



Medical Acupuncture

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THE MEDICAL ACUPUNCTURE JOURNAL'S MISSION STATEMENT

The aims and purpose of our journal are depicted in our Mission Statement:

"The *Medical Acupuncture* journal, published by the American Academy of Medical Acupuncture, is dedicated to publishing the highest quality of clinical and research articles to encourage the understanding and practice of acupuncture both from theoretical and practical perspectives.

Its goal is to be the premier national and international journal in this discipline. To achieve this goal, the journal welcomes and encourages original work that, transcending traditional scientific and medical paradigms, is able to rigorously formulate, propose, advance, and qualify the integrative field of acupuncture."

Uniform Requirements For Manuscripts Submitted To Biomedical Journals: Writing And Editing For Biomedical Publications

*International Committee Of Medical Journal Editors
Updated February 2006*

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I. STATEMENT OF PURPOSE

I. A. About the Uniform Requirements

A small group of editors of general medical journals met informally in Vancouver, British Columbia, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. The group became known as the Vancouver Group. Its requirements for manuscripts, including formats for bibliographic references developed by the National Library of Medicine, were first published in 1979. The Vancouver Group expanded and evolved into the International Committee of Medical Journal Editors (ICMJE), which meets annually. The ICMJE gradually has broadened its concerns to include ethical principles related to publication in biomedical journals.

The ICMJE has produced multiple editions of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Over the years, issues have arisen that go beyond manuscript preparation, resulting in the development of a number of Separate Statements on editorial policy. The entire Uniform Requirements document was revised in 1997; sections were updated in May 1999 and May 2000. In May 2001, the ICMJE revised the sections related to potential conflict

of interest. In 2003, the committee revised and reorganized the entire document and incorporated the Separate Statements into the text. The committee prepared this revision in 2005.

The total content of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals may be reproduced for educational, not-for-profit purposes without regard for copyright; the committee encourages distribution of the material.

Journals that agree to use the Uniform Requirements are encouraged to state in their instructions to authors that their requirements are in accordance with the Uniform Requirements and to cite this version. Journals that wish to be listed on www.ICMJE.org as a publication that follows the Uniform Requirements should contact the ICMJE secretariat office.

The ICMJE is a small working group of general medical journals not an open membership organization. Occasionally, the ICMJE will invite a new member or guest when the committee feels that the new journal or organization will provide a needed perspective that is not already available within the existing committee. Open membership organizations for editors and others in biomedical publication include the World Association of Medical Editors www.WAME.org and the Council of Science Editors www.councilofscienceeditors.org.

I.B. Potential Users of the Uniform Requirements

The ICMJE created the Uniform Requirements primarily to help authors and editors in their mutual task of creating and distributing accurate, clear, easily accessible reports of biomedical studies. The initial sections address the ethical principles related to the process of evaluating, improving, and publishing manuscripts in biomedical journals and the relationships between editors and authors, peer reviewers, and the media. The latter sections address the more technical aspects of preparing and submitting manuscripts. The ICMJE believes the entire document is relevant to the concerns of both authors and editors.

The Uniform Requirements can provide many other stakeholders — peer reviewers, publishers, the media, patients and their families, and general readers — with useful insights into the biomedical authoring and editing process.

I. C. How to Use the Uniform Requirements

The Uniform Requirements state the ethical principles in the conduct and reporting of research and provide recommendations relating to specific elements of editing and writing. These recommendations are based largely on the shared experience of a moderate number of editors and authors, collected over many years, rather than on the results of methodical, planned investigation that aspires to be “evidence-based.” Wherever possible, recommendations are accompanied by a rationale that justifies them; as such, the document serves an educational purpose.

Authors will find it helpful to follow the recommendations in this document whenever possible because, as described in the explanations, doing so improves the quality and clarity of reporting in manuscripts submitted to any journal, as well as the ease of editing. At the same time, every journal has editorial requirements uniquely suited to its purposes. Authors therefore need to become familiar with the specific instructions to authors published by the journal they have chosen for their manuscript — for example, the topics suitable for that journal, and the types of papers that may be submitted (for example, original articles, reviews, or case reports)—and should follow those instructions. The Mulford Library at the Medical College of Ohio maintains a useful compendium of instructions to authors.

II. Ethical Considerations in the Conduct and Reporting of Research

II.A Authorship and Contributorship

II.A.1. Byline Authors

An “author” is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications.¹ In the past, readers were rarely provided with information about contributions to studies from those listed as authors and in acknowledgments.² Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research.

Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, it leaves unresolved the question of the quantity and quality of contribution that qualify for authorship. The International Committee of Medical Journal Editors has recommended the following criteria for authorship; these criteria are still appropriate for those journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript.³ These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgments. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript.
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as “guarantors,” be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship.

The order of authorship on the byline should be a joint decision of the co-authors.

Authors should be prepared to explain the order in which authors are listed.

II.A.2. Contributors Listed in Acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who

might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Editors should ask authors to disclose whether they had writing assistance and to identify the entity that paid for this assistance. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as “clinical investigators” or “participating investigators,” and their function or contribution should be described—for example, “served as scientific advisors,” “critically reviewed the study proposal,” “collected data,” or “provided and cared for study patients.”

Because readers may infer their endorsement of the data and conclusions, all persons must give written permission to be acknowledged.

II.B Editorship

II.B.1. The Role of the Editor

The editor of a journal is the person responsible for its entire content. Owners and editors of medical journals have a common endeavor—the publication of a reliable and readable journal, produced with due respect for the stated aims of the journal and for costs. The functions of owners and editors, however, are different. Owners have the right to appoint and dismiss editors and to make important business decisions in which editors should be involved to the fullest extent possible. Editors must have full authority for determining the editorial content of the journal. This concept of editorial freedom should be resolutely defended by editors even to the extent of their placing their positions at stake. To secure this freedom in practice, the editor should have direct access to the highest level of ownership, not only to a delegated manager.

Editors of medical journals should have a contract that clearly states the editor’s rights and duties in addition to the general terms of the appointment and that defines mechanisms for resolving conflict.

An independent editorial advisory board may be useful in helping the editor establish and maintain editorial policy.

II.B.2. Editorial Freedom

The ICMJE adopts the World Association of Medical Editors’ definition of editorial freedom. This definition states that editorial freedom or independence is the concept that editors-in-chief should have full authority over the editorial content of their journal. Journal owners should not interfere in the evaluation; selection or editing of individual articles either directly or by creating an environment that strongly influences decisions. Editors should base decisions on the validity of the work and its importance to the journal’s readers not on the commercial success of the journal. Editors should be free to express critical but responsible views about all aspects of medicine without fear of retribution, even if these views might conflict with the commercial goals of the publisher. Editors and editors’ organizations have the obligation to support the concept of editorial freedom and to draw major transgressions of such freedom to the attention of the international medical, academic, and lay communities.

II.C. Peer Review

Unbiased, independent, critical assessment is an intrinsic part of all scholarly work, including the scientific process. Peer review is the critical assessment of manuscripts submitted to journals by experts who are not part of the editorial staff. Peer review can therefore be viewed as an important extension of the scientific process. Although its actual value has been little studied, and is widely debated,⁴ peer review helps editors decide which manuscripts are suitable for their journals, and helps authors and editors in their efforts to improve the quality of report-

ing. A peer reviewed journal is one that submits most of its published research articles for outside review. The number and kind of manuscripts sent for review, the number of reviewers, the reviewing procedures, and the use made of the reviewers’ opinions may vary. In the interests of transparency, each journal should publicly disclose its policies in its instructions to authors.

II.D. Conflicts of Interest

Public trust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Conflict of interest exists when an author (or the author’s institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from those with negligible potential to those with great potential to influence judgment, and not all relationships represent true conflict of interest. The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.

All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest. Disclosure of these relationships is also important in connection with editorials and review articles, because it can be more difficult to detect bias in these types of publications than in reports of original research. Editors may use information disclosed in conflict of interest and financial interest statements as a basis for editorial decisions. Editors should publish this information if they believe it is important in judging the manuscript.

II.D.1. Potential Conflicts of Interest Related to Individual Authors’ Commitments

When authors submit a manuscript, whether an article or a letter, they are responsible for disclosing all financial and personal relationships that might bias their work. To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist. Authors should do so in the manuscript on a conflict of interest notification page that follows the title page, providing additional detail, if necessary, in a cover letter that accompanies the manuscript. (See Section IV.A.3. *Conflict of Interest Notification Page*)

Authors should identify Individuals who provide writing assistance and disclose the funding source for this assistance.

Investigators must disclose potential conflicts to study participants and should state in the manuscript whether they have done so.

Editors also need to decide when to publish information disclosed by authors about potential conflicts. If doubt exists, it is best to err on the side of publication.

II.D.2. Potential Conflicts of Interest Related to Project Support

Increasingly, individual studies receive funding from commercial firms, private foundations, and government. The conditions of this funding have the potential to bias and otherwise discredit the research.

Scientists have an ethical obligation to submit creditable research results for publication. Moreover, as the persons directly responsible for their work, researchers should not enter into agreements that interfere with their access to the data and their ability to analyze it inde-

pendently, to prepare manuscripts, and to publish them. Authors should describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Biases potentially introduced when sponsors are directly involved in research are analogous to methodological biases of other sorts. Some journals, therefore, choose to include information about the sponsor's involvement in the methods section.

Editors may request that authors of a study funded by an agency with a proprietary or financial interest in the outcome sign a statement such as, "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis." Editors should be encouraged to review copies of the protocol and/or contracts associated with project-specific studies before accepting such studies for publication. Editors may choose not to consider an article if a sponsor has asserted control over the authors' right to publish.

II.D.3. Potential Conflicts of Interest Related to Commitments of Editors, Journal Staff, or Reviewers

Editors should avoid selecting external peer reviewers with obvious potential conflicts of interest, for example, those who work in the same department or institution as any of the authors. Authors often provide editors with the names of persons they feel should not be asked to review a manuscript because of potential conflicts of interest, usually professional. When possible, authors should be asked to explain or justify their concerns; that information is important to editors in deciding whether to honor such requests.

Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should disqualify themselves from reviewing specific manuscripts if they believe it to be appropriate. As in the case of authors, silence on the part of reviewers concerning potential conflicts may mean either that such conflicts exist that they have failed to disclose, or that conflicts do not exist. Reviewers must therefore also be asked to state explicitly whether conflicts do or do not exist. Reviewers must not use knowledge of the work, before its publication, to further their own interests.

Editors who make final decisions about manuscripts must have no personal, professional, or financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their financial interests (as they might relate to editorial judgments) and disqualify themselves from any decisions where they have a conflict of interest. Editorial staff must not use the information gained through working with manuscripts for private gain. Editors should publish regular disclosure statements about potential conflicts of interests related to the commitments of journal staff.

II.E. Privacy and Confidentiality

II. E.1. Patients and Study Participants

Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication.

Informed consent for this purpose requires that a patient who is identifiable be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet after publication.

Identifying details should be omitted if they are not essential. Complete anonymity is difficult to achieve, however, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained it should be indicated in the published article.

II.E.2. Authors and Reviewers

Manuscripts must be reviewed with due respect for authors' confidentiality. In submitting their manuscripts for review, authors entrust editors with the results of their scientific work and creative effort, on which their reputation and career may depend. Authors' rights may be violated by disclosure of the confidential details of the review of their manuscript. Reviewers also have rights to confidentiality, which must be respected by the editor. Confidentiality may have to be breached if dishonesty or fraud is alleged but otherwise must be honored.

Editors must not disclose information about manuscripts (including their receipt, content, status in the reviewing process, criticism by reviewers, or ultimate fate) to anyone other than the authors and reviewers. This includes requests to use the materials for legal proceedings.

Editors must make clear to their reviewers that manuscripts sent for review are privileged communications and are the private property of the authors. Therefore, reviewers and members of the editorial staff must respect the authors' rights by not publicly discussing the authors' work or appropriating their ideas before the manuscript is published. Reviewers must not be allowed to make copies of the manuscript for their files and must be prohibited from sharing it with others, except with the permission of the editor. Reviewers should return or destroy copies of manuscripts after submitting reviews. Editors should not keep copies of rejected manuscripts.

Reviewer comments should not be published or otherwise made public without permission of the reviewer, author, and editor.

Opinions differ on whether reviewers should remain anonymous. Authors should consult the information for authors of the journal they have chosen to learn whether the reviews are anonymous. When comments are not signed the reviewers' identity must not be revealed to the author or anyone else without the reviewer's permission.

Some journals publish reviewers' comments with the manuscript. No such procedure should be adopted without the consent of the authors and reviewers. However, reviewers' comments should be sent to other reviewers of the same manuscript, which helps reviewers learn from the review process, and reviewers may be notified of the editor's decision.

II.F. Protection of Human Subjects and Animals in Research

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should be asked to indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

III. Publishing and Editorial Issues Related to Publication in Biomedical Journals

III.A. Obligation to Publish Negative Studies

Editors should consider seriously for publication any carefully done study of an important question, relevant to their readers, whether the results are negative (that is, convincingly allow the null hypothesis to be accepted) or positive (that is, allow the null hypothesis to be rejected). Failure to submit or publish negative studies, in particular, contributes to publication bias. Many studies that purport to be negative are, in fact, inconclusive; publication of inconclusive studies is problematic, since they add little to biomedical knowledge and consume journal resources. The Cochrane Library may be interested in publishing inconclusive trials.

III.B. Corrections, Retractions and "Expressions of Concern"

Editors must assume initially that authors are reporting work based on honest observations. Nevertheless, two types of difficulty may arise.

First, errors may be noted in published articles that require the publication of a correction or erratum of part of the work. The corrections should appear on a numbered page, be listed in the contents page, include the complete original citation, and link to the original article and vice versa if online. It is conceivable that an error could be so serious as to vitiate the entire body of the work, but this is unlikely and should be handled by editors and authors on an individual basis. Such an error should not be confused with inadequacies exposed by the emergence of new scientific information in the normal course of research. The latter require no corrections or withdrawals.

The second type of difficulty is scientific fraud. If substantial doubts arise about the honesty or integrity of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued, usually by the authors' sponsoring institution. However, it is not ordinarily the task of editors to conduct a full investigation or to make a determination; that responsibility lies with the institution where the work was done or with the funding agency. The editor should be promptly informed of the final decision, and if a fraudulent paper has been published, the journal must print a retraction. If this method of investigation does not result in a satisfactory conclusion, the editor may choose to conduct his or her own investigation. As an alternative to retraction, the editor may choose to publish an expression of concern about aspects of the conduct or integrity of the work.

The retraction or expression of concern, so labeled, should appear on a numbered page in a prominent section of the print journal as well as in the online version, be listed in the contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author should be the same in the retraction as in the article, although under certain circumstances the editor may accept retractions by other responsible persons.

The text of the retraction should explain why the article is being retracted and include a full original citation reference to it.

The validity of previous work by the author of a fraudulent paper cannot be assumed. Editors may ask the author's institution to assure them of the validity of earlier work published in their journals or to retract it. If this is not done editors may choose to publish an announcement expressing concern that the validity of previously published work is uncertain.

III.C. Copyright

Many biomedical journals ask authors to transfer copyright to the journal. However, an increasing number of "open access" journals do not require authors to transfer copyright to the journal. Editors should make their position on copyright transfer clear to authors and to oth-

ers who might be interested in using editorial content from their journals. The copyright status of articles in a given journal can vary: some content cannot be copyrighted (articles written by employees of the U.S. and some other governments in the course of their work, for example); editors may agree to waive copyright on others; still others may be protected under serial rights (that is, use in publications other than journals, including electronic publications, is permitted).

III.D. Overlapping Publications

III.D.1. Duplicate Submission

Most biomedical journals will not consider manuscripts that are simultaneously being considered by other journals. Among the principal considerations that have led to this policy are: 1) the potential for disagreement when two (or more) journals claim the right to publish a manuscript that has been submitted simultaneously to more than one; and 2) the possibility that two or more journals will unknowingly and unnecessarily undertake the work of peer review and editing of the same manuscript, and publish same article.

However, editors of different journals may decide to simultaneously or jointly publish an article if they believe that doing so would be in the best interest of the public's health.

III.D.2. Redundant Publication

Redundant (or duplicate) publication is publication of a paper that overlaps substantially with one already published in print or electronic media.

Readers of primary source periodicals, whether print or electronic, deserve to be able to trust that what they are reading is original unless there is a clear statement that the article is being republished by the choice of the author and editor. The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources. Duplicate publication of original research is particularly problematic, since it can result in inadvertent double counting or inappropriate weighting of the results of a single study, which distorts the available evidence.

Most journals do not wish to receive papers on work that has already been reported in large part in a published article or is contained in another paper that has been submitted or accepted for publication elsewhere, in print or in electronic media. This policy does not preclude the journal considering a paper that has been rejected by another journal, or a complete report that follows publication of a preliminary report, such as an abstract or poster displayed at a professional meeting. Nor does it prevent journals considering a paper that has been presented at a scientific meeting but not published in full or that is being considered for publication in a proceedings or similar format. Press reports of scheduled meetings will not usually be regarded as breaches of this rule, but additional data or copies of tables and illustrations should not amplify such reports.

When submitting a paper, the author must always make a full statement to the editor about all submissions and previous reports that might be regarded as redundant or duplicate publication of the same or very similar work. The author must alert the editor if the manuscript includes subjects about which the authors have published a previous report or have submitted a related report to another publication. Any such report must be referred to and referenced in the new paper. Copies of such material should be included with the submitted paper to help the editor decide how to handle the matter.

If redundant or duplicate publication is attempted or occurs without such notification, authors should expect editorial action to be taken. At the least, prompt rejection of the submitted manuscript should be expected. If the editor was not aware of the violations and the article has already been published, then a notice of redundant or duplicate

publication will probably be published with or without the author's explanation or approval.

Preliminary reporting to public media, governmental agencies, or manufacturers, of scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances or public health hazards such as serious adverse effects of drugs, vaccines, other biological products, or medicinal devices, or reportable diseases.

This reporting should not jeopardize publication, but should be discussed with and agreed upon by the editor in advance.

III.D.3. Acceptable Secondary Publication

Certain types of articles, such as guidelines produced by governmental agencies and professional organizations, may need to reach the widest possible audience. In such instances, editors sometimes choose deliberately to publish material that is also being published in other journals, with the agreement of the authors and the editors of those other journals. Secondary publication for various other reasons, in the same or another language, especially in other countries, is justifiable, and can be beneficial, provided all of the following conditions are met.

1. The authors have received approval from the editors of both journals; the editor concerned with secondary publication must have a photocopy, reprint, or manuscript of the primary version.
2. The priority of the primary publication is respected by a publication interval of at least one week (unless specifically negotiated otherwise by both editors).
3. The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.
4. The secondary version faithfully reflects the data and interpretations of the primary version.
5. The footnote on the title page of the secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part and states the primary reference. A suitable footnote might read: "This article is based on a study first reported in the [title of journal, with full reference]." Permission for such secondary publication should be free of charge.
6. The title of the secondary publication should indicate that it is a secondary publication (complete republication, abridged republication, complete translation, or abridged translation) of a primary publication. Of note, the National Library of Medicine does not consider translations to be "republications," and does not cite or index translations when the original article was published in a journal that is indexed in MEDLINE.

III.D.4. Competing Manuscripts Based on the Same Study

Publication of manuscripts to air co-investigators disputes may waste journal space and confuse readers. On the other hand, if editors knowingly publish a manuscript written by only some of a collaborating team, they could be denying the rest of the team their legitimate co-authorship rights; they could also be denying the journal's readers access to legitimate differences of opinion about the interpretation of a study.

Two kinds of competing submissions are considered: submissions by coworkers who disagree on the analysis and interpretation of their study, and submissions by coworkers who disagree on what the facts are and which data should be reported.

Setting aside the unresolved question of ownership of the data, the following general observations may help editors and others dealing with these problems.

III. D.4.a. Differences in Analysis or Interpretation

If the dispute centers on the analysis or interpretation of data, the

authors should submit a manuscript that clearly presents both versions. The difference of opinion should be explained in a cover letter. The normal process of peer and editorial review of the manuscript may help the authors to resolve their disagreement regarding analysis or interpretation.

If the dispute cannot be resolved and the study merits publication, both versions should be published. Options include publishing two papers on the same study, or a single paper with two analyses or interpretations. In such cases it would be appropriate for the editor to publish a statement outlining the disagreement and the journal's involvement in attempts to resolve it.

III.D.4. b. Differences in Reported Methods or Results

If the dispute centers on differing opinions of what was actually done or observed during the study, the journal editor should refuse publication until the disagreement is resolved. Peer review cannot be expected to resolve such problems. If there are allegations of dishonesty or fraud, editors should inform the appropriate authorities; authors should be notified of an editor's intention to report a suspicion of research misconduct.

III.D.5. Competing Manuscripts Based on the Same Database

Editors sometimes receive manuscripts from separate research groups that have analyzed the same data set, e.g., from a public database. The manuscripts may differ in their analytic methods, conclusions, or both. Each manuscript should be considered separately. Where interpretations of the same data are very similar, it is reasonable but not necessary for editors to give preference to the manuscript that was received earlier. However, editorial consideration of multiple submissions may be justified in this circumstance, and there may even be a good reason for publishing more than one manuscript because different analytical approaches may be complementary and equally valid.

III.E. Correspondence

Biomedical journals should provide its readership with a mechanism for submitting comments, questions, or criticisms about published articles, as well as brief reports and commentary unrelated to previously published articles. This will likely, but not necessarily, take the form of a correspondence section or column. The authors of articles discussed in correspondence should be given an opportunity to respond, preferably in the same issue in which the original correspondence appears. Authors of correspondence should be asked to declare any competing or conflicting interests.

Published correspondence may be edited for length, grammatical correctness, and journal style. Alternatively, editors may choose to publish correspondence unedited for length or style, as for example in rapid response sections on the Internet; the journal should declare its editorial practice in this regard. Authors should approve editorial changes that alter the substance or tone of a letter or response.

Although editors have the prerogative to sift out correspondence material that is irrelevant, uninteresting, or lacking in cogency, they have a responsibility to allow a range of opinion to be expressed. The correspondence column should not be used merely to promote the journal's, or the editors', point of view. In all instances, editors must make an effort to screen out discourteous, inaccurate, or libelous statements, and should not allow ad hominem arguments intended to discredit opinions or findings.

In the interests of fairness and to keep correspondence within manageable proportions, journals may want to set time limits for responding to articles and correspondence, and for debate on a given topic. Journals should also decide whether they would notify authors when correspondence bearing on their published work is going to appear in standard or rapid

response sections. Journals should also set policy with regard to the archiving of unedited correspondence that appears on line. These policies should be published both in print and electronic versions of the journal.

III.F. Supplements, Theme Issues, and Special Series

Supplements are collections of papers that deal with related issues or topics, are published as a separate issue of the journal or as part of a regular issue, and are usually funded by sources other than the journal's publisher. Supplements can serve useful purposes: education, exchange of research information, ease of access to focused content, and improved cooperation between academic and corporate entities. Because funding sources can bias the content of supplements through the choice of topics and viewpoints, journals should consider adopting the following principles. These same principles apply to theme issues or special series that have external funding and/or guest editors.

1. The journal editor must take full responsibility for the policies, practices, and content of supplements, including complete control of the decision to publish all portions of the supplement. Editing by the funding organization should not be permitted.
2. The journal editor must retain the authority to send supplement manuscripts for external peer review and to reject manuscripts submitted for the supplement. These conditions should be made known to authors and external supplement editors before beginning editorial work on the supplement.
3. The journal editor must approve the appointment of any external editor of the supplement and take responsibility for the work of the external editor.
4. The sources of funding for the research, publication, and the products the funding source make that are considered in the supplement should be clearly stated and prominently located in the supplement, preferably on each page. Whenever possible, funding should come from more than one sponsor.
5. Advertising in supplements should follow the same policies as those of the rest of the journal.
6. Journal editors must enable readers to distinguish readily between ordinary editorial pages and supplement pages.
7. Journal editors and supplement editors must not accept personal favors or personal remuneration from sponsors of supplements.
8. Secondary publication in supplements (republishing of papers previously published elsewhere) should be clearly identified by the citation of the original paper. Supplements should avoid redundant or duplicate publication. Supplements should not republish research results, but the republishing of guidelines or other material in the public interest might be appropriate.
9. The principles of authorship and potential conflict of interest disclosure articulated elsewhere in this document should apply to supplements.

III.G. Electronic Publishing

Most biomedical journals are now published in electronic as well as print versions, and some are published in electronic form only. Electronic publishing (which includes the Internet) is publishing. In the interests of clarity and consistency, the medical and health information published on the Internet should follow the recommendations in this document whenever possible.

The nature of electronic publication requires some special considerations, both within and beyond this document. At a minimum, websites should indicate the following: names, appropriate credentials, affiliations, and relevant conflicts of interest of editors, authors, and contributors; documentation and attribution of references and sources for all content; information about copyright; disclosure of site ownership;

and disclosure of sponsorship, advertising, and commercial funding.

Linking from one health or medical Internet site to another may be perceived as an implicit recommendation of the quality of the second site. Journals thus should exercise caution in linking to other sites; when users are linking to another site, it may be helpful to provide an explicit message to that they are leaving the journal's site. If links to other sites are posted as a result of financial considerations, such should be clearly indicated. All dates of content posting and updating should be indicated. In electronic layout as in print, advertising and promotional messages should not be juxtaposed with editorial content, and commercial content should be clearly identifiable as such.

Electronic publication is an area that is in flux. Editors should develop, make available to authors, and implement policies on issues unique to electronic publishing. These issues include archiving, error correction, version control, and choice of the electronic or print version of the journal as the journal of record, publication of ancillary material, and electronic publication.

In no instance should a journal remove an article from its website or archive. If an article needs to be corrected or retracted, the explanation must be labeled appropriately and communicated as soon as possible on a citable page in a subsequent issue of the journal.

Preservation of electronic articles in a permanent archive is essential for the historical record. Access to the archive should be immediate and it should be controlled by a third party, such as a library, instead of a publisher. Deposition in multiple archives is encouraged.

III.H. Advertising

Most medical journals carry advertising, which generates income for their publishers, but advertising must not be allowed to influence editorial decisions. Journals should have formal, explicit, written policies for advertising in both print and electronic versions; website advertising policy should parallel policy for the print version as much as possible. Editors must have full and final authority for approving advertisements and enforcing advertising policy.

Where independent bodies for reviewing advertising exist editors should make use of their judgments. Readers should be able to distinguish readily between advertising and editorial material. The juxtaposition of editorial and advertising material on the same products or subjects should be avoided. Interleaving advertising pages within articles discourages readers by interrupting the flow of editorial content, and should be discouraged. Advertising should not be sold on the condition that it will appear in the same issue as a particular article.

Journals should not be dominated by advertising, but editors should be careful about publishing advertisements from only one or two advertisers, as readers may perceive that these advertisers have influenced the editor.

Journals should not carry advertisements for products that have proved to be seriously harmful to health—for example, tobacco. Editors should ensure that existing regulatory or industry standards for advertisements specific to their country are enforced, or develop their own standards. The interests of organizations or agencies should not control classified and other non-display advertising, except where required by law. Finally, editors should consider all criticisms of advertisements for publication.

III. I. Medical Journals and the General Media

The public's interest in news of medical research has led the popular media to compete vigorously to get information about research as soon as possible. Researchers and institutions sometimes encourage the reporting of research in the non-medical media before full publication in a scientific journal by holding a press conference or giving interviews.

The public is entitled to important medical information without unreasonable delay, and editors have a responsibility to play their part in this process. Biomedical journals are published primarily for their readers, but the general public has a legitimate interest in their content; an appropriate balance should therefore guide journals' interaction with the media between these complementary interests. Doctors in practice need to have reports available in full detail before they can advise their patients about the reports' conclusions. Moreover, media reports of scientific research before the work has been peer reviewed and fully published may lead to the dissemination of inaccurate or premature conclusions.

An embargo system has been established in some countries to prevent publication of stories in the general media before the original paper on which they are based appears in the journal. The embargo creates a "level playing field," which most reporters appreciate since it minimizes the pressure on them to publish stories which they have not had time to prepare carefully. Consistency in the timing of public release of biomedical information is also important in minimizing economic chaos, since some articles contain information that has great potential to influence financial markets. On the other hand, the embargo system has been challenged as being self-serving of journals' interests, and impeding the rapid dissemination of scientific information.

Editors may find the following recommendations useful as they seek to establish policies on these issues.

- Editors can foster the orderly transmission of medical information from researchers, through peer-reviewed journals, to the public. This can be accomplished by an agreement with authors that they will not publicize their work while their manuscript is under consideration or awaiting publication and an agreement with the media that they will not release stories before publication in the journal, in return for which the journal will cooperate with them in preparing accurate stories.
- Editors need to keep in mind that an embargo system works on the honor system; no formal enforcement or policing mechanism exists. The decision of any significant number of media outlets, or of biomedical journals, not to respect the embargo system would therefore lead to its rapid dissolution.
- Very little medical research has such clear and urgently important clinical implications for the public's health that the news must be released before full publication in a journal. In such exceptional circumstances, however, appropriate authorities responsible for public health should make the decision and should be responsible for the advance dissemination of information to physicians and the media. If the author and the appropriate authorities wish to have a manuscript considered by a particular journal, the editor should be consulted before any public release. If editors accept the need for immediate release, they should waive their policies limiting prepublication publicity.
- Policies designed to limit prepublication publicity should not apply to accounts in the media of presentations at scientific meetings or to the abstracts from these meetings (see Redundant Publication). Researchers who present their work at a scientific meeting should feel free to discuss their presentations with reporters, but they should be discouraged from offering more detail about their study than was presented in their talk.
- When an article is soon to be published, editors should help the media prepare accurate reports by providing news releases, answering questions, supplying advance copies of the journal, or referring reporters to the appropriate experts. Most responsible reporters find this assistance should be contingent on the media's cooperation in timing their

release of stories to coincide with the publication of the article.

- Editors, authors, and the media should apply the above stated principles to material released early in electronic versions of journals.

III.J. Obligation to Register Clinical Trials

The ICMJE believes that it is important to foster a comprehensive, publicly available database of clinical trials. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

The ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trials registry. The details of this policy are contained under editorials. The ICMJE encourages editors of other biomedical journals to adopt similar policy.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organization. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable. An acceptable registry must include at minimum the data elements in the following table. Trial registration with missing fields or fields that contain uninformative terminology is inadequate.

The ICMJE recommends that journals publish the trial registration number at the end of the Abstract.

Minimal Registration Data Set*

Items:

1. Unique trial number
Comment: The unique trial number will be established by the primary registering entity (the registry).
2. Trial registration date
Comment: The date of registration will be established by the primary registering entity.
3. Secondary IDs
Comment: May be assigned by sponsors or other interested parties (there may be none).
4. Funding source(s)
Comment: Name of the organization(s) that provided funding for the study.
5. Primary sponsor
Comment: The main entity responsible for performing the research.
6. Secondary sponsor(s)
Comment: The secondary entities, if any, responsible for performing the research.
7. Responsible contact person
Comment: Public contact person for the trial, for patients interested in participating.
8. Research contact person
Comment: Person to contact for scientific inquiries about the trial.
9. Title of the study
Comment: Brief title chosen by the research group (can be omitted if the researchers wish).
10. Official scientific title of the study
Comment: This title must include the name of the intervention,

the condition being studied, and the outcome (e.g., The International Study of Digoxin and Death from Congestive Heart Failure).

11. Research ethics review

Has the study at the time of registration received appropriate ethics committee approval (yes/no)? (It is assumed that all registered trials will be approved by an ethics board before commencing.)

12. Condition

Comment: The medical condition being studied (e.g., asthma, myocardial infarction, depression).

13. Intervention(s)

Comment: A description of the study and comparison/control intervention(s) (For a drug or other product registered for public sale anywhere in the world, this is the generic name; for an unregistered drug the generic name or company serial number is acceptable). The duration of the intervention(s) must be specified.

14. Key inclusion and exclusion criteria

Comment: Key patient characteristics that determine eligibility for participation in the study.

15. Study type

Comment: Database should provide drop-down lists for selection. This would include choices for randomized vs. non-randomized, type of masking (e.g., double-blind, single-blind), type of controls (e.g., placebo, active), and group assignment (e.g., parallel, crossover, factorial).

16. Anticipated trial start date

Comment: Estimated enrollment date of the first participant.

17. Target sample size

Comment: The total number of subjects the investigators plan to enroll before closing the trial to new participants.

18. Recruitment status

Comment: Is this information available (yes/no) (If yes, link to information).

19. Primary outcome

Comment: The primary outcome that the study was designed to evaluate. Description should include the time at which the outcome is measured (e.g., blood pressure at 12 months).

20. Key secondary outcomes

Comment: The secondary outcomes specified in the protocol. Description should include time of measurement (e.g., creatinine clearance at 6 months).

**The data fields were specified at a meeting convened by the WHO in April 2005; the explanatory comments are largely from the ICMJE.*

IV. Manuscript Preparation and Submission

IV.A. Preparing a Manuscript for Submission to a Biomedical Journal

Editors and reviewers spend many hours reading manuscripts, and therefore appreciate receiving with manuscripts that are easy to read and edit. Much of the information in journals' instructions to authors is designed to accomplish that goal in ways that meet each journal's particular editorial needs. The guidance that follows provides a general background and rationale for preparing manuscripts for any journal.

IV.A.1.a. General Principles

The text of observational and experimental articles is usually (but not necessarily) divided into sections with the headings Introduction, Methods, Results, and Discussion. This so-called "IMRAD" structure is not simply an arbitrary publication format, but rather a direct reflection of the process of scientific discovery. Long articles may need sub-

headings within some sections (especially the Results and Discussion sections) to clarify their content. Other types of articles, such as case reports, reviews, and editorials, are likely to need other formats.

Publication in electronic formats has created opportunities for adding details or whole sections in the electronic version only, layering information, cross-linking or extracting portions of articles, and the like. Authors need to work closely with editors in developing or using such new publication formats and should submit material for potential supplementary electronic formats for peer review.

Double spacing of all portions of the manuscript — including the title page, abstract, text, acknowledgments, references, individual tables, and legends — and generous margins make it possible for editors and reviewers to edit the text line by line, and add comments and queries, directly on the paper copy. If manuscripts are submitted electronically, the files should be double spaced, because the manuscript may need to be printed out for reviewing and editing.

During the editorial process reviewers and editors frequently need to refer to specific portions of the manuscript, which is difficult unless the pages are numbered. Authors should therefore number all of the pages of the manuscript consecutively, beginning with the title page.

IV.A.1.b. Reporting Guidelines for Specific Study Designs

Research reports frequently omit important information. The general requirements listed in the next section relate to reporting essential elements for all study designs. Authors are encouraged in addition to consult reporting guidelines relevant to their specific research design. For reports of randomized controlled trials authors should refer to the CONSORT statement. This guideline provides a set of recommendations comprising a list of items to report and a patient flow diagram. Reporting guidelines have also been developed for a number of other study designs that some journals may ask authors to follow (see Table: Reporting Guidelines). Authors should consult the information for authors of the journal they have chosen.

Reporting Guidelines

• **Initiative:** CONSORT

Type of Study: randomized controlled trials

Source: <http://www.consort-statement.org>

• **Initiative:** STARD

Type of Study: studies of diagnostic accuracy

Source: <http://www.consort-statement.org/stardstatement.htm>

• **Initiative:** QUOROM

Type of Study: systematic reviews and meta-analyses

Source: <http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf>

• **Initiative:** STROBE

Type of Study: observational studies in epidemiology

Source: <http://www.strobe-statement.org>

• **Initiative:** MOOSE

Type of Study: meta-analyses of observational studies in epidemiology

Source: <http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf>

IV.A.2. Title Page

The title page should carry the following information:

1. The title of the article. Concise titles are easier to read than long, convoluted ones. Titles that are too short may, however, lack important information, such as study design (which is particularly important in identifying randomized controlled trials). Authors should include all information in the title that will make electronic retrieval of the article both sensitive and specific.

2. Authors' names and institutional affiliations. Some journals publish each author's highest academic degree(s), while others do not.
3. The name of the department(s) and institution(s) to which the work should be attributed.
4. Disclaimers, if any.
5. Corresponding authors. The name, mailing address, telephone and fax numbers, and e-mail address of the author responsible for correspondence about the manuscript (the "corresponding author;" this author may or may not be the "guarantor" for the integrity of the study as a whole, if someone is identified in that role. The corresponding author should indicate clearly whether his or her e-mail address is to be published.
6. The name and address of the author to whom requests for reprints should be addressed or a statement that reprints will not be available from the authors.
7. Source(s) of support in the form of grants, equipment, drugs, or all of these.
8. A running head. Some journals request a short running head or foot line, usually of no more than 40 characters (count letters and spaces) at the foot of the title page. Running heads are published in most journals, but are also sometimes used within the editorial office for filing and locating manuscripts.
9. Word counts. A word count for the text only (excluding abstract, acknowledgments, figure legends, and references) allows editors and reviewers to assess whether the information contained in the paper warrants the amount of space devoted to it, and whether the submitted manuscript fits within the journal's word limits. A separate word count for the Abstract is also useful for the same reason.
10. The number of figures and tables. It is difficult for editorial staff and reviewers to tell if the figures and tables that should have accompanied a manuscript were actually included unless the numbers of figures and tables that belong to the manuscript are noted on the title page.

IV.A.3. Conflict of Interest Notification Page

To prevent the information on potential conflict of interest for authors from being overlooked or misplaced, it is necessary for that information to be part of the manuscript. It should therefore also be included on a separate page or pages immediately following the title page. However, individual journals may differ in where they ask authors to provide this information and some journals do not send information on conflicts of interest to reviewers. (See Section II.D. *Conflicts of Interest*)

IV.A.4. Abstract and Key Words

An abstract (requirements for length and structured format vary by journal) should follow the title page. The abstract should provide the context or background for the study and should state the study's purposes, basic procedures (selection of study subjects or laboratory animals, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), and principal conclusions. It should emphasize new and important aspects of the study or observations.

Because abstracts are the only substantive portion of the article indexed in many electronic databases, and the only portion many readers read, authors need to be careful that abstracts reflect the content of the article accurately. Unfortunately, many abstracts disagree with the text of the article.⁶ The format required for structured abstracts differs from journal to journal, and some journals use more than one structure; authors should make it a point to prepare their abstracts in the format specified by the journal they have chosen.

Some journals request that, following the abstract, authors provide,

and identify as such, 3 to 10 key words or short phrases that capture the main topics of the article. These will assist indexers in cross-indexing the article and may be published with the abstract. Terms from the Medical Subject Headings (MeSH) list of Index Medicus should be used; if suitable MeSH terms are not yet available for recently introduced terms, present terms may be used.

IV.A.5. Introduction

Provide a context or background for the study (i.e., the nature of the problem and its significance). State the specific purpose or research objective of, or hypothesis tested by, the study or observation; the research objective is often more sharply focused when stated as a question. Both the main and secondary objectives should be made clear, and any pre-specified subgroup analyses should be described. Give only strictly pertinent references and do not include data or conclusions from the work being reported.

IV.A.6. Methods

The Methods section should include only information that was available at the time the plan or protocol for the study was written; all information obtained during the conduct of the study belongs in the Results section.

IV.A.6.a. Selection and Description of Participants

Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. Because the relevance of such variables as age and sex to the object of research is not always clear, authors should explain their use when they are included in a study report; for example, authors should explain why only subjects of certain ages were included or why women were excluded. The guiding principle should be clarity about how and why a study was done in a particular way. When authors use variables such as race or ethnicity, they should define how they measured the variables and justify their relevance.

IV.A.6.b. Technical information

Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Authors submitting review manuscripts should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

IV.A.6.c. Statistics

Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as the use of P values, which fails to convey important information about effect size. References for the design of the study and statistical methods should be to standard works when possible (with pages stated). Define statistical terms, abbreviations, and most symbols. Specify the computer software used.

IV.A.7. Results

Present your results in logical sequence in the text, tables, and illus-

trations, giving the main or most important findings first. Do not repeat in the text all the data in the tables or illustrations; emphasize or summarize only important observations. Extra or supplementary materials and technical detail can be placed in an appendix where it will be accessible but will not interrupt the flow of the text; alternatively, it can be published only in the electronic version of the journal.

When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated, and specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid non-technical uses of technical terms in statistics, such as “random” (which implies a randomizing device), “normal,” “significant,” “correlations,” and “sample.”

Where scientifically appropriate, analyses of the data by variables such as age and sex should be included.

IV.A.8. Discussion

Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the Introduction or the Results section. For experimental studies it is useful to begin the discussion by summarizing briefly the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study, and explore the implications of the findings for future research and for clinical practice.

Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not adequately supported by the data. In particular, authors should avoid making statements on economic benefits and costs unless their manuscript includes the appropriate economic data and analyses. Avoid claiming priority and alluding to work that has not been completed. State new hypotheses when warranted, but clearly label them as such.

IV.A.9. References

IV.A.9.a. General Considerations Related to References

Although references to review articles can be an efficient way of guiding readers to a body of literature, review articles do not always reflect original work accurately. Readers should therefore be provided with direct references to original research sources whenever possible. On the other hand, extensive lists of references to original work on a topic can use excessive space on the printed page. Small numbers of references to key original papers will often serve as well as more exhaustive lists, particularly since references can now be added to the electronic version of published papers, and since electronic literature searching allows readers to retrieve published literature efficiently.

Avoid using abstracts as references. References to papers accepted but not yet published should be designated as “in press” or “forthcoming;” authors should obtain written permission to cite such papers as well as verification that they have been accepted for publication. Information from manuscripts submitted but not accepted should be cited in the text as “unpublished observations” with written permission from the source.

Avoid citing a “personal communication” unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text. For scientific articles, authors should obtain written permission and confirmation of accuracy from the source of a personal communication.

Some journals check the accuracy of all reference citations, but not all journals do so, and citation errors sometimes appear in the published version of articles. To minimize such errors, authors should therefore verify references against the original documents. Authors are responsible for checking that none of the references cite retracted articles except in the context of referring to the retraction. For articles published in journals indexed in MEDLINE, the ICMJE considers PubMed (<http://www.pubmed.gov>) the authoritative source for information about retractions. Authors can identify retracted articles in MEDLINE by using the following search term, where pt in square brackets stands for publication type: Retracted publication [pt] in pubmed.

IV.A.9.b. Reference Style and Format

The Uniform Requirements style is based largely on an ANSI standard style adapted by the National Library of Medicine (NLM) for its databases.⁷ For samples of reference citation formats, authors should consult National Library of Medicine web site.

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Identify statistical measures of variations, such as standard deviation and standard error of the mean.

Be sure that each table is cited in the text.

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V. References

A. References Cited in this Document

1. Davidoff F for the CSE Task Force on Authorship. Who's the Author? Problems with Biomedical Authorship, and Some Possible Solutions. *Science Editor*. July-August 2000: Volume 23 – Number 4:111-119.
2. Yank V, Rennie D. Disclosure of researcher contributions: a study of original research articles in *The Lancet*. *Ann Intern Med*. 1999 Apr 20;130(8):661-70.
3. Flanagan A, Fontanarosa PB, DeAngelis CD. Authorship for research

groups. *JAMA*. 2002;288:3166-68.

4. Godlee F, Jefferson T. *Peer Review in Health Sciences*. London: BMJ Books, 1999.

5. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2000 Dec 20;284(23):3043-5.

6. Pitkin RM, Branagan MA, Burmeister LF. Accuracy of data in abstracts of published research articles. *JAMA*. 1999 Mar 24-31;281(12):1110-1.

7. Patrias K. National Library of Medicine recommended formats for bibliographic citation. Bethesda (MD): The Library; 1991.

B. Other Sources of Information Related to Biomedical Journals

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Treatment Of Chronic Back Pain And Neck Pain Using Scalp Acupuncture: A Case Study

Chunbo Cai, MD

ABSTRACT

Background Acupuncture points on the scalp have been considered important points in the history of the practice of acupuncture. However, development of scalp acupuncture as an independent system took place in the last century. Scalp acupuncture was known to be developed as a systemic approach in China in the 1960s and 1970s. It is sophisticated and has branched out into different styles by the pioneers in this field. Among them, Zhu's style uses the 3-column zone theory to direct formulation of a treatment regimen.

Objective To investigate the effectiveness of treatment of chronic back pain and neck pain with scalp acupuncture.

Methods We used Zhu's style to treat 20 cases of chronic back pain and neck pain at a hospital-based spine center. The technique involved the use of 36-gauge 1.2 acupuncture needles at relevant points based on the 3-column zone theory. Among the 20 cases, there were 15 cases of chronic back pain, 5 cases of neck pain (13 men, 7 women). Ages were 37 to 80, with a mean of 51 years. Eight cases of 15 chronic back pain cases had a history of lumbar laminectomy surgery (53%).

Results Relief of pain took place within 10 to 20 minutes into treatment. The degree of pain reduction ranged from 40% to 100% at the end of a 30-minute treatment. The mean VAS scores were significantly improved from 6.4/10 to 2/10 ($P < .005$) in chronic back pain cases, and 5.5/10 to 1/10 ($P < .05$) in neck pain cases. The mean degrees of the lumbar pain-free range of motion were improved from 49° to 81° in flexion, from 10° to 28° in extension, at the end of a 30-minute treatment. The treatment effect continued to last from 1 to 5 weeks after 1 treatment.

Conclusion Zhu's style scalp acupuncture is an effective regimen for treatment of chronic back and neck pain. It is less complex to formulate tactics for treatment of particular symptomatology and yet more efficient compared to the body points approach. Further randomized controlled trials are needed to evaluate this approach.

KEY WORDS

Acupuncture, Chronic Low Back Pain, Chronic Neck Pain, Visual Analog Scale (VAS), Scalp Acupuncture

INTRODUCTION

Acupuncture points on the scalp are considered important in the history of acupuncture practice. Scalp acupuncture was developed into a complete acupuncture sub-system in China in the 1960s and 1970s.¹ The pioneers in this field had different styles in naming the points and treatment zones based on their own experiences and preferences. A standard of nomenclature for scalp acupuncture points was developed in the mid 1980s, with the consensus of 14 therapeutic lines or zones based on the combination and summarization of the different schools of scalp acupuncture.¹ However, few practitioners have adopted the standard in practice.¹⁻⁷

Dr Zhu Mingqing is one of the pioneers in the scalp acupuncture arena. Zhu's style is popular due to its relative simplicity in learning and application. It is based on 3-column zone theory to formulate grouping of the treatment points.⁷ In Zhu's scalp acupuncture, 9 therapeutic zones are used, and the manipulation is characterized by forceful, small-amplitude lifting and thrusting of the needle, coupled with physical and breathing exercises. Scalp acupuncture has been reported for its effectiveness in the treatment of neurological conditions such as strokes and spinal cord injury.⁷⁻¹⁵ In this study, we investigated Zhu's style scalp acupuncture in treatment of chronic back and neck pain.

METHODS

This descriptive study reported 15 cases of chronic low back pain and 5 cases of chronic neck pain that had failed other conservative treatment, including pain medications and physical therapy. Among the 20 cases, there were 13 men and 7 women, ages 37 to 80, with a mean of 51 years. Eight cases of 15 chronic back pain cases had a history of lumbar laminectomy surgery (53%). The patients were treated with scalp acupuncture by a spine physiatrist certified by the American Board of Medical Acupuncture, at the Spine Center of Lahey Clinic Medical Center in Burlington, Massachusetts.

Consent for acupuncture treatment was obtained from the patients before treatment. The patient was placed in a sitting position in a quiet treatment room. Three Zhu's scalp-acupuncture needles (12.5 inch 36 gauge, purchased from Zhu's Acupuncture Medical Neurology Center, Inc.) were placed into the cervical zone or lumbar zone on the scalp (Figure 1). One needle was inserted on the sagittal midline on the scalp, another 2 were placed 1 cm lateral to the midline on either side of the 1st needle. The Lower Jiao zone was also needled if the pulse diagnosis demonstrated Kidney deficiency (Figure 1) using the same technique. Depth of the needle insertion was 1/2 needle length. The needles were manipulated with a forceful, small-amplitude lifting and thrusting motion for 2 minutes, with patients being instructed to take deep breaths simultaneously. Then, the needles were left in place during the 30-minute treatment. No music, lighting, moxibustion, or electric stimulation were used. The needles were removed with cautions of avoiding bleeding at the end of the treatment. Only 1 treatment was provided for each patient. The longest follow-up was the 5th week after treatment. A *t* test was used for statistical analysis.

RESULTS

Pain relief occurred within 10-20 minutes into the treatment in all cases. The pain reduction ranged from 40% to 100% at the end of the 30-minute treatment among the 20 cases. Duration of the treatment benefit varied from 1 week to over 5 weeks. There were 2 chronic low back pain (13%), and 2 chronic neck pain cases; (40%) were still pain-free at the 5th week follow-up visits after the treatment.

Back Pain Cases

The mean visual analog scale score was significantly improved from 6.4/10 to 2/10 ($P < .005$) in chronic back pain cases. The mean degree of the lumbar spine pain-free ROM (range of motion) was improved from 49° to 81° in flexion, from 10° to 28° in extension, at the end of

the 30-minute treatment.

Neck Pain Cases

The mean VAS score was significantly improved from 5.5/10 to 1/10 ($P<.05$) in the chronic neck pain cases.

DISCUSSION

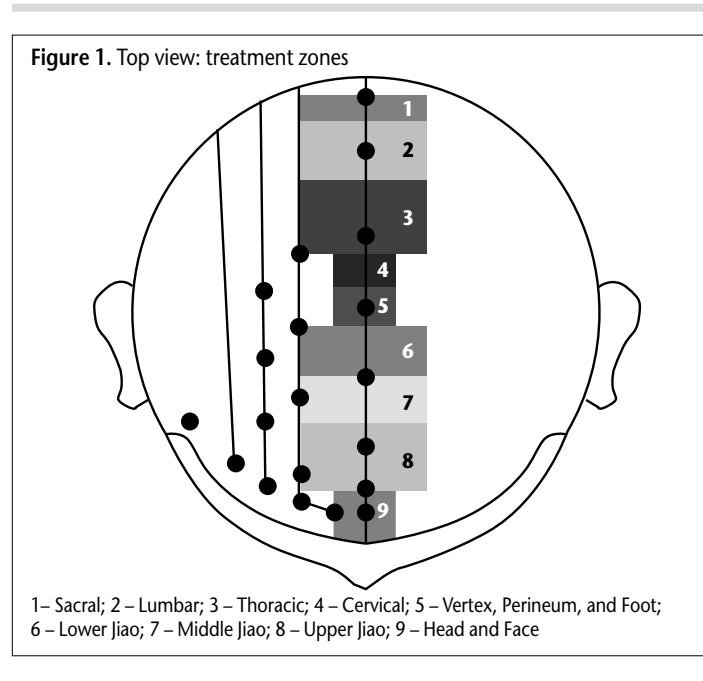
Many articles report utilizing acupuncture in the treatment of chronic low back and neck pain. The majority of the studies mainly utilized body acupuncture points. The reported length of the treatment is once or twice a week over 6 to 8 weeks on the average, and pain reduction ranged from 20% to 50% on VAS.¹⁶⁻¹⁹ In this study, we demonstrated that a single 30-minute scalp acupuncture treatment resulted in substantial improvement of chronic back and neck pain. Yet, the treatment benefit lasted from 1 week to over 5 weeks. The case series in this report indicate that the scalp acupuncture treatment may be more potent and efficient in the treatment of chronic back and neck pain that does not respond to other conventional treatment including pain medications, physical therapy, and massage. However, we report a descriptive study with a small number of cases. Further randomized and controlled studies are needed for additional investigation.

CONCLUSIONS

The results from this report indicate that the Zhu's style scalp acupuncture may be an efficient and simpler approach for treatment of chronic back and neck pain. More large-scale clinical trials would be valuable to evaluate this technique.

REFERENCES

1. Shoukang L. Scalp acupuncture therapy and its clinical application. *J Tradit Chin Med.* 1991;11(4):272-280.
2. Guorui J. An introduction to the study of acupuncture and moxibustion in China, Part II. *J Tradit Chin Med.* 1984;4(3):169-176.
3. Zaiwen C, Ling C. The treatment of enuresis with scalp acupuncture. *J Tradit Chin Med.* 1991;11(1):29-30.
4. Mingju Z. Treatment of 296 cases of hallucination with scalp-acupuncture. *J Tradit Chin Med.* 1988;8(3):193-194.
5. Hong P. 52 Cases of apoplexy treated with scalp acupuncture by the slow-rapid reinforcing-reducing method. *J Tradit Chin Med.* 1994;14(3):185-188.
6. Qiang T, et al. Study on somatosensory evoked potential in 60 cases of a-



- apoplectic hemiplegia with scalp acupuncture in relation to CT findings. *J Tradit Chin Med.* 1993;13(3):182-184.
12. Chunhui L, Ying W. Observation of curative effect of acupuncture therapy plus scalp acupuncture for restoring consciousness and inducing resuscitation in 80 cases of acute apoplexy. *J Tradit Chin Med.* 1996;16(1):18-22.
13. Zhijie W, et al. Study on the treatment of hemiplegia with scalp points. *Pract J Integrating Chin Mod Med.* 1996;9(4):199-200.
14. Yin Z, Jin W. Treatment of post-stroke syndrome by acupuncture. *Shanghai J Acupuncture Moxibustion.* 1997;16(2):9-10.
15. Yuxin W. Scalp acupuncture applied to treat 9 cases of infantile central aphasia. *Shanghai J Acupuncture Moxibustion.* 1997;16(2):20.
16. Ceccherelli F, Gagliardi G, Barbagli P, Caravello M. Correlation between the number of sessions and therapeutical effect in patients suffering from low back pain treated with acupuncture: a randomized controlled blind study. *Minerva Med.* 2003;94(4 Suppl 1):39-44.
17. Brinkhaus B, Witt CM, Jena S, et al. Acupuncture in patients with chronic low back pain: a randomized controlled trial. *Arch Intern Med.* 2006;166(4):450-457.
18. Giles LG, Muller R. Chronic spinal pain: a randomized clinical trial comparing medication, acupuncture and spinal manipulation. *Spine.* 2005;30(1):166.
19. White P, Lewith G, Prescott P, Conway J. Acupuncture versus placebo for the treatment of chronic mechanical neck pain: a randomized, controlled trial. *Ann Intern Med.* 2004;141(12):126.
7. Mingqing Z. *A Handbook for Treatment of Acute Syndromes by Using Acupuncture and Moxibustion.* Hong Kong, People's Republic of China: Eight Dragons Publishing; 1992.
8. Chengxun W. Treatment of 1228 cases of hemiplegia by scalp acupuncture. *J Tradit Chin Med.* 1990;10(3):227-228.
9. Hong Q, Liping R, Yi G. Combined application of scalp and body acupuncture in the treatment of pseudobulbar paralysis. *J Tradit Chin Med.* 1991;11(3):170-173.
10. Yunmeng C. Treatment of peripheral facial paralysis by scalp acupuncture: a report of 100 cases. *J Tradit Chin Med.* 1992;12(2):106-107.
11. Yukang W, et al. Treatment of

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Acupuncture Effect On Painful Electrical Stimulation Of The Dental Pulp

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ABSTRACT

Background Acupuncture was evaluated by the US National Institutes of Health (NIH) in 1997 and deemed an effective complementary and alternative medicine (CAM) for the treatment of myofascial pain, chronic pain, vomiting, nausea, and analgesia. Acupuncture has been shown to be effective for pain reduction in headaches, postoperative dental pain, and myofascial pain.

Objective To test the hypothesis that acupuncture would decrease the pain from electrical stimulation of the front teeth.

Design, Setting, and Patients At Universidad Mayor, Santiago, Chile, 40 volunteers (21 men and 19 women) were recruited to participate in this study. They were randomly assigned to receive either placebo or real acupuncture.

Intervention The real group received acupuncture at LI 4 and the placebo group also received placebo acupuncture at LI 4, both for 15 minutes. Both groups had an electric pain stimulation applied to the 4 upper front teeth, before and after acupuncture or placebo acupuncture was performed.

Results To analyze the results, a *t* test was used, comparing placebo vs real acupuncture on each front tooth, and also to compare left incisors with right incisors. No significant differences in pain reduction were found between the volunteers who received real acupuncture and those who received the placebo, or between left and right incisors.

Conclusion Acupuncture performed at LI 4 had no effect on the electric pain stimulation of the 4 upper front teeth.

KEY WORDS

Acupuncture, Placebo Acupuncture, Tooth Pain, Randomized Controlled Trial, Electric Pulp Test

INTRODUCTION

Acupuncture has been used in ancient China since 2500 BC.¹ Its origin is rooted in the ancient philosophy of the opposing forces of Yin and Yang. These 2 forces may have to be balanced in order for good health to exist. It is also believed that Qi flows through our body in channels (meridians). Any blockage of this flow will cause disease. Acupuncture is used to restore the balances of Yin and Yang and the flow of Qi.²

When acupoints are activated by the needle, a series of local and distant effects are produced that will affect the central and peripheral systems. To investigate the effects of acupuncture in the central nervous system, Cho et al⁶ used fMRI (functional magnetic resonance imaging) and determined that the anterior cingulate cortex and thalamic areas were activated due to pain stimulation. When acupuncture was performed, this activation was decreased. The US National Institutes of Health (NIH) in 1997 documented that alteration of the secretion of neurohormones and neurotransmitters, plus the changes in the regulation of blood flow (centrally and peripherally), are produced when acupuncture is done.¹

A systematic review of the scientific studies published on the use of acupuncture in dentistry established that 73% of the reviewed papers suggested the effectiveness for the treatment of temporomandibular dysfunction.¹⁴

Studies have shown the successful use of acupuncture for the treatment of myofascial pain, orofacial pain, and headache.^{1,7,9,10,14} Goddard et al¹⁰ reported a short-term reduction of myofascial pain of the jaw muscle after the use of both acupuncture and sham acupuncture (points on the skin areas not recognized as non-acupuncture points). Short-term pain reduction with acupuncture as treatment for orofacial pain was studied by Goddard et al.⁹ In a chart review of 29 patients who rated pain before and after acupuncture treatment on a 10-point numerical analog scale, significant differences of pain scores before and

after treatment were found. Dowson et al,⁷ in a single randomized study, evaluated the effects of acupuncture vs placebo (mock TNS) on migraine headaches. They concluded that acupuncture appeared to be approximately 20% more effective than a placebo in alleviating headache, but no statistically significant difference between the 2 treatments could be found.

Patel et al,¹³ in a meta-analysis of 14 randomized controlled trials of acupuncture for chronic pain, reported that most results favored acupuncture. Lao et al,¹¹ in a study of the efficacy of acupuncture on postoperative oral surgery pain, reported that subjects treated with acupuncture had longer pain-free duration times and less pain intensity than those who received placebo acupuncture.

Ernst and Pittler,⁸ in a systematic review of the effectiveness of acupuncture in treating acute dental pain, concluded from the data collected from 16 studies that acupuncture was effective in alleviating pain either during dental operations, following surgery, or during experimentally induced dental pain in human volunteers.

The NIH recognized that during acupuncture, opioid peptides are released and this may be the explanation of the analgesic effects of acupuncture.¹

The purpose of this study was to determine the analgesic effect of acupuncture on electric stimulation of the dental pulp. LI 4 (Hegu) is located at the highest point of the adductor pollicis muscle with the thumb and index finger adducted, between the 1st and 2nd metacarpals.¹⁷ It was chosen for this study because it is considered to be a powerful acupoint in head and neck treatment and is considered to be the most important analgesic point.¹⁶ In a neuromagnetic study, Yang et al²⁰ found that when Hegu point was stimulated, the activation of the jaw opening reflex was decreased.

The primary hypothesis was that the electrical pulp pain test scores

would be higher on those subjects' teeth who received real acupuncture than those who had placebo acupuncture. The secondary hypothesis was that for those who received real acupuncture, the scores would be higher on the right incisors compared to the left incisors, to examine if acupuncture on right LI 4 would have a greater effect on the right side or the left.

METHODS

Forty volunteers (21 men, 19 women) were recruited to participate in this study at Universidad Mayor, Santiago, Chile. All signed a consent form approved by the Universidad Mayor. The sample size was based on a prior study by Goddard et al that compared the validity of placebo vs real acupuncture.⁹

Inclusion Criteria

- Aged at least 18 years
- Never received acupuncture
- Had 4 superior incisors, healthy with no restorations or dental treatment.

Exclusion Criteria

- Pregnancy
- Needle phobias
- Coagulopathies
- Vascular diseases
- Missing any superior incisor or having any kind of dental restoration.

Randomization

A "random group table"¹⁵ was generated. Subjects were volunteers who were randomly assigned into 2 groups. One group received real acupuncture (n=20) and the other group received placebo acupuncture (n=20) treatment.

Blinding

Given that acupuncture studies cannot be double-blinded because it is impossible to blind the acupuncturist, in this study, the patients and the experimenter (who did the pulp test on volunteers' teeth) were blinded.

Equipment

Seirin acupuncture needles, J-type, 3-gauge x 30 mm length (SeirinAmerica.com) were used. To blunt the placebo needles (10 mm from original needle length), a sterile wire cutter was employed. Self-adhesive foam of 10 mm thick was cut into 20 X 20 mm squares and stuck to the skin over the LI 4 acupoint. A Neosono Co-Pilot Pulp Tester (Neosono Corp, USA) was utilized. Topical anesthesia gel, 20% benzocaine, was used as a conductor (purchased from Sultan Dental Products, Englewood, NJ, USA). Cotton rolls for insulation were used.

TREATMENT

After the 40 volunteers were randomly assigned to 1 of 2 groups

(real or placebo acupuncture treatment), they were scheduled individually for 30-minute appointments. This study was completed over 3 months. Another dentist, a member of the research team, gave the instructions to all the volunteers. First, he explained that they were going to receive the pulp test on the 4 superior incisors, and that they had to say when they first felt a sensation (such as tingling, pain, or numbness), so that the number indicating the amount of current expressed on the pulp tester instrument could be recorded. Next, he explained that they were going to receive acupuncture for 15 minutes and after that, they would have to return to the same dental chair so that the pulp test could be applied to the 4 superior incisors again.

The instructions were given to each volunteer and they were then seated on a dental chair and the teeth were isolated with cotton rolls. The 4 superior incisors were air-dried and topical anesthetic was put on the facial surface of the teeth to allow the electrical current to be conducted into the teeth, taking care not to allow any topical anesthetic to touch the soft tissues. The pulp test was applied on the 4 upper front teeth (Figure 1) and when the volunteer first felt a sensation, the number indicated on the pulp tester was recorded. Afterward, the teeth were cleaned with cold water and the cotton rolls removed.

In another dental chair, the patients received either real acupuncture or placebo acupuncture, depending on the group to which they had been assigned. (The acupuncturist who treated both groups was a dental student from Universidad Mayor, DA, who had 2 years of experience in acupuncture. She had successfully completed acupuncture courses at the University of California, San Francisco, and Universidad Mayor.) Acupuncture was performed for both groups on the right hand, for 15 minutes with needle stimulation (10 clockwise and counterclockwise rotations) every 5 minutes, at LI 4. In this procedure, a foam pad was stuck temporarily to the skin so the needle went through it, touching (placebo acupuncture) or penetrating (real acupuncture) the skin (Figure 2).

For those who received placebo acupuncture, the needle was blunted and only touched the skin without penetrating it. Conversely, for those who received real acupuncture, a sterile needle went through the foam pad at LI 4 and then penetrated the skin to a depth of 10-20 mm. The needles were given 10 clockwise and counterclockwise rotations in a 10-second period.

The placebo method used in this study was validated in a previous study using a blunted placebo needle inserted through a foam pad.⁹

The skin zone of LI 4 point was cleaned with an alcohol pad, air-dried, and then covered with the foam pad (20 x 20 x 10 mm), with the sticky side toward the skin. The acupuncture needle was inserted through its clear guide tube by tapping and twisting it very slightly through the foam pad.

Table 1. t test for pulp response on real acupuncture group

Tooth Number	Pre		Post		T	P
	Mean	SD	Mean	SD		
7	27.3	± 9.9	27.6	± 6.4	0.167	.87
8	27.9	± 9.9	30.3	± 9.1	1.545	.14
9	27.4	± 7.4	27.5	± 8.2	0.095	.93
10	30.0	± 7.7	29.9	± 7.5	0.145	.89

Table 2. t test for pulp response on placebo acupuncture group

Tooth Number	Pre		Post		T	P
	Mean	SD	Mean	SD		
7	25.5	± 5.3	26.6	± 4.1	1.599	.13
8	27.1	± 5.8	28.7	± 5.4	1.259	.22
9	25.3	± 5.4	27.4	± 4.4	1.616	.12
10	26.8	± 5.1	27.2	± 4.6	0.907	.38

The needle and the foam pad were removed after 15 minutes of either real or placebo acupuncture. The skin was cleaned with an alcohol pad.

The volunteer returned to the dental chair and repeated the same procedure of the pulp test. When this procedure ended, the volunteers were able to leave.

RESULTS

All 40 volunteers completed the study with no adverse effects during the study. The placebo acupuncture group had a 10/10 male-to-female ratio; the average age was 22.7 years. The real acupuncture group had a 11/9 male-to-female ratio; average age was 22.4 years.

A *t* test was done on the real acupuncture group to compare the pulp response of the upper front teeth to electric pulp pain stimuli before and after receiving acupuncture (Table 1). No statistical difference was found between the pulp response to pain of the 4 incisors before and after receiving real acupuncture. Acupuncture performed at LI 4 (Hegu) had no effect on electric pain stimulation of upper front teeth for acupuncture-naïve patients.

A *t* test was done to compare the pulp response of the 4 upper incisor teeth to electric pulp stimuli before and after receiving placebo acupuncture (Table 2). No statistical difference was found between the pulp response of the 4 incisors before and after receiving placebo acupuncture.

To compare the results of the placebo group with the real acupuncture group, a 2-tailed *t* test was done comparing each incisor in both groups. The results revealed that there was no significant difference between the placebo group and the real acupuncture group for each tooth either before (Table 3) or after (Table 4) receiving treatment.

Finally a *t* test was done (Table 5) to compare if there were any statistical differences in the real acupuncture group between left superior incisors and right superior incisors. The *P* value found was .88 (with a $P \leq .05$ considered statistically significant), indicating that there was no significant difference between the pulp responses of both right front teeth when compared to their counterparts on the opposite left side.

A *t* test was done to determine if there were any significant age differences between the 2 groups to verify that there was a good random sample. A *P* value of .85 was found, indicating that there was no significant difference in age between the subjects in the real acupuncture group and the placebo group. All the results showed that there was no statistical difference on the tooth pain responses of the 4 incisors for the placebo group and real acupuncture group before and after receiving



Figure 1. Dental pulp tester applied to tooth.



Figure 2. Acupuncture needle inserted through foam pad.

ing acupuncture, between the real and the placebo acupuncture group, and between the left and right incisors.

DISCUSSION

Comparison Of Studies

Taub et al,¹⁸ in a study of analgesia for operative dentistry, compared acupuncture with placebo treatment. In this study, they concluded that there were no differences in findings for the acupuncture and placebo procedure and that both appeared to provide adequate analgesia. Both procedures were 100% successful. Comparing this study with ours, Taub et al used electrical acupuncture, and we used manual acupuncture. They left the needles in place during the dental procedure, and we only left them for 15 minutes; the dental procedure took more than 15 minutes.

In another study, Taub et al¹⁷ evaluated the effectiveness of acupuncture as the sole analgesic for operative dentistry. The results indicated a high success rate and generally favorable rates of patient acceptance for all of the variations of acupuncture.

In the first part of this study, electroacupuncture and bilateral Hegu point were used; different from ours, which used unilateral Hegu point and manual acupuncture; the number of volunteers was a small sample, only 12 (which may not show a good population number); and the placebo method used was not shown to be validated (which may explain why both methods had positive findings).

Yukizaki et al²¹ studied the increases of tooth pain threshold in humans with electroacupuncture. They concluded that electroacupuncture at Hegu point caused ipsilateral increases of tooth pain threshold. The main difference from our study was that Yukizaki et al used electroacupuncture and we did not; and the number of subjects evaluated was very small, only 10 subjects, and there was no control group.

Bakke⁴ studied the effects of acupuncture on the pain perception thresholds of human teeth. In this study, he concluded that there was a small increase in pain threshold on those patients who received acupuncture, but this increase was after 45 minutes. (In our study, we did acupuncture for 15 minutes.) Also, he used 3 acupoints, LI 4, ST 44, and ST 2, and we used only LI 4.

Ernst and Pittler⁸ conducted a systematic review on the effectiveness of acupuncture in treating acute dental pain. Over the 16 studies reviewed, it was suggested that acupuncture may be effective in alleviating dental pain. From the 16 studies, 11 were done under clinical

Table 3. 2-Tailed *t* test for pulp response prior to receiving real or placebo acupuncture

Tooth Number	Acupuncture Real		Acupuncture Placebo		T	P
	Mean	SD	Mean	SD		
7	27.3	± 9.9	25.5	± 5.3	0.735	.47
8	27.9	± 9.9	27.1	± 5.8	0.312	.76
9	27.4	± 7.4	25.3	± 5.4	1.028	.31
10	30.0	± 7.7	26.8	± 5.1	1.545	.13

Table 4. 2-Sample *t* test for pulp response after receiving real or placebo acupuncture

Tooth Number	Acupuncture Real		Acupuncture Placebo		T	P
	Mean	SD	Mean	SD		
7	27.6	± 6.4	26.6	± 4.1	0.589	.56
8	30.3	± 9.1	28.7	± 5.4	0.677	.50
9	27.5	± 8.2	27.4	± 4.4	0.048	.96
10	29.9	± 7.5	27.2	± 4.6	1.423	.17

Table 5. *t* test for pulp response in real acupuncture group, comparing left and right incisors

Tooth Number	Post		T	P
	Mean	SD		
7-8 (left incisors)	28.9	± 7.2	0.105	.88
9-10 (right incisors)	28.7	± 7.2		

situation and only 5 under experimental setups, where dental pain was induced. From the 5 studies performed under experimental setups, all of them had an increase in pain threshold, but most of them were done with electroacupuncture and for longer than 15 minutes. From the 11 studies done under a clinical situation, 1 was done on a root canal procedure, 8 on oral surgery or oral extractions, and 2 on dental procedures. From these 2 studies, 124 had less pain after traditional acupuncture but had no formal test of statistics done, and the other had a success rate of 100% for sham and real acupuncture.²⁶

Andersson et al,³ in a study of electroacupuncture and its effect on pain threshold measured with electrical stimulation of teeth, concluded that in the great majority of participants, low-frequency electroacupuncture of cheeks and hands as well as electrical stimulation through surface electrodes resulted in an elevation of the pain threshold of teeth. In this study, 2 bilateral acupoints were used (Hegu and in the region of the infraorbital nerve in cheeks). In comparison to ours, we only used unilateral LI 4. Andersson showed that no change in pain threshold was produced (after 15-20 minutes of the insertion of the needle), but when electroacupuncture was applied, the pain threshold increased after 30 minutes and remained until the electroacupuncture was turned off. Another difference was that the volunteers felt pain; in our study, the volunteer only felt a sensation.

Mann,¹² in a study of acupuncture analgesia in dentistry, looked at the reduction of pain caused by cold from ethyl chloride applied to the tooth. He removed the cotton with ethyl chloride when the pain was intolerable. Then, he performed acupuncture at LI 4 and ST 44 stimulation (twisting the needle) for either 5, 10, or 15 minutes. Mann's results showed that for 2/4, no pain whatsoever was felt. However, the 4th case was different because the patient previously had a 3rd molar surgery with some damage to the nerve; ST 6 was added and the "electric shocks" that were felt before disappeared after 34 minutes of acupuncture. Considering the first 3 volunteers and comparing them with our study, we surmised that Mann used bilateral LI 4 and added bilateral ST 44. Also, he measured maximum pain tolerable and we only measured the first sensation of tingling, pain, or numbness (which may have been too low a pain level for acupuncture to affect the pain threshold).

Chapman et al⁵ compared the effects of acupuncture in Japan and the United States on dental pain perception. They concluded that acupunctural stimulation alters the perceptual ability of subjects undergoing painful dental dolorimetry, and that the analgesia observed was statistically significant compared to the control session (in which they received no kind of treatment). They used electroacupuncture for 30 minutes and used bilateral SI 18 and LI 20. These 2 points are located in the face nearer the teeth; no distal points were used, as we did. In our study, there was no statistical difference between the left incisors and the right ones when receiving acupuncture at LI 4 unilaterally (at the right hand). Tillu et al,¹⁹ in a prospective randomized trial on unilateral vs bilateral acupuncture on knee function in advanced osteoarthritis of the knee, showed that there was no statistical differ-

ence between unilateral and bilateral acupuncture, concluding that unilateral acupuncture is as effective as bilateral acupuncture.

Conversely, in our study, acupuncture was done unilaterally, but compared left and right incisors. The results could be compared because both studies were looking for the effects of acupuncture in the ipsilateral side and the contralateral side. So, we could have expected to find similar results between right and left incisors. In our study, no significant difference was found.

Even though the ideal standard experimental setup is to use a double-blind, placebo-controlled clinical trial, this study used a single-blinded method since the acupuncturist must be aware of what acupuncture method to use (real or placebo).

The same standards were used for all subjects by using the same dental chair and room. They had no interaction with the acupuncturist, and were able to interact only with the dentist who gave the instructions. The only questions asked were the ones related to what the procedure was about and their role in the study. All subjects were asked for confidentiality and supervised when leaving the room to ensure that they didn't communicate about the study. Subjects who had never received acupuncture were included in this study.

CONCLUSION

In this study, no significant difference was found on the pulp threshold to electric stimuli between the subjects who received placebo acupuncture and those who received real acupuncture. Other studies^{3,4,17,18,21} have shown that acupuncture decreased the readings to pulp stimulation but in our study, there was no difference.

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REFERENCES

1. Acupuncture. NIH Consensus Statement. 1997;15:1-34. <http://consensus.nih.gov/1997/1997Acupuncture107html.htm>.
2. Alexander R. Acupuncture: ancient art, modern enigma. *J Am Dent Assoc.* 1973; 86:813-816.
3. Andersson S, Ericson T, et al. Electro-Acupuncture: effect on pain threshold measured with electrical stimulation of teeth. *Brain Res.* 1973;63:393-396.
4. Bakke M. Effect of acupuncture on the pain perception thresholds of human teeth. *Scand J Dent Res.* 1976;84(6):404-408.
5. Chapman CR, Sato T, et al. Comparative effects of acupuncture in Japan and the United States on dental pain perception. *Pain.* 1982;12(4):319-328.
6. Cho ZH, Son Y, Han JY, et al. fMRI neurophysiological evidence of acupuncture mechanisms. *Medical Acupuncture.* 2003;14(1):11-12.
7. Dowson DI, Lewith GT, Machin D. The effects of acupuncture versus placebo in treatment of headache. *Pain.* 1985;21:35-42.
8. Ernst E, Pittler MH. The effectiveness of acupuncture in treating acute dental pain: a systematic review. *Br Dent J.* 1998;184(9):443-447.
9. Goddard G, Shen Y, Steele B. A controlled trial of placebo vs real acupuncture. *J Pain.* 2005;6(4):237-242.
10. Goddard G, Karibe H, McNeill C, et al. Acupuncture and sham acupuncture reduce muscle pain in myofascial pain patients. *J Orofac Pain.* 2002; 16:71-76.
11. Lao L, Bergman S, Langenberg P, et al. Efficacy of Chinese acupuncture on postoperative oral surgery pain. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* 1995;79:423-428.
12. Mann F. Acupuncture analgesia in dentistry. *Lancet.* 1972;1(7756):898-899.
13. Patel M, Gutzwiller F, et al. A meta-analysis of acupuncture for chronic pain. *Int J Epidemiol.* 1989;18:900-906.
14. Rosted P. The use of acupuncture in dentistry: a review of the scientific validity of published papers. *Oral Dis.* 1998;4(2):100-104.

15. Snedecor G, Cochran W. *Statistical Methods*. Séptima edición. Ames: The Iowa State University Press; 1980.
16. Stux G, Pomerantz B. *Basics of Acupuncture*. New York, NY: Springer Publishing; 1998.
17. Taub H, Beard M, et al. Studies of acupuncture for operative dentistry. *J Am Dent Assoc*. 1977;95:555-561.
18. Taub H, Mitchell J, et al. Analgesia for operative dentistry: a comparison of acupuncture and placebo. *Oral Surg Oral Med Oral Pathol*. 1979;48(3): 205-210.
19. Tillu A, Roberts C, Tillu S. Unilateral versus bilateral acupuncture on knee function in advanced osteoarthritis of the knee: a prospective randomized trial. *Acupunct Med*. 2001;19(1):15-18.
20. Yang ZL, Ouyang Z, Cheng YG, Chen YX. A neuromagnetic study of acupuncture LI-4 (Hegu). *Acupunct Electrother Res*. 1995;20(1):15-20.
21. Yukizaki H, et al. Electroacupuncture increases ipsilaterally tooth pain threshold in man. *Am J Chin Med*. 1986;14(1-2):68-72.

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The Autumn Pulse: A Discussion On The Seasonal Metal Pulse Profile

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ABSTRACT

Each season (spring, summer, autumn, winter) has a unique pulse position. (1) If autumn pulse is found on right cun during the 3 months of its own season, no illness is present in the Metal part of the 5-element grid. (2) If the pulse is not found on right cun during its own 3 months, there is an illness on Metal sector, or in other elements that have a relationship to it. (3) If the disturbed pulse profile of the autumn pulse returns to normal after a treatment, this confirms a correct diagnosis and treatment. (4) By working to establish a sound Metal during autumn, one can prevent serious illness on Wood during spring. (5) By learning mega horary pulse shifts, the clinician can get a larger feel to healing by the universal Qi, which is far more profound than diurnal 24-hour elemental Qi.

KEY WORDS

Pulses, Autumn Pulse, Acupuncture

INTRODUCTION

The pulse profile of 4 of the 6 pulse positions changes with each of the 4 seasons. This discussion centers on changes in right cun position during the autumn months.¹

THE PULSES

There are several advantages to learning the autumn pulse. (1) If autumn pulse is found on right cun during the 3 months of its own season, no illness is present in the Metal part of the 5-element grid. (2) If the pulse is not found on right cun during its own 3 months, there is an illness on Metal sector or in other elements that have a relationship to it. (3) If the disturbed pulse profile of the autumn pulse returns to normal after a treatment, this confirms a correct diagnosis and treatment. (4) By working to establish a sound Metal during autumn, one can prevent serious illness on Wood during spring. (5) By learning mega horary pulse shifts, the clinician can get a larger feel to healing by the universal Qi, which is far more profound than diurnal 24-hour elemental Qi.

The autumn pulse phase in 2006 began on August 5 and ends on November 3. On November 4, 2006, the autumn pulse fades and is replaced by the winter pulse, which has a strikingly different profile.

The division of the year into 4 seasons for 4 elements is as follows:² Wood rules 90 days in spring and ushers in the spring Wood pulse; Fire rules 90 days in summer and ushers in the summer Fire pulse; Metal rules 90 days in autumn and ushers in the autumn Metal pulse; and Water rules 90 days in winter and ushers in the Winter Water pulse.

The pulse positions correlate to the 4 seasonal pulses as follows: left wrist cun pulse position for Heart-Small Intestine correlates to summer; left wrist Guan pulse position for Liver-Gallbladder correlates to spring; left wrist Qi pulse position for Kidney-Urinary Bladder correlates to winter; right wrist cun pulse position for Lung-Large Intestine correlates to autumn; right wrist Guan pulse position for Spleen-Stomach correlates to *no season*; and right wrist Qi pulse position for Pericardium-Sanjiao correlates to *no season*.

In this manner, the 4 seasonal pulses have 4 positions of the 6, with 2 pulse positions having no seasonal correlation.

Earth has no season because it is central. Earth is not an element in the classical sense. Mae Jing classic considers the last month of summer as ruled by Earth. Another approach considers the last month of all 4 seasons as ruled by Earth.

In the author's understanding, all 360 days of all 4 seasons have as its basis Earth. In that sense, the Earth characteristic in pulse iconography called "Stomach" is universal in all 365 days.

What Does the Word Stomach Mean in Pulse Work?^{1,3}

Stomach means the unqualified matrix or substance of a pulse. When an element or a season imprints this with its quality a seasonal pulse results. Atmosphere, unqualified by seasons, is an ever-present matrix we hardly notice. When this takes on seasonal qualities, we have created a differentiation. Earth provides and rules the basic unqualified substance of a pulse. In that sense, it is present in all pulses irrespective of the season.

THE AUTUMN PULSE

Harvest is the typical autumn pulse iconogram.⁴ The main characteristics of a normal autumn pulse include a sparse pulse, larger than usual, incompact, incompact in the matrix, like a cloth bag filled with loose cotton, where periphery is looser than center. The main characteristics of the normal Metal pulse during other seasons include distinct characteristics at 3 different levels. (1) At the superficial level, it is choppy and short. (2) At the middle level, it is choppy and blocked. (3) At the deep level, it is hasty and blocked.

Characteristic Descriptors For Right Cun LU Pulse

In spring, summer, and autumn, descriptors include the following:

- Choppy – minute, uneven, short, irregular, rooted
- Short – a pulse that at any given beat does not fill all 3 positions
- Blocked – impeded, not freely arriving, delayed in leaving, hesitant, static
- Hasty – loses a beat at irregular intervals, seems rapid.

Characteristic Descriptors For Right Cun LU Pulse In Autumn

- Floating according to Mae Jing, confined only to autumn months and signifying health. Floating at any other time on this pulse is significant of illness.
- Arrives with "Stomach" and is slightly hair-like
- Arrives "light" and "floating" urgently, but retreating scattered
- Floating, choppy, and short
- Empty, floating, soft and fine or hair-like.

The Autumn Pulse In Practice

The autumn pulse is not weak, empty, hollow, spring onion, or deep.

How to get a tactile feel of an autumn pulse?

Gather fallen autumn leaves into both palms and gently bring both together without crushing the leaves. Place a cotton ball on a table and press with fingertips as though taking a pulse. Place your fingertips on your hair.

When in disharmony, what does the autumn pulse present as?

The abnormal autumn pulse is in a state of either excess or deficiency. If it is hair-like and hard in the center but unsubstantial at the periph-

ery, this signifies excess and an external illness, as pathogen and in the Wei. If it is hair-like and soft in the center but unsubstantial at the periphery, this signifies deficiency and an internal illness, as pathogen and in Zang Fu.

What are the patterns accompanying the disharmonious autumn pulse?

Excess patterns are due to an invasion of wind, cold, or damp. Thus, Qi will run counter to the usual pattern and rise in upper warmer and congeal in the back Shu point of LU at BL 13, and nearby 12, and upper spine; hence, the pain and discomfort. Deficient patterns are due to compromised organ Qi, so there will be difficulty in completing a breath at exhalation causing dyspnea and cough. Exhalation begins at HT and completes at LU; when this is incomplete, there will be Emptiness, which will be presently usurped by invading Damp (sputum), Heat (blood), and Water (rales).

Possible Pathways For Illness To Come Upon Metal

A Metal illness may originate from 5 separate elemental locations and the pulses will reflect this.

1. From Fire onto Metal. If HT is overwhelming LU, the pulse will develop characteristics of the usual HT pulse, which is exuberant coming in, and retreating weak and subdued. If the LU pulse feels surging, overly floating, large, HT overwhelming LU is suggested. Keywords are surging, overly floating, and large.
2. From Earth onto Metal. If SP is overwhelming LU, the pulse will become large and firmly substantial, as opposed to the usual autumn unsubstantial consistency. Or there may be a quality of slipperiness, which will also indicate an SP overcoming LU situation. Keywords are large, firmly substantial, and slippery.
3. From Water onto Metal. If KI is overwhelming LU, the pulse will become deep and soggy or water laden. The keyword here is deep.
4. From Wood onto Metal. If LV is overwhelming LU, the pulse will become wiry and long. The keyword is wiry.
5. From Metal onto Metal. If LU is overwhelming LU, the pulse will become hair-like with little substantiality. The keyword here is hair-like.

Changes In Autumn Pulse

If the LU pulse feels surging, overly floating, large, HT overwhelming LU, this is a serious situation that needs to be reversed at once.

Normal autumn pulse will feel floating but will have some low degree of substantiality within its substance. It will have a feel of "Stomach," which is to say that it will have a distinct Earthiness within it, even when it is soft and scattered and of a loosely formed matrix.

In its central axis, it will have a hair-like feel, which may be somewhat hard if the pulse shows excess, and light and weak if deficiency. It will arrive light and floating urgently, but will be retreating scattered. It may in turn and at different times show a choppy character, giving a feel of unevenness, uneven beat, and be quite minute, but at all times, this will have a root. Or it may show a scattered nature, so it is indistinct, wide, weak on slight pressure, disappears on heavy pressure but not entirely, some substance will always be there even if hair-like. Or it may show up as a short pulse, which falls short of its legitimate length.

At all times, the autumn pulse will show a characteristic unsubstantial substantiality, but there will always be a root.

If this pulse suddenly shows a surging character, feels overly floating, exuberant, and large, so that its characteristic unsubstantial substantiality is not felt anymore, the autumn pulse has been overwhelmed by HT pulse and a condition of Fire melting Metal has set in, with dangerous consequences.

The Most Common Signs Of An HT Illness

Although this article discusses the autumn pulse form, a few signs of an HT illness are mentioned here as a ready reference, as almost all

serious and chronic LU illnesses may have an HT dysfunction at its basis.

1. A median fissure on tongue beginning at least from the central third of the tongue body and extending to tip.
2. If it actually bifurcates or makes the tip bilobulate, the illness has reached an advanced state.
3. The earlobes carry the typical HT furrow. There is another furrow on the lobe, which denotes a tendency to low blood pressure (make sure to differentiate one from the other).
4. A tender left KI chain from KI 27 to a few points preceding it, at the left sternointercostal spaces. This is more significant if the right chain is not tender.
5. A tender left LV 14, when the right is not.
6. A tender Small Heart in the scapula at SI 11 or thereabouts.
7. A tender Ren 14.
8. A tender BL 14 or 15.
9. A malar flush of the HT SI variety which heats in the afternoon.

The Most Common Signs Of An LU Illness

1. Twin indentations just short of the tip of the tongue.
2. Small cracks on the same area, decidedly bilateral.
3. Entire or significant absence of sweating.
4. Dry skin, a dry patch at tip of thumb and index finger.
5. A tender KI chain on both sides of the sternointercostals.
6. Tender bilateral LU 1 and 2.
7. A tender BL 12 and 13.
8. A whitish shiny tinge under the eyes or elsewhere on the face.
9. A reddish discoloration and capillaries at LI 20.

The Most Common Signs Of An HT Overwhelming LU Illness

When some or more of the above signs are present, but HT signs came decidedly early on in the chronology of illness and LU signs came decidedly later, this points to an HT marauding on LU pattern.

CONCLUSIONS

With the discussion of the autumn pulse, it is hoped that practitioners will have opportunities of discovery during this season and in many others to come. In order to round out work with seasonal pulses, pulse profiles for winter, spring, and summer may be studied.

REFERENCES

1. Zhen LS. *Pulse Diagnosis*. Ku H, Seifert GM, eds. Brookline, MA: Paradigm Publications; 1981:Chap 3.3.
2. Fang SN. Pulse feeling and palpation. In: *Diagnostics of Traditional Chinese Medicine*. Jinan, China: Shandong Science and Technology Press; 2002:62.
3. Keikobad H. *The Autumn Pulse Audio Book on CD*. <http://www.acu-free.com/partners.htm>.
4. Porkert M. Palpation diagnosis. In: *The Essentials of Chinese Diagnostics*. Switzerland: Acta Medicinæ Sinensis, Chinese Medicine Publications; 1983:243.

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Evidence For Exponential Decay Behavior In Pain Relief By Acupuncture

Shui-Yin Lo, PhD

ABSTRACT

Background Pain is one of the most frequent symptoms of patients. Acupuncture has various degrees of success in relieving musculoskeletal pain. The research effort of establishing the validity of pain relief by acupuncture is extensive and is reviewed in a systematic way for head, neck, and shoulder pain.

Objective To report the results of our study on pain relief by acupuncture with an infrared imaging system that can record changes of temperature profile in the pain area.

Design, Setting, and Patients The pain relief felt by patients may be expressed as temperature changes in the pain area. These changes are measured with the accuracy of a hundredth of a degree. The decrease in the maximum temperature of the pain area has been found to follow a simple exponential curve. We studied pain relief in 15 patients.

Results The exponential decay has a time constant ranging from 4.3 to 63 minutes. The χ^2 per degree of freedom for the fit to exponential shape is from 0.006 to 0.048. The average time constant is 17.5 minutes. We discuss a simple physical model that can produce such an exponential curve.

Conclusions Our results support the view that pain relief by acupuncture comes from relieving pain at its source as well as from its effect on the central nervous system.

KEY WORDS

Acupuncture, Pain, Exponential Decay

INTRODUCTION

Musculoskeletal pain is generally related to the transmission of sensation from nerve fibers in the pain-generated area to the central nervous system. In Western medical practice, the direction of pain relief is toward blocking of the transmission of signal from nociceptors. Pain relief by acupuncture or its more dramatic manifestation in acupuncture analgesia is well known and accepted by many medical practitioners. Most of the existing experimental and clinical evidence attribute the effect of acupuncture on pain relief as going through the sympathetic system via mechanisms at the hypothalamic and brainstem levels, and then the hypothalamic β -endorphinergic system has inhibitory effects on the vasomotorcenter.¹⁻⁶ Nothing has addressed the question of whether acupuncture has a direct effect on the area where pain is being generated.

We present a clinical study of 15 patients who had pain and received acupuncture treatment in a thermally stable room. The treatment consisted of inserting 1 needle on an acupoint that was not in the pain area, but was on the meridian that passes through the pain area. Infrared pictures were taken continuously to monitor the temperature variation on the pain area. Variations in temperature at the same place were recorded in a series of thermographs.

REVIEW OF PREVIOUS STUDIES ON PAIN RELIEF

We review the recent scientific studies on pain relief from acupuncture on head, neck, and shoulder regions in Tables 1, 2, and 3, treating them all equally.⁷⁻²⁴ The most important features of various studies are stated uniformly in 5 columns of each table: subjects, objective, method, remarks, and authors (with their countries). The number of subjects range from 14 to 971, and to 1151 for 1 meta-study. The institutions that performed the research are located in Germany, Italy, United Kingdom, Netherlands, Hong Kong, Taiwan, and China. The methods are traditional needles, electrical acupuncture, or Japanese acupuncture. In some studies, the results are compared with other treatment such as massage or physiotherapy. In other cases, they are randomly

selected, single-blinded, or double-blinded. These studies confirm the effectiveness of acupuncture in relieving pain. The evidence for effectiveness mainly comes from pain registration, pain scores, reduction of pain pills, improvement of physical movement of the body, or visual analog scale of pain. They all lack an objective and numerical estimate of pain relief. Infrared imaging system can provide such a numerical and objective measure of pain relief to supplement the traditional way of measurement.

METHODS

Exponential Law

In our study, all patients were treated in the same clinic with the constant temperature at 21°C. Patient consent was obtained. The acupuncturist was required to use only 1 needle on 1 acupoint, which was not at the region of pain. The 1st case was a patient with buttock pain who was treated at the acupoint GB 34 (Yanglingquan), located in the depression anterior and interior to the small head of the fibula beneath the knee. We recorded continuously the temperature profile of the buttock area by infrared imaging system (Meditherm 2000), which had an accuracy of 0.01°C. The temperatures of the completely painful area changed after insertion of the needle, as recorded by the infrared camera. There were 20,000 pixels in 1 picture. Each pixel in the picture had an accurate temperature number associated with it. An enormous amount of numerical data was associated with each picture. For convenient presentation and ease of analysis, we report here only the change of 1 temperature, the maximum temperature in the pain area.

For pictorial presentation, we present the picture taken before the treatment and 2 pictures taken 8 and 20 minutes after insertion of the needle. Three of them are shown in Figure 1 for visual comparison. The maximum temperature of the complete painful area was found to reduce from 36.26°C to 35.6°C 8 minutes after the insertion of the needle. Then it was reduced further to 35.25°C by an amount of 1.0°C 20 minutes after the insertion of the needle. The normal statistical fluctuation of

temperature of a normal person is on the average 0.25°C.

A different patient with pain at the right leg joint is shown in Figure 2. In all cases of the present study, the painful area had more elevated temperature than the surrounding area. Normally, the most painful point seems to coincide with the point with the maximum temperature. The reduction of maximum temperature of the painful area can be regarded as an objective measurement of the pain relief by the patient. By tracing the change in maximum temperature, we regard this as a reliable method of tracing the reduction of pain by acupuncture. This patient was treated with a single needle at BL 60 Kunlun, located at the bottom of the leg far away from the joint. We show the changes in temperature profile after 2 and 6 minutes in Figure 2.

In Figure 3, we show the temperature profile of a patient with stomach pain who was treated at SP 6 (Sanyinjiao), an acupoint on the leg far away from the stomach.

In Figure 4, we show the temperature profile of a patient with neck

pain, which was treated at BL 40, located in the leg, again far away from the neck.

Top picture was before treatment, middle picture was 8 minutes after treatment, and the bottom picture was 20 minutes after treatment. The temperature of the hot spots decreased exponentially as a function of time.

In Table 4, we tabulated the exponential fit to the change of maximum temperature to patients we treated. We present cases where there were sufficient points taken during the treatment to fit a curve. We do not present data in the table where not enough points were taken during the treatment to fit a curve. The time decay constant *c*, which measured how fast the temperature drops off, varied greatly. For the cases we examined, it ranged from 4.5 minutes to 63 minutes. The average time constant was 17.5 minutes. The normal session for acupuncture lasted about half an hour. It was obvious that half an hour was more than enough for the pain relief, which had a time constant of 4.5 minutes, but not enough for the pain that subsided with a time constant

Table 1. The Effect of Acupuncture on Headache: Literature Review

Source	Patients	Objective	Methods	Results
Melchart et al ⁷ (Munich, Germany), 2001	26 trials in 1151 patients with idiopathic headache	Is acupuncture more effective than placebo	Randomized and quasi-randomized clinical trials on treatment quantitative meta-analysis not possible	Overall the existing evidence supports the value of acupuncture for the treatment of idiopathic headaches
Costantini et al ⁹ (Rome, Italy), 1997	700 patients	Electroacupuncture on craniofacial pain	20 Minutes of treatment with application number ranging from 10–20	Acupuncture and infrared laser reflex therapy represent a harmless and effective treatment
Johansson et al ¹⁰ (Gothenberg, Sweden), 1991	45 patients with facial pain or headache	Acupuncture vs occlusal splint vs control	Patients were randomly selected into these 3 groups	Both acupuncture and occlusal splint therapy significantly reduced subjective symptoms and clinical signs from the stomatognathic system; it is concluded that acupuncture is an alternative to traditional methods
Vincent, ¹¹ (London), 1990	14 patients with tension headache	Controlled single case design with time series analysis	8 weekly treatments, 4 true acupuncture and 4 sham	True acupuncture was shown to be significantly superior to sham, demonstrating specific therapeutic action in 4 patients
Junnilla, ¹² 1987	348 patients	Chronic pain syndromes	Finnish survey: mean No. of primary series = 5 sessions; 41% of patients received ≥ 1 series	Analysis showed significant relief of pain (≥ 40% reduction on the visual analog scale) in myofascial syndrome affecting the head, neck, shoulder, and arm
Hansen and Hansen, ¹³ 1985	8 patients with chronic tension headache	Controlled trial on patient with mean disease duration of 15 years	All patients had daily recurring headache, intensity recorded for 15 weeks; crossover and randomization used	Acupuncture was found to be significantly more pain-relieving than placebo, according to the pain registration of the patients themselves; the pain reduction was 31%

Table 2. The Effect of Acupuncture on Neck Pain: Literature Review

Source	Patients	Objective	Methods	Results
Irnich et al ¹⁴ (Munich, Germany), 2001	117 patients with chronic neck pain	Acupuncture vs massage	Maximum pain related to motion (visual analog scale); 3D ultrasound analyzer, pressure algometer; quality of life	Acupuncture showed significantly greater improvement in motion compared with massage (<i>P</i> < .005); especially better for those with myofascial pain syndrome > 5 years
David et al ¹⁵ (Reading, UK), 1998	70 patients with chronic neck pain	Acupuncture vs physiotherapy	Pain on visual analog scale; questionnaires	Both treatment groups improved in all criteria; acupuncture was more effective in patients with higher baseline pain scores
Birch et al ¹⁶ (the Netherlands), 1998	46 patients with chronic myofascial neck pain	Japanese acupuncture	Randomized single-blind trial of acupuncture vs NSAID; questionnaire, health survey, physiologic measure	Relevant acupuncture with heat contributed to modest pain reduction in persons with myofascial neck pain; alternative therapy recommended in future
Coen et al, ¹⁷ 1981	30 patients with cervical spine pain	Randomized controlled study of patients with pain of mean 8 years	12 weeks of treatment	80% of treated group felt improved, with a mean 40% reduction of pain score, 54% reduction of pain pills, 68% reduction of pain hours per day and 32% less limitation of activity; only 13 % of controlled felt better

Abbreviation: NSAID, nonsteroidal anti-inflammatory drug.

of 63 minutes. But, 30 minutes was a good average for most cases as is commonly done in an acupuncture session.

A Simple Physical Model

The temperature of the skin above normal condition is related to the number of additional biochemical reactions that occur per unit area. In general, the dependence of temperature can be expressed as a power series of the number of biochemical reactions n :

$$T - T_0 = a_0 + a_1 n + a_2 n^2 + \dots \quad (3)$$

Where a_0, a_1, a_2 are some constants, and T_0 is the normal temperature of the skin surface that is in thermal equilibrium with the room. When the person is well, there is no extra biochemical reactions $n=0$. There would be no additional heat generated. The temperature T is the same as its thermal equilibrium temperature T_0 . Therefore, we may set a_0 to be zero. It is probably a reasonable physical assumption that the additional abnormal biochemical reactions n is small compared with the normal biochemical reactions; then higher order terms in (3) can be neglected. We then have a linear relation between the temperature and the relevant number of biochemical reactions n :

$$T - T_0 = a_1 n \quad (4)$$

Taking the differential of eq (4), we have

$$dT = a_1 dn \quad (5)$$

When an acupuncture needle is inserted into the acupoint, according to Traditional Chinese Medicine, additional Qi is generated and propagated to the pain region. The interaction of Qi with cells produces a curing effect on the cell so that biochemical reactions in the cells are reduced. As long as such interaction is described by quantum theory, it is statistical. The reduction rate of n is proportional to the number of biochemical reactions n present:

$$dn = -\text{constant} \times n \times dt \quad (6)$$

Putting eq (6) and (5) together with (4), we have the differential equation:

$$dT / (t - T_0) = -\text{const} dt$$

The solution is the exponential decay of the temperature at the pain area:

$$T = T_0 + a_1 \exp(-t/c), \quad (7)$$

Where T_0 is the terminal temperature and c is the time decay constant. Before the treatment of acupuncture, which means $t=0$, the surface temperature T is $T_0 + a_1$. As time increases to very large, surface temperature T becomes T_0 , which we call terminal temperature. The 2

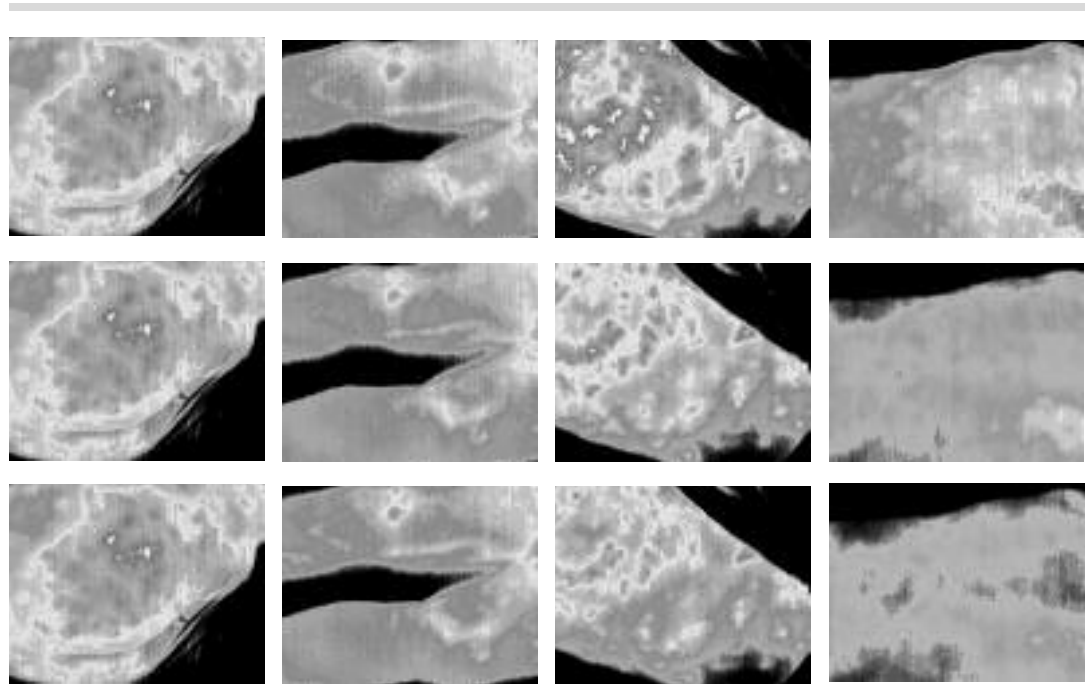


Figure 1. Acupuncture at GB 34 to treat buttock pain. Top: before treatment. Middle: 8 minutes later. Bottom: 20 minutes later. Maximum temperature reduced from 36.26°C to 35.6°C to 35.25°C. (Black and white scale: white for the hottest, black for the coldest.)

Figure 2. Acupuncture at right BL 60 to treat pain at right leg joint. Top: Before treatment. Middle: After 2 minutes. Bottom: After 6 minutes. Maximum temperature of right leg joint was reduced from 33.61°C to 33.23°C, to 33.08°C, a reduction of 0.38°C and 0.53°C, respectively.

Figure 3. Acupuncture at SP 6 to treat stomach pain. Top: before treatment. Middle: 8 minutes after treatment. Bottom: 21 minutes after treatment. Max temperature dropped from 36.75°C to 36.26°C to 36.03°C by amounts of 0.49°C and 0.72°C, respectively.

Figure 4. Acupuncture at BL 40, which is at the mid-point of the transverse crease of the popliteal fossa in the leg. The patient had neck pain, was lying with his back facing us, and head is on the right. The black patch above the neck is hair.

parameters T_0 and time constant c , are fitted to the exponential curve, and are given in Table 4.

DISCUSSION

In a clinical setting, acupuncturists generally use more than 1 needle. We used only 1 needle in each treatment away from the pain area because the effect from that single needle is then unambiguous. The relief pain for the patients may not be most optimal. The scientific interpretation is, however, more definite. Since the needle is inserted far from the pain area at the acupoint connected to the pain area by a meridian, our data gives scientific support to the traditional view that Qi travels from the needle to the pain area via the meridian.

What is the optimal duration of an acupuncture session? How long should one leave the needles inside the patient? Our finding suggests the effect of acupuncture decays exponentially. So in a period of $3c$, or 3 times the decay time constant c , majority of the beneficial effect of acupuncture has been accomplished. There is only a very small improvement equal to $\exp(-3)$, or 5% left. For instance, our average time constant is 17 minutes; 51 minutes later, the acupuncture will accomplish 95% of its asymptotic value. Duration longer than 50 minutes accomplishes little. Duration less than 17 minutes is too little to let acupuncture do its work. Therefore, the optimal duration to leave the needle inside the patient should be closer to 50 minutes.

Acupuncture is a treatment that takes into consideration individual differences. Acupuncturists often treat the same pain on different patients with different sets of acupoints. Our study suggests that the

duration of the period that needles stay in the body may also vary with individuals. Continuous monitoring of pain area during the entire period of acupuncture with infrared imaging system could be one way to insure the individualized treatment of acupuncture achieves its objective of relieving pain in the most optimal way.

It would be interesting to measure the conductivity on acupoints along various meridians concurrently as a function of time as we did with infrared imaging device. Therefore, we would find out whether there is correlation in optical measurement and electrical measurement due to acupuncture on acupoints of the same meridian. The existence of positive correlation simultaneously between electrical and optical signal, among various acupoints along the same meridian due to 1 needle inserted in a different acupoint of the same meridian, would favor strongly the physical reality of meridians.²⁵⁻²⁹

CONCLUSIONS

We used infrared imaging system to study the time-dependent effect of acupuncture on pain. We required only 1 needle to be used at an acupoint, which is not in the pain area, but is connected via a meridian to the pain area. An exponential fit to the time dependence of the decrease of temperature in the pain area was found to be statistically satisfactory to describe the data in all 15 cases.

The theoretical implications of this result are two-fold: First, pain relief by acupuncture is a relief of pain at the source, and not just due to the release of endorphin in the brain. Second, the exponential behavior of the decrease of temperature in the pain area can be derived

if the mechanism is quantum mechanical in nature.

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REFERENCES

1. Ulett GA, Han S, Han JS. Electroacupuncture: mechanisms and clinical application. *Biol Psychiatry*. 1998;44(2):129-138.
2. Hsieh JC, Tu CH, Chen FP, et al. Activation of the hypothalamus characterizes the acupuncture stimulation at the analgesic point in human: a positron emission tomography study. *Neurosci Lett*. 2001;307(2):105-108.
3. Zou CJ, Wang H, Ge L. The central mechanism of the depressor-bradycardia effect of Tinggong. *Acupunct Electrother Res*. 2000;25(3-4):145-153.
4. Wan Y, Wilson SG, Han J, Mogil JS. The effect of genotype on sensitivity to electroacupuncture analgesia. *Pain*. 2001;91(1-2):5-13.
5. Chiu JH, Cheng HC, Tai CH, et al. Electroacupuncture-induced neural activation detected by use of manganese-enhanced functional magnetic resonance imaging in rabbits. *Am J Vet Res*. 2001;62(2):178-182.
6. Uom ES, Min BI, Kim JH, Cho YW. Analgesic effect of the acupuncture using the method of quick insertion and withdrawal of the needle in rats. *Neurosci Lett*. 2001;298(1):21-24.
7. Melchart D, Linde K, Fischer P, et al. Acupuncture for idiopathic headache. *Cochrane Database Syst Rev*. 2001;(1):CD001218.
8. Amelin AV, Zaitsev AA, Ivanov VE, Ignatov IuD, Korenko LA, Skoromets AA. Study of mechanisms of action of amitriptyline and acupuncture using nociceptive flexor reflex in patients with chronic forms of headache. *Anesteziol Reanimatol*. 1998;(5):19-21.
9. Costantini D, Delogo G, Lo Bosco L, Tomasello C, Sarra M. The treatment

Table 3. The Effect of Acupuncture on Shoulder Pain: Literature Review

Source	Patients	Objective	Methods	Results
Ceccheerelli et al ¹⁸ (Italy), 2001	44 patients with shoulder myofascial pain	Superficial vs deep acupuncture area; 8 sessions	Treatment with 13 needles; 4 trigger points in the shoulder	Both techniques had efficacy in controlling pain; deep acupuncture was better at all times with significantly better results after treatment and follow up after 1 and 3 months
Sun et al ¹⁹ (Hong Kong), 2001	35 patients with frozen shoulder	Treatment effectiveness of acupuncture and exercise	Functional mobility, power and pain at 6 and 20 weeks assessed by Constant Shoulder Assessment	Improvements in scores by 39.6%, and 76.4% were seen by exercise and exercise plus acupuncture respectively; scores were 40.3% and 77.2% at 20 weeks (P<.025)
Kleinhenz et al, (Heidelberg, Germany), 1999	52 sportsmen	Acupuncture for rotator cuff tendinitis	Randomized single blind study; modified Constant-Murley score; new placebo needle	The acupuncture group improved 19.2 points, while the control group improved 8.37 points (P=.01)
Chen and Wu ²⁰ (Fuzhou, China), 1998	83 cases of post hemiplegic omalgia	Pathogenesis of shoulder pain	Large range of passive movement leading to omalgia	Findings suggest that painless movement of the shoulder joint should be limited; massage should be carried out immediately after acupuncture
Guo et al ²¹ (Hefei, China), 1995	40 cases of shoulder-hand syndrome	Treatment with electroacupuncture (EA)	Comparison with filiform needle acupuncture (FNA)	EA had better results in treating hand back swelling, hand skin temperature elevating, and the bending finger caused pain than that with FNA (P<.05); also better in shoulder joint improvement; total effective rate in EA is 75% vs 50% in FNA; EA produced a rhythmic muscle contraction
Lin et al ²² (Taipei, China), 1994	150 patients with frozen shoulder	EA plus nerve block	Pain relief from EA and regional nerve block by 1% xylocaine; 6 vector movement were checked	Results show that combined EA and nerve block had significant high pain control quality, longer duration, and better range of movement of shoulder joint than EA or nerve block used alone
Fang et al ²³ (Hangzhou, China), 1987	37 patients with frozen shoulder	Chronic neck and shoulder pain	All patients unresponsive to conventional or placebo treatments; double-blind evaluation was used	64.9% patients obtained significant long-term improvement; an increase in microcirculation might be responsible for the tissue healing and subsequent pain relief.
Fisher et al, ²⁵ 1984	971 cases	Acupuncture for different diseases	It was regarded successful if patients felt no pain without having significant improvement	Positive results for cephalalgias, sinusitis, cervical spine syndrome, shoulder-arm syndrome, back pain, constipation, ischialgias, herpes zoster, allergic rhinitis, and disturbances of peripheral blood flow

of cranio-facial pain by electroacupuncture and laser irradiation. *Ann Ital Chir.* 1997;68(4):505-509.

10. Johansson A, Wenneberg B, Wagersten C, Haraldson T. Acupuncture in treatment of facial muscular pain. *Acta Odontol Scand.* 1991;49(3):153-158.
11. Vincent CA. The treatment of tension headache by acupuncture: a controlled single case design with time series analysis. *J Psychosom Res.* 1990;34(5):553-561.
12. Junnila SY. Long-term treatment of chronic pain with acupuncture, part I. *Acupunct Electrother Res.* 1987;12(1):23-36.
13. Hansen PE, Hansen JH. Acupuncture treatment of chronic tension headache — a controlled cross-over trial. *Cephalalgia.* 1985;5(3):137-142.
14. Irnich D, Behrens N, Molzen H, et al. Randomized trial of acupuncture compared with conventional massage and "sham" laser acupuncture for treatment of chronic neck pain. *BMJ.* 2001;322(7302):1574-1578.
15. David J, Modi S, Aluko AA, Robertshaw C, Farebrother J. Chronic neck pain: a comparison of acupuncture treatment and physiotherapy. *Br J Rheumatol.* 1998;37(10):1118-1122.
16. Birch S, Jamison RN. Controlled trial of Japanese acupuncture for chronic myofascial neck pain: assessment of specific and nonspecific effects of treatment. *Clin J Pain.* 1998;14(3): 248-255.
17. Coan RM, Wong G, Coan PL. The acupuncture treatment of neck pain: a randomized controlled study. *Am J Chin Med.* 1981;9(4):326-332.
18. Ceccheerelli F, Bordin M, Gagliardi G, Caravello M. Comparison between superficial and deep acupuncture in the treatment of the shoulder's myofascial pain: a randomized and controlled study. *Acupunct Electrother Res.* 2001;26(4):229-238.
19. Sun KO, Chan KC, Lo SL, Fong DY. Acupuncture for frozen shoulder. *Hong Kong Med J.* 2001;7(4): 381-391.
20. Chen L, Wu Q. Clinical observation on treatment of 83 cases of posthemiplegic omalgia. *J Tradit Chin Med.* 1998;18(3):215-217.
21. Guo ZX, Wang RS, Guo XC. Clinical observation on treatment of 40 cases of apoplexy hemiplegia complicated shoulder-hand syndrome with electro-acupuncture. *Zhongguo Zhong Xi Yi Jie He Za Zhi.* 1995;15(11):646-648.
22. Lin ML, Huang CT, Lin JG, Tsai SK. A comparison between the pain relief effect of electroacupuncture, regional nerve block and electroacupuncture plus regional nerve block in frozen shoulder. *Acta Anaesthesiol Sin.* 1994;32(4):237-242.
23. Fang JQ, Liu YL, Mo XM. Clinical and experimental studies on analgesic effects of ipsilateral and contralateral stimulations with electro-acupunc-

- ture. *Zhongguo Zhong Xi Yi Jie He Za Zhi.* 1994 Oct;14(10):579-582.
24. Peng AT, Behar S, Yue SJ. Long-term therapeutic effects of electro-acupuncture for chronic neck and shoulder pain — a double blind study. *Acupunct Electrother Res.* 1987;12(1):37-44.
25. Fischer MV, Behr A, von Reumont J. Acupuncture—a therapeutic concept in the treatment of painful conditions and functional disorders. Report on 971 cases. *Acupunct Electrother Res.* 1984;9(1):11-29.
26. Lo Shui-yin and Li Wenchong. Onsager's Formula, Conductivity, and Possible New Phase Transition. *Modern Physics letters B, V. 13*(1999) 885-893.
27. Lo Shui-yin Lo and Bonavida B. *Proceedings of First Int. Symp. Of Physical, Chemical, and Biological Properties of Stable Water (IE) Clusters.* World Scientific. 1998.
28. Lo Shui-yin, Li W. C, Huang S. H. Water clusters in Life. *Med Hypotheses.* (2000)v 54(6),948-953.
29. Lo Shui-yin. Meridians in acupuncture and infrared imaging. *Med Hypotheses.* 2001;58:72-76.

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Table 4. Exponential Decay of Maximmm Temperature in the Pain Area

Patients	Acupoint	Measured Pain Area	Terminal Temperature, °C	Temperature Decrease, °C	Time Decay Constant, min	χ ² Result
1	GB 34	Right buttock	35.06	1.16	12.6	0.00639
2	GB 34	Right buttock	35.29	0.967	7.87	0.0167
3	DU 14	Left shoulder	34.3	0.769	4.5	0.016
4	BL 60	Left popliteal area	33.05	2.95	22.59	0.0242
5	BL 60	Right popliteal area	31.36	3.75	29.52	0.0189
6	SI 3	Shoulder	34.02	0.712	6.348	0.0432
7	LU 5	Fist area	35.99	1.501	6.28	0.029
8	LU 5	Fist area	35.9	1.553	7.47	0.00651
9	LU 5	Wrist	36.12	0.59	4.3	0.0186
10	BL 40	Right shoulder	35.54	3.89	25.26	0.00924
11	BL 40	Left arm	31.37	8.29	63.58	0.0475
12	BL 40	Right neck	37.81	2.929	20.14	0.0166
13	BL 40	Neck, left side	35.27	5.57	32.04	0.0308
14	DU 14	Neck, right side	36.64	0.396	10.58	0.0193
15	SI 3	Back	34.39	1.254	9.64	0.0228
Average			34.81	2.42	17.51	

Results Of A 1-Year Clinical Study Of The Application Of Laser Stimulation Of The Acupuncture Points Used For Arthritis, Neuropathy, Intractable Pain, And Pain From Acute Strain And Sprain

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Donna Roberts-Retzlaff, PhD

ABSTRACT

Background Laser acupuncture is part of the practice of acupuncture and has been shown in studies to reduce pain.

Objective To demonstrate the utility of laser acupuncture as an adjunct therapy for pain control and/or pain management.

Design, Setting, and Patients Prospective cohort study of 55 patients referred with uncontrolled pain for 4 well-documented conditions: arthritis, neuropathy, intractable pain, or pain from strain/sprain injury. Patients were treated each week (once or twice weekly) with a 500-mW laser at specific acupuncture points for 9 weeks. The study was performed at the Integrative Medicine Centre in Fairhope, Alabama, from September 2004 through February 2005.

Main Outcome Measures Patient-reported reduction and control of associated pain and discomfort of the condition on the McGill Pain Questionnaire and as determined by acupuncture diagnosis.

Results Initially, all patients rated their pain as 8-9 on the McGill questionnaire. There was a reduction of pain in all conditions after the first 3 weeks in all groups. There was further reduction after the next 3 weeks, but less during the last 3 weeks. A follow-up investigation after 6 months still found reduced pain in each group.

Conclusion Laser therapy may be a useful clinical therapeutic method for attenuating or eliminating pain and other symptoms in chronic and acute pain syndromes.

KEY WORDS

Acupuncture, Laser, Laser Acupuncture, Pain, Pain Management

INTRODUCTION

In addition to greater public awareness, clinical efficacy, low rates of adverse effects, low cost, and mounting clinical research evidence have helped enhance the popularity of acupuncture in the United States. A recent research innovation in acupuncture is the use of laser acupuncture, which involves the use of a laser in place of conventional needles.¹ Laser acupuncture is being touted by many scientific researchers as a viable and perhaps superior alternative to needle acupuncture in certain cases.

Needling in acupuncture dates back thousands of years and numerous studies have proven its effectiveness in pain relief.² Likewise, the laser has been used for more than 30 years in acupuncture clinical settings. There are many studies to support its effectiveness.³⁻⁵ Acupuncture and electroacupuncture have been widely used to relieve a variety of pain problems.⁶ In comparison with traditional acupuncture performed manually, laser acupuncture may offer convenience and a different stimulating effect to provide pain relief.⁵ Patients often seek alternative modalities, including laser therapy, when they do not achieve enough pain relief from conventional treatments.² We report patient response to selected acupuncture points and laser stimulation in this clinical study.

The authors were intrigued with the clinical question of laser pain control in chronic as well as acute conditions and sought to investigate the following research questions:

1. Is laser acupuncture as effective as needle acupuncture in given conditions?
2. Can pain relief be accomplished with laser acupuncture without the eliciting of De Qi?
3. Is there a difference in the effectiveness of the laser's application for acute pain vs chronic pain?

To investigate the questions above, some of the most medically resistant conditions were chosen for the study. Neuropathy, arthritis, chronic intractable pain, and acute pain from strain and sprain injury were selected as conditions to be investigated because optimal treatment parameters are not known. A sample of 55 patients were treated for 9 weeks with laser acupuncture. Both short-term and long-term results were recorded.

As a pilot study, a group of 25 patients (15 men, 10 women) who had been treated with needle acupuncture with limited success were treated with laser acupuncture. All 25 patients were being treated for a diagnosis of neck and back pain from a non-disk origin and ranged in age from 23-65 years. After 4 weeks of twice-weekly needle acupuncture, all patients reported pain of at least 6 on an adapted (1-no pain, 10-extreme pain) McGill Pain Questionnaire.

Pilot Study

After these patients' conditions proved resistant to needle acupuncture, laser acupuncture (500-mW laser) was administered. After 1 month of laser treatment, 80% of the patients reported pain of 3 or less on the pain scale. Thus, for this group of patients, laser acupuncture proved more effective than traditional needle acupuncture. The success of laser acupuncture for this group of patients led to the following larger study.

METHODS

This larger study was a clinical investigation performed at the Integrative Medicine Centre in Fairhope, Alabama, from September 2004 through February 2005. We studied 55 patients between the ages of 14 and 98 years. All patients experienced pain and were diagnosed by their physician with 1 of 4 conditions: arthritis, neuropathy, uncontrolled pain,

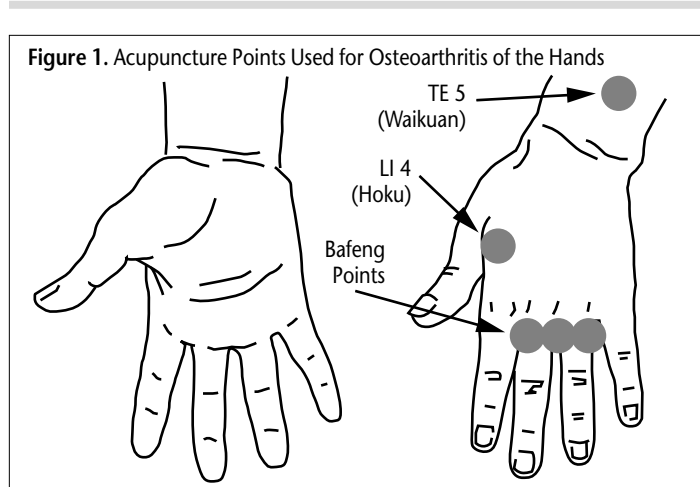
or strain/sprain. Patient informed consent was obtained before the start of the investigation and IRB approval was obtained.

Study selection criteria for the 3 chronic diagnoses required that patients have symptoms for more than 6 weeks and their condition proven resistant to other forms of medical intervention. For the acute strains/sprains, only 1 week was required. All required a medical diagnosis and a referral. Patients taking medication or not willing to discontinue medication were excluded from the study. No patients were accepted who were undergoing psychological treatment.

Patients were randomly placed in 1 of 2 groups: once- or twice-weekly treatments. Each diagnosis was assigned a pain score: 0 indicating absence of pain and 9, the most severe pain. All patients reported a score of 8-9 at the beginning of the study. Each patient's score was recorded before and after each treatment session all 9 weeks; the same procedure was used for the 6-month follow-up examination. Four patients dropped out of the study, leaving usable data for 51, with the distribution by diagnosis, sex, and age shown in Table 1.

We used an adapted visual analog scale (VAS) from the McGill Pain Questionnaire to determine the role of the laser in chronic and acute pain management.⁷ Patients were placed into groups depending on their diagnosis; each group was treated with laser for a total of 9 weeks at 1 or 2 times each week, depending on their time allotment. Each treatment consisted of 500 mW at 30 seconds at the selected acupuncture points.

Patients were positioned for treatment supine, sitting, or prostrate, depending on their condition and physical ability. The skin was prepared using an alcohol pad or cotton. The 500-mW laser was applied at the preselected sites of each diagnosis. The acupuncture points selected for each condition were based on the combined experience of a Traditional Chinese Medicine practitioner and a Japanese practitioner with more than 50 years' combined experience in acupuncture.^{8,9} Accuracy of the laser application was confirmed based on 30 years' acupuncture experience of the consultants. Stimulation intensity was at 30J per acupuncture point based on a random selection of 1 or 2 treat-



ments per week. Treatment was administered at the following bilateral points throughout the schedule (Table 2 and Figures 1-3).

RESULTS

The results for each diagnosis were analyzed to determine whether age, frequency, or sex had any significant effect. No significant relations was found.

The average result for each diagnosis is shown in Table 3 (in the row labeled Result 1). The best results were obtained for arthritis and strain. Patients with pain had the next best results, and neuropathy patients on average had the smallest improve-

ment. There was no statistically significant difference between the arthritis and strain results. There was a statistically significant difference between neuropathy and the arthritis groups, and between neuropathy and strain groups. This seems to indicate that laser treatment is most effective for treating arthritis and strain.

Patients' results 6 months after treatment were recorded in follow-up visits using the same pain scale. The average result for each diagnosis is shown in Table 3 (in the row labeled Result 6). The bottom row of the table shows the average change during the 6 months following treatment. Strain patients had the best results after 6 months, with an average of 1.67, which was significantly different from the other 3 diagnoses. There was no statistically significant difference among the other 3 groups.

A positive change value indicates that patients' conditions degraded over the 6-month interval but on average, these were very small. Only strain patients on average had improvement over the 6-month period, possibly because strain generally improves over time.

Arthritis

Age, sex, and frequency of treatment were not significant predictors of results after 6 months. However, the change of 1.4 (which is statistically significant) indicates that a patient's level of pain increased during the 6 months following treatment. In addition, there was a strong correlation between result 1 and result 6 for arthritis patients ($r=0.896$). This means that the patient's result immediately after treatment is a strong prediction of the patient's condition after 6 months.

Table 1. Distribution of Study Patients by Diagnosis, Sex, and Age

	Diagnosis				Total
	Arthritis	Neuropathy	Pain	Strain	
Sex					
Male	9	12	4	9	34
Female	1	7	6	3	17
Total	10	19	10	12	51
Age, y					
Mean	57.6	67.5	51.2	46.8	
Range	16-83	43-98	21-76	14-73	

Table 2. Acupuncture Treatment Points by Diagnosis

Diagnosis	Treatment Points
Arthritis	TE 5, LI 4, Bafeng points
Neuropathy	ST 36, SP 6, ST 42, LV 3, KI 1
Intractable Pain	PC 3, KI 10, ST 36, BL 10, TE 10, BL 54
Strain/Sprain	PC 6, LI 4, LV 4, SP 3, BL 60, GB 43

There was a slight indication that older patients experienced more degradation than younger patients during the 6 months following treatment, but it was not statistically significant.

Laser needles appear to be very effective in alleviating pain immediately for arthritis. In fact, this condition responded best of the 4 evaluated, reducing pain from 9 to 2.3 on average. By 6 months after treatment, a patient's pain level can be expected to increase by 1.4 on average.

Neuropathy

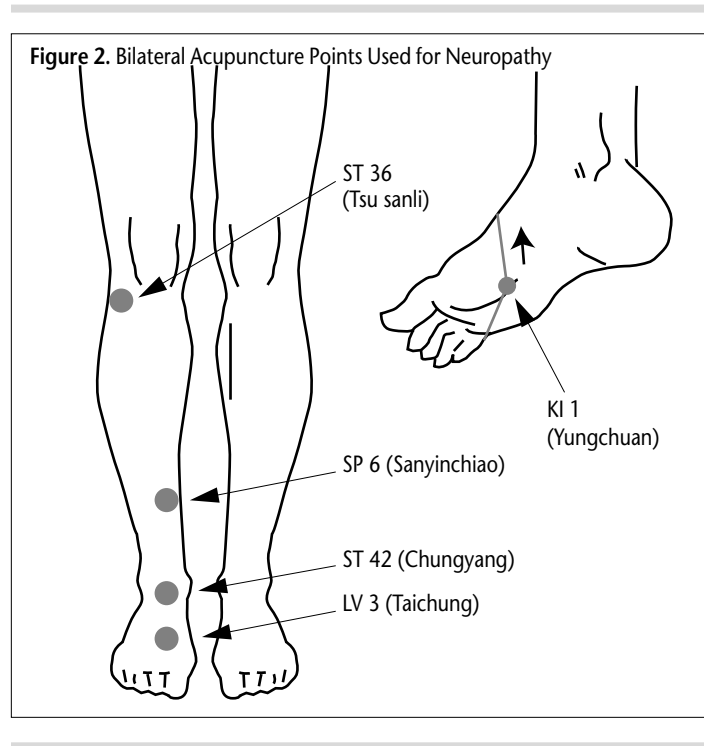
Similar to the results for arthritis, age, sex, and acupuncture frequency were not significant predictors of results after 6 months. On average, there was a small degradation (0.52) in the quality of results over the 6 months. However, this change was not statistically significant. The 2 sets of results were correlated ($r = 0.83$), which again means results immediately after treatment are a good predictor after 6 months.

Pain

Among pain patients, the average result immediately after treatment was 3.60, which increased to 4.10 after 6 months, an increase of 0.50. However, this change was not statistically significant. Unlike the previous 2 diagnoses, there was not a strong relation between the 2 results. Hence, a patient's results immediately after treatment were not necessarily a good predictor of results 6 months later. Yet there was a statistically significant relationship between the patient's age and the amount of change experienced from immediately after treatment until 6 months later. Older patients tended to experience deterioration over the 6 months while the youngest patients tended to experience improvement (Figure 4).

Strain

The strain/sprain diagnosis, which was the only acute condition, experienced one of the best responses to laser acupuncture with an average pain level immediately after treatment of 2.33. This was the only



diagnosis for which results on average improved over the 6 months. However, this improvement was not statistically significant. In fact, there were no significant relations among any of the variables for the strain diagnosis. Hence, laser acupuncture may be effective in treating this pain, and results will not be significantly different 6 months later.

DISCUSSION

The results of this study show that the laser is effective in reducing pain for all 4 of the diagnoses we treated: arthritis, neuropathy, intractable pain, and strain/sprain. In addition, the results were judged superior to those that would have been expected using traditional needle acupuncture on a similar sample of patients (based on a history of treating patients using traditional needle acupuncture).

Despite the fact that acupuncture has been widely used in treating both acute pain and chronic pain conditions for many years in different parts of the world, little is known about the underlying mechanism. Due to the inherent difficulty of study design and lack of scientific data, the use of acupuncture as a treatment modality has not been widely embraced in conventional pain management clinics.¹⁰ However, it has been noted that "more and more patients are finding that alternative medicine has a great deal to offer, especially for treating chronic conditions with which Western medicine has little success."¹¹

The stimulation of acupuncture points with laser light can evoke specific effects in the periphery of the nervous system and in the brain.¹²⁻¹⁴ These effects can be objectified and quantified using modern biomedical engineering techniques. Laser needle acupuncture represents a new, painless method for stimulation of acupuncture points. Laser needles are not inserted in the skin; the laser is simply applied to the acupuncture point. This method allows the simultaneous stimulation of individually combined points.¹⁵

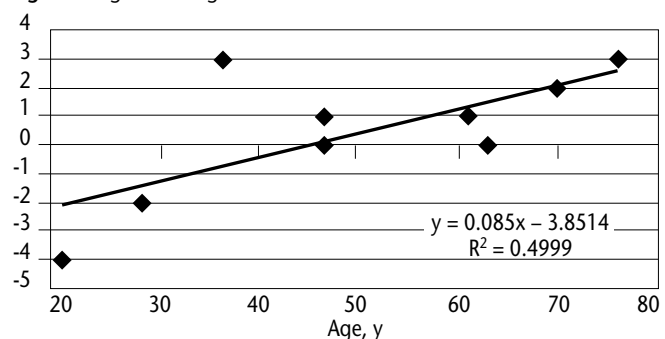
Several goals and limitations to the study existed. First, our goal was

Table 3. Pain Scale Results*

	Diagnosis				Average
	Arthritis	Neuropathy	Pain	Strain	
Result 1	2.30	4.11	3.60	2.33	3.24
Result 6	3.70	4.63	4.10	1.67	3.65
Change	1.40	0.52	0.50	-0.67	0.41

*Result 1 is immediately after treatment, result 6 is at 6 months' follow-up.

Figure 4. Age vs Change in Pain Score



to determine if pain control was available from this new technology; second, to determine if the laser could stimulate Qi flow without the benefit of De Qi stimulation. The shortfall of the study is that it was not a double-blind, randomized, controlled, cross-over study. Unfortunately, time and resources were not available to accomplish such a goal.

CONCLUSIONS

We report that laser acupuncture allows simultaneous stimulation of individual acupuncture point combinations that can reduce both chronic and acute pain. This study showed laser acupuncture to be at least as effective as needle acupuncture. Pain control can be accomplished without De Qi stimulation. Results for all 4 diagnoses were not affected by the frequency of treatment, the patient's age, or sex. Laser therapy may serve as an adjunctive tool in managing chronic and acute nonmalignant pain. The efficacy of specific treatments for different pain conditions and the corresponding underlying mechanism require more investigation for laser acupuncture to gain further acceptance in the scientific community.

ACKNOWLEDGEMENTS

We thank Professor Shingo Fukinbara and Professor Zhuodao Zhao for their valuable time and cooperation in this year-long investigation. We also thank Medical Systems Laser Division of Branford, Connecticut, for the use of the Luminex 500 Low Level Laser in this study.

REFERENCES

1. Liberman J. *Light Medicine of The Future*. Santa Fe, NM: Bear & Co Publishing; 1991.
2. Kim DH. Evolution of acupuncture for pain management. *Semin Integrative Med*. 2004;2(4):16-18.
3. Naeser MA, Hahn KA, et al. Carpal tunnel syndrome pain treated with low-

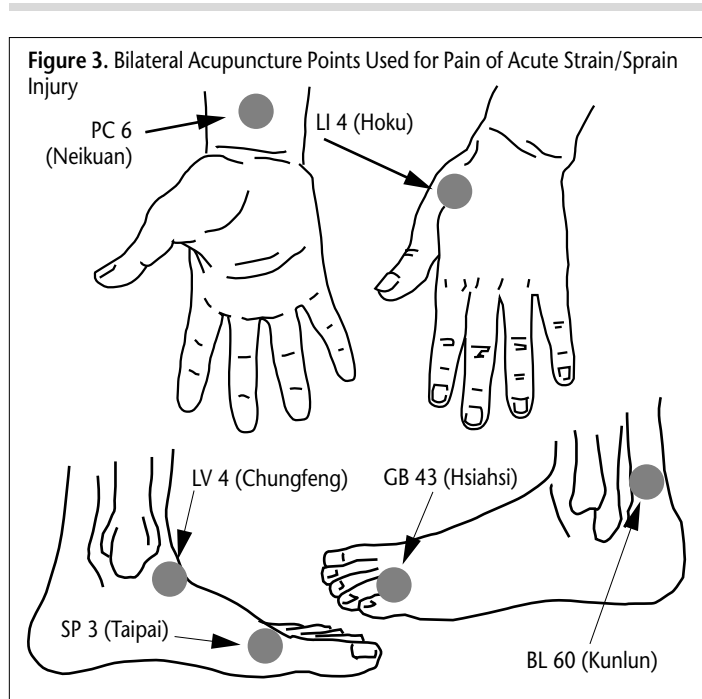


Figure 3. Bilateral Acupuncture Points Used for Pain of Acute Strain/Sprain Injury

laser and microamperes transcutaneous electric nerve stimulation: a comparative study. *Arch Phys Med Rehabil*. 2002;83(7):978-988.

4. Oezdemir F, Birtane M, Kokino S. The clinical efficacy of low-power laser therapy on pain and function in cervical arthritis. *Clin Rheumatol*. 2001; 20(3):181-184.
5. Tuner J, Hode L. *Low Level Laser Therapy: Clinical Practice and Scientific Background*. Grangesberg, Sweden: Prima Books; 1999:21.
6. Buck D. Biological basis of acupuncture. *American Acupunctureist*. Spring 2005:32.
7. Haas M, Nyiendo J. Diagnostic utility of the McGill pain questionnaire and the Oswestry disability questionnaire for classification of low back pain syndromes. *J Manip Phys*. 1992;15(2):90-96.
8. Selected acupuncture points based upon experience and education of: Professor Shingo Fukinbara, DiGaku Centre of Kobe, Japan and Zhuodao Zhao, MD,

PhD, Third Military Medical University, Chongqing, China.

9. Deadman P, AL-Khafaji M, Baker K. *A Manual of Acupuncture*. East Sussex, England: Journal of Chinese Medicine Publications; 2001.
10. Leung AY. Effect of acupuncture on the quality of life in patients with chronic pain: a prospective outcome measure. *Medical Acupuncture*. 2003;14(2):34-36.
11. Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR, Delbanco TL. Unconventional medicine in the United States: prevalence, costs, and patterns of use. *N Engl J Med*. 1993;328(4):246-252.
12. Karu T. *The Science of Low Power Laser Therapy*. Amsterdam, the Netherlands: Gordon and Beach Science Publishers; 1998.
13. Vargas JT. Low-Level Laser Acupuncture. *Medical Acupuncture*. 2005;16(2): 33-35.
14. Martin R. Inflammation/pain reduction and healing. *Practical Pain Manage*. Nov/Dec 2003:20-24.
15. Litscher G, Wang L, Schikora D, et al. Biological effects of painless laser needle acupuncture. *Medical Acupuncture*. 2004;16(1):7-8.

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Acupuncture As A Palliative Adjunctive Therapy In Children With Cerebral Palsy: A Randomized Controlled Trial

Soheil Torktorabi, MD
Parvin Ghassemi, MS

ABSTRACT

Background The incidence of cerebral palsy (CP) in developed countries is about 2-2.5/1000 live births. Since CP is a chronic neurological condition, parents often seek alternative treatments such as acupuncture. Anecdotal reports of body and scalp acupuncture have claimed efficacy for CP. However, evidence-based investigation of the efficacy of acupuncture in CP is lacking.

Objective To assess whether a short course of acupuncture could improve motor function in children with CP.

Design, Setting, and Patients A heterogeneous mix of 40 children with CP, aged 8-16 years, were randomly assigned to the treatment group (n=20) or the control group (n=20). The study was conducted from October 2003 to July 2004 at the Pouya Somatomotory Invalids Center in Isfahan, Iran.

Intervention Three acupuncture subdivisions were involved based on TCM and Western diagnoses. Manipulation (for skull) or electrical stimulation (for the body surface) with stainless steel needles was used. Treatment was twice weekly for 4 months. Vacceria seed was applied for stimulating an acupoint in the ear for 30-60 minutes, 3 times daily for 16 weeks.

Main Outcome Measure Comparison of scores on the Gross Motor Function Measure 66 (GMFM-66, a measure of mobility) before and after acupuncture, and between acupuncture and control groups.

Results The mean GMFM-66 score increased significantly in the acupuncture group from 133.6 before to 138.3 after acupuncture ($P<.001$). The mean difference in GMFM-66 score was significantly higher for the acupuncture group (mean [SD], 4.8 [2.9]) ($P<.001$) than for the control group (0.7 [0.8]) ($P<.001$).

Conclusions We could not change the impact of the brain developmental injuries in the CP child with conventional physical therapies and rehabilitation techniques, but acupuncture is offered as a potential palliation. Future randomized controlled trials should be conducted, with longer follow-up.

KEY WORDS

Acupuncture, Cerebral Palsy, Gross Motor Function, Children

INTRODUCTION

Childhood cerebral palsy (CP) is a major disease resulting in body disabilities among children. The incidence of CP is about 0.2%, for which there is no specific treatment.¹ With the development of perinatal medicine, the mortality of neonates has decreased dramatically although the morbidity of childhood CP has shown a rising trend.²⁷ A child with CP brings heavy economic and mental burdens to his/her family. Rehabilitation is a long and tedious process and requires tremendous energy physically, mentally, and financially from the parents. How to effectively reduce the costs for CP rehabilitation and improve the outcome is our ultimate objective. Our research focused on the effectiveness of this method of treatment for 40 CP patients. The efficacy of acupuncture in improvement of physical function is supported by findings on motor function scales and through our data such as neurological testings of finger to nose, heel to shin, and linear. The objective of this study was to assess whether a short course of acupuncture could improve motor function in children with CP.

Cerebral palsy is caused by injuries to the cerebral area that occur before or during birth, or in the first few months of life. The incidence of CP in developed countries is stable at about 2-2.5/1000 live births. Cerebral injuries occur in several ways: inadequate blood or oxygen supply to the fetus, premature birth or birth trauma, diseases in infancy (encephalitis, meningitis, herpes simplex, cytomegalovirus), intracranial hemorrhage of prematurely born infants, or blood vessel damage.

The 4 categories of CP are spastic, extrapyramidal or choreoathetoid, atonic, and mixed.¹ Rehabilitation management programs for patients with CP aim to achieve functional improvement, especially using new treatments such as botulinum toxin, selective dorsal rhizotomy, or intrathecal baclofen infusion.²⁻⁴ Since CP is a chronic neurological condition, parents often seek alternative treatments such as acupuncture. Anecdotal reports of body and scalp acupuncture for CP have demonstrated its efficacy.⁵⁻¹⁰ However, evidence-based investigation assessing the efficacy of acupuncture in CP is lacking.

According to the philosophy of Traditional Chinese Medicine (TCM), health is achieved by maintaining an uninterrupted flow of Qi along 14 meridians. Disease is caused by stagnation of the flow of this Qi or energy. Acupuncture can help to restore the smooth flow of Qi, thus restoring the internal balance.¹¹ Acupoints in the body are linked to 14 meridians. When these points are stimulated, resignaling or potentiate of neural receptors can transfer to the motor/somatosensory cortex through neural pathways that are connected to these 14 meridians. The result is improvement of motor function.¹²⁻¹⁴

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METHODS

Participants

A heterogeneous mix of 40 male and female children with CP, aged 8-16 years, were randomly assigned to the treatment group (n=20) or the control group (n=20). The study was conducted from October 2003 to July 2004. These children attend a special school. A history of each child was taken from the family and diagnostic data, including com-

puted tomography, skull magnetic resonance imaging, and electroencephalography, confirmed the severity of CP. Informed parental consent was given for each participant.

Control Group

Impairment in this group included quadriplegia (n=5), hemiplegia (n=7), bilateral hemiplegia (n=6), and triplegia (n=2). Thirteen children had moderate-grade mental retardation, and 7 had mild retardation.

Acupuncture Group

Impairment consisted of quadriplegia (n=2), hemiplegia (n=7), bilateral hemiplegia (n=5), triplegia (n=4), and ataxia (n=2). Five children had moderate-grade mental retardation, and 15 had mild retardation. The study was double-blinded: patients were not clearly aware of their involvement; the evaluator did not know the results of involvement. Both treatment and control groups received rehabilitation programs that included physiotherapy and physical therapy.

This study was conducted under the supervision of the Ministry of Education at (co-author) Dr Soheil Torktorabi’s acupuncture clinic in Isfahan, Iran. The study group was monitored for the duration of the program by Dr Torktorabi. Three acupuncture subdivisions (1) classic body acupuncture, (2) ear acupuncture, and (3) scalp acupuncture were involved, based on TCM and Western diagnoses. The study group was observed until the end of program. There was ethics review board approval.

Three acupuncture seeds were applied for stimulating in the ear: Kidney, Brain, and Brain Stem acupoints; 30-60 minutes, 3 times daily¹⁶ until the end of treatment.

Equipment

Stainless steel needles, 0.3 x 40 mm, with an insertion range of 0.5 to 1 inches, were used. Manipulation (for skull) or electrical stimulation for the body surface (KW88, Chinese-made) was used, with continuous wave frequency of 2-4 Hz.

Selective Points In The Treatment Group¹⁷

For the spasticity of upper limbs: LI 11¹⁸ (Quchi), and SI 3 (Hoaxi) were involved, based on TCM and Western diagnoses. Treatment was twice weekly for 4 months. Vacceria SI 3¹⁸ (Hoax).

For the spasticity of lower limbs: GB 34¹⁸ (Yanglingquan), KI 3, 18 (Taixi), and SP 6¹⁸ (Sanyinjiao).

For ataxia, a balanced area on the scalp was used: both of them, ST 40¹⁸ (Jiechi) and ST 36¹⁸ (Zusanli).

For Kidney Yin deficiency, points on the ear:¹⁶

Kidney. On the lower border of the inferior antihelices crus, directly above SI.

Spleen. At the lateral and superior of cavum conchae.

Brain. On the medial aspect of antitragus.

Brainstem. On the helix tragic notch.

Data Collection

The Gross Motor Function Measure 66 (GMFM-66) is a standardized observational instrument designed and validated to measure change in gross motor function over time in children with CP.¹⁹

The scoring key is meant to be a general guideline. However, most of the items have specific descriptors for each score. It is imperative that the guidelines contained in the manual be used for scoring each item. Scoring key: 0=does not initiate, 1=initiates, 2=partially completes, 3= completes, NT=not tested. Our test consisted of 5 items: laying and rolling; sitting; crawling and kneeling; standing, walking, and running; and jumping. The teacher and health instructor assessed both groups before and after the project.

Statistical Analysis

We used the independent sample test in SPSS-11 software (SPSS Inc, Chicago, IL) for comparing the groups, and a paired sample *t* test for comparison before and after acupuncture in the intervention group.

RESULTS

The mean GMFM-66 score increased significantly from 133.6 before acupuncture to 138.3 after ($P<.001$ by paired samples *t* test) (Table 1).

The increase in mean GMFM-66 score was significantly higher for the acupuncture group than for the control group ($P<.001$ by independent sample *t* test) (Table 2).

DISCUSSION

In TCM diagnoses, the kidney stores the essence of life that controls marrow; the reservoir of the marrow is the brain. Hence, human growth and development, including brain development, is dependent on the essence stored in the kidney. In TCM models, almost all children with CP have Kidney Yin deficiency. We strived to invigorate Kidney Yin or potentiate the spleen to interact on the kidney and because the spleen is related to muscle, we used Spleen points. In Western diagnoses, degeneration of the primary motor cortex of the primary motor area causes hypotonia because the primary motor cortex normally excretes a continual tonic stimulatory effect on motor neurons.¹⁵

The diagnosis of CP includes a heterogeneous group of nonprogressive motor disorders of the developing brain. The severity and level of injury determine abnormality and developmental deficiency in the motor cortex, basal ganglia, cerebellum, etc. These problems cause disability in motor function: motor cortex injury produces hypotonia, basal ganglia injury produces spasticity, and cerebellum injury causes loss of balance. In addition, injury can cause neurotransmitter problems. Neurotransmitters are chemicals that permit the passage of signals within the brain. Some of these chemicals, excitatory neurotransmitters, increase the amount of activity in the nervous system while others, inhibitory neurotransmitters, decrease the amount of activity. Dopamine is one of the chemicals, which has smothering action on voluntary movements.²⁰ Studies have proven that altering the pattern of electrical signaling in individual neurons changes the kind of neurotransmitters they produce.²¹

Electrical signals in cell membranes may be altered by the use of acupuncture and then produce some of the neurotransmitters such as dopamine.²² Acupuncture may also increase brain activity.²³⁻²⁵ Since

Table 1. Mean difference in Gross Motor Function Measure 66 scores in the acupuncture group

	No.	Mean (SD)	Standard Error
Before acupuncture	20	133.6 (56.6)	12.7
After acupuncture	20	138.3 (57.1)	12.8

Table 2. Mean difference between study groups in Gross Motor Function Measure 66 scores

Group	No.	Mean (SD)	Standard Error
Acupuncture	20	4.8 (2.9)	0.7
Control	20	0.7 (0.8)	0.2

there is no specific treatment for CP and the structure of the brain cannot be changed, we used acupuncture for the reduction of physical disabilities in children with CP.

CONCLUSIONS

We demonstrated that acupuncture may improve gross motor function in children with CP and reduce their disabilities. To our knowledge, our study is the 2nd randomized controlled trial of acupuncture in CP. The effectiveness of acupuncture in improvement of physical function is supported by findings on the GMFM-66 and through our neurological testing such as finger to nose, heel to shin, and linear tests.

Our recommendations include further studies of the physiological effects of acupuncture on the central nervous system of patients with CP (with emphasis placed on neurotransmitters and neurosignaling); randomized controlled trials with larger sample sizes with homogeneous CP; and longer follow-up.

REFERENCES

1. Behrman RE, ed. *Nelson Essentials of Pediatrics*. Philadelphia, PA: WB Saunders; 1998.
2. Graham HK, Aoki KR, Autti-Rämö I, et al. Recommendations for the use of botulinum toxin A in the management of cerebral palsy. *Gait Posture*. 2000;11:67-79.
3. McLaughlin J, Bjornson K, Temkin N, et al. Selective dorsal rhizotomy: meta-analysis of three randomized controlled trials. *Dev Med Child Neurol*. 2002;44(1):17-25.
4. Coffey RJ, Cahill D, Steers W, et al. Intrathecal baclofen for intractable spasticity of spinal origin: results of a long-term multicenter study. *J Neurosurg*. 1993;78:226-232.
5. Wang Y, Xu G, Li G, et al. Treatment of apoplectic hemiplegia with scalp acupuncture in relation to CT findings. *J Tradit Chin Med*. 1993;13:182-184.
6. Filipowicz WA. The application of modern acupuncture techniques and methods on children with cerebral palsy. *Am J Acupunct*. 1991;1:5-9.
7. Shi BP, Bu HD, Lin LY. A clinical study on acupuncture treatment of pediatric cerebral palsy. *J Tradit Chin Med*. 1992;12:45-51.
8. Lu WQ. Prompt pressure applied to peculiar points in the treatment of spasmodic infantile cerebral palsy: a report of 318 cases. *J Tradit Chin Med*. 1994;14:180-184.
9. Zhou XJ, Chen T, Chan JT. 75 Infantile palsy children treated with acupuncture, acupressure and functional training. *Chung-Kuo Chung Hsi Chieh Ho Tsa Chih*. 1993;13:220-222.
10. Sanner G, Sundequist U. Acupuncture for the relief of painful muscle spasms in dystonic cerebral palsy. *Dev Med Child Neurol*. 1981;23:544-555.
11. Stux G, Pomeranz B. *Basics of Acupuncture*. 5th ed. Berlin, Germany: Springer; 1998.
12. Cho ZH, Chung SC. New findings of the correlation between acupoints and corresponding brain cortices using functional MRI. *Proc Natl Acad Sci*. 1998;95:2670-2673.
13. Eng HC. Electroacupuncture-induced neural activation detected by use of manganese-enhanced functional magnetic resonance imaging in rabbits. *Am J Vet Res*. 2001;62:178-182.

14. Omura Y. Connections found between each meridian (heart, stomach, triple burner, etc.) and organ representation area of corresponding internal organs in each side of the cerebral cortex; release of common neurotransmitters and hormones unique to each meridian and a corresponding acupuncture point and internal organ after acupuncture, electrical stimulation, mechanical stimulation (including Shiatsu), Soft Laser Stimulation of Qi Gong. *Acupunct Electrother Res*. 1989;14:155-186.
15. Gang LY. *Advanced Modern Chinese Acupuncture Therapy*. Shanghai, People's Republic of China: New World Press; 2000.
16. Chen K, Yongqiang C. *Handbook of Chinese Auricular Therapy*. Shanghai, People's Republic of China: Foreign Language Press; 2000.
17. Wang W. *The Standard Meridians and Points of Chinese Acupuncture*. Toina: Jiangsu Science & Technology Press; 1997.
18. Jenkins M. A new standard international acupuncture nomenclature. *Acupunct Med*. 1990;7(1):21-23.
19. Russell DJ, et al. *Gross Motor Function Measure for Children With Cerebral Palsy*. London, England: MacKeith Press; 2002.
20. Guyton AC. *Textbook of Medical Physiology*. Philadelphia, PA: WB Saunders; 2003.
21. Borodinsky LN, Root CM, Cronin JA, Sann SB, Gu X, Spitzer NC. Activity-dependent homeostatic specification of transmitter expression in embryonic neuron. *Nature*. 2004;429:523-530.
22. Shang C. Mechanism of acupuncture: beyond neurohumoral theory. *Medical Acupuncture*. 1999/2000;11(2):36-41.
23. Hui KK, Liu J, Makris N, et al. Acupuncture modulates the limbic system and subcortical gray structures of the human brain: evidence from MRI studies in normal subjects. *Hum Brain Mapp*. 2000;13:13-25.
24. Futaesaku Y, Zhai N, Ono M, et al. Brain activity of a rat apparently reflects the stimulation of acupuncture. *Cell Mol Biol*. 1995;41:161-170.
25. Guillemin R, Vargo T, Rosier J, et al. Beta-endorphin and adrenocorticotropin are secreted concomitantly by the pituitary gland. *Science*. 1977;197:1367-1369.

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Registering Clinical Trials: Complementary And Alternative Medicine Research Challenges

Our journal, *Medical Acupuncture*, is listed by the International Committee of Medical Journal Editors (ICMJE) as adhering to its policies. I recently received an e-mail asking whether our journal would support the policy of "Obligation to Register Clinical Trials," since we have previously stated that we abide by their requirements. Indeed, I consider this to be an important step for future indexing of this journal into the National Library of Medicine (MEDLINE). What is stated is the following: "The ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trial registry." The ICMJE believes that research subjects and the general public should have an insight as to what researchers are engaging in, and that this information should be available in a public database that can easily be accessible.

The ICMJE believes that it is important to foster a comprehensive, publicly available database of clinical trials. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

The ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trials registry. The details of this policy are contained under editorials. The ICMJE encourages editors of other biomedical journals to adopt similar policy.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organization. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable. An acceptable registry must include at minimum the data elements in the following table. Trial registration with missing fields or fields that contain uninformative terminology is inadequate.

The ICMJE recommends that journals publish the trial registration number at the end of the Abstract (Table 1).¹

There are many upcoming challenges to be faced for publication in our journal. It will be a steep learning curve. Will this discourage manuscripts from clinical researchers who have performed a "small trial" that we see published so often? What about authors from outside of the United States; how will they register their trials, and in what language for it to be valuable in the public domain? Should we have a public database for acupuncture clinical trials associated with this journal? There are probably more questions than answers.

Medical Acupuncture will require that all authors performing clinical trials and submitting for publication after November 1, 2006, must adhere to ICMJE requirements as stated above. Smaller studies such as pilot projects may be exempt. As the Editorial staff becomes more conversant with the requirements, we will communicate this information. I plan to continue to discuss this matter with other journal editors. I would appreciate "Letters to the Editor" to hear directly from you. I trust this will be an opportunity also for increased communication.

I do not look at my role as "policeman." I want to encourage the publication of articles and concurrently meet the obligations of the ICMJE. The bottom line is this quote from the ICMJE:

"We recognize that requiring public registration of trials whose prespecified goal is to investigate the biology of disease or to direct further research might slow the forces that drive innovation. Therefore, each journal editor will decide on a case-by-case basis about reviewing unregistered trials in this category. Authors whose trial is unregistered will have to convince the editor that they had a sound rationale when they decided not to register their trial."

"The ICMJE currently recognizes the following registries:"

- Australian Clinical Trials Registry — <http://actr.org.au>
- Clinical Trials — <http://www.clinicaltrials.gov/>
- ISRCTN Register — <http://isrctn.org>
- Netherlands Trial Register — <http://www.trialregister.nl/trialreg/index.asp>
- UMIN Clinical Trials Registry — <http://www.umin.ac.jp/ctr>

Finally, all papers must have a statement addressing the IRB issue. Authors opting not to seek IRB approval or IRB waiver of subject consent will have to be justified in writing, and may require a letter to the Editor-in-Chief from the IRB.

Important to note also is that the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, on which we base our journal's "Instructions for Authors," were updated in February 2006. I leave it to prospective authors to review the changes at <http://www.icmje.org>.

For the convenience of authors, we are publishing "the Uniform Requirements for Manuscripts Submitted to Biomedical Journals" in its entirety (see page 8). Please retain for future use.

I wish to thank all of you in advance for helping make this the best journal possible in the field of Medical Acupuncture.

— Richard C. Niemtzow, MD, PhD, MPH
Editor-in-Chief

Table 1. Minimal Registration Data Set*

Item	Comment
1. Unique trial number	The unique trial number will be established by the primary registering entity (the registry).
2. Trial registration date	The date of registration will be established by the primary registering entity.
3. Secondary IDs	May be assigned by sponsors or other interested parties (there may be none).
4. Funding source(s)	Name of the organization(s) that provided funding for the study.
5. Primary sponsor	The main entity responsible for performing the research.
6. Secondary sponsor(s)	The secondary entities, if any, responsible for performing the research.
7. Responsible contact person	Public contact person for the trial, for patients interested in participating.
8. Research contact person	Person to contact for scientific inquiries about the trial.
9. Title of the study	Brief title chosen by the research group (can be omitted if the researchers wish).
10. Official scientific title of the study	This title must include the name of the intervention, the condition being studied, and the outcome (e.g., The International Study of Digoxin and Death from Congestive Heart Failure).
11. Research ethics review	Has the study at the time of registration received appropriate ethics committee approval (yes/no)? (It is assumed that all registered trials will be approved by an ethics board before commencing.)
12. Condition	The medical condition being studied (e.g., asthma, myocardial infarction, depression).
13. Intervention(s)	A description of the study and comparison/control intervention(s) (For a drug or other product registered for public sale anywhere in the world, this is the generic name; for an unregistered drug the generic name or company serial number is acceptable). The duration of the intervention(s) must be specified.
14. Key inclusion and exclusion criteria	Key patient characteristics that determine eligibility for participation in the study.
15. Study type	Database should provide drop-down lists for selection. This would include choices for randomized vs non-randomized, type of masking (e.g., double-blind, single-blind), type of controls (e.g., placebo, active), and group assignment, (e.g., parallel, crossover, factorial).
16. Anticipated trial start date	Estimated enrollment date of the first participant.
17. Target sample size	The total number of subjects the investigators plan to enroll before closing the trial to new participants.
18. Recruitment status	Is this information available (yes/no) (If yes, link to information).
19. Primary outcome	The primary outcome that the study was designed to evaluate. Description should include the time at which the outcome is measured (e.g., blood pressure at 12 months).
20. Key secondary outcomes	The secondary outcomes specified in the protocol. Description should include time of measurement (e.g., creatinine clearance at 6 months).

*The data fields were specified at a meeting convened by the WHO in April 2005; the explanatory comments are largely from the ICM.

REFERENCE

1. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication III. Obligation to Register Clinical Trials. Updated February 2006. <http://www.icmje.org>.

EDITOR INFORMATION

Dr Richard C. Niemtow is a Radiation Oncologist, Colonel in the United States Air Force, and practices Medical Acupuncture full-time at Malcolm Grow Medical Center, Andrews Air Force Base, Maryland. Dr. Niemtow is a newly-appointed Assistant Professor of Family Medicine at the Uniformed Services University of the Health Sciences, Bethesda, Maryland, and represents the Department of Defense at the National Center for Complementary and Alternative Medicine at the Advisory Council on Complementary and Alternative Medicine. He is President of the Maryland Society of Medical Acupuncture, Chairman of the American Academy of Medical Acupuncture (AAMA) Research Committee, and is Senior Editor of the Journal of Alternative and Complementary Medicine.

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From Conventional CME To CAM Program

It has been an extraordinarily busy year for planning the CME program of community hospitals in California. All physicians must complete at least 12 hours of a CME program on "pain management and care of terminal illness" in order to fulfill the California AB 487 by December 2006. The only 2 specialties exempt are pathology and radiology.

Being an academic pain management specialist, I wear both hats as clinician and educator. It is apparent that the CME program on pain management have become very popular as the deadline is approaching. My speaking engagements for community CME programs has been at least twice a month. I have had the opportunity to present topics such as "cancer pain management and palliative care," "pain management in the elderly," "complex regional pain syndrome," "acute pain management," "neck and back pain management," "neuropathic pain management," "pain management update for primary care providers," and "complementary and alternative pain management." I have constantly tried to start the presentation with a comprehensive assessment of pain and then recommend multidisciplinary management for every topic on pain management. Complementary and alternative medicine (CAM), especially medical acupuncture, has been an essential part of my presentation regardless of which specific pain topic is being discussed. I have certainly experienced very different interactions in these community CME programs as compared with teaching at medical school and postgraduate training programs.

These community CME programs were held mostly on weekdays with lunch buffet provided. Every time I was getting ready to set up with the audiovisual team, there was an early group of silver-haired physicians. They dressed casually and sat together in roundtable, socializing while enjoying lunch before the lecture started. These *retired physicians* would stay faithfully through the whole program and usually paid close attention for the entire presentation. I could always count on their candid feedback to help me prepare future CME presentations. Some of the physicians had been retired for more than 10 years. They often asked questions not only linked toward the specific pain topic but also their personal pain problems. These retired physicians may also have experienced the limit on how much conventional medicine can offer throughout their professional career. The retired physicians are more likely to have experienced the similar pain conditions as the topic of presentation. From time to time, the discussion would be based on their own testimony of trying alternative medicine first-hand for pain management. Often they felt that medical acupuncture may have scientific merit and it started to make sense for them after the program. They frequently asked for either a referral for themselves or for a family member for medical acupuncture treatment.

In contrast, their younger counterparts arrived late and frequently left early to answer a page or return to their office to continue another busy day. It is comprehensible that practicing physicians are just too busy to figure out alternative pain management. I have contemplated *how* to get the message effectively to practicing physicians that medical acupuncture truly *can* contribute to comprehensive pain management. It is possible that they have never been exposed to pain management utilizing CAM. Maybe it is because of the frustrations of fighting through the referral system for CAM in the era of managed care. I did get occasional inquiries about medical acupuncture from practicing physicians, mostly on pain conditions of either a personal nature or that of a family member. I would then get some degree of enthusiasm on discussion only if they had previous experience with acupuncture or were in need of a personal referral.

Note: I would like to propose a crusade to promote our *Medical Acupuncture* (journal) of the American Academy of Medical Acupuncture in the targeting of retired physicians, a wealth of viable, engaged professionals. The journal can serve as both a practical reference and alternative resource of CME for retired physicians. These physicians could then function not only as role models but also work to promote medical acupuncture to other physicians and the public at large.

As a devotee, I look forward to participating in more enthusiastic discussions and interactions for future CME programs on medical acupuncture. Hopefully, these endeavors would help to inspire current practicing physicians to pursue further training in medical acupuncture and integrate CAM into clinical practice.

— Eric S. Hsu, MD
Guest Editor

GUEST EDITOR INFORMATION

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Editor's Note: We welcome submissions of Guest Editorials for the journal.

Medical Acupuncture is a journal with an international scope, focusing on the evolving specialty of medical acupuncture. The editor welcomes articles on all aspects of medical acupuncture, including research, education, clinical practice, technology, policy, ethics, law, schools of thought, history, and related disciplines. Communications regarding Academy activities are also appropriate.

All material submitted should conform to the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, as formulated by the International Committee of Medical Journal Editors. These requirements appear in their entirety in the *Annals of Internal Medicine* (1997; 126:36-47) and are also available online at www.icmje.org/index.html.

Please adhere to STRICTA (Standards for Reporting Interventions in Controlled Trials of Acupuncture [see Vol. 13/No. 3/ pg. 9]); available online at www.ftcm.org.uk/stricta.htm.

Authorship

All persons designated as authors must qualify for authorship. Criteria include substantial contributions to the following: (a) conception, design, and/or analysis and interpretation of data; (b) writing or revising the manuscript for intellectual content; and (c) final approval of the article for publication. All 3 criteria must be met. Contributors who do not meet these 3 criteria should be listed, with their permission, in an acknowledgement paragraph.

The order of the author byline should be reached by consensus of the co-authors. All authors should be listed by full name, degrees, and affiliations along with other pertinent information for the "Author Information" section. Due to space constraints, senior or equal co-authors are limited to 35 words each, junior authors to 20 words each, not including name and address. The journal retains the right to edit if necessary.

Biographical and contact information (including address, phone and fax numbers, E-mail address, where applicable) for all authors must be initially provided.

All manuscripts should be mailed to the Editor-in-Chief, *Medical Acupuncture*, The American Academy of Medical Acupuncture, 4929 Wilshire Boulevard, Suite 428, Los Angeles, California 90010; 323.937.5514 voice; 323.937.0959 fax; email: jdowden@prodigy.net.

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Financial Disclosure

All affiliations with or financial involvement in any entity with a financial interest in or in competition with the article's subject matter must be disclosed. This includes stock ownership, employment, consultancies, honoraria, grants, patents, and royalties.

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If a submission could be considered redundant or duplicative of a previous published work, a full statement of such should be made to the editor. If duplicate publication is attempted without such notification, editorial action may be taken, including prompt rejection of the manuscript. Any subjects discussed in the submitted manuscript who have been mentioned in another publication should be noted, with a reference to the previous work. If a manuscript is submitted elsewhere concurrently, the manuscript will be withdrawn.

Informed Consent, Study Ethics Approval, and Subject Confidentiality

When articles include reports of studies on human subjects, state in the Methods section that an appropriate review board or ethics committee approved the study. Authors who do not have formal ethics review committees should follow the principles of the Declaration of Helsinki. In the Methods section, state that informed consent was obtained from subjects (specify oral or written).

In addition, text, photographs, and pedigrees should not reveal identifying information unless it is essential for scientific purposes (in which

case consent should be obtained). Masking the subjects' eyes in photographs is often insufficient to protect their identity.

Animals. The principal author must state that if animals were used experimentally, permission was obtained from the appropriate committee(s), and that the animals were treated humanely and conforming to the standards of current ethical animal research practices.

MANUSCRIPT PREPARATION

Title Page

The title page should include the article title, names and affiliations of all authors, and corresponding biographical information on all authors, including mailing address, fax and telephone numbers, and E-mail address, if applicable.

Abstract

For original research, reviews, and meta-analyses, provide a structured abstract of no more than 200 words. Include information as applicable for the following headings: *Background, Objective, Design, Setting, Patients (or Subjects), Intervention, Main Outcome Measures, Results, and Conclusions*. For all other major manuscripts, include an unstructured Abstract of no more than 100 words that summarizes the objective, main points, and conclusions of the article.

Key Words

Underneath the Abstract, provide 3-10 key words (preferably Medical Subject Heading terms) that will assist indexers and researchers using electronic databases such as *MEDLINE*.

Text

Introduction. Provide a brief background for the article, including the rationale for the study or observation. Do not present data from the current work.

Methods. Describe the selection of subjects, including demographics and study design. Identify the procedures in sufficient detail so others may replicate the results. Provide references to established methods and new techniques; provide the rationale for their use and also describe their limitations. Authors submitting review articles should describe the methods used to locate, select, extract, and synthesize data.

The principal author must state that verbal or written consent was obtained from the patient(s) when appropriate. The principal author must state whether a human research committee granted approval for treating and obtaining data or employing protocols which involved human subjects.

Statistics. As necessary, describe statistical methods and provide appropriate indicators of error or uncertainty (eg, 95% confidence intervals). Specify any statistical software used.

Results. Present results in a logical sequence. Do not duplicate data in the text and tables/figures.

Discussion. The discussion section should summarize the results and their implications. This section should also discuss rationale of acupoints used such as: consider mechanisms of action; clinical implications and usefulness; and benefit to patient.

Conclusion. Emphasize important and new findings of the study. Include implications of the findings and their limitations. Recommendations for future work may be included.

Nomenclature and Abbreviations

Authors must conform to the standard nomenclature for medical acupuncture, listed at the end of these instructions. As a general rule, use only these abbreviations and those easily recognizable in the literature. The full term should appear at first mention, followed by the abbreviation in parentheses. Standard units of measure are acceptable to abbreviate without expansion. When discussing particular products, it is preferable to use the non-proprietary (generic) name or descriptive term throughout. If desired, the brand name can be included parenthetically at first mention.

Acknowledgement

At the end of the article, include a paragraph, when appropriate, acknowledging support for

the work. This can include contributions that do not justify authorship, technical support, and financial and technical help. This is also an appropriate place to mention previous presentation (e.g., as an abstract or poster at a meeting). Relationships that may pose a conflict of interest should also be disclosed.

References

A minimum of 3 references is required. References should be numbered consecutively in the text; do not alphabetize the reference list but present citations in numerical order to correspond with mention in the text. References cited only in tables or figures should be numbered in accordance with the order established by the first mention of that table or figure in the text.

Use the formatting of reference citations as based on Index Medicus style. Avoid citing "personal communications" unless they provide essential information; do not list them in the references but place them parenthetically in the text. Authors should obtain permission from the source of such communications and indicate the date they occurred and whether the communication was oral or written.

Tables

Tables should be typed on separate pieces of paper, double-spaced. Number tables consecutively in the text as they appear. Provide a title for each, as well as column headings. Provide footnotes for explanatory material, using the following symbols in sequence: * † ‡ § || ¶ #. Identify statistical measures, such as mean (SD). Data from other sources require permission and a statement of such in a table footnote. The use of too many tables in relation to length of text may cause problems for journal page layout. Avoid duplicating data in text and tables/figures, with the exception of significant findings and main outcomes.

Figures

Submit 3 camera-ready copies of figures along with the text. Letters, numbers, and symbols should be clear and of sufficient size when printed in the journal. Label each figure on the back with the author's name, article title, and figure number. If pictures of patients are used, either the subjects must be completely unidentifiable or written informed consent must be obtained and submitted.

Figures reprinted from other sources should be acknowledged in the legend, and permission must be granted. The legend should be submitted as part of the text and not typed on the actual figure. Clearly identify all symbols and abbreviations, and explain scales if necessary. Any other explanatory information should be given in the legend.

ACUPUNCTURE CHECKLIST

(Based on STRICTA requirements)¹

1. Provide rationale for treatment, and style of acupuncture used.
2. Supply needling details: unilateral/bilateral points employed.
3. Number of needles inserted; needle type (gauge, length, manufacturer [include address]); insertion depth; responses elicited (Qi); twirled counter clockwise or clockwise.
4. Electrostimulator device (type, model, manufacturer [include address]); time; stimulation frequency; which leads are designated + or - and where placed.
5. State treatment regimen: number of treatments, frequency (treatments per week, etc.); interventions employed such as moxibustion, cupping, herbs, etc.; treatment duration; environment: music, lighting, aromatics, etc.

¹(MacPherson H, White A, Cummings M, Jobst K, Rose K, Niemtzwow RC, for the STRICTA Group. Standards for reporting interventions in controlled trials of acupuncture: the STRICTA recommendations. *Medical Acupuncture*. 2002;13 (3):9-11)

Submission and Editing Process

Submit 3 copies of the manuscript as well as the tables and figures. The journal prefers that the article be composed using a 12-point font in

Microsoft Word. Along with hard copies, submit a diskette with the manuscript and figures/tables saved to it. On the front of the disk, include author's name, article title, operating system used, and software. The author's request to withdraw the manuscript after undergoing the editing process will result in possible penalty fees based on editing costs, and possible exclusion from future publishing in *Medical Acupuncture*.

Manuscript Review Process

Each manuscript will be initially reviewed by the Editor-in-Chief for preliminary acceptance or rejection. The manuscript is then forwarded to a minimum of 3 AAMA physicians for review, and scored appropriately. The manuscripts are categorized as fully accepted, accepted pending revisions, or rejected with recommendations for resubmission. After submission, no revisions or new versions will be accepted unless requested by the Editor-in-Chief.

STANDARD NOMENCLATURE FOR MEDICAL ACUPUNCTURE

READERS: The standard nomenclature was revised May, 2002. Please read carefully.

The following names and abbreviations are to be used in *Medical Acupuncture*. Some recent changes in nomenclature have been adopted by the AAMA and are to be used in all papers submitted to this journal. Please pay strict attention to these changes. For the most part, this is the system endorsed by the World Health Organization (WHO). Common English anatomical, physiological, and pathological terms are capitalized to indicate their Chinese medical meanings, e.g., Lung, Blood, Heat Deficiency, etc. The Alphabetic Code was agreed on by participants and observers at a meeting of the WHO Scientific Group held in 1989.

STANDARD INTERNATIONAL NOMENCLATURE FOR MERIDIANS

NAME OF MERIDIAN ALPHABETIC CODE

<i>Principal Meridians</i>		
Lung Meridian		LU
Large Intestine Meridian		LI
Stomach Meridian		ST
Spleen Meridian		SP
Heart Meridian		HT
Small Intestine Meridian		SI
Bladder Meridian		BL
Kidney Meridian		KI
Pericardium Meridian		PC
Triple Energizer Meridian		TE
Gallbladder Meridian		GB
Liver Meridian		LR
Governor Vessel (Dumai)		GV
Conception Vessel (Renmai)		CV

Extra Meridians

GV	Dumai	Governor Vessel
CV	Renmai	Conception Vessel
TV	Chongmai	Thoroughfare Vessel
BV	Daimai	Belt Vessel
YinHV	Yinqiaomi	Yin Heel Vessel
YangHV	Yangqiaomai	Yang Heel Vessel
YinLV	Yinweimai	Yin Link Vessel
YangLV	Yangweimai	Yang Link Vessel

Miscellaneous

Fu	Hollow organs
Zang	Solid organs
Front Mu	Collecting points
Back Shu	Transporting points
Sheng	Generating cycle
Ke	Controlling cycle
Ah Shi	"Ouch" point
De Qi	Arrival of Qi

Command and Special Points

Ting	Well	Yuan	Source
Ying	Spring	Luo	Vessel
Shu	Stream	Xi	Cleft
Jing	River	Hui	Influential
He	Sea		

Energy Levels or Axes

Tai Yang	Tai Yin
Shao Yang	Shao Yin
Yang Ming	Jue Yin