Pulsed Electromagnetic Field in Patients with Shoulder Impingement Syndrome

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ABSTRACT

Study

Double-blind, randomized controlled trial.

Objectives

Evaluate the effects of pulsed electromagnetic field (PEMF) in reducing pain, improve function and muscle strength in patients with shoulder impingement syndrome (SIS).

Introduction

Recent studies show that a PEMF based program has been indicated for musculoskeletal disorders. However, there are few clinical studies to evaluate the results of this type of program for SIS.

Methods

Fifty-six patients were recruited, aged between 40 and 59 years, diagnosed with SIS. The participants were divided into two groups: PEMF (n = 26, average age of 50.77 years) and Placebo Group (n = 30, ages of 50.15 years). The variables UCLA, scale of constant Murley, EVA and internal and external rotation and shoulder elevation muscle strength were used.

Results

At the end of treatment, both groups showed improvements in all outcome measures in relation to baseline values. Changes over time at UCLA, Constant-Murley and EVA were not different between PEMF and placebo group.

Conclusion

The PEMF was effective in improving the function of the shoulder and pain relief in patients with SIS. There was a slight improvement of pain in both groups, after the application of PEMF and Placebo, with no statistically significant difference between the groups, which suggested there was a placebo effect.

Level of evidence

Therapy, level 1A

INTRODUCTION

Shoulder impact syndrome (SIS) is the most common cause of shoulder pain in adults (Imhoff et al., 2004; Jerosch et al.; 2002; Neer.; 1972). It is observed between 7 and

25 in every 1000 consultations with general clinicians. It´s prevalence in patients under 70 years is about 7 to 27%, and above this age it varies between 13.2 to 26% and is the third most pain cause in musculoskeletal disorders being only behind the spine and knee pain (Van der Windt et al.;1995; Luime et al., 2004).

The mains characteristic of the disease is pain, usually located in the anterolateral region of the shoulder and the lateral aspect of the arm (Fodor et al.; 2009). Most patients complain of night pain and difficulty to lie down on the affected shoulder (Ostor et al.;2005).

Several interventions have been used on the treatment of the SIS, which include the use of medications, surgery and physiotherapy (Rabini et al.; 2012; Haahr et al.; 2005). However, there is little evidence supporting the effectiveness of these therapeutic applications on shoulder pain (Akta et al.; 2007), among them, the use of Pulsed Electromagnetic Fields (PEMF).

The PEMF is indicated for the treatment of musculoskeletal disorders (Tashjian et al.; 2009), reduction of pain, accelerating process of soft tissue regeneration, muscular, tendinous and mostly bone and nerve tissues. However there is no consensus in the literature about the parameters to be used in the treatment of shoulder pain (Leclaire et al.;1991) (Markov et al.; 2007) and little evidence for its positive effects (Quittan et al., 2000; Green et al.; 1998; Aktas et al.; 2009).

Thus, the objective of this study was to evaluate the effects of PEMF in pain, function and muscle strength in patients with impingement syndrome of shoulder. We hypothesized that the group that receives the PEMF would demonstrate significantly better results when compared to placebo PEMF.

MATERIALS AND METHODS

This prospective, randomized, placebo-controlled, double blind was executed in the sector of physiotherapy of the Irmandade Santa Casa de Misericórdia de São Paulo (ISCMSP) from April 2009 to August 2011 in patients with SIS. The study was approved in advance by the Ethics Committee of the institution, under the protocol number 254/09 and registered at clinicaltrials.gov (registration number: NCT01452204).

The study sample was selected from a list of patients of the rehabilitation of the shoulder department of the ISCMSP and was made of sixty-six individuals. The sample size was calculated assuming an 80% power to detect 30% improvement in pain scores (Visual Analog Scale-EVA), with a significance level of 5% across the study by Bang (Bang et al., 2000) and resulted in a sample of 24 individuals per group.

The diagnosis was based on history, clinical examination and ultrasound imaging. The study subjects were of both genders, aged between 35 and 67 years and diagnosed with unilateral shoulder impingement syndrome grades I or II, according to criteria of Neer (Neer; 1983) with symptoms over 3 months. Exclusion criteria: non-steroidal anti-inflammatory drugs (NSAIDs) orally or by infiltration, physical therapy treatment within the past 60 days, pregnant women, subjects with a history of cancer or surgical procedure in the affected shoulder. Were also excluded patients with inflammatory joint diseases (rheumatoid arthritis, lupus, gout, etc), cervicobraquialgia or complex regional pain syndrome. During the screening, all individuals who made use of the medications cited previously interrupted the use seven days prior to starting treatment.

Individuals were randomized through a raffle with an opaque sealed envelope containing the name of the two groups: PEMF - treatment with PEMF and the Placebo group - Placebo (equipment in “stand by”).

The electromagnetic field equipment used was Magnetherp ® 330 Meditea brand, manufactured in 2007, with a previously calibrated pulsed form with a frequency of 50 Hz and field strength of 20 millitesla (mT) or 200 Gauss.

All subjects underwent nine sessions, three times a week with a 48-hour interval. The time of each application was 30 min-

utes, and the electrodes were positioned in the contraplanar technique.

EVALUATION

All patients selected for the study underwent a pretreatment assessment about pain, function and muscle strength. This same procedure was performed after the 3 weeks of pulsed electromagnetic field (PEMF post evaluation) treatment. All these evaluations were performed by a single blind examiner regarding the allocation of individuals. The research subjects were unaware that there was comparison with another group.

Pain and function

The Visual analogue scale of pain (EVA) was used to evaluate the pain, and the Constant-Murley scale (Constant et al.;1987) and the University of California at Los Angeles Shoulder Rating Scale - UCLA (Ellman et al.; 1986) were used to evaluate the functionality.

Muscular strength

The measurement of the strength of the rotator cuff (internal and external rotation) and elevation of the shoulder was performed with a brand manual dynamometer Lafayette ®- model 01163.

To measure the internal and external rotators strength, the subject was positioned in supine, with the shoulder abducted to 45° and with 30° of horizontal adduction (scapular plane), the elbow flexed at 90° and neutral rotation (MacDermid et al.; 2004, Kuhlman et al.; 1992) , with the dynamometer positioned on the wrist.

For the evaluation of strength during the elevation of the shoulder, the subject was kept in a sitting position, with a 45° shoulder abduction, 30° horizontal adduction, neutral rotation and extended elbow. The dynamometer was positioned on the dorsal surface of the wrist. It was required for the patients to perform maximum isometric contraction in all positions. All measurements were performed three times using the average of the three measurements.

Intra-class test (ICC) found satisfactory values for assessment of the medial rotators (ICC = 0.50), excellent for evaluation of lateral rotators (ICC = 0.93) and elevation (ICC = 0.88).

Analysis of the data

Data were analyzed with the SPSS program, version 13.0 (SPSS Inc, Chicago, IL. USES). Descriptive statistical analysis was performed to the demographics and all measurements of results being expressed as mean and standard deviation, followed by confidence interval (CI) of 95%. Comparisons of age, body mass, height, weight, pain scales, scales to determine muscle strength and functional homogeneity of the groups at baseline (pre-treatment) were performed

Figure 1. *CONSORT flow chart, including ITT analysis. Abbreviation ITT, intention to treat.*

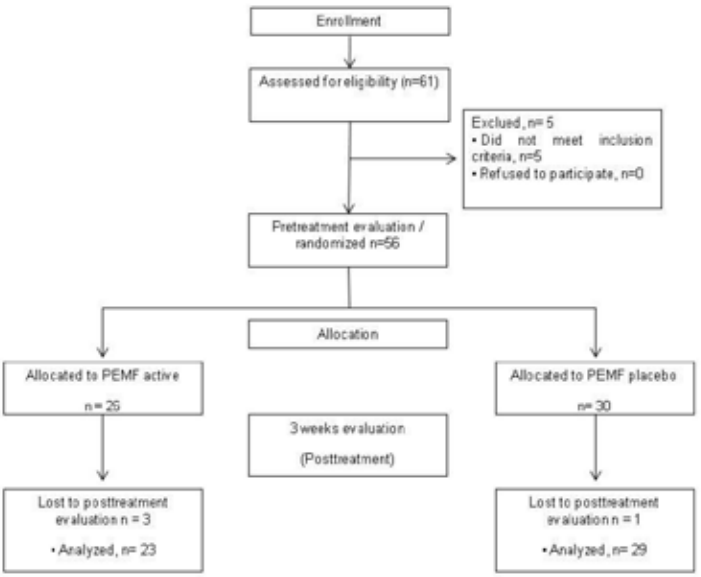

Table 1. *Demographic data of the PEMF and Placebo groups**

	PEMF	Placebo	*P* Value
Age, y	50.1 ± 8.2	50.8 ± 8.2	P >.05
Body mass, kg	76.3 ± 13.7	70.2 ± 12.6	P >.05
Height, m	1.66 ± 10.1	1.58 ± 8.4	P >.05
Body mass index, kg/m^2	27.8 ± 3.9	27.4 ± 4.4	P >.05
Duration of symptoms, mo	22.0 ± 17.7	21.2 ± 19	P >.05
Gender, n			
Male	10	10	
Female	16	20	

** Abbreviations: PEMF pulsed electromagnetic field * values are mean + SD. Only data for the participants who remained to the end of the study are invluded. THere were no differences between groups (P>.05)*

by the independent t test. The results for the pain scales (EVA), functional scales (UCLA and Constant), and muscle strength were analyzed using paired t-test. The statistical significance was considered when ($p < 0.05$).

RESULTS

Baseline and demographic data

In the pre-treatment analysis the groups presented homogeneity for age, height and body weight ($p <. 05$). There was also no statistical difference ($p <. 05$) between the groups for the studied variables at baseline (before intervention).

Fifty-six patients started treatment, however 4 patients did not reach final assessments due to lack of proper conduct or abandonment of the treatment, and were automatically excluded (Figure 1).

Pain, function and muscle strength

The comparison between the groups did not show statistically significant differences ($p <. 05$) for pain, muscle strength and functionality in all scales.

The analysis of pre-and post-intervention indicated that the active group showed improvement in pain and function after the application of PEMF (< p 0.05). However, the placebo group showed only improvements in the levels of pain ($p < 0.05$).

Table 3 summarizes the difference within the same group with association of the 95% confidence interval.

Intention-to-treat analysis

Sample loss of 4 participants during the study (Post-PEMF) did not affect the potential validity of the study because this dropout did not exceed 10% of the total, which required an intention-to-treat analysis.

DISCUSSION

This study aimed to assess the effects of pulsating electromagnetic field in the SIS. The results of this prospective, randomized, double-blind trial showed that the use of PEMF is effective for pain relief and function improvement.

It is estimated that the VAS MCID in shoulder pathology is defined as a decrease in the levels of pain to 1.4 centimeters (Tashjian et al., 2009). It was observed that both groups improved in pain levels, with a significant clinical improvement of 1.7 for the PEMF group and 2.0 cm for the placebo PEMF group. For the functional assessment using Constant and UCLA, the PEMF group achieved significant improvements in both scales, while the placebo group did not show improvements in function.

Meanwhile, Aktas (Aktas et al., 2007), conducted a study that used the PEMF as auxiliary conduct in the treatment of SIS. The results showed that the combined use of PEMF and exercise for SIS compared to the placebo group did not differ for the pain and function. Our results corroborate previous

Table 2. *Outcome Measures Pretreatment and 3 months post treatment for subjects in the PEMF (n=26) Placebo (n=30) groups who completed the study.*

Analysis Measures Outcome[1]		Pretreatment	PEMF
U.C.L.A. (0-30)[+]			
	PEMF	14.7 ± 5.7 (12.1; 17.2)	22 ± 5.7 (19.5; 24.53)
	Placebo	15 ± 4.8 (13; 17)	16.7 ± 7 (13.8; 19.7)
CONSTANT (0-100)*			
	PEMF	31.3 ±10.6 (26.6; 36)	40.7 ± 12.6 (35.18; 46.37)
	Placebo	35.8 ± 11.7 (31; 40.8)	35.6 ± 11.7 (30.6; 40.5)
VAS (0-10cm)[0]			
	PEMF	6.8 ± 2 (5.9; 7.7)	4.8 ± 2.4 (3.7; 5.8)
	Placebo	7.7 ± 1.9 (6.4; 8)	6 ± (4.9; 7.1)
External Rotation			
	PEMF	22.9 ± 8.55 (25.6; 39.7)	26.79 ± 12.91 (34.4; 49.6)
	Placebo	19.5 ± 7.01 (26; 35.4)	21.55 ± 10.27 (28.7; 38.9)
Internal Rotation			
	PEMF	32.6 ± 15.8 (25.6; 39.7)	38.1 ± 17 (30.5; 45.6)
	Placebo	30.7 ± 11.1 (26; 35.4)	33.75 ± 12 (28.6; 38.8)
Elevation			
	PEMF	23.8 ± 10.8 (19; 28.6)	24 ± 9.6 (19.7; 28.3)
	Placebo	18.9 ± 7.3 (15.8; 22)	19.7 ± 7.9 (16.3; 23)

[1]Presentation on average, standard deviation and 95% confidence interval
[+]Scale de 0-30
Scale Constant Murley 0-100
[0]Visual analogue scale factor of 0 means no pain and 10 the worst pain possible

studies generally found in the literature. Sutbeyaz et al. (2006), observed that the PEMF is effective for the treatment of cervical osteoarthritis, pain reduction and improvement in range of motion, however, compared to the placebo group such results do not have significant differences.

The variations in parameters used in PEMF, hinder a consensus. It is suggested that further studies with different frequency and intensity modulations of PEMF are made to evaluate the effects of different calibrations in individuals with SIS.

CONCLUSION

The PEMF proved to be effective in improving function and pain in individuals with SIS. However the PEMF did not obtain significant differences compared to the placebo group in all variables of the study.

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