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Aims and Scope

Annals of Rehabilitation Medicine (*ARM*) is the official journal of the Korean Academy of Rehabilitation Medicine. It is an international, peer-reviewed open access journal, which aims to be a global leader in sharing up-to-date knowledge dedicated to the advancement of care and enhancing the function and quality of life of persons with various disabilities and chronic illnesses. As the official journal of one of the largest societies of rehabilitation medicine in Asia and Oceania, nearly 8,000 physiatrists receive this journal every two months as a member benefit. This journal is endorsed by the International Society of Physical and Rehabilitation Medicine (ISPRM) and the Asia-Oceanian Society of Physical and Rehabilitation Medicine (AOSPRM). International members comprise approximately half the editorial board and conduct peer-review of submitted manuscripts.

The journal encompasses all aspects of physical medicine and rehabilitation, including clinical practice, experimental and applied research, and education. Research areas covered by this journal include rehabilitation of brain disorders and spinal cord injury; electrodiagnosis; musculoskeletal disorders and pain; pediatric, geriatric, cardiopulmonary, sports, cancer, cognitive, and robotic rehabilitation; neuromodulation; neuroimaging; orthotics and prosthetics; physical modalities; clinical trials; quality of life issues; and basic research, as well as other emerging fields in rehabilitation medicine.

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Editorial: Outcome Measures in Rehabilitation Medicine

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Outcome Measurement in Shoulder Diseases: Focus on Shoulder Pain and Disability Index (SPADI)

Du Hwan Kim, MD, PhD

Department of Physical Medicine and Rehabilitation, Chung-Ang University College of Medicine, Seoul, Korea

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Correspondence:
Du Hwan Kim
Department of Physical Medicine and Rehabilitation, Chung-Ang University College of Medicine, 102 Heukseok-ro, Dongjak-gu, Seoul 06973, Korea.
Tel: +82-2-6299-1884
Fax: +82-2-6299-1886
E-mail: ri-pheonix@hanmail.net

Physiatrists deal with the evaluation, diagnosis and nonsurgical management of neuromusculoskeletal conditions, of which shoulder pain (such as rotator cuff spectrum diseases, frozen shoulder, degenerative arthritis, instability, and rheumatic diseases) is one of the common manifestations. Outcome measures for shoulder care included pain severity, range of motion, and patient-reported outcome measures (PROMs). In this editorial, I would like to comment on some issues regarding PROMs applied to shoulder diseases and recommend options for appropriate PROMs in Korean clinical settings.

There are numerous PROMs with more than 30 different tools for measuring the symptoms and functional states of patients with shoulder diseases [1-4]. Validated legacy PROMs commonly refer to Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) and its Short Version (QuickDASH), Shoulder Pain and Disability Index (SPADI), American Shoulder and Elbow Surgeons (ASES) Society Standardized Shoulder Assessment Form, Constant (Murley) Score (CS), Simple Shoulder Test, Oxford Shoulder Score, and Western Ontario Rotator Cuff index (WORC) [5]. Previous articles summarized the psychometric properties of legacy PROMs for shoulder diseases [1,2,6]. While these instruments have an overall high quality of psychometric properties, respondent and administrative burdens and ceiling/floor effects have been reported in some PROMs such as ASES and DASH [6].

Most PROMs were developed in English. The preferred PROMs tend to differ depending on the continent because of the historical requirements and availability of the translated version [7]. A recent survey reported that ASES was most commonly used in articles originating from North America and Asia, while it was CS from Europe [7]. Although there are few reports on the transcultural adaptation validation of the ASES in Asia, the fact that many studies using the ASES have been published indicates that it involves a transcultural adaptation issue [8-10]. As far as my knowledge, validity studies on the Korean versions of the SPADI and DASH have been conducted, but there is no validation of the Korean versions of other commonly used evaluation tools, such as the ASES, CS, and WORC [11]. A transcultural adaptation procedure from the English version to the Korean version for major PROMs and a comparative analysis of the psychometric properties of the Korean and original versions are needed.

Currently, there is no consensus regarding the recommended PROMs for specific shoulder diseases. A recent study revealed that ASES was most commonly used for rotator cuff and subacromial pathology, followed by DASH and SPADI, while the use of SPADI is overwhelming for

shoulder stiffness, calcific tendinitis, and nonspecific shoulder pain [12]. Moreover, a recent study demonstrated that the SPADI can be used as a shoulder-specific PROMs in patients with rotator cuff tears because of its strong reliability and excellent discriminatory properties [13]. Considering the presence of the Korean version and good evidence in support of its high-quality psychometric properties, the SPADI can be recommended for monitoring common shoulder diseases such as rotator cuff pathology and shoulder stiffness in Korean clinical practice.

The SPADI was designed to evaluate the degree of shoulder pain and discomfort in performing activities of daily living by the patients themselves, without clinician components. The original version was developed by a panel of rheumatologists and physical therapists and was published in 1991 [14]. Because of this background, SPADI still tends to be preferred in the field of rheumatology and rehabilitation medicine. It has 13 items, with 5 items for pain and 8 items for disability. In the original version, items were rated using a visual analog scale; however, in the more recent version, each item used an 11-point numerical rating scale (0–10) (Table 1) [14,15]. SPADI takes 2–3 minutes to complete. The SPADI total score is the mean of the pain and disability sub-scores. SPADI has been shown to have excellent internal reliability/consistency (Cronbach's alpha=0.86–0.96) and test-retest reliability (intra-class correlation coefficient=0.84–0.95) [2,6]. SPADI total score correlated well with the ASES score, although there was a low correlation between the SPADI total score and the Short Form 36. However, some disability items (items 4, 7, and 8) showed unsuitable criterion validity [6]. Disability items included only one item to assess overhead words or heavy use. Therefore, the SPADI could have a ceiling effect because it is difficult to accurately evaluate activities that require high shoulder function. A previous study reported that the minimum clinically important difference (MCID) of 13.2 was smaller than the minimally detectable change (MDC) of 18.1%; thus, a change in the MDC is necessary to be confident in the MCID (Table 1) [16].

In conclusion, I recommend the SPADI as a shoulder-specific PROM in patients with shoulder stiffness, rotator cuff spectrum disease, and nonspecific shoulder pain, given the overall psychometric properties and availability of the Korean-language

Table 1. SPADI items, practical application and psychometric information

1. SPADI items	
Pain scale (5 items) (0=no pain, 10=the worst pain imagnable)	Disability scale (8 items) (0=no disability, 10=unable to perform)
(1) At its worst?	(1) Washing your hair?
(2) When lying on the involvled side?	(2) Washing your back?
(3) Reaching for something on a high shelf?	(3) Putting on an undershirt or jumper?
(4) Touching the back of your neck?	(4) Putting on a shirt that buttons down the front?
(5) Pushing with the involved arm?	(5) Putting on your pants?
Total pain score: _____/50×100=%	(6) Placing an object on a high shelf?
	(7) Carrying a heavy object of 10 pounds
	(8) Removing something from your back pocket?
	Total disability score: _____/80×100=%
Total SPADI score: _____/130×100=%	
2. Practical application and psychometric properties	
Time to complete	2–3 minutes to complete
Translation	Spanish, Chinese, Arabic, Danish, Norwegian, Dutch, Indian, Hindi, Greek, Turkish, Brazilian Portuguese, Persian, Thai, Nepali, Italian, German, and Korean
Reliability	Internal consistency (Cronbach's alpha=0.86–0.96)
	Test-retest reliability (intra-class correlation coefficient=0.84–0.95)
Validity	American Shoulder and Elbow Surgeon Score: r=0.77 in patients referred to an upper extremity clinic for shoulder problems
	Short Form 36 physical component scale: r=-0.46 in patients with shouder pain
Ability to detect change	Estimated minimal detectable change 18.1 for musculoskeletal upper extremity problems
	Estimated minimal clinically important difference 13.2 for musculoskeletal upper extremity problems

SPADI, Shoulder Pain and Disability Index.

version. Considering its frequency of use and psychometric properties, the ASES can also be an excellent option; however, the issue of transcultural adaptation remains.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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ORCID

Du Hwan Kim, https://orcid.org/0000-0002-9980-8549

REFERENCES

1. Aldon-Villegas R, Ridao-Fernández C, Torres-Enamorado D, Chamorro-Moriana G. How to assess shoulder functionality: a systematic review of existing validated outcome measures. Diagnostics (Basel) 2021;11:845.
2. Buchbinder R, Ramiro S, Huang H, Gagnier JJ, Jia Y, Whittle SL. Measures of adult shoulder function. Arthritis Care Res (Hoboken) 2020;72 Suppl 10:250-93.
3. Furtado R, Bobos P, Ziebart C, Vincent J, MacDermid J. Patient-reported outcome measures used for shoulder disorders: an overview of systematic reviews. J Hand Ther 2022;35:174-85.
4. Huang H, Grant JA, Miller BS, Mirza FM, Gagnier JJ. A systematic review of the psychometric properties of patient-reported outcome instruments for use in patients with rotator cuff disease. Am J Sports Med 2015;43:2572-82.
5. Matar RN, Shah NS, Grawe BM. Patient-reported outcomes measurement information system scores are inconsistently correlated with legacy patient-reported outcome measures in shoulder pathology: a systematic review. Arthroscopy 2021;37:1301-9.e1.
6. Angst F, Schwyzer HK, Aeschlimann A, Simmen BR, Goldhahn J. Measures of adult shoulder function: Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) and its short version (QuickDASH), Shoulder Pain and Disability Index (SPADI), American Shoulder and Elbow Surgeons (ASES) Society Standardized Shoulder Assessment Form, Constant (Murley) Score (CS), Simple Shoulder Test (SST), Oxford Shoulder Score (OSS), Shoulder Disability Questionnaire (SDQ), and Western Ontario Shoulder Instability Index (WOSI). Arthritis Care Res (Hoboken) 2011;63 Suppl 11:S174-88.
7. Narulla R, Song M, Karunaratne S, Smithers C, Petchell J. Trends in shoulder surgery patient-reported outcome measures. JSES Int 2023;7:653-61.
8. Gómez-Valero S, García-Pérez F, Flórez-García MT, Miangolarra-Page JC. Assessment of cross-cultural adaptations of patient-reported shoulder outcome measures in Spanish: a systematic review. Shoulder Elbow 2017;9:233-46.
9. Ho CA, Yun Ling JC, Abdul Karim S. Cross-cultural adaptation and measurement properties of the Malay Shoulder Pain and Disability Index. PLoS One 2022;17:e0265198.
10. Mosher ZA, Ewing MA, Collins CS, Young PG, Brabston EW, Momaya AM, et al. Usage trends of patient-reported outcome measures in shoulder literature. J Am Acad Orthop Surg 2020;28:e774-81.
11. Seo HD, Lee KW, Chung KS, Chung Y. Reliability and validity of the Korean version of shoulder pain and disability index. J Spec Educ Rehabil Sci 2012;51:319-36.
12. Padua R, de Girolamo L, Grassi A, Cucchi D. Choosing patient-reported outcome measures for shoulder pathology. EFORT Open Rev 2021;6:779-87.
13. Dabija DI, Pennings JS, Archer KR, Ayers GD, Higgins LD, Kuhn JE, et al. Which is the best outcome measure for rotator cuff tears? Clin Orthop Relat Res 2019;477:1869-78.
14. Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a Shoulder Pain and Disability Index. Arthritis Care Res 1991;4:143-9.
15. Williams JW Jr, Holleman DR Jr, Simel DL. Measuring shoulder function with the Shoulder Pain and Disability Index. J Rheumatol 1995;22:727-32.
16. Schmitt JS, Di Fabio RP. Reliable change and minimum important difference (MID) proportions facilitated group responsiveness comparisons using individual threshold criteria. J Clin Epidemiol 2004;57:1008-18.

Review Article

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Fact Sheet on Cardiac Rehabilitation for Cardiovascular Disease in South Korea

Ki-Hong Kim, MD, Jae-Young Han, MD, PhD

Department of Physical & Rehabilitation Medicine, Chonnam National University Medical School and Hospital, Gwangju, Korea

Cardiovascular disease (CVD) poses a significant health challenge globally, including in Korea, due to its status as a leading cause of death and its impact on cardiopulmonary function. Cardiac rehabilitation (CR) is a well-established program that not only aids in restoring cardiopulmonary function, but also improves physical and social conditions. The benefits of CR are widely recognized, and it is implemented globally. While the effectiveness of CR has been proven in Korea, it is underutilized. This fact sheet summarizes the current status of CR in Korea, including the prevalence of CVD, the clinical practice guidelines for CR programs, and the challenges of implementing CR in Korea.

Keywords: Cardiac rehabilitation, Health services misuse, Practice guideline, Statistics

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Correspondence:
Jae-Young Han
Department of Physical & Rehabilitation Medicine, Chonnam National University Medical School and Hospital, 42 Jebong-ro, Dong-gu, Gwangju 61469, Korea.
Tel: +82-62-220-5198
Fax: +82-62-228-5975
E-mail: rmhanjy@daum.net

INTRODUCTION

Cardiovascular disease (CVD) is the primary global cause of mortality, with ischemic heart disease accounting for approximately 12% of disability-adjusted life-years lost annually worldwide. Korea has a lower mortality rate than other countries, but trends of mortality and incidence vary depending on the type of CVD [1,2].

The number of patients with CVD is increasing, and CVD patients are now living longer with their symptoms due to major diagnostic and therapeutic advances in the past few decades. The extended survival of individuals with CVD is contributing to the growing prevalence of CVD, and the absolute number of CVD-related fatalities is expected to rise as the population ages [3-5].

Dual antiplatelet therapy is typically advised for a 12-month period following the onset of acute coronary syndrome. Secondary prevention measures are crucial to emphasize in order to reduce mortality rates. These include rigorous lipid-lowering therapy, antithrombotic treatment, and lifestyle modifications, which can be included in cardiac rehabilitation (CR) [1].

CR is a complex intervention that aims at enhancing cardiopulmonary function, well-being, and health-related quality of life in CVD patients. There is substantial evidence supporting the clinical and cost-effectiveness of CR for patients with acute coronary syndrome [6]. In Korea, numerous studies have confirmed the effectiveness of CR [7-10].

Although contemporary clinical guidelines strongly recommend referring CVD patients to CR, access to CR programs in Korea remains limited. About 40% of patients participate in CR worldwide, but in Korea, the participation rate is lower [11].

This fact sheet provides an overview of the epidemiology of CVD and the current status of CR programs in Korea, encompassing clinical practice guidelines and the implementation, effectiveness, and underutilization of CR. Since CVD is a very broad term, this fact sheet focuses primarily on coronary heart

diseases, such as acute myocardial infarction (AMI), angina, and heart failure.

PATTERNS OF CARDIOVASCULAR DISEASE INCIDENCE, PREVALENCE, AND MORTALITY TRENDS IN KOREA

Incidence and prevalence

Overall, the prevalence of CVD is increasing [2]. However, the trends in mortality and incidence vary depending on the specific type of CVD. Notably, heart failure is experiencing a rapid increase in both incidence and prevalence. The incidence of AMI peaked in 2006–2007 and has been gradually declining since then. However, it has recently started to rise again. Interestingly, while the incidence of myocardial infarction has not increased in specific age groups, its overall crude incidence seems to be rising due to the growing elderly population (Fig. 1) [12].

In 2016, the age-standardized incidence of hospitalization due to AMI in Korea was 43.2 cases per 100,000 people. When broken down by age group, the incidence of AMI per 100,000 people was as follows: The highest incidence was observed in individuals aged 80 or older, with 321.4 cases per 100,000 people. For those aged 70–79, the incidence rate was 197.4 cases per 100,000. The incidence for individuals aged 60–69 was 117.7 cases per 100,000, while those aged 50–59 had an incidence rate of 66.4 cases per 100,000. Among those aged 30–39, the incidence was 6.9 cases per 100,000. The lowest incidence was recorded for those under 29 years of age, at 0.3 cases per 100,000 [13].

Mortality

Until 1999, CVD was the leading cause of death. However, since that time, cancer has overtaken CVD, making it the second most common cause of death. Data on causes of death from 1983 to 2021, provided by the National Statistical Office of Korea, shows that the mortality rate from all circulatory system diseases decreased from 1982 to 2009, but then increased again from 2009 to 2021. Despite limitations in generalizability due to the inclusion of cerebrovascular disease, these statistics reveal the following trends. The mortality rate was 165.9 per 100,000 population in 1983, dropped to 109.2 per 100,000 population in 2009, and then rose to 121.5 per 100,000 population in 2021. The increase in mortality related to ischemic heart disease was primarily responsible for the overall rise in heart disease mortality in the early 2000s.

Conversely, the increase in heart failure mortality was asso-

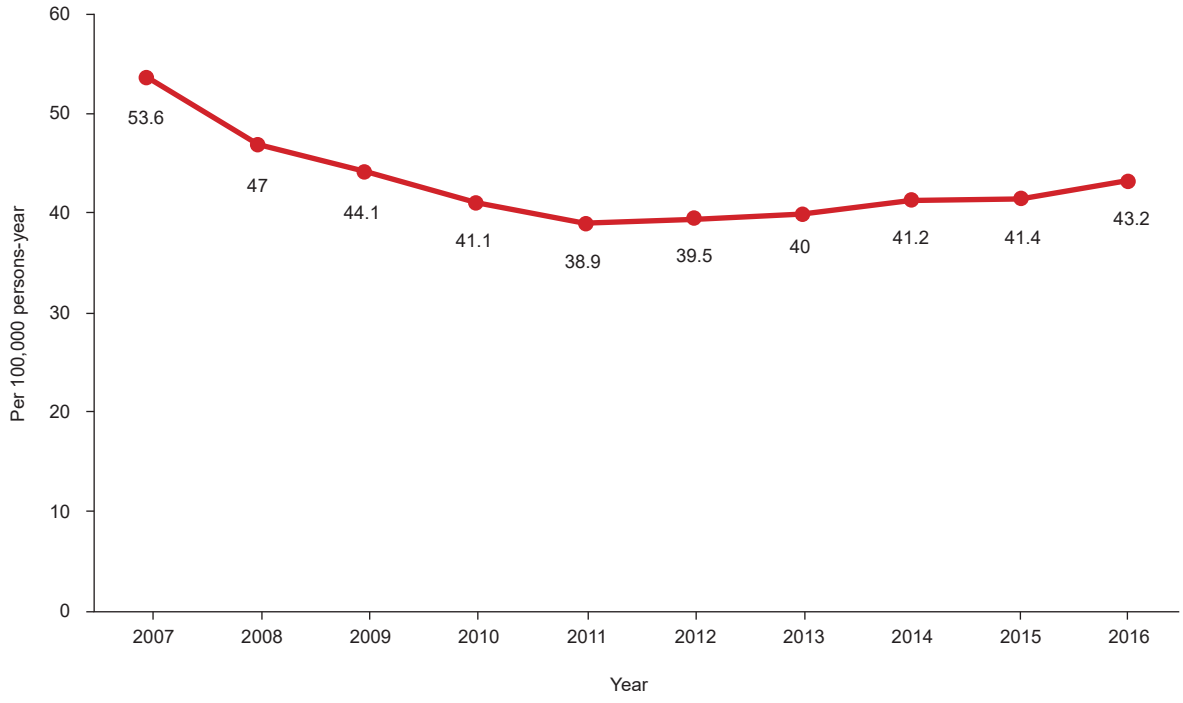

Fig. 1. Age-standardized incidence of hospitalization for acute myocardial infarction in Korea between 2007 and 2016. Adapted from the article of Kim et al. J Korean Med Sci 2019;34:e322 [12].

ciated with a rise in the 2010s. This recent surge in heart failure mortality in Korea can be primarily attributed to several factors, including an aging population, an increase in CVD survivors, and an improved rate of heart failure diagnoses (Fig. 2) [2,14].

In 2020, there were 9,927 deaths attributed to AMI. The crude mortality rate escalated with age, peaking at 19.3 per 100,000 population (21.8 for males and 16.8 for females). This rate dramatically increased to 260.7 per 100,000 population for individuals aged 80 or older. Importantly, the mortality rate was consistently higher in males across all age groups (Fig. 3) [13,15].

A study analyzing data from the National Health Insurance Service and the National Statistical Office revealed that in 2016, the hospitalization mortality rate (death within 7 days of hospitalization) for AMI patients in Korea who were hospitalized for more than one day was 2.8%. The mortality rates at 30 days, 90 days, 1 year, and 3 years were 6.2%, 8.8%, 13.1%, and 19.7%, respectively. It is notable that inpatient mortality decreased across all these time frames (30 days, 90 days, and 1 year) [13].

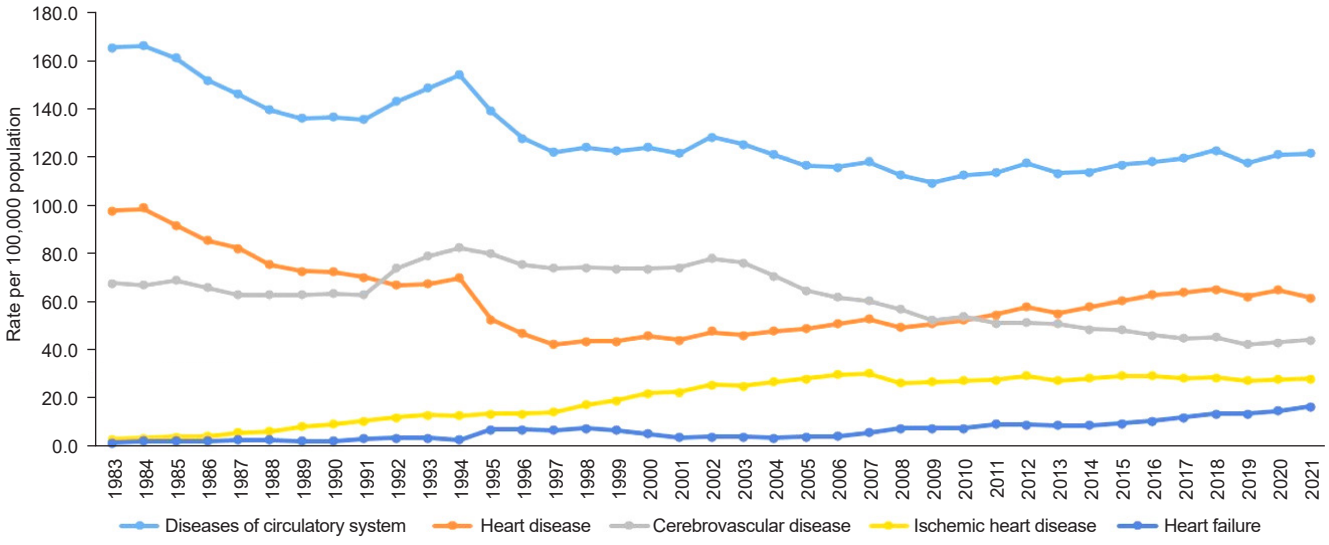

Fig. 2. Crude mortality of cardiovascular disease in Korea, 1983–2021. Adapted from Statistics Korea [14].

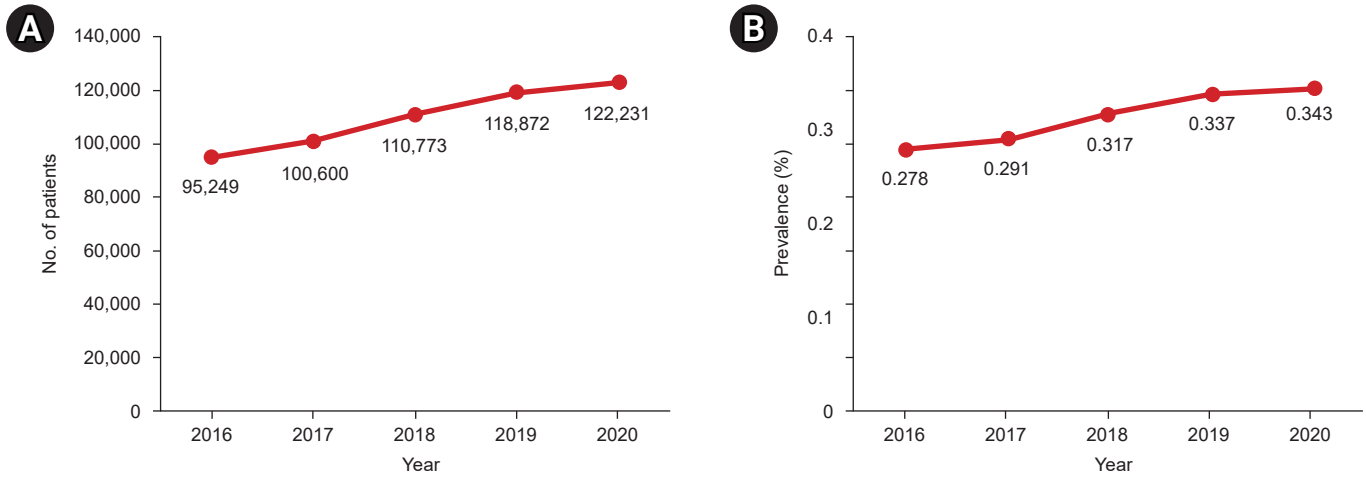

Fig. 3. Number of myocardial infarction patients (A) and prevalence of myocardial infarction (B) in Korea by year from 2016 to 2020. Adapted from the article of Kim et al. Epidemiol Health 2022;44:e2022057 [13].

CARDIAC REHABILITATION IN KOREA

CR is a multidisciplinary, team-based approach that involves both medical and non-medical professionals. This program is designed to deliver comprehensive, personalized care to patients with CVD. The level of evidence (LOE) is 1++. Typically, the program spans 6–12 weeks and is divided into three phases: inpatient, outpatient, and maintenance. The inpatient phase commences during hospitalization, with a focus on early patient mobilization and complication prevention. The outpatient phase encompasses exercise training, risk factor management, and psychosocial support. The maintenance phase is a lifelong commitment, aiming to sustain the benefits gained during the program and prevent future cardiovascular events. Exercise training is a crucial element of the CR program because exercise enhances cardiopulmonary function, provides symptom relief, and reduces mortality rates in patients with CVD. The exercise regimen usually includes aerobic and resistance training, tailored to individual needs and abilities (LOE: 2++). Risk factor management, including smoking cessation, blood pressure control, and lipid profile management, are also integral parts of the program (LOE: 1++) [6,16,17]. CR is utilized in various countries worldwide, with Western countries in particular having clinical practice guidelines for CR.

Each country organizes and applies these clinical practice guidelines for CR according to their specific circumstances [6,18].

Clinical practice guidelines for CR in Korea

In 2019, Korea established clinical practice guidelines for CR. The guidelines contain four main sections: Introduction, Assessments, Exercise Therapy, and Education for Secondary Prevention.

In the Introduction, the guidelines state that CR programs should be an integral component of the treatment approach for individuals recovering from acute coronary syndrome. The initiation of CR exercises should occur promptly following the acute phase of treatment. Additionally, these CR programs should adopt a holistic and interdisciplinary approach to address various aspects of patient recovery and well-being.

In the Assessments section, the guidelines state that customized CR plans should be meticulously crafted to align with each patient's specific needs. These individualized plans should be based on comprehensive personal assessments of patients who have been referred to CR, including checking for psychological problems. Furthermore, cardiopulmonary exercise testing, which assesses patients' cardiopulmonary exercise function, is essential for accurately prescribing exercises and predicting outcomes. If implementing a symptom-limited exercise test is challenging, it is advisable to consider using a submaximal exercise test, such as the 6-minute walk test, as an alternative approach.

In the Exercise Therapy section, the guidelines state that CR exercise programs should incorporate aerobic exercise as a fundamental component (or, for better results, high-intensity interval training), as well as resistance (strengthening) exercises. For patient safety during CR exercises, appropriate monitoring should be carried out based on the risk assessment results. Home-based CR programs can be a viable alternative to hospital-based CR programs, especially for low-risk patients. Additionally, it is essential to expand CR programs to include patients aged 65 years or older, as they can benefit significantly from these interventions to improve their cardiovascular health and overall well-being.

In the Education for Secondary Prevention section, the guidelines indicate that a smoking cessation program should be provided. Continuous programs of at least 4 weeks should be considered, and diet programs should also be designed. Food supplements are generally not recommended as a primary or sole strategy for secondary prevention of CVD [7].

Regional cardiocerebrovascular centers in Korea

CR is being implemented through collaboration with the 14 regional cardiocerebrovascular centers (RCCs) in Korea. The locations are as follows: one each in Gyeonggi, Incheon, Gangwon, Daejeon-Chungnam, Chungbuk, Jeonbuk, Busan, Gyeongnam, Ulsan, and Jeju and two each in Gwangju-Jeonnam and Daegu-Gyeongbuk.

RCCs were established to reduce the mortality and morbidity caused by cardiocerebrovascular disease (CCVD) through systematic and efficient operations throughout the entire CCVD cycle, including prevention, early diagnosis, emergency treatment, education, rehabilitation, and management. RCCs actively engage in efforts to narrow healthcare gaps across regions, and their CR programs are expected to serve as examples for post-acute CVD management in Korea.

There are 164 hospitals in Korea that perform percutaneous coronary artery intervention, which include the RCCs (103 are hospitals certified by the Korean Society of Interventional Cardiology). Of these 164 hospitals, 47 (29%) have CR programs (Table 1).

Research on Korean RCCs has indicated that 12 have the equipment, facilities, and medical personnel necessary for CR assessments (two RCCs were excluded from the study due to their short operational period). In addition, patient referral and education are performed relatively well at RCCs, as indicated by the CR referral rate (97%) and the patient education rate (78%). However, the inpatient CR exercise-training participation rate is about 56% and the enrollment rate is 47%, which are lower than the referral rate and the patient education rate. Notably, the outpatient CR program compliance rate is even lower, at around 17% [19,20]. The participation rate refers to the percentage of patients who have undertaken an exercise program for CR. The enrollment rate denotes an outpatient visit for CR following discharge. Finally, adherence refers to the completion of a CR program, which typically lasts between 6 to 12 weeks.

Effectiveness of CR in Korea

As previously noted, CR has numerous beneficial effects. It not only reduces mortality and re-hospitalization rates, but also prevents the recurrence of cardiovascular events and enhances health-related quality of life [6]. The efficacy of CR has been proven by various studies conducted in Korea.

The Eleven Tertiary Hospitals In Korea (ETHIK) study revealed that the 5-year survival rates for participants in CR and non-participants were 96.9% and 93.3%, respectively. The risk ratio for the total 5-year mortality rate among CR participants was approximately 0.41 times that of non-participants. Furthermore, the 5-year survival rate for patients who had suffered an AMI and participated in CR was 59% higher than for those who did not participate [10].

Other reviews have found that the group participating in CR experienced a 28% lower overall mortality rate compared to the group receiving conventional treatment. Additionally, the CR group had lower rates of recurrence and major adverse cardiovascular events compared to the non-CR group. The number of re-hospitalizations was also fewer in the CR group [8]. In Korea, the recovery of cardiopulmonary functions and the improvement of health-related quality of life due to CR have been substantiated. Cardiopulmonary function significantly increased during the initial 12 weeks of CR, and this improvement was sustained for nearly a year [9,18].

Table 1. Regional distribution of RCCs and hospitals performing PCI and CR in Korea

Region[a]	RCC	PCI hospital[b]	CR hospital[c]	Ratio (%)
Seoul	0	31	13	42
Gyeonggi	1	33	9	27
Incheon	1	9	3	33
Gangwon	1	5	2	40
Daejeon-Chungnam	1	12	1	8
Chungbuk	1	6	1	17
Gwangju-Jeonnam	2[d]	11	2	18
Jeonbuk	1	5	1	20
Busan	1	17	4	24
Gyeongnam	1	11	3	27
Ulsan	1	5	1	20
Daegu-Gyeongbuk	2[e]	15	6	40
Jeju	1	4	1	25
Total	14	164	47	29

Adapted from the article of Kim et al. J Clin Med 2021;10:5079 [19].
RCC, regional cardiocerebrovascular center; PCI, percutaneous coronary intervention; CR, cardiac rehabilitation.
[a]Province or metropolitan area.
[b]Hospitals that perform PCI.
[c]Hospitals with CR programs in the region.
[d]An RCC was established in the Jeonnam region in 2020 but was not included in the 2021 study.
[e]An RCC was established in the Gyeongbuk region in 2020 but was not included in the 2021 study.

UNDERUTILIZATION OF AND BARRIERS TO CARDIAC REHABILITATION

Despite the benefits of CR, its implementation faces several challenges in Korea. CR is strongly recommended, but the actual global CR participation rate is only about 30%–40% [17], and countries are striving to boost participation rates. In contrast, the participation rate in Korea is merely 1.5%, which is significantly lower than in many other countries [21].

There are various reasons for the low participation in CR in Korea. Numerous studies have been conducted to identify the causes, which primarily relate to patient-related factors, hospital-related factors, and factors related to governmental health policies in CR.

Patient factors that reduce participation in CR often include logistical issues or comorbidities/functional statuses. Groups that particularly exhibit low participation rates include the elderly, females, and rural residents. The reduced participation rate among elderly patients can be attributed to mobility challenges related to comorbidities, as well as transportation limitations. The lesser involvement of women in CR programs may be due to their greater family responsibilities and a lack of free time. Furthermore, the self-reliant attitudes common in rural areas, combined with limited access to medical facilities,

may lead to lower CR participation among rural residents. The inability of patients to accurately recognize the need for and the importance of CR, along with issues of accessibility, cost, and time constraints, also contribute to the low CR participation rate [21-24]. Factors within hospitals that contribute to reduced participation in CR include limited access to CR services, with only a small fraction of patients participating in CR. This is often due to a lack of physician referrals, as many physicians either lack awareness of the benefits of CR or do not prioritize it within their treatment plans [22,23]. A 2020 study revealed that out of 164 hospitals in Korea performing percutaneous coronary interventions, only 47 hospitals (29%) had implemented CR programs, despite being certified by the Korean Society of Interventional Cardiology [20].

There is a lack of public awareness and education about the benefits of CR because many patients and their families are not aware of the program or do not understand its purpose. Therefore, it is important to raise public awareness and provide education about the benefits of CR, as well as its potential to improve patient outcomes. Home-based CR enables patients to continue receiving CR after their cardiopulmonary function has been evaluated in hospitals. However, this approach also leads to underutilization [22,24,25].

Governmental health policy factors also contribute to low CR participation. In Korea, the National Health Insurance Service began providing insurance coverage for CR in February 2017. A survey study aimed at promoting CR participation revealed that healthcare providers underscore the importance of government-provided patient incentives. They perceive the government as playing a pivotal role in ensuring both the time and the right for patients to participate in CR [24]. There is also a shortage of hospitals that offer CR, indicating a need for government attention and effort to introduce community-based programs that can be managed on an ongoing basis [25].

We propose several strategies to address these barriers. To counter low participation rates due to a lack of understanding

Table 2. Barriers and ways to overcome the underutilization of cardiac rehabilitation

Barriers		Ways to overcomes
Patient factors		
Referral	Lack of awareness of CR	Active suggestions from medical staff
		Provide education about the need for CR
Enrollment	Cost burden	Community- or home-based CR
		Incentive system
	Psychosocial problems	Medical intervention
		Motivation interviewing
Adherence	Accessibility issues	Community- or home-based CR
	Lack of time	Greater autonomy in participation
		Patient-customized CR
	Restriction of participation in elderly and female patients	Patient-customized CR
		Education about the need for CR
		Increase family support
Hospital factors		
Referral	Lack of referrals	Automatic inpatient CR referral system
Enrollment	Lack of awareness of CR	Education of medical staff about the need for CR
		Regular assessment of CR quality
Adherence	Lack of various CR programs	Community- or home-based CR
		Patient-customized CR
Governmental health policy factors		
Referral	Socio-cultural factors	Campaigns and research for the promotion of CR
Enrollment	Cost burden	Strengthening health insurance coverage
Adherence	Accessibility issues	Support for hospitals providing CR
		More hospitals and networking to open CR programs
		Community- or home-based CR
		Improved system for patient transport

CR, cardiac rehabilitation.

about the importance or effectiveness of CR, we recommend promoting education about CR to both patients and healthcare providers. Active recommendations from medical staff, comprehensive education on the need for CR, motivational interviewing, and increased autonomy for participation (e.g., scheduling appointments, setting time schedules, and choosing locations) can all contribute to increased participation in CR. Improvements to the insurance system are also necessary to facilitate the active introduction of CR. Hospitals could offer a range of incentives or implement patient-customized CR programs. Another potential solution is the introduction of an automatic referral system or the strengthening of connections with community-based or home-based CR programs. These programs could be offered to patients who are unable to participate due to travel constraints, and the provision of transportation could be considered. To alleviate the cost burden, expanding insurance coverage could be beneficial. Additionally, various campaigns, studies, and research projects will be necessary to raise awareness about CR and underscore its importance at the government level (Table 2) [21-25].

CONCLUSION

While the mortality rate from CVD has declined in Korea, the overall burden of CVD continues to rise. This increase is primarily attributed to the rapidly aging population and the growing number of individuals diagnosed with CVD, a trend that is expected to continue. CR is being implemented in Korea for CVD patients, offering numerous benefits such as improved cardiopulmonary functions and reduced risks of re-hospitalization and mortality. Additionally, RCCs are striving to bridge the regional disparities in CR access (Table 3). However, compared to other countries, the participation rate in Korea remains relatively low. The implementation of CR continues to face numerous obstacles, including a lack of awareness, system participation, and medical costs. In this review, we provide an overview of CR in Korea, a resource that healthcare professionals and policymakers can use to strategize for CR implementation.

Table 3. Cardiac rehabilitation candidates, capacities, and densities for AMI in 12 RCCs

RCC	AMI admission[a)]	CR candidates[b)]	CR capacity[c)]	CR density[d)]
A	245	87	70	1.24
B	722	589	120	4.91
C	471	368	50	7.36
D	587	473	100	4.73
E	481	487	400	1.22
F	163	150	200	0.75
G	401	340	220	1.55
H	282	210	500	0.42
I	1,170	885	300	2.95
J	145	131	50	2.62
K	362	239	240	0.99
L	271	203	300	0.80
Total	5,300	4,162	2,550	1.77

AMI, acute myocardial infarction; RCC, regional cardiocerebrovascular center; CR, cardiac rehabilitation.
[a)]Annual number of AMI admissions for each RCC.
[b)]Annual number of CR candidates among AMI admissions at each RCC.
[c)]Median number of patients each RCC can serve per year.
[d)]CR candidates divided by CR capacity for each RCC.

CONFLICTS OF INTEREST

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ORCID

Ki-Hong Kim, https://orcid.org/0000-0003-0827-6813
Jae-Young Han, https://orcid.org/0000-0003-1672-8875

REFERENCES

1. Bergmark BA, Mathenge N, Merlini PA, Lawrence-Wright MB, Giugliano RP. Acute coronary syndromes. Lancet 2022;399:1347-58.
2. Kim HC. Epidemiology of cardiovascular disease and its risk factors in Korea. Glob Health Med 2021;3:134-41.
3. Townsend N, Kazakiewicz D, Lucy Wright F, Timmis A, Huculeci R,

Torbica A, et al. Epidemiology of cardiovascular disease in Europe. Nat Rev Cardiol 2022;19:133-43.
4. Duggan JP, Peters AS, Trachiotis GD, Antevil JL. Epidemiology of coronary artery disease. Surg Clin North Am 2022;102:499-516.
5. Ralapanawa U, Sivakanesan R. Epidemiology and the magnitude of coronary artery disease and acute coronary syndrome: a narrative review. J Epidemiol Glob Health 2021;11:169-77.
6. Taylor RS, Dalal HM, McDonagh STJ. The role of cardiac rehabilitation in improving cardiovascular outcomes. Nat Rev Cardiol 2022;19:180-94.
7. Kim C, Sung J, Lee JH, Kim WS, Lee GJ, Jee S, et al. Clinical practice guideline for cardiac rehabilitation in Korea. Ann Rehabil Med 2019;43:355-443.
8. Kim C, Choi I, Cho S, Kim AR, Kim W, Jee S. Do cardiac rehabilitation affect clinical prognoses such as recurrence, readmission, revascularization, and mortality after AMI?: systematic review and meta-analysis. Ann Rehabil Med 2021;45:57-70. Erratum in: Ann Rehabil Med 2021;45:165.
9. Kim C, Choi HE, Jang JH, Song JH, Kim BO. Do patients maintain proper long-term cardiopulmonary fitness levels after cardiac rehabilitation? A retrospective study using medical records. Ann Rehabil Med 2021;45:150-9.
10. Kim C, Choi I, Cho S, Han JY, Kim AR, Kim WS, et al. Cardiac rehabilitation and 5-year mortality after acute myocardial infarction. Report from 11 tertiary hospitals in Korea (ETHIK Study). Eur J Phys Rehabil Med 2020;56:489-95.
11. Park MS, Lee S, Ahn T, Kim D, Jung MH, Choi JH, et al. Current status of cardiac rehabilitation among representative hospitals treating acute myocardial infarction in South Korea. PLoS One 2021;16:e0261072.
12. Kim RB, Kim HS, Kang DR, Choi JY, Choi NC, Hwang S, et al. The trend in incidence and case-fatality of hospitalized acute myocardial infarction patients in Korea, 2007 to 2016. J Korean Med Sci 2019;34:e322.
13. Kim RB, Kim JR, Hwang JY. Epidemiology of myocardial infarction in Korea: hospitalization incidence, prevalence, and mortality. Epidemiol Health 2022;44:e2022057.
14. Statistics Korea. Annual report on the causes of death statistics, 2022 [Internet]. Statistics Korea; 2022 [cited 2023 Mar 21]. Available from: https://kosis.kr/statisticsList/statisticsListIndex.do?menuId=M_01_01&vwcd=MT_ZTITLE&parmTabId=M_01_01&statId=1999038#content-group
15. Kim Y, Ahn Y, Cho MC, Kim CJ, Kim YJ, Jeong MH. Current status of acute myocardial infarction in Korea. Korean J Intern Med 2019;34:1-10.
16. Simon M, Korn K, Cho L, Blackburn GG, Raymond C. Cardiac rehabilitation: a class 1 recommendation. Cleve Clin J Med 2018;85:551-8.
17. Epstein E, Maisel S, Maysent K, Taub PR. Cardiac rehabilitation for coronary artery disease: latest updates. Curr Opin Cardiol 2021;36:556-64.
18. Kweon S, Sohn MK, Jeong JO, Kim S, Jeon H, Lee H, et al. Quality of life and awareness of cardiac rehabilitation program in people with cardiovascular diseases. Ann Rehabil Med 2017;41:248-56.
19. Kim C, Sung J, Han JY, Jee S, Lee JW, Lee JH, et al. Current status of cardiac rehabilitation in the Regional Cardiocerebrovascular Centers in Korea. J Clin Med 2021;10:5079.
20. Baek S, Ha Y, Mok J, Park HW, Son HR, Jin MS. Community-based cardiac rehabilitation conducted in a public health center in South Korea: a preliminary study. Ann Rehabil Med 2020;44:481-92.
21. Kim SH, Ro JS, Kim Y, Leigh JH, Kim WS. Underutilization of hospital-based cardiac rehabilitation after acute myocardial infarction in Korea. J Korean Med Sci 2020;35:e262.
22. Kim C, Sung J, Han JY, Jee S, Lee JW, Lee JH, et al. A comparison of barrier factors between hospitals with and without cardiac rehabilitation programs in Korea: a nation-wide survey research. J Clin Med 2022;11:2560.
23. Im HW, Baek S, Jee S, Ahn JM, Park MW, Kim WS. Barriers to outpatient hospital-based cardiac rehabilitation in Korean patients with acute coronary syndrome. Ann Rehabil Med 2018;42:154-65. Erratum in: Ann Rehabil Med 2019;43:119.
24. Kim C, Kwak HB, Sung J, Han JY, Lee JW, Lee JH, et al. A survey of the perceptions of barriers to and facilitators of cardiac rehabilitation in healthcare providers and policy stakeholders. BMC Health Serv Res 2022;22:999.
25. Kim C, Sung J, Han JY, Jee S, Lee JW, Lee JH, et al. Evaluation of current resources available for community-based cardiac rehabilitation in Korea: a nationwide survey study. J Korean Med Sci 2022;37:e109.

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Post-Stroke Spastic Movement Disorder and Botulinum Toxin A Therapy: Early Detection And Early Injection

Jörg Wissel, MD, FRCP[1,2], Anatol Kivi, MD[1,2]

[1]*Department of Neurology, Neurorehabilitation Unit, Vivantes Klinikum Spandau, Berlin, Germany*
[2]*Neurology at Wittenbergplatz, Berlin, Germany*

Post-stroke spastic movement disorder (PS-SMD) develops in up to 40% of stroke survivors after a first ever stroke within the first year. Chronic PS-SMD is often associated with severe disabilities and complications, emphasizing the importance of its early recognition and early adequate management. Extensive research has aimed to accurately predict and sensitively detect a PS-SMD. Symptomatic therapies include conventional rehabilitation and local intramuscular injections of botulinum toxin A (BoNT-A). The latter is widely used, but primarily in the chronic phase of stroke. However, recent studies have shown the safety and efficacy of BoNT-A therapy even in the acute phase and early sub-acute phase after stroke, i.e., within three months post-stroke, leading to an improved long-term outcome in stroke rehabilitation. Local BoNT-A injections evolve as the primary approach in focal, multifocal, and segmental chronic or acute/subacute PS-SMD. Patients at high risk for or manifest PS-SMD should be identified by an early spasticity risk assessment. By doing so, PS-SMD can be integral part of the patient-centered goal-setting process of a multiprofessional spasticity-experienced team. The benefit of an early PS-SMD treatment by BoNT-A should predominate putative degenerative muscle changes due to long-term BoNT-A therapy by far. This, as early treatment effectively avoids complications typically associated with a PS-SMD, i.e., contractures, pain, skin lesions. The management of PS-SMD requires a comprehensive and multidisciplinary approach. Early assessment, patient-centered goal setting, early intervention, and early use of BoNT-A therapy prevents from PS-SMD complications and may improve rehabilitation outcome after stroke.

Keywords: Spastic, Movement disorder, Botulinum toxin, Stroke, Rehabilitation

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Correspondence:
Anatol Kivi
Department of Neurology, Neurorehabilitation Unit, Vivantes Klinikum Spandau, Neue Bergstraße 6, Berlin 13585, Germany.
Tel: +49-30-130132312
Fax: +49-30-130132934
E-mail: anatol.kivi@vivantes.de

INTRODUCTION

Post-stroke spasticity (PSS) and post-stroke spastic movement disorder (PS-SMD) are common conditions following stroke that include damage of the sensori-motor networks in the central nervous system (CNS) [1]. PSS is characterized by involuntary activation of skeletal muscles resulting in phasic and/or tonic muscle activity during rest and voluntary movement resulting in the PS-SMD in involved body-parts [2]. PSS is the result of the so-called positive signs of the upper motor neuron syndrome (UMNS). These positive signs of the UMNS are (a) spontaneous or triggered (stretch- or touch-induced) clonus activity or spasms during rest or movement; (b) spontaneous antagonistic co-activation during rest called spastic dystonia; (c)

involuntary spastic co-contraction of the antagonist while voluntary activation of the agonist; (d) velocity-dependent increase in muscle tone during rest; (e) increased tendon reflexes; and (f) Babinski sign and other pathological reflexes during rest or triggered by touch or movement [2,3].

Most of the prevalent data of PSS originates from studies that only used the criterion of velocity-dependent increase in muscle tone as a clinical marker of PSS [1,2]. This prevalence is high in the first year after first ever stroke, affecting up to 43% of stroke survivors [1,2,4]. PSS, resulting PS-SMD and complications can be a major contributor to stroke-related disability, low quality of life, and reduced social and professional participation [2]. PSS or PS-SMD that is perceived by the affected individual or care giver as hindering body functions, activities, and/or participation is defined as disabling PSS or disabling PS-SMD [2,4]. Published prevalent data of a severe spasticity (defined as increased muscle tone equal or more than 2 of the modified Ashworth scale [MAS]) and a disabling PSS (defined as spasticity that does need treatment) showed that up to 13%–16% of stroke survivors suffer from this complication after stroke [2,4,5].

The symptom velocity-dependent increase in muscle tone, characterized by resistance to passive stretch of the affected skeletal muscles, is still the key qualitative symptom that leads to the diagnosis and allows to characterize the topical distribution of the PSS over the body regions [2]. The documentation of the muscle tone with the Ashworth scale (AS), MAS, or Tardieu scale (TS) as a clinical quantification of the PSS is well established in most of the interventional and pivotal studies [2]. For a state-of-the-art-documentation and a precise communication of the topical distribution of the PSS the classification of the distribution as focal, multi-focal, segmental, multi-segmental, or generalized PSS is recommended [3,6,7]. For a standardized calculation of the severity of e.g., hemispasticity, para-, or tetraspasticity for calculation of sum scores the REsistance to PAssive Stretch scale (REPAS) with defined test positions and set of well standardized passive stretchings using the AS is recommended [8].

PS-SMD is associated with negative features of the UMNS namely muscle weakness, fatigue and fatigability creating dexterity problems with slowing and less forceful or even no voluntary movements in the affected body region. Therefore, the term spastic paresis (SP) is also used to describe the clinical picture on an impairment level in PS-SMD since it combines PSS (involuntary muscle activity) with muscle weakness, which are commonly present in the UMNS [2,9].

The UMNS with a PS-SMD consists of neuronal changes and progressive muscle and soft tissue changes. These changes shorten the involved structures and lead to a progressively reduced range of motion (ROM). This aspect of the UMNS is called the non-neuronal component, which led to the establishment of the term deforming spastic paresis (DSP). In the 2005 definition of Pandyan et al. [9], this non-neuronal component and the negative sign paresis of the UMNS are not part of the SPASM definion of spasticity.

Another severe complication resulting from a PS-SMD is the syndrome of spasticity-associated pain, which could be diagnosed by eliciting stretch-induced nociceptive pain in spastic muscles in affected body regions [2,10]. The pathophysiology is not totally understood, but the hypothesis is that it correlates with the quantity of some positive features of the UMNS (especially spastic dystonia) and also with malpositioning, sensory loss, and neglect syndrome that affect the involved limbs. Large randomized controlled trials (RCTs), cohort studies, and pooled data analysis of stroke survivors in the chronic phase showed that up to 64% of patients with PS-SMD had pain in the paretic limbs to some degree [10]. Both, randomized controlled studies and pooled RCTs [10] demonstrated a significant reduction of spasticity-associated pain if muscles are treated with botulinum toxin A (BoNT-A). This applies for all a focal, multi-focal, and segmental BoNT treatment regimens.

Currently, there is still no causal treatment for PSS and the resulting PS-SMD. However, various symptomatic therapeutic approaches have been introduced and discussed for managing PS-SMD [2]. In this article we provide information concerning the pathophysiology of PSS and its prediction, as well as the clinical assessment, management strategy including goal setting and multimodal treatment options with a focus on evidence-based methods and BoNT-A treatment.

PATHOPHYSIOLOGY OF PS-SMD

For the first time, an international group of specialists in neurology, neurorehabilitation, and restaurative neurology defined the different relevant pathophysiological phases following first-ever stroke [11]. According to the panel, there are four main phases after acute ischemic or hemorrhagic lesion of the cortical and subcortical brain tissue. These phases show specific histopathological and/or pathophysiological correlates: The *Hyperacute Phase* (within the first hours to 24 hours), the *Acute Phase* (first day to a week), the *Subacute Phase* (after first

week, up to 6 months), and the *Chronic Phase* (after 6 months) [1,11,12].

In the hyperacute and acute phase necrosis of the brain tissue happens with local inflammatory and secondary neuro-degenerative processes at and around the lesion site. In the first hours after stroke cortical and subcortical sensori-motor networks structures show acute loss of function in involved movement segments on the contralateral body side with acute flaccid paralysis and/or sensory loss. In this phase the limb is dependent on passive positioning, as there is a high chance of no voluntary control of the position of the limb. The loss of sensation results therefore in a high risk of secondary damage due to malpositioning [11-13].

With a latency of days to weeks neuroplasticity starts with re-connection of residual neurons and rewiring of new connetions of the lesioned area to new neuron pools in the sensori-motor network nearby. These complex and often overlapping processes happen with variable latency (days to weeks) in the late acute and ealy post-acute phase [11,12]. From epidemiological studies of large cohorts of stroke survivors, it is known that about 20% develop a SP [1]. The emerging regain of movements to a certain extent is paralleled by involuntary muscle activity, that is defined as spasticity [9,14]. In other words, the start of regaining of some voluntary muscle force and sensation could be concurrent altered by involuntary muscle activity, which is defined as spasticity or positive signs in the context of an UMNS [9,13,14].

The involved neuronal mechanisms resulting in an increased excitability of the sensori-motor spinal networks and promoting involuntary muscle activity are due to an imbalanced descending regulation of the spinal sensori-motor network. There is an imbalance between descending inhibitory dorsal reticulospinal tract (RST) and the excitatory medial RST and vestibulospinal tract and/or abnormal intraspinal processing of sensory input (enhanced sensitivity of Ia and IIa afferents, and reduced presynaptic inhibition on Ia-afferents, as well as facilitation of group Ib and II afferents) [13,15-17].

Additionally, there is also evidence of a shift of the chloride equilibrium potential in spinal cord motoneurons due to an altered function of the chloride extrusion mechanisms (KCC2) resulting in excitatory effects of GABA and glycine on motoneurons [18].

In this stage the affected limb develops to some extent the so-called spastic movement pattern that shows typical dysbalanced movements, joint positions with slowing in its performance compared to physiological movements on the less affected body side. By definition, if involuntary muscle activation is included in those typical movement patterns in a central paresis, this syndrome represents a PS-SMD [12].

Whether regaining of any sensori-motor function ends with either a residual loss of function or a regaining of most of the functions in the upper and lower limb in the late post-acute or in the chronic phase seems to be dependent of various factors. For sure, the lesion size in the sensori-motor cortical and subcortical network is important for both regaining any function [19] and for the development of spasticity/PSS [20,21]. The following clinical signs represent negative predictors for a good outcome and an high risk for the development of a severe PS-SMD: severe sensory loss, neglect or other relevant neuropsychological changes, paralysis or severe paresis without development of functional relevant muscle force (MRC below 3), severe PSS in multiple joints and adaptation to a severe PSS (MAS= or >than 2), development of a DSP with contractures and spasticity-associated pain [2]. The progressive so-called non-neuronal changes of muscles and soft tissue in the late post-acute and chronic phase (DSP) may lead to further functional impairments with progressive joint contractures, spasticity-associated pain and skin irritation or even skin lesions [22,23].

In summary, the *Acute and Early Subacute Phase* (first weeks to 3 months) is characterised by the start of reorganisation of the sensori-motor network. In this phase SP develops and involuntary muscle activity add the risk from paresis and may result in the development of complications from PS-SMD with development of contractures, spasticity-associated pain and DSP [1]. In the *Late Subacute Phase* (3–6 months) in most cases the development of PS-SMD is established and the sensori-motor system shows signs of (mal-) adaptation to involuntary muscle activity in up to 42% of stroke survivors [1]. In 13% this led to a syndrome of disabling PS-SMD [2,4]. Later on, in the *Chronic Phase* an established PS-SMD may further worsen with progressive immobility, joint contractures, stretch-sensitive spasticity-associated pain, and abnormal movement patterns [4,12].

The knowledge of the pathophysiology of the PS-SMD and its different time phases following a first-ever stroke is crucial for appropriate management strategies of an underlying UMNS with high risk of the development of a DSP [3,11,12,22]. However, the interconnection between the various facets of the neuronal and non-neuronal mechanisms of PS-SMD with involuntary muscle activity, defined as spasticity by the SPASM-group [9], on the one hand, and progressive muscle degeneration

(loss of myofibrills) and muscle and soft tissue shortening and stiffening are not yet fully understood [22-24]. The time scales of mechanisms of degeneration and reorganization parallels to some extent the time scale of neuroplasticity of the sensori-motor nervous system and peripheral tissues in the subacute phase [17,23].

Several cohort studies could show that changes in muscles and peripheral soft tissue (changes in tissue matrix, storing of collagen, degeneration of muscle fibres) starts already within a few weeks after first ever stroke [11,12]. Unfortunately, it is not fully understood yet, whether there are specific risk or trigger factors causing those tissue changes or whether it is the natural course after a first ever stroke.

Because there is currently no causal treatment for PS-SMD and it seems to develop in the *Acute and Early Subacute Phase* following stroke, it is crucial to catch the symptoms early and identify potential predictors of a PS-SMD to promptly initiate an appropriate management consisting of both physical and medical treatment [2]. Given the high prevalence of stroke as well as of a disabling PS-SMD, it has been strongly recommended for any initiating efforts to detect and treat early symptoms of PS-SMD as early as possible [2,12]. This is to achieve effective symptomatic management and avoid complications and maladaption to PSS.

Early PSS detection and management may imply a better chance for a better outcome of patients, who passed a comprehensive person-centered neurological rehabilitation program following stroke. Timely and appropriate physical management and medical treatment, including BoNT-A treatment, seems to be crucial to prevent further disability from PSS to DSP in the context of a PS-SMD and may improve the outcome for individuals suffering from PS-SMD [2].

MANAGEMENT OF PS-SMD

The prediction of PS-SMD and goal setting

The PS-SMD typically emerges between days and three months after the first-ever stroke. The prevalence of a PS-SMD increases with time and reaches a plateau at about three months after the stroke (Fig. 1) [1,2].

Chronic PS-SMD is considered as a phenomenon of post-stroke maladaptation, associated with neuronal re-organization within the CNS during a critical period of three to six months after stroke [17]. This three to six-month period is characterized by complex processes involving immunologic responses that aim to limit the damage caused by stroke but can also lead to further damage to the affected tissue [2,17]. The window of neuroplastic re-organization might increasingly narrow over six months indicating the importance of early detection and intervention to avoid hardly reversible maladaptation to PS-SMD [1,2].

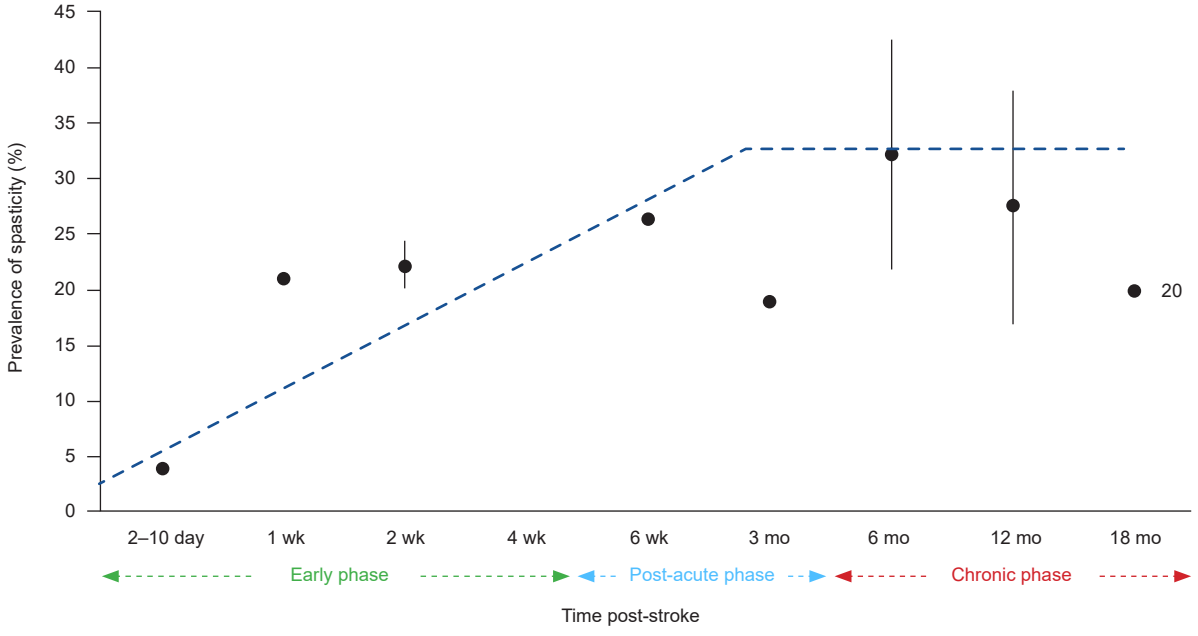

Fig. 1. Prevalence of post-stroke spasticity.

Prediction of PS-SMD

Many studies have identified clinical and brain-imaging data as predictors for early detection of patients at high risk of developing disabling PS-SMD (Table 1) [25-35].

Based on published predictors of PS-SMD a group of experts in the field published "The PSS Risk Classification System" to allow for prediction and identifying patients at risk to develop a PS-SMD within the acute and post-acute phases following a stroke [35,36]. This tool focuses on early identification of clinical and imaging risk factors and provides recommendations for managing PS-SMD.

Recent publications have identified additional red flags for predicting a PS-SMD. This includes high scores on the modified Ranking scale (mRS), the National Institute of Health Stroke Scale (NIHSS), and lower than 27 scores for mini-mental status examination (MMSE) within the first week after first ever stroke [37].

In addition to these clinical predictors, specific brain lesion localizations and volume were found to predict a PS-SMD, too. Lesions involving the basal ganglia, thalamus, insula, and white matter tracts (such as the internal capsule, corona radiata, external capsule, and superior longitudinal fasciculus) on cerebral magnetic resonance imaging scans taken in the first week after stroke have a high predictive value for PS-SMD when the lesion load affects the cortico-spinal tract. Larger lesion sizes in these areas also increase the risk for developing a PS-SMD [2,20,21].

Goal setting and attainment

Before starting with a rehabilitation program, a systematic examination of the patient with spastic movement disorder is necessary to identify the relevant problems on the levels of impairment, activities, and participation of the individual patient. This examination should include a detailed case history of the stroke with a detailed description of the evolution of the spastic movement disorder. If relevant, also other medical issues should be evaluated. This should be followed by a comprehensive neurological examination by the physician as well as a clinical evaluation by the members of the multiprofessional therapeutic team, specialized in the management of spastic movement disorder [2].

On the basis of this thorough evaluation realistic short- and long-term goals for the comprehensive person-centered rehabilitation program have to be established, always in collaboration with the patient/caregiver and members of the multiprofessional team (MPT). An expert physician in neurorehabilitation, specialized in the management of spastic movement disorder, should guide this important discussion on goals for the rehabilitation program. Patient-centered goal setting, aligned with the International Classification of Functioning, Disability and Health, can help to manage activity limitations or functional impairments [2,38].

Collaboration among patients, caregivers, clinicians, and the MPT is essential to define desired treatment outcomes for BoNT-A injections in a multimodal treatment program. The SMARTER matrix, which stands for Specific, Measurable, Agreed, Realistic, Time-bound, Evaluated, and Revised goals, can help in developing realistic individual goals. After agreement of realistic goals, the team formulates a PS-SMD-reha-

Table 1. Known predictors of post-stroke spastic movement disorder

Baseline (acute phase first week following stroke)	Any other time point (post-acute phase)
Severe paresis (led to spasticity by 6 months) [25-28]	Paresis (led to spasticity by 6 months) [25,26]
Low FMA (led to spasticity by 12 months) [29]	Increased muscle tone (led to severe spasticity by 12 months) [29,30]
Increased muscle tone (mAS≥1 led to spasticity by 3–6 months) [25]	Hemiparesis & low BI score (led to spasticity by 12 months) [31]
Moderately increased muscle tone (mAS≥2 led to severe spasticity[a] by 3–6 months) [26]	Low BI score, left-sided paresis (led to severe spasticity[a] by 12 months) [31]
Low BI score & EQ-5D (led to severe spasticity[a] by 3–6 months) [25,26]	Severe NIHSS, low Motricity Index (led to spasticity by 3 months) [32,33]
Hemihypesthesia (led to spasticity by 6 months) [26]	Extensive stroke lesions on CT & MRI (led to spasticity between 5 days and one year) [20,34]
High mRS+high NIHSS+low MMST (led to spasticity by 6 months) [29]	Severe paresis (led to spasticity by 12 months) [30]

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All risk factors were shown to be significantly ($p<0.05$) predictive of post-stroke spasticity in at least one study [35].

FMA, Fugl-Meyer Assessment; mAS, modified Ashworth Scale; BI, Barthel Index; EQ-5D, standardised instrument of health-related quality of life; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; MMST, mini-mental status test; CT, computed tomography; MRI, magnetic resonance imaging.

[a]Severe spasticity: MAS≥3 [35].

bilitation plan adapted on the patient's individual needs and abilities. If the impairment positive symptoms of a UMNS result in a SMD with a focal, multi-focal or segmental distribution, the multiprofessional rehabilitation program should include a management with BoNT-A [2,39].

Goals selected together with the patient and/or caregiver can be categorized into two domains: (1) symptoms and impairment, such as pain, involuntary movements, and ROM/contracture prevention, and (2) activities and functions, including passive and active function, as well as mobility [2].

During the individualized rehabilitation program assessing goal attainment is a main component of clinical assessment and optimal management of PS-SMD. Goal attainment scaling (GAS) is a commonly used tool for evaluating treatment goals, where patient-specific SMARTER goals are tracked using a standardized scale. It encourages patient's engagement in goal setting and has a positive impact on goal achievement, with evidence showing that involving patients in goal setting increases their likelihood of success [2,39].

The management of PS-SMD with BoNT-A

The efficacy of BoNT-A in the treatment of PS-SMD has been extensively studied. BoNT-A is considered as the treatment of choice for focal, multi-focal, and segmental PS-SMD, including spastic hypertonia, increased muscle tone, spastic dystonia, clonus, and spasms [2,3,5,6].

Numerous double-blind studies and systematic reviews have demonstrated improvements in reducing muscle tone and passive function in spastic limbs after stroke [2,3,12]. BoNT-A has been shown to reduce spasticity-associated pain, improve hygiene by increasing the passive range of joint movements, and reduce malpositioning of limbs caused by spastic dystonia and shortening of muscles due to spastic movement patterns [2,12,39]. It has also been proven to enhance active functional gains in certain subgroups of patients with PS-SMD who have difficulties with active movements due to simultaneously activated antagonists or increased muscle tone of antagonist muscles, such as reaching, gripping, or relieving movements with the hand or antagonistic ankle movements [40].

The onset of the effect of BoNT-A in PS-SMD typically occurs between 2 and 5 days after intramuscular injection, with maximal effect observed at 3–4 weeks. This clinically significant effect of BoNT-A lasts for 6–10 weeks, after which it gradually declines. The duration of the effect mainly depends on the injected dose of BoNT-A per muscle. As the uptake in the motor endplate of BoNT-A is an active process, induced contractions by passive stretch an/or electrical stimulation of the injected muscle after BoNT-A injection may help to increase and extend its effect size and duration. The overall effect of BoNT-A treatment typically lasts for about 3-6 months following injection [2,41].

Controlled studies have shown that early BoNT-A intervention within 3 months following stroke, can result in a longer duration of improvement of both spastic muscle tone and passive function while reducing the occurrence of complications like tendon shortening in long finger flexor tendons with a lower dosis of BoNT-A per injected muscle [2,12,42]. However, up to now the evidence does not indicate higher functional gains or effects on disability with earlier interventions with BoNT-A following stroke.

BoNT-A treatment in SMD has a good safety profile when used within the recommended therapeutic dose per muscle and treatment session and with proper injection techniques [2]. Common local adverse events include unwanted weakness of injected muscles, dysphagia (injection in cervical muscles), dry mouth and eyes, local pain, bleeding, or hematoma at the injection site. These side effects are reversible and not life-threatening. Systemic adverse events are rare and seemed to be less frequent if recommended doses are injected by use of guidance techniques directly into the target muscles in PS-SMD [2,41].

In the upper limbs, BoNT-A management of spastic movement disorder has shown dose-dependent effects in reducing spastic muscle tone, improving passive ROM and passive function, and reducing caregiver's burden. However, the effects on active functions of the hand or arm are limited [2,39]. BoNT-A injections may improve active function in some patients with spasticity of the upper limb, especially when spastic co-contraction of antagonistic muscles is the relevant cause of hindering active finger or elbow from movement. In such cases the injection of BoNT-A in spastic agonists is recommended to combine with active training of motor command and force for antagonistic muscle groups thereby allowing for improvements also in active function, e.g., finger, wrist, or elbow extension [2,10,39].

In the lower limbs, BoNT-A injections can be considered for clinically relevant lower limb PS-SMD that does not respond to conventional physiotherapeutic treatment. BoNT-A injections were shown to reduce spastic muscle tone and to improve passive joint mobility and joint position in the ankle, knee, and hip. Pivotal studies in the lower limb of BoNT-A products showed significantly reduced pes equinus and pes equinovarus position with reduced muscle tone in the calf muscles and improved

brace or orthosis tolerance. However, significant improvements in longitudinal gait parameters (gait speed and step length) have not been consistently observed [2,40,43].

BoNT-A treatment also showed reduced spasm frequency and clonus occurrence, as well as reduced stretch- or motion-related spasticity-associated nociceptive pain in both upper and lower limbs after stroke [2,3,6].

The technical guidance of BoNT-A injections, such as ultrasound or electrical stimulation guidance, improves the accuracy, safety, and efficacy of the injections compared to non-guided injections. Guided injections have been shown to be superior in terms of injection accuracy and avoidance of accidental vessel and nerve injury [2,41].

The appropriate dosing of BoNT-A is crucial for treatment effectiveness and to minimize adverse events. Dosing recommendations are currently based on limited studies and rely on pivotal studies that are documented in the product information, clinical experience of injectors, and expert consensus statements [2,3,41].

Recommended doses per injection site base on the assumption of a saturation of the motor endplates and led to the recommendation not to inject more than 50 units for onabotulinumtoxinA and incobotulinumtoxinA, and 125 units for abobotulinumtoxin A per injection site. Therefore, the number of injection sites per muscle depends on the maximal recommended dose per specific muscle. As a a rule of thumb the recommended doses vary for different muscle sizes, ranging from 15–25 units onabotulinumtoxinA and incobotulinumtoxinA, and 35–75 units for abobotulinumtoxin A for small limb muscles to 50–150 units onabotulinumtoxinA and incobotulinumtoxinA, and 125–500 units for abobotulinumtoxin A for large limb muscles [2,41].

As spastic muscle patterns of upper and lower limbs usually involve more than two or three muscles it seems to be important to calculate the total dose per injection session prior to the event and respect the maximum dose per injection session given in the product information and from expert consensus statements [2,41]. There are prospective studies that could show a superiority with respect to the benefit with higher dose, but for certain BoNT-A products, only [44]. More research is needed in this field to learn more about the safety margins of the different BoNT-A products.

Adjunctive therapies to botulinumtoxin injections

Evidence-based reviews report an enhanced effectiveness of adjuvant therapies to BoNT-A injections in spastic muscles in PS-SMD [2]. Such techniques include physiotherapy, modified constraint-induced movement therapy, electrical stimulation, casting, and dynamic splint treatment. Neuromuscular electrostimulation applied three days before and after BoNT-A therapy has shown positive effects on effect size and duration of BoNT-A injections. Other adjuvant therapies like stretching, taping, and robotic training may be used on an individual basis, but the published evidence on additional effects is limited [2].

Oral antispastic drugs have shown significant systemic side effects like sleepiness, drowsiness and general weakness and do not have sufficient evidence to support their superiority over local BoNT-A treatment in focal, multi-focal and segmental spasticity. But some studies have demonstrated effectiveness of systemic drugs like tizanidine or baclofen [2]. On the basis of clinical experience, in some patients the drug side effect 'sleepiness' may help for positive effect on lower limb spasms during night. Such timed drug therapy may be combinable with BoNT-A injections for treatment of a pes equinus or ankle clonus within the calf muscles.

A combination of diverse treatment modalities involving neurolysis (phenol, alcohol, or cryo-neurolysis) or even neurotomy with BoNT-A injections can be considered for PS-SMD that shows a multi-segmental or generalized topical distribution and does not respond adequately to recommended dose per session [2,45]. If the BoNT-A dose per session exceeds the limit documented in the product information or in consensus statements a combination of neurolysis of motor end branches or dominat motor nerves, like musculo-cutaneus or obturator nerve, are recommended in order to reduce the total dose of BoNT-A per session. However, the side effects and the long-term side effects of neurolysis should be taken into account [2,45].

Intrathecal baclofen (ITB) application can be considered for severe multi-segmental or generalized PS-SMD that does not respond to other interventions, e.g., systemic oral pharmacological antispastic treatment [2,3]. For ITB therapy was shown a superiority over conventional medical management with oral antispastics in terms of efficacy and pain control [46]. Surgical procedures, such as fasciotomy, tendon and muscle lengthening, and tendon transfer surgery, may be considered in chronic PS-SMD cases after exhausting of other reversible treatment options [2]. More research is needed to provide evidence for orthopedic surgery in the management of chronic PS-SMD and its combination with BoNT-A treatment.

BoNT-A therapy in the *Acute and Early Subacute Phase* following stroke

PS-SMD typically develops in the early post-acute phase of stroke, within the first three months [2,12]. Unfortunately, clinical detection and decision-making for appropriate management in many countries usually occur later, e.g., in the late subacute or even in the chronic phase [1,2]. In the late sub-acute phase degenerative changes in affected muscles and soft tissues already start and lead to more frequent complications like joint contractures, spasticity-associated pain syndromes, abnormal motion and limb patterns and even bony distortions can occure in the chronic phase - if the SMD is not adequately managed in the early sub-acute phase [2,13,17].

Studies have shown that early initiation of treatment after stroke could have beneficial effects on the reduction of spastic muscle tone without increased side effects [2,12,47]. Meta-analysis and systematic reviews indicate more favorable outcomes and better prognosis with early treatment compared to late treatment in the chronic phase of PS-SMD [2,12,42].

Based on the pathophysiological mechanisms leading to a SMD it has been considered to maintain or provide a normal sensory and proprioceptive input to the disrupted central sensorimotor network to prevent from adaptation or even mal-adaptation re-organization. BoNT-A injections in SMD developing muscles support to prevent the central network from overactive peripheral sensory input from intrinsic muscle fiber and tendon receptors (IA- and IIb-fibers). The pathologically enhanced tonic and phasic input on the spinal sensori-motor network via the proprioceptive system is believed to be one of the key factors for maintenance and augmentation of the spastic movement disorder [12,13,16,48]. It is hypothesized that this input to the spinal network from spastic muscles may play a significant role in the maladaptive processes in the CNS that leads to the chronic consequences from PS-SMD in UMNS [13,15-17,48].

It is suggested that the three-month transition phase following stroke is a period of enhanced neuroplasticity allows effective interventions. Such interventions include blocking afferences from spastic muscles thereby avoiding the development of complications like contractures and spasticity-associated pain syndromes. This is achievable by BoNT-A treatment in spastic muscles before the transition in the late post-acute phase. Therefore, this transition marks the cut-off for early vs. late BoNT treatment [12].

Based on the evidence that appropriate predictors are sufficient to detect patients at risk for developing a PS-SMD after a first ever stroke, it seems now possible to treat PS-SMD with BoNT-A already in the acute or late early subacute phase, i.e., within the first 3 months after stroke [2,12,42]. Treatment of PS-SMD with BoNT-A injections should be offert to those high risk patients to avoid complications from severe spasticity, e.g., contracture development. As well, involuntary muscle activity should be blocked early to avoid maladaptation to a disturbed feedback on the spinal network by increased Ia- and II-afferences from hyperactive muscle activity, e.g., from spastic dystonia. Spinal cord sensori-motor networks can be protected from an enhanced muscle/tendon proprioceptive input by early BoNT treatment. By doing this, the vicious circle can be interrupted and neurorehabilitation is facilitated. Insofar, in patients, who are at high risk for a disabling spasticity it is recommended to start a BoNT therapy early, when early signs like moderate increase in velocity dependend increase in muscle tone (MAS >1+) is present in two joints of the paretic limbs [35]. Goal-oriented management of PS-SMD, including BoNT-A therapy within a few weeks to three months after stroke onset, has shown to prevent or reduce the development of severe or disabling SMD and its complications like finger contractures [2,12]. Considering positive outcomes associated with early BoNT-A therapy, it is strongly recommended to initiate treatments including BoNT-A therapy in the acute to early subacute phase after stroke in patients with existing PS-SMD or at high risk of developing severe PS-SMD, to prevent or reduce post-stroke disability and improve rehabilitation outcome [2,12,42]. This is especially true for BoNT-A injections within 3 months following stroke in patients with beginning PS-SMD or at high risk to develop severe or disabling spasticity as controlled studies with early BoNT-A interventions showed longer endurance of BoNT-A effect with lower dose per muscle compared with dosis used in chronic spasticity and reduction in the probability to develop complications like contractures and spasticity-associated pain in the chronic phase after stroke [2,12,42].

In the chronic phase of focal, multi-focal, and segmental PS-SMD BoNT-A injections should primarily target spastic muscles that are either identified to create disability or muscles that already are involved in complications It should be underlined that therapeutic interventions for severe or disabling PS-SMD should be embedded in a multi-professional team approach that involves a comprehensive patient-centered multi-modal therapy program. This includes e.g., occupational and physical therapy, physical treatments (casting), electrical stimulation, and BoNT-A injections to the targeted spastic muscles [2,3].

Regardless of the fact that the majority of BoNT-A treament for PS-SMD is done in the chronic-phase after stroke - where spasticity and muscle deformities are already established, it should be noted that there is no restriction for the timing of BoNT-A treatment for any region of the upper and lower limbs based on product licenses.

Degenerative changes in affected spastic muscles

The long-term repeated or chronic use of BoNT-A injections for spasticity management has raised concerns about persistent muscle atrophy and degenerative changes in the affected and treated muscles [49]. Affected spastic muscles naturally undergo degenerative changes, including muscle fiber atrophy, fibrosis, and altered architecture. Based on that information the term "spastic myopathy" has been coined by Gracies [22]. As well repeated BoNT-A injections might cause changes in the muscle and might exacerbate these natural changes through muscle atrophy, fibrosis, and altered muscle fiber composition [49].

Prolonged dis-use from non-use in SP can cause muscle atrophy as well as atrophy from temporary neuromuscular endplate block of BoNT-A, leading to decreased protein synthesis and increased degradation. Chronic denervation resulting from BoNT-A injections may trigger fibrotic changes in spastic muscles via gene expression changes, reduced trophic support, and inflammation, leading to the deposition of collagen and a loss of muscle elasticity. Degenerative changes in spastic muscles could impact to the reduction of functional outcomes including muscle weakness, reduced ROM, and decreased muscle strength and contractile properties. Therefore, one obligation and goal of any rehabilitative therapy such as physical therapy, occupational therapy, and targeted exercise programs, as well as local Botulinumtoxin treatment is to prevent from or reduce chronic disability and such chronic changes in the muscle tissue [49].

In conclusion, the benefit of BoNT-A therapy generally outweight the risk of BoNT use associated degenerative changes in spastic muscles. Regular monitoring and individualized treatments can help to minimize these potential degenerative changes. Further studies in this field are warranted.

CONCLUSION

Early identification of PS-SMD has a key role in the management of PS-SMD. If physical management alone is insufficient to control the SMD with accompanying complications from increasing spastic muscle tone and involuntary phasic and tonic muscle activation, early consideration of additional treatment with BoNT-A in focal, multi-focal and segmental spasticty can help to promote effective neurorehabilitation and to avoid long-term complications. Predictors of PS-SMD, including clinical signs and brain imaging data, are established and are being ready to be applied in clinical practice. The first-line management of focal, multi-focal, and segmental PS-SMD involves comprehensive assessment, goal setting in the MPT, techniqual guided BoNT-A injections, and a setting of multimodal antispastic measures, e.g., time-adjusted adjunctive therapies like serial casting, taping, or functional electrical stimulation. Following evidence-based recommendations, multi-pattern BoNT-A therapy is safe and effective, with no severe side effects. Overall, BoNT-A treatment in the acute or early subacute phase and chronic phases of stroke can effectively reduce muscle tone and improve both passive and active functions, leading to an improved quality of life, in particular when combined with patient-centered care and multimodal or adjunctive other treatment modalities. Especially, BoNT-A injections within 3 months (early subacute phase) following stroke are strongly recommended in patients with PS-SMD or at its high risk as controlled studies with early BoNT-A interventions showed longer endurance of BoNT-A effect with lower dose per muscle and reduction in the probability to develop complications like contractures and spasticity-associated pain in the chronic phase after stroke.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

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ORCID

Jörg Wissel, https://orcid.org/0000-0001-6238-3578
Anatol Kivi, https://orcid.org/0009-0000-2959-2378

REFERENCES

1. Wissel J, Manack A, Brainin M. Toward an epidemiology of post-stroke spasticity. Neurology 2013;80(3 Suppl 2):S13-9.
2. Wissel J, Ri S. Assessment, goal setting, and botulinum neurotoxin a therapy in the management of post-stroke spastic movement disorder: updated perspectives on best practice. Expert Rev Neurother 2022;22:27-42.
3. Platz T, Wissel J, Donauer E, Vogel M, Tholen R, Lehmler L. [S2k: treatment of spastic syndromes] [Internet]. Deutsche Gesellschaft für Neurologie 2018 [cited 2023 Jul 13]. Available from: https://register.awmf.org/assets/guidelines/ 030-078k_S2k_Therapie_spastisches_Syndrom_2019-06-verlaengert.pdf. German.
4. Zeng H, Chen J, Guo Y, Tan S. Prevalence and risk factors for spasticity after stroke: a systematic review and meta-analysis. Front Neurol 2021;11:616097.
5. Mills PB, Phadke CP, Boulias C, Dukelow SP, Ismail F, McNeil SM, et al. Spasticity management teams, evaluations, and tools: a Canadian cross-sectional survey. Can J Neurol Sci 2022. doi: 10.1017/cjn.2022.326. [Epub ahead of print].
6. Wissel J, Ward AB, Erztgaard P, Bensmail D, Hecht MJ, Lejeune TM, et al. European consensus table on the use of botulinum toxin type A in adult spasticity. J Rehabil Med 2009;41:13-25.
7. Biering-Sørensen F, Charlifue S, Chen Y, New PW, Noonan V, Post MWM, et al. International Spinal Cord Injury Core Data Set (version 3.0)-including standardization of reporting. Spinal Cord 2023;61:65-8.
8. Platz T, Vuadens P, Eickhof C, Arnold P, Van Kaick S, Heise K. REPAS, a summary rating scale for resistance to passive movement: item selection, reliability and validity. Disabil Rehabil 2008;30:44-53.
9. Pandyan AD, Gregoric M, Barnes MP, Wood D, Van Wijck F, Burridge J, et al. Spasticity: clinical perceptions, neurological realities and meaningful measurement. Disabil Rehabil 2005;27:2-6.
10. Wissel J, Camões-Barbosa A, Carda S, Hoad D, Jacinto J. A practical guide to botulinum neurotoxin treatment of shoulder spasticity 2: injection techniques, outcome measurement scales, and case studies. Front Neurol 2022;13:1022549.
11. Bernhardt J, Hayward KS, Kwakkel G, Ward NS, Wolf SL, Borschmann K, et al. Agreed definitions and a shared vision for new standards in stroke recovery research: The Stroke Recovery and Rehabilitation Roundtable taskforce. Neurorehabil Neural Repair 2017;31:793-9.
12. Wissel J, Ri S, Kivi A. Early versus late injections of Botulinumtoxin type A in post-stroke spastic movement disorder: a literature review. Toxicon 2023;229:107150.
13. Burke D, Wissel J, Donnan GA. Pathophysiology of spasticity in stroke. Neurology 2013;80(3 Suppl 2):S20-6.
14. Lance JW. The control of muscle tone, reflexes, and movement: Robert Wartenberg Lecture. Neurology 1980;30:1303-13.
15. Li S, Francisco GE. New insights into the pathophysiology of post-stroke spasticity. Front Hum Neurosci 2015;9:192.
16. Mukherjee A, Chakravarty A. Spasticity mechanisms - for the clinician. Front Neurol 2010;1:149.
17. Li S. Spasticity, motor recovery, and neural plasticity after stroke. Front Neurol 2017;8:120.
18. Toda T, Ishida K, Kiyama H, Yamashita T, Lee S. Down-regulation of KCC2 expression and phosphorylation in motoneurons, and increases the number of in primary afferent projections to motoneurons in mice with post-stroke spasticity. PLoS One 2014;9:e114328.
19. Chen CL, Tang FT, Chen HC, Chung CY, Wong MK. Brain lesion size and location: effects on motor recovery and functional outcome in stroke patients. Arch Phys Med Rehabil 2000;81:447-52.
20. Ri S, Kivi A, Urban PP, Wolf T, Wissel J. Site and size of lesion predict post-stroke spasticity: a retrospective magnetic resonance imaging study. J Rehabil Med 2020;52:jrm00065.
21. Ri S, Glaess-Leistner S, Wissel J. Early brain imaging predictors of post-stroke spasticity. J Rehabil Med 2021;53:jrm00169.
22. Gracies JM. Pathophysiology of spastic paresis. I: paresis and soft tissue changes. Muscle Nerve 2005;31:535-51.
23. Baude M, Nielsen JB, Gracies JM. The neurophysiology of deforming spastic paresis: a revised taxonomy. Ann Phys Rehabil Med 2019;62:426-30.
24. Dietz V. [Clinical treatment of spasticity--spastic movement disorders]. Nervenarzt 2013;84:1508-11. German.
25. Wissel J, Schelosky LD, Scott J, Christe W, Faiss JH, Mueller J. Early development of spasticity following stroke: a prospective, observational trial. J Neurol 2010;257:1067-72.
26. Urban PP, Wolf T, Uebele M, Marx JJ, Vogt T, Stoeter P, et al. Occurence and clinical predictors of spasticity after ischemic stroke. Stroke 2010;41:2016-20.
27. Lundström E, Smits A, Terént A, Borg J. Time-course and determinants of spasticity during the first six months following first-ever stroke. J Rehabil Med 2010;42:296-301.
28. Picelli A, Tamburin S, Gajofatto F, Zanette G, Praitano M, Saltuari L, et al. Association between severe upper limb spasticity and brain

lesion location in stroke patients. Biomed Res Int 2014;2014:162754.
29. Opheim A, Danielsson A, Alt Murphy M, Persson HC, Sunnerhagen KS. Early prediction of long-term upper limb spasticity after stroke: part of the SALGOT study. Neurology 2015;85:873-80.
30. Kong KH, Lee J, Chua KS. Occurrence and temporal evolution of upper limb spasticity in stroke patients admitted to a rehabilitation unit. Arch Phys Med Rehabil 2012;93:143-8.
31. Leathley MJ, Gregson JM, Moore AP, Smith TL, Sharma AK, Watkins CL. Predicting spasticity after stroke in those surviving to 12 months. Clin Rehabil 2004;18:438-43.
32. Ryu JS, Lee JW, Lee SI, Chun MH. Factors predictive of spasticity and their effects on motor recovery and functional outcomes in stroke patients. Top Stroke Rehabil 2010;17:380-8.
33. Cheung DK, Climans SA, Black SE, Gao F, Szilagyi GM, Mochizuki G. Lesion characteristics of individuals with upper limb spasticity after stroke. Neurorehabil Neural Repair 2016;30:63-70.
34. Glaess-Leistner S, Ri SJ, Audebert HJ, Wissel J. Early clinical predictors of post-stroke spasticity. Top Stroke Rehabil 2021;28:508-18.
35. Wissel J, Verrier M, Simpson DM, Charles D, Guinto P, Papapetropoulos S, et al. Post-stroke spasticity: predictors of early development and considerations for therapeutic intervention. PM R 2015;7:60-7.
36. Bavikatte G, Subramanian G, Ashford S, Allison R, Hicklin D. Early identification, intervention and management of post-stroke spasticity: expert consensus recommendations. J Cent Nerv Syst Dis 2021;13:11795735211036576.
37. Glaess-Leistner S, Ri SJ, Audebert HJ, Wissel J. Early clinical predictors of post stroke spasticity. Top Stroke Rehabil 2021;28:508-18.
38. Jacinto J, Camões-Barbosa A, Carda S, Hoad D, Wissel J. A practical guide to botulinum neurotoxin treatment of shoulder spasticity 1: anatomy, physiology, and goal setting. Front Neurol 2022;13:1004629.
39. Turner-Stokes L, Baguley IJ, De Graaff S, Katrak P, Davies L, McCrory P, et al. Goal attainment scaling in the evaluation of treatment of upper limb spasticity with botulinum toxin: a secondary analysis from a double-blind placebo-controlled randomized clinical trial. J Rehabil Med 2010;42:81-9.
40. Esquenazi A, Brashear A, Deltombe T, Rudzinska-Bar M, Krawczyk M, Skoromets A, et al. The effect of repeated abobotulinumtoxinA (Dysport®) injections on walking velocity in persons with spastic hemiparesis caused by stroke or traumatic brain injury. PM R 2021;13:488-95.
41. Kivi A, Ri S, Wissel J. What clinicians and patients want: the past, the presence, and the future of the botulinum toxins. Toxicon 2020;177:46-51.
42. Rosales RL, Efendy F, Teleg ES, Delos Santos MM, Rosales MC, Ostrea M, et al. Botulinum toxin as early intervention for spasticity after stroke or non-progressive brain lesion: a meta-analysis. J Neurol Sci 2016;371:6-14.
43. Varvarousis DN, Martzivanou C, Dimopoulos D, Dimakopoulos G, Vasileiadis GI, Ploumis A. The effectiveness of botulinum toxin on spasticity and gait of hemiplegic patients after stroke: a systematic review and meta-analysis. Toxicon 2021;203:74-84.
44. Fheodoroff K, Scheschonka A, Wissel J. Goal analysis in patients with limb spasticity treated with incobotulinumtoxinA in the TOWER study. Disabil Rehabil 2022;44:1367-73.
45. Karri J, Mas MF, Francisco GE, Li S. Practice patterns for spasticity management with phenol neurolysis. J Rehabil Med 2017;49:482-8.
46. Creamer M, Cloud G, Kossmehl P, Yochelson M, Francisco GE, Ward AB, et al. Intrathecal baclofen therapy versus conventional medical management for severe poststroke spasticity: results from a multicentre, randomised, controlled, open-label trial (SISTERS). J Neurol Neurosurg Psychiatry 2018;89:642-50.
47. Lindsay C, Ispoglou S, Helliwell B, Hicklin D, Sturman S, Pandyan A. Can the early use of botulinum toxin in post stroke spasticity reduce contracture development? A randomised controlled trial. Clin Rehabil 2021;35:399-409.
48. Nielsen JB, Christensen MS, Farmer SF, Lorentzen J. Spastic movement disorder: should we forget hyperexcitable stretch reflexes and start talking about inappropriate prediction of sensory consequences of movement? Exp Brain Res 2020;238:1627-36.
49. Fortuna R, Vaz MA, Youssef AR, Longino D, Herzog W. Changes in contractile properties of muscles receiving repeat injections of botulinum toxin (Botox). J Biomech 2011;44:39-44.

Review Article

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Sarcopenic Dysphagia and Simplified Rehabilitation Nutrition Care Process: An Update

Shingo Kakehi, PT, MS, Eri Isono, PT, Hidetaka Wakabayashi, MD, PhD, Moeka Shioya, PT, Junki Ninomiya, PT, Yohei Aoyama, PT, Ryoko Murai, ST, Yuka Sato, PT, Ryohei Takemura, PT, Amami Mori, OT, Kei Masumura, OT, Bunta Suzuki, PT

Department of Rehabilitation Medicine, Tokyo Women's Medical University Hospital, Tokyo, Japan

Sarcopenic dysphagia is characterized by weakness of swallowing-related muscles associated with whole-body sarcopenia. As the number of patients with sarcopenia increases with the aging of the world, the number of patients with sarcopenic dysphagia is also increasing. The prevalence of sarcopenic dysphagia is high in the institutionalized older people and in patients hospitalized for pneumonia with dysphagia in acute care hospitals. Prevention, early detection and intervention of sarcopenic dysphagia with rehabilitation nutrition are essential. The diagnosis of sarcopenic dysphagia is based on skeletal and swallowing muscle strength and muscle mass. A reliable and validated diagnostic algorithm for sarcopenic dysphagia is used. Sarcopenic dysphagia is associated with malnutrition, which leads to mortality and Activities of Daily Living (ADL) decline. The rehabilitation nutrition approach improves swallowing function, nutrition status, and ADL. A combination of aggressive nutrition therapy to improve nutrition status, dysphagia rehabilitation, physical therapy, and other interventions can be effective for sarcopenic dysphagia. The rehabilitation nutrition care process is used to assess and problem solve the patient's pathology, sarcopenia, and nutrition status. The simplified rehabilitation nutrition care process consists of a nutrition cycle and a rehabilitation cycle, each with five steps: assessment, diagnosis, goal setting, intervention, and monitoring. Nutrition professionals and teams implement the nutrition cycle. Rehabilitation professionals and teams implement the rehabilitation cycle. Both cycles should be done simultaneously. The nutrition diagnosis of undernutrition, overnutrition/obesity, sarcopenia, and goal setting of rehabilitation and body weight are implemented collaboratively.

Keywords: Aging, Deglutition disorders, Frailty, Muscles, Sarcopenia

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Correspondence:
Hidetaka Wakabayashi
Department of Rehabilitation Medicine, Tokyo Women's Medical University Hospital, 8-1, Kawada-cho, Shinjuku-ku, Tokyo 162-8666, Japan.
Tel: +81-3-3353-8111
Fax: +81-3-5269-7639
E-mail: noventurenoglory@gmail.com

INTRODUCTION

Sarcopenia, defined as loss of muscle strength, muscle mass, and physical function, is increasing with the aging population [1]. According to the World Health Organization report, the percentage of the world population aged 65 and over is projected to increase from 5% in 1950 to 10% in 2022 and 16% by 2050 [2]. Aging is associated with a wide range of aging phenomena. Handgrip strength increases with age, peaking in the 30s and 40s, then declines thereafter [3,4]. Muscle mass increases with age, then maintains or decreases after the 40s and 50s [3,5,6]. The number of comorbidities increases with age in older people

[7], and they suffer from polypharmacy. Polypharmacy is a risk factor for sarcopenia [8]. Sarcopenia is associated with adverse outcomes of falls, fractures, mortality, decreased Activities of Daily Living (ADL), dysphagia, dyspnea, and decreased quality of life [9-11]. Therefore, treatment and prevention of sarcopenia are essential.

Poor swallowing muscle mass and strength and swallowing function worsen outcomes such as malnutrition, aspiration pneumonia, prolonged hospitalization, and survival in older people [12]. Many muscles are involved in swallowing, such as the tongue, geniohyoid, mylohyoid, digastric, stylohyoid, and temporal muscles. Unlike skeletal muscles, the geniohyoid muscle is a striated muscle, and its histological characteristics make it difficult for swallowing muscles to atrophy [13]. However, the geniohyoid muscle volume and cross-sectional area of the tongue decrease with age [14,15]. The prevalence of dysphagia in older people is approximately 20%–35%, although it varies by countries and regions [16,17]. The prevalence increases further in the presence of dementia and cerebrovascular diseases. Community-dwelling older people may be at risk for malnutrition and poor swallowing function [18], and hospitalized and institutionalized adults are at increased risk for malnutrition due to poor swallowing function [19]. Many patients hospitalized for community-acquired pneumonia may have dysphagia [20]. As many as 75% of aspiration pneumonia patients over the age of 65 have dysphagia, and dysphagia increases hospital stay by 3.5 days and mortality by 1.7 times [21]. The association of swallowing muscles and swallowing function/severity assessment with frailty and sarcopenia has been reported [22,23].

Sarcopenic dysphagia is due to whole-body sarcopenia and low muscle mass and strength related to swallowing [13]. Decreased limb and trunk skeletal muscle mass involved in postural retention leads to decreased swallowing muscle mass [14,23]. In a study of the effects of food abstinence in older hospitalized patients, 77% had sarcopenia and 26% had dysphagia after two months [24]. This development of dysphagia was related to the effects of bed rest and no oral intake during hospitalization. Effective intervention with rehabilitation nutrition can lead to the prevention of sarcopenic dysphagia [25,26].

Rehabilitation nutrition is defined as that (1) a holistic assessment using the International Classification of Functioning, Disability and Health and evaluation of the cause of malnutrition, sarcopenia, and excess or deficient nutritional intake, (2) diagnosis and goal setting through rehabilitation nutrition, (3) to improve the nutrition status, sarcopenia, frailty and disability to practice nutritional management from rehabilitation and rehabilitation from nutrition to maximize their function and quality of life [27].

Evidence on rehabilitation nutrition was gradually accumulating, and the 2020 Clinical Practice Guidelines for Rehabilitation Nutrition weakly recommend enhanced nutrition therapy in cerebrovascular disease, hip fracture, cancer, and acute illness [28]. The Japanese Association of Rehabilitation Nutrition have been reported 7 position papers, including "Goal setting for nutrition and body weight in rehabilitation nutrition" [29], "Nutritional, physical therapy for specific diseases" [30] and "Respiratory sarcopenia: a position paper by four professional organizations" [31].

With medical advances in today's aging population, the number of people with sarcopenia and frailty are expected to increase. The challenge is how to increase healthy life expectancy. Sarcopenia, dysphagia and oral frailty affect quality of life [32-34]. Early identification of patients with sarcopenic dysphagia and effective prevention and treatment strategies are important. This review describes the diagnosis, prevalence, epidemiology, treatment and prevention, and rehabilitation nutrition of sarcopenic dysphagia and the simplified rehabilitation nutrition care process.

SARCOPENIC DYSPHAGIA

Diagnostic criteria and screening

Diagnostic criteria for sarcopenic dysphagia are based on loss of skeletal and swallowing-related muscle mass and strength [35]. According to Wakabayashi [36], Diagnostic criteria for sarcopenic dysphagia is as follows: (1) Presence of dysphagia. (2) Presence of whole-body sarcopenia. (3) Results of imaging studies are consistent with loss of swallowing muscle mass. (4) Causes of dysphagia other than sarcopenia are excluded. Ultrasound, computed tomography, and magnetic resonance imaging can evaluate swallowing-related muscle mass [37-39]. In particular, ultrasound evaluation of the geniohyoid muscle shows good reliability and validity [40,41].

The diagnostic flowchart of sarcopenic dysphagia does not include an assessment of swallowing-related muscle mass [42]. Patients 65 years of age and older with no cognitive decline are evaluated and diagnosed for physical function, muscle mass, swallowing function, underlying disease, and strength of swallowing-related muscle (Fig. 1). Physical function and total body muscle mass are determined using the diagnostic criteria of

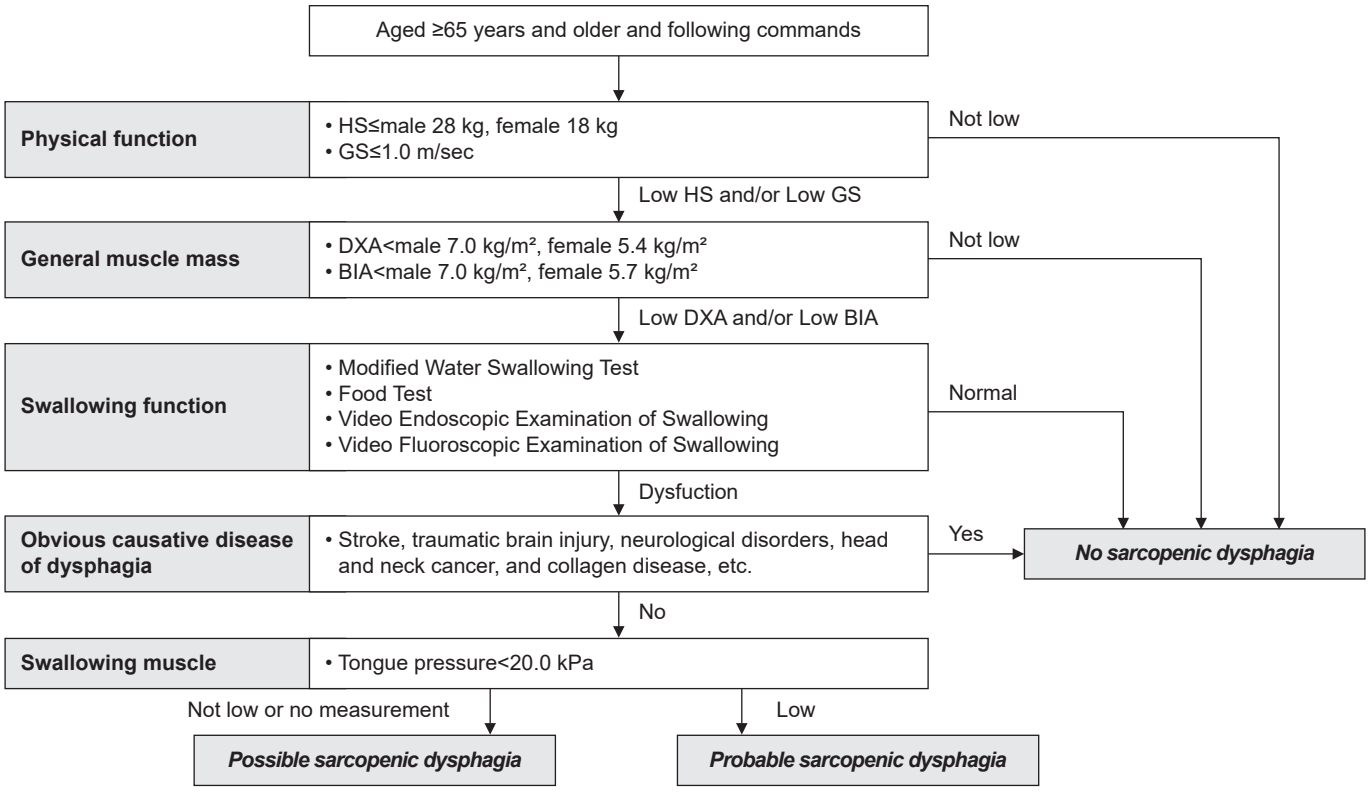

Fig. 1. Diagnostic flowchart of sarcopenic dysphagia. HS, hand grip strength; GS, gait speed; DXA, dual-energy X-ray absorptiometry; BIA, bioelectrical impedance analysis.

the European Working Group on Sarcopenia in Older People 2 [10] or the Asian Working Group for Sarcopenia (AWGS) 2019 [43]. The cut-off values for hand grip strength are determined by male≤28 kg, female≤18 kg, or gait speed<1.0 m/sec in the AWGS 2019 diagnostic criteria. Assessment of swallowing function includes the revised Modified Water Swallowing Test, Water Swallowing Test, Food Test, Video Endoscopic Examination of Swallowing, and Video Fluoroscopic Examination of Swallowing. Muscle strength of the swallowing-related muscle is assessed by tongue pressure [44-52]. A diagnosis of probable sarcopenic dysphagia is made if there is muscle weakness in tongue pressure (<20 kPa). If there is no weakness in tongue pressure or if tongue pressure is difficult to measure, a diagnosis of possible sarcopenic dysphagia is made.

Screening for sarcopenic dysphagia includes handgrip strength, calf circumference, or body mass index. The cut-off values were 19.7 kg for handgrip strength in males and 29.5 cm for calf circumference in females [53]. The body mass index cut-off value was 20.1 kg/m^2 in older dysphagia patients [54]. Early assessment of swallowing function may prevent sarcopenic dysphagia. Therefore, early screening and using the diagnostic flowchart is recommended [13].

Prevalence

Sarcopenic dysphagia has a high prevalence among institutionalized older people and patients hospitalized for pneumonia with dysphagia in acute care hospitals. Of 100 sarcopenic seniors aged 65 years and older in nursing homes, 45% had sarcopenic dysphagia [55]. In an acute general hospital, 32% of patients undergoing swallowing rehabilitation had sarcopenic dysphagia [56]. Among patients hospitalized for pneumonia with dysphagia, 81% had sarcopenic dysphagia [57]. Patients with lower skeletal muscle mass and grip strength at baseline <8 kg had a higher incidence of dysphagia at discharge in postoperative hip fracture inpatients [58]. Dysphagia is common in patients with older age, poor performance status, gait disturbance, low body weight, malnutrition, and poorer food intake [59]. Sarcopenic dysphagia in community-dwelling older people is underreported and its prevalence is unknown.

Prognosis

Patients with sarcopenic dysphagia have poor improvement in swallowing function and are prone to malnutrition [60]. In addition, patients with malnutrition have significantly weaker swallowing-related muscles, which can easily lead to a vicious cycle of further deterioration of swallowing function compared to patients with normal nutrition status [61]. Patients with sarcopenic dysphagia have less improvement in swallowing function than patients with non-sarcopenic dysphagia [60]. From a nutritional standpoint, sarcopenic dysphagia is associated with poor improvement in swallowing function because they tend to be malnourished. On the other hand, swallowing function improves better with swallow muscle strengthening interventions in patients with sarcopenic dysphagia compared to patients without sarcopenic dysphagia [62]. From a physiological perspective, targeting the swallowing muscles directly seems effective in improving swallowing function because they do not suffer from damage caused by diseases such as stroke and neck cancer.

Sarcopenic dysphagia is associated with increased mortality and poor ADL improvement in older people. Malnutrition is associated with muscle weakness, wasting, physical frailty, and complications during hospitalization, and impedes improvement in ADL and increases mortality [61,63]. Mortality is 1.4 times higher among older people with sarcopenic dysphagia than among those without dysphagia in care facilities [62]. The risk of death is higher, especially when they are affected by weight loss and malnutrition [64]. Patients with sarcopenic dysphagia tend to have low ADL independence and poor improvement compared to patients with non-sarcopenic dysphagia [60]. Moreover, ADL improvement is significantly lower in malnourished patients compared those with normal nutrition status.

High levels of inflammation are associated with poor improvement in swallowing function, and C-reactive protein (CRP) may be a prognostic predictor of swallowing function in patients with sarcopenic dysphagia [64]. Mori et al. [64] defined patients with CRP of ≥5.0 mg/L as the high-inflammation group and reported poor improvement in swallowing function in the high-inflammation group compared to the low-inflammation group. Adding the result of CRP levels to the initial assessment of swallowing function could predict the more accurate prognosis.

Treatment and prevention

The combination of aggressive nutrition therapy and rehabilitation can effectively treat sarcopenic dysphagia [13,25]. Aggressive nutrition therapy is nutritional care management that sets goals for total daily energy intake according to daily energy expenditure and daily energy accumulation [35]. Older patients require more than 250 kcal/day of daily energy accumulation to gain 1 kg of body weight per month [65]. A mean provided energy intake of ≥30 kcal/ideal body weight (kg)/day improved swallowing function in older patients with dysphagia, and ADL improved significantly in the patient undergoing rehabilitation in the acute care hospital [66]. Treatment of sarcopenic dysphagia could improve muscle strength and function throughout the body, including the swallowing muscles, by combining aggressive nutrition therapy, dysphagia rehabilitation, and physical interventions such as physical therapy [66-68].

Hospitalized patients need to evaluate and monitored to minimize sarcopenic dysphagia. Hospital-associated sarcopenia and acute sarcopenia are classified into iatrogenic and non-iatrogenic [69]. While prevention of non-iatrogenic sarcopenia is difficult, prevention of iatrogenic sarcopenia caused by the medical activities of health care professionals including doctors, nurses, and others is possible. The combination of rehabilitation, appropriate nutritional management, and medication review from admission may prevent sarcopenia during hospitalization [69].

Early detection and intervention are necessary because older people with presbyphagia are at risk for sarcopenic dysphagia. Presbyphagia is characterized by the fragility of the swallowing mechanism due to age-related changes [70-75]. Presbyphagia in older people could develop into sarcopenic dysphagia because of their disease, activity level, and nutrition status when hospitalized for diseases [36]. Monitoring nutrition status and swallowing function in older people by questionnaire such as the 10-item Eating Assessment Tool and clinical examination may be effective in preventing sarcopenic dysphagia during hospitalization [76-81].

REHABILITATION NUTRITION

Rehabilitation nutrition care process

The rehabilitation nutrition care process is a systematic problem-solving method used to assess the nutrition status, sarcopenia, and nutritional intake of people with disabilities and frail older people [82]. The rehabilitation nutrition care process consists of five steps [83]: (1) rehabilitation nutrition assessment and diagnostic reasoning, (2) rehabilitation nutrition diagnosis, (3) rehabilitation nutrition goal setting, (4) rehabilitation nutri-

tion intervention, and (5) rehabilitation nutrition monitoring. Collaboration between rehabilitation and nutrition helps set appropriate goals and develop appropriate rehabilitation and nutrition care management [26].

The simplified rehabilitation nutrition care process consists of a nutrition cycle and a rehabilitation cycle, each with five steps. Nutrition professionals and teams implement the nutrition cycle (Fig. 2). Rehabilitation professionals and teams implement the rehabilitation cycle. Goal setting is based on diagnostic reasoning about the presence and cause of malnutrition and sarcopenia. In addition, rehabilitation and nutrition professionals should work together to achieve rehabilitation and nutrition goals. The nutrition diagnosis of undernutrition, overnutrition/obesity, sarcopenia, and goal setting of body weight and rehabilitation should be implemented collaboratively. Both cycles should be done simultaneously. The physiatrists can conduct both cycles simultaneously.

Diagnostic reasoning in rehabilitation nutrition

Diagnostic reasoning is the thought process that leads to a diagnosis based on symptoms, laboratory findings, and test results [84]. Diagnostic reasoning is a fundamental skill for healthcare professionals, because the correct diagnosis of a condition leads to the appropriate treatment. Inadequate diagnostic reasoning about nutrition status and sarcopenia would cause an inappropriate rehabilitation nutrition. Therefore, proper diagnostic reasoning is required to provide effective rehabilitation nutrition.

The thought process in diagnostic reasoning consists of non-analytic (intuitive) and analytic reasoning and requires taking advantage of them properly. Non-analytic reasoning is a diagnostic method that quickly understands and recognizes disease patterns based on experience. Intuitive, automatic, and fast are the main attributes of this method, and experienced medical professionals often use it appropriately [85]. However, it is susceptible to bias and carries the risk of misdiagnosis. Analytic reasoning is a logical diagnostic method that is time-consuming and requires more resources than the other [86]. Analytic reasoning is often used by novices with limited clinical experience. Balancing both methods without showing bias toward one or the other is important for proper diagnosis.

Among the various nutritional problems, diagnostic reasoning in rehabilitation nutrition is critical in three of them [84]: causes of anorexia, weight loss, and sarcopenia. The causes of anorexia, weight loss, and sarcopenia are not necessarily a single cause, but rather multiple causes. Therefore, analytical reasoning is recommended in these conditions to infer these causes.

Goal setting in rehabilitation nutrition

Goal setting in rehabilitation nutrition is based on SMART, an effective goal setting method to improve goal attainment [87].

This method recommends incorporating five elements: Specific, Measurable, Achievable, Relevant, and Time-Bound [87]. For example, gaining 2 kg of body weight in one month and being able to walk independently indoors with a walking cane in two weeks are considered SMART goals. Goal setting based on SMART affects the rate of goal attainment. In a study of patients

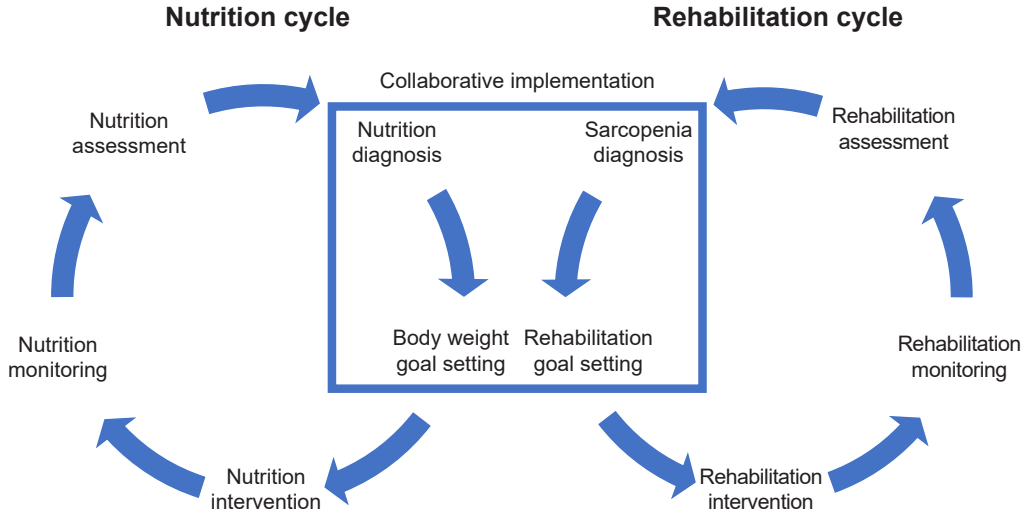

Fig. 2. Simplified rehabilitation nutrition care process.

with stage 3–4 chronic kidney disease, food intake was higher in the SMART goal-setting group than in the non-SMART goal-setting group [88]. Setting weight goals makes rehabilitation nutrition interventions more appropriate, whether to gain weight in underweight patients or to lose weight in overweight patients. In obese patients undergoing cardiac rehabilitation, setting a weight loss goal results in greater weight loss than not setting a goal [89].

Aggressive nutrition therapy

Aggressive nutrition therapy is a nutritional management method for malnutrition [35]. Aggressive nutritional therapy must be combined with active exercise and rehabilitation to increase muscle mass and strength. The target energy intake in this method is defined as the sum of the total energy expenditure and the daily energy accumulation used to gain or lose body weight intentionally. The energy requirements for weight gain in patients with malnutrition and sarcopenia depend on a variety of patient factors, including sex, age, nutrition status, functional status, changes in body composition, contents of exercise, systemic inflammation, and comorbidities.

The energy requirements are set by adding the amount of daily energy accumulation in patients with malnutrition. Older underweight post-stroke patients in convalescent rehabilitation ward require about 9,600 kcal intake to gain 1 kg of body weight [90]. On the other hand, the amount of energy intake is set lower than their actual activity to lose weight in patients with obesity.

The indication and timing of aggressive nutrition therapy depends on the etiology and severity of malnutrition. The efficacy of therapy, side effects, and comorbidities are monitored during the therapy [35]. Aggressive nutritional therapy is planned and implemented based on the four etiologies of the Global Leadership Initiative on Malnutrition criteria (Table 1) [91]. Nutritional intake should be adjusted according to the activity level to prevent malnutrition and maintain physical function and muscle strength in patients with diabetes mellitus. Energy intake and protein are calculated based on kilograms of ideal body weight. Specifically, ≥25–35 kcal/kg of energy intake is recommended according to the level of physical activity, and ≥1.0 g/kg of protein is required per day [66]. Monitoring is necessary during aggressive nutrition therapy because side effects such as hyperglycemia, dyslipidemia, elevated blood urea nitrogen, liver dysfunction, and electrolyte abnormalities may occur. The frequency of monitoring should be weekly rather than monthly for patients in convalescent rehabilitation wards [35]. Determination of whether to continue or modify aggressive nutrition therapy based on monitoring of function, body weight, fat mass, and muscle mass.

Nutritional physical therapy

Nutritional physical therapy was defined by the Nutrition and Swallowing Physical Therapy Committee of the Japanese Physical Therapy Association in September 2017. Nutritional physical therapy is the practice of setting goals based on an understanding of malnutrition, sarcopenia, and excess or deficient nutritional intake to maximize an individual's function, activity, participation, and quality of life. Therefore, physical therapists should share nutrition and physical therapy assessments with registered dietitians and other multidisciplinary professionals to determine nutritional care management and physical therapy

Table 1. Indication/timing/contraindication of aggressive nutrition therapy

No.	Indication	Timing	Contraindication
1	Cancer	Pre cachexia	Refractory cachexia
	Chronic obstructive pulmonary disease	Cachexia	
	Congestive heart failure		
	Chronic kidney disease		
2	Anorexia nervosa	Short bowel syndrome	Severe dementia
	Short bowel syndrome	Mild to moderate dementia	Bedridden
	Stroke		
	Amyotrophic lateral sclerosis		
	Dementia		
3	Major infection	Mildly invasive disease and transition to the anabolic phase	Acute disease or injuries with severe inflammation
	Burns		
	Trauma		
	Closed head injury		
4	Starvation	No symptoms or risks for refeeding syndrome	

that takes into account activity level, muscle tone, and involuntary movements [30].

Nutritional physical therapy overlaps with rehabilitation nutrition, and the two concepts share goals, assessment, and intervention strategies. The practice of these two concepts requires both perspectives [30]: physical therapy that considers nutrition status and nutritional care management that maximizes the effectiveness of physical therapy. Exercise therapy consists of flexibility exercises, resistance training, and aerobic training. Flexibility exercises are prescribed for patients with any nutritional condition. Patients with nutritional deficiencies should receive low-intensity exercise to maintain physical function. In contrast, patients with adequate nutrition should receive moderate or higher intensity exercise to improve physical function. Exercise load settings are determined using subjective exercise intensity (Borg scale) and other factors, and exercise frequency, intensity, and duration are adjusted. Exercise and nutrition therapy are effective, however few reports exist on the effectiveness of nutritional physiotherapy [30]. In addition, systematic clinical practice based on a bi-directional nutrition and physical therapy perspective is limited. Further clinical practice and studies of nutritional physical therapy are needed.

CONCLUSION

Sarcopenic dysphagia reduces swallowing function, ADL and life prognosis. The triad of rehabilitation, nutrition, and oral management may be useful for patients with dysphagia [92]. The triad of rehabilitation, nutrition and oral management requires a multimodal approach based on collaboration among different professions, institutions, and communities. Prevention of whole-body sarcopenia is the priority for sarcopenic dysphagia, and early diagnosis and treatment of sarcopenic dysphagia are essential. However, the use of tools diagnose sarcopenic dysphagia is inconsistent and heterogeneous, and validation against objective measures of swallowing dysfunction is limited [93]. A review of diagnostic criteria and the development of clinical practice guidelines for sarcopenic dysphagia are needed. The development of evidence on the simplified rehabilitation nutrition care process is required.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

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ORCID

Shingo Kakehi, https://orcid.org/0000-0002-6119-1993
Eri Isono, https://orcid.org/0009-0008-8078-3792
Hidetaka Wakabayashi, https://orcid.org/0000-0002-0364-0818
Moeka Shioya, https://orcid.org/0000-0002-9787-3654
Junki Ninomiya, https://orcid.org/0009-0000-7436-6564
Yohei Aoyama, https://orcid.org/0000-0001-6585-7425
Ryoko Murai, https://orcid.org/0009-0004-5639-3357
Yuka Sato, https://orcid.org/0009-0004-4427-3892
Ryohei Takemura, https://orcid.org/0000-0003-0591-1842
Amami Mori, https://orcid.org/0009-0008-4374-7792
Kei Masumura, https://orcid.org/0009-0004-6162-0040
Bunta Suzuki, https://orcid.org/0009-0009-6670-344X

REFERENCES

1. Kitamura A, Seino S, Abe T, Nofuji Y, Yokoyama Y, Amano H, et al. Sarcopenia: prevalence, associated factors, and the risk of mortality and disability in Japanese older adults. J Cachexia Sarcopenia Muscle 2021;12:30-8.
2. United Nations. World population prospects 2022: summary of results [Internet]. United Nations; 2022 [cited 2023 Jun 12]. Available from: https://www.un.org/development/desa/pd/content/World-Population-Prospects-2022.
3. Wen Z, Gu J, Chen R, Wang Q, Ding N, Meng L, et al. Handgrip strength and muscle quality: results from the national health and nutrition examination survey database. J Clin Med 2023;12:3184.
4. Dodds RM, Syddall HE, Cooper R, Kuh D, Cooper C, Sayer AA. Global variation in grip strength: a systematic review and meta-analysis of normative data. Age Ageing 2016;45:209-16.
5. Yamada M, Moriguch Y, Mitani T, Aoyama T, Arai H. Age-depen-

dent changes in skeletal muscle mass and visceral fat area in Japanese adults from 40 to 79 years-of-age. Geriatr Gerontol Int 2014;14 Suppl 1:8-14.
6. Keller K, Engelhardt M. Strength and muscle mass loss with aging process. Age and strength loss. Muscles Ligaments Tendons J 2014;3:346-50.
7. Ho IS, Azcoaga-Lorenzo A, Akbari A, Davies J, Hodgins P, Khunti K, et al. Variation in the estimated prevalence of multimorbidity: systematic review and meta-analysis of 193 international studies. BMJ Open 2022;12:e057017.
8. Prokopidis K, Giannos P, Reginster JY, Bruyere O, Petrovic M, Cherubini A, et al. Sarcopenia is associated with a greater risk of polypharmacy and number of medications: a systematic review and meta-analysis. J Cachexia Sarcopenia Muscle 2023;14:671-83.
9. Cruz-Jentoft AJ, Sayer AA. Sarcopenia. Lancet 2019;393:2636-46. Erratum in: Lancet 2019;393:2590.
10. Cruz-Jentoft AJ, Bahat G, Bauer J, Boirie Y, Bruyère O, Cederholm T, et al. Sarcopenia: revised European consensus on definition and diagnosis. Age Ageing 2019;48:16-31. Erratum in: Age Ageing 2019;48:601.
11. Nagano A, Wakabayashi H, Maeda K, Kokura Y, Miyazaki S, Mori T, et al. Respiratory sarcopenia and sarcopenic respiratory disability: concepts, diagnosis, and treatment. J Nutr Health Aging 2021;25:507-15.
12. Thiyagalingam S, Kulinski AE, Thorsteinsdottir B, Shindelar KL, Takahashi PY. Dysphagia in older adults. Mayo Clin Proc 2021;96:488-97.
13. Fujishima I, Fujiu-Kurachi M, Arai H, Hyodo M, Kagaya H, Maeda K, et al. Sarcopenia and dysphagia: position paper by four professional organizations. Geriatr Gerontol Int 2019;19:91-7.
14. Yamaguchi K, Nakagawa K, Yoshimi K, Ariya C, Nakane A, Ishii M, et al. Association between characteristics of swallowing-related muscles and trunk muscle mass. Sci Rep 2023;13:7814.
15. Nakao Y, Uchiyama Y, Honda K, Yamashita T, Saito S, Domen K. Age-related composition changes in swallowing-related muscles: a Dixon MRI study. Aging Clin Exp Res 2021;33:3205-13.
16. Rech RS, de Goulart BNG, Dos Santos KW, Marcolino MAZ, Hilgert JB. Frequency and associated factors for swallowing impairment in community-dwelling older persons: a systematic review and meta-analysis. Aging Clin Exp Res 2022;34:2945-61.
17. Rajati F, Ahmadi N, Naghibzadeh ZA, Kazeminia M. The global prevalence of oropharyngeal dysphagia in different populations: a systematic review and meta-analysis. J Transl Med 2022;20:175.
18. Tagliaferri S, Lauretani F, Pelá G, Meschi T, Maggio M. The risk of dysphagia is associated with malnutrition and poor functional outcomes in a large population of outpatient older individuals. Clin Nutr 2019;38:2684-9.
19. Blanař V, Hödl M, Lohrmann C, Amir Y, Eglseer D. Dysphagia and factors associated with malnutrition risk: a 5-year multicentre study. J Adv Nurs 2019;75:3566-76.
20. Almirall J, Rofes L, Serra-Prat M, Icart R, Palomera E, Arreola V, et al. Oropharyngeal dysphagia is a risk factor for community-acquired pneumonia in the elderly. Eur Respir J 2013;41:923-8.
21. Patel DA, Krishnaswami S, Steger E, Conover E, Vaezi MF, Ciucci MR, et al. Economic and survival burden of dysphagia among inpatients in the United States. Dis Esophagus 2018;31:1-7.
22. Yang RY, Yang AY, Chen YC, Lee SD, Lee SH, Chen JW. Association between dysphagia and frailty in older adults: a systematic review and meta-analysis. Nutrients 2022;14:1812.
23. Sakai K, Nakayama E, Yoneoka D, Sakata N, Iijima K, Tanaka T, et al. Association of oral function and dysphagia with frailty and sarcopenia in community-dwelling older adults: a systematic review and meta-analysis. Cells 2022;11:2199.
24. Maeda K, Takaki M, Akagi J. Decreased skeletal muscle mass and risk factors of sarcopenic dysphagia: a prospective observational cohort study. J Gerontol A Biol Sci Med Sci 2017;72:1290-4.
25. Wakabayashi H, Kishima M, Itoda M, Fujishima I, Kunieda K, Ohno T, et al. Diagnosis and treatment of sarcopenic dysphagia: a scoping review. Dysphagia 2021;36:523-31.
26. Nagano A, Nishioka S, Wakabayashi H. Rehabilitation nutrition for iatrogenic sarcopenia and sarcopenic dysphagia. J Nutr Health Aging 2019;23:256-65.
27. Wakabayashi H. Rehabilitation nutrition in general and family medicine. J Gen Fam Med 2017;18:153-4.
28. Nishioka S, Aragane H, Suzuki N, Yoshimura Y, Fujiwara D, Mori T, et al. Clinical practice guidelines for rehabilitation nutrition in cerebrovascular disease, hip fracture, cancer, and acute illness: 2020 update. Clin Nutr ESPEN 2021;43:90-103.
29. Wakabayashi H, Yoshimura Y, Maeda K, Fujiwara D, Nishioka S, Nagano A. Goal setting for nutrition and body weight in rehabilitation nutrition: position paper by the Japanese Association of Rehabilitation Nutrition (secondary publication). J Gen Fam Med 2021;23:77-86.
30. Inoue T, Iida Y, Takahashi K, Shirado K, Nagano F, Miyazaki S, et al. Nutrition and physical therapy: a position paper by the physical therapist section of the Japanese Association of Rehabilitation Nutrition (secondary publication). JMA J 2022;5:243-51.
31. Sato S, Miyazaki S, Tamaki A, Yoshimura Y, Arai H, Fujiwara D, et al. Respiratory sarcopenia: a position paper by four professional organizations. Geriatr Gerontol Int 2023;23:5-15.

32. Morisaki N. Relationship between swallowing functions and health-related quality of life among community-dwelling dependent older individuals. Jpn J Nurs Sci 2017;14:353-63.
33. Khanagar SB, Al-Ehaideb A, Shivanna MM, Ul Haq I, Al Kheraif AA, Naik S, et al. Age-related oral changes and their impact on oral health-related quality of life among frail elderly population: a review. J Contemp Dent Pract 2020;21:1298-303.
34. Veronese N, Koyanagi A, Cereda E, Maggi S, Barbagallo M, Dominguez LJ, et al. Sarcopenia reduces quality of life in the long-term: longitudinal analyses from the English longitudinal study of ageing. Eur Geriatr Med 2022;13:633-9.
35. Nakahara S, Takasaki M, Abe S, Kakitani C, Nishioka S, Wakabayashi H, et al. Aggressive nutrition therapy in malnutrition and sarcopenia. Nutrition 2021;84:111109.
36. Wakabayashi H. Presbyphagia and sarcopenic dysphagia: association between aging, sarcopenia, and deglutition disorders. J Frailty Aging 2014;3:97-103.
37. Kokura Y, Nishioka S, Maeda K, Wakabayashi H. Ultrasound utilized by registered dietitians for body composition measurement, nutritional assessment, and nutritional management. Clin Nutr ESPEN 2023;57:173-80.
38. Inamoto Y, González-Fernández M, Saitoh E. 3D-CT evaluation of swallowing: metrics of the swallowing response using swallowing CT. Dysphagia 2022;37:237-49.
39. Nakao Y, Yamashita T, Honda K, Katsuura T, Hama Y, Nakamura Y, et al. Association among age-related tongue muscle abnormality, tongue pressure, and presbyphagia: a 3D MRI study. Dysphagia 2021;36:483-91.
40. Ogawa N, Mori T, Fujishima I, Wakabayashi H, Itoda M, Kunieda K, et al. Ultrasonography to measure swallowing muscle mass and quality in older patients with sarcopenic dysphagia. J Am Med Dir Assoc 2018;19:516-22.
41. Allen JE, Clunie GM, Winiker K. Ultrasound: an emerging modality for the dysphagia assessment toolkit? Curr Opin Otolaryngol Head Neck Surg 2021;29:213-8.
42. Mori T, Fujishima I, Wakabayashi H, Oshima F, Itoda M, Kunieda K, et al. Development, reliability, and validity of a diagnostic algorithm for sarcopenic dysphagia. JCSM Clin Rep 2017;2:1-10.
43. Chen LK, Woo J, Assantachai P, Auyeung TW, Chou MY, Iijima K, et al. Asian Working Group for Sarcopenia: 2019 consensus update on sarcopenia diagnosis and treatment. J Am Med Dir Assoc 2020;21:300-7.e2.
44. Mori T, Wakabayashi H, Ogawa N, Fujishima I, Oshima F, Itoda M, et al. The mass of geniohyoid muscle is associated with maximum tongue pressure and tongue area in patients with sarcopenic dysphagia. J Nutr Health Aging 2021;25:356-60.
45. Machida N, Tohara H, Hara K, Kumakura A, Wakasugi Y, Nakane A, et al. Effects of aging and sarcopenia on tongue pressure and jaw-opening force. Geriatr Gerontol Int 2017;17:295-301.
46. Murakami T, Kamide N, Ando M, Hata W, Sakamoto M. Association between tongue pressure and skeletal muscle mass and muscle function in community-dwelling older people without sarcopenia. Eur Geriatr Med 2022;13:649-53.
47. Shimizu A, Maeda K, Wakabayashi H, Nishioka S, Ohno T, Nomoto A, et al. Sarcopenic dysphagia with low tongue pressure is associated with worsening of swallowing, nutritional status, and activities of daily living. J Nutr Health Aging 2021;25:883-8.
48. Shimizu A, Fujishima I, Maeda K, Wakabayashi H, Nishioka S, Ohno T, et al. Effect of low tongue pressure on nutritional status and improvement of swallowing function in sarcopenic dysphagia. Nutrition 2021;90:111295.
49. Chang KV, Wu WT, Chen LR, Wang HI, Wang TG, Han DS. Suboptimal tongue pressure is associated with risk of malnutrition in community-dwelling older individuals. Nutrients 2021;13:1821.
50. Kunieda K, Fujishima I, Wakabayashi H, Ohno T, Shigematsu T, Itoda M, et al. Relationship between tongue pressure and pharyngeal function assessed using high-resolution manometry in older dysphagia patients with sarcopenia: a pilot study. Dysphagia 2021;36:33-40.
51. Kaji A, Hashimoto Y, Kobayashi Y, Sakai R, Okamura T, Miki A, et al. Sarcopenia is associated with tongue pressure in older patients with type 2 diabetes: a cross-sectional study of the KAMOGAWA-DM cohort study. Geriatr Gerontol Int 2019;19:153-8.
52. Maeda K, Akagi J. Decreased tongue pressure is associated with sarcopenia and sarcopenic dysphagia in the elderly. Dysphagia 2015;30:80-7. Erratum in: Dysphagia 2015;30:88.
53. Kishimoto H, Wakabayashi H, Nishioka S, Momosaki R. Discriminative evaluation of sarcopenic dysphagia using handgrip strength or calf circumference in patients with dysphagia using the area under the receiver operating characteristic curve. J Clin Med 2022;12:118.
54. Togashi S, Wakabayashi H, Ohinata H, Nishioka S, Kokura Y, Momosaki R. Sensitivity and specificity of body mass index for sarcopenic dysphagia diagnosis among patients with dysphagia: a multi-center cross-sectional study. Nutrients 2022;14:4494.
55. Moncayo-Hernández BA, Herrera-Guerrero JA, Vinazco S, Ocampo-Chaparro JM, Reyes-Ortiz CA. Sarcopenic dysphagia in institutionalised older adults. Endocrinol Diabetes Nutr (Engl Ed) 2021;68:602-11.
56. Wakabayashi H, Takahashi R, Murakami T. The prevalence and

prognosis of sarcopenic dysphagia in patients who require dysphagia rehabilitation. J Nutr Health Aging 2019;23:84-8.
57. Miyauchi N, Nakamura M, Nakamura I, Momosaki R. Effect of early versus delayed mobilization by physical therapists on oral intake in patients with sarcopenic dysphagia after pneumonia. Eur Geriatr Med 2019;10:603-7.
58. Nagano A, Maeda K, Shimizu A, Nagami S, Takigawa N, Ueshima J, et al. Association of sarcopenic dysphagia with underlying sarcopenia following hip fracture surgery in older women. Nutrients 2020;12:1365.
59. Maeda K, Ishida Y, Nonogaki T, Shimizu A, Yamanaka Y, Matsuyama R, et al. Development and predictors of sarcopenic dysphagia during hospitalization of older adults. Nutrients 2019;12:70.
60. Nagai T, Wakabayashi H, Nishioka S, Momosaki R. Functional prognosis in patients with sarcopenic dysphagia: an observational cohort study from the Japanese sarcopenic dysphagia database. Geriatr Gerontol Int 2022;22:839-45.
61. Abe S, Kokura Y, Maeda K, Nishioka S, Momosaki R, Matsuoka H, et al. Effects of undernutrition on swallowing function and activities of daily living in hospitalized patients: data from the Japanese Sarcopenic Dysphagia Database. Nutrients 2023;15:1291.
62. Campo-Rivera N, Ocampo-Chaparro JM, Carvajal-Ortiz R, Reyes-Ortiz CA. Sarcopenic dysphagia is associated with mortality in institutionalized older adults. J Am Med Dir Assoc 2022;23:1720.e11-7.
63. Nishioka S, Wakabayashi H. Interaction between malnutrition and physical disability in older adults: is there a malnutrition-disability cycle? Nutr Rev 2023;81:191-205.
64. Mori T, Wakabayashi H, Kishima M, Itoda M, Fujishima I, Kunieda K, et al. Association between inflammation and functional outcome in patients with sarcopenic dysphagia. J Nutr Health Aging 2022;26:400-6.
65. Nishioka S, Nakahara S, Takasaki M, Shiohama N, Kokura Y, Suzuki T, et al. The concept of aggressive nutrition therapy and clinical indication: a position paper. Clin Nutr ESPEN 2022;52:322-30.
66. Shimizu A, Fujishima I, Maeda K, Wakabayashi H, Nishioka S, Ohno T, et al. Nutritional management enhances the recovery of swallowing ability in older patients with sarcopenic dysphagia. Nutrients 2021;13:596.
67. Kagaya H, Inamoto Y. Possible rehabilitation procedures to treat sarcopenic dysphagia. Nutrients 2022;14:778.
68. Nagano A, Maeda K, Koike M, Murotani K, Ueshima J, Shimizu A, et al. Effects of physical rehabilitation and nutritional intake management on improvement in tongue strength in sarcopenic patients. Nutrients 2020;12:3104.
69. Wakabayashi H. Hospital-associated sarcopenia, acute sarcopenia, and iatrogenic sarcopenia: prevention of sarcopenia during hospitalization. J Gen Fam Med 2023;24:146-7.
70. Feng HY, Zhang PP, Wang XW. Presbyphagia: dysphagia in the elderly. World J Clin Cases 2023;11:2363-73.
71. Yiğman ZA, Umay E, Cankurtaran D, Güzel Ş. Swallowing difficulty in the older adults: presbyphagia or dysphagia with sarcopenia? Int J Rehabil Res 2021;44:336-42.
72. Labeit B, Muhle P, von Itter J, Slavik J, Wollbrink A, Sporns P, et al. Clinical determinants and neural correlates of presbyphagia in community-dwelling older adults. Front Aging Neurosci 2022;14:912691.
73. Nienstedt JC, Müller F, Rösler A, Pflug C. Presbyphagia diagnostics using M-mode ultrasound: changes in the tongue movement pattern. Dysphagia 2020;35:696-701.
74. Namasivayam-MacDonald AM, Riquelme LF. Presbyphagia to dysphagia: multiple perspectives and strategies for quality care of older adults. Semin Speech Lang 2019;40:227-42.
75. de Lima Alvarenga EH, Dall'Oglio GP, Murano EZ, Abrahão M. Continuum theory: presbyphagia to dysphagia? Functional assessment of swallowing in the elderly. Eur Arch Otorhinolaryngol 2018;275:443-9.
76. Schindler A, Mozzanica F, Monzani A, Ceriani E, Atac M, Jukic-Peladic N, et al. Reliability and validity of the Italian Eating Assessment Tool. Ann Otol Rhinol Laryngol 2013;122:717-24.
77. Cheney DM, Siddiqui MT, Litts JK, Kuhn MA, Belafsky PC. The ability of the 10-Item Eating Assessment Tool (EAT-10) to predict aspiration risk in persons with dysphagia. Ann Otol Rhinol Laryngol 2015;124:351-4.
78. Wakabayashi H, Matsushima M. Dysphagia assessed by the 10-Item Eating Assessment Tool is associated with nutritional status and activities of daily living in elderly individuals requiring long-term care. J Nutr Health Aging 2016;20:22-7.
79. Izaola O, Gómez Hoyos E, López JJ, Ortola A, Torres B, Primo D, et al. The 10-Item Eating Assessment Tool is associated with nutritional status, mortality and hospital stay in elderly individuals requiring hospitalization with acute diseases. Nutr Hosp 2018;35:827-32.
80. Igarashi K, Kikutani T, Tamura F. Survey of suspected dysphagia prevalence in home-dwelling older people using the 10-Item Eating Assessment Tool (EAT-10). PLoS One 2019;14:e0211040.
81. Ko D, Oh J, Joo S, Park JY, Cho MS. Dietary habits, food product selection attributes, nutritional status, and depression in middle-aged and older adults with dysphagia. Nutrients 2022;14:4045.
82. Mizuno S, Wakabayashi H, Wada F. Rehabilitation nutrition for individuals with frailty, disability, sarcopenic dysphagia, or sarcopenic

respiratory disability. Curr Opin Clin Nutr Metab Care 2022;25:29-36.
83. Wakabayashi H. Positive psychology and rehabilitation nutrition. J Gen Fam Med 2022;23:293-94.
84. Wakabayashi H, Maeda K, Momosaki R, Kokura Y, Yoshimura Y, Fujiwara D, et al. Diagnostic reasoning in rehabilitation nutrition: position paper by the Japanese Association of Rehabilitation Nutrition (secondary publication). J Gen Fam Med 2022;23:205-16.
85. Brush JE Jr, Sherbino J, Norman GR. How expert clinicians intuitively recognize a medical diagnosis. Am J Med 2017;130:629-34.
86. Corazza GR, Lenti MV, Howdle PD. Diagnostic reasoning in internal medicine: a practical reappraisal. Intern Emerg Med 2021;16:273-9.
87. Bovend'Eerdt TJ, Botell RE, Wade DT. Writing SMART rehabilitation goals and achieving goal attainment scaling: a practical guide. Clin Rehabil 2009;23:352-61. Erratum in: Clin Rehabil 2010;24:382.
88. Chan CH, Conley M, Reeves MM, Campbell KL, Kelly JT. Evaluating the impact of goal setting on improving diet quality in chronic kidney disease. Front Nutr 2021;8:627753.
89. Barrett KV, Savage PD, Ades PA. Effects of behavioral weight loss and weight loss goal setting in cardiac rehabilitation. J Cardiopulm Rehabil Prev 2020;40:383-7.
90. Yoshimura Y, Wakabayashi H, Momosaki R, Nagano F, Bise T, Shimazu S, et al. Stored energy increases body weight and skeletal muscle mass in older, underweight patients after stroke. Nutrients 2021;13:3274.
91. Cederholm T, Jensen GL, Correia MITD, Gonzalez MC, Fukushima R, Higashiguchi T, et al. GLIM criteria for the diagnosis of malnutrition - a consensus report from the global clinical nutrition community. J Cachexia Sarcopenia Muscle 2019;10:207-17.
92. Wakabayashi H, Kakehi S, Kishima M, Itoda M, Nishioka S, Momosaki R. Impact of registered dietitian and dental hygienist involvement on functional outcomes in patients with dysphagia: triad of rehabilitation, nutrition, and oral management. Eur Geriatr Med 2023. doi: 10.1007/s41999-023-00833-7 [Epub ahead of print].
93. Abu-Ghanem S, Graf A, Govind J. Diagnosis of sarcopenic dysphagia in the elderly: critical review and future perspectives. Dysphagia 2022;37:1093-102.

Review Article

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E-Health Interventions for Older Adults With Frailty: A Systematic Review

Hyeong-Wook Han, MD[1], Si-Woon Park, MD[1], Doo Young Kim, MD[1], Bum-Suk Lee, MD[1], Daham Kim, MD[1], Namo Jeon, MD[1], Yun-Jung Yang, PhD[2]

[1]*Department of Rehabilitation Medicine, International St Mary's Hospital, Catholic Kwandong University College of Medicine, Incheon, Korea*
[2]*Department of Convergence Science, International St Mary's Hospital, Catholic Kwandong University College of Medicine, Incheon, Korea*

Objective: To systematically review the efficacy of e-Health interventions on physical performance, activity and quality of life in older adults with sarcopenia or frailty.
Methods: A systematic review was conducted by searching the MEDLINE, Embase, Cochrane Library, CINHAL, Web of Science, and the Physiotherapy Evidence Database for experimental studies published in English from 1990 to 2021. E-Health studies investigating physical activity, physical performance, quality of life, and activity of daily living assessment in adults aged ≥65 years with sarcopenia or frailty were selected.
Results: Among the 3,164 identified articles screened, a total of 4 studies complied with the inclusion criteria. The studies were heterogeneous by participant characteristics, type of e-Health intervention, and outcome measurement. Age criteria for participant selection and sex distribution were different between studies. Each study used different criteria for frailty, and no study used sarcopenia as a selection criteria. E-Health interventions were various across studies. Two studies used frailty status as an outcome measure and showed conflicting results. Muscle strength was assessed in 2 studies, and meta-analysis showed statistically significant improvement after intervention (standardized mean difference, 0.51; 95% confidence interval, 0.07–0.94; p=0.80, I^2=0%).
Conclusion: This systematic review found insufficient evidence to support the efficacy of e-Health interventions. Nevertheless, the studies included in this review showed positive effects of e-Health interventions on improving muscle strength, physical activity, and quality of life in older adults with frailty.

Keywords: Telemedicine, Frailty, Exercise, Aged, Muscle strength

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Correspondence:
Si-Woon Park
Department of Rehabilitation Medicine, International St Mary's Hospital, Catholic Kwandong University College of Medicine, 25 Simgok-ro 100beon-gil, Seo-gu, Incheon, 22711, Korea.
Tel: +82-32-290-3114
Fax: +82-32-290-3120
E-mail: seanpark05@gmail.com

INTRODUCTION

Frailty and sarcopenia are critical topics in geriatric healthcare. These two conditions are major contributors to the decline in health and function in older adults. Frailty represents a vulnerability resulting from a decline in physical, cognitive, and social functioning, which makes it difficult to maintain healthy aging. Frailty is diagnosed as positive when three or more of the following five criteria are met: unintentional weight loss, self-reported exhaustion, weakness, slow walking speed, and low physical activity level. This vulnerability increases the likelihood of hospitalization due to events such as infections, acute illnesses,

and traffic accidents and prolongs recovery periods after acute illnesses [1].

Sarcopenia, a problem resulting from a loss of muscle mass and function, also impairs functional ability and reduces quality of life (QoL) in older adults. The European Working Group on Sarcopenia in Older People 2 defines sarcopenia primarily by low muscle strength in handgrip strength (cut-off points for male<27 kg and female<16 kg) and chair stand (cut-off points; >15 seconds for five rises). To confirm the diagnosis of sarcopenia, low muscle quantity or quality is required as measured by magnetic resonance imaging, computed tomography, or dual-energy X-ray absorptiometry. Severe sarcopenia is identified by concurrent low muscle strength, quantity/quality, and reduced physical performance, as assessed by tests such as the Short Physical Performance Battery, gait speed, the 400 m walk test, or the Timed Up and Go Test [2]. It makes it difficult for older adults to perform daily activities and increases the risk of mobility impairment and falls. Additionally, sarcopenia is associated with metabolic disorders, cardiovascular diseases, and Alzheimer's disease, which increases the risk of developing such diseases [3].

Therefore, preventing and managing frailty and sarcopenia in geriatric healthcare is essential. This requires the use of various approaches, such as physical activity, nutrition, cognitive and social engagement, to maintain and improve older adults' health and function. Regular health checkups are also necessary to continually manage older adults' health [4].

The use of e-Health interventions in healthcare has become increasingly popular over the years. E-Health interventions refer to the use of digital technologies such as mobile apps, websites, wearable devices, and telemedicine to provide healthcare services remotely [5]. In the context of older adults with sarcopenia or frailty, e-Health interventions have the potential to address several challenges, including access to healthcare services, physical limitations, and social isolation [6]. However, older adults with sarcopenia or frailty may have difficulties participating in traditional exercise programs due to physical limitations, mobility issues, or a lack of access to resources. E-Health interventions can potentially address some of these barriers by providing personalized and adaptable exercise programs, remote monitoring and support, and social connections through virtual communities.

So, our study hypothesis is that e-Health interventions have the potential to increase physical activity and performance in older adults with sarcopenia or frailty. Previous studies suggest that e-Health could potentially improve rehabilitation outcomes for the elderly [7]. Various e-Health have shown a significant overall positive effect on strength and physical fitness in the elderly. However, the efficacy of e-Health on strength and physical fitness in the elderly with sarcopenia or frailty has not been established. This study aimed to systematically review the efficacy of e-Health interventions on physical performance, activity, and QoL in older adults with sarcopenia or frailty.

METHODS

Protocol and registration

The protocol for this systematic review was registered in PROSPERO (https://www.crd.york.ac.uk/PROSPERO). The registration number is CRD42022315152. This systematic review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA 2020) statement guidelines. The completed PRISMA 2020 checklist is shown in Supplementary Materials S1 and S2.

Criteria for this review (PICO)

(1) Participants (P): Aged population (over 65) with sarcopenia OR muscle atrophy OR frailty.
(2) Intervention (I): E-Health OR telemedicine OR web-based intervention.
(3) Comparison (C): No intervention.
(4) Outcomes (O): Main outcomes: physical activity, physical performance. Additional outcomes: health-related QoL, activity of daily living.

Criteria for considering the studies in this review

We included randomized controlled trials (RCTs) of the effects of e-Health on the elderly population (over 65) with sarcopenia, muscle atrophy, or frailty published in English. The types of interventions are e-Health, telemedicine, or web-based interventions. The types of comparators are no intervention. Exclusion criteria included: (1) full text is not available; (2) literatures includes diseases other than sarcopenia or frailty; (3) literatures does not include outcome parameters; and (4) duplicate publications.

Search strategies and data resources

We searched the MEDLINE, Embase, Cochrane Library, CINHAL, Web of Science, and the Physiotherapy Evidence Database (PEDro) for experimental studies published in English

from 1990 to 2021, to obtain RCTs that studied the efficacy of e-Health for older adults with frailty or sarcopenia. The following key search terms were used: "Frailty," "muscle atrophy," and "sarcopenia." The full search strategies, which were tailored according to the characteristics of the databases mentioned previously, are listed in Supplementary Material S3. We then manually searched the gray literature, reference lists of identified studies, MEDLINE, Embase, CINHAL, Web of Science, and PEDro for eligible RCTs.

Reviewing procedure and study selection

Two reviewers independently identified eligible studies according to inclusion and exclusion criteria. After removing duplicates, primary selection was performed based on titles and abstracts. Then, titles, abstracts, and potentially relevant full texts were thoroughly reviewed according to eligible criteria by six reviewers, and any disagreements were resolved by discussion. (1) Study population must be geriatric patients (defined as above 65 years old). (2) Study must have implemented a method for randomization. (3) Study must include outcome measures of muscle mass or functional outcome.

Data extraction

Data extraction was performed in the inclusion study. Data were extracted by two reviewers, including study design, participants, intervention type, outcome measures, and results. A cross-check was performed to ensure no mistakes.

Methodological quality assessment

Two reviewers independently assessed the risk of bias of each included study by using the revised Cochrane risk of bias tool for individually randomized trials. Discrepancies were resolved through a team discussion.

Data synthesis and analysis

We presented results as an effect with a standardized mean difference (SMD), and 95% confidence interval (95% CI) for continuous data and an odds ratio (OR), and 95% CI for binary data. Egger's test was performed to check for publication bias. The heterogeneity across studies was assessed using Cochrane's Q-test and I^2-statistic. The random effects model was used for the meta-analysis. Meta-analysis was performed using Stata/MP version 16 (StataCorp LLC).

RESULTS

Literature flow

Overall, 3,164 publications were identified, and after the exclusion of duplicates, 3,002 articles remained. Of these, 2,951 were excluded, leaving 51 publications for potential inclusion. Of these, after applying the eligibility criteria, 47 were selected for full-text reading, after which a total of 4 articles were selected (Fig. 1). We could not find any studies related to sarcopenia, and studies related to frailty were included in this review.

Study characteristics

Table 1 summarizes the characteristics and main results of the 4 articles. Across all studies, the minimum age was 60 years, and the earliest year of data collection was 2007 [8-11].

Participants

In total, 380 paticipants were enrolled in the included studies, 187 in the intervention group (IG) and 193 in the control group (CG). Two studies recruited only male or female participants. Peterson et al. [8] recruited participants aged 70 and over (age, 78.4±4.9 years), and eighty-one elderly male veterans were

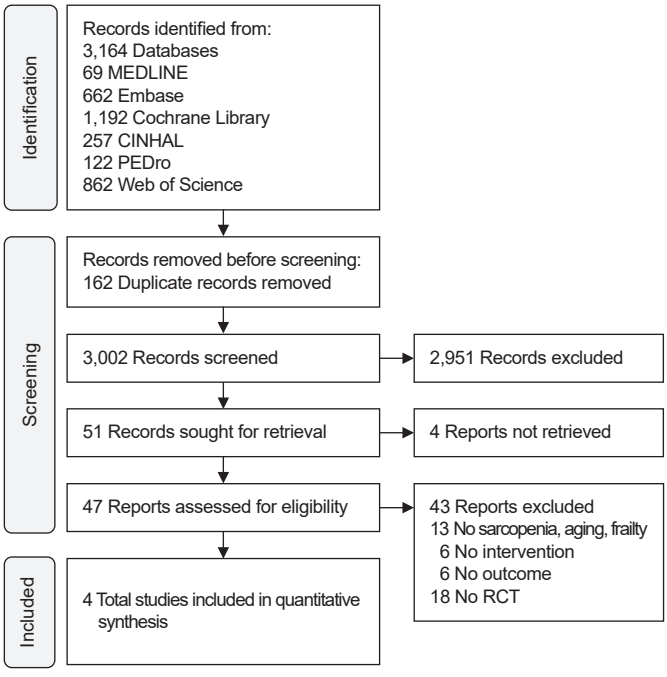

Fig. 1. PRISMA flow diagram. PEDro, Physiotherapy Evidence Database; RCT, randomized controlled trial.

Table 1. Characteristics and main results of the studies

Study	Participants (IG/CG) sample	Interventions	Outcome measures	Results
Peterson et al., 2007 [8]	N=81 (39/42) Male veterans, ages 70 and over Mean age: 78.4±4.9 yr	Telephone exercise counseling : follow-up telephone calls biweekly for 3 months and once a month for the remaining 3 months	Physical activity Physical performance Frailty status	In the IG, the proportion of frail was reduced by 18% over 6 months
Vestergaard et al., 2008 [9]	N=61 (30/31) Frail female≥75 yr IG mean age: 81.0±3.3 yr CG mean age: 82.7±3.8 yr	Home-based video exercise intervention : three times a week, for five months, 60 exercise sessions	Hand-grip strength (kg) Functional ability measurements Physical performance test EQ-5D (score)	Significant improvements in handgrip strength by 17.1% in the IG Significant difference in the changes observed in the IG and CG in EQ-5D
Upatising et al., 2013 [10]	N=205 (102/103) Aged 60 years or older with an ERA score of 16 or higher Mean age: 80.4±8.3 yr	Telemonitoring case management : for 12 months follow-up	Fried frailty criteria	No significant increase in functional decline during the first six months (OR, 1.41; 95% CI, 0.65–3.06; p=0.38) and the latter six months (OR, 5.94; 95% CI, 0.52–68.48; p=0.15)
Kwan et al., 2020 [11]	N=33 (16/17) Age ≥60 years, having cognitive frailty, and having physical inactivity Mean age: 71.0±9 yr	mHealth Intervention : The total intervention period lasted for 12 weeks	Hand-grip strength (kg) MVPA time (min/wk)	Handgrip strength: improvement was significant in the IGs (p=0.009). MVPA time (median difference 86 min/wk, p=0.04; median difference 18.5 min/valid day, p=0.02) increased significantly after the intervention in the IG only

Values are presented as mean±standard deviation.
IG, intervention group; CG, control group; EQ-5D, EuroQol five-dimension scale questionnaire; ERA, Elder Risk Assessment; OR, odds ratio; 95% CI, 95% confidence interval; MVPA, Moderate to Vigorous Physical Activity.

randomized to intervention (n=39) or combined CGs (n=42). In the study of Vestergaard et al. [9], community-dwelling frail female≥75 years old, receiving public home care were randomized into a training group (n=30, age, 81.0±3.3 years) and a CG (n=31, age, 82.7±3.8 years). Other studies recruited both sexes. Upatising et al. [10] enrolled 205 adults aged 60 years or older (n=205, age, 80.4±8.3 years) with a high risk of hospitalization and emergency department visits (Elder Risk Assessment score of 16 or higher). Kwan et al. [11] recruited 33 adults aged ≥60 years (n=33, age, 71.0±9 years) with cognitive frailty and physical inactivity.

Interventions

The e-Health interventions used in the selected articles were telephone exercise counseling, home-based video exercise intervention, telemonitoring case management, and mobile health (mhealth) intervention (i.e., smartphone-assisted programs using WhatsApp [Meta Platforms] and Samsung Health [Samsung Electronics]). The detailed interventions of each article are as follows. In the study of Peterson et al. [8], date, length, and specific exercise data for contact with the health care counselor were collected at the time of the call and recorded into the database. The health counselor followed up with phone calls once a month for the first three months and twice a week for the next three. Vestergaard et al. [9] provided all participants in the IG with a 30-minute video tape showing a booklet describing them, exercises, and an elastic resistance band. The IG exercised at home for 26 minutes, three times a week, for five months. In Upatising et al. [10], the telemonitoring process entailed installing the Intel® health guide, in addition to other peripheral devices, within the patient's residence and establishing a connection to the healthcare system through a broadband network. The primary outcome at 6 months compared with baseline and at 12 months compared with 6 months. Kwan et al. [11] used a mobile phone application. Samsung Health is a physical activity autotracking app, and it continuously and autonomously monitors the walking patterns (e.g., steps, walking speed, walking time, physical activity intensity) of the users. The total duration

of the intervention as a whole was 12 weeks.

Risk of bias assessment

According to the Cochrane risk of bias tool, all studies had a high risk of bias in the blinding of participants and personnel. One study had an unclear risk of bias in the allocation concealment. Half of the studies were had a risk of blinding of outcome assessment. All other bias categories had low risk of bias (Fig. 2).

Main outcome

Physical activity

Kwan et al. [11] examined physical activity with the Physical Activity Scale of Elderly and Moderate to Vigorous Physical Activity (MVPA) time (min/week) analysing 16 participants in the IG and 17 participants in the CG. In this study, MVPA time (median difference 86 min/week, p=0.04; median difference 18.5 min/valid day, p=0.02) significantly increased after the intervention in the IG only.

Physical performance

Vestergaard et al. [9] and Kwan et al. [11] examined physical performance with walking speed analysing 38 participants in the IG and 39 participants in the CG. In Vestergaard et al. [9], the IG significantly improved maximum walking speed by 8.2% (p=0.049), whereas the CG showed a significantly improved maximum walking speed of 7.4% (p=0.038).

Vestergaard et al. [9] and Kwan et al. [11] examined physical performance with hand grip strength (kg) analysing 40 participants in the IG and 43 participants in the CG. Within-group analysis showed significant improvements in handgrip strength by 17.1% in the IG, whereas no improvement was observed in the CG [9]. The forest plot showed that IG groups showed improvement after intervention, and no heterogeneity was noted (SMD, 0.51; 95% CI, 0.07–0.94; p=0.80, I^2=0%; Fig. 3).

For both of the above outcomes, the publication bias could not be analyzed because there were two papers to be analyzed.

Frailty status

Peterson et al. [8] and Upatising et al. [10] examined frailty status with Fried frailty criteria analysing 68 participants in the IG and 81 participants in the CG. Peterson et al. [8] found that almost 70% of the participants were frail at baseline. In the IG, the proportion of frailty was reduced by 18% over 6 months, whereas there was no change in proportion over time in the CG. Upatising et al. [10] did not provide sufficient evidence to show that the telemonitoring group did better than usual care in decreasing the decline of frailty states and death. The forest plot showed that both groups had similar values (OR, 0.80; 95% CI, 0.26–2.53; p=0.04; I^2=77.39%). A publication bias was observed (Egger's test, p=0.035; Fig. 4).

Additional outcome

QoL

Vestergaard et al. [9] examined QoL with EuroQol five-dimension scale questionnaire (EQ-5D), EQ visual analogue scale score, and S-R health analysing 24 participants in the IG and 27 participants in the CG. In this study, using an exercise video induced lasting health-related QoL (EQ-5D). In addition, im-

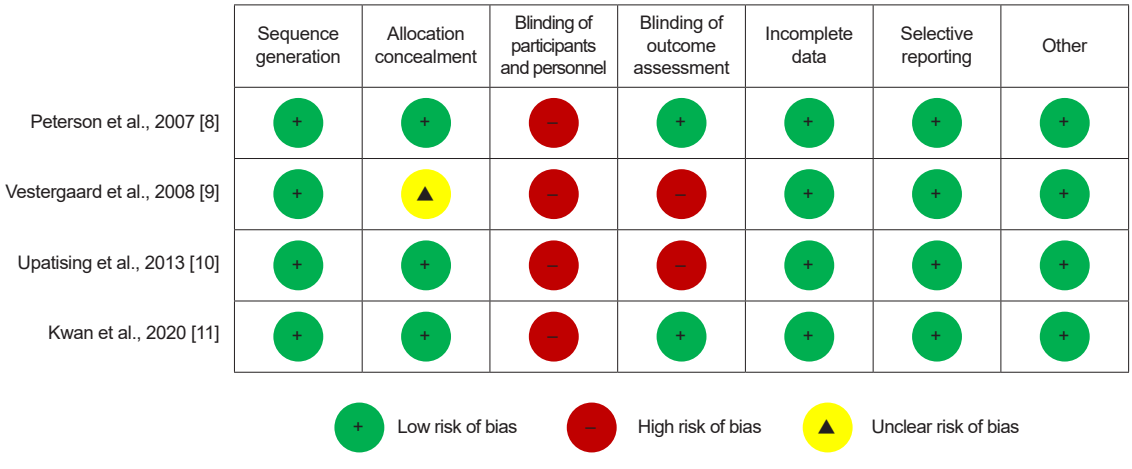

Fig. 2. The Cochrane Collaboration's tool for assessing the risk of bias in the included studies.

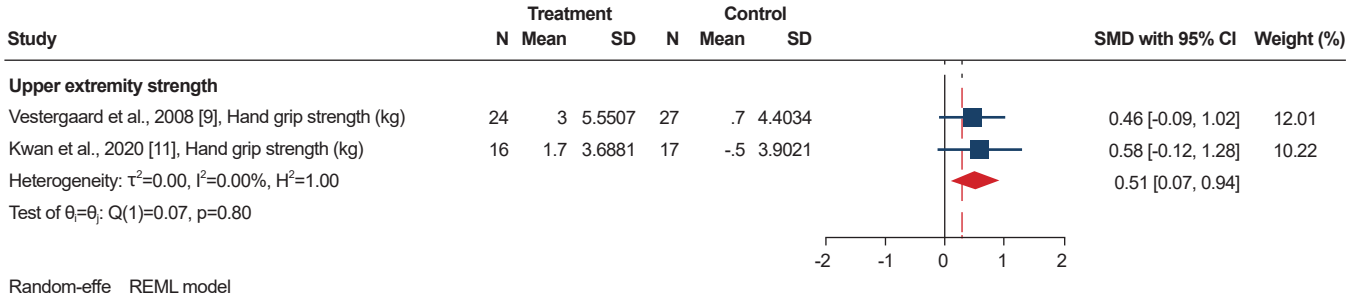

Fig. 3. Forest plot for upper extremity strength. SD, standard deviation; SMD, standardized mean difference; 95% CI, 95% confidence interval.

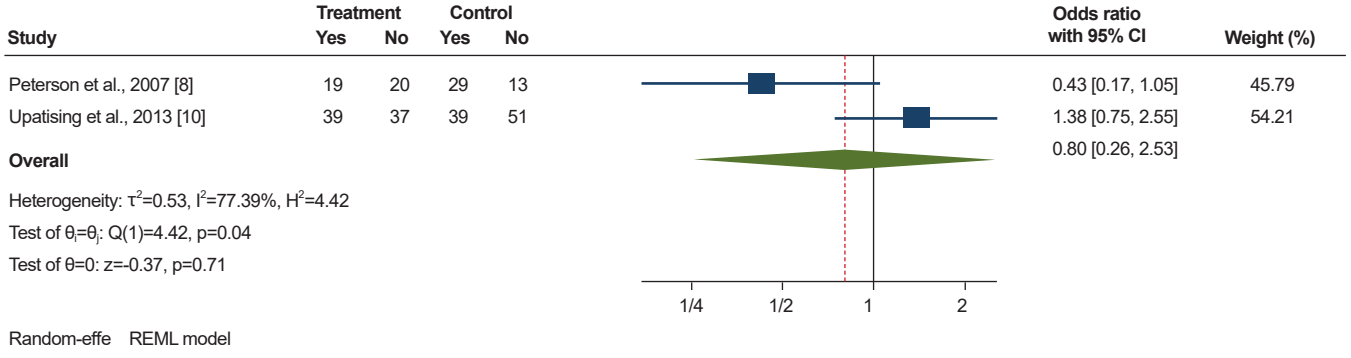

Fig. 4. Forest plot for frailty status. 95% CI, 95% confidence interval.

provements in physiological performance and functional capacity were generally observed [9].

DISCUSSION

In this systematic review and meta-analysis, we originally attempted to review RCTs of e-Health interventions for sarcopenia but could not find any. As a result, studies on frailty were included in the analysis, and we found insufficient evidence to support or oppose the efficacy of e-Health interventions on outcomes. Nevertheless, the studies included in this review showed positive effects of e-Health interventions on improving muscle strength, QoL, and physical activity in older adults with frailty or high risk. Two studies used frailty status as an outcome measure and showed conflicting results. Muscle strength was assessed in two studies, and a meta-analysis showed statistically significant improvement after intervention. Individual studies reported significant improvements in QoL and physical activity.

In another systematic review published recently, Esfandiari et al. [12] analyzed the effect of e-Health interventions on function and QoL for older adults with frailty. They analyzed data from 12 RCTs and found low evidence of benefits for telehealth interventions on function and the mental component of QoL. The effect of mHealth app interventions on sedentary time, physical activity and fitness in older adults (aged 55 years and older) was investigated in another systematic review by Yerrakalva et al. [13]. The review included six studies and found that mHealth app interventions may be effective in reducing sedentary time, increasing physical activity and improving fitness in the short term, but the results did not have a statistical significance. These reviews included more studies than ours due to different selection criteria, but their conclusions are consistent with ours.

The e-Health interventions used in the studies included in our review were various and not standardized. Earlier studies used only telephones [8] and videotapes [9] to encourage exercise. Upatising et al. [10] utilized broadband-based telemonitoring in addition to personal visits. Kwan et al. [11] introduced mobile technology to monitor and encourage exercise and give

feedback. E-Health interventions can offer several strategies to encourage physical activity, including tailored exercise programs, virtual coaching and feedback, monitoring and tracking, social support, and gamification techniques, which have shown promise in improving physical activity levels in older adults. However, these advantages were not fully adopted in any of the studies included in this review [14,15]. This calls for future research.

The most notable e-Health intervention among the studies in this review is the one conducted by Kwan et al. [11] According to Kwan et al. [11], older adults' levels of physical activity have increased by using mHealth activities. When considering the advantages of using a mobile phone over other forms of telerehabilitation, several key points emerge. Mobile phones have become ubiquitous, and a significant portion of the population owns smartphones and utilizes health-related applications. This widespread adoption of mobile technology makes it a convenient and accessible platform for delivering telerehabilitation services. And mobile phones offer a versatile and portable solution, enabling individuals to access therapy services anytime and anywhere, provided they have an internet connection. This flexibility promotes continuity of care and empowers patients to engage in rehabilitation exercises and activities conveniently. Moreover, mobile phones can support a range of multimedia capabilities, such as audio and visual communication, which are vital for effective telerehabilitation. Lastly, the use of mobile phones for telerehabilitation allows for personalized interactions and interventions through applications designed for healthcare professionals, medical students, patients, and the general public. These applications can provide tailored exercise programs, reminders, progress tracking, and educational resources, enhancing patient engagement and adherence to treatment plans. Their benefits, particularly in telerehabilitation, make them a powerful tool for delivering accessible, convenient, and personalized rehabilitation services.

The efficacy of e-Health in different populations has been reported by several studies. In one study, the effectiveness of a smartphone-based home care model for increasing the use of cardiac rehabilitation in myocardial infarction patients was evaluated. The study found that patients who used the smartphone-based home care model were more likely to complete their cardiac rehabilitation program and had better adherence to medication and lifestyle changes compared to those who received standard care. The study suggests that smartphone-based home care models may be a useful tool for improving the management of post-myocardial infarction patients [16]. Another study reported a pilot pragmatic RCT that evaluated how a mhealth app affected physical fitness and functional movement. Healthy male and female between the ages of 18 and 50 who could read and write English and who had a mobile phone that could download apps from the Apple App Store or Google Play Store were eligible to participate in the study. They were randomized to either an IG that utilized a mhealth app to track and monitor their physical activity or a CG that received standard care. According to the study, the IG significantly improved over the CG in functional movement and physical fitness. The authors conclude that the use of a mhealth app may be a useful tool for improving physical activity levels and functional movement in individuals [17]. Also, efficacy in a healthy geriatric population has been reported in several studies. Recent systematic reviews have demonstrated that eHealth interventions are successful at motivating elderly people (age>50 years) to exercise [18]. A healthy lifestyle is essential for reducing the prevalence of morbidity, functional restrictions, and impairment in older adults [19,20], increasing life expectancy, and enhancing overall QoL [21-23].

E-Health interventions are gaining more attention and importance, especially in the current post-pandemic era. A systematic review demonstrated the efficacy of telerehabilitation for patients experiencing disability due to coronavirus disease 2019 (COVID-19). The article's key message was that physical activity should be given to those who have limited mobility as a result of isolation or lockdown in order to decrease their risk of developing frailty, sarcopenia, cognitive decline, and depression [24]. A clinical trial included in the systematic review introduced a telerehabilitation program in which the participants used either an internet-based platform or an application installed on their mobile phones. The platform allowed the physical therapist to adjust the number of sets, repetitions, speed, and observations for each patient. Therapeutic exercises were delivered in the form of an educational video with a detailed description. Through educational movies, the therapeutic education recommendations were explained to the patients, giving them health and emotional advice on how to improve their QoL after COVID-19. They reported that telerehabilitation led to a clinical improvement in QoL, particularly in the physical component [25]. These interventions can provide individuals with access to rehabilitation programs in the comfort of their own homes. E-Health interventions can be a useful alternative for improving frailty and sarcopenia in older adults, particularly

during times of restricted mobility. In the future, the increased utilization of these interventions has the potential to enhance accessibility to rehabilitation programs for individuals in the convenience of their own homes, thereby improving their ability to maintain function and independence as they age. In one study [26], for hospitalized frail patients, the "VIVIFRAIL" multicomponent physical activity program was introduced [27]. This program consists of functional unsupervised exercises as well as supervised progressive resistance, balance, and walking exercises. Through the use of e-Health, patients can have access to such exercise programs and other healthcare services from the comfort of their homes, and the barriers to care for those who may have transportation or mobility issues or who live far away from specialists or clinics can be reduced. Additionally, e-Health can provide cost savings and convenience for both patients and healthcare providers [28]. By integrating exercise programs into e-Health platforms, patients can receive personalized exercise plans and have their progress monitored remotely by healthcare professionals, improving overall healthcare outcomes.

E-Health interventions can also be adopted for monitoring various aspects of patient information, such as nutrition and sleep quality, in addition to physical activities, for the purpose of improving frailty in older adults. E-Health can facilitate remote assessment and monitoring in multiple ways, provide personalized exercise programs, and offer virtual coaching and feedback [29]. The development of frailty in older persons is influenced by a number of significant modifiable factors, including nutrition [30]. And poor subjective sleep quality, various sleep symptoms, and longer sleep duration were found to increase the risk of frailty and even pre-frailty in an elderly population aged 70 to 84 years [31]. To manage these problems, an e-Health platform could provide information and resources on nutrition or sleep quality. One study showed a technique was developed and validated to assess pre-frailty risk in human activity patterns based on multimodal biomarkers, such as sleep duration, daily steps, and resting heart rate, collected from smartwatch sensors. specialized care. So, it could monitor sleep quality and provide feedback on how to improve sleep habits, which may help reduce the risk of frailty [32]. Additionally, researchers and practitioners can use motion sensors mounted on the upper limbs (i.e., lower arm/ wrist, upper arm) to evaluate dietary intake and eating behavior in both laboratory and free-living conditions by using wearable sensing technology (e.g., commercial inertial sensors, fitness bands, and smart watches) [33]. To know what kind of food and how much to eat, there is a study that uses data from people wearing audio and motion sensors along with ground truth from continuous-scale video and data [34]. Another study effectively used a mobile phone image-based nutritional evaluation tool to help people with type 2 diabetes lose weight [35]. In frailty patients, for whom protein and calcium intake are important, monitoring these through e-Health seems to be of great help in nutritional management. However, to improve the adherence of e-Health programs in frailty patients, additional research is required to identify the optimal interventions as well as the best delivery methods and technologies [36].

Protecting the privacy and security of patient information is critical in the digital era of e-Health. This is because unauthorized access and potential breaches in the virtual healthcare realm pose significantly higher risks. Cryptographic techniques, such as The Public Key Infrastructure, are essential to protect sensitive data. This method is additionally reinforced by the inclusion of biometric techniques. By utilizing distinctive individual traits like fingerprints or retina scans, biometric systems add a layer of security by guaranteeing that access is given only on the basis of physiological or behavioral characteristics. Additionally, it is essential to implement multi-factor authentication requiring several verifications prior to accessing the data and regular security audits. These thorough checks will ensure that the e-Health platforms are secure and safety [37,38].

There are several limitations in this systematic review. First, despite the growing interest in e-Health and telerehabilitation, there is still a lack of research on their effectiveness in improving frailty in older adults. Due to this limitation, only a few studies on this topic were included in our review. Second, the e-Health interventions in the four included studies were diverse and could not be standardized. More research is needed to better define effective e-Health measures for elderly population. Third, we found considerable heterogeneity among studies, stemming from diverse methodologies and outcomes, notably complicates our ability to draw cohesive conclusions. The specific criteria, settings, and population characteristics of these studies limit the generalizability of our findings to broader contexts. Thus, further research, emphasizing larger samples and consistent methodologies, is essential to advance our understanding.

Despite these limitations, our review suggests that e-Health may have a positive effect on frailty in older adults. Therefore, further research is necessary to determine the most effective e-Health interventions and understand their mechanisms of

action. By addressing these issues, we can improve the quality of care for older adults with frailty or sarcopenia and promote healthy aging.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

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SUPPLEMENTARY MATERIALS

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ORCID

Hyeong-Wook Han, https://orcid.org/0000-0001-7855-0203
Si-Woon Park, https://orcid.org/0000-0002-1787-4914
Doo Young Kim, https://orcid.org/0000-0003-1327-5348
Bum-Suk Lee, https://orcid.org/0000-0002-0506-0403
Daham Kim, https://orcid.org/0000-0002-6737-837X
Namo Jeon, https://orcid.org/0000-0002-8135-8375
Yun-Jung Yang, https://orcid.org/0000-0001-5461-1534

REFERENCES

1. Fried LP, Tangen CM, Walston J, Newman AB, Hirsch C, Gottdiener J, et al. Frailty in older adults: evidence for a phenotype. J Gerontol A Biol Sci Med Sci 2001;56:M146-56.
2. Cruz-Jentoft AJ, Bahat G, Bauer J, Boirie Y, Bruyère O, Cederholm T, et al. Sarcopenia: revised European consensus on definition and diagnosis. Age Ageing 2019;48:16-31. Erratum in: Age Ageing 2019;48:601.
3. Hutchison ED. A life course perspective. In: Hutchison ED, editor. Dimensions of human behavior: the changing life course. Sage Publications; 2010. p.1-38.
4. Dent E, Kowal P, Hoogendijk EO. Frailty measurement in research and clinical practice: a review. Eur J Intern Med 2016;31:3-10.
5. Hudson JL, Bower P, Kontopantelis E, Bee P, Archer J, Clarke R, et al. Impact of telephone delivered case-management on the effectiveness of collaborative care for depression and anti-depressant use: a systematic review and meta-regression. PLoS One 2019;14:e0217948.
6. Peek ST, Wouters EJ, van Hoof J, Luijkx KG, Boeije HR, Vrijhoef HJ. Factors influencing acceptance of technology for aging in place: a systematic review. Int J Med Inform 2014;83:235-48.
7. Núñez de Arenas-Arroyo S, Cavero-Redondo I, Alvarez-Bueno C, Sequí-Domínguez I, Reina-Gutiérrez S, Martínez-Vizcaíno V. Effect of eHealth to increase physical activity in healthy adults over 55 years: a systematic review and meta-analysis. Scand J Med Sci Sports 2021;31:776-89.
8. Peterson MJ, Sloane R, Cohen HJ, Crowley GM, Pieper CF, Morey MC. Effect of telephone exercise counseling on frailty in older veterans: project LIFE. Am J Mens Health 2007;1:326-34.
9. Vestergaard S, Kronborg C, Puggaard L. Home-based video exercise intervention for community-dwelling frail older women: a randomized controlled trial. Aging Clin Exp Res 2008;20:479-86.
10. Upatising B, Hanson GJ, Kim YL, Cha SS, Yih Y, Takahashi PY. Effects of home telemonitoring on transitions between frailty states and death for older adults: a randomized controlled trial. Int J Gen Med 2013;6:145-51.
11. Kwan RY, Lee D, Lee PH, Tse M, Cheung DS, Thiamwong L, et al. Effects of an mHealth brisk walking intervention on increasing physical activity in older people with cognitive frailty: pilot randomized controlled trial. JMIR Mhealth Uhealth 2020;8:e16596.
12. Esfandiari E, Miller WC, Ashe MC. The effect of telehealth interventions on function and quality of life for older adults with pre-frailty or frailty: a systematic review and meta-analysis. J Appl Gerontol 2021;40:1649-58.
13. Yerrakalva D, Yerrakalva D, Hajna S, Griffin S. Effects of mobile health app interventions on sedentary time, physical activity, and fitness in older adults: systematic review and meta-analysis. J Med Internet Res 2019;21:e14343.
14. Forman CR, Nielsen JB, Lorentzen J. Neuroplasticity at home: improving home-based motor learning through technological solutions. A review. Front Rehabil Sci 2021;2:789165.
15. Laver K, George S, Ratcliffe J, Quinn S, Whitehead C, Davies O, et al. Use of an interactive video gaming program compared with conventional physiotherapy for hospitalised older adults: a feasibility

trial. Disabil Rehabil 2012;34:1802-8.
16. Varnfield M, Karunanithi M, Lee CK, Honeyman E, Arnold D, Ding H, et al. Smartphone-based home care model improved use of cardiac rehabilitation in postmyocardial infarction patients: results from a randomised controlled trial. Heart 2014;100:1770-9.
17. Stork MJ, Bell EG, Jung ME. Examining the impact of a mobile health app on functional movement and physical fitness: pilot pragmatic randomized controlled trial. JMIR Mhealth Uhealth 2021;9:e24076.
18. Elavsky S, Knapova L, Klocek A, Smahel D. Mobile health interventions for physical activity, sedentary behavior, and sleep in adults aged 50 years and older: a systematic literature review. J Aging Phys Act 2019;27:565-93.
19. Peel NM, McClure RJ, Bartlett HP. Behavioral determinants of healthy aging. Am J Prev Med 2005;28:298-304.
20. Teichtahl AJ, Wang Y, Wluka AE, Szramka M, English DR, Giles GG, et al. The longitudinal relationship between body composition and patella cartilage in healthy adults. Obesity (Silver Spring) 2008;16:421-7.
21. Arem H, Moore SC, Patel A, Hartge P, Berrington de Gonzalez A, Visvanathan K, et al. Leisure time physical activity and mortality: a detailed pooled analysis of the dose-response relationship. JAMA Intern Med 2015;175:959-67.
22. Moore SC, Patel AV, Matthews CE, Berrington de Gonzalez A, Park Y, Katki HA, et al. Leisure time physical activity of moderate to vigorous intensity and mortality: a large pooled cohort analysis. PLoS Med 2012;9:e1001335.
23. Drewnowski A, Evans WJ. Nutrition, physical activity, and quality of life in older adults: summary. J Gerontol A Biol Sci Med Sci 2001;56 Spec No 2:89-94.
24. Ceravolo MG, de Sire A, Andrenelli E, Negrini F, Negrini S. Systematic rapid "living" review on rehabilitation needs due to COVID-19: update to March 31st, 2020. Eur J Phys Rehabil Med 2020;56:347-53.
25. Carpallo-Porcar B, Romo-Calvo L, Pérez-Palomares S, Jiménez-Sánchez C, Herrero P, Brandín-de la Cruz N, et al. Efficacy of an asynchronous telerehabilitation program in post-COVID-19 patients: a protocol for a pilot randomized controlled trial. PLoS One 2022;17:e0270766.
26. Izquierdo M. [Multicomponent physical exercise program: Vivifrail]. Nutr Hosp 2019;36:50-6. Spanish.
27. Pérez-Zepeda MU, Martínez-Velilla N, Kehler DS, Izquierdo M, Rockwood K, Theou O. The impact of an exercise intervention on frailty levels in hospitalised older adults: secondary analysis of a randomised controlled trial. Age Ageing 2022;51:afac028.
28. Centers for Disease Control and Prevention (CDC). Telehealth interventions to improve chronic disease [Internet]. CDC; 2021 [cited 2023 May 24]. Available from: https://www.cdc.gov/dhdsp/pubs/telehealth.htm.
29. Cranen K, Groothuis-Oudshoorn CG, Vollenbroek-Hutten MM, IJzerman MJ. Toward patient-centered telerehabilitation design: understanding chronic pain patients' preferences for web-based exercise telerehabilitation using a discrete choice experiment. J Med Internet Res 2017;19:e26.
30. Clegg A, Young J, Iliffe S, Rikkert MO, Rockwood K. Frailty in elderly people. Lancet 2013;381:752-62. Erratum in: Lancet 2013;382:1328.
31. Sun XH, Ma T, Yao S, Chen ZK, Xu WD, Jiang XY, et al. Associations of sleep quality and sleep duration with frailty and pre-frailty in an elderly population Rugao longevity and ageing study. BMC Geriatr 2020;20:9.
32. Kańtoch E, Kańtoch A. Cardiovascular and pre-frailty risk assessment during shelter-in-place measures based on multimodal biomarkers collected from smart telemedical wearables. J Clin Med 2021;10:1997.
33. Heydarian H, Adam M, Burrows T, Collins C, Rollo ME. Assessing eating behaviour using upper limb mounted motion sensors: a systematic review. Nutrients 2019;11:1168.
34. Mirtchouk M, Merck C, Kleinberg S. Automated estimation of food type and amount consumed from body-worn audio and motion sensors. In: Association for Computing Machinery, editor. Paper presented at: 2016 ACM International Joint Conference on Pervasive and Ubiquitous Computing; 2016 Sep 12-16; Heidelberg, Germany. New York: Association for Computing Machinery; 2016. p.451-62.
35. Rollo ME, Ash S, Lyons-Wall P, Russell AW. Evaluation of a mobile phone image-based dietary assessment method in adults with type 2 diabetes. Nutrients 2015;7:4897-910.
36. Stuck AE, Siu AL, Wieland GD, Adams J, Rubenstein LZ. Comprehensive geriatric assessment: a meta-analysis of controlled trials. Lancet 1993;342:1032-6.
37. Kumar P, Lee HJ. Security issues in healthcare applications using wireless medical sensor networks: a survey. Sensors (Basel) 2012;12:55-91.
38. Hussein NH, Khalid A. A survey of cloud computing security challenges and solutions. Int J Comput Sci Inf Secur 2016;14:52-6.

Review Article

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Improved Muscle Mass and Function With Protein Supplementation in Older Adults With Sarcopenia: A Meta-Analysis

Hyo Eun Kwon, MD, Nayeon Ko, MD, Doyoung Yuk, MD, Seo Won Choi, MD, Seong-Eun Koh, MD, PhD

Department of Rehabilitation Medicine, Konkuk University Medical Center, and Konkuk University School of Medicine, Konkuk University, Seoul, Korea

Objective: To systematically review the effects of protein supplementation in older adults with sarcopenia.
Methods: A systematic literature search was conducted in PubMed, Cochrane Library, and Embase databases until May 2023. The inclusion criteria were as follows: (1) randomized controlled trials with a quantitative study design; (2) studies with a study group of older adults with sarcopenia; (3) studies comparing muscle mass, muscle strength, and performance of older adults with sarcopenia after protein supplementation; and (4) studies published up to May 2023.
Results: Six retrospective comparative studies, including 715 patients, met the inclusion criteria. The nutritional supplementation group exhibited significant improvement in appendicular skeletal muscle mass (standardized mean difference [SMD]=0.41; 95% confidence interval [CI], 0.24–0.58; p<0.001; I^2=1%), while handgrip strength (SMD=0.37; 95% CI, -0.32–1.07; p=0.29; I^2=94%) and Short Physical Performance Battery (SPPB) (SMD=0.35; 95% CI, -0.47–1.18; p=0.40; I^2=94%) showed a tendency for improvement.
Conclusion: Nutritional supplementation with protein increased appendicular muscle mass in older adults with sarcopenia and improved handgrip strength and SPPB scores.

Keywords: Sarcopenia, Protein, Skeletal muscle, Meta-analysis

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Correspondence:
Seong-Eun Koh
Department of Rehabilitation Medicine, Konkuk University Medical Center, and Konkuk University School of Medicine, Konkuk University, 120-1 Neungdong-ro, Gwangjin-gu, Seoul 05030, Korea.
Tel: +82-2-2030-5346
Fax: +82-2-2030-5375
E-mail: kohse@kuh.ac.kr

INTRODUCTION

Age-related muscle attenuation, termed "sarcopenia," contributes to muscle weakness and impaired physical mobility. Sarcopenia and frailty are multidimensional syndromes characterized by a decreased reserve and diminished resistance to stressors [1,2]. Criteria for classifying older adults as having sarcopenia or high frailty risk have recently been established. In 2019, the Asian Working Group for Sarcopenia (AWGS) defined sarcopenia as "age-related loss of muscle mass, plus low muscle strength, or low physical performance." It proposed diagnostic cut-offs for each component [3]. Low muscle strength is a handgrip strength of <28 kg for male and <18 kg for female. The criteria for low physical performance are a 6-minute walk test slower than 1.0 m/s, a Short Physical Performance Battery (SPPB) score of ≤9, or a 5-time chair stand test of ≥12 seconds. Cut-offs for height-adjusted muscle mass through dual-energy X-ray absorptiometry were <7.0 kg/m^2 in male and <5.4 kg/m^2

in female and that through bioimpedance were <7.0 kg/m^2 in male and <5.7 kg/m^2 in female. Sarcopenia in older adults can be devastating, resulting in several adverse events, including increased risk for falls, impaired mobility, elderly depression, increased healthcare costs, and mortality [4,5].

Previous studies report that oral nutritional supplementation improves body composition and decreases functional disability. Among nutritional supplements, high-quality protein or amino acid supplementation is important for preventing a decrease in muscle mass. Whey protein stimulates postprandial muscle protein accretion more effectively than do casein or casein hydrolysate in older people [6]. Whey protein is a rapidly digested dietary protein beneficial for slowing muscle loss, particularly in older adults. When protein or amino acid intake is supplemented, the amount of synthesized muscle protein exceeds the amount broken down [7]. Sufficient protein intake is crucial to maintain muscle mass and function in older adults. The PROTAGE study group recommended at least 1.0–1.2 g protein/kg/day to maintain and increase muscle mass and function in individuals aged older than 65 years. A higher protein intake (>1.2 g/kg/day) is advised for those who regularly exercise and for community-dwelling older adults [8].

Previous systematic reviews and meta-analysis were limited to parameters related to muscle mass and investigated whether nutritional supplementation could improve muscle mass in older populations [9]. Few meta-analysis of the functional outcomes of nutritional supplementation in older adults with sarcopenia have been conducted. The meta-analysis on the effect of nutritional supplementation on elderly sarcopenia needs an update since several randomized controlled trials (RCTs) have been published after the previous meta-analysis. The management of sarcopenia should focus on increasing muscle mass and functional improvements to eventually prevent the progression of sarcopenia. This study aimed to conduct a focused meta-analysis of studies that used nutritional interventions with a protein-or amino acid-enriched formula in older adults with sarcopenia.

METHODS

Design

This meta-analysis was conducted according to the guidelines recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist (Supplementary Material) [10].

Literature search and study selection

The search was performed using PubMed, Cochrane Library, and Embase databases from inception to May 2023 using the following keywords: "older adults" AND "sarcopenia" AND "protein" OR "nutrition" AND "supplement" OR "muscle mass" OR "muscle strength" AND "short physical performance battery."

Inclusion and exclusion criteria

Studies were included if they satisfied all of the following selection criteria: (1) RCTs with a quantitative study design; (2) studies with a group of older adults (age ≥65 years) with sarcopenia; (3) studies comparing muscle mass, muscle strength, and functional performance of older adults with sarcopenia after receiving adequate protein supplementation; (4) the supplement intervention used protein sources, including whey protein or leucine, vitamins, and other nutrients; and (5) studies published up to May 2023. Studies published as case reports, case series, or prospectively designed trials without comparison groups were excluded from the analysis.

Analysis and data extraction

Data were extracted from each included study and are presented in an evidence table (Table 1) outlining the characteristics of the respective study designs and participants (group design, age, and sex), body composition assessment methods (bioimpedance analysis or dual-energy X-ray absorptiometry), the composition of nutritional supplements, follow-up period, and main measured outcomes [11-16].

Six studies compared older individuals with sarcopenia using diagnostic criteria proposed by the AWGS as quantitative values between the group with nutritional support and the group with placebo. These studies compared muscle mass, muscle strength, and functional performance, including at least two of the following: appendicular skeletal muscle mass (ASM), handgrip strength, and SPPB score, after receiving adequate protein supplementation.

Statistical analysis

We separately computed the effect sizes for each study for the primary and secondary outcome measures. The R metapackage was used for statistical analysis and graphics (http://www.r-project.org). The heterogeneity of the studies was calculated using the I^2 test to observe variations across studies and was estimated to be significant when $p<0.05$. The 95% confidence interval (CI)

Table 1. A summary of selected studies' characteristics

Study	Study design	Group	Age (yr)	Sex (female/male)	Body composition assessment method	Intervention (nutritional supplementation/exercise)	Follow-up period	Measured outcomes
Amasene et al., 2021 [11]	Randomized controlled trial	Intervention (N=21) Control (N=20)	82.9±5.67 81.2±6.14	12/9 10/10	DXA	20 g of whey protein isolate enriched with 3 g of leucine Supervised resistance training (3 times a week)	12 wk	ASM, handgrip strength, SPPB (balance, gait speed, chair stand), weight, BMI, calf circumference, body fat, lean mass, fat-free mass and bone mass, myostatin, follistatin, irisin
Peng et al., 2022 [12]	Randomized controlled trial	Intervention (N=12) Control (N=13)	67.1±6.7 68.9±6.2	8/4 11/2	DXA	Leucine 1 g, arginine 1.5 g, Vitamin D3 7.5 μg, chondroitin 400 mg, glucosamine 700 mg, and calcium 300 mg twice a day 45 minutes at the gym per week and two sessions of 30-minute exercise at home	12 wk	ASM, handgrip strength, 6-minute walk test, chair stand test, SPPB, MMSE Serum levels of the total protein, albumin, hepatic and renal function tests, blood lipids, glucose, insulin, HbA1c, electrolytes, and hS-CRP, 25-hydroxyvitamin D
Bauer et al., 2015 [13]	Randomized controlled trial	Intervention (N=184) Control (N=196)	77.3±6.7 78.1±7.0	120/64 129/67	DXA	20 g whey protein, 3 g total leucine, 9 g carbohydrates, 3 g fat, 800 IU vitamin D, and a mixture of vitamins, minerals, and fibers twice daily	7, 13 wk	ASM, hand grip strength, SPPB, chair-stand test, gait speed, balance test, serum 25-hydroxyvitamin D, serum IGF-1
Björkman et al., 2020 [14]	Randomized controlled trial	Intervention (N=73) Control (N=73)	83.6±4.7 83.7±5.1	51/21 129/67	BIA	20 g whey proteins twice a day Given instructions on home-based exercise	12 mo	Hand grip strength, SPPB, continuous summary physical performance scores, SMI, MNA, dietary record, MMSE
Yamada et al., 2019 [15]	Randomized controlled trial	Intervention (N=28) Control (N=28)	84.9±5.6 83.9±5.7	20/8 15/13	BIA	10.0 g of whey proteins and 800 IU vitamin D 30 minutes of body weight resistance exercise with slow movement speeds twice a week	12 wk	ASM, handgrip strength, knee extension torque, phase angle, echo intensity for rectus femoris, gait speed, one-leg standing time, chair-stand time
Rondanelli et al., 2020 [16]	Randomized controlled trial	Intervention (N=28) Control (N=28)	81±7.0 82±5.0	38/26 46/17	BIA	20 g of whey proteins, 2.8 g of leucine, 9 g of carbohydrates, 3 g of fat, 800 IU of vitamin D, and a mixture of vitamins, minerals (calcium 500 mg), and fibers 20–30-minute session; muscle-strengthening exercises, balance, gait exercises	4–8 wk	ASM, SMI, change in 4-m gait speed per month, handgrip strength, SPPB, chair-stand test, timed up and go test, body weight, MNA, CRP, serum 25-hydroxyvitamin D, cholesterol, albumin, creatinine

DXA, dual-energy X-ray absorptiometry; ASM, appendicular skeletal muscle mass; SPPB, Short Physical Performance Battery; BMI, body mass index; MMSE, Mini Mental State Examination; HbA1c, whole-blood glycated hemoglobin; hS-CRP, high-sensitivity C-reactive protein; IGF-1, insulin-like growth factor 1; BIA, bioimpedance analysis; SMI, skeletal muscle mass index; MNA, Mini Nutritional Assessment.

and two-tailed p-values are provided. All extracted outcome data were calculated as the standardized mean difference (SMD) compared to the control group. Fixed-effects or random-effects models were used depending on the existence of heterogeneity. A fixed-effects model was used when the statistical heterogeneity was insignificant (I^2 values were ≤50%); otherwise, a random-effects model was used.

RESULTS

Search results

Fig. 1 shows a flowchart of the selection process. Of the 332 studies retrieved using the above-mentioned keywords, 139 were selected after excluding duplicate articles. After confirming the title and abstract, 106 articles were excluded. In addition, 27 studies could not be included in the meta-analysis because of irrelevant study design or insufficient data. Six studies were finally included in this review.

Study characteristics

The nutritional interventions and protocols used for the exercise training are summarized in Table 1. The nutritional supplementation protocols varied widely among the included trials. The majority of the included RCTs provided extra protein supplements with amounts of whey protein ranging from 10.0 to 40.0 g/day [9]. One RCT used leucine (1 g), arginine (1.5 g), and vitamin-D 300 IU complex without whey protein. Vitamin-D levels ranged from 600 to 1,600 IU/day. One study used only whey protein as a nutritional supplement without other additives [14]. Regarding the mode of exercise, one RCT used only resistance exercise training. Four RCTs used multi-component exercise regimens. One RCT did not include an exercise program before supplement intake.

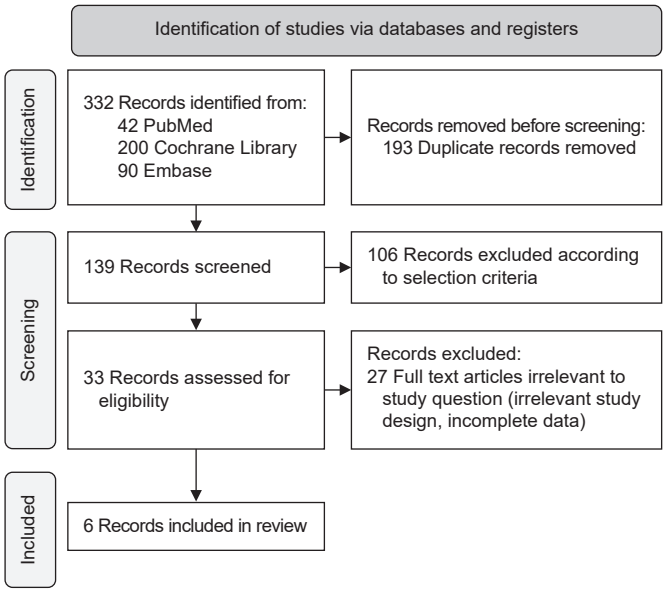

Fig. 1. Flowchart showing the study design.

Outcomes

In this meta-analysis, a group of patients who received whey protein or amino acid or vitamin-D supplementation was defined as the experimental group, and a group of patients who received a placebo was defined as the control group.

In the ASM analysis, of 536 patients, 263 in the experimental group received the protein supplementation, while 273 in the control group did not. There was a significant difference between the experimental and control groups with regard to ASM (SMD=0.41; 95% CI, 0.24–0.58; p<0.001; I^2=1%; Fig. 2).

In the analysis of handgrip strength, of 715 patients, 351 in the experimental group received the protein supplementation, while 364 in the control group did not. There was no statistically significant difference between the experimental and control groups in handgrip strength (SMD=0.37; 95% CI, -0.32–1.07; p=0.29; I^2=94%; Fig. 3A).

In the analysis of the SPPB scores, among 667 patients, 327 in the experimental group received the protein supplementation, while 340 in the control group did not. There was no statistically significant difference between the experimental and control groups in SPPB scores (SMD=0.35; 95% CI, -0.47–1.18; p=0.40; I^2=94%; Fig. 3B).

Quality assessment

In terms of methodological quality, all participants were randomized using established allocation sequences. Of the 42 domains among all studies, 31 domains (73.8%) were of low risk. Therefore, the overall risk of bias was determined to be low, and the studies included in this meta-analysis were assessed as of high quality (Fig. 4).

Publication bias

The funnel plot for the ASM was symmetrical. In contrast, the graphic funnel plots for handgrip strength and SPPB scores were asymmetrical (Fig. 5). In addition, Egger's linear regression test indicated an insignificant publication bias for ASM (p=0.12), handgrip strength (p=0.82), as well as SPPB (p=0.69).

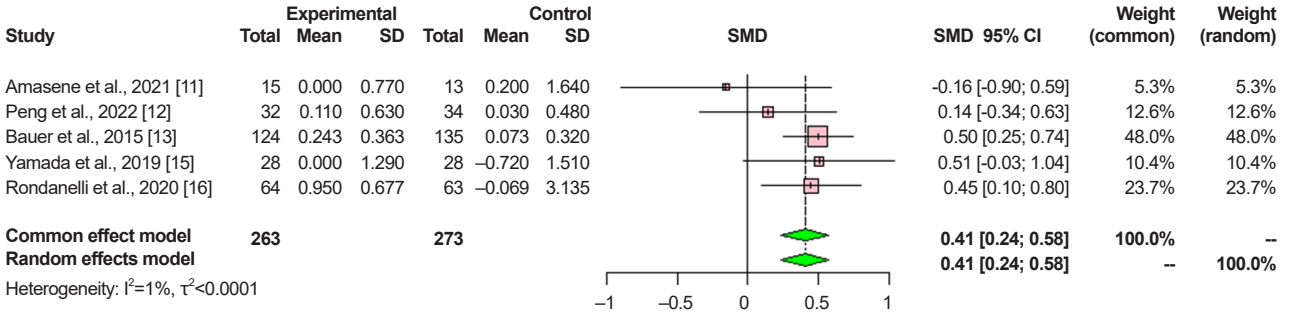

Fig. 2. Forest plot showing the results of appendicular muscle mass in sarcopenia after protein supplementation. SD, standard deviation; SMD, standardized mean difference; 95% CI, 95% confidence interval.

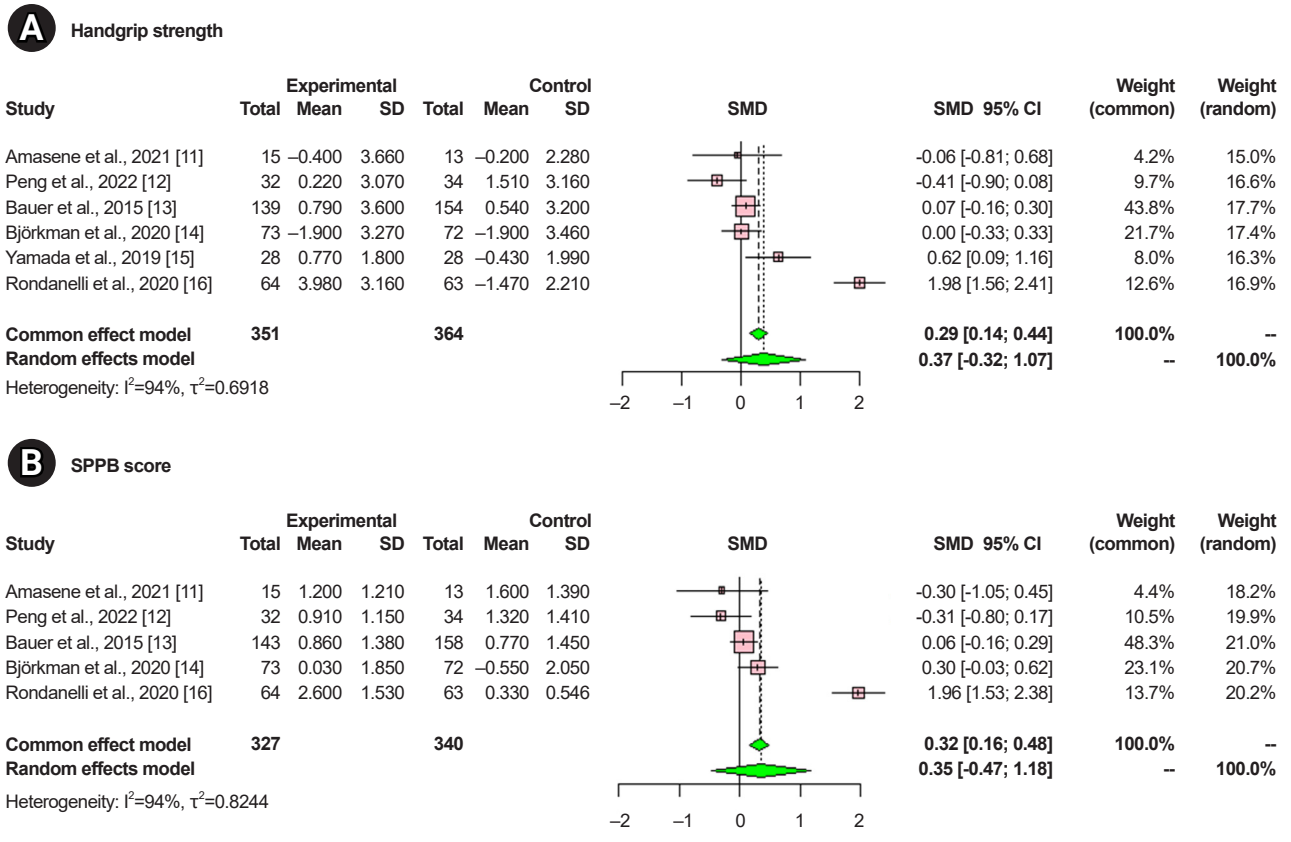

Fig. 3. Forest plot showing the results of (A) handgrip strength and (B) Short Physical Performance Battery (SPPB) scores after protein supplementation. SD, standard deviation; SMD, standardized mean difference; 95% CI, 95% confidence interval.

DISCUSSION

In this meta-analysis, protein supplementation significantly increased ASM in older adults with sarcopenia and tended to improve functional outcomes such as handgrip strength and SPPB scores. Sarcopenia is the progressive loss of muscle mass, strength, and function related to aging [17]. In older adults, chronic inflammation, motor neuron atrophy, reduced protein intake, and immobility can contribute to the progression of sarcopenia [18]. Furthermore, managing sarcopenia in older adults is crucial as it could lead to fatal adverse events, including increased risk for falls, impaired mobility, increased healthcare

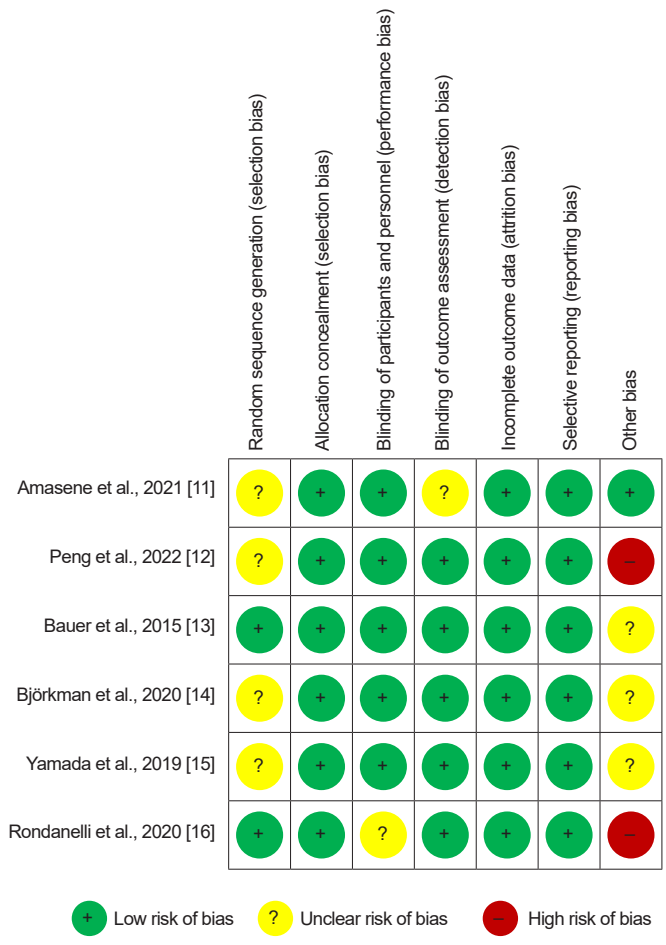

Fig. 4. Summary of the quality assessment of the randomized controlled trials included in the meta-analysis.

costs, and mortality [4].

In our study, the ASM increased significantly after protein supplementation (SMD=0.41). The groups in the six studies were homogeneous, and meaningful conclusions could be drawn (I^2=1%). These findings are consistent with those of a previous study showing that whey protein, leucine, or vitamin-D-enriched supplementation in patients with sarcopenia increased appendicular muscle mass [19]. In contrast, one RCT reported that protein supplementation does not increase ASM in older patients with sarcopenia but improves physical performance [20]. However, this study had some limitations as it did not implement the exercise therapy with nutritional support, in addition to a smaller sample size (n=65) compared to that in our study.

Previous studies reporting the effect of nutritional supplements on sarcopenia mainly concluded with primary outcome measures of sarcopenia indices, including lean body mass, appendicular lean mass, or skeletal mass index [21,22]. However, there were few studies with a large sample size whose outcome measures of functional performance were SPPB, gait speed, or chair-stand test [3].

Handgrip strength and performance scored with SPPB tended to improve, although this was not statistically significant (SMD=0.37; SMD=0.35). Another meta-analysis showed that changes in appendicular lean mass were significantly associated with leg strength and walking capability [23]. The heterogeneity of the participant groups included in the muscle strength and performance evaluation may have increased the variance in this study. As this study did not confirm a change in muscle mass affecting muscle strength and functional mobility, further studies are needed. Handgrip strength is a diagnostic tool for sarcopenia in the geriatric population and is known to reflect sarcopenic conditions better than other measurement tools, such as the chair-stand test [24]. Low handgrip strength could be a main predictor of mortality and adverse events in older individuals with sarcopenia [25]. In fixed-effect model, we observed a tendency for handgrip strength to improve after protein supsupplementation (SMD=0.29; p<0.001). Protein supplementation could increase muscle mass and improve physical function. This could eventually lead to reduced mortality and risk for falls and a better quality of life in older adults with sarcopenia [26]. Considering the heterogeneity, further studies with homogenous groups are needed.

The SPPB is suggested as a good alternative for gait speed to assess physical performance in sarcopenia. The SPPB consists of three tests for lower limb function, balance, strength, and mobility and is a comprehensive evaluation of functional mobility. The SPPB score predicts long-term mortality [27] and evaluates the ability to perform resistance and aerobic exercises to prevent sarcopenia. This study showed that protein supplementation would increase SPPB scores in fixed-effect model (SMD=0.32; p<0.001). Improvements in SPPB scores are expected to prevent frailty, hospitalization, and mortality in older adults [28].

In our analysis, studies involving the use of protein supplements and whey proteins were the primary focus. Selecting high-quality proteins as nutritional supplements could effectively increase muscle mass and functional performance. Such supplements are also easy for older adults to digest, considering the physiological and metabolic changes that occur with aging [29]. Whey protein affects muscle strengthening differently in

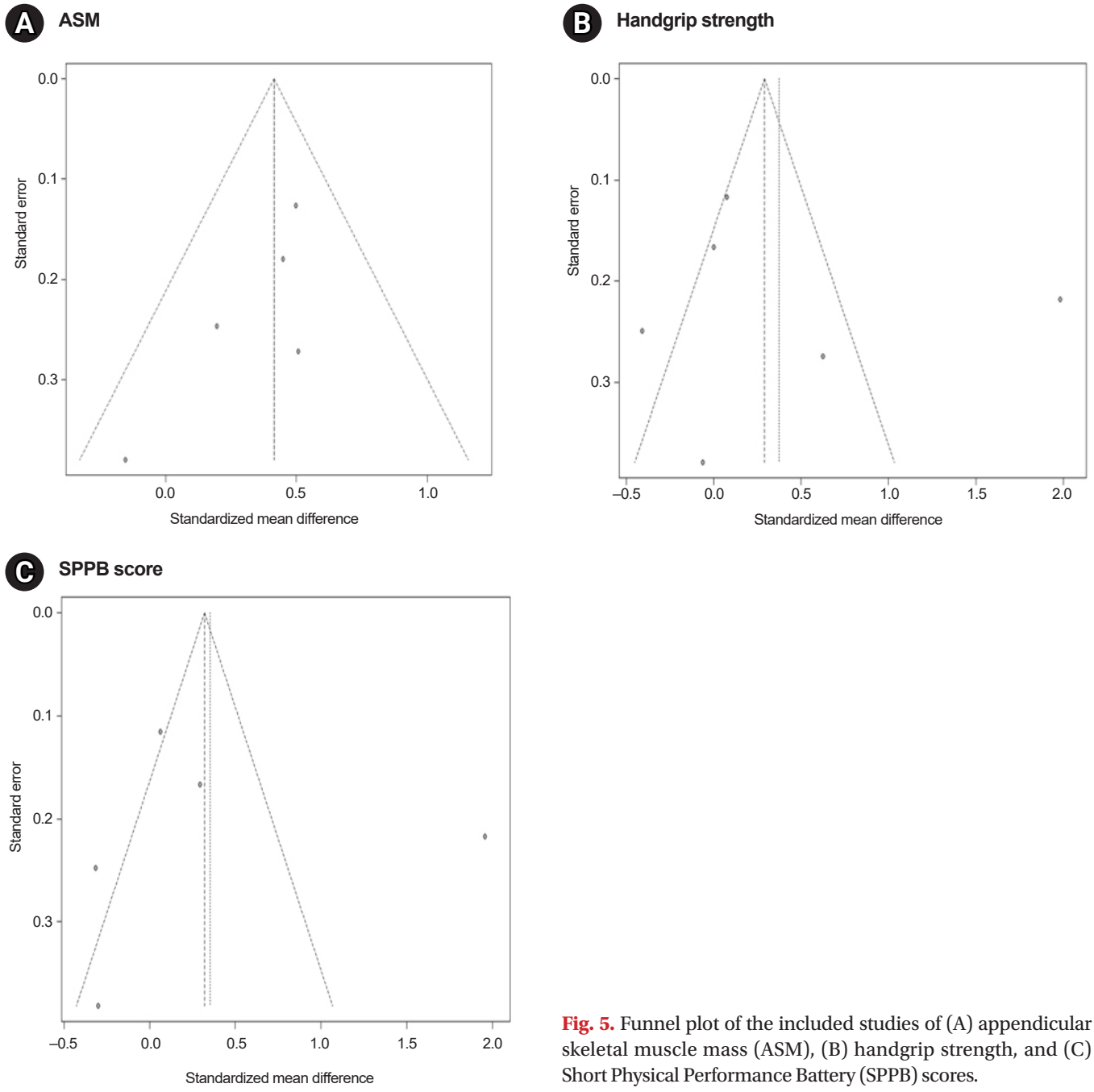

Fig. 5. Funnel plot of the included studies of (A) appendicular skeletal muscle mass (ASM), (B) handgrip strength, and (C) Short Physical Performance Battery (SPPB) scores.

older individuals than that in young individuals. Whey protein, a rapidly digested protein, is utilized more when consumed with other carbohydrates, especially in older adults. The addition of amino acids, or specifically, leucine, is also recommended [30].

This study showed that protein supplementation increased ASM, regardless of the type, duration, and intensity of exercise. Protein supplementation and muscle-strengthening exercises contribute to increased muscle strength and walking capability [23]. Aerobic and resistance exercises reduced the time interval between muscle protein breakdown and synthesis. Therefore, a protein nutritional supplement and a concomitant aerobic or resistance exercise program can be recommended to reduce the

rate of muscle loss. In addition, early exercise and nutritional intervention could be helpful in an earlier restoration of lower extremity muscle mass for sarcopenia in older adults. Appropriate early resistance training with nutritional support and subsequent structuralized home-based exercise should be administered [31].

This study has several limitations. The heterogeneity of the intervention regimen made it difficult to conclude the effectiveness of each protocol due to the variation among protein supplement regimens (protein source, supplied amounts, and timing of ingestion) and exercise regimens (type of training, training duration, and training volume). Among the six studies we selected, the functional mobility assessment protocols were inconsistent. This resulted in the extraction of only limited valid data. However, we attempted to select the main assessment tools for sarcopenia, such as handgrip strength and SPPB. Additionally, the follow-up was limited to a short-term period (12 weeks to 1 year). Well-designed RCTs with longer follow-up periods could help establish the long-term effect of protein supplementation in older patients with sarcopenia.

In conclusion, protein supplementation significantly increases appendicular muscle mass in older patients with sarcopenia and could lead to improvements in functional outcomes, such as handgrip strength and SPPB scores. Therefore, sufficient protein supplementation may be crucial for managing sarcopenia in older individuals.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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None.

AUTHOR CONTRIBUTION

Conceptualization: Kwon HE, Koh SE. Methodology: Kwon HE, Ko N. Formal analysis: Kwon HE, Yuk D, Choi SW. Project administration: Kwon HE, Ko N. Visualization: Kwon HE, Yuk D, Choi SW. Writing – original draft: Kwon HE, Ko N. Writing – review and editing: Kwon HE, Ko N, Yuk D, Koh SE. Approval of final manuscript: all authors.

SUPPLEMENTARY MATERIALS

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ORCID

Hyo Eun Kwon, https://orcid.org/0000-0003-3806-4387
Nayeon Ko, https://orcid.org/0000-0001-8706-0441
Doyoung Yuk, https://orcid.org/0009-0004-3326-6259
Seo Won Choi, https://orcid.org/0009-0003-1518-0147
Seong-Eun Koh, https://orcid.org/0000-0002-0446-1889

REFERENCES

1. Lee SY, Lee HJ, Lim JY. Effects of leucine-rich protein supplements in older adults with sarcopenia: a systematic review and meta-analysis of randomized controlled trials. Arch Gerontol Geriatr 2022;102:104758.
2. Saad F. The relationship between testosterone deficiency and frailty in elderly men. Horm Mol Biol Clin Investig 2010;4:529-38.
3. Chen LK, Woo J, Assantachai P, Auyeung TW, Chou MY, Iijima K, et al. Asian Working Group for Sarcopenia: 2019 consensus update on sarcopenia diagnosis and treatment. J Am Med Dir Assoc 2020;21:300-7.e2.
4. Cruz-Jentoft AJ, Sayer AA. Sarcopenia. Lancet 2019;393:2636-46. Erratum in: Lancet 2019;393:2590.
5. Chang KV, Hsu TH, Wu WT, Huang KC, Han DS. Is sarcopenia associated with depression? A systematic review and meta-analysis of observational studies. Age Ageing 2017;46:738-46.
6. Pennings B, Boirie Y, Senden JM, Gijsen AP, Kuipers H, van Loon LJ. Whey protein stimulates postprandial muscle protein accretion more effectively than do casein and casein hydrolysate in older men. Am J Clin Nutr 2011;93:997-1005.
7. Biolo G, Tipton KD, Klein S, Wolfe RR. An abundant supply of amino acids enhances the metabolic effect of exercise on muscle protein. Am J Physiol 1997;273(1 Pt 1):E122-9.
8. Bauer J, Biolo G, Cederholm T, Cesari M, Cruz-Jentoft AJ, Morley JE, et al. Evidence-based recommendations for optimal dietary protein intake in older people: a position paper from the PROT-AGE Study Group. J Am Med Dir Assoc 2013;14:542-59.
9. Wright J, Baldwin C. Oral nutritional support with or without exercise in the management of malnutrition in nutritionally vulnerable older people: a systematic review and meta-analysis. Clin Nutr 2018;37(6 Pt A):1879-91.

10. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Ann Intern Med 2009;151:264-9. W64.
11. Amasene M, Cadenas-Sanchez C, Echeverria I, Sanz B, Alonso C, Tobalina I, et al. Effects of resistance training intervention along with leucine-enriched whey protein supplementation on sarcopenia and frailty in post-hospitalized older adults: preliminary findings of a randomized controlled trial. J Clin Med 2021;11:97.
12. Peng LN, Yu PC, Hsu CC, Tseng SH, Lee WJ, Lin MH, et al. Sarcojoint®, the branched-chain amino acid-based supplement, plus resistance exercise improved muscle mass in adults aged 50 years and older: a double-blinded randomized controlled trial. Exp Gerontol 2022;157:111644.
13. Bauer JM, Verlaan S, Bautmans I, Brandt K, Donini LM, Maggio M, et al. Effects of a vitamin D and leucine-enriched whey protein nutritional supplement on measures of sarcopenia in older adults, the PROVIDE study: a randomized, double-blind, placebo-controlled trial. J Am Med Dir Assoc 2015;16:740-7.
14. Björkman MP, Suominen MH, Kautiainen H, Jyväkorpi SK, Finne-Soveri HU, Strandberg TE, et al. Effect of protein supplementation on physical performance in older people with sarcopenia-a randomized controlled trial. J Am Med Dir Assoc 2020;21:226-32.e1.
15. Yamada M, Kimura Y, Ishiyama D, Nishio N, Otobe Y, Tanaka T, et al. Synergistic effect of bodyweight resistance exercise and protein supplementation on skeletal muscle in sarcopenic or dynapenic older adults. Geriatr Gerontol Int 2019;19:429-37.
16. Rondanelli M, Cereda E, Klersy C, Faliva MA, Peroni G, Nichetti M, et al. Improving rehabilitation in sarcopenia: a randomized-controlled trial utilizing a muscle-targeted food for special medical purposes. J Cachexia Sarcopenia Muscle 2020;11:1535-47.
17. Rizzoli R, Reginster JY, Arnal JF, Bautmans I, Beaudart C, Bischoff-Ferrari H, et al. Quality of life in sarcopenia and frailty. Calcif Tissue Int 2013;93:101-20.
18. Malafarina V, Uriz-Otano F, Iniesta R, Gil-Guerrero L. Sarcopenia in the elderly: diagnosis, physiopathology and treatment. Maturitas 2012;71:109-14.
19. Chang MC, Choo YJ. Effects of whey protein, leucine, and vitamin d supplementation in patients with sarcopenia: a systematic review and meta-analysis. Nutrients 2023;15:521.
20. Tieland M, van de Rest O, Dirks ML, van der Zwaluw N, Mensink M, van Loon LJ, et al. Protein supplementation improves physical performance in frail elderly people: a randomized, double-blind, placebo-controlled trial. J Am Med Dir Assoc 2012;13:720-6.
21. Kim KM, Jang HC, Lim S. Differences among skeletal muscle mass indices derived from height-, weight-, and body mass index-adjusted models in assessing sarcopenia. Korean J Intern Med 2016;31:643-50.
22. Cawthon PM, Peters KW, Shardell MD, McLean RR, Dam TT, Kenny AM, et al. Cutpoints for low appendicular lean mass that identify older adults with clinically significant weakness. J Gerontol A Biol Sci Med Sci 2014;69:567-75.
23. Liao CD, Chen HC, Huang SW, Liou TH. The role of muscle mass gain following protein supplementation plus exercise therapy in older adults with sarcopenia and frailty risks: a systematic review and meta-regression analysis of randomized trials. Nutrients 2019;11:1713.
24. Verstraeten LMG, de Haan NJ, Verbeet E, van Wijngaarden JP, Meskers CGM, Maier AB. Handgrip strength rather than chair stand test should be used to diagnose sarcopenia in geriatric rehabilitation inpatients: REStORing health of acutely unwell adulTs (RESORT). Age Ageing 2022;51:afac242.
25. Ling CH, Taekema D, de Craen AJ, Gussekloo J, Westendorp RG, Maier AB. Handgrip strength and mortality in the oldest old population: the Leiden 85-plus study. CMAJ 2010;182:429-35.
26. Yeung SSY, Reijnierse EM, Pham VK, Trappenburg MC, Lim WK, Meskers CGM, et al. Sarcopenia and its association with falls and fractures in older adults: a systematic review and meta-analysis. J Cachexia Sarcopenia Muscle 2019;10:485-500.
27. Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. J Gerontol 1994;49:M85-94.
28. Beaudart C, Zaaria M, Pasleau F, Reginster JY, Bruyère O. Health outcomes of sarcopenia: a systematic review and meta-analysis. PLoS One 2017;12:e0169548.
29. Dangin M, Guillet C, Garcia-Rodenas C, Gachon P, Bouteloup-Demange C, Reiffers-Magnani K, et al. The rate of protein digestion affects protein gain differently during aging in humans. J Physiol 2003;549(Pt 2):635-44.
30. Luiking YC, Deutz NE, Memelink RG, Verlaan S, Wolfe RR. Postprandial muscle protein synthesis is higher after a high whey protein, leucine-enriched supplement than after a dairy-like product in healthy older people: a randomized controlled trial. Nutr J 2014;13:9.
31. Chang KV, Wu WT, Huang KC, Han DS. Effectiveness of early versus delayed exercise and nutritional intervention on segmental body composition of sarcopenic elders - a randomized controlled trial. Clin Nutr 2021;40:1052-9.

Original Article

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Korean Version of the Longer-Term Unmet Needs After Stroke Questionnaire

Sora Baek, MD, PhD[1], Won-Seok Kim, MD, PhD[2], Yul-Hyun Park, MD[2,3], Yun Sun Jung, MPH, PhD[2], Won Kee Chang, MD, MS[2], Gowun Kim, MD, PhD[1], Nam-Jong Paik, MD, PhD[2]

[1]*Department of Rehabilitation Medicine, Kangwon National University Hospital, Kangwon National University College of Medicine, Chuncheon, Korea*
[2]*Department of Rehabilitation Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Korea*
[3]*Department of Public Health Care, Seoul National University Bundang Hospital, Seongnam, Korea*

Objective: To translate the 22-item Longer-term Unmet Needs after Stroke (LUNS) questionnaire, validate it in the Korean stroke population, and assess the reliability of face-to-face and telephone surveys.

Methods: Sixty-six adult patients with stroke from Seoul National University Bundang Hospital and Kangwon National University Hospital were involved in the validation. Participants were interviewed twice using the LUNS Korean version: first, a face-to-face survey for validation, and second, a telephone survey for test-retest reliability. Participants completed the Frenchay Activities Index (FAI) and Short Form 12 (SF-12) Mental and Physical Component Summary (MCS and PCS) scores at the first interview. For concurrent validity, the differences in health status (FAI, SF-12 MCS and PCS) between the groups that reported unmet needs and those that did not were analyzed for each item. Cohen's kappa and percentage of agreement between the first and second administrations were calculated for each item to determine the test-retest reliability.

Results: The average age of the participants was 61.2±12.8 years and 74.2% were male. Fifty-seven patients were involved in the second interview. Depending on the unmet needs, SF-12 MCS, PCS, and FAI were significantly different in 12 of 22 items. In the test-retest reliability test, 12 items had a kappa of 0.6 or higher, and two had a kappa of <0.4.

Conclusion: The LUNS instrument into Korean (LUNS-K) is a reliable and valid instrument for assessing unmet health needs in patients with stroke. In addition, telephone surveys can be considered reliable.

Keywords: Stroke, Needs assessment, Factor analysis, Translations, Validation studies

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Correspondence:
Won-Seok Kim
Department of Rehabilitation Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, 82 Gumi-ro 173beon-gil, Bundang-gu, Seongnam 13620, Korea.
Tel: +82-31-787-7735
Fax: +82-31-787-4051
E-mail: wondol77@gmail.com

INTRODUCTION

Stroke is one of the leading causes of disability worldwide, including in Korea, resulting in a significant socioeconomic burden [1,2]. Stroke mortality rates have decreased dramatically with advancements in the emergency medical system and acute care after stroke. However, the stroke incidence rates have decreased less steeply, suggesting that more stroke survivors will

live with disabilities [1]. Although early and intensive rehabilitation after stroke is prioritized in many countries [3,4], many stroke survivors eventually experience long-term disabilities, even years after the onset of stroke [5]. A multicenter cohort study in Korea revealed that 38% of stroke survivors had at least one functional dependence, estimated using a functional independence measure 6 months after stroke [6]. During long-term follow-up after stroke in Korea, patients with stroke experience worsening problems in various domains (i.e., communication, cognition, pain, and mood), leading to lower health-related quality of life [7]. Consequently, many patients with stroke have long-term care needs. However, these needs have not been adequately met in several cases. In a recent systematic review of Longer-term Unmet Needs after Stroke (LUNS), approximately 73% of stroke survivors had at least one unmet need [8], which is associated with a low quality of life for stroke survivors or their caregivers [9-11].

Therefore, systematical identification of the current status of unmet needs in various domains using a validated tool is crucial for formulating a policy to adequately and efficiently address unmet needs. A LUNS monitoring tool consists of 22 items for various needs in multiple domains including information, service, social/emotional consequences, and health-related problems of stroke survivors, and it comprises dichotomous (yes/no) responses for each item. LUNS was developed based on previous literature and semi-structured interviews with stroke survivors [12,13]. In an original validation study among 850 British stroke survivors, LUNS showed good acceptability (average completion time of 6 minutes and low missing item rate) [12]. Test-retest reliability analysis revealed high agreement, ranging from 78%–99% for item responses, and a kappa coefficient ranging from 0.45–0.67. Additionally, the validity of the LUNS was corroborated by the identification of unmet needs that consistently correlated with poorer health, as measured by the Short Form 12 (SF-12) questionnaire and Frenchay Activities Index (FAI). However, the LUNS has not been widely translated and validated in languages other than Dutch [14]. The unmet needs of stroke survivors can be influenced by various health and social factors and different coping strategies are required depending on cultural backgrounds. Thus, using the same standardized and validated tool to evaluate unmet needs after stroke in various languages will allow for more inclusion of minority groups in multiethnic countries and enable global comparisons of unmet needs after stroke.

This study had two main objectives: the translation of the 22-item LUNS questionnaire into Korean and the evaluation of its validity among stroke patients in Korea. In addition, we analyzed the reliability between the face-to-face (first test) and telephonic (second test) surveys, to determine the reliability of follow-up telephonic surveys using the LUNS instrument. The successful implementation of this approach provides a valuable opportunity to include a larger cohort of stroke survivors in future research.

METHODS

Translation of the LUNS instrument into Korean

The translation of the LUNS instrument was conducted with permission from the authors of the original LUNS study for the use of the questionnaire. This study was structured into three distinct components. The first part involved the translation and cross-cultural adaptation of the original English version of the LUNS instrument into Korean (LUNS-K). The second part focused on the validation of the LUNS-K. Finally, we assessed the reliability between the face-to-face (first test) and the telephonic (second test) surveys. The translation and cross-cultural adaptation of the LUNS to Korean was based on the 10 steps described in the International Society for Pharmacoeconomics and Outcomes Research Patient-Reported Outcomes Translation and Linguistic Validation Task Force guidelines [15]. The Institutional Review Boards (IRBs) of Seoul National University Bundang Hospital (IRB No. B-2006-616-307) and Kangwon National University Hospital (IRB No. KNUH-2020-05-005-004) approved the study protocol. All participants provided written informed consent after receiving detailed information about the study.

The original version of the LUNS was initially translated from English to Korean. The translations were independently performed by three translators who were Korean native speakers. Two of the translators had no medical background, whereas the third translator was part of the medical team that participated in the study. The three translated versions were reviewed, and a few discrepancies were reconciled by consensus. A synthetic version was created. The reconciled Korean version was back-translated into English by two Korean-American native English speakers who were fluent in Korean (one medical personnel and one non-medical personnel), and blinded to the original English version. An expert committee comprising health professionals, translators, and linguists reviewed the synthesized and back-translated versions for inconsistencies before modifying them to reflect the most accurate meaning in Kore-

an. An expert committee reviewed the linguistic and cultural qualities of the modified version.

This pre-final version was field-tested on six Korean patients with chronic stroke (n=3 males; mean age, 65.8±23.5 years) at Seoul National University Bundang Hospital for the cognitive debriefing phase. The patients underwent qualitative semi-structured interviews investigating the questionnaire and their understanding of the questions. The interviewees were patients who visited our outpatient clinic because of chronic stroke. We measured the questionnaire completion time for four of the six patients. The semi-structured interviews were based on eight questions. All questions were answered on a visual analog scale of 100 mm where "0" represented "not useable at all" and "100" represented "very useable" [16]. After cognitive debriefing, ambiguous expressions were modified through discussion. An expert committee reviewed the final LUNS-K.

Participants for validation and reliability tests

The validation and reliability analysis of the LUNS-K involved a total of 66 post-stroke patients who attended the outpatient clinics of the Department of Rehabilitation Medicine at Seoul National University Bundang Hospital and Kangwon National University Hospital between July 2020 and February 2021. The study included adult stroke patients aged 18 years or older, who were outpatients and had experienced a stroke at least 6 months prior. Participants were required to have the communication and cognitive abilities necessary to independently complete the questionnaire. We included patients who reside at home and have surpassed a minimum of 3 months since stroke onset. Those unable to answer the questionnaire due to cognitive decline were excluded from the study.

During the initial face-to-face interview, participants provided information regarding their age, sex, education level, residence (home or facility), type of stroke (cerebral infarction, cerebral hemorrhage, or unknown), stroke stage (subacute, <6 months; early chronic, 6–18 months; late chronic, >18 months) [17], and modified Rankin Scale (mRS) were investigated (0=no symptoms; 1=no significant disability despite symptoms; 2=slight disability; 3=moderate disability; 4=moderately severe disability; and 5=severe disability) [18]. Two weeks after the first interview, a telephonic survey was conducted to verify the reliability of the LUNS-K for respondents who consented.

Concurrent validity

To evaluate the validity of the LUNS-K questionnaire, a survey was conducted using the FAI and the SF-12 to assess the quality of life. The FAI is a specific index developed to assess disability and handicap in stroke patients. It consists of 15 items that capture various activities related to the household, work or leisure, and outdoor life. Participants rated each item on a four-category scale ranging from "never" (1) to "most of the time" (4). The total FAI score ranges from 15 (lower activity) to 60 (higher activity). This index provides insight into activities that reflect a greater level of independence and social functioning. The Korean version of the FAI was translated and demonstrated satisfactory reliability, with a Cronbach's α coefficient of 0.796 [19].

We used the Korean version of the SF-12 v2 [20], a short-form health survey with 12 items obtained directly from the SF-36 v2. The SF-12 v2 consists of the following eight scales: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. We used scales of 0–100 based on the scoring manual. Two summary measures were derived from the 12 items (Physical Component Summary [PCS] and Mental Component Summary [MCS]).

The median and interquartile range (minimum-maximum) of values on the FAI, SF-12 MCS, and SF-12 PCS were calculated for patients with and without unmet needs per item. The Mann–Whitney U-test was used to determine the statistical significance of the difference in FAI, SF-12 MCS, and SF-12 PCS scores between those with and without unmet needs.

Reliability between the face-to-face and telephonic surveys

To evaluate the level of agreement between the face-to-face and the telephonic surveys, Cohen's kappa coefficient (κ), which ranges from -1 to +1, was measured. A κ-value of 0 indicates the level of agreement that would be expected by chance alone, while a value of 1 signifies a perfect agreement between the raters [21]. Additionally, the percentage agreement was calculated and ranged from 0 to 100 where 0 denotes no agreement and 100 represents perfect agreement.

Statistical analysis

Statistical analysis was performed using Jamovi version 1.2.27, a free open-source graphical user interface for R software, and statistical significance was set at $p<0.05$.

RESULTS

Translation and cultural adaptation

During the reconciliation of the forward-translated versions

into a single forward translation in the cognitive debriefing phase, six patients were requested to complete the LUNS-K and a questionnaire assessing their understanding of the questions. During the field testing of the prefinal LUNS-K version, the questionnaire completion time was <5 minutes on average. Furthermore, patients rated the length, readability, and clarity of the LUNS-K and reported that the questionnaire had a good layout and was organized in a clear manner (Table 1). Overall, 22 items were translated and validated (Supplementary Table S1).

Participant characteristics

In total, 66 patients with stroke participated in the initial evaluation, with 49 of those recruited from Hospital A and 17 from Hospital B. Five participants opted out of the re-evaluation process and four patients who initially agreed to the second evaluation did not respond to phone calls. Ultimately, 57 participants (86.4% of the original sample) completed the second (telephonic) survey. Table 2 shows the baseline characteristics of the 66 patients who participated in the first evaluation. Forty-nine of the 66 patients (74.2%) were male (mean age, 61.2±12.8 years). For the educational level, three patients did not respond and most responders were high school graduates (n=20, 31.7%). Most participants (98.5%) lived at home. For stroke type, ischemic, hemorrhagic, and unknown stroke types comprised 51.5%, 43.9%, and 4.5%, respectively. The proportion of participants with a period of 3–6 months, 6–18 months, and >18 months after stroke onset were 9.1%, 22.7%, and 68.2%, respectively. The disability level was assessed using the mRS, and moderate disability (mRS=3) was the most frequent disability (28.8%). The SF-12 MCS, SF-12 PCS, and FAI total scores were 41.5±13.8, 36.7±8.4, and 31.2±11.9, respectively.

Concurrent validity

The concurrent validity findings for the 66 participants are summarized in Table 3. Among the 21 items, individuals without unmet needs exhibited a higher level of daily activity and quality of life than those with unmet needs except one item (item #1), where individuals with unmet needs reported a higher daily activity and quality of life, although the difference was not statistically significant. Notably, significant differences were

Table 2. Socio-demographic characteristics of participants

Characteristics	Value (n=66)
Sex (male)	49 (74.2)
Age (yr)	61.2±12.8 (range, 34–87)
Education[a)]	
Middle school or lower	18 (28.6)
High school	20 (31.7)
College or university	18 (28.6)
Graduate school	7 (11.1)
Current residence (home)	65 (98.5)
Stroke types	
Ischemic	34 (51.5)
Hemorrhagic	29 (43.9)
Unknown	3 (4.5)
Stroke stage	
Subacute (3–6 mo)	6 (9.1)
Early chronic (6–18 mo)	15 (22.7)
Late chronic (>18 mo)	45 (68.2)
Modified Rankin Scale	
0	1 (1.5)
1	14 (21.2)
2	17 (25.8)
3	19 (28.8)
4	10 (15.2)
5	5 (7.6)
SF-12 Mental Component Summary score	41.5±13.8 (16.6–65.8)
SF-12 Physical Component Summary score	36.7±8.4 (20.2–58.7)
Frenchay Activities Index total score	31.2±11.9 (15–57)

Values are presented as number (%), mean±standard deviation, or mean±standard deviation (minimum–maximum).
SF-12, Short Form 12.
[a)]No response (n=3).

Table 1. The usability of the Longer-term Unmet Needs after Stroke instrument into Korean (n=6)

No.	Questionnaire items	Value
1	Is the questionnaire, in your opinion, useful to assess "unmet needs after stroke?"	76.0±29.0
2	Do you feel that the questionnaire inquires about your unmet needs after stroke?	90.3±13.4
3	What is your opinion about the length of the questionnaire?	77.8±19.0
4	Are the questions stated clearly?	79.0±22.0
5	Is the questionnaire well organized?	86.2±19.0
6	What is your feeling regarding the readability of the questionnaire?	91.0±11.9
7	What is your opinion regarding the difficulty of filling in the questionnaire?	89.7±14.2
8	What is your opinion regarding the layout of the questionnaire?	85.2±20.8

Values are presented as mean±standard deviation and are rated on a visual analogue scale from 0 to 100.

Table 3. Concurrent validity of the LUNS questionnaire using the FAI, SF-12 PCS, and SF-12 MCS scores (n=66)

LUNS items (no. of unmet need, %)	FAI score			SF-12 PCS score			SF-12 MCS score		
	No unmet need	Unmet need	p-value	No unmet need	Unmet need	p-value	No unmet need	Unmet need	p-value
1. Information on stroke (n=53, 80.3)	23 (19–31)	32 (23–41)	0.074	33.1 (29.8–40.4)	36.4 (30.4–42.3)	0.802	36.8 (24.7–51.5)	41 (31.5–54.8)	0.306
2. Medication or blood check-up (n=20, 30.3)	31 (22.3–39.8)	30.5 (18.5–39.0)	0.498	36.7 (30.7–42.8)	35.9 (30.0–39.6)	0.339	45.5 (30.7–54.7)	37 (29.7–47.8)	0.174
3. Pain (n=34, 51.5)	32 (23.3–39.8)	30.5 (19.0–38.8)	0.453	39.9 (34.9–43.1)	33.3 (29.1–36.3)*	0.080	45.8 (32.3–55.2)	37 (30.1–51.2)	0.257
4. Difficulties walking (n=21, 31.8)	32 (23–43)	25 (19.0–36.0)	0.046	39.9 (31.7–44.6)	33.5 (29.8–36.0)**	0.007	46.4 (32.5–55.5)	32 (25.2–43.5)	0.060
5. Fear of falling (n=43, 65.2)	32 (25.5–44.0)	30 (19.0–38.5)	0.170	39.5 (31.5–47.1)	35.7 (29.6–40.5)	0.041	51.6 (42.8–59.7)	34.8 (28.4–46.8)**	0.001
6. Need for aids or adaptations inside (n=21, 31.8)	36 (26–43)	22 (17–28)**	<0.001	39.9 (32.7–44.0)	32.3 (27.8–34.6)**	<0.001	44.7 (31.4–54.8)	34.8 (29.9–46.8)	0.391
7. Need for aids or adaptations outside (n=11, 16.7)	31 (20.5–40.5)	25 (21.0–34.5)	0.278	36.5 (31.2–42.7)	32.3 (28.6–34.9)*	0.057	43.5 (30.9–54.8)	34.8 (30.9–44.5)	0.665
8. Information on driving (n=23, 34.8)	31 (23.0–40.5)	26 (19.5–38.0)	0.400	36 (30.0–42.3)	36.3 (32–42)	0.859	41 (31.5–54.6)	40.8 (26.7–51.9)	0.421
9. Information on public transportation (n=20, 30.3)	31.5 (23.0–40.8)	24.5 (19.0–36.3)	0.114	38.4 (30.4–42.8)	34.4 (30.6–37.1)	0.230	46.6 (31.7–55.4)	33.4 (28.5–43.8)*	0.028
10. Help in the household (n=16, 24.2)	31 (21.5–39.8)	27.5 (19–39)	0.480	36.3 (29.9–42.8)	35.4 (32.9–41.5)	0.749	45.9 (32.1–54.8)	30.7 (24.5–37.5)*	0.013
11. Information on moving to another home (n=14, 21.2)	30 (19.0–39.3)	34.5 (24.5–38.8)	0.731	36.3 (30.4–42.5)	34.8 (31.5–41.0)	0.485	44.1 (30.4–55.0)	37 (31.4–45.0)	0.313
12. Advice on the diet (n=30, 45.5)	32 (22.0–39.5)	28.5 (20.3–39.0)	0.541	39.3 (31.1–43.1)	34.2 (29.3–40.2)	0.150	43.5 (34.6–52.4)	33.6 (30.1–55.0)	0.519
13. Help with managing money (n=21, 31.8)	32 (19–41)	26 (22–39)	0.237	39.6 (30.4–43.8)	35 (30.3–36.3)	0.139	41 (31.4–54.3)	40.6 (29.9–54.8)	0.845
14. Help with applying for benefits (n=36, 54.5)	36 (20.8–41.8)	26.5 (20.5–37.5)	0.265	40.5 (29.9–44.5)	34.2 (30.4–37.6)	0.203	43.5 (32–54)	35.9 (30.4–54.8)	0.618
15. Information on employment (n=16, 24.2)	32 (20.3–40.5)	27 (21.3–37.5)	0.480	36.4 (30.2–42.8)	34.3 (30.4–39.1)	0.427	44.1 (31.5–55.0)	33.6 (25.0–45.7)	0.057
16. Help with personal care (n=21, 31.8)	33 (23–42)	24 (19–33)	0.029	39.9 (31.4–44.6)	33.7 (30.3–36.0)*	0.010	43.4 (31.7–54.8)	34.8 (28.7–52.2)	0.278
17. Help with bladder or bowel problems (n=10, 15.2)	32 (22.8–40.3)	22 (19–26)	0.049	36.4 (31.3–42.5)	31.6 (29.2–34.4)	0.110	44.1 (31.1–55.0)	34.8 (29.4–36.6)	0.106
18. Advice on the physical relationship (n=6, 9.1)	31.5 (19.8–40.3)	24 (21.5–28.8)	0.249	36.3 (30.9–42.5)	30.6 (28.1–35.3)	0.074	42.2 (30.4–54.4)	35.8 (33.0–50.5)	0.710
19. Help with concentration or memory (n=30, 45.5)	36.5 (25.8–46.0)	24.5 (18.3–32.8)**	0.003	38 (31.3–45.1)	35.5 (30.3–39.8)	0.059	49.6 (39.8–57.4)	31.8 (24.6–40.9)**	<0.001
20. Help with mood (n=34, 51.5)	36.5 (25–46)	26 (19–36)*	0.006	36.8 (31.6–44.7)	35.5 (30.3–41.6)	0.247	54.5 (43.8–59.1)	31.8 (24.6–40.0)**	<0.001
21. Advice on daily occupations (n=28, 42.4)	36 (24.3–43.5)	25.5 (19–33)*	0.019	39.9 (31.6–44.9)	33.6 (30.4–37.6)*	0.032	47.9 (37.2–56.4)	33.3 (27.4–44.0)**	0.002
22. Information on holidays (n=24, 36.4)	36 (25.0–43.5)	23.5 (19–33)*	0.014	39.6 (31.6–44.5)	33.3 (30.2–36.1)*	0.024	47.9 (35.7–55.7)	31.8 (24.7–38.2)**	0.001

Values are presented as the median (interquartile range).

LUNS, Longer-term Unmet Needs after Stroke; FAI, Frenchay Activity Index; SF-12, Short Form 12; PCS, Physical Component Summary; MCS, Mental Component Summary.

*p<0.05, **p<0.01 using Mann–Whitney U-test.

observed in the SF-12 MCS, SF-12 PCS, and FAI scores for 12 items.

Among the 21 items, individuals without unmet needs demonstrated significantly higher FAI scores in areas related to levels of independence and social functioning, such as the need for aids or adaptations inside, assistance with concentration or memory, support for mood, advice on daily occupations, and information on holidays. Similarly, the SF-12 PCS scores in individuals without unmet needs were significantly higher for pain, difficulties walking, need for aids or adaptations inside, need for aids or adaptations outside, help with personal care, advice on daily occupations, and information on holidays. Regarding the SF-12 MCS, individuals without unmet needs had significantly higher scores for fear of falling, information on public transportation, help in the household, help with concentration or memory, help with mood, advice on daily occupations, and information on holidays.

Reliability between the face-to-face and telephonic surveys

Table 4 shows the results of the reliability evaluation conducted using 57 patients. One item had an almost perfect agreement (κ >0.80), 11 items demonstrated substantial agreement (κ, 0.61–0.80), eight items showed moderate agreement (κ, 0.41–0.60), and two items showed fair agreement (κ, 0.21–0.40), with the percentage of agreement ranging from 73.7% (pain) to 93.0% (help with bladder or bowel problems).

Unmet needs in the study population

Common unmet needs (>50%) reported by participants during the face-to-face (T1) interview included information on stroke (80%), fear of falling (65%), help with applying for benefits (55%), pain (52%), and help with mood (52%). Less common unmet needs (<30%) during T1 interviews included advice on physical relationships (9%), help with bladder or bowel problems (15%), need for aid or adaptations outside (17%), information on moving to another home (21%), information on employment (24%), and help in the household (24%; Fig. 1).

DISCUSSION

In this study, we translated and cross-culturally adapted the LUNS questionnaire to Korean and assessed its validity and

Table 4. Reliability between the face-to-face and telephonic LUNS-K surveys (n=57)

LUNS items	Kappa statistic (95% CI)	Percentage agreement (%)
1. Information on stroke	0.637** (0.372–0.902)	89.5
2. Medication or blood check-up	0.446** (0.191–0.701)	77.2
3. Pain	0.477** (0.253–0.701)	73.7
4. Difficulties walking	0.414** (0.158–0.670)	75.4
5. Fear of falling	0.632** (0.427–0.836)	82.5
6. Need for aids or adaptations inside	0.806** (0.644–0.967)	91.2
7. Need for aids or adaptations outside	0.394** (0.086–0.701)	82.5
8. Information on driving	0.763** (0.586–0.941)	89.5
9. Information on public transportation	0.531** (0.288–0.774)	80.7
10. Help in households	0.662** (0.433–0.890)	87.7
11. Information on moving to another home	0.579** (0.318–0.839)	86.0
12. Advice on diet	0.565** (0.356–0.774)	78.9
13. Help with managing money	0.630** (0.412–0.848)	84.2
14. Help with applying for the benefit	0.649** (0.451–0.846)	82.5
15. Information on employment	0.532** (0.292–0.773)	80.7
16. Help with personal care	0.605** (0.385–0.825)	82.5
17. Help with bladder or bowel problems	0.709** (0.441–0.977)	93.0
18. Advice on the physical relationship	0.397** (-0.029–0.824)	91.2
19. Help with concentration or memory	0.679** (0.487–0.870)	84.2
20. Help with the mood	0.573** (0.358–0.787)	78.9
21. Advice on daily occupation	0.709** (0.522–0.895)	86.0
22. Information on holidays	0.692** (0.495–0.889)	86.0

LUNS-K, Longer-term Unmet Needs after Stroke instrument into Korean; CI, confidence interval.
**p<0.01.

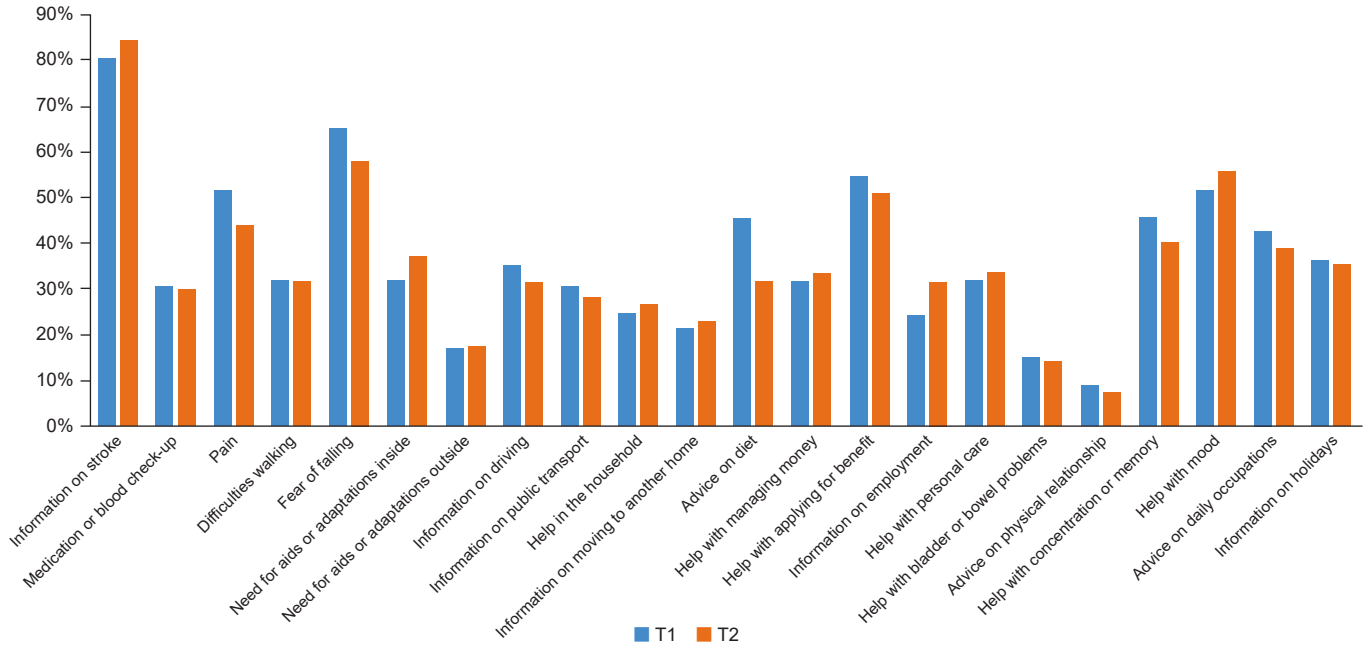

Fig. 1. The percentage of stroke survivors reporting unmet needs for each item of the Longer-term Unmet Needs after Stroke instrument into Korean during face-to-face (T1, n=66) and telephonic (T2, n=57) interviews.

test-retest reliability in stroke survivors. Our findings show that the LUNS-K is a reliable and valid instrument for measuring unmet needs in Korean patients with stroke. Field testing is a comprehensive and feasible method. In a larger group, field testing showed high agreement between the face-to-face and telephone tests and yielded a few missing items. For 12 of 22 items, those with unmet needs had significantly lower scores on one or more instruments for activities and quality of life, demonstrating their validity.

In terms of concurrent validity, the results of the original validation study conducted by the LoTS care LUNS study team showed that 21 items were significantly associated with lower scores on the FAI or the SF-12. In our study, however, only 12 items showed significant associations. This difference in concurrent validity findings could be attributed to several factors. First, our study had a smaller sample size, which might have lowered the statistical power and limited the ability to detect significant associations. Second, the higher percentage of unmet needs per item in our study population might have contributed to the reduced number of significant associations. Lastly, the longer timeframe in our study, including stroke survivors at various stages of recovery, could have influenced the concurrent validity results compared to the original study, which focused on participants within the 3–6 months post-stroke period.

In this study, we compared the results of the first survey conducted in person with the second survey conducted via telephone. Of 22 items, 20 showed a moderate reliability or better, while two items (items #7 and #18) showed a marginally fair reliability (κ=0.394 and 0.397, respectively). Considering that the two surveys were conducted using different methods, the reliability of the LUNS-K is believed to be acceptable for clinical usage [22].

The unmet need for aids or adaptation outside only showed marginal reliability between the surveys, with 16.7% of the participants providing a "yes" response to the question. The LUNS-K questionnaire included examples of outside adaptations such as "ramp" or "rail" as in the original LUNS. However, these modifications of the outside environment can be unfamiliar in a Korean setting, as Korean people tend to live in apartments. This lack of familiarity with outside adaptations may have made the question vague for the participants. Thus, a more detailed example or description of the item would increase the reliability of the LUNS-K.

Only 9% of the participants reported that they had an unmet need for "advice on physical relationships." The very low rate of this unmet need may be associated with its low test-retest

reliability (κ<0.4). A previous study including Korean female patients with cervical cancer reported a low response rate for obtaining sexuality-related information [23]. They reported that participants who did not respond to sexuality-related items showed significantly different characteristics from those who responded; they were more likely to be older, unmarried, less educated, unemployed, earning a lower income, and at an advanced stage of the disease. In this study, participants did not avoid responding to sex-related items. However, considering the avoidance of sexual questions among older Koreans, they might have avoided providing an accurate response by expressing no unmet needs. Therefore, we cannot rule out the possibility that they selected "no unmet need" rather than avoid answering because the first survey was conducted face-to-face. Moreover, the question regarding help with voiding/defecation difficulty, which patients may also tend to avoid had a low prevalence (15.2%) but showed substantial reliability (κ=0.709). As such, the causal relationship between low prevalence and low reliability remains unclear. Therefore, the results of sex-related needs in future surveys on unmet needs should be interpreted with caution, due to the older age of stroke survivors and the potential cultural influences affecting their responses.

Identification of unmet needs after stroke is crucial to inform health and social service provision. In addition, understanding the specific needs of stroke survivors is vital for providing patient-centered health and social care. The prevalence of unmet long-term needs is high among survivors of stroke [8]. Patients with stroke who participated in this study most frequently reported a need for information on stroke, followed by concerns about falls, pain, and depression/anger/anxiety. Our findings are corroborated by results from a study on a Dutch stroke population [14] that reported the highest unmet needs in the stroke information domain, suggesting that clinicians should assess the need and provide sufficient information to patients with chronic stroke.

The use of different survey methods is a notable characteristic of the study. We conducted the second survey via telephone, and the response rate was 86.4%. The telephone survey method reportedly has several advantages compared with the postal survey method, including a higher response rate, reduced responder selection bias, and higher retest reliability [24]. Additionally, administering questionnaires via telephone to non-responders of postal surveys resulted in higher response rates (>80%) [25]. Telephone surveys are particularly suitable for stroke patients with physical disabilities and limited mobility. Additionally, with the increasing adoption of social distancing procedures and telecommunication, as seen during the coronavirus disease 2019 pandemic, face-to-face and group meetings have significantly declined. As a result, non-face-to-face survey methods, including telephonic surveys, are now preferred over in-person surveys. Also, conducting in-person interviews requires substantial resources and is impractical for large community populations. Therefore, we anticipate that telephonic surveys will be increasingly employed in future studies.

Our study had a few limitations. First, the inclusion of participants at different stroke stages resulted in various post-stroke periods. Patients with stroke can be classified into different stages, including acute (<3 weeks), subacute (3 weeks–6 months), early chronic (6–18 months), and late chronic (>18 months) [17]. The possibility of changes in unmet needs between the two tests (initical and second surveys) in subacute post-stroke patients could not be excluded. However, the majority of our participants were in the late chronic stage (68.2%), implying that the test was performed in a stable population. Further research should investigate and analyze unmet needs based on the specific stages of chronicity in stroke patients. Second, we did not conduct a test-retest of the face-to-face survey. Instead, the second survey was conducted via telephone. The difference in survey methods may have affected the reliability assessment of the questionnaire, particularly because people tend to respond more easily to sensitive questions via telephone than face-to-face [26,27]. Nonetheless, the advantages of administering telephonic surveys were considerable; the response rate of the second survey was >80%. Moreover, assessing the LUNS-K using both face-to-face and telephone interviews confirmed the validity and reliability of this instrument, as well as its feasibility in clinical settings using different survey methods. Finally, the participants in this study comprised post-stroke patients with the cognitive ability to understand and answer the LUNS-K. This means that the prevalence and validity of the LUNS-K in patients with severe cognitive impairment remains uninvestigated. To address this issue, further studies should include patients with stroke who have severe cognitive impairments by including these patients' caregivers as needed.

In conclusion, the LUNS-K is a reliable and valid instrument for assessing unmet health needs in Korean patients with stroke. Unmet needs and low health questionnaire values (FAI, MCS, and PCS) were confirmed for 12 items when the validity of the LUNS-K was analyzed. Although the agreement is lower in some parts of the Korean version compared to the original En-

glish version, the reliability of the LUNS-K is still acceptable. In addition, this instrument can be reliably applied telephonically as well.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

Conceptualization: Baek S, Kim WS, Paik NJ. Methodology: Baek S, Kim WS, Jung YS, Chang WK, Paik NJ. Formal analysis: Baek S, Jung YS, Chang WK, Kim G. Funding acquisition: Paik NJ. Project administration: Baek S, Kim WS, Park YH, Jung YS, Chang WK, Kim G, Paik NJ. Visualization: Baek S, Kim WS, Jung YS, Chang WK. Writing – original draft: Baek S. Writing – review and editing: Baek S, Kim WS, Jung YS, Chang WK, Kim G, Paik NJ. Approval of final manuscript: all authors.

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SUPPLEMENTARY MATERIALS

Supplementary materials can be found via https://doi.org/10.5535/arm.23044.

ORCID

Sora Baek, https://orcid.org/0000-0003-3404-6202
Won-Seok Kim, https://orcid.org/0000-0002-1199-5707
Yul-Hyun Park, https://orcid.org/0000-0003-3103-293X
Yun Sun Jung, https://orcid.org/0000-0002-4628-3996
Won Kee Chang, https://orcid.org/0000-0001-9756-6817
Gowun Kim, https://orcid.org/0000-0002-5694-8111
Nam-Jong Paik, https://orcid.org/0000-0002-5193-8678

REFERENCES

1. GBD 2016 Stroke Collaborators. Global, regional, and national burden of stroke, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Neurol 2019;18:439-58.
2. Kim JY, Kang K, Kang J, Koo J, Kim DH, Kim BJ, et al. Executive summary of stroke statistics in Korea 2018: a report from the Epidemiology Research Council of the Korean Stroke Society. J Stroke 2019;21:42-59.
3. Winstein CJ, Stein J, Arena R, Bates B, Cherney LR, Cramer SC, et al. Guidelines for adult stroke rehabilitation and recovery: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke 2016;47:e98-169. Erratum in: Stroke 2017;48:e78. Erratum in: Stroke 2017;48:e369.
4. Kim DY, Kim YH, Lee J, Chang WH, Kim MW, Pyun SB, et al. Clinical practice guideline for stroke rehabilitation in Korea 2016. Brain Neurorehabil 2017;10(Suppl 1):e11.
5. Murray J, Ashworth R, Forster A, Young J. Developing a primary care-based stroke service: a review of the qualitative literature. Br J Gen Pract 2003;53:137-42.
6. Chang WH, Sohn MK, Lee J, Kim DY, Lee SG, Shin YI, et al. Predictors of functional level and quality of life at 6 months after a first-ever stroke: the KOSCO study. J Neurol 2016;263:1166-77.
7. Im HW, Kim WS, Kim S, Paik NJ. Prevalence of worsening problems using post-stroke checklist and associations with quality of life in patients with stroke. J Stroke Cerebrovasc Dis 2020;29:105406.
8. Chen T, Zhang B, Deng Y, Fan JC, Zhang L, Song F. Long-term unmet needs after stroke: systematic review of evidence from survey studies. BMJ Open 2019;9:e028137.
9. Andrew NE, Kilkenny MF, Lannin NA, Cadilhac DA. Is health-related quality of life between 90 and 180 days following stroke associated with long-term unmet needs? Qual Life Res 2016;25:2053-62.
10. Andrew NE, Kilkenny MF, Naylor R, Purvis T, Cadilhac DA. The relationship between caregiver impacts and the unmet needs of survivors of stroke. Patient Prefer Adherence 2015;9:1065-73.
11. Kim KT, Chang WK, Jung YS, Jee S, Sohn MK, Ko SH, et al. Unmet needs for rehabilitative management in common health-related problems negatively impact the quality of life of community-dwell-

ing stroke survivors. Front Neurol 2021;12:758536.
12. LoTS care LUNS study team. Validation of the longer-term unmet needs after stroke (LUNS) monitoring tool: a multicentre study. Clin Rehabil 2013;27:1020-8.
13. Murray J, Young J, Forster A, Ashworth R. Developing a primary care-based stroke model: the prevalence of longer-term problems experienced by patients and carers. Br J Gen Pract 2003;53:803-7.
14. Groeneveld IF, Arwert HJ, Goossens PH, Vliet Vlieland TPM. The Longer-term Unmet Needs after Stroke Questionnaire: cross-cultural adaptation, reliability, and concurrent validity in a Dutch population. J Stroke Cerebrovasc Dis 2018;27:267-75.
15. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for Translation and Cultural Adaptation. Value Health 2005;8:94-104.
16. Timmerman H, Wolff AP, Schreyer T, Outermans J, Evers AW, Freynhagen R, et al. Cross-cultural adaptation to the Dutch language of the PainDETECT-Questionnaire. Pain Pract 2013;13:206-14.
17. Ballester BR, Maier M, Duff A, Cameirão M, Bermúdez S, Duarte E, et al. A critical time window for recovery extends beyond one-year post-stroke. J Neurophysiol 2019;122:350-7.
18. Wilson JT, Hareendran A, Grant M, Baird T, Schulz UG, Muir KW, et al. Improving the assessment of outcomes in stroke: use of a structured interview to assign grades on the modified Rankin Scale. Stroke 2002;33:2243-6.
19. Han CW, Lee EJ, Kohzuki M. Validity and reliability of the Frenchay Activities Index for community-dwelling elderly in South Korea. Tohoku J Exp Med 2009;217:163-8.
20. Kim SH, Jo MW, Ahn J, Ock M, Shin S, Park J. Assessment of psychometric properties of the Korean SF-12 v2 in the general population. BMC Public Health 2014;14:1086.
21. Cohen J. A coefficient of agreement for nominal scales. Educ Psychol 1960;20:37-46.
22. Sim J, Wright CC. The kappa statistic in reliability studies: use, interpretation, and sample size requirements. Phys Ther 2005;85:257-68.
23. Shin DW, Choi JE, Miyashita M, Choi JY, Kang J, Baik YJ, et al. Cross-cultural application of the Korean version of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 15-Palliative Care. J Pain Symptom Manage 2011;41:478-84.
24. Duncan P, Reker D, Kwon S, Lai SM, Studenski S, Perera S, et al. Measuring stroke impact with the stroke impact scale: telephone versus mail administration in veterans with stroke. Med Care 2005;43:507-15.
25. Sibbald B, Addington-Hall J, Brenneman D, Freeling P. Telephone versus postal surveys of general practitioners: methodological considerations. Br J Gen Pract 1994;44:297-300.
26. Analysis of sexual behaviour in France (ACSF). A comparison between two modes of investigation: telephone survey and face-to-face survey. ASCF principal investigators and their associates. AIDS 1992;6:315-23.
27. Czaja R. Asking sensitive behavioral questions in telephone interviews. Int Q Community Health Educ 1987;8:23-32.

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Risk Factors for Suicidality in Individuals With Spinal Cord Injury: A Focus on Physical and Functional Characteristics

Sora Han, MD, Wooyeung Kim, MD, Onyoo Kim, MD

Department of Rehabilitation Medicine, National Rehabilitation Center, Seoul, Korea

Objective: To demonstrate the association between the physical and functional characteristics of individuals with spinal cord injury (SCI) and suicidality, an area of research that is less understood than the association with demographic, social, and psychological characteristics.
Methods: A retrospective cross-sectional study was conducted with 259 patients with SCI admitted for rehabilitation at the National Rehabilitation Center, Seoul, between January 2019 and December 2021. Demographic, SCI-related, physical, and functional data were collected from their medical records. Suicide risk was assessed using the Mini International Neuropsychiatric Interview.
Results: The 259 participants had an average age of 49.1 years, and 75.7% were male. The analysis revealed a statistically significant negative correlation between age and suicidality. No significant differences were found for sex, education, occupation, or SCI-related factors. Lower upper extremity motor score (UEMS) was significantly associated with higher suicide risk. Regarding functional factors, the inability to perform independent rolling, come to sit, wheelchair propelling, and self-driving were associated with increased suicidality. In the multiple linear regression analysis, lower UEMS, limited shoulder joint motion, upper extremity spasticity, and dependent wheelchair propulsion were predictors of higher suicide risk.
Conclusion: This study highlights the associations among physical status, functional dependency, and suicide risk in individuals with SCI. These findings emphasize the need to address psychological aspects and physical and functional factors in the management of individuals with SCI who are at a high risk of suicide.

Keywords: Suicide, Spinal cord injuries, Risk factors, Functional dependence, Upper extremity

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Correspondence:
Onyoo Kim
Department of Rehabilitation Medicine, National Rehabilitation Center, 58 Samgaksan-ro, Gangbuk-gu, Seoul 01022, Korea.
Tel: +82-2-901-1883
Fax: +82-2-901-1920
E-mail: ohnew33@korea.kr

INTRODUCTION

Spinal cord injury (SCI) is a devastating condition that often results in significant physical, psychological, and social consequences for affected individuals, potentially leading to even more serious outcomes such as suicide [1,2]. Understanding suicidality in the SCI population is of utmost importance, as individuals with SCI reportedly have more than a three-fold higher suicide incidence than those without SCI [3,4]. It has also been observed that 34.8% of individuals with chronic SCI experience suicidal ideation, with 17.3% having attempted suicide and a maximum of 11% resulting in fatalities [5].

Several studies have been conducted to elucidate risk factors for suicidality in patients with SCI [6-11]. Various psychological components, including a history of suicide attempts, depression, impulsivity, self-esteem issues, and alcohol misuse, have been

recognized as significant contributors to suicide risk in individuals with SCI [6,8]. Social disconnection, such as unemployment, has also been associated with increased suicidality [7,12].

While many studies have focused on the direct impact of mental and social aspects on SCI suicidality, there remains a relative lack of understanding regarding connections between the suicide tendencies of the SCI population and their physical and functional characteristics [9-11,13,14]. A fundamental consideration for the SCI population is that SCI primarily results in physical and functional challenges for affected individuals [15-17], in addition to psychosocial issues. While it is recognized that physical conditions like spasticity, pain, or reduced mobility often lead to greater dependency in daily activities and a diminished quality of life and self-identity [18-21], few studies have explicitly examined the impact of these physical and functional constraints on suicide risk [10,13]. Therefore, to identify those most at risk of suicide within the SCI population, it is important to understand how physical discomfort or functional dependency in SCI relates to suicide risk.

This study aimed to explore how certain physical and functional characteristics of individuals with SCI might correlate with reported suicidality. By understanding the combined psychosocial and physical risk factors for suicide, we aim to offer comprehensive prevention measures and early interventions for the SCI population.

METHODS

Participants

In this retrospective, cross-sectional study, the medical records of inpatients with SCI admitted to the SCI unit at the National Rehabilitation Center, Seoul, Korea, between January 2019 and December 2021 were assessed. The inclusion criteria for psychological evaluation encompassed individuals who were 18 years of age or older, possessed the capability of engaging in normal communication, and demonstrated the ability to understand and complete the survey. Individuals who did not understand the survey content or did not wish to participate were excluded. All psychological evaluations were conducted after obtaining informed consent from the participants. Among the 411 inpatients during the research period, 259 who underwent psychological evaluation were identified. This study was approved by the Institutional Review Board of the National Rehabilitation Center (#NRC-2022-01-005).

Data collection

Data collected included demographic factors (age, sex, body mass index, educational level, and current occupation) and SCI-related factors (duration from injury onset, severity of SCI or completeness of injury, neurological level of injury [NLI], and etiology of injury) from admission medical charts. Physical characteristics (upper extremity motor score [UEMS], lower extremity motor scores, limited range of motion [LOM] of the shoulder and hip, and spasticity of the upper and lower extremities) and functional characteristics (dependency on rolling, coming to sit, wheelchair propelling, functional ambulation categories scales, and capability of self-driving) were extracted from the physical therapy evaluation reports performed at the time of admission. These variables were classified into four groups (demographic, SCI-related, physical, and functional) based on each characteristic.

Measurement of suicidality

The assessment of suicidality was performed within one week from the date of admission. A psychologist with more than 10 years of clinical experience evaluated participants' suicidality using the Korean version of the Mini International Neuropsychiatric Interview (K-MINI) [22]. The K-MINI module comprises six questions: wish for death (1 point), wish for self-harm (2 points), suicidal thoughts (6 points), suicide plans (10 points), suicide attempts in the past month (10 points), and lifetime suicide attempts (4 points) [23]. The total K-MINI score was calculated from the sum of the six questions, and the severity of suicidality was determined. Those with a score of 5 or below indicated a low suicide risk group and those with a score of 6 or above indicated a high suicide risk group. Psychological counseling has been recommended for individuals in the high suicide risk group.

Statistical analysis

All the statistical analysis were performed using IBM SPSS Statistics 27.0 (IBM Corp.). Participant characteristics were presented as mean±standard deviation for continuous variables, and numerical values (n) and percentages (%) for categorical variables. The association between the variables (demographic, SCI-related, physical, and functional characteristics) and suicide risk was evaluated using an independent t-test for categorical data and a Pearson correlation test for numerical data. To examine the risk factors for suicidality, simple and multiple linear regression analysis were performed using K-MINI suicide

scores as the dependent variable. Beta (β) was used to represent the change in the dependent variable for each unit change in the independent variable. Statistical significance was set at $p<0.05$.

RESULTS

Table 1 shows the demographic and clinical characteristics of participants. The average age of the 259 participants was 49.1±16.5 years, and 196 were male (75.7%). Of the total sample, 150 (63.8%) were unemployed. Regarding SCI-related factors, the average duration since injury was 716.7±1,867.8 days. According to the American Spinal Injury Association classification [24], incomplete injuries were more prevalent (68.1%). Tetraplegia and paraplegia accounted for 55.1% (n=140) and 44.9% (n=114) of the cases, respectively. A total of 177 (70.2%) individuals had traumatic SCI. The UEMS group obtained an average score of 35.9±15.7. Among the physical values, 35.7% (n=91) of the study participants reported LOM of the shoulder and 28.2% (n=72) had upper extremity spasticity. Suicidality, as assessed by the K-MINI module, had an average score of 1.8±3.3.

When analyzing the association between associated factors and suicide risk (Table 2), age showed a statistically significant negative correlation with suicidality (r=-0.162, p=0.021). However, no significant correlations were observed with sex, education, or occupation. Regarding SCI-related factors, no statistical significance was found in terms of the duration of injury, completeness, NLI, injury etiology, or their relationships with suicidality (p>0.05). Regarding physical characteristics, a statistically significant negative correlation was observed between UEMS and suicidality (r=-0.144, p=0.042). Compared to the low risk group, the average UEMS in the high suicide risk group was 6.5 points lower (p=0.037) (Fig. 1). Although the average total K-MINI scores were respectively 0.9 and 1.2 points higher in individuals with LOM of the shoulder (p=0.070) and upper extremity spasticity (p=0.028), no statistically significant relationships were found between the presence of all types of LOM or spasticity and increased suicidality. Among the functional characteristics, a significantly higher suicide risk was observed in cases in which participants were incapable of performing independent rolling (p=0.014), sitting (p=0.018), and wheelchair propelling (p=0.004). In particular, the average total K-MINI score of the dependent wheelchair propellers was 1.86 points higher compared to that of the independent group (p<0.001). There was also significantly higher suicidality among partici-

Table 1. Demographics and clinical features of study participants

Characteristic	Value (n=259)
Demographic factor	
Age (yr)	49.1±16.5
Sex	
Male	196 (75.7)
Female	63 (24.3)
Body mass index (kg/m^2)	23.2±3.6
Education (yr)[a]	
>12	110 (43.5)
≤12	143 (56.5)
Current occupation[a]	
Yes	85 (36.2)
No	150 (63.8)
SCI related factor	
Duration from injury (day)	716.7±1,867.8
<3 mo	45 (17.4)
≥3 mo and <6 mo	51 (19.7)
≥6 mo	163 (62.9)
Severity of SCI[a]	
Complete injury	80 (31.9)
Incomplete injury	171 (68.1)
Neurological level of injury[a]	
Tetraplegia	140 (55.1)
Paraplegia	114 (44.9)
Etiology of injury[a]	
Traumatic	177 (70.2)
Nontraumatic	75 (29.8)
Physical characteristic	
ASIA motor score	
UEMS	35.9±15.7
LEMS	16.4±16.5
LOM of shoulder[a]	
Yes	91 (35.7)
No	164 (64.3)
LOM of hip[a]	
Yes	44 (17.3)
No	210 (82.7)
Spasticity of upper extremity[a]	
Yes	72 (28.2)
No	183 (71.8)
Spasticity of lower extremity[a]	
Yes	127 (49.8)
No	128 (50.2)
Functional characteristic	
Rolling[a]	
Independent	160 (63.2)
Dependent	93 (36.8)
Come to sit[a]	
Independent	126 (50.0)
Dependent	126 (50.0)
Wheelchair propelling[a]	
Independent	139 (63.8)
Dependent	79 (36.2)

(Continued to the next page)

Table 1. Continued

Characteristic	Value (n=259)
FAC scale	1.8±1.4
Self-driving[a)]	
Yes	28 (12.3)
No	199 (87.7)
Phychological factor	
Suicide (K-MINI)	1.8±3.3

Values are presented as mean±standard deviation or number (%).
SCI, spinal cord injury; AISA, American Spinal Injury Association; UEMS, upper extremity motor score; LEMS, lower extremity motor score; LOM, limited range of motion; FAC, functional ambulation categories; K-MINI, Korean version of the Mini International Neuropsychiatric Interview.
[a)]Analysis was conducted on the participants from whom data was available.

pants unable to drive compared to those capable of self-driving (p=0.001).

In the simple linear regression analysis examining the factors influencing suicide risk, as measured by the total K-MINI scores (Table 3), the following predictors were identified as statistically significant: age (β=-0.16, p=0.021), UEMS (β=-0.14, p=0.042), spasticity of the upper extremity (β=0.16, p=0.028), dependency of rolling (β=-0.20, p=0.005), come to sit (β=-0.17, p=0.016), and wheelchair propelling (β=-0.26, p<0.001).

A multiple linear regression analysis revealed that among the physical factors, lower UEMS (β=-0.63, p=0.027), shoulder LOM (β=0.33, p=0.031), and upper extremity spasticity (β=0.47, p=0.023) were significant predictors of increased suicide risk. Among the functional characteristics, independent wheelchair propelling was a predictor of lower suicide risk (β=-0.43, p=0.018; Table 4).

DISCUSSION

In this study, we analyzed the association between the demographic, SCI-related, physical, and functional characteristics of participants with SCI and their suicidality based on total K-MINI scores. Results indicated that age had a statistically significant negative correlation with suicide risk. No significant associations were found with SCI-related factors, including duration from injury, completeness, and NLI. Among the physical characteristics, UEMS was significantly associated with higher suicidality scores, and lower UEMS was found to be a predictor of increased suicide risk. In terms of functional characteristics, the inability to perform independent rolling, sitting, wheelchair propelling, and self-driving was associated with higher suicid-

Table 2. Association between suicide risk and characteristics of SCI participants

Characteristic	Mean±SD	r	p-value
Demographic factor			
Age (yr)		-0.162	0.021*
Sex			
Male	1.6±3.2		0.187
Female	2.3±3.7		
Body mass index (kg/m^2)		0.000	0.996
Education (yr)			
>12	1.4±3.0		0.234
≤12	2.0±3.5		
Current occupation			
Yes	1.6±3.4		0.427
No	2.0±3.5		
SCI related factor			
Duration from injury (day)		0.036	0.615
Severity of SCI			
Complete injury	1.7±3.3		0.817
Incomplete injury	1.9±3.4		
Neurological level of injury			
Tetraplegia	2.0±3.9		0.271
Paraplegia	1.5±2.6		
Etiology of injury			
Traumatic	1.7±3.4		0.483
Nontraumatic	2.1±3.2		
Physical characteristic			
ASIA motor score			
UEMS		-0.144	0.042*
LEMS		-0.083	0.246
LOM of shoulder			
Yes	2.4±3.9		0.097†
No	1.5±3.0		
LOM of hip			
Yes	2.0±3.0		0.458
No	1.6±3.1		
Spasticity of upper extremity			
Yes	2.7±4.6		0.089†
No	1.5±2.8		
Spasticity of lower extremity			
Yes	2.1±3.9		0.293
No	1.5±2.7		
Functional characteristic			
Rolling			
Independent	1.3±2.7		0.014*
Dependent	2.7±4.2		
Come to sit			
Independent	1.2±2.5		0.018*
Dependent	2.4±4.0		
Wheelchair propelling			
Independent	1.2±2.4		0.004**
Dependent	3.1±4.5		
FAC scale		-0.172	0.084†
Self-driving			
Yes	0.7±1.5		0.001**
No	2.1±3.6		

SCI, spinal cord injury; SD, standard deviation; AISA, American Spinal Injury Association; UEMS, upper extremity motor score; LEMS, lower extremity motor score; LOM, limited range of motion; FAC, functional ambulation categories.
***p<0.001, **p<0.01, *p<0.05, and †p<0.10.

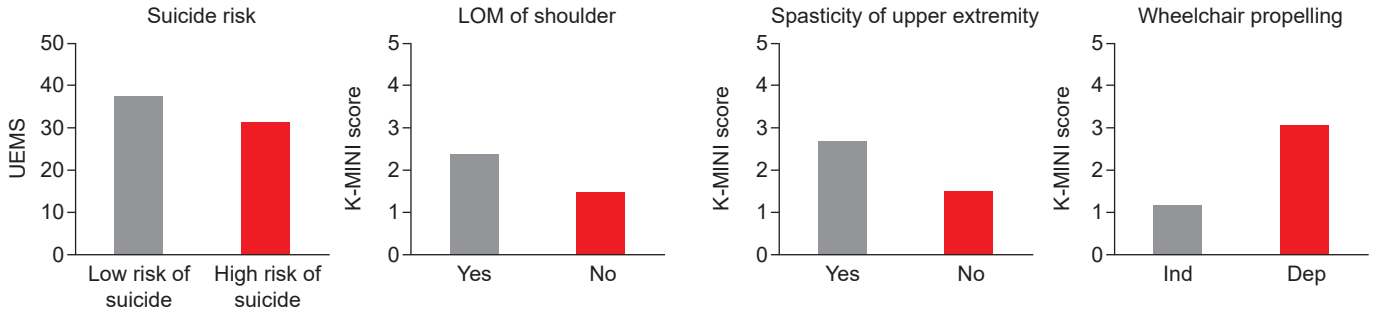

Fig. 1. Comparison of Korean version of the Mini International Neuropsychiatric Interview (K-MINI) scores with physical and functional characteristics of spinal cord injury participants. UEMS, upper extremity motor score; Low risk of suicide, K-MINI score <5; High risk of suicide, K-MINI score>6; LOM, limited range of motion; Ind, independent; Dep, dependent.

Table 3. Simple linear regression for suicide risk in spinal cord injury participants

Factor	Characteristic	B	SE	β	t	p-value
Demographic factor	Age (yr)	-0.03	0.01	-0.16	-2.32	0.021*
Physical characteristic	UEMS	-0.03	0.02	-0.14	-2.04	0.042*
	LOM of shoulder	0.91	0.50	0.13	1.82	0.070†
	Spasticity of upper extremity	1.20	0.54	0.16	2.21	0.028*
Functional characteristic	Rolling	-1.42	0.50	-0.20	-2.87	0.005**
	Come to sit	-1.14	0.47	-0.17	-2.42	0.016*
	Wheelchair propelling	-1.87	0.52	-0.26	-3.56	<0.001***
	FAC scale	-0.41	0.23	-0.17	-1.74	0.084†
	Self-driving	-1.41	0.75	-0.14	-1.90	0.059†

Reference group: come to sit (0=dependent); LOM of shoulder (0=no); rolling (0=dependent); self-driving (0=no); spasticity of upper extremity (0=no); wheelchair propelling (0=dependent).
SE, standard error; UEMS, upper extremity motor score; LOM, limited range of motion; FAC, functional ambulation categories.
***p<0.001, **p<0.01, *p<0.05, and †p<0.10.

Table 4. Multiple linear regression for suicide risk in spinal cord injury participants

Factor	Characteristic	B	SE	β	t	p-value
(Constant)		-3.24	3.60		-0.90	0.372
Demographic factor	Age (yr)	-0.04	0.02	-0.20	-1.64	0.106
Physical characteristic	UEMS	-0.20	0.09	-0.63	-2.27	0.027*
	LOM of shoulder	2.26	1.02	0.33	2.21	0.031*
	Spasticity of upper extremity	3.33	1.42	0.47	2.34	0.023*
Functional characteristic	Rolling	-0.62	1.28	-0.08	-0.48	0.632
	Come to sit	0.29	1.17	0.04	0.24	0.808
	Wheelchair propelling	-3.09	1.27	-0.43	-2.44	0.018**
	FAC scale	-0.18	0.30	-0.08	-0.60	0.549
	Self-driving	-0.95	0.96	-0.12	-0.99	0.327

Reference group: come to sit (0=dependent); LOM of shoulder (0=no); rolling (0=dependent); self-driving (0=no); spasticity of upper extremity (0=no); wheelchair propelling (0=dependent).
$F(9, 60)=2.71$ ($p<0.01$), $R^2=0.289$.
SE, standard error; UEMS, upper extremity motor score; LOM, limited range of motion; FAC, functional ambulation categories.
***p<0.001, **p<0.01, *p<0.05, and †p<0.10.

ality. Specifically, independent wheelchair propulsion was a predictor of lower suicide risk. The analysis also indicated that LOM of the shoulder and upper extremity spasticity were predictors of higher suicide risk.

Overall, the most notable study findings pertain to the physical and functional characteristics of suicidality. With regard to physical characteristics, a lower UEMS score was found to be a predictor of increased suicide risk. Considering that UEMS is an indicator of functional dependency in SCI [25] and that muscle strength plays a key role in independent self-care in individuals with SCI [26], study participants with lower UEMS scores were presumed to have struggled to pursue functional day-to-day lives. These dependencies could lead to diminished self-efficacy and desire for life [16,27,28]. Moreover, in the current study, LOM of the shoulder and upper extremity spasticity were identified as predictors of higher suicide risk. Together with the lack of muscle strength, these physical discomforts could have concurrently contributed to the participants' mental health deterioration by causing a range of functional disturbances [15,29-31]. Physical discomfort in the lower extremities was not of particular significance. A pilot study revealed that joint contractures, particularly in the upper extremities, can negatively affect functional abilities in individuals with SCI [29]. Similar to the associations observed with physical characteristics, our results on functional characteristics provided significant insights, especially with wheelchair propulsion, a functional movement performed using the upper extremities [15]. Overall, our findings underscored the need for appropriate interventional strategies for patients with SCI with physical and functional concerns, particularly in the upper extremities.

Interestingly, among the SCI-related factors, NLI and completeness did not demonstrate any significant associations with suicidality. Previously, some studies focused on the relationship between actual death by suicide and SCI-related characteristics. Prior investigations have reported the highest standardized mortality ratio in patients with complete paraplegic SCI [4,32] and recommended caution to prevent suicide in individuals with SCI and complete injury [10]. Other reports have presented a nearly two-fold higher suicide mortality rate in paraplegic SCI than in tetraplegic SCI [7,11]. However, as these earlier findings are refined to the actual mortality of suicide, further investigation is warranted to determine the tangible impact of completeness or the level of injury on overall suicidality in the SCI population.

A meaningful correlation among demographic factors was observed between age and suicidality. This result aligns with the outcomes of previous studies that demonstrated the vulnerability of the younger population with SCI to suicide [10,33]. Before injury, young individuals often maintain a higher level of physical activity and social interaction than older adults, which may lead to a relatively greater sense of impairment and discouragement [12,34]. However, in this study, occupation did not show any statistically significant correlations with suicidality. This result was inconsistent with findings from the general population [35]. It is important to note that the study participants reported their current employment status while they were hospitalized or on leave. As a significant number of SCI populations struggle against the uncertainties of returning to their prior occupations [36,37], reliable analysis should be conducted within social backgrounds.

The present study had several limitations. Owing to the retrospective cross-sectional study design, the establishment of a cause-and-effect relationship was challenging. Additionally, the single-center recruitment of participants and sole inclusion of inpatients with SCI jointly restrict the generalizability of the findings. Our study also lacked information about the participants' specific occupations, economic status, and information regarding their caregivers, whether paid or family. Lastly, as the analysis of suicidality was based on the total K-MINI score to reflect overall suicidal tendencies, the results should be applied with caution when it comes to capturing the nuances of individual elements such as suicidal thoughts, suicide plans, and suicide attempts.

Understanding physical and functional suicide risk factors in populations with SCI is essential for several reasons. It provides support for identifying high risk individuals for targeted interventions and informs the development of tailored rehabilitation programs. Our study demonstrated that physical factors of the upper extremities and certain functional dependencies in daily activities are associated with suicidality in individuals with SCI. Considering this, our findings can contribute to the advancement of early intervention strategies for suicide prevention in individuals with SCI. This can be achieved by highlighting the necessity for structured physical and functional rehabilitation programs that incorporate upper extremity training and wheelchair activities.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

Conceptualization: Kim O. Methodology: Han S, Kim W, Kim O. Formal analysis: Han S, Kim W. Funding acquisition: Kim O. Project administration: Han S, Kim W, Kim O. Visualization: Han S, Kim W. Writing – original draft: Han S, Kim O. Writing – review and editing: Han S, Kim W, Kim O. Approval of final manuscript: all authors.

ORCID

Sora Han, https://orcid.org/0000-0002-2287-4169
Wooyeung Kim, https://orcid.org/0000-0002-2233-2140
Onyoo Kim, https://orcid.org/0000-0001-9517-2240

REFERENCES

1. Kennedy P, Rogers BA. Anxiety and depression after spinal cord injury: a longitudinal analysis. Arch Phys Med Rehabil 2000;81:932-7.
2. Betthauser LM, Hoffberg AS, Stearns-Yoder KA, Harmon M, Coons D, Brenner LA. A systematic review of suicidal ideation and behaviors among adults with spinal cord injury. J Spinal Cord Med 2023;46:602-13.
3. Bombardier CH, Azuero CB, Fann JR, Kautz DD, Richards JS, Sabharwal S. Management of mental health disorders, substance use disorders, and suicide in adults with spinal cord injury: clinical practice guideline for healthcare providers. Top Spinal Cord Inj Rehabil 2021;27:152-224.
4. Cao Y, Massaro JF, Krause JS, Chen Y, Devivo MJ. Suicide mortality after spinal cord injury in the United States: injury cohorts analysis. Arch Phys Med Rehabil 2014;95:230-5.
5. Nam HS, Kim HR, Ha TH, Shin HI. Suicidal ideation in Korean persons with spinal cord injury. Spinal Cord 2013;51:789-93.
6. Judd FK, Brown DJ. Suicide following acute traumatic spinal cord injury. Paraplegia 1992;30:173-7.
7. Kennedy P, Garmon-Jones L. Self-harm and suicide before and after spinal cord injury: a systematic review. Spinal Cord 2017;55:2-7.
8. Charlifue SW, Gerhart KA. Behavioral and demographic predictors of suicide after traumatic spinal cord injury. Arch Phys Med Rehabil 1991;72:488-92.
9. Khazem LR. Physical disability and suicide: recent advancements in understanding and future directions for consideration. Curr Opin Psychol 2018;22:18-22.
10. McCullumsmith CB, Kalpakjian CZ, Richards JS, Forchheimer M, Heinemann AW, Richardson EJ, et al. Novel risk factors associated with current suicidal ideation and lifetime suicide attempts in individuals with spinal cord injury. Arch Phys Med Rehabil 2015;96:799-808.
11. Hartkopp A, Brønnum-Hansen H, Seidenschnur AM, Biering-Sørensen F. Suicide in a spinal cord injured population: its relation to functional status. Arch Phys Med Rehabil 1998;79:1356-61.
12. Budd MA, Gater DR Jr, Channell I. Psychosocial consequences of spinal cord injury: a narrative review. J Pers Med 2022;12:1178.
13. Ruan X, Luo JJ. Suicide before and after spinal cord injury. J Spinal Cord Med 2017;40:280-1.
14. Usta Sağlam NG, Aksoy Poyraz C, Doğan D, Erhan B. Suicidal ideation, post-traumatic stress disorder, and depression in traumatic spinal cord injury: what resilience tells us. J Spinal Cord Med 2023;46:309-16.
15. Ballinger DA, Rintala DH, Hart KA. The relation of shoulder pain and range-of-motion problems to functional limitations, disability, and perceived health of men with spinal cord injury: a multifaceted longitudinal study. Arch Phys Med Rehabil 2000;81:1575-81.
16. Lo C, Tran Y, Anderson K, Craig A, Middleton J. Functional priorities in persons with spinal cord injury: using discrete choice experiments to determine preferences. J Neurotrauma 2016;33:1958-68.
17. Hisham H, Justine M, Hasnan N, Manaf H. Effects of Paraplegia Fitness Integrated Training on physical function and exercise self-efficacy and adherence among individuals with spinal cord injury. Ann Rehabil Med 2022;46:33-44.
18. Burke D, Lennon O, Fullen BM. Quality of life after spinal cord injury: the impact of pain. Eur J Pain 2018;22:1662-72.
19. Cobb JE, Leblond J, Dumont FS, Noreau L. Perceived influence of intrinsic/extrinsic factors on participation in life activities after spinal cord injury. Disabil Health J 2018;11:583-90.
20. Maitan P, Frigerio S, Conti A, Clari M, Vellone E, Alvaro R. The effect of the burden of caregiving for people with spinal cord injury (SCI): a cross-sectional study. Ann Ist Super Sanita 2018;54:185-93.
21. Vural M, Yalcinkaya EY, Celik EC, Gunduz B, Bozan A, Erhan B. Assessment of quality of life in relation to spasticity severity and socio-demographic and clinical factors among patients with spinal cord injury. J Spinal Cord Med 2020;43:193-200.
22. Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E,

et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J Clin Psychiatry 1998;59 Suppl 20:22-33. quiz 34-57.
23. Baek JH, Kang ES, Fava M, Mischoulon D, Nierenberg AA, Yu BH, et al. Serum lipids, recent suicide attempt and recent suicide status in patients with major depressive disorder. Prog Neuropsychopharmacol Biol Psychiatry 2014;51:113-8.
24. Kirshblum S, Snider B, Rupp R, Read MS. Updates of the international standards for neurologic classification of spinal cord injury: 2015 and 2019. Phys Med Rehabil Clin N Am 2020;31:319-30.
25. Kramer JL, Lammertse DP, Schubert M, Curt A, Steeves JD. Relationship between motor recovery and independence after sensorimotor-complete cervical spinal cord injury. Neurorehabil Neural Repair 2012;26:1064-71.
26. Rudhe C, van Hedel HJ. Upper extremity function in persons with tetraplegia: relationships between strength, capacity, and the spinal cord independence measure. Neurorehabil Neural Repair 2009;23:413-21.
27. Velstra IM, Curt A, Frotzler A, Abel R, Kalsi-Ryan S, Rietman JS, et al. Changes in strength, sensation, and prehension in acute cervical spinal cord injury: European multicenter responsiveness study of the GRASSP. Neurorehabil Neural Repair 2015;29:755-66.
28. Sanguinetti RD, Soriano JE, Squair JW, Cragg JJ, Larkin-Kaiser KA, McGirr A, et al. National survey of mental health and suicidal thoughts in people with spinal cord injury. Spinal Cord 2022;60:444-50.
29. Hardwick D, Bryden A, Kubec G, Kilgore K. Factors associated with upper extremity contractures after cervical spinal cord injury: a pilot study. J Spinal Cord Med 2018;41:337-46.
30. Adams MM, Hicks AL. Spasticity after spinal cord injury. Spinal Cord 2005;43:577-86.
31. D'Amico JM, Condliffe EG, Martins KJ, Bennett DJ, Gorassini MA. Recovery of neuronal and network excitability after spinal cord injury and implications for spasticity. Front Integr Neurosci 2014;8:36. Erratum in: Front Integr Neurosci 2014;8:49.
32. DeVivo MJ, Black KJ, Richards JS, Stover SL. Suicide following spinal cord injury. Paraplegia 1991;29:620-7.
33. Savic G, DeVivo MJ, Frankel HL, Jamous MA, Soni BM, Charlifue S. Suicide and traumatic spinal cord injury-a cohort study. Spinal Cord 2018;56:2-6.
34. Lim SW, Shiue YL, Ho CH, Yu SC, Kao PH, Wang JJ, et al. Anxiety and depression in patients with traumatic spinal cord injury: a nationwide population-based cohort study. PLoS One 2017;12:e0169623.
35. Amiri S. Unemployment and suicide mortality, suicide attempts, and suicide ideation: a meta-analysis. Int J Ment Health 2022;51:294-318.
36. Kim HK, Leigh JH, Choi Y, Lee JH, Bang MS. Spinal cord injury fact sheet in Korea. Ann Rehabil Med 2023;47:4-10.
37. Mohammadi F, Oshvandi K, Bijani M, Borzou SR, Khodaveisi M, Masoumi SZ. Perception of facing life's challenges in patients with spinal cord injury in Iran: a qualitative study. BMC Psychol 2022;10:202.

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Epidemiology and Assessment of Traumatic Spinal Cord Injury With Concomitant Brain Injury: An Observational Study in a Regional Trauma Center

Tae Woong Yang, MD[1], Dong Ho Yoo, MD[1], Sungchul Huh, MD, PhD[2], Myung Hun Jang, MD[1], Yong Beom Shin, MD, PhD[3], Sang Hun Kim, MD, PhD[1]

[1]*Department of Rehabilitation Medicine, Biomedical Research Institute, Pusan National University Hospital, Busan, Korea*
[2]*Department of Rehabilitation Medicine, Research Institute for Convergence of Biomedical Science and Technology, Pusan National University Yangsan Hospital, Yangsan, Korea*
[3]*Department of Rehabilitation Medicine, Biomedical Research Institute, Pusan National University Hospital, Pusan National University School of Medicine, Busan, Korea*

Objective: To analyze the epidemiological information of patients with traumatic spinal cord injury (SCI) and concomitant traumatic brain injury (TBI) and to suggest points to be aware of during the initial physical examination of patients with SCI.
Methods: This study was a retrospective, observational study conducted in a regional trauma center. All the records of patients diagnosed with traumatic SCI between 2016 and 2020 were reviewed. A total of 627 patients with confirmed traumatic SCI were hospitalized. A retrospective study was conducted on 363 individuals.
Results: The epidemiological data of 363 individuals were investigated. Changes in American Spinal Injury Association Impairment Scale (AIS) scores in patients with SCI were evaluated. The initial evaluation was performed on average 11 days after the injury, and a follow-up examination was performed 43 days after. Fourteen of the 24 patients identified as having AIS A and SCI with concomitant TBI in the initial evaluation showed neurologic level of injury (NLI) recovery with AIS B or more. The conversion rate in patients with SCI and concomitant TBI exceeded that reported in previous studies in individuals with SCI.
Conclusions: Physical, cognitive, and emotional impairments caused by TBI present significant challenges in rehabilitating patients with SCI. In this study, the influence of concomitant TBI lesions could have caused the initial AIS assessment to be incorrect.

Keywords: Spinal cord injury, Traumatic brain injury, Epidemiology

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Correspondence:
Sang Hun Kim
Department of Rehabilitation Medicine, Biomedical Research Institute, Pusan National University Hospital, 179 Gudeok-ro, Seo-gu, Busan 49241, Korea.
Tel: +82-51-240-7485
Fax: +82-51-247-7485
E-mail: kel5504@gmail.com

INTRODUCTION

The incidence of spinal cord injury (SCI) and concomitant traumatic brain injury (TBI) varies from 25% to more than 60%, depending on the criteria used [1]. Physical, cognitive, and emotional impairments caused by TBI impede patient rehabilitation [2].

Prompt diagnosis of concomitant TBI in patients with SCI is vital for appropriate rehabilitation to manage TBI-related medical complications and maximize functional recovery [3,4]. In addition to having TBI affect the patient's prognosis, problems

such as consciousness, cognitive deficits, and agitation impact the initial neurological examination of patients with SCI. Accompanied by mechanical ventilators, sedation, and psychiatric illness also affect the initial neurological examination of patients with SCI [5]. Among them, TBI is more concerned with being underdiagnosed than other factors. The initial imaging evaluation of the brain might be normal; however, accompanying head trauma should always be considered when there are symptoms of loss of consciousness or cognitive impairment [6,7]. This study aimed to summarize the epidemiology of patients with SCI and concomitant TBI at a regional level I trauma center and suggest considerations for the initial evaluation.

METHODS

Ethical approval

This study was conducted in accordance with the ethical standards of the Declaration of Helsinki and was approved by the Institutional Review Board (IRB) of Pusan National University Hospital (IRB No. 2302-013-124). The informed consent requirement was waived due to the study's retrospective nature.

Study design, data collection, and definitions

This retrospective observational study was conducted at Pusan National University Hospital, Regional Trauma Center. All records of individuals diagnosed with traumatic-spinal cord injury (T-SCI) between 2016 and 2020 were reviewed. In total, 627 patients with confirmed T-SCI were hospitalized. A retrospective study was conducted on 363 individuals, excluding those with insufficient SCI documentation, such as the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI), nontraumatic etiology, or old SCI. Patients who underwent at least two ISNCSCI evaluations were included in this study (Fig. 1). The institutional ethics review board approved this study.

The TBI diagnostic criteria by the American Congress of Rehabilitation Medicine applied [8]. Based on the degree of loss of consciousness posttraumatic amnesia (PTA), imaging findings, and neuropsychological findings [7,9-12], the TBI severity was classified as mild, moderate, or severe. The highest rating of severity received was used to define each patient's TBI severity.

Typical areas of cognitive decline in people with TBI involve visuospatial, delayed recall, attention, and language [13]. The Montreal Cognitive Assessment (MoCA) is an excellent tool for evaluating this. The average MoCA score was 19, 18, and 13 points for patients with mild, moderate, and severe TBI, respectively (Table 1). Based on this, a Korean version of MoCA score of 19 or higher was considered mild TBI, 14–18 as moderate, and 13 or less as severe TBI.

The neurological examinations analyzed retrospectively in this study were performed only by skilled rehabilitation physicians who completed online training at the American Spinal Injury Association (ASIA) e-learning center; therefore, the physical examinations performed were reliable. After the accident, an

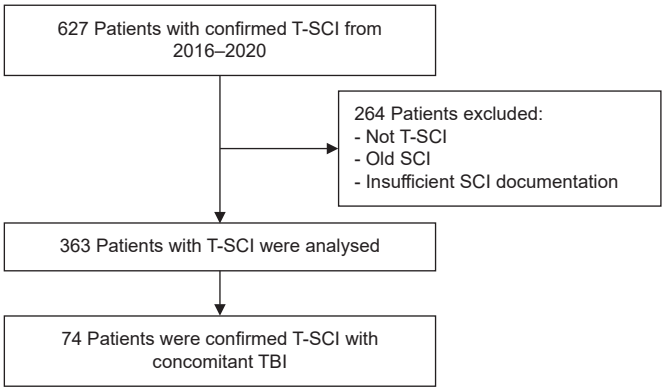

Fig. 1. Flow diagram of finding patients with traumatic spinal cord injury (T-SCI) and concomitant traumatic brain injury (TBI).

Table 1. Diagnostic criteria for the classification of TBI severity

Diagnostic criteria	Mild	Moderate	Severe
Altered level or loss of consciousness	GCS 13–15 and/or any LOC<30 min	GCS 9–12 and/or 30 min≤LOC≤6 h	GCS 3–8 and/or LOC>6 h
PTA	Any PTA<24 h	24 h≤PTA≤7 day	PTA>7 day
Neuroradiological findings due to TBI	No findings	Neuroradiological TBI findings	Neuroradiological TBI findings and neurosurgical operation
Neuropsychological findngs due to TBI	MoCA>18	14≤MoCA≤18	MoCA<14

TBI, traumatic brain injury; GCS, Glasgow Coma Scale; LOC, loss of consciousness; PTA, posttraumatic amnesia; MoCA, Montreal Cognitive Assessment.

initial assessment was quickly conducted when cooperation was possible, and a follow-up examination was carried out before discharge.

Statistical analysis

Statistical analysis were performed using R version 4.2.1 (R Foundation). An independent t-test or Wilcoxon rank-sum test was conducted for continuous variables based on normality. The chi-square test or Fisher's exact test was used for categorical variables. Statistical significance was set at a two-tailed p-value<0.05.

RESULTS

Overall incidence

Table 2 summarizes the epidemiology of 363 patients. Sex, age, neurologic level of injury (NLI), American Spinal Injury Association Impairment Scale (AIS) score, and traumatic etiology information of 363 patients with confirmed T-SCI were classified. In addition, differences in characteristics were analyzed by categorizing only the SCI patient group and the SCI with the concomitant TBI patient group.

Among 363 patients with T-SCI, 296 (81.5%) were males, and 67 (18.5%) were females. The average age was 57.1 years. C1–4 injuries accounted for 54.8% of the patients. This was followed by affected C5–8 at 20.4%, T1–12 at 14.0%, and L1–S5 at 8.0%. AIS A, B, C, and D accounted for 25.1%, 7.7%, 26.7%, and 37.2%, respectively. T-SCI etiology was classified as fall, transport, sports and leisure, assault, and other traumatic causes [14]. Among 363 patients, fall was the most common cause (205, 56.5%), followed by transport (113, 31.1%). When calculating the p-value, the unknown initial NLI or AIS scores were regarded as missing data. Supplementary Table S1 describes the epidemiological information reviewed above by subdividing patients

Table 2. Study characteristics

Variable	All (n=363)	Only SCI (n=289)	SCI+TBI (n=74)	p-value
Sex				0.536
Male	296 (81.5)	238 (82.4)	58 (78.4)	
Female	67 (18.5)	51 (17.6)	16 (21.6)	
Age (yr)				0.329
0–15	1 (0.3)	0 (0)	1 (1.3)	
16–30	28 (7.7)	22 (7.6)	6 (8.1)	
31–45	45 (12.4)	38 (13.1)	7 (9.5)	
46–60	114 (31.4)	91 (31.5)	23 (31.1)	
61–75	133 (36.6)	108 (37.4)	25 (33.8)	
>75	42 (11.6)	30 (10.4)	12 (16.2)	
Initial NLI				0.122
C1–4	199 (54.8)	167 (57.8)	32 (43.2)	
C5–8	74 (20.4)	60 (20.8)	14 (18.9)	
T1–12	51 (14.0)	36 (12.4)	15 (20.3)	
L1–S5	29 (8.0)	26 (9.0)	3 (4.1)	
Unknown	10 (2.8)	0 (0)	10 (13.5)	
Initial AIS				0.009
A	91 (25.1)	66 (22.8)	25 (33.8)	
B	28 (7.7)	25 (8.7)	3 (4.0)	
C	97 (26.7)	76 (26.3)	21 (28.4)	
D	135 (37.2)	120 (41.5)	15 (20.3)	
Unknown	12 (3.3)	2 (0.7)	10 (13.5)	
Traumatic etiology				
Fall	205 (56.5)	164 (56.8)	41 (55.4)	
Transport	113 (31.1)	81 (28.0)	32 (43.2)	
Sports and leisure	15 (4.1)	15 (5.2)	0 (0)	
Assault	2 (0.6)	2 (0.7)	0 (0)	
Others	28 (7.7)	27 (9.3)	1 (1.4)	

Values are presented as number (%).
SCI, spinal cord injury; TBI, traumatic brain injury; NLI, neurologic level of injury; AIS, American Spinal Injury Association Impairment Scale.

with SCI and concomitant TBI according to the TBI severity criteria.

AIS conversion rate

Table 3 shows the changes in the AIS changes in patients with SCI only and those in SCI patients with concomitant TBI (SCI+TBI). AIS conversion was examined by classifying the SCI-only patient groups and SCI+TBI. In addition, the subgroups were divided according to the TBI severity. In total, 318 patients had ISNCSCI follow-up records. The initial evaluation was performed 11 days (average) after the injury, and a follow-up was performed 43 days after.

In this study, ISNCSCI was performed in some patients, even in those with severe TBI. Since the initial evaluation of the injury determined TBI severity, the Glasgow Coma Scale (GCS) score was 3–8 during the trauma emergency room admission; however, the level of consciousness recovered subsequently, and ISNCSCI could be performed.

Fourteen of the 24 patients diagnosed with SCI+TBI and identified as AIS A in the initial evaluation showed neurologic recovery compared with AIS B or higher (Table 3). In contrast, in those with T-SCI without head injury, neurological recovery was confirmed in only 16 of 62 patients initially evaluated as AIS A (Fig. 2). In only patients with SCI, the conversion rate was 0.258 (95% confidence interval [CI], 0.149–0.367), whereas, in SCI+TBI, it was 0.583 (95% CI, 0.386–0.781). The conversion rate was statistically significant (p=0.010) between the SCI and the SCI+TBI groups.

Supplementary Table S2 summarizes the sex, age, TBI severity, NLI, and AIS conversion of patients with SCI+TBI whose AIS conversion was confirmed from initial AIS A to AIS B or higher.

DISCUSSION

This study investigated the epidemiology of patients with SCI alone and those with SCI+TBI. In Korea, regional trauma centers were opened in 2014, and 16 centers are currently opera-

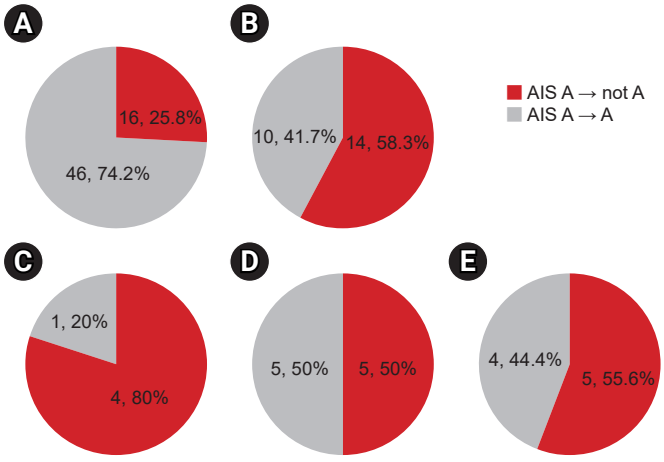

Fig. 2. Changes in American Spinal Injury Association Impairment Scale (AIS) scores (A) only spinal cord injury (SCI), (B) SCI+traumatic brain injury (TBI), (C) mild TBI, (D) moderate TBI, (E) severe TBI.

Table 3. Change of AIS

Variable	All (n=318)	Only SCI (n=256)	SCI+TBI (n=62)	Concomitant TBI severity			p-value
				Mild (n=12)	Moderate (n=30)	Severe (n=20)	
AIS (initial)							
A	86 (27.1)	62 (24.2)	24 (38.7)	5 (41.7)	10 (33.3)	9 (45.0)	
B	28 (8.8)	25 (9.8)	3 (4.8)	0 (0)	1 (3.3)	2 (10.0)	
C	91 (28.6)	70 (27.3)	21 (33.9)	3 (25.0)	13 (43.4)	5 (25.0)	
D	113 (35.5)	99 (38.7)	14 (22.6)	4 (33.3)	6 (20.0)	4 (20.0)	
AIS (follow up)							
A	56 (17.6)	46 (18.0)	10 (16.1)	1 (8.3)	5 (16.7)	4 (20.0)	
B	30 (9.4)	22 (8.6)	8 (12.9)	2 (16.7)	2 (6.7)	4 (20.0)	
C	83 (26.1)	61 (23.8)	22 (35.5)	4 (33.3)	13 (43.3)	5 (25.0)	
D	149 (46.9)	127 (49.6)	22 (35.5)	5 (41.7)	10 (33.3)	7 (35.0)	
AIS conversion							
AIS A → A	56 (65.1)	46 (74.2)	10 (41.7)				
AIS A → not A	30 (34.9)	16 (25.8)	14 (58.3)				0.010

Values are presented as number (%).
AIS, American Spinal Injury Association Impairment Scale; SCI, spinal cord injury; TBI, traumatic brain injury.

tional. This was a detailed retrospective analysis of T-SCI in a single institution after establishing a systematic regional trauma center in Korea. There is a lack of data worldwide, and this is the first study in Korea to investigate patients with SCI+TBI. A significant difference in the AIS conversion rate between the two groups was found.

Since there is a lack of consensus on evaluating patients with SCI+TBI, this study aimed to suggest considerations for initial evaluation, including ISNCSCI.

Sex

Among 363 patients with T-SCI, 296 (81.5%) were males, similar to the global 4:1 male-to-female ratio of T-SCI [15]. Similarly, according to spine epidemiological studies conducted in Korea, the ratio was 3.6:1 in the 2010s [16].

According to Asian studies, males were at a higher risk of T-SCI; the sex ratio ranged from 0.99:1 in Taiwan to 13.5:1 in India [17,18]. This inconsistency may be due to socioeconomic status and cultural background differences. Males are more likely to participate in trauma-related physical activities [19].

Age

The average age was 57.1 years, higher than the average age of T-SCI patients in the USA according to the 2021 National Spinal Cord Injury Statistical Center (NSCISC) annual report (42.2 years) [20]. Asian studies reported a range of 26.8–56.6 years [19]. A previous Korean study showed that the mean age at the time of injury increased from 32.4 years in the 1990s to 47.1 years in the 2010s [16].

This study's proportion of older adults aged >reached 48.2%. The increasing proportion of older adults will cause changes in epidemiology, such as changes in traumatic etiology.

NLI

Considering this study's initial NLI, affected C1–4 accounted for 54.8% of all patients with SCI, followed by affected C5–8 (20.4%). Cervical-level injuries accounted for 75.2% of the patients. This was followed by affected T1–12 at 14.0% and L1–S5 at 8.0%. In Korea, cervical-level injury accounted for 57.2% of all T-SCIs in the 2010s, of which NLI C4–6 accounted for the largest proportion over 30 years [16]. The proportion of cervical injuries was much higher than that in the current statistics. The higher-level cervical cord injuries above the meaning NLI C1–4 level accounted for 54.8%. This may be related to the characteristics of the regional trauma centers where patients with severe T-SCI visit.

Among the 74 patients with SCI+TBI, the affected C1–4 accounted for 43.2%, C5–8 for 18.9%, thoracic level for 20.3%, and lumbar level for 4.1%. There was no statistically significant difference in the initial NLI between the only SCI and the SCI+TBI groups. Macciocchi et al. [10] reported that the TBI co-occurrence rate is 70%–77% when the NLI is C1–4, 59%–67% for C5–8, and 11%–59% for levels below T1; therefore, higher-level cervical cord injury was shown to be common in patients with T-SCI and concomitant TBI [21]. Contrary to previous studies, the cervical-level injury rate in patients with SCI+TBI in this study was lower than that in patients with SCI alone. This may be due to the high severity of the patient group with cervical SCI +TBI who visited the regional trauma center. There may have been selection bias since ISNCSCI could not be performed for reasons such as death, critically ill medical condition, and persistent unconsciousness. In addition, the possibility of a certain number of undiagnosed TBIs due to another urgent trauma issue is considered cautiously.

AIS

When divided based on this study's initial AIS, AIS A, B, C, and D accounted for 25.1%, 7.7%, 26.7%, and 37.2%, respectively. In existing USA statistics, AIS A, B, C, and D account for 41.9%, 10.7%, 12.4%, and 29.4% of the cases, respectively [20]. It is characteristic that the ratio of AIS A is minute, and that of AIS C is larger than previously known values. According to the 2021 NSCISC annual report, gunshot wounds account for 15.3% of all SCI etiologies, and there are few other penetrating injuries, such as stab wounds, in other countries [20,22,23]. However, in Korea, most injuries involve blunt trauma since penetrating injuries are infrequent and personal gun possession is prohibited under Korean law. Hence, it was estimated that the rate of AIS A was lower than that reported in previous studies in other Western countries or registry collection results. In addition, one of the primary etiologies of SCI is transport, and Korea's highest seat belt-wearing rate may have contributed to this [23].

The rate of AIS A was relatively high in patients with double injuries. AIS A accounted for 22.8% of patients with SCI alone and 33.8% with double injuries. Hagen et al. [6] reported that completeness of T-SCI was strongly associated with clinical TBI. The complete injury rate among 179 individuals with SCI without TBI was only 34.6%. However, the complete injury rate reached 78.9% in individuals with SCI+severe TBI. The completeness of the T-SCI indicates high-energy trauma with an in-

creased risk of concomitant TBI. This study was also consistent with previous studies.

Traumatic etiology

Globally, transport is the most common cause of SCI, followed by falls [15]. In a Korean study, transport-based SCI decreased from 65% of all injuries in 1990–1999 to 41.9% in 2010–2019, while fall-based SCI increased from 24.9% in 1990– 1999 to 46.3% in 2010–2019 [16]. Falls were the most common cause of injury in the >60 age group, resulting in 59.1% T-SCI in the 2010s [16].

In this study, among 363 patients, fall was the most common cause (205, 56.5%), followed by transport (113, 31.1%). This is presumed to be related to the high proportion of older adults, and many cases have occurred due to slipping [24]. Older adults are vulnerable to falls due to deterioration of physical functions, including balance function, musculoskeletal system, visual perception, and cognitive function problems [25]. Besides, degeneration of various components of the vertebra is common in the elderly population. Spinal degenerative changes such as ossification of the posterior longitudinal ligament, disc disease, stenosis, and spondylolisthesis cause a higher risk of suffering SCI following a fall or another traumatic event in older adults [26]. Also, attempts to socially reduce traffic accidents, such as wearing seat belts and regulating the speed limit, could explain this change in etiology [27,28]. Other traumatic causes identified in this study included falling objects and industrial accidents, which accounted for 7.7% of the total, with 28 cases.

Among the 113 patients with transport in this study, 32 (28.3%) had TBI. Among the 205 patients with falls, 41 (20.0%) had TBI. There was no significant difference in TBI comorbidities between the two major etiology groups.

AIS conversion

Most importantly, as shown in Table 3, the initial AIS was A in patients with only SCI; however, the conversion rate to AIS B, C, or D in the follow-up examination was 25.8%. In contrast, in patients with SCI+TBI, AIS conversion was 58.3% (p-value 0.010). In a previous study, 20%–30% of individuals with AIS A SCI at baseline examination (within 30 days of injury) converted to an incomplete status [29-31]. However, existing studies regarding AIS conversion do not accurately identify whether TBI accompanies SCI. Besides, neurological conversion is rare after complete paraplegia (~15%–20%) relative to tetraplegia [29]. The higher neurological conversion in patients with tetraplegia than in those with paraplegia in a previous study is thought to be partly influenced by differences in the TBI frequency.

This was a single-center evaluation; however, the AIS conversion rate in SCI patients with TBI was significantly higher than that in patients with SCI alone. The patient might have been initially evaluated as AIS A due to decreased cognition and cooperation, resulting in high AIS conversion.

Supplementary Table S2 shows the patients who had AIS A at the initial evaluation but deviated from AIS A at the follow-up evaluation. Even if not accompanied by moderate or severe TBI, four patients with SCI concomitant with mild TBI were converted to AIS B or C. The two persons who were accompanied by mild TBI but converted from AIS A to C were intubated during evaluation or lightly sedated with a score of -1 on the Richmond Agitation-Sedation Scale (RASS).

In the intensive care unit, the degree of sedation and agitation was objectively indicated using the RASS [32]. The RASS score was classified from -5 to +5 points, and patients with a score between -1 and +1 points were considered eligible for reliable physical examination in this study. Since complete injury judgment is crucial in the initial evaluation, it was possible to identify deep anal pressure and voluntary anal contraction between RASS -1 and +1. In addition to accompanying TBI, other factors that may affect physical examination findings, such as endotracheal intubation, sedation, and delirium, should be closely considered. The initial AIS assessment could be incorrect owing to the influence of concomitant TBI lesions or decreased consciousness/cognitive state due to the factors mentioned above.

There are no clear standards for the arousal, awareness, or cooperation required to implement ISNCSCI. Even if ISNCSCI evaluation is possible, it is desirable to record the GCS score during evaluation and include cognitive evaluation results such as the mini-mental state examination (MMSE), MoCA, RASS score, and Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) indicating arousal, awareness, and cooperation (Supplementary Table S3). Moreover, interpreting ISNCSCI will be easier if the examiner records the presence of severe pain that may limit the physical examination, endotracheal intubation status, and level of cognitive decline due to the underlying disease.

ISNCSCI is known to show discrepancies among experienced examiners [33]. The evaluation and scoring are challenging. In the SCI+TBI group, there were many restrictions on the implementation of reliable ISNCSCI due to the reasons discussed above. Therefore, commenting regarding consciousness and

cognition during evaluation is crucial.

Furthermore, patients with an initial decline in consciousness and cognition need close follow-up since the possibility of neurological alterations in ISNCSCI may be high. Regarding the minimum requirements to properly perform ISNCSCI evaluation, further prospective studies are required on the arousal, awareness, and cooperation criteria.

In this study, serial cognitive function tests were rarely performed in patients with AIS conversion. There are limitations to performing serial cognitive function tests during the acute treatment period in patients with trauma. A series of cognitive evaluation tests are recommended in patients initially evaluated as having AIS A but whose neurologic recovery was beyond AIS B in the follow-up evaluation. Suppose AIS conversion is confirmed along with cognitive improvement in a series of evaluations. In that case, it can be inferred that the inaccurate ISNCSCI assessment is due to cognitive decline in the early phase of the injury.

The study has certain limitations. Since it was a retrospective study, the timing of initial and follow-up evaluations was inconsistent. The small sample size was not representative of the characteristics of Korea. The data were limited to a single university hospital. Considering the selection bias of a single institution, building a registry that includes the evaluation items that were limited in this study is necessary.

In conclusion, the study presents the epidemiology of SCI with concomitant TBI, lacking in research worldwide, and is the first study in Korea. Identifying the coexistence of TBI through the current national SCI registry is challenging. Hence, this is a relevant study. Establishing a global SCI patient registry and checking the medical records necessary for evaluation and follow-up is needed. In particular, when ISNCSCI is accompanied by TBI, a specific global consensus on the evaluation must be reached through further studies. The key issue is when a reliable physical examination can be performed.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

Conceptualization: Yang TW, Shin YB, Kim SH. Methodology: Yang TW, Shin YB, Kim SH. Formal analysis: Yang TW. Funding acquisition: Huh S, Kim SH. Project administration: Yang TW, Jang MH, Shin YB, Kim SH. Visualization: Yang TW, Yoo DH. Writing – original draft: Yang TW, Kim SH. Writing – review and editing: Huh S, Jang MH, Shin YB, Kim SH. Approval of final manuscript: all authors.

SUPPLEMENTARY MATERIALS

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ORCID

Tae Woong Yang, https://orcid.org/0000-0001-6348-256X
Dong Ho Yoo, https://orcid.org/0000-0002-4276-6659
Sungchul Huh, https://orcid.org/0000-0002-7740-8050
Myung Hun Jang, https://orcid.org/0000-0002-9694-5409
Yong Beom Shin, https://orcid.org/0000-0001-5026-1696
Sang Hun Kim, https://orcid.org/0000-0003-4849-5228

REFERENCES

1. Budisin B, Bradbury CC, Sharma B, Hitzig SL, Mikulis D, Craven C, et al. Traumatic brain injury in spinal cord injury: frequency and risk factors. J Head Trauma Rehabil 2016;31:E33-42.
2. Bradbury CL, Wodchis WP, Mikulis DJ, Pano EG, Hitzig SL, McGillivray CF, et al. Traumatic brain injury in patients with traumatic spinal cord injury: clinical and economic consequences. Arch Phys Med Rehabil 2008;89(12 Suppl):S77-84.
3. Garlanger KL, Beck LA, Cheville AL. Functional outcomes in patients with co-occurring traumatic brain injury and spinal cord injury from an inpatient rehabilitation facility's perspective. J Spinal Cord Med 2018;41:718-30.
4. Macciocchi SN, Bowman B, Coker J, Apple D, Leslie D. Effect of co-morbid traumatic brain injury on functional outcome of persons with spinal cord injuries. Am J Phys Med Rehabil 2004;83:22-6.
5. Burns AS, Lee BS, Ditunno JF Jr, Tessler A. Patient selection for clinical trials: the reliability of the early spinal cord injury examination. J Neurotrauma 2003;20:477-82.
6. Hagen EM, Eide GE, Rekand T, Gilhus NE, Gronning M. Traumatic spinal cord injury and concomitant brain injury: a cohort study.

Acta Neurol Scand Suppl 2010;(190):51-7.
7. Tolonen A, Turkka J, Salonen O, Ahoniemi E, Alaranta H. Traumatic brain injury is under-diagnosed in patients with spinal cord injury. J Rehabil Med 2007;39:622-6.
8. Ruff RM, Iverson GL, Barth JT, Bush SS, Broshek DK, NAN Policy and Planning Committee. Recommendations for diagnosing a mild traumatic brain injury: a National Academy of Neuropsychology education paper. Arch Clin Neuropsychol 2009;24:3-10.
9. de Guise E, Alturki AY, LeBlanc J, Champoux MC, Couturier C, Lamoureux J, et al. The Montreal Cognitive Assessment in persons with traumatic brain injury. Appl Neuropsychol Adult 2014;21:128-35.
10. Macciocchi S, Seel RT, Thompson N, Byams R, Bowman B. Spinal cord injury and co-occurring traumatic brain injury: assessment and incidence. Arch Phys Med Rehabil 2008;89:1350-7.
11. de Guise E, Leblanc J, Champoux MC, Couturier C, Alturki AY, Lamoureux J, et al. The mini-mental state examination and the Montreal Cognitive Assessment after traumatic brain injury: an early predictive study. Brain Inj 2013;27:1428-34.
12. Sun H, Luo C, Chen X, Tao L. Assessment of cognitive dysfunction in traumatic brain injury patients: a review. Forensic Sci Res 2017;2:174-9.
13. Miotto EC, Cinalli FZ, Serrao VT, Benute GG, Lucia MC, Scaff M. Cognitive deficits in patients with mild to moderate traumatic brain injury. Arq Neuropsiquiatr 2010;68:862-8.
14. Biering-Sørensen F, Charlifue S, Chen Y, New PW, Noonan V, Post MWM, et al. International Spinal Cord Injury Core Data Set (version 3.0)-including standardization of reporting. Spinal Cord 2023;61:65-8.
15. Singh A, Tetreault L, Kalsi-Ryan S, Nouri A, Fehlings MG. Global prevalence and incidence of traumatic spinal cord injury. Clin Epidemiol 2014;6:309-31.
16. Lee BS, Kim O, Ham D. Epidemiological changes in traumatic spinal cord injuries for the last 30 years (1990-2019) in South Korea. Spinal Cord 2022;60:612-7.
17. Yang NP, Deng CY, Lee YH, Lin CH, Kao CH, Chou P. The incidence and characterisation of hospitalised acute spinal trauma in Taiwan--a population-based study. Injury 2008;39:443-50.
18. Chacko V, Joseph B, Mohanty SP, Jacob T. Management of spinal cord injury in a general hospital in rural India. Paraplegia 1986;24:330-5.
19. Ning GZ, Wu Q, Li YL, Feng SQ. Epidemiology of traumatic spinal cord injury in Asia: a systematic review. J Spinal Cord Med 2012;35:229-39.
20. National Spinal Cord Injury Statistical Center (NSCISC). The 2021 annual statistical report complete public version for the Spinal Cord Injury Model Systems. University of Alabama at Birmingham; 2022. p. 1-161.
21. Holly LT, Kelly DF, Counelis GJ, Blinman T, McArthur DL, Cryer HG. Cervical spine trauma associated with moderate and severe head injury: incidence, risk factors, and injury characteristics. J Neurosurg 2002;96(3 Suppl):285-91.
22. Barbetta DC, Smanioto TR, Poletto MF, Ferreira R, Lopes A, Casaro FM, et al. Spinal cord injury epidemiological profile in the Sarah Network of Rehabilitation Hospitals-a Brazilian population sample. Spinal Cord Ser Cases 2018;4:32.
23. International Transport Forum. Road safety annual report 2020. International Transport Forum; 2020. p. 1-64.
24. Kim HS, Lim KB, Kim J, Kang J, Lee H, Lee SW, et al. Epidemiology of spinal cord injury: changes to its cause amid aging population, a single center study. Ann Rehabil Med 2021;45:7-15.
25. Harper A, Wilkinson I. Falls in older adults: causes, assessment and management. Medicine 2021;49:32-7.
26. Rhee JM, Shamji MF, Erwin WM, Bransford RJ, Yoon ST, Smith JS, et al. Nonoperative management of cervical myelopathy: a systematic review. Spine (Phila Pa 1976) 2013;38(22 Suppl 1):S55-67.
27. Chamberlain JD, Deriaz O, Hund-Georgiadis M, Meier S, Scheel-Sailer A, Schubert M, et al. Epidemiology and contemporary risk profile of traumatic spinal cord injury in Switzerland. Inj Epidemiol 2015;2:28.
28. Knútsdóttir S, Thórisdóttir H, Sigvaldason K, Jónsson H Jr, Björnsson A, Ingvarsson P. Epidemiology of traumatic spinal cord injuries in Iceland from 1975 to 2009. Spinal Cord 2012;50:123-6.
29. Kirshblum S, Snider B, Eren F, Guest J. Characterizing natural recovery after traumatic spinal cord injury. J Neurotrauma 2021;38:1267-84.
30. Khorasanizadeh M, Yousefifard M, Eskian M, Lu Y, Chalangari M, Harrop JS, et al. Neurological recovery following traumatic spinal cord injury: a systematic review and meta-analysis. J Neurosurg Spine 2019;30:683-99.
31. Spiess MR, Müller RM, Rupp R, Schuld C, EM-SCI Study Group; van Hedel HJ. Conversion in ASIA impairment scale during the first year after traumatic spinal cord injury. J Neurotrauma 2009;26:2027-36.
32. Ely EW, Truman B, Shintani A, Thomason JW, Wheeler AP, Gordon S, et al. Monitoring sedation status over time in ICU patients: reliability and validity of the Richmond Agitation-Sedation Scale (RASS). JAMA 2003;289:2983-91.
33. Armstrong AJ, Clark JM, Ho DT, Payne CJ, Nolan S, Goodes LM, et al. Achieving assessor accuracy on the International Standards for Neurological Classification of Spinal Cord Injury. Spinal Cord 2017;55:994-1001.

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Effect of Adding Physiotherapy Program to the Conservative Medical Therapy on Quality of Life and Pain in Chronic Rhinosinusitis Patients

Khaled Z. Fouda, PhD[1], Hadaya M. Eladl, PhD[2,3], Mariam A. Ameer, PhD[2,4], Nesma M. Allam, PhD[2,3]

[1]*Department of Basic Science for Physical Therapy, Faculty of Physical Therapy, Cairo University, Giza, Egypt*
[2]*Department of Physical Therapy and Health Rehabilitation, College of Applied Medical Science, Jouf University, Sakaka, Kingdom of Saudi Arabia*
[3]*Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University, Giza, Egypt*
[4]*Department of Biomechanics, Faculty of Physical Therapy, Cairo University, Giza, Egypt*

Objective: To assess the effectiveness of combining physiotherapy techniques with conservative medical treatment in chronic rhinosinusitis (CRS) patients.
Methods: Sixty-eight volunteers with CRS were randomly assigned. Group A received only traditional medical treatment, whereas group B received a physiotherapy program that included pulsed ultrasound therapy, sinus manual drainage techniques, and self-sinus massage technique in addition to traditional medical treatment. Interventions were applied 3 sessions a week for 4 weeks. The rhinosinusitis disability index (RSDI) served as the main outcome indicator for assessing the quality of life, and the secondary outcome measure was the pressure pain threshold (PPT) using a pressure algometer.
Results: Wilcoxon signed rank test revealed a significant reduction ($p<0.001$) in total RSDI values from 71.08±1.13 pretest to 47.14±1.15 posttest for group A, while it decreased from 70.64±1.20 pretreatment to 31.76±1.04 posttreatment for group B; furthermore, Mann–Whitney U-test revealed a significant difference ($p<0.001$) in total RSDI values between both groups when comparing the change of the pre-post data values, it was 23.94±0.95 for group A and 38.88±0.67 for group B. The independent t-test revealed a highly statistically significant increase ($p<0.001$) in the PPT values in the experimental group compared to the control group.
Conclusion: The physiotherapy program which included pulsed ultrasound therapy, sinus manual drainage technique, and self-sinus massage technique in conjunction with conventional medical treatment was more beneficial for enhancing the quality of life and PPT than traditional medical treatment alone in CRS patients.

Keywords: Sinusitis, Quality of life, Pain threshold, Ultrasound therapy, Manual therapy

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Correspondence:
Mariam A. Ameer
Department of Physical Therapy and Health Rehabilitation, College of Applied Medical Science, Jouf University, Airport Road, Sakaka 72388, Kingdom of Saudi Arabia.
Tel: +966-500094542
Fax: +966-500094542
E-mail: mariam.abdelmonim@cu.edu.eg

INTRODUCTION

A clinical illness known as chronic rhinosinusitis (CRS) is considered a persistent inflammation of the mucous membranes that line the paranasal sinuses and nasal cavity brought on by an infection, trauma, or exposure to irritants or allergens. Each year, 30 to 40 million people are impacted. According to estimates, 10% of Western populations are affected by CRS [1].

Nasal blockage, runny nose, facial pain, or, a smell abnormality must all be present for more than 12 weeks to be considered part of the condition. Because the symptoms are similar to those of other disorders, nasal endoscopy or diagnostic imaging must be used to confirm the presence of mucosal inflammation [2,3]. CRS is a prevalent clinical illness seen on a daily basis in otorhinolaryngology practice, and it significantly affects patients' quality of life (QoL) and ability to work, which results in a loss of productivity and leisure time. The illness costs the United States government more than 11 billion dollars every year [4,5].

Analgesia, topical decongestants, intranasal corticosteroids, oral antibiotics, and antihistamine drugs are among the treatment options for rhinosinusitis, while for serious and repetitive rhinosinusitis, operative procedures may be indicated [6,7]. Medical intervention for CRS is complicated and requires long-term antibiotic medication. Aside from the problems of long-term pharmacological treatment, persisting promotion and the emergence of drug-resistant bacterial populations prompted researchers to look into alternative therapies [8,9].

In recent years, therapeutic ultrasound (US) has been recommended as a potential treatment option for CRS individuals. The US treatment can be applied either continuously or pulsed. Although the US has an anti-inflammatory impact and can improve antibiotic treatment efficacy in CRS patients [10-13], most trials are small, short in duration, and poorly designed, and there is insufficient data to recommend US usage in clinical practice with a significant risk of bias. As a consequence, the US cannot be designated as a potential supplementary resource to current CRS treatment approaches. As a result, more clinical trials with a bigger sample size are required to demonstrate the efficacy of the US on CRS [14].

Other physical therapy modalities, such as manual therapy [15-17], laser therapy [18], and short-wave therapy [19], have been documented in the literature as a successful adjunct therapy in the treatment of CRS. As a result, the authors hypothesized that combining US therapy and manual therapy with traditional medical treatment improves the QoL and pressure pain threshold (PPT) in patients with CRS more than traditional medical treatment alone. Therefore, this study's goal was to determine how adding a combined physiotherapy program to traditional medical therapy affected CRS patients' PPT and QoL.

METHODS

This study was a prospective randomized controlled trial with a pretest/posttest, single-blind (assessor) design. The patients were recruited from outpatient clinics at Al-Qurayyat General Hospital in Al-Jouf region, Kingdom of Saudi Arabia, from September 2022 to March 2023. The current study was approved by the Research Ethics Committee, Qurayyat Health Affairs (IRB Approval No. 2022-38) and it was recorded prospectively in the Clinical Trial Registry (NCT05442606). All participants in this study gave informed consent and agreed that their data would be kept confidential and used anonymously in the analysis for the sole purpose of the study. Participants were made aware of the study's objectives and benefits, and they were free to leave at any time. The Consolidated Standards of Reporting Trials (CONSORT 2010) checklist was followed when reporting this study (available at https://www.equator-network.org/).

Participants

This study enrolled sixty-eight participants who suffering from CRS that have been clinically identified by an ear, nose, and throat (ENT) professional with the following criteria.

Inclusion criteria

Participants of both sexes, aged from 30 to 50 years, with a history of CRS lasting more than three months and clinical diagnostic criteria confirmation two or more main symptoms, or just one chief symptom (nasal blockage, pressure or soreness in the face, postnasal drip, and hyposmia) and two slight symptoms (headache, bad breath, exhaustion, tooth discomfort, and ear pain) and also confirmed by computed tomography (CT) scan outcomes [9].

Exclusion criteria

The exclusion criteria included the presence of any tumors or cysts (as proved by CT scan examination), nasal polyps, lesions on the face, illnesses, or allergies to the face, pregnancy, facial metal implants, previous surgery on the nose, and reduced heat perception (like uncontrolled type 2 diabetes), and deterioration of cognitive level.

Sample size calculation

The sample size was calculated prior to the experiment to eliminate type II error. The calculations were performed using the statistical tool G*Power 3.1.9.4 at α=0.05, β=0.2, and effect size=0.75. It was determined that the necessary sample size was n=62. The sample size was increased to 68 participants to account for the drop-off as shown in Fig. 1.

Randomization

Sixty-eight CRS patients were sorted into one of two groups at random: control (group A) or experimental (group B). The randomization was carried out by a statistician who was not involved in the data gathering and who used a computer-generated random number list. Sealable, sequentially numbered opaque envelopes were utilized to assure the secret allocation. The first author opened the envelopes and began the treatment, as directed by the group assignment. The second author, who was not aware of the group assignment, got the outcome measures. Participants were blinded because those in the control group were referred by an ENT specialist and only had two encounters with the researcher, once for pretest evaluation and once for posttest evaluation four weeks later. The participants in the control group did not match those in the experimental groups. Furthermore, the experimental group's physiotherapy sessions were private, separate, and held on different days and times. As a result, the participants have never met or know each other. In addition, the investigator ensures that participants in the study group are unaware of particular elements of the study.

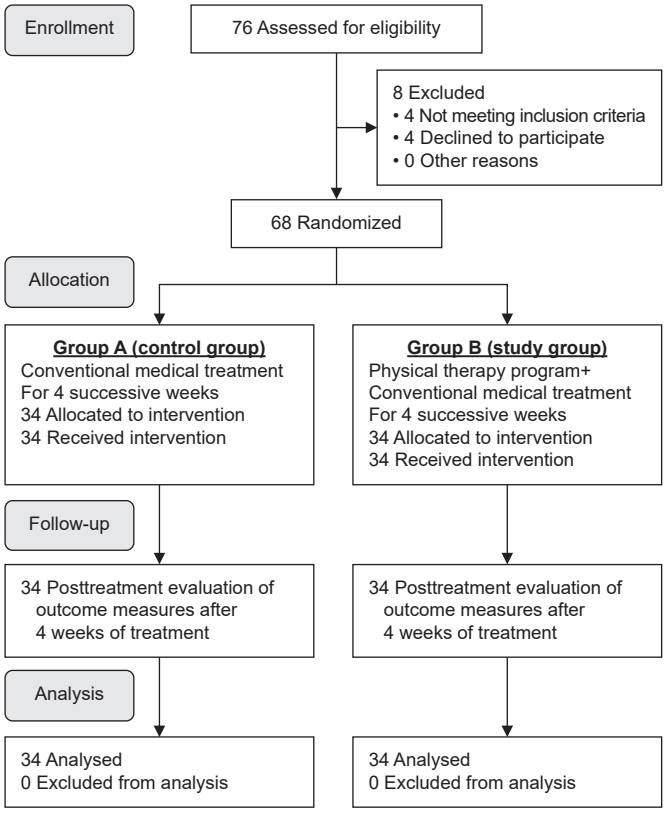

Fig. 1. Flow chart for participants' recruitment and allocation.

Intervention

The patients were divided into two equal groups at random (n=34). Group A (the control group) received just prescription medicine from an ENT doctor. Group B (experimental group) was treated with medicine by an ENT specialist and involved in a program of physiotherapy that included: (1) US therapy: Using Sonoplus 490 from Enraf-Nonius, the participants were instructed to lie on their backs with the therapist standing at head height. The patients underwent pulsed US (duty cycle 50%) therapy for the maxillary and frontal sinuses at intensities of 1 and 0.5 W/cm^2, respectively, and a 1 MHz collimating beam frequency with a 6:1 beam non-uniformity ratio, to deliver the US to the treatment area, A diminutive US applicator (0.8 cm^2) with a 0.6 cm^2 effective radiating area was utilized. The skin around the cheeks was utilized during application for the maxillary sinus and the forehead for the frontal sinus. Between the applicator and the skin, use an ultrasonic transmission gel, each maxillary sinus had a full contact approach for 5 minutes, while each frontal sinus received a 4 minutes full contact approach [10]. (2) Manual drainage techniques: It is performed from a supine lying position, while the therapist is seated behind the patient's head. (3) Self-sinus massage technique: Participants were also urged to self-massage their frontal and maxillary sinuses at home while reclining twice daily, in the morning and evening. Table 1 has a full explanation of all manual approaches [15-17,20,21]. Before the trial began, a demonstration session was conducted to present participants in the experimental group with a detailed explanation of the manual therapy technique. The physiotherapy program was applied three times a week (day after day) for twelve therapy sessions. The session started with US at the frontal sinuses then the maxillary sinuses followed immediately by manual drainage technique, the session lasted approximately 30 minutes.

Outcome measures

The measurable outcomes were assessed at baseline to 4 weeks

Table 1. Description of the manual techniques used for the experimental group

Manual techniques	Description
Frontal sinus drainage technique	With the thumbs placed just lateral to the midline of the forehead, apply gradual raised and released pressure down to the sinuses in a smooth rhythmic motion within the patient's acceptable pain level, and repeat 7 times. The center of the forehead is then positioned with the thumbs put side by side, and a sweeping motion from the center of the forehead and traveling inferiorly while remaining in front of the ears is used to help drain the frontal sinuses, which is performed 7 times [15].
Nasal passages drainage technique	The therapist positioned the patient's nose with the left thumb on the right side and the right thumb on the left side, the thumbs crossing above the bridge of the nose. Each thumb alternatively exerted pressure while moving down the nasal bone's length seven times, then uncrossing the thumbs allowed for a bilateral sweeping motion that was repeated 7 times along the sides of the nose and out across the maxillae [16].
Maxillary sinus drainage technique	The therapist used the thumb to provide gradual increasing and released pressure down to the maxillary sinuses in a smooth rhythmic motion within the patient's tolerable pain level, repeating 7 times. Then, drain the maxillary sinuses seven times with a sweeping motion from the maxillary sinuses down to just below the ears [17].
Self-sinus massaging technique	For the frontal sinus: The patient put his or her middle and index fingers just above the eyebrows on either side of the forehead, and performs gentle circular outward massaging for three sets of 30 seconds, repeated twice a day [20]. For the maxillary sinus: On either side of the nose, the patient placed his or her middle and index fingers in the space between the cheekbones and the upper jaw, perform gentle circular outward massaging for three sets of 30 seconds, repeated twice a day [21].

after treatment, directly after the completion of the twelve sessions of the treatment program by the author, who was blinded to the allocation. The participants were asked not to use any topical or systemic nasal drugs in the previous 24 hours before the baseline examination. The rhinosinusitis disability index (RSDI) was the primary outcome measure, while the PPT was the secondary outcome measure.

RSDI

The Arabic version of RSDI was used to evaluate the influence of CRS on patients' QoL. It is a precise, validated, and reliable (Cronbach's alpha=0.97) questionnaire for use with Arabic-speaking patients suffering from rhinosinusitis [22]. It includes 30 elements related to sinus and nasal symptoms that can result in distinct limitations on daily activities. The RSDI is divided into three areas: emotional (10 items), physical (11 items), and functional (9 items). Each item is assessed on a five-point Likert scale, between never (scored as 0) to always (scored as 4). The possible overall score runs from 0 to 120, with higher values indicating lower health-related QoL and higher levels of impairment [23,24].

PPT

The PPT in the target sinus, which is the least pressure that causes pain in tissue trigger sites [25], was measured using the FPX 25 Digital Algometer (Wagner Instruments). The measuring unit was calibrated as kg/cm^2 (capacity/graduation=10×0.01 kgf). Pressure algometry is a valid and reliable method of measuring pain in the muscles, fascia, joints, tendons, ligaments, and periosteum [26,27]. The patient was positioned supine, and the 1 cm^2 rubber-tipped end of the algometer which placed vertically to the skin surface over the predetermined areas in the frontal sinus (between the bridge of the nose and the inner side of the upper eyelid) and maxillary sinus (just below the cheekbones), respectively. A constant, mild pressure was administered until the patient felt pain for the first time and answered with "now." After removing the algometer, the value was recorded as the PPT for that sinus.

Statistical analysis

Descriptive statistics and an independent t-test were applied to compare the characteristics of the patients in both groups. The Wilcoxon signed rank test and Mann–Whitney u-test were used to compare the RSDI scores within and between groups. While the dependent t-test and independent t-test were used to compare the PPT scores within and between groups. The level of significance was fixed at alpha<0.05.

RESULTS

The patients comprised 31 male (45.59%) and 37 female (54.41%) with a mean age of 38.40 years and a body mass index of 26.79 kg/m^2. The independent t-test revealed that there were no significant differences (p>0.05) among the groups regarding patients' characteristics as shown in Table 2.

Wilcoxon signed-rank test indicated that there was a signifi-

cant reduction (p<0.001) in RSDI values for both groups when comparing the pretreatment values vs. the posttreatment values for each group as shown in Table 3. For control group (A), the physical disability index value decreased from 32.47±1.50 before treatment to 20.88±1.27 after treatment with a mean difference of 11.58 and the percentage of improvement was 35.66%, the functional disability index value also decreased from 19.03±1.44 before treatment to 12.88±1.34 after treatment with a mean difference of 6.14 and the percentage of improvement was 32.28%, the emotional disability index value decreased from 19.58±1.57 before treatment to 13.38±0.81 after treatment with a mean difference of 6.20 and the percentage of improvement was 31.66%, the total RSDI value decreased from 71.08±1.13 before treatment to 47.14±1.15 after treatment with a mean difference of 23.94 and the percentage of improvement was 33.68%.

While for the experimental group (B), the physical disability index value reduced from 32.88±1.37 before treatment to 14.17±1.33 after treatment with a mean difference of 17.91 and the percentage of improvement was 55.82%, the functional disability index value also reduced from 18.70±1.36 before treatment to 8.76±0.74 after treatment with a mean difference of 9.94 and the percentage of improvement was 53.15%, the emotional disability index value reduced from 19.82±1.48 before treatment to 8.82±0.86 after treatment with a mean difference of 11.00 and the percentage of improvement was 55.49%, the total RSDI value reduced from 70.64±1.20 before treatment to 31.76±1.04 after treatment with a mean difference of 38.88 and the percentage of improvement was 55.03%. The results revealed that the experimental group had a much higher percentage of improvement in RSDI values than the control group as shown in Table 3.

Table 2. Patients' characteristics

	Group A (n=34)	Group B (n=34)	Comparison	
			t	p-value
Age (yr)	39.17±6.07	38.64±6.54	0.347	0.729
Weight (kg)	75.97±4.58	76.26±4.11	0.278	0.781
Height (cm)	168.24±4.17	169.15±2.85	1.051	0.297
Body mass index (kg/m^2)	26.93±1.61	26.66±1.46	0.080	0.936
Duration of symptoms (mo)	6.47±2.21	7.11±2.42	1.149	0.254
Sex				
Male	16 (47.06)	15 (44.12)		
Female	18 (52.94)	19 (55.88)		

Values are presented as mean±standard deviation or number (%).
p>0.05 indicates no significance.

Table 3. Wilcoxon signed-rank test and Mann–Whitney U-test for comparing rhinosinusitis disability index values within and between groups

Wilcoxon signed-rank test within groups comparison								
Variables RSDI	Control group (A)				Experimental group (B)			
	Pre	Post	Mean difference (%)	p-value	Pre	Post	Mean difference (%)	p-value
Physical	32.47±1.50	20.88±1.27	11.58±1.33 (35.66)	<0.001*	32.88±1.37	14.17±1.33	17.91±1.11 (55.82)	<0.001*
Functional	19.03±1.44	12.88±1.34	6.14±0.43 (32.28)	<0.001*	18.70±1.36	8.76±0.74	9.94±0.91 (53.15)	<0.001*
Emotional	19.58±1.57	13.38±0.81	6.20±1.12 (31.66)	<0.001*	19.82±1.48	8.82±0.86	11.00±0.77 (55.49)	<0.001*
Total	71.08±1.13	47.14±1.15	23.94±0.95 (33.68)	<0.001*	70.64±1.20	31.76±1.04	38.88±0.67 (55.03)	<0.001*

Mann–Whitney U-test between groups comparison			
Variables RSDI	Pretest (control group vs. experimental group)	Posttest (control group vs. experimental group)	p-value of mean difference
Physical	p=0.302	p<0.001*	<0.001*
Functional	p=0.359	p<0.001*	<0.001*
Emotional	p=0.408	p<0.001*	<0.001*
Total	p=0.131	p<0.001*	<0.001*

Values are presented as mean±standard deviation.
RSDI, rhinosinusitis disability index.
p>0.05 indicates no significance, *p<0.05 indicates significance.

The Mann–Whitney U-test showed no evidence of a significant difference ($p>0.05$) in RSDI values between both groups at the pretest conditions, while for the posttest conditions, there was a highly statistically significant decrease ($p<0.001$) in RSDI values in the experimental group in comparison to the control group as shown in Table 3. Moreover, there was a statistically significant difference ($p<0.001$) between both groups when comparing the change of the pre-post data values.

For control group (A), the change between the pretest and posttest values for physical disability index was 11.58±1.33, for functional disability index was 6.14±0.43, for emotional disability index was 6.20±1.12, for the total RSDI was 23.94±0.95. While for the experimental group (B), the change between the pretest and posttest values for the physical disability index was 17.91±1.11, for the functional disability index was 9.94±0.91, for the emotional disability index was 11.00±0.77, for the total RSDI was 38.88±0.67 as shown in Table 3.

The dependent t-test showed that there was a significant increase ($p<0.001$) in PPT values for both groups when comparing the pretreatment values vs. the posttreatment values for each group. For control group (A), the PPT of the right frontal sinus increased from 1.45±0.16 before treatment to 2.06±0.16 after treatment with a mean difference of 0.61 and the percentage of improvement was 42.06%, while the left frontal sinus PPT increased from 1.43±0.14 before treatment to 2.03±0.13 after treatment with a mean difference of 0.60 and the percentage of improvement was 41.95%. The PPT of the right maxillary sinus also increased from 1.90±0.11 before treatment to 2.57±0.10 after treatment with a mean difference of 0.67 and the percentage of improvement was 35.26%, while the left maxillary sinus PPT increased from 1.86±0.06 before treatment to 2.52±0.09 after treatment with a mean difference of 0.66 and the percentage of improvement was 35.48%.

While for the experimental group (B), the PPT of the right frontal sinus increased from 1.48±0.11 before treatment to 3.07±0.17 after treatment with a mean difference of 1.59 and the percentage of improvement was 107.43%, while the left frontal sinus PPT increased from 1.44±0.08 before treatment to 3.05±0.13 after treatment with a mean difference of 1.60 and the percentage of improvement was 111.80%. The PPT of the right maxillary sinus also increased from 1.87±0.10 before treatment to 3.21±0.15 after treatment with a mean difference of 1.33 and the percentage of improvement was 71.65%, while the left maxillary sinus PPT increased from 1.84±0.07 before treatment to 3.17±0.11 after treatment with a mean difference of 1.32 and the percentage of improvement was 72.47%. According to the findings, the experimental group's PPT values improved by a much greater percentage than those of the control group as shown in Table 4.

Independent t-test showed no significant difference ($p>0.05$) in PPT values between both groups at the pretest conditions, while for the posttest conditions, there was a highly statistically significant increase ($p<0.001$) in PPT values in the experimental group compared to the control group. Furthermore, there was a statistically significant difference ($p<0.001$) between both groups when comparing the change of the pre-post data values.

For control group (A), the change between the pretest and posttest values of the right frontal sinus PPT was 0.61±0.16 and it was 0.60±0.14 for the left frontal sinus PPT. Whereas, the right maxillary sinus PPT was 0.67±0.06 and it was 0.66±0.09 for the left maxillary sinus PPT. While for the experimental group (B) the change between the pretest and posttest values of the right frontal sinus PPT was 1.59±0.16 and it was 1.60±0.14 for the left frontal sinus PPT. Whereas, the right maxillary sinus PPT was 1.33±0.05 and it was 1.32±0.08 for the left maxillary sinus PPT as shown in Table 4.

DISCUSSION

The present study's findings showed that the experimental group which received the physical therapy program in conjunction with conventional medical treatment demonstrated a highly statistically significant ($p<0.001$) enhancement in the measured outcomes after 4 weeks of treatment when compared to the control group that received only conservative medical therapy.

The current study's findings supported the authors' hypothesis that adding physical therapy programs including US therapy and manual therapy program to the traditional medical treatment was more effective than conventional medical treatment alone in treating patients with CRS in terms of QoL and PPT. QoL and pain enhancement can be attributed to a proposed strategy for the US that involves the breakdown of the biofilm structure of the bacterial population. The US was reported to reduce bacterial load by destroying biofilms [12]. Moreover, purulent discharge was frequently seen during or right after receiving US treatment. This could be because the US delivered mechanical energy to separate the purulent material from the sinus walls, relieving pressure and pain [28].

Pulsed US therapy for CRS patients has been shown to be sig-

Table 4. Dependent t-test and independent t-test for comparing pressure pain threshold values within and between groups

Dependent t-test within groups comparison				
Variables PPT	Control group (A)		Experimental group (B)	
	Frontal sinus	Maxillary sinus	Frontal sinus	Maxillary sinus
Right sinus				
Pre	1.45±0.16	1.90±0.11	1.48±0.11	1.87±0.10
Post	2.06±0.16	2.57±0.10	3.07±0.17	3.21±0.15
p-value	<0.001*	<0.001*	<0.001*	<0.001*
Mean difference (%)	0.61±0.16 (42.06)	0.67±0.06 (35.26)	1.59±0.16 (107.43)	1.33±0.05 (71.65)
Left sinus				
Pre	1.43±0.14	1.86±0.06	1.44±0.08	1.84±0.07
Post	2.03±0.13	2.52±0.09	3.05±0.13	3.17±0.11
p-value	<0.001*	<0.001*	<0.001*	<0.001*
Mean difference (%)	0.60±0.14 (41.95)	0.66±0.09 (35.48)	1.60±0.14 (111.80)	1.32±0.08 (72.47)
Independent t-test between groups comparison				
Variables PPT	Pretest (control group vs. experimental group)		Posttest (control group vs. experimental group)	p-value of mean difference
Frontal sinus				
Right	p=0.352		p<0.001*	<0.001*
Left	p=0.605		p<0.001*	<0.001*
Maxillary sinus				
Right	p=0.243		p<0.001*	<0.001*
Left	p=0.287		p<0.001*	<0.001*

Values are presented as mean±standard deviation.
PPT, pressure pain threshold.
p>0.05 indicates no significance, *p<0.05 indicates significance.

nificantly more efficient when combined with antibiotics, which can significantly reduce bacterial viability [28-31]. Additionally, 57 patients with CRS were successfully treated with low-intensity pulsed US. The investigators reported that the majority of both major and minor symptoms showed significant improvements following pulsed US therapy [32].

Other studies by Ansari et al. [8] showed a significantly larger decline in CRS symptoms following treatment with the US. Furthermore, when comparing pulsed and continuous therapeutic US, they did not identify any significant differences in outcomes between the two groups [9], however, pulsed US mode minimizes thermal activities by giving the coupling medium time to dissipate heat during treatment [33]. Another study included 20 patients who received six sessions of US three days per week. The severity of global sinonasal symptoms was evaluated after treatment using a 6-cm visual analog and the Sino-Nasal Outcome Test. Following treatment with the US, the patient's total severity assessment scores improved [34].

One more case series study incorporates manual therapy into the overall management of CRS symptoms, and they found that patients who received a combination of local and regional manual therapy procedures, improved in all measured outcomes. There was a significant reduction in craniofacial pain and an increase in PPTs over four precise sinus points, as well as a reduction in the severity of symptoms. These findings seemed to compare more positively with outcomes seen in similar patients treated with antibiotics or endoscopic surgery [15].

The PPT was found to be significantly increased, as measured by pressure algometry on the frontal and maxillary sinuses. The positive effect could be attributed to the thermal effects produced at the sinuses as a result of the manual therapy intervention, which assisted in draining the excess secretions that cause inflammation to the adjacent lymph nodes. This technique, in turn, helped to reduce sinus inflammation and pain [35]. In agreement with our findings, Ahmadi et al. [20] indicated that massage therapy can be incorporated into an exercise program as a treatment modality in patients with CRS, based on the findings of their study, which revealed that a special face massage therapy protocol can relieve facial congestion and tenderness in CRS patients.

A five-session study combining US and shortwave diathermy interventions using manual drainage procedures and suboccipital release showed significant improvements in patients with chronic sinusitis. However, when compared to the shortwave

diathermy group, the US therapy group experienced earlier and more rapid symptom reduction. As a result, the study recommended that US therapy would be applied as a treatment protocol for patients suffering from chronic sinusitis [19]. Thus, a novel approach to treating chronic sinusitis is currently being developed, which improves medical management and reduces antibiotic resistance, hence reducing the need for surgical surgery.

CRS has a similar negative influence on health as angina, chronic obstructive lung disorders, congestive heart failure, and low back pain [36], Surgery is typically the next step after oral, topical, and antibiotic therapy. The establishment of a new paradigm in the treatment of CRS could result from the effective deployment of a physical therapy program. To the best of the authors' knowledge, this is the initial research that evaluates the effect of adding US therapy to manual techniques using frontal, nasal, and maxillary sinus drainage, in addition to self-massage techniques and routine medical treatment.

This study was limited by the evaluation of improvement by CT in the area of para-nasal sinus, which might be a beneficial tool for the assessment of the anatomy and extent of improvement, thus more studies are recommended to evaluate the improvement by more additional assessment tools (sinuscopy and CT). In addition, only the short-term effect of the addition of a manual physical therapy program was evaluated, thus, long-term follow-up should be considered in further studies. Moreover, certain parameters of US were used in this study, different parameters will be recommended in future studies to assess their effects. In addition, further research is required to determine if manual techniques or US therapy plays a more important role in treating chronic instances of rhinosinusitis because the mixed physiotherapy program may not make clear which percentage of improvement was due to US therapy or manual techniques, so further study is needed to clarify this point. Furthermore, the sham US, sham sinus manual drainage techniques, and sham self-sinus massage weren't be given to the control group therefore future research should incorporate this type of intervention to improve study blinding. Also, this study was limited to a certain age group, therefore, more studies are recommended to assess the effect of different treatment periods of application on different categories of age.

In conclusion, according to the findings of this study, incorporating a physical therapy program that included pulsed US therapy, sinus manual drainage techniques, and self-sinus massage into conservative medical treatment was more effective than conservative medical treatment alone in improving QoL and PPT in CRS patients.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

Conceptualization: Fouda KZ. Methodology: Fouda KZ, Eladl HM, Allam NM. Formal analysis: Fouda KZ, Ameer MA. Project administration: Fouda KZ, Eladl HM, Ameer MA, Allam NM. Visualization: Fouda KZ, Eladl HM, Ameer MA, Allam NM. Writing – original draft: Fouda KZ, Eladl HM, Allam NM. Writing – review and editing: Fouda KZ, Ameer MA. Approval of final manuscript: all authors.

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ORCID

Khaled Z. Fouda, https://orcid.org/0000-0001-6121-9127
Hadaya M. Eladl, https://orcid.org/0000-0002-4083-7070
Mariam A. Ameer, https://orcid.org/0000-0002-1996-5131
Nesma M. Allam, https://orcid.org/0000-0002-2478-4474

REFERENCES

1. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, Brook I, Ashok Kumar K, Kramper M, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg 2015;152(2 Suppl):S1-39.
2. Fokkens WJ, Lund VJ, Hopkins C, Hellings PW, Kern R, Reitsma S, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. Rhinology 2020;58(Suppl S29):1-464.
3. Levy JM, Marino MJ, McCoul ED. Paranasal sinus balloon catheter dilation for treatment of chronic rhinosinusitis: a systematic review and meta-analysis. Otolaryngol Head Neck Surg 2016;154:33-40.

4. Rudmik L, Smith TL, Schlosser RJ, Hwang PH, Mace JC, Soler ZM. Productivity costs in patients with refractory chronic rhinosinusitis. Laryngoscope 2014;124:2007-12.
5. Orlandi RR, Kingdom TT, Hwang PH. International Consensus Statement on Allergy and Rhinology: Rhinosinusitis executive summary. Int Forum Allergy Rhinol 2016;6 Suppl 1:S3-21.
6. Bova R. Treatment decisions in adult rhinosinusitis. MedicineToday 2011;12:16-26.
7. Peters AT, Spector S, Hsu J, Hamilos DL, Baroody FM, Chandra RK, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol 2014;113:347-85.
8. Ansari NN, Naghdi S, Fathali M, Bartley J, Rastak MS. A randomized clinical trial comparing pulsed ultrasound and erythromycin phonophoresis in the treatment of patients with chronic rhinosinusitis. Physiother Theory Pract 2015;31:166-72.
9. Ansari NN, Fathali M, Naghdi S, Hasson S, Jalaie S, Rastak MS. A randomized, double-blind clinical trial comparing the effects of continuous and pulsed ultrasound in patients with chronic rhinosinusitis. Physiother Theory Pract 2012;28:85-94.
10. Feizabadi N, Sarrafzadeh J, Fathali M, Vasaghi-Gharamaleki B, Dadgoo M, Kardan-Yamchi J, et al. The pulsed ultrasound strategy effectively decreases the S. aureus population of chronic rhinosinusitis patients. BMC Res Notes 2019;12:576.
11. De Castro RB, Cruz-Daylo MAB, Jardin MLA. Low frequency ultrasound in Chronic Rhinosinusitis with Nasal Polyposis and recovery after endoscopic sinus surgery: a randomized controlled trial. Philipp J Otolaryngol Head Neck Surg 2017;32:6-13.
12. Bartley J, Ansari NN, Naghdi S. Therapeutic ultrasound as a treatment modality for chronic rhinosinusitis. Curr Infect Dis Rep 2014;16:398.
13. Rocha WA, Rodrigues KM, Pereira RR, Nogueira BV, Gonçalves WL. [Acute effects of therapeutic 1-MHz ultrasound on nasal unblocking of subjects with chronic rhinosinusitis]. Braz J Otorhinolaryngol 2011;77:7-12. Portuguese.
14. da Silva GS, Dos Santos Isoppo K. Therapeutic ultrasound as a treatment for chronic rhinosinusitis: a systematic review. Clin Respir J 2021;15:1275-85.
15. Méndez-Sánchez R, González-Iglesias J, Puente-González AS, Sánchez-Sánchez JL, Puentedura EJ, Fernández-de-Las-Peñas C. Effects of manual therapy on craniofacial pain in patients with chronic rhinosinusitis: a case series. J Manipulative Physiol Ther 2012;35:64-72.
16. Baisakhiya N. Efficacy of osteopathic manipulative treatment in the patient of chronic rhinosinusitis: a case report. Clin Rhinol An Int J 2018;11:58-60.
17. Lee-Wong M, Karagic M, Doshi A, Gomez S, Resnick D. An osteopathic approach to chronic sinusitis. J Aller Ther 2011;2:109.
18. Naghdi S, Ansari NN, Fathali M, Bartley J, Varedi M, Honarpishe R. A pilot study into the effect of low-level laser therapy in patients with chronic rhinosinusitis. Physiother Theory Pract 2013;29:596-603.
19. Kalekar S, Gurudut P. Effect of therapeutic ultrasound versus short-wave diathermy combined with suboccipital release and manual drainage techniques for chronic sinusitis: a randomized clinical trial. Indian J Phys Ther Res 2019;1:29-36.
20. Ahmadi F, Rostami F, Mahdavi R. The effect of therapeutic massage on the athletes with chronic sinusitis. J Paramed Sci Rehabil 2017;6:83-90.
21. Bahraini S. The effect of facial and head massage on the pain severity of sinus headache. J Paramed Sci Rehabil 2014;3:68-73.
22. Aldrees T, Almubarak Z, Hassouneh B, Albosaily A, Aloulah M, Almasoud M, et al. Translation, validation, and cultural adaptation of the Rhinosinusitis Disability Index and the Chronic Sinusitis Survey into Arabic. Ann Saudi Med 2018;38:159-66.
23. Lehrer-Coriat E, Mariño-Sánchez F, Alobid I, Mullol J. Quality of life measures in patients on rhinosinusitis trials. Clin Invest 2013;3:251-63.
24. Al Sayah F, Ishaque S, Lau D, Johnson JA. Health related quality of life measures in Arabic speaking populations: a systematic review on cross-cultural adaptation and measurement properties. Qual Life Res 2013;22:213-29.
25. Park G, Kim CW, Park SB, Kim MJ, Jang SH. Reliability and usefulness of the pressure pain threshold measurement in patients with myofascial pain. Ann Rehabil Med 2011;35:412-7.
26. Knapstad MK, Nordahl SHG, Naterstad IF, Ask T, Skouen JS, Goplen FK. Measuring pressure pain threshold in the cervical region of dizzy patients- the reliability of a pressure algometer. Physiother Res Int 2018;23:e1736.
27. Kamińska A, Dalewski B, Sobolewska E. The usefulness of the pressure algometer in the diagnosis and treatment of orofacial pain patients: a systematic review. Occup Ther Int 2020;2020:5168457.
28. Bartley J, Young D. Ultrasound as a treatment for chronic rhinosinusitis. Med Hypotheses 2009;73:15-7.
29. Rediske AM, Roeder BL, Nelson JL, Robison RL, Schaalje GB, Robison RA, et al. Pulsed ultrasound enhances the killing of Escherichia coli biofilms by aminoglycoside antibiotics in vivo. Antimicrob Agents Chemother 2000;44:771-2.
30. Carmen JC, Roeder BL, Nelson JL, Ogilvie RL, Robison RA, Schaalje GB, et al. Treatment of biofilm infections on implants with low-frequency ultrasound and antibiotics. Am J Infect Control 2005;33:78-82.
31. Ensing GT, Roeder BL, Nelson JL, van Horn JR, van der Mei HC, Busscher HJ, et al. Effect of pulsed ultrasound in combination with

gentamicin on bacterial viability in biofilms on bone cements in vivo. J Appl Microbiol 2005;99:443-8.
32. Ansari NN, Naghdi S, Farhadi M, Jalaie S. A preliminary study into the effect of low-intensity pulsed ultrasound on chronic maxillary and frontal sinusitis. Physiother Theory Pract 2007;23:211-8.
33. Polat BE, Hart D, Langer R, Blankschtein D. Ultrasound-mediated transdermal drug delivery: mechanisms, scope, and emerging trends. J Control Release 2011;152:330-48.
34. Young D, Morton R, Bartley J. Therapeutic ultrasound as treatment for chronic rhinosinusitis: preliminary observations. J Laryngol Otol 2010;124:495-9.
35. Gandhi M, Gurudut P. Comparative effectiveness of jade stone mobilisation, non-abrasive cupping, and manual drainage technique in subjects with chronic sinusitis: a randomized clinical trial. Internet J Allied Health Sci Pract 2022;20:21.
36. Schenkel EJ, Messina Jr. JC, Bodine A, Mcginley JS, Wirth RJ, Mahmoud RA. Disease burden of chronic rhinosinusitis (CRS) is as severe as other serious chronic diseases. J Allergy Clin Immunol 2018;141(2 Suppl):AB165.

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Translation, Cultural Adaptation, and Validation of a Korean Version of the Information Needs in Cardiac Rehabilitation Scale

Seungsu Jeong, MD[1], Heeju Kim, BS[1], Won-Seok Kim, MD, PhD[2], Won Kee Chang, MD[2], Seungwoo Cha, MD[2], Eunjeong Choi, BS[2], Chul Kim, MD, PhD[3], Sherry L. Grace, PhD[4,5], Sora Baek, MD, PhD[1]

[1]*Department of Rehabilitation Medicine, Kangwon National University Hospital, Kangwon National University School of Medicine, Chuncheon, Korea*
[2]*Department of Rehabilitation Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Korea*
[3]*Department of Rehabilitation Medicine, Sanggye Paik Hospital, Inje University College of Medicine, Seoul, Korea*
[4]*Faculty of Health, York University, Toronto, Canada*
[5]*KITE Research Institute–Toronto Rehabilitation Institute, University Health Network, University of Toronto, Toronto, Canada*

Objective: To translate and culturally adapt the Information Needs in Cardiac Rehabilitation (INCR) questionnaire into Korean and perform psychometric validation.

Methods: The original English version of the INCR, in which patients are asked to rate the importance of 55 topics, was translated into Korean (INCR-K) and culturally adapted. The INCR-K was tested on 101 cardiac rehabilitation (CR) participants at Kangwon National University Hospital and Seoul National University Bundang Hospital in Korea. Structural validity was assessed using principal component analysis, and Cronbach's alpha of the areas was computed. Criterion validity was assessed by comparing information needs according to CR duration and knowledge sufficiency according to receipt of education. Half of the participants were randomly selected for 1 month of re-testing to assess their responsiveness.

Results: Following cognitive debriefing, the number of items was reduced to 41 and ratings were added to assess participants' sufficient knowledge of each item. The INCR-K structure comprised eight areas, each with sufficient internal consistency (Cronbach's alpha>0.7). Criterion validity was supported by significant differences in mean INCR-K scores based on CR duration and knowledge sufficiency ratings according to receipt of education ($p<0.05$). Information needs and knowledge sufficiency ratings increased after 1 month of CR, thus supporting responsiveness ($p<0.05$).

Conclusion: The INCR-K demonstrated adequate face, content, cross-cultural, structural, and criterion validities, internal consistency, and responsiveness. Information needs changed with CR, such that multiple assessments of information needs may be warranted as rehabilitation progresses to facilitate patient-centered education.

Keywords: Cardiovascular diseases; Cardiac rehabilitation; Needs assessment; Health knowledge, attitudes, practice; Surveys and questionnaires

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Correspondence:
Sora Baek
Department of Rehabilitation Medicine, Kangwon National University Hospital, Kangwon National University College of Medicine, 156 Baengnyeong-ro, Chuncheon 24289, Korea.
Tel: +82-33-258-9262
Fax: +82-33-258-9097
E-mail: sora.baek@kangwon.ac.kr

INTRODUCTION

Cardiovascular diseases (CVDs) represent a significant global health burden [1]. The implementation of secondary prevention strategies for CVDs has demonstrated remarkable effectiveness [2]. However, successful secondary prevention relies on patients' knowledge and adoption of multiple health behavior changes [3]. Unfortunately, many patients do not achieve optimal risk reduction despite available interventions [4]. Therefore, it is crucial for healthcare providers to assess the information needs of cardiac patients to enhance treatment outcomes [5,6]. Nonetheless, accurately identifying patient information needs can be challenging for healthcare providers due to differences in perceived importance between clinical personnel and patients [7]. Moreover, patient information needs evolve over time, particularly as they transition back to their daily routines and incorporate various therapies [8]. Additionally, patient subpopulations may have diverse information needs based on factors such as sex, age, ethnicity, and socioeconomic status [7].

Extensive research has been dedicated to exploring patients' information needs following various cardiovascular events, such as revascularization [9], acute coronary syndrome [10], post-myocardial infarction [8], and heart failure [11]. Surprisingly, limited attention has been given to investigating information needs in the context of cardiac rehabilitation (CR), despite patient education being a fundamental element of CR programs that aim to assist patients in implementing secondary prevention recommendations [12]. It is therefore recommended that an assessment of patient information needs be conducted prior to initiating patient education within CR, enabling the customization of educational interventions to meet individual needs and optimize outcomes [13].

In order to facilitate the identification of specific information needs in CR patients, a self-administered questionnaire called the Information Needs in Cardiac Rehabilitation (INCR; Appendix 1) was developed and subjected to psychometric validation in a Canadian context [14]. The INCR has since undergone translation and cultural adaptation for Chinese, Spanish, and Portuguese populations [15-17]. In the Korean setting, limited research has been conducted on the information needs of individuals with cardiac disorders. While several instruments have been developed in medically advanced countries since the 1990s to assess the information needs of cardiac patients [10], the availability of locally developed tools in this area remains scarce in Korea. To address this gap, a recent study aimed to translate the INCR questionnaire into Korean [18]. However, this study had certain limitations, particularly in terms of sample size, with only 45 participants, which was insufficient to establish the validity of the tool. Additionally, previous studies did not assess the construct and criterion validities of the translated INCR questionnaire.

The primary objective of the current study was to translate and culturally adapt the INCR tool for implementation in the Korean context and subsequently conduct a comprehensive psychometric validation involving a participant sample size of over 100 individuals. Furthermore, the study aimed to determine the participants' highest priority information needs using the questionnaire.

METHODS

Design

This study was conducted in two stages. First, the INCR was translated and cross-culturally adapted into Korean version of the Information Needs in Cardiac Rehabilitation (INCR-K). Based on the COSMIN taxonomy [19], this first stage was to establish face, content, and cross-cultural validities of the scale. Face and content validities assess the extent to which a questionnaire accurately reflects its intended measurements. Several methods were employed to demonstrate face and content validities during translation, including cognitive debriefing, qualitative semi-structured interviews for feedback, and reviews conducted by an expert committee. The second step was the psychometric validation of the INCR-K through a cross-sectional survey, with repeated administration of the INCR-K in a random subsample. Structural validity, internal reliability, criterion validity, and responsiveness were assessed. This study was reviewed and approved by the Institutional Review Boards of Kangwon National University Hospital (IRB No. A-2022-01-005-002) and Seoul National University Bundang Hospital (IRB No. B-2207-769-303), and each participant provided informed written consent.

Materials

The INCR tool, developed and validated in English, assesses the information needs of patients undergoing CR. It consists of 55 items across 10 areas [14]. The 10 areas identified were the heart (physiology, symptoms, and surgical treatments), nutrition, exercise/physical activity, medication, work/vocational/social, stress/psychological factors, general/social concerns,

emergency/safety, diagnosis and treatment, and risk factors. Each item in the INCR-K, which assesses information needs, is rated on a 5-point Likert scale of 1 (really not important) to 5 (very important). The tool can be used to tailor educational interventions for patients undergoing CR, with higher scores indicating higher information needs. Furthermore, the tool can be used regardless of the CR participation duration.

Translation and cross-cultural adaptation of the INCR

The translation and cross-cultural adaptation of the INCR followed the Patient-Reported Outcomes Translation and Linguistic Validation Task Force guidelines by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) [20], which include the following steps: (1) forward translation, (2) reconciliation, (3) back translation and review, (4) harmonization, (5) cognitive debriefing, (6) review of cognitive debriefing results and finalization, and (7) proofreading and final report.

Two independent translators (one was a medical doctor involved in the study and the other was not medical doctor) forward translated the INCR into Korean. Afterward, the two translations were reviewed for ambiguities, and any discrepancies were reconciled. Back translation was performed by two bilingual native English speakers fluent in Korean and blinded to the original English version. One translator was a healthcare provider, whereas the other was not.

An expert committee consisting of eight health professionals and translators compared the back translations to the original instrument for harmonization; in addition, the committee reviewed translations for linguistic, semantic, technical, and conceptual consistencies. This process resulted in the prefinal version of the INCR-K.

Regarding cognitive debriefing, the prefinal version was tested with five Korean patients from Kangwon National University Hospital receiving outpatient CR. The time required to complete the questionnaire was recorded, and patients were asked to provide feedback through qualitative semi-structured interviews. The patients were asked to rate the readability, length, and clarity of the questionnaire through 10 items, eight of which (Table 1) were rated through a visual analogue scale of 0–100 mm; 0 meaning not usable at all and 100 meaning very usable (i.e., higher scores denote more positive perceptions of the scale). These were analyzed using descriptive statistics. The remaining two questions ("If any of the questions in the survey are unclear, please tell us what they are" and "If any of the questions in the survey are duplicated, please tell us which one is the question") were open-ended.

In the review of the input from cognitive debriefing by the expert committee, any ambiguous and redundant expressions were modified after a discussion. Finally, the refined version of the INCR-K was set for psychometric validation (Appendix 2).

Psychometric validation

Participants

In total, 104 patients were recruited from the CR programs at Kangwon National University Hospital and Seoul National University Bundang Hospital in Korea (Fig. 1). Seoul National University Bundang Hospital is situated in an urban locale, while Kangwon National University Hospital is located in a rural area. Sample size calculation for psychometric analysis was based on the recommendation of Hair et al. [21], which stipulates a minimum of 100 participants. The inclusion criteria consisted of patients diagnosed with CVDs who underwent CR between February 2022 and December 2022. Exclusion criteria encompassed individuals under the age of 18 years, those with literacy problems, and those with severe visual, cognitive, or mental impairments that hindered their ability to complete the question-

Table 1. Perceptions of the usability of the prefinal version of the INCR-K (n=5)

No.	Item	Value
1	Is the questionnaire, in your opinion, useful to assess "information needs in cardiac rehabilitation"?	81.2±13.9
2	Do you feel that the questionnaire asks about your information needs in cardiac rehabilitation?	73.8±20.1
3	What is your opinion about the length of the questionnaire?	59.6±31.0
4	Are the questions stated in a clear way?	67.8±31.0
5	Is the questionnaire well organized?	71.8±17.0
6	What is your feeling about the readability of the questionnaire?	59.0±36.4
7	What is your opinion about level of difficulty of filling-in the questionnaire?	77.8±20.4
8	What is your opinion about the layout of the questionnaire?	75.6±20.7

Values are presented as means±standard deviation and rated on a visual analogue scale, with a range of 0–100.
INCR-K, Korean version of the Information Needs in Cardiac Rehabilitation.

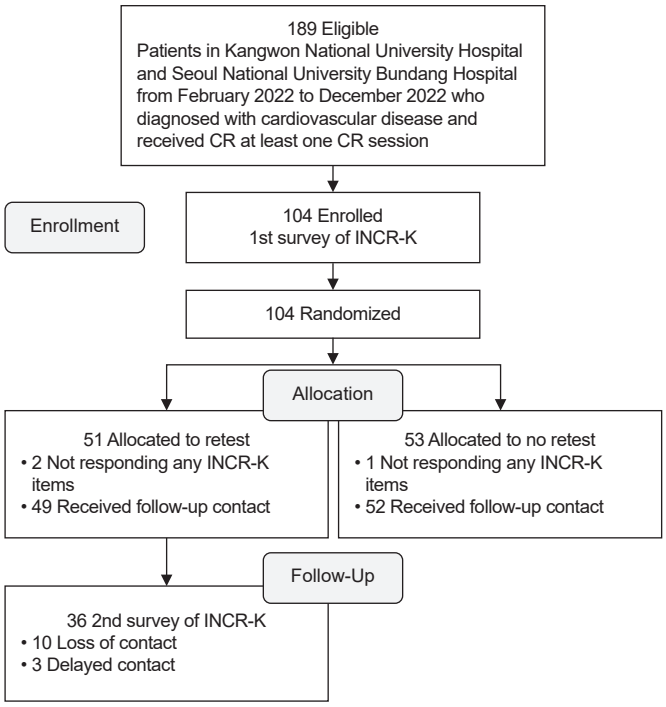

Fig. 1. Inclusion flowchart for the Korean Version of the Information Needs in Cardiac Rehabilitation (INCR-K) tool study. CR, cardiac rehabilitation.

naire. Upon enrollment, all participants underwent either a cardiopulmonary exercise test or an electrocardiogram-monitored exercise session. Additionally, all participants completed the CR education schedule, as documented in their medical records.

Measures

Participants completed the INCR-K questionnaire, and the scores of all items were averaged to determine the participants' total information needs. In addition, the average score per area was calculated. Data from participants who did not complete more than 20% of the items were excluded from analysis. In addition to completing the INCR-K, participants provided self-reported sociodemographic characteristics, such as sex, age, income, educational attainment, and work status. Although the participants completed their education sessions during CR, they were asked about their experience with receiving CR education in specific topics, including emergency, risk factor, exercise, and medication, with response options of "yes" or "no." The criterion for determining whether education had been received was based on the participants' self-report, regardless of the actual content or extent of education. In addition, the participants were requested to indicate their preferred mode of education delivery (Appendix 3). Data on risk factors [22], diagnosed CVDs, comorbidities, treatment procedures, duration of CR, and number of CR sessions undertaken were obtained from the patients' medical charts.

Statistical analysis (psychometric validations and descriptive analysis)

Structural validity was assessed using principal component analysis. The suitability of the data for this analysis was assessed using the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's sphericity test [23]. KMO values>0.60 were considered acceptable, and a p-value<0.05 in Bartlett's sphericity test was considered significant. Areas with eigenvalues>1.0 were extracted according to the Kaiser-Guttman criterion [24]. The matrix was interpreted using the varimax method with Kaiser normalization. Factor loading values>0.30 indicated representation in each area [25]. The internal consistency of each area was calculated using Cronbach's alpha, and a value>0.7 was considered to reflect satisfactory internal correlation between items of the same area [26].

Criterion validity was assessed using a t-test to compare the total INCR-K score (the mean of all items) among patients with different CR durations. The duration of CR was defined as the period starting from the initial of CR session, which could consist of either a cardiopulmonary exercise test or an electrocardiogram-monitored exercise session, up to the point of the completing of the questionnaire. The categorization of CR duration into two groups (≤1 week and >1 week) was motivated in the intention to observe potential changes in information needs between initial and subsequent participants after starting CR. The choice of using 1-week threshold was informed by that the average duration of phase 1 in CR is less than 1–2 weeks [27]. Furthermore, to assess the criterion validity of the newly introduced "knowledge sufficiency" scores, the INCR-K scores were compared to self-reported receipt of educational engagement.

To assess responsiveness, the questionnaire was re-administered 1 month after the first administration to half of the patients who were randomly selected using a computer-generated sequence. In our study, this 1-month interval was selected to correspond with the range of intervals (ranging from 3 weeks to 3 months) employed in previous studies [28,29]. Subsequently, the INCR-K scores for each area in the first and second administrations were compared using t-tests.

Descriptive statistics were used to describe the INCR-K scores

and determine whether patients had sufficient knowledge of each item. Data analysis was performed using IBM SPSS Statistics 25.0 (IBM Corp.). Statistical significance was set at $p<0.05$.

RESULTS

Translation and cultural adaptation

Forward translation, reconciliation, back translation, and harmonization

During the forward translation of the INCR from English to Korean, appropriate consideration was given to the cultural implications of the Korean honorifics. After back translation, the discrepancies between the original and back-translated versions were identified and resolved. During harmonization, the expert committee decided to remove three items from the original questionnaire (original INCR items 37, 38, and 41) [14] because of the differences in medical systems between Canada and Korea. Afterward, the resulting prefinal version, consisting of 52 items, was subjected to cognitive debriefing.

Cognitive debriefing

The prefinal version of the INCR-K was tested on five patients. The researchers maintained a neutral stance throughout the self-administration process, encouraging the participants to complete all the questions. The questionnaire was completed in an average of 7 minutes and 44 seconds. The results of the subsequent semi-structured interviews showed high ratings of the INCR-K in terms of usefulness (mean score, 81.2±13.9). In contrast, the INCR-K was rated as relatively difficult to read (59.0±36.4), lengthy (59.6±31.0), and possessing some unclear sentences (67.8±31.0; Table 1). During the interviews, some participants commented that the medical terminology in the prefinal version was difficult to understand. Other participants expressed dissatisfaction with the number of items, redundant content, and vague expressions in the questionnaire.

Review of cognitive debriefing results and finalization

After reviewing the results of cognitive debriefing, the expert committee and the developer of the original INCR (Sherry L. Grace) revised the prefinal version; the revisions were as follows: (1) Incomprehensible expressions were modified to make them easier to understand; (2) Items with redundant or less relevant content were deleted, thus reducing the total number of items from 52 to 41; and (3) Vague expressions were clarified. Details of each change are provided below.

Respondents in the cognitive debriefing phase commented that several items were difficult to understand, particularly the item "What is angioplasty?", which is an unfamiliar medical term to many patients. To address this problem, the word "stent" was added, making it #6 "What is angioplasty and stent placement?". The term "stent" is a well-known term to patients.

To address the issue of length in the prefinal version and improve the overall readability of the questionnaire, we removed items that contained overlapping content. Three items regarding drug intake were identified to be similar; thus, the items "How do I remember to take my medication?" and "Are there foods I should avoid while taking these medications?" were deleted, leaving only item "How do I take my medication in the right way?" (INCR-K#21). Three items regarding stress were had overlapping content, and the items "How does stress affect my heart?" and "What can I do to reduce stress in my life?" were deleted, leaving only item "How can I cope with stress?" (INCR-K#27). Furthermore, two items on angina and chest pain were identified to have similar meanings, and the item "How do I recognize angina symptoms?" was deleted, leaving item "What should I do if I feel angina or chest pain?" (INCR-K#30) in the questionnaire. Three items regarding risk factors were similar in content; thus, the items "What are the risk factors that I cannot control?" and "What are the risk factors that I can control?" were deleted. The remaining item "What can I do to bring my risk factors under control?" (INCR-K#36) was retained. Finally, three similar items regarding tobacco use were evaluated and items "What are the benefits of quitting smoking?" and "What supports are available to help me quit smoking?" were deleted, leaving INCR-K#40, "How does tobacco affect the heart?" in the questionnaire.

Items with vague expressions were rephrased. For example, the item "When should I stop physical exercise?" was revised to "When should I stop exercise for safety?" (INCR-K#18) to better convey the intent of the question, which was to assess patients' knowledge of the symptoms that should prompt the cessation of exercise during CR. To enhance clarity and comprehension, the item "What are the effects of complementary and alternative medications?" was revised to "Are complementary and alternative therapies (health supplements, Chinese medicine/acupuncture, massage, etc.) effective?" (INCR-K#23). This revision aimed to provide a clearer understanding of "complementary and alternative therapies." To ensure the relevance of the questionnaire to the Korean context, specific examples such as "health supplements, Chinese medicine/acupuncture,

massage, etc." were thoughtfully selected from two studies that specifically investigated the role of complementary and alternative treatments in CR [30,31]. These examples were carefully incorporated into the study to ensure that the questionnaire accurately reflected the Korean context. Finally, item "What feelings are common after a heart attack?" was revised to "What feelings are common after a heart attack? (Can I seek help if I feel depressed or anxious?)" (INCR-K#25) to clarify the intent of the question, which was to check for depression and anxiety that may occur after a heart attack.

Furthermore, to streamline the questionnaire, questions that were not applicable to all participants were excluded. This decision was primarily made to avoid an unnecessarily lengthy questionnaire, which could result in reduced response rates, respondent fatigue, and compromised data quality. Questions regarding specific topics such as preventing low blood sugar during exercise, caring for the feet during an exercise program, returning to an old job, or driving after a heart condition were removed. Instead, the questions focused on information needs relevant to a broader patient population, allowing for the development of a concise and efficient questionnaire. This approach improved the response rates and enhanced the overall quality of the collected data.

In the harmonization phase, two items were initially deleted because of differences between the Canadian and Korean medical systems. However, after revising the items to be appropriate for the Korean medical system, these two items were reintegrated into the INCR-K as "Is there a support system that can help patients with heart disease?" (INCR-K#29) and "When (in what cases) do I need to make an outpatient appointment or go to the emergency room?" (INCR-K#31). Initially, these questions were phrased as "What services, support organizations and groups are available?" and "When should I call the doctor?", respectively.

Finally, in addition, respondents were asked to rate not only the importance of each item, but also whether they perceived they already had sufficient knowledge of the topic area (yes/no). Thus, in CR programs, the focus of the medical staff education can be on the areas where the patients require more knowledge. The total knowledge sufficiency score was calculated based on the percentage of "yes" responses for all items.

Proofreading and final report

The final version of the 41-item INCR-K is provided in Appendix 2.

Psychometric validation

Characteristics of the participants

Initially, 104 patients provided informed consent to participate in the study; however, three patients were excluded from the analysis owing to failure to answer any of the items in the INCR-K, resulting in a total of 101 participants included in the study. As shown in Table 2, the item completion rates were high.

Table 3 shows the sociodemographic and clinical characteristics of the participants. Half the participants had recently started receiving CR. Approximately half of the participants had received heart education, but less than 25% had received education regarding medication at the time of survey administration.

Factor analysis and internal consistency

Through translation and adaptation, the original 55 items of the INCR were reduced to 41 items in the final INCR-K. To assess structural validity, a factor analysis was conducted on the 41 items of the INCR-K using principal component analysis. The results showed that the data was suitable for factor analysis, with a KMO index of 0.824 (above 0.60) and a Bartlett's test of sphericity of χ^2=2,880.63 ($p < 0.001$).

Eight areas were extracted, which accounted for 70.8% of the total variance. Table 4 presents the factor loading for the 41 items in the INCR-K. These areas included the heart, food and self-management, exercise, medication, emotion and return to previous roles, treatment and diagnosis, risk factors 1, and risk factor 2. The internal consistency of each area was assessed using Cronbach's alpha of 0.73–0.88. All areas were considered internally consistent ($\alpha > 0.70$), as shown in Table 4.

Criterion validity

As shown in Fig. 2A, the mean INCR-K scores were compared based on CR duration. For CR durations categorized as ≤1 week (n=51, 50.5%) and >1 week (n=50, 49.5%), the mean INCR-K scores were 4.27±0.49 and 4.51±0.32, respectively. The results showed that patients with a longer CR duration perceived information as more important ($p=0.005$). Among 51 patients who had CR duration ≤1 week, 32 were inpatients, while the remaining 19 were outpatients. All 50 patients with CR duration >1 week were all outpatients.

In addition, the criterion validity of the added knowledge sufficiency ratings was supported because the receipt of heart education was significantly related to these ratings of knowledge sufficiency ($p<0.05$), as shown in Fig. 3. Moreover, the criterion

Table 2. INCR-K responses including information needs and knowledge sufficiency

Area	Item	INCR-K information needs/ importance rating		Sufficient knowledge	
		Item score[a] (mean±SD)	Item completion rate (%)	Yes (%)	Completion rate (%)
The heart	1. How does a healthy heart work?	4.66±0.55	96.2	59.6	98.0
	2. What is "coronary artery disease"?	4.56±0.67	96.2	52.5	98.0
	3. What is angina?	4.50±0.61	97.1	62.9	96.0
	4. What happens when someone has a heart attack?	4.75±0.56	95.2	79.2	100
	5. What is "bypass surgery"?	4.27±0.88	93.3	30.3	98.0
	6. What is angioplasty and stent placement?	4.49±0.77	95.2	70.0	99.0
Food and self-management	7. What foods should I eat for a healthy heart?	4.57±0.61	97.1	64.6	98.0
	8. How can I choose healthy foods at the grocery store?	4.21±0.74	97.1	52.5	98.0
	9. How can I choose healthy foods when dining out?	4.19±0.76	97.1	52.5	98.0
	10. How do I read food labels?	3.80±0.87	97.1	45.5	98.0
	16. What types of exercise equipment are available? (where?)	3.95±0.75	97.1	51.5	98.0
	17. How can I exercise at home safely?	4.24±0.74	97.1	60.6	98.0
Exercise	11. How will exercise help my heart condition?	4.61±0.58	97.1	79.6	97.0
	12. What are the components of a safe exercise program?	4.51±0.70	96.2	54.5	98.0
	13. What is cardiovascular or aerobic exercise?	4.46±0.66	95.2	78.8	98.0
	14. How should I exercise in hot or cold weather?	4.35±0.76	96.2	59.6	98.0
	15. What is resistance training (i.e. exercise for strength)?	4.08±0.72	97.1	48.5	98.0
	35. What are the risk factors that I can control?	4.46±0.66	97.1	56.1	97.0
Medication	18. When should I stop physical exercise for safety?	4.57±0.59	97.1	61.6	98.0
	20. What medications do I need to help my heart?	4.50±0.67	97.1	46.9	97.0
	21. How do I take my medication in the right way?	4.57±0.62	97.1	63.6	98.0
	22. Which side effects are possible with my medication?	4.45±0.66	96.2	35.7	97.0
	23. Are complementary and alternative therapies (health supplements, Chinese medicine/ acupuncture, massage, etc.) effective?	3.54±1.06	97.1	34.3	98.0
Emotion and return to previous roles	19. Is sexual activity safe for me?	3.76±1.01	96.2	43.4	98.0
	24. When can I return to work and to my old activities?	4.20±0.78	100	44.4	98.0
	25. What feelings are common after a heart attack? (Can I seek help if I feel depressed or anxious?)	4.15±0.84	97	50.5	96.0
Treatment and diagnosis	27. How can I cope with stress?	4.57±0.57	97.1	54.1	97.0
	28. Do sleep problems affect my heart?	4.40±0.63	97.1	52.5	98.0
	30. What should I do if I feel angina or chest pain?	4.79±0.46	96.2	72.7	98.0
	31. When (in what cases) do I need to make an outpatient appointment or go to the emergency room?	4.64±0.63	96.2	74.7	98.0
	32. What are the tests used to diagnosis my heart condition?	4.28±0.76	97.1	38.4	98.0
	33. What treatments are available for my condition?	4.43±0.64	97.1	38.4	98.0
	36. What can I do to bring my risk factors under control?	4.47±0.63	97.1	41.4	98.0
Risk factor 1	26. How does stress affect my heart?	4.65±0.54	97.1	78.8	98.0
	37. How does cholesterol affect my heart?	4.53±0.64	97.1	67.7	98.0
	38. How does diabetes affect my heart?	4.55±0.59	97.1	68.7	98.0
	39. How does physical inactivity affect my heart?	4.38±0.66	97.1	62.6	98.0
Risk factor 2	29. Is there a support system that can help patients with heart disease?	4.07±0.92	100	12.1	98.0
	34. What are the risk factors for heart disease?	4.51±0.58	97.1	53.5	98.0
	40. How does tobacco affect my heart?	4.60±0.74	97.1	82.8	98.0
	41. How does alcohol affect my heart?	4.54±0.66	97.1	79.8	98.0
Total		4.38±0.43	99.5	55.3	97.8

INCR-K, Korean version of the Information Needs in Cardiac Rehabilitation; SD, standard deviation.
[a]Range, 1–5, with 5 being "very important."

Table 3. Socio-demographic and clinical characteristics of the participants and health care receipt

Characteristic	Value (n=101)
Socio-demographic	
Hospital	
Kangwon National University Hospital (rural)	60 (59.4)
Seoul National University Bundang Hospital (urban)	41 (40.6)
Age (yr)	59.46±11.90
<65	67 (66.3)
≥65	34 (33.7)
Sex	
Male	82 (81.2)
Female	19 (18.8)
Work status	
Paid job	63 (62.4)
Retired	22 (21.8)
No job	15 (14.8)
No response	1 (1.0)
Education	
Elementary school	11 (10.9)
Middle school	9 (8.9)
High school	31 (30.7)
University	38 (37.6)
Postgraduate	11 (10.9)
No response	1 (1.0)
Monthly income (USD)	
<1,000	10 (9.9)
1,000–2,000	21 (20.8)
2,000–3,000	20 (19.8)
3,000–4,000	19 (18.8)
4,000–7,000	14 (13.9)
>7,000	9 (8.9)
No response	8 (7.9)
Clinical	
Risk factor	
Family history	10 (9.9)
Tobacco use[a]	41 (40.6)
Sedentary lifestyle[b]	52 (51.5)
Obesity[c]	44 (43.6)
Hypertension	43 (42.6)
Diabetes	23 (22.8)
Dyslipidemia	53 (52.5)
Low high-density lipoprotein	91 (90.1)
Comorbidities	
Stroke	2 (2.0)
Chronic kidney disease	4 (4.0)
CR indication	
Acute myocardial infarction	84 (83.2)
Unstable angina	5 (4.9)
Heart failure	6 (5.9)
Peripheral artery disease[d]	3 (3.0)
Arrhythmia	3 (3.0)
Cardiac procedure	
Percutaneous coronary intervention	84 (83.2)
Bypass surgery	4 (4.0)
Valve surgery	4 (4.0)
Health service use	
Duration in CR (wk)	
≤1	51 (50.5)
>1	50 (49.5)
Received CR education	
Emergency response	46 (45.5)
Risk factor management	45 (44.6)
Exercise	56 (55.4)
Medication	17 (16.8)

Values are presented as number (%) or mean±standard deviation.
CR, cardiac rehabilitation.
[a]Current cigarette smokers or those who quit smoking within the previous 6 months or have been exposed to environmental tobacco smoke [37].
[b]Not participating in at least 30 minutes of moderate-intensity physical activity (40%–60% of oxygen consumption reserve) on at least 3 days of the week for at least 3 months [37].
[c]Body mass index≥25 kg/m^2.
[d]Patients with peripheral artery disease had cardiovascular risk factors.

validity was supported because a longer CR duration corresponded to a higher knowledge sufficiency (p=0.04; Fig. 2B).

Responsiveness

Of the randomly selected participants, 10 did not complete the INCR a second time and three completed the second questionnaire after more than 3 months (Fig. 1). Fig. 4 displays the INCR-K item scores per area at the first and second administrations. All areas were rated as more important during the second administration. There was a significant difference in information needs according to time in the following areas: the heart, exercise, and treatment and diagnosis. Specifically, during the first test, patients were most interested in learning about "the heart" and "treatment and diagnosis." However, during the second test, participants reported their greatest information needs to be related to "the heart" and "exercise."

Descriptive analysis of information needs and knowledge sufficiency and preferred educational delivery modes

The mean INCR-K score on the first administration was 4.38±0.43, with 85.1% of all participants rating the importance of the informational items as high (INCR-K score≥4). The three items with the highest ratings were as follows: #30 "What should I do if I feel angina or chest pain?" (4.79±0.46), #4 "What happens when someone has a heart attack?" (4.75±0.56), and #1

Table 4. Principal component analysis of 41 items of the INCR-K

Area	Item	Factor loading	Internal consistency (Cronbach's alpha)	Mean information needs score per area (mean±SD)	Knowledge sufficiency per area (%)
The heart	1. How does a healthy heart work?	0.687	0.88	4.54±0.70	59.1
	2. What is "coronary artery disease"?	0.747			
	3. What is angina?	0.617			
	4. What happens when someone has a heart attack?	0.704			
	5. What is "bypass surgery"?	0.658			
	6. What is angioplasty and stent placement?	0.697			
Food and self-management	7. What foods should I eat for a healthy heart?	0.546	0.87	4.16±0.78	54.5
	8. How can I choose healthy foods at the grocery store?	0.785			
	9. How can I choose healthy foods when dining out?	0.744			
	10. How do I read food labels?	0.820			
	16. What types of exercise equipment are available? (where?)	0.463			
	17. How can I exercise at home safely?	0.505			
Exercise	11. How will exercise help my heart condition?	0.498	0.87	4.41±0.70	62.9
	12. What are the components of a safe exercise program?	0.672			
	13. What is cardiovascular or aerobic exercise?	0.781			
	14. How should I exercise in hot or cold weather?	0.562			
	15. What is resistance training (i.e. exercise for strength)?	0.339			
	35. What are the risk factors that I can control?	0.420			
Medication	18. When should I stop physical exercise for safety?	0.548	0.77	4.33±0.83	48.4
	20. What medications do I need to help my heart?	0.830			
	21. How do I take my medication in the right way?	0.750			
	22. Which side effects are possible with my medication?	0.708			
	23. Are complementary and alternative therapies (health supplements, Chinese medicine/acupuncture, massage, etc.) effective?	0.416			
Emotion and return to previous roles	19. Is sexual activity safe for me?	0.611	0.73	4.04±0.90	46.1
	24. When can I return to work and to my old activities?	0.653			
	25. What feelings are common after a heart attack? (Can I seek help if I feel depressed or anxious?)	0.649			
Treatment and diagnosis	27. How can I cope with stress?	0.538	0.87	4.51±0.64	53.2
	28. Do sleep problems affect my heart?	0.527			
	30. What should I do if I feel angina or chest pain?	0.640			
	31. When (in what cases) do I need to make an outpatient appointment or go to the emergency room?	0.741			
	32. What are the tests used to diagnosis my heart condition?	0.537			
	33. What treatments are available for my condition?	0.379			
	36. What can I do to bring my risk factors under control?	0.613			
Risk factor 1	26. How does stress affect my heart?	0.534	0.86	4.53±0.61	69.5
	37. How does cholesterol affect my heart?	0.511			
	38. How does diabetes affect my heart?	0.709			
	39. How does physical inactivity affect my heart?	0.492			
Risk factor 2	29. Is there a support system that can help patients with heart disease?	0.503	0.74	4.43±0.76	57.1
	34. What are the risk factors for heart disease?	0.430			
	40. How does tobacco affect my heart?	0.733			
	41. How does alcohol affect my heart?	0.841			

INCR-K, Korean version of the Information Needs in Cardiac Rehabilitation; SD, standard deviation.

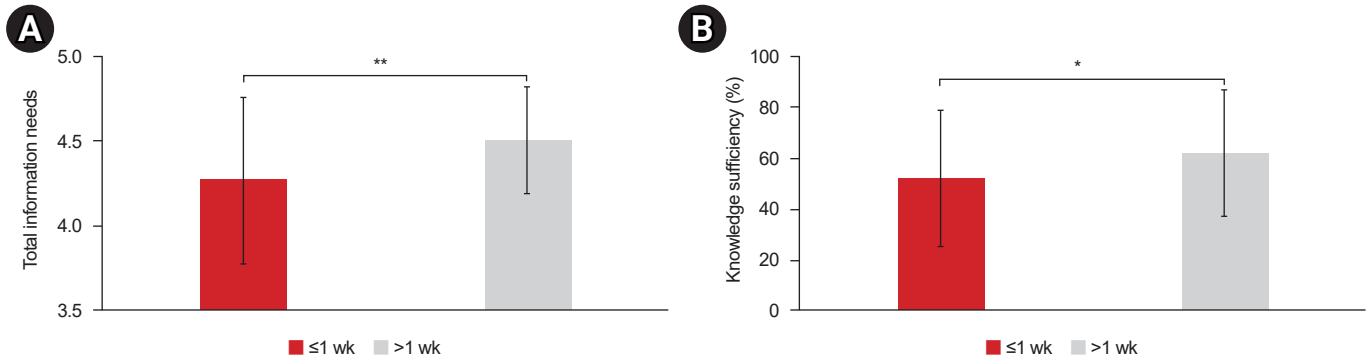

Fig. 2. Total information needs (range, 1–5) (A) and knowledge sufficiency (range, 0%–100%) (B) based on cardiac rehabilitation duration, n=101. Significant differences are indicated by asterisks (*p<0.05, **p<0.01).

"How does a healthy heart work?" (4.66±0.55). Whereas, three items with the lowest information need were #23 "Are complementary and alternative therapies (health supplements, Chinese medicine/acupuncture, massage, etc.) effective?" (3.54±1.06), #19 "Is sexual activity safe for me?" (3.76±1.01), and #10 "How do I read food labels?" (3.80±0.87; Table 2).

Among the eight areas of the INCR-K, participants rated "the heart" and "risk factor 1" (e.g., stress, cholesterol, diabetes, and physical inactivity) as the most important information needs (4.54±0.70 and 4.53±0.61, respectively). Meanwhile, "emotion and return to previous roles" and "food and self-management" were rated as the lowest information needs (4.04±0.90 and 4.16±0.78, respectively; Table 4).

Table 2 presents knowledge sufficiency, expressed as the percentage of "yes" responses for each item. Knowledge sufficiency was 12.1%–82.8%. Specifically, the items with the highest knowledge sufficiency were #40 "How does tobacco affect my heart?", #41 "How does alcohol affect my heart", and #11 "How will exercise help my heart condition?". Prior to psychometric validation, we hypothesized that items demonstrating higher knowledge sufficiency would indicate a reduced need for additional information. However, information needs remained high among participants with prior knowledge. The mean INCR-K score was 4.53±0.65 for participants with knowledge and 4.18±0.81 for those without knowledge (p<0.001).

Table 5 shows that the preferred method of educational delivery was face-to-face consultation with medical staff (53.5%). Conversely, the least preferred method was through audiovisual materials (4.0%).

DISCUSSION

Fulfilling the information needs of cardiac patients positively affects the patients' quality of life, satisfaction with care, and health outcomes [6]. To effectively address these needs, healthcare providers must evaluate the information needs of patients with cardiac diseases participating in CR programs. To assess the information needs in Korea, we translated the original INCR into Korean, culturally adapted it, and validated its psychometric properties. An abridged version comprising 41 items was finalized. This revised version also incorporated knowledge sufficiency rating, which may prove helpful in the current era where many patients receive health information online. The results supported the face, content, cross-cultural, and criterion validities of the INCR-K as well as its internal reliability and responsiveness.

The INCR enables healthcare providers to effectively identify and address the information needs of patients undergoing CR, thus bridging the information gap between medical staff and patients and ultimately resulting in improved outcomes [5,6]. In a previous study, the original version of the INCR was employed to identify the information needs of patients and gaps in the educational curriculum of patients undergoing CR [32]. Modifying the curriculum based on these findings can enhance the effectiveness and efficiency of education. Hence, further studies in Korea are warranted to assess the effectiveness of implementing the INCR-K in patient education.

The results of this study agrees with those of previous studies in some aspects but differ in others. First, similar to previous studies, this study established the criterion validity of INCR

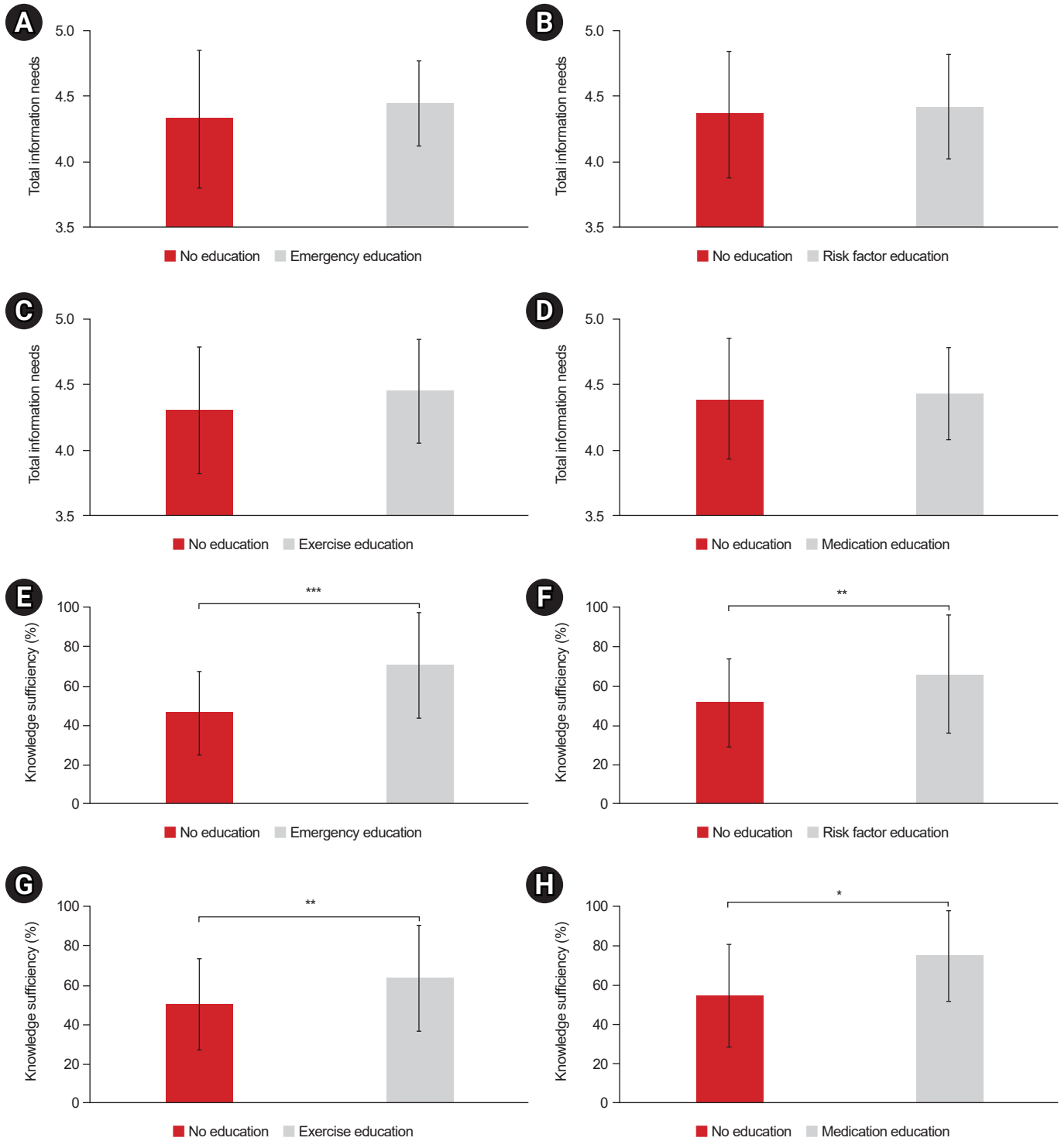

Fig. 3. Total information needs (range, 1–5) (A-D) and knowledge sufficiency (range, 0%–100%) (E-H) by receipt of cardiac rehabilitation education, by topic. Perceived knowledge sufficiency was significantly related to previous receipt of heart education, but there were no differences in information needs, suggesting that patients understood the importance of the topics. Significant differences are indicated by asterisks (*p<0.05, **p<0.01, ***p<0.001).

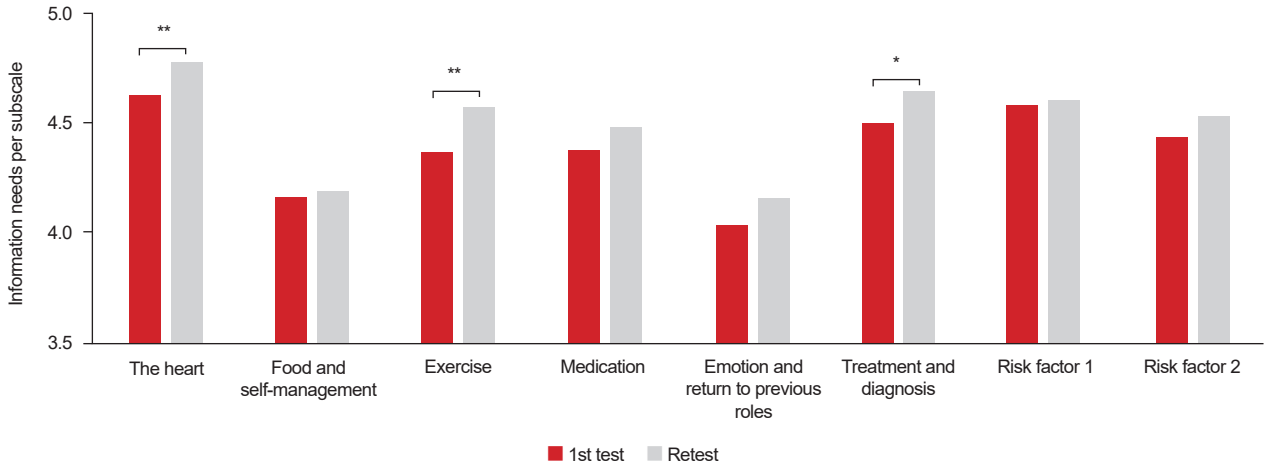

Fig. 4. Comparison of information needs (range, 1–5) per area for the first and second tests, n=36. Significant differences are indicated by asterisks (*p<0.05, **p<0.01).

Table 5. Preferred education delivery mode

	Value (n=101)
Face-to-face consultation with medical staff	54 (53.5)
Internet resources	46 (45.5)
Smartphone apps	41 (40.6)
Booklets	34 (33.7)
Face-to-face lecture	33 (32.7)
E-learning	13 (12.9)
Audiovisual materials	4 (4.0)

Values are presented as number (%).

based on CR duration [14,15]. Decker et al. [8] observed that as the duration of CR increased, there was a corresponding increase in patients' information needs. Initially, patients depend heavily on the clinicians' decisions, particularly when confronted with life-threatening situations. However, as the CR program progresses and their condition stabilizes, patients gradually become more involved in the decision-making process. Consequently, the increase in information needs is attributable to the growing number of questions related to decision making. According to Ghisi et al. [33], extended CR participation enhances knowledge sufficiency. Continuous engagement in a CR program allows patients to reinforce their knowledge through repeated training sessions.

Consequently, as the duration of CR increases, patients' knowledge sufficiency improves. Second, the item (INCR-K#30) with the highest information needs was related to emergency and safety issues, which is consistent with the results of previous studies [6,34,35]. Emergency situations such as angina and heart attack were considered the most important, and this finding was consistent regardless of the stage of the patient in the CR program. Furthermore, it was observed that the "risk factor 1" area (e.g., stress, cholesterol, diabetes, and physical inactivity) demonstrated elevated information needs compared to other areas (Table 4). This finding aligns with those of previous studies reporting significant level of information need in this area [34,36]. The primary reason for heightened information needs in relation to risk factors may be attributable the intense fear of heart disease recurrence among individuals. This indicates that patients with a history of heart disease, particularly those who have had myocardial infarction, exhibit the highest level of concern regarding the possibility of recurrence and recognize the importance of managing risk factors for prevention [36]. Third, following translation and cultural adaptation, the number of items in the INCR questionnaire decreased from 55 to 41. Although these two areas were omitted, the overall structure of the INCR-K remained consistent with that of the original English version [14]. The initial version of the INCR encompasses 10 areas: heart, exercise/physical activity, medication, work/ vocational/social, stress/psychological factors, general/ social concerns, emergency/safety, diagnosis and treatment, risk factors, and barriers/goal setting. After translation and cultural adaptation, the INCR-K was created. It underwent a subsequent factor analysis, resulting in the identification of eight areas, namely heart, food and self-management, exercise, medication, emotion and return to previous roles, treatment and diagnosis,

risk factor 1, and risk factor 2. Despite the variation in area composition between the original INCR and INCR-K, both questionnaires share common areas such as Heart, Exercise, Medication, Treatment and diagnosis, and Risk factor; thus ensuring the overall consistency of the questionnaire.

This study has several implications. First, it highlights the need for direct knowledge assessment to determine knowledge sufficiency more accurately. In the INCR-K, knowledge sufficiency was evaluated indirectly by asking patients to provide "yes" or "no" responses. However, solely confirming knowledge without direct assessment does not guarantee a precise understanding of the information. Although healthcare providers should prioritize addressing information that patients consider important and areas in which their knowledge is lacking, ascertaining patients' actual comprehension without direct assessment remains challenging. Therefore, it is essential to ensure that patients understand the information using direct assessment methods. Furthermore, a distinction was observed between the actual implementation of education and the patients' perceptions of receiving education. All 101 patients (100%) had received education as documented in their medical records; however, only 14 of 101 patients (13.9%) reported that they had received the complete education. This discrepancy suggests that patients may not feel confident about receiving sufficient education, thus highlighting the need for continued educational efforts. We believe that enhancing the curriculum by reinforcing education that patients did not acknowledge will result in a more effective delivery of education. Finally, the findings of this study emphasize the importance of regularly assessing patient information needs throughout their CR program, as these needs may change over time. This continued assessment can ensure that information needs are met and support optimal patient self-management.

To ensure efficient patient education in clinical settings, it is crucial to prioritize two key areas: the "area with the highest information needs" and "area with the lowest knowledge sufficiency." The area with the highest information needs corresponds to the topics that patients are most curious about, whereas the area with the lowest knowledge sufficiency relates to subjects that patients have the least understanding. Among the various areas examined, the "heart" area demonstrated the highest information needs, with a score of 4.54±0.70 (Table 4). This result can be attributed to the significance of heart disease and patients' priority of acquiring information and knowledge related to their heart health.

Therefore, it is recommended to develop and implement educational programs that specifically focus on the "heart" area in clinical practice to enhance the knowledge of heart health. In contrast, the area of "emotion and return to previous roles" displayed the lowest knowledge sufficiency (Table 4). Patients' lack of knowledge in this area is attributable to their perception of heart disease, primarily as a physical ailment, resulting in an insufficient understanding of the emotional challenges and importance of resuming their previous roles. Comorbid psychiatric disorders are prevalent in CR patients and significantly affect their quality of life [37]. Therefore, it is essential to incorporate regular psychiatric assessments into CR programs and provide robust support for patients to resume their previous roles [37].

This study had some limitations. First, although this study met the minimum sample size of 100 participants, as recommended by Hair et al. [21], the same authors suggested a minimum of five subjects per item for factor analysis, which would require 205 participants for the 41-item INCR-K. However, the assumptions were met for the factor analysis, and the solution converged, assuaging the sample size concerns. However, a larger sample size would be required to establish construct validity, although this has been established in other INCR versions; thus, any concerns in this regard would be minimal. In addition, this study was performed in only two regions of Korea. Future studies in other regions are warranted to establish generalizability.

In conclusion, the INCR-K questionnaire has satisfactory psychometric properties; hence, it can be used to assess the information needs of Korean patients undergoing CR. The results provide evidence of the face, content, cross-cultural, structural, and criterion validities, internal consistency, and responsiveness of the INCR-K. The INCR-K tool can support healthcare professionals in determining the information needs of patients undergoing CR. Therefore, education can be tailored to their individual needs.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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None.

AUTHOR CONTRIBUTION

Conceptualization: Baek S, Kim WS, Grace SL. Formal analysis: Jeong S, Baek S. Investigation: Jeong S, Kim H, Cha S, Choi E. Methodology: Jeong S, Kim WS, Chang WK, Kim C, Grace SL, Baek S. Project administration: Baek S. Visualization: Jeong S, Baek S. Writing – original draft: Jeong S, Baek S. Writing – review and editing: Jeong S, Kim WS, Chang WK, Grace SL, Baek S. Approval of final manuscript: all authors.

ORCID

Seungsu Jeong, https://orcid.org/0000-0003-4979-8976
Heeju Kim, https://orcid.org/0000-0002-9272-0042
Won-Seok Kim, https://orcid.org/0000-0002-1199-5707
Won Kee Chang, https://orcid.org/0000-0001-9756-6817
Seungwoo Cha, https://orcid.org/0000-0003-0236-9330
Eunjeong Choi, https://orcid.org/0000-0002-3431-3350
Chul Kim, https://orcid.org/0000-0001-8223-2945
Sherry L. Grace, https://orcid.org/0000-0001-7063-3610
Sora Baek, https://orcid.org/0000-0003-3404-6202

REFERENCES

1. GBD 2019 Diseases and Injuries Collaborators. Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet 2020;396:1204-22. Erratum in: Lancet 2020;396:1562.
2. Dibben G, Faulkner J, Oldridge N, Rees K, Thompson DR, Zwisler AD, et al. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev 2021;11:CD001800.
3. Visseren FLJ, Mach F, Smulders YM, Carballo D, Koskinas KC, Bäck M, et al. 2021 ESC Guidelines on cardiovascular disease prevention in clinical practice. Eur Heart J 2021;42:3227-337. Erratum in: Eur Heart J 2022;43:4468.
4. Teo K, Lear S, Islam S, Mony P, Dehghan M, Li W, et al. Prevalence of a healthy lifestyle among individuals with cardiovascular disease in high-, middle- and low-income countries: The Prospective Urban Rural Epidemiology (PURE) study. JAMA 2013;309:1613-21.
5. Moser DK, Dracup KA, Marsden C. Needs of recovering cardiac patients and their spouses: compared views. Int J Nurs Stud 1993;30:105-14.
6. Larson CO, Nelson EC, Gustafson D, Batalden PB. The relationship between meeting patients' information needs and their satisfaction with hospital care and general health status outcomes. Int J Qual Health Care 1996;8:447-56.
7. Scott JT, Thompson DR. Assessing the information needs of post-myocardial infarction patients: a systematic review. Patient Educ Couns 2003;50:167-77.
8. Decker C, Garavalia L, Chen C, Buchanan DM, Nugent K, Shipman A, et al. Acute myocardial infarction patients' information needs over the course of treatment and recovery. J Cardiovasc Nurs 2007;22:459-65.
9. Astin F, Closs SJ, McLenachan J, Hunter S, Priestley C. The information needs of patients treated with primary angioplasty for heart attack: an exploratory study. Patient Educ Couns 2008;73:325-32.
10. Czar ML, Engler MM. Perceived learning needs of patients with coronary artery disease using a questionnaire assessment tool. Heart Lung 1997;26:109-17.
11. Lile JB, Buhmann J, Roders S. Development of a learning needs assessment tool for patients with congestive heart failure. Home Health Care Manag Pract 1999;11:11-25.
12. Grace SL, Turk-Adawi KI, Contractor A, Atrey A, Campbell NR, Derman W, et al. Cardiac rehabilitation delivery model for low-resource settings: an international council of cardiovascular prevention and rehabilitation consensus statement. Prog Cardiovasc Dis 2016;59:303-22.
13. Pavy B, Barbet R, Carré F, Champion C, Iliou MC, Jourdain P, et al. Therapeutic education in coronary heart disease: position paper from the Working Group of Exercise Rehabilitation and Sport (GERS) and the Therapeutic Education Commission of the French Society of Cardiology. Arch Cardiovasc Dis 2013;106:680-9.
14. Ghisi GL, Grace SL, Thomas S, Evans MF, Oh P. Development and psychometric validation of a scale to assess information needs in cardiac rehabilitation: the INCR Tool. Patient Educ Couns 2013;91:337-43.
15. Ghisi GL, Dos Santos RZ, Bonin CB, Roussenq S, Grace SL, Oh P, et al. Validation of a Portuguese version of the Information Needs in Cardiac Rehabilitation (INCR) scale in Brazil. Heart Lung 2014;43:192-7.
16. Ghisi GLM, Anchique CV, Fernandez R, Quesada-Chaves D, Gordillo MX, Acosta S, et al. Validation of a Spanish version of the information needs in cardiac rehabilitation scale to assess information needs and preferences in cardiac rehabilitation. J Cardiovasc Nurs 2018;33:E29-34.
17. Ma C, Yang Q, Huang S. Translation and psychometric evaluation of the Chinese version of the information needs in cardiac rehabilitation tool. J Cardiopulm Rehabil Prev 2019;39:331-7.
18. Choi SYH, Kim JH. Reliability and validity of Korean-version of information needs in cardiac rehabilitation scale. J Korean Phys Ther

2022;34:234-41.
19. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, Bouter LM, de Vet HC. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol 2010;63:737-45.
20. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value Health 2005;8:94-104.
21. Hair JF, Anderson RE, Tatham RL, Black WC. Multivariate data analysis. 5th ed. Prentice Hall; 1998. p. 1-730.
22. Pescatello LS, American College of Sports Medicine. ACSM's guidelines for exercise testing and prescription. 9th ed. Wolters Kluwer/Lippincott Williams & Wilkins Health; 2014.
23. Shrestha N. Factor analysis as a tool for survey analysis. Am J Appl Math Stat 2021;9:4-11.
24. Kaiser HF. The application of electronic computers to factor analysis. Educ Psychol Meas 1960;20:141-51.
25. Taherdoost HA, Sahibuddin S, Jalaliyoon NE. Exploratory factor analysis; concepts and theory. Adv Appl Pure Math 2022;27:375-82.
26. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 2007;60:34-42.
27. Bjarnason-Wehrens B, McGee H, Zwisler AD, Piepoli MF, Benzer W, Schmid JP, et al. Cardiac rehabilitation in Europe: results from the European Cardiac Rehabilitation Inventory Survey. Eur J Cardiovasc Prev Rehabil 2010;17:410-8.
28. Stockler MR, Osoba D, Goodwin P, Corey P, Tannock IF. Responsiveness to change in health-related quality of life in a randomized clinical trial: a comparison of the Prostate Cancer Specific Quality of Life Instrument (PROSQOLI) with analogous scales from the EORTC QLQ-C30 and a trial specific module. European Organization for Research and Treatment of Cancer. J Clin Epidemiol 1998;51:137-45.
29. Kirkley A, Griffin S, McLintock H, Ng L. The development and evaluation of a disease-specific quality of life measurement tool for shoulder instability. The Western Ontario Shoulder Instability Index (WOSI). Am J Sports Med 1998;26:764-72.
30. Arthur HM, Patterson C, Stone JA. The role of complementary and alternative therapies in cardiac rehabilitation: a systematic evaluation. Eur J Cardiovasc Prev Rehabil 2006;13:3-9.
31. Wood MJ, Stewart RL, Merry H, Johnstone DE, Cox JL. Use of complementary and alternative medical therapies in patients with cardiovascular disease. Am Heart J 2003;145:806-12.
32. de Melo Ghisi GL, Grace SL, Thomas S, Evans MF, Sawula H, Oh P. Healthcare providers' awareness of the information needs of their cardiac rehabilitation patients throughout the program continuum. Patient Educ Couns 2014;95:143-50.
33. Ghisi GL, Britto R, Motamedi N, Grace SL. Disease-related knowledge in cardiac rehabilitation enrollees: correlates and changes. Patient Educ Couns 2015;98:533-9.
34. Chan V. Content areas for cardiac teaching: patients' perceptions of the importance of teaching content after myocardial infarction. J Adv Nurs 1990;15:1139-45.
35. Timmins F, Kaliszer M. Information needs of myocardial infarction patients. Eur J Cardiovasc Nurs 2003;2:57-65.
36. Wingate S. Post-MI patients' perceptions of their learning needs. Dimens Crit Care Nurs 1990;9:112-8.
37. Serber ER, Todaro JF, Tilkemeier PL, Niaura R. Prevalence and characteristics of multiple psychiatric disorders in cardiac rehabilitation patients. J Cardiopulm Rehabil Prev 2009;29:161-8; quiz 169-70.

Appendix 1. Original version of the Information Needs in Cardiac Rehabilitation (INCR) and preferences for educational delivery formats

Information Needs Assessment for Cardiac Rehabilitation Patients

You are being invited to fill out this questionnaire because you are in the cardiac rehabilitation program. Knowledge about your condition, treatments and risk factors is an important component about management. We would like to have a sense of how important a topic may be to increase your knowledge about heart disease as you have been recovering from your heart event.

The purpose of this questionnaire is to:
- assess your needs for information regarding heart disease;
- identify specific topics about your condition that you want to learn about;
- identify your preferences for educational delivery formats.

This questionnaire is **confidential** and completely **voluntary**.
It should take about 10 minutes to complete.

Instructions for Completion:	
1.	Please answer as many items as you can;
2.	Rate each topic on a 5-item scale related to 'how important do you think this topic is to increase your knowledge about heart disease';
3.	After completing the questionnaire, please return to the researcher or reception.
4.	If you do not wish to fill out the questionnaire, please leave it blank and place it in the collection box or return to the researcher.

INFORMATION NEEDS ASSESSMENT IN CARDIAC REHABILITATION

Rate the importance of each topic to increase your knowledge about coronary artery disease

	Really not important	Not important	Neutral	Important	Very Important
1. How does a healthy heart works?	☐	☐	☐	☐	☐
2. What is “coronary artery disease”?	☐	☐	☐	☐	☐
3. What is angina?	☐	☐	☐	☐	☐
4. What happens when someone has a heart attack?	☐	☐	☐	☐	☐
5. What is “bypass surgery”?	☐	☐	☐	☐	☐
6. What is an angioplasty?	☐	☐	☐	☐	☐
7. What foods should I eat for a healthy heart?	☐	☐	☐	☐	☐
8. How can I choose healthy foods at the grocery store?	☐	☐	☐	☐	☐
9. How can I choose healthy foods when dining out?	☐	☐	☐	☐	☐
10. How do I read food labels?	☐	☐	☐	☐	☐
11. How will exercise help my heart condition?	☐	☐	☐	☐	☐
12. What are the components of a safe exercise program?	☐	☐	☐	☐	☐
13. What is cardiovascular or aerobic exercise?	☐	☐	☐	☐	☐
14. What can I do to improve or maintain flexibility?	☐	☐	☐	☐	☐
15. How should I exercise in hot or cold weather?	☐	☐	☐	☐	☐
16. How do I prevent low blood sugar with exercise?	☐	☐	☐	☐	☐
17. How do I take care of my feet when in an exercise program?	☐	☐	☐	☐	☐
18. What is resistance training (i.e. exercise for strengthen)?	☐	☐	☐	☐	☐
19. What types of exercise equipment are available? (where?)	☐	☐	☐	☐	☐
20. How can I exercise at home safely?	☐	☐	☐	☐	☐
21. When should I stop physical exercise?	☐	☐	☐	☐	☐
22. Is sexual activity safe for me?	☐	☐	☐	☐	☐
23. What medications do I need to help my heart?	☐	☐	☐	☐	☐
24. How do I take my medication in the right way?	☐	☐	☐	☐	☐
25. Which side effects are possible with my medication?	☐	☐	☐	☐	☐
26. Do the medications I am taking interfere with each other?	☐	☐	☐	☐	☐
27. Are there foods I should avoid while taking these medications?	☐	☐	☐	☐	☐
28. What are the effects of complementary and alternative medications?	☐	☐	☐	☐	☐
29. When can I return to work and to my old activities?	☐	☐	☐	☐	☐
30. Can I go back to my same job?	☐	☐	☐	☐	☐
31. When can I start driving again?	☐	☐	☐	☐	☐
32. What feelings are common after a heart attack?	☐	☐	☐	☐	☐
33. How does stress affect my heart?	☐	☐	☐	☐	☐
34. How can I cope with stress?	☐	☐	☐	☐	☐
35. What can I do to reduce stress in my life?	☐	☐	☐	☐	☐
36. Do sleep problems affect my heart?	☐	☐	☐	☐	☐
37. What services, support organizations and groups are available?	☐	☐	☐	☐	☐
38. What support services are available to my family?	☐	☐	☐	☐	☐
39. How do I recognize angina symptoms?	☐	☐	☐	☐	☐
40. What should I do if I feel angina or chest pain?	☐	☐	☐	☐	☐
41. When should I call the doctor?	☐	☐	☐	☐	☐
42. When should I call 911 or go to the emergency room?	☐	☐	☐	☐	☐

INFORMATION NEEDS ASSESSMENT IN CARDIAC REHABILITATION

Rate the importance of each topic to increase your knowledge about coronary artery disease

	Really not important	Not important	Neutral	Important	Very Important
43. What are the tests used to diagnosis my heart condition?	☐	☐	☐	☐	☐
44. What treatments are available for my condition?	☐	☐	☐	☐	☐
45. What are the risk factors for heart disease?	☐	☐	☐	☐	☐
46. What are the risk factors that I cannot control?	☐	☐	☐	☐	☐
47. What are the risk factors that I can control?	☐	☐	☐	☐	☐
48. What can I do to bring my risk factors under control?	☐	☐	☐	☐	☐
49. How does cholesterol affect my heart?	☐	☐	☐	☐	☐
50. How does diabetes affect my heart?	☐	☐	☐	☐	☐
51. How does physical inactivity affect my heart?	☐	☐	☐	☐	☐
52. How does smoking affect my heart?	☐	☐	☐	☐	☐
53. What are the benefits of quitting smoking?	☐	☐	☐	☐	☐
54. What supports are available to help me quit smoking?	☐	☐	☐	☐	☐
55. How does alcohol affect my heart?	☐	☐	☐	☐	☐

What other topics would you like to describe?

PREFERENCES FOR EDUCATIONAL DELIVERY FORMATS

How would you prefer this information to be delivered?
You can mark as many options as you want.

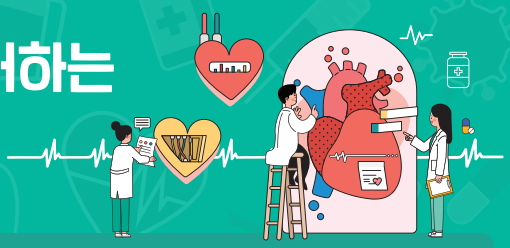
1. Printed book	☐
2. Internet Resources (website, videos)	☐
3. E-learning module (recorded lectures, slides)	☐
4. Lectures	☐
5. Audio: CD or “podcast”	☐
6. Discussion during consultations with healthcare provider	☐
7. Movies and videos that I can bring to home	☐

Other ideas for formats of education that you think would be helpful?

Thanks for your participation!

Appendix 2. Korean version of the Information Needs in Cardiac Rehabilitation (INCR-K)

심장재활 대상 환자들이 알고 싶어하는 교육주제 설문조사



심장질환의 적절한 자기관리를 위하여 모든 심장질환 환자는 자신의 상태나 치료 및 위험인자에 대해서 잘 알고 있어야 합니다. 이 설문지는 귀하께서 심장질환에 대해 알고자 할 때, 어떤 정보를 얼마나 알고 싶어 하는지를 조사하기 위하여 시행됩니다.

이 설문지의 목적은 다음과 같습니다.

- 심장 질환에 대해 어떤 정보를 필요로 하는지 확인합니다.
- 귀하의 상태에 대해 알고 싶은 특히 알고 싶어하는 정보가 무엇인지 확인합니다.
- 선호하는 교육 방식을 확인합니다.

이 설문지는 자발적이며 원하지 않으시면 설문을 중단할 수 있습니다.

총 문항은 심장 재활에 대한 정보의 중요성 평가항목 **41개**,

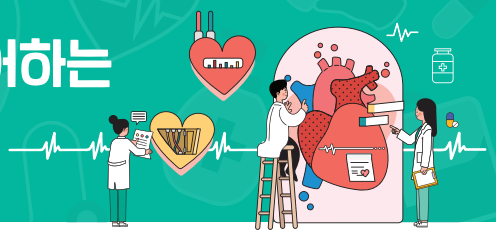
교육 전달 방식에 대한 선호도 항목 7개로 소요시간은 **약 10분**입니다.

▸ 작성 지침

1. 가능한 한 많은 항목에 응답해 주세요.
2. 각 항목마다 해당 내용이 '심장 질환에 대한 지식을 높이는 데 얼마나 중요하다고 생각'하는지를 5단계의 척도로 평가해 주세요.
3. 설문지 작성 후 담당자에게 연락 주시기 바랍니다.

작성일 : _____

심장재활 대상 환자들이 알고 싶어하는 교육주제 설문조사

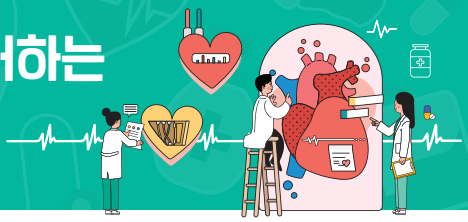


심장질환에 대한 당신의 지식을 늘리기 위해서, 각 항목의 정보가 얼마나 중요한지 (혹은 필요한지)를 평가해주세요.

또한 이미 각 질문을 잘 알고 있는 지를, '예' '아니오'로 표시해주세요.

	전혀 중요하지 않음	중요하지 않음	보통	중요함	매우 중요함	이미 이 내용을 잘 알고 있다. 예	아니오
1. 건강한 심장은 어떻게 작동하는가?	☐	☐	☐	☐	☐	☐	☐
2. "관상동맥질환"이란 무엇인가?	☐	☐	☐	☐	☐	☐	☐
3. "협심증"이란 무엇인가?	☐	☐	☐	☐	☐	☐	☐
4. 심장마비가 발생하면 어떻게 되는가?	☐	☐	☐	☐	☐	☐	☐
5. "관상동맥우회로 이식술(bypass surgery)"이란 무엇인가?	☐	☐	☐	☐	☐	☐	☐
6. "풍선확장술(angioplasty)", "스텐트(stent)시술"이란 무엇인가?	☐	☐	☐	☐	☐	☐	☐
7. 건강한 심장을 위하여 어떤 음식을 먹어야 하는가?	☐	☐	☐	☐	☐	☐	☐
8. 식료품 가게에서 건강에 좋은 식품을 고르는 방법은 무엇인가?	☐	☐	☐	☐	☐	☐	☐
9. 외식할 때 건강에 좋은 식사를 고르는 방법은 무엇인가?	☐	☐	☐	☐	☐	☐	☐
10. 식품 포장에 붙어 있는 영양성분표시는 어떻게 읽는가?	☐	☐	☐	☐	☐	☐	☐
11. 운동은 심장에 어떤 도움이 되는가?	☐	☐	☐	☐	☐	☐	☐
12. 심장에 안전한 운동은 어떻게 하는가?	☐	☐	☐	☐	☐	☐	☐
13. 심혈관 운동 또는 유산소 운동이란 무엇인가?	☐	☐	☐	☐	☐	☐	☐
14. 덥거나 추울 때는 운동을 어떻게 해야 하는가?	☐	☐	☐	☐	☐	☐	☐

심장재활 대상 환자들이 알고 싶어하는 교육주제 설문조사



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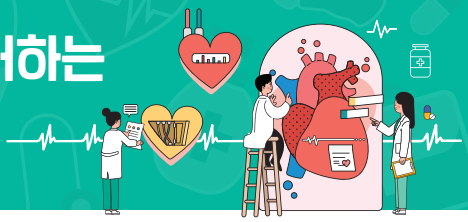
또한 이미 각 질문을 잘 알고 있는 지를, '예' '아니오'로 표시해주세요.

	전혀 중요하지 않음	중요하지 않음	보통	중요함	매우 중요함	이미 이 내용을 잘 알고 있다. 예	아니오
15. 저항 훈련(즉, 근력 운동)은 어떻게 하는가?	☐	☐	☐	☐	☐	☐	☐
16. 어떤 종류의 운동기구들이 유용한가? (어디서 운동할 수 있는가?)	☐	☐	☐	☐	☐	☐	☐
17. 어떻게 하면 집에서도 안전하게 운동할 수 있는가?	☐	☐	☐	☐	☐	☐	☐
18. 운동 중 안전을 위해 운동을 중단해야 하는 경우는?	☐	☐	☐	☐	☐	☐	☐
19. 성행위는 나에게 안전한가?	☐	☐	☐	☐	☐	☐	☐
20. 건강한 심장을 위하여 내게 어떤 약들이 필요한가?	☐	☐	☐	☐	☐	☐	☐
21. 올바른 약물 복용법은?	☐	☐	☐	☐	☐	☐	☐
22. 약물 복용으로 어떤 부작용이 생길 수 있는가?	☐	☐	☐	☐	☐	☐	☐
23. 보완대체치료(건강보조식품, 한약/침술, 마사지 등)는 효과가 있는가?	☐	☐	☐	☐	☐	☐	☐
24. 언제쯤 직장(원래 하던 일)과 이전 수준의 활동으로 돌아갈 수 있는가?	☐	☐	☐	☐	☐	☐	☐
25. 심장마비 후 보통 어떤 감정이 드는가? (기분이 우울하거나 불안하면 도움을 받을 수 있는가?)	☐	☐	☐	☐	☐	☐	☐
26. 스트레스는 심장에 어떤 영향을 주는가?	☐	☐	☐	☐	☐	☐	☐
27. 심장 건강을 위해 스트레스에 어떻게 대처해야 하는가?	☐	☐	☐	☐	☐	☐	☐
28. 수면장애는 심장에 어떤 영향을 주는가?	☐	☐	☐	☐	☐	☐	☐
29. 심장질환 환자에게 도움이 될 만한 지원제도가 있는가?	☐	☐	☐	☐	☐	☐	☐

심장재활 대상 환자들이 알고 싶어하는 교육주제 설문조사



심장질환에 대한 당신의 지식을 늘리기 위해서, 각 항목의 정보가 얼마나 중요한지 (혹은 필요한지)를 평가해주세요.

또한 이미 각 질문을 잘 알고 있는 지를, '예' '아니오'로 표시해주세요.

	전혀 중요하지 않음	중요하지 않음	보통	중요함	매우 중요함	이미 이 내용을 잘 알고 있다. 예	아니오
30. 협심증이 의심되거나 흉통이 느껴지면 어떻게 해야 하는가?	☐	☐	☐	☐	☐	☐	☐
31. 언제(어떤 경우에) 외래 진료를 예약하거나 응급실에 가야 하는가?	☐	☐	☐	☐	☐	☐	☐
32. 심장 상태를 평가하기 위하여 시행되는 검사들은 어떤 것들이 있는가?	☐	☐	☐	☐	☐	☐	☐
33. 내가 받을 수 있는 치료에는 무엇이 있는가?	☐	☐	☐	☐	☐	☐	☐
34. 심장질환의 위험 인자는 무엇인가?	☐	☐	☐	☐	☐	☐	☐
35. 심장재활이란 무엇인가?	☐	☐	☐	☐	☐	☐	☐
36. 심장질환의 위험 인자를 조절하려면 어떻게 해야 하는가?	☐	☐	☐	☐	☐	☐	☐
37. 콜레스테롤이 심장에 어떤 영향을 미치는가?	☐	☐	☐	☐	☐	☐	☐
38. 고혈압이 심장에 어떤 영향을 미치는가?	☐	☐	☐	☐	☐	☐	☐
39. 신체 활동 부족이 심장에 미치는 영향은 무엇인가?	☐	☐	☐	☐	☐	☐	☐
40. 담배가 심장에 어떤 영향을 미치는가?	☐	☐	☐	☐	☐	☐	☐
41. 음주가 심장에 어떤 영향을 미치는가?	☐	☐	☐	☐	☐	☐	☐

▸ 심장 질환을 잘 관리하기 위해서 더 알고 싶은 다른 주제가 있나요?

Appendix 3. Preferences for educational delivery formats (Korean version)

교육 방식에 대한 선호도

교육이 어떻게 제공되기를 원하십니까?
중복해서 선택할 수 있습니다.

1.	책자	☐
2.	인터넷 자료(웹사이트, 동영상)	☐
3.	스마트폰 앱(어플리케이션)	☐
4.	E-러닝 (동영상 강의, 강의 슬라이드)	☐
5.	대면 강의	☐
6.	오디오 자료: CD, 오디오 방송(“팟캐스트”)	☐
7.	의료진과의 대면 상담	☐

교육제공 방식에 대한 보다 좋은 아이디어가 있으신가요?

Original Article

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Physical Activity and Activities of Daily Living in Older Adult Patients With Heart Failure Admitted for Subacute Musculoskeletal Disease

Tomoko Shimizu, RPT, MSc[1,2], Chiaki Kanai, OTR, MSc[1,2], Keisuke Ueda, MD, PhD[1], Yasuyoshi Asakawa, PhD[2]

[1]*Department of Rehabilitation, The Anti-Tuberculosis Association, Shin-Yamanote Hospital, Tokyo, Japan*
[2]*Department of Physical Therapy, Graduate School of Human Health Science, Tokyo Metropolitan University, Tokyo, Japan*

Objective: To examine activities of daily living (ADL) and physical activity in older adults with heart failure admitted to a rehabilitation ward for subacute musculoskeletal disease.
Methods: This study included patients with musculoskeletal disease (aged ≥75 years) who were admitted to the rehabilitation ward. Data on age, ADL, and time for physical activity (metabolic equivalents [METs]) were collected. Patients were divided into groups with or without heart failure, and the differences were compared using Mann–Whitney U-test.
Results: This study included 84 musculoskeletal patients, including 25 with heart failure. The heart-failure group had similar levels of ADL independence compared to the without-heart-failure group (p=0.28) but had shorter duration of continuous and sustained physical activities and less total time (p<0.01) of light-intensity physical activity or higher.
Conclusion: Older adults with subacute musculoskeletal disease with heart failure do not necessarily require a large amount of physical activity to maintain ADL at the time of discharge. But very low physical activity may increase the risk for developing hospitalization-associated disability. Physical activity in older adults with subacute musculoskeletal disease with heart failure should be monitored separately from ADL.

Keywords: Activities of daily living, Heart failure, Aged, Sedentary behavior, Musculoskeletal disease

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Correspondence:
Tomoko Shimizu
Department of Rehabilitation, The Anti-Tuberculosis Association, Shin-Yamanote Hospital, 3-6-1, Suwa-cho, Higashimurayama-shi, Tokyo 189-0021, Japan.
Tel: +81-42-391-1425
Fax: +81-42-391-5760
E-mail: tshimizu.tmu@gmail.com

INTRODUCTION

Japan has one of the fastest aging populations worldwide. The number of heart failure patients in Japan, especially among older adults, is rapidly increasing [1]. The main clinical features of heart failure include physical inactivity with fatigue, shortness of breath, and mental distress [2]. In older adults, heart failure leads to a decreased tolerance for exercise, and eventually to an impairment in the ability to perform activities of daily living (ADL) [3,4]. A meta-analysis of the prevalence of ADL impairment in heart failure patients revealed that Japan had the highest prevalence at 58.2% [5]. In older inpatients, medical triggering events or complications, such as a decline in mobility and function due to bed rest [6] and hospitalization-associated disability, may occur due to less light-intensity physical activity [7]. Older inpatients may be treated in a convalescent rehabilitation ward to prevent physical decline, avoid prolonged bed rest, improve the performance of ADL, and establish independent living [8].

According to the Ministry of Health, Labor and Welfare [9], in people aged 75 years and older, symptoms due to decline in physiological function and the ability to perform ADL increase, and comprehensive management of symptoms of multiple chronic diseases is important. The prevalence of multiple chronic diseases is expected to increase in patients with heart failure, in particular in patients with musculoskeletal disease, where incidence increases with age [10]. Patients with chronic heart disease have altered function of the myosin molecule in skeletal muscle, resulting in muscle weakness, reduced physical activity level and ability to maintain balance [11], and increased risk for falls [12]. Gerber et al. [13] reported that in chronic heart failure patients older than 80 years, the incidence of femur fracture is 2.3-times higher in male and 4.18-times higher in female than that in patients without heart failure. Rahman et al. [14] reported that in older adults with chronic heart failure, osteoarthritis was 25% higher in male and 20% higher in female than that in those without heart failure.

For inpatients with musculoskeletal disease with femur fractures and knee osteoarthritis, rehabilitation through an interdisciplinary care program, focusing on physical exercise, is generally provided to improve motor function and ADL compromised by orthopedic injury to the best extent [15,16], which is required to assess the patient's independence in ADL and physical activities during hospitalization. It is predictable that physical activity may inevitably be limited in patients with heart failure. It is not well known whether the independence in ADL is actually low and how much physical activity is low among older adult musculoskeletal disease patients with heart failure admitted to a convalescent rehabilitation ward.

The purpose of this study was to investigate independence in ADL and physical activities with heart failure patients aged 75 years and older who were admitted to a convalescent rehabilitation ward due to subacute musculoskeletal disease, and to compare them with or without heart failure patients.

METHODS

Setting

This cross-sectional study was conducted between February 2020 and April 2021 in a 16-bed recovery rehabilitation ward attached to a secondary emergency hospital in Tokyo, Japan, which consisted of seven inpatient departments, 18 outpatient departments, and five 180-bed wards.

The applicable diseases, services, and duration of stay for convalescent rehabilitation wards are based on the medical fee determined by the government. The convalescent rehabilitation fee in the medical fee system ranges from 1 to 6, depending on the facility's standards. Differences in facility standards include the number of staff, availability of rehabilitation services on holidays, percentage of severe disease patients, and achievement quotas. Hospitalization fee-1 has the highest allocation of human resources and the highest achievement quota. The facility standard in this study was Hospitalization fee-5.

The facilities also provide treatment by specialists in each department for each of the complex diseases during hospitalization in the convalescent rehabilitation wards. For example, respiratory disease is treated by respiratory specialists, cardiovascular diseases by cardiology specialists, and gastrointestinal diseases by gastroenterology specialists, while liver, renal, allergic, and metabolic diseases including diabetes are treated by general internal medicine specialists, and mental disorders by psychosomatic medicine and clinical psychologists, forming a team for each patient. Pain is treated immediately after admission and continuously with oral and transdermal analgesics depending on the pain level and chronic disease status by an orthopedic surgeon and/or internist. Patients with severe conditions requiring treatment, such as patients with respiratory, hepatic, or renal disorders and patients with New York Heart Association (NYHA) functional classification class-III or higher [17] are treated in the acute care unit, not transferred to the convalescent rehabilitation ward. The heart failure patients included in this study were those who were diagnosed with heart failure in other departments and transferred to the convalescent rehabilitation unit, and due to the conditions of the convalescent rehabilitation hospital, NYHA class-II patients were of the majority. Patients were assessed by the attending physician and those with stable heart failure symptoms and able to tolerate practicing ADL were allowed to be transferred to the convalescent rehabilitation ward for the primary purpose of practicing ADL, even if their subjective symptoms were categorized as NYHA class-III. Patients received personalized one-on-one rehabilitation with a therapist for 1–2 hours per day during the rehabilitation hours. Personalized rehabilitation includes basic action practice, strength training, ADL, gait practice, and endurance exercise. In the presence of many comorbidities, the guidelines followed the general principle of exercise prescription, which states that "a combined exercise regimen consisting of aerobic exercise, resistance training, balance training, and flexibility exercises should be considered to improve exercise

capacity and physical function [18]," under the judgment and direction of the attending physician.

This facility surveyed physical activity in patients aged 75 years and older who were hospitalized for musculoskeletal diseases and examined the data on physical activity at discharge.

Participants

The participants were subacute musculoskeletal patients admitted to the recovery rehabilitation ward. Subacute phase in this study is defined as the period from the day of transfer to the rehabilitation ward to the day of discharge. The patient's transfer was permitted by the attending physician based on a combination of factors, including removal of the indwelling bladder catheter, no signs of wound infection, and the ability to take the required amount of food orally. Musculoskeletal disease is defined as the applicable conditions for admission to the convalescent rehabilitation ward, as follows: fractures of the femur, pelvis, vertebra, hip joints, knee joint, and hip joint replacement or knee joint replacement. The inclusion criteria for participants were as follows: (1) ≥75 years of age; (2) those who provided consent to participate in the study; and (3) a musculoskeletal disease applicable for admission to the convalescent rehabilitation ward. The exclusion criteria were as follows: (1) an admission diagnosis of a condition other than musculoskeletal disease; (2) comorbid disorders, long-term fever symptoms, and limitations in therapeutic or medical activities due to lower limb load restriction; (3) a mental state that would impair decision-making regarding participation in the study, including delirium; and (4) unstable mental or physical conditions and a high possibility of a sudden change in short-term physical conditions, judged by the physician upon admission into the ward.

Sample size

The required sample size was set at 80 participants using G*power (https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower) as follows: Wilcoxon–Mann–Whitney test (two groups), two tails, effect size 0.5, α err prob 0.05, power (1-β err prob) 0.5, and an allocation ratio of 2/1.

Ethics

This study was approved by the Institutional Review Board of The Anti-Tuberculosis Association, Shin-Yamanote Hospital (No. 19001) and by the research ethics committee of the Tokyo Metropolitan University, Arakawa Campus (No. 20038). Participants were informed of the content and purpose of the study verbally and in writing, and they provided written informed consent.

Data collection

Participant characteristics data

Potential confounders included age, sex, body mass index (BMI), length of hospital stay, ability to perform ADL, type of musculoskeletal disease diagnosed on admission, medical history, and mobility. Predictors included the presence of a history of heart failure. Outcomes were bout duration and the total time of physical activity classified by activity intensity. For patients with heart failure, the data on cardiac function variables were collected as patient characteristics.

Age, sex, BMI, length of hospital stay, the ability to perform ADL, musculoskeletal disease diagnoses, cardiac function variables, medical history, and mobility at discharge were collected from patient medical records. BMI was calculated by dividing the weight (kg) by height^2 (m^2). To assess the ability to perform ADL, the Functional Independent Measure (FIM) was selected as the evaluation index. FIM compares movement ability objectively independent of the patient's use of assistive devices, such as wheelchairs, walkers, canes, and railings, or communication skills, such as hearing, vision, verbal comprehension, and non-verbal comprehension. FIM quantifies the amount of ADL assistance provided to the patient and consists of 13 motor and five cognitive items on a 7-point scale ranging from 7 to 1 each, for a total score of 126 to 18 [19,20]. The data on FIM scores were collected from the medical records of entry and discharge conferences and were assessed by the ward nurses. "FIM at entry" was assessed within 24 hours of entry to the ward, and "FIM at discharge" was assessed the day before discharge. Preadmission indoor mobility was examined after admission based on the Living Space Assessment (LSA) [21]. The patients' level of independence according to the LSA level-3 categories "been to a neighborhood other than their yard or apartment during the past four weeks," and "needs help from others" were classified in our study as "personal assistance," while "equipment only," and "no equipment or personal assistance" were classified as "unassisted." For indoor mobility at the time of discharge, locomotion was assessed under the FIM motor domain and "walking" or "wheelchair" scores were collected for assessment. Walking with a cane or walker was classified as "walking," and those who were unable to walk 50 m (FIM walking score≤4) were classified as "wheelchair users" regardless of whether they were independent

wheelchair users. The musculoskeletal diseases that caused hospitalization were identified and recorded upon admission to the convalescent rehabilitation wards. A medical history of diabetes was included as patient characteristic variable because its incidence correlates inversely with the amount of physical activity [22]. The diagnosis of diabetes mellitus was based on hemoglobin A1c levels, ongoing treatment, and diagnostic history in the medical record. History of cerebrovascular disease was included as a patient characteristic variable because its sequelae are considered to increase the risk for reduced physical activity and ADL impairment [23]. The diagnosis of cerebrovascular disease was based on the medical history of previous stroke and cerebral hemorrhage, regardless of the severity of sequelae or the regular prescriptions. All study participants with a history of cerebrovascular disease were in the living phase of the disease, more than 6 months after disease onset.

Heart failure in this study was defined as having a diagnosis of heart failure, being on cardiovascular medication, and subjective symptoms with NYHA functional class-II or higher [17] prior to the onset of musculoskeletal disease: NYHA class-I, no symptoms with normal physical activity and function status; NYHA class-II, mild symptoms with normal physical activity, comfortable at rest, slight limitation of functional status, clinically walking more than two blocks on the level and climbing more than one flight of ordinary stairs, and performing to completion of any activity requiring 5 metabolic equivalents (METs); NYHA class-III, moderate symptoms with less than normal physical activity, comfortable only at rest, marked limitation of functional status, clinically walking one to two blocks on the level and climbing one flight of stairs, and patient can perform to completion of any activity requiring >2 METs; and NYHA class-IV, severe symptoms with features of heart failure with minimal physical activity and even at rest, severe limitation of functional status [17,24]. The research facility is a specialized rehabilitation ward for musculoskeletal diseases, and as a rule, does not accept patients in NYHA class-III or higher.

Division into groups with or without heart failure

Participants with the diagnosis of heart failure among patients with musculoskeletal disease were assigned to "with heart failure" group. Participants who were never diagnosed with heart failure, regardless of how many diseases they had, were assigned to the "without heart failure" group. Cardiac function indices of participants with heart failure were collected for presenting participant characteristics, as follows: brain natriuretic peptide (BNP) (pg/mL) which reflect worsening or improving hemodynamics, left ventricular ejection fraction (LVEF) (%), E velocity divided by A-wave velocity (E/A ratio), average E velocity divided by mitral annular e' velocity (average E/e'), septal e' velocity (cm/s), and tricuspid regurgitation (TR) velocity (m/s) as an echocardiographic parameter when investigating the cause of heart failure [25]. BNP test and echocardiography are not part of the usual practice for musculoskeletal disease. They are performed only when risk screening for cardiac function is appropriate at the start of musculoskeletal disease treatment. Subsequent echocardiographic testing was not performed. The conditions of participants with heart failure are assessed by BNP levels and clinical findings as needed.

Measurements

Accelerometer-measured physical activity

Physical activity was measured by attaching a triaxial accelerometer (Active Style Pro HJA750c; OMRON HEALTHCARE Co., Ltd) to the participant's waist. For the device, the validity and reliability of the measurements compared to expiratory gas analysis and doubly labeled water method has been shown for physical activity under free-living, including walking and non-ambulatory activities (such as reading, office work, and cleaning) [26-28]. Based on physical activity measurement methods in patients with heart failure from previous studies, the period of wear was initiated at least 4 days prior to discharge and comprised 24 consecutive hours, excluding bathing, for at least 3 days [29]. Data were analyzed for 15 hours during the day, from the wake-up time at 6:00 to the lights-out time at 21:00, based on the schedule of the facility. If the acceleration signal was zero for more than 120 minutes in a 15-hour period, it was considered as non-attached [30], and the corresponding day was excluded from the analysis as missing data. The data of patients with valid 3-day records were analyzed.

Physical activity intensity was expressed in METs. Activity intensity was classified according to sedentary behavior (1.0–1.5 METs), light-intensity physical activity (1.6–2.9 METs), and moderate-to-vigorous intensity physical activity and higher (≥3.0 METs) [31]. Activity intensity was calculated for light-intensity physical activity or higher (≥1.6 METs) and moderate-to-vigorous-intensity physical activity or higher (≥3.0 METs). For example, 1.5 METs: sitting, knitting, sewing; 2.0 METs: walking at less than 2.0 mph on level ground; 2.5 METs: light cleaning (dusting, straightening up, changing linen, and carrying out trash); 3.0 METs: walking at 2.5 mph; 3.5 METs:

standing, packing boxes, occasional lifting of household materials; and 3.8 METs: walking at 3.5 mph [31].

The data processing procedure for physical activity was as follows: (1) Activity intensity was compiled into time series on a Microsoft excel sheet at 10-s intervals by the data reading application of the used device. (2) Total activity time was calculated by counting the number of cells for each activity intensity. (3-1) "Single continuous period" was defined as the time when bout cells of the same activity intensity continued, and the value and frequency of occurrence of each were calculated. (3-2) "Single continuous period per hour" was used in the analysis for the longest value that occurred at least 45 times during the 45 hours of measurement in 3 days. For example, during the 45-hours, if 90-second single continuous period occur 5 times and 100-second single continuous period occur 40 times, since the 90-second single continuous period is included in the 100-second single continuous period, we use the value of 90-second single continuous period in the analysis.

Patients who required care in wearing and removing the device when changing clothes were assisted by ward and rehabilitation department staff, to prevent data loss due to forgetting to wear the device.

Statistical analysis

Participant characteristics data

The distribution of data for age, BMI, length of stay, and FIM scores were examined for normality using Shapiro–Wilk test, and descriptive statistics were performed. The analysis using non-parametric tests is as follows. To compare differences in BNP data between entry and discharge, Wilcoxon signed-rank test was used. To compare differences between with heart failure and without heart failure groups, Mann–Whitney U-test was used for continuous scale data, and χ^2 test or Fisher's exact test was used for sex, medical history, and mobility. As an analysis using parametric tests, the difference in change in FIM with and without heart failure was examined using two-way ANOVA.

Physical activity

The physical activity data distribution was checked using the Shapiro–Wilk test, and descriptive statistics were performed. To compare differences between with heart failure and without heart failure groups, the Mann–Whitney U-test was used with non-parametric tests. Effect size indices were examined for the non-parametric test, r (=Z/√N, Z: test statistic), and for the chi-squared test, φ. For additional analysis with parametric tests, multiple regression analysis forced entry method was used to extract risk factors, with physical activity as the dependent variable and patient characteristics variable as the independent variable. Next, repeated measures analysis of covariance (ANCOVA) was performed with the patient characteristics variable extracted as a risk factor as the covariate and the independent variable as the presence of heart failure.

Statistical analysis were performed using IBM SPSS Statistics 26 (IBM Corp.) and the significance probability was 5%.

RESULTS

Participant characteristics

A total of 84 participants were included in the study, including 25 with heart failure. No one failed to finish the study due to exacerbation of heart failure during the study period. The number of participants in each phase of the study is shown in the flowchart in Fig. 1. The descriptive statistics for all participants were as follows: age, 85 years (80.8–89.0 years) (median [interquartile range, 25th percentile–75th percentile]); female patients, 63 (75.0%), BMI, 20.5 (18.3–24.0) kg/m^2; duration of stay in the recovery rehabilitation ward, 30.5 (20.0–50.3) days; FIM at entry, 85.5 (72.0–96.0) points; FIM at discharge, 108.0 (96.5–117.0) points; number of patients with postoperative femur fracture, 38 (45.2%); number of patients under treatment for diabetes mellitus, 27 (32.1%); number of patients with a history of cerebrovascular disease, 12 (14.3%); number of patients with independent indoor mobility prior to admission due to musculoskeletal disease, 74 (88.1%); and number of patients discharged ambulatory, 78 (91.7%; Table 1).

No differences were found for all variables of participant characteristics between the with heart failure and without heart failure groups: age, sex, BMI, days from onset of musculoskeletal disease to ward transfer, length of ward stay, FIM at entry, type of orthopedic disease, diabetes mellitus, cerebrovascular disease, and mobility at preadmission and discharge (p=0.44, p=0.28, p=0.47, p=0.16, p=0.29, p=0.08, p=0.10, p=0.32, p=0.77, p=0.14, and p=0.11, respectively; Table 1). Similarly, no difference was found in FIM at discharge between the with heart failure group (108.0 [86.0–113.0] points) and without heart failure group (109.0 [97.5–117.0] points; p=0.28; Table 1). There was no statistical significance in the results of multivariate analysis of the difference in FIM score change between entry and discharge with and without heart failure (two-way ANOVA, p=0.40; Table 1). Risk factors affecting physical ac-

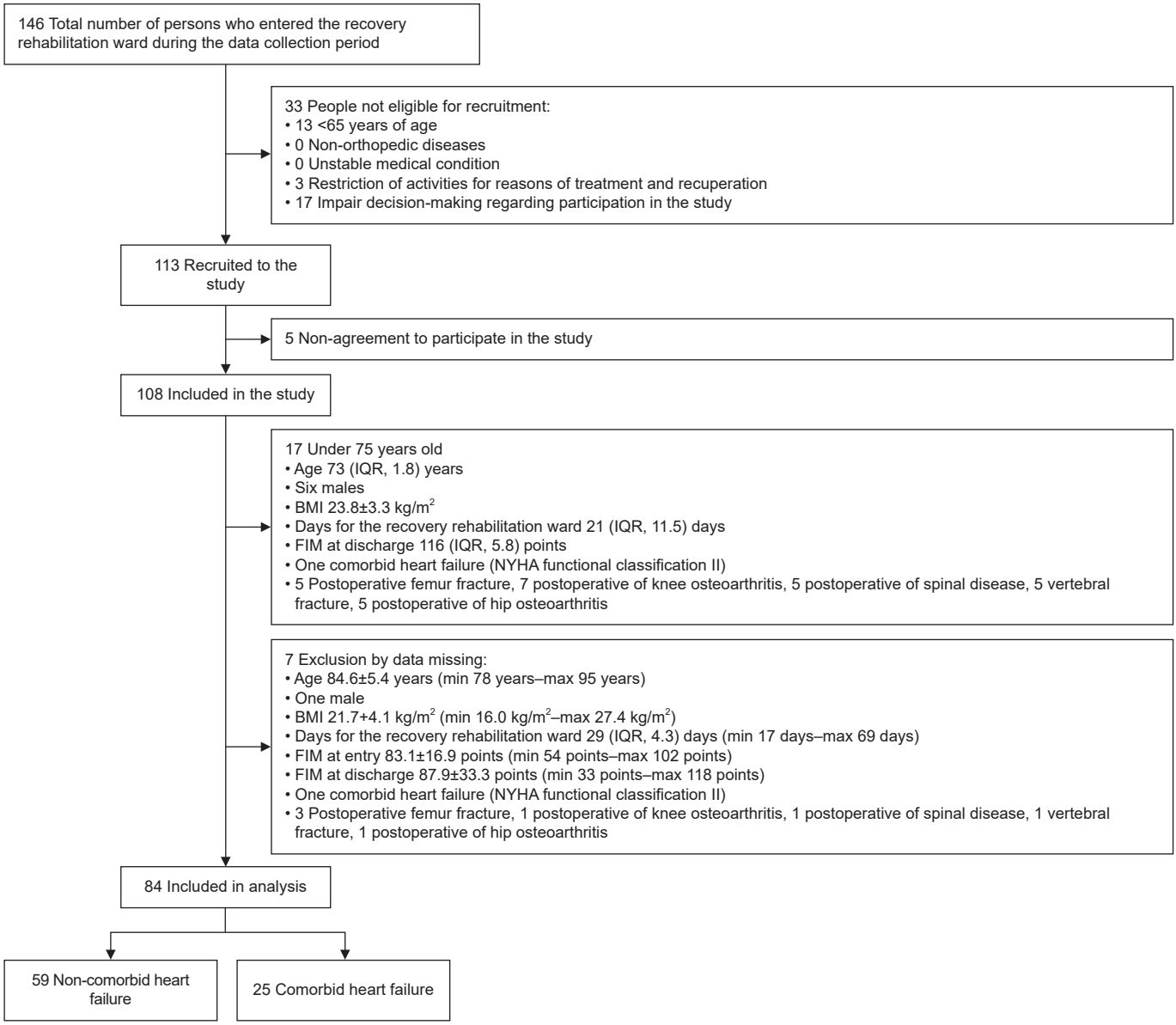

Fig. 1. This image presents a flowchart of study participant selection. IQR, interquartile range; BMI, body mass index; FIM, Functional Independent Measure; NYHA, New York Heart Association; min, minimum; max, maximum.

tivities were age and FIM at discharge (Table 2). Clinical data on cardiac functions for participants with heart failure BNP decreased from 124.5 (72.6–221.8) pg/mL at admission to 76.4 (42.7–182.5) pg/mL at discharge, but not significantly (p=0.11). LVEF was 67.0% (60.0%–72.0%; Table 3). Fourteen of the 25 patients had diastolic dysfunction and three had systolic and diastolic dysfunction. Other patients with heart failure had atrial fibrillation and tachyarrhythmia and were on drug therapy. Patients underwent outpatient treatment at home and had stable cardiac function. The study defined heart failure by NYHA classification based on subjective symptoms and drug therapy, the NYHA classification II and III and comprised 20 (80.0%) and 5 (20.0%) patients, respectively. Five participants of NYHA class-III were diagnosed with occasional complaints of palpitations and fatigue, but usually had only mild subjective symptoms.

Physical activities

Descriptive statistics for all physical activities were 180 (130–

Table 1. Characteristics of participants

	All (n=84)			With heart failure (n=25)			Without heart failure (n=59)			p-value [a),b),c)]	Effect size[a),b),c)]
	Value	Min	Max	Value	Min	Max	Value	Min	Max		
Age (yr)	85.0 (80.8–89.0)	76	98	86.0 (80.0–91.0)	76.0	95.0	85.0 (81.0–87.5)	76	98	0.44[a)]	0.08[d)]
Body mass index (kg/m^2)	20.5 (18.3–24.0)	14.2	30.5	20.2 (17.8–22.7)	15.0	30.5	21.6 (19.0–24.4)	14.2	30.1	0.47[a)]	0.08[d)]
Days from onset to admission to the rehabilitation ward (day)	13.0 (9.8–17.0)	0	70	15.0 (9.0–26.0)	7	48	13.0 (10.0–15.0)	0	70	0.16[a)]	0.23[d)]
Days for the rehabilitation ward (day)	30.5 (20.0–50.3)	10	88	34.0 (23.0–64.0)	10	88	29.0 (20.0–44.5)	12	79	0.29[a)]	0.11[d)]
FIM (point)											
At entry	85.5 (72.0–96.0)	33	119	76.0 (60.0–96.0)	33	111	86.0 (76.0–96.0)	51	119	0.08[a)]	0.15[d),f)]
At discharge	108.0 (96.5–117.0)	41	124	108.0 (86.0–113.0)	41	122	109.0 (97.5–117.0)	78	124	0.28[a)]	0.19[d),f)]
Sex										0.28[b)]	0.14[e)]
Male	21 (25.0)			4 (16.0)			17 (28.8)				
Female	63 (75.0)			21 (84.0)			42 (71.2)				
Postoperative femur fracture										0.10[b)]	0.19[e)]
Postoperative femur fracture	38 (45.2)			15 (60.0)			23 (39.0)				
Other than postoperative femur fracture	46 (54.8)			10 (40.0)			36 (61.0)				
Postoperative knee joint replacement	22			2			20				
Conservative treatment for osteoporotic compression fracture	9			3			6				
Postoperative osteoporotic compression fracture	7			2			5				
Postoperative spinal canal stenosis	5			3			2				
Postoperative hip joint replacement	3			0			3				
Diabetes mellitus	27 (32.1)			10 (40.0)			17 (28.8)			0.32[b)]	0.11[e)]
History of cerebrovascular disease	12 (14.3)			4 (16.0)			8 (13.6)			0.77[c)]	0.04[e)]
Preadmission indoor mobility—unassisted	74 (88.1)			20 (80.0)			54 (91.5)			0.14[b)]	0.16[e)]
Indoor mobility at discharge—ambulation	78 (92.9)			21 (84.0)			56 (94.9)			0.11[c)]	0.18[e)]

Values are presented as median (interquartile range [25th percentile–75th percentile]), number (%), or number only.
Min, minimum; Max, maximum; FIM, Functional Independent Measure.
[a)]Mann–Whitney U-test, [b)]chi-squared test, [c)]Fisher's exact test, [d)]$r=Z/\sqrt{N}$, and, [e)]φ. [f)]Analysis of the difference in FIM score change between entry and discharge with and without heart failure by two-way ANOVA, p=0.40.

220) seconds for a single continuous period of light-intensity physical activity or higher, 15 (10–20) seconds of moderate-to-vigorous-intensity physical activity or higher, 14,913.4 (10,569.2–19,502.5) seconds total time of light-intensity physical activity or higher, and 633.4 (354.6–927.5) seconds total time of moderate-to-vigorous-intensity physical activity or higher (Table 4). Descriptive statistics for physical activity in the group with heart failure were 130 (120–200) seconds for a single continuous period of light-intensity physical activity or higher, 10 (10–20) seconds for moderate-to-vigorous-intensity physical activity or higher, 11,296.6 (8,603.3–16,186.7) seconds total time of light-intensity physical activity or higher, and 383.3 (296.7–613.3) seconds total time of moderate-to-vigorous-intensity physical activity or higher (Table 4). Descriptive statistics for physical activity in the without heart failure group were 190 (150–220) seconds for a single continuous period of light-intensity physical activity or higher, 20 (10–20) seconds of moderate-to-vigorous-intensity physical activity or higher,

Table 2. Analysis of risk factors for physical activities

Factor	Physical activities							
	Single continuous period				Total time			
	≥LIPA		MVPA		≥LIPA		MVPA	
	Adjusted R^2: 0.31		Adjusted R^2: -0.03		Adjusted R^2: 0.32		Adjusted R^2: 0.10	
	p-value	Standardized coefficients	p-value	Standardized coefficients	p-value	standardized coefficients	p-value	Standardized coefficients
Intercept	0.038*		0.77		0.25		0.55	
Sex	0.17	0.1	0.31	0.12	0.029*	0.20	0.14	0.16
Age	0.007*	-0.3	0.65	0.06	0.031*	-0.23	0.87	0.02
FIM at discharge	0.002*	0.3	0.12	0.21	<0.001*	0.40	0.010	0.33
Days for recovery ward	0.44	0.1	0.63	0.06	0.30	0.10	0.80	-0.03
Chronic heart failure	0.007*	-0.3	0.35	-0.11	0.020*	-0.23	0.07	-0.20
Postoperative femur fractures	0.014*	0.1	0.50	-0.01	0.12	0.06	0.67	-0.02
Diabetes mellitus	0.28	0.0	0.97	0.08	0.52	-0.08	0.88	-0.07
Cerebrovascular disease	0.85	0.3	0.51	0.08	0.38	0.16	0.55	0.05

Multiple liner regression forced-entry method was used for analysis; outcomes were physical activities; factors were sex, age, FIM at discharge, days for recovery ward, chronic heart failure, postoperative femur fractures, diabetes mellitus, and cerebrovascular disease.
LIPA, light-intensity physical activity; MVPA, moderate to vigorous physical activity; FIM, Functional Independent Measure.
*p<0.05.

Table 3. Clinical data on cardiac function in patients with heart failure

	Value	Minimum	Maximum	p-value[a]	Effect size[b]
NYHA functional classification					
I	0 (0)				
II	20 (80.0)				
III	5 (20.0)				
IV	0 (0)				
Parameters of cardiac function					
BNP (pg/mL)				0.11	0.27
At admission	124.5 (72.6–221.8)	10.0	800.0		
At discharge	76.4 (42.7–182.5)	11.6	555.0		
LVEF (%)	67.0 (60.0–72.0)	36.0	81.0		
Average E/e'	13.6 (10.4–16.6)	7.1	28.4		
E/A	0.7 (0.6–0.9)	0.5	3.4		
Septal e' velocity (cm/s)	5.0 (4.5–7.0)	3.0	8.0		
TR velocity (m/s)	2.3 (1.9–2.5)	1.6	3.4		

Values are presented as number (%) or median (interquartile range [25th percentile–75th percentile]).
NYHA, New York Heart Association; BNP, brain natriuretic peptide; LVEF, left ventricular ejection fraction; Average E/e', average E velocity divided by average mitral annular e' velocity; E/A, E velocity divided by A-wave velocity; TR, tricuspid regurgitation.
[a]Wilcoxon signed-rank test and [b]$r=Z/\sqrt{N}$.

15,273.3 (12,270.0–20,546.7) seconds total time of light-intensity physical activity or higher, and 730 (538.4–1,071.7) seconds total time of moderate-to-vigorous-intensity physical activity or higher (Table 4).

Between the with heart failure and without heart failure groups, differences were found in single continuous period of light-intensity physical activity or higher (p=0.004), moderate-to-vigorous-intensity physical activity or higher (p=0.019), total activity time of light-intensity physical activity or higher (p=0.005), and moderate-to-vigorous intensity physical activity or higher (p<0.001). The heart failure group had a shorter duration of physical activity for all variables in univariate analysis (Table 4). Age and FIM were selected as risk factors of physical activity according to the results of multiple regression analysis (Table 3). The single continuous period for light-intensity physical activity or higher was shorter in the heart failure group in the multivariate analysis with age and FIM as covariates (Table 4).

Table 4. Physical activities

	All (n=84)			With heart failure (n=25)			Without heart failure (n=59)			p-value[a]	Effect size	p-value of ANCOVA[b]
	Median (IQR)	Min	Max	Median (IQR)	Min	Max	Median (IQR)	Min	Max			
Single continuous period (s)												
≥Light-intensity physical activity	180.0 (130.0–220.0)	110.0	300.0	130.0 (120.0–200.0)	70	300	190.0 (150.0–220.0)	110	310	0.004*	0.32	0.013*
Moderate to vigorous physical activity	15.0 (10.0–20.0)	10.0	20.0	10.0 (10.0–20.0)	10	50	20.0 (10.0–20.0)	10	21	0.019*	0.26	0.44
Total time (s)												
≥Light-intensity physical activity	14,913.4 (10,569.2–19,502.5)	7,428.0	25,950.9	11,296.6 (8,603.3–16,186.7)	4,485.0	26,086.6	15,273.3 (12,270.0–20,546.7)	7,050.0	33,433.4	0.005*	0.32	0.032*
Moderate to vigorous physical activity	633.4 (354.6–927.5)	201.2	1,560.5	383.3 (296.7–613.3)	150.0	2613.3	730.0 (538.4–1,071.7)	143.3	1,873.3	<0.001*	0.39	0.05

IQR, interquartile range (25th percentile–75th percentile); Min, minimum; Max, maximum; ANCOVA, analysis of covariance.
[a]Mann-Whitney U-test, [b]covariate: age, Functional Independent Measure at discharge.
*p<0.05.

DISCUSSION

The purpose of this study was to investigate independence in ADL and physical activities with heart failure patients aged 75 years and older who were admitted to a convalescent rehabilitation ward due to subacute musculoskeletal disease and to compare them with or without heart failure patients. The heart failure patients included in this study were those who were diagnosed with heart failure in other departments and transferred to the convalescent rehabilitation unit, and due to the conditions of the convalescent rehabilitation hospital, NYHA class-II patients were of the majority. This study showed that patients with heart failure had no significant differences in ADL but did have differences in physical activity compared to patients without heart failure.

The characteristics of cardiac function in the heart failure group in this study were three as follows: most were of NYHA class-II with minimal subjective impairment in ADL; left ventricular ejection rate was preserved as indicated by the LVEF values; their heart overload was slightly high according to the BNP values, although the cause of admission was musculoskeletal disease. BNP values did not change statistically significantly during hospitalization, indicating that cardiac overload remained unchanged. In this study, there was no difference in the level of independence in ADL at entry and discharge between musculoskeletal disease patients with heart failure and those without heart failure. Limitations of ADL were considered likely to have been determined by musculoskeletal disease rather than heart failure. In older adult patients, the number and combination of multiple morbidities and the difficulties they face in their daily lives differ with each person. It is assumed that in the convalescent rehabilitation ward, support and facilitation to maximize the patient's ADL functions are performed depending on the patient's individuality. The ADL at the time of discharge were considered to be the result of demonstrating actual ADL as a patient of subacute musculoskeletal disease.

The single continuous period of physical activity in this study was 180 seconds for light-intensity physical activity or higher. The reported average walking time of hospitalized older adults was <2 minutes per observation period [32]. Light-intensity physical activity or higher includes walking, slow walking, and ADL and basic actions that occur back and forth associated with walking [33]. Therefore, the operation durations measured in this study were considered reasonable. For the total time of physical activity, participants in the study were 75 years and

older, with an average age of 85 years. A systematic review of physical activity in hospitalized adults of 25–85 years of age with musculoskeletal disease reported that inpatients spent 76%–99% of their time supine or inactive [34]. The activity time, 1%–24%, was calculated to be 0.24–5.76 hours per 24 hours. Considering that the participants in this study were aged 75 years and older and not fully independent in ADL, the total activity time indicated in this study of 14,913 seconds (4.1 hours) was considered reasonable. It has been reported that the walking time of hospitalized older adults with geriatric disease is 10 minutes at discharge [35]. The results of this study showed that a total duration of 633 seconds (10.6 minutes) of moderate-to-vigorous physical activity was equivalent to "walking," which supported the findings of the previous study.

There were no differences between the participant characteristics variables for patients with and without heart failure. Therefore, it was considered that heart failure affected the difference in shorter physical activity. In general, for patients with subacute musculoskeletal disease, the more physical activity they have, the better their ADL. However, the results showed that participants with heart failure did not necessarily require greater amounts of physical activity to maintain ADL. There may be appropriate values for the physical activity duration for each patient with heart failure, regardless of the independence level of ADL. Regarding the difference in the duration of physical activity with and without heart failure, we consider that some kind of hypometabolism or muscle degeneration might be related to the amount of physical activity. Dysfunction of brawn adipose tissue (BAT) has been shown to occur with heart failure [36], and BAT has been reported to play an important role in metabolism and sarcopenia [37]. Secondary sarcopenia (disease-related sarcopenia) associated with heart failure [38] has been shown to result in atrophy of slow twitch muscle [39]; in contrast, age-related sarcopenia results in atrophy of fast twitch muscle [40]. The lower level of physical inactivity in heart failure patients may be different from the physical inactivity that occurs with aging or musculoskeletal disease. Although the patient's ADL may improve while preventing overwork and exacerbation of heart failure, if the total amount of physical activity is extremely low, older adult patients may develop hospitalization-associated disability and have a worse prognosis after discharge. For patients with heart failure, it is considered necessary to first gauge the adequacy of the individual's capacity for cardiac workload (single continuous period and total duration of activity). Elucidation of this point is considered to be a goal of future research. In older adults with heart failure and subacute musculoskeletal disease, physical activity should be monitored separately from independence in ADL.

Limitations

We used the longest continuous time per hour with an epoch length of a 10-s bout as the single continuous period in the analysis; therefore, the results may differ depending on how the single continuous period is defined. The accuracy of the accelerometer may vary with activity outcomes such as step, type of activity, limb position, and in populations with low mobility. The validity and reliability of non-free-living activities, such as exercises during rehabilitation period, remains unclear. Therefore, researchers should be cautious when applying the activity monitor to new populations or activities where the accuracy of the device has not been specifically tested. One selection bias of this study was that the facility conducting this research was situated within a general hospital. At the time of a scheduled admission or an emergency admission, patients with complex diseases other than musculoskeletal disease may intentionally select a hospital that can provide more comprehensive care. This may have induced bias in participants' medical history in this study. As for the other medical history (such as chronic obstructive pulmonary disease, liver disease, renal disorder, dementia, and joint disease), it was assumed that a certain number of patients had been diagnosed or had completed or discontinued treatment at other hospitals in the past or had not undergone checkups and had not been diagnosed. Our medical records did not cover this disease entirely; these missing data may have provided the information bias and were not included in the medical history variable. But these diseases are considered to be an urgent issue to be investigated. For physical activity in older adults, environmental factors should also be considered, such as area of residence, facility equipment, family members living together, and their caregiving ability, in addition to individual factors, such as motivation and life history.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTION

Conceptualization: Shimizu T, Kanai C. Methodology: Shimizu T, Ueda K, Asakawa Y. Formal analysis: Shimizu T, Asakawa Y. Project administration: Shimizu T, Kanai C. Visualization: Shimizu T. Writing – original draft: Shimizu T, Kanai C. Writing – review and editing: Shimizu T, Ueda K, Asakawa Y. Approval of final manuscript: all authors.

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ORCID

Tomoko Shimizu, https://orcid.org/0009-0006-0532-767X
Chiaki Kanai, https://orcid.org/0009-0007-1306-8505
Keisuke Ueda, https://orcid.org/0009-0000-4104-3208
Yasuyoshi Asakawa, https://orcid.org/0009-0008-4511-1608

REFERENCES

1. Shiba N, Nochioka K, Miura M, Kohno H, Shimokawa H, CHART-2 Investigators. Trend of westernization of etiology and clinical characteristics of heart failure patients in Japan--first report from the CHART-2 study. Circ J 2011;75:823-33.
2. Bauman A, Merom D, Bull FC, Buchner DM, Fiatarone Singh MA. Updating the evidence for physical activity: summative reviews of the epidemiological evidence, prevalence, and interventions to promote "active aging". Gerontologist 2016;56 Suppl 2:S268-80.
3. McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Böhm M, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur Heart J 2021;42:3599-726. Erratum in: Eur Heart J 2021;42:4901.
4. Xavier SO, Ferretti-Rebustini REL. Clinical characteristics of heart failure associated with functional dependence at admission in hospitalized elderly. Rev Lat Am Enfermagem 2019;27:e3137.
5. Lu J, Wang M, Zhang Y, Mao L, Chen X, Yin R, et al. The prevalence of activities of daily living impairment in patients with heart failure: a systematic review and meta-analysis. Front Cardiovasc Med 2022;9:952926.
6. Brown CJ, Friedkin RJ, Inouye SK. Prevalence and outcomes of low mobility in hospitalized older patients. J Am Geriatr Soc 2004;52:1263-70.
7. Pavon JM, Sloane RJ, Pieper CF, Colón-Emeric CS, Cohen HJ, Gallagher D, et al. Accelerometer-measured hospital physical activity and hospital-acquired disability in older adults. J Am Geriatr Soc 2020;68:261-5.
8. Okamoto T, Ando S, Sonoda S, Miyai I, Ishikawa M. "Kaifukuki rehabilitation ward" in Japan. Jpn J Rehabil Med 2014;51:629-33.
9. Health Care for the Elderly Division, Insurance Bureau, Ministry of Health, Labor and Welfare. April 2008 guidelines for health services based on the characteristics of the elderly [in Japanese] [Internet]. Health Care for the Elderly Division, Insurance Bureau, Ministry of Health, Labor and Welfare. 2019;[cited 2022 Aug 24]. Available from: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/hokenjigyou/index_00003.html.
10. Ministry of Health, Labour and Welfare. Statistics & White Papers, patient survey in 2017 –section on injury and disease classification – summary of results, yearly trend chart by injury and disease [in Japanese] [Internet]. Ministry of Health, Labour and Welfare. 2017;[cited 2023 Feb 1]. Available from: https://www.mhlw.go.jp/toukei/saikin/hw/kanja/ 10syoubyo/index.html.
11. Miller MS, Vanburen P, Lewinter MM, Lecker SH, Selby DE, Palmer BM, et al. Mechanisms underlying skeletal muscle weakness in human heart failure: alterations in single fiber myosin protein content and function. Circ Heart Fail 2009;2:700-6.
12. Dhalwani NN, Fahami R, Sathanapally H, Seidu S, Davies MJ, Khunti K. Association between polypharmacy and falls in older adults: a longitudinal study from England. BMJ Open 2017;7:e016358.
13. Gerber Y, Melton LJ 3rd, McNallan SM, Jiang R, Weston SA, Roger VL. Cardiovascular and noncardiovascular disease associations with hip fractures. Am J Med 2013;126:169.e19-26.
14. Rahman MM, Kopec JA, Anis AH, Cibere J, Goldsmith CH. Risk of cardiovascular disease in patients with osteoarthritis: a prospective longitudinal study. Arthritis Care Res (Hoboken) 2013;65:1951-8.
15. Jette DU, Hunter SJ, Burkett L, Langham B, Logerstedt DS, Piuzzi NS, et al. Physical therapist management of total knee arthroplasty. Phys Ther 2020;100:1603-31.
16. Gimigliano F, Liguori S, Moretti A, Toro G, Rauch A, Negrini S, et al. Systematic review of clinical practice guidelines for adults with fractures: identification of best evidence for rehabilitation to develop the WHO's Package of Interventions for Rehabilitation. J Orthop Traumatol 2020;21:20. Erratum in: J Orthop Traumatol 2021;22:7.
17. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/

American Heart Association Task Force on practice guidelines. Circulation 2013;128:e240-327.
18. Makita S, Yasu T, Akashi YJ, Adachi H, Izawa H, Ishihara S, et al. JCS/JACR 2021 Guideline on rehabilitation in patients with cardiovascular disease. Circ J 2022;87:155-235. Erratum in: Circ J 2023;87:937.
19. Hamilton BB, Laughlin JA, Fiedler RC, Granger CV. Interrater reliability of the 7-level functional independence measure (FIM). Scand J Rehabil Med 1994;26:115-9.
20. Gosman-Hedström G, Svensson E. Parallel reliability of the functional independence measure and the Barthel ADL index. Disabil Rehabil 2000;22:702-15.
21. Baker PS, Bodner EV, Allman RM. Measuring life-space mobility in community-dwelling older adults. J Am Geriatr Soc 2003;51:1610-4.
22. Kraus WE, Janz KF, Powell KE, Campbell WW, Jakicic JM, Troiano RP, et al. Daily step counts for measuring physical activity exposure and its relation to health. Med Sci Sports Exerc 2019;51:1206-12.
23. Gebruers N, Vanroy C, Truijen S, Engelborghs S, De Deyn PP. Monitoring of physical activity after stroke: a systematic review of accelerometry-based measures. Arch Phys Med Rehabil 2010;91:288-97.
24. Goldman L, Hashimoto B, Cook EF, Loscalzo A. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: advantages of a new specific activity scale. Circulation 1981;64:1227-34.
25. Nagueh SF, Smiseth OA, Appleton CP, Byrd BF 3rd, Dokainish H, Edvardsen T, et al. Recommendations for the evaluation of left ventricular diastolic function by echocardiography: an update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. J Am Soc Echocardiogr 2016;29:277-314.
26. Oshima Y, Kawaguchi K, Tanaka S, Ohkawara K, Hikihara Y, Ishikawa-Takata K, et al. Classifying household and locomotive activities using a triaxial accelerometer. Gait Posture 2010;31:370-4.
27. Murakami H, Kawakami R, Nakae S, Nakata Y, Ishikawa-Takata K, Tanaka S, et al. Accuracy of wearable devices for estimating total energy expenditure: comparison with metabolic chamber and doubly labeled water method. JAMA Intern Med 2016;176:702-3.
28. Ohkawara K, Oshima Y, Hikihara Y, Ishikawa-Takata K, Tabata I, Tanaka S. Real-time estimation of daily physical activity intensity by a triaxial accelerometer and a gravity-removal classification algorithm. Br J Nutr 2011;105:1681-91.
29. Schwendinger F, Wagner J, Infanger D, Schmidt-Trucksäss A, Knaier R. Methodological aspects for accelerometer-based assessment of physical activity in heart failure and health. BMC Med Res Methodol 2021;21:251.
30. Hutto B, Howard VJ, Blair SN, Colabianchi N, Vena JE, Rhodes D, et al. Identifying accelerometer nonwear and wear time in older adults. Int J Behav Nutr Phys Act 2013;10:120.
31. Ainsworth BE, Haskell WL, Whitt MC, Irwin ML, Swartz AM, Strath SJ, et al. Compendium of physical activities: an update of activity codes and MET intensities. Med Sci Sports Exerc 2000;32(9 Suppl):S498-504.
32. Doherty-King B, Yoon JY, Pecanac K, Brown R, Mahoney J. Frequency and duration of nursing care related to older patient mobility. J Nurs Scholarsh 2014;46:20-7.
33. Ainsworth BE, Haskell WL, Herrmann SD, Meckes N, Bassett DR Jr, Tudor-Locke C, et al. 2011 Compendium of Physical Activities: a second update of codes and MET values. Med Sci Sports Exerc 2011;43:1575-81.
34. Fazio S, Stocking J, Kuhn B, Doroy A, Blackmon E, Young HM, et al. How much do hospitalized adults move? A systematic review and meta-analysis. Appl Nurs Res 2020;51:151189.
35. Villumsen M, Jorgensen MG, Andreasen J, Rathleff MS, Mølgaard CM. Very low levels of physical activity in older patients during hospitalization at an acute geriatric ward: a prospective cohort study. J Aging Phys Act 2015;23:542-9.
36. Yoshida Y, Shimizu I, Shimada A, Nakahara K, Yanagisawa S, Kubo M, et al. Brown adipose tissue dysfunction promotes heart failure via a trimethylamine N-oxide-dependent mechanism. Sci Rep 2022;12:14883.
37. Chen Y, Hu Q, Wang C, Wang T. The crosstalk between BAT thermogenesis and skeletal muscle dysfunction. Front Physiol 2023;14:1132830.
38. Bauer J, Morley JE, Schols AMWJ, Ferrucci L, Cruz-Jentoft AJ, Dent E, et al. Sarcopenia: a time for action. An SCWD position paper. J Cachexia Sarcopenia Muscle 2019;10:956-61.
39. Zamboni M, Rossi AP, Corzato F, Bambace C, Mazzali G, Fantin F. Sarcopenia, cachexia and congestive heart failure in the elderly. Endocr Metab Immune Disord Drug Targets 2013;13:58-67.
40. Carmeli E, Reznick AZ. The physiology and biochemistry of skeletal muscle atrophy as a function of age. Proc Soc Exp Biol Med 1994;206:103-13.

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1. AIMS & SCOPE

Annals of Rehabilitation Medicine (ARM) is the official journal of the Korean Academy of Rehabilitation Medicine. It is an international, peer-reviewed open access journal, which aims to be a global leader in sharing up-to-date knowledge dedicated to the advancement of care and enhancing the function and quality of life of persons with various disabilities and chronic illnesses. As the official journal of one of the largest societies of rehabilitation medicine in Asia and Oceania, nearly 8,000 physiatrists receive this journal every two months as a member benefit. This journal is endorsed by the International Society of Physical and Rehabilitation Medicine (ISPRM) and the Asia-Oceanian Society of Physical and Rehabilitation Medicine (AOSPRM). International members comprise approximately half the editorial board and conduct peer-review of submitted manuscripts.

The journal encompasses all aspects of physical medicine and rehabilitation, including clinical practice, experimental and applied research, and education. Research areas covered by this journal include rehabilitation of brain disorders and spinal cord injury; electrodiagnosis; musculoskeletal disorders and pain; pediatric, geriatric, cardiopulmonary, sports, cancer, cognitive, and robotic rehabilitation; neuromodulation; neuroimaging; orthotics and prosthetics; physical modalities; clinical trials; quality of life issues; and basic research, as well as other emerging fields in rehabilitation medicine.

2. COPYRIGHTS AND CREATIVE COMMONS ATTRIBUTION LICENSE

3. GENERAL GUIDELINES

The manuscript guidelines for *ARM* are based on the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals" published by the International Committee of Medical Journal Editors (http://www.icmje.org), and instructions which are not mentioned in the present guidelines are referred to the guidelines stated in the Recommendations. There are no fees payable to submit in this journal.

1) ARTICLE TYPES

Manuscripts include original articles, review articles, brief reports, case reports, images in this issue, and letters to the editor.

(1) Original articles

This form of publication represents original research articles reporting the results of basic and clinical investigations that are sufficiently well documented to be acceptable to critical readers.

(2) Review articles

The Editorial Board welcomes state-of-the-art review articles. The *ARM* strongly prefers systematic reviews of the literature. Invited review articles provide a comprehensive review of a subject of importance to clinicians and researchers and are commissioned by the editorial board to an invited expert in the field.

(3) Brief reports

These manuscripts are short but important reports to provide preliminary communications with less complete data sets than would be appropriate for original contributions that present novel and impactful clinical and basic research of a more preliminary nature.

(4) Case reports

Case reports are considered for publication when at least one of the following criteria is met: (a) a rare condition is reported, (b)

atypical symptoms and signs are observed, (c) new diagnostic or therapeutic methods are introduced, (d) atypical clinical and laboratory findings for populations residing in Asia and the Pacific Rim. Descriptions of clinical cases (individual or a series) should be unique, should deal with clinical cases of exceptional interest or innovation and should preferably be a first-time report.

(5) Images in this issue

This form of publication represents images (e.g.,radiographs, CT, MRI, electrodiagnostic tracings, pathology, physical examination findings, photos of a patient or medical device) that are interesting and unique.

(6) Letters to the editor

Critical comments are welcomed for providing alternative interpretations or views about articles published in *ARM*. Letters should be directly related to the published article on which it comments. Letters being considered for publication ordinarily will be sent to the authors, who will be given the opportunity to reply. Letters will be published at the discretion of the editors and are subject to abridgement and editing for style and content.

2) LANGUAGE OF MANUSCRIPT

All manuscripts must be written in clearly under-standable English. Authors whose first language is not English are requested to have their manuscripts checked for grammatical and linguistic correctness before submission. Correct medical terminology should be used, and jargon should be avoided. Use of abbreviations should be minimized and restricted to those that are generally recognized. When using an abbreviated word, it should be spelled out in full on first usage in the manuscript followed by the abbreviation in parentheses. Numbers should be written in Arabic numerals, but must be spelled out when placed in the beginning of a sentence. Measurements should be reported using the metric system, and hematologic and biochemical markers should be reported in International System (SI) of Units. All units must be preceded by one space except percentage (%), temperature (°C), and degree (°).

4. RESEARCH AND PUBLICATION ETHICS

All manuscripts should be written with strict adherence to the research and publication ethics guidelines recommended by Council of Science Editors (http://www.councilscienceeditors.org/), International Committee of Medical Journal Editors (ICMJE, http://www.icmje.org/), World Association of Medical Editors (WAME, http://www.wame.org/), and the Korean Association of Medical Journal Editors (KAMJE, https://www.kamje.or.kr/en/main_en). For all studies involving human subjects, the principles embodied in the Declaration of Helsinki (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/) should be upheld, informed consent must be obtained from all participants, and must be approved by a recognized Institutional Review Board (IRB) or research ethics committee. The editor may request submission of copies of informed consents from human subjects in clinical studies or IRB approval documents. Experiments involving animals should comply with the NIH guidelines for the use of laboratory animals (https://www.nlm.nih.gov/services/research_report_guide.html) and/or be reviewed by an appropriate committee (e.g., Institutional Animal Care and Use Committee, IACUC) to ensure the ethical treatment of animals in research. Also, studies with pathogens requiring a high degree of biosafety should pass review of a relevant committee (e.g., Institutional Biosafety Committee, IBC). *ARM* will follow the guidelines by the Committee on Publication Ethics (COPE, http://publicationethics.org/) for settlement of any misconduct.

1) REDUNDANT PUBLICATION AND PLAGIARISM

All submitted manuscripts should be original and should not be considered by other scientific journals for publication at the same time. No part of the accepted manuscript should be duplicated in any other scientific journal without the permission of the editorial board. If plagiarism or duplicate publication related to the papers of this journal is detected, the manuscripts may be rejected, the authors will be announced in the journal, and their institutes will be informed. There will also be penalties for the authors.

2) AUTHORSHIP

ARM follows the recommendations by International Committee of Medical Journal Editors (ICMJE,http://www.icmje.org/) and and the Korean Association of Medical Journal Editors (KAMJE, https://www.kamje.or.kr/en/main_en). Authorship is credited to those who have direct involvement in the study and have made significant contributions to (a) substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (b) drafting the work or revising it critically for important intellectual content; AND (c) final approval of the version to be published; AND (d) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved as recommended by ICMJE. The primary investigator is designated the first author of the study, unless contested by the other authors. The correspond-

ing author is directly responsible for communication and revision of the submitted manuscript. Authors are required to include a statement of responsibility in the manuscript that specifies the contribution of every author at the end of the manuscript, in a section entitled "Author contribution". All persons who have made substantial contribution, but who are not eligible as authors should be named in the acknowledgments. In the case of change of authorship, a written explanation must be submitted. Change in either the first author or the corresponding author requires approval by the editorial board, and any changes in the other authors require approval by the editor-in-chief.

3) CONFLICT OF INTEREST

The corresponding author of an article is asked to inform the editor of the authors' potential conflicts of interest possibly influencing their interpretation of data. A potential conflict of interest must be disclosed during the online submission process on the appropriate web page. Such conflicts may be financial support or private connections to pharmaceutical companies, political pressure from interest groups, or academic problems based on the "ICMJE Uniform Disclosure Form for Potential Conflicts of Interest" (http://www.icmje.org/coi_disclosure.pdf). The editor will decide whether the information on the conflict should be included in the published paper. Before publishing such information, the editor will consult with the corresponding author. In particular, all sources of funding for a study should be explicitly stated.

4) REGISTRATION OF CLINICAL TRIAL

Clinical trial defined as "any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome" is recommended to be registered to the primary registry to be prior publication. *ARM* recommend, as a condition of consideration for publication, registration in a public trials registry. *ARM* accepts the registration in any of the primary registries that participate in the WHO International Clinical Trials Portal (http://www.who.int/ictrp/en/), NIH ClinicalTrials.gov (http://www.clinicaltrials.gov/), ISRCTN Resister (www.isrctn.org), ANZCTR (https://www.anzctr.org.au/), EudraCT Database (https://eudract.ema.europa.eu/), Clinical Trials Information System (https://euclinicaltrials.eu/), University Hospital Medical Information Network (www.umin.ac.jp/ctr/index/htm), EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/) or The Clinical Research Information Service (http://cris.nih.go.kr/). The clinical trial registration number will be published at the end of the abstract.

5) PROCESS FOR MANAGING RESEARCH AND PUBLICATION MISCONDUCT

When the journal faces suspected cases of research and publication misconduct such as redundant (duplicate) publication, plagiarism, fraudulent or fabricated data, changes in authorship, an undisclosed conflict of interest, ethical problems with a submitted manuscript, a reviewer who has appropriated an author's idea or data, complaints against editors, and so on, the resolution process will follow the flowchart provided by the Committee on Publication Ethics (COPE, https://publicationethics.org/guidance/Flowcharts). The discussion and decision on the suspected cases are carried out by the Editorial Board.

6) PROCESS FOR HANDLING CASES REQUIRING CORRECTIONS, RETRACTIONS, AND EDITORIAL EXPRESSIONS OF CONCERN

Cases that require editorial expressions of concern or retraction shall follow the COPE flowcharts available from: https://publicationethics.org/guidance/Flowcharts. If correction needs, it will follow the ICMJE Recommendation for Corrections, Retractions, Republications and Version Control available from: http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/corrections-and-version-control.html.

5. MANUSCRIPT SUBMISSION

All submissions are made online at the journal's online manuscript submission site (http://www.e-arm.org/submission) by the corresponding author. Submitted manuscripts are initially examined for format, and then appointed a submission number. For nonbiased peer review, authors' names and institutional affiliations should not be mentioned in the text. The revised manuscript should be submitted through the same web system under the same identification numbers. The date of final review for the manuscript will be the date of acceptance for publication. If you have any questions about the online submission process, contact the Editorial Office by e-mail at edit@e-arm.org.

1) ARTICLE PROCESSING CHARGES

Annals of Rehabilitation Medicine is an open access journal. To publish in *Annals of Rehabilitation Medicine*, authors are asked to pay an article processing charge (APC) on acceptance of their research paper. The APC for all published papers is as follows, plus VAT or local taxes where applicable. The currency KRW will be applied to the submissions from South Korea.

- Original article / Brief Reports / Unsolicited review article: 600 USD or 600,000 KRW

- Solicited article: Free
- Case report: 300 USD or 300,000 KRW
- Image in this issue: 170 USD or 170,000 KRW
- Correspondence / erratum: 100 USD or 100,000 KRW

†Note: As categorized by the World Bank, low-income countries will be eligible for a 20% discount on the updated APCs for original articles/brief reports/review articles/case reports. To find out if your country qualifies, please refer to the World Bank's classification available at https://datatopics.worldbank.org/world-development-indicators/the-world-by-income-and-region.html.

(This updated article processing charge is applied to all submissions as of Oct 1, 2023.)

6. PEER REVIEW PROCESS

1) EDITORIAL REJECT POLICY

Conformity of the submitted manuscript to the submission instructions is examined upon submission. The Editorial Board may reject the manuscript or request the author to resubmit in the following cases: 1) Topic clearly out of scope / insufficient perceptual content 2) Work clearly does not meet sufficient standards of novelty or quality 3) Manuscript incomplete or incorrectly formatted 4) Suspected plagiarism in the manuscript.

2) PEER REVIEW PROCESS

Submitted manuscripts will be reviewed by two or more peer reviewers selected from the board's database of expert reviewers. In addition, if deemed necessary, a review of statistics may be requested. Following review, the editorial board will decide whether the manuscript will be 1) accepted for publication, 2) subject to minor revision, 3) subject to major revision, or 4) rejected for publication. For manuscripts which are either subject to minor revision or subject to major revision, the corresponding author must resubmit the revised manuscript online. The revised manuscript should have the changes highlighted by using the Track Changes tool in Microsoft Office Word. In addition, the corresponding author must reply to both reviewers' comments point by point, and explain in detail what changes were made in the manuscript. When considered necessary, the editorial board may make changes to the structure and phrases of the manuscript without compromising the integrity of the original paper. After completion of the peer review process, the editorial board will determine acceptance for publication and notify the corresponding author by e-mail. Manuscripts which do not comply with the present guidelines will be notified for correction or withheld from publication.

When a manuscript is not resubmitted within 2 months of notification, it will be considered that the authors have withdrawn the manuscript from submission. Manuscripts accepted for publication are generally published in order of submission, depending on the category of the manuscript and the date of acceptance for publication.

7. PREPARATION OF THE MANUSCRIPT

Use Microsoft Office Word (versions after 2003) and ensure correct spelling and grammar. Setup the MS Word document for 1-inch margins on letter or A4-sized paper. The manuscript must be written in 12-point font and the sentences must be double-spaced, including tables and figure legends. Each page should be numbered in the middle of the lower margin, and all sentences must be numbered sequentially throughout the entirety of the manuscript, starting with the title page. All papers must be accompanied by a title page. The title page should contain the title of the manuscript, a short running title, the authors' names, academic degrees, respective affiliations, and ORCID. The corresponding author must be identified, and his or her contact information (postal address, e-mail, telephone and fax numbers) should be listed. The title should clearly describe the objective of the study and contain less than 20 words. The first letter of each word of the title should be in capital letters except for prepositions, articles, and conjunctions. Provide a short running title containing less than 10 words. In cases in which the authors belong to multiple affiliations, the affiliations during the study being reported should be matched to the authors' names using a superscript of Arabic numerals. Conflicts of interest, funding information, author contribution and acknowledgements (when applicable) should also be located in the title page.

1) ORIGINAL ARTICLES

Original papers should be structured in the following order: Abstract, Introduction, Methods, Results, Discussion, Conflict of interests, Funding information, Author contribution, Acknowledgments (when applicable), References, Tables, Figure legends, and Figures. Maximum word count is limited to 5,000 words.

(1) Abstract

A structured abstract with the headings of Objective, Methods, Results, and Conclusion must succinctly describe the paper in 250 words or less. Use complete sentences and do not number the results. At the end of the abstract, list up to 5 relevant keywords which are in accordance to the Medical Subject Headings (MeSH)

in the Index Medicus (http://www.nlm.nih.gov/mesh).

(2) Introduction

Clearly present the objective of the study and its relationship to earlier work in the field. A brief background to inform the readers of the relevance of the study may be necessary. However, avoid extensive review of the literature.

(3) Methods

Describe the participants or research materials of the study, and explain in detail the inclusion and exclusion criteria for both the experimental and control groups. Describe the experimental methods in a logical and systematic manner so that they can be reproducible by another investigator. Experimental drugs should be stated in the generic name. When proprietary brands are used, include the brand name and the name of the manufacturer in parentheses after the first mention of the generic name. When using experimental devices or other products, state the brand name then follow with the name of the manufacturer, in parentheses, e.g., Flow Cytometer (Coulter Electronic Inc.). To ensure anonymity during the peer review process, the authors' affiliations or institutional setting of the study should not be revealed. Statistical analysis and criteria for determining significance should be described in enough detail to allow the knowledgeable reader with access to the original data to verify the reported results. An ethics statement should be placed here when the studies are performed using clinical samples or data, and animals.

Ensure correct use of the terms sex (when reporting biological factors) and gender (identity, psychosocial or cultural factors), and, unless inappropriate, report the sex and/or gender of study participants, the sex of animals or cells, and describe the methods used to determine sex and gender. If the study was done involving an exclusive population, for example in only one sex, authors should justify why, except in obvious cases (e.g., prostate cancer). Authors should define how they determined race or ethnicity and justify their relevance.

(4) Results

Summarize and describe logically the significant findings and trends observed in the results using text, figures and tables. Avoid extensive repetition of contents of the tables and figures in the text.

In statistical expression, mean and standard deviation should be described as mean ± SD, and mean and standard error as mean ± SE. In general, p-values larger than 0.01 should be reported to two decimal places, those between 0.01 and 0.001 to three decimal places; p-values smaller than 0.001 should be reported as $p < 0.001$.

(5) Discussion

Interpret the results in respect to the objective of the study, and describe differences with previous studies and significant findings which lead to the deduction of the conclusion. Refrain from excessive review of historic studies, textbook facts, or irrelevant references. Accentuate newly obtained observations from the study, and include significant limitations of the study.

(6) Conflicts of interest

Any potential conflicts of interest relevant to the manuscript should be described. If there are no conflicts of interest, authors should state that none exists.

(7) Funding information

All sources of funding applicable to the study should be stated here explicitly. All original articles, editorials, reviews, and new technology articles must state funding sources for the study.

(8) Author contribution

The individual contributions of the authors to the manuscript should be specified in this section.

(9) Acknowledgments

Persons who have made contributions to the study, but who are not eligible for authorship can be named in this section. Their contribution must be specified, such as data collection, financial support, statistical analysis, or experimentation. The corresponding author must inform the named contributor of the acknowledgment, and acquire consent before manuscript submission.

(10) References

- Cite only references which are quoted in the text. Limit the number of references 40.
- When quoting a reference in the text, refrain from stating the author's name, and identify references with Arabic numerals in brackets such as [1], [2-4], and [5,7,9].
- The references should be listed in order of citation in the text.
- List all authors when there are 6 or fewer; when there are 7 or more, list the first 6, followed by "et al."
- Journal names should be abbreviated according to the format listed in the Index Medicus. If the journal is not listed in the Index Medicus, refer to the list of title word abbreviations by the ISSN network (http://www.issn.org/2-22660-LTWA.php).
- For more on references, refer to the NLM Style Guide for Authors, Editors, and Publishers (http://www.nlm.nih.gov/citingmedicine).

Journals

1. Jeon JH, Jung YJ, Lee JY, Choi JS, Mun JH, Park WY, et al. The effect of extracorporeal shock wave therapy on myofascial pain syndrome. Ann Rehabil Med 2012;36:665-74.
2. Geraud G, Spierings EL, Keywood C. Tolerability and safety of frovatriptan with short- and long-term use for treatment of migraine and in comparison with sumatripan. Headache 2002;42 Suppl:S93-9.

Book & Chapter of book

3. Frontera W, Silver JK, Rizzo TD. Essentials of physical medicine and rehabilitation. 2nd ed. Saunders; 2008. p. 579-82.
4. Esquenazi A. Upper limb amputee rehabilitation and prosthetic restoration. In: Braddon RL, editor. Physical medicine and rehabilitation. 2nd ed. Saunders; 2000. p. 263-78.

Proceedings of academic conference

5. Harnden P, Joffe JK, Jones WG. Germ cell tumours V. Proceedings of the 5th Germ Cell Tumour Conference; 2001 Sep 13-15; Leeds, UK. New York: Springer; 2002.

Thesis (Dissertation)

6. Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant, MI: Central Michigan University; 2002.

(11) Tables

Tables should be submitted separately from the text, and each table should be created in MS Word on separate pages, using double space throughout. They should be simple, self-explanatory, and not redundant with the text or the figures. Limit 5 tables per manuscript. The title of the tables should be written in phrases, and capitalized the first letter of the first word. The title should be placed above the table, and abbreviations and footnotes should be placed under the table. Number the tables in order of appearance in the text (e.g., Table 1, Table 2). All abbreviations used in the table must be spelled-out in full under the table in the following order: abbreviation, comma, full word (e.g., RM, rehabilitation medicine;). Table footnotes should be indicated in superscripts in the following order: [a], [b], [c]… but p-values should be indicated by asterisk (e.g., *$p < 0.05$, **$p < 0.01$. ***$p < 0.001$).

(12) Figure legends

Legends should be submitted separately from the text, and each legend should be typed on separate pages. They should be written in full sentences to describe the content of the figure, and only the first letter of the legend should be capitalized. For lengthy legends continuing beyond one line, the left margin of the following lines should start at the same point as the first line. Any symbols, marks or abbreviations made in the figure must be explained in the legend. Figures containing histologic slides should be accompanied by legends explaining tissue origin, stain method, and microscopic amplification.

(13) Figures

Figures should be uploaded online as separate files and numbered in order of appearance in the text (e.g., Fig. 1). When a single numbered figure contains 2 or more figures, the figure should be numbered with an alphabet letter following the number (e.g., Fig. 1A, Fig. 1B). Indicate focus points in the figures with markers such as arrows and arrowheads, etc. Image files must be of resolutions higher than 300 dpi, and less than 3 MB, in JPEG, GIF, TIFF, or Microsoft PowerPoint format. A single numbered figure containing more 2 or more figures such as Fig. 1A and Fig. 1B should be uploaded as a single file.

2) REVIEW ARTICLES

The abstract should contain no more than 250 words and 5 keywords. The text is structured in the order of Introduction, Main text, Conclusion, Conflict of interests, Funding information, Author contribution, Acknowledgments (when applicable), References, Tables, Figure legends, and Figures.

3) BRIEF REPORTS

General guidelines are the same as for the original article. The manuscript is structured in the order of Abstract, Main text, Conflict of interests, Funding information, Author contribution, Acknowledgments (when applicable), References, Tables, Figure legends, and Figures. A structured abstract is required and limited to 150 words, with no more than 3 keywords attached. Manuscripts should be limited to 1,500 words of text including references and figure legends (not including abstract, tables, and figures), and no more than 10 references. The total number of figures and/or tables is limited to 3.

4) CASE REPORTS

General guidelines and order of manuscript preparation are the same as for the original article. Case reports are considered for publication only if they report rare conditions, atypical symptoms and signs, novel diagnostic or therapeutic approaches, or describe atypical findings for populations residing in Asia and the Pacific Rim. The editorial board will determine whether the case report fulfills the above criteria for acceptance of publication. The manuscript is structured in the order of Abstract, Introduction, Case

report, Discussion, Conflict of interests, Funding information, Author contribution, Acknowledgments (when applicable), References, Tables, Figure legends, and Figures. The abstract should be nonstructured and limited to 150 words, with no more than 3 keywords attached. The introduction should briefly state the background and significance of the case. The actual case report should describe the clinical presentation and the diagnostic and therapeutic measures taken. The discussion should focus on the uniqueness of the case and should not contain extensive review of the disease or disorder. The combined number of tables and figures is limited to 5, and the number of references is limited to 10. Maximum word count is limited to 1,500 words including references and figure legends.

5) IMAGES IN THIS ISSUE

All images should be accompanied by a short description of the image and a brief and concise clinical review of the specific patient or clinical issue of no more than 500 words (excluding references) with references limited to 5. Image files must be of resolutions higher than 300 dpi for photographs, and 900 dpi for line art, waveforms, and graphs, in JPEG, GIF, TIFF, or Microsoft PowerPoint format. Images should make up a single figure, although they may contain more than one frame. The manuscript does not have an abstract.

6) LETTERS TO THE EDITOR

Letters should not have an abstract, tables, figures, and data supplements. Letters must be limited to roughly 500 words of text and no more than 5 references, 1 of which should be to the recent *ARM* article. Letters may have no more than 3 authors.

7) REPORTING GUIDELINES FOR SPECIFIC STUDY DESIGNS

For the specific study design, such as randomized control studies, studies of diagnostic accuracy, meta-analyses, observational studies, and non-randomized studies, it is recommended that the authors follow the reporting guidelines listed in the following table.

8. SUBMISSION APPLICATION & COPYRIGHT TRANSFER

All submitted manuscripts must be accompanied by the official Submission Application & Copyright Transfer Form of the Korean Academy of Rehabilitation Medicine. The Submission Application & Copyright Transfer Form must contain the title of the manuscript, date of submission, names of all authors, authors' affiliations, and written signatures. Note the corresponding author and provide his/her affiliation, e-mail, telephone and fax numbers, and mailing address.

For the copyrights of the contributions published in *ARM*, see Creative Commons (Attribution-Noncommercial) at http://creativecommons.org.

9. MANUSCRIPTS AFTER ACCEPTANCE

ARM is published in English bi-monthly on the last days of February, April, June, August, October, and December.

1) FINAL VERSION UPLOAD

When accepted for publication, the authors' institutional affiliations should be inserted into the text of the final revised manuscript and uploaded to the online submission system. Files containing figures should be of the highest resolution (at least 300 dpi for color figures, and 900 dpi for line art and graphs) should be also be uploaded in JPEG, GIF, or TIFF format, and must be named according to the figure number (e.g., Fig. 1.jpg).

2) GALLEY PROOF

Galley proofs will be sent to the corresponding author for final corrections. Corrections should be kept to a minimum, must be returned within 2 days, otherwise publication may be delayed. Any fault found after the publication is the responsibility of the authors. We urge our contributors to proofread their accepted manuscripts very carefully. After the publication, if there are critical errors, they should be corrected as Corrigendum or Erratum.

3) PUBLICATION

The editorial board retains the right to request minor stylistic and major alterations that might influence the scientific content of the paper. The final manuscript will be published following final approval by the editor-in-chief.

Checklist for Authors

Annals of Rehabilitation Medicine

General

☐ All elements of the manuscript are printed in English and double-spaced with 1-inch margins at top, bottom, and sides. Right margins are unjustified.

☐ All pages are numbered in the following order: title page, structured or standard abstract, body of the text, conflict of interests, Funding information, Author contribution, Acknowledgments (when applicable), references, legends, and tables.

☐ The text is consecutively line numbered.

☐ The Submission Application & Copyright Transfer Form is signed by the guarantor at original submission.

Abstract (applied to original articles, review articles, brief reports, and case reports)

☐ A structured abstract with the headings of Objective, Methods, Results, and Conclusion (A nonstructured abstract for case reports) must succinctly describe the paper.

☐ At the end of the abstract, relevant keywords are listed.

References

☐ All references have been checked for accuracy and completeness.

☐ Cite only references which are quoted in the text. Limit the number of references 40 for original articles, 10 for brief reports and case reports, and 5 for images in this issue and letters to the editor.

☐ Are numbered consecutively in the order they are cited in the text; all listed references have been cited in the text.

☐ Do NOT parenthesize the superscript numerals, and hyphenate (-) when citing 3 or more references in consecutive order.

☐ The format prescribed by the "Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations)" has been followed. Examples provided under Instructions for Authors have been uploaded.

☐ List all authors when there are 6 or fewer; when there are 7 or more, list the first 6, followed by "et al."

☐ Journal names should be abbreviated according to the format listed in the Index Medicus. If the journal is not listed in the Index Medicus, refer to the list of title word abbreviations by the ISSN network (http://www.issn.org/2-22660-LTWA.php).

Figure Legends

☐ Figure legends are provided for each figure.

☐ Figure legends are numbered and presented together in numeric order following reference page(s).

Tables

☐ Each table is headed by a title and numbered in Arabic numerals on a separate page.

☐ The title of the tables should be written in phrases, and capitalized the first letter of the first word.

☐ There are less than 5 tables in the text of original articles.

☐ Tables are cited in numeric sequence in the text.

Figures

☐ Each is numbered with an Arabic numeral and cited in numeric sequence in the text.

☐ Photographs of recognizable persons should be accompanied by a signed release from the patient or legal guardian authorizing publication. Masking eyes to hide identity is not sufficient.

Credits & Permissions

☐ In addition to the notice of informed consent and releases to publish photographs of recognizable persons, submit with the manuscript written permission to use non-original material (quotations exceeding 100 words, any table or illustration) from copyright holder of the original. No article will be accepted as a submission to Archives without all required permissions. Credit the source in a text or table footnote or in a legend.

A more complete description of each item that must be checked is provided under the appropriate heading in the Instructions for Authors.

I have reviewed this Checklist and have complied with its requirements.

Every author took a certain role and made contribution to the study and the manuscript. In case of publication, I agree to transfer all copyright ownership of the manuscript to the Korean Academy of Rehabilitation Medicine to use, reproduce, or distribute the article.

☐ Agree ☐ Disagree

Submission Application & Copyright Transfer Form

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Annals of Rehabilitation Medicine

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In signing this form:

1. The authors warrant that the article is original work which has not been published before, and is not being considered for publication elsewhere in its final form.
2. The authors concede that the article will be reviewed and may be edited by the Korean Academy of Rehabilitation Medicine (KARM).
3. The authors agree to transfer copyright of the article to the KARM upon publication in the Annals of Rehabilitation Medicine.

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