# Interferential and horizontal therapies in chronic low back pain: a randomized, double blind, clinical study

A. Zambito, D. Bianchini, D. Gatti, O. Viapiana, M. Rossini, S. Adami

Rheumatologic Rehabilitation, University of Verona, Italy.

# Abstract Objectives

Chronic Low Back Pain (CLBP) is one of the most frequent medical problems. Electrical nerve stimulation is frequently used but its efficacy remains controversial.

# Methods

Twenty-six men and 94 women with CLBP associated with either degenerative disk disease or previous multiple vertebral osteoporotic fractures were randomly assigned to either interferential currents (IFT), horizontal therapy (HT) or sham HT administered for 10, 40 and 40 minutes, respectively, daily for 5 days per week for two weeks together with a standard flexion-extension stretching exercise program, Blind efficacy assessment were obtained at baseline and at week 2, 6 and 14 and included a functional questionnaire (Backill), the standard visual analog scale (VAS) and the mean analgesic consumption.

# Results

At week 2 a significant and similar improvement in both the VAS and Backill score was observed in all three groups. The Backill score continued to improve only in the two active groups with changes significantly greater than those observed in control patients at week 14. The pain VAS score returned to baseline values at week 6 and 14 in the control group while in the IFT and HT groups it continued to improve (p< 0.01 vs controls). The use of analgesic medications significantly improved at week 14 versus pretreatment assessment and over control patients only in the HT group.

# Conclusions

This randomized double-blind controlled study provides the first evidence that IFT and HT therapy are significantly effective in alleviating both pain and disability in patients with CLBP. The placebo effect is remarkable at the beginning of the treatment but it tends to vanish within a couple of weeks.

# Key words

Chronic low back pain, multiple vertebral fractures, electrical nerve stimulation, interferential currents, horizontal therapy, double-blind placebo controlled trial.

Antonino Zambito, Donatella Bianchini, Davide Gatti, Ombretta Viapiana, Maurizio Rossini, Silvano Adami

Please address correspondence and reprint requests to: Prof. Silvano Adami, Rheumatologic Unit, University of Verona Ospedale, 37054 Valeggio s/Mincio, Verona, Italy.

E-mail: silvano.adami@univr.it

Received on January 11, 2006; accepted in revised form on April 11, 2006.

© Copyright CLINICAL AND EXPERIMEN-TAL RHEUMATOLOGY 2006.

#### Introduction

Chronic low back pain (CLBP) is one of the most common medical problems in developed countries (1-3). Analgesic therapies may provide temporary pain relief but the overall results remain largely unsatisfactory and their continuous use is often associated with serious side effects (4). Nonpharmacologic alternatives include electrical nerve stimulation, (transcutaneous electrical nerve stimulation (5, 6), interferential therapy (IFT) (7, 8) or percutaneous electrical nerve stimulation (9, 10), acupuncture (11, 12), spine manipulation (13) and exercise therapy (13, 14). The efficacy of all these alternative therapies remains controversial because most of the published studies lack appropriate control groups or blinding, or failed to include relevant comparators. In the few studies with acceptable methodological quality (9, 10), Fifteen - seventeen patients were assigned to each study group, a number that is inadequate for any sub-analysis on the co-factors influencing the study outcomes. It is claimed that IFT has an advantage over other electrical currents in that its carrier frequency is associated with relatively lower skin resistance while still producing low frequency effects within the tissues (15, 16). Despite the widespread use of IFT in clinical practice (15), the findings of controlled clinical trials are still inconclusive (18-20, 21).

Horizontal therapy (HT) (22) is a novel analgesic therapy that is expected to extend the advantages of the traditional IFT. In order to evaluate its efficacy we decided to test HT therapy in two "models" of back pain: patients with CLBP associated with degenerative disk disease or due to previous multiple vertebral osteoporotic fractures where chronic back pain is mostly related to misalignment of the spine with muscle contractions. To our knowledge, this is the first double-blind, placebo-controlled, randomized study on nonpharmacologic treatment of CLBP by IFT and the first report on HT.

### Methods

The study population comprises 26 men and 94 women (mean age  $\pm$ 

standard deviation [SD]  $71 \pm 8$  years; range 50 - 86 years) (Table I). The patients were recruited from 371 consecutive patients referred to our outpatient clinic for CLBP associated with degenerative disk disease without any component of radicular pain or established osteoporosis or other identifiable disease. One hundred and forty-two did not meet the study criteria and 109 did not agree to participate in the study most often due to their inability to attend the out-patient treatment sessions. The inclusion criteria were an age older than 50 years and a history of CLBP, which had been stable for the previous 3 months, due to either severe radiographic evidence of degenerative lumbar disk disease or multiple (more than one) compression fracture of the last thoracic or of the lumbar spine (T10 to L4) detected radiologically within the previous 6 months. Exclusion criteria were any illness involving major organ systems, history of alcohol abuse, use of opioid containing medication, presence of radicular pain, inability to complete the questionnaires, the use of a cardiac pacemaker, and previous experience with any type of electric therapy.

Patients with any professional commitment were also excluded. In all patients a lateral spine X-ray was obtained immediately before treatment randomization in order to exclude new or worsening vertebral fractures that had occurred less than 6 months previously. The study protocol was approved by the local ethical committee (E.C., Asl 22, Bussolengo Verona, Italy) and informed consent was obtained from all patients prior to any enrolment procedures.

The recruited patients were first stratified according to the etiology of CLBP (degenerative disk or vertebral fractures) and then assigned to either HT, IFT or sham HT. Fifteen computer-generated randomization blocks of 3:3:2 for HT, IFT and sham HT, respectively, were used for treatment assignment. Starting on the same day as randomization, all patients began a standard flexionextension stretching exercise program (23) over 45 minutes, 5 times a week for 2 weeks.

#### Electric therapies and chronic low back pain / A. Zambito et al.

## Treatment modalities

The IFT therapy consisted of the placement of 4 medium-sized (8X6 cm) cutaneous electrodal pads ( Phyaction 787, Uniphy, Einhoven, NL) in a standard dermatomal pattern, which were stimulated for 10 minutes at a modulated frequency of 200 Hz. HT therapy consisted of the placement of 3 cutaneous electrodal pads (8 x 13 cm), one in the lumbar zone and two others in the posterior proximal site of the thighs, with a stimulation frequency oscillating at 100 Hz between 4400 and 12300 Hz for the first 20 minutes and at the fixed frequency of 4400 Hz. for a further 20 minutes (PRO ElecDT 2000, Hako med: D).

The sham HT treatment consisted of the placement of the same pads for the same time but no electrical stimulation was applied to the probes. All treatments were administered for 5 days per week for two weeks.

## Assessment procedures

Before initiating treatments, at the end of the 2 weeks of therapy and then after 4 (week 6) and 12 weeks (week 14), the patients were asked to complete the Backill questionnaire (24), an extension of the McGill Pain Questionnaire, including 27 functional questions and 4 questions qualifying the type of pain. A standard 10 cm visual analog scale (VAS) was used to assess back pain, with a score of zero equaling no pain and 10 equaling worst bearable pain.

Patients were instructed not to change the type of non-opioid analgesic medications used during the course of the study, which were represented by nimesulide (63%), paracetamol (21%) and diclofenac (15%). Analgesic consumption was categorized as less than twice a week, 3 to 6 times per week, and daily. This information was collected for the week preceding treatment and for week 14. The treatment codes were given to a single physiotherapist who administered all electric stimulation therapies. The patients were kept blind to treatment assignment, as were the two physicians who evaluated the patients and administered the questionnaires. In order to assure the best possible blindness to treatment, we excluded patients familiar with electric therapies and with what is sensed.

Power analyses (25) were conducted to determine the sample size needed to demonstrate a difference of 1 in VAS and of 5 in Backill score (in either direction) assuming a standard deviation of 1.7 and 6.5 respectively. We calculated that 35 patients would be needed in each treatment arm with a power of 80% and an alpha of 0.05.

## Data analysis

The SPSS statistical software program (version 11.0) was used for all statistical analyses. The changes in the VAS and Backill scores over time (pairwise data and between groups) were analyzed with repeated measures analysis of variance and t-test, with a Bonferroni comparison test applied for multiple comparisons. Analysis of the categorical data on analgesic consumption for the three treatment modalities was performed using  $\chi^2$  test and Odds ratio where the changes in analgesic consumption were categorized as improved or unchanged or worsened. All analyses were repeated after adjusting the values for age, gender and number of prevalent vertebral fractures by covariance analysis. An intention-totreat analysis was preplanned but not applied since all patients completed the 3 month follow-up.

### Results

The main clinical characteristics of the study population are listed in Table I.

Table I. Clinical characteristics of study population.

	Horizontal therapy	Interferential therapy	Sham Horizontal
Gender n. M/F	10/35	10/35	6/24
Age mean (SD)	70.1 (7.3)	71.1 (7.9)	72.2 (9.1)
Vertebral fractures n. 2 n. 3 n. > 3	2 6 22	2 5 23	1 5 14
Degenerative disk disease	15	15	10
VAS baseline mean (SD)	7.9 (1.7)	8.2 (1.0)	8.1 (1.6)
Backill baseline	25.5 (6.0)	24.4 (6.5)	21.6 (6.4)
Analgesic consumption/week %			
≤ 2 times	33.3	35.6	48.3
3-6 times	44.4	40.0	40.0
≥ 7 times	22.2	4.4	11.7

All patients with prevalent vertebral fractures had been on treatment with bisphosphonates for more than 12 months. The study population was made up exclusively of retired people. The pretreatment evaluation for both the Backill score and the pain VAS score (Table I.) indicates that the quality of life of this population was severely deteriorated.

All patients attended the full therapeutic program even though the adherence to the physical exercise program in terms of strength and duration of the exercises was so variable from patient to patient and even from day to day that a proper assessment could not be carried out. Figure 1 shows the percentage changes in pain and functional outcomes. At week 2, immediately after the completion of the treatment program, a significant and similar improvement in both the VAS and Backill score was observed in all three groups. The Backill score continued to improve in all groups over baseline assessment, possibly in relationship with the exercise program. However, the changes observed in the HT group were significantly greater than those observed in the sham HT group control patients at week 14 (p < 0.05).

In the sham HT group, after the initial improvement the VAS score slowly worsened and it was not significantly different from baseline at week 14. In the IFT and HT groups the VAS score continued to improve with changes significantly different from those observed in control patients.



Fig. 2. Proportion of patients in whom the use of analgesic medications decreased during the last week of observation in comparison to pre-treatment week, in the 3 groups of patients The rate of improvement observed in the HT group were significantly greater (p = 0.05) than that observed in the sham HT group.



observations but also for the larger variability of the changes.

### Discussion

The current randomized controlled trial showed an initial significant and equal improvement over baseline in all treatment groups including the sham treated patients for both functional and pain scores. This clearly emphasizes the indispensable need for a proper control group for this type of clinical trial. During the subsequent weeks the results for both outcomes tended to diverge between active and sham treated groups, although the Backill functional score continued to improve also in control patients. However, this finding may be attributed to the stretching exercise program carried out by all patients (26).

The overall analysis of the results provides evidence that regimens of both IFT and HT treatments are significantly more effective than placebo, even though over a limited lag time (12 weeks). The difference versus the control group becomes apparent and then significant only during the posttreatment follow-up, when the effects in the sham HT group are wearing off (Fig. 1).

The HT therapy was more often significantly different from the control group and somewhat more effective than IFT for all outcomes but the differences between the two active groups never reached a statistical significance.

To our knowledge, this is the first clinical trial on HT and, for some aspects, the most accurate on IFT. In their randomized trial, Werners et al. (27) compared IFT and lumbar traction for low back pain. They reported a similar reduction in disability and pain, suggesting that both treatments are equally effective. However, it is also likely that the improvement simply represents the natural history of low back pain rather than any benefit from the treatments. The results of this latter study remain inconclusive because it lacked a placebo control. Hurley et al. (28) evaluated the effectiveness of 2 electrode placement techniques of IFT, i.e., "IFT painful area" and "IFT spinal nerve" in subjects with acute low back pain. They showed the superiority of the spinal nerve root technique over the painful area technique in reducing functional disability, but no differences were reported in pain score between the 2 active groups and the control group. Thus, both previous studies with IFT were unable to provide clear evidence of efficacy on low back pain. However, several methodological differences are apparent between these and our study. Firstly, we used only subjects with chronic low back pain (CLBP). In the two previous studies the recruited patients suffered from acute low back pain, which is more likely to undergo a process of spontaneous recovery thus hiding the effect of any treatment (29). Secondly, our study is the first randomized double-blind investigation adequately powered to detect changes in pain. The patients were selected in order to achieve the best compliance to the protocol, i.e., living close to our out-patient clinics, no compelling

**Fig. 1.** Percentage changes (mean and standard error) in functional (upper panel) and pain score (lower panel) in the 3 groups of patients. The Backill scores were significantly improved at all time points in all patients. A significant difference (\*= p < 0.05) between the Horizontal Therapy (HT) group and the sham HT group was found at week 14.

The time points where the percent changes in VAS score observed in the two active groups significantly differed from those of control group are highlighted with \*(p < 0.01).

The use of analgesic medications significantly improved at week 14 versus pre-treatment assessment only in the HT group and the proportion of patients who improved (57.8%) was significantly greater (p = 0.05 by  $\chi^2$ test) than that observed in the sham HT group (36.6%) (Fig. 2).

The significance of all these findings did not change when each outcome value was adjusted for age, gender, underlying cause of CLBP (degenerative disk disease and number of previous vertebral fractures) and baseline VAS and Backill score (data not shown).

We also examined the treatment outcomes separately for the two main group of patients (degenerative disk disease and number of previous vertebral fractures, data not shown).

The mean changes in the osteoporotic group were superimposable as well as the level of the between groups statistical significance (HT versus shame HT), despite the smaller number of patients. In the osteoarthritis group the changes remained equally the same but none of them reached a statistical significance, for the small number of

## Electric therapies and chronic low back pain / A. Zambito et al.

professional commitments, strongly motivated to participate in the study. Consequently, at variance with the two previous controlled studies, we did not have treatment withdrawals. It is generally believed that a complete blinding is difficult to achieve in view of the sensation differences in treatment and the unintended communication between patient and examiners. In order to circumvent these pitfalls we kept both patients and investigators blind to the true nature of the treatments. The operator had very few contacts with the patients, who had never had electrotherapies in the past and were therefore unaware of the tingling sensation associated with active electrotherapies. The results we obtained within the first two weeks clearly indicate that doubleblinding is critically important in this type of investigation! The electrotherapeutic modalities differed significantly among studies. In one study (28) the treatment duration was 30 minutes compared to 10-40 minutes in our study but the number of treatment sessions was variable with a median value of only 3 sessions.

In the study by Werner et al. (27) the patients had six 10-minute treatment sessions over a period of 14 to 21 days compared to our 10 sessions over 2 weeks. The bipolar electrode placement in the two previous studies was substituted by 3 (HT) and 4 (IFT) cutaneous electrodal pads in our study. Overall our treatment procedure can be considered more aggressive and it involved a greater number of patients. The main limitation of our study is the heterogeneity of the CLBP origin, even though there was no treatment-by-etiology of CLBP interaction (p = 0.817). In fact the active therapies seemed to be somewhat more effective in patients with CLBP due to misalignment for previous multiple vertebral fracture, than in the other group where the etiology of CLBP is surely uncertain and heterogeneous. What originally seemed a strength of the study (efficacy over a large variety of causes of CLBP) came out as a source of uncertainty.

In any case, in our study there are also important strengths, such as the age and socialenvironment homogeneity, the very high compliance of the study population, and the complete doubleblinding of the study protocol.

In conclusion, this study provides the first evidence that IFT and HT therapy are significantly effective in alleviating both pain and disability in a randomized, double-blind, placebo-controlled study in patients with CLBP. This is the first study providing evidence for an effective non-pharmacological approach to CLBP due to multiple vertebral fracture.

The slightly greater effectiveness of HT versus IFT may be attributed to either the electrotherapy method or to the duration of treatment (10 versus 40 minutes). We have already initiated separate studies powered for detecting the efficacy of HT in patients with homogeneous causes of CLBP, aimed to identifying the patients who most benefit from the treatment and to comparing efficacy and cost-effectiveness of these electrotherapies with other evidence-based approaches for CLBP.

## Acknowledgments

We are grateful to Alberto Chiaramonte, the physiotherapist who administered all therapies.

### References

- HADLER NM: Workers with disabling back pain. N Engl J Med 1997; 337: 341-3.
- SALAFFI F, DE ANGELIS R, STANCATI A, GRASSI W: MAche Pain: prevalence INvestigating Group (MAPPING) study. Healthrelated qualiity of life in multiple musculoskeletal conditions: a cross-sectional population based epidemiological conditions: a cross-sectional population based epidemiology. II. The MAPPING study. *Clin Exp Rheumatol* 2005; 23: 829-39.
- 3. SALAFFI F, DE ANGELIS R, STANCATI A, GRASSI W: MAche Pain: prevalence INvestigating Group (MAPPING) study. Prevalence of musculoskeletal conditions in an Italian population sample: results of a regional community-based study. I. The MAPPING study. *Clin Exp Rheumatol* 2005; 23: 819-28.
- FRYMOYER JW: Back pain and sciatica. N Engl J Med 1998; 318: 291-300.
- MELZACK R, VETERE P, FINCH L: Transcutaneous electrical nerve stimulation for low back pain. A comparison of TENS and Massage for pain and range of motion. *Phys Ther* 1983; 63: 489-93.
- KÖKE AJA, SCHOUTEN JSAG, LAMERICHS-GEELENC MJH *et al.*: Pain reducing effect of three types of transcutaneous electrical nerve stimulation in patients with chronic pain: a randomized crossover trial. *Pain* 2004; 108: 36-42.

- HURLEY DA, MINDER PM, MCDONOUGH SM, WALSH DM, MOORE AP, BAXTER DG: Interferential therapy electrode placement technique in acute low back pain: a preliminary investigation. Arch Phys Med Rehabil 2001; 82: 485-93.
- 7. JOHNSON MI, TABASAM G: A single-blind placebo-controlled investigation into the analgesic effects of interferential currents on experimentally induced ischaemic pain in healthy subjects. *Clin Physiol Funct Imaging* 2002; 22: 187-96.
- GHONAME EA, CRAIG W F, WHITE PF *et al.*: Percutaneous Electrical nerve Stimulation for low back pain: a randomized crossover study. *JAMA* 1999; 281: 818-23.
- WEINER DK, RUDY TE, GLICK RM *et al.*: Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults *J Am Ger Soc* 2003; 51: 599-608.
- LIAO SJ: Acupuncture for low back pain in huang di nei jing su wen (Yellow Emperor's Classic of Internal Medicine Book of Comman Questions). Acupunct Electrother Res 1992; 17: 249-58.
- 11. EZZO J, BERMAN B, HARDHAZY VA: s acupuncture effective for the treatment of chronic pain? A systematic review. *Pain* 2000; 86: 217-25.
- 12. TWOMEY L, TAYLOR J: Exercise and spinal manipulation in the treatment of low back pain. *Spine* 1995; 20: 615-19.
- MANNICHE C, LUNDBERG E, CHRISTENSEN I, HESSELSOE G: Intensive dynamic back exercises for chronic low back pain: a clinical trial. *Pain* 1991; 47: 53-63.
- KLOTH L: Interference current. *In*: NELSON R, COURRIER D (Eds.): *Clinical Electrotherapy*. St Louis, CA: Appleton & Lange, 1987: 183-207.
- MARTIN D: Interferential therapy. In: KITCHEN S, BAZIN S (Eds.): Clayton's Electrotherapy. London (UK); W.B. Saunders, 1996: 306-315.
- LINDSAY D, DEARNESS J, RICHARDSON C, CHAPMAN A, CUSKELLY G: A survey of electromodality usage in private physiotherapy practices. *Aust Physiother* 1990; 36: 249-56.
- SCHITZ RJ, MARTIN DE, PERRIN DH, IRAN-MANESH A, ROGOL RD: Effect of interferential current on perceived pain and serum cortisol associated with delayed onset muscle soreness. J Sport Rehabilitation 1997; 6: 30-7.
- JOHNSON MI, TABASAM GA: Double blind placebo controlled investigation into the analgesic effects of interferential currents (IFC) and transcutaneous electrical nerve stimulation (TENS) on cold induced pain in healthy subjects. *Physiother Theory Pract* 1999; 15: 217-33.
- PALMER ST, MARTIN DJ, STEEDMAN WM, RAVEY J: Alteration of interferential current and transcutaneous electrical nerve stimulation frequency: effects on nerve excitation. *Arch Phys Med Rehabil* 1999; 80: 1065-71.
- NOBLE J, LOWE A, WALSH D: Interferential therapy review: part 1. Mechanism of analgesic action and clinical use. *Phys Ther Rev* 2000; 5: 239-45.
- 21. HANSJÜRGENS A: Electrical Differatiation Therapy EDT American Academy of Pain

# Electric therapies and chronic low back pain / A. Zambito et al.

Management Annual Clinical Meeting 1999 Sep. 23-26,

- 22. SOUCHARD PE: Posture Mézières. Roma (Italy), Marrapese Editore D.E.M.I. 1982.
- TESIO L, GRANGER CV, FIEDLER RC: A unidimensional pain/disability measure for lowback pain syndromes. *Pain* 1997; 69: 269-78.
- 24. POCOCK SJ: Clinical trials, a practical approach. Chichester: John Wiley; 1983.
- 25. DEYO RA, WELSH NE, MARTIN DC, SCHOEN-

FELD LS, RAMAMURTHY S: A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. *N Engl J Med* 1990; 322: 1627-34.

- 26. WERNERS R, PYNSENT PB, BULSTRODE CJK: Randomized trial comparing interferential therapy with motorized lumbar traction and massage in the management of low back pain in a primary care setting. *Spine* 1999; 24: 1579-83.
- 27. HURLEY DA, MINDER PM, MCDONOUGH SM, WALSH DM, MOORE AP, BAXTER DG: Interferential Therapy Electrode Placement Technique in Acute Low Back Pain: A Preliminary Investigation. Arch Phys Med Rehabil 2001; 82: 485-93.
- 28. CROFT P, PAPAGEORGIOU A, MCNALLY R: Low back pain. In: STEVENS A, RAFFERTY J (Eds.): Health care needs assessment. 2nd ed. Oxford: Radcliffe Medical Pr;1997: 129-82.