

## EDITORIAL

# The Case of Acupuncture for Chronic Low Back Pain

*When Efficacy and Comparative Effectiveness Conflict*

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**E**fficacy signifies superiority over placebo controls in randomized controlled trials (RCTs). *Effectiveness* implies greater or equal clinical benefits compared to an already-established treatment. Two recent RCTs of acupuncture for chronic low-back pain (cLBP)—notable for their size, rigor, and innovative research designs that included both efficacy and effectiveness hypotheses—raise the interesting conundrum of what happens when these two forms of evidence conflict.

In the first German trial, patients with cLBP (n = 1162) were randomized to acupuncture treatments, placebo acupuncture treatments, or optimal mainstream care.<sup>1</sup> At 6 months, the primary endpoint, the proportion of positive clinical response was 47.6%, 44.2%, and 27.4% in acupuncture, placebo acupuncture, and conventional care, respectively. There was no statistical difference between acupuncture and placebo acupuncture ( $P = 0.39$ ), but both acupuncture and placebo acupuncture were statistically and clinically superior to mainstream care that included physiotherapy, exercises, and nonsteroidal anti-inflammatory drugs ( $P < 0.001$ ).

A recent American study replicated these findings.<sup>2</sup> Patients (n = 638) were randomized to four arms: individualized acupuncture treatment, standardized formula acupuncture, “simulated” (toothpick) acupuncture, and usual care. At 8 weeks, both genuine types of acupuncture and sham acupuncture were indistinguishable on the Roland-Morris dysfunction

scale (4.4, 4.5, and 4.4 points) and all three acupuncture arms were superior to usual care (2.1 points) ( $P < 0.001$ ). The results persisted at the 1-year follow-up. A recent systematic review of 23 RCTs (n = 6359) confirms these findings.<sup>3</sup> Putting aside the objections of acupuncturists who criticize the placebo controls or find another methodologic weakness<sup>4</sup> in these RCTs, at this time, it seems reasonable to conclude that for cLBP, acupuncture has little or no specific efficacy but has significant clinical effectiveness.

The cost-effectiveness data adds provocative information. Using the incremental cost-effectiveness ratio (ICER, *i.e.*, the ratio of effect size to cost of one quality-adjusted life year), a German study (n = 8300) found that the ICER for acupuncture treatment of headache, low-back pain, and neck pain to be less than €13,000, the international threshold for cost-effectiveness.<sup>5,6</sup> A British study confirmed these estimates.<sup>7</sup> What are the policy and clinical implications of this research?

Based on the efficacy, effectiveness, and cost evidence available at the time, in April 2006, the German Federal Committee of Physicians and Health Insurers approved acupuncture for cLBP.<sup>8</sup> In May 2009, the National Institute for Health and Clinical Excellence (NICE) in Britain recommended health care providers to offer cLBP patients.<sup>5</sup> The most authoritative American pronouncement, so far, comes from the American College of Physicians which, in 2007, recommended acupuncture as a second-line therapy.<sup>9</sup> These three policy guidelines seem to indicate that for cLBP, effectiveness research (especially in the context of cost-effectiveness) takes priority over efficacy data.

It seems that in our current cost-conscious environment, when it comes to acupuncture for cLBP, especially when other dependable and safe clinical options are unavailable, the medical community puts effectiveness above efficacy. This shift may represent a societal shift in which regulatory and insurance bodies and “patient-centered health care” have begun to outweigh the “evidence-based medicine” of researchers in determining an intervention’s legitimacy.

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