J Rehabil Med 2019; 51: Epub ahead of print

ORIGINAL REPORT

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DOES ELECTROMYOGRAPHIC BIOFEEDBACK IMPROVE EXERCISE EFFECTS IN HEMIPLEGIC PATIENTS? A PILOT RANDOMIZED CONTROLLED TRIAL

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Objective: **The aim of this pilot randomized study was to assess the efficacy potential of an electromyographic biofeedback-assisted exercise programme on clinical and functional outcomes of hemiplegic patients in comparison with sham electromyographic biofeedback.**

Patients and methods: **Thirty-four patients with hemiplegia were randomized into 2 groups. Both groups participated in an inpatient rehabilitation programme including exercise interventions and ambulation training 5 days a week for 2 weeks. Lower extremity exercises were performed via electromyographic biofeedback in Group 1 (*n* = 17), while a sham technique was used for patients in Group 2 (*n* = 17). Range of motion, spasticity, muscle strength, functional level and walking speed were assessed before and after treatment. Follow-up was performed at 1 and 3 months after treatment.**

Results: **Significant improvements were found for range of motion, muscle strength, Barthel Index and 10-m walking time in both groups.**

Conclusion: **This study suggests that exercise with or without electromyographic biofeedback is effective for improving clinical and functional parameters in hemiplegic patients. Larger studies are needed to determine whether electromyographic biofeedback-assisted exercises provide additional benefits.**

Key words: EMG biofeedback; exercise; stroke.

Accepted Dec 6, 2018; Epub ahead of print Jan 22, 2019

J Rehabil Med 2019; 51: 00–00

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LAY ABSTRACT

This study suggests that exercise with or without electromyographic biofeedback is effective for improving clinical and functional parameters in hemiplegic patients.

Stroke is the leading cause of death and disability worldwide. Although the incidence and mortality rates of stroke have decreased over time, the number of stroke survivors and the overall global burden of stroke are increasing (1, 2). Almost 50% of the community-dwelling stroke population is still living with sequelae after 6 months, and the most common impairment after stroke is motor impairment (3). Strength is one of the most impacted domains 6 years post-stroke and appropriate rehabilitation interventions are necessary to reduce the long-term negative impact (4). Therefore, much of the rehabilitation efforts are focused on motor impairment and walking ability. Various approaches can be used for motor recovery; however, the effectiveness of these approaches and their superiority remain controversial. Historically, corrective exercise based on orthopaedic principles, neurophysiological approaches and motor learning techniques have been used (5). Biofeedback (BF), which is a method that supports the motor learning principles, has been used in rehabilitation for over 40 years (6). Electromyographic BF (EMG BF) uses electrodes placed on patients' muscles to record an action potential creating a visual and auditory feedback after amplification. It may be possible for individuals to learn how to use the unaffected pathways through the artificial proprioception provided by the BF apparatus (7). Meta-analysis indicates that there is some evidence suggesting that EMG BF is beneficial when used with standard physiotherapy techniques, and emphasizes the need for randomized clinical trials using standardized assessment scales (8). The aim of this pilot randomized study was to assess the efficacy potential of an EMG biofeedback (EMG BF)-assisted exercise programme on clinical and functional outcomes of hemiplegic patients in comparison with sham EMG BF.

METHODS

A total of 34 patients with hemiplegia due to vascular causes who were over 18 years old were included in the study after approval by the Institutional Review Board. Written informed consent was obtained from each patient. Patients with visual, auditory or cognitive deficits who were incompatible with the treatment requirements and patients with peripheral vascular diseases and severe spasticity or contracture at the ankle were excluded. Since the patients's walking speed was to be measured, patients who could not walk with or without assistance were excluded.

Patients were randomly assigned to EMG BF or sham EMG BF treatment groups in a 1:1 ratio. Block randomization was performed in blocks of 4 to ensure balance between the groups. Random numbers generated using statistical software were used to select randomly among possible blocks (SO). Assessments were performed blind by the other investigator (SA).

Both groups received an inpatient rehabilitation programme, including exercise interventions and ambulation training. Ex-

doi: 10.2340/16501977-2513

ercises were designed as isometric, isotonic and progressive resistive for each patient according to their capabilities. Lower extremity exercises were performed via EMG BF in Group 1, while a sham technique was used for patients in Group 2. Patients in Group 1 received visual and auditory feedback during exercise, whereas Group 2 received no feedback. The inpatient rehabilitation programme lasted for 10 sessions (5 days a week for 2 weeks). All patients were trained to perform a routine home exercise programme at discharge and were encouraged at the 1st and 3rd month visits to continue exercises. A flow diagram of the study is presented in Fig. 1. Patients were assessed by the clinical and functional parameters listed below before and after treatment and at follow-up visits.

Assessment

Spasticity was evaluated with the MAS (Modified Ashworth Scale). 0: No increase in muscle tone; 1: Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion (ROM) when the affected part(s) is/are moved in flexion or extension; 2: Slight increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of the ROM, but affected part(s) moved easily; 3: More marked increase in muscle tone through most of the ROM, but affected parts moved easily 4: Considerable increase in muscle tone, passive movement difficult; 5: Affected part(s) rigid in flexion or extension.

Active range of motion (ROM) of the ankle and knee joint were measured with a goniometer while the patient was lying in a supine position.

Muscle strength was tested with an isokinetic dynamometer (Cybex Humac Norm 2004, CSMi, MA, USA) and electrophysiological activity of the muscles: maximal isometric contraction (peak torque, Nm) was noted for knee extension in a sitting position at 30° and 60° and for ankle dorsiflexion at 0° and 15°.

Electrophysiological activity of the muscles tested with surface electrodes of the EMG BF instrument (Neurotrac ETS Simplex 2005, Hampshire, UK): after the electrode placement on the belly of the target muscle, patients were instructed to contract the muscle 5 times with maximal effort. The highest score and the mean score (microvolt) were noted.

Functional assessment was made with the Barthel Index (9), and time to walk 10 m (the time needed to walk 10 m with or without an assistive device was recorded in s).

Intervention

Neurotrac ETS Simplex 2005 was used for EMG BF. The software was uploaded on a laptop, and 50 × 50 mm, self-adhesive, EMG-TENS electrodes were used. Active electrodes were placed 4 cm apart longitudinally, with 1 placed on the belly of the muscle. The ground electrode was placed on the other lower extremity 2–3 cm above the patella. The "stroke" mode of the instrument was used with a 5-s contraction and a 5-s relaxation time lasting for 15 min for each of the tibialis anterior and quadriceps femoris muscles. This programme was conducted 5 days a week for 2 weeks. With the supervision of a physiotherapist experienced in the EMG BF applications, muscle strengthening exercises were performed after the electrode placement. The muscle threshold was calculated for every patient and muscle individually, and it was accepted as 40% of the mean after 5 maximum contractions. The treatment group was able to see the monitor and follow the work done by the muscles and hear the feedback noise when the previously identified threshold was exceeded. The sham group worked with the computer volume off and the monitor turned around so that the patient did not receive any visual or auditory feedback. After 10 sessions of treatment, both groups were advised to continue the home exercise programme.

The data were analysed using the SPSS 17.0 for Windows (Chicago, IL, USA) software package. The normality of the variables was tested with the Shapiro-Wilk test. Since the variables were not normally distributed, they were given as median (range) values. Two independent and dependent groups were compared using the Mann-Whitney *U* test and the Wilcoxon test, respectively. Cohen's d was calculated as an effect size estimation (10). Categorical variables were given with the *n* (%) values. Pearson χ^2 test was used to compare categorical variables. The significance level was set as $\alpha = 0.05$.

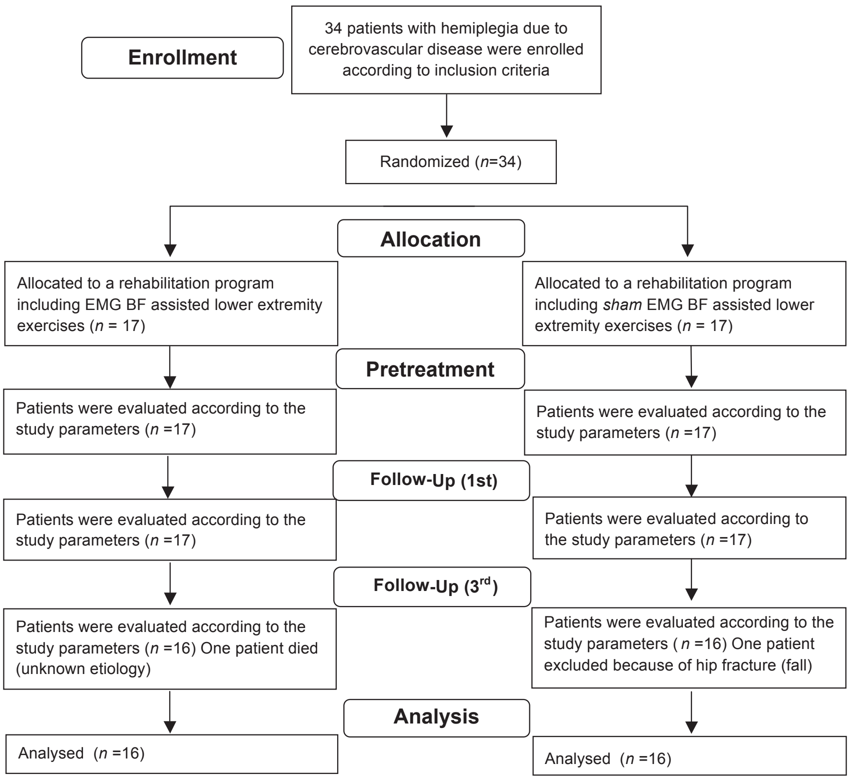

Fig. 1. Flow diagram of the study.

RESULTS

Twenty-two men and 12 women with a median age of 58.5 years (range 18–78) were enrolled in the study. The median time since stroke was 70.5 days (range 10–144 days). There were no statistically significant differences between the 2 groups considering age, sex, time since stroke and hemiplegic side (Table I).

In both groups, all the variables showed significant improvements after the treatment or after the 1st and 3rd month visits with medium and large effect sizes, except MAS score, which has small effect sizes for the after treatment, 1st and 3rd month visits in the sham group (Table II).

DISCUSSION

These results indicatae that rehabilitation programmes including lower extremity exercises via EMG BF or sham interventions improved the ROM, muscle strength, and functional level in hemiplegic patients with stroke.

Despite the fact that EMG BF has been in use for years, there is doubt about the efficacy of this technique. In 1998, a meta-analysis of 8 randomized controlled trials concluded that EMG BF was superior to conventional therapy for improving ankle dorsiflexion muscle strength in stroke patients (11). A more recent meta-analysis of 13 randomized controlled studies concluded that EMG BF did not show an additional treatment benefit over standard physiotherapy (8).

In the above-mentioned meta-analysis, motor strength, range of motion, gait and functional parameters were assessed; however, reduction in muscle tone was not evaluated. It has been proposed that regulation of muscle tone is disrupted by neuronal damage after stroke and that patients may have some unaffected pathways that are not initially obvious (7). With the help of EMG BF, it may be possible for patients to learn how to use these preserved pathways, and this control may result in the recovery of muscle function (8). EMG BF can be used either to increase the activity in weak or paretic muscles or to facilitate a reduction in muscle tone if it is spastic (12). A recent controlled trial administration of EMG BF after injection of botulinum toxin in spastic lower extremity muscles resulted in better reduction in muscle tone (13). EMG BF, in combination with conventional

Table I. Demographic characteristics of the groups

	EMG BF	Sham	*p*-value
Age, years, median (range)	59 (18–78)	58 (22–71)	0.892
Stroke duration, days, median (range)	95 (10–444)	68 (10–425)	0.734
Sex, female/male, *n* (%)	6 (35.3)/11(64.7)	6 (35.3)/11(64.7)	1.000
Hemiplegic side, right/left, *n* (%)	10 (58.8)/7(41.2)	6 (35.3)/11(64.7)	0.169

EMG BF: electromyographic biofeedback.

Table II. Pretreatment; posttreatment, 1st and 3rd month results of the EMG BF and the Sham Groups

	Pre-treatment Median (range)	Post-treatment Median (range)	1st month Median (range)	3rd month Median (range)
Range of motion				
Ankle dorsiflexion angle (active)				
EMG BF	10 (1–40)	15 (5–40)	15 (5–40)	17.5 (5–40)
ES EMG BF	–	–1.0	–0.9	–1.1
Sham	10 (1–40)	10 (1–40)	20 (50–40)	20 (50–40)
ES Sham	–	–0.7	–1.4	–1.3
Knee flexion angle (active)				
EMG BF	100 (60–130)	120 (90–130)	120 (90–130)	120(90–130)
ES EMG BF	–	–1.1	–1.4	–1.4
Sham	100 (60–130)	100 (60–130)	120 (90–130)	120 (90–130)
ES Sham	–	–0.9	–0.9	–1.0
Spasticity				
MAS				
EMG BF	1 (0–3)	1 (0–2)	1 (0–2)	1 (0–2)
ES EMG BF	–	0.6	0.8	0.8
Sham	1 (0–3)	1 (0–3)	1 (0–3)	1 (0–3)
ES Sham	–	0.0	0.1	0.3
Muscle strength				
Knee extension 600 peak torque (N/m)				
EMG BF	65 (18–123)	85 (35–229)	99 (38–308)	121 (41–302)
ES EMG BF	–	–1.0	–1.1	–1.4
Sham	52 (24–213)	72.5 (28–240)	88 (49–243)	102 (50–258)
ES Sham	–	–1.0	–1.3	–1.3
Knee extension 30° peak torque (N/m)				
EMG BF	50 (14–121)	72 (32–171)	91 (38–176)	98 (46–178)
ES EMG BF	–	–1.0	–1.4	–1.6
Sham	36 (11–220)	63.5 (24–228)	71 (23–255)	80 (29–247)
ES Sham	–	–1.3	–1.8	–1.6
Ankle dorsiflexion 15° peak torque (N/m)				
EMG BF	8 (1–27)	18 (3–33)	23 (9–46)	21 (11–49)
ES EMG BF	–	–1.0	–1.1	–1.0
Sham	11 (5–24)	16 (8–33)	20 (12–39)	30 (16–38)
ES Sham	–	–1.5	–1.6	–2.0
Ankle dorsiflexion 0° peak torque (N/m)				
EMG BF	5 (1–22)	15 (7–24)	22 (8–35)	20.5 (9–62)
ES EMG BF	–	–1.3	–1.6	–1.5
Sham	9 (1–28)	14.5 (3–31)	18 (10–33)	20 (12–35)
ES Sham	–	–1.4	–2.1	–2.3
Mean quadriceps MUP amplitude (μv)				
EMG BF	20.4 (8.2–46.1)	32.4 (18.1–69.8)	43.7 (14.7–82.6)	42.1 (22–58.6)
ES EMG BF	–	–1.3	–1.3	–1.5
Sham	20.6 (5.7–45)	24.5 (7.1–57.3)	30.6 (11.4–59.8)	49.4 (18–89.6)
ES Sham	–	–0.5	–0.8	–1.2
Mean tibialis anterior MUP amplitude (μv)				
EMG BF	12.1 (3.3–46.5)	27.3 (5.8–63.2)	24.3 (8.3–64.9)	26.8 (4–80.9)
ES EMG BF	–	–1.1	–1.0	–0.9
Sham	13 (5.1–30.6)	19.3 (10–57.9)	28.1 (8–43.2)	27.4 (17.7–38.8)
ES Sham	–	–0.9	–1.4	–1.8
Function				
Barthel Index				
EMG BF	55 (15–95)	70 (50–100)	75 (50–100)	75 (60–100)
ES EMG BF	–	–1.0	–1.2	–1.3
Sham	45 (30–85)	65 (40–85)	70 (40–85)	70 (40–95)
ES Sham	–	–1.4	–1.5	–1.5
10 m walking time (s)				
EMG BF	25 (13–69	20 (5–62)	16 (8–53)	15.5 (9–53)
ES EMG BF	–	0.9	1.1	1.1
Sham	30 (15–69)	26 (10–68)	22 (13–60)	20 (10–57)
ES Sham	–	1.6	1.2	1.2

MAS: Modified Ashworth Scale; MUP: motor unit potential; ES: effect size; EMG BF: electromyographic biofeedback.

therapy, resulted in better spasticity scores in hemiplegic patients in some studies, whereas the others recorded no statistically significant differences in the EMG BF group (14–16).

Only one study has been performed with sham EMG biofeedback for the lower extremity of the hemiplegic control group (17). Bradley and colleagues did not find any difference between the 2 groups after 18 sessions of treatment, including active movement, mobility and function. However, their patients were in the acute phase, and 14 out of 21 participants were not able to perform the 10-m walk test.

Muscle strength, in our study, was significantly improved in both groups. In contrast to the other studies, we tested the muscle strength with an isokinetic dynamometer. In the articles recording significant improvements in the EMG BF group, the results were based on manual testing or EMG activity (15, 18, 19).

In the study by Intiso et al. (15), Bartel Index results showed no significant improvement in either EMG BF or control groups. In contrast, our patients both in the exercise and EMG BF-assisted exercise groups reached significantly better results. The conflicting results between the 2 studies can be explained by the shorter stroke duration of our patients.

Various walking parameters were used to evaluate gait. Some of the studies assessed gait with video-recording methods. Cozean et al. (20) reported significant improvements in the EMG BF plus functional electrical stimulation group, but not in the EMG BF group. In the EMG BF-treated groups, Intiso (15) and Mulder (19) found statistically significant improvements in gait parameters after the treatment, and Burnside (18) recorded similar findings in the follow-up visits. Bradley et al. (17) found no difference between EMG BF and controls in the 10-m walking time, whereas Binder (21) reported significantly better results in the 50-m walking time in the EMG BF group.

This study has some limitations. The patients were not divided into acute, subacute or chronic groups according to stroke duration. Grouping patients by particular stroke duration could have been resulted in more reliable results. In addition, the number of treatment sessions can be considered as a limitation, as the treatment was limited to 10 sessions. However, the patients were advised to continue a home exercise programme and were encouraged at each visit to perform exercises.

In conclusion, this study suggests that exercise with or without EMG biofeedback is effective for improving clinical and functional parameters in hemiplegic patients. Larger studies are needed to determine whether EMG BF assisted exercises provide additional benefits.

The authors have no conflicts of interest to declare.

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