Cranial Electrotherapy (CES) is a non pharmaceutical treatment for anxiety, depression, insomnia, stress, headache and other painful conditions by applying microcurrent tot the ear lobes.

CES has been employed in the effective treatment of pain including chronic back pain, headache, toothache and myofascial pain.

CES can also enhance effectiveness of anesthesia by up to approximately 37% and reduce need for medications.

Following CES treatment relaxation response by slowing of brain wave, lowering of blood pressure, pulse rate, respiration and heart rate may be observed. Preoperative anxiety is common in more than two thirds of patients waiting for surgery. Fear of losing control, unfamiliar surroundings, fear of illness and death all contribute to increased anxiety and thus requires increased amount of anesthetics during surgery. Preoperative anxiety is a natural response to unpredictable situation but excessive anxiety will produce rapid pulse, elevated blood pressure, irregular heart beat and severe pain even after the surgery.

Patients are admitted to the facility the day before the surgery and visited by an anesthesiologist for clinical, psychological assessment and to establish trusting relationship. However, it is common to observe markedly elevated blood pressure due to severe anxiety in some patients. Preoperative anxiety increases production of stress hormone and thus by reducing anxiety stress induced hormonal response can be modified. For this reason various treatments including premedication, psychotherapy and other adjunctive modalities such as music therapy, muscle relaxation and humors are under evaluation. One recent survey indicates up to 75% of American anesthesiologist administer pre-medications including sedative/hypnotics such as barbiturates, benzodiazepines and α -2 adrenergic agonists. Barbiturates are generally shunned because of prolonged sedative effect. Small dose of benzodiazepines are most commonly used and among them midazolam is favored because of it's short half life and dosing flexibility. However, excessive dose of midazolam can cause respiratory suppression and hemodynamic side effects. α -2 adrenergic agonist represented by clonidine has weaker anxiolytic effect than midazolam and may induce lowering of blood pressure and heart rate during anesthesia and residual sedation afterwards. We wanted to explore if CES pretreatment can reduce preoperative anxiety and hemodynamic response and thus induce safer anesthesia. Reducing preoperative anxiety while waiting for surgery may also improve postsurgical prognosis. We are not aware of any studies using CES before surgery to reduce preoperative anxiety.

Subjects and Methods

We obtained approval by the institutional bioethics review board of the Korea University College of Medicine. We selected 60 adults between the ages of 18-65 awaiting surgery under general anesthesia meeting American Association of Anesthesiology Physical Classification Criteria 1 & 2.

Exclusion criteria include those with BMI over 25, are pregnant, have endocrinological, musculoskeletal, liver and kidney, vascular disorders, those wearing cardiac pace maker, awaiting high anxiety procedures such as tumor removal or amputation, those who are taking antidepressant and other psychotropics. Most subjects are for orthopedic, gynecological and ear, nose and throat procedures requiring about 2 hours and with similar risk factors.

Detailed explanations for study purpose and procedures were provided to the patient and their families and consents were obtained the night before the surgery. They were told that they will be held for 20-30 minutes in the pre-surgical waiting area and they will either receive or not receive CES and what sensation to expect from CES pretreatment in order to reduce anxiety.

All subjects were given glycopyrrolate 0.2 mg IM as a premedication about one hour before induction of anesthesia. They were brought to waiting area to be evaluated by the same anesthesiologist who visited them the night before. They were asked about level of anxiety and blood pressure and pulse rate was measured as physical index of anxiety. Anxiety was rated using Likert Scale measuring subjective experience of anxiety in 5 steps, 1) Strongly agree, 2) Disagree, 3) Neither Agree or Disagree, 4) Agree, 5) Strongly agree. The response to questionnaire items were rated from 1 to 5, 1 being the minimum and 5 being the highest 3 will be the medium. The higher the score the higher the anxiety level. The cohorts of 60 patients were divided randomly assigned into 2 groups (control, n=30, CES group, n=30). The CES group received 20 minutes of treatment while the control group received supportive nursing care. Entering the operating room the same investigator again rated anxiety scale and checked blood pressure and pulse rate. The investigator was blind to who received CES pretreatment. There were no differences in age, gender, height and weight distribution between two groups (Table 1). The CES group received 20 minutes of pretreatment in the operating room waiting area by application of microcurrent device (Alpha-Stim 100, Electromedical Products International, Inc, USA) fixed at below 200 μA. 0.5 Hz. Ear clips were attached to the ear lobes and the intensity of the currents adjusted to just below the level of feeling tingling sensation in the ear lobes or feeling dizzy.

Statistical analysis was performed by SPSS, version 13 (SPSS Inc, USA) and results except for gender were expressed in ± standard deviation. Blood pressure and pulse rate of each groups were compared between the waiting room and operating room measurements. Waiting room measurements were used as basis for percentage change of operating room measurements. P values of all the data below 0.05 was considered statistically significant.

Results

There was no difference in anxiety score of waiting room measurements between the control and CES groups. However, control group showed significant elevation in operating room score compared to waiting room measurement. CES group showed significant reduction of anxiety score in the operating room compared to waiting room measurement (p less than 0.05, Table 2)

Hemodynamic changes of blood pressure and pulse rate in the operating room were significantly elevated in both control and CES groups (p less than 0.05, Table 3). Value for CES group operating room score was significantly lower than that of control group (p less than 0.05, Table 3).

Discussion

CES applies microcurrent of less than 1mA to the head through attaching clip electrodes to the ear lobes. It is accepted as an effective nonpharmacological treatment for insomnia, depression and anxiety. CES may also be used as an adjunct to anxiolytic medication and/or psychotherapy, behavioral modification and other conservative methods of treatment. Studies have used CES devices to treat anxiety, depression and insomnia in treatment sessions of approximately 30 minutes in over 5-15 days. Most have concluded positive results immediately following final treatment with effects lasting for one weeks to 2 years.

Table 2. Changes of Anxiety Score

A pioneer in electromedicine, neurobiologist Kirsch, DL reported that effective control of anxiety is experienced during CES session or in a few hours or a day. One 20 session is often all that is needed to effectively control anxiety for at least a day and the effects appear to be cumulative. The mechanism by which CES produces its effect is not yet fully understood. It is postulated that the stimulation of brain tissue causes increased amounts of neurotransmitters to be released, specifically serotonin, beta endorphin and norepinephrine. These neurotransmitters, in turn, permit return to normal biochemical

homeostasis of the limbic system of the brain that may have been imbalanced by a stress related condition. It appears CES microcurrent waveform activates particular groups of nerve cells that are located at the brain stem, a site at the base of the brain that sits atop the spinal cord. These groups of nerve cells produce the neurotransmitters serotonin and acetylcholine, which can affect the chemical activity of the nerve cells that are both nearby and at more distant sites in the nervous system.

Table 3. Changes in Systolic & diastolic Blood Pressure & Heart Rate

By changing the electrical and chemical activity of certain nerve cells in the brain stem. Alpha-Stim appears to amplify activity in some neurological systems and diminish activity in others. This neurological "fine tuning", called modulation, occurs either as a result of or together with the production of certain type of electrical activity pattern in the brain known as an "alpha state". Such alpha rhythms are accompanied by feelings of calmness, relaxation, and increased mental focus. The neurological mechanism that are occurring during alpha state appear to decrease stress effects, reduce agitation and stabilize mood, and control both sensations and perceptions of particular type of pain. These effects can be produced after a single treatment, and repeated treatment have been shown to increase the relative strength and duration of these effects.

It is well known that surgery and anesthesia is an important stress inducing events in one's life. Preoperative anxiety is not only uncomfortable sensation but also increase required amount of anesthetic drugs and may induce negative physiological and psychological complications after surgery. Therefore, it is important to reduce preoperative anxiety for patient comfort, reducing complication and successful surgery and recovery. Anxiety may be caused by surgery itself, unfamiliar surroundings, bright lights and unfamiliar sounds. Age, sex, occupation, religion, marital status, educational level and past surgical history and type of surgery are the common influencing factors. Cancer surgery and genitourinary procedures are known to increase more anxiety in female patients. Anxiety activates Hypothlamic-Pituitary-Adrenal axis leading to increased secretion of cortisol. Stress induced catecholamines may be as high as 10 times baseline level. Hemodynamic changes such as elevated pulse rate can occur as a result of emotional stress by way of sympathetic activation and secretion of catecholamines. Non pharmacological treatment of anxiety related to surgery and anesthesia includes pre-surgical consultation by anesthesiologist and psychosomatic medicine treatment modalities such as hypnosis, medication and relaxation. Benzodiazepines as pre-anesthesia medication is widely used. Preoperative visit and premedication combined is the preferred method.

Most of CES studies thus far has been confined to the treatment of anxiety, depression and insomnia in psychiatric population. The current study is the first attempt to explore use of CES to reduce preoperative anxiety by applying 20 minute of CES treatment that brought about lowering of anxiety for 2 days. It is known that repeated CES treatment will induce enhanced antianxiety effect. We decided to

give CES sessions of 20 minutes as pretreatment to avoid bias caused by increased anxiety in control groups by prolonged wating period from longer treatment sessions. We obtained statistically significant reduction in anxiety score as pretreatment but the results are not robust enough to endorse clinical application. We hope to obtain better result by increasing number of CES sessions. It should be cautioned that administering electricity, though microcurrent to the patients without sufficient explanation and informed consent may cause more anxiety.

This study is limited by absence of corelation between objective measurement of stress hormone levels-cortisol and catecholamines and also the fact that surgeries were not confined to the same kind of procedures.

The current study shows significant reduction of anxiety scores in CES group in the operating compared to the control group. Elevation of blood pressure and pulse rate was significantly lower in the operating room for the CES group. In another words, CES pretreatment reduces preoperative anxiety and modification of hemodynamic effects of anxiety by suppressing sympathetic activation.

In conclusion, CES pretreatment is effective in reducing the level of preoperative anxiety and hemodynamic responses.