ACRM
AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2013;94:1007-14

JOURNAL-BASED CME ARTICLE

Randomized Controlled Trial of Surface Peroneal Nerve Stimulation for Motor Relearning in Lower Limb Hemiparesis

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Statement of Need

Stroke is a leading cause of motor impairment and disability with an incidence 41 of 795,000/year and prevalence of approximately 6.4 million in the U.S. Mobility limitations associated with walking may affect up to75% of the individuals who sustain a stroke each year. Footdrop is an important post-stroke lower extremity (LE) motor impairment that contributes to mobility-related disability. The rehabilitation intervention is an ankle foot orthosis (AFO). A peroneal nerve stimulator (PNS) has been proposed as an alternative to an AFO. A PNS appears to be superior to no device in improving ambulation function.

However, data on superiority to an AFO are inconsistent. Emerging data suggest that functionally relevant, active repetitive movement strategies facilitate motor relearning following stroke. In addition to dorsiflexing the ankle during functional ambulation, daily use of a PNS may facilitate motor relearning of the lower limb such that in the long-term, neither an AFO nor a PNS is needed. In contrast, ambulation with an AFO could limit active repetitive movements at the ankle and inhibit motor relearning. To date, however, the comparative effect of a surface PNS versus usual care, including an AFO, on post-stroke motor relearning has not been evaluated in a randomized controlled trial. The primary objective of this study was to compare the effects of a PNS and usual care on lower limb motor impairment among chronic stroke survivors.

This journal-based activity has been planned and developed in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the sponsorship of Professional Education Services Group (PESG).

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Credit Designation Statement

PESG designates this Journal-based CME activity for a maximum of 2.0 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

All other health care professionals completing continuing education credit for this activity will be issued a certificate of participation.

Educational Objectives

To support the attainment of knowledge, competence, and performance, the learner should be able to achieve the following objectives:

1. List motor relearning approaches in lower limb hemiparesis.
2. Describe comparative outcomes and assessment measures.
3. Compare motor relearning effect of surface peroneal nerve stimulator (PNS) versus other options.

Planning Committee

Lynne R. Sheffler, MD, Paul N. Taylor, PhD, Douglas D. Gunzler, PhD, Jaap H. Buurke, PhD, Maarten J. IJzerman, PhD, John Chae, MD, Allen W. Heinemann, PhD, ABPP (RP), FACRM, PESG staff, ACRM Editorial Office Staff.

Faculty Profiles & Disclosure Information

As a provider accredited by the ACCME, it is the policy of PESG to require the disclosure of anyone who is in a position to control the content of an educational activity. All relevant financial relationships with any commercial interests and/or manufacturers must be disclosed to participants at the beginning of each activity. The faculty and planners of this educational activity disclose the following:

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No relevant financial relationships to disclose.

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Paul N. Taylor is the co-inventor of the PNS device evaluated in this study and is named on 2 patents for the device. The patents are assigned to Salisbury NHS Foundation Trust. He also holds shares in Odstock Medical Limited.

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No relevant financial relationships to disclose.

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No relevant financial relationships to disclose.

ACRM Editorial Office Staff

No relevant financial relationships to disclose.

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Intended Audience

This program is intended for physicians and health care professionals responsible for the comprehensive care for individuals with chronic illness and disabilities.

0003-9993/13/$36 - see front matter
http://dx.doi.org/10.1016/j.apmr.2013.01.024

Method of Participation

In order to claim credit, participants must complete the following:

1. Pre-activity self-assessment questions.
2. Read the activity.
3. Complete the CME Test and Evaluation. Participants must achieve a score of 70% on the CME Test.

Participants can complete the pre-activity self-assessment and CME Test and Evaluation online by logging on to http://acrm.cds.pesgce.com. Upon successful completion of the online tests and evaluation form, you can instantly download and print your certificate of credit.

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This continuing education activity is active starting June 1, 2013 and will expire May 31, 2014.

Estimated time to complete this activity − 2.0 hours

Abstract

Objective: To compare the motor relearning effect of a surface peroneal nerve stimulator (PNS) versus usual care on lower limb motor impairment, activity limitation, and quality of life among chronic stroke survivors.

Design: Single-blinded randomized controlled trial.

Setting: Teaching hospital of academic medical center.

Participants: Chronic stroke survivors (N = 110; >12wk poststroke) with unilateral hemiparesis and dorsiflexion strength of ≤4/5 on the Medical Research Council scale.

Interventions: Subjects were stratified by motor impairment level and then randomly assigned to ambulation training with either a surface PNS device or usual care (ankle-foot orthosis or no device) intervention. Subjects were treated for 12 weeks and followed up for 6 months posttreatment.

Main Outcome Measures: Lower limb portion of the Fugl-Meyer (FM) Assessment (motor impairment), the modified Emory Functional Ambulation Profile (mEFAP) performed without a device (functional ambulation), and the Stroke Specific Quality of Life (SSQOL) scale.

Results: There was no significant treatment group main effect or treatment group by time interaction effect on FM, mEFAP, or SSQOL raw scores ($P>.05$). The time effect was significant for the 3 raw scores ($P<.05$). However, when comparing average change scores from baseline (t1) to end of treatment (t2, 12wk), and at 12 weeks (t3) and 24 weeks (t4) after end of treatment, significant differences were noted only for the mEFAP and SSQOL scores. The change in the average scores for both mEFAP and SSQOL occurred between t1 and t2, followed by relative stability thereafter.

Conclusions: There was no evidence of a motor relearning effect on lower limb motor impairment in either the PNS or usual-care groups. However, both the PNS and usual-care groups demonstrated significant improvements in functional mobility and quality of life during the treatment period, which were maintained at 6-month follow-up.

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Stroke is a leading cause of motor impairment and disability with an incidence of 795,000 per year and a prevalence of approximately 6.4 million in the United States.[1] Mobility limitations associated with walking may affect up to 75% of the individuals who sustain a stroke each year.[2] Footdrop, the decreased ability to dorsiflex the ankle during the swing phase of gait, is an important poststroke lower extremity (LE) motor impairment that contributes to mobility-related disability. The rehabilitation intervention considered usual care for treatment of moderate to severe poststroke dorsiflexion weakness during gait is an ankle-foot orthosis (AFO); patients with less severe dorsiflexion weakness are generally prescribed ankle-strengthening and gait-training exercises only. A peroneal nerve stimulator (PNS), which dorsiflexes the ankle during the swing phase of gait, has been proposed as an alternative to an AFO.[3-5] A PNS appears to be superior to no device in improving ambulation function.[6] However, data on superiority to an AFO are inconsistent.[6-10]

Emerging data suggest that functionally relevant, active repetitive movement strategies facilitate motor relearning after stroke.[11] Motor relearning is defined as the reacquisition of motor skills or the reduction of motor impairment after damage to the central nervous system.[12] Thus, in addition to dorsiflexing the ankle during functional ambulation, daily use of a PNS may facilitate motor relearning of the lower limb[4,5,13-21] such that in the long-term, neither an AFO nor a PNS is needed. In contrast, ambulation with an AFO could limit active repetitive movements at the ankle and inhibit motor relearning.[22,23] To date, however, the comparative effect of a surface PNS versus usual care, including an AFO, on poststroke motor relearning has not been evaluated in a randomized controlled trial.

The primary objective of this study was to compare the effects of a PNS and usual care on lower limb motor impairment among chronic stroke survivors. The secondary objective was to compare the effects of a PNS and usual care on lower limb activity limitation and overall quality of life. The demonstration of a surface PNS as an effective therapeutic intervention to facilitate motor relearning as measured on standard clinical scales could have significant impact on poststroke motor recovery, and potentially establish a new standard of care for stroke rehabilitation.

Supported by the National Institute of Child Health and Human Development (grant nos. R01HD44816, K23HD060689, and K24HD054600) and the National Institutes of Health National Center for Research Resources Clinical and Translational Science Collaborative of Cleveland (grant no. UL1RR024989).

A commercial party having a direct financial interest in the results of the research supporting this article has conferred or will confer a financial benefit on the author or 1 or more of the authors. Paul N. Taylor is the co-inventor of the PNS device evaluated in this study and is named on 2 patents for the device. The patents are assigned to Salisbury NHS Foundation Trust. He also holds shares in Odstock Medical Limited.

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 (Sheffler, Gunzler, Buurke, IJzerman, Chae).

Clinical Trial Registration Number: NCT00148343.