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The case of acupuncture for chronic low back pain: When efficacy and comparative effectiveness conflict

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Efficacy 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 ($n=1,162$) were randomized to either acupuncture treatments, placebo acupuncture treatments or optimal mainstream care.¹ 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 non-steroidal anti-inflammatory drugs ($p<0.001$).

A recent American study replicated these findings.² Patients ($n=638$) were randomized to four arms: individualized acupuncture treatment, standardized formula acupuncture, “simulated” (tooth-pick) 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 one year follow-up. A recent systematic review of 23 RCTs ($n=6,359$) confirm these findings.³ Putting aside the objections of acupuncturists who criticize the placebo controls or find other methodological weakness⁴ 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 ($n=8,300$) 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^{5,6}. A British study confirmed these estimates⁷. What are the policy and clinical implications of this research?

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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.⁸ In May 2009, The National Institute for Health and Clinical Excellence (NICE) in Britain recommended health care providers to offer cLBP patients.⁵ The most authoritative American pronouncement, so far, comes from the American College of Physicians which, in 2007, recommended acupuncture as a second-line therapy.⁹ 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 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” has begun to outweigh the “evidence-based medicine” of researchers in determining an intervention’s legitimacy.

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