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Safety and effectiveness of cranial electrotherapy stimulation in treating children with emotional disorders

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Abstract
AIM: To evaluate the safety and effectiveness of cranial electrotherapy stimulation (CES) in treating children with emotional disorders.
METHODS: Thirty-two children with emotional disorders were treated with CES by using Alpha-Stim 100 instrument in the psychological clinic of Beijing Children's Hospital from April 2003 to October 2004, and they were followed up for 6~12 months.
RESULTS: 13 cases had significant effect, 17 cases had effect, and the effect was invalid in 2 cases, and the total effective rate was 94%; there was no missing case. 26 cases were followed up by means of telephone visit and regular reexamination in the clinic at 3, 6, 9 and 12 months after the treatment respectively; among them, 24 cases had long lasting efficacy with relieved or eliminated symptoms, and 2 cases had insignificant efficacy without significant emotional improvement and with relapse of symptom.
CONCLUSION: CES is a new technique for the treatment of emotional disorders; it has the advantages of fast effect, significant efficacy, as well as the characteristics of accumulative effect, fewer relapse and no side effects.

KEY WORDS: Children; Emotional disorders; Cranial electrotherapy stimulation

0 Introduction

According to studies in recent years, cranial electrotherapy stimulation (CES) can improve or recover abnormal brain waves, and stimulate the release of endorphins in human body [1]. CES is capable of exciting the parasympathetic nervous system and correspondingly inhabiting the sympathetic nervous system [2], therefore adjusting the emotions and physiological status of human body, relieving tension and stress and improving sleep quality. Consequently, multiple efficacies of clinic treatment can be produced. At abroad, there have been thousands of reports on clinic application of CES that it can fast and effectively control the anxiety and depression state of

patients and treat psychosomatic disorders mainly reflected as pain and insomnia, with long lasting efficacy and accumulative effect, and without toxic and side effects which may exist in drugs [1, 2]. There are also reports on the application of CES in treating children [3, 4]. However, the studies in this area are still rare in China. To find a new method for treating children with emotional disorders and evaluate its safety and effectiveness, 32 children with emotional disorders were treated with CES by using Alpha-Stim 100 instrument; their conditions before and after the treatment were compared and observed, and they were followed up after the treatment.

1 Subjects and Methods

Design: Comparison of the patients' conditions before and after the treatment, taking children as the subjects of this study.

Organization: the neurorehabilitation center of an affiliated hospital of a university of medical sciences.

Subjects: The subjects of this study were children who visited doctors in the psychological clinic of Beijing Children's Hospital. Inclusion criteria: Those who were diagnosed to meet CCMD-3 [5]. The cases were initially diagnosed as mental disorder by an attending physician in the specialty of child psychosis after consultation with and evaluation by a professional psychologist. Exclusion criteria: anxiety and depression state caused by schizophrenia or other physical diseases. Drug therapy and psychotherapy were not applied. 32 cases were clinically diagnosed as mental disorder; among them, 15 cases were male and 17 cases were female; male to female ratio: 1:1.3; age: 9 ~17 years old, 13±2 years old on average.

Designer, performer and evaluator: The first and second authors were the designers of this experiment, and the third, fourth and fifth authors were the performers and evaluators. They have all received professional training on psychological counseling and psychotherapy, with vocational qualification certificates in psychotherapy and psychometrics issued by such institutions as the Ministry of Health of the People's Republic of China, and the Institute of Psychology, Chinese Academy of Sciences. The single blind method was adopted for the performers, evaluators and data statisticians.

Methods: Psychological test: all subjects voluntarily accepted treatment with CES in the context of informed consent. Evaluation with self-rating anxiety scale (SAS) and self-rating depression scale (SDS) was carried out. The treatment observation tables were filled in uniformly.

Physiological indexes: the skin temperature, blood pressure and pulse of each subject were recorded before and after each treatment.

Treatment with CES: The Alpha-Stim 100 instrument developed and produced by EPI in the U.S. was used. During treatment, the room should be quiet with dim light; curtains should be drawn; patient should relax their bodies, dismiss distracting thoughts, close their eyes and sit down to receive the treatment. The current intensity of the Alpha-Stim 100 instrument was adjusted to be 200~600μA and the frequency to be 0.5Hz, depending on the comfortableness of the patients. A course of treatment lasted 5 days, 1 time/day, 20min/time. Among the 32 cases, the shortest period of treatment lasted 3 days, while the longest 15 days; the average period was 7±3 days.

Follow-up: telephone visit and regular reexamination in the clinic at 1, 3, 6 and 9 months after the treatment respectively.

Functional measurement: The efficacy was divided into three categories according to the self feelings and psychological test results before and after the treatment, including significantly effective, effective and ineffective. Significantly effective: the patients after the treatment had good self feelings, stable emotions, and good social functions; the SAS and SDS scores recovered to the

normal values (SAS<50, SDS<0.5). Effective: their self feelings and emotions turned better than before; social functions were obtained to a certain degree; the psychological test scores dropped but did not recover to the normal values. Ineffective: their self feelings did not turn better and the psychological test scores did not drop.

Main observation targets: emotional experience, physiological indices (skin temperature, blood pressure and pulse) and psychological tests (SAS, SDS).

Statistical analysis: SPSS11.0 statistical software was used for processing of all data; *t*-test was performed for quantitative data; the significance level was determined as $P<0.05$. The fourth author provided assistance in the statistical processing.

2 Results

2.1 Descriptive Statistics

32 cases were included to be treated with CES and tests with scales before and after the treatment were performed. The data of the 32 cases were all used for statistical analysis of the efficacy of CES. However, 6 cases did not come for reexamination during the follow-up stage, so they were regarded as natural missing cases.

2.2 Statistical Inference

2.2.1 Comparison of Physiological Indices Before and After the Treatment with CES

Compared with the indices before the treatment, the skin temperature rose after the treatment and the difference was significant ($P<0.01$); the systolic blood pressure dropped and the pulse slowed down after the treatment, and the difference was significant ($P<0.05$). 24 cases showed significant changes in skin temperature, systolic blood pressure and pulse, accounting for 75% of all cases (Table 1).

Table 1 Patients' physiological indices before and after the treatment with CES ($\bar{x} \pm s, n = 32$)

Item	Before treatment	After treatment	*t*
Skin temperature (°C)	36.1±0.4	36.4±0.4	3.92[b]
Systolic blood pressure (mm Hg)	122±15	115±12	2.22[a]
Diastolic blood pressure(mm Hg)	78±12	74±9	1.38
Pulse (time/min)	83±12	77±13	2.12[a]

[a] $P<0.05$, [b] $P<0.01$

2.2.2 Comparison of SAS and SDS Scores Before and After the Treatment with CES

Compared with the scores before the treatment, the SAS standard score of all cases recovered to the normal value after the treatment (<50), and the difference was significant ($P<0.01$); the SDS score dropped, and the difference was significant ($P<0.01$) (Table 2).

Table 2 Comparison of SAS and SDS test results before and after the treatment with CES ($\bar{x} \pm s, n = 32$, point)

Item	Before treatment	After treatment	*t*
Self-rating anxiety scale	58.30±11.50	45.91±10.38	4.53[a]
Self-rating depression scale	0.64±0.08	0.52±0.10	5.14[a]

[a] P<0.01

2.2.3 Efficacy

Among the 32 cases of children with mental disorders who were treated with CES，13 cases had significant effect (41%), 17 cases had effect (53%), and the effect was invalid in 2 cases (6%);

the total effective rate was 94%.

2.2.4 Adverse Events and Side Effects

The patients could adhere to the treatment regime with good compliance; they did not have significant discomfort during or after the treatment; there was no adverse event. During the treatment, 3 cases occasionally felt dizziness and local irritation, but the symptoms were minor; as the treatment continued, these symptoms could be relieved or eliminated. All cases completed the treatment in the necessary period.

2.2.5 Follow-up Results

26 cases among the 32 cases were followed up (follow-up rate: 81%), of which, 24 cases had long lasting efficacy with relieved or eliminated symptoms, and 2 cases had insignificant efficacy without significant emotional improvement and with relapse of symptom; drugs were needed to control their symptoms.

3 Discussion

CES is a treatment technique introduced to China in the recent years, which is different from the traditional biofeedback. It is a procedure in which low-level, oscillatory and micro bioelectricity is directly applied across the head through the temporal skull. Its main working principle is that the cerebrum, hypothalamus, limbic system and reticular activating system that control mental and emotional activities are directly recuperated by direct application of micro bioelectricity which simulates brain electricity to the central nervous system; it can directly adjust abnormal brain waves to make them close to normal biological waves; it can directly stimulate the organism to produce tranquilizing endogenous enkephalins, thus to effectively control nervousness, anxiety and depression and adjust the emotional state.

In this experiment, it was observed that most children with emotional disorders (75%) had changes in physiological indices after the treatment such as rise of skin temperature (0.3~0.5°C) and drop of blood pressure and pulse. Such changes indicated that the parasympathetic nervous system got excited, which led to peripheral vasodilatation, and the organism generated warm, relaxed and comfortable feelings. The change in emotions was fast and significant; the emotions turned significantly better 3~5 days or 7~10 days after the treatment; the patients were in good moods, which could be seen from their body language without much conversation. In the whole process of the treatment, the patients were active with good compliance and without fear and resistance. After the treatment, the SAS and SDS scores both dropped significantly, reaching or close to the normal values, and the difference is significant (P<0.01); this was consistent with clinic improvement in symptoms; significant efficacy was shown in a short period of treatment. Compared with the traditional psychotherapy and pure drug therapy, treatment with CES can get rid of the disadvantages of pure psychotherapy such as long course, slow effect and easy missing, and also the disadvantages of pure drug therapy such as big influence on children in the stage of growth and development, unavoidable toxic and side effects and poor adherence to drug use of children. It can also be taken as another effective and safe psychological therapy technique apart from the traditional psychotherapy and pure drug therapy. In this study, 32 children with emotional disorders were treated with CES; among them, 26 cases were followed up for 6~12 months, 24 cases of whom had long lasting efficacy with relieved or eliminated symptoms and well recovered metal functions; 2 cases had insignificant efficacy without significant emotional improvement and with relapse of symptom, and they needed to be treated with drugs. All cases did not have significant discomfort during or after the treatment, and there was no adverse reaction.

Conclusion: In the authors' opinion, CES is a safe and effective technique with fast efficacy for

treatment of children with emotional disorders. It can be taken as a new therapeutic method in clinic application apart from psychotherapy and drug therapy.

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