ACADEMIC EXPLORATION

Recent Clinical Trials of Acupuncture in the West: Responses from the Practitioners

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ABSTRACT In the West, hundreds of randomized controlled trials (RCTs) have been performed testing acupuncture. They include two types: those that compare acupuncture to other therapies, usual care or no treatment (pragmatic trials), and those that have placebo controls (efficacy trials). Acupuncture has generally performed well against other therapies or no treatment, but until recently, the evidence from placebo controlled trials has been considered equivocal or contradictory. A recent series of large RCTs, mostly performed in Germany and also in the US have included both pragmatic and placebo comparisons. The evidence poises a conundrum for the profession of acupuncture. This essay first describes the two types of RCTs used to examine acupuncture and examine the results of two recent large RCTs for chronic low back pain as representative examples of recent large studies. The essay then presents the most common Euro-American acupuncture professions’ interpretation of these results. Western responses have included: (1) methodological weaknesses; (2) inappropriateness of placebo controls; (3) questions as to whether acupuncture placebo controls are “inert”; (4) rejection of evidence-based medicine epistemology; (5) discrepancy between acupuncture performed in RCTs with real world acupuncture; (6) enhanced placebo effects of acupuncture; and (7) needs to re-evaluate acupuncture theory. The authors do not necessarily agree with all of these responses; they are presented in an attempt to foster critical discussion. The paper also looks at recent neuroimaging experiments on acupuncture that may point to some worthwhile new avenues of investigation. Finally, the Euro-American health care policy consequences of these recent RCTs are discussed.

KEYWORDS acupuncture, sham acupuncture, low back pain, randomized controlled trials, acupuncture neuroimaging

Traditional acupuncture is based in the interpretation of classical texts, the accumulated clinical practice of thousands of years health care, mentorship from revered older teachers, and individual practitioner's clinical practice. In recent years, the profession of Chinese medicine (CM) has embraced the methods of biomedicine including the importance of evidence from randomized controlled trial (RCT). In the West, hundreds of RCTs have been performed evaluating the efficacy of acupuncture. Integrating the findings into a traditional acupuncture framework has been difficult. This essay reviews the two basic types of RCTs (pragmatic and efficacy) and focuses on two large RCTs of acupuncture for chronic low back pain as representative examples of the recent conundrum posed by recent acupuncture trials in the West. The article then reviews the main responses that have come forth from the Western profession of CM. Recent neuroimaging experiments on acupuncture and placebo acupuncture that point to new approaches are described. Finally, some of the health policy consequences of the recent RCTs in the West are presented.

Two Types of Randomized Controlled Trials

RCTs come in two broad categories: pragmatic (also known as effectiveness or comparative effectivity) and efficacy (also known as fastidious or explanatory) trials¹. Pragmatic trials...
compare two treatments under conditions in which they would be applied in routine care. They are not concerned with mechanism and explanation. The question is which works better? Placebo controls are not consequential. Generally, the research is carried out in normal or optimal environments with an emphasis on acquiring information necessary for making a clinical decision\(^2\). Recently, complementary and alternative medicine (CAM) or integrative investigators, among others, have labeled this method as "whole system" research\(^3,4\). In contradistinction, the efficacy approach asks is it better than placebo? It seeks to understand whether a treatment has effects beyond the context or ritual of the treatment. It is less concerned with clinical outcomes and privileges of causal pathways. Distinguishing whether the treatment has a "specific" impact on disease, as opposed to "mere" nonspecific effects, is the key issue. Placebos are the defining characteristic of such studies. The efficacy approach usually treats "nonspecific" as inconsequential or unnecessary noise in the experiment\(^5\). Western regulatory requirements for obtaining FDA labeling and scientific prestige reinforce the status and importance of such studies. The two types of RCTs manage to coexist although they embody implicit criticism of one another. Efficacy trials question the rigor of the science in pragmatic studies, while the pragmatic approach (even for pharmaceutical trials) implicitly raises questions about untested assumptions that "specific" and "nonspecific" effects are separable, noninteractive, stable, linear, and relatively constant during the duration of the trial\(^6\).

**Results of the Latest Randomized Controlled Trials for Chronic Low Back Pain**

In the last 20 years, there have been hundreds of both pragmatic and efficacy RCTs for acupuncture\(^7\). The results, with some notably exceptions like acupuncture for nausea and vomiting, have been inconsistent or contradictory\(^8\). More recently, there have been attempts to provide more definitive evidences with large RCTs. Especially noteworthy are two trials for chronic low back pain (cLBP): one initiated by the German government and funded by statutory health insurance grants for the purpose of determining reimbursement policy for acupuncture, and a recent NIH-funded trial performed by Seattle Group Health. What is remarkable about these two experiments is that they addressed a pragmatic question and an efficacy question simultaneously. Both trials included the pragmatic comparison, "how does acupuncture treatment compare to optimal or usual mainstream care?" and the efficacy test, "is verum (genuine) acupuncture superior to a dummy control?"

The German trial randomized 1 162 patient with cLBP to three arms: (1) 10 verum acupuncture treatments according to the principles of CM over five weeks; (2) 10 sham (placebo) acupuncture treatments consisting of superficial needling at nonacupuncture points over five weeks; or (3) optimal usual care consisting of a combination of drugs, physical therapy, and exercise that included 10 contact visits with mainstream providers\(^9\). If patients had a partial response to acupuncture or sham acupuncture, they could elect to have five additional sessions. The comparison of verum acupuncture (arm 1) and optimal mainstream care (arm 3) answered the practical clinical question, while contrasting verum acupuncture (arm 1) and sham acupuncture (arm 2) addressed efficacy beyond placebo. At six months after randomization, the primary endpoint, acupuncture was almost twice as effective as optimal mainstream care (47.6% versus 27.4%, \(P<0.001\)) and provided significant clinical benefits to patients. The answer to the efficacy question was not so comfortable for practitioners of East Asian medicine: verum and sham acupuncture had effects of identical magnitudes.

The Seattle story told a similar story. A total of 640 patients with cLBP were randomized to a total of 10 treatments over seven weeks to one of four arms: (1) standardized verum acupuncture treatment for cLBP, based on CM principles; (2) individualized verum acupuncture, based on a CM diagnostician's evaluation who then prescribed a unique treatment that could include any acupuncture points that could be needled with the patient prone (An acupuncturist different from the diagnostician performed the actual treatment.); (3) treatment using a toothpick in a guide tube that simulated acupuncture at the same eight acupuncture points used in the standardized treatment group; and (4) continued usual care involving medications (mostly nonsteriodal anti-inflammatory medicines, primary care, and physical therapy visits)\(^10\). At eight weeks, the primary endpoint, in the pragmatic comparison, 60% of those receiving acupuncture experienced clinically