Research on the Construction of a Prognostic Model for COPD Complicated with Sarcopenic Obesity Based on Bioelectrical Impedance Phase Angle Technology (COSAT)

Research Protocol

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Research Objectives:

This study aims to explore the diagnosis, impact, and prognostic factors of COPD complicated with sarcopenic obesity using multi-segment bioelectrical impedance phase angle technology. It seeks to clarify the diagnostic value and efficacy of body composition analysis in specific populations, analyze the relationship between phase angle and COPD severity as well as quality of life, investigate its predictive role for adverse outcomes, and reveal the effects of inflammation and metabolic disorders in sarcopenic obesity. The goal is to provide a basis for early screening and precise intervention to improve patient prognosis.

Proposed Research Methods

Inclusion Criteria

(**1**) **Age over 65 years**;

(**2**) **Ability to complete physical activity assessments and pulmonary function tests**; (**3**) **Complete medical records, willingness to adhere to follow-up arrangements, and provision of adverse event reports via telephone or outpatient visits, with signed informed consent**;

(**4**) **COPD diagnosis based on the American Thoracic Society** (**ATS**)/ **European Respiratory Society** (**ERS**) **GOLD definition, with a post-bronchodilator FEV1/FVC ratio < 0.70, current or former smokers with a smoking history of ≥10 pack-years.**

Exclusion Criteria:

(**1**) **Severe cognitive impairment or hand deformities** (**e.g., rheumatoid arthritis**) **preventing body composition measurements**;

(**2**) **Incomplete clinical or follow-up data or unwillingness/inability to undergo regular follow-up**;

(**3**) **Severe systemic edema**;

(**4**) **Presence of cardiac pacemakers or significant metal implants that may interfere with measurements**;

(**5**) **Voluntary withdrawal for any reason, including loss to follow-up.**

Data Collection:

Demographic and clinical data: **Gender, smoking status** (**never, former, current**), **age, height, weight, waist circumference, BMI, skeletal muscle index** (**SMI**), **body fat content,**

visceral fat index, and segmental phase angles measured via bioelectrical impedance analysis.

Clinical records: **Smoking history, comorbidities** (**Charlson Comorbidity Index**), **nutritional status** (**MNA-SF**), **physical performance** (**SPPB**), **medication use, pulmonary function tests, COPD exacerbations in the past year, CAT score, mMRC score, and St. George's Respiratory Questionnaire** (**SGRQ**).

Laboratory tests: **Blood samples for CBC, CRP, cholesterol, albumin, HbA1c, IL-6, and TNF-α** (**ELISA**).

Sample Size Calculation:

Using PASS 15.0 for repeated-measures ANOVA (α = **0.05, power** = **90**%), **with a COPD prevalence of 15**% **and a 2**:**1 ratio for sarcopenic obesity vs. non-sarcopenic groups, the study requires 200 participants** (**33 sarcopenic obese, 33 non-obese sarcopenic, 72 obese non-sarcopenic, and 72 non-obese non-sarcopenic**).

Diagnostic Criteria:

Sarcopenia: **Asian Working Group criteria**: **SMI** (**InBody S10**) <**7.0 kg/m²** (**men**) **or** <**5.7 kg/m²** (**women**); **grip strength** <**28 kg** (**men**) **or** <**18 kg** (**women**); **gait speed** <**0.8 m/s. Obesity**: **BMI** ≥**28 kg/m² or waist circumference** ≥**85 cm** (**men**)/≥**80 cm** (**women**); **body fat** ≥**24.3**% (**men**) **or** ≥**33.2**% (**women**).

sarcopenic Obesity: **Coexistence of sarcopenia and obesity.**

Assessments:

Physical Performance: **Short Physical Performance Battery** (**SPPB**: **balance, gait speed, chair stands**; **score 0–12**).

Nutritional Status: **Mini Nutritional Assessment** (**MNA-SF**; **score 0–12**).

Phase Angle: **Measured via InBody S10 at six frequencies** (**1kHz–1000kHz**) **across five body segments, calculated using resistance** (**R**) **and reactance** (**Xc**):

PHA = **arctan**((**Xc_right arm** + **Xc_trunk** + **Xc_right leg**)/(**R_right arm** + **R_trunk** + **R_right leg**)) × **180**°/π.

Follow-up Endpoints:

Primary: **Changes in pulmonary function, dyspnea scores, and body composition at 2 years.**

Secondary: **Acute exacerbations, hospitalizations, or death within 2 years. Follow-ups at 6, 12, and 24 months.**

Grouping patients based on whether they have sarcopenic obesity, the differences in clinical data between the two groups were analyzed. Statistical analysis was performed using SPSS 24.0 statistical software.

Analysis of Demographic Characteristics and Clinical Data:

The age and gender distribution of the patients were described. Based on whether the patients had sarcopenic obesity, they were divided into two groups. The differences in clinical data between the two groups, including age distribution, smoking status, obesity-related body fat, pulmonary function, whole-body and segmental phase angle, were analyzed. Continuous variables were expressed as mean ± standard deviation, and categorical variables were expressed as percentages. Differences between groups were analyzed using Student's t-test for continuous variables and the chi-square test for categorical variables, depending on the data type.

Analysis of Factors Associated with COPD Complicated by Sarcopenic Obesity:

Univariate and multivariate analyses were conducted on data from COPD patients with sarcopenic obesity. Using clinical data variables, nutritional status, physical activity capacity, whole-body and segmental phase angle, logistic regression was applied to analyze the factors associated with sarcopenic obesity in COPD patients.

Analysis of the Prognostic Predictive Value of Sarcopenic Obesity in Obstructive Pulmonary Disease:

The differences in hospital stay length, acute exacerbation readmission rate, and mortality between COPD patients with sarcopenic obesity and those without sarcopenia at baseline were compared. Kaplan–Meier analysis was used for statistical analysis, and differences were expressed using the log-rank test.

COSAT study

INFORMED CONSENT FORM

This document provides you with information to help you decide whether to participate in this clinical research study. Please read it carefully. If you have any questions, please direct them to the researcher in charge of this study.

Your participation in this study is voluntary. This research has been reviewed and approved by the institutional ethics review committee of our research institution.

The background, objectives, research process, and other important information are as follows:

Research Purpose:

Currently, studies on the impact of sarcopenia combined with obesity on the prognosis of elderly patients are mostly limited to community screenings, with insufficient in-depth exploration of hospitalized patients, particularly those with respiratory diseases. For elderly hospitalized patients, especially those with sarcopenic obesity, relying solely on body weight or body mass index (BMI) may underestimate or mask the lack of muscle mass. Research applying updated diagnostic guidelines and accurate measurement indicators remains very limited. Particularly in patients with respiratory diseases, studies investigating the impact of sarcopenic obesity on the prognosis of hospitalized patients are especially scarce. Therefore, an in-depth exploration of the incidence and prognostic impact of sarcopenic obesity in elderly hospitalized patients, particularly those with respiratory diseases, holds significant clinical and research value.

The primary objective of this study is to use multi-segment bioelectrical impedance phase angle technology to explore the diagnosis, impact, and prognostic factors of COPD complicated with sarcopenic obesity. The study aims to clarify the diagnostic value and efficacy of body composition analysis in specific populations, analyze the relationship between phase angle and COPD severity as well as quality of life, investigate its predictive role for adverse outcomes, and reveal the effects of inflammation and metabolic disorders in sarcopenic obesity. The goal is to provide a basis for early screening and precise intervention to improve patient prognosis.

For this purpose, you are invited to participate in this study.

Research Process:

If you visit the respiratory outpatient or emergency department of our hospital or are admitted as an inpatient, and your doctor has diagnosed you with significant obstructive pulmonary disease, you may be invited to participate in this study. Additionally, you must be at least 65 years old. If you agree to participate, we will assign you a study number and establish a medical record file.

The study does not involve any drug interventions beyond standard treatment. However, we will need to collect clinical data, administer questionnaires, assess muscle function and skeletal muscle mass, and collect blood samples from you. The blood collection process involves drawing 10 mL of venous blood from your arm to test for complete blood count (CBC), C-reactive protein (CRP), cholesterol levels, albumin levels, and inflammatory factors. These blood samples will be used for COPD diagnosis, disease assessment, and guiding treatment plans.

You will also be required to undergo additional body composition analysis, skeletal muscle strength testing, a walking test, grip strength testing, and a nutritional questionnaire. The study will last for 24 months. At the time of initial enrollment, you will undergo one blood sample collection, questionnaire completion, muscle strength testing, walking test, and grip strength testing. We will collect and record data on disease progression every 6 months during the 24-month follow-up period (all assessments will follow standard clinical guidelines, with no additional tests required, totaling 5 times). At the 24-month mark, we will conduct a final assessment of disease progression and follow-up.

Your samples will be used solely for this study, and all research-related testing costs will be covered by our research team.

Risks and Discomforts:

All your information will remain confidential. Blood sample collection will be performed under strict sterile conditions. The blood draw may involve minor risks, including temporary pain, local bruising, mild dizziness in rare cases, or extremely rare needle-related infections. Participating in questionnaires and interviews may cause some psychological discomfort.

Benefits:

Testing your samples will help provide a comprehensive and detailed diagnosis of your condition, offer necessary treatment recommendations, and contribute valuable information to disease research.

Costs:

The laboratory data collected during this study are part of routine clinical examinations. Additional costs for body composition and skeletal muscle mass assessments will be covered by our research team.

Compensation:

You will not need to pay any costs beyond standard treatment. As this is an observational, non-interventional study, there is no financial compensation.

Responsibilities as a Research Participant:

- Provide truthful information about your medical history and current health status.
- Inform the research doctor of any discomfort experienced during the study.
- Do not conceal acute exacerbations or other clinical events during the study.
- Inform the research doctor if you have recently participated in or are currently participating in other studies.

Privacy:

If you decide to participate, all personal data related to your participation will remain confidential. Your blood samples will be labeled with a study number rather than your name. Identifiable information will not be disclosed to anyone outside the research team without your permission. All research team members and sponsors are required to maintain confidentiality. Your records will be stored in a locked cabinet accessible only to researchers.

To ensure compliance with research regulations, government authorities or ethics review committee members may inspect your personal data at the research site when necessary. No personally identifiable information will be disclosed in any published results of this study.

Compensation for Research-Related Injuries:
If you suffer any harm related to this clinical research, you will be eligible for free treatment and/or appropriate compensation.

Voluntary Participation and Withdrawal:
You may choose not to participate or withdraw from the study at any time by notifying the researcher. Your data will not be included in the study results, and your medical care and rights will not be affected.

The research doctor may terminate your participation if you require other treatments, fail to comply with the study plan, experience research-related injuries, or for any other reason.

Contact Information:
You may inquire about study-related information and progress at any time. If new safety-related information arises, we will notify you promptly.

If you have questions about the study, experience any discomfort or injury during the research, or have concerns about your rights as a participant, you may contact Dr. Zhao Ting at 13764321007.

For questions or concerns about your rights and well-being as a participant, you may contact the institutional ethics committee:

- Phone: 62483180*720322
- Contact: Chen Lili

Informed Consent Signature Page

I have read this informed consent document.
I have had the opportunity to ask questions, and all questions have been answered to my satisfaction.
I understand that participation in this study is voluntary.
I may choose not to participate or withdraw from the study at any time without facing discrimination or retaliation. My medical care and rights will not be affected.
If I require other treatments, fail to comply with the study plan, experience

If I require other treatments, fail to comply with the study plan, experience research-related injuries, or for any other reason, the research doctor may terminate my participation.
I will receive a signed copy of this "Informed Consent Form."