

# ACUPUNCTURE: AN EVIDENCE-BASED REVIEW OF THE CLINICAL LITERATURE

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David J. Mayer

*Department of Anesthesiology, Medical College of Virginia, Virginia Commonwealth University, Richmond, Virginia 23298-0337; e-mail: mayer@hsc.vcu.edu*

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■ **Abstract** This chapter reviews the experimental literature on the effects of acupuncture treatment. The review covers the 14 medical conditions for which the National Institutes of Health Acupuncture Consensus Development Panel (NIHCDP) concluded that acupuncture either is effective (2 conditions) or may be useful (12 conditions). My conclusions partially support those of the NIHCDP. There is evidence that acupuncture is effective for the treatment of postoperative and chemotherapy-induced nausea and vomiting. Also, some data indicate that acupuncture may be useful for headache, low back pain, alcohol dependence, and paralysis resulting from stroke (4 of the 12 conditions for which the NIHCDP found that acupuncture may be useful). For most of the remaining conditions, there is little evidence that acupuncture is either effective or ineffective. It is recommended that workers in the field design double blind, sham controlled trials using adequate acupuncture treatment regimens, with specific hypotheses, and sample sizes sufficient to allow both positive and negative conclusions.

## INTRODUCTION

Two recent events have led to a revival of publicity (1), interest (2), and controversy (3, 4) about the medical uses of acupuncture. The first was a 1994 meeting entitled "Workshop on Acupuncture," sponsored by the United States National Institutes of Health (NIH) Office of Alternative Medicine and the United States Food and Drug Administration (FDA). This meeting served as a basis for the 1996 FDA reclassification of acupuncture needles from Class III (experimental) medical devices to Class II (nonexperimental but regulated) medical devices (4a). A second important event was that the NIH established a Consensus Development Panel (NIHCDP) to evaluate the clinical efficacy of acupuncture. The NIHCDP issued a report in November 1997 (5). Although the conclusions of both the Workshop on Acupuncture and the NIHCDP have been somewhat controversial (3, 4), they constitute the most recent and thorough reviews of the literature on the clinical efficacy of acupuncture. The present review relies heavily on their data.

After introducing some basic concepts of acupuncture, this review discusses experimental paradigms for the study of its clinical efficacy. It then presents a semiquantitative evaluation of the clinical efficacy of acupuncture in treating several syndromes for which a reasonable body of evidence exists.

## HISTORICAL CONTEXT

Acupuncture has been used as a medical modality for over 3000 years in China (6, 7). It has historically existed within the wider context of traditional Chinese medicine (TCM). TCM involves complex and interactive diagnostic and treatment procedures. The course of treatment is often altered depending on dynamically varying diagnostic criteria, such as alterations in pulse measurements. This complex context of acupuncture within TCM makes the design of clinical outcome trials difficult.

A few traditional terms and concepts should be understood in order to appreciate modern experimental evaluations of acupuncture. A key concept in TCM is Qi (pronounced “Chee”), or life energy. Qi is postulated to flow through the body in precisely located pathways or channels called meridians. These meridians are thought to be connected to various body organs as well as to each other. According to the principles of TCM, illness results from an imbalance of energy flow within these meridians. The rationale for acupuncture treatment is that intervention at particular points along meridians related to particular organ systems can restore the proper energy balance within the body and thus restore good health.

Acupuncture treatment is administered by manual needling of acupuncture points as well as by other methods of stimulation, such as electrical stimulation (electroacupuncture), heat (including moxibustion—burning of the herb moxa), pressure (acupressure), and laser-generated light. Generally, the experimental literature has addressed either manual needling or electroacupuncture because the stimulation parameters of these procedures are easiest to control. This review includes only papers examining one of these two procedures, unless otherwise stated, and no attempt is made to distinguish between them.

## EVALUATION OF ACUPUNCTURE AS A TREATMENT MODALITY

Two recent reviews of the clinical literature, mentioned above, are highly recommended to the reader. The first is the series of manuscripts (4a) generated by the FDA Workshop on Acupuncture in 1994. The other is the NIHCDP Consensus Statement (9), which concluded that

. . . 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.

In the remainder of this section, I examine the evidence that supports some of these conclusions. First, however, it is important to review the difficulties often encountered in the conduct of clinical trials of acupuncture.

## Experimental Design Issues

For acupuncture, as for any treatment regimen, clinical evidence of both safety and efficacy is desirable. The issue of safety was addressed by the FDA and, with only minor reservations (10), acupuncture is considered safe when practiced by appropriate professionals. The issue of efficacy is much more complicated.

The most important questions regarding efficacy generally concern the issue of comparative standards. For some authors (11), even if acupuncture were no more efficacious than a placebo manipulation, it would be of value. For the FDA, comparison with placebo is less important than comparison to another treatment of known efficacy (4a). For the scientist seeking to evaluate the theoretical mechanisms involved in acupuncture effects, it might be important to demonstrate not only that acupuncture is more efficacious than placebo but also that acupuncture treatment at putatively active sites is more efficacious than treatment at inactive sites. For the clinician attempting to treat specific medical conditions, the most efficacious procedure might be defined in terms of location, stimulation parameters, and perhaps dynamic outcome variables (e.g. pulse diagnosis) involved in TCM.

One result of such varied comparisons is that the vast literature on acupuncture (MEDLINE alone lists more than 6800 references) contains clinical trials of varying experimental design that are often difficult to compare and analyze using statistical procedures such as meta-analysis. Nevertheless, it is possible to classify the experimental designs into a limited number of categories and to evaluate their strengths and weaknesses (12, 13), as well as to characterize more precisely what hypotheses are supported by what types of scientific evidence.

It is useful to classify the designs of acupuncture treatment outcome trials into four types. In the first trial design, a group receiving acupuncture is compared with an untreated group or to a group on a wait list for treatment. As mentioned above, this design may demonstrate that acupuncture is more beneficial than doing

nothing but cannot discriminate this effect from placebo or other nonspecific treatment effects. For the purposes of this discussion, results from experiments using this design are of little value.

The second and most desirable trial design allows examination of what I call the strong hypothesis of acupuncture. The strong hypothesis states that acupuncture combined with TCM is superior to a comparable treatment modality in which a putatively ineffective procedure has been substituted for acupuncture. Few if any experimental designs have utilized this paradigm (13). The strong hypothesis is difficult to assess directly in the context of Western experimental design requirements. Here, I consider a test of the strong hypothesis an experiment hypothesizing that acupuncture at particular sites along particular classical meridians will be more effective for treating a specific syndrome than the same manipulation at putatively ineffective sites on the same meridian, on another meridian, or at a site not on a meridian.

A third design compares acupuncture to some commonly used, standard biomedical treatment. It is assumed that this standard treatment has been shown to be efficacious (i.e. to have a greater effect than placebo), but this is quite often not the case (11). If acupuncture treatment produces effects equal to or greater than those of the standard treatment, this third type of trial can, at best, shed light on what I call the weak hypothesis of acupuncture. This hypothesis is that acupuncture produces effects that are greater than those resulting from placebo manipulation. Support for the weak hypothesis does not require that theoretically correct acupuncture points be shown to have greater effects than theoretically incorrect control points. It only requires that acupuncture at theoretically correct acupuncture points have effects greater than placebo. This design is of value for our current purposes only when the standard treatment has been shown to be efficacious, or, preferably, when a placebo control group is included in the study.

There are several variants of a fourth design in which acupuncture is compared to various placebo or sham manipulations that test only the weak hypothesis. One common variant utilizes a placebo manipulation applied at the same point as the hypothesized effective manipulation. The placebo manipulation can be tapping of a blunt needle or application of inactive transcutaneous electrical nerve stimulation (TENS) electrodes. In another common variant of this type of trial, the placebo manipulation is a sham manipulation at the same point as active manipulation. That is, the needle is inserted but not manually rotated or electrically stimulated. These designs offer an advantage over standard treatment controls by including a placebo or sham manipulation. Thus, no assumptions need to be made about the efficacy of a standard control treatment arm.

## Evidence Supporting Efficacy of Acupuncture

In this section, I selectively examine the evidence for the clinical efficacy of acupuncture. I focus on those conditions for which the NIHCDP (5) concluded that there was scientific evidence that acupuncture treatment was effective or

“may be useful.” I believe the NIHCDP succeeded in selecting those areas of clinical acupuncture research in which the most interpretable clinical trials have been conducted.

The best support for the strong hypothesis of acupuncture comes from studies of acupuncture’s effects on nausea and vomiting. These data are examined first. Second, since a high percentage of the clinical data on acupuncture effects is related to treatment of pain (14) and the NIHCDP Consensus Statement (9) found acupuncture efficacious in treating postoperative dental pain, I review the evidence for this application. Finally, I examine the data on the several other conditions for which the NIHCDP concluded that acupuncture “may be useful.”

***Acupuncture Treatment of Nausea and Vomiting*** As quoted above, the NIHCDP concluded that there are results showing efficacy of acupuncture in adult postoperative and chemotherapy-induced nausea and vomiting. The abstracts of the conference contain little with which to evaluate the data on which this conclusion is based (5). The abstract on acupuncture treatment of nausea and vomiting for the NIHCDP Consensus Statement was authored by Parfitt (15). Parfitt also authored a recent review of the topic (16) derived from the FDA Workshop on Acupuncture mentioned above. It is likely that this review includes most, if not all, of the data considered by the NIHCDP. This section summarizes Parfitt’s review of the effects of acupuncture on perioperative and chemotherapy-induced nausea and vomiting.

Parfitt reviewed 12 studies on the effect of acupuncture on nausea and vomiting. Nine of these examined the effect of acupuncture on perioperative nausea and vomiting. Of these 9 trials, 5 reported results favoring acupuncture over various control manipulations (17–20), and 4 found no advantage of acupuncture treatment over control treatment (21–24). It should be noted that all but one of the studies reporting a reduction in nausea and/or vomiting emanated from one laboratory (Dundee’s). The design of these four trials (17–19) is quite varied because they represent a progressive refinement of the explicit hypotheses tested. The designs range from a preliminary open trial (17) to a complex, well-designed, sham-acupuncture controlled trial comparing standard antiemetic treatment with various forms of acupuncture (manual, electroacupuncture, acupressure) at the Pericardium 6 (P6) acupuncture point (19). The effects observed were large and statistically very reliable. Importantly, in the sham controlled trials, acupuncture at a nearby putatively inactive site was no more effective than no treatment, providing evidence for the strong hypothesis.

Of the 4 negative trials of acupuncture on perioperative nausea and vomiting, 3 (21–23) can probably be explained by the fact that acupuncture was administered while the patient was under general anesthetic. Dundee has criticized this design by providing evidence that acupuncture is much less effective when given under anesthesia (25). The fourth negative trial (24) is more difficult to reconcile with positive studies, but the negative results may be due to one or more of the many variables that differed between this study and the positive trials discussed

above (e.g. the intensity of the emetic effect elicited by the different surgical procedures or the type of acupuncture administered).

These studies allow several conclusions about acupuncture effects on perioperative nausea and vomiting. The number of independent trials is small, but several of them are of very high quality. Many of the positive trials come from one group, but the effect observed is large and reproducible. The negative evidence is less convincing, since 3 of the 4 negative trials can be discounted on experimental grounds. Additional trials by other groups are desirable, but Dundee's group has provided reasonably convincing evidence of acupuncture's effectiveness for the treatment of perioperative nausea and vomiting. Furthermore, they provide evidence supporting the strong hypothesis of acupuncture, in that acupuncture at a specific point, P6, is more effective than at a nearby putatively inactive control point.

Parfitt (16) also reviewed three other studies that examined the effect of P6 acupuncture on nausea and vomiting induced by chemotherapeutic agents in patients being treated for various carcinomas. In the most convincing of these studies, acupuncture at a nearby non-acupuncture point was used as a control in a crossover design (26). P6 acupuncture plus antiemetic medication produced greater antiemetic effects than antiemetic medication alone or antiemetic medication plus sham acupuncture. Because P6 acupuncture was shown to be effective in this trial, subsequent trials, for ethical reasons, could not utilize sham points. Nevertheless, Dundee's group went on to show very large and probably clinically important antiemetic effects of P6 acupuncture in large groups of patients (26). Similarly impressive results have been reported by another group (27). Thus, like the studies examining perioperative antiemesis, these studies provide support for the strong hypothesis of acupuncture analgesia.

Following Parfitt's review (16), a few studies have been published that support the above conclusions. Three additional studies of postoperative nausea and vomiting were reported. One of these (28) studied laser stimulation of P6 versus sham stimulation and found that the P6 group had a large reduction in postoperative vomiting. Two other studies (29, 30), however, failed to find any effect of P6 stimulation on postoperative nausea and/or vomiting. One of these studies (30) has been criticized on statistical grounds (31), but the authors provided a reasonable rebuttal to at least some of the criticism (32). Two additional studies showed that P6 stimulation with either an acupressure band (33) or acupressure (34) was highly effective in reducing nausea and/or vomiting from motion sickness. Overall, these studies support and expand the conclusion that specific site (P6) stimulation can provide a statistically reliable and clinically significant reduction of nausea and vomiting resulting from various causes.

***Acupuncture Effects on Pain*** Many studies have examined the effect of acupuncture on pain. This is not surprising for several reasons. First, TCM has commonly treated pain. Second, for over 20 years there has been convincing scientific evidence of an endorphinergic basis for acupuncture-induced decreases in at least

experimental pain in humans (35, 36). Third, whereas relatively small populations are affected by nausea and vomiting, the epidemiology of pain is dramatic and costly; over 10% of the population of the United States is affected for periods of more than three months in a given year (37). Finally, the chronic nature of pain syndromes and the difficulty in treating them invite the inclusion of any additional safe and effective treatments in the health care professional's armamentarium.

The NIHCDP Consensus Statement (9) concluded that there is evidence "showing efficacy of acupuncture . . . in postoperative dental pain" (5). This is as strong an endorsement as the Consensus Statement makes for the treatment of any condition. In addition, the Statement concluded that there are other pain syndromes, "such as . . . headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome . . . in which acupuncture may be useful" (9). In some cases, the NIHCDP Program and Abstracts indicate how these conclusions were reached (37, 38), but in other cases this is not so apparent. In this section, I review the available data on the treatment of various pain syndromes for which the NIHCDP Consensus Statement concluded that acupuncture was either effective or possibly effective. Where possible, I rely on the data within the NIH Consensus Abstracts (5), but where these are insufficiently detailed, I rely on other sources.

*Postoperative Dental Pain* This section summarizes Lao's review in the NIH Consensus Abstracts (38) of the evidence supporting the efficacy of acupuncture for postoperative dental pain. Lao reviewed three studies of postoperative dental pain (39, 40, 41). The first of these "indicated that acupuncture in combination with pain medication may be more effective than acupuncture, medication, or a placebo." This was indeed the case for 3 of the 6 consecutive 30-minute intervals for which measurements were taken, but for one of the other 3 points the opposite was true, and there was no difference between the groups for the other 2 measurements (39). At best, this study demonstrates that acupuncture is better than placebo for postoperative dental pain.

The second study (40) reviewed by Lao clearly found no effect whatsoever of acupuncture on postoperative dental pain. The discrepancy between the findings of the two studies is not surprising; they are not really comparable, since the first one measured pain over 3 hours and the second over 10 days. Lao noted that in the second study, a significant reduction in pain and medication consumption was observed over the 10-day follow-up period. Examination of the study reveals, however, that this reduction simply reflected the natural history of postoperative dental pain and did not differ among the treatment groups. This study provides little information about the usefulness of acupuncture for reducing postoperative dental pain.

In the third study (41), done by Lao's own group, 19 subjects received either acupuncture or placebo acupuncture with no needle insertion. Because this control procedure is likely to provide only a weak placebo effect and because of the single blind nature of the study, in my opinion, this study can provide only weak

support for the contention that acupuncture is useful for postoperative dental pain. Taken together, the evidence provided by Lao makes a weak case for the efficacy of acupuncture in treating postoperative dental pain. It seems more appropriate to conclude that these studies provide some data suggesting that acupuncture may be useful for the reduction of postoperative dental pain.

*Other Pain Conditions* The NIHCDP concluded that acupuncture “may be useful” in several other pain syndromes, including headache, menstrual cramps, tennis elbow, fibromyalgia, low back pain, and carpal tunnel syndrome. Headache and low back pain are the two categories for which most data exist.

In the NIHCDP Program and Abstracts, Birch (37) reviewed the studies examining the effect of acupuncture on headache. Although the studies are heterogeneous in experimental design and type of headache examined (e.g. tension, migraine, etc), Birch classified 16 studies into three design types: those using sham or placebo controls (9 studies), those using biomedical treatment or no-treatment controls (5 studies), and those with more complex designs (2 studies). Of six studies using a sham needle control, two reasonably well-designed studies found acupuncture more effective than sham needles in reducing self-reported pain (42, 43), and one of these two found a reduction in medication usage (43). Curiously, none of the 3 studies using placebo controls found acupuncture more effective than placebo. Birch pointed out that 8 of the 9 studies using sham or placebo controls found the acupuncture treatment more effective than the control treatment, but this effect reached statistical significance in only 3 of the studies. In addition, all 5 studies using biomedical or no-treatment controls found acupuncture about equal in efficacy to standard treatment. Taken together, studies on the effect of acupuncture on headache suggest that it may prove useful, but a definitive conclusion, particularly with regard to the strong hypothesis, awaits the results of experiments designed with more specific hypotheses and larger sample sizes.

The NIHCDP Consensus Statement provides little detail concerning how the NIHCDP derived their conclusions about the effects of acupuncture treatment on low back pain. Fortunately, Berman, the author of the NIHCDP overview of clinical trials on acupuncture treatment for pain (44), was a coauthor of a citizens’ petition filed with the FDA in connection with the FDA Workshop on Acupuncture. Portions of this petition were recently published (12) and provide a detailed summary of the important literature on the effects of acupuncture on low back pain. This summary (12) reviews acupuncture’s effects on almost all of the same syndromes for which the NIHCDP concluded acupuncture may be useful in treating pain. Indeed, it seems possible that the NIHCDP’s conclusions about the effects of acupuncture on pain are largely based on this paper.

Birch et al (12) reviewed 10 studies on low back pain. The studies were of widely varying quality and heterogeneous design but could be divided into five categories. Acupuncture was compared to TNS (3 studies), a wait-list control (1 study), standard treatment (1 study), placebo treatment (2 studies), and putatively

inactive acupuncture points (3 studies). Overall, 3 of the 10 studies provided statistically significant data favoring acupuncture and 7 studies were negative.

Of the three studies showing a statistical advantage of acupuncture over control treatments, one used a wait-list control, one a placebo control, and one a standard-treatment control. Taken together, these studies provide little indication that acupuncture is superior to any treatment other than placebo. Even the study using a standard-treatment control did not use an additional placebo control for comparison, so it is possible that the standard treatment in that study was acting as a placebo.

Three studies utilized a TNS control group. None reported any positive advantage of acupuncture, although all reported statistically insignificant trends favoring the acupuncture groups. This is not surprising in that TNS is generally considered a useful treatment for pain and may activate the same or overlapping pain modulation systems as does acupuncture (45). Comparing acupuncture to another effective treatment presents difficulties in achieving statistically reliable differences unless sample sizes are very large (46).

All three trials comparing acupuncture to putatively inactive acupuncture points, which might be considered tests of the strong hypothesis, were negative. Birch et al (12) critiqued each of these three studies as well as the other seven studies discussed. Although each of the negative tests of the strong hypothesis is flawed in some way, they seem, overall, no more flawed than the positive studies. Taken together, these studies on the effect of acupuncture on low back pain support the weak hypothesis but not the strong hypothesis. That is, there is some evidence that acupuncture is more effective than placebo for the treatment of low back pain but no evidence to support the explicit theoretical basis of acupuncture. In addition, there is only suggestive evidence that acupuncture is better than generalized treatments such as TNS. In fact, as has been pointed out in one of the studies of acupuncture versus TNS (47), there are reasons to prefer TNS to acupuncture if both treatments are equally effective. Overall, the conclusion of the NIHCDP that acupuncture "may be useful" for low back pain appears somewhat misleading. It has not yet been demonstrated that acupuncture is superior to equally safe procedures that are simpler, less invasive, and easier to repeat in a clinical setting, such as TNS.

Other pain conditions (menstrual cramps, tennis elbow, and fibromyalgia) for which the NIHCDP concluded that acupuncture may be useful were also reviewed (12). Only a few studies, of varying quality and design, were available for analysis. Results supporting the weak hypothesis but not the strong hypothesis of acupuncture were obtained for menstrual cramps (1 study), tennis elbow (2 studies), and fibromyalgia (1 study). Although these studies are encouraging, such small numbers should be interpreted cautiously before acupuncture is used for the nonexperimental treatment of such conditions.

The NIHCDP also concluded that acupuncture may be effective for pain from carpal tunnel syndrome. Naeser reviewed four studies on this condition in the NIHCDP Program and Abstracts (48). Two of these studies were uncontrolled

trials (49, 50). A third study by Naeser's own group (51), although difficult to interpret because it was published only in abstract form, appears to have been a well-designed test of laser acupuncture with encouraging results. A fourth study, also conducted by Naeser's group, which was not published at the time of the NIHCDP meeting, has subsequently been published (52). This study was an open-treatment protocol study of laser acupuncture and microamps TNS and secondarily of other alternative therapies. Because of its confounded design, this study is also difficult to interpret. Overall, except with the loosest interpretation, these four studies lend little support to the NIHCDP's conclusion that acupuncture may be effective for the treatment of carpal tunnel syndrome.

***Acupuncture Treatment of Other Conditions*** The NIHCDP concluded that acupuncture may be useful for addiction, stroke rehabilitation, and asthma. The NIHCDP Program and Abstracts (5) contains reviews of addiction and stroke rehabilitation (discussed below), but it does not mention studies on the effects of acupuncture on asthma, making it impossible to know how the NIHCDP concluded that acupuncture may be useful for this condition. Kleijnen et al (53) reviewed studies investigating the use of acupuncture for asthma and concluded that "claims that acupuncture is effective in the treatment of asthma are not based on the results of well performed clinical trials."

***Addiction*** The effect of acupuncture on treating various addictions has been a popular area of study because of the association of acupuncture with modulation of endogenous opioid systems (45). In spite of this compelling rationale, often absent in other areas of research on the clinical utility of acupuncture, research in this area has been controversial and, with some exceptions, generally negative.

Konefal (54) reviewed the effects of acupuncture on addiction to alcohol, cocaine, and cigarette smoking in the NIHCDP Program and Abstracts. This report is less systematic than other reviews of the field (55, 56, 57, 58) discussed below. Konefal mentions two acceptable positive studies and one acceptable negative study on treatment of alcohol addiction. With regard to treatment of cocaine addiction, she notes one "pilot" study with mixed results and her own study with positive results. Concerning treatment of cigarette smoking, she mentions seven studies characterized by "emotional tone," with no further details, and one positive study. Based on Konefal's report, the NIHCDP's conclusion that acupuncture may be useful for addiction seems somewhat misleading.

Other reviews of the use of acupuncture for addiction treatment have drawn varying conclusions from essentially the same literature. Culliton & Kiresuk (56), in a publication emanating from the FDA Workshop on Acupuncture, concluded that the results of the addiction studies were inconclusive because of methodological inadequacies. McLellan et al (57) reviewed the outcome of a 1991 National Institute on Drug Abuse Technical Review of acupuncture in the treatment of drug dependence. They concluded that there is no compelling evidence for the efficacy of acupuncture in the management of either opiate or cocaine

addiction. The authors believed that the work of Bullock (59) in the field of alcohol dependence represented the only methodologically sound study indicating that acupuncture is efficacious for any dependence disorder. They suggested that even this study needs to be repeated.

Ter Riet et al (58) conducted a meta-analysis of 22 controlled clinical studies assessing the effects of acupuncture on cigarette smoking, heroin, and alcohol addiction. They found the study designs “generally poor” and concluded that “claims that acupuncture is efficacious as a therapy for these addictions are thus not supported by results from sound clinical research.” Brewington et al (55) came to the more positive conclusion that controlled studies generally indicate that acupuncture can help active drug and alcohol users become abstinent. It is difficult to understand how Brewington et al reached this conclusion, however, since their review found positive results for only 1 of 5 opiate addiction studies, 2 of 2 alcohol addiction studies, and 1 of 8 smoking addiction studies, as well as mixed results in one cocaine study.

In conclusion, it appears that after over 25 years of research on the efficacy of acupuncture treatment for addiction, there are only two studies—both on alcohol addiction and both conducted by Bullock et al (59, 60)—that are generally considered positive, and some authors maintain that even these studies have failed to be replicated (57). Therefore, the NIHCDP’s conclusion that acupuncture may be useful for addiction appears to be misleading.

*Stroke rehabilitation* Naeser reviewed 10 studies on the effect of acupuncture on paralysis resulting from stroke (48). The studies are of heterogeneous design but can be divided into three categories: comparison to an inactive acupuncture point (1 study), comparison to a standard treatment (7 studies), and no control group (2 studies). The studies without any control group are of little value for our purposes here. None of the 7 studies comparing acupuncture to a standard treatment used an additional placebo control group, making it difficult to determine whether the standard treatment produced any more than a placebo effect. Nevertheless, although the quality of these studies was often poor, acupuncture in addition to the standard treatment was always better than the standard treatment alone. Thus, it can be concluded at least that acupuncture is probably better than placebo in improving paralysis resulting from stroke.

In addition, Naeser reported the results of a controlled trial conducted in her own laboratory (61), which used a sham acupuncture control group. The outcome of this trial is somewhat complicated by including as a variable the amount of damage to motor pathways as determined by a CT scan, but the results do indicate that real acupuncture is superior to sham acupuncture in patients who show damage in less than half of the motor pathway. This result implies that acupuncture may be a promising treatment for paralysis resulting from stroke, but this conclusion awaits the results of more carefully controlled clinical trials.

## CONCLUSIONS

This review has examined the scientific data on 14 conditions for which the NIHCDP concluded that acupuncture treatment was either effective (2 conditions) or “may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program” (12 conditions). Although it is sometimes difficult to know what is meant by phrases such as “may be useful,” the data reviewed here partially support the conclusions of the NIHCDP. It appears reasonable to conclude that acupuncture is effective for the treatment of one condition (postoperative and chemotherapy-induced nausea and vomiting), and some data indicate that acupuncture may be useful for the treatment of 4 of the 12 conditions given a less enthusiastic recommendation by the NIHCDP (headache, low back pain, alcohol dependence, and paralysis resulting from stroke). On the other hand, examination of the scientific data indicates that some conclusions of the NIHCDP are either misleading (i.e. the conclusions regarding postoperative dental pain, carpal tunnel syndrome, asthma, opiate dependence, cocaine dependence, cigarette dependence), difficult to interpret (low back pain), or supported by data insufficient to indicate other than experimental use (menstrual cramps, tennis elbow, fibromyalgia). The NIHCDP may have had access to information other than that in its report, but examination of the literature published before and after the report suggests that this generally was not the case.

The available data on acupuncture treatment of medical conditions, with the exception of treatment for postoperative and chemotherapy-induced nausea and vomiting, do not provide any compelling support for the strong hypothesis of acupuncture. Some evidence supporting the weak hypothesis is available for the treatment of headache, low back pain, alcohol dependence, and paralysis resulting from stroke.

Definitive conclusions regarding even these latter outcomes should be interpreted with caution. It is sometimes unclear whether acupuncture is better than similar but more easily controlled treatments, such as TNS for headache. For alcohol dependence, only a small number of well-designed but conflicting trials have been conducted. For paralysis resulting from stroke, there is an absence of data from truly double-blind sham-controlled trials.

However, there is little evidence that acupuncture is ineffective in treating most of these conditions. The absence of evidence is not evidence of its absence. Workers in the field should be encouraged to design truly double-blind, sham-controlled trials using adequate acupuncture treatment. It should be clear whether the strong or weak hypothesis of acupuncture is being tested, and sample sizes should be adequate to allow both positive and negative conclusions. Without such evidence, it seems unlikely that mainstream Western medicine will enthusiastically accept acupuncture as a viable treatment modality.

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## CONTENTS

Inferior Vena Cava Interruption: How and When?, <i>Philippe Girard, Bernard Tardy, Hervé Decousus</i>	1
Ductal Carcinoma In Situ of the Breast, <i>Melvin J. Silverstein</i>	17
Gene Therapy for Adenosine Deaminase Deficiency, <i>Robertson Parkman, Kenneth Weinberg, Gay Crooks, Jan Nolta, Neena Kapoor, Donald Kohn</i>	33
Acupuncture: An Evidence-Based Review of the Clinical Literature, <i>David J. Mayer</i>	49
Role of Telomerase in Cell Senescence and Oncogenesis, <i>Virginia Urquidi, David Tarin, Steve Goodison</i>	65
Coronary Artery Disease in the Transplanted Heart, <i>M. Weis, W. von Scheidt</i>	81
Measures of Success and Health-Related Quality of Life in Lower-Extremity Vascular Surgery, <i>Joe Feinglass, Mark Morasch, Walter J. McCarthy</i>	101
New Horizons in the Treatment of Autoimmune Diseases: Immunoablation and Stem Cell Transplantation, <i>Alberto M. Marmont</i>	115
The Surgical Treatment of Parkinson's Disease, <i>Kenneth A. Follett</i>	135
Atherogenic Lipids and Endothelial Dysfunction: Mechanisms in the Genesis of Ischemic Syndromes, <i>Mark R. Adams, Scott Kinlay, Gavin J. Blake, James L. Orford, Peter Ganz, Andrew P. Selwyn</i>	149
Management of Patients with Hereditary Hypercoagulable Disorders, <i>C. Kearon, M. Crowther, J. Hirsh</i>	169
Neurocysticercosis: Updates on Epidemiology, Pathogenesis, Diagnosis, and Management, <i>A. Clinton White Jr.</i>	187
Anti-Cytokine Therapy for Rheumatoid Arthritis, <i>R. N. Maini, P. C. Taylor</i>	207
Artificial Skin, <i>J. T. Schulz III, R. G. Tompkins, J. F. Burke</i>	231
Age-Associated Increased Interleukin-6 Gene Expression, Late-Life Diseases, and Frailty, <i>William B. Ershler, Evan T. Keller</i>	245
Streptococcal Toxic Shock Syndrome Associated with Necrotizing Fasciitis, <i>Dennis L. Stevens</i>	271
Role of Cytokines in the Pathogenesis of Inflammatory Bowel Disease, <i>Konstantinos A. Papadakis, Stephan R. Targan</i>	289
Anorexia and Bulimia Nervosa, <i>W. H. Kaye, K. L. Klump, G. K. W. Frank, M. Strober</i>	299
The Role of Protein Traffic in the Progression of Renal Diseases, <i>Piero Ruggenenti, Giuseppe Remuzzi</i>	315
Carotid Artery Dissection, <i>C. Stapf, M. S. V. Elkind, J. P. Mohr</i>	329
Bacterial Vaginosis, <i>Jack D. Sobel</i>	349
Current Concepts in Cobalamin Deficiency, <i>Ralph Carmel</i>	357
Adjuvant Therapy for Breast Cancer, <i>G. Hortobagyi</i>	377
Kidney Transplantation from Living Unrelated Donors, <i>J. Michael Cecka</i>	393
Global Epidemiology of Influenza: Past and Present, <i>N. J. Cox, K. Subbarao</i>	407
The Spectrum of Human Herpesvirus 6 Infection: From Roseola Infantum to Adult Disease, <i>Mark Young Stoeckle</i>	423

Catheter Ablation for Atrial Fibrillation, <i>Pierre Jaïs, Dipen C. Shah, Michel Haïssaguerre, Meleze Hocini, Jing Tian Peng, Jacques Clémenty</i>	431
Genetic Disorders Affecting Proteins of Iron Metabolism: Clinical Implications, <i>Sujit Sheth, Gary M. Brittenham</i>	443
Genetics of Psychiatric Disease, <i>Wade H. Berrettini</i>	465
The Marfan Syndrome, <i>Reed E. Pyeritz</i>	481
Nonsteroidal Anti-Inflammatory Drugs and Cancer Prevention, <i>John A. Baron, Robert S. Sandler</i>	511
Lymphatic Mapping and Sentinel Lymph Node Biopsy in Patients with Breast Cancer, <i>Charles E. Cox, Siddharth S. Bass, Christa R. McCann, Ni Ni K. Ku, Claudia Berman, Kara Durand, Monica Bolano, Jessica Wang, Eric Peltz, Sarah Cox, Christopher Salud, Douglas S. Reintgen, Gary H. Lyman</i>	525
The Genetics of the Amyloidoses, <i>Joel N. Buxbaum, Clement E. Tagoe</i>	543