

Study Protocol with Statistical Analysis Plan (SAP)

Official Title: Prevalence and Associated Factors of Sarcopenia in Stroke

Patients: A Cross-Sectional Observational Study

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Brief Description of Document: This document provides the full study protocol and statistical analysis plan for a cross-sectional observational study investigating the prevalence and associated factors of sarcopenia in post-acute and chronic stroke patients. The study includes comprehensive assessments of muscle mass, muscle strength, physical performance, nutritional status, and quality of life, and aims to compare sarcopenia-related characteristics across different stroke stages, age groups, and sexes.

A. BACKGROUND

Sarcopenia is a progressive and generalized skeletal muscle disorder characterized by the accelerated loss of muscle mass, strength, and physical performance. It has been recognized as a major public health concern in aging societies, with a prevalence exceeding 20% among individuals aged 65 years and older in Taiwan. Sarcopenia is strongly associated with adverse clinical outcomes, including increased risks of falls, frailty, hospitalization, disability, and mortality.

Stroke is a leading cause of long-term disability worldwide. Advances in acute stroke management have significantly improved survival rates; however, a growing population of stroke survivors now faces long-term complications. Among these, sarcopenia has emerged as a critical but often underrecognized condition. Stroke-related sarcopenia may result from multiple mechanisms, including immobilization, denervation, systemic inflammation, malnutrition, and reduced physical activity.

Previous studies have evaluated sarcopenia-related indicators in stroke populations, such as handgrip strength, calf circumference, or walking speed. However, most studies have relied on single-domain measurements and have not provided a comprehensive assessment integrating muscle mass, muscle strength, imaging-based muscle quality, and functional performance. Furthermore, comparisons between different stages of stroke recovery—particularly between post-acute care (PAC) and chronic stroke patients—remain limited.

Given that muscle decline may begin as early as 40 years of age and may vary by sex and disease severity, a multidimensional assessment across different subgroups is warranted. Therefore, this study aims to comprehensively evaluate sarcopenia-related variables in stroke patients using multiple clinical tools and to explore associated factors across different clinical conditions.

B. OBJECTIVES

The primary objective of this study is to comprehensively analyze sarcopenia-related variables in stroke patients using multiple clinical assessment tools, including body composition, muscle strength, imaging, and functional performance.

Specifically, this study aims to compare sarcopenia-related indicators between post-acute care (PAC) stroke patients and chronic stroke patients, and to evaluate differences across age groups (40–65 years versus >65 years), sex, and stroke severity.

The secondary objective is to determine the prevalence of sarcopenia in these populations and to identify potential factors associated with sarcopenia in stroke patients.

C. Study Design

This study is designed as a cross-sectional observational study conducted at Cishan Hospital, Ministry of Health and Welfare, Taiwan.

Participants are classified into two cohorts based on stroke stage. The first cohort includes chronic stroke patients whose stroke onset occurred more than six months prior to enrollment. The second cohort includes post-acute care (PAC) stroke patients who are at least 14 days post-stroke, have been assessed by a neurologist as eligible for PAC transfer, and are admitted to a PAC ward.

A case-control observational model is adopted to compare the characteristics between these two cohorts. The study follows a cross-sectional time perspective, with all data collected at a single time point.

D. Participants

The study population consists of adult patients aged 40 years or older who have been diagnosed with stroke by a qualified specialist and have corresponding ICD-10 diagnostic codes documented in the electronic medical record system of Cishan Hospital. Both ischemic and hemorrhagic stroke patients are eligible for inclusion.

Participants must have sufficient cognitive and physical function to complete sarcopenia-related assessments, including muscle strength testing, walking speed measurement, and questionnaire-based evaluations, as judged by the principal investigator.

Participants are recruited using a non-probability sampling method. A total of approximately 80 participants are expected to be enrolled, with a planned allocation ratio of 1:1 between chronic stroke patients and PAC stroke patients.

E. Study Procedures

All participants undergo a standardized assessment at a single time point upon enrollment.

The assessment protocol includes both objective and subjective measurements. Objective assessments encompass body composition analysis using bioelectrical impedance analysis (BIA), measurement of quadriceps muscle strength using a handheld dynamometer, ultrasound-based assessment of muscle thickness of the quadriceps and gastrocnemius muscles, calf circumference measurement, dominant handgrip strength testing, walking speed evaluation, and sarcopenia screening using the SARC-F questionnaire and the Mini Nutritional Assessment (MNA).

Subjective assessment includes evaluation of health-related quality of life using the EQ-5D questionnaire.

All measurements are conducted by trained healthcare professionals using standardized procedures to ensure reliability and reproducibility. To minimize measurement bias, consistent protocols and equipment settings are applied across all participants.

F. Outcome Measures

Primary outcome measures include appendicular skeletal muscle mass index (ASMI), dominant handgrip strength, and gait speed, which are key diagnostic components of sarcopenia according to established consensus criteria.

Secondary outcome measures include quadriceps muscle strength measured by maximal voluntary isometric contraction (MVIC), ultrasound-measured muscle thickness of the quadriceps and gastrocnemius muscles, calf circumference, SARC-F score, Mini Nutritional Assessment (MNA) score, and EQ-5D health-related quality of life score.

All outcome variables are measured at enrollment and analyzed as continuous or categorical variables as appropriate.

G. Statistical Analysis Plan

All statistical analyses are performed using SPSS software (version 19.0 or later; IBM Corp., Armonk, NY, USA).

Descriptive statistics are used to summarize baseline characteristics. Continuous variables are presented as mean \pm standard deviation (mean \pm SD), while categorical variables are expressed as frequencies and percentages.

The normality of continuous variables is assessed using appropriate tests such as the Shapiro–Wilk test.

For comparisons between two groups (e.g., PAC vs. chronic stroke, younger vs. older age groups), independent sample t-tests are used for normally distributed variables. For non-normally distributed data, the Mann–Whitney U test is applied.

Categorical variables, including sarcopenia classification categories, are analyzed using the chi-square test or Fisher’s exact test as appropriate.

If applicable, multivariate analyses (e.g., logistic regression) may be conducted to identify independent factors associated with sarcopenia.

A two-tailed p-value of less than 0.05 is considered statistically significant.