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Complementary and Alternative Medicine (CAM) Therapies in the Treatment of Ménière's Syndrome: Reviewing the Evidence for Acupuncture

Final Report

Andrew F Long, School of Healthcare, University of Leeds
Mei Xing, School of Community Health Sciences and Social Care, University of Salford
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Tony Bennett, Expert Patient

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Executive Summary

Background

Ménière's syndrome is a long term, progressive disease which damages the balance and hearing parts of the inner ear. Whilst conventional treatment includes drugs, exercise and changes to diet, some people who suffer from this syndrome have explored complementary and alternative medicine (CAM) therapies to alleviate their symptoms. To explore the potential benefit of one CAM therapy, acupuncture, a comprehensive review was undertaken of published evidence on the effectiveness of acupuncture treatment for Ménière's disease, across both English language and Chinese language sources. This report presents the findings from that review.

Methods

Two systematic reviews were undertaken. The first was based on a systematic search of English language literature in 2004/5 and formed the focus for a final year dissertation of an under-graduate student studying for a BSc in Traditional Chinese Medicine (Acupuncture) at the University of Salford. The second comprised an opportunistic search of Chinese language literature as part of a study visit of one of the authors to China in the winter of 2003. All included studies were critically appraised, using established evaluation tools, suitably adapted to add in appropriate search-specific and acupuncture-related aspects. A narrative approach to data synthesis was taken, with greater weight given to studies of greatest quality (minimising bias, accuracy of diagnosis and appropriateness of acupuncture treatment and use of appropriate outcome assessment).

Key Findings

Located Studies

Twenty-six studies were included in the two reviews (8 in the English language and 18 in the Chinese language).

Form of the Studies

The studies comprised: two randomised controlled trials (RCTs); three other controlled studies; four pre-test, post-test designs; nine post-test designs; and eight case series reports. Together they contained a total of 1,877 patients in the acupuncture treatment arm. Seventeen of the studies followed the patients up for at least a year after the end of treatment.

Nature of Treatment

The studies covered five types of acupuncture: body acupuncture; ear acupuncture; scalp acupuncture; fluid acupuncture point injection; and moxibustion. All such types can be classified as within the TCM style, ensuring the 'de-qi' sensation.

Half of the studies involved an individualised TCM prescription approach to the treatment and half used a pre-set prescription, itself based on TCM principles and approaches to treating the particular symptoms commonly experienced by persons with Ménière's, in particular, symptoms of dizziness, vertigo, nausea and vomiting.

Effectiveness of Acupuncture

The weight of evidence in the review, across all study types, is one of the beneficial effects from five types of acupuncture - body, ear or scalp acupuncture, fluid acupuncture point injection, or moxibustion:

- The two randomized controlled trials demonstrated a statistically significant benefit of body or scalp acupuncture against Western medicine and vitamins.
- A similar picture comes from the other three controlled trials, comparing body or scalp and ear acupuncture against Western medicine, Chinese herbal medicine or body acupuncture.
- The evidence from the four pre-test, post-test studies is equally supportive, for acupuncture, including moxibustion on acupoint Du-20, either on its own or combined with body and/or ear acupuncture or herbal medicine.
- The evidence from the post-test and case series studies supports the above conclusions.
- As twelve of the Chinese language studies included patients in an acute phase of Ménière's, the evidence suggests beneficial effects for both those in an acute phase and those who have had Ménière's for a number of years.
- There is insufficient evidence to recommend one or another particular type of acupuncture.
- Given the range in frequency and duration of acupuncture treatment, no firm conclusion can be drawn on the number of courses of treatment that might be needed for beneficial effect. Looking overall, a treatment 'once a day' for a course of 'up to 10 sessions' with the possibility of a second (or more) courses would appear necessary.

Implications and Further Research

Despite the range in the quality of the located evidence, the overall conclusion is of the potential benefit of acupuncture for persons with Ménière's disease. The review also demonstrates the importance of searching for studies in the Chinese language for such a therapy as acupuncture, given its lengthy historical tradition within Chinese medicine

As the quality of studies was varied, there remains a need for further research.

- To clarify questions around the appropriate frequency and number of treatment / courses of acupuncture. This is especially important in the current UK context where persons with Ménière's disease have to pay for any acupuncture treatment.
- To explore possible sets of pre-defined acupuncture points, given that not all acupuncturists in the UK or Europe adopt a TCM diagnosis and treatment approach.

Such research could valuably use a common set of outcome measures, based upon patient reports of symptom benefit and (time before any) recurrence and extent of severity/symptom relief at any recurrence. In addition, study reports need to ensure that sufficient detail over study methods and features of the acupuncture (following the STRICTA recommendations) is provided.

The full report is available at the following web address:

<http://www.healthcare.leeds.ac.uk/pages/research/documents/CAMMeniere2.pdf>

Introduction

Ménière's syndrome is a long term, progressive disease which damages the balance and hearing parts of the inner ear. Whilst conventional treatment includes drugs, exercise and changes to diet, some people who suffer from this syndrome have explored complementary and alternative medicine (CAM) therapies to alleviate their symptoms. However, there is little published information on which CAM therapies might help those with Ménière's.

The initial idea for the project arose from the interest and enthusiasm of a long-term sufferer from Ménière's (TB); he has had Ménière's for more than 25 years. His personal experience of conventional medical treatment and the continuation of his symptoms with their major impact on his life led him to try CAM therapies, in particular, given their general approach of exploring the individual person as a whole and within the context of their life environment. His positive experience with such therapies had encouraged him to make his journey available to others in order to indicate that there were options beyond conventional medicine and just living with the deleterious effects of Ménière's.

While his original interest was to develop a project exploring the benefits of acupuncture, a CAM therapy which had helped him considerably, the project took a wider thrust. Part One involved the undertaking of a comprehensive literature review of published evidence on the effectiveness of acupuncture treatment for Ménière's disease, across both English language and Chinese language sources. Part Two took the form of the collection and analysis of the narrative accounts of a self-selecting sample of persons with Ménière's disease who have used CAM as part of their treatment and care journey. These were recruited through newsletters of the Ménière's Society UK (*Spin*), the Ménière's Support Group of Victoria, Australia, (MSVG) (*Whirligig*) and via the Internet. The report on Part Two of the study is available as a companion document (Long et al 2008) and accessible via the Internet (<http://www.healthcare.leeds.ac.uk/pages/research/documents/CAMMeniere.pdf>).

The research was undertaken as a collaboration between the Universities of Leeds and Salford and a long-term sufferer from Ménière's. Initial funding for the research came from a small grant from the Research Development Fund of the University of Salford, to whom grateful acknowledgement is made.

This report on Part One of the study begins in Section One by providing a brief overview of the condition and biomedical and acupuncture approaches to its diagnosis and treatment. Section Two outlines the methods used in the systematic reviews, one drawing on English language research papers and the other on Chinese language literature. Section Three

presents the findings of the reviews, exploring the quality of evidence base, presenting the results of the reviews separately. Section Four draws together the evidence from the two reviews and the main conclusions and key messages arising.

Section One: Ménière's Disease, Biomedicine and Acupuncture

In 1861, the French physician Prosper Ménière's presented a paper "On a Particular Kind of Severe Hearing Loss Resulting from Lesions of the Inner Ear" to the Imperial Academy of Medicine in Paris. This was the first time that the symptoms of vertigo, tinnitus and hearing loss had been linked to the inner ear. At present, the terms Ménière's syndrome, Ménière's vertigo and endolymphatic hydrops are all used to refer to Ménière's disease (PDxMD 2003).

The onset of the disease may be mono-symptomatic, commonly with one ear being affected. In consequence, diagnosis may be difficult and delayed. The disease may become bilateral, commonly within 5 years. Attacks of vertigo reach maximum severity as the disease develops and subsequently the attacks become less severe, not so frequent and eventually disappear (Saeed 1998). In about 50% of cases, attacks cease after two years and, in 75%, attacks have ceased after eight years (PDxMD 2003).

Although Ménière's disease has been recognised as a disease entity, there has been confusion in the range of conditions covered by the term. In 1995, the Committee on Hearing and Equilibrium defined Ménière's disease as the 'idiopathic¹ syndrome of endolymphatic hydrops' (Beasley and Jones 1972:1112). Since Ménière's disease has no known cause, its occurrence can only be identified by a set of signs and symptoms (Table 1-1)

Ménière's disease is most common between the ages of 40 and 50. It is rare in children and for onset after the age of 60. Its incidence is about 1:1000 and equally distributed between men and women. The disease is well documented in Caucasian, African-American and Asian races (PDxMD 2003).

The aetiology of Ménière's disease is not fully understood. It has been found that endolymphatic hydrops² is present when Ménière's disease is present. Possible causes are multi-factorial. In a literature-based, clinical review of the diagnosis and treatment of Ménière's disease, Saeed (1998) pointed to possible risk factors including: viruses; vascular involvement and an association with migraine; genetic predisposition in a small percentage of cases; immune system involvement; and psychological factors.

¹ 'Idiopathic' is a term used to describe a disease which has no known cause.

² Endolymphatic hydrops is a condition where there is a distension of the endolymphatic space of the inner ear, probably caused by a build up of fluid (hydrops).

Table 1-1: Diagnosis of Ménière’s Disease (Committee on Hearing and Equilibrium 1995)

Certainty of Diagnosis of Ménière’s Disease	Necessary Criteria for diagnosis
Possible	Episodic vertigo of the Ménière’s type without documented hearing loss OR Senso-rineural hearing loss, fluctuating or fixed, with disequilibrium but without definitive episodes Other causes excluded
Probable	One definitive episode of vertigo Audiometrically documented hearing loss on at least one occasion Tinnitus or aural fullness in the treated ear Other causes excluded
Definite	Two or more definitive spontaneous episodes of vertigo for 20 minutes or longer Audiometrically documented hearing loss on at least one occasion Tinnitus or aural fullness in the treated ear Other causes excluded
Certain	Definite Ménière’s Disease Histo-pathological confirmation

Conventional Biomedical Treatment

Saeed (1998: 369-370) observed that ‘currently, the treatment of Ménière’s disease is empirical. As yet, no treatment has prospectively modified the clinical course of the condition and thereby prevented the progressive hearing loss.’ Conventional biomedical treatments are drugs, diet and surgery. *Drugs* often form the first line of treatment. These include: diuretics (to reduce sodium in the body); drugs to block symptoms of motion sickness, nausea and vomiting, and anxiety and vertigo; systemic or local cortico-steroids to reduce inflammation within the inner ear and to stop any immune reactions; ototoxic antibiotics; and drugs to improve blood flow in the inner ear (Salt 2004). The most commonly recommended *dietary* treatment is a low sodium diet. Patients have sometimes been helped by limiting certain components of their diet such as sugar, monosodium glutamate, caffeine and alcohol (Salt 2004). Doctors commonly recommend a restriction in caffeine and alcohol (PDxMD, 2003). *Surgical* treatment is the last resort of conventional medicine for Ménière’s disease, and the most controversial (Saeed 1998). Possibilities include: non-destructive (for example, endolymphatic sac decompression) and destructive (labyrinthectomy and vestibular nerve section) procedures.

Alternative Medicine Treatment – Acupuncture and Ménière’s Disease

Traditional Chinese Medicine (TCM) is a holistic system of medicine encompassing the whole person: body, mind and spirit. It has evolved over the last three thousand years and incorporates acupuncture, herbs, diet, bodywork (such as massage, acupressure and tuina) and qigong. All these therapies share the same underlying theories and diagnostic systems.

Core concepts relate to Yin and Yang, Qi and meridians. Yin and Yang refer to such qualities as cold and hot, wet and dry, quiet and restless, storage and transformation. All symptoms in Chinese medicine can be classified as Yin or Yang. Restoring health requires bringing Yin and Yang back into balance within the person. Kaptchuk (1983: 35) describes Qi as ‘matter on the verge of becoming energy, or energy at the point of materialising.’ Qi is seen as flowing through the meridians, a set of channels or pathways within the body. Disharmony in the internal organs is thus reflected in the meridians. In acupuncture, fine needles are inserted into specific points (acupoints) on the meridians to affect the flow of Qi and through that to affect the internal organs. Cupping, moxibustion and bleeding are other techniques which are also applied to acupoints.

In Chinese Medicine, the diagnosis is based on the symptoms and signs of the individual patient. These are obtained through interviewing and observing the patient. Much information is obtained through observing the tongue and palpating the radial pulses. Based on the signs and symptoms obtained through the consultation, the Chinese medical patterns of disharmony involved are determined. The patterns of disharmony are not dependent on the Western diagnosis or on any medical laboratory tests.

Western texts on acupuncture (Flaws and Soigneur 2001; Ross 1995; Bai 1996; Maciocia 1994) identify the following possible Chinese medical patterns of disharmony as being commonly associated with Ménière’s disease:

<p>Excessive Patterns</p> <p>Liver-Yang, Liver-Fire or Liver-Wind Rising (there is commonly underlying Liver-Yin, Liver-Blood or Kidney Yin deficiency where these patterns are present)</p> <p>Turbid Phlegm obstructing the Head or Middle Jiao</p> <p>Deficient Patterns</p> <p>Qi and Blood Deficiency</p> <p>Kidney Yin or Essence Deficiency</p>
--

The first step in treatment is to make a diagnosis of which patterns of disharmony are present in the symptom picture, regardless of whether they are included in those mentioned above or not. The next step is to select the treatment principles based upon the Chinese

medical patterns present in the case. For example, in the case of the Liver Yang Rising pattern, the treatment principle would be to subdue Liver-Yang and to nourish Liver-Yin, Liver-Blood or Kidney-Yin if there are underlying deficiencies. Once the treatment principles are defined, an acupoint prescription is made by selecting points which are known to have actions embodying those principles.

Concluding Comments

This section has tried to situate the systematic review within the wider context of the nature of Ménière's disease and possible approaches to its treatment, both within biomedicine and acupuncture. The next section presents the methods for the systematic review of published literature on the effectiveness of acupuncture in the treatment of Ménière's disease.

Section Two: Methods

Two systematic reviews were undertaken. The first was based on a systematic search of English language literature and formed the focus for a final year dissertation of an undergraduate student studying for a BSc in Traditional Chinese Medicine (Acupuncture) at the University of Salford in the academic year of 2004/5 (Morgan 2005), supervised by three of this report's authors (MX, AB and AFL). The second, undertaken by another of the authors (MX) in collaboration with AFL and AB, comprised an opportunistic search of Chinese language literature as part of her study visit to China in the winter of 2003. This section presents the methods adopted in each review.

Literature Searching Strategy

A different approach was adopted in each of the two reviews. Each is presented in turn.

English Language Review

A comprehensive approach was undertaken, following the step-by-step procedure laid down by Brettle and Grant (2004). The research question was broken into the elements of *acupuncture* and *Ménière's disease*. These 'controlled' terms were all exploded so that any sub-categories were included. To ensure that all papers relevant to Meniere's disease were included, the search terms included any controlled terms such as 'Meniere's disease' or 'endolymphatic hydrops.' Similarly, the search terms included any terms relevant to acupuncture, for example, 'acupuncture therapy' or 'electroacupuncture', depending on their presence in a particular database. The free text search terms, 'acupuncture' and 'electro?acupuncture', were also used.³ Finally, the components of the search terms were joined together using the Boolean operators 'and' and 'or'.

Searches were undertaken on five databases, all accessible from the University of Salford: MEDLINE (1966 to September 2004), The Cochrane Controlled Trials Register (on 12/09/2004), EMBASE (1974 to 12/09/2004), CINAHL (1982 to September 2004) and AMED (1985 to September 2004). An example of a search strategy can be seen in Appendix One. The inclusion and exclusion criteria are summarised in Table 2-1.

³ The symbol "?" is a wildcard symbol which can represent any character or no character.

Table 2-1: Inclusion and Exclusion Criteria (English Language Review)

Inclusion criteria:

Study on patients with a diagnosis of Ménière's disease
All types of acupuncture
Studies using cupping or moxibustion (both considered integral to acupuncture practice)
Study using acupuncture or moxibustion in addition to other TCM e.g. herbal medicine
Studies of any controlled type and case series if the sample size was ≥ 10
Studies in the English language

Exclusion criteria:

Studies with a sample size of < 10 or single case reports or reports of opinion

Chinese Language Studies

An opportunistic approach was taken to the identification of Chinese language literature. While at the TCM University at Guiyang, a librarian undertook a literature search of the Chinese database of Science and Technology for studies that had been undertaken between 1993 and 2003. Search terms included 'acupuncture' or 'Traditional Chinese Medicine' combined with the term 'Ménière's'. Alongside, MX conducted a hand-search of the most recent (in the previous three months, for example, Sept-Dec 2003) journals related to acupuncture or moxibustion. The inclusion and exclusion criteria are summarised in Table 2-2.

Table 2-2: Inclusion and Exclusion Criteria (Chinese Language Review)

Inclusion criteria:

Study on patients with a diagnosis of Ménière's disease
Study using TCM acupuncture or moxibustion
Study using acupuncture or moxibustion in addition to other TCM e.g. herbal medicine
Any study design with > 1 case
Studies in the Chinese language

Exclusion criteria:

Studies which treated dizziness, tinnitus or other symptoms of Ménière's disease without a diagnosis of Ménière's
Other forms of Traditional Chinese Medicine without Acupuncture or moxibustion
Single case reports or reports of opinion

Quality Appraisal

For each review, all included studies were critically appraised, using established evaluation tools, suitably adapted to add in appropriate search-specific and acupuncture-related aspects. KM employed the checklist developed by Reisch et al (1989), adding in aspects related to the STRICTA standards for reporting interventions in controlled trials of acupuncture (MacPherson et al 2002). The modified checklist can be seen in Appendix Two. For the Chinese language literature, data were extracted and simultaneously translated into English, using a standard template which included the following categories: study design; sample; treatment method; duration of treatment; outcome measurement; results; commentary on the appropriateness of acupuncture; and, overall comments/critique of the paper (Appendix Three).

Data Synthesis

A narrative approach to data synthesis was used, with greater weight given to studies of greatest quality (minimising bias, accuracy of diagnosis and appropriateness of acupuncture treatment and use of appropriate outcome assessment). A meta-analysis was inappropriate due to difference in study designs and outcome measures and the limited amount of quantitative data for individual patients. The set of studies related to each review were synthesised separately and then combined.

Concluding Comments

This section has provided insight into the ways that the two reviews – of English and Chinese language studies – were located, appraised and synthesised. The former involved a comprehensive, ‘systematic’ review process and the latter based on an opportunistic literature search combined with a rigorous approach to quality appraisal and synthesis. The next section presents the findings of the two reviews.

Section Three: Findings

This section of the report is in three parts. Parts A and B present the findings from the two, English and Chinese language, systematic reviews, commenting on the scope and quality of the evidence and ending by presenting the findings on effectiveness. Part C combines findings from the two reviews on the effectiveness of acupuncture in the treatment of Ménière's disease.

Part A: English Language Review

The Scope of the Evidence Base

Eight studies were identified as eligible for critical appraisal (Figure 3-1). Only one study had a comparison group (Yan 1999); no further detail on allocation to the treatment or comparison group was provided. Three studies (Dai and Liang 1993; Tian 1999; Zhang 2002) were purposively designed, post-test designs (following up a group of patients treated in the same manner and measuring the outcome). The remaining four were reports of a series of cases (Steinberger and Pansini 1983; Xu and Ge 1987; Tian 1991; Lu 1997).

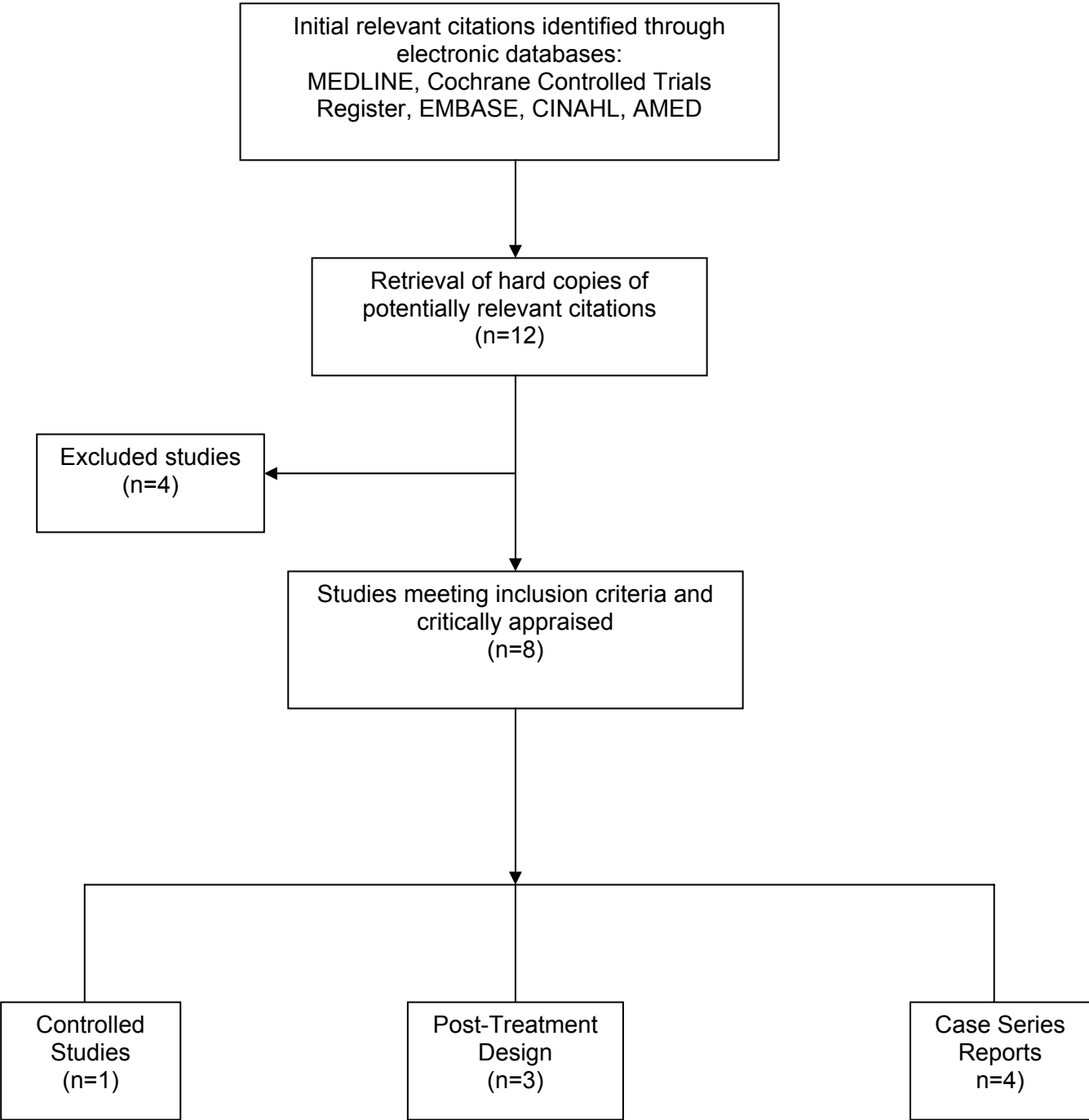
Quality of the Evidence Base

A number of weaknesses were evident in the studies.

Nature of the Study Design

As only one study had a comparison group, the risk of bias is high. Other possible causes of an improvement in the symptoms of Ménière's cannot be ruled out, including a remission in symptoms arising if the patients had not had acupuncture or moxibustion. For the one controlled study, comparison was with Chinese herbal medicine - and not with a placebo control. This could be seen as problematic, if interest lies in whether, or not, acupuncture is effective at all. Post-test and case series study evidence is at best suggestive and indicative of the potential for further investigation. Each of the reports on the case series provided at least one, and sometimes an extended, report of a particular, 'representative' case history.

Figure 3-1: Flowchart Literature Search Process (English Language Studies)



Certainty of Diagnosis

None of the studies provided precise details of their method of diagnosis of Ménière's and none can be confirmed as being 'definite' or 'certain' cases of Ménière's. Only one study reported using audiometric tests (Dai and Liang 1993). One of the case series reports (Steinberger and Pansini 1987) used audiometric data as part of their outcome measurement.

The patients in the studies had been suffering from Ménière's disease for varying lengths of time, from 1 to up to 20 years. Two of the studies indicated that the treatment was directed at patients in a particularly 'acute' phase of the condition.

Description of the Intervention

The eight studies covered three particular types of acupuncture: body acupuncture, ear acupuncture and moxibustion.

While substantial detail on the mode of acupuncture is provided, along with its rationale (whether a prescribed set of acupoints or points chosen according to TCM pattern differentiation), all of the reviewed studies had incomplete details of the acupuncture treatment, according to the STRICTA guidelines (MacPherson et al 2002). However, as all but one of the reports relate to studies conducted in China, the TCM researchers, would not be expected to report some of these details (for example, training, needling sensation) because they are assumed to be common practice or a 'given'. For example, a TCM practitioner will obtain the required sensation (de qi) when needling as a matter of course. In addition, all the studies predated the STRICTA publication guidelines.

While it is usual in the TCM style to individualise treatments in response to the particular symptom patterns the patient presents, this did not occur in two of the studies. Instead a set prescription of acupoints was applied (the controlled trial - Yan1999 - and one of the case series - Xu and Ge 1987). It cannot be assumed that a set prescription of acupoints for all patients will be as effective as an individually tailored prescription based upon the presenting patterns of the patient.

Nature of the Sample and Settings

Very limited detail is provided on the choice of study participants and none on the setting of the study. It can be inferred from the authors' details that all but one of the studies was conducted in China, the other in Yugoslavia. Sample sizes varied from 18 (Zhang 2002) to 189 (Yan 1999). The largest study (n=189 in the acupuncture treatment arm) was a controlled trial (Yan 1999). Five of the studies had 50 participants or fewer. All the case

series reports represent (presumably, 'all') cases of Ménière's disease treated by the author(s) during the indicated period. The total number of patients involved in the 'treatment arm' of the studies was 472.

Outcome Measurement

The main outcome across all the studies was reported in terms of the 'complete' cessation of Ménière's symptoms (sometimes described as 'cured'), 'partial' relieving of symptoms or the non-removal of symptoms, together with recurrence rate. 'Cured' had the common meaning of 'disappearance of all symptoms' and 'return to normal life'. Others talked in terms of 'symptom relief' and 'dizziness disappeared'. 'Partial' relief commonly related to 'symptom relief but occasional recurrence of some symptoms'. Particular symptoms were often mentioned as part of achieved outcomes. Most common were the symptoms of dizziness and vertigo.

No study attempted to quantify the number of attacks of vertigo, levels of hearing, severity or length of occurrence of tinnitus. Only Steinberger and Pansini (1983) undertook an audiometric test as part of their outcome assessment; this was used to corroborate the impact on the Ménière's symptoms.

The length of follow-up (and thus final outcome measurement point) varied. One study followed patients for two years, four studies for one year, and in the others it was either unstated or unclear.

Evidence on Effectiveness

The main results of the included studies are summarised in the evidence table (Appendix 4). All studies report very positive results. The studies consistently show the beneficial effect of the three types of acupuncture (body, ear or moxibustion) in reducing the symptoms of Ménière's disease (Table 3-1). There is insufficient evidence to show that any particular type of acupuncture is more effective than any other.

The best (strongest) evidence comes from the non-randomised controlled study (Yan 1999), relating to body acupuncture following a set prescription. This study provides indicative evidence of the effectiveness of body acupuncture with a set prescription, compared to Chinese herbal medicine. The other studies provide further supportive and suggestive evidence of benefit from acupuncture with an individualised prescription.

Looking overall, the reported range in 'total effect %' for body acupuncture, on its own or with other types of acupuncture, was 74%-100% (eight studies) and for moxibustion, with either body or ear acupuncture, 87%-100% (two studies).

Table 3-1: Effectiveness of Acupuncture (English Language Studies)

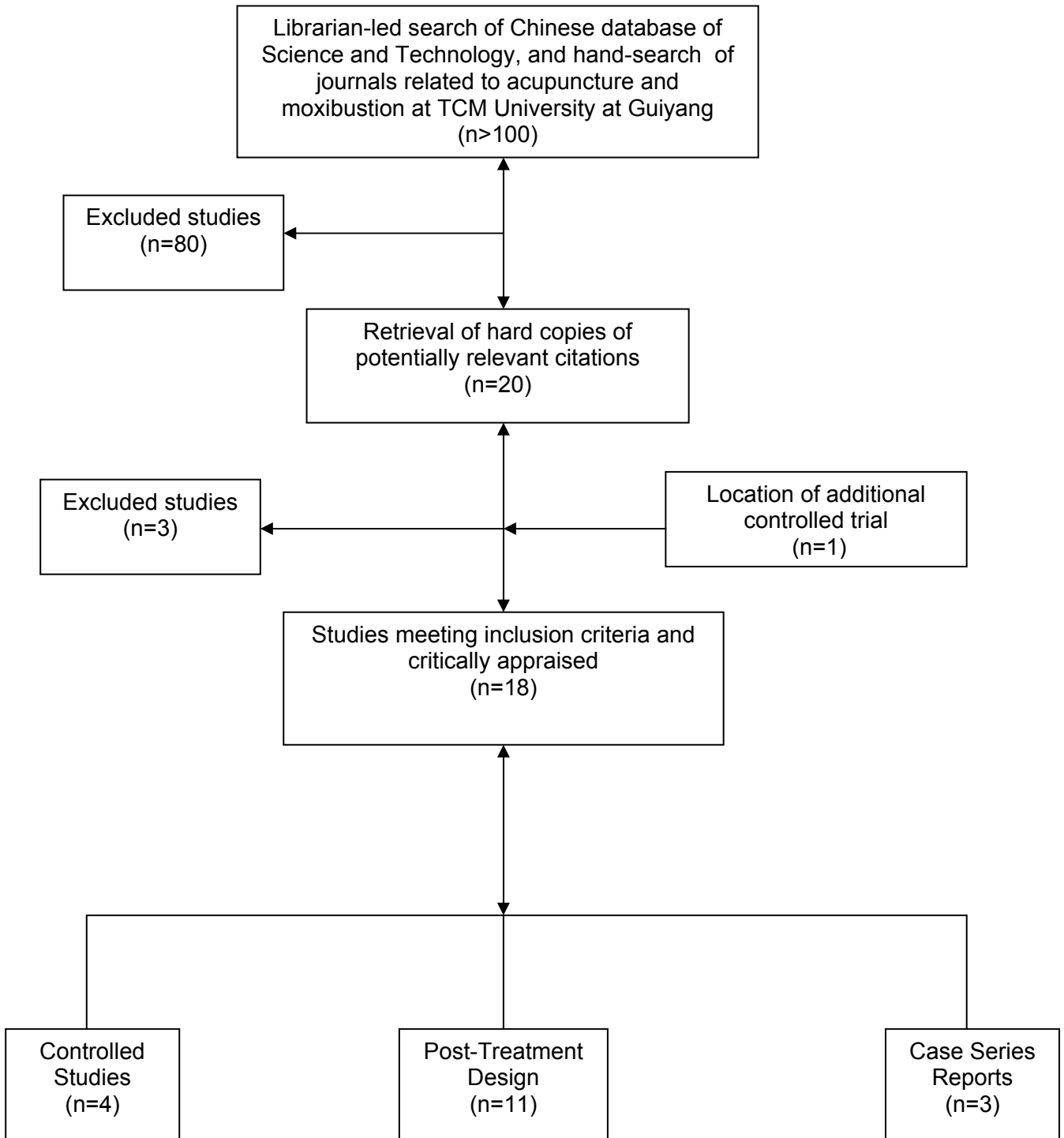
Study (Type)	Type of Prescription	Treatment	Total 'Cured' & 'Outstanding' Effect %
Controlled Trial			
Yan (1999)	Set prescription	Body acupuncture vs. Chinese herbal medicine	93% vs. 60% (p<0.001)
Post-Test Design			
Dai and Liang (1993)	Individualised prescription	Electro-acupuncture, body acupuncture and moxibustion	88%
Tian (1999)	Individualised prescription	Electro-body acupuncture	74%
Zhang (2002)	Individualised prescription	Body acupuncture	94%
Case Series			
Steinberger and Pansini (1983)	Individualised prescription	Body or ear electro/laser acupuncture and moxibustion	100%
Xu and Ge (1987)	Set prescription	Body acupuncture	72%
Tian (1991)	Individualised prescription	Body acupuncture	100%
Lu (1997)	Individualised prescription	Body acupuncture and moxibustion	87%

Part B: Chinese Language 'Opportunistic' Review

The Scope of the Evidence Base

The opportunistic search identified over 100 studies. These were screened and those not meeting the inclusion/exclusion criteria were excluded, resulting in 20 potentially relevant papers. Three papers were subsequently excluded from the analysis (Shi 2002; Lin undated; Jiao 1995) as they were single case reports. One additional paper in the Chinese language (Zhang et al 1983) was located in the search undertaken by KM; due to its study design and focus (a randomised controlled trial comparing acupuncture and Western medicine), it was decided to include it in this part of the systematic review (Figure 3-2).

Figure 3-2: Flowchart Literature Search Process (Chinese Language Studies)



Eighteen papers were included in the review and critically appraised. Four studies had a control/comparison group and before and after-intervention measurement; two (Zhang et al 1983; Gai and Ni 2002) were randomised controlled trials (RCT) and two (Yu and Shi 1997; Qin and Jia 2003) a controlled study (no further details on allocation to the treatments were provided). Four studies (Li and Li 1993; Li 1999; Dong and Zhou 2001; Sun and Li 2001) were pre-test, post-test designs, explicitly undertaking before- and after-intervention measurement. Six studies were purposively designed, post-test designs (following up a group of patients treated in the same manner and measuring the outcome) (Liu 1995; Chao 1996; Bo 2002; Wang and Chen 2002; Zhou 2002; and Zhang 2003). The remaining four were reports of a series of cases (Song and Yi 1992; Zhu 1995; Zhang and Shang 1996; and Wang 1999).

Quality of the Evidence Base

A number of weaknesses was evident in the studies.

Nature of the Study Designs

As only four of the studies had a comparison group, one cannot infer with confidence that any observed improved outcomes did not arise because of other factors. The same issue applies to pre-test, post-test designs. Moreover, post-test and case series evidence is at best in general suggestive and indicative of the need for further research. For the controlled studies, comparison was with Western medicine (Zhang et al 1983; Gao and Ni 2002; Yu and Shi 1997) or between different forms (scalp and ear vs. body) of acupuncture (Qin and Jia 2003).

Certainty of Diagnosis

Certainty over diagnosis is a necessary foundation for research project of a specific disease. One of the RCTs (Zhang et al 1983) included audiometric testing for three-quarters of participants, at baseline and the end-point of the study; the other (Gai and Ni 2002) recruited Ménière's disease patients according to the criteria of two esteemed medical committees within China. Three (Wang 2002; Bo 2002; Zhou 2002) adopted diagnostic criteria from published texts, for example, 'Clinical Neurology' or 'Standard of Diagnosis and Outcome Measurement of Common Diseases'. Another referred to patients with 'clinically confirmed' Ménière's, drawing on the criteria of the Chinese Association of Otolaryngology's Committee Hangzhou Conference of 1991 (Sun and Li 2001). In one study (Chao 1996), the patients' diagnosis was confirmed by the Otolaryngology department. No study reported using the Committee on Hearing and Equilibrium's guidelines (1995), which supposedly provides the international standard for Ménière's disease diagnosis.

Particular symptoms formed the focus of a number of studies, including vertigo (for example, Chao 1996) and dizziness (for example, Zhu 1995; Sun 2001), with explicit exclusion criteria being made for patients with the particular symptom that might be caused by other conditions such as hypertension, anaemia or neck problems. Most of the studies, however, did not provide detail on the inclusion / exclusion criteria.

The patients in the studies had been suffering from Ménière's disease for various periods of time, ranging from 1 to 24 years. Nine of the studies related to patients who had Ménière's for 'up to 10 years', five from '10 to up to 20' years, and for two no detail was given. Thirteen of the studies included patients at an acute phase, within one to 10 days of an acute attack. Two studies (Zhang et al 1983; Li and Li 1993) explicitly focused on the effects of acupuncture for acute symptom relief.

Description of the Intervention

The studies covered five particular types of acupuncture: body acupuncture, ear acupuncture, scalp acupuncture, fluid acupuncture point injection and moxibustion. All such types can be classified as within the TCM style, ensuring the 'de-qi' sensation. TCM individual diagnosis was adopted in six studies. Particular variations of the treatment styles and needling techniques are summarised below.

- The four controlled trials (Zhang et al 1983; Yu and Shi 1997; Gai and Ni 2002; Qin and Jia 2003) provided detailed descriptions of, and rationale for, the acupuncture style and needling, including points used, numbers of needles inserted, depths of insertion, responses elicited (de qi), needle stimulation (for example, manual or electrical), needle retention time, and needle type. The amount of detail fits well with the STRICTA (MacPherson et al 2002) recommendations.
- Eleven of the studies used body acupuncture, which is the most common and traditional treatment in Chinese medicine. Notwithstanding, in only three of these (Yu and Shi 1997; Liu 1995; Wang 1999) was individualised treatment based on TCM pattern differential diagnosis undertaken.
- Four of the studies (Dong and Zhou 2001; Gao and Ni 2002; Wang and Chen 2002; Qin and Jia 2003) used scalp acupuncture. Scalp acupuncture does not normally need TCM individual diagnosis (although this was used in one study – Dong and Zhou 2002) as it is not a Traditional Chinese medicine style of treatment but one based on experience developed from the combination of Chinese and Western medicine.
- Four studies used single points (Song and Yi 1992; Chao 1996; Zhang and Shang 1996; Sun and Li 2001), with either strong needling or liquid injection. These single

points are experiential points used by individual practitioners following other practitioners' experience or their own; their rationale was however not made explicit in the study report.

- Three studies (Zhu 1995; Zhang 1996; Bo 2002) used fluid injection of a herbal extract, vitamins or drugs into the acupuncture points. The aim is to increase the stimulation by combining a drug function with an acupuncture effect.
- Three studies used Moxibustion treatment, at acupoint Du-20, either on its own (Chao 1996; Sun and Li 1991) or combined with acupuncture (Wang 1999). Moxibustion belongs to acupuncture therapy, providing the only way to warm the acupuncture points in order to address 'cold' within Chinese medicine diagnosis.
- Seven studies (Zhang et al 1983; Li and Li 1993; Bo 2002; Gao and Ni 2002; Wang and Chen 2002; Qin and Jia 2003; Zhang 2003) used a set of prescribed acupuncture points for the treatment. This is appropriate for Ménière's disease, where patients commonly manifest symptoms of dizziness, tinnitus and loss of balance.

Not all the studies included details on the number of courses of treatment that the patients took and no single uniform number of courses or duration of treatment within each course was apparent. For example, in two of the controlled studies (Gao and Ni 2002; Qin and Jia 2003), once daily acupuncture was undertaken for a 10 day course. Another controlled study (Yu and Shi 1997) gave treatment from 5 to 26 days but did not describe how many treatments for each group and how often the treatment was given. In another study (Song and Yi 1992), patients continued with the treatment until symptom relief. Looking overall, a treatment 'once a day' for a course of 'up to 10 sessions' with the possibility of a second (or more) courses was common.

Nature of the Sample and Settings

All the studies were conducted in China. While none of studies mentioned the background of the acupuncturist, acupuncturists in China are all qualified medical doctors and at least four years training is required to work in a hospital. Sample sizes varied from 20 (Sun and Li 2001; Zhou 2002) to 286 (Zhang and Shang 1996). The four controlled studies had sample sizes ranging from 39-86 in the acupuncture arm. Four of the studies had 50 or few participants and seven 51-100. The largest study was a case series report on 286 patients (Zhang and Shang 1996).

Studies, in particular, most of the post-test or case series studies reported on patients treated in both an acute and chronic phase of the condition. Eleven of the studies included

patients in an acute phase (of one or more symptoms). In three studies, patients were either hospitalised (Dong and Zhou 2001) or focus explicitly lay on treating the condition in an acute phase (for example, Li and Li 1993; Zhu 1995). The total number of patients involved in the 'treatment arm' of the studies was 1,421.

Outcome Measurement

The majority of studies employed a graded outcome measurement approach, differentiating three to four categories: 'cured', 'outstandingly effective', 'effective/improved' or 'not effective'. 'Cured' had the common meaning of 'dizziness and other symptoms having disappeared' or 'all symptoms disappeared', and 'able to return to work/resume normal activities', and 'no recurrence within a 1 or 2 year period' (depending on the study's follow-up time). 'Outstandingly effective' was similar but there was a recurrence of symptoms 'occasionally' by, for example, six months. 'Effective/improved' related to 'relief of symptoms'.

All the studies mentioned 'control of dizziness' as the major symptom effect measure, along with a more general description of, 'and other symptoms'. Two studies (Zhang et al 1983; Gao and Ni 2002) also used audiometric tests to examine hearing improvement, and others spoke of 'control of dizziness and vomiting' (Zhang et al 1983; Zhu 1995). One of the three studies (Liu 1995) exploring acupuncture treatment for acute attacks also measured changes in the frequency of attacks.

The length of follow-up (and thus final outcome measurement point) varied. Seven studies had a follow-up time of two years, five one year, one for six months and in four no or little detail was provided.

Evidence on Effectiveness

The main results of the included studies are summarised in the evidence table (Appendix 5). All studies report very positive results from the five types of acupuncture (body, ear or scalp acupuncture, fluid acupuncture point injection, or moxibustion) (Table 3-2). There is insufficient evidence to show that any particular type of acupuncture is more effective than any other.

Table 3-2: Effectiveness of Acupuncture (Chinese Language Studies)

Study (Type)	Type of Prescription	Treatment	Total 'Cured' & 'Outstanding' Effect %
Randomised Controlled Trial			
Zhang et al (1983)	Set prescription	Body acupuncture vs. Western medicine & vitamins	79% vs. 50% (p<0.05)
Gao & Ni (2002)	Set prescription	Scalp acupuncture & Western medicine vs. Western medicine & vitamin injections	89% vs. 27% (p<0.001)
Controlled Trial			
Yu & Shi (1997)	Individualised prescription	Body acupuncture vs. Western medicine & vitamin injections	91% vs. 47% (p<0.001)
Qin & Jia (2003)	Set prescription	Scalp and ear acupuncture vs. body acupuncture	80% vs. 57% (p<0.001)
Pre-Test, Post-Test Design			
Li & Li (1993)	Set prescription	Body acupuncture	93%
Li (1999)	Individualised prescription	Ear acupuncture & herbal medicine	72%
Dong & Zhou (2001)	Individualised prescription	Scalp acupuncture & herbal medicine	88%
Sun & Li (2001)	Set acupoint	Moxibustion	100%
Post-Test Design			
Liu (1995)	Individualised prescription	Body acupuncture	91%
Chao (1996)	Set acupoint	Moxibustion	100%
Bo (2002)	Set acupoint	Acupoint injection	98%
Wang & Chen (2002)	Set prescription	Body and scalp acupuncture & injection	92%
Zhou (2002)	Individualised prescription	Body acupuncture	80%
Zhang (2003)	Set prescription	Body acupuncture	90%
Case Series			
Song & Yi (1992)	Individualised prescription	Body acupuncture	91%
Zhu (1995)	Set prescription	Body acupuncture	100%
Zhang & Shang (1996)	Individualised prescription	Body acupuncture	85%
Wang (1999)	Individualised prescription	Body acupuncture and moxibustion	97%

For the four controlled studies, the difference between the 'acupuncture' treatment and 'comparison' treatment was statistically significant ($p \leq 0.05$) or highly statistically significant ($p < 0.001$). The two RCTs demonstrate a positive benefit from either body or scalp acupuncture in contrast to Western (drug) medicine. The reported range in 'total effect %' for body acupuncture on its own was 79-93% (nine studies); for scalp acupuncture with other types of acupuncture, 80%-92% (four studies); for ear acupuncture with either scalp

acupuncture or herbal medicine, 72%-80% (two studies); and for moxibustion, either on its own or with body acupuncture, 97-100% (three studies).

Twelve of the Chinese language studies included patients in an acute phase of Ménière's. One pre-test, post-test study (Li et al 1993) explicitly focused on the effects of acupuncture for acute symptom relief. Others included patients with Ménière's within ten days of an acute attack. The evidence thus suggests beneficial effects for both those in an acute phase and those who have had Ménière's for a number of years.

Part C: A Synthesis of the Findings from the Two Reviews

Twenty-six studies were included in the two reviews. The studies comprised two RCTs, three other controlled studies, four pre-test post-test designs, nine post-test designs and eight case series reports. The studies contained a combined total of 1,893 patients in the acupuncture treatment arm. Seventeen of the studies followed the patients up for at least a year after the end of treatment. Half of the studies involved an individualised TCM prescription approach to the treatment and half used a pre-set prescription, itself based on TCM principles and TCM approaches to treating the particular symptoms commonly experienced by persons with Ménière's, in particular, symptoms of dizziness, vertigo, nausea and vomiting.

The overwhelming findings across all study types is one of the beneficial effects from up to five types of acupuncture - body, ear or scalp acupuncture, fluid acupuncture point injection, or moxibustion. The evidence also suggests beneficial effects for both those in an acute phase and those who have had Ménière's for a number of years.

Both RCTs, judged to be of 'good' overall quality, demonstrated a statistically significant benefit of body or scalp acupuncture against Western medicine and vitamins, with a difference in the 'total effect %' of 23-30% in favour of acupuncture. The other three controlled trials, all judged of 'fair' quality, support this. One (Yu and Shi 1997) found a 33% difference in favour of body acupuncture against Chinese herbal medicine, another (Yu and Shi 1997), a 44% difference in favour of body acupuncture compared to Western medicine and the third (Quin and Jia 2003) the superiority of scalp and ear acupuncture compared to body acupuncture (a 23% difference).

The evidence from the four pre-test, post-test studies is equally supportive, for acupuncture, including moxibustion on acupoint Du-20 either on its own or combined with body and/or ear acupuncture or herbal medicine. Finally, the evidence from the post-test and case series studies supports the above conclusions.

Section Four: Discussion and Conclusions

What is the Overall Quality of the Evidence Base?

The quality of the evidence base was quite varied. Only five had a comparison group and nine explicit, pre- and post-intervention measurement. Further, the comparison groups received a range of the different treatments, itself reflective of the lack of a 'standard', 'best' or 'better' Western or other treatment. In addition, not all of the studies explicitly indicated that the participants had confirmed Ménière's disease. Some included patients at an acute phase, whilst others did not. Similarly, some of the studies used a pre-set prescription, the others an individualised TCM prescription. Finally, many of the study reports were short reports and in consequence lacked much needed methodological detail in order to be confident in their design, findings and conclusions.

Whether or not a comparison group and pre-treatment measurement is essential in studies on the effectiveness of different treatments for Ménière's is moot. While the argument is valid in principle, in Ménière's disease, at least for chronic cases, the symptoms are long lasting and have not been resolved or relieved for a considerable length of time. In this light, while studies with a comparison group and/or pre-post measurement undoubtedly provide stronger evidence, for this chronic condition, evidence from other well-designed studies, in particular, post-test studies (a group followed over time with measurement of outcome at the end of the follow-up time), may provide appropriate, substantive evidence of potential effect. Such studies would need to have explicit sampling criteria, including details of the included participants, use an appropriate outcome measurement and follow participants up for an adequate length of time (at least 6-12 months, given the long-term nature of the condition).

What the appropriate comparison group might be in any controlled study is also unclear. There is no definitive, demonstrated bio-medical curative approach, at present, for Ménière's disease. In the European context, the first line of treatment for someone with Ménière's would likely be biomedical; comparison might thus appropriately be with drug treatment. In contrast, in China, to which most of the reviewed papers relate, and where both biomedical and Chinese medicine approaches are used, an appropriate contrast might be with a (Western) drug approach, or with different forms of TCM approaches (for example, types of acupuncture and/or herbal medicine). In essence, there is no obvious or common 'standard' treatment to compare acupuncture against.

An alternative argument would be to suggest that studies should have a 'placebo' (no active intervention) treatment. In the case of a chronic condition, such as Ménière's, this argument has little validity and is ethically problematic. It is unlikely that as part of normal treatment and care, either supervised by a primary care (or other) physician or self-management by the individual person with Ménière's, potential study participants will not be taking some medication or other approach to enable them to cope. This serves to reinforce the argument that the relevant standard treatment comparison must be culturally determined.

Whatever study design is applied, it is important that full methodological details are provided in the research report. The STRICTA recommendations for reporting controlled trials using acupuncture (MacPherson et al 2002) provide a useful guiding template in terms of the rationale for acupuncture, needling details, treatment and comparison treatment regimen, and (in the case of Western acupuncturists) practitioner background (for example, TCM or medical acupuncturist and training). In essence, the research report needs to provide adequate information on the protocol followed in the study and its rationale, in order to enable repeatability. This would include: rationale for all possible patterns in TCM described with treatment principles, with additional points for Ménière's disease patients (suitably referenced); guidelines on standardised needling techniques; the time for retention of needles; and, the frequency of acupuncture and number of treatments/courses. In addition, there is need for a full report on the choice of outcome measure(s) and follow-up time. Finally, the study must be undertaken in a rigorous manner.

Is Acupuncture Appropriate in the Treatment of Ménière's Disease?

The weight of evidence in the review, across all study types, is one of the beneficial effects from up to five types of acupuncture - body, ear or scalp acupuncture, fluid acupuncture point injection, or moxibustion.

- The two randomized controlled trials demonstrated a statistically significant benefit of body or scalp acupuncture against Western medicine and vitamins.
- A similar picture comes from the other three controlled trials, comparing body or scalp and ear acupuncture against Western medicine, Chinese herbal medicine or body acupuncture.
- The evidence from the four pre-test, post-test studies is equally supportive, for acupuncture, including moxibustion on acupoint Du-20 either on its own or combined with body and/or ear acupuncture or herbal medicine.

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- The evidence from the post-test and case series studies supports the above conclusions, suggesting the potential benefit of acupuncture, including moxibustion on acupoint Du-20, either on its own or combined with body and/or ear acupuncture.
 - As twelve of the Chinese language studies included patients in an acute phase of Ménière's, the evidence suggests beneficial effects for both those in an acute phase and those who have had Ménière's for a number of years.

There is insufficient evidence to recommend one or another particular type of acupuncture. Similarly, given the range in frequency and duration of treatment, there can be no firm conclusion on the number of courses of treatment that might be needed for beneficial effect. Looking overall, a treatment 'once a day' for a course of 'up to 10 sessions' with the possibility of a second (or more) courses would appear necessary. While in China, 'once a day' or 'every other day' is common practice, this is more problematic in the UK where clients pay for their acupuncture treatment. Further research is needed to investigate the appropriate number of frequency and number of treatments.

Given the nature of TCM diagnosis and treatment, definitive guidance on which set of points are useful would be inappropriate. Five of studies involved use of moxibustion at Du-20 and found beneficial effects. Studies which used a set of pre-defined acupuncture points for the treatment is a potentially acceptable approach, as most Ménière's disease patients manifest dizziness, tinnitus and loss of balance as common and key symptoms and all acupuncture points have a dual function (that is, the points can either reinforce 'vital' energy or reduce 'evil' energy in comparison with herbal medicine). These points can be put into a pool of possible acupuncture points for Ménière's disease, and may provide a good source for future randomised controlled trials.

What is the Added Value of Searching and Appraising Chinese Language Literature?

All but one of the studies in this review took place in China. Around two-thirds of the papers (18 out of 26) were published in the Chinese language. The addition of these papers adds to the evidence base and in principle (irrespective of study quality) strengthens the conclusions of the review. This is in line with the conclusions of Moher et al (2003), that substantial bias will occur in the results of a CAM systematic review if languages other than English are excluded. Given the very long historical tradition and use of acupuncture within Chinese medicine, accessing research literature published in the Chinese language needs to become a sine qua non in this type of literature review. However this will be challenging for many research groups, requiring access to Chinese language readers (Pilkington and Richardson 2004; Shekelle et al 2005). Optimal methods of accessing and including Chinese language literature need to be further explored.

At the same time, one cannot straightforwardly generalise and transfer findings from a Chinese cultural context, within its own established education and training approaches, to a Western European context, where the education and training of, and access to, acupuncturists might be very different (thus, the relevance of reporting studies using the STRICTA framework).

How Should the Benefits/Outcomes be Assessed, and Over What Time Period?

The majority of studies employed a graded outcome measurement approach, differentiating three to four categories: 'cured' / 'complete cessation of symptoms'; 'outstandingly effective', 'improved' / 'partial' relieving of symptoms; 'not effective' / non-relief of symptoms; and recurrence rate (for example, 'no', 'occasional' or 'yes' and at a particular point in time – two years, one year, six months). Particular symptoms were often mentioned as part of achieved outcomes. Most common were the symptoms of dizziness and vertigo. Only one study asked about the number of attacks of particular symptoms such as vertigo or undertook an audiometric test as part of their outcome assessment.

Such a graded approach seems appropriate, in gauging the patient's own reported experiential benefits, along with data on recurrence (again in a graded form). It would be helpful if a set of common, core symptoms was drawn up and the patient asked about both their occurrence and frequency (in a graded or numerical form). This would enable easy comparison of findings across studies and cultures. It is interesting to note that eight of the twenty-six studies reported following up the patients for up to two years. Such a length of follow-up is impressive but, while appropriate perhaps for a long standing condition as Ménière's, may not be possible in many studies.

Given the underlying theory of TCM acupuncture, and its emphasis on a holistic action including body, mind and spirit, it is to be expected that benefits beyond Ménière's symptoms may be experienced by the patient. This suggests the value of measuring not just symptom relief but also general health and well-being as well as greater resolve to cope with the illness.

Concluding Comments

The aim of this set of two systematic reviews was to locate and critically appraise evidence for acupuncture as a treatment for Ménière's disease, drawing from both English and Chinese language literature. Despite the range in the quality of the located evidence, the overall conclusion is of the potential benefit of acupuncture for persons with Ménière's disease. This includes acupuncture of five different types - body, ear or scalp acupuncture, fluid acupuncture point injection, or moxibustion. In addition, the evidence suggests

beneficial effects for acute attacks/phases of Ménière's and for those who had Ménière's for a number of years. The review also demonstrates the importance of searching for studies in the Chinese language for such a therapy as acupuncture, given its lengthy historical tradition within Chinese medicine.

Further research is needed to examine the frequency and number of treatment / courses of acupuncture. Such research could valuably use a common set of outcome measures, based upon patient reports of symptom benefit and (time before any) recurrence and level following recurrence. In addition, study reports need to ensure that sufficient detail over study methods and features of the acupuncture (following the STRICTA recommendations) is provided.

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Appendices

Appendix 1: English Language Review Search Terms

MEDLINE search terms:

meniere\$ or (endolymphatic adj hydrops)
exp endolymphatic hydrops/ or exp meniere's disease/
1 or 2
exp acupuncture therapy/ or exp chinese traditional/
acupuncture or electro?acupuncture or auriculotherapy or (auricular adj needles) or
(needling adj therapy) or (electric adj needling)
4 or 5
3 and 6

AMED search terms:

exp Electroacupuncture/
exp Acupuncture therapy/ or Acupuncture/
(acupuncture or electro?acupuncture)
1 or 2 or 3 or 4
exp meniere's disease
meniere\$ or (endolymphatic adj hydrops)
6 or 7
5 and 8

CINAHL and EMBASE search terms:

ACUPUNCTURE#.W..DE. OR ELECTROACUPUNCTURE#.W..DE
acupuncture or electroacupuncture
MENIERE-DISEASE#.DE OR HYDROPS#.W..DE OR ENDOLYMPH#.W..DE
meniere\$ or endolymphatic ADJ hydrops
1 OR 2
3 OR 4
6 AND 7

Cochrane Library search terms:

ACUPUNCTURE explode all trees
MENIERE'S DISEASE explode all trees
ENDOLYMPHATIC HYDROPS explode tree 1
ACUPUNCTURE THERAPY explode tree 1
ELECTROACUPUNCTURE single term
acupuncture
electroacupuncture
meniere* or (endolymphatic adj hydrops)
1 or 4 or 5 or 6 or 7
2 or 3 or 8
9 and 10

Appendix 2: Modified Check List for Assessing Therapeutic Acupuncture Studies (based upon Reisch et al 1989)

JOURNAL _____
 Volume _____ Number _____ Pages _____ to _____ Year _____
 AUTHOR _____
 TITLE _____

Y = Yes; N = No; U = Unclear or Unknown; NA = Not Applicable;

T/M = Treatment or Management Method

A "*" is noted beside desirable responses to the criteria considered most important.

A "+" appears beside "Not Applicable" responses to these criteria.

1. PURPOSE OF STUDY

- | | |
|--|--------|
| A. Title consistent with purpose of study | Y N U |
| B. Statement of purpose given | Y* N U |
| C. Outcome variables for therapeutic effects defined prior to study | Y* N U |
| D. Magnitude of difference in outcome of (T/M) groups under investigation specified prior to study | Y* N |
| E. Sources of support for study specified | Y N U |

2. EXPERIMENTAL DESIGN

- | | |
|---|-----------|
| A. Data Collection (Check only one) | |
| 1. Data collection planned prior to T/M of subjects; data collected prospectively under specified conditions. | _____* |
| 2. Data collection planned prior to T/M of subjects: data collected retrospectively by record review. | _____ |
| 3. Data collection not planned prior to T/M of subjects: data collected retrospectively. | _____ |
| B. Selection of Subjects (Check only one) | |
| 1. Subjects selected prior to T/M and evaluated prospectively | _____* |
| 2. Subjects followed from T/M to outcome but study planned after T/M | _____ |
| 3. Subjects selected according to outcome and T/M evaluated retrospectively. | _____ |
| 4. Unclear time relation of subject selection to outcome of T/M | _____ |
| C. Carry-over of refractory effects avoided or considered in the design of the study | Y* N U NA |

3. SAMPLE SIZE DETERMINATION

- | | |
|--|--------|
| A. Method | |
| 1. Sample size determined by: (indicate which) | Y* N U |
| a. predetermined number of subjects OR | _____ |
| b. sequential experimental design OR | |
| c. independent monitoring committee | |
| 2. Predetermined time period | Y N U |
| 3. Specified time period from _____ to _____ | Y N U |
| 4. No method specified (Check if applicable) | _____ |
| 5. Other (describe) _____ | Y N |
| B. Total number of subjects specified | Y* N U |
| Total number of subjects is _____ | |
| C. Adequate number of subjects ENROLLED to detect magnitude of T/M differences under investigation or sufficient hazards identified to preclude further study. | Y* N U |

4. DESCRIPTION AND SUITABILITY OF SUBJECTS

- A. Entry criteria
- 1. Age of subjects given Y N U NA
 - 2. Race of subjects given Y N U NA
 - 3. Sex of subjects given Y N U NA
 - 4. Socioeconomic status given Y N U NA
 - 5. Disease/health status given Y* N U
 - 6. Contraindications for T/M
- (can include other diseases or treatments) Y* N U NA+
- B. Eligible subjects who refuse to participate are adequately described Y N U NA
- C. Subjects adequately described for all appropriate criteria including those listed in 4A Y* N U
- D. Subjects selected for this study suitable for question(s) posed by these researchers Y* N U

5. RANDOMIZATION AND STRATIFICATION

- A. It is possible to design a randomised study to evaluate the T/M under consideration Y N U NA
- B. Randomization claimed and documented Y* N U NA
- C. Randomization not performed and bias is likely Y N U NA
- D. Use of either prognostic stratification prior to study entry or retrospective stratification during data analyses Y* N U NA+
- E. Group differences limit the interpretability of this study Y N U NA

6. COMPARISON GROUP(S) (CONTROL) USAGE

- A. Random T/M assignment (indicate which below) Y* N U NA
- 1. Unmatched subjects with randomised T/M assignment _____
 - 2. Subjects as own control with T/M order randomised _____
 - 3. Matched by subject with T/M assignment randomised _____
- B. No assignment method described Y N U
- [6C to 6I only apply to non-randomised studies]
- C. Historical Y N U
- D. Subjects matched/paired but assignment to T/M groups not randomised Y N U
- E. Subjects as own control but T/M order not randomised Y N U
- F. Subjects compared according to their response to the T/M procedure Y N U
- G. Convenience (Subjects selected for availability) Y N U NA
- H. Comparison (Control) group not included Y N U
- I. Other non-randomized (explain) _____ Y N U NA

7. PROCEDURES FOR TREATMENT/MANAGEMENT

- A. Informed consent obtained Y* N U NA+
- B. Clear specification of:
- 1. Style of acupuncture used (e.g. TCM, Worsley 5 element style) Y N U NA
 - 2. Rational for treatment given (e.g. TCM syndrome patterns, trigger points etc) Y N U NA
 - 3. Needling details
- a. Points used (uni/bilateral) Y N U NA
 - b. Number of needles inserted Y N U NA
 - c. Depths of insertion (e.g. cun or tissue level) Y N U NA
 - d. Responses elicited (e.g. de qi or twitch response) Y N U NA
 - e. Needle stimulation (e.g. manual or electrical) Y N U NA
 - f. Needle retention time Y N U NA
 - g. Needle type (gauge, length & manufacturer or material) Y N U NA
4. Treatment regimen

a. Number of treatment sessions	Y N U NA
b. Frequency of treatment	Y N U NA
5. Co-interventions eg. Moxibustion, cupping, lifestyle advice	Y N U NA
6. Practitioner background (duration of relevant training, length of clinical experience, expertise in specific condition)	Y N U NA
7. Indications for	
a. Initiation of T/M	Y* N U
b. Modification of T/M	Y* N U NA+
c. Discontinuation of T/M	Y* N U NA+
C. Subjects in different T/M groups appear to receive the same care other than that under investigation	Y N U NA
D. T/M adequately described for above or other appropriate criteria	Y* N U
E. T/M reasonable and appropriate to answer question(s) posed by these Researchers	Y* N U
8. BLINDING (MASKING)	
A. Blinding claimed and appears realistic	Y* N U NA
B. Blinding (masking) used where feasible for important variables* by the:	Y N U NA
1. investigators	Y N Some U NA
2. caregivers	Y N Some U NA
3. subjects (and family if appropriate)	Y N Some U NA
C. Mark Y if 8B1, B2, B3 are each marked Y or NA Mark NA+ if 8B1, B2, B3 are each marked NA.	Y* N NA+
D. Failure to use blinding likely to bias study results	Y N U NA
*We consider a variable important only when it is clearly identified by the author(s) in the abstract or in the statement of purpose to describe differences between groups related to their treatment or management.	
9. SUBJECT ATTRITION	
A. Predefined procedures for excluding subjects after entry	Y N U NA
B. Specific procedures established to minimize loss of subjects from this study.	Y N U NA
[Answer 'NA' to 9C and 9D if no subjects or records were lost or dropped.]	
C. Description of all subjects or their records which were lost or dropped	Y* N U NA+
D. Any loss of subjects or their records likely to bias results of this study	Y N U NA
10. EVALUATION OF SUBJECTS AND TREATMENT/MANAGEMENT	
A. All important clinical information reported	Y* N U
If no or unclear, explain _____	
B. Laboratory and other measurements appear standardized and consistent	Y* N U
C. Treatment compliance assessed	Y* N U NA+
D. Evaluation methods adequately described	Y* N U
E. Evaluation methods appropriate to answer question(s) posed by investigators	Y* N U
F. Prospective evaluation of important hazards or toxicity	Y* N U NA+
G. If use of T/M increases cost of care substantially, cost-effectiveness discussed	Y* N U NA+
11. PRESENTATION AND ANALYSIS OF DATA	
A. Text clearly understandable	Y N U
B. All comparisons involve same number of subjects or any discrepancy is explained	Y* N U NA+
C. Descriptive measures (mean, range, standard deviation, proportion,	

- etc.) identified for all important variables All SomeNone
 D. Computation errors or contradictions identified Y N* U
 E. Statistical test used for comparisons involving important variables All Some None U NA
 F. Reported statistical tests appear to be:
 1. clearly identified All Some None U NA
 2. appropriately used All Some None U NA
 3. appropriately interpreted All Some None U NA
 G. Responses to items 11E, F1, F2, F3 marked "ALL" Y* N

12. RECOMMENDATIONS/CONCLUSIONS

A. Recommendation(s) are:

- 1. nonexistent _____
- 2. unclear _____
- 3. for further study _____
- 4. for use of T/M _____
- 5. against use of T/M _____

B. Support for recommendation in 12A

[Respond to only one of the following items]

1. Recommendation for use of T/M method based on a controlled, randomised prospective study (if feasible); made only if convincing benefit is demonstrated and all important hazards assessed; and applied to subjects and conditions similar to those in this study. Y* N U

2. Recommendation against use of T/M method supported by data relating to cost, hazards or toxicity of T/M or supported by calculation or appropriate confidence intervals. Y* N U

3. Recommendations neither for nor against use of T/M method is appropriate since criteria in 12B1 and 12B2 are not met Y* N U

13. SUMMARY OF ITEMS REVIEWED

The summary of starred items can be used as an assessment of study quality by calculating the ratio of the starred items marked by the reviewer to the maximum total possible.

The maximum total possible is determined by subtracting the Total 'NA+' responses marked by the reviewer from 34. As many as 13 'NA' responses may be recorded (Section 4, 5, 6, 7, 8, 9,10, 11).

34 - _____ (Number of NA+ Responses) = _____ (Max. total possible)
 (Enter maximum total possible on line 14.)

Item No.		SYNOPSIS OF ITEM REVIEWED		
		No. of Starred Items Fulfilled	No. of Starred Items Possible	No. of NA+ Fulfilled
1	Purpose of Study		3	
2	Experimental Design		2	
3	Sample Size Determination		3	
4	Description & Suitability of Subjects		4	
5	Randomization and Stratification		2	
6	Comparison Group (Control) Usage		1	
7	Procedures for Treatment/Management		6	
8	Blinding (Masking)		1	

9	Subject Attrition		1	
10	Evaluation of Subjects and T/M		7	
11	Presentation & Analysis of Data		3	
12	Recommendations/Conclusions		1	
			34	
LINE				
13	TOTAL			
14	Maximum Total Possible			
15	Ratio of total to maximum possible			

Entries only required in non-shaded boxes.

Appendix Three: Evaluation Template for Chinese Language Studies

Bibliographic Details	Chao LY (1996) Moxibustion at Du-20 for the treatment of 32 cases of Ménière's syndrome
Type of Design	Post-test design
Sample	32 patients who were diagnosed with Ménière's syndrome by Otolaryngology department. 10 male, 22 female; aged 30-56 years; duration of the illness: up to 9 years.
Method of Treatment	Moxa at Du-20 only, 99 moxa corn for around 2 hrs each time, until blister forms
Duration of Treatment	3 sessions of treatment
Follow-up Time	2 years
Outcome Measurement	Symptom relief
Results	100% symptom relief (of dizziness only, rather than symptoms in general – this is implied, rather than explicitly stated) 8 experienced symptom relief after one session; 10 after two treatments; 14 after three treatments. At 2 years, none experienced recurrence
Appropriateness of Acupuncture	Moxibustion at Du-20 is a good experiential point for dizziness. It is unclear if differentiated diagnosis according to TCM theory was undertaken. Author, in discussion section, mentions that moxibustion on Du 20 is good for dizziness (not mentioning Ménière's disease symptoms)
Evaluative Comments	Strengths include: MD confirmed by Otolaryngology department; use of standard treatment duration; Du-20 an appropriate treatment point; and length of follow-up. Weaknesses include: unclear sampling criteria; sole focus on one MD symptom (dizziness); lack of mention of holistic (TCM) approach and lack of control group.
Quality Judgement	Fair

Appendix 4: Evidence Table for English Language Studies

Study & Study Type	Treatment, Sample Size, Setting & Follow-up Time	Confirmed Diagnosis & Time with Ménière's	Appropriateness of Treatment	Key Findings	Summary Evaluative Comments & Overall Quality
Controlled Trials				In principle, the addition of a comparison group strengthens the study, enabling greater confidence in inferring that the treatment, as opposed to other factors, brought about the changes.	
Yan (1999) CT	Body acupuncture vs. Chinese herbal medicine (for vertigo) 30 day treatment (Ac: Two courses of 15 sessions 1 p day, with 5 day rest) n=257; Ac=189; Hb=68 China Follow-up: 1 year	Patients with MD 102 patients had MD for ≤ 1 yr, 135 1-5 yrs and 20 >5 yrs	No TCM pattern diagnosis used to choose acupoints. Set acupoint prescription	93% (n=175) vs. 60% (n=41) 'complete' response (p<0.001) [complete disappearance of signs and symptoms] 99% (n=187) vs. 88% (n=59) 'complete' or 'partial' response 11% (n=21) vs. 49% (n=29) recurrence rate (p<0.001)	Short report on the study, but adequate details over patients and treatment points, and appropriate 2:1 case:comparison subject ratio. Discussion includes explanation of set acupoint prescription. Lack of detail over how patients were allocated to the treatment and comparison group (non-random) and meaning of 'disappearance of all signs and symptoms' in outcome measurement.
Post-Test Design				A purposively designed study (as opposed to a series of cases) of a selected group, with measurement of treatment effect after last treatment or at end of follow-up time.	
Dai & Liang (1993)	Electro acupuncture, acupuncture and moxibustion 1 treatment daily for up 6	MD patients who had auditory vertigo symptoms	One set point for acupuncture, another for moxibustion; other points added	70% (n=16) 'cured' [disappearance of all symptoms] 18% (n=4) 'excellent'	Targets only cases with auditory vertigo syndrome. Detailed description of other Ménière's symptoms of cases; full explanation of potential role of

	<p>days (30 min application)</p> <p>n=23</p> <p>China</p> <p>Follow-up: 1 year</p>	<p>Up to 17 yrs</p>	<p>according to TCM diagnosis</p>	<p>[disappearance of all symptoms, but occasional dizziness]</p>	<p>acupuncture in treating Ménière's.</p> <p>Note: the article ends with a one page 'typical case' summary.</p>
Tian (1999)	<p>Electro-acupuncture</p> <p>2-3 courses of 10 sessions daily, with 2 days rest between course (10-20 min application)</p> <p>n=72</p> <p>China</p> <p>Follow-up period: 1 yr</p>	<p>Patients with MD</p> <p>50 had had MD for 1-5 yrs, 22 >5 yrs</p>	<p>Treatment according to TCM pattern diagnosis</p>	<p>50% (n=36) 'marked improvement' [dizziness disappeared, hearing improved, no relapse during follow-up time]</p> <p>24% (n=17) 'improved' [dizziness disappeared, no hearing improvement]</p> <p>Treatment more effective in cases of shorter duration</p>	<p>Short presentation of study and, in consequence, limited details on methods, except on acupuncture treatment.</p> <p>Note: paper includes 1 brief case reports.</p>
Zhang (2002)	<p>Body acupuncture</p> <p>Courses of 10 sessions with a 2 day rest between (30 min application)</p> <p>n=18</p> <p>China</p> <p>Follow-up period: 2 yrs</p>	<p>Patients with MD</p> <p>Up to 6 yrs.</p>	<p>Treatment according to TCM pattern diagnosis</p>	<p>72% (n=13) cured [complete disappearance of clinical symptoms with no recurrence in 2 yrs]</p> <p>22% (n=4) marked effect [disappearance of clinical symptoms but recurrence within 1 yr]</p>	<p>Study report is from an abstract, translated from the original Chinese paper. Brief detail on methods is provided, with extensive detail on needling and TCM rationale.</p> <p>Note: paper includes a representative case reports.</p>

Case Series				All the following are reports on a series of cases with MD, treated over a range of years.	
Steinberger and Pansini (1983)	<p>Body acupuncture, ear acupuncture and moxibustion (rarely also scalp acupuncture)</p> <p>5 treatments, once a day [30 min application]</p> <p>n=34</p> <p>?Yugoslavia</p> <p>Follow-up period: unclear</p>	<p>Patients with MD – with confirmed auditory tests</p>	<p>Treatment according to TCM pattern diagnosis</p>	<p>100% success for vertigo after 3 treatments [note: vertigo was self-perceived as the worst symptom]</p>	<p>Very brief report on cases over 5 year period, with limited detail on outcome measurement (focus on vertigo). Strengths include: the use of audiometric tests (for auditory acuity) and extensive detail on needling and TCM treatment rationale.</p> <p>Note: paper includes 3 brief case reports.</p>
Xu & Ge (1987)	<p>Body acupuncture</p> <p>Courses of 10 sessions, once a day (20-30 min application)</p> <p>n=75</p> <p>China</p> <p>Follow-up period: 1 yr</p>	<p>Patients with MD according to clinical symptoms</p> <p>18 had had MD for < 1 yr, 57 ≥ 1 yr</p>	<p>Set acupoint prescription, with extra points if tinnitus and deafness were severe</p>	<p>39% (n=29) cured [symptoms such as vertigo, nausea and vomiting disappeared, with remission for ≥ 1 yr, and able to return to work]</p> <p>33% (n=25) 'marked' improvement [all symptoms markedly relieved and no recurrence within 1 yr]</p> <p>21% (n=16) improved (symptoms remained but milder)</p> <p>On average, needed 2 treatment courses (range of 1-5)</p>	<p>Reporting on 18 year case series of clinically confirmed MD cases. Short report, with limited but adequate detail (e.g. acupuncture treatment) provided.</p> <p>Note: paper includes 1 brief case reports.</p>

Tian (1991)	Body acupuncture 10-15 treatments n=21 China Follow-up period: unstated	Patients with MD, with a 'sudden onset' of symptoms	Treatment according to TCM pattern diagnosis	100% 'cured' (all symptoms disappeared) [8 had alleviation of symptoms after 4 treatments; 13 after 7; 21 after 10-15 treatments]	Brief report on cases treated since 1975 with very limited detail, except on rationale and approach to treatment (and possible ways that the treatment could be improved). Note: the article ends with a one page 'typical case' summary.
Lu (1997)	Body acupuncture and moxibustion One treatment per day [30 min application] n=30 China Follow-up: 1 year	Patients with MD Up to ≥ 10 yrs [22 patients had MD ≤ 10 yrs; 8 >10]	Treatment according to TCM pattern diagnosis	87% (n=26) cured [disappearance of symptoms – nausea, vomiting, dizziness, insomnia, fullness of ears, tinnitus, deafness] [2-14 daily treatments (mean of 7.4) needed] 30% (n=9) symptom free after 1 yr; 47% (n=14) re-occurrence within 6 mths	Short report on cases treated over a number of years. Argues that Ménière's syndrome belongs to the category of 'dizziness' in TCM. Strengths include one year follow-up and clear rationale for treatment. Note: the article ends with a one page 'typical case' summary.

Appendix 5 Evidence Table for Chinese Language Studies

Study & Study Type	Treatment, Sample Size, Setting & Follow-up Time	Confirmed Diagnosis & Time with Ménière's	Appropriateness of Treatment	Key Findings	Summary Evaluative Comments & Overall Quality
Controlled Trials				In principle, the addition of a comparison group strengthens the study, enabling greater confidence in inferring that the treatment, as opposed to other factors, brought about the changes.	
Zhang et al (1983) RCT	Body acupuncture vs. Western Medicine (drug + vitamins) 15 day treatment Acupuncture: once a day for 2-3 days; if symptom relief, then every other day Western medicine: two drugs (Serc ⁴ & Vitamin B ₃) and Vitamin B ₆ n=76 (I=39; C=37) China Follow-up: Short-term (end of treatment period)	MD patients attending hospital for acute attack Unknown duration	No TCM pattern diagnosis used to choose acupoints, but TCM rationale given Set acupoint prescription	69% (n=27) vs. 43% (n=16) symptom control (p<0.05) [symptoms of dizziness and vomiting controlled, return to normal life] 5% (n=2) vs. 5% (n=2) symptom relief [symptom relief, slight dizziness] Small, audiometrically confirmed, hearing change	Strengths of the study include: confirmed MD, random allocation to treatment groups, detailed overview of the treatments, and graded outcome measurements and audiometric testing. A detailed rationale for the treatment approach is also provided, including use of set acupoint prescription. The short length of follow-up limits the generalisation of the results, to evidence supporting short-term benefits only. The study reports also includes two case reports Overall quality judgement: Good

⁴ Serc is a drug whose active ingredient is betahistine, a medicine that closely resembles the natural substance histamine. *Betahistamine* aims to increase blood flow to the inner ear and is a diuretic, which may help decrease the pressure of fluid in the inner ear.

<p>Gao and Ni (2002)</p> <p>RCT</p>	<p>Scalp acupuncture & Western medicine vs. Western medicine & vitamin B₁ & B₁₂</p> <p>Acupuncture (or injected vitamins) once a day for 10 days as one course, total of 3 courses</p> <p>n=132: (I=58; C=74)</p> <p>China</p> <p>Follow-up: 2 yrs</p>	<p>Patients with MD, confirmed by two medical committees</p> <p>Up to 7 yrs</p>	<p>Set prescription without individualised diagnosis and treatment</p>	<p>89% (n=51) vs. 27% (n=20) total control of dizziness and hearing improvement (p<.001)</p> <p>[symptom control, on graded scale from total to basic, partial, not controlled and worse – symptoms measured in relation to the no. of attacks of a set of symptoms per month]</p> <p>84% vs. 49% hearing improvement (p<.001) [graded on scale from 0-14, 15-30 and >30 dB]</p>	<p>Strengths of the study include: confirmed MD, random allocation to treatment groups, detailed overview of the treatments, and graded (and quantitative) outcome measurements.</p> <p>Using scalp acupuncture is an appropriate treatment for symptoms originating from the nervous system, brain or ear. The chosen treatment approach is experimental, rather than a traditional TCM one.</p> <p>Overall quality judgement: Good</p>
<p>Yu & Shi (1997)</p> <p>CT</p>	<p>Acupuncture vs. Western medicine & vitamin</p> <p>Acupuncture - key points and specific points, according to individual diagnosis. Western medicine (vitamin C and Luminal (an anti-convulsive drug) injection)</p> <p>No details given on daily frequency or number of sessions of acupuncture</p> <p>n=168 (I = 86; C=82)</p>	<p>Unclear if confirmed MD</p> <p>1-7 yrs</p>	<p>Treatment group has TCM diagnosis and individualised treatment; control group has set acupoints.</p>	<p>60% (n=52) vs. 39% (n=32) cured [cured = all symptoms disappeared, return to work, no recurrence after 2 yrs] (p<0.01)</p> <p>30% (n=26) vs. 8% (n=7) outstanding improvement [all symptoms disappeared, return to work, no recurrence after 1 yr]</p> <p>9% (n=8) vs. (27% (n=22) effective [symptoms disappeared</p>	<p>Strengths include details over outcome measurement; length of follow-up; use of TCM pattern differentiation. Weaknesses include: lack of clarity over how patients are allocated to the two treatment groups; MD not confirmed; and limited detail over treatments (form or frequency).</p> <p>Overall quality judgement: Fair</p>

	China			but recur within 6 mths, return to work]	
	Follow-up: 2 yrs				
Qin & Jia (2003) CT	Scalp and ear acupuncture vs. body acupuncture Scalp and ear acupuncture once per day for 10 days, plus patients (taught to) self-treat for 5 days. Body acupuncture once a day for 10 days n= 102 (I=72; C=30) China Follow-up: none	Confirmed MD by hospital Duration – no information	Set prescription without individualised diagnosis and treatment	53% (n=43) vs. 33% (n=10) cured (p<0.01) [cured = dizziness and other symptoms disappeared] 27% (n=21) vs. 23% (n=7) marked improvement [symptoms relieved, can return to work] 18% (n=14) vs. 17% (n=5) 'effective' [relief of dizziness, but affects work and life]	Strengths include details over acupuncture treatment (and rationales) and outcome measurement. Weaknesses include: lack of follow-up; and lack of clarity over how patients are allocated to the treatment groups.. Scalp acupuncture is a relatively new treatment method and has been shown to be effective for the treatment of brain and nerve system originated problems. Overall quality judgement: Fair
Pre-Test, Post-Test Design				A purposively designed study (as opposed to a series of cases) of a selected group, with measurement of treatment effect before and after (last treatment or end of follow-up time).	
Li & Li (1993)	Acupuncture Once a day for 20 days n=56 China Follow-up: 1yr	Patients with MD in acute phase (all previously treated with Western medicine without effect) Up to 8 yrs	Set prescription, needling one point (Gang Shen), based on clear rationale	77% (n=43) acute symptom control after one treatment, 16 % (n=9) after two. All experienced beneficial results Most patients needed	Lack of detail over choice of participants, except in an acute phase. Gang Shen as an experimental point for Ménière's Disease. Extensive details over treatment procedure and rationale of the treatment methods are provided. Outcome measurement is inconsistent from pre to post-

				only 7 sessions to experience benefit.	treatment. Overall quality judgement: Fair
Li (1999)	Herbal medicine and ear acupuncture, for 2-60 days n=90 China Follow-up: 1 yrs	Patients with MD according to explicit criteria Up to 20 yrs	Individualised treatment following TCM principles for herbal medicine, ear acupuncture points set in conjunction with herbal medicine	72% (n=65) cured 18% (n=16) improved [definitions of 'cured' and 'improved' relate to TCM descriptions]	Strengths include: clear diagnostic criteria, appropriate TCM principles and outcome measurement in relation to these principles and descriptions. But lack of detail over treatment duration or choice of participants. Note: this is predominantly a herbal approach with ear acupuncture as an adjunct. Overall quality judgement: Good
Dong & Zhou (2001)	Scalp acupuncture plus herbal medicine Once daily acupuncture for 7 days; simple herbal tea (to continue tea for 1 yr) n=180 China Follow-up: 1 yr	MD acute stage (hospitalised following acute attack) Up to 10 yrs	TCM individualised diagnosis and treatment, with herbal remedy adjusted	70% (n=126) cured [dizziness and other symptoms disappeared, no recurrence] 18% (n=33) outstanding effect [dizziness and other symptoms disappeared, occasionally light recurrence] 8% (n=15) improved [dizziness improved or disappeared, sometimes recurring]	Strengths include: clarity over outcome measurement; TCM diagnosis and treatment; and length of follow-up. Overall quality judgement: Good

Sun & Li (2001)	Moxibustion at Du-20 Twice a day for 15 days n=20 China Follow-up: 1 yr	Patients with clinically confirmed MD Up to 2 yrs	Du-20 is a good experiential point Specific TCM pattern	75% (n=15) cured [all symptoms disappear, no recurrence at 1 yr] 25% (n=5) outstandingly improved [symptoms relieved, no recurrence at 6 mths]	Use of standard diagnosis criteria and outcome measurement criteria for Ménière's. Treatment also included advice on diet and emotion. Good detail on treatment procedure. Overall quality judgement: Good
Post-Test Design			A purposively designed study (as opposed to a series of cases) of a selected group, with measurement of treatment effect after last treatment or at end of follow-up time.		
Liu (1995)	Acupuncture 10 sessions for 1 month n= 51 China Follow-up: 2 yr	MD – query over criteria Duration – no information	Individualised treatment following TCM principles	22% (n=11) cured [all symptoms disappear, no recurrence within 2 yr] 69% (n=35) improved [relief of symptoms, reduction of attack frequency and shortened duration]	Strengths include: appropriate TCM principles. But lack of detail over treatment duration, choice of participants and diagnostic criteria for Ménière's. Overall quality judgement: Poor
Chao (1996)	Moxibustion at Du-20 (over 2 hours), for up to 3 sessions n=32 China Follow-up: 2 yrs	Confirmed MD (Otolaryngology department) av. 9 years	Du-20 is a good experiential point for dizziness. Not diagnosed according to TCM theory. Note: moxibustion only	100% symptom relief (8 from one session, 10 from two, and 14 after three). No recurrence after two years.	Strengths include: MD confirmed by Otolaryngology department; use of standard treatment duration; Du-20 an appropriate treatment point; and length of follow-up. Weaknesses include: unclear sampling criteria; sole focus on one MD symptom (dizziness); and lack of control group. Overall quality judgement: Fair

<p>Bo (2002)</p>	<p>Acupoint injection at Du-20</p> <p>Once a day for 10 days, 1 day break, then another course of treatment (3-30 sessions in total)</p> <p>n=88</p> <p>China</p> <p>Follow-up: not stated</p>	<p>Patients with MD according to 'book' of common diseases</p> <p>Up to 3 yrs</p>	<p>Set, single point used, with TCM rationale</p>	<p>75% (n=66) cured [dizziness and other symptoms relieved, no recurrence after stopping treatment]</p> <p>23% (n=20) improved [dizziness and other symptoms improved; after stopping treatment occasional recurrence]</p>	<p>Clear diagnostic criteria with detailed treatment procedure. But duration of follow-up is not stated. The outcome measurement seems to be that the causes of dizziness disappeared.</p> <p>Overall quality judgement: Fair</p>
<p>Wang & Chen (2002)</p>	<p>Acupuncture points injection with Dansheng liquid on one side at one time plus scalp acupuncture</p> <p>Acupuncture with injection once a day, with scalp acupuncture every other day, for 10 days. 5 day break, second course of treatment</p> <p>n=50</p> <p>China</p> <p>Follow-up: 2 yrs</p>	<p>Patients with MD (and detail provided on nature & duration of symptoms)</p> <p>Up to 14 yrs</p>	<p>Set prescription but based on good TCM treatment principles</p>	<p>62% (n=31) cured [all symptoms disappear, no recurrence at 2 yrs]</p> <p>30% (n=15) outstandingly improved [all symptoms disappear, occasional recurrence within 2 yrs]</p>	<p>Combined traditional and scalp needling plus points injection seems a potentially good treatment method, and based on TCM principles. While diagnosis is based on TCM principles, treatment is not individualised. Good detail on treatment procedures.</p> <p>Overall quality judgement: Fair</p>
<p>Zhou (2002)</p>	<p>Acupuncture</p> <p>3-15 sessions, once per</p>	<p>MD – query over criteria</p>	<p>TCM pattern differentiation</p>	<p>80% (n=16) cured [all symptoms disappeared]</p>	<p>Lack of detail over choice of participants or diagnostic criteria for Ménière's. While diagnosis is</p>

	day (average of 9) n=20 China Follow-up: 1 yr	Up to 8 yrs		20% (n=4) improved	individualised, the treatment points are only for one TCM diagnosis pattern. It is unclear if the treatment is individualised. Overall quality judgement: Poor
Zhang (2003)	Acupuncture Once a day for 10 days, 5 day break, another course n=60 China Follow-up: 2 yrs	MD – query over criteria Up to 10 yrs	Set acupoints based on explicit TCM rationale for point choice	60% (n=36) cured [all symptoms disappear, no recurrence at 2 yrs] 30% (n=18) outstandingly improved [all symptoms disappear, recurrence within 1 yr]	Strengths include: explicit rationale for set acupoint prescription, based on TCM theory and extensive details over treatment methods. It is unclear how many courses were provided and lack of detail over diagnostic criteria. Overall quality judgement: Poor
Case Series				All the following are reports on a series of cases with MD, treated over a number of years.	
Song & Yi (1992)	Acupuncture Once a day until all symptoms disappear (mean=5; range 2->10) n=152 China Follow-up: unclear	MD – query over criteria Up to 15 yrs	Treatment following TCM principles, but only for the one symptom of dizziness	91% (n=138) cured over short term [all symptoms disappear, no recurrence] 8% (n=2) improved	Strengths include: treatment based on appropriate TCM principles. But lack of detail over choice of participants or diagnostic criteria for Ménière's, treatment not individualised, no standard course of treatment, and unclear length of follow-up Overall quality judgement: Poor
Zhu (1995)	Acupuncture n=51	Patients with MD at an acute stage	No TCM diagnosis differentiation or	64% (n=32) cured [dizziness and vomiting ceased, after one	Following appropriate TCM principles for treating two symptoms of Ménière's, but

	China Follow-up: not indicated	Up to 6 yrs	individualised treatment. Use of correct treatment for dizziness with vomiting	treatment] 32% (n=16) outstanding effect [after 3 sessions, symptoms under control, no vomiting, some dizziness]	limited detail and no explicit follow-up mentioned. Overall quality judgement: Poor
Zhang & Shang (1996)	Acupuncture Once a day for 3 days (as one course) n=286 China Follow-up: 1 yr	Patients with MD Up to 24 yrs	Appropriate acupuncture at single point. No TCM pattern differentiation	57% (n=162) cured [all symptoms disappear, no recurrence] 28% (n=81) outstanding effect [all symptoms disappear, recur at 6 mths] 13% (n=36) effective [all symptoms disappear, recur at 3 mths]	The study reports on a large group of patients; the treatment provided is an integrated treatment for Ménière's. There is a lack of detail over the number of courses given. Overall quality judgement: Fair
Wang (1999)	Acupuncture plus moxibustion at Du-20 Once a day for 7 days as one course of treatment n=30 China Follow-up: 2 yrs	MD – query over criteria Up to 10 years	TCM pattern differentiation and treatment	97% (n=29) cured [all symptoms disappear, no recurrence at 2 yrs]	Reporting on cases treated since 1988 and paper comments on the benefits of acupuncture for dizziness. This raises a query over its focus (dizziness) and outcome measurement. Overall quality judgement: Poor

Key

RCT = Randomised controlled trial; CT = Controlled trial; MD = Ménière's Disease; I = Intervention; C = Comparison/Control