This article identifies and comments on published studies of acupuncture treatment for hypertension and stroke. In all, 27 appropriate papers were analysed: 13 were hypertension papers with 3 being of controlled trials, and 14 were stroke papers with 5 controlled trials. The articles consisted of randomised controlled trials (RCTs), controlled trials, and case series studies. The hypertension papers also involved some cohort studies. In general, sample sizes of these studies were small.

Acupuncture in these papers was used as a secondary intervention for treating hypertension and as a tertiary intervention for stroke rehabilitation. The RCTs (the top of the hierarchy of evidence) of hypertension showed that acupuncture was not more effective than sham acupuncture or the anti-hypertensive drug, reserpine; however, all the case series suggested that acupuncture was an effective treatment. The RCT evidence for stroke showed that the effectiveness of acupuncture was similar to that of conventional treatment. The conclusion was that from the papers analysed there is insufficient evidence to show that acupuncture produces better results than other treatments for hypertension or stroke.

Key words
Acupuncture, Hypertension, Literature review, Stroke.

Introduction
Stroke has been recognised as the “second most common world-wide cause of death, accounting for more than 4.6 million deaths world-wide.” and “the survivors may be severely disabled.” Hypertension is considered both as a disease category and one of the major risk factors for stroke. “Mortality and morbidity of stroke occur mainly in the over 65 age group, because blood pressure increases progressively with age” (1). Studies have shown that control of hypertension could reduce the morbidity and mortality from stroke in the population (2). Therefore, any effective treatment for controlling or curing hypertension and stroke will make a marked difference to morbidity and mortality in old age. Acupuncture is widely used for treating various diseases, including both hypertension and stroke. This article aims to identify and comment on the published literature.

Method
A search was made for acupuncture studies on humans in which hypertension or stroke were treated. Papers were expected to fulfil the following criteria: there should be investigation of stroke, or essential (primary) hypertension, and the investigation should include a control group. Papers in English and Chinese were reviewed, and animal studies were not included.

Search strategy
Various sources were used to identify papers which could meet the above criteria. The following electronic databases were searched: MEDLINE (1966 to January 1998), CINAHL (1985 to 1997), AMED (1985 to 1997), SIGLE and the Cochrane Library for published and unpublished papers. Also, relevant web sites were visited as follows:

http://altmed.od.nih.gov/  
(The National Center for Complementary and Alternative Medicine)

http://www.dmu.ac.uk/ln/cmn/  
(Cinese Medical News Website)

http://acupuncture.com/ or  
http://healingpeople.com/  
(Source for Complementary and Alternative Medicine)

http://www.CenterWatch.com/  
(The CenterWatch Clinical Trials Listing Service)
Since on-line searches do not necessarily locate all the relevant literature, other efforts were also made to identify papers. A key organisation, the British Medical Acupuncture Society, was contacted with requests for details of published and unpublished papers known to their members, and manual searches of selected journals were performed in the British Library at Boston Spa, U.K. These journals were as follows:

Clinical & Experimental Hypertension (1997)
Neuroepidemiology (1993)
Complementary Therapies in Medicine (1996-7)
American Journal of Acupuncture (1978-95)
Pennsylvania Medicine (1974)
Arthritis Care & Research (1994)
Physical Therapy (1991)
Journal of Neurological Rehabilitation (1992)
Clinical Rehabilitation (1994, 1997)
Federation Proceedings (1974)
American Journal of Chinese Medicine (1977-97)

The references of identified papers were also hand-searched.

Search words
The following words were used in searching the databases and journals: randomized controlled trial(s), controlled clinical trial(s), random allocation, double-blind method, single blind method, human not animal, clinical trial(s), placebos, random, research design, comparative study, evaluation studies, follow up studies, prospective studies, acupuncture, hypertension, high blood pressure, stroke, stroke rehabilitation, cerebrovascular disorder, vascular disease, paralysis, electroacupuncture, complementary medicine.

Factors considered in review
Form of trial: Randomised controlled trials (RCTs) are regarded as the gold standard for evaluating clinical interventions. A well-designed double-blinded RCT is thought to give the most reliable evidence. It requires that patients, investigators and treatment performers should have no awareness of the differences of allocation of intervention and control methods. However, this is almost impossible to achieve for an acupuncture study, due to difficulties in blinding the participants and selection of controls.

Sample size: The sample sizes of RCTs must be sufficient to detect significant differences between acupuncture treatment and control groups.

Controls: Ideally acupuncture should be compared to a real placebo. The two commonly used forms of placebo: acupuncture control and non-acupuncture placebo, both have disadvantages. Acupuncture controls may be sham or formula acupuncture. Sham acupuncture is putting needles into incorrect acupuncture points. This minimises the psychological weighting of the true acupuncture, but sham acupuncture treatment cannot be regarded as a placebo, since it may also have beneficial physiological effects on the disease. “Formula acupuncture is needling a pre-determined group of acupuncture points not selected in accordance with Traditional Chinese Medicine (TCM) principles and differential diagnosis for each individual subject, and therefore cannot be regarded as TCM” (5); but it may nonetheless have significant beneficial effect. Non-acupuncture controls involve routine treatment, or true placebo controls. The main disadvantage of these methods is that they may not have the psychological response of needling.

Blinding: The purpose of a double-blind design is that patients should be ignorant of their own status. Blind studies are very difficult to design in acupuncture because of the nature of the therapy. Acupuncturists are unlikely to be effectively blinded as they must use their skills and knowledge to choose the points, insert the needles and obtain needling sensation (4). Experienced patients are also unlikely to be suitably blinded because they will know what
they should be feeling when needled at the correct points (6). So a single blind design involving acupuncture naïve patients should be sought.

**Patient preference:** This can play an important part in clinical decision-making. If a Western patient expresses a preference for acupuncture treatment, it may imply that the patient has a chronic condition that has failed to respond with conventional treatment, or the patient may have expectations of good cost-effectiveness and risk benefit from acupuncture (7). In a controlled trial, patient preference may well be a significant factor in its success (8). Patients allocated to a less preferred treatment are more likely to drop out during the trial: a real threat to statistical significance.

**Standardised treatment:** This is important to allow repetition of the research by other workers. Since acupuncture needs to be performed according to an individual patient's condition, and one disease can be treated by a variety of acupuncture treatment methods, standardisation can be difficult (6), for example, the number of sessions given depend very much on the acupuncturist's habit (9).

**Duration of follow-up:** A suitable duration of follow up is an important means of measuring the effectiveness of acupuncture treatment; nevertheless, it is not easily determined. The duration ranges from a single session to quite long periods. Different severity of disease will have different response to acupuncture treatment, but a single session is unlikely to be sufficient to detect long-term clinical change (4).

**Results**

**Nature of studies**

The countries of origin of the reviewed papers (17-43) were: China (17), USA (5), Russia (3), Sweden (1) and Norway (1). There was a total of 5 RCT papers, 3 from Western countries, and 2 from China. The majority of the Chinese articles were reports of case series. Most of the studies (23 out of 27) were conducted from 1991 onwards, the rest were performed in the 1970s and 80s. All RCTs were published after 1991, and only one controlled trial was carried out prior to this, in 1989. Only 1 of the 5 RCT studies described its randomisation method.

The standard of papers reviewed for stroke is better than that for hypertension (Table 1). Five of 14 stroke papers were controlled trials and of these, four were randomised; only three of 13 hypertension papers were controlled trials, and of these one was single blind and randomised. There is a gap in the study design between the controlled trials and the case series for stroke papers: there were no cohort or case control studies of acupuncture on treating stroke in the searched literature. Possibly these studies exist in databases outside the search scope, in sources which were not included in the databases, or in papers written in languages other than English and Chinese.

There is no significant difference between the numbers of male and female patients in the reviewed hypertension and stroke studies. The age range of patients included in these articles is 35.5 ±11.8 (SD) years to 66.4 ± 9.2 (SD) years for hypertension papers, and 29.6 ± 15.1 (SD) to 73.9 ± 6.5 (SD) years for stroke papers.

**Characteristics of controlled trials**

Acupuncture was used as a secondary intervention for treating hypertension in all the papers, with the acupuncture points chosen varying between the different studies. Acupuncture was the tertiary intervention, combined with routine treatment, in stroke rehabilitation, with different sets of acupuncture points again being used in the different studies. As shown in Table 2, the controls of the stroke papers were routine. This, however, covers a multitude of actual therapeutic regimens, although the durations of treatment were similar. The controls and the duration of treatment of the hypertension papers included what might be termed the credible control of sham electrical stimulation. The results of the hypertension studies are likely to have been affected by factors other than the studied treatment. Not all studies took patient preference into account, and only about half the studies mentioned having gained patients’ consent: the others gave no detail about this, so it is possible that patients in these studies

<table>
<thead>
<tr>
<th>Study design</th>
<th>Number of papers</th>
<th>Hypertension</th>
<th>Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td>1</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Controlled trial</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Cohort + normal control</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Case series + comparison</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Case series</td>
<td>6</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td><strong>13</strong></td>
<td><strong>14</strong></td>
<td></td>
</tr>
</tbody>
</table>

Table 1
had inadequate explanation about the trial they were to participate in.

Only a few papers mentioned side effects and these claimed that no side effect happened in their studies. However, none stated the criteria for reporting side effects (10-13).

Evidence
From the controlled trial studies of hypertension there was no evidence to show that acupuncture was more effective than anti-hypertensive drug or sham acupuncture treatments. All the cohort studies of hypertension suggested that acupuncture was an effective treatment for decreasing high blood pressure, but these results must be considered unreliable: there were too many dropouts from the studies, and insufficient periods of follow up. The evidence from the case series suggests that acupuncture is an effective treatment for hypertension (Table 3), but the level of confidence placed in this evidence must be low because of the nature of the studies.

Some of the controlled trials and most of the case series studies used effective rate to measure the efficacy of acupuncture. These measurements are difficult to assess (14). Results from these studies must be seen as unreliable. The case series stroke papers claimed that acupuncture was effective in 6 out of 7 studies (85.7%). However, only 1 of the 7 used statistical analysis to evaluate its outcome, and this showed there was no significant difference between its two groups. Therefore, results from these studies are unlikely to be reliable.

Activities of daily living (ADL) is one of the main measurements used in assessing stroke rehabilitation. Three stroke RCT papers used ADL as one of their outcome measurements (30,31,33), and all three showed that acupuncture was likely to be an effective way of improving stroke patients' ADL (Table 4). However, overall, it seemed that the effectiveness of acupuncture was similar to that of conventional treatment, and, taken with other measurements (15), there was not evidence to show that acupuncture is more effective than the conventional treatment used in stroke rehabilitation; further RCTs using ADL should be conducted.

Overall, the papers included in the review were not of a high quality as regards their scientific assessment method. High quality research designs must at least be RCTs.

Discussion
This paper is not a systematic review, or even a comprehensive review, merely identification and comment on as many English and Chinese articles as possible of acceptable quality concerned with acupuncture treatment for hypertension and stroke. Thus the results are not generalisable.

Despite the efforts made to find all appropriate papers there is inevitably a search bias due to the impossibility of accessing all possible sources which might include eligible data for the review; in this case there are likely to be papers in languages other than English or Chinese, and in journals or years outside those searched.
Additionally there is a publication bias which can be defined as any factor that affects the amount of good scientific evidence appearing in the literature. It is considered to have three stages: prepublication bias, publication bias and post-publication bias. “Prepublication bias includes those factors that may influence both the undertaking and the performance of research and thus its eventual publication.” Publication bias exists in different forms. Reviewer bias is the most common one. Reviewers with different experience and skills have their own views of a paper. “Specialists tend to prefer their own approach and some may have difficulty appreciating the methods of another discipline” (16). A study revealed that between 1940 and 1984 the ratio of unpublished to published trials was 1:128; however, in 1990 the ratio had become 1:5. The comparison suggests that many more trials are currently being lost to general scientific inspection because trials with negative results are less likely to be published in the more widely read and cited journals (9). Post-publication bias refers to the possible wrong interpretation of published data by readers or reviewers: something that I have been at pains to avoid.

Papers on the acupuncture treatment of hypertension or stroke that have been identified, but that I have, for various reasons, not reviewed or commented upon are nonetheless included in the list of references (44-64).

**Table 4**

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Ref</th>
<th>Group</th>
<th>Baseline</th>
<th>ADL 1 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hu</td>
<td>30</td>
<td>(30)</td>
<td>Control</td>
<td>68.3</td>
<td>66.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acup</td>
<td>30.0</td>
<td>62.2</td>
</tr>
<tr>
<td>Johansson</td>
<td>78</td>
<td>(31)</td>
<td>Control</td>
<td>45.1</td>
<td>60.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acup</td>
<td>45.1</td>
<td>69.4</td>
</tr>
<tr>
<td>Sallstrom</td>
<td>49</td>
<td>(33)</td>
<td>Control</td>
<td>20.0</td>
<td>23.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acup</td>
<td>18.0</td>
<td>24.5</td>
</tr>
</tbody>
</table>

n = Sample size  
ADL = Activities of daily living

Evaluation of clinical intervention, so the results from case series studies can not be relied upon.

In general, the low quality of the majority of the papers reviewed means that it is simply not possible to draw any conclusions from their study.

**Conclusion**

The results from this review suggest that there is insufficient evidence to show that acupuncture is better than conventional treatment. However, acupuncture is arguably an effective treatment in stroke rehabilitation (based upon ADL). Further well designed RCT research is required to study the effectiveness of acupuncture in this field.

**References**


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