

Short Term Effect of PEMF Magnetotherapy on Chronic Low Back Pain

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The aim of double-blind, randomized and placebo-controlled study was to determine the therapeutic effect of pulsed electromagnetic fields (PEMF) therapy in treating chronic low back pain. The subjects were randomized into two groups: magnetotherapy group = 33 subjects, placebo group = 27 subjects. The group treated with magnetic field in solenoid received the therapy for 3 weeks – 5 times per week, total of 15 therapies. Magnetotherapy data: pulsed electromagnetic therapy, $B_{max} = 0,681$ mT, frequency 10 Hz, vector dB/dT = 0.976 mT/s, duration of therapy 20 minutes. In both groups the level of pain measured with VAS decreased and the function assessed with the Oswestry Disability Index improved immediately after the therapy and one month after the completed therapy, however the differences among groups were not statistically significant. Magnetotherapy with PEMF parameters and placebo therapy decreased the level of pain and improved the function in subjects but the differences between groups were not statistically significant.

Keywords : magnetotherapy, PEMF, chronic low back pain

1. Introduction

Low back pain (LBP) is a widespread condition and it is estimated that 70-85% of people experiences pain in the mentioned area at least once in a lifetime [1]. In the industrialized countries this condition is one of the most common reasons for seeking medical assistance [2]. It is often associated with biomechanical loads in life as well as at the workplace [3]. Acute low back pain lasts less than 6 weeks; however, chronic low back pain (CLBP) lasts more than 12 weeks and develops in 2-7% of people. It represents a problem regarding the effect on the quality of life of an individual patient and a social and economic problem on account of treatment costs and especially coverage of decreased ability to work [4].

Numerous methods are used for the treatment of CLBP but so far, the following methods have proved as effective: nonsteroidal anti-inflammatory drugs, cognitive-behavioral therapy, multidisciplinary biosocial rehabilitation, low-back pain school and kinesiotherapy [5].

Magnetotherapy (MGTH) represents an interesting possibility of physical therapy. It is a non-invasive, safe and simple form of treatment with direct impact on the

place of injury, source of pain, other types of diseases and pathologies [6].

Pulsed electromagnetic fields (PEMF) represent one form of MGTH. It represent numerous fields of different frequencies, specific wave forms and different amplitudes. They are used for treating numerous musculoskeletal disorders [7]. The fields have a stimulating effect at bio-molecular sub-cellular, cellular and tissue level. With induction they create electric currents in tissues, leading to an improvement of different pathological conditions [7, 8].

Numerous basic and clinical studies have established a decrease in pain under the effect of PEMF. The action of electromagnetic field (EMF) on the decrease of the pain is explained with the increase of nitric oxide (NO), the effect of calmodulin (CaM) and on opioid pathways [9].

Quittana *et al.* included in a review paper 31 clinical trials with at least one control group out of which 20 were double-blind, randomized and placebo-controlled trials. The majority of studies confirmed faster bone healing and better pain management by use of MGTH. The subjects were exposed to different EMFs: B_{max} 0.2-10 mT, frequency 12-100 Hz [10].

The effect of MGTH on low back pain has been the subject of several studies. Thuile *et al.* [11] have studied in a prospective, randomized and placebo-controlled study the effect of PEMF on the treatment of pain in patients

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with radiculopathy in segments L5/S1. In patients in the treated group statistically significant decrease of pain was identified. Omar *et al.* [12] have evaluated in a randomized, double-blind and placebo-controlled clinical study the effect of PEMF in patients with discogenic radiculopathy. In the active group they have established a statistically decreased pain intensity measured with VAS and improved capability of performing daily activities measured with the Modified Oswestry Low Back Pain Disability Questionnaire. In a pilot single-blind study, Harden *et al.* [13] confirmed PEMF as a possible effective and safe method in the treatment of CLBP. Arneja *et al.* [14] have determined in a double-blind, randomized and placebo-controlled study in a smaller number of subjects with CLBP an improvement of functional capabilities and decreased pain with the use of MGTH. Sorrel *et al.* [15] made the research about magnetotherapy at chronic postoperativa LBP at military service subjects. They found statistically significant less pain at PEMF in radiofrequency range of 27.12 MHz and pulse duration of 42 μ s but not at 38 μ s.

Kraht *et al.* [16] treated subjects with non-specific LBP for 6 weeks. Both groups had conventional physiotherapeutic treatment. MGTH group had added magnetotherapy for 8 sessions in 4 weeks. The results for MGTH group were statistically significant better.

Bebe *et al.* [17] published one-month follow-up MGTH pilot study at military service members with CLBP. Results showed significant improvement in quality of life, but insignificant in pain and disability.

Lee *et al.* [18] have studied in a randomized, double-blind, placebo-controlled study the effectiveness of PEMF (frequency 5-10 Hz, magnetic field strength from 1.3 to 2,1 T) in patients with chronic low back pain. The therapy was performed in the treated group ($n = 17$) or control group ($n = 19$) 5 times a week for 3 weeks. They have established that PEMF decreased the level of pain assessed with the Numeric Rating Scale (NRS) and decreased capabilities assessed with the Oswestry Disability Scores (ODS) and have concluded that PEMF is a useful therapeutic tool for conservative treatment of chronic low back pain. In a review paper on the effectiveness of PEMF in treating LBP Andrade *et al.* [19] have established a clear tendency of decreasing pain and minimal improvement of clinical parameters in PEMF therapy. They point out the considerable heterogeneity of interventional procedures and recommend further research.

Despite the positive results of PEMF impact on LBP in several studies, MGTH has still not been placed into the guidelines for treating this disease. Reviews of therapeutic possibilities for treating CLBP do not mention MGTH [5,

20, 21]. Conclusions of most studies recommend further research on a greater number of subjects to further confirm the effectiveness of MGTH in treating LBP. We designed a randomized, double-blind and placebo-controlled trial hypothesizing that magnetotherapy significantly decreases pain and improves functional abilities of patients with CLBP. The study was approved by the Slovenian National Medical Ethics Committee.

2. Work Methods

The study included subjects with chronic low back pain.

– **Inclusion criteria:** chronic low back pain lasting longer than 3 months, non-specific low back pain, possible present sciatica, willingness to participate and regular attend therapy

– **Exclusion criteria:** other nervous system disorders, e.g. diabetic polyneuropathy, other diseases causing low back pain, expressed problems with joints of lower extremities affecting the standing position, walking, undergoing physical therapy in the last 6 months, conditions contraindicated for magnet therapy (pacemaker and other electronic implants, cancer disease in medical history, serious infectious conditions, serious arterial blood flow disturbances, severe internal diseases (heart, liver, kidneys, diabetes).

The subjects meeting the set criteria have expressed their consent to participate in the study and signed the informed consent form. In the time of study the subjects were allowed to take their permanently analgetics in ordinary doses.

The subjects were randomized by a flip of a coin into two groups by a physical therapist who was not in contact with the subjects and did not perform the therapy:

– **group with magnetotherapy**

– **group with placebo therapy** (operative but non-functioning magnetotherapy device)

The subjects were examined and assessed three times: before the therapy, after the completed therapy and 1 month after the complete therapy. A questionnaire was used to obtain the following:

– subject's general data

– problems with low back pain in the medical history

– assessment of the low back pain intensity with VAS, which is often used as primary outcome measure in treating LBP [22]. VAS was measured on 10 cm long line; the patient put the sign without knowing the score-number; the result was read by researcher in mm values.

– assessment of degree of disability in everyday activities—Oswestry Disability Index (ODI), which is used

to prove the effectiveness of the therapy in CLBP [23]; we used the Slovene version of the scale with tested validity [24].

The study included 64 subjects who underwent the initial examination. They were randomized into MGTH (36 subjects) and placebo group (28 subjects). MGTH was considered complete when at least 13 visits were performed in the foreseen three weeks. 1 subject from the MGTH group (pain intensity increased) did not show up for the first control check-up after therapy. 3 additional subjects did not show up for the second control check-up (2 from MGTH (1 increased pain intensity), 1 from the placebo group). In the end 60 subjects performed the visits (93.75%) and were included in statistical analyses (33 in the MGTH group and 27 in the placebo group).

The magnetotherapy was performed with the Quattro Pro PMT (manufacturer ASA) device— Fig. 1.

In the study we used a preconfigured/pre-set software program. The data of the manufacturer regarding the parameters of MGTH are the following:

- electrode: solenoid (annular electrode)
- magnetic flux density 8.5 mT – depending on the diameter of the ring (50 cm)
- program for sciatica program 52



Fig. 1. (Color online) Quattro Pro PMT for magnet therapy with marked vector coordinates.

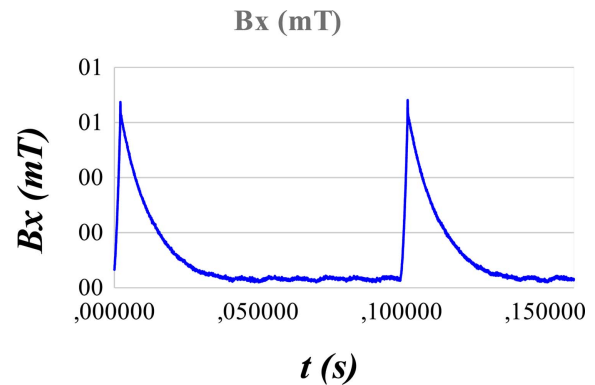


Fig. 2. (Color online) Pulse shape of PEMF.

- intensity 50% of maximal intensity
- frequency 10 Hz
- duration 20 min.

In studies on the effects of EMF on biological tissues a requirement has been determined for precise presentation of the therapeutic EMF parameters [25]. With the assistance of the Faculty of Electrical Engineering and Computer Science University of Maribor measurements



Fig. 3. (Color online) Magus device for PEMF therapy used for placebo therapy – the operating white box control device and the magnetotherapeutic green mat were disconnected.

Table 1. Parameters of PEMF in the lumbar spine area.

Type of field	PEMF
Magnetic flux density B (mT)	$B_{max}=0,681$ mT, $B_{mean}= 0,097$ mT, $B_{RMS}=0,162$ mT
Max. gradient (dB/dt)	0.976 (T/s)
Max. vector (dB/dx)	+1.371 (mT/m) or -1.503 (mT/m)
Frequency	10 Hz
Pulse shape	Figure 2
Time of exposure/center of solenoid	3 × 5 working days in 3 weeks for 20 minutes
Localization	Lumbar area in the centre of solenoid
Component (electric or magnetic)	Magnetic
Depth of penetration.	At 10 Hz this is not relevant data

have been performed of the EMF parameters at the site on the lower lumbar spine of the subject - the required data are shown in Table 1, the shape of PEMF pulse is displayed by Fig. 2.

The Quattro Pro PMT device could not be used for the placebo therapy, because the lowest possible magnetic flux density B can be set at 5% of maximal density and complete disconnection of the device is not possible if we want to retain the impression of an operating device. Therefore, the placebo therapy was performed on the Magus mat for PEMF therapy (Fig. 3), where the device functioned normally, the contact between the device and the mat was turned off and the subjects were under the impression that MGTH therapy is being carried out.

3. Statistical Analysis

The analyzed data was presented by mean ± SD for continuous variables, or by frequency and percentage distribution for categorical variables. Bivariate statistical tests were used to compare MGTH and placebo group. A repeated measure ANOVA with a Greenhouse-Geisser correction was used for a 3-step pain evaluation by ODI and VAS scale. Chi-square test was used to compare categorical pain improvement. Statistical analysis was performed using the IBM SPSS version 23 (IBM Corp., Armonk, NY). P < 0.05 was considered as statistically significant.

4. Results

A COMPARISON OF GROUPS BEFORE THERAPY did not show any statistically significant differences in any of the important and observed parameters (Table 2).

A COMPARISON OF PAIN INTENSITY according to VAS between both groups regarding all three points of observation have shown the following results (Table 3). A repeated measures ANOVA with a Greenhouse-Geisser correction determined non-significant interaction between

Table 2. Differences in subjects of both groups before the therapy.

Parameter	MGTH group	PLACEBO group	p
Number	33	27	
Gender – men/women	14 / 19	11 / 16	0.24
Age	57.45 ± 11.55*	57.37 ± 8.65*	0.97
Duration of LBP	14.30 ± 1.38*	11.05 ± 10.71*	0.26
Initial VAS of LBP	5.55 ± 2.24*	5.81 ± 1.51*	0.58
Initial ODI	20.21 ± 7.93*	20.19 ± 7.66*	0.99

*Mean ± STD

group type and VAS assessment point (df = 1.909, F = 1.550, p = 0.218).

A COMPARISON OF FUNCTIONAL LIMITATION IN EVERYDAY ACTIVITIES the Oswestry Disability Index (ODI) between both groups at all three observation points has shown the following results (Table 4). A repeated measures ANOVA with a Greenhouse-Geisser correction determined non-significant interaction between group type and ODI assessment point (df = 1.973, F = 0.422, p = 0.654).

Table 3. Change of VAS score in LBP in subjects of both groups at three observed time points. (results shown as Mean ± SD)

	ALL (n = 60)	MGTH (n=33)	PLACEBO (n=27)
Before therapy	5.7 ± 1.9	5.5 ± 2.2	5.8 ± 1.5
After therapy	4.9 ± 2.5	5.2 ± 2.6	4.4 ± 2.5
1 month after therapy	4.9 ± 2.0	5.0 ± 2.2	4.8 ± 1.9

Table 4. Change in ODI score in subjects from both groups at three observed time points. (results shown as Mean ± SD)

	ALL (n=60)	MGTH (n=33)	PLACEBO (n=27)
Before therapy	20.2 ± 7.7	20.2 ± 7.9	20.2 ± 7.7
After therapy	18.0 ± 8.3	18.5 ± 8.9	17.3 ± 7.7
1 month after therapy	17.9 ± 9.0	17.8 ± 9.2	18.0 ± 8.9

Table 5. Opinion of subjects in both groups on the change in LBP immediately after the therapy and one month after the therapy.

LBP assessment		MGTH n=33 (%)	PLACEBO n=27 (%)	Hi-square
After the therapy				
worse		2 (6.1)	1 (3.7)	5.464 p = 0.065
unchanged		15 (45.5)	5 (18.5)	
better		16 (48.5)	21 (77.8)	
LBP assessment				
1 month after the therapy				
worse		1 (3.0)	3 (11.1)	2.587 P = 0.274
unchanged		15 (45.5)	8 (29.6)	
better		17 (51.5)	16 (59.3)	

SUBJECTS' ASSESSMENT OF CHANGE IN LBP COMPARED TO THE CONDITION PRIOR TO THERAPY was obtained at the control check-up after the therapy and one month after the completed therapy. The results are shown in Table 5. The differences between groups were insignificant immediately after and one month after the therapy.

5. Discussion

The results of this study did not show statistically significantly better therapeutic effect of MGTH on CLBP in comparison with "MGTH" made by non-functioning placebo device. Compared to the positive results of the listed studies [11, 12, 13, 14, 16, 18] this result is negative. There are very few published studies with the negative results [15, 17]. The review papers place stress on the excessive heterogeneity in interventional protocols. For this reason this study tried to follow the protocols of two methodologically similar studies:

- Lee *et al.* [18]- MGTH was performed for 3 weeks, in total of 9 times for 15 minutes, the MGTH group had 17 and the placebo group 19 subjects, an improvement in pain intensity measured with the Numerical Rating Scale and functional disability in everyday activities assessed with the Oswestry Disability Scale was determined;
- Omar *et al.* [12] – MGTH was performed for 3 weeks, 15 times for 20 minutes, 20 subjects in the MGTH group and 20 in the placebo group, VAS-determined decrease in pain intensity and functional improvement established with ODI.

The differences in the results can largely be attributed to the use of PEMF with different parameters in this and other studies. It is important which form of EMF is used for treating a relevant medical condition. The Federal Drug Association (FDA) permitted the used of MGTH for treating pain and swelling of surface soft tissues by means

of PEMF within the radiofrequency of 27.12 MHz [26]. In most studies, only EMF density and frequency are mentioned. The differences in these parameters among the studies on the effect of MGTH on LBP are shown in Table 6.

The used EMF parameters are various. The EMF intensity can be compared to accessible data on effective windows of magnetic field B density: 0,05-0,1 mT, 15-20 mT in 45-50 mT [27].

In this study we performed a monotherapy for CLBP with MGTH. CLBP is a complicated chronic disease which disrupts the function of the safeguard mechanism (specific muscles) for the stabilization of the lumbar spine. MGTH is targeted on pain and course of tissue treatment; however, the effect is larger if kinesiotherapy is performed as well [28].

In this study it was not possible to perform a placebo therapy on the same MGTH device as in the treated group. The cause is of technical nature as the device does not enable a working therapy with the setting of EMF intensity at 0%. The minimum setting is 5% of maximum output of EMF B, which is according to the manufacturer 8.5 mT-5% EMF B intensity measuring 0,425 mT. The specter of extra low EMF density is extended down to nanotesla field intensities, which can have a biostimulating and bioresonant effect. Therefore also smaller magnetic fields cannot be identified as placebo [29].

The purpose of the study was to confirm the positive effect of PEMF in treating CLBP, which could help categorize this therapy among the effective ones in clinical guidelines. The result of the study is negative and MGTH cannot be confirmed as effective therapy. By considering the conclusion on different modes of action of various parameters of EMF, the negative conclusion can be attributed to these specific parameters.

6. Conclusion

The study examined the effectiveness of MGTH for decreasing pain and improving functional disability in patients with chronic LBP. The results of the study did not show a statistically significant improvement in the group of subjects with CLBP compared to control subjects who were exposed to a non-functioning MGTH. We can conclude that MGTH with specific parameters used in the study is not effective in treating patients with chronic LBP.

7. Conflict of Interest

All the authors responsible for this work declare no

Table 6. PEMF parameters in studies of LBP treatment.

Study	Intensity MF B (mT)	Frequency	Result
Galovic	0.68 mT*	10 Hz	negative
Lee (18)	1,3 – 2,1 mT	5 – 10 Hz	positive
Thuile (11)	0.01 – 0.02 – 0.03 mT	64 Hz	positive
Omar (12)	0,5 – 1,5 mT	7 Hz – 4 kHz	positive
Harden (13)	15 mT	?	positive
Arneja (14)	$2.74 \times 10^{-8} - 3.3 \times 10^{-9}$ mT	0,92 – 9,6 Hz	positive
Sorrell (15)	?	27.12 MHz	partly positive
Kraht (16)	80 mT	3 Hz	positive
Bebe (17)	?	?	pain negative

*measured at target spot on the lumbar spine

conflict of interest. The study was performed with an officially purchased MGTH device. The ASA manufacturer did not participate in the study and did not finance the study.

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