

Control of Cigarette Cravings with Cranial Electrotherapy Stimulation

by William S. Eidelman, MD

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Abstract

This study evaluated the efficacy of cranial electrotherapy stimulation (CES) to control cigarette cravings. Cigarette smokers who craved a cigarette were given a single 20-minute treatment of CES consisting of 0.500–500 microamperes of current, 0.5 Hz frequency, using earclip electrodes in a medical practice. In the US, the Food and Drug Administration authorizes CES devices that have passed its rigorous standards to be marketed for anxiety, insomnia, and depression by prescription from a licensed practitioner. They are available throughout the rest of the world over the counter.

Of 1,000 cigarette smokers treated, 972 (97.2%) lost their craving for cigarettes within 1 to 5 minutes into a 20-minute session of CES. Cravings typically returned in 2 to 8 hours (range 30 minutes to 16 hours). Additional benefits of relaxation and pain relief were reported by most subjects. Some of the smokers who also craved other addictive drugs reported a reduced desire for other substances. Some smokers used CES on a scheduled basis to successfully quit smoking. Three of the 1,000 smokers (0.3%) were unable to tolerate the treatment due to vertigo even at the lowest current setting. No other adverse effects were observed or reported.

Elimination of cravings in a single trial was nearly universal. The potential of this therapy as a treatment for cigarette addiction appears to be very high. The short-term benefits of CES applications to reduce cravings are widespread. It could prove invaluable in hospitals and other high-stress situations where smoking is prohibited. The therapy appears to have immediate benefits for patients, with few or no adverse effects. Widespread application could have a dramatic impact on health-care outcomes and costs. Further studies are warranted to examine the long-term effects of CES for smoking cessation.

Introduction

Cigarettes are a primary but preventable cause of many disabilities and premature death. Addiction to nicotine is notoriously strong and difficult to break. According to the National Institute on Drug Abuse, more than 90% of those attempting to stop smoking fail, usually within

a week. Nicotine withdrawal symptoms include irritability, craving, cognitive and attention deficits, sleep disturbances, and increased appetite. The early small craving that begins within a few minutes after smoking the last cigarette is the beginning of this withdrawal syndrome. It builds over a period that may vary from ten minutes

to an hour or two and in some cases longer, until the urge for a cigarette seems irresistible; and if the craving is not quenched, a full-blown withdrawal starts. Symptoms peak within the first few days and usually subside within a few weeks. For some people, however, symptoms may persist for months or longer.¹ Currently, there is no efficacious method to relieve cravings for cigarettes. Therapies based on pharmacology, behavioral and hypnotherapies, acupuncture, and biofeedback have all produced equivocal results.

Abstinence rates for pharmacotherapies range from approximately 16% to 30% at one-year follow-up, with efficacy odds ratios (ORs) compared with placebo of 1.7 for nicotine replacement therapy (NRT), 1.9 for bupropion, and 3.0 for varenicline. Behavior modification therapies have achieved quit rates of between 8% and 43% lasting as much as one year, with ORs compared with no treatment of between 1.2 and 2.2.²

A prospective randomized controlled trial was conducted using auricular acupuncture for smoking cessation in 118 adult subjects (mean age, 53.7 $\pm$ 16.8 years; 100 males,



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18 females) who wanted to stop smoking. The treatment group (n = 59) received auricular acupuncture for 8 weeks. The control group (n = 59) received sham treatment, with auricular acupuncture points unrelated to smoking cessation. Subjects were followed monthly after stopping the acupuncture treatment. There were no significant differences in the smoking cessation rate between the acupuncture-treatment group (16.6%) and the sham-treatment control group (12.1%) at the 6-month conclusion.³

Another study sought to determine whether hypnosis would be more effective in helping smokers quit than standard behavioral counseling when combined with nicotine patches (NP). A total of 286 smokers were enrolled in a randomized controlled smoking cessation trial at the San Francisco Veterans Affairs Medical Center. Participants in both treatment conditions were seen for two 60-minute sessions, and received 3 follow-up phone calls and 2 months of NP. At 6 months, 29% of the hypnosis group reported 7-day point-prevalence abstinence compared with 23% of the behavioral counseling group (relative risk [RR] = 1.27; 95% confidence interval [CI] 0.84–1.92). Based on biochemical or proxy confirmation, 26% of the participants in the hypnosis group were abstinent at 6 months compared with 18% of the behavioral group (RR = 1.44; 95% CI 0.91–2.30). At 12 months, the self-reported 7-day point-prevalence quit rate was 24% for the hypnosis group and 16% for the behavioral group (RR = 1.47; 95% CI 0.90–2.40). Based on biochemical or proxy confirmation, 20% of the participants in the hypnosis group were abstinent at 12 months compared with 14% of the behavioral group (RR = 1.40; 95% CI 0.81–2.42). It was concluded that hypnosis combined with NP compares favorably with standard behavioral counseling in generating long-term quit rates.⁴ However, 1 in 5

people treated cannot be considered a successful intervention. Nor have any of the studies revealed a reliable way to take away cravings for a cigarette at the moment the craving arises.

A small but promising pilot study of 6 smokers investigated the hypothesis that smoking frequency would decrease when individuals were trained via biofeedback procedures to increase 8–12 Hz (alpha) occipital EEG activity as a substitute for smoking. It was discovered that all subjects decreased their 8–12 Hz activity while actually smoking a cigarette. Two smokers who learned to continue producing high levels of alpha activity based on neurofeedback were able to quit completely at the end of an 8-month follow-up period.⁵

Dr. Meg Patterson, a surgeon, was first to discover CES to be an effective treatment for addiction. She found that heroin addicts given electromedical treatments to the brain as a means of surgical anesthesia in Hong Kong did not experience the expected withdrawal syndrome.⁶ That observation led her to spend the remainder of her career studying and developing devices for treating addictions. She reported that her patients were able to successfully and easily withdraw from cigarettes. While there have been numerous studies for CES treatment of addiction to opiates, cocaine, alcohol, and methamphetamines,⁷ no studies have been published on treatment of cigarette addiction with commercially available CES devices.

Only one double-blind study to date examined the effects of CES on short-term smoking cessation. Subjects were randomly assigned to CES (N = 51) or a sham-treated group (N = 50) on 5 consecutive days. Active treatment consisted of 30 microamperes of current at 10 Hz or no electrical current (sham). There were no significant differences between groups on daily cigarettes smoked, exhaled carbon monoxide, urinary cotinine levels, treatment retention, smoking urges, or total tobacco withdrawal scores. However, it was found that subjects in the

active CES group had fewer cigarette cravings and less anxiety during the first 2 experimental days. It should be noted that this study used an unknown CES device that has never been commercially available, with questionable electrodes never before used for CES; and 30 microamperes is a lower dose of current than used in any other CES study conducted to date. Also, 5 days of any therapy is inadequate to achieve long-term smoking cessation.⁸

CES devices have been used in our medical practice to treat pain, anxiety, insomnia, and depression since November 2004. In June 2006, a new patient requested help in overcoming a 4-year methamphetamine addiction, and a trial with CES was recommended.^{9,10} Treatment with CES created a successful and effortless withdrawal. Surprisingly, no physical cravings or withdrawal symptoms of any kind occurred.

In light of this dramatic experience, and because of the need to find an effective treatment for cigarette addiction, the present clinical study was undertaken to investigate the efficacy of CES for cigarette cravings.

Methods and Materials

Cigarette smokers who answered "yes" to the question "Do you need a cigarette?" in a medical practice were offered a free 20-minute application of CES using Alpha-Stim technology (Electromedical Products International Inc., Mineral Wells, Texas; www.alpha-stim.com). One thousand smokers were tested for single craving episodes between July 2006 and January 2008. Subjects were mainly patients in the practice but also included companions or drivers of patients. They were a diverse group in every way, varying in age, education, race, national origin, and financial status. There were more males than females.

Participants were told that the nature of the experiment was to determine if the CES treatment would remove their craving for a cigarette. Earclip electrodes were moistened with a conducting solution and

attached to the earlobes. Current levels of the CES device, which range from 100 to 500 microamperes (μ A), were adjusted following the manufacturer's recommendations to a comfortable level just below where vertigo is experienced, usually in the 200–300 microampere range. The device outputs 0.5 Hz in a 50% duty cycle.

After the 400th smoker, the question was changed to: "Imagine a scale of 0 to 10 of needing a cigarette. After smoking it is 0, and then it creeps up over time in a physical way until you are 'dying for a cigarette' at 10. What is your level now?" Smokers whose craving was 3 or above were included. They were requested to take note of the physical aspect of the craving.

Results

In the first group of 400 smokers, 376 (94%) said their craving was completely gone within the 20-minute CES treatment. Twenty-four (6%) said they still wanted a cigarette, though most said the craving was reduced.

In the second group of 600 smokers, 596, or all but four, lost their physical craving completely. This represents 99.3%. Combining the two groups, 97.2% of 1,000 smokers reported a complete disappearance of the physical craving.

The lack of need for a cigarette usually occurred within 2 minutes, and sometimes literally within seconds of beginning the treatment. In some, the very idea of smoking a cigarette became temporarily repulsive. Typical responses to the question, "How is your craving or need for a cigarette now?" usually asked after 2 or 3 minutes into the CES session, were: "I don't even want a cigarette, now," or "I'm not thinking about a cigarette now," accompanied by a surprised look.

Three of the 1,000 smokers were unable to tolerate the treatment. Even at the lowest possible setting, they experienced vertigo, though two were able to tolerate it long enough to see the craving disappear, but they remained dizzy even at the lowest

possible setting and were unable to complete the treatment. No other adverse effects were observed or reported.

Most of the smokers were not actively trying to stop smoking at the time they were treated with CES. Recruitment took place after the patient or companion was already at the medical office. Most smokers achieved a state of relaxation. About half noticed a more relaxed state

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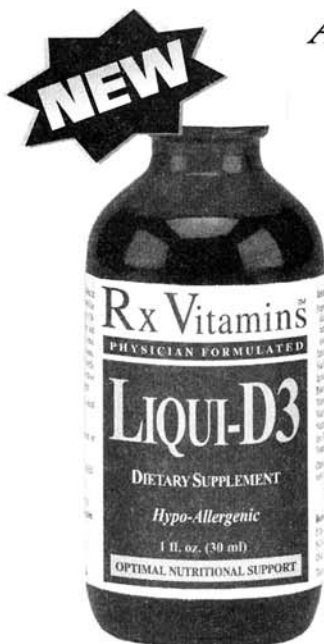
within 1 minute. Most of the others felt a relaxing effect within 5 to 15 minutes.

In those who were in the process of quitting and at the height of their withdrawal symptoms, cravings started to diminish within 2 minutes of initiating CES treatment, and usually

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disappeared within 10 minutes. Several were 2 or 3 weeks into quitting and still experienced cravings. One still craved a cigarette after 3 months. Another still had cravings after 18 months, and 2 after 2 years. The longest period of no smoking wherein craving persisted was 4 years. In all these cases, the craving disappeared within the first 2 minutes of CES.

Cravings always have a physical component. Some reported it as a taste in the mouth, often accompanied by salivation. Some reported sensations in the lungs. Some reported it in the hands, moving up the arms into the chest as it became more intense. Most could identify some location where they felt the desire or craving. All of the successes after the 400th patient reported that the physical aspect of the craving disappeared along with the desire for a cigarette. Most reported that the cravings returned in 2 to 8 hours. The shortest time was 10 minutes and the longest time reported was 16 hours.

Some participants came in with more than one craving. In addition to cigarette cravings, other cravings included alcohol, opiates, cocaine, methamphetamine, and Xanax. In each case, cravings disappeared within minutes. Subjects also reported other benefits aside from lack of craving for a cigarette. Many headaches were relieved, as has been shown in the CES literature.¹¹ Pain and muscle tension in the neck, shoulder, and upper back was generally diminished as well.¹² Anxiety was greatly reduced in most cases, again, consistent with the literature.^{13,14}

Two of the patients craving a cigarette were in psychiatric emergency states. In both cases, their states of emotional turmoil/agitation calmed to near normal, one in 2 minutes, the other in 10 minutes.¹⁵

Numerous patients who desired to quit smoking were provided a prescription to purchase a CES medical device, and those were usually able

to quit successfully. Some medical patients who were prescribed CES for treatment of other problems, without the specific intent to quit smoking also reported that they greatly reduced their cigarette consumption without effort.

Discussion

The immediate effect of suspending cigarette and possibly other cravings has widespread applications in hospitals and other places where smoking is prohibited. This is especially true as it is more difficult now to find areas where smoking is permitted. Cigarette smoking in a hospital is dangerous in many ways. By having CES available with standing orders to control cravings, patients may be better able to withstand the wait for medical care and be more helpful when seen.

Smokers who do not smoke while in a hospital will likely realize better outcomes than those who continue to smoke, resulting in reduced morbidity and mortality. Further, in experiencing the dissolution of the craving, replaced with a feeling of well-being, patients are more likely to look favorably on quitting, and may use several days in the hospital to get through the initial stages of withdrawal, which is usually the worst part, without any cravings. Should cravings return after hospitalization, patients would have the option of continuing CES treatment.

Some smokers who purchased the CES device to treat their cravings when they arose reported a complete cessation of cravings after 1 to 6 weeks. Making it easy to quit smoking could take a huge burden off the health care-system, as the enormous cost of treating diseases caused by smoking is well established. The consequence of smoking a pack of cigarettes is estimated to cost the US economy \$7.18 per pack in medical care and lost productivity, or about \$157 billion and 440,000 premature deaths each year.¹⁶

Effectiveness in relieving physical cravings makes the psychological aspects of the addiction more ac-

cessible. In the 6% who still wanted a cigarette, the desire could then be categorized as psychological or mental/emotional. It is difficult for most people to work on the psychological aspects of the addiction while the physical cravings are acute and often overwhelming. In the absence of the physical discomfort and emotional distortion caused by cravings and other withdrawal symptoms, it is easier to tackle the behavioral, emotional, and psychological issues associated with quitting.

Although CES treatment takes away physical cravings, it does not change the external factors causing one to desire the drug in the first place. Nor does it make the person who enjoys it want to quit. However for those who do, CES is a safe, effective, and low-cost PRN treatment for cravings that clearly enhances the possibility of success.

CES, an electrical treatment applied to the external ear, may achieve parasympathetic nervous system dominance by stimulating the auricular branch of the vagus nerve. Withdrawal symptoms are basically manifestations of sympathetic nervous system overflow or overactivity (such as tremors, sweating, tearing).¹⁰

The addictive craving has recently been hypothesized to involve an expression of receptors. A study has shown that, in rats, chronic nicotine use triggers the extrahypothalamic corticotropin releasing factor (CRF) system, a major brain stress system, which contributes to continued tobacco use by exacerbating anxiety and craving upon withdrawal. The researchers found that administering a compound that blocked the receptors involved in this stress system alleviated withdrawal symptoms.¹⁷ It is possible that the CES waveform somehow alters the receptor electrically instead of chemically, but this remains to be shown.

Existing brain imaging methods, when put to the question of CES mechanism of action, should be able to discover locations and types of changes involved. Such studies have already looked at cravings. Using

PET scans to see which areas of the brain were most active in craving and satiety, a study found that three specific regions were active when the smokers craved cigarettes: the thalamus, the striatum, and the anterior cingulate gyrus. Using PET scans looking at possible mechanisms for the reduction of cravings showed that brain cells in the anterior cingulate gyrus do not activate in response to cigarette-related cues when bupropion is taken.¹⁸ Studies with PET scans, fMRI, and other forms of imaging could help identify what role CES has, if any, in areas already known to be involved in cortical regulation of addictions.

Kennerly studied the EEG changes in 30 students treated with 30 minutes of Alpha-Stim CES, the same device used in this study, and found it to significantly increase 8–12 Hz alpha activity.¹⁹

Conclusion

One thousand cigarette smokers craving a cigarette were treated with CES. Treatment dramatically eliminated desire and cravings for a cigarette 97.2% of the time, usually within 2 minutes. Additional health benefits were reported by most subjects.

Such robust results warrant further research to confirm and expand on the results of this study. Specifically, studies are needed to determine if continued usage as needed to remove cravings will lead within days, weeks, or months to a total cessation of cravings, thus breaking the addiction. Additional studies might be conducted on the impact of this craving treatment in hospitals, intensive care units, emergency rooms, imaging, and other areas where situational anxiety is likely to be increased among smokers. Studies to elucidate the mechanisms of action using such advanced technologies as fMRI, SPECT scans, QEEG, PET, and others might be used to better understand the mechanisms of this safe and effective therapy.

No adverse effects were observed or reported in any of these subjects, with the exception of 3 (0.3%)

who were unable to tolerate the treatment due to vertigo. These preliminary observations represent a promising addition to the treatment armamentarium for addiction.

Efficacy of cranial electrotherapy stimulation, as described herein and documented in over 126 clinical studies, appears to have many applications worthy of immediate widespread application.⁷ The relaxation effect may have utility to calm patients in crisis in emergency medicine or any application where anxiety or even panic may be present. Once a device is purchased, ongoing costs are minimal, making this treatment cost-effective, safer, and more efficacious than many other interventions. As such it should be considered a possible first line of treatment, especially in refractory cases involving cravings.

William S. Eidelman, MD
1654 N Cahuenga Blvd
Hollywood, California 90028
323-463-3295
323-463-3740 fax
willameidelman@mac.com

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William S Eidelman, MD, is a consultant in natural medicine practicing in Hollywood, California. He is one of the pioneers in the field of medical cannabis under California's Compassionate Use Act. He is a member of ACAM, the American College for Advancement in Medicine. He has written *From Medicine to Mysticism*, concerning the interface of science and mysticism. He has been interested in the body's natural electromagnetism and ways to influence it for healing. His websites are www.DrEidelman.com and www.BeAddictionFree.com.

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