Haake M, Muller HH et al. German Acupuncture Trials (GERAC) for Chronic Low Back Pain. Arch Intern Med. 2007;167(17):1892-1898.

Reviewed, no change to conclusions, December 2016

Design: Randomized clinical trial

Population/sample size/setting:

- 1162 patients (470 men, 692 women, mean age 50) treated for chronic low back pain at university departments of orthopedics and pain management in Germany
- Inclusion criteria were clinical diagnosis of low back pain for 6 months or more, Von Korff Chronic Pain Grade Scale (CPGS) grade I or higher and Hanover Functional Ability Questionnaire less than 70%
- Exclusion criteria included previous spinal surgery or fractures, infections or tumors of the spine, systemic bone/joint disorders (e.g., rheumatoid arthritis), drug abuse, any acupuncture for back pain in the past, and any acupuncture for other indications in the past year
- All participants were told before randomization that true acupuncture would be offered at the end of the trial
- Before enrolling in the trial, each patient had the alternative of participating in a cohort study designed to examine the adverse effects of acupuncture; this was also intended to exclude patients with positive expectations of acupuncture and negative expectations of conventional therapy

Main outcome measures:

- Randomized to true acupuncture (n=387), sham acupuncture (n=387), or standard therapy (n=388)
- All randomized groups received ten 30-minute sessions
- True acupuncture consisted of needling fixed points chosen individually on the basis of traditional Chinese medicine diagnosis; 14 to 20 needles were inserted to a depth of 5 to 40 mm; with induction of “de qi” was elicited by manual stimulation
- Sham acupuncture was done with 14 to 20 identical needles on either side of lateral part of the back, avoiding all known acupuncture points or meridians; needles were inserted superficially (1-3 mm) and without stimulation
- Conventional therapy group received multimodal treatment program according to German evidence-based guidelines; it included 10 meetings with a physician or physiotherapist who administered PT, exercise, and such
    - Principal therapies were PT, massage, heat, electrotherapy, back school, injections; 95% received analgesics
- Communication with patients during true and sham acupuncture was limited to necessary explanations to avoid unblinding by suggestive remarks
- At baseline, all participants had high expectations of acupuncture (average of 7.7 on a scale where 0=’not at all helpful’ and 10=’extremely helpful’

- Follow-up was done by telephone interview at 6 weeks, 3 months, and 6 months by trained employees who were blinded to intervention group
- A "response" was defined as a 33% or better improvement on 3 pain-related items on the Von Korff CPGS or as a 12% or better improvement on the Hanover Functional Ability Questionnaire, taken at the 6 month follow-up assessment
- Such a response was recorded in 47.6% of true acupuncture, 44.2% of sham acupuncture, and 27.4% of conventional care groups
- There was no statistical difference between the true and sham acupuncture groups, but both groups differed significantly from conventional treatment
- Adverse events were recorded in 12 patients in both true and sham acupuncture groups, and in 16 patients in conventional treatment; none of these was judged to be causally related to the interventions
- Blinding was maintained; most patients did not correctly identify which form of acupuncture they had received

Authors' conclusions:

- The unexpected similar findings of effectiveness in the true and sham acupuncture groups raises questions about the underlying mechanism of acupuncture and whether the emphasis on learning the traditional Chinese acupuncture groups may be superfluous
- The specific (physiologic) and nonspecific (psychological) effects of acupuncture should be distinguishable by the difference between the true and sham group responses
    - The nonspecific influences include patient expectations about acupuncture, negative expectations about conventional treatment, more intensive physician contact, and the experience of needling
    - There may be no specific acupuncture effects at all
    - The specific effects may be very small and overlaid by nonspecific effects
    - There exist specific acupuncture effects of unknown nature which lead to symptom improvement independent of point selection and depth of needling
- The effectiveness of sham acupuncture suggests that a discussion is needed about the appropriate depth of needle insertion for reasons of harm reduction

Comments:

- In design and analysis, the trial meets enough criteria for control of bias to be considered as a high-quality study
- However, some desirable information for interpretation of the study was omitted
    - Patients were excluded if they had previous acupuncture for low back pain, but not if they had had it for other indications more than one year previously
    - The number of patients with previous acupuncture was not reported

    - The response rates of patients with and without previous acupuncture were not compared
    - Because some critics of acupuncture postulate that its placebo effects arise from a “novelty” effect, an opportunity to test this idea was lost
    - The success of blinding in patients with and without previous acupuncture was not reported
    - Expectations of acupuncture were reported in Table 2, and were high in all groups (7.7 on a scale from 0 to 10), but expectations of conventional treatment were not reported
    - It is very uncertain that the option of participation in a separate cohort study actually excluded patients with very different expectations of acupuncture and conventional treatment
- The randomization did what it is designed to do, producing balanced distribution of expectations of acupuncture
    - An unavoidable consequence of this is that the groups were probably unbalanced on expectations of the interventions to which they were allocated
    - The true and sham acupuncture groups were balanced on both their expectations of acupuncture and their expectations of allocated treatment, but the acupuncture and conventional groups were balanced on the first but not the second expectation
    - The comparison of the true and sham acupuncture groups is simple, because they differ only in the intervention received
    - The comparison of the acupuncture groups and conventional treatment is complex, because they differ both on the intervention received and their expectations of that intervention
    - Therefore, the comparison of both acupuncture with conventional treatment may be measuring the effect of the intervention, the effect of the expectation, or both

Assessment: High quality for evidence that acupuncture is effective in the treatment of low back pain in patients with positive expectations of acupuncture