Early reports					
Larry reports				i	
			:	·	
	,			*****	

Novel Auricular Therapy Enhances Retention Of Substance Use Disorder (SUD) Patients in Residential Treatment

Jay M. Holder, D.C., M.D., Ph.D., Kenneth Blum, Ph.D., Robert C. Duncan, Ph.D., Matthew Gissen, J.D., Michael Miller, Ph.D., John G. Cull, Ph.D., Eric R. Braverman, M.D., John A. Wise, Ph.D.

Department of Research Exodus Treatment Center, Miami Florida (JM Holder), St. Martin's College, Milwaukee, Wisconsin (JM Holder), American College of Addictionology and Compulsive Disorders, Miami, Florida (JM Holder, K Blum), Department of Biological Sciences, University of North Texas, Denton, Texas(K Blum) Department of Oncology, University of Miami, School of Medicine, Miami, Florida (R C Duncan), Village Addiction Treatment Center, Miami, Florida, (JM Holder, M Gissen, M Miller), Department of Rehabilitation & Counciling, Medical College of Virginia, School of Allied Health Professions, Richmond, Virginia (JG Cull), Department of Psychiatry, New York University School of Medicine, New York (ER Braverman), Natural Alternatives, Inc. San Marcos, California (JA Wise).

Address all corespodence to: Kenneth Blum, Ph.D.

University Of North Texas

1211 Lost Stone San Antonio, Texas

Reprint Requests to:

Jay M. Holder, D.C., M.D., Ph.D.

3303 Flamingo Dr.

Miami Beach, Florida 33140

This research was funded & sponsored by the State of Florida, Departmen of Health & Rehabilitative Services & The Village South , Inc. Miami Beach, Florida.

Introduction

This is the first report showing a significant reduction in AMA rates (the rate at which patients leave treatment Against Medical Advice) or enhanced retention of chemically dependent patients in residential treatment subjected to novel ear-acupuncture consisting of six points (limbic system, brain, zero, shen men, sympathetic, and kidney points). Heretofore, outcome results have indicated that using acupuncture for the treatment of substance use disorders (SUDs) has been only moderately successful and inconsistent in its efficacy. ¹⁻⁶ One possible explanation for these disparate results in comparison to our findings, may reside in the fact, that in the current study for the first time, we employed three new points including limbic, brain and zero.

Review of the literature reveals that, in 1990, a meta-analysis of studies into the effect of acupuncture on addiction. Suggested that the evidence did not support a role for acupuncture in addiction. A literature search revealed 22 controlled clinical studies on the efficiacy of acupuncture in three fields of addiction: cigarette smoking(fifteen), heroin (five), and alcohol (two). For smoking cessation, negative outcomes exceeded positive outcomes and for heroin and alcohol the meta-analysis could not find evidence for claims that acupuncture is efficacious as a therapy for these addictions.

Certainly, there is a clinical need to enhance retention of the chemically dependent person in treatment long enough to initiate the recovery process. It is well known that neurochemical perturbations in the meso-limbic system^{6, 7} leads to severe abstinence (withdrawal) symptoms associated with premature termination from treatment and relapse.⁸ In this regard abrupt withdrawal from opiates, ethanol, and cocaine results in the imbalance of limbic neurotransmitters (i.e. serotonin, opioid peptides, dopamine, and norepinephrine) which can be restored by a number of psychoactive agents (antidepressants, mao inhibitors, serotonergic re-uptake inhibitors, enkephalinase inhibitors, agonists, antagonists)⁹⁻¹³ and neutraceuticals or precursor amino acid therapies.²⁰ A review of the literature reveals that the appropriate use of both psychopharmacological and neutraceutical approaches to treatment have been shown to be moderately effective in reducing attrition rates of SUD patients in residential treatment.^{9, 14, 21}

There are definite links between acupuncture techniques (electrical cranial stimulation, electro-acupuncture, and direct needle insertion) and alterations of neurotransmitters in animals²² and humans³³ as well as attenuating detoxification abstinence (withdrawal) symptoms.²⁴ A series of papers by Culliton and associates support the use of acupuncture in addictive behaviors.^{1, 3} Based on these preliminary results, we and others, have proposed the use of ear-acupuncture or auricular therapy as a further adjunctive approach to reduce attrition of the SUD patient in residential treatment.⁴ The rationale for the current investigation was to determine the effects of auricular therapy on the reduction of AMA rates.

Summary

Background There is a clinical need to enhance retention of the Substance Use Disorder (SUD) patient in treatment long enough to initiate the recovery process. It is well known that neurochemical perturbations in the meso-limbic system leads to severe abstinence associated with premature termination from treatment and relapse. Heretofore, outcome results have indicated that using acupuncture for the treatment of SUD has been only moderately successful and inconsistent in it's efficacy.

Methods A total of 66 patient admissions to a primary 30 day residential chemical dependency facility volunteered for participation in this investigation. The diagnosis of SUD was based on the DSM1V diagnostic criteria, a one hour structured interview, and a psychiatric evaluation. The subjects were alternatively assigned to an acupuncture or a placebo group over a 14 day treatment regime. The placebo group consisted of daily administration of a starch-lactose placebo capsule. The acupuncture therapy group consisted of ten sessions of auricular therapy. The auricular therapy was applied once daily to six points (convential: shen men, sympathetic, kidney; novel: limbic, brain, zero) in each ear for 45 minutes. Comparitive retention and survival data were analysed using the ChiSquare test or Fisher's Exact Probability test and the Kaplan-Neir Product Limit Survival Method.

Findings This study demonstrates that patients who complete at least ten days of auricular therapy and do not receive intercurrent medications would be ten times more likely to complete a thirty (30) day residential treatment program (odds ratio =9.68, p=0.026) than they would without auricular therapy. Moreover, given the limits of the current study, this combination of ear -acupuncture points seems to enhance retention rates to a remarkably high level of 96% (95% confidence interval 88-100%).

Interpretation The results emphasize that the described select set of auricular points, for the first time, demonstrate positive outcome and effectiveness in retaining clients in a residential treatment setting. This unique approach may assist in reducing the previously observed negative outcome results in addiction, as described in earlier studies and provide the treatment community with a new tool to increase consistency in effect.

Key Words: Auricular therapy, substance use disorder, residential treatment, retention rates

THE STATE OF THE S

Patients and Methods

Patients and Program

A population of 66 patient admissions to a primary 30 day residential chemical dependency treatment facility (Exodus Treatment Center in Miami, Florida) volunteered for participation in this investigation. Table I details the demographics in terms of age, gender, and drug of choice of this population. The diagnosis of SUD was based on the *DSM IV* diagnostic criteria, a one hour structured interview, and a psychiatric evaluation (JMH). The entire study population took part in the "standard residential program." This included 1) a structured living environment, 2) adequate nutrition, 3) exercise training, 4) daily group therapy, 5) family therapy, 6) assertiveness training and relapse prevention training, and 7) educational seminars and a twelve-step fellowship participation.

Protocol

New patients who volunteered for the study were assigned alternatively to an acupuncture treatment group or to a placebo group. The treatment period was 14 days. The placebo group consisted of daily administration of a starch-lactose placebo capsule. The acupuncture group consisted of ten sessions of auricular therapy. The auricular therapy was applied once daily to six point in each ear for 45 minutes. Of the six points, three were formulated and used for the first time and include the limbic system, brain, and zero points. Additionally three of the more traditional points (shen men, sympathetic, and kidney) were incorporated.27, 32 Acupuncture therapy was delivered by 1/2 inch stainless steel Japanese needles; the insertion was performed by a licensed physician using the tube method. Electrical measurements of Jing-Well points (foot and hand) were completed on both groups at the beginning of the study and at the completion of the acupuncture period. Urine screens, using Roche Diagnostic Systems' Abusescreen®& Ontrack™, were performed every two and one-half days to identify chemical use. This study was approved by the Exodus Treatment Center's IRB. Each patient was informed about the risks associated with the use of ear-acupuncture and all the subjects signed an informed consent form prior to experimentation.

Statistical Analysis

All the data was entered into an Excell R spread sheet program which was E-mailed to the statician for subsequent analysis (RCD). Categorical data were analyzed using the Chi Square test or Fisher's Exact Probability test as required. Length of stay was analyzed using the Kaplan-Neier Product Limit Survival Method; mean scores on the questionnaire

items and on the AkabaneTM measurements were analyzed using repeated measures analysis of variance techniques. Statistical significance required probability levels to be less than or equal to 0.05. Failure was defined as early termination from treatment, either from staff action or client action (AMA). All patients on mood altering medications were excluded from the study.

Results

The 66 subjects of this study were evenly divided between the treatment group and the placebo group. Demographic data are presented in Table I. The subjects in the study were predominately male (18% of the treatment group was female and 25% of the placebo group was female). The distribution of drug use for each treatment group is shown in table one. There were 24 (73%) cocaine users in the acupuncture group and 26 (79%) in the placebo group; there were more polydrug users in the acupuncture group (n=11) than in the placebo group (n=5). A test for homogeneity revealed that there were no significant differences between the two groups with regard to SUDs (p<0.085). Moreover, Mantel-Haenszel Chi-Square analysis indicated that SUD (both cocaine use and/or polydrug dependence) did not have any differential effects on treatment outcome (failure) or any influence on time-on-study as indicated by the SAS Lifetest Statistical Program.

Eight of thirty-three of the acupuncture group (24%) failed to complete the thirty days required time-on-study compared to ten subjects in the placebo group (30%) who failed to complete the required time. This difference is not statistically significant (p= 0.580). The Kaplan -Meier analysis of the dropout pattern (subjects receiving less than 10 sessions of treatment) showed the acupuncture group with a mean of 27.6 days on-study while the placebo group had a mean of 27.3 days on-study (p=0.139). [see Table 2].

During the study, a number of patients placed on medications by the clinical staff, were terminated. When these patients taking psychoactive drugs were excluded, only four of the 29 in the acupuncture (treatment) group (13%) failed to complete treatment, while ten of 29 subjects in the placebo group (34.5%) failed to complete treatment. This difference though apparently stark did not reach a statistically significant level of difference (p<0.066). However, as observed in Figure 1, the Kaplan-Meier analysis on the dropout curves showed a mean time on study in the acupuncture group of 28 days while that for the placebo group was only 26.9 days, this difference is statistically significant (p<0.014). In figure 2, the survival cures for clients remaining on study are statistically significantly different from each with the placebo group showing a much higher rate of loss than does the acupuncture group (p=0.0139). While statistical analysis was not tested, it is noteworthy that, after completing treatment (assessed xxxX days later) no relapses occurred in the treatment group while four relapses occurred in the placebo group during the same time period.

When the data are restricted to those who finished at least ten days of treatment in either group and did not receive any psychoactive medications, a more robust finding was observed. The treatment group had only one of 24 subjects (4.2%) who failed to complete

the 30 days treatment program, while the placebo group had eight of 27 (29.6%) who failed to complete the full treatment program (see Figure 3). As observed in figure 1, this difference yields a statistically significant Chi-Square value (Chi Square= , df= , p<0.025).

Discussion

This study emphasizes that if patients receiving mood altering medications are provided with less than ten acupuncture treatments during treatment, the use of acupuncture would be no more effective than current treatment methods; however, what is important here is if patients were required to receive at least ten days of acupuncture treatment without receiving prescribed psychoactive medications, they would be approximately ten times more likely to complete a 30 days residential treatment program. Scrutiny of the literature reveals that a number of studies failled to show a positive outcome in using conventional acupuncture techniques to treat addiction. However, other studies have observed a moderate positive effect of acupuncture for the treatment of alcohism withdrawal²⁵, alcholism recidivism^{1,3}, smoking cessation²⁶, polysubstance abuse,²⁷ opioid dependence,²⁸ rapid narcotic detoxification, ^{24,29} & prisoner rehabilitation.³⁰

In conclusion, we believe that our results provide new evidence that a more appropriate set of auricular points may have greater efficacy than the standard five point technique previously used by Smith's group. ²⁷ and others. ³¹ In order to test this notion, our group is currently comparing these two techniques, in a large sample, to determine the relative clinical power of the newly described ear-acupuncture points as it relates to SUD patients.

Contributors

Jay M. Holder and Robert C. Duncan designed the study Mathew Gissen, Jay M. Holder and Michael Miller corridinated the study. Robert C. Duncan analysed the data. Kenneth Blum, Jay M. Holder, & Robert C. Duncan wrote the manuscript. John G. Cull edited the manuscript. Eric R. Braverman critiqued & reviewed the manuscript. John Wise reviewed the manuscript and up-dated all the references and finalized the graphics.

Acknowledgements

This research was sponsored by The Village South, Inc & the State of Florida, Department of Health & Rehabilitative Services. The study was funded by the State of Florida, Department of Health & Rehabilitative Services. The aurthors are grateful for the support of the Holder Institute, Miami Florida, American College Of Addictionology & Compulsive Disorders, CyberPharm, Inc. & Natural alternatives, Inc.

REFERENCES

- 1. Bullock ML, Culliton PD, & Olander RT. Controlled trial of acupuncture for severe recidivist alcoholism . Lancet 1989; 1 (8652); 1435- 9, 1989.
- 2.Sun ST, Yu ZS, Gao WB, et al. Clinical report of drinking intervention on 310 cases with auricule acupuncture. *J. Traditional Chinese Med* 8 (2); 123-4, 1988.
- 3. Bullock ML, Umen AJ, Culliton PD, Olander RT. Acupuncture treatment of alcoholic recidivism: a pilot study. *Alcoholism* 11 (3); 295-5, 1987.
- 4.Blum K, Newmeyer J, Inaba D. Whitehead C., Smith DE. Acupuncture as a common treatment modality in drug and alcohol dependence: Possible neurochemical rationale. *J. Pschedelic Drugs* 10; 105-115, 1978.
- 5. Ter Riet G, Kleijnen J, Knipschild P. A meta-analysis of studies into the efect of acupuncture on addiction. *Brit. J. Gen. Practice* 40 (338); 379-82, 1990.
- 6. Harris GC, & Aston-Jones G. Involvement of D2 dopamine receptors in the nucleus accumbens in opiate withdrawal syndrome. *Nature* 371; 155-157,1994.
- 7. Kuriyama K, Muramatsu M, Asio M, Ueno E. Alterations in beta-adrenergicv receptor binding in brain, lung and heart during morphine and alcohol dependence and withdrawal. *Neuropharmacology* **20**; 659-66, 1981.
- 8. Koob GF. Drug addiction: The Yin Yang of Hedonic Homostasis. Neuron 16: 893-96, 1996.
- 9. Hyman SE. Addiction to cocaine and amphetamine. Neuron 16; 901- 04, 1996.
- 10. Nestler EJ. Under Siege: The Brain on Opiates. Neuron 16; 897-900, 1996.
- 11. Rockman GE, Amit Z, Carr G, Brown, ZE. Attenuation of ethanol intake by 5-hydroxytryptamine uptake blockade in laboratory rats. 1. Involvement of brain 5-hydroxytryptamine in medication of the positive reinforcing properties of ethanol. Arch. Int. Pharmcodyn Ther 241; 245-59, 1979.

- 12. Volpicelli J, Alterman AI, Hayashidia M, O'Brien CP. Naltrexone in the treatment of alcohol dependence. *Archives General Psychiatry* **49**; 876-80, 1992.
- 13. Halikas JA, Nugent SM, Crosby RD, Carlson, GA. 190-191 survey of pharmacotherapies used in the treatment of cocaine abuse. *J. Addictive Diseases* 12; 129-139, 1993.
- 14. Tennant FS, Jr. Step-wise withdrawal from cocaine dependence with amino acids, dopamine agonists, and esiramine:outcomes of 106 consecutive cases. *Natl. Inst. Drug Abuse Res.* 81; 317- 1988.
- 15. Trachtenberg MC, Blum K. Alcohol and opiod peptides: Neuropharmacological rationale for physical craving of alcohol. *Am.J.Drug alcohol Abuse* **13**; 365-72, 1987.
- 16. Blum K, Allison D, Trachtenberg MC, Williams Rw, Loeblich LA.Reduction of both drug hunger and withdrawal against rate of cocaine abusers in a 30-day inpatient treatment program by the neuronutrient Tropamine. Cur Therap Res 43; 1204-14, 1988.
- 17. Cold JA. NeuRecover -SATM In the treatment of cocaine withdrawal and craving: a pilot study. Clin Drug Invest 12; 1-7, 1996.
- 18. Blum K. A commentary on neurotransmitter restoration as acommon mode of treatment for alcohol, cocaine and opiate abuse. *Integrat Psychiat* **6**; 199-04, 1989.
- 19. Blum K, Trachtenberg MC, Elliot, CE, Dingler ML, Sexton RL, Samuels Al, Cataldie L. Enkephalinase inhibition and precursor amino acid loading improves inpatient treatment of alcohol and polydrug abusers: Double -blind placebo-controlled study of the nutritional adjunct SAAVETM. Alcohol 5: 481-493,1989.
- 20.Brown RJ, Blum K, Trachtenberg MC, Neurodynamics of relapse prevention: A neuronutrient approach to outpatient DUI offenders. *J Psychoactive Drugs* **22**; 173-87, 1990.
- 21. Blum K, Holder, JM. *The Reward Deficiency Syndrome* (Smith, DE, forward), Amereon LTD. Mattituck, New York, 1997.
- 22. Chang RS. Pomerance BA. A combined treatment with D-amino acids and electro-acupuncture produces a greater analgesia than either treatment alone: Naloxone reverses these effects. *Pain* 8: 231- 1979.
- *23. Clement Jones V, Tomlin S, Rees L, McLoughlin G, Besser G, Wen HL. Increased beta- endorphin but not met-enkephalin levels in human cerebrospinal fluid after acupuncture for recurrent pain. *Lancet* --- 946-49, 1980.
- 24 Kroening RJ, Oleson TD. Rapid narcotic detoxification in chronic pain patients treated with auricular electroacupuncture electroacupuncture and naloxone. *International J Addictions* **20** (9); 1347-60, 1985.

- 25. Lewenberg A. Electroacupuncture and antidepressant treatment of alcoholism in a private practice. Clin Therapeutics 7(5); 611-7, 1985.
- 26. Zalesskiy VN, Belousova IA, Frolov GV. Laser- acupuncture reduces cigarette smoking: a preliminary report. Acupuncture & Electro-Therapeutics Res 8(3-4); 297-02,1983.
- 27. Smith MO, Khan I. An acupuncture program for the treatment of drug-addicted persons.

 Bulletin on Narcotics 40 (1); 35-41, 1988.
- 28. Johnson SH. Treatment of drug abusers in Malaysia: a comparison. International J addictions 18 (7); 951-8, 1983.
- 29. Newmeyer JA, Johnson G, Klot S. Acupuncture as adetoxification modality. J Psychoactive Drugs. 16 (3); 241-61, 1984.
- 30. Ali BE. The international Prisoners Aid association and drug abuse control. Bulletin On Narcotics. 43(10); 3-7, 1991.
- 31. Worner TM, Zeller B, Schwartz H, Zwas F, Lyon D. Acupuncture fails to improve treatment outcome in alcoholics. *Drug & Alcohol Dependence*. 30 (2); 169-73, 1992.