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The effectiveness of functional electrical stimulation for the treatment of shoulder subluxation and shoulder pain in hemiplegic patients: A randomized controlled trial

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Abstract

Purpose. To investigate the effect of functional electrical stimulation (FES) for the treatment of shoulder subluxation and shoulder pain in hemiplegic patients.

Method. A total of 50 hemiplegic patients with shoulder subluxation and shoulder pain were included in the study. The patients were randomly divided into the study and control groups. All patients were put on a rehabilitation program using conventional methods while the study group patients were additionally applied FES to supraspinatus and posterior deltoid muscles. The shoulder pain of all patients during resting, passive range of motion (PROM) and active range of motion (AROM) was measured with the visual analog scale (VAS) while the shoulder subluxation levels were evaluated with the classification developed by Van Langenberghe and by using the millimetric measurements on anteroposterior shoulder X-ray before and after the physical treatment and rehabilitation program and compared.

Results. Comparison of the resting AROM *vs.* PROM VAS value changes showed no significant difference between the groups. There was a significant difference between the two groups for the amount of change in shoulder subluxation in favor of the study group.

Conclusions. The results of our study have shown that applying FES treatment to the supraspinatus and posterior deltoid muscles in addition to conventional treatment when treating the subluxation in hemiplegic patients is more beneficial than conventional treatment by itself.

Keywords: *Hemiplegia, rehabilitation, shoulder subluxation, functional electrical stimulation*

Introduction

Stroke due to paralysis and cognitive disturbance in the patients that survive is a major cause of disability [1]. Problems related to the upper extremity have a negative effect on rehabilitation in patients with stroke. Shoulder problems are the most important component of upper extremity complications in patients with stroke. Disturbed shoulder biomechanics lead to subluxation and shoulder pain [2].

Functional electrical stimulation (FES) is the stimulation of muscles with disturbed nerve function by an electrical current to achieve functional and beneficial movement. Various studies have examined the effectiveness of FES in shoulder subluxation and shoulder pain treatment [3–10]. For instance, Faghri et al. [3] evaluated the shoulder pain and shoulder subluxation using lateral range of motion (ROM) test and a modification of the distance measured from a single anterior–posterior radiograph of the shoulder described by Prevost and coworkers. Chantraine et al. evaluated shoulder pain and shoulder subluxation by visual analog scale (VAS) evaluation in resting, passive, and active range of motion (AROM) and Batz subluxation scale, respectively [4]. Yu et al. [5] evaluated the affected shoulder with Brief Pain Inventory and a vertical distance between the most inferolateral point on the clavicular portion of the acromioclavicular joint and the center of the humeral head. Different from these

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studies, we investigated that the effectiveness of FES in shoulder subluxation and shoulder pain using the more assessment methods for evaluation in patients who developed hemiplegia because of stroke thus the results of our study had been strengthen. We evaluated the affected shoulder in our study at rest and during passive and active ROM of the shoulder using VAS and the classification developed by Van Langenberghe et al. [11] and the millimetric measurement and calculation using the shortest distance between two parallel lines drawn from the inferior border of the acromion and the superior border of the humerus head on the posteroanterior shoulder X-ray as defined by Hall et al. [12].

Methods

Patient sample and inclusion criteria

A total of 50 suitable patients with shoulder subluxation and shoulder pain were included in the study from a total of 530 patients who had developed hemiplegia due to stroke and put in the rehabilitation program as an inpatient between November 2006 and January 2008 at the Republic of Turkey Ministry of Health, Ankara Physical Treatment and Rehabilitation Training and Research Hospital. The patients were randomly divided into the study and control groups. Patients without shoulder subluxation and shoulder pain, patients with a cardiac pacemaker and especially those with cardiac failure with conduction problems, a continuing neurological deficit due to past contralateral stroke, a shoulder pathology not related to the stroke (tumor, infection, scapular instability, winged scapula), complicated regional pain syndrome or brachial plexus lesion, patients who were unco-operative and epilepsy patients who had suffered an attack within the last 6 months were excluded from the study (Figure 1).

All patients were provided information on the study and a written informed consent form was signed. The study was approved by the Ankara Physical Medicine and Rehabilitation Education and Research Hospital Training Planning Committee.

Assessments and outcome measures

The age, gender, hemiplegia etiology (thromboembolic-hemorrhagic), hemiplegia duration (the time from the onset of the disorder to the time they

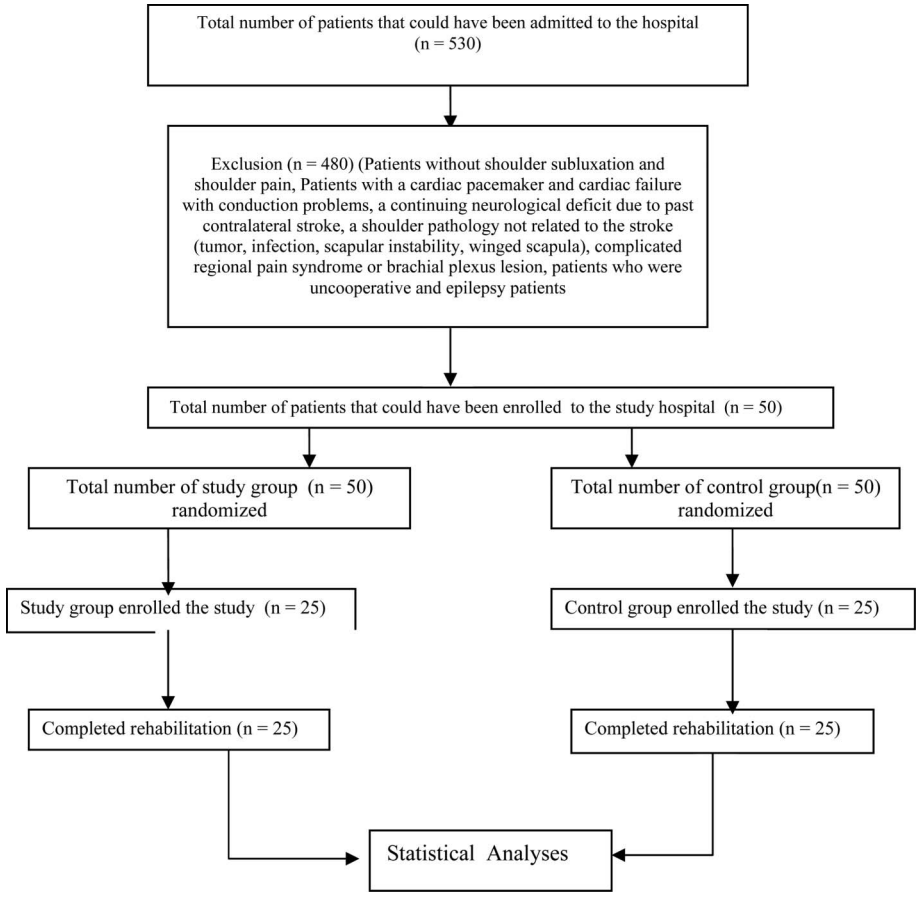

Figure 1. Flow diagram for randomized subject assignment in this study.

entered the rehabilitation program), and the side of the hemiplegia was recorded for all patients.

The evaluation of the affected side shoulder in the study and control groups was with pre- and post-rehabilitation VAS evaluation in resting, passive range of motion (PROM) and AROM in flexion and abduction of the shoulder. A 10 cm-long line was drawn and graded at 1 cm intervals for this purpose. Zero was defined as no pain and 10 as the most severe pain [13]. Shoulder subluxation was evaluated with pre- and post-rehabilitation anteroposterior shoulder X-rays using the classification developed by Van Langenberghe et al. [11]. The shortest distance between two parallel lines drawn from the inferior border of the acromion and the superior border of the humerus head on the anteroposterior shoulder X-ray was measured and calculated in millimeters [12]. The anteroposterior X-rays of both shoulders were taken while the patient sat straight with the arms at the side and with no arm support. X-ray was not taken until at least 24 h after the stimulation to eliminate any possible short-term effects.

All measurements were performed by the same investigator to provide data standardization.

All patients were put on a rehabilitation program using conventional methods while the study group patients were additionally applied FES treatment five times a day, 1 h daily for 4 weeks and a total of 20 sessions to the hemiplegic side supraspinatus and posterior deltoid muscles. Stimulation of the supraspinatus muscle with an active electrode would also stimulate the upper trapezius muscle and lead to shaking of the shoulder and we therefore placed the active electrode over the posterior deltoid muscle to prevent this occurrence. A shoulder sling and armchair arm were used during treatment to provide the proper position and protect the shoulder joint. A device with two superficial electrodes and adjustable open-closed stimulus cycle, stimulus intensity and start and finish periods of stimulus was used for FES treatment. The frequency of stimulation was set to 36 Hz to provide tetanized muscle contraction. FES intensity was adjusted to produce humerus elevation together with some abduction and flexion to withdraw the humerus head into the glenoid cavity. The contraction–relaxation ratio of FES sessions was adjusted progressively from 10/12 s to 30/2 s (Table I).

Table I. Parameters of FES devices applied on the patients.

Duration	60 min
Current	Biphasic
Stimulus duration	10 s–30 s
Fall duration	1 s
Rest duration	12 s–2 s
Raise duration	1 s
Impulse duration	250 μs
Frequency	36 Hz

Statistical analysis

Data analysis was with the SPSS 11.5 (Statistical Package for Social Sciences, SPSS, Chicago, IL) package software. The Shapiro–Wilk test was used to determine whether the continuous variable distribution was normal. Descriptive statistics were provided as mean $\pm$ standard deviation or median (minimum–maximum) for continuous variables while the number of cases and percentages were used for nominal variables. Student's *t*-test was used to determine whether a statistically significant difference was present between the groups for the normally distributed continuous variables and the Mann–Whitney *U* test was used to determine whether a statistically significant difference was present for continuous or orderable variables not normally distributed. The Wilcoxon Signed rank test was used to evaluate whether a statistically significant change had occurred at rehabilitation follow-ups compared to pre-rehabilitation within the groups. Pearson's Chi-square test was used for categorical comparisons. A p value <0.05 was considered statistically significant.

Results

There were 25 patients in the study group with 20 (80%) females and 5 (20%) males. There were 25 patients in the control group with 16 (64%) females and 9 (36%) males. The mean age was 60.7 $\pm$ 9.49 (44–76) in the study group and 62.0 $\pm$ 9.72 (42–79) in the control group. The median hemiplegia duration was 180 (30–1440) days in the study group and 90 (45–240) days in the control group. The stroke etiology was thromboemboli in 17 (68%) and hemorrhage in 8 (32%) patients in the study group while it was thromboemboli in 15 (60%) and hemorrhage in 10 (40%) patients in the control group. There were 8 (32%) right hemiplegics and 17 (68%) left hemiplegics in the study group and 10 (40%) right hemiplegics and 15 (60%) left hemiplegics in the control group. There were no statistically significant differences between the groups for age, gender, etiological cause, hemiplegia duration or hemiplegic side ($p > 0.05$).

There was no statistically significant difference between the pre-rehabilitation resting and Passive ROM (PROM) VAS values of the study and control groups ($p > 0.05$). There was no statistically significant difference between the pre- and post-rehabilitation resting and PROM VAS values of the study group ($p > 0.05$) while there was a statistically significant difference between the pre- and

post-rehabilitation resting and PROM VAS values of the control group ($p < 0.05$). Comparison of the changes between the pre- and post-rehabilitation resting and PROM VAS values did not reveal a statistically significant difference between the groups ($p > 0.05$) (Table II and III).

We found no statistically significant difference between the pre-rehabilitation Active ROM (AROM) VAS values of the study and control groups ($p = 0.245$). We found no statistically significant difference between the pre- and post-rehabilitation AROM VAS values of the study and control groups ($p = 0.073$ and $p = 0.174$, respectively). Comparison of the change between post-rehabilitation and pre-rehabilitation AROM VAS values did not reveal a statistically significant difference between the groups ($p = 0.385$) (Table IV).

We found no statistically significant difference between the pre-rehabilitation shoulder subluxation values according to the classification developed by Van Langenberghe et al. and the millimetric measurement of the study and control groups ($p > 0.05$). We found a statistically significant difference between the pre- and post-rehabilitation shoulder subluxation values of the study group ($p < 0.001$) but we did not find a statistically significant difference between the pre- and post-rehabilitation shoulder subluxation values of the control group ($p > 0.05$). Comparison of the change (decrease in subluxation levels) between post-rehabilitation and pre-rehabilitation shoulder subluxation values revealed a statistically significant difference between the groups in favor of the study group ($p < 0.05$). The amount of change in the study group (decrease in subluxation levels) was higher than in the control group (Tables V and VI).

Discussion

The incidence of shoulder pain is 5 to 84% in patients with stroke [14–16]. Glenohumeral joint subluxation is seen at an incidence of 17 to 81% in patients with stroke [17]. The aim of our study was to investigate the effectiveness of FES in the treatment of shoulder subluxation and shoulder pain

Table II. Comparison of the pre- and post-rehabilitation affected side shoulder resting VAS values of study and control groups.

	Pre-rehabilitation	Post-rehabilitation		Change amount
Study ($n = 25$) Median (min–max)	0.0 (0–7.5)	0.0 (0–5)	$p = 0.112$	0 (−5 to 4)
Control ($n = 25$) Median (min–max)	0.0 (0–10) $p = 0.442$	0.0 (0–7.5) $p = 0.857$	$p = 0.016$	0 (−7.5 to 0) $p^{\star} = 0.818$

The Wilcoxon signed rank test was used for within group comparisons and the Mann–Whitney *U* Test for the between group comparisons. *Δ Comparison of change values (Δ = BT–AT) between groups. BT, before treatment; AT, after treatment.

Table III. Comparison of the pre- and post-rehabilitation affected side shoulder PROM VAS values of study and control groups.

	Pre-rehabilitation	Post-rehabilitation		Change amount
Study ($n = 25$) Median (min–max)	7.5 (0–10)	0.0 (0–5)	$p = 0.148$	0 (−7 to 5.5)
Control ($n = 25$) Median (min–max)	5 (0–10) $p = 0.054$	7.5 (0–10) $p = 0.061$	$p = 0.007$	0 (−4.5 to 0) $p^{\star} = 0.975$

The Wilcoxon Signed Rank Test was used for within group comparisons and the Mann–Whitney *U* Test for the between group comparisons. *Δ Comparison of change values (Δ = BT–AT) between groups. BT, before treatment; AT, after treatment.

Table IV. Comparison of the pre- and post-rehabilitation affected side shoulder AROM VAS values of study and control groups.

	Pre-rehabilitation	Post-rehabilitation		Change amount
Study ($n = 25$) Median (min–max)	0.0 (0–7.5)	0.0 (0–5)	$p = 0.073$	0 (−5 to 3)
Control ($n = 25$) Median (min–max)	1.5 (0–7.5) $p = 0.245$	0.0 (0–10) $p = 0.054$	$p = 0.174$	0 (−3 to 2.5) $p^{\star} = 0.385$

The Wilcoxon Signed Rank Test was used for within group comparisons and the Mann–Whitney *U* Test for the between group comparisons. *Δ Comparison of change values (Δ = BT–AT) between groups. BT, before treatment; AT, after treatment.

Table V. Comparison of the pre- and post-rehabilitation shoulder subluxation stages (according to the classification developed by Van Langenberghe et al.) of study and control groups.

	Pre-rehabilitation	Post-rehabilitation		Change amount
Study ($n=25$) Median (min–max)	2 (1–4)	1 (0–4)	$p<0.001$	−1 (−2 to 0)
Control ($n=25$) Median (min–max)	2 (1–4) $p=0.428$	2 (0–4) $p=0.194$	$p=0.052$	0 (−2 to 1) $p^{\star}=0.003$

The Wilcoxon Signed Rank Test was used for within group comparisons and the Mann–Whitney U Test for the between group comparisons.
*Δ Comparison of change values (Δ = BT–AT) between groups. BT, before treatment; AT, after treatment.

Table VI. Comparison of the pre- and post-rehabilitation shoulder subluxation values of study and control groups.

	Pre-rehabilitation	Post-rehabilitation		Change amount
Study ($n=25$) Median (min–max)	10 (0–26)	5 (0–25)	$p<0.001$	−3 (−19 to 2)
Control ($n=25$) Median (min–max)	10 (0–23) $p=0.763$	10 (0–20) $p=0.042$	$p=0.077$	−2 (−11 to 5) $p^{\star}=0.025$

The Wilcoxon Signed Rank Test was used for within group comparisons and the Mann–Whitney *U* Test for the between group comparisons.
*Δ Comparison of change values (Δ = BT–AT) between groups. BT, before treatment, AT, after treatment.

in patients developing hemiplegia due to stroke. Various studies have examined the effectiveness of FES in shoulder subluxation and shoulder pain treatment [3–10]. Different from these studies, we investigated that the effectiveness of FES in shoulder subluxation and shoulder pain using the more assessment methods for evaluation in patients who developed hemiplegia due to stroke.

The incidence of stroke by gender varies in different studies. Davenport et al. [18] have reported a distribution of 54% females and 46% males in their 613 patients with stroke. Petruseviciene and Krisciūnas [19] reported a distribution of 53% females and 47% males in their 100 patients with stroke. Gamble et al. [20] reported a distribution of 52% females and 48% males in their study on hemiplegic patients with shoulder pain. Our distribution for the patients with stroke included in our study was 72% females and 28% males.

The mean age for the 59 patients with stroke in the Peurala et al. [21] study was 54.4 years while it was 69.1 years in the Dias et al. [22] study on 40 patients with chronic stroke and 62 in the Ikai et al. [23] study on 75 patients with stroke. The mean age of our patients was 61.3 years.

Chae et al. [24] have found 84% thromboembolic and 16% hemorrhagic stroke in their 61 patients with stroke, while Aras et al. [16] reported 70.5% thromboembolic and 29.5% hemorrhagic stroke in their 85 patients with stroke. Stroke was thromboembolic in 64% and hemorrhagic in 36% of our patients with stroke.

Paci et al. [25] reported the hemiplegic side distribution as 59% left and 41% right in their 107 patients with stroke while these figures were, respectively, 53.6% and 46.4% in the 28 patients with stroke in the study done by Chae et al. [26] and 48% and 52% in the 75 patients with stroke in the study of Ikai et al. [23]. Our distribution was 64% left and 36% right hemiplegia.

Faghri et al. [3] studied the effect of FES on shoulder pain in 26 hemiplegic patients. The pain level in the control group was found to be higher than in the study group at weeks 6 and 12.

Chantraine et al. [4] studied the effectiveness of FES in 120 patients who had traumatic brain damage or hemiplegia caused by stroke. The decrease in shoulder pain in the study group was found to be statistically significantly higher than in the control group.

Yu et al. [5] studied the effect of percutaneous intramuscular neuromuscular electrical stimulation (perc-NMES) on shoulder pain in eight chronic hemiplegic patients. There was a significant decrease in pain 24 h after the 6-week treatment while this decrease did not continue 3 months after the treatment and even showed an increase.

Renzenbrik and Ijzerman [6] applied percutaneous neuromuscular electrical stimulation to 15 patients with treatment-resistant chronic shoulder pain and shoulder subluxation due to hemiplegia. The pain intensity decreased markedly following treatment and this continued at follow-ups.

We evaluated the affected shoulder in the study and control groups at rest and during passive and

active ROM of the shoulder using VAS. There was no statistically significant difference between the rest, during AROM and PROM in the study group and during AROM in the control group post-rehabilitation compared to the pre-rehabilitation values while there was a statistically significant decrease in pain post-rehabilitation compared to pre-rehabilitation at rest and during PROM in the control group. Evaluation of pain at rest and during AROM and PROM with VAS revealed no statistically significant difference between the study and control groups when the post-rehabilitation change amount was compared to the pre-rehabilitation values in the study and control groups.

The study by Faghri et al. on 26 hemiplegic patients where they evaluated the effect on FES on shoulder subluxation measured the vertical and horizontal subluxation of the glenohumeral joint at study initiation and at weeks 6 and 12 with posteroanterior X-rays of the shoulder. There was a statistically significant decrease in the study group for week 6 vertical subluxation compared to the initial values but there was a mild increase in the shoulder subluxation at week 12 compared to week 6 although not statistically significant. The control group showed a statistically significant increase in vertical subluxation at week 6 compared to the initial values and the week 12 shoulder subluxation values showed a mild decrease compared to week 6 although not statistically significant. There was no statistically significant change in the study or control group for horizontal subluxation [3].

Wang et al. studied the effect of FES treatment on shoulder subluxation in acute and chronic hemiplegic patients. The patients were divided into short and long disease duration. There was a statistically significant decrease in the shoulder subluxation in the study group compared to the control group in patients who had the disease for a shorter period at the end of 6 weeks of treatment. However, this effect did not continue at week 12. Following the 2nd FES treatment, evaluation at week 18 showed a significant decrease in shoulder subluxation in the study group again. There was no significant difference between the study and control group shoulder subluxation values in patients with long-term disease [7].

Chantraine et al. studied the effect of FES on shoulder subluxation in patients with hemiplegia due to traumatic brain damage or stroke. They observed a significant difference between the study and control groups for shoulder subluxation at month 6 and found this difference to continue at month 12 and 24 [4].

A study by Baker and Parker [8] on chronic hemiplegic patients investigated the effect of electrical stimulation (ES) on shoulder subluxation in chronic hemiplegic patients. Evaluation following the 6-week treatment revealed a statistically significant decrease in shoulder subluxation in the control group compared to the study group.

Yu et al. [5] evaluated the effect of percutaneous intramuscular neuromuscular ES on shoulder subluxation in eight chronic hemiplegic patients. There was a statistically significant decrease in shoulder subluxation at week 6 compared to the pre-rehabilitation values and at month 3 compared to week 6.

Kobayashi et al. [9] studied the effect of ES on shoulder subluxation in 17 chronic hemiplegic patients and found a statistically significant decrease in shoulder subluxation at week 6 compared to study baseline in patients who received ES to the supraspinatus and deltoid muscles compared to the group that did not receive ES.

Linn et al. [10] studied the effect of ES on shoulder subluxation in 40 acute hemiplegic patients. The control group had more shoulder subluxation than the study group following 4-week ES treatment but week 12 evaluation did not show a statistically significant difference for shoulder subluxation between the study and control groups. They concluded that ES was effective on shoulder subluxation while treatment continued but that this effect did not continue for a long time following the treatment.

We evaluated our study and control group patients before and after treatment for hemiplegic shoulder subluxation using the classification developed by Van Langenberghe et al. and the millimetric measurement and calculation using the shortest distance between two parallel lines drawn from the inferior border of the acromion and the superior border of the humerus head on the posteroanterior shoulder X-ray as defined by Hall et al. [13]. The change (decreased subluxation levels) between the post-rehabilitation and pre-rehabilitation shoulder subluxation levels in the two groups was statistically significant in favor of the study group. The amount of change in the study group (decreased subluxation levels) was higher than in the control group. We did not classify our patients according to disease duration and we therefore did not test whether FES treatment had a different effect on patients with short and long disease durations. We also did not test the long-term effect of FES treatment on shoulder subluxation as we did not follow up the patients after the study.

The results of our study have shown that FES treatment application to the supraspinatus and posterior deltoid muscles in addition to conventional treatment methods for the treatment of shoulder subluxation in patients who develop hemiplegia following stroke is more beneficial than conventional treatment application by itself.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the article.

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