Neuromuscular Stimulation for Upper Extremity Motor and Functional Recovery in Acute Hemiplegia

John Chae, MD; Francois Bethoux, MD; Theresa Bohinc, OTR; Loreen Dobos, PT; Tina Davis, OTR; Amy Friedl, OTR

Background and Purpose—The purpose of this study was to assess the efficacy of neuromuscular stimulation in enhancing the upper extremity motor and functional recovery of acute stroke survivors.

Methods—Forty-six stroke survivors admitted to an inpatient rehabilitation unit were randomly assigned to receive either neuromuscular stimulation or placebo. Twenty-eight subjects completed the study. The treatment group received surface neuromuscular stimulation to produce wrist and finger extension exercises. The control group received placebo stimulation over the paretic forearm. All subjects were treated 1 hour per day, for a total of 15 sessions. Outcomes were assessed in a blinded manner with the upper extremity component of the Fugl-Meyer Motor Assessment and the self-care component of the Functional Independence Measure at pretreatment, after treatment, and at 4 and 12 weeks after treatment.

Results—The treatment subjects and control subjects had comparable baseline characteristics. Parametric analyses revealed significantly greater gains in Fugl-Meyer scores for the treatment group after treatment (13.1 versus 6.5; $P=0.05$), at 4 weeks after treatment (17.9 versus 9.7; $P=0.05$), and at 12 weeks after treatment (20.6 versus 11.2; $P=0.06$). Functional Independence Measure scores were not different between groups at any of the time periods ($P>0.10$).

Conclusions—Data suggest that neuromuscular stimulation enhances the upper extremity motor recovery of acute stroke survivors. However, the sample size in this study was too small to detect any significant effect of neuromuscular stimulation on self-care function. **(*Stroke*. 1998;29:975-979.)**

Key Words: hemiplegia ■ motor recovery ■ rehabilitation

Dedicated stroke units, which admit patients for acute medical management and subsequent interdisciplinary rehabilitation, enhance the overall medical, neurologic, and functional outcome of stroke survivors.[1,2] However, a robust relation between specific treatments directed at motor impairment and corresponding reduction in physical disability has not been established.[3] The degree of motor recovery after stroke varies widely and is directly related to the degree of initial severity and the interval from stroke to initiation of voluntary movement.[4–6] During this period, motor recovery is believed to be enhanced by various techniques such as the neurodevelopmental technique,[7] sensorimotor integration,[8] proprioceptive neuromuscular facilitation,[9] biofeedback,[10] and functional utilization of evolving synergies.[11] However, controlled studies have failed to demonstrate that any one method is superior to the others in enhancing motor or functional recovery of stroke survivors.[12–16]

Both basic and clinical studies suggest that poststroke motor recovery or motor relearning of the paretic limb may be maximized by the active repetitive use of the affected limb.[17–22] However, many acute stroke survivors exhibit a significant degree of hemiparesis, which limits the application of this strategy in the acute stroke rehabilitation environment. Furthermore, with significant reduction in acute inpatient rehabilitation length of stay and outpatient services, many rehabilitation service providers are forced to focus principally on compensatory strategies to maximize function in the shortest amount of time rather than the restoration of motor control.[23]

One technique that may facilitate motor restoration of stroke survivors is neuromuscular stimulation–induced repetitive movement exercises. Numerous studies have suggested that neuromuscular stimulation reduces spasticity[24–26] and enhances the muscle strength of the hemiparetic limb.[26–34] A recent meta-analysis of four randomized trials concluded that neuromuscular stimulation improves the motor strength of stroke survivors.[35] The authors write "Given the large burden of disability from cerebrovascular disease and the paucity of efficacious therapeutic modalities, further research on the use of electrostimulation would appear to be prudent (p 552)." In

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From the Departments of Physical Medicine and Rehabilitation (J.C., F.B., T.B., L.D., T.D.) and Orthopedics (J.C., F.B.), MetroHealth Medical Center, Cleveland, Ohio, and the Center for Physical Medicine and Rehabilitation (J.C.) and Rehabilitation Engineering Center (J.C., F.B.), Case Western Reserve University School of Medicine, Cleveland, Ohio.

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Correspondence to John Chae, MD, Center for Physical Medicine and Rehabilitation, Case Western Reserve University, MetroHealth Medical Center, 2500 MetroHealth Dr, Cleveland, OH 44109-1998.

E-mail jchae@metrohealth.org

view of the limitations of prior studies, Glanz and associates further recommend that "Future studies should be double-blinded and sham-controlled, and ideally should examine more sustained and complex aspects of neurofunctional recovery after stroke (p 552)." Thus this study uses a double-blind, placebo-controlled, randomized design to test the hypotheses that neuromuscular stimulation enhances the upper extremity motor and functional recovery of acute stroke survivors as reflected by the Fugl-Meyer Motor Assessment and the Functional Independence Measure (FIM), respectively. We test an additional hypothesis that the therapeutic effects of the neuromuscular stimulation are sustained for up to 3 months beyond the termination of treatments.

Subjects and Methods

Subjects

Stroke survivors admitted to an acute inpatient rehabilitation service within 4 weeks of their unilateral stroke were screened for inclusion. Subjects were 18 years old or older with moderate to severe upper extremity paresis (Fugl-Meyer score less than 44). Subjects were excluded if they had a history of potentially fatal cardiac arrhythmias, demand cardiac pacemaker placement, seizures within the 2 years before admission, active reflex sympathetic dystrophy, prior stroke with residual motor weakness, lower motor neuron lesion of the impaired upper extremity, spinal cord injury, traumatic brain injury, multiple sclerosis, or Parkinson's disease. Enrolled subjects were excluded after randomization if they could not tolerate the stimulation, if they were medically unstable, or if they were discharged before completing their treatment and were unable to continue with the treatment at home. When enrolled subjects were dropped from the study, the next subject who qualified for the study assumed the assignment of the dropped subject on enrollment. Subjects who were excluded after randomization were followed up by telephone to assess their disposition (home versus nursing home) and the degree of arm paresis.

Intervention

The study institution's human subjects committee approved the study protocol, and subjects signed informed consent. The treatment procedures were in accordance with institutional guidelines. Subjects were assigned to the treatment or placebo group by a computer-generated random number table. All subjects received standard physical, occupational, and speech therapy interventions as per routine of the inpatient stroke rehabilitation program. In addition, all subjects received 1 hour per day of electrotherapy with a portable, commercially available surface neuromuscular stimulation unit (FOCUS, Empi Inc). All subjects received a total of 15 sessions. The treatment group received stimulation of the extensor digitorum communis and the extensor carpi radialis (ECR) through circular 2.5-cm surface electrodes. The brevis and longus heads of the ECR could not be further differentiated with surface stimulation. The stimulation current intensity was set to produce full wrist and finger extension with a duty cycle of 10 seconds on and 10 seconds off. The stimulus pulse was a symmetric biphasic waveform with amplitude ranging between 0 to 60 mA, pulse width of 300 μsec, frequency ranging between 25 to 50 Hz, and ramp up and down time of 2 seconds each. The current amplitude and stimulus frequency were adjusted to subject comfort. The control subjects also received surface stimulation, but the electrodes were placed away from all motor points, producing only cutaneous stimulation just beyond sensory threshold and without motor activation. All treatments were carried out under the supervision of a trained occupational therapist. Subjects who were discharged before completing the treatment continued to receive the treatment at home under the supervision of a trained family member.

Assessments

All subjects were characterized with respect to demographics (age, sex, and stroke onset to treatment interval), medical comorbidities (hypertension, coronary artery disease, congestive heart failure, diabetes mellitus, and prior stroke), presence of sensory impairments and hemineglect, side of the hemiparesis, stroke type (hemorrhagic versus nonhemorrhagic), stroke level (cortical versus subcortical), and vascular distribution (anterior versus posterior). Blinded evaluations of upper extremity–related motor function and disability were performed before treatment, after treatment, and at 4 and 12 weeks after treatment by trained physical and occupational therapists, respectively. Blinding was assured by having separate therapists provide the treatment and the assessment. The assessing therapist was unaware of the treatment assignments. Subjects were instructed not to discuss the nature of their treatment with the treating and assessing therapists.

Motor function was assessed with the upper extremity motor subscore of the Fugl-Meyer Motor Assessment.[36] The items in the motor subsections were derived from Brunnstrom's stages of post-stroke motor recovery, although the specific stages were not used.[37] Reliability and validity of the Fugl-Meyer Motor Assessment have been documented.[38,39] The upper extremity–related disability was assessed with the self-care component of the FIM. The FIM, which was historically derived from the Barthel Index,[40] is primarily an ordinal scale with some interval characteristics. The reliability and validity of the FIM have been previously documented.[41–44]

Analysis

A sample size of 14 subjects per group was calculated by power analysis with anticipated difference in Fugl-Meyer scores between groups of 1 standard deviation in Fugl-Meyer scores with β of 0.2 and one-tailed α of 0.05. The anticipated difference between groups was based on results of a pilot study on the effects of electromyogram-triggered neuromuscular stimulation on the upper extremity motor recovery of acute stroke survivors.[45] The baseline characteristics of subjects who successfully completed the treatment protocol and those who dropped out after randomization were compared to assess for potential bias caused by dropout. Similarly, the baseline characteristics of treatment and control subjects were compared to assess the success of randomization. Continuous and nominal baseline variables were compared with the independent t and χ^2 tests, respectively. The gain in Fugl-Meyer and FIM scores were compared across groups at each test period with the independent t test.

Results

A total of 46 subjects initially enrolled in the study. Twenty-eight subjects completed the treatment protocol. Among those who completed the treatment protocol, 14 were assigned to the neuromuscular stimulation (NS) group and 14 to the control group. Eighteen subjects were excluded from the study after randomization for the various reasons shown in Table 1. Of the 18 subjects who were excluded, follow-up data were available for 17 subjects. All subjects were still alive at an average follow-up period of 17 months after treatment. Eighty percent (8 of 10) and 100% (7 of 7) of subjects assigned to the treatment and placebo groups, respectively, were back in the community at follow-up ($\chi^2=1.6$; $P=0.21$). Attempts to assess the degree of motor recovery for each group by telephone interview was unsuccessful because family and subjects often reported the degree of paresis to be significantly worse than the previously recorded baseline Fugl-Meyer scores. The baseline characteristics of subjects who completed the treatment protocol and those who were excluded from the study after randomization are shown in Table 2. The groups were comparable with respect to demographics, medical comorbidities, stroke char-

TABLE 1. Subjects Excluded After Randomization, Treatment Assignments, and Reasons for Exclusion

Reasons for Postrandomization Exclusion	Neuromuscular Stimulation	Control
Pain or discomfort from surface stimulation	7	1
Medical instability		
Pulmonary embolism and myocardial infarction	0	1
New-onset seizure	0	1
Chest pain	1	0
Did not finish treatment protocol and declined further treatment	3	2
Factitious hemiparesis	0	1
Unable to stimulate without motor activation	0	1
Total	11	7

acteristics, and baseline upper extremity Fugl-Meyer and self-care FIM scores.

The baseline characteristics of the NS and placebo subjects are shown in Table 3. There were no significant differences between the groups with respect to demographics, medical comorbidities, stroke characteristics, and baseline upper extremity Fugl-Meyer and self-care FIM scores. The gain in the upper extremity Fugl-Meyer and self-care FIM scores are shown in Table 4. In general, subjects in both groups experienced motor recovery in the untreated arm muscles (shoulder abduction-adduction, shoulder external-internal rotation, and elbow flexion-extension) before recovery in the treated forearm muscles (wrist and finger extension-flexion).

TABLE 2. Baseline Characteristics of Subjects Who Dropped Out of the Study After Randomization and Those Who Completed the Treatment Protocol

Variable	Excluded	Completed Treatment	*P*
n	18	28	
Age (SD)	62.2 years (9.4)	59.7 years (13.0)	0.48
Stroke onset to treatment (SD)	14.6 days (7.5)	15.7 days (6.5)	0.61
Female (%)	10 (55.6)	15 (53.6)	0.90
Coronary artery disease (%)	7 (38.9)	6 (21.4)	0.20
Congestive heart failure (%)	3 (16.7)	3 (10.7)	0.57
Hypertension (%)	16 (88.9)	19 (67.9)	0.10
Diabetes mellitus (%)	9 (50.5)	9 (32.1)	0.23
History of smoking (%)	6 (33.3)	10 (35.7)	0.87
First stroke (%)	13 (72.2)	21 (75.0)	0.83
Sensory impairment (%)	9 (52.9)	11 (42.3)	0.49
Hemineglect (%)	5 (29.4)	8 (28.6)	0.99
Right hemiparesis (%)	7 (38.9)	13 (46.4)	0.54
Nonhemorrhagic stroke (%)	15 (83.3)	25 (89.2)	0.56
Cortical stroke (%)	10 (55.6)	14 (50.0)	0.71
Anterior circulation stroke (%)	12 (66.7)	20 (71.4)	0.73
Upper extremity Fugl-Meyer (SD)	9.3 (9.9)	9.7 (9.6)	0.89
Self-care FIM (SD)	17.4 (5.4)	20.4 (6.0)	0.10

SD indicates standard deviation; FIM, Functional Independence Measure.

TABLE 3. Baseline Characteristics of Control and Neuromuscular Stimulation Groups

Variable	Control	Neuromuscular Stimulation	*P*
n	14	14	
Age (SD)	60.0 years (15.1)	59.4 years (11.1)	0.91
Stroke onset to treatment (SD)	17.8 days (5.9)	13.6 days (7.1)	0.10
Female (%)	8 (57.1)	7 (50.0)	0.71
Coronary artery disease (%)	5 (35.7)	2 (14.3)	0.19
Congestive heart failure (%)	1 (7.1)	2 (14.3)	0.54
Hypertension (%)	9 (64.3)	10 (71.4)	0.69
Diabetes mellitus (%)	3 (21.4)	6 (42.9)	0.23
History of smoking (%)	4 (28.6)	6 (42.9)	0.43
First stroke (%)	11 (78.6)	10 (71.4)	0.66
Sensory impairment (%)	6 (42.9)	5 (35.7)	0.69
Hemineglect (%)	5 (35.7)	3 (21.4)	0.47
Right hemiparesis (%)	8 (57.1)	5 (35.7)	0.33
Nonhemorrhagic stroke (%)	14 (100)	11 (78.6)	0.07
Cortical stroke (%)	9 (64.3)	5 (35.7)	0.13
Anterior circulation stroke (%)	11 (78.6)	9 (64.3)	0.40
Upper-extremity Fugl-Meyer (SD)	8.3 (8.8)	11.1 (10.4)	0.45
Self-care FIM (SD)	19.3 (5.5)	21.4 (6.5)	0.36

SD indicates standard deviation; FIM, Functional Independence Measure.

The analyses of the Fugl-Meyer gain scores with the independent *t* test revealed significantly greater motor improvement for the NS group before treatment ($t=-2.1$; $P=0.05$), at 4 weeks after treatment ($t=-2.2$; $P=0.05$), and at 12 weeks after treatment ($t=-2.0$; $P=0.06$). The effect sizes at each follow-up period were 0.73, 0.73, and 0.73, respectively. More conservative estimates of the effect size with the larger standard deviation of the two treatment groups for each period were 0.64, 0.64, and 0.62, respectively. The difference in the FIM gains scores between groups were not statistically significant at any of the follow-up periods ($P>0.10$).

TABLE 4. Gains in the Upper-Extremity Fugl-Meyer and Self-care FIM Scores After Treatment and at Follow-up Periods

	Neuromuscular Stimulation (SD)	Control (SD)	Difference (SE)	95% Confidence Interval
n	14	14		
Fugl-Meyer gain*				
After treatment	13.1 (10.3)	6.5 (6.1)	6.6 (3.2)	13.2, 0.1
4 weeks	17.8 (12.6)	9.7 (7.7)	8.1 (3.9)	16.2, 0.0
12 weeks	20.6 (15.1)	11.2 (8.7)	9.4 (4.7)	18.9, −0.2
FIM gain†				
After treatment	11.3 (3.0)	10.6 (5.9)	0.6 (1.8)	4.3, −3.0
4 weeks	13.9 (5.5)	13.6 (6.5)	0.3 (2.3)	5.0, −4.4
12 weeks	15.8 (5.8)	16.1 (6.7)	−0.3 (2.4)	4.6, −5.1

SD indicates standard deviation; SE, standard error; and FIM, Functional Independence Measure.

*Upper extremity motor component.

†Self-care component.

Discussion

The major finding of this double-blind, placebo-controlled, randomized study is that stroke survivors treated with surface neuromuscular stimulation gained significantly greater upper extremity motor recovery than did control subjects. However, the gains in the motor function did not translate into significant improvement in the performance of basic self-care activities. In contrast to prior studies, this study documents the effects of neuromuscular stimulation on the complex aspect of neurofunctional recovery as reflected by the Fugl-Meyer Motor Assessment and the FIM, and the outcomes are assessed for up to 3 months after treatment.

The study has several limitations. There was a high dropout rate, with pain from stimulation being the most common cause. Future studies should use alternative techniques such as percutaneous stimulation to minimize the discomfort of stimulation and the potential confounding effect of selective dropout. An intention-to-treat analysis should be used to further minimize the effect of dropout. The motor function of control subjects was somewhat lower than that of the treatment group. The control group also had more cortical stroke survivors, whereas the treatment group had more subcortical stroke survivors. Although the differences in these variables were not statistically significant, the small sample size places the study at risk for a type II error, allowing for the possibility that the treatment group was composed of individuals with greater potential for spontaneous recovery compared with that of control subjects. The small sample size in this study and the high dropout rate after randomization further limit the generalization of the results to the broader stroke population. As will be discussed below, the upper extremity–related disability measure used in this study may have been inadequate, and future studies should use measures more specific and sensitive to the intervention.

Given these limitations, conclusions must be drawn with caution. The study suggests that active repetitive exercises induced by neuromuscular stimulation enhance the motor recovery of acute stroke survivors. Furthermore, the effect appears to be sustained for up to 3 months after completion of treatment. This is consistent with the evolving basic and clinical data on central motor neuroplasticity that support the use of active repetitive training of the paretic limb to maximize motor recovery after stroke. The motor recovery enhancing effect of amphetamine in a rat model after unilateral ablation of the motor cortex is blocked if the animals are not allowed to actively and repetitively use their paretic limb.[17] A recent study in primates suggests that after local damage to the motor cortex, active repetitive training of the hemiparetic limb shapes subsequent functional reorganization in the adjacent intact cortex and that the undamaged motor cortex plays an important role in motor recovery.[18,19] A clinical study of subacute stroke survivors also emphasizes the importance of frequent active movement repetition for motor rehabilitation of the centrally paretic hand and challenges conventional physiotherapeutic strategies that focus on tone modification and functional compensation instead of early initiation of active movements.[20] Among stroke survivors who are beyond 6 months from their stroke, "forced" active repetitive movement of the paretic limb also appears to enhance motor and functional recovery.[21,22]

This study failed to demonstrate that neuromuscular stimulation enhances the upper extremity–related functional recovery of acute stroke survivors. Previous studies have demonstrated that motor and functional recovery roughly parallel one other.[5,6] Although the lower extremity motor status of stroke survivors correlates well with ambulatory function, the relation between upper extremity Fugl-Meyer and the self-care component of the FIM is modest at best.[46] This is due to the nature of the FIM. The self-care component of the FIM measures general disability and is not arm disability specific. Stroke survivors with severe upper extremity hemiplegia can score high on the self-care component of the FIM as long as they are able to learn compensatory single-handed techniques to perform the activity. The items in the self-care component of the FIM are basic in nature and patients are not penalized for using a single-handed versus a bimanual strategy. Future studies should use a functional outcome measure that is specific to the arm and is more sensitive to the degree of arm hemiparesis. Tests of arm function[47–49] that specifically assess the functional ability of the hemiparetic limb and more complex bimanual functional tasks may be more appropriate disability outcome measures for these types of studies.

This study suggests that surface neuromuscular stimulation enhances the upper-extremity motor recovery of acute stroke survivors and that the affect is maintained for up to 3 months after completion of treatment. However, the study failed to demonstrate any significant functional benefit. To make definitive recommendations, a large, multicenter, randomized clinical trial with intervention-specific objective measures of motor and functional impairment should be carried out. Future studies should also define the dose effect and elucidate the mechanism of action to further guide the clinical implementation of neuromuscular stimulation. While the definitive study remains to be carried out, the evidence from the present study, prior small studies,[25–34] and the recent meta-analysis[35] suggest that neuromuscular stimulation may be beneficial for a select group of stroke survivors in maximizing their motor recovery.

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