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Cranial electrotherapy stimulation and fibromyalgia

Marshall F Gilula

CONTENTS

Evidence for efficacy of CES in the treatment of FM

Role of the patient in FM treatment

Role of D-ribose in FM treatment

Stress reduction in FM treatment with the EPFX

Conclusion

Expert commentary

Five-year view

Information resources

Key issues

References

Affiliation

Cranial electrotherapy stimulation (CES) is a well-documented neuroelectrical modality that has been proven effective in some good studies of fibromyalgia (FM) patients. CES is no panacea but, for some FM patients, the modality can be valuable. This article discusses aspects of both CES and FM and how they relate to the individual with the condition. FM frequently has many comorbidities such as anxiety, depression, insomnia and a great variety of different rheumatologic and neurological symptoms that often resemble multiple sclerosis, dysautonomias, chronic fatigue syndrome and others. However, despite long-standing criteria from the American College of Rheumatology for FM, some physicians believe there is probably no single homogeneous condition that can be labeled as FM. Whether it is a disease, a syndrome or something else, sufferers feel like they are living one disaster after another. Active self-involvement in care usually enhances the therapeutic results of various treatments and also improves the patient's sense of being in control of the condition. D-ribose supplementation may prove to significantly enhance energy, sleep, mental clarity, pain control and well-being in FM patients. A form of evoked potential biofeedback, the EPFX, is a powerful stress reduction technique which assesses the chief stressors and risk factors for illness that can impede the FM patient's built-in healing abilities. Future healthcare will likely expand the diagnostic criteria of FM and/or illuminate a group of related conditions and the ways in which the conditions relate to each other. Future medicine for FM and related conditions may increasingly involve multimodality treatment that features CES as one significant part of the therapeutic regimen. Future medicine may also include CES as an invaluable, cost-effective add-on to many facets of clinical pharmacology and medical therapeutics.

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Cranial electrotherapy stimulation (CES) with Alpha-Stim[®] is a well-documented neuroelectrical modality that has been proven effective in some good studies of fibromyalgia (FM) patients (FIGURES 1 & 2). This article discusses aspects of both CES and FM and how they relate to the individual with the condition. CES is the US FDA- and EU-recognized generic category for medical devices using microcurrent levels of electrical stimulation applied across the head via transcutaneous electrodes for the treatment of anxiety, insomnia and depression. Microcurrent (<1000 μ A) stimulation usually means 1 mA or less, whereas transcutaneous electrical nerve stimulation (TENS) involves higher currents in the 60–100 mA range and with very different waveforms. CES treatment

of anxiety and depression began in the USA in the early 1960s, and is still being prescribed routinely by several hundreds of physicians today, but has yet to achieve ubiquitous acceptance in medical practice. That is possibly because sufficient information has not been made available to practitioners regarding the safety and efficacy of CES as a treatment for the approved indications of anxiety, insomnia and depression. Using an electromedical device requires more of an additional learning curve for both practitioners and patients who are accustomed to the pharmaceutical model of intervention. Ingesting a capsule or a tablet does not always require the attention to detail that correct application of ear clip electrodes, for example, demands. We have been conditioned

Life Energies Research Institute,
2510 Inagua Avenue, Miami,
FL 33133, USA
Tel.: +1 305 402 1475/
+1 305 720 6501
Fax: +1 305 854 8954
mgilula@mindspring.com

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by our healthcare to swallow pills, not apply electrodes. Ideally, both modalities require patient education, consistent follow-up and determinations of compliance [1].

Patients diagnosed with FM frequently have a combination of anxiety, insomnia and depression in addition to the musculoskeletal pain patterns that are allegedly the distinguishing hallmarks of this condition [2]. The spectrum of anxiety disorders is clearly bidirectionally comorbid with insomnia and depression. And CES can be cost effective as well as also being therapeutically effective [1].

This article documents that CES is also emerging as a complementary and standalone treatment for pain-related disorders. In truth, it is safe to assume that our healthcare culture will usually prescribe a medication such as a minor tranquilizer as the first treatment of choice for a number of comorbid anxiety patterns found with FM. But almost all of the pharmacological interventions employed for anxiety disorders tend to be dependency provoking, expensive and depression facilitating by virtue of the fact that they depress the CNS. This fact does not in any way detract from the utility of medications for any patient who is able to successfully adapt to the chemical. But a nonchemical approach, if clinically effective, might offer less of a 'treatment load' on the physiological systems of the individual with FM. This article will describe some of the evidence on the application of CES to FM that suggests CES should be a regularly tested modality with all FM patients who can tolerate the stimulation. The Alpha-Stim CES device uses easily-applied ear clip electrodes (FIGURE 1), and even hypersensitive individuals can easily tolerate the device when the current of the device is turned down close to 100 μ A. The electrodes have small circular felt pads that stick to the ear clips. Last but not least, this article will scrutinize some 'patient-in-control' aspects, and a



Figure 1. Alpha-Stim® Stress Control System microcurrent ear lobe electrode. Reproduced with permission from Electromedical Products International, Inc. (TX, USA); www.alpha-stim.com.



Figure 2. Alpha-Stim® Stress Control System microcurrent stimulator. Reproduced with permission from Electromedical Products International, Inc. (TX, USA); www.alpha-stim.com.

few newer facets of FM treatment. These include D-ribose supplementation for improving energy levels and evoked potential biofeedback with the EPFX for stress reduction.

Evidence for efficacy of CES in the treatment of FM

Today's treatment for the comorbid anxiety, depression and insomnia-related disorders of FM still does not regularly include CES [3], despite the fact that massage, acupuncture and cognitive behavioral therapy are considered pain reducers for FM patients. Nevertheless, there is already more than enough experimental evidence to nominate CES as a robust adjunct for medication regimens or other interventions carried out with many comorbid psychiatric features of FM. When CES is widely recognized for being the valuable modality that it is, CES will also emerge as an effective way to limit, decrease or modify the toxic or adverse effects of many pharmacological treatment regimens. This 'good with the bad' aspect of western pharmacology is almost universally accepted and often life-saving despite the adverse or side-effect profile that might be very prolonged. CES has a range of possible adverse effects that are fairly mild, unless the individual is intolerant of the electro-medical modality (see Key issues). FM and chronic fatigue syndrome (CFS) patients tend to show, in the author's experience, an inconstant oversensitivity to microcurrent. Thus, if one individual has previously not responded well to CES, it would be wise to gently try the CES again during another exacerbation or if there has been at least a few weeks passage since last trying CES. The Alpha-Stim CES device also lends itself very well to being adjusted so that the electrical signal is at a level that becomes just subsensory. CES will still work at a just subsensory level. As the overall muscular relaxation of the patient increases, the effect on the CES signal is that it suddenly appears to become more intense, and can be readjusted again to

the subsensory level. These points are very important to the clinician who attempts to use CES with an FM patient because treatment with this modality is not simply a matter of 'plug and treat'. Close supervision and instruction are necessary to enhance compliance as well as optimizing the treatment for both compliance and efficacy. Neuroelectric modalities such as CES have a much steeper initial learning curve than what is required for swallowing a pill. Of course, medications will likely have a much longer list of potential adverse effects than CES, but most healthcare practitioners are still more comfortable with the use of medications than CES.

Five recent studies of CES in the treatment of FM present intriguing evidence that suggests that CES is a worthwhile addition to the physician's armamentarium, not only for the comorbid psychiatric aspects of FM, but for the condition itself. The studies suggest efficacy but do not go into great detail explaining how applicable and acceptable the novel modality is to a group of patients considered by many physicians to be nonhomogenous in clinical features.

Kulkarni and colleagues studied microcurrent electrical therapy (MET) and CES study in pain patients. The study reported that FM cases in the group responded "extremely well" with 80–90% relief [4].

Lichtbroun and colleagues have shown that CES technology significantly eases the pain of FM [5]. Their findings conclude that CES was as effective as prescription drugs in relieving pain and "completely safe". The details of this IRB-sanctioned study of 60 randomly assigned patients are interesting and worthy of emulation. The patients all met the American Rheumatology College criteria [2] and were divided into treatment, sham treatment and control groups. The controls served to control for placebo effect in the sham-treated group, which experienced the same intervention with identical devices that had no output. This was possible because the treatment itself with the 'active' devices was carried out at the just subsensory level. The 3-week CES treatment was carried out at 0.5 Hz for 1 h/day in this double-blind, placebo-controlled investigation. A total of 58 of the 60 patients were female, and the age range was 23–82 years with a mean of 50 years. Duration of symptoms ranged from 1 to 40 years with a mean of 11 years. Patients treated with active CES experienced a significant improvement in tender point scores ($p < 0.01$), and a significant improvement in self-rated scores of general pain level ($p < 0.002$). Patients rating their quality of sleep as poor dropped from 60% at the beginning of the study to 5% ($p < 0.02$). There were also significant gains in the self-rated feeling of well-being ($p < 0.05$) and quality-of-life ($p < 0.03$), and some gains in all six stress-related psychological test measures of the Profile of Mood States. No placebo effect was observed among the sham-treated patients. Following the first 3 weeks of the study, 23 of the 40 control patients opted for actual CES in an open clinical trial during which they could increase the current of CES as needed. These patients also showed a significant improvement in tender point scores ($p < 0.001$) and in self-rated pain ($p < 0.005$), quality of sleep ($p < 0.001$), feeling of well-being ($p < 0.001$) and quality-of-life ($p < 0.001$).

Cork and colleagues conducted another double-blind, placebo-controlled study of CES with FM [6]. The results were similar to Lichtbroun's study. Of 74 patients, 39 were randomly assigned to the active CES treatment group and 35 to the sham-treated group. In total, 70 of 74 patients were female, with an average age of 53 years (range of 22–75 years). Following completion of the study's double-blind arm, 23 of the sham patients elected to crossover to an open clinical trial. Because subjective pain intensity was the primary measured variable in this study, pain intensity, McGill pain score, tenderpoint score, Profile of Mood States and Oswestry score measurements were taken at baseline and after 3 weeks. Three weeks after crossover of the 23 sham patients all measurements were repeated. Significant CES effects included an improvement in pain intensity ($p < 0.01$ compared with sham $p < 0.001$ in sham group after crossover), McGill score (not significant in initial 3-week trial; $p < 0.001$ in sham group after crossover), tenderpoint score ($p < 0.01$ compared with sham; $p < 0.001$ in sham group after crossover), and profile of mood states ($p < 0.01$ compared with sham; $p < 0.001$ in sham group after crossover). No significant effect was observed on Oswestry score, a quantitative disability scale rather than a functional assessment of pain. However, a longer study might be necessary to see changes in a subjective measure of disability among this tertiary pain management population. It was concluded that CES could play a significant role in the treatment of pain associated with fibromyalgia.

Other published results include a large number of case studies and series of cases that have been studied by meta-analysis. Meta-analysis is a statistical method of combining the results of several studies that address a set of related research hypotheses. The first meta-analysis was performed by Karl Pearson in 1904. Pearson attempted to overcome the problem of reduced statistical power in studies with small sample sizes. His hypothesis was that analyzing the results from a group of studies can permit more accurate data analysis. Meta-analysis is a slightly less rigorous statistical technique but is an accepted and excellent way of teasing out important trends from a collection of different data sets. The first meta-analysis of a medical treatment was not published until 1955. Because the results from different studies investigating different independent variables are measured on different scales, the dependent variable in a meta-analysis is some standardized measure of effect size. The usual effect size indicator is either the standardized mean difference or an odds ratio in experiments with outcomes of dichotomous variables (success vs failure) [7].

Describing the mechanism of action for CES is complex (FIGURE 3) and not always clear. This depiction is by no means the absolute last word, but it at least provides a temporary graphic structure to use for collating and interpreting clinical and research knowledge and findings. An earlier review article summarizes most of the pertinent research on this complicated mechanism of action question [1]. As in many areas of medical intervention, the evidence to date of CES effectiveness is in part empirical. It is generally believed that the effects are primarily mediated through a direct action on the brain at the limbic system, the reticular-activating system (RAS) and/or the

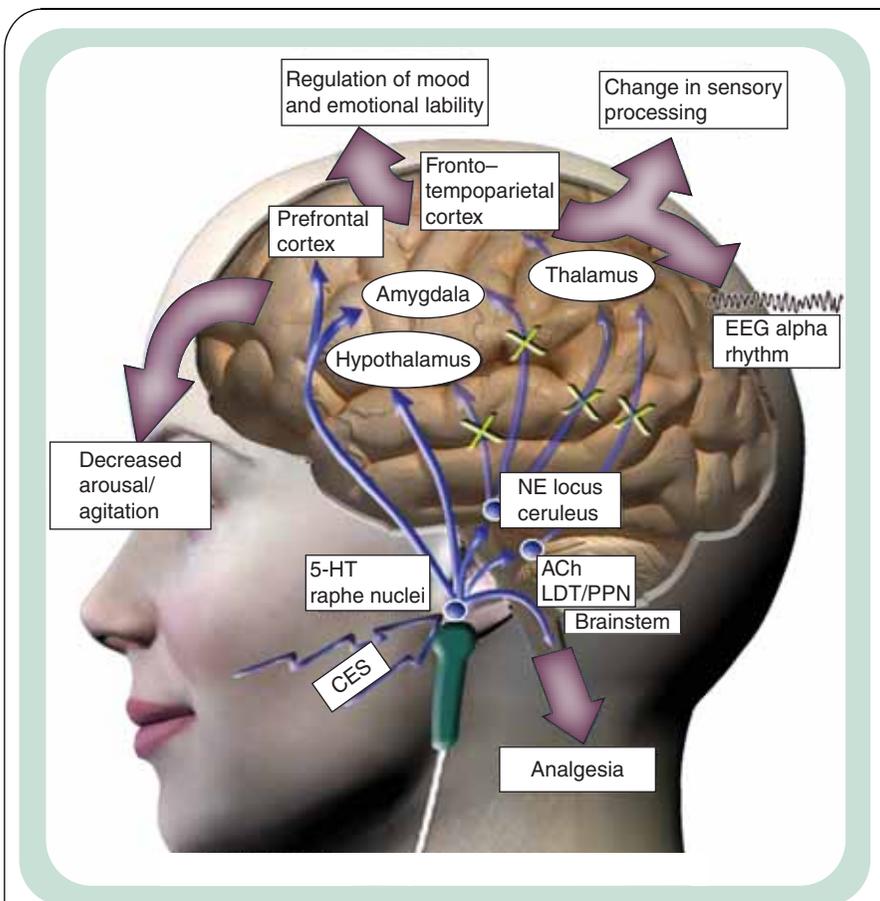


Figure 3. Mechanisms of CES action (note: diagram not to scale. Some structures are placed according to a diagram of impulse flow rather than according to correct neuroanatomic localization). Alpha-Stim® CES engages the serotonergic (5-HT) raphe nuclei of the brainstem. 5-HT inhibits brainstem cholinergic (ACh) and noradrenergic (NE) systems that project supratentorially. This suppresses thalamocortical activity, arousal, agitation, alters sensory processing and induces EEG alpha rhythm. In addition, 5-HT can act directly to modulate pain sensation in the dorsal horn of the spinal cord, and alter pain perception, cognition and emotionality within the limbic forebrain. Blue arrows: inhibitory interactions. Purple arrows: excitatory interactions. X: suppressed pathways/interactions. 5-HT: Serotonin; ACh: Acetylcholine; EEG: Electroencephalogram; LC: Locus ceruleus; LDT: Laterodorsal tegmental nucleus of the brainstem; NE: Norepinephrine; PPN: Pediculo-pontine nucleus of the brainstem. Diagram by James Giordano, Georgetown University. © 2006 All rights reserved. Reproduced with permission from Electromedical Products International, Inc. (TX, USA); www.alpha-stim.com.

the function of the limbic region of the midbrain affecting emotions. Substance P and enkephalin have been found in the trigeminal nucleus, and are postulated to be involved in the regulation of emotions within the limbic system. The auditory nerve might also be affected by CES, which would account for the dizziness one experiences when the current is too high. Ideally, CES electrodes are placed on the ear lobes because that is a convenient way to theoretically direct current through the midbrain and brain stem structures.

Studies of CES in monkeys measured 42–46% of the original current entering the brain, with the highest concentration being measured in the limbic region. Rat studies demonstrated as much as a three-fold increase in β -endorphin concentration after just one CES treatment. Canine research provided evidence that suggests CES releases dopamine in the basal ganglia, and the overall physiological effects appear to be anticholinergic and catecholamine-like in action. Other mammalian research found that the size, location and distribution of synaptic vesicles were all within normal limits after a series of ten, 1-h stimulations of Rhesus monkeys [1].

Over the past few decades, at least eight CES companies have applied for and received FDA clearance to market CES devices. In addition to the Alpha-Stim CES device, the other most prominent CES device is the Liss Cranial Stimulator, SheLi series [101]. In the USA, both these devices are available by prescription only. The sample size of most CES research has remained comparatively small. But a recent review by Kirsch listed an aggregate of

hypothalamus. The primary role of the RAS is in the regulation of electrocortical activity. The RAS, hypothalamus and limbic system are primitive brain structures. The functions of these areas and their influence on our emotional states were originally mapped using electrical stimulation. Electrical stimulation of the periaqueductal gray matter has been shown to activate descending inhibitory pathways from the medial brainstem to the dorsal horn of the spinal cord, in a manner similar to the actions of β -endorphins. Cortical inhibition, which may be augmented by CES is a factor in the Melzack–Wall Gate Control theory. It has also been suggested that CES produces its effects through parasympathetic autonomic nervous system dominance via stimulation of the vagus nerve, or of other cranial nerves such as the trigeminal, facial and glossopharyngeal. Electrocortical activity produced by stimulation of the trigeminal nerve is implicated in

more than 126 scientific studies of CES involving human subjects and 29 animal studies [8]. Most of the studies were performed in the USA over the past 30 years.

Role of the patient in FM treatment

FM has been described by Shealy as: “One of the most incapacitating and misunderstood of all reasonably common ailments. The prevalence of FM in the United States and in Europe is between 2 and 3% of the population. Although rheumatologists classify FM as a distinct entity, the vast majority of physicians are frustrated by it and consider patients with FM to be psychiatrically disturbed. Most FM patients are treated with antidepressants, which have a mediocre benefit in the long run. FM patients have high annual and lifetime utilization of all medical services. FM patients report more symptoms and other

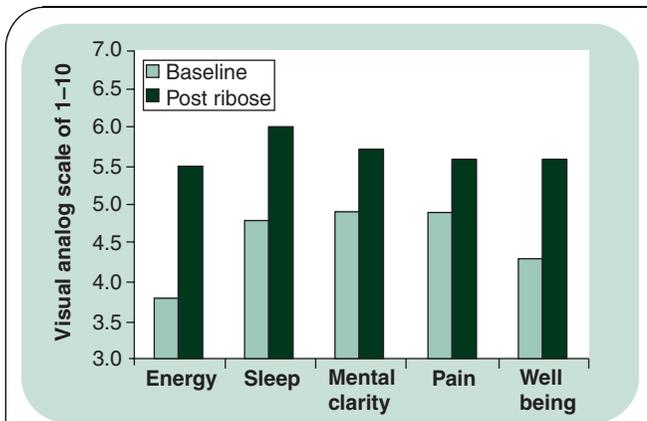


Figure 4. D-ribose pilot study results with fibromyalgia and chronic fatigue syndrome patients (n = 36). Each category of change was significant at the $p < 0.026$ or less.

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disorders than patients with other rheumatic conditions and the total symptom complex of FM patients leads to greater global disability” [9]. Shealy employs CES with his FM patients transcranially 1 h each morning for 4–12 weeks. In addition, he uses photostimulation for 1 h daily, transdermal magnesium 2 teaspoons twice daily, B complex 100 mg daily, physical conditioning and daily hot soaks or saunas.

In this unique regimen, Shealy focuses sensitively on the patient and inculcates a deep sense of personal responsibility for the daily maintenance of health, striving towards high-level wellness by continual emphasis on nutrition, exercise and self-regulation techniques such as meditation, affirmations, guided imagery and deep muscular relaxation. Putting the patient in the driver's seat has the potential for reducing the amount of stress experienced by the patient from the aversive stimulation of an illness and can also enhance the efficacy of treatment modalities and other interventions [10].

Role of D-ribose in FM treatment

One isolated case report of D-ribose's beneficial effect on a patient with FM [11] as well as a positive study of D-ribose supplementation following intense exercise in humans [12] led to a recent open-label, uncontrolled pilot study. This research was carried out to evaluate whether D-ribose 'could improve symptoms in FM and/or CFS patients' [13]. Five of the 41 patients were excluded for noncompliance factors, but 66% of the 36 patients experienced significant improvement while taking the D-ribose (FIGURE 4). Patients who completed the protocol took 5 g three-times

daily for 3 weeks, and then reduced to a maintenance dose of 5 g twice daily. FIGURE 4 shows the before and after scores on all five visual analog scales (VAS) used as metrics in this study. The VAS scores showed an average improvement in overall well-being of 30% ($p < 0.0001$). The lack of placebo controls and a technological metric to assess the severity of FM and CFS are two of the greatest weaknesses in this study, which suggests that addition of D-ribose may also offer a potential added benefit of treatment for these patients. The primary adverse effects during this pilot study were hyperanxious feeling, light-headedness and increased appetite. Although the effects were mild, three patients did not complete the study. Two of the 36 patient who remained with the study experienced transient nausea (one patient) and mild anxiety (another patient). Both of these mild problems were corrected by lowering the D-ribose dose.

Stress reduction in FM treatment with the EPFX

Another device, the EPFX, is an evoked potential biofeedback device that is used for stress reduction in the USA. The EPFX is known as the EPFX(QXCI)/SCIO in Europe and other countries outside the USA. The EPFX uses galvanic skin response electrodes attached to the wrists and ankles, and eight EEG electrodes applied to the forehead. This device has the potential for pointing out a large variety of relevant stressors for the individual patient and is an avenue for reducing stress in the patient by helping to restore energy balance in the human system [102,103]. Because many FM patients obtain at least

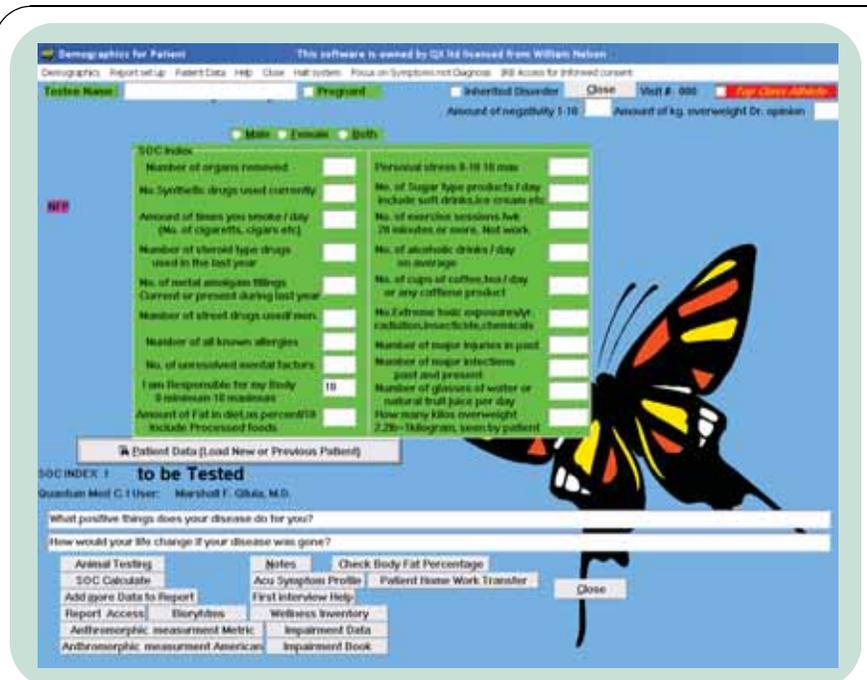


Figure 5. Screen shot of the EPFX showing the suppression and obstruction of cure principles that are assessed for each patient. This evoked potential biofeedback device is known as the EPFX(QXCI)/SCIO in Europe and other countries outside the USA and is used for stress reduction. Factors on the green panel are used to help assess the chief stressors and risk factors for illness that might impede the patient's built-in healing abilities.

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temporary pain relief from acupuncture, the EPFX is relevant here as I have been told by my patients that there are some elements of this biofeedback experience that produce a similar type of relief. Moreover, I have found that the 'suppression and obstruction to cure' function of the EPFX system (FIGURE 5) can be an ideal and nonpunitive way of identifying stress points in the patient's life and gently turning the patient's attention to those points that need to be addressed.

Conclusion

Intriguing experimental data strongly suggest the efficacy of CES with some FM patients. Patients are extremely individual in their ability to adapt to a neuromedical modality, and FM patients are no exception. The 'Key issues' at the end of this article reiterate a nonredundant list of some potential adverse aspects of CES, which albeit rare, nonetheless do occur. Even though more studies will be needed, the technique is now ready for careful clinical use and widespread testing. Any time CES is used by a patient who is gaining a sense of control over the device and how it works, there will also be a corresponding positive effect of patient's gaining some sense of greater control over a disease process that is often labeled as disastrous by patient and physician alike. With any disease process, the point at which the patient begins to eschew the role of 'victim' is always a positive transition from the long range point of view. CES can potentially remove the need for at least some of the medication-related adverse effects in addition to relieving pain itself. Furthermore, CES is also documented as effective in treating some psychiatric comorbidities of FM such as anxiety, depression and insomnia. Therefore, it is important for the thoughtful clinician, researcher and patient to consider the possibility of using CES as part of the FM treatment plan. This modality may require a learning curve by patient and clinician alike. CES does not work in every patient, but it is clearly worth consideration as a therapeutic modality for FM.

Expert commentary

Compared with the panoply of official and unofficial, mainstream and alternative treatment modalities and nostrums, CES has the distinguishing feature of possessing very few significant adverse effects, and this is rarely true of other modalities. However, with FM patients, the modality does have the potential of being effective only intermittently, and it is not clear at this point whether this reflects the fluctuating nature of the FM process or something else. Alpha-Stim CES is specifically designed so as to minimize the possibility of CNS 'tolerance' or adaptation to the electromagnetic signal of the device. Some of the most successful FM patients seen by the author have been 'take-charge' types and very heavily involved in their own treatment regimen. Some of these patients will put down the CES device in favor of traditional acupuncture, some will substitute CES later on instead of acupuncture or possibly some other less effective intervention they have obtained from the internet sources. My patients have taught me to respect this rhythm and to occasionally recognize it as part of a clinical cycle in which the patient recognizes more acutely than I do at the time. It has been so important in many

ways to step out of the white coat and meet my patients as cofacilitators of the treatment. This applies to all quality medical treatment, but is especially important for treating FM or any other similarly obscure and varying process.

D-ribose supplementation may be proven effective for enhancing energy levels and mental clarity of FM patients while also enhancing the efficacy of CES treatments. In addition, evoked potential biofeedback treatment with the EPFX can enhance CES efficacy by helping to identify and reduce stress factors.

Five-year view

CES using Alpha-Stim will continue to evolve to yet smaller device sizes and possibly even more efficacious waveforms. In medical devices we appear to be continually migrating towards the use of lower and lower biological frequencies and amplitudes with the human system. CES will become more of a first-line treatment for FM due to its potential efficacy that has already been demonstrated in controlled studies, but also because of the 'add-on' potential or dual treatment efficacy (including comorbidities) and relatively few adverse effects of the modality itself. More hands-on education for both physicians and patients will continue to be necessary. Future-oriented pharmaceutical researchers may learn that the 'add-on' function of CES is an indispensable methodology for enhancing medication efficacy while reducing adverse effects that make some medications impossible to use by some patients. Future researchers may therefore regard CES as a very economical 'delivery system add-on' for many classes of pharmacotherapies possessing worrisome adverse effects.

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Key issues

- Cranial electrotherapy stimulation (CES) is emerging as a complementary and standalone treatment for pain-related disorders.
- CES is a well-documented neuroelectric modality that has been proven effective in some decent controlled studies of fibromyalgia (FM) patients.
- FM frequently has many comorbidities such as anxiety, depression, insomnia and a great variety of different rheumatologic and neurological symptoms.
- FM patients with comorbid psychiatric disease have a greater tendency to experience rare temporary side effects such as exaggerated insomnia or headache, but these effects, related to activation, are easily handled by having the treatments carried out earlier in the day ensuring adequate current hydration (to prevent headache).
- Over the long run, CES has the potential for being recognized as an effective add-on to psychopharmaceuticals, with less adverse effects and greater cost-effectiveness.
- CES adverse effects usually come from clinical situations in which the patient has not been compliant with or understood physician instructions or simply has not presented for follow-up but continued using the device without assistance.
- When used as an add-on, CES can enable the physician to reduce the dosage of medications thereby reducing the potential for severe long-term adverse effects from the medication.
- Litigation-conscious physicians who fear being sued for failure to use a pharmaceutical at the beginning of treatment if CES is selected will need to present the patient with the risk-benefit equations of CES versus pharmaceuticals as well as educating themselves by using CES as a modality.
- Because FM patterns show so much individual and temporal variations, CES can be a superior and affordable device for the responsive patient to own and use for intermittent episodes of symptom exacerbation.
- Electromedicine is a future medicine that is available today for the physician willing to master a relatively short learning curve that will always involve teaching patients and office assistants.

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Affiliation

- Marshall F Gilula, MD
President and Director, Life Energies Research Institute, 2510 Inagua Avenue, Miami, FL 33133, USA
Tel.: +1 305 402 1475/+1 305 720 6501
Fax: +1 305 854 8954
mgilula@mindspring.com