



Research Partnership Defines Diagnostic Criteria for Sarcopenia, a Debilitating Condition in Older Adults

Foundation for the National Institutes of Health Led Five-Year Effort

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Bethesda, Md., April 15, 2014 — Low muscle mass and weakness are important contributors to sarcopenia, a common and potentially disabling condition in older adults. Diagnostic criteria have been proposed, but no consensus yet exists. A series of six special articles published online April 15, 2014, in the *Journals of Gerontology: Medical Sciences*, derived from the work of the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium Sarcopenia Project, provide data-driven diagnostic criteria for clinically relevant weakness and low muscle mass. These recommendations have the potential to influence treatment decisions, helping identify groups of patients at risk for poor outcomes, in which interventions should be tested, and clarifying categories of sarcopenia patients for insurers, including the Centers for Medicare and Medicaid Services.

The recommendations provide specific characterizations of how low lean mass and low strength relate to mobility disability. To arrive at the list of criteria, researchers looked at the association between body mass index (a weight-to-height ratio), appendicular lean mass (the sum of lean mass in the arms and legs), grip strength and gait speed. For example, the study defined grip strength of less than 26 kilograms (approximately 57 pounds) for men and 16 kilograms (approximately 35 pounds) for women as low because these values best discriminated who had slow gait speed. Similarly, it proposed that low muscle mass be defined as the ratio of muscle mass to body mass index as, in men, <0.789 and in women, <0.512 , because these values best discriminated the presence of weakness.

“The Sarcopenia Project took advantage of many thousands of participants who have already been studied over the years. By pooling data from observational longitudinal studies and clinical trials, a data-driven definition of what constitutes clinically important weakness and low lean mass was established,” said Stephanie Studenski, M.D., M.P.H., from the National Institute on Aging (NIA).

The FNIH Sarcopenia Project launched in 2010, bringing together multiple stakeholders from the National Institute of Health’s NIA and the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the Center for Drug Evaluation and Research of the Food and Drug Administration (FDA); academic institutions, including the University of Pittsburgh, California Pacific Medical Center Research

Institute, Columbia University, Hebrew SeniorLife/Harvard Medical School, School of Medicine University of Maryland, University of Connecticut and University of Central Florida; five industry partners (Abbott Nutrition; Amgen, Inc.; Eli Lilly; Merck & Co., Inc; and Novartis Pharmaceuticals Corporation); and a not-for-profit organization, the Dairy Research Institute.

“There is a significant need to develop scientifically valid and rigorous evaluation strategies for drugs intended to address clinically meaningful outcomes in patients with mobility disability” said the FDA’s Dragos Roman, M.D. “We are glad to be a part of this important partnership, spearheaded by FNIH.”

Researchers looked at data from nine sets of intervention and observational studies of older persons dwelling in the community. The pooled sample included 26,625 participants, 57 percent female and 43 percent male. Median age of women was 78.6 years and of men, 75.2 years.

The pooled studies were the Age, Gene/Environment Susceptibility (AGES)-Reykjavik Study; Boston Puerto Rican Health Study (BPRHS); Framingham Heart Study (original and offspring cohorts); Health, Aging and Body Composition Study; Invecchiara in Chianti (InChianti); Osteoporotic Fractures in Men Study (MrOS); Rancho Bernardo Study (RBS); a set of clinical trials based at the University of Connecticut and the Study of Osteoporotic Fractures (SOF)

“This public-private partnership involves key stakeholders in the sarcopenia field, brought together by FNIH, to address a critical, unmet medical need,” said Maria Freire, Ph.D., FNIH President. “Creating a data-driven definition of this medical condition will facilitate drug development as well as regulatory and clinical practice, providing a clear benefit to the growing world population of older adults.”

In the United States, the number of older adults (age 65 years and above) is expected to double to 86.7 million near 2050, resulting in a potential increase of comorbidities and the need for expensive institutionalization.

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