

# Studying the Acute Efficacy of Cranial Electrotherapy Stimulation in Patients with Anxiety: A Cross-sectional Study

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## Abstract

**Introduction:** Patients with anxiety disorders are encountered commonly in clinical practice. Certain studies have highlighted the effectiveness of cranial electrotherapy stimulation (CES) in addressing both key aspects of anxiety symptoms. This study seeks to evaluate the immediate effectiveness of CES in managing anxiety symptoms. **Materials and Methods:** The study involved patients having anxiety and were administered one CES session for 20 min. The efficacy was evaluated by measuring physiological markers of anxiety along with subjective ratings pre and post the session. **Results:** 100 participants (61 females and 39 males), aged 18–80 years, were included with majority diagnosed with major depressive disorder accompanied by anxious distress. Statistically significant improvement in physiological markers of anxiety as well as subjective improvement in anxiety levels with just one session of CES was reported. **Conclusions:** CES is safe treatment option for anxiety disorders, and larger sample size studies to establish its efficacy are warranted.

**Keywords:** Acute effect, anxiety disorders, cranial electrotherapy stimulation, depression, pain

## INTRODUCTION

Anxiety disorders affect millions worldwide, with a global prevalence of 7.3%.<sup>[1-3]</sup> Treatment is often challenging, as patients may respond variably to medications and struggle with compliance, potentially due to concerns about side effects and dependency.<sup>[2,4]</sup>

Noninvasive brain stimulation techniques, such as cranial electrotherapy stimulation (CES), present promising alternatives.<sup>[5-7]</sup> CES, an FDA-approved treatment, uses low-amplitude transmitting microcurrents between 0.5 and 50 mA, applied through electrodes on sites such as earlobes, temples, or mastoid processes to modulate nervous system activity.<sup>[2,5,7-9]</sup> CES effectively reduces anxiety, insomnia, and depression, with meta-analyses confirming a moderate effect size for anxiety reduction.<sup>[2,5-7,9,10]</sup> CES also benefits depressive symptoms in anxiety patients, though to a lesser degree.<sup>[9,10]</sup>

Studies suggest CES works by causing cortical deactivation, increasing relaxation-related alpha activity, and reducing fatigue-associated delta and beta activity. It also alters neurohormones and neurotransmitters, raising levels of

beta-endorphins, serotonin, and melatonin while lowering cortisol.<sup>[2,6-8,10,11]</sup> CES is cumulative, with many patients noting improvement even after one session.<sup>[7]</sup> It can be used alongside medications, psychotherapy, hypnosis, and biofeedback and is cost-effective, easily applicable in clinical and home settings, and well-tolerated, with minimal side effects reported.<sup>[2,5-7,11]</sup>

Despite CES's global relevance, data on its efficacy in India are limited, highlighting a need for further research on brain stimulation for anxiety in Indian populations. This study aims to address this gap by assessing CES's acute efficacy in treating anxiety among Indian individuals.

## MATERIALS AND METHODS

Institutional ethics committee approval and written informed consent from participants were taken before the start of the study. This study included patients who presented with anxiety symptoms at the psychiatry outpatient department of a tertiary

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general hospital. Participants were selected based on anxiety symptoms associated with various medical or surgical causes or mental disorders. Psychiatric diagnoses were made according to the Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> Edition.<sup>[12]</sup> Eligibility was restricted to patients aged 18 years and above, currently experiencing anxiety symptoms and willing to consent for the CES therapy. Those who did not consent for the said therapy were excluded. This was a single-centered, cross-sectional study conducted over 2 months from September 01, 2024, to October 31, 2024.

The patients were provided with an explanation of CES as a treatment option and were given the choice to opt for it voluntarily. Participation in the study and the decision to undergo CES treatment were entirely voluntary. Patients were administered the electrical stimulation for 20 min. The electrodes were placed on the bony mastoid prominences behind the ears, following the cleaning of the application site with medical spirit. The portable machine used was the GoRoga AntiStress Wearable Device. The machine has 3 levels of voltage range (50, 350, and 500  $\mu$ V). The level of impulse was tailored based on the sensations reported by patients at the contact points once the machine was activated. There were no changes made to the patients' existing medical treatments before initiating CES.

Data was collected using a semistructured questionnaire designed for the purpose of the study which was validated by 5 experts in the field. The questionnaire was validated by 5 experts in the field. Parameters such as blood pressure (BP), heart rate, oxygen saturation, and visual analog scale (VAS) rating of anxiety were measured before and after the 20-min session. The voltage applied throughout the session was noted. Data collected were entered in excel sheet and subjected to statistical analysis. Paired *t*-test was applied to determine if the means of pre- and postsession parameters were significantly different. Two-tailed *P* values where *P* < 0.05 were considered significant for all statistical analyses.

## RESULTS

Our study included 100 patients with age range of 18–80 years. The mean age of the patients was  $38.55 \pm 14.79$  years. Sixty-one (61%) female patients and 39 (39%) male patients were part of the study [Table 1]. 58 patients (58%) had a diagnosis of major depressive disorder with anxious distress, 19 (19%) had panic disorder, 17 (17%) had generalized anxiety disorder, and 6 (6%) had adjustment disorder with anxiety. Since each patient had unique diagnoses and treatment regimens, the specific details of their medication history were not addressed. All patients received a 20-min CES session. The presession mean systolic BP was  $124.41 \pm 8.24$ , whereas postsession, it was  $118.20 \pm 7.51$ ; presession diastolic BP was  $79.98 \pm 6.03$ , and postsession, it was  $77.46 \pm 5.55$ ; presession heart rate mean was  $88.82 \pm 7.90$ , whereas postsession heart rate mean was  $82.24 \pm 6.58$ ; and presession VAS rating was  $7.15 \pm 0.82$ , with postsession rating being  $3.46 \pm 0.80$ . The results of the paired *t*-test indicated a statistically significant difference between the pre- and

postsession scores (*P* < 0.01), thereby showing efficacy [Table 2]. None of the patients experienced major side effects.

## DISCUSSION

The study revealed that CES as a treatment for relieving objective markers of anxiety as well as subjective anxiety was effective in the patients studied. Similar results were drawn by Ching *et al.* in a systematic review of CES for anxiety symptoms, which found efficacy of CES in primary anxiety as well as anxiety associated with depressive disorders,<sup>[9]</sup> in line with our findings of significant improvement in patients both with and without depression. Subjective decrease in anxiety was found in our study, in line with findings by Overcash, who found significantly decreased perceived anxiety scores in their study on patients with acute anxiety disorders.<sup>[13]</sup>

A meta-analysis by Chung *et al.* showed therapeutic efficacy of CES being significantly better than that in the control groups for anxiety,<sup>[10]</sup> in keeping with our findings of significant decreases in anxiety parameters post-CES. CES was associated with a significant decrease in Hamilton Anxiety Rating Scale (HAM-A) scores in Bystritsky *et al.*'s pilot study in generalized anxiety disorder,<sup>[6]</sup> corroborative with our findings of improved physiological markers of anxiety and subjective VAS rating.

A recent study by Griffiths *et al.* also points toward significant improvement in anxiety scores and health-related quality of life using scales such as generalized anxiety disorder-7 and patient health questionnaire-9,<sup>[14]</sup> in keeping with our study which also shows statistically significant improvement in anxiety

**Table 1: Demographic details of the study population**

Parameters ( <i>n</i> =100)	Mean $\pm$ SD/frequency (%)
Age (years)	38.55 $\pm$ 14.79 (18–80)
Education (years)	6.55 $\pm$ 4.62 (0–17)
Gender	
Male	39 (39)
Female	61 (61)
Employment status	
Employed	34 (34)
Unemployed	15 (15)
Homemaker	51 (51)
Marital status	
Married	86 (86)
Unmarried	14 (14)

SD: Standard deviation

**Table 2: Comparing various clinical parameters before and after the session**

Parameter ( <i>n</i> =100)	Presession	Postsession	<i>t</i>	<i>P</i>
Systolic BP	124.41 $\pm$ 8.24	118.20 $\pm$ 7.51	17.80	<0.01*
Diastolic BP	79.98 $\pm$ 6.03	77.46 $\pm$ 5.55	10.86	<0.01*
Heart rate	88.82 $\pm$ 7.90	82.24 $\pm$ 6.58	17.95	<0.01*
VAS (out of 10)	7.15 $\pm$ 0.82	3.46 $\pm$ 0.80	46.11	<0.01*

\*Statistically significant. BP: Blood pressure, VAS: Visual analog scale

measures, for which we did not utilize screening instruments but instead relied on objective physiological parameters of anxiety and subjective rating in form of VAS.

Original research by Hefiernan recorded improvement in various physiological stress responses such as heart rate, skin temperature, and electromyogram with just one session of CES similar to our study with similar findings in heart rate reduction after a single CES session.<sup>[15]</sup>

No side effects were reported in our study, akin to research by multiple reviews and meta-analyses by researchers like Ching *et al.*, Marmann and Wiatrek, and Chung *et al.*,<sup>[8-10,16]</sup> highlighting the utility of this modality. Many patients with anxiety encounter side effects of anxiolytic drugs, such as excessive sedation, which can lead to dependence or noncompliance with therapy. Instead, CES is safe to use as a stand-alone alternative therapy, in conjunction with supportive counseling, or as a supplement to medication.<sup>[7]</sup>

Although the precise way that CES works to treat anxiety is still unknown, it appears that certain neurons in the brainstem are activated by the microcurrents and that these cells produce neurotransmitters such as dopamine, serotonin, and norepinephrine. After being dysregulated by stress, regulated production of these neurotransmitters helps return the brain to its normal biochemical balance. Studies have demonstrated that CES directly affects the brain's reticular activating system, which is crucial for controlling brain wave activity. CES is theorized to increase alpha frequencies and decrease delta and beta frequencies, improving relaxation along with mental clarity.<sup>[6-8,10]</sup> The resulting calm state brought on by CES aids in stress reduction and mood stabilization.

### Study strengths and limitations

The strengths of our study include it being one of the few studies on CES in the Indian population. Another strength was that not only subjective parameters but also objective values were analyzed pre- and postintervention, to uphold the result strength. Our study had limitations in the form of small sample size of 100 clinical cases, no control group was present, and the sample population was not homogeneous.

Larger studies, involving controlled conditions and comparisons between patients receiving pharmacotherapy and those who are not, will provide a clearer understanding of the efficacy of CES. Furthermore, our study measured acute effect of CES; hence, there is a need to conduct further studies testing the efficacy of CES after several sessions.

### CONCLUSIONS

Our study shows the efficacy of CES in acute management of anxiety symptoms. Over the course of a single 20-min session, significant decrease in objective as well as subjective markers of anxiety points toward the effectivity of this modality, importantly with no accompanying side effects. CES has a big potential for being a quickly effective, portable, easy-to-use adjunct to drug therapy and as a potentially independent modality of treatment for people prone to side effects of other

treatments. The findings of this study support the need for further larger studies in diverse patient populations to help us establish the place of CES in treatment algorithms for anxiety concurrent with any other mental or physical illnesses.

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### Conflicts of interest

There are no conflicts of interest.

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