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ACUPUNCTURE IN ALCOHOLISM TREATMENT: A RANDOMIZED OUT-PATIENT STUDY

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Abstract — Seventy-two alcoholics were treated with acupuncture to the ear in a randomized single-blind controlled design over 10 weeks. Orthodox points and incorrect points 3–5 mm from orthodox points were used. No initial differences were found regarding social characteristics, the responses to the Swedish version of the Alcohol Use Inventory and the Three-dimensional Personality Questionnaire, indicating a successful randomization. There were non-significant tendencies towards gender differential response after acupuncture treatment ($P = 0.07$). There was no difference in the number of drinking days or level of craving between treatment and control patients. Among females, those in the treatment group reported reduction of anxiety after 1 month, more often than those in the control group ($P < 0.05$). Response to acupuncture was not related to personality or drinking pattern. Patients' experience of needle placement was similar in the study and control groups. The effects of acupuncture were less pronounced than those previously reported.

INTRODUCTION

Acupuncture treatment for addictions has been used in China and other Far Eastern countries from time immemorial (Wen and Cheng, 1973). Reports on successful treatment of withdrawal and detoxification in drug addiction were published by Wen and co-workers in the 1970s (Wen and Cheng, 1973; Wen and Teo, 1975; Wen, 1979). Few controlled studies have been conducted. Bullock and co-workers have published two studies on alcoholism, using a single-blind randomized design with acupuncture on 'correct' and 'incorrect' placement points, respectively (Bullock *et al*., 1987, 1989). They found a reduction of craving and alcohol abuse in those receiving acupuncture on correct points, compared with incorrect points. In a recent study by Worner and co-workers, who used similar techniques, no effects of acupuncture were found. However, only 5% of the study group completed treatment (Worner *et al*., 1992).

There is a need to confirm the results of these studies. In the present study, the same technique with correct and sham (incorrect) acupuncture points was used. The study was performed by offering acupuncture as an adjunct to 'treatment as usual'. The protocol of Bullock *et al*. (1989) was changed in a few ways in order to improve the design. (1) No body points were included because the previously used Hoku point is often regarded as related to analgesia (Brewington *et al*., 1994) and is thus not relevant to the present study. (2) Measures of drinking characteristics and personality were added at the initial examination. (3) Changes in psychiatric symptoms and smoking were measured and used as secondary outcome data in addition to drinking outcome. (4) The subjects were asked if they believed that they were treated on correct or incorrect points.

The main objective of the present paper was to find out if the positive findings in Bullock's two studies could be confirmed in a new setting. They reported better compliance, lower craving, and less drinking in those having acupuncture on the correct points, compared with those receiving it on the incorrect points. The main outcome variables were compliance, craving, and drinking. The three hypotheses were thus whether those who were given acupuncture on the correct points had better compliance, less craving, and less drinking than those receiving it on the incorrect points.

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MATERIALS AND METHODS

Study population

The out-patient clinic at the Department of Alcohol and Drug Diseases, Malmoe University Hospital, offers detoxification, supportive psychosocial treatment and counselling, and psychopharmacological treatment including disulfiram and calcium carbimide. The staff consists of physicians, psychologists, social workers, registered, and other nurses. The number of treatment sessions is approximately 40 000/year. The study group was recruited from the clinic by self-referral. Seventy-two patients, 51 men and 21 women, were included in the study. Their mean age (±SD) was 45 (±9) years, with a range of 26 to 70 years. Fifty-four per cent were gainfully employed and 68% were married/cohabiting. All patients were alcohol-dependent according to DSM-III-R (Spitzer *et al*., 1992). The diagnosis was based on the Structural Clinical Interview for DSM-III-R (SCID) (American Psychiatric Association, 1987). Exclusion criteria were pregnancy, diabetes mellitus, thrombocytopenia, metal allergy, present warfarin or analgesic medication. A total of 76 subjects were screened; four were not included in the study, two with diabetes mellitus and two with metal allergy.

Acupuncture

Acupuncture was given to the ear by a male registered nurse (RSW) trained in acupuncture. The points and the general design were similar to the studies by Bullock *et al*. (1987, 1989) with the exception of the Hoku body points, which were used in the Bullock study, but not in ours. The points used were Sympathetic, Shen Men, and Lung; no other points were used. The points were identified by Diascope (Sedatelec, France). Bilateral points were used with a needling time of at least 30 min, and an average time of about 45 min. Non-specific ear points, located 3–5 mm from the specific points, were used in the control group. The patients were seated in comfortable chairs in a large, open room and the acupuncturist treated several patients at the same time, including both patients with specific and non-specific ear points.

Randomization was accomplished using sealed envelopes to specific ear points or non-specific ear points after obtaining the subjects' informed consent. The study was approved by the Ethics Committee of the Medical Faculty, Lund University, Sweden.

The patients and all staff at the out-patient clinic with the exception of the acupuncturist were blinded to the type of acupuncture. The treatment was divided into three phases: (1) phase 1, five treatments weekly (Monday–Friday) during the initial 2 weeks; (2) phase 2, three times weekly during the following 4 weeks; (3) phase 3, twice weekly during the final 4 weeks.

The acupuncture treatment was added to the ordinary out-patient treatment, which included mainly social support and aversive treatment with disulfiram or calcium carbimide. All subjects were alcoholics (narcotic addicts were treated at another department). No history of drug use was included initially and urine toxicology was not taken. Rates of patients (all followed-up subjects including treatment drop-outs) receiving disulfiram or calcium carbimide during the study were as follows: phase 1, 33/63 (52%); phase 2, 21/59 (36%); phase 3, 22/51 (43%).

Initial examination

Two self-report questionnaires were given at the initial examination before randomization. The first was the Swedish version of the Alcohol Use Inventory (AVI) (Berglund *et al*., 1988) consisting of 75 items adapted from the American version and an assessment of alcohol intake during a typical week of heavy drinking. The five secondary scales, alcohol abuse, psychological benefits, interpersonal complications, social drinking, and daily drinking, were used in the analysis. These scales had satisfactory reliability and specificity. Norms based on a sample of more than 600 alcoholic patients are available (Berglund *et al*., 1988). The AVI results are presented in Table 1. The second questionnaire was the Three-dimensional Personality Questionnaire (TPQ) (Cloninger, 1987), consisting of 100 items. The three scales, novelty seeking, harm avoidance, and reward dependence, were used in the analysis. The Swedish version of the TPQ has not been checked for reliability and validity. The items are identical to the US version.

Follow-up procedure

A personal follow-up was performed by an independent researcher (AF) at 1, 3 and 6 months after the start of treatment. The interview after 1 month was accomplished in 87% of the cases, in 82%

Table 1. Scores of background variables, the Swedish version of the Alcohol Use Inventory (AVI) and Three-dimensional Personality Questionnaire (TPQ) by study groups

Parameter	Treatment group	Control group
No. of men/women	25/11	26/10
Age (years)		
Men (mean ± SD)	46.9 ± 9.2	45.4 ± 9.8
Women (mean ± SD)	41.1 ± 4.4	42.8 ± 7.1
Married/cohabiting *n* (%) (any period during the last 6 months)	28 (78%)	21 (58%)
Gainfully employed *n* (%)	8 (21%)	6 (18%)
Present treatment with disulfiram, calcium carbimide *n* (%)	19 (53%)	14 (39%)
AVI (decentiles, mean ± SD)		
Alcohol abuse	7.0 ± 3.1	7.4 ± 2.6
Psychological benefits	5.7 ± 2.9	5.6 ± 2.6
Interpersonal complications	6.7 ± 2.4	6.4 ± 2.7
Social drinking	4.9 ± 2.3	5.6 ± 2.4
Daily drinking	4.5 ± 2.1	5.0 ± 2.2
TPQ (raw scores, mean ± SD)		
Novelty seeking	18.5 ± 6.2	18.4 ± 5.4
Harm avoidance	18.2 ± 7.6	15.8 ± 6.4
Reward dependence	18.4 ± 5.0	19.1 ± 4.8

after 3 months, and in 71% after 6 months. The researcher was blind to the type of acupuncture given.

The following seven variables were measured. (1) Number of days of alcohol consumption: a timeline follow-back procedure regarding quantity and frequency of drinking was used (Sobell and Sobell, 1992). (2) Number of days with a consumption of >60 g of alcohol (days of alcohol misuse): a successful drinking pattern was defined as a pattern with up to one misuse day during 1 month, up to two misuse days during 2 months and up to three misuse days during 3 months, respectively. (3) Craving: the patients rated craving from very strong, strong, somewhat, insignificant or none at all. (4) Depression, anxiety, irritation, and sleep disturbances: the patients rated changes compared with admission or previous follow-up, from much better, better, unchanged, worse, or much worse at the follow-up. (5) Smoking: the patients were asked about the total number of cigarettes smoked daily. (6) Needles on specific vs unspecific points: at the 3- and 6-month follow-ups, the patients were asked whether they thought they had received the treatment on specific or unspecific ear points. (7) Specific influences after acupuncture treatment: at the 1-month follow-up, the question 'Did you feel under the influence, as if you had been taking drugs?' was asked.

No corroborating interviews with relatives or significant others were performed. Blood chemistry tests, such as liver enzymes, were only checked in those with aversive therapy according to the clinical routine of the Department. No direct alcohol measures were performed. No history of drug use was included initially and no urine toxicology was taken.

Statistics

The Mann–Whitney test and ANOVA analysis were performed (SPSS Inc, 1988) in order to study differences between groups measured on an ordinal scale and ANOVA measured on an interval scale, respectively.

RESULTS

The results of background variables, the AVI and the TPQ, respectively, are presented in Table 1.

Table 2. Completion rates for the three study phases by sex

Treatment phase	Men		Women	
	Treatment group (n = 25)	Control group (n = 26)	Treatment group (n = 11)	Control group (n = 10)
1	21(84)	19(73)	10(90)	10(100)
2	19(76)	12(46)	5(45)	7(70)
3	17(68)	10(38)	4(36)	5(50)

Values are in numbers with % in parentheses.

No significant differences in sex, age, proportion of cohabitation, and employment status and AVI or TPQ scores were found between the treatment and control groups. No significant difference with respect to treatment with disulfiram and calcium carbimide was found, even if the control group had a somewhat lower rate. The alcohol abuse and interpersonal complication scales displayed higher values compared with the norms (Berglund *et al*., 1988), whereas the other characteristics were of average size (mean 5.5). The TPQ showed normal distributions. (In the American general population the mean is 17 and the SD 6.)

Completers of the full acupuncture series were compared with drop-outs. An ANOVA analysis was performed with sex and type of treatment as independent variables and completion of therapy as the dependent variable. A non-significant interaction between sex and therapy (P = 0.071) was found. Male and female subjects were separated in subsequent analyses.

In Table 2 the completion rates for the three study phases by sex are presented. Among the men, 68% of the subjects in the treatment group completed the total series compared with 38% in the control group ($P < 0.1$). No significant differences were found among the women.

The proportions of successful drinking pattern in the different groups are presented in Table 3. There were no significant differences between the treatment and control groups. The analysis included all subjects who had been followed-up, including patients who had not completed the acupuncture programme.

The proportion of slight to no craving is presented in Table 3. There were no significant differences between the different groups and no consistent tendency in any of the treatment groups was found. There was a strong relationship between successful drinking pattern and slight or no craving, with χ^2 values of 7.6 ($P < 0.01$), 8.4 ($P < 0.01$), and 18.9 ($P < 0.001$), after 1, 3, and 6 months of follow-up, respectively. The relationship was independent of type of acupuncture or gender.

The results of the psychiatric ratings have not been tabulated. Nine out of 10 females in the treatment group, who participated in at least one follow-up interview, rated their anxiety as reduced at first follow-up, including four subjects who rated it much reduced. In the control group, five out of 10 reported reduced anxiety, including one who rated much reduced ($P < 0.05$, Mann–Whitney one-tailed test). Women who reported their psychiatric condition concerning depression, dysphoric states, and sleep disturbances as much improved at first follow-up were four, four, and seven respectively in the treatment group (n = 10) and four, eight, and six, respectively in the control group (n = 10). No differences were found at the second and third follow-ups. In the male groups, no differences emerged.

There were no interactions between type of treatment (correct points, incorrect points) and the AVI scores (five scales) and the TPQ scores (three scales), respectively concerning attrition, craving or drinking outcome (data not shown).

The subjects' opinions of their needle placement were obtained and the results are presented in Table 4. There were no differences between the treatment group and the control group at 3- or 6-month follow-up, respectively.

At the 1-month follow-up, the question 'Did you feel under the influence as if you had been taking drugs?' was asked. In the treatment group, 21 subjects responded affirmatively and 11 negatively to

Table 3. Successful drinking pattern and slight or no craving by group and sex in follow-up subjects

Parameter	Men		Women	
	Treatment group (n = 25)	Control group (n = 26)	Treatment group (n = 11)	Control group (n = 10)
Successful drinking pattern				
0–1 months (0–1 abuse days)	19(76)	15(58)	10(91)	9(90)
2–3 months (0–2 abuse days)	12(48)	9(35)	5(45)	7(70)
4–6 months (0–3 abuse days)	6(24)	5(19)	3(27)	7(70)
Slight to no craving				
0–1 months	18(72)	17(65)	9(82)	9(90)
2–3 months	12(48)	14(54)	7(64)	9(90)
4–6 months	9(36)	8(31)	6(55)	6(60)

Values are in numbers with % in parentheses.
Patients not available for follow-up were scored as failures in the percentage calculations.
Abuse day = days with consumption of more than 60 g alcohol. No significant differences were found.

Table 4. Subject's opinion of needle placement by treatment group at 3- and 6-month follow-up

Opinion	3-month follow-up		6-month follow-up	
	Treatment group	Control group	Treatment group	Control group
Correct ear points	22(76)	22(73)	17(61)	16(70)
Incorrect ear points	1(3)	3(10)	1(4)	1(4)
Don't know	6(21)	5(17)	10(36)	6(26)

Values are in numbers, with % in parentheses.

the question. The corresponding answers in the control group were 18 and 13, respectively. Four female subjects, but no men, reported subjective strong reactions to the acupuncture treatment. One belonged to the treatment group and three to the control group.

Among the male subjects, 33 were smokers of whom 15 were treated on correct points and 18 on incorrect points. Eleven of 15 (73%) and eight of 18 (44%), respectively, cut down on smoking (n.s.). Fourteen female subjects were smokers, eight of them were treated on correct points and the remaining six on incorrect points. Three of eight (38%) and two of six (33%), respectively, reduced smoking (n.s.).

DISCUSSION

In the present study, solely ear acupuncture was administered to a heterogeneous group of alcohol-dependent individuals as an adjunct to the usual out-patient treatment at our department. The randomization may be regarded as having been successful, as both groups had similar characteristics concerning social function, drinking pattern, and personality structure.

One difference reached a significant level between the study group and the control group; women in the study group reported a stronger reduction of anxiety during the first month of

treatment, compared with the control group. In the male study group, there was a non-significant tendency towards remaining longer in treatment, compared to the male control group.

The present study group differed from that used in the studies of Bullock *et al*. (1987, 1989) in a number of important aspects. In the present study, the sample was more socially stable, other types of treatment were accepted simultaneously, and the level of reported craving was considerably less, compared with the study groups of Bullock *et al*. All these differences imply a larger sample heterogeneity in our study, compared with the Bullock studies, which obviously reduced the power of the current study. Also, we did not use any body points, unlike the Bullock studies. This was excluded from a theoretical point of view and we cannot rule out that this may partly explain the different results of these studies.

There are some major weaknesses in our study. Thus, there was no validation of the self-reported drinking outcome data with either collaterals or blood tests. The follow-up rate of 71% was relatively low and the sample size was relatively small. These drawbacks make the conclusions more uncertain. However, the present study has some important advantages compared with earlier studies. Firstly the drinking pattern was measured in a structured way during three periods of time, with intervals of 1, 2 and 3 months, respectively. A similar technique has shown a satisfactory reliability of recall for periods of up to 3 months (Sobell and Sobell, 1992). Secondly, a personality questionnaire was used in order to detect differential responses by personality structure. Thirdly, the patients were asked about their experiences of the needle placement. Almost all subjects were of the opinion that they received acupuncture at correct points, indicating that the study had been blinded satisfactorily. Neither drinking pattern nor personality structure influenced the effects of acupuncture.

The results from the studies by Bullock *et al*. (1987, 1989) could not be reproduced by Worner *et al*. (1992). These latter authors did not use the same type of placebo acupuncture used in both Bullock's and our studies. The present technique for placebo controls using points 3–5 mm from the correct points has been criticized lately following analgesic studies. Lewith and Machin (1983) showed that sham acupuncture appears to have an analgesic effect in 40–50% of the patients, in comparison with 60% for real acupuncture. However, the situation could be different in non-painful conditions in which the underlying physiological mechanisms are different. Sham acupuncture could possibly act as a valid placebo control treatment in such conditions (Vincent and Lewith, 1995).

The limitation of the present study is primarily the heterogeneity of the administered 'treatment as usual'. Future studies ought to standardize the psychosocial component of treatment preferably by a previously validated approach. The finding of anxiety reduction in female, but not in male, alcoholics has to be reproduced in order to be conclusive. To do this, it will be important to use standardized psychiatric rating scales to measure changes.

In conclusion, we found a much smaller effect of acupuncture than in a previous similar study. Male patients, who receive acupuncture on correct points, had a non-significant tendency to remain in treatment longer than the controls. In addition, female patients treated on correct points reported a stronger reduction of anxiety after 1 month compared with the female controls.

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