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ORIGINAL ARTICLE

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The effect of pulsed electromagnetic fields in the treatment of cervical osteoarthritis: a randomized, double-blind, sham-controlled trial

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Abstract The purpose of this study was to evaluate the effect of electromagnetic field therapy (PEMF) on pain, range of motion (ROM) and functional status in patients with cervical osteoarthritis (COA). Thirty-four patients with COA were included in a randomized, double-blind study. PEMF was administrated to the whole body using a mat 1.8×0.6 m in size. During the treatment, the patients lay on the mat for 30 min per session, twice a day for 3 weeks. Pain levels in the PEMF group decreased significantly after therapy ($p < 0.001$), but no change was observed in the placebo group. The active ROM, paravertebral muscle spasm and neck pain and disability scale (NPDS) scores improved significantly after PEMF therapy ($p < 0.001$) but no change was observed in the sham group. The results of this study are promising, in that PEMF treatment may offer a potential therapeutic adjunct to current COA therapies in the future.

Keywords Cervical osteoarthritis · Pulsed electromagnetic fields

Introduction

Cervical osteoarthritis (COA) is a clinical syndrome which is described as degenerative changes in the intervertebral disks, vertebral bodies, facet joints, and intervertebral ligaments [1]. Neck pain is a major symptom in COA, the source of which is not unique [2]. It originates from the posterior and posterolateral external fibers of the annulus fibrosus, the posterior longitudinal ligament, nerve roots, dura mater, apophysial joints and muscles. Central pain mechanisms also contribute [3]. In addition, some authors have stressed the importance of psychological and social factors for the onset, and that the development of neck pain and depression, anxiety, distress and related emotions are related to long-term pain and disability [4].

Pain reduces functional status by causing spasm in the surrounding muscles and by limiting the range of motion (ROM) of the neck; thus it is reasonable to assume that an appropriate pain treatment will lead to an improvement in functional status by relieving these underlying problems [5].

Pulsed electromagnetic fields (PEMF) have been used widely to treat nonhealing fractures and related problems in bone healing [6]. The original basis for the trials of this form of therapy was the observation that physical stress on bone causes the appearance of tiny electric currents (piezoelectric potentials) that are thought to be the mechanism of transduction of the physical stresses into a signal that promotes bone formation. Other structures such as collagen, cytoskeletal system structures and the extracellular matrix are also piezoelectric [7]. PEMF treatment is considered to promote the formation of collagen [8] and human chondrocytes [9] and accelerate bone repair [10, 11]. Recent clinical trials dealing with the treatment of osteoarthritis of the knee with PEMF report positive results [6, 7].

The current standard therapy for COA consists of drug therapy (analgesics, NSAIDs), neck support, exercise programs, physiotherapy and manipulation, epidural injections, traction in hospital and various operations [1, 12]. The management of symptomatic disease of COA is still far from optimal. Thus, magnetic therapy represents an attractive alternative for patients suffering from COA.

The purpose of this double-blind sham-controlled study was to evaluate the effect of PEMF on pain, ROM and the functional status and related disability in patients with COA.

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Materials and methods

Patients

A randomized controlled clinical trial was conducted at Ankara Physical Medicine and Rehabilitation Education and Research Hospital outpatient polyclinic from 1 March 2003 to 15 June 2004. Patients were initially consulted by the research physiatrist to receive a diagnostic workup, and to determine whether they met the inclusion criteria. Patients with symptoms indicating COA, such as a history of mechanical localized neck pain, osteophytes, joint-space narrowing, sclerosis of the vertebral margins and subchondral cysts were diagnosed as having COA [13]. Patients were included if they were between 30 and 70 years old, had suffered from neck pain over 3 months, had had no physical or manual therapy for neck pain during the previous 6 months and showed willingness to adhere to treatment and measurement regimens. Patients with brachialgy and pure cervical disk herniation diagnosed by physical examination and CT or MRI, muscle weakness due to cervical spondylotic myelopathy, evidence of a specific pathologic condition such as malignancy, patients suffering from neurological, rheumatologic, metabolic, or endocrine diseases, and patients with myofascial pain syndrome, and/or painful taut bands in the cervical muscles, cardiovascular or pulmonary disorders and cardiac pacemakers were excluded. Female patients who might be pregnant were also excluded.

The ethics committee of the Ankara Physical Medicine and Rehabilitation Education and Research Hospital approved the study protocol.

Randomization

After the baseline assessment and data collection, patients were randomized into two equal groups according to the therapy applied, i.e., PEMF or sham PEMF group.

An independent physician assigned the patients to different groups by using 2 and 4 permutated block size randomization by employing a sequence of random numbers obtained from a statistics textbook. The intent of this allocation strategy was to enroll comparable numbers of subjects receiving PEMF therapy and not receiving PEMF therapy. Randomization was performed by using sequential sealed envelopes prepared by the independent physician before enrollment of the subject. The sealed envelopes were then opened for each patient and patients were included in the study after taking a record of the allocation. Participants and physicians remained blind to the group allocation throughout the study.

PEMF therapy and its application

PEMF was administered to the whole body using a mat 1.8×0.6 m in size. The mat produced a pulsating electromagnetic field with a mean intensity of 40 μT (wave ranger professional, MRS 2000 + Home, Eschestrasse 500, FL-9492 Eschen). The frequency of the PEMF ranged from 0.1–64 Hz.

During the treatment the patient lay on the mat for 30 min per session twice a day for 3 weeks. The same applications were performed in the control group with the same device, but without the PEMF working.

Outcome measures

Patients in each group were investigated in terms of pain, paravertebral muscle spasm and range of neck motion restriction before and after therapy. The functional status was also evaluated before and after therapy. A physician, blinded to the type of therapy, evaluated changes with therapy.

Primary outcome measures were VAS and NPDS. The pain intensity was assessed by means of a visual analogue scale (VAS) [14]. Pain levels were labeled on a line in 10 categories, 10 points indicating unbearable pain and 0 no pain at all.

Functional status and related disability measure was assessed by the ''Neck Pain and Disability Scale'' (NPDS) before and after therapy. NPDS is a 20-item questionnaire developed by using the Million Visual Analogue Scale as a template. The items explore pain intensity; its interference with vocational, recreational, social and functional aspects of living, as well as presence and extent of the associated emotional factors [15]. Each item has a 10-cm VAS. Scoring of each item varies along a continuous scale from 0 to 5. The original version of the NPDS was evaluated and adapted to Turkish population [16].

Secondary outcomes measures included objective and subjective measures. Neck ROM was evaluated in both flexion and extension. Flexion was measured in terms of the distance from the mid-point of chin to the apex of sternal manubrium, in centimeters. Extension range was evaluated as the distance from the occipital tuberosities to the spinous process of C_7 [17]. Paravertebral muscle spasm was examined by the physician with manual pressure and was noted as either present or not.

At the end of the therapy, global patient assessment and need for analgesics or NSAIDs were also recorded. Patient satisfaction was rated as none, slight, good or excellent. Successful outcome was defined as having good or excellent patient satisfaction.

Statistics

The findings were analyzed by using SPSS version 11.0 for Windows. The Mann–Whitney *U* test and the chi-square test were used for statistical analysis.

The size of this study has been restricted because of financial resources and time limitation. The sufficiency of the sample size in the study has been assessed by

performing post hoc power analysis during the stage of interpretation of the results.

Results

A total of 61 consecutive patients were screened. Twenty-seven were excluded (13 did not meet the inclusion criteria, 9 met exclusion criteria and 5 refused to participate); thus a total of 34 patients were enrolled in the study (Fig. 1).

Two patients did not complete treatment. Both dropped out within 7 days after therapy. One (treatment group), the second (sham group) withdrew because of excessive pain.

The mean age of those completing treatment was 43.15 ± 10.31 and 42.10 ± 10.12 in the PEMF group and the sham group respectively. The PEMF group consisted of 11 females and 6 males; there were 10 females and 5 males in the sham group. No significant difference was found between the groups in terms of age and gender ($p > 0.05$) (Table 1). Baseline values of pain, paravertebral muscle spasm, ROM and NPDS scores were comparable in the two groups ($p > 0.05$).

Pain levels in the PEMF group decreased significantly after therapy, but no change was observed in the sham group (Table 2). The flexion and extension ranges, paravertebral muscle spasm and NPDS scores improved significantly after PEMF therapy, but no change was observed in the sham group.

The rate of patients using NSAIDs during the treatment was moderate. Twelve patients of the PEMF group and ten of the sham group used NSAIDs before and during the study.

At the end of the treatment 11 (64.7%) of PEMF patients but only 4 (26.6%) of placebo-treated patients reported subjective success of treatment. Twelve patients in the PEMF group (70.5%) were willing to undergo the treatment again, in contrast to three patients (18.5 %) in the placebo group.

Side effects; no untoward effects, symptoms, clinical findings, or laboratory observations were observed in any patient treated in our study.

Discussion

The aim of this study was to evaluate the efficacy of PEMF treatment in patients with COA. PEMF, in the described form, can also be used at home easily in the treatment of patients with neck pain. Several accepted functional instruments, such as the Neck Disability Index (NDI), the NPDS, and the Northwick Park Neck Pain Questionnaire (NPQ) are available to measure neck pain and related disability or functional status [18]. NPDS has been found to be a valid and reliable instrument to measure disability in English and French versions. Wlodyka-Demaile et al. [18] assessed the sensitivity to change of three algofunctional scales (NDI, NPDS and NPQ) for neck pain. The NPDS scores had

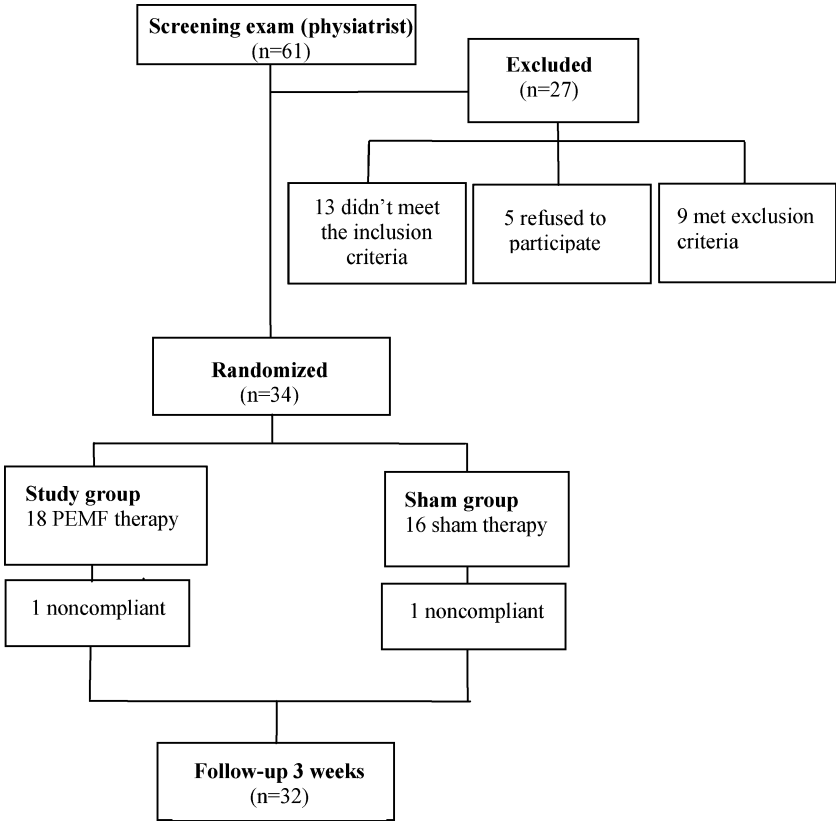

Fig. 1 Patient flow chart

Table 1 Baseline characteristics of the groups[a]

	PEMF group ($n=17$)	Sham group ($n=15$)
Age (years)	43.15 ± 10.31	42.10 ± 10.12
Gender distribution (women/men)	11/6	10/5
Pain levels (VAS) (mean ± SD)	6.9 ± 1.30	7.1 ± 1.43
Chin-manibrium distance (cm)	2.3 ± 1.5	2.1 ± 1.8
Occiput-C7 PS distance (cm)	3.1 ± 1.7	2.9 ± 1.9
Paravertebral spasm (absent/present)	3/14	2/13
NPDS score	78.6 ± 10.3	74.8 ± 12.3

[a] Baseline values of all parameters did not differ significantly between groups.

the best correlation with patients' global assessment on their neck disorders. Furthermore, NPDS has been found to be reliable and valid for the assessment of pain and disability in the Turkish population [16]. The results of our study showed a statistically-significant improvement in the pain and disability items of the NPDS questionnaire and in the VAS scores for the treatment group, but no such improvements could be observed in the patients who received sham therapy. Electromagnetic fields were applied to promote bone healing, to treat osteoarthritis and inflammatory disease of the musculoskeletal system, to alleviate pain, and to enhance healing of ulcers [19–22].

Quittan et al. [23] conducted a search of literature; they found 20 trials were designed double-blind, randomized and placebo-controlled. The action on bone healing and pain alleviation of the electromagnetic field was confirmed in most of the trials.

Reports on the beneficial effect of PEMF therapy on osteoarthritis of the knee joint have been more consistent [21, 24, 25]. However, the literature on its use in COA has been sparse.

In this double-blind randomized placebo-controlled trial, PEMF treatment improved pain, ROM, paravertebral muscle spasm and functional status (NPDS) in patients with COA.

Conservative treatment methods that are frequently used in general practice include analgesics, rest, physical therapy and manual therapy. Physical therapy may include passive treatment—such as massage, interferential current, TENS, or heat applications—and active treatment, such as exercise therapies. Although a combination of manual therapy and physical therapy that includes exercises appears to be effective for neck pain, these therapies have not been studied in sufficient detail to draw firm conclusions, and the methodological quality of most trials on neck pain is rather low [26].

Many authors have reported adverse reactions with the use of pharmacological agents, ranging from gastrointestinal ulcers to toxicity [27]. In contrast, no further side effects were reported with PEMF therapy [6, 27, 28].

Our results generally corroborate the findings of previous studies recorded in the literature [28, 29]. Trock et al. [28] reported that PEMF has a therapeutic benefit in painful osteoarthritis of the knee or cervical spine. Foley-Nolan et al. [29] reported that PEMF therapy seemed to be an extremely successful method of relieving symptoms in persistent neck pain.

PEMF application times varied from 15 min to 24 h per day for between 3 weeks and 18 months. It has also been proposed that there may be a relationship between longer daily application time and positive effects in particular in bone-healing [6, 23]. The actual mechanism of the action underlying the clinical effect of PEMF in osteoarthritis is not known. Many hypotheses have been developed to explain the action of PEMF on tissues, and numerous observations have been made of in vitro as well as experimental in vivo effects in laboratory situations, including specific effects on cartilage [9, 30, 31].

PEMF had a stimulatory effect on the osteoblasts in the early stages of culture, which increased bone tissue-like formation. This stimulatory effect was most likely associated with enhancement of the cellular differentiation, but not with the increase in the numbers of cells [34].

PEMF might enhance the repair of cartilage: an alteration of chondrocyte receptor activation and transformation of growth factor β by PEMF has been demonstrated. PEMF cause the movement of calcium and other ions across cell membranes, and stimulate transcription with increased protein synthesis [33, 34].

Moreover, the maximum proliferative response depends on the concentration of growth factor and exposure time to PEMF. This might be the reason why longer treatment times lead to better clinical results. In addition to these effects on chondrocytes, an increase in glycosaminoglycan has been observed. This mechanism possibly enhances the ability of cartilage to absorb more compressive stresses, thereby reducing the transmission of such stresses to the underlying bone [25].

A pain-relief effect of PEMF on the damaged cartilage has been proposed, but further studies are needed [23, 28]. Many problems remain to be solved. It is difficult, for example to adapt the dosage regimen to

Table 2 Effects of the treatment on pain levels, ROM values and NPDS scores in the groups after therapy

	PEMF group		Sham group	
	Baseline	After therapy	Baseline	After therapy
Pain levels (VAS ± SD)	6.9 ± 1.30	2.5 ± 1.4*	7.1 ± 1.43	6.7 ± 0.80[a]
Chin-manibrium distance (cm)	2.3 ± 1.5	0.8 ± 0.7*	2.1 ± 1.8	2.1 ± 1.6[a]
Occiput-C7 PS distance (cm)	3.1 ± 1.7	1.5 ± 1.1*	2.9 ± 1.9	2.7 ± 1.5[a]
NPDS score	78.6 ± 10	32.5 ± 7.6*	74.8 ± 12.3	65.6 ± 10.5[a]

* $p < 0.001$ (statistically significant).
[a] NS (not significant).

different patients and different stages of the disease. The results would probably be better with longer daily application time. Despite these limitations, we determined that there was a clear reduction in pain and an improvement in functional status in the PEMF group after therapy. Useful effects recorded in the parameters as a result of the PEMF treatment are promising that PEMF treatment may offer a potential therapeutic adjunct to current COA therapies in the future. We hope that the results of this study may stimulate further research on the use of PEMF in COA.

References

1. Lagattuta FP, Falco FJE (2000) Assessment and treatment of cervical spine disorders. In: Braddom RL (ed) Physical medicine & rehabilitation, 2nd edn. W.B Saunders, Philadelphia, pp 782–786
2. Borenstein DG (1998) The spine: low back pain. In: Klippel JD, Dieppe PA (eds) Rheumatology, 2nd edn. Mosby, London, pp 4.3.1–4.3.26
3. Duggan AW (1992) Neuropharmacology of pain. Curr Opin Neurol Neurosurg 5:503–507
4. Persson LCG, Lilja A (2001) Pain, coping, emotional state and physical function in patients with chronic radicular neck pain. A comparison between patients treated with surgery, physiotherapy or neck collar—a blind prospective randomized study. Disabil Rehabil 23(8):325–335
5. Ozdemir F, Birtane M, Kokino S (2001) The clinical efficacy of low-power laser therapy on pain and function in cervical osteoarthritis. Clin Rheumatol 20:181–184
6. Pipitone N, Scott DL (2001) Magnetic pulse treatment for knee osteoarthritis: a randomised, double-blind, placebo-controlled study. Curr Med Res Opin 17:190–196
7. Jacobson JI, Gorman R, Yamanashi WS, Saxena BB, Clayton L (2001) Low-amplitude, extremely low frequency magnetic fields for the treatment of osteoarthritic knees: a double-blind clinical study. Altern Ther 7(5):54–68
8. Farndale RW, Murray JC (1985) Pulsed electromagnetic fields promote collagen production in bone marrow fibroblasts via athermal mechanisms. Calcif Tissue Int 37:178–182
9. Pezzetti F, De-Mattei M, Caruso A, Cadessi R, Zucchini P, Carinci F et al (1999) Effects of pulsed electromagnetic fields on human chondrocytes: an in vitro study. Calcif Tissue Int 65:396–402
10. Fredericks DC, Nepola JV, Baker JT, Abbott J, Simon B (2000) Effects of pulsed electromagnetic fields on bone healing in a rabbit tibial osteotomy model. J Orthop Trauma 14:93–100
11. Holmes GB (1994) Treatment of delayed unions and non-unions of the proximal fifth metatarsal with pulsed electromagnetic fields. Foot Ankle Int 15:552–556
12. Loy T (1983) Treatment of cervical spondylosis. Med J Aust 2:32–34
13. Cooper C (1998) Osteoarthritis and related disorders. Epidemiyology. In: Klippel JH, Dieppe PA (eds) Rheumatology, 2nd edn. Mosby, London, pp 8.2.1–8.2.8.
14. Carlsson AM (1983) Assessment of chronic pain: aspects of the reliability and validity of the visual analogue scale. Pain 16:87–101
15. Wheeler AH, Goolkasion P, Baird AC, Darden BV (1999) Development of neck pain and disability scale. Item analysis, face, and criterion-related validity. Spine 24:1290–1294
16. Bıcer A, Yazıcı A, Camdeviren H, Erdogan C (2004) Assessment of pain and disability in patients with chronic neck pain: reliability and construct validity of the Turkish version of the Neck Pain and Disability Scale. Disabil Rehabil 26(16):959–962
17. Wolfenberger VA, Bui Q, Batenchuk GB (2002) A comparison of methods of evaluating cervical range of motion. J Manipulative Physiol Ther 25(3):154–160
18. Wlodyka-Demaille S, Poiraudeau S, Catanzariti JF, Rannou F, Fermanian J, Revel M (2004) The ability to change of three questionnaires for neck pain. Joint Bone Spine 71:317–326
19. Rubin CT, Mcleod KJ, Lanyon LE (1989) Prevention of osteoporosis by pulsed electromagnetic fields. J Bone Joint Surg 71:411–417
20. Tabrah F, Hoffmeier M, Gilbert FJR, Batkin S, Basset CA (1990) Bone density changes in osteoporosis-prone women exposed to pulsed electromagnetic fields (PEMFS). J Bone Miner Res 5:437–442
21. Trock DH, Bollet AJ, Dyer RH Jr, Fielding LP, Miner WK, Markoll R (1993) A double-blind trial of the clinical effects of pulsed electromagnetic fields in osteoarthritis. J Rheumatol 20:456–460
22. Carley PJ, Wainapel SF (1985) Electrotherapy for acceleration of wound healing: low intensity direct current. Arch Phys Med Rehabil 66:443–446
23. Quittan M, Schuhfried O, Wiesinger GF, Fialka-Maser V (2000) Clinical effectiveness of magnetic field therapy—a review of the literature. Acta Med Austriaca 27:61–68
24. Hulme J, Robinson V, DeBie R, Wells G, Judd M, Tugwell P (2002) Electromagnetic fields for the treatment of osteoarthritis. Cochrane Database Syst Rev 1:CD OO3523
25. Nicolakis P, Kollmitzer J, Crevenna R, Bittner C, Erdogmus CD, Nicolakis J (2002) Pulsed magnetic field therapy for osteoarthritis of the knee—a double-blind sham-controlled trial. Wien Klin Wochenschr 114:678–684
26. Gross AR, Aker PD, Goldsmith CH, Peloso P (2000) Physical medicine modalities for mechanical neck disorders. Cochrane Database Syst Rev CD000961 (PMID: 10796402)
27. Furst DE, Hillson J (2001) Aspirin and other nonsteroidal antiinflamatory drugs. In: Koopman WJ (ed) Arthritis and Allied Conditions, 14th edn. Lippincott Williams & Wilkins, Philadelphia, pp 665–703
28. Trock DH, Bollet AJ, Markoll R (1994) The effect of pulsed electromagnetic field in the treatment of osteoarthritis of the knee and cervical spine. Report of randomised, double-blind, placebo controlled trials. J Rheumatol 21:1903–1911
29. Foley-Nolan D, Barry C, Coughan RJ, O'Connor P, Roden D (1990) Pulsed high frequency (27 MHz) electromagnetic therapy for persistent neck pain. A double blind, placebo-controlled study of 20 patients. Orthopedics 13:445–451
30. Murray JC, Farndale RW (1985) Modulation of collagen production in cultured fibroblasts by a low-frequency pulsed magnetic field. Biochim Biophys Acta 838:98–105
31. Smith RL, Nagel DA (1983) Effects of pulsing electromagnetic fields on bone growth and articular cartilage. Clin Orthop 181:277–282
32. Diniz P, Shomura K, Soejima K, Ito G (2002) Effects of pulsed electromagnetic field (PEMF) stimulation on bone-tissue-like formation are dependent on the maturation stages of the osteoblasts. Bioelectromagnetics 23:398–405
33. Aaron RK, Ciombor DM (1992) Synergistic effects of growth factors and pulsed fields on proteoglycan synthesis in articular cartilage. J Orthop Res 17:527
34. Goodman R, Weu LX, Xu JL, Henderson A (1989) Exposure of human cells to low-frequency electromagnetic fields results in quantitative changes in transcripts. Biochem Biophys Acta 1009:216–220