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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 (IS-PRM) 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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Letter to the Editor

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Diabetic Distal Symmetric Sensorimotor Polyneuropathy: A Proposal of New Electrodiagnostic Evaluation

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According to the American Diabetes Association (ADA), there are two types of diabetic neuropathies (DPN): typical and atypical forms. The typical DPN is a distal symmetric sensorimotor polyneuropathy (DSPN) which is length-dependent and considered the most common variety. DSPN is a chronic neurodegenerative disorder; up to 50% of cases may have no neuropathic symptoms. However, DSPN significantly contributes to foot ulcers as the disorder progresses, which can lead to amputation, falls, and fractures. Therefore, clinicians must diagnose DSPN as early as possible to start early intervention for proper long-term care [1].

To diagnose DPN, Diabetes Control and Complications Trial (DCCT) had proposed an electrodiagnosis protocol [2], but something else is needed for DSPN by definition [3]. Original electrodiagnostic protocol for DPN proposed by DCCT included the nerves in the upper and lower extremity. By ADA definition, DSPN involves the sensory nerves first and motor nerves later in the lower extremity, followed by the upper extremity nerves later [1,4]. Electrodiagnosis for most typical DSPN can be made with lower extremity nerve conduction studies, and upper extremity nerve conduction study may be redundant, may consider the tests in cases of absent responses from lower extremity nerves [4].

Diagnosing the DSPN, nerve conduction studies for three major nerves-sural sensory, tibial, and peroneal nerves unilaterally or bilaterally (probably optional) are enough [5]. Many electrodiagnostic studies for diagnosing DSPN have been tried to achieve more sensitive tests: tibial F latency tests were reported to be the most sensitive parameter [6].

To establish normal reference values, we conducted a retrospective medical record review of tibial F wave data from 145 patients. The study received approval from the institutional review board. The electrodiagnosis of diabetic DSPN, particularly in its early stage, can be determined by examining the minimal latencies of the tibial and peroneal nerves. Among patients with diabetes, the tibial F latency is considered the most sensitive parameter [6]. The peroneal F latency is similar to the tibial latency (Spearman correlation coefficient 0.88, p-value<0.001) in our study. The severity of the condition is assessed based on the amplitudes of the sural and tibial nerves. If the compound muscle action potential of the tibial nerve measures less than 2 mV (indicating severe grading, excluding severe lumbosacral radiculopathies), the action potentials of the sural or medial plantar nerves cannot be recorded (based on our unpublished data from 12 out of 219 diabetic patients). Additionally, these patients exhibit both neuropathic symptoms

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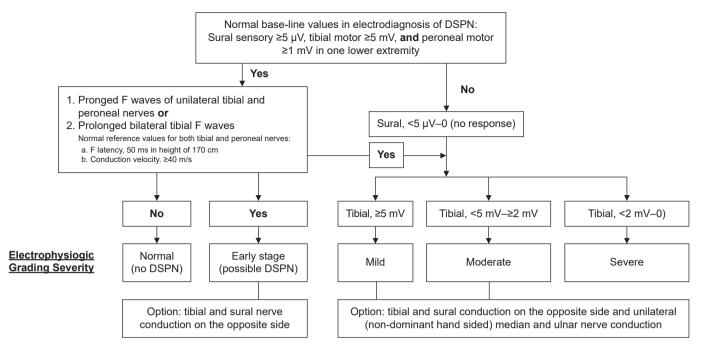


Fig. 1. Flowchart for electrophysiologic approach of diabetic distal symmetric sensorimotor polyneuropathy (DSPN). Data from the article of Consensus statement [2], Tankisi et al. [5], and Baba et al. [7].

and neuropathic signs, such as the absence of response to pinprick and tuning fork vibration response.

Because no effective treatments specifically address peripheral nerve damage, it is extremely important to focus on prevention in diabetes care. It is also crucial to screen for symptoms and signs of diabetic DSPN in practice, as this can help identify the initial stages of nerve damage, allowing early intervention [1].

We propose this algorithm formulated in conjunction with previously reported protocols [2,7,8] and our data for the early detection or estimation of severity for diagnosing DSPN (Fig. 1). If there is no evoked response, especially from the tibial motor nerve, it is advisable to conduct a conduction study of the median and ulnar nerves in the upper extremity. This additional test will contribute to a more comprehensive evaluation of DSPN. Needle electromyography can also provide additional insights into the severity of DSPN or any other underlying neuromuscular disorders, like radiculopathy or other types of neuropathy.

CONFLICTS OF INTEREST

Dong Hwee Kim is the Editorial Board member of Annals of Rehabilitation Medicine. The author did not engage in any part of the review and decision-making process for this manuscript. Otherwise, no potential conflict of interest relevant to this article was reported.

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Editorial

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Refined Diagnostic Protocol for Diabetic Polyneuropathy: Paving the Way for Timely Detection

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I carefully studied the proposal from Lee et al. [1] describing a nerve conduction study (NCS) algorithm for grading the severity of diabetic distal symmetric sensorimotor polyneuropathy (DSPN). Despite the article's brevity, it was evident that the authors put substantial effort into research and contemplation on the topic. Henceforth, I will refer to this diagnostic NCS algorithm as "Lee's Severity System" or "Lee's algorithm."

In 2020, the estimated prevalence of diabetes mellitus among Korean adults was 16.7% [2]. Diabetic neuropathy, which affects approximately one-third of the patients with type 1 or type 2 diabetes, increases the risk of painless foot ulcers leading to amputations [3]. Although the NCS is the most comprehensive and accurate diagnostic tool for DSPN, it is not routinely integrated into standard clinical care for diabetic patients. This reluctance is understandable; without concrete evidence that NCS enhances clinical outcomes, the associated costs, time commitments, and potential patient discomfort might deter clinicians.

In this regard, Lee's algorithm is primarily efficient, offering several advantages. Using this algorithm, NCS of the lower extremities that are more vulnerable at an earlier stage of DSPN can be first performed. If these results are within normal limits, the examination can be completed with only a tibial F-wave study in the contralateral lower limb. In addition, Lee's algorithm suggests that the contralateral lower extremity or non-dominant upper extremity can be examined only when there is an additional need. Taken together, Lee's Severity System has the potential to significantly reduce the NCS examination time, especially in patients with early-stage to mild DSPN. Applying these streamlined algorithms will minimize the time, cost, and discomfort associated with NCS, allowing its application to most patients with diabetes. The NCS is more sensitive than the Semmes-Weinstein monofilament test and can comprehensively assess the entire sensory and motor systems. It would greatly benefit if the NCS could be completed in as little as 30 minutes.

Lee's Severity System employs an ordinal scale that classifies DSPN severity into five stages based on NCS outcomes. This framework offers significant clinical utility, presenting a nuanced understanding of disease severity rather than a simple binary diagnosis of the presence or absence of DSPN. Furthermore, it identifies "early stage" DSPN, potentially a pivotal therapeutic juncture. Baba et al. introduced a comparable DSPN severity scale [4]. The mild, moderate, and severe grades in Lee's Severity System mirror grades 2, 3, and 4 of Baba's classification, diagnos-

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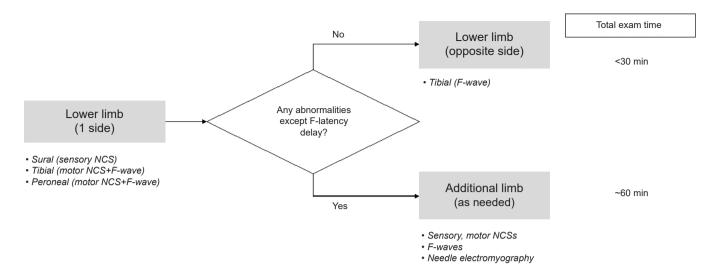


Fig. 1. A sample adaptation of nerve conduction study (NCS) in Lee's Severity System. The total turn-around time for the evaluation or distal symmetric sensorimotor polyneuropathy can be as short as 30 minutes, especially in the early stage.

tic criteria essentially aligning. However, disparities arise in the early-stage criteria. While Baba's proposal encompassed a range of tests, Lee's strategy streamlined the criteria by focusing on F-waves. This condensation enhances practicality, particularly because F-wave studies share electrode montages with motor NCS, enabling seamless and consecutive assessments. The projected NCS test flowchart suggests potential completion within 30 minutes for mild cases, suggesting proactive interventions for early-stage patients (Fig. 1). In essence, Lee's algorithm refines and optimizes Baba's classification, offering a new system for expedited evaluation.

However, some areas in Lee's Severity System could benefit from further exploration. Electrodiagnostic laboratories use a variety of reference standards. Future adaptations might consider universal criteria such as "age-adjusted mean-2SD" or "age-adjusted mean-extended uncertainty" instead of specific numbers such as "5 mV."

According to a study published by Kim et al. [5] on ARM in 2022, the lower limit or reference range of tibial compound muscle action potential amplitude in healthy Korean men and women in their 50s is 9.1 and 8.3 mV, respectively. This is significantly higher than the step criteria of 5 and 2 mV suggested by Lee's algorithm. Similarly, the cut-off value for the base-to-peak sensory nerve action potential amplitude of the sural nerve was 9.8 and 10.4 μV for men and women, respectively. Both Baba's and Lee's Severity System possess discernible grey

areas. Refining Lee's approach to accommodate age-based reference range variations is of paramount importance. Further investigations on the ramifications of early detection and proactive intervention for health outcomes are warranted.

CONFLICTS OF INTEREST

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Review Article

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Disaster Response and Management: The Integral Role of Rehabilitation

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With the increasing frequency of disasters and the significant upsurge of survivors with severe impairments and long-term disabling conditions, there is a greater focus on the importance of rehabilitation in disaster management. During disasters, rehabilitation services confront a greater load due to the influx of victims, management of persons with pre-existing disabilities and chronic conditions, and longer-term care continuum. Despite robust consensus amongst the international disaster response and management community for the rehabilitation-inclusive disaster management process, rehabilitation is still less prioritised. Evidence supports the early involvement of rehabilitation professionals in disaster response and management for minimising mortality and disability, and improving clinical outcomes and participation in disaster survivors. In the last two decades, there have been substantial developments in disaster response/management processes including the World Health Organization Emergency Medical Team (EMT) initiative, which provides a standardized structured plan to provide effective and coordinated care during disasters. However, rehabilitation-inclusive disaster management plans are yet to be developed and/or implemented in many disaster-prone countries. Strong leadership and effective action from national and international bodies are required to strengthen national rehabilitation capacity (services and skilled workforce) and empower international and local EMTs and health services for comprehensive disaster management in future calamities. This narrative review highlights the role of rehabilitation and current developments in disaster rehabilitation; challenges and key future perspectives in this area.

Keywords: Disaster, Rehabilitation, Disability, Impairment

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INTRODUCTION

Disaster is a "serious disruption of functioning of a community or a society causing widespread human, material, economic or environmental losses which exceeds the ability of the affected community or society to cope using its own resources" [1]. Disaster can be classified into:

- Natural (e.g., earthquakes, storms)
- Technological or man-made events caused deliberately by humans (e.g., armed conflicts, terror attacks and other situations of violence) or by human negligence (e.g., industrial or transport accidents)
- Complex humanitarian emergencies events from several different hazards or a complex combination of both natural

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and man-made disasters with different causes (e.g., food insecurity, epidemics/pandemics, displaced populations).

This review will focus on natural disasters which are defined as "situation or event caused by nature, which overwhelms local capacity, necessitating a request to a national or international level for external assistance; an unforeseen and often sudden event that causes great damage, destruction and human suffering" [2]. Natural disasters can be sub-classified into different categories based on their etiology (Table 1) [3].

All types of natural disasters are increasing globally. According to the Centre for Research on the Epidemiology of Disasters (CRED), between 2000 and 2019, 7,348 natural disaster events were recorded worldwide, which has almost doubled since 1998–1999 [4]. This is mainly attributed to a rise in the number

of climate-related disasters (floods, storms, heatwaves, etc.), accounting for over three fourth of the total natural calamities (6,681 climate-related disasters between 2000 and 2019) (Fig. 1) [4]. Floods are the most common type of disaster (accounting for 44% of total events), followed by storms (28%), earthquakes and volcanic activity (9%), extreme weather events (6%), droughts (5%), and wildfires (3%) [4].

Natural disasters occur disproportionately and the majority occur in the low-resourced regions of the world. Asia-Pacific is the most disaster-prone region accounting for over 40% of the world's disasters in the past decade [4,5]. This is largely due to seismic fault lines and landscapes in the region that represent a high risk of natural hazards, such as river basins, flood plains [6]. Between 2000 and 2019, overall, eight of the top 10 countries by disaster events were in Asia, with China experiencing the most

Table 1. Classification of natural disasters

Subgroup	Definition	Main type
Geophysical	Events originating from solid earth	Earthquake, volcano, mass movement (dry) (rockfall, landslide, avalanche, subsidence)
Meteorological	Events caused by short-lived/small to meso scale atmospheric processes (spectrum from minutes to days)	Storm (tropical cyclone, extra-tropical cyclone, local storm)
Hydrological	Events caused by deviations in the normal water cycle and/or overflow of bodies of water caused by wind set-up	Flood, mass movement (wet) (rockfall, landslide, avalanche, subsidence)
Climatological	Events caused by long-lived/meso to macro scale processes (in the spectrum from intra-seasonal to multi-decadal climate variability)	Extreme temperature (heat wave, cold wave, extreme weather condition), drought, wildfire (forest fire, land fire)
Biological	Disasters caused by the exposure of living organisms to germs and toxic substances	Epidemic (viral/bacterial/parasite/fungal/prion infectious disease), insect infestation, animal stampede

Adapted from Below et al. Centre for Research on the Epidemiology of Disasters (CRED); Munich Reinsurance Company [3].

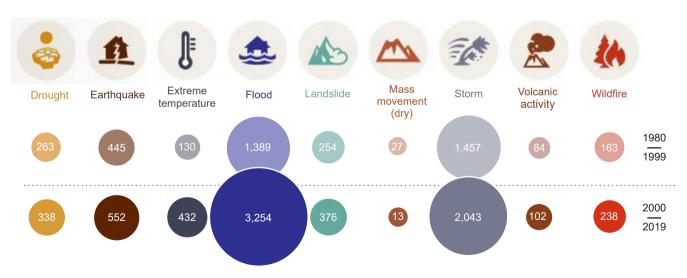


Fig. 1. Total natural disasters by type 1980–1999 vs. 2000–2019. Source: Centre for Research on the Epidemiology of Disasters (CRED); United Nations Office for Disaster Risk Reduction (UNISDR) (https://cred.be/sites/default/files/CRED-Disaster-Report-Human-Cost2000-2019.pdf) [4].

number of events (over 500 events) (Fig. 2) [4]. Further, Pacific Island Countries (PICs) are classified among the world's top 30 most vulnerable nations to natural disasters, with approximately 41 tropical cyclones occurring each year [7].

IMPACT OF NATURAL DISASTERS

Natural disasters result in significant loss of life and long-term disability from severe injuries. Depending on the nature and scale of disasters, the impacts on population, health, and infrastructure may differ, however, the outcomes to a large extent could be similar [8]. Between 2000 and 2019, the natural disaster claimed approximately 1.23 million lives (an average of 60,000 deaths per annum) and affected over 4 billion people (an average of 200 million per year) [4]. These have led to approximately USD 2.97 trillion in economic losses (almost doubled since 1980–1999) (Fig. 3). In recent years, there is a sustained rise in climate- and weather-related events (floods, storms, heatwaves, wildfires in particular) accounting for 41% of total deaths and over 3.9 billion affected in the period 2000–2019 [4]. Geophysical disasters (earthquakes including tsunamis) are

associated with the highest impact on the human toll among all other types of disasters put together (accounting for 59% of all disaster-related deaths) [4]. In 2022 alone, 387 natural disasters worldwide killed over 30,700 people, affecting 185 million others and costing above USD 223.8 billion [9]. Fig. 3 shows the human impact of disasters comparing 1980–1999 with two decades ahead (2000–2019).

High-income countries experienced more disasters compared to low-income countries, and tend to have the most total economic losses. However, these countries have lower numbers of people affected and killed by disaster events, relatively due to better risk governance, infrastructure, surveillance systems, and reduced exposure to natural hazards. Low-income countries account for 23% of total disaster deaths and the highest average number of deaths per disaster event (284 per event) [4]. This is accompanied by a significant proportionate economic loss and long-term negative consequences on human development in these countries (3 times higher gross domestic product [GDP] losses compare to high-income countries) (Fig. 4) [4]. For example, PICs bear, combined disaster damages of more than USD 280 million on average every year, costing some countries



Fig. 2. Total number of disasters reported per country/territory (2000–2019). Source: Centre for Research on the Epidemiology of Disasters (CRED); United Nations Office for Disaster Risk Reduction (UNISDR) (https://cred.be/sites/default/files/CRED-Disaster-Report-Human-Cost2000-2019.pdf) [4].

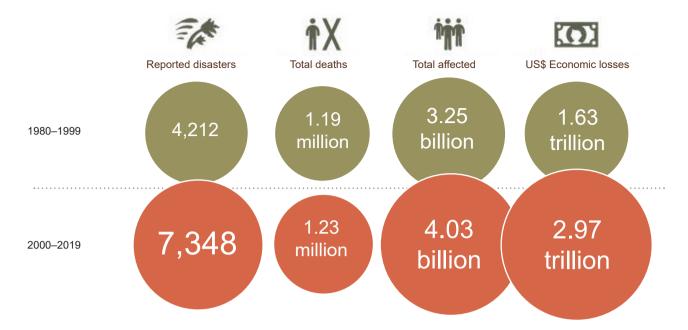


Fig. 3. Impact of natural disaster between 1980–1999 vs. 2000–2019. Source: Centre for Research on the Epidemiology of Disasters (CRED); United Nations Office for Disaster Risk Reduction (UNISDR) (https://cred.be/sites/default/files/CRED-Disaster-Report-Human-Cost2000-2019.pdf) [4].

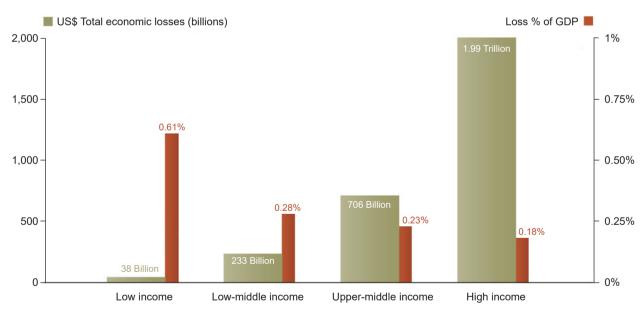


Fig. 4. Economic losses in absolute value (USD) compared to losses as a percentage of gross domestic product (GDP) by World Health Organization income group (2020). Source: Centre for Research on the Epidemiology of Disasters (CRED); United Nations Office for Disaster Risk Reduction (UNISDR) (https://cred.be/sites/default/files/CRED-Disaster-Report-Human-Cost2000-2019. pdf) [4].

up to 6.6% of their GDP [10]. The total value of economic damage and losses caused by the 2010 Haiti earthquake was estimated at USD 7.8 billion, surpassing the country's GDP in 2009, which could delay the country's economic development by 10 years [11]. Further, there was a substantial impact on health services with 30 out of 49 hospitals damaged or destroyed during this event [11].

REHABILITATION NEEDS IN DISASTER SETTINGS

Despite saving lives immediately following disasters being an urgent priority, current, advances in disaster response and management, have resulted in a significant increase in survivors compared to mortality. This includes an upsurge in survivors with complex impairments and disability (temporary or permanent) from common injuries, such as musculoskeletal (bone fractures, limb amputations, crush injuries), spinal cord and/ or traumatic brain injury, soft tissue and peripheral nerve injury, burns, etc. [12]. Overall injury patterns are poorly studied in natural disasters, and the type and severity of injuries vary according to various factors including the type of disasters and geological factors (disaster magnitude and intensity, epicentral distance, etc.), human/individual factors (demographics, physical location, and capabilities, behavior, etc.), and built environment (quality of building and infrastructure, population density, etc.) [13]. The most common type of injuries specifically in earthquakes, which contributes to the highest disaster-related mortality and morbidities, were reported to be orthopedic (87%), with lower extremities fractures being most prevalent (42%) [14,15]. Further, there is a substantial increase in the number of victims with exacerbation of non-communicable diseases (NCDs) (e.g., cardiovascular disease, cancer, chronic respiratory diseases, diabetes, etc.), psychological impairment (such as post-traumatic stress disorder [PTSD], depression, and other mental disorders) [16,17]. The common barriers reported to healthcare access during disasters included: limited and/or disrupted healthcare services, centralized healthcare infrastructure (mostly located in the metropolitan area), financial difficulties, access to transport, affordability of treatment and devices, displacement, and illiteracy [16]. Huang et al. [18] exploring the association of ischemic heart disease (IHD) with natural disasters in 193 countries reported an independent association between the IHD mortality rate (2.3 deaths per 100,000 population) and years of life lost (YLL, 31.1 years per 100,000), and occurrence of natural disasters (p<0.05 for both). Further, those with pre-existing disabilities are at risk of higher mortality rates and additional co-morbidities/ impairments, especially those with mobility impairments [12]. These signify the important role of medical rehabilitation in the comprehensive disaster management plan.

The critical importance of rehabilitation during and after a natural disaster for the survivors is well-documented and the World Health Organization (WHO) recognizes that "rehabilitation is one of the core functions of trauma care systems in regular health care and, as such, Emergency Medical Team (EMT) should have specific plans for the provision of rehabilitation services to their patients post sudden onset disaster" [19,20]. The rehabilitation need and demand can have different patterns in emergencies, and may also differ over time [20]. However, based on clinical needs rehabilitation is required at all stages of the disaster management cycle: in the initial acute stage when there is the influx of trauma and non-trauma emergencies; in the postacute period as complications arise and patients are prepared for discharge; and in the long-term in the community for those with complex, and permanent disabilities [20-22]. Demand for rehabilitation can peak in the first 3 weeks post-disaster and can increase over time, as triaging and discharge of patients (even those who are medically stable) can be problematic, due to the destruction or damage of their homes and livelihood. Further, demand for outpatient and community rehabilitation can spike post-disaster with added care requirements of persons with pre-existing disabilities and chronic conditions, creating additional service needs [20]. Thus, these indicate that rehabilitation services confront the greatest care burden during disasters. Fig. 5 indicates trends in the rehabilitation burden in disasters [21].

ROLE OF REHABILITATION PROFESSIONALS IN DISASTERS

The global health authorities emphasize that medical rehabilitation should be initiated acutely during the emergency disaster response and should be continued in the community over a longer-term [22-24]. The WHO World Report on Disability accentuates that "rehabilitation services are essential services to be provided by foreign aid for humanitarian crises" (p. 108) [25]. The "Sphere Project," in its handbook "Humanitarian Charter and Minimum Standards in Humanitarian Response," further reinforces the importance of rehabilitation and states that surgery provided during a humanitarian crisis without any immediate

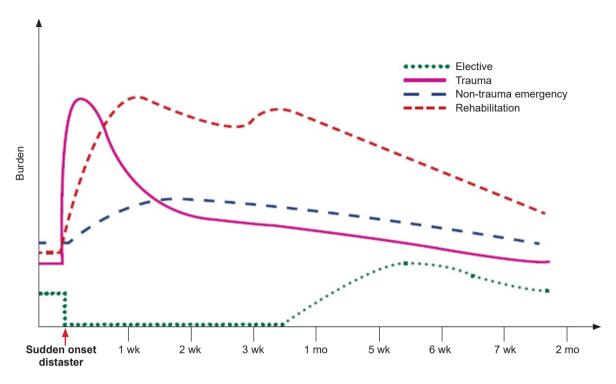


Fig. 5. Trends in the rehabilitation burden in sudden-onset disasters. Adapted from World Health Organization (Emergency medical teams:minimum technical standards and recommendations for rehabilitation; 2016) [20].

rehabilitation can result in poorer patient outcomes [26]. This implies that rehabilitation service is required at all phases of the disaster management continuum, which comprises mitigation/prevention, preparation, response, and recovery phases [22,23,27]. It presents holistic patient-centered care for disaster victims delivered by an interdisciplinary team (medical, nurses, and allied health professionals) developed within available resources, to optimize function, improve activity and participation within contextual factors (personal and environmental) [28]. The role of rehabilitation professionals can be complex and requires a multi-faceted mix of skills and training in disaster continuum phases, including diagnostic, clinical management, educational and advocacy capabilities [23,29]. At times rehabilitation professionals will be required to stretch beyond the roles they are trained for to meet the complex needs of the overwhelming number of disaster victims. Some of the potential roles of rehabilitation personnel in the disaster management cycle are listed in Fig. 6.

The number of international and local EMTs from governmental or non-governmental sources deployed to the disasters are steadily increasing. In many past disasters, deployment of

EMTs was not solely based on the assessed needs of the affected state, and wide variations in their capacities, competencies and adherence to professional ethics can be noted [30]. For example, during the 2010 Haiti earthquake, the international humanitarian response was catastrophic, with the influx of a large number of unregistered EMTs who were unfamiliar with the international emergency response systems and standards, or coordination mechanisms [11]. The WHO EMT initiative now sets the core standards and guidance for EMTs within defined coordination mechanisms in this area [20]. Various guidelines and protocols have been developed including rehabilitation guidelines during disasters, launched in 2016. It provides minimum standards/requirements for all EMTs during deployments to disasters, regarding workforce, field hospital environment, rehabilitation equipment/consumables and information management (Appendix 1-3) [20]. It is recommended that the EMT needs to establish an action plan in consultation with the WHO EMT secretariat, local healthcare authorities, International Society of Physical and Rehabilitation Medicine (ISPRM), and appropriate experts [31]. The following important themes are required for consideration:

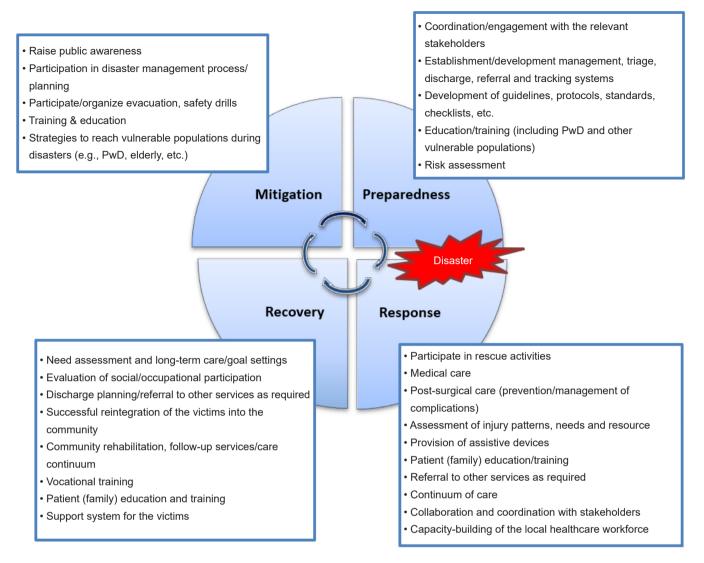


Fig. 6. Potential role of rehabilitation personnel in the disaster management cycle. PwD, persons with disabilities.

- Analysis: study the situation, risk assessments, requirements, etc.
- Objectives: set up key objectives, roles, and responsibilities
- Planning: team configurations, resources (finance, equipment), transportation, accommodation, logistics
- Execution: medical care, response, and management to achieve objectives
- Communication: briefing, reports, support activity, consultation
- Safety: patient and healthcare personal safety
- Transition: handover, care continuum of victims, local capacity building, foster partnership

• Research: evaluation, data collection, and dissemination, identify gaps/challenges, knowledge/information sharing

EVIDENCE OF REHABILITATION INTERVENTIONS IN DISASTER SETTINGS

Table 2 provides a summary of published studies evaluating various rehabilitation interventions in disaster settings. Early involvement in rehabilitation can result in better clinical outcomes, and improve participation and quality of life (QoL) of disaster victims [6,29,32,33]. Evidence from past disasters

Table 2. Summary of studies evaluating rehabilitation interventions in disaster settings

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References	Study type	Interventions	Key findings	Conclusion
Hospital-based rehabilitation program	on program			
Xiao et al. 2011 [40], China Disaster: 2008 Sichuan earthquake	Case series N=174 survivors with tibial shaft fractures	Institution-based rehabilitation interventions delivered by PT	•Functional recovery was positively associated with rehabilitation intervention (OR, 5.3; 95% CI, 2.38–11.67), but negatively correlated with immobilization duration (OR, 0.87; 95% CI, 0.798–0.947), age (OR [per 10 yr increase], 0.54; 95% CI, 0.418–0.707) & depressive symptomatology (OR, 0.21; 95% CI, 0.063–0.716)	Rehabilitation was associated with functional recovery of post-earth-quake survivors with fractures
Zhang et al. 2012 [42], China Cross-sectional qua-Disaster: 2008 Sichuan si-experimental stuearthquake N=390 survivors with fractures	a Cross-sectional quasi-experimental study N=390 survivors with fractures	Institutional-based rehabilitation (details not provided)	Institutional-based rehabilitation •Significant improvement in ADLs and life satisfaction (details not provided) •HRQoL improved higher in early intervention subjects compared with controls (p=0.008) •Good performance of ADL (p<0.001) and widowed marital status (p=0.032) predicted high HRQoL, while pain was associated with worse outcomes (p<0.001) •Rehabilitation therapy, remunerative employment & female gender were predictors of improved life satisfaction	Rehabilitation (early and late) significantly improved functional outcomes, HRQoL, and life sat- isfaction in earthquake fracture victims
Hu et al. 2012 [35], China Disaster: 2008 Sichuan earthquake	Prospective cohort study N=26 (SCI survivors)	Prospective cohort study Institution-based rehabilitation N=26 (SCI survivors) therapy (details not provided)	•Significant improvement in functional status (ADLs, mobility, walking) •Decrease in pain and depressive symptoms •Significant improvement in QoL in the community (p=0.011), self-ratings of QoL (p<0.001), general health (p<0.001), and satisfaction with social relationships (p=0.017) •Improvement in physical health and psychological health improved (not statistically significant)	Significant improvements in: functional status, QoL, general health, satisfaction with social relationships & some areas of community integration (physical independence, mobility)
Li et al. 2012 [32], China Disaster: 2008 Sichuan earthquake	Prospective cohort study N=51 (SCI survivors)	Prospective cohort study Individualized rehabilitation N=51 (SCI survivors) rehabilitation team (physician, allied health therapists (PT, OT, traditional modalities), nurses, volunteers & other medical specialists)	•Thirty-five percent patients achieved moderate ADLs independence and 90.2% regained self-care ability •Rehabilitation program was the strongest predictor of a significant increase in functional scores •Earlier rescue and rehabilitation were significant positive predictors of rehabilitation effectiveness	Significantly improved functional rehabilitation outcomes with organized programs
Ni et al. 2013 [39], China Disaster: 2008 Sichuan earthquake	Retrospective cohort study N=450 survivors with fractures	Institution-based comprehensive rehabilitation program (therapeutic interventions, training/education, and vocational and social rehabilitation (details not provided)	Institution-based comprehensive •Significant improvement in physical dysfunction rehabilitation program (therapeutic interventions, training/esignificant improvement in PTSD symptoms (p<0.05) education, and vocational and education, and vocational and social rehabilitation (details not nessed death and fearfulness were risk factors for PTSD provided) symptoms, 50 mo after the earthquake	Physical dysfunction and PTSD were significantly reduced by rehabilitation intervention

References	Study type	Interventions	Key findings	Conclusion
Li et al. 2015 [37], China Disaster: 2008 Sichuan earthquake	Prospective cohort study N=72 amputees	Institution-based rehabilitation to prevent joint contracture, desensitization, shaping of the residual limbs, joint mobilization, muscle strength training, PT, OT & psychotherapy	•Significant improvement in physical functioning (p=0.016) and decrease in pain scores (p<0.001) •No significant changes in QoL and life satisfaction subscales •Higher rates of literacy associated with better physical and mental health status •Higher age associated with decreased satisfaction with leisure activities & relationships	Significant improvement in functioning and pain over time, however, no change in QoL & life satisfaction
Wu et al 2019 [49], Taiwan Prospective observa- Disaster: 2015 Dust explo-tional study sion disaster, Formosa Fun N=16 hand burn vic- Coast tims; 8 participants both groups	Prospective observational study N=16 hand burn victims; 8 participants in both groups	LMC (virtual reality) video games 20 min after 40 min traditional OT Control group: traditional OT for 60 min 2 day/wk for 4 mo	•Significant improvements in hand function in the LMC group (p<0.05) compared to control group •In LMC-trained hand, thumb IP joint ROM & pinch strength increased, whereas the scar thickness over first dorsal interossei muscle decreased (p<0.05)	Leap motion training could help patients with hand burns to in- crease finger ROM, decrease scar thickness, and improve hand function
Mixed (hospital-and community -based) rehabilitation model Zhang et al. 2013 [43], China Longitudinal quasi-ex- Disaster: 2008 Sichuan perimental study (3- earthquake arm); N=510 follow Earth intervention group of: NG (NHV-E): 298; late depart intervention group volunt (NHV-L): 101; control	unity – based) rehabilitatio Longitudinal quasi-experimental study (3-arm); N=510 Early intervention group (NHV-E): 298; late intervention group (NHV-L): 101; control group: 111	n model NHV rehabilitation program - institutional-based rehabilitation followed by CBR comprised of: NGOs (N), local health departments (H), professional volunteers (V)	•Significant improvement in physical functioning (Barthel Index) in the both NHV-E and NHV-L intervention groups but not in the control group (11.14 points; 95% CI, 9.0–13.3) •Significant effects on spontaneous recovery (5.03 points; 95% CI, 1.73–8.34) •Effect of NHV-E (11.3 points; 95% CI, 9.0–13.7) was marginally greater than that of NHV-L (10.7 points; 95% CI, 7.9–13.6)	Significantly improved physical functioning of earthquake survivors
Li et al. 2019 [38], China Disaster: 2008 Sichuan earthquake	Cross-sectional study N=17 bilateral limb amputees	MD rehabilitation program – StandTall (exercise and education)	•Subjects with bilateral through-knee or transtibial amputations had less activity restriction (p<0.01) & higher mobility (p=0.03) •Subjects using prostheses >50% of waking time had better general adjustment (p=0.02) & less functional restriction (p=0.01) •StandTall program were associated with higher mobility (p=0.06) & mental quality of life (p=0.09)	MD rehabilitation program (Stand-Tall) was associated with positive functional and psychological outcomes in disaster survivors with complex needs (bilateral knee amputees)
Psychological programs Becker 2009 [44], India Disaster: 2004 tsunami	Prospective cohort study N=200	Community-based psychological program (group sessions)	Prospective cohort study Community-based psychological •Significant improvement in psychosocial symptoms IES scores: total (p<0.001) & avoidance (p<0.001), intrusion (p<0.001)	Effective in reducing emotional distress for women tsunami survivors
Berger and Gelkopf 2009 [45], Sri Lanka Disaster: 2004 tsunami	Quasi-RCT with wait-list controls N=166 elementary school students	Quasi-RCT with wait-list School-based mental health controls program N=166 elementary school students	•Significant improvement in PTSD severity (p<0.001), functional problems (p<0.001), somatic complaints (p<0.001), depression (p<0.001), and hope (p≤0.001) scores	Helpful in mitigating post-disaster-related symptoms in children, and those with more severe symptoms benefited most

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References	Study type	Interventions	Key findings	Conclusion
Zang et al. 2013 [41], China Disaster: 2008 Sichuan earthquake	RCT with wait-list controls N=22	NET	•Significant reductions in PTSD symptoms: avoidance, intrusion & hyper-arousal subscales (p<0.001 for all); anxiety & depression (p<0.001), general mental stress (p<0.0001) & increased posttraumatic growth (p<0.001)	Significant positive effect on psy- chological symptoms & general mental health
Jiang et al. 2014 [36], China Disaster: 2008 Sichuan earthquake	RCT with usual care controls N=49, intervention group: 27	12 weekly sessions of IPT, 1 h for 12 wk	•At 3 mo, compared to control group significant reduction IPT is a promising treatment for in the IPT group: PTSD (3.4% vs. 51.9%), major depres-reducing PTSD & depression is sive diagnoses (3.4% vs. 30.1%) • Treatment gains were maintained at 6 mo for the IPT disasters group	IPT is a promising treatment for reducing PTSD & depression in populations surviving natural disasters
Social activity and community programs	ity programs			
Huang and Wong 2013 [47], China Disaster: 2008 Wenchuan earthquake	Before and after qualitative study N=24	Huang and Wong 2013 [47], Before and after qualita- Recreational activity groups China tive study Disaster: 2008 Wenchuan N=24 earthquake	Participants' social networks broadened and strengthened ened Participant recognised the importance of mutual understanding and developed a sense of cooperation After participating in group activities, most women felt life was more meaningful or happy Participants' health improved	Effective in alleviating disaster survivors' feelings of distress & depression, & improves their psychosocial well-being and recovery
Tsuji et al. 2017 [17], Japan Disaster: Great East Japan Earthquake/tsunami 2011	Prospective observational study N=3,567 older survivors	Group exercise and regular walking	•Depressive symptoms slightly improved, mean change in GDS score increased by 0.1 point (95% CI, -0.003 to 0.207) •Frequency of group exercise participation & daily walking time increased by 1.9 day/yr & 1.3 min/day, respectively •After adjusting for all covariates, including personal experiences of disaster, increases in the frequency of group exercise participation (p=0.003) & daily walking time (p=0.054) were associated with lower GDS scores	Participation in group exercises or regular walking may mitigate the worsening of depressive symptoms
Akiyama et al. 2018 [46], Philippines Disaster: 2013 Typhoon Haiyan	Quasi-experimental trial, N=293 students from 3 schools, including 1 intervention school (n=51 students)	MAC: a coaching education program on sports activities	•MAC intervention showed a significant change in self-es- Results showed the feasibility and teem, with the mean score increasing from 20.2 to 21.1 a positive effect of sports activity (p=0.02) with the MAC post-disaster •Neither school in the control group showed a significant change	Results showed the feasibility and a positive effect of sports activity with the MAC post-disaster

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	Study type	Interventions	Key indings	Conclusion
Kuroda et al. 2018 [48], I Japan	Prospective cohort study	Group exercises (1 h twice a month for 1 yr)	•4-yr post-disaster incident functional disability reported Pre-disaster BCL domains were in 24.2% (280 cases): 196 (70%) mild, 84 (30%) severe useful to identify individuals a	Pre-disaster BCL domains were useful to identify individuals at
Disaster: Great East Japan Barthquake/tsunami 2011	N=115: exercise class group: 159 usual care control group: 1,000		•Participants who scored negative compared to those who scored positive in BCL: for the "Physical function" domain HR=2.04 (95% CI, 1.54-2.69) for incident functional disability; for "Cognitive function" HR=1.37 (95% CI, 1.06-1.77); for "Depression" HR=1.60 (95% CI, 1.24-2.08)	risk of functional disability Group exercise therapy showed a significant reduction in incident functional disability
			•Both low- and high-participation exercise groups had a significantly lower rate of incident functional disability compared to non-participating group (HR=0.27, 95%CI, 0.16–0.46; HR=0.30, 95%CI, 0.12–0.74, respectively)	
Fahmida et al. 2022 [50], Quasi-experim Indonesia Disaster: 2018 East Lombok <5 years old) earthquake Intervention gr (n=240); usua	Quasi-experimental trial (N=480 children <5 years old) Intervention group (n=240); usual service control group (n=240)	Community-based comprehensive nutrition rehabilitation, based on the holistic integrated early child development concept	•Significant reduction in depression in mothers in the intervention group (61% vs. 43% post-intervention, p<0.001); vention has a positive effect no change in control group (43% vs. 40%, p=0.272) •Child morbidity (cough) lower and dietary diversity (+1) in 6-23-month-old children, & weight-for-age Z-score (+0.26) & social-emotional score (+10 points) in 24-month-old children were higher in intervention group	Nutrition rehabilitation intervention has a positive effect on the growth & development of children

N, total number; PT, physiotherapists; OR, odd ratio; 95% CO, 95% confidence interval; ADL, activity of daily living; HRQoL, health-related quality of life; SCI, spinal cord injury; QOL, quality of life; MD, multidisciplinary; OT, occupational therapists; PTSD, post-traumatic stress disorder; LMC, leap motion control; IP, interphalangeal; ROM, range of motion; CBR, community-based rehabilitation; NGO, nongovernmental organization; IES, Impact of Event Scale; RCT, randomized controlled trial; NET, narrative exposure therapy; IPT, interpersonal psychotherapy; GDS, Geriatric Depression Scale; MAC, Mastery Approach to Coaching; BCL, Basic Checklist; HR, hazard ratio.

suggests that victims treated in centers with rehabilitation physician supervision had a reduced length of hospital stay, fewer complications and better clinical outcomes compared with patients without such provision [33,34].

Box 1. Summary of the desk review of the evidence of rehabilitation interventions in disaster settings

A rapid desktop review was conducted to update the evidence from our previous review published in 2015 [23] evaluating the effectiveness of medical rehabilitation intervention in natural disaster survivors. This comprehensive review included 10 studies (2 randomized controlled trials [RCTs] and 8 observational studies) that investigated a variety of medical rehabilitation interventions for natural disaster survivors, ranging from comprehensive multidisciplinary rehabilitation to community educational programs. This review highlighted the lack of high-quality evidence to support rehabilitation interventions used for disaster survivors. The gaps identified in the literature included the types of rehabilitation settings, modalities and duration of therapy, lack of effective care pathways, and long-term functional outcomes. A similar multipronged approach was used to search the literature (peer review, grey literature from the date of the last search date till May 2023) including search of the peer-review literature using medical and health science electronic databases (MEDLINE, PubMed, Embase, Cumulative Index to Nursing and Allied Health Literature, PsycINFO, Cochrane Library); manual search of bibliographies of relevant articles and journals; and search of grey literature using relevant Internet search engines and websites of prominent health care institutions, governmental and nongovernmental organizations associated with disaster management and rehabilitation.

The combined searches retrieved a total additional 260 published titles and abstracts. Twelve abstracts met preliminary inclusion criteria, and the full texts of these articles were assessed. In addition to the 10 articles included in our previous review [23], a further 8 articles (1 RCT, 2 controlled clinical trials, and 5 observational studies) which reported medical rehabilitation interventions after natural disasters were included (Table 2).

The published literature indicates that a wide variety of medical rehabilitation modalities are trialed in natural disaster survivors both in hospital and community settings. The evaluated interventions were heterogeneous (type, duration and mode of delivery) and specifically included, comprehensive multidisciplinary rehabilitation, physical modalities, psychological programs, community programs, and others. The majority included physical activity and psychosocial intervention as rehabilitation components. The study population group also differed in many facets.

The findings suggest that despite the lack of high-quality evidence for the effectiveness of many of the evaluated rehabilitation interventions, there is distinct evidence for the beneficial effect of medical rehabilitation for survivors of natural disasters in producing short and long-term gains for functional activities (activities of daily living, physical activity, etc.), impairments (e.g., psychological symptoms), and participation (QoL, social reintegration) [6,32,33]. Institution-based and community rehabilitation interventions provided by the multidisciplinary team to 2008 Sichuan earthquake victims in China were associated with significant improvement in functional outcomes, decrease symptoms and improved health-related QoL [32,35-43]. The rehabilitation interventions were the strongest predictor of increased and sustained functional gains and improved QoL in these patients [32]. Further, other studies demonstrated the beneficial effect of hospital-based and/or community-based rehabilitation programs in improving psychological issues such as anxiety, PTSD symptoms, distress and depression [17,36,39,41,44,45]. Zhang et al. [43] evaluated a long-term structured and coordinated rehabilitation services model that provided both comprehensive hospital and community-based rehabilitation, comprising nongovernmental organizations (NGOs), local health departments (H) and volunteers (V) for earthquake survivors in China. The findings suggest that the NHV comprehensive rehabilitation program benefitted the individual and society with significant improvement in longterm physical functioning [43]. Another study showed psychological rehabilitation intervention (structured in-community psychological care) significantly improved psychosocial symptoms (PTSD, depression, stress, etc.) in post-tsunami victims [44]. Group and social activities post-disaster were found to enhance victims' societal participation and improve psychosocial well-being [17,46-48]. Wu et al. [49] demonstrated that modern technological intervention (virtual reality videogames) adjunct to traditional occupational therapy interventions can

have better improvement in function, scar management, and hand function in patients with severe hand burns. In another study, Fahmida et al. [50] showed that integrated community-based nutrition rehabilitation intervention can have benefits in reducing maternal stress, child morbidity and in improving the growth and development of children in post-disaster conditions. However, there was no evidence for the best type/mode/intensity (frequency, duration) of these interventions or the superiority of one intervention over another. There is a limited number of robust studies in this area, which reflects various ethical, methodological and logistical challenges in conducting research in disaster situations.

CURRENT DEVELOPMENTS

Since the catastrophic disaster management process during the 2010 Haiti earthquake, there was a strong consensus amongst the international medical and humanitarian communities for a stringent approach to emergency response in future disasters in terms of governance, coordination, organisation, evaluation, professionalism and accountability. In the last decade, there have been many much-needed developments in disaster response and management (including rehabilitation) in international, regional and national collaboration and management capacities. The WHO's EMT initiative is fundamental in this area to improve the timeliness and quality of health services provided by EMTs and enhance the capacity of national health systems in leading the activation and coordination of rapid response capacities aftermath of a disaster, outbreak and/or other emergencies. It adopts a rigorous and systematic approach to EMT registration, deployment, and response, It has set out benchmark requirements and standards for all EMTs and classifies all medical teams according to their capability into 4 main types (Appendix 1) [19]. The WHO-EMT initiative highlights that rehabilitation is one of the core components of regular health care and, as such, all EMTs (both national and international) should have specific and coordinated medical response plans for the provision of rehabilitation services to their patients [20]. Minimum technical standards and recommendations for rehabilitation for EMTs are published in collaboration with the ISPRM, and global rehabilitation experts (Appendix 2) [20]. It is a mandatory requirement that all EMTs, including specialized care teams comply and adhere to these principles and standards. The efficacious coordination, leadership and governance role of the EMT initiative was demonstrated in various natural

disasters such as the 2013 typhoon Haiyan in the Philippines, the 2015 tropical cyclone Pam in the Pacific region, 2015 Nepal earthquakes, and others [30,51]. A comprehensive registration system for all EMTs was initiated (since July 2015), which enables the establishment of a global EMT registry for future deployment (Appendix 3) [19]. To date, 37 acute medical/surgical teams (Type 1: 21, Type 2: 12, Type 3: 2 and 1 Specialized cell) from different parts of the world have progressed to full verification and many more teams have commenced the mentorship and quality assurance process. However, currently, any rehabilitation specialized cell is yet to be verified. Further various reports and guidelines, including specific clinical practice guidelines from different sources, are now published [52-54] and e-learning [55] professional development courses in disaster management are being developed (https://www.disasterready. org/).

Some of the key global initiatives related to disaster rehabilitation are summarised in Table 3 [20,26,51,56-67].

CHALLENGES AND FUTURE PERSPECTIVES

Despite all aforementioned developments and significant improvements in emergency response and care, in many previous disasters rehabilitation services are less prioritised [12]. Further, many vulnerable cohorts, such as persons with disabilities and/ or with pre-existing NCDs, etc., are often overlooked throughout the disaster management cycle. The United Nations Office for Disaster Risk Reduction (UNDRR) estimates that 71% of persons with disabilities do not have an individual preparedness plan for disasters and almost 85% have not participated in community disaster management and risk reduction processes in their communities [68]. Regrettably, significant disparities and gaps still exist among the countries, with those with high disaster risk having a low-coping capacity and scarce resources (infrastructure, skilled workforce, etc.) to address the challenges of the increasing frequency of disasters and their impact [6]. In many disaster-prone countries, rehabilitation-inclusive disaster management plans are absent and rehabilitation services are generally inadequate or underdeveloped [6,7,69]. For example, the density of skilled rehabilitation professionals in many lowand middle-income countries (LMICs) is estimated to be 10 per 1 million population [70] and the unmet need is across many specialized rehabilitation services such as rehabilitation medicine, physiotherapy, occupational therapy, prosthetics and orthotics, and others [70]. There are also contrasts and imbalanc-

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Table 3. Ney global disaster reflabilitation-related militatives	on-related miniatives	
Initiative/strategy	Key features	Comments
Hyogo Framework for Action 2005–2015: Building the Resilience of Nations and Communities to Disasters, UNDRR 2005 [56]	Comprehensive global blueprint for disaster risk reduction adopted by 168 UN member states at the World Conference on Disaster Risk Reduction in Kobe, Japan, in 2005 Key 5 priorities for action Ensure that disaster risk reduction is a national and a local priority with a strong institutional basis for implementation Identify, assess and monitor disaster risks and enhance early warning Use knowledge, innovation and education to build a culture of safety and resilience at all levels Reduce the underlying risk factors Strengthen disaster preparedness for effective response at all levels	• Voluntary and non-binding • Embraced by central and local governments, the private sector and civil society groups • In 2015, Hyogo Framework focal points in 191 countries and 85 platforms for disaster risk reduction, and 141 countries have carried out at least one review of their efforts to implement this Framework for action
GFDRR, 2006 [57]	Key initiative to assist developing countries, reduce their vulnerability to natural hazards, with a global partnership of over 45 countries and international organisations Conducts post-disaster needs assessments and support in recovery and reconstruction, to reduce costs Implements programs in partnership with national, regional, and other international agencies, in accordance with the SFDRR, the Paris Agreement on Climate Change, and the UN SDGs	 Include rehabilitation and reconstruction, aligns with the SFDRR priorities and disaster-risk management activities No details of programs focused on building capacity in rehabilitation medicine
EMT Initiative, WHO 2016 [51]	18 18	 Categorised EMTs into 4 types Registration system (2015) to enable the establishment of a global registry of EMTs to improve the quality of medical team response in disasters Demonstrates a systematic organized approach for the deployment of EMTs in disasters
SFDRR 2015-2030, UNDRR 2015 [58]	Successor instrument to the Hyogo Framework and introduces innovations and emphasises on disaster risk management as opposed to disaster-management • Key 4 priorities for action: -Understanding disaster risk -Strengthen disaster risk governance to manage disaster risk -Investing in disaster risk reduction for resilience -Enhancing disaster preparedness for effective response, & to "Build Back Better" in recovery, rehabilitation & reconstruction	 Broadens disaster risk reduction significantly to focus on both natural and man-made hazards and related environ- mental, technological and biological hazards and risks Specified term "rehabilitation," (in Priority 4), however, more inclined towards the rehabilitation of infrastructure

Initiative/strategy	Key features	Comments
Sphere Project Handbook, Greaney et al. $2018[26]$	• Sets common principles and universal minimum standards for the delivery of • Voluntary initiative initiated by a group of humanitarian quality humanitarian response NGOs & the Red Cross and Red Crescent Movement in	 Voluntary initiative initiated by a group of humanitarian NGOs & the Red Cross and Red Crescent Movement in
	• Published handbook "Humanitarian Charter and Minimum Standards in Humanitarian Response"	1997 • Specifies: medical teams with inpatient capacity must be
	 Includes minimum standards in key response sectors: Water Supply, Sanitation and Hygiene Promotion (WASH); Food Security and Nutrition; Shelter and Settlement; & Health 	able to provide early rehabilitation
	\bullet Specifies the importance of timely access to rehabilitation services for restoring functional capacities, improving survival, QoL & social reintegration of victims	
EMT rehabilitation guidelines, WHO 2016 [20]	 Titled: "EMTs: minimum technical standards and recommendations for reha- Key minimum standards: bilitation" 	Key minimum standards: •≥1 Rehabilitation professional per 20 beds at time of initial
	• Developed by the Rehabilitation Working Group under the EMT initiative	deployment, with further recruitment as required
		• Allocation of purpose-specific rehabilitation space of >12
	 Provide the minimum standards for all EMTs regarding workforce, field hos- nital environment rehabilitation equipment/consumables and information 	III. 101 all type 3 EM 18 • Denlovment of FMTs with at least the essential rehabilita-
		tion equipment/ consumables
Disaster Rehabilitation Committee, ISPRM 2021 [59]	One of the key ISPRM committees promoting the ISPRM's policy statement of for the response to sudden onset disasters and to support its humanitarian mission	Coordinate activities on disaster rehabilitation with ISPRM National Societies (>70 with over 7,000 members) and the WHO-ISPRM Liaison Committee
	\bullet Advocate the rehabilitation medicine perspective in minimizing disability and optimizing functioning and HRQoL in disaster victims	
	\bullet Collaborates with the WHO Liaison Committee on WHO disaster-related disability initiatives	
	 Provides technical resources and expertise to relevant stakeholders including WHO, UN, local governments, NGOs, disability organisations, national PRM Societies & others 	
	 Capacity building through education/training Generate evidence through research & knowledge dissemination 	
SDGs, UN 2017 [60]	nclusive	 Disaster risk reduction and management incorporated into 10 out of 17 SDGs
	ure healthy lives and promote wellbeing for all at all ages" specifisises rehabilitation as the key health strategy	 SDGs aim to eliminate poverty, reduce inequalities, in- cluding new areas: climate change, economic inequality, innovation, sustainable consumption, and neace & instice
	 Disaster risk reduction is at the foreiront of the SDGs Develop policies to enhance the quality of life by improving rehabilitation services 	etc.
	\bullet Uphold the rights, ensure full inclusion & equitable healthcare for PwD	

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Initiative/strateow	Key features	Commente
"Rehabilitation 2030: A call for action," WHO 2017 [61,62]		• Input from rehabilitation stakeholders from health policy, clinical practice, users, funders, academia, and development experts from 46 countries • Highlights the critical work to enhance access to rehabilitation, particularly in LMICs
Global Cooperation on Assistive Technologies (GATE), WHO 2018 [63]	 Goal: to improve access to high-quality affordable assistive products globally as a part of UHC WHO partnership with stakeholders who represent international organizations, donor agencies, professional organizations, academia, and user groups. Focusing on five interlinked areas (5P): people, policy, products, provision, and personnel 	 Adopted in 71st World Health Assembly 2018 Emphasize the need for a comprehensive, sustainable and multisectoral approach Develop, implement & strengthen policies and programs within UHC
Health Emergency and Disaster Risk Management Framework, WHO 2019 [64]	 Vision: highest possible standard of health and well-being for all people who are at risk of emergencies, and stronger community & country resilience, health security, UHC and sustainable development Core principle: risk-based approach, comprehensive emergency management, all-hazard approach, inclusive, multisectoral & multidisciplinary collaboration, whole-of-health system based and ethical consideration Provide overview on: policies, strategies & legislation; planning & coordination; human & financial resources; information & knowledge management; risk communications; health infrastructure & logistics; community capacities; monitoring & evaluation 	 Focus on infectious disease outbreaks, emergencies due to natural, technological and societal hazards More inclined towards infrastructure rehabilitation
EMT 2030 Strategy, WHO 2022 [65]	Vision: every country has the capacity to respond rapidly and effectively to national emergencies Mey priorities: -Strength effective partnership, leadership & operational governance -Provide comprehensive, accessible and quality health service -Implement and scale up strategies for standardization and quality assurance -ance -Strengthen information system, evidence and research	 Developed in response to WHO's Strengthening the Global Architecture for Health Emergency Preparedness, Response and Resilience, 2022 Launched at the 5th EMT Global meeting, Armenia, 2022
World Rehabilitation Alliance (WRA), WHO 2023 [66]	 WHO global network of stakeholders whose mission is to support the implementation of the Rehabilitation 2030 Initiative through advocacy activities. Objectives: to conduct evidence-based advocacy activities that increase awareness and demand for rehabilitation, networking and knowledge-sharing and for creating a shared understanding and narrative around rehabilitation. Focuses on promoting rehabilitation as an essential health service that is integral to UHG and to the realization of SDG Goal 3: ensure healthy lives and promote well-being for all at all ages. 	 Launched in 2022 Consists 5 workstreams: workforce, primary care, research, emergencies, and external relations

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Initiative/strategy

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Comments	 Adopted in 27th World Health Assembly 	\bullet Support the implementation of "Rehabilitation $2030''$							
Key features	Resolution on "Strengthening rehabilita- • The resolution calls for expanding and integrating rehabilitation in health	systems as part of UHC, emphasizing the importance of rehabilitation in primary care and as part of emergency preparedness and response	• Aims to support member states in prioritizing rehabilitation within their	health systems, promoting equitable access to rehabilitation services, and im-	proving the lives of individuals with disabilities, injuries, and chronic health	conditions	• Key points: Broad definition of rehabilitation, recognition of the role of reha-	bilitation, health system strengthening, equity and human rights, data and	
Initiative/strategy	Resolution on "Strengthening rehabilita-	tion in health system" WHO 2023 [67]							

for Disaster Risk Reduction; NGO, nongovernmental organization; QoL, quality of life; ISPRM, International Society for Physical Rehabilitation Medicine; HRQoL, health-related quality of life; PRM, physical and rehabilitation medicine; PwD, persons with disabilities; GDAP, global UN, United Nations; GFDRR, Global Facility for Disaster Reduction and Recovery; SFDRR, Sendai Framework for Disaster Risk Reduction; SDG, Sustainable Development Goal; EMT Emergency Medical Team; WHO, World Health Organization; UNDRR, United Nations Office ! disability action plan; LMIC, low- and middle-income country; UHC, universal health coverage es within operational healthcare systems in many countries in terms of policies, funding structure/infrastructure, capacity, human and physical resources, technology, etc. Further, in largescale disasters, even the world's best healthcare systems can be overwhelmed due to damage and/or disruptions of local existing health service infrastructure and an influx of new victims. The coronavirus disease 2019 pandemic is such an example that has tested the resilience of robust health systems of most developed countries, like the United States, Australia, France, Italy, Spain, the United Kingdom, etc [71]. Moreover, various barriers and gaps still exist in the comprehensive rehabilitation-inclusive disaster management process, which includes poor awareness, insufficient leadership and governance, inadequate coordination, financial constraints, limited political, etc [31,72].

Global healthcare authorities acknowledge the important role of rehabilitation within the context of overarching disaster management systems and lack and/or limited rehabilitation services/workforce capacity can compromise outcomes. There is a need for effective action from national and international bodies for comprehensive rehabilitation-inclusive disaster responses to strengthen national capacity, and foster an environment of self-empowerment of rehabilitation medical personnel/teams for sustainable long-term care. This requires strong leadership from governing organizations and 'shared' responsibility from all actors in the field [31]. Various perspectives need to be considered for effective future disaster management, which include (but are not limited to):

- Strengthen robust collaboration and governance from healthcare organisations
- Strengthen political commitment and allocation of adequate resources at the highest level to rehabilitation inclusive disaster management process
- Emphasise on disaster risk reduction and climate change mitigation
- · Accelerate capacity building and training for skilled interdisciplinary rehabilitation workforce
- Increase public awareness and education
- Persistent and timely communication with the public, healthcare workers, government agencies, and industry
- Training and educational programs for healthcare professionals regarding rehabilitation-inclusive disasters manage-
- Embrace a system-wide approach for rehabilitation-inclusive disaster planning, with active participation/inclusion

- of disaster survivors/family, persons with disabilities, other stakeholders and the community at large
- Strengthen access to rehabilitation services including assistive devices
- Develop effective strategies for reaching/supporting vulnerable population cohorts during disasters (e.g., persons with disabilities)
- Development of innovative interventions and various alternative methods of service delivery including, telerehabilitation, rehabilitation in the home, mobile clinics
- Promote task shifting and coordination between international EMTs, local healthcare authorities and humanitarian actors
- Strengthen community-based rehabilitation and provision of long-term needs/support of disaster survivors Formulate a formal registry of accredited rehabilitation professionals for deployment to disaster settings
- Recognition of social and cultural barriers within the disaster settings
- Improve communication (information gathering, sharing and disseminating)
- Development of standardized assessment and monitoring tools, and injury-specific rehabilitation guidelines in disaster settings
- Strengthen research and data collection

CONCLUSION

Rehabilitation is an essential part of the disaster management and recovery process. It involves restoring the physical, psychological, and social functioning of affected individuals and can help to mitigate the long-term impacts of disasters (disabilities, health complications, mental health), improve QoL and provide an effective pathway to recovery and successful reintegration of the victims into the community, and reduce the burden on healthcare systems. While there is no one-size-fits-all approach to disaster rehabilitation, there is evidence suggesting various interventions/strategies that can be employed to ensure that the process is effective and efficient. It can be a complex and often lengthy process and requires all-inclusive planning and coordination approaches including strong governance and coordination, engaging with stakeholders (including vulnerable population cohorts such as persons with disabilities), developing a plan of action, and focusing on a long-term continuum of care.

There is strong consensus amongst global health authorities

that medical rehabilitation should be initiated in the immediate emergency response phase and should be continued post-disaster over a longer term. Despite this, rehabilitation services are often neglected in previous disasters and many disaster-prone countries still have low coping capacity and limited rehabilitation resources. The current endorsement of the landmark resolution by the World Health Assembly: "Strengthening Rehabilitation in Health Systems," the WHO aims to support member states in prioritizing rehabilitation within their health systems, promoting equitable access to rehabilitation services, and integrating rehabilitation and assistive technology in its EMTs including addressing the long-term rehabilitation needs of people affected by emergencies. Further, the WHO-EMT initiative and now set out a structure and standardization for future medical team deployments (including rehabilitation) to ensure that quality care is provided to those in need. There are still lots of challenges ahead and successful and effective rehabilitation-inclusive disaster management will depend on the proficient leadership of the governing bodies (international and national), and the willingness and commitment of countries to build systematic advance planning and preparedness, and building local rehabilitation capacities (skilled workforce, infrastructure, funding) to ensure that effective and timely services are available to vulnerable communities at risk in future calamities.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

Conceptualization: Amatya B. Methodology: Amatya B. Formal analysis: Amatya B, Khan F. Project administration: Amatya B. Visualization: Amatya B, Khan F. Writing – original draft: Amatya B. Writing – review and editing: Amatya B, Khan F. Approval of final manuscript: all authors.

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Appendix 1. Emergency Medical Team classification

Туре	Description	Minimal benchmark indicators (per day)	Minimum length of stay
Type 1 (mobile)	Provides daylight hours care for stabilization of acute trauma and nontrauma presentations, referrals for further investigation or inpatient care & community-based primary care with the ability to work in multiple locations over the period of a deployment		2 wk
Type 1 (fixed)	Provides daylight hours care for acute trauma and non-trauma presentations, referrals, and ongoing investigation or care & community-based prima- ry care in an outpatient fixed facility		2 wk
Type 2 Inpatient surgical emergency care	Provides Type 1 services plus general and obstetric surgery for trauma & other major conditions as well as inpatient acute care	>100 outpatients; 1 operating theatre with a minimum of 20 inpatients beds/operating table; 7 major or 15 minor operations	3 wk
Type 3 Inpatient referral care	Provides Type 2 services plus complex referral and intensive care capacity	>100 outpatients and >40 inpatients; at least 2 operating tables & 40 inpatient beds (20 beds/operating table) 15 major or 30 minor operations; at least 4 intensive care beds	4 wk
Specialized care team	Additional specialized care teams that can be embedded in local healthcare facilities or Type 2 or Type 3 unless specified otherwise, can provide the following services: outbreak, surgical, rehabilitation, mental health, reproductive and newborn care, interdisciplinary, interhospital and technical support.	Teams offering care embedded into existing fa- cilities & able to provide the equipment and con- sumables related to the services they are offering for the entire period of their deployment	

Adapted from World Health Organization (Classification and minimum standards for emergency medical teams; 2021. p. 1-147) [19].

Appendix 2. Summary of technical standards for rehabilitation specialized team

Team configuration Team should be comprised of ≥3 rehabilitation professionals, should be multidisciplinary and include at least one PT & other rehabilitation discipline(s): OT, rehabilitation physician, nurse, others Qualification & experience Rehabilitation professionals should have at least bacholor's degree or equivalent in their respective discipline, ≥3 yr experience in trauma injury rehabilitation ≥1 Team member (preferable the team leader) should have experience in emergency response & all team members should have undergone training in working in austere environments Rehabilitation equipment* Team should have capability to rapidly provide necessary equipment for deployment Team can provide >3 professionals representing at leas rehabilitation disciplines (one of which is PT), who are available for rapid deployment Team can provide copies of professional qualifications and declarations of at least three years clinical experience in trauma injury rehabilitation = (in trauma injury rehabilitation ence in trauma injury rehabilitation ence in trauma injury rehabilitation = (in trauma injury rehabilitation ence in trauma injury rehabilitation ence in trauma injury rehabilitation of an arrangement to have the equipment rapidly provided (including financial and logistical capability) in the event of the team's deployment Team that embeds into an EMT should stay for the minimum length of stay of that EMT (3 wk for Type 2; 4-6 wk for Type 3) A team that embeds into a local facility should plan to stay		Minimum technical standards	Requirements for verification
sionals, should be multidisciplinary and include at least one PT & other rehabilitation discipline(s): OT, rehabilitation physician, nurse, others Qualification & experience Rehabilitation professionals should have at least bachelor's degree or equivalent in their respective discipline, ≥3 yr experience in trauma injury rehabilitation ≥1 Team member (preferable the team leader) should have experience in emergency response & all team members should have undergone training in working in austere environments Rehabilitation equipment* Team should have capability to rapidly provide necessary equipment for deployment Team can provide copies of professional qualifications and declarations of at least three years clinical experience in trauma injury rehabilitation **Team can present either a stockpile of the rehabilitation equipment, or documentation of an arrangement to have the equipment rapidly provided (including finatial and logistical capability) in the event of the team's deployment Team that embeds into an EMT should stay for the minimum length of stay of that EMT (3 wk for Type 2; 4–6 wk for Type 3) A team that embeds into a local facility should plan to stay			
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for≥l mo	Length of stay	mum length of stay of that EMT (3 wk for Type 2; 4–6 wk for Type 3)	wk), to facilitate appropriate placement with an EMT or local facility if deployed

Adapted from World Health Organization [20].
PT, physiotherapists; OT, occupational therapists; EMT, Emergency Medical Team.

a) List of rehabilitation equipment is detailed in the guidelines (https://extranet.who.int/emt/guidelines-and-publications).

Appendix 3. Eight-step pathway of the global EMT classification process. Adapted from World Health Organization (Classification and minimum standards for emergency medical teams; 2021. p. 1-147) [19]. EMT, Emergency Medical Team; SOPS, Standard Operating Procedures; DG WHO, Director-General World Health Organization.

1 EXPRESSION OF INTEREST	SELF ASSESSMENT	3 MENTOR ASSIGNMENT	4 MENTORSHIP PROCESS	5 PRE- VERIFICATION VISIT	6 VERIFICATION VISIT	7 INTERNATIONAL REGISTRATION
Team applies online indicating the type of EMT or Specialized Care Team in which it wants to be classified.	Team performs a self- assessment according to guiding principles, core and technical standards to define the starting point and gaps.	The Global and the Regional EMT Secretariat assign a mentor to the team, who will support them during the entire process. Technical experts are available if needed.	Process to conform to with guiding principles, core and technical standards, through revision and/ or development of SOPS, training of staff and evidence compilation.	Present complete evidence package demonstrating compliance with guiding principles, core and technical standards, Agreement about readiness to proceed with verification visit.	Formal external peer review of the team's compliance with guiding principles, core and technical standards and recommendation for Classification if compliance demonstrated.	Team is formally registered in the category it has applied, valid for 5 years. Formal ceremony with the DG WHO.
			minimum standard level of quality tha	ntinuity of meeting t ds and maintaining t t allowed it to regist nationally.	he RECLASS	8 SIFICATION

Original Article

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Validation of Wearable Digital Devices for Heart Rate Measurement During Exercise Test in Patients With Coronary Artery Disease

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Objective: To assess the accuracy of recently commercialized wearable devices in heart rate (HR) measurement during cardiopulmonary exercise test (CPX) under gradual increase in exercise intensity, while wearable devices with HR monitors are reported to be less accurate in different exercise intensities.

Methods: CPX was performed for patients with coronary artery disease (CAD). Twelve lead electrocardiograph (ECG) was the gold standard and Apple watch 7 (AW7), Galaxy watch 4 (GW4) and Bio Patch Mobicare 200 (MC200) were applied for comparison. Paired absolute difference (PAD), mean absolute percentage error (MAPE) and intraclass correlation coefficient (ICC) were evaluated for each device.

Results: Forty-four participants with CAD were included. All the devices showed MAPE under 2% and ICC above 0.9 in rest, exercise and recovery phases (MC200=0.999, GW4=0.997, AW7=0.998). When comparing exercise and recovery phase, PAD of MC200 and AW7 in recovery phase were significantly bigger than PAD of exercise phase (p<0.05). Although not significant, PAD of GW4 tended to be bigger in recovery phase, too. Also, when stratified by HR 20, ICC of all the devices were highest under HR of 100, and ICC decreased as HR increased. However, except for ICC of GW4 at HR above 160 (=0.867), all ICCs exceeded 0.9 indicating excellent accuracy.

Conclusion: The HR measurement of the devices validated in this study shows a high concordance with the ECG device, so CAD patients may benefit from the devices during high-intensity exercise under conditions where HR is measured reliably.

Keywords: Wearable electronic devices, Cardiac rehabilitation, Heart rate, Exercise test

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INTRODUCTION

Cardiac rehabilitation (CR) is an essential component in the continuum of care for patients with cardiovascular disease. The safety and efficacy of CR are well documented, but CR participation rates remain low and suboptimal worldwide. Despite

being eligible candidates, over 80% of patients in the United States and 50% in the United Kingdom do not participate in CR [1,2]. Factors such as reluctance to participate in group rehabilitation, inconvenient exercise schedule, career responsibilities, transportation, and related costs were prominent barriers to CR participation [3,4]. In addition, during the coronavirus disease

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2019 pandemic, safe distancing measures have led to cessation of center based cardiac rehabilitation (CBCR) programs [4].

Home based cardiac rehabilitation (HBCR) has been introduced as an alternative strategy to expand access and participation over conventional CBCR [3,5]. In concept, HBCR could help overcome barriers for CBCR such as geographic, occupational and other access related barriers.

Heart rate (HR) is an important parameter for determining appropriate exercise intensity and establishing a safe zone when performing self-monitored aerobic exercise during HBCR [6,7]. Commonly, patients are instructed to take pulse rate (PR) at their radial or carotid artery and measure their arterial beats for 10 seconds (and multiply it with 6 to get HR per minute), but this method is difficult and inconvenient during aerobic exercise and also is less accurate [6].

With the recent development of technology, commercial electronic devices with HR monitor in forms of chest straps, smart watches and smart bands have been introduced and are being used worldwide. The HR measurement derived from these tools not only reflect patient's condition but also provides guidance for appropriate exercise [7].

Researches on the accuracy and validity of HR measuring wearable devices have been actively reported [6-13]. However, the reports on HR accuracy so far are somewhat inconsistent. Depending on type of the devices, such as chest strap, patch, smart band or smart watch, the HR accuracy was variable. Chest strap type tended to be more accurate than other wrist worn devices [8]. Smart watches were more accurate in terms of HR (actually PR) than relatively inexpensive smart bands [8-10]. Also, the accuracy of these devices fluctuated in accordance to the intensity or type of exercise [6,10]. HR measured by smart band seemed to be inaccurate with high intensity aerobic exercises [6].

To the best of our knowledge, although previous reports were made recently, these studies were conducted with relatively old and inexpensive series of available wearable devices [7,8-13]. In this study, we used the latest products from the two electronics companies with the largest market share in the world, which are Apple watch 7 (AW7; Apple Inc.) and Galaxy watch 4 (GW4; Samsung). We also included a recently introduced patch type HR monitoring device, Bio Patch Mobicare 200 (MC200; Seers Technology), to compare with the smart watches.

We hypothesized that the newer wearable devices compared to the older models would be more accurate with HR monitoring and show higher correlation with the 12 lead electrocardiograph (ECG), which is the gold standard. This study aimed to confirm the validity and accuracy of HR measurement in recently released commercial smart watches and chest patch device, during cardiopulmonary exercise test (CPX).

METHODS

The study protocol was approved by the Institutional Review Board of Inje University (no. 2021-10-007). All the participants provided written informed consent. The researcher explained the purpose, methods, advantages, and potential risk of the study to every participants. Patient privacy and data confidentiality were maintained throughout the study period. The smart watches used in the study were purchased at researcher's own expense. The authors declare no conflict of interest.

Sample size calculation

Since free software calculating sample sizes for reliability coefficients are relatively scarce, the calculation was performed on a web-based calculator in accordance to the article by Arifin [14]. The test-retest reliability of a measurement tool by intraclass correlation coefficient (ICC) is expected=0.9. The measurement was taken at two occasions (12 lead ECG vs. each wearable device). The lowest acceptable ICC is 0.75 [14,15]. A significance level of α =0.05 and a power of 90% were set. In conclusion, 44 subjects were required for this study.

Participants

This was a comparative observational study recruiting outpatients of Cardiac Rehabilitation Clinic at Inje University Sanggye Paik Hospital, Inje University College of Medicine, from June 2022 to September 2022. We included 44 patients aged 20 to under 75, diagnosed with coronary artery disease, including acute coronary syndrome and stable angina, and subsequently referred for CR. These patients were scheduled for outpatient CPX as a regular follow-up exam. For this study, the participants had to put on extra wearable devices while going through CPX. Patients with contraindications to CPX were excluded according to the guideline by the American Heart Association (AHA) [16]. Also, patients referred for CR with other cardiac etiologies, such as valvular or aortic disease, were excluded from the study.

CPX

CPX was performed on a treadmill and stress test system (T-2100 & CASE; GE Healthcare) according to the modified Bruce protocol. In this study, respiratory gas analyzer (Quark CPET; COSMED), automatic blood pressure and pulse monitor (TAN-GO M2; SunTech) were used to measure physiologic variables. The HR recorded from the CPX machine was set as the gold standard.

All three wearable devices used in this study were recently released products within a year. MC200 is a device approved for long term ECG recording by the Korean Ministry of Health and Welfare in February 2022. MC200 was attached along the axis of lead II, from lateral aspect of left upper sternum to apex of heart. GW4 and AW7, which are wrist strap type, were worn around left and right wrists respectively. We looked up in the product instructions and fitted the watches exactly where it should be (2–3 cm above styloid process of radius). It was fixed to a hole of a strap that could fit the device as tight as we could so it doesn't move sideways, but also not as much as it would choke patient's wrist. To reduce the bias caused while fastening the strap, one researcher helped put on the device in person so that the straps were adjusted to participants' wrist with less inconsistency.

In the rest phase, which lasted for 6 minutes, patients were sat on a chair while blood pressure and ECG were being monitored. HR from 12 lead ECG and wearable devices were recorded every two minutes during the rest phase. After 6 minutes, exercise phase started according to the modified Bruce protocol with gradual increase in intensity and HR was recorded every minute during all exercise stages until termination of the test. The participants held handrails in front of them to prevent seri-

ous harm during the CPX test since the most participants were middle-aged. Termination of the test was decided according to the "Indications for termination of exercise testing" of AHA guidelines [16]. Lastly, in the recovery phase, patients kept walking slowly for additional 5 minutes, and HR was measured every minute (Fig. 1).

Statistical analysis

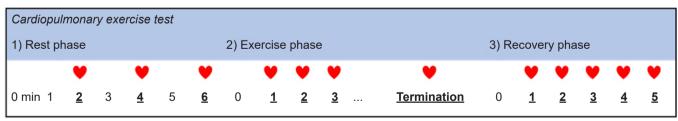
All data were analyzed using IBM SPSS ver. 25 (IBM Corp.) and the values were presented as means ±standard deviation (SD) or numbers and percentages. The HR data from gold standard 12 lead ECG and each wearable devices were analyzed with following parameters.

First, paired relative difference and paired absolute difference (PAD) were calculated to assess accuracy, by subtracting the HR recorded by wearable devices (HR $_{\rm DEV}$) from the HR recorded by the 12 lead ECG from CPX machine (HR $_{\rm ECG}$). Also, mean absolute percentage error (MAPE) values were calculated as the average absolute value of the errors of each wearable device relative to 12 lead ECG, the gold standard measure, expressed in percentage. Fokkema et al. [17] suggest a MAPE threshold of 5%, whereas Nelson and Allen [18] used a MAPE threshold of 10% to classify a wearable device as valid.

The degree of agreement between the values of two devices was examined using the ICC with 95% confidence interval (CI).

The thresholds suggested by Fokkema et al. [17] were used; excellent, 0.90 or above; good, 0.75–0.90; moderate, 0.60–0.75; and low, 0.60 or below.

In addition, Bland–Altman plot with 95% limits of agreement (LoA) was used to measure each outcome relative to the gold standard. The differences of each sample are scattered on the



♥=HR measurement

Fig. 1. Heart rate (HR) measurement during cardiopulmonary exercise test. HR was recorded at 2, 4, and 6 minutes in rest phase. HR was recorded every minute beginning from 1 minute during exercise phase until termination of the test. HR at termination, which was the beginning of recovery phase, was also recorded and once every minute subsequently in recovery phase. The time points for HR measurement are in bold and underlined. Also, these time points are marked with heart shape (\checkmark), respectively.

vertical axis and the average of two measurements are scattered on the horizontal axis. The plot contains three horizontal lines indicating the mean difference and upper and lower LoA which could be calculated as the mean difference±1.96 SD of differences [19].

RESULTS

Total 44 of 36 male and 8 female patients were included for the study. In CPX results, average attained stage was 6.0, lasting average 16 minutes 26 seconds. Average rate of perceived exertion was 16.4 with respiratory exchange ratio of 1.2. The average of peak oxygen uptake and peak metabolic equivalents were 25.8 and 7.4, respectively. The baseline characteristics and summary of CPX results are presented in Table 1. Incidence of arrhyth-

Table 1. Baseline characteristics of participants

Characteristic Age (yr) Sex, male:female	Value (n=44) 60.9±7.9 36:8 165.5±8.0
Sex, male:female	36:8
·	
	165.5±8.0
Height (cm)	
Weight (kg)	70.0±10.9
Body mass index (kg/m ²)	25.5±2.9
Diagnosis	
STEMI	12 (27.3)
NSTEMI	9 (20.5)
Unstable angina	13 (29.5)
Stable angina	10 (22.7)
Electrocardiograph at rest	
Normal sinus rhythm	20 (45.5)
Sinus bradycardia	16 (36.4)
1 °AV block	3 (6.8)
Premature atrial beat	7 (15.9)
Premature ventricular beat	4 (9.1)
Intervention	
Percutaneous coronary intervention	42 (95.5)
Coronary artery bypass graft	2 (4.5)
Cardiopulmonary exercise test results	
Attained stage	6.0 ± 0.59
Duration of test (min:s)	16:26±1:53
VO_{2AT} (mL/kg/min)	18.7±4.6
VO _{2peak} , (mL/kg/min)	25.8±5.1
$METs_{peak}$	7.4±1.5
$\mathrm{RPE}_{\mathrm{max}}$	16.4±1.4
Respiratory exchange ratio	1.2±0.1

Values are presented as mean±standard deviation, number only, or number (%). STEMI, ST segment elevation myocardial infarction; NSTEMI, non STEMI; 1 °AV block, 1st degree atrioventricular block; $VO_{\rm 2AD}$, oxygen uptake at anaerobic threshold; $VO_{\rm 2peak}$, peak oxygen uptake; METs_{peak}, peak metabolic equivalents; RPE_{max}, maximal rate of perceived exertion.

mias during CPX test and total number of HR records for each patient are described in Table 2. There were participants with frequent premature beats but there were no sustained arrhythmias that could fluctuate HR during CPX.

Average paired relative difference and relative percent difference of all the devices were within absolute value of 1 at all phases (Table 3). Average PAD were also around 1 at all phases, with AW7 showing maximal 1.29 at recovery phase. Absolute percent difference of all three devices at all phases did not exceed value of 2%. ICC of all the devices exceeded 0.99 at all the phases, except for AW7 resulting in 0.984 at rest phase but still showing excellent correlation.

On the other hand, influence of HR itself on accuracy of the devices were evaluated. HR recordings from exercise phase and recovery phase were grouped into two subgroups of "HR below 100" and tachycardia, which were "HR at or above 100" (Table 4). PAD, MAPE, and ICC were obtained. Although not always statistically significant, there were some tendency of HR accuracy variability according to HR and CPX phases. PAD values tended to be larger when HR was above 100, and MAPE values tended to be larger when HR was below 100. However, PAD and MAPE did not exceed value of 2 and ICC values were above 0.9 in every circumstances regardless of HR or phases.

Fig. 2 presents Bland–Altman analysis, where solid horizontal lines indicate the average HR differences in each device. Two dashed lines indicate upper and lower 95% confidence LoA for each device respectively. MC200 showed average difference of 0.24, with upper and lower LoA of 2.80 and –2.32, respectively. Average difference of GW4 was –0.18 with 95% LoA of 3.58 and –3.95. Lastly, AW7 had mean value of 0.11 and 95% LoA of 3.33 and -3.22, respectively.

In Table 5, ICC values of the devices in accordance to HR divided into interval of 20, ranging from below 100, 100–119, 120–139, 140–159 to at or above 160 were analyzed. The ICC value was highest at HR below 100 in all three devices. The accuracy decreased when HR was over 100 in all groups. GW4 showed the lowest ICC of 0.867 at HR at or above 160 and AW7 showed the lowest value of 0.925 at HR between 140–159. MC200, on the other hand, showed minimum ICC of 0.980 at HR between 100–119 and 120–139.

The overall ICC of three devices, analyzed with the overall HR measurements, were 0.999, 0.998, and 0.997 for MC200, AW7 and GW4 respectively with MC200 being the most accurate (Fig. 3).

Table 2. Numbers of arrhythmia and total heart rate measurements in each patient

Patient no.	Atrial premature complex	Ventricular premature complex	Paroxysmal supraventricular tachycardia	Other arrhythmias	No. of heart rate records
1	16	21	1	0	21
2	0	0	0	0	24
3	196	1	1	0	23
4	0	2	4	0	24
5	0	0	3	0	20
6	0	16	8	0	23
7	0	21	0	0	25
8	0	0	1	0	27
9	0	0	0	0	25
10	6	1	4	0	28
11	54	8	6	0	25
12	0	0	9	0	24
13	5	0	1	0	23
14	2	1	1	0	26
14 15	0	15	17	0	23
16	0	0		0	
			5		26
17	18	9	5	0	21
18	0	3	4	0	23
19	18	0	1	0	26
20	0	6	1	0	26
21	0	1	12	0	24
22	0	2	2	0	24
23	4	1	0	0	24
24	0	2	0	0	24
25	0	0	0	0	22
26	0	2	0	0	24
27	0	109	4	0	23
28	6	0	4	0	21
29	0	4	6	0	24
30	6	0	0	0	25
31	0	8	4	0	25
32	0	0	0	0	24
33	0	0	0	0	24
34	0	0	1	0	21
35	0	0	0	0	24
36	0	1	9	0	23
37	0	10	2	0	28
38	0	0	0	0	24
39	0	0	1	0	24
40	0	0	1	0	20
41	0	0	0	0	25
42	0	2	4	0	23
42 43		4			23 25
	4		4	0	
14	0	0	5	0	26

Values are presented as number for each variable.

DISCUSSION

In this study, we aimed to verify the accuracy of HR monitoring function of wearable devices by performing the CPX according to the modified Bruce protocol. The devices used in the study, all commercialized recently, were AW7 and GW4, both of which were released by the top 2 largest electronics companies in the global smart watch market. For comparison, MC200, a chest

Table 3. Average HR differences between each wearable device and 12 lead ECG

			HR differences	from 12 lead ECG		
Device		Paired relative difference ^{a)}	Paired absolute difference ^{b)}	Relative percent difference ^{c)}	Absolute percent difference ^{d)}	ICC
REST	MC200	0.17±1.47	0.85±1.21	0.27± 2.33	1.33±1.93	0.990
	GW4	-0.30 ± 1.46	0.86±1.21	-0.49±2.37	1.37±1.99	0.990
	AW7	-0.34±1.89	1.01±1.63	-0.49±2.81	1.55±2.39	0.984
EXE	MC200	0.18±1.23	0.67±1.05	0.16±1.38	0.70±1.20	0.999
	GW4	0.03±1.95	0.99 ± 1.57	-0.08±1.88	0.99±1.60	0.997
	AW7	0.33±1.41	0.78±1.22	0.25±1.50	0.78±1.31	0.998
REC	MC200	0.57±1.37	1.07±1.03	0.51±1.29	1.04±0.89	0.998
	GW4	-0.98±2.14	1.26±1.99	-1.00±2.33	1.25±2.49	0.994
	AW7	-0.46±2.24	1.29±1.88	-0.44±2.39	1.31±2.31	0.994

Values are presented as mean±standard deviation.

HR, heart rate; ECG, electrocardiograph; ICC, intraclass correlation coefficient; REST, rest phase; MC200, Mobicare 200; GW4, Galaxy watch 4; AW7, Apple watch 7; EXE, exercise phase; REC, recovery phase; DEV, test device.

Table 4. PAD, MAPE, and ICC of each device during exercise phase and recovery phase

	N	Mobicare 200		G	Galaxy watch 4			Apple watch 7		
	PAD	MAPE	ICC	PAD	MAPE	ICC	PAD	MAPE	ICC	
<exe100< td=""><td>$0.66\pm1.27^{a)}$</td><td>0.81±1.52^{b)}</td><td>0.989</td><td>$0.89\pm1.57^{\mathrm{b})}$</td><td>1.07±1.85^{b)}</td><td>0.983</td><td>$0.69\pm1.35^{a,b)}$</td><td>0.84±1.63</td><td>0.987</td></exe100<>	$0.66\pm1.27^{a)}$	0.81±1.52 ^{b)}	0.989	$0.89\pm1.57^{\mathrm{b})}$	1.07±1.85 ^{b)}	0.983	$0.69\pm1.35^{a,b)}$	0.84±1.63	0.987	
≥exe100	$0.68\pm0.73^{a)}$	$0.57\pm0.63^{b)}$	0.999	$1.10\pm1.56^{\mathrm{b}}$	$0.89\pm1.24^{b)}$	0.994	$0.88\pm1.03^{a,b)}$	0.70 ± 0.78	0.998	
<rec100< td=""><td>$0.86\pm0.74^{\mathrm{a,b})}$</td><td>1.01±0.84</td><td>0.991</td><td>1.24±2.52^{b)}</td><td>1.45±2.96</td><td>0.952</td><td>1.41±2.38^{a)}</td><td>1.64±2.68</td><td>0.947</td></rec100<>	$0.86\pm0.74^{\mathrm{a,b})}$	1.01±0.84	0.991	1.24±2.52 ^{b)}	1.45±2.96	0.952	1.41±2.38 ^{a)}	1.64±2.68	0.947	
≥rec100	$1.27\pm1.20^{a,b)}$	1.07±0.99	0.993	$1.27\pm1.30^{\rm b)}$	1.06±1.05	0.993	1.16±1.25 ^{a)}	0.98±1.08	0.993	

Values are presented as mean±standard deviation.

PAD, paired absolute difference; MAPE, mean absolute percentage error; ICC, intraclass correlation coefficient; <exe100, exercise phase with heart rate under 100 beats/min; <rec100, recovery phase with heart rate under 100 beats/min; ≥rec100, recovery phase with heart rate 100 or over 100 beats/min.

patch type device for a long-term ECG recording approved by the Korean Ministry of Health and Welfare on February 2022, was adopted.

A few earlier studies have assessed the HR accuracy of various smart devices. Boudreaux et al. [9] reported the average MAPE of Apple watch 2 as 4.14 and the average ICC as 0.9. But, the exercise intensity was reported to affect the HR accuracy with the MAPE as 7.16 at maximum at high intensity exercise and the ICC as 0.8 at minimum [9]. In another study, the values of the MAPE were all affected by the exercise intensity. The MAPE of Apple watch (series unclarified) varied from 1.14% to 6.70%—the highest MAPE value in the moderate intensity exercise; the MAPE of Fitbit from 2.38% to 16.99%; and the MAPE of Garmin Forerunner 225 from 7.87% to 24.38% [10]. Likewise, the overall HR accuracy depended on the type of devices, series, and models, and the type of exercise and intensity.

Many other studies have showed somewhat high MAPE and low correlation coefficient value with less accurate HR values of

the devices during exercise [7,8-13]. Though chest-patch devices are known to be more accurate than other types of devices, it was reported that even the chest-patch devices (Mobicare 100) showed a correlation coefficient of 0.69 during high intensity exercise with above HR 160 [6,8].

In contrast, the devices used in this study showed the MAPE value of less than 2% and ICC value of over 0.9 in every circumstance, which shows a high correlation with the gold standard 12 lead ECG—except the HR measurement from GW4 in high intensity exercise phase with HR over 160, showing ICC of 0.867. Still, the minimum value of ICC still showed a good correlation that is similar or higher than that of previous reports conducted with other older devices.

In the exercise phase of modified Bruce protocol, the exercise intensity increases every three minutes. Also, when the CPX terminates, the exercise intensity and the HR begins to decrease radically in recovery phase. The initial increase of HR in the exercise phase are caused by the parasympathetic withdrawal,

 $^{^{}a)}HR_{EGG}-HR_{DEW}$ b) the absolute value of $(HR_{EGG}-HR_{DEW})$, $^{c)}(HR_{EGG}-HR_{DEW})$ / $HR_{EGG}\times 100$, and $^{d)}$ the absolute value of $(HR_{EGG}-HR_{DEW})$ / $HR_{EGG}\times 100$.

^{a)}Significant difference (p<0.05) of parameters within each device in accordance to phases with same heart rate interval.

 $^{^{\}mathrm{b}}$ Significant difference (p<0.05) of parameters within each device, in accordance to heart rate interval within same phase.

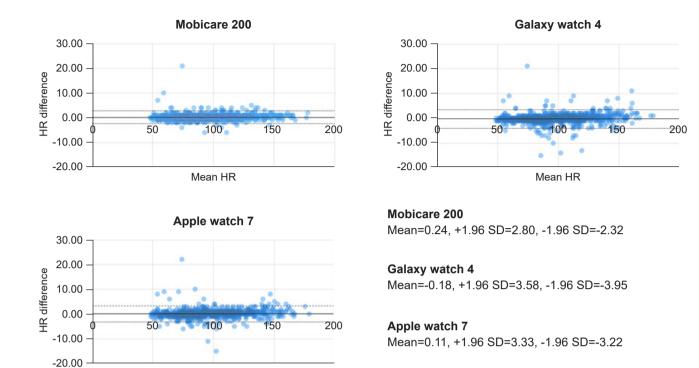


Fig. 2. Bland-Altman plots show agreement between 12 lead electrocardiograph, the gold standard and each wearable device. Solid horizontal lines indicate average heart rate (HR) differences in each device. Dashed lines indicate 95% confidence limits of agreement for each device. SD, standard deviation.

Table 5. Intraclass correlation coefficient in accordance to heart rate interval

Mean HR

Devices			Heart rate		
Devices	<100	100-119	120-139	140-159	≥160
Mobicare 200	0.994	0.980	0.980	0.984	0.990
Galaxy watch 4	0.989	0.955	0.970	0.912	0.867
Apple watch 7	0.989	0.979	0.977	0.925	0.970

Values are presented as intraclass correlation coefficient of each device in accordance to heart rate interval.

while sympathetic activation is responsible for HRs greater than 100 beats/minute. Also, the rapid drop in HR for the first minute after the cessation of exercise is mostly determined by parasympathetic reactivation [20]. Due to the impaired autonomic regulation, CAD patients show delayed HR recovery which may take up to five minutes [21,22]. We postulated that such changes in HR according to the exercise intensity would affect HR accuracy of the devices.

Accordingly, the HR measurements in the exercise and recovery phase were divided into four subgroups based on "HR below 100" and "HR above 100." Since the MAPE is an indicator expressed as percentage, the MAPE values tended to be small

when the denominator was greater than 100, and be big when the denominator was less than 100 (Table 4). Thus, the PAD was analyzed along with the MAPE for precise comparison.

The PAD values of MC200 and AW7 were significantly larger in recovery phase than in exercise phase. The PAD values of GW4 and MAPE values of all the devices did not show any significant difference between phases, but the values tended to be larger in recovery phase than those in exercise phrase as postulated. However, since the HR difference between phases were about 1 bpm on average, the difference would not indicate any clinical significance in the real world. Also, ICC values exceeded 0.9 in all conditions, which showed a high reliability.

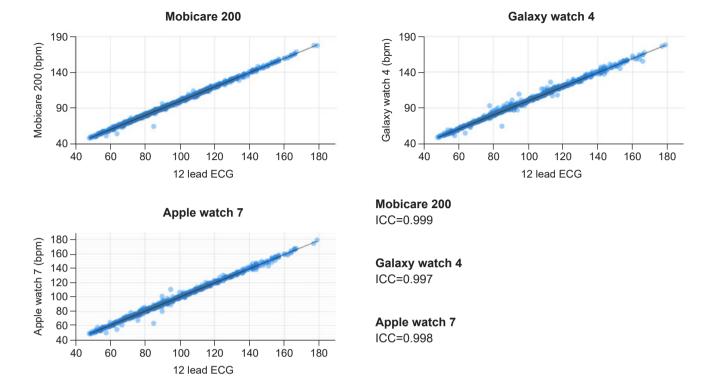


Fig. 3. Scatter plots show correlation between 12 lead electrocardiograph (ECG) vs. each wearable device. Diagonal lines are lines of identity. Each dot is a separate measurement of heart rate. ICC, intraclass correlation coefficient.

In addition, the comparison between the HR subgroups within the same phases showed some significant differences, but the results were inconsistent.

To examine HR accuracy in accordance with the exercise intensity, we stratified the HR measurements by the interval of 20. As in Table 5, the ICC of all three devices were highest when HR was below 100. Though the ICC tended to decrease as HR increased, the relationship was not linear, in that it showed the lowest ICC at the moderate intensity of HR between 140 and 159 in MC200 and AW7. It is consistent with the previous studies that suggest a higher accuracy with vigorous exercise than with slow walking [23-25]. However, as previously mentioned, the lowest ICC values of all three devices were still higher than those of other studies, indicating an overall high level of accuracy regardless of the exercise intensity.

As chest-strap-based HR monitors were first introduced in the 1980s, several studies have already confirmed the accuracy of these monitors as a prototype of HR measuring devices [26-28]. However, these devices were only used by elite athletes due to its inconvenience. Nowadays, new, convenient wrist-worn HR monitors have garnered public attention. Unlike the chest-

strap type directly sensing one's cardiac electric activity, these devices use photoplethysmogram (PPG) sensors that detect variations in blood volume in peripheral vessels produced by each cardiac contraction by projecting photons into body tissues and analyzing the reflected light. Such a PPG technique is one of the most widely adopted HR measuring technologies in smart devices produced these days [23].

Sampling frequency, defined by "the number of samples per second (or per other unit) taken from a continuous signal to make a discrete or digital signal," is an important concept to better understand mechanism and pitfalls of PPG sensors. A higher sampling frequency indicates a higher accuracy of analysis because more data samples are collected in the same time interval [29]. Gold standard ECG used in this study collects data at the frequency of 512 Hz, and MC200 collects at the frequency of 256 Hz. The exact sampling frequency of AW7 and SW4 are not made public. While the sampling frequency of the previous Samsung Watch is estimated to be between 20–25 Hz [30,31], Apple describe that their HR monitor blink hundreds of times per second to measure HR, without mentioning the precise sampling frequency [32]. Likewise, the discrepancy in

each sampling frequency may be an important reason for different accuracy between devices.

On the other hand, PPG sensors have some drawbacks. According to previous research, PPG sensors show low accuracy of HR measurements with darker skin likely because darker skin with more melanin absorbs more green light than lighter skin [29]. Moreover, the accuracy of PPG sensors are susceptible to motion artifact especially when the motion was cyclic or repetitive (e.g., walking and jogging). An accelerometer, which senses changes in velocity over time, is one of the methods used to detect motion artifact and filter this output as noise reference [29,33].

In this study, we established that the new devices demonstrate the high accuracy of HR measurements even in the high-intensity aerobic exercise and during a rapid change in HR. It could be attributable to advanced technologies such as algorithms for signal processing in the models released recently.

Still, there are several limitations in this study. First, there is an imbalance of the gender distribution of the participants with more male ones, probably due to male-dominant prevalence of CAD [34,35]. However, previous studies concluded that the effect of gender on HR accuracy is none or unlikely clinically relevant [35,36]. Second, participants with severe or sustained arrhythmia (such as atrial fibrillation or ventricular tachycardia) were not recruited for the study. The HR accuracy might decline when participants have such arrhythmias while measuring the HR. Third, participants held handrails in front of them for safety measures during the CPX. Since the hand position was fixed during the CPX, compared to regular running or jogging, the HR accuracy might have been overestimated with less motion artifact. Also, other aerobic exercises such as tennis. swimming, and skiing, or other forms of exercise such as resistance training may yield a different result.

Fourth, the results from this study may not be able to be generalized because only one device from each brand was used due to the cost. Some variations might be observed between devices when customers actually purchase these products. In addition, the effect of whether the wrist to wear a watch is left or right was not considered. One previous research concluded that neither left nor right hand wearing the device affected the accuracy of HR measurements [6]. Yet, it could have been more accurate if the hand wearing the device was randomized as part of an attempt to determine the factors affecting the accuracy of HR measurement. Also, even though one researcher helped the participants put on the devices as tight as possible, since the strap had holes in a straight line with regular interval for the users to

fasten the strap, the devices could not be worn with fine adjustment. The tightness of the strap was decided without objective measurement of tension or pressure, but rather subjectively. Hence, the tightness of the devices might not have been consistent among participants. Lastly, although the HR values from all the devices were displayed on the monitor in real-time, we were not able to check all the values simultaneously. However, the time lag between HR records were less than a few seconds. As the electronics technology advances with newer products, additional studies that supplements such limitations will be necessary in the future.

In the present study, we evaluated the HR accuracy of wearable devices recently released during the CPX test performed by participants holding handrails. We concluded that new devices demonstrate the superior accuracy of HR measurement, compared to previous studies conducted with old devices even during the high intensity exercise. It is likely that cardiac patients participating in the high-intensity exercise under condition where HR is measured reliably, may benefit from utilizing these wearable devices. Also, as many people worldwide already own these watches, it will be helpful for both cardiac patients and healthy people when they do self-exercise.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

Conceptualization: Kim C. Methodology: Kim C, Song JH, Kim SH. Formal analysis: Song JH, Kim SH. Project administration: Kim C. Visualization: Kim C, Song JH, Kim SH. Writing – original draft: Song JH. Writing – review and editing: Kim C, Song JH, Kim SH. Approval of final manuscript: all authors.

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The Effect of Home-Based Cardiac Rehabilitation on Cardiovascular Risk Factors Management

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Objective: To compare the efficacy of home-based cardiac rehabilitation (HBCR) and center-based cardiac rehabilitation (CBCR) in cardiovascular risk factor management.

Methods: We performed retrospective review of the electronic medical records of 72 patients who were hospitalized for acute coronary syndrome and participated in a cardiac rehabilitation (CR) program for the first time. The participants were stratified into the HBCR group, receiving educational programs and performing self-exercise at home, and the CBCR group, participating in electrocardiogram monitoring exercise training in hospital settings. The results of the Lifestyle Questionnaire survey were investigated at baseline, 3 months, and 6 months.

Results: Both groups showed significant improvements in serum low-density lipoprotein levels, frequency of alcohol consumption, eating habits and psychological status. Moderate-intensity exercise duration and the maximal metabolic equivalents values improved significantly in both groups but slightly more in the CBCR group. However, the number of current smokers increased in both groups, and no significant changes were found in body mass index, serum glycated hemoglobin levels, serum high-density lipoprotein levels, or high-intensity exercise duration.

Conclusion: Regardless of the CR program type, a patient's lifestyle can be modified. Therefore, patients should continue participating in any type of CR program.

Keywords: Acute coronary syndrome, Cardiac rehabilitation, Heart disease risk factors, Life style, Secondary prevention

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INTRODUCTION

After acute coronary syndrome (ACS), all survivors need to rigorously manage their documented cardiovascular (CV) risk factors to improve long-term outcomes. Cardiac rehabilitation (CR) is the most important evidence-based intervention for the secondary prevention after ACS [1,2].

CR is categorized into three main phases as follows: Phase 1 (early mobilization during acute in-patient hospitalization),

Phase 2 (rehabilitation services traditionally delivered in an outpatient setting that focus on health behavior change, risk factor modification, and psychosocial well-being), and Phase 3 (long-term maintenance of lifestyle changes) [3]. In Phase 2, patients typically receive center-based CR (CBCR) for approximately 3 months of outpatient-monitored exercise programs, but the participation rates are very low [4,5]. Therefore, home-based CR (HBCR) was introduced to expand the access and participation of patients compared with conventional CBCR [6].

According to a Cochrane Review [7], HBCR and CBCR showed similar effects in improving clinical health-related quality of life outcomes. Additionally, managing CV risk factors for patients with coronary artery disease (CAD) is as important as improving cardiorespiratory fitness (CRF) levels [8]. However many comparative studies of HBCR and CBCR have been focused on the efficacy of exercise-based CR program for increasing CRF level. Thus, it is necessary to assess the degree of CV risk factor management rather than exercise effect using CR.

This study aimed to retrospectively compare the effects of HBCR and CBCR, focusing on CV risk factor management by reviewing patients' electronic medical records (EMRs).

METHODS

Study design

We retrospectively analyzed patients' EMRs at a single center (Inje University Sanggye Paik Hospital). Patient privacy and data confidentiality were maintained throughout the study period. The study was approved by the Institutional Review Board of Inje University Sanggye Paik Hospital (IRB No. 2022-12-001). The requirement for informed consent was waived due to the retrospective nature of the study.

Participants

Patients who met the following criteria were included in the study: (1) patients who participated in the CR program for the first time between March 1, 2020 and December 31, 2021; (2) patients who were diagnosed with ACS and underwent percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG) surgery or treated with drugs, who were diagnosed with valvular heart diseases or aortic dissection and underwent surgery, who were diagnosed with cardiomyopathy or acute heart failure and treated with drugs; and (3) those who visited the CR clinic for regular follow-up for 3 and 6 months and performed the cardiopulmonary exercise (CPX) test.

The exclusion criteria were as follows: (1) inability to ambulate due to physical problems including paralysis due to stroke, spinal cord injury, amputation, severe musculoskeletal pain, and dyspnea, among others and (2) incomplete EMRs.

Group assignments were performed at outpatient visits. The decision of whether patients would receive CBCR or HBCR program was based on the risk of exercise-related CV events set by the American Association of Cardiovascular and Pulmonary Rehabilitation [9] and the socioeconomic factors of each patient

including time conflict to attend CBCR, distance between home and center, economical status, etc. High-risk patients were preferentially assigned to CBCR group and other patients were assigned to CBCR or HBCR according to each patient's choice by their socioeconomic status. Although patients were classified as "high-risk" according to the risk classification, they were assigned to the HBCR group if they could not participate in the CR program in a hospital setting. Also, if low-risk patients who might be assigned to the HBCR group wanted a CBCR program, they were assigned to the CBCR group to exercise. Fig. 1 presents the patients' selection flow chart.

Intervention

The CR program was performed at a single institution according to the exercise prescription by exercise test using modified Bruce protocol [10]. Patients were asked to visit the CR clinic within 2 weeks after discharge for those who received the PCI and within 4 weeks after discharge for those who had surgery. At the first visit, patients were asked to undergo a series of tests, including the CPX test and a questionnaire to understand their lifestyle. Real-time recording 12-channel electrocardiography

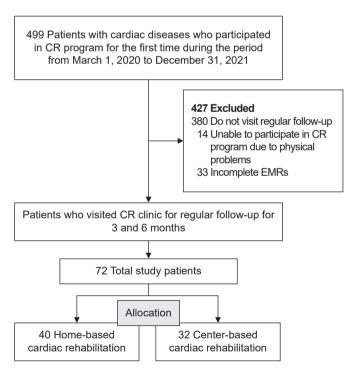


Fig. 1. Flow diagram indicating progress of patients through the study. CR, cardiac rehabilitation; EMRs, electronic medical records.

(CASE; GE-Marquette), respiratory gas analyzer (Quark CPET; COSMED Co.), automatic blood pressure and pulse monitor (TANGO M2; SunTech Medical Inc.), and treadmill (T-2100; GE-Marquette) were used in the CPX test. Several variables were measured in the CPX test, and changes of maximal metabolic equivalents (METs_{max}) were used to compare changes in CRF levels. If the respiratory exchange rate was not sufficiently obtained due to the patient's poor condition or other reasons, the test was performed again on a different date so that reliable results could be obtained.

The survey used the "Lifestyle Questionnaire" adapted from the "Health Insurance Corporation Health Checkup Questionnaire" [11]. The questionnaire included past history, family history, smoking and drinking habits, and questions about recent exercise habits, eating habits, and psychological status. Smoking habits were investigated as to whether or not to guit and maintain smoking. Drinking habits were examined to determine the number of times a person drank alcohol per month. Regarding exercise habits, the number of days and minutes per week of moderate-intensity and high-intensity exercises were assessed separately. In contrast, regarding eating habits, the intake of high-cholesterol food was identified by classifying it into three stages. Body mass index (BMI) was calculated by measuring the height and weight, and blood tests, including serum glycated hemoglobin (HbA1c), low-density lipoprotein (LDL), and high-density lipoprotein (HDL), were compared by referring to the blood test results performed as follow-up tests at the outpatient clinic of the cardiology department.

The CR exercise program was structured as follows: They were asked to exercise for approximately 1 hour a day, 3 to 4 times per week. It comprised 5 minutes of warm-up stretching, 3 to 5 minutes of light cycling or walking, up to 40 minutes of exercise, and 5 to 10 minutes of cool down. Exercise programs prescribed to each patient included fast walking, treadmill exercise, power walking, cycling, and jogging, depending on exercise ability and condition. The initial exercise intensity was gradually increased step by step according to the target heart rate. The target heart rate was set to 60%-85% of the heart rate reserve value calculated using the maximum and minimal heart rates obtained from the CPX test. At every exercise session, patients were supervised and followed the direction of CR staff for keeping above 85% of target heart rate goal. The CBCR group visited the hospital for exercise under supervision and participated in 36 sessions for 3 to 4 months. The CBCR group participated in at least 10 of the 36 sessions of the CR program in the hospital over 3 to 4 months. Subsequently, the patients were encouraged to exercise at home after completion of 36 sessions in hospital setting. In the HBCR group, they received education on CR exercise methods and conducted self-exercises near their residences after their first visit to the CR clinic. Patients in the HBCR group were instructed to monitor their heart rate by wearing a smart watch or smart band or checking their radial pulse. The HBCR group exercised alone based on the training content, and self-management including exercise was completely self-sufficient.

All patients in the CR programs were asked to manage their risk factors such as smoking and diet. On their first visit, they were asked to participate in a 30-minute educational program on dietary methods. This education was conducted by a nutritionist who is in charge of dietary education for outpatients at hospital. If patients had difficulty quitting smoking, they were instructed to receive counseling from the smoking cessation center, if necessary. The patients were then asked to revisit the CR clinic at 3 and 6 months. During the revisit, patients underwent follow-up CPX tests and questionnaires. They were also encouraged to continue risk factor management by receiving feedback on how effectively they did exercise and managed risk factors compared with their first visit. The study outcome was investigated based on the CPX test results, blood test results, and lifestyle surveys between the first visit and, 3 and 6 months. In particular, we focused on comparing how well each patient's risk factors are managed.

Statistical analysis

Data were analyzed using IBM SPSS version 25 (IBM SPSS). An independent t-test was used to compare the baseline characteristics of the two groups, including age and left ventricular ejection fraction (LVEF). Pearson's chi-square test was used to analyze the baseline characteristics of the two groups for sex, smoking history, cardiac diagnosis, comorbidity, family history of cardiac disease, type of intervention and change in number of smokers. To determine the association between time and the parameters of both groups, a two-way repeated-measures ANOVA model was performed. The comparison of the degree of changes in METs_{max} values between the two groups was analyzed using an independent t-test. Statistical significance was defined as p<0.05.

RESULTS

Baseline characteristics of the study participants

Among the 499 patients who first visited the outpatient clinic during the period, 72 patients completed follow-up visits twice for 6 months. Among them, there were 40 in the CBCR group and 32 in the HBCR group. Of the 40 patients in the CBCR group, 27 (67.5%) completed 36 CBCR sessions, and those who did not complete all 36 sessions attended 24.9 sessions in average. Table 1 shows the demographic data, and a comparison between the two groups showed no significant differences (p>0.05). However, the LVEF at baseline in the HBCR group was significantly higher than that in the CBCR group (56.0%±8.0% vs. 46.9%±12.8%; p<0.001). Fewer patients with ST-segment elevation myocardial infarction were found in the HBCR group than in the CBCR group (21.9% vs.

47.5%; p=0.022). The patients were predominantly male in both groups; however the number of females was low in the HBCR group (31 male and 1 female) than in the CBCR group (27 male and 13 female; p<0.001; Table 1).

Comparison of BMI values and laboratory findings over time between baseline in the HBCR and CBCR groups

No significant change in BMI was found between baseline and follow-up, and no significant difference was found between the two groups (p>0.05; Table 2, Fig. 2).

Table 2 summarizes the changes in laboratory findings to compare the management of other CV risk factors. Serum HbA1c levels (HBCR, 7.3%±0.7% and CBCR, 7.5%±0.6% at baseline) slightly decreased at 3 and 6 months (HBCR, 6.6%±0.6% and CBCR, 7.3%±0.5%; HBCR, 6.5%±0.4% and CBCR, 7.0%±0.4%; respectively), which was the same in both

Table 1. Baseline characteristics of patients in the HBCR and CBCR groups

Characteristic	HBCR (n=32)	CBCR (n=40)	p-value
Age (yr)	58.7±10.4	59.7±11.7	0.712
Sex, male:female	31:1	27:13	<0.001*
Left ventricle ejection fraction (%)	56.0±8.0	46.9±12.8	<0.001*
Smoking history			
Never	8 (25.0)	19 (47.5)	0.085
Ex-smoker	19 (59.4)	19 (47.5)	0.085
Current	5 (15.6)	2 (5.0)	0.085
Cardiac diagnosis			
Stable angina	4 (12.5)	1 (2.5)	0.128
Unstable angina	9 (28.1)	4 (10.0)	0.059
Non-STEMI	8 (25.0)	8 (20.0)	0.618
STEMI	7 (21.9)	19 (47.5)	0.022*
Others	4 (12.5)	8 (20.0)	0.394
Comorbidity			
Stroke	1 (3.1)	2 (5.0)	0.821
Hypertension	18 (56.3)	23 (57.5)	0.917
Diabetes mellitus	12 (37.5)	17 (42.5)	0.673
Dyslipidemia	8 (25.0)	9 (22.5)	0.807
Chronic kidney disease	0 (0.0)	1 (2.5)	0.375
Others	5 (15.6)	11 (27.5)	0.224
None	1 (3.1)	1 (2.5)	0.873
Family history of cardiac disease			
Yes	10 (31.3)	11 (27.5)	0.732
Intervention or operation			
PCI	27 (84.3)	30 (75.0)	0.337
Coronary artery bypass graft	0 (0.0)	2 (5.0)	0.160
Medication	2 (6.3)	4 (10.0)	0.574
Others	3 (9.4)	4 (10.0)	0.930

Values are presented as mean±standard deviation, number only, or number (%).

HBCR, home-based cardiac rehabilitation; CBCR, center-based cardiac rehabilitation; STEMI, ST-segment elevation myocardial infarction; PCI: percutaneous coronary intervention.

*p<0.05.

Table 2. Comparison of 6-month trend data between the HBCR and CBCR groups

Lifestyle and laboratory results -		HBCR (n=32)			CBCR (n=40)	
Lifestyle and laboratory results	Baseline	3 mo	6 mo	Baseline	3 mo	6 mo
Body mass index (kg/m²)	26.3±0.6	26.1±0.6	26.0±0.6	25.4±0.6	25.3±0.5	25.5±0.6
HbA1c (%)	7.3±0.7	6.6±0.6	6.5±0.4	7.5±0.6	7.3±0.5	7.0 ± 0.4
HDL (mg/dL)	45.4±3.3	43.9±2.8	42.5±3.7	45.0±2.5	42.4±2.1	45.8±2.8
LDL (mg/dL)	102.4±11.3	$62.6\pm6.4^{d)}$	$60.6\pm5.5^{d)}$	97.0±8.6	$67.1\pm4.8^{d)}$	65.8±4.2 ^{d)}
METs _{max} (mL/kg/min)	$6.6\pm0.3^{c)}$	$6.9\pm0.3^{d)}$	$7.1\pm0.3^{d)}$	$5.6\pm0.3^{c)}$	$6.6\pm0.3^{\rm d)}$	$6.5\pm0.3^{d)}$
Exercise habits (min/wk)						
High	26.3±20.5	52.8±22.5	17.8±8.5	30.5±18.4	33.6±20.9	16.6±7.6
Mod	109.7±24.8 ^{c)}	219.7±30.3 ^{d)}	210.6±29.2 ^{d)}	38.1±22.2 ^{c)}	132.9±27.1 ^{d)}	159.9±26.1 ^{d)}
Alcohol frequency (day/mo)	4.4±1.7	$1.6\pm0.5^{ ext{d})}$	$1.4\pm0.4^{ ext{d})}$	4.8±1.5	$0.8 \pm 0.4^{ m d)}$	$0.7\pm0.4^{ ext{d})}$
Diet habits ^{a)}	1.6±0.1	$1.9\pm0.1^{\rm d)}$	$1.9\pm0.1^{d)}$	1.8±0.1	$2.0\pm0.1^{d)}$	$2.1\pm0.1^{d)}$
Psychological status ^{b)}	1.3±0.1	$1.1\pm0.1^{d)}$	$1.2\pm0.1^{d)}$	1.4 ± 0.1	$1.3\pm0.1^{d)}$	$1.2 \pm 0.1^{d)}$
Current smokers (no.)	5	6	8	2	2	3

Values are presented as mean±standard deviation.

HBCR, home-based cardiac rehabilitation; CBCR, center-based cardiac rehabilitation; HbA1c, glycated hemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; METs_{max}, maximal metabolic equivalents.

groups, but not statistically significant (p>0.05). The change in serum HbA1c in the non-diabetic patients was $5.7\%\pm0.1\%$, $5.8\%\pm0.1\%$, $5.8\%\pm0.1\%$, $5.8\%\pm0.1\%$, in the CBCR group, and $5.8\%\pm0.1\%$, $5.8\%\pm0.1\%$, $5.9\%\pm0.1\%$ in the HBCR group, respectively, in chronological order. The change in serum HbA1c in the diabetic patients was $8.0\%\pm3.5\%$, $7.7\%\pm3.9\%$, $7.4\%\pm2.8\%$ in the CBCR group, and $7.6\%\pm2.4\%$, $6.9\%\pm0.4\%$, $6.8\%\pm0.4\%$ in the HBCR group, respectively, in chronological order. Changes in serum HbA1c were not statistically significant, with or without diabetes in both groups (p>0.05). Serum HDL levels at baseline (HBCR, 45.4 ± 3.3 and CBCR, 45.0 ± 2.5 mg/dL) did not differ between the two groups; and showed no significant changes at follow-up in both groups (HBCR, 43.9 ± 2.8 and CBCR, 42.4 ± 2.1 mg/dL; HBCR, 42.5 ± 3.7 and CBCR, 45.8 ± 2.8 mg/dL; respectively; p>0.05; Table 2, Fig. 2).

In contrast, serum LDL levels (HBCR, 102.4±11.3 and CBCR, 97.0±8.6 mg/dL at baseline) were significantly decreased at 3 months in both groups (HBCR, 62.6±6.4 and CBCR, 67.1±4.8 mg/dL, p<0.05), and the results were maintained even at 6 months (HBCR, 60.6±5.5 and CBCR, 65.8±4.2 mg/dL; p<0.05). In addition, no significant difference was found in serum LDL levels between the two groups (p>0.05; Table 2, Fig. 2).

Comparison of follow-up ${\rm METs_{max}}$ over time between baseline in the HBCR and CBCR groups

Table 2 summarizes the changes in CPX test results and lifestyle for the HBCR and CBCR groups. When comparing the METs_{max}

values between the two groups, the baseline values were significantly higher in the HBCR group (HBCR, 6.6 ± 0.3 and CBCR, 5.6 ± 0.3 mL/kg/min; p<0.05; Table 2, Fig. 2). However, both groups showed a statistically significant increase in values at 3 (HBCR, 6.9 ± 0.3 and CBCR, 6.6 ± 0.3 mL/kg/min; p<0.05) months and 6 (HBCR, 7.1 ± 0.3 and CBCR, 6.5 ± 0.3 mL/kg/min; p<0.05) months from baseline. No significant difference was found in the degree of change in the METs_{max} values between the two groups at 6 months (p>0.05). However at 3 months, the degree of change was significantly higher in the CBCR group (p<0.05; Table 3).

Comparison of lifestyle improvements over time between baseline in the HBCR and CBCR groups

Fig. 2 shows the changes in exercise duration. High-intensity exercise duration per week did not differ between the groups at baseline (HBCR, 26.3±20.5 and CBCR, 30.5±18.4 min/week; p>0.05), and did not significantly increase at 3 (HBCR, 52.8±22.5 and CBCR, 33.6±20.9 min/week) and 6 (HBCR, 17.8±8.5 and CBCR, 16.6±7.6 min/week) months from baseline in both groups (p>0.05). Regarding the moderate-intensity exercise duration at baseline, the HBCR group (109.7±24.8 min/week) exercised more time than the CBCR group (38.1±22.2 min/week; p<0.05). However, the duration of exercise increased significantly at 3 (HBCR, 219.7±30.3 and CBCR, 132.9±27.1 min/week) and 6 (HBCR, 210.6±29.2 and CBCR, 159.9±26.1 min/week) months in both groups (p<0.05), but the change was

a)Diet habits (eating high-cholesterol food): 1-often, 2-sometimes, 3-not. b)Psychological status: 1-calm, 2-mild unstable, 3-very unstable. c)Significant differences between the two groups at the same time, d)Significant differences from baseline; p<0.05.

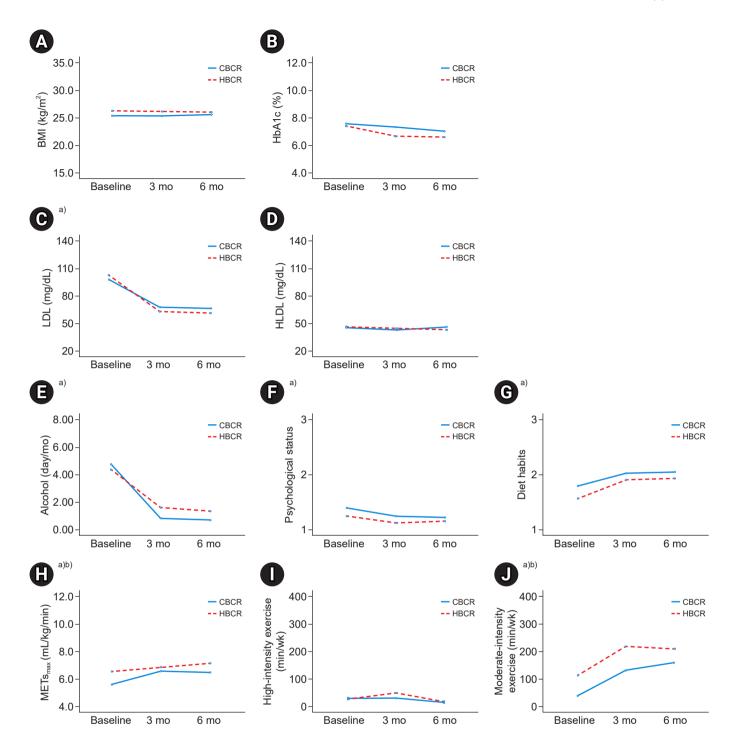


Fig. 2. Six months' trend of data between the HBCR (dotted line) and CBCR (solid line) groups. (A) BMI (kg/m²), (B) HbA1c (%), (C) LDL (mg/dL), (D) HDL (mg/dL), (E) alcohol habits (day/month), (F) psychological status (1-calm, 2-mild unstable, 3-very unstable), (G) diet habits of eating high-cholesterol food (1-often, 2-sometimes, 3-not), (H) METs_{max} (mL/kg/min), (I) high-intensity exercise habits (min/week), and (J) moderate-intensity exercise habits (min/week). CBCR, center-based cardiac rehabilitation; HBCR, home-based cardiac rehabilitation; BMI, body mass index; HbA1c, glycated hemoglobin; LDL, low-density lipoprotein; HDL, high-density lipoprotein; METs_{max}, maximal metabolic equivalents. ^{a)}p<0.05, significantly different at 3 and 6 months from the baseline value in both groups, no significant difference between 3 and 6 months in both groups. ^{b)}p<0.05, significantly different between the two groups at 5 and 6 months.

Table 3. Comparison of the rate of METs_{max} increase from baseline

	31	3 mo		no
	HBCR	CBCR	HBCR	CBCR
Changes of METs _{max} from baseline	0.36±0.92	0.95±1.02	0.58±0.93	0.84±0.95
	p=0.014*		p=0.255**	

METs_{max}, maximal metabolic equivalents; HBCR, home-based cardiac rehabilitation; CBCR, center-based cardiac rehabilitation.

not significantly different between the two groups (p>0.05; Table 2, Fig. 2).

Changes in lifestyle modification parameters, including frequency of alcohol consumption, eating habits, and psychological state, are shown in Fig. 2. All three parameters showed no significant differences between the two groups (p>0.05) and were dramatically improved during the follow-up period (p<0.05). The frequency of drinking and consuming high-cholesterol foods decreased, and psychological stability was achieved (Table 2, Fig. 2).

However, the number of current smokers increased in both groups at 6 months (HBCR, $5\rightarrow8$ and CBCR, $2\rightarrow3$), but more in the HBCR group (Table 2).

DISCUSSION

CR significantly reduces secondary CV events and mortality, and it is a class 1A recommendation by the American Heart Association and the American College of Cardiology [12]. However, many patients prefer HBCR over CBCR because of the lack of accessibility and time. Although HBCR can potentially expand patient access and participation, there is concern that inadequate direct supervision and lack of physical interaction with CR staff will reduce the physical and psychological benefits demonstrated by CBCR [12]. Ornish et al. [13] showed that the rate of coronary heart disease progression doubled over 5 years if intensive lifestyle changes were not made. Therefore, managing and maintaining risk factors for CR is as important as maintaining CRF levels. In the CBCR group, patients visited the center up to 36 times and exercised under supervision, whereas exercise training and risk factor management were entirely left to the patients in the HBCR group. Although feedback was provided through periodic outpatient follow-ups every 3 months, it was necessary to determine whether the risk factor management was effective in the patient undergoing HBCR, who had to manage themselves from the beginning after onset. The purpose of this study was to confirm how CV risk factors were

effectively managed in the HBCR compared to CBCR groups.

Our study has several important findings. First, lifestyle habits were greatly improved and effectively maintained in both groups. Additionally, in both groups, after commencing CR, the serum LDL level significantly decreased, the intake of high-cholesterol foods and alcohol decreased, and anxiety or depressive psychological conditions stabilized at 3 months. Notably, these results were maintained for approximately 6 months.

The guidelines of the European Society of Cardiology and the European Atherosclerosis Society recommend a LDL-C target value of <70 mg/dL (1.8 mmol/L). In Bernhard's study, participation in CR in Germany improved the control of modifiable CV risk factors, specifically LDL-C, in patients after acute myocardial infarction [14]. Sorting out the relative effects of CR and lipid therapy can be difficult, but Snow et al. suggested participation in CR significantly potentiates the lipid-improving effects of pharmacological therapy [15,16]. All patients who participated in our CR program were given a training session on diet, and the results showed that most patients ate less high-cholesterol foods. In our CR programs, serum LDL levels could be lowered by correcting eating habits combined with exercise. However, because of the nature of the CR program, which was centered on aerobic exercise, a significant change in serum HDL level could not be expected, and it was difficult to expect a significant change in serum HbA1c level in a short pe-

A significant reduction in the amount of alcohol consumed was also observed in our study. Athyros et al. [17] reported that heavy drinking was associated with an increase in the prevalence of metabolic syndrome, CAD, stroke, and peripheral arterial disease. In another study of alcohol-consuming populations, the amount of alcohol consumption significantly impacted blood pressure values, hypertension prevalence, and CV and allcause mortality [18]. In addition, patients' psychological states were stabilized in our CR program. Among patients with CAD, acute psychological stress has been shown to induce transient myocardial ischemia, and long-term stress can increase the risk

^{*}p-value of comparison between the two groups for the rate of METs_{max} change at 3 months from baseline.

^{**}p-value of comparison between the two groups for the rate of METs_{max} change at 6 months from baseline.

of recurrent ACS events and mortality [19]. Anxiety of patients was improved by explaining to them how much their CRF level was and how much it had improved based on the results of the CPX test. Therefore, through these lifestyle modifications, the effect of preventing the recurrence of CV disease in patients can be expected in CR program.

Second, we observed a marked improvement in patients' exercise habits. Comparing the time spent on moderate-intensity exercise for 1 week, both groups showed a significant increase in exercise duration at 3 and 6 months. Exercise duration increased by approximately 2 times in the HBCR group and 3 times in the CBCR group. The change in exercise time was slightly smaller in the HBCR group, which may be because the exercise time at baseline was significantly greater in the HBCR group than in the CBCR group. These baseline differences are believed to be because of the relatively greater allocation of patients from the low-risk group to the HBCR group. Nevertheless, the increased moderate-intensity exercise duration in both groups suggests that CR program has a positive effect on improving exercise habits.

However, we did not find any significant changes in the high-intensity exercise duration and showed increasing results in the number of patients smoking. Patients who were smoking or started smoking cessation were given feedback to quit smoking every 3 months at an outpatient visit, but quitting smoking was not easy and feedback about once every 3 months was not enough to get them to quit smoking, which is why this result appeared. Previous review studies have suggested that smoking is related to CAD severity and the location of the damaged artery in the heart [20]. Cameron et al. [21] reported that cigarette smoking cessation was associated with reduced postoperative angina. Therefore, we believe that our CR program will require a new approach for more reliable management that encourages high-intensity exercise and patients to quit smoking.

Third, in the case of the METs_{max} values representing CRF levels, both groups showed significantly improved results. Although the METs_{max} values at baseline in the two groups were different, one of the main findings of this study was that METs_{max} values increased in both groups and this finding is consistent with that of a previous study [22]. However, the rate of change from baseline was significantly higher in the CBCR group at 3 months. Aguiar Rosa et al. [23] reported that patients with lower baseline CRF levels presented more significant improvements in functional capacity after CR. Since METs_{max} were higher in the HBCR group at baseline, this finding could be attributed to

the different baseline METs_{max} values between the two groups at baseline. However at 6 months, no significant differences were found between the two groups. The METs_{max} values in the CBCR group were lower at 6 months than at 3 months, although the difference was not statistically significant. This is believed to be because the CBCR group started exercising at home after 4 months of exercise at the center. Therefore, for patients transitioning from CBCR to HBCR, strategies such as smartphone-based CR are needed for long-term management [24].

This study had several limitations. First, the main objective of this study, which was the investigation of lifestyle changes, was conducted using a questionnaire survey completed subjectively by patients. Therefore, the self-reported measures of diet, exercise duration, and psychological status may have been biased because the participants could have filled out the survey by exaggerating or understating information about their lifestyles. Second, this was a retrospective cohort study. Although meta-analysis had shown that CR training can effectively improve the patient's cardiac function indicators and self-care ability [25], this study lacks the necessary controls to identify the effect of CR. There is no clear evidence that a reduction or increase in multiple markers is solely attributable to CR. Third, there is a selection bias arising from the non-randomization process at the point of treatment selection. This resulted in statistically significant differences in baseline characteristics such as sex, diagnosis, and LVEF levels. Fourth, there is another selection bias due to the fact that only those who completed the 6-month follow-up were analyzed, and that patients with incomplete EMRs were excluded. Fifth, the study period was short, the sample size was relatively small, and the study was conducted at a single center. Therefore, it is difficult to generalize the study results, and further studies on long-term results are needed. Nevertheless, this is meaningful because it is the first study on whether lifestyle modifications are successful in CR programs. In addition, unlike the conventional CBCR, it was confirmed that the HBCR program requires self-management, but risk factors management can be sufficiently implemented through appropriate education.

In summary, whether patients do CR at home or in the center, lifestyle can be effectively modified regardless of the type of CR. Therefore, patients should participate in any form of CR to improve CRF levels and prevent heart diseases recurrences. Furthermore, in order to effectively manage the lifestyle at home for a long period of time, additional rehabilitation strategies

that can anticipate the long-term effects of CR, such as smartphone-based CR, are also needed. Additionally, more aggressive strategies are required to prevent smoking.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

Conceptualization: Kim C, Lee SH. Methodology: Kim C, Lee SH. Formal analysis: Lee SH. Project administration: Kim C. Visualization: Kim C, Lee SH. Writing – original draft: Lee SH. Writing – review and editing: Kim C, Lee SH. Approval of the final manuscript: all authors.

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Lower Limb Muscle Fatigue Alters Spatiotemporal Gait Parameters and Turning Difficulty Characteristics in Parkinson's Disease

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Objective: To determine the effects of lower limb muscle fatigue on spatiotemporal gait parameters and turning difficulty characteristics during the extended Timed Up and Go (extended TUG) test in individuals with different severity stages of Parkinson's disease (PD).

Methods: Forty individuals with PD, classified as Hoehn and Yahr (H&Y) stages 2 and 3 participated in this pre- and post-experimental study design. The participants performed a continuous sit-to-stand task from a chair based on 30 cycles/min set-up to induce lower limb muscle fatigue. They performed extended TUG test immediately before and after completing the fatique protocol. Spatiotemporal gait parameters and turning difficulty characteristics were recorded using two GoPro® Hero 4 Silver cameras. Data were subjected to a repeated-measure ANOVA.

Results: Individuals with PD experience significant changes in spatiotemporal gait parameters, specifically stride velocity and length, under conditions of lower limb muscle fatigue (p=0.001). These changes were more pronounced in individuals with PD in the H&Y stage 3 group. Additionally, both PD groups exhibited difficulty with turning, requiring more than five steps to complete a 180° turn and taking more than 3 seconds to accomplish it.

Conclusion: These findings highlight the impact of muscle fatigue on gait performance in PD and suggest that individuals in later stages of the disease may be particularly affected. Further research is needed to explore interventions that can mitigate these gait impairments and improve mobility in individuals with PD.

Keywords: Exercise, Gait, Fatigue, Parkinson disease

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INTRODUCTION

Turning during walking is a challenging locomotor task due to

the need for a complex integration among different motor control mechanisms [1]. Turning task requires the central nervous system to coordinate several body components to help change

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the direction while preserving the postural stability in the medio-lateral direction and continuing the ongoing step cycle [2]. A turn changes the direction of walking with a top-down coordination that begins with head rotation, followed by the trunk, pelvis, and feet, with body parts moving toward the inner side of the turn [3]. Difficulty in turning is one of the early gait abnormalities in individuals with Parkinson's disease (PD). These individuals suffer from several gait challenges during straight walking and turning while walking, which are even more challenging in the early stages of the disease [1,4]. As the disease progresses, individuals with PD present with reduced gait speed followed by shuffling gait and shorter steps, diminished arm swings bilaterally, and slower "en-bloc" turns, making it difficult to navigate turns or change in direction [5]. This phenomenon can result in falls due to losing balance when the patient suddenly stops moving or becomes unsteady.

Gait performance is influenced by age, gait speed, depression, fatigue, motor severity, executive function, and attention. These factors can exacerbate motor symptoms like bradykinesia, rigidity, and postural instability, leading to difficulty initiating and maintaining a steady gait [6]. Fatigue can further impair gait function in individuals with PD. Muscle strength and coordination may decrease, leading to increased difficulty initiating and maintaining a steady gait [7]. Furthermore, lower limb muscle fatigue among individuals with PD may limit their ability to pass or cross an obstacle [8]. A new segmental organization is required to maintain motor performance, as indicated by changes in spatiotemporal gait parameters during muscle fatigue [9]. Therefore, individuals with PD may demonstrate further spatiotemporal gait adjustments due to greater muscle fatigue and deterioration in motor control mechanisms [10].

Muscle fatigue among individuals with PD has gained increasing attention. An earlier study demonstrated no clear association between gait and gait-related activities and fatigue in people with PD [11]. By contrast, individuals with PD showed increased stride length and speed, reduced stride duration, and vertical braking impulses [12]. Another study found that lower limb muscle fatigue has contributed to slower walking speed among individuals with PD [13]. However, no significant decline in gait characteristics has been reported following lower limb muscle fatigue [14]. The discrepancies in existing studies may be due to differences in inducing fatigue protocols, outcome measures used, group of muscles measured, and patient characteristics. To date, no study has investigated the effects of lower limb muscle fatigue on spatiotemporal gait parameters

during the turning of individual with PD. Therefore, the effects of fatigue conditions on gait parameters should be investigated to gain further insights into gait recovery in PD.

The Timed Up and Go (TUG) test has been widely used as a clinical measure of balance and mobility [15]. This reliable test determines the ability and time needed to perform basic functional mobility tasks. The TUG test compromises fundamental activities of daily living, such as standing up, walking for 3 m, turning around, and sitting back [16-19]. The walking distance increased from 3 m in the classical TUG to 7 m in the extended TUG test to improve the ability to capture balance and gait impairments [20]. The reliability of the extended test was good [21]. The extended TUG test has a good association with gait speed and lower limb strength.

A previous study used the TUG test to capture the characteristics of turning difficulty in the older person [3]. They identified four indicators of turning difficulty: staggering, absence of pivoting, taking five or more steps, and taking 3 seconds or longer to achieve a turn. The characteristics of the TUG test make it a good tool for determining the effects of muscle fatigue conditions on gait parameters during walking and turning among individuals with PD. Exploring the characteristics of turning difficulty due to lower limb muscle fatigue is important to guide the development of a management plan for individuals with PD who are at high risk of falling. Therefore, this study aimed to determine the effects of lower limb muscle fatigue on spatiotemporal gait parameters during the straight walking and turning phases of the extended TUG test in individuals with PD. Another goal was identifying the turning difficulty characteristics after lower limb muscle fatigue. We hypothesized that lower limb muscle fatigue would lead to a greater effect on gait parameters for individuals with PD with higher severity than those with lower severity by using Hoehn and Yahr (H&Y) classification.

METHODS

Participants

Forty individuals with PD were recruited from a selected government-funded hospital with established services for neurological conditions. The effect size was calculated from a previous study [12]. The estimated sample was 40 participants to provide 90% power, with a risk of type 1 error of 0.05. All participants signed an informed consent form approved by the Research Ethics Committee, Universiti Teknologi MARA (REC/44/18)

and Medical Research Ethics Committee (MREC), Ministry of Health, Malaysia (NMRR-17-3490-39360 IIR).

The inclusion criteria were as follows: (1) diagnosis of PD with stages 2 or 3 based on H&Y classification confirmed by a neurologist; (2) Mini-Mental State Examination score≥24; (3) ability to walk 5 minutes without assistance or use of any aids; and (4) age between 45 and 80 years at the time of recruitment. Participants were excluded from the study if they presented visual field defects based on confrontation technique, had other diseases or injuries that could potentially disturb gait, or had artificial joints or orthotic devices and unstable co-existing medical conditions.

Outcome measures

This study used a modified TUG test, referred to hereafter as an extended TUG test. The extended TUG protocol with 7 m of walking may have been chosen to provide a longer distance for assessing gait performance and capture more gait cycles [22]. Furthermore, the 7 m distance may have been considered sufficient for evaluating functional recovery and mobility in certain populations, such as individuals with PD [23]. The reliability of the extended TUG test in the estimation of turn and turn-to-sit was high (p>0.75). A previous study suggested that the extended TUG test performance is a useful indicator of cognition, motor function, and quality of life among individuals with PD [20].

Procedures

The participants were instructed not to perform strenuous physical activity for 48 hours before the testing date. All assessments were conducted with patients in the "on" status, with participants taking their medications one hour before the assessment. The assessment procedure was completed within 2 hours to ensure participants were in the "on" status. The experiment was conducted in a hospital-based physiotherapy gymnasium. Participants' demographic and medical data were collected before testing. After the clinical assessment, the participants were asked to perform the extended TUG test [24].

Before testing, the researcher explained and demonstrated the procedures to the participants. They were required to stand up from a sitting position (without using their arms) and then walk at the marked distance of 7 m in a straight line at their comfortable self-selected speed. At the end of 7 m, the participants were required to make a 180° turn and then return to the starting chair and sit. The tester used a stopwatch to measure the total time needed to complete the extended TUG task. The

participants were allowed to carry out a one-time practice trial before the real test, the result of which was not used for analysis. The participants performed walking tasks thrice at their self-selected speed before the lower limb muscle fatigue protocol. The average time to complete the test was taken as the baseline measurement. The participants were allowed to wear their usual footwear. The layout for the extended TUG test was marked on the floor (7 m and turning areas), and these marks were clearly shown to the participants.

The lower limb muscle fatigue protocol was adopted from a previous study, in which the participants performed a continuous sit-to-stand task from a chair with arms across the chest region to induce lower limb muscle fatigue [12]. A standard chair without armrests was used in this task (43 cm in height, 41 cm in width, and 42 cm in depth). A metronome with 30 cycles/ min set-up was used to control the frequency of the sit-to-stand movement. The instructions to the participants were as follows: "with the beat of a metronome, please stand up into an upright position and then sit down; and repeat the task until you can no longer perform the task." Initially, the tester demonstrated to the participants the whole procedure, and the participants were allowed a one-time trial as familiarization. During the fatigue protocol, the assessor verbally encouraged the participants to continue the task until they felt too exhausted to do more repetitions. The participants were stopped from continuing the task when they met one of the following criteria: the task frequency was less than 30 cycles/min after encouragement, after 30 minutes of the sit-to-stand task, or when the participants indicated their inability to continue. The time needed to feel muscle fatigue was recorded using a digital stopwatch.

Given the possibility that this lower limb muscle fatigue protocol could exacerbate fatigue perception among the participants, the Borg Rating of Perceived Exertion was used to ensure that the participants did not indicate their perception of fatigue as their lower limb muscle fatigue. If the participants indicated their perception of fatigue before the lower limb muscle became fatigued, then they were allowed to rest. The lower limb muscle fatigue protocol was started again once their perception of fatigue was recovered. While the participants were performing the sit-to-stand task, their oxygen saturation level was monitored using a pulse oximeter. A small decrement in oxygen saturation level was allowed to stay at $\geq 94\%$ throughout the fatigue protocol to ensure that the participants did not indicate their poor exercise tolerance as lower limb muscle fatigue. The assessor encouraged the participants to continue the sit-to-stand task

if they were notified that their lower limbs had reached fatigue condition, but the oxygen saturation level was still above 94%. The walking task was carried out immediately after the fatigue protocol. The participants performed the extended TUG test immediately after the lower limb muscle fatigue protocol. The participants performed the walking task in less than 3 minutes after the fatigue protocol to prevent the full recovery of muscles.

Spatiotemporal gait parameters were captured using two digital video cameras. Two GoPro® Hero 4 Silver (GoPro Inc.) cameras were placed in the sagittal plane and used to capture data at 120 fps on a "normal" lens setting. Previous studies have suggested that digital video cameras, including GoPro cameras, can offer accurate and dependable measurements for gait analysis [25,26]. The video cameras were positioned on the right side of the participants at 5 m in the sagittal plane pathway. One video camera was positioned in the middle of the 7 m walking pathway, and another was set up at the turning area. The video cameras were mounted on a tripod to reduce the parallax error. The position of the video cameras was unaltered for the whole data collection process.

Data analysis

The recorded video was analyzed using a previously reported method [27]. Kinovea 0.8.15 (Kinovea.org) software was used to analyze the videos and determine step length and time. Stride length, stride time, and stride velocity were calculated using the following derived formulas: (1) stride length=left step length+right step length, (2) stride time=left step time+right step time, and (3) velocity=stride length/stride time.

The recorded videos were viewed and analyzed by two physiotherapists (mean years of working experience ≥9) with experience in gait evaluation of neurological patients to determine gait characteristics. A methodology published previously was used to describe the 180° turning characteristics [3]. The evaluators were given a form containing category definitions and

descriptions for each level. The principal investigator discussed and clarified the keyword with the evaluators. The principal investigator also viewed the sample video with the evaluators to ensure it was analyzed according to category definitions and descriptions. The evaluators viewed the recorded video individually in random order to prevent bias. The analyses were organized according to (1) the time and number of steps taken to complete the extended TUG test and (2) the time and number of steps taken to accomplish the turning phase of the extended TUG test. Turning difficulty characteristics were evaluated according to (1) the presence or absence of staggering during the turn; (2) the type of turn or strategy used to accomplish the turn; (3) the number of steps or weight shifts taken during the turn; and (4) the amount of time taken to accomplish the turn. If the disagreement persists after discussion, a third reviewer or an expert in the field is brought in to independently evaluate the indicators of turning difficulty. The intra-rater reliability of the turning difficulty in our sample was determined to be good, with intraclass correlation coefficients ranging from 0.83 to 0.88.

Statistical analysis was conducted using IBM SPSS statistical version 26.0 (IBM Corp.). Descriptive statistics were calculated, and tests for normality were conducted for all outcome variables. Repeated-measures ANOVA was used to analyze gait parameters across condition (pre- and post-lower limbs fatigue protocol) and group (H&Y 2 and 3). Post-hoc Bonferroni comparison was performed when the repeated-measure ANOVA test revealed a significant difference (p<0.05).

The turning difficulty characteristics were calculated in percentage.

RESULTS

The characteristics of the participants are presented in Table 1. A total of 40 individuals with PD participated in this study, with 20 participants in H&Y stage 2 and 20 participants in H&Y

Table 1. Demographic data of the participants

Description	Hoehn and	Hoehn and Yahr group				
Description	Stage 2 (n=20)	Stage 3 (n=20)	p-value			
Age (yr)	68.9±6.97	69.85±6.18	0.651			
Disease duration (mo)	15.2±6.06	20.35±5.08	0.006			
Height (m)	1.64±0.05	1.63±0.06	0.687			
Weight (kg)	68.91±4.16	68.69±3.61	0.862			
Body mass index (kg/m ²)	25.25±1.53	28.85±1.05	0.337			
Time to muscle fatigue (s)	199.85±30.22	186.8±38.30	0.239			

Values are presented as mean±standard deviation.

stage 3. Out of the 40 participants, approximately 82.5% identified as male. No statistical differences were found in age, disease duration, height, weight, body mass index, and time to fatigue of the lower limb muscles between the two groups.

As shown in Table 2, individuals with PD in the H&Y stage 3 group required a longer time and a higher number of steps to complete the walking task (group effect, both p=0.001). The time and the number of steps to complete the extended TUG task significantly increased after lower limb muscle fatigue (condition effect, both p=0.001). The effect was similar for both groups (condition×group interaction, p>0.05).

Individuals with PD in the H&Y stage 3 group presented significantly shorter stride length, longer stride time, and slower stride velocity during the walking task after lower limb muscle fatigue condition (group effect, all p=0.001) compared with those in the H&Y stage 2 group. Significant increases were found in the stride length, decreased stride time, and reduced stride velocity during the walking task after lower limb muscle fatigue (condition effect, all p=0.001). The effect on stride length and stride time was similar for both groups (condition×group interaction, p>0.05). However, significant interaction effect was detected for stride velocity between both groups

(condition \times group interaction, p=0.001).

Individuals with PD in the H&Y stage 3 group required significantly longer time and more steps to accomplish the turn during the extended TUG test (group effect, both p=0.001). The time and number of steps to accomplish turning the during extended TUG test significantly increased after lower limb muscle fatigue (condition effect, both p=0.001). The effect was similar for both groups (condition×group interaction, p>0.05).

As shown in Table 3, only two to three participants for each group showed staggering during the turn. Individuals with PD in the H&Y stage 3 group were presented with an absence of pivoting during the turn (80.0%) compared with those in the H&Y stage 2 group (35.0%). Both groups took more steps and time to accomplish the turn, indicating turning difficulty (100%).

DISCUSSION

This study aimed to determine the effects of lower limb muscle fatigue on spatiotemporal gait parameters and turning difficulty indicators during the extended TUG test among individuals with PD in H&Y stages 2 and 3. We found several important

Table 2. Spatiotemporal gait parameters during extended TUG test

	Stage 2 (n=20)		Stage 3 (n=20)		p-value		
Variable	Pre	Post	Pre	Post	Within group factor	Between group factor	Interaction
Extended TUG time (sec)	25.91±3.06	29.69±3.36	34.30±3.03	37.94±3.13	0.001*	0.001*	0.527
Extended TUG NOS	38.4±6.70	35.75±6.73	41.5±3.25	38.45±3.15	0.001*	0.001*	0.159
Stride length (cm)	116.36±9.71	120.97±9.84	90.14±7.9	95.06±8.37	0.001*	0.001*	0.343
Stride time (s)	1.95±0.62	1.51±0.45	3.21±0.77	2.95±0.54	0.001*	0.001*	0.681
Stride velocity (cm/s)	65.41±20.87	86.34±24.45	29.46±6.67	33.29±6.91	0.001*	0.001*	0.001*
Turning time (s)	3.78 ± 0.76	5.24±0.86	5.53±0.64	7.60 ± 1.22	0.001*	0.001*	0.074
Turning steps	4.55±0.51	7.15±1.35	6.5±0.83	8.00 ± 0.92	0.001*	0.001*	0.374

Values are presented as mean±standard deviation.

TUG, Timed Up and Go; NOS, number of steps.

Table 3. Indicators of turning difficulty

	H&Y group					
Category	Pre-fatigue			atigue		
	H&Y 2 (n=20)	H&Y 3 (n=20)	H&Y 2 (n=20)	H&Y 3 (n=20)		
Staggering during the turn	2 (10.0)	3 (15.0)	2 (10.0)	3 (15.0)		
Absence of pivoting during the turn	5 (25.0)	10 (50.0)	7 (35.0)	16 (80.0)		
Using 5 or more steps or weight shift to accomplish the turn	11 (55.0)	12 (60.0)	20 (100)	20 (100)		
Taking 3 seconds or longer to accomplish the turn	11 (55.0)	12 (60.0)	20 (100)	20 (100)		

Values are presented as number (%).

H&Y, Hoehn and Yahr.

^{*}The significance level was set at p<0.05.

findings. First, the PD groups showed significant spatiotemporal gait parameter changes under lower limb muscle fatigue conditions. Second, the stride velocity and length significantly increased after lower limb muscle fatigue. Third, the fatigue-related gait changes were more remarkable in individuals with PD in the H&Y stage 3 group. Lastly, both groups presented with turning difficulty; that is, they had nearly more than five steps to accomplish a 180° turn, and it took them more than 3 seconds to accomplish.

Individuals with PD in H&Y stages 2 and 3 experienced fatigue-related changes in spatiotemporal gait parameters, including increased stride length, decreased stride time, and reduced stride velocity during the walking task after lower limb muscle fatigue. This finding is possibly due to general hip and knee weakness and decreased ankle torque generation in the ankle among individuals with PD compared with controls [28]. These gait parameter changes could be an attempt to improve balance control in the anterior-posterior direction. The anterior margin of safety is negative during walking, which would cause a forward fall if the base of the support is not shifted forward by taking a further step [29]. Furthermore, increasing the step length during gait may retain the center of mass on the base of the support by decreasing the magnitude of the negative margin, making it easier to stop in a single step and avoid falling forward [29,30]. Similar changes in stride length after lower limb muscle fatigue were found in related studies [31,32]. Although the increase in stride length was small (~4 cm), it is still clinically relevant to individuals with PD. The possible explanation for this finding is that longer strides require more muscle activation, which could be a problem due to muscle weakness in this population [10].

Interestingly, the results reveal that the stride velocity and length significantly increased after lower limb muscle fatigue. The results are in line with the previous study that found both healthy individuals and patients with PD increased stride length and velocity after lower limb muscle fatigue [12]. Additionally, muscle fatigue decreased stride length in young adults and increased stride length in older adults [33]. This could be due to the fact that the body often employs compensation mechanisms to overcome muscle fatigue and maintain performance. These compensatory strategies may involve recruiting additional muscles or modifying movement patterns to generate the necessary force and velocity. Fatigue can also alter the biomechanics of movement, potentially leading to a stiffer and more propulsive gait pattern, allowing for a faster stride velocity. Additionally,

muscle fatigue can decrease the ability of lower limb muscles to absorb and dissipate forces during the stance phase of gait, leading to a compensatory adoption of a stiffer and more propulsive gait pattern [34].

The interaction between the PD stage and fatigue can indeed have a significant impact on stride velocity. PD is a progressive neurodegenerative disorder that affects the motor system responsible for controlling movement. Fatigue is a common symptom experienced by individuals with PD, which can further exacerbate the motor difficulties associated with the condition [35]. Additionally, the slow and shuffling gait in PD is associated with an inability to generate an appropriate stride length, while the cadence remains normal or increased to reach a normal gait velocity. Fatigue in PD can further contribute to gait dysfunction, as patients with PD are more susceptible to muscle fatigue, which can damage their gait [12]. Therefore, the PD stage and fatigue combination can significantly impact stride velocity in individuals with PD.

In this study, individuals with PD in the H&Y stage 3 group were presented with shorter stride lengths than those in the H&Y stage 2 group. This finding is expected because quadriceps muscle strength and activation deficits correlate strongly with PD severity [10]. Although the fatigue protocol used is most likely to affect the entire leg muscles and not specific muscles, it could affect mainly the quadriceps muscles. As reported in a previous study using a similar fatigue protocol, the knee extension strength was reduced after the lower limb muscle fatigue protocol [36]. Another study that used a similar fatigue protocol reported a marked decrease in lower limb muscle strength among individuals with PD in a fatigued state [37]. Therefore, small adjustments are clinically essential to avoid falls during walking under the fatigued muscle condition.

The stride time decreased with lower limb muscle fatigue. Previous work reported similar trends, in which individuals with PD had reduced stride time while walking in a fatigued state [12]. The stride time decreased under external perturbations [38]. Furthermore, reducing the parameter would enhance the center of mass control and promote postural control in the anteroposterior and mediolateral directions, which appear to be the preferred strategy to deal with balance threats [38].

Increased stride length and reduced stride duration contributed to increased walking speed, possibly leading to more gait stability [39]. This finding broadly supports the work of another study; however, the mean stride velocity in the present study was considerably slower than that in a previous study

(132.26±22.85) [12]. In line with the present findings, the gait speed with muscle fatigue increased in healthy older people [33]. Increased gait speed is associated with an increased risk of falls. However, the changes in stride length and duration are more critical in balance control than the resulting gait speed [38], and the stability of the gait pattern may be improved with a higher gait speed [39].

A significant increase in the number of steps and a longer time to complete the turning were observed among individuals with PD in this study. Similarly, previous work reported that the dynamic stability of individuals with PD was significantly smaller during fast turning. Thus, more time is taken for more dynamic stability during turning [40]. The same study reported that individuals with PD can turn more accurately at slow and preferred speeds. Another research indicated that individuals with early untreated PD can have a normal duration of the TUG test even though the 180° turn within the test was significantly slower than normal [4].

The timing deficit among the PD population is caused by faulty control of bilateral coordination [41]. Furthermore, a longer time to complete a turn is linked with freezing episodes [42]. However, none of the individuals with PD in the present study showed freezing episodes during walking and turning. Above all, the slower turning speeds of individuals with PD during turning angles might reflect a compensatory strategy to prevent dynamic postural instability [40]. Another study highlighted that the typical gait features of PD are more pronounced during turning than forward walking, especially in confined environments [43].

This study found that individuals with PD have been observed to experience increased turning difficulty following fatigue-induced fatigue simulation. Several studies have reported that fatigue can exacerbate motor symptoms in individuals with PD, including difficulties with turning [44,45]. They significantly took ≥ 5 steps to accomplish a turn under lower limb muscle fatigue conditions. Consistently, previous findings showed that individuals with PD without lower limb muscle fatigue took > 4 steps to complete a turn [46]. The same study reported that individuals with PD have a longer turn time (> 2 seconds) without being influenced by lower limb muscle fatigue. Moreover, individuals with PD in this study took ≥ 3 seconds to complete the turning task under lower limb muscle fatigue condition.

Although the results are relevant, this study has certain limitations that should be addressed. Several methodological factors should be considered because they can limit the capacity of

the study to compare the findings with previous articles. First, the lack of control groups may hinder some statements about whether changes occur due to the fatigue protocol or another uncontrolled factor (i.e., learning effect or the time duration of experimental procedures). Practice learning effects may have occurred before or after testing. Second, the reduced time for individuals with PD to perform the lower limb muscle fatigue protocol may have limited the ability to draw meaningful conclusions. The reduced time could have led to an exacerbated fatigue perception and may not have been sufficient to cause muscle overload and induce metabolic fatigue. PD-related apathy or fear of post-exercise soreness or tiredness was a strategy that enabled them to achieve lower limb muscle fatigue more quickly during the fatiguing session without providing the researcher with a clear indication that they were acutely fatigued. Third, other lower limb muscles may be involved and have been fatigued. Even though the protocol most likely affected the entire legs and not just the specific muscles, the fatigue of other leg muscles, e.g., ankle muscles (triceps surae muscle), might have other (more pronounced) effects. Fourth, the study's use of a GoPro camera instead of a force plate and three-dimensional camera may not adequately capture the complexities of gait patterns and mechanics, making applying the study's results to broader contexts challenging.

In conclusion, lower limb muscle fatigue affects spatiotemporal gait parameters among individuals with PD. Both groups demonstrated gait parameter changes that could be viewed as an attempt to improve balance and walking safety following lower limb muscle fatigue. Results indicated that individuals with PD in the H&Y stage 3 group had more difficulty turning while walking under lower limb muscle fatigued states than in the H&Y stage 2 group. These findings indicated an attempt to preserve balance and safety, probably to counteract the adverse effects of lower limb muscle fatigue. However, the gait adjustments could expose individuals with PD to a high risk of falling. Furthermore, the findings, coupled with a study reporting on the potential alteration of postural control in fatigued states among individuals with PD, strongly indicate that lower limb muscle fatigue has a measurable clinical effect on stability and potentially on the risk of falls among individuals with PD.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

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Original Article

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Torque Onset Angle of the Knee Extensor as a Predictor of Walking Related Balance in Stroke Patients

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Objective: To investigate the relationship between the torque onset angle (TOA) of the isokinetic test for knee extensors in the paretic side and walking related balance in subacute stroke patients.

Methods: We retrospectively reviewed patients with first-ever strokes who have had at least two isokinetic tests within 6 months of onset. 102 patients satisfied the inclusion criteria. The characteristics of walking related balance were measured with the Berg Balance Scale subscore (sBBS), Timed Up and Go test (TUG), 10-m Walk Test (10MWT) and Functional Independence Measure sub-score (sFIM). The second isokinetic test values of the knee extensor such as peak torque, peak torque to weight ratio, hamstring/quadriceps ratio, TOA, torque stop angle, torque at 30 degrees, and peak torque asymmetry ratio between paretic and non-paretic limb were also taken into account. Pearson's correlation, simple regression and multiple regression analysis were used to analyze the correlation between TOA and walking related balance

Results: TOA of the knee extensor of the paretic limb showed significant correlations with BBS, sBBS, TUG, 10MWT, and sFIM according to Pearson's correlation analysis. TOA also had moderate to good correlations with walking related balance parameters in partial correlation analysis. In multiple regression analysis, TOA of the paretic knee extensor was significantly associated with walking related balance parameters.

Conclusion: This study demonstrated that TOA of the paretic knee extensor is a predictable parameter of walking related balance. Moreover, we suggest that the ability to recruit muscle quickly is important in walking related balance.

Keywords: Stroke, Physical functional performance, Walking, Hemiplegia, Rehabilitation

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INTRODUCTION

Stroke is one of the most common causes of high mortality and long-term disability worldwide [1]. The sequelae of a stroke are variable and depend on the types of brain lesions. In stroke pa-

tients, there are long-term muscle changes such as loss in muscle mass and increased intramuscular fat deposition affecting walking related balance. Stroke patients have reduced functional capacity and ability to perform activities of daily living including transfers and locomotion [2,3]. The loss of balance in stroke

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patients is caused by complex factors including sensory impairment, reduced body awareness, and cognitive impairment, but one of the most prominent causes is lower extremity weakness [2,4].

Furthermore, several studies showed significant correlations between knee extensor torque and functional movement [2,4,5]. Muscle activation capacity as well as muscle strength is strongly related to functional performance such as standing-up performance, transfer capacity, gait, and stair climbing speeds [2,4,5].

Isokinetic dynamometry measures the muscular forces that accompany constant angular velocity limb movements in variable joints and it is a reliable test for evaluating muscle strength in patients with stroke [6]. Kristensen et al. [7] suggested that both paretic and non-paretic lower extremity strengths evaluated by the isokinetic device were correlated with walking related balance. Peak torque (PT) is considered to have good test-retest reliability as PT measures the maximal muscle force when the angle for knee flexion is in the range of 70° to 80° [8]. In other words maximum voluntary torque is known to be angle-dependent [9].

The rate of force development (RFD) is another parameter that examines how quickly force can be exerted [10]. The RFD measured by a handheld dynamometer during isometric contraction of the paretic knee extensor is established to predict the gait speed in stroke patients [10]. One study presented that the RFD during the first 150 ms of isometric knee extension helps predict gait speed better than PT after stroke [11]. Osawa et al. [12] reported that RFD was a significant predictor of gait speed during a 6m walk at usual and fast pace and time to complete 5 and 10 chair sit to stand tests in elderly men. Schlenstedt et al. [13] have confirmed the relationship between the enhancement of RFD and the improvement of postural control. Granacher et al. [14] reported that balance training resulted in significantly improved postural control, increased jumping height and enhanced RFD of the leg extensors. While explosive strength is the ability to make a torque as quickly as possible [15], explosive voluntary torque has been reported to be angle-independent during the early phase (≤75 ms) of contraction [16]. Maffiuletti et al. [17] reported that the RFD is determined by the capacity to produce maximal voluntary activation in the first 50 to 75 ms of explosive muscle contractions, which is the ability to increase motor unit recruitment and discharge rate. Moreover, Lodha et al. [18] demonstrated that motor control such as agility and accuracy is more meaningful than strength in predicting functional mobility in high-functioning stroke individuals.

But, Maffiuletti's research group asserted that the RFD measurement is quite difficult to come to valid and reliable evaluation [17]. Therefore, the purpose of this study is to identify which parameters among the routine isokinetic test indices are related to the explosive strength of the knee joint without utilizing additional devices such as electromyography and time recording dynamometer. To our knowledge, there are few studies related to TOA, and we assumed that TOA, the first detected point of torque, of the knee extensor reflects explosive strength in the knee extensor and it can be analogous to the RFD or explosive strength in the early contraction phase. In addition, because the type II muscle fiber ratio increases after stroke, we hypothesized that TOA, as an indicator related to initial explosive strength, would be related to walking-related balance parameters. Therefore, in this study, we studied the relationship between TOA and gait speed as well as other walking related balance parameters in stroke patients.

METHODS

Participants

We retrospectively reviewed stroke patients admitted to the rehabilitation unit in our institution from June 2010 to February 2020. The inclusion criteria were as follows: patients who (1) experienced a first-ever stroke; (2) were hemiplegic and had been diagnosed with hemorrhagic or ischemic supratentorial stroke using computed tomography or magnetic resonance imaging; (3) had post-onset duration less than 6 months; (4) had an isokinetic test of the knee at least twice and had walking related balance tests within a week of the second isokinetic test: (5) had sufficient mental capacity to be able to participate in the isokinetic test properly (Korean version of the Mini-Mental State Examination, K-MMSE≥24); and (6) were aged between 18 and 65 years. The following exclusion criteria were applied: (1) quadriplegic, double hemiplegic, and paraplegic patients; (2) patients who have ataxia; (3) patients who have any other brain lesion; (4) patients who have a musculoskeletal disease or severe osteoporosis that could affect walking related balance; (5) patients who have an uncontrolled medical problem; (6) patients whose motor grade of the lower extremity of hemiplegic side by manual muscle test were less than 3/5; (7) patients with limited knee joint movement; and (8) spasticity of L/Ex with Modified Ashworth Scale (MAS) grade higher than 2.

One hundred two patients satisfied the inclusion criteria. The baseline characteristics (sex, paretic side, subtype of stroke, age,

height, weight, body mass index [BMI], K-MMSE, onset duration (i.e., time since the onset of stroke), spasticity (by MAS), isokinetic test results and walking related balance parameters (Berg Balance Scale sub-score [sBBS], Timed Up and Go test [TUG], 10-m Walk Test [10MWT] and Functional Independence Measure sub-score [sFIM]) of these patients were collected retrospectively. All inpatients received physical therapy twice a day for 30 minutes, 5 days a week for a hospitalization period of 2 months on average, and isokinetic knee exercise of 3 times a week. The study protocol was approved by the Institutional Review Board (IRB) of Bundang Jesaeng Hospital (IRB No. 2022-05-008), and informed consent was waived owing to the retrospective design of the study.

Isokinetic parameters assessment

Patients performed three trials of isokinetic knee extension at an angle speed of 60/60 deg/sec using HUMAC NORM® isokinetic dynamometer and had a 10 seconds break between each trial. Several studies used the variable range of angular velocity to test the knee extensor at 12 to 500 degrees/second. Specifically, any speed between 60 and 180 degrees/second would generally meet most requirements for validity and the need for information about muscle performance [19]. Thus, we used 60 degrees/second angular velocity. In the test, patients were asked to extend their paretic side knee as much as possible with a tester's verbal encouragement. In addition, we delayed the test in case of complaints of fatigue or getting an inappropriate moment angle position (MAP) curve pattern. We used values from a follow-up test a month after the first test (i.e., the second isokinetic assessment after familiarizing patients with isokinetic exercise). Torque onset angle (TOA) is the angle at which the initial torque was detected in the MAP curve (Fig. 1). We also included other isokinetic parameters, such as peak torque angle (PTA), difference between TSA TOA values (TSA-TOA), PT, peak torque to weight ratio (PTWR), total work (TW), hamstring peak torque (HPT), hamstring/quadriceps ratio (H/ Q ratio), torque stop angle (TSA), torque at 30 degrees (TA30) and asymmetry ratio of peak torque between paretic limb and non-paretic limb comprising non-paretic peak torque minus paretic peak torque (PT deficit), Non-paretic peak torque/Paretic peak torque×100 (PT ratio) and Non-paretic torque at 30/Paretic torque at 30×100 (TA30 ratio) to determine which of the isokinetic parameters correlated most with the walking related balance parameters. TSA is the angle at which the last torque is detected in the MAP curve (Fig. 1).

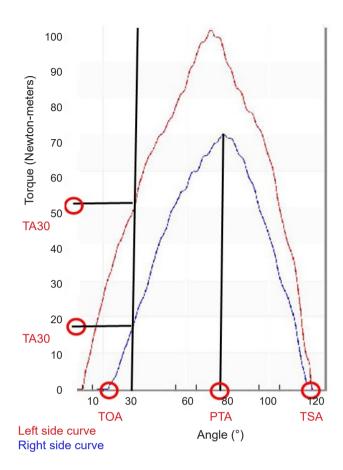


Fig. 1. Moment angle position curve. TA30, torque at 30°; TOA, torque onset angle; PTA, peak torque angle; TSA, torque stop angle.

Walking related balance parameters assessment

The parameters of walking related balance were measured with BBS sub-score (sBBS, turning 360° and placing alternate foot on stool), TUG, 10MWT, FIM sub-score (sFIM, transfers and locomotion) within a week of the isokinetic test for equivalent functional status. Patients were also tested on auditory feedback for maximal contraction. BBS is a 14-item assessment to evaluate the balance. Each item is rated on a five-point scale from 0 to 4, with a maximum score of 56. We checked sBBS consisting of turning 360° and placing alternate foot on stool while standing unsupported, which are related to the ability to initiate movement [20]. TUG is a test that evaluates functional mobility including static and dynamic balance. The test checks the time (in seconds) taken for patients to get up from a chair, walk 3 m as fast as possible, turn around, return back to the chair, and sit down [21]. 10MWT originally assesses gait speed in meters per second over 10 m, but instead, we measured the time taken

to walk 10 m. Participants were asked to walk 10 m as fast as possible and we measured the time using a stopwatch [22]. FIM is an 18-item measurement that evaluates self-care, sphincter control, transfers (mobility), locomotion, communication, and social cognition with a maximum score of 126. Among these items, we focused on transfers and locomotion items that are related to functional mobility in sFIM [23].

Statistical analysis

Pearson's correlation coefficient and partial correlation coefficient were used to measure the strength and direction of a linear relationship between isokinetic parameters and walking related balance parameters. We used multiple regression analysis with stepwise (backward elimination, p>0.10 for exclusion) to identify statistically significant isokinetic parameters associated with walking related balance parameters. In this study, we used IBM SPSS Statistics version 21.0 (IBM SPSS) for all statistical analysis. A p-value of less than 0.05 was defined as statistically significant.

RESULTS

Patient general characteristics

One hundred-two patients were enrolled. The baseline characteristics of the study population are presented in Table 1. The study population comprised 69 (67.6%) male and 33 (32.4%) female, 52 (51%) right hemiplegia and 50 (49%) left hemiplegia, 53 (52%) ischemic, and 49 (48%) hemorrhagic stroke patients. The patients' mean age was 49.8±11.5 years. The mean height and weight were 166.5±7.2 cm and 66.8±13.8 kg, respectively. The mean BMI was 24.0±4.2 kg/m². The patients' mean K-MMSE score at the time of the test was 26.7±2.3. The mean time since the onset of the stroke was 52.0±34.4 days. MAS score distribution ranged from 0 to 2, with an average of 0.15±0.38.

Outcome measures

Table 2 is the results of Pearson's correlation coefficients between walking related balance parameters and isokinetic parameters including the paretic and non-paretic sides of the knee, and asymmetry ratio values. TOA, PT, PTWR, TW, HPT, TSA-TOA and TA30 of the paretic limb were significantly associated with walking related balance parameters. TOA of the paretic limb showed moderate to good correlations with sBBS (r=0.556), TUG (r=0.646), 10MWT (r=0.629), sFIM (r=-0.229).

Table 1. Demographic characteristics and clinical characteristics

Characteristics	Value (n=102)
Sex	
Male	69
Female	33
Paretic side	
Right	52
Left	50
Subtype	
Ischemic	53
Hemorrhagic	49
Age (yr)	49.8±11.5 (17-65)
Height (cm)	166.5±7.2 (150–181)
Weight (kg)	66.8±13.8 (45-135)
Body mass index (kg/m²)	24.0±4.2 (16.5-44.6)
K-MMSE	26.7±2.3 (24-30)
Onset duration (day)	52.0±34.4 (24-169)
Spasticity (MAS)	0.15±0.38 (0-2)
PT (Nm)_N	88.2±30.7 (37–176)
PTWR (%)_N	133.0 ±37.1 (54-229)
PT (Nm)_P	60.8±30.4 (16–168)
PTWR (%)_P	92.3±40.5 (27-224)
PT deficit	27.4±18.4 (3-94)

Values are number only or mean±standard deviation (range). K-MMSE, Korean version of the Mini-Mental State Examination; MAS, Modified Ashworth Scale (MAS grades of 1 was considered as 1, while a score of 1+ was considered as 2 and so on up to a score of 4, which was considered as 5); PT_N, non-paretic peak torque; PTWR_N, non-peak torque weight ratio; PT_P, paretic peak torque; PTWR_P, paretic peak torque weight ratio; PT deficit, non-paretic peak torque-paretic peak torque

The results of the partial correlation between isokinetic parameters of the paretic side of the knee and walking related balance parameters adjusted by sex, age, height, weight, BMI, MMSE, onset duration, and spasticity are presented in Table 3. As a result, TOA, TSA-TOA, TA30, PT ratio, and TA30 ratio were significantly associated with walking related balance parameters. According to guidelines provided by Portney and Watkins, only TOA of the paretic limb showed moderate to good correlations (r-value between 0.50 and 0.75) walking related balance parameters, while TSA-TOA, TA30, PT ratio and TA30 ratio showed a fair correlation (r-value between 0.25 and 0.50) with walking related balance parameters [24]. Therefore, TOA showed the highest correlation with walking related balance parameters among isokinetic parameters.

In multivariate multiple regression using TOA, PT, TSA-TOA and TA30 as independent variables and walking related balance parameters as dependent variables, TOA was significantly associated with walking related balance parameters (BBS, sBBS,

Table 2. Pearson's correlation coefficients between isokinetic parameters of the paretic, non-paretic side of knee and asymmetry and walking related balance

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Isokinetic parameters	BBS	sBBS	TUG(s)	10MWT (s)	FIM	sFIM
Non-paretic						
PT (Nm)	0.194	0.068	-0.208*	-0.181	0.207*	0.203*
PTWR (%)	0.221*	0.108	-0.252*	-0.204*	0.155	0.253*
TW(J)	0.219*	0.108	-0.219*	-0.199*	0.189	0.165
HPT (Nm)	0.071	-0.033	-0.110	-0.081	0.232*	0.186
H/Q ratio	-0.178	-0.184	0.165	0.178	0.055	-0.006
TOA (°)	0.101	0.042	-0.020	0.040	0.027	0.053
TSA (°)	-0.096	-0.076	0.053	0.029	-0.070	-0.104
TSA-TOA	0.038	-0.012	-0.025	-0.097	-0.048	0.010
PTA	-0.134	-0.148	0.137	0.140	-0.073	-0.146
TA30 (Nm)	0.160	0.104	-0.115	-0.131	0.077	0.072
Paretic						
PT (Nm)	0.242*	0.197*	-0.306**	-0.280**	0.191	0.213*
PTWR (%)	0.281**	0.262**	-0.358**	-0.317**	0.129	0.227*
TW (J)	0.297**	0.249*	-0.360**	-0.337**	0.174	0.216*
HPT (Nm)	0.226*	0.228*	-0.302**	-0.324**	0.215*	0.225*
H/Q ratio	0.052	0.118	-0.031	-0.107	0.040	0.049
TOA (°)	-0.493**	-0.556**	0.646**	0.629**	-0.195*	-0.229*
TSA (°)	0.019	0.140	-0.279**	-0.246*	0.050	0.056
TSA-TOA	0.279**	0.402**	-0.439**	-0.470**	0.051	0.119
PTA	-0.024	-0.006	0.015	0.046	0.064	0.030
TA30 (Nm)	0.308**	0.292**	-0.332**	-0.302**	0.119	0.158
Asymmetry						
PT deficit	-0.077	-0.212*	0.160	0.160	0.030	-0.012
PT ratio	0.205*	0.300**	-0.353**	-0.328**	0.096	0.136
TA30 ratio	0.314**	0.339**	-0.420**	-0.351**	0.153	0.207*

BBS, Berg Balance Scale; sBBS, BBS sub-score; TUG, Timed Up and Go; 10MWT, 10-m Walk Test; FIM, Functional Independence Measure; sFIM, FIM sub-score; PT, peak torque; PTWR, peak torque weight ratio; TW, total work; HPT, hamstring peak torque; H/Q ratio, hamstring/quadriceps ratio; TOA, torque onset angle; TSA, torque stop angle; PTA, peak torque angle; TA30, torque at 30°; PT deficit, non-paretic peak torque-paretic peak torque; PT ratio, (non-paretic peak torque/paretic peak torque)×100; TA30 ratio, (non-paretic torque at 30/paretic torque at 30)×100.

*p<0.05 and **p<0.01.

Table 3. Partial correlation isokinetic parameters and outcomes of walking related balance evaluations for the paretic limb and asymmetry

Isokinetic parameters	BBS	sBBS	TUG (s)	10MWT (s)	FIM	sFIM
Paretic						
PT (Nm)	0.189	0.144	-0.228*	-0.199	0.093	0.208*
PTWR (%)	0.195	0.182	-0.240*	-0.222*	0.061	0.205*
TOA (°)	-0.478**	-0.535**	0.634**	0.617**	-0.195	-0.246*
TSA (°)	0.056	0.153	-0.314**	-0.252	0.121	0.102
TSA-TOA	0.327**	0.425**	-0.458**	-0.480**	0.130	0.162
PTA	-0.038	-0.014	0.069	0.064	0.038	0.030
TA30 (Nm)	0.254*	0.245*	-0.279**	-0.236**	0.073	0.155
Asymmetry						
PT ratio	0.185	0.280**	-0.326**	-0.305**	0.090	0.136
TA30 ratio	0.292**	0.316**	-0.401**	-0.337**	0.128	0.220*

BBS, Berg Balance Scale; sBBS, subscale of BBS; TUG, Timed Up and Go; 10MWT, 10-m Walk Test; FIM, Functional Independence Measure; sFIM, subscale of FIM; PT, peak torque; PTWR, peak torque weight ratio; TOA, torque onset angle; TSA, torque stop angle; PTA, peak torque angle; TA30, torque at 30°; PT ratio, (non-paretic peak torque/paretic peak torque)×100; TA30 ratio, (non-paretic torque at 30/paretic torque at 30)×100.
*p<0.05 and **p<0.01.

Table 4. Collection of results for torque onset angle variable in multivariate multiple regression analysis (stepwise)

	Adjusted R ²	В	Standardized β	VIF	F	p-value	Durbin-Watson
BBS	0.236	-0.488	-0.493	1.000	32.178	< 0.001	2.001
sBBS	0.302	-0.191	-0.556	1.000	44.685	< 0.001	2.001
TUG	0.417	0.782	0.646	1.000	71.443	< 0.001	1.971
10MWT	0.395	0.833	0.629	1.000	65.319	< 0.001	1.747
sFIM	0.053	-0.234	-0.229	1.000	5.559	0.020	1.899

VIF, variance inflation factor; BBS, Berg Balance Scale; sBBS, sub scale of BBS; TUG, Timed Up and Go; 10MWT, 10-m Walk Test; sFIM, sub-scale of Functional Independence Measure.

TUG, 10MWT, sFIM) except for FIM scores (Table 4). As the obtained variance inflation factor (VIF) values were all <2, it was concluded that there was no significant multicollinearity among the independent regressors. These results show that the TOA, as an explanatory variable, is independently associated with walking related balance parameters.

DISCUSSION

In this study, we aimed to find a new parameter to predict walking related balance. Many stroke centers conduct isokinetic training for strengthening and assessing the strength of the movement using special devices. Hence, we took the TOA among isokinetic test results into consideration. We assumed that it is analogous to the RFD or explosive strength in the early contraction phase. Additionally, it is relatively easy to obtain from the isokinetic test.

TOA

TOA of the paretic side has a moderate to good correlation coefficient with the walking related balance as shown in Table 2. As far as we are concerned, the concept of TOA has not received attention. Other studies use the time point above 2% of maximal voluntary isometric contraction as a torque onset [12,25]. Special devices are required to evaluate and measure the RFD during isometric contraction. However, TOA is easily obtained from the routine isokinetic test.

In terms of neuromuscular recruitment patterns, both slow, fatigue-resistant type I and fast, more fatigable type II muscle fibers are activated together at lower speeds. Whereas when the speed increases, type I fibers gradually get recruited less and eventually become inactive. Reaching 40% of the peak torque, type II muscle fibers work the most, then the work done by type II muscle fibers gradually decreases, and type I fibers do all the work [8]. TOA is likely to reflect a type II fibromuscular con-

dition, as it is detected during initial acceleration phase of the isokinetic test.

Hemiplegic patients have a lot of muscle abnormalities with a combination of denervation, disuse, remodeling, and spasticity. A decrease in muscle strength is a consequence of impaired motor unit recruitment and muscle changes such as atrophy [26,27]. Muscle tissue changes in normal aging are characterized by changes in the distribution of fiber types, with a decrease in type II fibers and an increase in mitochondria-rich type I fibers, resulting in the reduction of muscle strength. In contrast to this age-dependent muscle fiber type shift, a slow to fast fiber type conversion has been reported in the paretic limb muscle in stroke patients [28,29]. Muscle fibers can change their phenotype in response to environmental stimuli, including disuse, neural innervation patterns, and exercise. Under conditions of reduced muscle use and fast- frequency electrical stimulation, a slow, fatigue-resistant type I muscle fiber can alter its phenotype to a fast, more fatigable type II. In stroke patients, the total muscle fiber cross-sectional diameter decreases, and the ratio of type II muscle fibers increases due to various reasons. Thus, type II muscle fiber-related parameters may be a good indicator of muscle function in stroke patients. Therefore, we suggest the significance of TOA in predicting explosive strength in stroke patients [30].

In stroke patients, disturbed neural control, as a result of, for instance, impaired reciprocal inhibition, make an abnormal coactivation of antagonistic muscles during maximal voluntary contraction [4,31]. Abnormal muscle synergy is the cause of impairment of balance and gait speed [32]. This abnormal muscle synergy is also observed in spasticity, that is, spasticity can also be a factor in determining the TOA value. Therefore, we excluded patients with MAS grade 2 or higher. Rabita et al. [33] reported acceleration amount of the isokinetic device is not sufficient to generate a stretch reflex on spastic muscle, unlike the transient acceleration of the manual displacement. Additionally,

knee flexor spasticity in our study patients was in the range of MAS grade from 0 to 1+ (Table 1; mean, 0.15 ± 0.38 ; mostly 0 and 1). Furthermore, TOA is measured in the initial phase of motion, so MAS grade 1 or 2 spasticity is not likely to affect the TOA.

In stroke patients, strength and function are influenced by the onset duration, weight, center of gravity (height), spasticity, cognition, etc. [34-37]. So we performed a partial correlation analysis adjusted by variable factors. Table 3 shows that TOA showed a constant correlation with walking related balance parameters.

PT, PTWR, HPT, TW and H/Q ratio and asymmetry of PT ratio

PT, PTWR, HPT and TW which represent strength on the paretic side have also a correlation with walking related balance parameters (e.g., sBBS, TUG, 10WT, sFIM) [38].

Both paretic and non-paretic knee extensor muscle strengths correlated with locomotion [4,38]. But our study revealed that parameters of the isokinetic test on the non-paretic limb did not have a consistent relationship with the walking related balance parameters. We enrolled relatively high-function patients who are able to walk without ambulation aid and do the isokinetic test properly. If we enrolled patients with severe weakness, the isokinetic parameters of the non-paretic side might have been related to the walking related balance parameters because compensatory use of the intact limb is an important strategy to overcome functional impairment of weakness.

In this study, the PT ratio of hamstring to quadriceps (H/Q ratio) representing muscle balance was not related to walking related balance. Generally, the quadriceps will be twice the strength of the hamstring, and athletes have a higher H/Q ratio [39,40]. Our patients have a similar H/Q ratio to the general population, meaning there was no significant imbalance.

Limitations

First, our study included relatively high-functioning stroke patients who could take isokinetic test properly, and thus, we identified the validity of TOA in a narrow sample. Second, this is a retrospective study, we could not control the patients' conditions such as spasticity, warm-up status, capacity, and so on. Third, TOA is not a value that is recorded automatically from devices. We get the value of TOA using a mathematical formula by measuring the length from the result sheet. Therefore, there may be measurement errors, and since one tester performed it,

not seeing inter-tester reliability can be a limitation.

Most of all, more studies of TOA are needed to be done. TOA is an indicator that can be measured relatively easily in the isokinetic test, but it has not received much attention and there are few studies related to reliability. Therefore, it seems that more research on this seems to be needed in the future.

In conclusion, we have not been focusing on the TOA value in the isokinetic test parameters, but TOA of the knee extensor at the paretic limb can be a good parameter to predict walking related balance in stroke patients. Finally, our study suggests that the ability to recruit muscle fiber quickly is also important in walking related balance.

CONFLICTS OF INTEREST

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

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None.

AUTHOR CONTRIBUTION

Conceptualization: Cho TH, Ma MK, Moon HI. Methodology: Ma MK, Cho TH, Moon HI. Formal analysis: Ma MK, Cho TH, Lee JW, Moon HI. Project administration: Moon HI, Ma MK. Visualization: Ma MK, Cho TH, Lee JW. Writing – original draft: Ma MK, Cho TH. Writing – review and editing: Moon HI, Ma MK. Approval of final manuscript: all authors.

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Original Article

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Reliability and Validity of Caregivers' Fear of Falling Index When Caring for Home-Based Rehabilitation Patients With Fall-Related Fractures

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Objective: To evaluate the reliability and validity of this new measure, called the caregivers' fear of falling index (CFFI).

Methods: The study surveyed home-based rehabilitation patients with fall-related fracture, and their primary caregivers. The characteristics of these patients were evaluated, and the caregivers were surveyed using the CFFI and Falls Efficacy Scale-International (FES-I). The reliability of the CFFI was assessed using item-total correlation, while the validity of the CFFI was evaluated through correlation coefficients calculated between the CFFI and the FES-I. **Results:** The participants were 51 patient-caregiver pairs. The internal consistency of the CFFI showed an alpha coefficient of 0.904. No items were excluded in the corrected item-total correlations. The CFFI showed a moderate correlation with FES-I (r=0.432, p=0.002).

Conclusion: This study found the CFFI to be a reliable and valid tool for measuring the primary caregivers' fear. The CFFI may be a useful tool for healthcare professionals to identify and supporting these primary caregivers.

Keywords: Bone fractures, Accidental falls, Fear, Caregivers, Reproducibility of results

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INTRODUCTION

Fear of falling is a common issue among the elderly, particularly those who have experienced fall-related fractures. It is prevalent in elderly individuals, women, and those with a history of falls. The prevalence can range from 25%–85% [1-4] among commu-

nity-dwelling elderly [5-8] and is particularly high in patients with femoral neck fractures [9,10]. Fear of falling can decrease physical activity and create a vicious cycle that increases the risk of falling [8], which can lead to a decline in functional abilities [11].

In contrast, there are reports that primary caregivers may

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also fear that patients with fall-related fractures will fall during activities. In Japan, 66% of primary caregivers are family members residing with care recipients, many of whom are spouses or children [12]. Previous studies of patients with femoral neck fractures and their primary caregivers showed that primary caregivers' fear may actually be stronger than patients' fear [13]. Furthermore, it has been suggested that caregivers' fear of post-fracture patients falling also affects the care burden of primary caregivers [14]. Therefore, while it is important for caregivers to understand their fear of post-fracture patients falling in order for post-fracture patients to continue living at home, no general index exists to evaluate this.

In this context, we developed a scale to measure primary caregivers' fear [15]. The scale consists of 20 items, including the patient's physical function and care environment of the primary caregiver. The scale is self-administered, each item is rated on a 4-point scale, and the total score is calculated. Therefore, the aim of the study was to determine the reliability and validity of the measure of a caregiver's fear of post-fracture patients falling. The scale can be used to evaluate the fear of caregivers and provide them with appropriate support and interventions to alleviate such fear.

METHODS

A cross-sectional study was performed to investigate the psychometric properties of our proposed scale, termed caregivers' fear of falling index (CFFI). This study was conducted in accordance with the guidelines proposed by Declaration of Helsinki, and the study protocol was reviewed and approved by Institutional Review Board of International University of Health and Welfare (No. 20-Im-027). All participants received verbal and written explanations of the study and provided written consent to participate.

Panel of participants

Participants were patients who have experienced fall-related fractures in the past and received home-based rehabilitation service from July 1, 2021 to December 31, 2022, from data providing institutions, along with their primary caregivers. Home-based rehabilitation is one of the in-home rehabilitation services implemented under the long-term care insurance system in Japan, and it is broadly categorized into home-based rehabilitation and commuting rehabilitation services. The home-based

rehabilitation program is based on a comprehensive approach in the home environment, which includes resistance training, gait exercises, and Activities of Daily Living training, as necessary. In many cases, Patients received one-40 minute rehabilitation session per week. The data providers in this study were International University of Health and Welfare Ichikawa Hospital, Mihara Memorial Hospital, Home-Visit Nursing Station Ryugasaki, and Ushiku Aiwa General Hospital. The exclusion criteria were: fall-related fracture before age 65, living alone, the primary caregiver was not the spouse or a child, and the primary caregiver clearly had cognitive decline. Fractures of patients that occurred within the past 5 years were included. Primary caregiver surveys had to be conducted within one week of the patient's evaluation.

Measurement of patients' characteristics

Patients' data were obtained by rehabilitation personnel at each facility, including: age, sex, relationship with caregiver, long-term care level, fracture site, comorbidities stroke, intractable neurological disease, diabetes mellitus, heart disease, and neoplasm) Japanese version of Montreal Cognitive Assessment (MoCA-J), Short Physical Performance Battery (SPPB), Barthel Index, and Frenchay Activities Index.

Measurement of caregivers' fear of post-fracture patients falling

CFFI and Falls Efficacy Scale-International (FES-I) are questionnaires used to assess caregivers' fear of post-fracture patients falling. This study limited the primary caregivers to those who: live with the patient, are the patient's spouse or child, and do not have obvious cognitive decline. This was to ensure that caregivers could accurately answer the questionnaires and that their fear of patients' falls was not influenced by their own cognitive decline. Additionally, the rehabilitation staff provided instructions on how to answer the questionnaires to ensure that the caregivers understood how to complete them correctly.

CFFI is a self-rated questionnaire that measures the fear of falls among primary caregivers of patients with fall-related fractures (Fig. 1). The evaluation items consists of 20 items extracted from our previous study [15]. These 20 items included assessment of patients' physical function (e.g., 1. She/He has weak legs) and behavioral characteristics (e.g., 13. She/He often get caught up in unstable things), as well as assessment of the caregivers' home environment (e.g., 15. She/He stays at home alone during the day) and behavioral characteristics (e.g., 17. I'm

Caregivers' Fear of Falling Index (CFFI)

This questionnaire asks about you and the patient (Mrs./ Mr.) .

For each of the following items, please mark "1" if it does not apply at all and "4" if it applies very much.

For items related to frequency, please mark "1" if you encounter the matter infrequently, and "4" if you encounter it frequent

		Not at all applicable	Not very applicable	Somewhat applicable	Applicable
1	She/He has weak legs.	1	2	3	4
2	She/He stumbles indoors.	1	2	3	4
3	She/He stumbles outdoors.	1	2	3	4
4	She/He totters.	1	2	3	4
5	She/He walks with a limp.	1	2	3	4
6	She/He has dizziness.	1	2	3	4
7	She/He can't stand without support.	1	2	3	4
8	She/He has been hospitalized repeatedly.	1	2	3	4
9	She/He can't walk without support.	1	2	3	4
10	She/He forgets to have walking aid.	1	2	3	4
11	She/He gets out of wheelchair without braking.	1	2	3	4
12	I witness her/him fall.	1	2	3	4
13	She/He often gets caught up in unstable things.	1	2	3	4
14	She/He has fallen during hospitalization.	1	2	3	4
15	She/He stays at home alone during the day.	1	2	3	4
16	I have misgivings about caregiving for her/him.	1	2	3	4
17	I'm occupied with personal matters.	1	2	3	4
18	She/He and I have different physiques.	1	2	3	4
19	I don't know how to care for her/him.	1	2	3	4
20	I have been scared of caring for her/him.	1	2	3	4

Fig. 1. Caregivers' fear of falling index (CFFI). We developed a novel index based on 20 extracted items using the 3-round Delphi method [15]. This questionnaire was assessed using a 4-point scale, with a maximum score of 80 points.

occupied with personal matters). The questionnaire consists of 20 items, each rated on a 4-point scale: "not at all applicable"=1 point, "not very applicable"=2 points, "somewhat applicable"=3 points, and "applicable"=4 points, with a maximum score of 80 points. Since the questionnaire is targeted specifically at the primary caregiver, the caregiver and patient are explicitly identified at the beginning of the questionnaire as follows: "This questionnaire asks about you and the patient (name)."

FES-I is a self-administered questionnaire that originally asked patients to complete 16 items on an 84-point scale. How-

ever, it was also used for caregivers in previous studies [13]. The assessment items of FES-I questionnaire consist of activities that are relevant to daily living and could potentially cause falls, such as taking a bath or shower, walking around the house, and getting in or out of a chair. The respondents, the primary caregivers in this case, were asked to rate their confidence in the patients' ability to perform each of these activities on a scale. The scale ranged from 4, indicating the most confident, to 1, indicating the least confident. The FES-I was validated for reliability and validity by Yardley et al. [16].

Statistical analysis

For statistical analysis of CFFI, various methods were used to examine its reliability and construct validity. To examine reliability, item-total correlations were calculated, including Cronbach's alpha for internal consistency. The mean, variance, correlation coefficient with total score, and Cronbach's alpha were also calculated for each of the 20 items in CFFI, when each item was deleted. The sample size in this study was set at 48 participants, with an alpha of 0.8 based on Cronbach's alpha sample size calculation [17]. To determine construct validity, correlations with FES-I for primary caregivers were determined. Shapiro–Wilk examination was conducted to assess the normality of CFFI and FES-I. The data were analyzed using IBM SPSS 25 (IBM Corp.). A p-value less than 0.05 was considered significant; no correction for multiple testing was performed.

RESULTS

The characteristics of participants

There were 51 study participants (each participant being a patient and caregiver pair). The characteristics of the patients are described in Table 1. The mean age of the patients was 83.9 ± 8.6 years, and 62.7% (n=32) were female, 84.3% (n=43) showed a cognitive decline with MoCA-J scores<26 [18], and 56.9% (n=29) had a high risk of falls with SPPB scores<6 [19]. The caregiver relationships were spouse in 51.0% (n=26), and children in 49.0% (n=25).

Evaluation of reliability

The mean CFFI score for the 51 primary caregivers was 45.1±10.8, with a variance of 115.5. The internal consistency of CFFI showed an alpha coefficient of 0.904. The results of item-test correlation analysis are shown in Table 2. Corrected item-total correlations were greater than 0.2 for all items (range, 0.221–0.758). Cronbach's alpha if an item was deleted revealed positive and significant values (range, 0.892–0.908).

Evaluation of validity

Correlation coefficients between the CFFI and the FES-I were calculated to assess criteria-related validity (Fig. 2). The normality of CFFI and FES-I was calculated by the Shapiro-Wilk test, and both had a normal distribution. CFFI and the FES-I were shown to be significantly correlated (r=0.432, p=0.002),

Table 1. The characteristics of patients and caregivers

Characteristics	Value (n=51)			
Patients				
Age (yr)	83.9±8.6			
Sex, female	32 (62.7)			
Relationship with caregiver				
Spouse	26 (51.0)			
Children	25 (49.0)			
Long-term care-level				
Requiring support 2	8 (15.7)			
Long-term care level 1	8 (15.7)			
Long-term care level 2	10 (19.6)			
Long-term care level 3	14 (27.5)			
Long-term care level 4	9 (17.6)			
Long-term care level 5	2 (3.9)			
Fracture site				
Upper extremity	8 (15.7)			
Lower extremity	23 (45.1)			
Spinal column	14 (27.5)			
Others	6 (11.8)			
Comorbidities ^{a)}				
Stroke	9 (17.6)			
Intractable neurological disease	9 (17.6)			
Diabetes mellitus	10 (19.6)			
Heart disease	16 (31.4)			
Neoplasm	8 (15.7)			
MoCA-J (<26)	43 (84.3)			
SPPB (≤6)	29 (56.9)			
Barthel Index (<85)	22 (43.1)			
Frenchay Activities Index	9.5±7.8			
Caregivers (n=51)				
Caregivers' fear of falling index	45.1±10.8			
Falls Efficacy Scale-International	39.6±13.8			

Values are presented as mean±standard deviation or number (%).

Requiring support 2, requires support with movements such as walking due to instability; requiring long-term care 1, requires assistance with daily activities such as bathing; requiring long-term care 2, requires support with movements such as conversing; requiring long-term care 3, cannot walk independently; requiring long-term care 4, requires assistance with all Activities of Daily Living; requiring long-term care 5, completely dependent on care.

MoCA-J, Japanese version of Montreal Cognitive Assessment; SPPB, Short Physical Performance Battery.

^{a)}The totals are different because of overlapping comorbidities among the participants.

indicating that the index is a valid measure of caregivers' fear of post-fracture patients falling.

DISCUSSION

This study investigated the reliability and validity of CFFI in a

Table 2. Results of item-total correlation

Item	Mean if item deleted	Variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
1	42.078	108.474	0.515	0.900
2	42.529	107.094	0.590	0.898
3	42.686	104.140	0.652	0.896
4	42.510	101.695	0.758	0.892
5	42.392	102.243	0.720	0.894
6	43.412	107.087	0.678	0.896
7	42.294	101.892	0.743	0.893
8	43.235	99.904	0.592	0.899
9	42.510	104.415	0.648	0.896
10	43.882	109.906	0.467	0.901
11	44.020	109.020	0.596	0.898
12	43.804	108.561	0.629	0.897
13	43.784	108.373	0.434	0.902
14	44.118	113.266	0.451	0.902
15	43.275	112.963	0.223	0.908
16	43.588	112.447	0.344	0.903
17	43.333	106.187	0.638	0.896
18	43.686	109.140	0.457	0.901
19	43.686	115.500	0.221	0.905
20	43.863	110.281	0.432	0.902

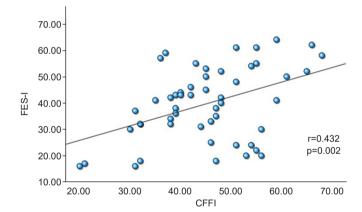


Fig. 2. Correlation between caregivers' fear of falling index (CFFI) and Falls Efficacy Scale-International (FES-I). This is a scatter plot with CFFI scores plotted on the X-axis and FES-I scores plotted on the Y-axis. The Pearson correlation coefficient and p-value are indicated in the figure.

sample of primary caregivers caring for community-dwelling patients with fall-related fractures. The internal consistency alpha was 0.904 (0.892–0.908), indicating high-level consistency. The correlation with FES-I was 0.432, indicating a moderate correlation. The strength of this study was that it standardized the measurement of caregivers' fear of post-fracture patients falling, for which a commonly utilized index does not exist.

This index can be used to examine whether the caregivers' fear of post-fracture falls affects the functional ability of the post-fracture patients. This is because excessive fear from primary caregivers may potentially decrease the activity levels of the post-fracture patients. If it is found that primary caregivers' fear is indeed a factor that negatively impacts the functional ability of the post-fracture patients, healthcare professionals should not only support primary caregivers in improving the environment for fall prevention and teaching appropriate caregiving techniques but also provide guidance to help primary caregivers themselves manage their excessive fear. It is important to empower caregivers to support patients in leading as independent a life as possible.

An item-test correlation is a measure of the association between an individual item on a test or questionnaire and the overall test score. It is used to assess the extent to which an individual item is related to the construct or trait that the test is designed to measure. Item-test correlation is often used as an indicator of item quality and as a way to determine which item to include in or exclude from a test [20]. It is generally accepted that items with a corrected item-total correlation below 0.2 should be considered for exclusion [21]. Because the corrected item-total correlation was greater than 0.2 (range, 0.221–0.758), no items were excluded.

It is possible that the high degree of consistency noted in the

present study, limited to patients living at home, could be related to the fact that the participants all shared similar experiences. Thus, they may have been more likely to respond in a similar way to items in the questionnaire, resulting in a higher degree of consistency across the items. This increased consistency may also be an indication that the questionnaire assesses a specific aspect of the construct that is relevant to the population studied and less relevant to other populations. However, it is important to note that other factors, such as the quality of the test items, the validity of the construct being measured, sample size, and representativeness of the population studied also have an impact on the degree of consistency noted in the study.

A moderate correlation between CFFI and FES-I scores could indicate that there is a relationship between the two measures, but it is not a strong one. This could be due to the difference in scope between the two measures. For example, FES-I assesses the self-reported confidence and perceived control of individuals to prevent falls, and other measures may assess the physical or cognitive abilities that can affect fall risk, such as balance, gait, or muscle strength [22]. Thus, the moderate correlation between these two measures could suggest that there is some overlap in the construct they measure, but they also assess different aspects of the fall risk.

There are three limitations of this study to consider. The first is that the number of participants in this study was relatively small. It was not easy for us to collect a lot of participants for this study sufficiently as we had expected, unfortunately. Now we consider that the inclusion and exclusion criteria for this study was somewhat strict, which could be one of the reasons for this insufficiency. However, on the other hand, we understand that the strictness of these criteria contributed to the appropriate analysis for this study, undoubtedly. The second limitation is that the period between the injury and the present measurement was not unified. In this study, the periods since the injury and living at home differed among the participants. This was because the timing of the start of home-based rehabilitation differed for each participant. It is possible that the experiences of the patients and primary caregivers during the period of living at home may have influenced the results of this scale. The third limitation was that the study failed to take into account the content of the rehabilitation implemented. The study focused on developing a tool to measure the fear of caregivers, but it did not consider the effect of rehabilitation on that fear. Rehabilitation programs can vary markedly in their content, focus, and intensity, and it is possible that certain types of rehabilitation may be more effective in reducing caregivers' fear of post-fracture patients falling than others [23]. Therefore, it may be beneficial for future studies to investigate the impact of different rehabilitation programs on caregivers' fear of post-fracture patients falling, and consider the rehabilitation content as a potential moderator of the fear level.

In conclusion, this study found CFFI to be a reliable and valid tool for measuring the primary caregivers' fear. These results suggest that CFFI may be a useful tool for healthcare professionals to identify and support primary caregivers who fear post-fracture patients falling and design interventions that can alleviate such a fear and support post-fracture patients' recovery.

CONFLICTS OF INTEREST

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

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None.

AUTHOR CONTRIBUTION

Conceptualization: Kakehi T, Kakuda W. Methodology: all authors. Formal analysis: Kakehi T, Kakuda W. Project administration: Kakehi T, Kakuda W. Visualization: Kakehi T, Kakuda W. Writing – original draft: Kakehi T, Kakuda W. Writing – review and editing: all authors. Approval of final manuscript: all authors.

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Association of Diaphragm Thickness and Respiratory Muscle Strength With Indices of Sarcopenia

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Objective: To evaluate the relationship between respiratory muscle strength, diaphragm thickness (DT), and indices of sarcopenia.

Methods: This study included 45 healthy elderly volunteers (21 male and 24 female) aged 65 years or older. Sarcopenia indices, including hand grip strength (HGS) and appendicular skeletal muscle mass/body mass index (ASM/BMI), were measured using a hand grip dynamometer and bioimpedance analysis, respectively. Calf circumference (CC) and gait speed were also measured. Maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP) were obtained using a spirometer, as a measure of respiratory muscle strength. DT was evaluated through ultrasonography. The association between indices of sarcopenia, respiratory muscle strength, and DT was evaluated using Spearman's rank correlation test, and univariate and multiple regression analysis.

Results: ASM/BMI (r=0.609, p<0.01), CC (r=0.499, p<0.01), HGS (r=0.759, p<0.01), and gait speed (r=0.319, p<0.05) were significantly correlated with DT. In the univariate linear regression analysis, MIP was significantly associated with age (p=0.003), DT (p<0.001), HGS (p=0.002), CC (p=0.013), and gait speed (p=0.026). MEP was significantly associated with sex (p=0.001), BMI (p=0.033), ASM/BMI (p=0.003), DT (p<0.001), HGS (p<0.001), CC (p=0.001) and gait speed (p=0.004). In the multiple linear regression analysis, age (p=0.001), DT (p<0.001), and ASM/BMI (p=0.008) showed significant association with MIP. DT (p<0.001) and gait speed (p=0.050) were associated with MEP.

Conclusion: Our findings suggest that respiratory muscle strength is associated with DT and indices of sarcopenia. Further prospective studies with larger sample sizes are needed to confirm these findings.

Keywords: Sarcopenia, Diaphragm, Respiratory muscles, Maximal respiratory pressures, Ultrasonography

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INTRODUCTION

Sarcopenia is a geriatric syndrome associated with loss of skeletal muscle mass and muscle strength [1]. Sarcopenia commonly

occurs as an age-related process and is also influenced by malnutrition, inactivity, disease, and other iatrogenic factors [2]. Sarcopenia is associated with low quality of life, increased risk of falls and fractures, disability, and loss of independence [3].

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The association between sarcopenia and respiratory diseases has been previously documented. One study reported a high prevalence of about 60% of sarcopenia in patients with respiratory failure [4]. On the other hand, a cross-sectional study based on the 2008–2011 Korean National Health and Nutritional Examination Survey showed that lower skeletal muscle mass is associated with reduced respiratory function in the elderly [5]. Reduced respiratory muscle strength can also impact respiratory health. A study conducted in Japan reported that respiratory muscle weakness and lower body trunk muscle mass increased the risk for pneumonia in older people [6]. A systematic review of adults with respiratory muscle weakness after stroke showed that respiratory muscle strength training decreased the risk of respiratory complications [7].

Diaphragm thickness (DT) can be decreased in a range of disease states, including sarcopenia. Ultrasonographic evaluation of the diaphragm showed that DT is reduced in patients on prolonged mechanical ventilation [8]. A study by Deniz et al. [9] revealed a significant reduction in DT among individuals with sarcopenia compared to non-sarcopenic elderly individuals. This reduction in DT is concerning, as it can contribute to diaphragm dysfunction and respiratory complications [10]. Recently, the concept of respiratory sarcopenia has emerged and ultrasonographic evaluation of DT has been proposed as a measure of respiratory muscle mass [11]. However, evaluation of the diaphragm by ultrasound is usually performed in the intensive care unit setting, and is not routinely measured in sarcopenia patients [12].

While previous studies have examined the correlation between respiratory muscle strength and sarcopenia [13], as well as DT and sarcopenia [9], there is a dearth of research investigating the association among all three factors simultaneously. Hence, our study aimed to assess the relationship between respiratory muscle strength, diaphragm muscle, and indices of sarcopenia within a single investigation.

METHODS

Study population

Healthy adult volunteers (25 male and 25 female) aged 65 years or older were consecutively recruited for this cross-sectional study through advertisements. Participants with functional problems due to lung disease (such as lung cancer, history of lung surgery, chronic obstructive pulmonary disease, asthma, or tuberculosis), diseases which can affect sarcopenia (such as

stroke, spinal cord injury, or peripheral neuropathy), or a history of major joint surgery were excluded. They were informed of the purpose and nature of the study and signed the written consent form. The study was approved by the Institutional Review Board of Chung-Ang University Hospital (No. 1751-003-281).

Skeletal muscle mass assessment

Bioelectrical impedance analysis (BIA), InBody S10 (Biospace) was used to measure skeletal muscle mass. BIA is a non-invasive, easy to administer tool for measuring body composition [14]. The participants were instructed to avoid eating or doing exercises at least 8 hours before the study. After measuring the height and weight, electrodes were attached to the four extremities of the participants in the supine position. Appendicular skeletal muscle mass (ASM) was obtained through the body composition analysis. Appendicular skeletal muscle mass/body mass index (ASM/BMI) was calculated as follows [15]:

ASM/BMI=appendicular skeletal muscle (kg)/body mass index Body mass index=weight (kg)/height (m)²

Thigh and calf circumference measurement

Thigh and calf circumference (CC) was measured with the patient in the supine position. The left knee was raised to form a 90° between the calf and the thigh [16]. The tape measure was placed around the left calf and thigh, and the maximal circumference was measured without compressing the subcutaneous tissue.

Muscle strength and physical performance measurements

Handgrip strength (HGS) was measured using a hand-grip dynamometer, T.K.K.5401 (Takei Scientific Instruments). Participants were asked to assume the following position: adduct and neutrally rotate the shoulder, flex the elbow to 90°, and place the forearm in a neutral position, with the wrist between 0° and 30° extension and between 0° and 15° ulnar deviation while sitting in a straight-backed chair [17]. Instruction was given to squeeze the grip handle as hard as possible for 3 seconds, and the maximum contraction force (kg) was recorded. The tests were performed three times in each hand with a 60-second rest between each trial. The average of the three values was used for the analysis.

Gait speed was measured to evaluate physical performance, and function of the lower extremities. Gait speed was evaluated on a hard surface by measuring the time taken to walk 4 m at

one's usual walking pace [18]. The participant walked a total 9-m distance, with 2.5 m at the start and end used for acceleration and deceleration. The measurements of three trials were averaged and used for the analysis.

Respiratory muscle strength

Maximal expiratory pressure (MEP) and maximal inspiratory pressure (MIP) were used as a measure of expiratory and inspiratory muscle strength [19]. MEP and MIP were measured in the sitting position using the portable spirometer (Pony FX; COSMED) [20]. To minimize errors, an experienced operator coached the subjects to completely seal their lips around the mouthpiece to prevent air leakage. Participants were encouraged to maximally expire for MEP measurements and to maximally inspire for MIP measurements. At least five trials were performed under supervision and the maximum value between trials which varied by less than 20% were recorded [21]. Each test was performed with a 1-minute break.

DT measurement

DT was measured by B-mode ultrasound using a 7.5 MHz linear transducer (SONOACE R7, Samsung Medison Inc.). The measurement of the diaphragm was conducted at the right side, at the zone of apposition in the 8th or 9th intercostal space as described by De bruin et al. [22]. The probe was placed between the anterior and mix-axillary lines. The participant was in the sitting position and measurements of the diaphragm were taken at the end of expiration (DTe) and inspiration (DTi) during quiet breathing by a single experienced physician. The mean value of DTe and DTi was used as a measure of DT. Thickening fraction (TF) of the diaphragm during quiet breathing was also calculated as follows [23].

$$TF = \frac{DTi - DTe}{DTe} \times 100$$

Statistical analysis

The baseline characteristics and measurement of participants are presented as the mean±standard deviation. The Mann–Whitney test was used to compare differences between the sexes. The Spearman's rank correlation test was used to evaluate correlation between the DT and other indices of sarcopenia. Linear regression analysis was used to evaluate association between respiratory muscle strength, DT and indices of sarcopenia. Multiple linear regression analysis with backward elimination was performed to identify factors predictive of respiratory

muscle strength. Statistical significance was defined as a p-value of less than 0.05. Statistical analysis was performed using the IBM SPSS Statistics ver. 19.0 (IBM Corp.).

RESULTS

Baseline characteristics

A total of 25 male and 25 female participants were recruited. Five participants with a history of lung disease (chronic obstructive pulmonary disease and asthma) were excluded. The baseline characteristics of the participants are shown in Table 1. The mean age was 76.76±1.13 years for male (n=21), and 76.42±1.03 years for female (n=24). Height, weight, HGS, CC, MEP, DT, and ASM/BMI were significantly different according to sex. Measures of gait speed, HGS, and CC were comparable to previously published normal range for age and sex [24].

Respiratory muscle strength, DT, and indices of sarcopenia

HGS (r=0.759, p<0.01), ASM/BMI (r=0.609, p<0.01), CC (r=0.499, p<0.01), and gait speed (r=0.319, p<0.05) were significantly correlated with DT. Additionally, HGS (r=0.437, p<0.01), CC (r=0.408, p<0.01), gait speed (r=0.328, p<0.05), and DT (r=0.652, p<0.01) showed significant correlations with MIP. Lastly, significant correlations were found between HGS (r=0.626, p<0.01), ASM/BMI (r=0.399, p<0.01), CC (r=0.507, p<0.01), gait speed (r=0.592, p<0.01), and DT (r=0.689, p<0.01) with MEP (Table 2).

In the univariate linear regression analysis, MIP was significantly associated with age (p=0.003), DTi (p<0.001), DTe (p<0.001), DT (p<0.001), HGS (p=0.002), CC (p=0.013), and gait speed (p=0.026). MEP was significantly associated with sex (p=0.001), BMI (p=0.033), ASM/BMI (p=0.003), DTi (p<0.001), DTe (p<0.001), DT (p<0.001), HGS (p<0.001), CC (p=0.001), and gait speed (p=0.004; Table 3).

In the multiple linear regression analysis with backward elimination, age (p=0.001), DT (p<0.001), and ASM/BMI (p=0.008) showed significant association with MIP. DT (p<0.001) and gait speed (p=0.050) were found to be associated with MEP (Table 4).

DISCUSSION

In this study we have demonstrated that indices of sarcopenia, DT, MIP, and MEP were intercorrelated with each other. In the univariate analysis, DTi, DTe, DT, HGS, CC, and gait speed were significantly associated with both MIP and MEP. Age was

Table 1. Baseline characteristics

Characteristics	Total (n=45)	Male (n=21)	Female (n=24)	p-value
Age	76.58±0.76	76.76±1.13	76.42±1.03	0.864
Height (cm)	155.02±1.32	162.86±0.81	148.17±1.17	< 0.001
Weight (kg)	58.22±1.49	64.14±1.75	53.04±1.76	< 0.001
$BMI (km/m^2)$	24.14±3.06	24.15±2.58	24.13±3.49	0.891
Gait speed (m/s)	1.02±0.04	1.06±0.05	0.98±0.05	0.270
HGS (kg)	21.61±1.13	28.03±1.17	15.99±0.76	< 0.001
CC (cm)	32.97±0.50	34.41±0.70	31.71±0.63	0.011
TC (cm)	38.31±0.55	38.33±0.74	38.29±0.82	0.973
MIP (cmH ₂ O)	66.49±3.45	71.81±5.63	61.83±4.05	0.255
MEP (cmH ₂ O)	106.36±4.39	121.76±6.16	92.88±4.83	0.001
DTi (cm)	0.20±0.02	0.22 ± 0.02	0.19±0.01	< 0.001
DTe (cm)	0.18±0.02	0.19±0.02	0.16±0.02	< 0.001
DT (cm)	0.19±0.03	0.20 ± 0.00	0.17 ± 0.00	< 0.001
TF	15.04±5.56	14.66±4.86	15.38±6.20	0.458
ASM/BMI	0.76±0.03	0.91±0.02	0.62±0.02	< 0.001

BMI, body mass index; HGS, hand grip strength; CC, calf circumference; TC, thigh circumference; MIP, maximal inspiratory pressure; MEP, maximal expiratory pressure; DTi, diaphragm thickness at the end of inspiration; DTe, diaphragm thickness at the end of expiration; DT, diaphragm thickness; TF, thickening fraction; ASM/BMI, appendicular skeletal muscle mass/body mass index.

Table 2. Spearman's correlation analysis of indices of sarcopenia, respiratory muscle strength, and DT

	HGS	ASM/BMI	CC	Gait speed	DT	MIP	MEP
HGS	1.00	0.790**	0.586**	0.396**	0.759**	0.437**	0.626**
ASM/BMI		1.00	0.353**	0.299*	0.609**	0.188	0.399**
CC			1.00	0.135	0.499**	0.408**	0.507**
Gait speed				1.00	0.319*	0.328*	0.455**
DT					1.00	0.652**	0.689**
MIP						1.00	0.592**
MEP							1.00

DT, diaphragm thickness; HGS, hand grip strength; ASM/BMI, appendicular skeletal muscle mass/body mass index; CC, calf circumference; MIP, maximal inspiratory pressure; MEP, maximal expiratory pressure.

*p<0.05 and **p<0.01.

Table 3. Associations of age, sex, indices of sarcopenia, and DT with MIP and MEP by univariate linear regression analysis

17:-1-1	MIP		MEI)
Variables	β±SE	p-value	β±SE	p-value
Age	-1.99±48.02	0.003	-1.31±0.86	0.136
Sex	-9.98±6.82	0.151	-28.89±7.74	0.001
BMI	2.19±1.10	0.053	3.07±1.39	0.033
ASM/BMI	29.60±19.57	0.138	72.62±23.08	0.003
DTi	670.17±116.99	< 0.001	912.46±140.81	< 0.001
DTe	763.33±127.56	< 0.001	904.16±171.51	< 0.001
DT	693.67±118.78	< 0.001	959.41±140.28	< 0.001
TF	-0.50±0.63	0.427	0.48 ± 0.80	0.553
HGS	1.39±0.42	0.002	2.56±0.45	< 0.001
CC	2.52±0.97	0.013	4.29±1.16	0.001
Gait speed	32.59±14.10	0.026	52.54±17.29	0.004

DT, diaphragm thickness; MIP, maximal inspiratory pressure; MEP, maximal expiratory pressure; SE, standard error; BMI, body mass index; ASM/BMI, appendicular skeletal muscle mass/body mass index; DTi, diaphragm thickness at the end of inspiration; DTe, diaphragm thickness at the end of expiration; TF, thickening fraction; HGS, hand grip strength; CC, calf circumference.

Table 4. Associations of age, sex, indices of sarcopenia, and DT with MIP and MEP by multiple linear regression analysis

Variables	MIP		MEP		
variables	β±SE	p-value	β±SE	p-value	
Age	-1.66±0.44	0.001	-	-	
ASM/BMI	-45.01±16.06	800.0	-	-	
DT	852.80±126.98	< 0.001	869.70±142.67	< 0.001	
Gait speed	-	-	27.01±13.41	0.050	

DT, diaphragm thickness; MIP, maximal inspiratory pressure; MEP, maximal expiratory pressure; SE, standard error; ASM/BMI, appendicular skeletal muscle mass/body mass index.

significantly associated with MIP and sex and ASM/BMI with MEP only. In the multivariate linear regression analysis DT showed significant association with both MIP and MEP. Age and ASM/BMI were significantly associated with MIP.

The diaphragm is a skeletal muscle like limb muscles. It is composed of roughly equal proportions of slow and fast fibers [25]. The main difference lies in structure and not composition. Compared to limb muscles, diaphragm fibers have smaller cross sectional area, allowing efficient oxygen supply and increased resistance to fatigue [25]. Due to similarity in fiber composition, the diaphragm muscle may be affected in situations where skeletal muscle wasting occurs, such as sarcopenia. An animal study found that sarcopenic rats induced by genetic modification have thinner diaphragm and weaker respiratory muscle strength than normal rats [26]. In their study of 30 sarcopenic and 30 non-sarcopenic elderly patients aged over 65, Deniz et al. [9] reported that DT was significantly reduced in the sarcopenic compared to the non-sarcopenic elderly individuals. Similarly, in our study of health elderly people, indices of sarcopenia were significantly associated with DT. Our findings suggest that the diaphragm may be affected in sarcopenia.

Respiratory muscle strength is closely related to diaphragmatic, abdominal, and intercostal muscle strength [21] and can be reduced in a range of diseases such as stroke [27], spinal cord injury [28], and neuromuscular disease [29]. Findings from previous studies suggest that respiratory muscle strength may also be reduced in sarcopenia. In a study on healthy elderly by Shin et al. [30], skeletal muscle mass index was significantly associated with MIP. In a cross-sectional study by Ohara et al. [31], MEP and MIP were associated with sarcopenia indicators such as muscle mass, hand grip strength, and gait speed. Our study findings were similar to prior research, illustrating a correlation between respiratory muscle strength and indicators of sarcopenia.

The diaphragm is a primary inspiratory muscle which con-

tracts during inhalation and relaxes during exhalation. Its correlation with MIP is apparent, given its fundamental role, and has been reported previously [32]. However, the reason DT was associated with MEP is not readily discernible. One possible explanation is that expiration was enhanced by greater elastic recoil of the rib cage and lung after stronger inspiration. Another possibility is that the DT was increased in subjects with already strong expiratory muscles. In a study by Souza et al. [33], elderly female who underwent inspiratory muscle strengthening training showed significant increases in MIP, MEP, and DT compared to the control group, indicating a positive correlation between respiratory muscle strength and DT. Our study demonstrated that DT is significantly associated with both inspiratory and expiratory muscle strength.

In the multiple regression analysis, MIP was negatively correlated with age and ASM/BMI, and positively correlated with DT. Age related decrease in MIP has been described before [34]. Possible explanations include age related muscle atrophy and loss of fast twitch fibers [34]. The association between MIP and skeletal muscle mass have also been reported in previous studies. In a study by Ro et al. [35], skeletal muscle mass was significantly associated with MIP in both young male and female. Similarly, Shin et al. [30] also reported that skeletal muscle mass showed significant correlation with MIP in the healthy elderly. Contrary to our study results, in both studies, the correlation was positive. However, they did not evaluate DT, a significant determinant of inspiratory strength. The reason skeletal muscle mass, which is a measure of limb muscle, was significantly negatively associated with MIP is unclear. Obesity may have been a contributing factor. In general, people who are obese tend to have larger muscle mass [36]. Obesity can affect respiratory function through mechanical factors and metabolic effects associated with proinflammatory state [37]. However, measures of obesity and central obesity such as waist circumference, and lipid profile were not evaluated. Skeletal muscle mass was measured using BIA, which may not be as accurate as dual-energy X-ray absorptiometry (DXA) [38]. If surrogate measures such as DXA, limb muscle ultrasound, magnetic resonance imaging were used results could have been different. Further studies are needed to validate this.

MEP was also significantly correlated with DT but not ASM/BMI in the multiple regression analysis. The significant positive correlation between ASM/BMI and MEP in the univariate linear regression analysis was not observed in the multiple regression analysis. This may be due to the fact that ASM/BMI

primarily reflects limb muscle mass rather than trunk muscles, which are more closely associated with expiratory muscle strength [21]. The results seem to indicate that the ASM/BMI has a lesser role in predicting expiratory strength. Therefore, it may be necessary to measure DT separately as an additional indicator of respiratory sarcopenia [39].

There are some limitations to this study. First, this was a cross-sectional study of healthy elderly volunteers with small sample size. Causal relationships cannot be confirmed and caution is needed in generalizing the findings. Second, skeletal muscle mass was measured by BIA. BIA may overestimate skeletal muscle mass compared to DXA [38]. However, studies have shown that BIA was reliable in measuring muscle mass, and strongly correlated with skeletal muscle measurement by DXA [40]. Third, TF of the diaphragm was measured only during quiet breathing and not maximal breathing. TF during maximal breathing may be better correlated with maximal respiratory pressure. Lastly, other possible confounding factors such as abdominal muscles involved in respiration were not evaluated.

This was the first study to demonstrate correlation between respiratory muscle strength, DT, and skeletal muscle mass in healthy Korean elderly. Sarcopenia patients may have decreased respiratory muscle strength associated with reduced DT. Therefore, assessment of respiratory muscle strength and DT may be needed in sarcopenia patients to prevent respiratory functional decline. Further studies are necessary to evaluate changes in DT in patients with sarcopenia and whether early interventions may help prevent pulmonary complications.

CONFLICTS OF INTEREST

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

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None.

AUTHOR CONTRIBUTION

Conceptualization: Son S, Kim DK. Methodology: Son S, Park MW, Kim DK. Formal analysis: Lee Y, Son S, Park MW, Kim DK. Visualization: Lee Y, Son S. Writing – original draft: Lee Y, Son S. Writing – review and editing: Lee Y, Park MW, Kim DK. Approval of final manuscript: all authors.

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Instructions for authors



Enacted in May, 2011 Revised on January 31, 2013 Revised on August 1, 2018 Revised on Mar 11, 2019 Revised on Mar 16, 2020 Revised on June 9, 2023

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.

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1) ARTICLE TYPES

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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 (°).

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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

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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.

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- For more on references, refer to the NLM Style Guide for Authors, Editors, and Publishers (http://www.nlm.nih.gov/citingmedicine).

Journals

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 Leeds, UK. New York: Springer; 2002.

Thesis (Dissertation)

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

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