THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 9, Number 1, 2003, pp. 151–159

Reporting of Clinical Details in Randomized Controlled Trials of Acupuncture for the Treatment of Migraine/Headaches and Nausea/Vomiting

ALEJANDRO ELORRIAGA CLARACO, M.D.,[1] STEVEN E. HANNA, Ph.D.,[2] and ANGELICA FARGAS-BABJAK, M.D.[1]

ABSTRACT

Objectives: The main purpose of this study was to investigate the degree of reporting of clinical details in a selected sample of 30 randomized control trials (RCT) on acupuncture efficacy for the treatment of migraine/headaches ($n = 11$) and for nausea/vomiting ($n = 19$). Additional goals included the assessment of the quality of randomization of the trials, and the assessment of the degree of reporting of information about the outcome measures used in each trial.

Methods: A checklist of 50 clinical details selected on the basis of a previous survey was used to evaluate the degree of reporting of information about patients, practitioners, diagnosis, and acupuncture treatments presented in each RCT. The likelihood of bias in the randomization process was assessed using a previously validated scale. Information about reliability/validity and clinical significance of the outcome measures used in each trial was assessed in terms of fully, partially, or not reported, with no attempt to evaluate their quality or appropriateness.

Results: In this sample of RCTs an average of 38.7% of important clinical details per trial were either fully or partially reported by researchers, the lowest being 26.4% for the migraine/headaches group. Studies with better quality of randomization were not more likely to report important clinical details. Only five studies (16.7%) provided information about reliability and validity of the outcome measures used, and only four studies (13.3%), all from the migraines/headache group, discussed the clinical significance of the outcome measures selected.

Conclusions: In this sample of 30 RCTs of acupuncture efficacy for the treatment of migraines/headache and nausea/vomiting, researchers neglected to report adequately on important clinical details, and often did not discuss the reliability, validity, and clinical significance of the outcome measures used in the trials, thus rendering potential readers of the articles unable to critically appraise them from a clinical standpoint. In addition, the fact that the quality of randomization of the trials was totally unrelated to the degree of reporting of clinical details renders potential reviewers of these studies unable to establish valid conclusions about acupuncture efficacy based on the general quality of the methodological design. In the future, all areas of clinical acupuncture research need to be reviewed in a similar manner, and recommendations about proper reporting of important clinical details and proper discussion of the validity, reliability, and clinical significance of the outcome measures used in each trial should be made. Only then could this research be used to generate meaningful evidence-based recommendations for the contemporary practice of acupuncture.

[1]Department of Anaesthesia, McMaster University, Hamilton, Ontario, Canada.
[2]Department of Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada.

INTRODUCTION

Acupuncture is a therapeutic system with several thousand years of tradition in the Orient and abundant anecdotal evidence regarding its clinical efficacy (Cheng, 1987; Helms, 1995). In the past few decades, acupuncture has been tested applying the biomedical model (Hammerschlag, 1998; Lewith and Vincent, 1996), and a considerable amount of clinical and basic research has been produced (Helms, 1995; Pomeranz, 1991). However, the actual impact of published clinical trials on the practice of acupuncture has been uncertain until now because clinical features of those trials have been either inconsistent with real-world clinical practice or inadequately reported or both (Hammerschlag, 1998; Vickers, 1996b).

Existing systematic reviews of randomized controlled trials of acupuncture efficacy for the treatment of pain (ter Riet, 1990) or other conditions (Vickers, 1996) have not evaluated the quantity and quality of the clinical information provided by the studies reviewed systematically. Consequently, and despite the recent official endorsement of acupuncture in the United States (Acupuncture. NIH, 1997), sufficient supportive data to establish evidence-based practice guidelines for the clinical use of acupuncture are still lacking. Additionally, there is still a great deal of controversy among Western acupuncture practitioners about the way acupuncture studies should be designed and conducted from a clinical standpoint (Hammerschlag and Morris, 1977; Vickers, 1996b). Thus, even statistically well-designed acupuncture trials may never have any practical repercussion unless enough clinical information is provided to practitioners for the critical clinical appraisal of the study.

In order to make a contribution in this important area of acupuncture clinical research, the authors assessed the extent of the reporting of clinical details in a selected group of randomized control trials from two existing reviews on acupuncture for the treatment of nausea and vomiting (Vickers, 1996a), and headaches (D. McCrory, personal communication, 1998). Quality of randomization of the trials and the extent of reporting of information about the outcome measures used on each trial were also assessed.

METHODS

Study selection

Studies were selected from two existing systematic reviews of clinical trials evaluating the efficacy of acupuncture for the treatment of headaches (Melchart, 1999; D. McCrory, personal communication, 1998), and nausea and vomiting (Vickers, 1996a). These reviews were chosen because they were recently conducted, involved systematic searches of the literature, and focused on two common clinical symptoms that have received considerable attention from clinicians and researchers alike. However, the studies on these reviews cannot be considered representative of all acupuncture literature.

Vickers' review included 33 controlled trials (Vickers, 1996) in which unilateral or bilateral stimulation of the acupuncture point Neiguan* was tested as a treatment for nausea/vomiting associated with surgery, cancer chemotherapy, or pregnancy. The treatment consisted of needling, acupressure, or electrical stimulation of the point.

In his review, McCrory (personal communication, 1998) identified 16 controlled trials involving the use of needling and/or electrical stimulation at multiple acupuncture points as a treatment for chronic tension headaches or migraines.

In order to exclude studies with designs that were most prone to bias or ambiguity in the interpretation of findings, the authors of this study decided to set the following selection criteria. To be eligible for analysis studies had to:

1. Be in English.
2. Present original data not previously published.
3. Be randomized control trials (RCT) in which a group treated with acupuncture or elec-

*Pericardium-6 or PC-6, in the international nomenclature, is located three finger breadths proximal to the palmar wrist crease, on the ulnar side of the tendon of the flexor carpi radialis muscle.

troacupuncture was compared to a concurrent control group of different patients who did not receive acupuncture. An additional group of studies from the nausea/vomiting review compared acupressure at PC-6 with other forms of treatment or no treatment. These latter studies were selected due to the practical clinical implications of this simple form of treatment; where appropriate analysis was conducted separately.

Selection criteria ruled out before and after time series designs, unless they include comparisons to differently treated controls. It also ruled out studies with historical or archival controls. Crossover designs were included if they presented data that made it possible to compare experimental and control groups before they switched.

4. Involve patients who were part of a real clinical population and who were referred to the study because they had sought treatment for clinically significant symptoms.

Two reviewers independently judged the eligibility of the studies, resolving discrepancies by discussion. Of the 33 trials identified by Vickers in his review, 13 studies were excluded because they lacked appropriate concurrent control group comparisons, and 1 was excluded because it was not in English. Of the 16 papers from McCrory's review, 4 studies were excluded because they lacked an appropriate concurrent control group for comparison, and 1 study was excluded because the study sample was not recruited from a clinical population. Thus the final selection for our analysis consisted of 11 RCTs of acupuncture treatment for headaches/migraine, 9 RCTs of one single acupuncture point treatment for nausea/vomiting, and 10 RCTs of acupressure of one single acupuncture point also for the treatment of nausea/vomiting.

Data extraction

Clinical details reporting extraction. Two reviewers independently evaluated the selected studies using a checklist of 50 clinical details generated from a previous survey (Elorriaga Claraco, 2003); details were grouped into four categories of information (i.e., about the practitioners participating in the study, the patients, the diagnostic procedures used, and the acupuncture treatment provided). Clinical details were coded as "not reported" if the authors made no mention of the detail; "partially reported" if some information about the clinical detail was reported but not adequately described; "reported" if the detail was fully reported; and "not relevant" if information about the detail was deemed not applicable to the study in question. Discrepancies between the judgements of the two reviewers were resolved by discussion.

Assessment of quality of randomization of trials. The quality of randomization of groups from the selected studies was assessed by applying a modified version of a previously validated scale (Jadad, 1996). This scale rates quality of randomization in terms of design features that tend to bias trial outcomes. Quality scores ranged from 0 to 5, with higher numbers indicating less likelihood of bias.

According to this scale, studies received 1 point if participants were assigned to the control and treatment groups randomly, and 1 additional point if the method of randomization was described and deemed appropriate (e.g., randomized from computer generated numbers). If randomization was judged inappropriate (e.g., by alternation, date of birth, or hospital number), 1 point was deducted. Similarly, studies received 1 more point if they were described as double-blinded, with an additional point given if the method of blinding was appropriately constructed so that neither the study participants, (i.e., the patients, nor the person performing the outcome assessment) could identify whether the participants were members of the treatment or control group. One point was deducted if the method of concealing group membership was judged as inadequate. Finally, studies received 1 last point if the study reported the number of persons who withdrew from the study, or were otherwise excluded from the analysis, along with information bearing on the reasons for their withdrawal. Two judges independently evaluated the studies using this instrument, with discrepancies resolved by discussion.

Reporting of outcome measures and discussion of their clinical significance. The goal was to determine to what extent the published trials had provided discussion about the outcome measures used, both in terms of reliability and validity, and clinical relevance. The latter refers to the discussion of the magnitude of the observed effects in terms of their practical clinical significance not just the statistical significance. In the opinion of these authors, this information is absolutely necessary to evaluate the cost effectiveness of the acupuncture interventions in the trials.

Reliability/validity and clinical relevance were coded separately as "fully reported" if the issues were mentioned and elaborated to some degree, "partially reported" if the issues were mentioned but not elaborated, and "not reported" if no discussion of the outcomes had been provided. Two judges independently evaluated the studies, with discrepancies resolved by discussion.

It is important to note that this coding did not attempt to evaluate the clinical quality or appropriateness of the chosen outcome measures but focused only on the presence or absence of the reporting of those issues. The acknowledgment of the presence of this information for a given trial did not mean that the outcome measure selected was a good indicator to measure meaningful clinical changes in the treated conditions. That level of discussion, in the opinion of the authors, needs to be addressed separately by future reviewers of clinical trials of acupuncture efficacy.

RESULTS

Reporting of clinical details

Clinical details selected for this analysis included only those judged highly important in general by clinicians in the abovementioned previous survey (Elorriaga Claraco, 2003), and considered relevant concerning a specific condition such as migraines/headache or nausea/vomiting.

In the abovementioned survey, a highly important detail was one with a minimum score of 3 on a scale from 0 to 4. A detail was considered relevant concerning a specific condition when more than 50% of respondents to the survey had selected "Yes" when answering that question.

A summary of these most relevant clinical details is presented in Table 1.

The results of the degree of reporting of clinical details are summarized in Table 2 (acupuncture studies), Table 3 (acupressure studies), and Figure 1 (combined acupuncture and acupressure). Because some of the details (e.g. the use of electrical stimulation), were not applicable to some of the studies the total number of details presented in Tables 2 and 3 varies among trials.

Tables 2 and 3 present the number and percentage of important clinical details as they were reported, fully or partially, in the studies reviewed. Studies have been organized by clinical condition treated, with a separate section for acupressure (Table 3), and listed alphabet-

Table 1. List of Important Clinical Details as Selected by Respondents to 1998 Survey[a]

Details about practitioners
Usual style or tradition of practice
Details about patients
Previous treatments used with this condition
Age
Diagnostic procedures
Standard medical history
Standard medical musculoskeletal examination
Body palpation (e.g., limbs, back)
Other standard medical exam (e.g., neurological)
Acupuncture treatment
Criteria for selecting points (e.g., classic)
Use of electrical stimulation
Use of medication (e.g., drug name, dose)
Number of treatments
Frequency of treatments
Summary of points used in all treatments
Duration needles left in place
Use of herbal treatments (e.g., name, dose)
Characteristics of electrical stimulation (e.g., frequency)
Use of other supplements (e.g., vitamins, ginseng)
Needle sites used in each treatment (local and distal)
Use of moxibustion or heat lamp
Use of ear points
Use of nutritional treatment or alternations
Use of ancillary methods (e.g., magnets, braces)
Was *de Qi* sensation elicited?
Were needles manipulated several times?
Needling technique (neutral, tonification, dispersion)
Details of how ancillary methods were used

[a]Data from Elorriaga Claraco (2003). See text for full explanation.

TABLE 2. ACUPUNCTURE STUDIES

Condition and studies discussion	Most important clinical details: Fully reported No.	%	Partially reported No.	%	QR score	Outcome measure: Reliability and validity	Clinical significance
Headache & Migraine Acupuncture (n = 11)							
Dowson et al. (1985)[a]	6/23	26.1	3/23	13.0	4	Partial	Yes
Hesse et al. (1994)[b]	5/16	31.3	3/16	18.8	4	No	Partical
Tavola et al. (1992)[c]	7/23	30.4	3/23	13.0	4	No	Yes
Carlsson et al. (1990a)[d]	5/24	20.8	6/24	25.0	3	Yes	No
Hansen et al. (1985)[e]	8/24	33.3	2/24	8.3	3	No	Yes
Vincent (1989)[f]	7/24	29.2	3/24	12.5	3	No	No
Carlsson et al. (1990b)[g]	8/25	32.0	5/25	20.0	2	Partial	No
Cecherelli et al (1987)[h]	3/25	12.0	2/25	8.0	2	No	No
Ahonen et al. (1984)[i]	5/22	22.7	4/22	18.2	1	No	No
Johansson et al. (1991)[j]	8/24	33.3	2/24	8.3	1	No	No
Wittchen et al. (1983)[k]	5/24	20.8	4/24	16.7	1	No	No
Mean =	6.1/23.1	26.4	3.4/23.1	14.7		Yes = 1	3
SD =	1.29		2.51	5.50		Partial = 2	1
						No = 8	7
Nausea & Vomiting Acupuncture (n = 9)							
Yentis & Bissonette (1991)[l]	8/16	50.0	0/16	0.0	4	No	No
Weightman et al. (1987)[m]	6/16	37.5	1/16	6.2	3	No	No
Yentis & Bisonette (1992)[n]	8/11	72.7	0/11	0.0	3	No	No
Dundee et al. (1986)[o]	8/17	47.1	1/17	5.9	2	No	No
Ho et al. (1990)[p]	10/18	55.6	0/18	0.0	2	No	No
Yang et al. (1993)[q]	5/10	50.0	0/10	0.0	2	No	No
Ghaly et al. (1987b)[r]	7/12	58.3	0/12	0.0	1	No	No
Dundee et al (1987)[s]	9/16	56.2	0/16	0.0	1	No	No
Ghaly et al. (1987b)[t]	9/15	60.0	1/15	6.7	0	No	No
Mean =	7.8/14.6	53.4	0.3/14.6	2.1		Yes = 0	0
SD =	1.56	9.78	0.501	3.14		Partial = 0	0
						No = 9	9

Reporting of clinical details deemed relevant by practitoners in previous survey (i.e., mean importance ratings ≥3 out of 4), and discussion of outcomes; all organized by studies, condition, and treatment method. Central column shows score for quality of randomization (QR). (5 = highest, 0 = lowest).

[a]Dowson DI, Lewith GT, Machin D. The effects of acupuncture versus placebo in the treatment of headache. Pain 1985;21:35–42.

[b]Hesse J, Mogelvang B, Simonsen H. Acupuncture versus metoprolo in migraine prophylaxis: A randomized trial of trigger point inactivation. J Int Med 1994;235:451–456.

[c]Tavola T, Gala C, Conte G, Invernizzi G. Traditional Chinese acupuncture in tension-type headache: A controlled study. Pain 1992;48:325–329.

[d]Carlsson J, Fahicrantz A, Augustinsson LE. Muscle Tenderness in tension headache treated with acupuncture or physiotherapy. Cephalalgia 1900a;10:131–141.

[e]Hansen E, Hansen JH. Acupuncture treatment of chronic tension headache: A controlled cross-over trial. Cephalagia 1985;5:137–142.

[f]Vincent CA. A controlled trial of the treatment of migraine by acupuncture. Clin J Pain 1989;5:305–312.

[g]Carlsson J, Augustinsson LE, Blomstrand, Sullivan M. Health status in patients with tension headache treated with acupuncture or physiotherapy. Headache 1990b;30:593–599.

[h]Cecherelli F, Ambrosio F, Avila M, Duse G, Munari, A, and Giron GP. Acupuncture vs. placebo in the common migraine: A double blind study. Cephalagia 1987;7(Suppl 6):499–500.

[i]Ahonen E, Hakumaki M, Mahlamaki S, Partanen J, Rickkinen P, Sivenius J. Effectiviness of acupuncture and physiotherapy on myogenic headache: A comparative study. Acupuncture and Electro-therapeutics Res. Int J 1984;9:141–150.

[j]Johansson A, Wenneberg B, Wagersten C. Acupuncture in treatment of facial muscular pain. Acta Odontol Scand 1991;49:153–158.

[k]Wittchen HU A bio-behavioral treatment program for chronic migraine patients. In: Holroyd KA, Schlote B, Zenz H, eds. Perspectives in Research on Headache. Lewiston NY CJ Hogrefe, 1983:183–197.

[l]Yentis SM, Bissonnette B. P6 acupuncture and postoperative vomiting after tonsillectomy in children BR J Anaesth 1991;67:779–780.

[m]Weightman WM, Zacharias M, Herbison P. Traditional Chinese acupunctural as an antiemetic. Br Med J (Clin Res Ed), 1987;295:1379–1380.

[n]Yentis Sm, Bissonnette B. Inffectiveness of acupuncture and droperidol in preveting vomiting following strabismus repair in children. Can J. Anaesth 1992;39:151–154.

[o]Dundee JW, Chestnutt WN, Ghaly RG, Lynas AGA. Traditional Chinese acupuncture: A potentially useful antiemetic? Br Med J (Clin Res Ed) 1986;293:583–584.

[p]Ho RT, Jawan B, Fung ST, Cheung HK, Lee JH. Electro-acupuncture and postoperative emesis. Anaesthesia 1989;45:327–329.

[q]Yang LC, Jawan B, Chen CN, Ho RT, Chang KA, Lee JH. Comparison of P6 acupoint injection with 50% glucose in water and intravenous droperidol for prevention of vominting after gynecological laparoscopy. Acta Anaesth Scand 1993;37:192–194.

[r]Ghaly RG, Lynas AGA, Dundee JW. Acupuncture also reduces the emetic effects of pethidine. Br J Anaesth 1987;59:135P.

[s]Dundee JW, Fitzpatrick KTJ, Ghaly RG. Is there a role for acupuncture in the treatment of postoperative nausea and vomiting? Anestheiology 1987;67:A165.

[t]Ghaly RG, Fitzpatrick KT, Dundee JW. Antiemetic studies with traditional Chinese acupuncture: A comparison of manual needling with electricl stimulation and commonly used antiemetics. Anaesthesia 1987;42:1108–1113.

TABLE 3. ACUPRESSURE STUDIES

Condition and studies	Most important clinical details: Fully reported No.	%	Partially No.	%	QR score	Outcome measure dicussion: Reliability and validity	Clinical significance
Nausea & Vomiting Reported Acupressure (n = 10)							
Bayreuther et al. (1994)[a]	5/11	45.5	1/11	9.1	5	No	No
Price et al. (1985)[b]	6/10	60.0	0/10	0.0	4	No	No
Belluomini et al. (1994)[c]	7/13	53.8	0/13	0.0	4	No	No
Frey (1986)[d]	1/4	25.0	1/4	25.0	3	No	No
Barsoum et al. (1990)[e]	2/4	50.0	0/4	0.0	3	No	No
Lewis et al. (1991)[f]	4/27	14.8	0/27	0.0	3	No	No
Phillips & Gill (1994)[g]	4/22	18.2	0/22	0.0	2	No	No
Dundee et al. (1988)[h]	6/22	27.3	0/22	0.0	2	No	No
Hyde (1989)[i]	5/11	45.5	1/11	9.1	1	Partial	No
Stone (1993)[j]	6/14	42.9	0/14	0.0	1	No	No
Mean =	4.6/13.8	33.3	0.3/13.8	2.2		Yes = 1	0
SD =	1.90	16.3	0.48	8.19		Partial = 1	0
						No =	8
10							
Table 2 and 3 summary All studies (n = 30)							
Mean =	61.6/17.4	38.74	1.4/17.4	7.46	Yes =	2	3
SD =	2.09	15.79	1.72	8.14	Partial =	3	1
					No =	25	26

Reporting of clinical details deemed relevant by practitoners in previous survey (i.e., mean importance ratings ≥3 out of 4), and discussion of outcomes; all organized by studies, condition, and treatment method. Central column shows score for quality of randomization (QR). (5 = highest, 0 = lowest).

SD, standard deviation.

[a]Bayreuther J, Lewith GT, Pickering R. A double-blind cross-over study to evaluate the effectiveness of acupressure at pericardium 6 (P6) in the treatment of early morning sickness. Complement Ther Med 1994;2:70–76.

[b]Price H, Lewith G, Williams C. Acupressure as an antiemetic in cancer chemotherapy. Complement Med Res 1991;5:93–94.

[c]Belluomini J, Litt RC, Lee KA, Katz M. Acupressure for nausea and vomiting of pregnancy: A randomized, blinded study. Obstet Gynecol 1994;84:245–248.

[d]Frey EN. Acupressure and postoperative vomiting. Anaesthesia. 1986;41:661–662.

[e]Barsoum G, Perry EP, Fraser IA. Postoperative nausea is relieved acupressure. JR Soc Med 1990;83(2):86–89.

[f]Lewis IH, Pryn SJ, Reynolds PI Pandit UA, Wilton NCT. Effect of P6 acupressure on postoperative vomiting in children undergoing outpatient strabisms correction. Br J Anaesth 1991;67:73–78.

[g]Phillips K, Gill L. The use of simple acupressure bands reduces post-operative nausea. Compl Therapies in Med 1994;2:158–160.

[h]Dundee JW. Surial FB, Ghaly RG, et al. P6 acupressure reduces morning sickness. J R Soc Med 1988;81:456–457.

[i]Hyde E. Acupressure therapy for morning sickness: A controlled clinical trial. J Nurse-Midwifery 1989;34:171–178.

[j]Stone CL. Acupressure wristbands for the nausea of pregnancy. Nurse Pract 1993;18:15,18,23.

ically in descending order according to their quality of randomization score.

Figure 1 displays the number of important details pooled into four groups: information about the practitioners involved in the study, the patients, the diagnostic procedures used, and the acupuncture and/or other treatment procedures used. The results of the list of acupressure studies have been added to Figure 1, because they only slightly changed the overall profile of the graphic.

The average reporting of important clinical details across studies was only 38.7%. The highest percentage of clinical details totally reported corresponds, with 53%, to the acupuncture studies on nausea/vomiting. Figure 1 shows that, in our sample of studies, most reported clinical details referred to the acupuncture and/or other treatment procedures used in the studies. However, even in this department more than half of the important clinical details were not reported.

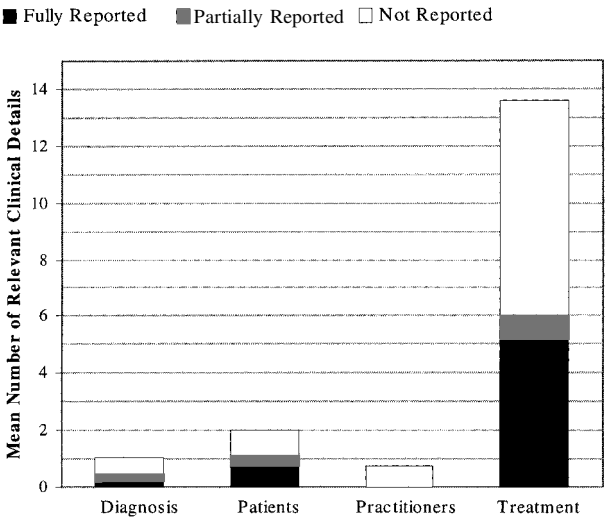

FIG. 1. Mean number of clinical details fully, partially and not reported in 30 studies about acupuncture for the treatment of headache/migraine (11) and nausea/vomiting (9), and acupressure for the treatment of nausea/vomiting (10), grouped by type of detail.

In addition, it is noticeable how little information about the diagnostic procedures used in the studies was considered to be relevant by the clinicians responding to the previously mentioned survey (see Table 1). This may be related to the fact that clinicians tend to use general label diagnoses rather than describing the clinical conditions with precision.

Quality of randomization of trials

Tables 2 and 3 present the results of this assessment in the second columns. As explained in the "Methods" section, the maximum quality of randomization score possible was 5, with higher scores indicating lower chances of bias. There was a wide range of quality scores in the reviewed studies (from 0 to 5) with no significant differences among conditions or treatment modes. The median of the quality scores for the overall group of studies is 2, a fairly poor score, more so when considering the stringent criteria used by the authors of this article in the selection of the studies.

Reporting of outcome measures and discussion of their clinical significance

The last two columns of Tables 2 and 3 present the results of this enquiry. The rating explained in the "methods" section has been modified on these tables as follows: fully reported = Yes; partially reported, and not reported = No. As stated before, we did not attempt to evaluate in any way the clinical value of the outcome measures themselves.

In our sample of studies, only 4 of the 11 headache studies provided some discussion of the clinical significance of the outcome measures utilized.

Surprisingly none of the nausea/vomiting studies provided any discussion of the clinical importance of the outcome measures used. This may be because some of the outcome measures in those studies were clinical events such as the number of times vomiting and self-reported episodes of nausea, the importance of which may have seemed self-evident to the researchers. However, we think that unless we discuss and study it appropriately, we cannot establish *a priori* whether a small but statistically significant difference in the amount of nausea or vomiting for a given patient is clinically relevant or not (i.e., whether there is a clearly positive cost/benefit ratio in this particular clinical situation). This issue was never directly addressed in the nausea/vomiting studies, although the presentation of the results provided by the researchers in those papers seemed to imply that the cost/benefit ratio of the intervention was positive.

DISCUSSION

The main goal of this study was to assess the extent to which a selected group of acupuncture research studies reported clinical details deemed important by a relatively small group of medical acupuncture practitioners, as reflected by their answers to a written survey in 1998 (Elorriaga Claraco, 2003). Even though we answered the question, because of the limitations of our study we cannot attempt to make any generalized statements about the meaning of our findings for the whole area of clinical acupuncture research. We have simply tried to develop a new approach to evaluate acupuncture clinical research that, when perfected, will allow future reviewers to extract more practical and meaningful information from clinical

research, with the ultimate goal of generating evidence-based recommendations for the practice of acupuncture.

In the present study, our main limitations were the low power of our conclusions as a result of the small size of both the group of practitioners answering the survey (n = 34) and the group of studies selected for final analysis (n = 30). However, few final comments can be done based on our findings.

It is the authors' opinion that in order to produce clinically applicable information, acupuncture clinical research should adequately report clinical details concerning practitioners, patients, diagnostic procedures, and treatment procedures used in the studies. This was not accomplished in our limited sample of studies. Other areas of acupuncture research need to be examined to confirm whether our data reflect a general tendency.

Based on the wide range of the quality scores found in our sample of studies, the authors think that it is inadequate at the present time, as it is often done in systematic reviews of acupuncture studies, to aggregate outcome from studies of greatly variable quality and use the results to validate or invalidate a particular therapeutic approach without considering the different real meaning of these outcomes. It is the authors' opinion that, in light of these considerations, a reevaluation of conclusions about acupuncture efficacy based on some existing reviews is warranted.

The final comments pertain to the outcome measures used in the studies. In our analysis, we did not attempt to evaluate their quality but only ascertain whether there was any discussion about them in the papers. The fact that most studies never discussed outcome measures, either in terms of reliability and validity or in terms of clinical significance, indicates to the authors of this paper the need for more attention to this important issue in future trials. The authors believe that regardless of the scientific merits of a piece of clinical research, it is the clinical significance of the outcome measures used in that study that determines whether the therapeutic intervention being tested is worth using in everyday practice because it has proven to be cost effective both economically and in human terms.

ACKNOWLEDGMENTS

This study was funded by a grant from the Acupuncture Foundation of Canada, Toronto, Ontario. We extend sincere thanks to Douglas McCrory, M.D., for generously providing the references for his 1998 unpublished (at the time of the study) review of the headache/migraine studies. We also thank Alex Jadad, M.D., Ph.D., and Rob Stevens, M.Sc., from the Department of Biostatistics & Epidemiology, McMaster University; Bruce Pomeranz, Ph.D., from the University of Toronto; Alan Best, M.D., from the Tzu Chi Institute in Vancouver; and Aileen Burford-Mason, Ph.D., from the Acupuncture Foundation of Canada for their helpful comments on aspects of this research.

We are also indebted to Mrs. Valerie Cannon for her outstanding secretarial assistance in preparing the manuscript.

REFERENCES

Acupuncture. NIH Consensus Statement 1997. 1997; 15:1–34.

Cecherelli F, Ambrosio F, Avila M, Duse G, Munari A, and Giron GP. Acupuncture vs placebo in the common migraine: A double blind study. Cephalagia 1987;7 (Suppl 6):499–500.

Cheng X, ed. Chinese Acupuncture and Moxibustion. Beijing: Foreign Language Press, 1987.

Elorriaga Claraco A, Fargas-Babjak A, Hanna S. The reporting of clinical acupuncture research: What do clinicians need to know? J Altern Complement Med 2003: 9:xx–xx.

Hammerschlag R. Methodological and ethical issues in clinical trials of acupuncture. J Altern Complement Med 1998;4:159–171.

Hammerschlag R, Morris M. Clinical trials comparing acupuncture with biomedical standard care: a criteria-based evaluation of research design and reporting. Complement Ther Med 1997;5:133–140.

Helms JM. 1995 Acupuncture Energetics: A Clinical Approach for Physicians. Berkeley, CA: Medical Acupuncture Publishers.

Jadad AR, Moore RA, Carrol D, Jenkinson C, Reynolds DJM, Gavaghan DJ, McQuay H. Assessing the quality of reports of randomized clinical trials: Is blinding necessary? Controlled Clin Trials 1996;17:1–12.

Lewith T, Vincent C. On the evaluation of the clinical effects of acupuncture: a problem reassessed and a framework for future research. J Altern Complement Med 1996;2:79–90.

Melchart D, Linde K, Fischer P, White A, Allais G, Vickers A. Acupuncture for recurrent headaches: A systematic review. Cephalalgia 1999;19:779–786.

Pomeranz B. Scientific Basis of Acupuncture. In: Stux G,

Pomeranz B. Basics of Acupuncture, 2nd ed. Springer-Verlag, Berlin, 1991:4–55.
ter Riet G, Kleijnen J, Knipschild P. Acupuncture and chronic pain: A criteria-based meta-analysis. J Clin Epidemiol 1990;43:1191–1199.
Vickers A. Can acupuncture have specific effects on health? A systematic review of acupuncture antiemesis trials. J R Soc Med 1996a;89:303–311.
Vickers A. Methodological issues in complementary and alternative medicine research: A personal reflection on 10 years of debate in the United Kingdom. J Altern Complement Med 1996b;2(4):515–524.

Address reprint requests to:
Alejandro Elorriaga Claraco, M.D.
Department of Anaesthesia
McMaster University
1200 Main Street West, Room HSC-2U
Hamilton Ontario L8N 3Z5
Canada

E-mail: aelorriaga@sympatico.ca