Use of Horizontal® Therapy in Chronic Backache: Evaluation of Therapeutic Efficacy

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Conclusions

The antalgic effect of transcutaneous electrotherapy methods is greater than that achievable with placebo. The placebo effect is, however, present and confirmed by reduction in painful symptoms, including lesser symptoms, in control group subjects.

The favorable difference in results for Horizontal® Therapy (HT) may be related to the presence of presumed "biological effects", reported as a characterizing element of this type of electroanalgesia, acting directly on anatomical-functional alterations of the various vertebral tissues.

Introduction

Osteoarthritis is a very common pathology in humans. It is a mono- or poly-articular chronic degenerative arthropathy of the subchondral bone, characterized by anatomico-pathological alterations of the joint cartilage, associated with inflammatory phenomena that affect the synovial-capsule membrane. The pathology involves high rehabilitator involvement, due to the functional limitations it causes and the frequent onset of pain accompanying this degeneration. More than 50 percent of adult subjects have an acute episode of backache due to osteoarthritis.

There are many rehabilitative proposals for treatment of osteoarthritis, with the advantage of offering methods that rarely present the contraindications and/or side effects occurring in pharmacological therapy.
One of the most commonly used pain relieving techniques is antalgic electrotherapy in its various forms (interferential, TENS), whose actual efficacy has often been disputed, above all due to the lack of controlled studies testifying to its real efficacy.[1,2]
Another problem with electrotherapy is the need to make uniform a series of parameters characterizing the supplied electrical stimulation, such as wave type, stimulation frequency, intensity, and duration.3

In this work, we wanted to evaluate a form of analgesic electric current recently introduced into the medical market in Italy – Horizontal® Therapy – to compare its efficacy against another antalgic electrotherapy form, interferential therapy, in the treatment of pain from chronic, uncomplicated backache.

Antalgic currents

Horizontal® Therapy (HT) is part of a new generation of electromedical devices that enable simultaneous bioelectrical and biochemical cell stimulation, both at the surface and deep down. To fully appreciate HT in comparison with interferential current (IF) it is essential to recall the concept of Electric Differential Therapy (EDT),[4,5,6] according to which the various current forms are classified on the basis of their therapeutic and side effects.

This classification takes account of the fact that all electrotherapies stimulate cells: varying the electrical intensity and producing action potentials with low frequencies and with constant intensity and applying alternating current with medium frequencies (above 1000 Hz).
In this way, two classes of effects are identified: the stimulatory (bioelectrical) class and non-stimulatory (biochemical) class.
The first comprises all therapy forms that stimulate between 1 and 1000 Hz. In this low frequency range, the current intensity is increased and reduced in order to obtain the desired effect. Effects are considered as bioelectrical, as they generate action potentials in excitable cells by means of repeated depolarization and repolarization. Low frequency currents (TENS, faradic, neofaradic, triangular, diadynamic, etc.) and modulated medium frequency currents (interferential) are numbered in this category.

The biochemical class, in contrast, is represented by the effects obtained with frequencies between 1000 and 100,000 Hz and achieved without producing action potentials. While the effects of the stimulatory class occur only in excitable cells, the medium frequency class has effects in both excitable and unexcitable cells.
Electrotherapy thus stimulates by varying electrical intensity or keeping it constant. From this point of view, "traditional" electrotherapy modulates vertically, making the simultaneous formation of the two classes of effects (biochemical and bioelectrical) impossible in the same area of treated tissue.

Interferential currents

Interferential currents (IF) are obtained by using two medium frequency (4000 Hz) sinusoidal alternating currents interfering with one another at low frequencies (1-200 Hz). They are used in electrotherapy for antalgic purposes, as they are able to penetrate deeper than other electroanalgesic forms precisely due to their medium frequencies.[3] Their action mechanism is tied to membrane hyper-polarization,

while deep down in the area of interference the "gate control" effect occurs.

According to the EDT concept, IF therapy combines the action mechanisms of both classes. Biochemical effects are obtained near the electrodes, thanks to the two unmodulated, constant intensity, medium frequency currents. Bioelectric effects are obtained in the area of interference of the two modulated medium frequency currents, which in fact, in the interference zone the two waves cancel each other out, producing the effect of a low frequency current.

Horizontal therapy

The attempt to overcome the limitations of traditional electrotherapy led to the study of a form of electroanalgesia named Horizontal Therapy (HT), which in contrast with the others is able to simultaneously combine biochemical and bioelectrical effects in the same treated zone, "horizontally" exceeding the stimulation threshold.

It uses constant electrical intensity with biochemical class frequencies (> 1000 Hz). According to Wyss,[7] an increase in frequency leads to an equal increase in intensity, to reach the stimulation threshold. HT exploits this concept, keeping intensity constant and modifying the frequency only.

In figure 1 it can be seen that in point 2 (12,300 Hz) the intensity value in relation to frequency is slightly below the stimulation threshold, thus producing only biochemical effects; while in point 1 (4400 Hz), using the same intensity but reducing the frequency, it is well above the stimulation threshold, thus producing action potentials and thus bioelectrical effects together with the biochemical effects.
In this way, the stimulation threshold is reached horizontally to create an action potential (bioelectrical effect), and the intensity is simultaneously maintained constant to obtain biochemical effects (Fig. 1).

Materials and Methods

In this protocol, three groups of twenty patients each were evaluated. They were aged between 65 and 80 (mean age 75.3), were all female, and were affected by chronic backache with an osteoarthritic basis. None presented a recent vertebral fracture or acute phase sciatic effects. Fifteen female patients of the same age, affected with chronic osteoarthritic backache, were used as the control group.
The patients inserted into the Horizontal® therapy and interferential treatment protocol were chosen at random: SCAN 1 (whole body therapy) – SCAN 2 (local lumbar rachis therapy) – interferential therapy, while the control group underwent the treatment with the equipment switched off.
The therapy cycle involved the application of ten treatments, of which five were consecutive (daily therapy) in the first week, followed by applications on alternate days.

SCAN 1treatment

The frequency changes slowly and horizontally from 4,357 Hz to 12,346 Hz and back, keeping intensity constant.
It should be subjectively perceived as a diminishing prickling sensation.

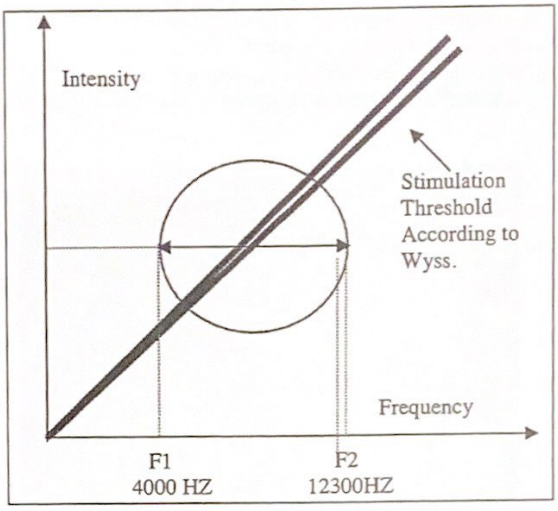

Figure 1 – Principle of Horizontal® Therapy

The electrodes are applied on the back of the hands and feet. The patient is in a supine or sitting position and the duration of the application is generally thirty minutes.

SCAN 2 treatment

The second program used was created to develop its action on a single body area, i.e., in the lumbar zone.
Electrode positioning: lumbar zone (see diagram)
Intensity setting: just perceptible
Treatment time: 30 minutes

Treatment with interferential currents

The apparatus used was the Enraf Nonlus Endomed 582, quadripolar interferential program, with electrode placement analogous to that used for HT; maximum interference frequency 100 Hz.
At the start (time T0), at the end (time T1), and three months later (time T2), patients were assessed by the Oswestry Disability Index, a scale of eleven items, each with six questions, whose responses depend on the condition at that moment (score from zero to five toward greater disability). Responses to single sections are summed to give a final score, which is then reported as percent disability.[8, 9]The VAS scale was contemporaneously executed at the three evaluation steps.

The responses to the OSW questionnaire were summed and the result multiplied by 2 to obtain a measurement of percent invalidity. A correlation study of the results of the two questionnaires was also performed, which demonstrated an excellent linear relationship between them (r=0.87).

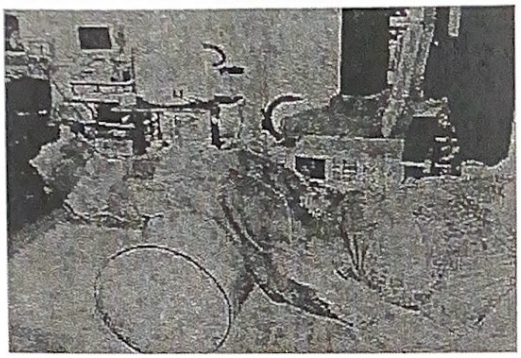

Figure 2 – Horizontal® Therapy electro therapy

For statistical analysis, variance analysis was performed at two levels: the treatment effect and the time effect, with measurements repeated over time (Figs. 2, 3).

Results

From the results reported in the following figures it can be seen that:

1) There is a significant effect in time for all three treatments (according to both questionnaires).
2) The acute effect is superimposable for all three treatments ($P < 0.005$) with a strong reduction in questionnaire values.
3) The effect in time after the end of treatment was well maintained for treatments 1 and 2, while treatment 3 showed worse progress, with an increase ($p < 0.05$ in comparison with measurement 2 and measurement 3) toward a value intermediate between the initial and end treatment values. Analogous behavior was also seen with the control group, which, especially according to VAS measurements, returned to near original values (Table I).

Conclusions

Analysis of data from our study confirms the concepts already known and reported in previous publications,[2-4] among which the following points are worth highlighting:

1) the antalgic effect of transcutaneous electrotherapy is greater than that achievable with placebo; however,
2) the placebo effect is present and confirmed by the reduction in painful symptoms, including lesser symptoms, in control group subjects;
3) antalgic electrotherapy techniques are very well tolerated, favoring excellent patient compliance and the constant absence of significant side effects.

The new element, which it is worth affirming, is the improvement in HT group patients' functional conditions and the reduction in their level of disability in the three-month evaluation with respect to those treated with interferential therapy (and even more so with respect to the placebo treated control group).

It is known that in chronic backache various vertebral pain component alterations arise in addition to pain symptomatology in a picture of deconditioning syndrome.[10,11] Such alterations are localized in the articular cartilage, intervertebral disc, bone tissue, circulation, paravertebral muscle groups, and ligament and tendon structures thereby contributing to the instillation of a vicious, self-powering circle. One of the main objectives of any antalgic intervention is thus the need to interrupt this vicious circle, doing so in such a way that the gradual gain in movement contributes to take the patient back to acceptable functional conditions and to reduce pain.

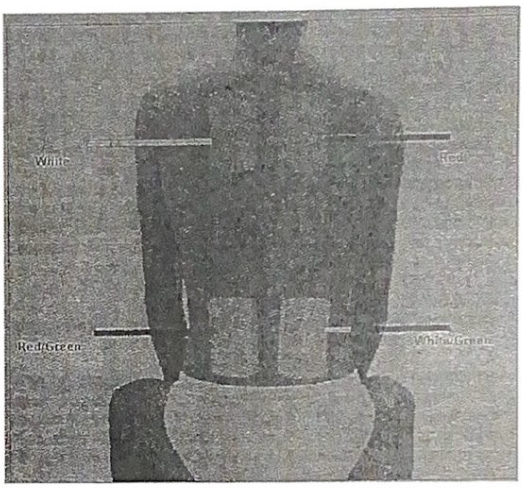

Figure 3 – Electrodes application

	Treatment 1 (HT tot body)		Treatment 2 (HT lumbar)		Treatment 3 (Interferential)		Control	
	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.
OSW0	78.0	10.3	75.7	11.6	73.5	12.8	68.8	13.6
OSW1	49.3	18.3	53.7	18.7	50.5	21.7	55.9	16.8
OSW2	48.8	18.1	53.2	20.9	58.1	19.6	58.5	15.0
VAS0	83.1	13.6	77.1	15.9	78.3	16.3	71.6	17.7
VAS1	36.6	26.3	36.7	27.0	41.1	29.0	55.3	21.1
VAS2	38.4	22.4	37.6	29.1	53.2	28.3	64.1	18.6

Table I – Descriptive statistics (mean and standard dev.) of results of the two questionnaires (OSW and VAS) relative to the three treatment types and the control group.

In our study, the checks performed at the end of the therapy cycles do not highlight any significant differences in analgesic efficacy between the HT and interferential methods. Thus, it cannot be presumed that the better performances seen in the HT group after three months can be correlated with a greater possibility of movement and its consequent beneficial effects manifested after a time interval, such as to allow the regression of alterations induced by prolonged hypomobility or immobility.

The better HT result may be related to the presence of presumed "biological effects", reported as the characterizing

element of this type of electroanalgesia, which acts directly on anatomical-functional alterations of the various vertebral tissues.

It is worth underlining during this discussion the high correlation seen between VAS and Oswestry scale data. This confirms the strict dependence between pain regression and reduction in disability levels, and induces some doubt on rehabilitative strategies which privilege functional recovery, placing it before pain control, which is considered as a non-decisive phenomenon in the process of readapting the patient to social and working activities. In reality, due to the vicious circle of pain-immobility alterations, which characterizes the medium-long term evolution of chronic backache forms, the placement of pain control as the primary objective in deciding the rehabilitative project for such patients cannot be left out of consideration, especially to start the realignment processes opposed to this vicious circle.

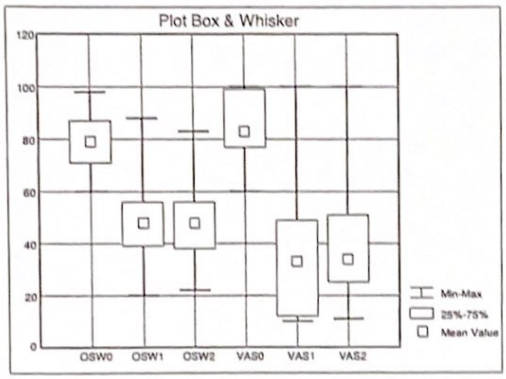

Figure 4 – Treatment 1

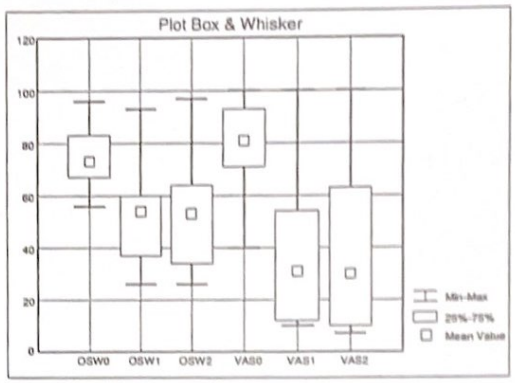

Figure 5 – Treatment 2

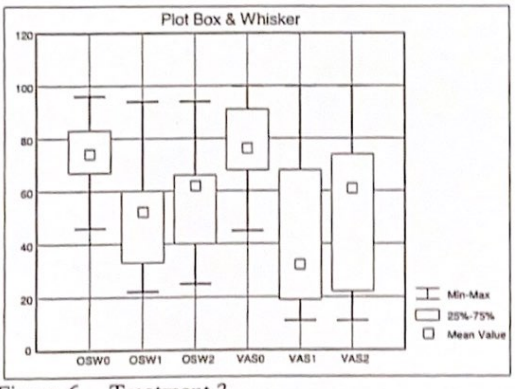

Figure 6 – Treatment 3

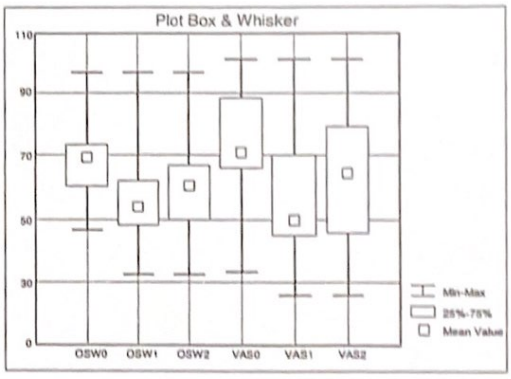

Figure 7 – Control

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