Addis Ababa University

College of Health Sciences

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Department of Pharmacology and Clinical Pharmacy

Validity and Reliability of the Amharic Version of the Chronic Obstructive Pulmonary Disease Assessment Test for Measuring Health-Related Quality of Life in Addis Ababa, Ethiopia: A Cross-Sectional Study

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A Thesis Submitted to the Department of Pharmacology and Clinical Pharmacy, School of Pharmacy, College of Health Sciences, Addis Ababa University for Partial Fulfillment of the Requirements for Master of Science Degree in Pharmacy Practice (MSc).

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This is to certify that the thesis prepared by Shimelis Engida, entitled: ***"Validity and Reliability of the Amharic Version of the Chronic Obstructive Pulmonary Disease Assessment Test for Measuring Health-Related Quality of Life in Addis Ababa, Ethiopia: A Cross-Sectional Study"*** and submitted in partial fulfillment of the requirements for the Degree of Master of Pharmacy in Pharmacy Practice, complies with the regulations of Addis Ababa University and meets the accepted standards regarding originality and quality.

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) significantly impacts health-related quality of life (HRQoL). As a result, there is a need for culturally and linguistically appropriate tools to assess HRQoL in Ethiopian COPD patients. While the COPD Assessment Test (CAT) is commonly used, reliability and validity have not been established among Ethiopian COPD patients.

Objective: This study aimed to evaluate the validity and reliability of the Amharic version of the COPD Assessment Test (CAT-Am) for measuring HRQoL in Ethiopian COPD patients.

Methods: A hospital-based cross-sectional study was conducted at three tertiary hospitals in Addis Ababa, Ethiopia, from June 2023 to December 2023. A total of 205 consecutive patients were recruited to complete the CAT-Am to assess HRQoL. Descriptive statistics were used to present patients' characteristics. Internal consistency was assessed using Cronbach's alpha, including an analysis of the impact of deleting individual items with a threshold of ≥ 0.70 considered satisfactory. Principal component analysis (PCA), confirmatory factor analysis (CFA), and known group analysis were used to test construct validity. Predictive validity was also assessed. Multivariable linear regression was used to identify factors influencing HRQoL. Data analysis was performed using STATA version 17, with statistical significance determined at p-value < 0.05.

Results: The study included 205 COPD patients with a mean (SD) age of 63.04 (11.0) years, of whom 64 (28.79%) had severe COPD. CAT-Am demonstrated high internal consistency with a Cronbach's alpha of 0.89, and PCA indicated that CAT-Am could be reduced into two components with a total variance of 71.98%. The predictive validity test showed a correlation between the CAT-Am and mMRC dyspnea scale (Pearson's r = 0.453). As measured by the CAT-Am score, include age (β = 0.11, 95% CI: 0.04, 0.17), lack of social support (β = 2.49, 95% CI: 0.74, 4.24), the total number of medications (β = 0.40, 95% CI: 0.10, 0.70), hospitalization history in the past years (β = 2.78, 95% CI: 1.68, 3.88), biomass fuel exposure (β = 4.57, 95% CI: 3.17, 5.97), low medication adherence (β = 2.79, 95% CI: 1.13, 4.46), GOLD stage 4 severity (β = 5.20, 95% CI: 2.37, 8.05), and the presence of comorbidities (β = 0.79, 95% CI: 2.48, 5.59), which were strong predictors of HRQoL.

Conclusion: CAT-Am is a reliable and valid tool for assessing HRQoL and can be routinely used in Ethiopian COPD patients and factors affecting patient HRQoL, enabling targeted interventions. Future studies should assess its applicability in broader settings.

Keywords: Chronic Obstructive Pulmonary Disease, HRQoL, COPD Assessment Test, CAT-Am, Ethiopia

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Acronyms and Abbreviations

AAU	Addis Ababa University
ACDS	Adherence in Chronic Disease Scale
BMI	Body Mass Index
CAT	Chronic Obstructive Pulmonary Disease Assessment Test
CAT-Am	Chronic Obstructive Pulmonary Disease Assessment Test-Amharic version
CCQ	Clinical COPD Questionnaire
CFA	Confirmatory Factor Analysis
COPD	Chronic Obstructive Pulmonary Disease
CRQ	Chronic Respiratory Disease Questionnaire
EQ-5D-5L	Euro Quality of Life Groups-5-Domain-5-Level Questionnaires
EQ-VAS	Euro Quality of Life Group's Visual Analog Scale
FEV1	Forced Expiratory Volume in 1 second
FVC1	Forced Vital Capacity in 1 second
GFI	Goodness of Fit Indices
GOLD	Global Initiative for Chronic Obstructive Lung Disease
HRQoL	Health-Related Quality of Life
ILD	Interstitial Lung Disease
IQR	Interquartile Range
KMO	Kaiser Meyer-Olkin
LGH	Lancet General Hospital
LMIC	Low- and Middle-Income Country
mMRC	modified Medical Research Council
PCA	Principal Component Analysis
QoL	Quality of Life
SEM	Structural Equation Model
SGRQ	St, George Respiratory Questionnaire
SGRQ-C	St, George's Respiratory Questionnaire-COPD
SPHMMC	St, Paul's Hospital Millennium Medical College
SSA	Sub-Saharan Africa
TASH	Tikur Anbessa Specialized Hospital
WHO	World Health Organization

1 Introduction

1.1 Background

Chronic Obstructive Pulmonary Disease (COPD) is a significant global health issue, defined by the Global Initiative for Obstructive Lung Disease (GOLD), it is characterized as a heterogeneous lung disease caused by abnormalities in the airways that lead to persistent and worsening airflow obstruction (1, 2). COPD is a primary cause of illness and mortality globally, affecting roughly 9-10% of persons aged 40 and older (3). COPD is influenced by various risk factors, with the most prominent being cigarette smoking, exposure to toxic gases, air pollution, occupational hazards, and health issues experienced during childhood or adulthood that contribute to the development of COPD (4-7). Tobacco smoking causes over 70% of COPD cases in high-income nations, while 30-40% in LMICs, followed by household air pollution as a factor (8). For instance, Zhang et al. found that biomass fuel is a highly prevalent risk factor for COPD patients in LMICs (9).

COPD symptoms, including shortness of breath, persistent cough, and excessive sputum production, significantly impact the patient's daily activities and overall health (10). Additionally, its treatment further impairs individuals' ability to perform daily activities by reducing their HRQoL (11). HRQoL is a comprehensive concept that assesses patients' physical, social, and psychological well-being to determine how their overall health affects their quality of life (QoL) (12). Therefore, it is essential to understand the impact of COPD on patients' daily lives to effectively manage the disease and enhance their overall QoL (13).

Several studies emphasize the importance of assessing HRQoL to understand the burden of the disease and its treatments (14-16). Healthcare professionals and researchers are increasingly recognizing the significance of evaluating HRQoL as an indicator of treatment outcomes (17). This understanding can significantly aid clinical research and enable healthcare professionals to better comprehend the effects of COPD (18).

Several validated tools and approaches are routinely used to assess HRQoL in patients with COPD. Among them, generic and disease-specific tools have been used to measure and evaluate HRQoL among patients (19). Those tools include the St. George's Respiratory Questionnaire (SGRQ) and its specific version, St. George's Respiratory Questionnaire for Patients (SGRQ-C) (20, 21). Additionally, the Chronic Respiratory Disease Questionnaire (CRQ), Clinical COPD Questionnaire (CCQ), and CAT have been extensively validated and used in clinical trials (22). However, due to

its complex calculation and long questionnaire completion time, the CAT (23) is recommended above SGRQ, SGRQ-C, and CRQ.

The GOLD guideline recommends combining CAT with spirometry classification for a more patient-centered assessment of symptoms, evaluating the impact of COPD on a patient's health status (24). CAT was developed to improve communication between the healthcare provider and the patient and provide a reliable assessment of the patient’s health status. It has been translated and validated for use in clinical settings (25). The CAT is a self-administered questionnaire consisting of eight items that assess the impact of COPD on various aspects of a patient's life, including cough, sputum, and dyspnea (26).

Therefore, to address the significant health challenge posed by COPD, it’s essential to identify and address the factors influencing the HRQoL of affected patients. Achieving this effectively requires the use of culturally adapted, reliable, and validated tools. Such validated instruments enhance confidence in accurately measuring the intended constructs. However, it's important to note that a tool validated in one context may not automatically retain its validity in another, as the items may not hold the same level of relevance and acceptance in the target population compared to the original setting.

1.2 Statements of the Problem

According to a report from the World Health Organization (WHO), COPD was the third leading cause of death globally, with 3.5 million deaths in 2021 (27). Furthermore, the global prevalence of COPD is projected to reach 600 million cases by 2050, representing a 23% increase in affected individuals compared to 2020 (28). The prevalence of COPD varies across regions, with nearly 90% of deaths occurring in LMICs, accounting for 83% of the global population (29). A systematic review and meta-analysis have shown that the prevalence of COPD in Africa ranges from 2% to 24% (30). Similarly, a systematic review and meta-analysis found that the overall prevalence of COPD in Sub-Saharan African (SSA) countries was 8% (31), and the total prevalence of COPD in East Africa was reported to be 13.3% (32). A study conducted in Ethiopia by Woldeamanual et al., 2019 indicated that the estimated prevalence of COPD in Ethiopia was 17.8% (33). This data indicates that COPD in Ethiopia has significantly increased.

COPD is associated with substantial morbidity, mortality, and reduced HRQoL for those affected individuals, particularly in LMICs like Ethiopia. According to studies, patients with COPD experience severe exacerbations, leading to increased healthcare resource utilization and declining lung function (34). Furthermore, this impact is worsened by insufficient healthcare resources and high-risk factors, resulting in a significant reduction in HRQoL among affected individuals (35). Despite improvement in medical care, many people with COPD still have poor HRQoL. Since COPD is chronic and incurable, managing symptoms and reducing their negative impact on a patient's HRQoL are the main goals of therapy.

According to studies conducted in India, the HRQoL of COPD patients was significantly declined (36, 37). Similarly, a study conducted in Egypt also found the QoL was impaired and deteriorated with severity (38). However, HRQoL COPD has not been well explored in Ethiopia, potentially due to the lack of validated tools. Having sensitive and validated tools to measure HRQoL is highly crucial. Ideally, those tools should be culturally appropriate, trustworthy, and valid, ensuring accurately assessing HRQoL across diverse populations. Such tools provide valuable information about how the disease affects a patient's daily activities and overall well-being.

Although numerous HRQoL assessment tools are available, none have been specifically validated and reliable, for the Ethiopian context. Among these, the CAT is a globally recognized and widely used tool for assessing HRQoL in COPD patients due to its simplicity and effectiveness. Despite its widespread adoption, the CAT has not been validated in the Amharic language nor evaluated for

its validity and reliability among Ethiopian COPD patients. This hinders the accurate assessment of the disease impact on their HRQoL and makes it challenging to reliably measure HRQoL in Ethiopian COPD patients.

Therefore, assessing the feasibility and psychometric properties of the CAT in the Ethiopian setting is crucial. This study aims to address this gap by carefully evaluating the CAT-Am to ensure that it provides a reliable and valid tool ultimately improving COPD therapy and patient outcomes across Ethiopia.

1.3 Significance of the Study

This study aims to validate the Amharic version of CAT for use among Ethiopian patients. Currently, there is a lack of validated tools for measuring HRQoL in this population. The validation of CAT-Am will provide valuable insights into the psychometric properties, enabling healthcare professionals to utilize a reliable tool for assessing HRQoL and monitoring COPD treatment outcomes in Ethiopia.

The availability of culturally adapted measurement tools that are easy to use across various healthcare levels is crucial. This study will contribute to establishing evidence-based approaches for COPD therapy, leading to improved patient outcomes and enhanced QoL for Ethiopians living with this chronic respiratory disease. Additionally, it will facilitate future research by offering a validated instrument for measuring the impact of COPD on patients' lives, which can lead to improved patient care and treatment results.

Assessing HRQoL in COPD outpatient clinics is crucial for optimizing treatment effectiveness and minimizing healthcare costs, particularly in Ethiopia, where financial constraints affect drug coverage. Reliable assessment tools, such as the CAT, can provide important insights into a patient's overall well-being and inform treatment decisions. This study seeks to address the knowledge gap regarding how sociodemographic and clinical variables influence HRQoL. It will help healthcare practitioners identify factors affecting HRQoL and areas needing improvement in patient care. Moreover, improving communication between patients and clinicians through standardized assessment tools like the CAT can lead to more tailored and successful treatment plans.

2 Literature Review

2.1 Burden of COPD

COPD is a debilitating respiratory condition that continues to pose a significant health challenge globally. The burden of COPD is multifaced, encompassing high mortality, morbidity and substantial economic costs. A 2019 systematic review estimated that COPD affects 10.3% of people aged 30 to 79, totaling around 391.9 million cases worldwide (39). Similarly, another systemic review estimate indicated a greater frequency of 13.1%, corresponding to around 212.3 million cases worldwide (40). Moreover, COPD is a major public health challenge, particularly in LMICs where healthcare resources are usually scarce (41). In addition, the prevalence of COPD is high in LMICs, with severe exacerbations reaching up to 20.1% (34). Furthermore, it is a chronic lung disease characterized by symptoms such as shortness of breath, coughing, and sputum production that is usually caused by emphysema or chronic bronchitis (42, 43).

Comorbidities such as cardiovascular risk, respiratory failure, and lung cancer contribute to the overall severity of the disease in individual patients (44, 45). A prospective study and systemic review and meta-analysis conducted in 2019 in China identified several factors that contribute to the burden of COPD, including smoking, indoor and outdoor air pollution from gases and fumes, genetics, occupational hazards, and childhood or adult infection (46, 47). Among these factors, a Meta-analysis conducted in 2026 highlighted cigarette smoking as the most common risk factor for COPD (48). However, in LMICs, 35% of COPD cases are attributed to chronic exposure to indoor smoke from burning biomass fuel (49, 50).

The occurrence of COPD also rises with age, particularly beyond 40 years, and occupational exposure is a significant risk factor associated with COPD development (51, 52). A study conducted in the USA projected that by 2030, COPD will be the direct underlying cause of 7.8% of all deaths, representing 27% of smoking-related deaths, following closely behind cancer and cardiovascular disease (53). A study conducted in Spain has shown that patients with COPD, especially those with severe cases, utilize significant healthcare resources due to exacerbations and comorbidities, leading to a mortality rate of 40.2 deaths per 1000 patients per year (54).

A systematic review showed that home air pollution from solid fuels was the major cause of COPD in SSA's 117% increase by 2019 (55). A study conducted by Rehman et al. in 2020 revealed that caregivers of COPD patients reported a (32%), reduced productivity, a 17.42% activity decline, and a 21.63% social activity limitation (56). A study conducted by Awokola et al. in 2022 found

that the population prevalence of COPD in SSA ranged from 1.7% to 24.8% (pooled prevalence: 8%, 95% CI 6–11) (31). A systematic review and meta-analysis conducted by Mebrahtom et al. in 2024, showed a high prevalence of COPD, approximately one in every seven individuals in East Africa has COPD (32).

2.2 HRQoL of Patients with COPD

COPD is a devastating and chronic lung condition that causes a significant burden on patients' HRQoL. The concept of QoL, which includes social, psychological, and physical health aspects, forms the foundation of HRQoL (57). The QoL of COPD patients is a crucial aspect of disease management, significantly affecting their well-being (58). HRQoL is a distinct term that includes areas relating to physical, mental, emotional, and social functioning, instead of physiological evaluations or survival outcomes. Assessment of HRQoL in patients may help healthcare professionals and policymakers develop successful strategies (59, 60).

Studies have shown that COPD patients often experience compromised QoL, with factors such as advancing age, disease severity, and duration of illness playing significant roles in determining the quality of life (61, 62). Similarly, education level, income, marital status, residence comorbidities, prescribed medication, number of medications, medication adherence, socioeconomic status, and environmental factors are identified as crucial factors influencing HRQoL in COPD patients. This highlights the importance of multidisciplinary approaches and patient-centered care to optimize outcomes and enhance the quality of life (63, 64).

There is a strong association between HRQoL and the severity of COPD. Studies showed that patients' quality of life significantly deteriorates as the disease's severity increases. According to research by Jarab et al., patients with COPD had an average HRQoL score of 55.2, indicating a considerable decline in their general well-being due to symptoms and functional restrictions (63). Similarly, Esteban et al. emphasized that HRQoL is essential for determining how COPD affects patients' day-to-day life and predicts death (65).

COPD patients experience significantly lower QoL, which worsens with disease progression (66). Additionally, physical exercise has a significant impact on COPD patients' HRQoL. Walking activity and HRQoL were significantly correlated by Egoshi et al., indicating that higher levels of physical activity are linked to better QoL (67). Exacerbations of COPD, which often result in

hospitalizations, might worsen psychological distress, further lowering HRQoL, according to a systematic study by Pooler and Beech (68).

2.3 HRQoL Measurement Tools in COPD

COPD is a progressive respiratory condition that significantly impacts HRQoL. The measurement of HRQoL in patients with COPD is essential for understanding the disease's impact, in addition to typical clinical tests like spirometry. Numerous tools have been developed to assess HRQoL, each possessing distinct strengths and applications. A range of questionnaires has been specifically designed to evaluate HRQoL in patients with COPD. These tools assess various aspects, including symptoms such as dyspnea, cough, and wheezing, as well as social and emotional well-being (64).

These tools include both generic and disease-specific tools such as EuroQol 5-dimension 5 level (EQ-5D-5L) and EuroQol visual analog scale (EQ-VAS), Chronic Respiratory Questionnaire (CRQ), CAT, St. George's Respiratory Questionnaire (SGRQ), and St. George's Respiratory Questionnaire COPD (SGRQ-C) (17). It is recommended to use the generic tools in conjunction with the COPD-specific tools to measure the HRQoL of patients (69). With the culturally and linguistically diverse global population, the use of a valid and reliable instrument is needed to measure subjectively.

The SGRQ is one of the most often used tools for evaluating HRQoL in COPD. This test is known for its capacity to capture multidimensional elements of health status, such as symptoms, activity limits, and the disease's overall influence on everyday life (70). The SGRQ has been validated across several groups and is commonly used in clinical studies to assess therapy effectiveness and illness progression (71, 72). A study as reported by Maguro et al, 2007 shows SGRQ-C is valid and reliable for the assessment of HRQoL in COPD patients (21). In a study in Malaysia, SGRQ-C exhibited strong validity, reliability, and responsiveness to illness severity equivalent to those of the original version (56).

EQ-5D-5L and VAS are used globally as they are valid to measure HRQoL in different languages including Amharic but are not in Ethiopian COPD patients (73). It is advised to be used together with additional disease-specific tools for patients with COPD like the CAT (74). The EQ-5D-5L questionnaire covers five dimensions of health, and the VAS records a patient's self-rated health on a scale from 0 to 100 (75). A study done in the UK and South Korea demonstrates that EQ-5D-5L is a valid, reliable, and responsive assessment of health status in COPD and may provide important

extra cost-effectiveness data in therapeutic trials (76-78). Similarly, a study conducted in Turkey and the Netherlands shows that the CRQ was valid and reliable for the assessment of HRQoL in COPD patients (79, 80).

2.4 The Validity of CAT

Assessing the HRQoL in COPD patients is crucial for developing effective management and treatment plans. The CAT is an 8-item questionnaire designed to assess the impact of COPD on patients' daily lives. The reliability of the CAT has been extensively studied in various populations across European, Asian, and African countries. Several studies demonstrate strong internal consistency, with Cronbach's alpha values ranging from 0.76 to 0.94, indicating that the items within the CAT measure the same underlying construct (81). Although there is currently no valid Amharic version of CAT, it has been validated and psychometric evaluations. Studies conducted in Saudi Arabia and Turkey showed that the CAT was valid and reliable (82).

In another study done in Japan on the validation CAT, 301 COPD patients were included and reported a Cronbach's alpha of 0.89 (83). In a Ugandan study examined to evaluate the validity of the CAT tool, 113 patients with COPD were included, and it found the tool to be reliable with Cronbach alpha 0.92 (84, 85). A systematic review by N. Gupta et al, 2014 demonstrates that CAT was reliable and valid and also reported Cronbach alpha was 0.85 – 0.98 and test-retest reliability was 0.80 – 0.96 (86). Similarly, a study conducted in South Korea reported a Cronbach alpha of 0.85 and a correlation with SGRQ of (r=0.74) (87).

2.5 Conceptual Framework

To accurately and critically assess HRQoL in patients with COPD, it is important to use brief, easily understandable, and accessible tools that have been validated. Therefore, the translation and validation of CAT-Am are crucial for assessing HRQoL in patients with COPD. CAT-Am is considered to be reliable and valid when the internal consistency, as expressed by Cronbach's alpha is, above the minimum cut-off value of greater or more than 0.7 (88) (Figure 1).

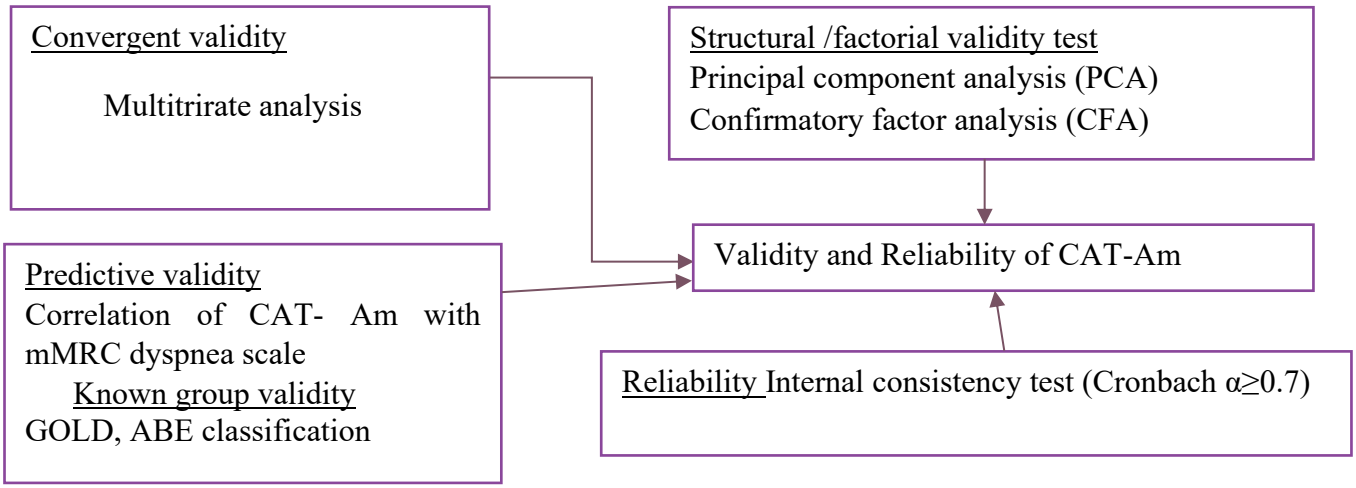

Figure 1: Conceptual framework for the validity and reliability of CAT-Am

3 Objective

3.1 General Objective

- This study aimed to evaluate the validity and reliability of the CAT-Am for measuring HRQoL among COPD patients at TASH, SPHMMC, and LGH in Addis Ababa, Ethiopia.

3.2 Specific Objectives

- To assess the reliability of CAT-Am
- To assess the validity of CAT-Am
- To identify possible factors that are associated with the HRQoL among patients with COPD
- To measure the impacts of COPD on HRQoL by CAT-Am of Ethiopian COPD patients

4 Methods

4.1 Study Setting

The study was conducted at the chest clinics of TASH, SPHMMC, and LGH. TASH, established in 1972, is Ethiopia's largest referral and tertiary specialized hospital. It is affiliated with Addis Ababa University's, College of Health Sciences and has 800 beds, treating between 370,000 and 400,000 patients annually. The hospital provides specialty clinics for chest, gastrointestinal, cancer, cardiology, and renal care. The chest clinic, in particular, is staffed by 16 physicians who focus on treating respiratory diseases such as COPD, asthma, Inflammatory Lung Disease, and pulmonary hypertension (89).

SPHMMC, established in 1968, is the second-largest public hospital, with 700 beds, and serves about 333,752 patients per year. The chest clinic treated around 2692 patients with respiratory illnesses, including COPD. The clinic operated primarily on Tuesdays and Fridays, with each patient's appointment term spanning between 15 and 45 days (90). LGH was established in 2015 as a private hospital. It is a prominent referral center with multidisciplinary teams of 24 experts specializing in internal medicine, surgery, oncology, hematology, orthopedics, gynecology and obstetrics, pediatrics, histopathology, radiology, and anesthesiology, including pulmonology and critical care medicine (91).

4.2 Study design and period

A hospital-based cross-sectional study was conducted from June 2023 to December 2023 among patients with COPD at TASH, SPHMMC, and LGH in Addis Ababa, Ethiopia.

4.3 Population

4.3.1 Source Population

All patients with COPD who were evaluated and treated at the outpatient chest clinic unit of TASH, SPHMMC, and LGH were considered the source population.

4.3.2 Study population

All patients diagnosed with COPD and treated in the outpatient chest clinics TASH, SPHMMC, and LGH who met the inclusion criteria were included in the study population.

4.4 Eligibility criteria

4.4.1 Inclusion criteria

- Stable patients with clinical and spirometry results confirming COPD.
- COPD patients with FEV1 to FVC1 ratio ≤70%.
- COPD patients with no recent history of acute exacerbations at least 40 days before enrollment.

4.4.2 Exclusion criteria

- patients who had undergone lung surgery.
- COPD patients with uncontrolled comorbidities, such as lung cancer, TB, or pulmonary hypertension.
- COPD patients with cognitive impairment
- COPD patients who were unable to respond and refused to participate.

4.5 Sample Size and Sampling Technique

4.5.1 Sample size determination

Three hospitals were selected based on patient flow and the availability of spirometry for COPD diagnosis. There is no common ground on the sample size required for factor analysis. The sample for this study was calculated using various literature recommendations. Some authors suggested following the rule of thumb regarding the minimum ratio of patients to variables (2:1) or extracted factors (20:1) (92). Hutcheson and Sofroniou state that a sample size of 150-300 participants is adequate for conducting PCA and factor analysis (93).

Since CAT has eight items, multiplying by the maximum recommended sample size yields 160 samples. Additionally, to improve the estimation, data collection continued until the end of the study period, resulting in data gathered from 205 patients. The selected hospitals included TASH with 140 patients, SPHMMC with 37 patients, and LGH with 28 patients.

4.5.2 Sampling technique

A consecutive sampling technique was used to select the study patients and during the data collection period, patients with COPD who were receiving treatment and evaluation at chest clinic units met eligibility criteria and were willing to participate in the study.

4.6 Study variables

4.6.1 Dependent variables

- HRQoL
- Validity and Reliability of CAT-Am

4.6.2 Independent variables

- Sociodemographic characteristics such as age of patients, gender, marital status, educational status, occupational status, religion, place of residence, average monthly income, region, smoking status, amount of smoking, duration of smoking, social support, health insurance coverage, and biomass fuel exposure.
- Clinical and disease-related characteristics were considered including the initial symptoms, presence of comorbidities, number of comorbidities, duration of COPD, current medication, number of medications, exacerbation history in the past year, hospitalization history in the past years, body mass index (BMI), forced expiratory volume in one second (FEV1) and forced vital capacity (FVC1), FEV1/FVC1, GOLD severity stage, GOLD ABE assessment tool,
- Adherence in chronic disease scale (ACDS) and mMRC dyspnea scale.

4.7 Data collection and management

The investigator recruited patients who satisfied the eligibility criteria and informed them of the study's objectives. Patients provided their consent before participation. A standardized questionnaire by interview administered, and patient medical document abstraction was used to collect data. The four-part data-collecting tool was created after conducting a literature study to capture the patients' demographic features and clinical factors to investigate the reliability and validity of the CAT-Am and HRQoL. (See Appendix, "Data Collection Instruments").

The first section contains questions designed to gather the socio-demographic information of the patient. The second part assesses the patient’s clinical characteristics such as GOLD COPD classification, GOLD ABE assessment test, duration of illness, presence of comorbidity, number of comorbidities, type of current medication, number of drugs, frequency of exacerbation history in the past years, and hospitalization history in the past years. Additionally, the third and the fourth contain the CAT and ACDS questionnaires respectively.

I. CAT-Am

St. George's Healthcare NHS Trust in London, UK, developed CAT to assess the impact of COPD symptoms on a patient's health. The original CAT included eight items examining current symptoms affecting daily activities and overall well-being: cough, phlegm, chest tightness, dyspnea, activity limitation, confidence, sleep, and energy. Each item is rated on a scale of 0 to 5, resulting in a total score of 0 to 40. Lower scores indicate fewer symptoms and better outcomes, while higher scores indicate a poorer medical condition (94). The original CAT was translated into the Ethiopian official language Amharic using a linguistic validation procedure following the International Society for Pharmacoeconomics and Outcome Research's translation and cultural adaptation approach for patient-reported outcomes (95).

CAT-Am is a translated version of the original COPD assessment test involving meticulous translation and back-translation (96). The cutoff point indicates the impact of COPD on HRQoL. The impact of COPD symptoms on patient's lives can be categorized into four levels based on the CAT score: low (CAT scores of 1–10), medium (CAT scores of 11–20), high (CAT scores of 21–30), and very high (CAT scores of 31–40).

II. Adherence in Chronic Disease Scale (ACDS)

The questionnaire consists of 7 questions. Questions 1–5 pertain to the patient’s behaviors related to medication, while questions 6 and 7 concern the physician-patient relationship. Each item on the scale is assigned 0-4 points based on the response. The total medication adherence score ranged from 0 to 28. A patient with a total score of >26 points is classified as having high adherence to treatment, while scores of 21–26 and <21 points indicate medium and low adherence respectively (96). The questionnaire is available for free of charge on the website of the Department of Health Promotion, Collegium Modicum, Nicolaus Copernicus University, Poland (97).

This assessment tool not only evaluates patient adherence to their pharmacotherapy but also identifies the underlying factors that influence their ability to adhere to treatment. The results of the ACDS can provide valuable insights to enable healthcare professionals to take appropriate actions aimed at improving medication adherence in clinical practice. In this study, the adherence level was measured using the ACDS, and its internal consistency with a Cronbach's alpha value of ($\alpha = 0.74$), was found to be within acceptable ranges.

III. **mMRC Dyspnea Scale**

The mMRC Dyspnea Scale, also known as the MRC Breathlessness Scale, is used to grade the impact of breathlessness on daily activities. It is a validated self-assessment tool that measures the impact of breathlessness on day-to-day activities and functional disability (98). The scale ranges from 0 to 4: 0 indicates no breathlessness except during strenuous exercise, 1 "indicates experiencing shortness of breath when hurrying on level ground or walking up a slight hill", 2 "indicates walking slower than people of the same age on level ground or needing to stop to catch a breath when walking at their own pace on the level", 3 "indicates needing to stop for breath after walking about 100 meters or a few minutes on the level", and 4 "indicates feeling too breathless to leave the house or experiencing breathlessness when dressing or undressing, with a higher score indicating worse health status" (99).

4.7.1 Requirement data collector and training

The data were collected by three individuals with prior experience in data collection, who are nurses (BSc nurses). They conducted administered interviews with patients to gather information. Demographic and clinical parameters were recorded using a structured questionnaire designed to capture various details, including disease-related characteristics such as GOLD stage severity, CAT, FEV1, ACDS, and mMRC scores during follow-up.

4.8 Data Quality Assurance

All questionnaires were translated into Amharic, and essential feedback was given to the data collectors at the end of each collection session. Structured and validated tools were used to ensure the accuracy and quality of the data. Questionnaire pretests were conducted on 5% of the study population, which included 11 COPD patients at TASH. The pre-test results were used to clarify ideas and statements, but the data was not included in the main results. Based on the results of the pre-test, necessary corrections were made before the actual study was conducted. Trained clinical nurses from the chest clinic were responsible for data collection. They underwent two hours of training on the questionnaire contents, identifying patients based on the eligibility criteria, and obtaining consent. The principal investigator continuously supervised and followed up to ensure the completeness, accuracy, and consistency of the data throughout the process.

4.9 Data Analysis and Interpretation

All questionnaires underwent manual review to ensure completeness and uniformity of responses. The data was cleaned, entered into Excel, and analyzed using STATA software version 17. Descriptive statistics (frequency, percentage, mean, SD, median, and interquartile range) were used to summarize sociodemographic and clinical and disease-related characteristics. To present the data table and chart were used. Categorical variables were presented as frequencies and percentages. The normality of continuous variables was verified using the Shapiro-Wilk test.

For normally distributed data, the results were displayed as mean and standard deviation (SD), and for non-normally distributed data, the results were shown as median, and interquartile range (IQR). Variables with a p-value less than 0.2 from the bivariate test were selected as candidate variables for the multivariable linear regression analysis. This analysis aimed to identify possible predictors of HRQoL. A p-value of less than 0.05 was considered statistically significant, and all tests were two-tailed.

The psychometric properties of the CAT-Am were assessed as follows:

Acceptability

In this study, we evaluated the acceptability of the CAT-Am by analyzing a variety of parameters, including response rate, percentage of missing data, and time necessary to complete the eight-item questionnaire. These measures were used to determine the general usability and acceptability of the CAT-Am in our study population.

Reliability CAT-Am

Cronbach's alpha coefficient was calculated to assess reliability, which measures the internal consistency of the responses. This coefficient determines the degree to which the scores of each item are correlated with the scores of all other items. This coefficient varies between 0 to 1, with higher values suggesting good reliability. Cronbach's alpha values ≥ 0.70 were considered acceptable; values greater than 0.8 were considered good; and values greater than 0.9 were considered excellent consistency. Whereas, a low alpha value suggests that the items do not measure the same thing or have high variability (100).

Construct validity

Constructive validity of CAT-Am-Structural or factorial validity refers to the degree to which the initial version factor or structure of the CAT can be replicated when applied in different contexts. PCA was employed to determine the dimensionality of CAT-Am. Factors were extracted using eigenvalues greater than 1, and items loading above 0.40 on a single factor were retained. The number of factors was determined based on clinical interpretability and fit to the model (101). The suitability of PCA was evaluated by using Bartlett's test of sphericity and Kaiser Meyer-Olkin (KMO), and the model construct was further validated by CFA. Furthermore, convergent validity was assessed using multitrait scaling analysis, which examined item-own scale correlations to confirm convergence validity. Item convergence was deemed present when an item showed a correlation of 0.40 or higher with its respective scale (102). The convergent validity of each scale was evaluated by calculating Pearson's correlation coefficient with CAT-Am.

Predictive validity

The predictive validity of CAT was assessed by determining the correlation between the CAT Am and mMRC dyspnea scale.

Known group validity

Known group validity was assessed by comparing the CAT-Am scores among patients grouped according to patients, GOLD severity stage, GOLD ABE assessment, and COPD exacerbation history in the past years. The hypothesis was that there was no difference in the level of HRQoL among Group A, Group B, and Group E, GOLD stage (I-IV), <2 exacerbation history in the past years with ≥ 2 exacerbations in the past years respectively by One way-ANOVA.

4.10 Plan for dissemination of results

The findings of the study will be shared with the staff of the School of Pharmacy and other relevant stakeholders. A copy of the research will be provided to the AAU School of Pharmacy, and the results will be published in appropriate scholarly journals.

4.11 Operational definition

COPD exacerbation: An acute and significant change in the patient's daily symptoms resulting in a change in therapy (103).

Convergent Validity: refers to the degree to which two constructs that should theoretically be related are related (104).

Psychometric properties: Refer to the validity and reliability of the measurement tool, including convergent validity, divergent validity, internal consistency, test-retest reliability, and CFA (105).

Medication adherence levels: The extent to which a person's behavior corresponds with recommendations from health care providers (106).

Current smoker: The term "current smoker" refers to someone who has smoked more than 100 cigarettes (such as hand-rolled cigarettes, cigars, cigarillos, and so on) throughout their lifetime and has smoked within the past 28 days (107).

Ex-smoker: Ex-smokers are those who have smoked more than 100 cigarettes in their lives but have not smoked in the past 28 days (108).

Non-smoker: refers to someone who has never smoked more than 100 cigarettes in their lives and does not smoke now (107).

Social support: assistance with some of your daily activities like dressing or showering, or instrumental activities of daily living like shopping or housework

Illiterate: The World Health Organization (WHO) defines illiteracy as the inability to read and write a short, simple statement about life in general.

4.12 Ethical consideration

Ethical approval was obtained from the School of Pharmacy Ethical Review Committee, Addis Ababa University (Ref no. ERB/SOP/523/15/2023), and the ethical committee of each hospital TASH (Ref no. PCP/239/15/23), SPHMMC (Ref no: PM 23/25) and LGH (Ref no: PCP/018/16/23) and obtained data collection permission. The official Amharic version of the CAT questionnaire was obtained from MAPI research trust, PROVIDE, 27 rue de la Villette, 69003 Lyon, France who are authorized to provide translated versions of the CAT questionnaire upon request. Informed consent has been obtained from patients after thoroughly explaining the aims and benefits of the study. Data confidentiality was maintained by omitting the names and addresses of the patients.

The data obtained for this study were not to be utilized for any other studies without the consent of each participant, and an explanation was given that there was no special benefit for the patients who volunteered to participate in the study.

5 Results

5.1 Sociodemographic characteristics of study patients

This study included a total of 205 COPD patients, of whom 81 were females (39.51%), and more than half were males, 124 (60.49%). The patients had a mean (SD) age of 63.08 (11.04) years. More than half of the patients, 109 (53.17%) were married, and 51 (24.88%), were illiterate. Furthermore, 120 (60.00%) were non-smokers, 71(34.63%) were ex-smokers, and 11 (5.37%) were current smokers. Additionally, 117 (57.07%) were exposed to biomass fuel, 127 (61.95%) were orthodox Christians, 150 (73.17%) had health insurance, and 33 (16.10%) had no social support (Table 1).

Table 1: Sociodemographic characteristics of COPD patients attending TASH, SPHMMC, and LGH chest clinic in Addis Ababa, Ethiopia, 2024 (n=205).

Variables		**n (%)**
Hospital	TASH	140 (68.29)
	SPHMMC	37 (18.0.5)
	LGH	28 (13.66)
Age (years) (Mean ±SD))		63.08 (11.04)
Sex	Male	124 (60.49)
	Female	81 (39.51)
Average monthly income (ETB) (Mean ±SD)		7300.22 (5322.542)
Educational status	Illiterate	51 (24.88)
	Primary school	71 (34.63)
	Secondary school	42 (20.49)
	Higher education	41 (20.00)
Marital status	Married	109 (53.17)
	Single	20 (9.76)
	Widowed	66 (32.20)
	Divorce	10 (4.88)
Residence	Rural	36 (17.56)
	Urban	169 (82.44)
Religion	Orthodox	127 (61.95)
	Muslim	39 (19.02)
	Protestant	36 (17.56)

	Others#	3 (1.46)
Biomass-fuel	No	88 (42.93)
	Yes	117 (57.07)
Smoking status	Current smoker	11 (5.37)
	Ex-smoker	71 (34.63)
	Non-smokers	123 (60.00)
Amount of smoking (pack/years) **(**Median (IQR)		22 (16-30)
Duration of smoking (years) (Median (IQR)		25 (20-30)
Occupational status	Farmers	16 (7.80)
	Housewife's	24 (11.71)
	Merchant	28 (13.66)
	Un employed	32 (15.61)
	Employee	59 (28.78)
	Retired	46 (22.44)
Social support	No	33 (16.10)
	Yes	172 (83.90)
Health insurance	No	55 (26.83)
	Yes	150 (73.17)

Abbreviations: ETB = Ethiopian Birr Others # catholic and waqefeta

5.2 Clinical characteristics of the study patients

The most common initial symptom was dyspnea, accounting for 78 (38.0%) cases. The mean (SD) FEV1 was 59.43 (23.70), the mean (SD) FVC1 was 90.2 (31.38), and the duration of illness was a mean (SD) of 2.51 (2.29) years. The mean (SD) of hospitalizations in the past years and exacerbations in the past were 1.00 (0.74), and 2.17 (0.83), respectively. 55 (26.83%) were in grade 4 on the mMRC dyspnea score and 93 (30.37%) were on ICS+LABA (Table 2).

Table 2: Clinical characteristics of the COPD patients attending at TASH, SPHMMC, and LGH chest clinic in Addis Ababa, Ethiopia, 2024 (n=205).

Variables		**n (%)**
Initial symptoms	Fatigue	26 (12.68)
	Dyspnea	78 (38.05)
	Cough	73 (35.61)
	Wheezing	28 (13.66)
Duration of illness (years)	(Mean ±SD)	2.51 (2.29)
Presence of comorbidities'	No	65 (31.71)
	Yes	140 (68.29)
Current COPD treatment	ICS+LABA	94 (30.73)
	ICS+LABA /SABA	64 (31.22)
	SABA	29 (14.15)
	ICS+SABA	10 (4.88)
	Oxygen	8 (3.90)
Number of medications	(Mean ±SD)	4.90 (2.28)
GOLD ABE assessment tool	Group-A	56 (27.32)
	Group -B	59 (28.78)
	Group- E	90 (43.90)
Body Mass Index (kg/m2)	<18.5	95 (46.34)
	18.5-24.9	81 (39.51)
	≥25	29 (14.15)
mMRC dyspnea scale	Grade 0	25 (12.20)
	Grade 1	55 (26.83)
	Grade 2	32 (15.61)

	Grade 3	38 (18.54)
	Grade 4	55 (26.83)
FEV1	(Mean ±SD)	59.43 (23.70)
FVC	(Mean ±SD)	90.2 (31.38)
FEV1/FVC	(Mean ±SD)	62.76 (8.56)
Number of hospitalizations in past years	(Mean ±SD)	1.00 (0.74)
Number of exacerbations in the past years	(Mean ±SD)	2.17 (0.83)

GOLD COPD Severity stage distribution

The disease was categorized into four severity levels based on the GOLD guideline criteria. A minor fraction of patients, 15.12%, were classified as GOLD stage 4; GOLD stage 3 (severe) represented 28.79%, followed by GOLD stage 2 (moderate) at 28.79% and GOLD stage 1 (mild) at 27.32% (Figure 2).

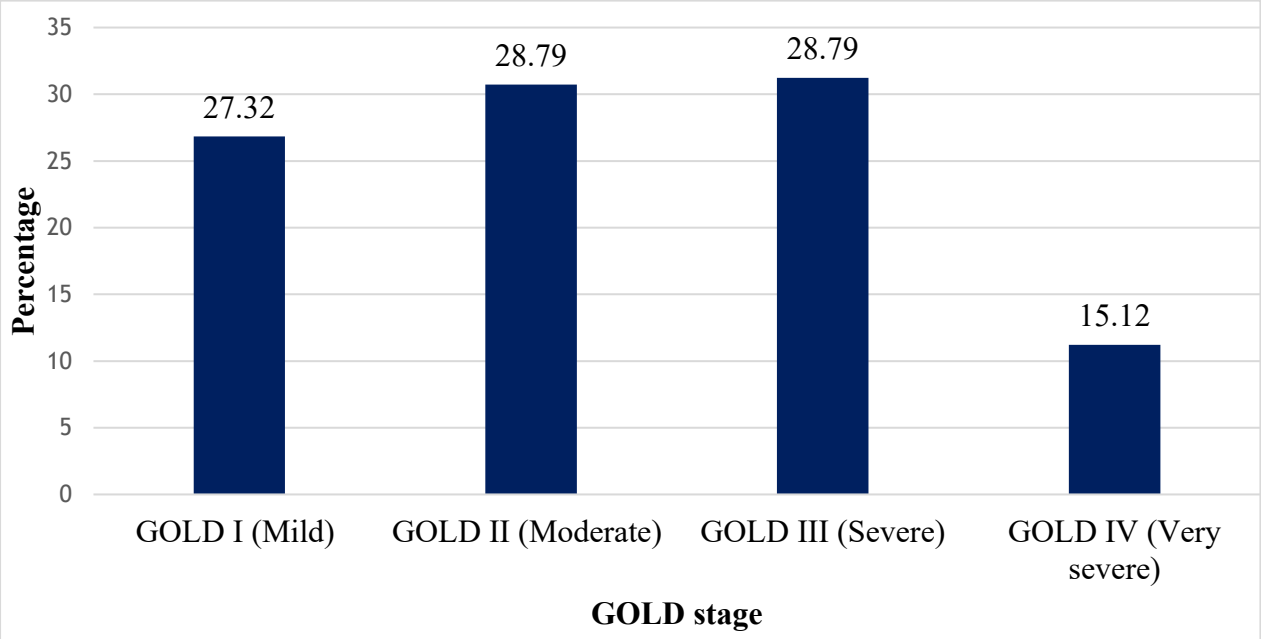

Figure 2: Based on the 2024 GOLD guidelines, the classification of COPD patients attending the chest clinics at TASH, SPHMMC, and LGH in Addis Ababa, Ethiopia, 2024 (n=205).

The most common types of comorbidities

The majority, 140 (68.29%), had comorbid conditions. Hypertension was the most frequently encountered comorbidity (22.35%), followed by hypertension with diabetes mellitus (14.12%), major depressive disorders (12.35%), and polycythemia (11.18%), asthma (4.7%), peripheral neuropathy (1.76%), and hypertension with peripheral arterial disease (2.35%) (Figure 3).

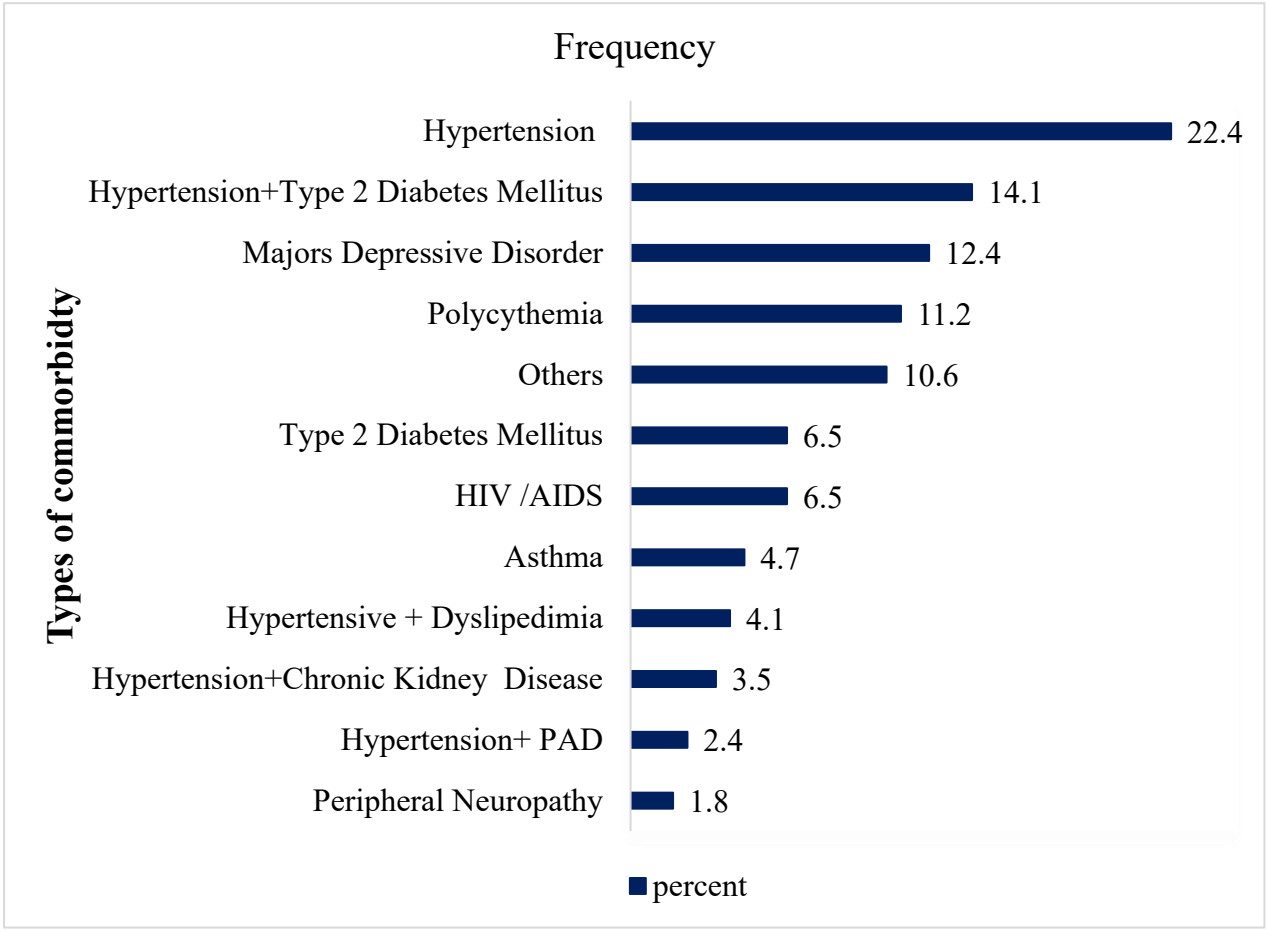

Figure 3: Types of comorbidities in COPD patients at TASH, SPHMMC, and LGH 2024 (n=205)

5.3 Level of medication adherence with ACDS of COPD patients

The ACDS questionnaire gives people with Chronic Obstructive Pulmonary Disease (COPD) scores that range from 8 to 28 points, with a median of 21 points for medication adherence. The mean adherence score was calculated to be 21.93 with a standard deviation of 4.96. Approximately 82 (40.00%) exhibited low adherence, 50 (24.37%) demonstrated medium adherence, and 73 (35.61%) displayed good adherence (refer to Figure 4).

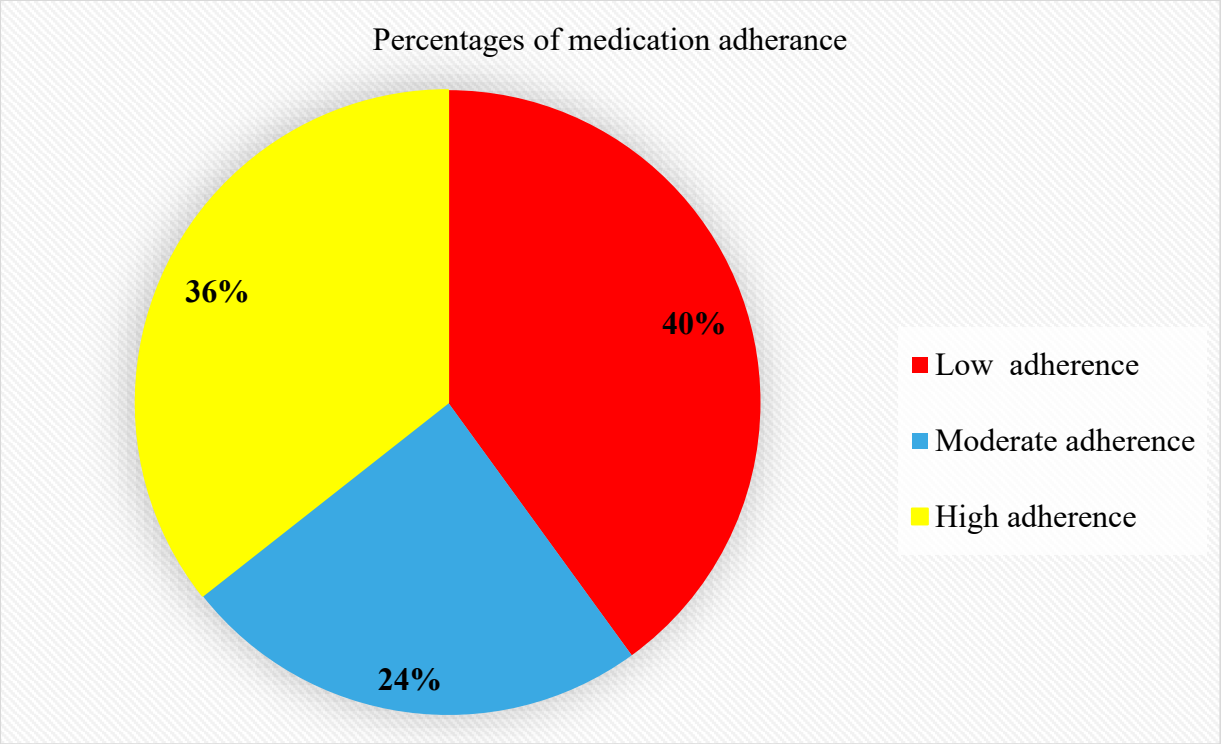

Figure 4: Level of adherence among COPD patients at TASH, SPHMMC, and LGH, Addis Ababa, Ethiopia 2024 (n=205)

5.4 Psychometric properties of the CAT-Am

Acceptability

A total of 205 patients completed the eight-item questionnaire in five to eight minutes. All patients agreed to participate, and there were no unanswered questions. Even patients with limited formal education found all questions clear and easy to understand. When assessing HRQoL, the mean score for each CAT-Am item ranged from 2.07 to 3.20. Higher scores indicate more significance of COPD and its symptoms on HRQoL.

Individual responses to items varied from 0 to 5. Item 4, "When I go up a hill or a flight of stairs, I am not breathless", received the highest mean (SD) score of 3.20 (1.33), while item 5, "I am not limited to doing any activities at home, scored 2.07" (1.26). The overall mean CAT-Am score was 20.24 (8.13).

Table 3: Descriptive statistics for individual CAT-Am items COPD patients attending at TASH, SPHMMC, and LGH chest clinic in Addis Ababa, Ethiopia, 2024 (n=205).

COPD Assessment Test (CAT)	Mean ± SD
I never cough	2.85±1.37
I have no phlegm (mucus) in my chest at all	2.55±1.51
My chest does not feel tight at all	2.68±1.45
When I walk up a hill or one flight of stairs, I am not breathless	3.20±1.33
I am not limited to doing any activities at home	2.07±1.26
I am confident leaving my home despite my lung condition	2.25±1.30
I sleep soundly	2.17±1.15
I have lots of energy	2.43±1.25
CAT Total Score	**20.24±8.13**

Data is expressed as mean (standard deviation); ratings were made on a numerical scale, 0, representing no effect; 5, as a negative effect.

Reliability of CAT-Am

The CAT-Am total score demonstrates high internal consistency, with a Cronbach's alpha of 0.89. Additionally, when individual items were deleted, Cronbach's alpha ranged from 0.88 for "when I walk up a hill or one flight of stairs, I am not breathless" to 0.89 for "I am not limited in doing any

activities at home". The scale's reliability improved with the internal consistency of the eight items (see Table 4).

Table 4: Reliability analysis of CAT-Am COPD patients attending at TASH, SPHMMC, and LGH chest clinic in Addis Ababa, Ethiopia, 2024 (n=205).

Variables	Cronbach alpha if Item deleted
Cough	0.8799
Mucus	0.8887
Chest tightness	0.8845
Breathlessness	0.8756
Home activities	0.8910
Confident	0.8849
Sleep	0.8876
Energy	0.8868
Cronbach's Alpha (overall)	**0.89**

The eight CAT-Am items based on the inter-item correlation coefficient, varied from "confident with mucus" (0.379) to a cough with mucus (0.764), as shown in (Table 5).

Table 5: Pearson correlation between scores on different items of the CAT-Am COPD patients attending at TASH, SPHMMC, and LGH chest clinic in Addis Ababa, Ethiopia, 2024 (n=205).

Variable	Cough	mucus	chest tightness	Breathlessness	home activities	confident	sleep	energy
Cough	1.000							
Mucus	0.764	1.000						
Chest tight	0.597	0.553	1.000					
Breathlessness	0.664	0.622	0.734	1.000				
Home Activities	0.410	0.379	0.379	0.499	1.000			
Confident	0.447	0.379	0.528	0.579	0.622	1.000		
Sleep	0.491	0.426	0.454	0.469	0.531	0.598	1.000	
Energy	0.503	0.380	0.443	0.537	0.570	0.570	0.626	1.000

Abbreviations: CAT-Am - COPD Assessment Test Amharic version

Construct Validity

Construct validity was assessed using PCA with Oblimin rotation and Kaiser normalization. First, Bartlett's sphericity test was performed to verify the adequacy of the sample size for factor analysis. The test yields a statistically significant result ($\chi 2$= 942.82, df = 28, P<0.001), indicating that the variance differed for various components of questionnaires, and the item correlations were strong enough for PCA analysis. The Kaiser Meyer-Olkin measure of sampling adequacy (KMO) was 0.87, suggesting that the samples were suitable for factor analysis. PCA revealed two distinct underlying components within the CAT-Am 8 questions. The eigenvalues for factors 1 and 2 were 4.69 and 1.07, respectively.

Factor 1 accounted for 58.73% of the data variability, while factor 2 accounted for 13.25%. Together, these two factors explained 71.98% of the variance, with all eight items scoring above 0.4 (Figure 5). Four of the eight CAT elements loaded onto the first factor, while the remaining four loaded onto the second factor (Table 6).

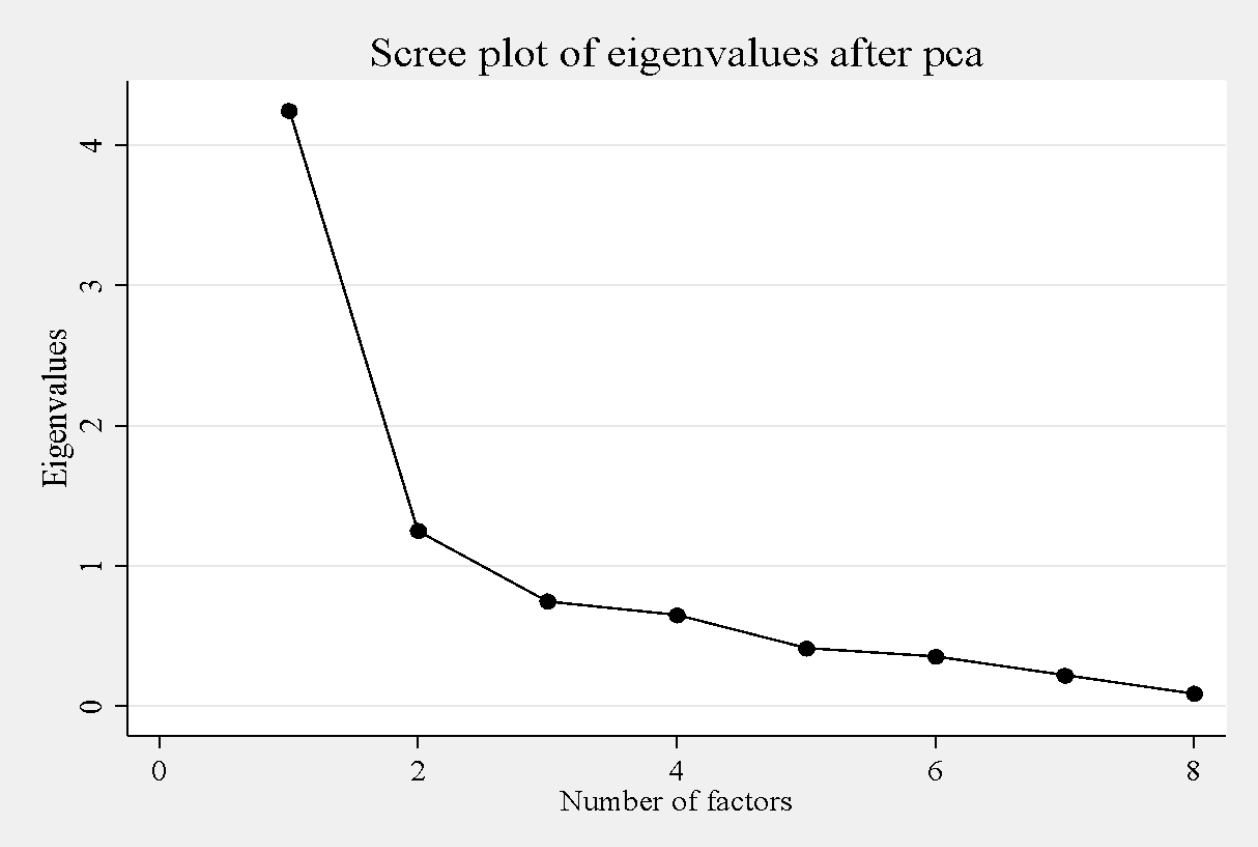

Figure 5: Eigenvalue of the CAT- Amharic version

Table 6: PCA of CAT-Am of COPD patients attending at TASH, SPHMMC, and LGH chest clinic in Addis Ababa, Ethiopia, 2024 (n=205).

Variables	Component 1	Component 2
Cough	0.5291	
Mucus	0.5748	
Chest tightness	0.4476	
Breathlessness	0.4300	
Home Activities		0.5256
Confidence		0.4914
Sleeping		0.4703
Energy		0.4849

Confirmatory factor analysis

After identifying a two-factor solution through PCA, confirmatory factor analysis (CFA) was conducted to further evaluate the factor model derived from PCA. First-order CFA models were used (see Figure 6). It was assumed that the CAT-Am consisted of two distinct correlated components. Goodness-of-fit indices (see Table 7) were used to determine the degree of fit between the data and the hypothesized models.

The loadings of items and factors were found to be statistically significant at the 0.05 level (t-values > 1.96). The $\chi 2$-associated P value was below the 0.05 significance threshold ($\chi 2$ =80.14, df = 19, and P < 0.001). Conversely, a good model should have an insignificant p-value. However, other fit indices in the model did not meet acceptable levels including ($\chi 2$/df =4.218, RMSEA =0.126, and RFI= 0.871), while indices such as (AGFI = 0.954, CFI =0.934, IFI = 0.935 TLI= 0.903 and GFI = 0.914) were within an acceptable range.

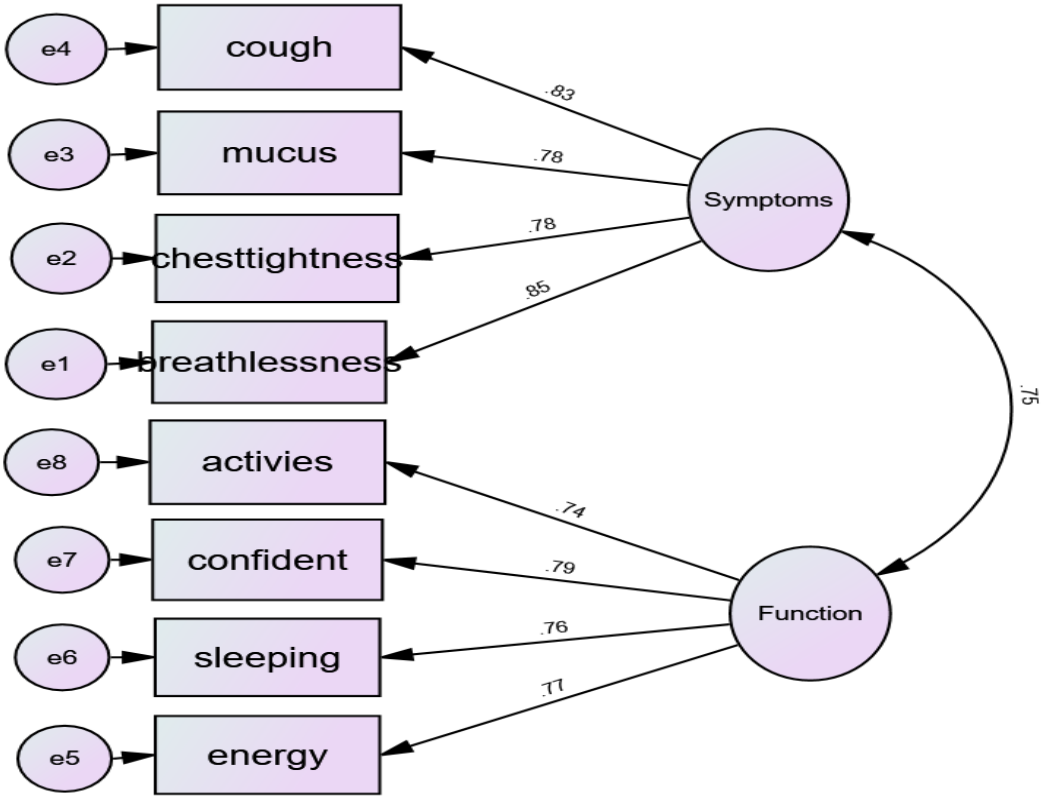

Figure 6: Confirmatory factor analysis of two factors of CAT-Am

Table 7: Model Fit Summary of CAT-Am

Model	**p-value**	**CMIN/DF**	**GFI**	**AGFI**	**RFI**	**IFI**	**TLI**	**CFI**	**RMSEA**
Default model	<0.001	4.218	0.916	0.954	0.871	0.935	0.903	0.934	0.126
Reference	0.005	3	≥0.9	≥0.9	≥0.9	≥0.9	≥0.9	≥0.9	<0.08

Abbreviations: AGFI = Adjusted goodness of fit index; CFI = Comparative fit index, CMIN/DF= Chi-square minimum; DF= Degree of Freedom, GFI = Goodness of fit index; TLI = Tucker-Lewis's index; RMSEA = Root mean square error of approximation.

Convergent validity

Before conducting a multi-trait scale analysis, the data normality was assessed using a box plot and confirmed to meet the assumption. Consecutively, the Pearson correlation was utilized to determine the correlation, with a significance level set at $p< 0.05$. Convergent validity was established by item-own scale correlations with all scales showing item-own scale correlation > 0.4. The breathless item-own scale correlation is near one. Additionally, all other scales have item-own correlation above 0.4. Analysis of item-own scale correlation suggests that the tool scales satisfied the convergent validity requirement (Table 8).

Table 8: Convergent validity of CAT-Am of COPD patients attending at TASH, SPHMMC, and LGH chest clinic in Addis Ababa, Ethiopia, 2024 (n=205).

Variables	Item- own scale correlation	Item-Own Scale Correlation After Correction for Overlap	p-value
Cough	0.806	0.7325	< 0.001
Mucus	0.7491	0.6478	< 0.001
chest tightness	0.7733	0.6843	<0.001
Breathlessness	0.8390	0.7790	<0.001
Home Activity	0.7080	0.6163	<0.001
Confident	0.7604	0.6792	<0.001
Sleeping	0.7340	0.6576	<0.001
Energy	0.7465	0.6649	<0.001

Predictive Validity

The study examined the correlation between the CAT-Am and the mMRC dyspnea scale to assess its predictive validity. The analysis included 205 individuals and resulted in a Pearson correlation value of $r=0.453$. This correlation was found to be statistically significant (p-value < 0.001), indicating a moderate positive correlation between the CAT-Am scores and the mMRC dyspnea scale (Table 9).

Table 9: Pearson correlation of predictive validity of CAT-Am with mMRC dyspnea scale

Variable	N	Correlations	P- value
mMRC dyspnea scale	205	0.453	<0.001

Known-Group Validity

The study assessed the known group validity of the CAT-Am by examining the mean differences among different groups, such as the GOLD ABE assessment test, GOLD stage, and exacerbation history in the past years. The result showed a higher mean CAT score in Group E compared to Group B and Group A based on the GOLD ABE assessment test, with a significant difference noted. Additionally, there were significant variations in mean CAT scores based on GOLD stage IV and COPD exacerbation history, indicating higher mean CAT scores in individuals with very severe COPD and those with more than two exacerbations in the past years respectively (Table 10).

Table 10: Known Group Validity assessment (One-Way ANOVA test) in TASH, SPHMMC, and LGH in Addis Ababa, Ethiopia, 2024 (n = 205).

Variable	Categories	Mean (SD)	p-value
GOLD ABE	Group A	14.21 (8.12)	< 0.001
	Group B	19.27 (6.91)	
	Group E	24.63 (6.05)	
GOLD stage	Mild	14.21 (8.12)	<0.001
	Moderate	19.27 (6.91)	
	Severe	23.56 (6.11)	
	Very severe	26.68 (5.44)	
Exacerbation history in the past years	<2	12.46 (5.67)	<0.001
	≥2	22.19 (7.47)	

5.5 HRQoL in COPD patients

5.5.1 Mean difference of CAT score with sociodemographic characteristics

The data satisfies the initial three assumptions of ANOVA, which include a continuous dependent variable, categorical independent variables, and independent observations. We have also assessed normal distribution, homogeneity of variance, and the presence of any significant outliers. A one-way ANOVA was performed to examine the impact of sociodemographic and clinical characteristics on HRQoL. The result of the one-way ANOVA indicated a statistically significant difference in patients' biomass fuel exposure (P <0.001). There were no statistically significant differences in the mean CAT scores based on sex (p = 0.976), average monthly income (p = 0.181), educational status (p = 0.235), marital status (p = 0.693), residence (p = 0.124), religion (p = 0.203), social status (p = 0.112), health insurance coverage (p = 0.377), smoking status (p = 0.709), amount of smoking (p = 0.466), duration of smoking (p = 0.337), and occupational status (p = 0.546) (See Table 11).

Table 11: Mean differences in CAT-Am with sociodemographic characteristics of patients with COPD at TASH, SPHMMC, and LGH in Addis Ababa, Ethiopia, 2024 (n=205).

Variable		CAT-score Mean (SD)	p-value
Sex	Female	20.22 (7.89)	0.976
	Male	20.26 (8.31)	
Educational status	Illiterate	20.29 (8.31)	0.235
	Primary school	21.48 (8.22)	
	Secondary school	20.10 (7.87)	
	Higher education	18.20 (7.86)	
Marital status	Married	20.28 (8.01)	0.693
	Single	18.9 (8.60)	
	Widowed	20.88 (8.01)	
	Divorce	18.4 (9.71)	
Residence	Rural	22.14 (8.06)	0.124
	Urban	19.84 (8.11)	
Religion	Orthodox	19.96 (8.06)	0.203
	Muslim	21.67 (8.78)	
	Protestant	19.05 (7.620	

	Others#	27.67 (0.577)	
Biomass-fuel exposure	No	15.30 (6.87)	**0.001**
	Yes	23.97 (6.95)	
Smoking status	Current smoker	21.91 (7.12)	0.709
	Ex-smoker	19.80 (8.45)	
	Non-smokers	20.35 (8.06)	
Occupational status	Farmers	17.63 (9.170	0.546
	Housewife's	19.83 (7.12)	
	Merchant	22.25 (7.40)	
	Un employed	19.41 (7.89)	
	Employee	20.78 (8.50)	
	Retired	20.04 (8.40)	
Social support	No	22.30 (7.62)	0.112
	Yes	19.85 (8.18)	
Health insurance coverage	No	19.42 (8.37)	0.377
	Yes	20.54 (8.04)	

5.5.2 Mean difference of CAT score with clinical characteristics of patients

A statistically significant difference was found between patients' clinical characteristics and the mean CAT score. Factors such as duration of COPD (p= 0.027), current COPD treatment (p=0.011), GOLD ABE group (p<0.001), mMRC dyspnea score (p<0.001), medication adherence (p<0.001), and GOLD stage severity (p<0.000) were all significantly associated with a higher impact of COPD on HRQoL. In contrast, BMI (p=0.323), initial symptoms (p=0.088), and presence of comorbidity (p=0.388), showed no statistical significance (Table 12).

Table 12: Mean differences in CAT with clinical characteristics of patients with COPD at TASH, SPHMMC, and LGH in Addis Ababa, Ethiopia, 2024 (n=205).

Variables		**CAT score Mean (SD)**	**p-value**
Initial symptoms during diagnosis	Fatigue	19 (8.12)	0.088
	Dyspnea	22.07 (7.33)	
	Cough	19.30 (8.25)	
	Wheezing	18.75 (9.34)	

Presence of comorbidities	No	13.57 (6.50)	**0.001**
	Yes	23.34 (6.85)	
Current COPD treatment	ICS+LABA	21.29 (7.66)	**0.011**
	ICS+LABA +SABA	18.75 (8.14)	
	SABA	20.97 (7.59)	
	ICS+SABA	23.9 (8.97)	
	Oxygen	12.75 (5.57)	
GOLD ABE assessment tool	Group-A	14.21 (8.12)	**<0.001**
	Group-B	19.27 (7.91)	
	Group- E	24.63 (6.05)	
GOLD stage severity	Mild	14.21(8.12)	**<0.001**
	Moderate	19.27 (6.91)	
	Severe	23.56 (6.11)	
	Very severe	14.21 (8.12)	
Body Mass Index	<18.5 kg/m2	19.36 (8.46)	0.323
	18.5-24.9 kg/m2	21.20 (7.78)	
	>25 kg/m2	20.48 (7.91)	
mMRC dyspnea scale	Grade 0	14.6 (8.67)	**<0.001**
	Grade 1	16.56 (7.37)	
	Grade 2	20.88 (5.87)	
	Grade 3	22.21 (6.63)	
	Grade 4	24.76 (7.72)	
Medication adherence level	poor adherence	23.70 (6.37)	**<0.001**
	moderate adherence	22.46 (6.72)	
	good adherence	14.85 (8.01)	

5.6 Factors Affecting HRQoL in COPD Patients

Univariate Analysis

In the univariate analysis, 12 variables were identified as having an association with HRQoL as measured by the CAT. This included categorical variables with multiple categories, such as biomass fuel exposure, social support, number of medications, and presence of comorbidity, as well as those with three or more categories like GOLD severity stage, mMRC dyspnea scale, and medication adherence. Additionally, continuous variables included age, FEV1, number of hospitalizations in the past years, number of exacerbations in the past years, and duration of illness.

Multivariable Linear Regression

The regression model produced a significant F-statistic of 27.78 (df = 18, 186; $P < 0.0001$). The model accounted for 72.89% of the variation in CAT scores ($R^2 = 0.7289$) and had an adjusted R^2 of 0.7026, indicating a good fit for the data. The root means square error (RMSE) was estimated at 4.43, showing the average deviation of projected values from actual values. Eight of the 12 variables used for multivariable linear regression analysis were identified as associated with HRQoL by stepwise and forward multivariable linear regression methods.

Older age, patients' lack of social support, biomass fuel, number of medications, number of hospitalizations in the past years, Low medication adherence and moderate medication adherence, and the presence of comorbidity were associated with HRQoL (Table 11).

Table 13: Factors associated with HRQoL of patients with COPD attending at TASH, SPHMMC, and LGH chest clinic in Addis Ababa, Ethiopia, 2024 (n=205)

Predictor variable	Unstandardized coefficient	p-value	β (95%CI)	
	β		**Lower bound**	**Upper bound**
Age (years)	0.105	**0.001**	0.0436101	0.1669829
FEV1	0.015	0.433	-0.0223639	0.0520174
Number of hospitalizations in the past years	2.781	**<0.001**	1.678854	3.882517
Number of exacerbations in the past years	0.147	0.753	-0.7757137	1.070518
Biomass fuel exposure (No)	Ref			
Yes	4.572	**<0.001**	3.172839	5.970988
Social support (yes)	Ref			
No	2.492	**0.005**	0.7425076	4.241873
Duration of illnesses (COPD)	0.132	0.355	-0.1486372	0.4120458
Number of medications	0.400	**0.010**	0.0975043	0.7030164
GOLD severity (GOLD 1)	Ref			
GOLD 2	2.115	**0.028**	0.2253855	4.004546
GOLD 3	3.383	**0.004**	1.105203	5.660593
GOLD 4	5.208	**<0.001**	2.369366	8.047113
mMRC dyspnea scale (grade 0)	Ref			
Grade 1	0.560	0.614	-1.628781	2.74813

Grade 2	1.324	0.301	-1.19446	3.842008
Grade 3	0.023	0.985	-2.485442	2.532841
Grade 4	0.197	0.873	-2.22959	2.622974
Medication adherence low adherence	2.793	**0.001**	1.131414	4.455166
Moderate adherence	3.379	**<0.001**	1.645849	5.112403
High adherence	Ref			
Presence of comorbidity (No)	Ref			
yes	4.033	**<0.001**	2.475175	5.589995

6 Discussion

This study is the first to assess the psychometric properties of the CAT and HRQoL in Ethiopian COPD patients using the Amharic language. The aim was to evaluate the psychometric properties of the culturally adapted Amharic version of CAT and identify relevant predictors of HRQoL within 205 individuals and the results indicate that the CAT-Am is valid and reliable for assessing HRQoL in Ethiopian COPD patients.

This suggests that effective psychometric methods can be applied successfully across different cultural groupings and also demonstrates that construct and predictive validity can be efficiently assessed in clinical settings, allowing for the collection of data on HRQoL and medication adherence in self-administered interviews. In this study, the CAT-Am showed good internal consistency with a Cronbach's alpha value of 0.89. This result aligns with the original version of CAT, which had a Cronbach's alpha value of 0.88. Similarly, Tsuda and colleagues reported a Cronbach's alpha value of 0.891 for the Japanese (83).

A systematic review, which included studies from several countries in Europe, North America, South America, Asia, and Africa, found the internal consistency of the CAT Cronbach alpha value mean from 0.85 to 0.98 (86). However, this is in contrast to the findings from the Korean and Thai versions of CAT, which reported a Cronbach alpha value of 0.85 (87, 109). Additionally, a study conducted in Canada, which included non-COPD subjects, reported the Cronbach alpha value for the CAT was 0.79 (110).

In a study conducted in Iran among Persian COPD patients Cronbach alpha value of 0.732 (111). Comparing this study to ours, we found a higher Cronbach alpha value. In contrast to earlier findings, our study found a lower Cronbach alpha value compared with the study conducted in Portuguese the Cronbach alpha value was 0.96 (112), and in Uganda reported a Cronbach alpha value of 0.924 (113). The strength of this correlation suggests that they all measure similar aspects of the disease, with the advantage of CAT-Am being its greater simplicity and ease of administration. The CAT's psychometric properties may vary between populations due to intercultural heterogeneity in the items used, which might explain the disparities. A scale with high dependability in one demographic may not be as reliable in another. To utilize measurements across cultures, items must be both linguistically and culturally verified to ensure consistency.

In this study, initial factor analysis generated two components. The factor solution for the Amharic version produced two factors with an eigenvalue over 1 (4.69 and 1.074), similar to another study

by P.W. Jones et al, all items are loaded on two factors (114), which are categories; symptoms and functional limitations. However, this finding is different from the study conducted in Turkey which has one component (115). Therefore, using a total CAT-Am score with the mean of all eight items should also be appropriate for the Amharic version, indicating good construct validity. Even though the study's factor analysis revealed two components for HRQoL, no meaningful theoretical concept underpinning each concept was identified.

A correlation test was used to determine the CAT-Am tool's convergent validity. All-item correlations within their scales exceeded 0.4. Item-own scale correlations for CAT-Am items revealed convergence on all scales. This study is consistent with previous observations (116, 117). This finding supports the reliability of the CAT-Am tool, indicating that its items effectively measure the same underlying constructs. Such convergence reinforces the tool's validity in assessing its intended dimensions.

In the mMRC dyspnea scale study correlation analysis was utilized to determine if the degree of HRQoL predicted COPD and to evaluate the predictive validity of the scale. The study found a significant correlation between the mMRC dyspnea scale and the CAT-Am ($r=0.453$) and all had a significant correlation, and consistency with studies (117-119). This suggests that as the severity of dyspnea increases, the impairment in HRQoL also becomes more pronounced. Additionally, the findings underscore the effectiveness of the CAT-Am as a reliable tool for assessing the impact of COPD on patients' everyday functioning and well-being.

Known-group validity was performed to check whether the CAT-Am was able to detect differences between distinct groups. As expected, the analysis revealed that patients in GOLD ABE assessment tool group E, GOLD 4, with two or more exacerbations in the past years reported higher CAT scores, indicating good known group validity. Our findings are consistent with studies conducted in Scotland (120). These studies also demonstrated that higher CAT scores correlate with increased symptom burden and reduced QoL among patients with severe COPD. This reinforces the importance of utilizing the CAT-Am as a reliable measure for assessing disease impact in diverse clinical populations. This suggests that the CAT-Am can effectively capture the severity of symptoms and their impact on patient's lives, making it a valuable tool for healthcare providers. By using this assessment, clinicians can better understand and address the needs of individuals suffering from severe COPD.

A possible rationale behind these discrepancies might be the variability of psychometric features of the CAT from population to population due to the nature of items included in the tool that might

have intercultural variability. These variations in Cronbach alpha may reflect cultural differences or other factors affecting the psychometric properties of the CAT. This means that a scale that shows high reliability within one group might not be as reliable within a different group. Therefore, when using measures across different cultures, it's important to translate the items effectively and validate them to maintain the instrument's reliability.

The multivariable linear regression analysis revealed that several factors influence the HRQoL in patients with COPD. The study identified key predictors of HRQoL for individuals with COPD, including age, social support, exposure to biomass fuel, adherence to medication, history of hospitalization, presence of comorbidities, the number of medications taken, and the severity of the disease as classified by the GOLD guidelines. This study showed that the age of patients increased by one, and the impact of COPD on HRQoL increased by 0.11 (β= 0.11, 95%CI: 0.04-0.17). Findings supported this research by Ahmed, *et al* (37). This suggests that as patients age, their HRQoL deteriorates more significantly due to the effects of COPD. These findings highlight the importance of targeted interventions for older patients to improve their HRQoL.

This study found that lack of social support increases the impact of COPD on HRQoL by 2.49 compared to those who have social support (β =2.49, 95%CI:0.74, 4.24). There are similar findings from the Netherlands (121), USA (108), Taiwan (122), and a recent systematic review that shows the negative impact of the lack of social support on the HRQoL of COPD patients (123).

Patients with COPD may struggle to stay motivated to manage their illness and adhere to medication in the absence of proper social support, which worsens symptoms and commonly leads to exacerbations which decrease HRQoL. According to research, a lack of social support is associated with poorer COPD outcomes, such as decreased QoL, increased respiratory symptoms, and an overall decline in functional status (121). However, in contrast to our findings, the study conducted in Indonesia (124) revealed that COPD patients with an absence of social support were not associated with poor HRQoL compared to their counterparts. This may be due to the respondents' culture and customs differences.

This study found that patients exposed to biomass fuel have a 4.57-fold increase in the impact of COPD compared to those who are not exposed to biomass fuel (β= 4.57, 95% CI: 3.17, 5.97). This study is consistent with previous research conducted in various regions, for instance, a study by Zhang et al. in China (125) highlights the high risk of biomass fuel exposure to poor HRQOL, Additionally, two studies were conducted in India (126, 127), and systemic review and meta-analysis by Po.et,2011, support the result (128). These findings highlight the critical need for

public health initiatives that reduce biomass fuel use, particularly among marginalized populations whom COPD disproportionately afflicts.

Implementing cleaner cooking technology and encouraging alternate energy sources might greatly reduce the health risks connected with biomass fuel consumption, eventually enhancing the quality of life for those impacted. Investing in education and awareness campaigns about the health dangers of using biomass fuel can help communities adopt safer practices and technology. Additionally, this study showed that the impact of COPD on HRQoL significantly increases with disease severity, particularly GOLD stage 4 found that 5.20-fold increased the impact of COPD on HRQoL compared to those in stage 1 (β = 5.20, 95% CI: 2.369, 8.047). These results are supported by GOLD guideline 2024 (126) and the study conducted in the Netherlands (129, 130).

The presence of the comorbidities increases the impact of COPD by 4.03 compared to those who have no comorbidity on HRQoL (β= 4.03, 95% CI:2.48, 5.59). Under the present results, previous studies have shown that the presence of comorbidities affects COPD patient's HRQoL. A study from Sweden (131), and Nepal (132). The increased complexity of the treatment regimen in the presence of comorbidity could lead to increased pill burden and polypharmacy that may ultimately affect the HRQoL of COPD patients. However, in contrast to our findings, a study conducted in Germany (17) revealed that COPD patients with comorbidity conditions do not associate with HRQoL. This may be interpreted with the fact that comorbid conditions may demand healthcare providers' special attention.

This study shows that with each additional hospitalization, the impact of COPD on patients' HRQoL increases by 2.78 (β=2.78, 95% CI:1.68-3.88). The figures show that with each consecutive hospitalization, COPD patients' HRQoL decreases by a factor of 2.781. This significant increase highlights the severe consequences of exacerbations and hospitalizations for these people's physical and emotional health. Likewise, the number of medications increased by one, and the impact of COPD on HRQoL increased by 0.40 (β= 0.40, 95%CI: 0.09-0.70). These results are consistence those observed in earlier studies in the UK (133, 134), in Greece (135). Increase the burden of pills, make it difficult to manage and its side effects as well as psychological effects decline the overall HRQoL in COPD patients.

The patient's low adherence to medication increased the impact of COPD by 2.79 folds, compared with high medication adherence (β= 2.79, 95%CI: 1.13-4.46) these results support previous research from the UK (135), Iran (136). The patients with COPD who do not adhere to their

medication lead to worsening symptoms, frequent hospitalization, psychological impacts, reduced functional status, and a cumulative decrease in HRQOL of patients with COPD. In contrast to this study, other studies do not support our finding that non-adherence is not related to HRQoL (137).

7 Strengths and limitations of the study

7.1 Strength of the study

The findings of this study are significant in terms of providing data to assist efforts to enhance HRQoL for individual COPD patients. Moreover, as the first study of its kind in Ethiopia, it was carried out in the country's three largest hospitals, encompassing both private and public hospitals. This provides a heterogeneous study population and insights for further study. The study also

introduces a validated CAT-Am tool to assess HRQoL in Amharic, specifically for use in the Ethiopian. Furthermore, this study sets the foundation for further studies on developing appropriate tools for measuring HRQoL and identifying factors associated with HRQoL among COPD patients in Ethiopia and other similar settings.

7.2 Limitations of the study

It is crucial to acknowledge that our study has few limitations. The use of self-reported questionnaires may introduce recall bias. Additionally, since our study is institution-based, generalizing the findings to other settings and populations may be challenging. Furthermore, due to the cross-sectional nature of our survey, establishing causal relationships between associated factors and HRQoL is not possible.

8 Conclusion

The Amharic version of the CAT was proven to be patient-friendly and well-accepted by COPD patients with a high completion rate and a low missing response rate of items. The findings of this study indicate that the Amharic version of the CAT-Am questionnaire can be used as an acceptable, reliable, and valid tool in clinical practice and research to assess the HRQoL of COPD patients in Ethiopia. Factors associated with HRQoL included increased patient age, exposure to biomass fuel, lack of social support, GOLD 4, presence of comorbidities, number of medications, number of hospitalizations in the past years, and poor medication adherence.

9 Recommendation

As the only research on the validity and reliability of CAT and assessment of HRQoL in Ethiopian COPD patients, further research on COPD is needed. Based on the study's findings, some of the following recommendations are.

- Researchers should focus on validating the CAT and other assessment tools to ensure a comprehensive evaluation of COPD.
- Healthcare professionals should deeply assess patients' HRQoL about treatment protocols.
- Health care providers should further evaluate treatment adherence to improve patient outcomes.
- Academics and research institutes should conduct Follow-up studies to determine changes in the patient's HRQoL influenced by various factors.
- Researchers and academics should include qualitative and longitudinal studies to better understand a patient's HRQoL.

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Questionnaire for data collection on assessment Validity and Reliability of the Amharic Version of the Chronic Obstructive Pulmonary Disease Assessment Test for Measuring Health-Related Quality of Life in Ethiopia health facilities

Appendix

Appendix I: Participant consent form and data collection tool

Title of the study: Validity and Reliability of the Amharic Version of the Chronic Obstructive Pulmonary Disease Assessment Test for Measuring Health-Related Quality of Life in Addis Ababa, Ethiopia

Principal investigator: Shimelis Engida (BPharm),

Adviser: Oumer Sada (BPharm, MSc, Assistant Professor of Clinical Pharmacy)

Co-adviser: Girma Tekle (BPharm, MSc, Assistant Professor of Clinical Pharmacy)

Co-advisor: Dr Amsalu Bitew (MD, Pneumologist, Internist, PCCM)

The objective of the study is to assess the reliability and validity of the HRQoL measurement in COPD patients at Tikur Anbessa Specialized Hospital, St. Paul's Hospital Millennium Medical College, and Lancet General Hospital in Addis Ababa, Ethiopia.

Subject Participation and Procedure: The research method is a hospitalized-based cross-sectional study. The expected duration of the patient's contact with the interviewer was not more than 15 minutes. Ask patients in this research because the trustful information provided an understanding of the purpose.

Confidentiality: To establish a secure safeguard of research data privacy, the patient information was coded during the data collection period instead of using a name. The information is not disclosed in the way it identifies your characteristics & privacy.

Benefit: The research does not have a short-term financial, health care, & capacity building benefit to the research participant as an individual or group but in the long run it will help the concerned organization & policy maker to have a policy consideration, direction, formation strategy & design to improve the quality of life among COPD patient.

Incentive, & compensation: This study has no form of incentive or compensation for the respondent.

Hello, my name is _____. We are currently carrying out a study on the Reliability and validity of the COPD Assessment Test (CAT) and assessment of the health-related Quality of Life of COPD patients who are served at TASH, SPHMMC, and LGH. Your collaboration is vital to gather adequate evidence for the study. The interview will take a maximum of 15 minutes, and your participation is voluntary. Participating in or refusing to take part in the study has no bearing on the service you receive from the health facility. You have the right to skip any question that makes you uncomfortable, or you can withdraw from the study at any point. You are under no obligation to answer every question unless you voluntarily confirm your participation. Your participation and all the information you provide will be kept confidential. Your name will not be mentioned under any circumstances, and access to the entire dataset is restricted to the principal investigator and research team. There are no right or wrong answers to the interview questions; we are only interested in your responses and feelings about the questions asked.

If you have any questions or concerns; please contact the principal investigator using the following address.

Persons to contact: Shimelis Engida
E-mail: shime2011ec@gmail.com/shimelis.engida@aau.edu.et
Are you willing to participate? Yes No
If the participant agrees to participate and gives his/her consent, proceed with the interview; if not proceed to the next participant.

Data Collection Instrument:

Part I: Socio-demographic characteristics of the patients

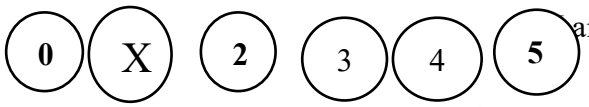
1. Name of health facility: _____ Level of care: _____
2. Gender □ Male □ Female
3. Age (in years) ----------
4. Marital status ❑ unmarried ❑ Married ❑ Divorce ❑ Widowed
5. Educational status
   a) No formal education
   b) Primary (1-8 Grade)
   c) Secondary (9-12 Grade)
   d) Higher education (diploma and above)
6. Employment status Employed----------non-employment----------
7. Religion Orthodox……. Protestant……. Muslim……. Others
8. Region Tigray……Amhara……. Oromia……. Others
9. Occupational status……
10. Residence Rural ……. Urban ….....
11. Average monthly income…….
12. Biomass and Fuel used for cooking Yes----------No----------
13. Lifestyle (Cigarette smoking)
    a) Current smoker
    b) Ex-smoker
    c) Never-smoker
14. amount of smoking (Pack year of smoking) ----------
15. duration of smoking (in years) ----------
16. Health Insurance Coverage Yes---------- No----------
17. Social support Yes ----------No ----------

Part II: Clinical Characteristics of Patients: -

1. Duration of illness (in years) …….
2. Presence Comorbidity yes ----------No----------
3. Types of comorbidities----------
4. Disease severity
   a) GOLD 1 (Mild): FEV1 ≥ 80% predicted
   b) GOLD 2 (Moderate): 50% ≤ FEV1 < 80% predicted
   c) GOLD 3 (Severe): 30% ≤ FEV1 < 50% predicted
   d) GOLD 4 (Very Severe): FEV1 < 30% predicted or FEV1 < 50% predicted plus chronic respiratory failure
5. Spirometry results FEV% FVC %
6. Current medication----------
7. Number of hospitalizations in the past years ----------
8. Number of exacerbations in the past years ----------
9. MBI (body mass index) ----------

Part II: Chronic obstructive pulmonary disease assessment test (CAT) questionnaire

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 

am very sad

I never cough	0	1	2	3	4	5	I cough all the time
I have no phlegm (mucus) in my chest at all	0	1	2	3	4	5	My chest is full of phlegm (mucus)
My chest does not feel tight at all	0	1	2	3	4	5	My chest feels very tight
When I walk up a hill or one flight of stairs, I am not breathless	0	1	2	3	4	5	When I walk up a hill or one flight of stairs, I am very breathless
I am not limited to doing any activities at home	0	1	2	3	4	5	I am very limited in doing activities at home
I am confident leaving my home despite my lung condition	0	1	2	3	4	5	I am not at all confident leaving my home because of my lung condition
I sleep soundly	0	1	2	3	4	5	I don't sleep soundly because of my lung condition
I have lots of energy	0	1	2	3	4	5	I have no energy at all

Part III: Adherence in Chronic Disease Scale (ACDS)

Below is a set of 7 questions with answers. Please rate, which response best reflects your behavior, your situation, and your opinions. Please provide honest answers by checking the appropriate one with X.

1. Do you always remember to take all your medications according to your doctor's instructions?
   a. Always
   b. Almost always
   c. Sometimes
   d. Hardly ever
   e. Never
2. Do you happen to change the dosing of your medications without prior consultation with your doctor?
   a. Never
   b. Only occasionally
   c. Sometimes
   d. Frequently
   e. I do not adhere to my doctor's recommendations at all
3. Do you adjust the dosing of your medications according to how you feel?
   a. No, I strictly follow the prescribed dosing, no matter how I feel
   b. Yes, I reduce the dosage of some medications when I feel good
   c. Yes, I skip doses of some medications when I feel good
   d. Yes, I temporarily discontinue some medications when I feel good
   e. Yes, I discontinue all medications when I feel good
4. On the appearance of medication-related side effects (e.g. stomach pain, liver pain, rash, lack of appetite, edema):
   a. I seek medical attention instantly
   b. I reduce the dosage of the medication and attempt to expedite the elective
   c. appointment with my doctor
   d. I discontinued the medication and attempted to expedite the elective appointment with my doctor

e. I discontinued all my medications and waited for the next elective appointment with my doctor.

5. Do you find all your medications necessary for your health?
    a. Yes, I do
    b. I find most of my medications to be beneficial for my health
    c. I find only some of my medications to be beneficial for my health
    d. I find some of my medications to be beneficial for my health, while the others to be harmful for me
    e. I find the majority of my long-term medications to be harmful for me
6. Does your doctor inquire about medication-related problems that you might possibly experience?
    a. Yes, on every appointment
    b. Yes, he/she usually does
    c. Yes, but only sometimes
    d. Yes, but only occasionally
    e. No, never
7. Do you tell the truth when asked by your doctor about medication-related problems?
    a. Yes, always
    b. Almost always
    c. I try to be honest, but sometimes it is hard to admit to non-compliance with doctor's recommendations
    d. Sometimes yes, another time no
    e. No, I don't. I find it my own private business

Appendix II: Amharic Version Information Sheet

የአማርኛ ትርጉም የተሳታፊ መረጃ ቅጽ

አዲስ አባባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ የፋረማሲ ትምህርት ቤት

<u>መግለጫ</u>

የጥናቱ ርዕስ፡

<u>መረጃ ለመስጠት ፈቃደኝነታቸዉን የሚገልፁበትና የመረጃ መሰብሰብያ መጠይቅ</u>

ጤና ይስጥልኝ እኔ _____ እባላለሁ በአሁኑ ሰዓት በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል ውስጥ በመታከም ላይ ስለህመማቸው ሁኔታ ጥናት እየተደረገ ስለሆነ ለጥናቱ የሚሆን መረጃ ለማግኘት የእረሶ ትብብር ያስፈልገናል፡፡ በመሰራት ላይ ያለው ጥናት አላማ ስለእርስዎ ጤንነትና ስለሚደረግልዎት ህክምና ለማጥናት ነው:: መጠይቁ ከጊዜዎ ቢበዛ 20 ደቂቃ የሚወስድ ሲሆን በዚህ ጥናት ውስጥ የእርስዎ ተሳታፊነት ሙሉ በሙሉ በእርስዎ ፈቃደኝነት ላይ የተመሰረተ ነዉ፡፡ በዚህ ጥናት ውስጥ ለመሳተፍም ሆነ ላለመሳተፍ መወሰንዎ በሆስፒታሉ ውስጥ በሚያገኙት አገልግሎት ላይ ምንም አይነት ተጽእኖ የማይኖረው ሲሆን ቃለመጠይቁን በማንኛውም ሰዓት ማቋረጥ ወይም ጥያቄዎችን አለመመለስ ይችላሉ፡፡

በጥናቱ ውስጥ ለተነሱት ጥያቄዎች የሚሰጧቸው መልሶችሙ በሙሉ በምስጢር የሚጠበቁ ሲሆን የእርስዎም ስም በማንኛዉም መልኩ በጥናቱ ውስጥ አይገለጽም፤ እንዲሁም የሚሰጡት ምላሽ ከእርስዎ ማንነት ጋር በማንኛውም መልኩ አይያያዝም፡፡ በዚህ መጠይቅ ውስጥ ለቀረቡት ማንኛውም ጥያቄዎች ትክክለኛ ወይም የተሳሳቱ የሚባሉ ምላሾች የሉም:: ዋናው የሚፈለገው በእነዚህጥ ያቄዎች ወይም አረፍተነገሮች ዙሪያ ያሎዎት ምላሽ ነው?

አድራሻ:

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Appendix VI: Amharic Version Consent Form

አዲስ አባባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ

የፋረማሲ ትምህርት ቤት የስምምነት ቅጽ

የጽሑፍ ስምምነት ቅጽ

ቀደም ሲል ስለ ጥናቱ በአጭሩ እንዲያውቁ ተደርጓል እና ዓላማውን በግልጽ ተረድተዋል ፡፡ አሁን በጥናቱ ለመሳተፍ ከተስማሙ እባክዎን ንገሩኝ?

1. ተስማማ ፣ አመሰግናለሁ! ቃለመጠይቁን ያካሂዱ

2. አልተስማማም ፣ አመሰግናለሁ! ወደ ቀጣዩ ብቁ ተሳታፊ ይቀጥሉ

በጥናቱ መግለጫ ገጽ ውስጥ ያለውን መረጃ ሰምቻለሁ እና የጥናቱን ዓላማ እና ፋይዳ ተረድቻለሁ ፡፡ የሚመለከቱ መረጃዎች ሁሉ እንደ ስም እና የምሠጣቸዉ መልሶች ሁሉ ወደ ሶስተኛ ወገን እንደማይተላለፉ ተረድቻለሁ ፡፡ በተጨማሪም በጥናቱ ላይ ለመሳተፍ ወይም ላለመሳተፍ ወይም በማንኛውም ጊዜ ከጥናቱ ለመላቀቅ መወሰን እንደምችል ተረድቻለሁ ፡፡

ከዚህ በታች ያለው ፊርማዎ በዚህ ጥናት ውስጥ ለመሳተፍ መስማማትዎን ያሳያል ፡፡

የተሳታፊ ፊርማ ፡ _____

የቃለ-መጠይቅ ጠያቂው ስም: _____ ፊርማ _____

ተቆጣጣሪ ስም: _____ፊርማ _____

የዋና ተመራማሪው ስም - ሽመልስ እንግዳ ተሰማ

አድራሻ - አዲስ አበባ ፣ ኢትዮጵያ

የሞባይል ስልክ: - 0933909341

የኢሜል አድራሻ: shimelis.engida@aau.edu.et

ፈቃደኛ መሆናቸውን ካረጋገጡ ቃለመጠይቁን ይጀምሩ ፈቃደኛ ካልሆኑ ወደሚቀጥለው ተገልጋይ ይሸጋገሩ

እርስዎን በተመለከተ አጠቃላይ መጠይቅ

ክፍል I. ማህበራዊ-ስነ-ህዝብ ባህሪዎች፤ የሚከተሉትን ጥያቄዎች ለመመለስ / ምልክት ያድርጉ

1. ጸታ	ሴት	ወንድ		
1.እድሜ (ዓመት)	_____			
2. የጋብቻ ሁኔታ	ያገባ/ች	ያላገባ/ች	ባልተት	የተፋታች
3. የትምህርት ሁኔታ	መደበኛ ትምህርት የለም	የመጀመሪያክፍል (1-8 ክፍል)	ሁለተኛ ደረጃ (9-12 ክፍል)	ከፍተኛ ትምህርት (ዲፕሎማና ከዚያ በላይ)
4. ክልል	አማራ	ትግራይ	ኦሮሚያ	ሌላ
5. የሥራ አይነት	_____			
6. የመኖሪያ ቦታ	ገጠር_____	ከተማ_____		
	_	_____		
7. አማካኝ ወርሃዊ ገቢ	_____			
8. ለምግብ ማብሰያ የሚጠቀሙጥ_____				
9. ሲጋራ ማጨስ			-	
የአሁኑ ያጨሳሉ	አዎ----- አላጨስም----	የማጨስ ዓመት	_____	ምን ያጨሳሉ_____
	የቀድሞ አጫሽ	የማጨስ ዓመት	_____	ምን ያጨሳሉ_____
10. የኢንሹራንስ ሽፋን	ፈጽሞ አላጫሽም አዎ	አይ		

11. ማህበራዊ ድጋፍ አዎ አይ

<u>ክፍል II የተሳታፊዎች ክሊኒካዊ ባህሪያት፡-</u>

የህመም ቆይታ ----------

ተደራቢ በሽታ ----------

GOLD (የበሽታ መከፋፈያ)

GOLD 1 (ትንሽ) ፡- FEV1 ≥ 80%

GOLD 2 (መጠነኛ) 50% ≤ FEV1 < 80%

GOLD 3 (ከባድ) 30% ≤ FEV1 < 50%

GOLD 4 (በጣም ከባድ)

FEV1 < 30% ወይም FEV1 < 50%

ስር የሰደደ የመተንፈሻ አካላት ችግር

የስፒሮሜትሪ ውጤቶች

FEV % .....

FVC % .....

የአሁኑ መድሃኒት .....

የሆስፒታል ማቆያ ወይም መባባስ ቁጥር .....

MBI (የሰውነት ብዛት ማውጫ).....

የምደሃኒት መጠን_.....

ክፍል III; የእርስዎ ሥር የሰደደ የሳንባ በሽታ (COPD) ያለበት ሁኔታ ምን ይመስላል? ሥር የሰደደ የሳንባ በሽታ ምርመራ (COPD Assessment Test™ (CAT)) ያድርጉ

ይህ መጠይቅ እርስዎ እና የእርስዎ የጤና ባለሙያ COPD (ሥር የሰደደ የሳንባ በሽታ) በደህንነትዎ እና በዕለት ተዕለት ህይወትዎ ላይ ያለውን ተጽዕኖ ለመለካት ያግዛቸኋል። የእርስዎ መልሶች እና የሚገኘው የምርመራ ውጤት የእርስዎን ሥር የሰደደ የሳንባ በሽታ (COPD) መቆጣጠርን ለማሻሻል እና ከሕክምና የተሻለውን ውጤት ለማግኘት በእርስዎ እና በእርስዎ የጤና ባለሙያ ጥቅም ላይ ሊውሉ ይችላሉ።

ለምሳሌ፡-በጣም ደስተኛ ነኝ

0	X 1	2	3	4	5

በጣም ሀዘን ተሰምቶኛል

1.	ሳል አስዬ አላውቅም	0	1	2	3	4	5	እኔ ሁልጊዜ ሳል አስላለሁ
2.	ደረቴ ላይ ምንም ዓንነት አክታ የለኝም	0	1	2	3	4	5	በደረቴ በሙሉ በአክታ የተሞላ ነው
3.	ደረቴ በጭራሽ አይጨናነቅም	0	1	2	3	4	5	ደረቴ በጣም የተጨናነቀ መስሎ ይሰማኛል
4.	ዳገት ስወጣ ወይም ከአንድ ወለል ወደ ሌላ ወለል ስወጣ ትንፋሽ አያጥረኝም	0	1	2	3	4	5	ዳገት ስወጣ ወይም ከአንድ ወለል ወደ ሌላ ወለል ስወጣ ትንፋሽ በጣም ያጥረኛል
5.	በቤት ውስጥ ማናቸውንም እንቅስቃሴዎች ለማድረግ አልገደብም	0	1	2	3	4	5	በቤት ውስጥ በማደርገው እንቅስቃሴ በጣም ውስን ነኝ
6.	የሳንባዬ ሁኔታ ጥሩ ባይሆንም ከቤት ስወጣ በራሴ እተማመናለሁ	0	1	2	3	4	5	የሳንባዬ ሁኔታ ጥሩ ስላልሆነ፣ ከቤት ስወጣ በራሴ ምንም አልተማመንም
7.	በእርጋታ እንቅልፍ እተኛለሁ	0	1	2	3	4	5	በሳንባዬ ሁኔታ ምክንያት በእርጋታ እንቅልፍ አልተኛም
8.	በጣም ጉልበት አለኝ	0	1	2	3	4	5	ምንም ዓንነት ጉልበት የለኝም

ክፍል 4

“ACDS” መድኃኒትን በታዘዘው መሰረት በአግባቡ ስለመውሰድ” መለኪያ

ከዚህ በታች መልስ የያዙ 7 ጥያቄዎች ተዘርዝረዋል ። እባከወ የትኛው ምላሽ የእርስወን ባህሪ፣ ሁኔታ እና አስተያይወትን በተሻለ ሁኔታ የሚያንዕባርቅ ነው።እባክወ መልስወን በ (X) ምልክት በሀቀኝነት የምረጡ።

1. በሐኪምዎ መመሪያ መሠረት ሁሉንም መድሃኒቶችዎን መውሰድዎን ሁልጊዜ ያስታውሳሉ?

   ሀ) ሁል ጊዜ

   ለ) ሁል ጊዜ ማለት ይቻላል

   ሐ) አንዳንድ ጊዜ

   መ) በጭራሽ በጭራሽ

   ሠ) በጭራሽ

2. ከሐኪምዎ ጋር ያለ ቅድመ ምክክር ያለዎትን የመድኃኒት መጠን ልክ ይለውጣሉ?

   ሀ) በጭራሽ

   ለ) አልፎ አልፎ

   ሐ) ብቻ አንዳንድ ጊዜ

   መ) በተደጋጋሚ

   ሠ) በጭራሽ የዶክተሮቼን ምክሮች አላከብርም

3. በሚሰማዎት ስሜት መሠረት የመድኃኒቶችዎን ልክ መጠን ያስተካክላሉ?

   ሀ) አይ ፣ እኔ ምንም ያህል ቢሰማኝም የታዘዘልኝን መድሃኒት በጥብቅ እከተላለሁ

   ለ) አዎ ፣ ጥሩ ስሜት ሲሰማኝ የአንዳንድ መድኃኒቶችን መጠን እቀንሳለሁ

   ሐ) አዎ ፣ ጥሩ ስሜት ሲሰማኝ የአንዳንድ መድኃኒቶችን መጠን እዘላለሁ

   መ) አዎ ጥሩ ስሜት ሲሰማኝ አንዳንድ መድሃኒቶችን ለጊዜው አቋርጣለሁ

   ሠ) አዎ ፣ ጥሩ ስሜት ሲሰማኝ ሁሉንም መድሃኒቶች አቋርጣለሁ

4. ከመድኃኒት ጋር የተዛመዱ የጎንዮሽ ጉዳቶች (ለምሳሌ የሆድ ህመም ፣ የጉበት ህመም ፣ ሽፍታ ፣ የምግብ ፍላጎት እጥረት ፣ እብጠት)

   ሀ) ወዲያውኑ የሕክምና እርዳታ እፈልጋለሁ

ለ) የመድኃኒቱን መጠን እቀንሳለሁ እና ከሐኪሜ ጋር የተመረጠውን ቀጠሮ ለማፋጠን እሞክራለሁ

ሐ) መድሃኒቱን አቋርጣለሁ እና ከሐኪሜ ጋር የተመረጠውን ቀጠሮ ለማፋጠን እሞክራለሁ

መ) መድሃኒቱን አቋርጬ ከሐኪሜ ጋር የሚቀጥለውን የምርጫ ቀጠሮ እጠብቃለሁ

ሠ) ሁሉንም መድኃኒቶቼን አቋርጬ ከሐኪሜ ጋር የሚቀጥለውን የምርጫ ቀጠሮ እጠብቃለሁ

5. ሁሉንም መድሃኒቶችዎን ለጤንነትዎ አስፈላጊ ሆነው አግኝታችዋቸዋል?

ሀ) አዎ፣ በሚገባ

ለ) አብዛኞቹ መድኃኒቶቼ ለጤንነቴ ጠቃሚ ሆነው አግኝቻቸዋለሁ

ሐ) ለጤንነቴ ጠቃሚ የሆኑ አንዳንድ መድኃኒቶቼን ብቻ አገኛለሁ

መ) አንዳንድ መድኃኒቶቼ ለጤንነቴ ጠቃሚ ሲሆኑ ሌሎቹ ደግሞ ለእኔ ጎጂ ሆነው አግኝቸዋለሁ

ሠ) አብዛኛዎቹ የረጅም ጊዜ መድኃኒቶቼ ለእኔ ጎጂ ሆነው አግኝቸዋለሁ

6. ሐኪምዎን ምናልባት ሊያጋጥሙዎት ከሚችሉት መድኃኒቶች ጋር ስለሚዛመዱ ችግሮች ይጠይቃል?

ሀ) አዎ ፣ በእያንዳንዱ ቀጠሮ ላይ

ለ) አዎ ፣ እሱ / እሷ ብዙውን ጊዜ ይነገረኛል

ሐ) አዎ፣ ግን አንዳንድ ጊዜ ብቻ

መ) አዎ ፣ ግን አልፎ አልፎ ብቻ ነው

ሠ) አይ ፣ በጭራሽ

7. ከመድኃኒት ጋር ስለሚዛመዱ ችግሮች በሐኪምዎ ሲጠየቁ እውነቱን ይናገራሉ?

ሀ) አዎ ፣ ሁል ጊዜ

ለ) ሁልጊዜ ማለት ይቻላል

ሐ) ሐቀኛ ለመሆን እሞክራለሁ ፣ ግን አንዳንድ ጊዜ የዶክተሮችን ምክሮች አለመከተል መቀበል በጣም ከባድ ነው

መ) አንዳንድ ጊዜ አዎ ፣ ሌላ ጊዜ የለም

ሠ) አይ, እኔ አላደርግም