A Retrospective Review of Patient Perception of Alpha Stimulation Treatment

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Background

Mild Traumatic Brain injury (mTBI) is among the most common injuries seen in U.S. personnel serving in Afghanistan and Iraq. It is estimated that 15%-20% of service members have experienced mTBI during deployment in these theaters. This does not include the many events that happen during routine training and off-duty activities, and many of these personnel have a history of more than one traumatic event.

The sequelae of mTBI range from cognitive disorders such as memory loss, affective disorders including depression and anxiety, and physical complaints of sleep disorders, headaches, chronic pain, and tinnitus.[1]

New treatments that have minimal side effects are being sought to alleviate symptoms associated with mTBI. The Intrepid Spirit Concussion Recovery Center (ISCRC) at Naval Hospital Camp Lejeune provides an integrative medicine approach that includes interdisciplinary conventional and complementary medicine in a collaborative environment following mTBI. Patients are referred for treatment based on reported symptoms and an openness to integrative medicine. Cranial electrotherapy stimulation (CES) uses a non-invasive prescriptive medical device that applies pulsed, low amplitude electrical current to the head via electrodes placed on the ear lobes.[2] Currently, the Alpha Stim M model (Figure 1) is being used for CES.

Earlier research has supported the incorporation of complimentary therapies into traditional pain management programs for veterans. This treatment has been more accepted than other mental health treatments and can be used to provide self-treatment at home for individuals in rural areas where access to treatment was a barrier.[3]

Objectives

To determine if cranial electrotherapy stimulation (CES) effectively reduces self reported symptoms in a military population of individuals under treatment for mild traumatic

Methods

A retrospective study of self reported data was conducted on 80 subjects who received CES treatment between 01 APR 2014 and 31 MAR 2015. Subjects were seen for no more than 10 sessions and rated their symptoms pre- and post-treatment on a scale of 0-10 (0 being no symptoms and 10 feeling they need to be hospitalized). The following symptoms were assessed: anxiety, depression, headache, tinnitus, and pain (other than headache).

Subjects were also asked to track hours of sleep from the previous night and hours of other symptom relief after the treatment session. Data was then extracted into a de-identified database and assigned a case number.

The data tested to be non-parametric and results were analyzed using the Friedman Test. The Friedman is a non-parametric alternative to the one-way repeated measures ANOVA test and is based on ranking. A Bonferroni correction was used for the multi-variate analysis.

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Figure 1

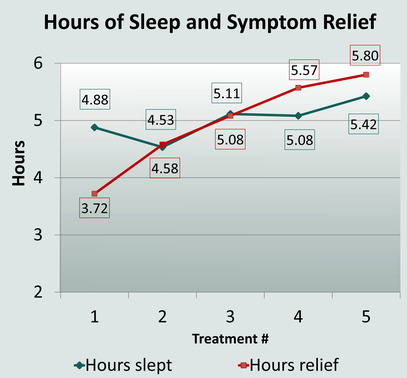
The Manufacturer of the Alpha Stim @CES devices is Electromedical Products International Inc. (2014). The Alpha Stim M model is currently being used at the ISCRC. This model features ear clips that provide Cranial Electrotherapy Stimulation along with probes for site-specific pain.[4]

Figure 2

Treatment 1 through Treatment 5 (n=49)	p value
Hours Slept	0.001
Hours Relief*	0.001
Pain Before	0.437
Pain After	0.550
Headache Before	0.486
Headache After	0.208
Anxiety Before	0.166
Anxiety After	0.578
Depression Before	0.040
Depression After	0.499
Tinnitus Before	0.562
Tinnitus After	0.671

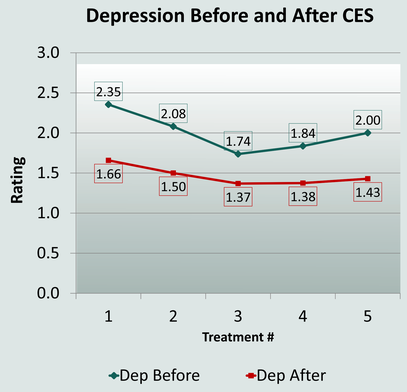
**Treatment 1 was excluded for lack of data*

Figure 3



Graphic representation of hours slept and hours of relief with CES

Figure 4



Graphic representation of depression before and after CES

Data obtained from protocol NHCL 2015.0011 "An Outcome Evaluation of Alpha Stimulation Therapy on Active Duty Service Members With a Concussion History" between APR 2014 and MAR 2014.

Results

This study evaluated CES over a period of 10 weeks. Initially, patients were scheduled to receive 10 consecutive treatments; however, there was a high dropout rate and the protocol was modified to administer 5 treatments. The protocol began with 80 subjects and finished with 8 after 10 treatments. We maintained 49 subjects through the first 5 treatment sessions and this data was used for analysis, which maintained statistical and clinical significance.

Self reported results after treatment demonstrated that hours slept, hours of other symptom relief, and depression were all significantly improved (Figure 2). Although none of the other individual symptoms (headache, pain, tinnitus, and anxiety) were significantly altered, as a composite group, they were. Hours of sleep before treatment 2 and 3 remained significant when using the Bonferroni adjustment for multiple comparisons.

Symptoms improved within treatment sessions but the affects of long term sustainability was not found.

Conclusions

CES therapy is a beneficial adjunct that can be used as a complimentary therapy as part of the treatment of mTBI symptoms, including insomnia, depression, and the cluster of headache, pain, tinnitus and anxiety. CES should be included in the integrative medicine treatment of mTBI along with standard pharmacotherapy and psychotherapy as an complimentary therapy for short term relief of symptoms.

We found that the use of CES treatment was shown to improve symptoms of insomnia, depression, and the cluster of headache, pain, tinnitus and anxiety temporarily. Due to our high dropout rate, however, we were not able to conclude that these symptoms were sustained long term.

Future Direction

Preliminary findings show temporary improvement of mTBI symptoms using CES. There are multiple avenues for further exploration .

1. A randomized controlled trail using CES and a sham device to ascertain if there is a placebo effect in mTBI patients using a device.
2. Trials of long term CES therapy to develop an effective duration and interval of treatment sessions to sustain therapeutic benefit.
3. Comparison of in clinic versus at home or self-directed CES treatment.
4. Identification of particular pharmaco or psychotherapy regimens that CES can be paired with for synergistic effect.

References

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