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Swallowing Disturbance Questionnaire: Clinimetrics and Global Validation

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The Swallowing Disturbance Questionnaire (SDQ) is a widely used tool for screening dysphagia in patients with Parkinson's disease (PD) [1]. Dysphagia, or swallowing difficulty, is a frequent problem in PD that can lead to serious consequences, such as malnutrition and aspiration pneumonia [2]. The SDQ is a quick and easy method for identifying patients at risk for dysphagia and referring them for further evaluation and treatment. It can be completed in just a few minutes, and no special skills or equipment are needed. This makes it easy to use in many different settings, including hospitals, nursing homes, and outpatient clinics.

The SDQ is a self-report questionnaire comprising 15 items that assess various aspects of swallowing function, including the ability to chew and swallow different types of food and liquids, the presence of coughing or choking during meals, and difficulty in breathing. Each item is scored on a 4-point scale, with higher scores indicating more frequent symptom experience, except the last question about the history of respiratory infection (yes/no).

The SDQ was originally developed and validated in 57 patients with PD in 2007 [1]. The Cronbach's alpha coefficient was reported as being 0.89. The presence of dysphagia was defined as any abnormal finding in clinical examination by dysphagia specialists or penetration/aspiration in the fiberoptic endoscopic evaluation of swallowing (FEES). The optimal cutoff value for detecting dysphagia was 11, with sensitivity of 80.5% and specificity of 81.3%.

The SDQ has been translated and adapted into several other languages, including Japanese, Persian, Korean, and Portuguese (Table 1). The Japanese version demonstrated Cronbach's alpha coefficient of 0.84, sensitivity of 77.8%, and specificity of 84.6% to detect patients with aspiration in the videofluoroscopic swallowing study (VFSS) [3]. In the Persian version, Cronbach's alpha coefficient was reported as 0.86, and sensitivity and specificity were 96.7% and 91.2%, respectively, for detecting aspiration during VFSS [4]. In the Korean version, Cronbach's alpha coefficient was 0.85, and sensitivity and specificity were 72.7% and 96.2%, respectively, for detecting aspiration during VFSS [5]. In the Portuguese version, Cronbach's alpha was 0.95, and an area under the receiver operating characteristics curve was 0.70 for detecting chewing and swallowing problems on the Movement Disorder Society-Unified Parkinson's Disease Rating Scale item 2.3, without reporting sensitivity and specificity [6].

The SDQ has also been applied as a dysphagia screening test for diseases other than PD. When applied to patients with dysphagia caused by various conditions, including neurologic disorders, head and neck tumors, and gastrointestinal diseases, it showed a sensitivity of 79.7%

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Table 1. Clinimetrics of the original and translated versions of the Swallowing Disturbance Questionnaire

Author	Year	Language	Cronbach's alpha	Sensitivity (%)	Specificity (%)	AUC
Manor et al. [1]	2007	English	0.89	80.5	81.3	NA
Yamamoto et al. [3]	2012	Japanese	0.84	77.8	84.6	NA
Rajaei et al. [4]	2014	Persian	0.86	96.7	91.2	NA
Lee et al. [5]	2016	Korean	0.85	72.7	96.2	NA
Cardoso et al. [6]	2021	Portuguese	0.95	NA	NA	0.70

AUC, area under the curve; NA, not available.

and a specificity of 73% for the detection of oromotor abnormalities on physical examination and pharyngeal abnormalities on FEES [7]. Although the accuracy was lower than PD, it suggests that the SDQ can be used as a screening tool for dysphagia caused by various diseases. Recently, the usefulness of the SDQ was evaluated in patients with multiple system atrophy (MSA), one of the atypical parkinsonism [8]. However, the sensitivity to detect dysphagia confirmed by FEES was only 54%. The authors constructed the MSA-SDQ subscore by extracting five items highly correlated with dysphagia in MSA patients. When the subscore was used, Cronbach's alpha coefficient was 0.81, and sensitivity of 85% and specificity of 100% were reported. However, further studies will be needed to validate the MSA-SDQ subscore because of the small sample size and lack of validation in an independent patient population. Recent evidence has further expanded the clinical utility of the SDQ as a valid screening tool for swallowing impairments and aspiration risk in patients with multiple sclerosis [9,10].

In conclusion, the SDQ is a valuable tool for screening dysphagia in patients with PD. Its simplicity and effectiveness make it an important tool for identifying patients at risk for dysphagia and referring them for further evaluation and treatment. Its high internal consistency, sensitivity, and specificity, as well as its availability in multiple languages, make it a reliable and widely applicable indicator of dysphagia in this population. Additional research will be needed for application to other disease groups.

CONFLICTS OF INTEREST

Han Gil Seo 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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Review Article

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Constraint-Induced Movement Therapy in Children With Hemiplegic Cerebral Palsy: A Scoping Review of Functional Outcomes and Neuroplasticity-Related Evidence

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Objective: To synthesize the available evidence on the effects of constraint-induced movement therapy (CIMT) in children with hemiplegic cerebral palsy (CP), focusing on upper limb functional outcomes and neuroplasticity-related changes assessed through direct or indirect measures.

Methods: This scoping review was conducted in accordance with PRISMA-ScR guidelines and was prospectively registered on the Open Science Framework (DOI: 10.17605/OSF.IO/DU8RE). A search of four databases (PubMed, Scopus, Embase, and Web of Science) was performed to identify studies involving children (0–18 years) with CP who received CIMT as the primary intervention. Eligible studies assessed neuroplasticity through neuroimaging or neurophysiological techniques.

Results: Eleven studies involving 221 children met the inclusion criteria. CIMT protocols varied in duration, intensity, and setting (e.g., clinical, home-based, camp-based). Across studies, CIMT was associated with improvements in upper limb function and spontaneous use. Neuroplastic changes included increased activation in the contralateral sensorimotor cortex, normalization of somatosensory responses, and structural brain adaptations. Adjunctive therapies such as repetitive transcranial magnetic stimulation, transcutaneous auricular vagus nerve stimulation, or occupational therapy further enhanced outcomes.

Conclusion: CIMT is an effective intervention that promotes cortical reorganization and improves motor function in children with hemiplegic CP. Customizing rehabilitation based on neurophysiological profiles may optimize clinical outcomes.

Keywords: Constraint-induced movement therapy, Cerebral palsy, Neural plasticity, Hemiplegia, Somatosensory cortex

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INTRODUCTION

Recent investigations into cerebral palsy (CP) have underscored the critical involvement of somatosensory system dysfunction in the emergence of atypical motor patterns. The primary somatosensory cortex (S1), also known as the postcentral gyrus, is situated in the parietal lobe and plays an essential role in the processing of afferent sensory inputs from the body, including tactile stimuli, temperature, nociception, and proprioception [1,2]. Once these sensory signals reach S1, they are integrated and interpreted to support accurate perceptual awareness and facilitate the generation of appropriate motor outputs. A hallmark of the somatosensory cortex is its somatotopic organization: discrete cortical territories correspond to specific regions of the body. This organizational principle was first elucidated by Wilder Penfield in the 1940s [3] through pioneering studies involving direct cortical stimulation, leading to the development of the sensory homunculus, a schematic depiction in which the cortical representation of each body part is scaled in proportion to its sensory innervation density [3]. Notably, body regions such as the hands and lips occupy disproportionately large cortical areas due to their heightened tactile acuity and functional significance [2,3].

In individuals with CP, particularly in hemiplegic presentations, aberrant somatosensory processing frequently disrupts the feedback mechanisms critical for motor learning, resulting in impaired sensorimotor integration [4-6]. The asymmetry in functional capability between the affected and less affected upper limbs is often paralleled by differences in somatosensory processing [7]. Children with hemiplegic CP commonly develop an early preference for the use of the less affected limb in daily activities, even when impairment in the contralateral limb is relatively mild [8]. This compensatory behavior fosters a phenomenon referred to as "learned nonuse," which further entrenches motor asymmetries.

Among the rehabilitative approaches aimed at counteracting this maladaptive pattern, constraint-induced movement therapy (CIMT) has emerged as a high-efficacy intervention. In a comprehensive evidence-based framework proposed by Novak and colleagues, CIMT was classified in the "green" category, indicating strong empirical support for its effectiveness [9]. The therapy involves intensive, task-specific training of the affected limb, thereby promoting functional use, enhancing intrinsic motivation, and leveraging experience-dependent neuroplasticity mechanisms.

Several systematic reviews, including the Cochrane review, have summarized the clinical effectiveness of CIMT in children with unilateral CP, largely focusing on school-aged populations and randomized controlled trials (RCTs). However, the extent to which CIMT induces neuroplastic changes, and how such changes are assessed through neuroimaging/neurophysiological measures or neuroplasticity-related proxies, has been less explicitly synthesized. Therefore, this scoping review aimed to map and synthesize the available evidence on the effects of CIMT in children with hemiplegic CP, with a focus on upper limb functional outcomes and neuroplasticity-related changes assessed through direct or indirect measures.

MATERIALS AND METHODS

Search strategy

This scoping review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines [10], to ensure transparency and methodological consistency (Supplementary Material S1). This review was prospectively registered on the Open Science Framework (OSF) under the DOI: 10.17605/OSF.IO/DU8RE.

A comprehensive literature search was conducted across four electronic databases: PubMed, Scopus, Embase, and Web of Science, without time restrictions, and encompassing all studies published up to January 2026. The search strategy combined MeSH (Medical Subject Headings) and free-text terms to identify studies addressing the effects of CIMT on neuroplasticity in children with CP (Supplementary Material S2). The search terms included: (("Plasticity" OR "Neuroplasticity" OR "Neuronal Plasticity" OR "Cortical Reorganization" OR "Brain Reorganization") AND ("Cerebral palsy" OR "Motor impairment" OR "Motor rehabilitation") AND ("Cimt" OR "Constraint induced movement therapy" OR "mCIMT" OR "Modified CIMT")).

Eligibility criteria

PCC Model

To ensure methodological rigor, the study selection process followed the PCC (Population, Concept, Context) framework, in line with the PRISMA-ScR guidelines [10]:

- Population: Studies that include pediatric participants aged <18 years with a clinical diagnosis of CP.
- Concept: Studies that investigated or applied CIMT as a primary intervention.

- Context: Studies that assessed neuroplasticity-related and/or functional outcomes associated with CIMT-based interventions, including measures of cortical reorganization, brain activity, neural mechanisms, or functional recovery, assessed through direct or indirect measures.

Inclusion criteria

Studies were included if they involved pediatric participants (aged <18 years) diagnosed with CP and investigated the application of CIMT as the primary intervention. Eligible studies had to assess neuroplasticity-related outcomes and/or functional outcomes considered as indirect markers of experience-dependent plasticity, such as cortical reorganization, changes in brain activity, or functional recovery, assessed through neurophysiological, neuroimaging, or standardized functional outcome measures. Studies in which CIMT was delivered alone or in combination with adjunctive interventions (e.g., neuromodulation or occupational therapy) were included, provided that CIMT represented a core component of the rehabilitation protocol. Only peer-reviewed experimental, quasi-experimental, and clinical studies published in English were considered.

Exclusion criteria

Studies were excluded if they involved adult populations or animal models, or if CIMT was not the main intervention. Additional exclusions included case reports, systematic reviews, meta-analyses, conference abstracts, narrative reviews, study protocols, and methodological papers without empirical data. Studies not available in full text or not published in English were also excluded.

A PRISMA-ScR flowchart summarizing the study selection process and exclusion reasons is presented in Fig. 1.

Study selection

The search results from all databases were imported into Rayyan, where duplicates were identified and removed. Two independent reviewers (MCV, RM) conducted a blind screening of titles and abstracts to determine eligibility based on predefined criteria. Disagreements were resolved through discussion or consulting with a third reviewer (MGM). The inter-rater agreement was 84%. Full-text articles of selected studies were then independently reviewed by the same reviewers, with conflicts resolved similarly.

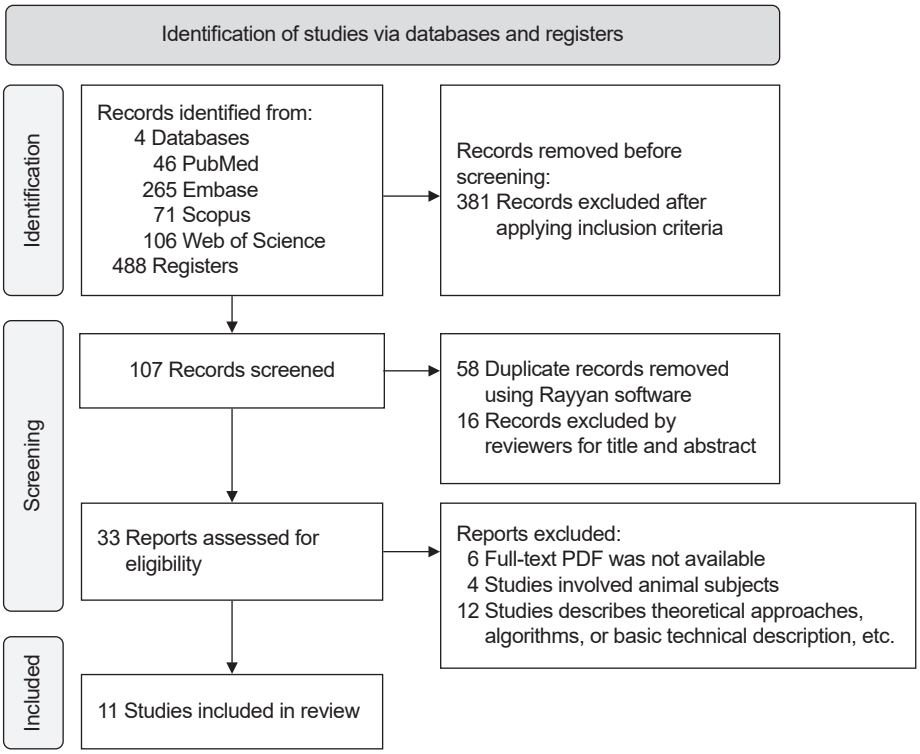

Fig. 1. PRISMA 2020 flow diagram of evaluated studies.

Data extraction and charting

Data extraction was independently performed by MCV and RM using a structured form in Microsoft Excel. Extracted variables included study design, participant characteristics (sample size, age, sex), intervention details, and neuroplasticity-related outcomes. Data consistency was ensured through cross-checking. Discrepancies resolved through consensus with MGM. Given the heterogeneity in study designs and outcomes, data were organized descriptively for narrative synthesis.

Data synthesis

Due to substantial variability in interventions and outcome measures, a meta-analysis was not feasible. Instead, a qualitative narrative synthesis was conducted using the SWiM (Synthesis Without Meta-analysis) framework [11]. This approach facilitated the identification of patterns and themes across studies regarding CIMT effectiveness, neuroplasticity outcomes, and gender-related differences. Table 1 summarizes the main characteristics of the included studies.

RESULTS

Study selection

A total of 488 records were identified through database searches: 46 from PubMed, 71 from Scopus, 265 from Embase, and 106 from Web of Science. All records were imported into the Rayyan review software, where 58 duplicates were identified and removed. This resulted in 107 records available for title and abstract screening, which was independently performed by two reviewers within the Rayyan platform. Following this phase, 33 articles were selected for full-text assessment. Of these, 6 were excluded due to the unavailability of the full-text PDF. As a result, 11 studies met the inclusion criteria and were included in the qualitative synthesis.

A detailed overview of the selection process, including reasons for exclusion at each stage, is provided in the PRISMA-ScR flow diagram (Fig. 1).

Overview of included studies

This scoping review included 11 studies, involving a total of 221 children with hemiparetic CP, aged between 10 months and 19 years. The studies adopted a range of designs, including RCTs [12,13], experimental studies with or without neurophysiological assessment, and camp-based interventional designs. The research was conducted across North America, Europe, and Asia.

All studies investigated the effects of CIMT or modified CIMT (mCIMT), with protocols varying in duration (5 days to 3 weeks), frequency (daily to alternate days), and total treatment hours ranging from 30 to 90 hours. Some interventions were delivered in camp-based or ecological settings [7,14], while others incorporated home tasks or group occupational therapy sessions. Several studies also included neurophysiological or imaging techniques to assess brain plasticity, such as magnetoencephalography (MEG), functional magnetic resonance imaging (fMRI), functional near-infrared spectroscopy, transcranial magnetic stimulation (TMS), and diffusion tensor imaging.

Adjunct therapies were integrated into many protocols. For example, repetitive TMS (rTMS) was paired with CIMT in three studies [13,15,16], and transcutaneous auricular vagus nerve stimulation (taVNS) was used in combination with CIMT in infants in the study by McGloon et al. [17] Occupational and/or physical therapy was frequently added to reinforce functional training, as in the studies by Jobst et al. [18], Manning et al. [19], and Matusz et al. [7].

Despite the heterogeneity in interventions and outcome measures, CIMT was generally well tolerated. Dropouts were minimal and mostly related to technical limitations during neuroimaging (e.g., MRI anxiety, incomplete scans). No adverse events directly attributable to CIMT were reported.

Across all studies, CIMT was consistently associated with functional improvements in upper limb use, alongside evidence of neuroplasticity, including increased sensorimotor activation, reorganization of cortical networks, and structural brain changes. These findings reinforce the role of CIMT as an effective and adaptable intervention in pediatric neurorehabilitation.

Standard CIMT and treatment dosage

Several studies investigated conventional CIMT protocols and intensity levels. Sterling et al. [20] demonstrated that a 3-week CIMT program (3 hours/day) improved spontaneous upper limb use and was associated with increased gray matter volume in the contralateral sensorimotor cortex, as measured via voxel-based morphometry (VBM).

Similarly, Friel et al. [12] implemented a standard CIMT protocol of 6 hours per day for 15 consecutive weekdays (totaling 90 hours) in children with unilateral CP, reporting significant gains in bimanual function and cortical reorganization.

Coker et al. [21] adopted a shorter CIMT protocol (6 hours/day for 5 consecutive days), which still fulfilled the core criteria of standard CIMT. Although the study primarily focused on gait pa-

Table 1. Synthesis of the studies included in this scoping review

Reference	Type of study	Aim	Sample characteristic	Intervention	Outcome measures	Main findings	Dropout/notes
Jobst et al., 2022 [18]	Experimental study	To evaluate somatosensory function and neural processing after CIMT	N=12, 9 M/3 F, aged 5.1–13 years; GMFCS I, MACS I–II	CIMT, 3 weeks total (1st week non-removable cast, 2nd week removable cast), 40 hours OT group sessions	JTHF, QUEST, AHA, grip strength, SWM, 2PD, stereognosis, proprioception, kinesthesia	Improvements in somatosensory outcomes (SWM, 2PD, stereognosis, proprioception, kinesthesia) and changes in cortical somatosensory processing assessed with MEG	2 Excluded (1 MRI anxiety, 1 poor MEG data)
Matusz et al., 2018 [7]	Neurophysiological experimental study	To investigate sensory activation changes post-CIMT	N=10, 5 M/5 F, aged 5–8 years; MACS I–III	5-day CIMT camp (120 hours casting, 22 hours structured OT/PT activities)	SWM, 2PD, ROM, strength (dynamometer), sensory tests	Post-intervention changes in sensory activation (neurophysiological assessment of sensory responses) accompanied by changes in sensory/motor outcomes (SWM, 2PD, ROM, dynamometry)	N/A
McGloon et al., 2024 [17]	Experimental study with neuromodulation	To evaluate the feasibility and potential of taVNS combined with CIMT to enhance functional movement, gross motor skills, and upper limb function in infants with hemiplegia by leveraging activity-dependent neuroplasticity	N=3 infants (10–14 months) with hemiplegia; GMFCS I–IV	taVNS+CIMT, 4 weeks, 40 hours total; outcomes assessed post, 1- and 3-month follow-up	QUEST, GMFM-88, DAYC-2, Goal Attainment Scaling	Feasibility/safety: adherence/retention and adverse events; Clinical outcomes: changes in QUEST, GMFM-88, DAYC-2, and Goal Attainment Scaling at post-intervention and follow-ups (1 and 3 months)	None
Kuo et al., 2022 [15]	Experimental study with rTMS+CIMT	To explore effects of rTMS combined with CIMT	N=45, aged 6–19 years; MACS I–IV	4 Groups: rTMS only, CIMT only, rTMS+CIMT, control; 80 hours upper limb therapy in 10 days	AHA, COPM, TMS parameters (MEP, SICI)	Neurophysiology: increased MEP and reduced SICI (TMS measures); Functional outcomes: changes in AHA and COPM across groups	Not specified
Cao et al., 2015 [14]	Camp-based interventional study with fNIRS	To examine effects of CIMT during a therapeutic camp	N=6 hemiplegic CP+5 typically developing children (ages ~10 years); MACS I–II	2-week pirate-themed CIMT camp, 6 h/day, 5 days/week	Melbourne Assessment, AHA, fNIRS (tapping tasks)	Clinical: changes in Melbourne Assessment and AHA; Neuroimaging: changes in task-related cortical activation measured with fNIRS during tapping tasks.	None
Sterling et al., 2013 [20]	Neuroimaging-based intervention pilot study	To evaluate structural brain changes and motor improvements post-CIMT	N=10 children, aged 2–7 years, hemiparetic CP	3 h/day CIMT for 3 weeks, VBM MRI pre/post/follow-up	PMAL-R, structural MRI	Structural MRI (VBM): increased gray-matter volume in sensorimotor regions; Clinical: increased spontaneous arm use assessed with PMAL-R (pre/post/follow-up)	None
Manning et al., 2016 [19]	Experimental study with rs-fMRI	To examine sensorimotor network reorganization post-CIMT	N=14 originally recruited, but N=11 were included in the study and analyzed (7 treated, 4 controls); aged 6–18 years	3-week CIMT (1st week non-removable cast, 2nd–3rd week camp+home tasks)	QUEST, COPM, JTTHF, rs-fMRI	rs-fMRI: increased bilateral sensorimotor network functional connectivity, maintained at 6 months; Clinical: changes in QUEST, COPM, and JTTHF	3 Skipped MRI for various reasons

(Continued on the next page)

Table 1. Continued

Reference	Type of study	Aim	Sample characteristic	Intervention	Outcome measures	Main findings	Dropout/notes
Friel et al., 2021 [12]	RCT (CIMT vs. HABIT)	To compare CIMT and HABIT efficacy in upper limb rehabilitation	N=83 children with spastic hemiparetic CP (ages ~6–17)	15-day camp, 6 h/day, 90 hours total; TMS+DTI imaging	JTTHF, AHA, Box and Block, ABILHAND-Kids, COPM, PEDI	CIMT vs. HABIT: comparable changes in JTTHF, AHA, Box and Block, ABILHAND-Kids, COPM, and PEDI; Neuroimaging/neurophysiology (DTI/TMS): outcomes reported irrespective of CST reorganization type	4 Total (1 dropout, 3 incomplete imaging)
Coker et al., 2010 [21]	Functional mobility and gait study	To assess impact of mCIMT on gait and upper limb function	N=12 children aged 2.5–6.2 years; GMFCS I–III	mCIMT, 6 h/day for 5 consecutive days	GAITRite gait descriptors (spatiotemporal measures)	Gait: changes in spatiotemporal parameters measured with GAITRite (e.g., stability/symmetry descriptors) after mCIMT	None
Gillick et al., 2014 [13]	RCT (rTMS+CIMT)	Evaluate the feasibility and efficacy of rTMS+CIMT to promote recovery of the paretic hand in CP	N=19 children with unilateral CP, aged 8–17 years, 10 F/9 M	2 Groups: 10 patients real rTMS+CIMT (5 treatments of real rTMS and 5 of CIMT on alternate weekdays for 2 weeks), 9 patients Sham rTMS+CIMT (13 days of continuous long-arm casting with 5 skin-check session, 10 hours total)	AHA,COPM, stereognosis	Safety/feasibility: completion/adverse events; Clinical outcomes: changes in AHA, COPM, and stereognosis after rTMS+CIMT vs. sham	None
Cope et al., 2010 [16]	A prospective pre-post observational study with a single group. (CIMT+fMRI)	Investigate the changes in brain reorganization after CIMT in children with hemiplegia using fMRI	N=10 children with hemiparetic CP, aged 7–14 years, 6 F/4 M	CIMT individualized treatment 4 h/day on weekdays over 2 consecutive Weeks for a total of 10 treatment days and 40 hours of therapy. Children were measured with fMRI before and after	MAS, bulb dynamometer, goniometer, proprioception, stereognosis, MUUL, PEDI, kinematic analysis of upper limb functional movements, peak velocity of reaching movement, movement time, movement units, joint angles	Neuroimaging: pre/post changes in fMRI activation patterns; Clinical/biomechanical outcomes: changes in MAS, strength (bulb dynamometer), ROM (goniometer), proprioception/stereognosis, MUUL, PEDI, and upper-limb kinematic variables	None

CIMT, constraint-induced movement therapy; M, male; F, female; GMFCS, Gross Motor Function Classification System; MACS, Manual Ability Classification System; OT, occupational therapy (terapia occupazionale); JTTHF (JTHF), Jebsen–Taylor Hand Function Test; QUEST, Quality of Upper Extremity Skills Test; AHA, Assisting Hand Assessment; 2PD, Two-Point Discrimination; SWM, Semmes–Weinstein Monofilaments; MEG, magnetoencephalography; MRI, magnetic resonance imaging; PT, physical therapy/physiotherapy (fisioterapia); ROM, range of movement; N/A, not applicable; taVNS, transcutaneous auricular vagus nerve stimulation; GMFM-88, Gross Motor Function Measure (88 items); DAYC-2, Developmental Assessment of Young Children, 2nd edition; TMS, transcranial magnetic stimulation; rTMS, repetitive TMS; MEP, motor evoked potentials; SICI, short-interval intracortical inhibition; COPM, Canadian Occupational Performance Measure; PEDI, Pediatric Evaluation of Disability Inventory; fNIRS, functional near-infrared spectroscopy; CP, cerebral palsy; PMAL-R, Pediatric Motor Activity Log–Revised; fMRI, functional MRI; VBM, voxel-based morphometry; rs-fMRI, resting-state functional MRI; RCT, randomized controlled trial; HABIT, Hand-Arm Bimanual Intensive Therapy; DTI, diffusion tensor imaging; ABILHAND-Kids, ABILHAND-Kids questionnaire (measure of manual ability in children); CST, corticospinal tract; mCIMT, modified CIMT; MAS, Modified Ashworth Scale; MUUL, Melbourne Assessment of Unilateral Upper Limb Function; GAITRite, GAITRite walkway system (instrumented walkway for gait analysis).

rameters, such as stability and symmetry, it highlights the potential feasibility and benefits of brief, high-intensity CIMT formats.

These findings support the effectiveness of traditional CIMT dosing schedules, whether intensive or brief, in promoting functional and, in some cases, neuroplasticity-related outcomes.

CIMT combined with occupational and physical therapy

CIMT is frequently paired with occupational therapy to enhance sensorimotor outcomes. Jobst et al. [18] implemented a 3-week CIMT protocol incorporating 40 hours of occupational therapy, reporting improvements in paretic hand use and somatosensory processing, supported by MEG and MRI data.

Similarly, Manning et al. [19] delivered CIMT alongside 20 hours per week of occupational therapy over three weeks, observing functional gains in upper limb use and sensorimotor network reorganization via fMRI.

Although Matusz et al. [7] did not include a combined OT program, the study demonstrated normalization of sensory responses in somatosensory areas of the affected hemisphere following CIMT, as measured by fMRI.

In addition, Friel et al. [12] compared CIMT with Hand-Arm Bimanual Intensive Therapy (HABIT) within a camp-based setting (6 hours/day for 3 weeks), reporting similar improvements in upper limb function and evidence of cortical reorganization through MRI.

CIMT combined with neuromodulation

Several studies have explored the combination of CIMT with neuromodulation. Gillick et al. [13] integrated CIMT with low-frequency rTMS in a randomized trial: 80% of children in the active rTMS group surpassed the minimal detectable change threshold in Assisting Hand Assessment (AHA) scores versus 22% in the sham group. Mufti et al. [22] applied rTMS priming followed by 1 Hz stimulation combined with mCIMT, reporting enhanced upper limb function (Quality of Upper Extremity Skills Test, QUEST), reduced spasticity (Modified Ashworth Scale, MAS), and neurophysiological changes. Kuo et al. [15] found functional improvements and increased cortical excitability after a 10-day rTMS+ CIMT intervention. McGloon et al. [17] explored the use of taVNS paired with CIMT, reporting gross motor improvements and plasticity, driven functional gains, supporting taVNS as a safe and promising adjunct for pediatric neurorehabilitation.

In these studies, neuromodulation techniques such as rTMS were implemented as adjunctive interventions, and neurophysiological measures (e.g., motor threshold or cortical excitability) were used to characterize between-group differences related to neuromodulation, rather than to directly assess neuroplastic changes induced by CIMT alone.

CIMT in camp-based and ecological settings

Delivering CIMT in enriched, structured environments such as therapeutic camps has shown promising results. Cao et al. [14] implemented a camp-based CIMT protocol (6 hours/day for 2 weeks), reporting sustained improvements in upper limb function (Melbourne Assessment, AHA) and a shift in cortical activation from the ipsilateral to the contralateral hemisphere. Similarly, Friel et al. [12] examined the efficacy of CIMT and HABIT within a camp setting (6 hours/day for 3 weeks), observing comparable gains in hand function and cortical reorganization. In contrast, Cope et al. [16] evaluated a home-based wearable CIMT model (2 hours/day for 3 weeks), which was found to be feasible and acceptable, with positive trends in affected arm use. These findings suggest that both structured camp-based and ecological home-based CIMT interventions may effectively promote functional outcomes in children with unilateral CP.

Functional and neuroplastic outcomes

Most of the included studies assessed upper limb function using standardized outcome measures such as the AHA [12-14], QUEST [22], Jebsen–Taylor Test of Hand Function (JTTHF) [20], and the Pediatric Motor Activity Log (PMAL) [16]. In addition, some studies employed goal-oriented or participation-level measures such as the Canadian Occupational Performance Measure (COPM) [16], Goal Attainment Scaling (GAS) [17], ABILHAND-Kids, and Pediatric Evaluation of Disability Inventory (PEDI) [18].

Neurophysiological and imaging-based outcomes were explored in a subset of the studies. For example, Sterling et al. [20] reported increased gray matter volume in the contralateral sensorimotor cortex using VBM; Cao et al. [14] observed a shift in cortical activation patterns using fMRI; Matusz et al. [7] and Jobst et al. [18] described sensory system reorganization through MEG and EEG. Changes in cortical excitability and organization were also documented using TMS [13,15].

Taken together, these findings suggest that CIMT interventions in pediatric populations are associated not only with functional improvements in upper limb use but also with measurable neuroplastic adaptations across different modalities of assessment.

DISCUSSION

This scoping review aimed to synthesize the available evidence on cortical neuroplastic adaptations associated with CIMT in children with hemiparetic CP. The 11 included studies suggest that CIMT, across various protocols and delivery modalities, can influence neuroplastic mechanisms in the developing brain.

Intervention parameters varied widely, with total durations ranging from 15 to 90 hours and daily sessions from 1 to 6 hours. In several studies, CIMT was delivered in combination with other approaches, such as occupational therapy, neuromodulation (e.g., rTMS or taVNS), or within enriched environments like therapeutic camps. Despite this heterogeneity, the reviewed studies consistently reported evidence of measurable cortical reorganization, particularly in the sensorimotor areas contralateral to the affected limb.

Several studies reported increased activation in the somatosensory and motor cortices following CIMT, as well as structural changes such as increased gray matter volume [20] and functional connectivity shifts toward contralateral hemisphere dominance [12,14]. These outcomes align with established models of activity-dependent plasticity, which suggest that intensive, task-specific training can drive both functional and anatomical remodeling of the brain [23]. In some studies, CIMT was also associated with sensory system reorganization [7,18], indicating that somatosensory input modulation may be an additional mechanism of action.

Moreover, functional improvements, such as enhanced upper limb use, improved grip and reach accuracy, and spontaneous use of the affected hand, were frequently observed in parallel with neurophysiological changes.

Notably, this review also highlights a key aspect of CIMT's implementation in clinical practice: its increasing integration into multimodal rehabilitation frameworks. In several studies, CIMT was not delivered in isolation but rather as part of a broader therapeutic strategy aimed at reinforcing interhemispheric balance and sensorimotor function. These findings suggest that CIMT may act as a catalyst for neuroplasticity when combined with context-specific, child-adapted interventions.

Concerns about the potential negative effects of constraint on the less affected limb, particularly regarding sensory deprivation or maladaptive plasticity, were reported in some experimental literature [24]. However, in the included studies, no enduring adverse sensory effects were documented, and parental reports at follow-up confirmed the acceptability of the interventions. Still, these risks warrant consideration, especially during critical periods of development.

This work is intended to complement previous systematic reviews (including the Cochrane review), which primarily focused on clinical effectiveness in school-aged children and RCTs. By contrast, the present scoping review specifically maps neuroplasticity-related outcomes (neuroimaging, neurophysiological measures and neuroplasticity-related proxies) alongside upper-limb functional changes, thereby providing a mechanistic perspective that helps interpret clinical improvements within an experience-dependent plasticity framework.

The comparison with broader literature confirms and extends previous findings. As reviewed by Charles and Gordon [25] and more recently by Robert et al. [26], CIMT is among the most studied interventions capable of eliciting neurophysiological changes in children with CP. The present synthesis adds to this body of knowledge by emphasizing that these effects are observable even in early developmental stages and that advanced neuroimaging and neurophysiological techniques (e.g., MRI, MEG, TMS) are increasingly used to document such changes.

Dropout rates were minimal and primarily related to the technical limitations of neuroimaging procedures, such as scanner-related anxiety, motion artifacts, or interference from epileptiform activity [13,17]. These aspects underscore the need for child-friendly, feasible neurophysiological assessments in future pediatric rehabilitation research.

In conclusion, CIMT emerges from this review not only as an effective intervention to improve upper limb function but also as a powerful modulator of neuroplastic mechanisms in the pediatric brain. Its impact spans across functional, structural, and sensory domains. Future research should aim to refine intervention parameters, integrate neurophysiological monitoring in routine practice, and personalize rehabilitation strategies based on individual patterns of plasticity.

This scoping review showed a comprehensive synthesis of current evidence on the neuroplastic effects of CIMT in children with hemiplegic CP, highlighting both functional outcomes and cortical reorganization. A key strength lies in the integration of heterogeneous methodologies, including neuroimaging and neurophysiological techniques, across different clinical and ecological settings (e.g., home-based, camp-based, and hospital-based interventions). This broad perspective enhances the ecological validity and translational value of the findings.

However, several limitations must be acknowledged. First, the

number of included studies remains limited, with small sample sizes and considerable variability in study design, intervention protocols, and outcome measures. This heterogeneity precludes quantitative synthesis and limits the generalizability of results. Additionally, many studies lacked long-term follow-up, making it difficult to assess the persistence of neuroplastic changes over time. The absence of standardized biomarkers for neural plasticity, along with inconsistencies in imaging protocols and timing of assessments, further limits the ability to compare findings across studies. Finally, a relevant limitation of the present review concerns studies in which CIMT was combined with neuromodulation techniques, such as rTMS or taVNS. In these multimodal interventions, it is not possible to disentangle the specific contribution of CIMT from that of neuromodulation, nor to determine whether the observed neuroplastic changes are attributable to CIMT alone or to a synergistic effect. Future studies employing factorial designs or appropriate control conditions are needed to clarify the independent and combined effects of these interventions.

Future research should aim to address these gaps by conducting large-scale, longitudinal studies with harmonized CIMT protocols and standardized neurophysiological and neuroimaging outcomes. Personalized approaches based on baseline neurofunctional profiles may also help identify responders to CIMT and optimize intervention strategies. Moreover, combining CIMT with adjunctive neuromodulatory techniques, such as rTMS or taVNS, holds promise and warrants investigation to clarify synergistic mechanisms.

Conclusions

This scoping review has highlighted that the application of CIMT represents a valuable approach for stimulating and promoting functionally advantageous neuroplasticity, resulting in improved motor and sensory function in children with hemiplegic CP. The forced use of the affected upper limb by constraining the less affected one encourages greater engagement of the contralateral somatosensory cortex, as evidenced by increased activation patterns and, in some cases, structural changes such as enhanced grey matter volume in the sensorimotor areas. Clinical outcomes across studies also reported greater spontaneous use of the paretic limb, improved precision in upper limb tasks, and favorable modulation of sensory processing. These findings underscore the potential of CIMT to support plastic reorganization across functional, structural, and sensory domains in the developing brain.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTION

Conceptualization: Maggio MG, Valeri MC, Calabrò RS. Methodology: Maggio MG, Calabrò RS, Morone G. Data curation: Maggio MG, Valeri MC, Maione R. Software: Maggio MG, Maione R, Calabrò RS. Validation: all authors. Formal analysis: Maggio MG, Maione R. Project administration: Calabrò RS, Morone G. Funding acquisition: Calabrò RS. Investigation: Maggio MG, Valeri MC, Maione R, Calabrò RS. Resources: Maggio MG, Valeri MC, Calabrò RS, Morone G. Writing – original draft: Maggio MG, Valeri MC, Maione R. Writing – review & editing: Maggio MG, Maione R, Valeri MC, Militi A, Cinnera AM, Ciancarelli I, Calabrò RS, Morone G. Visualization: all authors. Supervision: Maggio MG, Calabrò RS, Morone G. Approval of final manuscript: all authors.

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Artificial intelligence–assisted tools were used exclusively for language editing and stylistic refinement of the manuscript. No AI tools were used for the generation of scientific content, data analysis, interpretation of results, or the drawing of conclusions. The authors take full responsibility for the content of the manuscript.

DATA AVAILABILITY STATEMENT

Data supporting the findings of this review are available from the corresponding author upon reasonable request.

SUPPLEMENTARY MATERIALS

Supplementary materials can be found via https://doi.org/10.5535/arm.250165.

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Eccentric Cycling Improves Cardiopulmonary Fitness, Respiratory Function, and Quality of Life in Chronic Kidney Disease: A Randomized Controlled Trial

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Objective: To compare the effects of eccentric cycling (ECC), concentric cycling (CON), and standard care (CTL) on cardiopulmonary capacity, respiratory health, and quality of life (QoL) in patients with chronic kidney disease (CKD).

Methods: Thirty-one CKD patients were divided into the CTL, CON, and ECC groups. The CON and ECC groups participated in 8-week, 24-session cycling programs. Outcomes were assessed through cardiopulmonary exercise tests, respiratory function tests, and the 36-Item Short Form Survey Instrument questionnaire.

Results: The ECC group achieved significant improvements in maximal oxygen uptake, while the CTL group showed a decline. For oxygen uptake efficiency slope, significant changes were observed only in the ECC group, with a group-by-time interaction effect compared to CTL. Furthermore, the ECC group demonstrated the most significant increase in diaphragm movement and a significant increase in diaphragm thickness, with comparisons indicating that ECC outperformed both CTL and CON. Regarding QoL, the ECC group exhibited significantly greater improvements in Physical Component Summary and Mental Component Summary, with statistically significant differences compared with the CTL and CON groups.

Conclusion: ECC is a low-effort, high-benefit exercise modality that significantly enhances cardiopulmonary fitness, respiratory function, and QoL in patients with CKD.

Keywords: Chronic kidney disease, Exercise, Cardiopulmonary fitness, Eccentric cycling training

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INTRODUCTION

Chronic kidney disease (CKD) is defined by a glomerular filtration rate (GFR) of <60 mL/min/1.73 m^2, the presence of kidney damage markers, or both, persisting for at least 3 months [1]. The progression of CKD is associated with various clinical complications resulting from declining renal function, contributing to poor quality of life and increased morbidity and mortality [2,3]. As GFR declines with CKD progression, patients experience fluid retention, metabolic and endocrine disturbances, cardiovascular changes, and diastolic dysfunction. These alterations contribute to a higher prevalence of pulmonary edema and respiratory muscle dysfunction. Data from the US National Health and Nutrition Examination Survey indicate that restrictive pulmonary dysfunction affects 10% of CKD patients, while obstructive pulmonary dysfunction affects 16%, particularly in stages 1–4 [4,5].

As CKD progresses, systemic inflammation, oxidative stress, and metabolic imbalances disrupt the equilibrium between protein synthesis and degradation, impair mitochondrial function, and lead to muscle wasting and sarcopenia [6]. The weakening of skeletal muscles, including respiratory muscles, reduces gas exchange efficiency and lung function, exacerbating exercise intolerance. These changes contribute to increased fatigue, reduced physical activity, and declines in functional capacity and quality of life. A strong correlation exists between physical activity levels and mortality [7]. Patients with CKD stages 3–5 demonstrate greater sarcopenia and exercise intolerance. Therefore, individualized, progressive, and supervised exercise programs are indicated to improve exercise capacity and related clinical outcomes [8].

Regular low- to moderate-intensity physical activity has been shown to provide benefits for individuals with CKD, including improvements in aerobic and functional capacity and quality of life, without negatively affecting kidney function [9]. Furthermore, combined aerobic and resistance training has been shown to improve muscle function, increase exercise tolerance, and reduce resting systolic blood pressure in CKD patients [10]. Given the strong link between reduced maximal oxygen uptake (VO_2 max) and increased mortality in CKD patients, enhancing VO_2 max is a key goal of exercise interventions [11]. However, post-exercise fatigue often reduces motivation and leads to poor adherence. Addressing this issue may involve minimizing the perceived effort of physical activity [12]. Eccentric exercise, which requires less oxygen and energy than concentric exercise, offers advantages such as low energy cost, reduced motion perception, and decreased metabolic demand. The lower metabolic demand of eccentric exercise is particularly beneficial for individuals with exercise intolerance, enabling them to engage in higher-intensity training [12]. Eccentric cycling (ECC), a unique form of aerobic exercise, requires four times less cardiorespiratory energy than concentric cycling (CON), improving exercise efficiency at the same perceived exertion while reducing heart rate and oxygen uptake. ECC enhances muscle strength and promotes hypertrophy [13]. Recent discussions on ECC have focused on its application in training programs for specific populations, such as frail individuals and patients with chronic conditions. For instance, studies on patients with chronic obstructive pulmonary disease and chronic heart failure have shown that ECC improves functional capacity and muscle mass more effectively than CON [14-16].

Hypertension and an elevated risk of cardiovascular disease are common in CKD patients. While traditional aerobic exercise can raise blood pressure, increase cardiac workload, and heighten the risk of exercise-related adverse events, eccentric exercise poses lower hemodynamic demands, reducing these risks. This allows individuals with compromised cardiopulmonary function to achieve the necessary exercise intensity safely. As such, ECC may be a more suitable exercise option for CKD patients than traditional CON. However, its effectiveness in this population remains insufficiently studied in existing research.

This study aimed to compare the effects of ECC and CON on cardiopulmonary exercise capacity, respiratory function, and quality of life in patients with CKD under identical exercise intensity and duration. Additionally, it evaluated the differences between ECC, CON, and standard healthcare in this population. We hypothesize that ECC will have lower cardiopulmonary and metabolic demands than CON, allowing for a higher exercise load and significantly improving cardiopulmonary exercise capacity, respiratory functions, and quality of life.

METHODS

Research design and study participants

This single-center randomized controlled trial was conducted at the National Cheng Kung University Hospital (NCKUH) in Tainan, Taiwan, between March 2022 and September 2023. It followed the CONSORT (Consolidated Standards of Reporting Trials) statement and was registered on ClinicalTrials.gov (NCT06551311). Ethical approval was obtained from the In-

stitutional Review Board of NCKUH (approval no. A-BR-110-109). All participants provided written informed consent after a detailed explanation of the study procedures. The inclusion criteria for this study were as follows: (1) a GFR <60 mL/min/1.73 m^2 with a confirmed diagnosis of CKD; (2) age between 50 and 90 years; (3) ability to comprehend and follow instructions; and (4) capability to walk independently. Exclusion criteria included (1) acute renal failure; (2) hospitalization for an acute illness within the past 3 months; (3) severe joint disease or recent lower extremity surgery; (4) severe neurological conditions; (5) severe cardiovascular disease; and (6) unconsciousness or inability to cooperate during assessments. Thirty-one CKD patients were randomly assigned to one of three groups using a computer-generated sequence with equal allocation: the control group (CTL), which received standard healthcare, the CON group, or the ECC group. The CTL group continued to receive standard medical care according to institutional guidelines, which included routine nephrology follow-up, medication management, nutritional counseling, and received no study-delivered exercise training during the 8-week intervention. They were instructed to maintain their usual physical activity and underwent the same assessments at all study time points as the exercise groups.

Baseline assessments were conducted before the initiation of the exercise training program (Time point 1). Midterm assessments were performed after 12 exercise sessions (Time point 2), post-assessments after 24 exercise sessions (Time point 3), and follow-up assessments 4 weeks after the program concluded (Time point 4). All assessments and training sessions were performed under therapist supervision.

Interventions: cycling exercise training

Participants completed an 8-week cycling exercise program using either a stationary cycle ergometer or an eccentric stationary cycle ergometer (750R; Upwards Biosystems, a recumbent eccentric exercise machine manufactured in Taiwan). Both eccentric and CON were performed on a motor-driven cycle ergometer (750R). CON used the standard concentric mode. ECC used the same ergometer set to the motor-driven eccentric mode, with the cranks driven by the motor and resisted by the participant. The cranks rotate backward, and the rider resists this motion to perform muscle actions, producing large, coordinated eccentric contractions of the knee extensors and the hip extensors and flexors while maintaining the prescribed workload. The initial workload was 50% of peak power output, adjusted to a target Borg rating of perceived exertion (RPE) of 13. This strategy aligns with CKD recommendations for moderate intensity (40%–60% VO_2peak) and applies RPE monitoring to harmonize internal load and maintain tolerability and safety [17-19]. Exercise intensity was increased weekly by 5%–10% of the target power, adjusted to maintain an RPE level of 13. Each session lasted 30 minutes and was conducted three times a week for 24 sessions. Fig. 1 illustrates the outline of the current study and the time points at which outcome measurements were taken. Training power output (W) and mechanical work (kJ) were recorded each session. Weekly mean achieved power, weekly mechanical work, and cumulative work across the 8-week program were summarized and are reported in Supplementary Table S1.

Cardiopulmonary exercise testing

Cardiopulmonary exercise testing (CPET) was performed under medical supervision by trained staff in a laboratory equipped for advanced life support. CPET was conducted on an electronically braked cycle ergometer (Ultima CPX; MGC Diagnostics) using an individualized ramp protocol of 15–20 W/min at a cadence of 50–60 rpm, targeting an 8–12 minutes symptom-limited duration. Continuous 12-lead ECG and breath-by-breath gas exchange were recorded. Blood pressure was measured at 2–3 minutes intervals, pulse oximetry was monitored continuously, and Borg 6–20 ratings and symptoms were documented. Tests were terminated at the participant's request or for standard absolute or relative indications, including ischemic ST changes or angina, complex arrhythmias, abnormal blood pressure responses, severe desaturation, or ataxia/cyanosis. Maximal intensity was defined as the symptom-limited peak work rate/VO_2, supported by ≥1 objective criterion: respiratory exchange ratio ≥1.10, Borg RPE ≥17/20, or heart rate ≥85%–90% of age-predicted when not rate-limited by β-blockade or devices. Procedures conformed to ATS/ACCP 2003 [19] and ACSM Guidelines 2021.

Diaphragm ultrasonography

Diaphragm mobility and thickness were evaluated using diaphragm ultrasonography. Participants were positioned in a semi-recumbent position on a 30-degree wedge. Diaphragm excursion at the dome and muscle thickness at the zone of apposition (ZOA) were measured using ultrasound. Each measurement was repeated three times, and the average value was recorded. To minimize operator-dependent variability, all measurements were conducted by a single experienced therapist.

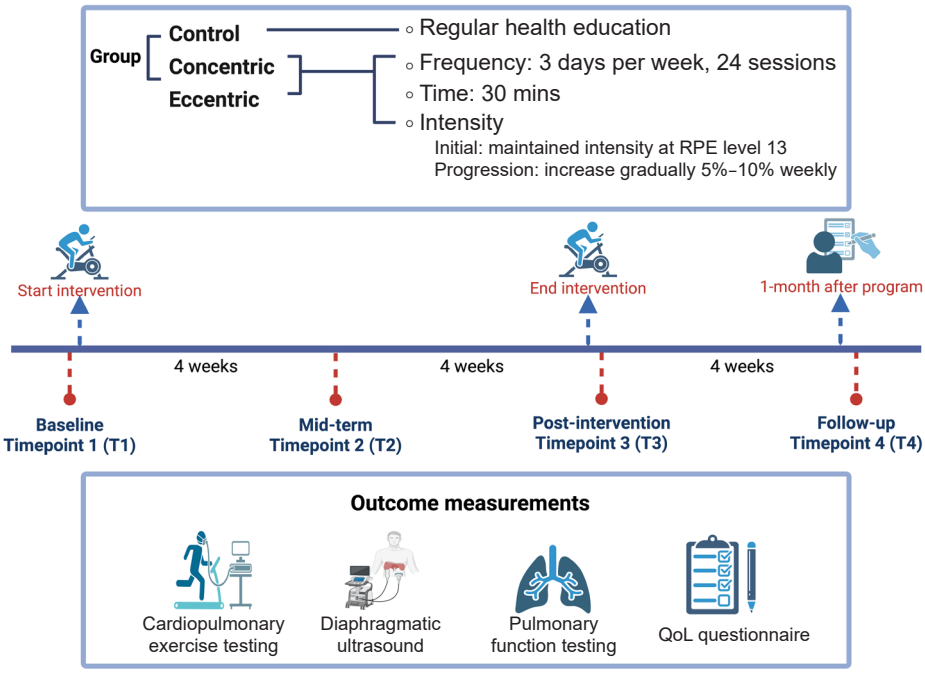

Fig. 1. The schematic outline of this study and the time points of outcome measurements. RPE, rating of perceived exertion; QoL, quality of life.

These procedures were intended to minimize operator-dependent variability and reduce random error, thereby improving the interpretability of modest absolute changes. Previous methodological reviews indicated good repeatability of diaphragmatic ultrasound when performed by experienced operators using standardized techniques [20]. In this study, all ultrasound assessments were performed by a single trained therapist, using a standardized protocol. The examiner has prior research experience involving diaphragmatic ultrasound as well.

Diaphragm excursion was measured during deep breathing. A curved probe (2–5 MHz) from the ultrasound machine (LOGIQ e; GE HealthCare) was placed between the midclavicular and anterior axillary lines below the right costal margin to visualize the diaphragm in M-mode. The displacement of the right diaphragm was recorded by noting the highest point during inhalation and the lowest point during exhalation. Diaphragm thickness was measured at the end of the inspiratory and expiratory phases of breathing, from functional residual capacity to total lung capacity. A linear probe (4–12 MHz) was positioned at the ZOA in the intercostal view between the eighth and ninth intercostal spaces. The diaphragm thickening fraction (TF) was calculated as the percentage difference between the diaphragm thickness at end-inspiration and end-expiration, relative to the thickness at end-expiration. This measurement reflects diaphragm contraction ability [20].

Respiratory muscle strength and pulmonary function test

Maximal respiratory pressures were measured during maximal voluntary inhalation and exhalation, following the guidelines of the American Thoracic Society and the European Respiratory Society. Participants were seated upright with a nose clip and used a mouthpiece connected to a pressure meter (GB60; JITTO). The procedure was repeated three times, and the highest value was used for analysis. Spirometry (microQuark; COSMED) was performed as a standard pulmonary function test (PFT) to assess air volume during forced respiratory maneuvers. Key parameters measured include forced expiratory volume in one second (FEV_1), forced vital capacity (FVC), and the FEV_1/FVC ratio. The participants repeated the measurements 3 times, taking the maximum value as a record as well [21].

Health-related quality of life

The 36-Item Short Form Survey Instrument (SF-36) scoring process transforms responses from 36 items into 8 domains: physical functioning, role limitations due to physical health, bodily pain, general health, vitality, social functioning, role limitations due to emotional health, and mental health. These

domains are combined into two summary scores: the Physical Component Summary (PCS) and the Mental Component Summary (MCS).

Statistical analysis

The sample size was determined using G*Power software (version 3.1.0), based on a standardized large effect size with a power of 0.80 and an alpha level of 0.05, considering three groups and four measurement time points. Effect size based on a similar workload-matched eccentric versus CON trial reporting meaningful exercise capacity changes. It reported effect sizes used for planning ranging from 0.6 to 1.2 [22]. We selected the lower volume (Cohen's f: 0.60) to remain conservative. The minimum required total sample size was 21 participants. Therefore, we enrolled 31 participants to account for anticipated withdrawal.

A total of 31 participants were enrolled in the study, of whom 22 completed follow-up assessments. Data are presented as mean±standard deviation (SD) for all variables, with a significant level of $p<0.05$. The Kruskal–Wallis and chi-squared tests assessed baseline differences among the three groups. Data from all randomized participants were included in the longitudinal analyses. Generalized estimating equations (GEE) were applied to analyze intragroup differences across time points 1–4 throughout the intervention. GEE was also used to evaluate intragroup effects over time and group-by-time interaction effects. At baseline, there were significant differences in body mass index (BMI) values across the three groups (Table 1). Since this could influence the calculation and interpretation of results, BMI was included as an adjustment variable when calculating the interaction effect by time group. All data analyses were performed using SPSS software (version 22.0; IBM Corp.).

RESULTS

Demographic and medical characteristics

Thirty-one participants were recruited in the study, with the majority being male (n=18, 58.1%) (Fig. 2). The demographic details are presented in Table 1. No significant differences in age, height, weight, or body composition were found among the three groups. There were also no significant differences in CKD stage or renal blood parameters (data not shown in Table 1). However, BMI showed substantial differences across groups. The clinical profiles of stages 3–5 CKD patients are inherently diverse, as reflected in the significant baseline BMI differences. Therefore, we adjusted for this by including BMI as a covariate in our statistical models.

Table 1. Demographic and clinical characteristics of CTL, CON, and ECC groups

Demographic data	CTL group (n=10)	CON group (n=10)	ECC group (n=11)	p-value
Age	73.40±10.30	74.50±8.95	73.18±8.77	0.923
Sex				0.958
Male	6	6	6	
Female	4	4	5	
Body composition				
Height (cm)	158.35±7.61	157.85±11.83	159.64±7.80	0.731
Weight (kg)	57.77±8.94	67.14±17.52	66.78±13.02	0.116
Body mass index (kg/m^2)	23.00±2.65	26.61±3.59	25.97±2.94	0.028*
Body fat	27.18±5.66	30.94±5.51	31.42±4.17	0.153
Visceral fat	8.60±4.95	13.70±6.13	13.00±6.83	0.068
Skeletal muscle rate (%)	29.71±4.18	27.08±3.07	27.20±2.54	0.239
Basal metabolic rate (kcal)	1,333.70±187.76	1,461.60±324.32	1,447.73±262.37	0.558
Renal function				
BUN (mg/dL)	40.88±25.00	35.22±25.07	33.64±13.59	0.782
Creatine (mg/dL)	3.04±2.61	2.66±2.63	2.16±1.13	0.899
eGFR (mL/min/1.73 m^2)	32.51±21.13	37.49±18.66	34.53±17.62	0.923

Values are presented as mean±standard deviation or number only.
Utilized Kruskal–Wallis to compare baseline data across the three groups.
Chi-square test was used to compare sex distribution among the three groups.
CTL, control; CON, concentric cycling; ECC, eccentric cycling; BUN, blood urea nitrogen; eGFR, estimated glomerular filtration rate.
*$p<0.05$ intragroup comparison with time effect.

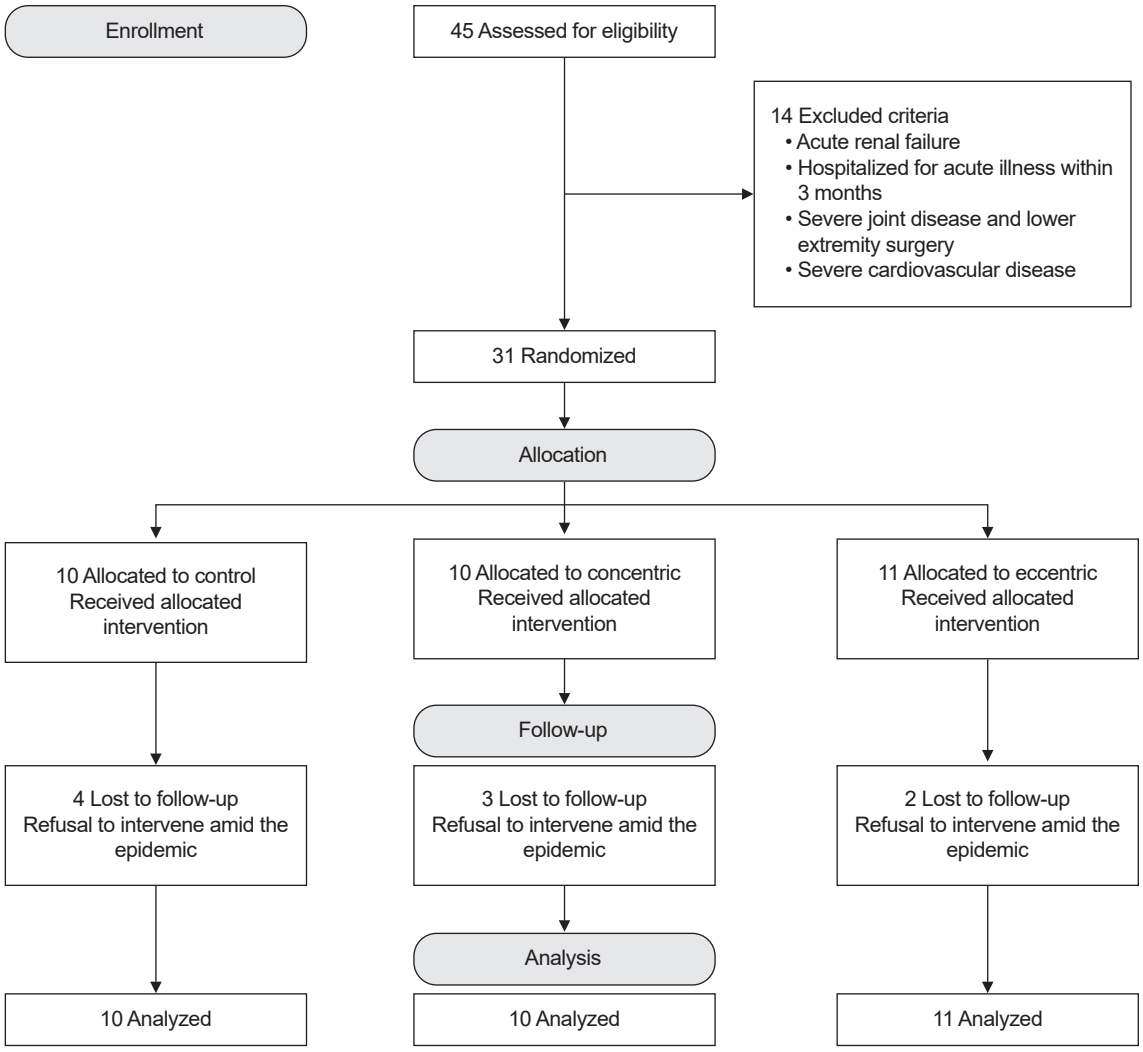

Fig. 2. CONSORT (Consolidated Standards of Reporting Trials) study flow diagram of participants in three groups.

ECC exercise effectively improves aerobic exercise capacity as measured by CPET, including VO_2, oxygen uptake efficiency slope, and minute ventilation to carbon dioxide production

Following an 8-week exercise intervention and a 1-month follow-up, the ECC group demonstrated a significant improvement in cardiopulmonary exercise capacity compared to the CTL and CON groups. Furthermore, the group-by-time interaction analysis revealed that the ECC group showed more significant improvements in specific cardiopulmonary parameters (Supplementary Table S2). The VO_2 max in the ECC group displayed a consistent upward trend across all groups, with significant intragroup variations ($p<0.001$, slope=0.113). A significant group-by-time interaction was observed between the ECC and CTL groups ($p<0.001$). VO_2/HR (oxygen pulse) maximal performance was also higher in the ECC group than in the other two groups ($p<0.001$, slope=0.378). Furthermore, the group-by-time interaction indicated that the ECC group was more beneficial than the CTL ($p<0.001$) and CON ($p<0.001$) groups. The minute ventilation to carbon dioxide production (VE/VCO_2 slope) values at the anaerobic threshold (AT) and maximal stage showed a downward trend in the ECC group, with statistically significant intragroup differences (AT stage, $p<0.001$, slope=-0.151; maximal stage, $p<0.001$, slope=-0.789). Further group-by-time interaction analysis revealed that the ECC group showed statistically significant differences compared to the CTL and CON groups. Moreover, the VE/VCO_2 slope showed the greatest decline in the ECC group compared with the other

groups, with significant differences from the CTL (p<0.001) and CON (p<0.001) groups. For oxygen uptake efficiency slope (OUES), the CON and ECC groups demonstrated a positive trend over time. A statistically significant improvement was observed only in the ECC group (ECC slope=0.036, p<0.001; CON slope=0.012, p=0.32). Moreover, significant group-by-time interaction was found when comparing the ECC group to the CTL group (ECC vs. CTL, p<0.001) (Fig. 3).

ECC improves respiratory functions, enhances diaphragm thickening and expiratory muscle strength

All three groups showed improvements in diaphragm excursion, with the ECC group demonstrating the most significant increase (p=0.001, slope=3.561). Regarding diaphragm thickness fraction, only the ECC group displayed a positive trend and significant intragroup differences (p=0.045, slope=14.585). The between-group analysis showed significant differences between the ECC and the other two groups (ECC vs. CTL, p<0.001) (Fig. 4). In conclusion, diaphragmatic ultrasound results indicated that the ECC group showed the greatest and most statistically significant enhancement. We recognize that diaphragm TF is relatively sensitive to operator technique and breathing pattern, and that small randomized controlled trials may show modest absolute changes with comparatively large SDs. To limit random error, we obtained three measurements for each ultrasound parameter and averaged; a single trained assessor conducted all exams using a standardized protocol. Next, we paid attention to studying respiratory muscle strength in CKD subjects, we found that the CON group showed the most significant improvement in maximal inspiratory pressure (MIP) over time (p<0.001, slope=-5.79). The ECC group had the second-largest improvement, while the CTL group showed the least improvement, with significant intragroup differences (p<0.001, slope=3.401). In addition, the CTL group experienced the most significant decline in maximal expiratory muscle strength at the end of the study, whereas the ECC group had the most minor reduction (CTL, p=0.705, slope=-8.553; ECC, p=0.229, slope=-0.0249). We, therefore, turned to studying the

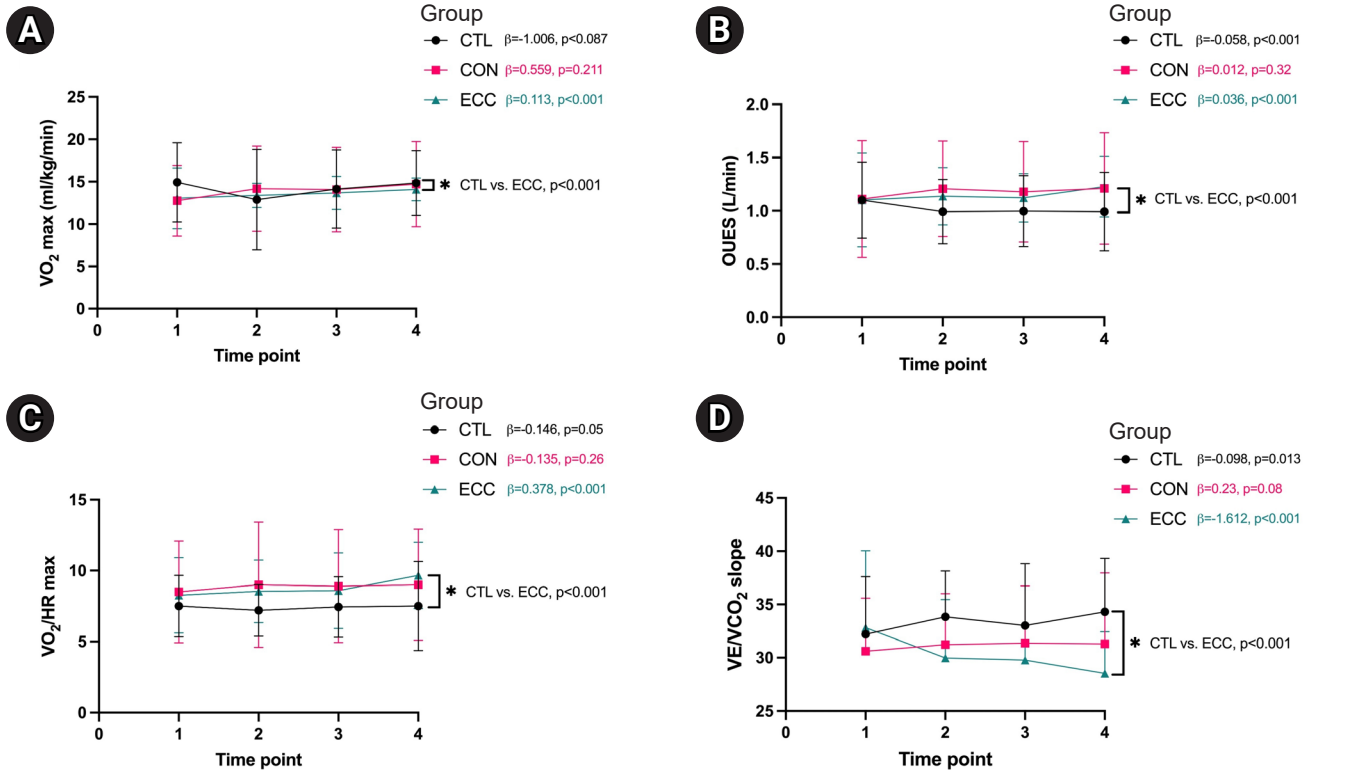

Fig. 3. Changes in cardiopulmonary exercise testing by groups. (A) VO_2 max. (B) OUES. (C) VO_2/HR max. (D) VE/VCO_2 slope. Data are presented as mean±standard deviation. VO_2 max, maximal oxygen uptake; OUES, oxygen uptake efficiency slope; HR, oxygen pulse; VE/VCO_2, minute ventilation to carbon dioxide production; CTL, control; CON, concentric cycling; ECC, eccentric cycling; Time point 1, baseline; Time point 2, 1st month; Time point 3, 2nd month; Time point 4, one-month follow-up. *p<0.05 between group comparison with group by time interaction effect.

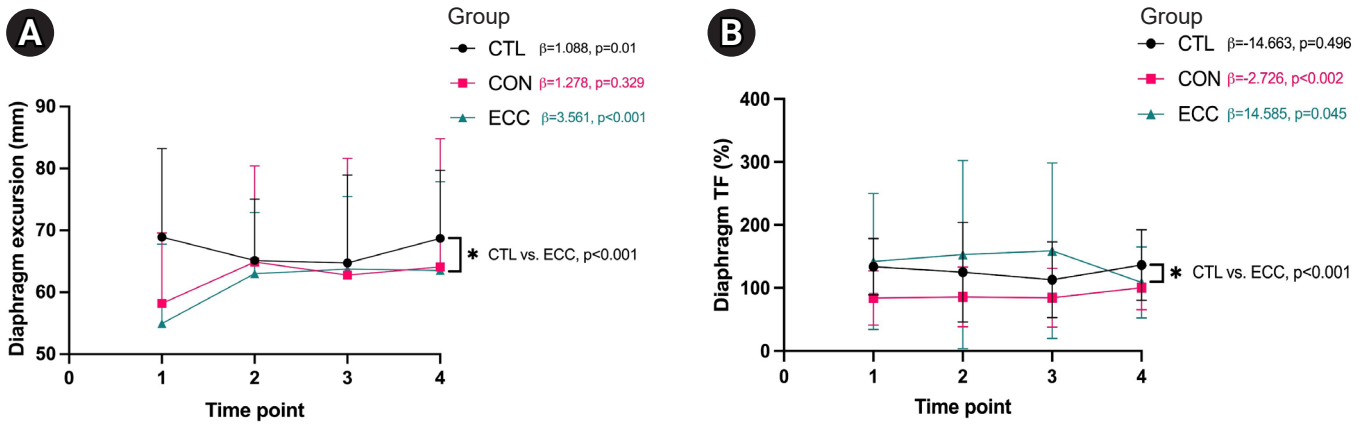

Fig. 4. Changes in diaphragmatic ultrasound by groups. (A) Diaphragm excursion. (B) Diaphragm TF. Data are presented as mean±standard deviation. TF, thickness fraction; CTL, control; CON, concentric cycling; ECC, eccentric cycling; Time point 1, baseline; Time point 2, 1st month; Time point 3, 2nd month; Time point 4, one-month follow-up. *p<0.05 between group comparison with group by time interaction effect.

lung function in CKD subjects. The PFT results revealed that the ECC group outperformed the other two groups in percentage predicted FVC (p=0.001, slope=1.364). The ECC group also performed better in percentage predicted FEV_1 compared to the other groups (p=0.195, slope=1.204), though no significant group-by-time interaction effect was observed. Notably, the CTL group showed the most favorable overall trend in the percentage predicted FEV_1/FVC among the three groups (p<0.001, slope=1.71) (Supplementary Table S3).

ECC exercise's impact on quality-of-life

Each group showed varying changes across the eight subitems. The ECC group demonstrated noticeable improvements in seven items, making it the most improved group overall. The ECC group demonstrated the most significant improvement in PCS and MCS scores, with statistically significant differences compared to the CTL and CON groups. For PCS, the results were as follows: ECC (p<0.001, slope=4.252), CON (p<0.001, slope=-5.371), and CTL (p<0.001, slope=3.572). For MCS, significant differences were observed between ECC and CTL (p=0.003) and between ECC and CON (p=0.01) (Supplementary Table S4).

DISCUSSION

As CKD progresses, physical activity decreases, resulting in a reduced quality of life and increased morbidity and mortality. Studies have shown that regular exercise improves cardiopulmonary, neuromuscular, and cognitive functions in CKD patients, enhancing their quality of life and lowering health risks at all stages of the disease. Despite these benefits, the adoption of exercise programs in clinical settings remains limited [23-25]. Therefore, this study aimed to create a new exercise model based on existing research to identify a more effective training strategy for CKD patients. The findings show that an 8-week ECC program significantly improved aerobic exercise capacity, pulmonary functions, and quality-of-life in individuals with stage 3–5 CKD.

Exercise has shown a significant impact on cardiorespiratory function in CKD patients [26]. A previous study indicated that exercising three times per week for 3 months significantly improved VO_2 in CKD patients, with even more significant improvements in programs lasting over 6 months [10]. Our results align with these findings. Both exercise intervention groups (ECC and CON) showed significant increases in VO_2 max over time. Additionally, a VO_2 peak exceeding 17.5 mL/min/kg strongly predicts survival in CKD patients [27]. Although neither group reached the 17.5 mL/min/kg threshold, both surpassed the clinically significant difference of 1.5 mL/min/kg [28] when comparing the experimental endpoint to the baseline. In contrast, the CTL group showed a significant decline by the experimental endpoint, with significant group-by-time interaction effects observed between the CTL and ECC groups and the CTL and CON groups. These results indicate that exercise interventions improve VO_2 max performance. Notably, the VO_2 max improvement appeared greater in the CON group than in

the ECC group, suggesting the need for further research into the validity of the OUES as an alternative indicator.

OUES is an objective and reproducible method for assessing cardiopulmonary function, serving as a novel indicator of cardiopulmonary functional reserve. It provides stable numerical performance throughout the CPET and reflects the relationship between oxygen uptake and minute ventilation. Combining respiratory, cardiovascular, and musculoskeletal functions into a single index, OUES may offer a more practical and safer alternative to maximal exercise testing, particularly for high-risk patients, such as those with heart failure or CKD [29-32]. A study on patients with end-stage renal disease (ESRD) undergoing hemodialysis after 20 weeks of aerobic exercise training (three times per week) showed that OUES and VO_2 were significantly higher in the training group than in the CTL. Additionally, OUES was strongly correlated with changes in VO_2 max ($r=0.78$, $p<0.001$) [32]. This supports the findings of our study, where the ECC group showed the most significant increase in OUES, which was significantly higher than that of the CTL group. One possible reason for the increase in OUES is a smaller rise in lactate production during exercise. Research has demonstrated that physical training reduces exercise-induced metabolic acidosis, with similar effects observed in both healthy individuals and patients with heart failure [33].

ECC involves muscles working against resistance while lengthening, unlike CON, where muscles shorten during contraction. The efficiency of eccentric contractions enables higher force production with lower energy expenditure, thereby reducing metabolic costs and minimizing lactate accumulation. Moreover, ECC results in a lower cardiopulmonary response at the same absolute power output than CON, leading to decreased blood lactate levels [34,35]. Our experimental results support these findings, demonstrating that cycling training effectively enhances the cardiopulmonary exercise capacity of patients with CKD. ECC enhances the benefits of the OUES by reducing metabolic costs and cardiopulmonary demands more than CON.

Decreased lung function and exercise tolerance in patients with CKD are closely linked to disease progression, malnutrition, anemia, a sedentary lifestyle, and muscle atrophy. Research has shown that reduced contractility in skeletal muscles may also affect respiratory muscles, leading to reduced respiratory muscle strength and worsening ventilation limitations, which further impair respiratory function [36,37]. A study involving patients undergoing hemodialysis at the ESRD stage found that, during dialysis, they completed 24 high-intensity CON exercise sessions, three times per week over 8 weeks. The training group showed better outcomes than the CTL in all respiratory-related measures, including the 6-minute walk test, maximum respiratory pressure, and PFT [36]. We found that the ECC group exhibited the best diaphragm function among the three groups, particularly in diaphragm excursion and diaphragm TF. The diaphragm TF in the ECC group showed significantly more improvement than the CTL and CON groups, highlighting a clear advantage in this measure. While the absolute improvements in diaphragm parameters were modest, the statistical robustness observed suggests that ECC provides a tangible physiological stimulus to the respiratory muscles. These small magnitude changes in ultrasound measures are common in chronic disease populations but are clinically meaningful when associated with improved functional capacity and reduced fatigue. Moreover, the ECC group demonstrated superior maximal expiratory pressure compared to the other groups, further supporting the effectiveness of this intervention. These results differ from those of previous studies, likely due to differences in the type of cycling training used in those studies. Although ECC training has improved muscle strength and functional capacity, its direct effects on respiratory muscle strength are less well-documented than inspiratory muscle training. Unlike targeted respiratory muscle training, which directly focuses on respiratory muscles, ECC primarily enhances skeletal muscle strength, functional capacity, and athletic performance. While it indirectly benefits respiratory function, it may not improve respiratory muscle strength to the same degree as specific respiratory muscle training. However, its lower cardiorespiratory demands and enhanced exercise tolerance help reduce fatigue, allowing for more sustainable exercise to maintain or improve respiratory muscle function over time [15]. Our findings support this phenomenon. Despite not directly targeting respiratory muscles, the reduced metabolic demands of eccentric exercise allow for a higher overall training volume, contributing to improvements in respiratory muscle function, as seen in enhanced diaphragm performance.

Physical activity levels in patients with CKD typically decline as the disease progresses, leading to a reduced quality of life and increased mortality [38]. A previous study showed that a 12-week renal rehabilitation program significantly improved the quality of life in CKD stages 3 and 4, as measured by the SF-36 scale [39]. Additionally, the Dialysis Outcomes and Practice Patterns Study found that higher exercise frequency was positively associated with improvements in both the MCS and

PCS scores of the Kidney Disease Quality-of-Life Short Form in hemodialysis patients [40]. In our study, the ECC group showed an improvement trend in both PCS and MCS scores on the SF-36 scale. Notably, the MCS exhibited the greatest improvement among the three groups, with statistically significant differences compared to the other two groups. Further analysis revealed that, within the "Vitality" item, the ECC group experienced a significant increase, with significant differences observed both within and between groups. These findings suggest that ECC may be more effective in enhancing vitality and overall quality of life in CKD patients.

This study has several limitations. First, the sample size of our study is relatively small, which increases the risk of attrition bias. Second, baseline BMI differences persisted despite adjustment, which may affect statistical power and the generalizability of our findings to the broader CKD population. Third, the 8-week intervention and 4-week follow-up are too short to establish durability, safety, or effects on hard clinical outcomes. Finally, the narrowly defined non-dialysis CKD cohort and use of a single ergometer model constrain reproducibility and broader applicability; larger multicenter trials with longer follow-up are warranted.

In conclusion, our study is the first to investigate the impact of ECC exercise on cardiopulmonary function in patients with CKD. The results show that an 8-week ECC training program significantly improves cardiopulmonary exercise capacity, respiratory functions, and quality of life. Furthermore, ECC showed favorable changes compared with CTL and comparable improvements to CON, with between-group advantages on selected outcomes. Importantly, no adverse effects were observed during the study. These findings offer preliminary evidence supporting ECC exercise as a potential new intervention for CKD patients.

CONFLICTS OF INTEREST

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

FUNDING INFORMATION

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AUTHOR CONTRIBUTION

Conceptualization: Huang YT, Lee HY, Yang HL, Sun CY. Data curation: Huang YT, Cheng HC, Su CC. Resources: Huang YT, Chang YT. Validation: Huang YT, Lee HY, Hung CH, Chang YT, Sun CY. Formal analysis: Lee HY, Cheng HC, Chang YT, Sun CY. Project administration: Lee HY, Hung CH, Tsai KL. Funding acquisition: Cheng HC. Investigation: Yang HL, Hung CH, Chang YT, Tsai KL. Methodology: Yang HL. Supervision: Hung CH, Su CC, Sun CY. Software: Su CC. Visualization: Tsai KL. Writing – original draft: Huang YT, Sun CY, Tsai KL. Writing – review & editing: Tsai KL. Approval of final manuscript: all authors.

DATA AVAILABILITY STATEMENT

The data supporting this study's findings are available from the corresponding author upon reasonable request.

SUPPLEMENTARY MATERIALS

Supplementary materials can be found via https://doi.org/10.5535/arm.250163.

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Predictive Factors Associated With Dysphagia in Patients With Traumatic Brain Injury

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Objective: To identify early clinical predictors associated with dysphagia and delayed swallowing recovery in patients with traumatic brain injury (TBI).

Methods: In this retrospective study, we enrolled adult TBI patients admitted to the rehabilitation unit of a tertiary medical center between June 2019 and June 2023. Data on baseline characteristics, neurological status, imaging findings, and rehabilitation-related variables were collected. Swallowing function was assessed using two indicators: (1) nasogastric (NG) tube retention and (2) the Functional Oral Intake Scale (FOIS) scores at 1, 4, and 12 weeks post-injury. Regression analyses were conducted to identify predictors associated with dysphagia and swallowing recovery.

Results: A total of 160 patients were included. At 1 week post-injury, longer intensive care unit (ICU) stay, poor initial sitting balance and use of sedative medication in ICU were associated with NG tube retention. At 4 weeks, lower initial Rancho Los Amigos Scale (RLAS) scores, immobility-related complications, longer hospitalization, and temporal lobe hematomas were associated with persistent NG tube dependence. By 12 weeks, older age, delayed ability to follow commands, and poor initial sitting balance remained associated with NG tube retention. FOIS outcomes were also associated with older age, delayed time to follow commands, impaired initial sitting balance, prolonged ICU stay, temporal lobe hematomas, lower initial RLAS scores, immobility-related complications, prolonged endotracheal tube placement and extended hospital stays.

Conclusion: Impaired cognitive status, poor physical function, immobility-related complications, and temporal lobe hematomas were key factors associated with dysphagia and delayed oral intake in individuals with TBI.

Keywords: Traumatic brain injury, Dysphagia, Recovery of function, Rehabilitation

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INTRODUCTION

Traumatic brain injury (TBI) is a major cause of long-term disability in adults, often resulting in persistent physical, cognitive, behavioral, and emotional impairments [1]. Dysphagia is a common and clinically significant complication of TBI, affecting a substantial proportion of patients in both acute and rehabilitation settings [2]. The reported prevalence of dysphagia among individuals with TBI varies widely, ranging from 25% to 93% in inpatient rehabilitation settings, with approximately 37% of severe TBI cases failing to regain an unrestricted diet even after prolonged rehabilitation [3,4].

Post-TBI dysphagia results from combined neuromuscular dysfunction, cognitive-communication deficits, and behavioral impairments across different swallowing phases [5-8]. The pathophysiology of dysphagia in TBI is distinct from that observed in stroke and other neurological conditions [9]. Unlike cerebrovascular accidents that typically cause focal brain lesions, TBI often results in a combination of focal injury, diffuse axonal injury, and secondary damage due to hypoxia or raised intracranial pressure [10]. Neuroimaging studies have implicated multiple cortical and subcortical structures, such as the opercular-insular region, basal ganglia, corona radiata, thalamus, and internal capsule, in the control of swallowing [11,12]. However, in contrast to stroke, where lesion location is a primary determinant of dysphagia severity, TBI-related dysphagia is influenced by the diffuse and multifactorial nature of the injury, making prediction and management more complex [9].

Previous studies have identified several factors associated with dysphagia severity and recovery following TBI, including lower Glasgow Coma Scale (GCS) scores, prolonged mechanical ventilation, tracheostomy, reduced cognitive function, and neurosurgical interventions [4,8,9,13-15]. However, much of the existing literature includes heterogeneous neurological populations or focuses on dysphagia at a single time point, limiting conclusions specific to TBI and obscuring how swallowing function evolves during recovery.

Despite an increasing amount of research on dysphagia in TBI, significant gaps still exist in our understanding of its disease progress and key predictive factors for post-TBI dysphagia. Many studies on neurogenic dysphagia include heterogeneous populations, incorporating patients with cerebrovascular accidents, brain neoplasms, or progressive neurological diseases, making it difficult to draw definitive conclusions specific to TBI [9,16,17]. Additionally, while previous studies have identified general predictors of dysphagia, they have not consistently examined its progression at different time points post-TBI [8,18].

Given these considerations, the present study aims to identify prognostic factors for dysphagia recovery in patients with TBI at 1-, 4-, and 12-weeks post-injury. By analyzing neurological, imaging, and rehabilitation-related predictors, we seek to improve the understanding of swallowing dysfunction in TBI, facilitate early intervention, and optimize long-term management, thereby informing more precise rehabilitation strategies.

METHODS

This study was approved by the Institutional Ethics Review Board of National Taiwan University Hospital (IRB No. 202410055RINA). Informed consent was waived by the ethics committee as the study involved retrospective analysis of de-identified data.

Study design

This retrospective study was conducted at a university hospital and included patients admitted to the rehabilitation ward between June 1, 2019, and June 30, 2023. This research followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [19]. Patients were included if they had a confirmed diagnosis of TBI by board-certified physical medicine and rehabilitation physicians, were 20 years or older, and had been admitted to the rehabilitation ward for post-TBI care. Exclusion criteria included a history of brain tumors or prior brain surgeries. Patients determined to be in end-of-life status by two specialists and subsequently placed on palliative care were also excluded.

Data collection

Patient demographics and laboratory findings

Baseline demographic and clinical data were extracted from medical records, including age, sex, body mass index, employment situation, and living status. Pre-existing medical conditions were documented. Additionally, prior neurological disorders, including ischemic stroke, hemorrhagic stroke, previous TBI, and neurodegenerative diseases were recorded. The mechanism of injury, including motor vehicle accidents, falls, assaults, or suicide attempts, along with the presence and type of additional injuries (e.g., maxillofacial trauma, chest or abdominal injuries, pelvic fractures, polytrauma), was reviewed. Baseline laboratory measurements were obtained upon hospital admission.

Hospitalization duration

To align with the clinical care pathway after TBI, hospitalization was categorized into two phases. The acute phase was defined as the interval from emergency department arrival to admission to the inpatient rehabilitation ward. The post-acute phase was defined as the interval from rehabilitation ward admission to hospital discharge. Total hospitalization duration was calculated as the sum of these two phases. All intervals were obtained from the electronic medical record system.

Neurological and imaging characteristics

Neurological status was evaluated using the GCS score upon hospital admission. Additional assessments included coma duration, time to follow commands, RLAS scores at acute admission, and Mini-Mental State Examination (MMSE) scores at acute admission. Time to follow commands was defined as the number of days from injury (or hospital admission) to the first documented ability to consistently follow simple verbal commands, as assessed by the treating rehabilitation team, such as the appropriate response to one-step commands during routine neurological or functional assessments. Data regarding acute management were also extracted, including steroid use in the intensive care unit (ICU), presence of hydrocephalus, placement of external ventricular drains (EVDs), and history of craniectomy or craniotomy. Information on airway management and critical care exposure was additionally collected, including duration of endotracheal tube (ETT) placement, history of tracheostomy during hospitalization, and use of sedative medications in the ICU. Post-traumatic amnesia was obtained from acute-care records and rehabilitation admission notes. Post-traumatic amnesia was defined as a period of impaired memory and disorientation after injury, with resolution determined by the documented return to continuous orientation. When a formal assessment was unavailable, resolution was defined as the first day with physician or nursing documentation of continuous orientation for ≥24 hours. Post-traumatic amnesia was coded as present versus absent at acute admission. Brain computed tomography (CT) scans performed at admission were analyzed for the presence and classification of hematomas, including epidural hematoma (EDH), subdural hematoma (SDH), intracerebral hemorrhage (ICH), subarachnoid hemorrhage (SAH), and intraventricular hemorrhage (IVH). Hematoma location after TBI was categorized as frontal, parietal, temporal, occipital lobes, basal ganglia, brainstem, or cerebellum.

Functional and rehabilitation assessments

Rehabilitation-related variables included time from injury to the first speech therapy session. Dysphagia therapy was delivered by experienced speech-language pathologists and typically provided 5 days per week, with each session lasting approximately 30–45 minutes Swallowing therapy included a combination of compensatory strategies such as postural adjustments and diet texture modification, direct swallowing exercises, oral–motor and sensory stimulation, and caregiver or patient education, as guided by bedside swallowing evaluations. The selection and progression of interventions were individualized based on the patient's level of alertness, cognitive status, swallowing safety, and observed clinical performance, rather than following a fixed protocol. The total number of dysphagia therapy sessions each patient received during hospitalization was recorded. Initial sitting ability was graded using a modified Functional Independence Measure (FIM) scale [20]. Only the helper-dependent categories were used: 5=supervision (subject performs 100%), 4=minimal assistance (≥75%), 3=moderate assistance (≥50%), 2=maximal assistance (≥25%), and 1=total assistance or not testable (<25%). We did not apply the "no-helper" levels (6=modified independence, 7=complete independence). In this study, a score of 5 was classified as normal sitting ability, whereas scores of 1–4 were classified as impaired. Initial sitting balance was assessed utilizing the "sitting-unsupported" item in Berg Balance Scale [21], with a score of 4 indicating normal sitting balance and 0–3 classified as impaired. These assessments were completed within 24–72 hours of rehabilitation admission. Complications of immobility were defined as pneumonia, urinary tract infection, pressure sores, or deep vein thrombosis during hospitalization.

Outcome measurements

The primary outcome was swallowing function, assessed using the Functional Oral Intake Scale (FOIS) at 1-, 4-, and 12-weeks post-injury. Additionally, nasogastric (NG) tube retention at the same time points was documented. No patients underwent gastrostomy during the study period. FOIS scores and NG tube status at 1 and 4 weeks were recorded during inpatient hospitalization. At 12 weeks, follow-up data were obtained from outpatient visits or, for patients transferred, through standardized telephone interviews conducted by speech-language pathologists or research staff. The FOIS, which uses an ordinal scale, assigns scores of 1–3 to indicate tube-dependent feeding, while scores of 4–7 reflect varying levels of oral intake, either with or without dietary modifications [22].

Statistical analysis

Descriptive statistics were reported for baseline characteristics, neurological, imaging, and rehabilitation-related variables. The normality of continuous variables was analyzed with Shapiro–Wilk test. The outcome measures included NG tube dependence as a binary variable and FOIS scores as an ordinal variable (levels 1–7). Associations with FOIS were examined using ordinal logistic regression, assuming proportional odds across FOIS categories. The reported odds ratios (ORs) represent cumulative ORs, indicating the odds of being at or below a given FOIS threshold, corresponding to worse swallowing function, for each one-unit increase in the predictor variable. Variables were prespecified based on prior literature and clinical relevance [8,10,23,24]. The univariable ordinal logistic regression/logistic regression screened all candidate predictors against FOIS and NG outcomes at 1, 4, and 12 weeks (screening threshold: $p<0.05$), followed by multivariable analysis using bidirectional stepwise selection on variables that passed screening, with entry and removal criteria both set at $p<0.05$. The stepwise procedure automatically evaluated each variable's independent contribution while controlling for other variables, retaining only those maintaining significance in the presence of other predictors. Although no variables were forced to remain in the final models, most clinically relevant factors (such as admission RLAS scores and ICU length of stay) reached significance in univariable analysis and were therefore included as candidate variables, indicating concordance between clinical importance and statistical selection. We also performed sensitivity analyses by excluding potential mediators, including ICU length of stay and total hospitalization duration, and re-estimated the multivariable models accordingly. We also performed subgroup analyses comparing outcomes across TBI severity groups defined by the GCS (mild 13–15, moderate 9–12, severe 3–8). Differences in NG tube retention were evaluated with the chi-square test, and differences in FOIS scores with the Kruskal–Wallis test, given the ordinal nature of FOIS score. A p-value<0.05 was considered statistically significant. All statistical analyses were carried out using SAS software (version 9.4, SAS Institute).

RESULTS

Baseline characteristics

The baseline characteristics of the 160 patients with TBI are summarized in Table 1. These patients represent the final eligible cohort after systematic screening and exclusion, as detailed

Table 1. Baseline characteristics of the study population

Parameter	Value (n=160)
Demographic and baseline status	
Age (yr)	66.04±18.91
Sex, male	108 (67.50)
Body mass index (kg/m^2)	23.27±3.82
Premorbid mRS 0–2	141 (88.13)
Unemployed	8 (5.00)
Living alone	17 (10.63)
Medical history	
Hypertension	91 (56.88)
Diabetes mellitus	51 (31.88)
Dyslipidemia	36 (22.50)
Psychiatric disease	8 (5.00)
Neurodegenerative disease	32 (20.00)
Prior ischemic stroke	20 (12.50)
Prior hemorrhagic stroke	6 (3.75)
Previous TBI	19 (11.88)
History of alcohol abuse	7 (4.38)
Initial laboratory data	
Hemoglobin (g/dL)	12.28±2.13
Platelet count (10^3/μL)	240.80±102.88
White blood cell count (10^3/μL)	10.58±4.36
Blood glucose (mg/dL)	161.13±68.02
C-reactive protein (mg/dL)	6.61±13.06
TBI-related characteristics	
Presence of additional injuries	54 (33.75)
Initial GCS score	13 [7]
TBI severity classification	
Mild (GCS 13–15)	84 (52.50)
Moderate (GCS 9–12)	36 (22.50)
Severe (GCS 3–8)	40 (25.00)
Initial RLAS score	5 [1]
Initial MMSE score	17 [12]
Duration of coma (day)	0.45±1.79
Time to follow command (day)	4.48±11.16
ICU length of stay (day)	9.12±9.77
Use of steroids in ICU	37 (23.12)
Use of sedative medication in ICU	87 (54.38)
Duration of ETT placement (day)	1.47±5.13
History of tracheostomy during hospitalization	5 (3.13)
Hydrocephalus	28 (17.50)
EVD placement	13 (8.13)
Craniectomy	23 (14.38)
Craniotomy	35 (21.88)
Seizures	28 (17.50)
Post-traumatic amnesia	121 (75.63)
Immobility-related adverse events	74 (46.25)
Total hospitalization duration (day)	53.44±33.32
Duration from ER admission to rehabilitation ward admission (day)	21.72±19.39
Duration from rehabilitation ward admission to discharge (day)	29.37±12.79
Acute care transfer during rehabilitation	7 (4.38)

(Continued on the next page)

Table 1. Continued

Parameter	Value (n=160)
Hemorrhage type	
EDH	18 (11.25)
SDH	114 (71.25)
ICH	77 (48.13)
SAH	107 (66.88)
IVH	11 (6.88)
Multiple hemorrhages	46 (28.75)
Hematoma location	
Frontal lobe	133 (83.13)
Parietal lobe	75 (46.88)
Temporal lobe	110 (68.75)
Occipital lobe	11 (6.88)
Basal ganglia	5 (3.13)
Brainstem	3 (1.88)
Cerebellum	6 (3.75)
Rehabilitation-associated characteristics	
Onset-to-first ST time (day)	16.44±16.79
ST sessions	25.48±12.55
Initial sitting ability	1 [2]
Normal	5 (3.13)
Initial sitting balance	2 [2]
Normal	30 (18.75)
Cause of injury	
Motor vehicle accident	69 (43.13)
Fall	88 (55.00)
Assault	1 (0.63)
Suicide attempt	2 (1.25)
Swallowing-related parameters	
FOIS score at 1 week	1 [4.5]
FOIS score at 4 weeks	3 [6]
FOIS score at 12 weeks	7 [1]
NG retention at 1 week	113 (70.62)
NG retention at 4 weeks	82 (51.25)
NG retention at 12 weeks	33 (20.63)

Values are presented as mean±standard deviation, number (%), or median [IQR] as appropriate.
IQR represents the difference between the 75th and 25th percentiles (Q3-Q1).
mRS, modified Rankin Scale; TBI, traumatic brain injury; GCS, Glasgow Coma Scale; RLAS, Rancho Los Amigos Scale; MMSE, Mini-Mental State Examination; ICU, intensive care unit; ETT, endotracheal tube; EVD, external ventricular drain; ER, emergency room; EDH, epidural hematoma; SDH, subdural hematoma; ICH, intracerebral hemorrhage; SAH, subarachnoid hemorrhage; IVH, intraventricular hemorrhage; ST, swallowing therapy; FOIS, Functional Oral Intake Scale; NG, nasogastric; IQR, interquartile range.

in the study flow diagram (Supplementary Fig. S1). The mean age was 66.04±18.91 years, and 67.50% of the patients were male. Most patients (88.13%) had an independent premorbid functional status, defined as a modified Rankin Scale score of 0–2. None of the patients had NG tube placement or received dysphagia therapy within 1 month before the TBI.

The most prevalent comorbidities were hypertension (56.88%), diabetes mellitus (31.88%), and dyslipidemia (22.5%). Additionally, 20% of patients had a neurodegenerative disease, and 11.88% had a history of prior TBI. Neurological assessments showed a median initial GCS score of 13, with 52.5% of patients classified as having mild TBI, 22.5% as moderate, and 25.0% as severe. Neuroimaging findings revealed that SDH was the most common hemorrhage type (71.25%), followed by SAH (66.88%) and ICH (48.13%); 28.75% of patients had multiple hemorrhage types. The frontal (83.13%), temporal (68.75%), and parietal (46.88%) lobes were the most frequently affected regions.

The mean total hospitalization duration was 53.44±33.32 days, comprising a mean of 21.72±19.39 days from emergency department arrival to rehabilitation ward admission (acute phase) and 29.37±12.79 days from rehabilitation ward admission to discharge (post-acute phase). During the rehabilitation stay, 7 patients (4.38%) required acute care transfer: 5 patients (3.1%) to the internal medicine ICU (2 for septic shock and 3 for respiratory failure) and 2 patients (1.3%) to the neurosurgery ICU due to deterioration of neurological status. Among patients receiving dysphagia therapy, the mean time from admission to initiation of therapy was 16.44±16.79 days. The total number of dysphagia therapy sessions during hospitalization was 25.48±12.55 sessions on average.

Swallowing function assessments demonstrated progressive improvement in FOIS scores over time, with a median score of 1 at 1 week, 3 at 4 weeks, and 7 at 12 weeks. The proportion of patients requiring NG tube feeding declined from 70.62% at 1 week to 51.25% at 4 weeks and 20.63% at 12 weeks.

Factors related to NG tube retention at 1, 4, and 12 weeks

Univariate analysis identified several factors significantly associated with NG tube retention at 1 week, including a lower initial GCS score (OR 0.760, p=0.0007), lower initial RLAS score (OR 0.603, p=0.002), lower initial MMSE score (OR 0.924, p=0.011), and longer ICU stay (OR 1.283, p<0.001). A longer time to follow commands (OR 1.316, p=0.018), the presence of post-traumatic amnesia (OR 2.921, p=0.008), and use of sedative medication in ICU (OR 2.428, p=0.019) were also identified as potential risk factors. Additionally, patients with additional injuries (OR 3.010, p=0.016) and those with temporal lobe hematomas (OR 3.520, p=0.001) had a significantly higher likelihood of NG tube dependence. Rehabilitation-related factors,

including reduced initial sitting ability (OR 0.569, p<0.001) and impaired initial sitting balance (OR 0.513, p<0.001), were also associated with NG tube retention (Supplementary Table S1). Multivariate analysis confirmed that longer ICU stay (adjusted OR [aOR] 1.196, p=0.003), impaired initial sitting balance (aOR 0.581, p=0.006), temporal lobe hematoma (aOR 2.857, p=0.043) and use of sedative medications in ICU (aOR 3.068, p=0.032) were independently associated with NG tube retention at 1 week (Table 2).

At 4 weeks (Supplementary Table S2), univariate analysis identified lower hemoglobin levels, lower initial GCS score, lower initial RLAS score, and lower initial MMSE score as factors significantly associated with NG tube retention. Additionally, patients with hydrocephalus, EVD placement, seizures, post-traumatic amnesia, sedative medication use in ICU and complications of immobility were at increased risk of prolonged NG tube dependence. A longer time to follow commands, extended ICU stay and longer hospitalization duration were also associated with persistent NG tube dependence. Furthermore, temporal lobe hematomas and delayed initiation of speech therapy were significant factors. Rehabilitation-associated characteristics, including impaired initial sitting ability and reduced initial sitting balance, were predictive of prolonged NG tube retention. Multivariate analysis further demonstrated that lower initial RLAS score (aOR 0.566, p=0.022), complications of immobility (aOR 2.842, p=0.033), longer hospitalization duration (aOR 1.044, p<0.001), and temporal lobe hematomas (aOR 3.005, p=0.038) were independently associated with NG tube retention at 4 weeks (Table 2).

At 12 weeks (Supplementary Table S3), univariate analysis identified several factors significantly associated with prolonged NG tube retention. These included older age, lower initial RLAS score, lower initial MMSE score, longer time to follow commands, and extended ICU stay. Structural and clinical factors such as the presence of hydrocephalus, EVD placement, prolonged ETT placement, history of tracheostomy during hospitalization, craniectomy, seizures, post-traumatic amnesia, and complications of immobility also showed strong associations with prolonged NG tube dependence. Additionally, longer total hospitalization duration and temporal lobe hematomas remained significant predictors. The cause of injury was a significant predictor, with falls associated with a higher risk of prolonged NG tube dependence. Rehabilitation-related factors, including delayed initiation of speech therapy, impaired initial sitting ability, and poor initial sitting balance, were also associated with poor swallowing outcomes. Multivariate analysis further demonstrated that older age (aOR 1.211, p=0.004), delayed time to follow commands (aOR 1.129, p=0.005), and poor initial sitting balance (aOR 0.175, p=0.005) were independently associated with NG tube retention at 12 weeks (Table 2). In addition, sensitivity analyses excluding potential mediators, including ICU length of stay and total hospitalization duration, yielded consistent directions of association for the main predictors of NG tube retention at 1, 4, and 12 weeks (Supplementary Table S4).

Table 2. Multivariate stepwise analysis of factors associated with NG tube retention at 1, 4, and 12 weeks

Parameter	Adjusted OR (95% CI)	p-value
NG tube retention at 1 week		
ICU length of stay (per day)	1.196 (1.065–1.344)	0.003**
Initial sitting balance (per point)	0.581 (0.394–0.857)	0.006*
Temporal lobe hematoma (yes vs. no)	2.857 (1.035–7.890)	0.043*
Use of sedative medication in ICU (yes vs. no)	3.068 (1.103–8.539)	0.032*
NG tube retention at 4 weeks		
Initial RLAS score (per point)	0.566 (0.348–0.920)	0.022*
Complications of immobility[a] (yes vs. no)	2.842 (1.088–7.426)	0.033*
Total hospitalization duration (per day)	1.044 (1.019–1.068)	<0.001**
Temporal lobe hematoma (yes vs. no)	3.005 (1.064–8.490)	0.038*
NG tube retention at 12 weeks		
Age (per year)	1.211 (1.065–1.377)	0.004**
Time to follow command (per day)	1.129 (1.037–1.230)	0.005**
Initial sitting balance (per point)	0.175 (0.052–0.589)	0.005**

NG, nasogastric tube; ICU, intensive care unit; RLAS, Rancho Los Amigos Scale; OR, odds ratio; CI, confidence interval.
*p<0.05 and **p<0.01.
[a]Complications of immobility included pneumonia, urinary tract infection, deep vein thrombosis, and pressure ulcer.

Factors related to lower FOIS levels at 1, 4 and 12 weeks

In the univariate analysis for lower FOIS levels at 1 week, several factors were significantly associated with lower FOIS scores, including a lower initial GCS score (OR 0.931, p=0.001), lower initial RLAS score (OR 0.852, p<0.001), lower initial MMSE score (OR 0.970, p=0.009), presence of additional injuries (OR 1.360, p=0.014), and longer ICU stay (OR 1.077, p<0.001). Patients with post-traumatic amnesia (OR 1.357, p=0.004), longer hospitalization duration (OR 1.006, p=0.011), use of sedative medications in ICU (OR 1.273, p=0.017), and temporal lobe hematomas (OR 1.430, p<0.001) had a significantly higher risk

of poor oral intake. Rehabilitation-related factors, such as poor initial sitting ability (OR 0.855, p<0.001) and poor initial sitting balance (OR 0.822, p<0.001), were also associated with lower FOIS scores (Supplementary Table S5). In the multivariate analysis, longer ICU stay (aOR 1.079, p=0.001), temporal lobe hematoma (aOR 1.694, p=0.008), poor initial sitting balance (aOR 0.789, p=0.002) and use of sedative medication in ICU (aOR 1.503, p=0.041) were independently associated with lower FOIS levels at 1 week (Table 3).

For FOIS levels at 4 weeks (Supplementary Table S6), univariate analysis identified lower hemoglobin levels, lower initial RLAS score, lower initial MMSE score, longer time to follow commands, longer ICU stay, and longer hospitalization duration as factors associated with lower FOIS scores. Additionally, the presence of hydrocephalus, EVD placement, seizures, prolonged ETT placement, post-traumatic amnesia, and complications of immobility were associated with worse FOIS outcomes. Temporal lobe hematomas and delayed initiation of speech therapy further increased the risk of poor swallowing function. The mechanism of injury demonstrated a significant correlation with FOIS scores, with falls being associated with an increased risk of poor swallowing recovery. Rehabilitation-related factors, including poor initial sitting ability and poor initial sitting balance, were also correlated with lower FOIS scores. Multivariate analysis demonstrated that lower initial RLAS score (aOR 0.854, p=0.004), presence of complications of immobility (aOR 1.265, p=0.031), longer hospitalization (aOR 1.009, p<0.001), and temporal lobe hematoma (aOR 1.324, p=0.017) were independently associated with lower FOIS scores at 4 weeks (Table 3).

For FOIS levels at 12 weeks (Supplementary Table S7), univariate analysis demonstrated that older age, lower initial RLAS score, and lower initial MMSE score were associated with worse swallowing function. Additionally, a longer time to follow commands, extended ICU stay, presence of hydrocephalus, prolonged ETT placement, history of tracheostomy during hospitalization, EVD placement, craniectomy, post-traumatic amnesia, and complications of immobility significantly increased the risk of persistent dysphagia. Temporal lobe hematomas, delayed initiation of speech therapy, poor initial sitting ability, and poor initial sitting balance were also correlated with lower FOIS scores. The cause of injury was also significantly associated with lower FOIS scores, with falls linked to a higher risk of poor swallowing recovery. In the multivariate analysis, older age (aOR 1.069, p=0.004), delayed time to follow commands (aOR 1.116, p=0.001), presence of complications of immobility (aOR 4.067, p=0.042), poor initial sitting balance (aOR 0.322, p=0.002) and prolonged ETT placement (aOR 1.131, p=0.003) were independently associated with lower FOIS scores at 12 weeks (Table 3). Similarly, sensitivity analyses excluding potential mediators, including ICU length of stay and total hospitalization duration, yielded consistent directions of association for the main predictors of FOIS outcomes at 1, 4, and 12 weeks (Supplementary Table S8).

Table 3. Multivariate stepwise analysis of factors associated with lower FOIS level at 1, 4, and 12 weeks

Parameter	Adjusted OR (95% CI)	p-value
Lower FOIS level at 1 week		
ICU length of stay (per day)	1.079 (1.030–1.131)	0.001**
Temporal lobe hematoma (yes vs. no)	1.694 (1.146–2.505)	0.008**
Initial sitting balance (per point)	0.789 (0.680–0.916)	0.002**
Use of sedative medication in ICU (yes vs. no)	1.503 (1.017–2.221)	0.041*
Lower FOIS level at 4 weeks		
Initial RLAS score (per point)	0.854 (0.767–0.951)	0.004**
Complications of immobility[a] (yes vs. no)	1.265 (1.022–1.566)	0.031*
Total hospitalization duration (per day)	1.009 (1.004–1.014)	<0.001**
Temporal lobe hematoma (yes vs. no)	1.324 (1.052–1.666)	0.017*
Lower FOIS level at 12 weeks		
Age (per year)	1.069 (1.021–1.119)	0.004**
Time to follow command (per day)	1.116 (1.048–1.188)	0.001**
Complications of immobilitya) (yes vs. no)	4.067 (1.050–15.763)	0.042*
Initial sitting balance (per point)	0.322 (0.159–0.649)	0.002**
Duration of ETT placement (per day)	1.131 (1.044–1.226)	0.003**

FOIS, Functional Oral Intake Scale; ICU, intensive care unit; RLAS, Rancho Los Amigos Scale; ETT, endotracheal tube; OR, odds ratio; CI, confidence interval.
*p<0.05 and **p<0.01.
[a]Complications of immobility included pneumonia, urinary tract infection, deep vein thrombosis, and pressure ulcer.

NG tube retention rates and FOIS scores stratified by TBI severity

Subgroup analyses stratified by TBI severity revealed significant differences in swallowing outcomes (Supplementary Table S9). For NG tube retention, patients with moderate and severe TBI showed substantially higher dependence than those with mild TBI: at 1 week, rates were 58.75%, 90.91%, and 89.74% in the mild, moderate, and severe groups, respectively (p<0.001); at 4 weeks, the corresponding rates were 41.46%, 63.64%, and 66.67% (p=0.012); and at 12 weeks, 15.58%, 32.26%, and 27.50% (p=0.111). FOIS scores also differed across groups, with

a significant group effect at 1 week ($p<0.001$) but not at 4 weeks ($p=0.164$) or 12 weeks ($p=0.512$).

DISCUSSION

Our study identified several factors associated with dysphagia recovery following TBI. Prolonged NG tube retention was significantly associated with ICU length of stay, impaired initial sitting balance, temporal lobe hematoma and use of sedative medication in ICU at 1 week; lower initial RLAS score, complications of immobility, longer hospitalization duration, and temporal lobe hematomas at 4 weeks; and older age, delayed time to follow commands, and impaired initial sitting balance at 12 weeks. Similarly, lower FOIS scores were independently linked to ICU length of stay, temporal lobe hematomas, impaired initial sitting balance and use of sedative medication in ICU at 1 week; lower initial RLAS score, complications of immobility, longer hospitalization duration, and temporal lobe hematomas at 4 weeks; and older age, delayed time to follow commands, complications of immobility, poor initial sitting balance and prolonged ETT placement at 12 weeks. According to our study, multiple factors are associated with swallowing dysfunction, emphasizing the complex and multifactorial nature of post-TBI dysphagia.

Our findings are consistent with previous studies showing that cognitive impairment is a key factor influencing dysphagia recovery in patients with TBI [8,9]. In our study, lower initial RLAS scores were significantly associated with NG tube placement at 4 weeks and lower FOIS scores at 4 weeks post-TBI. Deficits in cognitive-communication and behavioral regulation can compromise swallowing safety through impaired attention, awareness, and executive control, leading to delayed swallow initiation, poor adherence to safe swallowing strategies, and increased aspiration risk [8,9,25]. Previous research has consistently demonstrated an association between cognitive function and swallowing safety [7,14,18,26]. Terré and Mearin [18] reported a significant correlation between cognitive impairment and swallowing dysfunction in patients with TBI, noting deficits in tongue control, prolonged oral transit time, and an increased risk of penetration, as evaluated separately using RLAS and videofluoroscopy. Similarly, Mackay et al. [14] identified RLAS as an independent predictor of both the initiation and attainment of total oral feeding. A retrospective chart review further showed that lower RLAS scores were common among non-oral feeders, with recovery of oral intake paralleling cognitive improvement over time [2]. However, early TBI-related physiological and procedural factors, such as head and neck trauma, endotracheal intubation, ventilator dependence, and tracheostomy, may have contributed to swallowing dysfunction [13,15]. These factors may account for the absence of a significant association between initial RLAS score and dysphagia at 1 week post-TBI in our study.

Our study found that temporal lobe hematomas were independently associated with NG tube placement at 1 and 4 weeks and FOIS scores at 1and 4 weeks post-TBI. The temporal lobe has been implicated in cognitive, sensory, and integrative processes that may influence swallowing performance [27]. Deficits in attention, awareness, or comprehension may interfere with timely swallow initiation and adherence to swallowing instructions, particularly in the early recovery phase [28,29]. Sensory processing disturbances may further affect bolus control and swallowing responses [9]. In addition, the temporal lobe is anatomically connected with regions involved in swallowing control, including the insula, frontal lobe, and brainstem; disruption of these networks may contribute to delayed or inefficient swallowing [9,30]. However, the present study did not include lesion volumetry, laterality-specific analyses, or instrumented swallowing measures, which limits the ability to determine the specific pathways underlying this association. In patients with TBI, common findings from videofluoroscopic swallow study (VFSS) demonstrated aspiration or penetration, reduced laryngeal elevation, and impaired epiglottic inversion [8]. These patterns suggest that dysphagia in patients with TBI involves both oral-phase impairments and pharyngeal dysfunction. As cognitive function improves, swallowing function may also recover [9], which may explain why temporal lobe hematomas were not significantly associated with dysphagia at 12 weeks post-TBI in our study. Interestingly, the type of hematoma (e.g., SDH, EDH, ICH, SAH, IVH) was not significantly associated with dysphagia outcomes in our study, consistent with findings from a previous study [8]. This contrasts with findings from stroke-related research, where ICH volume and the presence of IVH were key predictors of swallowing dysfunction [31,32]. The absence of such an association in our TBI cohort may be attributed to the diffuse and multifocal nature of brain injury in TBI [9], in contrast to the more localized lesions seen in stroke [32]. Swallowing deficits in TBI are often the result of widespread cortical and subcortical damage rather than the effects of a single focal hematoma [16]. This finding demonstrates the intricate relationship between injury mechanisms, lesion distri-

bution, and dysphagia severity in patients with TBI.

Our study demonstrated a significant association between impaired sitting balance and prolonged post-TBI dysphagia. In patients with TBI, early structured interventions are essential for improving overall functional recovery and facilitating swallowing rehabilitation [33]. Sitting balance evaluation provides crucial insights into trunk stability, which is a key determinant of motor and functional recovery [34]. Beyond postural control, sitting balance may also represent an integrated functional marker encompassing arousal, attention, and motor coordination, all of which are essential for safe and effective swallowing [35]. Adequate trunk stability supports optimal head and neck alignment and facilitates coordinated activation of swallowing-related musculature, potentially contributing to improved airway protection [36]. Furthermore, previous studies have identified FIM scores recorded at admission as reliable predictors of oral feeding recovery throughout the rehabilitation process [37].

These findings emphasize the need for early functional assessments and personalized rehabilitation plans to optimize motor recovery and support dysphagia rehabilitation in individuals with TBI.

Interestingly, GCS score, a commonly used predictor of TBI severity, was not independently associated with dysphagia outcomes in our study. This differs from previous research, where lower GCS scores were linked to prolonged dysphagia [4,14,15]. The discrepancy may be due to differences in study populations, as our cohort included 52.5% patients with mild TBI (GCS 13–15), whereas prior studies predominantly examined patients with moderate-to-severe TBI [4,14,15]. In our healthcare system, patients with mild TBI may still be admitted for inpatient rehabilitation when they present with clinically significant functional impairments, such as dysphagia, cognitive-communication deficits, or balance limitations. Therefore, although classified as mild by GCS, many of these patients had substantial functional limitations that warranted inpatient rehabilitation. This suggests that GCS alone may not fully capture the complexity of swallowing impairment in a heterogeneous TBI population. At the same time, our severity-stratified analyses demonstrated a clear gradient in early swallowing outcomes, with higher NG tube dependence and worse FOIS scores at 1 week in moderate and severe TBI, and attenuation of these differences by 12 weeks. Taken together, these findings indicate that injury severity influences early dysphagia, but its effect is partially mediated or modulated by other clinical factors over the course of recovery. Consistent with this interpretation, prolonged ICU stays, complications of immobility, and extended hospitalization were associated with worse dysphagia outcomes in our multivariable models. These findings suggest that post-TBI dysphagia may be associated not only with the severity of the initial injury but also with ventilation dependence, tracheostomy, surgical interventions, and secondary complications [5,8,15]; however, some of these factors may also arise as consequences of persistent dysphagia or a prolonged recovery course rather than acting as independent predictors. In our cohort, tracheostomy and neurosurgical procedures occurred predominantly among patients with moderate-to-severe TBI, as expected, whereas prolonged dysphagia was less common in mild TBI but could still be observed in selected individuals with associated injuries, cognitive-communication deficits, or medical complications. Therefore, TBI-related dysphagia results from a combination of cognitive, structural, and medical factors rather than being solely determined by the initial injury severity.

In our study, EVD placement, craniectomy, seizures, and the presence of hydrocephalus were significantly associated with poorer swallowing outcomes in univariate analysis but did not remain significant in the multivariate model. This suggests that while these factors may contribute to dysphagia, their effects are likely mediated by other underlying variables, such as the severity of neurological impairment, CT findings, cognitive dysfunction, ventilation status, and associated complications [3,15,18]. Previous studies have highlighted that severe neuroimaging abnormalities requiring surgical intervention, such as midline shift, extensive hemorrhage, or brainstem involvement, are associated with an increased risk of dysphagia in patients with TBI [18]. The need for EVD placement and craniectomy often arises from low GCS scores and increased intracranial pressure [38], both of which reflect severe brain injury rather than serving as independent predictors of prolonged swallowing dysfunction. Similarly, hydrocephalus impairs cognition and motor control, and may disrupt corticospinal and corticobulbar tracts, which play a crucial role in coordinating swallowing reflexes and airway protection [39]. Seizures have also been reported as a risk factor for post-TBI dysphagia, likely due to their association with cortical excitability changes, transient hypoxia, and disruptions in sensorimotor control [40]. Additionally, patients experiencing recurrent seizures often require prolonged sedation, mechanical ventilation, and ICU stays, exacerbating oropharyngeal muscle deconditioning and aspiration risk [41]. While EVD placement, craniectomy, seizures, and hydroceph-

alus were associated with dysphagia in univariate analysis, their lack of significance in multivariate analysis suggests that their impact on swallowing function is mediated by the overall severity of brain injury and prolonged hospitalization.

Airway management and critical care–related factors were also associated with swallowing outcomes in this study. Prolonged ETT placement, tracheostomy during hospitalization, and sedative medication use in the ICU were associated with NG tube retention as well as poorer FOIS outcomes at specific time points. These factors may contribute to dysphagia through mechanisms such as laryngeal trauma, reduced sensory input, impaired airway protection, and deconditioning related to prolonged critical illness [42,43]. However, given the retrospective design, these variables may also represent markers of greater injury severity or more complicated clinical courses rather than independent causal factors.

Regional differences in enteral feeding practice should be considered when interpreting our findings. In many Western centers and in gastroenterology guidelines, NG tubes are typically used for short-term enteral access, with transition to percutaneous devices (e.g., gastrostomy or jejunostomy) recommended when feeding is expected to exceed approximately four weeks [44]. By contrast, prolonged NG feeding remains more common in many Asian centers, including our facility, due to a combination of anticipated swallowing recovery within the subacute period, temporary contraindications to percutaneous access, institutional protocols, and patient or family preferences [31]. Consistent with this pattern, no patients in our cohort underwent gastrostomy tube placement during the study period, and we therefore used NG tube retention as an indicator of prolonged dysphagia.

Our study has several limitations. First, as a retrospective, single-center study, it is susceptible to selection bias and missing data, which may have influenced our findings. Second, although clinically relevant key covariates were selected based on prior literature, the multivariable analyses incorporated a stepwise selection procedure. Stepwise modeling may be sensitive to sample-specific variation and is associated with risks of multicollinearity, model instability and overfitting; therefore, the identified associations should be interpreted as exploratory and associative rather than causal. Third, the limited number of patients restricts the generalizability of our results to broader TBI populations, and the results are most applicable to similar inpatient rehabilitation settings; generalizability to acute-care, outpatient, or other healthcare systems may be limited. The case mix, including a substantial proportion of mild TBI, may also influence effect estimates. Another important limitation is the inconsistent availability of standardized instrumental swallowing assessments, such as VFSS and fiberoptic endoscopic evaluation of swallowing. As a result, we relied primarily on clinical evaluations, NG tube dependency, and FOIS outcomes, which may underestimate the true prevalence and severity of dysphagia and limit detailed characterization of swallowing physiology. Future research should incorporate prospective, multicenter studies with standardized swallowing assessments to enhance the accuracy, validity and clinical applicability of these findings.

Conclusion

In conclusion, our study identified key factors associated with dysphagia recovery in patients with TBI, including age, ICU length of stay, initial RLAS score, initial sitting balance, complications of immobility, hospitalization duration, and temporal lobe hematomas. Early assessment and targeted rehabilitation are essential to improve swallowing outcomes and guide clinical management.

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: Yang SM, Lin MT. Methodology: Yang SM, Lai TJ, Lin MT. Formal analysis: Yang SM, Lai TJ, Lin MT. Investigation: Hsu YC, Cheng SH. Data curation: Lu YL, Chen HY, Tsai HT. Funding acquisition: Lin MT. Project administration: Yang SM, Lai TJ, Lin MT. Visualization: Yang SM, Lai TJ, Lin MT. Validation: Yang SM, Lai TJ, Lin MT. Supervision: Yang SM, Lai TJ, Hsiao MY, Lin MT. Writing – original draft: Yang SM, Hsu YC, Lin MT. Writing – review and editing: Yang SM, Lin MT. Approval of final manuscript: all authors.

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DATA AVAILABILITY STATEMENT

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

SUPPLEMENTARY MATERIALS

Supplementary materials can be found via https://doi.org/10.5535/arm.250157.

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Electrode Placement and Continence Outcomes in Pediatric Hirschsprung's Disease: Rectal Versus Surface Stimulation After Trans-Anal Pull-Through Surgeries

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Objective: To compare the outcome of rectal and surface electrode stimulation, when performed concomitantly with routine anal sphincter (AS) exercises and bio-feedback training, in children who have received corrective surgery to address Hirschsprung disease (HD).

Methods: Sixty-seven patients (pediatric) who underwent corrective surgery due to HD were randomly assigned to Group A (rectal electrode, n=34) or Group B (surface electrode, n=33). The two groups were given the same protocols of AS and bio-feedback training. The Pediatric Quality of Life Inventory (PedsQL), Bowel Function Score (BFS), Pediatric Incontinence and Constipation Scoring System Scale (PICSS) were measured at baseline, post intervention and follow-up.

Results: There were significant improvements in both groups over time across all outcomes. PedsQL increased (d=0.42–1.28, η^2p up to 0.37), BFS improved notably (d=1.21, η^2p=0.35), and PICSS decreased (d up to 1.15, η^2p=0.33). The greatest gains occurred from baseline to follow-up, with smaller but significant changes from post-treatment to follow-up, indicating sustained effects.

Conclusion: Electrical stimulation with rectal electrodes, combined with AS exercises and bio-feedback training, is a major way of improving bowel functioning, continence and quality of life in Hirschsprung child. Such results highlight the promise of multimodal rehabilitation and should be supported by additional multicenter studies.

Keywords: Hirschsprung disease, Child, Electric stimulation, Anal sphincter, Rehabilitation

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INTRODUCTION

Fecal incontinence (FI) is a clinically debilitating complication, which is normally caused by an underlying abnormality, operative procedure or a neurological deficiency [1]. The most common surgery that is performed to treat Hirschsprung disease

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(HD) is the transanal pull-through surgery (TAPTS) [2]. HD is a congenital absence of ganglion cells in the distal intestine. Despite the effectiveness of these procedures in restoring bowel continuity, postoperative FI is a frequent and painful complication that exposes patients to severe physical, emotional, and social disabilities [3].

There is geographical variation in the rate of FI in pediatric populations. Reported rates in high-income Western countries are 0.8%–4.1%, but in the few Asian countries, the incidences are 2%–7.8% [4]. There is limited epidemiological evidence on this topic in Egypt, which implies that postoperative FI is very common in this country after TAPTS of HD; nonetheless, there is a lack of large-scale studies on the topic nationwide [5].

FI has adverse effects on the quality of life (QOL), daily functioning, socialization, and education. Children suffer psychological trauma, humiliation and social isolation, which translate to low self-esteem, depression and anxiety [6].

Treatment of FI involves conservative and rehabilitative modes, such as behavioral training, biofeedback, and pelvic floor muscle training [7]. Electrical stimulation (ES) also seems to have the most potential, as it might help to increase the tone of the anal sphincter (AS), neuromuscular coordination, and voluntary bowel control [8]. The method may be performed through rectal electrodes directly stimulating external and internal sphincters or surface electrodes, which is a less invasive instrument [9]. The training of the AS is one of the essential elements in the rehabilitation process of FI, which is performed to enhance the external AS, improve the voluntary control, and bring functional benefits. There are maximum voluntary contractions (MVCs), rapid contractions, endurance holds and coordinated breathing exercises [10].

Since the AS training and ES may be potentially useful, but the body of comparative literature on the use of surface electrodes versus rectal electrodes placement in pediatric FI after TAPTS in HD is limited, the comparison between the efficacy of these modalities is urgently required. This kind of research would help to develop evidence-based, standardized rehabilitation guidelines, which result in the highest level of continence and QOL. On this basis, the current study aimed at contrasting the impact of rectal and surface electrode ES with and without AS exercise in children with postoperative FI [11,12]. The main aim was to determine the most effective intervention to improve sphincter performance, decrease the instances of incontinence and improve QOL. The results can be used to generate powerful clinical evidence to direct practice in pediatric physiotherapy as well as influence national rehabilitation policies and eventually reduce the psychosocial burden of FI among children with HD.

METHODS

Study design

The study was a prospective randomized controlled trial with a parallel-group design that compared the effectiveness of rectal versus surface electrode ES that was used in combination with AS exercises and biofeedback training in managing FI in children who had undergone TAPTS to treat HD. The researchers adopted a pre-test/post-test design whereby outcome assessment was done at baseline, after an 8-week intervention period, and later at a 12-week follow-up period after the study was over.

Sample size calculation

G*Power (version 3.1.9.7) was used to calculate the sample size with a primary hypothesis of a difference in time x group interaction in a repeated-measures design. A medium effect size (Cohen's f=0.25; synonymous with d=0.5) was chosen as the design parameters based on the findings of previous clinical trials assessing ES and biofeedback as bowel and pelvic-floor rehabilitation interventions in children [13]. G*Power analysis revealed that 60 participants would be needed to reject the null hypothesis and accept the alternative hypothesis that there is a specified group x time interaction, given that there are two groups and three measurement occasions (baseline, post-treatment, and follow-up) and 2 tails of alpha=0.05 and that there is a sphericity correction (1). To consider the possibility of attrition and maintain power, the sample size was increased by 10% to give the final target of 67 subjects (Group A, n=34; Group B, n=33).

Study setting

The study was implemented along a span of 9 months, between January and September 2025 at the outpatient clinic of the Faculty of Physical Therapy, Cairo University. The recruitment of the participants from Cairo University Hospitals after thorough examination and conclusive diagnosis by qualified and licensed pediatricians and consultants. The Institutional Review Board of the Faculty of Physical Therapy, Badr University in Cairo gave this research ethical approval (approval no.: IRB00014233-2) before the study was conducted. The study was registered as a clinical trial on the Pan African Clinical Trials Registry (PACTR) under the registration number PACTR202510484282271

(website: pactr.samrc.ac.za). The study followed the principles of ethics that were established in the Declaration of Helsinki and its further amendments. Informed consent was signed by parents or legal guardians of all the participating children after giving them a clear description of the study goals, procedures, risks, and pros that would be expected. The participants were assured that their personal information be disclosed and that they had the right to pull out of the study at any given time.

Participants

Sixty-seven children aged 6–14 years, who participated in this study, specified that they had persistent FI after TAPTS to correct HD. The participants were selected among a group of the patients diagnosed with the condition but had already received the specified operation, were in good health, and had given their consent and a recommendation of a pediatric surgeon and pediatrician to take part in the rehabilitation program. Each of the participants showed the ability to obey and understand the simple instructions and the necessary cooperation. The inclusion criteria were that there must be at least six months of FI after the operation. The exclusion criteria included any of the following: patients with neurological conditions that impact on continence, other congenital anomalies that might affect bowel function, severe intellectual disability which might exclude participation, perianal or gastrointestinal infection or dermatologic condition, and absence of informed or parental consent. Thus, the group that included a rectal electrode received AS exercises and biofeedback training (Group A) included 34 participants, whereas the group that received a surface electrode, and the use of AS exercises and biofeedback training (Group B) included 33 participants.

Randomization and allocation

The study (Group A) and control (Group B) groups were assigned participants in a computer-generated randomizing list, to prevent possible bias, opaque sealed envelopes with the randomization results were prepared by a non-involved team member. The opening of each envelope was done only when the intervention was initiated, which prevented any effect of the results by the enrolling clinician. Outcome assessors and data analysts were blinded where possible to the allocation of groups of participants. Assessment data was coded to prevent unintentional revelation of allocation status.

Outcome measures

Primary outcome:

(1) The Bowel Function Score

Bowel Function Score (BFS) is a strictly validated tool that has been used to assess the bowel capability and fecal continence in pediatric and clinical groups. Empirical evidence has supported its content validity, and sensitivity to clinically significant levels of change across time. Moreover, the BFS is highly reliable, which is proven by the fact that there is no significant variation in the results of tests conducted in succession and among different raters in case of following the standard set of instructions. Domains measured on the scale include the rate of soiling, stool features, the effects of the day-to-day activities and the QOL, and the possibility of the management plans. The scores are added to create a composite index with higher scores indicating more functioning although the delimiting of scores differs across versions [14]. In this trial the measurements were conducted at baseline, the post-intervention eight weeks later, and twelve weeks follow-up.

Secondary outcomes:

(1) Pediatric Incontinence and Constipation Scoring System

The Pediatric Incontinence and Constipation Scoring System (PICSS) is an effective instrument of the diagnosis and monitoring of the severity of FI and constipation in children, which has high reliability in the assessment of urinary incontinence and bowel activity [15]. Its construct validity is supported by its correlation with conventional measures of continence and constipation, and is responsive to clinically significant changes over time. The tool is especially useful due to the high incidence of bowel and bladder dysfunction in the pediatric urology clinic [16,17]. Additionally, a number of instruments have high levels of discriminative properties, but few have critically reviewed responsiveness or incorporated patient-reported bother rating, without which a full evaluation of symptom impact is incomplete. An evaluation was performed at baseline, mid-treatment (eight weeks of intervention), and follow-up (12 weeks after the intervention).

(2) Pediatric Quality of Life Inventory

Pediatric Quality of Life Inventory (PedsQL) is a standardized tool that is applied in measuring health-related QOL among children on key domains including physical, emotional, social, and school functioning. The Arabic adaptation has been culturally modified and demonstrated to be dependable, positively

valid and responsive to clinical change thus making it appropriate to Arabic-speaking pediatric patients. The assessment periods normally include baseline (pre-intervention), a midpoint assessment (eight weeks of intervention) and follow-up (12 weeks post-intervention) [18].

Intervention protocol

Electrical stimulation

(1) Group A (rectal electrode)

Intrarectal ES was conducted by a rectal pediatric probe that is modeled to reduce cross-infection. The probe was placed at an appropriate depth in the rectum slightly above the AS with the reference electrode at a more proximal position along the rectal wall to maximize dispersion of current and minimize mucosal irritation. A single-channel Chattanooga electrical stimulator (Austin) was used to provide stimulation with a pulse width of 200 μs and a frequency of 35 Hz. The duty cycle was 4 seconds contraction and 12 seconds relaxation (1:3 ratio) and 2 seconds ramp-up and 2 seconds ramp-down time to allow the patient to be comfortable and muscle to be gradually recruited. Intensity was adjusted to 8–15 mA to produce visible or palpable contraction of the pelvic floor muscle without pain to ensure the patient felt no pain, which was verified by both the therapist and the patient. The 15-minute duration of the session was chosen on the basis of previous clinical experience in pelvic floor stimulation in children where session durations are usually reported ranging between 5–30 minutes in order to produce effective neuromuscular response without causing undue patient discomfort and intolerability. Normal precautions of infection-control, such as perineal cleansing, sterile disposable probe use, and high hygiene standards were adhered to. Positioning of patients, checking of electrode positioning, step-wise adjustment of current, constant monitoring of patient comfort, and post-treatment evaluation of hygiene were part of every session. The sessions were three times a week in eight weeks.

Intrarectal ES was done with safety and tolerability in mind due to the pediatric population. A disposable sterile-covered rectal probe of small diameter with a smooth surface was utilized to lessen the discomfort and decrease the risk of infection. Gradual intensity increase, constant therapist supervision, and constant communication between the child and the caregiver in each session ensured acceptability. The adverse events were preemptively observed during the study, such as pain, mucosal irritation, bleeding, or any indication of infection. No side effects were noted and all participants went through the intervention with no complications meaning that under supervision, the rectal ES was well tolerated and clinically safe.

(2) Group B (surface electrode)

The position of the electrodes on the perianal surface was at the 3 o'clock position and 9 o'clock position to the anal border which helped facilitating the flow of current and reducing stimulation of the anal mucosa. The settings used were: one channel output, pulse width of 200 μs and a frequency of 35 Hz. The intensity is adjusted to 8–15 mA depending on patient tolerance and confirmed by palpation or contraction and the intervention delivered thrice per week in eight weeks and each session lasts 40 minutes. At the same time, children were also taught to make voluntary contractions of the AS. Before starting this procedure, perineum is washed using soap and water, hands were disinfected, and single-use and sterile materials were used. The skin is tested on whether it is irritated or not and results recorded as tolerated or not tolerated with continuous evaluation on whether it is painful or intolerable. Sessions were followed by placing the patient in a private, clean environment where a comprehensive observation of the patient was conducted, where the investigator verified the electrode placement and device settings, gradually increase the amperage to a comfortable level to the patient, and a final clean-up was done before documentation.

Anal sphincter exercise program (both groups)

The exercise regime is divided into three parts that were performed during the session to address the various functions of the pelvic floor: MVCs were exercises that involve a contraction of the AS in 5 seconds and a relaxation period of 10 seconds, performed 10 times each set, with 3 sets per session; quick contractions, or quick flicks, involved using rapid contractions of 1-second length with 1-second relaxation, 15 times each set; endurance holds involved using a sustained contraction up to 10 seconds. The exercises were to take place three times a week in an eight-week course.

Biofeedback training (both groups)

Every biofeedback session lasted approximately 40 minutes and had a well-planned procedure to ensure both the safety of the participants and consistency. All sessions were guided by a qualified pediatric physiotherapist who applied a surface electromyography biofeedback equipment (Myo Trace 400 of Medical Measuring Instruments). Electrodes were carefully put

around the anal canal (3 o'clock and 9 o'clock positions) with a reference electrode on the left thigh to measure the muscle activity. Foot supports were used to ensure the children were in a comfortable and effective position which resembles a natural defecation position with the hips bent approximately at 90 degrees. Such a position aided in the engagement of pelvic floor muscles. The visual feedback offered to the children during the session came in the form of engaging and animated computer games and made the experience a fun and motivating one.

The preparation time and the time to change the electrodes and to calibrate the system were 5 minutes. The core of the session was various exercises, MVCs for 5 minutes, quick contractions, so-called quick flicks for 5 minutes, and endurance holds for 5 minutes. During these exercises, the children were able to observe their muscle action in the screen which enabled them to know how to shape and train their pelvic floor muscles. Then it came to a short cool-down and eventually a final check, which took approximately 5 minutes. Key information such as the success of the child in adhering to the program and other problems such as pain or skin irritation was documented, which occupied several minutes after each session. To facilitate the continuation of the progress outside the clinic, simple exercises at home were also taught to the children to perform at least 15 minutes a day. These were exercises that comprised of the muscle contractions of 10 seconds and relaxation of 30 seconds, with the parents being the assisting eyes. Compliance was followed up with the daily diaries and frequent check-ups.

The in-clinic program was well designed to assimilate biofeedback with, where applicable, synchronous ES. The exercises were gradually advanced to warm-up then to MVCs, rapid flicks, endurance holds. At home children were advised to do 1 to 3 sets of 10 contractions every day depending on the comfort and age.

Statistical analysis

All the statistical analysis had been performed using SPSS version 26.0 (IBM Corp.). Continuous variables were measured in terms of mean and standard deviation, the frequencies and percentages were used to measure the categorical data. The tests on the normality of distribution were performed with Shapiro-Wilk test. Repeated-measures analysis of variance (ANOVA) was conducted for within-group comparisons at the three time points (baseline, post-intervention, and follow-up). The differences between groups were analyzed using mixed-model ANOVA to obtain the main effect times, group and time×group and what their interaction was. Post-hoc pairwise tests were adjusted to Bonferonni test to identify the source of significant effects. Cohen's d calculated was used to estimate a pairwise contrast effects, and partial eta squared was used to estimate ANOVA outcomes. Effect sizes for all outcome measures were calculated using Cohen's d to quantify the magnitude of the intervention effect. Effect sizes were considered small ($d \geq 0.2$), medium ($d \geq 0.5$) or large ($d \geq 0.8$). Furthermore, it can be reported in order to assess clinical relevance in addition to statistical significance. The level of statistical significance considered below 0.05.

RESULTS

Participants

One hundred and ninety children were eligibly screened. Of them, 20 refused to join the study, and 89 patients were evaluated to be included. Among them, 22 of the participants failed to pass the inclusion criteria and were eliminated before the randomization process.

The other 67 eligible subjects were randomly assigned to two treatment groups (34 Group A [rectal electrode stimulation] and 33 Group B [surface electrode stimulation]).

There was no dropout of any of the participants in the treatment period or in the follow-up evaluation and hence all the randomized individuals finished the study and were incorporated in the final analysis.

No side effects of the interventions during the treatment or follow-up were reported. In particular, none of the participants experienced pain, discomfort, skin irritation, and exacerbation of the symptoms.

No significant differences in baseline demographic and anthropometric characteristics of the participants were noted between the two groups. Group A and Group B had a mean age of 8.6±2.7 and 8.9±2.5, respectively. There was also no statistically significant difference between groups in body mass index, body weight, or height ($p>0.05$).

Sex was equally distributed with the same number of males and females in both groups. Statistical analysis showed that no significant differences in the baseline outcome measures between the rectal and surface electrode conditions were found, which proves that the process of randomization was successful and the likelihood of confounding factors was minimized (Table 1).

Outcomes

Bowel function (BFS)

The BFS showed a significant improvement in both groups after the intervention. The subjects also reported better bowel control and decrease in the frequency of incontinence episodes.

Nevertheless, Group A showed significantly more improvement than Group B, especially at the follow-up examination, indicating more long-term therapeutic advantages of rectal electrode stimulation (Tables 2-4).

Quality of life (PedsQL)

The two groups showed a significant increase in QOL scores (PedsQL) after the treatment program. Nonetheless, Group A

Table 1. Baseline characteristics of the study participants

Variable	Group A (rectal electrode, n=34)	Group B (surface electrode, n=33)	p-value
Age (yr)	8.6±2.7	8.9±2.5	0.72
Weight (kg)	28.4±6.2	27.9±5.9	0.81
Height (cm)	127.5±10.8	128.2±11.1	0.79
Body mass index (kg/m^2)	17.3±2.1	17.0±2.2	0.68
Sex			0.84
Male	19 (55.9)	18 (54.5)	
Female	15 (44.1)	15 (45.5)	
Symptom duration (mo)	13.4±4.6	12.9±4.9	0.63
Bowel movements per week	2.1±0.8	2.2±0.9	0.71
Soiling episodes/week	3.4±1.2	3.1±1.3	0.58
Abdominal pain	11 (32.4)	10 (30.3)	0.85
Use of laxatives	9 (26.5)	8 (24.2)	0.82

Values are presented as mean±standard deviation or number (%).
The independent samples t-test was used to obtain p-values on continuous variables, and the chi-square test was used to obtain p-values on categorical variables.

Table 2. Comparison of outcomes between groups at baseline, post-treatment, and follow-up

Outcome	Time	Group A	Group B	p-value	Cohen's d
PedsQL	Baseline	62.4±8.5	61.8±9.2	0.79	
	Post	78.9±7.6	71.2±8.1	<0.001*	0.82
	Follow-up	76.3±8.0	69.4±8.5	0.001*	0.71
BFS	Baseline	8.2±2.1	8.4±2.3	0.70	
	Post	13.7±2.3	11.1±2.0	<0.001*	0.98
	Follow-up	12.9±2.5	10.6±2.3	<0.001*	0.76
PICSS	Baseline	24.6±4.5	23.9±4.7	0.54	
	Post	15.8±3.9	18.6±4.1	0.004*	0.58
	Follow-up	16.2±4.1	19.1±4.2	0.005*	0.56

Values are presented as mean±standard deviation.
PedsQL, Pediatric Quality of life Inventory; BFS, Bowel Function Score; PICSS, Pediatric Incontinence and Constipation Symptom Score.
*p<0.05 was considered significant.

Table 3. Repeated measures ANOVA for study outcomes across time (baseline, post, and follow-up)

Outcome measure	Source of variation	F (df)	p-value	(Cohen's d)	(η^2p)
PedsQL	Time	32.45 (2, 130)	<0.001*	1.21	0.33
	Group	5.87 (1, 65)	0.018*	0.60	0.08
	Time×Group	4.96 (2, 130)	0.009*	0.50	0.07
BFS	Time	41.26 (2, 130)	<0.001*	1.36	0.39
	Group	6.72 (1, 65)	0.012*	0.64	0.09
	Time×Group	6.11 (2, 130)	0.003*	0.57	0.09
PICSS	Time	27.89 (2, 130)	<0.001*	1.08	0.30
	Group	4.35 (1, 65)	0.041*	0.51	0.06
	Time×Group	3.72 (2, 130)	0.027*	0.46	0.05

F (df) is F-value and associated degrees of freedom of each effect.
Time effect is an intra-group variation in terms of baseline, post-intervention, and follow-up.
Group effect indicates the differences between groups.
Time×Group interaction demonstrates changes in the two groups differed in the study period.
Cohen's d is a measure of the standardized effect size.
Analysis of variance (ANOVA) effect size is given by η^2p (partial eta squared).
PedsQL, Pediatric Quality of life Inventory; BFS, Bowel Function Score; PICSS, Pediatric Incontinence and Constipation Symptom Score.
*p<0.05 was considered significant.

Table 4. Pairwise comparisons of outcomes across time with effect sizes

Outcome measure	Comparison	MD (95% CI)	p-value	Cohen's d	(η^2p)
PedsQL	Baseline vs. Post	12.4 (9.1, 15.7)	<0.001*	1.05	0.31
	Baseline vs. Follow-up	15.8 (12.2, 19.4)	<0.001*	1.28	0.37
	Post vs. Follow-up	3.4 (0.5, 6.3)	0.022*	0.42	0.06
BFS	Baseline vs. Post	3.6 (2.4, 4.8)	<0.001*	0.92	0.27
	Baseline vs. Follow-up	5.1 (3.7, 6.5)	<0.001*	1.21	0.35
	Post vs. Follow-up	1.5 (0.3, 2.7)	0.014*	0.44	0.07
PICSS	Baseline vs. Post	-4.8 (-6.2, -3.4)	<0.001*	0.88	0.26
	Baseline vs. Follow-up	-6.9 (-8.5, -5.3)	<0.001*	1.15	0.33
	Post vs. Follow-up	-2.1 (-3.4, -0.8)	0.003*	0.49	0.07

The values were given in terms of mean difference (MD) and associated 95% confidence intervals (CIs).
The terms baseline, post, and follow-up were used to refer to measurements performed prior to intervention, at the time of intervention completion and after 3 months follow-up respectively.
The post hoc mixed-model analysis of variance (ANOVA) was used to calculate p-values based on post hoc pairwise comparisons after Bonferroni test.
Cohen's d is the standardized effect size of Cohen.
The ANOVA effect size is denoted as η^2p.
Mean differences were positive showing improvement whereas those showing negative reflecting reduction of symptoms with time.
PedsQL, Pediatric Quality of life Inventory; BFS, Bowel Function Score; PICSS, Pediatric Incontinence and Constipation Symptom Score.
*p<0.05 was considered significant.

(rectal electrode) showed much higher improvements than the surface electrode group.

The PedsQL scores of post-treatment and follow-up were significantly better in Group A than Group B ($p<0.05$) reflecting better overall quality of life improvement.

Repeated measures analysis indicated that there was a significant time effect, PedsQL scores improved significantly at the baseline, post treatment and follow-up assessments, indicating both short-term and long-term treatment effects. The effect sizes (both η 2 and partial eta 2) were large, which meant that the changes were significant in clinical terms (Tables 3, 4).

Incontinence severity (PICSS)

The two groups had a substantial decrease in Pediatric Incontinence Clinical Scoring System (PICSS) scores, which depict a lowered frequency and intensity of FI.

The decrease was highly observed in the rectal electrode group where Group A had lower PICSS scores at the post-treatment and follow up than Group B ($p<0.05$). These results show that rectal electrode stimulation achieved better continence outcomes (Tables 3, 4).

All outcomes were calculated to give effect sizes to supplement the significance testing. In PedsQL, BFS, and PICSS, the rectal electrode group experienced significant effect sizes. The Cohen's d revealed large time effects (PedsQL 1.21, BFS 1.36, PICSS 1.08) and moderate group (0.51–0.64) and time×group (0.46–0.57) effects, with significant improvements, especially in the intervention group. These results proved that the changes in bowel function, continence, and quality of life were statistically significant but also clinically meaningful.

DISCUSSION

The current research explored the effectiveness differences of rectal electrode and surface electrode ES with sphincter training exercises and biofeedback training in children with FI after TAPTS for HD. Findings showed that both treatment groups had significant improvement of health-related QOL, bowel functioning, and continence score with greater and longer-term improvement in the rectal electrode group. These results underlined the possible importance of rectal stimulation to be applied in a more targeted way and stimulate more specifically the AS and PFM.

The change in PedsQL scores in this study can be attributed to the overall effect of fecal continence on psychosocial health. It has been highlighted in the previous research that children with HD tend to have a poor QOL because their bowel functions remain dysfunctional, and they suffer social embarrassment and bullying [19,20]. Through improved continence, children were relieved physically, enhanced self-esteem, and social inclusion. QOL outcome effect sizes in the current trial were large, which highlighted the clinical significance of changes.

There was a substantial enhancement in the BFS over time, especially in the rectal electrode group. The results were in concurrence with previous reports that neuromodulation and ES have the potential of improving the contractility and endurance of the AS, resulting in improved fecal control [21]. A rectal electrode can generate more local and efficient stimulation of the internal and external AS, and hence, the neuromuscular re-education is facilitated more successfully by the rectal electrode than the surface electrode [22]. This justification is further supported by the differences found between the groups at follow-up.

The PICSS demonstrated the same result of decrease in the severity of the symptoms, indicating that the ES together with sphincter training can be effective in the reduction of incontinence and constipation-related complaints. These findings were consistent with other studies that have reported that a combination of muscular and neuromodulation approaches produces better results relative to a conservative management approach [23].

The current research supported and built on the existing body of literature on the topic of conservative rehabilitation of postoperative FI that is biofeedback, combined with pelvic-floor and AS training has always produced improvement in the continence scores, anorectal manometric measurements, and QOL indices in pediatric patients who still manifest symptoms after anorectal surgery [24].

Our results were consistent with those of Zhang et al., 2022 [25], who recorded improved resting and squeeze pressures after biofeedback in children who had anorectal malformations repaired, and were supported by an extensive review by Caldas Afonso et al., 2024 [26], who defined the mechanistic benefits of neuromuscular re-education. More importantly, this research added new evidence by showing that rectal electrode stimulation, combined with sphincter exercises, provides the best results compared to surface stimulation combined with AS exercises and biofeedback, which proved the increased physiological effectiveness of the rectal modality. These findings were also consistent with adult data (Elsawy et al., 2025 [27]), where-

by biofeedback and physiotherapy yielded significant improvements in functional outcomes and QOL after colorectal surgery. All of these findings supported the effectiveness of organized, exercise-based neuromuscular rehabilitation as the initial adjunctive treatment in the postoperative children with HD before the use of invasive interventions.

Direct effect of treatments was supported by comparisons of results between the baseline and post-treatment results, which demonstrated the most significant changes. The effects of treatment did not show instant results but kept on changing over time, in the course of the follow-ups, which is a sign of long-term effects of the treatments. These long-term effects are of clinical importance because the long-term QOL and continence are the most important outcomes in the rehabilitation of children with HD.

An interesting point related to the present study is the continuity of the benefits at the follow-up. The long-term gains indicated that the intervention brings not only short-term benefits, but also makes it possible to induce long-term neuromuscular changes. It is crucial in pediatric populations, where lasting results are a prerequisite to normal growth and social adaptation. Prolonged benefits can also minimize the necessity of repeated interventions that would decrease the burden of treatment among children and families.

The current results showed evident clinical relevance in addition to statistical significance. The extent of the health-related quality of life improvement was marked because the mean improvements in the PedsQL scores in the rectal stimulation group were greater than the previously established minimal clinically important difference in pediatric population. It showed that the changes that had been observed could be not only statistically significant but also significant in terms of patient-centered view. Furthermore, these findings were backed up by functional outcomes, with an increased percent of children in the rectal stimulation group moving to clinically improved continence groups on the basis of BFS and PICSS interpretive thresholds. All of these results indicated that intrarectal ES had clinically significant effects on functional bowel control and overall quality of life after pull-through surgery in HD.

Although the results were promising, a number of shortcomings need to be mentioned. Participants self-reported compliance with home-based sphincter exercises, which might have differed among the participants. These results should be further confirmed in more multicenter trials and objective exercise adherence measures in future research. Besides, a follow-up of the eight-week treatment aided in the determination of the sustainability of the gains into adolescence and adulthood.

The study gave valuable clinical insights as it supported the effectiveness of rectal electrode stimulation as an adjunctive therapy in children with postoperative FI in the rehabilitation phase following HD. Incorporation of these interventions in the rehabilitative procedures of pediatrics can assist in overcoming the physical, the psychological, and social problems related to this HD.

Future studies can include objective monitoring tools, including digital adherence monitoring, to make the research more accurate. A sham-stimulation or no-treatment control group was not used in the study, and this could have prevented the separation of the particular contribution of ES with the effect of placebo or natural recovery. These weaknesses should be overcome in future research by using larger and more heterogeneous samples, extending the follow-up period, and by providing strong control conditions. Moreover, the further investigation of the most effective stimulation plans, electrode shapes, and combinations with behavioral therapy might be used to optimize specific rehabilitation protocols. Investigations on patient and caregiver experience would also be valuable to find out the real-life acceptability and long adherence.

Conclusion

This study had shown that ES, especially through rectal electrodes, is an effective treatment of bowel motility, continence and quality of life in children undergoing a corrective surgery to treat HD. Tolerance of the intervention was high and the benefits were long-term at follow-up. Additional support of neuromuscular re-education and functional outcome was provided by incorporating AS exercises and biofeedback training. The inclusion of these modalities in the conventional rehabilitation strategies can help maximize the long-term outcomes and psychosocial growth.

CONFLICTS OF INTEREST

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

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None.

AUTHOR CONTRIBUTION

Conceptualization: Elgohary H. Methodology: Ahmed S. Formal analysis: Ahmed F. Visualization: Abutaleb E. Writing – original draft: Elgohary H, Ahmed S. Writing – review and editing: Elgohary H, Ahmed S, Salem S, Ahmed F, Abutaleb E, Eldesoky M. Approval of final manuscript: all authors.

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Instructions for authors

Annals of Rehabilitation Medicine

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The journal encompasses all aspects of physical medicine and rehabilitation, including basic, translational, clinical, and policy research, as well as rehabilitation education. Research areas covered by this journal include rehabilitation for brain disorders, spinal cord injuries, neuromuscular diseases, and dysphagia; cancer, cardiopulmonary, geriatric, pain & musculoskeletal, and pediatric rehabilitation; electrodiagnosis, orthosis & prosthesis, physical therapy, and sports medicine; and other emerging fields in rehabilitation medicine.

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

Journals

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.

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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.

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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 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.

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☐ 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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