Comparison of the Efficacy of Different Electrode Types of Interferential Current Therapy in the Treatment of Patients with Chronic Low Back Pain: A Randomized Controlled Single-Blinded Study

Kronik Bel Ağrılı Hastalarda İnterferansiyel Akım Tedavisi Uygulamasında Farklı Elektrot Tiplerinin Etkinliğinin Karşılaştırılması: Randomize Tek Kör Kontrollü Bir Çalışma

ABSTRACT Objective: Interferential current therapy (IFT) is one of the physical treatment modalities that has analgesic effects. The aim of this study was to evaluate the effectiveness of IFT on pain, disability, and quality of life (QoL) in patients with chronic low back pain (LBP) and to compare the advantages of IFT with vacuum electrodes and carbon silicon pad electrodes. Material and Methods: One hundred patients with LBP were randomized into three groups. Group 1 received IFT with vacuum electrodes, group 2 received IFT with carbon silicon pad electrodes and group 3 received no IFT therapy. Patients were evaluated three times: Before treatment, one week after treatment, and twelve weeks after treatment. Pain was assessed using a visual analogue scale (VAS), disability with the Oswestry Disability Index (ODI), and QoL with the Short Form-36 (SF-36). Results: Group 1 and 2 demonstrated a statistically significant reduction of pain, disability and QoL scores as compared with pretreatment. In group 3, there was no statistically significant improvement of VAS, ODI, and SF-36 scores. Intergroup analysis demonstrated that the greatest analgesic and functional effects was recorded in group 1, which were statistically significant better results than in group 2 and group 3. Conclusion: Treatment using IFT with vacuum electrodes resulted in a significantly greater and clinically meaningful reduction in VAS, ODI, and SF-36 scores than using IFT with carbon silicon pad electrodes in patients with LBP.

Keywords: Low back pain; interferential current therapy; electrode type; disability; quality of life; rehabilitation

ÖZET  Amaç: İnterferansiyel akım tedavisi (IFT) analjezik etkileri olan fizik tedavi yöntemlerinden biridir. Bu çalışmanın amacı IFT’nin kronik bel ağrısı (KBA) olan hastalarda ağrı, dizibilite ve yaşam kalitesi üzerindeki etkisini değerlendirmek ve IFT’nin vakum elektrotlar ve karbon silikon pad elektrotlar ile uygulanmasının avantajlarını karşılaştırmaktır. Gereç ve Yöntemler: KBA olan 100 hasta üç gruba randomize edildi. Grup 1’e vakum elektrotlar ile IFT, grup 2’ye karbon silikon pad elektrotlar ile IFT uygulandı; grup 3’e IFT tedavisi uygulandı. Hastalar tedaviden önce, tedavi bitiminden bir hafta sonra ve tedavi bitiminden on iki hafta sonra olmak üzere üç kez değerlendirildi. 

Anahtar Kelimeler: Bel ağrısi, interferansiyel akım tedavisi; elektrot tipi; dizibilite; yaşam kalitesi; rehabilitasyon
Non-specific chronic low back pain (LBP) is defined by a mechanical pain of musculoskeletal origin, which lasts more than three months and its cause is unspecified. Chronic LBP causes physical and psychological problems, disability, and reduced quality of life (QoL). The treatment of chronic LBP aims to prevent disability by reducing pain. Conservative treatment involves rest, drug therapy, physical therapy modalities, exercise, manipulation, bracing, and back school. Exercise is very important for treating patients with chronic LBP; however, patients cannot exercise because of their LBP. As such, participation in physical therapy for the reduction of pain may allow affected patients to join exercise programs at earlier stages.

The main goal of using electrophysical agents in treating LBP syndromes is to decrease pain and inflammation, and reduce muscle tension in the affected regions, which also shorten the duration of treatment and reduce costs as additional benefits. Despite the widespread use and popularity of interferential current therapy (IFT) for pain management among physicians, there is a lack of scientific evidence to support aspects of their claimed effectiveness.

Rajfur et al. investigated five different treatment approaches; conventional transcutaneous electrical nerve stimulation (TENS), acupuncture-like TENS, high-voltage electrical stimulation, interferential current (IFC) stimulation, diadynamic current, in 123 patients with chronic LBP compared with a control group. The results showed that electrical stimulation therapy with IFC was the most effective treatment for reducing pain. In another study, Hurley et al. compared the efficacy of IFT electrode placement with a control treatment in patients with acute LBP. Their results demonstrated that IFT electrode placement affected LBP-specific functional disability and pain. IFT can be administered by using two types of electrodes, vacuum electrodes and carbon silicon pad electrodes. To our knowledge, no studies in the literature have compared the efficacy of these two electrodes. Accordingly, the main objective of our study was to evaluate the short- and long-term effects of IFT on pain, disability, and QoL in patients with chronic LBP. The secondary objective was to compare the advantages of IFT with vacuum electrode and carbon silicon pad electrode applications.

**MATERIAL AND METHODS**

**STUDY DESIGN AND SUBJECTS**

This was a three-arm, randomized controlled trial with as assessor who was blinded to the group allocation. Two-hundred consecutive patients who were admitted to the outpatient clinic of Physical Medicine and Rehabilitation Department between 2015 and 2016 with chronic LBP were included in the study. One hundred patients were excluded for various reasons. Figure 1 shows a flowchart of patient enrollment. Ethical approval for this study was obtained from local ethics committee and the study was conducted in accordance with the Declaration of Helsinki. Patients were informed about the study, and their oral and written informed consents were taken. The clinical trial registration number of this study is IRCT2018010803826N3. Patient information including age, sex, body mass index, smoking habit, duration of illness, and occupational status were recorded. To be included in the study, patients had to have been seeking treatment for chronic LBP, defined as pain localized below the last rib and above the buttocks, without leg pain, which they had had for more than three months. Patients of both sexes aged between 18 and 65 years were included. Patients with cognitive dysfunction, neurologic deficits, extruded and/or sequestrated lumbar disc herniation, spinal fusion, pregnancy, malignancy, spinal compression fracture, spondylolisthesis, aortic aneurysm, severe peripheral neuropathy, vertebral infection, rheumatologic disease, and those who had undergone vertebral column surgery were excluded from the study. In addition, individuals with contraindications to electrotherapy such as skin lesions, abnormal sensitivity, infections, and heart pacemakers were excluded.

The occupational statuses of the patients were classified as deskwork, heavy-lifting work, standing work, driving work, retired, unemployed.
order to exclude other causes that could lead to low back-leg pain, laboratory and radiologic examinations were performed prior to treatment, including complete blood count, routine biochemistry, C-reactive protein, erythrocyte sedimentation rate, urine tests, four-way lumbar spine radiographs, and magnetic resonance imaging (MRI).

**INTERVENTION**

Casual randomization using the sealed numbered envelope technique was performed by an administrative assistant. A single physiatrist who was blinded to the randomization process evaluated each patient before treatment, and one week and 12 weeks after the treatments. After evaluation by the physiatrist, the patients were randomized into three groups:

Group 1 (n=34) underwent IFT with vacuum electrodes. Four vacuum electrodes were placed such that the painful area remained in the middle. The sponges were wetted with tap water and placed in the electrode cups. To apply the elec-
trodes to the patient, the cups were slightly squeezed, brought into contact with the skin, and held for a few minutes until suction occurred (Figure 2a). Before application of IFT, a hot pack was applied to the lower back for 20 minutes. The patients in group 1 also received exercise therapy, which will be explained in detail below. Group 2 (n=34) received IFT with carbon-silicone pad electrodes (5x5 cm). Treatment involved paraspinal application of the cathode and anode electrodes at the lateral limits of the painful area parallel to the vertebral column. The sponges for the pad electrodes were wetted with tap water and placed on the area to be treated using straps in the electrode cups (Figure 2b). A hot pack was applied to the lower back for 20 minutes before the application of IFT. Group 2 also received exercise therapy.

Group 3 (control group): The patients in this group (n=32) performed exercise therapy only and a hot pack was applied to the low back for 20 minutes.

The technique used in this study involved a bipolar mode with 2 channels located 5 cm from the T12 and L5 spinous processes. IFT units (ITO EU-920, Tokyo, Japan) were used to deliver standardized IFT stimulation parameters based on previous work.

All three groups were requested to do perform strengthening and spine stabilization exercises. The stabilization training included: activation techniques for the neutral spine position, training the transversus abdominis, external and internal obliques, diaphragmatic breathing, myofascial release techniques for the erector spinae muscle, coordination exercises for the superficial and deep trunk muscles, and postural and dynamic training.5,6 The exercises were performed 5 times per week. Each training session lasted 45 min (each exercise was performed once per day with 20 repetitions). Patients were underwent 15 treatments, 5 times per week (Monday to Friday) for a period of 3 weeks. The participants were under the care of the same physical therapists.

After completing the 15 sessions, the patients were reassessed by an independent evaluator who used the same instruments.

All patients educated about the correct use of the lumbar region, the benefits of strengthening the region and gaining flexibility, and the correct performance of repetitive movements while lying in bed, standing, sitting, bending, and lifting weights in daily life. Patients were not permitted to take non-steroidal antiinflammatory drugs during the study, they were only allowed paracetamol (2 g/day maximum) when needed.

OUTCOME MEASURES
The primary outcomes of the study were pain intensity and disability at the one and 12-week follow-ups. The secondary outcomes of the study were functional improvement and QoL, which were measured in the 3rd month.
Visual Analogue Scale (VAS)

A VAS pain assessment scale was used for the subjective assessment of pain, in which the patient scored their pain from 0 to 10, where 0 = no pain and 10 = severe pain. A 10-cm long horizontal ruler was used. The minimum clinical important difference (MCID) has been reported to be between 1 and 1.9 points after treatment for chronic low back pain.

Oswestry Low Back Pain Disability

The Oswestry questionnaire was used to evaluate the functional ability of patients. It is a widely recognized and reliable scale for the evaluation of patients with LBP. The questionnaire consists of 10 questions regarding symptoms and everyday activities for which the patients can choose from several options. The answers are then scored, the sum of which provides the Oswestry Disability Index (ODI). The Turkish reliability and validity study of the ODI was performed by Yakut et al.

Short Form 36 (SF-36)

Short Form 36 (SF-36) has been described frequently in the literature, but it is used to assess the QoL of patients. Turkish reliability and validity study of SF-36 was performed by Koçyiğit et al. SF-36 is a 36-item questionnaire that is completed by the patients themselves. The SF-36 has eight subgroups that describe aspects of health, which patients score from 0 to 100. Zero score indicates the worst health status and 100 reflects the best health status.

STATISTICAL ANALYSIS

Baseline data were coded and all outcome measure questionnaires were scored by the trial coordinator. All data were entered into spread sheets for analysis using the Statistical Package for the Social Sciences (SPSS Inc. Released 2008. SPSS Statistics for Windows, Version 22; Chicago). Descriptive statistics (mean and standard deviation) were calculated for demographic variables. Between-group differences in baseline characteristics were calculated using Kruskal-Wallis test.

The sample size was based on power calculations from these data. Power analyses showed that at least 33 participants were required for each group given an SD of 12 mm VAS, a difference in pain intensity between groups of 12 mm on the VAS, with a power level of 0.05 set at 80%.

For dependent variables, the non-parametric Friedman test was used, and for independent variables we used nonparametric Kruskal-Wallis variance analysis. The Tukey post hoc multiple comparisons test was used to identify the exact difference resulting from the variance analysis between individual groups. Statistical significance was accepted as p<0.05.

RESULTS

One hundred patients (mean age: 51.8±10.8 years; min:19 max:79; F/M:65/35) were included in the study. All patients completed the treatment.

The sociodemographic characteristics of the patients are presented in Table 1. No significant differences were observed between the groups regarding age, sex, occupation, education level, and pain duration (all p >0.05).

After the completion of the therapy, group 1 and 2 demonstrated a statistically significant reduction of pain as compared with baseline values, as measured using the VAS scale (Table 2). Similarly, a subjective reduction of scores was recorded using the ODI questionnaire in groups 1 and 2. The ODI scores improved significantly in groups 1 and 2 after the therapies at the first week, but post treatment scores in group 1 at the third month were statistically higher than in group 2 (Table 2). The greatest statistically significant improvement in pain severity, ODI scores, and SF-36 scores at 1 week and 3 months follow-up was in group 1 when compared with baseline levels. In group 2, there was a statistically significant improvement in the pain severity and ODI scores at 1-week follow-up when compared with baseline levels, but there were no statistically significant changes in ODI scores at the 3-month follow-up.

QoL changes measured with SF-36 scale are shown in Table 3. There was a statistically significant improvement in all subgroups of SF-36 scores in group 1. No statistically significant changes were
observed in the subgroups of the SF-36 scores in
group 2, except for pain and general health.
In group 3, after 1 week and three months
treatment, there was no statistically significant
improvement of functional ability measured according
to the ODI scores, VAS scores, and SF-36 scores.

According to the intergroup comparisons of
the percentage pain intensity reduction in VAS
scoring, the p value was <0.001. Post hoc analysis
revealed that p value for the difference between
groups 1 and 2 was 0.008, between groups 1 and 3
it was <0.001, and between groups 2 and 3 it was
<0.001.

According to the intergroup comparisons of
the percentage improvement of the disability level
in Oswestry scoring, the p value was <0.001. Post
hoc analysis revealed that p value in the difference
between groups 1 and 2 was 0.003, between groups 1
and 3 it was <0.001, and between groups 2 and 3
it was >0.05.
### Table 3: Comparison of SF-36 values of the groups.

<table>
<thead>
<tr>
<th>SF-36 Subgroups</th>
<th>Group 1 (Mean ± SD)</th>
<th>Group 2 (Mean ± SD)</th>
<th>Group 3 (Mean ± SD)</th>
<th>p1</th>
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<tr>
<td>Physical Function</td>
<td>46.2 ± 19.2</td>
<td>50.9 ± 23.8</td>
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<td>Physical Function</td>
<td>81.1 ± 12.9</td>
<td>55.0 ± 24.2</td>
<td>51.8 ± 22.4</td>
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<tr>
<td>Physical Role Difficulty</td>
<td>27.9 ± 19.2</td>
<td>26.4 ± 19.2</td>
<td>35.9 ± 20.6</td>
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<td>Physical Role Difficulty</td>
<td>84.3 ± 26.7</td>
<td>45.8 ± 44.0</td>
<td>35.0 ± 22.3</td>
<td>&lt;0.001</td>
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<td>Pain</td>
<td>38.3 ± 12.7</td>
<td>43.2 ± 19.3</td>
<td>41.1 ± 21.0</td>
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<td>Pain</td>
<td>71.0 ± 14.2</td>
<td>49.5 ± 22.3</td>
<td>44.5 ± 21.7</td>
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<tr>
<td>General Health</td>
<td>45.5 ± 18.2</td>
<td>43.6 ± 19.3</td>
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<td>General Health</td>
<td>62.8 ± 16.4</td>
<td>49.3 ± 20.8</td>
<td>49.0 ± 19.1</td>
<td>&lt;0.001</td>
<td>0.006</td>
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<td>Vitality</td>
<td>41.1 ± 17.3</td>
<td>49.2 ± 17.7</td>
<td>49.0 ± 20.4</td>
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<tr>
<td>Vitality</td>
<td>62.8 ± 15.3</td>
<td>52.5 ± 17.7</td>
<td>52.1 ± 19.5</td>
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<td>0.020</td>
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<td>Social Function</td>
<td>52.5 ± 18.9</td>
<td>61.0 ± 21.9</td>
<td>59.7 ± 26.3</td>
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<tr>
<td>Social Function</td>
<td>81.0 ± 12.3</td>
<td>61.2 ± 22.5</td>
<td>62.5 ± 22.0</td>
<td>&lt;0.001</td>
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<td>Emotional Role Difficulty</td>
<td>45.0 ± 33.2</td>
<td>49.9 ± 45.8</td>
<td>62.4 ± 42.1</td>
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<tr>
<td>Emotional Role Difficulty</td>
<td>89.5 ± 26.0</td>
<td>58.8 ± 42.6</td>
<td>67.7 ± 35.5</td>
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<tr>
<td>Mental Health</td>
<td>55.0 ± 19.0</td>
<td>58.4 ± 19.4</td>
<td>56.1 ± 20.5</td>
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<tr>
<td>Mental Health</td>
<td>70.2 ± 18.0</td>
<td>60.5 ± 20.4</td>
<td>58.5 ± 17.2</td>
<td>&lt;0.001</td>
<td>0.030</td>
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</table>

p1: comparison within the group (pretreatment vs posttreatment) Wilcoxon test
p2: comparison between groups (group 1,2,3) The Tukey post hoc multiple comparisons test
p value of <0.05 was considered statistically significant and significant values are shown as bold.
SF-36: Short Form 36
Finally, as regards overall progress, groups 1 and 2 had significant improvements from baseline to follow-up in self-reported specific functional disability scores for pain severity of LBP. However, intergroup analysis demonstrated that the greatest analgesic effect was recorded in group 1, which was a significantly better result than in group 2 and group 3.

**DISCUSSION**

The results of this study further our knowledge of the efficacy of combining IFT with the exercise in patients with chronic LBP. The results presented herein indicate a significant improvement in primary outcome measures (VAS, ODI) as well as a better recovery in SF-36 scores in favor of the additional IFT with vacuum electrodes. Currently, IFT studies on patients with LBP in the literature generally do not include control groups and no detailed randomization is performed. Moreover, the number of patients used in these studies is very low.12

The randomization, sample size, protocol, and clearly-defined intervention period of the present study has robust experimental design, different from previous studies. Our study is the first to compare different IFC electrodes in patients with LBP and to investigate the long-term effects of the treatment.

IFT is the most widely used electrotherapeutic method by physiatrists worldwide in the clinical management of LBP despite the paucity of scientific evidence for its superiority over other strategies.13-15 IFT has been shown to provide significant benefits in reducing pain and disability, albeit the effects were only maintained for a short period.16 Interferential current, which is more effective than placebo when combined with other therapies in reducing pain, afforded the same results.3 In our study, there were short and long-term improvements in pain, disability, and QoL scores the IFT group with vacuum electrodes.

To investigate TENS in patients with nonspecific chronic LBP, Facci et al. conducted a randomized clinical trial and compared its effects with those of IFC treatment.17 The authors demonstrated that the TENS and IFC therapy provided significant reductions in pain intensity and disability compared with a control group. However, there was no difference between TENS and IFC regarding chronic LBP treatment. Similarly, Lara-Palomo et al. demonstrated that IFC was more effective than superficial massage.16

In a randomized clinical trial, Hurley et al. investigated the difference in effectiveness of manipulative therapy and IFT for patients with LBP when used as sole treatments and in combination. The results from their study showed that there was no difference between the effects of combined manipulative therapy and IFT and either manipulative therapy or IFC therapy alone.18

Vacuum electrodes have never been used in previous IFT trials. We think that the treatment of IFT with vacuum electrodes, which we practice, produces neurophysiologic responses of cutaneous mechanoreceptors, mild vasodilatation, and circulation enhancement. This treatment may reduce edema, pain, and obtain muscle contraction. As a result, it has positive effects on pain, disability, and QoL.

Werners et al. compared the outcome of IFT and management using motorized lumbar traction and massage. This study showed a progressive reduction in ODI and VAS scores in patients with LBP treated with both methods.19 Rajfur et al. assessed the effects of treating LBP using selected electrical therapies (TENS, IFC, diadynamic current, high-voltage electrical stimulation). The results showed that electrical stimulation with IFC penetrated deeper into the tissues resulting in a significant reduction in pain, and an improvement of functional ability in patients with LBP.5

A number of hypoalgesic mechanisms have been attributed to IFT: stimulation of pain ‘gating’ and opioid mechanisms, stimulation of the reticular formation, and elimination of nociceptive substances.5 Prolonged afferent nociceptive impulses may lead to increased excitability of the central sensory neurons and changes in their plasticity, which leads to hypersensitivity resulting in an exaggerated response to pain; therefore, central sensitization reduction should be targeted for the treatment of pa-
tients with chronic low back pain. IFT reduces pain by stimulating thick nerve fibres. Improved circulation and muscle relaxation also reduces pain. TENS and manual therapy used in experimental models suggest that these treatments could reduce the central sensitization in animals and desensitize the central nervous system in humans.1

A primary objective of patients is to improve their level of functional disability. Despite the significantly better reduction in ODI scores in the IFT with vacuum electrode group compared with the other groups, it must be acknowledged that this group had slightly higher baseline ODI values, meaning greater functional disability, and accordingly having greater potential for change. This might account for the significant finding, at least in part.

There is evidence to support exercise therapy for patients with subacute and chronic LBP. Exercise therapy can be performed as self-care exercise performed by the patient or as supervised exercise. Supervised exercise therapy is recommended by clinical practice guidelines as an effective intervention for patients with chronic LBP. The results of our study showed that in the control group, there was a decrease in VAS and ODI scores, but these were not statistically significant. In addition, there was no statistically significant improvement of SF-36 subgroups scores in the first week and third month. These results may be due to the absence of supervised exercises or an inability to exercise properly due to pain.

LIMITATIONS
This study did not have a real control group where patients received no treatment because it was considered to be unethical to use a placebo group. This is a limitation of the study. Another limitation is that it was impossible to completely blind the patient’s due to the nature of the intervention.

CONCLUSION
These results provide the first evidence that IFT electrode affected LBP, specifically functional disability at 3-month follow-up. Treatment using IFT with vacuum electrodes and exercise in combination resulted significant reductions in VAS, ODI and SF-36 scores, superior to management with exercise alone or in combination with IFT with carbon silicon pad electrodes.

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