

## **Research in Acupuncture: An Oxymoron?**

By James Kimber Rotchford

My answer to the above question is **no**. However, it is of didactic value to argue that research in acupuncture is, at present, of questionable value. Other sources devoted to improving methodologies of clinical acupuncture research are widely available,<sup>1-3</sup> so this paper will not review specific methodological issues pertinent to improving research in acupuncture.

Instead, this brief discussion will simply question the role of some conventional research methodologies in evaluating acupuncture.

The goal of clinical research in acupuncture should be the promotion of improved health outcomes in people seeking medical care. This goal is met through the provision of sound epidemiological evidence to guide our clinical decisions.

Initial problems in meeting this goal arise in the definition of terms. What constitutes improved health? What constitutes acupuncture? The World Health Organization's (WHO) definition of health reflects the subjectivity and contextual aspect of health definitions:

"Health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity."<sup>4</sup>

I recently co-authored a paper describing the difficulties in precisely defining acupuncture.<sup>5</sup> It is impossible in this present space to give justice to the difficulty in defining our terms. If we can't precisely define our terms, however, how valuable is the research that studies them?

Before providing further theoretical reasons why clinical research in acupuncture is problematic, let me ask the following question: What evidence supports the hypothesis that current clinical research in acupuncture is of limited value? The most glaring evidence, I believe, is the discrepancy in acupuncture's long-term

acceptance all over the world, including the United States, and the lack of evidence demonstrating its clinical utility. The 1997 consensus conference that reviewed most of the world literature on acupuncture on the standards of evidence-based medicine found only a handful of conditions for which it was proven effective.<sup>6</sup> As of 2002, one could argue that, despite further funding of acupuncture research, the list of evidence-based interventions with acupuncture has changed little. Note as well that in the 20 years or so of my clinical practice in acupuncture, I have only rarely treated patients with postoperative or chemotherapy-induced nausea and vomiting or post-dental extraction pain. Nonetheless, these are the only conditions for which acupuncture has "proven" efficacy.

Likewise, I have used acupuncture to help many patients stop smoking, while acupuncture for smoking cessation has been demonstrated in the research literature to be ineffective.<sup>7</sup> This is the experience of countless clinicians providing acupuncture care to patients who have failed to respond to other interventions. Standard explanations for this discrepancy include the pragmatic fallacy that is committed when one argues that something is true because it works. For example, astrology works; numerology works; therapeutic touch works. What "works" means here is not clear. At the least, it means that one perceives some practical benefit in believing that it is true, despite the fact that the utility of a belief is independent of its truth-value. At this level, "works" seems to mean "I'm satisfied with it," which in turn might mean, "I feel better" or "It explains things for me." At most, "works" means "has beneficial effects" even though the evidence may be very weak for establishing causality.

I recognize two problems with the pragmatic fallacy explaining the above discrepancy. The first is that the pragmatic fallacy theory denies the relevancy and importance of the WHO's definition of health, which recognizes the importance of a sense of well-being. Second, in the case of stopping smoking with the help of acupuncture, the self-reported reduction or cessation of smoking is significant (greater than 60 percent in my experience, and with a number of colleagues). I think smoking less is a clear benefit for my patients.

As to the criticism of a lack of evidence for causality, perhaps acupuncture doesn't lend itself to research methodologies that evaluate causality. Traditional acupuncture theories emphasize contextual issues and individualized treatment. This aspect of acupuncture care is not consistent with simple cause-and-effect interventions that can be extrapolated to large populations. Of note, most interventions associated with addiction emphasize the importance of a contextual, individualized intervention. This may help explain why smoking cessation interventions with acupuncture have failed to show any objective benefit.

One might also explain the above discrepancy as a testimony to the placebo effect. I define this as the effect of nonspecific variables on health outcomes in clinical interventions. The Skeptic's Dictionary Web site<sup>9</sup> gives the following definition: "The placebo effect is the measurable, observable, or felt improvement in health not attributable to treatment." Current research methodologies designed for pharmaceutical interventions are primarily interested in determining specific variables affecting outcomes. It may well be that acupuncture works in part, or primarily through enhancing the placebo effect. In many cases, it may have nothing to do with penetrating the skin with a needle, while in other cases, it may simply be the result of the nonspecific effect of needling. Nonetheless, something about the context in which acupuncture is performed provides for satisfied patients. What's more, to dismiss this pragmatism (it works) as simply a fallacy is becoming more difficult as the amount of evidence that shows measurable physiological effects associated with acupuncture grows.

Perhaps *post hoc* reasoning explains the discrepancy. The *post hoc ergo propter hoc* (after this, therefore because of this) fallacy is based upon the mistaken notion that simply because one thing happens after another, the first event caused the second event. I agree it is problematic at best to ascribe causality to any one part of an acupuncture encounter. Nonetheless, to ascribe all of acupuncture's effects to *post hoc* reasoning flies in the face of so much evidence of people who reported getting better only after they visited the acupuncturist. What's more, the visit to the acupuncturist often follows multiple visits to other health care providers.

The discrepancy between proven efficacy and the apparent benefit, as attested by acupuncture's longstanding popularity, is therefore not to be lightly dismissed. I believe the evidence supports questioning the use of methods that look for specific effects on an intervention intended to have nonspecific contextual results. An example of this fallacy would be to design acupuncture research studies that poorly resemble actual clinical practice and then, from these studies, draw conclusions as to the efficacy of standard clinical acupuncture.

Most current clinical research is based on the hypothesis that one can determine the best clinical intervention by understanding population characteristics and extrapolating the probabilities of results based on such knowledge to the individual patient. Oriental medical theories postulate that the best of care is always based entirely on the context in which the patient presents, in contrast to a specific diagnosis or other population characteristic. I believe it would take another research design to properly evaluate the overall benefit of traditional acupuncture.

One of the major intents of current research in acupuncture appears to be the justification of third-party involvement. Perhaps the subjective quality of improvement in well-being experienced with acupuncture should preclude third-party involvement. I think this is a subject for an extensive and intensive social debate that puts into question the separation of church and state. Much of medical care provided is not evidence-based, but is part of a belief system. Others have provided evidence that supports the idea that the clinical practice of medicine often resembles the practice of religion.<sup>8</sup> Although we tend to hide behind objectivity in medicine, it is clear that most interventions fail to withstand the scrutiny of evidence-based trials. Even the value we place on objectivity in medicine is a subjective value. The religious aspect of medical care is to me self-evident, but this discourse is beyond the scope of this discussion. It is pertinent to our discussion if medicine is like religion, for then, I think we would all agree (aside, perhaps, from some Christians) that it would be rather ludicrous for Christians to define evaluation tools to determine the value of Hinduism. In medicine, we don't hesitate to have one "belief system" imposing its quality measures on another. What's more, it is likely counterproductive to define objective tools to determine the inherent value of one religion over another. Eventually, one filters down to core values that are objectively subjective. Herein, the illusion of objectivity in medicine is revealed.

Dr. Michael T. Greenwood, in a recent article, reviewed in-depth assumptions about objectivity in medicine. He reviewed theories on knowledge acquisition and, in an academic fashion, questioned the tenets of evidence-based medicine *vis-a-vis* acupuncture. He also clearly questioned the use of dualistic approaches to evaluate holistic ones. He considered this a blatant example of a "category error" (see [www.medicalacupuncture.org/aama\\_marf/journal/vol13\\_2/article4.html](http://www.medicalacupuncture.org/aama_marf/journal/vol13_2/article4.html)).

Is there any hope for useful clinical acupuncture research having utility? I think so. First, we need to do a much better job of defining what we are studying. Next, I foresee designs that emphasize outcomes rather than the specifics of the intervention taking precedence. These designs have been termed "black box" or "pragmatic" trials. That is, you control - to a large degree - the population that enters into the randomized boxes, and you reliably and validly measure the outcomes of the populations as they come out of the boxes. Initially, no attempt is made to specifically define the contents of the box other than through broad categories, such as care by clinicians who graduated from approved TCM schools, or physicians with at least 200 hours of extra training in acupuncture. Only after proper pilot studies have been conducted, when we have established objectively the proper role of specific styles of acupuncture with certain populations, should we examine the inside of the "black box." Hence, there is a strong case for objective pilot studies to

determine the type of acupuncture intervention used for larger clinical trials. It is not enough to depend solely on "expert" opinion, for these experts often adhere to the same belief system and style of acupuncture.

Finally, I refer back to the Skeptic's Dictionary home page on the topic of the "placebo effect," where the author, Robert Todd Carroll, discusses ethical questions as to administering possible placebo interventions:

"However, to those who say 'what difference does it make why something works, as long as it seems to work,' I reply that it is likely that there is something which works even better, something for the other two-thirds or one-half of humanity who, for whatever reason, cannot be cured or helped by placebos or spontaneous healing or natural regression of their pain. Furthermore, placebos may not always be beneficial or harmless. In addition to adverse side-effects ..." <sup>9</sup>

The above reflects a value with which I concur. I believe it is a rallying call to design studies which either: 1) use acupuncture as adjunctive care to evidence-based standards of care, or 2) compare acupuncture head-to-head with the best form of evidence-based care for the condition. We should also remember the importance of basic research in medicine, which has a proven track record of supporting clinical trials, not replacing them.

In conclusion, I believe research in clinical acupuncture is not an oxymoron. There is plenty of meaningful research to be done. I respect, however, those who lean to the opposing point of view based on acupuncture's research history. I encourage the reader to hold the tension between these opposing points of view.

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