

Auricular Acupuncture in the Treatment of Cocaine/Crack Abuse: A Review of the Efficacy, the Use of the National Acupuncture Detoxification Association Protocol, and the Selection of Sham Points

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ABSTRACT

Background: The United Kingdom has had a significant increase in addiction to and use of cocaine among 16–29-year olds from 6% in 1998 to 10% in 2000. In 2000, the United Kingdom had the highest recorded consumption of “recent use” cocaine in Europe, with 3.3% of young adults. Acupuncture is quick, inexpensive, and relatively safe, and may establish itself as an important addiction service in the future.

Aim: To select investigations that meet the inclusion criteria and critically appraise them in order to answer the question: “Is acupuncture effective in the treatment of cocaine addiction?” The focus shall then be directed toward the use of the National Acupuncture Detoxification Association (NADA) protocol as the intervention and the selection of sham points for the control group.

Data sources: The ARRC database was accessed from Trina Ward (M. Phil. student) at Thames Valley University. AMED, MEDLINE® and Embase were also accessed along with “hand” searching methods at the British library.

Inclusion and exclusion criteria: People addicted to either cocaine or crack cocaine as their main addiction, needle-acupuncture, single-double-blinded process, randomized subjects, a reference group incorporating a form of sham points. Exclusion criteria: use of moxibustion, laser acupuncture, transcutaneous electrical nerve stimulation (TENS) electroacupuncture or conditions that did not meet the inclusion criteria.

Quality assessment: The criteria set by ter Riet, Kleijnen and Knipschild (in 1990); Hammerschlag and Morris (in 1990); Koes, Bouter and van der Heijden (in 1995), were modified into one set of criteria consisting of 27 different values.

Results: Six randomized controlled trials (RCTs) met the inclusion criteria and were included in this review. All studies scored over 60 points indicating a relatively adequate methodology quality. The mean was 75 and the standard deviation was 6.80. A linear regression analysis did not yield a statistically significant association ($n = 6, p = 0.11$).

Conclusions: This review could not confirm that acupuncture was an effective treatment for cocaine abuse. The NADA protocol of five treatment points still offers the acupuncturist the best possible combination of acupuncture points based upon Traditional Chinese Medicine. Throughout all the clinical trials reviewed, no side-effects of acupuncture were noted. This paper calls for the full set of 5 treatment points as laid out by the NADA to be included as the treatment intervention. Points on the helix, other than the liver *yang* points, should be selected as sham points for the control group.

INTRODUCTION

Prevalence of cocaine addiction in the United Kingdom

Addiction is defined as: "Use of a substance that is addictive when it has a mixture of pleasant and unpleasant properties, nearly all of which make the organism function worse, but which also, with continued use, suppress the organism's awareness of most of the pleasant toxic properties" (Smith, 1979). In the United Kingdom there has been a significant increase in the use of and addiction to cocaine among 16–29 year olds from 6% in 1998 to 10% in 2000. A statistically significant correlation was found between arrestees who tested positive for drug use and all four measures of criminal behavior. Half of the arrestees held for burglary of nondwelling premises tested positive for cocaine/crack (DrugScope, 2001). Problem drug use is defined as: "Injecting drug use or long-duration/regular use of cocaine and/or amphetamines." In 2000, the United Kingdom had the highest recorded consumption of "recent use" cocaine in Europe, with 3.3% of young adults (Fig. 1). Cocaine is a stimulant drug extracted from leaves of the *Erythroxylon* coca bush and was developed to treat a wide variety of illnesses in the mid-19th century. The chemical name of the processed drug is cocaine hydrochloride and is generally sold "on the street" as a crystalline powder (European Mon-

itoring Center for Drugs and Drug Addiction, 2001; United Nations, 2000).

Past research on cocaine users showed that firm boundaries distinguish recreational users of cocaine powder (hydrochloride) from problem "base/crack" users, and cocaine injectors (homeless young people, sex workers, and problem heroin users in geographic patches within specific cities). However, the boundary between powder cocaine and base/crack may be weakened by an emerging trend in cocaine smoking in recreational and nightlife settings and in recent changes in the market (DrugScope, 2001; European Monitoring Center for Drugs and Drug Addiction, 2001). The United Kingdom has one of the lowest prices of cocaine in Europe; (\$60.63) and a generally high purity rate (European Monitoring Center for Drugs and Drug Addiction, 2002; Panorama, 2003). Acupuncture is quick, inexpensive, and relatively safe, and may establish itself as an important addiction service for the treatment of cocaine addiction in the future.

Auricular acupuncture

Auricular acupuncture points have been characterized as discrete anatomic loci measuring approximately 1–5 mm in diameter in the auricles (Falk et al., 2000). The first record of the auricles importance was recorded in the *Huang Di Nei Jing*, Chapter 28 of the Spiritual Axis (circa 100 BCE): "All the vessels congregate in the ear." During the 1950s Nogier first developed the practice of auricular acupuncture using the concept that each part of the body is represented on the ear. Wen and Cheung (1973a, 1973b, 1973c) further developed the use of auricular acupuncture in alleviating the addiction to opiate-based drugs. In 1985, Michael Smith M.D., Lincoln Hospital, Bronx, New York, developed this research into the newly formed National Acupuncture Detoxification Association (NADA) protocol.

The number of points on the auricle remains unclear; the number ranges from 43 to 900, depending on the author (Chen, 1991). Acupuncture acts to relieve withdrawal symptoms and prevent the craving for drugs (Smith and Khan, 1988). The standard NADA points are *Shenmen*, Sympathetic, Kidney, Liver, and Lung (Fig. 2).

Mechanisms of acupuncture

Cocaine is believed to exert its euphoric effects by blocking the reuptake of neurotransmitters (primarily dopamine) at nerve synapses in the brain. As a dopamine reuptake inhibitor, cocaine can be considered to be an indirect dopamine agonist because it potentiates the synaptic actions of dopamine that have been released endogenously (Xenova Group Plc, 2003). Blum and colleagues (1996) suggested that stimulating the vagus nerve, which is located in the concha and at the Lung point on the auricle (Fig. 2) with the insertion of an acupuncture needle, stimulates the hypothalamus. Under normal conditions,

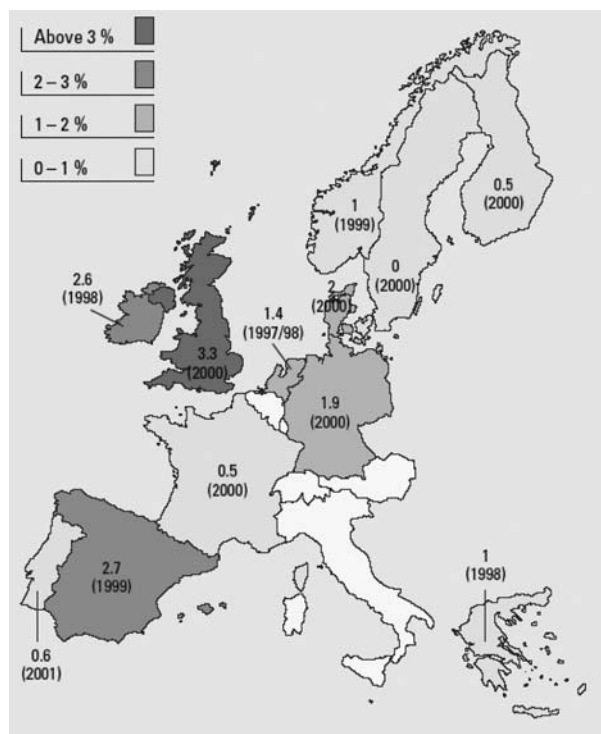


FIG. 1. Recent use (last 12 months) of cocaine among young adults, measured by national population surveys (European Monitoring Centre for Drugs and Drug Addiction, 2002, p. 12).

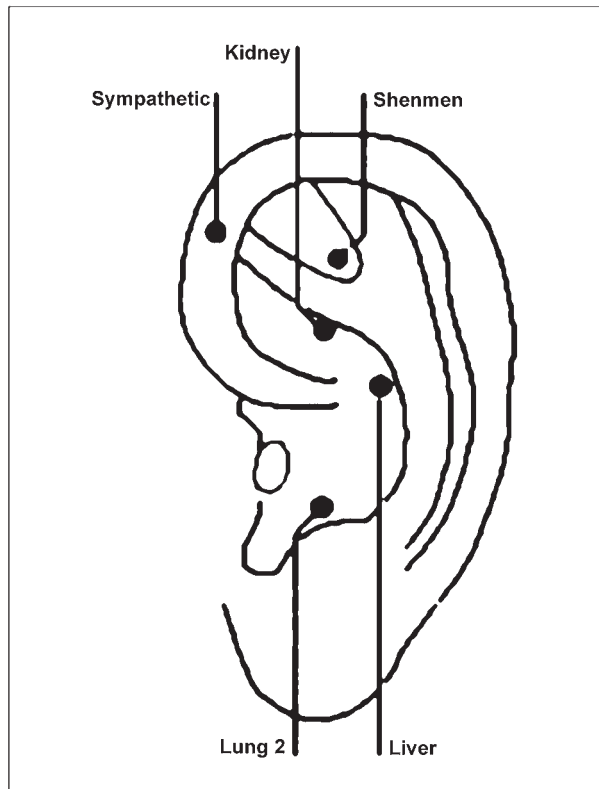


FIG. 2. The five points used for addiction as prescribed by the NADA (Given, 1997). Permission to reprint figure granted by the *Journal of Chinese Medicine*.

hypothalamic stimulation initiates the reward cascade. Hypothalamic neurons release serotonin (5HT), which activates methionine enkephalin, an opioid peptide. Met-enkephalin is released at the ventral tegmental region and interacts to inhibit receptors controlling the release of γ -aminobutyric acid (GABA). Met-enkephalin and/or other opioid peptides finely tune the system. The primary role of GABA is to control the output of dopamine in the ventral tegmental region. The result of inhibiting GABA is an increase in dopamine. Acupuncture acts to reduce craving, thereby assisting the drug addict into self-recovery. The NADA points act to tonify the *yin* of the Liver, Lung, Kidney, Heart (*Shenmen*) and the Sympathetic region, although this hypothesis of treatment effect has not been investigated within a Western biomedical framework.

Justification for a review of literature

The impact of national drug policies (more liberal versus more restrictive approaches) on problem drug use remains unclear because prevalence rates in countries with liberal drug policies (such as The Netherlands) and those with a more restrictive approach (such as Sweden) are not very different. What is clear is that new clients seeking treatment for heroin addiction are decreasing while those seeking treat-

ment for cocaine addiction are increasing (European Monitoring Centre for Drugs and Drug Addiction, 2001).

Legislation introduced in March 2001 by the U.K. government regulated the testing and related procedures on individuals suspected of driving under the influence of illicit substances (European Monitoring Centre for Drugs and Drug Addiction, 2002). Coupled with existing drug laws, the number of cocaine users being arrested has increased. Arrest-referral schemes and drug treatment and testing order schemes (DTTOs) have been found useful in the United Kingdom to increase the number of drug-using offenders in treatment. Research conducted by the DPAS (2000) demonstrated that the crisis of arrest is an important opportunity to target drug-misusing offenders with prevention and treatment services.

No medication has received widespread acceptance as an effective treatment for cocaine dependency (Rawson et al., 1990). Although some withdrawal treatment interventions have been subject to evaluation, more in-depth knowledge is needed in the pros and cons of the different modalities and on which type of withdrawal treatment should be used for which type of patient (European Monitoring Centre for Drugs and Drug Addiction, 2002). Drug treatment can be divided into the stages of detoxification, rehabilitation, and relapse prevention. Acupuncture has been used for all stages of drug treatment (Moner, 1996; Scott and Scott, 1997).

AIM OF THIS STUDY

The aim of this study was to select investigations that meet the inclusion criteria and appraise them critically in order to answer the question: "Is acupuncture effective in the treatment of cocaine addiction?" The focus shall be directed toward the use of the NADA protocol as the intervention and the selection of sham points for the control group.

MATERIALS AND METHODS

Data sources

A literature search was performed using ARRCBASE, MEDLINE® (1966–present), AMED (1985–present), and Embase (1989–present). Also "hand searching," manual methods were used at the British Library, to capture items that may have been indexed incorrectly or not indexed at all (Sim and Wright, 2000). Examination of reference lists in primary and review articles were conducted. Copies of original articles were obtained at all times so as to capture an undiluted source of data. Only full-length, English-language articles were sought. Abstracts and unpublished studies were not selected. Inclusion and exclusion criteria were then applied to establish the final set of articles to be reviewed.

Inclusion and exclusion criteria

Studies were included in this review if they met the criteria: people addicted to either cocaine or crack cocaine as their main addiction, needle-acupuncture, single-double-blinded process, randomized subjects, a reference group incorporating a form of sham points. The inclusion group also consisted of pilot studies. Studies that were rejected used moxibustion, laser acupuncture, transcutaneous electrical nerve stimulation (TENS) electroacupuncture, or did not meet the inclusion criteria.

Key words

The key words used by the administrator of the ARRC database were "cocaine" and "acupuncture" (T. Ward personal communication, July 17, 2003). These key words were further used during searches of other electronic sources.

Quality assessment

All randomized controlled trials (RCTs) were evaluated to determine the quality of the studies. The ter Riet et al. strategy (1990) was considered first but was criticized for only having a series of 18 criteria that limited the ability to adequately score the clinical trials (Birch, 2001; Lewith, 1995). Birch (2003) suggests a criteria range of 43, but remains unpublished. The ter Riet et al. criteria was therefore modified to include criteria from Hammerschlag and Morris (1990) and Koes et al. (1995). This selection of criteria was thought to be more comprehensive to enable this study to answer the research question. Twenty-seven (27) different criteria were set (Appendix A) A weighting was attached to indicate its relative importance. The potential maximum

score for each study was 100 points. The higher the score, the better the quality of the methodology. One assessor conducted the grading. The assessor was not blinded to the outcomes of the studies included in this review. This means that some degree of reviewer bias cannot be excluded (ter Riet et al., 1990). In instances where data were missing to correlate the studies to the grading criteria, authors were contacted and the necessary information gathered (S. Avants, personal communication, November 11, 2003; T. Killeen, personal communications, 2003; D. Lipton, personal communication, November 11, 2003; A. Margolin, personal communication October 29, 2003).

RESULTS

Six RCTs met the inclusion criteria and were included in this review (Avants et al., 2000; Bullock et al., 1999; Killeen et al., 2002; Lipton et al., 1994; Margolin et al., 2002a; Otto et al., 1998). Appendix B presents the results of the methodological assessment of the RCTs in a linear order. Appendix C summarizes all six studies. "Half-points" were given if the assessor felt that the research paper had succeeded partially a defined criteria (Appendix D). Because only one assessor graded the RCTs, these results are considered to be preliminarily only.

Of the six RCTs reviewed, two reported a positive outcome (Avants et al., 2000; Lipton et al. 1994) while four were negative in their conclusions (Bullock et al., 1999; Killeen et al., 2002; Margolin et al., 2002a; Otto et al., 1998). All studies scored over 60 points indicating a relatively adequate quality of methodology. The highest score was 83 (Bullock et al., 1999) while the lowest was 64 (Killeen et al., 2002) (Fig. 3). The mean was calculated at 75 with a

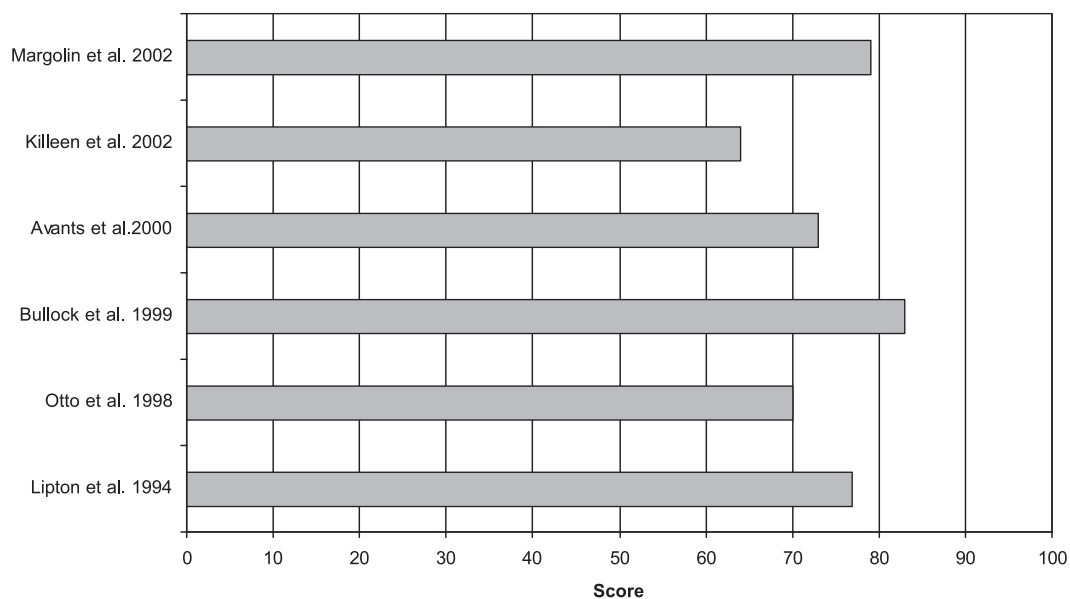


FIG. 3. The methodological scores of the randomized controlled trials reviewed.

standard deviation of 6.80. A linear regression analysis did not yield a statistically significant association ($n = 6, p = 0.11$). All studies scored full points on criteria 1, 2, 3, 5, 10, 11, 13, 15, 22, 25, and 26. No criteria scored zero across all studies.

Of the six studies, three excluded the Kidney point from the NADA protocol (Table 1). Three studies used proximal points, three used helix points, two of which avoided Liver yang points on the helix while one did not avoid the Liver yang points.

DISCUSSION

There have been many statements made against the use of RCTs in the study of acupuncture (Birch, 2003; Falk et al., 2000; Given, 1997; Guillaume, 1991; Margolin et al., 1998a; McLellan et al., 1993; Sherman et al., 2001; Suen et al., 2000). However, until a protocol is found that suits both paradigms of allopathic and traditional medicine, then current methodological criteria for RCTs remain the gold standard.

Looking at the RCT scoring, all studies scored more than 60 points, indicating that the RCTs had a good quality of methodology. However, a paradox exists; all studies scored better than average, yet had conflicting outcomes. The study by Lipton et al. (1994) has a positive outcome toward auricular acupuncture and a methodology score of 77, while the study by Margolin et al. (2002a) was negative in its conclusions yet achieved a scoring of 79. Therefore, this review

cannot provide a definite answer as to the efficacy of auricular acupuncture in the treatment of cocaine/crack abuse. This raises the following question: In spite of apparently good overall quality of methodology, are certain methodological criteria within the clinical studies of the effects of auricular acupuncture on cocaine abuse causing contradictory outcomes?

The selection of treatment points versus sham points is the most important aspect of any acupuncture research, especially research still in development. If “sham points” have active (positive) effects, the comparison of outcomes between the “treatment” and “sham” groups cannot show the true effect of acupuncture treatment, and the conclusion that treatment “had no significant effect” can be seriously wrong because the “sham” points were inappropriate.

The first documented research in auricular acupuncture and cocaine addiction started in the 1970s (Wen et al., 1973a, 1973b, 1973c). Since then, other studies have tried to replicate these findings in a more strict empirical clinical setting. Lipton et al. (1994), the first group to replicate the studies of Wen et al. (1973a, 1973b, 1973c), concluded that acupuncture gave a positive outcome (Table 1). Further studies found flaws in Lipton et al.’s (1994) selection of sham points proximal to sham points in the control group undermining the outcome result (Birch, 2003; Culliton and Kiresuk, 1996; Margolin et al., 1995, 1998a) Otto et al. (1998) and Bullock et al. (1999) both replicated the study by Lipton et al. (1994) and concluded with negative outcomes. In both of these replicated studies, inappropriate sham points (proximal to active points) were used in the control group.

TABLE 1. SUMMARY OF TREATMENT AND CONTROL POINTS USED, WITH OUTCOME IN THE RANDOMIZED CONTROLLED TRIALS REVIEWED

<i>Study/year</i>	<i>NADA points selected</i>	<i>Sham point selection</i>	<i>Outcome</i>
Lipton et al., 1994	Lung, Liver, Shenmen, and Sympathetic	Proximal	Positive
Otto et al., 1998	Lung, Liver, Shenmen, Sympathetic, and Kidney	Proximal	Negative
Bullock et al., 1999	Lung, Liver, Shenmen, Sympathetic, and Kidney	Proximal	Negative
Avants et al., 2000	Lung, Liver, Shenmen, and Sympathetic	Helix (no Liver yang points)	Positive
Killeen et al., 2002	Lung, Liver, Shenmen, Sympathetic, and Kidney	Helix (Liver yang points)	Negative
Margolin et al., 2002a	Lung, Liver, Shenmen, and Sympathetic	Helix (no Liver yang points)	Negative

Bolding highlights the use of kidney points and selected sham points on the auricle within the randomized controlled trials reviewed. NADA, National Acupuncture Detoxification Association.

Avants et al. (2000) used the newly developed selection of sham points on the auricular helix, although with a reduced number of treatment points, four instead of the standard five set by the NADA. They concluded with a positive outcome. Killeen et al. (2002) used the full set of NADA points and nonproximal auricular points but it is unclear which points were selected on the helix. Liver *yang* points may have been stimulated in the control group, thus flawing the control as a neutral intervention (Birch, 2003; T. Killeen, personal communication, November 11, 2003). Margolin et al. (2002a) replicated Avants et al. (2000) study by correctly using the helix without stimulation of the Liver *yang* points and excluded the Kidney point from the NADA treatment group. The outcome was negative.

Traditional Chinese Medicine (TCM) comprises a large and heterogeneous group of treatments, many of which are procedures not readily testable under blinded conditions and for which the choice of appropriate control conditions is by no means straightforward especially when compared to control procedures for pharmacotherapies. TCM has a theoretical basis, rooted in a cultural tradition that has little foundational research on which to base a controlled evaluation (Margolin et al., 1998b, 2002b). Therefore, and because it does not include the concept of a "placebo," TCM sheds little light on the issue of the selection of sham points.

There may be no "inactive" or "placebo" sites suitable for "negative controls" in acupuncture research. Sites far outside the active area may not be neutral. They may cause pain and thus would not be an appropriate sham or inactive placement, or may elicit a physiologic response that is considered by some to be another form of acupuncture and not a true placebo (Culliton et al., 1996; McLellan et al., 1993; Moner 1996).

Classically defined, a placebo effect is an effect that occurs after the administration of a therapeutically inactive substance, such as a lactose pillule, or a small dose of a weak saline solution. Nonspecific effects are those that occur after treatments that do not use medication or procedures with known or presumed mechanisms for their action (Culliton et al., 1996). In any study, both active and sham points must be correctly located, especially upon a body-mass as small as the auricle. To do so requires detailed and accurate charts of points and anatomic locations. All the studies reviewed relied upon ear maps. In the latest study by Margolin et al. (2002a), the location of sham points is referenced to one paper, namely Margolin et al. (1995). In the 1995 study, the location of the actual sham points was explained but poorly described. There was no reference to any auricular maps or standardized nomenclature. The currently accepted selection of sham points on the helix originated in the study by Margolin et al. (1995). A later study by Margolin and colleagues (1996) confirmed the hypothesis that points on the helix had a lower electrical resistance than those located proximal to active points. The ear charts used to identify the location of the active and sham points were those of Cheng (1999),

Manaka et al. (1995), and O'Connor and Bensky (1981). These ear charts differ greatly on the number of points, Manaka et al. (1995), number 108; O'Connor et al. (1981) 180; while Cheng (1999) number 79. Margolin et al. (1996), simply refer to these points as zone 1, 2, 3, and 4 and assumed that zones, as distinct regions of the ear, do in fact exist, that zones had well-defined and specific locations, that zones were congruent across subjects despite variations in auricular shape, and that zone quadrants had similar orientation across subjects, although this may not be the case.

Without a standard auricular nomenclature, it is difficult to see how studies used the ear charts to determine correct point location. The conclusion of all the studies reviewed, were made upon the findings derived from insertion of needles into "points." Confusion of names and locations of auricular points has seriously hindered the development of auricular therapy (Suen et al., 2000).

At present no auricular nomenclature exists. There are great differences between the French and Chinese systems. At present only 39 auricular points have been agreed upon (Oleson 1998; World Health Organization, 1990). Some points have more than one name and new points are constantly being added with new clinical discoveries (T. Oleson, personal communication, October 30, 2003). The Working Group of the WHO decided to withdraw its earlier Auricular Acupuncture Chart because it contained many points and should not be used for the purpose of further reference to localization of auricular points, or be used in view of the changes in the standardization of the anatomy of the areas of the ear (World Health Organization, 1990). There is a great need for standard terminology in the study of auricular acupuncture. There should be a standard reference chart of the ear that covers the following:

- Correct anatomic illustrations of the ear.
- An appropriate anatomical mapping of topographical areas, to be decided upon in consultation with experts in anatomy and auricular acupuncture.
- Illustrations of correct zones, in relation to auricular acupuncture and research.
- Actual delineation and localization of points, where possible (World Health Organization, 1990).

Oleson (1998) outlined a possible standardization of auricular nomenclature and will present his proposal as a journal article soon (T. Oleson, personal communication, October 30, 2003).

Relocation of sham points to the helix has assisted in the study of the NADA treatment protocol. Introduced of this standardized form of treatment helped to bring auricular acupuncture into the frame of empirical testing, although some have criticized that the standard form of treatment offered by the NADA is against the theoretical foundation of syndrome-differentiation-symptom pattern analysis that is essential in TCM (Given, 1997). Within all six studies the

NADA protocol or an amended version were used as the treatment intervention. However, there is no factual or scientific explanation for the selection of the five NADA points (Konefal et al., 1995; McLellan et al., 1993).

To understand acupoint selection as a treatment modality, it is necessary to understand addiction according to TCM and the role of the NADA protocol. The NADA protocol is based upon the understanding and relationship of the body's internal organs, known as the *Zangfu*. In TCM theory, drug abuse affects mainly the solid (*zang*, *yin*) organs: Lung, Liver, Heart, Spleen, and Kidney.

Cocaine abuse generally leads sequentially to four particular syndromes in TCM, which outline the pathology of drug abuse among the *Zangfu*.

1. Heart *yin* deficiency: nonpurposive symptoms: excessive sweating, insomnia and anxiety (Maclean and Lyttleton, 1998; Smith, 1979).
2. Kidney *yin* deficiency: purposive symptoms: paranoia (Smith, 1985).
3. Liver *yin* deficiency: purposive symptoms: irritability, euphoria, and anger (Brewington et al., 1994; Smith, 1979).
4. Spleen *qi* deficiency: nonpurposive symptoms: diarrhea and loss of appetite.

With the effects of withdrawal and excessive sweating, cocaine destroys Heart *yin* and causes *yang* to be greater than *yin* because a weakened *yin* cannot balance or regulate *yang* (Dale, 1993). TCM terms this situation as "Empty Fire" or "False Fire." Because Kidney and Heart have a unique relationship according to the *Ko* (Controlling) sequence of

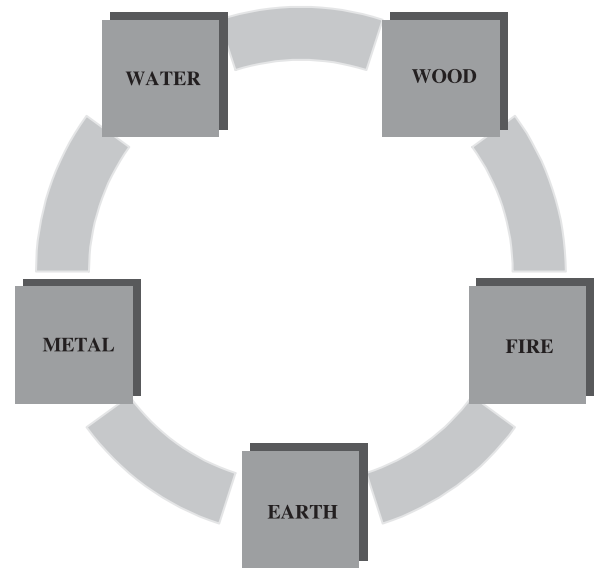


FIG. 5. The generating sequence of the Five Elements.

the Five Element Theory (Fig. 4), Empty/False Fire drains Kidney *yin*. Kidney (Water–Mother of Fire) regulates and controls the Heart (Fire–Child of Water). As the abuse of cocaine depletes Heart *yin*, which allows Heart Fire to arise, Kidney *yin* is further depleted by excessive demand leading to the syndrome of Kidney *yin* deficiency. This is known as Heart insulting Kidney.

Via the *Sheng* (Generating) sequence of Five Element Theory (Fig. 5), Kidney *yin* deficiency then inhibits Kidney (Mother of Wood) in its function of supplying *yin* to Liver (Wood, Child of Water), creating the Syndrome Liver *yang* Rising. The pathologic *yin* and *yang* mechanisms are the same as that of the Kidney–Heart relationship, although in this instance it is housed within the one organ. Liver *yang* Rising further exacerbates the Heat Syndrome and *yin* depletion. The more deficient the *yin*, the greater the Liver *yang* Rising. This leads to a greater degree of *yin* deficiency and perpetrates the cycle of *yin* deficiency. The *yin* depletion cycle moves back to the Kidney, which is the foundation for all the *yin* energies of the body (Maciocia, 1989) (Fig. 6).

Liver imbalance leads to the Syndrome Liver–Spleen disharmony. Here Liver invades Spleen causing spleen deficiency. Excessive loss of bodily fluids worsens the *yin* deficiency, because *yin* is essentially water. Injury to Spleen inhibits its function of generating *qi* and Blood for the whole body. This drains the body's reserves Pre-Heaven *qi*-Essence housed within the Kidney and increases the Kidney *yin* deficiency.

Many addicts are involved in excess sexual activity that damages Kidney *yin*. Chronic drug abuse may damage Kidney *yang* as well as Kidney *yin*. The abuse of sex that results from the False *yang* (Empty Heat) increases the *yin*

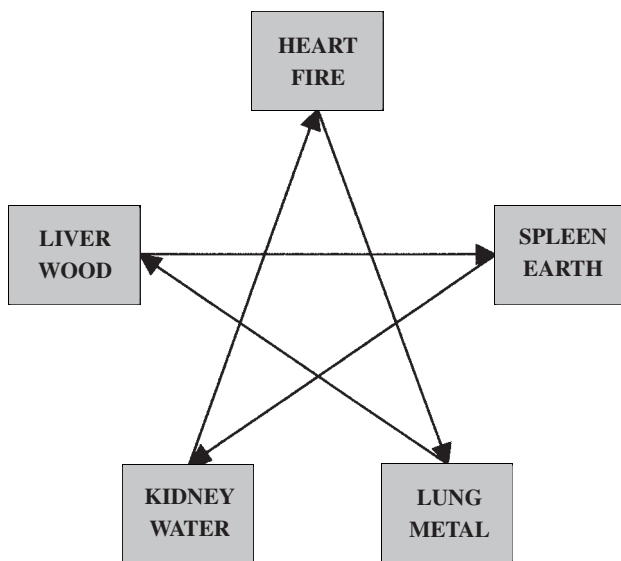


FIG. 4. The controlling sequence of the Five Elements.

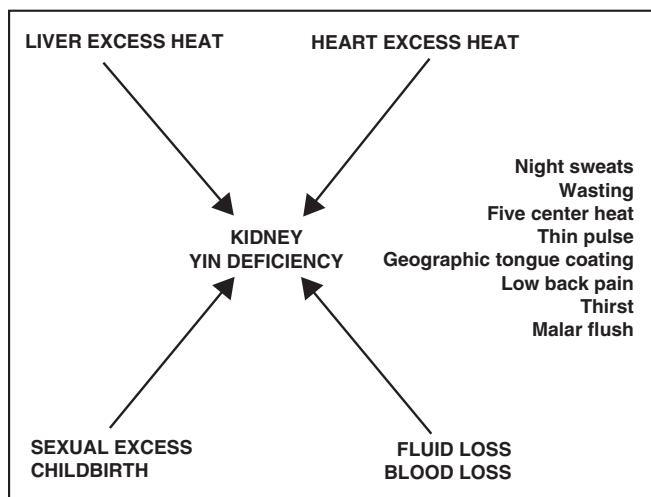


FIG. 6. The factors leading to Kidney *Yin* Deficiency (Given, 1997). Permission to reprint figure granted by the *Journal of Chinese Medicine*.

and *jing* (Essence) deficiency, which further exacerbates the False *yang*. In some patient populations, the addiction to and abuse of sex is a primary motivation for the abuse of the drug and these people may be addicted to the False *yang* itself (Dale, 1993; Given, 1997; Smith, 1985).

Allopathic medicine also recognizes the relationship between cocaine abuse and kidney damage. A wide spectrum of renal complications can occur with cocaine use, including renal infarction, atherosclerosis of the kidney, renal scleroderma, Henoch-Schönlein purpura, and renal failure as a result of rhabdomyolysis (Crowe et al., 2000).

In the six studies reviewed, the NADA protocol was modified to exclude the Kidney point in certain instances (Avants et al., 2000; Lipton et al., 1994; Margolin et al., 2002a). Lipton et al. (1994) and Avants et al. (2000) do not provide any reasoning for the exclusion. In the study by Margolin et al. 2002a, the justification was to avoid hyperstimulating the auricle in the control condition. There is no clinical evidence that suggests the Kidney point hyperstimulates the auricle in either the NADA protocol or the control group, including the debunked sham protocol of points 2–3 mm away from active sites or the newly developed control protocol of points located on the auricular helix. Margolin et al. (2002a) used dubious reference literature to justify their four-point selection. Their literature consisted of five articles: Bullock et al. (1989); Lipton et al. (1994); Avants et al. (1995); Bullock et al. (1999); Avants et al. (2000). Of these five studies, two (Avants et al., 2000; Lipton et al., 1994) gave no logical reasoning for the exclusion of the Kidney point. One study (Bullock et al., 1999) included the Kidney point while two studies (Bullock et al., 1989; Avants et al., 1995) excluded both the Liver and Kidney point. There is therefore no logical reasoning to exclude the Kidney point in any clin-

ical trial conducted to date. The NADA training manual does not stipulate the sole exclusion of the Kidney point as stated by Margolin et al. (2002a). Sometimes fewer points may be used on clients if they are for example, feeling very sensitive or delicate, or they are young, 14 or 15 years old. Then it is a case of using less points rather than excluding one in particular (R. Peckham, personal communication, November 23, 2003). Any competent TCM practitioner qualified in acupuncture knows that the Kidney point must be used as the main point of treatment to reduce drug cravings.

Avants (S. Avants, personal communication, November 11, 2003) cites an earlier study (Margolin et al., 1998a) that justifies the exclusion of the Kidney point in the Avants et al. (2000) study. Margolin et al. (1998a) suggested a reason to exclude the Kidney point—because unnamed “acupuncturists” wanting to achieve a lower “activity.” It is speculated here, that the idea of using points of lower “activity” arose from Ulett’s research into stimulation by frequency specific instruments of auricular point Lung (Fig. 2). The Lung point lies in concha of the ear, which is the place of greatest density of vagal innervation. Ulett—who based his research on the Wen et al. [1973b] study—claimed that only one point bilaterally is necessary. If point selection is to be based on the understanding of the acupuncture mechanics alone rather than the selection of the NADA points, then only the Lung point need be used (Blum et al., 1996; McLellan et al., 1993; Ulett, 1992). The landmark auricular study by Wen et al. (1973b), used only the Lung point until the subject felt they had the full dose of their addictive drug, with good results. There is no evidence as claimed by Avants that warrants the exclusion of the Kidney point.

Bullock et al. (1999) suggested another theory why the Kidney point was excluded from the traditional five-point NADA protocol. They excluded the Kidney point in relation to the now debunked use of proximal point selection 2–3 mm away from the active NADA points. Within this form of control, it was deemed necessary to reduce the number of needles in an effort to reduce “stimulus flooding.” Although it was not stated clearly, this may be related again to the idea to avoid hyperstimulation of the vagus nerve located at the auricular Lung point.

The NADA selection of points, including the Kidney, reduces the signs and symptoms of drug abuse and withdrawal (Given, 1997; Konefal et al., 1995; Margolin et al., 1993b; Richard et al., 1995; Smith, 1979; Smith et al., 1988). Using frequent repetitions of Kidney-related ear treatments is very effective in even severely debilitated addicts; in such cases the main treatment focus is to tonify the Kidney (Dale, 1993; Smith, 1985). By tonifying the *Jing*-Essence and strengthening the Kidney, rehabilitated patients can return to function on the every-day expected level of *Jing* function. Patients need ear-Kidney treatments before they are able to respond to other acupuncture. It cannot be overemphasized the critical importance of using ear-Kidney treat-

ment as the primary form of acupuncture for chemical dependency (Smith, 1985).

Clearly there has been an inadequate knowledge of the nature and scope of acupuncture leading to the selection of inappropriate treatment methods and sham point selection in many studies. The lack of nomenclature in auricular acupuncture increases the problem. These problems illustrate the necessity for more cooperative efforts to determine the best research methodologies to use (Birch 2003).

CONCLUSIONS

Implications for professional practice

Even though this review could not confirm the efficacy of acupuncture to treat cocaine abuse, the NADA five-point protocol offers the acupuncturist the best possible combination of acupoints based on TCM theories. Throughout all the clinical trials reviewed, it was impressive to note the low rate of side-effects with the acupuncture treatment (Margolin et al., 1993a; McLellan et al., 1993; Moner, 1996). Acupuncture is highly cost-effective. Overhead costs are low, equipment needs are negligible, and therapy is easily given on an outpatient basis. Also, one acupuncturist, supported by a small ancillary staff, can treat many patients simultaneously. Finally, increased use of acupuncture therapy may eventually decrease in the number of inpatient admissions to expensive treatment centres (Bullock et al., 1989).

Implications for research

The inconsistency in treatment protocols between studies, or the use of combined therapies, makes it impossible to draw a strong causal relationship between auricular therapy and its treatment effect, thus making replication of studies difficult (Suen et al., 2000). As the form of auricular acupuncture control has moved away from sites located 2–3 mm away from active sites to those located on the helix, there is a call for the reintroduction of the Kidney into the acupuncture treatment protocol. This may enhance treatment effectiveness and provide clarity in future clinical trials studying the effects of auricular acupuncture for crack/cocaine abuse. This paper calls for the standardization of methodology to be implemented systematically to all clinical studies researching the effects of auricular acupuncture on crack/cocaine abuse. The full five treatment points proposed by the NADA should be used at the treatment intervention. Points on the helix, other than the Liver *yang* points, should be selected as sham points for the control group. It is hoped that by doing so, clear studies can be conducted that will effectively conclude an outcome for the use of auricular acupuncture in the treatment of cocaine/crack abuse. Additional studies are needed to evaluate if endogenous opi-

ate release or hormonal changes occur with sham points located on the auricular helix to assess if the sham treatment is truly placebo.

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APPENDIX A. LIST OF CRITERIA USED TO ASSESS THE METHODOLOGY OF STUDIES OF ACUPUNCTURE (MAXIMUM SCORE 100)

<i>Criteria</i>	<i>Score</i>
<i>Comparability of prognosis</i>	
1. Informed consent obtained	2
2. Description of inclusion and exclusion criteria	2
3. Homogeneity of sample	2
4. Prestratification of sample	2
5. Randomization to control and treatment groups	9
6. Comparability of relevant baseline characteristics shown	2
7. At least 50 patients per group	8
8. No more than 20% loss to follow-up	5
9. Dropouts described for each study group separately	2
<i>Adequate intervention</i>	
10. Diffuse noxious inhibitory control avoided	2
11. Acupuncture treatment procedure adequately described	9
12. Existing treatment modality in reference group	3
13. Comparison with a placebo or sham therapy	5
14. Adequate description and appropriate use of placebo or sham	5
15. Good quality of acupuncturist mentioned	5
<i>Adequate effect measurement</i>	
16. Patients blinded	9
17. Evaluator blinded	5
18. Statistician blinded	2
19. Blinding evaluated and fully successful	2
20. Biochemical validation of self reported outcome	5
21. Follow-up after treatment for at least 6 months	5
22. Symptoms of withdrawal noted	2
23. Changes in occupational, social, psychologic status or criminal behaviour noted	1
24. Side-effects remarked upon	2
<i>Data presentation and analysis</i>	
25. Reader able to do inferential statistics	2
26. Literature review	1
27. Funding source acknowledged	1

Modified from ter Riet et al. (1990) and Hammerschlag et al. (1990) and Koes et al. (1995).

APPENDIX B. THE METHODOLOGICAL ASSESSMENT SCORES FOR THE RANDOMIZED CONTROLLED TRIALS ANALYZED

	14 (5)	15 (5)	16 (9)	17 (5)	18 (2)	19 (2)	20 (5)	21 (5)	22 (2)	23 (1)	24 (2)	25 (2)	26 (1)	27 (1)	Total score
13 (5)	0	5	9	5	2	0	5	0	2	0	0	2	1	1	77
5	0	5	9	5	0	0	5	5	2	0	2	2	1	1	70
5	0	5	9	5	0	0	5	5	2	1	2	2	1	1	83
5	5	5	4	5	0	1	5	0	2	0	2	2	1	1	73
5	2	5	9	0	2	0	0	0	2	0	0	2	1	1	64
5	5	5	0	5	0	0	5	5	2	1	2	2	1	0	79

APPENDIX B. THE METHODOLOGICAL ASSESSMENT SCORES FOR THE RANDOMIZED CONTROLLED TRIALS ANALYZED

Reference	Outcome	1 (2)	2 (2)	3 (2)	4 (2)	5 (9)	6 (2)	7 (8)	8 (5)	9 (2)	10 (2)	11 (9)	12 (3)
Lipton et al. 1994	Positive	2	2	2	2	9	2	8	0	2	2	9	0
Otto et al. 1998	Negative	2	2	2	0	9	0	0	0	2	2	9	0
Bullock et al. 1999	Negative	2	2	2	2	9	2	8	0	2	2	9	0
Avants et al. 2000	Positive	2	2	2	2	9	2	0	0	2	2	9	3
Killeen et al. 2002	Negative	2	2	2	2	9	2	0	5	0	2	9	0
Margolin et al. 2002a	Negative	2	2	2	2	9	0	8	0	2	2	9	3

1. Study: Lipton et al. (1994)*Method*

RCT, random number method.

Population size

Participants: 150 subjects.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria: over the age of 18, self-reported cocaine/crack smoking or intravenous cocaine use as primary substance abuse problem, reported use of cocaine/crack at least 3 days in the previous week, reported no prior experience with any type of acupuncture therapy, reported no serious back pain problems.

Control Method

Sham acupuncture group: five needles were inserted at auricular points; Elbow, Knee, Shoulder and Sciatic. One or two treatments were given daily for 6 days per week for a month.

Interventions

Unspecified acupuncturist inserted four needles into auricular points; Lung, Liver, Shenmen and Sympathetic. One or two treatments were given daily for 6 days per week for a month.

Outcome Criteria

Urine toxicology tests were conducted on all subjects daily.

Outcome Results

Urinalysis results over the 1-month study period favored the experimental group. Experimental subjects in treatment over 2 weeks had significantly lower cocaine metabolite levels relative to placebo subjects over a comparable period.

2. Study: Otto et al. (1998)*Method*

RCT, random number method

Population Size

Participants: 36 subjects.

Inclusion and Exclusion Criteria

Inclusion criteria: met the *DSM-III-R* criteria for cocaine dependence, provided informed consent. Exclusion criteria: had acute medical problems, current psychiatric comorbidity, met criteria for current dependence on other substances or dependence on nicotine or caffeine.

Control Method

Sham acupuncture group: five needles were inserted at auricular points; Knee, Sciatic nerve, Lumbosacral, Dorsal, and Cervical Vertebrae.

Interventions

U.S.A.-certified acupuncturists used the five-point NADA protocol (needles at auricular points Shenmen, Sympathetic, Kidney, Lung and Liver) in three phases. Phase I treatments lasted 30–45 minutes, 5 days per week for 2 weeks. Phase II treatments were given three times per week for 2 weeks. Phase III treatments were given once per week for 8 weeks.

Outcome Criteria

Urine toxicology tests conducted on all subjects semiweekly.

Outcome Results

Pilot study failed to show a significant difference between patients treated with different acupuncture protocols. Retrospective analysis did show a statistical significant difference in the study ($p = 0.02$).

3. Study: Bullock et al. (1997)*Method*

RCT, random number method

(continued)

Population Size

Participants: 438 subjects.

Inclusion and Exclusion Criteria

Inclusion criteria: used cocaine at least two times per week for the month preceding study enrollment, were age 18 or over, were not actively psychotic, suffering neurological, physical, or other mental illness that would impair the ability to comprehend the consent form, were willing to participate in a treatment program involving acupuncture. Exclusion criteria: are receiving antipsychotic, antidepressant, sedative, stimulant, or other mood-altering medications.

Control Method

Sham acupuncture group: three needles were inserted at unspecified locations in 28 sessions over 8 weeks.

Interventions

U.S.A.-certified acupuncturists used the five-point NADA protocol (needling auricular points Shenmen, Sympathetic, Kidney, Lung and Liver) plus Hegu (LI4) in 28 sessions over 8 weeks.

Outcome Criteria

Random weekly cocaine use assessment toxicology screens.

Outcome Results

No differences were observed between baseline and endpoints for positive urine tests between the different dosing schedules of 28 treatments (62% positive), 16 treatments (74% positive), and 8 treatments (73% positive [$\chi^2 = 2.69, p = 0.26$]).

4. Study: Avants et al. (2000)*Method*

RCT, computer-based, randomised procedure.

Population Size

Participants: 82 subjects.

Inclusion and Exclusion Criteria

Inclusion criteria: over the age of 18, *DSM-IV* criteria for cocaine abuse or dependence, self reported cocaine use the week before screening or provision of a cocaine positive urine screen at time of screening. Exclusion criteria: dependence on any substance other than opiates, cocaine or nicotine, current treatment for cocaine dependence, current use of a psychotropic medication, unless maintained on a regimen of this medication for at least 90 days, current acupuncture treatment or use of acupuncture in the previous 30 days, active suicidal or psychotic status.

Control Method

Control group: relaxation. Viewed nature videos 40 minutes each week for 8 weeks.

Sham acupuncture group: four needles inserted into the helix of the auricles. Treatment was given 40 minutes each week for 8 weeks.

Interventions

Stephen Birch, a licensed acupuncturist certified to provide the NADA protocol, inserted four needles into the auricle points Lung, Liver, Shenmen, and Sympathetic.

Outcome Criteria

Cocaine use was assessed by urine toxicology screens 3 times weekly.

Outcome Results

Longitudinal analysis of the urine data for the intent-to-treat sample showed that patients assigned to acupuncture were significantly more likely to provide cocaine-negative urine samples relative to both the relaxation control (odds ratio, 3.41; 95% confidence interval, 1.33–8.72; $p = 0.1$) and the needle-intervention control (odds ratio, 2.40; 95% confidence interval, 1.00–5.65; $p = 0.05$)

5. Study: Killeen et al. (2002)*Method*

RCT, random number method

Population Size

Participants: 30 subjects

Inclusion and Exclusion Criteria

Inclusion criteria: over the age of 18, *DSM-IV* criteria for cocaine abuse or dependence, identify cocaine as their primary drug of abuse and reported cocaine use within the last 5 days, able to give adequate informed consent and function at an intellectual level sufficient to allow accurate completion of assessment instruments, able to read and communicate in English, endorse a level of craving equal to or greater than 5 on a scale of 1 (indicating none) to 10 (indicating extreme). Exclusion criteria: diagnosed with a *DSM-IV* psychotic disorder, taking medications specifically for craving, dependent on substances other than nicotine or caffeine.

Control Method

Sham acupuncture group: Needles were inserted into the 5 points on the auricular helix.

Interventions

Needles were inserted as per the five-point NADA protocol (Shenmen, Sympathetic, Kidney, Lung, and Liver).

Outcome Criteria

Cocaine Craving Questionnaire-Now (CCQ-Now) and Skin Conductance Activity (SCA).

Outcome Results

t Tests on difference scores on the CCQ-Now total score ($p = 0.42$) or SCA ($p = 0.94$). There were no differences for presence of psychiatric diagnoses on CCQ-Now total score ($p = 0.64$) or SCA ($p = 0.09$).

6. Study: Margolin et al. (2002a)*Method*

RCT, permuted-block computer-based

Population Size

Participants: 620 subjects

Inclusion and Exclusion Criteria

Inclusion criteria: over 18 years old, been diagnosed with cocaine dependence according to the *Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (SCID)*, have evidence of recent cocaine use either by providing a cocaine-positive urine screen at or within 2 weeks before screening or by self-reporting abuse 1 week prior. Exclusion criteria: being dependent on any substance other than opiates, cocaine, or nicotine, currently receiving treatment for cocaine dependence, currently taking a prescription benzodiazepine, currently taking any other psychotropic medication unless maintained in this medication for at least 90 days, currently receiving acupuncture in the previous 30 days, being actively suicidal or psychotic.

Control Method

Control group: relaxation. Viewed nature videos 40 minutes each week for 8 weeks.

Sham acupuncture group: four needles were inserted into (1) region located between the helix apex and upper Liver *yang* point, (2) region located between the two Liver *yang* points, (3) region 3 located between the lower Liver *yang* and helix 4 points (two needles were inserted into this region). Treatment was given 40 minutes/week for 8 weeks.

Interventions

Licensed acupuncturists certified to provide the NADA protocol inserted four needles inserted into auricular point's Lung, Liver, Shenmen, and Sympathetic. Treatment was given for 40 minutes/week for 8 weeks.

Outcome Criteria

Urine toxicology testing for the cocaine metabolite benzoylecgonine was undertaken 3 times per week during treatment.

Outcome Results

Intent-to-treat analysis of urine samples showed a significant overall reduction in cocaine use (odds ratio, 1.40; 95% confidence interval, 1.11–1.74; $p = 0.002$) although no differences by treatment condition ($p = 0.90$ for acupuncture versus both control conditions). There were also no differences between the conditions in treatment retention (44%–46% for the full 8 weeks).

RCT, randomized controlled trial; NADA, National Acupuncture Detoxification Association; *DSM-IV*, Diagnostic and Statistical Manual of Mental Disorders, 4th ed.

Lipton et al. (1994)

1. Criteria 15 (good of acupuncturist mentioned). The word acupuncturist was mentioned but no qualifications were given. One point given out of a possible 5.

Otto et al. (1998)

None.

Bullock et al. (1997)

None.

Avants et al. (2000)

1. Criteria 16 (patients blinded). The patients were only partially blinded. Four points given out of a possible nine.
2. Criteria 19 (blinding evaluated and fully successful). Blinding was evaluated but not successful. One point given out of a possible two.

Killeen et al. (2002)

1. Criteria 14 (adequate description and appropriate use of placebo or sham). The helix of the auricle was used but precise location not given. Liver yang points may have been stimulated. Two points given out of a possible five.

Margolin et al. (2002a)

None.
