Commentary

Ethical considerations in sarcopenia research

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Introduction:

Considering the fact that the world population is aging and societies are facing the challenges of geriatric diseases, research about illnesses and ailments of this period in life is significant. Accordingly, due to the advanced age of these individuals, it is necessary to observe some ethical points in research on the various stages of epidemiology, genetics, diagnosis, prevention, and management of diseases (1). Any research project consists of a formal protocol, an objective, and a set of methods designed to carry out the project. In the case of medical research that includes human subjects, ethical principles must be observed in all the mentioned stages (2) These important principles include reliability of the scientific project, experiences of the investigators, ethics committee approval, informed consent, privacy, beneficence/no maleficence, and justice (3). On the other hand, research on the elderly calls for more sensitivity and observance of special ethical issues

Comorbidity, reduced life expectancy, polypharmacy, specific treatments and vulnerabilities are important issues that need to be considered in research on elderly subjects (4, 5).

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Among the common ailments in old age is sarcopenia or the age-related unintentional decrease in skeletal muscle mass and muscle function, which deteriorate linearly from the fourth to the eighth decade of life by 50% (6). Therefore, sarcopenia is a common disease in the elderly that requires observance of a series of ethical points in related research. Overlooking ethical issues in sarcopenia research leads to a decrease in the quality of primary health care and limits the prevention and management of this disease. Thus, compliance with moral and social principles will reduce the economic and social costs caused by this disease (7, 8).

In this article we discuss the ethical aspects of sarcopenia research from three perspectives:

1) ethical rules in research related to screening and diagnosis of sarcopenia, 2) ethical issues in intervention studies on the prevention and management of sarcopenia, and 3) sarcopenia research in low-income countries.

Ethical rules in research related to screening and diagnosis of Sarcopenia

Screening programs can reduce morbidity and mortality of diseases. However, various ethical issues need to be considered before and during these programs. Ethical issues relating to screening tests include consent, utility of the screening tests, funding of the screening programs, and equity of access to screening (9).

One sarcopenia screening tool is a simple questionnaire called SARC-F, which assesses strength, assistance with walking, rising from a chair, climbing stairs, and falls (10). Although this tool seems to be a suitable method for sarcopenia screening and a preventive strategy to reduce the risk of sarcopenia, more research is needed on the ethics of sarcopenia screening.

The diagnosis of sarcopenia is comprehensively based on three aspects: muscle quality, muscle strength and muscle function, which are measured by different methods (11). Dual energy X-ray absorptiometry (DXA), bioelectrical impedance assessment (BIA), computed tomography (CT), magnetic resonance imaging (MRI) and ultrasound (US) are some methods used to assess muscle quality (12, 13); testing hand grip strength, knee flexion and maximum expiratory velocity are used to measure muscle strength; and muscle function is evaluated through gait speed, simple body function assessment, standing test and walking test (3). Due to the laborious and time-consuming nature of some of these methods, which may be tiring for an elderly person, there is a need for professionally trained personnel. Some ethical principles in sarcopenia studies include employing expert researchers who are familiar with the affairs of the elderly and sarcopenia, as well as the correct way to treat these people and provide them with the necessary knowledge and training patiently and simply.

As with all research studies, ethical principles must be followed in the field of sarcopenia diagnosis and screening. Since this disease is age-related, more attention should be given to ethical principles, the main ones being beneficence, nonmaleficence, autonomy and justice (14).

The aim of any research study should be to maximize the benefits of the research and minimize potential risks and harms to participants and researchers, and robust precautions should be taken to achieve these aims (15).

Although studies on screening programs can help in finding useful tools to diagnose sarcopenia, false positive test results will produce anxiety, stigma and psychological harms, and false negatives will create unwarranted reassurance and subsequent complications of the disease. Therefore, it is important to consider the potential benefits and harms arising from screening tests. In addition, many diagnostic programs for sarcopenia, such as MRI, CT or DXA, are expensive, and the economic aspects and cost-effectiveness of these methods should be evaluated (16). A recent study compared various sarcopenia screening tools and showed which tool is more cost-effective than others (17).

From the other point of view, in studies conducted in the field of screening and diagnosis methods, the autonomy of subjects should be considered and they should be aware of the consequences of their participation. Also, it is essential to obtain informed consent, and the physician should provide the necessary information to the patients without maleficence.

Another important principle in research is justice, which is a further expression of respect for the participants. Researchers should pay attention to the social impact of their research both in the selection of subjects and in the benefits and burdens arising from it. For instance, it is not ethical to select participants from special groups, specific genders or those with low financial ability due to easy availability (18).

Ethical issues in interventional studies on the prevention and management of sarcopenia

In order to reduce the economic burden and slow down the development of sarcopenia and its adverse effects, identification of the elderly at risk and prevention can be effective. Furthermore, in the absence of preventive measures at the public health level, the population of individuals with undiagnosed sarcopenia is likely to escalate, along with the incidence of complications necessitating advanced technological interventions (6). A protein-rich diet and sufficient physical activity help maintain muscle in middle age and minimize loss in older age. There are some gaps that we need to understand about the prevention of sarcopenia, and the European Working Group on Sarcopenia in Older People (EWGSOP) suggests further studies. Sarcopenia work groups maintain that resistance-based training is first-line therapy to manage sarcopenia (11). Although adequate protein intake is important for older adults with sarcopenia, no recommendation considers protein supplementation as first-line therapy. There have been both pharmacological and non-pharmacological interventions aimed to manage sarcopenia and to understand the effectiveness of supplements; however, none have been deemed clinically effective in preserving or enhancing skeletal muscle mass or function without any unfavorable consequences (19).

Despite the abundance of scientific evidence about the prevention and treatment of sarcopenia, there is a need to conduct clinical trial studies for better management of this disease in practice. Ethical issues are of great significance in clinical trials. Considering ethical aspects in clinical trial research not only ensures the integrity of the results and the safety of participants in such studies, but can also help prevent the exploitation or unfair treatment of participants by the research team. In any research, there is inherent uncertainty about the extent of the risks (minor or serious, transient or long-term) associated with the drug, device, or new method being tested. Considering that most sarcopenia patients are physically disabled and may suffer co-morbidities, it is important to provide them with the necessary information about each of the new drugs and methods being used and their positive and negative effects. In short, it can minimize the risks and the discomfort, maximize the potential benefits, and determine the ratio of the potential benefits for individuals and the society to the risks. There are various reasons for people's non-cooperation in providing informed consent, including traditions and customs, lack of study benefits, fear of strangers, previous bad research experience, and inappropriate timing. Thus, in every case, giving complete information to patients, observing all ethical principles and inviting them to calm down and cooperate with the experts and even psychologists can help improve the situation (20). In addition, health professionals' awareness and knowledge of palliative care and the principles of medical ethics related to sarcopenia can help them make the right decisions and provide better care to elderly patients (21) .

Although there are ethical standards for conducting clinical studies on adults, they are not appropriate for studies on the elderly. Older adults usually suffer from cognitive impairments and co-morbidities and may be on several medications, all of which increase the risk of drug-related side effects; the reactions and risks related to research on the elderly are also higher, and in order to protect these patients in clinical studies, special and careful ethical attention is required in addition to observing the basic principles of medical ethics (1, 22).

In clinical trials involving sarcopenia patients, due to the subjects' physical disability and lack of muscle strength, basic regulation of the study conditions, including the duration of the study, is a vital ethical point. Moreover, the inability of these patients to move, the possibility of further danger and injury, and safe conditions and environment should be considered during the research period (23). Obtaining written, signed informed consent from elderly people is an important challenge in studies on geriatric diseases including sarcopenia. The findings show that the elderly consider every signed document as a contract, so they are more hesitant to sign the consent form in studies (22, 24). Therefore, to reduce the stress of the participants in sarcopenia studies, it is better to prepare the consent form in a non-contractual format. The consent form must be clear and legible, and the wording should be completely understandable for the reader. Also, the font should be suitable and easy enough to read for older people (25)

Ethical issues relating to sarcopenia research in low-income countries

While it is essential to conduct studies on chronic diseases in low-income countries, some of these diseases seem to be more important than others. Due to their high prevalence, people's lack of awareness and knowledge, insufficient information about genetics, and the social and cultural factors affecting such diseases, more studies need to be conducted, and along with that, it is necessary to pay attention to ethical principles. Studies have shown that sarcopenia is a very common disease not only in high-income societies but also in low- and middle-income countries. A study in Brazil revealed the prevalence of sarcopenia to be 18% based on the European consensus cut-off values (26). Another study in Africa showed a prevalence of 20% and 45% among men and women, respectively (27). Therefore, there is an imperative need to research the risk factors, rapid diagnostic tools, prevention and effective interventions for mitigating the adverse outcomes of sarcopenia.

This is an important and difficult issue, particularly in middle- and low-income countries, considering their growing number of city residents, fragmented infrastructure and limited human resources, which clearly affect sarcopenia diagnosis and management. Also, prevention and early intervention of other chronic diseases play a crucial role in the quality of life and survival rate of older people. Therefore, considering sarcopenia research as the priority in low-income countries may be ethically questionable.

Sarcopenia is closely associated with other age-related diseases such as diabetes, osteoporosis and cardiovascular conditions. Therefore, knowledge and health beliefs regarding sarcopenia may provide clues for the common pathogenesis and risk factors, prevention and intervention measures in the field of chronic diseases.

It is important to pay attention to the limitations of resources and facilities and access to them for patients and health-care workers in low-income areas in all stages of study design, prevention, diagnosis and treatment, among other ethical issues. Carrying out sarcopenia research in lower-income areas because of convenience, lower costs, ease of availability, acceptance of individuals and their compromised status or manipulability, instead of considering issues that are directly related to the problem under study, is far from human justice. Therefore, we should adopt an ethical approach to research programs on sarcopenia in low-income areas (28, 29).

Additionally, research into preventive measures and management of sarcopenia in low-income countries may render different results from developed regions due to people’s different lifestyles. It is therefore important to take the necessary measures in order to avoid frustration and psychological damage to people in low-income regions.

In research related to the identification and evaluation of a supplement or food effective in preventing sarcopenia, a series of ethical points should be considered. For instance, the product should not be recommended as a result of lobbying and market-driving between the researcher and the manufacturing company, it should be affordable and available for use in low-income and deprived areas, it must be safe and efficient and have FDA approval, and finally, it should be safe in terms of damage to the environment and production of environmental waste (22, 30). In this regard, traditional medicine may be able to promote effective prevention and non-pharmacological intervention by guiding evidence-based research. In general, an important experiment may be conducted for personal, organizational or social interests. Also, it is ethical to include an appropriate nutrition program to investigate the effect of multicomponent exercise training such as resistance and strength training in sarcopenic patients in low-income areas (19, 31). One justification for such programs is that there is a possibility that elderly people will be injured while performing these activities due to low muscle mass. The outcomes of sarcopenia studies in low-income areas may be different from other places due to the type of lifestyle and nutrition in such areas; it should therefore be noted that generalizing these results to an entire society and making policies accordingly is not in keeping with ethical principles.

Conclusion

Today, chronic diseases are among the major challenges in medicine, and sarcopenia is one such example that needs special attention. Early diagnosis and treatment can prevent the complication of this disease, but in order to face this challenge, we need proper research studies. We also need knowledgeable and trained researchers, as well as proportional allocation of health-care resources to diagnosis, management, prevention and treatment of sarcopenia, especially in low-income countries. Furthermore, the involvement of stakeholders such as medical device companies, pharmaceutical companies, diagnostic clinics, insurance companies, clinical trial research organizations (CROs), and other service providers in the realm of sarcopenia research necessitates an expansion of the ethical framework governing this field. Therefore, it is important to understand and discuss various ethical issues in sarcopenia research, for instance biomedical ethics, pharmaceutical ethics and health-care ethics. Also, it is essential to conduct value-centered research on the individual (patient) basis, taking into account an individual’s (the patient’s and the family’s) personal, cultural and religious values.

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Conflict of Interests

There are no competing interests to declare.

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