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Review Article

Variable Low Frequency-High Intensity-Pulsed Electromagnetic Fields in the Treatment of Low Back Pain: A Case Series Report and a Review of the Literature

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Abstract

Low Back Pain (LBP) is one of the most frequent causes of people seeking medical treatments. Its tendency to become chronic implies high morbidity ratio and social costs excess. Conventional treatments include analgesic - anti-inflammatory and myorelaxant drugs while non-invasive rehabilitative programs, integrated by physical therapies, provide the reconditioning of the biomechanical disturbance at the origin of this disabling condition. Surgery is reserved for severe osteo, discogenic and neurologic concerns. In force of anti-inflammatory, analgesic and regenerative effects, the biophysical stimulation induced by Pulsed Electromagnetic Fields (PEMF) has attracted a certain interest for the safety and effectiveness in pain modulation, as well as in restoring the metabolic and functional impairment for muscle-skeletal disorders. Intending to evaluate the effects of a singular Low Intensity – High Energy- Pulsed Electromagnetic Fields (LI-HI-PEMF) device that supply variable self-regulating bandwidth of the electromagnetic frequencies (CTU Mega 20® Periso SA – Switzerland CE) we studied 18 subjects which underwent this type of treatment because of low- back pain. The patients were evaluated at the baseline, after the first week and at the end of the treatments for pain (NRS score) and the Revised Oswestry Disability Index which reflects the patient's ability to manage the everyday life.

The result showed that this LF-HI PEMF treatment (Diamagnetotherapy) provided significant pain reduction ($P < 0.05$ compared with baseline) and the improvement of the disability as resulting from the revised Oswestry disability percentage from the baseline value to 4 weeks after completing therapy ($P < 0.05$). Furthermore, we analysed the state of the art related to the non-invasive biophysical treatments of LBP. Additional studies as RCT may be necessary to validate the effectiveness of the LF-HI-PEMF.

Keywords: Chronic pain; Diamagnetotherapy; Low back pain; LF-HI-PEMF

Introduction

Because of the difficulties of categorizing LBP, the treatment can be challenging and this may depend on the causes, the time of appearance, the various intrinsic and extrinsic factors, the clinical features and the stage of the disease [1,2]. Furthermore, patient's clinical history and physical examination discern specific from non-specific LBP and it implies, respectively, wait and see-approach or deeper diagnostic analysis as well as consequential adequate treatments. This occurs for neurologic deficits, red flags or when these symptoms do not improve after 4 to 6 weeks from the onset [3]. Supervised exercise therapy and stabilization exercise programs have widely used in low back rehabilitation as a first-line treatment [4]. On their part, physical energies may support the rehabilitative programs acting on pain and exerting myorelaxant effects. With different levels of evidence, Transcutaneous Electrical Nerve Stimulation (TENS) [5], Low-Level Laser Therapy (LLLT), [6] and Capacitive-Resistive Diathermy Therapy (TECAR) [7] have been proposed in this regard.

Over time, a certain interest has been addressed to the biophysical stimulation induced by Low-Frequency PEMF. Their use, once approved by the U.S. Food and Drug Administration in 1979 for the treatment of delayed union of the fractures and pseudarthroses, fast spread towards different painful muscle-skeletal conditions and other types of disorders [8,9]. The rationale to employ PEMF would be based on anti-inflammatory effects mediated by A2A and A3 Adenosine Receptors as observed in Human Chondrocytes and Osteoblasts [10] as well as in injured models of rat - tail intervertebral disc [11]. Regenerative effects involving mesenchymal stem cells have also been theorized by Viganò et al. [12] while positive effects have been described in the pain of various origin, such as in complex regional pain syndrome [13] or chronic pelvic pain [14]. More recently, different types of PEMF that exploit the properties of the High-Intensity Magnetic Field (LF-HI-PEMF), has drawn a certain interest in biophysical research having shown regenerative effects in experimental models of nerve injury and fresh fractures [15,16], also demonstrating the possibility to recover the elasticity of the tendinous structure [17] or in promoting the recovery in fibro-sclerotic conditions such as chronic lymphoedema and pulmonary fibrosis [18,19]. On these bases, intending to improve pain and the related functional impairment, we treated with an LF- HI-PEMF machine, in six months, a series of patients suffering from LBP of different origin.

Materials and Methods

A series of 18 patients (12 males, 6 females), with an average age of 54,8 yrs. and suffering from LBP due to different causes (discogenic, radiculopathy and arthritis of the spine), from June to December 2019 was addressed in the treatment with an LF-HI PEMF machine (CTU Mega 20® - Periso SA -Switzerland) at the Cell Regeneration Medical Organization – Bogotá (Colombia). This cohort of patients, suffering from chronic LBP including radicular pain, undergone to Diamagnetic treatment once received their informed consent. The patients had been evaluated for the intensity of pain by using the NRS scale as well as the functional impact of the treatments on the activities of daily living was assessed by the functional Revised Oswestry disability score. All the treated patients shared at the NRS score a cut off > 4 for pain and have had not received physical therapies during the 3-months prior while pain duration was > 3 months. As usual for the PEMF treatments, patients with any unstable medical disorder, the implant of a cardiac pacemaker, using any other electrical or electromagnetic devices, during pregnancy or with ferromagnetic parts material within the areas of the body to be treated had been excluded. In the beginning, at the end of the first session, after one week and at the end of the treatments, patients had been evaluated for the intensity of pain by using the NRS scale. Furthermore, to determine the functional impact of the treatment on the activities of daily living, the functional Revised Oswestry disability score was utilised at the baseline and four weeks after the end of the therapy.

During each treatment, the handpiece was placed about 3 cm away from the skin of the patient's lower back for 30 min. The treatment sessions were repeated three times a week for 3 weeks and the protocol included the following set-up of the machine:

Operating Mode	Frequency (Hz)	Intensity (J)	Diathermia (RF)	Liquids Movement Ratio	Endogenous, Biostimulation, PW	Minutes
Pain Control	**5 Hz**	**70**	/	/	/	10
Slow Nerve Fibres		/	**Res**	/	**4**	10
Extracellular	/	/	**Res**	**80%**	/	10
Intracellular				**60%**		

Table 1: Set up of the machine.

Frequency = repetition rate of the pulse - J (Joule) =Energy induced by the electromagnetic pulse. Diathermy in resistive mode (res). Liquids Movement (Diamagnetic Effect) = Displacement of liquids in Extracellular Matrix (Extracellular) or inside the cells (Intracellular) expressed as ratio values. Pain control and Slow Nerve Fibres setting corresponds to the proper bandwidth of the electromagnetic frequency stimulating the tissues (Endogenous Biostimulation).

Results

All patients have been able to complete the treatment and no pain or adverse events have been reported. The statistical analysis included the sum of the scores for pain assessment on a numerical rating scale (NRS) and of the revised Oswestry disability index. NRS score was evaluated at baseline, immediately after the first therapy session, 1 week and 4 weeks after completing therapy. The disability index was evaluated at baseline and 4 weeks after the last session of treatments. The collected data were analysed as mean difference values ± standard deviations for discrete numeric variables. The «t» test for normal distribution of the data was chosen to determine the statistical significance between the pre- and post-treatment. The significance level has been chosen for p< 0,05. All the treated patients showed significant decline of pain throughout the whole observational period at all three time-points respect to the baseline (P < 0.05), with a mean ± SD of change from baseline of 38 ± 11. The timeline of NRS values marked, respectively: 6,7 ± 1,7 SD at the baseline; 4,8 ± 1,2 SD immediately after the treatment; 4,4± 1,1 SD at the first week and 4,5 ± 1,2 SD four-week post therapy. The mean revised Oswestry disability score was significantly improved from the baseline and 4 weeks after completing therapy (p<0,05- 28 ± 30 SD).

Discussion

Low back pain is a common recurring condition due to different etiopathogenetic causes. Symptoms, age, gender, socio-demographic and psychosocial variables, the functionality of the spine, pain intensity and its characteristic if nociceptive or neuropathic, the duration in time as acute, subacute or chronic belongs to the diagnostic and prognostic pathways. Non-specific acute low back pain will improve within several weeks with or without treatment [1]. The severe functional deficit, red flags or pain that does not improve after 4 to 6 weeks from the onset, continuing pain, signs and symptoms of cauda equina syndrome require deeper diagnostic analysis and surgery should be considered [3]. Furthermore, psychosocial distress, poor managing skills and the degree of the early impairment increase the risk of prolonged disability and patients with acute or chronic low back pain should be advised to remain active. For this reason, the treatment of chronic non- specific low back pain involves a multidisciplinary approach targeted at preserving the function and preventing disability.

The management of LBP and associated radiculopathy may comprise different options. As a first approach, paracetamol, NSAIDs, corticosteroids and opioids are considered. Rehabilitation programs provide for patient education, supervised exercise, manual therapy, targeted treatment, [4] while more invasive actions, such as extraforaminal glucocorticoid injection, are reserved for rebellious situations. Nevertheless, in their entirety, these options are based on low to moderate consensus. The same considerations apply to physical therapies. Transcutaneous Electrical Nerve Stimulation (TENS) has been used for a long time in chronic LBP, but the therapeutic value is still uncertain and, despite the theoretical basis and the widespread use, TENS would be no more effective than placebo for the management of chronic LBP [5]. Contrarily, a successive metanalysis states a significant pain reduction after the application of TENS with less pain medication usage [20]. More recently, Lien-Chen Wu et al. reported that pain relief was not different between patients treated with TENS versus control patients and that other non-TENS treatments have been more effective in providing pain relief than TENS [21]. This paradigm of uncertainly applies to other technologies. For Low-Level Laser Therapy (LLLT), a meta-analysis suggests that, when used by itself or in combination with other modalities, this treatment may achieve a useful reduction in pain for up to 3 months with few adverse effects in non -specific chronic LBP. Furthermore, has been reported the limited improvement of disability in the short term with a moderate level of evidence [6]. For its part, The Efficacy Of Capacitive-Resistive Diathermy Therapy (TECAR) would demonstrate better results respect to LLLT immediately at the end of the treatments and until the third month [7]. This benefit has been reported in a previous prospective experimental report which demonstrated the effectiveness of diathermy versus placebo [22].

Anyway, recommended supervised exercise therapy and stabilization exercise programs have become widely used for low back rehabilitation as a first-line treatment. Systematic reviews [4] stated that these last are more effective than general exercises in reducing pain or improving the function of specific trunk muscles assumed to control the inter-segmental movement of the spine and enable the patient to regain the coordination of the spine and pelvis. In particular, increasing individual stabilization exercise and flexibility exercises such as stretching in the abdominal muscle, quadriceps, hamstring, tensor fascia lata, piriformis, and quadratus lumborum muscles. These programs include stabilization exercises in different positions (dead bug, side-lying, prone, bird dog, bridge, and plank positions) [23]. Very interesting is also the observation that PEMF combined with shoulder exercises in shoulder impingement syndrome have a potential analgesic and functional effects, probably due to the combined improvement of muscle strength [24].

Even if their mechanism of action is still incompletely known, appears that PEMF exert meaningful analgesic, anti-inflammatory and regenerative effects thanks to a multilevel electrochemical interaction in cells [12]. More particularly, as observed in disc nucleus pulposus cells thanks to dynamic imaging of mRNA transcription, PEMFS induce inhibitory effects on IL-6 transcription activated by the pro-inflammatory factor IL-1a, accompanying the disc generation [25]. This anti-inflammatory effect has also been observed in injured rat - tail intervertebral disc model [11] and could be mediated by A2A and A3 Adenosine Receptors [10]. Various RCT validate the usefulness of PEMF in LBP. Omar et al. report, in a placebo-controlled study on a series of subjects with discogenic LBP and radicular symptoms, observed a significant decrease of hypoesthesia, improvement of ankle hyporeflexia and straight leg raising test. Furthermore, significant differences between both groups relative to VAS and modified OSW score after PEMF therapy :$P = 0.024$ and $P < 0.001$ respectively [26]. In a systematic review [27], the main findings were that PEMF therapy reduces pain intensity and enhance better functionality in low back pain. When used alone, they seem to have greater effects on pain, independent of the LBP condition, compared to the addition of further therapies. Contrarily, other studies indicate that jointly PEMF and conventional physical therapy protocol consisting in TENS therapy for the low back (15 min 3days/week), and fixed pulsed ultrasound for 5 minutes, 1 Hz in continuous mode of application at 1.5 w/cm2, show the better result concerning to conventional physical therapy and sham electromagnetic field [28].

As for the great part of the biophysical energies, we may consider the real difficulty to compare different studies related to the efficacy of PEMF. This is principally due to the characteristics of the delivered impulse: carrier frequency, pulse rate/sec, burst width, magnetic flow density and the strength of the magnetic field [**27**). Our study confirms the efficacy of PEMF in improving pain and functional skill in chronic LBP. However, the biophysical stimulation of the CTU Mega 20® device is quite different from conventional Low Intensity -PEMF. The machine delivers a High Intensity -PEMF with a safety profile of the impulse due to the low frequency despite the strength of the magnetic field (2T - operating Energy up to 90 J). Besides, the rise time is very slow, (few μsec), as well as the bandwidth of the electromagnetic pulse is extremely variable, with a duration of the magnetic pulse up to few ms and the period is of 1000 ms. The distribution of the Magnetic Field has a volume of approximately 27 cm^3 [18], while the different amplitudes shapes and the broad spectrum of electromagnetic frequencies cover the bandwidth of the muscle-skeletal tissue. Otherwise, for LF-LI-PEMF machines, the peak of the Magnetic Field (MF) can vary from 1,6 to 2 mT, and the shape of the waveform is trapezoid or triangular. The signal frequency ranges from 3,8 kHz to 15 or 75 Hz, the rise time is measured in msec, the duration of the pulse varies from 5,56 ms to 25 ms [29].

As is known, the biological effects of the Electromagnetic pulses are mediated by changes in the voltage of the cell membrane affecting, on its turns, the electric properties of the stimulated cells and consequential metabolic responses occur, according to the Intensity and the Magnetic Field Gradient (T/sec). In other words, regardless of the Intensity of the Magnetic Field, high values of the magnetic field gradient, in the static field, can cause cell damage respect to lower values [30] by a significant change in the membrane potential of the cells. This may have a significant impact not only the properties and biological functionality of cells but also on cell fate. For the CTU Mega 20® machine the high intensity of the MF is offset by the safe gradient range (400T/s). The magnetic field delivered by the machine shares the bio-active properties of HI-PEMF, [17] but differs in the possibility to provide the so-called repulsive or Diamagnetic effect. This one, take rise from the force of a self-limiting, pulsed high-intensity magnetic field able to move liquids and solutes from the extracellular to the intracellular space and vice versa. This effect was named molecular diamagnetic acceleration [31]. Besides, a wide bandwidth of electromagnetic frequencies is carried at the cellular level to implement the biological effect of the magnetic field (endogenous biostimulation). In our protocol of treatments, the Diamagnetic effect was enforced by the concomitant use of the diathermia, provided by the machine.

Conclusions

In our study, the treatment with this technology is significantly effective in reducing pain and improving the functional aspect of patients suffering from chronic LBP. The results are in line with those settled by LI-PEMF as reported in the literature [13,14]. Nevertheless, the main drawback of our study is the small statistical sample and the absence of a control group, then further RCT are necessary to confirm these results.

References

1. P. Hüllemann, T. Keller, M. Kabelitz, J Gierthmühlen, R. Freynhagen, et al. (2018) Clinical Manifestation of Acute, Subacute, and Chronic Low Back Pain in Different Age Groups: Low Back Pain in 35,446 Patients. Pain Pract 18: 1011-1023.
2. M. J. Stochkendahl, P. Kjaer, J. Hartvigsen (2018) National Clinical Guidelines for non-surgical treatment of patients with recent-onset low back pain or lumbar radiculopathy. Eur Spine J 27: 60-75.
3. L. Golob, J E. Wipf (2014) Low Back Pain. Medical Clinics of North America 98: 405-428.
4. M Gomes-Neto, J Moura Lopes, C. Sena Conceiçao, et al. (2017) Stabilization exercise compared to general exercises or manual therapy for the management of low back pain: A systematic review and meta-analysis. Physical Therapy in Sport 23: 136-142.
5. Khadilkar, D. Oluwafemi Odebiyi, L. Brosseau, G. A Wells (2008) Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain (Review). Cochrane Database Syst. Rev 2008: CD003008.
6. G Glazov, M. Yelland, J. Emery (2016) Low-level laser therapy for chronic non-specific low back pain: a meta-analysis of randomised controlled trials. Acupunct. Med 34: 328-341.
7. A Notarnicola, G Maccagnano, M F Gallone, I Covelli, S Tafuri, B Moretti, et al. (2017) Short term efficacy of capacitive-resistive diathermy therapy in patients with low back pain: a prospective randomized controlled trial. J Biol. Regul. Homeost. Agents 31: 509-515.
8. Sharrard WJ (1990) A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. J Bone Joint Surg. Br 72: 347-355.
9. Binder A, Parr G. Hazleman B, Fitton-Jackson S (1984) Pulsed electromagnetic field therapy of persistent rotator cuff tendonitis. A double-blind controlled assessment. Lancet 1984: 695-698.
10. F. Vincenzi, M. Targa, C. Corciulo, S. Gessi, S. Merighi, et al. (2013) Pulsed Electromagnetic Fields Increased the Anti-Inflammatory Effect of A2A and A3 Adenosine Receptors in Human T/C-28a2 Chondrocytes and hFOB 1.19 Osteoblasts. PLoS One 8: 5561.
11. K. Chan, X. Tang, N. V. Mummaneni, et al. (2019) Pulsed electromagnetic fields reduce acute inflammation in the injured rat□tail intervertebral disc. JOR Spine 2: e1069
12. M Viganò, V. Sansone, M C d'Agostino, et al. (2016) Mesenchymal stem cells as a therapeutic target of biophysical stimulation for the treatment of musculoskeletal disorders. Journal of Orthopaedic Surgery and Research 11: 163.
13. Pleger B, Janssen F, Schwenkreis P, Volker B, Maier C, et al. (2004) Repetitive transcranial magnetic stimulation of the motor cortex attenuates pain perception in complex regional pain syndrome type I. Neurosci. Lett 356: 87-90.
14. Varcaccio-Garofalo G, Carriero C, Loizzo MR, Amoruso S, Loizzi P (1995) Analgesic properties of electromagnetic field therapy in patients with chronic pelvic pain. Clin Exp Obstet. Gynecol 22: 350-354.
15. Raji AR, Bowden RE (1983) Effects of high-peak pulsed electromagnetic field on the degeneration and regeneration of the common peroneal nerve in rats. J Bone Joint Surg. Br 65: 478-492.
16. S. Leisner, R. Shahar, I. Aizenberg, D Lichovsky, T. L. Harru (2002) The Effect of Short Duration, High-intensity Pulses on Fresh Ulnar Fractures in Rats. J. Vet. Med A-49: 33-37.
17. J. Prucha V. Socha, V. Sochova, L Hanakova, S. Stojic (2018) Effect of High-Induction Magnetic Stimulation on Elasticity of the Patellar Tendon. Journal of Healthcare Engineering 2018.
18. Izzo M, et al. (2010) The role of the diamagnetic pump (CTU Mega 18) in the physical treatment of limbs lymphoedema. The European Journal of Lymphology 21: 24-29.
19. F. Torres Obando, et al. (2020) "Effects of High-Intensity Pulsed Electromagnetic Fields (HI-PEMF) in Interstitial Lung Fibrosis due to the Anti-Synthetase Syndrome Associated with Sjogren's Syndrome. A Case Report". EC Pulmonology and Respiratory Medicine 2020.
20. J. J Jauregui, J J Cherian, C. U Gwam, M. Chughtai, J B Mistry, et al. (2016) A Meta-Analysis of Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain Surg. Technol. Int 28: 296-302.
21. L.-Chen Wu, P-Wei Weng, C.-Hsien C. Y-Y Huang, Y. -Hwei Tsuang, Chang-Jung Chiang (2018) Literature Review and Meta-Analysis of Transcutaneous Electrical Nerve Stimulation in Treating Chronic Back Pain. Regional Anaesthesia and Pain Medicine 43.
22. Shaik A, Abdus S, A. Khan (2009) Evaluation of the effects of shortwave diathermy in patients with chronic low back pain. Bangladesh Med Res Council Bull 35: 18-20.

23. J. H. Suhu, H. Kim, G. P. Jung, J. Y. Ko, Ju S. R (2019) The effect of lumbar stabilization and walking exercises on chronic low back pain. A randomized controlled trial. Medicine 2019.

24. Galace de Freitas D, et al. (2014) Electromagnetic Field and Exercises in Patients with Shoulder Impingement Syndrome: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial Archives of Physical Medicine and Rehabilitation 95: 345-352.

25. X. Tang, T. Alliston, D. Coughlin, S. Miller, N. Zhang, et al. (2018) Dynamic Imaging Demonstrates That Pulsed Electromagnetic Fields (PEMF) Suppress IL-6 Transcription in Bovine Nucleus Pulposus Cells. Orthop. Res 35: 778-787.

26. S. OMAR, M. A. AWADALLA, M. Abd EL-LATIF (2012) Evaluation of pulsed electromagnetic field therapy in the management of patients with discogenic lumbar radiculopathy. International Journal of Rheumatic Diseases 15: e101-e108.

27. R. Andrade, H. Duarte, R. Pereira, I. Lopes, H. Pereira, et al. (2016) Espregueira-Mendes Pulsed electromagnetic field therapy effectiveness in low back pain: A systematic review of randomized controlled trials. Porto Biomed. J 1:156-163.

28. M. Elshiwi, H. A. Hamada, D. Mosaad, I. M. A. Ragab, G. M. Kouraa, et al. (2019) Effect of pulsed electromagnetic field on non-specific low back pain patients: a randomized controlled trial. Brazilian Journal of Physical Therapy 23: 244-249.

29. L. Massari, F. Benazzo, B. Moretti, et al. (2011) Stimolazione elettrica dell'osteogenesi: efficacia e tecnologie a confronto. Electrical stimulation of osteogenesis: efficacy and technologies compared. GIOT dicembre 37: 272-279.

30. V Zablotskii, T Polyakova, O. Lunov, A Dejneka (2016) How a High-Gradient Magnetic Field Could Affect Cell Life. Scientific Reports 6: 37407.

31. Premi E, Benussi A, La Gatta A. et al. (2018) Modulation of long-term potentiation-like cortical plasticity in the healthy brain with low frequency-pulsed electromagnetic fields. BMC Neuroscience 19: 34.