

Acupuncture for vascular dementia (Review)

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Acupuncture for vascular dementia (Review)

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[Intervention Review]

Acupuncture for vascular dementia

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ABSTRACT

Background

Dementia is a widespread condition characterized by acquired global impairment of intellect, memory and personality, but with no impairment of consciousness. There is no definitive medical or surgical treatment for vascular dementia. Acupuncture is an ancient Chinese method which has been used for both the prevention and treatment of diseases for over three thousand years. Preliminary searches revealed more than 105 studies of acupuncture for treating vascular dementia. Benefit was reported in up to 70 to 91% of the treatment group. Body acupuncture and electroacupuncture were the most commonly used techniques. A comparison of electroacupuncture and acupuncture therapy alone suggested that the former was more effective in promoting the recovery of cognitive function.

Objectives

The objective is to assess the efficacy and possible adverse effects of acupuncture therapy for treating vascular dementia.

Search strategy

The trials were identified from a search of the Cochrane Dementia and Cognitive Improvement group's Specialized Register on 2 February 2007 which contains records from all major health care databases and many ongoing trials databases. In addition the Allied and Complementary Medicine Database was searched and the web was searched using the search engine Copernic.

Selection criteria

Randomized controlled trials testing acupuncture therapy in the treatment of vascular dementia were included regardless of language and publication types.

The intervention and control group had to receive identical treatment apart from the acupuncture intervention. In view of possible confounding, studies in which acupuncture was combined with other treatments were subjected to subgroup analyses.

Data collection and analysis

Titles and abstracts identified from the searches were checked by two reviewers. If it was clear that the study did not refer to a randomized controlled trial in vascular dementia, it was excluded. If it was not clear from the abstract and title, then the full text of study was obtained for an independent assessment by two reviewers.

The outcomes measured in clinical trials of dementia and cognitive impairment often arise from ordinal rating scales. Summary statistics were required for each rating scale at each assessment time for each treatment group in each trial for change from baseline.

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Main results

In the absence of any suitable randomized placebo-controlled trials in this area, we were unable to perform a meta-analysis.

Authors' conclusions

The effectiveness of acupuncture for vascular dementia is uncertain. More evidence is required to show that vascular dementia can be treated effectively by acupuncture. There are no RCTs and high quality trials are few. Randomized double-blind placebo controlled trials are urgently needed.

PLAIN LANGUAGE SUMMARY

There is no evidence from randomized controlled trials to determine whether acupuncture provides any effect when treating people with vascular dementia

Acupuncture is used to treat vascular dementia, but because no randomized controlled trials of acupuncture versus placebo were found, its efficacy and safety could not be analysed in this review. There is a need for randomized placebo controlled trials of acupuncture for people with vascular dementia.

BACKGROUND

Dementia is a widespread condition characterized by acquired global impairment of intellect, memory and personality, but not impairment of consciousness. The prevalence of moderate and severe dementia is approximately 5% in people aged 65 years and over (Jorm 1987; Williams 2003). Vascular dementia is defined as loss of cognitive function resulting from ischaemic, hypoperfusive, or hemorrhagic brain lesions due to cerebrovascular disease or cardiovascular pathology (Roman 2003). The frequency varies depending on the study population, screening methodology, diagnostic criteria, and time period (Gorelick 1994). In the United States and Europe it is generally believed that vascular dementia is the second leading cause (10-20% of cases) (Udea 1992) of progressive and irreversible dementia while Alzheimer's disease is the leading cause (50-60% of cases). However, in many Asian and developing countries, researchers have found the opposite (Tian 1997). In China, vascular dementia accounts for more than 68% of the total number of people aged over 65 with dementia (Huang 1998). According to some studies, vascular dementia shortens life expectancy by approximately 50% in men, in people with lower education, and in people with relatively poor performance in neuropsychological testing. The causes of death are complications of dementia, cardiovascular disease, and miscellaneous causes, including malignancy (Roman 2003).

The average duration of vascular dementia is five years, its survival

rate being much lower than those of patients with Alzheimer's disease. (Hebert 1995). The risk of vascular dementia has been examined with respect to age, male sex, race/ethnicity (Gorelick 1997), education level (Gorelick 1993; Tatemichi 1992), genetic factors (Bousser 1994; Slooter 1997), atherogenic risk factors (Desmond 1993; Gorelick 1997; Skoog 1998; Yoshitake 1995), stroke-related factors (Charletta 1995; Tatemichi 1993), periventricular white matter lesions (Gorelick 1997; Pantoni 1997), silent cerebral infarcts (Gorelick 1997; Meyer 1994), heart rhythm abnormalities (Skoog 1998), and other factors (Lindsay 1997; Skoog 1998). Among these factors age, hypertension, genetic factors, and stroke-related characteristics are the only well documented risk factor for vascular dementia at present (Gorelick 1997).

A set of eight vascular dementia subgroups has been established by Loeb and Meyer (Loeb 1996):

- (1) multi-infarct dementias;
- (2) strategically placed infarctions causing dementia;
- (3) multiple subcortical lacunar lesions;
- (4) Binswanger's disease;
- (5) mixtures of two or more of above vascular dementia subtypes;
- (6) haemorrhagic lesions causing dementia;

(7) subcortical dementias due to cerebral autosomally dominant arteriopathy with subcortical infarcts and leuko-encephalopathy (CADASIL);

(8) mixtures of Alzheimer's disease and vascular dementia.

The neuropathologic substrate of vascular dementia in relation to subcortical white matter changes, either focal infarcts or widespread diffuse changes, has been emphasized (Erkinjuntii 1996). It is believed that these lesions may be an important cause of vascular dementia (Nyenhuis 1998).

Neuropsychological research on vascular dementia has attempted to define the pattern of cognitive impairments and to compare it with the patterns of other dementia syndromes (Bentham 1997; Bogdanoff 1997; Starkstein 1996; Villardita 1993). However, much of this work has been difficult to replicate (Gfeller 1991; Metter 1993). Neuropathologic findings show that patients with vascular dementia demonstrate more psychiatric impairment, which differs in different ethnic groups (Sultzer 1993), including more behavioural retardation, depression, and anxiety.

Treatment

So far there is no definitive medical or surgical treatment for vascular dementia. Most of the current approaches to treatment focus on the mobilization of remaining cognitive and functional capacities as well as the possible prevention of further disease progression. The aim of therapy is to optimize patients' autonomy, activities of daily living and quality of life. The prevention of stroke is also an important aim to prevent further morbidity and mortality in patients with vascular dementia (Gorelick 1994).

In the field of medication, aspirin is widely prescribed for patients with vascular dementia (Dennis 1998). Frampton pointed out that there is limited evidence that propentofylline might benefit cognition, global function and activities of daily living of people with Alzheimer's disease and/or vascular dementia (Frampton 2003).

Furthermore, the haemorheological agent Pentoxifylline (Sha 2003), a vasoactive agent that reduces the cellular influx of calcium, Nimodipine (Lopez 2003; Pantoni 1996), Naloxone (Shi-Lei 2002), and Pyrimidine nucleosides (Fornai 2002), are also being developed for use in vascular dementia. Some Chinese herbal medicines such as, for instance, Xianlong Capsule and Yizhi Granule are widely used for treating vascular dementia in China (Du 1998; Li 2001b; Luo 2001; Taixiang 2005; Zhang 2002).

Acupuncture for vascular dementia

Acupuncture is an ancient Chinese method which has been used for both the prevention and treatment of diseases for over 3000 years (Ulett 1998). It is becoming increasingly popular in high-income countries as a therapy for a wide variety of disorders, most of

which are chronic and difficult to manage with conventional treatment (Helene 2001). At the same time, its mechanism of action remains uncertain (Lo 2003). In Traditional Chinese Medicine, the general principles of acupuncture treatment include regulating the Yin and Yang, strengthening body resistance and eliminating pathogenic factors, and distinguishing the primary physical and pathological factors from the secondary ones (Lu 2000). In recent years many reports have shown that acupuncture has remarkable effects on the pituitary gland and adrenal cortex system, the sympathetic nervous and adrenal medulla system, the pituitary gland and thyroid gland system, and the posterior pituitary system (Lu 2000). This winding of connective tissue may allow needle movements to deliver a mechanical signal into the tissue and may be key to the therapeutic mechanism of acupuncture (Langevin 2002).

Many kinds of acupuncture methods such as body acupuncture, scalp acupuncture, electroacupuncture, and laser acupuncture are in use for the treatment of vascular dementia in hospitals in China. Body acupuncture is a generalised term for acupuncture and is in common use with reference to acupuncture therapy. It means treating disease by applying acupuncture to points along the channels of the human body. Scalp acupuncture is a therapeutic method for treating diseases associated with the nerve system by using acupuncture needles along the surface of the head. Electroacupuncture is a therapeutic method combining acupuncture with electrical stimulation. Acupuncture therapy combined with medication is also used. A preliminary search has revealed more than 105 studies of acupuncture for treating vascular dementia. Benefit was reported in up to 70-91% of the treatment group (Gao 2001; Lai 1997; Li 1997). Body acupuncture and electroacupuncture were the most commonly used techniques. A comparison of electroacupuncture and acupuncture therapy alone suggested that the former was more effective in promoting the recovery of cognitive function (Lai 1998).

However, the effectiveness and side-effects of acupuncture for vascular dementia have not been systematically reviewed.

OBJECTIVES

To assess the efficacy and possible adverse effects of acupuncture therapy for treating vascular dementia.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials testing acupuncture therapy in the treatment of vascular dementia were eligible for inclusion, regardless of language and publication type. The intervention and control group had to receive identical treatment apart from the acupuncture intervention. In view of possible confounding, subgroup analyses will be used for different types of acupuncture, such as 'body acupuncture', 'scalp acupuncture', 'electroacupuncture', and 'laser acupuncture'.

Types of participants

Participants of any age or sex or ethnicity, with a diagnosis of vascular dementia according to accepted criteria, were eligible for inclusion. Diagnosis by other means such as scores on the HIS could be used in older trials. Participants living in their own homes or in residential care settings, and accessed through hospital inpatient or outpatient departments, were eligible to be included.

Types of interventions

Research comparing any type of acupuncture therapy with placebo or no intervention was considered. Acupuncture therapy could mean body acupuncture, scalp acupuncture, electroacupuncture, or laser acupuncture. Acupuncture therapy combined with medication was also included.

If sham (placebo) acupuncture were used, this would be defined as the needling of non-acupuncture points without needle manipulation, done either proximally and/or distally to the true acupuncture.

Types of outcome measures

1. Cognitive function
2. Activities of daily living
3. Behaviour
4. Global function
5. Institutionalization
6. Quality of life
7. Mood
8. Safety as measured by incidence and severity of adverse effects

Search methods for identification of studies

Trials were identified from searches of the following resources:

1. The Specialized Register of the Cochrane Dementia and Cognitive Improvement Group on 2 February 2007 using the term *acupunct**.

The Cochrane Dementia and Cognitive Improvement Group Specialised Register consists of records from the following databases:

Healthcare databases

- CENTRAL: (The Cochrane Library 2006, Issue 1);
- MEDLINE (1966 to 2006/07, week 5);
- EMBASE (1980 to 2006/07);
- PsycINFO (1887 to 2006/08, week 1);
- CINAHL (1982 to 2006/06);
- SIGLE (Grey Literature in Europe) (1980 to 2005/03);
- LILACS: Latin American and Caribbean Health Science Literature (<http://bases.bireme.br/cgi-bin/wxislind.exe/iah/online/?IsisScript=iah/iah.xis&base=LILACS&lang=i&form=F>) (last searched 29 August 2006);

Conference proceedings

- ISTP (<http://portal.isiknowledge.com/portal.cgi>) (Index to Scientific and Technical Proceedings) (to 29 August 2006);
- INSIDE (BL database of Conference Proceedings and Journals) (to June 2000);

Theses

- Index to Theses (formerly ASLIB) (<http://www.theses.com/>) (UK and Ireland theses) (1716 to 11 August 2006);
- Australian Digital Theses Program (<http://adt.caul.edu.au/>) (last update 24 March 2006);
- Canadian Theses and Dissertations (<http://www.collectionscanada.ca/thesescanada/index-e.html>): 1989 to 28 August 2006);
- DATAD - Database of African Theses and Dissertations (<http://www.aau.org/datad/backgrd.htm>);
- Dissertation Abstract Online (USA) (<http://www.lib.umi.com/dissertations/gateway>) (1861 to 28 August 2006);

Ongoing trials

UK

- National Research Register (<http://www.update-software.com/projects/nrr/>) (last searched issue 3/2006);
- ReFeR (<http://www.refer.nhs.uk/ViewWebPage.asp?Page=Home>) (last searched 30 August 2006);
- Current Controlled trials: Meta Register of Controlled trials (mRCT) (<http://www.controlled-trials.com/>) (last searched 30 August 2006) :
- ISRCTN Register - trials registered with a unique identifier
- Action medical research
- Kings College London
- Laxdale Ltd

- Medical Research Council (UK)
- NHS Trusts Clinical Trials Register
- National Health Service Research and Development Health Technology Assessment Programme (HTA)
 - National Health Service Research and Development Programme 'Time-Limited' National Programmes
 - National Health Service Research and Development Regional Programmes
 - The Wellcome Trust
 - Stroke Trials Registry (<http://www.strokecenter.org/trials/index.aspx>) (last searched 31 August 2006);

Netherlands

- Netherlands Trial Register (<http://www.trialregister.nl/trialreg/index.asp>) (last searched 31 August 2006);

USA/International

- ClinicalTrials.gov (<http://www.ClinicalTrials.gov>) (last searched 31 August 2006) (contains all records from <http://clinicalstudies.info.nih.gov/>);
 - IPFMA Clinical trials Register: www.ifpma.org/clinicaltrials.html. The Ongoing Trials database within this Register searches <http://www.controlled-trials.com/isrctn>, <http://www.ClinicalTrials.gov> and <http://www.centerwatch.com/>. The ISRCTN register and Clinicaltrials.gov are searched separately. Centerwatch is very difficult to search for our purposes and no update searches have been done since 2003.
 - The IFPMA Trial Results databases searches a wide variety of sources among which are:
 - <http://www.astrazenecaclinicaltrials.com> (seroquel, statins)
 - <http://www.centerwatch.com>
 - <http://www.clinicalstudyresults.org>
 - <http://clinicaltrials.gov>
 - <http://www.controlled-trials.com>
 - <http://ctr.gsk.co.uk>
 - <http://www.lillytrials.com> (zyprexa)
 - <http://www.roche-trials.com> (anti-abeta antibody)
 - <http://www.organon.com>
 - <http://www.novartisclinicaltrials.com> (rivastigmine)
 - <http://www.bayerhealthcare.com>
 - <http://trials.boehringer-ingenelheim.com>
 - <http://www.cmrinteract.com>
 - <http://www.esteve.es>
 - <http://www.clinicaltrials.jp>

This part of the IPFMA database is searched and was last updated on 4 September 2006;

- Lundbeck Clinical Trial Registry (<http://www.lundbecktrials.com>) (last searched 15 August 2006);

- Forest Clinical trial Registry (<http://www.forestclinicaltrials.com/>) (last searched 15 August 2006).

The search strategies used to identify relevant records in MEDLINE, EMBASE, PsycINFO, CINAHL and LILACS can be found in the Group's module.

2. AMED (Allied and Complementary Medicine Database) 1985-2005/07, using the term: *acupunct* And dement**.
3. Copernic, the super search engine, using the terms: *acupuncture dementia*.
4. HANDSEARCHES

The following journals published in Chinese were searched: Chinese Acupuncture and moxibustion (1981-2003), Journal of Clinical Acupuncture and Moxibustion (1985-2003), Journal of Traditional Chinese Medicine (1960-2003), New Journal of Traditional Chinese Medicine (1969-2003), Shanghai Journal of Acupuncture and Moxibustion (1982-2003), Research of Acupuncture and Moxibustion (1976-2003) from the first publication date onwards to 2003. Conference proceedings relevant to this topic in Chinese were also hand searched.

5. REFERENCES FROM PUBLISHED STUDIES

These were checked for further trials.

6. UNPUBLISHED LITERATURE

Unpublished and on-going trials were identified by correspondence with authors and from Internet searches.

7. CONFERENCE PROCEEDINGS

Major acupuncture conference proceedings and poster abstracts over the last 5 years were hand searched for further RCTs.

Data collection and analysis

STUDY SELECTION

Titles and abstracts identified from the searches were checked by two reviewers (WP and HZ). If it was clear that the study did not refer to a randomised controlled trial in vascular dementia, it was excluded. If it was not clear from the abstract and title, then the full text of study was obtained for an independent assessment by two reviewers (WP and HZ). The reviewers decided whether trials fitted the inclusion criteria. Any disagreement was resolved by discussion between the reviewers, with referral to a third reviewer (ZL) if necessary. Excluded studies were listed and reasons for exclusion were stated.

ASSESSMENT OF METHODOLOGICAL QUALITY

The following three areas were to be addressed, since there is some evidence that these are associated with biased estimates of treatment effect (Juni 2001):

- a) randomisation (method of generation and concealment of allocation)

b) masking (blinding of observers / participants to the treatment allocation)

c) loss to follow-up (presence of dropouts and withdrawals, and the analysis of these).

The quality assessment was to include an evaluation of the following components for each included study. Each component was categorised as Adequate, Unclear, or Inadequate. The randomisation criteria were as suggested by [Juni 2001](#).

- Randomisation (allocation generation) - adequate when the allocation sequence protects against biased allocation to the comparison groups
- Randomisation (allocation concealment) - adequate when clinicians and participants are unaware of future allocations
- Masking - adequate when the outcome assessor is unaware of the allocation
- Loss to follow up - adequate when more than 80% of participants are followed up, then analysed in the groups to which they were originally randomised (intention to treat)

In addition, assessment was to be made of the following:

- degree of certainty that participants have vascular dementia
- baseline comparison for severity of disease
- amount of acupuncture used during study period

A description of the quality of each study was given based on a summary of these components.

DATA EXTRACTION

This was to be performed by two reviewers (WP and HZ), who independently entered data onto a data extraction form. Discrepancies were to be resolved by a third reviewer (ZL). Missing data were to be obtained from authors when possible. Data were to be checked and entered into RevMan by two reviewers (WP and SW).

Data were to be extracted from the published reports. The summary statistics required for each trial and each outcome for continuous data were the mean change from baseline, the standard error of the mean change, and the number of patients for each treatment group at each assessment. Where changes from baseline were not reported, the mean, standard deviation and the number of patients for each treatment group at each time point were to be extracted if available.

For binary data the numbers in each treatment group and the numbers experiencing the outcome of interest were to be sought. The baseline assessment is defined as the latest available assessment prior to randomisation, but no longer than two months prior.

For each outcome measure, data were to be sought on every patient randomised. To allow an intention-to-treat analysis, the data were to be sought irrespective of compliance, whether or not the patient was subsequently deemed ineligible, or otherwise excluded from treatment or follow-up. If intention-to-treat data were not

available in the publications, “on-treatment” or the data of those who complete the trial were to be sought and indicated as such.

In studies where a cross-over design was used, only data from the first treatment phase after randomisation were eligible for inclusion.

ANALYSIS

The outcomes measured in clinical trials of dementia and cognitive impairment often arise from ordinal rating scales. Where the rating scales used in the trials had a reasonably large number of categories (more than 10) the intention was that data would be treated as continuous outcomes arising from a normal distribution.

Summary statistics (n, mean and standard deviation) would be required for each rating scale at each assessment time for each treatment group in each trial for change from baseline. For crossover trials only the data from the first treatment period would be used. When change from baseline results were not reported, the required summary statistics were to be calculated from the baseline and assessment time treatment group means and standard deviations. In this case a zero correlation between the measurements at baseline and assessment time was to be assumed. This method overestimates the standard deviation of the change from baseline, but this conservative approach is considered to be preferable in a meta-analysis.

Meta-analysis requires the combination of data from trials that may not use the same rating scale to assess an outcome. The measure of the treatment difference for any outcome would be the weighted mean difference when the pooled trials use the same rating scale or test, and the standardised mean difference, which is the absolute mean difference divided by the standard deviation when they used different rating scales or tests.

Duration of trials may vary considerably. If the range was considered too great to combine all trials into one meta-analysis, trials with similar durations would be grouped together and a separate meta-analysis would be conducted for each duration of treatment. Some trials might contribute data to more than one time period if multiple assessments were done. Data that had been recorded after treatment of less than 2 weeks would be considered as reflecting short-term benefit. This would be analysed separately from data that had been recorded for over a period of one month, which reflects a reasonable minimal time period to capture some aspect of disease chronicity.

For binary outcomes, such as clinical improvement or no clinical improvement, the odds ratio was to be used to measure treatment effect. A weighted estimate of the typical treatment effect across trials was to be calculated.

Overall estimates of the treatment difference were to be presented. In all cases the overall estimate from a fixed effects model would be presented and a test for heterogeneity using an I^2 statistic would be performed. If, however, there were evidence of heterogeneity of the treatment effect between trials then either only homogeneous

results would be pooled, or a random-effects model would be used (in which case the confidence intervals would be broader than those of a fixed-effects model).

The patient rated global assessment would be the primary outcome measure if available. If this were not available, the medical practitioner global rating would be used. Both measures would be taken into account where both were available.

Subgroup analysis would be performed where adequate information was given. The subgroups would be 'body acupuncture', 'scalp acupuncture', 'electroacupuncture', and 'laser acupuncture'. Reasons for heterogeneity in studies would be explored and, if necessary, sensitivity analyses would examine the effects of excluding study subgroups, e.g. those studies with lower methodological quality.

Non-randomised controlled studies were to be listed but not discussed further. Studies relating to adverse effects were to be described qualitatively.

Potential biases would be investigated using the funnel plot or other analytical methods according to [Egger 1997](#).

RESULTS

Description of studies

See: [Characteristics of excluded studies](#).

Results of the search

CDCIG searches found 19 references and the authors by electronic and hand searches retrieved 76 references, making a total of 95 references. All of the studies except one were published in Chinese. Authors of all these studies were contacted for information about trial design and procedure except one ([Zhai 2001](#)).

Included studies

None of the trials met the requirements for inclusion in this review.

Excluded studies

Only 17 studies out of 95 were RCTs. Sixteen of them were excluded upon further scrutiny and one is awaiting assessment.

The reasons for exclusion were as follows:

1) The control group of six studies received some type of Western medicine including Aniracetam Capsules ([Lai 1997](#)), Nimodipine ([Chen 2000](#)), Dihydroergotamine and DHET ([Li 2001a](#)), Hydergine ([Jiang 1998](#); [Zhao 2000](#)), Low Molecular Dextran and Composite Salvia injection ([Liu 2004](#));

2) Four studies were inadequately randomized including random by entry sequence ([Gao 2001](#); [Lai 1998](#); [Liu 1997](#)) and sortition or the drawing of lots ([Lun 2003](#));

3) Six studies could not evaluate the effect of acupuncture, because they used acupuncture with other therapy including acupoint-injection ([Chen 1992](#); [Gong 2003](#); [Li 2002](#)), herbal drugs and oxygen ([Geng 1999](#); [Hou 1998](#)), acupuncture and moxibustion ([Li 1999](#)).

Risk of bias in included studies

We did not identify any suitable trials for inclusion.

Effects of interventions

In the absence of any suitable randomized placebo-controlled trials in this area, we were unable to perform a meta-analysis.

DISCUSSION

Methodological limitations of trials

1. Four of the studies mentioned randomization, but none of them described the randomization procedure and allocation concealment in detail. Authors were asked to describe their methods of randomization and allocation. E-mail and telephone correspondence with the authors revealed that four studies had inadequate methods of randomization. Three ([Gao 2001](#); [Lai 1998](#); [Liu 1997](#)) of them adopted entry sequence, so they are pseudo-random allocation. One ([Lun 2003](#)) of them drew lots but allocation concealment was inadequate because random numbers were not put into the envelope, nor was the envelope opaque. None of studies mentioned blinding in the articles themselves though by calling authors we discovered that all four had adopted data analysis blinded ([Gao 2001](#); [Lai 1998](#); [Liu 1997](#); [Lun 2003](#)).

2. Six studies used drugs of uncertain efficacy as a control. Two studies ([Jiang 1998](#); [Zhao 2000](#)) used Hydergine and other four studies respectively used Nimodipine ([Chen 2000](#)), Low Molecular Dextran and Composite Salvia injection ([Liu 2004](#)), Aniracetam Capsules ([Lai 1997](#)), and Dihydroergotamine (DHET) ([Li 2001a](#)) as control. A Cochrane review considered that Hydergine's efficacy in dementia remains uncertain ([Olin 2000](#)) and there is no evidence of the effectiveness of the other interventions listed for dementia. Moreover the use of these interventions in the control arm makes interpretation of the efficacy of acupuncture impossible to assess. For example, it is possible that these 'control' interventions made patients worse than a placebo would, thereby accounting for an apparent treatment effect.

3. Six studies could not evaluate effect of acupuncture, because they used acupuncture with another therapy in the treatment group, including acupoint-injection (Chen 1992; Gong 2003; Li 2002), herbal drugs and oxygen (Geng 1999; Hou 1998), acupuncture and moxibustion (Li 1999). Therefore, they cannot give evidence for this review.

4. None of the studies used comprehensive sets of outcome measures. Institutionalization, Quality of life and Mood are absent. None of studies mentioned adverse events and side effects.

5. Number of participants in the studies is insufficient, the range of participants of every group in studies is from 16 to 50 patients. That cannot give powerful evidence on the effectiveness of acupuncture for vascular dementia.

Excluded studies

None of the studies were suitable to evaluate the effect of acupuncture. They give only poor evidence of the effectiveness of acupuncture for VD. In order to pool the available research literature for clinicians, information about the 16 excluded studies has been presented in Table 1.

Table 1. Excluded studies: further trial information

Study name	Participants/Methods	Interventions	Outcomes	Reported results
Chen 1992	Full text is unavailable	Acupuncture plus acupoint injection as a treatment therapy	No information	No information
Chen 2000	46 participants with VD were randomly allocated by a computer	Electroacupuncture (N=23) versus a control group treated with nimodipine (N=23)	HDS	A reported improvement from baseline on the HDS. Change from baseline scores: treatment effect = 3.76, 95% CI 1.04 to 13.65, p=0.04
Gao 2001	63 participants with VD were pseudo-randomised using entry sequence	Acupuncture (N=31) versus a control using Piracetam	HDS, SOD, LPO	HDS (treatment effect = 3.22, 95% CI 0.17 to 6.27, p = 0.04); SOD (treatment effect = 5.01, 95% CI 2.01 to 8.01, p = 0.001); LPO (treatment effect = -0.70, 95% CI -1.5 to 0.10, p = 0.09)
Geng 1999	100 participants with VD were "simply" randomised without allocation concealment.	Acupuncture plus inhalation of herbal drugs plus oxygen (N=50) versus a control group using some	Outcome scales were created by the author but are of uncertain design.	No information

Table 1. Excluded studies: further trial information (Continued)

		form of Western medicine (N=50) which the authors were unable to identify.		
Gong 2003	60 participants with VD were “simply” randomised without allocation concealment.	Acupoint injection of Yin Yang Huo plus oral almitrine+raubasine mixture plus Chuan Xiong Qin injection (N=30) versus a control using Chuan Xiong Qin injection (N=30)	MMSE, ADL	MMSE (treatment effect =0.83 95% CI -1.11 to 2.77, p = 0.40); ADL (treatment effect = -3.21, 95% CI -6.31 to -0.11, p = 0.04)
Hou 1998	150 participants with VD were “simply” randomised without allocation concealment.	Acupuncture plus inhalation of herbal drugs and oxygen (N=50) versus acupuncture plus inhalation of oxygen (N=50) versus acupuncture (N=50)	Outcome scales were created by the author but are of uncertain design.	No information
Jiang 1998	66 participants with VD were randomly allocated by a computer	Electroacupuncture (N=33) versus a control using Hydergine (N=33)	HDS, FAQ, LPO, SOD, NO	HDS (treatment effect = 5.10, 95% CI 1.47 to 8.73, p = 0.006); FAQ (treatment effect = -2.12, 95% CI -5.11 to 0.87, p = 0.16); LPO (treatment effect = -1.19, 95% CI -2.04 to -0.34, p = 0.006); SOD (treatment effect = 9.02, 95% CI 1.20 to 16.84, p = 0.02); NO (treatment effect = -0.23, 95% CI -0.36 to -0.10, p = 0.0004)
Lai 1997	60 participants with VD were randomly allocated by a computer	Electroacupuncture (N=30) versus a control using Aniracetam (N=30)	HDS	A reported improvement from baseline on the HDS. Change from baseline scores: treatment effect = 3.76, 95% CI 1.04 to 13.65, p=0.04
Lai 1998	46 participants with VD were pseudo-randomised using entry sequence	Electroacupuncture (N=23) versus a control using acupuncture (N=23)	HDS, FAQ, SOD, LPO, NO	HDS (treatment effect = 5.82, 95% CI 1.15 to 10.49, p = 0.01); FAQ (treatment effect = -2.13, 95% CI -5.62 to 1.36, p = 0.23); SOD (treatment effect = 189.20, 95% CI 26.30 to 352.10, p = 0.02); LPO (treatment effect = -

Table 1. Excluded studies: further trial information (Continued)

				1.27, 95% CI -2.24 to -0.30, $p = 0.01$); NO (treatment effect = -0.20, 95% CI -0.36 to -0.04, $p = 0.01$)
Li 1999	32 participants with VD were randomly allocated by a computer	Acupuncture plus moxibustion (general acupuncture pressure point therapy) combined with herbal medicine (N=16) versus a control group using the same herbal medicine only (N=16)	HDS, SOD, LPO, GSH-PX	HDS (treatment effect = 1.78 95% CI -4.12 to 7.68, $p = 0.55$); SOD (treatment effect = 5.29, 95% CI 0.74 to 9.84, $p = 0.02$); LPO (treatment effect = 0.03 95% CI -0.77 to 0.83, $p = 0.94$); GSH-PX (treatment effect = 10.11 95% CI -6.69 to 26.91, $p = 0.24$)
Li 2001a	68 participants with VD were randomly allocated using block randomisation	Electroacupuncture (N=34) versus a control using Dihydroergotamine, DHET (N=34)	HDS, FAQ, ADL	HDS (treatment effect = 6.73, 95% CI 3.74 to 9.72, $p < 0.001$); FAQ (treatment effect = -0.55, 95% CI -3.18 to 2.08, $p = 0.68$); ADL (treatment effect = 5.45, 95% CI -7.00 to 17.90, $p = 0.39$)
Li 2002	90 participants with VD were randomly allocated by a computer to equal size groups	Acupoint injection of Muskiness (N=30) versus intramuscular Muskiness injection (N=30) versus intramuscular saline injection (N=30)	MMSE, ADL	MMSE (treatment effect = 0.83 95% CI -1.08 to 2.74, $p = 0.39$); ADL (treatment effect = -3.23, 95% CI -6.24 to -0.22, $p = 0.04$)
Liu 1997	100 participants with VD were pseudo-randomised using entry sequence	Acupuncture at designated acupoints (N=50) versus control using acupuncture at designated different acupoints (N=50)	HDS, FAQ	HDS (treatment effect = 2.56, 95% CI 0.13 to 4.99, $p = 0.04$); FAQ (treatment effect = -2.24, 95% CI -4.42 to 0.06, $p = 0.04$)
Liu 2004	76 participants with VD were randomly allocated using a random number table	Acupuncture (N=38) versus a control using Low Molecular Dextran (N=38)	HDS, FAQ	HDS (treatment effect = 5.26, 95% CI 3.43 to 7.09, $p < 0.00001$); FAQ (treatment effect = -7.05, 95% CI -10.55 to -3.55, $p < 0.0001$)
Lun 2003	89 participants with VD were randomised using the drawing of lots but allocation concealment was not	Scalp acupuncture using electricity plus a Chinese herbal medicine (N=57) versus a	HDS	HDS (treatment effect = 2.04 95% CI -0.91 to 4.99, $p = 0.17$)

Table 1. Excluded studies: further trial information (Continued)

	applied	control using the same Chinese herbal medicine only (N=32)		
Zhao 2000	68 participants with VD were randomly allocated using a random number table	Electroacupuncture (N=36) versus a control using Hydergine (N=32)	MMSE, BDS	MMSE (treatment effect = 2.43, 95% CI 0.15 to 4.71, p = 0.04); BDS (treatment effect = -3.08, 95% CI -5.96 to -0.20, p = 0.04)

VD (vascular dementia), HDS (Hasegawa's Dementia Score), SOD (blood superoxide dismutase), LPO (lipid peroxides), MMSE (Mini Mental State Examination), ADL (Activities of Daily Living), FAQ (Functional Activity Questionnaire); NO (Nitric Oxide); GSH-PX (Glutathione Peroxidase); BDS (Blessed-Dementia-Scale)

AUTHORS' CONCLUSIONS

Implications for practice

There is currently no evidence available from sufficiently high quality randomised controlled trials to allow assessment of the efficacy of acupuncture in the treatment of vascular dementia.

Implications for research

Although acupuncture is widely used to treat VD in China and many relevant clinical studies were completed and published, true RCTs and high quality trials are non-existent. Randomised double-blind placebo-controlled trials are urgently needed.

Outcome measures including cognition, behaviour, global function, institutionalisation, quality of life, activities of daily living and mood outcomes should be evaluated. Adverse events should be critically assessed by standardized monitoring and more attention should be paid to the possible long-term adverse effects of acupuncture.

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Peng WN, Zhao H, Liu ZS, Wang S. Acupuncture for vascular dementia. *Cochrane Database of Systematic Reviews* 2007, Issue 2. [DOI: 10.1002/14651858.CD004987.pub2]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Chen 1992	Intervention is acupuncture plus acupoint-injection. The treatment effect may come from the injection and not purely the acupuncture.
Chen 2000	Electroacupuncture but versus a nimodipine control.
Gao 2001	Inadequately randomised and control uses piracetam.
Geng 1999	Intervention is acupuncture plus inhalation of herbal drugs and oxygen. Also the control uses some form of Western medicine which is not described.
Gong 2003	Intervention is acupuncture plus acupoint-injection of Yin Yang Huo Injection combined with oral almitrine+raubasine and mainline Chuan Xiong Qin Injection.
Hou 1998	Intervention is acupuncture combined with inhalation of herbal drugs and oxygen.
Jiang 1998	Intervention is electroacupuncture but versus a control using Hydergine.
Lai 1997	Intervention is electroacupuncture but versus a control using Aniracetam.
Lai 1998	Intervention is electroacupuncture versus a control using acupuncture but participants were randomised inadequately according to entry sequence.
Li 1999	Intervention is acupuncture plus moxibustion plus herbal medicine versus a control using the same herbal medicine only.
Li 2001a	Intervention is electroacupuncture versus a control using Dihydroergotoxine (DHET)
Li 2002	Interventions are acupoint injection of Muskiness versus intramuscular injection of Muskiness versus a control using an intramuscular saline injection.
Liu 1997	It is inadequately randomised since participants are chosen according to entry sequence. Intervention is acupuncture at certain acupoints versus acupuncture at different acupoints.
Liu 2004	Intervention is acupuncture but versus a control using Low Molecular Dextran.
Lun 2003	This was inadequately randomised using sortition without allocation concealment. The control group used a Chinese herbal medicine which was also present in the intervention.
Zhao 2000	Intervention was electroacupuncture but versus a control using Hydergine

DATA AND ANALYSES

This review has no analyses.

WHAT'S NEW

Last assessed as up-to-date: 1 February 2007.

10 November 2008	Amended	Sequence of authors changed
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HISTORY

Protocol first published: Issue 4, 2004

Review first published: Issue 2, 2007

20 June 2008	Amended	Converted to new review format.
2 February 2007	New search has been performed	Update search run 2 February 2007; no new studies were found

CONTRIBUTIONS OF AUTHORS

-Weina Peng initiated, designed the study and drafted the protocol. She extracted the data, conducted quality assessment, and statistical analyses.

-Hong Zhao provided methodological perspectives and techniques about writing protocol, as an ombudsman for data extraction and statistical analysis, revised the protocol.

-Zhishun Liu revised the protocol, checked the data extraction and commented on the protocol.

-Shi Wang searched trials, and extracted data.

Contact editor: Rupert McShane

Consumer editor: Zhilong Sun

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Department of Acupuncture and Moxibustion, Guang An Men Hospital, Chinese Academy of TCM, China.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Acupuncture Therapy; Dementia, Vascular [*therapy]

MeSH check words

Humans