Laser Acupuncture Therapy for the Treatment of Tobacco Addiction

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Abstract:

Objective This investigation studied the effectiveness of laser acupuncture on smoking cessation by applying up to 5 laser acupuncture treatments over a 2 week period, in combination with counseling, with the goal of reducing the amount of tobacco products consumed by subjects by at least 25% as measured from baseline to 30 day follow up.

Method A homogenous population aged 16 years of age or older, selected from 11 laser clinics located in 10 different states in the United States, was enrolled into the clinical study. Subjects were entered into the study if they met specific inclusion and exclusion criteria. The amount of tobacco products consumed by each subject was recorded at baseline, after every treatment session and 30 days post treatment.

Results Data was collected on 549 subjects, who received up to 5 laser treatments on specific auricular and peripheral acupuncture points with the Theralase therapeutic medical laser system. At the 30 day follow-up, 405 subjects had met the outcome criteria and had reduced their consumption of tobacco products by 25% or more (73.8%), with 373 of those subjects (67.9%) completely eliminating use of tobacco products and 32 of those subjects (5.8%) showing a reduction of at least 25%. 144 subjects showed less than 25% improvement in the quantity of tobacco products consumed at baseline (26.2%). There were no adverse effects reported by any subject in the clinical study.

Conclusion The authors conclude that the clinical protocol followed, and the laser device used in this clinical study were safe and effective in reducing the amount of tobacco products consumed by subjects from baseline to 30 day follow-up.

Introduction

Addiction is highly complex, can be triggered by a wide variety of stimuli and can affect subjects in many different ways. Due to the complexity of addiction and the poor success rate that alternative cessation methods have had, this clinical study was designed to enroll at least 500 subjects, male or female, from a homogeneous, cosmopolitan population to determine if a Theralase therapeutic laser system applied to specific auricular and acupuncture points could reduce smoking by 25% or more as measured by the consumption of tobacco products from baseline to 30 day follow-up.

Smoking is one of the most preventable illnesses that plague the North American population ⁽¹⁾. The addiction is a complex condition, which can disrupt a person's life, leading to health concerns, deterioration of major organs, incurable diseases and eventually pre-mature death ^(2, 3).

According to the World Health Organization, there are more than one billion smokers in the world, and tobacco is said to kill half of its users. The European Region of WHO, with only 15% of the world's population, faces nearly one third of the worldwide burden of tobacco related diseases. In addition, millions of lives could be saved with effective and comprehensive tobacco control strategy ⁽⁴⁾.

Acupuncture, likely the most well known 'alternative' medical treatment, has been shown to have effects in several types of animal model of drug dependence, including nicotine addiction.

A study conducted by Dong et al (2001) on the effects of acupuncture treatment on the long term effects of smoking cessation or reduction showed that five years after the last treatment the subjects in the test group smoked 37% less than before the first treatment (p<0.003) while for the subjects in the control group no significant difference from before the treatments was found (p=0.17)⁽⁵⁾. The authors reported that the study included 46 healthy men and women who reported smoking 20 \pm 6 cigarettes per day (mean \pm SD) volunteered in the study. They were randomly assigned to a Test Group (TG) or to a Control Group (CG) in which presumed anti-smoking acu-points were stimulated (TG) or acupuncture was applied to acupoints considered to have no effect on smoking cessation (CG). Before each treatment, after the last 1 and 8 months and 5 years after the last 1, each subject answered questionnaires about his or her smoking habits and attitudes. Blood samples for measuring variables related to smoking. (i.e., serum cotinine and serum thiocyanate) The results report that during the treatment period the cigarette consumption fell on average by 14 (TG) and 7 (CG) cigarettes per day (p < 0.001). For both groups the cigarette consumption rose on average by 5 to 7 cigarettes during the following 8 months, and then there was no systematic change thereafter. Consequently, TG showed a maintained reduction in smoking; while, no lasting effect was seen for the CG. The TG reported that cigarettes tasted worse than before the treatments and the desire to smoke fell. For TG the serum concentration of cotinine fell and the values correlated with the reported smoking ⁽⁵⁾. This clinical study confirms that adequate acupuncture treatment may help motivated smokers to reduce their smoking or even quit smoking completely and the effect may last for at least 5 years. Acupuncture may affect the subjects' smoking by reducing their taste of tobacco and their desire to smoke. Different acupoints have different effects on smoking

In 2002, Bier et al reported that ear points are the most effective body site for treating chemical withdrawal symptoms. Acupuncture has been used to treat addiction to a variety of substances, including alcohol, cocaine, heroin and tobacco. This study demonstrated that a 4 week acupuncture regimen (5 days a week) and a 5 week educational program (1.5 hour sessions twice weekly for weeks 1 and 2; once weekly for the remaining 3 weeks), alone and in combination, are effective in promoting a decrease in the number of cigarettes smoked as well as smoking cessation. Moreover, the combination of acupuncture with education demonstrated an effectiveness rate of 40% cessation and 53% post treatment reduction in total cigarettes smoked. This result is comparable to that produced by pharmacological treatment of nicotine addiction combined with behavioral support, which has an effectiveness rate of 20% to 25% at 1 year following treatment ⁽⁶⁾.

cessation.

The authors have demonstrated that acupuncture and education, alone and in combination, significantly reduce smoking; however, combined they show a significantly greater effect, as seen in subjects with a greater pack-year history ⁽⁶⁾.

In i991, J.P. Lebeau studied clinical (with follow-up for two years) reports of over 10,000 volunteers for giving up smoking with acupuncture and psychotherapy. He found that the average withdrawal rate was about 60% at the end of the treatment and, according to the

analysed data, this rate varied from 25% to 30% at 6 to 12 months after treatment in 4,000 smokers. Hence, only a few days of the active treatment could be enough for initial withdrawal ⁽⁷⁾. The data support the observations by Fuller et al (1981), who used 3 electric ear acupuncture procedures on 194 smokers and reported a 95% success rate; among them 41% subjects who completely stopped smoking after 6 months and 30% who remained smoke free after 2 years ⁽⁸⁾.

Body acupuncture or ear acupuncture, known as auriculotherapy, is reported in clinical literature to be an effective treatment modality for the alleviation of substance abuse. Results vary with clinical studies with reports of both positive and negative treatment outcomes. The external ear has been shown to have a somatotopic organization in an inverted fetus pattern; wherein, each part of the auricle corresponds to a specific part of the body. Detection of electrical conductance and tenderness palpation can reveal specific auricular reflex points which can be stimulated to alter pathological reflex patterns in the brain, in internal organs and in different peripheral regions of the musculoskeletal body ⁽⁹⁾.

It is postulated that stimulation of these body acupuncture and ear acupuncture points aids in the production of neurotransmitters ⁽¹⁰⁾ in the brain, which could subsequently result in a change in the addictive consumption habits of the subjects studied ⁽¹¹⁾.

According to Ballal et al (1992), performing smoking cessation acupuncture treatments for six weeks produced a smoking cessation rate of 50.1%, with 45.5% of the subjects reducing their consumption to 5 cigarettes per day while 4.3% failed to reduce smoking ⁽¹¹⁾. Many other authors have reported about successful clinical use of acupuncture in the treatment of tobacco addiction. For example, Hackett et al reported a success rate of 50%, 12 months after electric ear acupuncture ⁽¹²⁾; Choy et al reported a success rate of 88%, after using acupuncture treatment on 514 persons and a recurrence rate of 31% in the second year of treatment ⁽¹³⁾; and, Zalesskiy et al reported a smoking cessation rate of 71% in 85 subjects, using a laser acupuncture method ⁽¹⁴⁾.

Laser acupuncture is defined as the stimulation of traditional acupuncture points with lowintensity, nonthermal laser irradiation ⁽¹⁵⁾. The procedure has some distinct advantages over the traditional needle method. Many patients who are usually afraid of needles prefer laser acupuncture. Use of a laser makes it a typically noninvasive, aseptic procedure, which significantly reduces the pain and recovery time associated with invasive treatments ⁽¹⁶⁾.

Although the therapeutic use of laser acupuncture is rapidly gaining in popularity, objective evaluation of its efficacy in published studies is difficult because treatment parameters such as wavelength, irradiance, and beam profile are seldom fully described. The depth of laser energy transmission, likely an important determinant of efficacy, is governed not only by these parameters, but also by skin properties such as thickness, age, and pigmentation-factors, which have also received little consideration in laser acupuncture.

Thus, an open-label, multicenter clinical trial was designed to evaluate the efficacy of laser acupuncture therapy for the treatment of tobacco addiction.

MATERIAL and METHODS

TLC-1000 and TLC-1005H Therapeutic Laser Systems

The Theralase TLC 1000 laser instrument is a pulsed 905 nanometer Near Infrared (NIR) laser diode-based system. Because the total average power is less than 500 mW, the instrument is classified as 3B "low energy" or 'low level" non-surgical laser. The FDA has classified all low energy laser instruments as "non-significant" risk devices. The TLC 1000 (illustration 1) laser instrument has been approved for therapeutic and medical uses in the European Union, the United States, Japan, Canada, the Middle East, South America, Asia Pacific and many East European countries.

Theralase Inc. manufactures the TLC 1000 in an ISO-13485 certified manufacturing facility located in Toronto, Canada (Figure 1).

Figure 1 TLC-1005H – Single Probe Laser System

The Theralase TLC-1005 therapeutic medical laser system is a single probe laser system with a wavelength of 905 nm and a collimated beam spot size of 0.07 cm². The peak power of the 905 nm laser diode is 50,000 mW, with pulse duration of 200 nanoseconds, an average power of 100 mW, a power density of 1.4 W/cm² and an energy density of 86 J/cm²/minute. The product is ISO-13485, Health Canada, FDA and CE Mark approved.

Treatment procedure

Each subject was counselled for 1 hour on the benefits of quitting smoking prior to the first treatment being delivered to the subject.

Up to five (5) treatments of twenty one (21) minutes in duration were performed over two weeks. Either on Monday, Wednesday and Friday the first week followed by Monday and Wednesday of the second week or conversely Tuesday, Thursday and Saturday of the first week followed by Tuesday and Thursday of the second week.

A visit record of the subject treatment was kept in a log format within the subject file and subjects were asked to report any changes experienced in the area of treatment for detection of any possible side effects. The perceived changes that were self-reported by the participants included skin discoloration, temperature, and tenderness; joint stiffness, mobility, swelling or sounds; soft tissue issues including tenderness, swelling and/or temperature.

The treatments were delivered using the laser probe as specified by the Theralase clinical protocol. The laser probe was held in direct contact with the skin and applied perpendicular to the area of treatment. The laser probe made firm and complete contact with the subject's skin. The output of the laser instrument was tested by the Principal Investigator (PI) on a weekly basis using the built-in laser beam tester, available in the TLC 1000 instrument.

The Theralase TLC-1005 laser system was set to 100 mW average power delivering 30 second treatments (3 Joules per treatment location) to 17 auriculotherapy and peripheral acupuncture

points, bilaterally, and 2 additional points being treated bilaterally for 1 minute in total (6 Joules per treatment location) for a combined treatment time of 21 minutes per subject per treatment session. Treatments began with the auriculotherapy points on the right ear and proceeded from the top of the ear to the bottom of the ear. After the right ear points were treated, the PI or designated assistant treated the peripheral points on the right hand and wrist. Treatment points located on the right leg and foot were then treated. The process was then repeated on the left side of the subject's body commencing with the left ear.

Clinical Outcome Measure

The primary outcome measure was defined as the percent change in the consumption of tobacco products by the subject calculated from baseline to 30 day follow up. The success criterion was predefined to be a reduction of 25% or more in the consumption of tobacco products between these endpoints.

Subjects who met the eligibility criteria were enrolled in the study and received an information sheet describing the clinical study and briefly outlining the components of the protocol, the risks and benefits of participation. They were informed that they were being enrolled of their own free will and could discontinue treatment at any time without consequence.

The enrolled subject completed a patient subjective review assessing inclusion and exclusion criteria eligibility, an informed consent form and a patient data sheet. The informed consent form stated that the subject: has read and understood the informed consent form, may refuse to participate or may discontinue participation at any time, understands the risks and benefits and voluntarily agrees to participate.

Data Management and Computations

The clinical study was considered successful if it achieved its primary outcome measure of a 25% or more reduction in tobacco product consumption by the subject as measured from baseline to 30 day follow up after the final laser treatment. The change from baseline for each treatment plan was computed within subject with the mean and standard deviation computed for all subjects enrolled in the clinical study.

Subjects must adhere to the treatment schedule in order to be included in the analysis having received at least one laser treatment and subsequently providing feedback on tobacco products consumed at the 30 day follow up.

The subject identity was encrypted in all computer documents to ensure subject confidentiality, with all outcome data obtained from the experimental subjects stored in a database using Microsoft Excel in MS Office 2003. Statistical analyses were performed using unpaired t, Mann-Whitney U, ANOVA for repeated measurements and Chi-square tests.

Results

Data was collected on 549 smokers (272 male and 277 female) who received up to five laser acupuncture treatments on specific auricular and peripheral acupuncture points.

Data was collected from 11 laser clinics located in: Guthrie, Oklahoma; Riverton, Wyoming; Vandergrift, Pennsylvania; Alexandria, Louisiana; Farmingdale, New York; Oklahoma City, Oklahoma; Atlanta, Georgia; Slidell, Louisiana; Brentwood, Tennessee; Cary, Illinois and Saint Louis, Missouri. The clinical study protocol was approved by the Texas Applied Biomedical Services (TABS) Institutional Review Board (IRB).

All clinical personnel were trained in the clinical study protocol prior to commencing treatments and were approved by the IRB prior to enrolling subjects.

At the 30 day follow-up, 405 subjects, 198 (72.8%) male (with an average age of 46 +/- 11.8 years) and 207 (74.7%) female (with an average age of 49 +/- 12.3 years), had met the primary outcome criterion (25% or greater reduction in smoking from baseline to 30 day follow-up), Table 1. It should be noted that 74 (27.2%) male and 70 (25%.3) did not meet the outcome criterion and had less than 25% reduction in smoking from baseline to 30 day follow-up.

Table 1 Response Rates Male vs. Female

Moreover, 405 total subjects had met the outcome criteria and had reduced their consumption of tobacco products by 25% or more with 373 of those (405) subjects (67.9%) completely eliminating use of tobacco products and 32 of those subjects (5.8%) showing a reduction of at least 25%. There were 144 subjects who showed less than 25% improvement in the quantity of tobacco products consumed versus baseline measurements (26.2%), Table 2.

Table 2 Overall treatment outcome

The average quantity of tobacco products consumed by the 549 subjects at baseline was 25 +/-11.6 cigarettes. Remarkably, at the 30 day follow up, the average quantity of tobacco products consumed was reduced to 7.8 +/- 13.8 cigarettes (p<0, 0001), Table 3.

Table 3 Tobacco Consumption Rate from the Baseline vs. 30 day Follow-Up (All subjects)

Hence, of the 549 subjects treated, 405 subjects met the outcome criteria with 162 (40.0%) reducing their smoking by 25% or more at the 30 day follow up after only 1 laser treatment session. An additional 180 (44.4%) met the outcome criterion after 2 laser treatment sessions, with 40 (9.9%) and 23 (5.7%) person meeting the success criterion after 3 laser treatment sessions and 4 laser treatment sessions respectively, Table 4.

Table 4 Reduction in Tobacco Consumption per Treatment

Of the 144 subjects who did not meet the outcome criteria, 56 (38.9%) received only 1 laser treatment session, 61 (42.4%) receiving 2 laser treatment sessions, with 21 (14.6%) and 6

(4.2%) subjects receiving 3 laser treatment sessions and 4 laser treatment sessions respectively, see Table 5.

Table 5 Response Rates in Subjects Who Did Not Meet the Primary Outcome Criterion

Another interesting observation is that of the 144 subjects who did not meet the outcome criteria, their average cigarettes consumed at baseline was 28.2 +/- 12.4, which suggests on average that they were higher consumers of tobacco products prior to commencing laser acupuncture treatment than the total number of subjects overall.

There were not any treatment-related adverse reactions reported by subjects in any of the treatment groups.

Conclusion

Cigarette smoking has been associated with significant morbidity affecting all systems of the body, including the integumentary system. Regardless of efforts made to warn the public regarding the dangers of smoking, smoking remains the leading cause of preventable death. Tobacco smoking has been around since Christopher Columbus observed the American Arawak Indians smoking tobacco leafs in 1492. The tobacco plant was named *Nicotiana tabacum* after the French ambassador to Portugal, Jean Nicot, who introduced the plant to France. Nicotine, the primary alkaloid found in tobacco, was isolated in 1828 ⁽¹⁷⁾.

The purpose of this study was to examine the efficacy of the laser acupuncture therapy for the treatment of tobacco addiction.

An increasing number of studies have demonstrated that auricular acupuncture has a significant effect on inducing parasympathetic tone ⁽¹⁸⁾.

Acupuncture has been suggested to increase parasympathetic nerve stimulation and decrease pro-inflammatory cytokine levels ⁽¹⁹⁾.

Low-level laser therapy (LLLT) is widely used in physical therapy and, although skepticism has been expressed in the past, recent reviews and meta-analyses support its efficacy ^{(16).}

The authors hypothesized that release of neurotransmitters may play an important role in the mechanisms of LLLT ^(20, 21, 22).

This clinical study suggests that laser acupuncture treatment provide a safe and effective treatment to reduce the amount of tobacco products consumed by smokers by 25% or more as measured from baseline to 30-day follow-up.

The sample of 549 people enrolled in this clinical trial were representative of a large, homogenous, cosmopolitan population that has been selected from 11 independent laser clinics, which are interspersed throughout the United States.

The treatment groups were consisted of a fairly equal representation of male and female subjects with an average age in the mid forties.

Male subjects as well as female subjects with both clinical groups attaining high success rates (72.8% and 74.7% respectively) according to the primary outcome measure (25% or greater reduction in smoking from baseline to 30 day follow-up)

It's of clinical interest that 39.7% of the subjects receiving 1 treatment session, 43.9% receiving 2 laser treatment sessions and 11.1% and 5.3% respectively receiving 3 and 4 treatment sessions respectively.

Although no sham laser control was used in this clinical study, if one assumes a placebo effect of 30%, for lack of a sham laser, the results obtained would still be high with a net success rate for male and female subjects of 42.8% and 44.7%, respectively.

There were no side effects reported by any subject who was treated with Theralase laser acupuncture treatments.

On the contrary, there have been numerous reported side effects with other nictotine replacement and pharmaceutical treatment methodologies for smoking cessation including: skin irritations, nausea, mood or behavior changes, anxiety, panic attacks, trouble sleeping, irritability, hostile or aggressive tendencies, restlessness, hyperactivity (both mental or physical), depression and / or suicidal tendencies.

Therefore, Theralase laser acupuncture treatments may represent a safe and effective alternative for reducing the amount of tobacco products consumed by subjects.

This non-pharmacologic and non-invasive therapeutic modality may exceed the effectiveness of any other contemporary therapeutic options currently available for smoking cessation treatment, including nicotine patch, nicotine gum and other pharmaceutical alternatives.

Moreover, in addition to the literature findings, the results of this clinical study could account for the regulatory neuroimmunological effects of the conducted therapy that may result from the laser acupuncture-induced modulation of parasympathetic neural activity.

The results underline the potential role of auricular laser stimulation to induce an increase in vagal activity, and it therefore might be used as preventive or adjuvant therapeutic intervention promoting health.

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Legends

Figure 1 TLC-1005H – Single Probe Laser System



Table 1 Response Rates Male vs. Female



Table 2 Overall treatment outcome



Table 3 Tobacco Consumption Rate from the Baseline vs. 30 day Follow-Up (All subjects)



 Table 4 Reduction in Tobacco Consumption per Treatment



 Table 5 Response Rates in Subjects Who Did Not Meet the Primary Outcome Criterion

