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Original Article

Comparison of the effectiveness of interferential current and PEMF treatments in patients with chronic mechanical low back pain

Kronik mekanik bel ağrılı hastalarda interferansiyel akım ve PEMF tedavilerinin etkinliklerinin karşılaştırılması

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ABSTRACT

Introduction: We aimed to compare the effects of interference current (IFC) and pulsed electromagnetic field (PEMF) therapies combined with conventional physical therapy on pain, functional situation, and quality of life (QOL) in patients with mechanical chronic low back pain (CLBP).
Method: In this prospective randomized controlled study, 40 CLBP patients were divided into two groups: group I (Hot pack, ultrasound (US), and IFC combination therapy (n=20)), group II (Hot pack, US, and PEMF combination therapy (n=20)). A total of 10 sessions of therapy were performed on the participants, one session a day, five days a week, for two weeks. Evaluations were performed three times at before the treatment (BT), immediately after the treatment (AT) and 8 weeks after the treatment (AT-8), using the The Numerical Rating Scale (NRS), Roland-Morris Disability Questionnaire (RMDQ), EuroQol-Health-related Quality of Life Questionnaire (EQ-5D-3L), Fingertip-to-floor test (FtF).
Results: There was no difference in age, BMI, gender and baseline values in all two groups. No significant difference was found for RMDQ (F(2.76)=0.174; P=0.840), NRS(F(2.76)=0.155; P=0.857), and EQ (F(2.76)=0.273; P=0.762) scores in time–group interaction (F(2.76)=0.174; P=0.840). No significant differences were found between the groups in terms of RMDQ, NRS, EQ-5D-3L, and FtF scores (p>0.05).
Discussion and Conclusion: It has been proved that PEMF or IFC therapies in addition to conventional physical therapy programs are effective in mechanical CLBP treatment in terms of pain, functional status, and quality of life.

Keywords: chronic pain, interferential current electrotherapy, low back pain, magnetic field therapy

ÖZ

Giriş ve Amaç: Kronik mekanik bel ağrılı (KMBA) hastalarda geleneksel fizik tedavi ile birlikte interferansiyel akım (IFA) ve pulse elektromanyetik alan (PEMA) tedavilerinin ağrı, fonksiyonel durum ve yaşam kalitesi üzerindeki etkilerini karşılaştırmayı amaçladık.
Yöntem ve Gereçler: Bu prospektif randomize kontrollü çalışmada, 40 KMBA hastası iki gruba ayrıldı: grup I (Hot pack, ultrason (US) ve IFA kombinasyon tedavisi (n=20)), grup II (Hot pack, US ve PEMA kombinasyon tedavisi (n=20)). Katılımcılara iki hafta boyunca haftada beş gün, günde bir seans olmak üzere toplam 10 seans terapi uygulandı. Değerlendirmeler, tedaviden önce (TÖ), tedaviden hemen sonra (TS) ve tedaviden 8 hafta sonra (TS-8) olmak üzere üç kez, Sayısal Derecelendirme Ölçeği (SDÖ), Roland-Morris Engellilik Anketi (RMEA), EuroQol-Sağlıkla İlgili Yaşam Kalitesi Anketi (EQ-5D-3L), El parmak- zemin mesafesi testi (EPZM) kullanılarak yapıldı.
Bulgular: Her iki grupta da yaş, VKİ, cinsiyet ve başlangıç değerlerinde fark yoktu. RMEA (F(2.76)=0.174; p=0.840), SDÖ (F(2.76)=0.155; p=0.857) ve EQ (F(2.76)=0.273;

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p=0.762) puanları arasında anlamlı bir fark bulunmadı. zaman-grup etkileşimi (F(2.76)=0.174; p=0.840). RMEA, SDÖ, EQ-5D-3L ve EDZM skorları açısından gruplar arasında anlamlı fark bulunmadı (p>0.05).
Tartışma ve Sonuç: KMBA tedavisinde geleneksel fizik tedavi programlarına ek olarak PEMA veya IFA tedavilerinin ağrı, fonksiyonel durum ve yaşam kalitesi açısından etkili olduğu kanıtlanmıştır.

Anahtar kelimeler: bel ağrısı, interferensiyal akım elektroterapisi, kronik ağrı, manyetik alan tedavisi

INTRODUCTION

The lumbar region is the most common site of involvement for musculoskeletal pain conditions. Approximately 80% of the people living in industrialized countries suffer from lower back pain at least once in their lives, and about ten percent of them become chronic. The etiology of low back pain includes several factors that can contribute to discomfort. However, 85 to 90 percent of the cases remain inexplicable in terms of pathophysiological mechanism or etiological factors (1).

Low back pain typically occurs due to exposure to stress or strain to lower back muscles, tendons, and ligaments. Mechanical low back pain is chronic pain of varying intensity, often affects the lower part of the spine, and radiates to the gluteal region. During the day, the severity of pain increases by daily activities such as bending forward, turning, lifting weights, standing, or sitting for a long period. To characterize low back pain as mechanically induced, other etiologies such as inflammatory, infectious, tumoral, metabolic causes, and referred pain from visceral organs should be excluded (2).

Mechanical low back pain that lasts longer than 12 weeks is defined as chronic low back pain (CLBP). The purposes of CLBP treatment are to control pain, prevent new attacks, reduce the intensity of the pain and duration of the disease, prevent avoidable disabilities and psychological symptoms, augment functional activity level, and educate patients. In the treatment of the CLBP, different therapeutic approaches are currently available, including exercise, analgesic treatment, physical therapy modalities, acupuncture, yoga, cognitive behavioral therapy, spinal manipulation, progressive relaxation, and interdisciplinary rehabilitation (3, 4). Although analgesics are frequently used in treating chronic pain, to avoid their side effect profiles, physical therapy modalities came into prominence in the alternative. Therapeutic options, including hot packs, therapeutic ultrasound (US), transcutaneous electrical nerve stimulation (TENS), pulsed electromagnetic field (PEMF), and interference current (IFC), have been widely utilized in physical therapy clinics for a long time. However, there is no consensus about the optimal treatment method. Different electrotherapy modalities are often used in the treatment, but their superiority is still a dilemma (5).

IFC therapy is consisted of the superimposition of two medium frequency currencies into the tissue to form a low-frequency current (for example, 20-100 Hz) (6). IFC therapy is extensively practiced worldwide, but our knowledge is still limited (7). It is suggested that IFC therapy delivers current that penetrates deeper tissue with less irritation compared to TENS therapy (8). PEMF therapy is another therapeutic option frequently applied in knee, hip, and spine osteoarthritis treatment. The PEMF showed a beneficial tendency on the bone growth stimulation in acute fractures and efficient in relieving pain and enhancing bone formation in osteoporosis (9). Magnetic field therapy enhances local cellular activity, oxygen consumption in the tissue, and vasodilation without increasing local temperature. Despite a great number of clinical studies, the efficacy of the methods has not been proved (10). Although IFC and PEMF therapy can be implemented in patients with CLBP, there is a lack of data about their supremacy. This study aimed to compare the effects of IFC and PEMF therapies combined with conventional physical therapy on pain, functional situation, and quality of life (QOL) in patients with CLBP.

MATERIALS AND METHODS

Study design and setting

This research was planned as a prospective, randomized, single-blind study. The study was performed between March 2021 and September 2021 following the Helsinki Declaration and with permission from the ethical committee of Bolu Abant Izzet Baysal University (Clinical Research Ethics Committee 2021/05). All participants signed a written informed consent before being enrolled in this study.

Study participants

The participants were recruited from Bolu Abant Izzet Baysal University Physical Therapy and Rehabilitation Training and Research Hospital admissions.

Inclusion criteria:

- Being diagnosed with CLBP (Mechanical low back pain persists longer than three months)
- Being between 40-65 years old

Exclusion criteria:

- Subjects with neurological deficits in their lower extremities
- Inflammatory back pain (IBP)
- Severe osteoporosis or osteomalacia
- Spondylolisthesis
- History of malignancy
- History of trauma or major surgery to the lumbar region
- History of physical therapy in the past year
- Significant pathology in the waist, hip, or ankle joints that may affect the results
- Patients for whom electrotherapy is contraindicated (pregnancy, neurologic disorders like epilepsy, inner ear hearing aids, cardiac devices, infections, and cutaneous lesions)

Randomization

CLBP patients were enrolled in this prospective study were divided into two groups using Microsoft Excel© 2003 (Microsoft, Redmond, WA) random number production function, as follows: group I (Hot pack, US, and IFC combination therapy (n=20)), group II (Hot pack, US, and PEMF combination therapy (n=20)).

Treatment protocol

Superficial heat application (hot pack): A hot pack wrapped in a towel was applied to the lumbar region for 20 minutes.

Deep heat application (US): The application was performed with a therapeutic ultrasound device (Chattanooga - Intelect advanced - DJO International Headquarters – The United Kingdom) given at 1 W/cm^2 for ten minutes on the lumbar region.

PEMF therapy: The therapy was administered with a PEMF machine (Roland HC - Elettronica Pagani – Italy) at a frequency of 50 Hz and an intensity of 25 G for 20 minutes.

IFC therapy: IFC therapy was applied at a (Chattanooga - Intelect advanced - DJO International Headquarters – The United Kingdom) 4000 Hz carrier frequency, 50 Hz amplitude-modulated frequency (AMF), and in a 1/1 rectangular swing pattern, using four electrodes for 10 minutes according to their chronic pain conditions. The current dose was adjusted to the strongest level that the patient could tolerate.

A total of 10 sessions of therapy were performed on the participants, one session a day, five days a week, for two weeks.

An experienced physiotherapist performed all the treatments, the follow-up evaluations and results were tracked by a physician in an observational method. In the initial evaluation session, information about the cases considered suitable for participation was recorded on

patient evaluation forms. All evaluations were conducted three times, before the treatment (BT), immediately after the treatment (AT), and 8 weeks after the treatment (AT-8).

Outcome Measures

The Numerical Rating Scale (NRS)

NRS is used in the assessment of pain. The numerical scale often includes 11 digits to categorize the perceived pain intensity. In our study, the patients were instructed that "0" represented no pain and "10" the worst pain imaginable. The participant chose the number that best reflects it (11).

Roland-Morris Disability Questionnaire (RMDQ)

This questionnaire was developed to evaluate the physical disabilities caused by low back pain. The validity and reliability of Turkish test adaptation were demonstrated in 2001 (12).

In this questionnaire consisting of 24 sentences about functional disabilities, patients are asked to respond "yes" if the sentence fits their situation and "no" if it doesn't. Each "yes" answer is counted to calculate the total score, between 0-24, with a higher score indicating more disability.

EuroQol - Health-related Quality of Life Questionnaire (EQ-5D-3L)

The EQ-5D is a self-rated health status scale developed by EuroQol Group Association, a quality-of-life research community in Western Europe, to evaluate the quality of life with one question for each of the five dimensions. These five dimensions comprise mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. There are three levels of responses for each dimension: no problems, some problems, and extreme problems. As a result, the scale defines 243 possible different health outcomes. An index score calculation between -0.59 and 1 reflects five scale dimensions. A value of 0 indicates death and 1 indicates full health, while negative values mean unconsciousness, being confined to bed, etc. In addition, the EQ-VAS represents the patient's own opinion about their health on a visual analogue scale from 0 (worst imaginable health state) to 100 (best imaginable health state) (13).

Fingertip-to-floor test (FtF)

The FtF test is used to assess the active ROM of the back; a tape measure is used to assess the distance between the most distal point of the fingers and the floor. Accordingly, a smaller measure corresponds to a greater flexion performance.

Statistical Method

Statistical Package for the Social Sciences (SPSS) statistical software (SPSS Inc., Chicago, IL, US) version 22 for Windows was used for statistical analysis. The Shapiro-Wilk test was selected to state if the distributions were significantly different. The data were described as the mean ± standard deviation for continuous variables, the median (maximum-minimum) for ordinal variables, and the frequency with percent for categorical variables. A repeated-measures ANOVA with a Greenhouse-Geiser correction was used to determine the difference in both groups' RMDQ, NRS, and EQ scores between time points. Friedman's analysis of variance by ranks was used to determine the difference of *FtF* scores between time points in both groups. A two-way analysis of variance was conducted to examine the effect of treatment on RMDQ, NRS, and EQ scores. Post hoc analysis with a Bonferroni adjustment was used to analyze the mean differences between the time point of assessments in both groups between the first and second, and first and third assessments. Kendall's coefficient of concordance was used to analyze the mean differences between the time point of *FtF*. Wilcoxon signed-rank test was used to analyze the treatment effect on *FtF* scores. For the comparison of the categorical data, the chi-square test was assigned. A p-value less than 0.05 was considered significant.

RESULTS

A total of 40 patients were recruited in this study. In the intervention group, the mean age was 55.70±9.31 years and the mean onset of symptoms period was 6.40±1.95 months. In the control group, the mean age was 59.35±7.37 years and the mean onset of symptoms period was 5.55±1.79 months (Table 1). There were 12 (60%) female and 8 (40%) male participants in the IFC group, and there were 17 (85%) female and 3 (15%) male participants in the PEMF group. There were no significant differences between the two groups in terms of baseline characteristics (P>0.05) (Table 2). The mean RMDQ, NRS, and EQ scores differed significantly between time points in both groups (P<0.05). The *FtF* also scores differed statistically significantly between time points in both groups (P<0.05) (Table 3). A two-way analysis of variance was conducted to examine the effect of treatment on RMDQ, NRS, and EQ scores. No significant difference was found for RMDQ (F(2.76)=0.174; P=0.840), NRS (F(2.76)=0.155; P=0.857), and EQ (F(2.76)=0.273; P=0.762) scores in time–group interaction (F(2.76)=0.174; P=0.840). No significant difference was found between groups in terms of *FtF* scores (P>0.05)

In post hoc analysis, the mean differences between the time point of assessments showed a significant improvement in both groups between the first and second and first and third assessments (P<0.05). There was no significant difference between the second and third assessments for RMDQ, NRS, and EQ scores (P>0.05) (Table 4). The mean differences between the time point of *FtF* only showed a significant improvement in the Magnetic Field group's first and second assessments and first and third assessments (P<0.05). There was no significant difference between the other time points of both groups (P>0.05).

DISCUSSION

The main findings of the study were as follows:

1. It has been proved that PEMF or IFC therapies and conventional physical therapy programs are effective in mechanical CLBP treatment in terms of pain, functional status, and quality of life.

2. There are no significant differences between the groups' RMDQ, NRS, EQ-5D-3L, and *FtF* scores.

CLBP is a frequent disorder worldwide that causes chronic disability and socioeconomic burden. Therefore, the number of studies on this topic grows exponentially day by day.

Table 1. Patients' Characteristics.

	Interferential Current (n=20)	PEMF (n=20)	
	X±SD	X±SD	p
Age (year)	55.70±9.31	59.35±7.37	0.370
Symptom onset (months)	6.40±1.95	5.55±1.79	0.763
BMI(Kg/m^2)	30.61±5,08	31.07±5.15	0.974

BMI: Body Mass Index, p<0.05, SD: Standard Deviation

Table 2. Pre-test score comparison of groups.

	Interferential Current (n=20)	PEMF(n=20)		
	X±SD	X±SD	t	p
RMDQ	15.85±3.77	16.90±4.07	-0.845	0.403*
NRS	7.15±1.49	7.00±1.37	0.330	0.743*
EQ	9.65±1.08	10.00±1.16	-0.979	0.334*
	Med (Min-Max)	Med (Min-Max)	X^2	p
FtF	5 (0-30)	5 (0-35)	-0.076	0.940**

**t: Independent sample t-Test, ** Mann-Whitney U Test p<0.05*

Table 3. Comparison of pre-test, post-test, and follow-up scores between groups.

	Interferential Current (n=20)			PEMF (n=20)		
	X±SD	f	p	X±SD	f	p
RMDQ Pre-test	15.85±3.77			16.90±4.07		
RMDQ Post-Test	8.15±3.68	35.763	<0.001	8.40±4.23	36.945	<0.001
RMDQ Followup	8.50±4.72			8.80±4.28		
NRS Pre-test	7.15±1.49			7.00±1.37		
NRS Post-Test	3.25±1.58	30.930	<0.001	3.40±1.39	27.330	<0.001
NRS Followup	4.05±2.52			3.80±2.30		
EQ Pre-test	9.65±1.08			10.00±1.16		
EQ Post-Test	7.20±1.39	25.358	<0.001	7.20±1.19	33.022	<0.001
EQ Followup	7.20±1.60			7.55±1.76		
	Med (Min-max)	**X^2**	**p**	**Med (Min-max)**	**X^2**	**p**
***FtF* Pre-test**	5 (0-30)			5 (0-35)		
***FtF* Post-Test**	2.5 (0-)	11.267	0.004	2 (0-32)	14.333	0.001
***FtF* Followup**	3.5 (0-)			4 (0-28)		

X^2: Chi-square t: One-way ANOVA with repeated measures, p<0.05, SD: Standard Deviation

Table 4. Post hoc results of outcome measurements.

		Interferential Current (n=20)			PEMF (n=20)			Comparison of the IFC and PEMF groups
		Mean Difference (SE)	Confidence intervals (%95 CI)	p	Mean Difference (SE)	Confidence intervals (%95 CI)	p	p
	1-2	7.70(0,98)	5.10 / 10.3	<0.001*	8.50(1.28)	5.14 / 11.8	<0.001*	0.620
RMDQ	**1-3**	7.35(0.98)	4.77/ 9.92	<0.001*	8.10(1.18)	4.96 / 11.2	<0.001*	0.629
	2-3	-0.35(1.11)	-10.3 / -5.12	1.000*	-0.04(0.83)	-11.8 / -5.14	1.000*	0.972
	1-2	3.90(0,36)	2.97 / 4.83	<0.001*	3.60(0,44)	2.45 / 4.75	<0.001*	0.597
NRS	**1-3**	3.10(0,60)	1.51 / 4.68	<0.001*	3.20(0,62)	1.58 / 4.82	<0.001*	0.565
	2-3	-0.80(0,58)	-2,32 / 0.72	0.548*	-0.40(0,53)	-1,79 / 0,99	1.000*	0.613
	1-2	2.45(0,35)	1.53 / 3.37	<0.001*	2.80(0,37)	1.83 / 3.76	<0.001*	0.495
EQ	**1-3**	2.45(0,43)	1.32/ 3.58	<0.001*	2.45(0,38)	1.43 / 3.46	<0.001*	1
	2-3	0.01(0.40)	-1.06 / 1.60	1.000*	-0.35(0,37)	-1.33 / 0.66	1.000*	0.528
	1-2	2.35(0,76)	0.37 / 4.33	0.691**	2.80(0.73)	0.88 / 4.72	0.014**	0.602
FtF	**1-3**	2.15(0,88)	-0.17/ 4.47	0.822**	2.90(0,99)	0.31 / 5.50	0.022**	0.191
	2-3	-0.20(0.30)	-0.97 / 0,58	0.937**	0.10(0.50)	-1.40 / 1.20	0.874**	0.391

**Bonferroni post hoc analysis, ** Kendall's coefficient of concordance RMDQ: NRS: EQ: FtF, p<0.05*

In the literature, there are also studies about the efficiency of IFC and PEMF therapies, which are commonly performed treatments among physical therapy modalities. However, the results are controversial about the effectiveness of PEMF therapy in low back pain (14, 15).

In a study by Elshiwi et al., it was proven that PEMF treatment was more effective than sham PEMF treatment combined with the conventional physical therapy program in improving the symptoms of CLBP. They preferred operating low intensity (20 Gauss, 2mT) of PEMF with a frequency of 50 Hz following the World Health Organization's recommendations (16).

Khalid et al. reported that the PEMF treatment was not superior to sham therapy in pain control and improved functional status on CLBP (17). They used NRS and Rolland-Morris disability questionnaires; they did not find a significant difference between the groups regarding pain intensity and disability at the 6th and 13th-week assessments. Similar scales were used in our study, and the quality of life was also evaluated.

The meta-analysis by McCarty et al. revealed that PEMF therapy should be used as a complementary treatment rather than alone and should be included in treatment protocols (18). In our

study, we also applied PEMF treatment and the conventional methods.

Renato et al. evaluated six different studies about low-dose PEMF treatment application in lower back pain. Even though there were differences in the treatment protocols, they found that PEMF therapy had a favorable effect on low back pain and functionality (19). Our study observed that PEMF treatment combined with conventional therapies was potent in terms of pain and functionality in patients with CLBP. We also investigated the efficiency of IFC therapy frequently used in treating low back pain (20, 21).

Despite the widespread use of IFC treatment in daily clinical practice, therapeutic parameters are not defined strictly. The AMF settings in IFC devices allow the nervous system to inhibit repetitive currents to prevent desensitization. Previous studies have shown that the effect of IFC swing patterns is only theoretical and cannot be reflected in clinical practice (22, 23).

Although IFC therapy is superior to a placebo in musculoskeletal pain, it remains unclear whether IFC treatment alone is better than other alternatives due to the lack of evidence. In a recently published review, IFC treatment combined with conventional methods was effective in relieving musculoskeletal pain and seems to be more effective than placebo during 3 months follow-up (24).

Similarly, we applied IFC treatment in addition to conventional therapy. To the best of our knowledge, there is no study in the current literature comparing the effectiveness of IFC and PEMF therapies in CLBP. A few studies focused on the efficacy of IFC treatment and its comparison with others.

Rajfur et al. reported that using IFC treatment deeper into the tissues was more effective than the TENS currents and high voltage in eliminating pain and improving functional ability in patients with low back pain. On the other hand, diadynamic currents seem inefficacious (25).

Facci et al. compared IFC and TENS therapies in their study conducted on 152 patients. Their results showed that these modalities were effective in CLBP treatment, yet they were not superior to each other. Similarly, we applied 10 sessions of therapy in two weeks. In our study, IFC and PEMF treatments were compared, and positive effects on pain and functional status were de monstrated in both groups at the end of the therapy and eighth-week assessment. Additionally, improvement in quality of life was noticed in both groups (26).

The principal limitation of this study is the lack of a control group and a small sample size. The single-center research design is the other limitation of the study.

In conclusion, different therapeutic options, including combination therapies, such as PEMF & IFC dual therapies, can be performed to treat CLBP. However, placebo-controlled studies are required to establish cost-effective standard treatment protocols.

Ethics Committee Approval: The study protocol was approved by the Bolu Abant İzzet Baysal University Clinical Researches Ethics Committee on February 2, 2021 (Ethics committee registration number: 2021/05).

Conflict of Interest: The authors have declared that they have no conflict of interest.

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