editorial

Acupuncture for Blood Pressure Lowering
Needling the Truth

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Blood pressure–related disease remains a major public health problem in developed and developing countries alike. The Global Burden of Disease study estimates 62% of stroke, 49% of ischemic heart disease, and 14% of other cardiovascular disease can be attributable to mean systolic blood pressure levels $>$115 mm Hg worldwide.1 The mainstay of medical management of hypertension is a number of commonly used drugs,2 the mechanisms of action of which are well understood and grounded in conventional science. However, despite the strength of evidence supporting the efficacy of these agents and their wide endorsement in national and international guidelines, only about one half of those patients in whom treatment is indicated are compliant with drug therapy. Treatment cost, adverse effects, and complexity are commonly cited barriers to patient adherence,3,4 and such factors undoubtedly play an important role in the growing interest in alternative therapies for blood pressure control.

Acupuncture, one of the oldest and most commonly used forms of alternative medicine, has existed for 2500 years. In traditional acupuncture, fine needles are inserted into precisely defined specific points on the body, each of which has distinct therapeutic actions.3 For a long time, acupuncture was viewed by practitioners of Western medicine as “the Chinese equivalent of voodoo,”5 but certain events encouraged wider acceptance of this form of treatment beginning in the 1970s. One such event is said to have been President Richard Nixon’s goodwill visit to China in 1972 during which he saw acupuncture in practice. His personal physician subsequently wrote, “I have seen acupuncture work.” This statement not only increased public interest but also encouraged key figures in the medical community to travel to China to develop a better understanding of the therapy. Since that time, alternative medicine use, including acupuncture, has increased substantially in the United States and other countries. Findings from a US national survey suggest a 50% increase in visits to alternative medical practitioners between 1990 and 1997 (attributable to an increased number of individuals seeking such treatment rather than to an increase in the number of visits per person), exceeding total visits to all US primary care physicians. In 1997, 629 million visits to alternative therapists were estimated to cost US $21.2 billion.6 The number of practicing acupuncturists in the United States (about one third of whom also have conventional medical degrees) is also increasing, with the current number of registered practitioners ($\approx$11 000) projected to quadruple by 2015.6

Despite their wide use, demonstration of the safety and efficacy of alternative therapies, including acupuncture, has lagged behind that of orthodox therapies. Advocates have argued that alternative therapies cannot be subject to the same level of rigorous testing, and in many instances, case reports and other less robust forms of evidence have justified their ongoing use. Randomized trials of acupuncture have been conducted since the 1970s, but it was not until 1995 that the World Health Organization published clear guidelines for clinical research on acupuncture, including detailed information relating to the nature of control groups and blinding in randomized controlled trials.8 More recently, a National Institutes of Health Consensus Development Panel reiterated that acceptance of acupuncture as a reliable therapeutic choice would depend on its evaluation using study designs that could withstand careful scientific scrutiny.9

There have been very few data from controlled studies evaluating the efficacy of acupuncture for blood pressure lowering. The largest randomized controlled trial published to date is the Stop Hypertension With Acupuncture Research Program (SHARP).10 In this trial comparing individualized (and standard) Chinese acupuncture with a sham procedure, blood pressure declined in each group between randomization and the 10-week follow-up, but the differences in achieved blood pressure reduction between groups were not significant. Thus, the authors concluded that there was no evidence of benefit of acupuncture for blood pressure lowering. In this issue of Circulation, Flachskampf et al11 report the results of another clinical trial of acupuncture to lower blood pressure with results very different from those of SHARP.

Flachskampf et al report a single-institution, single-blind randomized controlled trial of 160 adult patients with grade 1 or 2 hypertension on stable blood pressure–lowering therapy or no therapy. Over a 6-week period involving a total of 22 treatment sessions, blood pressure–specific acupuncture was administered to intervention group subjects and sham acupuncture to control group subjects by Chinese physicians trained and accredited in Chinese traditional medicine. The authors report that the change in 24-hour ambulatory systolic blood pressure between baseline and 6 weeks (primary outcome) was significantly greater (−6 mm Hg) in the intervention group compared with the control group (1 mm Hg), although blood pressure in both groups returned to pretreatment levels within 12 weeks of treatment cessation. The authors conclude that acupuncture may offer an alternative antihypertensive therapeutic option especially in patients...
who want to avoid drug therapy or are attracted to the spiritual foundations of such a therapy.

So, given the other currently available evidence, should we consider acupuncture an effective clinical tool for the management of hypertension? There are issues relating to trial methodology such as administration of a suitable control therapy and assessor blinding that are particularly challenging in conducting trials of acupuncture and should be considered when the findings of such studies are interpreted. Any control regimen should ideally be inert, identical in appearance and sensation, and without nonspecific physiological effects. Although most acupuncture trials now use a “sham” control technique involving the insertion of the same number of needles at a similar depth but at different locations, the validity of sham acupuncture is still debated.12 In painful conditions, sham acupuncture appears to have an analgesic effect in ≈40% to 50% of patients, and even in nonpainful conditions, needling at other trigger points may produce physiological changes of uncertain impact.12 In the Flachs-kampf et al study, the physiological effects of the sham procedure may be of particular relevance in the interpretation of results. While not reaching conventional levels of statistical significance in this small group of participants, the mean 24-hour systolic and diastolic blood pressures were higher at 6 weeks compared with baseline in the sham acupuncture group. Indeed, one might expect a lower mean blood pressure following up-in the absence of any treatment because of regression to the mean13,14; this raises the possibility that the control procedure used in this trial may have a significant effect in increasing blood pressure levels.

Conducting a double-blind trial of acupuncture is also problematic. Although patients were blinded to their treatment assignment in the trial by Flachs-kampf et al, the administering physicians were not. However, the authors emphasize that communication between physician and patient was constrained by language barriers, which may have overcome any potential bias attributable to physician expectations. Perhaps more important is whether outcome assessors (ie, those measuring blood pressure) were blinded to patient treatment allocation, and this is not made clear in the article. In SHARP, diagnosing acupuncturists (also assessing outcomes) were blinded to treatment assignment, whereas treating acupuncturists were blinded to blood pressure measurement.15 Such role separation probably represents the ideal in acupuncture trials.

Clinical trials of acupuncture often are small because of logistical and cost constraints, limiting their ability to provide precise estimates of treatment effects. Only 160 participants were randomized in the study described by Flachs-kampf et al, and a large proportion (≈12%) was excluded from the primary analysis because of the absence of postintervention outcome data. Given the possibility of unbalanced randomization resulting from the small numbers (the summary of baseline characteristics suggests the possibility of such imbalance), proportionately large postrandomization exclusions further raise the possibility that confounding may be an important potential bias in this study.

Even if proved an effective blood pressure–lowering therapy, it seems unlikely that acupuncture can make an important contribution toward reducing the substantive disease burden because of nonoptimal blood pressure levels worldwide. In the event that patients are sufficiently motivated to undergo multiple weekly sessions of acupuncture, treatment adherence is still likely to be significantly constrained by access to appropriately trained providers and cost, especially because payment for acupuncture services is mostly out of pocket. At best, acupuncture might be considered an occasional useful adjunct to preventive lifestyle strategies and appropriately targeted drug therapy. However, even for such a recommendation, more evidence with due consideration to methodological issues is required, especially in light of the conflicting results from recent randomized controlled trials.

Disclosures

None.

References

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