A Randomized Controlled Clinical Trial of Auricular Acupuncture in Smoking Cessation

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Background: Tobacco smoking is responsible for human diseases of the lung, heart, circulatory system and various kinds of cancers, and is a serious public health problem worldwide. Acupuncture has been promoted as a treatment modality for smoking cessation. However, its efficacy still remains controversial.

Methods: We conducted a prospective, randomized, controlled trial using auricular acupuncture for smoking cessation in 131 adults who wanted to stop smoking. Thirteen subjects withdrew from the study and 118 subjects were included in the final analyses (mean age, 53.7 ± 16.8 years; 100 males, 18 females). The treatment group ($n = 59$) received auricular acupuncture in *Shen Men*, *Sympathetic*, *Mouth* and *Lung* points for 8 weeks. The control group ($n = 59$) received sham acupuncture in non-smoking-cessation-related auricular acupoints (*Knee*, *Elbow*, *Shoulder* and *Eye* points). The enrolled subjects were then followed monthly for 6 months after stopping the acupuncture treatment.

Results: Between both groups before acupuncture treatment, there was no significant difference with regard to gender, mean age, education level, and mean values for the age at which smoking started, smoking duration, daily number of cigarettes smoked and nicotine dependent score. At the end of treatment, cigarette consumption had significantly decreased in both groups, but only the treatment group showed a significant decrease in the nicotine withdrawal symptom score. Smoking cessation rate showed no significant difference between the treatment group (27.1%) and the control group (20.3%) at the end of treatment. There was also no significant difference in the smoking cessation rate between the treatment group (16.6%) and the control group (12.1%) at the end of follow-up. There were no major side effects of auricular acupuncture in both groups.

Conclusion: Our results showed that auricular acupuncture did not have a better efficacy in smoking cessation compared to sham acupuncture. Combined acupuncture with behavior counseling or with nicotine replacement therapy should be used in further smoking cessation trials to enhance the success rate of smoking cessation. [*J Chin Med Assoc* 2007; 70(8):331–338]

Key Words: acupuncture, nicotine dependent score, randomized controlled trial, smoking cessation, withdrawal symptoms

Introduction

Smoking is a serious public health problem worldwide.[1–3] According to the statistical analysis report announced in 2000 by the World Health Organization (WHO), there are nearly 1.3 billion adults who smoke in the world, and nearly 4.9 million people die of tobacco-related diseases every year.[4] According to a report from the Bureau of Health Promotion, Department of Health, 40% of male adults and 4.8% of female adults smoked in 2005 in Taiwan.[5] More and more adolescents in Taiwan smoke due to the westernized lifestyle and improvement in economic status. According to the statistics, there are nearly 15,000 people who die of smoking-related diseases in Taiwan every year. On average, 11% of all Taiwanese die of smoking-related diseases.

Smoking has been closely linked to human cancers such as lung cancer, oral cancer, laryngeal carcinoma, esophageal carcinoma, hepatocellular carcinoma, pancreatic carcinoma, bladder cancer and cervical carcinoma.[6] In addition, smoking is closely related to the development of chronic obstructive pulmonary diseases (chronic bronchitis, pulmonary emphysema) and

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cardiovascular diseases (hypertensive and coronary heart diseases) that are commonly seen in middle-aged and elderly populations.[7] However, compared with other causes of cancer death, smoking is the only one in which policies can be adopted to prevent earlier death, and with smoking cessation or decreasing smoking to change its prognosis.[8–14]

According to previous reports, acupuncture is increasingly used to treat problems of chemical dependency and alleviate the severity of chemical withdrawal symptoms.[15–17] Many clinical trials from Western countries have evaluated the efficacy of acupuncture as an aid to smoking cessation.[18–24] However, when only the clinical trials with blinded and controlled design were analyzed, a meta-analysis reported by the Cochrane Library showed no significant difference between acupuncture and placebo in smoking cessation.[25] The authors suggested that further research on smoking cessation treatment required high-quality studies including adequate sample sizes, an appropriate method of randomization, highly trained and experienced acupuncturists, longer time of follow-up, and biochemical validation of smoking cessation. Despite the fact that an increasing number of people smoking in Taiwan has been noted and acupuncture is commonly accepted by the general population in Taiwan, there has been no report of large series clinical trial using acupuncture in smoking cessation.[26,27] The purpose of our study was to evaluate the effect of auricular acupuncture in smoking cessation in Taiwan using a randomized, controlled clinical trial.

Methods

Subject recruitment

Participants were recruited by means of advertisement both on the hospital website and the hospital community service in the Bei-tou area of Taipei. Subjects who attended the smoking cessation clinics at the Department of Family Medicine, Taipei Veterans General Hospital, were also invited to join the study. Subjects were enrolled into the study if they wanted to quit smoking and satisfied the following inclusion criteria: age ≥ 18 years; smoke at least 10 cigarettes per day and has smoked for > 1 year; not actively psychotic or suffering from any neurologic or acute physical illness or other impairment that would prevent understanding of the research consent form; willing to participate in a treatment protocol involving acupuncture; not currently taking phenothiazines, tricyclic antidepressants, lithium carbonate, or beta-blocking agents, nor chronically using sympathomimetic drugs such as ephedra, ephedrine, amphetamines, and not abusing any other drugs during the course of study. Written informed consent was obtained from each subject before they entered the trial. Subjects then completed the initial evaluations of demographic data including age, sex, age at which they started smoking, smoking duration, daily cigarette consumption, previous smoking cessation experience, and Fagerstrom's nicotine dependence score,[28] and received the exhaled carbon monoxide (CO) detection test (Bedfont Smokerlyzers; Chia-Hsing Corp., Taipei, Taiwan).[29,30] This study was approved by the ethics committee of Taipei Veterans General Hospital.

Study methods

Eligible subjects were randomized into 2 groups using block randomization method with random number table. The treatment group received auricular acupuncture at the *Shen Men*, *Lung*, *Mouth* and *Sympathetic* points that are commonly used auricular acupoints for smoking cessation. The control group received sham acupuncture at the *Eye*, *Elbow*, *Shoulder* and *Knee* acupoints on the auricle that are irrelevant to smoking cessation. The whole acupuncture process during smoking cessation therapy in this study was standardized and conformed to the guidelines of the manual for sterile needle technique for acupuncturists. A qualified and experienced acupuncturist who had been certified by the National Acupuncture Boards of both Taiwan and the United States performed the acupuncture. After marking the acupoints over standard atlas position on the ears and sterilizing the acupoints with 75% alcohol preparation pads, the acupuncturist pierced the acupoints at 90 degrees vertically with sterile disposable 36-gauge 0.5-inch ear-piercing needles and then fixed the needles with 3M ventilation tape. In addition, universal blood and body fluid precautions, which assume that all subjects are potentially carrying a blood-borne pathogen and hence are contagious, were followed. This procedure reduces the risk of cross- or autogenous contamination, thereby decreasing hazards to participants. After the acupuncture, patients were educated on how to take care of the ear acupuncture site for 1 week.

Subjects were then followed weekly during the 8-week treatment period and then monthly up to the end of follow-up 6 months after the completion of acupuncture treatment. The acupuncturist replaced the auricular acupuncture needle once a week during the treatment period. At each visit, all subjects received counseling by a nurse to learn how to keep the area clean and to prevent the auricular acupuncture needles from falling out, and were provided with ways of

handling the problems encountered during smoking cessation, such as lack of support, bad mood or depression, strong withdrawal symptoms, weak will for smoking cessation and weight gain, to prevent their relapse back to smoking.

Subjects were also requested to complete questionnaires at each visit to evaluate the status of smoking cessation, including status of smoking, nicotine withdrawal symptom score (Hughes and Hatsukami's nicotine withdrawal symptom score),[31] and adverse effects of acupuncture. Nicotine withdrawal symptoms included anxiety for smoking, easily losing temper, being anxious, not able to focus attention, restlessness with anxiety, impatience, hunger or increasing appetite, insomnia or inability to sleep well, astriction, enterorrhea, dizziness, headache, tiredness, perspiration or other symptoms. The side effects of acupuncture included dizziness, pain, pruritus, and bleeding, hematoma or inflammation of punctured points. Concentration of exhaled CO was also determined during each visit. If the subject was not able to return to the clinic, research assistants tracked the status of smoking cessation by phone.

Sample size determination

When this study was designed, several reports had been published concerning the efficacy of auricular acupuncture in smoking cessation. However, the study designs and outcomes varied among these studies. Our study sample size was calculated according to a 32.1% success rate in smoking cessation by auricular acupuncture reported by Gillams et al[19] (the median values of success rates from the Cochrane reviews)[25] and a 6% success rate in smoking cessation by self-will.[32] When conducting a randomized placebo-controlled clinical trial, the number of enrolled subjects needed to achieve a study power of 0.8 and a statistical significance of 0.05 (2-tailed) was 100.

Study endpoints

The primary endpoint of this study was defined as the subjects being free of smoking at the end of the acupuncture treatment. The secondary endpoints included the rate of free of smoking at the end of follow-up, decrease of cigarette smoking both at the end of treatment and at the end of follow-up, and decrease in smoking withdrawal symptoms during the study period.

Statistical analyses

Data in the text and table are expressed as mean ± standard deviation (SD). Comparisons were performed using Student's t test, χ^2 test, cross-tabulation and paired t test depending on the type of data analyzed. Multivariate logistic regression analyses were performed to evaluate the predictive factors for the success of smoking cessation. The dependent variable was free of smoking at the end of treatment, and the independent variables included age, sex, education, occupation, mean smoking year, previous smoking cessation experience, mean nicotine dependant score and mean exhaled CO concentration before treatment. All statistical analyses were performed using SPSS version 12.0 (SPSS Inc., Chicago, IL, USA).

Results

A total of 131 subjects with smoking were enrolled in the study during the study period from May 1, 2003 to October 31, 2004. Thirteen subjects withdrew from the study, and 118 subjects were included in the final analyses. Among the 13 subjects who withdrew from the study, 5 were in the treatment group and 8 were in the control group. The reasons for withdrawal included no available time (total of 4, 2 in the treatment and 2 in the control group), lost contact (total of 6, 2 in the treatment group, 4 in the control group), and loss of willingness after randomization (total of 2, 1 in the treatment group and 1 in the control group). There was no significant difference in the demographic data between the 13 withdrawn subjects and the 118 subjects included in the final analyses.

Among the 118 subjects who completed the study (mean age, 53.7 ± 16.8 years; 100 males, 18 females), 59 were in the treatment group and 59 were in the control group. There was no significant difference in gender, mean age, education level, occupation, previous smoking cessation experience, and mean values for the age at which smoking started, smoking duration, daily number of cigarettes smoked, nicotine dependent score, and exhaled CO concentration between the 2 groups before acupuncture treatment started (Table 1). At the end of the 8-week treatment, 16 subjects (27.1%) in the treatment group and 12 (20.3%) in the control group had stopped smoking ($p = 0.517$). At the end of follow-up, 6 subjects (16.6%) in the treatment group and 4 (12.1%) in the control group had stopped smoking ($p = 0.737$) (Table 2).

At the end of acupuncture treatment, the mean daily number of cigarettes smoked had decreased significantly from pretreatment values in both groups (Figure 1). The average percentage decrease in cigarette consumption showed no significant difference between the 2 groups (48% in the treatment group, 43% in the control group). At the end of acupuncture treatment, the mean nicotine withdrawal symptom score had decreased significantly from the first treatment value

Table 1. Pretreatment demographic data of subjects in the auricular acupuncture treatment group and sham acupuncture (control) group*

	Acupuncture treatment ($n=59$)	Sham acupuncture ($n=59$)	p
Male/female	48/11	52/7	0.443
Mean age (yr)	54.3±16.9	53.0±16.9	0.683
Education (≤ junior high school/senior high school/≥ college	12/26/21	13/22/24	0.536
Occupation (white collar/blue collar/ merchant/retired/none)	8/9/10/23/9	6/8/17/20/8	0.658
Mean age of starting smoking (yr)	20.1±7.2	19.6±7.5	0.718
Mean smoking years	33.8±18.3	32.8±17.4	0.716
Mean daily smoking amount (pieces)	16.7±10.6	20.7±13.1	0.071
Previous smoking cessation (yes/no)	41/18	44/15	0.538
Mean nicotine dependence score	5.4±3.0	6.4±2.5	0.105
Mean exhaled carbon oxide concentration (ppm)	13.8±8.0	15.2±9.4	0.271

**Data are expressed as mean±standard deviation or n.*

Table 2. Comparisons at the end of 8-week auricular acupuncture treatment and at the end of follow-up (6 months after stopping treatment) in the acupuncture treatment group and sham acupuncture (control) group

	Acupuncture treatment	Sham acupuncture	p
At the end of treatment ($n=118$)			
Subjects who had stopped smoking	16 (27.1%)	12 (20.3%)	0.517
At the end of follow-up ($n=69$)			
Subjects who had stopped smoking	6 (16.6%)	4 (12.1%)	0.737

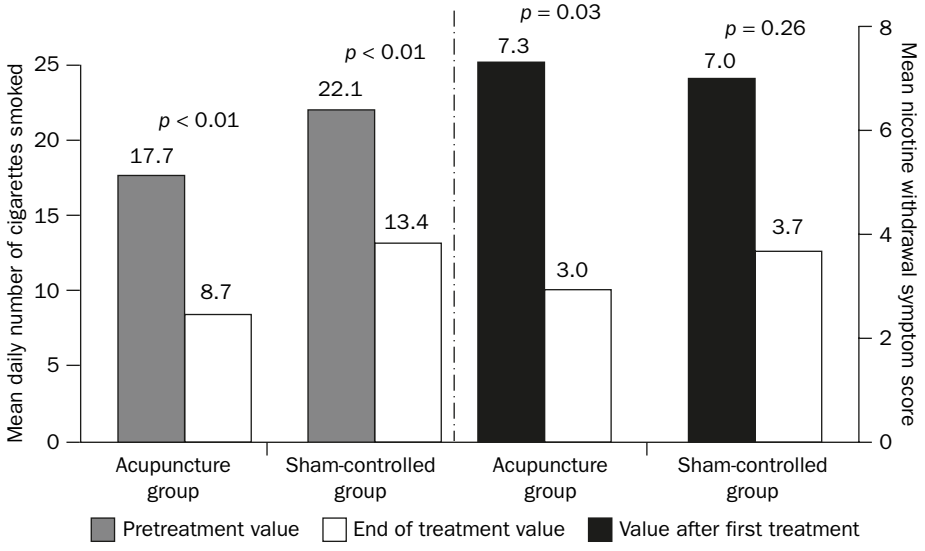

Figure 1. Changes in the mean daily number of cigarettes smoked before treatment and at the end of treatment and changes in mean nicotine withdrawal symptom score after the first acupuncture treatment and at the end of treatment in the acupuncture treatment and sham acupuncture (control) groups.

(7.3±5.4 *vs.* 3.0±2.7; $p=0.03$) in the acupuncture treatment group, while no significant difference was noted in the control group (7.0±5.4 *vs.* 3.7±3.0; $p=0.26$).

Table 3 reveals the comparisons between subjects who had succeeded or failed to stop smoking at the end of the 8-week acupuncture treatment. There was no significant difference between subjects who had

Table 3. Comparison between subjects who succeeded or failed to stop smoking at the end of the 8-week auricular acupuncture treatment*

	Succeeded in smoking cessation ($n=28$)	Failure in smoking cessation ($n=90$)	p
Acupuncture treatment/sham acupuncture (control)	16/12	43/47	0.517
Male/female	25/3	75/15	0.558
Mean age (yr)	57.8±13.9	52.4±17.5	0.139
Education (≤ junior high school/senior high school/≥ college	7/6/15	18/42/30	0.155
Occupation (white collar/blue collar/ merchant/retired/none)	2/3/8/11/4	9/13/24/30/14	0.611
Mean age of starting smoking (yr)	21.8±10.1	19.3±6.2	0.118
Mean smoking years	35.1±15.7	32.7±18.4	0.525
Mean pretreatment daily number of cigarettes smoked	17.0±11.6	19.2±12.2	0.411
Previous smoking cessation experience (yes/no)	25/3	60/30	0.028
Mean pretreatment nicotine dependence score	2.0±1.1	2.2±1.0	0.190
Mean pretreatment exhaled carbon monoxide concentration (ppm)	14.5±10.2	14.5±9.3	0.996

**Data are expressed as mean±standard deviation or n.*

Table 4. Side effects in subjects who received auricular acupuncture treatment or sham acupuncture (control)

	Acupuncture treatment ($n=59$)	Sham acupuncture ($n=59$)	p
Minor bleeding	2	1	0.500
Hematoma	0	1	0.500
Dizziness	1	3	0.309
Fainting	0	0	1.000
Nausea	1	1	0.752
Feeling of residual needling	13	11	0.410
Tenderness sensation	23	27	0.288
Minor infection	1	0	0.500

succeeded or failed to stop smoking at the end of treatment with regard to treatment group, gender, mean age, education level, occupation, and mean values for the age at which smoking started, smoking duration, daily number of cigarettes smoked, nicotine dependent score, and exhaled CO concentration. However, subjects with previous smoking cessation experience had a significantly higher success rate of smoking cessation than those without previous smoking cessation experience (29.4% *vs.* 9.1%; $p=0.028$). Only 3 subjects (10.7%) among the 28 subjects who succeeded in smoking cessation were receiving the smoking cessation program for the first time, the other 25 subjects (89.3%) had previous smoking cessation experience. Stepwise multivariate logistic regression revealed that previous smoking cessation experience was the only significantly predictive factor for successful smoking cessation (odds ratio, 4.24; 95% confidence interval, 1.14–15.74; $p=0.031$).

The side effects during the period of acupuncture therapy for smoking cessation included tenderness sensation (50 subjects, 42%), feeling around residual needles (24 subjects, 23%), dizziness (4 subjects, 3.4%), minor bleeding when withdrawing the needles (2 subjects, 1.7%), and nausea sensation (2 subjects, 1.7%). These side effects were commonly seen during the initial period of acupuncture treatment and gradually declined later. With regard to the side effects of acupuncture treatment, there was no significant difference between the treatment and control groups (Table 4).

Discussion

In 2000, approximately 500,000 deaths were attributable to cigarette smoking in the United States, accounting for 20% of all deaths.[4] In Taiwan in 2005, there were 40% of adult males and 4.8% of adult females smoking. An increasing number of adolescents are also smoking in Taiwan.[5] Lung carcinoma has become the leading cause of cancer-related death in recent years. Smoking is a serious public health problem worldwide.[1–3] However, cigarette smoking is the single most preventable cause of premature death in the United States, and smoking cessation has been proven to reduce the complication of smoking-related morbidity and mortality.[7,9,32,33] Although this study did not reveal any significant difference in the smoking cessation rate between the auricular acupuncture treatment group and the sham acupuncture group, our results showed a smoking cessation rate of 23.7% among the 113 enrolled subjects at the end of treatment, and it was 14.4% at 6 months after the completion of treatment. In addition, cigarette consumption was significantly decreased in both the acupuncture treatment and control groups at the end of treatment. The success rate of smoking cessation in our study was better than the success rate of 3–6% in subjects who stop smoking depending on their own individual will.[32,34] However, our results did not show a better result than behavior counseling on smoking cessation by medical staff.[35,36] The addition of behavior counseling may be needed to enhance the success rate in subjects who receive acupuncture for smoking cessation.[37]

Our results were also consistent with previous Cochrane Collaboration meta-analysis in which acupuncture showed no significant difference in the smoking cessation rate between acupuncture treatment and sham acupuncture. We have followed the suggested guidelines for acupuncture smoking cessation research proposed by the Cochrane Library. The present study was performed according to these guidelines by including blinded randomization, sample size calculation, biochemical validation of smoking cessation and use of a single licensed and experienced acupuncturist to avoid possible bias between acupuncturists. However, we did not include a long-term follow-up in this study. High drop-out rate has been shown in previous smoking cessation studies. This study showed that only 58.5% of enrolled subjects could be traced 6 months after the end of acupuncture treatment. It is difficult to complete long-term follow-up in the busy real world. In addition, relapse back into smoking after the completion of acupuncture intervention can be related to many environmental and personal factors not related to the long-term effect of acupuncture.

In this study, we used auricular acupuncture, rather than body or extremity acupuncture, with an intention to have a durable 1-week acupuncture effect and increase in subjects' compliance. It is not practical for subjects to come back to the clinic 3–5 times a week to receive conventional body or extremity acupuncture for smoking cessation. Although the auricular acupuncture theory is not based on the theory of Chinese traditional meridians, Nogier inferred that the ear shell represents a reversed fetus according to reflection phenomenon (e.g. head was relevant to earlobe and internal organs relevant to the interior auricular conche).[38] Previous studies also showed a 6.3–60% success rate of smoking cessation using auricular acupuncture with various study designs and different auricular acupoints selected.[18,19,21–24,39–41] In this study, we included most of the auricle acupoints that had been previously mentioned for smoking cessation. Our results did not show a higher success rate of smoking cessation when compared with previous reports. Possible reasons include older mean age in our enrolled subjects (53 years old) and greater mean smoking years (32 years).

Our results showed no significant difference in the smoking cessation rate between the auricular acupuncture treatment and sham acupuncture groups. For the sham acupuncture group, we did not choose the sham acupoints 2–5 mm near the smoking cessation acupoints as in previous reports,[18,22,40] but chose 4 control acupoints irrelevant to smoking cessation over the auricular helix to avoid the possible bias of a placebo effect. Our results were consistent with previous reports and may indicate that auricular acupuncture has a placebo effect or ritualized function and produces biological effect of a nonspecific noxious central inhibitory effect despite the different acupoints selected.[20,23,25,38,39,41] In our study, the mean nicotine withdrawal symptom score at the end of acupuncture treatment decreased significantly from the first acupuncture treatment in the acupuncture treatment group, while no significant difference was noted in the sham acupuncture control group. Our results were consistent with previous reports and indicated that the acupoints we chose for smoking cessation were effective in the control of chemical-dependent related withdrawal symptoms through acupuncture-induced release of endogenous opioid peptide.[42–47]

According to the multivariate logistic regression analyses, our results showed that only previous smoking cessation experience could significantly predict success in smoking cessation using auricular acupuncture. Similar findings have been shown in previous smoking

cessation trials and may indicate that behavior modification using Prochaska's transtheoretical model should be adopted in order to enhance the success rate of smoking cessation.[48–51]

Nowadays, nicotine replacement therapy and bupropion as well as behavior counseling are used in smoking cessation; however, the success rates are still limited.[52–55] This study showed that ear acupuncture is a safe method for smoking cessation. Only minor side effects were noted during treatment. Nevertheless, because the success rate of smoking cessation using ear acupuncture is still far from satisfactory, the addition of behavior counseling and/or nicotine replacement therapy may be needed in future clinical trials.

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