Treating Spinal Cord Injury Pain with Cranial Electrotherapy Stimulation

G Tan, PhD[1,2] DH Rintala, PhD[1,2] J Thornby, PhD[1,2] J. Yang, MD[3] WH Wade, MD[1,2] C Vasilev[4]

[1]Michael E. DeBakey Veterans Affairs Medical Center, [2]Baylor College of Medicine, Dept. of PM&R

[3] Washington, DC Veterans Affairs Medical Center, [4]University of Texas M. D. Anderson Cancer Center

INTRODUCTION

Chronic pain is a serious problem following spinal cord injury (SCI) and a major impediment to successful rehabilitation. Cranial electrotherapy stimulation (CES) has been shown to "normalize" neurotransmitter homeostasis, stimulate the hypothalamic-pituitary axis by increasing IGF-1 production, and bring neurotransmitters in stressed subjects to normal levels of homeostasis. Recent studies have shown CES to be effective in reducing pain and enhancing quality of life of chronic pain sufferers with a number of pain conditions, including fibromyalgia, which has a centrally mediated pain component. A pilot study was undertaken to assess the effectiveness of CES in persons with SCI.

CHARACTERISTICS OF THE SAMPLE

	GROUP	
	SHAM CES	ACTIVE CES
Number	20	18
	Mean	Mean
Age (years)	56.6	56.0
Time Since Onset of SCI (years)	19.7	20.1
	Percent	Percent
Male gender	100	100
Race/Ethnicity		
White	65	67
African-American	20	28
Hispanic	15	6
Educational Status		
High School or Less	35	22
Some College or More	65	78
Marital Status		
Married	50	44
With Significant Other	5	6
Neither	45	50
Level and Completeness of SCI		
Tetraplegia (ASIA A, B, or C)	20	29
Paraplegia (ASIA A, B, or C)	50	29
All ASIA D	25	43
Cervical Spondylosis	5	0
Type of Pain		
Neuropathic	55	67
Musculoskeletal	45	33

There was no significant difference between the Sham and Treatment groups on any of the characteristics listed in this table.

PROCEDURE

1. Recruited veterans with SCI known to have pain from the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) SCI registry via telephone
2. Obtained informed consent and pre-treatment data in person at the MEDVAMC (See Measures below)
3. For each participant's worst pain (study target pain), a physician determined whether it was neuropathic or musculoskeletal
4. Trained participants in the use of the cranial electrotherapy device and daily pain rating sheet
5. Randomized (double blind) participants into Sham and Active groups
6. Participants used the device one hour per day for 21 consecutive days and completed the Daily Pain Rating Sheet before and after each session
7. Contacted participants weekly by telephone to assure compliance, identify and solve any problems, and answer questions
8. Obtained post-treatment data in person at the MEDVAMC and collected the device and the daily pain rating sheet
9. Provided an open-label device to Sham group to use for another 21 days, which allowed participants to adjust the level of stimulation
10. Obtained post-open-label data from Sham group in person at the MEDVAMC and collected the device and the daily pain rating sheet

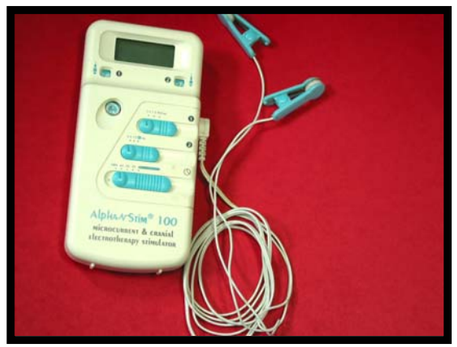
MEASURES

1. Demographic information
2. Level and completeness of injury from medical records
3. Brief Pain Inventory (BPI) – Pain Intensity and Pain Interference scales
4. Daily Pain Rating Sheet – Numeric pain intensity on 0 – 10 scale before and after each daily session

This pilot study was sponsored by the Veterans Affairs Rehabilitation Research and Development Service Center of Excellence on Healthy Aging with Disabilities

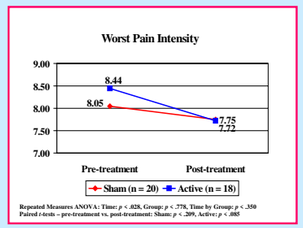
DEVICE

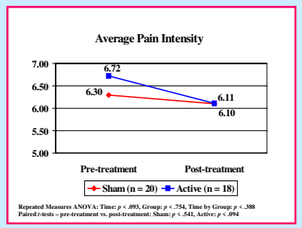
1. AlphaStim® Cranial Electrotherapy Stimulator
2. Treatment group received 100 micro amp sub-sensation cranial electrotherapy stimulation (CES)
3. Device for Sham group delivered no CES

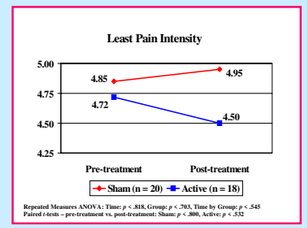


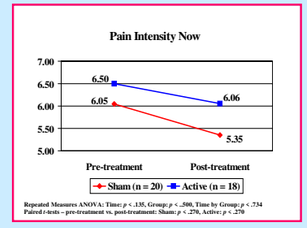
RESULTS

Brief Pain Inventory - Pain Intensity – 0 to 10 Scale



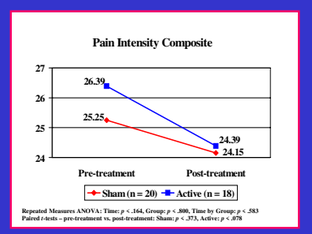




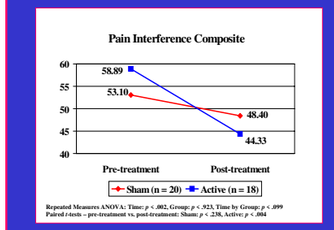


Pain decreased more in the Active group than in the Sham group for pain at its worst, average pain, and least pain, however the differences were not statistically significant. Change from pre- to post-treatment within the Active group approached significance ($p < .10$) for worst and average pain.

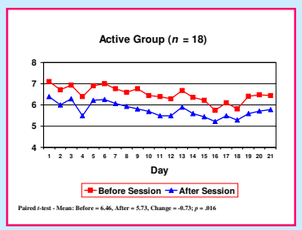
Composite Pain Intensity (0 to 40 scale) and Pain Interference Scores (0 to 100 scale)

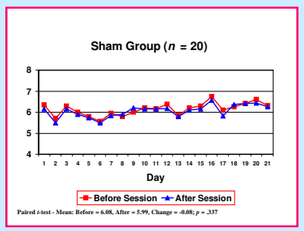


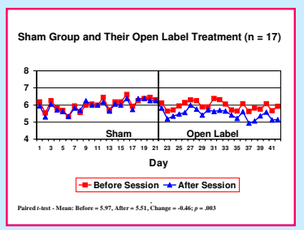
Decrease in pain intensity approached significance in a within-group paired *t*-test. Pain interference in daily activities had a main effect of time and a time by group interaction. Interference decreased significantly in the Active CES group, but not in the Sham CES group.



Pain Ratings Before and After Each Daily Session – 0 to 10 Scale







Pain was reduced after the sessions in the Active group and in the Open-Label treatment for the Sham group. An independent-samples *t*-test comparing Active and Sham average daily change was significant (-.73 vs. -.08, $p = .034$).

CONCLUSIONS

Based on reported pain reduction pre and post each session, the Active CES treatment was found to be significantly more efficacious than the Sham treatment with a moderate to large effect size (Cohen's $d = .76$). Future studies will be needed to evaluate the long-term effectiveness of CES.