Auricular Acupuncture, Education, and Smoking Cessation: A Randomized, Sham-Controlled Trial

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Objectives. This study examined the effect of acupuncture alone and in combination with education on smoking cessation and cigarette consumption.

Methods. We prospectively studied 141 adults in a quasi-factorial design using acupuncture, sham acupuncture, and education.

Results. All groups showed significant reductions in smoking and posttreatment cigarette consumption, with the combined acupuncture–education group showing the greatest effect from treatment. The trend continued in follow-up; however, significant differences were not maintained. Greater pack-year history (i.e. the number of years smoking multiplied by baseline number of cigarettes smoked per year, divided by 20 cigarettes per pack) negatively correlated with treatment effect. Trend analysis suggested 20 pack-years as the cutoff point for this correlation.

Conclusions. 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. (*Am J Public Health.* 2002;92:1642–1647)

Acupuncture is increasingly being used to treat problems of chemical dependency.[1] Wen and Cheung first described the effects of acupuncture in alleviating the severity of opiate withdrawal symptoms.[2–3] They reported that individuals addicted to opiates who underwent acupuncture anesthesia experienced a substantial reduction in the severity of their withdrawal symptoms. Acupuncture procedures based on Wen's initial protocol, which used electroacupuncture on 2 ear points, have become varied and diverse. Reports have generally noted that ear points seem the most effective body site for treating chemical withdrawal symptoms.[4] Acupuncture has been used to treat addiction to a variety of substances, including alcohol, cocaine, heroin, and tobacco.

Several controlled studies have evaluated acupuncture as an aid to smoking cessation. In a recent meta-analysis reported in the Cochrane database[5] and in print format,[6] White et al. examined all of the published studies listed in MEDLINE and hand-searched the non-MEDLINE literature. They found 18 trials; however, only those that used a blinded, sham-control design were included in the analysis. The meta-analysis showed no difference between acupuncture and placebo treatment of smoking. White and colleagues' study also rated the trials and judged their overall quality to be poor. They noted several concerns regarding design flaws in the trials and offered suggestions for improving the quality of future trials. The authors stated that further research on the role of acupuncture in smoking cessation treatment requires higher-quality studies with the following components: a clear hypothesis; calculation and recruitment of adequate sample sizes; an appropriate method of randomizing subjects; concealment of randomization; minimization of therapist bias (e.g., intention or expectation bias); long-term follow-up for at least 6, and preferably 12 months; highly trained and experienced acupuncturists; and biochemical validation of smoking cessation. Our study improves on previous work in the field by using a more rigorous research design that addresses all but the final concern.

METHODS

Subject Recruitment, Study Sample, and Power

Participants were recruited by means of advertisements on radio and in local print media. Those who qualified as participants after telephone screening interviews were scheduled for an initial appointment and randomly assigned to groups; they then signed all necessary consent forms and completed an intake questionnaire that collected demographic information and the baseline dependent variables.

Subjects were accepted into the study if they satisfied the following inclusion criteria: aged 18 years or older; had attempted to stop smoking at least once without success; not actively psychotic or suffering from any neurological or physical illness or other impairment that would prevent understanding of the research consent form; able to read and write sufficiently to understand and complete the forms; willing to participate in a treatment protocol involving acupuncture; not currently taking phenothiazines, tricyclic antidepressants, lithium carbonate, or beta-blocking medications, nor chronically using sympathomimetic drugs such as ephedra, ephedrine, amphetamines, or sedative medication; and not abusing any other drug during the course of the research treatment period. All treatments given during the course of the study were provided to subjects free of charge.

The sample size determination assumed a comparison for 3 treatment groups: true acupuncture treatments, true acupuncture treatments plus 5 weeks of an educational smoking cessation program, and sham acupuncture treatments plus 5 weeks of an educational smoking cessation program. The power analysis and sample size determination are for a mixed model with repeated measures. This analysis assumes that the covariance between any 2 periods is part of an autoregressive relation. The criterion for significance (α) was set at .05 for a power of .80. The sample size obtained from the power analysis varied from 90 to 144.

Assignment to Group and Study Design

A quasi-factorial design was used to study the effects of acupuncture and an educational program alone and in combination with a

smoking cessation program. A classic factorial design would contain 4 groups representing all combinations of true acupuncture–sham acupuncture and educational program–no educational program. For ethical reasons, the sham acupuncture–no education program was dropped, leaving 3 treatment groups.

A random-number table provided by the project statistician was used in patient randomization, which was conducted by a research associate blind to treatment assignment. Patients randomized to true acupuncture received acupuncture bilaterally at 5 ear points commonly used in treatment for chemical dependency. The auricular points used were the Shen Men, Sympathetic, Lung, Kidney, and Liver, as well as the LI-4 (Hegu) point on the wrist. Patients randomized to sham acupuncture received acupuncture at ear and wrist points that were located within 5 mm of the true point but were not themselves active acupuncture points, as per research by Bullock and Culliton.[4,7] This proximity to specific points minimized differences in appearance between participants receiving acupuncture in the true and sham point groups, thus ensuring that participants remained unaware of their treatment group assignment.

Standardized acupuncture treatments were administered by highly trained and experienced acupuncturists. Each treating acupuncturist was trained in China as a traditional Chinese medical doctor and was a diplomate in acupuncture of the National Certification Commission for Acupuncture and Oriental Medicine, the national body whose certification is a prerequisite to licensing in all states that license acupuncturists, except California. Additionally, the acupuncturist completed training with the National Acupuncture Detoxification Association, the acupuncture organization dedicated to research and clinical work with addictions treatment.

Independent and Dependent Variables

The independent variables used in the study were true acupuncture, sham acupuncture, and a smoking cessation educational program. The dependent variables used in the study were Beck Depression Inventory (BDI) score; Zung Self-Rating Anxiety Scale (SAS) score; number of cigarettes smoked per day; age at smoking initiation; number of years smoking; smoking or nonsmoking at visit; percentage decrease in smoking; decrease in number of cigarettes smoked; a visual analogue scale (VAS) score; and pack-year history, defined as number of years smoking multiplied by baseline number of cigarettes smoked per year divided by 20 cigarettes per pack.

The BDI is a self-rating scale designed to assess the severity of depression in adolescents and adults and to identify depression in nonclinical populations.[8] The symptoms and attitudes assessed include mood, pessimism, sense of failure, self-dissatisfaction, guilt, punishment, self-dislike, self-accusations, suicidal ideation, crying, irritability, social withdrawal, indecisiveness, body image change, work difficulty, insomnia, fatigability, loss of appetite, weight loss, somatic preoccupation, and loss of libido.[9] The SAS consists of 20 questions used to measure anxiety in a nonclinical population.[10] The VAS used to rate levels of craving in the study population at all measurement points consisted of a 10-cm line anchored with "no craving" on the left side and "great craving" on the right. Subjects were instructed to mark a point along the line that best describes their level of craving. Level of craving was determined by measuring from "no craving" to the subject's mark, scaled as a continuous integer from 0 to 10. VAS scores are commonly used in research because of their reliability and ease of use[11–15] for the measurement of variables such as appetite[16] and for their ability to detect changes over time.[17]

Participants were given a cigarette-pack self-monitoring smoking chart; they then began recording the number and time that cigarettes were smoked in the 7 days before beginning treatment to establish their baseline smoking behavior. Participants continued to monitor their smoking behavior in this manner throughout the study and used the chart to self-report their smoking behavior at each visit.

Study Procedures and Treatment Regimens

Acupuncture practices were standardized to conform to the guidelines of the manual for clean needle technique for acupuncturists.[18] Acupuncture points were prepared with 75% alcohol prep pads. Sterile, disposable 36-gauge 0.5-inch needles (Helio Medical Supplies, San Jose, Calif) were used. In addition, Universal Blood and Body Fluid Precautions, which assume that all subjects are potentially carrying a bloodborne pathogen and hence are contagious, were followed. This procedure reduces the risk of cross- or autogenous contamination, thereby decreasing hazards to participants. Participants were monitored at all treatments and follow-up visits for signs or reports of adverse effects.

Treatments were administered without manual stimulation and lasted approximately 30 minutes, with participants seated in comfortable chairs. Interaction was limited to the time required for needle placement and withdrawal, and only essential verbal communication took place between participants and acupuncturists. Research assistants blinded to the participant's treatment group supervised the treatment to ensure that only essential communication took place.

Each selected participant was randomly assigned to 1 of 3 treatment groups: 20 (5 per week) true acupuncture treatments; 20 (5 per week) true acupuncture treatments plus 5 weeks of an educational smoking cessation program; or 20 (5 per week) sham acupuncture treatments plus 5 weeks of an educational smoking cessation program. The treatment lasted 4 weeks (4 weeks of acupuncture treatment without the educational smoking cessation program) or 5 weeks (4 weeks of acupuncture treatment provided concurrently with 5 weeks of educational smoking cessation program), with follow-up immediately after completion of the acupuncture treatments and at 3, 6, 12, 15, and 18 months after baseline. The design included control through randomization of addiction severity, pack-year history, and other characteristics of interest.

The educational program involved a multisession, multicomponent approach that included behavioral training, education, social support, and relapse prevention—techniques known to be among the most successful approaches to smoking cessation.[7] Subjects met for 1.5-hour sessions twice weekly for the first 2 weeks and once weekly thereafter. The sessions were conducted by a presenter with

an MPH degree and with experience in state-funded group smoking cessation programs. Sessions were designed to help participants learn the patterns of their addiction, devise a strategy to break that pattern, develop their own specific coping mechanisms, and learn how to maintain a nonsmoking status. Inclusion of an educational component is consistent with the methods described by Bullock et al.[4,7] and with model substance abuse programs in New York at Lincoln Hospital[1,19] and in Dade County, Fla.[20]

Hypotheses

The aims of this study were to (1) compare the effects of sham acupuncture and true acupuncture, alone and in combination with an educational smoking cessation program, at baseline and after 1, 3, 6, 12, 15, and 18 months of treatment, on certain variables: smoking cessation, number of cigarettes smoked, cigarette craving, depression, anxiety, and dropout rate; (2) identify any differences in response to treatment by subgroup characteristics such as age, pack-year history, and sex; (3) identify predictor variables to determine who might or might not respond to intervention; and (4) identify adverse effects of acupuncture treatment.

Data Analysis

Because smoking information was measured at unequally spaced time points, a multifactor repeated-measures design with mixed models was used in comparing treatment groups. These data from the smoking data record consisted of repeated measurements of the smoking behavior of patients at 6 unequally spaced intervals. Each of the 3 possible treatment levels were considered to be a fixed effect in the modeling of the data.

It is useful to consider some kind of time-series covariance structure, wherein the correlations of the repeated measurements are assumed to be smaller for observations that are further apart in time. Most models for these kinds of data assume equal spacing. In the structure we used to model our unequally spaced data, we assumed that the covariance between any 2 measurements in times is $\text{cov}(y_{t1},y_{t2}) = \sigma^2 \rho^{|t1-t2|}$, where ρ is an autoregressive parameter assumed to satisfy $|\rho| < 1$, and σ^2 is an overall variance.

Initial scores at intake (cigarettes smoked, craving) were used as covariates. The measurements for each participant provided the repeated scores. The predictor variables consisted of treatment group, educational program, and the BDI and SAS scores.

A multifactor repeated-measures design with a covariate was used to analyze the data. The covariate is used to take into account preexperimental conditions and adjusts for any preexisting effects. Thus, the final model addressed the effects of treatment on smoking cessation. A repeated-measures design usually is an example of a mixed model, with the observational unit (i.e., the person) a random effect and the treatment on the observational units the fixed effects. A mixed model is appropriate in this setting because the treatment groups were fixed but the effect on each person over time was random. In this repeated-measures design, 6 measurements were taken sequentially for each patient.

RESULTS

Demographics

No differences between groups were found in sex, current age, age at smoking initiation, or cigarettes per day at baseline; therefore, the randomization was successful. Seventy men and 71 women with a mean age of 46.4 years (range: 26–81 years) and a mean age at smoking initiation variable of 15.7 years (range: 5–30 years) enrolled in the trial. Mean baseline cigarette use per day was 27.2 (range: 6.4–80.0), with a mean pack-year history of 42.5 (range: 4.6–154.0).

Data

The number of subjects in each group at each point are shown in Table 1. Because of the high dropout rate, a comparison of all baseline demographics was performed on subjects who remained in the study at 18 months and those who dropped out before completion of the study. In our analyses we found no significant differences between baseline variables of those who remained in the trial and baseline variables of those who dropped out, showing no effect of dropouts. Percentages of subjects who had successfully quit smoking at each of the periods are presented in Table 2 and Figure 1. The number of participants who successfully quit smoking immediately after treatment differed among the groups ($P = .023$). The combination of acupuncture and education (40%) demonstrated almost twice the cessation rate of education and sham acupuncture (22%) and 4 times the rate of acupuncture alone (10%).

The percentage decrease in cigarettes smoked at all periods is presented in Table 2 and Figure 2. The percentage decrease in cigarettes per day differed among the groups ($P = .003$), with the combined acupuncture and education group showing the largest decrease.

The treatment effect trend persisted in the combined acupuncture and education group over the 18-month follow-up period; however, the differences between groups became nonsignificant (cessation: $P = .17$; percentage cigarette decrease: $P = .28$) owing to decreased power resulting from small sample size caused by dropout. No adverse effects of

TABLE 1—Number of Subjects per Treatment Group: Arizona Acupuncture and Education Smoking Cessation Study, 1996–1997

Period	True Acupuncture and Education	Sham Acupuncture and Education	True Acupuncture Only
Baseline	45	58	38
Follow-up, mo			
1	22	42	44
3	16	25	15
6	16	25	13
12	16	24	12
15	15	24	11
18	16	20	12

TABLE 2—Percentage of Subjects Not Smoking and Percentage Decrease in Smoking at Each Study Period, by Treatment Group: Arizona Acupuncture and Education Smoking Cessation Study

	True Acupuncture and Education		Sham Acupuncture and Education		True Acupuncture Only	
Period	Not smoking, %	% Decrease in Smoking	Not smoking	% Decrease in Smoking	Not smoking	% Decrease in Smoking
Baseline	0	0	0	0	0	0
Follow-up, mo						
1	40	53	22	40	10	49
3	40	40	17	34	20	25
6	40	48	6	13	20	25
12	40	51	11	26	20	21
15	40	51	18	43	20	29
18	40	52	22	31	20	20

acupuncture treatment were noted except for infrequent minor bleeding upon needle removal.

Neither BDI nor SAS scores showed statistical differences between groups at any point. The SAS scores declined over time ($P = .0123$) in all groups; however, there was no difference between groups in reduction rates over time ($P = .4732$). Baseline scores on both tests did not predict which subjects responded to treatment, either immediately following treatment or at any follow-up point. A VAS reading to measure craving showed no significant differences between treatment groups at baseline or at any follow-up point ($P = .961$).

By allowing such a wide range of smoking history, differential effectiveness for subpopulations could be lost. The estimated pack-year history was correlated with the decrease in total number of cigarettes used from baseline to immediately after treatment. A correlation matrix revealed that for all groups, subjects with a greater baseline pack-year history decreased their posttreatment cigarette use significantly more than did subjects with a lower baseline pack-year history. Trend analysis of this matrix (Figure 3) suggests that 20 pack-years is the cutoff point, for the reason that those with a lower pack-year history showed very little or no decrease and those with a greater pack-year history showed significant decreases in posttreatment cigarette use.

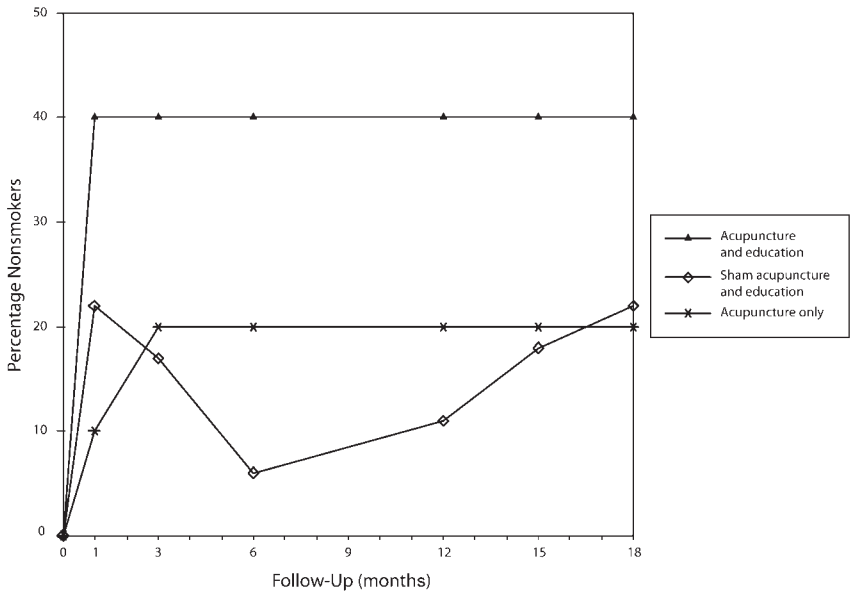

FIGURE 1—Percentage of subjects nonsmoking at follow-up, by treatment group.

DISCUSSION

Cigarette smoking is the single most preventable cause of premature death in the United States. In 1985, approximately 390 000 deaths were attributable to cigarette smoking,[21] and more than 434 000 deaths occurred in 1988.[22] During 1990, 418 690 US deaths, roughly 20% of all deaths, were attributed to smoking.[22]

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 remaining 3 weeks), alone and in combination, are effective in promoting a decrease in the number of cigarettes smoked as well as smoking cessation. The combination of acupuncture with education demonstrated an effectiveness rate of 40% cessation and 53% posttreatment 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%–25% at 1 year following treatment.[21] The combination of acupuncture and education maintained a cessation rate of 40% through the 18-month follow-up; however, the power associated with the remaining sam-

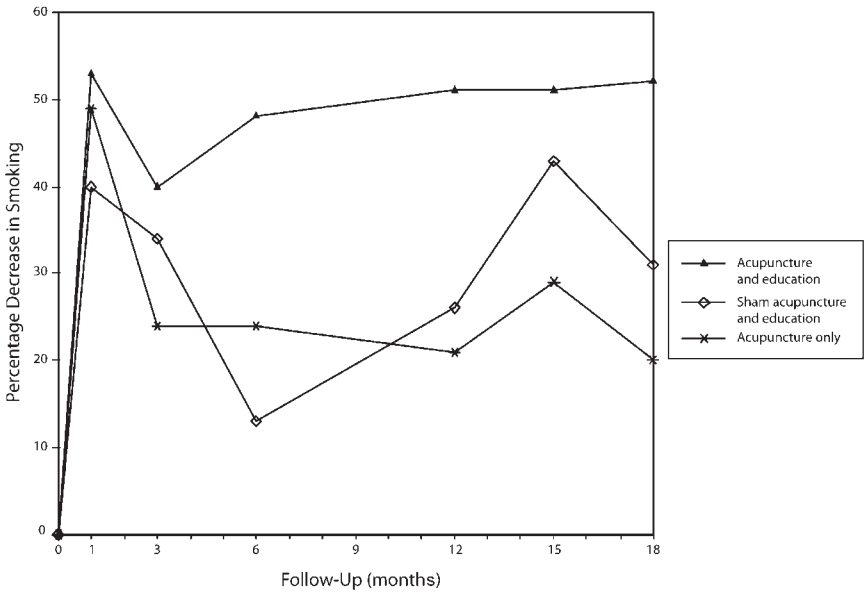

FIGURE 2—Percentage decrease in smoking at follow-up, by treatment group.

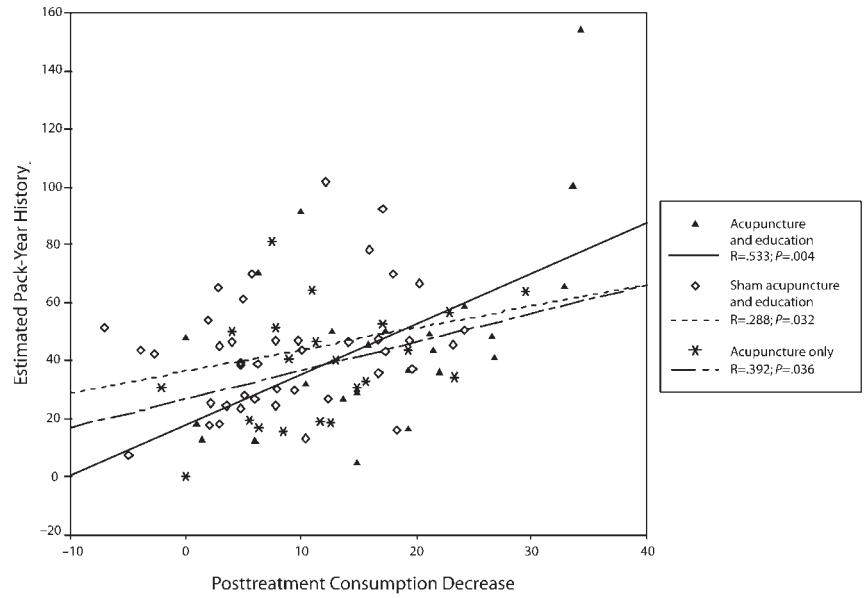

FIGURE 3—Change in posttreatment cigarette use and pack-year history, by treatment group.

ple was small because of the high dropout rate, and as a result, statistical significance was not reached.

Further studies with more power are needed to determine whether the abstinence rate demonstrated at the end of treatment can be maintained throughout the 18-month follow-up period. Another limitation of the study was the use of subject self-reports to determine cigarette use, which could have biased the results if reporting was not accurate or truthful.

A new finding from this study is the significant correlation in all groups between estimated pack-year history and decrease in cigarette use following acupuncture treatment. The relationship was strongest in the true acupuncture and smoking cessation education group, followed by the acupuncture-only group. These results demonstrate that the greater the estimated pack-year history of the subject before treatment, the greater the decrease in total number of cigarettes smoked per day following treatment. This finding is extremely important, as it indicates that the combined treatment protocol is effective in the population that is most addicted and at the greatest risk of developing smoking-related-diseases. The conflicting results seen in previous studies, as reported in the Cochrane meta-analysis, may have been due in part to some studies having more subjects with a lower pack-year history, where acupuncture is less effective.

The recent Cochrane Collaboration meta-analysis[5,6] suggested several guidelines for future acupuncture–smoking cessation research. The present study responded to these guidelines by including several hypotheses, sample size calculations, blinded randomization, oversight of therapists by blinded research associates to ensure that no bias occurred, follow-up over 18 months, and use of a licensed acupuncturist certified in acupuncture addictions treatment, thereby fulfilling all of the guidelines except biochemical validation. Contrary to the assessment of the Cochrane meta-analysis, this trial showed significant effects of acupuncture treatment on both total cigarettes smoked and smoking cessation following treatment. A further trial, currently under way, uses a similar research design with a larger sample size, greater power, biochemical markers for smoking, and a participant population with a history of greater than 20 pack-years. It is hoped that this trial will answer some of the questions raised in the present study. ■

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Human Participant Protection

The study was approved by the institutional review board of the Arizona State University.

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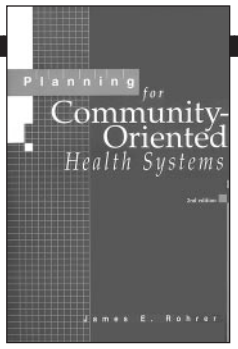

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