Cho Y-J, Song Y-K, et al Acupuncture for Chronic Low Back Pain. Spine 2013;38(7):549-557.

Reviewed, modification of conclusions, December 2016

Design: Randomized clinical trial

Population/sample size/setting:

- 116 patients (18 men, 98 women, mean age 42) who completed a randomized trial of acupuncture for chronic low back pain (LBP) in a university department of rehabilitation medicine in Seoul, Korea
- Eligibility criteria were age 18 to 65 with at least 3 months of nonspecific LBP with a VAS bothersomeness score of at least 5 on a scale from 0 to 10, with an intact neurological examination
- Exclusion criteria were sciatic pain, pain mainly below the knee, serious spinal disorders such as malignancy and fracture, history of previous spinal surgery or scheduled surgery for a variety of chronic diseases such as fibromyalgia, cardiovascular disease, diabetic neuropathy, rheumatoid arthritis, etc), acupuncture treatment in the past month, conditions affecting the safety of acupuncture (clotting disorders, pregnancy, seizure disorders, anticoagulant medication), and history of use of steroids, narcotics, muscle relaxants, or herbal medicine to treat LBP

Main outcome measures:

- 130 patients were originally randomized to either true acupuncture (n=65) or to sham acupuncture (n=65)
- For both groups, the treatment duration was 6 weeks of twice weekly sessions for a total of 12 treatment sessions
- True acupuncture was done by selecting a group of acupuncture points according to the 3 types of meridian patterns of classical acupuncture, including manual stimulation to induce “deqi” sensation signaling the desired response at the designated acupuncture point
- Sham acupuncture was done with the same technique and protocol, but with use of a nonpenetrating semi-blunt rather than a sharp penetrating needle, placed at points in the low back unrelated to traditional acupuncture points
- The primary outcome was the VAS LBP bothersomeness score, measured at baseline and at 8 weeks; the same outcome was also measured at 6, 12, and 24 weeks
- Secondary measures included the VAS pain score, the Oswestry disability score (with exclusion of questions regarding sexual function), and health-related quality of life with the SF-36
- Attrition was about equal in the two groups, such that there were 57 true acupuncture and 59 sham acupuncture patients available for analysis at the end of the study

- For the main endpoint of VAS bothersomeness, both groups reported decreases between baseline and the end of the study, but the average decrease was greater for the true acupuncture group (3.36 points) than for the sham acupuncture group (2.27 points)
- Most of the secondary endpoints also showed improvement in both groups; the improvements were significantly greater for true acupuncture over sham acupuncture for only the primary VAS bothersomeness and for the VAS pain intensity scores, not for the Oswestry or SF-36 scores
- Adverse events were reported by 16 patients, none of them persisting beyond one week, and approximately equally distributed between treatment groups
- Blinding was maintained as evidenced by the equal accuracy with which treatment groups guessed their treatment allocation at the end of the trial

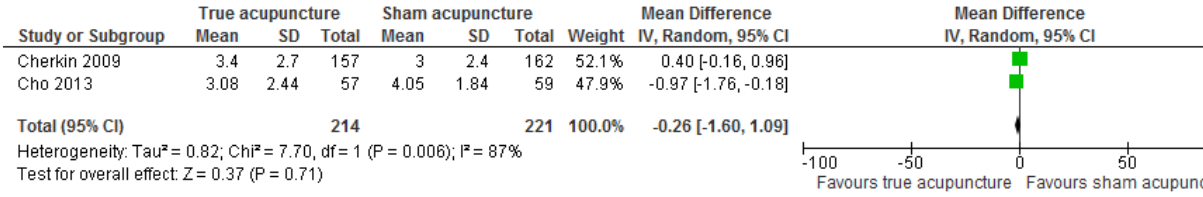
Authors' conclusions:

- There is evidence that acupuncture at traditional meridian points individualized to the patient is more effective than sham acupuncture in reducing pain bothersomeness and pain intensity for nonspecific LBP
- No conclusions could be drawn for disability or quality of life between the two treatments

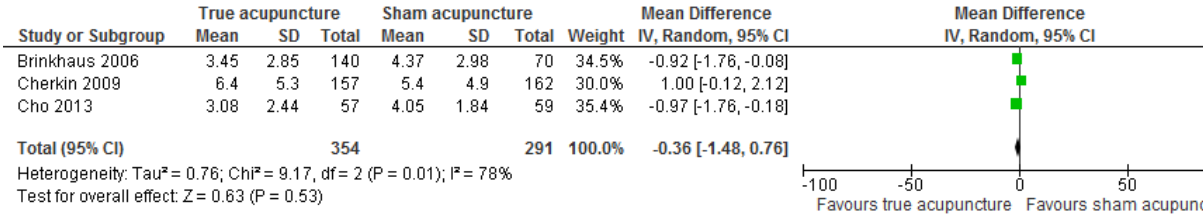
Comments:

- Many criteria of a well-performed randomized trial are met: descriptions of inclusion/exclusion criteria are interpretable, randomization and allocation concealment methods are likely to control selection bias, the endpoints are measured for both long and short term durations, and blinding of the patients was likely to have controlled assessment bias
- The analysis appears to have been done with per-protocol rather than intention-to-treat analysis; since the flow diagram does not show crossover between the start and end of the trial, this distinction is not of great importance
- The table numbers are not labeled, but Table 3 is the one at the bottom of page 554, and appears to display the proportion of the pain bothersomeness and intensity which has decreased in the treatment groups
- The between-group difference in the main outcome of improving VAS bothersomeness was just over one point (3.36 in the true and 2.27 in the sham acupuncture group), a difference of marginal clinical importance, and there were no differences in the Oswestry disability scores
    - Table 2 on the top of page 554 shows the VAS bothersomeness scores at the 8 week primary end point assessment, but does not display a confidence interval for the difference between groups, reporting only a p value for the difference

- Although the VAS bothersomeness score is not a direct measure of disability (as are the Oswestry and Roland-Morris scores), it may be predictive of work absence at a later date (Dunn and Croft 2005)
- The study would be more convincing if there had been group differences in the Oswestry disability scores, and the bothersomeness score is an imperfect surrogate for disability, but is not entirely irrelevant as an outcome measure
- An earlier, larger trial (Cherkin 2009) comparing true and sham acupuncture with pain bothersomeness at 8 weeks was also of methodologic high quality and did not show a difference between individualized acupuncture (the intervention most closely related to the comparison in Cho 2013) and sham acupuncture
- It is possible to pool the data from the two studies, which when combined, do not show that true and sham acupuncture are different:



- A random effects model is shown, since there is heterogeneity between the studies, with a nonsignificantly lesser bothersomeness score at 8 weeks in the sham than in the true acupuncture group for Cherkin 2009, and a significantly lower bothersomeness score at 8 weeks with Cho 2013; a fixed effect model, however, yields the same answer that true and sham acupuncture are not differently effective
- Another earlier study (Brinkhaus 2006) was also of high quality, and reported similar effects of true and minimal acupuncture done at non-acupuncture points; again, acupuncture was superior to a no acupuncture waiting list, but true and sham acupuncture did not differ from one another
- Although Brinkhaus 2006 reported pain intensity rather than bothersomeness, the measures are closely related and can be put on a common 10 point scale; again, pooling all three studies continues to show a pooled effect size which is not different between true and sham acupuncture:



- Although the Cho 2013 study is of high methodologic quality, and reports a marginal superiority of true over sham acupuncture, the overall estimate of the treatment difference, incorporating data from larger high quality studies,

appears not to show that there are differences between true and sham acupuncture

- The conclusion that there is evidence of true acupuncture being meaningfully superior to sham acupuncture is not supported by the data as a whole, especially since there is not a “no acupuncture” group for comparison

Assessment: High quality study which does not support evidence that true acupuncture is meaningfully superior to sham acupuncture with blunt needles in relieving the bothersomeness of nonspecific low back pain, and that the overall evidence from similar high quality studies does not support evidence of a treatment difference between true and sham acupuncture

References:

Brinkhaus B, Witt CM et al. Acupuncture in Patients With Chronic Low Back Pain. A Randomized Controlled Trial. Arch Intern Med 2006;166:450-457.

Cherkin DC, Sherman KJ, et al. A Randomized Trial Comparing Acupuncture, Simulated Acupuncture, and Usual Care for Chronic Low Back Pain. Arch Intern Med 2009;169(9):858-866.