The Use of Cranial Electrotherapy Stimulation in the Treatment of Multiple Sclerosis

by Ray B. Smith, PhD

Cranial electrotherapy stimulation (CES) involves the passing of small electrical impulses across the head, usually from electrodes placed on or near the ears. The pulse rates vary from .5-100 Hz in different CES devices, and stimulation intensities range from 0-1.5 mA via sinusoidal or modified square waves. The duty cycles range from 20-80%, with most devices pulsing on a 50% duty cycle. CES treatment is by medical prescription only, and the initial treatment instructions are usually to use the device at home for an hour a day for at least the first three weeks, followed by a treatment response evaluation. It is also used in inpatient settings.

CES arrived in the US almost 40 years ago in the early 1960s. It was then called "electrosleep," and was thought to be of benefit in inducing sleep in anxious and distressed patients so that their body could properly heal itself of any number of presenting symptoms. It was not long before researchers discovered that CES did not, in fact, necessarily induce sleep, 2-4 but that it was effective in treating stress-related conditions whether or not the patient went to sleep and that its effects were not just due to suggestibility, 6.7 but appeared to be real, as measured by double blind research protocols. 8,9

In animal studies at the University of Tennessee Medical Center, researchers used drugs to deliberately upset the homeostatic balance among the brain's neurotransmitters in canine subjects. In this way they induced Parkinson-like behavior in the dogs. Once all drugs were removed from their bloodstream, and the animals were put back on normal feeding schedules, they returned to normal behavior within 3-7 days. If CES treatment was applied at the time the drugs were removed, all animals returned to normal within 2-8 hours. The researchers concluded that CES was effective in bringing back to pre-stress homeostasis, neurotransmitters that had become imbalanced. 10

If that were a mechanism of action, then many kinds of medical conditions should respond to CES, and research soon found that CES was effective in the treatment of addictions, ¹¹⁻¹³ in head injury, ¹⁴ in various types of cognitive dysfunctions, ¹⁵⁻¹⁶ and more recently in reflex sympathetic dystrophy. ¹⁷⁻¹⁸ In addition, the use of CES in the treatment of many types of pain patients has been documented, ^{19,20} and ongoing studies are documenting the effectiveness of its use in treating patients suffering from the difficult fibromyalgia syndrome. ²¹⁻²²

Still, it came as something of a surprise when within the past 12 months, two testimonial letters arrived in our office from MS patients describing highly positive experiences with CES. One woman noted, "I have used the CES for about three weeks. It relieves intense pain and puts me in a very relaxed state. I use it at least three to four hours a day." A man wrote regarding his wife's use of CES for her MS, "My wife suffers from MS. She is classified as a chronic progressive patient. Within a few days of using the (CES device), my wife was not getting tired as fast as before. She could hold up to eight hours of activity instead of 3-4 hours ... my wife has cut back dramatically on the amount of medication she used to take."²³

Once alerted by the two letters, we searched back through more than 3,000 of the most recent warranty cards that patients had sent in following physicians' prescription of CES devices for the treatment of their various medical conditions. On the warranty card, patients are allowed to volunteer information regarding their diagnosis, the length of time they used the device before sending in the card, and an estimation of their treatment outcome to date. The vast majority of persons who are prescribed CES devices do not send in warranty cards, and among those who do, many do not volunteer the particulars of their diagnosis and/or treatment outcome. Nonetheless, we found 12 cards from

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MS patients who did complete the card. Ten (83%) were female, their ages ranging from 21-52 (average: 39 years). They had used their CES device from 1-8 weeks (average: 4.4 weeks), and had experienced treatment improvement from 0-99% (average: 46.57%)

Some had entered comments at the bottom of the card, such as, "This helps keep pain down," or "More effective than anything else I have ever used for my MS symptoms of tingling, headaches, pain and stress. I love this miracle unit. It has given me my life back and much relief from this very painful disease," or "Plan to continue use — optimistic about future results." We decided that a clinical research trial was overdue.

Subsequently, one of our CES distributors agreed to run a pilot study using a protocol we developed from the information given above. A physician with a large MS practice gave her the names of six MS patients who had signed a volunteer consent form to be in the study. Each had been diagnosed with MS from 10-38 years previously (average: 21 years). There were four females and two males, with ages ranging from 53-68 (average: 60 years). They were each given cranial electrotherapy stimulation units and asked to wear them for one hour a day for one month. The units were preset to treat at 0.5 Hz, with a modified square wave, and the patients were told to turn the stimulation up to a comfortable level, usually between 100 and 300 microamperes, and wear it at that level for the hour.

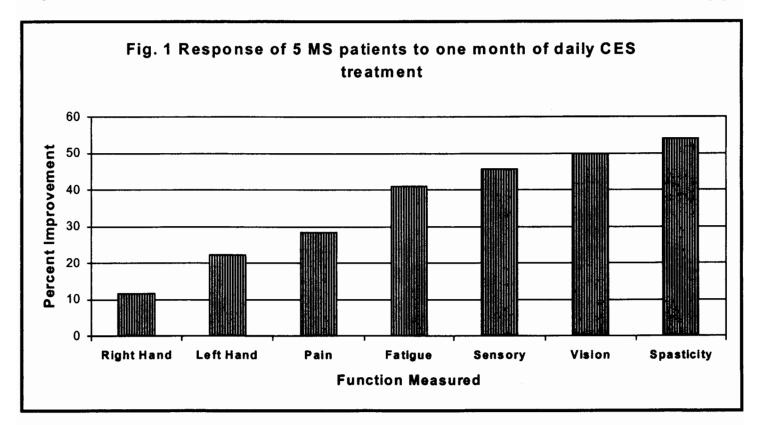
They filled out self-rated 10-point scales just prior to beginning treatment and immediately following the final treatment. The self rated factors were:

- Mobility/gait problems
- Right-hand function problems
- Left-hand function problems
- Vision problems
- Fatigue
- Cognitive problems
- Bladder problems
- Sensory symptoms (numbness, tingling, burning)
- Spasticity (muscle tightening, stiffness, jumping, cramping)
- Pain

One female did not complete the pretreatment ratings, so her data was lost to the study. The results of the other five patients are shown in figure 1, which shows the percent improvement on those variables that showed a significant response.

Note that spasticity had the largest improvement, followed by vision, sensory, fatigue, and pain, while bladder, cognitive, and mobility/gait problems were not rated as significantly improved by the patients.

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While this is recognized to be only a pilot study and should be followed up by a double-blind, placebo-controlled study, it does reflect the information we had previously gained from patients' letters and warranty card responses, so it is probably a fairly accurate assessment of what a physician could expect when prescribing a CES device for use by his MS patients.

Conclusion

While CES was accepted early on by the FDA for treatment of the stress-related conditions of anxiety, depression, and insomnia, its wider uses in other stress-related illnesses are quickly becoming apparent, both through double-blind research, and from clinical input from patients such as the MS patients described above. While better studies with stronger scientific protocols still need to be completed with MS patients, it is becoming apparent that, increasingly, MS patients and their physicians are not waiting for that kind of data to become available. They are reacting increasingly to word of mouth reporting regarding the effectiveness of CES in ameliorating their MS symptoms.

Acknowledgements

About the Author

Dr. Ray B. Smith is a physiological psychologist and His major interests are cognitive dysfunction and cranial electrotherapy stimulation which he has been studying since 1972. In 1969, he received a grant from NIH for the study of alcoholism and drug addiction in the District of Columbia. The grant was attached to the DC Government's Department of Human Resources, Mental Health Administration. During his 13 years in that position, he began to study the remarkable effects of CES on the cognitive dysfunction of that subject population. It was during this time that he found upon repeated studies that CES could bring back to normal within three weeks, the short term memory loss and other cognitive dysfunctions of addicted persons, which ordinarily take from two to three years of continuous sobriety.

Since that time, he has researched CES in subject populations as varied as alcoholics, drug abusers, people with eating disorders, phobias, anxiety and (Continued on next page)

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depression, attention deficit disorder, and various forms of chronic pain. All of his studies have been at least single-blind, and most have been double-blind, with the psychometrist and statisticians also blind to the treatment condition in each case. His studies have involved well over 1,500 subjects to date. working as research consultant to various CES firms from 1980 to 1998, Dr. Smith joined Electromedical Products International, Inc. in 1998 where he currently serves as Director of Science. He continues to bring his in-depth knowledge of the scientific aspects of CES plus his considerable clinical skills into play on the professional lecture circuit. As of early 2000, Dr. Smith is involved in over 30 major clinical studies in Croatia, Germany, Washington, Louisiana, New Mexico, New Jersey, California, Illinois, Indiana, Georgia, North Carolina and Texas.

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