

COMPLEMENTARY THERAPY ASSESSMENT ACUPUNCTURE FOR OCULAR CONDITIONS AND HEADACHES

May 2003

SUMMARY

INTRODUCTION TO THE TOPIC

Acupuncture refers broadly to a group of procedures that stimulate the skin. The most common technique uses thin, solid metallic needles, which are manipulated either manually or by electrical stimulation.

CONCLUSIONS

Based on available evidence in the peer-reviewed scientific literature, the Task Force on Complementary Therapies believes that sufficient scientific evidence has not been found to demonstrate the safety or effectiveness of acupuncture for treatment of various ocular conditions when compared to standard therapies. The National Institutes of Health (NIH) Consensus Development Panel concluded that the evidence is not sufficient at this time to provide a determination of efficacy on the use of acupuncture for headaches. Two reviews have concluded that in studies analyzed there is at least a trend toward a benefit for acupuncture in the treatment of headache. The NIH Consensus Development Panel concluded that acupuncture may be useful as an adjunct treatment or as an acceptable alternative to standard therapies or be included in a comprehensive management program for headaches.

BENEFITS

Ocular Conditions

Acupuncture use has been reported for treating and alleviating a variety of ocular conditions. One randomized controlled double-masked study was found that examined the use of acupuncture for dry eye. Statistically significant differences were found between the needle acupuncture group and the control group ($P < 0.01$). Longer-term studies with larger samples of patients and adequate sham control groups to compare with needle acupuncture are needed to validate the results of this one study.

Headaches

In the NIH Consensus Development Panel report, sixteen controlled studies of the use of acupuncture for tension and migraine headaches were reviewed. In eight of the nine studies, acupuncture was found to be more effective than the control, reaching significance in three studies. In seven of the studies that compared acupuncture to standard therapy, acupuncture

Complementary Therapy Assessment: Acupuncture for Ocular Conditions and Headaches

was found to be as effective as standard therapy. However, these studies are not considered methodologically rigorous. A Cochrane Library systematic review on acupuncture for idiopathic headache included 26 studies with a total of 1151 patients and found that in the trials comparing true and sham acupuncture in migraine and tension-type headache patients the majority show at least a trend in favor of true acupuncture.

RISKS

Overall, the rate of general adverse effects from acupuncture has been reported to be low. They result from improper needling, organ puncture injuries, and the risk of infection related to use of unsterilized needles. Specific risks with use of acupuncture in ocular conditions have not been described.

REPORT

DESCRIPTION OF THE TECHNOLOGY

Acupuncture has been a part of the health care system in China for several thousand years. It refers broadly to a group of procedures that stimulate the skin using a variety of techniques, and they are usually performed in an office setting. The most common technique involves inserting thin, solid metallic needles no more than three inches into the surface of the skin to the deep tissue. They are manipulated either manually or by electrical stimulation. This assessment focuses on the application of acupuncture for eye conditions and for tension and migraine headaches. Other techniques, such as moxibustion that applies heat to an acupuncture point, have too few studies to evaluate.

MECHANISM OF ACTION

The rationale behind acupuncture is that there is an energy flow (Qi) along specific channels throughout the body. According to this theory, disease occurs when there is too little or too much Qi or when the flow is blocked or interrupted. Stimulation of acupuncture points corrects the imbalance of energy flow. Studies in animals and humans have demonstrated that biological responses occur as a result of acupuncture.^{1,2} These responses include the release of opioid peptides, which can account for the analgesic effects of acupuncture. There are also studies that have shown that acupuncture can alter immune functions, the secretion of neurotransmitters and neurohormones, and the regulation of blood flow. However, there is much that remains unknown about the anatomy and physiology of acupuncture points and the scientific basis for the theory of circulating energy flow. Further research is important.

DEFINITION OF THE PROBLEMS

Ocular Conditions

Acupuncture use has been reported for treating and alleviating a variety of ocular conditions, including myopia,^{3,4} high myopia,⁵ paralytic strabismus,⁶ retinitis pigmentosa,⁷ optic atrophy, retrobulbar neuritis, maculopathy,⁸ iritis, conjunctivitis, cataracts, and dry eye.⁹ Acupuncture has also been used for anesthesia during extraocular muscle surgery.

Headaches

Headache is a common complaint that patients present with when visiting an ophthalmologist. It is reported that up to 14% of all males and 28% of all females in the United States complain of relatively frequent headaches.¹⁰ Headaches secondary to ocular causes are rare. Migraine headaches are characterized by repetitive bouts of headaches, and they occur more commonly in women and can have associated visual symptoms. Tension headaches are precipitated by stress, and are chronic in nature; they are characterized by aching pain. Treatment of headaches is guided by the type of headache and symptoms. It can include eliminating contributory factors and using analgesics such as ergotamines, serotonergic agents, nonsteroidal anti-inflammatory and other medications.

Complementary Therapy Assessment: Acupuncture for Ocular Conditions and Headaches

FDA STATUS

In 1996, the US Food and Drug Administration removed acupuncture needles from the category of Class 3 “experimental medical devices” and now regulates them as Class 2 devices, subjecting them to good manufacturing practices and single-use standards of sterility.

SUMMARY OF EVIDENCE

Statistical Issues and Study Design

There are inherent difficulties and complexities in designing studies of acupuncture, mainly in using appropriate controls, such as placebos and sham acupuncture groups. This is complicated by the fact that many of the published studies involve issues of methodology, including insufficient sample size, questions about the effectiveness of randomization, lack of use of standardized outcome measures, short follow-up intervals, and inadequate placebo treatments for control groups.¹¹ The NIH Consensus Development Panel on Acupuncture concluded that “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 studies on acupuncture in the biomedical literature consist of case reports, case series, or intervention studies with designs inadequate to assess efficacy.”¹¹

Search Methods and Study Selection

Ocular Conditions In March 1999, the American Academy of Ophthalmology searched through MEDLINE in the English language for articles from January 1970 to March 1999 relating to acupuncture and ocular conditions. A total of 12 articles were identified; a total of 7 were defined as relevant and were reviewed for study design and implementation. An update search was conducted in MEDLINE, EMBASE, and the Cochrane Library for the years 1999 to 2002 and yielded 22 citations. Of these, two were relevant and reviewed for study design and implementation.

Headaches In November 1997, a 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, and biophysics were assembled as the NIH Consensus Development Panel on Acupuncture. The panel developed conclusions based on scientific literature and evidence presented by experts. The evidence presented in this assessment is based on the reports and data presented at this conference. The NIH Consensus Development Panel searched through MEDLINE, Allied and Alternative Medicine, EMBASE, MANTIS, and journals not indexed by the National Library of Medicine for the period from January 1970 to October 1997. An extensive bibliography of 2,302 references was assembled. An update search was conducted in MEDLINE and the Cochrane Library for the years 1999 to 2002 and yielded 23 citations. Of these, one was relevant for adverse reaction information, three were evidence-based or critical reviews, and two were randomized controlled trials not included in the Cochrane Library systematic review.

Complementary Therapy Assessment: Acupuncture for Ocular Conditions and Headaches

BENEFITS

Ocular Conditions

Of the nine articles reviewed, two were randomized controlled, double-masked studies. The rest of the articles were reports of case series (5 articles) or comparative studies without adequate control groups. One randomized double-masked study of dry eye used soft laser devices to deliver the point stimulation treatment similar to needle acupuncture, one emitting infrared light (32 cases) and one without any function (30 cases) as a placebo.⁹ These patients were compared with a group of 30 patients treated with needle acupuncture and 22 patients treated with artificial tears. Outcomes were defined as results of the Schirmer II test, break-up time, and frequency of use of artificial tears. The multiple Tukey-Kramers test was used for statistical analysis. Statistically significant differences were found between the two lasers that were used (the functional laser group showing improved outcomes), and between the needle acupuncture group and the control group (the needle acupuncture group showing improved outcomes) ($P < 0.01$). There was no statistically significant difference between the functional laser group and the needle acupuncture group.

One randomized cross-over study was designed to show a specific effect of acupuncture on the brain and eye using Doppler ultrasound technique.¹⁰ There were 13 participants with various ophthalmological diseases: retinitis pigmentosa (2), cone dystrophy (2), glaucoma (2), optic nerve atrophy (2), keratoconjunctivitis (2), iridocyclitis (1), intermediate uveitis (1), and endocrine orbitopathy (1). When these patients underwent acupuncture the study demonstrated a statistically significant increased blood flow velocity in either the supratrochlear artery or middle cerebral artery compared to the value obtained before acupuncture. The artery that demonstrated increased blood flow differed with the placement of the acupuncture needles so that needles placed at special eye points resulted in increased supratrochlear artery blood flow but not middle cerebral artery blood flow and the reverse was also found. Longer-term studies with larger samples of patients and adequate sham control groups compared with needle acupuncture are needed to expand upon the suggestive findings of these small studies.

Headaches

In the NIH Consensus Development Panel report, 16 controlled studies for acupuncture of tension and migraine headaches were reviewed. In nine of the studies, acupuncture was compared to a control group receiving needling treatment or some form of placebo treatment. In eight of these studies, acupuncture was found to be more effective than the control, reaching significance in three studies. In seven other studies, acupuncture was compared to standard treatment such as medication or physiotherapy. In all of these studies acupuncture was found to be as effective as standard therapy. However, most of these studies were not adequately designed, with insufficient sample size, outcome measures, problems with the control group, or inadequate use of acupuncture.¹¹ Thus, the weight of evidence seems positive, with a need for larger, well-designed studies for replication of previous results.¹² The NIH Consensus Development Panel concluded that although research evidence is not sufficient to provide firm evidence of efficacy at this time, acupuncture may be useful as an adjunct treatment or as an acceptable alternative that could be included in a comprehensive management program for headaches.

A Cochrane Library systematic review¹³ on acupuncture for idiopathic headache included 26 studies with a total of 1151 patients. Of the 26 studies, 16 were conducted among patients with

Complementary Therapy Assessment: Acupuncture for Ocular Conditions and Headaches

migraine, six among patients with tension-type headache patients, and four among patients with various types of headaches. Seventeen trials reviewed in the systematic review were 'placebo'-controlled, by needling of points distant from acupuncture points, superficial needling, or another procedures that did not involve penetration of the skin. The trials compared acupuncture with drug treatment, physiotherapy, combined relaxation and massage, traditional Chinese drug therapy, no treatment, or a biobehavioral treatment program. The median treatment period was 8 weeks with eight treatment sessions. Twenty-one trials followed patients after completion of the treatment phase; the median follow-up time was 26 weeks in those reports. The reviewers concluded that the majority of the trials comparing true and sham acupuncture in migraine and tension-type headache patients show at least a trend in favor of true acupuncture. However most trials however were small, many were either inadequately reported or had methodological flaws, and there was great variation in the exact type of acupuncture intervention and outcomes used to assess treatment among the studies included in the review.

A second review paper used the data from the NIH Consensus Development Panel and agreed with the Panel conclusions.¹⁴ A critical review of 27 clinical trials concluded that acupuncture offers benefits in the treatment of headache.¹⁵ Both reviews expressed the same concerns about the quality of the studies and reports. Two randomized controlled trials (n=69, n=50) not included in the review papers showed no significant differences between the treatment and control arms for the outcome of frequency of headaches.^{16,17}

RISKS

The overall rate of general adverse effects from acupuncture has been reported to be low.¹⁸ There have been rare events of potentially life-threatening events such as pneumothorax caused by improper needling or other organ puncture injuries. Fainting, local infection, and increased pain are more common adverse effects. It has been reported that 126 cases of hepatitis B have been linked to practitioners using unsterilized needles. Technical problems that can occur include bent or broken needles. Risks have not been described with use of acupuncture in ocular conditions.

QUESTIONS FOR SCIENTIFIC INQUIRY

If further scientific investigation is desired, the following questions are posed:

Ocular Conditions

- What is the biological basis for acupuncture for treating various eye conditions, i.e., dry eye, myopia, optic nerve atrophy?
- Is acupuncture effective treatment for ocular conditions using randomized controlled clinical trials in larger, well-designed studies with adequate statistical analyses?
- How effective is acupuncture compared to standard therapies for these ocular conditions?

Headaches

- What is the biological basis for using acupuncture to treat headaches?
- Is acupuncture effective treatment for headaches in a randomized controlled clinical trial, with larger, well-designed studies?
- How effective is acupuncture compared to conventional therapies for headache?

Complementary Therapy Assessment: Acupuncture for Ocular Conditions and Headaches

INFORMATION FOR PATIENTS

Physicians can advise their patients who are contemplating acupuncture treatment to ask the following questions:

- Does the provider have state licensure and credentialing? (A majority of states provide licensure or registration.)
- What other treatment options are available?
- What are the expected prognosis and risks associated with the use of acupuncture?
- What safety protocols are in place to minimize the risks of acupuncture?
- Does the provider follow FDA regulations for acupuncture needles, including using sterile, single-use needles?

SUMMARY AND CONCLUSIONS

Ocular Conditions

Based on available evidence in the peer-reviewed scientific literature, the Task Force on Complementary Therapies believes that sufficient scientific evidence has not been found to demonstrate the safety or effectiveness of acupuncture to treat various ocular conditions compared to standard therapies. These conditions include myopia, high myopia, paralytic strabismus, retinitis pigmentosa, optic atrophy, retrobulbar neuritis, maculopathy, iritis, conjunctivitis, cataracts, and dry eye.

Headaches

The NIH Consensus Development determined that the quality of the scientific evidence is not sufficient to provide a determination of efficacy at this time on the use of acupuncture for headaches. Two reviews have concluded that there is at least a trend in studies analyzed toward a benefit for acupuncture in the treatment of headache. All reviews state that the evidence has several inadequacies in study design and reporting. The NIH Consensus Development Panel concluded that acupuncture could be useful for headaches as part of a comprehensive management program or as an alternative for patients who have not had satisfactory results with conventional therapies. The clinician relies on clinical experience, scientific evidence regarding conventional therapies, weighing the benefits and risks, and information about patient characteristics and preferences to make these decisions.

DEVELOPMENT OF COMPLEMENTARY THERAPY ASSESSMENTS

Complementary, or alternative therapies, are a growing part of health care in America. Americans spend an estimated \$14 billion a year on alternative treatments. Most U.S. medical schools offer courses in alternative therapies. The editors of the *Journal of the American Medical Association* announced that publishing research on alternative therapies will be one of its priorities. More scrutiny and scientific objectivity is being applied to determine whether evidence supporting the effectiveness of complementary and alternative therapies exists.

Complementary Therapy Assessment: Acupuncture for Ocular Conditions and Headaches

The National Institutes of Health National Center for Complementary and Alternative Medicine has broadly defined complementary and alternative medicine as those treatments and health care practices that are not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies. The Cochrane Collaboration Complementary Medicine Field defines complementary medicine as including all such practices and ideas which are outside the domain of conventional medicine in several countries and defined by its users as preventing or treating illness, or promoting health and well being. These practices complement mainstream medicine by 1) contributing to a common whole; 2) satisfying a demand not met by conventional practices; and 3) diversifying the conceptual framework of medicine.¹⁹

In the fall of 1998, the Board of Trustees appointed a Task Force on Complementary Therapy to evaluate the peer-reviewed scientific literature on complementary therapies in eye care and develop an assessment on their safety and effectiveness in order to inform ophthalmologists and their patients. A scientifically grounded analysis of the data will help ophthalmologists and patients evaluate the research and thus make more rational decisions on appropriate treatment choices.

The Academy believes that complementary therapies should be evaluated similarly to traditional medicine: evidence of safety, efficacy, and effectiveness should be demonstrated.²⁰ Many therapies used in conventional medical practice also have not been as rigorously tested as they should be. Given the large numbers of patients affected and the health care expenditures involved, it is important that data and scientific information be used to base all treatment recommendations. In this way, we can encourage high-quality, rigorous research on complementary therapies.²¹

Ideally, a study of efficacy compares a treatment to a placebo or another treatment, using a double-masked controlled trial and well-defined protocol. Reports should describe enrollment procedures, eligibility criteria, clinical characteristics of the patients, methods for diagnosis, randomization method, definition of treatment, control conditions, and length of treatment. They should also use standardized outcomes and appropriate statistical analyses.

The goal of these assessments is to provide objective information about complementary therapies and to provide a scientific basis for physicians to advise their patients, when asked.

To accomplish these goals, the assessments, in general, are intended to do the following:

- Describe the scientific rationale or mechanism for action for the complementary therapy.
 - Describe the methods and basis for collecting evidence.
 - Describe the relevant evidence.
 - Summarize the benefits and risks of the complementary therapy.
 - Pose questions for future research inquiry.
 - Summarize the evidence on safety and effectiveness.
-

REFERENCES

1. NIH consensus conference. Acupuncture. JAMA 1998; 280:1518-24. [Also available at <http://consensus.nih.gov>]
2. Leake R, Broderick JE. Treatment efficacy of acupuncture: a review of the research literature. Integrative Medicine 1998; 1:107-15.
3. Liu H, Lu Y, Dong Q, Zhong X. Treatment of adolescent myopia by pressure plaster of semen impatientis on otoacupoints. J Tradit Chin Med 1994; 14:283-6.
4. Yang C, Hu L, Zhu F, Li L. 268 cases of myopia treated with injection and pellet pressure at auriculoacupoints. J Tradit Chin Med 1993; 196-8.
5. Wong S, Ching R. The use of acupuncture in ophthalmology. Am J Chin Med 1980; 8:104-53.
6. Liu C, Wang Y. 81 cases of paralytic strabismus treated with acupuncture. J Tradit Chin Med 1993; 13:101-2.
7. Dabov S, Goutoranov G, Ivanova R, Petkova N. Clinical application of acupuncture in ophthalmology. Acupunct Electrother Res 1985; 10:79-93.
8. Omura Y. Non-invasive circulatory evaluation and electro-acupuncture and TES treatment of diseases difficult to treat in western medicine. Acupunct Electrother Res 1983; 8:177-256.
9. Hepp J, Wedrich A, Akramian J et al. Dry eye treatment with acupuncture; a prospective, randomized, double-masked study. In: Sullivan DA, Dartt DA, Meneray MA, eds. Lacrimal gland, tear film and dry eye syndromes 2. New York: Plenum Press, 1998.
10. Litscher G, Wang L, Yang NH, Schwarz G. Computer-controlled acupuncture. Quantification and separation of specific effects. Neurol Res 1999; 21:530-4.
11. Birch S. Overview of the efficacy of acupuncture in the treatment of headache and face and neck pain. NIH Consensus Development Conference on Acupuncture, Bethesda, MD, 1997. [Available at <http://consensus.nih.gov>]
12. Berman BM. Overview of clinical trials on acupuncture on pain. NIH Consensus Development Conference on Acupuncture, Bethesda, MD, 1997. [Available at <http://consensus.nih.gov>]
13. Melchart D, Linde K, Fischer P, et al. Acupuncture for idiopathic headache (Cochrane Review). In: The Cochrane Library, Issue 1, 2003. Oxford: Update Software.
14. Mayer DJ. Acupuncture: an evidence-based review of the clinical literature. Annu Rev Med 2000; 51:49-63.
15. Manias P, Tagaris G, Karageorgiou K. Acupuncture in headache: a critical review. Clin J Pain 2000; 16:334-9.

Complementary Therapy Assessment: Acupuncture for Ocular Conditions and Headaches

16. Karst M, Reinhard M, Thum P, et al. Needle acupuncture in tension-type headache: a randomized, placebo-controlled study. *Cephalalgia* 2001; 21:637-42.
 17. White AR, Resch KL, Chan JC, et al. Acupuncture for episodic tension-type headache: a multicentre randomized controlled trial. *Cephalalgia* 2000; 20:632-7.
 18. Yamashita H, Tsukayama H, Hori N, et al. Incidence of adverse reactions associated with acupuncture. *J Altern Complement Med* 2000; 6: 345-350.
 19. Ernst E RK, Mills S, et al. Complementary medicine - a definition. *Br J Gen Pract* 1995;45:506.
 20. Fontanaros PB, Lundberg GD. Alternative medicine meets science [editorial]. *JAMA* 1998; 280: 1618-9.
 21. Margolin A, Avants SK, Kleber HD. Investigating alternative medicine therapies in randomized controlled trials. *JAMA* 1998; 280:1626-8.
-

Prepared by the American Academy of Ophthalmology Complementary Therapy Task Force

Ivan R. Schwab, MD, Chair
Pamela S. Chavis, MD
Roger Husted, MD
Jeffrey Todd Liegner, MD

Harold P. Koller, MD
William F. Mieler, MD
Sayoko E. Moroi, MD, PhD
Peter R. Holyk, MD, Consultant

Academy Staff: Flora Lum, MD
Nancy Collins, RN, MPH

Approved by the Quality of Care Secretariat June 1999
Revised April 2003 and approved by the Quality of Care Secretariat May 2003
Copyright© 2001 to 2003 American Academy of Ophthalmology® All rights reserved