REVIEW ARTICLE

THE EFFECTIVENESS OF AURICULAR ACUPUNCTURE FOR DRUG ADDICTION: A REVIEW OF RESEARCH EVIDENCE FROM CLINICAL TRIALS

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Abstract

Objectives: **This review aims to compile and evaluate all available randomised controlled trials (RCTs) of auricular acupuncture (AA) treatment in drug addiction population with emphasis on the length of treatment course, needle-points, outcome measures, reported side-effects and overall outcomes.** ***Methods:*** **Science Direct, Medline and EBSCOhost databases were searched. From the year 1990 until 2010, only full-length English articles incorporating RCTs related to AA studies (needle-based only) in drug addiction such as heroin, morphine, methamphetamine and cocaine were included. Studies involving the usage of various methods of electro-acupuncture and investigations relating to cigarette-smoking or alcohol addiction were excluded.** ***Results:*** **Eight RCTs met all inclusion criteria comprising of 1,594 respondents (age = 19 - 46 years; male = 57% - 76%). Most were involved in cocaine addiction. Overall, trials were designed with brief periods of treatment course and utilised three to five standard National Acupuncture Detoxification Association (NADA) points (*Sympathetic, Lung, Liver*, *Kidney* and *Shen men*), but inconsistent *sham* points. All trials included urine toxicology test as the main outcome measure while data on side-effects incidence was insufficient.** ***Conclusions:*** **Overall, four of the RCTs reported positive outcomes although at this point, AA's effectiveness and safety could not be substantially confirmed. For the future, high-quality RCTs of AA are urgently required to provide a clearer understanding on the usefulness of this complementary therapy in drug addiction treatment.** ***ASEAN Journal of Psychiatry, Vol.13(1), January – June 2012: XX XX***

Keywords: Acupuncture, addictions, randomised controlled trials.

Introduction

Drug abuse and addiction have become major social and serious public health problems which had resulted in the world-wide spread of infectious diseases such as HIV/AIDS, hepatitis B and hepatitis C. These diseases are highly associated with the shared use of needles amongst intravenous drug users [1]. From the statistics of the World Drug Report, it has been estimated that between 155 - 250 million people or 3.5% - 5.7% of the total population aged 15 and above had used illicit substances in 2008. Cannabis remains as the world's most widely produced and used illicit substance involving between 130 - 190 million people per year. In addition, more than 15 million opiate users were also reported globally. However, there are signs of increase in synthetic drug use such as amphetamine-

type stimulant and the usage is comparatively higher than cocaine and opiate drugs. Cocaine use itself is common in North America, Europe and some other countries [2].

Expectedly, drug addiction treatment and rehabilitation programmes have been initiated in many countries in which examples include naltrexone, buprenorphine and the synthetic opioid methadone, the latter has been demonstrated to be effective for opioid dependence in many northern and western European countries [3,4]. Another treatment alternative which has been tested is levo-alpha-acetylmethadol (LAAM) which was approved for use in the USA as an opioid

maintenance drug in 1993 [5]. However, these pharmacological modalities are plagued with numerous side-effects such as constipation, decreased sexual desire, drowsiness and vomiting [6]. Furthermore, the number of drug treatment centres and access to these facilities around the world are still lacking [2]. The same report estimated that in 2008, only around one fifth of drug users worldwide had received treatment in the previous year which meant that another 20 million drug dependent people did not receive treatment at all [2]. This scenario became complicated as further statistics showed significant increase in the number of relapse despite treatment provision [7].

Therefore, in attempts to reduce the relapse rate, to minimise the various side-effects of conventional treatment as well as to increase the availability of addiction treatment, new treatment approaches such as those involving alternative therapies need to be persistently explored. The use of auricular acupuncture (AA) for the treatment of addiction has grown substantially in the past decade and it is in widespread use in drug rehabilitation centres especially across China [8].

The use of AA was first developed by a French physician in 1951 and later it was serendipitously observed that AA could relieve opiate withdrawal signs in addicts [9,10]. AA is the procedure of inserting and manipulating very fine needles into the acupuncture points on the external surface of the ears (auricles) bilaterally. Based on the theory that the ear is a microsystem representing the entire human body, the stimulation of AA points would therefore impose a therapeutic impact on bodily organs, systems and functions. Consequently, it can be beneficially used to treat a wide range of health problems including drug addiction [9]. The National Acupuncture Detoxification Association (NADA) of AA protocol or often referred to as the NADA or five-point protocol is universally recognised as the general treatment guideline for addiction. The standard NADA points for addiction or detoxification are *Shen men, Sympathetic, Kidney, Liver* and *Lung* points [11].

Despite the complexity of the underlying mechanisms of AA, many researchers agree that illicit substances mainly alter the concentration of opiate peptides in the brain [12]. Incidentally, various studies have linked AA to the production of endogenous opiate peptides [13]. The dopamine pathway is also believed to be the final route for drug actions such as cocaine, heroin, morphine and alcohol. It is associated with feelings of well-being, pleasure and reinforcement; contributing to the continued drug abuse and the development of drug addiction [14,15]. In the brain, drugs of abuse act to produce a large increase in dopamine which has long been associated with addictive behaviours [16]. A recent study by Yang and colleagues found that acupuncture helps in balancing the dopamine levels through both positive and negative reinforcements of addiction pathway in the brain, hence reducing their craving and withdrawal symptoms as well as strengthening the role of acupuncture in drug dependent treatment [17].

Existing clinical evidence seemed to support the notion that AA is somehow effective in ameliorating withdrawal and craving symptoms associated with opiate and cocaine dependence, leading to its increasing popularity and acceptance as a treatment option in Western countries [18]. Intriguingly, the co-administration of acupuncture with modern medicine has even showed some synergistic effects in detoxification [19]. The

advantages of acupuncture included its low cost, favourable safety profile, lack of side-effects and simple administration [20].

Although a number of preliminary studies investigating the effectiveness of AA for the treatment of drug addiction have reported positive outcomes, findings from the more scientifically controlled studies have to-date been inconclusive [13]. A systematic review by D'Alberto could not strongly confirm that AA was an effective treatment for cocaine abusers [20]. By focusing on merely six RCTs, the author concluded that the NADA protocol of five treatment points still offer the best possible combination of acupuncture points and this review also did not elaborate on the study duration or the outcome measures employed [20]. Other review articles have largely concentrated on acupuncture in the management of both alcohol addiction as well as cocaine dependence [21-23]. In 2006, Jordan completed a review on the efficacy of acupuncture as treatment for opiate addiction, covering 33 years of reported literature and abstracts. This review generated findings that supportive evidence often came from non-controlled and non-blinded trials with no significant evidence for the effectiveness of acupuncture coming from RCTs. Nevertheless, the review was not specific to only AA in RCTs and no dates were used as the search cut-off periods [24].

To complement the existing gaps, our current review serves to dissect several new issues in addition to the previous work because to the best of our knowledge, there was no other review article which had discussed information on all outcome measures and the duration of treatment course of AA in RCTs, particularly for drug addiction treatment in the past 20 years. In the light of the recent introduction of Traditional and Complementary Medicine (T/CM) in our country [25], alternative approaches in tackling many chronic health disorders including drug addiction are now highly sought by patients. This scenario is further propelled by the growing global interest and the increasing acceptance for T/CM such as traditional Malay massage and acupuncture which have been offered in selected government hospitals in Malaysia.

Essentially, AA has been evaluated in only a few well-controlled clinical trials and concrete results to support its application as a standard treatment for substance dependency is still controversial. Consistent outcomes are currently lacking. In order for these problems to be dealt with effectively, a review of the available RCTs to dissect important issues such as treatment duration, needle-points, reported side-effects and outcome measures is timely. The specific directions as to where future efforts in addiction treatment need to be focused and emphasized on are hence indicated.

Methods

Search strategy and selection criteria

The Science Direct, EBSCOhost and Medline databases were searched. The following terms were entered and combined as keywords: "ear / auricular / acupuncture", "addiction / substance (ab)use / drug (ab)use / cocaine / heroin / methamphetamine / morphine / opioid" and "randomised / control / trial". The window time frame of article publication was set for the past 20 years (1990-2010). Only full-length English articles reporting RCTs related to AA studies (needle-based only) in drug addiction were selected. Additionally, all related articles on AA for the treatment of illicit drugs abused such as heroin, morphine, methamphetamine and cocaine were also included. Excluded studies were those involving the usage of any method of electro-acupuncture and other related techniques as well as techniques involving other parts of the body. Investigations relating to cigarette-smoking or alcohol addiction plus abstracts, unpublished studies and reviews were also not selected.

Data collection and analysis

Demographic information for all participants in the selected studies was summarized according to their publication year, country, title of study and age (presented as mean,

standard deviation and range). Besides that, the type of drug used, existing treatment, employment status, gender and ethnicity were depicted as percentages. In addition, the following key information was extracted from each study i.e. first author, publication year, sample size, experimental and control treatment, NADA points, main outcome measure(s), reported side-effects, and main findings.

Results

From the year 1990 until 2010, a total of eight articles involving RCTs of AA therapy for cocaine and opioid detoxification were found. Articles from the Journal of Substance Abuse Treatment (n=5) were the majority and the rest of the articles were published in the Journal of Alternative and Complementary Medicine, Archives of Internal Medicine Journal and Journal of American Medical Association (one article each). All included trials were carried out in the USA, United Kingdom and Sweden [26-33]. However, a second study by Bullock and colleagues has not been included in this review due to the additional acupuncture points used on the wrist area instead of solely intervening on the ear lobes (auricular) [29]. Overall, these studies have mainly focused on cocaine addiction.

Table 1. An overview of demographic indicators of respondents enrolled in auricular acupuncture (AA) randomised controlled trials (RCTs) from the year 1993 until 2009.

No	Authors (year)	Country	Age (year) (Mean / Mean ± SD / Range)	Drug used (%)	Existing treatment(s)	Employment status (%)	Gender (%) / ratio	Ethnicity (%)
1	Avants et al. [26] (2000)	USA	37.0 ± 6.0	• Cocaine = 100.0	• Methadone	• Employed = 10.0 • Unemployed = 90.0	• Male = 57.0 • Female = 43.0	• Caucasian = 44.0 • African American = 38.0 • Hispanic = 16.0 • Others = 2.0
2	Bearn et al. [27] (2009)	United Kingdom	35.9 ± 6.6	• Cocaine = 34.5 • Heroin = 64.3 • Amphetamine = 2.5 • Cannabis = 33.5 • Others = 24.1 (Percentage ≠ 100% because each patient had used ≥ 1 drug)	• Methadone	NA	• Male = 76.0 • Female = 24.0	NA
3	Berman et al. [28] (2004)	Sweden	33.5	• Heroin = 12.0 • Amphetamine = 59.0 • Cannabis = 18.0 • Others = 14.0 (Percentage ≠ 100% because each patient had used ≥ 1 drug)	None	NA	• Male = 61.0 • Female = 39.0	NA
4	Bullock et al. [29] (1999)	USA	30.2 ± 6.0	• Cocaine = 100.0	None	NA	• Male = 69.9 • Female = 30.1	• Caucasian = 21.2 • African American = 66.7 • American Indian = 2.5 • Puerto Rican = 0.2 • Cuban = 0.7

								• Others = 8.2
5	Lipton et al. [30] (1994)	USA	30.1 / 19.0 – 46.0	• Cocaine = 46.6 • Heroin = 12.7 • Cannabis = 38.7 • Others = 24.7 (Percentage ≠ 100% because each patient had used ≥ 1 drug)	• Methadone	• Full-time = 48.0 • Part-time = 14.0 • Unemployed = 32.0 • Retired / disabled = 6.0	• Male = 72.0 • Female = 28.0	• Caucasian = 6.7 • African American = 60.7 • Hispanic = 32.6
6	Margolin et al. [31] (2002a)	USA	37.5 ± 6.3	• Cocaine = 100.0	None	• Employed = 10.3 • Unemployed = 89.7	• Male = 60.8 • Female = 39.2	• Caucasian = 51.0 • African American = 32.7 • Hispanic = 13.9 • Others = 2.4
7	Margolin et al. [32] (2002b)	USA	38.8 ± 7.6	• Heroin = 64.3 • Amphetamine = 2.5 • Cocaine = 7.5 • Cannabis = 33.5 • Others = 27.5 (Percentage ≠ 100% because each patient had used ≥ 1 drug)	None	• Full-time = 24.5 • Unemployed = 75.5	• Male = 69.2 • Female = 30.6	• Caucasian = 28.9 • African American = 60.2 • Hispanic = 7.3 • Others = 3.6
8	Washburn et al. [33] (1993)	USA	40.5	• Heroin = 100.0	• Methadone	• Full-time = 9.5 • Part-time = 12.0 • Unemployed = 78.0	• Male = 68.0 • Female = 32.0	• Caucasian = 30.0 • African American = 60.0 • American Indian = 1.0 • Mexican = 5.0 • Other Latino = 4.0

Note: NA = not available.

Demographic indicators

The total number of participants enrolled in all the included RCTs was 1,594 from the year 1993 until 2009. A total of six studies were carried out in the USA. The average age of participants across all studies ranged from 19 - 46 years old. Most of the respondents were unemployed (32% - 90%). Across all studies, the most common drugs of abuse were cocaine and heroin. About half of the participants have been receiving methadone as part of their treatment for drug addiction problems. The percentage of male respondents was generally higher (57% - 76%) than the females (24% - 43%). According to sample ethnicity, the three major ethnic groups involved in these trials were African American (32.7% - 66.7%), Caucasian (6.7% - 51.0%) and Hispanic (7.3% - 32.6%). These demographic information are as depicted in Table 1.

Length of treatment course

The length and number of treatment sessions varied between studies. Majority of the studies applied five sessions of AA weekly for a total duration of two to eight weeks. Overall, the studies provided at least 14 sessions to a

maximum of 40 sessions of AA treatment. The longest duration of treatment course was eight weeks - Table 2.

Auricular acupuncture points

The five standard needle-points suggested by NADA protocol included *Symphathetic, Lung, Liver, Kidney and Shen men*. Of the eight studies, five trials did not include the *Kidney* point [26,30-33]. One study used three needle-points [29]. Another two studies utilised five needle points [27,28]. For the control group, most researchers preferred to use non-specific or *sham points* such as helix control and only one study used oil and metal clips on the ears [27,28,31,32]. The average duration of needling time was 20 to 45 minutes per session.

Side-effects

Only five trials recorded the side-effects during treatment. The most commonly-reported side-effects were pain and *De Qi* [26,31,32]. The *De Qi* response has been reported to be related to warmth or fullness sensation felt upon needle insertion. Pain at the needle points was reported in only one trial [28]. In another study, slight bleeding at the site of needle insertion, dizziness and mild nausea have been recorded [33].

Table 2. An outcome summary of Randomised Controlled Trials (RCTs) for drug-dependent population using auricular acupuncture (AA) as intervention.

No.	Authors (year)	Sample (n)	Experimental treatment	Control treatment	NADA points	Main outcome measures	AA side-effect(s)	Main results (Positive / Negative)	Comments
1	Avants et al. [26] (2000)	82 patients (on MMT)	• 5 AA sessions weekly for 8 weeks (40 minutes per session)	• *Sham points* • Relaxation (3 different video shows)	• *Symphathetic* • *Lung* • *Liver* • *Shen men*	• 3 times weekly urine toxicology • Addiction Severity Index (ASI) • Treatment Credibility Scale (TCS) • SOCRATES-8D	• Pain • *De Qi*	• Significant cocaine free in urine for experimental vs relaxation control (odds ratio = 3.41, 95% CI = 1.33 - 8.72, p = 0.01) • Significant overall reduction in cocaine use for both Experimental and sham point treatment (odds ratio = 2.40, 95% CI = 1.00 - 5.75, p = 0.05) • Overall conclusion: positive	• No elaboration of side-effect(s) • 4 points instead of 5 points were used
2	Bearn et al. [27] (2009)	83 patients (on MMT)	• 5 AA sessions weekly for 14 days (30 - 40 minutes per session)	• Application of oil and five metal clips on the ears.	• 5 points in the ear cartilage ridge area	• 3 times weekly urine toxicology • Maudsley Craving Scale (MCS) • The 10-item Short Opiate Withdrawal Scale (SOWS)	• NA	• No significant difference in the severity of opiate withdrawal scores between experimental and control treatment • No significant difference in mean craving scores for both experimental and control treatment • Overall conclusion: negative	• Treatment duration was short • Control treatment could be recognised by the patients due to its non-needle application • NADA point selection was not specified • No mention of side-effect(s) • Positive effects of AA could not be experienced by the patients probably due to brief treatment duration
3	Berman et al. [28] (2004)	158 prison inmates	• 5 AA sessions at the first week and 3 AA sessions weekly for 3 weeks (40 minutes per session)	• 5 points on the helix of the auricles bilaterally	• *Symphathetic* • *Lung* • *Liver* • *Kidney* • *Shen men*	• Every other day urine toxicology • Simple drug use questionnaire • Treatment Credibility Scale (TCS) • Symptom Check List 90 (SCL-90) • Acupuncture Treatment Assessment Scale (ATAS)	• Pain	• No significant side-effect was detected for both experimental and control treatment • Symptoms of discomfort were reduced for both treatments • Sleeping time was improved for experimental and control treatment • Overall conclusion: negative	• The control treatment, side-effects, the NADA point selection and outcome parameters were properly explained. • Seemed a relatively more structured study design compared to others • The data did not show any difference between the effect of experimental and control treatment

No.	Authors (year)	Sample (n)	Experimental treatment	Control treatment	NADA points	Main outcome measures	AA side-effect(s)	Main results (Positive / Negative)	Comments
4	Bullock et al. [29] (1999)	236 patients	• 1st arm – Conventional Multicomponent Residential Treatment (CMRT) • 2nd arm - CMRT + NADA points • 3rd arm - CMRT +control treatment - 28 AA sessions for 8 weeks (45 minutes per session) - Note: CMRT– behavioural therapy and education counselling were provided)	• *Sham* AA (any 3 non-specific points)	Any 3 NADA points	• Random urine toxicology - weekly • Addiction Severity Index (ASI) • Beck Depression Inventory (BDI) • Medical Outcome Study (SF-36) • Craving measure -weekly	• NA	• Significant differences between treatments failed to be identified • Overall conclusion: negative	• Did not mention which 3 NADA points were selected • No elaboration on *Sham point* • No side- effect was mentioned • Less number of NADA points used - could be insufficient to produce better results • Experimental treatment was quite complicated and high commitments from the patients were needed
5	Lipton et al. [30] (1994)	150 patients	• 6 AA sessions weekly for 4 weeks (45 minutes per session, up to 2 AA sessions per day	• Non-specific control (*Knee, Sciatic, Elbow & Shoulder*)	• *Symphathetic* • *Lung* • *Liver* • *Shen men*	• Daily urine toxicology • Addiction Severity Index (ASI) • Craving measure	• NA	• Lower cocaine metabolite levels in experimental subjects relative to control treatment • Significant decrease in cocaine consumption by both treatment groups • Overall conclusion: positive	• Incentive was provided • 4 points instead of 5 points were used • No mention of side-effect(s)
6	Margolin et al. [31] (2002a)	165 patients (on MMT)	• 5 AA sessions weekly for 8 weeks (40 minutes per session)	• *Sham points* (inserted into the helix of the auricles bilaterally) • Relaxation (3 different video shows)	• *Symphathetic* • *Lung* • *Liver* • *Shen men*	• 3 times weekly urine toxicology • Addiction Severity Index (ASI) • Treatment Credibility Scale (TCS) • SOCRATES-8D	• Pain • *De Qi*	• Positive effect for AA in group 1 (received either experimental or control treatment including individual counselling, coping skill therapy and no incentive were provided) • No significant effect in group 2 (received treatment similar with group 1 but relaxation treatment and incentive were provided) • Overall conclusion: positive	• No elaboration of side-effect(s) • 4 points instead of 5 points were used

No.	Authors (year)	Sample (n)	Experimental treatment	Control treatment	NADA points	Main outcome measures	AA side-effect(s)	Main results (Positive / Negative)	Comments
7	Margolin et al. [32] (2002b)	620 patients (on MMT)	• 5 AA sessions weekly for 8 weeks (40 minutes per session)	• *Sham points* (inserted into the helix of the auricles bilaterally) • Relaxation (video shows & soft music) • Adjunct weekly individual drug counselling	• *Symphathetic* • *Lung* • *Liver* • *Shen men*	• 3 times weekly urine toxicology • Addiction Severity Index (ASI) • Treatment Credibility Scale (TCS) • SOCRATES-8D • Self-reported cocaine use - weekly • The Treatment Services Review (TSR)-weekly	• Pain • *De Qi*	• Significant overall reduction in cocaine use for both treatments (odds ratio = 1.40, 95% CI = 1.11 - 1.74, p = 0.01) • No significant difference in treatment condition for experimental vs control treatment • No difference between both experimental and control treatment in terms of retention rate • Overall conclusion: negative	• 4 points instead of 5 points were used • Incentive was provided • Utilisation of many outcome measures could be burdening to the patients, hence hindering the effectiveness of AA
8	Washburn et al. [33] (1993)	100 patients	• Daily AA session for 3 weeks (20-45 minutes)	• *Sham points*	• *Symphathetic* • *Lung* • *Liver* *Shen men*	• Weekly urine toxicology • Withdrawal symptoms checklist • Self-reported drug use (daily)	• Slight bleeding at needle insertion site • Mild nausea • Dizziness	• Experimental patients were retained longer than those on control treatment • Experimental treatment was more effective for those with lighter addiction habits • Overall conclusion: positive	• *Sham point* selection was not specified • The duration of AA session was not standardised • Urine test was not included in methodology but was presented in the results • Incentive was given • 4 points instead of 5 points were used

Note: AA = auricular acupuncture; MMT = Methadone Maintenance Treatment; NADA= National Acupuncture Detoxification Association; NA = not available; RCT = randomised controlled trial; vs = versus.

Outcome measures

The urine toxicology test to ascertain for abstinence from illicit drug use was implemented by all studies. A total of five studies utilised the ASI questionnaires to assess the frequency of drug use as well as other psychosocial areas [26,29,30-32]. Four trials have used the TCS which assessed confidence level with the treatment received and the SOCRATES-8D questionnaire was employed by three studies to evaluate readiness for behavioural change in drug use [26,28,31,32]. Based on the overall outcome measures, the other instruments used included BDI (assessing anxiety and depression symptoms), craving measures, TSR (to monitor treatment services received), SCL-90 (to measure psychiatric status), ATAS (physical and psychological well-being assessment), MCS (to evaluate the multi-dimensional nature of drug craving), SOWS (measuring severity of opiate withdrawal), simple drug use questionnaire, Medical Outcome Study SF-36 (assessing respondent's general health) and cocaine craving questionnaire.

Based on the urine toxicology outcomes, instead of the expected significant reduction in drug use, many researchers frequently discovered that there was no significant difference between experimental and control treatments. Similar findings were shown for the frequency of drug use and the patients' readiness to change their addictive behaviours. However, patients' confidence level towards acupuncture increased over time for participants in the experimental group but decreased instead in the control group [28]. An evaluation of psychiatric condition was only carried out in two studies by utilizing the BDI and SCL-90 [28,29]. Despite this, researchers were unable to detect any significant difference between experimental and control respondents in terms of amelioration of psychiatric symptoms. Three RCTs utilised instruments related to drug withdrawal and craving measures but did not indicate any significant difference between groups [27,30,33]. Only one trial assessed the respondent's general well-being by using the SF-36 questionnaire, demonstrating a trend of improvement in most domains [29].

Overall findings

According to the assessment of the overall results, of the eight RCTs reviewed, four reported positive outcomes while another four trials were negative in their findings (i.e. studies which failed to produce significant outcomes). Most studies utilised four rather than five needle points as suggested by NADA as well as a mixed range of treatment duration, unstandardised needling time and various selection of control treatment. All included trials were carried out in developed countries.

Discussion

This paper intends to provide a review of published RCTs of AA over the past 20 years mostly with regard to cocaine and opioid addiction. Trend of reviews, suggestions for future research directions as well as limitations of this study have been importantly highlighted.

Overall, the published AA trials were designed with a variety of duration of treatment courses which might have produced different results, thus contributing bias towards the final study outcomes. In addition, most studies did not perform any long-term observation to evaluate the over-time effects of AA on drug dependence. Ezzo and colleagues discovered that sufficient treatment sessions were significantly associated with treatment outcome whereby six or more treatment sessions were more effective than fewer sessions, thus strengthening the argument on the importance of targeting for longer study duration [34]. Consequently, it was rather difficult to draw concrete conclusions regarding the treatment effectiveness based on their length of treatment course even though more than half of the trials with at least five sessions showed positive outcomes in terms of drug urine test, drug consumption, side-effect(s) and withdrawal symptoms.

The selection of treatment points was another most important aspect of AA research especially when such research is still in its infancy. There was some variability in terms of the number of needle points utilised in these RCTs which would have been better if they were consistent [35]. In addition, the absence of detailed information on the needle points selected in two studies have somehow hindered more appropriate conclusion on our part.

With regard to the control treatment, some researchers used non-specific points without explaining which points were their main targets. If *sham points* had active (positive) effects, the comparison of outcomes between the treatment and *sham* groups would not show the true impact of AA treatment and the conclusion that this treatment had no significant effect could be seriously wrong because the *sham points* were inappropriate. However, a few studies preferred to use the helix points as

control treatment. This was encouraging because most results had shown that needle insertion into the helix sites had the lowest systemic effect and most appropriate for this purpose [35]. In addition, the usage of oil and metal clips on the ears as the control treatment in one study might have introduced bias towards the study findings which could be recognised by the patients due to its non-needle application compared to other studies [28].

With respect to needling time, most included studies have adhered to the standard NADA protocol whereby in the normal sessions, the needles were required to be left in for 30 to 45 minutes except for a single trial which was carried out by Washburn and colleagues [33]. In this latter trial, once needles were inserted, they were only left for 20 minutes at a minimum (no reason was given) until the maximum duration of 45 minutes.

Throughout all the clinical trials reviewed, insufficient and unavailable data has prevented further complete analysis on the side-effects of AA. The subjective sensation or feeling called *De Qi* reported by patients that included heaviness, soreness, numbness and sense of swelling was supposedly associated with beneficial effects [36]. This was likely the result of the rhythmic contraction of muscle fibers surrounding the AA needle [8]. However, no further information could be found with regard to other serious form of side-effects. Thus, the adverse outcomes of this traditional treatment modality could not be ascertained at this point although it was generally noted that the rate of side-effects with the AA treatment was encouragingly low. This was supported by a previous study which claimed that no side-effect of AA was noted throughout all the clinical trials reviewed by D'Alberto [20].

Urine screens were the most valid method for determining the effectiveness of illicit drug detoxification [36]. This biochemical validation gave the most reliable indication of the drug used. However, it seemed to somehow "burden" most patients in terms of its need for regular urine sampling, leading to reduced follow-up rates. Only a small handful of studies have provided incentives to overcome the problem of high attrition rates which imposed logistic difficulties on subsequent analysis. Financial payments are often used in large clinical trials to ensure a sufficient enrolment of participants. Although the amount of money was not a particularly large sum, this financial

incentive might have motivated the participants to support their addictive lifestyle than to generate a sincere desire to abstain from drugs [36].

Long-term drug free period was probably the most important outcome because treatments would not be regarded as very useful if they merely reduced patients' drug use during the active treatment period. Hence, a follow-up time frame of at least several months was therefore crucial to the assessment of AA's effectiveness whereas the longest follow-up period was only eight weeks from most trials we have gathered [37]. Therefore, the positive effects of AA could not have been adequately experienced by patients probably due to the short treatment duration. As we have gathered from the literature, AA's effects are usually highly dependent on the severity of the disease and the vitality of individuals. Therefore, the number of treatments needed would vary between persons and longer term therapy was required to truly experience its positive effects [38].

Overall, a lack of consistent instruments utilised in AA trials was also obvious. Besides, there has been relatively little focus on the psychiatric symptoms of anxiety and depression in the outcome measures employed. Based on our observation, most of the studies were mainly focusing on objective evaluation rather than subjective assessment such as readiness to behavioural change and health-related quality of life (HRQoL). In recent years, a paradigm shift from disease-focused to patient-focused has taken place in many healthcare systems

designed to meet the needs and wishes of the patients [21]. Therefore, patients' own evaluation of their well-being should be encouraged in AA trials because it has been universally accepted to be as important as other parameters in medical care. Furthermore, the influence of addiction itself on HRQoL has been widely established [39]. In addition, HRQoL instruments specific for drug addiction are evidently still lacking. Other subjective evaluations could also be considered such as extensive assessments of psychiatric status and satisfaction level. In general, high confidence and satisfaction levels seemed to be influential on the treatment received and might be indicative of condition improvement [40,41].

Suggestions and future research directions

The efficacy of AA as a drug treatment has been subjected to conflicting findings in clinical trials. Some findings have been promising but others showed no difference between standard NADA treatment and *sham* AA. Furthermore, trials in AA possessed numerous methodological challenges, for example issues in selecting a suitable control, depth, angle and site of needle insertion need to be appropriately addressed. A more comprehensive data on side-effects of AA should be beneficial from the trial findings, so that any related problems could be dealt with effectively.

As addiction problem must be addressed for the entire country, future studies should be more focused on samples in other parts of the world such as in developing and Asian countries, apart from the first world countries to account for socio-cultural diversity in AA trials. It hence seems beneficial to organize frequent joint dialogues between medical healthcare personnel and the acupuncture practitioners to discuss and resolve many intriguing questions which are still plaguing this research area. Hopefully, the therapeutic value of AA can be defined more thoroughly for its mechanism of action to be completely understood.

Limitations

The overall information presented here was of course not without flaws. Even though a thorough search strategy was utilised, we could not be certain that all relevant trials have been included because many acupuncture trials have been reported in languages other than English, particularly in Chinese, Japanese and Korean which were not identified and analysed. Moreover, the major databases used for literature search such as Science Direct, Medline and EBSCOhost contain predominantly English language articles, hence articles in other languages might have been overlooked. As majority of the trials have been conducted in USA, this review may not be generalisable to studies in other regions. Therefore, additional investigations should be embarked upon among diverse samples of participants with more comprehensive coverage.

Conclusion

From the still limited evidence gathered, the overall effectiveness of AA in treating drug addiction remains inconclusive. Nonetheless, this therapy seemed to hold some potential as alternative or additional component of substance abuse management because of its lack of adverse effects, simple administration and general acceptability to patients. Considering these possibilities, more rigorous and extensive studies are warranted which should target larger sample sizes to detect tangible and beneficial treatment effects with longer duration of treatment course, minimal rate of attrition, documentation of side-effects as well as appropriate needle-points as recommended by the NADA protocol. We hence could not provide a concrete conclusion at this point due to the inextensive evidence from small number of available RCTs. Perhaps future studies should also look into developing novel HRQoL instruments which could play a crucial role in assessing HRQoL specific and unique to this cohort because of the different HRQoL concerns affecting addict individuals.

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