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ARTICLE

Acupuncture for the Treatment of Cocaine Addiction

Investigation of a Needle Puncture Control

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Abstract — *We conducted a 6-week, single-blind study of acupuncture for cocaine dependence in methadone-maintained patients (*N = 40*) for the purpose of identifying an appropriate needle puncture control for use in future large-scale clinical trials. Patients were randomly assigned to receive daily acupuncture in three auricular sites plus one body site (LI-4), or in control sites within 2–3 mm of the four active sites. Overall, there was a positive response to treatment on a variety of drug-related and psychosocial measures. Cocaine use decreased significantly for patients in both needle puncture groups. The only statistically significant difference between the two types of needle puncture was on ratings of craving. Subjects rated each type of needle puncture as equally credible and perceived no significant differences on the acute effects of the two types of needle insertions. Power calculations based on these findings suggest that very large sample sizes would be required to detect treatment differences between this control condition and active acupuncture. Alternative controls are suggested, and the challenges inherent in implementing controlled clinical trials of acupuncture are discussed.*

Keywords — cocaine; methadone; acupuncture; substance abuse; methodology.

INTRODUCTION

METHADONE MAINTENANCE HAS BEEN SHOWN to be an effective treatment for opioid dependence, with important psychosocial and medical benefits (Ball et al., 1987). However, the high rates of cocaine abuse in some methadone programs (Condelli, Fairbank, Den-

nis, & Rachal, 1992) directly undermines a primary goal of methadone maintenance — the cessation of all illicit drug use. Contributing to the difficulty in resolving this problem is the dearth of demonstrably effective pharmacologic or psychological treatments for cocaine dependence for either opiate- or non-opiate-dependent populations (Rawson, McCann, Hasson, & Ling, 1994).

A number of studies and clinical reports have suggested that auricular acupuncture may show promise as a treatment for cocaine abuse (Brumbaugh, 1993). Clinical reports from Lincoln Hospital's Substance Abuse Treatment Clinic state that after several weeks of acupuncture treatment approximately 40 percent of cocaine-dependent patients submit a series of clean

urines (Smith, 1988). A controlled study conducted at this same clinic by Lipton, Brewington, & Smith (1994) found some support for these clinical reports. Patients at that facility receiving acupuncture in sites commonly used for the treatment of addiction, and who remained in treatment for more than 2 weeks, were found to have significantly lower levels of benzoylecgonine in urine screens relative to patients in the needle puncture control condition who received acupuncture in sites not typically used in the treatment of addiction.

In light of these promising reports, and faced with the need for effective treatments for cocaine dependence in methadone maintenance programs, our team embarked on a series of studies preparatory to conducting a full-scale randomized clinical trial of acupuncture in this patient population. Our first step was to conduct an uncontrolled study (Margolin, Avants, Chang, & Kosten, 1993a) in which cocaine-abusing methadone patients received acupuncture in sites used for the treatment of addiction at Lincoln Hospital. Treatment was provided for a total of 8 weeks: 5 days a week for 6 weeks and 3 days a week for the last 2 weeks. We found that 44% of patients, 88% of treatment completers, were able to attain abstinence in the last 2 weeks of treatment. These results compared favorably to those found for historical controls — cocaine-abusing methadone-maintained patients at our site who had participated in pharmacotherapy trials for cocaine addiction.

Our next step was to investigate an appropriate control for needle insertion. As noted in two recent reviews of acupuncture for the treatment of the addictions (McLellan, Grossman, Blain, & Haverkos, 1993; ter Riet, Kleijen, & Knipshild, 1990), acupuncture research poses numerous methodological challenges. Primary among the issues to be resolved is the selection of a suitable control. By analogy with the placebo in pharmacotherapy trials, needle insertion into inactive or "sham" points in the ear has been employed as a control procedure (e.g., Bullock, Culliton, & Olander, 1989). However, this is a highly controversial issue both from Eastern and Western theoretical perspectives. Traditional Chinese medicine does not include the concept of a "placebo;" nor does the organismic model that underlies acupuncture theory embody a concept of a systematically "inert" treatment (cf. Chiu, 1986; Wiseman & Ellis, 1985). From a Western biomedical perspective, Ulett (1992) has argued that auricular acupuncture's effects are due to stimulation of the vagus nerve, which innervates the ear concha — a corollary of this view is that needles placed *anywhere* in the concha, regardless of their alignment with points claimed by acupuncture theory to be ailment-specific, should produce the same effects.

The task of identifying a suitable control for auricular acupuncture is therefore highly complex. There are many variables that can be considered when insert-

ing a needle into the skin (cf. Liao, Lee, & Ng, 1994): for example, depth and angle of needle insertion, needle manipulation, site of insertion, sensations elicited, influence of diffuse noxious inhibitory control mechanisms (Lebars, Dickenson, & Besson, 1979), patient belief system concerning acupuncture, and patient/treatment-provider relationship. As a first step, we have been investigating a needle puncture control at a fairly gross level, examining various sites for control needle insertion. Our approach to date has primarily focused on one particular needle puncture control that has been used in previous addiction research (e.g., Bullock et al., 1989). In this control condition needles are placed in the same region as, and relatively close to (i.e., with 2–3 mm), the active sites (i.e., sites used for the treatment of addiction). Using a galvanometer, control sites register as points of relatively high electrical resistance. Because the active and control sites are close together, this control condition has the advantage of making it difficult for subjects treated in a group setting to determine which needle puncture condition other subjects were assigned to.

Our investigation has concentrated on two key questions: (a) do active and control sites differ with respect to the intensity of aversive sensations produced (e.g., pain), which could differentially influence drop-out rate in the two groups, and (b) does needle insertion into the proposed active and control sites produce acute or long-term effects so similar that they both constitute "active" treatments.

We began to address the issue of possible aversiveness of needle insertion into control sites by conducting a single-blind study comparing the effects of needle insertion into active and "sham" sites in a nonclinical sample (i.e., staff members and acupuncture students) (Margolin et al., 1993b). In that study, subjects received needle placement in active sites in one ear and in control sites, located 2–3 mm from the active sites, in the other ear, simultaneously. We found that the "active" treatment, not the control needle puncture, was rated as more painful; however, neither was considered particularly painful. There were no other differences between the two conditions, and the ability of subjects to guess which ear received which type of needle puncture did not rise above the level of chance. Results of this study suggested that needle puncture close to, and within the same region as, "active" sites might be a suitable control for a clinical trial insofar as it would not be expected to differentially influence treatment drop-out or to produce diffuse noxious inhibitory control. However, this study did not address the possibility that the insertion of needles into these control sites could constitute an "active" treatment when provided to a clinical sample.

Even though insertion of needles into these control sites would not be hypothesized to produce a therapeutic effect based on existent ear maps (O'Conner &

Bensky, 1981) or galvanometer readings, little research has been done to validate the suppositions underlying this hypothesis. Therefore, it is certainly possible and, according to some investigators, even probable (e.g., Liao, et al., 1994; Ulett, 1992), that the sites we selected for the control condition were, in fact, active. Before embarking on a large scale study, we therefore decided to address this issue by conducting a small-scale, randomized clinical trial, in cocaine-abusing methadone-maintained patients, using the same method for identifying control points that was used in our previous study with a nonclinical sample (Margolin, Chang, Avants, & Kosten, 1993b).

The purpose of the current paper is to present the results of this study. We had several goals: (a) to derive means and standard deviations for measures of cocaine use in the two treatment groups, which could be used to estimate an effect size for the difference between the active and control treatments; (b) to identify acute effects of the two types of needle puncture by having patients complete presession and postsession ratings (the first two goals would conjointly shed light on the relative "inertness" of the control points); and (c) to determine if the findings from our first, uncontrolled, clinical trial (Margolin et al., 1993a) would be replicated.

METHOD

Subjects

Forty subjects, 22 men and 18 women, participated in the study. All subjects were enrolled in an inner-city methadone program and were maintained on a stable dose of methadone. Patients were excluded from the study who had an outer-ear infection, or were actively psychotic or suicidal. Twenty-four subjects (60%) were white; 14 subjects (35%) were African American; two subjects (5%) were Hispanic. The subjects' mean age was 35.2 years ($\pm$7.4) years. Nineteen subjects (47.5%) were high school graduates; all were unemployed. Thirty-two subjects (80%) had children; 20 (50%) were living with a significant other; 11 subjects (27.5%) reported that their significant other also used drugs. The mean daily methadone dose was 72.6 mg ($\pm$18.7). They had been using opiates for an average of 14 ($\pm$8.9) years.

All subjects met *DSM-III-R* criteria for cocaine dependence. Subjects used an average of 1.7 ($\pm$4.2) grams of cocaine in the week prior to entry into the study and used an average of 2.3 ($\pm$1.8) days per week. They had been using cocaine regularly for an average of 13.0 ($\pm$7.2) years. Nineteen subjects (47.5%) used cocaine by the intravenous route of administration, 15 (37.5%) by smoking, and 6 (15%) intranasally. Eighteen subjects (45%) were HIV positive; 10 of these subjects were taking azidothymidine (AZT). Twenty

subjects (50%) had a *DSM-III-R* Axis II diagnosis of Antisocial Personality Disorder.

Acupuncture Treatments

Patients were randomly assigned to receive one of two types of needle puncture. The "active" and "control" conditions consisted of needle insertion into four sites — three needles bilaterally in each ear and one needle bilaterally in each hand.[1] In the "active" condition, the three auricular points were those commonly used for the treatment of addiction: "sympathetic" (located in the deltoid fossa at the junction of the infra-antihelix crus and the medial border of the helix); "lung" (located in the center of the cavum concha); and "shen men" (located in the inferior corner of the bifurcating point of the antihelix). The body point, "he gu — LI 4," (located between the first and second metacarpal bones, approximately in the middle of the second metacarpal bone on the radial side), is a site commonly used by acupuncturists.

The control points in the ear consisted of needle insertion approximately 2 mm from the active auricular points. This was the control procedure used in our previous investigation of the acute effects of needling active and "sham" points in a nonclinical sample (Margolin et al., 1993b). The control body point was needle insertion to a minimal depth, with the needle not twisted, close to the active point, in a site determined to be nonactive (i.e., "*de qi*" sensation was not elicited).

Needles were left in place for 45 minutes. Needle placement into active and control auricular sites was verified with a galvanometer, with active sites registering as points of high conductivity and control sites registering as points of lower conductivity. Active points, and not control points, also tended to be tender when probed and associated with skin discoloration in the ear. Needles were inserted in auricular points, in both active and control conditions, to a depth of 2 mm. Body needles, in the active condition, were inserted into LI 4 to a depth of approximately 10 mm. In the control condition, the body needle was inserted to a depth of 2 mm. The acupuncture needles (Seirin Co., Ltd.) were 0.20 mm wide and 15 mm long. Needles were stainless steel, disposable type, sterilized

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[1]Our first uncontrolled study in a clinical sample used five auricular needles bilaterally. The use of five auricular sites in a controlled study, however, poses problems; the more needles that are to be inserted in the control condition, the more difficult it is to avoid hitting active sites. In our second study conducted with a nonclinical sample, we used four of the five points. In the current study, our acupuncturist recommended the use of three auricular points and the addition of one body point to compensate for a possible diminution of treatment intensity due to use of fewer auricular points. Other acupuncture researchers in the addictions, for similar reasons, are also using three auricular needles bilaterally (P. Culliton, personal communication, 1994).

with ethylene oxide gas, and individually packaged in sterile containers that were opened by the acupuncturist immediately before insertion. The primary acupuncturist for the study was one of the current authors (PC), a trained acupuncturist with over 16 years of experience (Canton School of Traditional Medicine, China; NADA certification).[2] Beyond performing the acupuncture procedure, the acupuncturist had minimal contact with the patients. All study personnel, with the exception of the acupuncturist, were blind to treatment assignment.

In both conditions patients were treated for 5 days per week (Monday through Friday) for a total of 6 weeks. Treatments were administered in a quiet room of an outpatient primary care clinic while patients were recumbent on clinic beds. Each room contained two single beds, each of which was occupied by a subject during treatment.

Each treatment session adhered to the following format:

1. Subject sits on clinic bed, cleans ears and hands with a pad saturated with 70% isopropyl alcohol.
2. Acupuncturist inspects ears and hands, provides further cleaning if needed.
3. Acupuncturist inserts three needles into each ear, and one needle into each hand.
4. Subject reclines quietly for 45 minutes.
5. Acupuncturist removes needles and disposes of them in a "sharps" box.

Treatments were administered between 11:30 a.m. and 1:30 p.m. after the subjects had received their daily methadone dose.[3]

Measures

Cocaine Use. Cocaine use was determined by urine toxicology screens. Urine samples were collected twice a week, for a total of 7 weeks (the week prior to study entry and for 6 weeks during the study). Urine samples were analyzed on-site for benzoylecgonine, using the Abbott Tdx method. This assay yields quantitative values for levels of benzoylecgonine between 0 and 5000 ng/ml. A reading greater than 300 was regarded as positive. Self-reported cocaine use and cocaine craving were also measured. Assessed at baseline and weekly thereafter were (a) self-reported frequency of cocaine use (number of days cocaine had been used the previous week); (b) self-reported amount of cocaine used

(number of grams used the previous week); and (c) cocaine craving, measured on a 0 (not at all) to 10 (extreme) scale.

Psychosocial Measures. In order to assess changes in depression, psychosocial functioning, and general symptoms of distress, the following questionnaires were administered at entry into treatment and again at the completion of the 6-week study: the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961); the Addiction Severity Index (ASI; McLellan, Luborsky, Woody, & O'Brien, 1980); and the Symptom Checklist-90 (SCL-90; Derogatis, Lipman, & Covi, 1973). A demographics questionnaire was also completed pretreatment.

Acupuncture-Related Measures. The Treatment Credibility Scale (TCS; Vincent, 1990) is a scale that has been recommended for use in acupuncture research to ensure equal credibility of the two needle puncture treatments. It was administered at entry into the study and again upon completion of the 6-week treatment. Questions asked on the TCS, as modified in the current study, are shown in Table 2. Subjective acute effects of the two needle puncture treatments were assessed using a series of scales, developed by our team, to assess the subjective acute effects of a single acupuncture treatment. These scales were administered weekly, immediately before and after that day's treatment session. Each question reads: how (_) do you feel right now? Items are shown in Table 3. Postsession, subjects were also asked to rate the intensity of pain they experienced upon needle insertion into the ear, into the hand, and during the course of the session.[4]

Procedure

Patients were referred to the study by their counselors, and an interview was scheduled with one of the researchers. After a determination that the patient met entrance criteria, the study was explained, informed consent was obtained, and screening urines were taken. Patients were stratified by HIV status[5] and were randomly assigned to receive needle insertion into either active or control sites. During a subsequent pretreatment session, the patient completed an intake package consisting of the Beck, SCL-90, ASI, self-report ratings, and demographic questionnaire. Treatments

[2]When PC was on vacation, he was replaced by another acupuncturist experienced in treating drug-addicted populations. PC provided training to the replacement acupuncturist in the method used to locate control points.

[3]Cross tolerance between acupuncture and methadone may not occur because acupuncture analgesia has been hypothesized to be dynorphin mediated, whereas methadone binds poorly to kappa receptors, the main target of dynorphin.

[4]A more detailed analysis of the acute effects of the two types of needle insertion used in the current study will be the focus of a separate report.

[5]We identified HIV-status as a potentially important patient characteristics that could differentially impact treatment outcome. We stratified the sample by this variable prior to randomization, as recommended by ter Riet et al. (1990) in their meta-analysis of acupuncture studies.

lasted for 6 weeks. At the completion of the 6-week study, subjects completed the same assessment battery. All measures and weekly self-report ratings were administered by staff blind to subject assignment to active or control needle puncture. Patients who missed three consecutive treatments were discontinued from the study.

RESULTS

Retention

Collapsed across type of acupuncture received, 75% of subjects entering the study (30 out of 40) completed the 6-week study, receiving an average of 18.1 (±6.3) acupuncture treatments (average of three per week). Chi-square analyses revealed no significant difference on retention between active (80%; 16/20) and control conditions (70%; 14/20). Subjects assigned to the active condition attended an average of 17.6 (±6.7) treatments; subjects assigned to the control condition attended an average of 18.6 (±6.1) treatments. Treatment completers did not differ from treatment dropouts on any demographic or pretreatment drug use variable.

Drug Use Outcomes

A series of 2 (Treatment: active or control acupuncture) × 7 (Time: Weeks 0–6 of the study) mixed ANOVAs were conducted for treatment completers, with the following drug use measures as dependent variables: percent of urines testing positive for cocaine each week; self-reported amount (grams) of cocaine used per week during the study; self-reported frequency (days) of cocaine use per week during the study; self-reported craving per week during the study.[6] Differences between treatment groups on the number of subjects who initiated abstinence during the last week of treatment (both urines negative for cocaine) was examined using chi-square analyses. Missed urine screens were coded as positive for cocaine metabolite. Missing data for self-reported frequency, amount, and craving for cocaine were replaced with the respective means for the treatment group. Means and standard deviations for these drug use variables can be found in Table 1.

Urine Toxicology. A main effect was revealed for Time [Wilks's lambda $F(6,23) = 3.93, p < .008$]. As can be seen in Table 1, the percentage of urines positive for cocaine decreased steadily across the 6-week study

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[6]Drug use outcomes were also examined by sex, race, antisocial personality disorder, and route of cocaine administration. There were no main effects and no significant interactions for these variables on any drug use outcome measure.

(from 93.3% positive at baseline to 55.0% positive during the sixth week of the study). Collapsed across time, subjects who completed the study submitted 65.8% (±33.6) cocaine-positive urines (Active needle puncture: 62.5% [±36.9]; control needle puncture: 69.6% [±30.2]). There was no main effect for type of acupuncture received, and no significant interaction. Similar results were found when urine data were analyzed for the intention to treat sample ($n = 40$) with missed urines again coded as positive. There was a main effect for Time [Wilks's lambda $F(6,33) = 3.29, p < .01$], no main effect for type of acupuncture, and no significant interaction. During the course of the study, the intention to treat sample submitted 73.7% (±32.3) cocaine-positive urines (Active: 69.2% [±35.7]; Control: 78.3% [±28.5]).

Self-Reported Amount of Cocaine Used per Week. There was a main effect for Time [$F(6, 168) = 3.40, p < .003$]. Subjects who completed treatment reported decreasing the amount of cocaine they used across the 6-week study period, from 1.5 grams per week to 0.2 grams. There was no main effect for type of acupuncture and no significant interaction.

Self-Reported Frequency of Cocaine Use per Week. There was a main effect for Time [$F(6, 168) = 8.34, p < .001$]. Subjects who completed treatment reported decreased frequency of cocaine use across the 6-week study, from 2.1 days per week to 0.6 days per week. There was no main effect for type of acupuncture, and no significant interaction.

Craving. There was a main effect for Time [$F(6, 168) = 5.05, p < .001$], and a main effect for type of acupuncture [$F(1, 28) = 4.18, p < .05$]. Craving decreased significantly across the 6-week study, and was lower overall during the 6 weeks for subjects receiving active needle puncture ($M = 0.85 ± 0.73$) than for subjects receiving control needle puncture ($M = 2.15 ± 1.77$).

Initiation of Abstinence. Overall, 36.7% (11/30) of subjects who completed the 6-week course of acupuncture treatment (27.5% of the intention to treat sample) initiated abstinence (defined as submitting two consecutive cocaine-free urines in Week 6). Of those subjects receiving active needle puncture, 43.7% initiated abstinence; of those receiving control needle puncture, 28.6% initiated abstinence. This difference was not statistically significant.

Psychosocial Outcomes

A series of 2 (Treatment) × 2 (Time: Pre/Post) mixed ANOVAs were conducted on the Beck depression scores, the ASI composite scores, and the SCL-90 subscale scores.

TABLE 1

Means (SDs) for Cocaine Use Variables for Treatment Completers (n = 30) at Baseline and Over the Course
of the 6-Week Study by Type of Needle Puncture Treatment Received

	Study Week						
	0	1	2	3	4	5	6
Urine Toxicology							
Percent Cocaine Positive							
Active acupuncture	93.7	71.9	65.6	62.5	65.6	56.2	53.1
	(25.0)	(40.7)	(47.3)	(46.5)	(43.7)	(44.2)	(46.4)
Control needle puncture	92.9	82.1	71.4	67.9	71.4	67.9	57.1
	(26.7)	(31.7)	(37.8)	(46.4)	(42.6)	(42.1)	(43.2)
Self-Report							
Grams Used per Week							
Active acupuncture	1.3	1.4	0.3	0.2	0.2	0.6	0.2
	(2.9)	(3.0)	(0.4)	(0.3)	(0.3)	(1.2)	(0.5)
Control needle puncture	1.7	1.1	0.9	0.9	0.7	0.5	0.2
	(3.5)	(1.4)	(0.9)	(1.4)	(1.0)	(0.7)	(0.3)
Number of Days Used Per Week							
Active acupuncture	2.2	1.8	1.2	0.9	0.6	1.0	0.6
	(1.8)	(1.8)	(1.2)	(1.0)	(0.6)	(1.0)	(1.0)
Control needle puncture	2.1	1.8	2.0	1.5	1.4	1.1	0.6
	(1.9)	(1.8)	(1.4)	(1.5)	(1.7)	(1.0)	(0.7)
Craving rating: (Scale: 0-10)							
Active acupuncture	3.3	1.6	1.1	0.7	0.6	0.6	0.4
	(3.5)	(2.3)	(1.3)	(1.4)	(1.0)	(0.9)	(0.9)
Control needle puncture	3.3	2.3	2.1	2.0	2.0	1.8	2.7
	(3.4)	(2.4)	(2.1)	(2.1)	(2.4)	(2.5)	(2.7)

Note. Missed urine = positive for cocaine metabolite; missed self-report = weekly mean for subject's treatment group.

Beck Depression Inventory. There was a main effect for Time ($F[1, 28] = 9.95, p < .004$). Depression decreased significantly across the 6-week study [Pretreatment $M = 19.6$ (±12.4); Posttreatment $M = 14.1$ (±10.6)]. There was no main effect for type of acupuncture, and there was no significant interaction.

ASI Composite Scores. There were main effects for Time for the following composite scores: Intensity of Drug Problems ($F[1, 28] = 7.40, p < .01$; pretreatment $M = .35$ ($\pm.13$); posttreatment $M = .29$ ($\pm.11$)), and Intensity of Legal Problems ($F[1, 28] = 6.20, p < .02$; pretreatment $M = .07$ [$\pm.12$]; posttreatment $M = .03$ [$\pm.07$]). There were no main effects for type of acupuncture and no significant interactions.

SCL-90 Scores. There were main effects for Time for the following subscale scores: Somatization ($F[1, 28] = 8.05, p < .008$; pre $M = 1.27$ [$\pm.91$]; post $M = 0.92$ [$\pm.69$]); Depression ($F[1, 28] = 7.57, p < .01$; pre $M = 1.35$ [$\pm.99$]; post $M = 1.01$ [$\pm.93$]); Anxiety ($F[1, 28] = 9.28, p < .005$; pre $M = 1.12$ [$\pm.90$]; post $M = 0.74$ [±77]); Phobic Anxiety ($F[1, 28] = 5.50, p < .03$; pre $M = 0.76$ [$\pm.75$]; post $M = 0.53$ [$\pm.68$]); and Psychoticism ($F[1, 28] = 6.03, p < .02$; pre $M = 0.81$ [$\pm.74$]; post $M = 0.61 \pm .66$]). There were no main effects for type of acupuncture, and no significant interactions.

Attitudes Toward and Subjective Responses to Acupuncture

Treatment Credibility Scale. Means and standard deviations for scores on the TCS are shown in Table 2. A series of 2 (type of acupuncture) × 2 (pre/post 6-week treatment period) mixed ANOVAs were conducted on the five TCS items. Collapsed across type of acupuncture, confidence that acupuncture would help with drug use, and confidence in recommending acupuncture to a friend increased from pretreatment to post-6-week treatment ($F[1, 28] = 5.03, p < .03$, and $F[1, 28] = 14.55, p < .001$, respectively). There was no significant change in how logical the treatment seemed either for drug use or for other health problems, or in subjects' confidence that the treatment would be useful for the treatment of other health problems. There were no main effects for type of acupuncture on any of the five items and no significant interactions. Pearson correlations revealed no significant relation between confidence in acupuncture and percent of urines positive for cocaine submitted during the course of the study, either by type of needle puncture received, or collapsed across needle puncture conditions.

Acute Effects of Acupuncture (AEA) Scales. A series of 2 (type of acupuncture) × 2 (pre/post acupuncture

TABLE 2
Treatment Credibility Scale Means (±SD) Preacupuncture and Postacupuncture Treatment for
Treatment Completers (n = 30)

	Pretreatment	Posttreatment
How confident are you that acupuncture can help you with your drug problem?*		
Active acupuncture	2.75 (±0.86)	3.31 (±0.79)
Control needle puncture	2.64 (±0.63)	3.00 (±1.04)
How confident are you that acupuncture can help you with any health problems you have?		
Active acupuncture	2.62 (±0.88)	2.87 (±0.72)
Control needle puncture	2.54 (±0.65)	2.79 (±0.89)
How confident are you in recommending acupuncture to a friend with similar problems?*		
Active acupuncture	2.56 (±1.21)	3.19 (±0.83)
Control needle puncture	2.50 (±0.94)	3.43 (±0.94)
How much sense does it make that acupuncture would help you with your drug problem?		
Active acupuncture	2.43 (±0.89)	3.00 (±0.97)
Control needle puncture	2.79 (±0.89)	3.00 (±0.55)
How much sense does it make that acupuncture would help you with other health problems?		
Active acupuncture	2.25 (±0.93)	2.50 (±1.09)
Control needle puncture	2.21 (±0.97)	2.57 (±0.76)

Note. Scale: 0 (not at all) to 4 (extremely).
*Significant difference pre/post 6-week treatment collapsed across type of needle puncture. There were no differences between the two types of needle puncture on these measures of treatment credibility.

session) mixed ANOVAs were conducted on the eight AEA items. The mean subjective responses to a single acupuncture session (active or control needle puncture) during the first week of treatment are presented in Table 3.

There were several main effects for Time. Collapsed across type of needle insertion, nervousness and depression decreased ($F[1, 15] = 7.40, p < .02$ and $F[1, 15] = 11.12, p < .005$, respectively), and relaxation, sleepiness, and lightheadedness increased ($F[1, 15] =$

TABLE 3
Acute Subjective Effects of a Single Acupuncture Session During the First Week of Treatment

	Active (n = 7)		Control (n = 10)	
	Pre-Session	Post-Session	Pre-Session	Post-Session
Nervous*	1.29 (1.11)	0.29 (0.76)	0.60 (0.97)	0.30 (0.48)
Depressed*	1.71 (1.25)	0.71 (0.76)	1.10 (1.20)	0.60 (0.70)
Relaxed*	1.14 (0.69)	3.00 (1.15)	1.80 (1.40)	2.60 (0.97)
Happy	1.42 (0.79)	1.86 (0.69)	1.40 (0.84)	1.60 (0.70)
Sleepy*	0.71 (0.76)	1.71 (0.76)	0.80 (1.03)	1.60 (1.35)
Energetic	1.42 (0.53)	0.86 (0.69)	0.30 (0.48)	1.20 (0.92)
Body feels heavy	0.71 (0.95)	1.00 (0.82)	1.10 (1.20)	0.70 (1.06)
Lightheaded*	0.43 (0.79)	1.00 (1.00)	0.50 (0.71)	1.20 (0.42)
Pain:				
Upon insertion/ears	—	0.50 (0.76)	—	0.45 (0.69)
Upon insertion/hands	—	0.29 (0.76)	—	0.20 (0.42)
During session	—	0.25 (0.46)	—	0.18 (0.40)

Note. Scale 0 (not at all) to 4 (extremely).
*Significant changes pre/post session collapsed across type of needle puncture. There were no significant differences between the two types of needle puncture on any measured acute effect of a single acupuncture session.

$21.32, p < .001; F[1, 15] = 17.25, p < .001$; and $F[1, 15] = 7.23, p < .02$, respectively). There was no change pre/post session in feelings of happiness, energy, or heaviness. There were no main effects for type of acupuncture and no significant interactions. Comparing posttreatment pain ratings for active and control needle puncture, t tests revealed no significant differences in pain ratings between the two types of needle puncture conditions; as shown in Table 3 intensity of pain either upon insertion of needles or during the course of the session was minimal for either type of needle insertion.

Exploratory Analyses by HIV Status

HIV Status. There was good treatment retention among both HIV-negative and HIV-positive patients; 77.8% (14/18) of HIV-positive patients and 72.7% (16/22) of HIV-negative patients completed the 6-week study. There was a trend for HIV-positive patients who completed treatment to provide fewer cocaine-positive urines during the course of the study (Mean $= 54.2\%$ $\pm$ 34.6) than HIV-negative patients (Mean $= 76.0\%$ $\pm$ 30.1) ($F[1, 28] = 3.44, p < .07$). In addition, 50% of HIV-positive patients (compared to 25% of HIV-negative patients) were able to initiate abstinence by study completion.

DISCUSSION

We conducted a propaedeutic trial in order to investigate several issues critical to the design of a large-scale study of acupuncture for the treatment of cocaine addiction in methadone-maintained patients. Results, overall, showed a significant decrease in cocaine use from baseline, with good treatment retention. In addition, significant improvements were seen on a number of psychosocial measures (i.e., Beck depression, ASI drug severity, and several SCL-90 subscales). We found no statistically significant difference between the active and control needle puncture treatments on any measure, with the exception of craving; the active acupuncture group reported significantly less craving for cocaine during the course of the study than did the control needle puncture group.

Appropriateness of the Needle Puncture Control Condition

Power calculations were conducted to determine the sample size necessary to detect the difference between needle puncture groups for percentage of urines testing positive for cocaine during the course of the study (active: 69.17% [±35.67]; control: 78.33% [±28.54]).

We calculated that with power at .80 and alpha at .05, 196 subjects per treatment group would have been necessary to detect this relatively small effect size of .28. This is a considerably larger sample than is suggested by either Lewith and Machin's (1983) or Pomeranz' (1987) power calculations for detecting differences between "real" and "sham" acupuncture. Assuming that subjects in the active acupuncture group did, in fact, receive an optimally *active* treatment, several findings from the current study suggest that the control needle puncture procedure we used might have been a relatively "active" treatment. These include the small treatment effect size, lack of significant differences in the subjective ratings between the two groups after an acupuncture session, as well as between the groups on their ratings of confidence in acupuncture either pretreatment or posttreatment—both increased. Other researchers using a needle puncture control condition similar to that employed in this study—insertion of needles into theoretically "inactive" points close to active sites—have also reported overall reductions in illicit drug use, but no significant differences between treatment groups (Jackson, Wells, Diaz, Staton, & Saxon, 1994). Lipton et al. (1994) employed points used for treating skeletomuscular disorders, which are within 5 mm of active points and which are not indicated for the treatment of addiction, as control points. They, too, speculate that these control points may have been too "active."

Our study does not, of course, demonstrate that the control sites we employed were entirely inappropriate; in fact, means on all drug outcome measures were in the direction of an effect for the active needle puncture condition. It is also possible that an undocumented, idiosyncratic aspect of our acupuncturist's technique may have influenced results. However, in view of the considerable investment of resources needed to conduct clinical trials, we think that sites with less apparent activity should be chosen as controls in future studies. A promising strategy might be to locate auricular control points entirely outside of the regions of active points. For drug addiction studies this would mean that control points should not be located within the ear concha. We have begun to investigate the ear helix as a possible location for auricular control points, in particular, sites on the helix that are not hypothesized to be active treatments for addiction in any system of acupuncture. We are conducting a single-blind study in which patients provide ratings after needle insertion into helix points, active sites, and two "control" configurations—the control used in the present study, and the control used by Lipton et al. (1994).—Preliminary findings suggest that the helix points are perceived by patients as the least active (Margolin, Avants, Chang, Birch, & Kosten, in press).

Comparison to Previous Studies at Our Site

In this study we sought to determine if results from our previous uncontrolled study using acupuncture with this patient population (Margolin et al., 1993a) would be replicated. We found that the 73% overall rate of cocaine positive urine screens in our previous study for the intention-to-treat sample was virtually identical to the 74% rate in the current study, although patients receiving active acupuncture in the current study did somewhat better (69% positive urine rate). However, fewer patients who completed the entire 6-week course of treatment attained abstinence by study completion (37%) relative to patients who completed the previous 8-week study (88%). Possible reasons for this difference will be discussed in a later section.

As in our previous study, we compared the results of this acupuncture trial with a recent pharmacotherapy study conducted at our site with the same patient population in which desipramine and amantadine were compared to placebo for the treatment of cocaine addiction (Kosten, Morgan, Falcioni, & Schottenfeld, 1992). We found that treatment retention in the current study (75%) was comparable to retention in the pharmacotherapy study (79%) and better than that in our previous acupuncture study (50% retention). The percentage of cocaine-positive urines in the current study was comparable to rates found in the pharmacotherapy study, and in the active treatment group the percentage was somewhat lower. For example, the rate of cocaine-positive urines for the first 6 weeks of treatment was 88% in the desipramine group, 79% in the amantadine group, and 80% in the placebo group. Furthermore, rates of abstinence initiation in the 6th week was better for both needle puncture groups compared to the pharmacotherapy groups (Active acupuncture = 35%; Control needle puncture = 20%; AMA = 0%; DMI = 17%; placebo = 4%).

Further Considerations

This study functioned as a prototype in order to explore design issues for future studies. There are several areas of concern: treatment duration, setting, ancillary psychosocial intervention, maintaining the blind, and experience of acupuncturist.

1. Duration of Treatment. In our previous study the duration of treatment was 8 weeks, 5 times a week for the first 6 weeks, 3 times a week for the last 2 weeks. In the current study, we used a 6-week treatment regimen. It was our impression that our severely cocaine-dependent subjects could have benefitted from at least an additional 2 weeks of treatment, evidenced by pa-

tient self-report and by the fact that fewer subjects attained abstinence by study completion than in our previous 8-week acupuncture study. The treatment duration for pharmacotherapy studies conducted at our site is typically between 12 and 24 weeks. We do not suppose that acupuncture would be as effective as a pharmacotherapeutic agent in one-half or one-quarter of the time. Therefore, in future studies we suggest a treatment duration of a minimum of 8 weeks.

2. Treatment Setting. In our previous outcome study, patients were treated in a domestically furnished room, five or six at a time, while seated in reclining chairs. In the current study patients were treated in a medical setting, while they reclined on clinic beds, two to a room. This setting had the advantage of allowing staff greater monitoring and control over patient activity during the course of treatment. However, it was our impression that a group room was nevertheless preferable, insofar as patients tended to form a group identity, seemed to find seeing other patients relaxing facilitative of their own relaxation, as well as finding interactions with other patients before and after treatment to be helpful. We therefore suggest that, wherever possible, research into acupuncture for the treatment of cocaine addiction be conducted in a group room setting, as is the standard procedure at Lincoln Hospital.

3. Ancillary Psychosocial Treatments. Patients in this study received acupuncture in addition to standard care, which consisted of attending one group counseling session a week. This level of psychosocial support seemed to us minimally adequate for our severely addicted population. We would suggest that acupuncture research for cocaine addiction be conducted with patients who are receiving an intensive, systematic psychosocial intervention conducted by an experienced clinician. A similar point concerning the need for psychosocial services in acupuncture studies is made by Lipton et al. (1994).

4. Maintenance of the Blind. A poll of study research personnel and subjects after study completion showed that no staff member and no subject was aware of treatment assignment. We noted that patients seemed to show little interest in the specifics of the acupuncture procedure, beyond detecting that needles were being inserted into the ear. It is possible that the blind was successfully maintained in part because of the similarity of needle placement. Precautions against patients viewing of other patients may still need to be taken if the two needle puncture conditions are in conspicuously different regions of the ear, such as the con-

cha and the helix. The need to isolate patients in order to maintain the blind may conflict with the creation of a setting in which patients can observe each other during treatment. The proper resolution of these two conditions would need to be worked-out before embarking on a full-scale study, for example, by segregating patients by group by treatment assignment.

5. Experience of Study Acupuncturists. Experience in this study reinforced our opinion that acupuncture studies with needle puncture controls place special demands on study acupuncturists and, therefore, require practitioners who possess technique of the highest caliber who are able to work within the strictures of a research protocol. Acupuncture in research studies should be delivered only by acupuncturists who have had extensive experience in full-body and auricular acupuncture and who have had considerable practice honing the control procedure.

We would like to briefly discuss an alternative interpretation of our data. Our findings could be interpreted as patients' response to a novel, somewhat invasive, procedure in both groups — that is, to the administration of an active placebo. Furthermore, it is possible that the overall improvements found in drug use and psychosocial functioning were due to nonspecific factors such as daily staff attention, increased staff and patient monitoring of drug use, or to a relaxing effect of reclining for an hour in a quiet room each day. The addition of a relaxation control group in future studies would allow for an assessment of some of the nonspecific effects of acupuncture treatments upon treatment outcome. However, given the present state of our knowledge concerning acupuncture, there is no obvious way to *definitively* resolve issues concerning the effect of placebo response on treatment outcome. In order for this to be accomplished, the needle puncture control condition would have to be shown to be inert, a priori and independently of patient response, like a pill placebo in pharmacotherapy studies. Acupuncture research methodology is not sufficiently advanced to conduct "conclusive" studies. In our opinion, findings from the current study, such as overall improvement in outcome measures related to addiction, good treatment retention, relatively favorable abstinence rates in the 6th week of the study, and the overall response of HIV positive patients to acupuncture, suggest that further investigations of this treatment modality are warranted. We hope that these investigations will be characterized by increasing methodological refinement and that the current study will have contributed to this goal.

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