100,000 people, as reported in the 2023 global tuberculosis report(12). Ethiopia, as identified in the same global report, remains one of the 30 high-burden countries for TB, with an annual TB incidence rate of 126 cases per 100,000 people in 2022, underscoring the ongoing challenges in combating this disease(12).

Mediastinal lesions both benign and malignant are also not so rare in our clinical practice here in Ethiopia, SPHMMC. For example, lymphoma is one of the common mediastinal tumors with non-Hodgkin lymphoma being 5th common cancer in Ethiopia based on incidence; while Hodgkin's lymphoma ranks the 20th (10)

Despite the above-mentioned burden of the diseases, we only have very few studies that focused on thoracic masses in Ethiopia. Especially to our knowledge no published report was found on

radiologic and pathologic correlation of thoracic masses after image guided biopsy. This is despite the fact that there were multiple similar studies done in other countries. This can be explained by the fact CT-guided biopsy is a recent introduction in Ethiopia. Radiologist especially here in our country report chest imagings before any pathologic evidence was done and only sometimes do they know what the histological findings of their reports turned out to be. Even when they know the finding of their patients, it will be only on a specific case they reported, not compiled report of multiple cases. This is a gap that needs to be filled since practicing radiologists and radiology residents at SPHMMC specifically and in Ethiopia in general who report multiple chest imagings have to practice evidence-based medicine, appropriate to the epidemiology of their working environment rather than relying on outside studies only.

1.3. Significance of the Study

Understanding what the histopathologic findings of chest pathologies initially diagnosed on imaging on a certain population is very crucial for both the clinician and the radiologist. The radiologist will use the histopathologic findings to give further recommendations, as well as it will be of help on how subsequent follow-up radiologic imagings should undergo. Above all compiled data on a certain population showing the concordance between the imaging and the histopathologic findings will help the radiologist and radiology residents on putting appropriate diagnoses and differentials for the future. This is especially important considering the epidemiologic difference between the developed nations where standard radiologic books are written with that of developing nations like Ethiopia. For instance, one could anticipate that, more frequently in Ethiopia than in western nations, suspiciously malignant-appearing masses on chest CT scans would be pathology-proven infections like tuberculosis.

In Ethiopia, CT-Guided intrathoracic biopsy was started in 2016 in BLH(13). In SPHMMC it was started on the previously operational 64 slice CT-scan machine. Currently it is also being done by the new 128 slice CT scan machine by our consultant interventional radiologists and interventional radiology fellows under the guidance of the consultants. As one may anticipate ultrasound guided biopsy and FNAC were started much earlier.

Despite the presence of image guided biopsy services, to our knowledge no study was published to prove the contribution it holds in clinical practice of our hospital. This study attempted to demonstrate the extent to which our radiologic reports were consistent with the histopathologic

findings, thereby giving radiologists and radiology trainees at Saint Paul's Hospital and in Ethiopia generally an idea of what to expect in their future practice.

Our thesis also showed how much guided imaging is contributing for our clinical practice. We can determine from our research how many of the biopsies performed by our interventional radiology department provided sufficient samples for the pathologist to make a certain diagnosis. Conversely, we were only be able to determine the percentage of inadequate samples without assessing most of the contributing factors. This is because assessing the reason for inadequate sampling requires a prospective study examining the circumstances where the samples were taken, location and size of the lesion, instrument types and other factors. Our study tried to shade some light on the general data of the samples taken while encouraging further prospective studies.

2. Literature Review

Lung lesions include a wide range of etiologies and differing clinical presentations, which makes diagnosis extremely difficult. To choose the best course of action for treatment and to maximize patient results, an accurate diagnosis is essential. Image-guided Fine-needle aspiration cytology (FNAC) and transthoracic biopsies have become useful diagnostic tools for assessing suspected lung lesions. Under radiological guidance, these procedures enable focused sampling of lesions. Nonetheless, in order to fully utilize these image-guided sample strategies, assessments of concordance between pathology findings and radiological imaging results are required. They are essential to figuring out how accurate imaging reports are in diagnosing lung lesions and for evaluating the factors driving radio-pathologic discordance. The success rate of image-guided sampling of thoracic lesions, factors affecting the success rate, and possible complications of the procedure can also be assessed by such investigations. This literature review aims to explore the current state of knowledge regarding these issues.

The degree of concordance between pathology findings from image-guided transthoracic biopsy and radiological imaging results in individuals undergoing diagnostic evaluation for suspected lung lesions has been the subject of numerous researches. In a recent 2023 investigation on routine radiology-pathology concordance of CT-guided lung biopsies in 828 patients, it was reported that 27% of cases were non-malignant. Among these non-malignant cases, 62% were concordant with imaging findings, while 24% were discordant, and the remaining 14% were deemed indeterminate. Interestingly, all malignant results were concordant with imaging findings. In this investigation, pathology that is consistent with imaging results was referred to as concordant; pathology that cannot explain imaging results was referred to as discordant; and pathology that can explain imaging results but raises the possibility of malignancy was referred to as indeterminate (14). A similar study conducted in 2022 also discovered that 11% of the 926 cases they looked into were discordant, 57% of these cases proving to be malignant subsequently(15).

Another study conducted in 2015 used a unique method to look at imaging-histologic discordance in 186 individuals who underwent percutaneous lung biopsies. Because patient histories and individual findings can vary widely, evaluating concordance at the individual level could be laborious and complex. Instead, the researchers used Fleiss' kappa statistic to assess inter-reader agreement of both radiological and pathological reports. Cohen's kappa was then utilized to

evaluate the agreement between the pathology and radiological results. For four specific diagnostic categories, the results showed a moderate concordance between radiography and pathology, with fair agreement noted for the combined overall category. The following categories' kappa values for concordance were found: malignant (0.448), primary lung cancer (0.517), lung metastasis (0.449), benign (0.510), and overall agreement (0.381). Twelve discordant benign instances were also found in the study; with four of them being false negatives, leading to a delay in diagnosis. Six cases had initial radiologic diagnoses of malignancy, but had specific benign histologic diagnoses (granulomatous infection, hamartoma, and amyloidoma) confirming false positive radiologic diagnosis of malignancy. They stated that the presence of various focal lung pathologies, non-specificity of reports (similar imaging features may have different histologies), and the absence of a standardized vocabulary or method for reporting degree of suspicion on thoracic radiologic reports—unlike in other areas like the breast, which uses BIRADS—may have contributed to the moderate concordance(16).

In one study conducted on exploring radiologic-pathologic correlation for non-diagnostic CT-guided lung biopsies 81 incidences of non-diagnostic lung biopsies out of 1525 lung biopsies were found. It is noteworthy that 42% of these instances had a final malignant determination with a 58% negative predictive value (NPV). The investigators suggested that thoracic radiologists examine nondiagnostic lung specimens for radiologic-pathologic concordance to identify patients who would benefit from a second biopsy, highlighting the importance of radiologic-pathologic correlation for diagnostic accuracy(17).

Two distinct studies conducted in consecutive years in 2014 and 2013 delved into the diagnostic value and cytologic-radiologic correlation of CT-guided lung biopsies. The first examined cytologic-radiologic correlation using transthoracic CT-guided fine-needle aspiration (FNA) for lung and mediastinal masses in 74 cases, utilizing cytology as the gold standard. They found predominant lesion to be malignancy (85.1%), followed by suspicions of malignancy and inflammatory pathology (5.40% each). Of the malignant lesions adenocarcinoma being the most common subtype (48%), followed by squamous cell carcinoma (40%), small cell carcinoma (8%), and undifferentiated carcinoma (4%). Their study reported a cytoradiological correlation rate of 89.2%, with 100% concordance observed for metastatic and mediastinal lesions (18). In comparison, a larger cohort of 623 cases were examined in the second study to determine the

diagnostic utility of CT-guided lung biopsy for malignant tumors. They found a high positive rate of 99.2%. The most common pathologic classification (62.1%) was adenocarcinoma, followed by squamous carcinoma (26.6%), small cell lung cancer (4.8%), and undifferentiated cancer (2.9%) (19). In the first study discordance was found in five primary lung lesions. Interestingly, granulomatous inflammation and pyogenic abscess were the cytologic findings in two of discordant cases, which had radiologic malignant diagnosis(18). Two studies, one conducted in India and the other in Italy also found comparable results with adenocarcinoma being the most common tumor followed by squamous cell carcinoma and small cell carcinoma respectively(20,21). This is in keeping with the prevalence of lung cancer in the general populations indicating the disease prevalence from image guided biopsy follows the general population trend (22). The higher prevalence of malignancy in males and the association of malignancy with tobacco usage especially for squamous cells carcinoma is also in keeping with the general trend (7,18,22)

The literature on image-guided thoracic biopsy demonstrates its safety, efficacy, and high diagnostic yield across multiple facilities worldwide. In their 2019 study, César et al. discovered that 235 patients' CT-guided transthoracic core-needle biopsies of lung and mediastinal lesions had an overall accuracy of 91.1%, with good sensitivity (87.1%) and specificity (98.8%) (23). Technical success rate was 87.2% with a low mortality rate of 0.12% in a comparable study conducted on 867 cases in 2017 (24). Likewise, a large study on 1108 cases, revealed a high degree of sensitivity (95.7%), specificity (100%), and accuracy (97.0%) for the detection of malignancy along with a technical success rate of 99.6% (25). Similarly high diagnostic yield of 96.6% on 1000 patients was reported for CT-guided FNAC and/or core needle biopsies(26). In a 2013 Indian study, which examined 130 cases with CT-guided FNAC, 95% diagnosis accuracy rate was reported (20). A slightly lower diagnostic accuracy of 78.6% for malignancy detection was found in an earlier 2009 investigation with 139 patients(27). These studies underscore the robustness and effectiveness of image-guided thoracic biopsy techniques in diagnosing thoracic lesions across different populations.

Various predictive factors, including lesion size, location, and nodule density, have been investigated to evaluate the efficacy of image-guided transthoracic biopsies. The above mentioned older 2009 study observed that nodules larger than 1.5 cm were more likely to yield diagnostic

specimens compared to smaller nodules, a finding corroborated by a more recent 2019 study (27,28). One above mentioned study also discovered that lesions in the lower lobe and lesions with a diameter of less than 1 cm were major risk factors for diagnostic failure(25). In their investigation of size-dependent variations in diagnostic accuracy, writers of one paper observed that nodules with sizes ranging from 0.7 to 3 cm showed variable degrees of accuracy, with the maximum accuracy observed in those between 2 and 3 cm (29). They also discovered that lesion location was a factor in diagnostic accuracy, with nodules in the middle and lingula exhibiting the highest accuracy rates (90.9%), and those in the pulmonary upper lobe showing the lowest accuracy rates (84.2%), followed by those in the lower lobe (85.3%) (29).

Transthoracic biopsies, while generally considered safe, carry the risk of minor complications, with pneumothorax and hemorrhage being the most frequently reported in the literature. According to a study from Sao Paulo university, Brazil, pneumothorax occurred in 20.8% and hemorrhage in 15.7% of cases(23). In a similar vein, other researchers recorded a rate of 1.8% for hemothorax and 25.7% for pneumothorax, of which 6.5% necessitated chest tube drainage(24). Pneumothorax was once again the most common complication, happening in 5.7% of patients in a different report (30). Other published papers also showed pneumothorax in 17% and 34.5% patients and hemoptysis in 6.9% and overall minor procedure-related problems in 47.3% of patients (25,27,31). However, one Greece study found that hemorrhage was more common (6.2%) than pneumothorax (2.8%), and lesions smaller than 4 cm were associated with a threefold increased risk of sequelae(26).

Researches specifically addressing image-guided mediastinal biopsies have also shown how effective this technique is for acquiring samples. The results of a meta-analysis on 1310 patients showed that CT-guided core needle biopsy (CNB) of mediastinal masses had high pooled proportions of diagnostic yield (92%) and accuracy (94%) (32). Another report identified only 11.3% of biopsies resulted in diagnostic failure, with 97.2% of biopsies producing appropriate sample(33). Similarly, it was found that the material obtained was satisfactory in 95.2% of patients in a similar study(34). However, one 2015 report from Boston USA observed a comparatively lower diagnostic yield of 77% for CT-guided percutaneous biopsy of anterior mediastinal masses in their study involving 52 patients (35). These findings collectively highlight the overall effectiveness of image-guided mediastinal biopsy in obtaining diagnostic samples.

Over the course of the historical evolution of lung biopsy methods in Ethiopia, notable transformations have taken place. The earliest published lung biopsy report, conducted by Teklu in 1986, utilized a high-speed drill and relied solely on X-ray for lesion localization, resulting in a modest diagnostic yield of 49%(36). A pivotal advancement emerged in 2016 with the introduction of thoracic CT-guided fine-needle aspiration (FNA) by American radiologists from the Medical University of South Carolina to Tikur Anbessa Hospital(13). Despite the likelihood of earlier adoption, the precise introduction of ultrasound-guided sampling is unclear. We found only two published studies that explored image-guided sampling in Ethiopia, both focusing on ultrasound-guided FNA. G. Assefa's initial report in 2000 at Tikur Anbessa shed light on diagnostic and interventional experiences in 72 patients, underscoring the role of such procedures in avoiding unnecessary surgeries, reducing morbidity and mortality, cutting costs, and aiding treatment planning(37). In a recent 2019–2020 study, Simon Shiferaw Melese and colleagues assessed the yield of ultrasound-guided FNA at Black Lion Hospital and found that 75.7% of aspirates were appropriate for cytologic diagnosis; with no significant variations observed based on lesion location, sampling techniques, needle passes, or operator expertise(38). To the best of our knowledge, no research from SPHMMC or Ethiopia has looked at radiologic-pathologic concordance or diagnostic yield of transthoracic image-guided biopsy,

In conclusion, the literature emphasizes the value of concordance studies and evaluates the technical success rate of image-guided biopsies in the diagnosis of thoracic lesions. The literature shows a moderate degree of radio-pathologic concordance, which may be brought about by the lack of standardized reporting guideline. Adenocarcinoma is the most prevalent malignancy. Many studies also support the safety and effectiveness of image guided sample techniques, and lesion location and size are found to be important factors affecting the success of biopsies. Minor complications, notably pneumothorax and hemorrhage, may occur, emphasizing the importance of careful procedure management. The majority of sampled lesions in the literature were diagnosed as malignant. However, most reviewed papers were from developed countries, leaving a gap in understanding prevalence in developing countries like Ethiopia, where infectious chest lesions such as TB are more common. Our study intends to fill this vacuum in the literature by investigating the application of transthoracic biopsy in the Ethiopian setting, particularly in SPHMMC, and may open the door for further research.

3. Objectives

3.1. General objectives

- To assess the concordance between radiologic and pathologic findings of patients with image guided transthoracic biopsy/FNAC.

3.2. Specific objectives

- To determine the level of agreement between chest CT reports and histopathologic results in patients with thoracic mass lesions.
- To identify the prevalence of different benign and malignant lesions among patients who visited SPHMMC interventional radiology unit for image guided transthoracic biopsy/FNAC.
- To identify pathologic diagnostic yield of image guided transthoracic biopsy/FNAC done at SPHMMC interventional radiology unit.
- To identify some of the potential factors affecting the targeted sample pathologic yield of image guided transthoracic biopsy.

4. Methodology

4.1. Study setting

This study was conducted at St. Paul's Hospital Millennium Medical College (SPHMMC) in Addis Ababa Ethiopia. It is one of the tertiary referral hospitals in the country and governed by the Federal Ministry of Health (FMOH). St. Paul's Hospital Millennium Medical College is a teaching hospital for undergraduate and postgraduate medical students enrolled in various programs at the College. The hospital has a total bed capacity of more than 700 beds, and on average evaluates 1200 emergency and outpatient clients daily. The hospital college provides both academic and clinical service in various disciplines.

The department of radiology interventional and vascular imaging unit provides image guided transthoracic sampling service using ultrasound and 128 slice CT-scan.

4.2. Study period

This study was conducted from June to August 2024.

4.3. Study design

This retrospective patient's clinical chart review study included a diverse population of patients sent for image guided transthoracic tissue sampling after lung or mediastinal lesions were identified on chest CT-scan. Data collection template was prepared to collect data based on a review of literature.

4.4. Study population

- **Source Population:** All patients who visited interventional and vascular radiology unit for image guided transthoracic biopsy/FNAC after chest CT done in SPHMMC during the study period.
- **Study Population:** All patients who had image guided transthoracic biopsy done at interventional and vascular radiology unit after a mass/nodule detected on chest CT-scan in SPHMMC during the study period.

- **Study Units:** Medical records of patient with mass/nodule detected on chest CT and had image guided transthoracic biopsy/FNAC and histopathologic result during the study period.

Inclusion Criteria:

- All patients who visited interventional and vascular radiology unit for image guided transthoracic biopsy after chest CT done in SPHMMC during the study period.

Exclusion criteria:

- Missing CT-scan or biopsy results.
- Patients referred from other hospitals for image guided transthoracic sampling and does not have chest CT-scan result.
- Chest CT lesion was not a suspicious nodule or a mass
- Biopsy done for other tissue than lung or mediastinal tissue (e.g. chest wall, vertebral)
- Histopathology known at the time of diagnostic interpretation

4.5. Sample size determination

A total of 148 image-guided transthoracic CNB/FNAC procedures were scheduled at the IR unit of SPHMMC from November 2019 to May 2024 following chest CT scans showing suspicious nodules or masses. Out of these, 7 cases were canceled: two due to small nodule size less than 1 cm, with follow-up recommended by the interventional radiologist, and five due to size reduction on repeat imaging while on empiric antibiotic/anti-TB treatment. Of the remaining 141 cases, 39 were excluded due to loss of chart records or incomplete data. The final sample size included in our study was 102 cases where image-guided transthoracic CNB/FNAC was performed.

4.6. Study variables

4.6.1. Independent variables

- Age
- Sex
- Smoking history

- Lesion location
- Lesion size
- Type of image guidance used
- Immediate post-procedural complication.
- Lesion histologic finding (benign, malignant)
- Lesion radiologic diagnoses.

4.6.2. Dependent variables:

- Radiologic-pathologic concordance level
- Biopsy sampling diagnostic yield/success

4.7. Operational definition of variables

- Concordant: Pathologic finding that is consistent with the chest CT imaging report
- Discordant: Pathologic finding that is not consistent with the chest CT imaging report
- Discordant benign: Imaging interpretations indicate a malignant lesion but the pathology was benign.
- Discordant malignant: Imaging interpretations indicate a benign lesion but the pathology was malignant.
- Diagnostic/successful sample: adequate sample taken from the target lesion enough for pathologic interpretation.

4.8. Data Collection Procedure

Data were collected from patient charts by the principal investigator and one trained radiology resident from June 1 to June 15 2024. The data were collected by filling in the data-collecting template for each patient. A structured data collecting template containing important variables gathered from literature including histopathologic results was used.

As our institution does not currently have a standard for reporting chest CT scans, individual reporting discrepancies were expected, unlike the standardized reporting and data systems for breast (BIRADS), prostate (PIRADS), etc. To overcome this pitfall in our paper we used an approach implemented by a 2015 paper done in Los Angeles, California, USA (16). Each chest CT report was provided to three volunteering radiology residents who are familiar and experienced

not only on how to read and interpret but also on how to write chest CT reports. Their task was to assign each report as benign lesion (non-neoplastic mediastinal lesion), malignant (not otherwise specified), primary lung (pleural) malignancy or mediastinal neoplastic tumor and metastatic lesion. For histopathologic concordance assessment the majority(dominant) imaging classification was used.

4.9. Data management and Analysis

The collected data was coded and entered into kobo toolbox, cleaned, stored and transferred to Statistical Package for Social Sciences, version 27 (SPSS v27). The data was analyzed using SPSS version 27 software. Descriptive statistics using measures of frequency was used to summarize categorical variables. Then the information presented by using simple frequencies, summary measures, tables and figures.

To evaluate agreement kappa statistics was employed. Using Fleiss' Kappa, the agreement among readers of the radiologic report was evaluated first. The degree of agreement between the radiologic and pathologic results was next evaluated using Cohen's Kappa statistics, which offers a measure of concordance beyond chance. The interpretation of Kappa values was used to show the degree of agreement as follows: values ≤ 0 as indicating no agreement and 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41– 0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement(16,39). Finally, binary logistic regression was employed to identify potential factors associated with sampling success. Independent variables such as age, gender, lesion size, lesion location, smoking history, and procedural complication were included in the model, with sampling diagnostic yield as the dependent variable. Due to retrospective nature of the study, image guided sampling procedure associated factors which are also potential factors of sample success were not included and this is taken as limitation of the study. Odds ratio, P-value and 95% CI for odds ratio are used for testing significance and interpretation of results. Variables with P-value ≤ 0.05 were considered as statistically associated with outcome variable. Adequacy of the final model was checked using the Hosmer and Lemeshow goodness of fit test where p value of >0.05 (P=0.967) showed the final model fitted for the data well.

4.10. Data Quality control

Data quality was assured through appropriate and detailed patient record revision using checklists from data collection template. Then it was checked for its completeness, clarity and accuracy by the principal investigator. Incomplete data were excluded from study.

4.11. Ethical clearance

Ethical clearance was obtained from SPHMMC's research review board. Since this is a record review of anonymity, privacy and confidentiality was respected. There was and will not be any risk or benefit that go forth to individuals of the record.

4.12. Dissemination of Results.

The final findings of the study will be submitted to the department of Radiology and MRT, SPHMMC, in the form of a written document. The result will also be presented for fulfilment of final year post-graduate course in radiology to the department and all other interested bodies. Other Interested hence invited departments might include the department of internal medicine, especially the pulmonology unit, department of surgery, especially cardiothoracic surgery unit, department of oncology and department of pathology staffs and trainees. Publications will be made in the Peer-reviewed reputable journals.

5. Results

5.1. Sociodemographic Characteristics and Response Status Distribution

This study involved 102 participants, comprising 52 (51.0%) males and 50 (49.0%) females. The average age of the participants was 47.96 years, with a standard deviation of 18.23 years.

Table 1

Sociodemographic characteristics of the respondents (N=102)

Variable	Description	Frequency	Percent
Age	≤ 10 years	2	2
	11-20yrs	6	5.9
	21-30yrs	12	11.8
	31-40yrs	18	17.6
	41-50yrs	16	15.7
	51-60yrs	22	21.6
	61-70yrs	18	17.6
	≥71yrs	8	7.8
Sex	female	50	49
	male	52	51

5.2. Clinical history

In our research, none of the 102 study participants had a family history of lung cancer. Ten patients had a documented history of smoking in their medical records, with nine being male. The majority of subjects, 90 (88.2%), did not have a documented history of smoking, while smoking status was not recorded for two subjects.

5.3. Sampled lesion location

All 102 patients underwent image-guided transthoracic tissue sampling at SPHMMC interventional radiology unit. Among them, 72 (70.6%) had samples taken from the lung, while 21 (20.6%) were from the mediastinum, and the remaining 9 (8.8%) were from the pleura as illustrated in Figure 1. Figure 2 illustrates the distribution of lesion locations by depicting the frequencies and percentages of the lesions in specific right or left lobes.

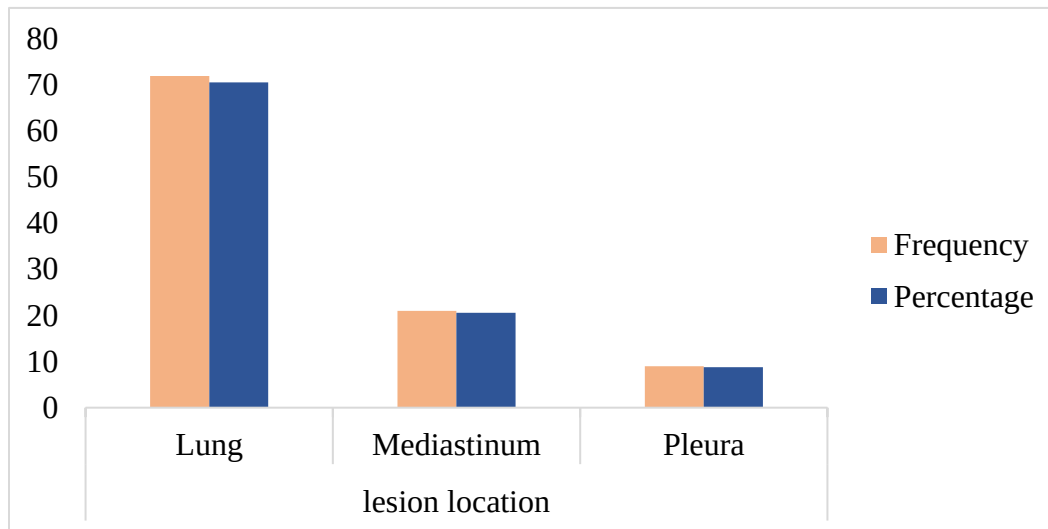


Figure 1: thoracic site of the lesions undergoing tissue sampling

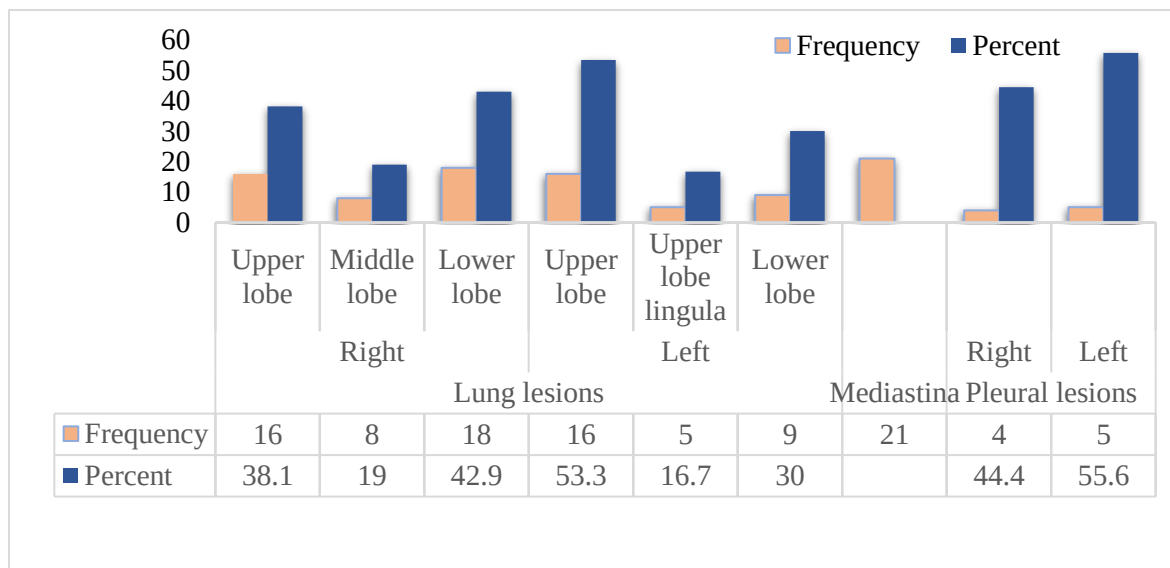


Figure 2: Specific site and lobar location of sampled thoracic lesions

5.4. Size distribution of sampled lesions

The size of the thoracic lesions sampled under image guidance ranged from 1.2cm to 26cm, with a median size of 6cm and an interquartile range of 5.53cm (3.47cm - 9cm). This distribution is illustrated in the box plot provided below (Figure 3).

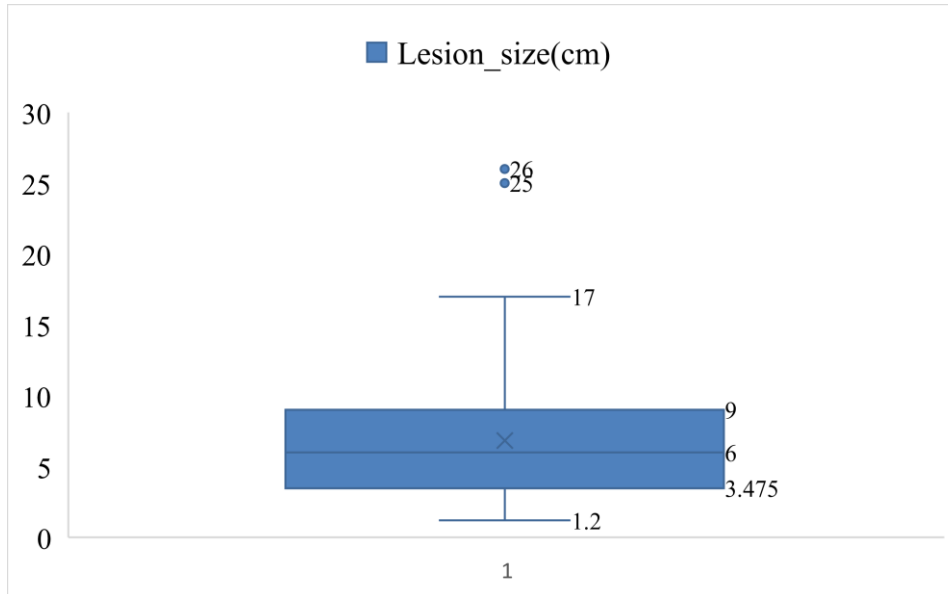


Figure 3: box plot showing distribution of size of the sampled thoracic lesions

5.5. Tissue sampling techniques used

CT-guided and ultrasound-guided transthoracic lesion sampling techniques were employed for the 102 subjects. Among these, 57 (55.9%) samples underwent CT-guidance specifically for core needle biopsies. Ultrasound-guided sampling was conducted for 45 (44.1%) patients, with 2 cases having fine needle aspiration cytology and the remaining 43 cases undergoing core needle biopsies. Figure 4 depicts the distribution of sampling techniques used in the study.

5.6. Immediate post-procedural complications

The charts of the study subjects were reviewed to identify any immediate complications documented during the study. Among the patients, the sole complication observed was minimal pneumothorax, which occurred in 7 individuals, representing 6.9% of all procedures conducted.

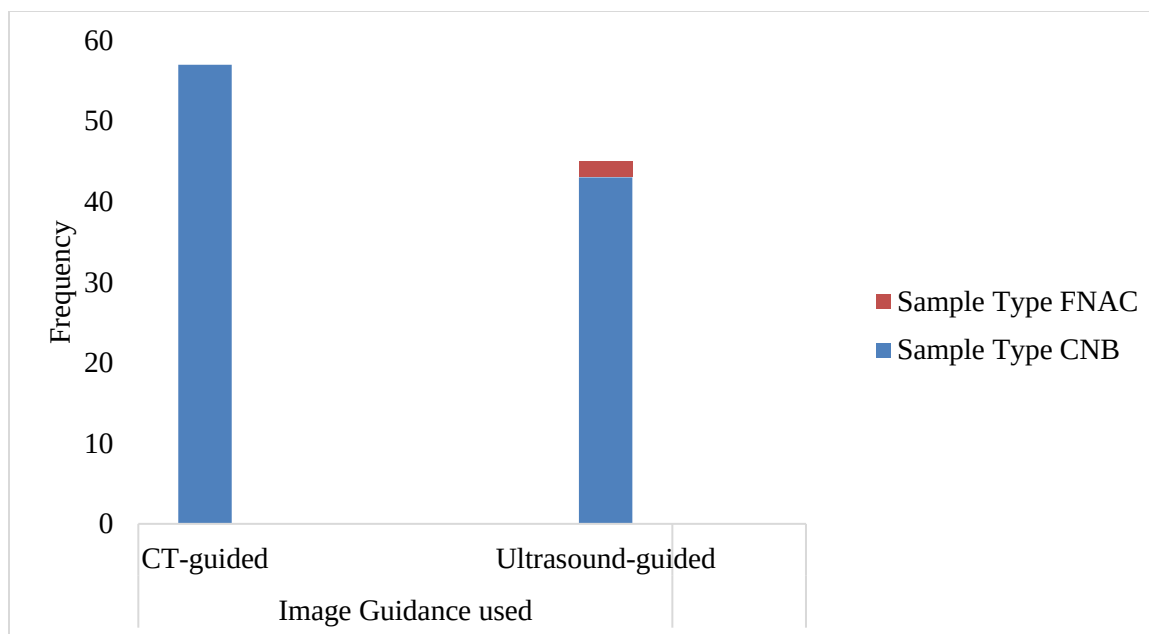


Figure 4: frequency of sampling techniques used (FNAC = fine needle aspiration cytology, CNB = core needle biopsy)

5.7. Diagnostic yield of image guided transthoracic sampling performed at SPHMMC

Out of the 102 cases, 88 samples yielded a diagnostic pathology report, resulting in a diagnostic yield of 86.3% for image-guided transthoracic sampling at SPHMMC's interventional radiology unit. Fourteen samples (13.7%) were non-diagnostic, with 12 (85.7%) from lung lesions and 2 (14.3%) from mediastinal lesions. Ten of these non-diagnostic samples were reported as insufficient samples, three were normal alveolar spaces hence lung tissue and one of the samples were taken from a necrotic tissue. Table 2 illustrates the detailed breakdown of diagnostic and non-diagnostic outcomes.

Out of the 14 non-diagnostic samples, three underwent repeat sampling, revealing subsequent diagnoses of malignant lung lesions: adenocarcinoma and high-grade sarcoma (pleomorphic leiomyosarcoma) in the first two cases, and anterior mediastinal non-Hodgkin lymphoma in the third. Four patients were placed on follow-up, with one showing a documented decrease in lesion size on repeat imaging. However, there were no records of repeat imaging for the other three patients. For the remaining seven non-diagnostic cases, no subsequent plans or imaging reports were documented after the initial pathologic reports.

Table 2

Diagnostic yield of image guided transthoracic sampling by sampled lesion location(N=102)

		Final diagnostic yield	
		Diagnostic	Non diagnostic
Lesion location	Lung	60	12
	Mediastinal	19	2
	Pleural	9	0
Total	Frequency	88	14
	Percentage	86.30%	13.70%

Since three initially non-diagnostic cases later received pathologic diagnoses upon repeat sampling, the total number of patients with pathologic diagnoses following transthoracic sampling increased to 91. These subjects were included in the assessment of pathologic and radiopathologic concordance.

5.8. Pathologic Diagnoses

Among the 91 study participants with confirmed pathologic diagnoses, the majority underwent sampling from the lungs (62), followed by the mediastinum (20), and pleura (9). Notably, all 20 mediastinal lesions were diagnosed as neoplastic, a term encompassing both malignant and benign masses such as benign thymomas. Of these samples, 55 from the lungs and 6 from the pleura were identified as malignant (see Table 3). To facilitate analysis, malignant lesions were further categorized as primary, metastatic, or not otherwise specified, a classification method also applied to radiologic findings for concordance assessment.

Table 3

Categorized pathologic findings after image guided transthoracic sampling by lesion location (N=91)

		Pathologically benign (Non neoplastic mediastinal) lesion	Pathologically malignant (neoplastic mediastinal) lesion		
			Primary	Metastatic	Not otherwise specified
Lesion location	Lung	7	50	4	1
	Mediastinal	0	17	1	2
	Pleural	3	0	5	1

Table 3 also indicates that no primary pleural malignancies were identified. Among the pleural samples, five were metastatic—four originating from primary lung lesions, while the fifth was diagnosed as adenocarcinoma of unknown origin. The remaining one case was suspicious malignant peripheral nerve sheath tumor.

Ten benign pathological lesions were found in our study; three were pleural lesions and seven were lung lesions. Three cases of necrotizing granulomatous inflammation suggestive of tuberculosis, two cases of nonspecific chronic inflammation (one of which was later clinically diagnosed as sarcoidosis), two cases of solitary fibrous tumors of the pleura, one case of fibrotic process, one case of suppurative inflammation without granuloma, and one case of an unidentified benign lesion were among these benign pathologies.

From the pathologic reports of our study subjects, a total of 54 primary lung malignant lesions were found, including the metastatic pleural lesions. Equal number of female and male patients (27 each) was seen among patients who had primary lung cancer and the mean age in these patients was 53.81 ± 15.12 yrs. With 68.5% of the cases, adenocarcinoma was the most frequent primary lung carcinoma, followed by squamous cell carcinoma (16.7% of the cases). Three carcinoid

tumors, one adenosquamous cell carcinoma, one pleomorphic leiomyosarcoma, and one primary lung synovial sarcoma were among the rare non-small cell lung cancers found. The distribution of primary malignant lung lesions is shown in Figure 5 below.

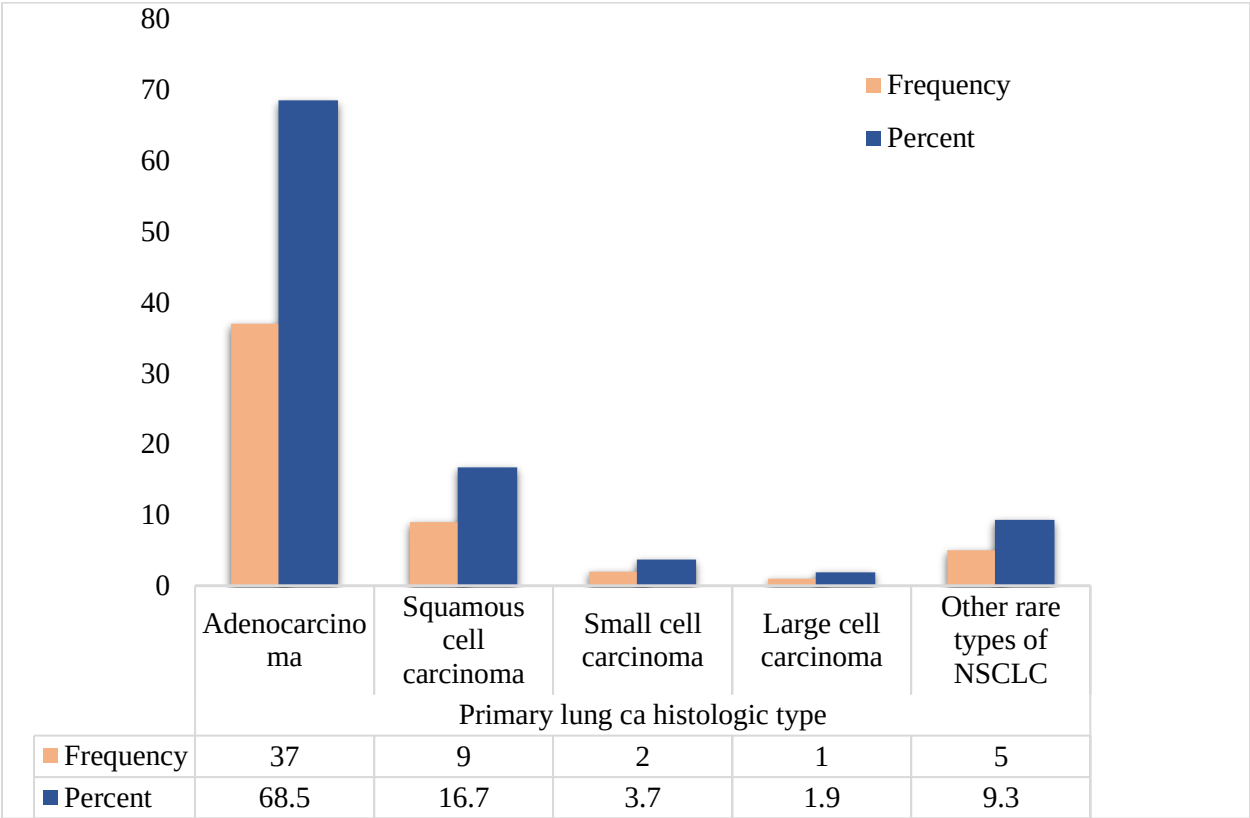


Figure 5: histopathologic types of primary lung malignancies among study subjects

As depicted in the bar chart in Figure 6, thymoma was the most common neoplastic lesion among the sampled mediastinal lesions, making up 30% of the cases. This was followed by non-Hodgkin lymphoma, which accounted for 25% of the cases, and Hodgkin lymphoma, representing 15% of the cases. When combine lymphoma represent 40% of the cases thereby being the most common mediastinal neoplastic lesion detected among our study subjects.

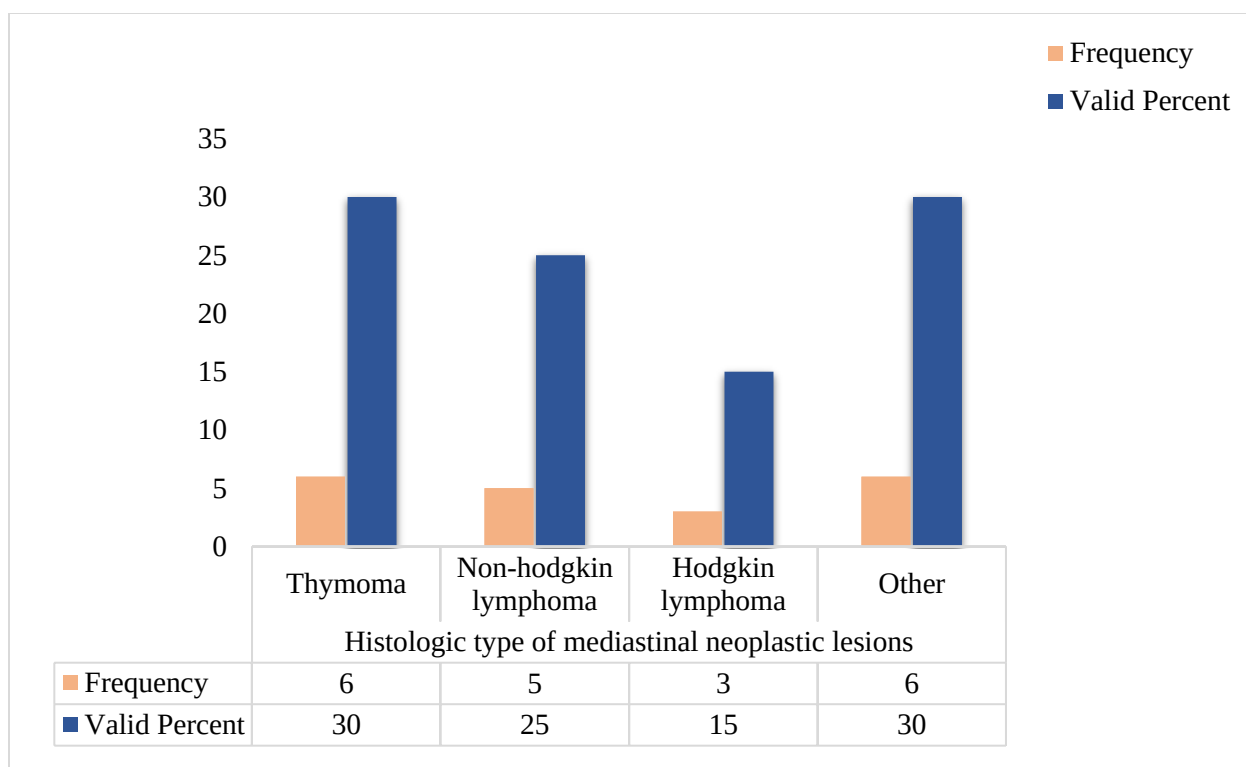


Figure 6: histologic classes of mediastinal neoplastic lesions among study subjects

5.9. Concordance study among readers/interpreters of radiologic reports

In this study, due to variations in chest CT reporting styles among radiologists and trainees, direct comparison of radiologic reports with pathologic findings posed challenges. Chest CT reports were categorized into four groups: malignant (not-otherwise-specified), primary lung (pleural) malignancy or mediastinal neoplastic tumor, metastatic lesion, and benign lesion (non-neoplastic mediastinal lesion). Three radiology residents independently classified each report, showing almost perfect inter-reader agreement with a Fleiss' kappa value of 0.812 (95% CI: 0.729-0.895), as illustrated in Table 4. Based on this strong agreement, we proceeded to assess the concordance between radiologic and pathologic reports using the majority chest CT report category as the reference radiologic category.

Table 4

Fleiss Kappa score assessing inter-reader agreement in interpreting radiologic reports

Rating Category	Fleiss Kappa	Asymptotic 95% Confidence Interval	
		Lower Bound	Upper Bound
Malignant (not-otherwise-specified)	1	0.888	1.112
Primary lung(pleural) malignancy or mediastinal neoplastic tumor	0.812	0.7	0.924
Metastatic lesion	0.713	0.601	0.825
Benign lesion (non-neoplastic mediastinal lesion).	0.87	0.758	0.982
Overall Agreement	0.812	0.729	0.896

5.10. Concordance between the majority radiologic disease category and pathologic diagnoses

We categorized both the predominant radiologic category and pathologic diagnoses into corresponding categorical values and evaluated their agreement using Cohen's kappa coefficient. In instances where the pathologic report provided a definitive diagnosis, it served as the basis for subsequent clinical management decisions by the treating physicians for our study participants. Therefore, we used the pathologic diagnoses as the standard against which to assess the accuracy of the CT reports.

The combined Cohen's kappa value between the radiologic disease category and pathologic diagnoses was 0.406 (95% CI: 0.214-0.598), indicating borderline moderate agreement. Kappa values were also individually assessed for each disease category, revealing fair to borderline moderate agreement across categories, with the lowest kappa measure observed in the benign category, as depicted in Table 5.

Table 5

Cohen Kappa score assessing agreement between the majority radiologic disease category and pathologic diagnosis

Disease Category	Cohen Kappa	Asymptotic 95% Confidence Interval	
		Lower Bound	Upper Bound
Malignant (not-otherwise-specified)	0.389	-0.15	0.928
Primary lung(pleural) malignancy or mediastinal neoplastic tumor	0.407	0.189	0.625
Metastatic lesion	0.384	0.078	0.69
Benign lesion (non-neoplastic mediastinal lesion).	0.261	0.038	0.56
Combined	0.406	0.214	0.598

The percent agreement, which does not account for chance agreement, indicated an overall concordance of 80.2%, with 18 discordant cases observed. Upon assessing percent concordance by lesion location, the lowest agreement was noted for pleural lesions, showing only 33.3% concordance, detailed in Table 6. To address this variability, Cohen's kappa was recalculated focusing exclusively on lung lesions to mitigate the impact of discordant pleural cases. This analysis revealed a moderately improved overall agreement of 0.466 (95% CI: 0.209-0.723), with the highest kappa observed for metastatic lesions and the lowest for benign lesions, as shown in Table 7.

Eighteen discordant cases were identified, comprising 5 discordant benign lesions with a final pathological diagnosis of benign disease, and 13 discordant malignant lesions with a final pathological diagnosis of malignant disease. A list of these individual discordant cases, along with their corresponding radiologic and pathologic diagnoses, is provided in Table 8.

Table 6

Frequency and percent of concordance of disease category by location (N=91)

			Concordance	
			Concordant	Discordant
Lesion location	Lung	Frequency	52	10
		Percent of lung Lesions	83.90%	16.10%
	Mediastinal	Frequency	18	2
		Percent mediastinal Lesions	90.00%	10.00%
	Pleural	Frequency	3	6
		Percent of pleural Lesions	33.30%	66.70%

Table 7

Cohen Kappa score assessing agreement between the majority radiologic disease category and pathologic diagnosis for sampled lung lesions

Disease Category	Cohen Kappa	Asymptotic 95% Confidence Interval	
		Lower Bound	Upper Bound
Malignant (not-otherwise-specified)	*	*	*
Primary lung malignancy	0.483	0.208	0.757
Metastatic lesion	0.783	0.494	1.071
Benign lesion	0.227	-0.124	0.578
Combined	0.466	0.209	0.723

*Kappa value not calculated since only one case found

Table 8

List of radiologic and corresponding pathologic diagnoses of discordant cases(N=18)

Sample tissue location	Radiologic category	Radiologic diagnoses	Pathologic diagnoses	Frequency
Lung	Benign	Cavitating pneumonia, Angio-invasive aspergilloma	Malignant, Adenocarcinoma	1
		Hamartoma	Typical carcinoid tumor	1
		Organizing Pneumonia	Malignant, Adenocarcinoma	2
	Malignant	Lung carcinoma	Necrotizing granulomatous inflammation, TB	2
			Suppurative inflammation	1
			Negative for malignancy*	1
		Metastasis (thyroid)	Malignant, Adenocarcinoma	1
			Chronic non-specific inflammation (clinically sarcoidosis)	1
Mediastinal	Benign	TB spondylitis	Giant cell tumor of soft tissue	1
	Malignant	Lymphoma	Undifferentiated carcinoma (papillary thyroid carcinoma metastasis)	1
Pleural	Malignant	Mesothelioma	Secondary adenocarcinoma (Lung primary)	3
			Secondary adenocarcinoma (unknown primary)	1
		Metastasis (colonic carcinoma)	Fibrotic process	1
		Pleural based large mass likely lung carcinoma	Solitary fibrous tumor of the pleura	1

5.11. Factors associated with diagnostic failure

Since our study is a chart review, we did not assess procedural factors affecting the diagnostic yield of image-guided transthoracic biopsy and FNAC, such as the experience level of the radiologist. Lesion distance from the pleura was not also assessed as a variable since it was not regularly being mentioned on CT reports. However, we attempted to identify any potential factors influencing diagnostic yield from the data we collected. Although unassessed confounding factors limit the interpretation of these results, this analysis can direct future investigations.

To identify factors affecting diagnostic yield, we conducted a binary logistic regression analysis on eight variables: sex, smoking history, thoracic lesion location, laterality (right or left) of lung lesions, lobar location of lung lesions, image guidance used for the procedure, presence of documented complications (such as pneumothorax), lesion size, and age. Given the large lesion sizes in our study subjects, likely due to patients presenting at advanced stages, a cutoff of 2 cm was used (4). Only four cases had lesions smaller than 1.5 cm, a cutoff mentioned in the literature (27,28). From these study variables, three with a significance level of $P < 0.2$ were retained for subsequent multivariable logistic regression: patient age, lesion size, and presence of post-procedural pneumothorax. Multivariable regression analysis revealed that lesion size and post-procedural pneumothorax were the two variables that were statistically significant ($P < 0.05$).

As shown in Table 9 below thoracic lesions less than 2 cm had 6.052 times higher odds of yielding a non-diagnostic sample after image-guided transthoracic biopsy or FNAC compared to lesions greater than 2 cm (AOR = 6.052, 95% CI: 1.103-33.192).

Patients who had immediate post-procedural pneumothorax also had 6.854 times increased odds of yielding a non-diagnostic sample after image guided transthoracic biopsy or FNAC compared to patients who developed no such complication (AOR=6.854, 95% CI: 1.165-40.314).

Table 9

Bivariate and multivariable logistics regression analysis of factors associated with diagnostic yield of image guided transthoracic biopsy/FNAC

Variable	Category	Diagnostic yield		COR (95% CI)	AOR (95% CI)	P-value
		Non-diagnostic(%)	Diagnostic(%)			
Age	≤ 20yrs	1(12.5)	7(87.5)	0.619 (0.069-5.516)	1.131 (0.118-10.807)	0.915
	20-40yrs	1(3.3)	29(96.7)	0.149 (0.018-1.208) *	0.238 (0.028-2.053)	0.192
	≥ 40yrs	12(18.8)	52(81.3)	1		
Lesion size	≤ 2cm	4(50)	4(50)	8.4 (1.813-38.916) *	6.052 (1.103-33.192) **	0.038
	≥ 2.1cm	10(10.6)	84(89.4)	1		
Post-procedural pneumothorax	Yes	4(57.1)	3(42.9)	11.333 (2.212-58.08) *	6.854 (1.165-40.314) **	0.033
	No	10(10.5)	85(89.5)	1		

*P<0.2, **P<0.05

6. Discussion

An almost equal proportion of female and male study subjects were included in our study, with the majority being adults, and the mean age was 47.96 years. This distribution aligns with the known risk factor of age for lung disease(40). Additionally, the observation of only 10 patients with a smoking history is consistent with previous studies in Ethiopia, which indicated no significant personal tobacco use among lung cancer patients in our epidemiological context (4).

Most study subjects underwent lung biopsies, followed by mediastinal and pleural sites. The median lesion size was 6 cm (IQR: 5.53 cm), with only four cases under 1.5 cm. This larger lesion size likely reflects the advanced stage of disease at presentation in our setup as described in a study from Tikur Anbesa Hospital and radiologists' preference to avoid complications and non-diagnostic procedures with smaller lesions (4). During our data collection, we encountered at least two such cases under 1 cm whose biopsy was deferred, and follow-up was recommended.

Both CT and ultrasound-guided transthoracic biopsies were performed, with CT guidance used more frequently. The choice of modality likely depended on lesion accessibility and patient condition to maximize diagnostic yield and minimize complications. Only two FNAC samples were taken under ultrasound guidance, while the rest were core needle biopsies; the reason for this might be the need for accurate histopathologic diagnoses of the thoracic lesions. But it is noteworthy that seven additional thoracic FNAC procedures were excluded due to incomplete records.

The only immediate post-procedural complication recorded was pneumothorax, occurring in 6.9% of the procedures. In all cases, it was minimal, requiring no surgical consultation or chest tube placement. No records of hemorrhage were found. This incidence is comparable to a study showing a 5.7% occurrence of pneumothorax and better than other studies reporting higher rates ranging from 15.7% to 34.5% (23–25,27,31). The low incidence of minimal pneumothorax and absence of hemorrhagic complications indicate the safety of transthoracic image-guided CNB/FNAC procedures performed at the SPHMMC interventional radiology unit.

Concordance assessment among three interpreters of radiologic reports revealed almost perfect agreement, with a Fleiss' kappa of 0.812 (95% CI: 0.729-0.895). Comparing the majority report category of chest CT scans to pathologic results, categorized into malignant (not otherwise

specified), primary lung (pleural) malignancy or mediastinal neoplastic tumor, metastatic lesion, and benign lesion (non-neoplastic mediastinal lesion), showed a combined category agreement with a borderline moderate Cohen's kappa of 0.406 (95% CI: 0.214-0.598). Individual category Cohen's kappa values also ranged from fair to borderline moderate agreement, with the lowest kappa observed in benign lesions, indicating higher disagreement in benign diagnoses.

Several factors could contribute to the moderate agreement of chest CT reports, including local epidemiology, radiologists' experience, limitations of chest CT (such as overlapping appearances of different pathologies), lack of standardized report formats in our setup, and tissue handling and pathologic constraints(16). This finding parallels a 2015 California study on imaging-histologic discordance after percutaneous lung biopsies, suggesting these challenges are not confined to our institution but are likely inherent to chest CT reporting or pathologic limitations (16).

The percent concordance level between radiologic and pathologic diagnoses after image-guided transthoracic biopsy in our study was 80.2%. This percentage varies across studies, ranging from 100% concordance for malignant lesions to 62% for non-malignant lesions, to an overall concordance of 89% reported in another study(14,15).

In our study, we identified 18 discordant cases, including 5 discordant benign and 13 discordant malignant lesions. Our study design limited the assessment of each chest CT image for lesion patterns while not controlling for the experience level of the radiologists, which could impact the assessment of CT pattern-related factors contributing to discordance. Nonetheless, we attempted to compare the radiologic diagnostic conclusions of these discordant cases with their pathologic findings.

The lowest concordance, 33%, was found for pleural lesions, including 4 discordant malignant and 1 discordant benign case. Interestingly, all four initially suspected mesothelioma cases on imaging were pathologically diagnosed as secondary adenocarcinomas, three being primary lung cancers. This underscores the rarity of primary mesothelioma compared to more common metastatic pleural lesions (41). Reporting these lesions should consider both epidemiological factors related to pleural and metastatic lung cancers. Additionally, rare pseudomesotheliomatous carcinomas of lung, which mimic pleural mesothelioma, should be considered, especially in cases without asbestos exposure(42–44). Pattern interpretation of these discordant cases by thoracic radiologists is recommended for future reference.

Inflammatory lung lesions were a significant cause of discordant reports in our study. Three cases of primary lung adenocarcinomas were misinterpreted as benign lesions on chest CT scans (one cavitating pneumonia, two organizing pneumonia). Additionally, a posterior mediastinal giant cell tumor of soft tissue was inaccurately diagnosed as TB spondylitis. Conversely, cases reported as malignant on CT turned out to be benign pathologically, including two TB cases, sarcoidosis, fibrotic process, and suppurative inflammation. During data collection, five biopsies were deferred due to lesion size reduction observed on repeat imaging in patients undergoing empirical antibiotic and TB treatment, indicating similar scenarios. These findings underscore the prevalence of inflammatory lesions, including TB, as major contributors to discordant radiopathologic results. Further study of these patterns in our epidemiological context is recommended to improve diagnostic accuracy.

In our study group of 54 cases of primary lung cancer, adenocarcinomas constituted 68.5%, followed by squamous cell carcinoma (16.7%), small cell carcinoma (3.7%), and large cell carcinoma (1.9%). These distributions are consistent with similar research findings and also reflect the general population trends in lung cancer prevalence (18–22). Higher adenocarcinoma predominance in our study, compared to finding of another study in Ethiopian lung cancer patients (35.7% adenocarcinoma, 19.2% squamous cell carcinoma), may stem from selecting more peripheral tumors for image-guided biopsy over more centrally located lung cancers like squamous cell carcinomas which are typically biopsied via bronchoscopy (4,45).

In our study group, lymphoma was more prevalent among anterior mediastinal masses (40% total, comprising 25% NHL and 15% HL), compared to thymoma, which accounted for 30% of cases. This distribution aligns with the incidence of cancer in Ethiopia, where NHL ranks as the 5th most common cancer and HL as the 20th, whereas thymoma is not among the top 32 according to GLOBOCAN 2022 (10).

The diagnostic yield of image-guided transthoracic CNB/FNAC at the interventional radiology unit of SPHMMC is 86.3%, with only 14 non-diagnostic samples among 102 patients in our study. Several studies have shown this procedure to be effective, with diagnostic accuracies ranging from 78.6% to 97% in our literature search with one large study involving 1000 patients demonstrating a diagnostic yield of 96.6% for CT-guided CNB/FNAC (20,23–27). This underscores the effectiveness of image-guided transthoracic CNB/FNAC in our setup where it plays a pivotal role

in diagnosing thoracic lesions through a minimally invasive procedure. This is particularly significant given the recent introduction of the procedure in our country (13). Nonetheless, there remains potential for improvement in the diagnostic yield, as demonstrated by several studies reporting yields above 90% (20,23–26).

Due to the retrospective nature of our chart review study, we were unable to exhaustively assess all potential factors that could limit the diagnostic yield of image-guided transthoracic sampling in our setup. These factors may include distance from the pleura, procedural variables, patient clinical conditions, and the experience of the interventional radiologist. Despite these confounding factors, we assessed the available data for factors influencing diagnostic yield.

Lobar location of lesions, previously noted as factors in other studies, did not show a significant association with diagnostic yield in our study (25,29). Similarly, the choice of imaging modality (ultrasound vs. CT) for guidance did not impact diagnostic yield, consistent with findings from prior research (46,47).

Lesion size emerged as a statistically significant factor ($P < 0.05$), with sizes less than 2 cm significantly increasing the odds of diagnostic failure (AOR = 6.052). This aligns with other studies that identified size thresholds of 1 cm to 1.5 cm affecting diagnostic outcomes (25,27,28). Hence, knowledge of this lesion size cut-off helps our interventionist to anticipate the possibility of diagnostic failure beforehand and plan potential solutions or alternatives proactively, before proceeding with non-diagnostic invasive procedures. Additionally, immediate post-procedural pneumothorax was identified as another significant factor associated with diagnostic failure (AOR = 6.854). This factor may be influenced by procedural factors, technical difficulties, patient clinical condition, and lesion depth from the pleura. Despite this, the presence of pneumothorax might indicate a high probability of diagnostic failure, suggesting that the operator should plan on-site mitigation strategies accordingly. Further prospective studies are recommended to validate these findings and comprehensively assess all factors impacting diagnostic yield, aiming to enhance the safety and efficacy of image-guided thoracic biopsies in our clinical setting.

7. Conclusion

Our study found that the radiopathologic agreement level is borderline moderate among patients undergoing image-guided transthoracic biopsy/FNAC at our hospital's interventional radiology unit. Major diseases identified in discordant cases included pleural metastatic adenocarcinomas that mimicked mesothelioma and common inflammatory lesions like TB and its mimickers. We propose that factors such as local epidemiology, radiologists' experience, limitations of chest CT (including similar appearances of different pathologies), lack of standardized reporting formats in our setup, and issues with tissue handling and pathology may contribute to this discordance. We recommend a detailed pattern analysis of these discordant cases by thoracic radiologists for future reference.

Image-guided transthoracic CNB/FNAC demonstrates safety and efficacy in our setting, achieving a diagnostic yield of 86.3% with only 6.9% of cases experiencing minimal immediate post-procedural pneumothorax. We found that lesion size under 2cm and the occurrence of immediate post-procedural pneumothorax are significant factors affecting diagnostic yield. Conducting a more detailed prospective study to assess these and other unassessed confounding factors could help further improve the diagnostic yield in our setup.

8. Strengths and limitations of the study

8.1. Strengths of the study

- To the best of our knowledge, this is pioneering study at SPHMMC and in Ethiopia to evaluate the role of transthoracic image-guided CNB/FNAC while assessing radiopathologic concordance among study subjects.
- By focusing on Ethiopia's specific epidemiological context, the study provides tailored insights that can directly benefit local radiologic and clinical practices.

8.2. Limitations of the study

- Loss of chart records and incomplete data led to the exclusion of potential study subjects from our research.
- This study did not examine the specific radiologic features on the chest CT-scan images of discordant cases, as it was not radiologic pattern analysis study.
- The retrospective nature of our chart review study design prevented exhaustive assessment of factors influencing diagnostic yield, such as procedural techniques, specific patient clinical conditions during the procedure and radiologists' experience levels.

9. Recommendations

- Radiologists and radiology trainees should integrate their knowledge of local and general disease epidemiology to reduce discordant chest CT reports.
- Interdisciplinary sessions involving clinicians, radiologists, and pathologists are recommended to review discordant cases, optimizing patient management and advancing medical knowledge.
- Interventional radiologists and trainees should expand their practice of safe and effective transthoracic sampling procedures, while gaining in-depth knowledge of factors that influence diagnostic yield to optimize outcomes.
- We recommend the Department of Radiology at SPHMMC to help researchers conduct study on radiopathologic discordant chest CT patterns, and integrating the findings into teaching and learning processes to enhance reports tailored to our epidemiological context.
- We recommend the Ethiopia's Ministry of Health and policymakers promote the expansion of safe and effective minimally invasive interventional radiology procedures. This includes funding training programs and establishing fully equipped facilities nationwide. These initiatives will reduce patient suffering, improve management, minimize unnecessary invasive procedures, and lower long-term healthcare costs.
- Experienced radiologists shall conduct research on radiologic patterns of and contributing factors to radiopathologic discordant cases, to improve our understanding of these discrepancies.
- We recommend an exhaustive prospective study on factors affecting the diagnostic yield of transthoracic image-guided sampling to help improve yield.

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Annex 1

Data Collection Template

- Name of data collector _____
- Signature _____
- Date _____

Structured data collecting Template.

Patient demographic data

MRN	
Age (yrs)	
Sex	

Patient medical history

Family history of lung cancer	yes	No
Smoking history	yes	No

Instructions-please follow these instructions while collecting data from medical records on the table provided below

- For the variables in number 1.2 please state the specific number.
- For the variables 1.3 and 3.2 write in full the type the radiologic and histologic conclusions
- For the rest of the other variable please mark the finding by using ✓ symbol;
- For procedural complication and sampled tissue type if finding is not specified in the table write in full under provided row that has “(specify)

1. Radiologic report			Data
1.1. Lesion location	Right lung	Upper lobe	
		Middle lobe	
		Lower lobe	
	Left lung	Upper lobe	
		Upper lobe (lingula)	
		Lower lobe	
	Mediastinal mass		
Pleural mass	Right		
	Left		
1.2. Lesion size(cm)			
1.3. Final radiologic conclusion in writing			
2. Image guided transthoracic imaging associated documented data			
2.1. Transthoracic sampling technique used	CT-guided		
	Ultrasound guided	Biopsy	
		FNAC	
2.2. Any documented post-procedural complication (if any)	Pneumothorax		
	Hemorrhage		
	Any other complication (specify)		
3. Pathologic report			
3.1. Diagnostic sample characteristic	Adequacy	Adequate	
		Inadequate	
	Tissue type	Target lesion	
Not targeted lesion (specify; normal lung, liver or any other tissue)			
3.2. Final pathologic report (specific)			
3.3. Pathologic report category (for concordance assessment)	Malignant (not otherwise specified)		
	Primary lung (pleural) malignancy or neoplastic mediastinal lesion		
	metastatic		
	Benign (non-neoplastic mediastinal) lesion		

Annex 2

Radiologic report recategorization format based on three readers

MRN(case no.)		Malignant (not otherwise specified)	Primary lung (pleural) malignant or mediastinal neoplastic lesion	metastatic	Benign (non-neoplastic mediastinal) lesion
	Reader number one				
	Reader number two				
	Reader number three				
	Final report (most mentioned)				

Annex 3

Format for radiologic-pathologic concordance for individual cases

MRN(case no)	Concordant	Lung	Benign (specific pathology)	
			Malignant (specific pathology)	
		Mediastinal (specific pathologic result)		
	Discordant	Lung	Benign (specific pathology)	
			Malignant (specific pathology)	
		Mediastinal lesion	Benign (specific pathology)	
			Malignant (specific pathology)	