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Wearable Robots for Rehabilitation and Assistance of Gait: A Narrative Review

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Wearable robotic exoskeletons have emerged as promising technologies for enhancing gait rehabilitation and providing mobility assistance in individuals with neurological and musculoskeletal disorders. This narrative review summarizes recent advances in wearable robots—including both rigid exoskeletons and soft exosuits—and evaluates their clinical application across diverse conditions such as stroke, spinal cord injury, cerebral palsy, and Parkinson's disease. For rehabilitation purposes, these devices enable repetitive, task-specific gait training that promotes motor learning, reduces therapist burden, and facilitates improvements in walking speed, balance, and endurance. Rigid exoskeletons provide substantial joint support and are particularly effective for patients with severe gait impairments, whereas soft exosuits offer lightweight assistance suited to individuals with milder deficits or fatigue, albeit with limited capacity to deliver high-torque support. Beyond rehabilitation, wearable robots are increasingly used as assistive devices to compensate for permanent gait limitations and restore mobility in daily life. However, widespread clinical adoption remains constrained by several challenges, including a lack of standardized protocols; limited evidence from large-scale, multicenter studies; and practical issues such as device weight, comfort, and ease of use in community settings. Recent developments—such as adaptive control algorithms, volition-adaptive assistance, and artificial intelligence integration—are addressing these barriers by enabling more personalized and responsive support. With continued research investment, user-centered design, and supportive policies, wearable exoskeletons hold considerable potential to improve independence, participation, and quality of life for individuals across a broad spectrum of mobility impairments.

Keywords: Robotic exoskeleton, Wearable devices, Assistive devices, Rehabilitation, Mobility limitation

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INTRODUCTION

Gait impairments affect millions worldwide, particularly those suffering from not only neurological and musculoskeletal disorders, but also aging and associated frailty. With the global rise in the aging population and the incidence of stroke and spinal cord injuries, there is an increasing demand for effective interventions to restore walking ability because freedom of movement is one of the most fundamental elements for leading a healthy and fulfilling life.

The advancement of robotics is precipitating revolutionary changes across diverse medical fields, notably in rehabilitative

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medicine, and presenting new opportunities for incumbent service providers. For individuals with disabilities and the elderly, whose activities are often restricted and societal participation limited, robotic technologies present promising avenues to foster greater autonomy, minimize dependence on caregivers, and enhance overall well-being. Over the past several decades, rehabilitation robotics has progressed rapidly in both scale and sophistication, signaling a paradigm shift in the way rehabilitative care is delivered and managed.

Robot-assisted gait training (RAGT) is increasingly recognized as an effective approach for improving gait and balance, as it enables task-specific and intensive rehabilitation sessions [1]. This is a new global physiotherapy modality that applies robotics technology along with high-intensity repetitive exercises to improve mobility of patients with neuromuscular disorders. RAGT offers a controlled setting that facilitates the delivery of higher therapy intensity and greater training volume. In a study involving children with cerebral palsy (CP), RAGT enabled participants to take nearly 1,000 steps during a 30-minute session, representing approximately 4.7 times the training intensity of conventional therapy [2]. It can also provide the individually tailored therapy settings and reduce the physical burden on the therapist. Therefore, robotics for rehabilitation holds considerable promise, as it delivers at least similar effectiveness with improved efficiency. The development of rehabilitation robots for the lower extremity began in 1994 with the design of the Lokomat® (Hocoma AG), which combined body-weight-supported treadmill training with robotic gait orthosis assistance [3].

Robot-assisted rehabilitation techniques are generally categorized into three types: tethered exoskeletons, end-effector devices, and wearable exoskeletons. Tethered exoskeletal systems, such as the Walkbot® (P&S Mechanics) [4] deliver movement assistance through a rigid, jointed frame that synchronizes with a bodyweight support mechanism to guide the patient's leg motions. End-effector devices, such as the Morning Walk® (Curexo) [5], operate by constraining the distal part of the leg, thereby defining its path while exerting less robotic influence on the proximal joints. Wearable exoskeletons, such as the ReWalk® (Lifeward Ltd.) [6] and Angel Legs® (Angel Robotics Co., Ltd.) [2], are powered suits with articulated joints and onboard control systems, enabling a more natural walking experience [7]. RAGT especially with the tethered devices allows early mobilization and verticalization especially for the patients with acute and severe disabilities. Although most research has not demonstrated a clear advantage of RAGT over traditional rehabilitation approaches, there is evidence to suggest that individuals who are non-ambulatory may gain more from RAGT than those who can already walk. As recovery of locomotor ability progresses—especially in proximal joints—patients may transition from tethered exoskeletal support to end-effector devices. This can then be followed by gait training on level ground using wearable robotic exoskeletons with minimal assistance [8].

Wearable powered exoskeletons offer the benefits of fixed robotic systems while enabling gait training in real-life settings, thereby promoting greater user engagement and presenting increased physical challenges [9]. Their use is rapidly expanding across various fields, including healthcare, rehabilitation, assistive technology, military, and industrial applications [10]. Early designs of wearable powered exoskeletons primarily targeted individuals with near-complete paralysis due to spinal cord injury (SCI), a population for whom gait training imposes significant physical demands on therapists [6]. As clinical adoption of wearable locomotor training devices grows, their use has extended to individuals with diverse conditions—such as incomplete SCI and stroke—who often benefit from either reduced support or tailored asymmetrical assistance [8]. Moreover, wearable devices have recently been developed using various materials, such as rigid or soft components, and have been designed to support different body parts and assistive strategies. These innovations support ongoing rehabilitation beyond the hospital setting and assist in addressing remaining functional impairments during everyday activities. Given the recent rapid advancements and growing interests, this review explores the technologies underpinning wearable robots focusing on their application and clinical efficacy across various conditions in the context of gait rehabilitation and mobility assistance, then also discuss the challenges and future directions.

OVERVIEW OF WEARABLE ROBOTIC GAIT SYSTEMS

Wearable robotic gait systems can be classified into two major types: rigid exoskeletons and soft exosuits. Rigid exoskeletons consist of powered actuators that provide joint movement through a rigid structure. They are often heavy and bulky due to the rigid structure, actuators, and batteries. For instance, the average weight of hip-knee exoskeletons for adults is about 15 kg. This weight, which is more than half the weight of an average adult human leg, can add to the metabolic cost. However, this rigid structure can support user body weight and facilitate

a more efficient transfer of high assistive torque to severely weakened limbs. In contrast, soft exosuits are made of flexible materials and typically used to augment gait in individuals with mild impairments or fatigue. Most soft exosuits are based on wire-driven actuation mechanisms, which offer lighter weight and less restriction but limit assistance for individuals with severe motor impairments [11].

In addition to this distinction between rigid and soft designs, these wearable robotic gait systems can also be categorized by the joints they actuate, with various commercially available devices targeting the hip, knee, and ankle in different combinations (Fig. 1).

Furthermore, their application can be broadly divided into two main purposes: rehabilitation and assistance. The first application is aimed at replacing traditional, therapist-assisted gait training with RAGT. Numerous neuroscience studies have demonstrated that damaged brain and spinal cord functions can be partially recovered through repetitive rehabilitation therapy. Such rehabilitation therapy promotes functional recovery through repetitive training based on appropriate assistance provided by a therapist. This reliance on human skill and experience poses challenges for standardizing treatment quality and limits the duration of therapy. Robotic rehabilitation equipment can deliver prolonged, repetitive training in a more precise, objective, and standardized manner, thereby maximizing functional recovery.

The second application involves assisting individuals with permanent or progressive physical impairments. Even with advanced rehabilitation, some degree of residual disability often remains, particularly in conditions such as lower limb paralysis or age-related muscle weakness. Mobility impairments are a major barrier to social participation and quality of life. Traditional assistive tools such as lower limb orthoses, canes and walkers offer limited compensation due to their passive mechanics and fixed structural properties. As a result, they are not suitable for all users and often provide suboptimal functional improvement. To address these limitations, wearable robotic technologies that actively assist movement by detecting user intent and applying power at key joints have emerged as promising solutions—especially for conditions such as sarcopenia and neuromuscular disorders [9].

As described above, wearable robotic gait systems can be

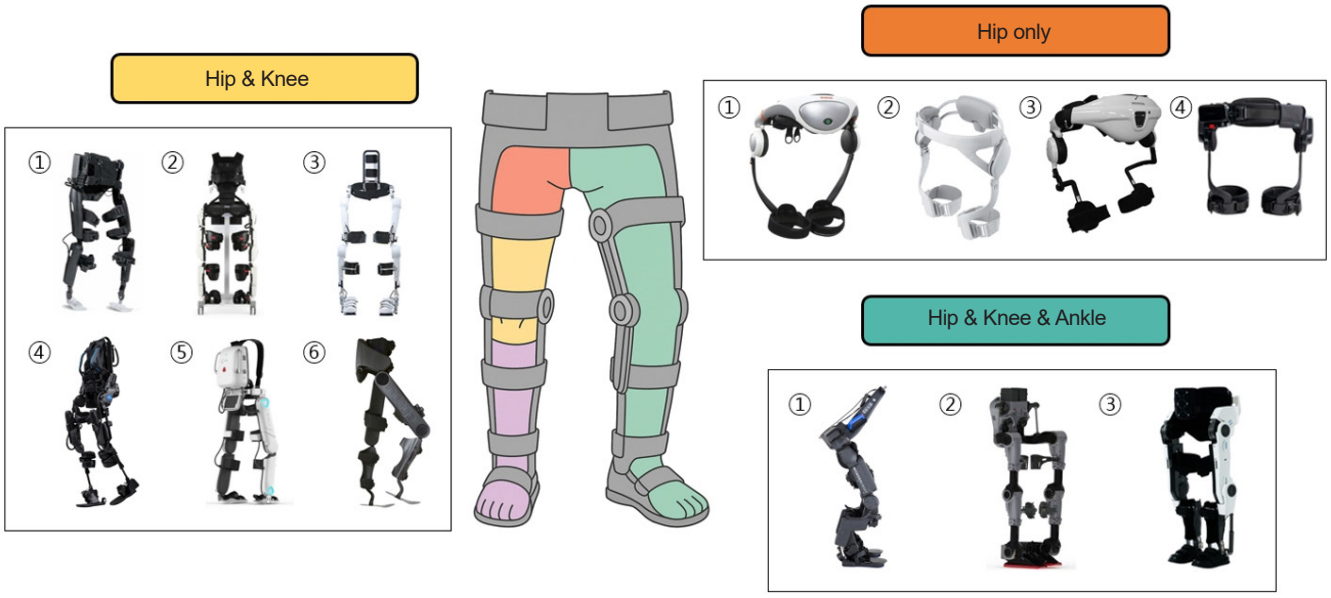

Fig. 1. Classification of lower-limb wearable robotic exoskeletons by joint actuation level. Wearable robotic exoskeletons can be categorized based on the joints they assist—hip only, hip and knee, or hip, knee, and ankle. Representative devices for each category are illustrated. Hip & Knee: ① ReWalk® (Lifeward Ltd.), ② Angel Legs M20® (Angel Robotics Co., Ltd.), ③ HAL® (CYBERDYNE Inc.), ④ Ekso GT® (Ekso Bionics), ⑤ BEAR-H1® (Milebot Robotics), ⑥ Indego® (Parker Hannifin Corporation). Hip only: ① SMA® (Honda R&D Co., Ltd.), ② GEMS® (Samsung Electronics Co., Ltd.), ③ HWA-01® (Honda R&D Co., Ltd.), ④ Angel Legs H10® (Angel Robotics Co., Ltd.). Hip & Knee & Ankle: ① Atalante X® (Wandercraft), ② XoMotion® (Human In Motion Robotics), ③ WalkOn Suit® (Angel Robotics Co., Ltd.).

broadly classified by structural design, targeted joints, and clinical application [12]. Among these, the following sections will elaborate on two major applications—rehabilitative and assistive use—in more detail.

CLINICAL EVIDENCE OF RAGT USING WEARABLE ROBOT-ASSISTED GAIT TRAINING

Stroke

Wearable robot-assisted gait training (w-RAGT) clinically applied in stroke rehabilitation can be categorized into rigid and soft devices. Rigid devices include HAL® (CYBERDYNE Inc.), Ekso GT® (Ekso Bionics), BEAR-H1® (Milebot Robotics), and Angel Legs M20® (Angel Robotics Co., Ltd.) which support the hip and knee joints, as well as devices such as SMA® (Honda R&D Co., Ltd.) and GEMS® (Samsung Electronics Co., Ltd.), which primarily assist the hip joint [13-19]. In contrast, soft exosuits have not yet been widely commercialized, although active research and development are ongoing in this area [20]. These systems are used under therapist supervision to facilitate overground gait training and promote active trunk and limb movement.

A systematic review and meta-analysis demonstrated w-RAGT significantly improves walking speed and balance compared to dose-matched conventional gait training (CGT). Most studies suggest that effective interventions typically consist of sessions lasting 45–60 minutes, performed three to five times per week for at least four weeks [21]. In particular, w-RAGT in individuals with chronic stroke (more than six months post-onset) showed superior improvements in walking speed, balance, and endurance compared to the CGT group [13,22], whereas no greater benefits have been observed over CGT in the earlier stages of recovery [16,19].

Among recent studies, an interim analysis involving 93 subacute stroke patients reported that overground gait training with a torque-assisted exoskeleton showed gait function improvement comparable to conventional rehabilitation, with additional gains in lower extremity strength [23].

Moreover, w-RAGT is actively exploring new strategies for correcting gait asymmetry, such as adjusting hip joint stiffness, with promising initial results. Studies on unimpaired individuals have shown neural adaptation for symmetric gait retraining using bilateral asymmetric hip stiffness [24,25], and research with healthy subjects mimicking hemiplegic gait through artificial impairment has demonstrated effective gait symmetry restoration with adaptive torque control [26]. However, their therapeutic effectiveness for correcting gait asymmetry in actual stroke populations remains to be fully validated.

SCI

For w-RAGT of SCI patients, several clinical studies have reported improvements in key gait parameters such as walking speed, step length, cadence, and lower limb motor scores following robot-assisted interventions, particularly in individuals with incomplete SCI. For example, HAL® has been applied during the early and subacute phases of rehabilitation after spinal decompression, with significant gains in locomotor outcomes and no adverse events [27]. Similarly, short-term application of the hip-focused robotic device HWA-01® (Honda R&D Co., Ltd.) in individuals with chronic SCI resulted in improvements in walking speed and step length [28].

Moreover, a recent network meta-analysis further highlighted the superior effectiveness of overground wearable exoskeletons in improving walking speed compared to treadmill-based robotic systems, as evidenced by greater gains in the 10-Meter Walk Test [29]. Collectively, these findings support the therapeutic value of wearable robotic exoskeletons as rehabilitation devices for enhancing locomotor outcomes in individuals with SCI.

Meanwhile, unlike brain injury populations who often present with cognitive dysfunction, the presence of cognitively intact individuals in certain groups has enabled a broader range of experimental applications and innovative approaches using wearable exoskeletons. For example, systems incorporating volition-adaptive control—which use neural signals to trigger and modulate exoskeleton assistance in real time—have enabled user-intent-driven gait training, leading to personalized movement trajectories and progressive improvements in joint kinematics [30].

CP

Distinct from other adult-onset neurological disorders, CP children present with unique gait characteristics shaped by early-onset spasticity and developmental motor impairments, prompting the exploration of w-RAGT as a targeted intervention to improve walking efficiency and motor control. Notably, w-RAGT offers advantages in promoting active engagement—a key factor for successful pediatric RAGT—[31] and recent randomized controlled trials have demonstrated its effectiveness in

improving gross motor function, gait symmetry, balance, and endurance [2,32].

Moreover, resistance-based training protocols have been proposed based on motor learning principles to target selective muscle recruitment during the propulsive phase of gait. For example, short-term interventions with ankle exoskeletons providing adaptive resistance have resulted in significant gains in plantar flexor activity, reduced co-contraction with antagonist muscles, and improved biomechanical gait parameters such as increased ankle push-off power and reduced metabolic cost of transport [33].

Parkinson's disease

In patients with Parkinson's disease (PD), wearable robotic exoskeletons are used not only to compensate for muscle weakness and provide experience of normative gait patterns—the traditional goal of RAGT, but also to specifically target and correct characteristic pathological gait features such as reduced stride length, hypokinesia, and freezing of gait. Several recent clinical studies demonstrate the feasibility and efficacy of RAGT in this population [34,35]. For example, w-RAGT using hip exoskeletons with adaptive oscillators, which assist hip motion based on real-time joint angles rather than fixed patterns, has been shown to improve natural gait variability and key gait outcomes [36,37]. Additionally, another study has proposed RAGT protocols that integrate functional magnetic resonance imaging and electroencephalography data synchronized with rigid exoskeletal robots, enabling the design of rehabilitation strategies that simultaneously address both neuromuscular and biomechanical features [38].

Other conditions

In addition to aforementioned major neurological conditions, wearable robotic exoskeletons have been applied to a wide range of pathological neurologic disorders, including multiple sclerosis [39], cerebellar ataxia (such as spinocerebellar ataxia and multiple system atrophy) [40,41], essential tremor, Huntington's disease [42], myelomeningocele or spina bifida [43], peripheral nerve injuries, and chronic inflammatory demyelinating polyneuropathy [44], as well as in patients with gait impairments after brain tumor surgery and poliomyelitis [45].

Beyond neurologic disorders, these systems have also been used in musculoskeletal conditions—particularly for gait rehabilitation following total knee arthroplasty in osteoarthritis and rheumatoid arthritis, and post-operative recovery after anterior cruciate ligament reconstruction [46], as well as for patients with spinal stenosis and ossification of the posterior longitudinal ligament [47,48]. Furthermore, wearable robots have shown promise in critically ill patients, such as improving mobility and exercise tolerance in patients with chronic lung disease and advanced heart failure [49,50]. They are also increasingly utilized in aging-related conditions, including elderly individuals with reduced mobility and transfemoral amputees, and even in those recovering from lower extremity burn injuries [51-53]. While these expanding applications highlight the versatility of wearable exoskeletons, further robust, disease-specific clinical studies are necessary to establish their efficacy across these diverse populations.

ASSISTIVE USE OF ROBOTIC GAIT ORTHOSES

Many wearable robots are designed not only for therapy but also for day-to-day use. These assistive orthoses are valuable tools for restoring independence in individuals with permanent mobility loss. Wearable devices exhibit considerable diversity depending on the specific joints they assist and the intended purpose of assistance. The initial development of wearable robots for assistive use of gait impairment group originated in lower limb paralysis, such as those with complete SCI, who rely on wheelchairs for mobility. The first pilot study evaluating the ReWalk® exoskeleton suit for ambulation in individuals with complete SCI was published in 2012 [6]. Since then, assistive robotic devices such as HAL®, Indego® (Ekso Bionics), and WalkON Suit (Angel Robotics Co.) [54], have been developed to address the limitations of earlier-generation exoskeletons. However, the practical implementation of these early versions of assisted wearable robots was often limited. Key challenges included the overall weight of the robot, the need for batteries capable of sustaining high power demands, and pre-programmed movement trajectories that made it difficult to adapt to various walking environments. Additionally, real-world adoption remains restricted by safety concerns, difficulties in navigating uneven terrain, and the inability to perform hands-free tasks, which continue to pose barriers to widespread use in home and community settings [55].

With advancements in actuator technology and controller precision, which allow more refined and adaptive motion control, efforts have been made to overcome these limitations. One notable direction has been the development of robots that assist

only selective joints rather than the entire lower limb. For instance, hip-assist robots have been applied to aging populations. A soft robotic hip exosuit has been shown to instantly eliminate freezing of gait in medication-refractory PD and improve stride length and walking speed, although the study was limited to a single subject [56]. In addition to the hip-assist robots, robotic devices targeting other joints such as the knee and ankle joints have also been developed and applied to populations with neurologic impairments, such as stroke, and CP.

Beyond patient applications, the scope of exoskeleton technology is evolving towards alleviating locomotion burden for able-bodied individuals and potentially extending to those with diverse gait impairments. Supporting this broader applicability, recent research reports a custom hip exoskeleton achieving a notable reduction in walking metabolic rate by an average of 24.3% in non-disabled healthy persons [57].

However, despite numerous attempts to explore their clinical potential, most reports remain at the level of case studies involving a very limited number of patients or have shown effectiveness only under constrained walking environments [58-60]. Accordingly, large-scale investigations across diverse populations are essential to validate the clinical efficacy of these devices beyond constrained experimental settings.

CURRENT CHALLENGES AND FUTURE DIRECTIONS

As discussed above, a variety of wearable robotic exoskeletons have been developed and utilized for diverse purposes, including both rehabilitation and assistive applications. However, several challenges remain before these technologies can achieve widespread and effective integration into routine clinical and daily life settings as below.

First, the clinical integration of wearable robotic devices remains challenging due to a lack of sufficient evidence guiding their use across diverse patient populations and device types. Establishing clinical validity is essential but time-consuming and expensive, leaving key parameters—such as indications, timing, frequency, and intensity—undefined. With numerous devices and varied clinical presentations, clearer guidance on selection and settings is still needed [8].

Second, human-robot interaction is crucial but underexplored compared to technical performance. Wearable robots exchange mechanical and physiological signals with the user, and misalignment from poor fitting can cause discomfort, higher metabolic cost, or injury. The weight and bulk of many current devices also reduce usability [11]. Improving interaction quality is essential for safety and efficiency. Further research and developments are needed, such as advanced sensing for better user intent detection or the development of more compliant and adaptive control strategies.

Third, although personalization plays a key role in enhancing the effectiveness of wearable robots, related research remains insufficient. Adaptive approaches, such as assist-as-needed control using torque-assisted wearable robots, can adjust joint-level force based on the user's effort [2,8,11,61]. These systems are essential for maximizing motor learning by promoting active participation and dynamic gait pattern adaptation. Artificial intelligence (AI) integration further enables real-time responsiveness to movement and environmental demands [62]. Given the diversity of user needs, wearable robots must be designed with user-specific adaptability rather than relying on a one-size-fits-all solution.

Fourth, wearable robots should be developed to meet the specific size, weight, and fit requirements of children, who differ significantly from adults in anthropometry [2]. To address this, lightweight designs and mechanisms that allow continuous adjustment for growth are essential, as the wide variability in body size presents unique challenges in achieving effective and adaptable pediatric applications.

Fifth, expanding wearable robot use into home and low-resource environments requires innovations that improve affordability, accessibility, and ease of use [8]. High device costs, lengthy donning/doffing processes, and fitting challenges are major barriers [11,63]. Despite these issues, opportunities remain for innovation to make wearable robotic solutions more practical and widely available.

CONCLUSION

Wearable exoskeletons have shown significant potential to enhance mobility and independence in individuals with neurological and musculoskeletal conditions, including stroke, SCI, CP, and PD [64]. While clinical evidence is expanding, challenges remain in translating research into real-world practice. To maximize their impact, continued research, technological innovation, and supportive policy frameworks are essential. Successful adoption depends on user-device co-adaptation and designs that reflect the practical needs and lived experiences of end-users. As rehabilitation enters a new era driven by ad-

vanced technologies—such as robotics, AI, sensor systems and augmented reality—these tools are reshaping clinical practice. This transformation underscores the growing importance of interdisciplinary collaboration, particularly the role of engineers as key contributors within rehabilitation teams to ensure the effective development and implementation of wearable robotic systems [8].

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

Conceptualization: Cha JM, Hong J, Rha D. Writing – original draft: Cha JM. Writing – review and editing: Hong J, Yoo J, Rha D. Approval of final manuscript: all authors.

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Potential Effects of Computer-Based Cognitive Training on Postural Stability and Locomotion in Parkinson's Disease Patients: A Randomized Controlled Trial

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Objective: To examine the short-term and long-term effects of computer-based cognitive training on postural stability, locomotion, and cognitive performance in Parkinson's disease (PD) patients.

Methods: Sixty-eight PD participated in this randomized-controlled trial, were randomly allocated into two groups; control group (GA) received a designed physiotherapy program for 60 minutes, and an experimental group (GB) got 30 minutes physiotherapy program as GA, along with 30 minutes of computerized cognitive training. Treatment sessions were three times/week for eight weeks. Primary outcomes were balance and spatiotemporal gait parameters; cognition was a secondary outcome. Primary and secondary measures were examined at baseline, immediately post-treatment, and three months post-treatment.

Results: From baseline to post-treatment, GB showed greater reductions in postural sway compared to GA. The mean differences in stability indices were 1.461±1.240, 0.982±1.185, and 1.006±0.982 in GB, vs. 0.581±1.503, 0.426±1.459, and 0.374±1.072 in GA. For gait parameters (gait velocity, stride length, and cadence), GB demonstrated larger improvements, with mean differences of -0.361±0.245, -0.242±0.158, and -11.606±12.628, compared to -0.155±0.254, -0.191±0.248, and -4.516±10.773 in GA. PD-Cognitive Rating Scale improved more substantially in GB (-16.091±6.978) than in GA (-1.129±4.552). These gains in postural stability, gait, and cognition were statistically significant ($p<0.001$) and sustained at the 3-month follow-up.

Conclusion: Computerized cognitive training as an add-on in the rehabilitation of PD is efficient in improving postural stability and locomotion, as well as the cognitive performance. The consistency of these findings for 3 months is an imperative point in the clinical course of PD patients.

Keywords: Computerized cognitive training, Cognitive dysfunction, Postural balance, Locomotion, Parkinson's disease

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INTRODUCTION

Parkinson's disease (PD) is a widespread progressively deteriorating neurodegenerative disorders worldwide. Dopamine insufficiency is the primary precursor that affects specific deep brain regions like the substantia nigra and basal ganglia [1]. The Middle East and North African regions had 309.9 thousand prevalent instances of PD in 2019, with a 15.4% rise since 1990 [2]. Resting tremor, bradykinesia, stiffness, and postural instability are the cardinal motor features of PD, along with a wide range of non-motor characteristics including psychological, sleep, vegetative, and cognitive disorders with a subsequent deterioration in the quality of life [3].

Postural stability and locomotion problems are the most irritating manifestations in PD patients, which typically get worse over time. Research suggests that postural instability is most closely accompanied with increased falls and elevation of mortality and morbidity in PD population [4]. Balance control depends on a complex network, which demands integrating information from different sensory systems for the motor adjustments [5]. In normal instances, balance is automatically controlled and mostly depends on sub-cortical systems such as the brainstem, basal ganglia, and cerebellum, however, excessive suppression of the motor and premotor areas as well as disruption of subcortical pathways cause PD [6]. Consequently individuals with PD usually depend on compensatory methods, such as elevating the sensory input, attention/concentration, and cognitive demands, for the successful accomplishment of a particular motor task [7].

One of PD major non-motor symptoms is cognitive impairment, which is an indicator of executive function inadequacy, where mild cognitive impairment representing up to 60% of the prevalence rate. Cognitive impairments in PD are usually accompanied with defective quality of life and elevated rates of disability and mortality, since they are among the most subsequent attributes of the disease [8]. PD patients with deficits in global cognitive function (particularly attention & concentration) showed severe gait impairments represented by postural instability and freezing of gait. On the other hand, visuospatial impairments were correlated with severe gait freezing, while higher postural instability was associated with poorer memory function [9]. In individuals with PD whose primary symptom is postural stability, impairment of the executive functions is a common sign; this relationship is significant since executive functions are correlated to other motor control activities as planning, motor coordination and anticipatory postural adjustments [10].

Computerized cognitive rehabilitation based on the execution of repeated computer-based tasks that involves specific skills [11]. It is considered a motivational stimulus likewise the majority of tools using audio-video feedback. Additionally, these tools permit adjustments in the duration, task category, and complexity of the assessments to align the intervention with the person's skills. In order to prevent frustration caused by tasks that are either too simple or too complicated, the exercises are assigned based on the cognitive domain that is stimulated and difficulty level is tailored according to the patient's level [12]. It has been shown that inventive interventions, such as computer-based therapies, could be used to restore cognitive function by simulating diverse cognitive domains, which would increase the patient's motivation, also when compared to traditional cognitive training (using paper and pencil), computerized cognitive training demonstrated beneficial for PD individuals with minor cognitive impairments [13]. Despite the various privileges of computerized cognitive approaches, there are diverse limitations accompanying the use of these devices such as the need for computer skills; photosensitive issues; acceptability and availability of the devices. However, there are neither explicit recommendations nor cautions regarding the use of this approach [14].

The current study is an attempt to provide alternative therapies for people with PD, it is crucial to look into approaches that allow intermingling between motor and cognitive tasks particularly since a correlation between impairments of balance and cognitive dysfunctions has been proven [9,10]. Early diagnosis is mandatory for proper management of these abnormalities and rehabilitative outcomes. Therefore, the optimum standard in managing PD includes a mix of cognitive, motor, and dopaminergic therapy as well as occupational therapy [15,16]. As far as we know, no previous researches in the literature are comparable to the one proposed in this clinical trial, that labels and verifies the efficacy of adding computerized cognitive training to a designed rehabilitation program on postural stability, spatiotemporal gait parameters and motor symptoms in patients with PD; adding to this investigating the long-term proficiency of both interventions after 3-month follow-up.

METHODS

Design of the study

A randomized, follow-up, controlled study. Participants were randomized into 2 parallel groups with allocation ratio 1:1; where a real computerized cognitive training compared to a conventional physical rehabilitation program. The assessor and the patients were blinded to the groups' allocation. Participants were recruited from Department of Neurology, Faculty of Medicine, Cairo University and the study was handled in the cognition training lab at Faculty of Physical Therapy, Cairo University, between May 2024 and February 2025. This study was approved by the Ethics Committee of Faculty of Physical Therapy, Cairo University (P.T.REC/012/004746) and carried out in compliance with the Declaration of Helsinki's ethical guidelines. The ethics committee waived the need to obtain specific patient consent due to the nature of the study, in accordance with applicable institutional rules and ethical requirements. The study was prospectively registered with ClinicalTrials.gov (NCT06104072).

Randomization and masking

Randomization was conducted via sealed envelopes by an external assessor. To avoid bias, treatment was executed by one therapist while assessment was applied by another therapist who was oblivious to the patients' group allocation.

Participants and selection criteria

Participants' selection were according to the following criteria; age, 55 to 70 years; a verified clinical diagnosis by a neurologist and computed tomography, attained the UK criteria for diagnosis of idiopathic PD [17], duration since onset of PD is from two to five years [18]. Patients with mild to moderate PD manifestations in accordance with Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale (scoring between 20–35) [19] and stages (2.5&3) in modified Hoehn and Yahr (H&Y) scale were included [20]. Patients with mild cognitive impairment were included according to Parkinson's Disease-Cognitive Rating Scale (PD-CRS); scores (65–81) [21]. Exclusion criteria were other neurological conditions that may affect gait, balance, and cognition, secondary parkinsonism (medications or illness that cause manifestations similar to PD), aphasic patients, severe physical, visual, or auditory impairment affecting the test completion, severe musculoskeletal disorders such as lower limb fractures, fixed deformities, total replacements of lower limb joints, severe arthritis, knee surgeries, use of any drugs that could influence cognition (e.g., donepezil, rivastigmine, and galantamine, etc.), current use of medications that affect alertness as sedative, neuroleptic or anxiolytic medications or sleeping aids, intractable or illiterate patients.

Treatment interventions

The intervention program consisted of 24 sessions for both groups applied as follows; 3 times per week, 60 minutes per session, for eight consecutive weeks, and to compensate any absence or skip in the sessions it was extended to 10 weeks. A designed physical therapy program was delivered to all patients in both groups, which included balance training on different surfaces with graduated stability, stretching for upper and lower limb as well as back flexors, postural correction, motor coordination, agility, anticipatory and reactive postural corrections, in addition to multi-directional gait training [22].

A designed physical therapy program was given to the control group (GA) for a whole 60 minutes, while for the experimental group (GB), Rehacom computerized cognitive training was conducted for 30 minutes as well the same physical therapy program as GA for 30 minutes. RehaCom cognitive rehabilitation software (HASOMED GmbH) is an extensive program relying on the use of computer systems for cognitive rehabilitation (https://hasomed.de/en/products/rehacom/). This software consists of therapeutic modules categorized into eight main groups, each with multiple subgroups [23]. Each Patient was asked to use the Rehacom custom panel, which is a particular type of keyboard with big, unsophisticated, and obvious keys. This personalized panel features six huge keys: two large green keys to confirm selection and four large white keys to go up, down, right, and left among the options displayed; two other keys (red one for urgent test termination and yellow one for inquiries about the procedure) and one joystick (Fig. 1) [24]. Four main cognitive domains were targeted in this study; figural memory, attention/concentration, visual response control, and auditory response control. Each cognitive domain includes hundred levels of difficulty for each test, with an average of 22 subtests. Tasks are auto-adjustable; therefore based on the way the patient answers questions, the degree of task difficulty is either automatically increased or decreased (Fig. 2) [25].

Outcome measures

All evaluations took place during the "on" period of the medicine (one hour after the treatment was administered). One

Fig. 1. Rehacom computerized device in the cognition lab.

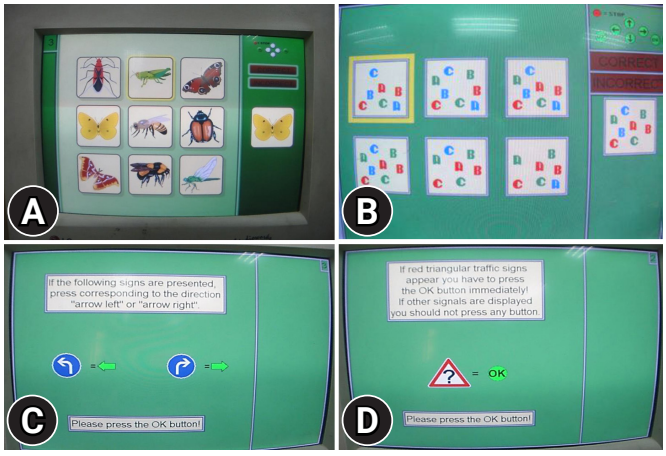

Fig. 2. Rehacom computerized cognitive training different tasks. (A) Example of the figural memory task. (B) Example of the attention/concentration task. (C) Example of the visual response control. (D) Example of the auditory response control.

external evaluator was responsible for the assessment for all the included patients. Primary outcomes were overall stability, medio-lateral stability, anteroposterior stability as well as spatio-temporal gait parameters including cadence, velocity, and stride length, while cognitive performance was the only secondary outcome. All assessments were administered to both groups at baseline, just after the intervention, and three months later.

Primary outcomes

(1) Multidirectional postural stability

A computerized balance platform, the Biodex Balance System (BSS) (Model 945-302, 3.12 software versuion; Biodex Medical Systems, Inc.) was used to assess; the anterior-posterior stability index (APSI) which indicates the patient's capacity to regulate balance both forward and backward, the medio-lateral stability index (MLSI) that represents the patient's ability to maintain balance sideways, as well as the overall stability index (OSI) indicates the patient's capacity to regulate postural stability in many directions. Higher values indicate more balance disturbance. The system comprises a movable circular platform that tilts the surface in numerous directions from the horizontal plane by up to 20 degrees. The degree of the surface instability can be adjusted from minimum instability (level eight) to maximum instability (level one). The protocol, stability level, and test duration are chosen by the clinician. Individuals were instructed to keep the center of mass in the middle of a centered circle that is displayed on a screen in front of the patient [23,26].

(2) Spatiotemporal gait parameters (velocity, cadence and stride length)

A digital 2D video camera (Sony Cyber-Shot 14.1 Megapixels, Model No. DSC-W530, including a 2.7-inch LCD and a Carl Zeiss Vario-Tessar 4x Wide-Angle Optical Zoom Lens) was used to capture the patient's gait in the sagittal plane [27]. The captured film was then analyzed using special motion analysis software (Kinovea); it is a computer-based program used for analysis, measurement, and comparison of motion videos. Each patient was asked to walk along the 10-meter walkway with the regular walking pattern and speed and do not stop walking except at the end of the walkway. The measured parameters were;

Velocity: the actual distance that the patient walked/time in seconds.

Cadence: the number of steps/minute, which was estimated by dividing the number of steps that the patient walked over the actual duration of walking.

Stride length: the distance from the first foot contact in the first frame to the ipsilateral foot's subsequent first touch in the second frame.

Secondary outcomes

(1) Overall cognitive performance

PD-CRS, a specific neuropsychological scale was used for evaluating cognitive deterioration in patients with PD. It is a valid and reliable screening tool to measure PD-related cognitive decline [28]. There are nine tests or assignments total, with a maximum score of 134, as shown in (PD-CRS English & Arabic versions) (Supplementary Table S1).

Data analysis

Sample size determination

The sample size was determined using the following criteria: a two-tailed significance level (α) of 0.05 and an effect size of 0.5 indicate a moderate effect size according to Cohen's criterion; an effect size f^2 (V)=0.1363 with 2 independent groups using a power (1-β) of 0.80 to compare seven primary variable outcomes in order to lower the possibility of type II errors. The sample size was determined using G*Power 3.1 software, taking into account these characteristics and a previous study that received comparable treatments [12]. According to the computations, 29 persons each group (GA and GB) were advised in order to examine a notable difference with 80% power and a 5% level of significance; nevertheless, the number was raised to 34 participants per group, for a total of 68 participants in the study to consider the drop out from the time of patients' group allocation to the end of the treatment protocol.

Statistical analysis

SPSS package version 25 for Windows was used to do statistical analysis (IBM Corp.). Shapiro–Wilk and Levene's tests were used to evaluate the data's normality and homogeneity. Since the data were homogenously distributed, parametric analysis was performed; data was expressed using the mean and standard deviation (SD). Numbers and percentages were used to express categorical data. The two groups' baseline demographic and clinical characteristics were compared using Student t-tests for continuous data and χ^2 testing for categorical data. Comparing the multiple dependent variables at the baseline, post-intervention and follow-up between both groups were applied using MANOVA. To compare each set of the measuring periods (baseline to post intervention, post intervention to follow-up, and baseline to follow-up), post-hock multiple pairwise comparisons were performed. Spearman's rho correlation (r) was used to assess the correlation between postural and gait functions in relation to the enhancements in cognitive performance following the intervention. All statistical tests have a significance level of $p<0.05$.

RESULTS

Flow of participants and adherence to the study protocol

During eligibility screening a total of 100 participants underwent screening, 32 participants were eliminated; 15 patients rejected to join the study, 11 patients did not adhere to the inclusion criteria, and 6 patients weren't able to withstand the cognitive training session. Sixty-eight levodopa-dependent PD from both sexes agreed to participate and met the inclusion criteria. Participants' progress through the trial is shown in CONSORT flow diagram (Fig. 3). There was no drop-out to follow-up during the study.

Characteristics of the participants

Patients' characteristics and demographics were assessed as part of the baseline examination and were presented descriptively in Table 1. Regarding age (years), weight (kg), height (cm), body mass index (kg/m^2), disease duration (years), and UPDRS-motor score, both groups were homogeneous in the initial assessment. For H&Y scale staging and the sex distribution, both groups were homogenous in the percentage of patients' distribution (Table 1).

For all of the evaluated primary and secondary outcomes, between-groups analysis showed no discernible differences between groups at the baseline assessment. See Table 2, the baseline mean values and SDs of the participants for stability indices, spatiotemporal gait parameters, overall cognitive performance, and UPDRS for Parkinson's motor symptoms, where $p>0.05$.

Effects of the intervention

In this study, for the tested groups effect, Wilks' Lambda (Λ=0.216) which is quite low, indicating a large difference between the groups across the dependent variables. Partial eta^2 (η^2=0.784) indicating a very large effect size. This means 78.4% of the variance in the dependent variables is explained by group differences. For the group effect (F=29.004, $p<0.001$) which is statistically significant. The measuring period effect showed

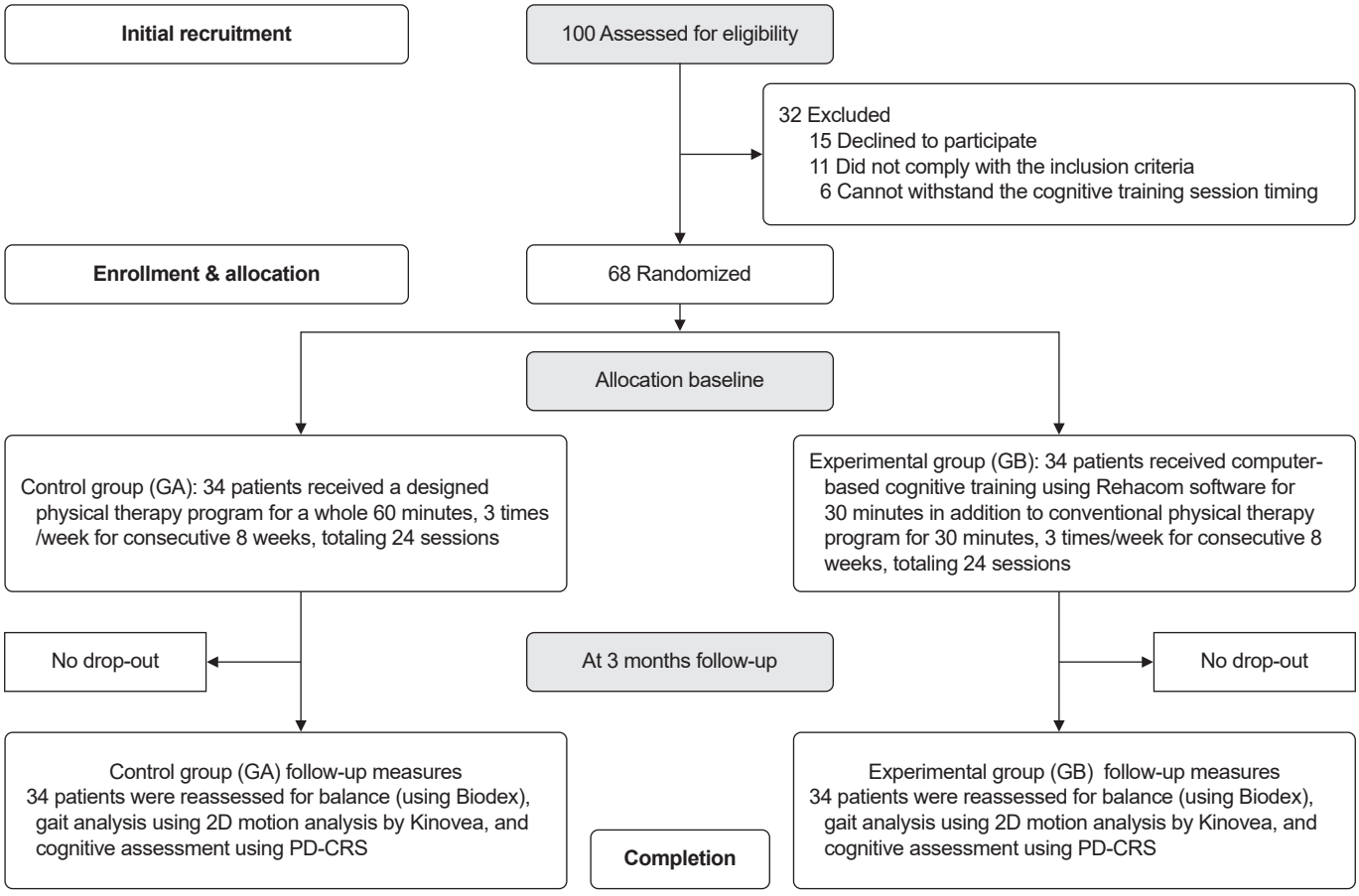

Fig. 3. CONSORT flow diagram. PD-CRS, Parkinson's Disease-Cognitive Rating Scale.

Table 1. Patient's demographics and general characteristics for both groups

Characteristic		Control group (GA) (N=34)	Experimental group (GB) (N=34)	p-value
Age (yr)		60.97±2.58	62.03±2.68	0.10
Weight (kg)		72.97±3.36	75.03±5.49	0.07
Height (cm)		164.23±4.83	165.48±5.04	0.28
Body mass index (kg/m^2)		27.14±1.41	27.39±1.31	0.40
Disease duration (yr)		4.265±1.136	4.735±1.02	0.08
UPDRS-motor score		33.47±3.77	35.09±4.76	0.13
H&Y staging	Stage 2.5	16 (47.1)	14 (41.2)	0.63
	Stage 3	18 (52.9)	20 (58.8)	
Sex distribution	Male	21 (61.76)	24 (70.59)	0.44
	Female	13 (38.24)	10 (29.41)	

Values are presented as mean±standard deviation or number (%).
UPDRS, Unified Parkinson's Disease Rating Scale; H&Y, modified Hoehn and Yahr.
Non-significant=p>0.05.

that (Λ=0.063) indicating very strong time-based differences (pre vs. post-intervention), partial eta² (η^2=0.937) reflecting an extremely large effect size, where 93.7% of variance is explained by the measuring period with F=51.782, p<0.001 reflecting a high significance. The Interaction Effect (group×time), Wilks' Lambda was very low (Λ=0.139) proving that the groups behaved differently over time through the study, with very strong interaction effect (partial eta²=0.861), where 86.1% of vari-

Table 2. Mean values and standard deviations of the measured dependent variables between groups at baseline, post treatment, and follow-up

Variables	Time	Control group (GA) (N=34)	Experimental group (GB) (N=34)	p-value
Stability indices				
Overall stability index	Baseline	4.56±1.15	4.73±1.05	0.534
	Post treatment	3.98±0.97	3.27±0.66	0.001*
	Follow-up	4.07±0.93	3.45±0.67	0.003*
	p-value	<0.001*	<0.001*	
Anterior-posterior stability index	Baseline	3.86±1.06	3.76±1.06	0.724
	Post treatment	3.43±1.00	2.78±0.53	0.002*
	Follow-up	3.49±0.95	2.86±0.58	0.002*
	p-value	0.0007*	0.0001*	
Medio-lateral stability index	Baseline	3.25±0.92	3.25±0.61	0.987
	Post treatment	2.87±0.55	2.24±0.77	<0.001*
	Follow-up	2.91±0.53	2.28±0.77	<0.001*
	p-value	0.0018*	<0.001*	
Spatiotemporal gait parameters				
Velocity (m/s)	Baseline	0.50±0.21	0.49±0.13	0.801
	Post treatment	0.65±0.15	0.85±0.21	<0.001*
	Follow-up	0.65±0.15	0.82±0.20	<0.001*
	p-value	<0.001*	<0.001*	
Stride length (m)	Baseline	0.71±0.23	0.73±0.15	0.516
	Post treatment	0.90±0.15	0.98±0.06	0.006*
	Follow-up	0.88±0.12	0.95±0.08	0.004*
	p-value	<0.001*	<0.001*	
Cadence	Baseline	72.03±6.64	74.33±10.42	0.293
	Post treatment	76.47±8.48	85.94±7.18	<0.001*
	Follow-up	76.42±8.37	85.64±7.33	<0.001*
	p-value	<0.001*	<0.001*	
Cognition				
PD-CRS score	Baseline	67.53±3.27	69.18±3.74	0.068
	Post treatment	68.68±3.16	85.27±5.92	<0.001*
	Follow-up	68.48±3.04	83.88±7.03	<0.001*
	p-value	0.93	<0.001*	

Values are presented as mean±standard deviation.
PD-CRS, Parkinson's Disease-Cognitive Rating Scale.
*p<0.05.

ance explained the interaction effect between groups and time (F=21.639, p<0.001) reflecting a statistically significant interaction (Table 3).

Primary outcomes

There was reduction in the amount of postural sway represented by a marked decrease in all the Biodex stability indices in GB compared to GA (p<0.05), see post intervention mean values and SDs (Table 2). There was significant reduction in overall stability by 1.461 points compared to 0.581 points for the GA, for antero-posterior stability by 0.982 points compared to 0.426 points for the GA, and for medio-lateral stability by 1.006 points compared to 0.374 points for the GA, see the mean differences of the pairwise comparison (baseline to post-treatment) for both groups (Table 4).

There was improvement in the spatiotemporal parameters represented by an elevation in all the spatiotemporal parameters in GB compared to GA (p<0.05). See post intervention mean values and SDs (Table 2). Velocity increased by -0.361 points post intervention for the GB compared to -0.155 points for the GA, stride length increased by -0.242 points post intervention for the GB compared to -0.191 points for the GA, and cadence increased by -11.606 points for the GB compared to -4.516 points for the GA, see Table 4, the mean differences of the pairwise comparison (baseline to post-treatment) for both groups.

The follow-up measures revealed that the improvement

Table 3. Main effects of independent variables by MANOVA test for all dependent measuring variables

Source of variation	Wilks' Lambda value	Partial eta^2 (η^2)	F-value	p-value
Tested groups effect	0.216	0.784	29.004	<0.001*
Measuring period effect	0.063	0.937	51.782	<0.001*
Interaction effect	0.139	0.861	21.639	<0.001*

*p<0.05.

Table 4. Post Hoc comparison of all dependent measures between each two measuring periods in both groups

Variable	Pairwise comparison	Control group (GA) (N=34)			Experimental group (GB) (N=34)		
		Mean difference±SD	95% CI	p-value	Mean difference±SD	95% CI	p-value
Overall stability index	Baseline–Post treatment	0.581±1.503	0.053, 1.103	0.002	1.461±1.240	1.027, 1.893	<0.001*
	Baseline–Follow-up	0.481±1.477	-0.026, 1.002	0.008	1.285±1.245	0.846, 1.714	<0.001*
	Post treatment–Follow-up	-0.100±1.341	-0.557, 0.377	0.550	-0.176±0.941	-0.508, 0.148	0.053
Anterior-posterior stability index	Baseline–Post treatment	0.426±1.459	-0.079, 0.939	0.009	0.982±1.185	0.567, 1.393	<0.001*
	Baseline–Follow-up	0.371±1.423	-0.126, 0.866	0.04	0.906±1.208	0.479, 1.321	<0.001*
	Post treatment–Follow-up	-0.055±1.381	-0.422, 0.542	0.418	-0.076±0.785	-0.193, 0.353	0.3
Medio-lateral stability index	Baseline–Post treatment	0.374±1.072	0.005, 0.755	0.008	1.006±0.982	0.666, 1.354	<0.001*
	Baseline–Follow-up	0.335±1.061	-0.029, 0.709	0.017	0.976±0.982	0.627, 1.313	<0.001*
	Post treatment–Follow-up	-0.039±0.764	-0.305, 0.225	0.088	-0.033±1.089	-0.369, 0.389	0.233
Velocity (m/s)	Baseline–Post treatment	-0.155±0.254	0.064, 0.242	<0.001*	-0.361±0.245	0.272, 0.443	<0.001*
	Baseline–Follow-up	-0.154±0.252	0.065, 0.241	<0.001*	-0.335±0.234	0.249, 0.411	<0.001*
	Post treatment–Follow-up	-0.001±0.208	-0.072, 0.072	>0.999	0.026±0.288	-0.123, 0.066	0.215
Stride length (m)	Baseline–Post treatment	-0.191±0.248	0.105, 0.278	<0.001*	-0.242±0.158	0.195, 0.305	<0.001*
	Baseline–Follow-up	-0.170±0.233	0.096, 0.242	<0.001*	-0.218±0.164	0.157, 0.271	<0.001*
	Post treatment–Follow-up	0.022±0.192	-0.088, 0.046	0.326	0.024±0.097	-0.086, 0.030	0.213
Cadence (No. of steps/min)	Baseline–Post treatment	-4.516±10.773	0.752, 8.248	0.035	-11.606±12.628	7.208, 16.008	<0.001*
	Baseline–Follow-up	-4.419±7.686	1.752, 7.113	0.041	-11.303±12.708	9.089, 13.511	<0.001*
	Post treatment–Follow-up	0.097±6.708	-2.482, 2.201	>0.999	0.303±11.913	-2.184, 1.963	0.088
PD-CRS score	Baseline–Post treatment	-1.129±4.552	-0.413, 2.768	0.513	-16.091±6.978	13.662, 18.531	<0.001*
	Baseline–Follow-up	-0.935±4.716	-0.312, 2.972	0.935	-14.697±6.117	-1.458, 1.762	<0.001*
	Post treatment–Follow-up	0.194±4.643	0.412, 4.663	>0.999	1.394±5.349	-1.291, 2.429	0.083

SD, standard deviation; CI, confidence interval PD-CRS, Parkinson's Disease-Cognitive Rating Scale.
*p<0.05.

gained post intervention in the stability indices and spatiotemporal parameters were maintained in favor to the GB (p<0.05), see follow-up mean values, SDs, and the base to follow (Table 4). However there was no further improvement in the follow-up findings in most of the primary outcomes for both groups compared to the post intervention findings, where p>0.001, see post to follow (Table 4).

Secondary outcomes

The experimental intervention significantly improved overall cognitive performance represented by an elevation in PD-CRS scores only in GB (p<0.05), see post intervention mean values and SDs (Table 2). Post intervention PD-CRS scores increased by -16.091 points for the GB compared to -1.129 points for the GA. See Table 4, the mean differences of the pairwise comparison (baseline to post-treatment) for both groups.

The follow-up measures revealed that the improvement gained post intervention in PD-CRS scores were maintained only in the GB (p<0.05), see follow-up mean values, SDs and the base to follow (Table 4). However there was no further improvement in the follow-up findings in the secondary outcomes for both groups compared to the post intervention findings, where p>0.001, see post to follow (Table 4).

Interpretation of the outcomes in terms of minimal clinically important differences

Primary outcomes

For the postural stability, based on a previous study, a change of 0.22°, 0.26°, and 0.41° for OSI, APSI, and MLSI respectively was considered as the minimal detectable change when assessing

balance using the BSS in PD patients and often interpreted as clinically meaningful [29]. Our findings revealed that, Baseline to post intervention mean differences for OSI, MLSI and APSI were 1.46°, 1.01°, and 0.98°, respectively. On the other hand, the baseline to follow-up mean differences for the same variables were 1.28°, 0.97°, and 0.9°, respectively. Accordingly, such post intervention and follow-up improvements suggest that the intervention produced not only statistically significant but also clinically relevant benefits in postural control for individuals with Parkinson's disease.

Regarding the spatiotemporal parameters, the minimal clinically important differences (MCIDs) when assessing spatiotemporal gait parameters in patients with PD, for gait velocity ranged from 0.05 to 0.22 m/s while for stride length, it has been determined to be 3.6 cm (0.036 m) [30]. Our findings revealed that, baseline to post intervention mean differences for gait velocity and stride length were 0.357 m/s and 0.25 m respectively. On the other hand, the baselines to follow-up mean differences for the same variables were 0.31 m/s and 0.22 m respectively. Thus, the post intervention and the follow-up findings for the spatiotemporal parameters in PD patients had exceeded the MCID thresholds, which imply that the improvements were both statistically significant and clinically important.

Secondary outcomes

In PD-CRS, A 4.5-point change in total score has been proposed as the MCID in early to mid-stage PD patients [31]. The study findings showed that baseline to post intervention mean difference for PD-CRS was 16.1 points, while for the baseline to follow-up mean difference, it was 14.7 points. Therefore, the post-intervention and follow-up results for cognitive performance in PD patients had beyond the MCID criteria, suggesting that the changes were both clinically relevant and statistically significant.

Correlations between postural stability and gait vs. cognitive performance post-intervention

Spearman's rho correlation (r) was used to assess the correlation between postural stability represented by (OSI, MDSI, APSI) scores and cognition represented by PD-CRS following the intervention in PD patients. Correlation coefficient between OSI scores and PD-CRS was r=-0.829, for APSI vs. cognition was r=-0.664, and r=-0.688 for the correlation between MLSI vs. cognition. This suggests that as cognitive performance improves, postural stability tend to improve as well (i.e., lower index scores), particularly for overall stability (OSI).

For the post intervention correlation between cognition (PD-CRS) and spatiotemporal gait parameters (represented by velocity, cadence and stride length), Spearman's rho correlation (r) was used. The correlation between gait velocity scores and PD-CRS was r=+0.798, for stride length vs. cognition was r=+0.652, and r=+0.647 for the correlation between cadence vs. cognition. This suggests that enhancements in cognitive performance were accompanied with improvements in gait velocity, stride length and cadence.

DISCUSSION

Findings of the study proved that adding Rehacom computerized cognitive training to conventional physiotherapy is prioritized for the outcomes of balance, gait, and cognitive function in PD patients. Considering the time effect, it also showed immediate post-treatment benefits on all the assessed outcomes in addition to the consistency of the gained results for 3 months. Adding computerized cognitive training to a designed physical therapy program relied on the idea that balance is multimodal and that it is strongly recommended to reconcile various frameworks [32]. However, the results available in the literature on the best treatment indication are still divergent.

Some prior studies tried to compare the effect of motor rehabilitation vs. cognitive rehabilitation, they established a correlation between cognitive and motor training, by comparing two interventions; balance training vs. cognitive-motor activities using Nintendo Wii Fit, the study findings revealed improvement in overall stability, medio-lateral stability, cadence, and cognition for both groups [33]. Similar effects were observed in our investigation, with more focus on spatiotemporal gait metrics, balance, and cognition in Parkinson's population.

Our findings demonstrated that the improvements in the balance domains were associated with consolidation of the gained results at the follow-up, these results agreed with a study that assured that the increased physical activity in response to multi-domain cognitive training, possibly due to effects of intermingling the cognitive training with physical training on the executive functions, however the long term effect was not examined [34]. For the spatiotemporal gait parameters, our findings agreed with the results of another study which claimed that computerized cognitive training using a designated "brain training" programs such as Sudoku, which targeted working memory, processing speed, and visuospatial skills positively im-

proved gait performance in PD patients particularly gait freezing [35].

Regarding the cognitive abilities and disease course in PD patients, our results were congruent to another study that suggested that remote cognitive rehabilitation for PD patients, twice per week, for one hour, over 8 weeks is practicable, entertaining, and may help decelerate the deterioration of cognitive decline [36]. This also agreed with a study which conducted a six-week cognitive training program for PD, results showed improvement in the patients' cognitive functions which consequently improve the quality of life [37].

In this study, the correlation coefficient findings revealed that higher cognition scores were associated with lower postural sway; this agrees with Fernandes et al. [38] who proved that executive functions can act as predictors of balance deficit in individuals with Parkinson's disease. This highlighted the importance of cognitive training as preliminary part in the motor rehabilitation for PD patients with balance and gait problems. Our study also revealed that higher cognition scores were associated with increase in gait velocity, stride length and cadence as well; this concur with Geritz et al. [39] who claimed that PD showed change in the walking performance relatable to deficits in visuospatial and divided attention, with slower speed and shorter stride lengths particularly in walking situations with additional cognitive demand.

The clinical relevance of our study was proved in relation to the MCID findings of previous studies, where the post intervention and follow-up findings of postural stability, gait and cognition in this study exceeded the established MCID range suggesting that the treatment effect is not only statistically significant but also clinically meaningful for individuals with PD [29,30,31]. These findings reinforce the clinical value of computerized cognitive training in PD, this aligning with earlier evidence supporting its use in comparable contexts such as; combined physical executive interventions, multi-domain cognitive training, remote cognitive remediation therapy, and cognitive-motor dual task training aiming to reduce risk of falling and improve balance as well as the gait kinematics [34,35]. However, the long term efficacy of such interventions has not been examined; also it is necessary not to generalize the results broadly since the MCID values were derived from slightly different demographics.

The study findings are not conjuring with Akin et al.'s [40] study who claimed that 8-weeks program of motor-cognitive dual task program and motor-motor dual task training showed no remarkable difference on postural stability, falling possibilities, walking practicality and muscle strength in older adults. Also, this study disagrees with Terra et al. [11] who claimed that in terms of enhancing balance in PD patients, cognitive-motor therapy was not better than motor therapy.

The points of strength in our study can be listed as following: (1) the novel therapy method that blends computer-based cognitive training and motor training; (2) the planned clinical study is exclusive to PD patients in the literature; (3) the duration of the intervention (24 sessions); (4) the program's attributes are direct, supervised, inexpensive, accurate and widely applicable in clinical settings; and (5) a three-month follow-up of the outcomes to evaluate the consistency of the gained results.

It is also necessary, to point out some important limitations in this study. The study findings cannot be applied to all PD patients, especially those who are in more advanced stages, only patients with mild cognitive deficits were included; cognition was evaluated only by the PD-CRS, gait assessment focused only on the spatiotemporal gait parameters without considering PD characteristic patterns of walking, such as stiff gait and freezing of gait.

Conclusion

This work provides evidence regarding the potential benefits of adding computer-based cognitive training to a traditional physical treatment program; at improving cognitive performance, postural stability, spatiotemporal gait parameters in PD patients. An additional noteworthy impact of computerized cognitive training was the retention of the gained results for 3 months and the possible ability of this intervention to retard progression to PD-dementia. These findings have implications for exercise prescription and cognitive training in the rehabilitation program of patients with PD, in consideration with the clinical practicality, simplicity and inexpensive nature of the suggested treatment.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

Conceptualization: Moustafa EBS, Darwish MH. Methodology: Moustafa EBS. Investigation: El-Tamawy MS. Formal analysis: Khalifa HA. Project administration: Moustafa EBS, Darwish MH. Visualization: El-Tamawy MS. Writing – original draft: Moustafa EBS. Writing – review and editing: Darwish MH, El-Tamawy MS, Mazen MM, Abo-Zaid NA, Khalifa HA. Approval of final manuscript: all authors.

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SUPPLEMENTARY MATERIALS

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Original Article

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Comparing Multiple Versus Sustained Insertion Dry Needling Therapy for Myofascial Neck Pain: A Randomized Controlled Trial

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Objective: To compare the Hong (GH) and sustained insertion (GS) dry needling methods in patients with myofascial neck pain, this experimental study was conducted.
Methods: A randomized controlled trial included 30 participants, assigned to either the GH (n=15) or GS (n=15) group. Each group received treatment on either the right or left side, with one side receiving experimental DN and the other receiving control (sham) DN. The GS method involved a single needle insertion per myofascial trigger point for one minute, while the GH method used multiple rapid needle insertions over two minutes without needle retention. Measurements were taken before therapy, 5 minutes post-DN session (post-5min), 24 hours post-session (post-24h), and 7 days post-session (post-7d). Muscle tension (MT) and muscle stiffness (MS) were measured with a myotonometer, pressure pain threshold (PPT) with an algometer, maximum isometric strength (Fmax) with a handheld dynamometer, and transcutaneous perfusion (PU) with laser Doppler flowmetry. Power Doppler Score (PDS) and minor adverse events were also recorded.
Results: Results showed that GH led to significantly higher MT and MS values at post-24h and post-7d ($p<0.001$). In contrast, GS showed greater PPT and Fmax at post-5min, post-24h, and post-7d ($p<0.001$). Additionally, GH exhibited higher PU values at post-5min and post-7d ($p<0.001$), while GS showed higher PDS values at post-5min and post-24h ($p<0.001$).
Conclusion: The GH method resulted in less favorable outcomes in terms of MT and MS, while the GS method showed superior improvements in pain relief and functional recovery.

Keywords: Muscle tonus, Regional blood flow, Physical therapy modalities, Pain management, Muscle strength

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INTRODUCTION

Myofascial pain syndrome (MPS) has garnered considerable attention in clinical practice due to its complex etiology and the challenges it presents for effective treatment [1]. Among various therapeutic approaches, dry needling (DN) has emerged as a prominent intervention to alleviate pain and restore function by targeting myofascial trigger points (MTrPs) [2]. These trigger points are palpable nodules within taut bands of muscle fibers that can cause local tenderness and referred pain patterns [3]. The effectiveness of DN is closely linked to the procedural methodology employed, including factors such as the number of insertions, the depth and technique of needling, and the specific muscle groups targeted [4].

Cervical myofascial pain, commonly referred to as neck pain, is a prevalent musculoskeletal condition characterized by the presence of MTrPs, leading to acute or chronic pain [5]. It is often associated with muscle stiffness (MS), tightness, tenderness, and a limited range of motion [6]. This condition may occur independently or alongside other musculoskeletal disorders, predominantly affecting individuals aged 27 to 50 [1]. Chronic muscle overload or injury frequently contributes to local pain that can radiate, leading to functional impairment and a reduced quality of life [4]. Recent studies underscore the physiological implications of myofascial pain, indicating that MTrPs may influence muscle performance and systemic factors such as blood perfusion and biomechanical properties [7]. For instance, laser Doppler flowmetry (LDF) studies have shown that myofascial pain significantly affects muscle elasticity and pressure pain thresholds (PPTs), revealing a complex interaction between pain perception and muscle function [8].

According to the American Physical Therapy Association, DN involves the use of fine acupuncture needles to stimulate muscle and connective tissue trigger points to treat neuromusculoskeletal disorders [9]. DN aims to relieve and normalize muscle tension (MT) and MS, modulating pain at muscle trigger points through mechanisms that are not yet fully understood [10]. The consensus is that the physiological mechanisms of DN in myofascial pain involve a complex interplay between peripheral and central sensitization, neuromuscular responses, and pain modulation systems [11]. Peripheral sensitization modulates nociceptive stimuli, often indirectly, through factors like serotonin. Central sensitization involves the activation of neural networks in the central nervous system, typically through N-methyl-D-aspartate receptor activation [12]. DN may influence these sensitization processes by mechanically disrupting trigger points, releasing pain mediators, and interrupting the pain cycle at the spinal cord level (pain gating theory) [8,13].

Establishing an effective DN methodology, including the appropriate frequency and number of insertions, is crucial for optimizing myofascial pain management outcomes [14]. Many studies describe a sustained insertion DN (GS) methodology, involving a maximum of five punctures per MTrP until a local twitch response (LTR) is elicited [13,15]. However, recent studies have questioned the reliability of LTR as a diagnostic criterion for MTrPs and the efficacy of DN therapy [8]. An alternative technique is the Hong (GH) method, which involves multiple rapid needle insertions to treat MPS pain [16,17]. This method aims to stimulate nociceptors in the MTrP region, potentially activating the descending pain inhibitory system for immediate and significant pain relief. It is effective for quickly restoring normal muscle function and achieving long-lasting therapeutic effects [18].

Comparative studies evaluating different DN techniques remain limited. One of the few available studies directly compared deep DN and the peppering technique, finding both approaches effective in managing MPS. Specifically, both methods significantly reduced pain and depressive symptoms and improved functional outcomes for up to 12 weeks post-treatment [19]. Despite comparable efficacy and adverse event profiles, deep DN was associated with lower procedural pain, suggesting it may be better tolerated [19]. However, inconsistencies in the application of DN techniques—such as variation in the number and depth of needle insertions—pose methodological challenges. Clinical observations and survey data indicate that increasing the number of insertions may heighten the risk of adverse effects, including post-treatment pain, hematomas, burning sensations, and fatigue [20]. Additionally, patients may tolerate repeated insertions poorly. A systematic review of the literature recommends DN, alone or in combination with other interventions, for treating musculoskeletal pain conditions associated with MTrPs [1]. Various DN techniques appear to be similarly effective in reducing myofascial pain intensity [14].

Despite the apparent efficacy of DN in treating myofascial pain, critical methodological issues remain unresolved. Diagnostic studies of perfusion and PPTs following GS applications support its effective use [21]. However, concerns persist regarding the optimal number of insertions and the procedural framework used in clinical practice.

Further research into standardized protocols and the integration of DN with other treatment modalities is essential to fully understand its role and maximize patient outcomes in myofascial pain management. Thus, this randomized controlled trial aimed to compare the procedural methodologies (sustained insertion and multiple DN techniques) to determine their efficacy in treating MTrPs and their effects on muscle perfusion, strength, and biomechanical properties of the trapezius muscle in individuals with neck pain. Our hypothesis is that GS therapy will demonstrate greater immediate efficacy and patient tolerance, with no significant long-term differences in the measured variables.

METHODS

The CONSORT guidelines were followed in reporting this randomized trial [22]. This research was approved by the Ethics Committee of the National Council of Physiotherapists (approval number 26/2022, dated January 12, 2023) and registered as a clinical trial (ISRCTN16484644). The study adhered to the principles outlined in the Declaration of Helsinki. Participants were informed they could withdraw at any time without providing a reason. Each signed informed consent, completed a health questionnaire, and was briefed on potential adverse effects.

Study design

In this single-masked study, participants were allocated randomly in a 1:1 ratio using simply randomization in a dedicated software to either the GH method (n=15) or the GS method (n=15). To ensure proper concealment of group allocation, randomization was conducted before baseline measurements were taken. Furthermore, each group was randomly assigned to the right or left side for the experimental (DN therapy) and control (sham dry needling [shamDN] therapy) conditions. This approach allowed participants to serve as their own control through random side assignment [23].

Participants were evaluated at four time points: rest (before therapy), 5 minutes post-DN session (post-5min), 24 hours post-session (post-24h), and 7 days post-session (post-7d).

Participants

After recruitment, the study involved 30 volunteers (n=30) with MPS and active MTrPs in the upper trapezius muscle, comprising both males and females. Participants met the following inclusion criteria: (1) bilateral neck pain persisting for over a month; (2) a neck pain score of 4 or higher on the Numeric Pain Rating Scale (NPRS); (3) a palpable tight band in the muscle; (4) a hypersensitive, tender point within the tight band; (5) local or referred neck pain triggered by pressure; and (6) restricted neck mobility. The diagnostic criteria used in this study were based on international consensus and classical literature on the subject. The diagnosis of active MTrPs was based on: the presence of a taut band, a hypersensitive point within this band, referred pain when the point is pressed, limited range of motion and pain during muscle contraction [9]. Exclusion criteria included: (1) receiving physiotherapy or pharmacological treatment within three months of pain onset; (2) radicular diseases or radicular pain; (3) neck pain linked to whiplash; (4) dizziness; (5) prior neck surgery; (6) other connective tissue diseases like systemic sclerosis or fibromyalgia; (7) cervical discopathy-induced pain; (8) nickel allergy; (9) needle phobia; (10) occlusive syndromes of the jugular and vertebral arteries and veins; and (11) pregnancy.

Interventions

Each group was randomly assigned an experienced physical therapist, one per group, to ensure the treatments were administered. In the GS, DN treatment was provided by inserting a sterile SOMA needle (0.30×0.30 mm, Acus Med Spółka z ograniczoną odpowiedzialnością) into the active, painful point along the midline of the upper trapezius muscle (Fig. 1A). The procedure followed strict safety protocols, such as disinfecting the puncture site and the therapist wearing protective gloves. DN treatment was performed with the participant in a prone position, the head supported by a special couch at a 15-degree

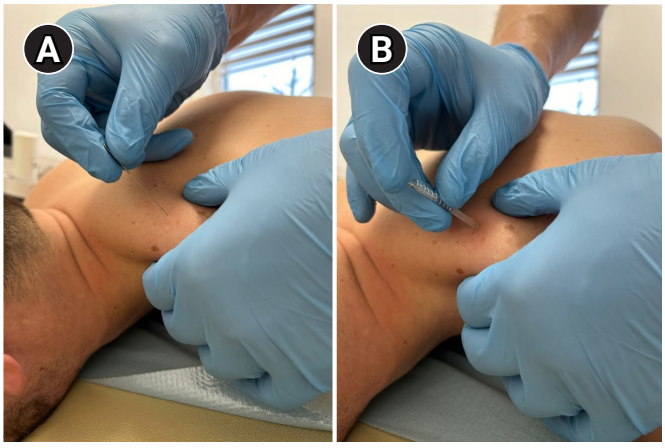

Fig. 1. (A) Traditional acupuncture needle used in dry needling. (B) Telescopic needle sham therapy.

flexion angle [7]. Each trigger point was treated with a single needle puncture, observing for a LTR. This method has been previously described in studies [4,24] that showed its effectiveness in reducing MT and improving tissue perfusion. If no LTR appeared after five punctures without skin removal, the needle was inserted as deeply as possible and left in place for one minute [25]. MTrPs were identified by palpable tenderness along a taut band in the upper trapezius muscle, generally located in the muscle's middle region. The entire DN procedure took about two minutes, with the treatment being stopped if participants experienced severe pain or any adverse reactions. The number of adverse events was recorded.

In the GH, the same safety protocols and diagnostic criteria were followed, but the technique involved rapid, repetitive needle movements over a period of two minutes, without leaving the needle in the skin, regardless of how many LTRs appeared (an average of 40 punctures per trigger point). The GH technique with multiple (average 40) needle insertions over 2 minutes was based on previous studies [16,17] that supported the efficacy of this method in rapid pain modulation by activating the descending inhibitory system and inducing multiple LTRs.

For the control condition, a quasi-needle was used instead of the classic needle, ensuring no skin penetration. This quasi-needle, which contained a spring mechanism, was used with a technique that created a sensation similar to that of a real DN needle (telescopic needle-sham therapy) [8]. Participants could not see the needle being used due to the prone position (Fig. 1B). Throughout the experiment, participants were instructed not to engage in intensive exercise or physical labor that might strain their neck muscles. They were also instructed to avoid physiotherapy treatments, painkillers, and anti-inflammatory medications. Each participant underwent both a therapeutic session and a sham session.

Outcomes

All measurements and treatments were conducted in the Medical Center, under controlled conditions in a room set at 21°C, with monitoring via electronic sensors. The following measurements were taken at specific time points: (i) MT (Hz), (ii) MS (N/m), (iii) PPT (N/cm), (iv) maximum isometric strength (Fmax [kgf]), (v) transcutaneous perfusion response ([PU] perfusion unit – arbitrary units), (vi) Power Doppler Score (PDS) (scale 0–3), and (vii) minor adverse events (MAEs [number]). These measurements were conducted at the following moments: (i) at rest (before therapy), (ii) post-5min, (iii) post-24h, and (iv) post-7d.

MT and MS

After identifying the MTrP based on the previously mentioned criteria and marking the measurement location on the upper trapezius muscle with a marker, the biomechanical properties of the muscle, including MT and MS, were assessed using the MyotonPRO myotonometer (AS, Myoton Ltd). The MyotonPRO is a digital device featuring a body and a push-in probe (Ø 3 mm). Its reliability and repeatability have been confirmed in scientific literature [26]. The process begins by applying an initial pressure of 0.18 N to the surface via the probe, which compresses the underlying tissue. The device then delivers a mechanical impulse of 0.4 N for 15 ms, briefly deforming the tissue [27]. Resting MT is measured based on the frequency of muscle vibrations at rest, which is recorded by the silent electromyographic signal [27]. MS is calculated by evaluating the tissue's resistance to deformation using a logarithmic scale [28].

PPT

The PPT at trigger points plays a crucial role in diagnosing and treating myofascial pain [29]. To measure the PPT, an algesimeter (FDIX; Wagner Instruments) was used. Participants underwent three pressure tests with a probe (r=4 mm) applied to the tissue area (mm). The average force value (kg) of the three measurements was calculated and displayed digitally. If any significant deviation from the measured value occurred, the device signaled the need for a retest. The pressure was gradually increased until the participant found the sensation unpleasant [29]. Pressure altimeters, a widely used tool in clinical practice, have been validated as a reliable method for diagnosing and assessing treatment in MPSs, with high reliability in repeated measures [29,30]. All measurements were taken while the participant was in the treatment position.

Isometric muscle strength assessment

Handheld dynamometers are commonly utilized for measuring isometric muscle strength due to their portability and user-friendly design. These devices are known for providing reliable and valid measurements, making them ideal for both clinical and field applications [31]. The Kinvent K-Force Push v 3 handheld dynamometer, a reliable and repeatable tool [32], was used for isometric muscle strength testing. While seated, the device was positioned on the upper arm of the tested side. The participant was instructed to lift the arm upward, engaging the upper trapezius muscle, among others (Fig. 2). Each contraction lasted for 3 seconds [33]. The test was performed twice,

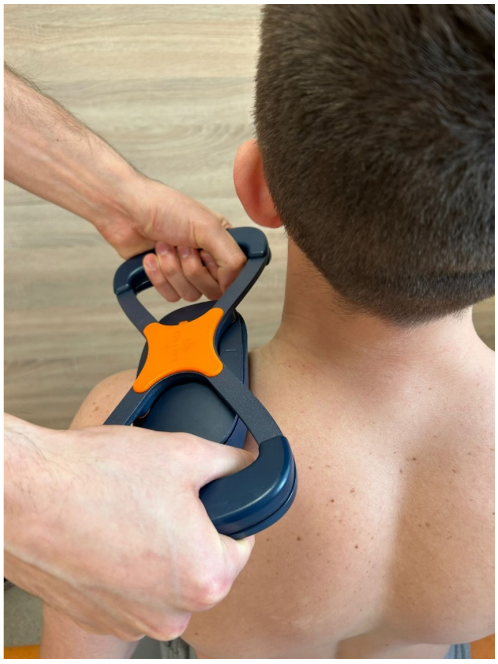

Fig. 2. Measurement of maximum isometric strength using the Kinvent K-Force Push v 3 handheld dynamometer.

and the strength values were averaged.

Tissue perfusion (PU)

MTrP is often associated with altered blood flow caused by MT and local ischemia. LDF is a technique capable of detecting these changes, offering a quantitative assessment of the muscle's physiological state. LDF is widely used for perfusion assessment and is recognized as a reliable, repeatable, and non-invasive method, making it the gold standard in this field [34,35]. Tissue perfusion was measured using a Perimed device, manufactured in Sweden in 2004. LDF measurements were taken at a skin tissue volume of 1 mm^3 and a depth of 2.5 mm, with two contact laser probes placed on the marked MTrP. The technique utilizes emitted radiation that penetrates deep into the tissue, where it interacts with moving blood cells, causing a change in their oscillation frequency due to the Doppler effect [36]. A photodetection system then analyzes the returning light, and the resulting voltage is directly proportional to the speed and number of moving blood cells, enabling the evaluation of blood supply to the tissue area based on the principles outlined by [37]. The final result of this process is the PU.

PDS

The PDS is an important tool in medical imaging, particularly for evaluating vascularity and inflammation in various conditions [38]. It provides valuable insight into blood flow and changes in vascular tissue, which helps assess disease activity and severity. PDS is frequently applied in the context of musculoskeletal disorders, rheumatoid arthritis, and obstetric conditions, among others [39]. As a safe, non-invasive, and cost-effective imaging method, PDS offers a quick and sensitive approach for visualizing hyperperfusion in tissues affected by penetrating or inflammatory interventions. The effectiveness of PDS in evaluating synovitis has been validated by comparing its results with those from magnetic resonance imaging, histology, and arthroscopy, with significant positive correlations reported, further confirming its reliability and reproducibility [40,41] In this study, PDS was conducted by an experienced operator. The SonoScape P20 with a 6–15 MHz linear probe was employed. Standardized PDS settings included a pulse repetition rate of 1,200 Hz and a color mode frequency of 8 MHz. The probe was positioned over the marked MTrPs, and the measurement window was set to a depth corresponding to the needle penetration during DN therapy. A semiquantitative visual scale was used to categorize the results: 0 for standard or minimal degree, 1 for mild degree, 2 for moderate degree, and 3 for severe degree (Fig. 3) [40].

MAEs

The effects and types of adverse events were recorded in the table as part of the study, following the survey previously developed and published [20].

Sample size

Based on findings from an earlier study on DN in combat sports [7], the sample size for this investigation was established in advance. To examine both within-group and between-group interactions across four measurement points, a repeated measures ANOVA was conducted. The effect size (f) of 0.758, derived from a partial eta squared of 0.341 observed in PPT [7], was used in the analysis. With a significance level set to 0.05 and a desired power of 0.95 for two groups and 8 measurements, G*Power software calculated that a minimum of 6 participants would be required. Although the statistical minimum was 6 participants, we opted to recruit more participants to accommodate potential dropouts and ensure the study's sample size remained adequate. As a result, we aimed to recruit 30 participants, which is often considered sufficient for the central limit theorem to apply, allowing the sampling distribution to

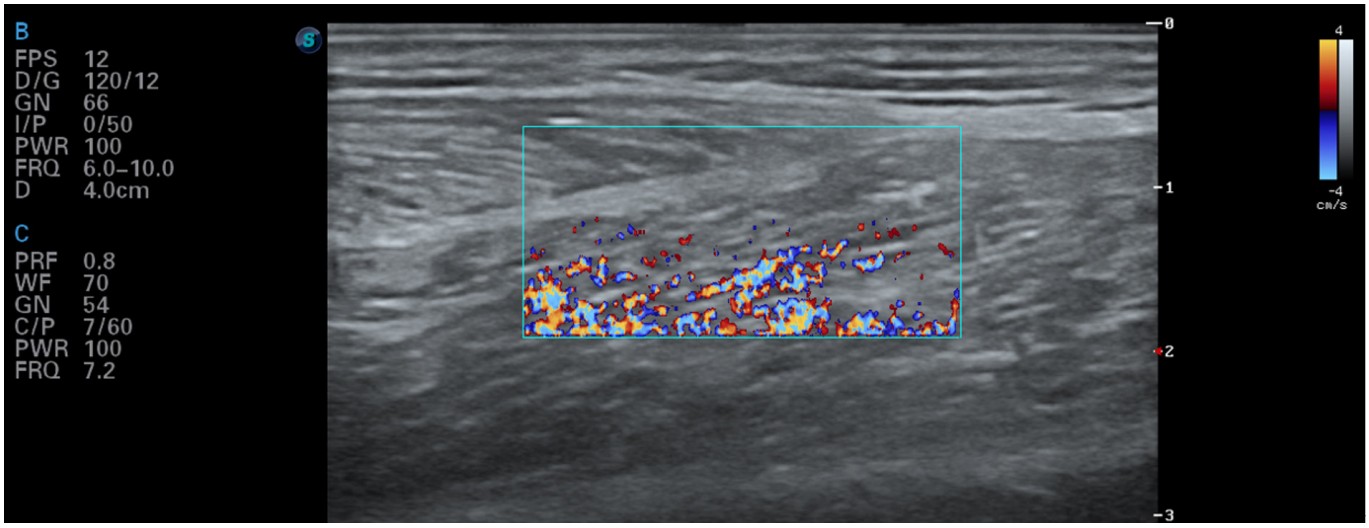

Fig. 3. Power Doppler Score (II degree).

approximate a normal distribution [42].

Randomization

The randomization process was overseen by a researcher not involved in later assessments to ensure the blinding procedure remained intact. Using a simple randomization method, participants were assigned to groups in a 1:1 ratio in a dedicated software (research randomizer). To guarantee impartial allocation, participants were allocated prior to their initial assessments.

Blinding

The participants were the only ones blinded to the experiment, while the physiotherapists and evaluators were aware of the DN protocols being applied.

Statistical methods

The Kolmogorov–Smirnov test was applied to assess the normality of the sample, yielding p-values greater than 0.05. Following this, Levene's test was conducted to evaluate the homogeneity of variances, with p-values also exceeding 0.05. A mixed ANOVA was then performed to analyze the interaction between time (four timing points×DN therapy and shamDN therapy) and group (GS and GH). To calculate effect sizes for pre- and post-intervention comparisons, Cohen's d was used. Effect sizes were categorized based on the thresholds [43]: small (≥0.10), moderate (≥0.30), large (≥1.2), and very large (≥2.0). Bonferroni-corrected post-hoc tests were conducted to follow up significant ANOVA findings. An independent t-test was conducted to compare baseline anthropometric data between groups, following verification of normality and homogeneity. Statistical analysis was carried out using SPSS software (version 28.0; IBM Corp), with a significance threshold of $p<0.05$.

RESULTS

After recruitment, 30 participants were included in the study and subsequently analyzed (Fig. 4). Among the 30 participants, 20 were males (age, 31.3±5.2 years; height, 179.7±8.1 cm; body mass, 86.6±6.9 kg; body mass index [BMI], 25.9±2.4 kg/m²) and 10 were females (age, 32.4±6.0 years; height, 167.8±7.5 cm; body mass, 64.1±10.5 kg; BMI, 24.0±2.8 kg/m²). The demographic characteristics and anthropometric data for each group are provided in Table 1. An independent t-test revealed no statistically significant differences between the GS and GH groups at baseline for age (GS, 31.9±5.1 years; GH, 31.4±5.8 years; p=0.791), body mass (GS, 79.9±13.0 kg; GH, 78.3±14.3 kg; p=0.912), height (GS, 175.9±9.1 cm; GH, 175.5±10.5 cm; p=0.761), and NPRS scores (GS, 5.13±0.99; GH, 5.53±1.06; p=0.294). However, a significant difference was observed in BMI between the groups (GS, 26.3±3.0 kg/m²; GH, 24.2±1.9 kg/m²; p=0.029). However, a significant difference was found in BMI (p=0.014), with the GS group exhibiting greater values. It is important to clarify that these are descriptive outcomes and are not part of the main analysis.

The Table 2 describes the mean and standard deviation of the outcomes across different time points and conditions in both

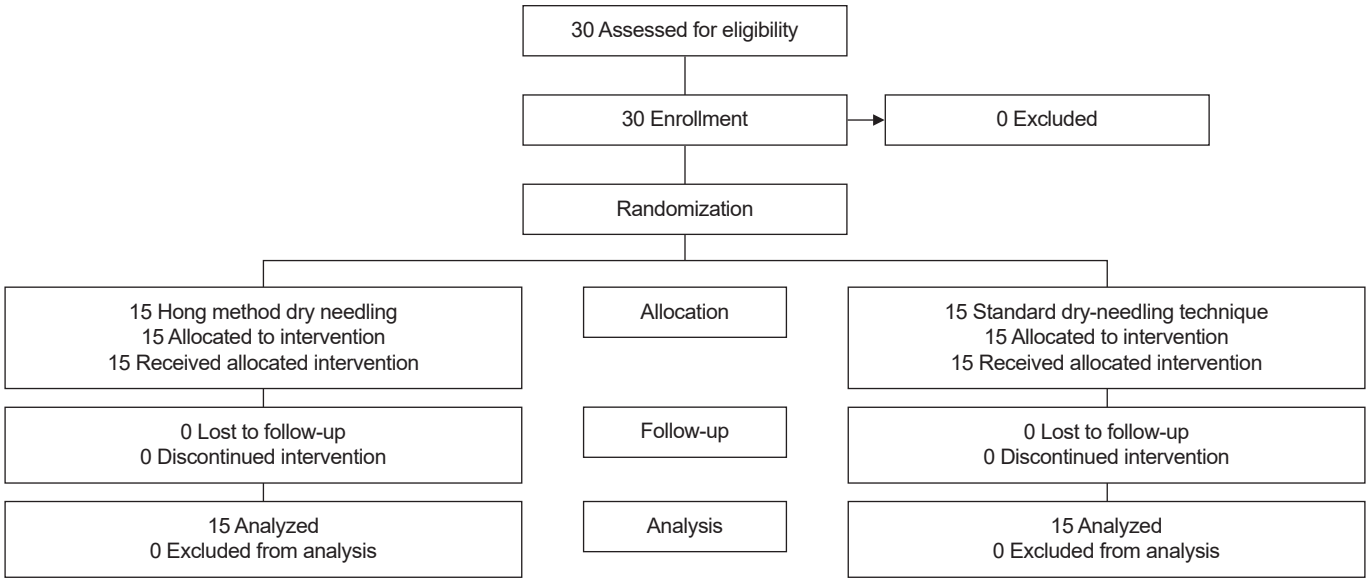

Fig. 4. Participants flowchart.

Table 1. Demographic characteristics and anthropometric data of the participants

	GS (n=15) DN	GS (n=15) ShamDN	GH (n=15) DN	GH (n=15) ShamDN	p-value
Male	10		10		-
Female	5		5		-
Age (yr)	31.9±5.1		31.4±5.8		0.791
Body mass (kg)	79.9±13.0		78.3±14.3		0.912
Height (cm)	175.9±9.1		175.5±10.5		0.761
Body mass index (kg/m^2)	26.3±3.0		24.2±1.9		0.029*
NPRS (A.U.)	5.13±0.99		5.53±1.06		0.294
MT rest (Hz)	19.6±0.8	19.6±0.8	18.8±0.7	18.7±0.6	GS vs. GH: F=8.168; p=0.008*; η_p^2=0.226 GSsham vs. GHsham: F=15.462; p=0.001*;η_p^2=0.356
MS rest (N/m)	346.5±19.2	350.9±17.8	346.2±23.6	348.9±25.8	GS vs. GH: F=0.001; p=0.973; η_p^2=0.001 GSsham vs. GHsham: F=0.061; p=0.807; η_p^2=0.002
PPT rest (N/cm)	79.0±6.4	79.5±4.2	82.1±3.2	80.8±2.8	GS vs. GH: F=2.952; p=0.097; η_p^2=0.095 GSsham vs. GHsham: F=0.977; p=0.331; η_p^2=0.034
Fmax rest (kgf)	30.1±5.1	31.9±3.5	33.1±3.1	32.2±3.6	GS vs. GH: F=3.924; p=0.057; η_p^2=0.123 GSsham vs. GHsham: F=0.057; p=0.812; η_p^2=0.002
PU rest (A.U.)	8.2±0.7	8.0±0.8	8.5±0.7	8.3±0.6	GS vs. GH: F=1.144; p=0.294; η_p^2=0.039 GSsham vs. GHsham: F=1.206; p=0.282; η_p^2=0.041
PDS rest (A.U.)	0.0	0.0	0.0	0.0	-

Values are presented as number only or mean±standard deviation.
GS, sustained insertion dry needling; GH, Hong method; DN, dry-needling; NPRS, Numeric Pain Rating Scale; MT, muscle tension; MS, muscle stiffness; PPT, pressure pain threshold; Fmax, maximum isometric strength; PU, transcutaneous perfusion response; PDS, Power Doppler Score.
*Significantly different between groups at p<0.05.

experimental groups.

Table 3 presents the post hoc comparisons within groups (GS vs. GH) and between conditions (experimental vs. sham, depending on the condition to which each group was exposed).

Table 4 presents the post hoc comparisons between groups (GS vs. GH) in each time point.

Fig. 5 provides a descriptive illustration of the main outcome values observed across the different time points.

Table 2. Descriptive statistics of the outcomes across different time points and conditions in both experimental groups

	GS (n=15)	GS (n=15)	GH (n=15)	GH (n=15)	Mixed ANOVA (time×group)	Between-group comparisons	Between-group comparisons
	DN	ShamDN	DN	ShamDN		DN	ShamDN
MT (Hz)							
Post-5min	17.7±0.6	19.5±0.8	17.4±0.9	18.4±0.5	F=75.562; p<0.001*; η_p^2=0.730	F=0.891; p=0.353; η_p^2=0.031	F=20.371; p<0.001*; η_p^2=0.421
Post-24h	16.4±0.7	19.5±0.7	20.5±0.7	18.4±0.5		F=255.377; p<0.001*; η_p^2=0.901	F=25.131; p<0.001*; η_p^2=0.473
Post-7d	17.1±0.4	19.5±0.8	17.7±0.3	18.7±0.6		F=18.906; p<0.001*; η_p^2=0.403	F=10.108; p=0.004*; η_p^2=0.265
MS (N/m)							
Post-5min	315.7±15.4	347.1±16.8	332.0±33.9	335.5±30.9	F=20.701; p<0.001*; η_p^2=0.425	F=2.886; p=0.100; η_p^2=0.093	F=1.634; p=0.212; η_p^2=0.055
Post-24h	294.5±10.0	348.7±17.6	357.2±19.1	346.3±21.9		F=127.339; p<0.001*; η_p^2=0.820	F=0.109; p=0.743; η_p^2=0.004
Post-7d	304.1±6.8	351.0±16.5	339.3±34.8	353.1±38.7		F=14.830; p=0.001*; η_p^2=0.346	F=0.036; p=0.850; η_p^2=0.001
PPT (N/cm)							
Post-5min	82.8±5.8	81.6±4.2	79.1±2.8	82.5±3.2	F=30.638; p<0.001*; η_p^2=0.522	F=4.786; p=0.037*; η_p^2=0.146	F=0.491; p=0.489; η_p^2=0.017
Post-24h	88.6±6.3	82.6±3.9	72.7±3.9	83.1±3.4		F=68.312; p<0.001*; η_p^2=0.709	F=0.167; p=0.686; η_p^2=0.006
Post-7d	94.8±4.6	81.3±3.8	88.7±3.7	83.0±4.0		F=16.201; p<0.001*; η_p^2=0.367	F=1.419; p=0.244; η_p^2=0.048
Fmax (kgf)							
Post-5min	32.6±4.2	33.1±3.1	33.4±3.3	32.5±3.5	F=4.996; p=0.016*; η_p^2=0.151	F=0.303; p=0.586; η_p^2=0.011	F=0.267; p=0.609; η_p^2=0.009
Post-24h	35.1±4.5	32.8±3.3	31.5±3.1	32.6±3.8		F=6.330; p=0.018*; η_p^2=0.184	F=0.021; p=0.887; η_p^2=0.001
Post-7d	36.1±4.6	33.0±3.0	35.0±2.4	32.8±3.7		F=0.692; p=0.412; η_p^2=0.024	F=0.017; p=0.898; η_p^2=0.001
PU (A.U.)							
Post-5min	10.6±1.0	8.1±0.8	12.8±1.2	8.3±0.5	F=12.683; p<0.001*; η_p^2=0.312	F=28.349; p<0.001*; η_p^2=0.503	F=0.803; p=0.378; η_p^2=0.028
Post-24h	11.6±0.9	8.2±0.8	11.6±0.5	8.3±0.6		F=0.031; p=0.861; η_p^2=0.001	F=0.058; p=0.811; η_p^2=0.002
Post-7d	8.9±0.6	8.1±0.7	10.0±0.5	8.3±0.5		F=26.961; p<0.001*; η_p^2=0.491	F=0.736; p=0.398; η_p^2=0.026
PDS (A.U.)							
Post-5min	1.2±0.4	0.0	0.2±0.4	0.0	F=51.978; p<0.001*; η_p^2=0.650	F=43.750; p<0.001*; η_p^2=0.610	-
Post-24h	1.6±0.5	0.0	0.2±0.4	0.0		F=68.600; p<0.001*; η_p^2=0.710	-
Post-7d	0	0.0	0.0	0.0		-	-

Values are presented as mean±standard deviation.
GS, sustained insertion dry needling; GH, Hong method; DN, dry-needling; MT, muscle tension; MS, muscle stiffness; PPT, pressure pain threshold; Fmax, maximum isometric strength; PU, transcutaneous perfusion response; PDS, Power Doppler Score; Post-5min, 5 minutes post-DN session; Post-24h, 24 hours post-session; Post-7d, 7 days post-session.
*Significantly different between groups at p<0.05.

MT

Significant interactions (time and groups) were observed in the MT (F=75.562; p<0.001; η_p^2=0.730). In the DN condition, between-group comparisons revealed that MT was significantly greater in GS than in GH at rest (F=8.168; p=0.008; η_p^2=0.226). Conversely, GH showed significantly higher values at post-24h (F=255.377; p<0.001; η_p^2=0.901) and post-7d (F=18.906; p<0.001; η_p^2=0.403). In the shamDN condition, GS was significantly higher than GH at rest (F=15.462; p=0.001; η_p^2=0.356), post-5min (F=20.371; p<0.001; η_p^2=0.421), post-24h (F=25.131; p<0.001; η_p^2=0.473) and post-7d (F=10.108; p=0.004; η_p^2=0.265).

Within the GS group, comparisons revealed significant dif-

Table 3. Post hoc comparisons using the Bonferroni correction for multiple comparisons, illustrating within-group variations across different time points

	GS	GSsham	GH	GHsham
MT (Hz)				
Rest vs. post-5min	p<0.001*	p=0.374	p<0.001*	p=0.003*
Rest vs. post-24h	p<0.001*	p>0.999	p<0.001*	p=0.275
Rest vs. post-7d	p<0.001*	p>0.999	p<0.001*	p>0.999
Post-5min vs. post-24h	p=0.004*	p>0.999	p<0.001*	p>0.999
Post-5min vs. post-7d	p=0.357	p>0.999	p>0.999	p=0.110
Post-24h vs. post-7d	p=0.012*	p>0.999	p<0.001*	p=0.086
MS (N/m)				
Rest vs. post-5min	p<0.001*	p>0.999	p=0.208	p=0.305
Rest vs. post-24h	p<0.001*	p>0.999	p=0.013*	p>0.999
Rest vs. post-7d	p<0.001*	p>0.999	p>0.999	p>0.999
Post-5min vs. post-24h	p=0.009*	p>0.999	p=0.001*	p=0.756
Post-5min vs. post-7d	p>0.999	p>0.999	p>0.999	p=0.347
Post-24h vs. post-7d	p>0.999	p>0.999	p=0.078	p>0.999
PPT (N/cm)				
Rest vs. post-5min	p<0.001*	p<0.001*	p=0.001*	p<0.001*
Rest vs. post-24h	p<0.001*	p<0.001*	p<0.001*	p=0.022*
Rest vs. post-7d	p<0.001*	p=0.379	p<0.001*	p=0.082
Post-5min vs. post-24h	p<0.001*	p>0.999	p<0.001*	p>0.999
Post-5min vs. post-7d	p<0.001*	p>0.999	p<0.001*	p>0.999
Post-24h vs. post-7d	p<0.001*	p=0.101	p<0.001*	p>0.999
Fmax (kgf)				
Rest vs. post-5min	p=0.002*	p<0.001*	p>0.999	p=0.863
Rest vs. post-24h	p<0.001*	p<0.001*	p=0.324	p=0.036*
Rest vs. post-7d	p<0.001*	p=0.001*	p=0.013*	p=0.293
Post-5min vs. post-24h	p=0.039	p=0.615	p=0.330	p>0.999
Post-5min vs. post-7d	p<0.001*	p>0.999	p=0.181	p>0.999
Post-24h vs. post-7d	p>0.999	p>0.999	p>0.999	p>0.999
PU (A.U.)				
Rest vs. post-5min	p<0.001*	>0.999	p<0.001*	p>0.999
Rest vs. post-24h	p<0.001*	p<0.001*	p<0.001*	p>0.999
Rest vs. post-7d	p=0.007*	p=0.671	p<0.001*	p>0.999
Post-5min vs. post-24h	p<0.001*	p=0.016	p<0.001*	p>0.999
Post-5min vs. post-7d	p<0.001*	p>0.999	p<0.001*	p>0.999
Post-24h vs. post-7d	p<0.001*	p=0.210	p<0.001*	p>0.999
PDS (A.U.)				
Rest vs. post-5min	p<0.001*	Not applicable	p>0.999	Not applicable
Rest vs. post-24h	p<0.001*	Not applicable	p>0.999	Not applicable
Rest vs. post-7d	Not applicable	Not applicable	p>0.999	Not applicable
Post-5min vs. post-24h	p=0.168	Not applicable	p>0.999	Not applicable
Post-5min vs. post-7d	p<0.001*	Not applicable	p>0.999	Not applicable
Post-24h vs. post-7d	p<0.001*	Not applicable	p>0.999	Not applicable

GS, sustained insertion dry needling; GH, Hong method; MT, muscle tension; MS, muscle stiffness; PPT, pressure pain threshold; Fmax, maximum isometric strength; PU, transcutaneous perfusion response; PDS, Power Doppler Score; Post-5min, 5 minutes post-dry-needling session; Post-24h, 24 hours post-session; Post-7d, 7 days post-session.

*A significant difference was observed within the specific group and condition, representing a within-group comparison across time points (p<0.05).

ferences in MT (F=42.747; p<0.001; η_p^2=0.932). Within the GS group under the DN condition, analysis revealed that MT was significantly higher at rest compared to post-5min (p<0.001, Bonferroni correction for 8 comparisons), post-24h (p<0.001) and post-7d (p<0.001). Additionally, MT at post-24h was significantly lower than at post-5min (p=0.004) and post-7d

Table 4. Post hoc comparisons between groups for each of the time points, using the Bonferroni correction for multiple comparisons

	GS vs. GH	GSsham vs. GHsham
MT (Hz)		
Rest	p=0.008	p<0.001*
Post-5min	p=0.353	p<0.001*
Post-24h	p<0.001*	p<0.001*
Post-7d	p<0.001*	p=0.004*
MS (N/m)		
Rest	p=0.973	p=0.807
Post-5min	p=0.100	p=0.212
Post-24h	p<0.001*	p=0.743
Post-7d	p<0.001*	p=0.850
PPT (N/cm)		
Rest	p=0.097	p=0.331
Post-5min	p=0.037	p=0.489
Post-24h	p<0.001*	p=0.686
Post-7d	p<0.001*	p=0.244
Fmax (kgf)		
Rest	p=0.057	p=0.812
Post-5min	p=0.586	p=0.609
Post-24h	p=0.018	p=0.887
Post-7d	p=0.412	p=0.898
PU (A.U.)		
Rest	p=0.294	p=0.282
Post-5min	p<0.001*	p=0.378
Post-24h	p=0.861	p=0.811
Post-7d	p<0.001*	p=0.398
PDS (A.U.)		
Rest	Not applicable	Not applicable
Post-5min	p<0.001*	Not applicable
Post-24h	p<0.001*	Not applicable
Post-7d	Not applicable	Not applicable

GS, sustained insertion dry needling; GH, Hong method; MT, muscle tension; MS, muscle stiffness; PPT, pressure pain threshold; Fmax, maximum isometric strength; PU, transcutaneous perfusion response; PDS, Power Doppler Score; Post-5min, 5 minutes post-dry-needling session; Post-24h, 24 hours post-session; Post-7d, 7 days post-session.
*A significant difference was observed between group, representing a between-group comparison in each time points (p<0.05).

(p=0.012). No significant differences were observed in MT within the GS group across the time points in the shamDN condition. MT was significantly greater in the GS shamDN condition compared to the DN condition at post-5min (p<0.001), post-24h (p<0.001), and post-7d (p<0.001).

Similarly, within the GH group, comparisons revealed significant differences in MT (F=44.471; p<0.001; η_p^2=0.934). In the GH group under the DN condition, MT was significantly higher at post-24h compared to rest (p<0.001, Bonferroni correction for 8 comparisons), post-5min (p<0.001) and post-7d (p<0.001). Additionally, MT at rest was significantly higher than at post-5min (p<0.001) and post-7d (p<0.001). No significant differences in MT were observed within the GH group across the time points in the shamDN condition. MT was significantly greater in the GH group under the shamDN condition compared to the DN condition at post-5min (p=0.005), but significantly lower in the shamDN condition compared to the DN condition at post-24h (p<0.001) and post-7d (p<0.001).

MS

Significant interactions (time and groups) were observed in the MS (F=20.701; p<0.001; η_p^2=0.425). For MS in the DN condition, GH exhibited significantly higher values than GS at both post-24h (F=127.339; p<0.001; η_p^2=0.820) and post-7d (F=14.830; p=0.001; η_p^2=0.346). In terms of PPT, GS had significantly greater values than GH at post-5min (F=4.786; p=0.037; η_p^2=0.146), post-24h (F=68.312; p<0.001; η_p^2=0.709), and post-7d (F=16.201; p<0.001; η_p^2=0.367) at DN condition. For Fmax in the DN condition, GS exhibited significantly higher values than GH at post-24h (F=6.330; p=0.018; η_p^2=0.184).

Within the GS group, comparisons revealed significant differences in MS (F=56.189; p<0.001; η_p^2=0.947). Within the GS group under the DN condition, analysis revealed that MS was significantly higher at rest compared to post-5min (p<0.001), post-24h (p<0.001) and post-7d (p<0.001). Additionally, MS at post-24h was significantly lower than at post-5min (p=0.009). No significant differences were observed in MS within the GS group across the time points in the shamDN condition. MS was significantly greater in the GS shamDN condition compared to the DN condition at post-5min (p=0.007), post-24h (p<0.001), and post-7d (p<0.001).

Similarly, within the GH group, comparisons revealed significant differences in MS (F=6.985; p<0.001; η_p^2=0.690). In the GH group under the DN condition, MS was significantly higher at post-24h compared to rest (p=0.013), and post-5min (p<0.001). No significant differences in MS were observed within the GH group across the time points in the shamDN condition. No significant differences in MS were found between the GH group's shamDN and DN conditions at any time point.

PPT

Significant interactions (time and groups) were observed in the PPT (F=30.638; p<0.001; η_p^2=0.522).

Within the GS group, comparisons revealed significant differences in PPT (F=45.448; p<0.001; η_p^2=0.935). Within the GS

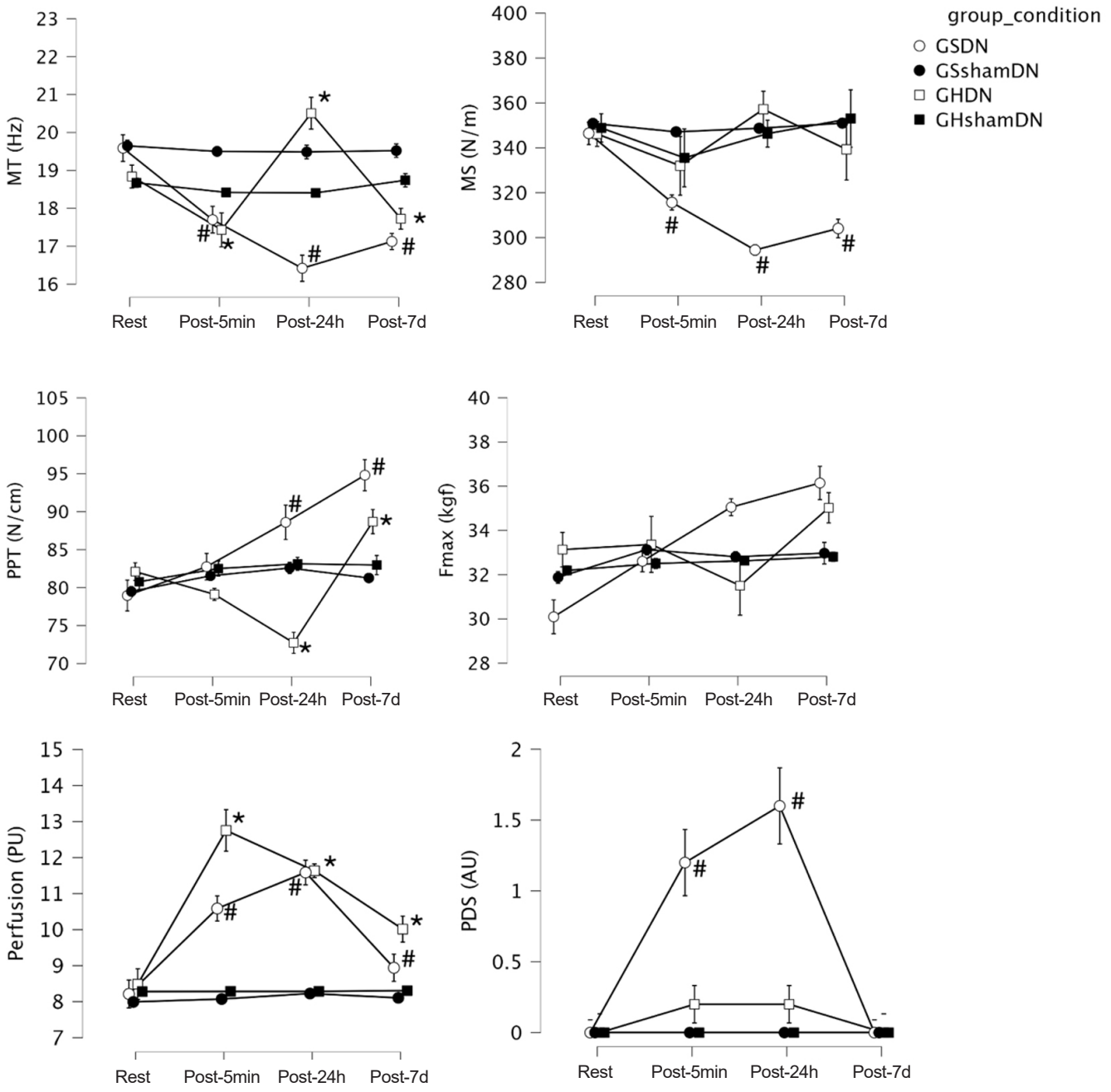

Fig. 5. Mean and standard deviation of muscle tension (MT), muscle stiffness (MS), pressure pain threshold (PPT), muscle strength (Fmax), perfusion response (PU), and Power Doppler Score (PDS) at rest, 5 minutes post-DN session (post-5min), 24 hours post-session (post-24h), and 7 days post-session (post-7d) in both conditions (dry needling, DN; sham dry needling, shamDN) for the Hong method (GH) and sustained insertion DN (GS) groups. *Significantly different between DN and shamDN in the GH group ($p<0.05$), using the Bonferroni correction for multiple comparisons within the group (i.e., 6 comparisons). #Significantly different between DN and shamDN in GS group ($p<0.05$), using the Bonferroni correction for multiple comparisons within the group (i.e., 6 comparisons).

group under the DN condition, analysis revealed that PPT was significantly smaller at rest compared to post-5min (p<0.001), post-24h (p<0.001) and post-7d (p<0.001). Additionally, PPT at post-5min was significantly lower than at post-24h (p=0.001) and post-7d (p<0.001). Finally, PPT at post-24h was significantly lower than at post-7d (p<0.001). In the shamDN condition, PPT at rest was significantly lower than at post-5min (p<0.001) and post-24h (p<0.001). Significant smaller PPT was found in DN than in shamDN conditions in the GS group at post-24h (p=0.001) and post-7d (p=0.001).

Similarly, within the GH group, comparisons revealed significant differences in PPT (F=38.944; p<0.001; η_p^2=0.925). In the GH group under the DN condition, PPT was significantly lower at post-24h compared to rest (p<0.001), and post-5min (p<0.001) and post-7d (p<0.001). Additionally, PPT at post-7d was significantly higher than at rest (p<0.001), and post-5min (p<0.001). PPT at post-5min was also significantly lower than at rest (p=0.001). Interestingly, in the shamDN condition, the GH group had significantly higher PPT at post-5min compared to rest (p<0.001). In the GH group, PPT was significantly higher in the shamDN condition compared to the DN condition at post-24h (p<0.001), whereas at post-7d, PPT was lower in the shamDN condition than in the DN condition (p<0.001).

Maximal force

Significant interactions (time and groups) were observed in the Fmax (F=4.996; p=0.016; η_p^2=0.151). Within the GS group, comparisons revealed significant differences in Fmax (F=55.730; p<0.001; η_p^2=0.947). Within the GS group under the DN condition, analysis revealed that Fmax was significantly greater at post-7d compared to rest (p<0.001), and post-5min (p<0.001). Additionally, PPT at post-24h was significantly greater than at post-5min (p=0.039). In the shamDN condition, Fmax at rest was significantly lower than at post-5min (p<0.001), post-24h (p<0.001), and post-7d (p<0.001). No significant differences were observed between the GS shamDN and DN conditions at any time point (p>0.05).

Similarly, within the GH group, comparisons revealed significant differences in Fmax (F=11.963; p<0.001; η_p^2=0.792). In the GH group under the DN condition, Fmax was significantly lower at rest compared to post-7d (p=0.013). Additionally, Fmax at post-24h was significantly smaller than at post-7d (p<0.001). In the shamDN condition, the GH group had significantly smaller Fmax at rest compared to post-24h (p=0.036). No significant differences were observed between the GS shamDN and DN conditions at any time point (p>0.05).

Perfusion

Significant interactions (time and groups) were observed in the, PU (F=12.683; p<0.001; η_p^2=0.312). For the PU variable in the DN condition, GH showed significantly higher values than GS at both post-5min (F=28.349; p<0.001; η_p^2=0.503) and post-7d (F=26.961; p<0.001; η_p^2=0.491).

Within the GS group, comparisons revealed significant differences in PU (F=45.715; p<0.001; η_p^2=0.936). Within the GS group under the DN condition, analysis revealed that PU was significantly smaller at rest compared to post-5min (p<0.001), post-24h (p<0.001) and post-7d (p=0.007). Additionally, PU at post-24 was significantly greater than at post-5min (p=0.001) and post-7d (p<0.001). Finally, PU at post-5min was significantly greater than at post-7d (p<0.001). In the shamDN condition, PU at rest was significantly lower than at post-24 (p<0.001), while PU was significantly smaller at post-5min compared to post-24h (p=0.016). Significant smaller PU was found in shamDN than in DN conditions in the GS group at post-5min (p=0.001), post-24h (p<0.001) and post-7d (p=0.004).

Similarly, within the GH group, comparisons revealed significant differences in PU (F=40.428; p<0.001; η_p^2=0.928). In the GH group under the DN condition, PU was significantly lower at rest compared to post-5min (p<0.001), post-24h (p<0.001) and post-7d (p<0.001). Additionally, PU at post-5min was significantly higher than at post-24h (p<0.001), and post-24h (p<0.001). PU at post-24h was also significantly greater than at post-7d (p=0.001). In the shamDN condition, no significant differences of PU were found comparing the different time points. In the GH group, PU was significantly higher in the DN condition compared to the shamDN condition at post-5min (p<0.001), post-24h (p<0.001) and post-24h.

PDS

Significant interactions (time and groups) were observed in the PDS (F=51.978; p<0.001; η_p^2=0.650). PDS in the DN condition, GS showed significantly higher values than GH at post-5min (F=43.750; p<0.001; η_p^2=0.610) and post-24h (F=68.600; p<0.001; η_p^2=0.710).

Regarding the PDS variable, comparisons between time points under the DN condition for the GS group revealed that values at rest were significantly lower compared to post-5min (p<0.001) and post-24h (p<0.001). Additionally, values at post-7d were significantly lower than at post-5min (p<0.001) and

post-24h (p<0.001). Comparisons of PDS between the shamDN and DN conditions in the GS group revealed significantly higher values in the DN condition at post-5min (p<0.001) and post-24h (p<0.001).

Within the GS group, comparisons revealed significant differences in PDS (F=114.091; p<0.001; η_p^2=0.894). In the GH group, no significant differences in PDS were found between time points in either the DN (p>0.05) or shamDN (p>0.05) conditions. Additionally, no differences were observed between the shamDN and DN conditions at the same time points (p>0.05).

Adverse events

Table 5 summarizes the minor adverse effects reported immediately after the interventions and 24 hours later. It shows that in the GH group, 33.3% of participants reported increased pain immediately after the intervention, with this number rising to 73.3% 24 hours later. In the GS group, 6.7% reported increased pain immediately after the session, which increased to 13.3% 24 hours later.

Additionally, although no small hematomas were reported immediately after the session in both GH and GS groups, 40.0% of participants in the GH group had small hematomas 24 hours later, compared to just 13.3% in the GS group. Burning sensations were reported exclusively by participants in the GH group, affecting 20.0% of participants both immediately after the intervention and 24 hours later.

Fatigue was reported by 20.0% of GH participants 24 hours after the session, while only 6.7% of GS participants reported fatigue at the same time. Fainting was observed in GH participants 24 hours after the intervention, while no fainting was reported in the GS group.

DISCUSSION

The study revealed significant interactions between time and group across the different outcomes, indicating differential responses to GH and GS in managing myofascial neck pain. The GS group was consistently better than the GH group, showing greater reductions in MT and MS, increased PPT, and improved Fmax over time, particularly in the DN condition. In contrast, the GH group exhibited delayed or less pronounced improvements, with some measures like PU showing higher immediate responses but less sustained benefits. The shamDN condition showed minimal improvements across both groups, reinforcing the efficacy of actual DN therapy. Additionally, the GS group experienced fewer MAEs, suggesting better safety and tolerability.

MT and MS

The study showed that MT and MS significantly reduced in the GS group compared to the GH group across various time points in the DN condition. The GS method showed consistent decreases in MT and MS post-5min, post-24h, and post-7d, whereas the GH group exhibited higher MT and MS values at post-24h and post-7d, indicating less effective outcomes. Within-group comparisons highlighted that the GS method led to significant and sustained reductions in MT and MS over time, while the GH method's improvements were less consistent. The GS method's superior outcomes may be due to its sustained needle retention strategy, which facilitates LTRs that help release MT and improve muscle flexibility [7]. This approach likely optimizes the mechanical and neurological responses necessary for effective treatment [44]. In contrast, the GH method's rapid needle insertions may insufficiently trigger these responses. DN's efficacy over shamDN is supported by its ability to induce LTRs, reduce nociceptive substances, and enhance local blood flow, thereby promoting tissue repair and reducing MT and MS [45], being our results aligned with previous studies considering the effects of DN in neck pain.

Table 5. Description of minor adverse effects reported immediately after the interventions and 24 hours later

	GH	GH	GS	GS
	Immediately after the session	After 24-h	Immediately after the session	After 24-h
Small hematoma	0	6	0	2
Increased pain	5	11	1	2
Fatigue	0	3	0	1
Burning	3	3	0	0
Fainting	0	2	0	0

Values are presented as number only.
GH, Hong method; GS, sustained insertion dry needling.

PPT

The study showed that the GS method resulted in significantly higher PPT values compared to the GH method at post-5min, post-24h, and post-7d in the DN condition, indicating more effective pain relief. Within-group analysis showed that PPT improved over time in both groups, but the GS method consistently outperformed the GH method. The enhanced PPT in the GS group can be attributed to the sustained needle insertion technique, which may provide more consistent mechanical and biochemical stimulation of MTrPs, leading to better modulation of nociceptive pathways [2]. This prolonged engagement likely enhances endogenous pain inhibitory mechanisms, resulting in greater pain relief than the multiple rapid insertions used in the GH method [46]. The significant difference between DN and shamDN conditions supports the physiological effectiveness of DN in reducing pain through neuromodulation and localized muscle relaxation, which have been confirmed in previous studies in neck pain [47].

Maximal force

The study indicated that Fmax improvements were not significantly greater in the DN condition compared to the shamDN condition, being different from previous studies [48]. These results suggest that while DN may have some impact on muscle strength recovery, it was not more effective than the shamDN condition in enhancing Fmax as observed in evaluations carried out in athletes [7]. The lack of substantial differences between DN and shamDN in Fmax improvements might be due to the nature of the strength measurement, which can be influenced by multiple factors, including neural adaptation and muscle fatigue [49]. It is possible that the interventions did not sufficiently activate the neuromuscular mechanisms necessary for significant strength improvements.

Perfusion

In both the GS and GH groups, DN was associated with significant changes in PU over time. In the GS group, DN led to a transient increase in tissue perfusion, with PU being significantly higher at post-24h compared to post-5min and post-7d, and smaller than at rest. This suggests that DN might temporarily enhance blood flow, promoting tissue recovery [50]. Importantly, the DN condition showed smaller PU compared to shamDN at all time points, indicating that the mechanical effects of needling itself, rather than placebo, played a key role in these changes. In the GH group, DN consistently increased PU at all post-needling time points compared to rest, with the greatest values observed at post-5min, suggesting an immediate effect on blood flow. Between-group analysis revealed that the GH method was more effective than the GS method at post-5 minutes, but no differences were observed at the remaining time points.

The observed changes in PU in both the GS and GH groups suggest that DN influences tissue perfusion primarily through the induction of local vasodilation [51]. In the GS group, DN led to a transient increase in blood flow, with PU at post-24h being higher than post-5min and post-7d but still smaller than at rest, indicating that DN initially enhances circulation, but the effects diminish over time. The higher PU observed in the DN condition compared to shamDN across all time points underscores the mechanical effect of needling, such as needle-induced microtrauma and muscle stimulation, which likely activates local vasodilation and enhances perfusion [51]. In the GH group, DN consistently increased PU at all post-needling time points, with the greatest effect at post-5min, suggesting a stronger or more immediate vasodilatory response, potentially due to deeper tissue penetration or a different mechanical response from the GH method. This sustained increase in blood flow might contribute to better nutrient and oxygen delivery to tissues, aiding in muscle recovery [52]. However, between-group analysis revealed that the GH method showed a stronger effect at post-5min, while differences between methods became less pronounced over time, indicating that both techniques may induce similar physiological effects in the long term.

PDS

The results from the PDS indicate that the GS group experienced significant changes in tissue perfusion following DN, with a marked increase in PDS at post-24h compared to post-5min and post-7d, suggesting a transient enhancement of blood flow. This increase in perfusion may reflect the vasodilatory effects of DN, promoting improved circulation and tissue recovery [51]. The smaller PDS in the shamDN group compared to the DN group across all time points further supports the hypothesis that the mechanical stimulation from needling, rather than placebo effects, contributed to these changes. In contrast, the GH group did not exhibit significant changes in PDS at any time point, nor were there differences between DN and shamDN conditions. This lack of response could be attributed to various factors, such as the possibility that the deeper needling technique used in the GH method did not induce the

expected local microvascular changes or that the time frame for observing such effects may differ. This suggests that the technique may influence the magnitude and timing of these effects, warranting further investigation into optimal parameters for maximizing vascular response.

Adverse effects

In this study, the GH group experienced a higher frequency of adverse effects compared to the GS group, both immediately post-session and 24 hours later. These differences can likely be attributed to the more intense and invasive nature of the GH method, which involves deeper needle insertions and may cause greater mechanical irritation. In contrast, the GS method, being less invasive, resulted in fewer side effects, suggesting that it may be a safer alternative for individuals who are more sensitive to discomfort or disposed to adverse reactions.

Study limitations, future research and practical applications

This study had some limitations that should be considered when interpreting the findings and planning future research. First, the sample size may limit the generalizability of the results, as larger and more diverse populations (e.g., older) could provide more robust evidence of the differential effects between the GS and GH methods. Additionally, the study focused on short- and medium-term outcomes (5 minutes, 24 hours, and 7 days post-treatment), which leaves unclear the long-term efficacy of these techniques in managing myofascial neck pain. Moreover, the relatively high number of needle insertions (averaging 40) may contribute to the observed outcome trends, potentially introducing procedural bias. Future comparative studies should standardize or account for the recommended number of insertions per technique to ensure methodological consistency and achieve a balanced evaluation. Additionally, future studies could explore the long-term effects of GS and GH methods, particularly regarding the duration of pain relief. Furthermore, while the study observed significant differences in several outcome measures, the lack of significant findings in some areas, such as Fmax improvements, suggests the need for further investigation into the physiological mechanisms underlying these outcomes, as other factors like neural adaptation or muscle fatigue may have influenced the results. Finally, the higher incidence of adverse events in the GH group suggests that the method may carry more risk, and future research should focus on refining techniques to reduce discomfort and enhance safety, potentially incorporating personalized approaches to treatment based on patient sensitivity.

Despite these limitations, the results of the current study suggest that the GS method is more effective and safer than the GH method in reducing MT and MS, improving PPT, and enhancing local tissue perfusion. This indicates that the GS method may be a better option for patients suffering from myofascial pain. Clinicians may consider adopting the GS approach, particularly for patients who experience more pronounced pain or are sensitive to deeper, more invasive needling techniques. The consistent reductions in MT and pain observed with the GS method also highlight its potential for providing longer-lasting benefits, making it a viable option for patients seeking sustained relief from chronic neck pain. Additionally, the lower incidence of adverse events in the GS group highlights its better tolerability, which could lead to improved patient compliance and satisfaction. For clinicians, this study advocates for a careful selection of the needling technique based on the patient's condition, sensitivity, and response to treatment, which could optimize therapeutic outcomes and minimize risks.

Conclusions

The findings of this study reveal that the GS method is more effective than the GH method in managing myofascial neck pain, particularly in reducing MT and MS, improving PPT, and enhancing local tissue perfusion. The GS approach's superior outcomes are likely due to its sustained needle retention strategy, which facilitates more consistent mechanical and neurological responses, leading to better pain relief. Additionally, the GS method was associated with fewer adverse events, highlighting its better safety profile and tolerability. While both DN techniques showed generally greater efficacy than shamDN, the GH method's results were less consistent and more disposed to delayed improvements. These findings support the clinical use of the GS method as a safer and more effective treatment option for individuals with myofascial pain, emphasizing the importance of individualized treatment approaches based on individual patient needs. Further research is needed to explore the long-term effects and underlying mechanisms of these interventions.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

Conceptualization: Olaniszyn G. Data curation: Olaniszyn G, Trybulski R. Investigation: Olaniszyn G, Kużdżał A, Kawczyński A, Matuszczyk F, Gałęziok K. Methodology: Olaniszyn G, Kużdżał A, Kawczyński A, Matuszczyk F, Gałęziok K. Formal analysis: Clemente FM. Project administration: Trybulski R. Resources: Olaniszyn G. Software: Olaniszyn G. Visualization: Clemente FM, Trybulski R. Supervision: Trybulski R. Writing – original draft: Olaniszyn G, Kużdżał A, Kawczyński A, Matuszczyk F, Gałęziok K, Clemente FM, Trybulski R. Writing – review and editing: Olaniszyn G, Kużdżał A, Kawczyński A, Matuszczyk F, Gałęziok K, Clemente FM, Trybulski R. Approval of final manuscript: all authors.

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Unilateral Vibratory Stimulation Inhibits Contralateral Spinal Anterior Horn Cells in Homonymous Muscles for the First 75 Seconds

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Objective: To investigate muscle tone changes over time in contralateral homonymous muscles when unilateral muscles are stimulated, using F-wave measurements, we examined whether vibratory stimulation on the contralateral homonymous muscle of the affected side may reduce spasticity, whose optimal duration remains unclear.
Methods: Vibratory stimulation was applied to the right hand of healthy adults, using parameters of 80 Hz frequency, 0.4 mm amplitude, 400 g load, and 195 seconds of duration on the abductor digiti minimi muscle. F-wave was measured in the left hand before stimulation, at seven intervals during stimulation, and immediately after.
Results: The F/M amplitude ratio decreased immediately at stimulation onset, at 30 seconds, and at 60 seconds compared to baseline. A least-squares analysis revealed a negative slope from baseline to 60 seconds ($f(x)=-0.11x+1.12$), while the slope became positive after 90 seconds, continuing after stimulation ended ($f(x)=0.04x+0.82$).
Conclusion: Unilateral vibratory stimulation may decrease excitability in the spinal anterior horn cells of the contralateral homonymous muscle for up to 75 seconds post-stimulation, suggesting a potential mechanism for spasticity management.

Keywords: Vibration therapy, Muscle tone, Thumb, Occupational therapy, Physical therapy modalities

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INTRODUCTION

Spasticity is a typical symptom of cerebrovascular disease, characterized by increased muscle tone, particularly in the fingers and wrist joints [1]. Furthermore, in rehabilitation situations, patients often experience spasticity in these areas, making it difficult for them to release objects they have grasped. Spasticity also inhibits patients' activities of daily living (ADL) and quality of life [2], and increases the burden on caregivers [3]. Therefore, reducing muscle tone in the fingers is crucial for improving ADL. To address this issue, various methods have been developed to suppress muscle tone, including vibratory stimulation [4]. Vibration is a wave that remains constant and oscillates, and is composed of amplitude and wavelength. Amplitude refers to the height of the wave, and wavelength is the periodic length of the wave. Frequency is the number of times the vibration is

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repeated per unit time, and is closely related to wavelength. By applying these stimuli to the human body, it is possible to alter muscle tonus. Typical methods include direct stimulation of the affected muscle to induce neurotransmitter depletion and changes in muscle spindle sensitivity [5-7], as well as stimulation of the antagonist muscle corresponding to the affected muscle, to induce reciprocal inhibition. These aforementioned methods [8,9], have been reported to impede the inhibitory effect of the muscle tonus following vibratory stimulation [10,11]. This refers to the fact that exercise therapy after vibratory stimulation causes an immediate increase in muscle tonus. Furthermore, it is difficult to combine exercise therapy with vibratory stimulation because it is necessary to immobilize the stimulation site in order to provide vibratory stimulation to the affected muscle or its antagonist muscle. As such, the clinical application of combining vibratory stimulation and exercise therapy remains to be explored. One potential solution to this problem is to suppress the muscle tonus of the affected muscle by stimulating the contralateral homonymous muscle that corresponds to the affected muscle [12]. This approach involves providing vibratory stimulation to the contralateral homonymous muscle corresponding to the affected muscle while performing exercise therapy for the affected muscle, thereby combining vibratory stimulation and exercise therapy. However, in our previous research, the results were limited to those obtained when the vibration stimulation time was set to an extremely short 15 seconds, and it can be said that the appropriate vibration stimulation time needs to be investigated for application in clinical settings [12]. Muscle tonus and spinal nerve function are closely related, and F-wave and H-reflex are representative tests. Moreover, F-wave is often used as an evaluation index for demonstrating treatment efficacy for post-stroke spasticity due to its strong association with muscle tonus [13,14]. The F-wave is a compound action potential that is elicited from the dominant muscle after an electrical stimulus applied to the motor nerve conducts retrogradely through the axon and re-fires in the anterior horn cells of the spinal cord. Furthermore, this action potential can be easily derived from the abductor pollicis brevis (APB) muscle of the hand. In contrast, the H-reflex is generally derived from the radial carpometacarpal flexor and radial carpometacarpal extensor muscles, making it more challenging to be derived from the hand muscles. When focusing on the hand muscles that limit ADL, the F-wave is often used as an evaluation index. The objective of this study was to investigate the effect of the duration of unilateral vibratory stimulation on the muscle tonus of the contralateral homonymous muscle using the F-wave.

METHODS

Participants

The subjects were 14 healthy right-handed adults (25.4±1.3 years) with no orthopedic or neurological history. Informed by previous studies indicating that a sample size of 10 to 20 participants is generally necessary, the number of participants in this study was set accordingly [15]. The Edinburgh Handedness Inventory was used to assess handedness, with a laterality index of 64 [16]. All the participants received verbal and written explanations of the study content and ethical considerations to ensure adequate understanding, including the risks and freedom to participate, before enrollment. Written informed consent was obtained from all participants. The study conformed to the guidelines of the Declaration of Helsinki. The Research Ethics Review Committee of Kansai University of Health Sciences approved the study (approval number 22-12) before initiation of the protocol.

Study procedure

Vibratory stimulation was administered to the right hand of all participants. F-wave were recorded from the left hand while vibratory stimulation was being administered to the right hand. F-wave measurements were taken while the participants were seated in a relaxed position. F-wave were recorded at the following time points: pre-vibratory stimulation (pre), immediately after initiating vibratory stimulation (0–15 seconds), 30 s (30–45 seconds), 60 s (60–75 seconds), 90 s (90–105 seconds), 120 s (120–135 seconds), 150 s (150–165 seconds), and 180 s (180–195 seconds), and immediately after the end of vibratory stimulation (post). The subjects were in a resting state without vibratory stimulation before and after the vibratory stimulation, and F-wave were recorded during the vibratory stimulation sessions.

Interventions

Vibratory stimulation typically involves setting the frequency, amplitude, load, stimulation site, and stimulation time [11,17]. In the present study, vibratory stimulation at a frequency of 80 Hz, an amplitude of 0.4 mm, and a load of 400 g was applied to the right short thumb abductor muscle. In previous studies, it was considered that by applying vibratory stimulation, the mus-

cle spindles of the stimulated muscle become excited, and the sensation transmitted via the Ia fibers suppresses the excitability of the anterior horn cells of the spinal cord corresponding to the contralateral homonymous muscle [12]. In other words, it is necessary to set the vibratory stimulation conditions that make the muscle spindles of the stimulated muscle more likely to become excited. Therefore, we set the frequency, amplitude, load weight, and stimulation site that would easily excite the muscle spindle, with reference to previous studies [18-22]. The muscle belly of APB was identified in the middle of the line connecting the base of the first basal phalanx and the navicular bone to control the recording site. To confirm that the muscles could be stimulated during the vibratory stimulation, the movement of the thumb produced by the tonic vibration reflex was verified [8]. Regarding the duration of vibratory stimulation, in previous studies, when vibratory stimulation was administered to suppress the muscle tonus, the targeted muscle was often stimulated for 60–300 seconds [23,24]. In our study, the vibratory stimulation was set for 195 seconds, and changes in the F-wave derived from the contralateral homonymous muscle to the stimulated muscle were monitored. A muscle-tendon vibratory stimulation device, MGV-1000-F (Uchida Electron Co., Ltd.), was utilized to apply the vibratory stimulation (Fig. 1).

F-wave recording

Neuropack S3 (Nihon Kohden Co., Ltd.) was used for F-wave recording. The recording conditions for the F-wave were as follows: stimulation site, median nerve; stimulation frequency, 2 Hz; and stimulation duration, 0.2 ms. The minimum amplitude standard for the F-wave was set at 30 μV [25], and the waveform analysis items were F/M ratio and F-wave persistence. The F-wave measurements for each participant were performed at a randomly assigned time between 17:00 and 19:00, with the room temperature maintained at 25°C [26].

Statistical analysis

Statistical analysis was performed using a generalized liner mixed model with the F/M amplitude ratio at each time point as the dependent variables. The time factor was set as a fixed effect, and individual differences were set as a random effect. The main effect was compared with each time point starting from the F/M amplitude ratio at pre-stimulation. The effect size was evaluated by calculating the correlation coefficient between the observed and predicted values, and then squaring this value to obtain a pseudo coefficient of determination (R^2), which was used to indicate the goodness of fit of the model. The slope was determined using the least squares method from the time before the significant difference to the time when the significant difference was observed, and from the time when the significant difference was not found to the time immediately following the vibration stimulus. In addition, by plotting the median for each time point, a scatter plot was created, and a regression line was drawn to provide a visual overview of the characteristics over time. Statistical analysis was performed using IBM SPSS Sta-

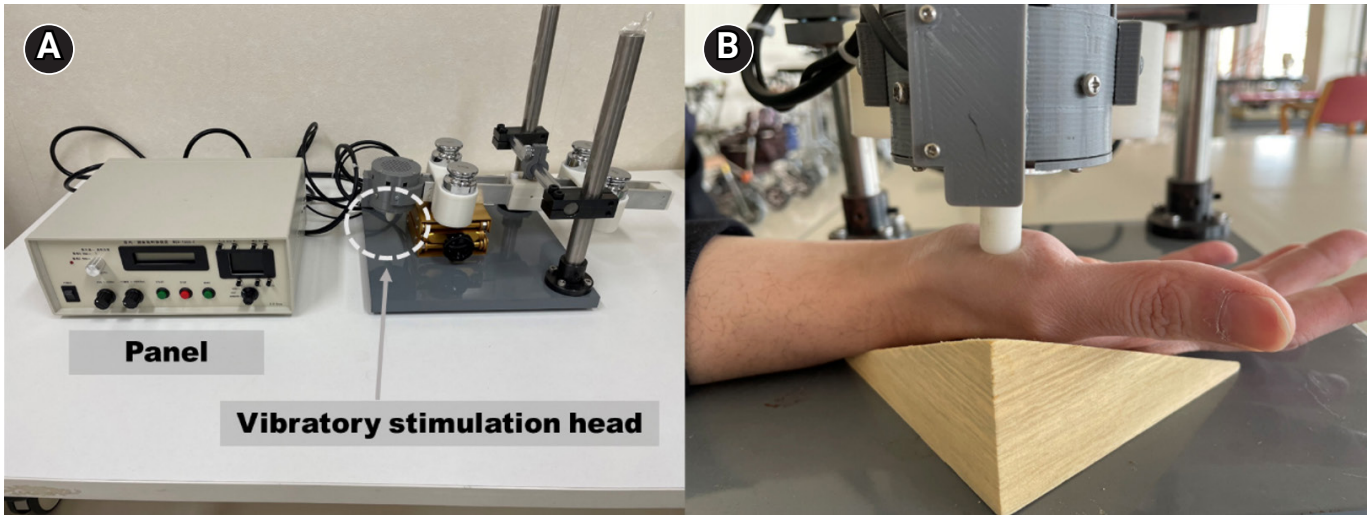

Fig. 1. Vibration stimulator used in this study. The vibratory stimulation head is the part that provides the vibration stimulus. The panel allows you to adjust the frequency, amplitude and stimulus time (A). The location of the focal vibrator was the muscle belly of the right abductor pollicis brevis (B).

tistics for Windows version 28.0 (IBM Corp.) at a significance level of 5%.

RESULTS

The mean F/M amplitude ratio was 1.2±0.8% before vibratory stimulation, 0.7±0.4% immediately after initiating vibratory stimulation, 0.8±0.4% at 30 s, 0.8±0.5% at 60 s, 1.0±0.8% at 90 s, 1.0±0.7% at 120 s, 0.9±0.7% at 150 s, 1.0±0.7% at 180 s, and 1.0±0.7% immediately after vibratory stimulation was completed. The results are summarized in Table 1.

The results at each time point were compared using the pre-vibratory stimulation value as the reference time point. The results revealed a significant decrease from immediately after inhibition of vibration stimulation to 60 s, and no change was observed at the later time points (Fig. 2). The pseudo R^2 was 0.042, indicating a low goodness of fit between the observed and predicted values. The slope of the regression line from before the start of the vibratory stimulation to the 60-second time point was calculated to be f(x)=-0.11x+1.12. The slope of the re-

Table 1. Changes over time in the F/M amplitude ratio

	F/M amplitude ratio±SD (%)	95% CI lower	95% CI upper	p-value
Pre stimulation	1.2±0.8	-	-	-
0 s	0.7±0.4	-0.756	-0.115	0.002*
30 s	0.8±0.4	-0.671	-0.029	0.024*
60 s	0.8±0.5	-0.699	-0.058	0.011*
90 s	1.0±0.8	-0.456	0.185	>0.999
120 s	1.0±0.7	-0.521	0.121	0.678
150 s	0.9±0.7	-0.549	0.092	0.394
180 s	1.0±0.7	-0.456	0.185	>0.999
Post stimulation	1.0±0.7	-0.449	0.192	>0.999

SD, standard deviation; CI, confidence interval.
*Statistically significant, p<0.05.

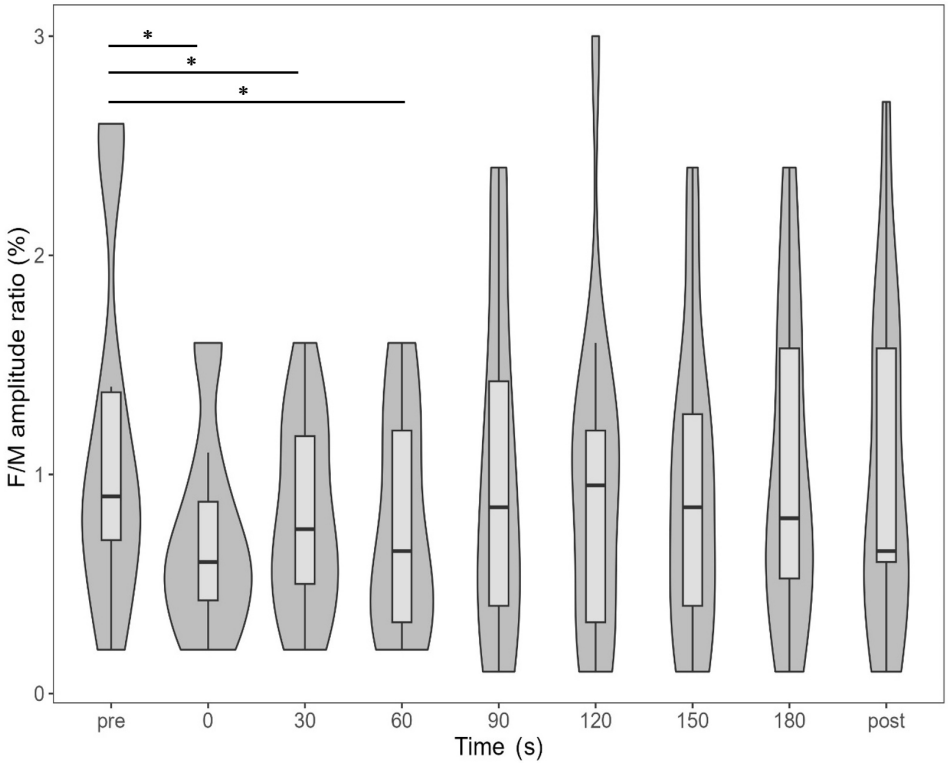

Fig. 2. Generalized liner mixed model results in F/M amplitude ratio. *Statistically significant, p<0.05.

gression line from the time of 90 s to just after the end of the vibratory stimulation showed a positive slope of f(x)=0.04x+0.82 (Figs. 3, 4).

DISCUSSION

In this study, vibratory stimulation at a frequency of 80 Hz, an amplitude of 0.4 mm, and a load of 400 g was applied to the right APB for 195 seconds, with F-waves recorded from the left APB every 15 seconds after stimulation onset. The F/M amplitude ratio decreased until 60 seconds but gradually returned to baseline levels thereafter. There are several previous studies that have examined the effects of unilateral vibration stimulation on muscle tone in the contralateral side [27,28]. However, there is no consistent view on the effects. One reason for this is the variation in vibration stimulation conditions. In particular, parameters such as frequency, amplitude, duration, site of stimulation, and muscle condition during stimulation vary across studies. Therefore, in order to solve these problems, this study differs from previous studies in that it confirmed the effects of vibratory stimulation after setting the vibratory stimulation conditions that are considered to be likely to excite the muscle spindle based on a review of previous studies. It has been demonstrated that vibration-induced excitation of the muscle spindle transmits sensory information via Ia fibers [29,30]. Furthermore, sensory input from the stimulated APB muscle spindle transmitted via Ia fibers and spinal interneurons activates inhibitory interneurons on the opposite side, contributing to the suppression of muscle tone in the opposite APB [31,32]. Previous studies have emphasized that there are no changes in the primary motor cortex that controls the contralateral homonymous muscle corresponding to the vibrated muscle [33,34]. These results suggest that the vibration stimulus transmitted sensory input from the muscle spindle of the stimulated APB via spinal interneurons, and suppressed the F/M amplitude ratio of the contralateral APB. The F/M amplitude ratio of the contralateral homonymous muscle corresponding to the vibratory stimulation muscle was suppressed via the commissural interneurons in the spinal cord. Next, regarding the change in F/M amplitude ratio over time, past research has shown that when a vibration stimulus is applied, the muscle spindle of the stimulated muscle can remain in an excited state for up to 20 seconds [18]. As a neurophysiological mechanism for these findings, previous studies have shown that the stimulation of the spinal cord by vibratory stimulation produces a tonic vibration reflex, a monosynaptic reflex mediated by Ia fibers, in the vibratory stimulation muscle, which acts promptly on the spinal cord anterior horn cells corresponding to the vibratory stimulation muscle [8,9]. However, the sensory input via Ia fibers is not a stimulatory stimulus because the sensitivity of the muscle spindle changes over time and the stimulating muscles are not affected. The sensitivity of the muscle spindle to sensory input via Ia fibers changes over time, inhibiting sensory input from the stimulating muscle and making it difficult to transmit sensory information [7]. The results of the present study suggest that, although the sensory information via Ia fibers is input at 20 seconds after the start of stimulation, the sensitivity of the muscle spindle on the vibratory stimulation side gradually changes, and the suppression effect of the muscle tonus on the contralateral homonymous muscle corresponding to the stimulated muscle is impaired after 75 seconds. In summary, the F/M amplitude ratio decreased immediately after the start of vibratory stimula-

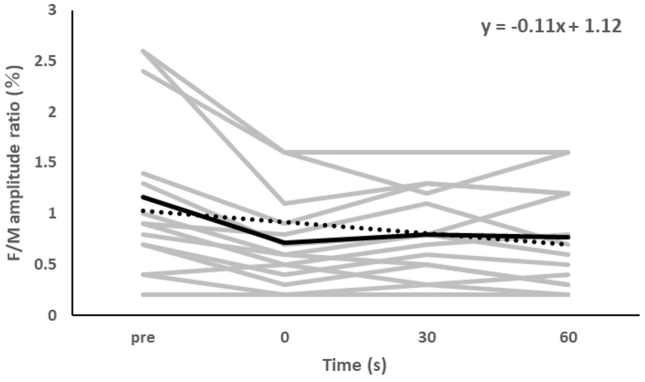

Fig. 3. Regression line from the start of the least-squares stimulation to the 60-second time point.

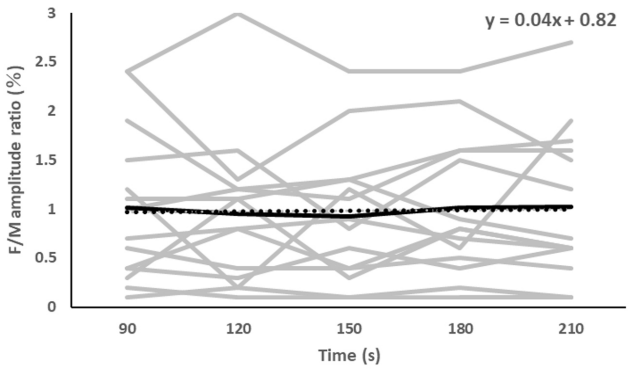

Fig. 4. Regression line from the time of 90 seconds to the end of stimulation by the least-squares method.

tion and continued to do so up to 75 seconds. This decrease in the F/M amplitude ratio likely reflects the suppression of anterior horn cell excitability in the contralateral homonymous muscle, mediated by Ia fiber input and commissural interneurons. However, after 90 seconds, a threshold shift in the muscle spindle's responsiveness is believed to reduce its inhibitory influence on the excitability of anterior horn cells in the spinal cord of the contralateral homonymous muscle corresponding to the stimulated muscle, and the muscle approaches a resting state.

Next, we will discuss clinical applications. The F-wave used in this study is a typical indicator for evaluating spasticity and is closely related to clinical indicators. In previous studies, persistence and F/M amplitude ratio were used as evaluation indicators for F-waves, and it was interpreted that the smaller these values were, the less spasticity there was [25,35]. In the results of this study, the F/M amplitude ratio at 0, 30, and 60 seconds after vibration stimulation was significantly reduced compared to before vibration stimulation. This suggests that the vibration stimulation used in this study may contribute to the alleviation of spasticity for about one minute. Recently, this method has been applied in clinical practice as a rehabilitation technique that promotes motor control [36]. However, limited clinical studies have been conducted in spasticity patients, and the efficacy of this intervention remains inconclusive. Patients with spasticity are forced to exert excessive force due to increased muscle tone, and abnormal joint movement is likely to occur. As a result, it becomes difficult to properly regulate force, and this may lead to incorrect motor learning. From the perspective of clinical application, the results of this study suggest that applying vibration stimulation to patients with spasticity may reduce muscle tone in the contralateral limb and promote deviation from abnormal joint movement. However, the results of this study only suggest short-term effects, and further research is needed to investigate the long-term effects of sustained stimulation and the cumulative effects of repeated application.

In addition, the small number of subjects is a limitation of this study, which may limit the generalizability of the findings. Therefore, it is necessary to increase the sample size and conduct further studies in the future.

CONFLICTS OF INTEREST

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

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None.

AUTHOR CONTRIBUTION

Conceptualization: Kunoh K, Suzuki T. Methodology: Kunoh K, Suzuki T. Formal analysis: Kunoh K, Kimura D. Project administration: Suzuki T. Visualization: Kunoh K. Writing – original draft: Kunoh K. Writing – review and editing: Takenaka T, Kimura D, Suzuki T. Approval of final manuscript: all authors.

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Temporal and Kinematic Measurements of Hyoid Bone Excursion in Patients With Head and Neck Cancer

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Objective: To investigate the temporal and kinematic parameters of hyoid bone excursion (HBE) in head and neck cancer (HNC) patients with and without aspiration.

Methods: Videofluoroscopic swallowing study images from 28 HNC patients were divided into aspiration and non-aspiration groups. The kinematic parameters of HBE, including displacement, instantaneous velocity, and instantaneous acceleration, as well as the timing of reaching maximal values in these parameters, were analyzed.

Results: The timings of reaching maximal horizontal (2.37±1.10 seconds vs. 1.09±1.58 seconds, p=0.010; 0.68±0.28 vs. 0.37±0.26, p=0.010 for percentage of time), vertical (1.83±2.06 seconds vs. 0.86±1.42 seconds, p=0.020) and hypotenuse instantaneous velocities (2.36±1.96 seconds vs. 0.79±1.20 seconds, p=0.006; 0.60±0.33 vs. 0.33±0.24, p=0.028 for percentage of time), as well as the timings of reaching maximal horizontal (2.22±1.50 seconds vs. 0.90±1.26 seconds, p=0.009; 0.60±0.32 vs. 0.37±0.29, p=0.041 for percentage of time), vertical (2.09±1.94 seconds vs. 0.83±1.19 seconds, p=0.003), and hypotenuse instantaneous accelerations (2.49±1.93 seconds vs. 0.81±1.24 seconds, p=0.004; 0.65±0.34 vs. 0.34±0.28, p=0.026 for percentage of time) were significantly prolonged in the aspiration group. After signal smoothing, the aspiration group exhibited delayed timing in reaching maximal horizontal instantaneous velocity (2.07±1.09 seconds vs. 0.74±1.10 seconds, p=0.004; 0.58±0.29 vs. 0.32±0.24, p=0.017 for percentage of time), as well as maximal horizontal (2.18±1.16 seconds vs. 1.12±1.46 seconds, p=0.008) and hypotenuse accelerations (2.21±2.50 seconds vs. 0.81±1.21 seconds, p=0.011). There were no significant between-group differences in other kinematic parameters, except for horizontal displacement (7.66±6.26 mm vs. 12.14±5.82 mm, p=0.042).

Conclusion: The timings of reaching maximal instantaneous velocities and accelerations of HBE, rather than the maximum values of these kinematic parameters, may be critical parameters related to aspiration in HNC patients.

Keywords: Dysphagia, Head and neck cancer, Hyoid bone kinematics, Aspiration and penetration, Videofluoroscopic swallowing study

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INTRODUCTION

Dysphagia is an important clinical issue in patients with head and neck cancer (HNC). Long-term dysphagia affects 46% of patients with HNC, despite improvements in treatments [1]. Dysphagia may cause aspiration pneumonia and malnutrition [2], which have impacts on patient's survival [3] and life quality [4]. The upward and forward movements of the hyoid bone excursion (HBE) are among the most critical events in the pharyngeal phase of swallowing, related to airway protection and upper esophageal sphincter opening. This process facilitates the entry of the bolus into esophagus and helps avoid pyriform sinus stasis [5-7]. However, in most of previous HBE analyses in videofluoroscopic swallowing study (VFSS), only the maximal displacement and mean velocity of the upward and forward movement of HBE have been investigated, presumed to be possible determinants to predict aspiration. Nevertheless, previous studies have shown inconsistent results in populations with different diagnoses [7-15]. Also, the temporal parameters related to hyoid burst were seldom discussed, which include peak velocity, peak acceleration and timing of reaching these values. The hyoid burst, indicating the rapid abrupt movement of the hyoid in an anterosuperior trajectory, plays an important role for the laryngeal vestibule closure (LVC) [16,17]. A previous study had demonstrated that the timing of reaching peak velocity is closely linked to the timing of achieving LVC in normal population [18]. Recent studies of HBE tracking have also shown that stroke patients with aspiration were associated with a lower maximal horizontal instantaneous velocity and acceleration and prolonged time to these values compared to the non-aspirators [19,20]. Accordingly, these temporal kinematic parameters may be highly associated risk of aspiration.

In a previous kinematic study of HNC patients with dysphagia, it was found that the forward displacement and velocity of HBE in the nasopharyngeal carcinoma (NPC) patients were less than those of healthy subjects. Additionally, the NPC subjects with aspiration experienced less forward displacement of the hyoid bone than those without aspiration [9]. Another study demonstrated a significant decrease not only in the maximal distance but also in the maximal velocity of HBE in both the anterior and the superior direction in postoperative advanced tongue cancer patients who underwent intra-arterial chemoradiotherapy [21]. One study revealed that HNC patients with reduced superior hyoid displacement subjectively perceived more significant swallowing impairment, according to a study-specific subjective swallowing questionnaire. However, kinematic measurements, including anterior and superior hyoid displacements, and temporal measurements, including the hyoid bone elevation onset and duration, were not correlated with the penetration-aspiration score (PAS) score or residual scores [22]. Collectively, these studies suggest that the temporal kinematic parameters of HBE play an important role in dysphagic NPC patients, but inconsistent results have been observed. Furthermore, limited research has investigated the instantaneous kinematics parameters and the timing of HBE in HNC patients. Therefore, the aim of this study is to investigate the temporal kinematic parameters of HBE, including instantaneous velocity and instantaneous acceleration of HBE, between aspiration and non-aspiration groups of HNC patients.

METHODS

Participants and materials

This study collected VFSS videos from 301 patients who presented with swallowing problems at our outpatient clinic and underwent VFSS between May 2015 and May 2020. Only thin liquid test videos from patients diagnosed with HNC were included. If a patient had two examinations within this period, only the latest exam was considered. All the VFSS videos underwent de-identification before data analysis. The trimmed video segment captures the entire hyoid motion during swallowing. Specifically, the kinematic data were extracted from the frame marking the onset of the hyoid burst, defined as the point at which the hyoid bone begins a rapid, abrupt anterosuperior movement, until the end of the excursion, defined as the return of the hyoid bone to its resting position. The VFSS results were categorized into 2 groups: the aspiration group and the non-aspiration group. The aspiration group was defined as PAS in the range of 6–8, while the non-aspiration group included the VFSS images scored as PAS 1–5 [23]. Videos with poor image quality, defined as those with a blurred or poorly visualized hyoid bone, significant motion artifacts, or the presence of metal implants obscuring the region of interest, were excluded. In addition, videos without an obvious swallowing reflex—defined as the absence of a distinct hyoid burst during the swallowing attempt—were also excluded. This retrospective study was approved by the Institutional Review Board of National Taiwan University Hospital (No. 202006027RINC); the requirement for written informed consent was waived because only de-identified data were analyzed, in accordance with institutional regulations and

the Declaration of Helsinki.

Twenty-eight candidates were included in this study, with tumor sites among HNC patients encompassing the oral cavity, oropharynx, nasopharynx, hypopharynx, and larynx. The majority of HNC patients were at stage III–IV. All the HNC patients included had undergone concurrent chemoradiation therapy (CCRT). The mean age and height of the HNC patients in these 2 groups were similar. Demographic data is provided in Table 1.

VFSS study

To conduct standardized VFSS, a remote-controlled fluoroscopy with a frame rate of 30 frames per second was utilized (Ultimax-i DREX-UI80; Canon). Subjects were positioned on a customized chair (VFES chair) with a headrest to controlled the head posture, maintaining a fixed distance to the videotape recorder. The patients maintain an upright posture with their head in a neutral position. Each patient ingested 5 mL of a standardized barium sulfate formula (Baritop LV 300 g in 180 mL water) in each single test, using a spoon in most cases. However, for patients with severely impaired lips or tongue movement, a syringe was used when necessary to ensure safe and effective delivery. The thin, thick and paste barium sulfate consisted of 100 mL of Baritop LV suspension and 1.5, 2, 2.5 g of thickener (neo-high toromeal iii). The viscosities (cP=centipoise=10^{-4} kg·m^{-1}·s^{-1}=10^{-4} Pa·s) were 0.89, 1,700, and 10,500 cPs, respectively.

Measurement

This study utilized the AetherAI platform (provided by AetherAI Corp.) to identify points of interest and record each parameter during swallowing [20]. Two physiatrists (SHC and KCW) identified six anatomic landmarks (Fig. 1) on the platform, including the anterior-inferior corner of the mandible, anterior-inferior corner of the hyoid bone, and anterior-inferior corner of C2 to C5 vertebrae. These landmarks of C spine vertebrae were employed to transform the coordinate system. The new y-axis was defined by the anterior-inferior corner of C3 and C5, while the new x-axis was perpendicular to the new y-axis and across the anterior-inferior corner of C4. The anterior-inferior C4 vertebrae was established as the origin of the new coordinate system. The coordinates of the hyoid bone position in each VFSS time frame were obtained, and these data were converted from pixel to millimeters (mm). In this coordinate system, anterior displacements were coded as negative values on the x-axis (Fig. 1). To adopt the more intuitive convention where positive

Table 1. Demographic data of head and neck cancer patients

Characteristic	Aspiration (n=12)	Non-aspiration (n=16)	p-value
Age (yr)	58.9±9.7	64.2±5.6	0.077
Sex			
Male	10	15	
Female	2	1	
Height (cm)	165.3±6.1	164.5±6.4	0.871
Tumor site			
Oral cavity	3	8	
Oral pharynx	1	0	
Nasopharynx	5	4	
Hypopharynx	2	3	
Larynx	1	1	
Tumor stage			
I–II	2	1	
III–IV	8	14	
Unknown	2	1	
Post-operation			
Yes	5	7	
No	7	9	
Post-radiotherapy time (yr)			
<1	1	6	
≥1	11	10	

Values are presented as mean±standard deviation or number only.
p-value by Mann–Whitney U-test.

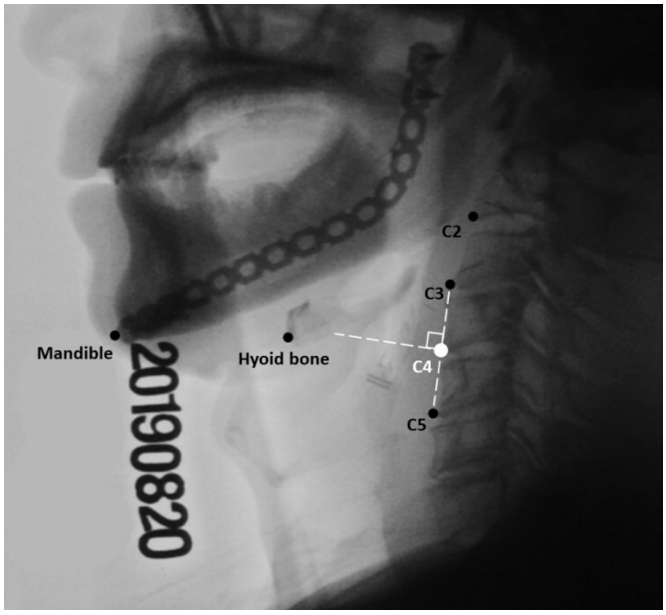

Fig. 1. The points of interests including (1) the anterior-inferior corner of mandible; (2) the anterior-inferior corner of hyoid bone; and (3) the anterior-inferior corner of C2 to C5 vertebrae, were figured out on the AetherAI platform. The landmarks of C spine vertebrae were used for transformation of the coordinate system. The new y-axis was the anterior-inferior corner of C3 and C5, and the new x-axis was perpendicular to the new y-axis and across the anterior-inferior corner of C4. The anterior-inferior C4 vertebrae was defined as the origin of a new coordination system.

values denote anterior motion, we have inverted the sign of horizontal displacement (Dx), so that positive Dx now corresponds to anterior movement, while the vertical displacement (Dy) remains unchanged, with positive values indicating superior motion.

Data processing and statistical analysis

To improve the reliability of signal features such as peak values and timing, displacement signals in both horizontal and vertical directions underwent signal smoothing using a Hilbert–Huang Transform (HHT) based method [24]. First, each displacement signal was decomposed into intrinsic mode functions (IMFs) via empirical mode decomposition. For each IMF combination, the reconstructed signal was smoothed using a third-order Savitzky–Golay (SG) filter with a window size equivalent to one-fifth of the sampling rate (fs=30 Hz), and aligned to the original starting value [25].

To determine the optimal IMF range for reconstruction, a weighted error metric was calculated for each combination, comprising the absolute difference in peak magnitude and the temporal difference of the peak location between the original and the reconstructed signals. The total error was defined as:

$$Total\ error = w_{val} \times |peak_{orig} - peak_{smooth}| + w_{time} \times |time_{orig} - time_{smooth}|$$

The weights for amplitude and timing were fixed at w_{val}=1 and w_{time}=10, in order to preserve the temporal accuracy of peak displacement while avoiding the amplification of physiologically irrelevant minor oscillations. The IMF range yielding the lowest total error was selected for final signal reconstruction.

Instantaneous velocities and accelerations were computed using the central difference method. For each time point, velocity was approximated by the difference between adjacent displacement values divided by twice the time interval, and acceleration was computed by the second-order symmetric difference formula. The time interval was defined as the inverse of the sampling rate (1/30 s). These calculations were applied to both the original and the smoothed displacement signals. For each subject, the maximal values of displacement, velocity, and acceleration along each axis (Dx, Dy, D, Vx, Vy, V, Ax, Ay, A), and the corresponding time points, were extracted from both the original and smoothed signals. The timing of peak values was also normalized as a percentage of total HBE duration. The representative images of the maximal values of these temporal and kinematic parameters before and after smoothing were demonstrated in Fig. 2.

The results were presented as means and standard deviations. The Mann–Whitney U-test was utilized to analyze the difference in each kinematic and temporal parameter between the aspiration group and the non-aspiration group. All processing and statistical analyses were conducted using MATLAB R2024b (MathWorks Inc.). Statistical significance was considered when the p-value was <0.05.

RESULTS

The main results of kinematic and temporal analysis of HBE are presented in Table 2 and Table 3, as well as Fig. 3. The Dx of the hyoid bone was significantly lower in the aspiration group (7.66±6.26 mm) compared with the non-aspiration group (12.14±5.82 mm) (p=0.042 by Mann–Whitney U-test). There was no significant between-group difference in vertical and hypotenuse displacement, instantaneous velocity, and instanta-

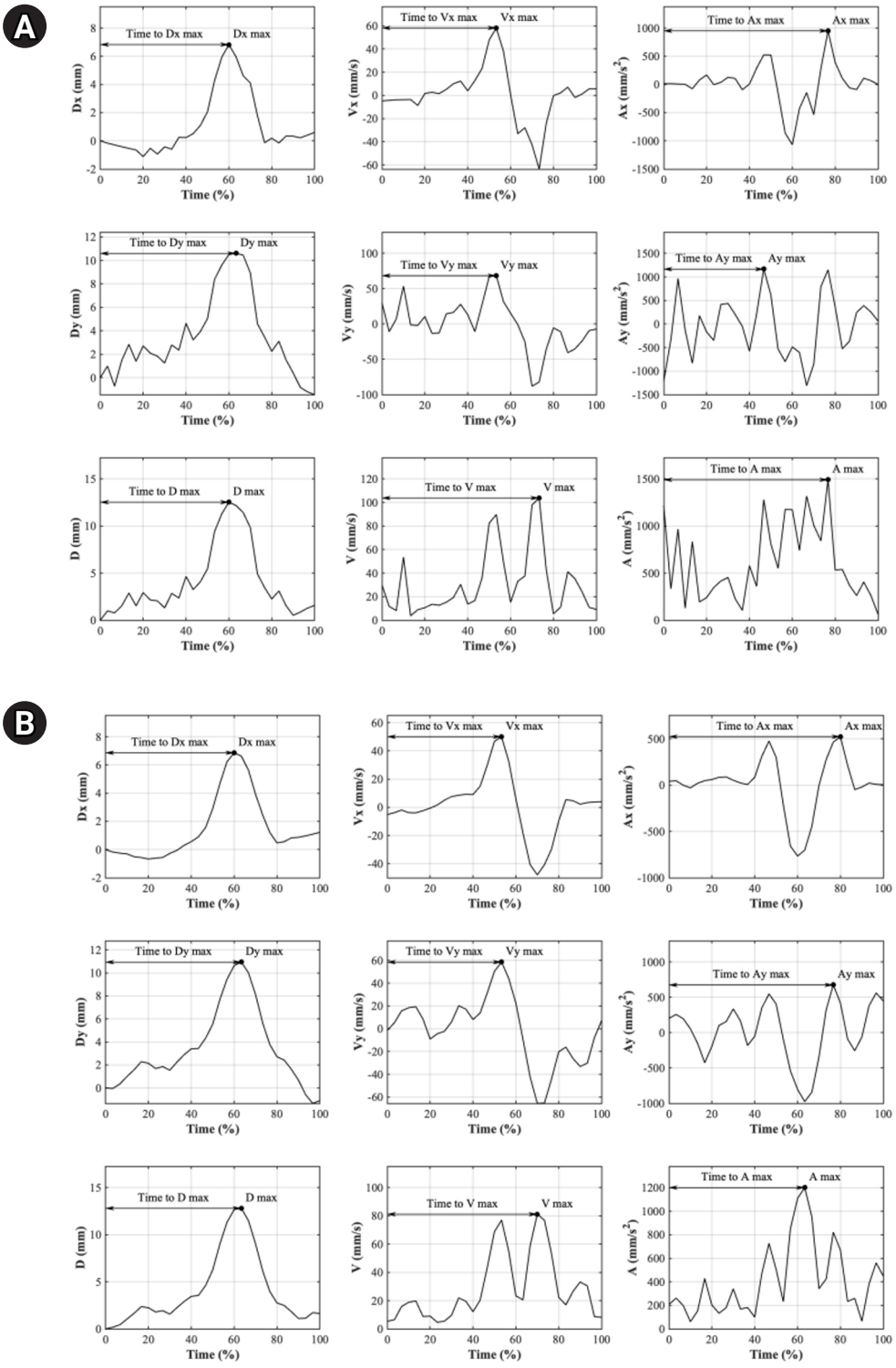

Fig. 2. Representative images of the maximal values of the temporal and kinematic parameters before and after signal smoothing. (A) Before signal smoothing, measurement noise and trajectory irregularities are evident. (B) After signal smoothing, noise is reduced while the amplitude and timing of key features are preserved. Dx max, maximal horizontal displacement; Dy max, maximal vertical displacement; D max, maximal hypotenuse displacement; Vx max, maximal horizontal velocity; Vy max, maximal vertical velocity; V max, maximal hypotenuse velocity; Ax max, maximal horizontal acceleration, Ay max, maximal vertical acceleration; A max, maximal hypotenuses acceleration.

Table 2. Comparison of temporal and kinematic variables between the aspiration and non-aspiration groups using thin liquid barium

Parameter	Aspiration (n=12)	Non-aspiration (n=16)	p-value
Dx max (mm)	7.66±6.26	12.14±5.82	0.042*
Time to Dx max (s)	2.12±1.26	1.19±1.33	0.017*
% Time to Dx max	0.59±0.25	0.48±0.22	0.189
Dy max (mm)	18.97±15.25	15.36±10.25	0.664
Time to Dy max (s)	1.74±1.56	1.02±1.04	0.364
%Time to Dy max	0.46±0.35	0.48±0.22	0.591
D max (mm)	23.54±12.17	19.93±8.16	0.537
Time to D max (s)	1.85±1.47	1.36±1.72	0.192
%Time to D max	0.53±0.35	0.51±0.22	0.864
Vx max (mm/s)	77.45±34.67	100.60±65.00	0.302
Time to Vx max (s)	2.37±1.10	1.09±1.58	0.010*
%Time to Vx max	0.68±0.28	0.37±0.26	0.010*
Vy max (mm/s)	174.89±134.21	122.45±65.77	0.347
Time to Vy max (s)	1.83±2.06	0.86±1.42	0.020*
% Time to Vy max	0.42±0.24	0.34±0.23	0.189
V max (mm/s)	246.30±200.03	158.10±75.11	0.159
Time to V max (s)	2.36±1.96	0.79±1.20	0.006*
% Time to V max	0.60±0.33	0.33±0.24	0.028*
Ax max (mm/s^2)	1,399.16±773.01	1,633.26±909.07	0.568
Time to Ax max (s)	2.22±1.50	0.90±1.26	0.009*
%Time to Ax max	0.60±0.32	0.37±0.29	0.041*
Ay max (mm/s^2)	3,598.07±3,142.75	2,317.94±1,013.76	0.324
Time to Ay max (s)	2.09±1.94	0.83±1.19	0.003*
%Time to Ay max	0.52±0.25	0.36±0.25	0.157
A max (mm/s^2)	4,510.25±4,646.28	2,962.52±1,582.85	0.397
Time to A max (s)	2.49±1.93	0.81±1.24	0.004*
%Time to A max	0.65±0.34	0.34±0.28	0.026*

Values are presented as mean±standard deviation.
Dx max, maximal horizontal displacement; Dy max, maximal vertical displacement; D max, maximal hypotenuse displacement; Vx max, maximal horizontal velocity; Vy max, maximal vertical velocity; V max, maximal hypotenuse velocity; Ax max, maximal horizontal acceleration; Ay max, maximal vertical acceleration; A max, maximal hypotenuse acceleration.
*p<0.05 by Mann–Whitney U-test.

neous acceleration, in both original and smoothed signals.

In the aspiration group, significant temporal differences were observed compared to the non-aspiration group across key temporal parameters. The timing of reaching maximal horizontal velocity was notably delayed in the aspiration group (2.37±1.10 seconds vs. 1.09±1.58 seconds, p=0.010; 0.68±0.28 vs. 0.37±0.26, p=0.010 for percentage of time). Similarly, the timing of reaching maximal vertical instantaneous velocity showed a significant extension (1.83±2.06 seconds vs. 0.86±1.42 seconds, p=0.020), as did the timing of reaching maximal hypotenuse instantaneous velocity (2.36±1.96 seconds vs. 0.79±1.20 seconds, p=0.006; 0.60±0.33 vs. 0.33±0.24, p=0.028 for percentage of time). Furthermore, the timing of reaching maximal horizontal instantaneous acceleration was significantly longer in the aspiration group (2.22±1.50 seconds vs. 0.90±1.26 seconds, p=0.009; 0.60±0.32 vs. 0.37±0.29, p=0.041 for percentage of time). Correspondingly, the timing of reaching maximal vertical instantaneous acceleration was also prolonged in the aspiration group (2.09±1.94 seconds vs. 0.83±1.19 seconds, p=0.003), as did the timing of reaching maximal hypotenuse instantaneous acceleration (2.49±1.93 seconds vs. 0.81±1.24 seconds, p=0.004; 0.65±0.34 vs. 0.34±0.28, p=0.026 for percentage of time).

In the smoothed signal analysis, several statistically significant differences still noted between groups in temporal parameters. The aspiration group exhibited delayed timing in reaching maximal horizontal instantaneous velocity (2.07±1.09 seconds vs. 0.74±1.10 seconds, p=0.004; 0.58±0.29 vs. 0.32±0.24, p=0.017 for percentage of time). Further delays were observed in the timing of reaching maximal horizontal instantaneous acceleration (2.18±1.16 seconds vs. 1.12±1.46 seconds, p=0.008) and in reaching the peak of hypotenuse acceleration (2.21±2.50 seconds vs. 0.81±1.21 seconds, p=0.011). These findings collec-

Table 3. Comparison of temporal and kinematic variables after signal smoothing between the aspiration and non-aspiration groups using thin liquid barium

Parameter	Aspiration (n=12)	Non-aspiration (n=16)	p-value
Dx max (mm)	7.04±5.33	10.79±5.89	0.133
Time to Dx max (s)	2.02±1.37	1.19±1.33	0.054
% Time to Dx max	0.54±0.26	0.48±0.21	0.397
Dy max (mm)	16.56±14.33	14.59±10.16	1.000
Time to Dy max (s)	1.74±1.53	1.25±1.52	0.317
%Time to Dy max	0.46±0.33	0.51±0.24	0.457
D max (mm)	20.17±11.68	18.37±9.29	0.767
Time to D max (s)	1.58±1.55	1.31±1.57	0.591
%Time to D max	0.39±0.28	0.50±0.21	0.133
Vx max (mm/s)	52.88±23.33	72.63±52.11	0.423
Time to Vx max (s)	2.07±1.09	0.74±1.10	0.004*
%Time to Vx max	0.58±0.29	0.32±0.24	0.017*
Vy max (mm/s)	93.11±73.46	82.89±49.48	0.909
Time to Vy max (s)	1.66±2.18	0.79±1.44	0.245
% Time to Vy max	0.38±0.33	0.30±0.24	0.837
V max (mm/s)	119.22±67.29	122.60±64.03	0.873
Time to V max (s)	2.25±2.04	1.26±1.73	0.098
% Time to V max	0.57±0.35	0.45±0.30	0.415
Ax max (mm/s^2)	685.53±294.83	775.24±404.56	0.631
Time to Ax max (s)	2.18±1.16	1.12±1.46	0.008*
%Time to Ax max	0.63±0.25	0.45±0.29	0.146
Ay max (mm/s^2)	1,366.70±1,436.23	1,165.68±661.25	0.767
Time to Ay max (s)	1.97±2.61	1.29±1.60	0.296
%Time to Ay max	0.43±0.28	0.50±0.29	0.423
A max (mm/s^2)	1,644.20±1,341.04	1,585.34±879.55	0.664
Time to A max (s)	2.21±2.50	0.81±1.21	0.011*
%Time to A max	0.54±0.33	0.37±0.27	0.121

Values are presented as mean±standard deviation.
Dx max, maximal horizontal displacement; Dy max, maximal vertical displacement; D max, maximal hypotenuse displacement; Vx max, maximal horizontal velocity; Vy max, maximal vertical velocity; V max, maximal hypotenuse velocity; Ax max, maximal horizontal acceleration; Ay max, maximal vertical acceleration; A max, maximal hypotenuse acceleration.
*p<0.05 by Mann–Whitney U-test.

tively highlight the notable temporal alterations in HBE within the aspiration group.

DISCUSSION

This study investigated the temporal and kinematic parameters of the hyoid burst in HNC patients. Compared with the non-aspiration group, the timings of reaching maximal velocity and acceleration in the horizontal, vertical and hypotenuse axes, were significantly prolonged in the aspiration group. After signal smoothing, these temporal differences remained observable, although statistical significance was attenuated. Consistent with previous studies, the aspiration group of HNC patients had a lower maximal Dx of the HBE. However, there were no significant differences in instantaneous velocity and acceleration between the aspiration group and the non-aspiration group of HNC patients.

To the best of our knowledge, this is the first study to explore temporal HBE kinematics parameters including instantaneous velocity and acceleration in the HNC patients. Additionally, our results demonstrate that it is the timing of reaching maximal velocity and acceleration rather than the maximal values that is associated with aspiration in this patient group. These findings may enhance the current VFSS-based assessment by providing more sensitive and objective indicators of dysphagia risk. Furthermore, they suggest a potential direction for rehabilitation strategies focusing on improving the coordination and timing of swallowing-related muscle activity, in addition to muscle strength. The identification of such temporal features may serve as a basis for developing biofeedback-based training programs,

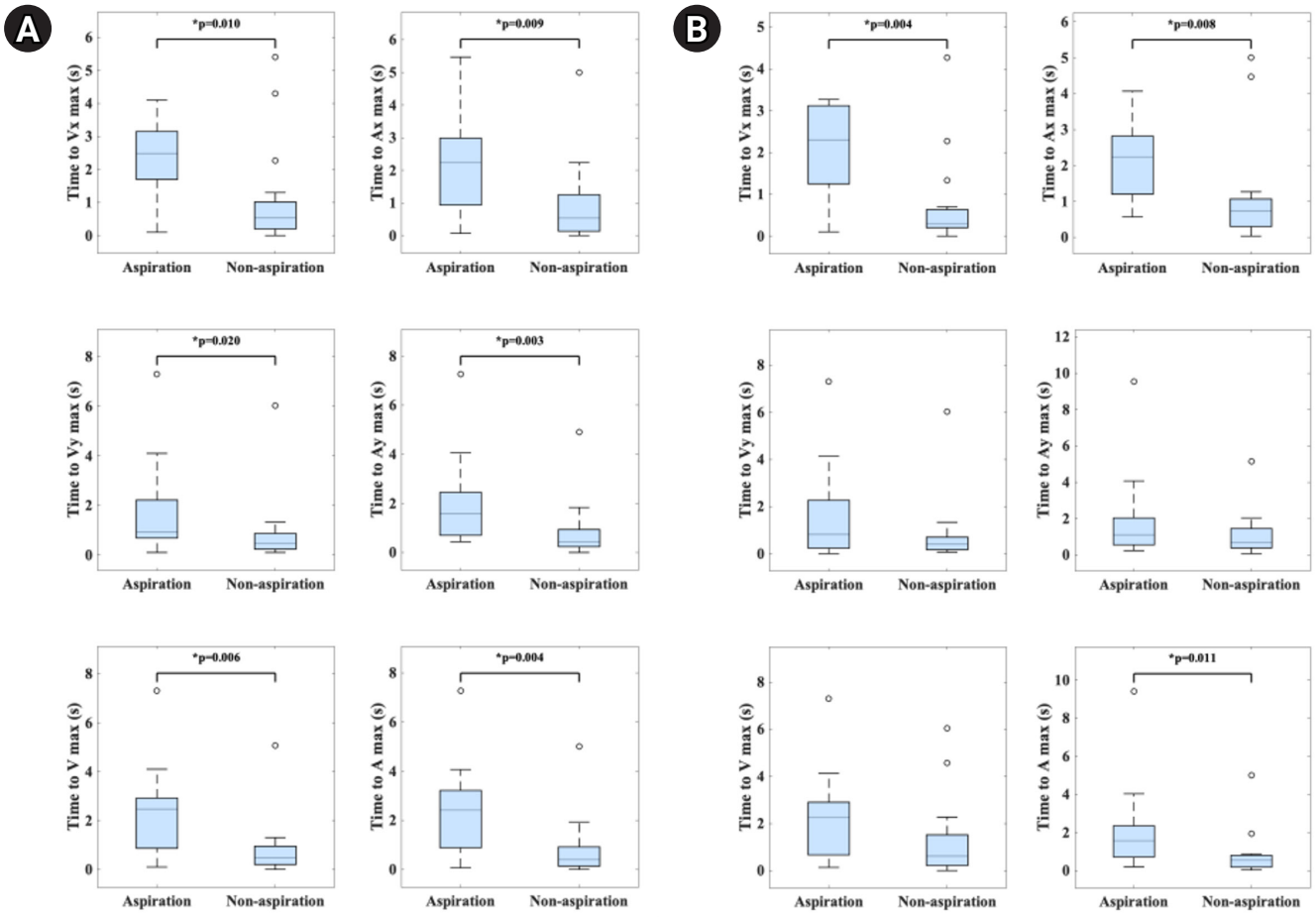

Fig. 3. Timing of reaching maximal values of the kinematic parameters before and after signal smoothing. (A) Before signal smoothing, significant temporal differences are observed between the aspiration and non-aspiration groups. (B) After signal smoothing, significant between-group differences remain, including the timing of reaching maximal horizontal instantaneous velocity, maximal horizontal instantaneous acceleration, and hypotenuse instantaneous acceleration. Vx max, maximal horizontal velocity; Vy max, maximal vertical velocity; V max, maximal hypotenuse velocity; Ax max, maximal horizontal acceleration; Ay max, maximal vertical acceleration; A max, maximal hypotenuses acceleration. *p<0.05 by Mann–Whitney U-test.

aiming to improve the precision and synchrony of swallowing function.

To minimize the influence of measurement noise and reduce trajectory irregularities in hyoid kinematic analysis, we applied signal smoothing to the displacement data. Given that the timing of peak velocity and acceleration is highly susceptible to noise, smoothing may enhance the accuracy of these parameters. In this study, we adopted a combination of HHT and SG filtering for data smoothing while minimizing signal distortion. HHT decomposes non-stationary displacement signals into IMFs, allowing flexible reconstruction. However, smoothing can obscure physiologically relevant peaks. To address this, SG filtering was applied to reduce noise while preserving the amplitude and timing of key features. We further calibrated the IMF range using the peak magnitude and temporal difference of velocity and acceleration, retaining only IMFs that preserved essential kinematic information and avoided noise amplification in derivatives.

In the healthy population, a prior study revealed a statistically significant correlation between the timing of reaching peak hypotenuses velocity of the hyoid bone and the timing of the LVC [18]. Another study conducted in a stroke patient group demonstrated greater disorganization in the temporal events of the pharyngeal phase in the aspiration group [11]. While Kendall et al. [26] found no difference in the time required for reaching maximal elevation between post-radiotherapy HNC

patients and normal subjects, the onset of hyoid bone elevation was delayed in HNC patients. Additionally, the time the hyoid remained elevated was significantly longer in the patient group. Starmer et al. [27] further demonstrated that higher radiation exposure of the geniohyoid muscle may be related to changes in hyoid kinematic parameters, including a prolonged duration to maximum hyoid elevation, in the post-radiotherapy oropharyngeal cancer patients. Chang et al. [28] studied the trend of abnormal VFSS findings in post-irradiated NPC patients. The proportion of incomplete hyoid elevation and delayed swallowing trigger time both increased over time.

The timing of reaching the maximal velocity and acceleration may reflect a timely hyoid burst, requiring a sequenced and balanced contraction of the suprahyoid and infrahyoid muscles. Delayed timing of reaching maximal velocity and acceleration may have a physiological meaning of impaired protective mechanisms during swallowing. This could be a consequence of interrupted anatomic structures in dysphagic HNC patients after receiving treatments, including surgery and radiotherapy. In healthy individuals, coordinated sequential firing of the suprahyoid and infrahyoid muscles results in smooth hyoid excursion [29,30], and the timing of reaching maximal horizontal velocity typically precedes maximal Dx, reflecting a forceful and coordinated hyoid burst during this process. However, HNC treatments, such as surgical resection and radiotherapy, often cause fibrosis and adhesions in the suprahyoid and infrahyoid musculature, as well as in adjacent soft tissues. These post-treatment fibrotic changes not only stiffen the surrounding soft tissues, but also compress peripheral nerve tracts, leading to denervation of the swallowing muscles and consequently reduce the capacity for active contraction and passive extension [31]. Such changes may introduce passive recoil forces that counteract active muscle contraction and disrupt the normal firing sequence between these muscle groups. As a result, the loss of synchrony between the suprahyoid and infrahyoid muscles may generate an oscillatory hyoid motion pattern, delaying the occurrence of maximal horizontal velocity.

In terms of maximal instantaneous velocity and acceleration, we hypothesized these parameters might be altered in the aspiration group. However, the result of the presenting study did not align with our original hypothesis. A previous study conducted in stroke patients revealed that maximal instantaneous velocity in the horizontal and vertical axes showed no significant difference between the no penetration/aspiration group, penetration group, and aspiration group. However, when compared with the healthy control group, the study found that both horizontal and vertical instantaneous velocity were slower in the stroke group [8]. Accordingly, these two kinematic parameters may have less predictive value for aspiration or non-aspiration in the HNC patient groups. Nevertheless, further investigation of these kinematic parameters in HNC patients compared with healthy subjects and its physiological meaning may be needed.

Previous studies have demonstrated that horizontal hyoid bone kinematics, including displacement and velocity, may be a pivotal role in dysphagia, and this observation is consistent across various disease diagnoses. A study conducted by Steele et al. [15] revealed that reduced anterior hyoid bone displacement was associated with higher penetration-aspiration and pharyngeal stasis. Additionally, Zhang et al. [12] found that maximal anterior movement of hyoid bone might serve as a predictor of penetration-aspiration in patients with dysphagia. In specific diseases, the stroke patient group exhibited decreased maximal horizontal velocity compared to healthy controls [8]. Lee et al. [32] observed that the maximal Dx and velocity of forward hyoid motions were significantly reduced in patients with poor prognosis, defined as necessitates tube placement or diet modification at 6 months after the onset of stroke. In patients with Parkinson's disease, maximal Dx and velocity significantly decreased during the initial backward and forward motions compared to elderly controls [33].

Previous studies focusing on hyoid bone kinematics in HNC patients with dysphagia have primarily investigated hyoid bone displacement and overall velocity, emphasizing the importance of the horizontal hyoid bone kinematic in dysphagic HNC patients. Wang et al. [9] found that both overall and forward displacement, as well as the overall movement velocity of the hyoid bone in NPC patients were less than those in healthy controls. Moreover, when comparing the aspiration group with the non-aspiration group of NPC patients, they observed a significantly decrease in overall displacement and movement velocity of the hyoid bone in the aspiration group. Cheng et al. [34] demonstrated a remarkable association between anterior hyoid bone displacement and penetration-aspiration in NPC patients, correlating it with the cross-sectional area of the geniohyoid under ultrasonography. Regarding the vertical movement of the hyoid bone, Ishida et al. [35] concluded that upward displacement of the hyoid bone in swallowing was primarily related to events in the oral cavity, while forward displacement was associated with pharyngeal processes, especially the opening of the upper esophageal sphincter. However, a previous study

did not show a significant difference in the vertical hyoid bone displacement between irradiated NPC patients and a control group, as well as between aspiration and non-aspiration group of irradiated NPC patients [9]. In the present study, horizontal hyoid bone displacement significantly decreased in the aspiration group, aligning with findings from previous studies. HNC treatments, including surgery and radiotherapy, may induce fibrosis and adhesion of structures such as suprahyoid muscles, infrahyoid muscles, and nearby soft tissues. These pathological changes may lead to reduced anterior hyoid bone displacement, potentially resulting in inadequate airway protection and an increased risk of aspiration [9,36].

This study has several limitations. First, the retrospective design may introduce selection bias and limit control over confounding variables, such as radiation dose, tumor locations and stages, or surgical methods. The patient cohort consisted of HNC patients with varying tumor locations and clinical stages, these differences in disease characteristics and treatment exposure may result in heterogeneous swallowing pathophysiology. Nevertheless, all patients underwent CCRT, a primary contributor to dysphagia in this patient population. Second, while we postulated that involvement and coordination of suprahyoid and infrahyoid muscles may influence the temporal and kinematic features of HBE, we did not evaluate the individual muscular contributions using electromyographic or sonographic assessment. Further studies should focus on delineating the relationship between suprahyoid and infrahyoid muscle activities and HBE. Third, the relatively small sample size may reduce the statistical power and limit the generalizability of the findings. In terms of the VFSS study itself, our hospital employs a 5 mL single bolus volume for each test, and the commercial barium contrast agent (Varibar® E-Z-EM, Inc) is not available. Therefore, the bolus size and consistency in our hospital did not adhere to the standard MBSImP protocol. Therefore, future large-scale studies using standardized VFSS protocols are warranted.

Conclusion

This work quantitatively measured hyoid kinematic and temporal parameters, demonstrating that the timings of reaching maximal instantaneous velocities and maximal instantaneous accelerations were significantly prolonged in the VFSS-confirmed aspiration group in HNC patients. Consistent with findings from previous studies, the Dx of HBE during swallowing were significantly lower in the aspiration group. This study provides a more detailed discussion about hyoid kinematics in HNC patients with dysphagia and suggested possible aspects of hyoid temporal and kinematic study for further investigation in the future.

CONFLICTS OF INTEREST

Ming-Yen Hsiao is an 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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AUTHOR CONTRIBUTION

Conceptualization: Cheng SH, Wang TG, Hsiao MY. Data curation: Cheng SH, Wei KC, Wang TG. Methodology: Cheng SH, Hsiao MY. Formal analysis: Cheng SH, Wei KC. Project administration: Wang TG, Hsiao MY. Visualization: Cheng SH. Supervision: Wang TG, Hsiao MY. Writing – original draft: Cheng SH. Writing – review and editing: Wang TG, Hsiao MY. Approval of final manuscript: all authors.

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Evaluation of the Psychometric Properties of the Thai Version of the Cardiac Rehabilitation Barriers Scale

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Objective: To increase participation in cardiac rehabilitation among outpatients with heart disease in Thailand. Factors contributing to low participation are poorly understood. A scale is needed to identify barriers to participation in cardiac rehabilitation. This study aimed to evaluate the psychometric properties of the newly translated Cardiac Rehabilitation Barriers Scale Thai version to justify its use in the Thai population with cardiovascular diseases.

Methods: Psychometric testing was conducted using a cross-sectional survey of 200 outpatients at a Bangkok hospital eligible for the cardiac rehabilitation program from April 2023 to mid-April 2024. Construct validity was evaluated using principal axis factor analysis and first- and second-order confirmatory factor analysis. Cronbach's alpha assessed the scale's internal consistency.

Results: The average age of the total sample was 62.60±12.37 years. Principal axis factoring with Oblimin rotation and Kaiser normalization extracted four components (subscales) that explained 61.8% of the cumulative percentage of variance. These were labeled work and time conflicts, lack of perceived need factors, comorbidities, and logistical barriers. Values for the confirmatory factor analysis goodness of fit indices exceeded recommended minimum thresholds. The internal consistencies for the total scale and the four components were entirely acceptable.

Conclusion: The Cardiac Rehabilitation Barriers Scale Thai version has acceptable psychometric properties for Thai outpatients with cardiovascular diseases. It may be used to identify barriers to participating in cardiac rehabilitation, promote rehabilitation attendance, and improve patient care.

Keywords: Cardiac rehabilitation, Cardiovascular diseases, Factor analysis, Psychometrics, Thailand

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INTRODUCTION

Cardiovascular diseases (CVDs) constitute a principal cause of mortality globally, with an alarming rise in prevalence [1]. In Thailand, coronary artery disease accounts for 11.5% of total deaths [2]. The burden of CVDs is unsparing among the Thai population, diminishing the quality of life and straining the healthcare system and national budget.

Cardiac rehabilitation (CR) is recognized as a multidisciplinary intervention and is recommended in evidence-based clinical guidelines as a secondary prevention strategy for individuals diagnosed with CVDs [3]. Effective CR aims to restore

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optimal cardiac function, reduce morbidity and mortality associated with cardiac conditions, enhance psychosocial well-being, and improve overall quality of life [4,5]. Organizations, such as the European Society of Cardiology [6], the American Heart Association [7], and the American College of Cardiology [8], advocate for the implementation of CR in treatment protocols, underscoring its efficacy in managing CVDs.

Despite substantial evidence supporting CR, participation rates in CR programs remain suboptimal [6]. Various factors at the individual, provider, and health system levels influence the uptake and adherence to CR [9]. However, the specific factors affecting participation among Thai individuals with CVDs are less understood. To improve the uptake and accessibility of CR in Thailand, a valid instrument to identify and measure potential barriers to CR would enhance understanding of the unique challenges encountered by Thai individuals with CVDs. The Cardiac Rehabilitation Barriers Scale (CRBS), developed in Canada and recently revised [10], has been translated into Thai and demonstrates promise in identifying barriers to CR for the Thai population. This follow-up study after translation into Thai aimed to assess the scale's construct validity and internal consistency among Thai individuals diagnosed with CVD.

METHODS

Study design

The study was conducted in two stages. The initial phase involved translating the Cardiac Rehabilitation Barriers Scale Thai version (CRBS-T) (Supplementary Material S1), with results reported elsewhere [11]. This report focuses on the second phase, which examines the psychometric properties of the new CRBS-T to ascertain its construct validity and internal consistency.

Setting and sample

The participant pool was outpatients from the medical-surgical clinics and cardiac rehabilitation center at a large university-based tertiary care hospital in Bangkok, Thailand. These individuals were referred to the cardiac rehabilitation program because of their medical conditions, such as acute coronary syndrome, revascularization, and heart failure [12]. Programs are tailored to address individual rehabilitation needs. Inclusion criteria required participants to be aged 18 or older, able to read Thai on a self-administered survey, and willing to participate in the study. Exclusion criteria included outpatients documented by healthcare providers as having cognitive impairments or limited physical abilities from strokes or other impairments. The recruitment employed a convenience sampling method.

Based on an expected effect size of 0.20, a statistical power of 80%, 21 observable variables, four latent variables, and a significance level of 0.05, the required sample size was determined to range from 116 to 342 participants [13]. Consequently, the total sample size of 200 participants was deemed adequate for conducting factor analysis.

Instruments

A sociodemographic questionnaire collected data on participants' age, sex, ethnicity, education, marital status, employment status, monthly family income, religion, health insurance, cardiac rehabilitation costs, distance to the cardiac rehabilitation center, and use of CR services.

Originally developed in English by Shanmugasegaram et al. [14], the CRBS is a widely used 21-item tool designed to assess the barriers to enrollment and participation in CR programs, spanning from the individual to the health system level [15,16]. The original CRBS consists of four subscales: perceived need for CR/healthcare factors (nine items), logistical factors (five items), work schedule/time conflicts (three items), and comorbidities/functional status (four items) [14]. Participants indicate their level of agreement on a 5-point Likert scale (1=strongly disagree to 5=Strongly agree), with higher scores reflecting more barriers to accessing the CR program. In 2024, the original CRBS was revised (CRBS-R) to enhance its applicability to hybrid CR across diverse settings [10].

The CRBS has been translated into at least 18 languages [17], with specific translations and validations conducted in Brazilian Portuguese [18], Korean [19], Turkish [20], Malay [21], Czech [22], Persian [23], Mandarin/Simplified Chinese [24], Greek [25], and Arabic [26]. The first translation of CRBS-T underwent cross-cultural validation [11], but its psychometric properties were not assessed until the current stage of this study.

Data collection

Data collection for this study occurred between April 2023 and mid-April 2024. Study participants were returning to the hospital's outpatient clinics for follow-up care. The participants completed self-administered survey questionnaires after their appointments at either the medical-surgical clinics or the cardiac rehabilitation center.

Data analysis and psychometric testing

Data preparation

During data preparation, critical checks were conducted to ensure the dataset integrity, including the examination for data entry errors, missing data, and extreme outliers. Frequencies, percentages, patterns, and item distributions were calculated to analyze participant characteristics. Statistical analyses were conducted using IBM SPSS ver. 23 (IBM Corp.) and Mplus, ver. 7.1 (Scientific Software International).

Analysis confirmed that all surveys were complete, with no missing data. However, among the 248 participants, 48 individuals (19.35%) were identified as extreme outliers and were excluded from the factor analysis. Consequently, 200 participants were retained for both factor analysis and reliability analysis. The measurement properties of the instruments were assessed based on the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) taxonomy and guidelines [27].

Structural validity

Several statistical techniques were used to evaluate the instrument's construct validity, including principal axis factor analysis (PAF) and first- and second-order confirmatory factor analysis (CFA). PAF was conducted to identify items related to each factor and to assess the alignment of the CRBS-T factors with the original English CRBS. Following PAF, CFA was performed to confirm the identified factors (subscales) and elucidate the relationships between them.

The suitability for conducting PAF was determined through the Kaiser-Meyer-Olkin (KMO) test for sampling adequacy, Bartlett's sphericity test for correlation matrix adequacy, and the determinant for assessing heterogeneity and matrix singularity. PAF analysis was used to examine the factor structure, employing Oblimin rotation with Kaiser normalization. Factors were selected based on eigenvalues greater than 1.0 [28] and factor loadings of at least 0.40 [29]. The scree plot was analyzed to identify the "elbow" point where the eigenvalues leveled off. Items loading on multiple factors were interpreted according to the highest loading [30]. The internal consistency of the identified factors was assessed using Cronbach's alpha, with coefficients at least 0.70 considered satisfactory. The significance level for all statistical tests was set at 0.05.

First-order CFA assessed the theoretical model identified through PAF to further explore construct validity by comparing it with the actual data. A simple factor structure was posited, indicating that each item could measure only one factor. The correlation structure of the data was tested against a hypothesized structure using goodness of fit indices. Second-order CFA assessed factor loadings applying a standard threshold of at least 0.70 for adequate loadings and evaluating the model's fit indices. Model fit was deemed acceptable if the comparative fit index and Tucker–Lewis index were both ≥0.90, and the root mean square error of approximation was ≤0.08 [31,32]. Each factor exhibited factor loadings of at least 0.70 and fit indices meeting or exceeding acceptable thresholds.

Mann–Whitney U-tests were performed to assess the criterion validity of the CRBS-T, examining differences in mean scores between participants who attended CR programs and those who did not. The internal consistency of the CRBS-T was assessed to determine the degree of interrelatedness among the measurement items [27]. Cronbach's alpha was used to assess the CRBS-T scale's internal consistency [33], with values of at least 0.70 indicating sufficient internal consistency [34].

Ethical considerations

The study protocol received approval from the human research ethics committees of Faculty of Medicine Ramathibodi Hospital (COA.MURA2023/313). Ethical considerations, aligned with the principles outlined in the Helsinki Declaration, were prioritized throughout the research process. All participants gave written informed consent to participate in the study. Permission to use the CRBS was obtained from Shanmugasegaram et al. [14].

RESULTS

Characteristics of the participants

The sample consisted of 200 participants with a mean age of 62.60±12.37 years, range: 18–90 years) (Table 1). The demographic composition predominantly included Buddhist Thai males who were married, unemployed or retired, and reported a family income of at least 20,000 Thai baht (approximately US $600, contingent upon current exchange rates). Nearly half of the participants had a tertiary education. Over 80% were covered by Thailand's universal health plan or were civil servants benefiting from medical benefits. Over three-fourths attended CR, although two-thirds resided at least 30 km from the nearest CR center. Financial implications varied, with approximately one-third positioned at either the lower or upper extremes of the cost range for individual CR sessions. Despite the geograph-

Table 1. Sociodemographic characteristics of participants

Characteristic	Value (N=200)
Age(yr)	
<60	65 (32.5)
60–69	87 (43.5)
≥70	48 (24.0)
Sex	
Male	133 (66.5)
Female	67 (33.5)
Ethnicity	
Thai	196 (98.0)
Thai Chinese heritage	4 (2.0)
Educational level (yr)	
<6	36 (18.0)
6–12	24 (12.0)
Tertiary or more than 12	140 (70.0)
Marital status	
Married	147 (73.5)
Single, separated, divorced, and widowed	53 (26.5)
Employment status	
Employed	78 (39.0)
Unemployed or retired	122 (61.0)
Family income a month (Thai baht)	
<10,000	22 (11.0)
10,000–20,000	30 (15.0)
>20,000	148 (74.0)
Religion	
Buddhist	186 (93.0)
Muslim	9 (4.5)
Christian	5 (2.5)
Health insurance	
Universal health coverage	59 (29.5)
Civil servant medical benefits	105 (52.5)
Social security	12 (6.0)
Private insurance	9 (4.5)
Voluntary payment	15 (7.5)
CR cost per session (Thai baht)	
<1,000	70 (35.0)
1,000–2,000	55 (27.5)
>2,000	75 (37.5)
Distance from home to CR (km)	
<30	64 (32.0)
≥30	136 (68.0)
CR attendance	
Attendance	154 (77.0)
Not attendance	46 (23.0)

Values are presented as number (%).
CR=cardiac rehabilitation.

ical and financial barriers, the majority of participants attended CR.

Spearman's rank correlation showed two significant demographic variables with weak relationships to CR attendance. Health insurance was positively related (rs=0.15, p=0.03), while the method of transportation was negatively related (rs=-0.20, p<0.01).

Construct validity

The scale's structure was initially evaluated through PAF. The KMO yielded a value of .910, indicating that the sample size was appropriate for factor analysis. Furthermore, Bartlett's test produced a significant result of 2,243.744 (p<0.05), suggesting robust correlations among variables. From PAF, the components with eigenvalues greater than 1.00 were extracted, revealing four components with eigenvalues ranging from 1.005 to 8.683, collectively accounting for 61.8% of the total variance (Table 2). The scree plot's elbow appears to break at Factor 3, but the fourth eigenvalue is slightly above 1.0 (Fig. 1).

Factor loadings represent the degree of correspondence between each variable and the underlying factor, reflecting the correlation of each item with the respective component. Loadings with values of at least .40 indicate a more substantial representation of variables within the factor [35]. Table 2 displays the factor structure of the CRBS-T, presenting item loadings associated with each component.

The first- and second-order CFA results of CRBS-T revealed factor loadings of four components, ranging from .669 to .939 (Fig. 2). The CFA goodness of fit indices met or exceeded the recommended values [31]. Results of second-order CFA were used for the final interpretation of factors as subscales.

Internal consistency

The CRBS-T demonstrated a Cronbach's alpha of .927, indicating acceptable internal consistency. Each scale component exhibited strong internal consistency, with alpha values ranging from .815 to .878. The component related to work and time conflicts showed the lowest alpha value of .815, whereas the logistical barriers component achieved the highest alpha value of .878 (Table 2).

Criterion validity

Criterion validity was assessed by comparing the total and subscale CRBS-T scores between participants who attended CR programs and those who did not. The results revealed that total scores were significantly higher among non-attendees, indicating they experienced more barriers to CR participation. Mean scores across the four components—lack of perceived need, logistical aspects, comorbidities, and work and time conflicts—

Table 2. Principle axis factor analysis with Oblimin rotation and Kaiser normalization, percentages of variance, factor eigenvalues, and internal reliabilities of the CRBS-T (N=200)

Scale item	Components (subscales) and factor oadings			
	F1	F2	F3	F4
1. I do not need cardiac rehabilitation	.557			
2. I can manage on my own	.585			
3. My doctor did not feel it was necessary	.537			
4. Many people with heart problems do not go to cardiac rehabilitation and they are fine	.734			
5. I prefer to take care of my health alone	.475			
6. I already exercise at home or in my community	.604			
7. I did not know about cardiac rehabilitation	.577			
8. I think I was referred but the rehab program did not contact me	.634			
9. It took too long to get referred and into the program	.487			
10. Cost		.823		
11. Transportation problems		.859		
12. Distance		.767		
13. Family responsibilities		.758		
14. Severe weather		.639		
15. I don't have the energy			.868	
16. I find exercise tiring or painful			.711	
17. Other health problems prevent me from going			.626	
18. I am too old			.754	
19. Work responsibilities				.782
20. Time constraints				.908
21. Travel				.619
Initial eigenvalues[a]				
Eigenvalue	8.683	2.061	1.218	1.005
Variance explained (%)	41.348	9.814	5.799	4.787
Total variance explained 61.8%				
Cronbach's alpha coefficients of the subscales[b]	.831	.878	.828	.815
Cronbach's alpha coefficient: total CRBS-T=.927				

CRBS-T, Cardiac Rehabilitation Barriers Scale Thai version. F1, lack of perceived need factors; F2, logistical barriers; F3, comorbidities; F4, work and time conflicts.
[a]Extraction method: principal axis factoring.
[b]Internal reliability method.

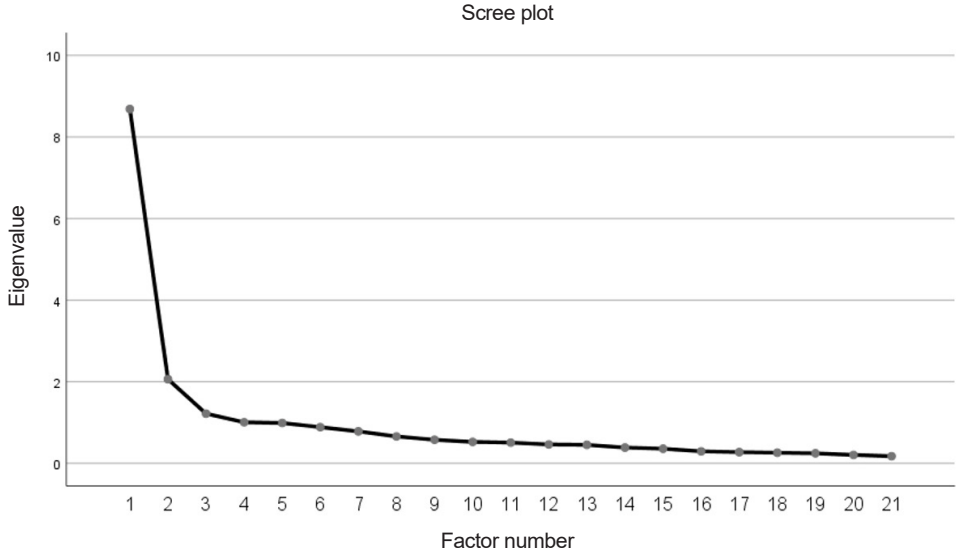
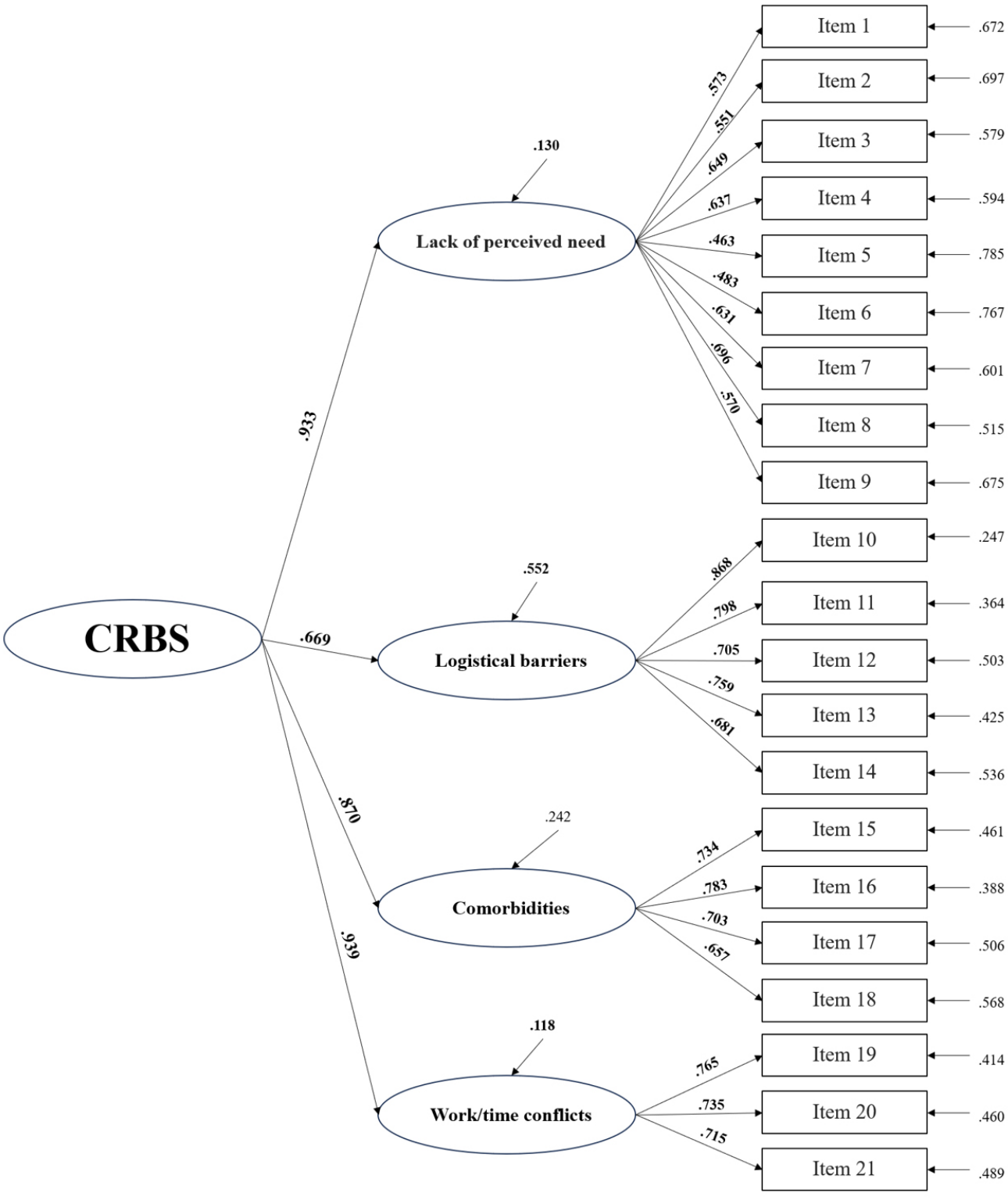


Fig. 1. Scree plot from principal axis factor analysis of the Cardiac Rehabilitation Barriers Scale Thai version.



χ^2 (df = 174, N = 200) = 265.67, p = .000, χ^2/df = 1.57, CFI = .937, TLI = .924, $RMSEA$ = .051, $SRMR$ = .065

Fig. 2. Second-order confirmatory factor analysis of the Cardiac Rehabilitation Barriers Scale (CRBS) Thai version.

were significantly higher among non-attendees than attendees (Table 3).

Table 3 shows the mean item, total, and CRBS-T factor scores. The most frequently reported barriers to participation were related to prior exercise. Other common barriers included distance, transportation difficulties, cost, and family responsibilities. Among these factors, logistical barriers emerged as the most critical impediments to CR uptake.

DISCUSSION

This study reports the psychometric properties of the newly translated CRBS-T. Results indicate that the scale's construct validity and internal consistency are satisfactory for identifying and measuring potential barriers to CR among Thai people with CVDs.

The translated CRBS-T retains the 21 items and a four-component structure consistent with the original English version and most other translations [14,17,18]. We opted to retain the fourth component, notwithstanding its marginally low eigenvalue, preserving the original scale structure based on statistical and theoretical considerations. The four components are work and time conflicts, the lack of perceived factors, comorbidities, and logistical barriers. Although strong similarities exist with the English scale, the CRBS-T's overall internal consistency, ordering/sequencing of the four components, and item loadings differ from the original [14]. This may be attributed to cross-cultural variability and variations between healthcare sys-

Table 3. Comparisons of the CRBS-T mean scores by cardiac rehabilitation participation status for four components and individual items (N=200)

CRBS-T components (subscales) and their respective items		Total (N=200)	CR attendees (n=154)	CR non-attendees (n=46)	Mann–Whitney U (Z)	p-value[a]
Lack of perceived need		2.36±0.72	2.29±0.69	2.62±0.74	-2.82	<0.01
Item 1	I do not need cardiac rehabilitation	2.07±1.00	1.98±0.99	2.37±0.97	-2.59	0.01
Item 2	I can manage on my own	2.02±1.02	2.00±1.04	2.07±0.98	-0.63	0.53
Item 3	My doctor did not feel it was necessary	2.54±1.15	2.46±1.13	2.83±1.18	-1.81	0.07
Item 4	Many people with heart problems do not go to cardiac rehabilitation and they are fine	2.06±1.00	2.03±1.03	2.17±0.90	-1.23	0.22
Item 5	I prefer to take care of my health alone	2.18±1.12	2.15±1.11	2.26±1.16	-0.55	0.58
Item 6	I already exercise at home or in my community	3.18±1.23	3.15±1.23	3.30±1.25	-0.80	0.42
Item 7	I did not know about cardiac rehabilitation	2.39±1.23	2.26±1.19	2.83±1.29	-2.69	<0.01
Item 8	I think I was referred but the rehab program did not contact me	2.37±1.10	2.26±1.02	2.74±1.29	-2.22	0.03
Item 9	It took too long to get referred and into the program	2.61±1.23	2.55±1.22	2.83±1.25	-1.37	0.17
Logistical barriers		2.78±0.99	2.67±0.94	3.14±1.08	-2.96	<0.01
Item 10	Cost	2.83±1.20	2.69±1.16	3.28±1.22	-2.92	<0.01
Item 11	Transportation problems	2.93±1.23	2.85±1.20	3.22±1.28	-1.83	0.07
Item 12	Distance	3.06±1.23	2.97±1.25	3.35±1.34	-1.83	0.07
Item 13	Family responsibilities	2.77±1.22	2.63±1.17	3.24±1.29	-2.87	<0.01
Item 14	Severe weather	2.32±1.05	2.23±0.98	2.61±1.20	-1.81	0.07
Comorbidities		2.14±0.88	2.07±0.86	2.38±0.91	2.14	0.03
Item 15	I don't have the energy	2.10±1.05	2.01±1.02	2.37±1.12	-2.00	0.04
Item 16	I find exercise tiring or painful	2.12±1.05	2.05±1.03	2.37±1.06	-2.04	0.04
Item 17	Other health problems prevent me from going	2.20±1.08	2.12±1.06	2.43±1.13	-1.68	0.09
Item 18	I am too old	2.15±1.09	2.09±1.09	2.33±1.10	-1.39	0.17
Work/time conflicts		1.90±0.82	1.85±0.83	2.12±0.75	-2.40	0.02
Item 19	Work responsibilities	1.88±0.92	1.81±0.89	2.13±0.98	-2.17	0.03
Item 20	Time constraints	1.92±0.92	1.85±0.94	2.15±0.82	-2.52	0.01
Item 21	Travel	1.93±0.99	1.88±1.04	2.07±0.83	-1.86	0.06

Values are presented as mean±standard deviation.
CRBS-T, Cardiac Rehabilitation Barriers Scale Thai version; CR, cardiac rehabilitation.
[a]Mann–Whitney U-test.

tems in Canada and Thailand, and local socio-cultural differences among Thai outpatients. The same reasons may account for differences between the CRBS-T and versions from Korea, Malaysia, and China [19,21,24,36].

Most validations of the translated CRBS scale, including those in Arabic [26] Czech [22], Greek [25], Malay [21], and Persian [23] retain the four components. However, the Brazilian Portuguese [18], Mandarin/Simplified Chinese versions [24], and Turkish [20], and identified five factors, while the Korean version identified six factors [19]. The four factors derived yielded from our analyses closely align with those identified in other translated CRBS versions, strengthening the scale's validity of the factor structure. The CRBS-T exhibited acceptable internal consistency, with Cronbach's alpha values consistent with or exceeding those reported in various translations, including the Czech (α=0.77), Greek (α=0.70), Korean (α=0.65–0.83), Malay (α=0.82), and Mandarin (α=0.67–0.82) versions.

The criterion validity of the scale is evidenced by the higher mean CRBS-T scores of outpatients who did not attend CR compared to those who did. However, it should be acknowledged that the number of non-attendees was disproportionately smaller than attendees. Recent studies indicate that CR non-attendees report significantly more perceived barriers across four domains: lack of awareness, logistic challenges, personal health limitations, and work/time conflicts [37]. Although CR programs are increasingly available in Thailand, the claim of not needing CR may stem from limited public awareness. Patients often report a lack of knowledge about CR and insufficient communication from CR staff, leading to gaps in patient education.

Logistical concerns, including cost and family responsibilities, mirror findings in other countries [38]. Despite Thailand's universal health insurance covering CR sessions [39], out-of-pocket and indirect costs, such as transportation, remain substantial barriers to participation. Physical limitations, such as fatigue or pain, underscore the necessity for tailored CR programs to accommodate patients with multiple comorbidities and limited physical function. Work-related barriers, especially for working-age adults, highlight the need for more flexible CR delivery models, such as telerehabilitation options.

The factor structure from the second-order CFA indicates that the work and time conflicts subscale had the highest variance percentage. This perceived barrier may stem from the nature of the CR program in Bangkok, where outpatients can access the services only on weekdays. The lack of weekend options may prevent some outpatients from attending. This situation may differ from where the original English, Korean [19], Malay [21], and Mandarin [24] versions were developed.

The subscale addressing the lack of perceived need ranked second in variance. The majority of the Bangkok hospital outpatients were post-cardiac surgery, predominantly coronary artery bypass grafting, who may have perceived little or no need for CR after successful surgical outcomes [40]. They may also not have received professional encouragement from some healthcare providers to attend CR for similar reasons or because Thailand's CR referral system is less implemented.

The subscale addressing comorbidity/health status of outpatients ranked third in variance. Outpatients who may wish to attend CR may be hesitant or prevented from doing so due to their health conditions. For those whose physical conditions suggest they would benefit from CR, further health assessments and emotional support from healthcare professionals may be necessary.

The subscale addressing the logistical factors subscale had the lowest variance percentage. This ranking diverges from the original English version [14,15]. CR in Thailand is still developing and requires more outpatient referrals; however, there are insufficient CR centers nationwide to meet demand. Travel distances from home to the CR center present significant transportation problems for Thai individuals with CVDs [11]. To address these issues, new CR delivery models, such as home-based CR or hybrid CR, warrant consideration, using various approaches, including telemedicine [10].

In response to a shift towards hybrid delivery in CR, the originator of the CRBS published a revised version in 2024, known as CRBS-R. Should Thailand adopt a hybrid service model, efforts should be initiated to validate a Thai adaptation of the CRSB-R to ensure its effectiveness and relevance in the local context.

Limitation

A convenience sample from one university-based tertiary care hospital in Thailand's largest city may inhibit generalizability to other regions which may possess different infrastructural characteristics. Over 19% of the original sample was excluded because data did not meet statistical test assumptions, raising concerns about potential selection bias, as also might the over-representation of males in the sample. Differences in sociodemographic characteristics existed between CR attendees and non-attendees. While responses may also have varied between

participants with acute coronary syndrome and chronic heart failure, these distinctions were not analyzed separately.

Future use of the CRBS-T in other regions in Thailand, including among rural populations with different CR programs should further examine the scale's psychometric properties. Notably, this study was conducted before the latest revision of the CRBS; therefore, future translated studies should incorporate items addressing technology and hybrid CR models to mitigate the barriers to participation [10].

Conclusions

The CRBS-T demonstrates satisfactory psychometric properties for identifying and measuring potential barriers to cardiac rehabilitation among Thai people with CVDs. Future clinical research may use this scale to suggest targeted interventions aimed at increasing CR program attendance. By fostering attendance, individuals with CVDs are more likely to strengthen their cardiac functioning, well-being, and quality of life.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

Conceptualization: Kotcharoen R, Payngulume K. Methodology: Kotcharoen R, Payngulume K. Formal analysis: Kotcharoen R, Payngulume K, Chintapanyakun T. Funding acquisition: Kotcharoen R, Payngulume K. Project administration: Kotcharoen R, Payngulume K. Visualization: Kotcharoen R, Payngulume K. Writing – original draft: Kotcharoen R, Payngulume K. Writing – review and editing: Kotcharoen R, Payngulume K. Approval of final manuscript: all authors.

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SUPPLEMENTARY MATERIALS

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Corrigendum

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Annals of Rehabilitation Medicine

Correction: The Effects of Inspiratory Muscle Training in Individuals With Cervical Spinal Cord Injuries: A Systematic Review and Meta-Analysis

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In Table 1 of this article, the term "VC" in Sikka et al.'s outcome measures should be revised to "SVC (slow vital capacity)." The Table 1 should be corrected as follows:

We sincerely apologize for any confusions that we may have caused.

Table 1. Features of the trials included

Reference	Sex (M/F)	Sample size (T/C)	Stage of injury	Level of injury	Training protocol	Control	Intervention duration (wk)	Outcome measures
Liaw et al., 2000 [39]	16/4	10/10	Acute, sub-acute	C4–C7	Training commenced with the lowest level of inspiratory resistance (blue, 7 mm). Duration: 15–20 minutes, twice a day, 7 days/wk	Usual care	6	MIP, MEP, VC, FVC, FEV1
Mueller et al., 2013 [38]	12/4	8/8	Sub-acute, chronic	C5–C8	80% MIP, 90 repetitions for 10 minutes session, 4 days/wk	Placebo	8	MIP, MEP, VC, FEV1, QoL (SF-12)
West et al., 2014 [13]	9/1	5/5	Chronic	C5–C7	60% MIP, 30 repetitions each session, twice a day, 5 days/wk	Placebo	6	MIP, MEP, FVC, FEV1
Boswell-Ruys et al., 2020 [10]	57/3	29/31	Acute, sub-acute, chronic	C4–C7	80% MIP, 3–5 sets of 12 breaths with a rest period of 2 minutes, twice daily, for 5 days a week	Sham intervention	6	MIP, MEP, VC, FVC, FEV1, QoL (SF-36)
Sikka et al., 2021 [37]	72/24	48/48	Acute	C4–C7	70% MIP, 6 sets of 12 repetitions each session, twice a day, 5 days/wk	Conventional intervention	4	MIP, MEP, SVC, FVC, FEV1

M/F, male/female; T/C, treatment/control; MIP, maximal inspiratory pressure; MEP, maximal expiratory pressure; VC, vital capacity; FVC, forced vital capacity; FEV1, forced expiratory volume in 1 second; QoL, quality of life; SF-12, Short Form 12 Health Survey; SF-36, 36-Item Short Form Survey; SVC, slow vital capacity.

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Annals of Rehabilitation Medicine

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

Authors who used AI technology to conduct their study should describe its use in the Methods section with sufficient detail to enable replication of the approach. This should include the name of the tool, version number, and the prompts used, where applicable.

(4) Results

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

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

(5) Discussion

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

(6) Conflicts of interest

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

(7) Funding information

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

(8) Author contribution

The individual contributions of the authors to the manuscript should be specified in this section. Each author's contribution must be clearly described using the CRediT (Contributor Roles Taxonomy) system. To qualify for authorship, individuals must have participated in at least one of the core 12 CRediT roles (e.g., conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization) and at least one of the writing contributions (preparation of the original draft and/or critical review and revision of the manuscript). These contributions will be published in the final article, and all authors must review and approve their statements before submission.

(9) Acknowledgments

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

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- Journal names should be abbreviated according to the format listed in the Index Medicus. If the journal is not listed in the Index Medicus, refer to the list of title word abbreviations by the ISSN network (http://www.issn.org/2-22660-LTWA.php).
- For more on references, refer to the NLM Style Guide for Authors, Editors, and Publishers (http://www.nlm.nih.gov/citingmedicine).

Journals

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

Book & Chapter of book

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

Proceedings of academic conference

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

Thesis (Dissertation)

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

(11) Tables

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

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Annals of Rehabilitation Medicine

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

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

☐ The text is consecutively line numbered.

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

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

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

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

References

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

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

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