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Acupuncture Heroin Detoxification: A Single-Blind Clinical Trial

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Abstract— *The increasing prevalence of HIV infection among injection drug users mandates the development of innovative treatments. While extensive clinical experience suggests that acupuncture detoxification is both safe and acceptable to those in withdrawal, little research has been conducted to assess its efficacy as a treatment modality. In this first controlled study of acupuncture heroin detoxification, 100 addicted persons were randomly assigned, in a single-blind design, to the standard auricular acupuncture treatment used for addiction or to a "sham" treatment that used points that were geographically close to the standard points. Attrition was high for both groups, but subjects assigned to the standard treatment attended the acupuncture clinic more days and stayed in treatment longer than those assigned to the sham condition. Additionally, attendance varied inversely with self-reports of frequency of drug use, suggesting that those with lighter habits found the treatment modality more helpful. Limitations of the study are discussed.*

Keywords— acupuncture detoxification; heroin detoxification, clinical trial; auricular acupuncture; drug treatment.

HEROIN ADDICTION continues to be a major public health problem. Traditional opioid detoxification methods include 21-day methadone treatment, narcotic antagonist withdrawal, and the use of various medications to ameliorate the symptoms of withdrawal.

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Methadone-supported withdrawal, as a widely used treatment modality, has been extensively studied (e.g., Sorensen, Hargreaves, & Weinberg, 1982; Rawson, Mann, Tennant, & Clabough, 1983; Tennant, 1986), but little is known about alternative treatments. The increasing prevalence of HIV infection among intravenous drug users (Miller, Turner, & Moses, 1990), as well as the high personal and societal costs of addiction, mandates the development of innovative treatment modalities.

Acupuncture is a nontraditional method of treatment that merits controlled study. For centuries, China and other Eastern countries have used acupuncture to treat a variety of ailments (Steiner, 1983). In recent years, practitioners of Chinese medicine have used acupuncture in the treatment of substance abuse. A number of studies (Clement-Jones, McLoughlin, Lowrey, Besser, Rees, & Wen, 1979; Pert, A., Dionne, Ng, Bragin, Moody, & Pert, C., 1981; Kiser, Khatami, Gatchel, Huang, Bhatia, & Altshuler, 1983) have linked

auricular acupuncture to increased production of endogenous opiate peptides such as beta-endorphins and enkephalins; this is thought by some researchers (e.g., Copolov & Helme, 1983) to be the mechanism of action of the treatment's purported effects on opiate withdrawal.

The National Acupuncture Detoxification Association, with 570 certificated members, estimates that there are now 200 acupuncture detoxification programs in the United States and Europe (M. Smith, personal communication, May 14, 1991). For the past 17 years, acupuncture detoxification has been the primary method of treatment at the Lincoln Hospital in New York. An average of 200 addicted persons are treated daily in this city-owned hospital. A recent paper reported that 40% of new patients dependent on crack cocaine gave clean urine tests several weeks after treatment (Smith & Khan, 1988). The authors relate that acupuncture detoxification patients experienced general relaxation, relief of withdrawal symptoms and craving, and enhancement of mental and physical functioning.

While clinical experience suggests that acupuncture detoxification is both safe and acceptable to patients, little research has been conducted to assess its efficacy as a drug treatment modality. Nearly all of the studies reported in the literature have employed non-randomized, unblinded designs (Newmeyer, Johnson, Klot, & Moon, 1981; Kroenig & Oleson, 1985; Lewenberg, 1985). Exceptions include two studies of the use of acupuncture in treating severe recidivist alcoholics by Bullock and his colleagues (Bullock, Umen, Culliton, & Olander, 1987; Bullock, Culliton, & Olander, 1989).

In these single-blind studies, Bullock's group randomly assigned alcoholics either to treatment with ear acupuncture points specific to addiction or to treatment using "sham" ear points. Outcomes were similar in both studies with significantly more of the subjects receiving the standard acupuncture completing all phases of treatment than those receiving sham acupuncture. In the second, larger study ($n = 80$), subjects received acupuncture 5 times a week for 2 weeks; then, acupuncture 3 times a week for 4 weeks; and, finally, acupuncture twice a week for 2 weeks. Of the 40 patients in the treatment group, 21 (52.3%) completed all phases of the program compared to 1 (2.5%) of the 40 controls. Only 3 (7.5%) treatment patients left the program during phase I, while 19 (47.5%) of the control patients left treatment during the first 2 weeks. Bullock et al. (1989) found, at the 6-month follow-up, that 6 of the 21 patients in the treatment group who had completed the program reported that they had not taken any alcohol in the interim. By contrast, 39 control patients and all treatment patients who had failed to complete the program reported drinking episodes during the 6-month follow-up period.

The study reported here is the first controlled investigation of the use of acupuncture in heroin detoxification. We attempted to extend the work of Bullock's group with alcoholics to the outpatient treatment of opioid dependent persons. A single-blind design was employed to test whether the standard acupuncture protocol for addiction would have an effect on treatment retention and on opiate use when compared to a placebo, or "sham," treatment.

METHOD

This study was conducted at the Bayview-Hunter's Point Foundation, a non-profit human services agency located in a primarily African-American community in San Francisco. The Foundation's substance abuse services include 21-day methadone detoxification, methadone maintenance, and acupuncture detoxification. Subjects were 100 heroin-addicted adults residing in or near San Francisco who met two selection criteria: They reported a history of intravenous use of heroin confirmed by physical examination for signs of recent needle use, and they were not currently enrolled in a methadone detoxification program. Prospective study participants were excluded if they were pregnant or on parole or probation.

Subjects gave informed consent and provided sociodemographic data and information concerning drug use and treatment history at intake into the 21-day acupuncture trial. A 21-day treatment length was chosen in order to provide outcome results comparable to those for existing methadone detoxification programs.

During treatment stay, staff followed subjects daily for withdrawal signs and asked for reports of drug use. There were no penalties for drug-positive reports. On the first treatment day and weekly thereafter, subjects completed a withdrawal symptoms checklist and gave a urine sample. An off-site laboratory conducted the urinalyses, using thin layer chromatography to screen samples for the presence of 16 drug metabolites, including those for heroin, methadone, and cocaine. Confirmation tests were done on positive samples; the particular tests varied according to the drug(s) found. Subjects received \$5.00 for each urine sample and \$20.00 for time spent responding to intake questionnaires.

After intake, subjects were randomly assigned to one of two treatment conditions, either "standard" or "sham" acupuncture; they were blind to condition. The standard protocol used the four ear points that were employed in Bullock's studies (Bullock et al., 1987; 1989): sympathetic, shenmen, kidney, and lung. Points were judged by geographic location and by client-report of a tingling or a hot sensation when the targeted area was touched with a blunt instrument. The placebo, or "sham," condition used four ear points that are not thought to be specific for addiction. These

points, which are geographically close to the standard points, were judged by lack of tingling or hot sensation. Single-use, disposable needles were used for the study. Once needles were inserted, they were left in place for 20–45 minutes. No manual or electrical stimulation was employed. Subjects removed their own needles and disposed of them in a container for hazardous wastes.

Treatment was administered in a large room that seated 40 people. Subjects receiving the two types of acupuncture were treated together and were asked to sit quietly throughout the 40-minute treatment. Interaction with the acupuncturist was limited to the time required for needle placement and collection of signs and symptoms data.

In addition to acupuncture, all subjects received support services identical to those provided to Bayview-Hunter's Point methadone detoxification clients. These services included an entrance physical examination, counseling and discharge planning, and AIDS education. Subjects were permitted to continue treatment beyond the 21-day detoxification period with the proviso that it be in the condition to which they were initially assigned.

Data were analyzed using SPSSX running on an IBM 3090 mainframe computer. Pearson chi-square tests and *t*-tests were used, as appropriate, for comparisons of the sociodemographic, drug history, and drug use data collected at intake. The treatment groups were compared on two measures of attendance: total number of days received treatment and last day in treatment of the 21-day period. Because the distributions for both of these variables were highly skewed, the Mann-Whitney U test was used for the analyses. The relationship between total days in treatment and length of stay was examined using the Pearson product-moment correlation.

The two groups were compared on two additional measures of attendance: percent attending the acupuncture clinic by day in the treatment course and number of clients who stayed in treatment past 21 days. Data for the second measure were analyzed using the chi-square test.

Finally, two-way analyses of variance were conducted to evaluate the variation in mean number of days in treatment and mean length of stay by treatment condition and frequency of drug use. For the second factor, self-reports of drug use in the 30 days prior to treatment entry were stratified into three levels as follows: light use, defined as once daily or less; medium use, two to three times daily; and heavy use, more than three times daily. Because both number of days in treatment and last day in treatment were highly skewed, the natural logarithms of these values were used for the analyses. The following covariates were also examined: age, gender, ethnicity, age at first use, and symptom score on the first day of treatment.

RESULTS

Client Characteristics

Of the 100 study participants, 55 received standard acupuncture and 45 the sham treatment. The two treatment groups were compared on a variety of demographic and clinical measures. As Table 1 shows, no significant differences were detected between the groups on any of the variables examined. The groups were also compared on withdrawal signs and symptoms at intake. Of subjects in the standard group, 70.0% evidenced signs of withdrawal and of those in the sham group, 66.0%; this difference was not statistically significant. Scores on the withdrawal symptoms instrument could range from 17 to 85; the mean scores for the standard group and for the sham group were not significantly different, at 35.8 and 31.9 respectively.

Attendance Patterns; Treatment Retention

Figure 1 compares the percentage of subjects in the two treatment conditions attending the acupuncture clinic by day in the treatment course: The number attend-

TABLE 1
Characteristics of Participants in Acupuncture Trial

	Sham treatment (<i>n</i> = 45)	Standard treatment (<i>n</i> = 55)
Males	73%	63%
Mean age	40.4	40.5
Ethnicity		
White	29%	31%
African-American	62%	58%
American Indian	2%	0%
Mexican	2%	7%
Other Latino	4%	4%
Mean highest grade completed	11.9	11.8
Employment status		
Full-time	9%	10%
Part-time	11%	13%
Unemp. — Seeking work	38%	36%
Unemp. — Not seeking work	42%	40%
Mean age of first use/abuse	20.2/23.1	21.5/24.1
Drug use in past 30 days		
Once	2%	2%
Once/week	0%	4%
2–3 times/week	9%	7%
3–6 times/week	9%	7%
Once daily	9%	13%
2–3 times/day	62%	44%
>3 times/day	9%	24%
Mean prior admissions to any treatment program	3.0	4.1

Note: None of the differences between the standard and sham groups were statistically significant.

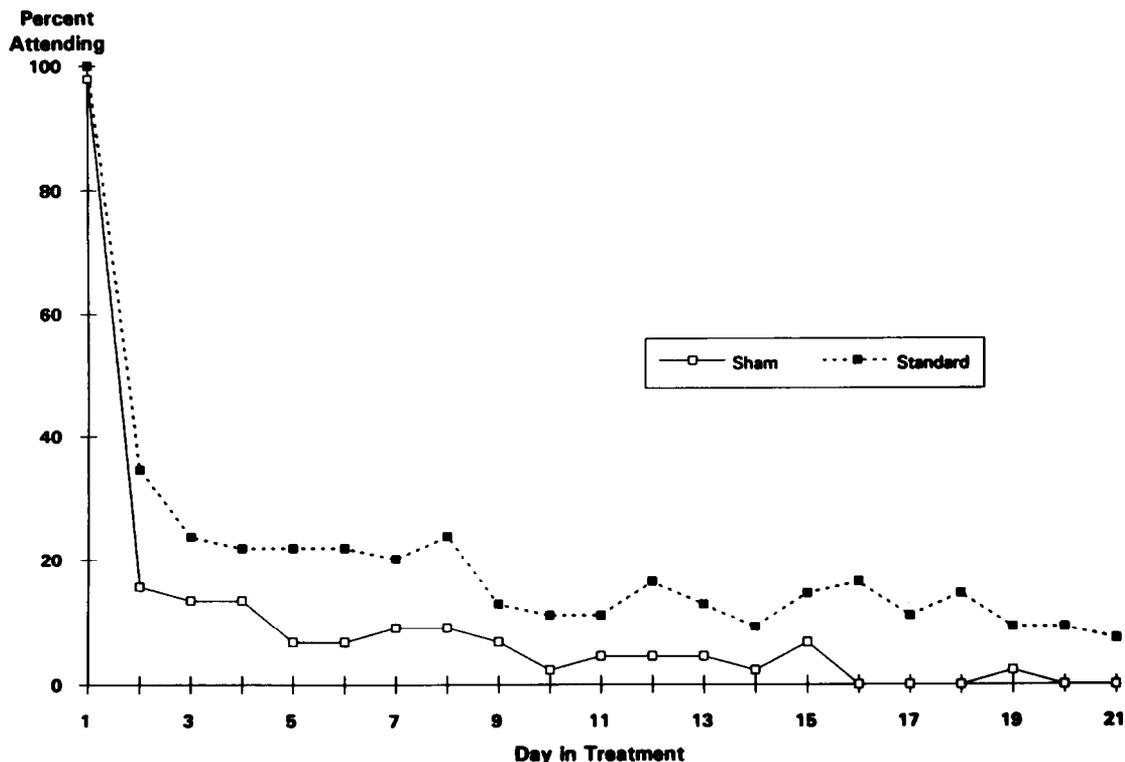


FIGURE 1. Percent attendance by treatment condition.

ing on a particular treatment day of the 21-day regimen was divided by the total number assigned to the group. Although both groups show a sharp initial drop in attendance, the sham treatment group showed a greater decline. On any given day in the treatment course, a larger proportion of clients receiving standard acupuncture attended the clinic than clients assigned to the sham condition.

Table 2 compares the two treatment groups on three additional measures of attendance: median number of days in treatment, median last day (of 21), and number of subjects staying in treatment beyond 21 days. The table shows that subjects receiving the standard acupuncture treatment attended the clinic more days

than subjects receiving the sham treatment; this effect was statistically significant at $p < .05$. The mean number of days in treatment was 2.1 for the sham group and 4.2 for the standard. The two groups also differed on the second length-of-stay measure reported in the table; the median last day in treatment was 1 for the sham and 2 for the standard subjects. The mean last day in treatment (of 21) was 3.8 for the sham and 6.6 for the standard subjects. Not surprisingly, these two attendance measures were highly correlated at $r_{xy} = .845$ ($p < .0001$). (When those who had dropped out of treatment after the first day were excluded from the analysis, the correlation coefficient was nearly as high at $r_{xy} = .763$ ($p < .01$.) The third comparison between the two groups was also significantly different ($p < .05$) with subjects receiving standard acupuncture more likely to continue treatment beyond the initial 21 days than those receiving the sham acupuncture. Of the subjects in the standard group who returned after the first treatment, 46.9% continued coming to the clinic after the 21-day detoxification period.

Table 3 lists mean number of days in treatment by condition and self-reports of frequency of heroin use in the 30 days preceding entry into the study. A two-way ANOVA of days in treatment showed main effects for both treatment condition $F(1,93) = 10.09, p < .01$; and frequency of use $F(2,93) = 5.27, p < .01$. The interaction was not significant at $F(1,93) = .236,$

TABLE 2
Length-of-Stay for Acupuncture Trial Participants

	Sham treatment (n = 45)	Standard treatment (n = 55)	95% confidence interval
Median number of days	1	2*	— ^a
Median last day (of 21)	1	2*	—
Number staying beyond 21 days	4 (.09)	16* (.29)	.06 .34

^aConfidence intervals cannot be computed for the median values compared by the Mann-Whitney U test if the n's are unequal.
* $p < .05$.

TABLE 3
Mean Number of Days in Treatment by Treatment Condition and Self-reports of Frequency of Heroin Use

	Treatment condition			
	Standard acupuncture (<i>n</i> = 55)		Sham acupuncture (<i>n</i> = 45)	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Frequency of use				
Light (<i>n</i> = 31)	6.11	6.02	3.08	3.82
Medium (<i>n</i> = 52)	3.92	4.10	1.75	1.96
Heavy (<i>n</i> = 17)	2.23	3.30	1.25	.50

Note: Main effects for both treatment condition and frequency of use were significant at $p < .01$.

$p = .79$. The great variability in days in treatment within all of the cells is reflected in the large standard deviations reported in the table.

Additional ANOVAs were run for number of days in treatment with the following variables as separate covariates: age, gender, ethnicity, age at first use, and symptom score on the first day of treatment. None of these factors were found to significantly effect the attendance measure.

Other Outcome Measures

At intake, the urine samples of 46.5% of the study subjects assigned to the sham group and 61.1% of those assigned to the standard group tested positive for opiates. (The urine samples collected from 3 subjects could not be tested.) These baseline figures were not significantly different. Because of the high attrition rates, few samples were collected during the second and third weeks of treatment. Of the 4 urine samples from the sham group in the second week, 2 tested positive for opiates. Of the 17 samples collected from standard subjects, 11 were positive for opiates. If we assume that subjects for whom we lack data used heroin during the second week, then the urine samples of only 4.4% of the sham and 10.9% of the standard group were negative for opiates for this round of testing. For the third week, 1 of the 4 samples given by sham subjects and 5 of the 9 samples from standard subjects tested positive. Percentage of known clean urines, then, for the third week was 6.7% for the sham and 7.3% for the standard group.

Side Effects

Total number of acupuncture treatments during the clinical trial was 608. Slight bleeding at the site of nee-

dle insertion was not uncommon. Other side effects were infrequent, however, limited primarily to mild nausea and dizziness. The acupuncture staff noted relief of these conditions when the needles were removed from subjects' ears. There were no episodes of fainting during the clinical trial nor were any grave side effects—such as infection at the site of needle insertion or breaking of the needle under the skin—observed.

DISCUSSION AND CONCLUSIONS

Efficacy of Acupuncture Detoxification

The results presented here demonstrate that acupuncture produces a significant effect in terms of treatment retention when compared with a sham, or placebo, procedure. Subjects receiving the standard acupuncture treatment for addiction attended the clinic more days than subjects in the sham group. This finding is consistent with those noted by Bullock and his colleagues in their studies of acupuncture-assisted alcohol detoxification (Bullock et al., 1987, 1989), although the effects of treatment condition on length-of-stay were less pronounced in the data reported here. Bullock's group was able to house clients on an in-patient unit, creating a more stable environment for those receiving treatment. Additionally, his group treated alcoholism whereas this study examined heroin addiction, with many of our subjects reporting use of other drugs as well.

Of significance was the finding that lighter users attended the acupuncture clinic more days and over a longer period of time than those with heavier habits. Subjects who injected heroin at least three times a day apparently found that acupuncture did not help relieve withdrawal symptoms or reduce craving and, thus, terminated treatment early. That this was true for subjects in both the standard and sham groups suggests that the heavier users may have had little expectation that a drug-free treatment modality would help them. (We discuss this issue further below; indeed, we found that individuals who injected heroin at least three times a day were less likely to volunteer to participate in the study than were the lighter users.)

Another finding of note was that subjects receiving standard acupuncture were more likely than subjects receiving the sham treatment to return for additional treatment beyond the 21-day detoxification period. Some of the clients receiving treatment beyond the detoxification episode were using acupuncture as an adjunct to methadone detoxification or maintenance; others seemed to seek additional treatment to detoxify after relapse to heroin use. Since prolonging a client's treatment is uniformly regarded to be one of the primary goals of any drug treatment program, the find-

ing that a number of subjects continued treatment well beyond the 21-day trial period warrants further study.

Limitations of the Study

That California state law prohibits unlicensed acupuncturists from administering treatment made it impossible to conduct a double-blind trial. It is conceivable that at least part of the effect of treatment condition found in this study was due to differential enthusiasm of clinical staff for the standard over the "sham" protocol. In our judgement, however, the effect of any staff bias was likely small: Aside from the particular acupuncture points used for treatment, study subjects were treated the same in every respect, e.g., all received the same ancillary services.

A second limitation of the study was the high attrition rate for the standard, as well as for the sham, condition. Fewer than one-fourth of the standard acupuncture clients remained in treatment beyond two weeks. One explanation for the high attrition rate was the fact that most of the money that subjects received for participating in the study was dispensed on the first day of treatment; research staff found that a number of addicts seemed to have volunteered because they were reimbursed for participation rather than because they were motivated for treatment.

Another limitation was that, because of insufficient resources, we were unable to follow up the subjects from the two treatment groups to determine long-term effects, if any, of the detoxification episode. What we did find was that nearly one-third of the subjects assigned to the standard condition continued to seek acupuncture treatment after completing the 21-day trial.

Finally, the finding that the urine samples of only 53% of the study subjects tested positive for opiates at intake warrants further consideration. (These data are consistent, however, with self-reports of drug use in the 30 days preceding treatment entry with nearly a third in each group having indicated that they used heroin less than once daily [See Table 1].) We reran the main analyses using only those subjects whose intake urine samples tested positive for opiates. The principal findings for this subgroup were the same as for the group as a whole: Subjects receiving the standard acupuncture treatment ($n = 35$) attended the clinic significantly more days than subjects in the sham group ($n = 21$) ($p < .05$), and attendance was greater for lighter users regardless of treatment condition.

It may be that heavier users were reluctant to volunteer for the study for fear of receiving the sham treatment. Alternatively, the heavier users may have preferred methadone-supported detoxification, while the drug-free acupuncture treatment was attractive to opiate addicts with lighter habits. For whatever reason, those treated in this study may not be represen-

tative of addict populations seen in many inner-city treatment facilities.

Conclusions

While the study reported here found a treatment effect in terms of retention for subjects assigned to the standard acupuncture condition, we have no evidence that even those who completed the 21-day program detoxified from heroin. This is not altogether surprising. Unlike methadone detoxification, acupuncture is a drug-free, rather than a replacement, treatment. Moreover, numerous studies have shown that short-term, i.e., 21-day, methadone withdrawal is, at most, modestly successful (Sorensen et al., 1982; Rounsaville, Kosten, & Kleber, 1985), with high attrition rates after the tapering phase of treatment begins. This treatment modality continues to be widely used, however, for a number of reasons. For example, with long waiting lists for methadone maintenance programs at many treatment facilities, methadone detoxification is often the only option for many patients. Recent research has evaluated various adjuncts to methadone detoxification, as well as the relative merits of lengthening treatment beyond 21 days, to determine how best to increase its efficacy (Iguchi & Stitzer, 1991).

Similar research is needed with acupuncture drug treatment. Given the client acceptability and the paucity of side effects, acupuncture may be a feasible treatment modality either for lighter users or for segments of the heroin-addicted population for whom methadone is not a viable option, e.g., those who do not want to, in effect, substitute one drug for another. The Bayview-Hunter's Point Acupuncture Clinic, though established for purposes of this study, has also treated individuals with other drug-related problems, such as cocaine-addicted adults and infants, individuals who abuse alcohol and prescription drugs, and methadone maintenance patients. Clinical experience with each of these groups suggests that acupuncture may be a useful adjunctive therapy. Additional research is needed to determine how acupuncture might best be incorporated into comprehensive substance abuse treatment programs.

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