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Effect of pulsed electromagnetic field therapy in patients with supraspinatus tendon tear

Mesut Özdemir[1]*, Mustafa Fatih Yaşar[2], Elif Yakşi[2]

SUMMARY

OBJECTIVE: The aim of this study was to compare the effect of transcutaneous electrical nerve stimulation (TENS), ultrasound (US), and pulsed electromagnetic field (PEMF) combination with TENS and US therapy alone in patients with supraspinatus tear.

METHODS: Forty patients were included in this study. The patients were randomly divided into two groups as follows: PEMF (n=20) and Sham (n=20) groups. PEMF was applied to the first group at a frequency of 50 Hz, 25 G intensity, and 20 min/session. The device was turned off while PEMF was applied to the second group. Diathermy (US) and electrotherapy (TENS) were applied to both groups for 10 sessions. Numerical Rating Scale (NRS), University of California–Los Angeles (UCLA) Shoulder Scale, and Shoulder Pain and Disability Index (SPADI) were used as outcome measures.

RESULTS: In both groups, there was a significant improvement in the NRS, UCLA Shoulder Scale, and SPADI scores after treatment compared with pretreatment (p<0.05). In the comparison of the difference between the pretreatment and posttreatment measurement values between the groups, no significant difference was found between PEMF and Sham groups according to the NRS (p=0.165), UCLA Shoulder Scale (p=0.141), and SPADI (p=0.839) scores.

CONCLUSIONS: In our study, a combination of PEMF therapy with conventional physical therapy modalities was not found to be superior to the conventional therapy alone, and adding it to the routine treatment of symptomatic supraspinatus tear would not provide any additional benefit.

KEYWORDS: Diathermy. Rotator cuff. Magnetic field therapy. Transcutaneous electric nerve stimulation.

INTRODUCTION

Shoulder pain is an important cause of disability and morbidity in individuals' daily life activities causing limitedness and loss of workforce[1]. Rotator cuff pathologies lead by up to 70% among the causes of shoulder pain[2]. It is observed that supraspinatus tendon is mostly affected by the background of subacromial impingement syndrome. Chronic tears are seen later in life as a result of chronic overuse and degeneration[3].

Degenerative tears, which make up most of rotator cuff tears, can be partial or complete. It can be accompanied by symptoms such as pain and loss of function, but it may remain asymptomatic. Conservative treatment should be preferred in partial rotator cuff tears. The surgical indication is limited to symptomatic cases that cause loss of function in full-thickness tears. The purpose of conservative treatment is to reduce pain, eliminate joint motion limitation, improve shoulder functions, and improve muscle strength. Physical therapy modalities and exercise are becoming increasingly important due to the side effects of analgesic drugs. Heat application with therapeutic ultrasound (US) and transcutaneous electrical nerve stimulation (TENS) are the physical therapy modalities that have been widely used in rehabilitation clinics for a long time. The pulsed

[1]Kaçkar State Hospital, Clinic of Physical Therapy and Rehabilitation, Rize, Turkey
[2]Bolu Abant Izzet Baysal Üniversitesi, Medical Faculty, Department of Physical Therapy and Rehabilitation, Bolu, Turkey
*Corresponding author: otebostan@gmail.com
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electromagnetic field (PEMF), which is among the physical therapy methods, has started to be used in the treatment of many musculoskeletal diseases. Magnetic field therapy increases the local cellular activity, provides the organization of collagen fibers, increases the use of oxygen in the tissues, and accelerates the circulation by increasing the vasodilation of blood vessels without increasing local temperature[4]. There are insufficient data on its evidence-based efficacy and superiority to physical therapy agents.

This study aims to compare the effect of TENS, US, and PEMF combination on pain and functional status in patients diagnosed with supraspinatus tear with TENS and US therapy alone.

METHODS

This study was performed according to the Declaration of Helsinki and with permission from the local ethics committee (No. 2018/04). All patients included in this study were informed in detail about this study, and written informed consent forms were obtained.

This study was a prospective randomized study. A total of 40 patients who were diagnosed as supraspinatus tear by MRI and who had fulfilled the inclusion criteria were included in this study. The patients were randomly divided into two groups as follows: the patients who received PEMF therapy (Group 1, n=20) and those who received Sham–PEMF therapy (Group 2, n=20). A sealed envelope method was used for randomization. The patients were treated with PEMF in Group 1, and the device was set to 0 to prevent from current flow when applying to the patients in Group 2. Diathermy application (US) and TENS treatments were applied to all patients within the scope of the standard physical therapy program.

Treatments were done by a physiotherapist, and the results were followed up by experienced physiatrists observationally. Information about the cases deemed eligible to participate in the study was recorded in the patient assessment form prepared at the first evaluation session. All patients were evaluated twice routinely with shoulder pain and functionality measurements, at the beginning and the end of the treatment program.

All patients were included in the physical therapy program, i.e., one session a day, 5 days/week for a period of 2 weeks. Diathermy application was performed with a therapeutic US device (Chattanooga, Intelect Advanced, United Kingdom) for 10 min to the relevant shoulder at a dose of 1 W/cm^2. The TENS device (Fizyomed Fizyotens, Turkey) with two electrodes surrounding tendon was performed for 30 min at a frequency of 100 Hz for current application. The intensity of current was applied in the amplitude, which does not create muscle contraction and creates a feeling of numbness and tingling.

In the PEMF application, with the PEMF device (Roland HC, Pagani Elettronica, Italy), two solenoid applicators were placed at the anterior and posterior positions in the patient's shoulders and applied for 25 min at 25 G intensity at a frequency of 50 Hz.

All cases were evaluated clinically and radiographically. For a definitive diagnosis, anamnesis, locomotor system examination, biochemical tests, and shoulder MRI images were used. Numerical Rating Scale (NRS), University of California–Los Angeles (UCLA) Shoulder Scale, and Shoulder Pain and Disability Index (SPADI) were used before and after treatment to assess pain and functional status.

Statistical analysis

All statistical analyses were performed using SPSS software for Windows version 24.0 (SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test was used to test the normal distribution of continuous variables. The Wilcoxon signed-rank test was used to determine the change of values within the groups before and after treatment scores. The Mann–Whitney *U*-test was used to evaluate the difference between patients' pretreatment and posttreatment scores by groups. A p-value <0.05 was considered statistically significant.

RESULTS

Out of 40 patients, 13 were males and 27 were females with a median age of 66 (range: 45–85) years. Regarding the type of tear, the complete tear was detected in 5 (12.5%) of all patients and the partial tear in 35 (87.5%) patients. There was no significant difference between the two groups in terms of age, gender, and impaired shoulder (Table 1).

When the NRS, UCLA Shoulder Scale, and SPADI scores of the PEMF (Group 1) and Sham (Group 2) groups were compared between the first and the last measurements of within-group values, a significant decrease was found in the NRS, UCLA Shoulder Scale, and SPADI values in both groups (p<0.001; Table 2).

When comparing the difference between the pretreatment and posttreatment values between the groups, there was no statistically significant difference between Group 1 and Group 2 according to the NRS, UCLA Shoulder Scale, and SPADI scores (p-values are 0.146, 0.141, and 0.839, respectively; Table 3).

DISCUSSION

Rotator cuff syndrome is the most common cause of shoulder pain seen on the background of subacromial impingement syndrome, which can be seen with different settings from tendinitis to complete tear in the rotator cuff. It can be partial or full thickness according to the affected tendon region. In the classification of Neer's subacromial impingement syndrome, rotator cuff tears are included in Stage 3, whereas reversible edema and tendinitis develop in Stage 1, tendinosis develops in Stage 2, and tear occurs in Stage 3[5]. In our study, patients with chronic rotator cuff tear (Stage 3) were treated. There may be symptoms, such as pain and loss of function in rotator cuff tears, and asymptomatic tears may also occur. Partial tears become more symptomatic due to the tension in the intact muscle fibers and increase the admissions to the hospitals[6]. The partial tear dominance in our study may be related to this situation.

In cases other than acute traumatic tear, the conservative approach is recommended for the treatment. In addition to medical therapy, physical therapy agents such as electrotherapy, superficial and deep heaters, and their combination with exercise practices are often used. The conservative treatment applications in patients with full-thickness tear help reduce inflammation, control pain, and maintain muscle strength. Moosmayer et al.[7] investigated the results of surgical and conservative (i.e., physiotherapy) treatment of patients with full-thickness tears. After 1 year of follow-up, patients in the surgery group showed better results than the physiotherapy group; however, they reported that 82% of patients in the second group also showed acceptable improvement. In the literature, physical therapy applications are more effective on pain and functional status than placebo in the treatment of rotator cuff syndrome[8].

There are few studies in the literature regarding the use of PEMF therapy in rotator cuff syndrome. Hypotheses on this

Table 1. Demographic data of the groups.

	Group 1 (PEMF)	Group 2 (Sham)	p
Average age	65.6±6.6	64.6±11.5	0.727
Gender (females/males)	13/7	14/6	0.736
Impaired shoulder (right/left)	10/10	7/13	0.337
Impaired shoulder (dominant/nondominant)	11/9	7/13	0.204

PEMF: pulsed electromagnetic field.

Table 2. In-group evaluation results of the scales.

		Pretreatment Median (min–max)	Posttreatment Median (min–max)	*z*	p
NRS	PEMF	4.5 (0–8)	2 (0–5)	-3.49	<0.001
	Sham	4.5 (0–8)	0.5 (0–4)	-3.53	<0.001
UCLA	PEMF	14.5 (11–31)	25 (21–35)	-3.828	<0.001
	Sham	15 (10–29)	24.5 (14–31)	-3.632	<0.001
SPADI	PEMF	70 (13.07–90.7)	50.75 (0–80)	-3.823	<0.001
	Sham	69.2 (26.15–86.1)	46.9 (16.9–62)	-3.921	<0.001

NRS: Numerical Rating Scale; UCLA: University of California–Los Angeles Shoulder Scale; SPADI: Shoulder Pain and Disability Index; PEMF: pulsed electromagnetic field.

Table 3. Comparison of changes in groups before and after treatment.

	Group 1 (PEMF) Median (min–max)	Group 2 (Sham) Median (min–max)	*z*	p
NRS	2 (0–5)	2.5 (0–8)	-1.38	0.165
UCLA	10 (0–23)	9 (0–14)	-1.471	0.141
SPADI	21.5 (0–68)	21.53 (6–46.9)	-0.203	0.839

NRS: Numerical Rating Scale; UCLA: University of California–Los Angeles Shoulder Scale; SPADI: Shoulder Pain and Disability Index; PEMF: pulsed electromagnetic field.

subject are based on the effect of the magnetic field to promote soft tissue healing. Tucker et al.[9] showed earlier improvement of the rotator cuff tendons and an increase in bone quality histopathologically after the application of PEMF therapy to the shoulder joint in rats. In a study conducted with cell cultures, it was shown that growth factors and the expression of cytokines increased in tendon cells with a low-frequency pulsed magnetic field, and it was concluded that PEMF stimulates tendon cell proliferation and has no toxic effect[10].

We found that the oldest clinical study regarding the use of PEMF on the shoulder was published by Binder et al.[11] in 1984. They reported that PEMF therapy is beneficial in severe and persistent chronic rotator cuff lesions.

Aktaş et al.[12] examined the effectiveness of PEMF therapy in two groups of patients with 46 subacromial impingement syndromes in a double-blind randomized controlled study. For the first group, PEMF therapy has been applied for 15 sessions, and Sham–PEMF therapy has been applied to the second group for the same period. At the end of 3 weeks, there was a significant improvement in the Visual Analog Scale (VAS) scores, Constant score, and Shoulder Disability Questionnaire scores of the two groups compared with the baseline, but they did not find any difference between the two groups.

Freitas et al.[13], in a study investigating the effectiveness of PEMF in patients with impingement syndrome, have applied PEMF therapy to the treatment group and Sham–PEMF therapy to the control group. Then, they included the patients in both groups on a 6-week home exercise program. From the patients who were followed up for 3 months after the treatment, the group receiving active PEMF therapy showed more functional improvement and fewer pain symptoms at all stages than the initial value. The authors concluded that PEMF therapy had positive effects on functional improvement, muscle strength, and pain relief in patients with subacromial impingement syndrome.

Finding the results of these studies in opposition to each other may be due to the difference in the methods used. Both studies were conducted in a double-blind randomized prospective and placebo-controlled process. The most important methodological difference is in the intensity of the applied electromagnetic field (EMF). DeFreitas et al. stated that the optimal dosimeter was not developed in the treatment with EMFs and remained true to the parameters (i.e., 200 G and 50 Hz) previously determined by the device manufacturer. Although we also adopted this method, we found that the default dose of our device for shoulder pathologies was significantly lower than that of DeFreitas (i.e., 25 G and 50 Hz). Aktaş et al. did not give a reason in their study, but they used a magnetic field close to the dose we used (i.e., 30 G and 25 Hz). However, it is possible to assume that they use the default settings on the device when determining the dose.

The main factor that distinguishes our study from previous studies is that the use of MRI for the detection of rotator cuff tear and the comparison of PEMF therapy with Sham. We found a significant improvement in the NRS, SPADI, and UCLA Shoulder Scale scores in both groups compared with baseline values. The score changes in the NRS and SPADI scores of both groups were above the minimum clinically significant difference value and were statistically significant, but there was no significant difference between the groups. Significant improvements were observed in the total scores of the UCLA Shoulder Scale questionnaires of both treatment and control groups and all subsection scores (i.e., pain, function, active forward flexion, flexion muscle strength, and patient satisfaction) at the end of treatment compared with baseline. However, there was no statistically significant difference in the UCLA Shoulder Score change in the between-group evaluation.

The main limitation of this study was low sample size and single-center design. Other limitations of this study were that the long-term effects of PEMF and the effect of PEMF without conventional therapy were also not investigated.

CONCLUSIONS

Our study showed that standard physical therapy in rotator cuff tears had a positive effect on the symptomatic and functional status in the early period. However, the combination of PEMF therapy with other physical therapy agents was found to be similarly effective with the placebo group, and adding it to our routine treatment program did not provide additional benefit. PEMF is supported as an inexpensive, reliable, and alternative therapy method. More studies are needed to establish the standard protocols in PEMF applications.

ETHICS STATEMENT

All participants provided written informed consent forms before enrolling in this study. This study was carried out in compliance with the principles of the Declaration of Helsinki. The study protocol was approved by Bolu Abant Izzet Baysal University Clinical Research Ethics Committee (No. 2018/04).

AUTHORS' CONTRIBUTIONS

MÖ: Conceptualization, data curation, formal analysis, investigation, and writing – original draft. **MFY:** Conceptualization, supervision, and writing – review and editing. **EY:** Conceptualization, supervision, and writing – review and editing.

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