

A single-blind, placebo-controlled trial of a simple acupuncture treatment in the cessation of smoking

NORMA R WAITE

JOANNE B CLOUGH

SUMMARY

Background. Tobacco smoking is a major cause of preventable disease and premature death. Physicians should play an active role in the control of smoking by encouraging cessation and helping the smoker to choose the most suitable aid to cessation.

Aim. To evaluate a simple, ear acupuncture treatment for the cessation of smoking.

Method. Randomized, single-blind, placebo-controlled trial of 78 currently smoking volunteers from the general public. Volunteers attended an acupuncture clinic in a general practice setting and were given a single treatment of electroacupuncture using two needles at either an active or a placebo site plus self-retained ear seeds for two weeks. The major outcome measure was biochemically validated total cessation of smoking at six months.

Results. A total of 12.5% of the active treatment group compared with 0% of the placebo group ceased smoking at six months ($P = 0.055$, 95% confidence interval -0.033 to 0.323).

Conclusion. This simple ear electroacupuncture treatment was significantly more effective in helping volunteers to quit smoking than placebo treatment.

Keywords: acupuncture; smoking; randomized controlled trial.

Introduction

EACH year, around 30% of tobacco smokers make a serious attempt to stop, but less than 10% of those who try are successful.¹ A number of aids to stopping smoking are available, and numerous trials have attempted to evaluate them. However, no one single best method has been identified.²

The efficacy of acupuncture as an aid to smoking cessation has come under close scrutiny. A review of smoking cessation methods in the United States of America (USA) and Canada³ reported that rates for cessation of smoking with acupuncture at one-year follow-up ranged from 8% to 40%. The lowest cessation rate of 8% was achieved in the only study that attempted to validate cessation by biochemical means.⁴ The median cessation rate for 13 studies with at least a six-month follow-up was 25%. No trial of smoking cessation to date that has attempted to combine biochemical validation with a randomized, placebo-controlled design has shown significant benefit of acupuncture over placebo treatment.

The mechanism of acupuncture in smoking cessation is thought to be through the production of endorphins. It has been

argued that a needle placed anywhere in the body could have this effect, and this may explain why previous trials have been unable to demonstrate a difference between active and placebo treatment.^{5,6} However, in these studies, the placebo sites chosen have been adjacent to the active sites, and no study to date has attempted to use a distant placebo site.

The aim of this study was to evaluate an acupuncture treatment for smoking cessation that is suitable for use in an outpatient or general practice setting. Much criticism has been levelled against trials in complementary medicine for poor design and methodology.⁷ This study attempted to address these issues by using a single-blind, placebo-controlled design for the trial of a simple ear acupuncture treatment, with power-based calculation of sample size, stratification for gender, randomization of volunteers into treatment groups, careful selection of a distant placebo, and follow up at six months with biochemical validation of smoking history.

Method

Ethical permission for the study was obtained from the Joint Ethics Sub-Committee of the Southampton University Hospitals Trust. Power-based calculation of sample size, assuming a cessation rate of 30% for acupuncture and 5% for physician counselling alone,³ concluded that, in order to demonstrate a difference between the groups with 80% power and 95% probability, 36 subjects would be required in each group.

Volunteers were recruited in three ways: first, by advertising in the local news section of Teletext (this method attracted the most volunteers); secondly, using a poster displayed in the local general hospital; and, thirdly, by word of mouth. Volunteers were required to have been smoking at least 10 cigarettes each day and to be over 18 years of age. Subjects were excluded if they had had acupuncture for smoking cessation previously or were fitted with a pacemaker. The physician responsible for all subject contact, recruitment, counselling, and treatment was a general practitioner (NRW) with a Licentiate in Acupuncture from the British College of Acupuncture.

The nature of the investigation and randomization procedure was explained to the volunteers at the first appointment. A smoking history was taken, including details of previous attempts to stop and methods used. Nicotine dependency was assessed using the Fagerstrom questionnaire,⁸ which considers the number and strength of cigarettes smoked as well as smoking pattern. All subjects received structured counselling before randomization about the dangers of smoking using an information booklet⁹ and were given written information regarding acupuncture.¹⁰ They were asked to try not to use other cessation methods during the trial period. As part of the counselling, a stop date was chosen mutually.¹¹ This was also to be the date of their second appointment at which the acupuncture treatment was to be performed. A urine specimen was obtained for measurement of urinary cotinine, a principal urinary metabolite of nicotine, using a double antibody nicotine metabolite (Diagnostic Products Corporation, Los Angeles, USA). In this assay, a urinary cotinine of more than 0.5 mg l⁻¹ is considered a positive result, confirming this subject

Norma R Waite, BM, research fellow, Joanne B Clough, DM, FRCA, FRCPC, senior lecturer, Child Health, Southampton Hospital, Southampton. Submitted: 4 July 1997; accepted: 4 March 1998.

© British Journal of General Practice, 1998, 48, 1487-1490.

to be a smoker. Eighty-three volunteers attended the first appointment, four withdrawing before treatment.

The remaining 79 subjects were randomized and stratified for gender into active and placebo groups. The active treatment used a point detector to locate the lung point in the ear.¹² A 32-gauge, 1.5-inch acupuncture needle was inserted at the point of maximal response in each ear, and both needles were then connected to a portable desktop needle stimulator (AWQ-104, manufactured in China, distributed by OMS Baintree, MA, USA). The needles were stimulated for 20 minutes using an intermittent, biphasic square pulse at a frequency of 4 Hz. The intensity was one at which the patient was aware of the stimulation but found it comfortable. The needles were then removed and a seed (Chinese cow herb) was placed at each needle site, held in place with adhesive tape. The subjects were instructed to keep the seed in place for as long as they found it helpful, and were told to put pressure on the seeds whenever they experienced the desire to smoke. An appointment was made for follow-up after six months.

The placebo group received a similar regime, the needles and seeds being placed on the medial aspect of each patella. The point detector was used and made to appear to register by using it over recognized acupuncture points around this location. However, the needles were then placed superficially where no reading was obtained to ensure that the effect of the electrostimulation would be minimal.

All subjects were contacted by telephone two weeks after receiving treatment and received a postal questionnaire at two months and four months to record their smoking habits and to remind them of their follow-up appointment at six months. At this follow-up appointment, smoking habit was documented. If still smoking, subjects completed a second Fagerstrom questionnaire. If not smoking, they were asked if other additional cessation methods had been used. A further urine sample for urinary cotinine measurement was obtained to verify the smoking history, and the analysis was carried out blind to treatment group and smoking history.

Results were analysed using the Fisher's exact test and chi square (StatXact 3.0 statistical software).

Results

Seventy-nine patients were treated, 44 men and 35 women, and none was lost to follow-up. One had to be excluded because of the use of nicotine patches in addition to the acupuncture. Of the remaining 78, 40 (22 men and 18 women) received active treatment and 38 (21 men and 16 women) received placebo treatment.

Table 1 summarizes the mean age, gender, pretreatment smoking history, and mean Fagerstrom questionnaire scores of the two treatment groups. As the groups were well matched, the data were analysed unadjusted for these characteristics.

Details of length of time that the seeds remained in place was obtained at two weeks from 37 who received active treatment and from 35 who received placebo treatment. On average, the seeds at the active site were retained for five days and at the placebo site for seven days. Side-effects of itch or soreness at the site of the seeds were described by three (8%) of the placebo group, whereas eight (21%) of the active group reported side-effects: five who continued smoking described stickiness, itching, or soreness and three of those confirmed non-smokers at six months reported soreness or pain at the site of the seeds. No other side-effect of the treatment was reported.

All pretreatment urinary cotinines were positive ($> 0.5 \text{ mg l}^{-1}$), confirming subjects' eligibility as current smokers. Post-treatment urinary cotinine levels in subjects who admitted to be still smoking were obtained in all but one subject, and they were all

positive ($> 0.5 \text{ mg l}^{-1}$), confirming the smoking history.

Seven subjects, all from the active treatment group, claimed not to be smoking at six months. Two of these had positive post-treatment urinary cotinines (Table 2). They were subsequently recontacted, admitted to having been smoking when the urine specimens were taken, and considered as treatment failures in the final analysis.

Smoking histories were obtained from all 78 subjects at each stage of the study (Table 3). Five subjects (12.5%) who received active treatment were confirmed to be non-smokers biochemically at six months compared with none (0%) in the placebo treatment group (Fisher's exact test, two-tailed, $P = 0.055$, mid P value = 0.0275, confidence interval -0.033 to 0.323).

Discussion

In this single-blind, placebo-controlled trial, the biochemically validated quit rate of 12.5% in the active treatment group suggests that this simple ear electroacupuncture treatment was significantly more effective than placebo treatment (cessation rate 0%) in smoking cessation.

This study achieved a 100% follow-up at six months, an acceptable follow-up period for studies of smoking cessation.^{3,7} Longer follow-up was not considered feasible, as 87.5% of the subjects had resumed smoking and were poorly motivated for further study.

We attempted to compare the efficacy of appropriate active acupuncture treatment for smoking cessation with a placebo acupuncture treatment administered at a carefully selected distant site because, to date, no such study has been reported. It could be argued that the placebo regime was unconvincing, subjects being aware of the usual active sites used in acupuncture for smoking cessation. Additionally, as it was impossible for the therapist to be blind to the treatment used, the low cessation rate in the placebo group might have been caused by the therapist's lack of belief in the effect of counselling alone. The smoking histories, however, showed that the placebo group achieved a short-term success in stopping (a cessation rate of 18% at two weeks) and that the subjects were sufficiently convinced of the authenticity of the treatment to retain the seeds for an average of seven days. A higher proportion of the subjects receiving active treatment complained of discomfort from the seeds, and this was particularly marked in those who ceased smoking. This may suggest greater sensitivity at the active site. The mechanism of action of acupuncture in smoking cessation is, as yet, poorly understood but may involve the production of endorphins at the stimulated site.¹² If this is so, then the innervation of both the active and the placebo sites may be important, and a placebo site should be one of sparse innervation if it is indeed to act as a placebo. The choice of the knee as the placebo site in this study attempted to address this issue, but the choice of placebo site is an area warranting further attention.^{5,13}

The mean pretreatment Fagerstrom scores of both treatment groups showed high nicotine dependence and were similar to those seen in other cessation programmes.⁸ The subjects subsequently ceasing smoking in this trial were predominantly men who were moderate to heavy smokers of long standing. Although the numbers are too small to be conclusive, these results suggest that this category responds well to acupuncture treatment.

The presence of raised urinary cotinine levels in two of the seven subjects who claimed not to be smoking illustrates the importance of biochemical validation of smoking history and calls into question all previous smoking cessation studies that have used smoking history alone as the outcome measure. Urinary cotinine measurement itself has limitations, giving infor-

Table 1. Demographic details and pretreatment smoking histories of the two treatment groups and of the biochemically validated non-smokers [mean, (range) or number and proportion (%)].

	Active (n = 40)	Placebo (n = 38)	Non-smokers (n = 5)
Age (years) (range)	40 (24–67)	45 (23–69)	49 (29–64)
Sex			
Male	22	21	4
Female	18	17	1
No. of cigarettes smoked per day			
Light 15 or less	2 (5%)	6 (15.5%)	0 (0%)
Moderate 16–25	20 (50%)	20 (53%)	2 (40%)
Heavy >25	18 (45%)	12 (31.5%)	3 (60%)
No. of years smoking	26 (5–53)	28 (4–53)	44 (5–43)
Pretreatment FTQ score	7.1 (4–11)	6.3 (3–10)	6.4 (4–10)
Previous attempts to quit smoking	39 (98%)	35 (92%)	5 (100%)
Using gum	20 (50%)	15 (39%)	3 (60%)
Using patches	15 (38%)	12 (32%)	1 (20%)
Will power alone	31 (78%)	30 (79%)	4 (80%)
Other methods	8 (2%)	15 (39%)	1 (20%)

mation about nicotine intake in the preceding 48 hours, and it could be argued that subjects may have abstained just long enough to produce a negative specimen. This is considered unlikely, as the subjects were unaware of this time factor.

A recent review of the effectiveness of interventions intended to help people stop smoking included eight acupuncture trials and concluded that acupuncture was ineffective. The statistically significant cessation rate of 12.5% in this trial suggests that acupuncture is effective, and its efficacy compares favourably with the cessation rate of 13% achieved in the trials of nicotine replacement therapy also reviewed.¹⁴ Success rates in smoking cessation programmes tend to be low, as most people who successfully quit smoking do so without the help of professionals

and such organized programmes. These, therefore, attract subjects who have found it difficult to stop in the past by their own efforts³ but who are highly motivated. Although motivation was not measured formally, subject randomization to the two treatment groups ensured that selection bias was avoided. Physician advice alone can be effective in smoking cessation.¹⁴ In this study, both treatment groups received a similar degree of physician counselling and support. However, the acupuncture group was more successful in stopping smoking.

The aim of this study was to evaluate a simple acupuncture treatment that could easily be applied by a practitioner with minimal training on an outpatient basis. The treatment involved only two needles and one treatment session, was well tolerated by the subjects with minimal side-effects, and achieved a small but statistically significant improvement in smoking cessation. We suggest that this treatment should be as available as other cessation methods to patients who express a desire to quit smoking.

Table 2. Pretreatment and post-treatment urinary cotinine levels in subjects who claimed to be not smoking at six months.

Subject	Sex	Treatment	Pretreatment cotinine (mg l ⁻¹)	Post-treatment cotinine (mg l ⁻¹)
CH	F	Active	3.11	<0.50
SS	F	Active	3.01	3.86
AS	M	Active	3.25	4.10
MD	M	Active	3.87	<0.50
JL	M	Active	7.40	<0.50
AL	M	Active	7.09	<0.50
JN	M	Active	5.81	<0.50

References

1. Fiore M, Novotny E, Pierce J, *et al.* Methods used to quit smoking in the United States. Do cessation programs help? *JAMA* 1990; **263**: 2760–2765.
2. Schwartz J. Methods for smoking cessation. *Clin Chest Med* 1991; **12**: 737–753.
3. Schwarz J. *Review and evaluation of smoking cessation methods: the United States and Canada, 1978–1985.* Division of Cancer Prevention and Control National Cancer Institute.

Table 3. Number of subjects smoking and not smoking with cessation rates (percentages) at each point of contact, based on history and amended after urine analysis.

Treatment group	Outcome	Based on subjects' history				Biochemically validated six months
		Two weeks	Two months	Four months	Six months	
Active	Smoking	25	29	31	33	35
	Not smoking	15 (37.5%)	11 (27.5%)	9 (22.5%)	7 (17.5%)	5 (12.5%)
Placebo	Smoking	31	34	38	38	37 ^a
	Not smoking	7 (18.4%)	4 (10.5%)	0 (0%)	0 (0%)	0 (0%)

^aOne subject failed to provide a specimen.

4. Clavel F. Helping people to stop smoking: randomised comparison of groups being treated with acupuncture and nicotine gum with control group. *BMJ* 1985; **291**: 1538-1539.
5. Lewith GT. A measure of success. *Br J Gen Pract* 1997; **47**: 47-49.
6. Lewith GT, Vincent C. Evaluation of the clinical effects of acupuncture. A problem reassessed and a framework for future research. *Pain Forum* 1995; **4**: 29-39.
7. Ter Reit G, Kleijnen J, Knipschild P. A meta-analysis of studies into the effect of acupuncture on addiction. *Br J Gen Pract* 1990; **40**: 379-382.
8. Fagerstrom K. Measuring nicotine dependence: a review of the Fagerstrom Tolerance Questionnaire. *J Behav Med* 1989; **12**: 159-182.
9. *Smoking*. The Flora project for heart disease prevention (educational leaflet).
10. *The theory and practice of acupuncture: a basic guide to responsible acupuncture*. The British Medical Acupuncture Society (educational leaflet).
11. Glynn T. *Physician-initiated smoking cessation trials at the U.S. National Cancer Institute: results and recommendations*. Bethesda: National Cancer Institute.
12. Gillams J, Lewith GT, Machin D. Acupuncture and group therapy in stopping smoking. *The Practitioner* 1984; **228**: 341-344.
13. Ernst E. Acupuncture research: where are the problems? *Acupuncture Med* 1994; **12**: 93-97.
14. Law M, Tang JL. An analysis of the effectiveness of interventions intended to help people stop smoking. *Arch Intern Med* 1995; **155**: 1933-1941.

Acknowledgements

We thank Allen and Hanbury for funding the study, Drs J. Gallagher and C. Hackett for the loan of the premises, Dr A. Hunt for cotinine analysis, and Dr K. Palmer for his help and encouragement.

Address for correspondence

J B Clough, Child Health, Southampton General Hospital, Southampton SO16 6YD.