Version 1

Cesano Boscone, 19/05/2026

Study Protocol: SARCODIAB

Tools for screening and diagnosing sarcopenia in patients with diabetes

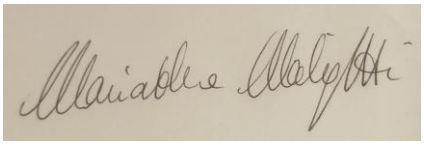
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Sarcopenia, type 2 diabetes mellitus, STAR algorithm, handgrip test, chair stand test, comorbidities, frailty.

ABBREVIATIONS LIST

GH	Growth Hormone
TNF	Tumore Necrosis Factor
THE 6	InterLeuchina 6
BMI	Body Mass Index
DM2	Type 2 diabetes mellitus
HbA1c	Glycated hemoglobin
CST	Chair Standing Test
STAR	Sarcopenia Tools for Assessment and Recognition
CKD	Chronic Kidney Disease (Malattia Renale Cronica)
VD	Cardiovascular Disease
AOCP	Chronic Peripheral Arterial Disease
RD	Diabetic Retinopathy
PN	Polyneuropathy
T0	Zero time (first access)
HGT	Hand Grip Test

HINT

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1.INTRODUCTION

1.1Definition of Sarcopenia

Sarcopenia is a musculoskeletal syndrome characterized by a progressive loss of muscle mass, strength and function, with a significant impact on the person's state of health, especially in old age. It represents a central condition in the so-called "frailty" of the elderly.

Unlike cachexia, the presence of an underlying active disorder is not identified.

The European Working Group on Sarcopenia in Older People (EWGSOP) provided in 2010 a first definition, updated in 2019 (EWGSOP2), according to which:

"Loss of muscle strength is the most reliable parameter for identifying sarcopenia, while reduced muscle mass confirms the diagnosis and poor physical performance indicates its severity" (1).

Etiopathogenesis: The main mechanisms underlying sarcopenia include medical factors and environmental factors.

Medical factors include:

- **Aging**: associated with reduced protein synthesis, muscle apoptosis, neuromuscular alterations.
- **Chronic inflammation**: TNF-α, elevated IL-6 promote protein catabolism.
- **Endocrine** dysfunctions: drop in GH, testosterone, estrogen, resulting in increased cellular catabolism.
- **Insulin resistance**: reduces the entry of amino acids into myocytes and impairs muscle growth.
- **Physical inactivity and immobilization**: accelerate muscle decline.
- **Malnutrition and protein deficiencies**: frequent in the elderly, in patients with chronic comorbidities (2,4) and with swallowing difficulties (due to dysphagia, dental problems, chronic oral pain).

Sarcopenia has documented prognostic relevance: it is associated with an increased risk of falls, fractures, disability, frailty, hospitalizations and mortality (5).

2. SARCOPENIA IN THE GENERAL POPULATION AND IN DIABETIC PATIENTS

The prevalence of sarcopenia in the general elderly population varies from 5% to 13% in subjects between 60 and 70 years of age, and can exceed 50% in the over 80s (2). In patients with type 2 diabetes mellitus, Sarcopenia has a higher prevalence than non-diabetics, ranging from 20% to 40%, depending on the criteria and the population analyzed (3; 10).

Diabetes contributes to the development of sarcopenia through several pathophysiological mechanisms:

- **Chronic low-grade inflammation**
- **Insulin resistance**
- **Muscle mitochondrial impairment**
- **Endothelial dysfunction and reduced nutrient delivery to muscles** (4,5)

3.OBJECTIVE OF THE SARCODIAB STUDY

The study conducted at the territorial diabetology clinic of Cesano Boscone (MI), with the aim of evaluating the prevalence of sarcopenia in patients with DM2 followed at the diabetology clinic of Casa di Cura Ambrosiana.

3.1 Endpoints primari

To detect the prevalence of sarcopenia in patients with DM2 followed at the diabetes clinic of Casa di Cura Ambrosiana.

3.2 Endpoints secondari

- Analyze the relationship between sarcopenia and clinical variables: age, sex, hypoglycemic therapy, glycemic control (HbA1c);
- Evaluate the effectiveness of simple and repeatable tools such as the iSarcoPRM algorithm as outpatient screening tools

4.STUDY DESIGN

Observational, cross-sectional, and retrospective study. Patient-related data will be extracted from diabetes medical records maintained in the center.

No diagnostic or therapeutic or monitoring procedures have been applied to patients outside of normal clinical practice as defined by the PDT of Casa di Cura Ambrosiana (attached to the documentation) and the data will be collected in pseudonymized form.

5.POPULATION AND METHOD

5.1Inclusion criteria

- Documented diagnosis of DM2 with age ≥ 65 years or age < 65 years with at least one comorbidity associated with increased risk of sarcopenia , including: CKD, RD, AOCP, CVD, PN, obesity, chronic sedentary lifestyle, metabolic liver disease, heart failure, depression, transplantation, steroid therapy, significant weight loss, osteoarthritis, cognitive impairment, neurological diseases, previous cerebrovascular events, recent hospitalization, repeated falls, chronic fatigue, fatigue, mobility limitations progressive minds;

- Patients belonging to the Diabetology clinic of Casa di Cura Ambrosiana in Cesano Boscone (MI).

5.2Exclusion criteria

- Unstable clinical status (acute infections, acute heart or kidney failure) or neoplasms;
- Objective impossibility to perform the required functional tests.

6. EVALUATION CRITERIA FOR SARCOPENIA

1. **Initial functional assessment through two fundamental tests**:
   - **Handgrip test** (manual grip strength): pathological if <32 kg in men and <19 kg in women;
   - **Chair Stand Test** (CST): considered positive if the time required for 5 lifts from the chair - without aid - exceeds 12 seconds.

2. **Instrumental examination (second step):**
   Only if both tests are positive**,** a muscle ultrasound of the quadriceps femoris is carried out to objectify the thickness of the muscle itself.

3. **BMI indexing**:
   - The value of muscle thickness (in cm) is divided by the patient's BMI to obtain the muscle/BMI index.
   - Diagnostic cut-offs:
     - < **1.4** in men
     - < **1.0** in women

5.1Parameters and Tests Used

For patients included in the study, the following parameters were analyzed:

- T0 blood tests: HbA1c, creatinine;
- Anthropometric evaluations: weight, height, BMI, waist circumference
- Hypoglycemic therapy in progress.

Muscle functional tests:

- Handgrip Test: evaluation of grip strength (kg);
- Chair Standing Test (CST): measure of the time needed to perform 5 lifts from the chair with arms crossed;
- Muscle ultrasound of the quadriceps femoris (carried out if both of the above tests were positive).

6. DURATION OF RECRUITMENT

Observation of cases detected in the medical record in the period from 01/01/2025 to 30/06/2025.

7. SAMPLE SIZE

Given the observational nature of the present study, all patients who meet the inclusion criteria in the predefined period should be considered. The sample size was not defined a priori but resulted from the availability of clinical data of eligible subjects in the considered period (convenience sampling; consecutive inclusion of all patients with complete data). However, a precision estimate for the descriptive objective shows that, assuming a prevalence of sarcopenia of 25.2%, approximately 805 subjects would be required to achieve a 95% confidence interval with accuracy ±3%.

8. CLINICAL IMPORTANCE

The early detection of sarcopenia in diabetic patients allows:

- Prevention of disability and fractures
- Improved glycometabolic management (muscle being an insulin target organ)
- Improved quality of life
- Reduction of indirect health costs related to hospitalizations, rehabilitation and institutionalization (5,6)

9. CONCLUSIONS

Sarcopenia is an underestimated but common complication present in diabetic patients, especially in elderly or frail patients. The SARCODIAB protocol proposes an **integrated evaluation model** (clinical, functional and instrumental) that is effective and potentially applicable in local outpatient settings.

Quadriceps femoris **ultrasound** has several **advantages** as a sarcopenia assessment tool (**Non-invasive** and radiation-free, unlike CT and MRI). **Cost-effective** and relatively accessible. **Portable**, so it can be used in clinical or outpatient settings. **Repeatable**, making it ideal for monitoring changes in muscle mass over time) and has proven to be a **reliable** and **useful** technique for the diagnosis of sarcopenia, especially in at-risk populations such as elderly, diabetic patients. It can be an effective method for monitoring muscle loss, with potential application in clinical practice as a screening and monitoring tool.

10. BIBLIOGRAPHIC SOURCES

1. Cruz-Jentoft AJ, et al. Sarcopenia: revised European consensus on definition and diagnosis. *Age Ageing*. 2019; 48(1):16–31.
2. Narici MV, Maffulli N. Sarcopenia: characteristics, mechanisms and functional significance. *Br Med Bull*. 2010; 95(1):139–159.
3. Batsis JA, et al. Sarcopenia and sarcopenic obesity in older adults with type 2 diabetes: a systematic review. *J Diabetes Complications*. 2016; 30(3):398–407.
4. Leenders M, et al. Skeletal muscle mass and mortality in type 2 diabetes. *Acta Diabetol*. 2013; 50(6):1005–1012.
5. Zamboni M, et al. Sarcopenic obesity: a new category of obesity in the elderly. *Nutr Metab Cardiovasc Dis*. 2008; 18(5):388–395.
6. Shafiee G, et al. Prevalence of sarcopenia in the world: a systematic review. *J Diabetes Metab Disord*. 2017;16:21.
7. Kalyani RR, et al. Diabetes, sarcopenia and frailty. *Curr Opin Endocrinol Diabetes Obes*. 2014; 21(3):196–202.
8. LoMauro A, Gervasoni F, Ricci V, Salce G, Andreoli A, Pantoni L, Özçakar L. Sarcopenia and multisensory integration deficit in post-COVID syndrome patients: the Clinical, Ultrasound and Robotic Evaluation (CURE) protocol in a cross-sectional study. *Am J Phys Med Rehabil*. 2024 Mar; 103(3):181-187.
9. Heymsfild SB Gonzalez MC, Lu J *et al*. Skeletal muscle mass andquality: evolution of modern measurement concepts in the context of sarcopenia. Porc Nutr Soc 2015; 74: 355-66
10. Choi et al. (2019), *"Prevalence of Sarcopenia and its Association with Glycemic Control in Patients with Type 2 Diabetes"*, Diabetes Care, Luglio 2019
11. Lima, V. L., Silva, A. S., & Santos, J. F. (2019). Use of quadriceps femoris muscle thickness measured by ultrasound for diagnosing sarcopenia: A cross-sectional study. *Journal of Geriatric Physical Therapy, 42*(4), 157–163. https://doi.org/10.1519/JPT.0000000000000250
12. Mohammadi, A., Rezaei, H., & Zadeh, S. R. (2020). The role of ultrasound in assessing quadriceps muscle mass and function in cancer patients: A pilot study. *Journal of Clinical Oncology, 38*(14), 1432–1438. https://doi.org/10.1200/JCO.19.02878
13. He, X., Zhang, T., & Wu, Z. (2021). Ultrasonographic evaluation of quadriceps femoris muscle thickness as a biomarker for sarcopenia in elderly patients. *Journal of Aging and Physical Activity, 29*(2), 223–230. https://doi.org/10.1123/japa.2020-0085
14. Aydin, M., Demir, O., & Tuncer, T. (2020). Ultrasound assessment of quadriceps muscle thickness in patients with type 2 diabetes and its relationship with sarcopenia. *Diabetes Research and Clinical Practice, 163*, 108119. https://doi.org/10.1016/j.diabres.2020.108119