Australian Journal of Acupuncture and Chinese Medicine

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18 – 20 May 2007

First Announcement & Call For Abstracts

Brisbane Convention and Exhibition Centre
Merivale Street (Cnr Glenelg), South Bank, Brisbane, Queensland AUSTRALIA

The Australian Acupuncture and Chinese Medicine Association Ltd (AACMA) cordially invites you to attend the Australasian Acupuncture and Chinese Medicine Annual Conference (AACMAC) from 18 to 20 May 2007 in the delightfully diverse river city of Brisbane – offering a tantalising blend of dining, shopping, nightlife and culture.

AACMAC 2007 will be held at the state-of-the-art Brisbane Convention & Exhibition Centre set in the inner-city riverside South Bank Parklands precinct. As with previous conferences, papers and workshops will cover a broad range of themes in research, theory and clinical application.

Pre-conference drinks will be held in the Plough Inn Tavern, situated within South Bank Parklands.

The AACMAC Brisbane 2007 Gala Dinner will be held within walking distance of the conference venue at the superb South Bank River Room. You will be able to enjoy a magnificent riverside location with uninterrupted views along the Brisbane River.

Academic conferences are important vehicles, not only to promote academic exchange and to encourage debate and dialogue within the profession, but also for the formation and development of friendships and networks between individual practitioners, academics and researchers. AACMAC Brisbane 2007 is the peak regional convention for networking between acupuncture and Chinese medicine practitioners and should not be missed.

CONFERENCE PROGRAM

Friday 18 May	(10.00 am)	|	AACMAC Registration Desk Opens
Friday 18 May	(1.00 pm – 5.30 pm)	|	Workshops (Day 1)
Friday 18 May	(6.00 pm – 7.00 pm)	|	Cocktail Party – Plough Inn Tavern, South Bank
Saturday 19 May	(8.00 am – 4.00 pm)	|	Annual Conference & Trade Exhibition (Day 2)
Saturday 19 May	(4.00 pm – 6.00 pm)	|	AACMA/AESO Annual General Meeting
Saturday 19 May	(7.00 pm – 12.00 am)	|	AACMAC Gala Dinner – The River Room, South Bank
Sunday 20 May	(8.30 am – 5.00 pm)	|	Annual Conference & Trade Exhibition (Day 3)

Information on delegate registration and guidelines/deadlines for submitting an abstract for oral, poster or workshop presentation can be obtained from the conference website **www.acupuncture.org.au** or on application to AACMAC Secretariat (details below).

For more information, please contact:
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Editorial

Welcome to this first issue of the *Australian Journal of Acupuncture and Chinese Medicine*.

In 2000 Victoria became the first state to introduce statutory registration of Chinese medicine. This is not only the first for Australia, but also one of the first outside China. The empowering legislation signifies the rapid development of Chinese medicine in Australia. Today, over 50% of all Australians use alternative and complementary medicine products and services, including acupuncture and Chinese medicine.[1] Four universities and three private institutions in Australia offer degree-level courses in acupuncture and/or Chinese herbal medicine. The current number of primary practitioners is likely to be between 2000 and 3000, increased from 1500 in 1996.[2]

Unlike in China, where Chinese medicine is integrated into the public health system and provides 40% of the national health care,[3] in Australia it is considered a complementary medicine. Over the years, Australian practitioners and academics have developed Chinese medicine alongside Western medicine and found and established our own place for promoting and maintaining the health of the Australian population.

It is timely that we have a journal in which we share our wealth of knowledge, experience and thoughts, a journal that reflects the standards and quality of Chinese medicine health services, education and research, and a journal that leads its further development. The Australian Acupuncture and Chinese Medicine Association Ltd (AACMA) has made this possible. In 2005 the *Australian Journal of Acupuncture and Chinese Medicine* (AJACM) was conceived.

Since then, various international and Australian practitioners and researchers have accepted invitations to be on the International Advisory Board and Editorial Board. Each of the Editorial Board members is involved in the production of the Journal. My job as the Editor-in-Chief is to draw together all these efforts and to ensure that high standards are maintained.

The Journal is a high quality, peer-reviewed journal, and aims to promote the integration of research, education and practice, and to help answer questions such as, 'how effective is acupuncture or Chinese medicine?', 'how can we enhance its efficacy?', 'how is acupuncture or Chinese medicine practised?' and 'how can we produce graduates of the highest quality?' The Journal acknowledges and respects the diversity of practice and research in Chinese medicine.

In this first issue, a systematic review of acupuncture for migraine brings us positive news and illustrates the importance of high quality clinical research. A general paper argues that acupuncture clinical research needs to generate knowledge that helps practitioners' clinical decision-making. In order to encourage clinicians to publish their clinical experience, a guideline on how to write a case report has been constructed for this Journal and a model case included. Other papers in the first issue are about reporting adverse reactions to Chinese herbal medicine and its current status, and standards for reporting clinical trials of herbal medicine. Book reviews and brief accounts of current research and clinical application are presented for our busy practitioners. For those who would like to learn more about cited research, we provide URLs for further reading.

This Journal is essentially for Australian practitioners and academics and also aims to attract international contributors and readers. We would like to hear what you have to say about the Journal. You are most welcome to write to or e-mail the Editor to express your views and suggestions.

Since announcing the commencement of the Journal in late 2005, we have received a number of submissions from overseas and Australia. We would like to thank all the contributors for their support. The Journal will be published biannually from 2007. However, we envisage that within a short period it will be published quarterly.

Finally, I would like to thank the Editorial Board and the editorial team for their hard work. Without their enthusiasm, expertise and late night work, the first issue would not have been possible. My appreciation also goes to the Managing Editor and staff and Management Committee for their financial and administrative support.

Zhen Zheng
Editor-in-Chief

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Introduction to the Editorial Board

Zhen Zheng

Zhen lectures within the Division of Chinese Medicine in the School of Health Sciences at RMIT University in Melbourne and is also a practitioner of acupuncture and Chinese herbal medicine. Zhen is a director on the AACMA Board, a member of the AACMA Research Committee and a member of the Course Approval and Hearing Panels of the Chinese Medicine Registration Board of Victoria. Zhen's research interests include assessing and understanding the efficacy of acupuncture analgesia through clinical trials and research with healthy humans. She has been actively promoting the modern understanding of pain and the use of acupuncture for pain management to both conventional and complementary health professions. Her other area of interest is the teaching of critical thinking skills required in the conduct of research.

Christopher Zaslawski

Chris is the director of the College of Traditional Chinese Medicine at the University of Technology, Sydney (UTS) and is also a practitioner of acupuncture and Chinese herbal medicine. He is a member of the UTS Human Research Ethics Committee as well as a member of the Australian Council for Chinese Medicine Education Ltd. Chris's research interests cover the area of acupuncture and pain, as well as research methodology and human research ethics.

John Deare

John is a part-time lecturer in Chinese medicine at the Australian College of Natural Medicine in Southport, Queensland, and is also in private practice. He is currently undertaking research towards a Doctorate of Philosophy at RMIT University. John is the Vice-President of AACMA, Chair of the AACMA Research Committee and a director of the Australian Council for Chinese Medicine Education Ltd. John's interests lie in the area of needling techniques for pain management and acupuncture physiology.

Peter Ferrigno

Peter is a lecturer in Chinese medicine at Victoria University, where he is a candidate for a Doctorate of Philosophy. Peter is interested in the transmission and reconstruction of Chinese medicine ideas in Australia, particularly the understanding of acupoint functions and herbal formulae, as well as the clinical experience of patients and practitioners, the therapeutic alliance and ways of enhancing student learning.

Damien Ryan

Damien is a senior lecturer in Chinese medicine and is currently the Acting Head of the School of Health Sciences at Victoria University. He is a foreign editor of the Chinese Archives of Traditional Chinese Medicine and an honorary professor at Liaoning College of Traditional Chinese Medicine and the affiliated hospital in Shenyang, China. Damien's research interests include the uses, application and effectiveness of Chinese medicine, the characteristics of and use of evidence in Chinese medicine practice and education in Australia, and the cultural influences upon health and health practice.

Caroline Smith

Caroline is an adjunct associate professor in the Centre for Complementary Medicine Research at the University of Western Sydney. She is currently a visiting research fellow at the University of Adelaide, South Australia. In addition to being a practising acupuncturist, Caroline conducts leading research into acupuncture for women's health and is interested in the integration of Chinese medicine and biomedical research protocols as well as prevalence studies of complementary and alternative medicines.

Acupuncture for Migraine: A Systematic Review

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ABSTRACT

Background: Migraine is a highly prevalent and often severely disabling disorder. Migraine patients often employ therapies such as acupuncture. To date a systematic review of acupuncture for migraine headache alone has not been published. Given that migraine has a pathophysiology that is distinct from other headaches, it is appropriate and timely that the studies of acupuncture for the treatment of migraine be systematically reviewed. Objectives: To determine whether acupuncture is more effective than no treatment for migraine, more effective than 'sham' or placebo acupuncture for migraine, or as effective as other interventions used to treat and prevent migraine. Selection criteria: Randomised controlled trials of needle acupuncture that breaks the skin for migraine headache. Data collection: The authors used a standardised collection form to abstract data independently. Information on acupuncture protocol, STRICTA criteria, methodological quality (Jadad, IVS) and treatment outcomes were collected. Results: Twenty-five studies with a total of 3004 patients (median = 62; range = 30–794) met the inclusion criteria. Three trials compared acupuncture to waiting list. Eleven trials compared acupuncture to sham acupuncture studies. The results were heterogeneous. Five studies found no significant effects over the sham procedure. Four studies reported a trend in favour of acupuncture. The remaining two small studies reported results in which the acupuncture group did significantly better than those in the sham group. Thirteen studies compared acupuncture to various pharmacotherapies and all found acupuncture to be at least as effective as drug treatment. Conclusion: The current evidence suggests that acupuncture is significantly superior to waiting list, at least as good as sham acupuncture, and of comparable efficiency to several proven drug therapies for the treatment and prevention of migraine.

KEYWORDS acupuncture, migraine, headache.

Introduction

Migraine is a highly prevalent and often severely disabling disorder. As many as 16% of men and 25% of women will experience migraine in their lifetime.[1] Olesen[2] suggests that the total sum of suffering from migraine is greater than for any other kind of headache. Migraine is defined as a moderate to severe recurrent headache lasting between four and 72 hours, usually unilateral and pulsatile in quality. It is often accompanied by nausea or vomiting and is aggravated by routine activities, light and noise.[2] According to Edmeads,[3] up to 48% of migraine sufferers have tried complementary therapies, while only 44% see a medical practitioner. Patients who access complementary therapies are more likely to use them in combination with mainstream treatment.[3] Despite the fact that migraine patients employ therapies such as acupuncture on a regular basis, until recently very little high quality clinical evidence existed to support or refute its efficacy.

A recent Cochrane review of acupuncture for idiopathic headache[4] (including migraine) concluded that, overall, the existing evidence supports the value of acupuncture treatment for this condition, but the quality of evidence is not fully convincing.[4] Since this review was undertaken in 2000, at least nine randomised controlled trials of acupuncture for

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the treatment of migraine headache have been published.[5-13] To date, a systematic review of acupuncture for migraine headache alone has not been published. Given that migraine has a pathophysiology that is distinct from other headaches,[2] it is appropriate and timely that the studies of acupuncture for the treatment of migraine be systematically reviewed.

OBJECTIVES

The objective of this review is to determine whether acupuncture is:

- more effective than no treatment for migraine;
- more effective than 'sham' or placebo acupuncture for migraine; or
- as effective as other interventions used to treat and prevent migraine.

Criteria for considering studies for this review

TYPES OF PARTICIPANTS

Trials which explicitly stated that they were conducted among patients with migraine headaches were considered for inclusion. Criteria such as those of the International Headache Society[14] or those of the Ad Hoc Committee[15] were used to define migraine, but included studies were not limited to these definitions. Studies of patients with tension-type headache, cluster headache, facial pain or imprecisely classified chronic or recurrent primary headache were excluded.

TYPES OF INTERVENTION

Only studies with needle insertion that breaks the skin at acupuncture points, pain points or trigger points were included. Studies which employed only non-invasive interventions, such as acupressure, laser or TENS, were excluded, as were studies in which a substance was injected into the needled point.

Control interventions considered were:

- no treatment,
- sham or placebo acupuncture, or
- other treatment.

TYPES OF OUTCOME MEASURES

Studies were included if they reported at least one clinical outcome related to headache (e.g. pain intensity, global assessment of headache). Trials reporting only physiological or laboratory parameters were excluded.

TYPES OF STUDIES

Only randomised, controlled clinical trials with parallel or cross-over design were considered for inclusion.

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

The following sources were searched:

- MEDLINE, 1966 to March 2006;
- EMBASE, 1989 to March 2006;
- CISCOM;
- AMED;
- The database of the Cochrane Field for Complementary Medicine;
- The Cochrane Controlled Trials Register, 3rd quarter, 2005;
- Bibliographies of review articles and included studies;
- Bibliographies of textbooks on acupuncture, pain and headache;
- Attempts were made to contact authors via e-mail for unpublished data.

The search terms used for the electronic databases were '(acupuncture AND (headache OR migraine))'. Translators were accessed for all identified non-English language publications. However, publication bias is possible as no foreign language databases were searched. An update to this article is planned following review of any non-English language articles identified (languages to be searched include Chinese, French, Italian, German, Spanish, Swedish and Russian).

Methods of critical review of the literature

ELIGIBILITY

All references identified by the literature search were screened by the authors. The first step was to identify all articles on acupuncture treatment of migraine headaches that reported original data. Of the 162 studies so identified, 72 were excluded because they did not mention a valid control condition. The eligibility of the remaining 90 studies was then assessed in detail. Thirty-six were excluded because the subjects suffered from a headache other than migraine. A further 12 were eliminated because the intervention did not involve needle insertion that breaks the skin and 13 because they did not report a relevant clinical outcome. Four studies were excluded due to insufficient information regarding randomisation. A total of 25 studies met the inclusion criteria and were analysed. The characteristics of the included studies are summarised in Table 1 (pp. 8–11).

DATA EXTRACTION

Data were extracted independently by the authors using a standardised collection form. Information on patients, methods, interventions, outcomes and results was extracted using a standardised form similar to that of Melchart and colleagues.[4] Trials were categorised by headache type: migraine and migrainous disorders or mixed (patients with different

types of headache, including migraine), and by the type of control intervention used (no treatment, sham acupuncture, other treatment).

ASSESSMENT OF QUALITY

Quality was assessed by each author independently using both the Jadad Scale[16] and the Internal Validity Scale (IVS), which has been used in several systematic reviews of complementary medicine[4,17,18] to assess the methodological quality of included trials.

The Standards for Reporting Intervention in Controlled Trials of Acupuncture (STRICTA)[19] checklist was used by the authors to ascertain the type and quality of acupuncture treatment for each of the studies. The quality of acupuncture was assessed by the authors who have each undertaken a minimum of five years of full-time undergraduate and postgraduate training in acupuncture and have been in clinical practice for a minimum of seven years. Disagreements between reviewers regarding inclusion/exclusion, methodological quality or quality of acupuncture treatment were resolved by discussion.

Descriptions of included studies according to STRICTA criteria are summarised together with Jadad and IVS scores in Table 1.

However, STRICTA does not offer a scale to make a critical evaluation of studies. Therefore the scale used by Melchart and colleagues[4] was adopted with adaptations. The current authors decided independently, based on their clinical experience and review of the acupuncture literature, whether they would treat the patients in a given study 'exactly or almost exactly the same way', 'similarly', 'differently', 'completely differently', or 'could not assess' due to insufficient information (based on STRICTA criteria). Individualised treatment was considered most reflective of clinical acupuncture practice, followed by formula acupuncture, trigger points, etc.

The authors then rated the degree of confidence that acupuncture was applied in an appropriate manner, with 0% = complete absence of evidence that the acupuncture was appropriate and 100% = total certainty that the acupuncture was appropriate.[4] These ratings are included along with Jadad and IVS scores in Table 1.

SUMMARISING THE RESULTS

The pre-defined main outcome measure for quantitative analysis was the number of days with headache per month in the last follow-up period. Other pre-planned outcomes included intensity of pain, duration and frequency of headache attacks and medication use. However, when the data were extracted the type and timing of outcome measures were so inconsistent and the presentation of results so often insufficient that it was not possible to calculate effective size estimates for the majority of the trials. No power analysis was carried out.

Data on global response to treatment or frequency of headache was extracted. Response was defined as at least 33% improvement from baseline. The relative risk was then calculated with 95% confidence intervals by the proportion of responders in the acupuncture group and proportion of responders in the control group, using the Toronto University EBM Stats Calculator.[20]

Methodological Assessment

Twenty-five studies with a total of 3004 patients (median = 60; range = 30–794) met the inclusion criteria.[5-13,21-36] The majority of the trials had methodological and/or reporting shortcomings. Allocation concealment was described in only seven trials.[6,7,9,11-13,22] The mean Jadad Score was 2.3 (range = 1–5) from a possible maximum score of 5, and the mean Internal Validity Score was 3 (range = 0.5–6) from a possible maximum score of 6.

Overall the reporting of the complex headache data was poor but has improved significantly since the systematic review of acupuncture for idiopathic headache by Melchart and colleagues.[4] The authors were unable to assess the quality of acupuncture in four trials due to insufficient information.[11,22-24] Relevant details according to the STRICTA criteria were lacking for most studies (see Table 1). In seven trials the authors would have treated in a different or completely different manner, in thirteen trials similarly, and in one trial in exactly the same way.[5,9,21,31,33,35,36] The degree of confidence that acupuncture was applied appropriately ranged from 10% to 95% (see Table 1).

The acupuncture interventions used varied considerably. In seven studies the rationale behind the choice of points was explicitly stated to be Traditional Chinese Medicine.[7,8,10,12,25-27] Diener,[12] Linde[8,9] and Wylie[27] stated the source for their point selection strategy. Ten trials provided some information on the qualification and experience of trial acupuncturists.[5-7,9,11-13,29,30,33] Deqi was reported in ten studies.[5,6,8,9,12,13,22,29,30,34]

The median treatment period was eight weeks (range = 2 hours – 24 weeks) with eight treatment sessions (range = 1–16). Nineteen studies followed up after at least six months.[5,7-13,21-26,29-31,34,35] The median follow-up time was 42 weeks (range = 4–104).

The most commonly reported outcomes were headache frequency and pain intensity, but in many studies results were reported in insufficient detail. Medication use, quality of life, days off work and cost effectiveness were reported in a minority of trials. Nineteen trials used headache diaries for outcome assessment.[5,7-9,11-13,22-24,26-33,36]

TABLE 1 Acupuncture reporting and quality (STRICTA/JADAD/IVS)

Author	Acupuncture rationale	Needling details	Treatment regime
Agró et al.[10]	Formula acupuncture or acupuncture based on TCM principles of syndrome differentiation	Formula: ST8, GB5, GB20, GV14, LU7; or points according to TCM differentiation of syndromes	6 months treatment; 3 sessions; 15 days interruption; no information on number or duration of treatments
Alecrim-Andrande et al.[13]	Semi-standardised acupuncture vs sham acupuncture	Local points: GB12, GB20, GB21, BL10; plus points selected according to location of pain: BL60, SI3: BL22, ST36, GV23, LI4, TE5, GB34, GB8: SI3, GV20, LR3: PC6; Deqi achieved	Treatments twice weekly for 4 weeks then weekly for 8 weeks
Allais et al.[5]	Formula acupuncture. No sources given for treatment protocol	16 0.3 × 52 mm needles inserted bilaterally to a depth of 10–30 mm at SP6, ST36, CV12, LI4, PC6, GB20, GB14, Ex-HN5, GV20 and manipulated with the even method to achieve Deqi	Total of 12 treatment sessions: 1 weekly for 2 months then 1 monthly for 4 months
Baust et al.[28]	Formula acupuncture applied according to location of pain	If pain mainly frontal, GB14, Ex-HN3, LI4; temporal, Ex-HN9, GB20, TE5; occipital, GV15, BL10, BL60; no information on needling or Deqi	Total of 6 treatments at two day intervals
Ceccherelli et al.[32]	Formula acupuncture	Points used: BL2, BL10, BL60, GB3, GB20, GV11, GV20, LR3, CV13, Ex-HN1, ST8; no information on Deqi	Total of 10 weekly treatment sessions
Diener et al.[12]	Semi-standardised point selection based on differentiation of syndromes according to TCM based on Chinese and German texts	10–25 needles, 0.25–0.30 mm × 25–40 mm inserted 2–20 mm; Deqi achieved	1–2 treatments weekly; 10–15 treatments; 30 min duration
Doerr-Proske et al.[33]	Formula acupuncture at local points only; no sources given for protocol	Ex-HN2, GB2, TE5; no information on Deqi	Total of 10 treatment sessions, probably 1 per week
Dowson et al.[22]	Individualised acupuncture according to location of pain; no rationale or sources given	Point selection according to location of pain; Deqi achieved; no information on points, needles or technique	Total of 6 sessions, 1 per week
Gao et al.[25]	Acupuncture based on differentiation of syndromes according to Traditional Chinese Medicine	Filiform needles 0.25–0.30 × 50 mm. Evil-wind: BL60, SI7, GV20, GB20. Liver: LR3, GB43, GV20. Taiyang Kidney: KI3, BL23, ST36. Taiyang Stagntn: GB34, SP10. Ex-HN5, GV20, GB8; no information on Deqi	4–5 sessions per week; 10 treatments per course; 1–3 courses
Henry et al.[21]	Formula-based electroacupuncture; no source given for treatment protocol	Needling with electrostimulation at LI4, ST36, BL2, BL10, LR3, BL60; no information on Deqi	8 sessions of 30 min each; 6 × 1 per week; 2 × 1 per month
Hesse et al.[31]	Trigger-point acupuncture points chosen according to muscle groups and tenderness according to principles of trigger-point therapy	Needling at most tender trigger points plus placebo tablet; needling for few seconds only; no information on Deqi or on exact points or depth of needling	Individualised
Heydenreich et al.[35]	Individualised needle acupuncture or TENS to acupuncture points	Individually selected points from LR3, KI6, SP6, ST36 or 44, BL60 or 62, LU7, PC6, TE5, LI4, SI3 and local tender points; no information on needling or Deqi	12–16 sessions; 1 per week

Co-intervention	Practitioner background	Control interventions	Quality
No information	No information	Formula acupuncture vs acupuncture according to TCM differentiation of syndromes vs various pharmacotherapy	Jadad: 1-0-0-0-0 IVS: 1-0-1-0-0-0 Acu: similarly 70%
Rescue medications only; patients on prophylactic drugs were excluded	'Medical acupuncture specialist'	Minimal acupuncture with no manipulation to the following points bilaterally: Ex-B1, TE17, TE20, SP7, ST37, LU5	Jadad: 1-1-1-1-1 IVS: 1-1-1-1-1-1 Acu: similarly 50%
No limitation was placed on concurrent use of medications but these were recorded and used as an outcome measure	'3 experienced and qualified acupuncturists.' No information on duration of training or clinical experience	Control group received flunarizine, a well-documented drug for migraine prophylaxis; no attempt at blinding	Jadad: 1-1-0-0-1 IVS: 1-0-1-0-1-1 Acu: differently 50%
No information	No information	Sham points 2–3 cm distant from true points. No attempt at blinding; patients probably not completely informed that they might receive sham	Jadad: 1-0-1-1-0 IVS: 1-0-0-1-1-0 Acu: similarly 75%
No information	No information	Complex procedure without real needling suggesting anaesthesia to the patient; no source to validate sham intervention; patients blind	Jadad: 1-0-0-0-0 IVS: 1-0-0.5-1-0-1 Acu: similarly 70%
Acute medications recorded and allowed in all groups	>140 hours of acupuncture training; >2 years clinical experience (median = 8.5 years)	Sham acupuncture at non-acupoints on arm, back and thigh; 3 mm insertion; no stimulation	Jadad: 1-1-1-1-1 IVS: 1-1-1-1-1-1 Acu: similarly 75%
No limitation on concurrent use of medications, but these were recorded as an outcome measure	Anaesthetist trained in acupuncture; no information on duration of training or experience	Waiting list and bio-behavioral treatment program; no attempt at blinding	Jadad: 1-0-0-0-0 IVS: 1-0-0-0-0-0 Acu: completely differently 20%
No information	No information	Mock TENS; patients blinded, but likely ineffectively	Jadad: 1-1-0-0-0 IVS: 1-0.5-0.5-0.5- 0.5-0.5 Acu: insufficient data
Control group received ergotamine for acute attacks but other co-interventions not reported	No information	A traditional Chinese herbal preparation (*Zheng tian wan*), 1 bd plus ergotamine for acute attacks; no attempt at blinding	Jadad: 1-0-0-0-0 IVS: 1-0-0-0-0-0 Acu: similarly 85%
Medications recorded and used as outcome measure, but diary not employed	No information	Dry needling 1 cm away from points used in acupuncture group; patient and evaluator blind	Jadad: 1-0-1-1-0 IVS: 1-0-1-1-1-0 Acu: completely differently 40%
Medications and other co-interventions not mentioned	No information	Metroprolol and placebo stimulation (touch with blunt end of the needle); patients and evaluators blind; unusual acupuncture technique as sham distinguishable	Jadad: 1-0-1-0-1 IVS: 1-0-1-0.5-1-0.5 Acu: completely differently 50%
Medications recorded and used as outcome measure but method of measurement unclear (?diary)	No information	TENS or medication (iprazochrom and dihydroergotocin mesylate); no attempt at blinding	Jadad: 1-0-0-0-0 IVS: 1-0-1-0-0-0 Acu: differently 70%

TABLE 1 Continued

Author	Acupuncture rationale	Needling details	Treatment regime
Kubiena et al.[23]	Individualised acupuncture applied according to the Vienna school	4–5 local and 4–5 distal points; Vienna school points not given; no information on technique or Deqi	10–15 sessions; 1 per week
Lehmann et al.[24]	Needle acupuncture or electroacupuncture; no information on points, protocol or source	No information on points, needling or Deqi	12 sessions; 1 per week
Linde et al.[8]	Formula acupuncture based on earlier studies, manuals and personal advice from the University of TCM, Shanghai	15 × 0.25 mm or 30 × 0.30 mm needles inserted 10–30 mm at: GB8, GB20, LI4, LR3, SP6 and GB14 or Ex-HN5 or BL10; Deqi achieved	Needling on 8th, 5th and 3rd day before menstruation for 3 months; 9 sessions total
Linde et al.[9]	Semi-standardised formula acupuncture	Basic points GB20, 40, or 41 or 42, GV20, LR3, TE3 or 5 bilaterally, plus additional individual points; Deqi achieved	12 × 30 min sessions over 8 weeks
Loh et al.[36]	Brief acupuncture with strong stimulation; no information on rationale or source	Brief, strong needling at local points in neck and temporal region, e.g. GB20, GB21; distal points usually LI4 and LR3; 6 needles minimum	No information
Melchart et al.[6]	Individualised acupuncture; no information on rationale or source	0.3 × 4.0 mm or 0.25 × 2.5 mm needles inserted bilaterally, mainly at GB14, GB15, GB10, GB8, GB21, GB41, LI4, LR3, TE5, CV20, Ex-HN5, according to individual symptoms; Deqi achieved.	At the onset of an acute attack, 1–2 treatments within 2 hours
Melchart et al.[7]	Individualised acupuncture according to the principles of TCM	Example of individual treatment given for up stirring of wind heat with phlegm-damp and blood stasis: GB20, GB14, Ex-HN5, LI4, LI20, GV20, LR3	12 treatments over 4 weeks as TCM hospital inpatient
Vickers et al.[11]	Individualised acupuncture; no specification of type, rationale or source	No information	6–11 weekly sessions
Vincent[26]	Individualised acupuncture points selected on the basis of tenderness according to TCM text	8 points (4 bilateral) inserted 1–2 cm, chosen from LR3, GB20, GB21, BL10, BL11, TE15, SI14, SI15, Ex-HN5; no information on Deqi	6 sessions of 15 min; 1 per week
Weinschutz et al.[29]	Individualised acupuncture points chosen according to pain localisation and modalities	Up to 10 points chosen according to pain localisation and modalities with stimulation to achieve Deqi; no information on needling technique	8 sessions of 15 min; 1 per week
Weinschutz et al.[30]	Individualised acupuncture points chosen according to pain localisation and modalities	Up to 10 points chosen according to pain localisation and modalities with stimulation to achieve Deqi; no information on needling technique	8 sessions of 15 min; 1 per week
Wylie et al.[27]	Individualised acupuncture applied according to TCM	Points selected from CV20, GB20, SP6, BL2, ST36, ST40, GB41, KI3, GB14, LI4, TE5, PC6, Ex-HN5, Ex-HN3, Ah-shi; no information on needling or Deqi	6 sessions with unclear frequency

Co-intervention	Practitioner background	Control interventions	Quality
Medications recorded and used as outcome measure but data uninterruptible due to loss to follow-up	No information	Sham acupuncture at points 1.5–2 cm away from acu points; patients blind	Jadad: 1-1-1-0-0 IVS: 1-0-0-1-0.5-0 Acu: insufficient data
Medications recorded in diary and used as outcome measure	No information	Propanolol 75–150 mg/d; no attempt at blinding	Jadad: 1-0-0-0-0 IVS: 1-0-0-0-0-0 Acu: insufficient data
Medications recorded in diary and used as outcome measure	Experienced physiotherapist; no information on acupuncture training or experience	Varied pharmacotherapy; no attempt at blinding	Jadad: 1-0-1-1-1 IVS: 1-0-1-1-0.5 Acu: similarly 90%
Medications recorded in diary and used as outcome measure	Physicians trained (>140 hours) and experienced (c. 10 years) in acupuncture	At least 10 minimally inserted needles at non-acupoints; no stimulation; waiting list	Jadad: 1-1-1-1-1 IVS: 1-1-1-1-1-1 Acu: differently 75%
No prophylactic medication allowed; medications recorded in diary. Included as part of a global outcome measure	No information	Individualised medications usually propranolol; no attempt at blinding	Jadad: 1-0-0-0-0 IVS: 1-0-0-0-0-0.5 Acu: completely differently 25%
No other interventions allowed	Experienced Chinese acupuncturist trained at Beijing University of TCM	Sumatriptan or placebo injection; patients blind to injection content but not to acupuncture	Jadad: 1-1-0-0-1 IVS: 1-1-1-0-0-1 Acu: similarly 80%
Individualised Chinese herbal preparations	'Specifically trained and highly experienced Chinese physicians'	Waiting list	Jadad: 1-1-0-0-1 IVS: 1-1-1-0-0-1 Acu: exactly the same 95%
All treatments for headache recorded in diary and used in outcome measure	Physiotherapists with 250 hours of acupuncture training and median 12 years experience	Standard GP care; no attempt at blinding	Jadad: 1-1-0-0-1 IVS: 1-1-1-0-0-1 Acu: insufficient data
Medications recorded in diary and used as outcome measure	No information	Superficial needling 2–3 cm from classical points; patients blind	Jadad: 1-0-1-0-0 IVS: 1-0-1-1-0-0 Acu: similarly 60%
Not reported	1 experienced and qualified acupuncturist	Sham acupuncture; superficial needling 2–3 cm from true points; patients blind	Jadad: 1-0-0-0-0 IVS: 1-0-0.5-0.5-0-0 Acu: similarly 75%
Not reported	1 experienced and qualified acupuncturist	Sham acupuncture; superficial needling 2–3 cm from true points; patients blind	Jadad: 1-0-0-0-0 IVS: 1-0-0.5-0.5-0-0 Acu: similarly 75%
Acupuncture group received lifestyle counselling; other co-interventions not recorded	No information	Massage and relaxation	Jadad: 1-0-0-0-0 IVS: 1-0-0-0-0-0 Acu: similarly 80%

Results

Relative risk calculations for high quality studies where dichotomous responder rates were reported are presented in Table 2. These calculations must be interpreted with caution due to the differing outcome measures of various studies.

ACUPUNCTURE VS SHAM CONTROLLED TRIALS

Eleven trials (*N* = 1324) compared acupuncture to sham acupuncture among patients with migraine.[8,9,12,13,21,23,26,28-30,32] Two compared acupuncture to other sham procedures.[6,22] Melchart[6] compared acupuncture to placebo injection while Dowson[22] compared acupuncture to mock TENS. Two studies comparing acupuncture to sham were not analysed due to poor methodological quality or reporting flaws.[29,30] The study by Melchart[6] is analysed separately below because the outcomes relate solely to relief of acute migraine attacks.

Five studies[8,9,13,22,28] found no significant effects over the sham procedure (RR 0.973 95%CI [0.74–1.17]). Three studies[12,21,23] reported a trend in favour of acupuncture (RR 1.18 95%CI [0.93–1.50]). The remaining two small studies[26,32] reported results in which the acupuncture group did significantly better than those in the sham group (RR 1.82 95%CI [1.1–3.1].

Diener[12] conducted the largest study to date (*n* = 794), which compared true acupuncture, sham acupuncture and standard migraine prophylaxis. It was methodologically rigorous but suffered from a large dropout rate. The strengths of the study were its large sample size, comparison to sham and established pharmacotherapy, valid outcome measures and an acupuncture protocol similar to clinical practice. All three arms improved significantly over baseline and there was no consistent difference in outcomes between groups. However, an explorative analysis favours true acupuncture over sham acupuncture, particularly for mean reduction in headache days (true = 2.3 days 95%CI [1.9–2.7]; sham = 1.5 days 95%CI [1.1–2.0]).

TRIALS COMPARING ACUPUNCTURE TO WAITING LIST

Three trials (*N* = 434) compared acupuncture to waiting list.[7,9,33] The data from the study by Doerr-Proske[33] was not analysed due to poor methodological quality.

Melchart[7] was the only study of inpatient management of migraine with acupuncture and co-interventions including Chinese herbal medicine and Qigong. Patients were randomised to four weeks of inpatient treatment in a German Traditional Chinese Medicine hospital or waiting list. Patients receiving acupuncture had significantly better outcomes compared to controls (>50% decrease in headache days RR 3.35[1.61–6.99]).

The study by Linde[9] is large and methodologically rigorous. It compared formula acupuncture, sham acupuncture and waiting list. Both formula acupuncture and sham acupuncture were significantly superior to waiting list (RR 3.53 95%CI [2.00–6.23]), but formula acupuncture was not superior to sham.

The combined results of the 404 patients in both of the well-designed trials[7,9] strongly suggest that acupuncture is significantly superior to waiting list (RR 3.17 95%CI [2.00–5.00]).

TRIALS COMPARING ACUPUNCTURE WITH ANOTHER TREATMENT

Thirteen trials (*N* = 2243) comparing acupuncture to another treatment were analysed.[5,6,10-12,24,25,27,31,33-36] Two studies compared acupuncture to other non-pharmacological therapies but due to poor methodological quality and inadequate reporting, no meaningful data could be extracted.[27,33] In studies comparing acupuncture to pharmacotherapy, all showed results for the acupuncture group that were as good as or better than the pharmacotherapy group.[5,6,10-12,24,25,31,34-36] Five studies were of high methodological quality, had larger sample sizes and were more clearly reported.[5,6,11,12,31] The remaining six studies were of low methodological quality and suffered significant reporting deficits, which prevented extraction of meaningful data.[10,24,25,34-36]

Hesse[31] compared trigger-point acupuncture and a placebo tablet with metoprolol and sham acupuncture. The strength of this study was that it attempted to blind both patients and evaluators, but it is likely that the sham intervention (touching with the blunt end of the needle) was discernable from true needling. The authors claimed that intervention and control were equally effective. However, metoprolol also had more side effects. Both groups showed significant improvements in migraine frequency and intensity but responder rates were not recorded and as such the data cannot be pooled with the other studies.

Allais[5] compared acupuncture with the calcium channel blocker flunarizine for women with migraine headache. Flunarizine has been unequivocally demonstrated to be effective and well tolerated in almost 20 placebo controlled trials. Allais[5] found that both acupuncture and flunarizine were effective in migraine prophylaxis (RR 1.31 95%CI [0.52–3.25]). Acupuncture was more effective in the first four months and more effective in reducing intensity and analgesic use with fewer side effects.

Vickers[11] randomised 401 patients to either 'use acupuncture' or 'avoid acupuncture' in addition to 'standard' therapy. Their findings suggested that a policy of 'use acupuncture' in addition to 'standard' therapy resulted in a significant and cost-effective reduction in migraine frequency and intensity compared to 'standard' therapy and a policy of 'avoid acupuncture' (RR 2.03

TABLE 2 Results: Acupuncture for Migraine Prophylaxis[a]

Study	Acu[b] (n_R/n_P)	Control (n_R/n_P)	Relative risk (95% CI)	Weight (%)	Relative risk (95% CI)
Acupuncture vs sham procedure			0.1 Favours control 1 Favours acupuncture 10		
Baust et al.[28]	14/23	14/21		4.1%	0.91[0.58–1.43]
Alecrim-Andrande et al.[13]	6/12	3/12		2.2%	2.00[0.65–6.20]
Diener et al.[12]	87/290	84/317		55.9%	1.13[0.88–1.46]
Dowson et al.[22]	11/25	13/23		4.6%	0.78[0.44–1.38]
Henry et al.[21]	11/20	3/10		2.7%	1.83[0.66–5.12]
Kubiena et al.[23]	3/7	4/11		1.6%	1.18[0.37–3.76]
Linde et al.[8]	2/13	2/13		2.6%	0.77[0.15–3.91]
Linde et al.[9]	66/145	42/81		21.0%	0.88[0.67–1.16]
Vincent[26]	7/15	6/15		2.7%	1.17[0.51–2.66]
All acupuncture vs sham procedure trials	220/565	177/520		100%	1.14[0.98–1.34]
Acupuncture vs waiting list					
Melchart et al.[7]	24/46	7/45		29.2%	3.35[1.61–6.99]
Linde et al.[9]	66/145	11/76		70.8%	3.53[2.00–6.23]
All acupuncture vs waiting list	90/191	18/121		100%	3.17[2.00–5.00]
Acupuncture vs pharmacotherapy					
Allais et al.[5]	10/77	7/73		18.0%	1.31[0.52–3.25]
Diener et al.[12] (True acupuncture arm)	87/257	45/128		46.0%	0.96[0.72–1.29]
Diener et al.[12] (Sham acupuncture arm)	84/275	45/128		N/A	0.87[0.65–1.17]
Vickers et al.[11]	49/161	21/140		36.0%	2.03[1.28–3.21]
All acupuncture vs pharmacotherapy trials	146/495	73/341		100%	1.38[1.08–1.76]

[a] High quality trials only (Jadad or IVS ≥3); n_R/n_P = number of responders/number of participants. [b] Acu = acupuncture

95%CI [1.28–3.21]). The pragmatic trial design does not test the effects of a therapy but those of a policy. Consequently, the claims based on this study cannot be made regarding acupuncture itself, but only the policy of recommending it to migraine sufferers.

A unique study by Melchart[6] compared acupuncture, sumatriptan and placebo to treat acute migraine headache. The acupuncture and sumatriptan groups showed similar response rates (21/60 vs 21/58; RR 0.97 95%CI [0.59–1.58]) and were significantly better than placebo in aborting acute migraine attacks (primary outcome) (RR 1.94 95%CI [1.03–3.67]). However, a second dose of sumatriptan was significantly better than a second application of acupuncture at interrupting an established attack after failure of the initial treatment (4/31 vs 11/31) (Table 3).

Diener,[12] as discussed above, compared both true acupuncture and sham acupuncture to standard migraine prophylaxis with beta-blockers, calcium channel blockers or anti-epileptics. All three arms improved significantly over baseline and there was no consistent difference in outcomes between groups (acupuncture vs pharmacotherapy RR 0.96 95%CI [0.72–1.29]; sham vs pharmacotherapy RR 0.87 95%CI [0.65–1.17]).

Discussion

The current evidence suggests that acupuncture is significantly superior to waiting list, at least as good as sham acupuncture and of comparable efficacy to several proven drug therapies for the treatment and prevention of migraine. It is interesting to note the positive results for sham acupuncture in two of the largest trials indicating that sham acupuncture is likely to be an active placebo.

This systematic review builds on the results of the previous review by Melchart,[4] which supported the value of acupuncture in the treatment of idiopathic headache but found the quality

and amount of evidence lacking. The methodological quality of acupuncture research has improved substantially, largely as a result of the work by Melchart,[4] who has led many of the recent large-scale trials.

The size of trials has increased dramatically over the past five years. In the Cochrane review,[4] only two migraine studies[34,35] had more than 100 participants, whereas seven[5-7,9-12] of the eight[5-12] most recent studies have over 100 patients and three have over 300 patients.[9,11,12] This is particularly important because it provides the statistical power needed to draw firmer conclusions.

Three studies[9,11,12] since 2000 stand out for their methodological quality and large sample size. Their results are substantially homogeneous with respect to the efficacy of true acupuncture compared to pharmacotherapy, but differ in their findings with regards to the relative activity of sham acupuncture. Bearing in mind that the conventional pharmaceuticals used for the treatment of migraine have shown unequivocal superiority to inert placebos in hundreds of randomised controlled trials, it seems reasonable to hypothesise that sham acupuncture that breaks the skin is not therapeutically inert.

The fact that sham acupuncture is likely to be an active placebo is particularly relevant when analysing the results of the study by Linde,[9] which found no significant difference between true acupuncture and sham. It is likely that sham acupuncture activates endogenous antinociceptive mechanisms.

Non-specific needling effects may also account for the results of a recent small study by Alecrim-Andrande[13] who found true acupuncture equivalent to a sham procedure. These effects are likely to be compounded by the fact that real acupoints were needled in the so-called sham group. Alecrim-Andrande[13] clearly states that the points chosen as sham are not specifically indicated for headache in the Traditional Chinese Medicine literature. However, the use of points on the head and neck is likely to activate segmental antinociceptive mechanisms.[38]

Sham acupuncture often involves insertion of needles into non-acupoints. This methodology allows the examination of specific point related effects but adds the confounding factor of non-specific needling effects. In fact, the minimally inserted needle technique used in many studies as sham acupuncture is very similar to true acupuncture as practised by members of the Japanese Meridian Therapy, Keiraku Chiryo and Toyohari schools.[39] Furthermore, finding a neutral point is problematic because all points on the body are considered to be connected to the meridian system from the surface of the skin (cutaneous regions) through to the deep pathways of the primary and divergent channels.[40] This is also true from a neurobiological perspective, as any needle that breaks the skin causes a neurochemical response, which may lead to long-term changes in nociceptive processing.[38]

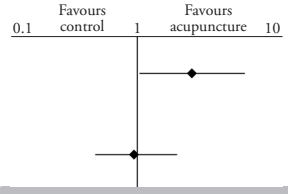
Placebo acupuncture with non-inserted needles has also been used and has the advantage of resembling real acupuncture and eliminating non-specific effects of needling in the control group. However, with placebo acupuncture it is difficult to maintain blinding in long-term studies and may only be effective for acupuncture-naive patients.

Alternatively, acupuncture can be compared to standard medical care. This has the advantage of allowing comparisons of effects and adverse events. However, it is often impossible to achieve adequate blinding and increases the risk of type II error. Ten trials have compared acupuncture to various types of pharmacotherapy and have all shown the results of acupuncture to be as good as or better than the control treatment.[5,6,10-12,24,25,31] In particular, the pragmatic trial by Vickers[11] comparing acupuncture with standard care indicates that acupuncture is beneficial and cost-effective under real-life conditions.

According to Vickers[11] standard care plus acupuncture resulted in persisting, clinically relevant benefits for migraine sufferers compared with controls treated with standard pharmacotherapy. However, because the study had no placebo control it is possible that the benefits in the acupuncture group were part

TABLE 3 Results: Acupuncture for Acute Migraine[a]

Study	Acupunct. (n_R/n_P)	Control (n_R/n_P)	Relative risk (95% CI)	Weight (%)	Relative risk (95% CI)
Acupuncture vs sham procedure (Melchart et al.[6])	21/60	11/61			1.94[1.03–3.67]
Acupuncture vs pharmacotherapy (Melchart et al.[6])	21/60	21/58			0.97[0.59–1.58]



[a] High quality trials only (Jadad or IVS ≥3); n_R/n_P = number of responders/number of participants.

of a placebo effect. Nonetheless, Vickers[11] states that the overall cost of managing migraine headache is reduced by the addition of acupuncture. As such, he called for the inclusion of acupuncture in addition to standard pharmacological treatment for migraine within the National Health Service in the United Kingdom.

IMPLICATIONS FOR RESEARCH

It seems likely that acupuncture has a place in the treatment of migraine, but several questions remain unanswered. The variety of acupuncture techniques examined in the literature and used in clinical practice makes it difficult to recommend specific acupuncture treatment strategies. Indeed, the work of Linde[9] calls into question the importance of point selection, location and needling technique in the treatment of migraine. Studies comparing true acupuncture, sham acupuncture and placebo needling would help to clarify the relative contribution of non-specific needling effects and placebo to the positive results of acupuncture for migraine.

It would also be informative to study the effects of true acupuncture and placebo pill against placebo needling and placebo pill, against a third arm of standard pharmacotherapy and placebo needling. This would help to clarify the relative contribution of placebo effects to the positive results of acupuncture.

Finally, it must be asked how much more evidence is necessary before acupuncture can be recommended to migraine sufferers. Diener[12] states that the efficacy of the treatment may be more important than unequivocal knowledge of its mechanism of action. The majority of pharmacotherapies used for migraine are clearly effective but have unclear mechanisms. Perhaps research efforts directed at maximising the therapeutic effects of acupuncture alone or in combination with drug treatment would be a more productive use of research funding.

IMPLICATIONS FOR CLINICAL PRACTICE

Advising migraine patients to use acupuncture is likely to reduce frequency of migraine headache, both in combination with or independent of medication. These benefits are associated with minimal side effects,[42,43] but the mechanism of action is unclear. The optimal acupuncture protocol has not been established by clinical trials. However, both shallow and deep needling techniques at a variety of points have been shown to significantly improve clinical outcomes.

Conclusion

The current evidence suggests that acupuncture is significantly superior to waiting list, at least as good as sham acupuncture and of comparable efficacy to several proven drug therapies for the treatment and prevention of migraine. Recent high quality evidence suggests that the addition of acupuncture to standard care is cost effective and improves outcomes in migraine headache. It is still unclear as to whether this is due to the specific effects of needling at acupuncture points or to the non-specific effects of needling and a potent placebo effect. Large scale, randomised, controlled trials comparing acupuncture with proven pharmacotherapies are warranted to assess the place of acupuncture in the management of migraine headache. The recent study by Vickers[11] indicates that it can be beneficially combined with standard therapy to improve outcomes. However, the variety of acupuncture techniques examined in the literature and used in clinical practice makes it difficult to recommend specific acupuncture treatment strategies.

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Ensuring the Safety of Traditional Medicines: Detecting and Reporting Suspected Adverse Effects and Interactions

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During the years 1961–1962, particularly in Europe, there was a sudden and dramatic upsurge in the numbers of babies born with phocomelia. This congenital abnormality is characterised by the poor or absent development of the arms and legs and often there is little limb to see apart from a small portion of a hand or foot protruding from the shoulder or hip, rather like the flipper of a seal. This extremely disabling abnormality was not unknown before, but was very rare. The sudden increase had its cause in the prescription medicine, thalidomide, taken by mothers in early pregnancy when the limb buds of the developing child were forming. The 'thalidomide disaster', as it became known, sparked worldwide concerns and most countries urgently put in place a system for monitoring the safety of prescription medicines in the hope of preventing any similar occurrence. It was not feasible to do this through a compulsory reporting rule and voluntary reporting of suspected adverse effects to a central authority has subsequently become the method of choice in most countries.

In Australia, the regulatory body for all medicines, whether prescription only, over-the-counter preparations or traditional/complementary medicines is the Therapeutic Goods Administration (TGA), a division of the Australian Government Department of Health and Ageing. In order to monitor the occurrence of medicine-related adverse events, an Adverse Drug Reactions Unit (ADRU) was set up within the TGA to receive and review spontaneous reports coming from medical practitioners and pharmacists of suspected adverse events, whether it appeared likely that the medicine was, in fact, the cause or not. The TGA has been advised since 1970 by the Adverse Drug Reactions Advisory Committee (ADRAC), composed of medical practitioners who help make the often difficult judgement as to whether the event reported is likely ('possibly', 'probably' or 'certainly') to have been caused directly by the medicine, by an interaction between two or more medicines or to be unlikely to relate to medicines and have more to do with the disease or condition being treated. As reports come in, a particular medicine may stand out as a possible cause of adverse events, particularly if the pattern of adverse events repeats itself with each new case reported. This may lead the TGA to issue a warning to health professionals on the TGA website (www.tga.gov.au) or directly to all prescribers, pointing out the suspected risk, featuring it in the bi-monthly publication *The Australian Adverse Drug Reactions Bulletin*, or, if sufficiently serious, informing health practitioners and the public immediately and, if necessary, revoking the licence for that particular product. A recent (2001) example of the withdrawal of a prescription medicine from the market because of serious adverse events was that of cerivastatin, a cholesterol-lowering medicine which caused muscle damage in an unacceptably large proportion of patients. Spontaneous reports from health professionals contributed to this regulatory decision.

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In contrast, traditional (including Chinese) and other complementary medicines are usually regarded as low-risk and commonly have a long history of apparently safe use by traditional practitioners, provided they are prepared according to traditional methods. However, simply because they have a tradition of use does not guarantee their invariable safety and the TGA has a responsibility to monitor any emerging risks associated with these products. For example, aristolochic acids from plants of the genus *Aristolochia* have been found as adulterants in some Chinese medicines. It was only as recently as 2000 that these substances were reported to cause renal impairment and a particular form of renal cancer.[1] The laboratories at TGA have subsequently screened many traditional medicines for the presence of these acids and products containing them have been removed from the market. Other traditional medicines such as kava (*Piper methysticum*) and black cohosh (*Cimicifuga racemosa*) occasionally produce impairment of liver function and remain under regular scrutiny.

Until recently, reporting of suspected adverse events has largely come from those prescribing or using prescription medicines. However, it is estimated that about a half of all Australians take some traditional/complementary medicine in any year, and so it is vital to have as much comprehensive information as possible about the potential risks. The Adverse Drug Reactions Unit and ADRAC have opened the reporting of suspected adverse events beyond medical practitioners and pharmacists. As a result, health practitioners using traditional products as well as members of the public (normally through a health professional) are beginning to add their information to the database. Reporting is done easily on the TGA's Blue Form, a copy of which is inserted in this issue of AJACM. The reporting system also has a facility to accept reports electronically. Most importantly, reporting is not a mechanism for blaming a practitioner, nor is it necessary to be sure that what was observed was directly related to the medicine given. Suspected adverse events and the medicines (all of them) that were being taken at the time of the event are all that need be reported. Reports are acknowledged by the ADRU.

The Complementary Medicines Evaluation Committee of the TGA meets regularly to review all aspects of the regulation of complementary medicines. At each meeting we devote a substantial amount of time to reviewing reports of suspected adverse responses. These have already been seen and passed on to us by ADRAC (on which a member of our Committee sits) and gradually we build up a picture of the risks – small or large – that may be associated with particular products. More recently, we have taken a particular interest in interactions between medicines. The herbal preparation St John's Wort (*Hypericum perforatum*), for example, may alter the way some prescription medicines are handled in the intestine and the liver and in turn may lead to a reduced effect of the prescribed medicine.

There is an urgent need for better education about traditional/complementary medicines for Western-trained medical practitioners and pharmacists, and also for the public, who often do not recognise that there could be a potential for interaction between their prescription medicines and the herbal products they buy or have dispensed for them by traditional practitioners.

To aid that education program (which has been agreed to as part of the Government's response to the Report of the Expert Committee on Complementary Medicines in the Health System[2]) we need the best information about how traditional medicines perform and the risks, whatever they may be, associated with their use in our society. Reporting suspected adverse events is a contribution that all practitioners can make, whether they are from the Western, Chinese or other traditions.

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Questions and Answers: Reporting Adverse Reactions Associated with Chinese Herbal Medicine

Interview with Ian W Boyd* PhD
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Dr Ian W Boyd from the Adverse Drug Reactions Unit at the Therapeutic Goods Administration earlier in 2006 kindly agreed to respond further in a question and answer format to provide an update on recent developments and to encourage reporting of adverse drug reactions (ADRs) among Chinese medicine practitioners.

AJACM: What are the Complementary Medicines Evaluation Committee's (CMEC) strategies for encouraging Chinese medicine practitioners or complementary medicine practitioners to report suspected adverse events?

Boyd: One of the measures recommended by CMEC is to make Chinese medicine practitioners or complementary medicine practitioners more aware of the reporting scheme. While there are no funds available for a publicity campaign, members of CMEC, ADRAC (Adverse Drug Reactions Advisory Committee) and their respective secretariats are attempting to find opportunities to increase awareness. The preceding article is one such opportunity.

AJACM: What is the current situation with regard to reporting suspected adverse reactions associated with Chinese medicine? How many such reactions have been reported and what types?

Boyd: This question is difficult to answer because the database does not have the appropriate grouping terms for such an analysis. We currently receive about 200 reports of complementary medicines ADRs each year. Most reports have been forwarded in the past five years.

A small proportion of these involve Chinese medicines. These are grouped according to the name of the product. In some cases we do not know the name so it is coded as 'Chinese medicine'. Cases in which the association between the adverse reaction and the medicine is considered 'unrelated', 'very unlikely' or 'un-assessable' on the basis of the information supplied are excluded from the database. Only those cases in which the association is considered 'certain', 'probable' or 'possible' are included.

Thirty identified and seven unidentified Chinese herbal medicines have been associated with 45 reports since 1972. Chinese herbal medicine products were the only suspected medicine in 24 of those 45 cases. In most cases more than one adverse reaction was reported and in total, 136 suspected adverse reactions have been reported in the 45 cases. For 92 of the 136 reactions, the Chinese medicine products were the only suspected medicine.

Like Western medications, the more commonly reported adverse reactions are relatively minor. A few life-threatening reactions have also been reported. Table 1 illustrates the number and nature of common reactions.

AJACM: Are there certain products associated with more adverse reactions than other products?

Boyd: The above-mentioned adverse reactions are associated with 30 identified Chinese medicine herbal products. Of those, each of the ten products had one report, whereas the remaining 20 products were related to two or more reports.

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TABLE 1 Number and nature of commonly reported adverse reactions associated with 30 identified Chinese medicine herbal products reported since 1972

System	Symptoms	No. of reports	Sole suspected
Eye disorders	Mydriasis	2	2
Gastrointestinal disorders	Nausea	6	5
	Vomiting	5	3
	Diarrhoea	3	1
	Abdominal pain	3	1
General disorders	Malaise	6	6
	Fatigue	2	1
Hepatobiliary disorders	Abnormal hepatic functions	3	2
	Jaundice	3	2
	Hepatic failure	2	2
Musculoskeletal and connective tissue disorders	Back pain	3	1
Nervous system disorders	Dizziness	3	0
	Abnormal co-ordination	2	0
	Convulsion	2	0
Psychiatric disorders	Hallucination	3	1
	Confused state	2	2
Renal and urinary disorders	Renal impairment	2	2
Skin disorders	Pruritus	7	5
	Rash	6	5
	Purpura	3	2

Usually one case was reported against each product and occasionally more than one case was reported. For instance, four cases were reported against *Long dan xie gan wan* (Gentiana combination).

AJACM: Can you clarify the origin of the source of reporting?

Boyd: Yes. For example, if we take unspecified Chinese medicines, we have four cases of adverse effects reported by hospitals, two by specialists and one from a community pharmacist. In another example, six cases were reported by general practitioners, one by a hospital, two by a specialist and one by a consumer.

In general, it is unusual for companies that sponsor Chinese medicines or complementary medicines or Chinese medicine practitioners to report such events. We know that spontaneous reporting is subject to gross under-reporting, so the Chinese medicines reported to us are just a sample of what is occurring.

The Use of Evidence in Acupuncture Clinical Practice

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ABSTRACT

This paper reports on a qualitative study of beginner acupuncture clinicians' experiences of clinical practice. An analysis of the 42 interview transcripts revealed that these practitioners relied primarily upon traditional, experiential and reflexive knowledge in clinical decision-making. None of the practitioners interviewed used evidence arising from formal research in clinical practice decision-making. A subsequent review of acupuncture research reports showed that most acupuncture research had been undertaken to prove the therapeutic efficacy of acupuncture rather than generate knowledge that could be used to inform clinical decision-making. This paper suggests that the dominant acupuncture research emphasis of proving therapeutic efficacy, compounded with a paucity of research-generated knowledge relevant to acupuncture clinical decision-making, has been detrimental to the development of evidence-based acupuncture practice. The paper proposes that partnerships between researchers and practitioners are essential in developing research that informs practice, improves the quality of practice and leads to the heightened use of evidence in acupuncture clinical decision-making.

KEYWORDS acupuncture, evidence-based practice, clinical practice, research.

Background

In Australia there is a high level of community acceptance of complementary health modalities[1] and most private health funds provide member rebates for services from accredited complementary medicine practitioners. A representative population survey of over 3000 persons in South Australia found that 52% of participants used at least one form of complementary medicine.[2] Acupuncture is one of the most broadly accepted and widely practised forms of complementary medicine in Australia. Four universities offer undergraduate acupuncture programs with course structure and content closely aligned with the curriculum of Chinese medicine education in China. Practitioner comments and clinical reports indicate that many acupuncturists in Australia view 'best practice' as the replication of extensively used, yet under-researched, traditional acupuncture knowledge and skills. This paper reports on a qualitative study of university-trained non-medical acupuncturists' experiences of clinical practice.[3] In particular, the paper examines practitioners' use of knowledge in clinical practice.

Method

As a second-order study that sought understanding of phenomena from the standpoint of participants and their experiences, phenomenography was selected as the preferred research method.[4,5] The study was not undertaken with any a priori set of themes or perspectives that would be applied and tested; instead the research sought understanding through a process of discovery. Semi-structured interviews (n = 42) focused on uncovering participants' experiences of clinical practice, as distinct from what the participants or experts believed 'should' occur in the clinical encounter. Each interview lasted approximately 45 minutes, with these being audio-taped and later transcribed for analysis.

An iterative process of reading and re-reading of the interview transcripts was employed in analysing the data to identify the major styles of practice and the types of knowledge that participants drew upon in clinical decision-making. This paper reports upon the types of knowledge that participants used in clinical practice and explores the implications of

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these knowledge categories with respect to informed clinical decision-making. In analysing the interview data, no attempt was made to categorise individual participants as pertaining to one or more approach to knowledge usage, because the study assumed that each practitioner might draw upon a range of knowledge categories in clinical decision-making.

Results

In addition to identifying distinct modes of practice and the modus operandi of each, the study provided insight into the types of knowledge that practitioners drew upon to inform practice. The knowledge categories were differentiated on the basis of the qualitatively different types of knowledge that practitioners drew upon in practice. Three major knowledge categories were identified. The analysis did not sub-divide these into smaller categories relative to the various ways in which knowledge was acquired and/or used, although it is acknowledged that such analysis could be useful in discussions about learning strategies. The study identified three knowledge categories: Traditional Knowledge, Experiential Knowledge and Reflexive Knowledge.

A. TRADITIONAL KNOWLEDGE

This represented the commonly accepted theories and skills of Chinese medicine contained in major textbooks and the undergraduate curricula of university acupuncture programs. Participants appeared to view this knowledge as 'factual' and therefore saw 'good practice' as the correct application of the traditional knowledge rather than the adaptation or reinterpretation of the traditional knowledge within a contemporary Western health context.

B. EXPERIENTIAL KNOWLEDGE

This category of knowledge represented the collection of views and skills that practitioners had tried and found to be effective in clinical practice. It comprised traditional knowledge and practices that had been tried by the individual practitioner and found to be therapeutically useful. It omitted theories and skills that had been found to be ineffective and those that had not been tested in practice. This category represented pragmatically based, largely unreflected knowledge that was accorded value because individuals found it worked. From this perspective 'good practice' was primarily concerned with 'getting results', and if results were not forthcoming, then clinical strategies were changed.

C. REFLEXIVE KNOWLEDGE

This category contained knowledge that arose from reflection. It included practitioners' reflections on their own clinical experiences, insights from other practitioners and reinterpretations of Chinese medical theories by contemporary Western authors. Some participants mentioned the writings of Leon Hammer and Loni Jarrett as examples of valued reflexive knowledge. From this perspective 'good practice' required the adaptation of traditional knowledge to contemporary health issues. In reflecting on experiences, some participants reported that they consulted with their peers or other colleagues to discuss, reflect and gain insight in the diagnosis and treatment of clinical presentations.

A comparison of these findings with those from Hsu's ethnographic study of Chinese medicine practice in China,[6] revealed that Category A, Traditional Knowledge, was similar to what Hsu identified as 'Standardised Knowledge'. This body of knowledge is the collective historical experience of Chinese medicine expressed in theories, historical writings and modern textbooks. Even though this body of knowledge is grounded in Chinese socio-cultural views of health and disease, and expressed in theories that remain largely un-researched, it is arguably the dominant knowledge category in contemporary acupuncture practice in both Asia and the West.

Parallels between Category B, Experiential Knowledge, and Hsu's category of 'Personal Knowledge' exist with respect to the fact that they are both highly subjective, practitioner-centred, un-researched sources of information. Experiential Knowledge represents a highly pragmatic non-reflexive approach to the use of knowledge in clinical practice wherein practitioners reapply that which has worked in previous clinical contexts. A major limitation of this non-reflexive approach is that it assumes a subjective stance to understanding therapeutic effectiveness and providing best-practice treatments.

Hsu's category of 'Secret Knowledge' was not significantly present in the data of the Australian study; however, this author acknowledges that some practitioners place high credence upon personal knowledge gained from senior master practitioners. Socio-cultural differences between the cohorts in the respective Australian and Chinese studies[3,6] may account for the presence of a 'Secret Knowledge' category in Hsu's China-based study and its absence in this author's Australia-based study.

Reflexive Knowledge, with its emphasis upon reinterpreting Chinese medical knowledge in the contemporary Western health setting, highlights a significant issue for practitioners in the West. The Reflexive Knowledge category recognises that theory, practice and one's understanding of these are highly 'culture bound'.[7] Reflection, especially when undertaken in conjunction with colleagues, arguably improves the quality and relevance of practice knowledge.

Absent from the practitioner interview transcripts was any reliance upon research-based knowledge in clinical decision-making. This omission, combined with a heavy reliance upon traditional under-researched knowledge, is a matter of concern

in a world in which health professionals are required to justify their diagnoses and treatments.

In view of this finding the author conducted a number of discussions with practitioner colleagues to explore the use/non-use of research-based knowledge in clinical decision-making. These discussions confirmed the finding of the study that 'research-generated knowledge' is not commonly referenced in acupuncture clinical decision-making. Three reasons are advanced in explanation of this trend:

1. Difficulty in accessing acupuncture research;
2. Difficulty in understanding the research and/or being able to evaluate the quality of the research study outcomes;
3. Reservations about the relevance of acupuncture research to clinical practice.

1. DIFFICULTY IN ACCESSING THE RESEARCH

In Australia, the considerable level of practitioner interest in 'new knowledge' is evident in the high proportion of practitioners who attend both national and international acupuncture conferences. In addition, there is an increasing number of practitioners who, after some years in practice, report their clinical insights at national conferences. This author suggests that these trends are indicative of a maturing profession, eager for information that will enhance the quality of clinical practice.

However, for many practitioners in the West, locating quality information is a complex enterprise. There are very few online journals with free-of-charge article abstract summaries. Furthermore, much research undertaken in China is not reported in English journals and very few Chinese medicine journals are subsumed within electronic medical databases such as Medline or PubMed. The compounding effect of these limitations is that practitioner information searches occur in a somewhat hit-or-miss fashion.

Even in disciplines where practitioners have ready access to research-generated knowledge, speed of information transfer from 'that which is known' to 'that which is used in practice' is a substantial issue. In North America, it is estimated that there is a seventeen-year time lag from when clinically relevant biomedical information is generated to when the same research knowledge is broadly applied in clinical practice.[8] This time lag in biomedical knowledge transfer has substantial implications for the quality of patient care and Grol[9] has estimated that 30% to 40% of patients receive biomedical treatments that have not been proven to be effective. McGlynn et al.[10] have estimated that 20% to 25% of patients receiving biomedical care are given treatments that are either unnecessary or potentially harmful.

In Australia, the Commonwealth Government has established the National Institute of Clinical Studies to address the time lag in 'knowledge uptake' in biomedical practice by identifying the critical gaps in evidence uptake and implementing strategies to redress these throughout the health care system.[11] While no comparable organisation exists to address the issue in complementary medicine, one can surmise that poor access to current knowledge has a negative effect on the quality of clinical practice.

2. DIFFICULTY IN UNDERSTANDING THE RESEARCH

Familiarity with research terminology and methodologies is critical to understanding and evaluating research reports. The apparent need for practitioner up-skilling in this area suggests needed changes in university acupuncture curricula and practitioner professional development programs.

Undergraduate and postgraduate university programs in Chinese medicine tend to incorporate subjects on research methods and designs. In such subjects students achieve a basic understanding of research planning, ethical issues, research methodologies and analytical procedures, especially with respect to Chinese medicine. While critique of current research is also included in these subjects, greater attention may need to be given to assisting students in evaluating research articles and exploring ways in which research knowledge can enhance the quality of clinical practice. Such a strategy would go some way towards enhancing the scope and depth of knowledge that practitioners draw upon in clinical decision-making and assist in lessening the gap between 'that which is known' and 'that which is applied'.

3. RESERVATIONS ABOUT THE RELEVANCE OF RESEARCH

A review of peer-reviewed acupuncture journals available in English revealed that many articles report and discuss acupuncture research. It is also apparent that major acupuncture conferences have a high emphasis upon reporting the findings of laboratory and clinical studies in acupuncture. A more detailed examination of the focus of this research reveals that most acupuncture research has been undertaken for the purpose of 'proving' that acupuncture is effective in the treatment of specific medical conditions (usually defined in biomedical parameters) or exploring the biomedical basis of the 'acupuncture effect'.

The outcomes of such research are of notable interest to acupuncture practitioners as these studies help validate acupuncture. However, knowing that needling certain acupuncture points produces measurable neurological or biochemical effects is of limited benefit in improving the quality of clinical decision-making in acupuncture practice. A detailed

review of peer-reviewed journals shows that there are very few studies undertaken for the purpose of exploring clinical practice issues. Moreover, very few articles explore the clinical application of research findings and Claraco et al.[12] suggest that researchers need to be more sensitive to 'practitioner needs' and provide summaries of research undertakings in succinct form.

Critique of prevailing acupuncture research agenda was evident at the 2004 World Federation of Acupuncture-Moxibustion Societies (WFAS) 6th World Conference on Acupuncture. At that conference McDonald[13] suggested that the designs of many acupuncture randomised clinical trials (RCTs) were flawed because the RCT did not reflect the manner in which acupuncture was practised. Similarly, Janz[14] suggested that inconclusive results in RCTs that measured the effectiveness of acupuncture in relieving lower-back pain was indicative of poor RCT design. Inconsistencies between the outcomes of RCTs and well established clinical experience, as in the case of lower-back pain studies, is possibly one reason for practitioner dissatisfaction with some RCT acupuncture research. The RCT use of selective homogeneous populations and clinical procedures that only vaguely replicate the clinical practice environment may also be a source of discrepancies between RCTs and practitioner experiences.

With respect to acupuncture research, there are also questions about the clinical relevance of the findings from many RCTs. For example, even if RCTs proved that acupuncture was highly effective in treating lower-back pain, it is unlikely that such results would change the way practitioners treat lower-back pain. If on the other hand there were studies that explored the relative effectiveness of various acupuncture points on different types of lower-back pain, then such research would have significant relevance for clinical practice.

While research that proves therapeutic efficacy of acupuncture has helped establish its credibility amongst the biomedical profession, health policy-makers and the community at large, it appears to have had little impact upon improving the depth and quality of knowledge applied in clinical decision-making. This author suggests that in order to broaden the acupuncture research agenda to incorporate practitioner research interests, practitioners and researchers will need to build research partnerships.

Key points

- Practitioners rely primarily upon traditional knowledge, clinical experience and reflexive knowledge in clinical practice.
- This paper does not suggest that the collective body of traditional knowledge and practitioner experience is unimportant or invalid, but raises concerns about acupuncturists' reliance upon under-researched knowledge in clinical decision-making.
- This study explored the types of knowledge that informed practitioners' clinical practice and raised concerns about the lack of research-generated knowledge in clinical decision-making.
- The paper suggests that one major reason for this phenomenon is that, because acupuncture research has focused upon proving clinical efficacy, there is a considerable lack of research-generated knowledge that can be applied in clinical decision-making.
- Partnerships between practitioners and researchers are necessary in developing clinically relevant acupuncture research.

Conclusion

This paper has reported some of the findings of a qualitative study of acupuncturists' experiences of clinical practice. Participants reported that they rely upon traditional knowledge, experiential knowledge and reflexive knowledge in diagnosis and treatment. The study found that there was a low use of research-based knowledge in clinical decision-making.

This paper has highlighted some of the obstacles practitioners face in accessing and understanding acupuncture research, and commented upon the lack of clinically relevant acupuncture research. While the research focus upon proving clinical efficacy and exploring the scientific basis of the acupuncture effect has been important in ensuring the acceptance of acupuncture in the West, this paper suggests that the research agenda need expansion to include clinical practice issues and generate knowledge that will improve the quality of information that practitioners draw upon in clinical decision-making.

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Writing Chinese Medicine Case Reports: Guidelines for the Australian Journal of Acupuncture and Chinese Medicine

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ABSTRACT

Case reports, like other styles of research, form part of the much larger tradition of knowledge transmission. The case report offers an ideal starting point for presenting accounts from clinical practice, stimulating discussion and pointing the way for future research. Even though the presentation of case reports may be considered a weaker form of evidence-based data in comparison to that which arises from controlled clinical studies, the importance of these should not be underestimated. Within the domain of Chinese medicine, case reports are critical in knowledge transmission and the advancement of clinical practice. This paper offers an overview of the role of case reports and asks two questions: what should one report? and how should one do it? The authors argue that case reports are brief and concise accounts of new material, which follow a structured approach in organising and presenting evidence from clinical practice. This article also presents guidelines for reporting clinical cases in the *Australian Journal of Acupuncture and Chinese Medicine*.

KEYWORDS case reports, Chinese medicine, research.

Introduction

In a considered paper on the role and significance of the case reports, case series and single-case experimental designs in Western medical literature, Vandenbroucke[1] poses a number of questions that are also meaningful and instructive for the Chinese medicine profession. The questions are framed within a broader context of current research imperatives that require evidence, which is collected, organised, analysed and presented in a way that retains a potent explanatory power. Research endeavours in the medical field are subject to the notion of a hierarchy of evidence with randomised clinical trials and meta-analyses of multiple randomised clinical trials being identified as absolutely essential and indispensable for generating scientific knowledge. Retrospective studies, case reports/case series and unsystematic observations are considered to offer the least evidentiary power.[2,3] Accepting that case reports do not supply the kind of 'scientific truth' for making causal conclusions and

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providing objective evidence for use in clinical decisions,[4] why then include a section which encourages practitioners to submit case reports in this journal? This paper affirms the view that all types of research, provided that the research is methodically undertaken and interpreted with due care, has a place in the advancement of Chinese medical knowledge.[5]

The case report has functioned as part of a time-honoured tradition in medicine in the West and in the East. Indeed, what we understand as the scholarly Nei Jing tradition of Chinese medicine retains a much longer, continuous tradition which gives prominence to reporting on case experience. The premier text of this scholarly approach to medicine retains as one of its prime directives the goal of instructing practitioners and students of healing on how to become 'good physicians'. One important message in this text is that to practise Chinese medicine one must be able to embody its ideas and practices as well as being able to treat and educate one's clients and student protégés.[6-8]

Similarly, but not quite in the same way, medical reporting in the West has occupied an important role in advancing and transmitting a body of therapeutic insights, practices and beliefs. However, because contemporary research imperatives demand a particular approach to generating knowledge, the value and explanatory power of the single case report is often denigrated to the level of anecdotal knowledge in Western medical science. A criticism of case reports may be that while they may be interesting to read, the kinds of conclusions that can be drawn from a case report are limited when compared to the outcomes from randomised clinical trails or meta-analyses of such trials.[2,3,5]

In the West, the documentation of Chinese medicine case reports is a new and developing phenomenon that mirrors the growing maturity of Chinese medicine practice. However, in China, Farquhar[9] notes that practitioners continue to learn from the documented clinical experiences of notable physicians and the oral transmission of clinical experience and insight. How case studies and practitioner engagement in therapeutic interventions are described and accounted for offers insights into Chinese medical ways of knowing and knowledge transmission, which vary substantially, while contemporary Western medicine demands objective facts and proven causal relationships. While randomised clinical trials are considered the 'gold standard' in Western medical research, in the domain of Chinese medicine, the role of case reports should not be underestimated in developing theory, improving practice and transmitting knowledge.

In order to avoid, or at best minimise, the pitfalls of case-report writing, Hoffman[2] argues for a re-appraisal of case reporting so that these are a 'reader friendly yet erudite and sophisticated resource for clinicians in both community and academic practice'. He suggests that case reports should have one of the following objectives:

1. To advance a new approach to diagnosis and/or treatment;
2. To report on a rare condition;
3. To describe unusual manifestations of a commonly seen condition.

1. A NEW APPROACH TO DIAGNOSIS OR TREATMENT

The case report that documents a new approach or treatment is offered to stimulate discussion, feedback and relevant research questions. In this scenario the case report stimulates the desire to 'find out more' and refine or re-assess one's understanding. In the Chinese medical literature, Dharmananda[10] offers an example of how the formula *Xue fu zhu yu tang* (*Persica* and *Achyranthes* combination) was devised. Reportedly, the physician Wang Qing Ren (eighteenth century) formulated the prescription based on his observations of cadavers during what was probably a measles and dysentery epidemic. Even though his eighteenth-century contemporaries considered the prescription to be potentially flawed from a Chinese medical perspective, the formula is now 'routinely employed in the treatment of a number of diseases and injuries to promote blood circulation, remove stasis and activate the flow of Qi to relieve pain'.[9]

In another example of 'case reporting', Morelli and Adelasco[10] document how a contemporary Chinese acupuncturist (Dr Zhang Shijie of Gulou Hospital, Beijing) establishes and determines an acupuncture point prescription. Citing a medical treatise from a classical text,[11] the authors identify the practitioner's approach as being similar to that of 缘物比类 (*Yuan wu bi lei*). This method, which predates the current 辨证论治 (*Bian zheng lun zhi*) approach and is arguably less suitable, is reputably clinically effective in the observational study of Morelli and Adelasco.[12]

Notable as well is that in these clinical reports the practitioner is also a point of focus. In such reports the practitioner's thinking processes, how observation and reasoning are used, in addition to the clinical insights being advanced, become instructive and useful. The notion of highlighting the practitioner in case reporting is instructive to practitioner colleagues and somewhat different from the contemporary Western medical emphasis upon objectified, decontextualised clinical accounts.[12,13]

2. A RARE CONDITION

The second type of case report is where authors report on a rare condition of interest to other practitioners. While only few practitioners are likely to encounter the reported 'rare condition', the report acts as a 'reflexive account' for others and documents what may become, over the course of time, a more

prevalent condition. Case reports of this kind function as a way of logging and tracking conditions that fall outside what is usually seen as common.

3. AN UNUSUAL MANIFESTATION OF A COMMON CONDITION

The third type of case report typically describes an unusual manifestation of a commonly seen condition and, according to Hoffman,[2] this is by far the most frequently reported. In his view, this kind of report can be misleading because, by highlighting differentiations from the norm and occurrences which are sometimes bizarre or unusual, the reader's attention is diverted from what usually occurs. One important characteristic of such reports is that they alert clinicians to the unexpected, since the unexpected may give rise to new and different clinical decisions, insights and research questions.

In the contemporary practice of Chinese medicine, variations from the traditional body of knowledge are not uncommon, especially when one considers that the tradition and the health issues from which it arose were rooted in an ancient socio-cultural context. Tropical diseases and health conditions associated with poor hygiene are at worst rare in the post-industrial societies of the West. In contrast, conditions that accompany the affluence of modern living, the iatrogenic effects of biomedical interventions, or the effects of substance abuse are more commonplace in the West. In addition, the cultural beliefs and practices that impact upon the health perceptions of practitioners and patients, and the effect of these upon the prognosis in any health intervention are critical in a modern culturally diverse society such as Australia.

With respect to varied diagnoses, Chinese medicine has a range of commonly occurring patterns, such as liver Qi invading the spleen, 肝气犯脾 (*Gan qi fan pi*), depletion of both Qi and Yin, 气阴两虚 (*Qi yin liang xu*), or insufficiency of kidney Yin, 肾阴虚 (*Shen yin xu*), and at the same time allows for variations on these. Hence, case reports that document variations on the common patterns in different contexts, with reflections on why and how symptoms remain or vary, are worth reporting. Such reports should elaborate on how the practitioner was able to identify the unexpected and the variations in treatment protocol(s) that were employed. Reflections on why the practitioner's treatment protocols differed (or did not differ) should also be included in such reports.

In summary, case reports establish a level of evidence that is important but different from that which results from controlled clinical studies. In Chinese medicine the case report has the important role of documenting clinicians' experiences, stimulating discussion, providing insight, generating questions for further research, and providing a living record of the evolution of knowledge and theory in this medical tradition.

What are the characteristics of cases that lend themselves to being reported?

Most practitioners work as 'generalist clinicians' who care for people with commonly known health problems and/or patients whose conditions seem to be intractable. Because patients in the West often come to Chinese medicine 'as a last resort', practitioners confront unusual and unique presentations worthy of documentation in a case report. The inclusion of a case report section in the *Australian Journal of Acupuncture and Chinese Medicine* (AJACM) provides practitioners with an avenue for reporting significant clinical experiences in a structured manner.

Case reports are written for the purpose of generating discussion, providing insight, breaking new ground and suggesting theory development, and as such they are quite different from the 'case discussions' found in contemporary and classical texts of Chinese medicine, which provide classical examples of particular patterns of disharmony. Such examples are useful for undergraduate students of Chinese medicine, but are of limited value to the experienced practitioner who is faced with the vast array of clinical presentations and experiences that differ from textbook offerings.

Case reports provide a venue for learning and reflecting with fellow practitioners, and therefore should focus on the following[14]:

- Describing an encounter with unusual outcomes or events;
- Presenting a clear lesson to be learnt for the author and for other practitioners;
- Raising questions about theory or the application of theory;
- Presenting patterns of disharmony that differ from the usual textbook presentations. For example, the report may suggest that symptom patterns may change in time and in different social settings;
- Reporting adverse reactions to acupuncture and/or Chinese herbs or the interaction between Chinese herbs and pharmaceuticals;
- Describing unusual symptom patterns not recognised in the literature;
- Presenting patterns that appear confusing and/or contradictory, thus creating treatment dilemmas;
- Reconceptualising particular acupuncture or herbal treatment protocols/prescriptions for documented symptom patterns;
- Reflecting upon the therapeutic encounter and the effect on the client, practitioner or both. This particular type of case report, not usually seen in the literature, is noteworthy since the practitioner–patient relationship is a significant feature

of any therapeutic encounter and such accounts may give impetus to re-evaluating the ways in which practitioners engage with and care for patients.

The authors of this article do not suggest that the above list is complete, but rather offer this by way of highlighting some clinical situations worthy of documentation. Reports on such clinical experiences, when presented in a structured and reflective manner, provide fertile opportunities for learning and advancing the practice of Chinese medicine.

How should a case report be written?

The foregoing discussion focused largely on what kind of cases should be reported and the importance of framing the case report within a Chinese medical perspective. How then should an author present a case report to colleagues? Case reports do give attention to the uncommon, unexpected and the rare which at the outset will attract a reader's attention. Indeed, Nathan argues strongly that a case report should 'appeal to the emotions',[15] suggesting that the case report gain the attention of the reader because it has relevance to practice experience. Secondly, the clinical observations and experience may be unusual, and reporting these may provide valuable education and research stimulus. In simple terms, if there is something special about the case that will attract interest, it merits consideration for reporting.

With respect to the protocols in formatting case reports, there is a high level of agreement between authors.[16-18] In providing a detailed account in a structured manner, case reports should include the following: abstract/introduction, case history

TABLE 1 A worksheet for section headings and contents for case reports

Title	
Author	
Abstract	• The clinical question/problem; • Concise summary of literature review; • Summary/conclusions/recommendations.
Case history description	• A description of the patient; • The presenting condition and history; • The examination; • Any relevant tests; • Initial tentative diagnosis/treatment/management; • Expected outcome/actual outcome.
Literature review	• Search terms; • Database(s) used; • Brief overview of results of the search, what you found.
Discussion	• What is special about this report? • The clinical question and relationship to the experience; • The course of the illness: tables, graphs, charts, photos; • What happened? For instance, adverse reactions (Chinese herbs and/or acupuncture to pharmaceuticals, acupuncture adverse reactions); • Contradictions, dilemmas, observations, questions; • Reflexive considerations about: what happened, practitioner's role/engagement in the encounter, significance for the practitioner/colleagues.
Conclusions/summary	• The central point of the case report; the lesson(s) to be learnt; recommendations.
References	• Vancouver style.[22]

description, literature review, discussion, conclusions/summary. The suggested total word length of the report is approximately 1500 words. Descriptive guidelines for each section of the case report are as follows.

ABSTRACT

The abstract should be around 150–175 words, providing the reader with a concise statement of the case report. The abstract provides the reader with a snapshot of the report and facilitates database listing for practitioners engaged in a reference search.

CASE HISTORY DESCRIPTION

This section of the report provides a concise account of the case, typically drawn from the practitioner's clinical progress notes. Here the patient is introduced, as it were, providing a history of the clinical presentation and encounter. Care must be taken to de-identify the client information so that privacy and confidentiality are assured.

Details of examinations, which may vary from case to case, are listed in summary form. In some situations there may be investigations/examinations that are not usually part of traditional Chinese medicine examinations, such as lab tests, x-rays or other tests relevant to the case report and discussion. The initial diagnosis, treatment plans and protocols should be included and any complicating factors that may have emerged. If acupuncture was the principal modality applied, full details using STRICTA criteria are recommended.[19] Regarding nomenclature, acupuncture points should be named according to both Pinyin and the numerical code recommended by the World Health Organization.[20] In relation to Chinese herbs, the *Pharmacopoeia of the People's Republic of China* (English edition) nomenclature and specification is recommended.[21] The inclusion of photographs, tables or charts to describe the case report are useful additions provided their inclusion is appropriate to the case being reported.

If measuring symptom relief is central to the case report then the method of measuring change must be made explicit in the report. Where a case report gives attention to reflective accounts of practice, the report needs to be written in a style that includes the practitioner as a participant in the case.

The aim of the case history description is to include only the essential data that gives emphasis to what makes the author's case unique, different and appealing to the reader. The challenge in this section is one of providing essential information in succinct form.

LITERATURE REVIEW

The literature review should offer a concise overview of the literature relevant to the case history and subsequent discussion. Offering a full-scale review is not the intention, but rather one that provides context to the report. The purpose of the literature review will reflect and inform on the question(s) being explored. AJACM uses the Vancouver referencing system,[22] commonly used in the medical domain, as it provides the reader with the necessary information to locate the full text of references used. The challenge in this section is one of locating and exploring information that directly relates to the focus of the case report under discussion. As the case report is for an audience experienced in Chinese medicine, a level of basic information is assumed, and referencing common Chinese medical knowledge must be avoided.

DISCUSSION

The discussion section is the centrepiece of the report where the author attempts to make sense of the case. This section requires that the author explore those aspects that make the particular report compelling. In other words, why are you presenting the case and what do you expect colleagues to learn from the case. Indeed, what lesson did the practitioner/author learn? Findings from extant literature are drawn upon in describing how this case differs from similar ones. If the report is to contain reflexive writing then this section must articulate those issues relevant to the case report and any implications for practice.

CONCLUSION/SUMMARY

The report closes with the conclusions that emerge from the case study. For instance, how the case changes understanding in Chinese medicine practice and the lesson(s) learnt. It could mean that next time I will do and consider things differently, or perhaps suggest a research path for others to follow. Perhaps the case report questions or counters an established 'truth' in Chinese medicine. In other words, the conclusion carries a simple message: the lesson learnt in caring for the patient and a recommendation or a suggestion for future research. This section should be brief and contain one or two paragraphs.

Conclusion

This article presents a set of guidelines for case reports in Chinese medicine that are not dissimilar to those used in other health care disciplines. It provides a guide for those submitting case report articles to the *Australian Journal of Acupuncture and Chinese Medicine* so that practitioners write thorough and concise reports.

The article has highlighted the need for case reports which:

- Are brief, concise accounts of new, different material;
- Capture the attention and appeal to the emotions of colleagues;
- Provide opportunities for learning, discussion and reflection;
- Present material in a structured and organised manner.

As members of the AJACM Editorial Board, the authors of this article encourage practitioners to give serious consideration to identifying and documenting clinical experiences worthy of a case report article submission.

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Oculomotor Palsy Treated with Electroacupuncture: A Case Report

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ABSTRACT

Oculomotor palsy is a mononeuropathy, which causes sudden unilateral ptosis and double vision. It often affects older people who have concurrent diabetes and/or hypertension. Oculomotor palsy generally resolves over three to four months as regeneration of affected nerve fibres. There is no effective biomedical treatment. In this report, I present a 76-year-old man who experienced left-sided oculomotor-nerve palsy. Biomedical intervention had been unsuccessful and electroacupuncture led to complete symptom relief after four weeks of treatment.

KEYWORDS electroacupuncture, oculomotor-nerve palsy, case report.

Introduction

Oculomotor palsy, called 'dropping upper eyelid' in Chinese medicine, presents itself with sudden-onset unilateral ptosis and inability to turn the eye upward, downward or inward, causing visual disturbances[1-3] such as diplopia or blurred vision for near objects. It is common in people older than 60 years of age and in those with prominent or long-standing atherosclerotic risk factors, such as diabetes or hypertension.[1,4] In adults, the palsy is usually the result of vascular or compressive lesions.[1] In juveniles it is most commonly due to head trauma, tumours, migraine, vasculopathies and demyelinating diseases.[5] In children, oculomotor palsy is usually congenital.[6]

Biomedical treatment for acquired oculomotor palsy is targeted at removing the cause of the palsy. In cases where the cause is unknown, the treatment is mostly supportive and cannot alter the course of the disease. Patients experience tremendous suffering and distress. Isolated third-nerve palsy due to ischaemic vasculopathy often spontaneously resolves and recovers over a period of three to six months.[1-3]

I describe in this case report an elderly patient's acquired unilateral oculomotor palsy that improved during electroacupuncture after conventional medicine treatments were unsuccessful.

Case history

A 76-year-old man came to the Department of Acupuncture and Moxibustion complaining of an inability to open his left eye for one month; if the eyelid was manually elevated, he experienced diplopia.

Upon the onset of the problem, the patient went to Yongdong Severance Hospital in Seoul, Korea. Brain and orbital MRI, haematology, urinalysis, clinical chemistry tests, and cerebrospinal fluid (CSF) analysis showed normal results. Brain MR angiography showed atherosclerotic change involving the middle cerebral artery (MCA), posterior cerebral artery (PCA) and vertebral artery, and a mild degree of atherosclerotic change of the left proximal internal carotid artery (ICA). The findings

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of an abdominal ultrasound scan included the presence of mild fatty liver, simple hepatic cyst and bilateral renal cysts. The patient was diagnosed with oculomotor palsy with an unclear aetiology. Biomedical supportive treatment (Cozaar 50 mg, Adalat Oris 30 mg, Rhonal-baby 50 mg, YuYu Clid 250 mg and Mylanta-A 1T) commenced. His symptoms did not improve after one month of treatment.

On examination, he had a pale facial complexion and cold extremities. His appetite and digestion were good. He did not complain of any other problems such as stool, urine or sleep disturbances. The pulse was weak and the tongue was normal.

Complete left-sided ptosis was observed with an inability to turn the eye upward, downward or inward. The eye was in a 'down-and-out' position and the pupil was sluggishly responsive to light. No extremity weakness was noted, and other cranial nerve functions, as well as the rest of the neurological examination, such as mental state, language, dysphasia, reflexes, muscle power, cerebellar function and sensation, did not reveal any signs of additional pathology.

The patient had a history of a mild cerebrovascular accident (cerebral haemorrhage) 30 years ago, with no residual neurological deficit. He had also been diagnosed with idiopathic hypertension for 30 years.

The diagnosis of his current condition was meridian Qi stagnation around the eye, with general Qi deficiency. Electroacupuncture was selected because it delivers continuous stimulation on specific acupuncture points. Acupuncture points were selected based on Chinese medicine theory, which used nearby and remote points. The following local acupuncture points around the eye were treated on the left side of the forehead: BL2 *Zanzhu*, Ex-HN4 *Yuyao*, Ex-HN *Guangming* (head) and GB14 *Yangbai*. The remote acupuncture points were bilateral LI4 *Hegu*. LI4 was chosen because it is a distal point for any facial conditions. Prior to needling, the patient's skin was sterilised with alcohol and disposable stainless steel acupuncture needles (0.25 × 40 mm, Dong Bang Co., Korea) were used.

Electrical stimulation was delivered with a pulse stimulator (Ito Co., Japan) producing a bipolar square wave at 4 Hz frequency. Bipolar square wave was applied to stimulate the motor neurons.[7] The current intensity was adjusted so that localised muscle contractions could be seen. Low-frequency electroacupuncture has been shown to stimulate ergoreceptors – afferents that are sensitive to metabolic and mechanical changes in the muscle.[8] The patient felt a tingling sensation around the eye when the electrical stimulation was delivered. Two pairs of electrodes were attached to BL2 (cathode) and *Guangming* (head) (anode), and Ex-HN4 (cathode) and GB14 (anode) on the affected side. Electroacupuncture was applied for 20 min each time, and was delivered twice a week for one month.

After two treatment sessions, the ptosis and eye movement were slightly improved. From the fourth session onwards, the patient's symptoms improved quickly and by the eighth session he was able to open his eyelid and move his eye completely. The pupil was totally reactive and normal. He did not complain of diplopia.

Discussion

When seeing an oculomotor palsy case, it is important to make a clear diagnosis to exclude some emergency cases.

The third cranial nerve palsy may be partial or complete, congenital or acquired, isolated or accompanied by signs of more extensive neurological involvement.[1] The patient usually presents with sudden-onset unilateral ptosis, which is frequently accompanied by significant eye or head pain. The patient rarely complains of double vision because the ptosis obscures the vision in the affected eye; however, if the lid is manually elevated, the patient will experience diplopia. Acuity is typically unaffected unless damage occurs in the superior orbital fissure and cranial nerve II is also involved. The pupil may be dilated and minimally reactive to light, totally reactive and normal, or may be sluggishly responsive.[1,2] In complicated third nerve palsy where other neural structures are involved, patients are required to undergo an MRI for differential diagnosis with ischaemic vasculopathy, tumour and aneurysm. In isolated third nerve palsy with no pupillary involvement where the patient is over 50 years old, MRI scanning, an ischaemic vascular evaluation and daily pupil evaluation are indicated. If the patient is under 50 years old and has a non-pupillary involved isolated third nerve palsy, intracranial angiography is indicated since ischaemic vasculopathy is less likely to occur in this age group than aneurysm. If an adult patient of any age presents with complete or incomplete isolated third nerve palsy with pupillary involvement, consider this to be a medical emergency and have the patient undergo intracranial angiography immediately. In these cases, the cause is likely subarachnoid aneurysm and the patient may die if the aneurysm ruptures. Children under the age of 14 rarely have aneurysms and the majority of third nerve palsy cases in this age group are traumatic or congenital.[1,2,6,9]

In this case, the patient was over 50 years old and had no pupillary involvement. MRI showed that there was no significant finding for ischaemic vasculopathy, tumour or aneurysm. This case represents an isolated oculomotor palsy with undetermined aetiology. It took four weeks of acupuncture treatment to recover completely.

A Medline search covering the years until 2004 found 179 articles describing acupuncture treatment for paralysis. The majority of these articles are peripheral facial paralysis and stroke. There is only one article describing a case of oculomotor palsy treated with acupuncture, by Frenkel and Frenkel.[10] They selected the local and distal acupuncture points based on meridians that transverse the area of pain. The following local acupuncture points were treated on the affected side: GB1 *Tongziliao*, GB14 *Yangbai*, GB19 *Naokong*, GB20 *Fengchi*, GV26 *Shuigou* and Ex-HN4 *Yuyao*. The distal points treated were bilateral LR3 *Taichong* and LI4 *Hegu*.

The acupuncture points selected are similar to the current protocol, but the stimulation method is different. Frenkel and Frenkel[10] applied manual manipulation, whereas electroacupuncture was used in this case. Unlike manual manipulation, electrical stimulation can be easily controlled and reliably repeated. Low-frequency electroacupuncture produces muscle contraction and improves paralysis. The recovery time is similar in both cases. Frenkel and Frenkel[10] reported a recovery process of oculomotor palsy that began one week after initiation of acupuncture treatment and ended only four to five weeks after the condition appeared.

Conclusion

This case report describes electroacupuncture treatment that led to a complete and rapid recovery from acquired unilateral oculomotor palsy of undetermined aetiology; however there is no firm evidence that acupuncture is indicated as a primary therapy for oculomotor palsy. More case reports are needed and controlled clinical studies should be planned to further examine the role of acupuncture for the treatment of oculomotor palsy.

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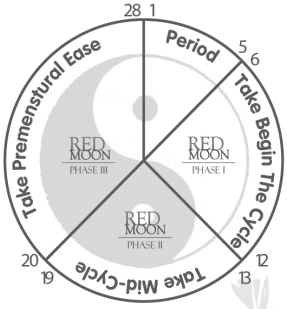
Day 1-5 The first day of menstrual bleeding marks the onset of the follicular phase and is called Day one of the menstrual cycle.

Menstruation usually lasts 3-5 days. We do not usually recommend taking herbs during your menstrual cycle, unless directed by your healthcare practitioner for a particular reason. We recommend taking Red Moon Menstrual support from the next phase of your cycle.



(Phase 1) From day 6 to day 12 use **"Begin the Cycle"**. This formula provides nourishment to support the qi, blood and yin of the body after menstrual bleeding has ceased or from day 6 of the cycle.

(Phase 2) From day 13 to day 19, use **"Mid-Cycle Support"** to support the body and enhance normal ovulation. This formula contains herbs to nourish Kidneys and support the blood.

(Phase 3) From day 20 until menstruation begins use **"Premenstrual Ease"** to support a stress free lead up to normal menstruation.

Phase I

Begin the Cycle
Ba Zhen Yi Mu Pian

Phase II

Mid-Cycle Support
Yi Shen Tiao Jing Pian

Phase III

Premenstrual Ease
Xiao Yao Pian

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Reporting Randomised, Controlled Trials of Herbal Interventions: An Elaborated CONSORT Statement

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ABSTRACT

Herbal medicinal products are widely used, vary greatly in content and quality, and are actively tested in randomised, controlled trials (RCTs). The authors' objective was to develop recommendations for reporting RCTs of herbal medicine interventions, based on the need to elaborate on the 22-item CONSORT (Consolidated Standards of Reporting Trials) checklist. Telephone calls were made and a consensus meeting was held with 16 participants in Toronto, Canada, to develop these recommendations. The group agreed on context-specific elaborations of nine CONSORT checklist items for RCTs of herbal medicines. Item 4, concerning the herbal medicine intervention, required the most extensive elaboration. These recommendations have been developed to improve the reporting of RCTs using herbal medicine interventions.

Introduction

Randomised, controlled trials (RCTs) of herbal interventions often inadequately describe important aspects of their methods.[1-4] Although the quality of reporting of these trials may be improving with time, many still lack important information, particularly about the composition of the herbal intervention.[4,5] Crude herbal drugs are natural products and their chemical composition varies depending on several factors, such as geographic source of the plant material, climate in which it was grown and time of harvest. Commercially available herbal medicinal products also vary in their content and concentration of chemical constituents from batch to batch and when products containing the same herbal ingredient are compared among manufacturers.[6-14] Even when herbal products are standardised for content of known active or marker compounds to achieve more consistent pharmaceutical quality, there is variation in the concentrations of other constituents. These variations can result in differences in pharmacologic activity in vitro[15] and in bioavailability in humans.[16] Mindful of these issues, we elaborated on the 22-item checklist of the

* The members of the CONSORT Group are listed on the following web site: www.consort-statement.org/profiles/partners.html

Aust J Acupunct Chin Med 2006;1:35–39.

Consolidated Standards of Reporting Trials (CONSORT) statement[17] to help authors and editors improve reporting of RCTs of herbal interventions.

Methods

We developed these reporting recommendations in three phases that included pre-meeting item generation, a consensus meeting, and post-meeting feedback. The individuals who participated are listed in the Appendix (available at www.annals.org). To generate items, one investigator conducted telephone interviews of 16 participants with expertise in the method and reporting of RCTs (five participants), pharmacognosy (four participants), herbal medicinal products (five participants), medical statistics (one participant), and herbal product manufacturing (one participant). The investigator asked participants to suggest revisions to existing CONSORT checklist items and also to additional items required for reporting trials of herbal interventions. He asked participants to nominate revisions or new items on the basis of empirical evidence that not reporting the item would bias estimates of treatment effect. When no empirical evidence was available, commonsense reasoning was acceptable. After completing all telephone calls, the investigator thematically grouped items and circulated them by e-mail to each participant for review.

Fourteen participants attended the consensus meeting. The meeting began with a review of the pre-meeting checklist item suggestions. We emphasised minimising item elaborations and additions and basing elaborations on evidence whenever possible. Each item suggestion was presented and followed by debate for its inclusion, deletion, or modification. This process was repeated until all items were reviewed and a consensus emerged.

After the consensus meeting, we circulated a draft summary report to all participants to ensure that it accurately represented decisions made during the consensus meeting. We then circulated the report to the wider CONSORT Group for input and revised it on the basis of their suggestions. Ethical approval was obtained from The University of Toronto Health Sciences Ethics Review Committee on 23 January 2004.

Financial support for the consensus meeting was provided by the Canadian Institutes of Health Research. The funding body had no role in the design, conduct, or analysis of this study and did not influence the decision to submit the manuscript for publication. All researchers are independent of the funders.

Results

The group did not recommend any new CONSORT checklist items or modifications in the CONSORT flow diagram. We did, however, elaborate on nine of the 22 CONSORT checklist items to enhance their relevance to trials of herbal interventions (Table 1, Figure 1; Appendix Table, available at www.annals.org), including minor recommendations for eight items (item 1 [title and abstract], item 2 [background], item 3 [participants], item 6 [outcomes], item 15 [baseline data], item 20 [interpretation], item 21 [generalisability], and item 22 [overall evidence]) and detailed recommendations for one item (item 4 [interventions]).

Table 1 shows the detailed recommendations for item 4 and an example of good reporting related to each recommendation. These recommendations begin with the words 'where applicable' to indicate that all information suggested may not be applicable to every type of herbal medicine intervention. For

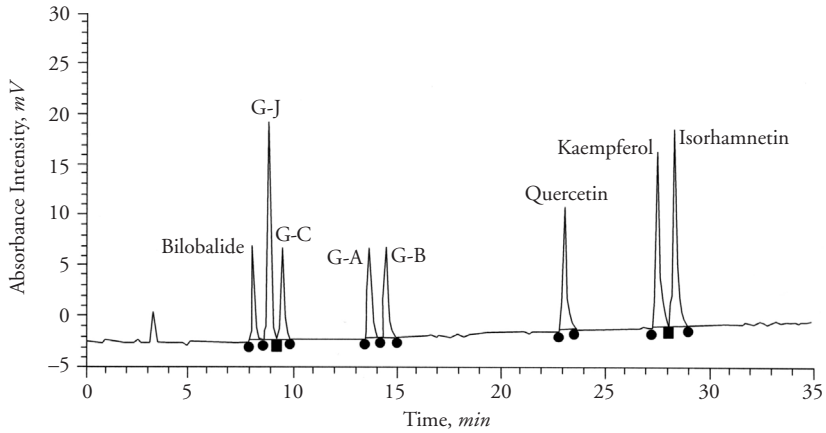

FIGURE 1 The high-pressure liquid chromatography chemical fingerprint for the extract of *Gingko biloba*[19]

G-A = gingkolide A; G-B = gingkolide B; G-C = gingkolide C; G-J = gingkolide J.

TABLE 1 Proposed elaboration of CONSORT checklist item 4 (Interventions) for reporting randomised, controlled trials of herbal medicine interventions

Item	Descriptor	Examples of good reporting[a]
4	Where applicable, the description of a herbal intervention should include:	
4A: Herbal medicinal product name	1. The Latin binomial name together with botanical authority and family name for each herbal ingredient; common name(s) should also be included.	The herbal medicine intervention used in this trial was an extract of *Ginkgo biloba* L. (Ginkgoaceae; maidenhair tree).
	2. The proprietary product name (i.e. brand name) or the extract name (e.g., EGb-761) and the name of the manufacturer of the product.	The product used was LI 1370, an extract of *Ginkgo biloba* L., manufactured by Lichtwer Pharma (Berlin, Germany).[18]
	3. Whether the product used is authorised (licensed, registered) in the country in which the study was conducted.	This product is registered for use as a natural health product in Canada.
4B: characteristics of the herbal product	1. The part(s) of plant used to produce the product or extract.	The extract was obtained from leaves of *Ginkgo biloba* L.
	2. The type of product used (e.g. raw [fresh or dry], extract).	The herbal medicine intervention was an extract of *Ginkgo biloba* L.
	3. The type and concentration of extraction solvent used (e.g. 80% ethanol, 100% H2O, 90% glycerine, etc.) and the ratio of herbal drug to extract (e.g. 2 to 1).	The solvent used in the extract was alcohol (80% ethanol) and the ratio of herbal drug to extract was 5 to 1.
	4. The method of authentication of raw material (i.e. how done and by whom) and the lot number of the raw material. State if a voucher specimen (i.e. retention sample) was retained and, if so, where it is kept or deposited, and the reference number.	A staff botanist visually identified the growing plant. The lot number for the *Ginkgo biloba* L. extract used in this study was #557-05. A voucher specimen was retained (#23-673) and is kept at the manufacturer headquarters in Toronto, Canada.
4C: Dosage regimen and quantitative description	1. The dosage of the product, the duration of administration, and how these were determined.	Each capsule contained 60 mg of the extract. A total of 3 capsules were given each day, 1 before each of 3 meals, for 3 months. This dosage regimen was determined by referring to previous clinical trials testing the effects of similar *Ginkgo biloba* L. extracts for the same indication.
	2. The content (e.g. as weight, concentration; may be given as range where appropriate) of all quantified herbal product constituents, both native and added, per dosage unit form. Added materials, such as binders, fillers, and other excipients (e.g. 17% maltodextrin, 3% silicon dioxide per capsule), should also be listed.	The percentages of quantified chemical constituents per capsule was as follows: 15 mg (25%) flavonoids, 3 mg (5%) ginkgolides, 1.8 mg (3%) bilobalides.
	3. For standardised products, the quantity of active/ marker constituents per dosage unit form.	The percentages of marker constituents per capsule were as follows: 25% flavonoids, 5% ginkgolides, 3% bilobalides.
4D: Qualitative testing	1. Product's chemical fingerprint and methods used (equipment and chemical reference standards) and who performed the chemical analysis (e.g. the name of the laboratory used); whether a sample of the product (i.e. retention sample) was retained and if so, where it is kept or deposited.	The high-pressure liquid chromatography chemical fingerprint for the extract of *Ginkgo biloba* L. can be seen in Figure 1.[19] The method for performing this analysis was as follows: High-pressure liquid chromatography was achieved using a minibore Phenomenex Luna 5-m $C18^2$ column with dimensions 250 × 2.00 mm at 45°C with a one-step linear gradient using acetonitrile:formic acid (0.3%) at a flow rate of 0.4 mL/min.[20] The analysis was done by an individual with 12 years' experience in the methods, at an independent laboratory, CanHerba Labs Inc. (Windsor, Ontario, Canada). The product sample is also kept at CanHerba Labs

	2. Description of any special testing/purity testing (e.g. heavy metal or other contaminant testing) undertaken, which unwanted components were removed and how (i.e. methods).	Laboratory personnel were blinded to the identity of the extract and control capsules. Concentrations (g/g) of lead, mercury, and arsenic were measured by x-ray fluorescence spectroscopy 23 equipped with a tungsten x-ray tube, a Si(Li)-semiconductor detector, and software version 2.2R03 I (Spectro Analytical Instruments, Kleve, Germany). National Institute of Standards and Technology solid standard reference materials 2709, 2710, 2711, 24, and liquid certified standards (SCP Science, Champlain, New York) containing specified heavy metal concentrations served as positive and negative controls.[21]
	3. Standardisation: what to standardise (e.g. which chemical components of the product) and how (e.g. chemical processes or biological/functional measures of activity).	The *Ginkgo biloba* L. extract used in this trial was standardised to contain 25% flavonoids, 5% ginkgolides, and 3% bilobalides. Methods included high-pressure liquid chromatography using a minibore Phenomenex Luna 5-m $C18^2$ column with dimensions 250 × 2.00 mm at 45°C with a one-step linear gradient using acetonitrile:formic acid (0.3%) at a flow rate of 0.4 mL/min.[3] We used the following reference standards: bilobalide (95%), ginkgolides A (90%), B (95%), C (95%), J (99%) purchased from HerbalChems (San Francisco, California)[b], and Quercetin (95%) purchased from Sigma (St. Louis, Missouri) and kaempferol (90%) and isorhamnetin (99%) purchased from Indofine Chemical Company (Hillsborough, New Jersey). The purity of these reference standards was assumed as provided by the suppliers.[3]
4E: Placebo/ control group	The rationale for the type of control/placebo used.	The placebo capsules used in this trial were identically sized capsules filled with lactose powder, and coloured (with food colouring) to match the *Ginkgo biloba* L. capsules.
4F: Practitioner	A description of the practitioners (e.g. training and practice experience) that are a part of the intervention.	Clinicians choosing the appropriate treatment and dosage were trained as primary care physicians; were licensed in Ontario, Canada; had been practising medicine for an average of 12 years; and had attended continuing medical education lectures on evidence-based herbal medicine interventions.

[a] Examples included are not from actual publications unless directly referenced. They were developed explicitly to provide extremely specific and concise examples of good reporting for each item. All examples are for the same herbal medicine intervention, which contains just 1 herbal medicinal product, *Ginkgo biloba* L. Referenced sections were changed slightly from the original reports to be consistent with respect to the particular herbal medicine intervention used across these examples. [b] This is a fictional company that was added for the completeness of the report.

example, a herbal medicinal product comprising crude herbal material (for example, leaves and stems) simply prepared as a tea or decoction does not require description of the 'type and concentration of solvent used and the ratio of herbal drug to extract' (item 4B.3). Also, not every herbal medicine intervention will have a finished product or extract name or manufacturer (item 4A.2), but instead may be made by the investigators specifically for the study. In such circumstances, all methods used in preparing and formulating the product must be reported. Similarly, item 4F is not required for herbal interventions when the practitioner is not a part of the intervention. With these exceptions, we recommend that all information shown in Table 1 be reported for all herbal interventions.

Discussion

We developed recommendations to be used in conjunction with the existing CONSORT checklist when reporting RCTs of herbal interventions. In particular, we thought it imperative that reports of RCTs provide clear and complete descriptions of the herbal intervention. We think that our recommendations might also be relevant for reporting herbal interventions in other research designs, whether preclinical (for example, in vivo or in vitro) or clinical (for example, N of 1 trials), and refer interested readers to a detailed explanatory document that further describes each of our recommendations and provides additional examples of good reporting.[22] We hope that authors find our recommendations instructive and that journals will endorse their use and modify their instructions to authors accordingly.

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POTENTIAL CONFLICTS OF INTEREST

Grants received: J Barnes (Lichtwer Pharma); Grants pending: J Barnes (Lichtwer Pharma); Royalties: J Barnes (Pharmaceutical Press, Churchill Livingstone).

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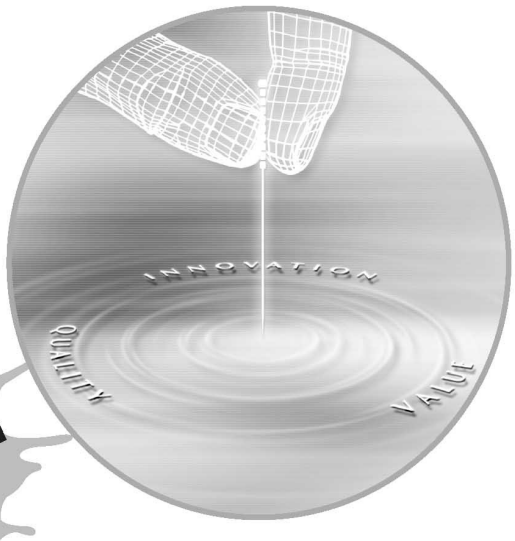

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Current Research and Clinical Applications

A Clinical Snapshot of Acupuncture and IVF

Recently the American journal *Fertility and Sterility* (May 2006) published three original research studies[1,2,3] on acupuncture as an adjunctive therapy for In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI) and Embryo Transfer (ET). Assisted Reproductive Technology, in particular IVF, was first used successfully in the early 1980s and has gone on to be a frequently used technique for couples experiencing trouble conceiving. To date, studies using acupuncture to support IVF have mostly revolved around the ET period, with Paulus et al.[4] establishing the first protocol in 2002.

Smith and colleagues[1] undertook a clinical trial randomising 228 women into a two-armed study, either receiving true acupuncture or non-invasive sham acupuncture (Streitberger placebo needle[6]). Three acupuncture treatments were given to all groups. Results showed pregnancy rates in the acupuncture group were 31% vs 23% for control (P = 0.81), which means the odds of getting pregnant were one and a half times higher in the acupuncture group. Also, the pregnancy rate at 18 weeks was higher in the acupuncture group (28% vs 18%; P = 0.08); however, neither outcome reached statistical significance. This study included a review of significant past studies, which resulted in the current undertaking being more vigorous. The study concluded that a smaller treatment effect could not be excluded. While this study was carried out in an IVF clinic, the protocol was different to Paulus et al.[4] as Smith et al.[1] added an extra treatment at day nine (before ET). Loss to follow-up of 37 participants in both groups was due to the cycle being cancelled or no ET taking place. Of note, the women's age group had no bearing on the results.

Dieterle and colleagues[2] undertook a randomised, prospective, controlled clinical study allocating 225 women into a two-armed study. One group received true acupuncture before and after ET and the other received placebo acupuncture. (Note: actual points are not known to influence fertility, as per Traditional Chinese Medicine.) Results indicate that the true acupuncture group had significantly better outcomes compared to the placebo acupuncture group for clinical pregnancy (33.6% vs 15.6% respectively; $P < 0.01$) and on-going pregnancy (28.4% vs 13.8%; $P < 0.01$). Thus pregnancy was twice as likely with acupuncture compared to placebo in this trial. There may have been a possible placebo effect due to the lack of sufficient statistical analysis in some age groups. There was no loss to follow-up in this study.

Westergard and colleagues[3] undertook a prospective randomised trial by allocating 273 women into a three-armed study. One was a control group receiving no acupuncture. The first acupuncture group received acupuncture on the day of ET as well as before and after the procedure. The second acupuncture group received the same with an added acupuncture treatment again two days later. Results showed that clinical and on-going pregnancy rates in the acupuncture groups were higher than the control (39% vs 26%; P = 0.038) and (36% vs 22%; P = 0.049) respectively. This effectively means that the odds of getting pregnant were increased by one third. The second acupuncture arm did not reach statistical significance; however it was higher than the control (36% vs 26%; P = 0.049). On the other hand, this group did have a higher early pregnancy loss (33%) than the control (21%) compared to the first acupuncture group (15%). The study may have been unwittingly unblinded due to the use of the IVF clinical nurses undertaking the acupuncture, as opposed to utilising an independent clinician. Loss to follow-up was 27 participants in all groups due to the cycle being cancelled or ET not taking place.

In conclusion, there is a need for larger studies providing acupuncture sub-analysis detail to observe relevant clinical

and research benefits. Interestingly, when comparing the results of all three studies, it seems that prescription acupuncture is slightly better than TCM individualised acupuncture. Finally, the observation of clinical success appears challenging to reproduce in clinical trials, which may be due in part to operator dependency, environmental factors and possibly placebo effect. However, these results are very promising.

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John C Deare and Sean W Scott

Neck Pain and Acupuncture

In the following, one very recent clinical trial[1] and one systematic review[2] on acupuncture and neck pain are summarised. Overall, acupuncture is effective for reducing chronic neck pain and improving patients' quality of life when it is used with or without conventional therapies. The effect is often long-lasting, from three months to one year. The results should not surprise our clinicians, but they do reassure our practice and enable us to show the evidence to both patients and other health practitioners.

Witt et al. Acupuncture for patients with chronic neck pain.[1]

This is a multi-site, randomised, controlled trial involving 14 161 chronic neck pain patients in Germany, and is the largest acupuncture clinical trial reported so far. One quarter of the patients were randomly allocated to manual acupuncture (MA) and routine care control (RCC) groups. The other 75% of patients were treated with MA without randomisation. MA was individualised and delivered by physicians who had more than 140 hours of training in acupuncture. Patients in the MA group also received RCC. Types of RCC were not specified. We can only assume that RCC included medications, physical therapy, massage and exercise.

On average, patients were treated for ten sessions of acupuncture (maximum of 15) over three months. MA groups including both randomised and non-randomised patients had pain and disability reduced significantly (28.9% and 321.7%) more than the RCC group (5.8%). More importantly, the effect was maintained for more than three months after acupuncture.

Patients with 20% reduction in pain and disability were considered responders and the rates for MA and RCC groups were 56.6% and 21.6%, respectively. Patients who were female or treated early responded better than others. In addition, quality of life was also improved in the MA in compassion to the RCC group.

The results indicate that MA in addition to routine care (RC) is about 25% better than RC alone. However, neither patients nor physicians were blind from the intervention allocation, and there was no placebo or sham acupuncture group. MA treatment protocol decided by physicians is both a weakness and a strength. The readers do not know the acupoints used. However, this arrangement does allow individualised treatment, which mimics clinical scenario.

The reduction of pain is, however, less than that reported by a recent single blind and placebo-controlled trial,[3] in which pain relief was about 60% and lasted for one year. Individualised acupoint selection includes distal and local acupoints and Ashi points based on the distribution and location of pain and tenderness. Of course, with a smaller sample size of 135 patients, the study by White et al.[3] might have over-estimated the effect size.

To view treatment protocol applied in this study, visit www.iasp-pain.org/journal.html.

Trinh et al. Acupuncture for neck disorders (review).[2]

This is a Cochrane systematic review that was conducted by the researchers from the Cervical Overview Group. Ten clinical trials were reviewed and both the scientific quality and effect of acupuncture were assessed. Data presented show that acupuncture with either mixed local and distal acupoints or distal points alone can relieve chronic neck pain due to cervical spine degenerative changes, myofascial conditions or whiplash and neck pain with radicular symptoms. The relief often lasts up to three months after treatment. Real acupuncture reduced pain 30% more than sham acupuncture.

Commonly used acupoints in the ten trials were GB20 *Fengchi*, GB21 *Jianjing*, GV14 *Dazhui*, LI4 *Hegu* and SI3 *Houxi*. Often local small intestine points and tender points were used. The common treatment sessions were six. In general, individualised acupoint selection based on either Traditional Chinese Medicine theory or meridian theory or distribution of pain produced better outcomes than standard point selection. However, it was not the intention of this review to compare different forms of acupuncture.

Overall, there is moderate evidence that acupuncture is effective for chronic neck pain. Studies published in the last five years have better scientific quality.

In addition to acupuncture, many therapies have been reviewed for their effectiveness. There is strong evidence that massage combined with manipulation or mobilisation produces both short- and long-term pain reduction, whereas alone, neither of them is particularly effective.[4,5] Intramuscular injection of lidocaine is more effective than saline injection or dry needling in terms of short-term relief.[6] There is limited or conflicting evidence that non-steroidal anti-inflammation drugs (NSAIDs), psychotic medications, Botox A intramuscular injection, patient education, transcutaneous electrical nerve stimulation (TENS), radiofrequency and multidisciplinary rehabilitation are effective for chronic neck pain when compared with sham or other types of control procedure.[6-10]

EDUCATION SECTION

The Commonwealth Government funds the national subscription to the Cochrane Library so that Australians can access evidence free of charge and be informed of the effectiveness and safety of therapies. The web address is http://www.nicsl.com.au/cochrane/index.asp.

For information about systematic reviews and Cochrane collaboration, please visit the following website, http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME.

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Zhen Zheng

Book Reviews

Foundations for Integrative Musculoskeletal Medicine: An East-West Approach

Alon Marcus
North Atlantic Books, 2005
ISBN 1-5564-3540-1
760 pages

A Tooth from the Tiger's Mouth: How to Treat Your Injuries with Powerful Healing Secrets of the Great Chinese Warriors

Tom Bisio
Simon & Schuster, 2004
ISBN 0-7432-4551-2
384 pages

The 'bread and butter' of an acupuncture practice (and probably a herbal medicine clinic) is the treatment of pain, more specifically pain that often arises from musculoskeletal injury, degeneration or overuse. The recent text, *Foundations for Integrative Musculoskeletal Medicine: An East–West Approach* by Alon Marcus is an excellent example of the integration of Traditional Chinese Medicine (both acupuncture and herbal medicine) and modern musculoskeletal medicine. This hardcover, 760-page text is an advanced-level manual that sets the benchmark for the future. Consisting of eleven chapters, the text is well laid-out and has extensive line drawings, tables and photographs that supplement the text. Chapter one, a huge 120 pages, outlines the basic theory underlying Chinese medicine with an emphasis on those theories that inform the treatment of musculoskeletal pain. Chapter two looks at the mechanisms and theories underlying pain both from a Western and an Eastern perspective. Both acute and chronic pain phases are discussed. Chapter three reviews the anatomical structure as well as the physiological and pathological processes associated with muscle, joint, ligament, bone and tendon dysfunction. There is an emphasis on the spine and gait. The chapter concludes with a three-page section entitled 'A Systems Model for Biomechanical Construction', which outlines the concept of 'tensegrity' and the 'icosahedron-space-truss-model' and its application to the human torso and bodywork. Chapter four examines the current state of orthopaedic examination, including physical, neurological and orthopaedic testing procedures as well as the interpretation of information obtained from medical imaging and radiology.

At this stage of the book a very comprehensive and detailed picture of the theoretical side of musculoskeletal medicine has been relayed, giving a solid theoretical basis for the rest of the book, which concentrates on the practicalities of treatment. Chapter five details the treatment principles associated with acupuncture, while chapter six identifies and examines additional acupuncture microsystems, such as auricular, wrist and ankle and Korean hand acupuncture, as adjunct treatment approaches. The following chapter seven highlights the use of Chinese herbal medicine for the treatment of musculoskeletal pain. The important concept of blood stasis is discussed as well as the use of individual herbs, with the associated herbal formula for a wide variety of conditions given in a tabulated form. Chapter eight returns to the related acupuncture techniques associated with electrotherapeutics. Electro-stimulation, laser and magnetic fields are discussed as well as the role they play in pain control and healing.

Chapter nine recounts the many traditional Chinese medicine and Western manual therapies used for the diagnosis and treatment of musculoskeletal pain and dysfunction. Postural alignment examination techniques, mobilisations, exercise regimes and osteopathic treatment techniques are outlined and line drawings used to assist the reader in utilising many of the techniques. A very short chapter ten relates the treatment of acute injuries associated with ligamentous sprain, muscle strain and soft tissue damage. Tables are used to give a clear step-like

approach to identifying both Traditional Chinese Medicine and Western treatment principles and treatment strategies. The final chapter eleven, which comprises 200 pages, discusses the presentation and treatment of a range of musculoskeletal disorders and conditions. Included are degenerative and joint disorders such as rheumatoid arthritis, fibromyalgia, myofascial pain, spinal pain and disc disorders, whiplash as well as the painful Bi syndromes in Traditional Chinese Medicine. The final section of the book consists of an extensive list of references cited in the text, as well as a detailed index making navigation of the book manageable.

My only criticism of *Foundations for Integrative Musculoskeletal Medicine* is the level of detail and technical complexity that may obscure the more practical aspects of treatment documented in the text. Nevertheless if you want a book with very current and comprehensive information concerning musculoskeletal medicine, this is it!

Another book in a similar vein is *A Tooth from the Tiger's Mouth* by Tom Bisio. Although a lot less technical than the previous book, this easy-to-read book focuses on the treatment of trauma with both acupuncture and Chinese herbal medicine. The author, a martial artist, has gathered various herbal formulae and other therapies including acupuncture for the treatment of injuries arising from the practice of martial arts. The book is broken into four segments. The first segment looks at the principles of Chinese sports medicine. The concepts behind sports injuries, both East and West, are discussed including the contentious application of ice and heat. Also included are detailed herbal approaches to acute, sub-acute and chronic injuries associated with ligaments and bone fractures. As well, herbal formulae such as *san huang san* (Three Yellow Powder), bleeding, cupping, liniments and movement exercise and the role they play in healing are discussed.

The second segment looks at injury prevention and the role that exercise, diet and health preservation play. Strength training and the Eight Brocade as well as other traditional exercises are outlined. Line drawings assist the reader in following and performing the exercises. Of special interest is the role that foods play in assisting as well as preventing the healing process. Bisio also gives his opinion on detoxification diets, nutritional supplements and colon cleansing and their use in injury rehabilitation.

The third segment contains nine chapters, which detail the therapies of Chinese sports medicine. These chapters describe the use of cupping and bleeding, liniments, poultices and plasters, herbal soaks, acupoints, massage, internal herbal medicine and moxibustion. Various lotions and plasters are discussed and their indications are highlighted.

The final segment outlines a variety of different injuries and their treatment. For each condition a range of treatment options is given, including first aid (acute phase), follow-up treatment, traditional exercises, acupoints, massage and dietary advice. Conditions represented include Achilles tendinitis, tennis elbow, hip pain, torn meniscus and rotator cuff tear – in all, a total of 33 different sports or trauma injuries. Appendices include the equipping of a Chinese sports medicine First Aid Kit and a listing of stores and suppliers where the herbal substances can be ordered. Unfortunately, only suppliers in the United States are listed.

This is a practical little book that has relevance for the Chinese medicine practitioner, the martial artist as well as the general reader who is interested in finding out more about Chinese sports medicine.

Chris Zaslawski

AJACM Instructions for Authors

The *Australian Journal of Acupuncture and Chinese Medicine* (AJACM) is the official journal of the Australian Acupuncture and Chinese Medicine Association Ltd (AACMA). It is a peer-reviewed journal published biannually and it has an Editorial Board and an International Advisory Board. The Instructions for Authors are available online from: www.acupuncture.org.au/ajacm.cfm.

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