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REVIEW

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Developing Consensus Criteria for Sarcopenia: An Update

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ABSTRACT

KEY WORDS:

Introduction

In humans, skeletal muscle mass decreases by almost 50% between ages 20 and 90 years, and muscle strength, which peaks around age 30 years, is lost at a rate of 15% per decade starting around age 50 years and subsequently accelerates to about 30% per decade at age 70 years.[1] These ubiquitous age-related changes in skeletal muscle are major causes of impaired physical function in older adults, which contributes to mobility disability, falls, and hospitalizations.[2–4] Lower muscle mass and strength are associated with lower bone mineral density,[5–7] which is consistent with the mechanostat theory of bone loss due to reduced forces of muscle on bone,[8] and with the possibility that there are pleiotropic genes that determine of both bone and muscle tissue integrity.[9] Decreased strength is also a primary risk factor for falls,[10,11] a common precipitant of osteoporotic fractures. Not surprisingly, there is evidence that low muscle mass and strength are associated with fractures.[12,13] Given the important role for age-related muscle impairment in bone health, clinicians should be able to identify those individuals with low muscle mass and strength in order to better assess fracture risk in their patients. Additionally, low muscle mass and weakness are potentially reversible, as it has been shown that even the most frail older adults can demonstrate improvements with exercise interventions.[14] Thus, improving muscle health could be an important part of fracture prevention for many older adults.

In contrast to widely-used levels of bone density that reflect reduced bone strength and increased fracture risk, the precise definition of low muscle mass and strength has not been established. The term "sarcopenia" is most often used to describe the age-related reduction in muscle mass and strength, and is commonly considered analogous to osteoporosis. Yet, unlike osteoporosis, which can be diagnosed based on widely accepted clinical criteria,[15] sarcopenia is not recognized as a clinical condition. Without a consensus definition of sarcopenia that can be used across population-based studies, the true global public health impact of age-related loss of muscle mass and strength is unattainable. Further, in the absence of diagnostic criteria for sarcopenia, clinicians have no guidance on how to identify older adults with clinically meaningful low muscle mass or strength. This conundrum is compounded by the recognition that even if sarcopenia could be identified, treatment options are currently limited because the absence of sarcopenia criteria is also a major hindrance to the development of new muscle function–promoting therapies. There are several therapies directed to sarcopenia that are in the pipeline (eg, myostatin inhibitors and type II activin receptor inhibitors, follistatin, selective androgen receptor modulators [SARMs], angiotensin-converting-enzyme [ACE] inhibitors, ghrelin mimetics) at several pharmaceutical companies, yet clinical trials are challenging to conduct because there are no criteria to identify potential participants, and there are no validated, clinically appropriate sarcopenia endpoints for assessment of efficacy. Without the ability to recognize or treat sarcopenia, a key aspect of fracture prevention remains elusive. The field of aging research could help to fill this gap because there is currently a major push to establish consensus criteria for a diagnosis of sarcopenia, a critical step for its recognition as a clinical condition. Recent work holds promise that we are coming ever closer to reaching this goal.

The concept of sarcopenia has steadily evolved since it was first introduced by Irwin Rosenberg[16] in 1988 when he stated that the most dramatic and significant age-related physical decline was the loss of lean body mass. Dr. Rosenberg felt that this phenomenon was largely overlooked in the aging field, and should be named in order to gain the recognition it rightfully deserved. He suggested the term "sarcopenia," which is Greek for "poverty of the flesh." Although at that time he could not offer a specific definition of sarcopenia, Dr. Rosenberg did succeed in bringing greater attention to the field because the number of studies focusing on "sarcopenia" proliferated in the

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1990s. Baumgartner and colleagues[17] were the first to propose a method for identifying sarcopenia based on measures of lean mass obtained by dual-energy X-ray absorptiometry (DXA). Among older adults participating in the New Mexico Aging Process Study (NMAPS), sarcopenia was operationalized as "low relative muscle mass." Because absolute lean mass is highly correlated with height, relative muscle mass was calculated as appendicular skeletal muscle mass (sum of lean mass in the arms and legs) divided by height squared. The investigators defined sarcopenia as a relative muscle mass more than two standard deviations below the sex-specific means of a reference population consisting of adults aged 18 to 40 years participating in the Rosetta Study. In cross-sectional analyses of the NMAPS older adults, sarcopenia prevalence increased with age, up to more than 50% in adults aged 80 years and older, and was associated with higher rates of self-reported physical disability. The article by Baumgartner and colleagues[17] was among the first to highlight the potential public health impact of sarcopenia, and their DXA-based definition of sarcopenia was subsequently used in several epidemiologic studies, including a study by Janssen and colleagues[18] that attributed approximately $18 billion in U.S. healthcare expenditures to sarcopenia in the year 2000.

Though this definition of sarcopenia has since been used in several subsequent epidemiologic studies, it possesses some important limitations. Although DXA has good accuracy, aging is associated with accumulation of water and deposition of fibrous tissue in muscle, both of which may lead to overestimation of lean mass in older adults.[19] Furthermore, although the lean mass-based operational sarcopenia definition was based on the conceptual framework that the age-related decline in muscle *strength* was due to a parallel decline in muscle *mass*, as the sarcopenia field progressed studies showed that the age-related loss of strength outpaces the loss of mass.[20] Thus, although muscle mass is an important determinant of muscle strength,[21,22] age-related loss of muscle mass only partially explained loss of muscle strength. Given the modest correlation between age-related changes in muscle mass and strength, Manini and Clark[23] suggested that different terms be used for these apparently independent phenomena: "sarcopenia" to describe the loss of mass, as originally done by Baumgartner and colleagues,[17] and "dynapenia" to describe the loss of strength. Furthermore, in an informal meta-analysis of the existing literature, they demonstrated that low lean mass was generally a poor predictor of impaired physical performance, functional limitation, and physical disability, whereas muscle weakness was more consistently associated with greater risk of these outcomes.[23] Clearly, a definition of sarcopenia based on muscle mass alone is insufficient for identifying older adults with clinically meaningful age-related changes in skeletal muscle, and this realization has become a key concept among the latest efforts to develop consensus criteria.

Several groups of experts have convened in recent years with the goal of establishing consensus diagnostic criteria for sarcopenia,[24–27] and a common theme has emerged across all their recommendations: a diagnosis of sarcopenia should include both low muscle mass and poor muscle function, indicated by either low muscle strength or impaired physical performance, such as slow gait speed. These efforts were a significant step forward in arriving at a definition for sarcopenia as a clinical condition, yet they were limited in that recommendations for low lean mass and muscle weakness were based on review of the literature and expert opinion, not on empirical evidence. In particular, across all the proposed sarcopenia definitions, the suggested cut-points for low lean mass were based solely on the statistical characteristics of the lean mass distribution within a single population (eg, the Baumgartner and colleagues[17] criteria). Although such cut-points are likely to identify those older adults with the lowest lean mass, it is not clear that they are meaningful for the important *outcomes* of muscle strength and function, which are more directly related to physical performance. Furthermore, none of the prior recommended sarcopenia criteria were validated for their ability to predict any clinical outcomes that may be relevant to age-related loss of muscle mass and strength, such as mobility disability, fractures, and mortality.

The latest proposed diagnostic criteria for sarcopenia are a significant step forward for the field because they were developed to overcome these important gaps in knowledge. The Foundation for the National Institutes of Health (FNIH) Sarcopenia Project recently published a series of five manuscripts[28–32] describing the rationale, methods, and recommendations resulting from a years-long effort supported by the FNIH Biomarkers Consortium, a public-private collaboration involving representatives from the NIH (National Institute on Aging, National Institute of Arthritis and Musculoskeletal and Skin Diseases), the U.S. Food and Drug Administration, academia, and the pharmaceutical industry. The goal of the project was to gather together previously collected data from multiple, diverse cohorts of older adults, including both observational studies and randomized trials, with longitudinal measures of muscle mass and function, to conduct analyses to develop definitions of muscle weakness and low lean mass that were clinically oriented, evidence-based, and empirically derived.

Toward this overarching goal, the Sarcopenia Project used an approached based on the paradigm of clinicians making a differential diagnosis that would identify, among older adults with physical limitations, those who are physically limited because they are weak, and those who are weak because they have low muscle mass (Fig. 1). This is based on the understanding that muscle weakness is just one among many causes of physical limitation among older adults, and that there are many causes of muscle weakness apart from low muscle mass. In using this approach, the Sarcopenia Project was poised to answer two primary questions: (1) What is a clinically important degree of muscle weakness for older adults? and (2) Among older adults who are weak, for which ones is low lean mass a treatable contributing cause?

To answer these questions, the Sarcopenia Project set two specific aims: (1) determine a level of muscle weakness associated with mobility disability (clinically relevant muscle weakness) and (2) determine a degree of muscle mass that identifies muscle weakness (clinically relevant low lean mass). In order to validate the criteria for predicting clinically relevant outcomes, a third aim was designed to determine, among older adults without mobility disability, whether the criteria for muscle weakness and low lean mass are associated with incident mobility impairment.

The Sarcopenia Project assembled data from eight observational cohort studies of older adults: (1) Age, Gene/Environment Susceptibility-Reykjavik Study; (2) Boston Puerto Rican Health Study; (3) Framingham Heart Study; (4) Health Aging and Body Composition Study; (5) Invecchiare in Chianti; (6) Osteoporotic Fractures in Men Study; (7) Rancho Bernardo Study; and (8) Study of Osteoporotic Fractures. Also included was a set of six clinical trials of various interventions aimed at improving

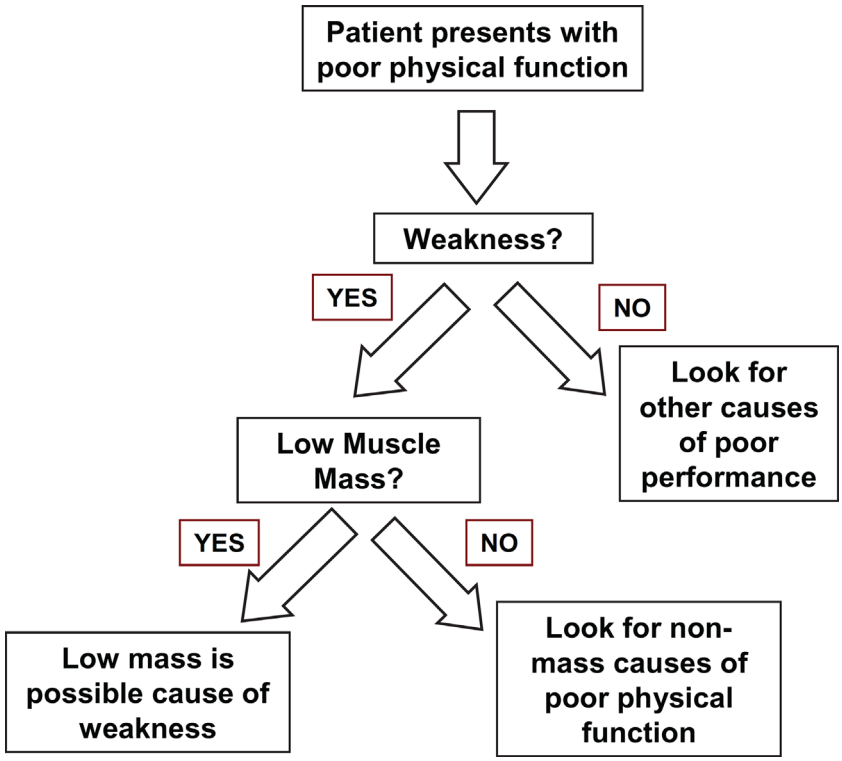

Fig. 1. The conceptual framework for the FNIH Sarcopenia Project, based on a clinical paradigm of identifying, among older adults with mobility limitation, those who are limited because they are weak, and those who are weak because they have low lean mass (reprinted with permission from Studenski and colleagues[28]).

physical function, conducted at the University of Connecticut. Data from over 26,000 men and women aged 65 years and older were available for inclusion in analyses, and individual-level data were pooled across studies to address the project's aims. For the first aim of the project, classification and regression trees analysis (CART) was used to obtain sex-specific cut-points of hand grip strength that discriminate individuals with mobility impairment, defined as gait speed less than 0.8 m/s.[29] The investigators noted that whereas CART analyses identified cut-points of absolute grip strength for both sexes, grip strength standardized to body mass index (BMI) provided a marginally better fit in women. CART was again used in the second aim to derive cut-points for appendicular lean mass, measured by DXA, that are associated with weakness defined by the cut-points calculated in the first aim.[30] When several measures of lean mass, both absolute and adjusted for body size, were included simultaneously in the CART model, absolute appendicular lean mass emerged as the single best discriminator of weakness (low grip strength). Sensitivity analyses also indicated that obesity influences the relation between lean mass and muscle strength, thus alternate cut-points were derived for appendicular lean mass standardized to BMI as a discriminator of weakness. In the third aim—validation analyses among older adults without current mobility impairment (gait speed <0.8 m/s)—those classified as having low absolute grip strength at baseline had twice the risk for developing mobility impairment over 3 years of follow-up (men: odds ratio [OR] = 2.31, 95% confidence interval [CI] = 1.34 to 3.99; women OR = 1.99, 95% CI = 1.23 to 3.21), and there was a similar association for those with low grip strength standardized to BMI (men: OR = 3.28, 95% CI = 1.92 to 5.59; women: OR = 2.54, 95% CI = 1.10 to 5.83). Low appendicular lean mass standardized to BMI was associated with a more modest increased risk for mobility impairment compared to low grip strength (men: OR = 1.58, 95% CI = 1.12 to 2.25; women: OR = 1.81, 95% CI = 1.14 to 2.87), whereas low absolute appendicular lean mass was not associated with mobility impairment.[31] Among those classified as weak by the low grip strength criteria, the risk for mobility limitation did not differ between those with and without low lean mass, indicating that weakness is the primary determinant of future mobility problems. Nevertheless, the investigators noted that among those with weakness there was likely a subgroup for whom low lean mass was the underlying cause of their weakness, and these individuals could be targeted for treatment with therapies that increase muscle mass. Thus, the Sarcopenia Project recommended a set of sex-specific, derived cut-points for low absolute grip strength and low appendicular lean mass standardized to BMI as potential criteria for clinically relevant weakness and low lean mass, respectively, in older men and women (Table 1).

The FNIH Sarcopenia Project recommendations are a significant advancement for the sarcopenia field. They are the first data-driven criteria, based on their relations with a clinical outcome (slow gait speed) that is directly relevant to muscle impairment. Also, these criteria are perhaps the most generalizable to date, because pooling data across multiple cohorts for analyses yielded large sample sizes representing a wide range of community-dwelling older adults. The FNIH Sarcopenia Project investigators envisioned that their recommended criteria could

Table 1. FNIH Sarcopenia Project: Recommended Criteria for Clinically Relevant Weakness and Low Muscle Mass[28]

Criterion	Measure	Cut-point	
		Men	Women
Primary			
Weakness	Hand grip strength	<26 kg	<16 kg
Low muscle mass	Appendicular lean mass (DXA) divided by BMI	<0.789	<0.512
Alternate			
Weakness	Hand grip strength divided by BMI	<1.0	<0.56
Low muscle mass	Appendicular lean mass (DXA)	<19.75 kg	<15.02 kg

FNIH = Foundation for the National Institutes of Health.

be used to identify participants for trials of interventions for both treatment and prevention of mobility limitations in older adults with weakness and low lean mass.

Still, the Sarcopenia Project investigators acknowledged that there remain important questions which could not be addressed by their work. The Project focused on gait speed as the primary measure of mobility limitation, mainly due to challenges in harmonizing available variables across the previously collected data sets from the different studies, most of which were not designed specifically to study sarcopenia. Other clinically relevant outcomes, such as falls, fractures, and hospitalizations, should be examined. Another complication which arose from pooling data from multiple studies was that different tools were used to measure the individual components of the sarcopenia definition. Recent work has showed that the prevalence of low lean mass or weakness depends on the method of assessment,[33] thus further work is needed to reach a consensus on the diagnostic tools used to diagnose sarcopenia. The prevalence of mobility impairment was quite low in the participating cohorts, because these studies tended to include mostly older adults robust enough to participate in research studies. It is likely that the relations of muscle mass and strength with mobility impairment differ in more frail older adults and in special clinical populations. Data on nonwhites was too sparse to examine potential differences among racial and ethnic groups. In Sarcopenia Project analyses, fat mass was recognized as an important modifier of the relation between lean mass and muscle strength. The importance of fat mass was first demonstrated by Newman and colleagues,[34] who built upon the work by Baumgartner and colleagues[17] and proposed that when assessing sarcopenia, measures of lean mass should be adjusted for both height and fat mass. Additionally, the concept of defining "sarcopenic-obesity," the coexistence of low lean mass and high fat mass, has gained widespread attention in recent years because it may describe a an extreme state of impaired body composition that is more strongly associated with functional limitations than low lean mass alone.[35,36] FNIH investigators speculated that fat mass could explain important gender differences in thresholds for low muscle mass and strength. The role of fat mass is clearly an area that warrants further investigation. The influence of the proposed criteria on other relevant outcomes should be explored, including falls, fractures, and hospitalizations. Also muscle quality, operationalized as strength per unit of muscle mass,[37] should be considered as an alternate indicator of muscle status. Finally, only grip strength was considered in analyses, yet strength of the lower extremities is more directly associated with mobility limitations. Given these remaining gaps in knowledge, the FNIH Sarcopenia Project investigators envisioned their recommendations as a foundation upon which future work may be done to refine these criteria for eventual use in clinical practice.

What are the next steps needed to establish consensus diagnostic criteria for sarcopenia? Many of the above-mentioned limitations can be addressed using either additional existing data sources or new studies designed to answer these specific questions, and such efforts are currently in development. This work will be critical for further honing the current recommendations to establish clear and specific criteria for clinically relevant weakness and low lean mass, and to determine the most appropriate clinical outcomes. Once these are set, the next challenge is to gain consensus within the medical community, which will come about through collaboration among researchers, clinicians, and regulators. Efforts toward this goal are currently being spearheaded by the Aging in Motion Coalition (http://www.aginginmotion.org), a group of organizations representing a broad range of stakeholders in the sarcopenia field, including patient groups, scientific organizations, and healthcare providers. As one of their primary undertakings, the Coalition recently submitted a proposal to the Centers for Disease Control and Prevention for the establishment of an International Classification of Diseases, Tenth Revision (ICD-10) code for sarcopenia. A unique code for diagnosing sarcopenia would be a significant advancement for the sarcopenia field.

As discussed earlier in this article, consensus diagnostic criteria for sarcopenia could also be an important advancement for the bone field. A definition of sarcopenia would allow clinicians to consider muscle health in their assessment of fracture risk. The inclusion of sarcopenia as an additional risk factor in fracture prediction tools such as Fracture Risk Assessment Tool (FRAX) could potentially improve model performance.[38,39] Furthermore, a consensus definition would advance the development of pharmacological therapies for muscle, which would provide clinicians with additional treatment options for preventing fractures in weak older adults.

In conclusion, the evolution of the field of sarcopenia has progressed significantly over the past decade, yet it continues to lag behind the clinical assessment, treatment, and outcomes that have been well-established in the field of osteoporosis. With ongoing FNIH activities in the Biomarkers Consortium, further refinements of sarcopenia criteria are expected. This will further advance the field, and bring this important contributor to age-related falls, fractures, and disability into the mainstream of clinical care, pharmacologic interventions, and nonpharmacologic interventions, and ultimately to a better quality of life with aging.

Disclosures

RRM and DPK served as investigators on the FNIH Sarcopenia Project. DPK has received grants from Eli Lilly, Amgen, and Merck Sharp & Dohme, and has served on scientific advisory boards for Eli Lilly, Amgen, Novartis, and Merck Sharp & Dohme.

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UPDATE SULLA SARCOPENIA

Abstract e commento al lavoro "Developing Consensus Criteria for Sarcopenia: An Update" pubblicato su Journal of Bone and Mineral Research 2015 Apr; 30(4):588-92, effettuato dalla Dottoressa Daniela Merlotti (*Dipartimento di Medicina Interna Scienze Endocrino Metaboliche e Biochimiche, Università di Siena).*

ABSTRACT

Sarcopenia, the age-related loss of muscle mass and strength, is a major cause of impaired physical function, which contributes to mobility disability, falls and hospitalizations in older adults. Lower muscle mass and strength are also associated with lower bone mineral density and greater risk for osteoporotic fractures. Thus, identification of sarcopenia could be important for fracture prevention as it may help improve fracture risk assessment, and muscle mass and strength can be improved with exercise, even among the frailest older adults. Unfortunately, there are no consensus diagnostic criteria for sarcopenia. Consequently there is no guidance to help clinicians identify older adults with clinically meaningful low muscle mass or weakness. Further, development of novel sarcopenia therapies is hindered not only due to the difficulty in identifying participants for clinical trials, and but also because there are no validated, clinically appropriate endpoints for assessment of treatment efficacy. There is currently a major push to establish a consensus definition of sarcopenia, and recent work holds promise that this goal may be within reach. This article discusses the evolution of the definition of sarcopenia, and focuses on the latest recommended diagnostic criteria proposed by the Foundation for the National Institutes of Health (FNIH) Sarcopenia Project. While these empirically-based cut-points for clinically important low muscle mass and weakness are a significant step forward for the sarcopenia field, important questions remain to be answered before consensus diagnostic criteria can be definitively established. Ongoing work to refine sarcopenia criteria will further advance the field and bring this important contributor to falls, fractures and disability into the mainstream of clinical care and ultimately lead to better quality of life with aging.

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COMMENTO

La sarcopenia viene definita come la perdita di massa e forza muscolare che si verifica con l'avanzare dell'età. Essa costituisce una delle maggiori cause di compromissione dell'attività fisica con aumento della disabilità, riduzione della mobilità, aumento del rischio di caduta e di ospedalizzazione specialmente nei soggetti anziani. Inoltre la riduzione della massa e della forza muscolare spesso si associa a bassi livelli di densità minerale ossea e quindi ad un incremento del rischio di frattura. Tuttavia attualmente non vi sono linee guida ufficiali sull'inquadramento clinico-diagnostico e conseguentemente sulla gestione terapeutica di tale patologia. Questo articolo prende in analisi le recenti acquisizioni sulla definizione di sarcopenia e le ultime raccomandazioni proposte dalla Foundation for the National Institutes of Health (FNIH) Sarcopenia Project anche se tuttavia ulteriori studi sono necessari per poter capire meglio la complessità di tale patologia che ha importanti ripercussioni sulla qualità di vita dei pazienti.

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