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BRIEF REPORT

Additional effect of pulsed electromagnetic field therapy on knee osteoarthritis treatment: a randomized, placebo-controlled study

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Abstract The aim of this study was to evaluate if pulsed electromagnetic field therapy (PEMF) has additional effect on the classical physical treatment of knee osteoarthritis (OA) composed of hot pack, therapeutic ultrasound, and terminal isometric exercises. Forty patients (29 women and 11 men), ages 44 to 78 (mean age was 61.3±7.8 years) were included in our study. Patients with knee osteoarthritis [Kellgren–Lawrence criteria grade 2 and above and an average pain intensity of 40 or more on a 100-mm visual analog scale (VAS)] recruited from outpatient physical medicine and rehabilitation clinic were randomly assigned to receive PEMF or sham PEMF treatment in addition to their physical therapy. Both the PEMF and sham PEMF treatments being evaluated were 55 min/session, five sessions per week for 2 weeks. Each session comprise 20-min hot pack, 5-min therapeutic ultrasound, and 30-min PEMF or sham PEMF treatment applied to the knee of the patients. Patients were evaluated by the Western Ontario and McMasters Universities Osteoarthritis (WOMAC) Index and VAS at the baseline and at the end of treatment. Both PEMF and sham PEMF treatment groups showed statistically significant improvement in WOMAC pain and functional scores at the end of treatment ($p<0.001$ in both groups). There were no statistically significant differences between groups in WOMAC pain, stiffness, and physical function scores after treatment ($p=0.906$, $p=0.855$, $p=0.809$, respectively). There was neither difference in concomitant used acetaminophen dose in both groups ($p=0.289$). The results of this study show that PEMF does not have additional effect on the classical physical treatment in reducing symptoms of knee OA.

Keywords Knee · Osteoarthritis · Pulsed electromagnetic field therapy

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Introduction

Osteoarthritis (OA) is a major health problem and is the most common rheumatologic disease and a frequent cause of pain among middle-aged and elderly people. Although there is no cure for OA, many different pharmacologic and non-pharmacologic treatment modalities have been used to reduce pain and maintain and/or improve joint mobility and limit functional impairment [1, 2].

Despite the lack of knowledge of its effects over placebo, pulsed electromagnetic field therapy (PEMF) has been shown to have beneficial therapeutic effects on a variety of bone- and cartilage-related disorders for the last three decades [1, 3]. PEMF uses electromagnetic fields creating small electrical fields in tissue [3], with an effect of pulsing to produce athermal effects that promote tissue healing and relieve pain and inflammation [1]. Recently, a number of papers have suggested that PEMF can be used for the treatment of OA [2, 4–7], and also the European League Against Rheumatology has rated PEMF treatment

for OA as 1B of evidence and has given a B rating for strength of recommendation [3].

Piezoelectric potentials formed by PEMF may act as the transduction signals that promote bone formation; a similar mechanism exists in cartilage that stimulates chondrocytes to increase proteoglycan synthesis [8]. PEMF enhances chondrogenic differentiation and the synthesis of cartilage extracellular matrix proteins of aggrecan and type II collagen [9].

The aim of this study was to evaluate if PEMF has additional effect on the classical physical treatment in knee OA composed of hot pack, therapeutic ultrasound, and terminal isometric exercises.

Materials and methods

Patients were recruited from the outpatient clinic at the Department of Physical Medicine and Rehabilitation, Hacettepe University Hospital in Ankara from March 2005 through March 2007. Patients were included in our study if they were aged 45–75 years and had been diagnosed with knee osteoarthritis according to the American College of Rheumatology criteria. Patients had had radiological alterations in the knee joint according to the Kellgren–Lawrence criteria grade 2 and above and an average pain intensity of 40 or more on a 100-mm visual analog scale (VAS) in the last 1 week. Informed consent was taken from all patients. The exclusion criteria were pain in the knee due to inflammatory, malignant, or autoimmune disease or other reasons for pain in the knee such as serious varus or valgus defective position. Furthermore, patients were excluded if they had had knee surgery or arthroscopy of the affected knee in the past year, chondroprotective or intra-articular injection in the past 4 months, systemic corticosteroid or physiotherapy in the past 1 month, and if they were unable to understand the questionnaire.

This was a randomized, controlled, double-blind study. Patients were recruited from the outpatient clinic and randomly assigned to the treatment and sham groups according to the randomization chart at the physical treatment and rehabilitation unit. Patients in the treatment and sham groups were unaware of their treatment allocation. Study interventions were developed in a consensus process with our department experts. In each session, 20-min hot pack, 5-min therapeutic ultrasound, and 30-min PEMF were applied to each knee of the patients.

Hydrocollator 53×33-cm hot packs were used as a superficial heating agent that were immersed in tanks at 70°C and applied over three or four layers of insulating towels while patients are in a sitting and knees in extended positions.

Ultrasound was used as a deep heating technique. The Chattanooga Intelect 300 Sound (Chattanooga, US) ultrasound device was used. Ultrasound was applied in a continuous duty cycle. The intensity was 1.5 W/cm^2, and the frequency was 1 MHz. For each knee, the applicator is moved slowly with normal pressure in a circular manner around the patella for 5 min. The applicator sound head size was 5 cm^2, and commercially available coupling gels were used as a coupling medium.

PEMF treatment was supplied by the device Elettronica Pagani, Energy Plus Roland Serie (Italy). Magnetic field was generated by two pairs of solenoid applicators. The applicators were held at the sides of the knee by a Velcro band. PEMF was applied at a frequency of 50 Hz, 30-G intensity, 90-s interval, and 30-min duration in each session. We explained to the patients that they should not expect any noise or particular sensation from the device. The apparatus was applied to the sham PEMF treatment group; however, the intensity of the device was near zero.

Terminal isometric knee exercise was taught to all patients at the beginning of the treatment by one physiotherapist. Patients were sat on a table and a 10-cm diameter rolled towel or wooden cylinder was put under their knee. One-kilogram weight was placed on the patients' ankle, and they were conducted to lock their knee in extension for 5 s and then relax. The patients repeated this exercise program three times a day, 30 repeats each.

Table 1 Patients' characteristics at baseline

	PEMF		SHAM		*p*
	Mean	SD (±)	Mean	SD (±)	
Age	60.55	7.702	62.15	8.152	0.527
Weight (kg)	71.9	10.4	77.3	14.9	0.191
Height (cm)	162.4	7.3	159.4	3.8	0.136
Kellgren–Lawrence score	2.575	0.6	2.3	0.5	0.135
Duration of symptoms (month)	20.55	19.5	35.45	41.16	0.152
WOMAC pain	9.95	3.42	9.5	3.5	0.684
WOMAC stiffness	2.65	1.78	2.8	1.85	0.796
WOMAC disability	32.75	9.3	34.2	12.1	0.675

Patients were randomized to receive PEMF and placebo (SHAM) treatment. No statistical difference was found at baseline between the two groups for any of the variables. All data are expressed as mean with 95% confidence ratio

Table 2 Changes in main outcome measures with treatment

	PEMF (mean, 95% CI)		*p*	SHAM (mean, 95% CI)		*p*
	Before	After		Before	After	
WOMAC pain	9.95	5.3	0.000	9.5	5.45	0.001
WOMAC stiffness	2.65	1.65	0.019	2.8	1.75	0.010
WOMAC disability	32.75	19.05	0.000	34.2	20.1	0.000
VAS	6.42	3.96	0.000	6.86	3.65	0.000

Assessment of the patients at the end of the study (at week 2) revealed a significant reduction in WOMAC subscales (pain, stiffness, and disability) and VAS score in the group of patients receiving PEMF and SHAM treatments. All data are expressed as mean with 95% confidence ratio

Both the PEMF and sham group treatments consisted of ten sessions administered over 2 weeks. For patients with bilateral osteoarthritis, both knees were treated simultaneously with the same duration. In both groups, patients were allowed to take acetaminophen for knee pain if necessary, and the doses taken were documented. The use of other pain treatments including non-steroidal anti-inflammatory drugs (NSAIDs) was not allowed. Patients completed standard questionnaires at the baseline and at the end of treatment. The first questionnaire was given to the patients by the study physician who was blinded and completed before the start of treatment.

The primary outcome measure was the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC, Turkish version) [10]. This questionnaire assesses the severity of joint pain on five questions, joint stiffness on two questions, and limitation of physical functioning on 17 questions. In cases of bilateral osteoarthritis, the average of both knees was assessed. Additionally, the questionnaire included questions on socio-demographic characteristics, 100 mm VAS for pain, the duration of the patients' complaint, and the dosage of acetaminophen that patients used during the treatment session.

SPSS 11.0 for Windows (Chicago, IL, USA) software was used for statistical analysis. Data are reported as mean±SD at a significance level of $p \leq 0.05$. Comparisons within groups were done by Student's paired *t* test. Independent sample *t* test was used to assess the significant difference between PEMF-treated and SHAM-treated patients. This study with 20 patients in each group has 80% power at 5% type I error level to detect a difference of 1.5 unit change in VAS scores between the two study groups, given the observed data structure.

Results

Forty patients fulfilled the study entry criteria. Each of the 20 patients was randomly allocated to the active treatment and placebo groups. All patients completed the study. None of the patients were excluded from analysis. At baseline, there was no statistically significant difference between groups according to age, gender (data not shown), weight, height, Kellgren–Lawrence scores, disease duration, VAS scores, and WOMAC subscales (Table 1). Paired analysis of the follow-up observations on each patient showed statistically significant improvement on each group in the WOMAC pain, disability, and stiffness scores, as well as in the VAS score at study end as compared to baseline (Table 2). No significant difference between the active and sham treatment groups was found with any outcome measure (WOMAC subscales, VAS score, and acetaminophen usage dosages) at study end (Table 3).

Discussion

The present study was performed in order to investigate the additional effect of PEMF on the treatment of OA of knee for improving symptoms. Although the present study is different from previous placebo-controlled studies [3–6], it has similarities with Ay and Evcik's study [11] about the design of trial in that we apply PEMF in addition to another physical therapy modality. In order to evaluate the responsiveness of patients to the treatment, we chose a validated subjective outcome measure that reflects pain,

Table 3 Differences in main outcomes between groups after treatment

	PEMF (mean)	SHAM (mean)	*p*
WOMAC pain	5.30	5.45	0.906
WOMAC stiffness	1.65	1.75	0.855
WOMAC disability	19.05	20.10	0.809
VAS	3.96	3.66	0.637
Paracetamol (mg)	925	1,675	0.289

No significant difference between PEMF and SHAM treatment groups in WOMAC subscales (pain, stiffness, and disability), VAS score, and paracetamol usage dosage at independent sample *t* test. All data are expressed as mean with 95% confidence ratio

stiffness, and disability [12]. The results of this study showed that PEMF does not have any additional effect on reducing symptoms of knee OA evaluated by WOMAC subscales and VAS to traditional heat physiotherapy. Also, the usage of acetaminophen dosage along treatment period did not show any significant difference between active and placebo PEMF treatment groups.

At baseline, placebo and active PEMF-treated groups did not differ in any significant aspects. Both groups had 100% adherence rate to the treatment. WOMAC questionnaire is a disease-specific and sensitive measurement for knee osteoarthritis and recently validated for Turkish language [10, 13]. Patients were not allowed to continue their individual analgesic medication, including NSAIDs, except acetaminophen. It is well known that NSAIDs cause improvement in symptoms and functions of patients with knee OA. In this study, we did not allow our patients to take NSAIDs to clarify the effect of conventional physiotherapy and PEMF. We measured the total amount of acetaminophen taken by active and placebo PEMF groups and did not find any difference between groups, in accordance with Thamsborg et al. [3].

Our findings are in accordance with previous reports [3–6] describing significantly improved WOMAC subscales and VAS scores and acetaminophen usage dose within-group analyses. However, analyzed data between groups did not show any significant findings in these outcome measures that differ from the studies of Trock and Zizic et al. [5, 7].

The differences in the outcomes are largely due to difference in the materials and methods of the studies. In the systematic review of McCarthy et al. [1] on PEMF effect on knee OA, it is concluded that PEMF has little or no value in the management of knee OA. They included five good quality randomized controlled trials in their meta-analysis which used different types of PEMF and different treatment protocols. Our findings are in some respects in accordance with this meta-analysis.

Recently, Ay and Evcik [11] also reported that PEMF has no additional benefits in knee OA treatment. Although experimental data have demonstrated that PEMF has an anabolic effect on osteoblasts and chondrocytes [14–17], within the short duration of the present study, the proliferative effect of PEMF in knee OA could not be shown by improving symptoms. Up-regulation of gene expression of members of the TGF-ß superfamily, the preservation of extracellular matrix (ECM) integrity of cultured cartilage explants, the increase in glycosaminoglycan (GAG) levels in embryonic and immature cartilage and in an experimental model of decalcified bone matrix-induced endochondral ossification were achieved by PEMF application [9, 18–20]. The similar outcomes in both groups in our study cannot completely reject the possible cellular healing effect of PEMF as shown in vitro in animal and in clinical studies [21–25]. Unfortunately, we were unable to measure short-term changes in bone and cartilage metabolism to demonstrate an effect of PEMF.

In this study, we did not use an inactive control group and the follow-up period was not sufficient (final assessment was at the end of 2-week treatment). The placebo effect is expected in this type of trials [3], and we could not exclude this effect in particular since the control device generated some heat. Statistically, our study was able detect a difference of 1.5 unit in VAS score changes between groups. It is true that smaller changes could have been observed with more patients. On the other hand, the difference in changes observed is also clinically insignificant and the decrease in VAS scores is even higher in the sham group, which leads us to believe that the benefit from PEMF remains to be proven.

In conclusion, this study has demonstrated that PEMF added to the treatment of classical superficial and deep heating did not show statistically significant benefit in terms of reduction of pain, stiffness, and disability in patients with OA of knee. Further studies with long-term follow-up are needed to prove the efficacy of PEMF therapy for reducing symptoms irrespective to placebo therapy.

Disclosures No conflict of interest has been declared by all authors.

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