

Interferential and horizontal therapies in chronic low back pain due to multiple vertebral fractures: a randomized, double blind, clinical study

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Abstract

Summary Chronic low back pain due to multiple vertebral fractures is of difficult management. Electrical nerve stimulation is frequently used, but its efficacy has never been properly evaluated. In a randomized placebo-controlled clinical trial, we have shown that both interferential currents and horizontal therapy are more effective than placebo for functional.

Introduction Multiple vertebral fractures almost invariably ensue in chronic low back pain that remains of difficult management. Electrical nerve stimulation is frequently used but its efficacy has never been properly evaluated.

Methods One hundred and fifteen women with chronic back pain due to previous multiple vertebral osteoporotic fractures (CBPMF) were randomly assigned to either interferential currents (IFT), horizontal therapy (HT) or sham HT administered for 30 minutes daily for 5 days per week for two weeks together with a standard exercise program. Efficacy assessment was 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 the three groups. The two scores continued to improve in the two

active groups with changes significantly ($p < 0.001$) greater than those observed in control patients at week 6 and 14. The use of analgesic medications improved only in the HT group.

Conclusion 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 CBPMF.

Keywords Chronic low back pain · Double-blind placebo controlled trial · Electrical nerve stimulation · Horizontal therapy · Interferential currents · Multiple vertebral fractures

Introduction

A common consequence of osteoporosis is the occurrence of vertebral deformities. About 25% of the elderly population suffers from vertebral deformities [1]. Vertebral deformities may cause long-term pain [2], decreased physical functioning, social isolation, and depression [3, 4]. The acute pain following incident new vertebral fracture is traditionally managed with rest and analgesic therapies. However, multiple prevalent vertebral deformities ensue almost invariably in chronic back pain [2], mostly related to misalignment of the spine with muscle contractions. This is associated with permanent disability and often continuous use of analgesic compounds, which can lead to serious side effects [5]. Heat, cold, ultrasound, transcutaneous electrical stimulation, and massage therapy have been tested for the treatment of chronic back pain, but not osteoporosis [6, 7]. Electrical nerve stimulation included transcutaneous electrical nerve stimulation (TENS) [8, 9], interferential therapy (IFT) [10, 11] or percutaneous electrical nerve stimulation [12]. The efficacy of all these

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alternative therapies remains controversial since only few studies had an acceptable methodological quality [7, 12]. Despite the total lack of reports on the efficacy of electro-analgesic procedures, TENS or IFT are often used in the attempt to mitigate chronic pain including chronic back pain (CBP) associated with multiple vertebral fractures (CBPMF).

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 [13, 14]. Horizontal therapy (HT) [15] is a novel analgesic therapy that is expected to extend the advantages of the traditional IFT. We have been able to ascertain only in part these advantages in a study comparing IFT to HT in patients with chronic low back pain mainly due to degenerative disc disease [16]. Taking advantage of this experience we decided to test HT therapy in patients with CBP due to previous multiple vertebral osteoporotic fractures (CBPMF) in whom back pain is more constant and predictable.

Methods

The study population comprises 105 women (mean age \pm standard deviation [SD] 71 ± 8 years; range 50 – 88 years). The inclusion criteria were an age older than 50 years and a history of CBP, which had been stable for the previous 3 months, due to multiple (more than one) moderate or severe [17] compression fracture of the last thoracic or of the lumbar spine (T10 to L4) (CBPMF) detected radiologically within the previous 6 months. From the same X-ray the presence of degenerative disk alterations was also recorded. Exclusion criteria were any illness involving major organ systems, history of alcohol abuse, 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 on opioids (with the exception of the commercially available combination of paracetamol with codeine) were also excluded because this might be associated with a transient flare of severe pain due to a recent new fracture. Patients with any professional commitment that might hamper the attendance to the therapeutic sessions 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 patients were recruited from 361 consecutive patients referred to our out-patient clinic for CBP due to established osteoporosis. One hundred and forty-two did not meet the study criteria. The most frequent cause of exclusion was: the absence of more than one moderate-severe vertebral fracture, a new vertebral fracture

occurred within the last 6 months and previous experience with electric therapies. One hundred fourteen patients did not agree to participate in the study most often due to their inability to attend the out-patient treatment sessions. No patients were excluded or refused to participate for the severity of pain or for professional commitments.

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 enrollment procedures.

The recruited patients were assigned to either HT, IFT or sham HT from fifteen computer-generated randomization blocks. Starting on the same day as randomization, all patients began a standard flexion-extension stretching exercise program [16] over 45 minutes, 5 times a week for 2 weeks.

Treatment modalities

The IFT therapy consisted of the placement of 4 medium-sized (8×6 cm) cutaneous electroal pads (Phyaction 787, Uniphy, Eindhoven, NL) in a standard dermatomal pattern, which were stimulated for 30 minutes at a modulated frequency of 200 Hz.

HT therapy consisted of the placement of 3 cutaneous electroal pads (8×13 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).

For the location of the electrical pads we strictly followed the instructions provided by the manufacturers of the instruments.

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 [18], which includes 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 analgesic medications used during the course of the study, which were represented by nimesulide (63%), paracetamol in combination with codeine (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. None of the patients were familiar with electric therapies and they were kept blind to treatment assignment, as were the two physicians who evaluated the patients and administered the questionnaires.

Power analyses 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, similar to those seen in a previous pilot study [19]. We calculated that 30 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 χ^2 test and Odd ratio where the changes in analgesic consumption, categorized as improved or unchanged or worsened. All analyses were repeated after adjusting the values for age, and number of prevalent vertebral fractures by covariance analysis. An intention-to-treat analysis was preplanned, but not applied since all patients completed the three-month follow-up.

Results

The main clinical characteristics of the study population are listed in Table 1. 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 women or housewives. The pretreatment evaluation for both the Backill score and the pain VAS score (Table 1) indicates that the quality of life of this population was severely impaired.

All patients attended the full therapeutic program. However, the adherence to the physical exercise program in terms of strength and duration of the exercises was so variable from patient to patient and 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

Table 1 Clinical characteristics of study population

	Horizontal therapy	Interferential therapy	Sham horizontal
Number	35	35	35
Age mean (SD)	70.5 (7.6)	70.8 (7.4)	70.5 (8.3)
Degenerative disk disease (N.)	5	5	6
Vertebral fractures n. 2	4	3	6
n. 3	9	9	7
n. >3	22	23	22
VAS baseline mean (SD)	8.6 (1.2)	8.7 (1.1)	8.6 (1.0)
Backill baseline mean (SD)	23.2 (5.0)	23.3 (6.4)	23.0 (5.0)
Analgesic consumption/week %			
≤ 2 times	34.3	31.4	33.3
3-6 times	40.0	40.0	39.0
≥ 7 times	25.7	28.6	27.6

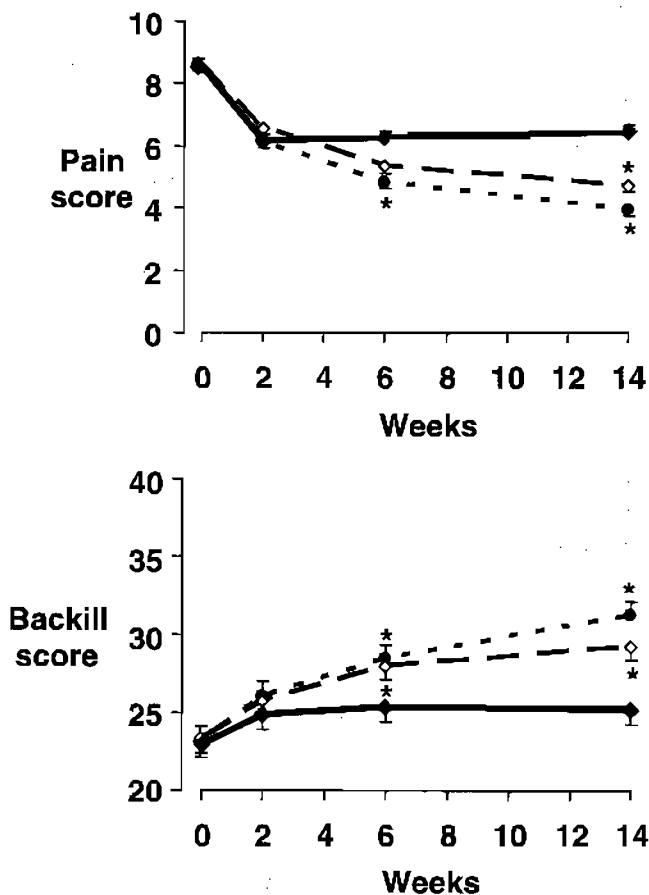


Fig. 1 Percentage changes (mean and standard error) in pain (upper panel) and functional score (lower panel) in patients undergoing Horizontal therapy (HT, dashed line and closed circle), Interferential therapy (IFT, dashed line and open diamond) and sham HT (continuous line and closed diamond). *— $p < 0.01$ versus sham HT group

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 and IFT groups thereafter were significantly greater than those observed in the sham HT group at week 6 and 14 ($p < 0.01$) with slightly not-significant greater effects in the HT group as compared to IFT group.

In the sham HT group, after the initial improvement, the VAS score slowly worsened while in the IFT and IIT groups the VAS score continued to improve with changes significantly different from those observed in control patients.

The use of analgesic medications improved from baseline to week 14 by 57.1%, 48.6%, and 31.4% in HT, IFT and sham HT groups, respectively. The proportion of patients who improved in the HT group was significantly greater (OR=0.34, 95% CI 0.13–0.91; $p=0.03$ by χ^2 test) than that observed in the sham HT group. This rate of improvement was not significant for IFT versus sham HT (OR=0.49, 95% CI 0.18–1.29). The significance of all these findings did not change when each outcome value was adjusted for age, body weight, number of previous vertebral fractures, presence of degenerative disk disease, baseline VAS and Backill score (data not shown).

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 [16].

Thus, the real benefit of electric therapy versus placebo is the beneficial effect extended well beyond the treatment course. The mechanism of this effect, which is commonly seen even though rarely assessed and described, is still poorly understood.

The overall analysis of the results provides evidence that regimens of both IFT and HT treatments are significantly more effective than placebo. The difference versus the control group becomes apparent and then significant only during the post-treatment 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 randomized clinical trial on the effects of electrical stimulation on chronic back pain due to multiple vertebral deformities (CBPMF), and it is also the first clinical trial on HT and, for some aspects, the most accurate on IFT. In their randomized trial, Werners et al. [20] 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 lower back pain rather than any benefit from the treatments. The results of this latter study remain also inconclusive for the lack of a placebo control. Hurley et al. [10] evaluated the effectiveness of two 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 two active groups and the control group. It appears that both previous studies with IFT were unable to provide clear evidence of efficacy on lower back pain due to methodological limitations not shared by our study, which has a number of relevant strengths. We used only subjects with chronic low back pain. In the two previous studies the recruited patients suffered from acute low back pain, not related to vertebral fracture, which is more likely to undergo a process of spontaneous recovery [21]. 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 professional commitments, strongly motivated to participate in the study. This was associated with no treatment discontinuations even though the selection of the patients implies that the beneficial effect, we found can be extended only to patients able to offer the same excellent compliance to treatment.

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. On the other hand, the results we obtained within the first two weeks confirm the stringent necessity of a double-blind investigation when assessing efficacy on CBP. 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. In our study the electrotherapeutic modalities were

consistent all throughout. In a previous study [10] the number of treatment sessions was variable with a median value of only three sessions and in the study by Werners et al. [20] 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 three (HT) and four (IFT) coetaneous electrode pads in our study. Overall our treatment procedure can be considered more aggressive and it involved a greater number of patients. A limitation of our study is the lack of information on quality of life and the relatively limited assessment of function.

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 chronic back pain due to multiple vertebral deformities with a slight greater effectiveness of HT versus IFT. Additional investigations are needed in order to compare efficacy and cost-effectiveness of these electrotherapies with other evidence-based approaches.

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