Research Abstracts

A Pilot Study of Cranial Electrotherapy Stimulation for Generalized Anxiety Disorder

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This is an IRB approved study of cranial electrotherapy stimulation (CES) for DSM-IV diagnosis of generalized anxiety disorder (GAD). Twelve patients (9 females and 3 males) from 29 to 58 years old (mean of 42.83 ± 10.27) were enrolled from the University of California Los Angeles Anxiety Disorders Program at the Semel Institute for Neuroscience and Human Behavior. Inclusion criteria was a Hamilton Rating Scale for Anxiety (HAM-A) of ≥ 16 and a score of < 17 on the Hamilton Rating Scale for Depression (HAM-D-17) at baseline. Exclusion criteria were Axis I disorders other than GAD, mental retardation, neurologic impairments, substance abuse, suicidal ideation, personality disorders, and pregnancy. Those on stable, therapeutic range SSRI or SNRI medications for at least 3 months and still symptomatic and those on benzodiazepines PRN of no more than 2 doses per week were permitted to take part in the study. Five patients (41.7%) had been taking psychotropic medications (venlaflaxine, N = 2; alprazolam, N = 2; and lorazepam, N = 1). Two had failed 2 previous adequate trials of SSRIs.

Alpha-Stim CES (Electromedical Products International, Inc., www.alpha-stim.com) was administered for 6 weeks in an open label design at home for 60 consecutive minutes daily between 3:00 PM and 7:00 PM with waveform parameters set at 0.5 Hz and a current level determined to be just below the reported threshold of sensation by the investigator during the initial visit. All 12 chose 300 µA as just below the sensation threshold.

Three discontinued after baseline evaluation due to dizziness (N = 2) and headache (N = 1). The remaining 9 were compliant. Data was analyzed on the entire intent to treat sample using last observation carried forward. A 1-sample paired t-test was used to compare endpoint to baseline means on the HAM-A. CES was associated with a significant decrease in HAM-A scores from baseline of 21.25 ± 5.82 to endpoint of 12.67 ± 5.47 ($t = 3.083$, $p = .01$). Six patients had met criteria of a 50% decrease in HAM-A scores (50% of the intent to treat sample and 67% of completers). These patients also had a significant improvement in the Clinical Global Impressions-Improvement (CGI-I) scale to a score of 1 (“much improved”) to 2 (“very much improved”) and therefore considered responders to treatment. One additional patient significantly improved in anxiety scores but did not meet the criteria for response. HAM-D-17 scores also changed significantly from 10.50 ± 15.01 at baseline to 6.00 ± 3.64 ($t = 3.01$, $p = .01$) as did the FDADS-Anxiety subscale scores from 30.58 ± 11.24 at baseline to 23.83 ± 7.57 ($t = 2.35$, $p = .039$).

The adverse effects consisted of headaches and nausea were most likely due to the fixed level of current and are suggestive of the presence of a central nervous system effect. Clinically the current can be reduced for each individual to avoid such effects.

The authors concluded that this study suggests that CES may reduce symptoms of GAD. The efficacy and overall tolerability of CES suggest that the clinical use of CES and its putative mechanisms of action clearly warrant investigation in further studies.

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