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The effect of combined therapy (ultrasound and interferential current) on pain and sleep in fibromyalgia

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Abstract

Multidisciplinary treatment has proven to be the best therapeutic option to fibromyalgia (FM) and physiotherapy has an important role in this approach. Considering the controversial results of electrotherapy in this condition, the aim of this study was to assess the effects of combined therapy with pulsed ultrasound and interferential current (CTPI) on pain and sleep in FM. Seventeen patients fulfilling FM criteria were divided into two groups, CTPI and SHAM, and submitted to pain and sleep evaluations. Pain was evaluated by body map (BM) of the painful areas; quantification of pain intensity by visual analog scale (VAS); tender point (TP) count and tenderness threshold (TT). Sleep was assessed by inventory and polysomnography (PSG). After 12 sessions of CTPI or SHAM procedure, patients were evaluated by the same initial protocol. After treatment, CTPI group showed, before and after sleep, subjective improvement of pain in terms of number (BM) and intensity (VAS) of painful areas ($P < 0.001$, both); as well as objective improvement, with decrease in TP count and increase in TT ($P < 0.001$, both). Subjective sleep improvements observed after CTPI treatment included decrease in morning fatigue and in non-refreshing sleep complaint ($P < 0.001$, both). Objectively, PSG in this group showed decrease in sleep latency ($P < 0.001$) and in the percentage of stage 1 ($P < 0.001$), increase in the percentage of slow wave sleep ($P < 0.001$) and in sleep cycle count ($P < 0.001$). Decrease in arousal index ($P < 0.001$), number of sleep stage changes ($P < 0.05$) and wake time after sleep onset ($P < 0.05$), were also observed and no difference regarding pain or sleep parameters were verified after SHAM procedure. This study shows that CTPI can be an effective therapeutic approach for pain and sleep manifestations in FM.

Keywords: Fibromyalgia; Physiotherapy; Pain; Sleep

1. Introduction

Fibromyalgia (FM) is a common disorder of unknown etiology characterized by chronic musculoskeletal pain and increased tenderness at standardized tender points (Wolfe et al., 1990). Additional symptoms are fatigue, sleep disturbances, deconditioning and reduced quality of life (Moldofsky et al., 1975; Yunus et al., 1981; Bengtsson and Henriksson, 1989; Martinez et al., 1995; Harding, 1998; Bernard et al., 2000). In FM a multidisciplinary approach is currently considered (Bennett, 1996; Turk et al., 1998; Keel, 1999; Worrel et al., 2001), including cognitive-behavioral training (Nielson et al., 1992; White and Nielson, 1995; Singh et al., 1998), biofeedback (Ferraccioli et al., 1987; Sarnoch et al., 1997), physical exercise programs (McCain et al., 1988; Rush and Shore, 1994; Martin et al., 1996; Jentoft et al., 2001), acupuncture (Deluze et al., 1992; Sprott et al., 1998, 2000), chiropractic manipulations, massage, baths (Pioro-Boisset et al., 1996; Blunt et al., 1997; Ammer and Melnizky, 1999; Hains and Hains, 2000) and physiotherapy (Samborski et al., 1999; Rosen, 1994; Minor and Sanford, 1999; Offenbacher and Stucki, 2000) as co-adjuvant to medication (Simms, 1994; Smith, 1998; Rossy et al., 1999). The combination of different types of physical therapies is also described in FM and other painful conditions (Malone and Strube, 1988; Wingers et al., 1996; Buckelew et al., 1998; Gam et al., 1998; Esenyel et al., 2000). The wide variability in the response to different therapy modalities is regarded to the fact that patients with higher physical disability are not able to perform exercise programs or, in some situations, physical approach can exacerbate symptoms (Turk et al., 1996; Berman et al.,

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1999; Henriksson and Liedberg, 2000; Meyer and Lemley, 2000; Clark et al., 2001; Vierck et al., 2001). In this context, the treatment in FM should consider the individuality of each patient (Rosen, 1994; Mengshoel et al., 1995; Martin et al., 1996; Keel, 1999; Offenbacher and Stucki, 2000).

Electrotherapy, including transcutaneous electrical stimulation (TENS), electro-acupuncture, functional electrical stimulation, iontophoresis, laser, interferential therapy and ultrasound, has been used in musculoskeletal pain conditions (Kaada, 1989; Graff-Radford et al., 1989; Johnson et al., 1991; Deluze et al., 1992; Sunshine et al., 1996; Cheing and Hui-Chan, 1999; El-Sayed et al., 1999; Ghoname et al., 1999; Esenyel et al., 2000; Watson, 2000). Interferential electrotherapy with amplitude modulated at low frequencies reaches deep muscles and nerves (Goats, 1990; Alex and Valma, 1998; Watson, 2000), stimulates voluntary muscles (Ferry and Poumarat, 1994), promotes an increase in peripheral blood flow (Currier et al., 1986), accelerates bone healing (May et al., 1985), and reduces pain (Goats, 1990; Taylor et al., 1987). The efficiency of ultrasound treatment in myofascial pain (Esposito et al., 1984) is regarded to the effect of increasing blood flow (Fabrizio et al., 1996), membrane permeability (Watson, 2000), and capillary density in skeletal muscles (Wyper et al., 1978; Hogan et al., 1982). Besides different sites of action, the combination of electrical therapy and ultrasound is more effective than each of them separately because it provides localized analgesia on previous detected painful areas (Hoogland, 1985).

The aim of this single (investigator)-blinded, controlled study was to evaluate the effects of CTPI in terms of pain manifestations and sleep disturbances in FM. Given that ultrasound may reduce muscle tension and increases microcirculatory flow at tender points and that interferential current may increase pain threshold, we hypothesize that the Combined Therapy with Ultrasound and Interferential Current (CTPI) might be of greater clinical benefit than individual therapies in FM.

2. Methods

2.1. Subjects

Seventeen outpatients who fulfilled FM diagnostic criteria (Wolfe et al., 1990) participated in this research. The sample was derived from a population of 120 available female FM patients from the Rheumatology Service of UNIFESP, Brazil, during the period of January to July 2001. Patients were eligible for the study if they were women older than 50 years, with pain and sleep complaints for the previous six months, able to participate of 12 physiotherapy sessions within a four-week period and to sleep during four nights in the Sleep Laboratory, equivalent to two sleep recordings preceded by adaptation nights. Patients were excluded from the study if they showed evidence of neurological, muscular, infectious, endocrine, other inflammatory rheumatic diseases, or sleep disorders. Patients who used drugs acting on the central nervous system such as antidepressants, analgesics or hypnotics were also excluded, as were patients with previous experience with any kind of electrotherapy. The 40 consecutively selected subjects were randomly assigned to CTPI or SHAM groups, matched by age, ethnic, body mass and educational characteristics. The final group of 17 patients with FM reflects those who completed all stages of study protocol: nine participants of the CTPI group (56 ± 6 years old, eight Caucasians and one mulatto), and eight of the SHAM group (57 ± 5 years old, seven Caucasians and one mulatto).

2.2. Treatment modalities

Patients of CTPI group were submitted to the combined therapy with pulsed ultrasound and interferential current. They underwent electrodiagnosis of painful areas by means of continuous ultrasound (1 MHz; 0.5 W/cm^2) and interferential current (4000 Hz; AMF − 100 Hz; intensity in the tactile sensation threshold). After mapping these areas, treatment was carried out with pulsed ultrasound (1 MHz; 2.5 W/cm^2) and interferential current at each point (Sonoplus 992, Enraf-Nonius Partner for Life, Delft, the Netherlands). The SHAM approach was a simulation of the above described methodology, applied to different body topographies with the system in an inactive mode (without electric current or ultrasound activity). The patients of the SHAM group could not differentiate whether they were in the SHAM or Experimental group, since they had no previous experience with electrotherapy. Considering that it would be expected that CTPI group should experience a pricking sensation at the sites of electrical current application they were not allowed to have any verbal exchange with participants of the SHAM group. The treatment consisted of 12 sessions within a 4-week period. Since the participants were blinded to the treatment modality, all of them were given an opportunity to undergo the efficient procedure after the end of this study. The UNIFESP research ethics board approved all procedures and experimental protocol used in the present study.

2.3. Assessment procedures

Subjects were blindfolded throughout the experiment. The researcher who applied CTPI or SHAM procedure was not blinded to the treatment, and evaluations of pain and sleep parameters before and after treatment were performed by the other investigators blinded to the group of treatment to which the patient belonged.

2.3.1. Pain evaluation

2.3.1.1. Body map (BM). A modified Wisconsin body map (Daut et al., 1983), including anterior, posterior, right lateral and left lateral views of the body, with the more important muscular groups divided into 64 quadrants was used, for the painful area count. The topography of the painful areas was signaled by the patient, who also quantified pain intensity in each of the quadrants by visual analog scale (VAS).

2.3.1.2. Tender points (TP). Evaluation of the 18 TP by digital pressure (Wolfe et al., 1990) was performed bilaterally in suboccipital area, transverse processes of C5 to C7, trapezium muscle, supraspinal muscle, second chondrocostal junction, elbow lateral epicondyle, gluteus medium, femoral trochanter and knee.

2.3.1.3. Tender point threshold (TT). Fisher's dolorimeter (Pain Diagnostics and Thermography, Great Neck, NY, USA) was used to assess tenderness of TP (Fischer, 1987). The average of the pain thresholds at 16 of the TP (excluding cervical points) was obtained.

2.3.2. Sleep evaluation

2.3.2.1. Sleep questionnaire. The Brazilian Inventory for Sleep Disorders (Braz et al., 1987) was completed by all participants. Questions about fatigue, daytime sleepiness, restless sleep, presence of awakenings during the night, behavioral and respiratory sleep disorders, and use of sleep medications were graded on frequency scale of 0 = never to 10 = always. Complaints of non-refreshing sleep and morning fatigue were evaluated by VAS (0 = non-refreshing and 10 = refreshing sleep; 0 = no fatigue and 10 = intense fatigue).

2.3.2.2. Polysomnography (PSG). Before and after treatment an all-night sleep recording preceded an adaptation night to the Sleep Laboratory was performed using Sonolab system (Meditron, São Paulo, Brazil), 32 channels, 20 EEG, two EOG, three EMG and four channels for respiratory analysis. Sleep scoring was blindly performed analyzing sleep and REM latency, efficiency, total sleep time, sleep stage percentages, number of cycles, index of arousals (number per hour), and of sleep stage change (number per hour) and wake time after sleep onset (WASO) (Rechtschaffen and Kales, 1968).

2.4. Study design

The steps of the study were: (1) pre-treatment topographic and intensity evaluation of tender areas by BM, TP count, and TT and sleep questionnaire applied before and after sleep recording (PSG); (2) CTPI or SHAM treatment; (3) post-treatment tender areas evaluation similar to the pre-treatment one was performed before and after PSG.

2.5. Statistical analysis

Two-way analysis of variance (ANOVA) was used (Factor group: CTPI, SHAM; Factor time: before, after) with repeated measures in the factor time, followed by the Tukey Honest significant difference test whenever necessary for the following variables: number of pain regions (BM), mean pain intensity (VAS), TP count, TT, non-refreshing sleep sensation (VAS), and morning fatigue (VAS).

For PSG parameters the Tukey Honest significant difference test detected differences in the pre-treatment situation, and one-way analysis of covariance (ANCOVA) was used (Factor group: CTPI, SHAM). Sleep parameters measured before treatment were used as the covariate for both groups in the analysis of total sleep time (TST), sleep efficiency, % stage 1, % stage 2, % slow wave sleep (SWS), % REM, stage 2 latency, REM latency, quantification of sleep cycles, arousals, sleep stage changes, and WASO. The Fisher exact test was used to analyze the treatment modification in sleep and in pain parameters before and after sleep. For pain assessment, BM, VAS, TP, and TT were considered. For sleep, sleep latency, % SWS, arousals, number of sleep stage changes, WASO and sleep cycle count were the parameters taken into account. Results of pain and sleep were parametric and expressed as mean ± standard deviation (SD). The level significance was $P < 0.05$, except for the multiple comparison Fisher's results, which were considered significant when $P < 0.001$.

3. Results

3.1. Treatment effects on pain and sleep parameters

Differences in pain parameters between CTPI and SHAM groups were only detected after treatment. Reduction in painful areas count (BM) and in average pain scores (VAS) was observed in CTPI group comparing to SHAM, before and after sleep. An interaction effect was detected in both analysis (Table 1).

In objective evaluation, patients exhibited more than 11 TP at the beginning of the study and the average of TT values was lower than 4 kgf/cm^2. After treatment, only CTPI group exhibited a reduction in TP count as well as in average of TT values, before and after sleep, with interaction effect in both situations (Table 2).

The complaint of non-refreshing sleep (VAS) improved in the CTPI in comparison to SHAM, with an interaction effect, after treatment. Morning fatigue was also reduced in CTPI group, with an interaction effect (Table 3).

Compared to pre-treatment condition, improvement in sleep architecture was verified in CTPI group, with a decrease in stage 1 percentage, an increase in SWS percentage, a reduction in sleep latency, and an increase in the number of sleep cycles (Table 3), as well as a decrease in arousals, a decrease in WASO and a decrease in the number of sleep stage changes. No differences in TST, sleep

Table 1
Subjective pre- and post-sleep pain parameters modified by treatment

Pain parameters	Sleep	Sham treatment		CTPI treatment		2-Way ANOVA $F(1,15)$		
		Before	After	Before	After	A	B	C
Body map (number)	Pre	21.1 ± 4.5	18.8 ± 11.8	17.8 ± 8.0	1.2 ± 1.1[a,b]	41.2*	49.8*	31.2*
	Post	19.6 ± 7.4	18.1 ± 10.7	15.6 ± 4.7	1.4 ± 1.2[a,b]	24.1*	47.4*	38.2*
Pain intensity (VAS)	Pre	7.3 ± 1.5	7.2 ± 2.1	6.8 ± 1.4	3.0 ± 2.1[a,b]	6.7#	14.0*	12.6#
	Post	7.4 ± 1.4	7.3 ± 2.0	7.4 ± 1.5	2.8 ± 2.6[a,b]	5.8#	15.6*	13.3#

Mean ± SD. Two-way ANOVA: A, factor group; B, factor time; C, Interaction factor. $*P < 0.001$; $^{\#}P < 0.005$.
[a] CTPI group after treatment is different from SHAM group after treatment, $P < 0.001$, THSD test.
[b] CTPI group after treatment is different from CTPI group before treatment, $P < 0.001$, THSD test.

efficiency, stage 2 and REM percentages or REM latency were detected after treatment (Table 4).

3.2. Treatment effects in association between pain and sleep parameters

After treatment, all nine CTPI patients presented a decrease in painful areas (BM) before and after sleep, and also an increase in %SWS. This improvement in %SWS was not observed in the patients of SHAM group with decrease in painful areas (Fisher, $P < 0.001$, both).

The analysis of the number of sleep stage changes and arousal index after treatment was performed in seven out of nine patients in the CTPI group and in seven out of eight patients in the SHAM group. All seven CTPI patients exhibited a decrease in painful areas (BM) and TP count and an increase in TT, before and after sleep. Two SHAM patients exhibited a decrease in painful areas (BM) before and after sleep. The above-mentioned CTPI patients also improved in terms of number of sleep stage changes and arousal index, events that were not observed in the SHAM group (Fisher, $P < 0.001$, for all above mentioned variables). The analysis of WASO was performed in eight out of nine patients in the CTPI group and in seven out of eight patients in the the SHAM group. All eight CTPI patients exhibited a decrease in TP and TT, before and after sleep, with a concomitant decrease in WASO ($P < 0.001$, both). In SHAM, the one patient who showed a decrease in painful areas did not show a decrease in WASO.

Improvement in TP count and TT before and after sleep was observed in all CTPI patients. All of them also exhibited an increase in %SWS and number of sleep cycles. None of the patients in the SHAM group presented improved TT before or after sleep, and all of them exhibited a decrease in %SWS and number of sleep cycles at the end of the study (Fisher, $P < 0.001$, both).

4. Discussion

To our knowledge, this is the first study addressing the effects of electrotherapy in FM, combining two physical modalities: interferential current and pulsed ultrasound. Specifically in FM, electroanalgesia by TENS (Kaada, 1989) and electro-acupuncture (Deluze et al., 1992) has been used with controversial results. The use of CTPI has already been described in myofascial pain (Bratslavskaia et al., 1976; Khan et al., 1996; Gum et al., 1997) and the combination of ultrasound, diathermy and galvanic currents in osteoarthritis (Svarcova et al., 1987). In this research CTPI proved to be a valid therapeutic option to FM improving not only pain manifestations but also the sleep pattern in a subjective and objective evaluation. By providing electrodiagnosis of hyperalgic regions (Gierlich

Table 2
Objective pre- and post-sleep pain parameters modified by treatment

Pain parameters	Sleep	Sham treatment		CTPI treatment		2-Way ANOVA $F(1,15)$		
		Before	After	Before	After	A	B	C
Pain threshold (kgf/cm^2)	Pre	2.4 ± 0.6	1.8 ± 0.7	2.8 ± 0.4	5.6 ± 1.1[a,b]	49.8*	20.7*	47.2*
	Post	2.4 ± 0.6	2.0 ± 0.7	3.0 ± 0.1	5.7 ± 1.1[a,b]	54.5*	17.0*	40.9*
Tender points (number)	Pre	17.3 ± 1.7	17.1 ± 1.4	15.0 ± 2.1	2.0 ± 1.9[a,b]	86.5*	213.9*	198.9*
	Post	17.7 ± 0.7	16.5 ± 2.3	14.8 ± 3.1	2.7 ± 1.7[a,b]	97.3*	108.6*	71.8*

Mean ± SD. Two-way ANOVA: A, factor group; B, factor time; C, Interaction factor. $*P < 0.001$.
[a] CTPI group after treatment is different from SHAM group after treatment, $P < 0.001$,THSD test.
[b] CTPI group after treatment is different from CTPI group before treatment, $P < 0.001$, THSD test.

Table 3
Subjective sleep parameters modified by treatment

Sleep parameters	Sham treatment		CTPI treatment		2-Way ANOVA $F(1,15)$		
	Before	After	Before	After	A	B	C
Refreshing sleep (VAS)	2.8 ± 0.6	2.9 ± 0.6	2.1 ± 0.7	7.5 ± 0.7[a,b]	45.3*	229.0*	229.0*
Morning fatigue (VAS)	8.0 ± 0.5	8.3 ± 0.5	7.0 ± 1.2	2.6 ± 1.0[a,b]	84.4*	71.7*	101.5*

Mean ± SD. Two-way ANOVA: A, factor group; B, factor time; C, Interaction factor. *$P < 0.001$.
[a] CTPI group after treatment is different from SHAM group after treatment, $P < 0.001$, THSD test.
[b] CTPI group after treatment is different from CTPI group before treatment, $P < 0.001$, THSD test.

and Jung, 1968) the CTPI approach takes into account the individuality of each patient in terms of painful areas.

The interferential electric current is characterized by a medium frequency wave with low frequency modulated amplitude. It acts as TENS does (Kaada, 1989; Offenbacher and Stucki, 2000) and promotes analgesia by blocking pain potentials in the dorsal horn of the spinal cord (DHSC) (Goats, 1990; Martin, 1998; Watson, 2000). Furthermore, it prevents synaptic plastic rearrangement of the wide dynamic range (WDR) cells of the hypersensitized cells, by reducing arborization of free-nerve terminations. In FM, it has been proposed that synaptic plastic alterations in DHSC and free nerve endings, in conjunction with insufficient pain suppression are involved in pain threshold decrease, hyperalgesia and allodynia (Lautenbacher and Rollman, 1997; Mountz et al., 1998; Russell, 1998; Bennett, 1999; Schadrack and Zieglgansberger, 2000; Millan, 1999; Mense, 2000). Interferential current reduces pain by acting in the common aspects of the theories proposed to explain the blockage of nociceptive stimuli in the DHSC (Melzack and Wall, 1965) which are the stimulation of Aβ myelinated fibers and the blockage of C amyelinated nociceptive afferents, as well as increase in the opioid release (Melzack and Wall, 1965; Goats, 1990; Watson, 2000; Mayer and Price, 2001).

Although muscular pain has been a central feature of FM syndrome, controlled studies are controversial in supporting a role for muscle in pathophysiology of this condition (Simms, 1996; Olsen and Park, 1998). Perfusion and metabolic changes have been proposed to explain focal sustained contraction (Bengtsson and Henriksson, 1989; Yunus and Kalyan-Raman, 1989; Yunus, 1994; Park et al., 1998) as well as, muscle deconditioning (Bengtsson and Bengtsson, 1988; Bennett, 1989; Nativig et al., 1998; Borman et al., 1999; Nielens et al., 2000). In this study, the use of pulsed ultrasound is justified by its effects in reducing pain and ischemic phenomenon (Coakley, 1978; Yung, 1998). It improves sustained muscle contraction (Esposito et al., 1984) by increasing the permeability of the cell membrane (Dyson, 1985; Mortimer and Dyson, 1988); improves intracellular energy consumption (Young and Dyson, 1990; Montes Molina et al., 2000); increases angiogenesis in ischemic tissues (Fabrizio et al., 1996; Nussbaum, 1997); and promotes tissue repair (Guerino et al., 1999; Fujioka et al., 2000).

The effect of CTPI in pain manifestations in FM could be evidenced subjectively and objectively. Decrease in number and intensity of painful areas, as well as decrease in TP and increase in TT, were observed. The efficiency of this treatment might be due to the individualized approach to each patient, since electrodiagnosis provides the possibility of treating each true painful region individually. The simultaneous application of analgesic current by the ultrasound device, in specific painful areas, would be not possible with classical interferential bipolar therapies (Ersch, 1992).

Sleep disturbances detected in this study are the same as those reported by others authors in FM (Moldofsky et al., 1975; Branco et al., 1994; Drewes et al., 1995; C-ote and Moldofsky, 1997; Perlis et al., 1997; Harding, 1998; Drewes, 1999; Roizenblatt et al., 2001). Regarding subjective complaints, non-restorative sleep and morning

Table 4
Parameters of sleep fragmentation before and after treatment

Sleep parameters	Sham treatment		CTPI treatment		1-Way ANCOVA	
	Before	After	Before	After	A	P
Arousals	19.7 ± 7.8	21.4 ± 4.5	26.6 ± 10.0	9.4 ± 3.0*	$F(1,1) = 38.5$	<0.001
Sleep stage changes	13.3 ± 4.5	13.9 ± 3.9	18.7 ± 4.7	11.0 ± 3.3*	$F(1,11) = 8.7$	<0.05
WASO	39.8 ± 35.2	44.6 ± 32.1	77.8 ± 63.1	35.2 ± 21.3*	$F(1,12) = 4.9$	<0.05

Mean ± SD. One-way ANCOVA: A = Factor group (SHAM, CTPI). *CTPI group is different from SHAM group after treatment. WASO, wake after sleep onset.

fatigue, improvements were reported after CTPI. Objective parameters of PSG showed decrease in sleep latency and % stage 1, and increase in %SWS, as well as a reduction in arousal index and sleep stage changes. Although the significant increase in % stage 1 in the SHAM group after treatment could not be detected by ANCOVA, this modification could be attributed to the anxiety of the patient in obtaining an improvement sensation from SHAM treatment (Eich et al., 2000).

To our knowledge, this is the first study to assess the modifications in sleep structure induced by physiotherapy using polysomnography, and questionnaires. Improvement in pain and sleep conditions occurred concomitantly after CTPI treatment, and pain improvement could be detected before and after sleep. In SHAM group only two of the patients improved in terms of painful areas (BM). These patients did not show concomitant modification in objective assessment of pain or in sleep parameters, excluding the possibility of a placebo effect on our results. Despite the substantial significant statistical differences between SHAM and CTPI groups, to minimize the risk of a type II error an enlargement of the samples is necessary. The limited number of subjects in each group is justified by the strictness of the inclusion criteria and of the design of the research. We made a concerted effort to blind the study subject and investigator interpreting the results to the treatment group assignment. As such, we believe that the data were not unduly influenced by subject or investigator biases. Yet, the nature of the intervention prevented us from blinding the investigator involved with applying the treatment. This is unlikely to have contributed to any analysis bias, since that investigator (TFA) was not involved in the interpretation of the individual subject collected data.

The association between pain symptoms and sleep quality has been reported in FM (Moldofsky et al., 1975; Yunus et al., 1981; Agargun et al., 1999; Roizenblatt et al., 2001) and also in normal individuals (Lentz et al., 1999). This study suggests that sleep disorder in FM might be due to a pre-sleep pain condition and also that the improvement in sleep can lead to less pain in the morning. Thus, we conclude that CTPI, acting as an electrodiagnostic tool and as a modality of physical therapy, provides an effective pain treatment, with consequent sleep improvement in FM. Additionally, these data highlight the efficacy of different therapeutic modalities focused on tender point topography. Further studies, with enlarged casuistic, are necessary to confirm this findings.

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