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.

Reviewed, no change to conclusions, December 2016

Design: Randomized clinical trial

Population/sample size/setting:

- 298 patients (292 women, 96 men, mean age 59) with low back pain for more than 6 months seen in university medical center in Berlin
- Eligible if had 40 mm or more of pain on 100 mm visual analog scale (VAS) in past 7 days and use of only NSAID for pain relief in past 4 weeks
- Excluded if had protrusion or prolapse of any disc with concurrent neurologic symptoms; prior back surgery, radiculopathy, fracture, spinal stenosis, or any acupuncture treatment in past 12 months

Main outcome measures:

- Seen by acupuncture physicians with at least 3 years experience, randomized to semi-standardized acupuncture at specified acupuncture points (n=147), minimal acupuncture at predefined non-acupuncture points (n=75), and waiting list with no acupuncture (n=79), who received acupuncture after 9 weeks
- Treatments done in 12 sessions of 30 minutes over 8 weeks
- Principal outcome was difference in VAS (pain relief) between baseline and 8 weeks
- Additional outcomes included VAS at 26 and 52 weeks, measures of back function, depression, German version of SF-36 quality of life questionnaire
- Complete data available for 284 pts at end of week 8; pts in acupuncture group had mean VAS decrease of 28.7 mm; pts in minimal acupuncture group had mean decrease of 23.6 mm, and pts in waiting list had VAS decrease of 6.9 mm; difference between acupuncture and minimal acupuncture groups were not statistically significant, but differences between acupuncture and waiting list were statistically significant
- Later follow-up at 26 and 52 weeks showed tendency for better results in acupuncture than minimal acupuncture in most secondary outcomes, but most of these were not statistically significant
- When waiting list pts received acupuncture between 9 and 16 weeks, they experienced pain relief similar to group randomized to acupuncture at outset
- Adverse events, mostly hematoma and bleeding, reported in 22 pts: 13 in acupuncture group, 4 in minimal acupuncture, and 5 in waiting list (not stated whether this was during the 9-16 week interval when that group was receiving acupuncture)

Authors' conclusions:

- Acupuncture provides significant pain relief compared to no acupuncture for chronic low back pain

- Role of correct needle location may play only limited role
- Study design was compromise between flexibility (desired by acupuncturists) and reproducibility (desirable for researchers)
- Strong response to minimal acupuncture may have accounted for minimal difference between acupuncture and minimal acupuncture

Comments:

- Minimal acupuncture, although done at non-acupuncture points, was done by trained acupuncturists, which may account for part of strong response and may have minimized difference between acupuncture and minimal acupuncture groups
- Approximately one third of participants had previous experience with acupuncture, which may account for why the efficacy of blinding was less than perfect
- Difference between minimal acupuncture group and waiting list at 8 weeks (data in Table 3) was also statistically significant ($p<.001$)
- Therefore, skill of practitioner may still play an important role and no inference should be made that an untrained person could achieve good results by placing needles at random; study may underestimate effect of experienced acupuncturist placing needles in individually tailored manner
- Scatterplot in Figure 2 is not clear; VAS score at 8 weeks is on x axis, and "VAS Score" is on y axis, but was this the VAS at baseline or at some other time?
- If the y axis of Figure 2 refers to the VAS at baseline, then the points above the broken line represent patients who improved between baseline and 8 weeks, while points below the broken line represent patients who got worse between baseline and 8 weeks; the predominance of the former over the latter on the left of Figure 2 indicate that most patients improved in the acupuncture group
- Authors calculated sample size to obtain 80% power and 5% significance level based on estimated standard deviation of 22.5 mm VAS difference, but actual standard deviations were greater (30.3 and 31 mm), meaning that power would be eroded due to measured variances being greater than anticipated; power calculation yields effective power of only 49% to detect a 10 mm difference between groups
- Therefore, "statistically insignificant" differences between acupuncture and minimal acupuncture groups should be interpreted with caution, since there is a 50% chance of missing an effect size equal to the 10 mm VAS difference thought to be clinically important
- Analgesic use in true acupuncture group in Table 3 was less than for sham acupuncture, as was the time with limited function in the past 2 months
- Disc disease and radicular pain patients were excluded, and there is no information concerning the effectiveness of acupuncture for these patients

Assessment: Adequate for evidence that acupuncture is better than no acupuncture for axial chronic low back pain.

Inadequate for evidence that there is no difference between true and sham acupuncture.