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Original Research Article

Effect of pulsed electromagnetic field on pain, functionality and quality of life in the treatment of chronic non-specific low back pain: a randomized controlled trial

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ABSTRACT

Background: Pulsed electromagnetic field therapy is a new device and its efficiency on pain treatment needs to be clarified. Our aim is to investigate the effects of PEMF therapy in combination with conventional physical therapy modalities in patients with chronic non-specific low back pain.
Methods: Prospective, randomized, patient-blinded, controlled trial with twenty-nine subjects having chronic nonspecific LBP were randomized into experimental and control groups.
The experimental group received PEMF in addition to conventional physical therapy, whereas the control group received a sham electromagnetic field with conventional physical therapy for ten sessions over a four-week period. Pain intensity, functional disability and lumbar range of motion measures were collected.
Results: Twenty-seven participants with chronic non-specific LBP completed the study (Experimental group N=13, control group N=14). There were significant within-subject effects and treatment*time effects for pain intensity, ODI, and lumbar ROM results. The change in pain intensity ($p=0.004$), ODI ($p=0.012$) and lumbar ROM ($p<0.001$) were significantly higher in the PEMF group compared to the control group.
Conclusions: Compared to conventional physical therapy, combining PEMF therapy with conventional physical therapy provides greater clinical improvement in terms of pain intensity, functional disability and lumbar ROM in subjects with non-specific LBP.

Keywords: Pulsed electromagnetic field, Chronic low back pain, Disability

INTRODUCTION

Low back pain (LBP) is a common global health problem and one of the leading causes of seeking medical treatment among adult individuals. Recent reports indicate that 84% of adults are estimated to suffer from LBP at some point during their lives.[1] In addition to impairment of health-related quality of life, LBP also leads loss of labor.[2] It has been reported that LBP forces more people out of the workplace than major chronic diseases, including heart disease, diabetes, hypertension, pulmonary diseases, and cancer.[3]

The European evidence-based guidelines on behalf of the COST B13 working group have defined low back pain as discomfort and pain, below the costal margin and above the inferior gluteal with or without leg pain.[4] The etiology of LBP is multi-factorial and has been associated with many acute or chronic problems, such as muscle or ligament strains, arthritis, herniated discs, alteration in the spine curvature, and osteoporosis-related fractures.[5] However, a clear etiology and anatomical cause cannot be identified in the majority of subjects with LPB; thus, most cases are defined as non-specific LBP. Non-steroidal anti-inflammatory drugs, paracetamol, skeletal muscle

relaxants, tricyclic antidepressants, benzodiazepines, and opioids have been used in the pharmacological treatment of chronic LBP.[6] However, the risk/benefit ratio of pharmacotherapy may increase with long term treatment. Therefore, pharmacological agents are usually combined with non-pharmacological therapies, including manual therapy, exercise, massage, ultrasound, transcutaneous electrical nerve stimulation, or acupuncture.[7,8]

Pulsed electromagnetic field (PEMF) therapy, which produces membrane disturbances and activation of multiple intracellular pathways has been established as a drug-free, non-thermal therapy.[9,10] It shows beneficial effects in a variety of clinical conditions, including osteoarthritis, fibromyalgia, osteoporosis, acute fractures (through acute pain relief), wound healing, edema, and inflammation.[11-13] PEMF therapy appears to relieve pain and improve functionality in individuals with painful musculoskeletal conditions.[14,15] However, data comparing PEMF therapy with conventional treatment modalities are limited and needs to be improved. The purpose of the present study was to investigate the additional effects of PEMF therapy when combined with conventional non-invasive treatment modalities in subjects with chronic non-specific LBP.

METHODS

The present randomized, controlled, and patient-blinded pilot trial was conducted on patients with chronic low-back pain who applied to our clinic between September-October 2019. The study was performed in accordance with the most recent version of the Helsinki Declaration. Thirty consecutive patients with chronic LBP who were referred to the physical therapy department were enrolled in the study.

Inclusion and exclusion criteria

Inclusion criteria were as follows: to have a diagnosis of chronic non-specific LBP for more than 3 months, pain level is 4 or above according to visual analog scale (VAS), being aged between 18 and 60 years. Participants with cardiopulmonary diseases, radicular pain, previous spine surgery, pregnancy and known malignancy and pacemakers or metalic implants were excluded.

Before randomization, all eligible subjects received standardized verbal and written information from a research fellow. Written informed consent was obtained from all subjects. Patients were allocated to an experimental group or a control group by using computer-generated randomization and these randomized groups were placed into sealed envelopes, including a card designating the study group of patients.

Participants randomized to the experimental group received PEMF and conventional physical therapy protocol, whereas those randomized to the control group received sham PEMF and conventional physical therapy, for ten sessions on alternate days over a four-week period. PEMF was applied to the patients in the experimental group with magnetic field device (BTL 6000 Superinductive system). Treatment frequencies in the device's chronic pain protocol are used for this study (Table 1).

Table 1: BTL superinductive system-chronic pain protocol.

Part	Duration	Frequency modulation	Amplitude modulation
1	30 sec	5-50 Hz Alternative	1 sec signal/ 1 sec rest
2	30 sec	1 Hz	1 sec signal
3	3 min	1-5 Hz, Alternative	10 sec signal/ 5 sec rest
4	3 min	5-10 Hz, Alternative	10 sec signal/ 5 sec rest
5	2 min	50 Hz	1 sec signal/ 1 sec rest
6	1 min	1 Hz	1 sec signal

The applicator (15×15 cm) was placed 1-3 cm above the skin surface at the treated area patient lying in prone position. Protocol was used with chronic pain conditions consisting of 6 sections. The frequency was changed from 1 to 50 Hz.

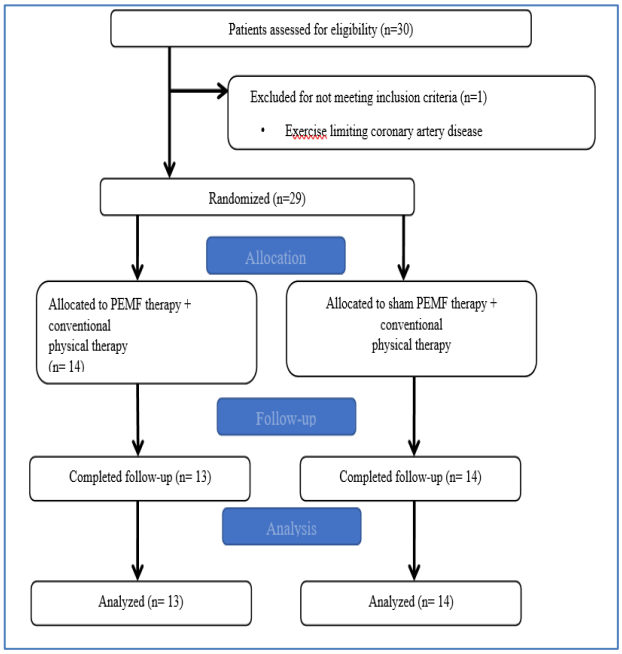

Figure 1: Flow chart demonstrating patient enrolment.

The procedure affected the tissue based on the endorphin theory and was applied using motor threshold intensity. The session lasted for 10 minutes. Application was easy and no side effects were observed during the study. The control group received sham procedure with the device is off and did not produce a radiofrequency electromagnetic

field. The conventional physical therapy protocol included ten sessions of treatment with hot packs (20 minutes) and ultrasound to the lumbar area (1.5 w/cm² 1 Hz for 5 mins) during a period of 4 weeks. The conventional physical therapy protocol also included exercise programs consisting of strengthening and stretching exercises for the back, pelvis, and lower limb muscles 3 sessions a week during the 4-week period (on alternate days). All treatments, ultrasound deliveries, and exercise prescriptions were provided by the same licensed and experienced physiotherapist who was blinded to study protocol.

Pain intensity, as the primary outcome measure, was assessed by a 10-point visual analogue scale (0 indicating no pain-10 indicating worst pain). The Oswestry Disability Index (ODI), and spinal range of motion (SROM) were the secondary outcome measures.[16] ODI is derived from the Oswestry Low Back Pain Questionnaire and is a valid tool for quantifying the disability due to LBP during daily activities. The questionnaire is comprised of 10 sections addressing the level of disability across different aspects of daily living. Each section was scored on a 0-5 scale, 5 representing the greatest disability. The scores for all questions answered are summed and then multiplied by two to obtain the index (range 0 to 100).

The lumbar flexion range of motion (ROM) was measured according to the modified- Schober method. Briefly, the two posterior superior iliac spines were connected with a line on the skin, and the middle of the line (first mark) and 15 cm above (second mark) were marked. The distance between the two marks was measured in lumbar flexion and subtracted from the 15 cm distance in the neutral position.[17,18]

Statistical analysis

All analyses were performed on SPSS v21 (IBM, Armonk, NY). The Shapiro-Wilk test was used for the normality check. Data are presented as mean ± standard deviation or median (minimum-maximum) for continuous variables, with regard to normality. Categorical variables were compared with the Pearson Chi-square test. Normally distributed variables were analyzed with Student's t-test. Non-normally distributed variables were analyzed with the Mann Whitney U test. A 2x2 mixed design MANOVA was used to compare the tested variables of interest at different tested groups and measuring periods. A two-sided $p<0.05$ was accepted as the level of significance in all statistical analyses.

RESULTS

A total of 30 subjects were eligible for the study, and 29 were randomized to one of the study arms. Fourteen subjects received PEMF (9 males and 5 females), and 15 participants underwent the sham procedure (8 males and 7 females).

One subject in each group were lost to follow-up. Thus, longitudinal data were available for 27 subjects (Figure 1). Age, gender distribution, and body mass indices of the study groups were similar (Table 2). A 2x2 mixed design MANOVA showed that there were significant within-subject effects and treatment*time effects for pain intensity, ODI, and lumbar ROM results. However, the between-subject effect was not significant for any of these parameters (Table 3). As shown in (Table 4), the change in pain intensity ($p=0.004$), ODI ($p=0.012$), and lumbar ROM ($p<0.001$) were significantly higher in the PEMF group compared to the control group.

Table 2: Demographic characteristics of the study group.

Parameters	Study group	Control group	P value
Gender, male/female, N (%)	9 (69.2)/4 (30.8)	8 (57.1)/6 (42.9)	0.695≠
Age (years)	46.7±12.8 (26-69)	42.6±7.2 (34-57)	0.310*
Body mass index (kg/m²)	27.2±3.0 (22.6-33.8)	27.0±6.0 (19.8-44.3)	0.481#

≠Chi-square test *Student t-test # Mann Whitney U test. Data are presented as mean±SD (min.- max.) for continuos variables and frequency (percentage) for categorical variables.

Table 3: Comparison of pre and post-treatment outcomes with regard to groups.

Parameters	Study group		Control group		Within subject effect p (F)	Treatment time p (F)	Between subject effect p (F)
	Pre	Post	Pre	Post			
Pain intentsity	7.15±1.34	3.31±2.69	6.43±1.50	4.79±1.25	<0.001 (55.852)	<0.001 (8.999)	0.521 (0.423)
Functional disability	39.8±10.0	24.8±12.8	32.4±10.2	27.6±8.0	<0.001 (34.259)	0.006 (9.005)	0.527 (0.411)
Lumbar flexion	3.08±0.89	3.85±0.69	4.09±1.09	4.05±0.97	<0.001 (18.430)	<0.001 (22.194)	0.092 (3.079)

Table 4: Comparison of the changes in pain intensity, functional disability index and lumbar flexion ROM in the pre and post-treatment period in both groups.

Parameters		Mean Change	Mean	95% CI of the difference		Partial Eta Squared	P value
Change in pain intensity	Study	3.85±2.64	2.20	0.69	3.71	0.580	0.004#
	Control	1.64±0.74					
Change in ODI	Study	15.08±11.2	10.22	3.21	17.23	0.421	0.012#
	Control	4.86±5.75					
Change in Lumbar ROM	Study	-0.77±0.44	-0.81	-1.16	-0.45	0.520	<0.001*
	Control	0.04±0.45					

*Student t Test # Mann Whitney U test

DISCUSSION

The present randomized controlled trial aimed to investigate the beneficial effects of PEMF therapy on pain intensity, functional disability, and lumbar ROM when added to conventional treatment in patients with chronic LBP. Our findings indicate that, compared to conventional treatment alone, combination of PEMF therapy with conventional treatments (hot pack, ultrasound and exercise) decreases pain intensity and degree of the disability, while improving lumbar flexion and extension ROM in patients with chronic non-specific LBP.

Pulsed electromagnetic field therapy has been identified as an effective and safe tool for conservative treatment of LBP.[19,20] Moreover, as a consequence of the low risk of side-effects and high tolerance, the reported compliance with PEMF is favorable.[21] Previous data have shown that PEMF therapy, when used alone, appears to reduce pain intensity in LBP in a variety of conditions including lumbar radiculopathy, lumbar myalgia, and chronic non-specific LBP.[20-22] However, combination of PEMF therapy with standard physiotherapy or analgesic therapy has not been proved to yield additional benefit. A previous randomized controlled trial conducted by Krammer et al. revealed that pulsed electromagnetic energy provides no significant additional benefit to physiotherapy in terms of pain severity and functional disability in subjects with acute LBP.[23] In another study, Park et al. have shown that PEMF therapy leads to improvements in pain intensity and discomfort arising from LBP in patients with lumbar myalgia.[20]

The efficacy of PEMF therapy in chronic LBP was evaluated in a few randomized controlled trials. Harden et al. compared PEMF therapy with a sham procedure in 40 patients with chronic LBP and found that the improvement in treated subjects was significantly higher than that of those receiving sham treatment.[24] Similar results were reported by Lee et al., where the authors performed a similar study comparing active PEMF therapy with placebo in patients with chronic LBP.[25] In a more recent prospective randomized trial, Elshiwi and colleagues investigated the role of PEMF therapy in 50 patients with non-specific chronic LBP.[26] In that study, half of the subjects were randomized to receive PEMF in combination with conventional physical therapy protocol, and the other half were randomized to receive conventional physical therapy protocol alone. Their results indicated that adding PEMF therapy to conventional physical therapy provides superior clinical improvement in terms of pain intensity, functional disability, and lumbar ROM. Our results demonstrated a significant improvement in pain intensity and functional disability in both active treatment and placebo arms. However, the improvements in pain intensity and functional disability were greater with the combination of PEMF therapy and the conventional non-invasive treatment modalities when compared to conventional treatment alone. From this point of view, our findings are consistent with the previous evidence indicating the superiority of combining PEMF therapy with conventional physical therapy.

Although the exact mechanism by which the PEMF therapy reduces pain intensity in LBP has not been clarified, some possible explanations have been put forth to describe the analgesic activity of PEMF therapy. These mechanisms can be listed as follows: enhanced cellular activity, increased central β-endorphin production, hyperpolarization at the motor endplate causing muscle relaxation, a local increase in blood flow, and modulation of cytokine release.[23,27-29] Since LBP has a complex nature and may result from various conditions, any of the factors described above could be the result of the favorable effects of PEMF therapy in non-specific chronic LBP. With this in mind, our results show that PEMF therapy is promising as a potentially useful therapeutic tool for the conservative management of chronic LBP when combined with conventional physical therapy protocols.

Limitations

Limitations of the present study are is lack of long-term follow up of the subjects with LBP, and not providing any mechanistic explanation to the nature of the effects of PEMF. These results therefore need to be interpreted with caution. However, due to the randomization and study design that included blinding, our results regarding the effects of PEMF therapy are promising. Nevertheless, further research with longer follow-up is required to provide additional information regarding the long-term efficacy of PEMF therapy in chronic LBP.

CONCLUSION

The results of the present study demonstrate that combining PEMF therapy with conventional physical treatment modalities provides greater clinical improvement in terms of pain intensity, functional disability, and lumbar ROM in subjects with non-specific LBP, compared to conventional physical therapy alone. Further research is required to address the long-term efficacy of PEMF in LBP conditions.

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REFERENCES

1. Deyo RA, Tsui-Wu Y-J. Descriptive epidemiology of low-back pain and its related medical care in the United States. Spine. 1987;12:264-8.
2. Balagué F, Mannion AF, Pellisé F, Cedraschi C. Non-specific low back pain. Lancet. 2012;379:482-91.
3. Schofield DJ, Shrestha RN, Passey ME, Earnest A, Fletcher SL. Chronic disease and labour force participation among older Australians. Med J Australia. 2008;189:447-50.
4. van Tulder M, Becker A, Bekkering T. European guidelines for the management of acute nonspecific low back pain in primary care. Eur Spine J. 2006; 15(2):S169-91.
5. Amirdelfan K, McRoberts P, Deer TR. The differential diagnosis of low back pain: a primer on the evolving paradigm. Neuromodulation: Technol Neural Interface. 2014;17:11-7.
6. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. Lancet. 2017;389:736-47.
7. van Tulder M, Hayden J, van Tulder M, Malmivaara A, Koes B. Exercise therapy for treatment of non-specific low back pain. Cochrane Database System Rev. 2005;20:CD000335.
8. Rubinstein SM, van Middelkoop M, Assendelft WJ, de Boer MR, van Tulder MW. Spinal manipulative therapy for chronic low-back pain. Cochrane Database System Rev. 2011.
9. Funk RH. Coupling of pulsed electromagnetic fields (PEMF) therapy to molecular grounds of the cell. Am J Translat Res. 2018;10:1260-72.
10. Wang T, Yang L, Jiang J, Liu Y, Fan Z, Zhong C. Pulsed electromagnetic fields: promising treatment for osteoporosis. Osteopor Int. 2019;30:267-76.
11. Hazlewood C, Markov M, Kostarakis P. Magnetic fields for relief of myofascial and/or low back pain through trigger points. Proceed Int Workshop Biol Effects Electromagnet Field. 2006;3:475-83.
12. Markov MS. Pulsed electromagnetic field therapy history, state of the art and future. Environmentalist. 2007;27:465-75.
13. Fini M, Giavaresi G, Carpi A, Nicolini A, Setti S, Giardino DR. Effects of pulsed electromagnetic fields on articular hyaline cartilage: review of experimental and clinical studies. Biomed Pharmacother. 2005;59:388-94.
14. Andrade R, Duarte H, Pereira R, Lopes I, Pereira H, Rocha R, et al. Pulsed electromagnetic field therapy effectiveness in low back pain: A systematic review of randomized controlled trials. Porto Biomed J. 2016;1:156-63.
15. Zarkovic D, Kazalakova K Repetitive peripheral magnetic stimulation as pain management solutıon ın musculoskeletal and neurological disorders - a pilot study. Int J Physiother. 2016;6:671-5.
16. Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine. 2000;25:2940-52.
17. Verma Y, Goyal M, Narkeesh D. Pain, range of motion and back strength in chronic mechanical low back pain before & after lumbar mobilisation. Int J Physioth Res. 2013;3:48-57.
18. Saidu IA, Maduagwu SM, Abbas AD, Adetunji OO, Jajere AM. Lumbar spinal mobility changes among adults with advancing age. J Midlife Health. 2011;2(2):65-71.
19. Harden RN, Remble T, Houle T, Long J, Markov M, Gallizzi M. Prospective, randomized, single-blind, sham treatment-controlled study of the safety and efficacy of an electromagnetic field device for the treatment of chronic low back pain: A Pilot Study. Pain Pract. 2007;7:248-55.
20. Park W, Sun S, Lee S, Kang B, Lee J, Hwang D. Effect of Pulsed Electromagnetic Field Treatment on Alleviation of Lumbar Myalgia: A Single Center, Randomized, Double-blind, Sham-controlled Pilot Trial Study. J Magnet. 2014;19:161-9.
21. Lee PB, Kim YC, Lim YJ, Lee C, Choi SS, Park SH, et al. Efficacy of pulsed electromagnetic therapy for chronic lower back pain: a randomized, double-blind, placebo-controlled study. J Int Med Res. 2006;34:160-7.
22. Omar AS, Awadalla MA, El-Latif MA. Evaluation of pulsed electromagnetic field therapy in the management of patients with discogenic lumbar radiculopathy. Int J Rheumat Dis. 2012;15:e101-8.
23. Krammer A, Horton S ,Tumilty S. Pulsed electromagnetic energy as an adjunct to physiotherapy for the treatment of acute low back pain: a randomised controlled trial. New Zealand J Physiother. 2015;43:16.
24. Harden RN, Remble TA, Houle TT, Long JF, Markov MS, Gallizzi MA. Prospective, randomized, single-blind, sham treatment-controlled study of the safety and efficacy of an electromagnetic field device for the treatment of chronic low back pain: a pilot study. Pain Pract. 2007;7:248-55.
25. Lee PB, Kim YC, Lim YJ, Lee CJ, Choi SS, Park SH, et al. Efficacy of pulsed electromagnetic therapy for chronic lower back pain: a randomized, double-blind, placebo-controlled study. J Int Med Res. 2006;34:160-7.

26. Elshiwi AM, Hamada HA, Mosaad D, Ragab IMA, Koura GM, Alrawaili SM. Effect of pulsed electromagnetic field on nonspecific low back pain patients: a randomized controlled trial. Braz J Physical Ther. 2019;23:244-9.
27. Trock DH, Bollet AJ, Markoll R. The effect of pulsed electromagnetic fields in the treatment of osteoarthritis of the knee and cervical spine, Report of randomized, double blind, placebo controlled trials. Int J Rheumat Dis. 1994.
28. Vallbona C, Richards T. Evolution of magnetic therapy from alternative to traditional medicine. Physical Med Rehab Clin. 1999;10:729-54.
29. Pilla A, Muehsam D, Markov M. A dynamical systems/Larmor precession model for weak magnetic field bioeffects: Ion binding and orientation of bound water molecules. Bioelectrochem Bioenerget. 1997;43:239-49.

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