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Magnetic Pulse Treatment for Knee Osteoarthritis: A Randomised, Double-Blind, Placebo-Controlled Study

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SUMMARY

We assessed the efficacy and tolerability of low-frequency pulsed electromagnetic fields (PEMF) therapy in patients with clinically symptomatic knee osteoarthritis (OA) in a randomised, placebo-controlled, double-blind study of six weeks' duration. Patients with radiographic evidence and symptoms of OA (incompletely relieved by conventional treatments), according to the criteria of the American College of Rheumatology, were recruited from a single tertiary referral centre. 75 patients fulfilling the above criteria were randomised to receive active PEMF treatment by unipolar magnetic devices (Medicur) manufactured by Snowden Healthcare (Nottingham, UK) or placebo. Six patients failed to attend after the screening and were excluded from analysis. The primary outcome measure was reduction in overall pain assessed on a four-point Likert scale ranging from nil to severe. Secondary outcome measures included the WOMAC Osteoarthritis Index (Likert scale) and the EuroQol (Euro-Quality of Life, EQ-5D). Baseline assessments showed that the treatment groups were equally matched. Although there were no significant differences between active and sham treatment groups in respect of any outcome measure after treatment, paired analysis of the follow-up observations on each patient showed significant improvements in the actively treated group in the WOMAC global score ($p = 0.018$), WOMAC pain score ($p = 0.065$), WOMAC disability score ($p = 0.019$) and EuroQol score ($p = 0.001$) at study end compared to baseline. In contrast, there were no improvements in any variable in the placebo-treated group. There were no clinically relevant adverse effects attributable to active treatment. These results suggest that the Medicur unipolar magnetic devices are beneficial in reducing pain and disability in patients with knee OA resistant to conventional treatment in the absence of significant side-effects. Further studies using different types of magnetic devices, treatment protocols and patient populations are warranted to confirm the general efficacy of PEMF therapy in OA and other conditions.

Introduction

Low-frequency electromagnetic radiation has been used for centuries since the time of Paracelsus to control pain and treat a number of disorders, but proper scientific investigations into its putative properties have been conducted only over the last decades[1–3]. Broadly speaking, there are two main types of treatment that exploit electromagnetic radiation: static magnetic fields and low-frequency pulsed electromagnetic fields (PEMF). PEMF is the most popular type of treatment and employs

unipolar or bipolar magnets. Unipolar magnet therapy uses several discrete magnets aligned with the same magnetic pole towards the skin; usually the pole facing the patient is the negative one, hence the term *unipolar*[4]. In contrast, bipolar magnet therapy uses magnetic material arranged in an alternating pattern, so that both positive and negative poles face the skin[4]. Experimental observations have documented a significant impact of PEMF on a number of biological processes. In particular, PEMF have been demonstrated to enhance fibroblast[5], chondrocyte[6,7] and osteoblast metabolism[8], as well as to modulate the effects of hormones and neurotransmitters on the receptors of different cell types[9]. However, despite the wealth of data on the *in vitro* effects of PEMF, it is unclear to what extent such mechanisms of action may have clinical relevance. Beneficial effects following PEMF treatment have been claimed in a whole array of different conditions. More specifically, PEMF have been used for the treatment of avascular necrosis of the hips[10,11], Legg-Perthes' disease[12], osteoporosis[13], tendinitis[14–16], chronic pain due to musculoskeletal disorders[4,17,18] and delayed bone fractures[19]. So far, the latter is the only indication that has received approval by the Food and Drug Administration[17]. Conclusive proof for the clinical efficacy of PEMF beyond the licensed indication is still lacking, and the American College of Rheumatology currently does not recommend PEMF treatment for osteoarthritis of the hips and knees because of inadequate scientific documentation[20]. Nevertheless, PEMF therapy continues to enjoy a vast popularity, which has translated into worldwide sales of $5 billion[21]. Therefore there has been a call for further clinical studies to determine exactly the efficacy and indications of PEMF treatment in human diseases[22].

Osteoarthritis (OA) is the commonest rheumatological disease and a frequent cause of pain: an estimated 80% of the world population over 75 years of age has radiological signs of OA[23], and approximately 40–80% of subjects with radiographic OA have symptomatic disease[24,25]. The management of OA is still far from optimal, because the medications currently available provide limited symptomatic relief and are fraught with a number of side-effects[20]. Thus, not surprisingly, magnetic therapy represents an attractive alternative for patients suffering from OA.

In this study, we aimed to assess the efficacy of PEMF treatment using unipolar magnetic devices (Medicur) manufactured and supplied by Snowden Healthcare (Nottingham, UK) in patients with clinically symptomatic OA. We selected the knee as study joint because the knee is frequently involved in OA and because it is easily accessible to electromagnetic radiation. Finally, since knee OA is a relatively well-defined clinical entity, PEMF efficacy could be tested in the absence of significant confounding factors that would otherwise compound the data analysis.

Patients and Methods

Study Design

This was a randomised, placebo-controlled, double-blind study. The duration of treatment per patient was six weeks. The Local Research Ethics Committee approved the study and all subjects gave written informed consent prior to participation. An information sheet notifying the patients' participation was sent to the general practitioners.

Study Population

Patients were recruited from a tertiary referral centre, the Rheumatology Department of King's College Hospital (London, England), from March 2000 through to December 2000. Patients were required to have radiographic evidence and symptoms of OA (incompletely relieved by conventional treatments) as judged by the criteria of the American College of Rheumatology. Exclusion criteria were pregnancy or lack of contraception use in women of childbearing age; use of pacemaker, insulin pump, or of any implanted electrical device; inflammatory joint disease; periarticular Paget's disease; uncontrolled or untreated gout; pseudogout; avascular necrosis and osteonecrosis; Charcot's arthropathy; acromegaly;

Table 1. *Initial assessments (patients' characteristics at baseline). Patients were randomised to receive the active magnetic treatment (active) or the sham magnets (control). WOMAC Global is the global score of the WOMAC index, which comprises three discrete sections: assessment of pain (A), stiffness (B) and disability (C). No statistical difference was found at baseline between the two groups for any of the variables described. All data are expressed as median with 95% confidence ratio, except for sex distribution male:female (m:f) expressed as ratio, and age and disease duration expressed as median with range. For further details, see* Outcome Measures *in the section entitled* Patients and Methods

	Active	Control
Age (years)	62.0 (40–84)	64.0 (48–84)
Sex (m:f)	22:12	28:7
Disease duration (months)	48 (12–216)	96 (5.5–372)
WOMAC Global	50.7 (44.2, 57.1)	51.5 (46.5, 56.5)
WOMAC A	9.9 (8.6, 11.3)	9.9 (8.7, 11.1)
WOMAC B	4.4 (3.8, 5.1)	4.3 (3.8, 4.9)
WOMAC C	36.4 (31.6, 41.2)	37.2 (33.7, 40.8)
EuroQoL	9.2 (8.8, 9.7)	9.5 (9.0, 10.0)

clinically overt hypothyroidism or hyperthyroidism; haemochromatosis; Wilson's disease; ochronosis; osteopetrosis; Marfan's syndrome; Ehlers-Danlos syndrome; terminal illnesses/malignancies (except for *in situ* carcinoma and basal cell carcinoma); pain referred to the knee in the absence of local symptoms and signs; intra-articular glucocorticoid injection within one month of study entry; and inability to understand/fill out the questionnaires, or to write.

A total of 75 subjects met the study criteria. Six patients failed to attend after the screening visit and were excluded from the analysis. The general features of the patients enrolled in the study are reported in Table 1. Written informed consent for entry into a double-blind trial was obtained at study entry.

Randomisation

Patients fulfilling the study criteria were randomised on study entry to receive active PEMF treatment with the Medicur magnetic devices or placebo using a 12 × 12 randomisation table. Neither the patients nor the medical assessor were aware of the treatment group. The manufacturer (Snowden Healthcare Ltd, Nottingham, UK) supplied an equal number of active and sham devices identified by code numbers. The code numbers were not broken until all patients had completed the study. The active devices produced no noise or sensation and were entirely indistinguishable from the placebos.

Treatment

Treatment was administered by unipolar magnetic devices manufactured and supplied by Snowden Healthcare Ltd (Nottingham, UK). These are exclusively pain therapy devices that generate pulses of magnetic energy via a soft iron core treated with 62 trace elements. Pulses are selectable at three base frequencies (3 Hz, 7.8 Hz and 20 Hz). They have a rise time of 1 μs, a decay time of 10 μs, a low magnetic output (< 0.5 gauss) and a range of activity of up to 30 cm around the unit. Medicur® devices run on 9 V batteries and switch off automatically after a 10 min period. Each device is fitted with a control light that shows as long as the device is in operation. Based on previous evidence from uncontrolled observations, patients were instructed to use the Medicur magnetic devices three times a day (once in the morning, once in the afternoon and once in the evening) for the whole duration of the study. The 7.8 Hz frequency was prescribed for the morning and afternoon treatment, while the 3 Hz frequency was prescribed for the evening. The Medicur devices require no wires or electrodes and need only be held close to the area to be treated, which facilitates the patients' compliance. Since the magnetic energy emitted by this device can penetrate as far as 30 cm, both knees could be treated simultaneously whenever necessary by holding the device between the knees or by placing the device on one knee while keeping the knees together. A Velcro® band was provided to hold the device in place, but its use was left to the discretion of the patients. We explained to the patients that they should not expect the devices to cause any noise or particular sensation. Patients were instructed to record the treatment in a special sheet to facilitate assessment of compliance and not to change their basic therapeutic regimen for the duration of the study. The use of medications was checked at each assessment, although no formal pill counts were done. Finally, we encouraged patients to report any adverse event that they might experience during the treatment with the magnetic devices.

Data Collection

Specially designed case report forms (CRFs) were used to collect the patients' data.

Evaluations

Evaluations were carried out at baseline and on an alternate week basis for the whole duration of the study. All assessments were performed by a single rheumatologist (NP) with the exception of two assessments that were done by an intern in rheumatology who had been specifically trained for this purpose. Data collected at baseline included enrolment eligibility, clinical history, intake of medications and physical examination. In accordance with a well-established research practice, the impact of the magnetic treatment was determined at each evaluation point based on the patients' assessments of their symptoms and disabilities (see the following section).

Outcome Measures

The primary outcome measure was reduction in overall pain assessed on a four-point Likert scale ranging from nil to severe. Secondary outcome measures were: pain at rest, pain on movement, pain at night, patients' global assessment of their condition, and patients' satisfaction with the treatment received (all measured on a 100 mm visual analogue scale [VAS]); duration of early morning stiffness and duration of post-exertional stiffness measured on a four-point arbitrary scale (1: 0–30 min, 2: 31–60 min, 3: 61–120 min and 4: > 120 min); pain intensity after use of the magnetic device, measured on a five-point arbitrary scale (–2: much worse; –1: worse; 0: the same; +1: better; +2: much better); and evaluation of patients' symptoms, disability and general health profile by means of the following four questionnaires: Lequesne Index, the Western Ontario and McMaster Universities' (WOMAC) Osteoarthritis Index

(version LK3.1), the UK 36-item short form of the Medical Outcomes Study (SF-36) and the EuroQol (Euro-Quality of Life, EQ-5D). Two of these questionnaires (the Lequesne Index and the WOMAC Osteoarthritis Index) are disease-specific measures validated for use in patients with knee or hip OA[26,27]. The Lequesne Index for knee OA evaluates three components: pain/discomfort, maximum distance walked and activities of daily living[26,28], while the WOMAC Osteoarthritis Index probes pain, stiffness and physical disability[27,28]. In contrast, the SF-36 and the EuroQol are generic health profile questionnaires[29]. The SF-36 measures nine dimensions of general health status: physical function, role limitation due to physical problems, role limitation due to emotional problems, social functioning, mental health, energy and vitality, pain, general health perception, and change in health[30,31]. The EuroQol consists of two sections[32]. The first section comprises five questions that cover mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each with three levels of response. The second section (EuroQol-VAS) consists of a 20 cm vertical VAS ranging from 0 (worst imaginable health status) to 100 (best imaginable health status). Both the SF-36 and the EuroQol have been used to measure health-related quality of life in patients with knee OA[29]. All outcome measures were evaluated at baseline and at 2, 4 and 6 weeks after study entry, with the exception of the Lequesne Index and SF-36 (evaluated at baseline and week 6 only). Patients' satisfaction with the treatment received and pain intensity after use of the magnetic device were not assessed at baseline for obvious reasons.

Statistical Analysis

Data were analysed on an intention-to-treat basis. Parametric or non-parametric tests were used depending on whether the data followed a Gaussian or non-Gaussian distribution, respectively. Analysis of variance (ANOVA), Kruskal-Wallis' test and the two-tailed paired *t*-test was used to compare within-group changes from baseline for each observation. Between-group differences were evaluated using the two-tailed unpaired *t*-test or Mann–Whitney rank sum test. Power was set at 0.80 and a p-value < 0.05 was considered significant. All the data were expressed as mean ± SD unless indicated otherwise.

Results

75 patients fulfilled the entry criteria for the study. 39 patients were randomly allocated to the active treatment group and 36 to the placebo group. Five patients in the active treatment group and one patient in the placebo group, respectively, attended only for screening and were excluded from the analysis. The patient allocated to placebo and two patients in the active treatment group withdrew because they requested active, unblinded treatment; of the remaining three patients allocated to active treatment, two withdrew without giving any reason, and one died for causes judged to be unrelated to the magnetic treatment. Five patients randomised to receive the active treatment and five allocated to placebo dropped out before completing treatment. The reasons for withdrawal were lack of efficacy (three patients in the active treatment and five patients in the placebo group); personal reasons precluding further attendance (one patient receiving active treatment); and worsening of the symptoms (one patient receiving active treatment). Thus, 34 patients in the active group and 35 patients treated with placebo, including dropouts, were evaluated. At baseline, there was no statistically significant difference between the two groups in respect to age, gender distribution and disease duration, although the latter was longer in the placebo group (see Table 1). Similarly, the two patients groups did not differ in any of the variables measured in our study to evaluate outcome with treatment (data not shown). The only exception was subjective definition of health status (measured on the 20 cm VAS of the EuroQol), which was significantly higher (indicative of better health status) in the active group as compared to the placebo group (58.1 ± 20.3 vs. 46.2 ± 19.8; $p = 0.02$). No other differences in the baseline characteristics were observed, suggesting a similar disease severity in both treatment groups. The difference in the EuroQol perception of health status persisted at study end with an even larger gap between the two groups (65.3 ± 26.2 vs. 49.2 ± 23.1; $p = 0.01$), suggesting a greater improvement in the active treatment group, although the difference between baseline and post-treatment values in the active group did not reach statistical significance. No significant difference between magnet and sham treatment was found with any other outcome measure either at baseline or at study end (data not shown). Paired analysis of the follow-up observations on each patient showed a statistically significant improvement in the actively treated group in the WOMAC global score, WOMAC pain score (A) and WOMAC disability score (C), as well as in the EuroQol score at study end as compared to baseline. In contrast, no improvement occurred in any variable followed in the placebo-treated group at any point (see Table 2 and Figure 1).

Table 2. *Changes in main outcome measures with treatment. Assessment of the patients at week 6 at the end of the study revealed a significant reduction in the global score of the WOMAC index. The WOMAC index comprises three sections: assessment of pain (A), stiffness (B) and disability (C). There was a significant reduction (i.e. clinical improvement) in the WOMAC global score and in pain and disability of the WOMAC index in the group of patients who received active magnetic treatment, but not in those who received placebo. Similarly, the score of the EuroQol, which is a composite index reflecting the general health status of the patients, showed an improvement in the active treatment but not in the control group. All data are expressed as median with 95% confidence intervals. For further details, see* Outcome Measures *in the section entitled Patients and Methods*

	Active		Placebo	
	Mean (95% CI)	*Significance*	*Mean (95% CI)*	*Significance*
WOMAC Global	5.06 (0.94, 9.18)	0.018	1.00 (–3.93, 5.93)	NS
WOMAC A	0.88 (0.06, 1.82)	0.065	0.49 (–0.78, 1.76)	NS
WOMAC B	0.32 (–0.29, 0.94)	NS	0.26 (–0.32, 0.83)	NS
WOMAC C	3.62 (0.64, 6.69)	0.019	0.26 (–3.29, 3.80)	NS
EuroQoL	0.59 (0.24, 0.93)	0.001	0.20 (–0.25, 0.65)	NS

Consumption of Medications

As a rule, at study entry we instructed patients not to change their basic therapeutic regimen for the duration of the study, but did not expressively discourage them from doing so. Five patients treated with the magnets decreased the dosage of anodyne medications during the study, while three patients receiving sham treatment decreased the dosage of anodyne tablets, non-steroidal anti-inflammatory medications and neutraceuticals (glucosamine/chondroitin sulphate), respectively. No patient in either group increased the dosage of anodyne or non-steroidal anti-inflammatory medications.

Side-effects

Side-effects were reported by two patients in the active treatment group and four patients treated with placebo. The side-effects reported by the two patients actively treated were increased pain in the knees (one patient) and pain/numbness in the feet and poor sleep quality (one patient). Four patients allocated to placebo reported, respectively, increased pain in the knees (two patients), paraesthesia of the right foot and exacerbation of pre-existent diverticulitis (one patient), and tenderness in a sternoclavicular joint associated with local swelling, diagnosed as Tietze's syndrome (one patient). One patient randomised to receiving the magnet treatment died for causes judged to be unrelated to his treatment; it is doubtful whether he had any chance of starting the magnetic treatment at all. Thus our results have confirmed the excellent tolerability and safety of PEMF treatment attested by previous studies[4,14,15,17,18] and by the World Health Organization[33].

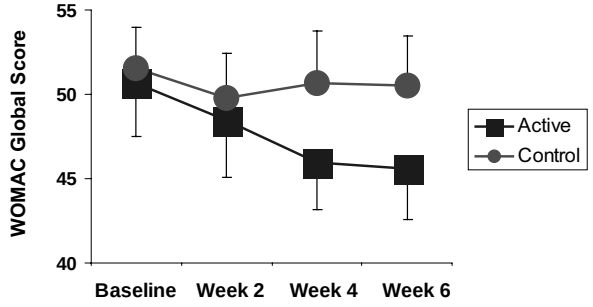

Figure 1. *WOMAC global score. Paired analysis of the global score of the WOMAC index at different time points in the patients that received the active magnetic treatment (active) or the sham magnets (control). Compared with baseline, there was a significant reduction at study end in the WOMAC global score (i.e. clinical improvement) in the patients treated actively ($p = 0.018$), but not in the control group ($p > 0.05$)*

Discussion

The aim of this study was to evaluate the efficacy and the safety of PEMF treatment using the Medicur magnetic devices in patients with knee OA. Since knee OA offers few objective clinical variables that lend themselves to sequential follow-up, in order to evaluate the patients' response to treatment we chose a number of validated subjective outcome measures that reflect pain, stiffness, disability and general health status[26,29]. The results of this study showed a statistically significant improvement in respect to pain and disability of the WOMAC questionnaire and EuroQol score in the active treatment group, but not in the patients who received placebo. In contrast, there was no difference between magnet and sham treatment for VAS pain, general health status measured by SF-36 or any of the variables that describe the Lequesne Index.

The WOMAC OA index is currently regarded as one of the most sensitive tests, if not as the test of choice, to evaluate the outcome of treatment for the knees[29]. Compared with the WOMAC index, the Lequesne index is less sensitive to change[34], while VAS has shown significant weakness in sensibility owing to large variability between different subjects, probably because of the emotional response to pain[35]. Thus, it is not surprising that the mild amelioration induced by treatment with PEMF could be picked up using the WOMAC index, but not the Lequesne Index or VAS. Such amelioration remained confined to the area where the magnetic devices were applied (i.e. the knee), since patients recorded no benefit at other painful sites after treatment. Furthermore, PEMF treatment did not appear to affect significantly the general health status, as suggested by the lack of change in the SF-36 score before and after treatment in both groups. As a matter of fact, although there was a significant reduction in the EuroQol score following treatment in the patients who received the magnets as compared to the controls, in view of the results of the aforesaid indices, this change is far more likely to reflect an improvement in articular function/dexterity (Items 1–3 of the EuroQol[32]) rather then a heightened feeling of well-being.

The results of our study are overall in agreement with those of previous trials that investigated PEMF treatment in patients with knee OA[17,18,36]. However, the magnitude of the therapeutic effect observed in our study was consistently smaller and the clinical response in the placebo group was virtually nil. These differences may be related to the characteristics of our study population, which consisted largely of patients with moderate to severe knee OA resistant to conventional treatment. On the other hand, since magnet devices vary significantly in shape, size and polarity, comparison of studies based on PEMF treatment is notoriously difficult. The comparative analysis is further compounded by the fact that there is no standardised treatment schedule for PEMF therapy[4], and to date no study has endeavoured to investigate systematically the dose-response to pain relief provided by magnetic treatment. Theoretically, the action of PEMF in knee OA could be mediated by a whole array of different mechanisms, including activation of mesenchymal cell metabolism[5–8], suppression of inflammation[37] and modulation of pain perception at a local[38] or central[39] level. In practice, the mechanisms underlying the clinical effects observed in this and other studies remain largely unclear, nor was this study designed to elucidate them. However, in view of the lack of an overall improvement at painful sites, it is highly unlikely that PEMF affected the central response to pain perception.

In conclusion, this study has demonstrated a statistically significant benefit in terms of reduction of pain and disability in patients with knee OA resistant to conventional treatment in the absence of significant side-effects. Given the study design, the results obtained in our population cannot possibly be generalised to all patients with painful conditions. Further studies using different types of magnets, treatment protocols and patient populations are needed to prove or refute the efficacy of PEMF therapy in different conditions.

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