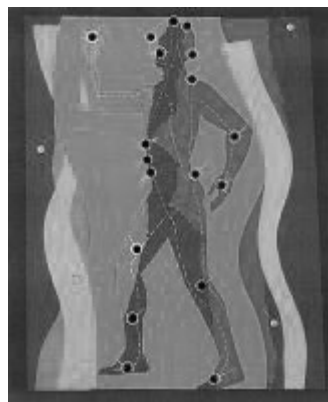




Acupuncture

National Institutes of Health
Consensus Development Conference Statement
November 3-5, 1997



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Abstract

Objective.

To provide health care providers, patients, and the general public with a responsible assessment of the use and effectiveness of acupuncture for a variety of conditions

Participants.

A non-Federal, nonadvocate, 12-member panel representing the fields of acupuncture,

pain, psychology, psychiatry, physical medicine and rehabilitation, drug abuse, family practice, internal medicine, health policy, epidemiology, statistics, physiology, biophysics, and the public. In addition, 25 experts from these same fields presented data to the panel and a conference audience of 1,200.

Evidence.

The literature was searched through Medline, and an extensive bibliography of references was provided to the panel and the conference audience. Experts prepared abstracts with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience.

Consensus Process.

The panel, answering predefined questions, developed their conclusions based on the scientific evidence presented in open forum and the scientific literature. The panel composed a draft statement, which was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference. The panel finalized the revisions within a few weeks after the conference. The draft statement was made available on the World Wide Web immediately following its release at the conference and was updated with the panel's final revisions.

Conclusions.

Acupuncture as a therapeutic intervention is widely practiced in the United States. While there have been many studies of its potential usefulness, many of these studies provide equivocal results because of design, sample size, and other factors. The issue is further complicated by inherent difficulties in the use of appropriate controls, such as placebos and sham acupuncture groups. However, promising results have emerged, for example, showing efficacy of acupuncture in adult postoperative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma, in which acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program. Further research is likely to uncover additional areas where acupuncture interventions will be useful.

Introduction

Acupuncture is a component of the health care system of China that can be traced back for at least 2,500 years. The general theory of acupuncture is based on the premise that there are patterns of energy flow (Qi) through the body that are essential for health. Disruptions of this flow are believed to be responsible for disease. Acupuncture may correct imbalances of flow at identifiable points close to the skin. The practice of acupuncture to treat identifiable pathophysiological conditions in American medicine was rare until the visit of President Nixon to China in 1972. Since that time, there has been an explosion of interest in the United States and Europe in the application of the technique of acupuncture to Western medicine.

Acupuncture describes a family of procedures involving stimulation of anatomical locations on the skin by a variety of techniques. There are a variety of approaches to diagnosis and treatment in American acupuncture that incorporate medical traditions from China, Japan, Korea, and other countries. The most studied mechanism of stimulation of acupuncture points employs penetration of the skin by thin, solid, metallic needles, which are manipulated manually or by electrical stimulation. The majority of comments in this report are based on data that came from such studies. Stimulation of these areas by moxibustion, pressure, heat, and lasers is used in acupuncture practice, but because of the paucity of studies, these techniques are more difficult to evaluate.

Acupuncture has been used by millions of American patients and performed by thousands of physicians, dentists, acupuncturists, and other practitioners for relief or prevention of pain and for a variety of health conditions. After reviewing the existing body of knowledge, the U.S. Food and Drug Administration recently removed acupuncture needles from the category of "experimental medical devices" and now regulates them just as it does other devices, such as surgical scalpels and hypodermic syringes, under good manufacturing practices and single-use standards of sterility.

Over the years, the National Institutes of Health (NIH) has funded a variety of research projects on acupuncture, including studies on the mechanisms by which acupuncture may produce its effects, as well as clinical trials and other studies. There is also a considerable body of international literature on the risks and benefits of acupuncture, and the World Health Organization lists a variety of medical conditions that may benefit from the use of acupuncture or moxibustion. Such applications include prevention and treatment of nausea and vomiting; treatment of pain and addictions to alcohol, tobacco, and other drugs; treatment of pulmonary problems such as asthma and bronchitis; and rehabilitation from neurological damage such as that caused by stroke.

To address important issues regarding acupuncture, the NIH Office of Alternative Medicine and the NIH Office of Medical Applications of Research organized a 2-1/2-day conference to evaluate the scientific and medical data on the uses, risks, and benefits of acupuncture procedures for a variety of conditions. Cosponsors of the conference were the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Dental Research, the National Institute on Drug Abuse, and the Office of Research on Women's Health of the NIH. The conference brought together national and international experts in the fields of acupuncture, pain, psychology, psychiatry, physical medicine and rehabilitation, drug abuse, family practice, internal medicine, health policy, epidemiology, statistics, physiology, and biophysics, as well as representatives from the public.

After 1-1/2 days of available presentations and audience discussion, an independent, non-Federal consensus panel weighed the scientific evidence and wrote a draft statement that was presented to the audience on the third day. The consensus statement addressed the following key questions:

- What is the efficacy of acupuncture, compared with placebo or sham acupuncture, in the conditions for which sufficient data are available to evaluate?
- What is the place of acupuncture in the treatment of various conditions for which sufficient data are available, in comparison or in combination with other interventions (including no intervention)?
- What is known about the biological effects of acupuncture that helps us understand

how it works?

- What issues need to be addressed so that acupuncture can be appropriately incorporated into today's health care system?
- What are the directions for future research?

1. What Is the Efficacy of Acupuncture, Compared With Placebo or Sham Acupuncture, in the Conditions for Which Sufficient Data Are Available to Evaluate?

Acupuncture is a complex intervention that may vary for different patients with similar chief complaints. The number and length of treatments and the specific points used may vary among individuals and during the course of treatment. Given this reality, it is perhaps encouraging that there exist a number of studies of sufficient quality to assess the efficacy of acupuncture for certain conditions.

According to contemporary research standards, there is a paucity of high-quality research assessing efficacy of acupuncture compared with placebo or sham acupuncture. The vast majority of papers studying acupuncture in the biomedical literature consist of case reports, case series, or intervention studies with designs inadequate to assess efficacy.

This discussion of efficacy refers to needle acupuncture (manual or electroacupuncture) because the published research is primarily on needle acupuncture and often does not encompass the full breadth of acupuncture techniques and practices. The controlled trials usually have involved only adults and did not involve long-term (i.e., years) acupuncture treatment.

Efficacy of a treatment assesses the differential effect of a treatment when compared with placebo or another treatment modality using a double-blind controlled trial and a rigidly defined protocol. Papers should describe enrollment procedures, eligibility criteria, description of the clinical characteristics of the subjects, methods for diagnosis, and a description of the protocol (i.e., randomization method, specific definition of treatment, and control conditions, including length of treatment and number of acupuncture sessions). Optimal trials should also use standardized outcomes and appropriate statistical analyses. This assessment of efficacy focuses on high-quality trials comparing acupuncture with sham acupuncture or placebo.

Response Rate.

As with other types of interventions, some individuals are poor responders to specific acupuncture protocols. Both animal and human laboratory and clinical experience suggest that the majority of subjects respond to acupuncture, with a minority not responding. Some of the clinical research outcomes, however, suggest that a larger percentage may not respond. The reason for this paradox is unclear and may reflect the current state of the research.

Efficacy for Specific Disorders.

There is clear evidence that needle acupuncture is efficacious for adult postoperative and chemotherapy nausea and vomiting and probably for the nausea of pregnancy.

Much of the research is on various pain problems. There is evidence of efficacy for postoperative dental pain. There are reasonable studies (although sometimes only single

studies) showing relief of pain with acupuncture on diverse pain conditions such as menstrual cramps, tennis elbow, and fibromyalgia. This suggests that acupuncture may have a more general effect on pain. However, there are also studies that do not find efficacy for acupuncture in pain.

There is evidence that acupuncture does not demonstrate efficacy for cessation of smoking and may not be efficacious for some other conditions.

Although many other conditions have received some attention in the literature and, in fact, the research suggests some exciting potential areas for the use of acupuncture, the quality or quantity of the research evidence is not sufficient to provide firm evidence of efficacy at this time.

Sham Acupuncture.

A commonly used control group is sham acupuncture, using techniques that are not intended to stimulate known acupuncture points. However, there is disagreement on correct needle placement. Also, particularly in the studies on pain, sham acupuncture often seems to have either intermediate effects between the placebo and 'real' acupuncture points or effects similar to those of the 'real' acupuncture points. Placement of a needle in any position elicits a biological response that complicates the interpretation of studies involving sham acupuncture. Thus, there is substantial controversy over the use of sham acupuncture in control groups. This may be less of a problem in studies not involving pain.

2. What Is the Place of Acupuncture in the Treatment of Various Conditions for Which Sufficient Data Are Available, in Comparison or in Combination With Other Interventions (Including No Intervention)?

Assessing the usefulness of a medical intervention in practice differs from assessing formal efficacy. In conventional practice, clinicians make decisions based on the characteristics of the patient, clinical experience, potential for harm, and information from colleagues and the medical literature. In addition, when more than one treatment is possible, the clinician may make the choice taking into account the patient's preferences. While it is often thought that there is substantial research evidence to support conventional medical practices, this is frequently not the case. This does not mean that these treatments are ineffective. The data in support of acupuncture are as strong as those for many accepted Western medical therapies.

One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted medical procedures used for the same conditions. As an example, musculoskeletal conditions, such as fibromyalgia, myofascial pain, and tennis elbow, or epicondylitis, are conditions for which acupuncture may be beneficial. These painful conditions are often treated with, among other things, anti-inflammatory medications (aspirin, ibuprofen, etc.) or with steroid injections. Both medical interventions have a potential for deleterious side effects but are still widely used and are considered acceptable treatments. The evidence supporting these therapies is no better than that for acupuncture.

In addition, ample clinical experience, supported by some research data, suggests that acupuncture may be a reasonable option for a number of clinical conditions. Examples are postoperative pain and myofascial and low back pain. Examples of disorders for which the

research evidence is less convincing but for which there are some positive clinical trials include addiction, stroke rehabilitation, carpal tunnel syndrome, osteoarthritis, and headache. Acupuncture treatment for many conditions such as asthma or addiction should be part of a comprehensive management program.

Many other conditions have been treated by acupuncture; the World Health Organization, for example, has listed more than 40 for which the technique may be indicated.

3. What Is Known About the Biological Effects of Acupuncture That Helps Us Understand How It Works?

Many studies in animals and humans have demonstrated that acupuncture can cause multiple biological responses. These responses can occur locally, i.e., at or close to the site of application, or at a distance, mediated mainly by sensory neurons to many structures within the central nervous system. This can lead to activation of pathways affecting various physiological systems in the brain as well as in the periphery. A focus of attention has been the role of endogenous opioids in acupuncture analgesia. Considerable evidence supports the claim that opioid peptides are released during acupuncture and that the analgesic effects of acupuncture are at least partially explained by their actions. That opioid antagonists such as naloxone reverse the analgesic effects of acupuncture further strengthens this hypothesis. Stimulation by acupuncture may also activate the hypothalamus and the pituitary gland, resulting in a broad spectrum of systemic effects. Alteration in the secretion of neurotransmitters and neurohormones and changes in the regulation of blood flow, both centrally and peripherally, have been documented. There is also evidence of alterations in immune functions produced by acupuncture. Which of these and other physiological changes mediate clinical effects is at present unclear.

Despite considerable efforts to understand the anatomy and physiology of the "acupuncture points," the definition and characterization of these points remain controversial. Even more elusive is the scientific basis of some of the key traditional Eastern medical concepts such as the circulation of Qi, the meridian system, and other related theories, which are difficult to reconcile with contemporary biomedical information but continue to play an important role in the evaluation of patients and the formulation of treatment in acupuncture.

Some of the biological effects of acupuncture have also been observed when "sham" acupuncture points are stimulated, highlighting the importance of defining appropriate control groups in assessing biological changes purported to be due to acupuncture. Such findings raise questions regarding the specificity of these biological changes. In addition, similar biological alterations, including the release of endogenous opioids and changes in blood pressure, have been observed after painful stimuli, vigorous exercise, and/or relaxation training; it is at present unclear to what extent acupuncture shares similar biological mechanisms.

It should be noted also that for any therapeutic intervention, including acupuncture, the so-called "non-specific" effects account for a substantial proportion of its effectiveness and thus should not be casually discounted. Many factors may profoundly determine therapeutic outcome, including the quality of the relationship between the clinician and the patient, the degree of trust, the expectations of the patient, the compatibility of the backgrounds and belief systems of the clinician and the patient, as well as a myriad of factors that together define the therapeutic milieu.

Although much remains unknown regarding the mechanism(s) that might mediate the

therapeutic effect of acupuncture, the panel is encouraged that a number of significant acupuncture-related biological changes can be identified and carefully delineated. Further research in this direction not only is important for elucidating the phenomena associated with acupuncture, but also has the potential for exploring new pathways in human physiology not previously examined in a systematic manner.

4. What Issues Need To Be Addressed So That Acupuncture Can Be Appropriately Incorporated Into Today's Health Care System?

The integration of acupuncture into today's health care system will be facilitated by a better understanding among providers of the language and practices of both the Eastern and Western health care communities. Acupuncture focuses on a holistic, energy-based approach to the patient rather than a disease-oriented diagnostic and treatment model.

An important factor for the integration of acupuncture into the health care system is the training and credentialing of acupuncture practitioners by the appropriate State agencies. This is necessary to allow the public and other health practitioners to identify qualified acupuncture practitioners. The acupuncture educational community has made substantial progress in this area and is encouraged to continue along this path. Educational standards have been established for training of physician and non-physician acupuncturists. Many acupuncture educational programs are accredited by an agency that is recognized by the U.S. Department of Education. A national credentialing agency exists for nonphysician practitioners and provides examinations for entry-level competency in the field. A nationally recognized examination for physician acupuncturists has been established.

A majority of States provide licensure or registration for acupuncture practitioners. Because some acupuncture practitioners have limited English proficiency, credentialing and licensing examinations should be provided in languages other than English where necessary. There is variation in the titles that are conferred through these processes, and the requirements to obtain licensure vary widely. The scope of practice allowed under these State requirements varies as well. While States have the individual prerogative to set standards for licensing professions, consistency in these areas will provide greater confidence in the qualifications of acupuncture practitioners. For example, not all States recognize the same credentialing examination, thus making reciprocity difficult.

The occurrence of adverse events in the practice of acupuncture has been documented to be extremely low. However, these events have occurred on rare occasions, some of which are life-threatening (e.g., pneumothorax). Therefore, appropriate safeguards for the protection of patients and consumers need to be in place. Patients should be fully informed of their treatment options, expected prognosis, relative risk, and safety practices to minimize these risks before their receipt of acupuncture. This information must be provided in a manner that is linguistically and culturally appropriate to the patient. Use of acupuncture needles should always follow FDA regulations, including use of sterile, single-use needles. It is noted that these practices are already being done by many acupuncture practitioners; however, these practices should be uniform. Recourse for patient grievance and professional censure are provided through credentialing and licensing procedures and are available through appropriate State jurisdictions.

It has been reported that more than 1 million Americans currently receive acupuncture each year. Continued access to qualified acupuncture professionals for appropriate conditions should be ensured. Because many individuals seek health care treatment from both

acupuncturists and physicians, communication between these providers should be strengthened and improved. If a patient is under the care of an acupuncturist and a physician, both practitioners should be informed. Care should be taken to ensure that important medical problems are not overlooked. Patients and providers have a responsibility to facilitate this communication.

There is evidence that some patients have limited access to acupuncture services because of inability to pay. Insurance companies can decrease or remove financial barriers to access depending on their willingness to provide coverage for appropriate acupuncture services. An increasing number of insurance companies are either considering this possibility or now provide coverage for acupuncture services. Where there are State health insurance plans, and for populations served by Medicare or Medicaid, expansion of coverage to include appropriate acupuncture services would also help remove financial barriers to access.

As acupuncture is incorporated into today's health care system, and further research clarifies the role of acupuncture for various health conditions, it is expected that dissemination of this information to health care practitioners, insurance providers, policymakers, and the general public will lead to more informed decisions in regard to the appropriate use of acupuncture.

5. What Are the Directions for Future Research?

The incorporation of any new clinical intervention into accepted practice faces more scrutiny now than ever before. The demands of evidence-based medicine, outcomes research, managed care systems of health care delivery, and a plethora of therapeutic choices make the acceptance of new treatments an arduous process. The difficulties are accentuated when the treatment is based on theories unfamiliar to Western medicine and its practitioners. It is important, therefore, that the evaluation of acupuncture for the treatment of specific conditions be carried out carefully, using designs that can withstand rigorous scrutiny. In order to further the evaluation of the role of acupuncture in the management of various conditions, the following general areas for future research are suggested.

What Are the Demographics and Patterns of Use of Acupuncture in the United States and Other Countries?

There is currently limited information on basic questions such as who uses acupuncture, for what indications is acupuncture most commonly sought, what variations in experience and techniques used exist among acupuncture practitioners, and are there differences in these patterns by geography or ethnic group. Descriptive epidemiologic studies can provide insight into these and other questions. This information can in turn be used to guide future research and to identify areas of greatest public health concern.

Can the Efficacy of Acupuncture for Various Conditions for Which It Is Used or for Which It Shows Promise Be Demonstrated?

Relatively few high-quality, randomized, controlled trials have been published on the effects of acupuncture. Such studies should be designed in a rigorous manner to allow evaluation of the effectiveness of acupuncture. Such studies should include experienced acupuncture practitioners to design and deliver appropriate interventions. Emphasis should be placed on studies that examine acupuncture as used in clinical practice and that respect the

theoretical basis for acupuncture therapy.

Although randomized controlled trials provide a strong basis for inferring causality, other study designs such as those used in clinical epidemiology or outcomes research can also provide important insights regarding the usefulness of acupuncture for various conditions. There have been few such studies in the acupuncture literature.

Do Different Theoretical Bases for Acupuncture Result in Different Treatment Outcomes?

Competing theoretical orientations (e.g., Chinese, Japanese, French) currently exist that might predict divergent therapeutic approaches (i.e., the use of different acupuncture points). Research projects should be designed to assess the relative merit of these divergent approaches and to compare these systems with treatment programs using fixed acupuncture points.

In order to fully assess the efficacy of acupuncture, studies should be designed to examine not only fixed acupuncture points, but also the Eastern medical systems that provide the foundation for acupuncture therapy, including the choice of points. In addition to assessing the effect of acupuncture in context, this would also provide the opportunity to determine whether Eastern medical theories predict more effective acupuncture points.

What Areas of Public Policy Research Can Provide Guidance for the Integration of Acupuncture Into Today's Health Care System?

The incorporation of acupuncture as a treatment raises numerous questions of public policy. These include issues of access, cost-effectiveness, reimbursement by State, Federal, and private payers, and training, licensure, and accreditation. These public policy issues must be founded on quality epidemiologic and demographic data and effectiveness research.

Can Further Insight Into the Biological Basis for Acupuncture Be Gained?

Mechanisms that provide a Western scientific explanation for some of the effects of acupuncture are beginning to emerge. This is encouraging and may provide novel insights into neural, endocrine, and other physiological processes. Research should be supported to provide a better understanding of the mechanisms involved, and such research may lead to improvements in treatment.

Does an Organized Energetic System That Has Clinical Applications Exist in the Human Body?

Although biochemical and physiologic studies have provided insight into some of the biologic effects of acupuncture, acupuncture practice is based on a very different model of energy balance. This theory might or might not provide new insights to medical research, but it deserves further attention because of its potential for elucidating the basis for acupuncture.

How Do the Approaches and Answers to These Questions Differ Among Populations That Have Used Acupuncture as a Part of Their Healing Tradition for Centuries,

Compared With Populations That Have Only Recently Begun to Incorporate Acupuncture Into Health Care?

Conclusions

Acupuncture as a therapeutic intervention is widely practiced in the United States. There have been many studies of its potential usefulness. However, many of these studies provide equivocal results because of design, sample size, and other factors. The issue is further complicated by inherent difficulties in the use of appropriate controls, such as placebo and sham acupuncture groups.

However, promising results have emerged, for example, efficacy of acupuncture in adult post-operative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma for which acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program. Further research is likely to uncover additional areas where acupuncture interventions will be useful.

Findings from basic research have begun to elucidate the mechanisms of action of acupuncture, including the release of opioids and other peptides in the central nervous system and the periphery and changes in neuroendocrine function. Although much needs to be accomplished, the emergence of plausible mechanisms for the therapeutic effects of acupuncture is encouraging.

The introduction of acupuncture into the choice of treatment modalities readily available to the public is in its early stages. Issues of training, licensure, and reimbursement remain to be clarified. There is sufficient evidence, however, of its potential value to conventional medicine to encourage further studies.

There is sufficient evidence of acupuncture's value to expand its use into conventional medicine and to encourage further studies of its physiology and clinical value.

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Bibliography

The speakers listed above identified the following key references in developing their presentations for the consensus conference. A more complete bibliography prepared by the National Library of Medicine at NIH, along with the references below, was provided to the consensus panel for its consideration. The full NLM bibliography is available at the following Web site: <http://www.nlm.nih.gov/pubs/cbm/acupuncture.html>.

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