

EFFICACY OF PULSED ELECTROMAGNETIC FIELDS IN THE TREATMENT OF EARLY OSTEOARTHRITIS OF THE KNEE

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INTRODUCTION

Pulsed electromagnetic fields (PEMF) have been used in the treatment of delayed union, non-union¹, avascular necrosis² and failed arthrodesis³. An *in vitro* study⁴ showed that PEMF can also reduce the degradation of pre-existing sulphated glycosaminoglycans and promote the synthesis of new sulphated glycosaminoglycans in cultured cartilage explants. In this study, a medical device, consisting of a magnetic field generator, an electronic interface and a toroid coil, was utilized. The coil has an internal diameter of 11 inches. The magnetic field generator generates varying wave pulses in the 1-30Hz range with specific energy characteristics designed to stimulate the repair and restoration of cartilage by mimicking the streaming potential generated in cartilage when it undergoes mechanical compression.

OBJECTIVE

We embarked on a prospective double-blind randomized study to investigate the clinical efficacy of this pulsed electromagnetic field in the treatment of early osteoarthritis of the knee.

MATERIALS AND METHODS

Patients

All patients met the criteria for the diagnosis of osteoarthritis (OA) as published by Altman⁵. Radiographs of the knee in the anteroposterior (weight bearing), lateral and skyline view at 30 degrees were taken from all patients. The severity of the OA was based on the classification by Brandt⁶. Patients were at least 35 years of age with symptoms of pain and stiffness for longer than 6 months. Radiographs had to show 1st to 3rd degree osteoarthritis of the knee as defined by Brandt⁶. Patients who were pregnant, had unstable medical problems, pacemakers, malignancy or who were being treated with glucosamine, were excluded from the study. Patients suffering from any uncontrolled chronic obstructive lung disease, cardiac disease or alcoholism, were also excluded. In addition, patients on steroids and those who had had a change in analgesic medication or physical therapy in the last 4 weeks were not selected. Patients with a reasonably good health and an American Society of Anesthesiologist (ASA) rating of III or less were selected. Patients on daily doses of non-steroidal anti-inflammatory drugs were instructed not to change their medication throughout the study period. The use of medication and compliance to the protocol was checked at each consultation. Informed consent for participation in the double-blind randomized study was obtained from each patient.

Treatments

The treatments were administered using a pulsed signal carried on an electromagnetic wave from a medical device utilizing direct current and producing a quasi-rectangular waveform with a field strength of 12.5G and a frequency of 1-30Hz. The frequency is pulse modulated and implementation is by a free-wheeling diode. Patients rested their knee joints on a pillow encircled by the air-coil. The air-coil produces a uniform (homogenous) magnetic flux throughout the x, y and z axes. Although the joint under treatment is positioned off-center, it is completely within the magnetic flux. There was no contact between the air-coil and the patient throughout the treatment period. Since the device applied a pure magnetic field through the air coil, no heat is generated. Treatments were given over nine, one-hour sessions, on nine consecutive days with allowed interruption over the weekend.

Randomization

Upon satisfying the above criteria, patients were informed of the study and all details provided to them by the physician. Once informed consent was obtained, each patient was randomized into either the placebo or treatment group using envelopes, each containing 4 identical smart cards. The only distinction between the cards was the serial number. There were 2 active and 2 placebo cards placed in each envelope. The ON/OFF control of the pulsed signal therapy device was in the ON position and the red light indicator also lighted up for both the active and placebo groups. The device produced no sound or heat such that the physician, the patient and the physiotherapist administering the treatment, remained blind as to whether each treatment was active or placebo. The decoded serial numbers were kept with the manufacturer and were only disclosed at the end of 6 months.

Data Collection

A questionnaire regarding the above inclusion and exclusion criteria was given to patients and each question was answered in the presence of the attending physician. Anteroposterior (weight bearing), lateral and skyline radiographs of the knee were taken. Evaluation of patients with the 10cm visual analog scale (VAS) was made at 4 points during the study: baseline, 1 month, 3 months and 6 months.

Statistical method

Statistical analysis was carried out with the Statistical Package for Social Sciences (SPSS) software program. The Paired T test was used to analyze the difference in the mean VAS score at 1 month, 3 months and 6 months compared to baseline. Significant testing was two tailed, with $p < 0.05$ accepted as statistically significant.

RESULTS

Forty-one patients were recruited into the study. Twenty-one were randomized into the placebo group and 20 into the active group. There were no patients lost in the follow-up periods nor were any withdrawn from the study. The two groups of patients did not differ significantly with respect to age, sex, race, body weight or duration of symptoms. The mean baseline VAS score of the two groups was not statistically different ($p = 0.82$). Both groups showed progressive improvement in the VAS score compared to the baseline score (graph 1). In the active group, the improvement in the VAS score at 1 month, 3 months and 6 months when compared to the baseline VAS score was statistically significant (table 1). However the placebo group did not show any statistical significance (table 2). There were no adverse effects reported by any patients. There were no patients who reported using more than their usual medication or requiring new medications for their knee pain during the study period.

Graph 1. Mean VAS score at various intervals for the placebo and active groups

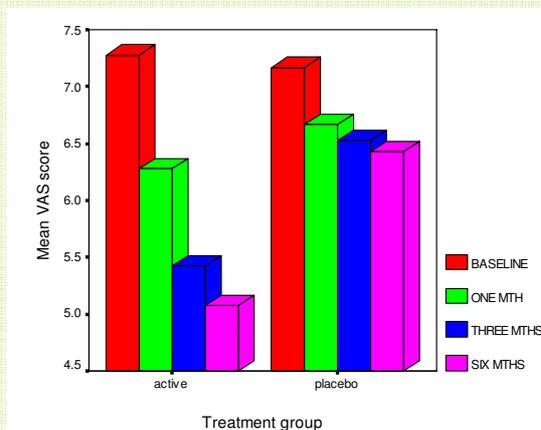


Table 1. Active Treatment Group – the mean VAS scores at various intervals and p-values when comparing the means at these intervals to the baseline.

N = 20	Baseline	One month	Three months	Six months
Mean VAS score	7.28	6.28	5.43	5.08
Standard error mean	0.36	0.49	0.52	0.60
p-value		<0.05	<0.05	<0.05

Table 2. Placebo Group - the mean VAS scores at various intervals and p-values when comparing the means at these intervals to the baseline.

N = 21	Baseline	One month	Three months	Six months
Mean VAS score	7.17	6.67	6.52	6.43
Standard error mean	0.31	0.39	0.39	0.47
p-value =		0.72	0.68	0.61

DISCUSSION

The use of PEMF therapy aims to provide long-term relief through the regeneration and retardation of cartilage degeneration. Clinical studies supporting the modulation of actions of hormones and neurotransmitters at the surface receptor sites of a variety of cell types when exposed to PEMF, are available in the literature. Basic science research has also shown that PEMF can augment mRNA and protein synthesis^{7,8,9}. An *in vitro* study⁴ has shown that PEMF can also reduce degradation of pre-existing sulphated glycosaminoglycans and promote the synthesis of new sulphated glycosaminoglycans in cultured cartilage explants. This form of non-ionizing radiation has been used extensively in clinical applications without any reported adverse events.

CONCLUSION

The results of our prospective double-blind randomized study using a pulsed electromagnetic field for the treatment of early osteoarthritis of the knee, showed significant pain improvement as measured by the visual analogue scale. Pain improvement begins as early as one month and lasts for as long as 6 months after treatment.

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