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ORIGINAL ARTICLE

Effects of Repetitive Peripheral Magnetic Stimulation on Upper-Limb Spasticity and Impairment in Patients With Spastic Hemiparesis: A Randomized, Double-Blind, Sham-Controlled Study

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Abstract

Objective: To investigate short-term and long-term effects of repetitive peripheral magnetic stimulation (rpMS) on spasticity and motor function.

Design: Monocentric, randomized, double-blind, sham-controlled trial.

Setting: Neurologic rehabilitation hospital.

Participants: Patients (N=66) with severe hemiparesis and mild to moderate spasticity resulting from a stroke or a traumatic brain injury. The average time ± SD since injury for the intervention groups was 26±71 weeks or 37±82 weeks.

Interventions: rpMS for 20 minutes or sham stimulation with subsequent occupational therapy for 20 minutes, 2 times a day, over a 2-week period.

Main Outcome Measures: Modified Tardieu Scale and Fugl-Meyer Assessment (arm score), assessed before therapy, at the end of the 2-week treatment period, and 2 weeks after study treatment. Additionally, the Tardieu Scale was assessed after the first and before the third therapy session to determine any short-term effects.

Results: Spasticity (Tardieu >0) was present in 83% of wrist flexors, 62% of elbow flexors, 44% of elbow extensors, and 10% of wrist extensors. Compared with the sham stimulation group, the rpMS group showed short-term effects on spasticity for wrist flexors ($P=.048$), and long-term effects for elbow extensors ($P<.045$). Arm motor function (rpMS group: median 5 [4−27]; sham group: median 4 [4−9]) did not significantly change over the study period in either group, whereas rpMS had a positive effect on sensory function.

Conclusions: Therapy with rpMS increases sensory function in patients with severe limb paresis. The magnetic stimulation, however, has limited effect on spasticity and no effect on motor function.

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An increase in muscle tone is observed several weeks or months after a stroke or trauma causing pyramidal or extrapyramidal tract lesions. Often the increased muscle tone is combined with a disturbance of the proprioceptive input.[1] Physiotherapeutic and occupational therapeutic approaches, as well as pharmacologic treatments or electrical stimulation, are generally used to reduce pathologic muscle tone and to stimulate cortical reorganization. Recently, however, Malhotra et al[2] criticized the current methods of treatments or therapies for spasticity and contractures as unsatisfactory. Therapeutic interventions include surgery, pharmacologic treatments, and nonpharmacologic treatments such as stretching, casting, thermotherapy, transcutaneous electrical stimulation, or biofeedback. Two recently published reviews by Thibaut[3] and Sunnerhagen[4] and colleagues highlighted that there are no evidence-based guidelines yet for the application of different nonpharmacologic therapies in patients with spasticity. For example, stretching does not induce significant changes in

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spasticity, whereas for the other approaches no or only limited evidence exists.

Repetitive peripheral magnetic stimulation (rpMS) is an innovative therapy option. It generates repetitive contraction-relaxation cycles that enhance proprioceptive input from the affected extremity. Like functional neuromuscular stimulation, rpMS stimulates action potentials in motor axons that evoke muscle contraction, but it has the advantage that it penetrates into deeper regions of muscles and is considered nearly painless and, therefore, more tolerable. However, the source of stimulation is electrical for functional neuromuscular stimulation and magnetic for rpMS. The 2 approaches have been shown to have similar effects on spasticity.[5] So far, however, only a few cohort studies[6,7] have investigated the short-term effects of rpMS in patients with spasticity. These studies have demonstrated that spasticity was reduced and finger extension movements enhanced in patients with spastic paresis after traumatic or nontraumatic brain lesions. Forty-seven of 52 patients in whom measurements were obtained before and after a single session of rpMS to the paretic upper extremity showed an improvement on the Ashworth Scale by 1 or 2 categories. In addition, electromyographic activity and motor performance were measured in 8 patients. Electromyographic activity of finger flexors was significantly reduced, and extension could be performed with a reduced electromyographic activity of the extensors, while movement amplitude and velocity improved. However, no control group or control intervention was investigated. To promote the application of rpMS as an accepted clinical rehabilitation treatment, it is necessary to demonstrate that in addition to its short-term efficacy as shown by Struppler et al,[6-8] rpMS can also produce beneficial longterm effects.

The aim of this study was to determine whether 2 weeks of rpMS has short-term and long-term effects on spasticity and motor function of the severely affected paretic upper limb. Spasticity, as defined by the SPASM (Support Program for Assembly of Database for Spasticity Measurement) consortium, is a disorder of sensorimotor control after an upper motor neuron lesion that leads to an intermittent or persistent involuntary activation of muscles. This includes various functional limitations and impairments patients have because of spasticity, and therefore several approaches have been used to measure it. In this study, spasticity is defined as the resistance of muscles to manual passive stretch, excluding contraction.[9,10]

Methods

This investigation was a randomized, double-blind, sham-controlled study, conducted at a neurologic rehabilitation hospital.

Participants

Patients participating in the study met the following inclusion criteria: (1) hemiparesis caused by a stroke or a traumatic brain injury; (2) spasticity of an upper extremity, with a score of 1 to 3 on the Tardieu Scale; and (3) ages between 18 and 75 years. So far, there are no safety criteria for rpMS, so the following exclusion criteria were defined according to the safety criteria for transcranial magnetic stimulation proposed by Wassermann[11]: (1) metal implant in the head or within the stimulation area; (2) medical implanted devices (cardiac pacemaker, cochlea implant, or medication pumps); (3) pregnancy; (4) comorbidity with other neurodegenerative disorders or other neurologic, orthopedic disorders; (5) increased intracranial pressure; and (6) unstable fractures of the paretic upper extremity. The study was approved by the Ethics Committee of the Bavarian State Chamber of Physicians, and all patients or their legal representative gave written, informed consent.

List of abbreviations:

BI	**Barthel index**
FM	**Fugl-Meyer**
HAMD-7	**Hamilton Depression Scale—7 items**
PP	**per protocol**
pROM	**passive range of motion**
rpMS	**repetitive peripheral magnetic stimulation**

Study protocol

Patients were randomly assigned to receive rpMS or sham stimulation. Different block lengths were used for randomization to ensure an unpredictable allocation of treatment, which was stratified according to the side of lesion, regardless of whether it was in the dominant or nondominant hemisphere. For both strata, a randomization list was generated, and patients' names were consecutively entered to their appropriate list. Randomization was done by an individual not involved in any other part of the study, to ensure concealment of allocation.

All subjects participated in 20-minute therapy sessions of rpMS or in a sham stimulation, plus an additional 20 minutes of occupational therapy, approximately 2 times a day, 5 times a week, for 2 weeks.

Interventions

The rpMS and sham stimulation were applied by trained physical therapists, who were the only therapists aware of the specific therapy.

The rpMS consisted of 5000 stimuli at a stimulation frequency of 25Hz, a train duration of 1 second, and an intertrain interval of 2 seconds. Intensity was individually set at 10% above the level that evoked a wrist or elbow movement taken at rest. Stimuli were distributed consistently among extensors and flexors of the upper and lower arm. Magnetic stimuli were generated by Signal software (Signal for Windows[a]), and the digital outputs were fed through an analogue-digital converter (Micro 1401 mk II[a]) into the magnetic stimulator (P-Stim 160[b]). The P-Stim 160 magnetic stimulator generated double cosine pulses with a magnetic induction of maximally 1 tesla. Two butterfly magnetic coils (diameter, 2 × 100mm) were used for interventions: an active coil, connected with the stimulator, producing typical discharge noises; and a nonactive, nonconnected passive coil. Patients in the rpMS group were treated with the active coil. The same procedure was followed in the control group, but the nonactive coil was used; the active coil produced the typical noise on the side. A curtain in front of the patient's arm obstructed sight of the verum or sham stimulation. The experimental setup is shown in figure 1.

Subsequently, the patients received 20 minutes of occupational therapy, consisting of self-administered range-of-motion exercises and slow passive stretches executed by the therapists according to proprioceptive neuromuscular facilitation movement patterns throughout the hemiparetic upper extremity. During self-administered range-of-motion exercises, the participants clasped their hands or arms together using the strength of the less-affected arm to move the affected arm through the available range of motion at each joint. Slow passive stretches with the stretch held at the end of the range lasted about 30 seconds. The proprioceptive neuromuscular facilitation