The Journal of International Medical Research
2006; 34: 160 – 167

Efficacy of Pulsed Electromagnetic Therapy for Chronic Lower Back Pain: a Randomized, Double-blind, Placebo-controlled Study

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This randomized, double-blind, placebo-controlled clinical trial studied the effectiveness of pulsed electromagnetic therapy (PEMT) in patients with chronic lower back pain. Active PEMT (*n* = 17) or placebo treatment (*n* = 19) was performed three times a week for 3 weeks. Patients were assessed using a numerical rating scale (NRS) and revised Oswestry disability scores for 4 weeks after therapy. PEMT produced significant pain reduction throughout the observation period compared with baseline values. The percentage change in the NRS score from baseline was significantly greater in the PEMT group than the placebo group at all three time-points measured. The mean revised Oswestry disability percentage after 4 weeks was significantly improved from the baseline value in the PEMT group, whereas there were no significant differences in the placebo group. In conclusion, PEMT reduced pain and disability and appears to be a potentially useful therapeutic tool for the conservative management of chronic lower back pain.

KEY WORDS: Pulsed electromagnetic therapy; Lower back pain; Revised Oswestry disability score

Introduction

Since obtaining approval from the United States Food and Drug Administration in 1979, pulsed electromagnetic therapy (PEMT) has been widely used to counteract pain resulting from various conditions such as arthritis of the knee joint,[1 – 3] ligament and muscle injuries,[1,4,5] delayed union fracture,[6] whiplash injury,[7] chronic pelvic pain,[8] headache,[9] complex regional pain syndrome type I[10] and multiple sclerosis.[11] In addition, PEMT has also been used to prevent osteoporosis[12,13] and enhance scar healing.[14,15] However, its efficacy and the optimal modes of magnetic field administration remain intensely controversial.

A small number of randomized, double-blind clinical studies[1 – 3] have suggested that PEMT is a promising therapy for knee osteoarthritis, but double-blind, placebo-controlled studies have not been conducted on its efficacy in patients with lower back

pain. Back pain is one of the most common reasons for seeking medical treatment and the development of effective symptomatic treatment is vital. If PEMT can be shown in placebo-controlled studies to have a positive effect on lower back pain, it offers a useful treatment modality. We therefore studied the efficacy of PEMT in a randomized, double-blind, placebo-controlled clinical trial in patients with chronic lower back pain.

Patients and methods

PATIENTS

Patients with chronic lower back pain with or without radicular pain, with a score of > 4 on an 11-point numerical rating scale (NRS) for pain assessment, who had not received pain treatment (e.g. physiotherapy, nerve blocks, analgesics) during the 3-month period prior to the study, and who had a pain duration of > 3 months were recruited. Patients with any unstable medical disorder not controlled by standard treatment and those with a cardiac pacemaker or using any other electrical devices were excluded from the study.

All patients provided written informed consent. Institutional review board approval was obtained for the study.

PROCEDURES

Patients were assigned randomly to receive PEMT or placebo (sham) treatment. PEMT was administered using the CR-3000 system (CR Technology Co., Kyungki-do, Korea). This system has a maximum output amplitude of 2 tesla (± 5%) and a frequency range of 1 – 50 Hz. The magnetic pulse produced is bi-phasic and has a pulse width of 270 μs (± 5%).

In the patient group, the output port was placed about 5 cm away from the skin of the lower back and electromagnetic pulses alternating every 5 s between frequencies of 5 Hz and 10 Hz were applied for 15 min. The amplitude used ranged from 1.3 to 2.1 tesla depending on patient tolerability. At each session, the amplitude used started at a low level and was gradually increased to as high as the patient could bear.

For the placebo group, an identical procedure was followed, except the magnetic coil was detached from the transducer and fixed beneath the apparatus to avoid it being seen (Fig. 1). The same rhythmic sound was produced during irradiation.

The 15-min treatment/placebo sessions were repeated three times a week for 3 weeks, and subjects were followed up for 4 weeks post-therapy.

ASSESSMENT

Any treatments, including pain medications, topical analgesics and physiotherapy, were prohibited throughout the study period (3 weeks of therapy and 4 weeks of post-therapy evaluation).

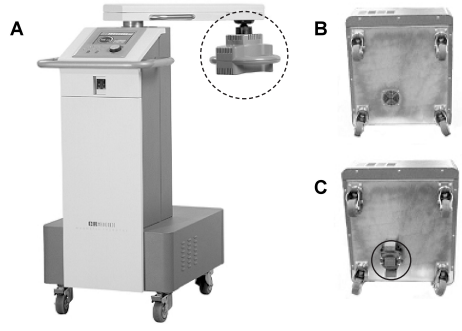

FIGURE 1: The CR-3000 system used to administer pulsed electromagnetic therapy in both the active treatment and the placebo groups. (A) Whole system, showing the transducer (dotted circle). (B) Base of the apparatus when used for active treatment. (C) Base of the apparatus when used in the placebo group; the magnetic coil was detached from the transducer and fixed beneath the apparatus (solid circle) to avoid it being seen

Outcome was measured using pain assessment on a numerical rating scale (NRS) and revised Oswestry disability scores.[16] NRS scores were evaluated at baseline, immediately after the last therapy session, and 1 and 4 weeks after completing therapy. Revised Oswestry disability scores were evaluated at baseline and again at 1 and 4 weeks after completing therapy; the total score for all the items in the questionnaire was multiplied by two to give the revised Oswestry disability percentage.

The examining physician, the patients and the clinician administering the therapy and collecting data were all blinded to the study details.

STATISTICAL ANALYSIS

Patients who did not receive therapy in more than three of the nine sessions of PEMT or who did not attend both the follow-up assessments were excluded from the data analysis.

Patient characteristics were compared using the *t*-test, χ^2 test or Fisher's exact test. The percentage changes from baseline in the NRS score and revised Oswestry disability percentage within the groups were compared using Friedman repeated measures analysis of variance on ranks test followed by Dunn's method. Intergroup comparisons were performed using the Mann–Whitney rank sum test. A *P*-value < 0.05 was considered to be statistically significant.

Results

To provide a statistical power of 80% to detect a 30% difference in the percentage change in the NRS score of the two groups,[17] 14 patients were needed to complete the therapy in each group. With the expectation of a 30% dropout rate, a total of 40 patients (20 in each group) were recruited to ensure the study had sufficient statistical power.

Of the 40 patients enrolled, four were excluded from the data analysis: one patient in the placebo group received only three therapy sessions, two patients in the PEMT group did not attend both of the follow-up assessments, and one patient in the PEMT group was excluded due to violation of the protocol.

Baseline patient characteristics for both the PEMT group and the placebo group are given in Table 1. There were no significant differences between the groups in any of the parameters measured except for height.

The results of pain assessment in the two groups using an 11-point NRS are shown in Table 2. Patients who received active PEMT consistently showed significant pain reduction throughout the whole observation period ($P < 0.05$ compared with baseline). Pain reduction was also seen in the placebo group; this reduction was statistically significant compared with the baseline value 1 and 4 weeks post-therapy.

The percentage change in the NRS score from baseline was significantly greater in the active treatment group than in the placebo group at all three time-points after therapy (Fig. 2). At 4 weeks after therapy, the mean ± SD percentage change from baseline was 38 ± 11% and 22 ± 24% in the PEMT and placebo groups, respectively ($P < 0.05$). Approximately 20% of the patients in the placebo group and 47% in the PEMT group showed a > 40% pain reduction from baseline at 4 weeks after therapy.

The mean revised Oswestry disability percentage in the PEMT group was significantly improved from the baseline value 4 weeks after completing therapy ($P < 0.05$) (Fig. 3); there were no significant differences in the placebo group. In addition, no statistically significant differences were observed between the two groups. At 4 weeks after therapy, the change in disability percentage (mean ± SD) was 28 ± 30% in the PEMT group and 8 ± 32% in the placebo group. However, no statistically

TABLE 1:
Baseline characteristics in patients with lower back pain receiving either pulsed electromagnetic therapy (PEMT) or placebo

	PEMT group (n = 17)	Placebo group (n = 19)
Age (mean ± SD, years)	75 ± 5	74 ± 4
Gender		
Male	5	14
Female	12	5
Height (mean ± SD, cm)	156 ± 9[a]	164 ± 6
Weight (mean ± SD, kg)	58 ± 11	60 ± 8
Duration of pain (mean ± SD, months)	120 ± 147	91 ± 111
History of		
Diabetes mellitus	2	–
Hypertension	8	7
Other	1	–
Radicular pain	9	10
Neurogenic intermittent claudication	8	7
Neurological examination		
Decreased sensory function	1	1
Decreased motor power	1	1
Physical examination		
Facet joint tenderness	6	13
Iliolumbar tenderness	8	8
Sacroiliac tenderness	4	4
Positive Patrick test	3	4
Positive Gaenslen test	1	2

[a]$P < 0.05$ versus placebo group.

TABLE 2:
Pain assessments using an 11-point numerical rating scale in patients with lower back pain receiving either pulsed electromagnetic therapy (PEMT) or placebo

	PEMT group (n = 17)	Placebo group (n = 19)
Baseline	6.7 ± 1.7	6.5 ± 1.7
Immediately post-therapy	4.8 ± 1.2[a]	5.5 ± 1.5
1 week post-therapy	4.4 ± 1.1[a]	5.5 ± 2.1[a]
4 weeks post-therapy	4.5 ± 1.2[a]	5.4 ± 2.3[a]

Values are mean ± SD.
[a]$P < 0.05$ versus baseline.

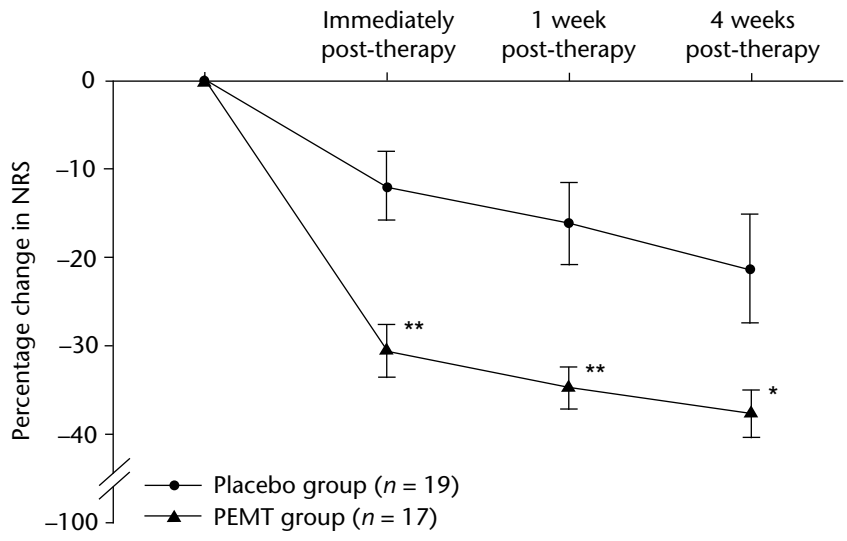

FIGURE 2: Percentage change from the baseline in pain assessed using an 11-point numerical rating scale (NRS) in patients with lower back pain receiving either pulsed electromagnetic therapy (PEMT) or placebo. Values are mean ± SE. *$P < 0.05$ and **$P < 0.01$ versus placebo group

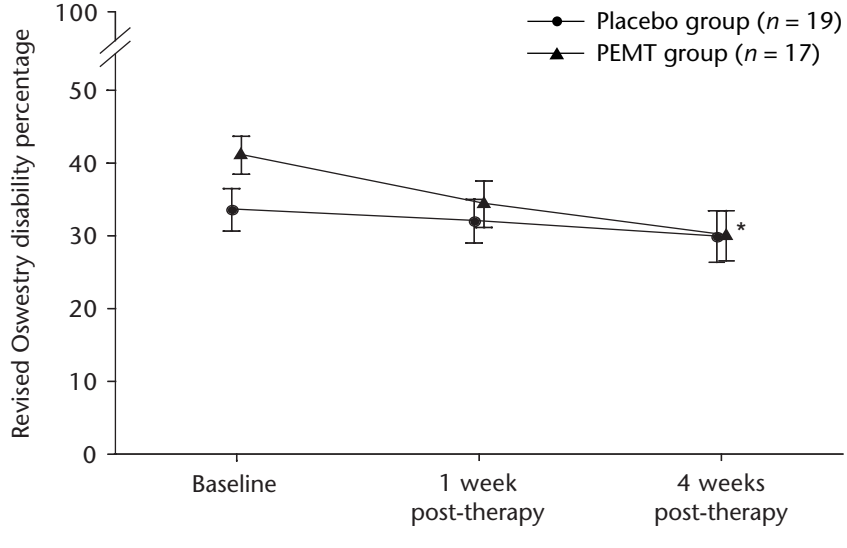

FIGURE 3: Percentage change from the baseline in the revised Oswestry disability percentage in patients with lower back pain receiving either pulsed electromagnetic therapy (PEMT) or placebo. Values are mean ± SE. *$P < 0.05$ versus baseline

significant differences in disability percentage were observed between the two groups at the time-points studied.

Discussion

In the present study, PEMT was found to reduce pain and disability in patients with chronic lower back pain. The use of a randomized, double-blind trial design strengthens the validity of this data. Although a strong placebo effect was observed, as is usual for new forms of therapy for back pain, and considerable variability in the therapeutic effect was evident between patients, a greater degree of improvement was consistently found in the PEMT group compared with placebo by the end of the study period.

A 31% reduction in the mean NRS score at the end of treatment and a 38% reduction 4 weeks after treatment were observed in those treated with PEMT. This compared with a 12% reduction at the end of treatment and a 22% reduction 4 weeks after treatment in the placebo group. These results are consistent with the findings of Trock *et al.*,[1] who reported a 30 – 35% reduction in pain at the end of treatment and a 20 – 39% reduction 1 month after treatment in the active PEMT group versus a 17 – 27% reduction at the end of treatment and a 0 – 18% reduction 1 month after treatment in the placebo group in patients with cervical facetal osteoarthritis. They also reported that a 29 – 36% reduction in pain was observed at the end of PEMT in patients with knee osteoarthritis, whereas the placebo group showed only an 11 – 19% reduction. In these patients, pain reductions of 21% to 31% and –0.3% to +16% were observed 1 month after therapy in the PEMT and placebo groups, respectively.[1]

Reports on the effects of non-steroidal anti-inflammatory drugs (NSAIDs) in patients with lower back pain can be usefully compared with PEMT results. Coats *et al.*[18] studied the effectiveness of valdecoxib on chronic lower back pain using a 4-week, randomized, placebo-controlled trial. After 1 week of treatment, there was a 40% reduction in pain in the valdecoxib group compared with a 24% reduction in the placebo group. At the end of 4 weeks' treatment, pain reduction was 57% in the valdecoxib group and 43% in the placebo group. Patients were not followed up after discontinuation of the medication. Pallay *et al.*[19] studied the effectiveness of two doses of etoricoxib on lower back pain using a randomized, double-blind, placebo-controlled trial. After 4 weeks of treatment, 60 and 90 mg/day of etoricoxib produced 34% and 32% pain reductions versus baseline, respectively, and this therapeutic effect was maintained for 12 weeks after discontinuing medication. Thus, the therapeutic effectiveness of PEMT seen in the present study is comparable with that of NSAIDs. Recently, Giles and Muller[20] conducted an interesting randomized, non-placebo-controlled clinical trial to compare medication (an NSAID), acupuncture and chiropractic manipulation. Chiropractic manipulation achieved a 50% reduction in lower back pain (final score of 3 on a 10-point visual analogue scale compared with a baseline score of 6). However, medication and acupuncture were not found to reduce lower back pain.

Transcutaneous electrical nerve stimulation for chronic lower back pain[21] and therapeutic ultrasound for knee osteoarthritis[22] have been shown to have efficacies similar to placebo therapy. In the present study, PEMT had a therapeutic efficacy that was comparable or better than that obtained with NSAIDs,[18 – 20] chiropractic manipulation[20] or acupuncture,[20] and therefore appears to have the potential to be an important therapeutic tool for the conservative therapy of chronic lower back pain.

In this study, an 11% mean improvement in the revised Oswestry disability percentage

(41% disability at baseline and 30% disability 4 weeks after completing therapy) was observed in the PEMT group. In the study of Giles and Muller,[20] improvements in Oswestry low back disability percentages achieved by chiropractic manipulation were similar to the results obtained in the present study, whereas acupuncture produced only a 4% improvement and an NSAID produced no improvement.

Although the mechanism by which PEMT reduces pain is unclear, several explanations have been put forward to explain its analgesic effect, including the stimulation of descending inhibition and a subsequent increase in central β-endorphin production, hyperpolarization at the motor end plate and subsequent muscle relaxation[1,2,23] and the stimulation of chondrogenesis.[24] Lednev[25] proposed that nociceptive C-fibres have a lower threshold potential and that a magnetic field may selectively attenuate neuronal depolarization by shifting the membrane resting potential. The promotion of increased blood flow to tissues[24] and the modulation of the release of cytokines or other factors[26] have also been suggested. Any of these proposed mechanisms could be responsible for the results of the present study since lower back pain has a complex nature and originates from multiple sources, including musculoskeletal structures and spinal nerves.

The most effective PEMT frequency and exposure mode remain controversial. Low frequency pulses such as those in the present study are most often used.[1,27] In an animal study, Lee *et al.*[4] reported that lower frequency PEMT had a greater effect on inflammation reduction and promoted tendon return to histological normality. In addition, frequencies < 60 Hz were found to affect cell behaviour by increasing transcription[28] and DNA synthesis.[29] Sakai *et al.*[29] reported that intermittent exposure to PEMT stimulation was superior to continuous exposure in an *in vitro* study. Further studies using different modes, intervals and durations of PEMT as well as different follow-up periods may help to determine the optimal protocol for this treatment.

In conclusion, PEMT is a non-invasive method that, if correctly applied, is not associated with any side-effects. It is extremely well tolerated by patients and therefore has a high degree of compliance. In the present study, PEMT reduced pain and disability in patients with chronic lower back pain and appears to be a potentially useful therapeutic tool for the conservative management of such patients. Further studies are required to confirm these findings and to determine the optimal treatment protocol.

Acknowledgement

The authors thank CR Technology Company for its help with the placebo CR-3000 system.

Conflicts of interest

No conflicts of interest were declared in relation to this article.

• Received for publication 21 September 2005 • Accepted subject to revision 10 October 2005
• Revised accepted 24 November 2005

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