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Titel des Beitrags:
Influence of control group on effect size in trials of acupuncture for chronic pain: a secondary analysis of an individual patient data meta-analysis.

Abstract:
In a recent individual patient data meta-analysis, acupuncture was found to be superior to both sham and non-sham controls in patients with chronic pain. In this paper we identify variations in types of sham and non-sham controls used and analyze their impact on the effect size of acupuncture. Based on literature searches of acupuncture trials involving patients with headache and migraine, osteoarthritis, and back, neck and shoulder pain, 29 trials met inclusion criteria, 20 involving sham controls (n = 5,230) and 18 non-sham controls (n = 14,597). For sham controls, we analysed non-needle sham, penetrating sham needles and non-penetrating sham needles. For non-sham controls, we analysed...
non-specified routine care and protocol-guided care. Using meta-regression we explored impact of choice of control on effect of acupuncture. Acupuncture was significantly superior to all categories of control group. For trials that used penetrating needles for sham control, acupuncture had smaller effect sizes than for trials with non-penetrating sham or sham control without needles. The difference in effect size was -0.45 (95% C.I. -0.78, -0.12; p = 0.007), or -0.19 (95% C.I. -0.39, 0.01; p = 0.058) after exclusion of outlying studies showing very large effects of acupuncture. In trials with non-sham controls, larger effect sizes associated with acupuncture vs. non-specified routine care than vs. protocol-guided care. Although the difference in effect size was large (0.26), it was not significant with a wide confidence interval (95% C.I. -0.05, 0.57, p = 0.1). Acupuncture is significantly superior to control irrespective of the subtype of control. While the choice of control should be driven by the study question, our findings can help inform study design in acupuncture, particularly with respect to sample size. Penetrating needles appear to have important physiologic activity. We recommend that this type of sham be avoided.

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