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.

Reviewed, no change to conclusions, December 2016

Design: Randomized clinical trial

Population/sample size/setting:

- 638 adults (62% women, mean age 47) treated for chronic low back pain at Kaiser Permanente in California and Group Health Cooperative in Seattle
- Eligible if they were identified through electronic records with diagnosis codes consisted with uncomplicated low back pain within the prior 3 to 12 months, with duration of pain 3 months or more
- Excluded if they had specific causes of back pain (cancer, fractures, spinal stenosis , infections), complicated back problems (sciatica, prior back surgery, medicolegal issues), fibromyalgia, rheumatoid arthritis, pregnancy, coagulation disorders, paralysis, psychosis
    - Also excluded were persons with previous acupuncture

Main outcome measures:

- Patients were randomized to one of four groups: individualized acupuncture (n=157), standardized acupuncture (n=158), sham acupuncture (n=162), and usual care (n=161)
    - All patients receiving any acupuncture had twice weekly sessions for 3 weeks and then weekly sessions for 4 weeks
    - Electrostimulation, moxibustion, herbs, and other non-needle treatments were not permitted
    - Individualized acupuncture was done by a trained acupuncturist following a prescription from a Chinese medical diagnostician acupuncturist, done with the patient lying prone, with no constraints on number of needles, depth of insertion, or needle manipulation; duration of needle insertion was about 18 minutes
    - Standardized acupuncture was done following a prescription considered effective by experts for low back pain, with needle insertion lasting 20 minutes; therapists manipulated the needles until perceiving a response of “de qi” which occurs when the tissue tightens about the inserted needle and constricts its movement

    - Sham acupuncture was done with toothpicks in a guide tube, with gentle tapping of the toothpick to simulate needle insertion, with the simulation lasting 20 minutes
    - Usual care group received the care they and their physicians chose, consisting of medication and physical therapy plus a self-care booklet on exercise and lifestyle modifications
- Outcomes were measured at 8, 26, and 52 weeks
    - Primary outcomes were pain bothersomeness on a VAS scale from 0 to 10 and disability on the Roland Morris Disability Questionnaire (RMDQ), with the 8 week evaluation as the primary end point
- At 8 weeks, the RMDQ had improved in all 4 groups, but the 3 acupuncture groups had more improvement than the usual care group
    - The 3 acupuncture did not differ from one another, but the advantage over usual care was from 2.47 to 2.91 points
- At 8 weeks, the bothersomeness scores had a pattern similar to the RMDQ scores; all 4 groups improved, the 3 acupuncture groups did not differ from one another, but all 3 acupuncture groups had more improvement than the usual care group (from 1.05 to 1.56 points greater improvement)
- The blinding of patients appeared to be effective; the simulated and true acupuncture treatments could not be told apart by the patients
- A few adverse effects were reported; 12 patients had treatment-related pain, 6 in the individualized acupuncture, 6 in the standardized acupuncture, but none in the sham acupuncture group

Authors' conclusions:

- Compared to usual care, individualized, standardized, and simulated acupuncture led to greater improvements in pain bothersomeness and disability at 8 weeks
- There was no apparent difference between true and sham acupuncture; even though sham acupuncture was superior to usual care, the treatment effect is likely to be nonspecific
- The equal improvements between true and sham acupuncture raise questions about the purported mechanism of action of acupuncture

Comments:

- Several secondary analyses were done, the most pertinent of which was the 1 year follow-up, showing that the acupuncture groups remained with less disability than the usual care group, although the bothersomeness scores were no longer significantly different

- The study appears to have been careful to control sources of bias which might threaten internal validity, selecting patients with nonspecific back pain longer than 3 months, and excluding patients with specific diagnoses such as sciatica and stenosis
- The occurrence of adverse effects in the groups which received true acupuncture but not in the sham acupuncture group, may or may not be a chance artifact; needle penetration may have produced the reported increases in pain in those patients

Assessment: High quality study for evidence that acupuncture, true or sham, is superior to usual care for the reduction of disability and pain in patients with chronic nonspecific low back pain, but that true and sham acupuncture are likely to be equally effective