ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

DOI:10.31609/jpmrs.2019-71464

The Effectiveness of Combined Transcutaneous Electrical Nerve Stimulation and Interferential Current Therapy on Chronic Low Back Pain: A Randomized, Double-Blind, Sham-Controlled Study

Transkutanöz Elektrik Sinir Stimülasyonu ve İnterferansiyel Akımın Kombine Tedavisinin Kronik Bel Ağrısına Etkisi: Randomize, Çift Kör, Sham Kontrollü Çalışma

Sibel KİBAR[a], Hatice Ecem KONAK[a], Saime AY[a], Beyza DOĞANAY ERDOĞAN[c], Deniz EVCİK[b]

[a]Ufuk University Faculty of Medicine, Department of Physical Medicine and Rehabilitation, Ankara, TURKEY
[b]Ankara University Haymana Vocational Faculty, Department of Physical Therapy and Rehabilitation, Ankara, TURKEY
[c]Ankara University Graduate Faculty of Health Sciences, Department of Statistics, Ankara, TURKEY

ABSTRACT Objective: There are some electrotherapy studies regarding transcutaneous electrical nerve stimulation (TENS) and interferential current therapy (IFT), but none have examined their synergistic effects. This investigation was performed to assess the effectiveness of TENS/IFT in relieving chronic low back pain (LBP). **Material and Methods:** In this double-blind, placebo-controlled study, a total of 123 patients were divided into four groups using a computer method. Group 1 received TENS, Group 2 IFT, Group 3 combined TENS/IFT, and Group 4 sham TENS/IFT five times a week for 3 weeks. All participants also received hotpack therapy. Lumbar range of motion (ROM) was assessed via an inclinometer and the modified Schober test, and pain during activity was evaluated using a Visual Analog Scale (VAS) along with patient and physician global assessments. The Rolland-Morris Disability Questionnaire (RMDQ) was administered to determine functional capacity. **Results:** Groups 1, 2, and 3 showed significant improvement, but Group 4 showed none ($p<0.001$). Group 3 was superior to Group 2 with regard to the RMDQ, VAS, and global assessments ($p<0.001$). **Conclusion:** Combined TENS/IFT was more effective than IFT in improving functional level and decreasing pain during activity in patients with chronic LBP, however it was not superior to TENS therapy alone. The findings of this study offer insight that can be applied to future investigations concerning combined TENS/IFT therapy with different application frequencies and modes or other combined therapies. We observed marked improvement in function and pain during activity with the combination of both therapies; however, improvement was not significantly greater to that achieved with TENS therapy alone. Combined therapy was also superior to the other treatments with respect to doctor and patient global assessments, but this was not significantly different compared with that in the TENS and IFT alone groups. No improvements were found in the control (sham) group.

Keywords: Transcutaneous electrical nerve stimulation (TENS); interferential current; low back pain

ÖZET Amaç: Transkütanöz elektriksel sinir stimülasyonu (TENS) ve interferansiyel akım (IF) ile ilgili birçok elektroterapi çalışmalar bulunmaktadır, fakat bunların hiçbiri sinerjistik etkilerini incelememiştir. Bu araştırmada, TENS ve IF'nin kronik bel ağrısını azaltmadaki etkinliğini değerlendirmek amaçlandı. **Gereç ve Yöntemler:** Bu çift kör, plasebo kontrollü çalışmada toplam 123 hasta bilgisayar yöntemi kullanılarak dört gruba ayrıldı. Grup 1 TENS, Grup 2 IF, Grup 3 kombine TENS ve IFT ve Grup 4 sham olarak haftada beş kez 3 hafta boyunca tedavi aldılar. Tüm katılımcılar ayrıca sıcak paket tedavisi aldılar. Lomber hareket aralığı (EHA) inklinometre ve modifiye Schober testi ile değerlendirildi. Aktivite sırasındaki ağrı ise hasta ve doktorun global görsel analog skalası (VAS) birlikte kullanılarak değerlendirildi. Fonksiyonel kapasiteyi belirlemek için Rolland-Morris Engellilik Anketi (RMEA) uygulandı.**Bulgular:** Grup 1, 2 ve 3 anlamlı düzelme gösterirken, Grup 4'te hiçbir düzelme gözlenmedi ($p<0,001$). Grup 3 için değerlendirilen RMEA, hasta ve doktor global ağrı skorları Grup 2'den daha üstündü ($p<0,001$). **Sonuç:** Kombine TENS ve IF tedavisi, kronik bel ağrılı hastalarda fonksiyonel seviyeyi arttırmada ve aktivite sırasındaki ağrıyı azaltmada IF'den daha etkiliydi, ancak sadece TENS tedavisinden daha üstün bulunmadı. Bu çalışma bize, farklı uygulama sıklıkları ve modları ile uygulanacak olan kombine TENS / IF tedavisi veya diğer kombine tedavilerle ilgili gelecekteki araştırmalara bir öngörü sunabilmektedir.

Anahtar Kelimeler: Transkutanöz elektrik sinir stimulasyonu (TENS); interferansiyel akım; bel ağrısı

Correspondence: Hatice Ecem KONAK
Ufuk University Faculty of Medicine, Department of Physical Medicine and Rehabilitation, Ankara, TURKEY/TÜRKİYE
E-mail: ecemyildiz711@hotmail.com

Peer review under responsibility of Journal of Physical Medicine and Rehabilitation Science.

Received: 17 Sep .2019 ***Received in revised form:*** 22 Nov 2019 ***Accepted:*** 09 Dec 2019 ***Available online:*** 19 Dec 2019

1307-7384 / Copyright © 2020 Turkey Association of Physical Medicine and Rehabilitation Specialist Physicians. Production and hosting by Türkiye Klinikleri.

Low back pain (LBP) is a common musculoskeletal problem that is a major contributor to the global healthcare burden as it is among the main causes of disability.[1,2]

Treatment options differ for acute and chronic LBP.[3] In recent years, multidisciplinary biopsychosocial rehabilitation programs have been suggested for chronic LBP.[4] These programs can include physical, psychological, and/or occupational therapy.[5] Electrotherapy in the form of transcutaneous electrical nerve stimulation (TENS) and interferential current therapy (IFT) plays a vital role in physical therapy programs for chronic LBP patients, with TENS being the most recommended mode.[6]

TENS has been used in pain management for four decades. A few hypotheses have been advanced to explain the effectiveness of this modality.[7] The gate-control theory suggests that TENS may prevent pain pathways in the spinal cord dorsal horn from working.[8] Additionally, it is thought that stimulating the nervous system via transcutaneous electrodes modifies pain perception and induces release of endogenous analgesic substances such as endorphins.[8,9]

IFT also affects the tissues through the gate-control theory, but it works by clearing pain-inducing chemicals from the affected area via increased blood flow.[10,11] In IFT, two medium-frequency alternating ("carrier") currents are crossed at a slightly different frequency so that they interfere with each another, producing an amplitude-modulated, low-frequency ("resultant") current that is used to minimize skin impedance. The two frequencies are simultaneously applied to the body and combine to generate a low-frequency "beating" effect that occurs in deeper areas.[10]

Though some randomized controlled trials have assessed electrotherapy for LBP, there is still no strong consensus regarding the most efficient treatment method for chronic LBP. Although the choice of treatment is usually based on anecdotal evidence, only a few qualified studies have examined the effect of IFT and TENS on LBP.[12-14] A limited number of studies have reported that TENS is effective for this condition, but others disagree.[7,15,16] The reality is that there is limited, inconsistent evidence to support the use of TENS as an isolated intervention to manage chronic LBP.[14] A recent meta-analysis by Fuentes et al. found that IFT alone was not superior to other treatment methods or placebo, and they suggested that it could be used in conjunction with other therapies or as a supportive therapy.[13] The present study was performed to examine the combined application of TENS and IFT in chronic LBP.

MATERIAL AND METHODS

Participants AND STUDY DESIGN

This randomized, double-blind, placebo-controlled study enrolled individuals from a pool of 826 patients between the ages of 18 and 70 with LBP who were admitted to the Physical Medicine and Rehabilitation outpatient clinic between 2011 and 2013. We included the patients with LBP localized between the inferior gluteal fold and costal margin that persisted for at least 3 months who had at least one visual analog scale (VAS) pain score ≥4 at rest, at night, or during physical activity. Having radicular pain was not an exclusion criterion; these patients were included if they had normal electroneuromyography findings. The patients with electroneuromyography findings of abnormal spontaneous activities in paraspinal muscles and related lower limb muscles at rest were excluded.

Patients with a neurological deficiency due to any low back pathology; acute radicular symptoms; spondylolisthesis of grade 2 or more; spondylolysis on radiographic evaluations; vertebral compression fractures that developed in the previous 3 months; a history of interventional injections or physical therapy to the lower back region in the previous 6 months; a history of low back surgery; and those with implanted cardiac pacemakers, defibrillators, or other electronic devices were excluded from the study. So were patients with rheumatic disorders (e.g., rheumatoid arthritis, sacroiliitis, or spondyloarthropathy), a history of malignancy, acute infections, or neurological disorders. Additionally, patients who were pregnant or suspected of being pregnant and those with a cognitive deficit that would prevent their evaluation were not included. Since sham electrotherapy was part of the study design, patients who had a history of previous physical therapy were excluded.

We originally enrolled 134 patients, but 11 dropped out (1 with a skin reaction, 3 with other medical issues, 1 with increasing pain, and 6 who voluntarily quit due to personal reasons). A total of 123 patients (mean age=59.00, range 23-70) completed the study. A researcher who was blinded to the treatment procedures used a computer to randomly assign subjects to the following four groups using the patient record numbers: Group 1, TENS and hotpack (n =34); Group 2, IF current and hotpack (n=33); Group 3, TENS+ IF current and hotpack (n=33); and Group 4, placebo TENS+IF current and hotpack (n=34).

Baseline and final evaluations were made by two other independent researchers who were blinded to the treatment groups. The allocation and randomization processes are shown in Figure 1.

For pain relief, the patients were only allowed to use acetaminophen (500 mg, maximum three times daily). All participants received instructions regarding the exercises at treatment initiation and were also given a detailed information sheet. This study was conducted according to the Declaration of Helsinki and was approved by the Ufuk University Faculty of Medicine Research Ethics Committee. We also obtained each patient's written informed consent for their participation.

TREATMENT PROCEDURES

All patients received physical therapy five times a week for three weeks under the supervision of the same physiotherapist. The TENS and IFT were applied using the Intelect® Legend Stimulator (DJO, LLC, Vista, CA, USA) for 30 minutes.

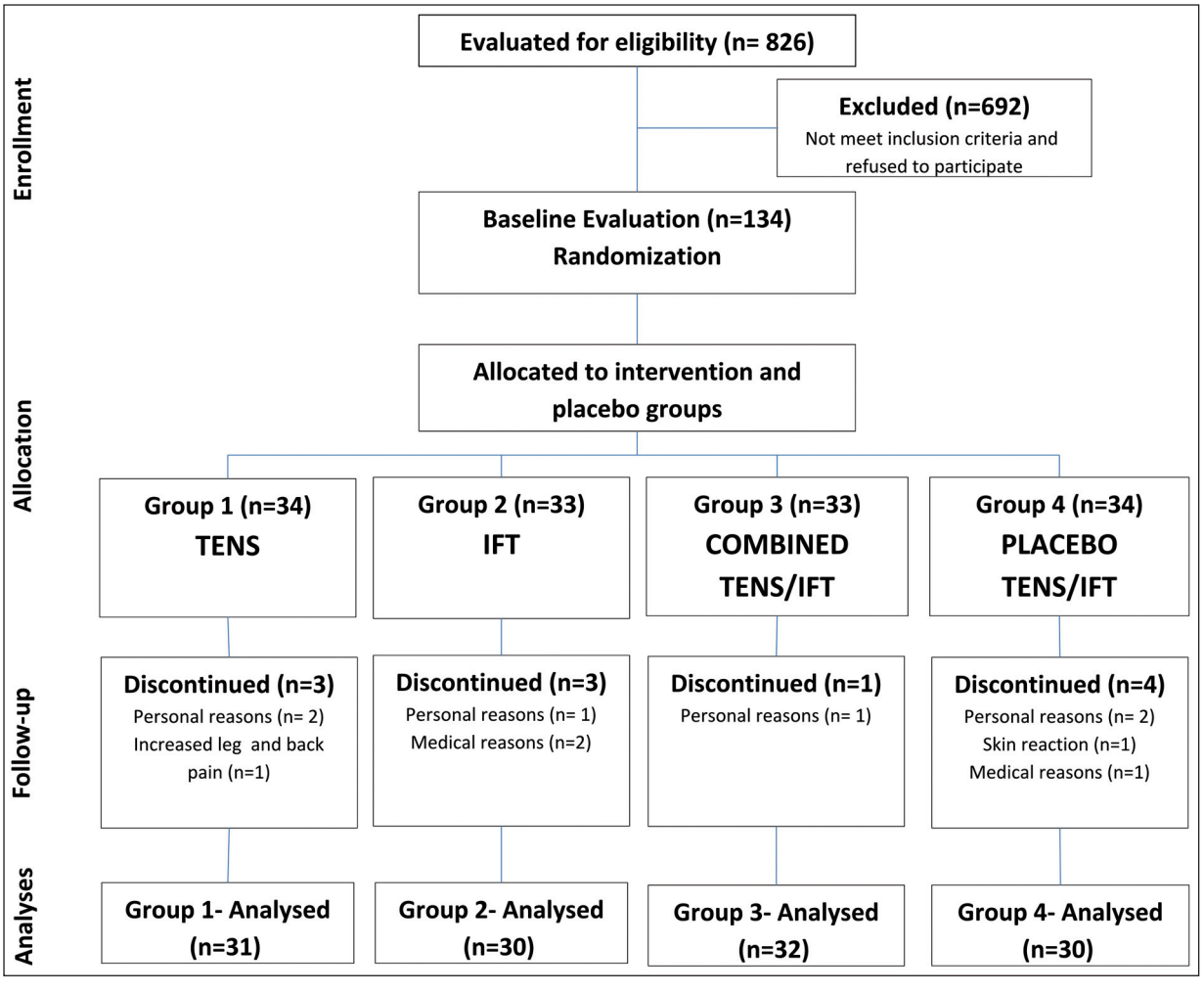


FIGURE 1: Flow of participants (allocation and randomization process).

A total of four self-adhesive surface electrodes (5×5 cm) were placed over the lumbar area: two at the lumbar 1 paravertebral level and two at the sacral 2 paravertebral level. The TENS and IFT intensities were progressively increased until there was a painless tingling sensation; if this was not felt, the intensity was elevated up to a maximum of 30 mA.

Group 1 received a combination of conventional (continuous stimulation) and burst mode TENS for 30 minutes. The conventional mode was set at a frequency of 100 Hz with a wave duration of 50-100 μs and an amplitude within 0-60 mA, which caused painless paresthesia in the lower back. The burst mode (discontinuous stimulation) was applied at a low frequency of 2 Hz every 3 seconds with a wave duration of 100-400 μs, which caused weak muscle twitches in the lower back. In each of the 3 weekly sessions, the patients received treatment in the following order: conventional, burst, and conventional.

In Group 2, true IFT with a four-electrode arrangement therapy included a rectangular alternating waveform with carrier frequencies of 4000 and 4100 Hz for 30 minutes. The beat frequency was set to 100 Hz.

Thirty minutes of TENS followed by 30 minutes of IFT was applied to Group 3 as described above. Patients in Group 4 received placebo therapy, and the electrotherapy device appeared to be working with lights on without current transfer during the 30-minute sessions. All patients also received hotpack application over the lower back region for 20 minutes.

Before beginning the therapy program, the physiotherapist told patients that the exercises should be performed for 20 minutes a day for at least 5 days a week. Instruction was provided regarding the pelvic tilt exercise, hamstring stretching, and quadruped cat and camel exercises. The exercise program was initiated at the end of the first week, and the patients were educated concerning improper behaviors that could increase LBP.

MEASUREMENTS

We recorded the patients' sociodemographic information (i.e., age, sex, employment status, body mass index [body weight in kg^2/height in cm], and related variables).

The VAS was used to evaluate pain intensity at rest, during movement, and at night, with scores ranging from 0 (absence of pain) to 100 mm (severe pain). The VAS was also employed for patient and physician global assessments.

Patient functional status was measured by the self-administered Rolland-Morris Disability Questionnaire (RMDQ). The test-retest reliability, validity, and responsiveness of this instrument have been shown to be sufficient.[17] The RMDQ was designed to determine the physical disability of the patients with LBP and includes 24 questions (score of 1 for "yes" and 0 for "no"). Total scores of 0 and 24 indicate no disability and severe disability, respectively.

Lumbar range of motion (ROM) was evaluated with an inclinometer (Baseline Digital Inclinometer, EN-121057, Baseline Products, USA). This technique is highly reliable and valid.[18] In the neutral position, the patients stood in comfortably with their hands hanging toward the ground in a relaxed manner, and the inclinometer was placed over the T12-L1 spinous processes. The patients then performed maximum flexion followed by maximum extension with their knees straight, especially at the end of the movement. The inclinometer was zeroed, and the lumbar spine movements were taken directly from the inclinometer scale at the extremes of flexion and extension.[18]

The modified Schober test (MST) was also used to evaluate lumbar flexion. First, the lumbosacral junction was established by determining the exact locations of the dimples of Venus, and the intersection at the top of these indentations was marked with a horizontal line to serve as a landmark. Lines were then drawn 10 cm above and 5 cm below this landmark, and the difference between the measurements in the erect and flexion positions was measured to the nearest millimeter. A measurement difference between erect and flexion positions <5 cm indicated modified system impairments (MSI).[19]

SAMPLE SIZE

A sample size of 9 for each group was required to reach 80% power with α level of 0.05 to detect a 2 (±10) unit difference of VAS scores between and

within groups and also interaction in a 4-group and 2-wave repeated measures design. This 2-unit difference with ±10 standard deviation (SD) corresponds to an effect size (an index of the size of the mean effect values relative to the SD) of 0.2, which is considered small by Cohen.[20]

STATISTICAL ANALYSIS

The Shapiro-Wilks test was used to test whether the data was normally distributed. Non-parametric tests were also performed because of the ordinal nature of the data or skewed distributions. Continuous data are summarized using mean±SD (standard deviation) and median (minimum-maximum), whereas frequencies and percentages are used for categorical data. Kruskal-Wallis, chi-square, and Fisher's exact tests were used to compare demographic characteristics in the four groups. To compare the pre- and post-treatment measurements, the robust, rank-based, non-parametric method were used to analyze the longitudinal data in factorial settings.[21] With this method, relative treatment effects (RTEs) are given as descriptive point estimators, and the 95% confidence intervals (CIs) of RTEs were used to make post hoc inferences. If the related 95% CIs did not overlap, we concluded that there were significant differences between the pre- and post-treatment measurements or the groups themselves. In addition, an F1_LD_F1 design was used to analyze the repeated measurements of four groups. All analyses were performed in R version 3.0.1 (R Development Core Team), and the nonparametric longitudinal data (nparLD)_library was used for the non-parametric repeated F1_LD_F1 design.[22,23] *P* values <0.05 were considered statistically significant.

RESULTS

The patients, sociodemographic characteristics are listed in Table 1. The only statistically significant difference was the working status of patients in TENS therapy group (p=0.006).

Pre-treatment clinical measurements were com-

TABLE 1: Demographic characteristics of the patients.

		TENS (n=31)	IFT (n=30)	TENS/IFT (n=32)	CONTROL (n=30)	p
Age		53.64±13.7 57(23-69)	59±7.9 60(35-70)	53.5±13.7 59.5(23-68)	53.7±11.59 56(31-68)	0.404¥
BMI	<18.5	4(6.5%)	0(0.0%)	2(3.1%)	0(0.0%)	0.065ŧ
	18.5-24.9	24(38.7%)	14(23.3%)	20(31.2%)	22(36.7%)	
	>=25	34(54.8%)	46(76.7%)	42(65.6%)	38(63.3%)	
Gender	Female	21(67.7%)	20(66.7%)	23(71.9%)	23(76.7%)	0.824£
	Male	10(32.3%)	10(33.3%)	9(28.1%)	7(23.3%)	
Education	Illiterate	0(0.0%)	2(6.7%)	1(3.1%)	0(0.0%)	0.229ŧ
	Primary	4(12.9%)	10(33.3%)	5(15.6%)	2(6.7%)	
	Secondary	7(22.6%)	5(16.7%)	3(9.4%)	7(23.3%)	
	High school	12(38.7%)	9(30.0%)	14(43.8%)	14(46.7%)	
	Graduate	8(25.8%)	4(13.3%)	9(28.1%)	7(23.3%)	
Working status	Not working	15(48.4%)	15(50.0%)	13(40.6%)	208(66.7%)	0.006£
	Working	13(41.9%)	6(20.0%)	5(15.6%)	7(23.3%)	
	Retired	3(9.7%)	9(30.0%)	14(43.8%)	3(10.0%)	

Mean±standard deviation and median (minimum-maximum) were given for continuous variables; frequencies and percentages were given for categorical variables.
p values were based on ¥: Kruskal Walls test ; £: Chi- Square test; ŧ: Fisher's exact test; BMI: Body Mass Index.

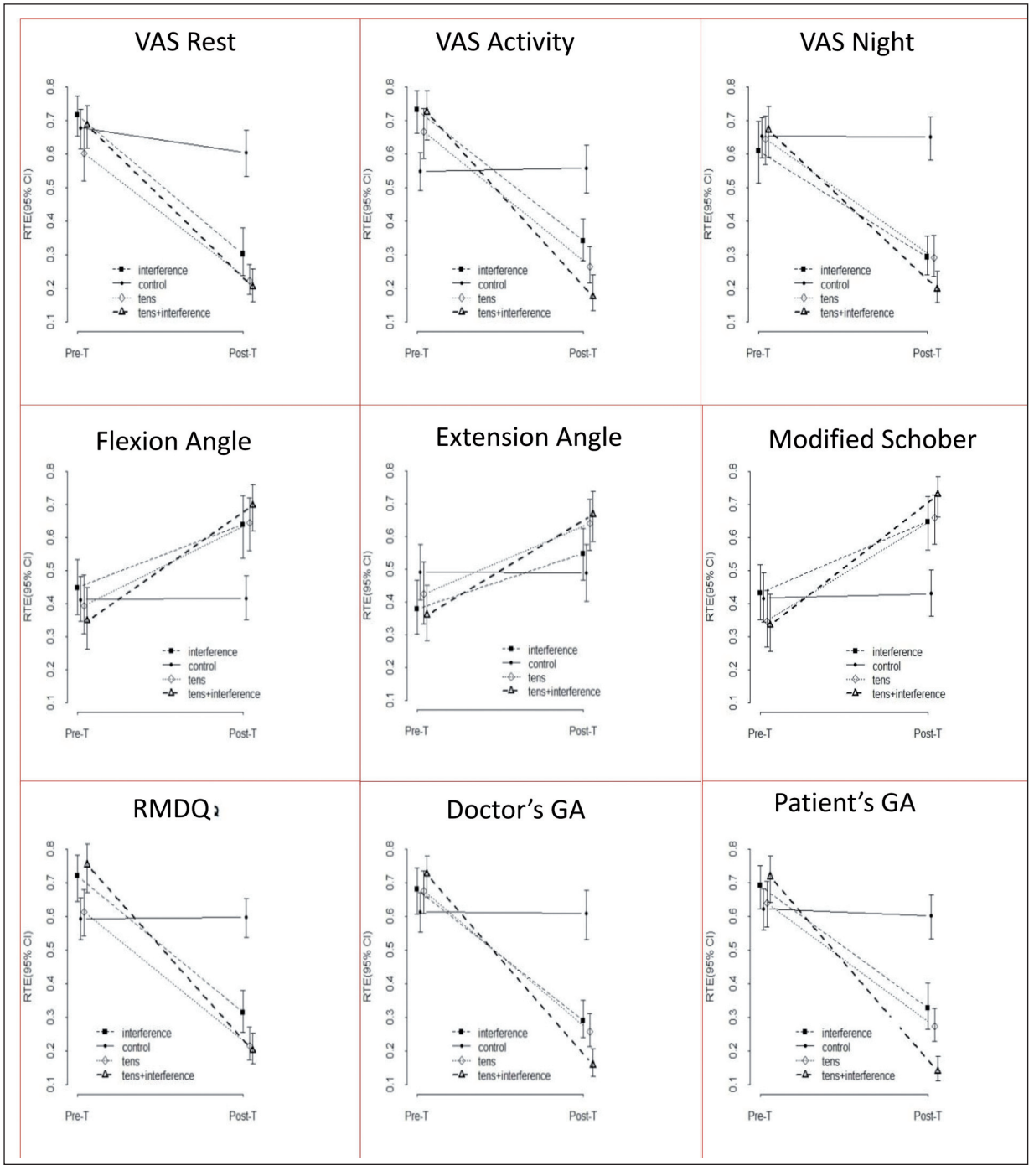


FIGURE 2: The overlaps of the baseline and post-treatment relative treatment effect scores.

RTE (95% CI) lines are shown in the graphic. Pre-treatment lines overlapped for VAS (rest) and VAS (night) but not VAS (activity). The RTE score of Group 4 was smaller than those of Groups 2 and 3, with no overlapping for pre-treatment RTE scores. Pre-treatment lines overlapped for all other parameters (ROM, RMDQ, global assessments).

VAS: Visual analog scale; RMDQ: Rolland Morris Disability Questionnaire; GA: Global Assesment; Pre-T: Pretreatment; Post- T: Posttreatment; RTE: Relative treatment effect.

pared in all four groups, and the 95% CIs of the RTEs of those variables overlapped (Figure 2). The only significant difference was in VAS activity scores between Group 4 (6.33±1.21, RTE 95% CI=0.55 [0.49-0.60]), Group 2 (7.533±1.306, RTE 95% CI=0.732 [0.662-0.788]), and Group 3 (7.40±1.86, RTE 95%

TABLE 2: Pre-treatment and post-treatment scores for four groups.

		TENS		IFT		TENS/IFT		Control		p
		Median (min-max)	RTE (CI 95%)	Median (min-max)	RTE (CI 95%)	Median (min-max)	RTE (CI 95%)	Median (min-max)	RTE (CI 95%)	
Flexion	Pre-treatment	68 (40-90)	0.4 (0.3-0.5)	69 (35-90)	0.4 (0.3-0.5)	66 (35-90)	0.3 (0.3-0.4)	68.5 (60-77)	0.4 (0.3-0.4)	
	Post-treatment	73 (60-90)	0.6 (0.5-0.7)	73.5 (50-90)	0.6 (0.5-0.7)	75 (66-90)	0.7 (0.6-0.7)	68.5 (60-77)	0.4 (0.3-0.4)	0.001*
Extension	Pre-treatment	19 (10-30)	0.4 (0.3-0.5)	19(10-24)	0.4 (0.3-0.4)	18(0-40)	0.3 (0.2-0.4)	18.5 (10-30)	0.4 (0.4-0.5)	
	Post-treatment	20 (10-30)	0.6 (0.5-0.7)	20(14-27)	0.5 (0.4-0.6)	20.5(15-40)	0.6 (0.5-0.7)	19 (10-30)	0.5 (0.4-0.5)	0.001*
Modified Schober	Pre-treatment	17.5(15-19.5)	0.3 (0.2-0.4)	19(15-22)	0.4 (0.3-0.5)	17(15-24)	0.3 (0.2-0.4)	19 (16-22)	0.4 (0.3-0.5)	
	Post-treatment	21(16-23)	0.6 (0.5-0.7)	20.5(15-23)	0.6 (0.5-0.7)	21(18.5-24.5)	0.7 (0.6-0.7)	19 (16-22)	0.4 (0.3-0.5)	0.001*
VAS activity	Pre-treatment	7(4-9)	0.6(0.6-0.7)	8 (5-10)	0.7 (0.6-0.8)	8(0-10)	0.7 (0.6-0.7)	6 (4-9)	0.5 (0.4-0.6)	
	Post-treatment	4(0-7)	0.3 (0.2-0.3)	5 (1-7)	0.3 (0.3-0.4)	3(0-8)	0.1 (0.1-0.2)	6 (3-9)	0.5 (0.4-0.6)	0.001*
VAS rest	Pre-treatment	6 (0-8)	0.6 (0.5-0.6)	6 (4-9)	0.7 (0.6-0.7)	6 (3-8)	0.6 (0.6-0.7)	6 (4-9)	0.6 (0.6-0.7)	
	Post-treatment	2(0-5)	0.2 (0.2-0.3)	3 (0-7)	0.3 (0.2-0.4)	2 (0-6)	0.2 (0.1-0.2)	5 (0-8)	0.6 (0.5-0.6)	0.001*
VAS night	Pre-treatment	5 (0-8)	0.6 (0.5-0.7)	5 (0-8)	0.6 (0.5-0.6)	5 (0-9)	0.6 (0.6-0.7)	5 (0-8)	0.6 (0.5-0.7)	
	Post-treatment	2 (0-6)	0.3 (0.2-0.3)	3 (0-6)	0.3 (0.2-0.3)	2 (0-5)	0.2 (0.1-0.2)	5(0-8)	0.6 (0.5-0.7)	0.001*
RMDQ	Pre-treatment	12(5-23)	0.6 (0.5-0.7)	14(6-19)	0.7 (0.6-0.7)	14.5(4-21)	0.7 (0.6-0.8)	11(5-17)	0.6 (0.5-0.6)	
	Post-treatment	6 (0-12)	0.2 (0.2-0.3)	8(0-13)	0.3 (0.2-0.3)	5(0-10)	0.2 (0.2-0.2)	12(5-17)	0.5 (0.5-0.6)	0.001*
Patient GA	Pre-treatment	6(3-8)	0.6 (0.5-0.7)	6(3-9)	0.7 (0.6-0.7)	6(3-10)	0.7 (0.6-0.7)	5(3-8)	0.6 (0.5-0.6)	
	Post-treatment	3 (0-5)	0.6 (0.5 -0.7)	3(1-7)	0.3 (0.2-0.4)	280-5)	0.1 (0.1-0.2)	5(1-8)	0.6 (0.5-0.6)	0.001*
Physician GA	Pre-treatment	5(3-8)	0.6 (0.5-0.6)	5(1-8)	0.7 (0.6-0.7)	5(3-10)	0.7 (0.6-0.7)	5(2-8)	0.6 (0.5-0.6)	
	Post-treatment	5(1-8)	0.6 (0.5-0.6)	2(1-5)	0.3 (0.2-0.3)	1.5(0-5)	0.2 (0.1-0.2)	5(1-8)	0.6 (0.5-0.6)	0.001*

Abbreviaations: VAS: Visual analog scale, GA: Global assesment, RMDQ: Rolland Morris Disability Questionnaire.

CI=0.72 [0.64-0.78]). The whole RTE (95% CI) scores of the groups are shown in Table 2.

There were marked improvements in most functional parameters before and after treatment in Groups 1, 2, and 3 (Figure 2). We observed statistically significant improvements in Groups 1, 2 and 3 in all parameters except lumbar extension ($p<0.001$). No significant improvement was measured in the control group (Group 4) compared to baseline (Figure 2).

The only statistically significant change in post-treatment VAS RTE scores was between Group 2 (IFT) and Group 3 (TENS/IFT), demonstrating that combined TENS/IFT therapy is superior to IFT alone with regard to VAS activity. Additionally TENS therapy was not different from IFT and combined TENS/IFT in terms of any VAS score (Figure 2).

All post-treatment RTE scores overlapped with regard to lumbar ROM assessments (flexion, extension and MST) between Groups 1, 2, and 3. Thus, there was no statistically significant difference in ROM between the three treatment groups.

The improvement in RMDQ in the combined therapy group was statistically larger than for IFT alone group, but it was not larger than that in the TENS group. There was no difference between the TENS and IFT therapy groups (Figure 2).

Patient and doctor global assessments improved significantly for Group 3 compared with Groups 1 and 2, but the differences were not statistically significant. The pre- and post-treatment RTE scores are shown in Figure 2 and Table 2.

DISCUSSION

This study aimed to compare the effectiveness of

combined TENS/IFT therapy with TENS or IFT alone in patients with chronic LBP. We observed marked improvement in function and pain during activity with the combination of both therapies; however, improvement was not significantly greater to that achieved with TENS therapy alone. Combined therapy was also superior to the other treatments with respect to doctor and patient global assessments, but this was not significantly different compared with that in the TENS and IFT alone groups. No improvements were found in the control (sham) group.

Moore et al. administered sequential TENS and neuromuscular electrical stimulation (NMES) to 24 patients with chronic LBP and observed significant improvement in pain relief compared with placebo.[6]

Our findings suggest a relationship between decreased pain during activity and improved function. This was also shown in a previous study that investigated the effect of TENS and percutaneous neuromodulation therapy on chronic LBP.[24] They also demonstrated the superiority of TENS compared with placebo electrotherapy but reported no prominent difference between high and low frequencies for conventional TENS. A few other studies have been carried out comparing TENS and placebo electrotherapy, and some found that TENS was more effective, while others did not. Additionally, a recent review reported that there have only been two qualified studies regarding the effect of TENS on chronic LBP.[7,14-16,23] These data are inadequate, and additional studies with larger number of patients are needed.[14]

A recent meta-analysis suggested that IFT therapy alone could be used as a supplemental therapy in conjunction with other treatments.[13] A few qualified studies have been conducted that compared IFT with placebo electrotherapy, but to our knowledge, this comparison has not been made in patients with chronic LBP.[25,26] We investigated the effect of IFT alone and in combination with TENS and also compared with placebo electrotherapy. Although we observed significant improvement in the patients who received IFT (Group 2) compared with sham treatment (Group 4), the combination of TENS and IFT was more effective in terms of functional level, pain activity, and patient and doctor global assessments. Another randomized controlled study reported that combined IFT/NMES therapy was more effective than TENS therapy alone on functional level and pain in patients with knee osteoarthritis.[27] Facci et al. compared TENS and IFT therapy in patients with chronic LBP and found no significant differences between the two groups regarding functional level and pain; however, the lack of placebo treatment was a serious limitation of that investigation.[28] In our study, we did not find significant differences between the TENS alone and IFT alone groups.

We prefer the use of the four-electrode arrangement (true IFT) so that the device has a more potent effect on the center of the lumbar region. Employing this arrangement with TENS provided a powerful analgesic via an electrical current on the paravertebral region of the lower back. It was therefore possible to obtain effective painless regional control via a combination of TENS and IFT, but we failed to show the superiority over TENS therapy alone in most of the parameters except doctor and patient global assessments.

We found significant improvements in lumbar ROM and pain in all groups except the control group. Combined TENS/IFT achieved greater improvement for pain during activity and lumbar extension. It is possible that a 3-week treatment period was too short to improve other lumbar ROM measurements and pain during rest and at night.

This study has some limitations. As previously mentioned, global assessment scores significantly improved in the combination therapy group, but these patients received longer therapy sessions because there were two electrotherapy applications. We hypothesize that sequential application of different electrical currents can increase patient satisfaction and trust regarding therapy programs, but we have no objective support for this. On the other hand, better results may be achieved by using different electrode applications and/or frequencies, along with longer treatment durations. This study has a statistical method limitation in that we did not perform an intention-to-treat analysis since it can introduce bias due to selective data loss.

The major limitation of this study was that we only performed evaluations before and after 3 weeks of therapy. Since there was no prospective evaluation after the end of the study period, we were not able to determine whether treatment effects persisted. Therefore, prospective studies of combined electrotherapy methods with longer follow-up periods should be conducted.

CONCLUSION

Combined TENS/IFT therapy is effective in patients with chronic LBP. It seems to be superior to IFT therapy alone with regard to improving function and reducing pain during activity. It is our hope that the findings of this study can offer insight for future investigations concerning combined TENS/IFT therapy with different application frequencies and modes or other combination therapies.

REFERENCES

1. Vos T, Flaxman AD, Naghavi M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012;380:2163-96. [PubMed]
2. Buchbinder R, Blyth FM, March LM, et al. Placing the global burden of low back pain in context. Best Pract Res Clin Rheumatol. 2013;27:575-89. [Crossref] [PubMed]
3. Chou R, Huffman LH. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Ann Intern Med. 2007;147:492-504. [Crossref] [PubMed]
4. Kamper SJ, Apeldoorn AT, Chiarotto A, et al. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain. Cochrane Database Syst Rev. 2014;9:CD000963. [Crossref] [PubMed]
5. Guzmán J, Esmail R, Karjalainen K, et al. Multidisciplinary rehabilitation for chronic low back pain: systematic review. BMJ. 2001;322:1511-6. [Crossref] [PubMed] [PMC]
6. Moore SR, Shurman J. Combined neuromuscular electrical stimulation and transcutaneous electrical nerve stimulation for treatment of chronic back pain: a double-blind, repeated measures comparison. Arch Phys Med Rehabil. 1997;78:55-60. [Crossref] [PubMed]
7. Jarzem PF, Harvey EJ, Arcaro N, et al. Transcutaneous electrical nerve stimulation [TENS] for chronic low back pain. J Musculoskelet Pain. 2005;13. [Crossref]
8. Melzack R, Wall PD. Pain mechanisms: a new theory. Science. 1965;150:971-7. [Crossref] [PubMed]
9. Hughes GS Jr, Lichstein PR, Whitlock D, et al. Response of plasma beta-endorphins to transcutaneous electrical nerve stimulation in healthy subjects. Phys Ther. 1984;64:1062-6. [Crossref] [PubMed]
10. Atamaz FC, Durmaz B, Baydar M, et al. Comparison of the efficacy of transcutaneous electrical nerve stimulation, interferential currents, and shortwave diathermy in knee osteoarthritis: a double-blind, randomized, controlled, multicenter study. Arch Phys Med Rehabil. 2012;93:748-56. [Crossref] [PubMed]
11. Goats GC. Interferential current therapy. Br J Sports Med. 1990;24:87-92. [Crossref] [PubMed] [PMC]
12. Ozcan J, Ward AR, Robertson VJ. A comparison of true and premodulated interferential currents. Arch Phys Med Rehabil. 2004;85:409-15. [Crossref] [PubMed]
13. Fuentes JP, Armijo Olivo S, Magee DJ, et al. Effectiveness of interferential current therapy in the management of musculoskeletal pain: a systematic review and meta-analysis. Phys Ther. 2010;90:1219-38. [Crossref] [PubMed]
14. Khadilkar A, Odebiyi DO, Brosseau L, et al. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain. Cochrane Database Syst Rev. 2008;8:CD003008. [Crossref] [PubMed]
15. Jarzem PF, Harvey EJ, Arcaro N, et al. Transcutaneous electrical nerve stimulation [TENS] for short-term treatment of low back pain-randomized double blind crossover study of sham versus conventional TENS. J Musculoskelet Pain. 2015;13. [Crossref]
16. Deyo RA, Walsh NE, Martin DC, et al. A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. N Engl J Med. 1990;322:1627-34. [Crossref] [PubMed]
17. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. Spine (Phila Pa 1976). 1983;8:141-4. [Crossref] [PubMed]
18. Saur PM, Ensink FB, Frese K, et al. Lumbar range of motion: reliability and validity of the inclinometer technique in the clinical measurement of trunk flexibility. Spine (Phila Pa 1976). 1996;21:1332-8. [Crossref] [PubMed]
19. Moll JM, Wright V. Normal range of spinal mobility. An objective clinical study. Ann Rheum Dis. 1971;30:381-6. [Crossref] [PubMed] [PMC]
20. Brunner E, Puri ML. Nonparametric methods in factorial designs. Statistical Papers. 2001;42:1-52. [Crossref]
21. Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd ed. Hillsdale, NJ: Lawrence Earlbaum Associates; 1998. p.567.
22. The R Development Core Team. A language and environment for statistical computing. R Foundation for Statistical Computing. Vienna, Austria: 2012. [Link]
23. Noguchi K, Gel YR, Brunner E, et al. An R software package for the nonparametric analysis of longitudinal data in factorial experiments. J Stat Softw. 2012;50. [Crossref]
24. Topuz O, Özfidan E, Ozgen M, et al. Efficacy of transcutaneous electrical nerve stimulation and percutaneous neuromodulation therapy in chronic low back pain. J Back Musculoskelet Rehabil. 2004;17:127-33. [Crossref]
25. Van Der Heijden GJ, Leffers P, Wolters PJ, et al. No effect of bipolar interferential electrotherapy and pulsed ultrasound for soft tissue shoulder disorders: a randomised controlled trial. Ann Rheum Dis. 1999;58:530-40. [Crossref] [PubMed] [PMC]
26. Gundog M, Atamaz F, Kanyilmaz S, et al. Interferential current therapy in patients with knee osteoarthritis: comparison of the effectiveness of different amplitude-modulated frequencies. Am J Phys Med Rehabil. 2012;91:107-13. [Crossref] [PubMed]
27. Burch FX, Tarro JN, Greenberg JJ, et al. Evaluating the benefits of patterned stimulation in the treatment of osteoarthritis of the knee: a multi-center, randomized, single-blind, controlled study with an independent masked evaluator. Osteoarthritis Cartilage. 2008;16(8):865-72. [Crossref] [PubMed]
28. Facci LM, Nowotny JP, Tormem F, et al. Effects of transcutaneous electrical nerve stimulation (TENS) and interferential currents (IFC) in patients with nonspecific chronic low back pain: randomized clinical trial. Sao Paulo Med J. 2011;129:206-16. [Crossref] [PubMed]