ORIGINAL ARTICLE

Cyclic Functional Electrical Stimulation Does Not Enhance Gains in Hand Grasp Function When Used as an Adjunct to OnabotulinumtoxinA and Task Practice Therapy: A Single-Blind, Randomized Controlled Pilot Study

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ABSTRACT. Weber DJ, Skidmore ER, Niyonkuru C, Chang C-L, Huber LM, Munin MC. Cyclic functional electrical stimulation does not enhance gains in hand grasp function when used as an adjunct to onabotulinumtoxinA and task practice therapy: a single-blind, randomized controlled pilot study. Arch Phys Med Rehabil 2010;91:679-86.

Objective: To determine whether onabotulinumtoxinA injections and task practice training with or without functional electrical stimulation (FES) improve upper limb motor function in chronic spastic hemiparesis.

Design: Randomized controlled trial.

Setting: Outpatient spasticity clinic.

Participants: Participants (N=23) had chronic spastic hemiparesis with moderate-severe hand impairment based on Chedoke-McMaster Assessment greater than or equal to 2.

Interventions: OnabotulinumtoxinA injections followed by 12 weeks of postinjection task practice. Participants randomly assigned to FES group were also fitted with an orthosis that provided FES.

Main Outcome Measures: Motor Activity Log (MAL)–Observation was the primary outcome. Secondary outcomes were Action Research Arm Test (ARAT) and MAL-Self-Report.

Results: For the entire cohort, MAL-Observation mean item scores improved significantly from baseline to week 6 (P=.005) but did not remain significant at week 12. MAL-Self-Report mean item scores improved significantly (P=.009) from baseline to week 6 and remained significantly higher (P=.014) at week 12. ARAT total scores also improved significantly from baseline to week 6 (P=.018) and were sustained at week 12 (P=.032). However, there were no significant differences between the FES and no-FES groups for any outcome variable over time.

Conclusions: Rehabilitation strategies that combine onabotulinumtoxinA injections and task practice therapy are feasible and effective in improving upper-limb motor function and reducing spasticity in patients with chronic spastic hemiparesis. However, the cyclic FES protocol used in this study did not increase gains achieved with the combination of onabotulinumtoxinA and task practice alone.

Key Words: Botulinum toxins; Electric stimulation; Muscle spasticity; Recovery of function; Rehabilitation; Stroke.

STROKE IS THE LEADING cause of disability in the United States, with an estimated 795,000 new or recurrent cases of stroke each year.[1] About 55% to 75% of stroke survivors sustain impaired upper extremity function, although with routine interventions, only about 12% of survivors recover fully within 6 months of injury.[2,3] Unfortunately, the vast majority continue to experience upper extremity impairment 6 months poststroke and beyond, with little or no prospect for additional motor improvement after that.

Task-oriented practice is effective for promoting motor recovery after chronic stroke and TBI.[4,5] In clinical practice, task practice protocols involve the development of home exercise programs using 4 to 5 activities chosen by the therapist to match the patient's interests. However, the level and quality of participation in task practice activities may be limited for persons with moderate to severe muscle weakness and/or spasticity, prompting the need for adjunctive treatments to augment hand grasp function during activity-based training.

Concurrent treatments for muscle spasticity and weakness have the potential to improve gains made during task practice in persons with spasticity. For example, intramuscular injections of onabotulinumtoxinA, a U.S. Food and Drug Administration–approved medication for cervical dystonia that

List of Abbreviations

ARAT	Action Research Arm Test
CI	confidence interval
EMG	electromyogram
FES	functional electrical stimulation
MAL	Motor Activity Log
MAS	Modified Ashworth scales
OT	occupational therapy
TBI	traumatic brain injury

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Supported by an unrestricted grant from Allergan, Inc; the National Institutes of Health Post-Doctoral Training grants (Training Rehabilitation Clinicians for Research Careers, grant no. T32 HD049307) and Career Development Training (Comprehensive Opportunities for Rehabilitation Research Training, grant no. K12 HD055931). Additional support was provided by the National Institutes of Health from the National Institute of Biomedical Imaging and Bioengineering (grant no. 1R01EB007749) and National Institute of Neurological Disorders and Stroke (grant no. 1R21NS056136) and the Telemedicine and Advanced Technology Research Center U.S. Army Medical Research and Material Command Agreement (no. W81XWH-07-1-0716).

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

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0003-9993/10/9105-00006$36.00/0
doi:10.1016/j.apmr.2010.01.010

blocks the release of acetylcholine at the neuromuscular junction,[6] can temporarily decrease muscle spasticity. In addition, FES can strengthen weaker muscles and is frequently used in clinical practice.[7,8] Cyclic FES (FES) involves a fixed timing pattern of stimulation for specified muscle groups—for example, to produce alternating cycles of flexion and extension actions to aid grasp and release of objects.

Thus, a rehabilitation program that combines onabotulinumtoxinA injections, task practice, and FES treatments may enhance motor performance by simultaneously targeting multiple mechanisms impeding recovery. In fact, clinical practice rarely relies on a single intervention to treat a complex condition, and prior studies have shown that interventions based solely on onabotulinumtoxinA injections or OT alone provide limited benefit for improving hand function in persons with chronic spastic hemiparesis.[9] However, a recent report suggests that the combination of task practice and onabotulinumtoxinA is associated with improvements in upper limb quality of movement among individuals with chronic spastic hemiparesis.[10]

The present study was designed to determine whether outcomes for hand function are improved by adding FES to our standard intervention, which consists of onabotulinumtoxinA injections and task practice therapy. Our hypothesis is that the addition of FES to our standard intervention will increase the magnitude and durability of improvements in hand grasp and release motor function among patients with spastic hemiparesis.

METHODS

The University of Pittsburgh institutional review board approved all protocols for this study.

Participants

This was a single-blind, randomized controlled pilot study. We recruited a convenience sample of patients with chronic hemiparesis from the Department of Physical Medicine and Rehabilitation Spasticity Clinic at the University of Pittsburgh Medical Center. All participants had a minimum of 6 months of unilateral spastic hemiparesis and had at least 2 prior sessions of onabotulinumtoxinA injections for treatment of spasticity. This prior exposure confirmed that participants tolerated injection therapy without adverse reactions with a predictable dosage. Subjects had preinjection Modified Ashworth scores of 2 or greater in at least 1 of the following muscle groups: wrist flexors or finger flexors. Additionally, they had to attain at minimum a stage 2 classification on the Chedoke McMaster Assessment of hand impairment,[11] plus demonstrate the ability to do at least 1 of the following stage 3 tasks: active wrist extension greater than half range, active finger/wrist flexion greater than half range, or actively touch thumb to index finger when the hand was placed in supination with thumb fully extended. Participants without any voluntary motion or severe fixed joint contracture in the affected arm were excluded. Although participants were required to have some voluntary motor function in the hand, these criteria were used to select people who were unable to grasp and release objects reliably prior to treatment.

A masked trained evaluator administered baseline assessments for each outcome measure after obtaining informed consent and determining whether participants met inclusion criteria. Participants meeting the inclusion criteria were assigned randomly to 1 of 2 groups. The no-FES group received our standard intervention consisting of onabotulinumtoxinA injections and task practice therapy, while the FES group received FES in addition to the standard intervention. Outcomes were measured at 3 time points: baseline (preinjection), week 6 postinjection, and week 12 postinjection.

Standard Intervention: OnabotulinumtoxinA Injections and Task Practice Therapy (Both Groups)

Participants in both groups received onabotulinumtoxinA injections performed by an experienced physician (M.C.M.) as part of clinical management for spasticity within 2 weeks after baseline assessment. All patients were positioned supine with the arm abducted and forearm supinated as much as feasible. Muscles were localized using a combination of EMG guidance or ultrasound direct visualization procedures for forearm flexor muscles. The individual bellies of the flexor digitorum superficalis were injected separately,[12] and all other muscles had 1 injection site. All doses of the toxin were prepared using a 1:1 dilution.

Within 7 days after onabotulinumtoxinA treatment, participants in both groups attended an initial instructional visit with an occupational therapist involved in this study (L.M.H.). During the initial visit, participants received 1 hour of therapy that included instructions for the home exercise program and instruction on how to complete a daily patient exercise diary. Participants in the FES group received 1 additional hour of therapy so that they could be fitted and trained to use the H200 device.[a]

The postinjection intervention for both groups included a home exercise program that required a total of 60 minutes of task practice daily for 12 weeks using a standardized protocol without constraining the unimpaired arm. Participants were encouraged to set aside a target of 60 minutes a day to devote to their home exercise program, incorporating rest breaks between tasks as needed. We selected 60 minutes a day based on our experience in implementing task practice protocols clinically in our facility. We selected 12 weeks given the expected duration of therapeutic effects provided by the onabotulinumtoxinA injections.[13] The task practice home exercise program was developed by an experienced occupational therapist (L.M.H.) and consisted of 4 to 5 functional tasks that were selected in collaboration with the participants according to their interests and abilities. Examples included stacking canned goods, dealing cards, sorting pennies, and wiping down counters. Participants practiced their individually designed task practice programs for 60 minutes a day with rest breaks as needed. The implementation of these home exercise programs was monitored during 5 additional 1-hour visits with the occupational therapist to ensure that the participants could complete the program independently without difficulty.

Experimental Treatment: Cyclic FES (FES Group Only)

Participants in the FES group were fitted with an H200 device during their initial OT visit. A detailed description of the device can be found elsewhere.[14] The device consists of a battery-powered programmable stimulator and a forearm-wrist-hand orthosis containing 5 electrodes positioned to provide reliable activation of the following muscles: extensor digitorum communis and extensor pollicis brevis, flexor pollicis longus, flexor digitorum superficialis, and thenar muscles. The size and location of each electrode were custom fit to each patient following procedures recommeded by the manufacturer (Bioness, Inc[a]). The intensity of stimulation was set to a level that provided comfortable and consistent activation of the extensor and flexor muscles to achieve whole hand opening and functional grasping. Reliable functioning of the device was verified by the occupational therapist during subsequent visits, and adjustments to the device fit and/or stimulation settings were