

Original Paper

The Use of Microcurrent Electrical Therapy and Cranial Electrotherapy Stimulation in Pain Control

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ABSTRACT: The use of cranial electrotherapy stimulation (CES) in pain management is new to the pain field and only recently has begun being documented in US clinical literature. While we are familiar with transcutaneous electrical nerve stimulation (TENS), we were told that microcurrent electrical therapy (MET) and CES were an entirely different approach to pain management. In this open clinical study, we evaluated this potential new treatment combination to assess its effectiveness with our patients who had been refractory to previous treatments. The treatments were scheduled for 1 hour/day, 5 days a week, for 3 weeks. Although 3 patients out of 20 obtained no relief from this treatment, 6 obtained complete relief, and an additional 8 patients received significant relief of 33% to 94%. We conclude that CES and MET are effective treatments for chronic pain patients.

The purpose of the present study was to assess the effectiveness of microcurrent electrical therapy and cranial electrotherapy stimulation separately or together to effect a significant treatment response in chronic pain patients.

Cranial electrotherapy stimulation (CES) is an FDA-accepted treatment for depression, anxiety, and insomnia. A recent review article reported that it has also been effectively used to treat various pain syndromes such as chronic spinal pain, headaches, dental pain, and fibromyalgia. It reportedly also potentiated anesthetics used in general surgery up to 37% when applied during surgery, thus requiring significantly less medication to keep the patient anesthetized.¹

CES involves the use of low-level electrical stimulation across the head. In worldwide research over more than 30 years, it has been shown to be effective as a drug-free treatment of anxiety, depression, and insomnia.² Its mechanism of action is widely thought to be its ability to bring neurotransmitters in stressed subjects back into normal, prestress levels of homeostasis.³⁻⁵

That alone could account for any effect it might have on pain perception in chronic pain patients. Schuster⁶ states, for example, "Patients' psychological states influence their perceptions of pain; anxiety can decrease patients' pain thresholds. Increased anxiety . . . can increase pain."

On the other hand, there is new interest in what is now called the pain neuromatrix, located in the cerebral cortex, with connections throughout much of the brain.⁷ The neuromatrix theory was developed from studies of phantom limb pain in amputees. It is believed that this

center is responsible for firing pain messages into various parts of the body, even in the absence of bodily pathology, and may account for much chronic pain for which a cause cannot be found and whose treatment response remains refractory. While it is known that the electrical pulses from CES pass through this area of the brain, among others,⁸ there is presently no knowledge of how it may interact with this area of the brain to change the pain signaling process, if in fact it does.

Microcurrent electrical therapy (MET) is usually provided directly to the body of the pain patient, either via hand-held probe electrodes or self-adhesive electrodes. Unlike TENS, which is thought to close the spinal gate to pain impulses so that they will not ascend to the brain,⁹ MET is thought to have a strong anabolic, healing response, with up to 500% increase of ATP into the treated area following a treatment of 1 hour or less, increased movement of amino acids into the area, and an increase in protein synthesis at the site treated.¹⁰

One neurosurgeon has reported using CES alone to effectively reduce or eliminate pain in 28 chronic spinal pain patients, obviating surgery in many.¹¹ We decided to follow his CES protocol, plus the protocol provided in a MET device manual, to learn what the combination effect of these 2 reportedly effective treatments would be for our patients.

It should be noted that the MET probe electrodes used in this study were formerly used by pain therapists, and are still often used, on acupuncture points as a modified form of electroacupuncture. Even though there are strong theoretical reasons for such use, acupuncture

points were not sought out in the placement of the probe electrodes in the present study. The operating manual accompanying the device suggested that the sharp spike wave form which initiates each current pulse from the device negates the need to search out areas of less skin resistance when treating with it.

Methodology

Twenty refractive chronic pain patients in a hospital pain clinic near Bombay, India, were added to the study in the order in which they presented at the clinic. Ages ranged from 30 to 75 years (mean = 44 years). Fifteen were females. Their type or areas of pain are given in Table 1. All signed voluntary consent forms. Our hospital does not have an IRB, but the clinical oversight group approved the study prior to its initiation.

Patients were asked to come to the hospital daily, Monday through Friday, for 3 consecutive weeks, for 1-hour treatment sessions. In addition, they were given no

pain medications during the study and were requested to avoid taking analgesics during the study.

The treatment strategies available under this protocol were either CES, MET via probe electrodes, MET via self-adhesive electrodes, or a combination of CES and one or the other type of MET electrode. MET, when given, was given by either probes or self-adhesive electrodes at 600 microamperes. CES was given to all patients in which clinical depression or anxiety states appeared to accompany their pain complaint. The current intensity of the CES was regulated by the patient, all of whom were instructed to turn the current up until they felt a bit lightheaded and then turn it down to their comfort level. The intensities used ranged from 100 to 300 microamperes, and often varied from day to day. Both CES and MET treatments were given with the Alpha-Stim 100 device which applies CES via ear clip electrodes (Electromedical Products International, Inc., Mineral Wells, Texas, 76067, USA). Figure 1 shows how the CES ear clip electrodes are applied. They are put as high on the

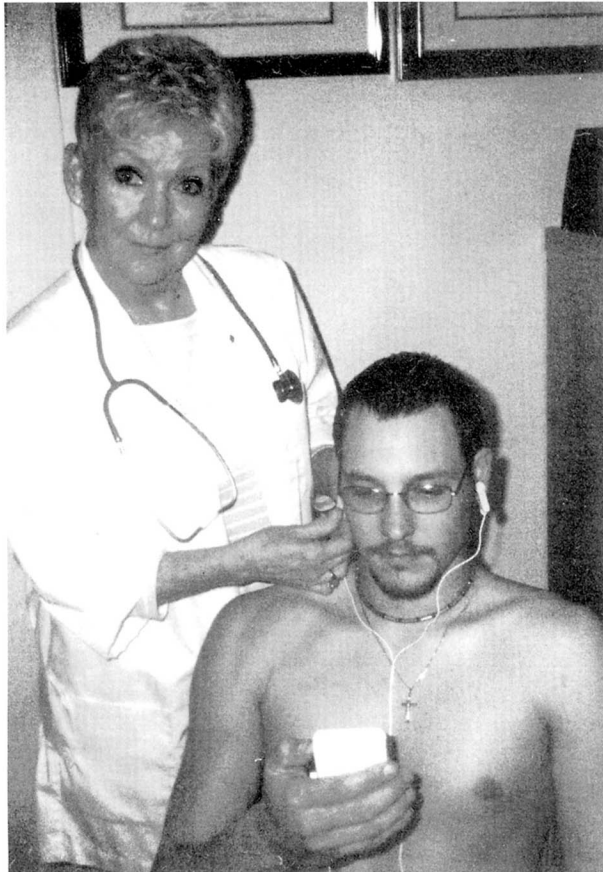
TABLE 1
Subject Characteristics, Treatment Parameters, and Treatment Outcome

Pt	Sex	Age	Type of Pain and Duration	No. Rxs	Rx Given*	Pre-Score**	Post-Score	% Gain
1	F	30	Bilateral scapular, 5 yrs	15	C,A	7	0	100%
2	F	30	Radiating, neck to hand, 10 yrs	15	C,A	8	1	88%
3	F	62	Rheum arth, bilateral, knees, 4 months	5	C,P	8	0	100%
4	F	40	Low back pain, 7 yrs	15	C	3	2	33%
5	F	35	Radiating pain, C7 to right arm, 6 yrs	12	C,P	8	0	100%
6	M	41	Back pain, T8, 1 year	10	C,A	5	1	80%
7	F	30	L3 and L4 pain, 6 yrs	12	C,A	8	0	100%
8	F	46	Low back, 2 yrs, both knees, 1 yr	10	C	6	3	50%
9	M	52	Ankilosing spondilosis, 10 yrs, rheum arth	10	C,A	8	7	13%
10	M	40	Back pain, 4 yrs	15	C,P	7	0	100%
11	F	48	Fibromyalgia, 1 yr	10	C	5	0.5	90%
12	F	41	Fibromyalgia, 3 yrs	8	C	5	0.5	90%
13	F	31	Rheum arth, right leg to toe, 5 months	10	C,P	4	1.5	63%
14	M	75	Low back, knee, 7 yrs	10	C	5	5	0%
15	F	40	Pain, left heel, 1 yr	10	P	6	6	0%
16	F	65	Sciatica, 3 yrs	8	C,P	7	6	14%
17	F	42	Right knee pain, stiffness, 7 months	2	C,P	8	0	100%
18	F	42	Cervical spondilosis, 2 yrs	15	C,A	8	7	13%
19	M	44	Cervical spondilosis, 2 months	5	C,P	8	0.5	94%
20	F	44	Bilateral knee, osteoarthritis, 4 yrs	7	C,A	10	10	0%

* P indicates probes: C, cranial electrotherapy stimulation; A, self-adhesive pads.

** 10-point visual analogue scale.

FIGURE 1
Showing how the CES electrodes are attached to the ear with ear clip electrodes



earlobes and as close to the cheek as possible. Figure 2 shows a typical use of the probe electrodes, which are placed so that the microcurrent will trace a direct path through the area of pain, between the electrodes. The probes are repositioned each 10 seconds following a beep from the device, but are always placed so that the current traces a direct path through the area of complaint or trauma.

Pain was scored by the patients on an 11-point self-rating VAS scale, with 0 being no pain and 10 being the most intense pain the patient had experienced to date. Pain evaluations were scheduled to be obtained every Friday following treatment.

Findings and Analysis

In practice, many patients found it difficult to come to the hospital daily for the entire 3-week period. Nine patients (45%) left the study early following the reduc-

tion of their pain to 0 or no higher than 1.5 on the self-rating scale. One such patient had complete remission of her pain after only 2 treatment sessions with the probe electrodes and CES. Of the 3 patients who received no relief, none returned for the final week of treatment.

The 7 patients (35%) who were treated with CES plus the self-adhesive electrodes began at an average pain level of 7.7 (range 5–10) and ended at an average of 3.7 (range 0–10), or 52% reduction in pain level from an average of 12 days of treatment (range 7–15).

The 7 patients (35%) who were treated with CES plus the probe electrodes fared even better, beginning with an average pain score of 7.1 (range 4–8) and ending at an average of 1.1 (range 1–6), or an 85% reduction in pain level from an average of 8.1 days of treatment (range 2–15).

Five patients (25%) were treated with CES only. They experienced an average 50% drop in pain level from 4.4 (range 3–7) to 2.2 (range 0.5–5), following an average of 10.6 days of treatment (range 8–15).

While we had originally planned a double-blind, placebo-controlled study, with all patients receiving the identical treatment or sham treatment, we found that our patient group could not be depended on for that kind of cooperation. In running an open clinical trial instead, we let the therapist decide what specific treatment regimen might be indicated, based on the presenting symptoms. Upon later data analysis, we found that there was a significant tendency ($P < .001$, $t = 4.98$, $df = 26$) for the staff to assign those with higher pain scores (average = 7.4) to treatment with both CES and MET, while those assigned to receive only 1 treatment modality began with lower pain ratings (average = 5.0). Nonetheless, patients did not differ significantly in final pain scores (2.4 and 2.8, ns, respectively), suggesting that what was basically clinical intuition at work in the treatment selection in fact functioned quite well in practice. Of course, we have no data on what the outcome would have been if the procedure had been reversed.

A closer inspection of Table 1 does show that among those staying for at least 2 weeks of treatment, those patients who received 2 modalities of treatment experienced an average 73% improvement, while those receiving only 1 modality improved an average of only 35%. Of course, the latter group, having started with significantly less pain, had less distance to go in showing treatment response.

When we looked at the patients' treatment response by the length of time they had had the pain, we found that patients who had been in pain for 2 months and 4 months improved 94% and 100%, respectively. Among the others who experienced 100% pain reduction were patients whose pain had lasted 4 years, 5 years, and 6 years. The overall correlation between duration of pain and improvement following treatment was -0.19 , not

significant with this number of subjects. When this was broken down into those whose pain had lasted less than a year and compared with those whose pain had lasted 5 years or more, the correlation was -0.05 and -0.42 , neither of which was statistically significant.

When correlations between the various columns in Table 1 were calculated, the only one of significance ($r=.53$) was between the number of years patients had experienced the presenting pain and the number of treatments they came for. In other words, patients who had experience their pain longer may have been either more desperate to try anything new that might work, or they were more used to attendance at pain clinics.

When years of pain, number of treatments given, and prescore pain intensity were held constant in a multilinear regression, the percent improvement in the patients correlated strongly across these study elements ($r=.85$), leaving an unusually small error variance of 28% unaccounted for. That suggests that the improvement seen in the study was due directly to the effect of the CES and MET treatment, with little input from extraneous variables.

Patients had been asked to note any negative side effects of CES or MET during the study. No negative side effects were reported.

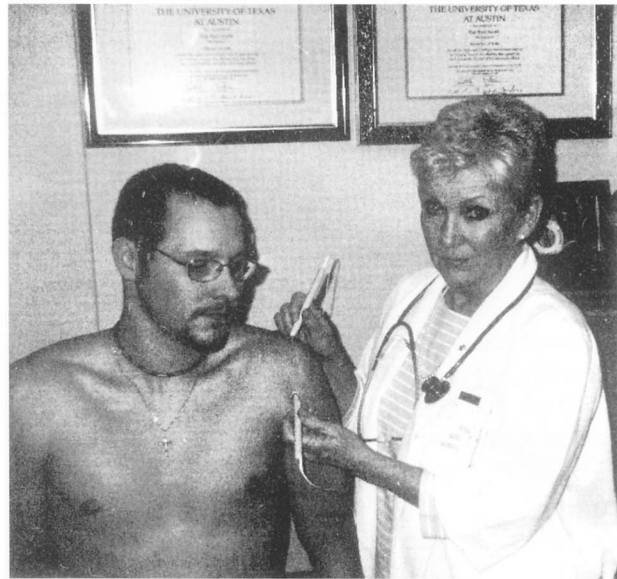
Discussion

CES, originally called electrosleep, is not new to the Indian subcontinent, having been studied in both humans and monkeys back in 1971.¹² The goal of Singh et al's study was to determine the effect of CES on subjects' EEGs as it related to sleep and consciousness mechanisms. Only recently has CES begun to come into its own as a pain treatment modality. MET is also slowly coming to be seen as distinctly different from TENS as a pain treatment modality, as shown in the present study design and in other studies cited above.¹⁰ While studies have shown that CES can enhance or potentiate medications,¹³ it can also potentiate the effects of such pain treatments as biofeedback.¹⁴ The present study shows, however, that CES and MET can stand together or alone as significant, drug-free treatments for otherwise intractable chronic pain, as seen with the majority (70%) of the patients in the present study.

Conclusions

While double-blind studies are now showing the effectiveness of CES as a pain treatment, we have found no other study that has combined CES and MET. We found the combination to be a very effective treatment for the patients in the present study and have seen that this treatment is very good for long-standing chronic pain as well as for pain of shorter duration. We conclude that CES and MET would be an effective addition to the treatment program in pain clinics.

FIGURE 2
Showing a typical placement of the probe electrodes (as shown here, for shoulder pain)



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