Cranial Electrotherapy Stimulation: The New Science of Neuromodulation For Mood Disorders, Post Traumatic Stress Disorder, Terrorism Trauma Syndrome and Insomnia

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Fellow, American Institute of Stress

Certified in Homeland Security, Level III

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Consulting Editor, Journal of Neurotherapy, Senior Editor PTSD

Electromedicine Dept, Editor, Practical Pain Management

Member, Inter-Pain (Society of German/Swiss Pain Specialists)

Member, Presidents Council, University of North Texas

Pain, Stress and PTSD Research and Practice Consultant to the US Army and Veterans Affairs Medical Centers

Disclosure

Daniel L. Kirsch, PhD, DAAPM, FAIS

Chairman, Electromedical Products International, Inc.

A 29 Year Old Multinational Medical Device Company that Manufactures CES Devices

CES Devices are the Subject Matter of This Lecture

Abstract

Over the past decade the US Food and Drug Administration (FDA) has issued black box warnings for antidepressant medications due to the new established increase in suicidal ideation and other adverse effects. Simultaneously, research has shown that antidepressants may not be as effective as previously believed in people with mild depression. On top of that America is a nation at war and there has been a surge in mood disorders from the war effort both in our Service Members and civilian populations. America is in turmoil over its political leaders and the economic downturn. That, coupled with one of the highest unemployment rates in USA history has resulted in the need for a safer and more effective treatment for mood disorders and insomnia.

Cranial electrotherapy stimulation (CES) offers a viable solution for these problems and is being used and studied by the US Army, US Air Force, Veterans Affairs Medical Centers and by civilian physicians and psychologists for a diverse number of conditions including on label claims of anxiety, insomnia, depression, and off label claims of fibromyalgia and other centrally mediated pain disorders, post traumatic stress disorder, spinal cord injuries, mild traumatic brain injury and post concussion syndrome, attentional disorders and substance abuse. Mechanistic studies using IMRI have recently been completed at University of California at LA.
Objectives
This session will describe cranial electrotherapy stimulation (CES) as a primary, FDA-cleared prescriptive anxiolytic and antidepressive therapy, as well as a treatment for insomnia via treatment of the brain. It will cover the 40+ year history of CES in the USA, indications, contraindications, adverse effects and research (overview of over 144 human plus experimental animal studies and several meta-analyses) of this safe and effective brain therapy using mild electrical current of up to one half milliampere (500 microamperes).

1. The participant will gain an understanding of cranial electrotherapy stimulation (CES) theory and 40+ years of research for the commonly seen disorders of anxiety, insomnia and depression in both civilian and military contexts;
2. To be able to use CES and prescribe CES immediately following this lecture;
3. To be able to evaluate patient responses to CES;
4. To be able to manage patients on CES long term, including adverse effects.

Pre Test Questions
1. Which is true regarding scientific studies of CES:
   a) You can double blind CES studies just as well as drugs
   b) There are less than 50 published CES studies
   c) Subjects need to feel CES stimulation for it to be effective
   d) Researchers have found significant adverse side effects in CES studies

Pre Test Questions
2. Which of the following outcomes would not be expected from the use of CES:
   a) The patient could feel more relaxed, with a greater feeling of well being
   b) The patient could develop sudden onset tinnitus following CES treatment
   c) The patient’s psychoactive medications could be reduced by one third to one half following CES treatment
   d) The patient could report having the most restful sleep that he/she has had in years
Pre Test Questions

3. Which of the following has not been shown to respond to CES:
   a) Anxiety
   b) insomnia
   c) depression
   d) Acute Nephritis

We are still programmed for fight or flight but we don’t do that anymore – we just suffer the consequences.

Traditional View of Synaptic Activity

But only 2% of neuronal communication occurs at the synapse.

Electrical Synapses

Electrical synapses are formed by the direct connection of neurons via gap junctions (GJs) which are specialized cell-to-cell contacts consisting of a collection of intercellular channels.

The Neural Network

Synaptic transmission is communication between neurons accomplished by the movement of chemicals or electrical signals across a synapse. Information flows between the blue neurons through electrical synapses. Information flows from yellow neuron A, through blue neuron B, to pink neuron C via chemical synapses.

Electrical and chemical synapses differ fundamentally in their transmission mechanisms

(A) Electrical synapses are much faster but get weaker over distances. At electrical synapses, gap junctions between pre- and postsynaptic membranes permit current to flow passively through intercellular channels. This current flow initiates or inhibits generation of postsynaptic action potentials.

(B) Chemical synapses are slower but exhibit gain (strengthening signal). At chemical synapses, there is no direct flow of current from pre- to postsynaptic cell. Current can only flow across the postsynaptic membrane in response to the secretion of neurotransmitters which open or close postsynaptic ion channels after binding to receptor molecules.

Models of Receptor Activation

19th & 20th Century
The Current Theory: Structural Matching; Chemical / Molecular Physical Communication

The 3D nature of the ligand matches the receptor. Physical proximity induces receptor conformational changes which triggers the cascade of events prompting cell function.

The New 21st Century
Theory: Physical / Atomic Electromagnetic Communication (similar to tuning a radio)

Proximity favors co-resonance specific bioelectrical signals with frequencies that perfectly match the resonance of the receptor to amplify molecular conformational changes at all steps of the cascade including cell function, even from long distances.


Proposed Mechanisms of CES
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 thalamo-cortical activity, arousal, sleep/wake, altered sensory processing and induces EEG alpha rhythm. 5-HT can also act directly to modulate pain sensation in the dorsal horn of the spinal cord, alter pain perception, cognition and emotionality within the limbic forebrain. Legend:
Blue arrows: inhibitory interactions
Purple arrows: excitatory interactions
Gray arrows: supressed pathways/interactions
Acb: accumbens nucleus
LDT: laterodorsal tegmental nucleus of the brainstem
PPN: pediculo-pons nucleus of the brainstem
NE: norepinephrine
LC: locus ceruleus
5HT: serotonin


Effects of CES on Cerebrospinal Fluid and Plasma Neurochemicals

Beta-endorphins

98% in plasma
219% in CSF

Serotonin

15 - 40% in plasma
50 - 200% in CSF

The Effects of Electrostimulation on ATP Concentrations in Rat Skins

<table>
<thead>
<tr>
<th>Electrical Current in Microamperes</th>
<th>ATP Concentration in Micromols/gram</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>4.2 +/- 0.8</td>
</tr>
<tr>
<td>10</td>
<td>10.0 +/- 1.5</td>
</tr>
<tr>
<td>50</td>
<td>14.2 +/- 1.2</td>
</tr>
<tr>
<td>100</td>
<td>16.9 +/- 1.9</td>
</tr>
<tr>
<td>500 (P&lt;.001)</td>
<td>20.1 +/- 2.2</td>
</tr>
<tr>
<td>1,000 (1 mA)</td>
<td>15.0 +/- 1.8</td>
</tr>
<tr>
<td>5,000 (5 mA – below normal)</td>
<td>3.9 +/- 0.6</td>
</tr>
</tbody>
</table>


♦ Increase in alpha activity with a simultaneous decrease in delta activity
♦ P300 amplitude
♦ Positive shifts in alpha, beta, theta, and delta spectra in patients who were abnormal
♦ More alert on EEG
♦ In FFT spectral smoothing
♦ 10x in RMS amplitude
♦ P< 5-10 Hz during reaction time measurements
♦ Latency of alpha, beta, theta, and delta
♦ Slower frequencies with quality and quantity of alpha and amplitude in occipital-parietal leads
♦ Normal restoration of sleep rhythm
♦ EEG confirmation of sleep induction
♦ Alpha index which culminated in spindle and slow sleep
♦ In latency of sleep onset, in % of bed time awake, in total sleep time in stage 4 and total delta sleep

14 Electroencephalogram (EEG) Studies

- Schroeder MJ. Acquisition and quantitative analyses of EEG during CES and concurrent use of CES and neurofeedback. Doctoral dissertation, The Graduate School of the University of Texas at Austin, Pp. 1 - 191, 1999
- Schredl M. Acquisitions and qualitative analyses of EEG during CES and concurrent use of CES and transcranial magnetic stimulation. The Graduate School of the University of Texas at Austin, Pp. 11-125, 1998

References next slide
QEEG Changes in 30 Subjects Treated with 20 Minutes of CES

There is an increase in alpha activity with a simultaneous decrease in delta.
Blue = decrease  Red = increase

FFT Relative Power Difference (%)

Relative p-value topographical EEG map for CES. Statistically significant changes (P<.05 or better) after a single 0.5 Hz CES treatment are indicated by color; white indicates no significant change. Arrows indicate direction of change. Significant decreases were seen in delta & beta with significant increases in alpha.

Low Resolution Tomography

Paired t-test for 8 Hz LORETA: Significant differences after 20 minutes of 0.5 Hz CES
Effects of Cranial Electrotherapy Stimulation on fMRI Brain Activity in the Resting State

Regional deactivation associated with 0.5 Hz (blue) and 100 Hz (yellow)

Regions positively associated with current intensity for 0.5 Hz


Local maxima for significant between-groups activations

<table>
<thead>
<tr>
<th>0.5 Hz Deactivation:</th>
<th>Z score</th>
<th>x, y, z</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilateral paracingulate cortex</td>
<td>3.34</td>
<td>6, 12, 50</td>
</tr>
<tr>
<td>Pre- and post-central gyrus</td>
<td>3.20</td>
<td>-46, -10, 52</td>
</tr>
<tr>
<td>Bilateral precuneus</td>
<td>3.13</td>
<td>-2, -74, 46</td>
</tr>
<tr>
<td>Middle frontal gyrus</td>
<td>2.86</td>
<td>-30, 5, 54</td>
</tr>
<tr>
<td>Left frontal pole</td>
<td>2.85</td>
<td>-38, 52, 6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>100 Hz Deactivation:</th>
<th>Z score</th>
<th>x, y, z</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postcentral gyrus</td>
<td>3.16</td>
<td>41, -34, 58</td>
</tr>
<tr>
<td>Precentral gyrus</td>
<td>3.12</td>
<td>-22, -18, 70</td>
</tr>
<tr>
<td>Right superior parietal lobule</td>
<td>2.94</td>
<td>13, -55, 70</td>
</tr>
</tbody>
</table>

Research Methodology of 86 Pivotal (out of 126) Studies of CES

35 Double-Blind Placebo-Controlled RCT’s
9 Single-Blind
15 Controlled Study
6 Crossover
22 Open Clinical Trial
2 Retrospective Study
3 Case Study
13 Follow-up
How To Double-Blind CES Devices for RCT Research

- The current is locked in to a subsensory level of 100 µA by oscilloscope.
- The treatment time is locked at 1 hour to compensate for the reduced current dose.
- The frequency is locked to desired Hz.
- Half the wires are non-conducting.
- The controls are taped over so only the power-on button and battery compartments are accessible.
- Serial numbers are then randomized as per protocol (researchers must record serial number for each subject).

Topics of Scientific Research on CES

Number of Pivotal Scientific Studies:

- 42 Anxiety + 1 Phobia
- 26 Depression
- 27 Insomnia
- 10 stress

Anxiety...
Two Meta-Analyses Reconfirmed the Significance of CES Research for Treating Anxiety:

♦ University of Tulsa

♦ Department of Health Policy and Management, Harvard School of Public Health

Both Found CES Significantly Effective for Anxiety (P<.05)

Meta-Analysis of CES for Anxiety

- 40 Studies
- r Effect Size = .58
- 17 Double Blind Studies
- 34 of 40 studies have P<.05

- Effect sizes of r = .44 to r = .70 would be expected to be found in the next 99 out of 100 meta-analyses (400 Studies) of CES for anxiety
  - R effect size = % improvement based on 100%
  - Scale: .10 is small, .30 is moderate, .50+ is considered high


Anxiety Scores Before and After CES Based on 4 Studies Using Different Rating Scales


Presented at the Eighth International Montreux Congress on Stress, Montreux, Switzerland, February, 1996.

Situational Anxiety in Dentistry Following One Real or Sham CES Treatment


Response of Anxious Impulse Control Parolees


P< .02

Stress Measure Used

Situational Anxiety in Dentistry Following One Real or Sham CES Treatment

Hamilton Anxiety Scores
Changes from CES in Polysubstance Abusers
1 - 2 weeks of treatment


CES Significantly Reduced the Symptom Burden of GAD with a Decrease in HARS Score Similar to that Found in HARS Score Similar to that Found in Clinical Psychopharmacology Trials – APA 2009

Improvement of Stress Measures in 182 Anxious Patients Following 9, 25 Minute CES Treatments

Anxiety Scores Pre and Post CES and Sham CES in Alcoholic Patients

20 treatments over 4 weeks


Effect of CES on PTSD in Burned Outpatients
US Army Institute of Surgical Research

- COL Kathryn Gaylord
- MAJ Elizabeth A. Mann
- Alan Young, DO
- Scott Dewey, PT, CHT, OCS
- Larry Price, PhD

Completed

Outcomes of Cranial Electrotherapy Stimulation (CES) with Soldiers for Combat-related Symptoms
Brooke Army Medical Center (BAMC)

- LTC Mona O. Bingham
- Alice Inman, PhD
- Stacey Young-McCaughan, PhD

Completed
### PTSD in a 54 Year Old Male Veteran

Overall Decrease in Severity by 39% in One Month

<table>
<thead>
<tr>
<th>PTSD Symptom Scale – Interview (PSS-I)</th>
<th>PRE</th>
<th>POST</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSS-I (Range: 0-51)</td>
<td>34</td>
<td>13</td>
</tr>
<tr>
<td>Re-experiencing (0-15)</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Avoidance (0-21)</td>
<td>15</td>
<td>7</td>
</tr>
<tr>
<td>Increased Arousal (0-15)</td>
<td>12</td>
<td>4</td>
</tr>
</tbody>
</table>


### PTSD in a 38 Year Old Male Veteran

Overall Decrease in Severity by 43% in One Month

<table>
<thead>
<tr>
<th>PTSD Symptom Scale – Interview (PSS-I)</th>
<th>PRE</th>
<th>POST</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSS-I (Range: 0-51)</td>
<td>29</td>
<td>10</td>
</tr>
<tr>
<td>Re-experiencing (0-15)</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>Avoidance (0-21)</td>
<td>11</td>
<td>3</td>
</tr>
</tbody>
</table>


### Mood Disorders in ADD with 18 Month Follow-up

Mood and Cognitive Tests after 3 weeks and 18 months

- Depression
- State Anxiety
- Trait Anxiety
- Verbal I.Q.
- Performance I.Q.
- Full Scale I.Q.

Percent Improvement

\[ P < .001 \]

41% reduction in episodes of violence (P<.001); 40% reduction in episodes requiring restraint (P<.001) and seclusion (P=.02), and 42% fewer as-needed emergency medications (P<.05).

The decrease of 271 PRN med doses in 3 months saved $12,000 for these med expenses alone.

Depression...
**Meta-Analysis of CES for Depression**

- 20 Studies
- r Effect Size = .50
- 9 Double Blind Studies
- 14 of 20 studies have P<.05
- Effect sizes of r = .32 to r = .68 would be expected to be found in the next 99 out of 100 meta-analyses (200 Studies) of CES for depression
  - R effect size = % improvement based on 100%
  - Scale: .10 is small, .30 is moderate, .50+ is considered high


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**Effects of Antidepressant Treatments Above Placebo**

![Graph showing effects of antidepressant treatments above placebo.]


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**Effects of 1 and 2 Weeks of CES on Depression**

![Graph showing effects of 1 and 2 weeks of CES on depression.]

Effects of 2 and 3 Weeks of CES on Depression

4 Studies that used the POMS Depression/Dejection Scale

Pre CES

Post CES

Group Means

P< .05

P< .001

P< .03


Hamilton Depression Scores

Changes in Polysubstance Abusers

1 - 2 weeks of treatment

Pre CES

Post CES

Sham

Controls

P< .05

Bianco Jr., Faust. The efficacy of cranial electrotherapy stimulation (CES) for the relief of anxiety and depression among polysubstance abusers in chemical dependency treatment. Ph.D. dissertation. The University of Tulsa Graduate School, Pg. 1-224, 1994

CES Induced Changes in Beck Depression Inventory Over 7 Months in Alcoholic Patients

Pre-test

Mid-test

Post-test

P< .05

May, Brad & May, Carole. Pilot project using the Alpha-stim 100 for drug and alcohol abusers. August, 1990
Insomnia...

Meta-Analysis of CES for Insomnia

- 20 Studies
- *r* Effect Size = .64
- 7 Double Blind Studies
- 15 of 20 studies have *P* < .05

- Effect sizes of *r* = .41 to *r* = .87 would be expected to be found in the next 99 out of 100 meta-analyses (200 Studies) of CES for insomnia

- *R* effect size = % improvement based on 100%
- Scale: .10 is small, .30 is moderate, .50+ is considered high


CES for Insomnia With 2 Year Follow-up

- Sleep Onset Latency
- % Bed Time Awake
- Stage One Sleep
- Delta Sleep
- % Felt Very Rested in AM

3 Week RCT of CES for Insomnia in Fibromyalgia Patients

Sleep Pattern of Study Groups

<table>
<thead>
<tr>
<th></th>
<th>Pre Study</th>
<th>Sham Rx</th>
<th>Subsensation CES</th>
<th>Sensate CES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time in Sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tired or No Sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate Sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good, Very Restful Sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


CES May Improve Efficacy of Meds, and May Warrant Reduced Dose

The Use of CES to Potentiate Anesthesia in Surgery

Anesthetic Required

- Anesthesia Plus CES
- Anesthesia Alone

Fentanyl

* P<.05 N

N 50%

P<.05

N 62.5%

P<.05

N 75%

P<.05

0

10

20

30

40

50

60

70

80

90

100

2 Studies

Anesthetic Used

- Anesthesia Plus CES
- Anesthesia Alone

CES May Improve Efficacy of Meds, May Warrant Reduced Dose

Experimental Rat Studies of CES

Tail Flick Latency (TFL) studies

TFL as % of baseline

- Drug Alone
- Drug Plus CES

Revealed a significant increase in the potency of morphine (10 micrograms) with CES treatment (Krupisky, 1991).


Results were also obtained after intracerebroventricular injection of morphine (10 micrograms; analgesic effect increase from 152% to 267% with CES suggesting that CES potentiation of opiate-induced analgesia is centrally mediated.
## Comments on Follow-up from all CES Research Studies

### FROM PIVOTAL SCIENTIFIC STUDIES:

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>N</th>
<th>Subject Description</th>
<th>Authors’ Comments on Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brotman, Philip</td>
<td>1986</td>
<td>36</td>
<td>classical migraine pts</td>
<td>CES group responded significantly better than the other 2 groups over the 3 month follow-up.</td>
</tr>
<tr>
<td>Brovar, A.</td>
<td>1984</td>
<td>25</td>
<td>cocaine abusers</td>
<td>No CES patients had returned for treatment, while 95% of the CES refusers and 39% of the controls recurred in 6 to 8 months.</td>
</tr>
<tr>
<td>Flemenbaum, A.</td>
<td>1974</td>
<td>28</td>
<td>anxiety, depression, insomnia</td>
<td>Those who had beneficial results maintained them throughout the 6 month follow-up.</td>
</tr>
<tr>
<td>Hearst, E.D.</td>
<td>1974</td>
<td>28</td>
<td>outpatients unresponsive to medication</td>
<td></td>
</tr>
<tr>
<td>Heffernan, Michael</td>
<td>1995</td>
<td>20</td>
<td>generalized stress pts &gt;1 year, unresponsive to medication</td>
<td>1 week follow-up measures in the CES group showed significant carryover effects in EMG and HR</td>
</tr>
<tr>
<td>Magora, F.</td>
<td>1967</td>
<td>20</td>
<td>anxiety, depression, insomnia</td>
<td>A: Follow-up has continued for 8-12 months after treatment and has revealed no relapse.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>9</td>
<td>hospitalized polysubstance abusers</td>
<td>B: The asthmatic attacks stopped completely in 3 children and 4 months later the children felt well without taking any drugs.</td>
</tr>
<tr>
<td>Matteson, Michael</td>
<td>1986</td>
<td>62</td>
<td>CES graduate students, controls</td>
<td>A follow-up measure 2 weeks post study found that 11 of the 13 variables were still significantly improved in the treatment group.</td>
</tr>
<tr>
<td>Moore, J.A.</td>
<td>1975</td>
<td>17</td>
<td>anxiety and insomnia pts</td>
<td>a remarkable improvement” in their symptoms 2 - 3 weeks after CES.</td>
</tr>
<tr>
<td>Patterson, M.</td>
<td>1984</td>
<td>186</td>
<td>hospitalized alcohol and polysubstance abusers</td>
<td></td>
</tr>
<tr>
<td>Smith, Ray</td>
<td>1999</td>
<td>23</td>
<td>psychiatric outpatients with anxiety, depression, ADD</td>
<td>On 12 - 18 month follow-up the patients performed as well or better than in the original study.</td>
</tr>
<tr>
<td>Weiss, Marc</td>
<td>1973</td>
<td>10</td>
<td>insomnia patients</td>
<td>All differences found were maintained at the 2 week and 2 year follow-up.</td>
</tr>
<tr>
<td>Overcash, Stephen</td>
<td>1999</td>
<td>197</td>
<td>anxiety outpatients</td>
<td>On 6 - 8 month follow-up, 73% of the patients were “well satisfied with their treatment and had no significant regression or other anxiety disorder.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>78.5% were addiction-free (80.3% of drug addicts) 1 to 8 years after CES, with an average time in rehabilitation of only 16 days.</td>
</tr>
</tbody>
</table>

### Comments on Follow-up from all CES Research Studies (Continued):

- **Hoffman, Michael (1995)**: Follow-up measures in the CES group showed significant carryover effects in EMG and HR.
- **Magora, F. (1967)**: Follow-up continued for 8-12 months after treatment and has revealed no relapse.
- **Matteson, Michael (1986)**: Follow-up measure 2 weeks post study found that 11 of the 13 variables were still significantly improved in the treatment group.
- **Moore, J.A. (1975)**: A remarkable improvement” in their symptoms 2 - 3 weeks after CES.
- **Overcash, Stephen (1999)**: Follow-up, 73% of the patients were “well satisfied with their treatment and had no significant regression or other anxiety disorder.
- **Patterson, M. (1984)**: 78.5% were addiction-free (80.3% of drug addicts) 1 to 8 years after CES, with an average time in rehabilitation of only 16 days.
- **Smith, Ray (1999)**: On 12 - 18 month follow-up the patients performed as well or better than in the original study.
- **Weiss, Marc (1973)**: All differences found were maintained at the 2 week and 2 year follow-up.
Safety Considerations

Adverse Effects From CES
From 144 human studies encompassing 10,556 people where 8,792 received active CES:

9 myogenic/cervicogenic headaches (0.10%, 1:977)
6 cases of skin irritation at electrode sites (0.07%, 1:1,465)

These are both mild and self-limiting
If the current is set too high headaches, vertigo or nausea could develop and might endure for hours to days in people with a history of vertigo

If the treatment is stopped too soon, a heavy feeling accompanied by disorientation might persist for hours or even days. Always continue treatment until at least 2 minutes after the patient feels “light”

CES may lower blood pressure in essential hypertension

Primary Contraindications
Interference with pre-1998 implants (e.g., pacemakers and defibrillators) – No longer applicable?
Pregnancy – possible miscarriage and potential unsubstantiated legal arguments in case of developmental defects
Embryofetal Effects of CES on Rats

844 fetal rats had 1 hour/daily CES throughout their pregnancy at 10, 100, or 1,000 Hz, 1 volt, 125 uA via ear tag electrodes. Autopsy revealed no congenital anomalies.

- More pregnancy resorptions and fewer offspring in all groups, but only significant in the 1,000 Hz group.
- Average fetal weight and brain weight were inversely proportional to frequency.
- Behavior resembled CES in humans, even in this aggressive species; treated rats were not as active as the controls, so the decrease in fetal weights may be due to lowered food intake.

**Conclusion:** CES may be embryoletal in the very early stages of pregnancy and might cause some miscarriages, but there is no evidence of fetotoxic effects.

Litha, Bert and Patterson, Margaret A. Embryofetal effects of neurolelectric therapy. Electro and Magnetoence: 15(3)/4, 1996.

Cranial Electrotherapy Stimulation (CES)

4-Step Procedure:
1. Wet Electrodes
2. Place on Ear Lobes
3. Turn on CES Device
4. Set to Comfortable Current for 20 Minutes to 1 Hour

The application of low level current, (usually <1 mA) applied across the head for medical or psychological conditions, or just as an aid in relaxation

FDA cleared by Rx in the USA for anxiety, depression and insomnia
Approved for OTC sale worldwide outside of the USA

Feelings Experienced During CES Treatment Stages

Dosage equals time inversely proportional to current level (i.e., less current requires longer treatment time per session)

- ALERT: Some patients feel light right away
- LIGHT FEELING: No “fibrofog”, vision is clear, and energetic as if the patient slept all night
- 20 minutes to 1 or more hours
- SLEEPY: HEAVY, GROGGY, EUPHORIC (never stop here)

TIME
For Annotated Abstracts of All the CES Research

Post Test Questions
1. If a patient reports feeling “heavy” during a CES treatment:
   a) Stop the treatment immediately for that day
   b) Continue until 2 minutes after the patient feels light
   c) Continue for an additional 2 minutes after the heavy feeling then stop
   d) Discontinue CES permanently because this patient is not a good candidate for CES

Post Test Questions
2. CES treatments have been shown to:
   a) Increase relaxation and increase alertness
   b) Increased alpha brain waves and decreased delta brain waves on EEG
   c) Reduce general anxiety disorder similar to clinical psychopharmacology trials
   d) All of the above
Post Test Questions

3. Which of the following has not been shown to respond to CES:
   a) Anxiety
   b) Insomnia
   c) Depression
   d) Alzheimer's Disease

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Are Your Patients Stressed? Anxious? Depressed? Having Difficulty Sleeping?

Why Not Try CES?
Questions? email: dan@epii.com
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Dr. Daniel L. Kirsch is a world renowned neurobiologist. He was board-certified by the American Academy of Pain Management in 1990 and named a Fellow of the American Institute of Stress in 1997. In 2008 he was awarded the Richard S. Weiner Educator of the Year Award in Pain Management by AAPM. He is also a Member of the American Board for Certification in Homeland Security, the International Society for Neurotherapy and Research and Inter-Pain (Switzerland/Germany). He is an Editor of the Journal of Neurotherapy and the Electromedical Department Editor of the journal Practical Pain Management. He is an expert research consultant at the Houston VAMC, Brooke Army Medical Center and the US Army Institute for Surgical Research. He has presented at the San Antonio Trauma Symposium, Force Health Protection, the American Veterinary Medical Association, and many other civilian medical conferences including the American Academy of Pain Management, American Academy of Orthopedics Medicine, Inter-Pain, American Institute of Stress, International Society for Neurotherapy and Research, American Association for Sensory Medicine, Sedona Psychiatric Association Psychoneurotherapy Update, American Society for Pain Management Nursing, American Academy of Anti-Aging Medicine, Southwest Symposium, and he conducts Grand Rounds at military and civilian hospitals worldwide. In May of 2008 he was in China working with the mental health teams for the survivors of the great earthquake in Sichuan. He served as Clinical Director of The Center for Pain and Stress Related Disorders at Columbia-Presbyterian Medical Center, New York City, and of The Sports Medicine Group, Santa Monica, California, and was the guest of the Minister of Health of Kuwait in 1992 where he taught pain and stress management for physical and mental trauma from the Persian Gulf War. Dr. Kirsch is the author of articles and books including: The Science Behind Cranial Electrotherapy Stimulation (2nd Ed., Medical Scope Publishing, 2002) and Schmerzen lindern ohne Chemie CES, die Revolution in der Schmerztherapie (Internationale Ärztegesellschaft für Energiemedizin, Austria 2000; in German). In addition to his consulting and lecturing, Dr. Kirsch is Chairman of Electromedical Products International, Inc. of Mineral Wells, Texas.